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Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF GOVERNMENT ETHICS

5 CFR Part 2604

Technical Amendments to Office of Government Ethics Freedom of Information Act Regulation: Change in Decisional Officials

AGENCY: Office of Government Ethics (OGE).

ACTION: Final rule; technical amendments.

SUMMARY: The Office of Government Ethics is amending its Freedom of Information Act (FOIA) regulation to indicate a change in OGE decisional officials thereunder.

EFFECTIVE DATE: January 16, 2001.

FOR FURTHER INFORMATION CONTACT: William E. Gressman, Senior Associate General Counsel, Office of Government Ethics, telephone: 202–208–8000, ext. 1110; TDD: 202–208–8025; FAX: 202–208–8037.

SUPPLEMENTARY INFORMATION: The Office of Government Ethics is amending its FOIA regulation to indicate a restructuring of decisional authority for handling FOIA requests, appeals and related matters that OGE receives as a Federal agency. The OGE FOIA Officer (instead of the OGE General Counsel) now will decide initial access requests and related matters such as fees. Further, the OGE General Counsel (instead of the OGE Deputy Director) will decide administrative FOIA appeals.

Matters of Regulatory Procedure

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b) and (d), as Director of the Office of Government Ethics, I find good cause exists for waiving the general notice of proposed rulemaking, opportunity for public comment and 30-day delay in effectiveness as to these amendments. The notice, comment and delayed effective date provisions are being waived because these technical FOIA regulation amendments concern matters of agency organization, practice and procedure.

Executive Order 12866

In promulgating these minor amendments, OGE has adhered to the regulatory philosophy and the applicable principles of regulation set forth in section 1 of Executive Order 12866, Regulatory Planning and Review. These amendments have not been reviewed by the Office of Management and Budget under that Executive order, since they are not deemed "significant" thereunder.

Executive Order 12988

As Director of the Office of Government Ethics, I have reviewed this final amendatory regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certify that it meets the applicable standards provided therein.

Regulatory Flexibility Act

As Director of the Office of Government Ethics, I certify under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this rulemaking will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this amendatory rulemaking does not contain information collection requirements that require the approval of the Office of Management and Budget.

Congressional Review Act

The Office of Government Ethics has determined that this amendatory rulemaking is a nonmajor rule under the Congressional Review Act (5 U.S.C. chapter 8) and has provided a report thereon to the Senate, House of Representatives and General Accounting Office in accordance with that law.

List of Subjects in 5 CFR Part 2604

Administrative practice and procedure, Archives and records, Confidential business information, Conflict of interests, Freedom of information, Government employees.

Approved: January 9, 2001.

Amy L. Comstock,

Director, Office of Government Ethics.

Accordingly, the Office of Government Ethics, pursuant to its authority under the Ethics in Government Act and the Freedom of Information Act, is amending 5 CFR part 2604 as follows:

PART 2604—FREEDOM OF INFORMATION ACT RULES AND SCHEDULE OF FEES FOR THE PRODUCTION OF PUBLIC FINANCIAL DISCLOSURE REPORTS

1. The authority citation for part 2604 continues to read as follows:

Authority: 5 U.S.C. 552; 5 U.S.C. App. (Ethics in Government Act of 1978); E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

2. Section 2604.103 is amended by removing the definition of "*General Counsel*", and by adding a new definition, for "*FOIA Officer*", to read as follows:

§ 2604.103 Definitions.

FOIA Officer means the OGE employee designated to handle various initial FOIA matters, including requests and related matters such as fees.

* * * * *

§§ 2604.301, 2604.302, 2604.303, 2604.305, 2604.402 [Amended]

3. Sections 2604.301(a) and (b)(2), 2604.302(a) and (d), 2604.303(a), (b) (introductory text) and (b)(2), 2604.305(a)(1) and (a)(2), and 2604.402(c) (introductory text), (c)(2), (e) (introductory text), (e)(3), (f), (g)(1) and (g)(4) are amended by removing the words "General Counsel" wherever they appear and adding in their place in each instance the words "FOIA Officer".

§ 2604.304 [Amended]

4. Section 2604.304(a) is amended by removing the words "Deputy Director" between the words "the" and "of" and adding in their place the words "General Counsel".

[FR Doc. 01–1170 Filed 1–12–01; 8:45 am]
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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 212

[INS No. 2089–00]

RIN 1115–AE73

Additional Authorization To Issue Certificates for Foreign Health Care Workers; Speech-Language Pathologists and Audiologists, Medical Technologists and Technicians, and Physician Assistants

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Interim rule with request for comments.

SUMMARY: This interim rule amends the regulations of the Immigration and Naturalization Service (Service), to enable the Commission on Graduates of Foreign Nursing Schools (CGFNS) to issue certificates to aliens seeking admission as, or adjustment of status to permanent residents on the basis of the following occupations: Speech language pathologist and audiologists, medical technologist (also known as "clinical laboratory scientist"), physician assistant, and medical technician (also known as "clinical laboratory technician"). The Service has consulted with the Department of Health and Human Services before promulgating this interim regulation. This rule ensures that foreign health care workers have the same training, education and licensure as similarly employed United States workers.

DATES: *Effective Date:* This interim rule is effective March 19, 2001.

Comment date: Written comments must be submitted on or before March 19, 2001.

ADDRESSES: Please submit written comments, in triplicate, to the Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street NW., Room 4034, Washington, DC 20536. To ensure proper handling, please reference the INS No. 2089–00 on your correspondence. Comments are available for public inspection at the above address by calling (202) 514–3048 to arrange for an appointment.

FOR FURTHER INFORMATION CONTACT: John W. Brown, Adjudications Officer, Adjudications Division, Immigration and Naturalization Service, 425 I Street NW., Room 3214, Washington, DC 20536, telephone (202) 353–8177.

SUPPLEMENTARY INFORMATION:

What Are the Provisions of 8 U.S.C. 1182(a)(5)(C)?

The Illegal Immigration Reform and Immigrant Responsibility Act (IIRIRA), Public Law No. 104–208, section 343, 110 Stat. 3009, 636–37 (1996) created a new ground of inadmissibility now codified at 8 U.S.C. 1182(a)(5)(C), section 212(a)(5)(C) of the Immigration and Nationality Act (Act). It provides that an alien who seeks to enter the United States for the purpose of performing labor as a health care worker, other than a physician, is inadmissible unless the alien presents a certificate from CGFNS or an equivalent independent credentialing organization approved by the Attorney General in consultation with the Secretary of Health and Human Services (HHS) verifying:

(1) that the alien's education, training, license, and experience meet all applicable statutory and regulatory requirements for admission into the United States under the classification specified in the application; are comparable with that required for an American health care worker of the same type; are authentic and, in the case of a license, unencumbered;

(2) the alien has the level of competence in oral and written English considered by the Secretary of HHS, in consultation with the Secretary of Education, to be appropriate for health care work of the kind in which the alien will be engaged, as shown by an appropriate score on one or more nationally recognized, commercially available, standardized assessments of the applicant's ability to speak and write English; and,

(3) if a majority of States licensing the profession in which the alien intends to work recognize a test predicting an applicant's success on the profession's licensing or certification examination, the alien has passed such a test, or has passed such an examination. Section 212(r) of the Act mandates separate certification procedures for certain aliens.

How Has the Service Implemented 8 U.S.C. 1182(a)(5)(C)?

Section 212(a)(5)(C) of the Act became effective upon enactment on September 30, 1996. Shortly thereafter, the Service met and conferred with HHS, the Department of Labor (DOL), the Department of Education (DOE), the Department of Commerce (DOC), the Office of the United States Trade Representative (USTR), and the Department of State (DOS) to reach consensus on the best approach for implementation. In addition to meetings among the affected agencies, several meetings were held with interested organizations including CGFNS, the American Occupational Therapists Association, the National Board for Certification in Occupational Therapy (NBCOT), the Federated State Board of Physical Therapy, and the American Physical Therapy Association.

The Service in consultation with HHS initially identified, on the basis of the legislative history, seven categories of health care workers subject to the provisions of 8 U.S.C. 1182(a)(5)(C). The seven categories are nurses, physical therapists, occupational therapists, speech-language pathologists, medical technologists (also known as "clinical laboratory scientist"), medical technicians (also known as "clinical laboratory technicians") and physician assistants. Upon the suggestion of HHS, this rule lists the alternative terms "clinical laboratory scientist" and "clinical laboratory technician" to reflect both the legislative history and current health professions categorizations.

After weighing the complexity of the implementation issues, anticipating the length of time for rule making, and considering the need for health care facilities across the country to remain fully staffed and provide a high quality of service to the public, the DOS and the Service agreed to exercise their statutory discretion under 8 U.S.C. 1182(d)(3), section 212(d)(3) of the Act, and have granted a blanket waiver of inadmissibility to nonimmigrant health care workers until final regulations are promulgated. The blanket waiver of inadmissibility applies to nonimmigrant health care workers already in possession of nonimmigrant visas and visa exempt aliens, including Canadians applying for classification pursuant to 8 U.S.C. 1184(e), section 214(e) of the Act (TN classification). The Service published an interim rule (First Interim Rule) in the **Federal Register** on October 14, 1998 at 63 FR 55007 in which the adoption of this policy regarding nonimmigrant health care workers was announced. The First Interim Rule amended 8 CFR part 212 and 245. A formal application or fee is not required for a nonimmigrant health care worker to obtain the waiver. Nonimmigrant health care workers are admitted on a multiple entry Form I–94 for 1 year. In addition, otherwise admissible dependents are also authorized admission into the United States for the specific dates of stay authorized for the principal alien. A new waiver is not required if the nonimmigrant health care worker makes an application for admission to the United States during

the validity period of the previously issued Form I–94. Nonimmigrants applying for TN classification are not required to pay the admission fee described at 8 CFR 214.6(f) when applying for admission during the validity period of the previously issued Form I–94. Finally, nonimmigrant health care workers are eligible for extensions of the waiver and corresponding extensions of stay in increments of 1 year.

The Services has issued two interim rules implementing the certification requirements of section 212(a)(15)(C) of the Act with respect to immigrant health care workers. The First Interim Rule, previously referenced, and a Second Interim Rule which was published in the **Federal Register** on April 30, 1999 at 64 FR 23174. The Second Interim Rule also amended 8 CFR part 212.

What Were the Provisions of the 1st and 2nd Interim Rules?

The First Interim Rule temporarily enabled CGFNS to issue certificates to immigrants coming to the United States to work in the field of nursing, and temporarily authorized NBCOT to issue certificates in the field of occupational therapy. The Service adopted the First Interim Rule without the notice and comment period ordinarily required by 5 U.S.C. 553 because it found that delay in the implementation of 8 U.S.C. 1182(a)(5)(C) could adversely affect the provision of health care, particularly in medically under-served areas for nursing and occupational therapy. Given this context, the Service identified two criteria for the selection of certifying organizations on a temporary basis:

(1) That a sustained level of demand for foreign workers for the particular occupation exists; and

(2) That an organization with an established track record in providing credentialing services exists.

The First Interim Rule defined the term "sustained level of demand" as the presence of an existing demand for foreign health care workers in a particular occupation that is expected to continue in the foreseeable future. The term "organizations with an established track record" was defined as an organization which has a record of issuing actual certificates, or documents similar to a certificate, that are generally accepted by the state regulatory bodies as certificates that an individual has met certain minimal qualifications. The Service found, on the basis of information provided by DOL, that there was a sustained level of demand for foreign workers in nursing and occupational therapy. After consultation with HHS, CGFNS and NBCOT were found to qualify as organizations with an established track record in providing credentialing services for nursing and occupational therapy respectively. As required by 8 U.S.C. 212(a)(5)(C), the rule also established the appropriate English language competency levels for foreign nurses and occupational therapists, and specified exemptions from English language proficiency testing.

The First Interim Rule provided that the Service would apply the two criteria to other organizations seeking authorization to issue certificates while the interim rule remained in effect. Finally, the Service deferred consideration of whether CGFNS is authorized to issue certificates for other health care occupations.

The Second Interim Rule temporarily enabled CGFNS to issue certificates to immigrants coming to the United States to work in the fields of occupational therapy and physical therapy, and temporarily authorized the Foreign Credentialing Commission on Physical Therapy (FCCPT) to issue certificates in physical therapy. As with the First Interim Rule, the Service adopted the Second Interim Rule without the notice and comment period ordinarily required by 5 U.S.C. 553 because it found that delay in the implementation of 8 U.S.C. 1182(a)(5)(C) could adversely affect the provision of health care in medically under-served areas. The Service, in consultation with HHS, evaluated CGFNS' and FCCPT's applications for authorization to issue certificates under the criteria promulgated by the First Interim Rule. The Service found that both CGFNS and FCCPT met the "establishment or proven track record" criterion. With respect to the second criterion, the Service relied on its findings in the First Interim Rule to conclude that there was a sustained level of demand for occupational therapists. In addition, after considering data compiled by DOL, the Service concluded that there was a sustained level of demand for physical therapists that could adversely affect the provision of health care in medically under-served areas. The Second Interim Rule also established the appropriate English language competency levels for physical therapists.

Why Is the Service Promulgating a Third Interim Rule To Implement 8 U.S.C. 1182(a)(5)(C)?

After careful consideration, the Service believes that it is in the public interest to temporarily adopt this rule without notice and comment procedures, and that it would be impracticable to do otherwise. The Service will invite post promulgation comments to this temporary rule. In addition the Service anticipates publishing a Notice of Proposed Rule Making (NPRM) within the next 6 months.

The IIRIRA was a major, complex legislative scheme, which significantly changed existing immigration law and imposed many administrative duties upon the Service. Many provisions of the IIRIRA, including section 343 became immediately effective. The Service had a tremendous responsibility to rapidly promulgate numerous regulations implementing the new provisions of the law. Since enactment of the IIRIRA, the Service has diligently worked on an NPRM to implement 8 U.S.C. 1182(a)(5)(C) via ordinary notice and comment procedure, but has experienced considerable administrative difficulty in coordinating the needs and concerns of the large number of federal agencies and private interested parties affected by 8 U.S.C. 1182(a)(5)(C). Several substantive issues require the technical expertise of other agencies and further consultation before they can be definitively addressed. For example, the provisions of 8 U.S.C. 1182(a)(5)(C) may affect United States obligations under international treaties to facilitate the movement of professionals. Second, the Service is required to further define which, if any, other health care occupations fall under the ambit of the statute. Because of the delays in promulgating the larger rule, the Service believes the promulgation of this regulation as an interim rule is imperative to enable the Service to execute its adjudicative functions and to eliminate a growing backlog of pending immigrant applications filed by aliens seeking to immigrate to the United States as speech language pathologists and audiologists, medical technologists, physicians assistants and medical technicians. The Service has held such immigrant petitions in abeyance until promulgation of implementing regulations and as a result, certain immigrant health care workers have suffered extended periods of separation from family members and petitioning employers have been forced to operate without needed employees.

What Criteria Will the Service Use To Evaluate Organizations Applying for Authority to Issue Certifications?

The Service will continue to use the "proven track record" criterion previously promulgated in the First and Second Interim Rules. The legislative history of the IIRIRA indicates that the factors to be considered for selection of

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credentialing organizations are the following (1) the independence and freedom of material conflicts of interest of the organization regarding whether an alien receives a visa; (2) whether the organization has the ability to evaluate credentials and English competency; (3) whether the organization maintains comprehensive and current information on foreign educational institutions; and (4) whether the organization can conduct examinations outside of the United States. *See* H.R. REP. NO. 104–828 at 227 (1996). The Service intends to fully address each of these factors in the NPRM. However since this is a temporary rule, the Service believes that the "proven track record" criterion adequately addresses the factors outlined in the legislative history.

After careful consideration, the Service has decided it will not use the "sustained level of demand" criterion utilized in the First and Second Interim Rules. As discussed *supra*, the Service promulgated those interim rules under the rationale that failure to process immigrant petitions for certain health care occupations would adversely affect the provision of health care in medically under-served areas. Given that rationale for promulgation of those interim rules, "sustained level of demand" was initially an important consideration in the approval of credentialing organizations. In contrast, the Service is promulgating this interim rule because it has experienced tremendous administrative difficulty in promulgating permanent regulations due to the complexity of the issues to be addressed, and because the Service is unable to execute its adjudicative functions with respect to a growing backlog of petitions without an implementing regulation. Therefore, "sustained level of demand" is not a relevant consideration at this time because the Service is unable to execute its adjudicative function with respect to these occupations.

What Is the Purpose of This Interim Rule?

The purpose of this interim rule is to provide notice that CGFNS may issue certificates pursuant to section 212(a)(5)(C) of the Act, on a temporary basis, to foreign health care workers coming to the United States as immigrants or applicants for adjustment of status to work in the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants, and medical technicians (clinical laboratory technicians).

This rule does not establish procedures for the Service to accept certificates issued by CGFNS or equivalent credentialing organizations to aliens seeking temporary admission to the United States to perform services in a health care occupation. An alien's application for admission as a nonimmigrant will be processed pursuant to the Service's temporary policies previously described.

This interim rule also lists the passing scores for the English language tests for the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants, and medical technicians (clinical laboratory technicians). This interim rule also amends the regulations concerning what organizations may administer the English language tests to reflect recent changes concerning one of the testing organizations.

Has CGFNS Shown That It Has an Established Track Record?

Based on consultations with HHS, the Service finds that CGFNS has an established track record in issuing certificates for speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants and medical technicians (clinical laboratory technicians). In addition to 20 years of experience in evaluating the credentials of foreign nurses, CGFNS has experience beyond nursing with regard to educational comparability and credentials evaluation. CGFNS has an extensive database covering health-related academic programs in foreign countries, much of which is applicable beyond nursing. Finally CGFNS, through their credential evaluation service, has evaluated foreign credentials, including educational degrees and foreign licenses for psychiatric technicians, physician assistants, emergency medical technicians and other occupations. With the establishment of "Professional Standards Committees" CGFNS has developed certification standards that may be used to assess comparability for the occupations of speech language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants and medical technicians (clinical laboratory technicians).

What Are the Passing English Test Scores for Speech-Language Pathologists and Audiologists, Medical Technologist (Clinical Laboratory Scientists), and Physician Assistants?

In order to obtain a certificate, the alien must demonstrate to the credentialing organization that he or she has passed either the English tests given by the Educational Testing Service or the Michigan English Language Assessment Battery (MELAB). In order to obtain a certificate an alien must be competent in written, oral, and spoken English.

The HHS has determined that speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), and physician assistants must obtain the following scores on the English tests administered by the Educational Testing Service (ETS): Test of English as a Foreign Language (TOEFL): paper-based 540, computer-based 207; Test of Written English (TWE): 4.0; Test of Spoken English (TSE): 50.

The HHS has determined that speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), and physician assistants must obtain the following scores on the English tests administered by the Michigan English Language Assessment Battery (MELAB): Final Score 79; Oral Interview 3+. It is noted that, effective June 30, 2000, the MELAB Oral Interview Speaking Test is no longer being given overseas and is only being administered in the United States and Canada. Applicants may take MELAB Parts 1, 2 and 3, plus the TSE offered by the ETS. In addition, the exemptions for the English language tests described in § 212.15(g)(2) apply to the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), and physician assistants.

What Are the Passing English Test Scores for Medical Technicians (Clinical Laboratory Technicians)?

In order to obtain a certificate, the alien must demonstrate to the credentialing organization that he or she has passed either the English tests given by the Educational Testing Service or the Michigan English Language Assessment Battery (MELAB). In order to obtain a certificate an alien must be competent in written, oral, and spoken English.

The HHS has determined that medical technicians (clinical laboratory technicians) must obtain the following scores on the English tests administered by ETS: TOEFL: paper-based 530, computer-based 197; TWE: 4.0; TSE: 50.

The HHS has determined that medical technicians (clinical laboratory technicians) must obtain the following scores on the English tests administered by the MELAB: Final Score 77; Oral Interview 3+. Again, the MELAB Oral Interview Speaking Test is no longer being given overseas and is only being administered in the United States and Canada. Applicants may take MELAB Parts 1, 2 and 3, plus the TSE offered by the ETS. In addition, the exemptions for the English language tests described in § 212.15(g)(2) apply to the occupation of medical technicians (clinical laboratory technicians).

What Aliens Are Exempt From the English Tests?

According to § 212.15(g)(1), aliens who have graduated from a college, university, or professional training school located in Australia, Canada, (except Quebec), Ireland, New Zealand, the United Kingdom, and the United States are exempt from the English language requirement.

Does This Interim Rule Alter Any of the Service's Policies With Respect to the Admission of Nonimmigrant Health Care Workers?

No, this rule enables CGFNS to issue certificates to foreign health care workers seeking admission as immigrants or adjustment of status in the occupations previously discussed. It does not alter any of the Service's policies with respect to the admission of nonimmigrant aliens coming to perform services in health care occupations that were described in the first interim rule.

How Does This Rule Amend the Existing Regulation?

This interim rule amends the regulation at § 212.15(c) by adding the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants, and medical technicians (clinical laboratory technicians) to the list of occupations.

This interim rule also amends the regulation at § 212.15(e) to add the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants, and medical technicians (clinical laboratory technicians) to the list of occupations for which CGFNS can issue certificates.

Finally, this interim rule amends the regulation at § 212.15(g) to list the passing English scores for the occupations of speech-language pathologists and audiologists, medical technologists (clinical laboratory scientists), physician assistants, and medical technicians (clinical laboratory technicians). This interim rule further amends the regulations at § 212.15(g) by describing the changes in testing that have been instituted by MELAB.

Good Cause Exception

This interim rule is effective 60 days from the date of publication in the **Federal Register**, and the Service invites post-promulgation comments to be weighed and considered in the forthcoming NPRM. For the following reasons, the Service for good cause finds that it is in the public interest to temporarily adopt this rule without notice and comment procedures, and that it would be impracticable to do otherwise.

First, the Service has diligently worked on an NPRM for 8 U.S.C. 1182(a)(5)(C), but has experienced considerable administrative difficulty in coordinating the needs and concerns of the large number of federal agencies and private interested parties affected by 8 U.S.C. 1182(a)(5)(C). Several substantive issues, including how the provisions of 8 U.S.C. 1182(a)(5)(C) affect United States obligations under international treaties, and how to define which occupations fall under the ambit of the statute, require the technical expertise of other agencies and further consultation before they can be definitively addressed.

Second, the Service believes that promulgation of this regulation as an interim rule is imperative to enable the Service to execute its adjudicative functions with respect to pending immigrant applications filed by aliens seeking to immigrate to the United States as speech language pathologists, medical technologists, physician assistants and medical technicians. Such immigrant applications have been held in abeyance until promulgation of implementing regulations resulting in a backlog. Further, because these immigrant applications have been held in abeyance, certain immigrant health care workers have unfortunately suffered extended periods of separation from family members and petitioning employers have been forced to operate without needed employees. In the long term, the Service's continued policy with respect to these immigrants could have the unintended consequence of chilling future immigration of alien health care workers in these occupations.

While the Service plans to issue an NPRM in 6 months that covers more than this interim rule, it does not anticipate speedy promulgation of a final rule due to the numerous public comments expected in response to the NPRM. In light of this, the Service finds that it would be contrary to the public interest to continue to hold these immigrant applications in abeyance pending final rules when the admission or adjustment of these aliens under temporary procedures will only serve to benefit the public health.

Regulatory Flexibility Act

The Commissioner of the Immigration and Naturalization Service, in accordance with 5 U.S.C. 605(b), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule has been drafted in a way to minimize the economic impact that it has on small business while meeting its intended objective. The health care workers who will be issued certificates are not considered small entities as the term is defined in 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is considered by the Department of Justice, Immigration and Naturalization Service, to be a "significant regulatory action" under E.O. 12866, section 3(f), Regulatory Planning and Review. Accordingly, this rule has been submitted to the Office of Management and Budget (OMB) for review.

Executive Order 13132

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in

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accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988 Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

The information required on the certificate for health care workers showing that the alien possesses proficiency in the skills that affect the provision of health care services in the United States (as provided in § 212.15(f)) is considered an information collection that has been approved for use by the Office of Management and Budget (OMB) under OMB control number 1115–0226. It is estimated that the number of respondents will increase as a result of adding the five additional health care occupations listed in § 212.15(c). Accordingly, the Service will submit an adjustment form to OMB increasing the total annual burden hours.

List of Subjects in 8 CFR Part 212

Administrative practice and procedures, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

Accordingly, part 212 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

1. The authority citation for part 212 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1187, 1225, 1226, 1227, 1228, 1252; 8 CFR part 2.

2. Section 212.15 is amended by:

a. Adding new paragraphs (c)(4) through (c)(7);

b. Revising paragraph (e)(1);

c. Revising paragraph (g)(3)(i); and

d. Adding new paragraphs (g)(4)(iv) and (g)(4)(v), to read as follows:

§ 212.15 Certificates for foreign health care workers.

* * * * *

(c) * * *

(4) Speech-Language Pathologists and Audiologists.

(5) Medical Technologists (Clinical Laboratory Scientists).

(6) Physician Assistants.

(7) Medical Technicians (Clinical Laboratory Technicians).

* * * * *

(e) * * *

(1) The Commission on Graduates of Foreign Nursing Schools may issue certificates pursuant to 8 U.S.C. 1182(a)(5)(C), and section 212(a)(5)(C) of the Act for the occupations of nurse (licensed practical nurse, licensed vocational nurse, and registered nurse), physical therapist, occupational therapist, speech-language pathologist and audiologist, medical technologist (clinical laboratory scientist), physician assistant, and medical technician (clinical laboratory technician).

* * * * *

(g) * * *

(3) * * *

(i) Michigan English Language Assessment Battery (MELAB). Effective June 30, 2000, the MELAB Oral Interview Speaking Test is no longer being given overseas and is only being administered in the United States and Canada. Applicants may take MELAB Parts 1, 2, and 3, plus the Test of Spoken English offered by the Educational Testing Service.

* * * * *

(4) * * *

(iv) *Speech-language pathologists and Audiologists, medical technologists (clinical laboratory scientists), and physician assistants.* An alien coming to the United States to perform labor as a speech-language pathologist and audiologist, a medical technologist (clinical laboratory scientist), or a physician assistant must have the following scores to be issued a certificate: ETS: TOEFL: Paper-Based 540, Computer-Based 207; TWE: 4.0; TSE: 50; MELAB: Final Score 79; Oral Interview: 3+.

(v) *Medical technicians (clinical laboratory technicians).* An alien coming to the United States to perform labor as a medical technician (clinical laboratory technician) must have the following scores to be issued a certificate: ETS: TOEFL: Paper-Based 530, Computer-Based 197; TWE: 4.0; TSE: 50; MELAB: Final Score 77; Oral Interview: 3+.

Dated: November 28, 2000.

Mary Ann Wyrsch,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 01–1203 Filed 1–12–01; 8:45 am]

BILLING CODE 4410–10–M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

RIN 3150–AG54

List of Approved Spent Fuel Storage Casks: FuelSolutions Addition

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to add the FuelSolutions cask system to the list of approved spent fuel storage casks. This amendment allows the holders of power reactor operating licenses to store spent fuel in this approved cask system under a general license.

EFFECTIVE DATE: This final rule is effective on February 15, 2001.

FOR FURTHER INFORMATION CONTACT: Stan Turel, telephone (301) 415–6234, e-mail spt@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended (NWPA), requires that "[t]he Secretary [of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission." Section 133 of the NWPA states, in part, "[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 218(a) for use at the site of any civilian nuclear power reactor."

To implement this mandate, the NRC approved dry storage of spent nuclear fuel in NRC-approved casks under a general license, publishing a final rule in 10 CFR part 72 entitled "General License for Storage of Spent Fuel at Power Reactor Sites" (55 FR 29181; July 18, 1990). This rule also established a new Subpart L within 10 CFR part 72 entitled, "Approval of Spent Fuel Storage Casks," containing procedures and criteria for obtaining NRC approval of dry storage cask designs.

Discussion

This rule will add the FuelSolutions cask system to the list of approved spent fuel storage casks in 10 CFR 72.214. Following the procedures specified in 10 CFR 72.230 of subpart L, BNFL Fuel Solutions submitted an application for NRC approval with the Safety Analysis Report (SAR) entitled, "Final Safety Analysis Report for the FuelSolutions Spent Fuel Management System." The NRC evaluated the BNFL Fuel Solutions submittal and issued a preliminary Safety Evaluation Report (SER) and a proposed Certificate of Compliance (CoC) for the FuelSolutions cask system. The NRC published a proposed rule in the **Federal Register** (65 FR 42647; July 11, 2000) to add the FuelSolutions cask system to the listing in 10 CFR 72.214. The comment period ended on September 25, 2000. Two comment letters were received on the proposed rule.

Based on NRC review and analysis of public comments, the NRC has modified, as appropriate, the CoC, SER, SAR, and the Technical Specifications (TS) for the FuelSolutions cask system.

The NRC finds that the FuelSolutions cask system, as designed and when fabricated and used in accordance with the conditions specified in its CoC, meets the requirements of 10 CFR Part 72, Subpart L. Thus, use of the FuelSolutions cask system as approved by the NRC will provide adequate protection of public health and safety and the environment. With this final rule, the NRC is approving the use of the FuelSolutions cask system under the general license in 10 CFR part 72, Subpart K, by holders of power reactor operating licenses under 10 CFR part 50. Simultaneously, the NRC is issuing a final SER and CoC that will be effective on February 15, 2001. Single copies of the final CoC and SER will be available by January 30, 2001 for public inspection and/or copying for a fee at the NRC Public Document Room (PDR),11555 Rockville Pike, Rockville, Maryland 20852 and electronically at *http://ruleforum.llnl.gov.*

Documents created or received at the NRC after November 1, 1999, are also available electronically at the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/NRC/ADAMS/index.html.* The public can gain entry from this site into the NRC's Agency wide Document Access and Management System (ADAMS), which provides text and image files of the NRC's public documents. An electronic copy of the final CoC, Technical Specifications, and SER for the FuelSolutions cask system can be found in ADAMS under Accession No. ML003759247. However, because the NRC must incorporate the date of publication of this **Federal Register** notice into the CoC, these documents are not yet publicly available. The NRC will make these documents publically available by January 30, 2001. Contact the NRC PDR reference staff for more information. PDR reference staff may be reached at 1–800–397–4209, 301–415–4737, or by e-mail at *pdr@nrc.gov.*

Summary of Public Comments on the Proposed Rule

The NRC received two comment letters from one commenter within the nuclear industry on the proposed rule. Copies of the public comments are available for review in the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852 and electronically at *http://ruleforum.llnl.gov.*

Comments on the FuelSolutions Cask System

The comments and responses have been grouped into four subject areas: Safety Evaluation Report (SER), Certificate of Compliance (CoC), Technical Specifications (TS), and Safety Analysis Report (SAR). The NRC's decision to list the FuelSolutions cask system within 10 CFR 72.214, "List of approved spent fuel storage casks," has not been changed as a result of the public comments. A review of the comments and the NRC's responses follow:

A: Safety Evaluation Report

Comment A–1: The commenter requested that within the Draft Safety Evaluation Report, Section 4.1, under BFS Methodology for Calculating Maximum Allowable Cladding Temperature, a clarifying statement be added, stating that for PWR and BWR fuel assemblies with burnups under 45,000 MWD/MTU cladding oxide thickness measurement is not required. The commenter remarked that the last sentence in the sixth paragraph of this section notes that the strain limit is defendable for spent fuels having oxide thicknesses less than 70 micrometers, irrespective of burnup. The last paragraph of this section states that for fuel with burnups between 45,000 and 60,000 MWD/MTU the cladding thickness must be measured. A statement that this is not required for fuels with burnups less than 45,000 MWD/MTU would clarify the requirements for lower burnup fuels.

Response: The NRC agrees with the proposed clarification, and the SER has been revised to add a sentence stating that oxide measurements are not required for burnups below 45,000 MWD/MTU.

Comment A–2: The commenter requested an editorial clarification within the Draft Safety Evaluation Report, Section 5.1.1, noting that in the first sentence of the first paragraph, the term "steel-lead-water-steel" includes a redundant term "steel." The composite shielding of the transfer cask includes the three materials listed (*i.e.*, steel-lead-water).

Response: The NRC agrees with the proposed clarification and the SER has been revised accordingly.

Comment A–3: The commenter requested an editorial clarification within the Draft Safety Evaluation Report, Section 5.3.1, where under Adjoint Model, the word "discrete" is misspelled.

Response: The misspelled word has been corrected.

Comment A–4: The commenter stated that within the Draft Safety Evaluation Report, Section 8.1.4, the time values listed in the fifth, sixth, and seventh sentences are for the W21 canister. The values for the W74 canister are seven hours, four hours, and four hours, respectively. The commenter requested that the SER be revised either to clarify that the values shown are for the W21 canister or to report the values for both canisters explicitly.

Response: NRC agrees with the comment. Section 8.1.4 of the SER has been revised for clarity. Values for both canisters have been stated explicitly.

Comment A–5: The commenter stated that within the Draft Safety Evaluation Report, Section 8.3, the general actions for canister unloading listed in the second sentence are not in the actual sequence of operations as reported in the WSNF–200 SAR, Section 8.2.3. The commenter requested that to avoid confusion, the sentence be revised to list the actions in sequence, as follows:

(a) Move the action "lowering the cask into the pool" to after the action "removing the canister lid."

(b) Change "removing the canister lid" to "removing the canister lids" (note that there are two lids—inner and outer).

(c) Add "removing the shield plug" before "and removing the fuel assemblies from the storage basket."

Response: The NRC agrees with the comment and the SER has been revised to clarify the sequence of actions.

Comment A–6: The commenter requested that within the Draft Safety Evaluation Report, editorial clarifications be made in Section 10.3.2, third paragraph as follows:

(A) Fourth sentence—per WSNF–200 SAR Table 10.4–8, the dose rate listed

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is calculated for one year. The dose for 30 days would need to be factored from the values presented as follows: Take 1/12 of the 64 cask accident direct and of the 63 cask normal release, then add the 1 cask accident release (approx. 931 mrem for 30 days). This comment also affects the conclusion statement in the eighth sentence.

(B) Fifth sentence—per WSNF–200 SAR Section 10.4.3, the maximum transfer cask loss of neutron shield accident dose is 25.3 mrem per 24 hours, not per hour.

(C) Sixth sentence—delete the words "of the WSNF–200 SAR" from the end of the sentence. The NRC staff's review is documented in the SER, not the WSNF–200 SAR.

(D) Seventh sentence—the 751 mrem dose was calculated for the bone, not the lung.

Response: The NRC agrees with the comments:

(A) The dose rate was calculated for a one year period. The SER has been revised to state that the maximum dose at 100 meters is about 2900 mrem from the storage cask array, assuming an individual is present for a year, for accident conditions. This sentence is now in agreement with the eighth sentence.

(B) The SER has been revised to state that the maximum dose from the transfer cask for a loss of neutron shield accident is 25.3 mrem for a 24-hour period.

(C) The SER has been revised to state that the NRC staff's review is discussed in Section 7 of the SER.

(D) The SER has been revised to state that the 751 mrem dose was calculated for the bone.

B: Certificate of Compliance

Comment B–1: The commenter requested that within the Draft Certificate of Compliance, in 1.b, second paragraph, that the statement "The ten unfueled guide tube positions are mechanically blocked to prevent loading in these positions" be revised to read "The ten unfueled cell locations are mechanically blocked to prevent loading in these positions." The commenter stated that this terminology agrees with that in the previous sentence, and reflects the fact that there are no guide tubes in the unfueled cell locations.

Response: The NRC agrees with the comment and the CoC has been revised to clarify the statement.

C: Technical Specifications

Comment C–1: The commenter requested that LCO 3.3.2 (Storage Cask Temperatures During Storage) for the W21 Canister be revised to modify REQUIRED ACTION B.2 to allow for the use of alternative means to be developed by the licensee to bring the CASK into compliance with the LCO. Alternatively, REQUIRED ACTION B.2 should be deleted and replaced with a requirement for the licensee to develop the means to meet the LCO and notify NRC of the action taken. The commenter's logic was that the specification of a specific method to meet the LCO when there are other alternatives available is overly restrictive and may not be feasible in some conditions. This will permit decommissioning facilities to meet the LCO in the absence of a spent fuel pool. In addition, the additional flexibility can better satisfy ALARA by mitigating the personnel exposure associated with the removal of spent fuel from the CANISTER.

Response: The NRC disagrees with the comment. Currently, no alternative means of complying with the LCO have been proposed by the licensee or evaluated by the staff for acceptability. Any alternative means to meet the LCO shall be approved by the staff prior to implementation.

Comment C–2: The commenter requested that LCO 3.3.3 (Storage Cask Temperatures During Horizontal Transfer) for the W21 Canister be revised to modify REQUIRED ACTION C.1 to allow for the use of alternative means to be developed by the licensee to bring the CASK into compliance with the LCO. Alternatively, REQUIRED ACTION C.1 should be deleted and replaced with a requirement for the licensee to develop the means to meet the LCO and notify NRC of the action taken. The commenter's logic was that the specification of a specific method to meet the LCO when there are other alternatives available is overly restrictive and may not be feasible in some conditions. This will permit decommissioning facilities to meet the LCO in the absence of a spent fuel pool. In addition, the additional flexibility can better satisfy ALARA by mitigating the personnel exposure associated with the removal of spent fuel from the CANISTER.

Response: The NRC disagrees with the comment. Currently, no alternative means of complying with the LCO have been proposed by the licensee or evaluated by the staff for acceptability. Any alternative means to meet the LCO shall be approved by the staff before implementation.

Comment C–3: The commenter requested that LCO 3.3.2 (Storage Cask Temperatures During Storage) for the W74 Canister be revised to modify REQUIRED ACTION B.2 to allow for the use of alternative means to be developed by the licensee to bring the CASK into compliance with the LCO. Alternatively, REQUIRED ACTION B.2 should be deleted and replaced with a requirement for the licensee to develop the means to meet the LCO and notify NRC of the action taken. The commenter's logic was that the specification of a specific method to meet the LCO when there are other alternatives available is overly restrictive and may not be feasible in some conditions. This will permit decommissioning facilities to meet the LCO in the absence of a spent fuel pool. In addition, the additional flexibility can better satisfy ALARA by mitigating the personnel exposure associated with the removal of spent fuel from the CANISTER.

Response: The NRC disagrees with the comment. Currently, no alternative means of complying with the LCO have been proposed by the licensee or evaluated by the staff for acceptability. Any alternative means to meet the LCO would be approved by the staff prior to implementation.

Comment C–4: The commenter requested that LCO 3.3.3 (Storage Cask Temperatures During Horizontal Transfer) for the W74 Canister be revised to modify REQUIRED ACTION C.1 to allow for the use of alternative means to be developed by the licensee to bring the cask into compliance with the LCO. Alternatively, REQUIRED ACTION C.1 should be deleted and replaced with a requirement for the licensee to develop the means to meet the LCO and notify NRC of the action taken. The commenter's logic was that the specification of a specific method to meet the LCO when there are other alternatives available is overly restrictive and may not be feasible in some conditions. This will permit decommissioning facilities to meet the LCO in the absence of a spent fuel pool. In addition, the additional flexibility can better satisfy ALARA by mitigating the personnel exposure associated with the removal of spent fuel from the CANISTER.

Response: The NRC disagrees with the comment. Currently, no alternative means of complying with the LCO have been proposed by the licensee or evaluated by the staff for acceptability. Any alternative means to meet the LCO shall be approved by the staff prior to implementation.

Comment C–5: The commenter requested that the Technical Specification for the FuelSolutions Storage System, Section 4.2.2.1 (Storage Cask), be revised to add a note clarifying the requirements for site-specific pad designs that have different values from those listed. The following is requested to be added at the end of Section 4.2.2.1: "Any site-specific pad design with parameters that differ from those listed must be evaluated by the licensee to confirm that the design basis deceleration loads for the storage cask and canister are not exceeded. This evaluation must be performed using the same methodology as described in WSNF–200 SAR Section 3.7.3.1."

Response: The NRC agrees with the comment. The Technical Specification for the FuelSolutions Storage System, Section 4.2.2.1 (Storage Cask) has been revised accordingly.

Comment C–6: The commenter requested that the Technical Specification for the FuelSolutions Storage System, Section 4.2.2.2 (Transfer Cask), be revised to add a note clarifying the requirements for site-specific pad designs that have different values from those listed. The following is requested to be added at the end of Section 4.2.2.2: "Any site-specific pad design with parameters that differ from those listed must be evaluated by the licensee to confirm that the design basis deceleration loads for the transfer cask and canister are not exceeded. This evaluation must be performed using the same methodology as described in WSNF–200 SAR Section 3.7.5.1."

Response: The NRC agrees with the comment. The Technical Specification for the FuelSolutions Storage System, Section 4.2.2.2 (Transfer Cask) has been revised accordingly.

D: Safety Analysis Report

Comment D–1: The commenter requested that editorially, within the Safety Analysis Report in WSNF–200 SAR Table 12.1–1, the following references to the Technical Specifications be revised:

(a) Under Radiological Protection, 3.4.1 should be 5.3.5, and 3.5.1 should be 3.5.1.

(b) Under Structural Integrity, 3.5.1 should be 3.4.1.

Response: The NRC agrees with the comment. The editorial corrections were made to Table 12.1–1.

Summary of Final Revisions

Based on the responses above, the CoC, the TSs, the SAR, and the SER have been modified as follows:

1. The SER has been revised (Comments A–1 through and including A–6).

2. The CoC has been revised (Comment B–1).

3. The Technical Specification for the FuelSolutions Storage System, Section 4.2.2.1 (Storage Cask) has been revised. (Comment C–5).

4. The Technical Specification for the FuelSolutions Storage System, Section 4.2.2.2 (Transfer Cask) has been revised (Comment C–6).

5. Editorial corrections were made to Table 12.1–1 of the SAR (Comment D–1).

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the NRC on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, th NRC is adding the FuelSolutions cask system to the list of NRC-approved cask systems for spent fuel storage in 10 CFR 72.214. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Finding of No Significant Environmental Impact: Availability

Under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR part 51, the NRC has determined that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore, an environmental impact statement is not required. This final rule adds an additional cask to the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites without additional site-specific approvals from the NRC. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852 and electronically at *http://ruleforum.llnl.gov*. Single copies of the environmental assessment and finding of no significant impact are available from Stan Turel, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6234, e-mail *spt@nrc.gov*.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

On July 18, 1990 (55 FR 29181), the Commission issued an amendment to 10 CFR part 72. The amendment provided for the storage of spent nuclear fuel in cask systems with designs approved by the NRC under a general license. Any part 50 nuclear power reactor licensee can use cask systems with designs approved by the NRC to store spent nuclear fuel if it notifies the NRC in advance, the spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. In that rule, four spent fuel storage casks were approved for use at reactor sites and were listed in 10 CFR 72.214. That rule envisioned that storage casks certified in the future could be routinely added to the listing in 10 CFR 72.214 through the rulemaking process. Procedures and criteria for obtaining NRC approval of new spent fuel storage cask designs were provided in 10 CFR part 72, subpart L.

The alternative to this action is to withhold approval of this new design and issue a site-specific license to each utility that proposes to use the casks. This alternative would cost both the NRC and utilities more time and money for each site-specific license. Conducting site-specific reviews would ignore the procedures and criteria currently in place for the addition of new cask designs that can be used under

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a general license, and would be in conflict with Nuclear Waste Policy Act (NWPA) direction to the Commission to approve technologies for the use of spent fuel storage at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site reviews. This alternative also would tend to exclude new vendors from the business market without cause and would arbitrarily limit the choice of cask designs available to power reactor licensees. This final rule will eliminate the above problems and is consistent with previous NRC actions. Further, the rule will have no adverse effect on public health and safety.

The benefit of this rule to nuclear power reactor licensees is to make available a greater choice of spent fuel storage cask designs that can be used under a general license. The new cask vendors with casks to be listed in 10 CFR 72.214 benefit by having to obtain NRC certificates only once for a design that can then be used by more than one power reactor licensee. The NRC also benefits because it will need to certify a cask design only once for use by multiple licensees. Casks approved through rulemaking are to be suitable for use under a range of environmental conditions sufficiently broad to encompass multiple nuclear power plants in the United States without the need for further site-specific approval by NRC. Vendors with cask designs already listed may be adversely impacted because power reactor licensees may choose a newly listed design over an existing one. However, the NRC is required by its regulations and NWPA direction to certify and list approved casks. This rule has no significant identifiable impact or benefit on other Government agencies.

Based on the above discussion of the benefits and impacts of the alternatives, the NRC concludes that the requirements of the final rule are commensurate with the Commission's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and thus, this action is recommended.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule affects only the licensing and operation of nuclear power plants, independent spent fuel storage facilities, and BNFL Fuel Solutions. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the Small Business Size Standards set out in regulations issued by the Small Business Administration at 13 CFR part 121.

Backfit Analysis

The NRC has determined that the backfit rule (10 CFR 50.109 or 10 CFR 72.62) does not apply to this rule because this amendment does not involve any provisions that would impose backfits as defined in the backfit rule. Therefore, a backfit analysis is not required.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 72

Criminal penalties, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

1. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 as amended by Pub. L. 10d—48b, sec. 7902, 10b Stat. 31b3 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c),(d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244, (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In § 72.214, Certificate of Compliance 1026 is added to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1026.
SAR Submitted by: BFNL Fuel Solutions.
SAR Title: Final Safety Analysis Report for the FuelSolutions Spent Fuel Management System.
Docket Number: 72–1026.
Certificate Expiration Date: March 19, 2021.
Model Number: WSNF–200, WSNF–201, and WSNF–203 systems; W–150 storage cask; W–100 transfer cask; and the W–21 and W–74 canisters

* * * * *

Dated at Rockville, Maryland, this 22nd day of December 2000.

For the Nuclear Regulatory Commission.

John W. Craig,

Acting Executive Director for Operations.

[FR Doc. 01–1172 Filed 1–12–01; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–44–AD; Amendment 39–12071; AD 2001–01–01]

RIN 2120–AA64

Airworthiness Directives; BMW Rolls-Royce GmbH Models BR700–710A1–10 and BR700–710A2–20 Turbofan Engines.

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to BMW Rolls-Royce (RR) GmbH models BR700–710A1–10 and BR700–710A2–20 turbofan engines with oil filter differential pressure switch part number (P/N) 21SN04–419 or P/N 21SN04–431 installed. This action requires inspections of oil filter differential pressure switches, and replacement if necessary, in accordance with Rolls-Royce Service Bulletin No. SB–BR700–79–900215, Revision 2, dated August 2, 2000. This amendment is prompted by a report of severe engine oil loss, caused by oil leakage from a defective oil filter differential pressure switch. The actions specified in this AD are intended to prevent defective oil filter differential pressure switches from causing severe engine oil loss, resulting in in-flight shutdowns.

DATES: Effective January 31, 2001. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 31, 2001.

Comments for inclusion in the Rules Docket must be received on or before March 19, 2001.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–NE–44–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: "9-ane-adcomment@faa.gov". Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from BMW Rolls-Royce GmbH, Postfach 1246, 61402 Oberursel, Germany; telephone: International Access Code 011, Country Code 49, 33 7086–2935, fax: International Access Code 011, Country Code 49, 33 7086–3276. This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone: 781–238–7176, fax: 781–238–7199.

SUPPLEMENTARY INFORMATION: The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified the Federal Aviation Administration (FAA) that an unsafe condition may exist on BMW RR GmbH models BR700–710A1–10 and BR700–710A2–20 turbofan engines. The LBA received a report of severe engine oil loss, caused by oil leaking from a defective oil filter differential pressure switch, resulting in an in-flight engine shutdown. BMW RR has identified and provided in a list, serial numbers for pressure switches that are not defective. BMW RR has determined that for pressure switches with less than 200 flight hours-since-new, that are not one of the listed switches, and are not leaking, 50 flight hours will be allowed after the effective date of this AD before the required replacement with a serviceable switch. For pressure switches with 200 or more flight hours-since-new, 150 flight hours will be allowed after the effective date of this AD before the required replacement with a serviceable switch. This is based on calculations that pressure switches with 200 or more flight hours-since-new have successfully passed a threshold for failure. An analysis conducted by BMW RR revealed that the engine shutdown rate due to oil leaking from defective oil filter differential pressure switches is unacceptable, and could result in multiple engine in-flight shutdowns. The actions specified in this AD are intended to prevent defective oil filter differential pressure switches from causing severe engine oil loss, resulting in in-flight engine shutdowns.

Service Information

RR has issued Service Bulletin No. SB–BR700–79–900215, Revision 2, dated August 2, 2000, which specifies procedures for inspecting, marking, and if necessary replacing oil filter differential pressure switch P/N 21SN04–419 or P/N 21SN04–431 with a serviceable switch. The LBA issued AD No. 2000–257/2, in response to the service bulletin to assure the airworthiness of these engines in Germany.

Bilateral Airworthiness Agreement

These engine models are manufactured in Germany and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Required Actions

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design registered in the United States, this AD is being issued to prevent defective oil filter differential pressure switch P/N 21SN04–419 or P/N 21SN04–431 from causing severe engine oil loss, resulting in in-flight shutdown. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Immediate Adoption

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NE–44–AD." The postcard will be date stamped and returned to the commenter.

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Regulatory Impact

This action does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposal.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–01–01 BMW Rolls-Royce GmbH: Amendment 39–12071. Docket 2000–NE–44–AD.

Applicability: This airworthiness directive (AD) applies to BMW Rolls-Royce (RR) GmbH models BR700–710A1–10 and BR700–710A2–20 turbofan engines with oil filter differential pressure switch part number (P/N) 21SN04–419 or P/N 21SN04–431 installed. These engines are installed on, but not limited to Bombardier Inc. BD–700 and Gulfstream Aerospace Corp. G–V series airplanes.

Note 1: This AD applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance

Compliance with this AD is required as indicated, unless already done. To prevent defective oil filter differential pressure switches from causing severe engine oil loss, resulting in in-flight shutdowns, perform the following:

Number Checking, Marking, and Replacement

(a) Within 50 flight hours after the effective date of this AD, mark or replace the oil filter differential pressure switch as follows:

(1) If the oil filter differential pressure switch serial number is listed in Appendix 1 of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000, then mark the switch in accordance with the Accomplishment Instructions, Section 3, of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000. No further action is required.

(2) If the oil filter differential pressure switch serial number is not listed in Appendix 1 of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000, then replace the switch as follows:

(i) For oil pressure switches with less than 200 flight hours-since-new on the effective date of this AD, replace the pressure switch with a serviceable switch, within 50 flight hours after the effective date of this AD, in accordance with Accomplishment Instructions, Section 3, Part 2 of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000.

(ii) For oil pressure switches with 200 or more flight hours-since-new on the effective date of this AD, replace the pressure switch with a serviceable switch, within 150 flight hours after the effective date of this AD, in accordance with Accomplishment Instructions, Section 3, Part 2 of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000.

Definition of Serviceable Switch

(b) For the purpose of this AD, the definition of a serviceable switch is an oil filter differential pressure switch P/N 21SN04–419 or 21SN04–431 that has a manufacturer-applied orange stripe on the switch cap, or, a pressure switch whose serial number is listed in Appendix 1 of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000, and has been marked with orange paint in accordance with the Accomplishment Instructions, Section 3, of RR Service Bulletin SB–BR700–79–900215, Revision 2, dated August 2, 2000.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the ECO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The actions required by this AD must be performed in accordance with BMW RR Service Bulletin No. SB–BR700–79–900215, Revision 2, dated August 2, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from BMW Rolls-Royce GmbH, Postfach 1246, 61402 Oberursel, Germany; telephone: International Access Code 011, Country Code 49, 33 7086–2935, fax: International Access Code 011, Country Code 49, 33 7086–3276. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date of This AD

(f) This amendment becomes effective on January 31, 2001.

Issued in Burlington, Massachusetts, on January 4, 2001.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–917 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

[Docket No. 00331092–0315–02; I.D. 030100F]

Fisheries of the Exclusive Economic Zone Off Alaska; License Limitation Program for the Scallop Fishery; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule and application period; correction.

SUMMARY: This document corrects the final rule for the License Limitation Program by adding an Office of Management and Budget (OMB) control number to § 902.1. The OMB control number was inadvertently omitted from the final rule implementing Amendment 4 to the Fishery Management Plan for the Scallop Fishery off Alaska.

DATES: Effective January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Gretchen Harrington, 907-586-7228.

SUPPLEMENTARY INFORMATION: The final rule for Fisheries of the Exclusive Economic Zone off Alaska; License Limitation Program for the Scallop Fishery (65 FR 78110, December 14, 2000) established permit requirements to implement Amendment 4 to the Fishery Management Plan for the Scallop Fishery off Alaska. The permit requirements were approved by OMB but the control number was not added to § 902.1(b).

Correction

In rule FR Doc 00-31649, published on December 14, 2000 (65 FR 78110) make the following correction. On page 78115, in the third column, after the signature, add the following text:

For reasons set out in the preamble, 15 CFR part 902, is amended as follows:

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

2. In § 902.1, the table in paragraph (b) under 50 CFR is amended by adding in numerical order an entry for § 679.4(g) with a new OMB control number to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control number the information (All numbers begin with 0648–)
* * * * *	
679.4 (g)	–0420
* * * * *	

Dated: January 8, 2001.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1214 Filed 1–12–01; 8:45 am]

BILLING CODE: 3510–22–S

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 381

[Docket No. RM01–3–000]

Annual Update of Filing Fees

January 9, 2001.

AGENCY: Federal Energy Regulatory Commission (DOE).

ACTION: Final rule; annual update of Commission filing fees.

SUMMARY: In accordance with § 381.104 of the Commission's regulations, the Commission issues this update of its filing fees. This notice provides the yearly update using data in the Commission's Payroll Utilization Reporting System and the Commission's Management, Administrative, and Payroll System to calculate the new fees. The purpose of updating is to adjust the fees on the basis of the Commission's costs for Fiscal Year 1999.

EFFECTIVE DATE: February 15, 2001.

FOR FURTHER INFORMATION CONTACT: Troy Cole, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Room 42–66, Washington, DC 20426, 202–219–2970.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Public Reference Room at 888 First Street, NE., Room 2A, Washington, DC 20426.

The Commission Issuance Posting System (CIPS) provides access to the texts of formal documents issued by the Commission. CIPS can be accessed via Internet through FERC's Home Page (http://www.ferc.fed.us) using the CIPS link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII, WordPerfect 6.1 and WordPerfect 8.0 format. User assistance is available at 202–208–2222 or by E-mail to CipsMaster@ferc.fed.us.

This document is also available through the Commission's Records and Information Management System (RIMS), an electronic storage and retrieval system of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed. RIMS is available in the Public Reference Room or remotely via Internet through FERC's Homepage using the RIMS link or the Energy Information Online icon. User assistance is available at 202–208–2222, or by E-mail to RimsMaster@ferc.fed.us.

Finally, the complete text on diskette in WordPerfect format may be purchased from the Commission's copy contractor, RVJ International, Inc. RVJ International, Inc., is located in the Public Reference Room at 888 First Street, NE., Washington, DC 20426.

The Federal Energy Regulatory Commission (Commission) is issuing this notice to update filing fees that the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to § 381.104 of the Commission's regulations, the Commission is establishing updated fees on the basis of the Commission's Fiscal Year 1999 costs. The adjusted fees announced in this notice are effective February 15, 2001. The Commission has determined with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this final rule is not a major rule within the meaning of section 251 of Subtitle E of SBREFA. [5 U.S.C. § 804(2)] The Commission is submitting this final rule to both Houses of Congress and to the Comptroller General.

The new fee schedule is as follows:

Fees Applicable to the Natural Gas Policy Act

1. Petitions for rate approval pursuant to 18 CFR 284.123(b)(2). (18 CFR 381.403): $7,840.

Fees Applicable to General Activities

1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act). (18 CFR 381.302(a)): $15,760.

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2. Review of a Department of Energy remedial order:

Amount in controversy

$0–9,999. (18 CFR 381.303(b)): $100.
$10,000–29,999. (18 CFR 381.303(b)): $600.
$30,000 or more. (18 CFR 381.303(a)): $23,010.

3. Review of a Department of Energy denial of adjustment:

Amount in controversy

$0–9,999. (18 CFR 381.304(b)): $100.
$10,000–29,999. (18 CFR 381.304(b)): $600.
$30,000 or more. (18 CFR 381.304(a)): $12,060.

4. Written legal interpretations by the Office of General Counsel. (18 CFR 381.305(a)): $4,520.

Fees Applicable to Natural Gas Pipelines

1. Pipeline certificate applications pursuant to 18 CFR 284.22. (18 CFR 381.207(b)): $1,000.

Fees Applicable to Cogenerators and Small Power Producers

1. Certification of qualifying status as a small power production facility. (18 CFR 381.505(a)): $13,550.
2. Certification of qualifying status as a cogeneration facility. (18 CFR 381.505(a)): $15,340.
3. Applications for exempt wholesale generator status. (18 CFR 381.801): $1,310.

List of Subjects in 18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

Thomas R. Herlihy,
Executive Director and Chief Financial Officer.

In consideration of the foregoing, the Commission amends Part 381, Chapter I, Title 18, *Code of Federal Regulations*, as set forth below.

PART 381—FEES

1. The authority citation for Part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

§ 381.302 [Amended]

2. In § 381.302, paragraph (a) is amended by removing "$14,710" and inserting "$15,760" in its place.

§ 381.303 [Amended]

3. In § 381.303, paragraph (a) is amended by removing "$21,470" and inserting "$23,010" in its place.

§ 381.304 [Amended]

4. In § 381.304, paragraph (a) is amended by removing "$11,260" and inserting "$12,060" in its place.

§ 381.305 [Amended]

5. In § 381.305, paragraph (a) is amended by removing "$4,220" and inserting "$4,520" in its place.

§ 381.403 [Amended]

6. Section 381.403 is amended by removing "$7,320" and inserting "$7,840" in its place.

§ 381.505 [Amended]

7. In § 381.505, paragraph (a) is amended by removing "$12,650" and inserting "$13,550" in its place and by removing "$14,320" and inserting "$15,340" in its place.

§ 381.801 [Amended]

8. Section 381.801 is amended by removing "$1,530" and inserting "$1,310" in its place.

[FR Doc. 01–1149 Filed 1–12–01; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

RIN 1076–AD90

Acquisition of Title to Land in Trust

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule revises and clarifies the procedures used by Indian tribes and individuals to request the Secretary of the Interior to acquire title to land into trust on their behalf. It describes the criteria that the Secretary will use in determining whether to exercise his or her authority to accept title to land to be held in trust for the benefit of Indian tribes and individuals. This rule also describes the procedure for mandatory acquisitions of title and establishes a process to address the difficulties encountered by Indian tribes which have no reservation, have no trust land or have trust land the character of which renders it incapable of being developed.

DATES: Effective February 15, 2001.

FOR FURTHER INFORMATION CONTACT: Questions concerning this rule should be directed to: Terry Virden, Director, Office of Trust Responsibilities, Mail Stop: 4513–MIB, 1849 C Street NW., Washington, DC 20240; telephone: 202–208–5831; electronic mail: TerryVirden@BIA.GOV.

SUPPLEMENTARY INFORMATION: The regulation makes more clear the process that is followed by the Secretary in the exercise of this discretionary authority. The regulation also makes clear that we will follow a process which reflects (1) a presumption in favor of the acquisition of trust title when an application involves title to lands located inside the boundaries of a reservation ("on-reservation lands"), and (2) a more demanding standard for the acquisition of title when the application involves title to lands located outside the boundaries of a reservation ("off-reservation lands"). The delineation of these differing processes will better enable the Secretary to carry out the responsibility for assisting Indian tribes in re-establishing jurisdiction over land located within their own reservations. It also creates a framework that more adequately addresses concerns non-Indian governments may have about the potential ramifications of placing off-reservation lands into trust.

This regulation also describes the procedure for mandatory acquisitions of title. The general statutory authority giving the Secretary discretion to acquire title to lands in trust is found in section 5 of the Indian Reorganization Act (IRA) of 1934, 25 U.S.C. 465. Occasionally, Congress enacts more narrow legislation granting the Secretary discretionary authority to acquire title to land into trust for some specific purpose. Acquisitions of trust title under the IRA and other more narrow statutes that grant discretionary authority to the Secretary are referred to as "discretionary acquisitions" of title. Mandatory acquisitions of title are those that Congress has directed the Secretary to complete by removing any discretion in the administrative decision making process. The processing of these mandated acquisitions has not always been well-understood. The rule identifies the types of acquisitions that we consider mandatory and defines the process by which we acquire the title.

Finally, this regulation establishes a process to address the unique difficulties encountered by Indian tribes which have no reservations, have no trust land or have trust land the character of which renders it incapable of being developed. The process enables such tribes to designate a "Tribal Land Acquisition Area" (TLAA) in which it plans to acquire land. The TLAA requires approval of the Secretary and, when approved, will enable the tribe to acquire title to the lands within the TLAA into trust under the on-reservation provision of this regulation for a prescribed period of time.

On April 12, 1999, the proposed rule for the acquisition of title to land in trust was published in the **Federal Register** (Vol. 64, No. 69, pages 17574–17588). The initial deadline for receipt of comments was July 12, 1999, but extensions to the comment period were granted to allow additional time for comments on the proposed rule. The comment period expired on December 29, 1999. Comments were received from a wide variety of Indian tribes and individuals, tribal groups, local and state governments and other interested groups and individuals. The development of this final rule making was achieved through formal consultation on the record with affected tribal governments. A panel discussion meeting with federal, state and local governments, Indian tribes and various organizations was held in Washington, DC in May, 1999. Panel members included persons from California Indian Lands Office, attorneys representing various tribal and municipal clients, Minority Staff Director and Counsel of House Resources Committee for Indian Affairs, Majority Staff Director of Senate Committee on Indian Affairs, two tribal chairpersons, Deputy Attorney General of South Dakota and National Association of Convenience Stores. In addition, in accordance with the government-to-government relationship with Indian tribes, formal consultations were held throughout the United States during the comment period to explain and provide interested parties with an opportunity to understand and comment on the final rule. Five nationwide consultation meetings with Indian tribes and individuals were conducted during the comment period. These meetings were held in Albuquerque, New Mexico in May 1999; St. Paul, Minnesota in May 1999; Sacramento, California in June 1999; Mesa, Arizona in June 1999 and Portland, Oregon in August 1999. In total, comments were received from 342 Indian tribes, 335 individuals, 65 state and local governments, 9 congressional offices and 7 federal agencies. Tribal participation was also achieved by consultation with the National Congress of American Indians (NCAI) for its member tribes. NCAI established a working group to assist in the development of the comments on the proposed regulations.

This notice is published in exercise of the authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs pursuant to Part 290, Chapter 8, of the Departmental Manual.

Summary of Regulations and Comments Received

The following narrative and discussion of comments is keyed to specific subparts of the rule.

Subpart A—Purpose, Definitions, General

Summary of Subpart

This subpart addresses the purpose and scope of the regulation and provides interpretation for the key terms of the regulation. Subpart A also addresses the types of transactions affecting this regulation, how to apply to have title to land placed in trust, how requests are processed, what occurs after a decision is made on a request, when title to land attains trust status and the taking of fractional interests of land into trust.

Comments

Comments were received regarding the implementation of the proposed regulation, with some comments requesting that the rule be withdrawn. The suggestion was not accepted because the Secretary must ensure that his authority over the acquisition of title to land into trust is implemented in an orderly and fair manner.

There were several comments concerning the definition of "reservation." One suggestion was that term the "reservation" should be defined the same as the statutory term "Indian country." Another suggestion was that the definition of "reservation" should remain the same as in the existing regulation. Other comments suggested that "reservation" include a provision for Pueblo grant lands, others suggested that it include hunting and fishing treaty areas. The comments were duly considered and accepted to clarify that Pueblo lands within the exterior boundaries of lands granted or confirmed to, or acquired by, the Pueblo as reported by the Pueblo Lands Board under section 2 of the Act of June 7, 1924, ch. 331, 43 Stat. 636, plus any other lands reserved, set aside, or held in trust by the United States for the use of the Pueblo or its members are reservation lands for purposes of this regulation. Also, the term "reservation" is clarified to include lands created by federal agreement, Secretarial proclamation or final judicial determination. Further, the term "reservation" is clarified to include lands established by Executive or Secretarial proclamation in the State of Oklahoma. These changes to the definition of reservation appear in § 151.2 of the rule.

There were many comments suggesting that lands contiguous to a reservation should be treated as on-reservation acquisitions. To define contiguous lands as on-reservation lands would enable applicants to use the less burdensome process which reflects a presumption in favor of the acquisition of trust title to on-reservation lands. The comments were considered but rejected and the rule remains as proposed that land(s) contiguous to reservation land will be treated as off-reservation acquisitions for purposes of this regulation, although because of their proximity to an existing reservation, the tribe will receive more favorable consideration than if the lands were more remote.

There were several comments regarding the type of acquisition transactions covered by the regulation. Comments suggested that only those acquisitions of title from fee simple to trust or restricted fee to trust or exchanges involving fee simple to trust should be governed by this regulation. The proposed rule included trust to trust, restricted fee to restricted fee, restricted fee to trust and land exchange acquisitions. The comments have been accepted and the rule is amended in § 151.3 to provide that the requirements of the rule only apply to conveyances from fee simple to trust, fee simple to restricted fee and land exchanges involving fee simple land. The rationale for excluding the other types of acquisitions from the regulation is that trust to trust and restricted fee to restricted fee, restricted fee to trust and land exchanges not involving fee land do not have an impact on the local governments because these lands are not already under their jurisdiction. We accepted the comments and have revised § 151.3(b) of the regulation to exclude these transfers.

There were comments suggesting that the final rule should establish special treatment for government-to-government trust transfers, because these lands already are exempt from local taxation and jurisdiction and because the federal transfer process involves similar criteria as the Part 151 process, and requiring another regulatory review would be duplicative and burdensome. These comments were accepted and § 151.3(b) has been amended to exempt federal agency transfers of title of land from one federal agency to the BIA or tribe.

There were numerous comments suggesting that a time frame should be established for issuance of a decision to accept title to land in trust. The comments were accepted and the rule amended to provide that the applicant will be notified when an application is

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complete. Once an applicant is notified that their application is complete, the BIA will issue a decision on the request within 120 working days. Subsection (f) has been added to § 151.5 to reflect this change.

There were several comments seeking clarification regarding the treatment of applications that are pending when the regulation becomes final. The comments were considered and the regulation now provides a definition of "Complete application" in § 151.2. A new subsection (e) is added to § 151.5 that establishes the standard for a request to be considered a complete application. Applications that satisfy the definition of complete application at the time this rule becomes final, will be processed under the previous rule. If it is determined that an application is not complete at the time the rule becomes final, the application will be processed in accordance with the requirements of this rule.

There were several comments concerning the authority to take land into trust in Alaska. The preamble to the proposed rule addressed in some detail the question of whether to continue the bar in the existing regulations to the acquisition of trust title in land in Alaska (other than for the Metlakatla Indian Community or its members). See 64 FR 17577–78 (1999). As the discussion there indicated, the Department had earlier received, and invited public comment on (See 60 FR 1956(1995)), a petition by Native groups in Alaska which requested that the Department initiate a rulemaking to remove the prohibition in the regulations on taking Alaska land in trust. That discussion also noted that the Associate Solicitor for Indian Affairs had concluded, in a brief September 15, 1978 Opinion, that the Alaska Native Claims Settlement Act (ANSCA) precluded the Secretary from taking land into trust for Natives in Alaska (except for Metlakatla).

The Solicitor has considered the comments and legal arguments submitted by Alaska Native governments and groups and by the State of Alaska and two leaders of the Alaska State Legislature on whether the 1978 Opinion accurately states the law. The Solicitor has concluded that there is substantial doubt about the validity of the conclusion reached in the 1978 Opinion. Among other things, the Associate Solicitor found "significant" that in 1976 Congress repealed section 2 of the Indian Reorganization Act (IRA). That section had extended certain provisions of the IRA to Alaska, and had given the Secretary the authority to designate certain lands in Alaska as Indian reservations. See 43 U.S.C. 704(a), 90 Stat. 2743, repealing 49 Stat. 1250, 25 U.S.C. 496. The 1978 Opinion gave little weight to the fact that Congress has not repealed section 5 of the IRA, which is the generic authority by which the Secretary takes Indian land into trust, and which Congress expressly extended to Alaska in 1936. See 25 U.S.C. 473a. The failure of Congress to repeal that section, when it was repealing others affecting Indian status in Alaska, five years after Congress enacted the Alaska Native Claims Settlement Act, raises a serious question as to whether the authority to take land in trust in Alaska still exists. Accordingly, the Solicitor has signed a brief memorandum rescinding the 1978 Opinion.

At the same time, the position of the Department has long been, as a matter of law and policy, that Alaska Native lands ought not to be taken in trust. Therefore, the Department has determined that the prohibition in the existing regulations on taking Alaska lands into trust (other than Metlakatla) ought to remain in place for a period of three years during which time the Department will consider the legal and policy issues involved in determining whether the Department ought to remove the prohibition on taking Alaska lands into trust. If the Department determines that the prohibition on taking lands into trust in Alaska should be lifted, notice and comment will be provided.

Subpart B—Discretionary Acquisitions of Title On-Reservation

Summary of Subpart

This subpart describes the information that must be included in a request involving land located inside a reservation boundary or an approved TLAA. This subpart also establishes the criteria that will be used to evaluate requests for the acquisition of title to lands located inside the reservation or an approved TLAA. Further, this subpart defines the consent needed of the recognized governing body when an Indian tribe or individual acquires land inside another tribe's reservation or approved TLAA.

Comments

One comment suggested that the regulation require applicants to address potential impacts to local governments when the land being acquired is located on-reservation. The comment was rejected because state and local governments already are invited to submit comments on a proposed acquisition and may address such impacts in their comments. One comment suggested that the final rule clarify the distinction between on-reservation and off-reservation land. We believe the regulation already clearly defines the terms of "reservation" and "TLAA" which are used for on-reservation acquisitions. There were a few comments concerning appropriate land use of a proposed acquisition. Comments suggested that the rule should require clarification of anticipated future uses after acquisition in trust, describe how appropriate use will be enforced and propose strict criteria for future uses of the land. These comments were rejected because the IRA allows Indian tribes to manage and control their lands in accordance with tribal policy. Therefore, the regulation provides that anticipated future uses are those identified that are reasonably foreseeable and achievable. There were a few comments suggesting that the regulation should allow acquisitions for cultural, religious, or ceremonial uses. The proposed regulation continues the existing practice of accepting applications for the acquisition of title to lands in trust for these purposes. There were comments suggesting that the Secretary more thoroughly consider the impact on the state and local governments by the taking of title to land into trust, loss of tax revenue, and that he resolve jurisdictional issues and impact to municipal and local services prior to deciding to take land into trust. The regulation provides state and local governments with the opportunity to comment on potential impacts of the proposed acquisition, and the Secretary may fully consider the potential impacts prior to making a decision to take title to land into trust.

There were numerous comments suggesting that the final rule should require objective standards for the Secretary to use in making decisions to take on-reservation land into trust. The comments were accepted and the regulation has been amended to provide clearer standards to evaluate on-reservation requests. Section 151.10 is amended to provide that once an application is complete, we will accept title to land into trust on-reservation or inside a TLAA if the application facilitates tribal self-determination, economic development, Indian housing, land consolidation or natural resource protection. We will deny applications to accept on-reservation lands in trust if the acquisition will result in severe negative impact to the environment or severe harm to the local government. Evidence of such harm must be clear and demonstrable and supported in the record.

There were several comments suggesting that the rule should encourage tribes to make payments in lieu of taxes. These comments were rejected. While it is the Department's policy to encourage tribes to work with local communities, the decision to consider in lieu contributions to the local governments is a matter for the tribe, not the United States. A few comments suggested that applicants not be required to provide an explanation or reason for the need for the trust acquisition. The comments stating that no documentation need be submitted were rejected because the information is needed by the Secretary in order to make an informed and supportable decision. Under the final rule, there is a presumption in favor of accepting land into trust for on-reservation acquisitions but the Secretary still requires basic information in order to make his determination. One comment suggested that the regulation should include an economic analysis of the intended use of the property. The comment was rejected because the Secretary must consider many factors in the decision making process, and the decision as to the economics of the tribal use of land is for the tribe to resolve, not the Secretary.

Subpart C—Discretionary Acquisitions Off-Reservation

Summary of Subpart

This subpart describes the information that must be included in an off-reservation request, that is, involving land located outside a reservation or TLAA. This subpart also sets forth the criteria that will be used to evaluate an off-reservation request. Further, this subpart establishes exceptions to the prohibition for individual Indians acquiring land that is located outside an individual Indian's reservation.

Comments

One comment suggested that the Department should recognize the benefits of off-reservation acquisitions. We agree. The Department has always, and continues to recognize such benefits. There were comments suggesting that the notification requirement as well as the public comment period be expanded. We believe the regulation provides adequate notification and comment periods. There were several comments suggesting that the regulation limit off-reservation acquisitions in a number of ways, such as treating disputed lands as off-reservation, limiting off-reservation acquisitions to former tribal lands, not allowing off-reservation trust acquisitions, securing Congressional approval for off-reservation acquisitions and creating a presumption against trust status for off-reservation lands. We believe these approaches are inconsistent with the Secretary's responsibilities under existing laws and the IRA. Affected parties are given the opportunity to comment on these proposed off-reservation acquisitions and such comments are thoughtfully considered in the decision-making process. There were numerous comments suggesting that the final rule should require objective standards for the Secretary to use in making decisions to take off-reservation land into trust. The comments were accepted and § 151.14 has been amended to provide clear standards to evaluate off-reservation requests. Once an application is complete, we will accept title to land in trust outside a reservation or outside an approved TLAA only if the application shows that the acquisition is necessary to facilitate tribal self-determination, economic development, Indian housing, land consolidation or natural resource protection and that meaningful benefits to the tribe outweigh any demonstrable harm to the local community. Furthermore, we will not accept title to land in trust outside a reservation or outside an approved TLAA if the acquisition would result in severe negative impacts to the environment or significant harm to the local community. Evidence of the harm must be clear and demonstrable and supported in the record.

Subpart D—Mandatory Acquisitions of Title

Summary of Subpart

This subpart describes the information that is required to process a mandatory transfer of title to trust and how the request will be processed. Further, this subpart provides for an appeal of a determination that an acquisition is mandatory.

Comments

One comment suggested that the Department should treat an acquisition as mandatory only if Congress has mandated the Secretary to accept title to specific tracts of land. This comment was rejected because the Department cannot administratively limit Congress' authority to direct the Department to accept land into trust, and there clearly have been situations in which Congress has directed the Secretary to acquire land into trust, but does not specify clearly the parcel or parcels of land to be acquired. There were a few comments suggesting that the Secretary should view lands acquired under certain specific statutes as mandatory acquisitions. These comments were rejected as each mandatory acquisition must be reviewed on a case-by-case basis. Several comments were received that suggested that the term "mandatory" acquisition should be broadened to include "on-reservation" acquisitions, permit mandatory acquisition for the first 150,000 acres of land and make mandatory the acquisition of title to land in approved TLAAs. These suggestions were rejected since only Congress has the authority to mandate an acquisition and the Secretary cannot mandate acquisitions through these regulations. Each determination of whether an acquisition is mandatory or not must be made on a case-by-case basis, based on specific statutory direction provided by Congress.

One comment suggests that applicants should be permitted to file an appeal of a determination on whether or not an acquisition is mandatory. The comment is accepted and section § 151.16 has been amended to reflect that denials or approvals of a determination that an acquisition is mandatory may be appealed under the provisions of part 2. One comment suggested that the appeal process outlined in 25 CFR part 900 be used. This comment was rejected as part 900 applies to contracts issued under the Indian Self-Determination and Education Assistance Act, 25 U.S.C. 450 *et. seq.*, and, thus, is inapplicable to the provisions of this rule.

There were a couple of comments suggesting that the Department of Justice title evidence standards should not apply to on-reservation gifts of lands, nor should the warranty deed requirement apply when tribes have purchased land through a quit claim deed and the title is accompanied by title insurance. These suggestions were rejected as the standards imposed by the Department of Justice must be met for the United States to acquire land into trust for a tribe or individual Indian.

Subpart E—Tribal Land Acquisition Areas

Summary of Subpart

The subpart defines a TLAA, describes the information that must be included in a request for approval of a TLAA, describes how the request will be processed, identifies the criteria that will be used to evaluate requests and describes how to apply to modify an approved TLAA. This subpart also

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clarifies under what circumstances an Indian tribe can include in its TLAA land located inside another Indian tribe's reservation or TLAA. Further, this subpart establishes that an Indian tribe is not prohibited from acquiring land off-reservation if its request for a TLAA is denied. Lastly, this subpart clarifies that land acquired within an approved TLAA does not automatically attain reservation status.

Federal policy has for many decades viewed the existence of a tribal land base as integral to the cultural, political, and economic well-being of Indian tribes. Because of the overwhelming importance of a tribal land base, this rule facilitates acquisitions by landless Indian tribes. The process to address these situations is the use of a TLAA. Upon approval of a TLAA by the Secretary, tribes will be able to benefit from the on-reservation acquisition provisions to create a homeland, and strive for tribal self-determination and economic self-sufficiency.

Comments

Several comments suggested that the final rule should be expanded to include not just reservation-less tribes but also Indian tribes which do not have trust land or which have a trust land base of which is incapable of being developed to create a homeland and strive for tribal self-determination and economic self-sufficiency. The comments were accepted and the definition of a TLAA at § 151.17 is amended to include Indian tribes that have no trust land or have trust land the character of which renders it incapable of being developed to take advantage of the TLAA. A new § 151.18 was added to make more clear what tribes are eligible to apply for a TLAA. One comment suggested that existing tribal consolidation areas approved pursuant to the current acquisition regulation should be grand-fathered and treated as a TLAA while another comment suggested that the rule should clarify whether or not tribes with existing approved tribal consolidation areas must reapply under the final rule for a TLAA. While this final rule eliminates the ability of tribes to obtain tribal consolidation areas as provided under the existing regulation, this rule provides an alternative mechanism in the form of a TLAA. Tribal consolidation areas approved under the existing regulation will remain in force and effect for the purposes for which they were approved, but such tribal consolidation areas are not deemed to constitute a TLAA under these regulations. In the event a tribe wants to amend or modify an existing approved tribal consolidation area to include the provisions of a TLAA, the proposed amendment or modification must be reviewed under the requirements of approval for a TLAA under the final rule. One comment suggested that TLAA receive congressional approval. We believe that the Secretary has the authority, and indeed the responsibility to prescribe procedures to fulfill the purposes of the IRA.

There were comments expressing the views that tribes should not be required to submit documentation that was different from that required for discretionary acquisitions; information documenting the history of the tribe, and information about the tribe; such as taxes, revenues and services; or other information that was viewed as impractical, unwarranted, or imposes a financial burden or is not readily available. We believe the information required under the final rule is reasonable, necessary, relevant to the decision making process and not burdensome upon the applicant as it may be readily obtained from existing sources. Further, the information is consistent with the kinds of information requested by applicants seeking off-reservation acquisitions. One comment suggested that the rule should clarify the requirements for notifying other governmental entities. We believe the rule provides sufficient notice requirements. One comment suggested that the 50-mile radius for notice be re-evaluated. The comment was rejected because the defined radius is considered a reasonable area that could be impacted by a trust acquisition and will provide sufficient notice to others.

There were a few comments concerning the 10 year term for an approved TLAA. The comments suggested that 10 years was an insufficient amount of time to acquire lands within the TLAA due the requirements for completing and securing approval to an acquisition. The comments were accepted and § 151.17 is amended to provide for a 25-year term for a TLAA.

There were several comments concerning the establishment of criteria or standards for evaluating requests for the approval of a TLAA. We believe that the regulation provides clear criteria for the Secretary to use in determining whether to approve a tribe's request for a TLAA. The criteria used for approving a TLAA is separate and distinct from the criteria and standards used to evaluate an on-or off-reservation acquisition request. Once a TLAA is approved by the Secretary, the on-reservation criteria will be used to determine whether to accept the title to land in trust. One comment suggested that a formal appeal process should be established when a request for a TLAA is denied. Section 151.6(a) sets out the process for the appeal of a decision under this part. One comment suggested that tribal trust land should be equivalent to reservation status. The comment was rejected because it was not within the scope of this rule and is governed by principles of Indian law. One comment suggested that the rule should clearly define a streamlined process for modification of approved tribal consolidation areas. The comment was rejected because the final rule establishes the criteria for the TLAA and eliminates the process to obtain a tribal consolidation area. Approved tribal consolidation areas, however, may form the basis for the development of a TLAA.

Subpart F—False Statements, Record-Keeping, Information Collection

Summary of Subpart

This subpart describes the penalties for making false statements pertaining to a request. This subpart also describes the record keeping and reporting requirements under this part as well as the information collection requirements.

Comments

One comment received suggested that Indian tribes should not be penalized for making false statements and another comment suggested the penalty for false statements should also apply to non-Indians. The first comment was rejected, and the second deemed already addressed because the False Statements Accountability Act of 1996 (18 U.S.C. 1001) applies to all statements submitted in connection with a trust title acquisition whether such statements are made by the applicant or interested parties. Section 151.27 was amended to clarify who owns the records associated with this part and a new § 151.28 was added to clarify how records associated with this part will be preserved.

Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. This regulation has been written in a question and answer format, arranged in a manner to make it easier to follow, with technical language or jargon eliminated to make it is easier to understand.

Regulatory Planning and Review (Executive Order 12866)

In accordance with the criteria in Executive Order 12866, this rule is not a significant regulatory action and is not subject to review by the Office of Management and Budget.

(a) The amendments to this rule basically conform to the policies and practices that currently guide the Department's decision making on land into trust applications. The rule does not have an annual effect of $100 million or more on the economy. It does not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This rule simply identifies a "minimum standard" of criteria and requirements to be considered in the exercise of the Secretary's discretion to place lands in trust for individual Indians and tribes.

Looking at the overall picture of how much land we have taken into trust historically, the annual number of requests to place lands in trust has been small. Based on the BIA's Annual Report of Indian Lands for 1996, only 35 States have Indian lands, four of which have fewer than 1,000 acres of Indian lands. The 1996 report indicated that there were 6,941 total applications (fee-to-trust; trust-to-trust; restricted-to-restricted; restricted-to-trust) involving 212,000 acres cumulatively, *i.e.*, the average amount of land involved in an application was only about 30 acres. Based on the annual caseload report for FY 1996, the total dollar amount Tribes and individual Indians paid for acquisitions of land in trust is $19,420,303.81. The trust-to-trust, restricted-fee-to-restricted fee, and restricted fee-to-trust land acquisitions do not impact local and state governments because these lands are not presently subject to state or local jurisdiction or taxation. Some States and local governments may have a decrease in revenues derived from taxes from the Secretary's determination to accept title to land in trust. However, the loss in annual revenues for State and local jurisdictions is only be a fraction of the value of the land involved. Moreover, some tribes may choose to offset this loss by making payments in lieu of taxes, or supplying services to the local communities. Finally, any losses or gains to State or local tax rolls would be spread over several states and many local governments. Thus, overall, the net changes in tax revenues due to this rule are minimal, and do not significantly affect State or local governments.

(b) This rule does not create a serious inconsistency or otherwise interfere with an action taken or planned by another Federal agency. Actions taken by this rule affect tribal or individual Indian land titles. The Department of the Interior, Bureau of Indian Affairs is the only governmental agency that makes the determination whether to take land into trust.

(c) This rule does not alter the budgetary effects or entitlement, grants, user fees, or loan programs or the rights or obligations of their recipients. This rule sets out the criteria and procedures the Secretary uses in determining whether to accept title of certain Indian lands to the United States, as trustee, for the benefit of an individual Indian or a tribe.

(d) OMB has determined that this rule does not raise novel legal or policy issues and is therefore not subject to review under Executive Order 12866.

Regulatory Flexibility Act

The Department of the Interior certifies that this regulation does not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A Regulatory Flexibility analysis is not required. See our initial analysis above item 1(a) under Regulatory Planning and Review. The effect on small entities is minimal.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. See the initial analysis above, item 1(a) under Regulatory Planning and Review. This rule:

(a) Does not have an annual effect on the economy of $100 million or more. An economic analysis is not required.

(b) Does not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Actions under this rule only affect title to tribal or individual Indian owned lands.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. Actions under this rule only affect title to tribal or individual Indian owned lands.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*):

(a) The rule does not significantly or uniquely affect small governments, or the private sector. A Small Government Agency Plan is not required. Additional expenses may be incurred by the requesting tribe or individual Indian to provide information to the Secretary. Tribes or an individual Indian provide information in order to receive a benefit.

(b) This rule does not produce a federal mandate of a $100 million or greater in any year. The overall effect of this rule is likely not to be significant to the State, local, or tribal governments or the private sector.

Takings (Executive Order 12630)

With respect to Executive Order 12630, the rule does not have significant takings implications. A takings implication assessment is not required because actions under this rule do not constitute a taking. Tribes or individual Indians are voluntarily transferring title to the United States for their own benefit.

Federalism (Executive Order 13123)

With respect to Executive Order 13123, the rule does not have significant federalism implications to warrant the preparation of a Federalism Assessment. The local tax base may be affected. Actions in this rule apply only to a relatively small amount of land. Due to the loss of tax revenue, the relationship between the State and local governments with tribes and/or the Federal Government may be affected. However, the loss of revenue overall is likely to be minimal and the vast majority of the land to be acquired will likely be within the boundaries of reservations where there is already a measure of Indian sovereignty. Therefore, the effects are "insignificant" within the meaning of Executive Order 13123.

Civil Justice Reform (Executive Order 12988)

With respect to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the order. This rule contains no drafting errors or ambiguity and is written to minimize litigation, provides clear standards, simplifies procedures, reduces burden, and is clearly written. These regulations do not preempt any statute. They do supersede the current land acquisition regulations and the current procedure for establishing Indian Land Consolidation Areas. They would not be retroactive with respect to any land already taken into trust, but would apply to applications that are determined not be complete at the time of final publication of this rule.

Paperwork Reduction Act

This regulation requires an information collection from ten or more

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parties and a submission under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The information collection requirements in §§ 151.9, 151.12, 151.15, 151.19, and 151.28 under 44 U.S.C. 3501 *et seq.* were submitted to the Office of Management and Budget (OMB) for approval. We will publish a notice in the **Federal Register** when OMB approves this collection. This information is required from Indian tribes and individual Indians who wish to convey land into trust status.

Information is collected from Indian tribes and individuals to support their request to the Secretary to acquire title to land in trust for their benefit. The Secretary uses the information to evaluate the request and forms the basis of a decision to accept or deny a request for the taking of title to land in trust.

The total average annual burden hours for the collection of information for the above specified sections of the regulation is broken down as follows.

Citation 25 CFR 151	Information	Average number of hours	Average number per year	Annual burden hours
151.9 for on-reservation	Applicant must submit: (a) Copy of authority; (b) Explanation of need; (c) Explanation of ownership status (tribe); (d) Explanation of ownership status (individual); (e) Title evidence	16	850	13,600
	(f) Documentation for NEPA—tribe and individual	40	120	4,800
	(f) Documentation for NEPA—tiering	20	200	4,000
151.12 for off-reservation acquisitions.	Applicant must submit: (a) Copy of authority; (b) Explanation of need; (c) Description of proposed use; (d) Description of location of land; (e) Description of effect on state & political subdivisions; (f) Description of jurisdictional issues; (g) Title evidence	56	150	8,400
	(h) Documentation for NEPA—tribe provides documentation	40	150	6,000
151.15 for Mandatory acquisitions	Applicant must submit: (a) Copy of authority; (b) Title evidence; (c) Additional information upon request.	.5	69	35
151.19 for Tribal Land Acquisition Areas (TLAA).	Applicant must submit: (a) Copy of authority; (b) Copy of tribal documents to establish TLAA; (c) Summary of purposes and goals; (d) Summary of tribe's history; (e) Description of TLAA; (f) Location of rights of way; (g) Description of effect on state and political subdivisions; (h) Description of jurisdictional and land use issues	96	325	31,200

We invite the public to provide any comments concerning the accuracy of the burden estimate and any suggestions for reducing the burden. Submit comments to the Bureau of Indian Affairs, Director, Office of Trust Responsibilities, 1849 C Street, NW., MS–4513–MIB, Washington, DC 20240.

The collection of information is voluntary in order for an Indian tribe or individual to obtain a benefit, acquiring title to land in trust. None of the solicited information is confidential. However, if the applicant submits an application that contains financial information, it is covered by the Privacy Act.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required because this rule is of an administrative, technical, and procedural nature.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of May 14, 1998, "Consultation and Coordination with Indian Tribal Governments" (FR Vol. 63, No. 96, Pages 27655–27657) and 512 DM 2, we evaluated any potential effects upon Federally recognized Indian tribes and have determined that there are no potential adverse effects. No action is taken under this rule unless a tribe or an individual Indian voluntarily requests that the United States place land in trust for their benefit. Tribes were asked for comments prior to publication as a final regulation of this rule and their comments were considered prior to publication.

List of Subjects in 25 CFR Part 151

Indians—lands, Reporting and recordkeeping requirements.

Accordingly, the Bureau of Indian Affairs is revising 25 CFR part 151 to read as follows:

PART 151—ACQUISITION OF TITLE TO LAND IN TRUST

Subpart A—Purpose, Definitions, General

Sec.

151.1 What is the purpose of this part?
151.2 How are key terms defined in this part?
151.3 To what types of transactions does this part apply?
151.4 How does an individual Indian or a tribe apply to have title to land conveyed to the United States in trust?
151.5 How does BIA process a request?
151.6 How does BIA proceed after making a decision on a request?
151.7 When does the land attain trust status?
151.8 Will BIA accept and hold in trust an undivided fractional interest in land for an individual Indian or a tribe?

Subpart B—Discretionary Acquisitions of Title On-Reservation

151.9 What information must be provided in a request involving land inside a reservation or inside an approved Tribal Land Acquisition Area?
151.10 What criteria will BIA use to evaluate a request involving land inside a reservation or inside an approved Tribal Land Acquisition Area?
151.11 Can an individual Indian or a tribe acquire land inside a reservation or inside an approved Tribal Land Acquisition Area of another tribe?

Subpart C—Discretionary Acquisitions of Title Off-Reservation

151.12 What information must be provided in a request involving land outside a reservation or outside a Tribal Land Acquisition Area?
151.13 Can an individual Indian acquire land outside his or her own reservation?
151.14 What criteria will BIA use to evaluate a request involving land outside a reservation or outside an approved Tribal Land Acquisition Area?

Subpart D—Mandatory Acquisitions of Title

151.15 What information must be provided in a request to process a mandatory transfer of title into trust status, and how will BIA process the request?
151.16 Can our determination that a transfer of title into trust status is mandatory be appealed?

Subpart E—Tribal Land Acquisition Areas

151.17 What is a Tribal Land Acquisition Area?
151.18 What tribes are eligible to apply for approval of a Tribal Land Acquisition Area?
151.19 What must be included in a request for Secretarial approval of a Tribal Land Acquisition Area?
151.20 How is a tribal request for Secretarial approval processed?
151.21 What criteria will BIA use to decide whether to approve a proposed Tribal Land Acquisition Area?
151.22 Can a tribe include in its Tribal Land Acquisition Area land inside another tribe's reservation or Tribal Land Acquisition Area?
151.23 If a Tribal Land Acquisition Area is not approved, is the tribe prohibited from acquiring land within it?
151.24 If a Tribal Land Acquisition Area is approved, does the land taken into trust within it attain reservation status?
151.25 Can a Tribal Land Acquisition Area be modified after approval?

Subpart F—False Statements, Recordkeeping, Information Collection

151.26 What is the penalty for making false statements in connection with a request that BIA place land in trust?
151.27 Who owns the records associated with this part?
151.28 How must a record associated with this part be preserved?

Authority: R.S. 161: 5 U.S.C. 301. Interpret or apply 46 Stat. 1106, as amended; 46 Stat. 1471, as amended; 48 Stat. 985, as amended; 49 Stat. 1967, as amended, 53 Stat. 1129; 63 Stat. 605; 69 Stat. 392, as amended; 70 Stat. 290, as amended; 70 Stat. 626; 75 Stat. 505; 77 Stat. 349; 78 Stat. 389; 78 Stat. 747; 82 Stat. 174, as amended; 82 Stat. 884; 84 Stat. 120; 84 Stat. 1874; 86 Stat. 216; 86 Stat. 530; 86 Stat. 744; 88 Stat. 78; 88 Stat. 81; 88 Stat. 1716; 88 Stat. 2203; 88 Stat. 2207; 18 U.S.C. 1001; 25 U.S.C. 2, 9, 409a, 450h, 451, 464, 465, 467, 487, 488, 489, 501, 502, 573, 574, 576, 608, 608a, 610, 610a, 622, 624, 640d-10, 1466, 1495, and other authorizing acts.

Subpart A—Purpose, Definitions, General

§ 151.1 What is the purpose of this part?

The purpose of this part is to describe the authorities, policies, and procedures that we use to decide whether to accept title to land in the name of the United States to be held in trust for the benefit of an individual Indian or a tribe.

§ 151.2 How are key terms defined in this part?

Alienation means a conveyance or transfer of title to property.

Bureau means the Bureau of Indian Affairs within the Department of the Interior.

Complete Application means an application that contains all the documentation, analysis and information required by § 151.5(f).

Discretionary acquisitions of title means those acquisitions of trust title which Congress has authorized, but not required us to accept administratively.

Encumbrance means a limitation on the title of property, such as a claim, lien, easement, charge, or restriction of any kind.

Fee simple land means land held absolute and clear of any condition or restriction, and where the owner has unconditional power of disposition.

Governing tribe means the tribe having governmental jurisdiction over the land being acquired.

Individual Indian means a person who:

(1) Is a member of a federally recognized tribe; or

(2) Was physically residing on a federally recognized Indian reservation as of June 1, 1934, and is a descendant of an enrolled member of a federally recognized tribe; or

(3) Possesses a total of one-half degree or more Indian blood of a federally recognized tribe.

Land means real property or any title interest therein, as defined by the statute that authorizes the land acquisition.

Legislative transfer of title means the direct transfer of title to land into trust status for the benefit of an individual Indian or Indian tribe by Congress through legislation. The regulations in this part do not apply to legislative transfers of title.

Mandatory acceptance of title means a conveyance of trust title which Congress has required the Secretary to accept if certain specified conditions over which the Secretary has no control are met.

Reservation means, for purposes of this part, that area of land which has been set aside or which has been acknowledged as having been set aside by the United States for the use of the tribe, the exterior boundaries of which are more particularly defined in a final treaty, Federal agreement, Executive or secretarial order, Executive or secretarial proclamation, United States patent, Federal statute, or final judicial or administrative determination, provided that:

(1) In the State of Oklahoma, *reservation* means that area of land constituting the former reservation of the tribe. *Former reservation* means lands that are within the jurisdictional area of an Oklahoma Indian tribe and are within the boundaries of the last reservation established by final treaty, Federal agreement, Executive or secretarial order, Executive or secretarial proclamation, United States patent, Federal statute, or final judicial or administrative determination; and

(2) For Pueblo Indian tribes in the State of New Mexico, *reservation* means lands within the exterior boundaries of lands granted or confirmed to or acquired by the Pueblo as reported by the Pueblo Lands Board under section 2 of the Act of June 7, 1924, ch. 331, 43 Stat. 636, notwithstanding any finding of extinguishment of title, plus any other lands reserved, set aside, or held in trust by the United States for the use of the Pueblo or its members.

Restricted fee land means land the title to which is held by an individual Indian or a tribe and which can only be alienated or encumbered by the owner with the approval of the Secretary because of limitations in the conveyance instrument pursuant to federal law.

Secretary means the Secretary of the Interior or an authorized representative.

Tribal Land Acquisition Area (TLAA) means an area of land approved by the Secretary and designated by a tribe that

(1) Does not have a reservation; or

(2) Does not have trust land; or

(3) Has a trust land base which is incapable of being developed in a manner that promotes tribal self-determination, economic development and Indian housing, and within which the tribe plans to acquire land over a specified period of time.

Tribe means any Indian tribe, nation, band, pueblo, town, community, rancheria, colony, or other group of Indians, which is recognized by the Secretary as eligible for the special programs and services provided by the

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Bureau of Indian Affairs, and listed in the **Federal Register** under Public Law 103–454, act of Nov. 2, 1994 (108 Stat. 4791; 25 U.S.C. 479a (1994)).

Trust land means land, or an interest therein, for which the United States holds fee title in trust for the benefit of an individual Indian or a tribe.

Undivided fractional interest means an interest of co-owners which is in the entire property, that is not divided out from the whole parcel. (Example: If you own 1/4 interest in 160 acres, you do not own 40 acres. You own 1/4 interest in the whole 160 acres because your 1/4 interest has not been divided out from the whole 160 acres.)

We/Us/Our means the Secretary of the Interior or an authorized representative.

§ 151.3 To what types of transactions does this part apply?

(a) Except as provided in paragraphs (b) and (c) of this section, this part applies to all fee simple land-to-trust, fee simple land-to-restricted fee or land exchanges involving fee simple land.

(b) This part does not apply to the following transactions:

(1) Trust-to-trust;

(2) Restricted-fee to restricted-fee;

(3) Transfer of title to trust and restricted land through inheritance, devise or escheat;

(4) Legislative transfer of title into trust status; or

(5) Federal agency transfers of title.

(c) We will not accept title to land in trust in the State of Alaska, except for the Metlakatla Indian Community of the Annette Island reserve of Alaska or its members.

§ 151.4 How does an individual Indian or a tribe apply to have title to land conveyed to the United States in trust?

Individual Indians and tribes must send us a written request asking that we accept title and place the land into trust.

(a) The request must:

(1) Identify the applicant (including the applicant's tribal affiliation);

(2) Include the legal description of the land to be acquired; and

(3) Include all information which shows that the proposed acquisition meets the applicable requirements in this regulation.

(b) The request does not need to be in any special form. However, we strongly urge the applicant to address each section of this part that is relevant to the type of acquisition (*e.g.*, on- or off-reservation, discretionary or mandatory), in the order it appears here. Constructing the request in this way will enable us to review the request more efficiently.

(c) We may also ask for additional information to aid us in reaching a decision.

§ 151.5 How does BIA process the request?

(a) After we receive the request, we will notify the State, county, and municipal governments having regulatory jurisdiction over the land. We will send all notices under this section by certified mail, return receipt requested. The notice will contain the information described in paragraph (a)(1) or (a)(2) of this section, as appropriate.

(1) If the request is for on-reservation lands or lands inside an approved TLAA, the notice we send under this section will:

(i) Include the name of the applicant;

(ii) Describe the lands proposed to be taken in trust;

(iii) State the proposed use of the land; and

(iv) Invite the State and local governments from the State in which the land is located to comment in writing within 30 days from date of receipt of the notice on the proposed acquisition.

(2) If the request is for land outside a reservation and outside a TLAA, the notice we send under this section will:

(i) Include the name of the applicant;

(ii) Describe the lands proposed to be taken in trust;

(iii) Describe the proposed use of the land; and

(iv) Invite the State and local governments from the State in which the land is located to comment in writing within 60 days from the date of receipt of notice on the acquisition's potential effects on the State and local governments, including on their regulatory jurisdiction, real property taxes, and special assessments.

(b) After the comment period has ended, we will send to the applicant copies of any comments made by State and local governments on the applicant's request. We will give the applicant a reasonable time in which to reply to the comments.

(c) Subject to restrictions on disclosure required by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), and the Trade Secrets Act (18 U.S.C. 1905) the request will be available for review at the local BIA agency or area office having administrative jurisdiction over the land.

(d) We will consider all the documentation that the applicant submits.

(e) A complete application consists of the following:

(1) The applicant's request that the land be taken into trust, as follows:

(i) If the applicant is an Indian tribe, the written request must be a properly prepared and executed tribal resolution requesting trust status, or

(ii) If the applicant is an individual Indian, the written request must be a signed letter requesting trust status.

(2) Documentation that the applicant has addressed all the applicable information requirements in this section;

(3) A map depicting the location of the land to be acquired, and either:

(i) A legal description of the land, including a statement of the estate being acquired, *e.g.* all surface and mineral rights, surface rights only, surface rights and a portion of the mineral rights, etc., or

(ii) A survey if the land cannot be described by an aliquot legal description. The survey must be completed by a land surveyor registered in the State in which the land is located when the land being acquired is fee simple land,

(4) Hazardous level I survey,

(5) Environmental documentation,

(6) Title evidence,

(7) Impact notification letters, including all associated responses,

(8) Statement from the applicant that any existing rights of way, easements or encumbrances will not interfere with applicant's intended use of the land, and

(9) Any additional information we have requested, in writing, if warranted by the specific application.

(f) After BIA is in possession of a complete application, we will:

(1) Notify the applicant, in writing, that the application is complete,

(2) Issue a decision on an application within 120 working days after issuance of the notice of a complete application.

§ 151.6 How does BIA proceed after making a decision on a request?

(a) Within 120 days of our having a complete application package, we will send the applicant a certified letter describing our decision to accept or deny a request. We will also send a copy of the decision letter to everyone (including State and local governments) who sent us written comments on the request. The notice to interested parties will explain that they have a right to appeal our decision under part 2 of this title.

(b) If our decision is to deny the request, we will take no further action.

(c) If our decision is to approve the request, after the exhaustion of administrative remedies, we will:

(1) Complete a preliminary title examination. For both discretionary and mandatory acquisitions, after we examine the title evidence, we will notify the applicant of any liens, encumbrances, or infirmities. If the liens, encumbrances, or infirmities make title to the land unmarketable, we will require the applicant to eliminate the liens, encumbrances, or infirmities before we act on the application.

(2) Publish in the **Federal Register**, or in a newspaper of general circulation serving the affected area, a notice of the decision to take land into trust under this part. The notice will state that we have made a final decision to take land in trust and that we will accept title in the name of the United States no sooner than 30 days after the notice is published;

(3) Respond to any judicial appeals that may be filed; and

(4) After sufficient opportunity for judicial relief has been provided, accept trust title to the land by issuing or approving an appropriate instrument of conveyance. If we determine to accept trust title to land in a case before all judicial remedies have been exhausted, we will give the party/parties opposing the acquisition at least five days notice before we take any action.

§ 151.7 When does land attain trust status?

After the Secretary has published a notice of intent to take the land into trust pursuant to § 151.6(c)(2), the time period for appeal has run, and all title objections have been cleared, we will approve or issue the appropriate instrument of conveyance. Only after these steps have been completed will the land attain trust status. The approved deed will then be recorded in the county where located, title evidence will be updated, a final title opinion will be issued and the deed will be recorded in the appropriate Bureau of Indian Affairs Land Titles and Records Office under part 150 of this chapter.

§ 151.8 Will BIA accept and hold in trust an undivided fractional interest in land for an individual Indian or a tribe?

We will not accept and hold in trust for an individual Indian or a tribe an undivided fractional interest in land, except under one of the following conditions:

(a) The individual Indian or tribe already owns an undivided fractional restricted or trust interest in the land, and is acquiring the additional interest(s) to consolidate ownership.

(b) The individual Indian or tribe acquires the undivided fractional interest as the result of a gift under § 152.25(d) of this chapter and the conveyance does not result in further fractionation of interest in the land.

(c) The individual Indian or tribe is acquiring fee simple interest and there are existing undivided fractional trust or restricted interests in the same land.

(d) The individual Indian or tribe offers and agrees to purchase the remaining undivided fractional trust or restricted interest in the land, at not less than fair market value.

(e) A specific statute grants the individual Indian or tribe the right to purchase an undivided fractional interest in trust or restricted land without offering to purchase all interests.

(f) The owner(s) of a majority of the interests of the remaining undivided trust or restricted fractional interest agree in writing that the individual Indian or tribe may acquire the interest.

(g) A tribe acquires an undivided fractional interest in trust or restricted land under the Indian Land Consolidation Act, 25 U.S.C. 2201 *et seq.*, under one of the following conditions:

(1) The land is inside the tribe's reservation, or inside an approved Tribal Land Consolidation Area, or is otherwise subject to the tribe's jurisdiction, and

(2) The tribe acquires the land:

(i) At not less than the fair market value; and

(ii) With the written consent of a majority of the owners of the remaining undivided fractional trust or restricted interest of this land;

(h) The tribe acquires, at not less than the fair market value, part or all of the undivided fractional interests in a parcel of trust or restricted land within the tribe's reservation, or subject to the tribe's jurisdiction and:

(1) Over 50 percent of the owners of the undivided fractional interests consent in writing to the acquisition; or

(2) An individual Indian makes an offer under paragraph (e) of this section;

(i) An individual Indian:

(1) Already owns an undivided fractional interest in the land;

(2) Offers to match a tribal offer to purchase under paragraph (d) of this section; and

(3) Has used and possessed the land for at least 3 years preceding the tribe's offer to purchase.

Subpart Part B—Discretionary Acquisitions of Title On-Reservation

§ 151.9 What information must be provided in a request involving land inside a reservation or inside an approved Tribal Land Acquisition Area?

A request from an individual Indian or a tribe asking that the United States accept title to land inside a reservation boundary or to land inside an approved TLAA must include:

(a) A complete description, or a copy, of the federal statute that authorizes the United States to accept the land in trust and any limitations contained in the authority.

(b) An explanation of why the individual Indian or tribe needs land to be in trust and how the land will be used.

(c) If the applicant is a tribe, an explanation of whether the tribe:

(1) Already owns an undivided fractional trust or restricted interest in the land; and

(2) Maintains jurisdiction over the land.

(d) If the applicant is an individual Indian, an explanation of:

(1) Whether the applicant already owns an undivided fractional trust or restricted interest in the land;

(2) The amount of land that the applicant already owns and the status of the land (fee, restricted, or trust); and

(3) Whether the applicant needs assistance in handling real estate affairs. For example, tell us if the applicant is a minor or has been declared legally incompetent.

(e) Title insurance or an abstract of title that meets the *Standards for the Preparation of Title Evidence in Land Acquisitions by the United States*, issued by the U. S. Department of Justice. Copies of the standards are available from the U.S. Department of Justice, Environmental and Natural Resources Division, Land Acquisition Section, Room 6136, 601 Pennsylvania Avenue NW., Washington, DC 20004.

(f) Documentation that we need to comply with 516 DM 6, Appendix 4, National Environmental Policy Act (NEPA) Revised Implementing Procedures, and 602 DM 2, Land Acquisitions: Hazardous Substances Determinations. (For copies of these directives, write to the Department of the Interior, Bureau of Indian Affairs, 1849 C Street, NW., Mail Stop: 4513–MIB, Washington, DC 20240). Include a record of consultation with appropriate authorities regarding environmental, endangered species, water quality, fish and wildlife, wetlands, transportation, air quality, cultural, historical value, hazardous waste, and toxic material issues.

§ 151.10 What criteria will BIA use to evaluate a request involving land inside a reservation or inside an approved Tribal Land Acquisition Area?

Upon receipt of the information required under § 151.9 and upon a determination that the application is complete:

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(a) We will approve the application and accept title to land in trust inside a reservation or inside an approved TLAA if we determine that the application facilitates tribal self-determination, economic development, Indian housing, land consolidation or natural resources protection; except that

(b) Notwithstanding a determination in paragraph (a) of this section, we may not approve the application and accept transfer of title into trust for land inside a reservation or inside an approved TLAA if the approval of the acquisition will result in severe negative impact to the environment or severe harm to the local government. Evidence of such harm must be clear and demonstrable and supported in the record.

§ 151.11 Can an individual Indian or a tribe acquire land inside a reservation or inside an approved Tribal Land Acquisition Area of another tribe?

An individual Indian or a tribe, including individual Indians and tribes in Oklahoma, may acquire land in trust on another tribe's reservation, or inside another tribe's approved TLAA, if the recognized tribe's governing body consents in writing. No consent is required if:

(a) An individual Indian or tribe already owns an undivided fractional trust or restricted interest in the parcel of land to be acquired; or

(b) The proposed acquisition is inside a reservation or an approved TLAA that is shared by two or more tribes, and the acquisition is for one of these tribes, or one of these tribes' members.

Subpart C—Discretionary Acquisitions of Title Off-Reservation

§ 151.12 What information must be provided in a request involving land outside a reservation or outside a Tribal Land Acquisition Area?

A request from an individual Indian or a tribe asking that the United States accept title to land outside a reservation boundary and outside an approved TLAA, must include:

(a) A complete description, or a copy of, the statutory authority that authorizes the United States to accept land in trust and any limitations contained in the authority;

(b) An explanation of the need of the individual Indian or tribe for land in trust and how the land will be used. This explanation is a crucial factor in determining if the request should be approved. The request must explain:

(1) Why the present land base is not appropriate or adequate for the activity contemplated in the request;

(2) Why the applicant needs the land to be in trust for the proposed use; and

(3) How trust status will benefit the applicant's economic and/or social conditions.

(c) A description of how the applicant will use the land. This description must include an explanation of:

(1) The past uses of the land;

(2) The present use of the land;

(3) The anticipated future uses of the land;

(4) The cultural or historical interest in the land;

(5) The objectives that the individual Indian or tribe hopes to attain; and

(6) If the acquisition is for housing:

(i) The projected number of units to be built; and

(ii) The number of members who will benefit.

(7) If the applicant is acquiring the land for business purposes, the tribe must provide a business plan that specifies the anticipated economic benefits of the proposed use.

(d) As complete a description as is possible of the following:

(1) The location of the land relative to State boundaries;

(2) The distance of the land from the boundaries of the tribe's reservation;

(3) The distance of the land from the Bureau's nearest agency or area office;

(4) The location of roads and rights-of-way that provide access to the land; and

(5) The location of land in relation to the tribe's other trust lands.

(e) A description of the effect on the State and its political subdivisions of removing the land from tax rolls. Describe any measures the applicant will take to reduce these effects. The description of effects must include an explanation of:

(1) The amount of annual taxes currently assessed by the local government(s);

(2) The amount of annual revenue lost from special assessments to the local government(s), if any;

(3) The amount of annual revenue lost from mineral receipts to the local government(s), if any; and

(4) The local government's ability to provide public safety services for the land.

(f) A description of any jurisdictional and land use infrastructure issues that might arise. The description must address each of the following issues.

(1) Zoning, including:

(i) The current zoning of the land;

(ii) Any proposed use conflicts with current zoning; and

(iii) Any tribal zoning ordinances.

(2) Law enforcement and cross-deputizing, including:

(i) Who currently provides law enforcement services for the land;

(ii) If the applicant is a tribe, whether the tribe already has its own law enforcement;

(iii) Who will supply law enforcement if the land is approved for trust status; and

(iv) Any additional resources required to provide adequate law enforcement and how they will be funded.

(3) Safety factors, including:

(i) Who supplies fire protection service for the land;

(ii) Who supplies emergency medical service for the land; and

(iii) Whether the land is in a flood area or flood control area.

(4) Traffic, roads, and streets, including:

(i) A description of existing access to the land;

(ii) Description and quantification of increased traffic in the area anticipated from the proposed use; and

(iii) A description of whether existing roads and streets are adequate to handle any anticipated increase in traffic caused by the proposed use.

(5) Sanitation, including whether:

(i) The land is served by a city sewage system;

(ii) The land is served by an some other type of sewage system that is adequate to meet applicable standards;

(iii) Trash pickup service or another method of trash disposal is available for the land;

(iv) The city or another facility supplies services to the land;

(v) There is an adequate water supply for the proposed use and any future anticipated uses; and

(vi) Whether the applicant tribe has water rights to the available water supply.

(6) Utilities, including:

(i) Whether a city or a rural electric company supplies electricity to the land; and

(ii) The source of heating for any structures located on or to be located on the land, such as: natural gas, propane, oil, coal, wood, electric, or solar.

(7) Whether there are any cooperative agreements or voluntary actions intended to address jurisdictional and land use conflicts.

(8) Whether the applicant has made any provisions to compensate the State or local governments for revenue lost because of the removal of the land from the tax rolls. (Include any increases in Title IX funding from the Indian Education Act or Impact Aid funding.)

(g) Whether there is title evidence that meets the *Standards for the Preparation of Title Evidence in Land Acquisitions by the United States*, issued by the U.S. Department of Justice. The evidence will be examined to determine if the applicant has marketable title. Copies of the standards are available from the U.S. Department of Justice, Environmental and Natural Resources Division, Land Acquisition Section, Room 6136, 601 Pennsylvania Avenue NW., Washington, DC 20004.

(h) The documentation that we need to comply with 516 DM 6, Appendix 4, National Environmental Policy Act (NEPA) Revised Implementing Procedures, and 602 DM 2, Land Acquisitions: Hazardous Substances Determinations. (For copies of these directives, write to the Department of Interior, Bureau of Indian Affairs, 1849 C Street, NW., Mail Stop: 4513–MIB, Washington, DC 20240). Include a record of consultation with appropriate authorities regarding environmental, endangered species, water quality, fish and wildlife, wetlands, transportation, air quality, cultural, historical value, hazardous waste, and toxic material issues.

(i) If the request is for an individual Indian, documentation demonstrating that the applicant's request meets one of the criteria described in § 151.13.

§ 151.13 Can an individual Indian acquire land outside his or her own reservation?

Except as provided in paragraphs (a) and (b) of this section, we will not accept title to land in trust outside an individual Indian's reservation. We may approve acquisitions of land outside an individual Indian's reservation if:

(a) The individual Indian already owns an undivided fractional trust or restricted interest in the property being acquired; or

(b) The individual Indian has sold trust or restricted interest in land and the money received from the sale is reinvested in other land selected and purchased with these funds, or the individual Indian is purchasing land with funds obtained as a result of a sale of trust or restricted land under 25 U.S.C. 409a.

§ 151.14 What criteria will BIA use to evaluate a request involving land outside a reservation or outside an approved Tribal Land Acquisition Area?

Upon receipt of the information required under § 151.12 and upon a determination that the application is complete:

(a) We will approve the application to accept land into trust outside a reservation or outside an approved TLAA only if the application shows that the acquisition is necessary to:

(1) Facilitate tribal self-determination, economic development, Indian housing, land consolidation or natural resource protection; and

(2) We determine that the acquisition provides meaningful benefits to the Tribe that outweigh any demonstrable harm to the local community.

(b) Notwithstanding a determination in paragraph (a) of this section that the acquisition is necessary to facilitate tribal self-determination and that the benefits of the acquisition to the tribe outweigh any harm to the local community, we may disapprove an application to accept land into trust outside a reservation or outside an approved TLAA if the acquisition will result in:

(1) Severe negative impacts to the environment, or

(2) Significant harm to the local community. Evidence of such harm must be clear and demonstrable and supported in the application record; or

(3) The inability of the Bureau of Indian Affairs to adequately handle the additional law enforcement and other responsibilities that would result from the acquisition of the land into trust status.

(c) When making a determination under paragraph (a) or (b) of this section to approve or deny an application, we will consider the location of the land relative to the state boundaries, and its distance from the boundaries of the tribe's reservation and whether that distance is reasonable based on the following:

(1) If the land is in a different state than the tribe's reservation, the tribe's justification of anticipated benefits from the acquisition will be subject to greater scrutiny

(2) As the distance between the tribe's reservation or approved TLAA and the land to be acquired increases, the tribe's justification of anticipated benefits from the acquisition will be subject to greater scrutiny

(3) As the distance between the tribe's reservation or approved TLAA and the land to be acquired increases, the concerns raised by the state and local governments will be given greater weight.

Subpart D—Mandatory Acceptance of Title

§ 151.15 What information must be provided in a request to process a mandatory transfer of title into trust status, and how will BIA process the request?

(a) To help us determine whether we are mandated by legislation to accept trust title to a specific tract of land, we require submission of the following documentation:

(1) A complete description, or a copy of, the statutory authority that directs the Secretary to place the land in trust, and any limitations contained in that authority;

(2) Title insurance or an abstract of title that meets the *Standards for the Preparation of Title Evidence in Land Acquisitions by the United States*, issued by the U. S. Department of Justice (copies are available from the U.S. Department of Justice, Environmental and Natural Resources Division, Land Acquisition Section, Room 6136, 601 Pennsylvania Avenue NW., Washington, DC 20004); and

(3) Any additional information that we may request.

(b) If we determine that the transfer of title into trust status is mandatory, we will publish that determination along with a notice of intent to take the land in trust in the **Federal Register** or in a newspaper of general circulation serving the affected area.

§ 151.16 Can our determination that a transfer of title into trust status is mandatory be appealed?

The Department's determination that a transfer of title into trust status is or is not mandatory may be appealed according to requirements set forth in part 2 of this title.

Subpart E—Tribal Land Acquisition Areas

§ 151.17 What is a Tribal Land Acquisition Area?

A TLAA is an area of land approved by the Secretary and designated by a tribe within which the tribe plans to acquire land over a 25-year period of time. If the Secretary approves the TLAA under this part, the tribe can acquire parcels of land within the TLAA during that 25-year period under the on-reservation provisions of this part.

§ 151.18 What tribes are eligible to apply for approval of a Tribal Land Acquisition Area?

Tribes which may apply for approval of a TLAA are those tribes which:

(a) Do not have a reservation,

(b) Do not have trust land, or

(c) Have a trust land base which is incapable of being developed in a manner that promotes tribal self-determination, economic development and/or Indian housing.

§ 151.19 What must be included in a request for Secretarial approval of a Tribal Land Acquisition Area?

A request for Secretarial approval of a TLAA must be made in writing, although we do not require that it take any special form. However, we strongly urge the applicant to address each applicable section of this part in the order it appears here. Constructing the

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application in this way will help us review the request more efficiently. To be complete, a request for Secretarial approval of a TLAA must identify the applicant tribe, and must include:

(a) A complete description, or a copy, of the federal statute(s) that authorize the Secretary to accept land in trust on behalf of the tribe, and any limitations contained in that authority.

(b) Copies of tribal documents relating to the establishment of the TLAA and the acquisition of land within it, including:

(1) A copy of the tribe's constitution and by-laws, corporate charter, resolution, or excerpts from those documents that identify and grant tribal officials the authority to acquire tribal lands on behalf of the tribe;

(2) A copy of a tribal resolution designating the TLAA, including a legal description of the lands located within it; and (3)

(3) A copy of a tribal resolution requesting that the Secretary approve the proposed TLAA.

(c) A narrative summary that describes the purposes and goals for acquiring lands in trust within the TLAA, including general information about whether the lands are to be used for residential, governmental, educational, economic development, or other purposes.

(d) A narrative of the tribe's history that explains:

(1) When the tribe was federally recognized, and whether it was through legislation, treaty, or the Bureau of Indian Affairs' Federal Acknowledgment Process; and

(2) If applicable, how the tribe became dispossessed of its former reservation lands.

(e) A description of the TLAA, including:

(1) A legal description of the lands within the TLAA;

(2) Information about whether the lands are within the tribe's former reservation or aboriginal homelands;

(3) Information about whether the lands are Federal lands, State lands, or private lands;

(4) Information about whether the lands overlap with another tribe's jurisdictional area;

(5) Information about the significance of the land to the tribe, including whether the land has any particular historical, cultural, religious, or other value to the tribe; and

(6) Information about the distance of the TLAA from the Bureau's nearest agency or area office.

(f) A description of the location of roads and rights-of-way, or of additional rights-of-way that may be needed to provide access to lands located within the TLAA.

(g) A description of the reasonably anticipated overall effect on the State and its political subdivisions of removing lands located within the TLAA from tax rolls, and a description of any measures the applicant will take to reduce these effects. The description of effects must include an explanation of:

(1) The amount of annual taxes currently assessed by the local governments for lands located within the TLAA;

(2) The amount of annual revenue which would be lost from special assessments to the local governments, if any;

(3) The amount of annual revenue lost from mineral receipts to the local governments, if any; and

(4) The local governments' ability to provide public safety services for lands located within the TLAA.

(h) A description of any overall jurisdictional and land use infrastructure issues that might arise if the lands within the TLAA is taken into trust. The description must address each of the following issues.

(1) Zoning, including:

(i) The current zoning of the land;

(ii) Any proposed use conflicts with current zoning; and

(iii) Applicable tribal zoning ordinances.

(2) Law enforcement and cross-deputizing, including:

(i) Who currently provides law enforcement services for the land;

(ii) Whether the tribe already has its own law enforcement;

(iii) Who will supply law enforcement if the land is approved for trust status; and

(iv) Whether additional resources would be needed to provide adequate law enforcement.

(3) Safety factors, including:

(i) Who supplies fire protection service for lands located within the TLAA;

(ii) Who supplies emergency medical service for lands located within the TLAA; and

(iii) Information about whether lands located within the TLAA are in a flood area or flood control area.

(4) Traffic, roads, and streets, including:

(i) A description of current access to the land;

(ii) Describes and quantifies anticipated increased traffic in the area from proposed use; and

(iii) A description of whether existing roads and streets are adequate to handle any anticipated increase in traffic caused by the proposed use.

(5) Sanitation, including whether:

(i) The lands located within the TLAA are on a city sewage system;

(ii) The lands located within the TLAA are served by an adequate sewage system that meets applicable standards;

(iii) Trash pickup service or another method of trash disposal is available for lands located within the TLAA;

(iv) The city or another facility supplies sanitation services to the lands located within the Tribe Land Acquisition Area;

(v) There is an adequate water supply for the proposed use and any future anticipated uses; and

(vi) Whether the tribe has water rights to the available water supply.

(6) Utilities, including:

(i) Whether a city or a rural electric company supplies electricity to lands located within the TLAA; and

(ii) The source of heating for lands located within the TLAA, such as: natural gas, propane, oil, coal, wood, electric, or solar.

(7) Whether there exist any cooperative agreements or voluntary actions intended to address jurisdictional and land use conflicts.

(8) Whether the tribe has made any provisions to compensate the State and local governments for revenue lost because of the removal of the lands from the tax rolls. (Include any increases in Title IX funding from the Indian Education Act or Impact Aid funding.)

§ 151.20 How is a tribal request for Secretarial approval processed?

When we receive a request for Secretarial approval of a TLAA, we will review the supporting documentation to determine if the request meets the requirements of this part. If the request is complete, we will:

(a) Provide notice of the request for Secretarial approval to the Governor's Office, to appropriate local government officials, and to appropriate officials of tribes located within a 50-mile radius of the boundaries of the proposed TLAA. Recipients of the notice will be provided 60 days from the date of receipt in which to comment on the proposed TLAA and the request supporting it. Other interested parties may also submit comments during the 60-day consultation period.

(b) After the close of the comment period, based on the criteria described in § 151.21, we will decide whether to approve the TLAA. Our decision on whether to approve the TLAA will be communicated in the form of a certified letter to the applicant. We also will provide notice of our decision to interested parties by sending a copy of the decision letter to everyone (including State and local governments) who sent us written comments on the request for approval.

(c) If we decide not to approve the TLAA, we will take no further action.

(d) If we decide to approve the TLAA, we will:

(1) Publish in the **Federal Register**, or in a newspaper of general circulation serving the affected area, a notice of the decision to approve the TLAA; and

(2) Thereafter, for a period of 25 years, review requests to accept trust title land located within the TLAA as "on-reservation" acquisitions under the applicable on-reservation provisions in this part.

§ 151. 21 What criteria will BIA use to decide whether to approve a proposed Tribal Land Acquisition Area?

In general, because tribes without reservations are significantly disadvantaged, both in terms of cultural preservation and in terms of being ineligible for federal land-based programmatic funding and technical assistance, there is a presumption in favor of the tribe's need for at least some trust land. However, in determining whether to approve establishment of a TLAA, we will consider the individual circumstances of each applicant tribe, surrounding community, and affected land base. There are some standard criteria which will help direct our decision-making process. These standard criteria include:

(a) The request must be complete and contain all supporting documents;

(b) The statutory basis upon which the tribe proposes creation of the TLAA. If the tribe is the subject of a statute directing the Secretary to take some unspecified land into trust for the tribe's benefit, the tribe will enjoy a greater presumption in favor of approval of its proposed TLAA. (For example, there is statutory language such as "the Secretary shall take land into trust within the tribe's service area," or "the Secretary shall take land into trust within X and Y counties.")

(c) The size of the proposed TLAA in relation to the size of the tribe's membership: we will look for a reasonable connection between the amount of land the tribe wishes to take into trust, and the basic trust needs (housing, health, employment opportunities) of the tribe's membership.

(d) The relationship of the tribe to the lands located within the TLAA: we will give greater weight to a request for approval of a TLAA that encompasses lands to which the tribe has established a strong cultural, historical, and/or legal connection.

(e) The ability of the tribe and the local non-Indian community to adjust to the jurisdictional changes that will occur if the lands within the TLAA are taken into trust, including:

(1) That there are adequate arrangements for provision of police and fire protection and other emergency response for persons living within the TLAA (whether living on trust or non-trust property);

(2) That there are adequate arrangements for provision of other municipal-type services, such as garbage removal, water, sewage;

(3) That adverse impacts on local governments and communities are reasonable compared to the benefits flowing to the applicant.

§ 151.22 Can a tribe include in its Tribal Land Acquisition Area land inside another tribe's reservation or Tribal Land Acquisition Area?

A tribe may include land inside the reservation boundaries or within an approved TLAA of another tribe, if:

(a) The tribe's governing body consents in writing;

(b) The tribe already owns undivided fractional trust or restricted interests in the tracts of land identified in its TLAA; or

(c) The tracts of land to be included in the TLAA are inside a reservation or an approved TLAA that is shared by two or more tribes, and the plan is for one of these tribes.

§ 151.23 If a Tribal Land Acquisition Area is not approved, is the tribe prohibited from acquiring land within it?

No. However, the tribe will have to apply to have individual parcels taken into trust under the off-reservation provisions of this part.

§ 151.24 If a Tribal Land Acquisition Area is approved, does the land taken into trust within it attain reservation status?

No. Lands taken into trust within a TLAA will enjoy "Indian country" status as that term has been defined in relevant federal statutes and case law. However, those lands do not attain "reservation" status by virtue of the TLAA having been approved by the Secretary. Reservation status can only be attained if:

(a) The tribe has applied to the Secretary under 25 U.S.C. 467; or

(b) There is a federal statute specifically designating the land as a reservation.

§ 151.25 Can a Tribal Land Acquisition Area be modified after approval?

Yes. However, the changes must be submitted with a request for approval in compliance with the criteria in this part and must be approved by the Secretary.

Subpart F—False Statements, Recordkeeping, Information Collection

§ 151.26 What is the penalty for making false statements in connection with a request that BIA place land into trust?

Anyone who knowingly and willfully makes a false statement in connection with a trust title acquisition request may be subject to criminal prosecution under the False Statements Accountability Act of 1996, 18 U.S.C. 1001.

§ 151.27 Who owns the records associated with this part?

(a) Records are the property of the United States if they:

(1) Are made or received by a tribe or tribal organization in the conduct of a federal trust function under this part, including the operation of a trust program; and

(2) Evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under this part.

(b) Records not covered by paragraph (a) of this section that are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior under this part are the property of the tribe.

§ 151.28 How must a record associated with this part be preserved?

(a) Any organization, including tribes and tribal organizations, that have records identified in § 151.26(a) must preserve the records in accordance with approved Departmental records retention procedures under the Federal Records Act, 44 U.S.C. chapters 29, 31, and 33. These records and related records management practices and safeguards required under the Federal Records Act are subject to inspection by the Secretary and the Archivist of the United States.

(b) A tribe or tribal organization should preserve the records identified in § 151.26(b) for the period of time authorized by the Archivist of the United States for similar Department of the Interior records in accordance with 44 U.S.C. chapter 33. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under this part, it may prevent the tribe or tribal organization from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

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Dated: December 29, 2000.
Kevin Gover,
Assistant Secretary—Indian Affairs.
[FR Doc. 01–470 Filed 1–12–01; 8:45 am]
BILLING CODE 4310–02–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–00–055]

Drawbridge Operation Regulations; Great Egg Harbor Bay, New Jersey

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Route 9/Beesleys Point Bridge across Great Egg Harbor Bay, mile 3.5, between Somers Point and Beesleys Point, in New Jersey. Beginning at 7 a.m. on January 22, 2001, through 5 p.m. on March 22, 2001, the bridge may remain in the closed position. This closure is necessary to conduct the installation of a new deck.

DATES: This deviation is effective from 7 a.m. on January 22, 2001, until 5 p.m. on March 22, 2001.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at (757) 398–6222.

SUPPLEMENTARY INFORMATION: The Coast Guard received a letter by fax from the contractor on December 1, 2000, requesting a temporary deviation from the current operating schedule of the Route 9/Beesleys Point Bridge. The draw currently is required to open on signal at all times. This requirement is included in the general operating regulations at 33 CFR 117.5. The contractor intends to install a new deck on the bascule span of the bridge. To facilitate the installation, the bascule span will be bolted down in the closed position so that the old deck can be removed and a new deck installed. This work requires completely immobilizing the operation of the bascule span. In the event of an emergency, openings of the span will be provided as quickly as possible, but may take up to 48 hours to accomplish. Requests for emergency openings can be made by calling the bridge manager at (609) 390–3190 or (609) 624–0949.

In accordance with 33 CFR 117.35, the District Commander approved the contractor's request for a temporary deviation from the governing regulations in a letter dated December 12, 2000.

The Coast Guard has informed the known commercial users of the waterway of the bridge closure so that these vessels can arrange their transits to minimize any impact caused by the temporary deviation.

The temporary deviation allows the Route 9/Beesleys Point Bridge across Great Egg Harbor, mile 3.5, between Somers Point and Beesleys Point, New Jersey to remain closed from 7 a.m. on January 22, 2001, until 5 p.m. on March 22, 2001.

Dated: December 21, 2000.
John E. Skhor,
U.S. Coast Guard, Commander, Fifth Coast Guard District.
[FR Doc. 01–1212 Filed 1–12–01; 8:45 am]
BILLING CODE 4910–15–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136, 141, and 143

[FRL–6918–2]

RIN 2040–AD59

Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct Final Rule.

SUMMARY: EPA is approving the use of updated versions of test procedures (i.e., analytical methods) for the determination of chemical, radiological, and microbiological pollutants and contaminants in wastewater and drinking water. These updated versions of analytical methods have been published by one or more of the following organizations: American Society for Testing Materials (ASTM), United States Geological Survey (USGS), United States Department of Energy (DOE), American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF). Previously approved versions of the methods remain approved. Today's action will give the analytical community a larger selection of analytical methods. Today's action also corrects typographical errors and updates references where appropriate.

DATES: This final rule is effective on May 16, 2001 without further notice, unless EPA receives adverse comment by March 19, 2001. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule (or distinct amendments, paragraphs, or sections of this rule) will not take effect.

The incorporation by reference of the publications listed in today's rule is approved by the Director of the Federal Register as of May 16, 2001.

For judicial review purposes, this final rule is promulgated as of 1:00 p.m. (Eastern time) on January 30, 2001 as provided in 40 CFR 23.2 and 23.7.

ADDRESSES: You may submit written comments either by mail or electronically. Send comments to the Methods Update Comment Clerk (W–99–21), U.S. Environmental Protection Agency, Water Docket, MC–4101, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. Submit electronic comments to *OW-Docket @epa.gov*. Please submit copies of any references cited in your comments. EPA would appreciate an original and 3 copies of your comments and enclosures (including references).

This **Federal Register** document is also available on the Internet at: *http://www.epa.gov/fedrgstr*. The record for this rulemaking has been established under docket number W–99–21. Supporting documents (including references and methods cited in this notice) are available for review at the U.S. Environmental Protection Agency, Water Docket, East Tower Basement, Room EB57, 401 M Street, SW., Washington, DC 20460. For access to the docket materials, call 202/260–3027 on Monday through Friday, excluding Federal holidays, between 9:00 a.m. and 3:30 p.m. Eastern Daylight Standard Time for an appointment.

Copies of final methods published by ASTM are available for a nominal cost through American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. Copies of final methods published by USGS are available for a nominal cost through the United States Geological Survey, U.S. Geological Survey Information Services, Box 25286, Federal Center, Denver, CO 80225–0425. Copies of final methods published by DOE are available for a nominal cost through the Environmental Measurements Laboratory, U.S. Department of Energy, 376 Hudson Street, New York, NY 10014–3621. Copies of Standard Methods are available for a nominal cost from the American Public Health Association,

1015 Fifteenth Street, NW., Washington, DC. 20005.

FOR FURTHER INFORMATION CONTACT: For information regarding wastewater methods contact Dr. Maria Gomez-Taylor, Engineering and Analysis Division (4303), USEPA Office of Science and Technology, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460 (e-mail: *Gomez-Taylor.Maria@epa.gov*). For information regarding the drinking water methods, contact Dr. Richard Reding, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (e-mail: *Reding.Richard@epa.gov*).

SUPPLEMENTARY INFORMATION:

Potentially Regulated Entities

A. Clean Water Act

EPA Regions, as well as States, Territories, and Tribes, are authorized to implement the National Pollutant Discharge Elimination System (NPDES) program and issue permits that comply with the technology-based and water quality-based requirements of the Clean Water Act. In doing so, the NPDES permitting authority, including authorized States, Territories, and Tribes, make a number of discretionary choices associated with permit writing, including the selection of pollutants to be measured and, in many cases, limited in permits. If EPA has "approved" (*i.e.*, promulgated through rulemaking) standardized testing procedures for a given pollutant, the NPDES permit must specify one of the approved testing procedures or an approved alternate test procedure. Permitting authorities may, at their discretion, require the use of any method approved at 40 CFR part 136 in the permits they issue. Therefore, dischargers with NPDES permits could be affected by the standardization of testing procedures in this rulemaking, because NPDES permits may incorporate the testing procedures in today's rulemaking. In addition, when a State, Territory, or authorized Tribe provides certification of Federal licenses under Clean Water Act section 401, States, Territories, and Tribes are directed to use the standardized testing procedures. Categories and entities that may ultimately be affected include:

Category	Examples of potentially regulated entities
Regional, State and Territorial Governments and Indian Tribes	States, Territories, and Tribes authorized to administer the NPDES permitting program; States, Territories, and Tribes providing certification under Clean Water Act section 401; Governmental NPDES permittees
Industry	Industrial NPDES permittees
Municipalities	Publicly-owned treatment works with NPDES permits

B. Safe Drinking Water Act

Public water systems are the regulated entities required to conduct analyses to measure for contaminants in water samples. However, EPA Regions, as well as States, local, and tribal governments with primacy to administer the regulatory program for public water systems under the Safe Drinking Water Act, sometimes conduct analyses to measure for contaminants in water samples. If EPA has established a maximum contaminant level ("MCL") for a given drinking water contaminant, the Agency also "approves" (*i.e.*, promulgates through rulemaking) standardized testing procedures for analysis of the contaminant. Once EPA standardizes such test procedures, analysis using those procedures (or approved alternate test procedures) is required. Public water systems required to test water samples must use one of the approved standardized test procedures. Categories and entities that may ultimately be regulated include:

Category	Examples of potentially regulated entities	SIC
State, Local, & Tribal Governments	States, local and tribal governments that analyze water samples on behalf of public water systems required to conduct such analysis; States, local, and tribal governments that themselves operate public water systems required to conduct analytic monitoring.	9511
Industry	Industrial operators of public water systems	4941
Municipalities	Municipal operators of public water systems	9511

C. These tables are not intended to be exhaustive, but rather provide a guide for readers regarding entities potentially regulated by this action. The tables list the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the tables could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability language at 40 CFR 141.2 (definition of public water system) and 40 CFR 136.1 (NPDES permits and CWA). If you have questions regarding the applicability of this action to a particular entity, consult the appropriate person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

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I. Legal Authorities

A. Clean Water Act

This regulation is promulgated under the authority of sections 301, 304(h), and 501(a) of the Clean Water Act (CWA), 33 U.S.C. 1311, 1314(h), 1361(a) (the "Act"). Section 301 of the Act prohibits the discharge of any pollutant into navigable waters unless the discharge complies with a National Pollutant Discharge Elimination System (NPDES) permit, issued under section 402 of the Act. Section 304(h) of the Act requires the EPA Administrator to "promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section 401 of this Act or permit applications pursuant to section 402 of this Act." Section 501(a) of the Act authorizes the Administrator to "prescribe such regulations as are necessary to carry out his functions under this Act." EPA publishes CWA analytical method regulations at 40 CFR part 136. The Administrator also has made these test procedures applicable to monitoring and reporting of NPDES permits (40 CFR part 122, §§ 122.21, 122.41, 122.44, and 123.25), and implementation of the pretreatment standards issued under section 307 of the Act (40 CFR part 403, §§ 403.10 and 403.12).

B. Safe Drinking Water Act

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to promulgate national primary drinking water regulations (NPDWRs) which specify maximum contaminant levels (MCLs) or treatment techniques for drinking water contaminants (SDWA section 1412 (42 U.S.C. 300g–1)). NPDWRs apply to public water systems pursuant to SDWA section 1401 (42 U.S.C. 300f(1)(A)). According to SDWA section 1401(1)(D), NPDWRs include "criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures.* * *" (42 U.S.C. 300f(1)(D)). In addition, SDWA section 1445(a) authorizes the Administrator to establish regulations for monitoring to assist in determining whether persons are acting in compliance with the requirements of the SDWA (42 U.S.C. 300j–4). EPA's promulgation of analytical methods is authorized under these sections of the SDWA as well as the general rulemaking authority in SDWA section 1450(a), (42 U.S.C.300j–9(a)).

II. Overview of Methods Updates

EPA has promulgated analytical methods for all currently regulated wastewater and drinking water pollutants and contaminants. In most cases, EPA has approved use of more than one analytical method for measurement of a contaminant, and laboratories may use any approved method for determining compliance with a monitoring requirement. After any regulation is published, EPA may amend the regulations to approve new methods or modifications to approved methods.

Many of the analytical methods already promulgated by EPA have been published by other organizations, including the American Society for Testing Materials (ASTM), United States Geological Survey (USGS), and United States Department of Energy (DOE). In addition, three other organizations (American Public Health Association, American Water Works Association and Water Environment Federation) jointly publish *Standard Methods for Examination of Water and Wastewater* (referred to as "Standard Methods"). This rule approves use of updated versions of currently promulgated ASTM Methods, Standard Methods, and USGS methods at 40 CFR part 136 for compliance with wastewater standards and monitoring requirements. This rule also approves updated versions of currently promulgated methods in the tables of analytical methods listed at 40 CFR parts 141 and 143 for analyses of drinking water contaminants. The drinking water methods included in this rule are published by ASTM, Standard Methods, and DOE. These organizations publish updated manuals of methods from time to time. Some of the methods in the updated manuals contain no change from previously published editions. Other methods contain no significant changes, only minor technical improvements that make the methods safer and/or easier to use. Today's amendments contain only methods that have no changes or only minor technical improvements. No EPA methods are being updated.

This rule does not withdraw from use any currently promulgated method. For an NPDES permit, the permitting authority should decide the appropriate method based on the nature of the particular water sample to be tested and based on the measurement level of concern.

Today's amendments allow use of updated versions of methods, as outlined below. Each write-up uniquely defined by an identifying method number is counted as a single updated method, regardless of the nature of changes. Even if the only change to the method is its inclusion in a more recent published edition of a methods manual (e.g, 19th Edition of Standard Methods), it is considered an updated method.

A. Amendments to Methods at 40 CFR Part 136 for Monitoring Wastewater

Today's amendments allow use of 19 updated methods published by the American Society for Testing and Materials (ASTM) in the 1999 *Annual Book of ASTM Standards*, Vols. 11.01 and 11.02 for determinations of chemical and radionuclide contaminants, and physical parameters. Previously published versions of these methods, if already promulgated by EPA, remain approved.

Today's amendments also allow use of 189 updated methods published by the Standard Methods Committee in *Standard Methods for the Examination of Water and Wastewater*, 19th edition, 1995, and 20th edition, 1998, for determinations of chemical, microbiological and radionuclide contaminants, and physical parameters.

EPA is also amending 40 CFR Part 136 to update USGS Method I–1472–85 to Method I–4471–97 for determination of cadmium, and 21 methods published by USGS in open file reports and method compendiums. The 21 USGS methods are for the determination of one or more analytes . These methods employ the same analytical procedures and technologies that are employed in promulgated EPA and VCSB methods. These USGS methods will give the analytical community a greater selection of methods.

Finally, today's amendments correct typographical errors in the tables of methods, table footnotes, and sources.

B. Amendments to Methods at 40 CFR Part 141 for Monitoring Primary Drinking Water Contaminants

Today's amendments allow use of 12 updated methods that are published in the 1999 *Annual Book of ASTM Standards*, Vols. 11.01 and 11.02, for determinations of chemical and radionuclide contaminants, and physical parameters. Use of previously promulgated versions of ASTM methods that are published in these volumes, but have not been revised from previous editions, is also allowed.

Today's amendments also allow use of 62 updated methods published by the Standard Methods Committee in *Standard Methods for the Examination of Water and Wastewater*, 20th edition, 1998, for determinations of chemical, microbiological and radionuclide contaminants, and physical parameters.

Today's amendments allow use of six updated methods published by DOE in the document "EML Procedures Manual," 28th Edition, Volume 1, 1997, for determinations of radionuclide contaminants.

C. Amendments to Methods at 40 CFR Part 143 for Monitoring Secondary Drinking Water Contaminants

Today's amendments list an updated version of one chemistry method (D 4327–97) published in the 1999 *Annual Book of ASTM Standards*, Vol. 11.01.

Today's amendments also list updated versions of 12 methods published by the Standard Methods Committee in *Standard Methods for the Examination of Water and Wastewater*, 20th edition, 1998, for determinations of secondary chemical contaminants and physical parameters.

III. Reasons for Using Direct Final Rulemaking

The Agency is promulgating these amendments as a "direct final" rule. EPA is publishing this rule without prior proposal because we view this as noncontroversial amendments and anticipate no adverse comment. Today's action approves updated versions of analytical methods published by several organizations in recent editions of methods manuals or recent publications. These updated versions contain no significant changes, only minor technical improvements that make the methods safer and/or easier to use. However, in the "Proposed Rules" section of today's **Federal Register**, we are publishing a separate document that will serve as the proposal to update these methods if adverse comments are filed. This rule will be effective on May 16, 2001 without further notice unless we receive adverse comment by March 19, 2001. If EPA receives adverse comment on one or more distinct amendments, paragraphs, or sections of this rulemaking, we will publish a timely withdrawal in the **Federal Register** indicating which provisions will become effective and which provisions are being withdrawn due to adverse comment. Any distinct amendment, paragraph, or section of today's rulemaking for which we do not receive adverse comment will become effective on the date set out above, notwithstanding any adverse comment on any other distinct amendment, paragraph, or section of today's rule. We will address all public comments in a subsequent final rule based on the companion proposed rule published elsewhere in today's **Federal Register**. We will not institute a second comment period on the action. Any parties interested in commenting must do so at this time.

IV. Description of the Amendments in Today's Actions

The Agency is amending the tables of methods at 40 CFR Parts 136, 141 and 143 to include recently updated versions of certain analytical methods and to correct typographical errors as explained below.

A. Approval of Updated Versions of Analytical Methods

The updated versions of methods listed at 40 CFR Parts 136, 141, and 143 discussed in this section contain updates of currently promulgated methods that interested parties, such as public water systems, NPDES permit writers, pretreatment coordinators, laboratory personnel, certification officials, and regulatory authorities, will consider to be noncontroversial and generally useful.

1. American Society for Testing and Materials (ASTM) Methods for Analyses of Wastewater and Drinking Water

In today's rule, EPA is amending 40 CFR Parts 136, 141, and 143 to include updated ASTM methods that are published in Vols. 11.01 and 11.02 of the ASTM's *Annual Book of Standards* [ASTM 1999]. The changes, if any, in the updated ASTM methods that are included in today's rule are editorial changes or minor technical clarifications. An example of an editorial change is the replacement of the unit for the measurement of radioactivity, picocurie, with the unit, Becquerel; 1 Becquerel equals 27 picocuries. The change to Becquerel conforms the ASTM methods to the unit of radioactivity measurement that is recommended by the International Union for Pure and Applied Chemistry (IUPAC), which is an international organization that recommends standards for units of measurement.

Examples of minor technical changes are recommendations for the safe handling of hazardous materials and safer or better ways to conduct certain hazardous or complicated analytical procedures. Some of the ASTM methods have been augmented with additional tables of method performance data. The updated ASTM methods do not contain substantive changes in procedures or instrumentation. Because EPA is not withdrawing approval of the currently approved version of any ASTM method, approval of the revised methods should have no adverse effect on users.

a. Wastewater Methods

Nineteen ASTM methods that are published in the 1999 *Annual Book of Standards* (ASTM 1999) and that have been updated from previous versions of these methods are approved in today's rule at 40 CFR Part 136 for wastewater compliance monitoring. Table 1 lists the 19 revised ASTM wastewater methods.

TABLE 1—REVISED ASTM WASTEWATER METHODS

Currently Approved Version	1999 Edition Version
D 858–90	D 858–95
D 859–88	D 859–94
D 1068–90	D 1068–96
D 1125–91	D 1125–95
D 1126–86(92)	D 1126–96
D 1246–82(88)	D 1246–95
D 1252–88	D 1252–95
D 1426–93	D 1426–98
D 1688–90	D 1688–95
D 1889–88	D 1889–94
D 2036–91	D 2036–98
D 2972–93	D 2972–97
D 3557–90	D 3557–95
D 3558–90	D 3558–94
D 3559–90	D 3559–96
D 3859–93	D 3859–98
D 3867–90	D 3867–99
D 4190–82(88)	D 4190–94
D 4382–91	D 4382–95

b. Drinking Water Methods for Primary and Secondary Drinking Water Contaminants

Twelve ASTM methods that are published in the 1999 *Annual Book of Standards* (ASTM 1999) and that have been updated from previous versions of these methods are approved in today's rule at 40 CFR part 141 for drinking water compliance monitoring. Because one of the updated methods, D 4327–97, is also applicable to determinations of both chloride and sulfate, this method is also recommended in the table at 40 CFR part 143 for monitoring of these secondary contaminants. Three methods, D 3972 for uranium, and D 2460 and D 3454 for radium, have been updated to describe an optional computation of a total propagated uncertainty (TPU). EPA is approving these updated radionuclide methods. Although the TPU computation is technically satisfactory, it requires more

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effort than the uncertainty computation for radionuclide measurements specified at 40 CFR 141.25(c) and 141.26(a). EPA does not preclude use of the TPU computation, but the Agency believes that this computation is not necessary to obtain an accurate determination of uncertainty. Therefore, use of the computation specified in the CFR is recommended. Table 2 lists the 12 revised ASTM drinking water methods.

TABLE 2.—REVISED ASTM DRINKING WATER METHODS

Currently Approved Version	1999 Edition Version
D 2036–91	D 2036–98
D 2460–90	D 2460–97
D 2907–91	D 2907–97
D 2972–93	D 2972–97
D 3454–91	D 3454–97
D 3559–95	D 3559–96
D 3645–93	D 3645–97
D 3859–93	D 3859–98
D 3972–90	D 3972–97
D 4327–91	D 4327–97
D 4785–88	D 4785–93
D 5174–91	D 5174–97

2. APHA/AWWA/WEF Methods (Standard Methods)

a. Wastewater Methods

In today's rule, EPA is amending 40 CFR part 136 to include 189 updated methods that are published in the 19th (APHA 1995) and 20th (APHA 1998) Editions of Standard Methods. 40 CFR Part 136 currently includes only methods listed in the 18th Edition (APHA 1992). Because EPA is not withdrawing approval of the currently promulgated version of any Standard Method, approval of these methods in this rulemaking should have no adverse effect on users.

Thirty of the 189 Standard Methods being approved contain minor technical and/or editorial revisions to the corresponding promulgated 18th Edition versions. The revisions are intended to improve method usability. Examples of these changes include: better explanations on conducting a specific step in the method; recommendations for safer handling or disposal of hazardous reagents; and options to use alternative procedures, reagents, or equipment (such as the option to use capillary columns in Method 6200 C, and the merger of Methods 6220 B and 6230 B into one method, 6200 C).

The other 159 methods remain unchanged from the currently promulgated methods. The only difference is that they are included in a more recent edition of Standard Methods and in some cases contain a different identifying method number. Method number changes between the 18th, 19th, and 20th editions occurred in 27 instances. These changes in numbering are provided in Table 3.

TABLE 3.—STANDARD METHODS NUMBER CHANGES

18th Edition	19th Edition	20th Edition
3500–Al D	3500–Al D	3500–Al B
3500–As C	3500–As C	3500–As B
3500–Be D	3500–Be D	Dropped
3500–Cd D	3500–Cd D	Dropped
3500–Ca D	3500–Ca D	3500–Ca B
3500–Cr D	3500–Cr D	3500–Cr B
3500–Cu D	3500–Cu D	3500–Cu B
3500–Cu E	3500–Cu E	3500–Cu C
3500–Fe D	3500–Fe D	3500–Fe B
3500–Pb D	3500–Pb D	3500–Pb B
3500–Mg D	3500–Mg D	Dropped
3500–Mn D	3500–Mn D	3500–Mn B
3500–K D	3500–K D	3500–K B
3500–Na D	3500–Na D	3500–Na B
3500–V D	3500–V D	3500–V B
3500–Zn E	3500–Zn E	Dropped
3500–Zn F	3500–Zn F	3500–Zn B
4500–NH_3 C	Dropped	Dropped
4500–NH_3 E	4500–NH_3 C	4500–NH_3 C
4500–NH_3 F	4500–NH_3 D	4500–NH_3 D
4500–NH_3 G	4500–NH_3 E	4500–NH_3 E
4500–NH_3 H	4500–NH_3 G	4500–NH_3 G
4500–S^{-2} E	4500–S^{-2}F	4500–S^{-2} F
4500–Si D	4500–Si D	4500–SiO_2 C
6210 B	6210 B	6200 B
6220 B	6220 B	6220 C
6230 C	6230 B	6230 C

Five methods have been dropped from recent editions of Standards Methods. These methods are not being withdrawn from 40 CFR Part 136 because the methods are technically sound and there may be laboratories successfully using these methods. The five methods dropped from Standard Methods are Method 4500–NH_3 C, which was not included in the 19th edition, and Methods 3500–Be D, 3500–Cd D, 3500–Mg D, and 3500–Zn E, which were not included in the 20th edition.

b. Drinking Water Methods for Primary and Secondary Drinking Water Contaminants

EPA is also amending 40 CFR Parts 141 and 143 to add 71 methods that are published in the 20th Edition of Standard Methods. Previous promulgated versions of these methods, which are published in 18th and 19th Editions of Standard Methods, are listed at 40 CFR Parts 141 and 143. Because EPA is not withdrawing approval of the currently promulgated version of any Standard Method, approval of the updated revised methods in this rulemaking should have no adverse effect on users.

Of the 71 Standard Methods methods included in today's rule, 52 methods are unchanged from previous versions. The remaining 19 methods contain minor editorial changes or technical clarifications. Some of these revisions are minor modifications or voluntary but useful options, such as better explanations on conducting a specific step in the method; recommendations for safer handling or disposal of hazardous reagents; and options to use alternative procedures, reagents, or equipment. The method numbers for five methods changed between the 19th and 20th editions. These changes in numbering are provided in Table 4.

TABLE 4.—STANDARD METHODS NUMBER CHANGES

19th Edition	20th Edition
3500–Ca D	3500–Ca B
3500–Mg E	3500–Mg B
4500–Si D	4500–SiO_2 C
4500–Si E	4500–SiO_2 D
4500–Si F	4500–SiO_2 E

3. USGS Methods for Analyses of Wastewater

In today's rule, EPA is amending 40 CFR Part 136 to update USGS Method I–1472–85 to Method I–4471–97 for the determination of cadmium, and to allow use of 21 updated methods published by USGS in open file reports and method compendiums. At the request of USGS, the 21 methods are being promulgated for the determination of one or more analytes. These 21 USGS methods employ the same analytical procedures and technologies that are employed in approved EPA and voluntary consensus standards bodies (VCSB) methods. Approval of these USGS methods will give the analytical community a greater selection of methods.

4. DOE Methods for Analyses of Radionuclides in Drinking Water

In today's rule, EPA is amending 40 CFR Part 141 to add updated versions of six radionuclide methods that are published by DOE in the *EML Procedures Manual*, 28th Edition, Volume 1, 1997 (DOE 1997). The six methods are Ra–05, Sr–01, Sr–02, U–02, U–04, and Ga–01–R. Two of the methods in the 1997 DOE manual have been renumbered. Method Ra–05 is now Ra–04 and the method referred to as Sect. 4.5.4.3 in the 1990 manual has been given the method number Ga–01–R. Four of the methods in the 1997 DOE manual are unchanged. One method, Method Ga–01–R, has minor editorial changes. In Method U–02, alpha spectrometry for uranium determinations, the sample preparation procedure has been revised and now allows proceeding directly to the microprecipitation step. This change eliminates the mercury cathode electrolysis isotope separation step without affecting the sensitivity or selectivity of the analysis. In the 1990 version of Method U–02, this isotope separation step was optional for drinking water samples. This previous version of U–02 continues to be approved along with the 1990 versions of the other five DOE methods. The Agency, however, strongly recommends use of the 1997 version of U–02, because it eliminates the need for radiochemistry laboratories to handle large quantities of liquid mercury.

B. Typographical Errors

Today's rule corrects typographical errors in the CFR tables at 40 CFR Part 136, and also updates references as appropriate. All of the amendments to the tables are minor, and do not impose any new analytical requirements. Today's rule incorporates the following technical corrections:

(1) Footnote 38 to Table IB at 40 CFR Part 136.3 is corrected and updated to reference Trichlorotrifluorethane (1,1,2-trichloro-1,2,2-trifluoroethane; CFC–113) and n-hexane as approved extraction solvents for the oil and grease Standard Method 5520 B. Previously, trichlorofluoromethane (CFC–11) was incorrectly listed.

(2) The Standard Methods digestion procedure that precedes Kjeldahl Nitrogen determination is corrected to reference Standard Methods 4500–Norg B or C. Previously, Standard Methods 4500 NH_3 B or C were listed, which provide procedures for ammonia distillation and titrimetric determination (not digestion), respectively.

(3) Footnote 34 and its associated source listing is updated to reflect a change in method ownership for Direct Current Plasma (DCP) Method AES0029, developed by Fisons and acquired by Thermo Jarrell Ash.

(4) The reference for the Nickel Colorimetric (Heptoxime) method is corrected to include Standard Method 3500–Ni D from the 17th Edition instead of the 18th Edition. Method 3500–Ni D was not included in the 18th Edition of Standard Methods.

(5) Incorrect page number listings for USGS methods were corrected.

(6) The CFR contains two references with the same number. The second reference (40) in Section 136.3(b) has been renumbered (41) and reference (41) has been renumbered (42).

C. Performance-based Measurement System

On March 28, 1997, EPA proposed a rule (62 FR 14976) to streamline approval procedures and use of analytical methods in water programs through implementation of a performance-based approach to environmental measurements. On October 6, 1997, EPA published a notice of the Agency's intent to implement a performance-based measurement system (PBMS) in all media programs to the extent feasible (62 FR 52098). EPA's water program offices have developed a plan to implement PBMS. EPA anticipates that the final rule to implement PBMS in water programs will be based on the March 28, 1997 proposed rule.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or

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adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, we defined: (1) Small businesses according to SBA size standards; (2) small governmental jurisdictions as governments of a city, county, town, school district or special district with a population less than 50,000; and (3) small organizations as any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Today's rule approves new and revised versions of currently approved ASTM Methods, Standard Methods, United States Geological Survey (USGS), and United States Department of Energy (DOE) methods for compliance with wastewater monitoring and drinking water standards and monitoring requirements but does not require their use. Previous versions of these ASTM, Standard Methods, USGS, and DOE methods will not be withdrawn. Public water systems and laboratories performing analyses on behalf of these systems may continue to use the previous versions after the promulgation of today's rule. The final rule merely provides additional options. Any of the testing procedures currently approved at 40 CFR parts 136, 141, or 143 can be used if monitoring is otherwise required for this pollutant under the CWA or SDWA. This rule also makes minor technical corrections, amendments, and clarifications to the regulations.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. This rule imposes no enforceable duty on any State, local or tribal governments or the private sector. EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rule is not subject to the requirements of sections 202, 203, and 205 of the UMRA.

This rule approves the use of analytical methods for conducting analysis for contaminants in wastewater and drinking water and thus provides operational flexibility to laboratory analysts. Since the rule does not withdraw earlier versions of methods, EPA anticipates no increase in expenditure or burden.

D. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* This action merely provides additional options on the selection of testing procedures when monitoring is otherwise required under the CWA or SDWA. Any of the testing procedures approved at 40 CFR parts 136, 141, or 143 can be used if such monitoring is required for a pollutant or contaminant.

E. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standard bodies. NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when EPA decides not to use available and applicable voluntary consensus standards.

In this rulemaking EPA is approving newer versions of voluntary consensus standards published by ASTM and Standard Methods for many wastewater and drinking water contaminants. EPA recognizes that other voluntary consensus standards may also be available for the contaminants covered by this rule. In order to expedite publication of this rule as a direct final rule, EPA has chosen not to propose other voluntary consensus methods at this time. EPA plans to address the availability of other voluntary consensus methods in subsequent rules.

F. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This rule is not subject to Executive Order 13045 because it is neither "economically significant" as defined under Executive Order 12866, nor does it concern an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children.

G. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's rule approves the use of additional analytical methods by laboratories conducting analysis in wastewater and drinking water. Today's action does not, however, require use of the alternative methods. The rule provides laboratory analysts with other options to the list of currently approved testing procedures under 40 CFR parts 136, 141, and 143 which can be used if monitoring is otherwise required for these pollutants under the CWA or SDWA. Thus, Executive Order 13132 does not apply to this rule.

H. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This rule approves new and updated analytical methods for drinking water compliance monitoring and wastewater compliance monitoring. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on May 16, 2001.

VI. References

APHA 1992. Eighteenth edition of Standard Methods for the Examination of Water and Wastewater, 1992, American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

APHA 1995. Nineteenth edition of Standard Methods for the Examination of Water and Wastewater, 1995, American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

APHA 1998. Twentieth edition of Standard Methods for the Examination of Water and Wastewater, 1998, American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

ASTM 1999. 1999 Annual Book of ASTM Standards, Vols. 11.01 and 11.02, American Society of Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428–2959.

AWWA 1996. "Standard Methods—A Closer Look," Posavec, Steve, in Opflow, Vol.22, No.2, February 1996, American Water Works Association, 6666 West Quincy Avenue, Denver, CO 80235.

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USGS 1989. Fishman, M.J., et al, "Methods for Analysis of Inorganic Substances in Water and Fluvial Sediments," U.S. Department of the Interior, Techniques of Water-Resource Investigations of the U.S. Geological Survey, Denver, CO.

USGS 1992. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Total Phosphorus by Kjeldahl Digestion Method and an Automated Colorimetric Finish That Includes Dialysis" Open File Report (OFR) 92–146 of the U.S. Geological Survey, Denver, CO.

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USGS 1993. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Chromium in Water by Graphite Furnace Atomic Absorption Spectrometry", Open File Report (OFR) 93–449 of the U.S. Geological Survey, Denver, CO.

USGS 1994. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Triazine and Other Nitrogen-containing Compounds by Gas Chromatography with Nitrogen Phosphorus Detectors" of the U.S. Geological Survey, Denver, CO.

USGS 1997. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Molybdenum by Graphite Furnace Atomic Absorption Spectrophotometry", Open File Report (OFR) 97–198 of the U.S. Geological Survey, Denver, CO.

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USGS 1998 "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Ammonia Plus Organic Nitrogen by a Kjeldahl Digestion Method and an Automated Photometric Finish that Includes Digest Cleanup by Gas Diffusion and an Automated Photometric Finish That Includes Digest Cleanup by Gas Diffusion". Open File Report (OFR) 00–170 of the U.S. Geological Survey, Denver, CO.
USGS 1998. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Arsenic and Selenium in Water and Sediments by Graphite Furnace-Atomic Absorption Spectrometry" Open File Report (OFR) 98–639. Table IB, Note 49.
USGS 1998. "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Elements in Whole-water Digests Using Inductively Coupled Plasma-Optical Emission Spectrometry and Inductively Coupled Plasma-Mass Spectrometry", Open File Report (OFR) 98–165 of the U.S. Geological Survey, Denver, CO.

List of Subjects

40 CFR Part 136

Environmental protection, Analytical methods, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Intergovernmental relations, Radiation Protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 143

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Water supply.

Dated: December 11, 2000.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations, is amended as follows:

PART 136—GUIDELINES ESTABLISHING TEST PROCEDURES FOR THE ANALYSIS OF POLLUTANTS

1. The authority citation for Part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a) Pub. L. 95–217, 91 Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*) (The Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977.)

2. Section 136.3 is amended:

a. In paragraph (a) by revising Tables IA, IB, IC, ID, and IE.

b. In paragraph (b) revise references (6) and (10), remove reference (41), redesignate the second reference (40) as (41), redesignate reference (43) as (51), and add references (42) through (50) to read as follows:

§ 136.3 Identification of test procedures.

* * * * *

(a) * * *

TABLE 1A.—LIST OF APPROVED BIOLOGICAL METHODS

Parameter and units	Method [1]	EPA	Standard Methods 18th, 19th, 20th Ed.	ASTM	USGS
Bacteria:					
1. Coliform (fecal), number per 100 mL..	Most Probable Number (MPN), 5 tube. 3 dilution, or Membrane filter (MF) [2], single step.	p.132 [3] p.124 [3]	9221C E [4] 9222D [4]		B–0050–85 [5]
2. Coliform (fecal) in presence of chlorine, number per 100 mL..	MPN, 5 tube, 3 dilution, or MF, single step [6]	p.132 [3] p.124 [3]	9221C E [3] 9221D [4]		
3. Coliform (total), number per 100 mL..	MPN, 5 tube, 3 dilution, or MF [2], single step or two step.	p.114 [3] p. 108 [3]	9221B [4] 9222B [4]		B–0025–85 [5]
4. Coliform (total), in presence of chlorine, number per 100 mL..	MPN, 5 tube, 3 dilution, or MF [2] with enrichment	p. 114 [3] p. 111 [3]	9221B [4] 9222(B+B.5c) [4]		
5. Fecal streptococci, number per 100 mL..	MPN, 5 tube, 3 dilution, ... MF [2], or .... Plate count	p. 139 [3] p. 136 [3] p.143 [3]	9230B [4] 9230C [4]		B–0055–85 [5]
Aquatic Toxicity:					
6. Toxicity, acute, fresh water organisms, LC50, percent effluent..	Daphnia, Ceriodaphnia, Fathead Minnow, Rainbow Trout, Brook Trout, or Bannerfish Shiner mortality.	Sec. 9 [7]			
7. Toxicity, acute, estuarine and marine organisms, LC50, percent effluent..	Mysid, Sheepshead Minnow, or Menidia spp. mortality.	Sec. 9 [7]			
8. Toxicity, chronic, fresh water organisms, NOEC or IC25, percent effluent..	Fathead minnow larval survival and growth.	1000.0 [8] 1001.0 [8]			
	Fathead minnow embryo-larval survival and teratogenicity.	1002.0 [8] 1003.0 [8]			
	Ceriodaphnia survival and reproduction.				
	Selenastrum growth				

TABLE 1A.—LIST OF APPROVED BIOLOGICAL METHODS—Continued

Parameter and units	Method [1]	EPA	Standard Methods 18th, 19th, 20th Ed.	ASTM	USGS
9. Toxicity, chronic, estuarine and marine organisms, NOEC or IC25, percent effluent..	Sheepshead minnow larval survival and growth.	1004.0 [9] 1005.0 [9]			
	Sheepshead minnow embryo-larval survival and teratogenicity.	1006.0 [9] 1007.0 [9]			
	Menidia beryllina larval and growth.	1008.0 [9]			
	Mysidopsis bahia survival, growth, and fecundity.	1009.0 [9]			
	Arbacia punctulata fertilization.				
	Champia parvula reproduction.				

Notes to Table IA:

[1] The method must be specified when results are reported.

[2] A 0.45 µm membrane filter (MF) or other pore size certified by the manufacturer to fully retain organisms to be cultivated and to be free of extractables which could interfere with their growth.

[3] USEPA. 1978. Microbiological Methods for Monitoring the Environment, Water, and Wastes. Environmental Monitoring and Support Laboratory, U.S. Environmental Protection Agency, Cincinnati, Ohio. EPA/600/8–78/017.

[4] APHA. 1998, 1995, 1992. Standard Methods for the Examination of Water and Wastewater. American Public Health Association. 20th, 19th, and 18th Editions. Amer. Publ. Hlth. Assoc., Washington, DC.

[5] USGS. 1989. U.S. Geological Survey Techniques of Water-Resource Investigations, Book 5, Laboratory Analysis, Chapter A4, Methods for Collection and Analysis of Aquatic Biological and Microbiological Samples, U.S. Geological Survey, U.S. Department of Interior, Reston, Virginia.

[6] Because the MF technique usually yields low and variable recovery from chlorinated wastewaters, the Most Probable Number method will be required to resolve any controversies.

[7] USEPA. 1993. Methods for Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms. Fourth Edition. Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, Cincinnati, Ohio. August 1993, EPA/600/4–90/027F.

[8] USEPA. 1994. Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms. Third Edition. Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency USEPA. 1994, Cincinnati, Ohio. (July 1994, EPA/600/4–91/002).

[9] Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms. Second Edition. Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, Cincinnati, Ohio (July 1994, EPA/600/4–91/003). These methods do not apply to marine waters of the Pacific Ocean.

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
1. Acidity, as $CaCO_3$, mg/L:					
Electrometric endpoint or phenolphthalein endpoint.	305.1	2310 B(4a) [18th, 19th, 20th].	D1067–92	I–1020–85	
2. Alkalinity, as CaCO3, mg/L:					
Electrometric or Colorimetric titration to pH 4.5, manual or automatic.	310.1	2320 B [18th, 19th, 20th].	D1067–92	I–1030–85	973.43. [3]
	310.2	.....		I–2030–85	
3. Aluminum—Total, [4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	202.1	3111 D [18th, 19th].		I–3051–85	
AA furnace	202.2	3113 B [18th, 19th].			
Inductively Coupled Plasma/Atomic Emission Spectrometry (ICP/AES) [36].	[5] 200.7	3120 B [18th, 19th, 20th].		I–4471–97 [30]	
Direct Current Plasma (DCP) [36].	.....	.....	D4190–94		Note 34.
Colorimetric (Eriochrome cyanine R).	3500–Al B [20th] and 3500–Al D [18th, 19th]				
4. Ammonia (as N), mg/L:					

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TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Manual, distillation (at pH 9.5) [6] followed by:	350.2	4500–NH_3 B [18th, 19th, 20th].			973.49.[3]
Nesserization	350.2	4500–NH_3 [18th].	D1426–98(A)	I–3520–85	973.49.[3]
Titration	350.2	4500–NH_3C [19th, 20th] and 4500–NH_3 C [18th].			
Electrode	350.3	4500–NH_3 D or E [19th, 20th] and 4500–NH_3 F or G [18th].	D1426–98(B)		
Automated phenate, or	350.1	4500–NH_3 G [19th, 20th] and 4500–NH_2 H [18th].		I–4523–85	
Automated electrode					Note 7.
5. Anitomy—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	204.1	3111 B [18th, 19th].			
AA furnace	204.2	3113 B [18th, 19th].			
ICP/AES [36]	200.7 [5]	3120 B [18th, 19th, 20th].			
6. Arsenic—Total,[4] mg/L:					
Digestion [4] followed by	206.5				
AA gaseous hydride	206.3	3114 B 4.d [18th, 19th].	D2972–97(B)	I–3062–85	
AA furnace	206.2	3113 B [18th, 19th].	D2972–97(C)	I–4063–98 [49]	
ICP/AES [36] or	200.7 [5]	3120 B [18th, 19th, 20th].			
Colorimetric (SDDC)	206.4	3500–As B [20th] and 3500–As C [18th, 19th].	2972–97(A)	I–3060–85	
7. Barium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [14]	208.1	3111 D [18th, 19th].		I–3084–85	
AA furnace	208.2	3113 B [18th, 19th].	4382–95		
ICP/AES [14]	200.7 [5]	3120 B [18th, 19th, 20th].			
DCP [14]					Note 34.
8. Beryllium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	210.1	3111 D [18th, 19th].	D3645–93(88)(A)	I–3095–85	
AA furnace	210.2	3113 B [18th, 19th].	D3645–93(88)(B)		
ICP/AES	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP, or			D4190–94		Note 34.
Colorimetric (aluminon)		3500–Be D [18th, 19th].			
9. Biochemical oxygen demand (BOD_5), mg/L:					
Dissolved Oxygen Depletion.	405.1	5210 B [18th, 19th, 20th].		1–1578–78 [8]	973.44,[3] p. 17.[9]
10. Boron [37]—Total, mg/L:					
Colorimetric (curcumin)	212.3	4500–B B [18th, 19th 20th].		I–3112–85	

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
ICP/AES, or	200.7 [5] 20th]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP			D4190–94		Note 34.
11. Bromide, mg/L:					
Titrimetric	320.1		D1246–95(C)	I–1125–85	p. S44.[10]
12. Cadmium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	213.1	3111 B or C [18th, 19th].	D3557–95 (A or B)	I–3135–85 or I–3136–85.	974.27,[3] p. 37.[9]
AA furnace	213.2	3113 B [18th, 19th].	D3557–95(D)	I–4138–89 [44]	
ICP/AES [36]	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP [36]			D4190–94		Note 34.
Voltametry,[11] or			D3557–95(C)		
Colorimetric (Dithizone)		3550–Cd D [18th, 19th].			
13. Calcium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	215.1	3111 B [18th, 19th].	D511–93(B)	I–3152–85	
ICP/AES	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP, or					Note 34.
Titrimetric (EDTA)	215.2	3500–Ca B [20th] and 3500–Ca D [19th, 20th].	D551–93(A)		
14. Carbonaceous biochemical oxygen demand ($CBOD_5$), mg/L: [12]					
Dissolved Oxygen Depletion with nitrification inhibitor.		521 B [18th, 19th, 20th].			
15. Chemical oxygen demand (COD), mg/L;					
Titrimetric,	410.1	5220 C [18th, 19th, 20th].	D1252–95(A)	I–3560–85	973.46,[3] p. 17.[9]
or	410.2 410.3			I–3562–85	
Spectrophotometric, manual or automatic.	410.4	5220 D [18th, 19th, 20th].	D1252–95(B)	I–3561–85	Notes 13, 14.
16. Chloride, mg/L:					
Titrimetric (silver nitrate) or		4500–Cl B [18th, 19th, 20th].	D512–89(B)	I–1183–85	
(Mercuric nitrate)	325.3	4500–Cl C [18th, 19th, 20th].	D512–89(A)	I–1184–85	973.51.[3]
Colorimetric, manual or				I–1187–85	
Automated (Ferricyanide)	325.1 or 325.2	4500–Cl E [18th, 19th, 20th].		I–2187–85	
17. Chlorine—Total residual, mg/L; Titrimetric:					
Amperometric direct	330.1	4500–Cl D [18th, 19th, 20th].	D1253–86(92)		
Iodometric direct	330.3	4500–Cl B [18th, 19th, 20th].			
Back titration ether endpoint [15] or.	330.2	4500–Cl C [18th, 19th, 20th].			
DPD–FAS	330.4	4500–Cl F [18th, 19th, 20th].			

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TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA[1,3,5]	Standard methods [Edition(s)]	ASTM	USGS[2]	Other
Spectrophotometric, DPD Or Electrode.	330.5	4500–Cl G [18th, 19th, 20th].			Note 16.
18. Chromium VI dissolved, mg/L; 0.45 micron filtration followed by:					
AA chelation-extraction or	218.4	3111 C [18th, 19th].		I–1232–85	
Colorimetric (Diphenylcarbazide).	.....	3500–Cr B [20th] and. 3500–Cr D [18th, 19th].	D1687–92(A)	I–1230–85D	
19. Chromium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration[36]	218.1	3111 B [18th, 19th].	D1687–92(B)	I–3236–85	974.27.[3]
AA chelation-extraction ...	218.3	3111 C [18th, 19th].			
AA furnace	218.2	3113 B [18th, 19th].	D1687–92(C)	I–3233–93[46]	
ICP/AES[36]	200.7[5]	3120 B [18th, 19th, 20th].			
DCP,[36] or	.....	.....	D4190–94		Note 34.
Colorimetric (Diphenylcarbazide).	3500–Cr B [20th and 3500–Cr D [18th, 19th]				
20. Cobalt—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration	219.1	3111 B or C [18th, 19th].	D3558–94(A or B)	I–3239–85	p. 37.[9]
AA furnace	219.2	3113 B [18th, 19th].	D3558–94(C)	I–4243–89[44]	
ICP/AES	200.7[5]	3120 B [18th, 19th, 20th].		I–4471–97[50]	
DCP	.....	.....	D4190–94		Note 34.
21. Color platinum cobalt units or dominant wavelength, hue, luminance purity:					
Colorimetric (ADMI), or (Platinum cobalt), or	110.1	2120 E [18th, 19th, 20th].			Note 18.
Spectrophotometric	110.2	2120 B [18th, 19th, 20th].		I–1250–85	
	110.3	2120 C [18th, 19th, 20th].			
22. Copper—Total,[4] mg/L; Digestion4 followed by:					
AA direct aspiration[36]	220.1	3111 B or C [18th, 19th].	D1688–95(A or B)	I–3270–85 or I–3271–85	974.27[3] p. 37.[9]
AA furnace	220.2	3113 B [18th, 19th].	D1688–95(C)	I–4274–89[44]	
ICP/AES[36]	200.7[5]	3120 B [18th, 19th, 20th].		I–4471–97[44]	
DCP[36] or	.....	.....	D–4190–94		Note 34.
Colorimetric (Neocuproine) or.	.....	3500–Cu B [20th] and 3500 Cu D [18th, 19th].			
(Bicinchoninate)	.....	3500–Cu C [20th] and 3500–As B [18th, 19th].			Note 19.
23. Cyanide—Total, mg/L:					
Manual distillation with $MgCl^{22}$ followed by.	.....	4500–CN C [18th, 19th, 20th].	D2036–98(A)		

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA[1,3,5]	Standard methods [Edition(s)]	ASTM	USGS[2]	Other
Titrimetric, or	.....	4500–CN D [18th, 19th, 20th].			p. 22.[9]
Spectrophotometric, manual or.	[31] 335.2	4500–CN E [18th, 19th, 20th].	D2036–98(A).	I–3300–85	
Automated[20]	[31] 335.3	.....		I–4327–85	
24. Cyanide amenable to chlorination, mg/L:					
Manual distillation with $MgCl_2$ followed by titrimetric or Spectrophotometric.	335.1	4500–CN G [18th, 19th, 20th].	D2036–98(B)		
25. Fluoride—Total, mg/L:					
Manual distillation[6] followed by.	.....	4500–F B [18th, 19th, 20th].			
Electrode, manual or	340.2	4500–F C [18th, 19th, 20].	D1179–93(B)		
Automated	.....	.....		I–4327–85	
Colorimetric (SPADNS) ...	340.1	4500–F D [18th, 19th, 20th].	D1179–93(A)		
Or Automated complexone.	340.3	4500–F E [18th, 19th, 20th].			
26. Gold—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration	231.1	3111 B [18th, 19th].			
AA furnace, or DCP	231.2				
.....	.....	.....			Note 34.
27. Hardness—Total, as $CaCO^{23}$, mg/L					
Automated colorimetric, ..	130.1				
Titrimetric (EDTA), or Ca plus Mg as their carbonates, by inductively coupled plasma or AA direct aspiration. (See Parameters 13 and 33)..	130.2	2340 B or C [18th, 19th, 20th].	D1126–86(92)	I–1338–85	973.528.[3]
28. Hydrogen ion (pH), pH units					
Electrometric measurement, or Automated electrode.	150.1	4500–H+ B [18th, 19th, 20th].	D1293–84 (90)(A or B)	I–1586–85	973.41.[3]
.....	.....	.....		I–2587–85	Note 21.
29. Iridium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration or AA furnace.	235.1	3111 B [18th, 19th]. 235.2.			
30. Iron—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration[36]	236.1	3111 B or C [18th, 19th].	D1068–96(A or B)	I–3381–85	974.27.[3]
AA furnace	236.2	3113 B [18th, 19th].	D1068–96(C) ICP/AES[36]	200.7[5]	I–4471–97[50]
DCP[36] or	.....	.....	D4190–94		Note 34.
Colorimetric (Phenanthroline).	.....	3500–Fe B [20th] and 3500–Fe D [18th, 19th].	D1068–96(D)		Note 22.
31. Kjeldahl Nitrogen—Total, (as N), mg/L:					

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TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Digestion and distillation followed by:	351.3	4500–N_{org} B or C and 4500–NH_3 B [18th, 19th, 20th].	D3590–89(A)		
Titration	351.3		D3590–89(A)		973.48 [3]
Nesslerization	351.3	4500–NH_3 C [18th].	D3590–89(A)		
Electrode	351.3	4500–NH_3 C [19th, 20th] and 4500–NH3 E [18th].			
Automated phenate colorimetric.	351.1	4500–NH_3 D or E [19th, 20th] and 4500–NH_3 F or G [18th].	I–4551–78 [8]		
Semi-automated block digestor colorimetric.	351.2		D3590–89(B)	I–4515–91 [45]	
Manual or block digestor potentiometric.	351.4		D3590–89(A)		
Block Digester, followed by:					
Auto distillation and Titration, or Nesslerization.				Note 40.	
Flow injection gas diffusion.	973.483				Note 41.
32. Lead—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	239.1	3111 B or C [18th, 19th].	D3559–96(A or B)	I–3399–85	974.27.[3]
AA furnace	239.2	3113 B [18th, 19th].	D3559–96(D)	I–4403–89 [44]	
ICP/AES [36]	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–9750	
DCP [36]			D4190–94		Note 34.
Voltametry [11] or			D3559'96(C)		
Colorimetric (Dithizone)		3500–Pb B [20th] and 3500–Pb D [18th, 19th].			
33. Magnesium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	242.1	3111 B [18th, 19th].	D511–93(B)	I–3447–85	974.27.[3]
ICP/AES	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP or					Note 34.
Gravimetric		3500–Mg D [18th, 19th].			
34. Manganese—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	243.1	3111 B [18th, 19th].	D858–95(A or B)	I–3454–85	974.27.[3]
AA furnace	243.2	3113 B [18th, 19th].	D858–95(C)		
ICP/AES [36]	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP,[36] or			D4190–94		Note 34.
Colorimetric (Persulfate), or.	3500–Mn B [20th] and	3500–Mn D [18th, 19th].			920.203.[3]
(Periodate)					Note 23.
35. Mercury—Total,[4] mg/L:					
Cold vapor, manual or	245.1	3112 B [18th, 19th].	D3223–91	I–3462–85	977.22.[3]
Automated	245.2				

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Oxidation, purge and trap, and cold vapor atomic fluorescence spectrometry (ng/L).	[43] 1631				
36. Molybdenum—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	246.1	3111 D [18th, 19th].		I–3490–85	
AA furnace	246.2	3113 B [18th, 19th].		I–3492–96 [47]	
ICP/AES	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP					Note 34.
37. Nickel—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	249.1	3111 B or C [18th, 19th].	D1886–90(A or B)	I–3499–85	
AA furnace	249.2	3113 B [18th, 19th].	D1886–90(C)	I–4503–89 [44]	
ICP/AES [36]	200.7 [5]	3120 B [18th, 19th, 20th].		I–4471–97 [50]	
DCP,[36] or			D4190–94		Note 34.
Colorimetric (heptoxime)		3500–Ni D [17th].			
38. Nitrate (as N), mg/L:					
Colorimetric (Brucine sulfate), or Nitrate-nitrite N minus Nitrite N (See parameters 39 and 40).	352.1				973.50,[3] 419D,[17] p. 28.[9]
39. Nitrate-nitrite (as N), mg/L:					
Cadmium reduction, Manual or.	353.3	4500–NO3_E [18th, 19th, 20th].	D3867–99(B)		
Automated, or	353.2	4500–NO3–F [18th, 19th, 20th].	D3867–99(A)	I–4545–85	
Automated hydrazine	353.1	4500–NO3–H [18th, 19th, 20th].			
40. Nitrite (as N), mg/L; Spectrophotometric:					
Manual or	354.1	4500–NO2–B [18th, 19th, 20th].			Note 25.
Automated (Diazotization)				I–4540–85	
41. Oil and grease—Total recoverable, mg/L:					
Gravimetric (extraction)	413.1	5520B [18th, 19th, 20th] [38].			
Oil and grease and nonpolar material, mg/L:		5520B [18th, 19th, 20th] [39].			
Hexane extractable material (HEM): n-Hexane extraction and gravimetry [42].	1664A				
Silica gel treated HEM (SGT–HEM): Silica gel treatment and gravimetry [42].	1664A				
42. Organic carbon—Total (TOC), mg/L:					
Combustion or oxidation	415.1	5310 B, C, or D [18th, 19th, 20th].	D2579–93 (A or B)		973.47,[3] p. 14.[24]
43. Organic nitrogen (as N), mg/L:					

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TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Total Kjeldahl N (Parameter 31) minus ammonia N (Parameter 4).					
44. Orthophosphate (as P), mg/L; Ascorbic acid method:					
Automated, or	365.1	4500–P F [18th, 19th, 20th].		I–4601–85	973.56.[3]
Manual single reagent	365.2	4500'P E [18th, 19th, 20th].	D515–88(A)		973.55.[3]
Manual two reagent	365.3				
45. Osmium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration, or	252.1	3111 D [18th, 19th].			
AA furnace	252.2				
46. Oxygen, dissolved, mg/L:					
Winkler (Azide modification), or.	360.2	4500–O C [18th, 19th, 20th].	D888–92(A)	I–1575–78[6]	973.45B.[3]
Electrode	360.1	4500–O G [18th, 19th, 20th].	D888–92(B)	I–1576–78[6]	
47. Palladium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration, or	253.1	3111 B [18th, 19th].			p. S27.[10]
AA furnace	253.2				p. S28.[10]
DCP					Note 34.
48. Phenols, mg/L:					
Manual distillation[28]	420.1				Note 27.
Followed by:					
Colorimetric (4AAP) manual, or.	420.1				Note 27.
Automated[19]	420.2				
49. Phosphorus (elemental), mg/L:					
Gas-liquid chromatography.					Note 28.
50. Phosphorus—Total, mg/L:					
Persulfate digestion followed by.	365.2	4500–P B, 5 [18th, 19th, 20th].			973.55.[3]
Manual or	365.2 or 365.3	4500–P E [18th, 19th, 20th].	D515–88(A)		
Automated ascorbic acid reduction.	365.1	4500–P F [18th, 19th, 20th].		I–4600–85	973.56.[3]
Semi-automated block digestor.	365.4		D515–88(B)	I–4610–91[48]	
51. Platinum—Total,[4] mg/L: Digestion[4] followed by:					
AA direct aspiration	255.1	3111 B [18th, 19th].			
AA furnace	255.2				
DCP					Note 34.
52. Potassium—Total,[4] mg/L: Digestion[4] followed by:					
AA direct aspiration	258.1	3111 B [18th, 19th].		I–3630–85	973.53.3.[3]
ICP/AES	200.7[5]	3120 B [18th, 19th, 20th].			

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Flame photometric, or		3500–K B [20th] and 3500–K D [18th, 19th].			
Colorimetric					317 B.[17]
53. Residue—Total, mg/L:					
Gravimetric, 103–105°	160.3	2540 B [18th, 19th, 20th].		I–3750–85	
54. Residue—filterable, mg/L:					
Gravimetric, 180°	160.1	2540 C [18th, 19th, 20th].		I–1750–85	
55. Residue—nonfilterable (TSS), mg/L:					
Gravimetric, 103–105° post washing of residue.	160.2	2540 D [18th, 19th, 20th].		I–3765–85	
56. Residue—settleable, mg/L:					
Volumetric, (Imhoff cone), or gravimetric.	160.5	2540 F [18th, 19th, 20th].			
57. Residue—Volatile, mg/L:					
Gravimetric, 550°	160.4			I–3753–85	
58. Rhodium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration, or	265.1	3111 B [18th, 19th].			
AA furnace	265.2				
59. Ruthenium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration, or	267.1	3111 B [18th, 19th].			
AA furnace	267.2				
60. Selenium—Total,[4] mg/L; Digestion[4] followed by:					
AA furnace	270.2	3113 B [18th, 19th].	D3859–98(B)	I–4668–98[49]	
ICP/AES,[36] or	200.7[5]	3120 B [18th, 19th, 20th].			
AA gaseous hydride		3114 B [18th, 19th].	D3859–98(A)	I–3667–85	
61. Silica[37]—Dissolved, mg/L; 0.45 micron filtration followed by:					
Colorimetric, Manual or	370.1	4500–SiO_2 C [20th] and 4500–SiD. [18th, 19th].	D859–94	I–1700–85	
Automated (Molybdosilicate), or.				I–2700–85	
ICP	200.7[5]	3120 B [18th, 19th, 20th].		I–4471–97[50]	
62. Silver—Total,[4] mg/L: Digestion[4, 29] followed by:					
AA direct aspiration	272.1	3111 B or C [18th, 19th].		I–3720–85	974.27,[3] p. 37.[9]
AA furnace	272.2	3113 B [18th, 19th].		I–4724–89[44]	
ICP/AES	200.7[5]	3120 B [18th, 19th, 20th].		I–4471–97[50]	
DCP					Note 34.
63. Sodium—Total,[4] mg/L; Digestion[4] followed by:					
AA direct aspiration	273.1	3111 B [18th, 19th].		I–3735–85	973.54.[3]
ICP/AES	200.7[5]	3120 B [18th, 19th, 20th].		I–4471–97[50]	
DCP, or					Note 34.

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
Flame photometric		3500 Na B [20th] and 3500 Na D [18th, 19th].			
64. Specific conductance, micromhos/cm at 25° C:					
Wheatstone bridge	120.1	2510 B [18th, 19th, 20th].	D1125–95(A)	I–2781–85	973.40.[3]
65. Sulfate (as SO_4), mg/L:					
Automated colorimetric (barium chloranilate).	375.1				
Gravimetric	375.3	4500–SO_4 $^{-2}$C or D [18th, 19th, 20th].			925.54.[3]
Turbidimetric	375.4		D516–90		426C.[30]
66. Sulfide (as S), mg/L:					
Titrimetric (iodine), or	376.1	4500–S $^{-2}$F [19th, 20th] or 4500–S $^{-2}$ E [18th].		I–3840–85	
Colorimetric (methylene blue).	376.2	4500–S $^{-2}$D.			
67. Sulfite (as SO_3), mg/L:					
Titrimetric (iodine-iodate)	377.1	4500–SO_3 $^{-2}$B [18th, 19th, 20th].			
68. Surfactants, mg/L:					
Colorimetric (methylene blue).	425.1	5540 C [18th, 19th, 20th].	D2330–88		
69. Temperature, °C:					
Thermometric	170.1	2550 B [18th, 19th, 20th].			Note 32.
70. Thallium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	279.1	3111 B [18th, 19th.			
AA furnace	279.2				
ICP/AES	200.7 [5]	3120 B [18th, 19th, 20th].			
71. Tin—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	282.1	3111 B [18th, 19th].		I–3850–78 [6]	
AA furnace, or	282.2	3113 B [18th, 19th].			
ICP/AES	200.7 [5]				
72. Titanium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	283.1	3111 D [18th, 19th].			
AA furnace	283.2				
DCP					Note 34.
73. Turbidity, NTU:					
Nephelometric	180.1	2130 B [18th, 19th, 20th].	D1889–94(A)	I–3860–85	
74. Vanadium—Total,[4] mg/L; Digestion [4] followed by:					
AA direct aspiration	286.1	3111 D [18th, 19th].			
AA furnace	286.2		D3373–93		
ICP/AES	200.7 [5]	3120 B[18th, 19th, 20th].		I–4471–97 [50]	
DCP, or			D4190–94		Note 34.
Colorimetric (Gallic Acid)		3500–V B [20th] and 3500–V D [18th, 19th].			

TABLE 1B.—LIST OF APPROVED INORGANIC TEST PROCEDURES—Continued

Parameter, units and method	Reference (method number or page)				
	EPA [1,3,5]	Standard methods [Edition(s)]	ASTM	USGS [2]	Other
75. Zinc—Total,[4], mg/L; Digestion [4] followed by:					
AA direct aspiration [36]	289.1	3111 B or C [18th, 19th].	D1691–95(A or B)	I–3900–85	974.27,[3] p. 37.[9]
AA furnace	289.2				
ICP/AES [35]	200.7 [5]	3120 B [18th, 19th, 20 [th]].		I–4471–97 [50]	
DCP,[36] or			D4190–94		Note 34.
Colorimetric (Dithizone) or.		3500–Zn E [18th, 19th].			
(Zincon)		3500–Zn B [20th] and 3500–Zn F [18th, 19th].			Note 33.

Table 1B Notes:

[1] "Methods for Chemical Analysis of Water and Wastes," Environmental Protection Agency, Environmental Monitoring Systems Laboratory-Cincinnati (EMSL–CI), EPA–600/4–79–020, Revised March 1983 and 1979 where applicable.

[2] Fishman, M.J., et al. "Methods for Analysis of Inorganic Substances in Water and Fluvial Sediments," U.S. Department of the Interior, Techniques of Water—Resource Investigations of the U.S. Geological Survey, Denver, CO, Revised 1989, unless otherwise stated.

[3] "Official Methods of Analysis of the Association of Official Analytical Chemists," methods manual, 15th ed. (1990).

[4] For the determination of total metals the sample is not filtered before processing. A digestion procedure is required to solubilize suspended material and to destroy possible organic-metal complexes. Two digestion procedures are given in "Methods for Chemical Analysis of Water and Wastes, 1979 and 1983". One (Section 4.1.3), is a vigorous digestion using nitric acid. A less vigorous digestion using nitric and hydrochloric acids (Section 4.1.4) is preferred; however, the analyst should be cautioned that this mild digestion may not suffice for all samples types. Particularly, if a colorimetric procedure is to be employed, it is necessary to ensure that all organo-metallic bonds be broken so that the metal is in a reactive state. In those situations, the vigorous digestion is to be preferred making certain that at no time does the sample go to dryness. Samples containing large amounts of organic materials may also benefit by this vigorous digestion, however, vigorous digestion with concentrated nitric acid will convert antimony and tin to insoluble oxides and render them unavailable for analysis. Use of ICP/AES as well as determinations for certain elements such as antimony, arsenic, the noble metals, mercury, selenium, silver, tin, and titanium require a modified sample digestion procedure and in all cases the method write-up should be consulted for specific instructions and/or cautions.

NOTE TO TABLE 1B NOTE 4: If the digestion procedure for direct aspiration AA included in one of the other approved references is different than the above, the EPA procedure must be used.

Dissolved metals are defined as those constituents which will pass through a 0.45 micron membrane filter. Following filtration of the sample, the referenced procedure for total metals must be followed. Sample digestion of the filtrate for dissolved metals (or digestion of the original sample solution for total metals) may be omitted for AA (direct aspiration or graphite furnace) and ICP analyses, provided the sample solution to be analyzed meets the following criteria:

a. has a low COD (<20)
b. is visibly transparent with a turbidity measurement of 1 NTU or less
c. is colorless with no perceptible odor, and
d. is of one liquid phase and free of particulate or suspended matter following acidification.

[5] The full text of Method 200.7, "Inductively Coupled Plasma Atomic Emission Spectrometric Method for Trace Element Analysis of Water and Wastes," is given at Appendix C of this Part 136.

[6] Manual distillation is not required if comparability data on representative effluent samples are on company file to show that this preliminary distillation step is not necessary: however, manual distillation will be required to resolve any controversies.

[7] Ammonia, Automated Electrode Method, Industrial Method Number 379–75 WE, dated February 19, 1976, Bran & Luebbe (Technicon) Auto Analyzer II, Bran & Luebbe Analyzing Technologies, Inc., Elmsford, N.Y. 10523.

[8] The approved method is that cited in "Methods for Determination of Inorganic Substances in Water and Fluvial Sediments", USGS TWRI, Book 5, Chapter A1 (1979).

[9] American National Standard on Photographic Processing Effluents, Apr. 2, 1975. Available from ANSI, 1430 Broadway, New York, NY 10018.

[10] "Selected Analytical Methods Approved and Cited by the United States Environmental Protection Agency", Supplement to the Fifteenth Edition of Standard Methods for the Examination of Water and Wastewater (1981).

[11] The use of normal and differential pulse voltage ramps to increase sensitivity and resolution is acceptable.

[12] Carbonaceous biochemical oxygen demand ($CBOD_5$) must not be confused with the traditional BOD_5 test method which measures "total BOD". The addition of the nitrification inhibitor is not a procedural option, but must be included to report the $CBOD_5$ parameter. A discharger whose permit requires reporting the traditional BOD_5 may not use a nitrification inhibitor in the procedure for reporting the results. Only when a discharger's permit specifically states $CBOD_5$ is required can the permittee report data using a nitrification inhibitor.

[13] OIC Chemical Oxygen Demand Method, Oceanography International Corporation, 1978, 512 West Loop, P.O. Box 2980, College Station, TX 77840.

[14] Chemical Oxygen Demand, Method 8000, Hach Handbook of Water Analysis, 1979, Hach Chemical Company, P.O. Box 389, Loveland, CO 80537.

[15] The back titration method will be used to resolve controversy.

[16] Orion Research Instruction Manual, Residual Chlorine Electrode Model 97–70, 1977, Orion Research Incorporated, 840 Memorial Drive, Cambridge, MA 02138. The calibration graph for the Orion residual chlorine method must be derived using a reagent blank and three standard solutions, containing 0.2, 1.0, and 5.0 mL 0.00281 N potassium iodate/100 mL solution, respectively.

[17] The approved method is that cited in Standard Methods for the Examination of Water and Wastewater, 14th Edition, 1976.

[18] National Council of the Paper Industry for Air and Stream Improvement, Inc. Technical Bulletin 253, December 1971.

[19] Copper, Biocinchoinate Method, Method 8506, Hach Handbook of Water Analysis, 1979, Hach Chemical Company, P.O. Box 389, Loveland, CO 80537.

[20] After the manual distillation is completed, the autoanalyzer manifolds in EPA Methods 335.3 (cyanide) or 420.2 (phenols) are simplified by connecting the re-sample line directly to the sampler. When using the manifold setup shown in Method 335.3, the buffer 6.2 should be replaced with the buffer 7.6 found in Method 335.2.

[21] Hydrogen ion (pH) Automated Electrode Method, Industrial Method Number 378–75WA, October 1976, Bran & Luebbe (Technicon) Autoanalyzer II. Bran & Luebbe Analyzing Technologies, Inc., Elmsford, NY 10523.

[22] Iron, 1,10-Phenanthroline Method, Method 8008, 1980, Hach Chemical Company, P.O. Box 389, Loveland, CO 80537.

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[23] Manganese, Periodate Oxidation Method, Method 8034, Hach Handbook of Wastewater Analysis, 1979, pages 2–113 and 2–117, Hach Chemical Company, Loveland, CO 80537.

[24] Wershaw, R.L., *et al.*, "Methods for Analysis of Organic Substances in Water," Techniques of Water-Resources Investigation of the U.S. Geological Survey, Book 5, Chapter A3, (1972 Revised 1987) p. 14.

[25] Nitrogen, Nitrite, Method 8507, Hach Chemical Company, P.O. Box 389, Loveland, CO 80537.

[26] Just prior to distillation, adjust the sulfuric-acid-preserved sample to pH 4 with 1 + 9 NaOH.

[27] The approved method is cited in Standard Methods for the Examination of Water and Wastewater, 14th Edition. The colorimetric reaction is conducted at a pH of 10.0±0.2. The approved methods are given on pp 576–81 of the 14th Edition: Method 510A for distillation, Method 510B for the manual colorimetric procedure, or Method 510C for the manual spectrometric procedure.

[28] R.F. Addison and R.G. Ackman, "Direct Determination of Elemental Phosphorus by Gas-Liquid Chromatography," Journal of Chromatography, Vol. 47, No. 3, pp. 421–426, 1970.

[29] Approved methods for the analysis of silver in industrial wastewaters at concentrations of 1 mg/L and above are inadequate where silver exists as an inorganic halide. Silver halides such as the bromide and chloride are relatively insoluble in reagents such as nitric acid but are readily soluble in an aqueous buffer of sodium thiosulfate and sodium hydroxide to pH of 12. Therefore, for levels of silver above 1 mg/L, 20 mL of sample should be diluted to 100 mL by adding 40 mL each of 2 M $Na_2S_2O_3$ and NaOH. Standards should be prepared in the same manner. For levels of silver below 1 mg/L the approved method is satisfactory.

[30] The approved method is that cited in Standard Methods for the Examination of Water and Wastewater, 15th Edition.

[31] EPA Methods 335.2 and 335.3 require the NaOH absorber solution final concentration to be adjusted to 0.25 N before colorimetric determination of total cyanide.

[32] Stevens, H.H., Ficke, J.F., and Smoot, G.F., "Water Temperature—Influential Factors, Field Measurement and Data Presentation," Techniques of Water-Resources Investigations of the U.S. Geological Survey, Book 1, Chapter D1, 1975.

[33] Zinc, Zincon Method, Method 8009, Hach Handbook of Water Analysis, 1979, pages 2–231 and 2–333, Hach Chemical Company, Loveland, CO 80537.

[34] "Direct Current Plasma (DCP) Optical Emission Spectrometric Method for Trace Elemental Analysis of Water and Wastes, Method AES0029," 1986—Revised 1991, Thermo Jarrell Ash Corporation, 27 Forge Parkway, Franklin, MA 02038.

[35] Precision and recovery statements for the atomic absorption direct aspiration and graphite furnace methods, and for the spectrophotometric SDDC method for arsenic are provided in Appendix D of this part titled, "Precision and Recovery Statements for Methods for Measuring Metals".

[36] "Closed Vessel Microwave Digestion of Wastewater Samples for Determination of Metals", CEM Corporation, P.O. Box 200, Matthews, NC 28106–0200, April 16, 1992. Available from the CEM Corporation.

[37] When determining boron and silica, only plastic, PTFE, or quartz laboratory ware may be used from start until completion of analysis.

[38] Only the Trichlorotrifluorethane (1,1,2-trichloro-1,2,2-trifluoroethane; CFC–113) and *n*-hexane extraction solvents are approved.

[39] Nitrogen, Total Kjeldahl, Method PAI–DK01 (Block Digestion, Steam Distillation, Titrimetric Detection), revised 12/22/94, OI Analytical/ALPKEM, PO Box 9010, College Station, TX 77842.

[40] Nitrogen, Total Kjeldahl, Method PAI–DK02 (Block Digestion, Steam Distillation, Colorimetric Detection), revised 12/22/94, OI Analytical/ALPKEM, PO Box 9010, College Station, TX 77842.

[41] Nitrogen, Total Kjeldahl, Method PAI–DK03 (Block Digestion, Automated FIA Gas Diffusion), revised 12/22/94, OI Analytical/ALPKEM, PO Box 9010, College Station, TX 77842.

[42] Method 1664, Revision A "n-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated n-Hexane Extractable Material (SGT–HEM; Non-polar Material) by Extraction and Gravimetry" EPA–821–R–98–002, February 1999. Available at NTIS, PB–121949, U.S. Department of Commerce, 5285 Port Royal, Springfield, Virginia 22161.

[43] The application of clean techniques described in EPA's draft Method 1669: Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels (EPA–821–R–96–011) are recommended to preclude contamination at low-level, trace metal determinations.

[44] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediment", Open File Report (OFR) 93–125.

[45] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Ammonia Plus Organic Nitrogen by a Kjeldahl Digestion Method", Open File Report (OFR) 98–xxx.

[46] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Chromium in Water by Graphite Furnace Atomic Absorption Spectrophotometry", Open File Report (OFR) 93–449.

[47] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Molybdenum by Graphite Furnace Atomic Absorption Spectrophotometry", Open File Report (OFR) 97–198.

[48] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Total Phosphorus by Kjeldahl Digestion Method and an Automated Colorimetric Finish That Includes Dialysis" Open File Report (OFR) 92–146.

[49] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Arsenic and Selenium in Water and Sediment by Graphite Furnace-Atomic Absorption Spectrometry" Open File Report (OFR) 98–639.

[50] "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Elements in Whole-water Digests Using Inductively Coupled Plasma-Optical Emission Spectrometry and Inductively Coupled Plasma-Mass Spectrometry", Open File Report (OFR) 98–165.

TABLE 1C.—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS

Parameter[1]	EPA method number[2,7]			Other approved methods		
	GC	GC/MS	HPLC	Standard methods [Edition(s)]	ASTM	Other
1. Acenaphthene	610	625, 1625	610	6440 B, 6410 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
2. Acenaphthylene	610	625, 1625	610	6440 B, 6410 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
3. Acrolein	603	604, 1624[4]				
4. Acrylonitrile	603	624, 1624[4]	610			
5. Anthracene	610	625, 1625	610	6410 B 6440 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.
6. Benzene	602	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6220 B [18th, 19th].		
7. Benzidine		625, 1625[5]	605			Note 3, p.1.
8. Benzo(a)anthracene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
9. Benzo(a)pyrene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
10. Benzo(b)fluoranthene	610	625, 1625	610	6410 B 6440 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.
11. Benzo(g, h, i)perylene	610	625, 1625	610	6410 B 6440 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.
12. Benzo(k)fluoranthene	610	625, 1625	610	6410 B 6440 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.

TABLE 1C.—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS—Continued

Parameter[1]	EPA method number[2,7]			Other approved methods		
	GC	GC/MS	HPLC	Standard methods [Edition(s)]	ASTM	Other
13. Benzyl chloride						Note 3, p. 130: Note 6, p. S102.
14. Benzyl butyl phthalate	606	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
15. Bis(2-chloroethoxy)methane.	611	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
16. Bis(2-chloroethyl)ether	611	625, 1625		6410 3 [18th, 19th, 20th]		Note 9, p. 27.
17. Bis(2-ethylhexyl)phthalate.	606	625, 1625		6200 C [20th] and 6230 B [18th, 19th], 6410 B [18th, 19th, 20th].		Note 9, p. 27
18. Bromodichloromethane	601	624, 1624		6200 C [20th] and 6230 B [18th, 19th], 6200 B [20th] and 6210 B [18th, 19th].		
19. Bromoform	601	624, 1624		6200 C [20th] and 6230 B [18th, 19th], 6200 B [20th] and 6210 B [18th, 19th].		
20. Bromomethane	601	624, 1624		6200 C [20th] and 6230 B [18th, 19th], 6200 B [20th] and 6210 B [18th, 19th].		
21. 4-Bromophenylphenyl ether.	611	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
22. Carbon tetrachloride	601	624, 1624		6200 C [20th] and 6230 B [18th, 19th], 6410 B [18th, 19th, 20th].		Note 3, p. 130.
23. 4-Chloro-3-methyl-phenol.	604	625, 1625		6410 B, 6420 B [18th, 19th, 20th].		Note 9, p. 27.
24. Chlorobenzene	601, 602	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6220 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		Note 3, p. 130.
25. Chloroethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th].		
26. 2-Chloroethylvinyl ether	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th].		
27. Chloroform	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th].		Note 3, p. 130.
28. Chloromethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th].		
29. 2-Chloronaphthalene	612	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
30. 2-Chlorophenol	604	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
31. 4-Chlorophenylphenl ether.	611	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
32. Chrysene	610	625, 1625	610	6410 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.
33. Dibenzo(a,h)anthracene.	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
34. Dibromochloromethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th].		
35. 1,2-Dichlorobenzene	601, 602, 612	624, 625, 1625		6200 B [20th] and 6220 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th], 6410 B [18th, 19th, 20th].		Note 9, p. 27.
36. 1,3-Dichlorobenzene	601, 602, 612	624,625, 1625		6200 B [20th] and 6220 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th], 6410 B [18th, 19th, 20th].		Note 9, p. 27.
37. 1,4-Dichlorobenzene	601, 602, 612	624, 625, 1625		6200 B [20th] and 6220 B [18th, 19th], 6200 C [20th] and 6230 B [18th 19th], 6410 B [18th, 19th, 20th].		Note 9, p. 27.
38. 3,3-Dichlorobenzidine		625, 1625	605	6410 B [18th, 19th, 20th]		
39. Dichlorodifuoromethane	601			6200 B [20th] and 6230 B [18th, 19th].		
40. 1,1-Dichloroethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th].		

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TABLE 1C.—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS—Continued

Parameter[1]	EPA method number[2,7]			Other approved methods		
	GC	GC/MS	HPLC	Standard methods [Edition(s)]	ASTM	Other
41. 1,2-Dichloroethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
42. 1,1-Dichloroethene	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
43. trans 1,2-Dichloroethene.	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
44. 2,4-Dichlorophenol	604	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
45. 1,2-Dichloropropane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
46. cis-1,3-Dichloropropene	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
47. trans-1,3-Dichloropropene.	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
48. Diethyl phthalate	606	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
49. 2,4-Dimethylphenol	604	625, 1625		6410 B, 6420 B [18th, 19th, 20th].		Note 9, p. 27.
50. Dimethyl phthalate	606	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
51. Di-n-butyl phthalate	606	625, 1625		6410 B [18th, phthalate 19th, 20th].		Note 9, p. 27.
52 Di-n-octyl phthalate	606	625, 1625		6410 B [18th, phthalate 19th, 20th].		Note 9, p. 27.
53. 2,3-Dinitrophenol	604	625, 1625		6410 B, 6420 B [18th, 19th, 20th].		
54. 2,4-Dinitrotoluene	609	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
55. 2,6-Dinitrotoluene	609	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
56. Epichlorohydrin						Note 3, p. 130; Note 6, p. S102.
57. Ethylbenzene	602	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6220 B [18th, 19th].		
58. Fluoranthene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
59. Fluorene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
60. 1,2,3,4,6,7,8-Heptachlorodibenzofuran.		1613				
61. 1,2,3,4,7,8,9-Heptachlorodibenzofuran.		1613				
62. 1,2,3,4,6,7,8-Heptachlorodibenzo-*p*-dioxin.		1613				
63. Hexachlorobenzene	612	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
64. Hexachlorobutadiene	612	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
65. Hexachlorocyclopentadiene.	612	625, 1625B[5]		6410 B [18th, 19th, 20th]		Note 9, p. 27.
66. 1,2,3,4,7,8-Hexachlorodibenzofuran.		1613				
67. 1,2,3,6,7,8-Hexachlorodibenzofuran.		1613				
68. 1,2,3,7,8,9-Hexachlorodibenzofuran.		1613				
69. 2,3,4,6,7,8-Hexachlorodibenzofuran.		1613				
70. 1,2,3,4,7,8-Hexachlorodibenzo-*p*-dioxin.		1613				
71. 1,2,3,6,7,8-Hexachlorodibenzo-*p*-dioxin.		1613				
72. 1,2,3,7,8,9-Hexachlorodibenzo-*p*-dioxin.		1613				
73. Hexachloroethane	616	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.

TABLE 1C.—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS—Continued

Parameter[1]	EPA method number[2,7]			Other approved methods		
	GC	GC/MS	HPLC	Standard methods [Edition(s)]	ASTM	Other
74. Ideno(1,2,3-cd)pyrene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
75. Isophorone	609	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
76. Methylene chloride	601	624, 1624		6200 C [18th, 19th, 20th]		Note 3, p. 130.
77. 2-Methyl-4,6-dinitrophenol.	604	625, 1625		6420 B, 6410 B [18th, 19th, 20th].		Note 9, p. 27.
78. Naphthalene	610	625, 1625	610	6440 B, 6410 B [18th, 19th, 20th].		Note 9, p. 27.
79. Nitrobenzene	609	625, 1625		6410 B [18th, 19th, 20th]	D4657–92	Note 9, p. 27.
80. 2-Nitrophenol	604	625, 1625		6410 B, 6420 B [18th, 19th, 20th].		Note 9, p. 27.
81. 4-Nitrophenol	604	625, 1625		6410 B, 6420 B [18th, 19th, 20th].		Note 9, p. 27.
82. N-Nitrosodimethylamine.	607	625, 1625		6410 B [18th, 19th, 20th]		Note 9, p. 27.
83. N-Nitrosodi-n-propylamine.	607	625, 1625[5]		6410 B [18th, 19th, 20th]		Note 9, p. 27.
84. N-Nitrosodiphenylamine.	607	625, 1625[5]		6410 B [18th, 19th, 20th]		Note 9, p. 27.
85. Octachlorodibenzofuran		1613				
86. Octachlorodibenzo-*p*-dioxin.		1613				
87. 2,2-Oxybis(1-chloropropane).	611	625, 1625		6410 B [18th, 19th, 20th].		
88. PCB–1016	608	625		6410 B [18th, 19th, 20th]		Note 3, p. 43.
89. PCB–1221	608	625		6410 B [18th, 19th, 20th]		Note 3, p. 43.
90. PCB–1232	608	625		6410 B [18th, 19th, 20th]		Note 3, p. 43.
91. PCB–1242	608	625		6410 B [18th, 19th, 20th]		Note 3, p. 43.
92. PCB–1248	608	625				
93. PCB–1254	608	625		6410 B [18th, 19th, 20th]		Note 3, p. 43.
94. PCB–1260	608	625		6410 B, 6630 B [18th, 19th, 20th].		Note 3, p. 43.
95. 1,2,3,7,8-Pentachlorodibenzofuran.		1613				
96. 2,3,4,7,8-Pentachlorodibenzofuran.		1613				
97. 1,2,3,7,8,-Pentachlorodibenzo-*p*-dioxin.		1613				
98. Pentachlorophenol	604	625, 1625		6410 B, 6630 B [18th, 19th, 20th].		Note 3, p. 140; Note 9, p. 27.
99. Phenanthrene	610	625, 1625	610	6410 B, 6440 B [18th, 19th, 20th].	D4657–92	Note 9, p. 27.
100. Phenol	604	625, 1625		6420 B, 6410 B [18th, 19th, 20th].		Note 9, p. 27.
101. Pyrene	610	625, 1625	610	6440 B, 6410 B [18th, 19th, 20th].	D4675–92	Note 9, p. 27.
102. 2,3,7,8-Tetrachlorodibenzofuran.		1613				
103. 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin.		613, 1613[5]				
104. 1,1,2,2-Tetrachlooethane.	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		Note 3, p. 130.
105. Tetrachloroethene	601	624, 1624		6200 C [20th] and 6230 B [18th, 19th], 6410 B [18th, 19th, 20th].		Note 3, p. 130.
106. Toluene	602	624. 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6220 B [18th, 19th].		
107. 1,2,4-Trichlorobenzene.	612	625, 1625		6410 B [18th, 19th, 20th]		Note 3, p. 130; Note 9, p. 27.
108. 1,1,1-Trichloroethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
109. 1,1,2-Trichloroethane	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		Note 3, p. 130.

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TABLE 1C.—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS—Continued

Parameter[1]	EPA method number[2,7]			Other approved methods		
	GC	GC/MS	HPLC	Standard methods [Edition(s)]	ASTM	Other
110. Trichloroethene	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
111. Trichlorofluoromethane	601	624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		
112. 2,4,6-Trichlorophenol	604	625, 1625		6420 B, 6410 B [18th, 19th, 20th].		Note 9, p. 27.
113. Vinyl chloride	601	624, 1624		6200 B [20th] and 6210 B [18th, 19th], 6200 C [20th] and 6230 B [18th, 19th].		

Table IC notes:
[1] All parameters are expressed in micrograms per liter (µg/L) except for Method 1613 in which the parameters are expressed in picograms per liter (pg/L).
[2] The full text of Methods 601–613, 624, 625, 1624, and 1625, are given at Appendix A, "Test Procedures for Analysis of Organic Pollutants," of this Part 136. The full text of Method 1613 is incorporated by reference into this Part 136 and is available from the National Technical Information Services as stock number PB95–104774. The standardized test procedure to be used to determine the method detection limit (MDL) for these test procedures is given at Appendix B, "Definition and Procedure for the Determination of the Method Detection Limit," of this Part 136.
[3] "Methods for Benzidine: Chlorinated Organic Compounds, Pentachlorophenol and Pesticides in Water and Wastewater," U.S. Environmental Protection Agency, September, 1978.
[4] Method 624 may be extended to screen samples for Acrolein and Acrylonitrile. However, when they are known to be present, the preferred method for these two compounds is Method 603 or Method 1624.
[5] Method 625 may be extended to include benzidine, hexachlorocyclopentadiene, N-nitrosodimethylamine, and N-nitrosodiphenylamine. However, when they are known to be present, Methods 605, 607, and 612, or Method 1625, are preferred methods for these compounds.
[5a] 625, Screening only.
[6] "Selected Analytical Methods Approved and Cited by the United States Environmental Protection Agency," Supplement to the Fifteenth Edition of Standard Methods for the Examination of Water and Wastewater (1981).
[7] Each Analyst must make an initial, one-time demonstration of their ability to generate acceptable precision and accuracy with Methods 601–603, 624, 625, 1624, and 1625 (See Appendix A of this Part 136) in accordance with procedures each in Section 8.2 of each of these Methods. Additionally, each laboratory, on an on-going basis must spike and analyze 10% (5% for Methods 624 and 625 and 100% for methods 1624 and 1625) of all samples to monitor and evaluate laboratory data quality in accordance with Sections 8.3 and 8.4 of these Methods. When the recovery of any parameter falls outside the warning limits, the analytical results for that parameter in the unspiked sample are suspect and cannot be reported to demonstrate regulatory compliance.
Note: These warning limits are promulgated as an "interim final action with a request for comments."
[8] "Organochlorine Pesticides and PCBs in Wastewater Using Empore TM Disk" 3M Corporation Revised 10/28/94.
[9] USGS Method O–3116–97 from "Methods of Analysis by U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediments" U.S. Geological Survey, Open File Report 93–125.

TABLE 1D.—LIST OF APPROVED TEST PROCEDURES FOR PESTICIDES[1]

Parameter	Method	EPA[2,7]	Standard methods 18th, 19th, 20th Ed.	ASTM	Other
1. Aldrin	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; note 8.
	GC/MS	625	6410 B		
2. Ametryn	GC				Note 3, p. 83; Note 6, p S68.
3. Aminocarb	TLC				Note 3, p. 94; Note 6, p. S16.
4. Atraton	GC				Note 3, p. 83; Note 6, p. S68.
5. Atrazine	GC				Note 3, p. 83; Note 6, p. S68; Note 9.
6. Azinphos methyl	GC				Note 3, p. 25; Note 6, p. S51.
7. Barban	TLC				Note 3, p. 104; Note 6, p. S84.
8. α-BHC	GC	608	6630 B & C	3086–90	Note 3, p. 7; Note 8.
	GC/MS	625[5]	6410 B		
9. β-BHC	GC	608	6630 C	D3086–90	Note 8.
	GC/MS	625[5]	6410 B		
10. δ-BHC	GC	608	6630 C	D3086–90	Note 8.
	GC/MS	625[5]	6410 B		
11. δ-BHC (Lindane)	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410 B		
12. Captan	GC		6630 B	D3086–90	Note 3, p. 7.
13. Carbaryl	TLC				Note 3, p. 94, Note 6, p. S80.
14. Carbophenothion	GC				Note 4, p. 27; Note 6, p. S73.
15. Chlordane	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410 B		
16. Chloropropham	TLC				Note 3, p. 104; Note 6, p. S64.
17. 2,4-D	GC		6640 B		Note 3, p. 115; Note 4, p. 40.
18. 4,4'-DDD	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410 B		
19. 4,4'-DDE	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410 B		
20. 4,4'-DDT	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.

TABLE 1D.—LIST OF APPROVED TEST PROCEDURES FOR PESTICIDES[1]—Continued

Parameter	Method	EPA[2,7]	Standard methods 18th, 19th, 20th Ed.	ASTM	Other
21. Demeton-O	GC/MS	625	6410 B		
22. Demeton-S	GC				Note 3, p. 25; Note 6, p. S51.
23. Diazinon	GC				Note 3, p. 25; Note 6, p. S51.
24. Dicamba	GC				Note 3, p. 25; Note 4, p. 27; Note 6, p. S51.
25. Dichlofenthion	GC				Note 3, p. 115.
26. Dichloran	GC				Note 4, p. 27; Note 6, p. S73.
27. Dicofol	GC		6630 B & C		Note 3, p. 7.
28. Dieldrin	GC	608	6630 B & C	D3086–90	
	GC/MS	625	6410 B		Note 3, p. 7; Note 4, p. 27; Note 8.
29. Dioxathion	GC				Note 4, p. 27; Note 6, p. S73.
30. Disulfoton	GC				Note 3, p. 25; Note 6 p. S51.
31. Diuron	TLC				Note 3, p. 104; Note 6, p. S84.
32. Endosulfan I	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625[5]	6410 B		
33. Endosulfan II	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 8.
	GC/MS	625[5]	6410 B		
34. Endosulfan Sulfate	GC	608	6630 C		Note 8.
	GC/MS	625	6410 B		
35. Endrin	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625[5]	6410 B		
36. Endrin aldehyde	GC	608			Note 8.
	GC/MS	625			
37. Ethion	GC				Note 4, p. 27; Note 6, p. S73.
38. Fenuron	TLC				Note 3, p. 104; Note 6, p. S64.
39. Fenuron-TCA	TLC				Note 3, p. 104; Note 6, p. S64.
40. Heptachlor	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410 B		
41. Heptachlor epoxide	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 6, p. S73; Note 8.
	GC/MS	625	6410 B		
42. Isodrin	GC				Note 4, p. 27; Note 6, p. S73.
43. Linuron	GC				Note 3, p. 104; Note 6, p. S64.
44. Malathion	GC		6630 C		Note 3, p. 25; Note 4, p. 27; Note 6, p. S51.
45. Methiocarb	TLC				Note 3, p. 94; Note 6, p. S60.
46. Methoxychlor	GC		6630 B &C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
47. Mexacarbate	TLC				Note 3, p. 94; Note 6, p.S60.
48. Mirex	GC		6630 B & C		Note 3, p. 7; Note 4, p. 27.
49. Monuron	TLC				Note 3, p. 104; Note 6, p. S64.
50. Monuron	TLC				Note 3, p. 104; Note 6, p. S64.
51. Nuburon	TLC				Note 3, p. 104; Note 6, p. S64.
52. Parathion methyl	GC		6630 C		Note 3, p. 25; Note 4, p. 27.
53. Parathion ethyl	GC		6630 C		Note 3, p. 25; Note 4, p. 27.
54. PCNB	GC		6630 B & C		Note 3, p. 7.
55. Perthane	GC			D3086–90	Note 4, p. 27.
56. Prometron	GC				Note 3, p. 83; Note 6, p. S68; Note 9.
57. Prometryn	GC				Note 3, p. 83; Note 6, p. S68; Note 9.
58. Propazine	GC				Note 3, p. 83; Note 6, p. S68; Note 9.
59. Propham	TLC				Note 3, p. 104; Note 6, p. S64.
60. Propoxur	TLC				Note 3, p. 94; Note 6, p. S60.
61. Secbumeton	TLC				Note 3, p. 83; Note 6, p. S68.
62. Siduron	TLC				Note 3, p. 104; Note 6, p. S64.
63. Simazine	GC				Note 3, p. 83; Note 6, p. S68; Note 9.
64. Strobane	GC		6630 B & C		Note 3, p. 7.
65. Swep	TLC				Note 3, p. 104; Note 6, p. S64.
66. 2,4,5-T	GC		6640 B		Note 3, p. 115; Note 4, p. 40.
67. 2,4,5-TP (Silvex)	GC		6640 B		Note 3, p. 115; Note 4, p. 40.
68. Terbuthylazine	GC				Note 3, p. 83; Note 6, p. S68.
69. Toxaphene	GC	608	6630 B & C	D3086–90	Note 3, p. 7; Note 4, p. 27; Note 8.
	GC/MS	625	6410B		
70. Trifluralin	GC		6630 B		Note 3, p. 7; Note 9.

Table ID notes:
[1] Pesticides are listed in this table by common name for the convenience of the reader. Additional pesticides may be found under Table 1C, where entries are listed by chemical name.
[2] The full text of Methods 608 and 625 are given at Appendix A. "Test Procedures for Analysis of Organic Pollutants," of this Part 136. The standardized test procedure to be used to determine the method detection limit (MDL) for these test procedures is given at Appendix B, "Definition and Procedure for the Determination of the Method Detection Limit," of this Part 136.
[3] "Methods for Benzidine, Chlorinated Organic Compounds, Pentachlorophenol and Pesticides in Water and Wastewater," U.S. Environmental Protection Agency, September 1978. This EPA publication includes thin-layer chromatography (TLC) methods.
[4] "Methods for Analysis of Organic Substances in Water and Fluvial Sediments," Techniques of Water-Resources Investigations of the U.S. Geological Survey, Book 5, Chapter A3 (1987).

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[5] The method may be extended to include α-BHC, ι-BHC, endosulfan I, endosulfan II, and endrin. However, when they are known to exist, Method 608 is the preferred method.

[6] "Selected Analytical Methods Approved and Cited by the United States Environmental Protection Agency." Supplement to the Fifteenth Edition of Standard Methods for the Examination of Water and Wastewater (1981).

[7] Each analyst must make an initial, one-time, demonstration of their ability to generate acceptable precision and accuracy with Methods 608 and 625 (See Appendix A of this Part 136) in accordance with procedures given in Section 8.2 of each of these methods. Additionally, each laboratory, on an on-going basis, must spike and analyze 10% of all samples analyzed with Method 608 or 5% of all samples analyzed with Method 625 to monitor and evaluate laboratory data quality in accordance with Sections 8.3 and 8.4 of these methods. When the recovery of any parameter falls outside the warning limits, the analytical results for that parameter in the unspiked sample are suspect and cannot be reported to demonstrate regulatory compliance. These quality control requirements also apply to the Standard Methods, ASTM Methods, and other Methods cited.

Note: These warning limits are promulgated as an "Interim final action with a request for comments."

[8] "Organochlorine Pesticides and PCBs in Wastewater Using Empore™ Disk", 3M Corporation, Revised 10/28/94.

[9] USGS Method O–3106–93 from "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Triazine and Other Nitrogen-containing Compounds by Gas Chromatography with Nitrogen Phosphorus Detectors' U.S.Geological Survey Open File Report 94–37

TABLE 1E.—LIST OF APPROVED RADIOLOGIC TEST PROCEDURES

Parameter and units	Method	Reference (method number or page)			
		EPA [1]	Standard methods 18th, 19th, 20th Ed.	ASTM	USGS [2]
1. Alpha-Total, pCi per liter	Proportional or scintillation counter.	900	7110 B	D1943–90.	pp. 75 and 78.[3]
2. Alpha-Counting error, pCi per liter.	Proportional or scintillation counter.	Appendix B	7110 B	D1943–90	p. 79.
3. Beta-Total, pCi per liter	Proportional counter	900.0	7110 B	D1890–90	pp. 75 and 78.[3]
4. Beta-Counting error, pCi	Proportional counter	Appendix B	7110 B	D1890–90	p. 79.
5. (a) Radium Total pCi per liter.	Proportional counter	903.0	7500Ra B	D2460–90	
(b) Ra, pCi per liter	Scintillation counter	903.1	7500Ra C	D3454–91	p. 81.

Table 1E notes:

[1] Prescribed Procedures for Measurement of Radioactivity in Drinking Water, EPA–600/4–80–032 (1980), U.S. Environmental Protection Agency, August 1980.

[2] Fishman, M.J. and Brown, Eugene, "Selected Methods of the U.S. Geological Survey of Analysis of Wastewaters," U.S. Geological Survey, Open-File Report 76–177 (1976).

[3] The method found on p. 75 measures only the dissolved portion while the method on p. 78 measures only the suspended portion. Therefore, the two results must be added to obtain the "total".

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(b) * * *

References, Sources, Costs, and Table Citations

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(6) American Public Health Association. 1992, 1995, and 1998. Standard Methods for the Examination of Water and Wastewater. 18th, 19th, and 20th Edition (respectively). Amer. Publ. Hlth. Assoc., 1015 15th Street NW., Washington, DC 20005. Table IA, Note 4. Tables IB, IC, ID, IE.

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(10) Annual Book of ASTM Standards, Water, and Environmental Technology, Section 11, Volumes 11.01 and 11.02, 1994 and 1999 in 40 CFR 136.3, Tables IB, IC, ID, and IE.

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(42) USEPA, January 1999 Errata for the Effluent and Receiving Water Testing Manuals: Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms; Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Marine and Estuarine Organisms. U.S. Environmental Protection Agency, Office of Research and Development, Duluth, MN. EPA–600/R–98–182.

(43) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediment", Open File Report (OFR) 93–125. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 44; Table IC, Note 9.

(44) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Ammonium Plus Organic Nitrogen by a Kjeldahl Digestion Method and an Automated Photmetric Finish that Includes Digest Cleanup by Gas Diffusion", Open File Report (OFR) 00–170. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 45.

(45) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Chromium in Water by Graphite Furnace Atomic Absorption Spectrometry", Open File Report (OFR) 93–449. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 46.

(46) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Molybdenum by Graphite Furnace Atomic Absorption Spectrophotometry", Open File Report (OFR) 97–198. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 47.

(47) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Total Phosphorus by Kjeldahl Digestion Method and an Automated Colorimetric Finish That Includes Dialysis" Open File Report (OFR) 92–146. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 48.

(48) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Arsenic and Selenium in Water and Sediments by Graphite Furnace-Atomic Absorption Spectrometry" Open File Report (OFR) 98–639. Table IB, Note 49.

(49) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Elements in Whole-water Digests Using Inductively Coupled Plasma-Optical Emission Spectrometry and Inductively Coupled Plasma-Mass Spectrometry", Open File Report (OFR) 98–165. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table IB, Note 50.

(50) "Methods of Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Triazine and Other Nitrogen-containing Compounds by Gas Chromatography with Nitrogen Phosphorus Detectors" U.S.Geological Survey Open File Report 94–37. Available from: U.S. Geological Survey, Denver Federal Center, Box 25425, Denver, CO 80225. Table ID, Note 9.

(c) * * *

(d) * * *

(e) * * *

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for Part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

2. Section 141.21 is amended by revising footnote 1 to the table in paragraph (f)(3) to read as follows:

§ 141.21 Coliform sampling.

* * * * *

(f) * * *

(3) * * *

[1] Standard Methods for the Examination of Water and Wastewater, 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005. The cited methods published in any of these three editions may be used.

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3. Section 141.23 is amended by revising the table to read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

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(k) * * *

(l) * * *

Contaminant	Methodology [1,3]	EPA	ASTM [3]	SM [4] (18th, 19th ed.)	SM [4] (20th, ed.)	Other
1. Alkalinity	Titrimetric		D1067–92B	2320 B	2320 B	
	Electrometric titration					I–1030–85 [5]
2. Antimony	Inductively Coupled Plasma (ICP)-Mass.	200.8 [2]				
	Spectrometry					
	Hydride-Atomic Absorption		D3697–92			
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace			3113 B		
3. Arsenic [4]	Inductively Coupled Plasma	200.7 [2]		3120 B	3120 B	
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace		D2972–97C	3113 B		
	Hydride Atomic Absorption		D2972–97B	3114 B		
4. Asbestos	Transmission Electron Microscopy.	100.1 [9]				
	Transmission Electron Microscopy.	100.2 [10]				
5. Barium	Inductively Coupled Plasma	200.7 [2]		3120 B	3120B	
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Direct			3111 D		
	Atomic Absorption; Furnace			3113 B		
6. Berylium	Inductively Coupled Plasma	200.7 [2]		3120 B	3120B	
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace		D3645–97B	3113 B		
7. Cadmium	Inductively Coupled Plasma	200.7 [2]				
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace			3113 B		
8. Calcium	EDTA titrimetric		D511–93A	3500–Ca D	3500–Ca	
	Atomic Absorption; Direct Aspiration.		D511–93B	3111 B		
	Inductively Coupled Plasma	200.7 [2]		3120 B	3120 B	
9. Chromium	Inductively Coupled	200.7 [2]		3120 B	3120 B	
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace			3113 B		
10. Copper	Atomic Absorption; Furnace		D1688–95C	3113 B		
	Atomic Absorption; Direct Aspiration.		D1688–95A	3111 B		
	Inductively Coupled Plasma	200.7 [2]		3120 B	3120 B	
	ICP–Mass spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
11. Conductance	Conductivity		D1125–95A	2510 B	2510 B	
12. Cyanide	Manual Distillation followed by		D2036–98A	4500–CN⁻ C	4500–CN⁻ C	
	Spectrophotometric, Amenable		D2036–98B	4500–CN⁻ G	4500–CN⁻ G	
	Spectrophotometric Manual		D2036–98A	4500–CN⁻ E	4500–CN⁻ E	I–3300–85 [5]
	Spectrophotometric Semi-automated.	335.4 [6]				
Selective Electrode		4500–CN– F	D4500–CN- F			
13. Fluoride	Ion Chromatography	300.0 [6]	D4327–97	4110 B	4110 B	
	Manual Distill.; Color. SPADNS.			4500–F⁻ B,D	4500–F⁻ B,D	
	Manual Electrode		D1179–93B	4500–F⁻ C	4500–F⁻ C	
	Automated Electrode					380–75WE [11]
	Automated Alizarin			4500–F⁻ E	4500–F⁻	129–71W [11]
14. Lead	Atomic Absorption; Furnace		D3559–96D	3113 B		

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Contaminant	Methodology [1,3]	EPA	ASTM [3]	SM [4] (18th, 19th ed.)	SM [4] (20th, ed.)	Other
	ICP-Mass spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Differential Pulse Anodic Stripping Voltammetry.					Method 1001 [15]
15. Magnesium	Atomic Absorption		D511–93 B	3111 B		
	ICP	200.7 [2]		3120 B	3120 B	
	Complexation Titrimetric Methods.		D511–93 A	3500–Mg E	3500–Mg B	
16. Mercury	Manual, Cold Vapor	245.1 [2]	D3223–97	3112 B		
	Automated, Cold Vapor	245.2 [1]				
	ICP-Mass Spectrometry	200.8 [2]				
17. Nickel	Inductively Coupled Plasma	200.7 [2]		3120 B	3120 B	
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Direct			3111 B		
	Atomic Absorption; Furnace			3113 B		
18. Nitrate	Ion Chromatography	300.0 [6]	D4327–97	4110 B	4110 B	B–1011 [8]
	Automated Cadmium Reduction.	353.2 [6]	D3867–90A	4500–NO_3– F	4500–NO_3– F	
	Ion Selective Electrode			4500–NO_3– D	4500–NO_3– D	601 [7]
	Manual Cadmium Reduction		D3867–90B	4500–NO_3– E	4500–NO_3– E	
19. Nitrite	Ion Chromatography	300.0 [6]	D4327–97	4110 B	4110 B	B–1011 [8]
	Automated Cadmium Reduction.	353.2 [6]	D3867–90A	4500–NO_3– F	4500– NO_3– F	
	Manual Cadmium Reduction		D3867–90B	4500–NO_3– E	4500–NO_3– E	
	Spectrophotometric			4500–NO_2– B	4500–NO_2– B	
20. Ortho-phosphate [12].	Colorimetric, Automated, Ascorbic Acid.	365.1 [6]		4500–P F	4500–P F	
	Colorimetric, ascorbic acid, single reagent.		D515–88A	4500–P E	4500–P E	
	Colorimetric Phosphomolybdate.					[5] I–1601–85
	Automated-segmented Flow					[5] I–2601–90
	Automated Discrete					[5] I–2598–85
	Ion Chromatography	300.0 [6]	D4327–97	4110 B	4110 B	
21. pH	Electrometric	150.1 [1]	D1293–95	4500–H^+ B	4500–H^+ B	
		150.2 [1]				
22. Selenium	Hydride-Atomic Absorption		D3859–98A	3114 B		
	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				
	Atomic Absorption; Furnace		D3859–98B	3113 B		
23. Silica	Colorimetric, Molybdate Blue;					[5] I–1700–85
	Automated-segmented Flow					[5] I–2700–85
	Colorimetric		D859–94			
	Molybdosilicate			4500–Si D	4500–SiO_2 C	
	Heteropoly blue			4500–Si E	4500–SiO_2 D	
	Automated for Molybdate-reactive Silica.			4500–Si F	4500–SiO_2 E	
	Inductively Coupled Plasma	200.7 [2]		3120 B	3120 B	
24. Sodium	Inductively Coupled Plasma	200.7 [2]				
	Atomic Absorption; Direct Aspiration.			3111 B		
25. Temperature	Thermometric			2550	2550	
26. Thallium	ICP-Mass Spectrometry	200.8 [2]				
	Atomic Absorption; Platform	200.9 [2]				

[1] "Methods for Chemical Analysis of Water and Wastes", EPA/600/4–79/020, March 1983. Available at NTIS, PB84–128677.

[2] "Methods for the Determination of Metals in Environmental Samples—Supplement I", EPA/600/R–94/111, May 1994. Available at NTIS, PB95–125472.

[3] *Annual Book of ASTM Standards*, 1994, 1996, or 1999, Vols. 11.01 and 11.02, American Society for Testing and Materials; any year containing the cited version of the method may be used. The previous versions of D1688–95A, D1688–95C (copper), D3559–95D (lead), D1293–95 (pH), D1125–91A (conductivity) and D859–94 (silica) are also approved. These previous versions D1688–90A, C; D3559–90D, D1293–84, D1125–91A and D859–88, respectively are located in the *Annual Book of ASTM Standards*, 1994, Vol. 11.01. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[4] Standard Methods for the Examination of Water and Wastewater, 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005. The cited methods published in any of these three editions may be used, except that the versions of 3711 B, 3111 D, 3113 B and 3114 B in the 20th edition may not be used.

[5] Method I–2601–90, Methods for Analysis by the U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediments, Open File Report 93–125, 1993; For Methods I–1030–85; I–1601–85; I–1700–85; I–2598–85; I–2700–85; and I–3300–85 See Techniques of Water Resources Investigation of the U.S. Geological Survey, Book 5, Chapter A–1, 3rd ed., 1989; Available from Information Services, U.S. Geological Survey, Federal Center, Box 25286, Denver, CO 80225–0425.

[6] "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R–93/100, August 1993. Available at NTIS, PB94–120821.

[7] The procedure shall be done in accordance with the Technical Bulletin 601 "Standard Method of Test for Nitrate in Drinking Water", July 1994, PN 221890–001, Analytical Technology, Inc. Copies may be obtained from ATI Orion, 529 Main Street, Boston, MA 02129.

[8] Method B–1011, "Waters Test Method for Determination of Nitrite/Nitrate in Water Using Single Column Ion Chromatography," August 1987. Copies may be obtained from Waters Corporation, Technical Services Division, 34 Maple Street, Milford, MA 01757.

[9] Method 100.1, "Analytical Method For Determination of Asbestos Fibers in Water", EPA/600/4–83/043, EPA, September 1983. Available at NTIS, PB83–260471.

[10] 10 Method 100.2, "Determination of Asbestos Structure Over 10-μm In Length In Drinking Water", EPA/600/R–94/134, June 1994. Available at NTIS, PB94–201902.

[11] Industrial Method No. 129–71W, "Fluoride in Water and Wastewater", December 1972, and Method No. 380–75WE, "Fluoride in Water and Wastewater", February 1976, Technicon Industrial Systems. Copies may be obtained from Bran & Luebbe, 1025 Busch Parkway, Buffalo Grove, IL 60089.

[12] Unfiltered, no digestion or hydrolysis.

[13] Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2X preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559–90D unless multiple in-furnace depositions are made.

[14] If ultrasonic nebulization is used in the determination of arsenic by Methods 200.7, 200.8, or SM 3120 B, the arsenic must be in the pentavalent state to provide uniform signal response. For methods 200.7 and 3120 B, both samples and standards must be diluted in the same mixed acid matrix concentration of nitric and hydrochloric acid with the addition of 100 μL of 30% hydrogen peroxide per 100ml of solution. For direct analysis of arsenic with method 200.8 using ultrasonic nebulization, samples and standards must contain one mg/L of sodium hypochlorite.

[15] The description for Method Number 1001 for lead is available from Palintest, LTD, 21 Kenton Lands Road, P.O. Box 18395, Erlanger, KY 41018. Or from the Hach Company, P.O. Box 389, Loveland, CO 8053.

4. Section 141.24 is amended by revising the 11th, 12th and last sentences in paragraph (e)(1), before the Table, to read as follows:

§ 141.24 Organic chemicals, sampling and analytical requirements.

* * * * *

(e) * * *

(1) * * * Method 6651 shall be followed in accordance with Standard Methods for the Examination of Water and Wastewater, 18th edition (1992), 19th edition (1995), or 20th edition (1998), American Public Health Association (APHA); any of these three editions may be used. Method 6610 shall be followed in accordance with Standard Methods for the Examination of Water and Wastewater, (18th Edition Supplement) (1994), or with the 19th edition (1995) or 20th edition (1998) of Standard Methods for the Examination of Water and Wastewater; any of these three editions may be used. * * * ASTM Method D 5317–93 is available in the *Annual Book of ASTM Standards* (1999), Vol. 11.02, American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, or in any edition published after 1993.

* * * * *

5. Section 141.25 is amended by revising the Table in paragraph (a) to read as follows:

§ 141.25 Analytical methods for radioactivity.

(a) * * *

Contaminant	Methodology	Reference (method or page number)								
		EPA [1]	EPA [2]	EPA [3]	EPA [4]	SM [5]	ASTM [6]	USGS [7]	DOE [8]	Other
Naturally occurring:										
Gross alpha [11] and beta.	Evaporation	900.0	p 1	00–01	p 1	302, 7110 B		R–1120–76		
Gross alpha [11].	Co-precipitation			00–02		7110 C				
Radium 226.	Radon emanation,	903.1	p 16	Ra–04	p 19	7500–Ra C	D 3454–97	R–1141–76	Ra–04	N.Y. [9]
	Radiochemical	903.0	p 13	Ra–03		304, 305, 7500–Ra B	D 2460–97	R–1140–76		
Radium 228.	Radiochemical	904.0	p 24	Ra–05	p 19	7500–Ra D		R–1142–76		N.Y. [9]
										N.J. [10]
Uranium [12]	Radiochemical	908.0				7500–U B				
	Fluorometric	908.1				7500–U C (17th Ed.)	D2907–97	R–1180–76	U–04	
								R–1181–76		
	Alpha spectrometry			00–07	p 33	7500–U C (18th, 19th or 20th Ed	D 3972–97	R–1182–76	U–02	
	Laser Phosphorimetry						D 5174–97			
Man-made:										
Radioactive cesium.	Radiochemical	901.0	p 4			7500–Cs B	D 2459–72	R–1111–76		
	Gamma ray spectrometry.	901.1			p 92	7120	D 3649–91	R–1110–76	4.5.2.3	
Radioactive iodine.	Radiochemical	902.0	p 6			7500–I B				
			p 9			7500–I C				
	Gamma ray					7500–I D	D 3649–91			
	spectrometry	901.1			p 92	7120	D 4785–93		4.5.2.3	
Radioactive	Radiochemical	905.0	p 29	Sr–04	p. 65	303, 7500–Sr B		R–1160–76	Sr–01	
Strontium 89, 90.									Sr–02	

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Contaminant	Methodology	Reference (method or page number)								
		EPA[1]	EPA[2]	EPA[3]	EPA[4]	SM[5]	ASTM[6]	USGS[7]	DOE[8]	Other
Tritium	Liquid scintillation	906.0	p 34	H–02	p. 87	306, 7500–3H B	D 4107–91	R–1171–76		
Gamma emitters.	Gamma ray	901.1			p 92	7120	D 3649–91	R–1110–76	Ga–01–R	
	Spectrometry	902.0				7500–Cs B	D 4785–93			
		901.0				7500–I B				

The procedures shall be done in accordance with the documents listed below. The incorporation by reference of documents 1 through 10 was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the documents may be obtained from the sources listed below. Information regarding obtaining these documents can be obtained from the Safe Drinking Water Hotline at 800–426–4791. Documents may be inspected at EPA's Drinking Water Docket, 401 M Street, SW., Washington, DC 20460 (Telephone: 202–260–3027); or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

[1] "Prescribed Procedures for the Measurement of Radioactivity in Drinking Water", EPA 600/4–80–032, August 1980. Available at the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (Telephone 800–553–6847), PB 80–224744.

[2] "Interim Radiochemical Methodology for Drinking Water"; EPA 600/4–75–008(revised), March 1976. Available NTIS, ibid. PB 253258.

[3] "Radiochemistry Procedures Manual", EPA 520/5–84–006, December, 1987. Available NTIS, ibid. EMSL LV 053917.

[4] "Radiochemical Analytical Procedures for Analysis of Environmental Samples", March 1979. Available at NTIS, ibid. EMSL LV 0539.

[5] "Standard Methods for the Examination of Water and Wastewater", 13th, 17th, 18th, 19th Editions, or 20th edition, 1971, 1989, 1992, 1995, 1998. Available at American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005. Methods 302, 303, 304, 305 and 306 are only in the 13th edition. Methods 7110B, 7110C, 7500–Ra B, 7500–Ra C, 7500–Ra D, 7500–U B, 7500–Cs B, 7500–I B, 7500–I C, 7500–I D, 7500–Sr B, 7500–3H B are in the 17th, 18th, 19th and 20th editions. Method 7500–U C Fluorometric Uranium is only in the 17th Edition, and 7500–U C Alpha spectrometry is only in the 18th, 19th and 20th editions. Method 7120 is only in the 19th and 20th editions. Methods 302, 303, 304, 305 and 306 are only in the 13th edition.

[6] *Annual Book of ASTM Standards*, Vol. 11.02, 1999; American Society for Testing and Materials; any year containing the cited version of the method may be used. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[7] "Methods for Determination of Radioactive Substances in Water and Fluvial Sediments", Chapter A5 in Book 5 of Techniques of Water-Resources Investigations of the United States Geological Survey, 1977. Available at U.S. Geological Survey (USGS) Information Services, Box 25286, Federal Center, Denver, CO 80225–0425.

[8] "EML Procedures Manual", 28th (1997) or 27th (1990) Editions, Volume I and Volume II; either edition may be used. In the 27th Edition Method Ra-04 is listed as Ra-05 and Method Ga-01–R is listed as Sect. 4.5.4.3. Available at the Environmental Measurements Laboratory, U.S. Department of Energy (DOE), 376 Hudson Street, New York, NY 10014–3621.

[9] "Determination of Ra-226 and Ra-228 (Ra-02)", January 1980, Revised June 1982. Available at Radiological Sciences Institute for Laboratories and Research, New York State Department of Health, Empire State Plaza, Albany, NY 12201.

[10] "Determination of Radium 228 in Drinking Water", August 1980. Available at State of New Jersey, Department of Environmental Protection, Division of Environmental Quality, Bureau of Radiation and Inorganic Analytical Services, 9 Ewing Street, Trenton, NJ 08625.

[11] Natural uranium and thorium-230 are approved as gross alpha calibration standards for gross alpha with co-precipitation and evaporation methods; americium-241 is approved with co-precipitation methods.

[12] In uranium (U) is determined by mass, a 0.67 pCi/μg of uranium conversion factor must be used. This conversion factor is based on the 1:1 activity ration of U–234 and U–238 that is characteristic of naturally occurring uranium..

6. Section 141.74 is amended by revising the footnote 1 to the Table in paragraph (a)(1) and by revising the first three sentences of paragraph (a)(2) to read as follows:

§ 141.74 Analytical and monitoring requirements.

(a) * * *

(1) * * *

[1] Except where noted, all methods refer to Standard Methods for the Examination of Water and Wastewater, 18th edition (1992), 19th edition (1995), or 20th edition (1998), American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005. The cited methods published in any of these three editions may be used.

* * * * *

(2) Public water systems must measure residual disinfectant concentrations with one of the analytical methods in the following table. Except for the method for ozone residuals, the disinfectant residual methods are contained in the 18th, 19th, and 20th editions of Standard Methods for the Examination of Water and Wastewater, 1992, 1995, and 1998; the cited methods published in any of these three editions may be used. The ozone method, 4500–O_3 B, is contained in both the 18th and 19th editions of Standard Methods for the Examination of Water and Wastewater, 1992, 1995; either edition may be used. * * *

* * * * *

PART 143—NATIONAL SECONDARY DRINKING WATER REGULATIONS

1. The authority citation for Part 143 continues to read as follows:

Authority: 42 U.S.C. 300f *et seq.*

2. Section 143.4 is amended by revising the Table in paragraph (b) to read as follows:

§ 143.4 Monitoring.

* * * * *

(b) * * *

Contaminant	EPA	ASTM[3]	SM[4] 18th and 19th ed.	SM[4] 20th ed.	Other
1. Aluminum	[2]200.7		3120 B	3120 B	
	[2]200.8		3113 B		
	[2]200.9		3111 D		
2. Chloride	[1]300.0	D4327–97	4110 B	4110 B	
	.....		4500–Cl^- D	4500–Cl^- D	
	.....	D512–89B	4500–Cl^- B	4500–Cl^- B	
3. Color	.....		2120 B	2120 B	
4. Foaming Agents	.....		5540 C	5540 C	
5. Iron	[2]200.7		3120 B	3120 B	
	[2]200.9		3111 B		
	.....		3113 B		
6. Manganese	[2]200.7		3120 B	3120 B	
	[2]200.8		3111 B		
	[2]200.9		3113 B		
7. Odor	.....		2150 B	2150 B	
8. Silver	[2]200.7		3120 B	3120 B	[5]I–3720–85
	[2]200.8		3111 B		
	[2]200.9		3113 B		
9. Sulfate	[1]300.0	D4327–97	4110 B	4110 B	
	[1]375.2		4500–SO_4^{2-} F	4500–SO_4^{2-} F	
	.....		4500–SO_4^{2-} C, D	4500–SO_4^{2-} C, D	
	.....	D516–90	4500–SO_4^{2-} E	4500–SO_4^{2-} E	
10. Total Dissolved Solids	.....		2540 C	2540 C	
11. Zinc	[2]200.7		3120 B	3120 B	
	[2]200.8		3111 B		

[1] "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R–93–100, August 1993. Available at NTIS, PB94–120821.

[2] "Methods for the Determination of Metals in Environmental Samples—Supplement I", EPA/600/R–94–111, May 1994. Available at NTIS, PB 95–125472.

[3] *Annual Book of ASTM Standards*, 1994, 1996, or 1999, Vols. 11.01 and 11.02, American Society for Testing and Materials; any year containing the cited version of the method may be used. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428.

[4] *Standard Methods for the Examination of Water and Wastewater*, 18th edition (1992), 19th edition (1995), or 20th edition (1998). American Public Health Association, 1015 Fifteenth Street, NW., Washington, DC 20005. The cited methods published in any of these three editions may be used, except that the versions of 3111 B, 3111 D, and 3113 B in the 20th edition may not be used.

[5] Method I–3720–85, *Techniques of Water Resources Investigation of the U.S. Geological Survey*, Book 5, Chapter A–1, 3rd ed., 1989; Available from Information Services, U.S. Geological Survey, Federal Center, Box 25286, Denver, CO 80225–0425.

[FR Doc. 01–178 Filed 1–12–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 411, 413, and 489

[HCFA–1112–CN]

RIN 0938–AJ93

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction notice.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on July 31, 2000 entitled, "Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update."

EFFECTIVE DATE: This correction is effective October 1, 2000, except for certain wage index corrections that are effective December 1, 2000.

FOR FURTHER INFORMATION CONTACT: Bill Ullman (410) 786–5667 or Susan Burris (410) 786–6655.

SUPPLEMENTARY INFORMATION:

Background

In the July 31, 2000 final rule entitled, "Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities" (FR Doc. 00–19004, July 31, 2000), there were several technical errors in the preamble.

In the first column of Tables 3 through 6 of the preamble there was a typographical error. We are correcting the heading of the column from "RUG IV category" to "RUG III category."

We are also correcting several SNF PPS wage index values as published in Tables 7 and 8. Specifically, effective October 1, 2000, in Table 7, the wage index value for the Allentown-Bethlehem-Easton, PA MSA (area 0240) is corrected from 1.0040 to 0.9925 and the wage index value for the Kansas City, KS–MO MSA (area 3760) is corrected from 0.9498 to 0.9509.

Effective December 1, 2000, in Table 7, the wage index value for the Alexandria, LA MSA (area 0220) is corrected from 0.8151 to 0.8123, the wage index value for the Kansas City, KS–MO MSA (area 3760) is corrected again from 0.9509 (as corrected in the previous paragraph) to 0.9527, and, in Table 8, the wage index value for rural LA (area 19) is corrected from 0.7668 to 0.7681.

In accordance with our longstanding policies, these technical and tabulation errors are being corrected prospectively, effective on the dates noted above. This correction notice conforms the published SNF PPS wage index values to the prospectively revised values.

We are also taking this opportunity to provide a correction regarding the applicable time period to which a special market basket inflation factor is to be applied for certain providers that participated in the Multistate Nursing Home Case-Mix and Quality Demonstration (NHCMQD), the demonstration project that served as the forerunner to the national skilled nursing facility (SNF) prospective payment system (PPS). In the May 12, 1998 SNF PPS interim final rule (63 FR 26288), we explained that for those providers that received payment under the NHCMQD during a cost reporting period that began in calendar year 1997, we derived a special market basket index inflation factor of 1.031532. We used this factor to adjust the 1997 costs to the midpoint of the rate setting period in calculating their facility-specific rate. The May 1998 interim final rule indicated that the initial rate setting period (which applied to those providers beginning their *first* cost reporting period under the SNF PPS) encompassed the 15-month period from July 1, 1998, to September 30, 1999.

Under the statute's phased transition from facility-specific to full Federal rates, this inflation factor was to be successively updated for the second and third cost reporting periods under the SNF PPS. However, for demonstration providers beginning their *second* cost reporting period under the SNF PPS, the

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July 30, 1999 SNF PPS update notice (64 FR 41697) inadvertently included the same inflation factor of 1.031532 that had been displayed for the first cost reporting period in the May 1998 interim final rule, along with the same time period of July 1, 1998, to September 30, 1999. Although a subsequent correction notice published in the **Federal Register** on October 5, 1999 (64 FR 54030) provided the correct inflation factor of 1.062244 for the second cost reporting period, it did not make a similar correction to the applicable time period.

Further, while the July 2000 final rule (65 FR 46787) did update both the inflation factor (1.105788) and the applicable time period (October 1, 2000, to September 30, 2001) for these demonstration providers, the latter change failed to reflect that it is possible for such a provider to begin its *third* cost reporting period under the SNF PPS as early as July 1, 2000. Accordingly, we are hereby correcting the start date for the demonstration providers for the applicable time period that was displayed in the 2000 final rule, from October 1, 2000, to July 1, 2000.

In addition, there was an error in the Regulatory Impact Analysis, section VI of the preamble, that resulted in two columns of incorrect figures displayed in the impact analysis table. Based on the correct percent changes in the two columns, some dollar figures and percentages mentioned throughout the preamble are also in error.

Specifically, on pages 46793 and 46794, column 3, we referenced $3.1 billion as the aggregate increase in payments associated with this final rule; however, we made a technical error in our calculation and the correct number is $2.6 billion. Additionally, in this section (page 46795, column 3), we made another technical error in our calculation that the payments will increase by 21.8 percent. The correct figure is 18.3 percent.

Accordingly, we are reprinting Table 11 of the preamble (64 FR 46795), entitled "Projected Impact of FY 2001 Update to the SNF PPS," with the corrected figures displayed in the last two columns of the table and a corrected figure for the total number of facilities. Further, we note that Table 11 presents the projected effects of the policy changes in the SNF PPS from FY 2000 to FY 2001, as well as statutory changes effective for FY 2001 for SNFs. As such, these corrections do not represent any changes to the policies set forth in the final rule.

The corrections appear in this document under the heading "Correction of Errors." The provisions in this correction notice are effective as if they had been included in the document published in the **Federal Register** on July 31, 2000, that is, as of October 1, 2000, except for those wage index value corrections that we specifically noted to be effective as of December 1, 2000.

Correction of Errors

In FR Doc. 00–19004 of July 31, 2000 (64 FR 46770), we are making the following corrections:

Corrections to Preamble

1. In the first column of Table 3 (on pages 46775–76), Table 4 (on pages 46776–77), Table 5 (on pages 46777–78), and Table 6 (on page 46778), the column heading is revised to read "RUG III category".

2. On page 46779, in column 2, the entry of "0.8151" for Alexandria, LA, under "Wage Index for Urban Areas" is revised by adding "0.8123 (effective December 1, 2000)".

3. On page 46779, in column 3, the entry of "1.0040" for Allentown-Bethlehem-Easton, PA, under "Wage Index for Urban Areas" is revised to read "0.9925".

4. On page 46782, in column 2, the entry of "0.9498" for Kansas City, KS–MO, under "Wage Index for Urban Areas" is revised to read "0.9509".

5. On page 46782, in column 2, the revised entry of "0.9509" for Kansas City KS–MO, under "Wage Index for Urban Areas" is further revised by adding "0.9527 (effective December 1, 2000)".

6. On page 46785, in column 3, the entry of "0.7668" for Louisiana, under "Wage Index for Rural Areas" is revised by adding "0.7681 (effective December 1, 2000)".

7. On page 46787, in column 2, first full paragraph, the last sentence is revised to read: "In addition, we derive a special market basket inflation factor, which is 1.105788, to adjust the 1997 costs to the midpoint of the rate setting period (July 1, 2000 to September 30, 2001.)'

8. On page 46793, in column 3, section VI, Regulatory Impact Analysis, paragraph 2, the third sentence is revised to read: "This final rule is a major rule as defined in Title 5, United States Code, section 804(2), because we estimate its impact will be to increase the payments to SNFs by approximately $2.6 billion in FY 2001."

9. On page 46794, in column 3, first full paragraph, the first sentence is revised to read: "As stated previously in this rule, the aggregate increase in payments associated with this final rule is estimated to be $2.6 billion."

10. On page 46795, in column 3, first full paragraph, the third sentence is revised to read: "It is assumed that payments will increase by 18.3 percent in total, assuming facilities do not change their care delivery and billing practices in response."

11. Table 11 (Projected Impact of FY 2001 Update to the SNF PPS) is corrected as set forth below.

TABLE 11.—PROJECTED IMPACT OF FY 2001 UPDATE TO THE SNF PPS

	Number of facilities	Transition to Federal rates (percent)	Add on to Federal rates (percent)	Update change (percent)	Wage index change (percent)	20 (percent) add on	Total FY 2001 change (percent)
Total	9037	4.2	3.5	2.3	0.0	7.2	18.3
Urban	6300	3.6	3.5	2.3	−0.1	7.1	17.4
Rural	2737	7.1	3.7	2.2	0.8	7.7	23.2
Hospital based urban	683	−4.5	3.0	2.4	0.0	6.8	7.6
Freestanding urban	5617	5.1	3.6	2.3	−0.1	7.2	19.3
Hospital based rural	533	2.0	3.4	2.3	0.9	8.7	18.3
Freestanding rural	2204	8.2	3.7	2.2	0.7	7.5	24.1
Urban by region:							
New England	630	10.5	3.8	2.2	−0.8	7.8	25.4
Middle Atlantic	877	14.3	3.8	2.2	−0.3	9.0	31.8
South Atlantic	959	−0.4	3.3	2.3	−0.4	6.2	11.3
East North Central	1232	6.1	3.6	2.2	0.4	7.0	20.7
East South Central	212	1.9	3.5	2.3	−0.7	6.9	14.5
West North Central	469	3.6	3.5	2.3	0.4	6.7	17.5
West South Central	519	−5.2	3.0	2.4	1.0	6.3	7.3
Mountain	303	−4.0	3.1	2.4	0.0	4.8	6.2
Pacific	1070	−2.3	3.2	2.4	−0.5	6.9	9.8
Rural by region:							
New England	88	14.4	3.9	2.2	−0.9	8.4	30.5
Middle Atlantic	144	13.1	3.9	2.2	0.0	9.0	30.9
South Atlantic	373	5.3	3.6	2.2	1.1	8.0	21.7
East North Central	561	9.2	3.7	2.2	1.0	7.4	25.5
East South Central	255	4.2	3.6	2.3	0.6	8.8	20.9
West North Central	581	11.1	3.7	2.2	0.8	8.3	28.5
West South Central	354	1.2	3.4	2.3	1.1	6.9	15.7
Mountain	204	3.3	3.5	2.3	0.7	6.4	17.2
Pacific	151	3.2	3.5	2.3	0.3	6.3	16.5

(**Authority:** Section 1888 of the Social Security Act (42 U.S.C. 1395yy))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 2, 2001.

Brian P. Burns,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 01–1187 Filed 1–12–01; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WT Docket No. 97–192; FCC 00–408]

Procedures for Reviewing Requests for Relief from State and Local Regulations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission addresses the issues raised in a previous Commission Notice of Proposed Rule Making regarding its review of requests for relief from impermissible State and local regulation of personal wireless service facilities regarding environmental effects of radiofrequency (RF) emissions. We establish that such requests under the Communications Act of 1934, as amended, shall be filed as petitions for declaratory ruling. Further, we establish certain required and recommended procedures regarding the service of pleadings and comment periods in such proceedings. The procedures adopted will facilitate the prompt resolution of such while ensuring that State and local governments have an opportunity to respond to issues raised in the context of these proceedings.

DATES: The rule change set forth in this document contains an information collection requirement that has not yet been approved by OMB. The FCC will publish a document in the **Federal Register** announcing the effective date of these rule changes. Comments from the public, OMB, and other agencies on the information collections contained in this document are due March 19, 2001.

ADDRESSES: A copy of any comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Edward C. Springer, OMB Desk Officer, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to edward.springer@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Joel Taubenblatt at (202) 418–1513 (Wireless Telecommunications Bureau). For additional information concerning the information collection contained in this document, contact Judy Boley at 202–418–0214, or via the Internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Report and Order in WT Docket No. 97–192 (the "R&O"), FCC 00–408, adopted November 13, 2000 and released November 17, 2000. The complete text of the document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Services, (202) 857–3800, 445 12th Street, SW., CY–B400, Washington, DC 20554. The full text of this R&O is also available via the Internet at *http://www.fcc.gov/Bureaus/Wireless/Orders/2000/fcc00408.doc.*

Paperwork Reduction Act

This R&O contains a new information collection. Specifically, the Report and Order amends Note 1 to paragraph (a) of 47 CFR .1206 of the Commission's rules so that the expanded service requirements set forth in that note apply to petitions filed pursuant to 47 U.S.C. 332(c)(7)(B)(v) (i.e., petitions for relief from impermissible State and local regulation of personal wireless service facilities on the basis of RF emissions). Thus, petitioners seeking relief under 47 U.S.C. 332(c)(7)(B)(v) must serve a copy of such petitions on those State and local governments that are the subject of the petitions as well as on those State and local governments otherwise specifically identified in the petitions whose actions petitioners argue are inconsistent with federal law.

The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public, Office of Management and Budget (OMB), and other federal agencies to comment on the information collection(s) contained in this R&O as required by the Paperwork Reduction Act of 1995, Public Law 104–13. It will be submitted to the OMB for review under Section 3507(d) of the PRA. Public, OMB, and other agency comments are due March 19, 2001. Comments should address: (a) Whether the new collection of information is necessary for the proper performance of the functions of the Commission,

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including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

All comments on the information collections contained herein should be submitted to Judy Boley, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to jboley@fcc.gov, and to Edward C. Springer, OMB Desk Officer, Room 10236 NEOB, 725 17th Street, NW., Washington, DC 20503 or via the Internet to edward.springer@omb.eop.gov.

OMB Control Number: 3060–XXXX.

Title: Procedures for Reviewing Requests for Relief from State and Local Regulations Pursuant to Section 332(c)(7)(B)(v) of the Communications Act of 1934, *Report and Order* (Preemption of State and Local Government Regulation of Tower Siting on the Basis of the Environmental Effect of Radiofrequency Emissions).

Form No.: NA.

Type of Review: New collection.

Respondents: Business or other for-profit; not-for-profit institutions; state and/or local or tribal governments.

Number of Respondents: 10.

Estimated Time per Response: .5 hr.

Total Annual Burden: 5 hrs.

Total Annual Costs: $100.

Needs and Uses: These procedures will ensure that petitions seeking relief under 47 U.S.C. 332(c)(7)(B)(v) will be resolved efficiently, with an opportunity for all interested parties to participate.

Synopsis of Report and Order

The Report and Order ("R&O") addresses the issues raised in the RF *Procedures NPRM*, 62 FR 48034, regarding the Commission's review of requests for relief from impermissible State and local regulation of personal wireless service facilities based on the environmental effects of radiofrequency (RF) emissions. Specifically, the R&O provides that such requests under 47 U.S.C. 332(c)(7)(B)(v) shall be filed as petitions for declaratory ruling, and establishes certain required and recommended procedures regarding the service of pleadings and comment periods in such proceedings. The R&O also concludes that the other issues raised in the *RF Procedures NPRM* are best addressed through case-by-case adjudication. In particular, the R&O notes the Commission's expectation that the recently-adopted *Local Official's Guide* will facilitate the common sense resolution of disputes regarding demonstrations of compliance with the Commission's RF emissions rules, without resort to litigation or other formal dispute resolution.

Discussion

The R&O provides that requests for relief from the Commission under 47 U.S.C. 332(c)(7)(B)(v) shall be filed as petitions for declaratory ruling pursuant to 47 CFR 1.2 of the Commission's rules. In addition, the R&O concludes that such petitions shall be subject to the Commission's procedures applicable to petitions for declaratory ruling, with the exception of the pleading cycle guidelines and service rules set forth as follows. The pleading cycle guidelines set forth in the *Section 253 Procedures Public Notice* are equally appropriate for petitions for declaratory ruling that seek relief under 47 U.S.C. 332(c)(7)(B)(v). Specifically, the R&O anticipates that the pleading cycle for petitions for declaratory ruling that seek relief under 47 U.S.C. 332(c)(7)(B)(v) will be approximately 30 days for oppositions and approximately 15 days for replies. The specific pleading cycle for each petition will be established by the Wireless Telecommunications Bureau (Bureau) by public notice, and may vary from the approximate timeframe listed above if the Bureau finds that variation is appropriate.

The R&O also finds that petitions for declaratory ruling seeking relief under 47 U.S.C. 332(c)(7)(B)(v) are similar to petitions seeking Commission preemption of State or local government authority, and should be subject to the *Ex Parte Order's* expanded service rules referenced above. Accordingly, the R&O amends the expanded service requirements in the ex parte rules to include petitioners seeking relief under 47 U.S.C. 332(c)(7)(B)(v). Thus, petitioners seeking relief under 47 U.S.C. 332(c)(7)(B)(v) must serve a copy of such petitions not only on those State and local governments that are the subject of the petitions, but also on those State and local governments otherwise specifically identified in the petitions whose actions petitioners argue are inconsistent with federal law.

In addition, the R&O recommends that, if a petition involves a local statute, regulation, ordinance or legal requirement, the petitioner should serve the appropriate state entity, in addition to the appropriate local entity. The R&O also recommends that, subsequent to the filing and service of the initial petition, each party, including the petitioner and each respondent State or local government entity, should serve all other parties with a copy of its pleadings and any filing made pursuant to the *Commission's ex parte rules.*

The R&O finds that these procedural guidelines, in combination with the *Ex Parte Order's* expanded service rules and other Commission rules generally applicable to petitions for declaratory ruling, will facilitate the prompt resolution of petitions seeking relief from the Commission under 47 U.S.C. 332(c)(7)(B)(v), while ensuring that State and local governments have an opportunity to respond to allegations raised against them in the context of these proceedings.

The R&O also concludes that the other issues raised in the *RF Procedures NPRM* are best addressed through case-by-case adjudication. In particular, with respect to requirements related to demonstrating compliance with the Commission's RF emissions rules, the R&O notes the Commission's expectation that the *Local Official's Guide* will facilitate voluntary resolution of most disputes regarding this issue. With respect to the other issues, the R&O finds that a rulemaking is unnecessary in light of the relatively low level of controversy and the complexity of the issues.

Final Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (RFA),[1] the RF Procedures NPRM incorporated an Initial Regulatory Flexibility Analysis (IRFA) of the proposed rules pursuant to 5 U.S.C. 605. No comments were filed on the IRFA. Section 604 of the Regulatory Flexibility Act, as amended, requires a final regulatory flexibility analysis in a notice and comment rulemaking proceeding unless the Commission certifies that "the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." The RFA generally defines "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA). The Commission believes, as discussed below, that the rule adopted in this proceeding will not have a significant economic impact on a substantial number of small entities.

[1] See 5 U.S.C. 603. The RFA, see 5 U.S.C. 601 et Seq., has been amended by the Contract With America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

The Commission is making one rule change in this Report and Order. Specifically, the Commission amends Note 1 to paragraph (a) of 47 C.F.R. 1.1206 of its rules so that the expanded service requirements set forth in that note apply to petitions filed pursuant to 47 U.S.C. 332(c)(7)(B)(v) (i.e., petitions for relief from impermissible State and local regulation of personal wireless service facilities on the basis of RF emissions). Thus, petitioners seeking relief under 47 U.S.C. 332(c)(7)(B)(v) must serve a copy of such petitions on those State and local governments that are the subject of the petitions as well as on those State and local governments otherwise specifically identified in the petitions whose actions petitioners argue are inconsistent with federal law. Given that the Commission has received only one petition for relief under 47 U.S.C. 332(c)(7)(B)(v), we do not anticipate that numerous State and local governments will be the subject of such petitions or identified in such petitions. Thus, we do not expect that the service requirement adopted in this Report and Order will impose a significant burden of cost and time on petitioners, including petitioners that are small entities. We believe that this service requirement will facilitate the efficient resolution of petitions seeking relief under 47 U.S.C. 332(c)(7)(B)(v). Moreover, we believe that this requirement will ensure that State and local governments, including those governments that are small entities, have an opportunity to participate in proceedings under 47 U.S.C. 332(c)(7)(B)(v).

Accordingly, the Commission certifies, pursuant to 5 U.S.C. 605(b) of the Regulatory Flexibility Act, as amended by the Contract with America Advancement Act of 1996, that the rule adopted in this Report and Order will not have a significant economic impact on a substantial number of small entities. The Commission will send a copy of the Report and Order, including a copy of this final certification, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996. In addition, the Report and Order and this certification will be sent to the Chief Counsel for Advocacy of the Small Business Administration, and a summary will be published in the **Federal Register**

Report to Congress

The Commission will send a copy of this Report and Order, including the Final Regulatory Flexibility Certification, to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, see 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of this Report and Order, including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration. A copy of this Report and Order (or summary thereof) and the Final Regulatory Flexibility Certification will also be published in the **Federal Register**. See 5 U.S.C. 604(b).

Ordering Clauses

Accordingly, pursuant to the authority of Sections 4(i), 303(r), and 332(c)(7) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 303(r), and 332(c)(7), it is ordered that this Report and Order is hereby adopted.

The rule changes set forth in this Report and Order contain an information collection requirement that has not yet been approved by OMB. The FCC will publish a document in the **Federal Register** announcing the effective date of these rule changes.

The motion of the City of Fountain, Colorado, to consider late-filed comments is granted.

The Commission's Consumer Information Bureau, Reference Information Center, shall send a copy of this Report and Order, including the Final Regulatory Flexibility Certification, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Part 1

Communications common carriers, Telecommunications, Permit-but-disclose proceedings.

Federal Communications Commission.

Shirley S. Suggs,

Chief, Publications Group.

Rule Change

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR Part 1 as follows:

PART 1—PRACTICE AND PROCEDURES

1. The authority citation for Part 1 continues to read as follows:

Authority: 47 U.S.C. 151, 154, 303, and 309(j) unless otherwise noted.

2. Section 1.1206, Note 1 to Paragraph(A) is revised to read as follows:

§ 1.1206 Permit-but-disclose proceedings.

(a) * * *

Note 1 to Paragraph (A): In the case of petitions for declaratory ruling that seek Commission preemption of state or local regulatory authority and petitions for relief under 47 U.S.C. 332(c)(7)(B)(v), the petitioner must serve the original petition on any state or local government, the actions of which are specifically cited as a basis for requesting preemption. Service should be made on those bodies within the state or local governments that are legally authorized to accept service of legal documents in a civil context. Such pleadings that are not served will be dismissed without consideration as a defective pleading and treated as a violation of the ex parte rules unless the Commission determines that the matter should be entertained by making it part of the record under § 1.1212(d) and the parties are so informed.

* * * * *

[FR Doc. 01–1086 Filed 1–12–01; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 122200B]

Fisheries of the Exclusive Economic Zone Off Alaska; Bycatch Rate Standards for the First Half of 2001

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Pacific halibut and red king crab bycatch rate standards; request for comments.

SUMMARY: NMFS announces Pacific halibut and red king crab bycatch rate standards for the first half of 2001. Publication of these bycatch rate standards is necessary under regulations implementing the vessel incentive program. This action is necessary to implement the bycatch rate standards for trawl vessel operators who participate in the Alaska groundfish trawl fisheries. The intent of this action is to avoid excessive prohibited species bycatch rates and to promote conservation of groundfish and other fishery resources.

DATES: Effective 1201 hours, Alaska local time (A.l.t.), January 20, 2001, through 2400 hours, A.l.t., June 30, 2001. Comments on this action must be

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received no later than 4:30 p.m., A.l.t., February 15, 2001.

ADDRESSES: Comments may be submitted to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668, Attn: Lori Gravel. Comments also may be sent via facsimile (fax) to 907–586–7465. Comments will not be accepted if submitted via e-mail or Internet. Courier or hand delivery of comments may be made to NMFS in the Federal Building, Room 453, Juneau, AK 99801.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228, fax 907–586–7465, e-mail mary.furuness@noaa.gov.

SUPPLEMENTARY INFORMATION: The domestic groundfish fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands management area (BSAI) and Gulf of Alaska (GOA) are managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area and the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMPs). The FMPs were prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and are implemented by regulations governing the U.S. groundfish fisheries at 50 CFR part 679.

Regulations at § 679.21(f) implement a vessel incentive program to reduce halibut and red king crab bycatch rates in the groundfish trawl fisheries. Under the incentive program, operators of trawl vessels must not exceed Pacific halibut bycatch rate standards specified for the BSAI and GOA midwater pollock and "other trawl" fisheries, and the BSAI yellowfin sole and "bottom pollock" fisheries. Vessel operators also must not exceed red king crab bycatch rate standards specified for the BSAI yellowfin sole and "other trawl" fisheries in Bycatch Limitation Zone 1 (defined in § 679.2). The fisheries included under the incentive program are defined in regulations at § 679.21(f)(2).

Regulations at § 679.21(f)(3) require that halibut and red king crab bycatch rate standards for each fishery included under the incentive program be published in the **Federal Register**. The standards are in effect for specified seasons within the 6-month periods of January 1 through June 30, and July 1 through December 31. Because the Alaskan groundfish fisheries are closed to trawling from January 1 to January 20 of each year (§ 679.23(c)), the Administrator, Alaska Region, NMFS (Regional Administrator), is promulgating bycatch rate standards for the first half of 2001 effective from January 20, 2001, through June 30, 2001.

As required by § 679.21(f)(4), bycatch rate standards are based on the following information:

(A) Previous years' average observed bycatch rates;

(B) Immediately preceding season's average observed bycatch rates;

(C) The bycatch allowances and associated fishery closures specified under §§ 679.21(d) and (e);

(D) Anticipated groundfish harvests for that fishery;

(E) Anticipated seasonal distribution of fishing effort for groundfish; and

(F) Other information and criteria deemed relevant by the Regional Administrator.

At its October 2000 meeting, the Council reviewed halibut and red king crab bycatch rates experienced by vessels participating in the fisheries under the incentive program during 1996–2000. Based on this and other information presented here, the Council recommended halibut and red king crab bycatch rate standards for the first half of 2001. These standards are unchanged from those specified for the past 5 years except for the first quarter BSAI bottom pollock fishery. The Council's recommended bycatch rate standards are listed in Table 1.

TABLE 1.—BYCATCH RATE STANDARDS, BY FISHERY AND QUARTER, FOR THE FIRST HALF OF 2001 FOR PURPOSES OF THE VESSEL INCENTIVE PROGRAM IN THE BSAI AND GOA.

Fishery and quarter	2001 bycatch rate standard
Halibut bycatch rate standards (kilogram (kg) of halibut/metric ton (mt) of groundfish catch	
BSAI Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
BSAI Bottom pollock:	
Qt 1	5.0
Qt 2	5.0
BSAI Yellowfin sole:	
Qt 1	5.0
Qt 2	5.0
BSAI Other trawl:	
Qt 1	30.0
Qt 2	30.0
GOA Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
GOA Other trawl:	
Qt 1	40.0
Qt 2	40.0
Zone 1 red king crab bycatch rate standards (number of crab/mt of groundfish catch)	
BSAI yellowfin sole:	
Qt 1	2.5
Qt 2	2.5
BSAI Other trawl:	
Qt 1	2.5
Qt 2	2.5

Bycatch Rate Standards for Pacific Halibut

The BSAI pollock combined A/B season currently begins January 20 through June 10. In 2000, the inshore and offshore component fisheries for pollock ended 9 to 12 weeks prior to June 10, depending on the processing component and area. Directed fishing for pollock by the inshore and offshore component fisheries did not reopen until June 10, the start of the pollock combined C/D season. Also, the community development quota (CDQ) pollock fishery ended 9 weeks before the end of the combined A/B season and did not resume until just prior to July 1. As in past years, the directed fishing allowances specified for the 2001 pollock combined A/B season likely will be reached before the end of the combined A/B season.

As in past years, the halibut bycatch rate standard recommended for the BSAI and GOA midwater pollock fisheries (1 kg halibut/mt of groundfish) is higher than the bycatch rates normally experienced by vessels participating in these fisheries. The recommended standard is intended to encourage vessel operators to maintain off-bottom trawl operations.

Since January 1999, nonpelagic trawl gear has been allocated zero mt of the non-CDQ BSAI pollock total allowable catch. In May 2000, NMFS permanently prohibited the use of nonpelagic trawl gear in the BSAI non-CDQ directed pollock fishery (§ 679.24(b)(4)). On June 15, 2000, the Pacific halibut and crab PSC limits and associated bycatch allowances for the BSAI trawl fisheries were reduced under regulations prohibiting the use of nonpelagic trawl gear in the BSAI non-CDQ directed pollock fishery (65 FR 31105, May 16, 2000). Assignment to a fishery for purposes of the vessel incentive program is based on catch composition instead of gear type. A vessel using pelagic trawl gear may be assigned to the BSAI bottom pollock fishery defined at § 679.21(f)(2). The prohibition on the use of nonpelagic trawl gear has reduced the number of hauls assigned to the BSAI bottom pollock fishery and the bycatch rates are lower. The average halibut bycatch rate for the 2000 first and second calendar quarter fisheries was equal to 0.58 and 4.01 kg halibut/mt groundfish, respectively. With the prohibition on the use of nonpelagic trawl gear, the bycatch rates will likely remain low. It is recommended that the halibut bycatch rate standard for the first quarter BSAI bottom pollock fishery be reduced from 7.5 to 5 kg halibut/mt groundfish and the halibut bycatch rate standard for the second quarter remain at 5 kg halibut/mt groundfish.

Other factors that could affect the spatial and temporal distribution of the directed pollock fishery include the 2001 allocations of pollock among the inshore and offshore fleets under the American Fisheries Act and the implementation of conservation measures that are necessary under the Endangered Species Act to mitigate pollock fishery impacts on Steller sea lions. At this time, the effects of these changes on halibut bycatch rates in the pollock fishery are unknown.

Data available on halibut bycatch rates in the BSAI yellowfin sole fishery during the first and second quarters of 2000 showed an average bycatch rate of 0.02 and 0.17 kg halibut/mt of groundfish, respectively. These rates are significantly lower than in past years. The Council and NMFS have presumed that a continued bycatch rate standard of 5.0 kg halibut/mt of groundfish for the yellowfin sole fishery will continue a bycatch rate standard that represents an acceptable level of halibut bycatch in this fishery and will encourage vessel operators to take action to avoid excessively high bycatch rates of halibut.

For the "other trawl" fisheries, the Council supported a 30-kg halibut/mt of groundfish bycatch rate standard for the BSAI and a 40-kg halibut/mt of groundfish bycatch rate standard for the GOA. Observer data collected from the 2000 BSAI "other trawl" fishery show first and second quarter halibut bycatch rates of 8.11 and 20.77 kg halibut/mt of groundfish, respectively. Observer data collected from the 2000 GOA "other trawl" fishery show first and second quarter halibut bycatch rates of 22.77 and 54.44 kg halibut/mt of groundfish, respectively.

With the exception of the GOA second quarter "other trawl" fishery, the average bycatch rates experienced by vessels participating in the GOA and BSAI "other trawl" fisheries have been lower than the specified bycatch rate standards for these fisheries. The Council and NMFS have determined that the recommended halibut bycatch rate standards for the "other trawl" fisheries, including the second quarter GOA fishery, would continue bycatch rate standards that represent an acceptable level of halibut bycatch in these fisheries and will encourage vessel operators to avoid high halibut bycatch rates while participating in these fisheries. Furthermore, these standards would provide some leniency to those vessel operators who choose to use large-mesh trawl gear or other devices as a means to reduce groundfish discard amounts, or who are forced to fish in different seasons or fishing grounds under measures implemented to mitigate fishing impacts on Steller sea lions and their critical habitat.

Bycatch Rate Standards for Red King Crab

For the BSAI yellowfin sole and "other trawl" fisheries in Zone 1 of the Bering Sea subarea, the Council's recommended red king crab bycatch rate standard is 2.5 crab/mt of groundfish. This standard is unchanged since 1992. The red king crab bycatch rates experienced by the BSAI yellowfin sole fishery in Zone 1 during the first and second quarters of 2000 averaged 0.23 and 0.45 crab/mt of groundfish, respectively. Although these rates are lower than the standards, these rates are significantly higher than bycatch rates experienced in similar quarters in previous years. The average bycatch rates of red king crab experienced in the "other trawl" fishery during the first and second quarter of 2000 were 0.22 and 0.32 crab/mt groundfish, respectively. The low 2000 red king crab bycatch rates primarily were due to trawl closures in Zone 1 that were implemented to reduce red king crab bycatch.

For the period January through October 2000, the total bycatch of red king crab by trawl vessels fishing in Zone 1 is estimated at 74,000 crab, considerably less than the 97,000-red king crab bycatch limit established for the trawl fisheries in Zone 1. NMFS anticipates that the 2001 red king crab bycatch in Zone 1 will be similar to 2000 because the crab bycatch reduction measures and the bycatch limit of 97,000 crab will remain the same.

In spite of anticipated 2001 red king crab bycatch rates being significantly lower than 2.5 red king crab/mt of groundfish, the Council recommended that the red king crab bycatch rate standards be maintained at these levels. These levels continue to represent acceptable rates of bycatch in these fisheries and provide some leniency to those vessel operators who choose to use large-mesh trawl gear as a means to reduce groundfish discard amounts.

The Regional Administrator has determined that the recommended bycatch rate standards are appropriately based on the information and considerations necessary for such determinations under § 679.21(f). Therefore, the Regional Administrator establishes the halibut and red king crab bycatch rate standards for the first half of 2001 as set forth in Table 1. These bycatch rate standards may be revised and published in the **Federal Register** when deemed appropriate by the Regional Administrator pending his consideration of the information set forth at § 679.21(f)(4).

As required in regulations at §§ 679.2 and 679.21(f)(5), the 2001 fishing months are specified as the following periods for purposes of calculating vessel bycatch rates under the incentive program:

Month 1: January 1 through January 27;

Month 2: January 28 through February 24;

Month 3: February 25 through March 31;

Month 4: April 1 through May 5;

Month 5: May 6 through June 2;

Month 6: June 3 through June 30;

Month 7: July 1 through July 28;

Month 8: July 29 through September 1;

Month 9: September 2 through September 29;

Month 10: September 30 through October 27;

Month 11: October 28 through December 1; and

Month 12: December 2 through December 31.

Classification

NMFS finds that the prevention of excessive prohibited species bycatch rates constitutes good cause to waive the requirement for prior notice and comment period pursuant to 5 U.S.C. 553(b)(B) as such procedures are contrary to the public interest. Because the halibut and red king crab bycatch rate standards for the first half of 2001 must be effective by January 20, 2001, when the Alaska groundfish trawl fishing season opens, NMFS finds for good cause that the implementation of

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this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

This action is taken under 50 CFR 679.21(f) and is exempt from OMB review under Executive Order 12866.

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.* and 3631 *et seq.*

Dated: January 9, 2001.

Clarence Pautzke,

Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1213 Filed 1–12–01; 8:45 am]

BILLING CODE 3510–22–U

Proposed Rules

Federal Register
Vol. 66, No. 10
Tuesday, January 16, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 96–016–33]

RIN 0579–AA83

Karnal Bunt; Compensation for the 1999–2000 Crop Season

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Karnal bunt regulations to provide compensation for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey who incur losses and expenses because of Karnal bunt in the 1999–2000 crop season. The payment of compensation is necessary in order to reduce the economic effect of the Karnal bunt regulations on affected wheat growers and other individuals and to help obtain cooperation from affected individuals in efforts to contain and reduce the prevalence of Karnal bunt.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by March 19, 2001.

ADDRESSES: Please send your comment and three copies to:

Docket No. 96–016–33, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238

Please state that your comment refers to Docket No. 96–016–33.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Vedpal S. Malik, National Karnal Bunt Coordinator, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–6774.

SUPPLEMENTARY INFORMATION:

Background

Karnal bunt is a fungal disease of wheat (*Triticum aestivum*), durum wheat (*Triticum durum*), and triticale (*Triticum aestivum* X *Secale cereale*), a hybrid of wheat and rye. Karnal bunt is caused by the smut fungus *Tilletia indica* (Mitra) Mundkur and is spread by spores, primarily through the movement of infected seed. In the absence of measures taken by the U.S. Department of Agriculture (USDA) to prevent its spread, the establishment of Karnal bunt in the United States could have significant consequences with regard to the export of wheat to international markets. The regulations regarding Karnal bunt are set forth in 7 CFR 301.89–1 through 301.89–16 (referred to below as the regulations). Among other things, the regulations define areas regulated for Karnal bunt and restrict the movement of certain regulated articles, including wheat seed and grain, from the regulated areas.

In a final rule published in the **Federal Register** and effective on June 25, 1999 (64 FR 34109–34113, Docket No. 96–016–35), the Animal and Plant Health Inspection Service (APHIS) amended the regulations by adding compensation provisions for 1997–1998 crop season wheat.[1] That final rule made compensation available for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey who incurred losses and expenses because of Karnal bunt in the 1997–1998 crop season. These provisions are in § 301.89–15, "Compensation for growers, handlers, and seed companies in the 1996–1997 and 1997–1998 crop seasons," and § 301.89–16, "Compensation for grain storage facilities, flour millers, and National Survey participants for the 1996–1997 and 1997–1998 crop seasons."

APHIS did not propose to provide compensation for the 1998–1999 crop season. Surveys conducted in 1999 determined that no Karnal bunt host crops harvested in 1999 in the regulated area were positive for Karnal bunt. Therefore, no growers, handlers, seed companies, owners of grain storage facilities, flour millers, or participants in the National Karnal Bunt Survey incurred losses or expenses because of Karnal bunt for the 1998–1999 crop season. We have no reason to believe the situation will be different for this crop season. However, we are proposing to establish compensation provisions for the 1999–2000 crop season so that, if Karnal bunt is detected, compensation may be provided in a timely manner to those who incur losses or expenses.

In the future, for crop seasons beyond the 1999–2000 crop season, APHIS will not propose to provide compensation for growers, handlers, or seed companies in regulated areas. These persons know they are in an area regulated for Karnal bunt at the time planting and contracting decisions are made for future crop seasons. Understanding the restrictions, growers, handlers, and seed companies can choose to alter their planting or contract decisions to avoid experiencing losses due to Karnal bunt. However, APHIS may, for crop seasons beyond the 1999–2000 crop season, propose to provide compensation for National Karnal Bunt Survey participants whose wheat or grain storage facility tests positive for Karnal bunt. We expect, however, that the proposed compensation for these persons would be limited to one crop season.

We expect that any costs to growers and other entities related to the Karnal bunt program in the 1999–2000 crop season would be similar to those incurred in the 1997–1998 crop season. Therefore, we are proposing to amend the regulations to provide the same compensation for the 1999–2000 crop season as was provided in the 1997–1998 crop season.

[1] The 1997–1998 crop season is that season in which wheat was harvested in 1998. The 1999–2000 crop season is that season in which wheat is harvested in 2000.

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Compensation for Growers and Handlers

Section 301.89–15 of the regulations provides compensation to growers and handlers for the loss in value of wheat seed and grain from the 1996–1997 and 1997–1998 crop seasons due to Karnal bunt. We are proposing to make these provisions apply also to growers, handlers, and seed companies in the 1999–2000 crop season.

The compensation in § 301.89–15 is for wheat grain, certified wheat seed, and wheat grown with the intention of producing certified wheat seed. The compensation calculation for certified wheat seed and wheat grown with the intention of producing certified wheat seed is the same as that offered for wheat grain. Requiring that wheat seed be certified or grown with the intention of producing certified wheat seed ensures that the compensation is limited to market-ready seed and will not be paid for seed in other stages of development. Further, the compensation in § 301.89–15 is only for wheat that was tested by APHIS and found positive for Karnal bunt.

For the 1996–1997 and 1997–1998 crop seasons, § 301.89–15 provides two different levels of compensation for growers and handlers of positive wheat, depending on which of the following two sets of circumstances applies: (1) The wheat is from an area that became regulated for Karnal bunt after the 1996–1997 crop or 1997–1998 crop was planted, or for which an Emergency Action Notification (PPQ Form 523)(EAN) was issued after the 1996–1997 crop or 1997–1998 crop was planted, and that remained regulated or under an EAN at the time the wheat was sold; or (2) the wheat is from an area that became regulated for Karnal bunt before the 1996–1997 crop or 1997–1998 crop was planted, or for which an EAN was issued before the 1996–1997 crop or 1997–1998 crop was planted, and that remained regulated or under an EAN at the time the wheat was sold. These areas are called "areas under the first regulated crop season" and "previously regulated areas," respectively. Growers, handlers, and seed companies in areas under the first regulated crop season would not have known that their area was to become regulated for Karnal bunt at the time they made their planting and many of their contracting decisions and would not have been prepared for the loss in value of their wheat due to Karnal bunt. Growers, handlers, and seed companies in previously regulated areas knew they were in an area regulated for Karnal bunt at the time planting and contracting decisions were made for the 1996–1997 or 1997–1998 crop season. Understanding the restrictions, growers, handlers, and seed companies could have chosen to alter their planting or contract decisions to avoid experiencing losses due to Karnal bunt. The 1999–2000 crop season is the fifth regulated crop season for most regulated areas. The compensation provisions for areas under the first regulated crop season are in § 301.89–15(a); the compensation provisions for previously regulated areas are in § 301.89–15(b).

First Regulated Crop Season

At the present time, there are no areas that meet the first regulated crop season criteria for 1999–2000. We would consider all areas that are currently regulated to be previously regulated areas for the 1999–2000 crop season. APHIS is continuing to monitor for Karnal bunt throughout wheat producing areas in the United States. If Karnal bunt is found to exist in an area outside the currently regulated areas during the 1999–2000 crop season, APHIS will regulate that area, and if the area is under a declaration of extraordinary emergency, growers and handlers would be eligible for compensation for the loss in value of their wheat in accordance with the provisions for areas under the first regulated crop season.

Under § 301.89–15(a), growers, handlers, and seed companies in areas under the first regulated crop season criteria are eligible for compensation for 1996–1997 crop season wheat or 1997–1998 crop season wheat (as appropriate) and for wheat inventories in their possession that were unsold at the time the area became regulated. For the 1999–2000 crop season, we would likewise state that growers, handlers, and seed companies in areas under the first regulated crop season criteria are eligible for compensation for 1999–2000 crop season wheat and for wheat inventories in their possession that were unsold at the time the area became regulated for Karnal bunt.

Under § 301.89–15(a)(1), growers of wheat in an area under the first regulated crop season criteria who sell wheat that was tested by APHIS and found positive for Karnal bunt prior to sale, or that was tested by APHIS and found positive for Karnal bunt after sale and the price received by the grower is contingent on the test results, are eligible to receive compensation as follows:

- If the wheat was grown under contract and a price was determined in the contract before the area where the wheat was grown became regulated for Karnal bunt, compensation will equal the contract price minus the actual price received by the grower; or
- If the wheat was not grown under contract or a price was determined in the contract after the area where the wheat was grown became regulated for Karnal bunt, compensation will equal the estimated market price for the relevant class of wheat (meaning type of wheat, such as durum or hard red winter) minus the actual price received by the grower.

For both situations described above, compensation for positive-testing wheat will not exceed $1.80 per bushel under any circumstances.

Under § 301.89–15(a)(2), handlers and seed companies who sell wheat grown in an area under the first regulated crop season criteria are eligible to receive compensation only if the wheat was not tested by APHIS prior to purchase by the handler or seed company but was tested by APHIS and found positive for Karnal bunt after purchase by the handler or seed company, as long as the price to be paid is not contingent on the test results. Compensation will equal the estimated market price for the relevant class of wheat minus the actual price received by the handler or seed company. However, compensation for positive-testing wheat will not exceed $1.80 per bushel under any circumstances.

Estimated market prices used in the compensation calculations described above for growers and handlers are calculated by APHIS for each class of wheat, taking into account the prices offered by relevant terminal markets (animal feed, milling, or export) during the harvest months for the area, with adjustments for transportation and other handling costs. Separate estimated market prices are calculated for certified wheat seed and wheat grown with the intention of producing certified wheat seed and wheat grain.

This proposal would make the provisions in § 301.89–15(a)(1) and (a)(2) apply to growers, handlers, and seed companies in the 1999–2000 crop season if they have wheat grown in areas under the first regulated crop season criteria.

Previously Regulated Areas

As discussed previously in this document, all of the areas currently listed as regulated areas in the Karnal bunt regulations, and all the areas currently regulated for Karnal bunt under EAN's, would be considered to be previously regulated areas for the 1999–2000 crop season.

Under § 301.89–15(b), growers, handlers, and seed companies in previously regulated areas are eligible for compensation only for 1996–1997 and 1997–1998 crop season wheat. We would amend § 301.89–15(b) to state that growers, handlers, and seed companies in previously regulated areas are eligible for compensation under paragraph (b) only for 1996–1997, 1997–1998, and 1999–2000 crop season wheat.

Under § 301.89–15(b), growers who sell wheat are eligible to receive compensation only if the wheat was tested by APHIS and found positive for Karnal bunt prior to sale, or was tested by APHIS and found positive for Karnal bunt after sale and the price received by the grower is contingent on the test results. Compensation will be at the rate of $.60 per bushel of positive testing wheat. Handlers and seed companies who sell wheat are eligible to receive compensation only if the wheat was not tested by APHIS prior to purchase but was tested by APHIS and found positive for Karnal bunt after purchase, as long as the price to be paid is not contingent on the test results. Compensation will be at the rate of $.60 per bushel of positive-testing wheat. This proposal would make this same compensation available to growers, handlers, and seed companies in the 1999–2000 crop season.

Growers, Handlers, and Seed Companies—To Claim Compensation

In past crop seasons, the Farm Service Agency (FSA) of USDA has processed Karnal bunt compensation claims from growers, handlers, and seed companies for the loss in value of their wheat. Under this proposal, FSA would continue to process such claims in the 1999–2000 crop season.

Under § 301.89–15(c), we require 1996–1997 and 1997–1998 crop season claimants to submit a number of documents in support of their claim. We would require the same documents to be submitted for 1999–2000 crop season compensation. The requirements in paragraph (c) are as follows:

Growers, handlers, and seed companies who are eligible for compensation under either the provisions for the first regulated crop season or the provisions for previously regulated areas need to provide the same documents for claiming compensation, with a few exceptions. Growers, handlers, and seed companies must submit a Karnal Bunt Compensation Claim form, provided by FSA. If the wheat was grown in an area that is not a regulated area, but for which an EAN has been issued, the grower, handler, or seed company must submit a copy of the EAN. Growers, handlers, and seed companies must also submit a copy of the Karnal bunt certificate issued by APHIS that shows the Karnal bunt test results and verification as to the actual (not estimated) weight of the wheat that tested positive (such as a copy of a facility weigh ticket or other verification). For compensation claims for wheat seed, a grower or seed company must submit documentation showing that the wheat is either certified seed or was grown with the intention of producing certified seed. This documentation may include one or more of the following types of documents: an application to the State seed certification agency for field inspection; a bulk sale certificate; certification tags or labels issued by the State seed certification agency; or a document issued by the State seed certification agency verifying that the wheat is certified seed.

In addition, growers must submit a copy of the receipt for the final sale of the wheat, showing the total bushels sold and the total price received by the grower. Growers compensated under the provisions for areas in the first regulated crop season must submit a copy of the contract the grower has for the wheat, if the wheat was under contract. Growers compensated under the provisions for previously regulated areas and who sold wheat that was not yet tested by APHIS must submit documentation showing that the price paid to the grower was contingent on test results (this information could appear on the receipt for the final sale of the wheat or on a contract the grower has for the wheat, if the wheat was under contract).

In addition, handlers and seed companies must provide the FSA office with a copy of the receipt for the final sale of the wheat. The handler or seed company must submit documentation showing that the price paid or to be paid to the grower is not contingent on the test results (this documentation could appear on the receipt for the purchase of the wheat from the grower or on a contract for the purchase of the wheat, if the wheat was purchased under contract).

Compensation for Grain Storage Facilities, Flour Millers, and National Survey Participants

The June 1999 final rule (Docket No. 96–016–35) also amended § 301.89–16 of the regulations. This section sets forth compensation provisions for the decontamination of grain storage facilities, heat treatment of millfeed, and losses to National Karnal Bunt Survey participants whose wheat or grain storage facility tests positive for Karnal bunt in the 1996–1997 or 1997–1998 crop season. We are proposing to amend § 301.89–16 to make its provisions also apply to the 1999–2000 crop season.

Decontamination of Grain Storage Facilities

As part of the Karnal bunt program, APHIS may require the decontamination of grain storage facilities that have been determined by APHIS to be contaminated with Karnal bunt. For the 1996–1997 and 1997–1998 crop seasons, § 301.89–16(a) provides that owners of grain storage facilities that are in States where the Secretary has declared an extraordinary emergency, and who have decontaminated their grain storage facilities pursuant to either an EAN issued by an inspector or a letter issued by an inspector ordering decontamination of the facilities, are eligible to be compensated, on a one-time-only basis for each facility for each covered crop year wheat, for up to 50 percent of the direct cost of decontamination. However, compensation will not exceed $20,000 per grain storage facility. General cleanup, repair, and refurbishment costs are excluded from compensation. Under this proposed rule, this same compensation would be available to owners of grain storage facilities in the 1999–2000 crop season.

Paragraph (a) also states that compensation payments will be issued by APHIS and sets forth provisions for claiming compensation. To claim compensation, the owner of the grain storage facility must submit to an inspector records demonstrating that decontamination was performed on all structures, conveyances, or materials ordered by APHIS to be decontaminated.

The records must include a copy of the EAN or the letter from an inspector ordering decontamination, contracts with individuals or companies hired to perform the decontamination, receipts for equipment and materials purchased to perform the decontamination, time sheets for employees of the grain storage facility who performed activities connected to the decontamination, and any other documentation that helps show the cost to the owner and that decontamination has been completed. These provisions would also apply to compensation claims in the 1999–2000 crop season.

Treatment of Millfeed

In the 1996–1997 crop season, millfeed made from wheat produced in certain regulated areas was required to be heat treated in order to help prevent the spread of Karnal bunt, and we paid

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compensation to flour millers who incurred expenses for heat treatments. Under a final rule published in the **Federal Register** and effective on September 23, 1998 (63 FR 50747–50752), only millfeed resulting from the milling of wheat, durum wheat, or triticale that tested positive for Karnal bunt was required to be heat treated. However, we continued to provide compensation in the 1997–1998 crop season at the same rate. In § 301.89–16, paragraph (b) provides that flour millers who, in accordance with a compliance agreement with APHIS, heat treat millfeed that is required by APHIS to be heat treated are eligible to be compensated at the rate of $35.00 per short ton of millfeed. We would make this same rate of compensation available to flour millers in the 1999–2000 crop season.

Paragraph (b) provides for the 1996–1997 and 1997–1998 crop seasons that the amount of millfeed compensated will be calculated by multiplying the weight of wheat from the regulated area received by the miller by 25 percent (the average percent of millfeed derived from a short ton of grain). Compensation payments will be issued by APHIS. To claim compensation, the miller must submit to an inspector verification as to the actual (not estimated) weight of the wheat (such as a copy of a facility weigh ticket or a copy of the bill of lading for the wheat, if the actual weight appears on those documents, or other verification). Flour millers must also submit verification that the millfeed was heat treated (such as a copy of the limited permit under which the wheat was moved to a treatment facility and a copy of the bill of lading accompanying that movement; or a copy of PPQ Form 700 (which includes certification of processing) signed by the inspector who monitors the mill). This proposed rule would make these same provisions apply to compensation claims for heat treatment of millfeed in the 1999–2000 crop season.

National Karnal Bunt Survey Participants

Each year since 1996, APHIS has conducted a National Karnal Bunt Survey to demonstrate to our trading partners that areas producing wheat for export are free of the disease. In past crop seasons, we offered compensation to participants in the Survey whose wheat or grain storage facility tested positive for Karnal bunt, if the participant is in a State in which the Secretary of Agriculture has declared an extraordinary emergency for Karnal bunt. For the 1996–1997 and 1997–1998 crop seasons, the provisions for this compensation are in § 301.89–16(c). We are proposing to make these provisions also apply to participants in the National Karnal Bunt Survey in the 1999–2000 crop season.

For the 1996–1997 and 1997–1998 crop seasons, paragraph (c) provides that, if a grain storage facility participating in the National Karnal Bunt Survey tests positive for Karnal bunt, the facility will be regulated, and may be ordered decontaminated, pursuant to either an EAN issued by an inspector or a letter issued by an inspector ordering decontamination of the facility. If the Secretary has declared an extraordinary emergency in the State in which the grain storage facility is located, the owner will be eligible for compensation as follows:

- The owner of the grain storage facility will be compensated for the loss in value of positive wheat. Compensation will equal the estimated market price for the relevant class of wheat minus the actual price received for the wheat. The estimated market price will be calculated by APHIS for each class of wheat, taking into account the prices offered by relevant terminal markets (animal feed, milling, or export) during the relevant time period for that facility, with adjustments for transportation and other handling costs. However, compensation will not exceed $1.80 per bushel under any circumstances. Compensation payments for loss in value of wheat will be issued by the FSA. To claim compensation, the owner of the facility must submit to the local FSA office a Karnal Bunt Compensation Claim form, provided by FSA. The owner of the facility must also submit to FSA a copy of the EAN or letter from an inspector under which the facility is or was quarantined; verification as to the actual (not estimated) weight of the wheat (such as a copy of a facility weigh ticket or a copy of the bill of lading for the wheat, if the actual weight appears on those documents, or other verification); and a copy of the receipt for the final sale of the wheat, showing the total bushels sold and the total price received by the owner of the grain storage facility.
- The owner of the facility will be compensated on a one-time-only basis for each grain storage facility for each covered crop year wheat for the direct costs of decontamination of the facility at the same rate described under § 301.89–16(a) (discussed earlier)(up to 50 percent of the direct costs of decontamination, not to exceed $20,000 per grain storage facility). Compensation payments for decontamination of grain storage facilities will be issued by APHIS, and claims for compensation must be submitted in accordance with the provisions in § 301.89–16(a).

Under this proposed rule, the compensation in § 301.89–16(c) described above would also be available to National Karnal Bunt Survey participants in the 1999–2000 crop season.

For the 1997–1998 crop season, claims for compensation under §§ 301.89–15 and 301.89–16 had to be received by FSA or APHIS on or before October 25, 1999. This is 120 days after the date the June 1999 final rule was published in the **Federal Register**. For the 1999–2000 crop season, we would likewise require that claims for compensation be received by APHIS on or before October 25, 2000, or the date that is 120 days after a final rule for this proposal is published in the **Federal Register**, whichever is later. The Administrator may extend this deadline, upon written request in specific cases, when unusual and unforeseen circumstances occur that prevent or hinder a claimant from requesting compensation on or before that date.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

This proposed rule would establish compensation provisions for certain growers, handlers, seed companies, owners of grain storage facilities, flour millers, and participants in the National Karnal Bunt Survey to mitigate losses and expenses incurred in the 1999–2000 crop season because of the Karnal bunt quarantine and emergency actions.

In accordance with Executive Order 12866, this analysis examines the economic effects of providing such compensation. The wheat industry within the regulated area is largely composed of businesses that can be considered "small" according to guidelines established by the Small Business Administration. Therefore, this analysis also fulfills the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), which requires agencies to consider the economic impact of rule changes on small entities.

Upon detection of Karnal bunt in Arizona in March 1996, the U.S. Department of Agriculture (USDA) imposed Federal quarantine and emergency actions to prevent the interstate spread of the disease to other wheat producing areas in the United States. The unexpected discovery of

Karnal bunt and subsequent Federal emergency actions disrupted the production and marketing flows of wheat in the quarantined areas. It was estimated that the effect of Karnal bunt and subsequent Federal actions on the wheat industry totaled $44 million in the 1995–1996 crop season.

In order to alleviate some of the economic hardships and to ensure full and effective compliance with the quarantine program, USDA offered compensation to mitigate certain losses incurred by growers, handlers, seed companies, and other affected persons in the areas regulated for Karnal bunt in the 1995–1996, 1996–1997, and 1997–1998 crop seasons. The payment of compensation is in recognition of the fact that, while benefits from regulation accrue to a large portion of the wheat industry outside the regulated areas, the regulatory burden falls predominately on a small segment of the affected wheat industry within the regulated areas. A final rule promulgating compensation regulations for the 1997–1998 crop season was effective and published in the **Federal Register** on June 25, 1999 (64 FR 34109–34113, Docket No. 96–016–35). The compensation proposed in this document for the 1999–2000 crop season is the same as the compensation offered in the 1997–1998 crop season.

We are proposing that growers, handlers, and seed companies would be eligible for compensation for losses in the 1999–2000 crop season due to wheat grain or seed that tested positive for Karnal bunt. Only positive-testing wheat would be eligible for compensation because of the lack of restrictions on the movement of negative-testing wheat. As in the 1997–1998 crop season, we are proposing different levels of compensation depending on whether the wheat was grown in an area under the first regulated crop season or in a previously regulated area. An area in the first regulated crop season is an area that became regulated for Karnal bunt after the 1999–2000 crop was planted. A previously regulated area is an area that became regulated for Karnal bunt before the 1999–2000 crop was planted. Currently, there are no regulated areas in the first regulated crop season.

For growers, handlers, and seed companies in previously regulated areas, the proposed compensation for positive grain or seed would be $.60 per bushel. Growers, handlers, and seed companies in the first regulated crop season would be eligible for compensation at a rate not to exceed $1.80 per bushel. These compensation rates would apply to both wheat grain and seed. The difference in compensation rates reflects the fact that affected entities in areas under the first regulated crop season would not have known that their area was to become regulated for Karnal bunt at the time that they made planting and contracting decisions and would not have been prepared for the loss in value of their wheat due to Karnal bunt. Growers and handlers in previously regulated areas knew they were in an area regulated for Karnal bunt at the time that they made planting and contracting decisions for the 1999–2000 crop season. Given the restrictions, growers and handlers could have chosen to alter planting or contract decisions to avoid experiencing potential losses due to Karnal bunt. The proposed compensation rates are the same as those offered in the 1997–1998 crop season.

At this time, all areas that are regulated for Karnal bunt are previously regulated areas. We estimate that approximately 37,000 acres of wheat will be harvested in 2000 from the regulated areas. In the 1998–1999 crop season, no wheat grown in the regulated areas tested positive for Karnal bunt. However, if we assume that 1 percent of wheat harvested from the regulated areas will test positive for Karnal bunt in the 1999–2000 crop season, compensation for wheat grain and seed grown in currently regulated areas would total approximately $17,760 (1 percent of 37,000 acres equals 370 acres; using an estimate of 80 bushels per acre crop yield, 370 acres multiplied by 80 equals 29,600 bushels; 29,600 bushels multiplied by $.60 per bushel equals $17,760). The estimated total compensation of $17,760 would translate into a per grower average of $987, assuming that 18 growers, or 10 percent of the approximately 180 growers in the regulated area, produce wheat that tests positive for Karnal bunt. The positive-testing wheat would have a market value of approximately $133,200 in the absence of Karnal bunt.

To compare, compensation for wheat grain and seed in the 1996–1997 crop season totaled about $149,000. Approximately 122,000 acres of wheat were harvested from regulated areas in the 1996–1997 crop season, with a Karnal bunt infection rate of 0.8 percent. Compensation for wheat grain and seed in the 1997–1998 crop season is estimated to total about $1.9 million. Approximately 181,540 acres of wheat were harvested from regulated areas in the 1997–1998 crop season, with an infection rate of 3.2 percent. The increase in the amount of compensation paid in the 1997–1998 crop season resulted from wetter weather conditions, which increased the infection rate, and the fact that positive wheat was commingled with negative wheat in grain storage facilities in the certification area in Arizona before it was known that the wheat was positive.

We cannot determine at this time whether there will be areas eligible for compensation under the provisions for first regulated crop season areas in the 1999–2000 crop season. APHIS is in the process of conducting the 1999 National Karnal Bunt Survey in wheat producing areas throughout the United States. Any areas that become regulated in the 1999–2000 crop season as a result of the 1999 National Survey might be eligible for first regulated crop season compensation. During the 1998 National Survey for Karnal bunt, none of the wheat samples tested positive for Karnal bunt.

This proposed rule would also provide compensation under specific criteria for the decontamination of grain storage facilities found with positive wheat, the treatment of millfeed, and participants in the National Karnal Bunt Survey whose wheat or grain storage facility is found to be positive for Karnal bunt. Compensation for decontamination of grain storage facilities will be on a one-time-only basis for up to 50 percent of the cost of decontamination, not to exceed $20,000. We cannot determine at this time how many, if any, grain storage facilities in currently regulated areas will store positive wheat in the 1999–2000 crop season or how many, if any, will be found to contain positive wheat during the 1999 National Survey for Karnal bunt. In the 1996–1997 crop season, compensation paid for the decontamination of grain storage facilities totaled approximately $120,000. In the 1997–1998 crop season, the compensation paid for the decontamination of grain storage facilities totaled approximately $10,700.

We are also proposing compensation for the cost of heat treating millfeed that APHIS requires to be treated, at the rate of $35.00 per short ton of millfeed. No millfeed made from wheat grown in the regulated area was required to be heat treated in the 1998–1999 crop season. Under current regulations, APHIS requires heat treatment of millfeed made from wheat that tested positive for Karnal bunt. Since little or no positive wheat is expected to be used for milling in the 1999–2000 crop season, compensation for the heat treatment of millfeed in the 1999–2000 crop season would be minimal.

The Regulatory Flexibility Act requires that agencies consider the economic effects of rules on small businesses, organizations, and governmental jurisdictions. Growers

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and handlers of wheat grain and seed, and wheat seed companies, would be those most affected by this proposed rule. In the 1999–2000 crop season, we estimate that there are a total of 180 wheat growers in the regulated areas: 58 in Arizona, 23 in California, 27 in New Mexico, and 72 in Texas. Most of these entities have total annual sales of less than $0.5 million, the Small Business Administration's threshold for classifying wheat producers as small entities. Accordingly, the economic effects of this proposed rule would largely be on small entities.

This proposed rule is expected to have a positive economic effect on all affected entities, large and small, but few entities are likely to be affected. As indicated above, we estimate that only about 18 growers in regulated areas would produce wheat that tests positive for Karnal bunt in the 1999–2000 crop season. Compensation for the loss in value of wheat that tests positive for Karnal bunt serves to encourage compliance with testing requirements within the regulated area, thereby aiding in the preservation of an important wheat growing region in the United States. It also serves to encourage participation in the National Karnal Bunt Survey.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 96–016–33. Please send a copy of your comments to: (1) Docket No. 96–016–33, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would require that growers, handlers, and seed companies provide certain records and documents to a local Farm Service Agency (FSA) office in order to claim compensation. Growers, handlers, and seed companies would also have to sign a Karnal Bunt Compensation Claim form (completed by an employee of FSA using the information provided by the claimant) to attest that the information on the form is accurate and to demonstrate acceptance of the compensation. This proposal would also require that owners of grain storage facilities and flour millers provide certain records and documents to an APHIS inspector in order to claim compensation. This information collection is necessary in order to verify a claimant's eligibility for compensation and to provide documentation of compensation claims and payments.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average .4938 hours per response.

Respondents: Wheat growers, handlers, seed companies, owners of grain storage facilities, flour millers, FSA personnel.

Estimated annual number of respondents: 18.

Estimated annual number of responses per respondent: 4.5.

Estimated annual number of responses: 81.

Estimated total annual burden on respondents: 40 hours.

Copies of this information collection can be obtained from: Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 would continue to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

2. Section 301.89–15 would be amended by revising the section heading, the introductory text to the section, the introductory text to paragraph (a), paragraph (b), and the introductory text to paragraph (c), to read as follows:

§ 301.89–15 Compensation for growers, handlers, and seed companies in the 1996–1997, 1997–1998, and 1999–2000 crop seasons.

Growers, handlers, and seed companies are eligible to receive compensation from the United States Department of Agriculture (USDA) for the 1996–1997, 1997–1998, and 1999–2000 crop seasons to mitigate losses or expenses incurred because of the Karnal bunt regulations and emergency actions, as follows:

(a) *Growers, handlers, and seed companies in areas under first regulated crop season.* Growers, handlers, and seed companies are eligible to receive compensation for the loss in value of their wheat in accordance with paragraphs (a)(1) and (a)(2) of this section if: the wheat was grown in a State where the Secretary has declared an extraordinary emergency; and the wheat was grown in an area of that State that became regulated for Karnal bunt after the crop was planted, or for which an Emergency Action Notification (PPQ Form 523) was issued after the crop was planted; and the wheat was grown in an area that remained regulated or under Emergency Action Notification at the time the wheat was sold. Growers, handlers, and seed companies in areas under the first regulated crop season are eligible for compensation for 1996–1997 crop season wheat, 1997–1998 crop season wheat, or 1999–2000 crop season wheat (as appropriate) and for wheat inventories in their possession that were unsold at the time the area became regulated. The compensation provided in this section is for wheat grain, certified wheat seed, and wheat grown with the intention of producing certified wheat seed.

* * * * *

(b) *Growers, handlers, and seed companies in previously regulated areas.* Growers, handlers, and seed companies are eligible to receive compensation for the loss in value of their wheat in accordance with paragraphs (b)(1) and (b)(2) of this section if: the wheat was grown in a State where the Secretary has declared an extraordinary emergency; and the wheat was grown in an area of that State that became regulated for Karnal bunt before the crop was planted, or for which an Emergency Action Notification (PPQ Form 523) was issued before the crop was planted; and the wheat was grown in an area that remained regulated or under Emergency Action Notification at the time the wheat was sold. Growers, handlers, and seed companies in previously regulated areas are eligible for compensation only for 1996–1997, 1997–1998, or 1999–2000 crop season wheat. The compensation provided in this section is for wheat grain, certified wheat seed, and wheat grown with the intention of producing certified wheat seed.

(1) *Growers.* Growers of wheat in a previously regulated area who sell wheat that was tested by APHIS and found positive for Karnal bunt prior to sale, or that was tested by APHIS and found positive for Karnal bunt after sale and the price received by the grower is contingent on the test results, are eligible to receive compensation at the rate of $.60 per bushel of positive testing wheat.

(2) *Handlers and seed companies.* Handlers and seed companies who sell wheat grown in a previously regulated area are eligible to receive compensation only if the wheat was not tested by APHIS prior to purchase by the handler, but was tested by APHIS and found positive for Karnal bunt after purchase by the handler or seed company, as long as the price to be paid by the handler or seed company is not contingent on the test results. Compensation will be at the rate of $.60 per bushel of positive testing wheat.

(c) *To claim compensation.* Compensation payments to growers, handlers, and seed companies under paragraphs (a) and (b) of this section will be issued by the Farm Service Agency (FSA). Claims for compensation for the 1996–1997 crop season had to be received by FSA on or before October 8, 1998. Claims for compensation for the 1997–1998 crop season had to be received by FSA on or before October 25, 1999. Claims for compensation for the 1999–2000 crop season must be received by FSA on or before October 25, 2000, or [*the date 120 days after the final rule is published in the* **Federal Register**], whichever is later. The Administrator may extend the deadline, upon request in specific cases, when unusual and unforeseen circumstances occur that prevent or hinder a claimant from requesting compensation on or before these dates. To claim compensation, a grower, handler, or seed company must complete and submit to the local FSA county office the following documents:

* * * * *

§ 301.89–16 [Amended]

3. Section 301.89–16 would be amended as follows:

a. In the heading, by removing the words "1996–1997 and 1997–1998 crop seasons" and adding the words "1996–1997, 1997–1998, and 1999–2000 crop seasons" in their place.

b. In the introductory text, by removing the words " 1996–1997 and 1997–1998 crop seasons" and adding the words "1996–1997, 1997–1998, and 1999–2000 crop seasons" in their place.

c. In paragraphs (a), (b), (c)(1), and (c)(2), by removing the last two sentences in each paragraph and by adding three sentences in their place to read as follows: "Claims for compensation for the 1997–1998 crop season had to be received by APHIS on or before October 25, 1999. Claims for compensation for the 1999–2000 crop season must be received by APHIS on or before October 25, 2000, or [*the date 120 days after the final rule is published in the Federal Register*], whichever is later. The Administrator may extend these deadlines upon written request in specific cases, when unusual and unforeseen circumstances occur that prevent or hinder a claimant from requesting compensation on or before these dates."

Done in Washington, DC, this 9th day of January 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–1198 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–66–AD]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model EMB–120 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Supplemental notice of proposed rulemaking; reopening of comment period.

SUMMARY: This document revises an earlier proposed airworthiness directive (AD), applicable to all EMBRAER Model EMB–120 series airplanes, that would have superseded an existing AD that currently requires repetitive visual checks or inspections to verify that the flight idle stop system circuit breakers are closed, and repetitive functional tests to determine if the backup flight idle stop system is operative. That notice of proposed rulemaking (NPRM) would also have required modification of the secondary flight idle stop system (SFISS), which would terminate the repetitive actions. That NPRM also would have removed certain airplanes from the applicability. That NPRM was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. This new action revises the proposed rule by changing the compliance time and certain procedures for modifying the SFISS. The actions specified by this new supplemental NPRM are intended to prevent an inoperative backup flight idle stop system.

DATES: Comments must be received by February 12, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–66–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

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Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–66–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: Linda Haynes, Aerospace Engineer, Propulsion Branch, ACE–117A, FAA, Atlanta Aircraft Certification Office, One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703–6091; fax (770) 703–6097.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the supplemental NPRM is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–66–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this notice of proposed rulemaking (NPRM) by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–66–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add an airworthiness directive (AD), applicable to certain EMBRAER Model EMB–120 series airplanes, was published as an NPRM in the **Federal Register** on April 11, 2000 (65 FR 19345). That NPRM proposed to supersede AD 92–16–51, amendment 39–8355 (57 FR 40838, September 8, 1992), which is applicable to all EMBRAER Model EMB–120 series airplanes. That NPRM would have continued to require repetitive visual checks or inspections to verify that the flight idle stop system circuit breakers are closed, and repetitive functional tests to determine if the backup flight idle stop system is operative. That NPRM would have added a modification of the secondary flight idle stop system (SFISS), which would terminate the repetitive actions. That NPRM also would have removed certain airplanes from the applicability.

Actions Since Issuance of Previous Proposal

Since the issuance of that NPRM, EMBRAER has issued two new service bulletins that revise certain procedures that were included in earlier revisions of the service bulletins to further improve the reliability of the SFISS.

EMBRAER Service Bulletin 120–76–0018, Change No. 03, dated May 26, 2000, includes new and revised procedures for replacing the SFISS with a new system. The actions specified in this service bulletin are intended to reduce maintenance efforts by eliminating certain repetitive inspections and tests, and to provide warning lights if either of the two secondary flight idle locks become inoperable during flight. This new revision divides the text into Part I and Part II, as follows:

- Part I revises modification procedures for replacing the flight idle lock assembly with a new assembly within 4,000 flight hours.
- Part II includes modification procedures for an inspection to determine the type of bolt used to attach the power control Teleflex cable end to the nacelle secondary flight idle locking mechanism, and replacement of any hex-head bolt with a countersunk-head bolt within 400 flight hours.

EMBRAER Service Bulletin 120–76–0022, Change No. 01, dated October 9, 2000, revises the procedures in Parts I, II, and III, and adds Part IV procedures.

- Part I revises the procedure for installing the new power control bellcrank.
- Part II adds an inspection procedure and corrective action if a protruding hex-head bolt is found during the inspection.
- Part III revises the procedures for replacing the existing solenoid assembly by adding procedures for releasing the control cable end from the power control bellcrank and installing the new power control bellcrank.
- Part IV adds procedures for inspecting and replacing the bolt used to attach the power control cable end to the power control bellcrank.

Comments Received

Due consideration has been given to the comments received in response to the original NPRM:

Request To Use Later Service Information

One commenter requests changing the revision number of Embraer Service Bulletin 120–76–0018, from Revision 01 to Revision 03 to reflect the latest improvements in the new design for the SFISS. This new design provides a significant reduction in maintenance requirements and a positive warning of an inoperative condition.

The FAA concurs that the later revision of this service bulletin, which is Change No. 03, dated May 26, 2000 (rather than Revision 03), is the correct reference. Paragraph (d)(2) of the supplemental NPRM has been revised accordingly.

Request To Revise Compliance Time for Modifying the SFISS

One commenter strongly recommends incorporating the new SFISS in all

EMB–120 series airplanes that are in operation at the earliest scheduled heavy maintenance opportunity (within the next 4,000 flight hours). The commenter proposes this change because the improved SFISS specified in Service Bulletin 120–76–0018, Change No. 03, significantly reduces maintenance efforts and provides a positive warning of an inoperative condition.

The FAA partially concurs with the commenter's request to change the compliance time for modifying the SFISS in accordance with the new revision of Service Bulletin 120–76–0018. However, we have determined that the modification specified in Part I of that service bulletin must be accomplished "within 18 months or within 4,000 flight hours after the effective date of this AD, whichever occurs earlier." We have also determined that the modification specified in Part II of that service bulletin must be accomplished "within 18 months or within 400 flight hours after the effective date of this AD, whichever occurs earlier." In developing the appropriate compliance times, the FAA considered the safety implications, parts availability, and normal maintenance schedules for timely modification of the SFISS. In consideration of these factors, we have determined that the compliance times, as proposed in this supplemental NPRM, represent appropriate intervals in which the modifications can be accomplished in a timely manner within the fleet and still maintain an adequate level of safety. We have specified the new proposed compliance times in paragraphs (d)(2) and (d)(3) and have added paragraph (d)(4) of the supplemental NPRM accordingly.

Conclusion

The FAA has revised this supplemental NPRM to specify new requirements based on revisions to the previously referenced service bulletins and on certain comments previously described. Since these changes expand the scope of the originally proposed rule, we have determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

Cost Impact

The FAA estimates that 230 EMBRAER Model EMB–120 series airplanes of U.S. registry would be affected by this supplemental NPRM.

The actions that are currently required by AD 92–16–51 take approximately 5 work hours per airplane to accomplish, at an average labor rate of $60 per work hour.

Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $69,000, or $300 per airplane, per inspection cycle.

The approximate cost, at an average labor rate of $60 per work hour, for the modifications proposed by this AD are listed in Table 1, as follows:

TABLE 1.—ESTIMATED COSTS

Service bulletin	Work hours	Parts cost	Cost per airplane
120–76–0015:			
Part I	4	$4,376	$4,616
Part II	2	14,331	14,451
120–76–0018:			
Part I	50	20,000 (varies with configuration)	23,000
Part II			
120–76–0022:			
Part I	2	14,150	14,270
Part II	2	2,429	2,549
Part III	2	14,229	14,349
Part IV	1	53	113

Therefore, based on the figures included in Table 1, the cost impact of the modification proposed by this AD on U.S. operators is estimated to range from $113 to $23,000 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

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§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8355 (57 FR 40838, September 8, 1992), and by adding a new airworthiness directive (AD), to read as follows:

Empresa Brasileira de Aeronautica, S.A. (EMBRAER): Docket 2000–NM–66–AD. Supersedes AD 92–16–51, Amendment 39–8355.

Applicability: Model EMB–120 series airplanes, certificated in any category; serial numbers 120004 through 120354 inclusive.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent an inoperative backup flight idle stop system, accomplish the following:

Restatement of Certain Requirements of AD 92–16–51:

(a) For all airplanes: Within 5 days after September 23, 1992 (the effective date of AD 92–16–51, amendment 39–8355), and thereafter prior to the first flight of each day until the requirements of paragraph (d) of this AD have been accomplished, accomplish paragraph (a)(1) or (a)(2) of this AD, as applicable:

(1) For airplanes on which an inspection window has been installed on the left lateral console panel that permits visibility of the flight idle stop solenoid circuit breakers:

Using an appropriate light source, perform a visual check to verify that both "FLT IDLE STOP SOL" circuit breakers CB0582 and CB0583 for engine 1 and engine 2 are closed.

Note 2: This check may be performed by a flight crew member.

Note 3: Instructions for installation of an inspection window can be found in EMBRAER Information Bulletin 120–076–0003, dated November 19, 1991; or EMBRAER Service Bulletin 120–076–0014, dated July 29, 1992.

(2) For airplanes on which an inspection window has not been installed on the left lateral console panel: Perform a visual inspection to verify that both "FLT IDLE STOP SOL" circuit breakers CB0582 and CB0583 for engine 1 and engine 2 are closed.

(b) As a result of the check or inspection performed in accordance with paragraph (a) of this AD: If circuit breakers CB0582 and CB0583 are not closed, prior to further flight, reset them and perform the functional test specified in paragraph (c) of this AD.

(c) Within 5 days after September 23, 1992, and thereafter at intervals not to exceed 75 hours time-in-service, or immediately following any maintenance action where the power levers are moved with the airplane on jacks, until the requirements of paragraph (d) of this AD have been accomplished, conduct a functional test of the backup flight idle stop system for engine 1 and engine 2 by performing the following steps:

(1) Move both power levers to the "MAX" position.

(2) Turn the aircraft power select switch on.

(3) Open both "AIR/GROUND SYSTEM" circuit breakers CB0283 and CB0286 to simulate in-flight conditions with weight-off-wheels. Wait for at least 15 seconds, then move both power levers back toward the propeller reverse position with the flight idle gate triggers raised. Verify that the power lever for each engine cannot be moved below the flight idle position, even though the flight idle gate trigger on each power lever is raised.

(4) If the power lever can be moved below the flight idle position, prior to further flight, restore the backup flight idle stop system to the configuration specified in EMBRAER Service Bulletin 120–076–0009, Change No. 4, dated November 1, 1990, and perform a functional test.

Note 4: If the power lever can be moved below flight idle, this indicates that the backup flight idle stop system is inoperative.

(5) Move both power levers to the "MAX" position.

(6) Close both "AIR/GROUND SYSTEM" circuit breakers CB0283 and CB0286. Wait for at least 15 seconds, then move both power levers back toward the propeller reverse position with the flight idle gate triggers raised. Verify that the power lever for each engine can be moved below the flight idle position.

(7) If either or both power levers cannot be moved below the flight idle position, prior to further flight, inspect the backup flight idle stop system and the flight idle gate system, and accomplish either paragraph (c)(7)(i) or (c)(7)(ii) of this AD, as applicable:

(i) If the backup flight idle stop system is failing to disengage with weight-on-wheels, prior to further flight, restore the system to the configuration specified in EMBRAER Service Bulletin 120–076–0009, Change No. 4, dated November 1, 1990.

(ii) If the flight idle gate system is failing to open even though the trigger is raised, prior to further flight, repair in accordance with the EMBRAER Model EMB–120 maintenance manual.

(8) Turn the power select switch off. The functional test is completed.

New Requirements of This AD

(d) Modify the secondary flight idle stop system (SFISS), as specified by paragraph (d)(1), (d)(2), (d)(3), or (d)(4), as applicable, of this AD. Accomplishment of the modification constitutes terminating action for the requirements of this AD.

(1) For airplane serial number 120066, within 18 months or within 4,000 flight hours after the effective date of this AD, whichever occurs earlier: Modify the SFISS in accordance with Parts I and II of EMBRAER Service Bulletin 120–76–0015, Change No. 05, dated September 9, 1999.

(2) For certain airplanes listed in EMBRAER Service Bulletin 120–76–0018, Change No. 03, dated May 26, 2000, that HAVE NOT accomplished the actions specified in earlier revisions of that service bulletin: Within 18 months or within 4,000 flight hours after the effective date of this AD, whichever occurs earlier, modify the SFISS (including replacing the bolts, washers, nuts, and cotter-pins of the engine power control cable for the left and right engines with new components; replacing the flight idle lock assembly with a new assembly; and replacing certain other components with new components), in accordance with Part I of that service bulletin.

(3) For certain airplanes listed in EMBRAER Service Bulletin 120–76–0018, Change No. 03, dated May 26, 2000, that HAVE accomplished the actions specified in that service bulletin: Within 18 months or within 400 flight hours after the effective date of this AD, whichever occurs earlier, modify the SFISS (including an inspection to determine the type of bolt used to attach the power control cable end at the bellcrank in the left and right nacelles, and replacement of any protruding hex-head bolt with a new countersunk-head bolt), in accordance with Part II of that service bulletin.

Note 5: This AD references Service Bulletin 120–76–0018, Change No. 03, dated May 26, 2000, and Brazilian airworthiness directive 90–07–04R4, dated October 4, 1999, for applicability, inspection, and modification information. In addition, this AD specifies compliance-time requirements beyond those included in the Brazilian airworthiness directive or the service information. Where there are differences between the AD and previously referenced documents, the AD prevails.

(4) For airplanes listed in EMBRAER Service Bulletin 120–76–0022, Change No. 01, dated October 9, 2000: Within 18 months or within 4,000 flight hours after the effective date of this AD, whichever occurs earlier, modify the SFISS in accordance with Part I, II, III, or IV, as applicable, of that service bulletin.

Note 6: Accomplishment of the requirements of paragraph (d) of this AD does not remove or otherwise alter the requirement to perform the repetitive (400-flight-hour) CAT 8 task checks specified by the Maintenance Review Board.

Alternative Methods of Compliance

(e)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Atlanta Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

(2) Alternative methods of compliance, approved previously for paragraphs (a), (b), and (c) of AD 92–16–51, are considered to be approved as alternative methods of compliance with the inspection requirements of paragraphs (a), (b), and (c) of this AD. No alternative methods of compliance have been approved in accordance with AD 92–16–51 as terminating action for this AD.

Note 7: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 8: The subject of this AD is addressed in Brazilian airworthiness directive 90–07–04R4, dated October 4, 1999.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1239 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–116–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 767 series airplanes. This proposal would require removing the two existing escape ropes in the flight compartment; installing new escape ropes, bags, and placards; and replacing the nylon straps with new straps; as applicable. This action is necessary to ensure that flight crew members safely reach the ground from a flight compartment window in the event of an emergency evacuation. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by March 2, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–116–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–116–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Jim Cashdollar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2785; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–116–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–116–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received a report indicating that the escape ropes provided at the flight deck windows on certain Model 767 series airplanes are too short when the airplane is in a tail-tip condition (*i.e.*, airplane resting on one main landing gear (MLG), the engine on the side of the collapsed MLG, and the aft fuselage). The length of the end of the existing ropes is approximately 10½ to 12½ feet above the ground when the airplane is in a tail-tip condition. To establish the appropriate length of an escape rope, all conditions of a collapsed landing gear must be considered to determine how high the flight deck windows will be above the ground. When the length of the 767 escape ropes was established, it was assumed that the engine on the same side of the airplane as a collapsed MLG would shear off of the wing due to the weight of the airplane. However, service experience has shown that the engines on both sides of the airplane can remain attached when an MLG collapses. If this condition were to occur, the height of the flight deck windows would be higher than originally calculated, and thus, the escape ropes at the flight deck windows would be too short if a tail-tip condition occurs. This condition, if not corrected, could prevent flight crew members from safely reaching the ground from a flight compartment window in the event of an emergency evacuation.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 767–25A0265, dated May 27, 1999, which describes procedures for removing the two existing escape ropes in the flight compartment; installing new escape ropes, bags, and placards; and replacing

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the nylon straps with new straps; as applicable. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

There are approximately 321 Model 767 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 136 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $4,718 per airplane. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $649,808, or $4,778 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2000–NM–116–AD.

Applicability: Model 767 series airplanes, as listed in Boeing Alert Service Bulletin 767–25A0265, dated May 27, 1999; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To ensure that flight crew members safely reach the ground from a flight compartment window in the event of an emergency evacuation, accomplish the following:

Replacement

(a) Within 18 months after the effective date of this AD, do the actions specified in paragraphs (a)(1) and (a)(2) of this AD, as applicable, per Boeing Alert Service Bulletin 767–25A0265, dated May 27, 1999.

(1) For all airplanes: Remove the two existing escape ropes and install new escape ropes, bags, and placards, as applicable, in the flight compartment.

(2) For airplanes having serial numbers 1 through 107 inclusive; on which Boeing Service Bulletin 767–25–0149, dated March 7, 1991 has been accomplished; or on which neither Boeing Service Bulletin 767–25–0149, dated March 7, 1991, nor 767–25A0242, dated October 31, 1996, has been accomplished: Replace the nylon straps with new straps.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1238 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–178–AD]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB 2000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Saab Model SAAB 2000 series airplanes. This proposal would require a modification involving nondestructive test inspections of the 34 fastener holes in each rear wing spar, corrective action, if necessary, and cold working of the holes to increase fatigue life of the rear spar web. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent fatigue cracking, which could result in fuel leakage and reduced structural integrity of the wings.

DATES: Comments must be received by February 15, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–178–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–178–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Saab Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linkping, Sweden. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–178–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–178–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Luftfartsverket (LFV), which is the airworthiness authority for Sweden, notified the FAA that an unsafe condition may exist on certain Saab Model SAAB 2000 series airplanes. The LFV advises that, during fatigue tests, cracks have been detected at some fastener holes in the lower trailing edge support angles on both wings. This cracking condition, if not corrected, could result in fuel leakage and reduced structural integrity of the wing.

Explanation of Relevant Service Information

Saab has issued Service Bulletin 2000–57–037, dated April 13, 2000, which describes procedures for a modification involving nondestructive test inspections of the 34 fastener holes in each rear wing spar to detect discrepancies (including cracking, scratches, or other damage, and incorrect hole size) and cold working of the holes to increase fatigue life. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The LFV classified this service bulletin as mandatory and issued Swedish airworthiness directive 1–157, dated April 13, 2000, in order to assure the continued airworthiness of these airplanes in Sweden.

FAA's Conclusions

This airplane model is manufactured in Sweden and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the LFV has kept the FAA informed of the situation described above. The FAA has examined the findings of the LFV, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences Between Proposed Rule and Service Bulletin

Operators should note that, although the service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, this proposal would require the repair of those conditions to be accomplished in accordance with a method approved by either the FAA, or the LFV (or its delegated agent). In light of the type of repair that would be required to address the identified unsafe condition, and in consonance with existing bilateral airworthiness agreements, the FAA has determined that, for this proposed AD, a repair approved by either the FAA or the LFV would be acceptable for compliance with this proposed AD.

Cost Impact

The FAA estimates that 3 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 64 work hours per airplane to accomplish the proposed inspections and modification, and that the average labor rate is $60 per work hour. Required parts would be supplied by the manufacturer without cost to the operators. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $11,520, or $3,840 per airplane.

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The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Saab Aircraft AB: Docket 2000–NM–178–AD.

Applicability: Model SAAB 2000 series airplanes, certificated in any category, serial numbers –003 through –063 inclusive.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fuel leakage and reduced structural integrity of the wings due to fatigue cracking, accomplish the following:

Modification

(a) Except as required by paragraph (b) of this AD: Prior to the accumulation of 13,000 total flight cycles, accomplish the modification of the rear spar on both wings [including applicable nondestructive test inspections to detect discrepancies (including cracking, scratches, or other damage, and incorrect hole size) and cold working of fastener holes] in accordance with Saab Service Bulletin 2000–57–037, dated April 13, 2000.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Repair

(b) If any discrepancy is found during any inspection required by paragraph (a) of this AD, prior to further flight, repair in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, or the Luftfartsverket (LFV) (or its delegated agent). For a repair method to be approved by the Manager, International Branch, ANM–116, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and who will then send the requests and comments to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 4: The subject of this AD is addressed in Swedish airworthiness directive 1–157, dated April 13, 2000.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1237 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–290–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F.28 Mark 0070 and Mark 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to all Fokker Model F.28 Mark 0070 and Mark 0100 series airplanes, that currently requires revising the Airplane Flight Manual (AFM) to provide the flightcrew with instructions not to arm the liftdumper system prior to commanding the landing gear to extend. For Model F.28 Mark 0100 series airplanes, the existing AD also requires modification of the grounds of the shielding of the wheelspeed sensor wiring of the main landing gear (MLG) and installation of new electrical grounds for the wheelspeed sensor channel of the anti-skid control box of the MLG. The proposed AD would remove the previous revision of the AFM and would require a new limitation and a new warning. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent inadvertent deployment of the liftdumpers during approach for landing or reduced brake pressure during low speed taxiing, and consequent reduced controllability and performance of the airplane.

DATES: Comments must be received by February 15, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–290–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–290–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Fokker Services B.V., P.O. Box 231, 2150 AE Nieuw Vennep, the Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–290–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–290–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On September 21, 1999, the FAA issued AD 99–20–07, amendment 39–11337 (64 FR 52219, September 28, 1999), applicable to all Fokker Model F.28 Mark 0070 and Mark 0100 series airplanes, to require revising the Airplane Flight Manual (AFM) to provide the flightcrew with instructions not to arm the liftdumper system prior to commanding the landing gear to extend. For Model F.28 Mark 0100 series airplanes, the existing AD also requires modification of the grounds of the shielding of the wheelspeed sensor wiring of the main landing gear (MLG) and installation of new electrical grounds for the wheelspeed sensor channel of the anti-skid control box of the MLG. That action was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The requirements of that AD are intended to prevent electromagnetic interference generated by electrical wiring that runs parallel to the wheelspeed sensor wiring, which could result in inadvertent deployment of the liftdumpers during approach for landing or reduced brake pressure during low speed taxiing, and consequent reduced controllability and performance of the airplane.

Since Issuance of Previous Rule

Since the issuance of AD 99–20–07, the Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, reports another inadvertent deployment of the liftdumpers that occurred on a Fokker Model F.28 Mark 0100 series airplane. The pilot's report indicated that the flightcrew had armed the liftdumpers just after making the landing gear DOWN selection, whereupon the liftdumpers extended almost instantaneously. The RLD has issued Dutch airworthiness directive 1998–042/2, dated February 29, 2000, to ensure the continued airworthiness of these airplanes in the Netherlands. The Dutch airworthiness directive advises the flight crew not to arm the liftdumpers before the landing gear is down and locked.

FAA's Conclusions

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would supersede AD 99–20–07 to require revising the AFM by removing the previous revision which instructed the flightcrew not to arm the liftdumper system prior to commanding the landing gear to extend and by inserting a new limitation and a new warning not to arm the liftdumpers before the landing gear is down and locked in position. For Model F.28 Mark 0100 series airplanes, the proposed AD would continue to require modification of the grounds of the shielding of the wheelspeed sensor wiring of the MGL and installation of new electrical grounds for the wheelspeed sensor channel of the anti-skid control box of the landing gear.

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Cost Impact

There are approximately 123 airplanes of U.S. registry that would be affected by this proposed AD.

The modifications that are currently required by AD 99–20–07 take approximately 33 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts cost approximately $755 to $1,236 per airplane. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be between $336,405 and $395,568, or between $2,735 and $3,216 per airplane.

The revision to the AFM that is proposed in this AD would take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $7,380, or $60 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–11337 (64 FR 52219, September 28, 1999), and by adding a new airworthiness directive (AD), to read as follows:

Fokker Services B.V.: Docket 2000–NM–290–AD. Supersedes AD 99–20–07, Amendment 39–11337.

Applicability: All Fokker Model F.28 Mark 0070 and Mark 0100 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent inadvertent deployment of the liftdumper systems during the approach for landing or reduced brake pressure during low speed taxiing, and consequent reduced controllability and performance of the airplane, accomplish the following:

Restatement of Certain Requirements of AD 99–20–07

Corrective Actions

(a) For Model F.28 Mark 0100 series airplanes having serial numbers as listed in Fokker Service Bulletin SBF100–32–067, Revision 1, dated July 6, 1998: Within 6 months after November 2, 1999 (the effective date of AD 99–20–07, amendment 39–11337), modify the grounds of the shielding of the wheelspeed sensor wiring of the main landing gear (MLG) in accordance with part 1, 2, 3, or 4 of the Accomplishment Instructions of the service bulletin, as applicable.

Note 2: Modifications accomplished prior to November 2, 1999, in accordance with Fokker Service Bulletin SBF100–32–067, dated March 12, 1993, are considered acceptable for compliance with the requirements of paragraph (a) of this AD.

(b) For Model F.28 Mark 0100 series airplanes having serial numbers as listed in Fokker Service Bulletin SBF100–32–037, Revision 2, dated December 4, 1998: Within 12 months after November 2, 1999, install new electrical grounds for the wheelspeed sensor channel of the anti-skid control box of the MLG in accordance with part 1, 2, or 3 of the Accomplishment Instructions of the service bulletin, as applicable.

Note 3: Installations accomplished prior to November 2, 1999, in accordance with Fokker Service Bulletin SBF100–32–037, dated November 12, 1990, or Revision 1, dated November 16, 1998, are considered acceptable for compliance with the requirements of paragraph (b) of this AD.

New Actions Required by This AD

Revision of the Airplane Flight Manual

(c) Within 10 days after the effective date of this AD, revise the Limitations and Normal Procedures sections of the FAA-approved Airplane Flight Manual (AFM) in accordance with paragraphs (c)(1), (c)(2), (c)(3) and (c)(4) of this AD. This may be accomplished by inserting a copy of this AD into the appropriate sections of the AFM.

(1) Remove the following information from the Limitations section:

"LIFTDUMPER SYSTEM—DO NOT ARM THE LIFTDUMPER SYSTEM BEFORE LANDING GEAR DOWN SELECTION."

(2) Add the following information to the Limitations section in the Miscellaneous Limitations sub-section:

"FLIGHT CONTROLS—NORMAL OPERATION OF LIFTDUMPERS: DO NOT ARM THE LIFTDUMPER SYSTEM BEFORE LANDING GEAR IS DOWN AND LOCKED."

(3) Remove the following information from Section 5—Normal Procedures, sub-section Approach and Landing, after the subject Approach:

"BEFORE LANDING—WARNING: DO NOT ARM THE LIFTDUMPER SYSTEM BEFORE LANDING GEAR DOWN SELECTION. Selecting Landing Gear DOWN after arming the liftdumper system may result in inadvertent deployment of the liftdumpers, because the liftdumper arming test may be partially ineffective."

(4) Add the following information to Section 5—Normal Procedures, sub-section Approach and Landing, after the subject Approach:

"BEFORE LANDING— WARNING: DO NOT ARM THE LIFTDUMPER SYSTEM BEFORE LANDING GEAR IS DOWN AND LOCKED."

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 5: The subject of this AD is addressed in Dutch airworthiness directive 1998–042/2, dated February 29, 2000.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1236 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–303–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 777–200 series airplanes. This proposal would require repetitive detailed visual and ultrasonic inspections of the lower flange of the flaperon inboard support to find cracking, and corrective actions, if necessary. This proposal also would require a modification, which would terminate the repetitive inspections. This action is necessary to prevent fracture of the inboard support structure, which could result in an in-flight loss of the inboard flaperon, structural damage, and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by March 2, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–303–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–303–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Stan Wood, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2772; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–303–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–303–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Flight testing of certain Boeing Model 777–200 series airplanes showed that high engine thrust conditions during takeoff cause tremendous cyclic loads on the support structure of the inboard flaperon. Based on engineering analysis, fatigue cracks of the support structure could develop at approximately 4,000 flight cycles. Such fatigue cracking could result in fracture of the inboard support structure, in-flight loss of the inboard flaperon, significant damage to the surrounding structure, and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999, which describes procedures for detailed visual and ultrasonic inspections of the lower flange of the flaperon inboard support to find cracking, and corrective actions if cracking is found. The corrective actions consist of accomplishment of the terminating action in Part 2 of the service bulletin. The terminating action includes, but is not limited to, a high frequency eddy current inspection to find cracks of the aft holes that attach the failsafe strap to the lower flange, oversizing of the holes if cracks are found, and installation of a failsafe strap. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions

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specified in the service bulletin described previously, except as discussed below.

Differences Between Service Bulletin and This Proposed AD

While the effectivity listing of the service bulletin includes airplanes having line numbers (L/N) 2 through 9 inclusive; this proposed AD would apply to airplanes having L/N's 1 through 9 inclusive. The FAA has determined that the subject area on the airplane with L/N 1 is identical to the subject areas on the Model 777–200 series airplanes listed in the service bulletin; so the airplane with L/N 1 is also subject to the identified unsafe condition.

Although the service bulletin specifies that the manufacturer may be contacted for instructions on repair of certain conditions, this proposed AD would require the repair of those conditions to be accomplished per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Cost Impact

There are approximately 9 airplanes of the affected design in the worldwide fleet.

The FAA estimates that 1 airplane of U.S. registry would be affected by this proposed AD.

It would take approximately 3 work hours per airplane to accomplish the proposed inspections, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspections proposed by this AD on U.S. operators is estimated to be $180 per airplane, per inspection cycle.

It would take approximately 6 work hours per airplane to accomplish the proposed terminating action, at an average labor rate of $60 per work hour. Required parts would cost approximately $2,932 per airplane. Based on these figures, the cost impact of the terminating action proposed by this AD on U.S. operators is estimated to be $3,292 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 2000–NM–303–AD.

Applicability: Model 777–200 series airplanes, line numbers (L/N) 1 through 9 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance per paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fracture of the inboard support structure of the flaperon, which could result in an in-flight loss of the inboard flaperon, structural damage, and consequent reduced controllability of the airplane, accomplish the following:

Repetitive Inspections

(a) Before the accumulation of 4,000 total flight cycles, or within 90 days after the effective date of this AD, whichever occurs later: Do a detailed visual and an ultrasonic inspection of the lower flange of the flaperon inboard support to find cracks per Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999.

(1) If no cracking is found: Repeat the applicable inspections thereafter at intervals not to exceed 300 flight cycles until accomplishment of the terminating action specified in paragraph (b) of this AD.

(2) If any cracking is found, before further flight, do the terminating action required by paragraph (b) of this AD, except, where the service bulletin specifies to contact Boeing for instructions, before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

Terminating Action

(b) On or before the accumulation of 8,000 total flight cycles, or within 1,200 flight cycles after the effective date of this AD, whichever occurs later: Do the terminating action (a high frequency eddy current inspection to find cracks of the aft holes that attach the failsafe strap to the lower flange, oversizing of the holes if cracks are found, and installation of a failsafe strap), per Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999. Accomplishment of this paragraph terminates the repetitive inspections required by paragraph (a) of this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle ACO, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(d) Special flight permits may be issued per sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1235 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 807

[Docket No. 00N–1625]

Medical Devices; Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations under which FDA may rescind a decision issued under the Federal Food, Drug, and Cosmetic Act (the act) that a device is substantially equivalent to a legally marketed device, and, therefore, may be marketed. In addition, under this proposal, a premarket notification (commonly known as a "510(k)") holder may request administrative review of a proposed rescission action. This proposed rule is being issued in order to standardize the procedures for considering rescissions.

DATES: Submit written comments by April 16, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device Amendments (Public Law 94–295) (the amendments) to the act (21 U.S.C. 301 *et seq.*) were enacted on May 28, 1976. Among other things, the amendments directed FDA to issue regulations classifying all medical devices into one of three regulatory control categories. The classification depends upon the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of the device.

Under section 513(a)(1)(A) of the act (21 U.S.C. 360c(a)(1)(A)), class I devices are subject to a comprehensive set of regulatory provisions applicable to all classes of devices, e.g., registration and listing, prohibitions against adulteration and misbranding, and good manufacturing practice requirements. A class I device is exempt from the premarket notification requirements of the act unless it is intended for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury under section 510(l) of the act (21 U.S.C. 360(l)). Class II devices are subject to special controls as well as general controls. These special controls may consist of performance standards, postmarket surveillance, patient registries, FDA guidelines, or other appropriate controls under section 513(a)(1)(B) of the act. Class III devices require premarket approval (PMA) or a completed product development protocol by FDA before they may be marketed, unless they are class III devices for which we have not called for PMA's under section 515(b) of the act (21 U.S.C. 360e(b)).

II. Premarket Notification Requirements

Section 510(k) of the act requires each person who is required to register and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k).

Throughout this proposal, we use the following terms:

1. The "510(k) submitter."—the person who submitted the 510(k) to the FDA.

2. The "510(k) holder"—the person who possesses the rights to market the device that is the subject of a 510(k) substantial equivalence order. (The 510(k) submitter and the 510(k) holder may or may not be the same person.)

3. The "510(k) holder of record"—the person whom FDA has on file as being the 510(k) holder.

The proposed rule adds these definitions to 21 CFR 807.3.

There may be instances when 510(k) ownership has changed without FDA's knowledge. In the event of a proposed rescission, FDA would provide notice to the 510(k) holder of record. FDA would attempt to notify the holder of record by registered letter. FDA would also post notice of a proposed rescission on FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. To protect the privacy of the 510(k) holder, only the proposed rescission would be listed; the factual basis and reasons for the rescission would not be posted on CDRH's home page on the Internet.

Under the 510(k) process, the 510(k) submitter may claim that its new device is substantially equivalent to a legally marketed class I or class II device or to a preamendments class III device that is not yet required to be the subject of an approved premarket approval application. If, after reviewing the 510(k), the agency determines that the device is substantially equivalent to the legally marketed device (as defined in 21 CFR 807.92(a)(3)), the agency will issue an order permitting the 510(k) submitter to market its device without the need for the more rigorous premarket approval under section 515 of the act.

The criteria the agency must use to determine substantial equivalence are in section 513(i) of the act. Section 513(i) of the act defines substantial equivalence to mean that the device has the same intended use as the predicate device and that FDA, by order, has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)—(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by FDA, that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the legally marketed device.

The statute allows 510(k) marketing clearance only for devices that FDA determines are comparable in safety and effectiveness to a legally marketed device. New devices that are not substantially equivalent must remain in class III and meet the premarket approval requirements under section 515 of the act before they can be marketed, unless the device is reclassified under section 513(f) of the act.

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III. Authority to Rescind

On October 25, 1994, the Health Industry Manufacturers Association (HIMA) submitted a petition [Docket No. 94A–0388] to FDA in which they requested that FDA issue an advisory opinion stating that the act does not provide authority for FDA to withdraw a premarket notification (510(k)) order. In the alternative, HIMA requested that, if FDA determined that it did have the authority to withdraw a premarket notification order, FDA should: (1) Refrain from rescinding such a decision without establishing procedures assuring the 510(k) holder due process rights; (2) provide the 510(k) holder an opportunity for an informal hearing under section 201(x) (formerly 201(y)) of the act (21 U.S.C. 321(x)) before issuing a rescission order; and (3) issue a regulation providing the 510(k) holder with the opportunity to request a hearing to challenge a proposed withdrawal.

On September 11, 1995, FDA issued an interim response to the HIMA petition. In this interim response, FDA said that it intended to issue a proposed rule specifying the authority for rescinding a substantial equivalence decision as well as the grounds under which such decisions can be made. The interim response also stated that, pending the completion of this rulemaking process, FDA would only rescind, or propose to rescind, substantial equivalence orders in cases involving: (1) A serious adverse risk to public health or safety, (2) data integrity or fraud, or (3) other compelling circumstances. On September 22, 1997, FDA issued a final response to the petition that restated the policy established in the interim response.

Although the act does not expressly address rescission of substantial equivalence orders, section 513(f) and (i) of the act indicate that rescission is consistent with FDA's authority under the act to allow marketing of a device under the 510(k) process only if the device is substantially equivalent to a legally marketed device.

FDA has authority under its administrative procedure regulations to reconsider the issuance of substantial equivalence orders § 10.33(a) and (h) (21 CFR 10.33(a) and (h)). Section 10.33(a) states the "Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person." Section 10.33(h) states the "Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken." Both § 10.33(a) and (h) provide the agency with authority to reconsider and rescind an order determining a device to be substantially equivalent.

Section 10.75 (21 CFR 10.75) also provides the agency with authority for supervisory review of decisions made by an employee other than the Commissioner of Food and Drugs (the Commissioner). This internal review can be undertaken to resolve agency disputes, review policy and unusual situations affecting public interest, or as required by delegations of authority. Section 10.75 supports the agency's authority to correct the decisions that it determines were made in error by employees other than the Commissioner.

Case law also supports FDA's authority to correct inappropriate decisions even in the absence of explicit statutory or regulatory authority. In *American Therapeutics Inc.* v. *Sullivan*, 755 F. Supp. 1, 2 (D.D.C. 1990), FDA rescinded a drug approval that had been issued by mistake. The court held that, although there were no regulations or statutory provisions that expressly contemplated rescission of an approval by mistake, the agency must be given latitude to correct mistakes.

The Supreme Court has also recognized an implied authority in agencies to reconsider and rectify errors, even if the applicable statute and regulations do not expressly provide for such reconsideration. For example, in concluding that the Interstate Commerce Commission could order a refund to correct a prior error, the Supreme Court stated that "[a]n agency, like a court, can undo what is wrongfully done by virtue of its order." *United Gas Improvement Co.* v. *Callery Properties, Inc.*, 382 U.S. 223, 229 (1965). See also *American Trucking Association* v. *Frisco Trans.*, 358 U.S. 133, 145 (1958) ("the presence of authority in administrative officers and tribunals to correct [inadvertent ministerial] errors has long been recognized—probably so well recognized that little discussion has ensued in the reported cases."); *Copley* v. *Elliot*, 948 F. Supp. 586, 589 (W.D. Va. 1996) ("[i]t is generally always within the power of a government agency to correct its mistakes.").

Other courts have similarly recognized this implied authority, *Iowa Power and Light Co.* v. *United States*, 712 F.2d 1292, 1294–97 (8th Cir. 1983) (ICC could retroactively impose higher tariff to correct legal error), cert. denied, 466 U.S. 949 (1984); *Bookman* v. *United States*, 453 F.2d 1263, 1265 (Ct. Cl. 1972) allowing agency to reconsider decisions in absence of statutory or regulatory authorization after noting general rule that "[e]very tribunal, judicial or administrative, has some power to correct its own errors or otherwise appropriately to modify its judgment, decree, or order") (quoting 2 K. Davis, Administrative Law Treatise, section 18.09 (1958)).

Moreover, some courts have held that FDA has a duty to correct errors if it learns its prior position was incorrect. See *United States* v. *60 28-Capsule Bottles,*. 211 F. Supp. 207, 215 (D. N.J. 1962) (FDA has a duty to change its position with reference to the efficacy of a drug if it subsequently learns that its original position was in error); see also *Bentex Pharmaceuticals Inc.* v. *Richardson*, 463 F.2d. 363, 368 n. 17 (4th Cir. 1972) *rev'd Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1979) (noting FDA not estopped from alleging product was a "new drug," even though the agency had given the opinion that similar drugs were not "new drugs").

IV. Bases for Proposing Rescission of a 510(k) Substantial Equivalence Decision

FDA examines a vast array of device technologies each year under the premarket notification (510(k)) process. Under the 510(k) process, each submitter has the burden of demonstrating that its device is at least as safe and effective as a legally marketed device. If FDA discovers that a premarket notification submission does not meet the criteria of substantial equivalence and the submission was cleared in error, FDA will issue a registered letter to the 510(k) holder of record proposing to rescind the order of substantial equivalence. FDA will also post notice of the proposed rescission on CDRH's home page on the Internet.

Under proposed § 807.103, FDA may propose rescission of a substantial equivalence decision if one or more of the following criteria are met. FDA believes that, if any one of these criteria is met, there is no longer reasonable assurance that the device is at least as safe and effective as a legally marketed device.

1. The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence.

2. Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

3. (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or (ii) a court has issued a judicial order determining the legally marketed device(s), on which the substantial equivalence determination was based, to be misbranded or adulterated.

4. The premarket notification contained or was accompanied by an untrue statement of material fact.

5. The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable Institutional Review Board regulations (21 CFR part 56) or informed consent regulations (21 CFR part 50) in a way that the rights or safety of human subjects were not adequately protected.

6. The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under 21 CFR 812.119.

These would be bases to rescind because information in the 510(k) is incorrect, incomplete, unreliable, or not evaluated properly by FDA in accordance with section 513(f) and (i) of the act.

V. Procedures for Rescinding a 510(k) Substantial Equivalence Order

Before issuing an order rescinding a 510(k) substantial equivalence decision, FDA would notify the 510(k) holder of record of its intent to rescind by registered mail. This notice would state the facts upon which the action is based and would notify the 510(k) holder of record of an opportunity for a hearing under part 16 (21 CFR part 16). The notice would include the time within which a hearing may be requested and the name, address, and telephone number of the FDA employee to whom any request for a hearing is to be addressed. FDA would also post notice of a proposed rescission on CDRH's home page on the internet. The Internet site will only state that a rescission of the 510(k) is proposed and information about the hearing and will not state the facts upon which the action is based. Because FDA may be unaware that ownership of a 510(k) has changed, the notification by Internet site would serve as an additional means of assuring that the current 510(k) holder has notice.

If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with §§ 16.24(d), 16.60(h) and 10.19, waive, suspend, or modify any part 16 procedure or procedures stated in part 807. Ordinarily, the amount of time specified in the notice for requesting a hearing will be not less than 3 working days. FDA ordinarily would provide notice by registered mail. Under circumstances presenting the need for immediate action, FDA may, for example, attempt to contact the 510(k) holder by telephone instead of registered mail.

If a 510(k) holder fails to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing, FDA will consider the failure to request a hearing a waiver of such hearing and FDA will issue a letter rescinding the order determining substantial equivalence.

If, after a part 16 hearing is held, the agency decides to proceed with the rescission of an order determining substantial equivalence, FDA will issue to the 510(k) holder of record an order rescinding the order determining substantial equivalence. The rescission order will state each ground for rescinding the substantial equivalence determination. FDA will give the public notice of an order rescinding a determination of substantial equivalence. The notice will be placed on CDRH's home page on the Internet.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities, if a rule would have a significant economic impact on a substantial number of small entities. The proposed rule will not have a significant economic impact on a substantial number of small entities. FDA has only proposed five rescissions from 1997 through 1999 and one rescission through May 2000. FDA does not believe that this level of activity represents a significant impact on a substantial number of small entities. In addition, the rule will be applied only when the criteria for rescission are met. The agency therefore certifies that this rule, if finalized, will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

VIII. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by April 16, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m. Monday through Friday.

IX. Paperwork Reduction Act of 1995

FDA has tentatively determined that this proposed rule contains no collections of information. Therefore, clearance from the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner

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of Food and Drugs, it is proposed that 21 CFR parts 16 and 807 be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 807.103 to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 807.103 relating to rescission of substantially equivalent orders and rescission appeal procedures.

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

3. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

4. Section 807.3 is amended by adding new paragraphs (t), (u), and (v) to read as follows:

§ 807.3 Definitions.

* * * * *

(t) *510(k) submitter* means the person who submitted the 510(k) to FDA.

(u) *510(k) holder* means the person who possesses the rights to market a device that is the subject of 510(k) substantial equivalence order.

(v) *510(k) holder* of record means the person FDA has on file as being the holder of the 510(k).

5. Section 807.103 is added to subpart E to read as follows:

§ 807.103 Rescission of 510(k) substantially equivalent orders and rescission appeal procedures.

(a) *Grounds for rescinding a substantially equivalent order.* FDA may issue an order rescinding a determination of substantial equivalence under this section, if FDA determines that any one of the following grounds exist:

(1) The premarket notification does not satisfy the criteria under § 807.100(b)(1) or (b)(2) for a determination of substantial equivalence.

(2) Based on new safety or effectiveness information, the device is not substantially equivalent to a legally marketed device.

(3) (i) FDA or the 510(k) holder has removed from the market, for safety and effectiveness reasons, one or more legally marketed device(s) on which the substantial equivalence determination was based, or

(ii) A court has issued a judicial order determining the legally marketed device(s) on which the substantial equivalence determination was based to be misbranded or adulterated.

(4) The premarket notification contained or was accompanied by an untrue statement of material fact.

(5) The premarket notification included or should have included information about clinical studies and these clinical studies failed to comply with applicable institutional review board regulations (part 56 of this chapter) or informed consent regulations (part 50 of this chapter) in a way that the rights or safety of human subjects were not adequately protected.

(6) The premarket notification contained clinical data submitted by a clinical investigator who has been disqualified under § 812.119 of this chapter.

(b) *Notice of proposed rescission and opportunity for a hearing.* Before issuing an order rescinding a substantial equivalence order, FDA will issue the 510(k) holder of record a notice of the agency's intent to rescind the 510(k) by registered letter, together with a notice of an opportunity for an informal hearing under part 16 of this chapter. FDA will also post notice of a proposed rescission on the FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with §§ 16.24(d), 16.60(h), and 10.19 of this chapter, waive, suspend, or modify any part 16 procedure and, in accordance with this section, waive, suspend, or modify any part 807 procedure.

(c) *Failure to request a hearing.* If a 510(k) holder fails to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing, FDA will consider the failure to request a hearing a waiver of such hearing and FDA will issue a letter rescinding the order determining substantial equivalence.

(d) *Rescission order.* If the 510(k) holder does not request a hearing or if, after proceedings in accordance with this part and part 16 of this chapter are completed, the agency decides to proceed with the rescission of an order determining substantial equivalence, FDA will issue to the 510(k) holder of record an order rescinding the order determining substantial equivalence. The rescission order will state each ground for rescinding the substantial equivalence determination.

(e) *Public notice of final action.* FDA will give the public notice of the order rescinding a determination of substantial equivalence. If FDA determines not to finalize a proposed rescission, FDA will also give the public notice of this determination. These notices will be placed on FDA's home page on the Internet.

Dated: January 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1128 Filed 1–12–01; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 136, 141, and 143

[FRL–6918–1]

RIN 2040–AD59

Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing action on a methods update rule that approves revised versions of test procedures (*i.e.*, analytical methods) for the determination of chemical, radiological, and microbiological pollutants and contaminants in wastewater and drinking water. The revisions concern methods published by one or more of the following organizations: American Society for Testing Materials (ASTM), United States Geological Survey (USGS), United States Department of Energy (DOE), American Public Health Association (APHA), American Water Works Association (AWWA), and Water Environment Federation (WEF). Previously approved versions of the methods remain approved. This rule will give the analytical community a larger selection of analytical methods. Today's action also corrects typographical errors and updates references where appropriate.

DATES: Written comments must be received by March 19, 2001.

ADDRESSES: You may submit written comments either by mail or electronically. Send comments to the Methods Update Comment Clerk (W–99–21), U.S. Environmental Protection Agency, Water Docket, MC–4101, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460. Submit electronic comments to *OW-Docket@epa.gov*. Please submit copies of any references cited in your comments. EPA would appreciate an original and 3 copies of your comments and enclosures (including references).

This **Federal Register** document is also available on the Internet at: *http://www.epa.gov/fedrgstr*. The record for this rulemaking has been established under docket number W–99–21. Supporting documents (including references and methods cited in this notice) are available for review at the U.S. Environmental Protection Agency, Water Docket, East Tower Basement, Room EB57, 401 M Street, SW., Washington, DC 20460. For access to the docket materials, call 202/260–3027 on Monday through Friday, excluding Federal holidays, between 9 a.m. and 3:30 p.m. Eastern Daylight Standard Time for an appointment.

Copies of final methods published by ASTM are available for a nominal cost through American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. Copies of final methods published by USGS are available for a nominal cost through the United States Geological Survey, U.S. Geological Survey Information Services, Box 25286, Federal Center, Denver, CO 80225–0425. Copies of final methods published by DOE are available for a nominal cost through the Environmental Measurements Laboratory, U.S. Department of Energy, 376 Hudson Street, New York, NY 10014–3621. Copies of Standard Methods are available for a nominal cost from the American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For information regarding wastewater methods contact Dr. Maria Gomez-Taylor, Engineering and Analysis Division (4303), USEPA Office of Science and Technology, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460 (e-mail: Gomez-Taylor.Maria@epa.gov). For information regarding drinking water methods contact Dr. Richard Reding, Office of Ground Water and Drinking Water, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268 (e-mail: Reding.Richard@epa.gov).

SUPPLEMENTARY INFORMATION: We are proposing to approve revisions to the Guidelines Establishing Test Procedures for the Analysis of Pollutants Under the Clean Water Act; National Primary Drinking Water Regulations; and National Secondary Drinking Water Regulations; Methods Update. Elsewhere in today's **Federal Register**, the Agency is promulgating this rule as a direct final rule without prior proposal because we view these as non-controversial revisions and do not expect adverse comments. We want to allow immediate use of the methods for compliance monitoring, and believe that it is in the public interest to do so. For further information, please see the information provided in the direct final rule which is located in the "Rules and Regulations" section of this **Federal Register** publication.

If EPA does not receive adverse comment, we will not take further action on this proposal. If we receive adverse comment, we will withdraw the direct final rule (or the distinct amendment, paragraph, or section to which comments apply) and it (they) will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in making comments must do so at this time. For the various statutes and executive orders that require findings for rulemaking, EPA incorporates the findings from the direct final rulemaking into this companion notice for the purpose of providing public notice and opportunity for comment.

List of Subjects

40 CFR Part 136

Environmental protection, Analytical methods, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 141

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 143

Environmental protection, Chemicals, Incorporation by reference, Indian-lands, Water supply.

Dated: December 11, 2000.

Carol M. Browner,

Administrator.

[FR Doc. 01–179 Filed 1–12–01; 8:45 am]

BILLING CODE 6560–60–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA 00–8633]

RIN 2127–AH96

Federal Motor Vehicle Safety Standards—Motor Vehicle Brake Fluids

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes technical modifications in two of the tests included in our standard on brake fluid, *i.e.*, the evaporation test and the corrosion test. The purpose of the modifications would be to improve the repeatability and reproducibility of the tests. This document also requests comments concerning retention of the evaporation test. A committee of the Society of Automotive Engineers, which originally developed the test, recently voted to delete the test from its standard on brake fluid. While we have tentatively concluded that the test should remain in our standard, we are requesting comments on that issue.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: You should mention the docket number of this document in your comments and submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590. Alternatively, you may submit your comments to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on "Help & Information" or "Help/Info" to obtain instructions for filing the document electronically. (This website also enables you to view the materials in the docket for this rulemaking.) You may call Docket Management at 202–366–9324. You may visit the Docket from 10 a.m. to 5 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: *For legal issues:* Edward Glancy, Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590 (202–366–2992).

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For other issues: Sam Daniel, Office of Crash Avoidance Standards, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590 (202–366–4921).

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I. Background

Safety Standard No. 116, *Motor Vehicle Brake Fluids,* specifies requirements for fluids for use in hydraulic brake systems of motor vehicles, containers for these fluids, and labeling of the containers. The purpose of the standard is to reduce failures in the hydraulic braking systems of motor vehicles which may occur because of the manufacture or use of improper or contaminated fluid.

Among the requirements of Standard No. 116 are ones addressing the evaporation and corrosiveness of brake fluid. Both of these characteristics of brake fluid are important for the safe and effective operation of vehicles equipped with hydraulic brake systems. For example, if brake fluid evaporates, fluid volume is reduced, "vapor locking" can occur, and reduced braking performance or brake failure can occur. Similarly, if brake fluid causes corrosion of brake system components, brake fluid leaks can result, with effects similar to that of evaporation.

In administering Standard No. 116, we have identified several modifications in the standard's evaporation and corrosion tests that we believe would improve repeatability and reproducibility.[1] Those modifications, which we are proposing to incorporate in the standard, are discussed in the sections which follow.

[1] In order for a test to have good repeatability, there must not be undue variability in results when the same test is replicated at the same site. In order for a test to have good reproducibility, there must not be undue variability in results when the same test is replicated at different sites.

II. Proposal

A. Evaporation Test

Standard No. 116 specifies various performance requirements relating to evaporation that must be met when brake fluid is tested according to a specified procedure that involves heating the brake fluid in an oven for an extended period of time. Among other things, the loss by evaporation must not exceed 80 percent by weight. See S5.1.8 and S6.8 of the standard.

For a number of years, the agency has been concerned that the evaporation test may allow too much variability in test results. Because of this, we sponsored a study titled "Evaporation Test Variability Study," which was published in May 1993. The study sought to identify and evaluate parameters of the brake fluid evaporation test procedure of Standard No. 116 that influence the high variability of results between laboratories. It also sought to develop procedural improvements to increase the precision and reproducibility of brake fluid evaporation measurements. This included validating procedural modifications by an interlaboratory round robin program using four designated brake fluids.

The study identified four means by which test result variability could be reduced: (1) Using a rotating shelf in the oven with a 6 rpm sample rotation, (2) specifying the location of the shelf supporting the sample within the oven, (3) controlling the oven temperature monitoring point, and (4) using oven calibration fluid for purposes of oven standardization. We are placing a copy of the study in the docket.

After we published the study, the Society of Automotive Engineers (SAE) committee on brake fluids initiated work to consider revising its evaporation test procedure to address these points. The SAE evaporation test procedure is set forth as part of Motor Vehicle Brake Fluid-SAE J1703 JAN95. The SAE committee developed a draft procedure that uses a rotating shelf oven, defines shelf placement, and includes temperature monitoring. The committee did not reach agreement on an oven calibration fluid because of concerns about lot variability.

More recently, however, the SAE committee voted to eliminate the evaporation test from its standard. Members of the committee believed that the requirement is outdated. The test was developed at a time when brake fluids did not have as good resistance to evaporation as today's brake fluids, and vehicle brake fluid systems were not sealed. Members of the committee also believed that the evaporation test is redundant with the boiling point test, which evaluates similar brake fluid properties.

Particularly given that the evaporation test included in Standard No. 116 was originally developed by SAE, we have considered, in light of SAE's action to delete the test from its standard, whether the test should be retained in our standard. We have tentatively concluded that the evaporation test should be retained in Standard No. 116. We are concerned that even though today's brake fluids may well have better resistance to evaporation than those in use when the test was originally developed, deletion of the test from Standard No. 116 could permit the introduction of inferior brake fluids into the United States market. Even if current brake fluid manufacturers would be unlikely to introduce such products, such introduction could come from new market entrants. Accordingly, we have tentatively decided to retain the evaporation test in Standard No. 116. We are, however, requesting comments on this issue.

Assuming that the evaporation test is retained in Standard No. 116, we believe it is appropriate to improve the repeatability and reproducibility of the test. While we believe there are unresolved technical issues concerning oven calibration fluid, we believe that the repeatability and reproducibility of the evaporation test can be improved by adopting the other means for reducing test result variability that were identified by the NHTSA-sponsored report and included in the SAE committee draft procedure. Accordingly, we are proposing to amend the test procedure to specify use of a rotating shelf oven, define shelf placement, and specify temperature monitoring.

We request comments on whether there are any other modifications to the evaporation test that would improve repeatability and reproducibility. Depending on the comments, we may, in the final rule, adopt additional modifications to the current test procedure and/or make changes in the specific modifications we are proposing.

B. Corrosion Test

Standard No. 116's corrosion test involves placing six metal strips (steel, tinned iron, cast iron, aluminum, brass and copper) in a standard brake wheel cylinder cup in a test jar, immersing the entire assembly in the brake fluid being tested, and then heating the fluid for an extended period of time. The metal strips and wheel cylinder cup represent the materials that comprise brake system components that are in contact with brake fluid (master cylinders, brake lines, caliper pistons, wheel cylinders, etc.).

A variety of performance requirements must be met at the end of the corrosion test procedure. Among other things, the metal strips are examined for weight change, which must not exceed specified percentages. See S5.1.6 and S6.6 of the standard.

While we do not have as much information concerning variability of the corrosion test as we do for the evaporation test, we have identified a change in the specification concerning how the metal strips are prepared prior to testing that we believe would improve repeatability and reproducibility. The standard currently specifies that each of the strips, other than the tinned iron strips, is to be abraded with wetted silicon carbide paper grit No. 320A until all surface scratches, cuts and pits are removed, and then polished with grade 00 steel wool.[2] We believe that less variability would result if the strips were further abraded with wetted silicon carbide paper grit No. 1200 instead of being polished with grade 00 steel wool, and if a visual acuity requirement for evaluating the presence of surface scratches, cuts and pits were specified.

The steel wool may produce slight surface irregularities due to interaction with dissimilar metals that the No. 1200 silicon carbide paper would not. The visual acuity requirement would ensure removal of all surface scratches, cuts and pits that are visible to an observer having corrected visual acuity of 20/40 (Snellen ratio) at a distance of 300 mm (11.8 inches).

[2] Tinned iron strips are not abraded or polished during preparation for corrosion testing because the tin coating is very thin and the test strips are highly polished to begin with.

III. Effective Date

We are proposing to make the amendments proposed in this document effective one year after publication of a final rule in the **Federal Register**.

IV. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document is not economically significant. It was not reviewed by the Office of Management and Budget under E.O. 12866, "Regulatory Planning and Review."

The proposed amendments would not affect the stringency of Standard No. 116, but would instead improve the repeatability and reproducibility of the standard's evaporation and corrosion tests. This would facilitate both the manufacturers' efforts in certifying their brake fluid and the agency's efforts in enforcing the standard.

The costs of the proposed amendments would be minimal. We estimate that there are five to 10 brake fluid manufacturers that provide brake fluid for the United States market, including OEM and aftermarket brake fluid, and a somewhat larger number of packagers of brake fluid. There are also as many as five independent organizations with brake fluid testing capability.

Each manufacturer, packager and organization that tested brake fluid would likely need to upgrade at least one oven so that it has a rotating shelf. We estimate the cost of modifying an existing oven at approximately $200. The cost of a new oven, which has a life expectancy of 10 to 20 years, is approximately $3,000.

Any change in cost of conducting an evaporation test or corrosion test would be so minimal as to be nonquantifiable. Therefore, the proposed rule is unlikely to result in any change in the cost of brake fluid.

B. Regulatory Flexibility Act

We have considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. § 601 *et seq.*) I hereby certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required for this action.

As discussed above, the proposed amendments would not affect the stringency of Standard No. 116, but would instead make technical modifications in the standard's evaporation test and corrosion test to improve repeatability and reproducibility. Any change in cost of conducting an evaporation test or corrosion test would be so minimal as to be nonquantifiable, and the proposed rule is unlikely to result in any change in the cost of brake fluid. Therefore, the proposed amendments would not have any significant economic impacts on small businesses, small organizations or small governmental jurisdictions.

C. National Environmental Policy Act

NHTSA has analyzed this proposed amendment for the purposes of the National Environmental Policy Act and determined that it would not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

The agency has analyzed this proposal in accordance with the principles and criteria set forth in Executive Order 13132 and has determined that it does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The proposed rule would have no substantial effects on the States, or on the current Federalism-State relationship, or on the current distribution of power and responsibilities among the various local officials.

E. Unfunded Mandates Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). The proposed rule would not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually.

F. Executive Order 12778 (Civil Justice Reform)

This proposed rule would not have any retroactive effect. Under section 49 U.S.C. 30103, whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. 49 U.S.C. 30161 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

G. Paperwork Reduction Act

This rulemaking action does not include any collections of information.

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H. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

I. Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

—Have we organized the material to suit the public's needs?
—Are the requirements in the rule clearly stated?
—Does the rule contain technical language or jargon that is not clear?
—Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
—Would more (but shorter) sections be better?
—Could we improve clarity by adding tables, lists, or diagrams?
—What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this NPRM.

J. Executive Order 13045

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental, health or safety risk that NHTSA has reason to believe may have a disproportionate effect on children. This regulatory action does not meet either of those criteria.

K. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) requires NHTSA to evaluate and use existing voluntary consensus standards [3] in its regulatory activities unless doing so would be inconsistent with applicable law (*e.g.*, the statutory provisions regarding NHTSA's vehicle safety authority) or otherwise impractical. We note that the current evaporation and corrosion tests of Standard No. 116 are based on an SAE recommended practice. The proposed amendments, which would make modifications in those tests, are based on a draft procedure developed by an SAE committee.

[3] Voluntary consensus standards are technical standards developed or adopted by voluntary consensus standards bodies. Technical standards are defined by the NTTAA as "performance-based or design-specific technical specifications and related management systems practices." They pertain to "products and processes, such as size, strength, or technical performance of a product, process or material."

V. Submission of Comments

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESS**.

Comments may also be submitted to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on "Help & Information" or "Help/Info" to obtain instructions for filing the document electronically.

How Can I Be Sure That my Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR Part 512.)

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date. If Docket Management receives a comment too late for us to consider it in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How Can I Read the Comments Submitted by Other People?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Docket Management System (DMS) Web page of the Department of Transportation (http://dms.dot.gov/).

(2) On that page, click on "search."

(3) On the next page (*http://dms.dot.gov/search/*), type in the four-digit docket number shown at the beginning of this document. Example: If the docket number were "NHTSA–1998–1234," you would type "1234." After typing the docket number, click on "search."

(4) On the next page, which contains docket summary information for the docket you selected, click on the desired comments. You may download the comments.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, we propose to amend 49 CFR Part 571 as set forth below.

1. The authority citation for Part 571 would continue to read as follows:

Authority. 49 U.S.C. 322, 30111, 30115, 30117 and 30166; delegation of authority at 49 CFR 1.50.

2. Section 571.116 would be amended by:

a. revising S6.6.3(e);
b. in S6.6.4(a), revising the first and third sentences;
c. revising S6.8.2(b); and
d. in S6.8.3, revising the fourth sentence and adding three new sentences after the fourth sentence.

The revised and added paragraphs would read as follows:

§ 571.116 Standard No. 116; Motor vehicle brake fluids.

* * * * *

S6.6.3 * * *

* * * * *

(e) *Supplies for polishing strips.* Waterproof silicon carbide paper, grit No. 320A and grit 1200; lint-free polishing cloth.

* * * * *

S6.6.4 * * *

(a) * * * Except for the tinned iron strips, abrade corrosion test strips on all surface areas with 320A silicon carbide paper wet with ethanol (isopropanol when testing DOT 5 SBBF fluids) until all surface scratches, cuts and pits visible to an observer having corrected visual acuity of 20/40 (Snellen ratio) at a distance of 300 mm (11.8 inches) are removed. * * * Except for the tinned iron strips, further abrade the test strips on all surface areas with 1200 silicon carbide paper wet with ethanol (isopropanol when testing DOT 5 SBBF fluids), again using a new piece of paper for each different type of metal. * * *

* * * * *

S6.8.2 * * *

* * * * *

(b) *Oven.* A top-vented gravity-convection oven equipped with a 6 rpm rotating shelf and capable of maintaining a temperature of 100° ± 2° C. (212° ± 4° F.). The center of the top surface of the rotating shelf coincides with the center of the oven.

* * * * *

S6.8.3 * * *

Level the oven and place the four petri dishes, each inside its inverted cover, on the rotating shelf in the oven at 100° ± 2° C. (212° ± 4° F.) for 46 ± 2 hours. The thermometer for monitoring oven temperature is placed 25 mm ± 5 mm (1 inch ± 0.2 inch) above the rotating oven shelf containing the petri dishes. The 100° C. mark on the thermometer is either outside the oven or the thermometer is capable of being read from outside the oven without opening the oven door. The oven door is not opened to read the thermometer during the test. * * *

* * * * *

Issued on: January 8, 2001.

Stephen R. Kratzke,
Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1219 Filed 1–12–01; 8:45 am]
BILLING CODE 4910–59–P

VOL 66 ISS 10 JA 16 2001 UMI

Notices

Federal Register
Vol. 66, No. 10
Tuesday, January 16, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 98–085–3]

Aquaculture; Public Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This is to notify the aquaculture industries, interested parties, and the general public that a public meeting will be held to discuss how and to what extent the Animal and Plant Health Inspection Service should regulate aquatic species, and to discuss any other issues concerning possible regulation of aquaculture by the Agency.

DATES: The public meeting will be held on Friday, February 16, 2001, from 9 a.m. to 3 p.m.

ADDRESSES: The public meeting will be held at the Radisson Inn Cincinnati Airport, Cincinnati/Northern Kentucky International Airport, Hebron, KY, in conjunction with the annual meeting of the North Central Regional Aquaculture Center.

FOR FURTHER INFORMATION CONTACT: For information about the APHIS public meeting, contact Dr. Otis Miller, Jr., National Aquaculture Coordinator, Center for Planning, Certification, and Monitoring, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231, (301) 734–6188.

For information regarding the annual meeting of the North Central Regional Aquaculture Center, contact Liz Bartels at bartels@pilot.msu.edu or (517) 353–1962.

SUPPLEMENTARY INFORMATION: On May 4, 1999, the Animal and Plant Health Inspection Service (APHIS) published in the **Federal Register** (64 FR 23795–23796, Docket No. 98–085–1) an advance notice of proposed rulemaking (ANPR) titled "Aquaculture: Farm-Raised Fin Fish." We published the ANPR after receiving petitions [1] asking us to regulate aquaculture in various ways. Many petitioners asked us to define farmed aquatic animals as livestock. In general, the petitioners seemed to be interested in receiving the same services that domestic producers of livestock receive for animals moving in interstate and foreign commerce. However, based on the petitions alone, it was difficult for us to determine what segments of the industry want services and exactly what services they want. It was also difficult to determine the objectives sought by the petitioners who were requesting Federal regulation. We published the ANPR in an attempt to clarify the industry's needs, the nature of the services sought, and the concerns the petitioners had with regard to such regulations.

We received 55 comments [2] in response to the ANPR. A majority of the commenters supported the idea of APHIS regulation of cultured fin fish. Unfortunately, the commenters generally did not clearly distinguish between fin fish raised for food and ornamental fin fish. Commenters who wanted regulation were, however, very clear that they want programs to prevent and control disease and to support increased commerce, both domestic and export.

The commenters also suggested that any rulemaking initiated by APHIS be a negotiated rulemaking. In negotiated rulemaking, industry representatives and other interested persons meet with APHIS officials and draft proposed regulations together. The proposed regulations are then published for public comment. Negotiated rulemaking is designed to ensure that all interested persons are involved together from the start in the development of regulations.

Unfortunately, negotiated rulemaking is not suitable for all situations. It works well when there is a small number of interested parties, and the parties are easy to identify. This is not the case with regard to aquaculture. The aquaculture industry is very large and diverse. It would be difficult for us to identify everyone who should be represented in a negotiated rulemaking. In addition, there are many parties outside aquaculture that would have a substantial interest in such a rulemaking. In our view, the number of people who would need to participate in a negotiated rulemaking would be too large and would suggest that negotiated rulemaking is not appropriate. Furthermore, a negotiated rulemaking would be expensive, and APHIS does not have adequate funds. Therefore, we have concluded that it would not be appropriate to pursue an aquaculture negotiated rulemaking.

We have not, however, decided whether to pursue aquaculture rulemaking by other means. Before we make that decision, we want to have as much information as possible from all interested persons, and we want to provide the aquaculture industries and other interested persons with as much opportunity as possible to discuss with us and inform us regarding the relevant issues.

Therefore, we are holding a series of public meetings. Public meetings allow anyone who is interested—industry representatives, producers, consumers, and others—to present their views and to exchange information among themselves and with APHIS.

There are no set agendas for the meetings. Any issues and concerns related to aquaculture and possible APHIS regulatory action can be discussed. However, there are three specific issues on which we would like more information. These are issues that the people and organizations who commented on our ANPR either did not address or were unclear about. Specifically, if APHIS does propose regulations: (1) Should our program be mandatory or voluntary; (2) should we cover shell fish; and (3) should we cover ornamental fin fish?

Information elicited at the meetings could result in a new APHIS regulatory program, or in changes to aquaculture-related services currently provided by APHIS.

We have scheduled this public meeting, the second meeting in our series, for Friday, February 16, 2001, at the Radisson Inn Cincinnati Airport. If you wish to speak at the meeting, please register in advance by calling the Regulatory Analysis and Development voice mail at (301) 734–8139. Leave a message with your name, telephone number, organization, if any, and an estimate of the time you need to speak. You may also register at the meeting itself. Please register at the meeting room between 8:30 a.m. and 9 a.m., before the meeting officially begins. Starting with the advance registrants, we will call speakers in the order in which they registered.

The meeting will begin at 9 a.m. and is scheduled to end at 3 p.m. We may end the meeting early if all the registered speakers have had a chance to speak and if no one else wants to speak. We may also extend the meeting, or limit the time allowed for each speaker, if necessary, so all interested persons have an opportunity to participate.

An APHIS representative will preside at the meeting. The meeting will be recorded. We encourage speakers to present written statements, though it is not required. If you choose to present a written statement, please provide the chairperson with a copy. The complete record, including the transcript and all written comments, will be available to the public.

This meeting is the second in our series of public meetings. The first public meeting will be held on January 25, 2001, in Lake Buena Vista, FL. We plan to hold additional meetings in Idaho, Maine, Mississippi, Pennsylvania, and Washington. We will publish a notice or notices in the **Federal Register** announcing the dates, times, and locations of the meetings.

Done in Washington, DC, this 9th day of January 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–1199 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–34–P

[1] All the petitions and comments we received are a part of the rulemaking record for Docket No. 98–085–1. You may read the petitions and comments in our reading room. The reading room is locatd in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

[2] All the petitions and comments we received are a part of the rulemaking record for Docket No. 98–085–1. You may read the petitions and comments in our reading room. The reading room is locatd in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service; Cooperative State Research, Education, and Extension Service Biotechnology Risk Assessment Research Grants Program for Fiscal Year 2001; Request for Proposals and Request for Input

AGENCY: Agricultural Research Service; Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CSREES) are announcing the Biotechnology Risk Assessment Research Grants Program (the "Program") for fiscal year (FY) 2001. Proposals are hereby requested from eligible institutions as identified herein for competitive consideration of Biotechnology Risk Assessment Grant awards. The authority for the Program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921). The Program is administered by CSREES and ARS of the U.S. Department of Agriculture.

CSREES also requests comments regarding this request for proposals (RFP) from any interested party. These comments will be considered in the development of the next RFP for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA).

DATES: All proposals must be received at USDA on or before March 15, 2001. Proposals not received on or before this date will not be considered for funding.

User comments are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Proposals must be submitted to the following mailing address: Biotechnology Risk Assessment Research Grants; *c/o* Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Ave., SW.; Washington DC 20250–2245.

The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is: Biotechnology Risk Assessment Research Grants; *c/o* Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, S.W.; Washington DC 20024. Telephone: (202) 401–5048.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA–CSREES; STOP 2299; 1400 Independence Avenue, SW.; Washington, DC 20250–2299; or via e-mail to: RFP-OEP@reeusda.gov. (This e-mail address is intended only for receiving stakeholder input comments regarding this RFP, and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT: Dr. Deborah Sheely; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Stop 2241; 1400 Independence Avenue, SW.; Washington, DC 20250–2241; Telephone: (202) 401–1924; e-mail: dsheely@reeusda.gov; or Dr. Robert M. Faust; Agricultural Research Service; U.S. Department of Agriculture; Room 338, Building 005, BARC–West; Beltsville, MD 20705; Telephone: (301) 504–6918; e-mail: rmf@ars.usda.gov.

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Stakeholder Input

CSREES is requesting comments regarding this RFP from any interested party. In your comments, please include the name of the program and the fiscal year of the RFP to which you are responding. These comments will be considered in the development of the next RFP for the program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). Comments should be submitted as provided for in the

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ADDRESS and **DATES** portions of this Notice.

Part I. General Information

A. Legislative Authority

The authority for the Program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921). The administrative regulations for this program are found at 7 CFR part 3415.

B. Applicant Eligibility

Proposals may be submitted by any United States public or private research or educational institution or organization.

Part II. Program Description

CSREES and ARS will competitively award research grants to support science-based biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically modified organisms into the environment and helping regulators to develop policies regarding such introduction.

The Program's emphasis is on risk assessment, which is defined as the science-based evaluation and interpretation of factual information in which a given hazard, if any, is identified, and the consequences associated with the hazard are explored. Research funded through this program will be relevant to risk assessment and the regulatory process. When evaluating transgenic organisms, regulators must answer the following four general questions: (1) Is there a hazard (potential hazard identification)?; (2) how likely is the hazard to occur (quantifying the probability of occurrence)?; (3) what is the severity and extent of the hazard if it occurs (quantifying the effects)?; and (4) is there an effect above and beyond what might occur with an organism, with similar traits, developed using other technologies?

Although investigators are not required to perform actual risk assessments in the research they propose, they should design studies that will provide information useful to regulators for making science-based decisions in their assessments of genetically-modified organisms. Accordingly, program applicants are encouraged to address the following questions in their proposals: (1) What is the relevance of this research to the evaluation of transgenic organisms?; (2) What information will be provided by this research to help regulators adequately assess transgenic organisms?; and (3) How does this research model appropriate studies necessary to identify and/or characterize hazards associated with introducing genetically-modified organisms into the environment.

The Program does not support risk management research, which is defined to include either (1) research aimed primarily at reducing effects of specific biotechnology-derived agents or (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the consequences identified in a risk assessment. Proposals must be relevant to risk assessment to be eligible for this Program.

In addition to addressing the questions posed above, proposals must include a statement describing the relevance of the proposed project to one or more of the research topics requested in this RFP. In addition, proposals should include detailed descriptions of the experimental design and appropriate statistical analyses to be done.

Awards will not be made for clinical trials, commercial product development, product marketing strategies, or other research deemed not appropriate to risk assessment.

A. Purpose of the Program

The purpose of the Program is to assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically modified organisms, including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The Program accomplishes this purpose by providing scientific information derived from the risk assessment research that it funds. Research proposals submitted to the Program must be applicable to the purpose of the Program to be considered.

B. Available Funding

Subject to the availability of funds, the anticipated amount available for support of the Program in FY 2001 is $1.5 million. The agency intends to award these funds for project proposals in the targeted areas with no more than two awards for conference proposals.

Pursuant to section 1462 of NARETPA, 7 U.S.C. 3310, indirect costs charged against a grant awarded under this program may not exceed 19 percent of the total Federal funds provided under the grant award. (An alternative method to calculate this limitation is to multiply total direct costs by 23.456 percent.)

C. Areas of Research To Be Supported

Proposals addressing the following topics are requested:

1. Research relevant to assessing the effects of the introduction into the environment of genetically engineered organisms. Potential subject areas include but are not limited to: (a) research on the potential for recombination between plant viruses and plant-encoded viral transgenes; (b) research on the potential for non-target effects of introduced foreign gene products expressed in genetically modified plant-associated microorganisms (e.g., compounds in phyllosphere or rhizosphere-inhabiting bacteria) or in plants (e.g., *Bacillus thuringiensis* delta-endotoxin), especially in regard to persistence of the organisms and material in the environment, including their impact on beneficial or soil organisms; (c) changes in ecosystem or agro-ecosystem function and composition; (d) research on gene flow from transgenic crops to related plants and exploration of factors influencing gene transfer rates. Gene flow experiments on crops with a high potential for gene introgression into wild or weedy relatives (e.g., those with high rates of outcrossing and with overlapping habitats are of particular interest); (e) research on the role that insects and/or pathogens play in limiting populations of crops and weeds as this relates to acquisition of transgenic pest protection by crops and/or weeds; (f) research on how transgenic plants, especially grasses, that are resistant or tolerant to environmental stresses (such as drought or salt) affect land use practices (new habitats or tillage), water use (irrigation) patterns, and species displacement.

The data collected may include: survival; reproductive fitness; genetic stability (e.g., transgene retained during backcrossing); genetic recombination; horizontal gene transfer; loss of genetic diversity; or enhanced competitiveness. As long as the data gathered are relevant to the assessment of the effects of genetically modified organisms, the experiments need not utilize transgenic organisms. When feasible, measures of risk should include estimates of expected frequency and impact, and address the availability of effective mitigation measures to reduce or avoid impacts.

2. Research on large-scale deployment of genetically engineered organisms, especially commercial uses of such organisms, with special reference to considerations that may not be revealed through small-scale evaluations and tests and may address cumulative effect concerns. Studies should attempt to project impacts over as large a spatial and temporal scale as feasible. Potential focus areas include but are not limited to:

(a) Studies of insects and viruses that have developed resistance to plants possessing transgenic protection from them. This may be done by monitoring locations where such plants are grown on a commercial scale or in large scale production. The analysis of resistant viral strains should include analyzing whether the strain arose via recombination between viral transgenes and the viral genome and an analysis of how the resistance was effected (e.g., changed coat protein with increased seed or insect vector transmissibility). The potential for transcapsidation in transgenic plants to alter seed transmission can be evaluated by comparing the levels of infected seed from transgenic plants inoculated with a virus, that could be transcapsidated, with seed from nontransgenic plants inoculated in a similar manner. Analysis should include the presence of satellite RNA (satRNA) which may replicate with the help of a suitable helper virus. Such projects should survey the production sites for two to three years.

(b) Studies to assess the impact of transgenic plants, especially insect resistant or herbicide tolerant plants, on biodiversity of agro-ecosystems. This could include changes in population dynamics and species diversity of nontarget arthropods (particularly beneficial predators, parasites, and pollinators), plants, mammals, avian or microbial species (including both pathogenic or beneficial fungi or bacteria associated with the crop plant). These studies should be conducted in such a way as to compare the impacts of transgenic plants to nontransgenic cultivars with otherwise similar phenotypes using the commonly recommended or adopted practices for tillage, irrigation, and control of pests or weeds. Also, effects of these plants on soil erosion or water quality could be included. Extensive documentation of agricultural practices will be a necessary component.

(c) Monitoring for the occurrence of individual or stacked resistance traits in wild/weedy relatives of commercialized transgenic crops, and subsequently, any effects of such genes on fitness, competitiveness, and weediness.

3. Research to assess the effects of transgenes in wild relatives of crop species. This research could evaluate the potential for unexpected fitness effects by comparing fitness characteristics in hybrids or introgressants between a transgenic line and the wild relative to hybrids or introgressants between the nontransgenic line and the wild relatives, or could evaluate fitness effects of the introduced trait by evaluating survival or reproductive success under natural conditions, or through planned competition experiments. Crop species could include those with compatible wild relatives in the U.S. which have been deregulated (e.g., rice, rapeseed, melon, and squash) or are being developed (e.g., sunflower, turfgrasses, strawberry). Introduced traits could include those that have potential effects on fitness (e.g., pest or disease resistance), or that have potential physiological or metabolic effects.

4. Research to assess the effects of genetically engineered plants with "stacked" resistance genes or genes that confer broad resistance to insects or diseases. These genes may give recipient plants a greater selective advantage and lead to less predictable ecological consequences. Possible areas of research include, but are not limited to: (a) The impact of gene stacking on non-target species; (b) the effects of stacked genes on pest populations; (c) transmission and establishment of multiple resistance genes into weedy relatives; (d) influence of genetic factors such as linkage on the transmission and establishment of multiple genes; and (e) ecological importance in weedy hosts of pest complexes sufficiently variable as to require broad resistance or stacked genes for their control.

5. Research to develop statistical methodology and quantitative measures of risks associated with field testing of genetically modified organisms.

6. The Program will, subject to resource availability, provide partial funding to organize a conference that brings together scientists, regulators, and others to review the science-based data relevant to risk assessment of genetically modified organisms released into the environment. The steering committee for the conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate. The goals of such a conference may include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings will be required. The Program will fund a maximum of two conference proposals.

Part III. Content of a Proposal

The format guidelines for full research proposals, found in the administrative provisions for the Program at 7 CFR 3415.4(d), should be followed for the preparation of proposals under the Program in FY 2001. In addition, please note the following items: (1) the Department elects not to solicit preproposals in FY 2001; (2) a proposal's project summary may not exceed one single- or double-spaced page. Include on this page the proposal title, as well as names and institutions of each investigator; (3) Proposal budgets (Form CSREES–55) must include funds sufficient for travel by all principal investigators to Washington, D.C. for one meeting during the period of the award. The purpose of this meeting is to report on the progress of the research to USDA program and regulatory staff; and (4) a separate conflict of interest list must be submitted with the proposal for all key personnel for whom a curriculum vita (C.V.) is required. This list is necessary to assist program staff in excluding from proposal review those individuals who have conflicts of interest with the project personnel in the grant proposal.

For all key personnel (as described in the proposal project description), list alphabetically the full names of only the individuals in the following categories. It is not necessary to list individuals in each category separately; rather, a single alphabetized list for all key personnel is preferred. Additional pages may be used as necessary. A conflict of interest list must be submitted before a proposal is considered complete. Inclusion of a C.V. or publication list in lieu of a conflict of interest list is not sufficient. Other investigators working in the applicant's specific research area are not in conflict of interest with the applicant unless those investigators fall within one of the categories listed below:

(A) All collaborators on research projects within the past four years, including current and planned collaborations;

(B) All co-authors on publications within the past four years, including pending publications and submissions;

(C) All persons in your field with whom you have had a consulting or financial arrangement within the past four years; and

(D) All thesis or postdoctoral advisees/advisors within the past four years.

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Compliance With the National Environmental Policy Act (NEPA)

As outlined in 7 CFR Part 3407 and 7 CFR Part 520 (the CSREES and ARS regulations implementing the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*)), environmental data or documentation for the proposed project is to be provided to CSREES and ARS in order to assist CSREES and ARS in carrying out their responsibilities under NEPA. These responsibilities include determining whether the project requires an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) or whether it can be excluded from this requirement on the basis of the categorical exclusions listed in 7 CFR 3407.6. To assist CSREES and ARS in this determination, the applicant should review the categories defined for exclusion to ascertain whether the proposed project may fall within one of the exclusions.

Form CSREES–1234, NEPA Exclusions Form (copy in Application Kit), indicating the applicant's opinion of whether or not the project falls within one or more categorical exclusions, along with supporting documentation, must be included in the proposal. The information submitted in association with NEPA compliance should be identified in the Table of Contents as "NEPA Considerations" and Form CSREES–1234 and supporting documentation should be placed after the Form CSREES–661, Application for Funding, in the proposal.

Even though the applicant considers that a proposed project may fall within a categorical exclusion, CSREES and ARS may determine that an EA or an EIS is necessary for an activity if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present that may cause such activity to have a significant environmental effect.

Part IV. How To Obtain Application Materials

Copies of this RFP, the administrative provisions for the Program (7 CFR Part 3415), and the Application Kit, which contains required forms, certifications, and instructions for preparing and submitting applications for funding, may be obtained by contacting: Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245; Telephone Number: (202) 401–5048.

Application materials also may be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov which states that you wish to receive a copy of the application materials for the FY 2001 Biotechnology Risk Assessment Research Grants Program. The materials will then be mailed to you (not e-mailed) as quickly as possible.

This RFP and other application information and materials also are available at the Program's website (http://www.reeusda.gov/crgam/biotechrisk/biotech.htm).

Part V. Submission of a Proposal

A. What To Submit

An original and 14 copies of a proposal must be submitted. Proposals should be typed on 8 ½" x 11" white paper, single-or double-spaced, and one side of the page only. The text of the proposal should be prepared using no type smaller than 12 point font size and one-inch margins. Each copy of each proposal must be stapled securely in the upper lefthand corner. (DO NOT BIND.) All copies of the proposal must be submitted in one package.

B. Where and When to Submit

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before March 15, 2001, at the following address: Biotechnology Risk Assessment Research Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307; Waterfront Centre; 800 9th Street, S.W.; Washington, D.C. 20024. The telephone number is (202) 401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received on or before March 15, 2001. Proposals submitted through the U.S. mail should be sent to the following address: Biotechnology Risk Assessment Research Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2245.

C. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged via the Internet (e-mail). Therefore, it is important to include your e-mail address on Form CSREES–661 when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

Part VI. Proposal Evaluation

Proposals will be evaluated by the Administrators of ARS and CSREES assisted by a peer panel of scientists for scientific merit, qualifications of project personnel, adequacy of facilities, and relevance to both risk assessment research and regulation of agricultural biotechnology. Proposals for funding a scientific research conference grant will be evaluated on the following criteria: choice of topics and selection of speakers; general format of the conference, especially with regard to its appropriateness for fostering scientific exchange and/or public understanding; provisions for wide participation from the scientific and regulatory community and others as appropriate; qualifications of the organizing committee and appropriateness of invited speakers to the topic areas being covered; and appropriateness of the budget requested and qualifications of the project personnel. All proposals are considered together in making award decisions. However, no more than two conference grants will be awarded.

Part VII. Supplementary Information

A. Applicable Regulations

This Program is subject to the administrative provisions found in 7 CFR Part 3415, which set forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, the awarding of grants, and post-award administration of such grants. Several other Federal statutes and regulations apply to grant proposals considered for review or to grants awarded under this Program. These include but are not limited to:

7 CFR Part 3019—USDA implementation of OMB Circular A–110, Uniform Administrative Requirements for Grant and Agreements with Institutions of Higher Education, Hospitals and Other Nonprofit Organizations.

B. Programmatic Contact

For additional information on the Program, please contact: Dr. Deborah Sheely; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Stop 2241; 1400 Independence Avenue, S.W.; Washington, D.C. 20250–2241; Telephone: (202) 401–1924; e-mail: dsheely@reeusda.gov; or Dr. Robert M. Faust; Agricultural Research Service; U.S. Department of Agriculture; Room 338, Building 005, BARC-West; Beltsville, MD 20705; Telephone: (301) 504–6918; e-mail: rmf@ars.usda.gov.

C. Additional Information

The Biotechnology Risk Assessment Research Grants Program is listed in the Catalog of Federal Domestic Assistance under No. 10.219. For reasons set forth in the final rule-related Notice to 7 CFR Part 3015, subpart V (48 FR 29115, June 24, 1983), this Program is excluded from the scope of Executive Order No. 12372 which requires intergovernmental consultation with State and local officials.

Under the provisions of the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524–0022.

Done at Washington, D.C., on this 4th day of January, 2001.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

Edward B. Knipling,

Acting Administrator, Agricultural Research Service.

[FR Doc. 01–1018 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Interim National Drought Council

AGENCY: Farm Service Agency, USDA.

ACTION: Notice of Interim National Drought Council meeting.

SUMMARY: The Interim National Drought Council (Interim Council) was established through a Memorandum of Understanding (MOU). It's purpose is to coordinate activities between and among Federal Agencies, States, local governments, tribes and others. The first meeting of the Interim Council was held November 9, 2000. All meetings are open to the public; however, seating is limited and available on a first-come basis.

DATES: The Interim Council will meet on January 25, 2001, in Room 233 of the Hall of the States building located at 444 North Capitol Street, NW. in Washington, DC from 10:00 a.m. to 11:30 a.m. and then from 12:30 p.m. to 3:00 p.m.. All times noted are Eastern Standard Time. This meeting will be devoted to revising the work plan and other Interim Council business.

FOR FURTHER INFORMATION CONTACT: Leona Dittus, Executive Director, Interim National Drought Council, United States Department of Agriculture (USDA), 1400 Independence Avenue, SW, Room 6701–S, STOP 0501, Washington, D.C., 20250–0501 or telephone (202) 720–3168; FAX (202) 720–9688; internet *leona.dittus@usda.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the MOU is to establish a more comprehensive, integrated, coordinated approach toward reducing the impacts of drought through better preparedness, monitoring and prediction, risk management, and response to drought emergencies in the United States. The Interim Council will encourage cooperation and coordination between and among Federal, State, local, and tribal governments and others, relative to preparation for and response to serious drought emergencies. Activities of the Interim Council include providing coordination to: (a) Resolve drought related issues, (b) exchange information about lessons learned, and (c) improve public awareness of the need for drought planning and mitigation measures. The Interim Council is co-chaired by the Secretary of Agriculture or his designee, and a non-federal co-chair, selected from among the members who are not Federal officers or employees. Ms. Ane D. Deister, Executive Assistant to the General Manager, Metropolitan Water District of Southern California, representing urban water interests, was selected as the non-federal co-chair at the Interim Council's organizational meeting. Administrative staff support essential to the execution of the Interim Council's responsibilities shall be provided by USDA. The Interim Council will continue in effect for 5 years or until Congress establishes a permanent National Drought Council.

If special accommodations are required, please contact Leona Dittus, at the address specified above, by COB January 22, 2001.

Signed at Washington, D.C., on January 10, 2001.

George Arredondo,

Administrator, Farm Service Agency.

[FR Doc. 01–1226 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

Meeting on the Implementation of the United States Warehouse Act

AGENCY: Farm Service Agency, Agriculture.

ACTION: Notice of meeting.

SUMMARY: To solicit comments and options for consideration in implementing the United States Warehouse Act of 2000 that was enacted on November 9, 2000 (USWA 2000), the Department of Agriculture (USDA) will conduct a public meeting.

The meeting is open to the public with attendance limited to space that will be available on a first come basis. All attendees are asked to be prepared to share information concerning their current and future e-commerce activities. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations should notify the contact person listed below in advance of the meeting. No registration is required and there is no fee to attend the public meeting.

DATES: The public meeting to present implementation options and to solicit oral comments will be held on January 23, 2001, from 9 a.m. to 4 p.m. E.S.T., in the Jefferson Auditorium of the U.S. Department of Agriculture South Building, 1400 Independence Avenue, SW., Washington, DC, near the Smithsonian Metro Station.

FOR FURTHER INFORMATION CONTACT: Roger Hinkle, Chief, Licensing Authority Branch, Warehouse and Inventory Division, Farm Service Agency, 1400 Independence Avenue SW., STOP 0553, Washington DC 20250, telephone (202) 720–7433; e-mail: Roger_Hinkle@wdc.fsa.usda.gov.

SUPPLEMENTARY INFORMATION: The USWA 2000 was enacted on November 9, 2000, to replace the original United States Warehouse Act (USWA) that was enacted in 1916. USWA 2000 can be found online at: www.fsa.usda.gov/daco/uswamain/public-law-106-472.pdf. This statute was enacted to make Federal warehouse licensing and operations more relevant to today's agricultural marketing and financial systems. USWA 2000 authorizes the Secretary of Agriculture to promulgate regulations governing (1) The issuance and transfer of electronic warehouse receipts across State and international boundaries; (2) the manner in which electronic documents relating to the shipment, payment, and financing of the sale of agricultural products may be

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issued or transferred, including transfers across State and international boundaries; and (3) the standardization of such electronic documents. This new paperless flow of agricultural commodities from the farm to the end-user will provide significant savings and efficiencies for producers, bankers, warehouse operators, and other affected parties across the nation and throughout the world, and will make U.S. agricultural more competitive in world markets.

Included in USWA 2000 were statutory deadlines for the issuance of proposed and final regulations, and the new statute provides that the current USWA that was enacted in 1916 expires no later than August 1, 2001.

Items that will be discussed in the subject meeting include, but are not limited to the following:

(1) What documents and transactions should USDA make available for e-commerce?

(2) Should USDA standardize criteria and formats for e-commerce concerning commodity warehousing? Financial and business records? Electronic data interchanges? Recordkeeping? Commodity merchandising?

(3) The regulations at 7 CFR 735.100 through 735.105 currently provide specifically for cotton Electronic Warehouse Receipts (EWR) and EWR provider requirements and standards. Should similar regulations and processes be adopted or expanded when including additional commodities? If not, what criteria and requirements should USDA establish for electronic warehouse commerce providers?

(4) What industry and business-based processes should USWA offer?

The agenda includes: (1) Presentation on options currently under consideration for implementing USWA 2000; (2) discussions on the implementation of electronic commerce authorized under USWA 2000, with opportunity for comment; and (3) discussions on warehouse issues, with opportunity for comment.

From 9 a.m. to 12 p.m., the discussion will concentrate on electronic commerce initiatives that are authorized by USWA 2000, and from 1 p.m. to 4 p.m. the discussion will concentrate on the statutory changes that will affect warehousing issues. Each session will (1) outline options that are under consideration for implementing USWA 2000, and (2) provide attendees with an opportunity to present oral comments and submit written and oral questions. An official transcript will be prepared and will be available online at www.fsa.usda.gov/daco/uswamain/uswa2000-transcript.pdf. This official transcript will also be available for public inspection in Room 5968, South Agriculture Building, U.S. Department of Agriculture, 1400 Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons with disabilities who require alternative means for communication of regulatory information (braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Comments: Written comments can be submitted in hard copy by mail to Roger Hinkle at the address shown above, or by fax at (202) 690–3123, or by e-mail to Roger_Hinkle@wdc.fsa.usda.gov. In order to ensure comments will be received before the meeting, submit written comments no later than January 15, 2001.

Signed at Washington, DC on January 8, 2001.

Carolyn B. Cooksie,

Acting Administrator, Farm Service Agency.

[FR Doc. 01–1020 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00–053N]

Codex Alimentarius Commission: Meeting of the Codex Committees on Fats and Oils and Methods of Analysis and Sampling

AGENCY: Office of the Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS) are sponsoring a public meeting on Wednesday, January 17, 2001. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States' positions that will be discussed at two upcoming Codex Committee meetings. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the Sessions of the Codex Committee on Fats and Oils (CCFO) and the Codex Committee on Methods of Analysis and Sampling (CCMAS) and to address items on the agenda.

DATES: The public meeting is scheduled for Wednesday, January 17, 2001, from 9:00 a.m. to 12:00 noon.

ADDRESSES: The public meeting will be held in Room 1813, Federal Office Building 8, Food and Drug Administration, 200 C Street, SW., Washington, DC 20204. To receive copies of the documents referenced in this notice, contact the FSIS Docket Room, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. The documents will also be accessible via the world wide web at the following address: *http://www.fao.org/waicent/faoinfo/economic/esn/codex.*

Submit one original and two copies of written comments to the FSIS Docket Room at the address above and reference docket number 00–053N. All comments submitted in response to this notice will be available for public inspection in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Patrick J. Clerkin, Assistant U.S. Manager for Codex, U.S. Codex Office, FSIS, Room 4861, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC 20250. Telephone (202) 205–7760; Fax (202) 720–3157. Persons requiring a sign language interpreter or other special accommodations should notify Mr. Clerkin at the above number.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius Commission (Codex) was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the major international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and correctly labeled.

The public meeting announced in this notice will provide information and an opportunity for public comment on two upcoming Codex Committee meetings:

• Seventeenth Session of the Codex Committee on Fats and Oils (CCFO) that will be held in London, United Kingdom, February 19–23, 2001.

• Twenty-third Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) that will be held in Budapest, Hungary, February 26–March 2, 2001.

The CCFO was established to elaborate worldwide standards for fats and oils and their products. The CCMAS performs multiple functions such as defining criteria appropriate to Codex methods of analysis and sampling, specifying reference methods of analysis and sampling, endorsing methods of analysis and sampling proposed by the Codex Committees, elaborating sampling plans, and considering specific sampling and analysis problems. The Government of the United Kingdom will chair the CCFO meeting and the Government of Hungary will chair the CCMAS meeting.

Issues To Be Discussed at the Public Meeting

The U.S. delegate for the Codex Committee on Methods Analysis and Sampling will discuss the following subjects at the public meeting from 9:00 a.m. to 10:30 a.m.

Agenda item	Subject matter	Document reference
1	Adoption of the Agenda.	
2	Matters referred to the committee	CX/MAS 01/2.
3	Proposed draft general guidelines on sampling at step 4	CX/MAS 01/3.
4	Criteria for evaluating acceptable methods of analysis for Codex purposes	CX/MAS 01/4.
	(a) Proposed draft guidelines on the application of the criteria approach at step 4	CX/MAS 01/4, Add. 1.
	(b) Amendments to the procedural manual of the Codex Alimentarius Commission relevant to the criteria approach. —Principles for the establishment of Codex methods of analysis and sampling. —Relations between commodity committees and general committees.	ALINORM 99/23, Appendix II.
5	Consideration of harmonized guidelines for the use of recovery information in analytical measurements.	CX/MAS, 01/6.
6	Harmonization of analytical terminology in accordance with international standards: "measurement limits".	CX/MAS, 01/7.
7	Measurement uncertainty.	
	(a) Progress report by relevant Organizations.	
	(b) Relationship between the analytical result, the measurement uncertainty and the specification in the Codex standard.	CX/MAS, 01/8.
8	In-house method validation	CX/MAS, 01/9.
9	Endorsement of methods of analysis provisions in Codex standards	CX/MAS, 01/10.

The U.S. delegate for the Codex Committee on Fats and Oils will discuss the following subjects at the public meeting from 10:30 a.m. to 12:00 noon.

Agenda item	Subject matter	Document reference
1	Adoption of the Agenda.	
2	Matters referred to the Committee	CX/FO, 01/2.
3	Draft revised standard for olive oils and olive pomace oils at step 7	CL 2000/32–FO.
4	Proposed draft amendments to the standard for named vegetable oils (including provisions for high oleic acid safflower oil and high oleic sunflower oil at step 4).	CL 2000/25–FO, CL 2000/25 A. FO.
5	Proposed draft standard for fat spreads and blended spreads at step 3	ALINORM 99/1, Appendix VI.
6	Proposed draft amendment to the code of practice for the storage and transport of edible fats and oils in bulk: lists of acceptable previous cargoes and lists of banned immediate previous cargoes at step 4.	CL 2000/26–FO, Part I and II.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on-line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Done at Washington, DC, on: January 9, 2001.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 01–1157 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–DS–P

DEPARTMENT OF AGRICULTURE

Forest Service

Southwest Washington Provincial Advisory Committee Meeting Notice

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Southwest Washington Provincial Advisory Committee will meet on Wednesday, January 31, 2001, at the Gifford Pinchot National Forest

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Office, located at 10600 NE 51st Circle, Vancouver, Washington. The meeting will begin at 9 a.m. and continue until 4:15 p.m. The purpose of the meeting is to: (1) Review Forest Monitoring for FY 2000, (2) Discuss the Secure Rural Schools and Community Self-Determination Act of 2000, (3) Discuss the mission of the committee, and (4) Provide for a Public Open Forum. All Southwest Washington Provincial Advisory Committee meetings are open to the public. Interested citizens are encouraged to attend. The "open forum" provides opportunity for the public to bring issues, concerns, and discussion topics to the Advisory Committee. The "open forum" is scheduled as part of agenda item (4) for this meeting. Interested speakers will need to register prior to the open forum period. The committee welcomes the public's written comments on committee business at any time.

FOR FURTHER INFORMATION CONTACT: Direct questions regarding this meeting to Linda Turner, Public Affairs Specialist, at (360) 891–5191, or write Forest Headquarters Office, Gifford Pinchot National Forest, 10600 NE. 51st Circle, Vancouver, WA 98682.

Dated: January 9, 2001.

Claire LaVendel,

Forest Supervisor.

[FR Doc. 01–1228 Filed 1–12–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–815 & A–580–816]

Notice of Final Results of Antidumping Duty Administrative Reviews: Certain Cold-Rolled and Corrosion-Resistant Carbon Steel Flat Products From Korea

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Antidumping Duty Administrative Reviews and Intent Not to Revoke Antidumping Duty Order in Part.

SUMMARY: On September 7, 2000, the Department of Commerce ("Department") published the preliminary results of the administrative reviews of the antidumping duty orders and intent not to revoke antidumping duty order in part on certain cold-rolled and corrosion-resistant carbon steel flat products from Korea. These reviews cover three manufacturers/exporters. The period of review ("POR") is August 1, 1998 through July 31, 1999.

Based on our analysis of the comments received, we have made changes in the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled "Final Results of the Reviews."

EFFECTIVE DATE: January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Michael Panfeld (the POSCO Group), Marlene Hewitt (Dongbu) and (Union), or James Doyle, Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, N.W., Washington, D.C. 20230, telephone 202–482–0172 (Panfeld), 202–482–1385 (Hewitt), or 202–482–0159 (Doyle), fax 202–482–1388.

SUPPLEMENTARY INFORMATION:

Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930 ("Act") are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act ("URAA"). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations at 19 CFR Part 351 (1998).

Scope of the Reviews

The review of "certain cold-rolled carbon steel flat products" covers cold-rolled (cold-reduced) carbon steel flat-rolled products, of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished or coated with plastics or other nonmetallic substances, in coils (whether or not in successively superimposed layers) and of a width of 0.5 inch or greater, or in straight lengths which, if of a thickness less than 4.75 millimeters, are of a width of 0.5 inch or greater and which measures at least 10 times the thickness or if of a thickness of 4.75 millimeters or more are of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the Harmonized Tariff Schedule ("HTS") under item numbers 7209.15.0000, 7209.16.0030, 7209.16.0060, 7209.16.0090, 7209.17.0030, 7209.17.0060, 7209.17.0090, 7209.18.1530, 7209.18.1560, 7209.18.2550, 7209.18.6000, 7209.25.0000, 7209.26.0000, 7209.27.0000, 7209.28.0000, 7209.90.0000, 7210.70.3000, 7210.90.9000, 7211.23.1500, 7211.23.2000, 7211.23.3000, 7211.23.4500, 7211.23.6030, 7211.23.6060, 7211.23.6085, 7211.29.2030, 7211.29.2090, 7211.29.4500, 7211.29.6030, 7211.29.6080, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7215.50.0015, 7215.50.0060, 7215.50.0090, 7215.90.5000, 7217.10.1000, 7217.10.2000, 7217.10.3000, 7217.10.7000, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090. Included in this review are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling") —for example, products which have been beveled or rounded at the edges. Excluded from this review is certain shadow mask steel, *i.e.*, aluminum-killed, cold-rolled steel coil that is open-coil annealed, has a carbon content of less than 0.002 percent, is of 0.003 to 0.012 inch in thickness, 15 to 30 inches in width, and has an ultra flat, isotropic surface.

The review of "certain corrosion-resistant carbon steel flat products" covers flat-rolled carbon steel products, of rectangular shape, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating, in coils (whether or not in successively superimposed layers) and of a width of 0.5 inch or greater, or in straight lengths which, if of a thickness less than 4.75 millimeters, are of a width of 0.5 inch or greater and which measures at least 10 times the thickness or if of a thickness of 4.75 millimeters or more are of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the HTS under item numbers 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0090, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.1000, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7212.60.0000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090. Included in this review are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling")—for example, products which have been beveled or rounded at the edges. Excluded from this review are flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead ("terne plate"), or both chromium and chromium oxides ("tin-free steel"), whether or not painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating. Also excluded from this review are clad products in straight lengths of 0.1875 inch or more in composite thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness. Also excluded from this review are certain clad stainless flat-rolled products, which are three-layered corrosion-resistant carbon steel flat-rolled products less than 4.75 millimeters in composite thickness that consist of a carbon steel flat-rolled product clad on both sides with stainless steel in a 20%–60%–20% ratio.

These HTS item numbers are provided for convenience and U.S. Customs purposes. The written descriptions remain dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to these administrative reviews are addressed in the "Issues and Decision Memorandum" ("Decision Memo") from Joseph A. Secretary for Import Administration to Troy H. Cribb, Assistant Secretary for Import Administration, dated January 5, 2001, which is hereby adopted by this notice. A list of the issues which parties have raised and to which we have responded, all of which are in the Decision Memo, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in these reviews and the corresponding recommendations in this public memorandum which is on file at the U.S. Department of Commerce, in the Central Records Unit, in room B–099. In addition, a complete version of the Decision Memo, accessible in B–099 and on the Web at *http://ia.ita.doc.gov*. The paper copy and electronic version of the Decision Memorandum are identical in content.

Use of Facts Available

In accordance with section 776 of the Act, we have determined that the use of facts available is appropriate for certain portions of our analysis of the POSCO Group. For a discussion of our determination with respect to this matter, see comments 1 and 2 of the POSCO Group's company-specific section of the Decision Memo, accessible in B–099 and on the Web at *http://ia.ita.doc.gov*.

Sales Below Cost in the Home Market

The Department disregarded home market below-cost sales that failed the cost test for Dongbu, the POSCO Group, and Union in these final results of review.

Request for Revocation

The POSCO Group

On August 31, 1999, POSCO submitted a request, in accordance with 19 CFR 351.222(e), that the Department revoke the order covering cold-rolled carbon steel flat products from Korea with respect to its sales of this merchandise. In accordance with 19 CFR 351.222(e), this request was accompanied by certifications from POSCO that it had sold the subject merchandise in commercial quantities, at not less than NV for a three-year period, including this review period, and would not sell at less than NV in the future. POSCO also agreed to immediate reinstatement in the relevant antidumping order, as long as any firm is subject to the order, if the Department concludes under 19 CFR 351.216 that, subsequent to revocation, POSCO sold the subject merchandise at less than NV.

The Department conducted verifications of POSCO's responses for this period of review. In the two prior reviews of this order we determined that POSCO sold cold-rolled carbon steel flat products from Korea at not less than NV or at *de minimis* margins. We have determined that POSCO sold cold-rolled carbon steel flat products at not less than NV during the instant review period.

However, in determining whether a requesting party is entitled to a revocation inquiry, the Department must be able to determine that the company has continued to participate meaningfully in the U.S. market during each of the three years at issue. *See Pure Magnesium from Canada*, 63 FR 26147 (May 12, 1998). This practice has been codified by § 351.222(e) where a party requesting a revocation review is required to certify that it has sold the subject merchandise in commercial quantities. *See also* § 351.222(d)(1) of the Department's regulations, which state that, "before revoking an order or terminating a suspended investigation, the Secretary must be satisfied that, during each of the three (or five) years, there were exports to the United States in *commercial quantities* of the subject merchandise to which a revocation or termination will apply." (emphasis added); *See also*, the preamble of the Department's latest revision of the revocation regulation stating: "The threshold requirement for revocation continues to be that respondent not sell at less than normal value for at least three consecutive years and that, during those years, respondent exported subject merchandise to the United States in *commercial quantities*" (emphasis added). *Amended Regulation Concerning the Revocation of Antidumping and Countervailing Duty Orders*, 64 FR 51236, 51237 (September 22, 1999).

For purposes of revocation, the Department must be able to determine that past margins reflect a company's normal commercial activity. Sales during the POR which, in the aggregate, are an abnormally small quantity do not provide a reasonable basis for determining that the discipline of the order is no longer necessary to offset dumping. As the Department has previously stated, the commercial quantities requirement is a threshold matter. *See e.g., Pure Magnesium from Canada*, 64 FR 50489, 50490 (September 17, 1999). Thus, a party must have meaningfully participated in the marketplace in order to substantiate the need for further inquiry regarding whether continued imposition of the order is warranted.

Based on the current record, we find that POSCO did not sell merchandise in the United States in commercial quantities during the fourth administrative review (one of the three consecutive reviews cited by POSCO to support its request for revocation). During the POR covered by that review (August 1996 though July 1997), POSCO appeared to have made only one sale in the United States. Moreover, the total tonnage of this sale was small. *See Preliminary Analysis Memo* at Appendix II (August 30, 2000) ("*Prelim. Analysis Memo*"). By contrast, during the period covered by the antidumping investigation, which was only six months long (January 1992 through June 1992), POSCO made several thousand sales whose total quantity is 400 times greater than the quantity for the fourth administrative review period. In other words, POSCO's sales for the entire year covered by the fourth review period were only 0.27% of its sales volume during the six-months covered by the investigation. Similarly, during the current POR, POSCO sold

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approximately 400 times more subject merchandise in the United States than during the fourth administrative review.

Consequently, although POSCO received a *de minimis* margin during the fourth administrative review, this margin was not based on commercial quantities within the meaning of the revocation regulation. The number of sales and total sales volume is so small, both in absolute terms, and in comparison with the period of investigation and other review periods (*see Prelim. Analysis Memo*), that it does not provide any meaningful information of POSCO's normal commercial experience. Therefore, we find that POSCO did not meaningfully participate in the marketplace for purposes of qualifying for a revocation analysis and thus, because it has not sold the subject merchandise for three years in commercial quantities within the meaning of 351.222(e) does not qualify for a revocation analysis. For a full discussion, see Decision Memo at Comment 9.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made certain changes in the margin calculations. We have also corrected certain programming and clerical errors in our preliminary results, where applicable. Any alleged programming or clerical errors with which we do not agree are discussed in the relevant sections of the Decision Memo, accessible in B–099 and on the Web at *http://ia.ita.doc.gov*.

Final Results of the Reviews

We determine that the following percentage weighted-average margins exist for the period August 1, 1998 through July 31, 1999:

Producer/manufacturer/exporter	Weighted-average margin
Certain Cold-Rolled Carbon Steel Flat Products:	
Dongbu	1.35
The POSCO Group	0.12
Union	1.53
Certain Corrosion-Resistant Carbon Steel Flat Products:	
Dongbu	0.13
The POSCO Group	2.24
Union	0.21

The Department shall determine, and the U.S. Customs Service ("Customs") shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b), we have calculated exporter/importer-specific assessment rates. With respect to both export price and constructed export price sales, we divided the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each importer. We will direct Customs to assess the resulting percentage margins against the entered Customs values for the subject merchandise on each of that importer's entries under the relevant order during the review period.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative reviews for all shipments of cold-rolled and corrosion-resistant carbon steel flat products from Korea entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed companies will be the rates shown above except that, for firms whose weighted-average margins are less than 0.5 percent and therefore de minimis, the Department shall require no deposit of estimated antidumping duties; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less than fair value ("LTFV") investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 14.44 percent (for certain cold-rolled carbon steel flat products) or 17.70 percent (for certain corrosion-resistant carbon steel flat products). These rates are the "all others" rates from the LTFV investigations. See Antidumping Duty Orders on Certain Cold-Rolled Carbon Steel Flat Products and Certain Corrosion-Resistant Carbon Steel Flat Products from Korea, 58 FR 44159 (August 19, 1993).

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective orders ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: January 5, 2001.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

Appendix

Issues in Decision Memo

Comments and Responses

General Comments

1. The Net Financial Expenses of POSCO, Dongbu and Union's U.S. Selling Affiliates Should Be Included As Part of POSCO, Dongbu and Union's U.S. Indirect Selling Expenses.
2. Home Market "credit adjustment".

Company-Specific Comments

Dongbu Steel Co., Ltd. ("Dongbu")

3. Calculation and Allocation of U.S. Indirect Selling Expenses.
4. Total Entered Value and the Assessment Rate.
5. Weighting Factors for Quality in the Model Match.

Pohang Iron and Steel Co., Ltd. ("POSCO"), Pohang Coated Steel Co., Ltd. ("POCOS"), and Pohang Steel Industries Co., Ltd. ("PSI") (collectively, "POSCO Group")

6. Home Market Imputed Credit Expenses.
7. Treatment of PSI Rebates.
8. Ministerial Errors.
9. Eligibility for Revocation.
10. Treatment of Sales with Warranty Expenses.
11. Cost Variances.

Union Steel Manufacturing Co., Ltd. ("Union")

12. Value Added Tax ("VAT").
13. Obsolete Sales in the Home Market.
14. Home Market Weights v. U.S. Weights.

[FR Doc. 01–1223 Filed 1–12–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–822/823]

Notice of Final Results of Antidumping Duty Administrative Reviews and Determination Not To Revoke in Part: Certain Corrosion-Resistant Carbon Steel Flat Products and Cut-to-Length Carbon Steel Plate From Canada

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Final results of antidumping duty administrative reviews and determination not to revoke in part.

SUMMARY: On September 8, 2000, the Department of Commerce (the Department) published the preliminary results of the administrative reviews of the antidumping duty orders on certain corrosion-resistant carbon steel flat products (CORE) and cut-to-length carbon steel plate (CTL) from Canada (65 FR 54481). These reviews cover five manufacturers. The period of review is August 1, 1998 through July 31, 1999.

Based on our analysis of the comments received, we have made changes in the margin calculations. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled "Final Results of the Reviews."

EFFECTIVE DATE: January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Mark Hoadley at (202) 482–0666 (Dofasco Inc. and Sorevco Inc. (collectively, Dofasco) and Gerdau MRM Steel Co. (MRM)), Elfi Blum-Page at (202) 482–0197 (Continuous Colour Coat, Ltd. (CCC) and Clayson Steel Co. (Clayson)), or Abdelali Elouaradia at (202) 482–1374, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR Part 351 (1999).

Background

On September 8, 2000, the Department published the preliminary results of administrative reviews of the antidumping duty orders on CORE and CTL from Canada (65 FR 54481). We invited parties to comment on the preliminary results of the reviews. On October 9 and 10, 2000, petitioners, CCC, Clayson, Dofasco, and MRM filed case briefs. On October 14 and 16, 2000, petitioners, Clayson, and Dofasco filed rebuttal briefs. The Department has conducted these administrative reviews in accordance with section 751 of the Act.

Scope of Reviews

The merchandise covered by these orders consists of two separate "classes or kinds" of merchandise: (1) CORE, and (2) CTL plate. The first class or kind, CORE, includes flat-rolled carbon steel products, of rectangular shape, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel- or iron-based alloys, whether or not corrugated or painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating, in coils (whether or not in successively superimposed layers) and of a width of 0.5 inch or greater, or in straight lengths which, if of a thickness less than 4.75 millimeters, are of a width of 0.5 inch or greater and which measures at least 10 times the thickness or if of a thickness of 4.75 millimeters or more are of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the Harmonized Tariff Schedule (HTS) under item numbers 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0090, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.1000, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7212.60.0000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, and 7217.90.5090. Included in this review are corrosion-resistant flat-rolled products of non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling") for example, products which have been beveled or rounded at the edges. Excluded from this review are flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (terne plate), or both chromium and chromium oxides (tin-free steel), whether or not painted, varnished or coated with plastics or other nonmetallic substances in addition to the metallic coating. Also excluded from this review are clad products in straight lengths of 0.1875 inch or more in composite thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness. Also excluded from this review are certain clad stainless flat-rolled products, which are three-layered corrosion-resistant carbon steel flat-rolled products less than 4.75 millimeters in composite thickness that consist of a carbon steel flat-rolled product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The second class or kind, CTL plate, includes hot-rolled carbon steel universal mill plates (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the HTS under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, and 7212.50.0000. Included in this review are flat-rolled products of non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling") for example, products which have been beveled or rounded at the edges. Excluded from this review is grade X–70 plate. Also excluded is cut-to-length carbon steel plate meeting the following criteria: (1) 100% dry steel plates, virgin steel, no scrap content (free of Cobalt-60 and other radioactive nuclides); (2) .290 inches maximum thickness, plus 0.0,

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minus .030 inches; (3) 48.00 inch wide, plus .05, minus 0.0 inches; (4) 10 foot lengths, plus 0.5, minus 0.0 inches; (5) flatness, plus/minus 0.5 inch over 10 feet; (6) AISI 1006; (7) tension leveled; (8) pickled and oiled; and (9) carbon content, 0.03 to 0.08 (maximum). With respect to both classes or kinds, the HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive of the scope of these reviews.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to these administrative reviews are addressed in the "Issues and Decision Memorandum" (Decision Memo) from Joseph A Spetrini, Deputy Assistant Secretary, Import Administration, to Troy H. Cribb, Assistant Secretary for Import Administration, dated January 8, 2001, which is hereby adopted by this notice.

On November 21, 2000, petitioners and Dofasco submitted a letter to the Department withdrawing their respective case briefs and rebuttal briefs. They requested that we not consider these briefs for our final results. We have decided to grant this request and, therefore, the Decision Memo does not contain a discussion of any issues relating to Dofasco.

A list of the issues which parties have raised and to which we have responded, all of which are in the Decision Memo, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, located in room B–099 of the main Department of Commerce Building. In addition, a complete version of the Decision Memo can be accessed directly on the Web at *http://ia.ita.doc.gov*. The paper copy and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made certain changes in the margin calculations. We have also corrected certain programming and clerical errors in our preliminary results, where applicable.

Determination Not To Revoke the CTL Order in Part

Based on our analysis of comments received, the Department has decided not to alter its preliminary determination not to revoke the order as it pertains to shipments to the United States from MRM. Our analysis of these comments are also contained in the Decision Memo.

Sales Below Cost in the Home Market

The Department disregarded home market below-cost sales that failed the cost test for CCC, Clayson, Dofasco, and MRM in the final results of review.

Determination To Apply the Adverse Facts Available Rate to Metaux Russel Inc.

The Department received no comments on its preliminary determination to apply an adverse facts available rate to Metaux Russel Inc., a respondent in the CTL review. Therefore, we have not altered this decision for these final results of review.

Final Results of Review

We determine that the following weighted-average margins exist for the period August 1, 1998 through July 31, 1999:

Manufacturer/exporter	Margin (percent)
Certain Corrosion-Resistant Carbon Steel Flat Products:	
Continous Colour Coat, Ltd ..	1.81
Dofasco Inc. and Sorevco Inc	0.51
Certain Cut-to-Length Carbon Steel Plate:	
Clayson Steel Co	0.27
Gerdau MRM Steel Co	0.00
Metaux Russel Inc	68.70

Liquidation

The Department shall determine, and Customs shall assess, antidumping duties on all appropriate entries. In accordance with 19 CFR 351.212(b), we have calculated exporter/importer-specific assessment rates. We divided the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each importer. We will direct Customs to assess the resulting percentage margins against the entered Customs values for the subject merchandise on each of that importer's entries under the relevant order during the review period.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative review for all shipments of CORE from Canada entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed company will be the rate shown above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 18.71 percent. This rate is the "All Others" rate from the LTFV investigation.

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

As a result of a Sunset Review, the Department has revoked the antidumping duty order for CTL from Canada, effective January 1, 2000. *See Revocation of Antidumping and Countervailing Duty Orders on Certain Carbon Steel Products From Canada, Germany, Korea, the Netherlands, and Sweden*, 65 FR 78467 (Dec. 15, 2000). Therefore, we have instructed the Customs Service to terminate suspension of liquidation for all entries of CTL made on or after January 1, 2000, and antidumping cash deposit requirements for this merchandise are no longer necessary.

Entries of subject merchandise made prior to January 1, 2000, will continue to be subject to suspension of liquidation and antidumping duty deposit requirements. The Department will complete any pending reviews of this order and will conduct administrative reviews of subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

Reminders

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: January 8, 2001.

Troy H. Cribb,

Assistant Secretary for Import Administration.

Appendix—List of Issues

for CCC:
1. Clerical Errors
for Clayson:
1. Model Match
2. General and Administrative Expenses
3. Quantity Adjustments
4. Hourly Production Rates
5. Overhead Exclusions
6. Clerical Errors
for Dofasco:
No Issues
for MRM:
1. Revocation

[FR Doc. 01–1224 Filed 1–12–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–816]

Certain Cut-to-Length Carbon Steel Plate From Germany: Final Results of Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results in the antidumping duty administrative reviews of certain cut-to-length carbon steel plate from Germany.

SUMMARY: On September 7, 2000, the Department of Commerce ("Department") published the preliminary results of the administrative reviews of the antidumping duty order on certain cut-to-length carbon steel plate from Germany. These reviews cover one manufacturer/exporter. The periods of review ("PORs") are August 1, 1997 through July 31, 1998, and August 1, 1998 through July 31, 1999.

Based on our analysis of the comments received, we have not made any changes in the margin calculations. Therefore, the final results do not differ from the preliminary results. The final adverse facts available margins for the reviewed firm are listed below in the section entitled "Final Results of the Reviews."

EFFECTIVE DATE: January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Bolling, or James Doyle, Enforcement Group III, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230, telephone 202–482–3434 (Bolling), or 202–482–0159 (Doyle), fax 202–482–1388.

SUPPLEMENTARY INFORMATION:

Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930 ("the Act") are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act ("URAA"). In addition, unless otherwise indicated, all citations to the Department's regulations are to the regulations at 19 CFR Part 351 (1999).

Background

The Department published an antidumping duty order on certain cut-to-length carbon steel plate from Germany on August 19, 1993. Antidumping Duty Orders and Amendments to Final Determinations of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products, Certain Cold-Rolled Carbon Steel Flat Products, Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Germany, 58 FR 44170 (August 19, 1993) ("Antidumping Duty Order"). On August 11, 1998, the Department published a notice of opportunity to request administrative review of this order for the period August 1, 1997 through July 31, 1998. See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review, 63 FR 42821 (August 11, 1998). Novosteel, a Swiss exporter of subject merchandise, timely requested that the Department conduct an administrative review of Novosteel's sales for this period ("97–98 Review"). On September 24, 1998, Novosteel requested that the Department defer the 97–98 Review for a one year period, in accordance with 19 CFR 351.213(c); the Department agreed to this request. See Initiation of Antidumping and Countervailing Duty Administrative Review, Requests for Revocation in Part and Deferral of Administrative Reviews, 63 FR 58009 (October 29, 1998). On August 11, 1999, the Department published a notice of opportunity to request administrative review of this order for the period August 1, 1998 through July 31, 1999. See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review, 64 FR 43649 (August 11, 1999). On August 13, 1999, Novosteel timely requested that the Department conduct an administrative review of Novosteel's U.S. entries for this period ("98–99 Review"). On August 31, 1999, Petitioners also timely requested that the Department conduct an administrative review of Novosteel's U.S. entries for the 98–99 period of review ("POR"). In accordance with section 751(a) of the Act, the Department published in the **Federal Register** notices of initiation of the 97–98 Review and the 98–99 Review. See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part, 64 FR 60161 (November 4, 1999) (97–98); Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part, 64 FR 53318 (October 1, 1999) (98–99).

On October 4, 1999, the Department issued Novosteel its questionnaire for the 97–98 Review and the 98–99 Review. On December 9, 1999, Novosteel responded to Section A of the Department's questionnaires. In the Section A response, sales documentation demonstrated that the producer of the subject merchandise, Reiner Brach, had knowledge that the subject merchandise was being exported to the United States. *See* Exhibits 3 and 4 of the December 9, 1999 response. Also, on January 7, 2000, Novosteel responded to Sections B and C of the Department's questionnaires. On January 18, 2000, Petitioners submitted a request that the Department terminate the administrative reviews with respect to Novosteel, arguing that a review of Novosteel, a non-producing exporter, would only be appropriate where the supplier did not have knowledge that the merchandise would be exported to the United States. Petitioners argued that Novosteel's supplier, producer Reiner Brach, had knowledge that the merchandise would be sold to the United States and that, thus, the appropriate sales to be reviewed were those made by Reiner Brach to Novosteel. On February 2, 2000, Reiner Brach submitted a letter opposing termination of the administrative review of Novosteel and agreed to become a respondent for these administrative reviews.

Based on the Novosteel's questionnaire responses, the Department determined that Reiner Brach not only was the producer of the subject merchandise, but also had knowledge that the products were

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destined for the United States, and that, thus, the sale between Reiner Brach and Novosteel was the appropriate link in the sales chain upon which the Department should be conducting its antidumping analysis regarding these sales of the subject merchandise in the United States during the aforementioned PORs. While the result of this change in focus is that the margin calculated in these reviews will be that of Reiner Brach, rather than of Novosteel, per se, Novosteel affirmatively accepted the change of analytical focus to Reiner Brach, and Petitioners have not disagreed with this approach. Therefore, bearing these factors in mind, and in consideration of the small size and lack of experience of Reiner Brach, in addition to noting that two PORs are at issue, the Department determined that it was proper use of its discretion to conduct administrative reviews for the 97–98 and 98–99 PORs of Reiner Brach's sales.

On August 31, 2000, the Department issued the preliminary results of these administrative reviews. See Certain Cut-to-Length Carbon Steel Plate from Germany: Preliminary Results of Antidumping Duty Administrative Reviews, 65 FR 54205 (September 7, 2000) ("German Plate"). The Department has now completed these administrative reviews in accordance with section 751 of the Act.

Scope of the Reviews

The products covered by these administrative reviews constitute one "class or kind" of merchandise: certain cut-to-length carbon steel plate. These products include hot-rolled carbon steel universal mill plates (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the Harmonized Tariff Schedule ("HTS") under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, and 7212.50.0000. Included are flat-rolled products of nonrectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling")—for example, products which have been beveled or rounded at the edges. Excluded is grade X–70 plate. These HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to these administrative reviews are addressed in the "Issues and Decision Memorandum" ("*Decision Memorandum*") from Joseph A. Spetrini, Deputy Assistant Secretary, Import Administration, to Troy H. Crib, Assistant Secretary for Import Administration, dated January 5, 2001, which is hereby adopted by this notice. A list of the issues which parties have raised and to which we have responded, all of which are in the *Decision Memorandum*, is attached to this notice as an Appendix. Parties can find a complete discussion of all issues raised in these reviews and the corresponding recommendations in this public memorandum which is on file at the U.S. Department of Commerce, in the Central Records Unit, in room B–099. In addition, a complete version of the *Decision Memorandum*, is accessible in B–099 and on the Web at ia.ita.doc.gov. The paper copy and electronic version of the Decision Memorandum are identical in content.

Use of Facts Available

In accordance with section 776 of the Act, we have determined that the use of facts available is appropriate for these proceedings for our analysis of Reiner Brach's entries. For a discussion of our determination with respect to this matter, see the facts available section of the *Decision Memorandum*, accessible in B–099 and on the Web at ia.ita.doc.gov.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have not made any changes in the margin calculations. See "*Decision Memorandum*," accessible in B–099 and on the Web at ia.ita.doc.gov.

Final Results of the Reviews

We determine the following margins for the periods August 1, 1997 through July 31, 1998 and August 1, 1998 through July 31, 1999:

CERTAIN CUT-TO-LENGTH CARBON STEEL PLATE

Producer/ manufacturer/exporter	Margin (percent)
Reiner Brach (97–98 Review) ..	36.00
Reiner Brach (98–99 Review) ..	36.00

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of this notice of final results of administrative reviews for all shipments of cut-to-length plate from Germany entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Act: (1) The cash deposit rates for the reviewed company will be the rate shown above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less than fair value ("LTFV") investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 36.00 percent. This rate is the "all others" rates from the LTFV investigation. See Antidumping Duty Orders and Amendments to Final Determinations of Sales at Less Than Fair Value: Certain Hot-Rolled Carbon Steel Flat Products, Certain Cold-Rolled Carbon Steel Flat Products, Certain Corrosion-Resistant Carbon Steel Flat Products and Certain Cut-to-Length Carbon Steel Plate From Germany, 58 FR 44170 (August 19, 1993) ("Antidumping Duty Order").

These deposit requirements shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective orders ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305 or conversion to judicial protective order is requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this determination and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: January 5, 2001.

Troy H. Cribb,

Assistant Secretary for Import Administration.

Appendix

1. Respondent Cooperation
2. Request to Extend Final and Submit Additional Data
3. The Application of Total Adverse Facts Available
4. The Facts Available Margin

[FR Doc. 01–1225 Filed 1–12–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Public Hearing on Establishment of Import Restrictions on Certain Steel Products From Ukraine to the United States

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 16, 2001.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning the public hearing and/or public comments, contact Lesley Stagliano at (202) 482–0190. All other questions should be directed to Edward Yang at (202) 482–0406.

SUPPLEMENTARY INFORMATION: On June 1, 1990, pursuant to Title IV of the Trade Act of 1974 (the Trade Act), the Governments of the United States of America and Union of Soviet Socialist Republics entered into the Agreement on Trade Relations Between the United States of America and the Union of Soviet Socialist Republics. On May 6, 1992, this agreement became effective between the United States of America and Ukraine (the 1992 Agreement). Article XI of the 1992 Agreement provides that the Parties will consult with a view toward finding means of remedying or preventing actual or threatened market disruption, and it authorizes the Parties to take action, including the imposition of import restrictions, to achieve this goal.

In January 2001, the United States Department of Commerce and the Ministry of Economy of Ukraine entered into negotiations and consultations pursuant to Article XI of the Agreement on Trade Relations Between the United States of America and Ukraine. In these negotiations, the Parties are considering whether the conditions of Article XI have been met with respect to U.S. imports of certain steel products from Ukraine and, if so, what action should be taken.

Pursuant to Article XI, the United States is considering establishing import restrictions on Ukrainian exports to the United States of the following 21 steel products:

1. Steel Concrete Reinforcing Bar (Re-Bar)
2. Hot-Rolled Carbon Quality Steel Products
3. Cold-Rolled Carbon Quality Steel Products
4. Hot-Rolled Steel Stainless and Alloy Products
5. Cold-Rolled Stainless, Alloy and Other Carbon Steel Products
6. Galvanized Sheet Products
7. Other Metallic Coated Flat-Rolled Products
8. Rails
9. Electrical Sheet Products
10. Heavy Structural Shapes
11. Hot-Rolled Bars
12. Hot-Rolled Light Shapes
13. Cold-Finished Bars
14. Certain Tin Mill Products Pipe and Tube Products
15. Wire Rod Products
16. Tool Steel
17. Drawn Wire
18. Wheels and Axles
19. Fabricated Structural Shapes
20. Semifinished Steel Products
21. Pig Iron

Each category of steel would have a separate export limit. In addition to the issuance of export licenses by the Ministry of Economy of Ukraine, the United States would establish a border enforcement mechanism to ensure compliance with the export limits. The border mechanism will be in the form of denial of entry for any shipment of steel, covered by the categories listed above, which exceeds the limits or lacks the required documents.

Section 125(c) of the Trade Act (19 U.S.C. 2135(c)) provides that whenever the United States, acting in pursuance of any of its rights or obligations under any trade agreement entered into pursuant to the Trade Act, modifies any obligation with respect to the trade of any foreign country or instrumentality, the President is authorized to proclaim increased duties or other import restrictions, to the extent, at such times, and for such periods as he deems necessary or appropriate, in order to exercise the rights or fulfill the obligations of the United States.

Section 125(f) of the Trade Act (19 U.S.C. 2135(f)) requires the President to provide the opportunity for interested parties to present views at a public hearing prior to taking action pursuant to section 125(b), (c), or (d) of the Trade Act (19 U.S.C. 2135(b), (c), or (d)). Such an opportunity is being provided by scheduling such a hearing for Wednesday, January 17, 2001, at the United States Department of Commerce. If the consultations and negotiations with the Ministry of Economy of Ukraine result in a tentative agreement, the Department will publish the proposed agreement on its Import Administration website (http://ia.ita.doc.gov) no later than 12:00 p.m. on Tuesday, January 16, 2001, and conduct the hearing on January 17, 2001.

Notice of Public Hearing: Pursuant to section 125(f) of the Trade Act of 1974 (19 U.S.C. 2135(f)), the International Trade Administration of the Department of Commerce, has scheduled a public hearing beginning at 10 a.m., on January 17, 2001, at Room 1412 of the Herbert C. Hoover Building, U.S. Department of Commerce, 14th and Constitution Ave., NW, Washington, DC.

Requests to Present Oral Testimony: Parties wishing to testify orally at the hearing must provide written notification of their intention not later than 5 p.m., January 16, 2001 to Troy H. Cribb, Assistant Secretary for Import Administration: In re Public Hearing on Establishment of Import Restrictions on Certain Steel Products From Ukraine to the United States, Room 1870, Herbert C. Hoover Building, U.S. Department of Commerce, 14th and Constitution Ave., NW, Washington, DC. The notification should include (1) the name of the person presenting the testimony, their address and telephone number; (2) the organization or company they are representing, if appropriate; (3) a list of issues to be addressed; and (4), if applicable, any request for an extension of the time limitation on the oral presentation. This notification may be submitted via facsimile to Vicki Sullivan at (202) 273–0957. Those parties presenting oral testimony must also submit a written brief, in 20 copies, not later than 10 a.m., January 18, 2001, to the above-mentioned address.

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Hearing presentations should be limited to no more than five minutes to allow for possible questions from the Chairman and the panel. Additional time for oral presentations may be granted as time and the number of participants permit. Any business proprietary material must be clearly marked as such on the cover page (or letter) and succeeding pages. Such submissions must be accompanied by a public summary thereof.

Written Briefs: Those persons not wishing to participate in the hearing may submit written comments, in 20 typed copies, not later than 10 a.m., January 18, 2001, to Troy H. Cribb, Assistant Secretary for Import Administration: In re Public Hearing on Establishment of Import Restrictions on Certain Steel Products From Ukraine to the United States, Room 1870, Herbert C. Hoover Building, U.S. Department of Commerce, 14th and Constitution Ave., NW, Washington, DC. Comments should state clearly the position taken and describe with particularity the evidence supporting that position. Any business proprietary material must be clearly marked as such on the cover page (or letter) and succeeding pages. Such submissions must be accompanied by a public summary thereof. Public submissions will be available for public inspection at the Import Administration Central Records Unit. An appointment to review the file may be made by contacting Thomas Harley at (202) 482–1248.

Dated: January 10, 2001.

Troy H. Cribb,

Assistant Secretary for Import Administration.

[FR Doc. 01–1247 Filed 1–12–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010901E]

Western Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The 76th meeting of the Western Pacific Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will convene January 30 through February 1, 2001, in Honolulu, HI.

DATES: The SSC meeting will be held from 9 a.m. to 5 p.m. on January 30 and from 8:30 a.m. to 5 p.m. on January 31 and February 1, 2001.

ADDRESS: The 76th SSC meeting will be held at the Council office conference room, 1164 Bishop St., Suite 1400, Honolulu, HI; telephone: (808–522–8220).

Council address: Western Pacific Fishery Management Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone: 808–522–8220.

SUPPLEMENTARY INFORMATION: The SSC will discuss and may make recommendations to the Council on the agenda items below. The order in which agenda items will be addressed can change.

Tuesday, January 30, 2001, 9 a.m.

1. Precious corals fisheries
   A. Status of 2000 framework adjustment regarding Hawaiian Islands exploratory area quota increase
   B. Growth rates of gold coral
   C. November research surveys
   D. Summary of Draft Environmental Impact Statement (DEIS)
   E. Plan Team recommendations
2. Crustaceans fisheries (Northwestern Hawaiian Islands [NWHI] lobsters)
   A. Status of framework closure of fishery
   B. Status of spring research tagging charter
   C. Status of plans for 5–year review/technical review panel
   D. Status of DEIS
3. Bottomfish fisheries
   A. Status of the NWHI stocks
   B. Status of litigation
   C. Status of DEIS

Wednesday, January 31, 2001, 8:30 a.m.

4. Pelagic fisheries
   A. 3rd quarter 2000 Hawaii and American Samoa longline fishery reports
   Exclusion of purse seiners from provisions of 50 nm closed area around American Samoa
   B. Turtle management
   (1) Pelagic EIS: NMFS preferred alternative
   (2) NMFS Biological opinion, recommended measures
   (3) Turtle Mitigation Working Group
   (4) Atlantic Turtle Working Group (TWG)
   (5) Turtle Recovery Plan
   (6) Criteria for de-listing species under Endangered Species Act (ESA)
   C. Shark management
   Amendment 9 blue shark quota following state & federal finning bans
   D. Seabird management
   U.S. Fish & Wildlife (FWS) Biological opinion on short-tailed albatross and Council recommended mitigation regime
   E. Kingman Reef Environmental Assessment(EA)
   F. Hawaii offshore handline fishery and gear conflicts at Cross seamount
   G. Other issues

Thursday, February 1, 2001, 8:30 a.m.

5. Ecosystem and Habitat
   A. Draft Coral Reef Ecosystem FMP/DEIS
   (1) Aspects for further discussion
   (2) Review of (initial) public/agency comments
   B. Impacts of Clinton's Executive Order (EO) on NWHI fisheries
   C. Marine/wildlife inventory at remote atolls
   D. Other issues
6. De-listing of protected species (green sea turtle)/allowing for cultural take
7. Other business
8. Schedule for 2001

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, 808–522–8220 (voice) or 808–522–8226 (fax), at least 5 days prior to meeting date.

Dated: January 10, 2001.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1215 Filed 1–12–01; 8:45 am]

BILLING CODE: 3510–22–S

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Notice of Policy Guidance on Title VI's Prohibition Against National Origin Discrimination as It Affects Limited English Proficient Persons

AGENCY: Corporation for National and Community Service.

ACTION: Notice of policy guidance.

SUMMARY: The Corporation for National and Community Service (Corporation) is publishing policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons. This policy clarifies the existing responsibilities of Corporation grantees to take reasonable steps to provide access to their programs and activities for persons with limited English proficiency. This document provides an opportunity for public comment. The Corporation will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

DATES: This guidance is effective immediately. Comments must be submitted on or before March 19, 2001.

ADDRESSES: Interested persons should submit written comments to Ms. Wilsie Y. Minor, Associate General Counsel, Corporation for National Service, 1201 New York Ave., NW., Washington, DC 20525. Comments may also be submitted by facsimile at 202–565–2796.

FOR FURTHER INFORMATION CONTACT: Wilsie Y. Minor, Corporation for National Service, 1201 New York Ave., NW., Washington, DC 20525. Telephone 202–606–5000, ext. 129; TDD: 202–565–2799. Arrangements to receive the policy in an alternative format may be made by contacting Wilsie Y. Minor.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.*, and its implementing regulations provide that no person shall be subjected to discrimination on the basis of race, color, or national origin under any program or activity that receives federal financial assistance.

The purpose of this policy guidance is to clarify the responsibilities of recipients of federal financial assistance from the Corporation for National and Community Service (Corporation) ("grantees"), and assist them in fulfilling their responsibilities to limited English proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964 and implementing regulations. The policy guidance reiterates the Corporation's longstanding position that in order to avoid discrimination against LEP persons on the grounds of national origin, grantees must take reasonable steps to ensure that such persons have meaningful access to the programs, services, and information those grantees provide, free of charge.

The text of the complete guidance document follows:

Providing Access to Limited-English Proficient (LEP) Persons to the Programs and Activities of Grantees of the Corporation for National Service

A. Overview

1. What Does the Document Do?

This policy guidance does not create new obligations but rather clarifies the existing responsibilities of Corporation for National Service (hereinafter Corporation) grantees to take reasonable steps to provide access to their programs and activities for persons with limited English proficiency (LEP). This document:

(a) Discusses the policies, procedures and other steps that Corporation grantees can take to provide access by LEP persons to national service programs and to other programs and activities of our grantees.

(b) Clarifies that failure to take one or more of these steps does not necessarily mean noncompliance with Title VI of the Civil Rights Act of 1964 or with Executive Order 13166.

(c) Provides that the Corporation's Equal Opportunity (EO) Office will determine compliance on a case-by-case basis, and that assessments will take into account:

- Number or proportion of LEP individuals in the service area;
- Frequency of contact with LEP language groups;
- Nature and importance of the program or activity; and
- Total resources available to the recipient.

(d) Provides that small grantees and those with limited resources will have flexibility in achieving compliance.

(e) Applies to all beneficiaries of our grantees' programs or activities.

In this document, "beneficiary" refers to:

- Clients, former clients, and client applicants of a grantee's programs or activities;
- Members of the public who receive or are eligible to receive benefits or services from our grantees; and

Participants, former participants, and participant applicants for positions as a service member or volunteer.

Our grantees' programs or activities include:

- Federally assisted programs such as AmeriCorps*State/National;
- Part-time programs such as Foster Grandparents or participants in Learn and Serve America; and
- Part federally-conducted/part federally-assisted programs such as AmeriCorps*VISTA or AmeriCorps*NCCC.

Our grantees' programs or activities include not merely the national service programs operated by the grantees, but in most cases they include all operations of the organization. (See Legal Underpinnings below for an explanation of a grantee's "programs and activities".)

2. Why Do Our Grantees Need To Ensure Their Programs or Activities Provide Services to LEP Persons?

Grantees must comply with various civil rights statutes, including Title VI of the Civil Rights Act of 1964 which prohibits denial of services to and other forms of discrimination against persons on the basis of national origin, color, and race. Often, language identifies national origin. Language barriers may be rooted in intentional discrimination. Most frequently, failure to provide language assistance to LEP persons on the basis of national origin leads to actions having the effect of discrimination. Such actions have consistently been held to violate Title VI. (See Legal Underpinnings below for more information on Title VI, and on Executive Order 13166 which clarifies Title VI in the LEP context.)

English is the predominant language of the United States. According to the 1990 Census, English is spoken by 95% of its residents. Of the U.S. residents who speak languages other than English at home, the 1990 Census reports that 57% above the age of four speak English "well to very well." However, the U.S. is also home to millions of national origin minority individuals who are "limited English proficient" (LEP). That is, they cannot speak, read, write or understand the English language at a level that permits them to interact effectively with teachers and education officials, health care providers, social service agency staff, police and emergency workers, officials of public benefit programs, etc.

Because of these language differences and their inability to speak or understand English, LEP persons are often excluded from programs, experience delays or denials of services, or receive care and services based on inaccurate or incomplete information. Federal agencies have found that persons who lack proficiency in English frequently are unable to obtain basic knowledge of how to access various benefits and services for which they are eligible. Agencies have also found that LEP persons are sometimes exploited by unscrupulous persons or unwittingly are pawns in frauds against benefit programs.

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3. What Is Our Policy on Ensuring Our Grantees' Programs or Activities Provide Access to Their Services to LEP Persons?

It is our policy to ensure that our grantees fully comply with the requirements of the various civil rights acts and requirements applicable to federal grantees, including Title VI of the Civil Rights Act of 1964 and Executive Order 13166. One aspect of compliance is to ensure that our grantees take reasonable steps to provide meaningful access for LEP persons to their program or activities, including provision of language interpretive services within the parameters set forth in this policy document.

B. Legal Underpinnings of This Policy

1. What Are the Basic Requirements Under Title VI in the LEP Context?

Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000–d) prohibits discrimination on the basis of race, color, or national origin in programs and activities that receive federal financial assistance. Recipients of federal financial assistance (referred to as "grantees" in this policy) may not, on the basis of race, color, or national origin:

- Provide services, financial aid, or other benefits that are different or provide them in a different manner;
- Restrict an individual's enjoyment of an advantage or privilege enjoyed by others;
- Deny an individual the right to participate in federally assisted programs; and
- Defeat or substantially impair the objectives of federally assisted programs.

A grantee whose policies, practices or procedures exclude, limit, or have the effect of excluding or limiting, the participation of any LEP person in a federally assisted program or activity on the basis of national origin may be engaged in discrimination in violation of Title VI. In order to ensure compliance with Title VI, grantees must take reasonable steps to ensure that LEP persons who are eligible for their programs or activities have access to the services they provide. The most important step in meeting this obligation is for grantees to provide the language assistance necessary to ensure such access and to do so at no cost to the LEP person.

2. What Does Executive Order 13166 Require in the LEP Context? Does It Impose Requirements Beyond Those of Title VI?

On August 11, 2000, the President issued Executive Order 13166 entitled "Improving Access to Services for Persons with Limited English Proficiency." The purpose of this Executive Order is to eliminate, to the maximum extent possible, limited English proficiency as an artificial barrier to full and meaningful participation by beneficiaries in federally assisted programs and activities. It clarifies existing Title VI responsibilities for grantees regarding access for LEP persons, but does not impose additional requirements. On August 16, 2000, the Department of Justice issued policy guidance which may be found at 65 Fed.Reg. 50123 or *www.usdoj.gov/crt/cor.*

3. Who Are Grantees? What Is Federal Financial Assistance?

In this document, a grantee is any entity receiving federal financial assistance from us to operate a federally assisted program. Grantees include, but are not limited to, the State Commissions, AmeriCorps*VISTA and Senior Corps sponsors, State Educational Agencies, and AmeriCorps*NCCC projects. Grantees also include other direct recipients, service sites and intermediary service programs (entities between the primary grantee and the service sites).

For example, the Corporation funds a grant to a state agency. The state agency provides funding to non-profits or local governments throughout the state. These organizations place volunteers with local organizations. Each level is a grantee for civil rights purposes.

Federal financial assistance includes funds, property or services, including technical assistance, provided to non-federal organizations to promote activities serving the public interest. For civil rights purposes, it also includes aid that enhances the ability to improve or expand allocation of a grantee's own resources. This may be through the services of, or training by, service members or volunteers or federal personnel at no cost or at less than full market value. Therefore, assignment of service members or volunteers (including VISTA or NCCC)—whether supported, in whole or in part, under a Corporation grant or through an Education Award Program—is a form of federal financial assistance.

The definition of the "program or activity" receiving federal financial assistance is quite broad and for most organizations extends beyond their national service program. For example, it includes all operations of a department, agency or district of a State or local government; a college, university, local education agency; and an entire corporation or private organization which is principally engaged in providing education, health care, housing, social services, or parks and recreation when any part of these entities receives federal financial assistance.

A grantee may receive financial assistance directly from us or through another grantee. A grantee may be a Native American tribe. While tribes have sovereign immunity in many respects, when they receive federal financial assistance, by the terms of the grant, they agree to comply with the civil rights requirements in the operation of their national service programs.

4. Who Are Beneficiaries? Why Are They Beneficiaries? What Rights Do They Have?

Service members and volunteers are beneficiaries of federally assisted programs. They receive a stipend, an allowance for living expenses, an education award or post-service stipend, child care or child care allowance, and/or health care coverage, or cost reimbursements paid in whole or in part, directly or indirectly, by the Corporation. Former service members or volunteers and service member and volunteer applicants are also beneficiaries as it relates to their connection to a national service program funded by the Corporation.

The persons served by the service members and volunteers (including AmeriCorps*NCCC members) are beneficiaries of federally assisted programs. They receive benefits, be it tutoring, housing, employment, or substance abuse counseling, immunizations, personal living assistance, etc. which they would not have but for the national service programs funded in whole or in part by the Corporation. Persons previously served or applying to be served by service members and volunteers are also beneficiaries.

The persons served, eligible to be served, or previously served by other programs and activities of the grantee are also beneficiaries of federally assisted programs. They receive benefits from a recipient of federal financial assistance, so by definition they are beneficiaries. Similarly, members of the public who receive or are eligible to receive benefits or services from our grantees are beneficiaries.

All beneficiaries of federal financial assistance have the right not to be subjected to prohibited discrimination. In the LEP context, this means they have the right to have the grantee take reasonable steps to provide meaningful access to its programs and activities to enable LEP persons to participate. All beneficiaries also have the right to file a discrimination complaint with the Corporation if he or she believes discrimination has occurred.

5. Can We Presume That Service Members or Volunteers Must Be Proficient in English?

No. Programs should assess whether individuals with limited English proficiency can effectively serve in their programs with or without language assistance. Programs may not deny access on the basis of lack of English proficiency unless providing language assistance would fundamentally alter the nature of their program or unreasonably burden the organization. There may be programs where the member or volunteer must be proficient in English, but in some of the Corporation's programs such as Senior Companions, limited English proficiency may not hinder the ability to serve. Individuals who speak the language of one of the minority groups within a community, even when they are LEP, may effectively help to serve the community.

6. If a Grantee Is Covered by a State or Local "English-only" Law, Must It Still Comply With the Title VI Obligation and Corporation Guidance Interpreting That Obligation?

Yes. State and local laws may provide additional obligations to serve LEP individuals, but cannot compel grantees to violate Title VI. For instance, given our constitutional structure, State or local "English-only" laws do not relieve an entity that receives federal funding or other financial assistance from its responsibilities under federal anti-discrimination laws. Entities in States and localities with "English-only" laws are certainly not required to accept federal funding—but if they do, they have to comply with Title VI, including its prohibition against national origin discrimination by recipients of federal assistance. Failing to make federally assisted programs and activities accessible to individuals who are LEP will, in certain circumstances, violate Title VI.

C. LEP Requirements

1. What Are the Basic Requirements Under Title VI for LEP Persons?

The basic requirement is to provide meaningful access for LEP persons to a grantee's programs and activities. There is no "one size fits all" solution for providing meaningful access, and our assessment of a grantee's compliance will be made on a case-by-case basis. A grantee will have considerable flexibility in determining precisely how to fulfill this obligation, and we will focus on the grantee's end result. The key to providing meaningful access is to ensure that the grantee and the LEP person can communicate effectively. Effective communication means the LEP person is:

- Able to understand the services and benefits available;
- Able to receive those benefits for which he or she is eligible; and
- Able to effectively communicate the relevant circumstances of his or her situation to the service provider.

The type of language assistance provided depends on a variety of factors, including:

- Number or proportion of LEP individuals in the service area;
- Frequency of contact with LEP language groups;
- Nature and importance of the program or activity; and

total resources available to the recipient.

2. What Are the Basic Elements of an Effective Language Assistance Program?

Effective language assistance programs usually contain four elements:

- Assessment;
- Comprehensive written policy;
- Staff training; and
- Monitoring.

Failure to incorporate or implement one or more elements does not necessarily mean noncompliance with Title VI, and we will focus on whether meaningful access is achieved. Further, if implementation of one or more accessibility options would be so financially burdensome as to defeat the legitimate objectives of a grantee's program, the grantee will not be found in noncompliance with Title VI.

3. How Does a Grantee Assess the Language Needs of the Affected Population (the First Key for Ensuring Meaningful Access to LEP Persons)?

A grantee assesses language needs by considering a variety of factors, including the total resources and size of the recipient/covered entity, the number or proportion of the eligible LEP population it serves, the nature and importance of the program or service, including the objectives of the program, the total resources available to the recipient/covered entity, and the frequency with which particular languages are encountered and the frequency with which LEP persons come into contact with the program.

Assessing the number or proportion of the eligible LEP population may be done through review of census data, client utilization data from client files, data from local school systems and community agencies and organizations, or other sources. Grantees are encouraged to identify local organizations that serve the LEP populations in their community. Collaborations with these organizations may not only assist in assessing language needs, but may improve outreach to and recruitment from the communities they serve.

4. What Should Be Included in a Comprehensive Written Policy and Procedures on Language Access (the Second Key for Ensuring Meaningful Access to LEP Persons)?

Presuming the assessment reveals more than merely a few LEP persons being served or eligible to be served or likely to be directly affected by the program, a grantee should develop and implement a language assistance policy, including implementation procedures. The policy should be comprehensive and should be in writing. It should address periodic staff training and monitoring the effectiveness of the program. Ideally, a range of oral language assistance options should be included, and it should provide for translation of vital written materials in certain circumstances. (See D.2.)

The implementation procedures should be comprehensive, should be in writing, and should include:

- How to identify and assess the language needs of LEP persons, and to record this information in individual client files, as applicable;
- How to notify LEP persons, in a language they can understand, of their right to receive free language assistance;
- Identify where in the program or activity language assistance is likely to be needed;
- Identify what resources are likely to be needed, their location, and their availability;
- How to access these resources to provide language assistance in a timely manner.

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5. How Does a Grantee Effectively Train Its Staff Regarding the Policy and Procedures (the Third Key for Ensuring Meaningful Access to LEP Persons)?

A grantee must disseminate its policy to all employees, especially to those likely to have contact with LEP persons. It must also periodically train its employees. Effective training ensures that employees are knowledgeable and aware of LEP policies and procedures, are trained to work effectively with in-person and telephone interpreters, and understand the dynamics of interpretation between clients, providers and interpreters. Training should be part of the orientation for new employees, and all employees in client contact positions need to receive additional training. For AmeriCorps*State/National grantees, State Commissions request Professional Development and Training Funds (PDAT) funds to provide professional development and training for AmeriCorps staff. To support the LEP initiatives, funds might be used for activities that train AmeriCorps staff about best practices for working with LEP members, and for building the language capacity of LEP AmeriCorps members.

6. How Does a Grantee Effectively Monitor and Evaluate Its Language Assistance Program To Ensure It Provides Meaningful Access to LEP Persons (the Fourth Key for Ensuring Meaningful Access to LEP Persons)?

A grantee should monitor its language assistance program at least annually. As part of the monitoring, the grantee should seek feedback from clients and advocates. The monitoring and evaluation should:

- Assess the current LEP makeup of its service area and frequency of contact with LEP language groups;
- Assess the current communication needs of LEP applicants and clients;
- Determine whether existing assistance is meeting the needs of such persons;
- Evaluate whether staff is knowledgeable about the policy and procedures and how to implement them; and
- Determine whether sources of and arrangements for assistance are still current and viable.

D. Specific LEP Implementation Methods, Their Pros and Cons

1. What Does a Grantee Need To Know About Providing Trained and Competent Interpreters?

Meaningful access to programs and activities includes providing trained and competent interpreters and other oral language assistance services in a timely manner. This may include taking some or all of the following steps:

- Bilingual Staff—Hire bilingual staff for critical direct client contact positions (such as emergency room intake personnel). Bilingual staff must be trained and must demonstrate competence as interpreters.
- Staff Interpreters—Hire paid staff interpreters, especially when there is a frequent and/or regular need for interpreting services. These persons must be competent and readily available.
- Contract Interpreters—Use contract interpreters, especially when there is an infrequent need for interpreting services, when less common LEP language groups are in the service areas, or when there is a need to supplement in-house capabilities on an as-needed basis. Contract interpreters must be readily available and competent.
- Community Volunteers—Use community volunteers. While volunteers may be cost-effective, to use them effectively, grantees must enter into formal arrangements for interpreting services with community organizations so the organizations are not subjected to *ad hoc* requests for assistance. Volunteers must be competent as interpreters and understand their obligation to maintain client confidentiality. Additional language assistance must be provided where competent volunteers are not readily available during all hours of service. (**NOTE:** Except in the conditions explained at the end of this section, use of family member volunteers, especially children, is never appropriate, and, even if a child speaks English, the parent must be able to fully understand in order to provide informed consent for medical services or participation in program activities.)
- Telephone Interpreter Lines—Utilize a telephone interpreter service line, as a supplemental system or when a grantee encounters a language that it cannot otherwise accommodate. Such a service often offers interpreting assistance in many different languages and usually can provide the service in quick response to a request. However, the interpreters may not be familiar with the terminology peculiar to the particular program or service. (**Note:** this should not be the only language assistance option used, except where other language assistance options are unavailable (*e.g.*, in a rural clinic visited by an LEP patient who speaks a language that is not usually encountered in the area).)

In order to provide effective services to LEP persons, a grantee must ensure that it uses persons who are competent to provide interpreter services. Competency does not necessarily mean formal certification as an interpreter, though certification is helpful, but competency requires more than self-identification as bilingual. The competency requirement contemplates:

- Demonstrated proficiency in both English and the other language;
- Orientation and training that includes the skills and ethics of interpreting (*e.g.* issues of confidentiality);
- Fundamental knowledge in both languages of any specialized terms or concepts peculiar to the grantee's program or activity;
- Sensitivity to the LEP person's culture; and
- A demonstrated ability to accurately convey information in both languages.

A grantee may expose itself to liability under Title VI if it requires, suggests, or encourages an LEP person to use friends, minor children, or family members as interpreters, as this could compromise the effectiveness of the service. Use of such persons could result in a breach of confidentiality or reluctance on the part of individuals to reveal personal information critical to their situations. In a medical setting, this reluctance could have serious, even life threatening, consequences. In addition, family and friends usually are not competent to act as interpreters, since they are often insufficiently proficient in both languages, unskilled in interpretation, and unfamiliar with specialized terminology.

If, after a grantee informs an LEP person of the right to free interpreter services, the person declines such services and requests the use of a family member or friend, the grantee may use the family member or friend, if the use of such a person would not compromise the effectiveness of services or violate the LEP person's confidentiality. The grantee should document the offer and declination in the LEP person's file. Even if an LEP person elects to use a family member or friend, the grantee should suggest that a trained interpreter sit in on the encounter to ensure accurate interpretation.

2. What Does a Grantee Need to Know About Providing Translation of Written Materials?

An effective language assistance program may include providing translation of certain written materials. For instance, written materials routinely provided in English to applicants, clients and the public should be available in regularly encountered languages other than English. Spanish, Chinese, Vietnamese, Tagalog, and Korean are the major languages spoken by non-English speaking persons in the U.S. It is particularly important to ensure that vital documents are translated into the non-English language of each regularly encountered LEP group eligible to be served or likely to be directly affected by the grantee's program. Examples of vital documents include:

- Applications for benefits or services;
- Consent forms;
- Documents containing important information regarding participation in a program (such as descriptions of eligibility for tutoring, assignment of a Senior Companion, instructions for filing for reimbursement of expenses, application for health care or child care benefits);
- Notices pertaining to the reduction, denial or termination of services or benefits, or to the right to appeal such actions or that require a response from beneficiaries;
- The member contract, job description, and an explanation of the Grievance Procedure;
- Notices advising LEP persons of the availability of free language assistance; and
- Other outreach materials.

In contrast, documents prepared for a selected portion of the public, such as laws, regulations, and detailed policy manuals, may not be a priority for translation and perhaps only short summaries of the contents are needed.

When making decisions about doing written translation of documents, it is important to consider the level of literacy in the ethnic community's first language. If a document is translated in writing for a community with high rates of first language illiteracy, access for LEP individuals may still be denied. Meaningful access may require making the information available in an oral format.

It is important to ensure that the person translating the materials is well qualified. Verbatim translations may not accurately or appropriately convey the substance of what is contained in the written materials. An effective way to address this potential problem is to reach out to community-based organizations to review translated materials to ensure that they are accurate and easily understood by LEP persons. Recent technological advances have made it easier to store translated documents. It is advisable to maintain a data base of translated documents, to avoid the cost and time of repeated translations of the same document.

3. Is Corporation Funding Available to Assist With the Cost of Translation?

The cost of translation may be an allowable cost of a grant.

Grant funds are not available for AmeriCorps*NCCC project sponsors.

4. What Does a Grantee Need to Know About Effectively Notifying LEP Persons of Their Right to Language Assistance and of the Availability of Language Assistance Free of Charge?

For a language assistance program to be effective, LEP persons need to know they have the right to receive language assistance, and that the language assistance will be provided at no charge to them. Effective notification methods include, but are not limited to:

- Posting and maintaining signs in regularly encountered languages other than English in waiting rooms, reception areas and other initial points of entry. In order to be effective, these signs must inform applicants and beneficiaries of their right to free language assistance services and invite them to identify themselves as persons needing such services.
- Including statements about the services available and the right to free language assistance services, in appropriate non-English languages, in brochures, booklets, outreach and recruitment information and other materials that are routinely disseminated to the public.
- Providing this information to advocacy organizations, faith-based organizations, and societies providing services to LEP persons in the community.

5. What Other Innovative Methods Are There To Provide Meaningful Access to LEP Persons?

- Simultaneous Translation—This allows a grantee and client to communicate using wireless remote headsets while a trained competent interpreter, located in a separate room, provides simultaneous interpreting services. The interpreter can be miles away, and thereby reduces delays since the interpreter does not have to travel to the grantee's facility. In addition, a grantee that operates more than one facility can deliver interpreter services to all facilities using this central bank of interpreters, as long as each facility is equipped with the proper technology.
- Language Banks—In several parts of the country, both urban and rural, community organizations and providers have created community language banks that train, hire and dispatch competent interpreters to participating organizations, reducing the need to have on-staff interpreters for low demand languages. These language banks are frequently nonprofit and charge reasonable rates. This approach is particularly appropriate where there is a scarcity of language services or where there is a large variety of language needs.
- Language Support Office—This is an office that tests and certifies all in-house and contract interpreters, provides agency-wide support for translation of forms, client mailings, publications and other written materials into non-English languages, and monitors the policies of the agency and its vendors that affect LEP persons.
- Multicultural Delivery Project—This is a project that finds interpreters for immigrants and other LEP persons. It uses community outreach workers to work with LEP clients and can be used by employees in solving cultural and language issues. A multicultural advisory committee helps to keep the county in touch with community needs.
- Pamphlets—The pamphlets are intended to facilitate basic communication between clients and staff as they await receipt of interpreter services. They are not intended to replace interpreters but may aid in increasing the comfort level of LEP persons as they wait for services.

E. Compliance Monitoring

1. By What Mechanisms Does the Corporation Ensure its Grantees Comply With These LEP Requirements?

The Corporation uses or may use a variety of mechanisms to monitor compliance with civil rights requirements, including LEP requirements, by its grantees. These include review of grant application submissions, pre-award and/or post-award compliance reviews (desk audit or on-site), discrimination complaint investigations, and information gathered during outreach and technical assistance activities. Other federal agencies often provide far more monetary federal assistance to its grantees than does the Corporation. Each federal agency extending federal financial assistance maintains mechanisms to ensure compliance with Title VI and its implementing regulations. Compliance determinations by larger federal agencies are given great weight by the Corporation, and grantees receiving substantial federal financial assistance from agencies such as the U.S. Department of Health and Human Services, the U.S. Department of Education, the U.S. Department of

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Veteran's Affairs, the U.S. Department of Justice, and the U.S. Department of Housing and Urban Development should make sure to be familiar with the Title VI enforcement mechanisms of all federal agencies. If the Corporation receives a complaint alleging failure to provide effective access to LEP persons, we may refer it for processing to a larger federal agency who also funds the grantee. However, under these circumstances, we maintain our authority to independently determine a grantee's compliance.

2. What Can Happen to a Grantee if Its Actions Are Determined by the Corporation's EO Office To Be Discriminatory?

The Corporation is obligated to take appropriate action regarding any grantee that does not comply with the civil rights laws, implementing regulations and policies. If the Equal Opportunity Director finds that a grantee has discriminated, it is in noncompliance with the civil rights laws. If the grantee refuses to voluntarily correct the noncompliance, the Corporation may pursue a number of options, including suspension, termination or the discontinuation of aid. The ultimate sanction may be termination of all federal funding to the program or activity.

However, the purpose of the civil rights laws is to achieve compliance with the laws, not to terminate federal funding to programs. Therefore, we make great efforts to encourage our grantees to voluntarily comply with the laws.

3. What Responsibilities and Liabilities Do Primary Grantees Have When a Subgrantee Discriminates?

A primary grantee extends federal financial assistance to subgrantees. A primary grantee has continuing oversight responsibilities for ensuring the operations of each of its subgrantees comply with the civil rights laws. When reviewing grant proposals, the primary grantee should consider whether applicants for subgrants have identified a means for providing access to LEP persons. During the term of the grant, the primary grantee should monitor the provision of meaningful access in the same manner that it monitors compliance with other grant provisions.

When a beneficiary claims a subgrantee has discriminated, the primary grantee should take action to bring the subgrantee into voluntary compliance, and take appropriate action when a subgrantee does not voluntarily comply. In cases of noncompliance, appropriate action may include but is not limited to:

- Providing relief to the beneficiary;
- Submitting reports of any internal investigation to our EO Director for review;
- Initiating action to terminate, suspend, or refuse to grant federal financial assistance to the discriminatory subgrantee; and
- Notifying our EO Director of the subgrantee's noncompliant status so our EO Office may take appropriate action, including notifying other federal granting agencies.

4. May Our EO Director Restore Compliant Status When a Grantee Remedies Violations?

Yes. Our EO Director may restore a grantee to compliant status if it satisfies terms and conditions established by the Corporation, or if it otherwise brings itself into compliance and provides reasonable assurance of future compliance.

Examples of Promising Practices That Provide Access to LEP Persons

The Association of Farmworker Opportunity Programs AmeriCorps program recruits former farmworkers to serve as AmeriCorps members. Most members are bilingual, and many are LEP. Members are encouraged to take English as a Second Language classes as a part of their member development plan. The program provides pesticide safety training to farmworkers and their families. Members conduct the training in Spanish.

The program uses the following techniques to ensure that members understand their terms of service and benefits:

- ☐ Recruiting posters, flyers and the Member Service Contract are provided in Spanish.
- ☐ AmeriCorps project staff are bilingual (Spanish/English).
- ☐ Orientation training is provided in Spanish and English.
- ☐ Conference calls are held in Spanish when all members speak Spanish.
- ☐ Two bilingual second-year members led a team of members that communicated about their service projects exclusively in Spanish.
- ☐ Members had to be bilingual, but did not require English as the first language.
- ☐ Recruitment took place at the local field office level, and candidates were often from the farmworker community.

The Parents Making a Difference AmericCorps program recruits a diverse corps including many bilingual members to provide outreach to parents in low-income school communities. Members translate at parent-teacher conferences, call parents about absent children, and organize a wide variety of parent-oriented outreach and educational activities.

"Classroom in the Kitchen" gives parents tips on how to support the educational growth of their children in their homes. Diverse language abilities and cultural knowledge is extremely important in this regard. The range of English proficiency is varied, allowing members to help each other, and communication about program activities is largely bilingual.

The program provides English-Second-Language classes for LEP AmericCorps members as part of their Member Development Plan. (This language support is required by the Rhode Island Commission for all AmericCorps programs, in the same vein as the GED training requirement.)

The Temple University Center for Intergenerational Learning, Students Helping in the Naturalization of Elders (SHINE) program. SHINE is a national, multicultural, intergenerational service-learning initiative in five cities. College students provide language, literacy, and citizenship tutoring to elderly immigrants and refugees. Currently, students serve as coaches in ESL/citizenship classes or as tutors in community centers, temples, churches, housing developments, and ethnic organizations.

Northeastern University, San Francisco State University, Loyola University, Florida International University and Temple University are involved with SHINE. Students participate through courses, work study, and campus volunteer organizations. SHINE program coordinators partner with local community organizations; recruit, train, place, and monitor students at community sites; and provide support and technical assistance.

Since 1997, more than 60 faculty from education, social work, anthropology, political science, modern languages, sociology, English, Latino, and Asian studies have offered SHINE as a service-learning option in their courses. Over 1,000 students provided over 25,000 hours of instruction to 3,500 older learners at 37 sites in Boston, San Francisco, Chicago, Miami, and Philadelphia.

The Albuquerque Senior Companion Program (SCP), sponsored by the City of Albuquerque, Department of Senior Affairs, serves a diverse senior population with Native American, Hispanic, and Anglo volunteers. Senior Companions assist the frail elderly with household tasks and companionship.

Ten of its volunteer stations are located on Pueblos. Each Pueblo has its own language. The program works closely with its site managers/supervisors who are bilingual employees of the individual Pueblo governments and generally are residents of the Pueblos. Senior Companions serve on their own Pueblos and walk to the homes of their clients.

Due to language and cultural barriers these supervisors assist with all areas of the program. They are familiar with the population in their individual Pueblos and use this knowledge to assist with recruitment, placement, and training. Each Pueblo celebrates "Days of Feast" separately. In order to honor individual feasts, the program has adjusted the "leave time" for Pueblo volunteers. Each volunteer is given paid leave to celebrate his or her Pueblo's feast. This is one of the ways the program remains culturally sensitive.

ACCION International, a VISTA project sponsor, is a nonprofit that fights poverty through microlending. ACCION Chicago did outreach to home-based businesses that rarely have access to capital. A VISTA found that many of the women make ends meet through programs such as Mary Kay cosmetics. The VISTA worked with the ACCION loan officer to develop a loan product specifically for these women and has organized bilingual information sessions throughout Chicago neighborhoods.

Bring New Jersey Together is an AmeriCorps program in Jersey City, New Jersey that seeks to bridge the cultural and linguistic barriers separating new Americans from the rest of the community. AmeriCorps members serve LEP community members by translating documents and escorting them to places such as medical appointments, the grocery stores, or anywhere else where a translator may be necessary. The primary languages of the program are Spanish, Russian, and Vietnamese, but also Albanian, Creole, Indian languages, and others depending on the influx of refugees.

The New Jersey Commission built a partnership with the International Institute of New Jersey, which had provided services to the immigrant community for fifty years, to establish an AmeriCorps program that served the needs of the community. The best practice aspect of this example is that program was designed in partnership with an established organization instead of starting a brand new AmeriCorps project to address this issue.

The Honolulu Chinese Citizenship Tutorial Program is a service-learning project site in the *Champus Compact National Center for Community Colleges "2+4=Service on Common Ground"*. The University of Hawai'i at Monoa's College of Social Sciences collaborated with the Kapl'olani Community College, Chaminade University, the Chinese Community Action Coalition and Child and Family Service.

Local bilingual college students serve as tutors (during a 10-week session) for Chinese immigrants to help them pass their citizenship exams. The immigrants are recruits by visiting adult education classes, through Chinese radio programs, flyers, and Chinese language newspapers. The Chinese Community Action Coalition provides the curriculum and resources such as Scrabble, books, word-picture matching games, and card games for constructing simple English sentences.

The tutorial sessions focus on passing the INS exam and conversational English. Many of the immigrants are senior citizens. The classes are held in Chinatown. Since the project began, about 1,000 immigrants and refugees have enrolled. Over 300 students have participated as tutors and approximately one-third of the Chinese immigrants became citizens.

Transitional House, Santa Barbara, C.A., is a facility that primarily serves homeless Hispanic women. The services are tailored to meet the needs of each family to help women and their children move from homelessness and unemployment to employment and permanent housing. The VISTAs assigned to the project are bilingual. The clientele is 60% monolingual Spanish speakers.

The VISTAs are creating a Career Development Curriculum that is fully translated into Spanish and members host seminars about immigration and consumer credit counseling services. There was a need to improve communication with clients. One of the VISTAs developed "halfsheets", one side in Spanish, the other in English, that explain the services offered by Transition House.

The VISTAs are responsible for placement of children in daycare to enable parents to work. They accompany families to childcare providers to assist with translation and to help make the families feel at ease with placing their children in childcare.

Dated: January 9, 2001.

Wendy Zenker,

Chief Operating Officer, Corporation for National and Community Service.

[FR Doc. 01–1171 Filed 1–12–01; 8:45 am]

BILLING CODE 6050–28–U

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Meeting

Pursuant to the provision of the "Government in the Sunshine Act" (5 U.S.C. § 552b), notice is hereby given of the Defense Nuclear Facilities Safety Board's (Board) meeting described below.

TIME AND DATE OF MEETING: 9 a.m., February 13, 2001.

PLACE: The Defense Nuclear Facilities Safety Board, Public Hearing Room, 625 Indiana Avenue, NW, Suite 300, Washington, DC 20004.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Defense Nuclear Facilities Safety Board ("Board") will convene the fourteenth quarterly briefing regarding the status of progress of the activities associated with the Department of Energy's Implementation Plan for the Board's Recommendations 95–2, Integrated Safety Management ("ISM"). Specific topics will include the status of ISM implementation in the DOE complex and key actions at DOE Headquarters to fully implement ISM. The status of implementing Recommendation 98–1, Integrated Safety Management (Response to Issues Identified by the Office of Internal Oversight) will also be presented. Specific matters related to Recommendation 98–1 will include the status of the Corrective Action Management team, the corrective action tracking system, and the implementation of issues identified during the Recommendation 98–1 verification review. Finally, the status of implementing Recommendation 2000–2, Configuration Management, Vital Safety Systems, will be discussed. Topics will include the Recommendation 2000–2 Executive Team membership, roles and responsibilities, as well as the status of commitments in the Recommendation 2000–2 Implementation Plan.

CONTACT PERSON FOR MORE INFORMATION: Richard A. Azzaro, General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW., Suite 700, Washington, DC 20004, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The Defense Nuclear Facilities Safety Board reserves its right to further schedule and

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otherwise regulate the course of this meeting, to recess, reconvene, postpone or adjourn the meeting, and otherwise exercise its authority under the Atomic Energy Act of 1954, as amended.

Dated: January 10, 2001.

John T. Conway,

Chairman.

[FR Doc. 01–1341 Filed 1–11–01; 2:12 pm]

BILLING CODE 3870–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education (DOE).

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before March 19, 2001.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.*, new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: January 10, 2001.

John Tressler,

Leader Regulatory Information Management, Office of the Chief Information Officer.

Office of Education Research and Improvement

Type of Review: Extension.

Title: Standards for Evaluation of the Performance of OERI Grants, Cooperative Agreements, and Contracts.

Frequency: Annually.

Affected Public: State, Local, or Tribal Gov't, SEAs or LEAs; Businesses or other for-profit; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 1.

Burden Hours: 1.

Abstract: P.L. 103–227 reauthorized the Office of Educational Research and Improvement (OERI) and required the Assistant Secretary to establish standards for evaluating the performance of recipients of OERI grants, cooperative agreements, and contracts (20 U.S.D. 6011 (l)(2)(B)(ii)).

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address OCIO__IMG__Issues@ed.gov or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her internet address Kathy__Axt@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–1245 Filed 1–12–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 15, 2001.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Acting Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren_Wittenberg@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: January 10, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of the Undersecretary

Type of Review: New.

Title: Evaluation of the State Grants Program and Teacher Recruitment Grants Program of Title II of the Higher Education Act.

Frequency: Annually.

Affected Public: Individuals or households; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 2,200

Burden Hours: 1,000

Abstract: In 1999, the federal government funded a major effort toward increasing teacher quality through the State Grants Program and Teacher Recruitment Grants Program. Together, the programs allow states, institutions of higher education, and/or local education agencies to increase the quality of the teacher workforce through certification reform, recruitment efforts, alternative certification routes, and accountability measures. This evaluation looks at both programs to determine how federal funds were spent, what issues arose in implementing the programs, and the impact of the programs.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, D.C. 20202–4651. Requests may also be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Jacqueline Montague at (202) 708–5359 or via her internet address Jackie_Montague@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–1244 Filed 1–12–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA Nos. 84.339A; 84.339B]

Fund for the Improvement of Postsecondary Education—Learning Anytime Anywhere Partnerships (LAAP) (Preapplications and Applications) Notice Inviting Applications for New Awards for Fiscal Year (FY) 2001.

Purpose of Program: To provide grants or enter into cooperative agreements to enhance the delivery, quality, and accountability of postsecondary education and career-oriented lifelong learning through asynchronous distance education.

For fiscal year (FY) 2001, the Secretary encourages applicants to design projects that focus on the invitational priorities set forth in the invitational priorities section of this application notice.

Eligible Applicants: Partnerships consisting of two or more independent agencies, organizations, or institutions, including institutions of higher education, associations, corporations, community organizations, and other public and private institutions, agencies, and organizations.

Note: A nonprofit organization must serve as the fiscal agent for a funded partnership.

Applications Available: January 16, 2001.

Deadline for Transmittal of Preapplications: March 15, 2001.

Deadline for Transmittal of Applications: June 15, 2001.

Note: All applicants must submit a preapplication to be eligible to submit a final application.

Deadline for Intergovernmental Review: August 8, 2001.

Available Funds: $15,500,000.

Note: Federal funds available under this competition may not pay for more than 50 percent of the cost of a project. Grantees are required to share project costs by matching the requested Federal funds dollar for dollar. The non-Federal share of project costs may be in cash or in kind, fairly evaluated, including services, supplies, or equipment.

Estimated Range of Awards: $100,000 to $500,000 per year.

Estimated Size of Awards: $333,333 per year.

Estimated Number of Awards: 30–40.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 82, 85, 86, 97, 98, and 99.

Authorized Activities

Funds awarded to an eligible partnership must be used to conduct one or more of the following activities:

(a) Develop and assess model distance learning programs or innovative educational software.

(b) Develop methodologies for the identification and measurement of skill competencies.

(c) Develop and assess innovative student support services.

(d) Support other activities consistent with the statutory purpose of this program.

Invitational Priorities

The Secretary is particularly interested in applications that meet one or more of the following invitational priorities. However, an application that meets one or more of these invitational priorities does not receive competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Invitational Priority 1—Projects that achieve economies of scale by delivering programs over large geographic regions covering more students, faculty and institutions; and by promoting cost-sharing, resource sharing, and faculty collaboration across institutions.

Invitational Priority 2—Projects that develop high quality, interactive software that is both modular or sufficiently flexible for faculty modification of academic content, as well as portable for wide-scale implementation across institutions.

Invitational Priority 3—Projects that package courses and programs to assist students in accessing the offerings of multiple providers and to assist institutions in cooperating and sharing resources.

Invitational Priority 4—Projects that use skill competencies and learning outcomes to measure student progress and achievement in asynchronous distance learning programs.

Invitational Priority 5—Projects that improve quality and accountability of asynchronous distance education, thereby ensuring that credentials are meaningful, providers are accountable, and courses meet high standards.

Invitational Priority 6—Projects that create new asynchronous distance education opportunities for underserved learners, especially those who have not always been well served by traditional campus-based education or common forms of distance education, including: individuals with disabilities; individuals who have lost their jobs; individuals making the transition from welfare to the workforce; and individuals seeking basic or technical skills or their first postsecondary education experience.

Invitational Priority 7—Projects that improve support services for students seeking asynchronous distance education to ensure that they have complete and convenient access to needed services such as registration, financial aid, advising, assessment, counseling, libraries, and many others.

Invitational Priority 8—Projects that remove or revise institutional, system, State, or other policies, which are barriers to the implementation of new types of asynchronous distance education.

Selection Criteria

The Secretary selects from the criteria in 34 CFR 75.210 to evaluate preapplications and applications for this competition. Under 34 CFR 75.201, the

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Secretary announces in the application package the selection criteria and factors, if any, for this competition and the maximum weight assigned to each criterion.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs via its Web site http://www.ed.gov/pubs/edpubs.html or you may contact ED Pubs at its e-mail address: edpubs@inet.ed.gov

If you request an application from ED Pubs, be sure to identify the competition as follows: CFDA number 84.339A.

FOR FURTHER INFORMATION CONTACT: The Fund for the Improvement of Postsecondary Education (FIPSE), U.S. Department of Education, 1990 K Street, N.W., Washington, DC 20006–8544. Telephone: (202) 502–7500. Individuals may also request applications or request information by submitting the name of the competition, their name, and postal mailing address to the e-mail address: LAAP@ed.gov.

The application text may be obtained from the Internet address http://www.ed.gov/FIPSE/LAAP

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact office listed under **FOR FURTHER INFORMATION CONTACT.**

Individuals with disabilities also may obtain a copy of the application package in an alternative format by contacting the e-mail address: LAAP@ed.gov

However, the Department is not able to reproduce in alternative format the standard forms included in the application package.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites: http://ocfo.ed.gov/fedreg.htm http://www.ed.gov/news.html

To use PDF you must have the Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO) toll free at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at:

http://www/access.gpo.gov/nara/index.html

Program Authority: 20 U.S.C. 1070f *et seq.*

Dated: January 9, 2001.

A. Lee Fritschler,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 01–1243 Filed 1–12–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission of Data by State Educational Agencies

AGENCY: National Center for Education Statistics, Department of Education.

ACTION: Notice of dates of submission of State revenue and expenditure reports for fiscal year 2000 and of revisions to those reports.

SUMMARY: The Secretary of Education announces dates for the submission by State educational agencies (SEAs) of expenditure and revenue data and average daily attendance statistics on ED Form 2447 (the National Public Education Financial Survey) for fiscal year (FY) 2000. The Secretary sets these dates to ensure that data are available to serve as the basis for timely distribution of Federal funds. The U.S. Bureau of the Census is the data collection agent for the Department's National Center for Education Statistics (NCES). The data will be published by NCES and will be used by the Secretary in the calculation of allocations for FY 2002 appropriated funds.

DATES: The date on which submissions will first be accepted is March 15, 2001. The mandatory deadline for the final submission of all data, including any revisions to previously submitted data, is September 4, 2001.

ADDRESSES: SEAs may mail ED Form 2447 to: Bureau of the Census, ATTENTION: Governments Division, Washington, DC 20233–6800.

Alternatively, SEAs may hand deliver submissions by 4 p.m. (Eastern Time) to: Governments Division, Bureau of the Census, 8905 Presidential Parkway, Washington Plaza II, Room 508, Upper Marlboro, MD 20772.

If an SEA's submission is received by the Bureau of the Census after September 4, 2001 in order for the submission to be accepted, the SEA must show one of the following as proof that the submission was mailed on or before the mandatory deadline date:

1. A legibly dated U.S. Postal Service postmark.
2. A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
3. A dated shipping label, invoice, or receipt from a commercial carrier.
4. Any other proof of mailing acceptable to the Secretary.

If the SEA mails ED Form 2447 through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

1. A private metered postmark.
2. A mail receipt that is not dated by the U.S. Postal Service.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an SEA should check with its local post office.

FOR FURTHER INFORMATION CONTACT: Mr. Lawrence R. MacDonald, Chief, Bureau of the Census, ATTENTION: Governments Division, Washington, DC 20233–6800. Telephone: (301) 457–1574. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to: Frank Johnson, National Center for Education Statistics, U.S. Department of Education, Washington, DC 20208–5651. Telephone: (202) 502–7362.

SUPPLEMENTARY INFORMATION: Under the authority of section 404(a) of the National Education Statistics Act of 1994 (20 U.S.C. 9003(a)), which authorizes NCES to gather data on the financing of education, NCES collects data annually from SEAs through ED Form 2447. The report from SEAs includes attendance, revenue, and expenditure data from which NCES determines the average state per pupil expenditure (SPPE) for elementary and secondary education, as defined in the Elementary and Secondary Education Act of 1965 (ESEA) (20 U.S.C. 8801(12)).

In addition to using the SPPE data as useful information on the financing of elementary and secondary education, the Secretary uses these data directly in calculating allocations for certain formula grant programs, including Title I of the Elementary and Secondary Education Act of 1965 as amended by the Improving America's Schools Act of 1994 (Title I), Impact Aid, and Indian Education. Other programs such as the Technology Literacy Challenge Fund, the Education for Homeless Children and Youth Program under Title VII of the Stewart B. McKinney Homeless Assistance Act, the Dwight D. Eisenhower Professional Development Program, and the Safe and Drug-Free Schools and Communities Program make use of SPPE data indirectly because their formulas are based, in whole or in part, on State Title I allocations.

In January 2001, the Bureau of the Census, acting as the data collection agent for NCES, will mail to SEAs ED Form 2447 with instructions and request that SEAs submit data to the Bureau of the Census on March 15, 2001, or as soon as possible thereafter. SEAs are urged to submit accurate and complete data on March 15, or as soon as possible thereafter, to facilitate timely processing. Submissions by SEAs to the Bureau of the Census will be checked for accuracy and returned to each SEA for verification. All data, including any revisions, must be submitted to the Bureau of the Census by an SEA not later than September 4, 2001.

Having accurate and consistent information, on time, is critical to an efficient and fair allocation process, as well as the NCES statistical process. To ensure timely distribution of Federal education funds based on the best, most accurate data available, NCES establishes, for allocation purposes, September 4, 2001 as the final date by which ED Form 2447 must be submitted. However, if an SEA submits revised data after the final deadline that results in a lower SPPE figure, its allocations may be adjusted downward or the Department may request the SEA to return funds. SEAs should be aware that all of these data are subject to audit and that, if any inaccuracies are discovered in the audit process, the Department may seek recovery of overpayments for the applicable programs. If an SEA submits revised data after September 4, 2001 the data may also be too late to be included in the final NCES published dataset.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites: http://ocfo.ed.gov/fedreg.htm; http://www.ed.gov/news.html.

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, 1–888–293–6498; or in the Washington DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Regulations is available on GPO access at: http://www.access.gpo.gov/nara/index.html

Authority: 20 U.S.C. 9003(a).

Dated: January 10, 2001.

C. Kent McGuire,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 01–1242 Filed 1–12–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Office of Science and Office of Environmental Management; Office of Science Financial Assistance Program Notice 01–19; Environmental Management Science Program: Research Related to Deactivation and Decommissioning Issues

AGENCY: Department of Energy.

ACTION: Notice inviting grant applications.

SUMMARY: The Offices of Science (SC) and Environmental Management (EM), U.S. Department of Energy (DOE), hereby announce their interest in receiving grant applications for performance of innovative, fundamental research to support specifically innovative, fundamental research to investigate DOE deactivation and decommissioning issues.

DATES: The deadline for receipt of formal applications is 4:30 P.M., E.S.T, March 20, 2001, in order to be accepted for merit review and to permit timely consideration for award in Fiscal Year 2001.

ADDRESSES: Formal applications referencing Program Notice 01–19 should be sent to: U.S. Department of Energy, Office of Science, Grants and Contracts Division, SC–64, 19901 Germantown Road, Germantown, MD 20874–1290, ATTN: Program Notice 01–16. This address must be used when submitting applications by U.S. Postal Service Express, commercial mail delivery service, or when hand carried by the applicant.

FOR FURTHER INFORMATION CONTACT: Dr. Roland F. Hirsch, SC–73, Mail Stop F–237, Medical Sciences Division, Office of Biological and Environmental Research, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290, telephone: (301) 903–9009, fax: (301) 903–0567, E-mail: roland.hirsch@science.doe.gov, or Mr. Mark Gilbertson, EM–52, Office of Basic and Applied Research, Office of Science and Technology, Office of Environmental Management, 1000 Independence Avenue, SW, Washington, DC 20585, telephone: (202) 586–7150, E-mail: mark.gilbertson@em.doe.gov. The full text of Program Notice 01–19 is available via the Internet using the following web site address: *http://www.science.doe.gov/production/grants/grants.html.*

SUPPLEMENTARY INFORMATION: The Office of Environmental Management, in partnership with the Office of Science, sponsors the Environmental Management Science Program (EMSP) to fulfill DOE's continuing commitment to the clean-up of DOE's environmental legacy.

The DOE Environmental Management program currently has ongoing applied research and engineering efforts under its Technology Development Program. These efforts must be supplemented with basic research to address long-term technical issues crucial to the EM mission. Basic research can also provide EM with near-term fundamental data that may be critical to the advancement of technologies that are under development but not yet at full scale nor implemented. Proposed basic research under this Notice should contribute to environmental management activities that would decrease risk for the public and workers, provide opportunities for major cost reductions, reduce time required to achieve EM's mission goals, and, in general, should address problems that are considered intractable without new knowledge. This program is designed to inspire breakthroughs in areas critical to the EM mission through basic research and will be managed in partnership with SC. The Office of Science's well-established procedures, as set forth in the Office of Science Merit Review System, available on the World Wide Web at: *http://www.science.doe.gov/production/grants/merit.html* will be used for merit review of applications submitted in response to this Notice. Subsequent to the formal scientific merit review, applications that are judged to be scientifically meritorious will be evaluated by DOE for relevance to the objectives of the Environmental Management Science Program. Additional information can be obtained at: http://www.emsp.em.doe.gov/main.htm. Additional Notices for the Environmental Management Science Program may be issued during Fiscal

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Year 2001, covering other areas within the scope of the EM program.

Purpose

The purpose of the EMSP is to foster basic research that will contribute to successful completion of DOE's mission to clean-up the environmental contamination across the DOE complex.

The objectives of the Environmental Management Science Program are to:

- Provide scientific knowledge that will revolutionize technologies and clean-up approaches to significantly, reduce future costs, schedules, and risks;
- "Bridge the gap" between broad fundamental research that has wide-ranging applicability such as that performed in DOE's Office of Science and needs-driven applied technology development that is—conducted in EM's Office of Science and Technology; and
- Focus the Nation's science infrastructure on critical DOE environmental management problems.

The focus of the EMSP is on basic research and the objective of this research Program is to develop a long-range science plan for deactivation and decommissioning (D&D). The National Research Council, Committee on Long-Term Research Needs for Deactivation and Decommissioning at Department of Energy Sites, December 5, 2000 report provided technical advice on the "recommended areas of research where the EM Science Program can make significant contributions to solving (D&D) problems and adding to scientific knowledge generally."

Representative Research Areas

Basic research is solicited in all areas of science with the potential for addressing problems in deactivation and decommissioning. Relevant scientific disciplines include, but are not limited to: chemical sciences (including fundamental interfacial chemistry, computational chemistry, actinide chemistry, and analytical chemistry and instrumentation), engineering sciences (including control systems and optimization, diagnostics, transport processes, fracture mechanics and bioengineering), materials science (including other novel materials-related strategies), and bioremediation (including microbial science related to ex situ treatment of organics, metals and radionuclides and in situ treatment of organics).

Project Renewals

Lead Principal Investigators of record for Projects funded under Office of Science Notice 98–04, Environmental Management Science Program: Research Related to Decontamination and Decommissioning of Facilities, are eligible to submit renewal applications under this solicitation.

It is recognized that many of the projects funded in FY1998 of the program have already been very successful. At the same time, we believe that many of these research groups have the potential to make significant additional contributions toward addressing the science needs of the Office of Environmental Management (EM).

Program Funding

It is anticipated that up to a total of $4,000,000 of Fiscal Year 2001 Federal funds will be available for new Environmental Management Science Program awards resulting from this Notice. Multiple-year funding of grant awards is anticipated, contingent upon the availability of appropriated funds. Award sizes are expected to be on the order of $100,000–$300,000 per year for total project costs for a typical three-year grant. Collaborative projects involving several research groups or more than one institution may receive larger awards if merited. The program will be competitive and offered to investigators in universities or other institutions of higher education, other non-profit or for-profit organizations, non-Federal agencies or entities, or unaffiliated individuals. DOE reserves the right to fund in whole or part any or none of the applications received in response to this notice. A parallel announcement with a similar potential total amount of funds will be issued to DOE Federally Funded Research and Development Centers (FFRDCs) and may be accessed on the World Wide Web at: *http://www.science.doe.gov/production/grants/LAB01_19.html*. All projects will be evaluated using the same criteria, regardless of the submitting institution.

Collaboration and Training

Applicants to the EMSP are strongly encouraged to collaborate with researchers in other institutions, such as universities, industry, non-profit organizations, federal laboratories and Federally Funded Research and Development Centers (FFRDCs), including the DOE National Laboratories, where appropriate, and to incorporate cost sharing and/or consortia wherever feasible. Refer to: *http://www.sc.doe.gov/production/grants/Colab.html* for details.

Applicants are also encouraged to provide training opportunities, including student involvement, in applications submitted to the program.

Application Format

Applicants are expected to use the following format in addition to following instructions in the Office of Science Financial Assistance Program Application Guide. Applications must be written in English, with all budgets in U.S. dollars.

- SC Face Page (DOE F 4650.2 (10–91))
- Application classification sheet (a plain sheet of paper with one selection from the list of scientific fields listed in the Application Categories Section)
- Table of Contents
- Project Abstract (no more than one page)
- Budgets for each year and a summary budget page for the entire project period (using DOE F 4620.1)
- Budget Explanation. Applicants are requested to include in the travel budget for each year funds to attend the annual National Environmental Management Science Program Workshop, and also for one or more extended (one week or more) visits to a clean-up site by either the Principal Investigator or a senior staff member or collaborator.
- Budgets and Budget explanation for each collaborative subproject, if any
- Project Narrative (recommended length is no more than 20 pages; multi-investigator collaborative projects may use more pages if necessary up to a total of 40 pages)
- Goals
- Significance of Project to the EM Mission
- Background
- Research Plan
- Preliminary Studies (if applicable)
- Research Design and Methodologies
- Literature Cited
- Collaborative Arrangements (if applicable)
- Biographical Sketches (limit 2 pages per senior investigator)
- Description of Facilities and Resources
- Current and Pending Support for each senior investigator

Application Categories

In order to properly classify each application for evaluation and review, the documents must indicate the applicant's preferred scientific research field, selected from the following list.

Field of Scientific Research

1. Actinide Chemistry
2. Analytical Chemistry and Instrumentation
3. Bioremediation
4. Engineering Sciences
5. Interfacial Chemistry
6. Materials Science
7. Other

Application Evaluation and Selection

Scientific Merit

The program will support the most scientifically meritorious and relevant work, regardless of the institution. Formal applications will be subjected to scientific merit review (peer review) and will be evaluated against the following evaluation criteria listed in descending order of importance as codified at 10 CFR 605.10(d).

1. Scientific and/or Technical Merit of the Project,
2. Appropriateness of the Proposed Method or Approach,
3. Competency of Applicant's Personnel and Adequacy of Proposed Resources,
4. Reasonableness and Appropriateness of the Proposed Budget.

The evaluation will include program policy factors such as the relevance of the proposed research to the terms of the announcement and the Department's programmatic needs. DOE shall also consider, as part of the evaluation, program policy factors such as an appropriate balance among the program areas, including research already in progress. External peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Non-federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

Relevance to Mission

Researchers are encouraged to demonstrate a linkage between their research projects and significant contamination problems at DOE sites. Researchers could establish this linkage in a variety of ways—for example, by elucidating the scientific problems to be addressed by the proposed research and explaining how the solution of these problems could improve D&D capabilities. Subsequent to the formal scientific merit review, applications which are judged to be scientifically meritorious will be evaluated by DOE for relevance to the objectives of the Environmental Management Science Program.

DOE shall also consider, as part of the evaluation, program policy factors such as an appropriate balance among the program areas, including research already in progress. Research funded in the Environmental Management Science Program in Fiscal Years 1996 through 2000, can be viewed at: *http://emsp.em.doe.gov/portfolio/multisearch.asp*.

Application Guide and Forms

Information about the development, submission of applications, eligibility, limitations, evaluation, the selection process, and other policies and procedures may be found in 10 CFR Part 605, and in the Application Guide for the Office of Science Financial Assistance Program. Electronic access to the Guide and required forms is made available via the World Wide Web at: *http://www.science.doe.gov/production/grants/grants.html*. DOE is under no obligation to pay for any costs associated with the preparation or submission of applications if an award is not made.

Major Environmental Management Challenges

The safety for workers conducting D&D operations is an issue that will grow as DOE takes on the more challenging D&D tasks. Workers deal with special hazards that are different from those in other parts of DOEs Accelerating Clean-up Paths to Closure (DOE, 1998a), including the following:

- Working in confined spaces in areas of high radioactivity,
- Disassembling and removing massive steel and concrete structures,
- Direct, hands-on manual labor with powerful saws, torches, and lifting devices, and
- Incomplete knowledge of the highly complex systems they are dismantling.

Scientific Issues

The recognized issues pose challenges in characterization, decontamination, and remote systems where current technology is inadequate and where EMSP funded, research could make significant contributions include:

Characterization

Characterization of contaminated materials is critical at several stages of D&D. Initially, the nature and extent of contamination with both radionuclides and toxic materials must be accurately assessed to ensure adequate protection of workers and the environment, as well as to allow the selection of appropriate methods of decontamination. During decontamination and/or demolition of contaminated equipment and structures, there must be some means of monitoring progress and potential contaminant releases. Finally, after decontamination, the nature and extent of residual contamination must be assessed to determine the final classification and disposal of the item in question.

(1) The identification and development of means, preferably real-time, minimally invasive, and field usable, to locate and quantify difficult to measure contaminants significant to D&D. These means should be applicable to the major materials and configurations of interest, such as concrete, stainless steel, and packaged wastes. The contaminants of interest, includes tritium, technetium-99, plutonium-239 and other actinides, beryllium, mercury, asbestos, and polychlorinated biphenyls (PCBs).

Rationale: The varied nature of D&D facilities has led to a wide range of contaminant types and site-specific characterization challenges, each generally requiring a detector tailored specifically to the contaminant being measured and its matrix. Some 2,700 buildings, constructed mostly of concrete and containing 180,000 metric tons of metals, are currently within EM's D&D task. Four areas where research can advance the state of art: (1) Methods to assess the distribution of contaminants within concrete; (2) sensors to measure contaminants on the surface and within micro-cracks of metals; (3) remote sensing of contaminants; and (4) biosensors.

The development of minimally and non-invasive real-time in situ sensing technologies to characterize the concentration of contaminants, as a function of depth within concrete, would eliminate difficulties associated with core sample collection and subsequent analysis. Minimally invasive schemes like laser ablation mass spectroscopy or non-intrusive techniques like neutron activation and x-ray analysis appear to be attractive candidates for further research.

More sensitive detectors, for example for alpha particles (USDOE, 1999), as well as simple-to-use techniques, such as chemical indicators are needed to quickly certify levels of nuclides, hazardous metals, and other toxic substances on structural surfaces and equipment. This will help ensure safety in the workplace and reduce costs—for example by allowing non-hazardous waste to be disposed in landfills. Analysis of residual low-energy beta emitters like tritium and Tc-99 is particularly challenging when these isotopes are inside equipment or mixed in heterogeneous waste matrices, because the beta articles cannot penetrate through most materials.

Remote sensing systems can provide both economic and safety benefits by distancing the worker from hazardous work areas. Remote mapping of activity

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levels using gamma cameras (USDOE, 1998b) is now being used to great advantage in D&D operations. Smaller, higher sensitivity and resolution versions of these instruments would be desirable and may be achievable through further research on detector materials and geometries. Fiber-optic sensing for remote detection of some chemical species is feasible. Further research could lead to its use in sensing chemical contaminants relevant to D&D. Fiber-optic radiation sensors are a more recent development and opportunities exist for both improved performance and novel features such as optical interrogation.

(2) The basic research that could lead to development of biotechnological sensors to detect contaminants of interest may provide a completely new way to meet the needs for characterization of contaminated materials. The field of biotechnology is rapidly expanding, and the contaminants of interest and the materials and configurations in which they must be detected, is noted in (1).

Rationale: There has been tremendous growth in development and commercialization of a broad range of biosensor devices and applications. Modern devices can range from fiber-optic and micro-cantilever-linked immuno assays to subcellular and cellular micro-electronic. Analytes measurable by biosensors include a vast array of organic chemicals, biochemicals, inorganics, and metals and more recently ionizing radiation. Research to integrate microelectronics and nanotechnology with elements of gene array technology and cellular engineering may lead to new sensor technology (see *http://www.nano.gov/press.htm* for details). This technology could create new capacity for continuous and remote monitoring in chemically and physically complex environmental and structural systems characteristic of DOE's site D&D needs.

Decontamination

The decontamination of equipment and facilities is necessary at several stages of the D&D process. Initially, radiation and contamination levels may have to be reduced to allow worker access or to limit their exposure to radiation and other hazards. Decontamination may be required before dismantling or demolition work to prevent the spread of radioactive or toxic materials. Unplanned releases can have off-site as well as on-site consequences. Decontamination procedures are intended to result in a small volume of the most hazardous waste, and much larger volumes of waste that has low or no hazard, thus reducing the cost and long-term risk of disposal. Some decontaminated equipment or facilities might be recycled or reused. The end state of any decontamination activity must be consistent with both site-specific and overall DOE clean-up objectives.

(3) The basic research toward fundamental understanding of the interactions of important contaminants with the primary materials of interest in D&D projects, including concrete, stainless steel, paints, and "strippable" coatings is needed.

Rationale: Scientific understanding of the interactions among contaminants and construction materials is fundamental to developing more effective D&D technologies. Both radioactive and toxic contaminants can exist in a variety of chemical forms (for example, in different valence states, complexes, or as colloids), which exhibit very different behaviors. While a good deal of chemical data on the contaminants themselves exist as well as data on their transport in the environment there is little information of direct relevance to D&D problems. Such information includes how contaminants bind to steel and concrete surfaces, how they penetrate into these materials, their migration into pores, fissures, and welds, and time-dependent "aging" effects. Once sufficient thermodynamic and kinetic data on these interactions are obtained to allow their modeling from first principles, the models would allow various decontamination approaches to be evaluated and provide a better way to interpret data from characterization.

(4) The basic research on biotechnological means to remove or remediate contaminants of interest from surfaces and within porous materials.

Rationale: The capacity of microbiological processes to destroy, transform, mobilize, and sequester toxins, pollutants, and contaminants is well-established. Through research to extend well-known technology in mineral ore leaching and metal recovery, these biochemical capacities may be exploitable for removal of metals and radionuclides from concrete and building debris. An excellent example of which was recently described in an American Society for Microbiology report (see ASM News. 66:133). In addition, microbial biocorrosion processes for structural metals and concrete are well established and the opportunity exists to investigate fundamental processes that could facilitate volumetric reduction of waste from D&D activities. Biotechnical advances in surface treatments of contaminated structures and materials are anticipated from continuing R&D activities, elucidation of biocatalytic properties of biological systems and engineering chemicals, and biosurfactants with unique physical chemical properties. A fundamental understanding of the biological processes would also help to ensure that waste by-products from the decontamination could be safely treated and stabilized.

Remote Systems

For D&D work, remote systems provide a unique means to separate workers from hazardous work areas, thus enhancing their safety and productivity. This technology crosscuts all of the other D&D areas—characterization, decontamination, and dismantlement—and has the potential for substantial performance enhancement and cost reduction. There are broad ranges for potential applicability of fundamental advances in this area.

(5) The basic research toward creating intelligent remote systems that can adapt to a variety of tasks and be readily assembled from standardized modules. Today's remote systems are one-of-a-kind devices of high cost and limited capability. Their inflexibility leads to rapid obsolescence and is a barrier to their deployment. The recommended initial research focus would be as follows:

a. Actuators

Rationale: The actuator is the power (muscle) of remote systems, and as such, it is the key to performance, reliability, and cost. Except for better construction materials and improved control electronics, most actuator technology has not changed for several decades. Today's actuators typically use only one sensor (for position) so that virtually no real time data (for example, force and velocity) are available to make them "intelligent." More complete sensory input, coupled with decision-making software can produce intelligent actuators that are able to adapt to a variety of tasks. Achieving a relatively inexpensive modular design to allow "plug and play" deployment of these devices would be especially useful because equipment that fails or becomes contaminated is usually discarded. Research to answer the question of granularity (What is the minimum number of required standard modules?) to enable the assembly on demand of the maximum number of remote systems would make the overall system substantially more cost effective in deployment and maintenance.

b. Universal Operational Software To Provide Criteria-Based Decision Making

Rationale: Criteria-based decision making is the essence of intelligence in robotic systems. What is the best use of the system's resources to perform the task at hand? Today's control of robotic devices is derived from techniques developed during World War II in which control is linear (based only on the difference between two measured parameters). A robot capable of mimicking human adaptability, however, would require a non-linear control system coupled to many parameters corresponding to the physical features that accurately represent performance of the task. The criteria-based software could be universal in the same sense that operating systems on personal computers are universal—one system supports many different applications.

c. Virtual Presence of the Worker in Hazardous Environments

Rationale: In the initial planning and characterization phases of D&D work, workers often must enter an area of high radiation and contamination that is also congested with left-in-place equipment and materials for which removal inevitably involves physical stress (fatigue) and the potential for personal injury. Virtual reality systems could allow workers to perform essential survey and decision making functions from a remote location thus enhancing their safety and productivity. Advances in the state of the art as now used in deep sea exploration should be pursued to improve overall system performance by providing force feedback, remote vision, collision avoidance, and radiation resistant sensor technology.

The nature and extent of contamination with both radionuclides and toxic materials must be accurately assessed to ensure adequate protection of workers and the environment, as well as to allow the selection of appropriate methods of decontamination.

Background

DOE expects to spend some $30 billion for D&D of weapons complex facilities after 2006. For example the Savannah River and Hanford sites present the biggest D&D challenges and will be undertaken after 2006 with about half of the $30 billion being saved through use of innovative technologies that it expects could be developed by that time.

The United States involvement in nuclear weapons development for the last 50 years has resulted in the development of a vast research, production, and testing network known as the nuclear weapons complex. The Department has the challenge of deactivating 7,000 contaminated buildings and decommissioning 900 contaminated buildings that are currently on DOE's list of surplus facilities. It is also responsible for decontaminating the metal and concrete within those buildings and disposing of 180,000 metric tons of scrap metal. Deactivation refers to ceasing facility operations and placing the facility in a safe and stable condition to prevent unacceptable exposure of people or the environment to radioactive or other hazardous materials until the facility can be decommissioned. Typically, deactivation involves removal of fuel and stored radioactive and other hazardous materials and draining of systems. Decommissioning is the process of decontaminating or removing contaminated equipment and structures to achieve the desired end state for the facility. Desired end states include complete removal and remediation of the facility, release of facility for unrestricted use, or release of facility for restricted use. Decontamination is the removal of unwanted radioactive or hazardous contamination by a chemical or mechanical process.

Details of the programs of the Office of Environmental Management and the technologies currently under development or in use by Environmental Management Program can be found on the World Wide Web at: *http://www.em.doe.gov/index4.html* and at the extensive links contained therein. The programs and technologies should be used to obtain a better understanding of the missions and challenges in environmental management in DOE when considering areas of research to be proposed.

References

Note: World Wide Web locations of these documents are provided where possible. For those without access to the World Wide Web, hard copies of these references may be obtained by writing Mark A. Gilbertson at the address listed in the **FOR FURTHER INFORMATION CONTACT** section.

DOE. 1995. Closing the Circle on the Splitting of the Atom: The Environmental Legacy of Nuclear Weapons Production in the United States and What the Department of Energy is Doing About It. The U.S. Department of Energy, Office of Environmental Management, Office of Strategic Planning and Analysis, Washington, DC, *http://www.em.doe.gov/circle/index.html*

DOE. 1998a. Accelerating Clean-up: Paths to Closure—June 1998. *http://www.em.doe.gov/closure*

DOE. 1998. Report to Congress on the U.S. Department of Energy's Environmental Management Science Program—April 1998. *http://emsp.em.doe.gov/*

DOE. 2000. Environmental Management Advisory Board. *http://www.em.doe.gov/emab/*

DOE. 2000 Environmental Management Science Program, Project Summaries. *http://emsp.em.doe.gov/*

DOE. 2000. Office of Integration and Disposition. *http://www.em.doe.gov/office.html*

DOE. 2000 Office of Science and Technology (EM–50). *http://www.ost.em.doe.gov/*

Environmental Management Advisory Board Science Committee. 1997. Resolution on the Environmental Management Science Program dated May 2, 1997.

National Research Council. 1996. Affordable Clean-up? Opportunities for Cost Reduction in the Decontamination and Decommissioning of the Nation's Uranium Enrichment Facilities. Washington, DC: National Academy Press.

National Research Council. 1998. A Review of Decontamination and Decommissioning Technology Development Programs at the DOE. Washington, DC: National Academy Press.

National Research Council. 1997. Building an Environmental Management Science Program: Final Assessment. National Academy Press, Washington, DC, *http://www.nap.edu/readingroom/books/envmanage/*

National Research Council. 2000. Letter Report, Committee on Long-Term Research Needs for Deactivation and Decommissioning at Department of Energy Sites December 5, 2000. *http://books.nap.edu/books/NI000321/html/1.html#pagetop*

Secretary of Energy Advisory Board. Alternative Futures for the Department of Energy National Laboratories. February 1995. Task Force on alternative Futures for the Department of Energy National Laboratories. Washington, DC, *http://www.hr.doe.gov/seab/galvin/tf-rpt.html*

The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR Part 605.

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Issued in Washington DC on January 9, 2001.

John Rodney Clark,

Associate Director of Science for Resource Management.

[FR Doc. 01–1182 Filed 1–12–01; 8:45 am]

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DEPARTMENT OF ENERGY

Office of Science and Office of Environmental Management; Office of Science Financial Assistance Program Notice 01–16: Environmental Management Science Program: Basic Science Research Related to High Level Radioactive Waste

AGENCY: Office of Science and Office of Environmental Management, Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Offices of Science (SC) and Environmental Management (EM), U.S. Department of Energy (DOE), hereby announce their interest in receiving grant applications for performance of innovative, fundamental research to support specific activities for high level radioactive waste; which include, but are not limited to, characterization and safety, retrieval of tank waste and tank closure, pretreatment, and waste immobilization and disposal.

DATES: The deadline for receipt of formal applications is 4:30 p.m. E.S.T., March 8, 2001, in order to be accepted for merit review and to permit timely consideration for award in Fiscal Year 2001.

ADDRESSES: Formal applications referencing Program Notice 01–16 should be sent to: U.S. Department of Energy, Office of Science, Grants and Contracts Division, SC–64, 19901 Germantown Road, Germantown, MD 20874–1290, ATTN: Program Notice 01–16. This address must be used when submitting applications by U.S. Postal Service Express, commercial mail delivery service, or when hand carried by the applicant.

FOR FURTHER INFORMATION CONTACT: Dr. Roland F. Hirsch, SC–73, Mail Stop F–237, Medical Sciences Division, Office of Biological and Environmental Research, Office of Science, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290, telephone: (301) 903–9009, fax: (301) 903–0567, E-mail: roland.hirsch@science.doe.gov, or Mr. Mark Gilbertson, Office of Basic and Applied Research, Office of Science and Technology, Office of Environmental Management, 1000 Independence Avenue, SW., Washington, DC 20585, telephone: (202) 586–7150, E-mail: Mark.Gilbertson@em.doe.gov. The full text of Program Notice 01–16 is available via the World Wide Web using the following web site address: *http://www.sc.doe.gov/production/grants/grants.html.*

SUPPLEMENTARY INFORMATION: The Office of Environmental Management, in partnership with the Office of Science, sponsors the Environmental Management Science Program (EMSP) to fulfill DOE's continuing commitment to the clean-up of DOE's environmental legacy. The program was initiated in Fiscal Year 1996. Ideas for basic scientific research are solicited which promote the broad national interest of a better understanding of the fundamental characteristics of highly radioactive chemical wastes and their effects on the environment.

The DOE Environmental Management program currently has ongoing applied research and engineering efforts under its Technology Development Program. These efforts must be supplemented with basic research to address long-term technical issues crucial to the EM mission. Basic research can also provide EM with near-term fundamental data that may be critical to the advancement of technologies that are under development but not yet at full scale nor implemented. Proposed basic research under this Notice should contribute to environmental management activities that would decrease risk for the public and workers, provide opportunities for major cost reductions, reduce time required to achieve EM's mission goals, and, in general, should address problems that are considered intractable without new knowledge. This program is designed to inspire "breakthroughs" in areas critical to the EM mission through basic research and will be managed in partnership with SC. The Office of Science's well-established procedures, as set forth in the Office of Science Merit Review System, available on the World Wide Web at: *http://www.science.doe.gov/production/grants/merit.html* will be used for merit review of applications submitted in response to this Notice. Subsequent to the formal scientific merit review, applications that are judged to be scientifically meritorious, will be evaluated by DOE for relevance to the objectives of the Environmental Management Science Program and for relevance to the technical focus of this solicitation (see "Relevance to Mission" section below). Additional information can be obtained at *http://emsp.em.doe.gov.* Additional Notices for the Environmental Management Science Program may be issued during Fiscal Year 2001 covering other areas within the scope of the EM program.

Purpose

The purpose of the EMSP is to foster basic research that will contribute to successful completion of DOE's mission to clean-up the environmental contamination across the DOE complex.

The objectives of the Environmental Management Science Program are to:

1. Provide scientific knowledge that will revolutionize technologies and clean-up approaches to significantly reduce future costs, schedules, and risks;
2. "Bridge the gap" between broad fundamental research that has wide-ranging applicability such as that performed in DOE's Office of Science and needs-driven applied technology development that is conducted in EM's Office of Science and Technology; and
3. Focus the Nation's science infrastructure on critical DOE environmental management problems.

Representative Research Areas

Basic research is solicited in areas of science with the potential for addressing problems in the clean-up of high level radioactive waste. Relevant scientific disciplines include, but are not limited to, chemistry (including actinide chemistry, analytical chemistry and instrumentation, interfacial chemistry, and separation science), computer and mathematical sciences, engineering science (chemical and process engineering), materials science (degradation mechanisms, modeling, corrosion, non-destructive evaluation, sensing of waste hosts, canisters), and physics (fluid flow, aqueous-ionic solid interfacial properties underlying rheological processes).

Project Renewals

Lead Principal Investigators of record for Projects funded under Office of Science Notice 98–08, Environmental Management Science Program: Research Related to High Level Radioactive Waste, are eligible to submit renewal applications under this solicitation.

Program Funding

It is anticipated that up to a total of $4,000,000 of Fiscal Year 2001, Federal funds will be available for new Environmental Management Science Program awards resulting from this Announcement. Multiple-year funding of awards is anticipated, contingent upon the availability of appropriated funds. Award sizes are expected to be on the order of $100,000–$300,000 per year for total project costs for a typical three-year award. Collaborative projects involving several research groups or more than one institution may receive larger awards if merited. The program will be competitive and offered to investigators in universities or other institutions of higher education, other non-profit or for-profit organizations, non-Federal agencies or entities, or unaffiliated individuals. DOE reserves the right to fund in whole or part any or none of the applications received in response to this Notice. A parallel announcement with a similar potential total amount of funds will be issued to DOE Federally Funded Research and Development Centers (FFRDCs) and may be accessed on the World Wide Web at *http://www.science.doe.gov/production/grants/LAB01_16.html.* All projects will be evaluated using the same criteria, regardless of the submitting institution.

Collaboration and Training

Applicants to the EMSP are strongly encouraged to collaborate with researchers in other institutions, such as universities, industry, non-profit organizations, federal laboratories and Federally Funded Research and Development Centers (FFRDCs), including the DOE National Laboratories, where appropriate, and to incorporate cost sharing and/or consortia wherever feasible. Refer to *http://www.sc.doe.gov/production/grants/Colab.html* for details.

Applicants are also encouraged to provide training opportunities, including student involvement, in applications submitted to the program.

Applications

Applicants are expected to use the following format in addition to following instructions in the Office of Science Financial Assistance Program Application Guide. Applications must be written in English, with all budgets in U.S. dollars.

- SC Face Page (DOE F 4650.2 (10–91))
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- Budget Explanation. Applicants are requested to include in the travel budget for each year funds to attend the annual National Environmental Management Science Program Workshop, and also for one or more extended (one week or more) visits to a clean-up site by either the Principal Investigator or a senior staff member or collaborator
- Budgets and Budget explanation for each collaborative subproject, if any
- Project Narrative (recommended length is no more than 20 pages; multi-investigator collaborative projects may use more pages if necessary up to a total of 40 pages)
- Goals
- Significance of Project to the EM Mission
- Background
- Research Plan
- Preliminary Studies (if applicable)
- Research Design and Methodologies
- Literature Cited
- Collaborative Arrangements (if applicable)
- Biographical Sketches (limit 2 pages per senior investigator)
- Description of Facilities and Resources
- Current and Pending Support for each senior investigator

Application Categories

In order to properly classify each application for evaluation and review, the application must indicate the proposer's preferred scientific research field, selected from the following list.

Field of Scientific Research

1. Actinide Chemistry
2. Analytical Chemistry and Instrumentation
3. Separations Chemistry
4. Engineering Sciences
5. Geochemistry
6. Geophysics
7. Hydrogeology
8. Interfacial Chemistry
9. Materials Science
10. Other

Application Evaluation and Selection

Scientific Merit

The program will support the most scientifically meritorious and relevant work, regardless of the institution. Formal applications will be subjected to scientific merit review (peer review) and will be evaluated against the following evaluation criteria listed in descending order of importance as codified at 10 CFR 605.10(d):

1. Scientific and/or Technical Merit of the Project
2. Appropriateness of the Proposed Method or Approach
3. Competency of Applicant's Personnel and Adequacy of Proposed Resources
4. Reasonableness and Appropriateness of the Proposed Budget.

The evaluation will include program policy factors such as the relevance of the proposed research to the terms of the announcement and the Department's programmatic needs. DOE shall also consider, as part of the evaluation, program policy factors such as an appropriate balance among the program areas, including research already in progress. External peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Non-federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

Relevance to Mission

Subsequent to the formal scientific merit review, applications which are judged to be scientifically meritorious will be evaluated by DOE for relevance to the objectives of the Environmental Management Science Program and for relevance to the technical focus of the solicitation (see section below).

"Researchers are encouraged to demonstrate a linkage between their research projects and significant clean up related problems at DOE sites. Researchers could establish this linkage in a variety of ways—for example, by elucidating the scientific problems to be addressed by the proposed research and explaining how the solution of these problems could improve remediation capabilities." (National Research Council, Board on Radioactive Waste Management, December 1998)

DOE shall also consider, as part of the evaluation, program policy factors such as an appropriate balance among the program areas, including research already in progress. Research funded in the Environmental Management Science Program in Fiscal Year 1996 through Fiscal Year 2001, can be viewed at *http://www.doe.gov/em52/science-grants.html.*

Application Guide and Forms

Information about the development, submission of applications, eligibility, limitations, evaluation, the selection process, and other policies and procedures may be found in 10 CFR Part 605, and in the Application Guide for the Office of Science Financial Assistance Program. Electronic access to the Guide and required forms is available via the World Wide Web at: *http://www.sc.doe.gov/production/grants/grants.html.* DOE is under no obligation to pay for any costs associated with the preparation or submission of applications if an award is not made.

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Technical Focus of the Solicitation

This research announcement has been developed for Fiscal Year 2001, along with a development process for a long-term program within Environmental Management, with the objective of providing continuity in scientific knowledge that will revolutionize technologies and clean-up approaches for solving DOE's most complex environmental problems. A general description of the high level waste problem can be found in the Background section of this Notice. Detailed descriptions of the specific technical (science) needs and areas of emphasis associated with this problem area are available on the Tanks Focus Area web site at *http://www.pnl.gov/tfa.*

Long Term Research Agenda for High Level Radioactive Waste

The National Academy of Science's National Research Council was requested to assist the DOE in developing a long-range science plan for the management of radioactive high-level waste at DOE sites. The Committee empanelled to study that issue determined that some High Level Waste related problems will require further research and development to minimize risk and program cost and to improve the effectiveness of clean-up. Their recommendations in four topic areas are the focus of this solicitation and are described below. More detailed descriptions of the specific technical (science) needs in these four topic areas are available on the Tanks Focus Area web site at: *http://www.pnl.gov/tfa.*

1. Long-Term Issues Related to Tank Closure

An example of research activities to address this issue is innovative methods for in situ characterization of the High Level Waste remaining in the tanks after retrieval to facilitate tank closure.

2. High-Efficiency, High-Throughput Separation Methods That Would Reduce High-Level Waste Program Costs Over the Next Few Decades Including

a. High-efficiency separation, and
b. Minimization of the volume of secondary waste.

Applications on separation sciences addressing these two areas are encouraged. The projects should address all types of separations: solids from liquids from gases, High Level Waste from low level waste, and radionuclides from organic compounds.

An example of a project addressing separation issues could be research on processes that remove multiple radionuclides in a single step.

1. Robust, High Loading, Immobilization Methods and Materials That Could Provide Enhancements or Alternatives to Current Immobilization Strategies including

a. Alternatives to borosilicate glasses using slurry-fed electric (Joule) melter as an immobilization matrix, and
b. Alternatives melter techniques.

As an example, a research project might study alternative immobilization matrixes, tailored to either High Level Waste or low level waste, such as cement or crystalline ceramics. Applications to conduct research on alternative melter techniques that would increase the processes available to address different waste streams leading to more efficient immobilization results are encouraged.

4. Innovative Methods To Achieve Real-Time, and, When Practical, in situ Characterization Data for High Level Waste and Process Streams That Would Be Useful for all Phases of the Waste Management Program With Emphasis on

a. Characterization of the waste after retrieval, for instance in process streams and melter feeds.

Applications aimed at developing techniques to achieve shorter turn-around times for the analytical results, which in turn would allow better control of High Level Waste processing are encouraged. An example of such a project is research on fiber-optical interrogation to characterize process streams.

Attendant to paragraph 1. above, there was another area highlighted by the National Research Council regarding long-term issues related to characterization of surrounding areas including radionuclide and metal contamination problems in the near-field around the tanks, and engineered surface or subsurface barriers. These topics will be a matter of a future solicitation for research regarding subsurface contamination.

Specific High Level Waste Science Needs

Detailed information on the specific high level waste technical (science) needs within the general topic areas of this solicitation are available from the Tanks Focus Area Home Page at: *http://www.pnl.gov/tfa.* Relevance to mission reviews will consider responsiveness to the four topic areas of this solicitation and these corresponding specific technical needs. Additional general science research needs and information is also available at: *http://emsp.em.doe.gov/focus_area.htm.*

The aforementioned areas of emphasis do not preclude, and DOE strongly encourages, any innovative or creative ideas contributing to solving EM High Level Waste challenges mentioned throughout this Notice.

For further information regarding the Tanks Focus Area please contact: Mr. Theodore P. Pietrok, Tanks Focus Area, U.S. Department of Energy, P.O. Box 550, Mail Stop K8–50, Richland, WA 99352, telephone: (509) 372–4546, Fax: (509) 372–4037, E-mail: *Theodore_P_Pietrok@rl.gov.*

Background

Environmental Management (EM) is responsible for the development, testing, evaluation, and deployment of remediation technologies to characterize, retrieve, treat, concentrate, and dispose of radioactive waste stored in the underground storage tanks at DOE facilities and ultimately stabilize and close the tanks. The goal is to provide safe and cost-effective solutions that are acceptable to both the public and regulators.

Radioactive high level waste is stored at four sites across the DOE complex:

1. Hanford Site near Richland, Washington
2. Savannah River Site (SRS) near Aiken, South Carolina
3. Idaho National Engineering and Environmental Laboratory (INEEL) near Idaho Falls, Idaho
4. West Valley Demonstration Project (WVDP) in West Valley, New York

At these sites, 282 underground storage tanks have been used to process and store radioactive and chemical mixed waste generated from weapon materials production and manufacturing. Collectively, these tanks hold approximately 90 million gallons of high-level and low-level radioactive liquid waste in sludge, saltcake, and as supernate and vapor.

Tanks vary in design from carbon or stainless steel to concrete, and concrete with carbon steel liners. Two types of storage tanks are most prevalent: the single-shell and double-shell concrete tanks with carbon steel liners. Capacities vary from 5,000 gallons (19m3) to 1,300,000 gallons (4920m3). Most tanks are covered with a layer of soil ranging from approximately 3 to 10 feet thick.

Most of the waste is alkaline and contains a diverse mixture of chemical constituents including nitrate and nitrite salts (approximately half of the total waste), hydrated metal oxides, phosphate precipitates, and ferrocyanides. The 784 MCi of radionuclides are distributed primarily among the transuranic (TRU) elements and fission products, specifically strontium-90, cesium-137, and their decay products yttrium-90 and barium-137. In-tank atmospheric conditions vary in severity from near ambient to temperatures over 93° C. Radiation fields in the tank void space can be as high as 10,000 rad/h.

Hanford has 177 tanks that contain approximately 53 million gallons of hazardous and radioactive waste. There are 149 single-shell tanks that have exceeded their original design life. Sixty-seven of these tanks have known or suspected leaks. Due to several changes in the production processes since the early 1940s, some of the tanks contain incompatible waste components, generating hydrogen gas and excess heat that further compromise tank integrity.

Radioactive waste at SRS consists of 33 million gallons of salt, salt solution, and sludge stored in 51 double-shell underground storage tanks, two of which have been closed (emptied of all waste and filled with grout). Twenty-three tanks are being retired, because they do not have full secondary containment. Nine tanks have leaked detectable quantities of waste from the primary tank to secondary containment.

Unlike the other DOE sites, radioactive waste at INEEL was stored in acidic conditions in stainless steel tanks rather than alkaline conditions. The 11 stainless steel tanks at INEEL store approximately 1.2 million gallons of acidic radioactive liquids. Additionally, approximately 4000 m3 of calcined waste solids are stored in seven stainless steel bin sets enclosed in massive underground concrete vaults.

At the West Valley Demonstration Project nearly all of the original 600,000 gallon of HLW has been retrieved and vitrified. This site is now in the process of cleaning the storage tanks and preparing for closure.

The general process for waste tank remediation involves a number of critical steps including:

- Safe waste storage.
- Waste characterization.
- Retrieval of tank waste.
- Pretreatment and separation of tank waste.
- Waste immobilization.
- Tank closure, and
- Immobilized waste disposal.

Tank remediation problems within these critical process steps are described below. Several process steps are combined for the purpose of describing related technical issues

Characterization and Safety

DOE, contractors, and stakeholders have committed to a safe and efficient remediation of HLW, mixed waste, and hazardous waste stored in underground tanks across the DOE complex.

Currently, there are only limited fully developed or deployed in situ techniques to characterize tank waste. In situ characterization can eliminate the time delay between sample removal and sample analysis and aid in guiding the sampling process while decreasing the cost (approximately $1 million is spent for one tank core extrusion) of waste analysis. Most importantly, remote analysis eliminates sample handling and safety concerns due to worker exposure. However, analysis of extruded tank samples allows a more complete chemical and physical characterization of the waste when needed. Knowledge of the chemical and radioactive composition and physical parameters of the waste is essential to safe and effective tank remediation.

There are three primary drivers for the development of new chemical analysis methods to support tank waste remediation: (1) Provide analyses for which there are currently no reliable existing methods, (2) replace current methods that require too much time and/or are too costly, and (3) provide methods that evolve into on-line process analysis tools for use in waste processing facilities.

Characterization of the elemental and isotopic chemical constituents in DOE tank waste is an important function in support of DOE tank waste operation and remediation functions. Proper waste characterization enables: safe operation of the tank farms; resolution of tank safety questions; and development of processes and equipment for retrieval, pretreatment, and immobilization of tank waste. All of these operations are dependent on the chemical analysis of tank waste.

Current techniques of tank waste analysis involve the removal of core samples from tanks, followed by costly and time consuming wet analytical laboratory testing. Savings in both cost and time could be realized in techniques that involve in situ probes for direct analysis of tank materials.

Leakage from the single shell tanks at Hanford is among the safety concerns. As indicated earlier many of the 149 single shell tanks are known or suspected to leak. This presents a grave problem for retrieval of waste from these tanks since the baseline method for retrieval is to sluice thousands of gallons of water into the tank to dissolve and suspend the waste. HLW waste leakage into the environment can threaten the ground water. There is a need to develop instrumentation to determine the location of a leak, measure the amounts of contamination that may have leaked, and assess the environmental impact.

Another safety concern is the long-term performance of waste forms. Performance assessments of radionuclide containment rely primarily on the geologic barriers (e.g., long travel times in hydrologic systems or sorption on mineral surfaces). The physical and chemical durability of the waste form, however, can contribute greatly to the successful isolation of radionuclides; thus the effects of radiation on physical properties and chemical durability of waste forms are of great importance. The changes in chemical and physical properties occur over relatively long periods of storage, up to a million years, and at temperatures that range from 100 to 300 degrees Celsius, depending on waste loading, age of the waste, depth of burial, and the repository-specific geothermal agent. Thus, a major challenge is to effectively simulate high-dose radiation effects that will occur over relatively low-dose rates over long periods of time at elevated temperatures. Similarly, there is a paramount need for improved understanding and modeling of the degradation mechanisms and behavior of primary radioactive waste hosts and/or their containment canisters, corrosion mechanisms and prevention in aqueous and/or alkali halide containing environments, and remote sensing and non-destructive evaluation.

Examples of specific science research challenges include but are not limited to: basic measurement science and sensor development required for remote detection of low concentrations of hydrogen inside tanks and in containers; basic analytical studies needed to develop new methods for chemical and physical characterization of solid and liquids in slurries and for development of advanced processing methodologies; basic instrument development needed to perform in situ radiological measurements and collect spatially resolved species and concentration data; basic materials and engineering science needed to develop radiation hardened instrumentation.

Retrieval of Tank Waste and Tank Closure

Underground tanks throughout the DOE complex have stored a diverse accumulation of wastes during the past fifty years of weapons and fuel production. If these tanks were isolated in a manner that would preclude the

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escape of radiation into the environment for thousands of years, there would be no reason to disturb them. However, a number of the storage tanks are approaching the end of their design life, and 90 tanks have either leaked or are suspecting of having leaked waste into the soil and sediments near the tanks.

Recently, dewatering processes have removed much of the free liquid from the alkaline waste tanks. The tanks now contain wastes ranging in consistency from remaining supernate and soft sludge to concrete-like saltcake. Tanks also contain miscellaneous foreign objects such as Portland cement, measuring tapes, samarium balls, and in-tank hardware such as cooling coils and piping. Unlimited sluicing, adding large quantities of water to suspend solids, is the baseline method for sludge removal from tanks. This process is not capable of retrieving all of the material from tanks. Besides dealing with aging tanks and difficult wastes, retrieval also faces the problem of the tank design itself. Retrieval tools must be able to enter the tanks, which are under an average of 10 feet of soil, through small openings called risers in the tops of the tanks.

Retrieval of tank waste and tank closure requires tooling and process alternative enhancements to mixing and mobilizing bulk waste as well as dislodging and conveying heels. Heel removal is linked to tank closure. The working tools and removal devices being developed include suction devices, rubblizing devices, water and air jets, waste conditioning devices, grit blasting devices, transport and conveyance devices, cutting and extraction tools, monitoring devices, and various mechanical devices for recovery or repair of waste dislodging and conveyance tools.

The areas directly below the access risers are often disturbed or contain a significant amount of discarded debris. Therefore, evaluation of tank waste characteristics by measurements taken at these locations may not be representative of the properties of the waste in other areas of the tanks.

To monitor current conditions and plan for tank remediation, more information on the tank conditions and their contents is required. Current methods used at DOE tank sites are limited to positioning sensors, instruments, and devices to locations directly below access penetrations or attached to a robotic arm for off-riser positioning. These systems can only deploy one type of sensor, requiring multiple systems to perform more than one function in the tank.

Currently, decisions regarding necessary retrieval technologies, retrieval efficiencies, retrieval durations, and costs are highly uncertain. Although tank closure has been completed on only two HLW tanks (at Savannah River), the tank contents proved amenable to waste retrieval using current technology. DOE has just begun to address the issue of how clean a tank must become before it is closed. Continued demonstration that tank closure criteria can be developed and implemented will provide substantial benefit to DOE.

A related problem that retrieval process development is examining the current lack of a retrieval decision support tool for the end users. As development activities move forward toward collection of retrieval performance and cost data, it has become very evident that the various sites across the complex need to have a decision tool to assist end users with respect to waste retrieval and tank closure. Tank closure is intimately tied to retrieval, and the sensitivity of closure criteria to waste retrieval is expected to be very large.

All the existing processes and technologies that could be used as a baseline for tank remediation have not yet been identified. Identifying these processes is one of EM's major issues in addressing the tank problems. The overall purpose of retrieval enhancements is to continue to lead the efforts in the basic understanding and development of retrieval processes in which waste is mobilized sufficiently to be transferred out of tanks in a cost-effective and safe manner. From that basic understanding, data are provided to end users to assist them in the retrieval decision-making process. The overall purpose of retrieval enhancements is to identify processes that can be used to reduce cost, improve efficiency, and reduce programmatic risk.

Basic engineering and separation science studies are needed to support tank remediation of liquids, which contain high concentrations of solids.

Pretreatment and Separation Processes for Tank Waste

About 90 million gallons of HLW are stored in tanks at four primary sites within the DOE complex. It is neither cost-effective nor practical to treat and dispose of all of the tank waste to meet the requirements of the HLW repository program and the Nuclear Waste Policy Act. The pretreatment area seeks to address multiple needs across the DOE complex. The primary objectives are to reduce the volume of HLW, reduce hazards associated with treating LLW, and minimize the generation of secondary waste.

The current baseline technology systems for waste pretreatment at DOE's tank waste sites are expensive, and technology gaps exist. Large volumes of HLW will be generated, while there is limited space in the planned Nuclear Waste Repository for HLW from DOE. Even if adequate space were made available, treatment and disposal of HLW is still very expensive, estimated to be about $1 million for each canister of vitrified HLW. Only a small fraction of the tank waste, by weight, is made up of HLW radionuclides. The bulk of the waste is chemical constituents intermingled with, and sometimes chemically bonded to, the radionuclides. The chemicals and radionuclides can be separated into HLW and LLW fractions for less costly treatment and disposal.

Most of the tank waste was generated as a result of nuclear fuel processing for weapons production. In that process, irradiated fuel and its cladding were first dissolved, uranium and plutonium were recovered as products, and the highly radioactive fission product wastes were concentrated and sent to the tanks for long-term storage.

Fuel processing at SRS did not change substantially from the beginning of operations in about 1955 to the present. While these wastes are fairly uniform, they still require pretreatment to separate the LLW from HLW prior to immobilization. Liquid waste at INEEL is stored under acidic pH conditions in stainless steel tanks. The original liquid high level waste has been calcined at high temperature to a dry powder. At Hanford, several processes were used over the years (beginning in 1944), each with a different chemical process. This resulted in different waste volumes and compositions. Wastes at Hanford and SRS are stored as highly alkaline material so as not to corrode the carbon steel tanks. The process of converting the waste from acid to alkaline resulted in the formation of different physical forms within the waste.

The primary forms of tank waste include sludge, saltcake, and liquid. The bulk of the radioactivity is known to be in the sludge which makes it the largest source of HLW. Saltcake is characteristic of the liquid waste with most of the water removed. Saltcake is found primarily in older single-shell tanks at Hanford.

Saltcake and liquid waste contain mostly sodium nitrate and sodium hydroxide salts. They also contain soluble radionuclides such as cesium. Strontium, technetium, and transuranics are also present in varying concentrations. The radionuclides must be removed; leaving a large portion of waste to be treated and disposed of as LLW and a very small portion that is combined with HLW from sludge for subsequent treatment and disposition.

Over the years, tank waste has been blended and evaporated to conserve space. Although sludge contains most of the radionuclides, the amount of HLW glass produced (vitrification is the preferred treatment of HLW) could be very high without pretreatment of the sludge. Pretreatment of the sludge by washing with alkaline solution can remove certain nonradioactive constituents and reduce the volume of HLW. Pretreatment can also remove constituents that could degrade the stability of HLW glass. The pretreatment area seeks to address multiple needs across the DOE complex. The primary objectives are to reduce the volume of HLW, reduce hazards associated with treating LLW, and minimize the generation of secondary waste.

The concentration of certain chemical constituents such as phosphorus, sulfur, and chromium in sludge can greatly increase the volume of HLW glass produced upon vitrification of the sludge. These components have limited solubility in the molten glass at very low concentrations. Some sludge has high concentrations of aluminum compounds, which can also be a controlling factor in determining the volume of HLW glass produced. Aluminum above a threshold concentration in the glass must be balanced with proportional amounts of other glass-forming constituents such as silica. There are estimated to be 25 different types of sludge at Hanford distributed among more than 100 tanks. Samples from 49 tanks would represent approximately 93 percent of the sludge in Hanford tanks. Testing of enhanced sludge washing, the combination of caustic leaching and water washing of sludge, on all of these samples is needed to determine whether enhanced sludge washing will result in an acceptable volume of HLW glass destined for the repository and will allow processing in existing carbon steel tanks at Hanford and SRS.

The efficiency of enhanced sludge washing is not completely understood. Inadequate removal of key sludge components could result in production of an unacceptably large volume of HLW glass. Improvements are needed to increase the separation of key sludge constituents from the HLW.

Enhanced sludge washing is planned to be performed batch-wise in large double-shell tanks of nominal one million gallon capacity. This will generate substantial volumes of waste solutions that require treatment and disposal as LLW. Settling times for suspended solids may be excessive and the possibility of colloid or gel formation could prohibit large-scale processing. Alternatives are needed that will reduce the amount of chemical addition required and prevent the possibility of colloid formation. Sludge at SRS and Hanford will be washed to remove soluble components prior to vitrification. Removing suspended solids from the wash solutions is inherently inefficient due to long intervals required for the solids to settle out.

Approximately 1.2 million gallons of acidic liquid waste are stored in single-shell, stainless steel, underground storage tanks at INEEL. In 1992, a Notice of Noncompliance was filed by the State of Idaho stating that the tanks did not meet secondary containment requirements of the Resource Conservation and Recovery Act. Subsequently, an agreement was reached between DOE, the Environmental Protection Agency, and the Idaho Department of Health and Welfare that commits DOE to remove the liquid waste from all underground tanks by the year 2015. Recent discussions with the state of Idaho have accelerated this date to 2012.

The baseline treatment for INEEL liquid and calcine waste was recently reviewed as part of the site's Environmental Impact Statement process. The site is now developing a revised roadmap to pursue direct vitrification of the liquid waste and determine the best path to treat the calcine.

The transuranic extraction process for removal of actinides, or transuranics, from acidic wastes has been tested on actual Idaho waste in continuous countercurrent process equipment. The strontium extraction process shows promise for co-extraction of strontium and technetium and also has been demonstrated on Idaho waste in continuous countercurrent operation.

DOE's underground storage tanks at Hanford, SRS, and INEEL contain liquid wastes with high concentrations of radioactive cesium. Cesium is the primary radioactive constituent found in alkaline supernatant wastes. Since the primary chemical components of alkaline supernatants are sodium nitrate and sodium hydroxide, the majority of the waste could be disposed of as LLW if the radioactivity could be reduced below Nuclear Regulatory Commission limits. Processes have been demonstrated that removed cesium from alkaline supernatants and concentrate it for eventual treatment and disposal as HLW.

At Hanford, cesium must be removed to a very low level (3 Ci/m3) to allow supernatant waste to be treated as LLW and disposed of in a near-surface disposal facility. The revised Hanford Federal Facility Agreement and Consent Order, or Tri-Party Agreement (between DOE, Environmental Protection Agency and the Washington State Department of Ecology) also recommends treatment of LLW in a contact-maintained or minimally shielded vitrification facility to speed remediation and reduce costs. Cesium removal performance data are needed to estimate dose rates for this process and provide input to the design of an LLW pretreatment facility for Hanford supernatants.

At SRS, cesium removal from saltcake waste was planned to be accomplished through use of an in-tank precipitation process. Due to safety and technical challenges, that process was abandoned. Three alternatives including alkaline solvent extraction, cesium ion exchange using crystalline silicotitanate and small tank tetraphenylborate precipitation are currently being evaluated for use in treating the SRS saltcake waste. Cesium removal may also be needed to separate cesium from Defense Waste Processing Facility recycle, or offgas condensate, to greatly reduce the amount of cesium that is routed back to the waste storage tanks.

Technetium (Tc)-99 has a long half-life (210,000 years) and is very mobile in the environment when in the form of the pertechnetate ion. Removal of Tc from alkaline supernatants and sludge washing liquids is expected to be required at Hanford to permit treatment and disposal of these wastes as LLW. The disposal requirements are being determined by the long-term performance assessment of the LLW waste form in the disposal site environment. It is also expected that Tc removal will be required for at least some wastes to meet Nuclear Regulatory Commission LLW criteria for radioactive content. To meet these expected requirements, there is a need to develop technology that will separate this extremely long-lived radionuclide from the LLW stream and concentrate it for feed to HLW vitrification.

A number of liquid streams encountered in tank waste pretreatment contain fine particulate suspended solids. These streams may include tank waste supernatant, waste retrieval sluicing water, and sludge wash solutions. Other process streams with potential for suspended solids include evaporator products and ion exchange

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feed and product streams. Suspended solids will foul process equipment such as ion exchangers. Radioactive solids will carry over into liquid streams destined for LLW treatment, increasing waste volume for disposal and increasing the need for shielding of process equipment. Streams with solid/liquid separation needs exist at all of the DOE tank waste sites.

Some examples of specific science research challenges include but are not limited to: fundamental analytical chemical studies needed for improvement of separation processes; materials science of waste forms germane to their performance; elucidation of technetium chemistry; basic engineering and separation science studies required to support pretreatment activities and the development of solid/liquid separations; fundamental separations chemistry of precipitating agent and ion exchange media needed to support the development of improved methods for decontamination of HLW; fundamental physical chemistry studies of sodium nitrate/nitrite needed for HLW processing; basic materials science studies concerned with the dissolution of mixed oxide materials characteristic of calcine waste needed to design improved pretreatment processes; basic chemistry of sodium when mixed with rare earth oxides needed for the development of alternative HLW forms.

Waste Immobilization and Disposal

Waste immobilization processes convert radioactive waste into solid waste forms that will last in natural environments for thousands of years. DOE tank wastes requiring immobilization include LLW such as the pretreated liquid tank waste and HLW such as the tank sludge. There are also a number of secondary wastes requiring immobilization that result from tank waste remediation operations, such as resins from cesium and technetium removal operations.

The baseline technologies to immobilize radioactive wastes from underground storage tanks at DOE sites include converting LLW to either grout or glass and converting HLW to borosilicate glass. Grout is a cement-based waste form that is produced in a mixer tank and then poured into canisters or pumped into vaults. Glass waste forms are created in a ceramic-lined metal furnace called a melter. Tank waste and dry materials used to form glass are mixed and heated in the melter to temperatures ranging from 1,800 F to 2,200 F. The molten mixture is then poured into log-shaped canisters for storage and disposal. The working assumption is that the LLW will be disposed of on site, or at the Waste Isolation Pilot Plant if transuranic elements are present. The HLW will be shipped for off-site disposal in a licensed HLW repository, such as the one proposed at Yucca Mountain, Nevada.

Methods are needed to immobilize the LLW fraction resulting from the separation of radionuclides from the liquid and high-level calcine wastes at INEEL. LLW is to be mixed with grout, poured into steel drums, and transferred to an interim storage facility, but alternatives are being considered. Tests must be conducted with surrogate and actual wastes to support selection of a final waste form. SRS has selected saltstone grout (pumped to above ground concrete vaults and solidified) as the final waste form for LLW.

DOE sites at Hanford, SRS, and INEEL will remove cesium from the hazardous radioactive liquid waste in the underground storage tanks. If cesium is removed, it costs less to treat the rest of the waste. However, cesium removal from tank waste, while cost-effective, creates a significant volume of solid waste that must be turned into a final waste form for ultimate disposal. The plan is to separate cesium from the liquid waste using ion exchange or other separations media, treat the cesium-loaded separations media to prepare it for vitrification, and convert the cesium product into a glass waste form suitable for final disposal. Personnel exposures during processing and the amount of hazardous species in the offgases must be kept within safe limits at all times.

The effectiveness of advanced oxidation technology for treating organic cesium-loaded separations media prior to vitrification is not proven. After a suitable melter feed is obtained, vitrification of the cesium-loaded media must be demonstrated. Technology development is needed because: (1) Compounds are in the separation media that must be destroyed or they will cause flammability problems in the melter and decrease the durability and waste loading of the final waste form; (2) High beta/gamma dose rates are associated with handling cesium-containing waste; and (3) Cesium volatizes in the melter and becomes a highly radioactive offgas problem.

Confidence and assurance that long-term immobilization will be successful in borosilicate glass warrants research and improved understanding of the structural and thermodynamic properties of glass (including the structure and energetics of stable and metastable phases), systematic irradiation studies that will simulate long term self-irradiation doses and spectra, (including archived glasses containing Pu or Cm, and over the widest range of dose, dose rate and temperature) and predictive theory and modeling based on computer simulations (including ab initio, Monte Carlo, and other methods).

Some examples of specific science research challenges include but are not limited to: fundamental chemical studies needed to determine species concentrations above molten glass solutions containing heavy metals, cesium, strontium, lanthanides, actinides, with and without a cold cap composed of unmelted material; materials science studies of molten materials that simulate conditions anticipated during vitrification and storage in vitrified form of HLW needed to develop improved processes and formulations; fundamental physical chemistry studies of sodium nitrate/nitrite mixtures needed for HLW stabilization.

References for Background Information

Note: World Wide Web locations of these documents are provided where possible. For those without access to the World Wide Web, hard copies of these references may be obtained by writing Mark A. Gilbertson at the address listed in the **FOR FURTHER INFORMATION CONTACT** section of this Notice.

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NRC. 2000. Alternatives for High-Level Waste Salt Processing at the Savannah River Site. *http://www.nap.edu/books/0309071941/html/.*

NRC. 1999. Disposition of High-Level Radioactive Waste Through Geological Isolation: Development, Current Status, and Technical and Policy Challenges. *http://books.nap.edu/books/0309067782/html/1.html.*

NRC. 1999. Interim Report—Committee on Cesium Processing Alternatives for High-Level Waste at the Savannah River Site. *http://books.nap.edu/books/NI000350/html/index.html.*

NRC. 1999. Alternative High-Level Waste Treatments at the Idaho National Engineering and Environmental Laboratory. *http://books.nap.edu/books/030906628X/html/129.html.*

(The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR Part 605.)

Issued in Washington, DC, on January 9, 2001.

John Rodney Clark,

Associate Director of Science for Resource Management.

[FR Doc. 01–1184 Filed 1–12–01; 8:45 am]

BILLING CODE 6450–01–U

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy; Federal Energy Management Advisory Committee

AGENCY: Office of Energy Efficiency and Renewable Energy; Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Federal Energy Management Advisory Committee (FEMAC). The Federal Advisory Committee Act (Public Law 92—463, 86 Stat. 770) requires that these meetings be announced in the **Federal Register** to allow for public participation. This notice announces the second meeting of FEMAC, an advisory committee established under Executive Order 13123, "Greening the Government through Efficient Energy Management."

DATES: Thursday, January 25, 2001; 1:30 p.m. to 5:00 p.m.; Friday, January 26, 2001; 9:00 a.m. to 4:00 p.m.

ADDRESSES: Loews L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Steven Huff, Designated Federal Officer for the Committee, Office of Federal Energy Management Programs, U.S. Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585; (202) 586–3507.

SUPPLEMENTARY INFORMATION:

Purpose of meeting: To provide advice and guidance on Federal Energy Management.

Tentative Agenda: Agenda will include discussions on the following:

Thursday, January 25, 2001, and Friday, January 26, 2001

- Federal energy management budget
- Energy-savings performance contracts
- Utility energy-efficiency service contracts
- Procurement of ENERGY STAR (Registered Trademark) and other energy efficient products
- Building design
- Process energy use
- Applications of efficient and renewable energy technologies (including clean energy technologies) at Federal facilities
- Public comment

Public Participation: In keeping with procedures, members of the public are welcome to observe the business of the Federal Energy Management Advisory Committee. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Steven Huff at (202) 586–3507 or *Steven.Huff@ee.doe.gov.* You must make your request for an oral statement at least five business days before the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chair of the Committee will make every effort to hear the views of all interested parties. The Chair will conduct the meeting to facilitate the orderly conduct of business. This notice is being published less than 15 days before the date of the meeting due to programmatic issues that had to be resolved prior to publication.

Minutes: The minutes of the meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room; Room 1E–190; Forrestal Building; 1000 Independence Avenue, SW., Washington, DC, between 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, D.C., on January 10, 2001.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–1183 Filed 1–12–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–201–000]

Columbia Gas Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 9, 2001.

Take notice that on December 29, 2000, Columbia Gas Transmission Corporation (Columbia) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheets, bearing a proposed effective date of February 1, 2001:

Forty-eighth Revised Sheet No. 25
Forty-eighth Revised Sheet No. 26
Forty-eighth Revised Sheet No. 27
Forty-third Revised Sheet No. 28
Fifth Revised Sheet No. 28B
Sixteenth Revised Sheet No. 29
Twenty-second Revised Sheet No. 30A

Columbus states that this filing is being submitted pursuant to an order issued September 15, 1999, the Federal Energy Regulatory Commission (Commission) approved an uncontested settlement that resolves environmental cost recovery issues in the above-referenced proceeding. *Columbia Gas Transmission Corporation,* 88 FERC ¶ 61,217 (1999). The settlement established environmental cost recovery through unit components of base rates, all as more fully set forth in Article VI of the settlement agreement filed April 5, 1999 (Phase II Settlement).

Columbia is required to file annually a limited NGA Section 4 filing to adjust its environmental unit components effective February 1 to recover its environmental costs covered by the Phase II Settlement, within agreed-upon ceilings and recovery percentages. For the annual period February 1, 2001 through January 31, 2002, the Phase II Settlement permits Columbia to collect "no more than $14 million annually in Main Program Costs", and "no more than $3 million annually in Storage Well Program Costs." Article VI(B) of the Phase II Settlement. The instant filing satisfies that requirement. It provides for the February 1, 2001 effectiveness of revised unit components designed to collect $7.8 million in Main Program Costs and $2.8 million of Storage Well Program Costs

Columbia states that copies of its filing have been mailed to all firm customers, interruptible customers and affected state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the

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Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

David P. Boergers,

Secretary.

[FR Doc. 01–1145 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2566–010; Project No. 11616–000]

Consumers Energy Company, City of Portland, MI; Notice of Section 10(j) Teleconference

January 9, 2001.

a. Date and Time of Meeting: January 31, 2001, 10 am EST.

b. FERC Contact: Tom Dean at (202) 219–2778; thomas.dean@ferc.fed.us.

c. Purpose of the Teleconference: The Federal Energy Regulatory Commission, the Michigan Department of Natural Resources, and the U.S. Fish and Wildlife Service intend to discuss the resource agency's recommendations that were not recommended for adoption in the Portland Municipal Hydroelectric Project No. 11616–000 and the Webber Hydroelectric Project No. 2566–010 draft environmental assessment issued on September 19, 2000.

d. Proposed Agenda:

A. Introduction
   Recognition of Participants
   Teleconference Procedures and Objectives
B. Section 10(j) issues discussion
C. Issues outside of Section 10(j)
D. Summary of meeting
E. Follow-up actions

e. Anyone wishing to participate in the teleconference should call toll free, 1–888–399–8606. The caller will need to give the operator the passcode "Dean", and the team leader name "Thomas Dean", to join the teleconference.

David P. Boergers,

Secretary.

[FR Doc. 01–1140 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–544–000]

Cook Inlet Power, LP; Notice of Issuance of Order

January 9, 2001.

Cook Inlet Power, LP (Cook Inlet) submitted for filing a rate schedule under which Cook Inlet will engage in wholesale electric power and energy transactions at market-based rates. Cook Inlet also requested waiver of various Commission regulations. In particular, Cook Inlet requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Cook Inlet.

On January 3, 2001, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Cook Inlet should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Cook Inlet is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Cook Inlet's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 2, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1135 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–163–002]

Dominion Transmission, Inc.; Notice of Proposed Changes in FERC Gas Tariff

January 9, 2001.

Take notice that on January 3, 2001, Dominion Transmission Inc. (DTI), tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following revised tariff sheet, with an effective date of January 1, 2001:

Second Substitute Fourth Revised Sheet No. 32.

DTI states that the purpose of this filing is to amend the tariff sheet referenced above, in accordance with the Commission's December 27, 2000 Letter Order.

DTI states that copies of its letter of transmittal and enclosures have been served upon all parties on the official service list.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1139 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–545–000]

Duke Energy Lee, LLC; Notice of Issuance of Order

January 9, 2001.

Duke Energy Lee, LLC (Duke Lee) submitted for filing a rate schedule under which Duke Lee will engage in wholesale electric power and energy transactions at market-based rates. Duke Lee also requested waiver of various Commission regulations. In particular, Duke Lee requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Lee.

On January 5, 2001, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Duke Lee should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Duke Lee is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Duke Lee's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 5, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, D.C. 20426. The Order may also be viewed on the Internet at *http:www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1134 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–195–000]

Kinder Morgan Interstate Gas Transmission LLC; Notice of Filing of Reconciliation Report

January 9, 2001.

Take notice than on December 19, 2000, Kinder Morgan Interstate Gas Transmission LLC (KMIGT) tendered for filing its annual reconciliation filing pursuant to Section 35 (Crediting of Imbalance Revenue) of its General Terms and Conditions of its FERC Gas Tariff, Fourth Revised Volume No. 1–B.

KMIGT states that it has served copies of the filing upon all jurisdictional customers, interested State Commission, and other interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before January 16, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1144 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–331–015]

National Fuel Gas Supply Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 9, 2001.

Take notice that on January 4, 2001 National Fuel Gas Supply Corporation (National Fuel) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, Fourth Revised Sheet No. 12, with a proposed effective date of February 3, 2001.

National Fuel states that the filing is made to revise two negotiated rate agreements between National Fuel and TXU Energy Trading Company, accepted by the Commission by order dated April 6, 2000, in Docket No. RP96–331–013. The revised charges would take effect upon April 1, 2001, when the second contract year commences.

National Fuel states that copies of this filing were served upon its customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions

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on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1143 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–202–000]

National Fuel Gas Supply Corporation; Notice of Tariff Filing

January 9, 2001.

Take notice that on December 29, 2000, National Fuel Gas Supply Corporation (National) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the following tariff sheet to become effective January 1, 2001.

Thirty First Revised Sheet No. 9

National asserts that the purpose of this filing is to comply with the Commission's order issued February 16, 1996, in Docket Nos. RP94–367–000, et al. Under Article I, Section 4, of the settlement approved in that order, National must redetermine quarterly the Amortization Surcharge to reflect revisions in the Plant to be Amortized, interest and associated taxes, and a change in the determinants. The recalculation produced an Amortization Surcharge of 7.15 cents per dth.

Further National states that under Article II, Section 2, of the settlement, it is required to recalculate the maximum Interruptible Gathering ("IG") rate monthly and to charge that rate on the first day of the following month if the result is an IG rate more than 2 cents above or below the IG rate as calculated under Section 1 of Article II. The recalculation produced an IG rate of 39 cents per dth. In addition, Article III, Section 1 states that any overruns of the Firm Gathering service provided by National shall be priced at the maximum IG rate.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1147 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP99–176–027, RP99–176–028, RP99–176–029, and RP99–176–030]

Natural Gas Pipeline Company of America; Notice of Compliance Filing

January 9, 2001.

Take notice that on January 4, 2001, Natural Gas Pipeline Company of America (Natural) tenders for filing with the Commission, its FTS–SW Agreement No. 118138, in Docket Nos. RP99–176–027 and RP99–176–028.

Natural as also tendered for filing to become part of its FERC Gas Tariff, Sixth Revised Volume No. 1, in Docket Nos. RP99–176–029 and RP99–176–030, the following tariff sheets, to be effective November 22, 2000:

Fourteenth Revised Sheet No. 3
Substitute Original Sheet No. 260
Original Sheet No. 414
Sheet Nos. 415–499

Natural states that the purpose of this filing is to comply with the Commission's "Order Accepting Tariff Sheet and Negotiated Rate Agreement Subject to Conditions" issued on December 20, 2000, in Docket Nos. RP99–176–022 and RP99–176–023 (Order).

Natural requests waiver of the Commission's Regulations to the extend necessary to permit the revised tariff sheets to become effective November 22, 2000.

Natural states that copies of the filing are being mailed to all parties set out on the Commission's official service list in Docket No. RP99–176.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1142 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–62–000]

Northwest Pipeline Corporation; Notice of Application

January 9, 2001.

Take notice that on January 5, 2001, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84158, filed in Docket No. CP01–62–000 an application pursuant to Section 7(c) of the Natural Gas Act for a blanket certificate of public convenience and necessity authorizing Northwest to install and operate, on a temporary and limited basis, three existing portable compressor units to provide incremental horsepower and physical capacity at its existing Kemmerer, Pegram and Lava Hot Springs Compressor Stations in Wyoming and Idaho all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Northwest proposes to establish an additional secondary function for its three portable compressor units that current have a primary function of temporarily replacing out-of-service permanent compressor units.[1] Specifically, when the temporary units are not required for their primary function, Northwest will operate the units to temporarily supplement northflow capacity through the Kemmerer, Wyoming to Pegram, Idaho segment (the Kemmerer Corridor) of its system. The increased northflow capacity will reduce the level of operational flow orders issued to provide sufficient displacement capacity to accommodate firm contractual obligations through the Kemmerer Corridor. Northwest states that the temporary supplemental compression will increase the physical northflow capacity through the Kemmerer Corridor by about 22 MDth per day.

Any questions regarding the application should be directed to Gary K. Kotter, Manager, Certificates, Northwest Pipeline Corporation, P.O. Box 58900, Salt Lake City, Utah 84158–0900 at 801–584–7117 or at garold.k.kotter@williams.com.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before January 19, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents field by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents field by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–1137 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

[1] Two of the portable compressor units have a current secondary function by virtue of Northwest's blanket authority to operate the portable units at two compressor sites in Washington state when necessary to augment southflow in order to offset displacement capacity shortfalls.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER–01–562–000]

SEI Michigan, L.L.C.; Notice of Issuance of Order

January 9, 2001.

SEI Michigan, L.L.C. (SEI) submitted for filing a rate schedule under which SEI will engage in wholesale electric power and energy transactions at market-based rates. SEI also requested waiver of various Commission regulations. In particular, SEI requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by SEI.

On January 5, 2001, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by SEI should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, SEI is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of SEI's issuance of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene

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or protests, as set forth above, is February 5, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, N.E., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1136 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–205–000]

Southern Natural Gas Company; Notice of Tariff Filing

January 9, 2001.

Take notice that on December 29, 2000, Southern Natural Gas Company (Southern), tendered for filing as part of its FERC Gas Tariff, Seventh Revised Volume No. 1, the tariff sheets listed on Attachment A to the filing, with an effective date of February 1, 2001.

Southern states that the purpose of the filing is to permit Southern to charge negotiated rates for its storage and transportation services in accordance with the Statement of Policy issued by the Commission on January 31, 1996 in Docket No. RP95–6–000 (Policy Statement). Southern states that the tariff sheets include a new Section to its General Terms and Conditions describing the terms and conditions under which it would perform negotiated rate transactions and conforming language to other sections of the Tariff to reflect the ability of Southern to charge negotiated rates.

Southern states that copies of the filing will be served upon its shippers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing maybe viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1146 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP–20–000]

Texas Eastern Transmission Corporation; Notice of Proposed Changes in FERC Gas Tariff

January 9, 2001.

Take notice that on December 29, 2000 Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1 and Original Volume No. 2, revised tariff sheets listed on Appendix A to the filing to become effective February 1, 2001.

Texas Eastern states that these revised tariff sheets are filed pursuant to Section 15.1, Electric Power Cost (EPC) Adjustment, of the General Terms and Conditions of Texas Eastern's FERC Gas Tariff, Sixth Revised Volume No. 1.

Texas Eastern states that Section 15.1 provides that Texas Eastern shall file to be effective each February 1 revised rates for each applicable zone and rate schedule based upon the projected annual electric power costs required for the operation of transmission compressor stations with electric motor prime movers and to also reflect the EPC Surcharge which is designed to clear the balance in the Deferred EPC Account.

Texas Eastern states that the rate changes proposed to the primary firm capacity reservation charges, usage rates and 10% load factor average costs for full Access Area Boundary service from the Access Area Zone, East Louisiana, to the three market area zones are as follows:

Zone	Reservation	Usage	100% LF
Market 1	$0.017/dth	$.0001/dth	$.0007/dth.
Market 2	$0.051/dth	$.0002/dth	$.0019/dth.
Market 3	$0.074/dth	$.0002/dth	$.0026/dth.

Texas Eastern states that copies of its filing have been mailed to all affected customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with with Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(ii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1141 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–260–000]

Texas Gas Transmission Corporation; Notice of Settlement Conference

January 9, 2001.

Take notice that an informal settlement conference will be convened in this procedure at 10:00 am on Tuesday, January 16 and possibly continuing to January 17, 2001, at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purpose of discussing the settlement of issues in the proceeding.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact William J. Collins at (202) 208–0248.

David P. Boergers,

Secretary.

[FR Doc. 01–1148 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–191–000]

Transcontinental Gas Pipe Line Corporation; Notice of Refund Report

January 9, 2001.

Take notice that on December 15, 2000, Transcontinental Gas Pipe Line Corporation (Transco) filed a report reflecting the flow through of refunds received from Dominion Transmission, Inc.

On December 15, 2000, in accordance with Section 4 of its Rate Schedule LSS and Section 3 of its Rate Schedule GSS, Transco states that it refunded to its LSS and GSS customers $336,777.46 resulting from the refund of Dominion Transmission, Inc. Docket No. TM00–1–22–00. The refund covers the period from November 1999 to June 2000.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before January 16, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us//online/rims.htm (call 202–208–222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/dorrbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1138 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR01–2–000, et al.]

Big West Oil Company, et al.; Electric Rate and Corporate Regulation Filings

January 8, 2001.

Take notice that the following filings have been made with the Commission:

1. Big West Oil Company v. Frontier Pipeline Company and Express Pipeline Partnership

[Docket No. OR01–2–000]

Take notice that on January 5, 2001, Big West Oil Company (Big West), tendered for filing a complaint against Frontier Pipeline Company (Frontier) and Express Pipeline Partnership (Express).

Big West states that it is a shipper of crude oil on tariffs filed by Frontier as well as on joint tariffs published by Frontier and Express for the shipment of crude petroleum between International Boundary, Canada and Salt Lake City, Utah. Big West further alleges that the rates being charged on the Frontier tariff and on the Frontier portion of the Frontier/Express joint tariffs are unjust and unreasonable and unduly discriminatory and unduly preferential, and therefore in violation of the Interstate Commerce Act.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice. Answers to the complaint shall also be filed on or before January 25, 2001.

2. PSEG Power New York Inc.

[Docket No. ER01–643–001]

Take notice that on January 3, 2001, PSEG Power New York Inc. (PSEG Power New York), tendered for filing pursuant to Section 205 of the Federal Power Act (FPA), 16 U.S.C. § 824d (1994), and Part 35 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR Part 35, an amended application for waiver of certain filing requirements associated with the production of electric capacity, energy and ancillary services generated at the Albany Steam Station by PSEG Power New York.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. EWO Marketing, L.P.

[Docket No. ER01–666–001]

Take notice that on December 28, 2000, EWO Marketing, L.P., tendered for filing an amendment to its application for authorization to sell wholesale power at market-based rates pursuant to Section 205 of the Federal Power Act.

Copies of this filing have been served upon all parties listed on the official service list maintained by the Secretary of the Commission for these proceedings.

Comment date: January 18, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Axia Energy, L.P.

[Docket No. ER01–667–001]

Take notice that on December 28, 2000, Axia Energy, L.P., tendered for filing an amendment to its application for authorization to sell wholesale power at market-based rates pursuant to Section 205 of the Federal Power Act.

Comment date: January 18, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Illinois Power Company

[Docket No. ER00–3419–001]

Take notice that on January 4, 2001, Illinois Power Company (Illinois Power), 500 South 27th Street, Decatur, Illinois 65251–2200, tendered for filing with the Commission service agreement designations as required by Order No. 614.

Illinois Power requests a waiver of the 30-day filing requirement set forth in the Commission's order of October 18, 2000 in this proceeding.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

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6. Southwestern Electric Power Company

[Docket No. ER01–651–000]

Take notice that on January 3, 2001, Southwestern Electric Power Company (SWEPCO), tendered for filing an amendment to SWEPCO's December 12, 2000, filing in the above-captioned proceeding. The amendment contains the exhibits to the testimony of Samuel C. Hadaway, Exhibits SWP–2 through SWP–7. The exhibits were inadvertently omitted from the December 12, 2000 filing.

SWEPCO states that a copy of the amended filing has been served on the affected customers and on the Public Utility Commission of Texas, the Louisiana Public Service Commission and the Arkansas Public Service Commission.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. United States Department of Energy, Bonneville Power Administration

[Docket No. EF01–2011–000]

Take notice that on January 5, 2001, the Bonneville Power Administration (BPA) tendered for filing a proposed rate adjustment to its Unauthorized Increase Charge (UAI) contained in the 1996 General Rate Schedule Provisions, pursuant to section 7(a)(2) of the Pacific Northwest Electric Power Planning and Conservation Act, 16 U.S.C. 839e(a)(2). BPA seeks interim approval of its proposed rates effective February 1, 2001, pursuant to Commission Regulation 300.20, 18 CFR 300.20. Pursuant to Commission Regulation 300.21, 18 CFR 300.21, BPA seeks interim approval and final confirmation of the proposed rates for the periods set forth in this notice.

BPA requests approval effective February 1, 2001, through September 30, 2001, for the proposed rate adjustment to its Unauthorized Increase Charge. BPA states that this approval is necessary for it to maintain the effectiveness of the penalty nature of the UAI Charge.

Comment date: January 22, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Delta Person Limited Partnership

[Docket No. ER01–138–001]

Take notice that on December 29, 2000, Delta Person Limited Partnership (Delta), tendered for filing its redesignated FERC Rate Schedule No. 1 in accordance with the Commission's letter order in the above-referenced docket.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Wisconsin Electric Power Company

[Docket No. ER01–848–000]

Take notice that on December 28, 2000, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing, pursuant to Section 35.12 of the Commission's regulations, 18 CFR 35.12, a Service Agreement with Wisconsin Public Power, Inc. (WPPI) pursuant to Wisconsin Electric's FERC Electric Tariff Second Revised Volume No. 2 for the provision of Dynamic Regulation and Frequency Response Service and Energy Imbalance Service to load served by WPPI and located within the historic, geographically-defined control areas operated by Wisconsin Power & Light Company and Wisconsin Public Service Corporation.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Wisconsin Electric Power Company

[Docket No. ER01–849–000]

Take notice that on December 28, 2000, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing, pursuant to Section 35.12 of the Commission's regulations, 18 CFR 35.12, a Wholesale Distribution Delivery Service Agreement between Wisconsin Electric and the City of Oconto Falls, Wisconsin (Oconto Falls) for the provision of wholesale distribution service to Oconto Falls beginning January 1, 2001.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Wisconsin Electric Power Company

[Docket No. ER01–850–000]

Take notice that on December 28, 2000, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing, pursuant to Section 35.12 of the Commission's Regulations, 18 CFR 35.12, a Wholesale Distribution Delivery Service Agreement between Wisconsin Electric and Wisconsin Public Power, Inc. (WPPI). The purpose of the agreement is to provide wholesale distribution service to five of WPPI's members—the City of Cedarburg, Wisconsin, the City of Lake Mills, Wisconsin, the City of Slinger, Wisconsin, the City of Waterloo, Wisconsin, and the City of New London, Wisconsin.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Northeast Utilities Service Company, Select Energy, Inc.

[Docket No. ER01–851–000]

Take notice that on December 29, 2000, Northeast Utilities Service Company (NUSCO) and Select Energy, Inc. (Select), tendered for filing under section 205 of the Federal Power Act four amendments to existing power supply agreements under which Holyoke Water Power Company (HWP) and Holyoke Power and Electric Company (HP&E) may sell electric power to Select, and purchase electric power from Select. Applicants state that the agreements extend the term of each power supply agreement by one additional year, to December 31, 2001.

The Applicants state that copies of this filing have been sent to HWP, HP&E, and Select.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Twelvepole Creek, LLC

[Docket No. ER01–852–000]

Take notice that on December 29, 2000, Twelvepole Creek, LLC, with an office located at c/o Orion Power Holdings, Inc., 7 E. Redwood Street, 10th Floor, Baltimore, Maryland 21202, which will own and operate a natural gas-fired electric generating facility to be constructed in Wayne County, West Virginia submitted for filing with the Federal Energy Regulatory Commission its initial FERC Electric Rate Schedule No. 1 which will enable Twelvepole Creek to engage in the sale of electric energy and capacity, and certain ancillary services at market-based rates.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. New England Power Pool

[Docket No. ER01–853–000]

Take notice that on December 29, 2000, the New England Power Pool (NEPOOL), Participants Committee filed for acceptance material to permit NEPOOL to expand its membership to include Amerada Hess Corporation (AHC) and to terminate the membership of Hess Energy, Inc., (HEI).

NEPOOL requests a January 1, 2001 effective date for the commencement of AHC participation in and the termination of HEI from NEPOOL.

The Participants Committee states that copies of these materials were sent to the New England state governors and regulatory commission and the Participants in NEPOOL.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. American Transmission Company LLC

[Docket No. ER01–854–000]

Take notice that on December 29, 2000, American Transmission Company LLC (ATCLLC), tendered for filing a Network Operating Agreement and Network Integration Transmission Service Agreement between ATCLLC and Wisconsin Public Service Corporation.

ATCLLC requests an effective date of January 1, 2001.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Wisconsin Electric Power Company, LLC

[Docket No. ER01–855–000]

Take notice that on December 29, 2000, Wisconsin Electric Power Company (Wisconsin Electric), tendered for filing a fully executed Coordinated Operating Agreement, dated December 22, 2000 between Wisconsin Electric and Consumers Energy Company.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Bangor Hydro Electric Company

[Docket No. ER01–856–000]

Take notice that on December 29, 2000, Bangor Hydro-Electric Company tendered for filing Notices of Cancellation of its FERC Electric Rate Schedules Nos. 7 (Eastern Maine Electric Cooperative, Inc.), 27 (Swan's Island Electric Cooperative), and 52 (Isle Au Haut Electric Power Company) to be effective March 1, 2001.

Copies of the filing were served upon the affected purchasers, Swan's Island Electric Cooperative, Eastern Maine Electric Cooperative, Inc., Isle Au Haut Electric Power Company, the Maine Public Utilities Commission, and Maine Public Advocate.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–857–000]

Take notice that on January 2, 2001, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Service Agreement No. 96 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply requests a waiver of notice requirements for an effective date of September 11, 2000 for Oglethorpe Power Corporation.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Commonwealth Edison Company

[Docket No. ER01–858–000]

Take notice that on December 29, 2000, Commonwealth Edison Company tendered for filing an Interconnection Agreement with Calpine Morris, LLC and Equistar Chemicals, LP to interconnect a 167 MW plant to the ComEd system at Morris, Illinois.

ComEd requests waiver of the prior notice requirements and an effective date of January 1, 2001.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Duke Energy Corporation

[Docket No. ER01–860–000]

Take notice that on December 29, 2000, Duke Energy Corporation (Duke), tendered for filing amendments to its May 2, 1997 Contract with the Southeastern Power Administration.

Duke requests that the amendments be made effective January 1, 2001.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. PacifiCorp

[Docket No. ER01–861–000]

Take notice that on December 29, 2000, PacifiCorp tendered for filing in accordance with 18 CFR 35 of the Commission's Rules and Regulations, a Long-Term Firm Transmission Service Agreement with Bonneville Power Administration (Bonneville) under PacifiCorp's FERC Electric Tariff, Second Revised Volume No. 11 (Tariff).

Copies of this filing were supplied to the Washington Utilities and Transportation Commission and the Public Utility Commission of Oregon.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. Alliant Energy Corporate Services, Inc.

[Docket No. ER01–865–000]

Take notice that on January 2, 2001, Alliant Energy Corporate Services, Inc., (Alliant Energy) on behalf of Wisconsin Power & Light (WPL) and Interstate Power Company (IPC) tendered for filing a Negotiated Capacity Transaction (Agreement) between WPL and IPC for the period January 1, 2001 through December 31, 2001. The Agreement was negotiated to provide service under the Alliant Energy System Coordination and Operating Agreement among IES Utilities Inc., Interstate Power Company, Wisconsin Power & Light Company and Alliant Energy.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. Alliant Energy Corporate Services, Inc.

[Docket No. ER01–862–000]

Take notice that on January 2, 2001, Alliant Energy Corporate Services, Inc. (Alliant Energy) on behalf of Interstate Power Company (IPC) and Wisconsin Power & Light (WPL) tendered for filing a Negotiated Capacity Transaction (Agreement) between IPC and WPL for the period January 1, 2001 through December 31, 2001. The Agreement was negotiated to provide service under the Alliant Energy System Coordination and Operating Agreement among IES Utilities Inc., Interstate Power Company, Wisconsin Power & Light Company and Alliant Energy.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

24. Alliant Energy Corporate Services, Inc.

[Docket No. ER01–863–000]

Take notice that on January 2, 2001, Alliant Energy Corporate Services, Inc. (Alliant Energy) on behalf of Wisconsin Power & Light (WPL) and IES Utilities Inc. (IESU), tendered for filing a Negotiated Capacity Transaction (Agreement) between WPL and IESU for the period January 1, 2001 through December 31, 2001. The Agreement was negotiated to provide service under the Alliant Energy System Coordination and Operating Agreement among IES Utilities Inc., Interstate Power Company, Wisconsin Power & Light Company and Alliant Energy.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

25. Alliant Energy Corporate Services, Inc.

[Docket No. ER01–864–000]

Take notice that on January 2, 2001, Alliant Energy Corporate Services, Inc. (Alliant Energy) on behalf of Interstate Power Company (IPC) and Wisconsin

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Power & Light (WPL) tendered for filing a Negotiated Capacity Transaction (Agreement) between IPC and WPL for the period December 1, 2000] through March 31, 2001. The Agreement was negotiated to provide service under the Alliant Energy System Coordination and Operating Agreement among IES Utilities Inc., Interstate Power Company, Wisconsin Power & Light Company and Alliant Energy.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

26. Citizens Communications Company

[Docket No. ER00–3211–001]

Take notice that on January 2, 2001, Citizens Communications Company in compliance with the Commission's August 17, 2000] letter order in this proceeding, tendered for filing revised tariffs and rate schedules to reflect its name change and other designation requirements of Order No. 614.

A copy of this filing was served on the service list in this Docket, and on each of Citizens Communications Company's wholesale customers. In addition, a copy is available for inspection at the offices of Citizens' Vermont Electric Division during regular business hours.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

27. Lighthouse Energy Trading Company, Inc.

[[Docket No. ER01–174–001]

Take notice that on December 28, 2000, Lighthouse Energy Trading Company, Inc., a South Dakota Corporation (Lighthouse), tendered for filing an amended Rate Schedule FERC No. 1, in compliance with the Commission's Order No. 614.

Lighthouse intends to engage in wholesale electric power and energy purchases and sales as a marketer. Lighthouse is not in the business of generating or transmitting electric power.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

28. Naniwa Energy LLC

[Docket No. ER01–457–001]

Take notice that on December 28, 2000, Naniwa Energy LLC tendered for filing an amendment to its initial rate filing in the above-captioned proceeding.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

29. Consolidated Edison Company of New York, Inc.

[Docket No. ER01–478–001]

Take notice that on December 28, 2000, Consolidated Edison Company of New York, Inc. (Con Edison), tendered the conformed title page of the Indian Point 3 Interconnection Agreement, dated as of November 9, 2000, by and between Con Edison and Entergy Nuclear Indian Point 3, LLC, in the above-captioned

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1133 Filed 1–12–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6932–9]

Public Water System Supervision Program Revision for the State of Alabama

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of tentative approval.

SUMMARY: Notice is hereby given that the State of Alabama is revising its approved Public Water System Supervision Program. Alabama has adopted drinking water regulations establishing administrative penalty authority, and which revise the definition of a Public Water System. EPA has determined that these revisions are no less stringent than the corresponding federal regulations. Therefore, EPA intends on approving this State program revision.

All interested parties may request a public hearing. A request for a public hearing must be submitted by February 15, 2001, to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial request for a public hearing is made by February 15, 2001, a public hearing will be held. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on his own motion, this determination shall become final and effective on February 15, 2001. Any request for a public hearing shall include the following information: (1) The name, address, and telephone number of the individual organization, or other entity requesting a hearing; (2) A brief statement of the requesting person's interest in the Regional Administrator's determination and a brief statement of the information that the requesting person intends to submit at such hearing; (3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, at the following offices:

Alabama Department of Environmental Management, Water Division, Water Supply Branch, 1400 Coliseum Boulevard, Montgomery, Alabama 36110–2059; or at the Environmental Protection Agency, Region 4, Drinking Water Section, 61 Forsyth Street SW, Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Tom Plouff, EPA Region 4, Drinking Water Section at the Atlanta address given above or at telephone (404) 562–9476.

SUPPLEMENTARY INFORMATION

Authority: Sections 1401 and 1413 of the Safe Drinking Water Act, as amended (1996), and 40 CFR Parts 141 and 142.

Dated: December 20, 2000.

A. Stanley Meiburg,

Acting Regional Administrator, EPA Region 4.

[FR Doc. 01–1051 Filed 1–12–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL HOUSING FINANCE BOARD

[No. 2001–N–1]

Federal Home Loan Bank Members Selected for Community Support Review

AGENCY: Federal Housing Finance Board.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Board (Finance Board) is announcing the Federal Home Loan Bank (Bank) members it has selected for the 2000–01 fourth quarter review cycle under the Finance Board's community support requirement regulation. This notice also prescribes the deadline by which Bank members selected for review must submit Community Support Statements to the Finance Board.

DATES: Bank members selected for the 2000–01 fourth quarter review cycle under the Finance Board's community support requirement regulation must submit completed Community Support Statements to the Finance Board on or before March 2, 2001.

ADDRESSES: Bank members selected for the 2000–01 fourth quarter review cycle under the Finance Board's community support requirement regulation must submit completed Community Support Statements to the Finance Board either by regular mail at the Office of Policy, Research and Analysis, Program Assistance Division, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006, or by electronic mail at FITZGERALDE@FHFB.GOV.

FOR FURTHER INFORMATION CONTACT: Emma J. Fitzgerald, Program Analyst, Office of Policy, Research and Analysis, Program Assistance Division, by telephone at 202/408–2874, by electronic mail at FITZGERALDE@FHFB.GOV, or by regular mail at the Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006. A telecommunications device for deaf persons (TDD) is available at 202/408–2579.

SUPPLEMENTARY INFORMATION:

I. Selection for Community Support Review

Section 10(g)(1) of the Federal Home Loan Bank Act (Bank Act) requires the Finance Board to promulgate regulations establishing standards of community investment or service Bank members must meet in order to maintain access to long-term advances. *See* 12 U.S.C. 1430(g)(1). The regulations promulgated by the Finance Board must take into account factors such as the Bank member's performance under the Community Reinvestment Act of 1977 (CRA), 12 U.S.C. 2901 et seq., and record of lending to first-time homebuyers. *See* 12 U.S.C. 1430(g)(2). Pursuant to the requirements of section 10(g) of the Bank Act, the Finance Board has promulgated a community support requirement regulation that establishes standards a Bank member must meet in order to maintain access to long-term advances, and review criteria the Finance Board must apply in evaluating a member's community support performance. *See* 12 CFR part 944. The regulation includes standards and criteria for the two statutory factors—CRA performance and record of lending to first-time homebuyers. 12 CFR 944.3. Only members subject to the CRA must meet the CRA standard. 12 CFR 944.3(b). All members, including those not subject to CRA, must meet the first-time homebuyer standard. 12 CFR 944.3(c).

Under the rule, the Finance Board selects approximately one-eighth of the members in each Bank district for community support review each calendar quarter. 12 CFR 944.2(a). The Finance Board will not review an institution's community support performance until it has been a Bank member for at least one year. Selection for review is not, nor should it be construed as, any indication of either the financial condition or the community support performance of the member.

Each Bank member selected for review must complete a Community Support Statement and submit it to the Finance Board by the March 2, 2001 deadline prescribed in this notice. 12 CFR 944.2(b)(1)(ii) and (c). On or before January 29, 2001, each Bank will notify the members in its district that have been selected for the 2000–01 fourth quarter community support review cycle that they must complete and submit to the Finance Board by the deadline a Community Support Statement. 12 CFR 944.2(b)(2)(i). The member's Bank will provide a blank Community Support Statement Form, which also is available on the Finance Board's web site: WWW.FHFB.GOV. Upon request, the member's Bank also will provide assistance in completing the Community Support Statement.

The Finance Board has selected the following members for the 2000–01 fourth quarter community support review cycle:

FEDERAL HOME LOAN BANK OF BOSTON—DISTRICT 1

Union Savings Bank	Danbury	Connecticut.
Jewett City Savings Bank	Jewett City	Connecticut.
First National Bank of Litchfield, IL	Litchfield	Connecticut.
Naugatuck Valley Savings & Loan Association	Naugatuck	Connecticut.
The New Haven Savings Bank	New Haven	Connecticut.
Newtown Savings Bank	Newtown	Connecticut.
Fairfield County Savings Bank	Norwalk	Connecticut.
Ridgefield Bank	Ridgefield	Connecticut.
First County Bank	Stamford	Connecticut.
Northeast Bank, F.S.B.	Auburn	Maine.
Bangor Savings Bank	Bangor	Maine.
Bar Harbor Savings and Loan Association	Bar Harbor	Maine.
First Citizens Bank	Presque Isle	Maine.
South Adams Savings Bank	Adams	Massachusetts.
Andover Bank	Andover	Massachusetts.
Barre Savings Bank	Barre	Massachusetts.
Brookline Savings Bank	Brookline	Massachusetts.
Boston Federal Savings Bank	Burlington	Massachusetts.
Cambridgeport Bank	Cambridge	Massachusetts.
North Cambridge Co-operative Bank	Cambridge	Massachusetts.
Canton Co-operative Bank	Canton	Massachusetts.
The Edgartown National Bank	Edgartown	Massachusetts.
First Federal Savings Bank of America	Fall River	Massachusetts.

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Fidelity Co-operative Bank	Fitchburg	Massachusetts.
Fitchburg Savings Bank, FSB	Fitchburg	Massachusetts.
Greenfield Co-operative Bank	Greenfield	Massachusetts.
Haverhill Co-operative Bank	Haverhill	Massachusetts.
Hyde Park Cooperative Bank	Hyde Park	Massachusetts.
Ipswich Co-operative Bank	Ipswich	Massachusetts.
Lowell Co-operative Bank	Lowell	Massachusetts.
Medford Bank	Medford	Massachusetts.
Milford National Bank and Trust Company	Milford	Massachusetts.
Natick Federal Savings Bank	Natick	Massachusetts.
Revere Federal Savings & Loan Association	Revere	Massachusetts.
Heritage Co-operative Bank	Salem	Massachusetts.
Salem Five Cents Savings Bank	Salem	Massachusetts.
Peopie's Savings Bank of Brockton	South Easton	Massachusetts.
Stoneham Savings Bank	Stoneham	Massachusetts.
Country Bank for Savings	Ware	Massachusetts.
Wellesley Co-operative Bank	Wellesley	Massachusetts.
South Shore Cooperative Bank	Weymouth	Massachusetts.
Winchester Co-operative Bank	Winchester	Massachusetts.
Bay State Savings Bank	Worcester	Massachusetts.
Cape Cod Co-operative Bank	Yarmouth Port	Massachusetts.
The Berlin City Bank	Berlin	New Hampshire
Village Bank and Trust	Gilford	New Hampshire.
Granite Bank	Keene	New Hampshire.
Lancaster National Bank	Lancaster	New Hampshire.
Profile Bank	Rochester	New Hampshire.
Bank of Newport	Newport	Rhode Island.
Citizens Bank of Rhode Island	Providence	Rhode Island.
Westerly Savings Bank	Westerly	Rhode Island.
Brattleboro Savings and Loan Association, FA	Brattleboro	Vermont.
Lyndonville Savings Bank and Trust Company	Lyndonville	Vermont.

FEDERAL HOME LOAN BANK OF NEW YORK—DISTRICT 2

Cape Savings Bank	Cape May Court House	New Jersey.
United Roosevelt Savings Bank	Carteret	New Jersey.
Commerce Bank, N.A.	Cherry Hill	New Jersey.
Unity Bank	Clinton	New Jersey.
First Constitution Bank	Cranbury	New Jersey.
Delanco Federal Savings Bank	Delanco	New Jersey.
Columbia Savings Bank	Fair Lawn	New Jersey.
Haven Savings Bank	Hoboken	New Jersey.
Manasquan Savings Bank	Manasquan	New Jersey.
Equity Bank	Marlton	New Jersey.
West Essex Bank	Pine Brook	New Jersey.
First Bank of Sea Isle City	Seaville	New Jersey.
Union Center National Bank	Union	New Jersey.
Wawel Savings Bank, SLA	Wallington	New Jersey.
Crest Savings Bank, SLA	Wildwood Crest	New Jersey.
Charter One Commercial	Albany	New York.
Bridgehampton National Bank	Bridgehampton	New York.
Atlas Savings and Loan Association	Brooklyn	New York.
Tompkins County Trust Company	Ithaca	New York.
Medina Savings & Loan Association	Medina	New York.
Isreal Discount Bank of New York	New York	New York.
NBT Bank, N.A.	Norwich	New York.
The Oneida Savings Bank	Oneida	New York.
Suffolk County National Bank of Riverhead	Riverhead	New York.
Adirondack Bank, N.A.	Saranac Lake	New York.
Sawyer Savings Bank	Saugerties	New York.
Bank of Smithtown	Smithtown	New York.
Walden Federal Savings and Loan Association	Walden	New York.
Fourth Federal Savings Bank	White Plains	New York.
City & Suburban Federal Savings Bank	Yonkers	New York.
Westernbank Puerto Rico	Mayaguez	Puerto Rico.
Banco Bilbao Vizcaya Puerto Rico	Santurce	Puerto Rico.

FEDERAL HOME LOAN BANK OF PITTSBURGH—DISTRICT 3

Christiana Bank and Trust Company	Greenville	Delaware.
The First National Bank of Wyoming	Wyoming	Delaware.
American Bank of the Lehigh Valley	Allentown	Pennsylvania.
Iron Workers Savings Bank	Aston	Pennsylvania.
Pennwood Savings Bank	Bellevue	Pennsylvania.
Brentwood Savings Bank	Bethel Park	Pennsylvania.
Madison Bank	Blue Bell	Pennsylvania.
National Penn Bank	Boyertown	Pennsylvania.

Union Building and Loan Savings Bank	Bridgewater	Pennsylvania.
Carnegie Savings Bank	Carnegie	Pennsylvania.
Suburban Community Bank	Chalfont	Pennsylvania.
Community Bank and Trust Company	Clarks Summit	Pennsylvania.
Clearfield Bank and Trust Company	Clearfield	Pennsylvania.
Vartan National Bank	Dauphin	Pennsylvania.
First Financial Bank	Downingtown	Pennsylvania.
First County Bank	Doylestown	Pennsylvania.
The Dime Bank	Honesdale	Pennsylvania.
Indiana First Savings Bank	Indiana	Pennsylvania.
Manor National Bank	Manor	Pennsylvania.
First National Bank of Marysville	Marysville	Pennsylvania.
Standard Bank PaSB	Monroeville	Pennsylvania.
Commonwealth Bank	Norristown	Pennsylvania.
Roxborough-Manayunk Bank	Philadelphia	Pennsylvania.
Mt. Troy Savings Bank, FSB	Pittsburgh	Pennsylvania.
PNC Bank, N.A.	Pittsburgh	Pennsylvania.
Pennsylvania Capital Bank	Pittsburgh	Pennsylvania.
Schuylkill Savings & Loan Association	Schuylkill Haven	Pennsylvania.
Somerset Trust Company	Somerset	Pennsylvania.
Omega Bank, N.A.	State College	Pennsylvania.
Mechanics Savings and Loan FSB	Steelton	Pennsylvania.
Compass Federal Savings Bank	Wilmerding	Pennsylvania.
Sovereign Bank, FSB	Wyomissing	Pennsylvania.
Capital State Bank, Inc.	Charleston	West Virginia.
Hancock County Savings Bank, F.S.B.	Chester	West Virginia.
Citizens National Bank of Elkins	Elkins	West Virginia.
Monongahela Valley Bank, Inc.	Fairmont	West Virginia.
Fayette County National Bank	Fayetteville	West Virginia.
Rock Branch Community Bank	Nitro	West Virginia.
The Bank of Romney	Romney	West Virginia.
Traders Bank	Spencer	West Virginia.
Progressive Bank	Wheeling	West Virginia.

FEDERAL HOME LOAN BANK OF ATLANTA—DISTRICT 4

First Federal Savings Bank	Bessemer	Alabama.
Citizens Federal Savings Bank	Birmingham	Alabama.
SouthTrust Bank, N.A.	Birmingham	Alabama.
First Federal Bank	Fort Payne	Alabama.
City Bank of Hartford	Hartford	Alabama.
Pinnacle Bank	Jasper	Alabama.
Farmers National Bank	Opelika	Alabama.
First Federal Bank, a fsb	Tuscaloosa	Alabama.
Amerifirst Bank N.A.	Union Springs	Alabama.
The Bank of Delmar, N.A.	Seaford	Delaware.
Independence Federal Savings Bank	Washington	D.C.
Community National Bank at Bartow	Bartow	Florida.
First Southern Bank	Boca Raton	Florida.
Crown Bank, a fsb	Casselberry	Florida.
Harbor Federal Savings Bank	Fort Pierce	Florida.
Homosassa Springs Bank	Homosassa Springs	Florida.
First Federal Savings Bank of Lake County	Leesburg	Florida.
City National Bank of Florida	Miami	Florida.
Interamerican Bank	Miami	Florida.
Intercredit Bank, N.A.	Miami	Florida.
Pacific National Bank	Miami	Florida.
Farmers and Merchants Bank	Monticello	Florida.
First National Bank of Naples	Naples	Florida.
Union Bank of Florida	Plantation	Florida.
First Community Bank of America	Port Charlotte	Florida.
First South Bank	Tallahassee	Florida.
Valrico State Bank	Valrico	Florida.
Fidelity Federal Savings Bank of Florida	West Palm Beach	Florida.
Bank of North Georgia.	Alpharetta	Georgia.
First Port City Bank	Bainbridge	Georgia.
Baxley Federal Savings Bank	Baxley	Georgia.
Peoples State Bank & Trust	Baxley	Georgia.
West Georgia National Bank	Carrollton	Georgia.
The Bank of Fitzgerald	Fitzgerald	Georgia.
Glennville Bank and Trust Company	Glennville	Georgia.
Commercial Banking Company	Hahira	Georgia.
First Flag Bank	LaGrange	Georgia.
Security Bank of Bibb County	Macon	Georgia.
Riverside Bank	Marietta	Georgia.
Quitman Federal Savings Bank	Quitman	Georgia.

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Citizens Bank of Washington County	Sandersville	Georgia.
First National Bank of Effingham	Springfield	Georgia.
Eagle Bank and Trust	Statesboro	Georgia.
Bank of Worth	Sylvester	Georgia.
Thomas County FS&LA	Thomasville	Georgia.
Stephens Federal Bank	Toccoa	Georgia.
Mountain National Bank	Tucker	Georgia.
Darby Bank and Trust Company	Vidalia	Georgia.
Vidalia Federal Savings and Loan Association	Vidalia	Georgia.
Bank of Dooly	Vienna	Georgia.
The Peoples Bank of Willacoochee	Willacoohee	Georgia.
The Peoples Bank	Winder	Georgia.
Arundel Federal Savings Bank	Baltimore	Maryland.
Chesapeake Bank of Maryland	Baltimore	Maryland.
Fairmount Federal Savings Bank	Baltimore	Maryland.
Golden Prague FS&LA	Baltimore	Maryland.
Hopkins Federal Savings Bank	Baltimore	Maryland.
Madison Square Federal Savings Bank	Baltimore	Maryland.
Parkville Federal Savings Bank	Baltimore	Maryland.
Rosedale Federal Savings and Loan Association	Baltimore	Maryland.
Westview Savings Bank	Baltimore	Maryland.
The Washington Savings Bank, F.S.B.	Bowie	Maryland.
The Patapsco Bank	Dundalk	Maryland.
Farmers & Mechanics National Bank	Frederick	Maryland.
OBA Federal Savings and Loan Association	Gaithersburg	Maryland.
Columbian Bank, a F.S.B.	Havre de Grace	Maryland.
Suburban Federal Savings Bank	Landover Hills	Maryland.
Heritage Savings Bank	Lutherville	Maryland.
Senator Savings Bank, FSB	Towson	Maryland.
Community Bank of Tri-County	Waldorf	Maryland.
Woodsboro Bank	Woodsboro	Maryland.
Asheville Savings Bank	Asheville	North Carolina.
Community Savings Bank, SSB	Burlington	North Carolina.
First State Bank	Burlington	North Carolina.
Cherryville FS&LA	Cherryville	North Carolina.
First Federal Savings Bank	Dunn	North Carolina
Mutual Community Savings Bank, SSB	Durham	North Carolina
First Federal Savings and Loan Association	Lincolnton	North Carolina.
Progressive Savings and Loan Ltd.	Lumberton	North Carolina.
Mooresville Savings Bank, SSB	Mooresville	North Carolina.
Roxboro Savings Bank, SSB	Roxboro	North Carolina.
Citizens Savings Bank of Salisbury, SSB	Salisbury	North Carolina.
Home Savings, Inc., SSB	Thomasville	North Carolina.
FirstSouth Bank	Washington	North Carolina.
Abbeville Savings and Loan Association	Abbeville	South Carolina.
The Bank of Abbeville	Abbeville	South Carolina.
First FS&LA of Cheraw	Cheraw	South Carolina.
First Savers Bank	Greenville	South Carolina.
Citizens Building and Loan Association	Greer	South Carolina.
Mutual Savings Bank	Hartsville	South Carolina.
Atlantic Savings Bank, FSB	Hilton Head Island	South Carolina.
Pee Dee Federal Savings Bank	Marion	South Carolina.
Coastal Federal Savings Bank	Myrtle Beach	South Carolina.
Mid State Bank	Newberry	South Carolina.
Oconee Federal Savings and Loan Association	Seneca	South Carolina.
First Federal Bank	Spartanburg	South Carolina.
Community First Bank	Walhalla	South Carolina.
First Federal of South Carolina, F.S.B.	Walterboro	South Carolina.
Citizens Bank and Trust Company	Blackstone	Virginia.
Caroline Savings Bank	Bowling Green	Virginia.
Acacia Federal Savings Bank	Falls Church	Virginia.
First Virginia Bank	Falls Church	Virginia.
Virginia Savings Bank, FSB	Front Royal	Virginia.
First FS&LA	Martinsville	Virginia.
Chevy Chase Bank, FSB	McLean	Virginia.
Harbor Bank	Newport News	Virginia.
CENIT Bank	Norfolk	Virginia.
Essex Savings Bank, FSB	Norfolk	Virginia.
Bank of Tazewell County	Tazewell	Virginia.
Approved Federal Savings Bank	Virginia Beach	Virginia.

FEDERAL HOME LOAN BANK OF CINCINNATI—DISTRICT 5

Home FS&LA of Ashland	Ashland	Kentucky.
Bank of Buffalo	Buffalo	Kentucky.
The First National Bank of Columbia	Columbia	Kentucky.

Kentucky Federal Savings and Loan Association	Covington	Kentucky.
Greensburg Deposit Bank & Trust Company	Greensburg	Kentucky.
Citizens National Bank & Trust of Hazard	Hazard	Kentucky.
The Casey County Bank	Liberty	Kentucky.
Independence Bank	Livermore	Kentucky.
Commonwealth Bank and Trust	Louisville	Kentucky.
Home Savings Bank, fsb	Ludlow	Kentucky.
Madisonville Building and Loan Association	Madisonville	Kentucky.
Bank of Maysville	Maysville	Kentucky.
Hart County Bank and Trust Company	Munfordville	Kentucky.
The Farmers Bank	Nicholasville	Kentucky.
Community Trust Bank, N.A.	Pikeville	Kentucky.
Cumberland Security Bank	Somerset	Kentucky.
Commercial Bank	West Liberty	Kentucky.
Antwerp Exchange Bank Company	Antwerp	Ohio.
Hocking Valley Bank	Athens	Ohio.
Citizens Federal Savings and Loan Association	Bellefontaine	Ohio.
The Guernsey Bank, FSB	Cambridge	Ohio.
Castalia Banking Company	Castalia	Ohio.
Mercer Savings Bank	Celina	Ohio.
Cheviot Building and Loan Company	Cheviot	Ohio.
Bramble Federal Savings & Loan	Cincinnati	Ohio.
Cincinnati Federal Savings & Loan Association	Cincinnati	Ohio.
North Side Bank and Trust Company	Cincinnati	Ohio.
National City Bank	Cleveland	Ohio.
Ohio Savings Bank	Cleveland	Ohio.
The Home Loan Savings Bank	Coshocton	Ohio.
The Covington Savings and Loan Association	Covington	Ohio.
The Delaware County Bank and Trust Company	Delaware	Ohio.
The Northern Savings and Loan Company	Elyria	Ohio.
The Genoa Savings and Loan Company	Genoa	Ohio.
Indian Village FS&LA	Gnadenhutten	Ohio.
The Hicksville Bank	Hicksville	Ohio.
Home Builders Association	Lynchburg	Ohio.
The Citizens Savings Bank	Martins Ferry	Ohio.
People's Building, Loan and Savings Company	Mason	Ohio.
Peoples FS&LA of Massillon	Massillon	Ohio.
Clermont Savings Bank, FSB	Milford	Ohio.
The Commercial & Savings Bank of Millersburg	Millersburg	Ohio.
The First National Bank of Nelsonville	Nelsonville	Ohio.
Peoples National Bank	New Lexington	Ohio.
Geauga Savings Bank	Newbury	Ohio.
The First National Bank of Pandora	Pandora	Ohio.
Century Bank, F.S.B.	Parma	Ohio.
Farmers Bank and Savings Company	Pomeroy	Ohio.
Capital Bank, N.A.	Sylvania	Ohio.
The Commercial Savings Bank	Upper Sandusky	Ohio.
Versailles Savings and Loan Company	Versailles	Ohio.
The Wayne Savings Community Bank	Wooster	Ohio.
Commerce National Bank	Worthington	Ohio.
The Home Savings and Loan Company	Youngstown	Ohio.
Century National Bank	Zanesville	Ohio.
Athens Federal Community Bank	Athens	Tennessee.
First National Bank and Trust Company	Athens	Tennessee.
Bells Banking Company	Bells	Tennessee.
Benton Banking Company	Benton	Tennessee.
People's Bank and Trust Company of Picket Co	Byrdstown	Tennessee.
Rhea County National Bank	Dayton	Tennessee.
Greenfield Banking Company	Greenfield	Tennessee.
First Peoples Bank of Tennessee	Jefferson City	Tennessee.
Lawrenceburg FS&LA	Lawrenceburg	Tennessee.
Community National Bank	Lexington	Tennessee.
Union Bank and Trust Company	Livingston	Tennessee.
BankTennessee	Memphis	Tennessee.
EFS National Bank	Memphis	Tennessee.
The Community Bank	Nashville	Tennessee.
First Trust and Savings Bank	Oneida	Tennessee.
Citizens Bank and Trust Company	Rutledge	Tennessee.
Bank of Waynesboro	Waynesboro	Tennessee.

FEDERAL HOME LOAN BANK OF INDIANAPOLIS—DISTRICT 6

Peoples Trust Bank	Corydon	Indiana.
Heritage Bank and Trust Company	Darlington	Indiana.
Elberfield State Bank	Elberfield	Indiana.
Mutual Savings Bank	Franklin	Indiana.

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Calumet National	Hammond	Indiana.
First FS&LA of Hammond	Hammond	Indiana.
Citizens First State Bank	Hartford City	Indiana.
First Indiana Bank, a FSB	Indianapolis	Indiana.
Farmers State Bank	LaGrange	Indiana.
Linden State Bank	Linden	Indiana.
MFB Financial	Mishawaka	Indiana.
St. Joseph Capital Bank	Mishawawka	Indiana.
West End Savings Bank	Richmond	Indiana.
Scott County State Bank	Scottsburg	Indiana.
Macomb Community	Clinton Township	Michigan.
Michigan State University FCU	East Lansing	Michigan.
MetroBank	Farmington Hills	Michigan.
Citizens Bank	Flint	Michigan.
Grand Haven Bank	Grand Haven	Michigan.
Old Kent Bank	Grand Rapids	Michigan.
D&N Bank, FSB	Hancock	Michigan.
Mainstreet Savings Bank, FSB	Hastings	Michigan.
The Bank of Holland	Holland	Michigan.
The Honor State Bank	Honor	Michigan.
Ionia County National Bank	Ionia	Michigan.
First National Bank of Iron Mountain	Iron Mountain	Michigan.
Mayville State Bank	Mayville	Michigan.
Wolverine Bank, F.S.B.	Midland	Michigan.
Central Savings Bank	Sault Ste. Marie	Michigan.
Sturgis Bank and Trust Company	Sturgis	Michigan.
First Savings Bank	Three Rivers	Michigan.
Standard Federal Bank, a FSB	Troy	Michigan.
Charter Bank	Wyandotte	Michigan.

FEDERAL HOME LOAN BANK OF CHICAGO—DISTRICT 7

Citizens National Bank of Albion	Albion	Illinois.
Farmers State Bank of Western Illinois	Alpha	Illinois.
Apple River State Bank	Apple River	Illinois.
Arcola Homestead Savings Bank	Arcola	Illinois.
The First National Bank of Arcola	Arcola	Illinois.
The First National Bank of Arenzville	Arenzville	Illinois.
Ben Franklin Bank of Illinois	Arlington Heights	Illinois.
The Atlanta National Bank	Atlanta	Illinois.
First State Bank	Atwood	Illinois.
Scott State Bank	Bethany	Illinois.
First State Bank of Bloomington	Bloomington	Illinois.
Midland Federal Savings and Loan Association	Bridgeview	Illinois.
Farmers and Merchants State Bank of Bushnell	Bushnell	Illinois.
Byron Bank	Byron	Illinois.
First State Bank of Campbell Hill	Campbell Hill	Illinois.
Carrollton Bank	Carrollton	Illinois.
Bankillinois	Champaign	Illinois.
Bank of Chestnut	Chestnut	Illinois.
Chesterfield Federal S&LA of Chicago	Chicago	Illinois.
Hoyne Savings Bank	Chicago	Illinois.
Loomis Federal Savings and Loan Association	Chicago	Illinois.
North Side FS&LA of Chicago	Chicago	Illinois.
Royal Savings Bank	Chicago	Illinois.
Seaway National Bank of Chicago	Chicago	Illinois.
Second Federal Savings and Loan	Chicago	Illinois.
Central Federal Savings and Loan Association	Cicero	Illinois.
MidAmerica Bank, fsb	Clarendon Hills	Illinois.
Central State Bank	Clayton	Illinois.
DeWitt Savings Bank	Clinton	Illinois.
First Federal Bank, F.S.B.	Colchester	Illinois.
First United Bank	Crete	Illinois.
Soy Capital Bank and Trust Company	Decatur	Illinois.
Castle Bank, National Association	DeKalb	Illinois.
Union Bank of Illinois	East St. Louis	Illinois.
Galena State Bank and Trust Company	Galena	Illinois.
Community State Bank	Galva	Illinois.
Howard Savings Bank	Glenview	Illinois.
Security State Bank of Hamilton	Hamilton	Illinois.
Harvard Savings Bank	Harvard	Illinois.
First National Bank of La Grange	La Grange	Illinois.
Exchange State Bank	Lanark	Illinois.
The Lemont National Bank	Lemont	Illinois.
Lisle Savings Bank	Lisle	Illinois.
Bank and Trust Company	Litchfield	Illinois.

Union Bank/West	Macomb	Illinois.
Continental Community Bank & Trust Company	Maywood	Illinois.
A.J. Smith Federal Savings Bank	Midlothian	Illinois.
Southeast National Bank	Moline	Illinois.
Security Savings Bank	Monmouth	Illinois.
Farmers State Bank Chadwick and Mt. Carroll	Mt. Carroll	Illinois.
The First National Bank	Mulberry Grove	Illinois.
Hawthorn Bank	Mundelein	Illinois.
Warren-Boynton State Bank	New Berlin	Illinois.
Ottawa Savings Bank	Ottawa	Illinois.
State Bank of Paw Paw	Paw Paw	Illinois.
First Capital Bank	Peoria	Illinois.
The Heights Bank	Peoria Heights	Illinois.
Pleasant Plains State Bank	Pleasant Plains	Illinois.
Town and Country Bank of Quincy	Quincy	Illinois.
Rantoul First Bank, s.b.	Rantoul	Illinois.
First National Bank of Raymond	Raymond	Illinois.
First Ridge Farm State Bank	Ridge Farm	Illinois.
Community State Bank of Rock Falls	Rock Falls	Illinois.
Rushville State Bank	Rushville	Illinois.
AmericaUnited Bank & Trust Company USA	Schaumburg	Illinois.
Illini Bank	Springfield	Illinois.
Tuscola National Bank	Tuscola	Illinois.
Bank of Warrensburg	Warrensburg	Illinois.
State Bank Winslow-Warren	Winslow	Illinois.
The Portage County Bank	Almond	Wisconsin.
Pioneer Bank	Auburndale	Wisconsin.
First National Bank of Baldwin	Baldwin	Wisconsin.
The First National Bank and Trust Co. of Baraboo	Baraboo	Wisconsin.
Black River Country Bank	Black River Falls	Wisconsin.
Bonduel State Bank	Bonduel	Wisconsin.
Red Cedar Bank, N.A.	Boyceville	Wisconsin.
Dairyman's State Bank	Clintonville	Wisconsin.
Farmers and Merchants Union Bank	Columbus	Wisconsin.
Cumberland Federal Bank, FSB	Cumberland	Wisconsin.
Community Bank of Grafton	Grafton	Wisconsin.
Highland State Bank	Highland	Wisconsin.
Park Bank	Holmen	Wisconsin.
Security State Bank	Iron River	Wisconsin.
East Wisconsin Savings Bank, S.A.	Kaukauna	Wisconsin.
Greenwood's State Bank	Lake Mills	Wisconsin.
First Bank and Trust	Menomonie	Wisconsin.
Bank of Milton	Milton	Wisconsin.
Milwaukee Western Bank	Milwaukee	Wisconsin.
St. Francis Bank, F.S.B.	Milwaukee	Wisconsin.
Universal Savings Bank, F.A.	Milwaukee	Wisconsin.
Associated Bank, N.A.	Neenah	Wisconsin.
Clare Bank, N.A.	Platteville	Wisconsin.
First National Platteville	Platteville	Wisconsin.
Mound City Bank	Platteville	Wisconsin.
Intercity State Bank	Schofield	Wisconsin.
Community Bank & Trust	Sheboygan	Wisconsin.
Bank of Sun Prairie	Sun Prairie	Wisconsin.
First Federal Savings Bank of Wisconsin	Waukesha	Wisconsin.
KeySavings Bank	Wisconsin Rapids	Wisconsin.
River Cities Bank	Wisconsin Rapids	Wisconsin.
Wood County National Bank	Wisconsin Rapids	Wisconsin.

FEDERAL HOME LOAN BANK OF DES MOINES—DISTRICT 8

Iowa Savings Bank	Carroll	Iowa.
Central Trust and Savings Bank	Cherokee	Iowa.
Linn County State Bank	Coggon	Iowa.
Farmers Savings Bank	Colesburg	Iowa.
Citizens Bank	Corydon	Iowa.
Fortress Bank of Cresco	Cresco	Iowa.
Valley State Bank	Eldridge	Iowa.
First National Bank in Fairfield	Fairfield	Iowa.
Farmers State Bank	Jesup	Iowa.
First State Bank of Mapleton	Mapleton	Iowa.
Farmers Savings Bank	Mt. Pleasant	Iowa.
New Vienna Savings Bank	New Vienna	Iowa.
First State Bank	Nora Springs	Iowa.
American State Bank	Osceola	Iowa.
Perry State Bank	Perry	Iowa.
Readlyn Savings Bank	Readlyn	Iowa.

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Community Savings Bank	Robins	Iowa.
Premier Bank	Rock Valley	Iowa.
Iowa State Bank	Sac City	Iowa.
Sanborn Savings Bank	Sanborn	Iowa.
The State Bank	Spirit Lake	Iowa.
Union Bank and Trust Company	Strawberry Point	Iowa.
The State Bank of Toledo	Toledo	Iowa.
Farmers Savings Bank	Walford	Iowa.
Iowa State Bank	Wapello	Iowa.
Washington Federal Savings Bank	Washington	Iowa.
State Bank of Waverly	Waverly	Iowa.
First State Bank	Webster City	Iowa.
Union State Bank	Winterset	Iowa.
First State Bank of Bayport	Bayport	Minnesota.
CreditAmerica Savings Company	Brainerd	Minnesota.
The First National Bank of Coleraine	Coleraine	Minnesota.
Western National Bank	Duluth	Minnesota.
Fidelity Bank	Edina	Minnesota.
State Bank of Fairmont	Fairmont	Minnesota.
Citizens State Bank of Gaylord	Gaylord	Minnesota.
Commerce Bank	Geneva	Minnesota.
The First National Bank of Gilbert	Gilbert	Minnesota.
Yellow Medicine County Bank	Granite Falls	Minnesota.
Northwestern State Bank of Hallock	Hallock	Minnesota.
1st American State Bank of Minnesota	Hancock	Minnesota.
First Southeast Bank	Harmony	Minnesota.
First Federal fsb	Hutchinson	Minnesota.
United Prairie Bank—Jackson	Jackson	Minnesota.
Cornerstone State Bank	La Sueur	Minnesota.
First Community Bank Lester Prairie	Lester Prairie	Minnesota.
The State Bank of Loretto	Loretto	Minnesota.
First National Bank of Luverne	Luverne	Minnesota.
US Bank, N.A.	Minneapolis	Minnesota.
First National Bank of Montgomery	Montgomery	Minnesota.
United Farmers & Merchants State Bank	Morris	Minnesota.
Northland Community Bank	Northome	Minnesota.
Citizens State Bank of Norwood	Norwood Young America	Minnesota.
Odin State Bank	Odin	Minnesota.
Prinsburg State Bank	Prinsburg	Minnesota.
Randall State Bank	Randall	Minnesota.
Woodland Bank	Remer	Minnesota.
Richfield Bank and Trust Company	Richfield	Minnesota.
First Community Bank	Savage	Minnesota.
Home Federal Savings Bank	Spring Valley	Minnesota.
St. Anthony Park State Bank	St. Paul	Minnesota.
Heartland State Bank	Storden	Minnesota.
The Northwestern State Bank of Ulen	Ulen	Minnesota.
Wells Federal Bank, a FSB	Wells	Minnesota.
First State Bank of Pipestone, Rushmore	Worthington	Minnesota.
Worthington Federal Savings Bank, f.s.b.	Worthington	Minnesota.
First Missouri National Bank	Brookfield	Missouri.
BC National Banks	Butler	Missouri.
Carroll County Trust Company	Carrollton	Missouri.
Chillicothe State Bank	Chillicothe	Missouri.
Investors Federal Bank	Chillicothe	Missouri.
Boone National Savings & Loan Association, FA	Columbia	Missouri.
First State Community Bank	Farmington	Missouri.
Ozarks Federal Savings and Loan Association	Farmington	Missouri.
Bank Northwest	Hamilton	Missouri.
Town & Country Bank	Hardin	Missouri.
Allen Bank and Trust Company	Harrisonville	Missouri.
Bank of Hayti	Hayti	Missouri.
First National Bank	Houston	Missouri.
Kennett National Bank	Kennett	Missouri.
Bank of Kimberling City	Kimberling City	Missouri.
First National Bank	Lamar	Missouri.
Lamar Bank and Trust Company	Lamar	Missouri.
Central Bank	Lebanon	Missouri.
Linn State Bank	Linn	Missouri.
First National Bank	Malden	Missouri.
Pioneer Bank and Trust Company	Maplewood	Missouri.
Wood & Huston Bank	Marshall	Missouri.
First National Bank of Audrain County	Mexico	Missouri.
Peoples Bank of the Ozarks	Nixa	Missouri.
First Midwest Bank of Piedmont	Piedmont	Missouri.
Peoples Savings Bank of Rhineland	Rhineland	Missouri.

Hardin Federal Savings Bank	Richmond	Missouri.
The State Bank	Richmond	Missouri.
Farmers State Bank of Schell City	Schell City	Missouri.
Citizens National Bank of Springfield	Springfield	Missouri.
Bank of Thayer	Thayer	Missouri.
Quarry City Savings and Loan Association	Warrensburg	Missouri.
Citizens State Bank of Pembina County	Cavalier	North Dakota.
Wells Fargo Bank of North Dakota, N.A.	Fargo	North Dakota.
First State Bank Langdon	Langdon	North Dakota.
BankFirst, N.A.	Sioux Falls	South Dakota.
Home Federal Savings Bank	Sioux Falls	South Dakota.
F&M Bank	Watertown	South Dakota.

FEDERAL HOME LOAN BANK OF DALLAS—DISTRICT 9

First Financial Bank, fsb	El Dorado	Arkansas.
Fordyce Bank and Trust Company	Fordyce	Arkansas.
Forrest City Bank, NA	Forrest City	Arkansas.
Bank of Lockesburg	Lockesburg	Arkansas.
Southeast Arkansas Bank	Parkdale	Arkansas.
Pine Bluff National Bank	Pine Bluff	Arkansas.
Arvest Bank	Rogers	Arkansas.
First Arvest Bank	Siloam Springs	Arkansas.
Bank of Coushatta	Coushatta	Louisiana.
St. Tammany Homestead S&LA	Covington	Louisiana.
Teche Federal Savings Bank	Franklin	Louisiana.
Florida Parishes Bank	Hammond	Louisiana.
LBA Savings Bank	Lafayette	Louisiana.
Guaranty Savings and Homestead Association	Metairie	Louisiana.
Mutual Savings and Loan Association	Metairie	Louisiana.
Horizons Bank	Monroe	Louisiana.
Eureka Homestead Society	New Orleans	Louisiana.
Hibernia Homestead and Savings Association	New Orleans	Louisiana.
Peoples Bank & Trust Company of Pointe Coupee	New Roads	Louisiana.
Ponchatoula Homestead Association, F.A.	Ponchatoula	Louisiana.
Bank of West Baton Rouge	Port Allen	Louisiana.
Ruston Building and Loan Association	Ruston	Louisiana.
First National Bank of Springdale	Springdale	Louisiana.
Bank of St. Francisville	St. Francisville	Louisiana.
American Bank	Welsh	Louisiana.
The Bank of Commerce	White Castle	Louisiana.
Amory Federal Savings & Loan Association	Amory	Mississippi.
Delta Bank and Trust	Drew	Mississippi.
Britton & Koontz First National Bank	Natchez	Mississippi.
Mechanics Bank	Water Valley	Mississippi.
International Bank	Raton	New Mexico.
Tucumcari Federal Savings & Loan Association	Tucumcari	New Mexico.
First National Bank of Athens	Athens	Texas.
First National Bank of Bridgeport	Bridgeport	Texas.
Citizens State Bank	Cross Plains	Texas.
Cuero State Bank, s.s.b.	Cuero	Texas.
Beal Bank, SSB	Dallas	Texas.
Mercantile Bank & Trust, FSB	Dallas	Texas.
Provident Bank	Dallas	Texas.
First National Bank of Texas	Decatur	Texas.
First United Bank	Dimmitt	Texas.
Union State Bank	Florence	Texas.
Omni American Federal Credit Union	Fort Worth	Texas.
Summit Community Bank N.A.	Fort Worth	Texas.
Security Bank, N.A.—Garland	Garland	Texas.
Hebbronville State Bank	Hebbronville	Texas.
Prime Bank	Houston	Texas.
Central Bank of Houston	Houston	Texas.
MetroBank, N.A.	Houston	Texas.
Texas Guaranty Bank, N.A.	Houston	Texas.
Texas State Bank	Joaquin	Texas.
First Nichols National Bank	Kenedy	Texas.
First National Bank of Lake Jackson	Lake Jackson	Texas.
Commerce Bank	Laredo	Texas.
First Federal Savings and Loan Association	Littlefield	Texas.
First National Bank of Livingston	Livingston	Texas.
Plains National Bank of West Texas	Lubbock	Texas.
Mason National Bank	Mason	Texas.
Inter National Bank	McAllen	Texas.
Mineola Community Bank, SSB	Mineola	Texas.
City National Bank	Mineral Wells	Texas.

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Commercial Bank of Texas, N.A.	Nacogdoches	Texas.
Western National Bank	Odessa	Texas.
Orange Savings Bank, ssb	Orange	Texas.
Gulf Coast Educators Federal Credit Union	Pasadena	Texas.
Lone Star National Bank	Pharr	Texas.
Fort Bend Federal Savings & Loan Association	Rosenberg	Texas.
Community Bank of Central Texas	Smithville	Texas.
Town and Country Bank	Stephenville	Texas.
Heritage Savings Bank, SSB	Terrell	Texas.
First National Bank	Trinity	Texas.
First National Bank of Bosque County	Valley Mills	Texas.
FirstCapital Bank, ssb	Victoria	Texas.
Fannin Bank	Windom	Texas.

FEDERAL HOME LOAN BANK OF TOPEKA—DISTRICT 10

Commerce Bank	Aurora	Colorado.
Premier Members Federal Credit Union	Boulder	Colorado.
Del Norte Federal Savings & Loan Association	Del Norte	Colorado.
Premier Bank	Denver	Colorado.
TCF National Bank Colorado	Englewood	Colorado.
FirstBank of Evergreen	Evergreen	Colorado.
Bank of Grand Junction	Grand Junction	Colorado.
FirstBank of Greeley	Greeley	Colorado.
First National Bank of Julesberg	Julesberg	Colorado.
The State Bank—La Junta	La Junta	Colorado.
First National Bank of Lake City and Creede	Lake City	Colorado.
FirstBank of Parker	Parker	Colorado.
Rocky Ford National Bank	Rocky Ford	Colorado.
First National Bank of Stratton	Stratton	Colorado.
Bank of Commerce	Chanute	Kansas.
Home Savings Bank	Chanute	Kansas.
Legacy Bank	Colwich	Kansas.
State Bank of Conway Springs	Conway Springs	Kansas.
Landmark Federal Savings Bank	Dodge City	Kansas.
Citizens State Bank and Trust Company	Ellsworth	Kansas.
State Bank of Fredonia	Fredonia	Kansas.
Gardner National Bank	Gardner	Kansas.
Farmers State Bank	Oakley	Kansas.
First Kansas Federal Savings Bank	Osawatomie	Kansas.
First Bank	Sterling	Kansas.
Chisholm Trail State Bank	Wichita	Kansas.
The State Bank	Winfield	Kansas.
Bank of Bennington	Bennington	Nebraska.
Washington County Bank	Blair	Nebraska.
Custer Federal Savings and Loan Association	Broken Bow	Nebraska.
Citizens State Bank	Carleton	Nebraska.
CerescoBank	Ceresco	Nebraska.
First Bank and Trust	Cozad	Nebraska.
First State Bank	Enders	Nebraska.
First National Bank in Exeter	Exeter	Nebraska.
Farnam Bank	Farnam	Nebraska.
American National Bank of Fremont	Fremont	Nebraska.
First State Bank	Fremont	Nebraska.
Henderson State Bank	Henderson	Nebraska.
Kearney State Bank and Trust Company	Kearney	Nebraska.
Firstate Bank	Kimball	Nebraska.
Farmers and Merchants Bank	Milligan	Nebraska.
Centennial Bank	Omaha	Nebraska.
Citizens Bank of Ada	Ada	Oklahoma.
First National Bank	Broken Arrow	Oklahoma.
Bank of Chelsea	Chelsea	Oklahoma
1st Bank Oklahoma	Claremore	Oklahoma.
American Bank and Trust	Edmond	Oklahoma.
InterBank, N.A.	Elk City	Oklahoma.
Liberty Federal Savings Bank	Enid	Oklahoma.
Fairview Savings and Loan Association	Fairview	Oklahoma.
First Southwest Bank	Frederick	Oklahoma.
Stockmans Bank	Gould	Oklahoma.
City National Bank and Trust Company	Guymon	Oklahoma.
The Bank of Kremlin	Kremlin	Oklahoma.
Bank of Elgin	Lawton	Oklahoma.
Morris State Bank	Morris	Oklahoma.
Arvest Bank	Norman	Oklahoma.
Osage Federal Savings & Loan Association	Pawhuska	Oklahoma.
NBC Bank	Pawhuska	Oklahoma.

First Priority Bank	Pryor	Oklahoma.
Peoples Bank and Trust	Ryan	Oklahoma.
Spencer State Bank	Spencer	Oklahoma.
Bank of Commerce	Stillwell	Oklahoma.
Sooner State Bank	Tuttle	Oklahoma.
First State Bank	Valliant	Oklahoma.
Citizens' Bank	Velma	Oklahoma.
First State Bank	Watonga	Oklahoma.
Peoples Bank	Westville	Oklahoma.

FEDERAL HOME LOAN BANK OF SAN FRANCISCO—DISTRICT 11

Placer Sierra Bank	Auburn	California.
Western Security Bank, N.A.	Burbank	California.
Mt. Diablo National Bank	Danville	California.
Hawthorne Savings, F.S.B.	El Segundo	California.
Murphy Bank	Fresno	California.
Eldorado Bank	Irvine	California.
Downey Savings & Loan Association	Newport Beach	California.
Universal Bank	Orange	California.
Rancho Santa Fe National Bank	Rancho Santa Fe	California.
Feather River State Bank	Redding	California.
Provident Savings Bank, FSB	Riverside	California.
First Bank of California	Roseville	California.
First Federal Credit Union	Sacramento	California.
River City Bank	Sacramento	California.
Pan American Bank, FSB	San Mateo	California.
Tamalpais Bank	San Rafael	California.
Los Padres Savings Bank, FSB	Solvang	California.
Sonoma Valley Bank	Sonoma	California.
First Security Bank of California, NA	West Covina	California.
Quaker City Bank	Whittier	California.

FEDERAL HOME LOAN BANK OF SEATTLE—DISTRICT 12

Citizens Security Bank (Guam), Inc.	Agana	Guam.
FirstBank Northwest	Lewiston	Idaho.
First Security Bank Missoula	Kalispell	Montana.
First National Bank of Lewiston	Lewiston	Montana.
Empire Bank	Livingston	Montana.
Ronan State Bank	Ronan	Montana.
Linn-Benton Bank	Albany	Oregon.
Pioneer Bank, F.S.B.	Baker City	Oregon.
Evergreen FS&LA	Grants Pass	Oregon.
Bank of Eastern Oregon	Heppner	Oregon.
Banner Bank of Oregon	Hermiston	Oregon.
Klamath First Federal Savings and Loan	Klamath Falls	Oregon.
Orchard Bank	Ontario	Oregon.
American Marine Bank	Bainbridge Island	Washington.
The Bank of Edmonds	Lynnwood	Washington.
Whidbey Island Bank	Oak Harbor	Washington.
Olympia Federal Savings & Loan Association	Olympia	Washington.
Heritage Savings Bank	Olympia	Washington.
First Federal Savings and Loan Association	Port Angeles	Washington.
Riverview Community Bank	Riverview	Washington.
Asia-Europe-Americas Bank	Seattle	Washington.
Key Bank N.A.	Seattle	Washington.
Washington Mutual Bank	Seattle	Washington.
Washington Mutual Bank fsb	Seattle	Washington.
Farmers and Merchants Bank of Rockford	Spokane	Washington.
Yakima Federal Savings and Loan Association	Yakima	Washington.
American National Bank of Rock Springs	Rock Springs	Wyoming.
Rock Springs National Bank	Rock Springs	Wyoming.
Tri-County Federal Savings Bank	Torrington	Wyoming.

II. Public Comments

To encourage the submission of public comments on the community support performance of Bank members, on or before January 29, 2001, each Bank will notify its Advisory Council and nonprofit housing developers, community groups, and other interested parties in its district of the members selected for community support review in the 2000–01 fourth quarter review cycle. 12 CFR 944.2(b)(2)(ii). In reviewing a member for community support compliance, the Finance Board will consider any public comments it has received concerning the member. 12 CFR 944.2(d). To ensure consideration by the Finance Board, comments concerning the community support performance of members selected for the 2000–01 fourth quarter review cycle must be delivered to the Finance Board on or before the March 2, 2001 deadline for submission of Community Support Statements.

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By the Federal Housing Finance Board.
James L. Bothwell,
Managing Director.
[FR Doc. 01–382 Filed 1–12–01; 8:45 am]
BILLING CODE 6725–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 8, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Admiral Family Banks, Inc., Alsip, Illinois; to acquire 100 percent of the voting shares of Federated Bancorp, Inc., Loda, Illinois, and thereby indirectly acquire voting shares of Federated Bank, Onarga, Illinois.

Board of Governors of the Federal Reserve System, January 9, 2001.
Robert deV. Frierson
Associate Secretary of the Board.
[FR Doc. 01–1124 Filed 1–12–01; 8:45 am]
BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 30, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Worth Bancorp, Spartanburg, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of Worth Bank (in organization), Spartanburg, Indiana, which will merge with Greensfork Township State Bank, Spartanburg, Indiana.

Board of Governors of the Federal Reserve System, January 10, 2001.
Robert deV. Frierson
Associate Secretary of the Board.
[FR Doc. 01–1227 Filed 01–12–00; 8:45 am]
BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. § 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans No.	Acquiring	Acquired	Entities
Transactions Granted Early Termination—11/27/2000			
20010384	Bunzl plc	Lawrence D. Starr	Koch Supplies Inc.
20010443	Bunzl plc	Edward S. Reiner	Schrier Bros., Inc.
20010445	Knauf International GmbH	USG Corporation	USG Corporation.
20010490	AmeriPath, Inc	Pathology Consultants of America, Inc	Pathology Consultants of America, Inc.
20010505	Ali M. & Ather Jaferi	Bay View Capital Corp	Bay View Franchise Mortgage Acceptance Company.
20010507	NICE Systems, Ltd	Steven D. Kaiser	Stevens Communications, Inc.

Trans No.	Acquiring	Acquired	Entities
20010547	Solectron Corporation	Sony Corporation	Sony Industries Taiwan Co., Ltd Sony Nakanlida Corporation.
20010593	Chorum Technologies, Inc	Polytronix, Inc	Polytronix, Inc.
Transactions Granted Early Termination—11/28/2000			
20010423	Oak Investment Partners IX, Limited Partnership.	United Messaging, Inc	United Messaging, Inc.
20010468	Swander Pace Capital Fund, L.P	Bruckmann, Rosser, Sherrill & Co., L.P	Burns & Ricker, Inc.
20010477	Perot Systems Corporation	Health Systems Design Corporation	Health Systems Design Corporation.
20010480	General Electric Company	Gannett Co., Inc	Space Holding Corp.
20010481	Greylock IX Limited Partnership	Gannett Co., Inc	Space Holding Corp.
20010482	Venrock Associates II	Gannett Co., Inc	Space Holding Corp.
20010484	Third Avenue Trust	Tejon Ranch Company	Tejon Ranch Company.
20010492	Carl Marks Strategic Investments, L.P	Tejon Ranch Company	Tejon Ranch Company.
20010524	Nationwide Mutual Insurance Company.	White Mountains Insurance Group, Ltd	Waterford Insurance Company.
20010536	Advent International Corporation	Datek Online Holdings, Corp	Datek Online Holdings, Corp.
20010537	Silver Lake Partners, L.P	Datek Online Holdings, Corp	Datek Online Holdings, Corp.
20010538	TA IX, L.P.	Datek Online Holdings, Corp.	Datek Online Holdings, Corp.
20010553	Naomi C. Dempsey	International Paper Company	International Paper Company.
20010575	Adelphia Communications Corporation	Everett J. Mundy	Tele-Media Company of Green River. Tele-Media Company of Southern Virginia. Tele-Media Kentucky Trading Company, G.P.
20010576	Adelphia Communications Corporation	Robert E. Tudek	Tele-Media Company of Green River. Tele-Media Company of Southern Virginia. Tele-Media Kentucky Trading Company, G.P.
20010838	TA/Atlantic and Pacific IV, L.P	Datek Online Holdings Corp	Datek Online Holdings Corp.
Transactions Granted Early Termination—11/29/2000			
20010444	Patton R. Corrigan	Equilease Holding Corp	Mansfield Plumbing Products, Inc.
20010494	Global Sports, Inc	Fogdog, Inc	Fogdog, Inc.
20010500	Wind Point Partners IV, L.P	Weyerhaeuser Company	Weyerhaeuser Company.
20010504	David Frederick Griffin Trust No. 1	A.H. Belo Corporation	KOTV, Inc.
20010509	The 1818 Fund III, L.P	Mortimer B. Fuller, III	Genesee & Wyoming Inc.
20010510	El.Fi. Electrofinanzaria S.p.A	Moulinex S.A	Moulinex S.A.
20010512	Duke Energy Corporation	El Paso Energy Corporation	PG&E National Energy Goup, Inc.
20010514	SEACOR SMIT Inc	SCF Corporation	SCF Corporation.
20010515	Fabrikant International Corporation	SEACOR SMIT Inc	SEACOR SMIT Inc.
20010516	Textron, Inc	George Sbordone, Jr	Tempo Research Corporation.
20010527	Radio One, Inc	Sunburst Dallas, L.P	Sunburst Dallas, L.P.
20010529	Safeguard Scientifics, Inc	Steven D. Siegfried	Palarco International, Inc Palarco, Inc.
20010531	AMT Group, Inc	HCA—The Healthcare Company	Columbia Hospital Corporation of Houston.
20010535	Global Private Equity III Limited Partnership.	Datek Online Holdings, Corp	Datek Online Holdings, Corp.
20010539	FleetBoston Financial Corporation	Jeffrey Chizmas	Cider Mill Farms Company, Inc Snuffy's Pet Products, Inc.
20010540	FleetBoston Financial Corporation	Whitehall Associates, L.P	APP Holding Corporation.
20010543	O. Bruton Smith	Robert R. & Margaret E. Baillargeon	Richardson Ford, Inc.
20010555	CDC Finance	CDC North America Inc	CDC North America Inc.
Transactions Granted Early Termination—11/30/2000			
20010489	InterWest Partners V, L.P	Corixa Corporation	Corixa Corporation.
20010499	Paul G. Allen	One-on-One Sports, Inc	One-on-One Sports, Inc.
20010508	Fresenius AG	Everest Healthcare Services Corporation.	Everest Healthcare Services Corporation.
20010546	Dover Corporation	RailAmerica, Inc	Kalyn/Siebert I Incorporated.
20010548	Sheldahl, Inc	Morgenthaler Venture Partners V, L.P	International Flex Holdings, Inc.
20010550	Munich Re	Loews Corporation	Loews Corporation.
20010556	FedEx Corporation	American Freightways Corporation	American Freightways Corporation
20010557	F. Sheridan Garrisson	FedEx Corporation	FedEx Corporation.
20010588	Software AG	Saga Systems, Inc	Saga Systems, Inc.
20010594	Cox Enterprises, Inc	Radio One, Inc.	Radio One Licenses, Inc.
20010598	Cisco Systems, Inc	Integrated Micromachines Incorporated	Integrated Micromachines Incorporated.
20010600	Kulicke & Soffa Industries, Inc	Siegal-Robert, Inc	Probe Technology, Corporation.

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Trans No.	Acquiring	Acquired	Entities
20010601	Estate of Charles A. Sammons	William L. Baker	Coastline Equipment Co., Inc.
20010603	Fuji Seal, Inc	Owens-Illinois, Inc	Owens-Illinois Labels Inc.
20010604	Exelon Corporation	Blair Park Services, Inc.	Blair Park Services, Inc.
20010605	Best Buy Co., Inc	Leonard M. Tweten	Magnolia Hi-Fi, Inc.
20010607	Andrew J. McKelvey	Satinder Garcha	People.com Consultants, Inc.
20010618	Intuit Inc	FrontLine Capital Group	Employee Matters, Inc.
20010639	Bain Capital Fund VII, L.P	Datek Online Holdings, Corp	Datek Online Holdings, Corp.
20010641	Apollo Investment Fund IV, L.P	Wareco Service, Inc	Wareco Service, Inc.
20010644	Mosaic Group Inc	Paradigm Direct, Inc	Paradigm Direct, Inc.
20010645	Computershare Limited	Merrill Lynch & Co., Inc	Merrill Lynch & Co., Inc.
20010647	Investor AB	Molecular Staging Inc	Molecular Staging Inc.
20010649	Broadcom Corporation	SiByte, Inc	SiByte, Inc.
20010651	Andrew J. McKelvey	SPEC Group Holdings, Inc	SPEC Group Holdings, Inc.
20010653	Smith International, Inc	Emerson Electric Co	Emerson Electric Co.
20010655	Pitney Bowes, Inc	Royal Dutch Petroleum Company	Services Integration Group, L.P. SIG–GP, LLC
	Transactions Granted Early Termination—12/01/2000		
20010485	Hollinger Inc	The James S. Copley Marital Trust	Fox Valley Press Inc.
	Transactions Granted Early Termination—12/04/2000		
20010622	MBNA Corporation.	Citizens Banking Corporation	Citizens Bank, F&M Banking-Iowa.
20010673	The Black & Decker Corporation	Emglo Products, L.P	Emglo Products, L.P.
	Transactions Granted Early Termination—12/05/2000		
20010532	Ernst & Young U.S. L.P	Teach.com, Inc	Teach.com, Inc.
20010551	International FiberCom, Inc	John W. Perry, Jr	Faulk & Foster Real Estate, Inc.
20010552	Cephalon, Inc	Abbott Laboratories	Abbott Laboratories
20010554	Aether Systems, Inc	RTS Wireless, Inc	RTS Wireless, Inc.
20010606	James Chao	New Focus, Inc	New Focus, Inc.
20010608	KKR 1996 Fund L.P	About.com, Inc	About.com, Inc.
20010612	Cisco Systems Inc	iPass Inc	iPass Inc.
20010621	Exelon Corporation	Conectiv, Inc	Atlantic City Electric Company. Delmarva Power & Light Company.
20010623	Ocwen Financial Corporation	Empire Funding Corp	Empire Funding Corp.
20010624	Juniper Networks, Inc	Calient Networks, Inc	Calient Networks, Inc.
20010625	Rocco B. Commisso	AT&T Corp	TCI TKR of the Gulf Plains, Inc.
20010630	Victorinox A.G	Swiss Army Brands, Inc	Swiss Army Brands, Inc.
20010632	Kleiner Perkins Caufield & Byers IX–A, L.P.	Naxon Corporation	Naxon Corporation
20010633	Sky Financial Investment, LLC	Tricon Global Restaurants, Inc	Tricon Global Restaurants, Inc.
20010636	The Zukerman Family Trust	Eli Epstein	Calcined Coke Corporation.
20010637	The Bank of New York, Inc.	Citigroup, Inc.	Schroder & Co., Inc.
20010640	The Chase Manhattan Corporation	Citigroup, Inc.	Lewco Securities Corp.
20010648	Avocent Corporation	Equinox Systems Inc	Equinox Systems Inc.
20010650	Aether Systems, Inc	Michael J. Saylor	Strategy.com, Incorporated.
20010662	David Smilow	Mutual of American Life Insurance Company.	Lifxo Holding Company,,Inc.
20010664	Henry L. Hillman	Patrick P. Lee	Hughes Hi-Tech, Inc. SAS Fluid Power, Inc.
20010670	Ripplewood Partners, L.P	Adaptive Broadband Corporation	Adaptive Broadband Corporation
20010674	AAR Corp	AAR Corp	Turbine Engine Asset Management, LLC.
20010675	General Electric Company	AAR Corp	Turbine Engine Asset Management, LLC.
20010678	General Electric Company	General Electric Company	Aviation Inventory Management Co.; LLC (AIMCO)
20010679	White Mountain Insurance Group, Inc	CGNU plc	CGU Corporation.
20010680	Salem Communications Corporation	Sumner M. Redstone	Infinity Broadcasting Corporation.
20010682	Financial Holding Corporation	ORIX Corporation	Morgan Premium Finance Corp. Morgan Premium Finance of California, Inc.
20010683	General Motors Corporation	Suzuki Motor Corporation	Suzuki Motor Corporation.
20010685	Internet Capital Group, Inc.	Anderson Consulting LLP	ePValue.com, Inc.
20010688	Windward Capital Partners II, L.P	First National of Nebraska, Inc	RPSI, Inc. d/b/a Retriever Payment Systems.
20010692	Mican Limited	CGI Holding Comany	CGI Holding Company.
20010693	Startec Global Communications Corp	Iceberg Transport, S.A	Capsule Communications, Inc.
20010702	Dell Computer Corp	StorageApps Inc	StorageApps Inc.
20010707	Atlantic Equity Partners III, L.P	Thermo Electron Corporation	Peek Ltd.
20010712	David and Sherry Gold	99¢ Only Stores	Odd's-N-End's, Inc Universal International, Inc.

Trans No.	Acquiring	Acquired	Entities
20010713	Footstar Inc	J. Baker, Inc	JBI, Inc Morse Shoe, Inc.
20010714	Alliant Energy Corporation	National Grid Group, plc	EUA Congenex Corporation.
20010720	E.I. du Pont de Nemours and Company.	Haci Omer Sabanci Holding A.S	Kordsa Sabanci DuPont Industrial Yarn & Tire Cord Fabric Man.
20010723	Close Brothers Group plc	Vereniging Aegon	Transamerica Insurance Finance Company.
20010725	Ashish Bhutani	Dresdner BanK AG	Dresdner Bank AG.
20010726	Jeffrey A. Rosen	Dresdner Bank AG	Dresdner Bank AG.
20010727	Michael J. Biondi	Dresdner Bank AG	Dresdner Bank AG.
20010728	Robert Pruzan	Dresdner Bank AG	Dresdner Bank AG.
20010730	Molson Inc	Philip Morris Companies Inc	Molson USA, LLC.
20010732	Siebel Systems, Inc	Sales.com, Inc	Sales.com, Inc.
20010735	Brentwood Associates Private Equity III, L.P.	William Fielding	Dramatic Holdings, Inc.
20010736	Brentwood Associates Private Equity III, L.P.	John Fielding	Dramatic Holdings, Inc.
20010741	Grotech Partners V, L.P	USinternetworking, Inc	USinternetworking, Inc.
20010748	Faithful Central Bible Church	Philip F. Anschutz	L.A. Forum Holdings, LLC.
20010749	Bayerische Hypo -und Vereinsbank AG.	BA Holding AG	Bank Austria Commerical Paper LLC, Bank Austria AG.
20010763	Inktomi Corporation	Adero, Inc	Adero, Inc.
20010774	Capital Z Financial Services Fund II, L.P.	Lending Tree, Inc	Lending Tree, Inc.
	Transactions Granted Early Termination—12/06/2000		
20010051	Robert N. Smith	Stephens Group, Inc	Stephens Group, Inc.
20010448	VoiceStream Wireless Corporation	Cook Inlet Region, Inc	Cook Inlet GSM, Inc Cook Inlet Telecommunications, Inc.
20010454	Robert E. Shaw	Berkshire Hathaway, Inc	Berkshire Hathaway, Inc.
20010475	Martin Marietta Materials, Inc	MAC Acquisitions, Inc	MAC Acquisitions, Inc.
20010523	Heartland Industrial Partners, L.P	Global Metal Technologies, Inc	Global Metal Technologies, Inc.
20010562	VerticalNet, Inc	SierraCities.com. Inc	SierraCities.com Inc.
20010564	New Focus, Inc	James Chao	JCA Technology, Inc.
20010565	Apollo Investment Fund IV, L.P	Rail Van, Inc	Rail Van, Inc.
20010566	Richard Haworth	US Office Products Company	Pear Commercial Interiors, Inc Price Modern, Inc.
20010570	SAIA-Burgess Electronics Holding AG	TRW Inc	TRW Sensors and Components Inc.
20010571	Donald R. Draughon, Jr.	East Coast Oil Corporation	East Coast Oil Corporation.
20010652	Meriter Health Services, Inc	Physicians Plus Insurance Corporation	Physicians Plus Insurance Corporation.
20010709	J.W. Childs Equity Partners II, L.P	Leonard N. Stern	Hartz Mountain Corporation.
20010845	PJM Interconnection, L.L.C	PPL Corporation	PPL Corporation.
20010846	PJM Interconnection, L.L.C	Public Service Enterprise Group Incorporated.	Public Service Enterprise Group Incorporated.
20010847	PJM Interconnection, L.L.C	Exelon Corporation	Exelon Corporation.
20010853	Sociedad General de Aguas de Barcelona, S.A.	Daniel J. Keating, III	Keating Technologies, Inc.
20010858	Allianz AG	Arthur E. Nicholas	Nicholas-Applegate LLC.
20010864	The Virginia Insurance Reciprocal	Alabama Hospital Association Trust	Coastal Insurance Enterprises, Inc.
	Transactions Granted Early Termination—12/07/2000		
20010488	Minnesota Mining & Manufacturing Company.	MicroTouch Systems, Inc	MicroTouch Systems, Inc.
20010573	Empirix Inc	Teradyne, Inc	SFTG LLC.
20010584	Anderson-Tully Company	Naomi C. Dempsey	Soterra LLC.
20010597	Alan B. Miller	Behavioral Healthcare Corporation	BHC Clinicas Del Este Hospital, Inc. BHC Health Services of Puerto Rico, Inc BHC San Juan Capestrano Hospital, Inc CPC Clinicas Del Este, Inc., Integrated HealthCare Sys Corp.
20010614	Manuel Alba	Marvell Technology Group Ltd	Marvell Technology Group Ltd.
20010615	Avigdor Willenz	Marvell Technology Group Ltd	Marvell Technology Group Ltd.
20010656	David E. Barensfeld	Allegheny Technologies Incorporated	TDY Industries, Inc.
20010668	Patterson Energy, Inc	Lawayne Jones	Jones Drilling Corp., Henderson Welding, Inc. LEJ Truck and Crane, Inc.
20010669	Zemex Corporation	Hecla Mining Company	Hecla de Brasil Empreendimentos de Participacoes Ltda. Kentucky-Tennessee Clay Company.

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Trans No.	Acquiring	Acquired	Entities
20010716	Centre Capital Investors III, L.P.	Terence J. Goodling	Grass Valley Group Inc.
20010718	Unaxis Holding AG	Applied Films Corporation	Applied Films Corporation.
20010719	Panhandle-Plains Higher Education Authority, Inc.	Abilene Higher Education Foundation	Abilene Higher Education Resources Corporation.
20010762	Reinhard Mohn	Frank V. Cappo	Coral Graphics Services of Virginia, Inc Coral Graphics Services, Inc.
	Transactions Granted Early Termination—12/08/2000		
20010542	Credit Suisse Group	Enron Corp	Basic Energy Services, Inc.
20010545	Compagnie de Saint-Gobain	Magic Manufacturing, Inc	Magic Manufacturing, Inc.
20010567	Internet Capital Group, Inc	Cephren, Inc	Cephren, Inc.
20010568	General Electric Company	Cephren, Inc	Cephren, Inc.
20010572	Royal Bank of Canada	Dain Rauscher Corporation	Dain Rauscher Corporation.
20010574	Teradyne, Inc	Empirix Inc	Empirix Inc.
20010589	Allied Capital Corporation	BLC Financial Services, Inc	BLC Financial Services, Inc.
20010592	Germain Lamonde	Burleigh Instruments, Inc	Burleigh Instruments, Inc.
20010610	Whitney V, L.P	Michael J. Hartnett	Roller Bearing Holding Company, Inc.
20010619	Electronic Data Systems Corporation	Electronic Data Systems Corporation	TransAlliance L.P.
20010620	Berkshire Hathaway Inc	Benjamin Moore & Co	Benjamin Moore & Co.
20010646	AT&T Corporation	Sumner M. Redstone	Viacom Inc. Westinghouse CBS Holding Company. Westinghouse Electric G.m.b.H.
20010663	Washington Mutal Inc	The PNC Financial Services Group, Inc.	PNC Mortgate Corp. of America. PNC Mortgage Securities Corp PNC Reinsurance Corp.
20010681	Menasha Corporation	Accurate Box, Carton and Container Corp.	Accurate Box, Carton and Container Corp.
20010689	Crescendo III, L.P	VeloCom Inc	VeloCom Inc.
20010690	GTCR Fund VII, L.P	First Tennessee National Corporation	First Tennessee Bank National Association.
20010697	Bank of America Corporation	American Fidelity & Liberty, Inc	American Fidelity & Liberty, Inc.
20010700	George E. Robb Jr	LaBranche & Co. Inc	LaBranche & Co. Inc.
20010701	LaBranche & Co. Inc	George E. Robb Jr	Robb Peck McCooey Financial Services, Inc.
20010708	Monrovia Nursery Company	Horticultural Farms, Inc	Horticultural Farms, Inc.
20010711	Harrowston Inc	AvinMeritor, Inc	Meritor Heavy Vehicle Systems, LLC.
20010715	Honeywell Electronic Manufacturing Services, Inc.	Mitsubishi Chemical Corporation	Mitsubishi Chemical America, Inc.
20010717	Cendant Corporation	Avis Group Holdings, Inc	Avis Group Holdings, Inc.
20010734	Brambles Industries Limited	Instashred Security Services, Inc	Instashred Security Services, LLC.
20010739	Comverse Technology	PacketVideo Corporation	PacketVideo Corporation.
20010743	Phillips Petroleum Company	Phillips Petroleum Company	Sweeny Olefins Limited Partnership.
20010744	William Davidson	TruServ Corporation	TruServ Corporation.
20010745	Paxton Media Group, Inc	A.H. Belo Corporation	Henderson Gleaner, Inc. Owensboro Messenger-Inquirer, Inc.
20010746	NDS Holdings, L.P	Sarno Heirs Trust	SML, LLC.
20010747	Gerald W. Schwartz	La Francaise Bakery, Inc	La Francaise Bakery, Inc.
20010752	Praxair Inc	Viscount III, LLC	HealthCare Partners, LLC, HCP, Inc HealthCare Partners-Indiana, Inc., HCP Pediatric Care Ser.
20010753	The Bear Stearns Companies Inc	Helios Management LLC	Helios Group Illinois LLC. Helios Holding LLC, Helios Futures and Options LLC.
20010766	Phillip R. Bennett	Sukhmeet (Micky) Dhillon	Main Street Trading Company/Newhall Discount Futures, Inc.
20010777	Tom T. Gores	Lanier Worldwide, Inc	Lanier Worldwide, Inc.
20010781	Russel Metals Inc	Pitt-Des Moines, Inc	Pitt-Des Moines, Inc.
20010795	James Fine Chemicals, Inc. d/b/a JFC Technologies.	Schweizerhall Holding AG	Schweizerhall Development Corporation. Schweizerhall Manufacturing Corporation.
20010797	Arnett Physician Group, P.C.	PhyCor, Inc	PhyCor-Lafayette, LLC, Arnett Health Plans, Inc.
20010798	Michael Luke	SIG Schweizerische Industrie-Gesellschaft Holding AG.	SIG Arms Inc.
20010799	Thomas Ortmeier	SIG Schweizerische Industrie-Gesellschaft Holding AG.	SIG Arms Inc.
20010803	Mark Cuban	FXM, Inc	FXM, Inc.
20010804	Keller Group, Inc	Nucor Corporation	Nucor Corporation.

Trans No.	Acquiring	Acquired	Entities
20010809	Stephen E. Myers	The Walt Disney Company	Vista-United Telecommunications Partnership.
20010812	American National Insurance Company	Farm Family Holdings, Inc	Farm Family Holdings, Inc.
20010814	FreeBorders.com, Inc	Internet Capital Group, Inc	Animated Images, Inc.
20010815	Internet Capital Group, Inc	FreeBorders.com, Inc	FreeBorders.com, Inc.
20010816	PNC Financial Services Group, Inc	Dana Corporation	Dana Corporation.
20010819	Amkor Technology, Inc	Toshiba Corporation	Iwate Toshiba Electronics Co., Ltd.
20010825	Unitrin, Inc	Curtiss-Wright Corporation	Curtiss-Wright Corporation.
20010828	Zurich Financial Services	The First Australia Fund, Inc	The First Australia Fund, Inc.
20010844	PJM Interconnection, L.L.C	GPU, Inc	GPU, Inc.
20010859	General Motors Corporation	Bank of America Corporation	Banc of America Commercial Corporation.
20010861	Cook Inlet Region, Inc	John S. Boyd	BCN Communications, L.L.C.
20010886	Brown & Brown, Inc	John R. Riedman	Riedman Corporation.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–1168 Filed 1–12–01; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

Trans No.	Acquiring	Acquired	Entities
	Transactions Granted Early Termination—12/11/2000		
20010684	Heerema Holding Company, Inc	INTEC Engineering Partnership, Ltd.	INTEC Engineering Partnership, Ltd.
20010892	Cardinal Health, Inc	Martina Nowak	International Processing Corporation.
20010893	Cardinal Health, Inc	Kenneth W. Olsen	International Processing Corporation.
20010896	The Virginia Insurance Reciprocal	Healthcare Workers' Compensation Self-Insurance Fund.	Healthcare Workers' Compensation Self-Insurance Fund.
20010912	ABN AMRO Holding N.V	Trade.com Global Markets, Inc	Trade.com Global Markets, Inc
20010915	Kerry J. Dukes	Trade.com Global Markets, Inc	Trade.com Global Markets, Inc
20010922	Kamal Mustafa	Trade.com Global Markets, Inc	Trade.com Global Markets, Inc
	Transactions Granted Early Termination—12/12/2000		
20010909	Matthew D. Castagna	Trade.com Global Markets, Inc	Trade.com Global Markets, Inc
20010925	Bernard Arnault	Datek Online Holdings, Corp	The Island ECN, Inc
	Transactions Granted Early Termination—12/13/2000		
20010818	General Electric Company	James A. Glaser	ACT Communications, Inc
	Transactions Granted Early Termination—12/14/2000		
20010563	Eastman Kodak Company	Lumisys Incorporated	Lumisys Incorporated.
20010613	Telecom Partners III, L.P	VeloCom Inc	VeloCom Inc
20010616	Centennial Fund VI, L.P	VeleCom Inc	VeleCom Inc
20010703	Wrenchead.com, Inc	Raymond J. and Lewena Noorda	Profit Pro, Inc
20010704	Raymond J. Noorda and Lewena Noorda.	Wrenchead.com, Inc	Wrenchead.com, Inc
20010722	Trintech Group PLC	GlobeSet, Inc	GlobeSet, Inc J. Driscoll & Associates, Inc
20010731	Lone Star Opportunity Fund, L.P	Greenbriar Corporation	Greenbriar Corporation.
20010750	Iowa Farm Bureau Federation	The Kansas Farm Bureau	The Kansas Farm Bureau.
20010773	NSB Retail Systems PLC	3068358 Canada Inc	STS Systems, Inc
20010775	TeleCorp PCS, Inc	ALLTEL Corporation	ALLTEL Communications, Inc

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Trans No.	Acquiring	Acquired	Entities
20010776	The Kansas Farm Bureau	Iowa Farm Bureau Federation	FBL Financial Group, Inc
20010778	The McGraw-Hill Companies, Inc	Mayfield Publishing Company	Mayfield Publishing Company.
20010782	First Data Corporation	Wells Fargo & Company	Wells Fargo Merchant Services, LLC.
20010808	Scott Kurmit	PRIMEDIA Inc	PRIMEDIA Inc
20010824	Weyerhaeuser Company	Willamette Industries, Inc	Willamette Industries, Inc
20010897	MDMI Holdings, Inc	American Technical Molding, Inc	American Technical Molding, Inc
	Transactions Granted Early Termination—12/15/2000		
20003935	The Valspar Corporation	Lilly Industries, Inc	Lilly Industries, Inc
20004870	Transocean Sedco Forex Inc	R&B Falcon Corporation	R&B Flcon Corporation.
20010334	Kinder Morgan Energy Partners, L.P	NOVA Chemicals Corporation	NOVA Chemicals Corporation.
20010483	French Fragrances, Inc	Unilever N.V	Conopco, Inc
20010611	Summer M. Redstone	Robert L. Johnson	BET Holdings II, Inc
20010659	Pierre Fabre	Alain Merieux	bioMerieux Alliance, SA.
20010817	Wind Point Partners IV, L.P	SMR ECR Holding, Inc	Alexandria Sports, Inc, Burke Sports, Inc Eden Sports," Inc, Leesburg Sports, Inc, Trumbull PT Corp SMR Banyan Tree, Inc, Professional rehab Associates, Inc
20010826	Global TeleSystem Inc	MCT of Russia, L.P	MCT Corp
20010827	Varco Inrnternational, Inc	The Beacon Group Energy Investment Fund, L.P.	Quality Tubing, Inc
20010831	Cisco Systems, Inc	Active Voice Corporation	Active Voice Corporation.
20010837	Dycom Industries, Inc	Point to Point Communications, Inc	Point to Point Communications, Inc
20010854	Dr. Roy J. Shanker	Waste Management, Inc	Signal Capital Sherman Station One Inc Signal Capital Sherman Station, Inc Waste Management, Inc Wheelabrator Cum Services, Inc Wheelabrator Frackville Energy Company Inc Wheelabrator Frackville Properties Inc Wheelabrator Fuel Services, Inc Wheelabrator Hudson Energy Company, Inc Wheelabrator Lassen Inc Wheelabrator Martell Inc Wheelabrator NHC Inc Wheelabrator Polk Inc Wheelabrator Ridge Energy Inc Wheelabrator Shasta Energy Company, Inc Wheelabrator Sherman Station Two Inc
20010855	Duke Energy Corporation	Waste Management, Inc	Signal Capital Sherman Station One Inc Signal Capital Sherman Station, Inc Waste Management, Inc Wheelabrator Cum Services, Inc Wheelabrator Frackville Energy Company Inc Wheelabrator Frackville Properties Inc Wheelabrator Fuel Services, Inc Wheelabrator Hudson Energy Company Inc Wheelabrator Lassen Inc Wheelabrator Martell Inc Wheelabrator NHC Inc Wheelabrator Polk Inc Wheelabrator Ridge Energy Inc Wheelabrator Shasta Energy Company, Inc Wheelabrator Sherman Station Two Inc
20010856	Duke Energy Corporation	BTA Holdings, Inc	BTA Holdings, Inc
20010871	Carson/LIN SBS, L.P	Western New York Public Broadcasting Association.	Western New York Public Broadcasting Association.
20010872	Joe Fojtasek	Western New York Public Broadcasting Association.	Western New York Public Broadcasting Association.

Trans No.	Acquiring	Acquired	Entities
20010981	Metsaliito Osuuskunta	International Paper Company	International Paper Deutschland, Inc
	Transactions Granted Early Termination—12/18/2000		
20010764	Equilease Holding Corp	Delta, plc	Delta America Inc, United Power Corporation.
20010843	PJM Interconnection, L.L.C.	Conectiv	Conectiv.
20010903	Spectrum Holding, Inc	BP Amoco p.l.c.	BP Amoco p.l.c.
20010919	Pharmaceutical Product Development Inc.	Axys Pharmaceuticals, Inc	PPGx, Inc
20010931	Maurice B. Tose	XYPOINT Corporation	XYPOINT Corporation.
	Transactions Granted Early Termination—12/19/2000		
20010691	Froedtert Health Systems, Inc	Community Health Care Services of Menomonee Falls, Inc.	Community Health Care Services of Menomonee Falls, Inc
20010729	Bruce Wasserstein	Dresdner Bank AG	Dresdner Bank AG.
20010780	Stephen Adams	PNE Media Holdings, LLC	PNE Media, LLC.
20010802	eVolution Global Partners L.P	American Express Company	MarketMile, Inc
20010836	Manafort Brothers, Inc	Allied Waste Industries, Inc	American Disposal Services of Missouri, Inc
20010838	Hunting PLC	Estate of Charles A. Sammons	Composite Thread Protectors, Inc Vinson Supply Company.
20010841	C–MAC Industries Inc	Honeywell International, Inc	Honeywell International, Inc
20010842	Alec E. Gores	Honeywell International Inc	Honeywell International Inc
20010850	Tyco International Ltd	Eaton Corporation	Eaton Corporation.
20010851	Hick, Muse, Tate & Furst Equity Fund III, L.P.	ABFM Corporation	ABFM Corporation.
20010852	Willis Stein & Partners II, L.P	Anthony G. Telese	Quality Metal Works, Inc
20010862	SPX Corporation	Ray Ryan and Nancy Ryan	Central Tower, Inc Ryan Construction, Inc
20010863	Zahren Alternative Power Corporation	Northeast Utilities	Countryside Genco, LLC, Countryside Landfill Gasco, LLC. Morris Genco, LLC, Morris Gasco, LLC.
20010876	Thomas Weisel Capital Partners, L.P	Innovance, Inc	Innovance, Inc
20010906	Johnson & Johnson	SK Corporation	SK Corporation.
20010917	InterCept Group, Inc (The)	Shrigovin Misir	ICPT, LLC. SLMsoft.com, Inc
20010923	Reuters Group plc	Pearson plc	Financial Times Energy, Inc
20010934	Artisan Components, Incorporated	Synopsys Incorporated	Synopsys Incorporated.
20010961	Republic Services, Inc	Allied Waste Industries, Inc	BFI Waste Systems of North America, Inc
20010983	Limestone Electron Trust	El Paso Energy Corporation	West Georgia Generating Company, L.L.C.
20010986	Nokia Corporation	Ramp Networks, Inc	Ramp Networks, Inc
	Transactions Granted Early Termination—12/20/2000		
20003903	Computer Sciences Corporation	Policy Management Systems Corporation.	Policy Management Systems Corporation.
20010672	The B.F. Goodrich Company	Raytheon Company	Raytheon Optical Systems.
20010765	Danaher Corporation	Equilease Holding Corp.	United Power Corporation.
20010792	Highland Holdings	Brian L. Roberts	Comcast Corporation.
20010793	Brian L. Roberts	Highland Holdings	Highland Holdings.
20010796	Harry J. Pappas	Thomas O. Hicks	Southwest Sports Television, L.P
20010866	SSPS Inc	ShowCase Corporation	ShowCase Corporation.
20010869	Radian Group Inc	Enhance Financial Services Group Inc	Enhance Financial Services Group Inc
20010870	Morgenthaler Partners VI, L.P	Innovance, Inc	Innovance, Inc
20010874	The AES Corporation	Andrew R. Fellon	Fellon-McCord & Associates, Inc, Alliance Gas Services, Inc
20010875	The AES Corporation	John C. McCord	Fellon-McCord & Associates, Inc, Alliance Gas Services, Inc
20010877	Azure Capital Partners	Innovance, Inc	Innovance, Inc
20010904	Cree, Inc	Spectrian Corporation	Spectrian Corporation.
20010907	Enron Corp.	Dr. Roy J. Shanker	Cabazon Holdings, LLC. Victory Garden Power Partners LLC.
20010910	Germain Motor Company	Richard F. Ruhl	Dick Ruhl Ford Sales, Inc
20010911	FL Selenia S.a.r.l	Pennzoil-Quaker State Company.	Pennzoil-Quaker State Company.
20010913	Jim Ratcliffe	Imperial Chemical Industries Plc	Chlor-Chemicals Businesses, Klea and Crosfield businesses.
20010920	Pequot Private Equity Fund II, L.P	Everest Broadband Networks, Inc	Everest Broadband Networks, Inc

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Trans No.	Acquiring	Acquired	Entities
20010921	Leap Wireless International, Inc	Century Tel, Inc	MVI Corp., Inc, Century Personal Access Network, Inc
20010924	Pogo Producing Company	NORIC Corporation	NORIC Corporation.
20010926	Capital One Financial Corporation	InnoVentry Corp.	InnoVentry Corp.
20010928	Tyco International Ltd.	Simplex Time Recorder Business Trust	Simplex Time Recorder Business Trust.
20010929	Twin City Co-ops Federal Credit Union	Pioneer Plus Federal Credit Union	Pioneer Plus Federal Credit Union.
20010932	Audax Private Equity Fund, L.P	Patrick J. Purcell	Herald Media, Inc
20010933	Weston Presidio Captial IV, L.P	Patrick J. Purcell	Herald Media, Inc
20010937	SCI Systems, Inc	Telefonaktiebolaget L M Ericsson	Ericsson, Inc
20010940	Telecom Partners III, L.P	Formus Communications, Inc	Formus Communications, Inc
20010942	Finisar Corporation	Shomiti Systems, Inc	Shomiti Systems, Inc
20010945	724 Solutions, Inc	TANTAU Software, Inc	TANTAU Software, Inc
20010980	The Huron Fund LP	Jordan Industries, Inc	Riverside Book and Bible House Incorporated. World Bible Publishers, Inc

Transactions Granted Early Termination—12/21/2000

20010763	El Paso Energy Corporation	PG&E Corporation	PG&E Gas Transmission Teco, Inc PG&E Gas Transmission, Texas Corporation.
20010433	Thoratec Laboratories Corporation	Thermo Electron Corporation	Thermo Cardiosystems Inc
20010436	Thermo Electron Corporation	Thoratec Laboratories Corporation	Thoratec Laboratories Corporation.
20010751	Biovail Corporation	Aventis	Aventis Pharma, Inc. Aventis Pharmaceuticals Inc.
20010908	Franciscan Services Corporation	Franciscan Sisters of the Poor	The Franciscan at St. Leonard.
20010947	London Bridge Software Holdings plc	Phoenix International Ltd., Inc	Phoenix International A.P. New Zealand. Phoenix International New York, Inc.
20010948	Institutional Venture Partners VIII, L.P.	Homestead.com, Inc	Homestead.com,Inc.

Transactions Granted Early Termination—12/22/2000

20010676	Valence Technology, Inc	Science Applications International Corporation.	Telcordia Technologies, Inc.
20010677	Science Applications International	Valence Technology, Inc	Valence Technology, Inc.
20010800	The B.F. Goodrich Company	Autoliv, Inc	OEA Aerospace, Inc.
20010873	MediaNews Group, Inc	AT&T Corp	Kearns-Tribune, LLC.
20010878	Paul Marciano	Guess?, Inc	Guess?, Inc.
20010879	Armand Marciano	Guess?, Inc	Guess?, Inc.
20010883	Yodlee.com, Inc	S1 Corporation	VerticalOne Corporation.
20010884	S1 Corporation	Yodlee.com, Inc	Yodlee.com, Inc.
20010887	Ferro Corporation	Imperial Chemical Industries, PLC	Indpoco Inc. (d/b/a/National Starch and Chemical Company).
20010889	Robert G. Liggett, Jr	Louis Elias	Elias Brothers Restaurants, Inc.
20010890	North Shore Long Island Jewish Health System, Inc.	Doctors' Hospital of Staten Island, Inc	Doctors' Hospital of Staten Island, Inc.
20010891	William A. Robinson	DHL International Limited	DHL International Limited.
20010894	Amerada Hess Corporation	LASMO plc	LASMO plc.
20010895	The Regence Group	Northwest Washington Medical Bureau	Northwest Washington Medical Bureau.
20010899	Verizon Communication Inc	ALLTEL Corporation	ALLTEL Communications, Inc.
20010901	Reilly Family Limited Partnership	Thomas Leclair	American Outdoor Advertising LLC.
20010902	Reilly Family Limited Partnership	Jonathan Levine	American Outdoor Advertising LLC.
20010938	The Procter & Gamble Company	Dr. Johns Products, Ltd	Dr. Johns Products, Ltd.
20010946	Exelon Corporation	Richard E. Wenniger	The Wenninger Company, Inc.
20010949	Tyco International Ltd	Rollin W. Mettler, Jr	Mechatronics, L.L.C. Molded Interconnect Device, LLC.
20011950	Tyco International, Ltd	John H. Mettler	Mechatronics, L.L.C. Molded Interconnect Device, LLC.
20010951	State Automobile Mutual Insurance Company.	Meridian Mutual Insurance Company	Meridian Mutual Insurance Company.
20010952	Delta Galil Industries, Ltd	Norton Sloan	Inner Secrets Inc.
20010956	Advance Food Company	Cargill, Inc.	Excel Corporation.
20010957	Cargill, Incorporated	Advance Food Company	Advance Retail Holdings, Inc.
20010964	State Automobile Mutual Insurance Company.	Meridian Insurance Group, Inc	Meridian Insurance Group, Inc.

Trans No.	Acquiring	Acquired	Entities
20010965	The Royal Bank of Scotland Group plc	Rolls-Royce plc	Certified Alloy Products, Inc. Trucast Inc. Ross Catherall Group plc and Ross & Catherall Limited. Trucast Limited, Vickers Engineering plc.
20010969	Verizon Communications Inc	James E. Douglas, Jr. and Jean A. Douglas.	HLD Cellular Corporation.
20010973	James A. Radley	Royal & Sun Alliance Insurance Group plc.	Alliance Assurance Company of America.
20010974	Affiliated Computer Services, Inc	Tyler Technologies, Inc	Business Resources Corporation Capital Commerce Reporter, Inc. Government Records Services, Inc. PRETS Holdings, Inc. RAM Quest Software, Inc. RTS Holdings, Inc. Title Records Corporation.
20010978	Anadarko Petroleum Corporation	Western Gas Resources, Inc	Pinnacle Gas Treating, Inc.
20010982	The SKM Equity Fund III, L.P	Whole Duty Investment, Ltd	Viewpoint International, Inc.
20010985	New York University	The Grand Union Company (debtor-in-possession).	The Grand Union Company (debtor-in-possession).
20010987	DLJ Merchant Banking Partners III, L.P.	Credit Suisse Group	Focus Technologies, Inc.
20010988	Medisys PLC	Chronimed Inc	MEDgenesis Inc.
20010989	Paul B. Prager	The Montana Power Company	Continental Energy Services, Inc.
20010990	William E. Bindley	Cardinal Health, Inc	Cardinal Health, Inc.
20010992	Safeway Inc	Genuardi's Willco, Inc	Genuardi's Willco, Inc.
20010995	Agilera.com, Inc	Applicast, Inc	Applicast, Inc.
20010996	Leica Geosystems Holdings AG	Dennis F. Nardoni	Laser Alignment, Inc.
20010997	Reinhard Mohn	Mortimer B. Zuckerman	F.C. Holdings, L.L.C. Fast Company Media, LLC.
20010998	Gerald W. Schwartz	I and K Distributors, Inc	I and K Distributors, Inc.
20010999	International Rectifier Corporation	Unisem, Inc	Unisem, Inc.
20011000	Agilent Technologies, Inc	Objective Systems Integrators, Inc	Objective systems Integrators, Inc.
20011001	SEACOR SMIT Inc	Philip G. & Judy C. Plaisance	Plaisance Marine Inc., LaSalle Offshore Inc. Seahorse Marine Inc.
20011002	L–3 Communications Holdings, Inc.	Thermo Electron Corporation	Coleman Research Corporation.
20011005	GATX Corporation	Rolls-Royce Plc.	Pembroke Group Limited.
20011008	Sesame Workshop	EM. TV & Merchandising AG	The Jim Henson Company, Inc.
20011011	GTFC Equity Investors, L.L.C.	MicroAge, Inc.	MicroAge Technology Services, L.L.C.
20011013	Reed International P.L.C.	George Schussel	DCI Management, Inc. DCI Massachusetts Business Trust. IT Media Group, Inc. O&P Incorporated. Software Lists, Inc.
20011014	Elsevier NV	George Schussel	DCI Management, Inc. DCI Massachusetts Business Trust. IT Media Group, Inc. O&P Incorporated. Software Lists, Inc.
20011017	Nextel Communications, Inc.	Chadmoore Wireless Group, Inc.	Chadmoore Wireless Group, Inc.
20011018	Constellation Brands, Inc.	Daniel R. Baty	Corus Brands, Inc.
20011032	Odyssey Investment Partners Fund, L.P..	Jeffrey D. Church	Trevecca Holdings, Inc.
20011036	Nordea Plc	Christiania Bank og Kreditkasse ASA	Christiania Bank og Kreditkasse ASA.
20011037	SEACOR SMIT Inc.	Rincon Marine, Inc.	Rincon Marine, Inc.
20011038	NextMedia Investors LLC	NextMedia Group II, Inc.	NextMedia Group II, Inc.
20011039	Plum Creek Timber Company, Inc.	Plum Creek Manufacturing Holding Company, Inc.	Plum Creek Manufacturing Holding Company, Inc.
20011043	National Software Corporation	Catapulse, Inc.	Catapulse, Inc.
20011045	Centrica plc	Sempra Energy	Energy America LLC.
20011046	Kingspan Group plc	Daniel and Patricia Baker, husband and wife.	Tate Global Corporation.
20011048	Francisco Partners, L.P.	marchFirst, Inc	marchFirst, Inc.
20011050	Krug International Corp.	Charterhouse Equity Partners, II, L.P.	Southern Health Corp./Clanton Hospital, Inc./Dexter Hospital.
20011052	Microsoft Corporation	USinternetworking, Inc	USinternetworking, Inc.
20011057	Bodycote International plc	Lindberg Corporation	Lindberg Corporation.
20011059	Medline Industries, Inc.	Sun Healthcare Group, Inc.	Sun Healthcare Group, Inc.

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Trans No.	Acquiring	Acquired	Entities
20011060	The Drees Company	Allen G. Zaring, III	Zaring Homes, Inc., Zaring Homes of Indiana LLC. Zaring National Corporation.
20011064	Mott MacDonald Group Limited	Thermo Electron Corporation	The Killam Group Inc.
20011065	IAWS Group plc	Marvin M. Schwan	Orion Food Systems International, Inc.
20011072	Stone Energy Corporation	Basin Exploration, Inc.	Basin Exploration, Inc.
20011074	Toyota Automatic Loom Works, Ltd.	Toyota Motor Corporation	Toyota Motor Sales U.S.A., Inc. Toyota-Lift of Los Angeles, Inc.
20011077	The Auto Club Group f/k/a/ AAA Michigan/Wisconsin, Inc.	Cornhusker Motor Club	Cornhusker Motor Club.
20011082	Caterpillar Inc.	J. Garner Scott	Federal Financial Services, Inc. IronMart, Inc. Pioneer Machinery, Inc.
20011095	Boston Ventures Limited Partnership V	Jeremiah J. Harris	Production Resource Group, L.L.C., Signal Perfection, Ltd.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, DC 20580, (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–1169 Filed 1–12–01; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[File No. 011 0022]

Winn-Dixie Stores, Inc., Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before February 8, 2001.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Richard Parker or James Fishkin, FTC/H–374, 600 Pennsylvania Ave., NW., Washington, DC 20580. (202) 326–3300 or 326–2663.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for January 9, 2001), on the World Wide Web, at *http://www.ftc.gov/os/2001/01/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room H–130, 600 Pennsylvania Avenue, NW., Washington, D.C. 20580, either in person or by calling (202) 326–3627.

Public comment is invited. Comments should be directed to: FTC/Office of the Secretary, Room 159, 600 Pennsylvania, Ave., NW., Washington, DC 20580. Two paper copies of each comment should be accompanied, if possible, by a 3½ inch diskette containing an electronic copy of the comment. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Analysis of the Complaint and Proposed Consent Order To Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted for public comment from Winn-Dixie Stores, Inc. "Winn-Dixie" or "the Proposed Respondent") and Agreement Containing Consent Order "the proposed consent order"). The Proposed Responent has also reviewed a draft complaint that the Commission contemplates issuing. The proposed consent order is designed to furnish the Commission with prospective relief in the markets affected by the proposed acquisition by Winn-Dixie of supermarkets and other assets of Jitney-Jungle Stores of America, Inc. ("Jitney-Jungle"). A plan of sale pertaining to the supermarkets involved in this case has been confirmed by the United States Bankruptcy Court for the Eastern District of Louisiana in In re Jitney-Jungle Stores of America, Case No. 99–17191, on December 15, 2000.

II. Description of the Parties and the Proposed Acquisition

Jitney-Jungle, owned principally by Bruckmann, Rosser, Sherill & Co., an investment company, runs most of its stores under the names "Jitney-Jungle" and "Delchamps." Prior to its filing under Chapter 11 of the Bankruptcy Act on October 12, 1999, Jitney-Jungle operated nearly 200 supermarkets, and a lesser number of nearby gas stations and liquor stores, in Mississippi, Alabama, Louisiana, Florida, Arkansas, and Tennessee. Following that filing, Jitney-Jungle has closed more than 45 supermarkets and sold off at least ten (10) others. Following the solicitation of buyers for any and all of its stores, Jitney-Jungle proposed to sell 72 supermarkets to Winn-Dixie for a total purchase price of $85 million. Following an auction held under the auspices of the bankruptcy court, and as limited by the proposed consent order, Winn-Dixie plans instead to acquire 68 of the Jitney-Jungle stores for a reduced consideration.

Winn-Dixie is a Florida corporation headquartered in Jacksonville, Florida. It operates more than 1,000 supermarkets in fourteen southeastern states and the Bahamas. Winn-Dixie reported sales of $14.1 billion for fiscal 1999.

III. The Draft Complaint

The draft complaint alleges that the relevant line of commerce (*i.e.*, the product market) is the retail sale of food and grocery items in supermarkets. Supermarkets provide a distinct set of products and services for consumers who desire to one-stop shop for food and grocery products. They carry a full line and wide selection of both food and nonfood products (typically more than 10,000 different stock-keeping units ("SKUs")), as well as a deep inventory of those SKUs in a variety of brand names and sizes. To accommodate the large number of food and nonfood products necessary for one-stop shopping, supermarkets are large stores that typically have at least 10,000 square feet of selling space. So called "supercenters" operated by mass merchants such as Wal-Mart, which have full-line supermarkets attached to general merchandise stores, are included in the product market.

Supermarkets compete primarily with other supermarkets that provide one-stop shopping for food and grocery products. Supermarkets base their food and grocery prices on the prices primarily of food and grocery products sold at nearby supermarkets. They do not regularly price-check food and grocery products sold at other types of stores such as cub stores or limited assortment stores, and do not significantly change their food and grocery prices in response to prices at other types of stores. Most consumers shopping for food and grocery products at supermarkets are not likely to shop elsewhere in response to a small price increase by supermarkets.

Retail stores other than supermarkets that sell food and grocery products, such as neighborhood "mom & pop" grocery stores, limited assortment stores, convenience stores, specialty food stores (*e.g.*, seafood markets, bakeries, etc.), club stores, and mass merchants, do not effectively constrain most prices at supermarkets. These other stores operate significantly different retail formats and sell far more limited assortments of items. None of these formats would constrain a price increase taken by supermarkets.

The draft complaint alleges that the relevant sections of the country in which to analyze the acquisition include, among others, the areas in and near the following cities and towns: Niceville, Florida; Gulf Breeze, Florida; Destin, Florida; and the Gulfport-Biloxi area of Mississippi, which consists of the parts of Hancock, Harrison, and Jackson counties that include Waveland, Bay Saint Louis, Pass Christian, Long Beach, Gulfport, Biloxi D'Iberville, and Ocean Springs, and narrower markets contained therein, including Gulfport and Biloxi (the "Relevant Geographic Markets").

Jitney-Jungle and Winn-Dixie are actual and direct competitors in all of the above listed markets. The acquisition will eliminate that competition. The draft complaint alleges that each of the post-merger markets would be highly concentrated, whether measured by the Herfindahl-Hirschman Index (commonly referred to as "HHI") or by four-firm concentration ratios.[1] The acquisition would substantially increase concentration in each market. Jitney-Jungle and Winn-Dixie would have a combined market share that ranges from slightly less than 34% to 100% in the Relevant Geographic Markets. The post-acquisition HHIs in the Relevant Geographic Markets range from just over 2,400 points to 10,000 points.

The draft complaint further alleges that entry is difficult and would not be timely, likely, or sufficient to prevent anticompetitive effects in the Relevant Geographic Markets.

Notwithstanding all of this, Winn-Dixie's acquisition of Jitney-Jungle assets is not likely to create or enhance market power, or facilitate its exercise, to the extent that the imminent failure of Jitney-Jungle would cause those assets, or some of them, to exit the market. To that extent, post-acquisition performance in the relevant market is not likely to be worse than performance had the acquisition been blocked and the assets exited.

As previously indicated, Jitney-Jungle has sought protection from its creditors pursuant to Chapter 11 of the Bankruptcy Act. A review of that proceeding indicates that Jitney-Jungle will not be able to reorganize successfully under Chapter 11, and that but for the auction sale conducted under the auspices of the bankruptcy court Jitney-Jungle would be thrown into liquidation proceedings under Chapter 7 of the Bankruptcy Act. The key question, therefore, is whether Jitney-Jungle has made unsuccessful good-faith efforts to elicit reasonable alternative offers of acquisition of the Jitney-Jungle assets. Through a variety of means, including the retention of appropriate professionals to elicit offers for its assets and culminating in the previously mentioned auction sale under the auspices of the bankruptcy court, Jitney-Jungle has sought to elicit reasonable alternative bids. In the four Relevant Geographic Markets, Jitney-Jungle has been able to elicit bids that are timely, above the liquidation value of the assets, and otherwise acceptable to creditors. Therefore, the Commission concluded that in the Relevant Geographic Markets the proposed acquisition would be anticompetitive because it would eliminate substantial, direct, and ongoing competition. In all other areas where Winn-Dixie directly competes against Jitney-Jungle, Jitney-Jungle has been unable to elicit bids that are timely, likely, above liquidation value of the assets, and otherwise acceptable to creditors. Therefore, the other areas where Winn-Dixie and Jitney-Jungle directly compete are not being challenged.

The draft complaint alleges that Winn-Dixie's proposed acquisition of various supermarket assets of Jitney-Jungle, if consummated, may substantially lessen competition in the four Relevant Geographic Markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by eliminating direct competition between supermarkets presently owned or controlled by Jitney-Jungle and supermarkets owned or controlled by Winn-Dixie; by increasing the likelihood that Winn-Dixie will unilaterally exercise market power; and by increasing the likelihood of, or facilitating, collusion or coordinated interaction among the remaining supermarket firms. Each of these effects raises the likelihood that the prices of food, groceries or services will increase, and the quality and selection of food, groceries or services will decrease, in the Relevant Geographic Markets alleged in the proposed complaint.

IV. Terms of the Agreement Containing Consent Order

The proposed consent order will furnish prospective relief in the markets affected by the proposed acquisition.[2] Under the terms of the proposed consent order, the Proposed Respondent must not, for a period of ten (10) years from the date the proposed consent order becomes final, acquire any interest in four identified Jitney-Jungle

[1] The HHI is a measurement of market concentration calculated by summing the squares of the individual market shares of all the participants.

[2] Acceptance of the proposed consent order for public comment terminates the Hart-Scott-Rodino waiting period and enables Winn-Dixie immediately to acquire the Jitney-Jungle assets.

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supermarkets without the prior approval of the Commission.

Also for a period of ten (10) years, the Proposed Respondent must provide written notice to the Commission prior to acquiring any interest in a supermarket owner or operator, or any facility that has operated as a supermarket within the previous six (6) months, located in any of the Relevant Geographic Markets. Following notice, Proposed Respondent may not complete such an acquisition until after it has provided any information requested by the Commission during a specified waiting period. This provision does not restrict the Proposed Respondent's construction of new supermarket facilities on its own; nor does it restrict the Proposed Respondent from leasing facilities not operated as supermarkets within the previous six (6) months.

The proposed consent order also prohibits the Proposed Respondent, for ten (10) years, from entering into or enforcing any agreement that restricts the ability of any acquirer of any supermarket, leasehold interest in a supermarket, or interest in any retail location used as a supermarket within Okaloosa, Santa Rosa or Walton counties in Florida; Hancock, Harrison, Jackson or Lauderdale counties in Mississippi; St. Tammany Parish, Louisiana; or Mobile County, Alabama on or after January 1, 2000, to operate a supermarket at that site if such supermarket was formerly owned or operated by the Proposed Respondent. In addition, the Proposed Respondent may not remove fixtures or equipment from a store or property owned or leased in these counties that is no longer in operation as a supermarket, except (1) prior to a sale, sublease, assignment, or change in occupancy, (2) to relocate such fixtures or equipment in the ordinary course of business to any other supermarket owned or operated by Proposed Respondent, or (3) otherwise with the prior approval of the Commission.

The Proposed Respondent is required to provide to the Commission a report of compliance with the consent order beginning one (1) year from the date the proposed consent order becomes final and annually for each of the following nine (9) years.

V. Opportunity for Public Comment

The proposed consent order has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed consent order and the comments received and will decide whether it should withdraw from the agreement or make the proposed consent order final.

By accepting the proposed consent order subject to final approval, the Commission anticipates that the competitive problems alleged in the complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed consent order to aid the Commission in its determination of whether to make the proposed consent order final. This analysis is not intended to constitute an official interpretation of the proposed consent order nor is it intended to modify the terms of the proposed consent order in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 01–1167 Filed 1–12–01; 8:45 am]

BILLING CODE 6750–01–M

GENERAL SERVICES ADMINISTRATION/DEPARTMENT OF STATE

Office of Communications; Cancellation of an Optional Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The Department of State is cancelling the following Optional Form because of low usage:

OF 298, Interagency Foreign Service National Employee Position Description.

DATES: Effective January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: January 3, 2001.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 01–1210 Filed 1–12–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards and Security.

Time and Date: 8:30 a.m. to 5 p.m., February 1, 2001 or ; 8:30 a.m. to 2 p.m., February 2, 2001.

Place: Room 705A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open.

Purpose: The purpose of this hearing is to monitor to the progress of implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act (HIPAA) and identified issues that need to be addressed to insure successful implementation. Specific hearing topics for the first day include: the Designated Standard Maintenance Organization's change process; data and transaction standard issues identify by the Healthcare Industry to date; Institutional Provider NDC code set concerns; and a status report from the standard developers on digital/electronic signature standards. The second half-day session will include a discussion of the Subcommittee's next steps related to Patient's Medical Record Information standards and the annual NCVHS report to Congress on HIPAA Administrative Simplification implementation progress.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card will have to have the guard call for an escort to the meeting.

CONTACT PERSON FOR MORE INFORMATION: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from J. Michael Fitzmaurice, Ph.D., Senior Science Advisor for Information Technology, Agency for Health Care Research and Quality, 2101 East Jefferson Street, #600, Rockville, MD 20852, phone: (301) 594–3938; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS website: *http://www.ncvhs.hhs.gov/* where an agenda for the meeting will be posted when available.

Dated: January 8, 2001.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 01–1188 Filed 1–12–01; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1679]

Draft Compliance Policy Guidance for FDA Employees and Industry on Blood Donor Incentives; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft compliance policy guidance entitled "Sec. 230.150 Blood Donor Incentives." The draft guidance is intended to provide guidance to FDA employees and industry for evaluating blood donor incentives that may consist of cash or other incentives.

DATES: Submit written comments on the draft guidance by March 19, 2001. General comments on agency guidance documents may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. You may fax your request to 301–827–0852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1242.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 13, 1978 (43 FR 2142), FDA published a final rule requiring that blood and blood products intended for transfusion include a statement on the labels that indicated whether the products were collected from paid or volunteer donors. This labeling requirement appears at § 606.121(c)(5) (21 CFR 606.121(c)(5)). The regulation defines a "paid donor" as a person who receives monetary payment for a blood donation (§ 606.121(c)(5)(i)). A volunteer donor is a person who does not receive monetary payment for a blood donation (§ 606.121(c)(5)(ii)). The regulation also defines certain benefits that do not constitute monetary payment. Those benefits, described in § 606.121(c)(5)(iii), include time off from work, membership in blood assurance programs, and cancellation of non-replacement fees, as long as the benefits are not readily convertible to cash. Products collected from blood donors who have received such incentives may be labeled with the "volunteer donor" classification statement.

The requirement that the label of a blood product indicate whether the product came from a volunteer or a paid donor applies only to blood and blood components intended for transfusion. It does not apply to products that will be used for further manufacturing, such as Source Plasma.

If the donor receives an incentive other than cash, the incentive must be evaluated to determine if it is readily convertible to cash. The draft guidance document provides FDA employees and industry with some examples of incentives and identifies some factors to consider when determining whether an incentive is readily convertible to cash. The draft guidance advises FDA employees that they may cite deviations from blood and blood product labeling requirements on Form FDA 483 (inspectional observations).

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on blood donor incentives. The draft guidance is not intended for implementation at this time. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's) which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This draft guidance document is being issued as Level 1 guidance consistent with GGP's.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by March 19, 2001. Submit to the contact person (address above) written comments regarding this draft guidance after March 19, 2001. Such comments will be considered when the draft guidance is finalized. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons interested in obtaining a copy of the draft guidance on the Internet may access the draft at http://www.fda.gov/ora/compliance_ref/cpg/default.htm.

Dated: January 5, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–1127 Filed 1–12–01; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4633–N–01]

Revisions to PHA Project-Based Assistance Program; Initial Guidance

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The HUD Appropriations Act for Fiscal Year 2001 amends the existing laws that govern the amount of tenant-based housing choice voucher funding that may be used for project-based assistance. HUD plans to issue a rule revising the project-based program regulations at 24 CFR part 983 in accordance with the new law. However, many of the statutory changes do not involve or require agency discretion on implementation of the new law, and are immediately effective. This notice provides guidance to public housing agencies (PHAs) and other interested members of the public on those provisions that are effective immediately, and identifies statutory changes that require further rulemaking.

FOR FURTHER INFORMATION CONTACT: Gerald J. Benoit, Office of Public and

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Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4210, Washington, DC 20410; telephone (202) 708–0477 (this is not a toll-free number). Persons with hearing or speech impairments may access these numbers via TTY by calling the Federal Information Relay Service at (800) 877–8339.

Rod Solomon, Deputy Assistant Secretary for Policy, Program and Legislative Initiatives, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4116, Washington, DC 20410; telephone (202) 708–0713 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

Introduction

On October 27, 2000, the President signed into law the Fiscal Year 2001 Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act (Pub. Law 106–377, 114 Stat. 1441) ("Appropriations Act"). Section 232 of the Appropriations Act substantially revises the provisions of the U.S. Housing Act of 1937 that govern the authority of a PHA to designate a portion of its available tenant-based voucher funds for project-based assistance (see 42 U.S.C. 1473f(o)(13) (as amended by "Section 232" of the Appropriations Act). The Conference Report on the Appropriations Act stated that the statutory changes to the project-based voucher program are intended to make project-basing of voucher assistance more flexible.

Consistent with legislative intent, it is also HUD's objective to make the project-based voucher program more flexible and more workable, and to help PHAs, owners, and eligible families in need of housing take immediate advantage of the new statutory features.

This notice provides information on the requirements of the new law for eligible families, PHAs, owners and other interested members of the public. The notice identifies which elements of the new project-basing law are effective immediately, and states how the law is to be implemented pending issuance of revised program regulations. The notice also identifies elements of the new law that must be implemented by rulemaking.

Section I: Important Changes to the Project-Based Program

The important changes made by section 232 of the Appropriations Act to the project-based program include:

• *Existing housing.* Prior law granted a PHA authority to project-base a portion of its available tenant-based funding only for (1) newly constructed units, or (2) rehabilitated units. Section 232 provides that a PHA may also use tenant-based funding to attach assistance to existing units.

• *Percent limit.* Under prior law, the number of units that a PHA could project-base was capped at the number supported by 15 percent of the total funding available to the PHA under its consolidated Annual Contributions Contract (ACC) for tenant-based assistance. The new law raises this cap to 20 percent of the funding available, and consequently to 20 percent of the baseline number of units in the PHA's voucher program. A PHA may now utilize funding for project-basing up to this new percent limit.

• *PHA Plan and deconcentration goals.* The new law integrates the project-based voucher option with the PHA Plan requirements. A PHA may enter into a housing assistance payments (HAP) contract to provide project-based voucher assistance only if the HAP contract is consistent with the PHA Plan (see 42 U.S.C. 1437c–1, implemented at 24 CFR part 903). Consistency with the PHA Plan means that there are circumstances indicating that project-basing of the units, rather than tenant-basing of the same amount of assistance, is an appropriate option. In addition, project-basing must be consistent with the statutory goals of "deconcentrating poverty and expanding housing and economic opportunities."

• *Partially assisted buildings.* The new law places a new cap of 25 percent on the number of dwelling units in any one building that may have project-based voucher assistance. However, the following types of housing are exempt from this cap: project-based dwelling units in single family properties and dwelling units specifically for elderly families, disabled families (as defined in 5 CFR 5.403(b)), or families receiving supportive services.

• *Family choice to move with continued assistance.* The family choice requirement has two components, a "mobility" component and a "continued assistance" component.

• *Mobility.* The HAP contract must provide that a family may move out of a project-based unit after 12 months.

• *Continued assistance.* If a family moves out of its project-based unit at any time after the first year of assisted occupancy, the PHA must offer the family available tenant-based rental assistance, either under the voucher program or under another comparable form of tenant-based assistance as will be defined in HUD regulations. Such alternative tenant-based assistance must be comparable to assistance under the voucher program in terms of income, assistance, rent contribution, affordability and other requirements.

• *Contract term.* HUD's present regulations only permit a PHA to provide project-based assistance within funding currently available under the ACC. Since voucher funding has recently been provided in one-year increments, PHAs have been permitted to enter into HAP contracts for the same period. Section 232 provides that the HAP contract between the PHA and the owner may be for a term of up to 10 years, although payments under that contract are subject to the future availability of appropriations and future availability of funding under the ACC.

• *Extension of contract term.* Section 232 revised the former statutory provision on extension of the HAP contract term (former 42 U.S.C. 1437f(o)(13)(B)). The new law provides that the PHA may contract with the owner of a project-based unit to extend the term of the HAP contract for such period as the PHA determines appropriate to achieve long-term affordability of the housing or to expand housing opportunities. All HAP contract extensions, however, must be contingent upon the future availability of appropriated funds.

• *Maximum initial gross rent, rent to owner and rent adjustments.* The new law provides that the HAP contract shall establish gross rents that do not exceed 110 percent of the established Fair Market Rent ("FMR"), or any HUD-approved "exception payment standard" (*i.e.*, a payment standard amount (for the PHA's tenant-based voucher program) that exceeds 110 percent of the published FMR) for the area where the project is located. In addition, if a unit has been allocated a low-income housing tax credit under the Internal Revenue Code of 1986 at 26 U.S.C. 42, but is not located in a "qualified census tract" under that law, the rent to owner may be established at any level that does not exceed the rent charged for comparable units in the same building that receive the tax credit but do not have additional rental assistance.

The new law provides that a HAP contract between the PHA and an owner must provide for adjustments of rent to owner during the contract term, and the adjusted rents must be reasonable in comparison with rents charged for comparable units in the private, unassisted local market. The statutory maximum rent limits apply both to the establishment of the initial rent to owner (as defined in 24 CFR 982.4) at the beginning of the HAP contract term, and to adjustments of rent to owner during the HAP contract term.

Within the limitations mentioned above, the initial gross rent to owner may differ from payment standard amounts for the PHA's tenant-based voucher program. However, just as in the regular tenant-based program, and in the project-based program under prior law, the initial and adjusted rent to owner must be reasonable in relation to rents charged in the private market for comparable unassisted units (see 42 U.S.C. 1437(f)(o)(10)(A), 24 CFR 982.507, and the "reasonable rent" element of SEMAP, 24 CFR 985.3(b)).

• *Tenant selection.* Section 232 revises and substantially codifies the tenant selection process for project-based voucher units. The new law states that the PHAs may place applicants referred by owners on the PHA's waiting list in accordance with the PHA's local waiting list policies and selection preferences.

As under the current program regulations, a PHA may not penalize applicants who reject an offer of a project-based unit or who are rejected by the owner of the housing. The PHA must maintain such applicant in the same position on the tenant-based assistance list as if an offer had not been made. In accordance with existing admission requirements, PHAs may establish selection preferences for project-based units that are consistent with the selection preferences in the PHA Plan.

As under the current program regulations, the PHA may elect to establish a separate waiting list for project-based voucher assistance, or to use a single common list for admission to the PHA's tenant-based and project-based assistance programs. If the PHA chooses to maintain a separate waiting list for project-based units, all PHA tenant-based assistance waiting list families who want project-based units must be permitted to place their names on the separate list.

The new law provides that admission to the project-based voucher program is subject to the same statutory income targeting requirement as the tenant-based program (42 U.S.C. 1437n(b)), instead of the individual project income targeting requirement that applies to other Section 8 project-based assistance (42 U.S.C. 1437n(c)(3)). The income targeting requirement provides, in general, that in any PHA fiscal year, at least 75% of the families admitted to a PHA's voucher program (which would include project-based voucher assistance) must be families whose annual income does not exceed 30 percent of median income for the area, as determined by HUD (see HUD definition of "extremely low income families" at 24 CFR 5.603).

• *Unit inspection and housing quality standards.* Units assisted with tenant-based or project-based voucher assistance must meet or exceed housing quality standards (HQS) established by HUD (42 U.S.C. 1437f(o)(8)). Section 232 states that the same HUD-prescribed HQS standards apply to project-based voucher assistance as apply to tenant-based voucher assistance (42 U.S.C. 1437f(o)(13)(F)).

Before and during the term of assistance, units are inspected for compliance with the HQS. In general, the same statutory PHA inspection requirements apply to project-based voucher assistance as to the tenant-based voucher program (42 U.S.C. 1437f(o)(8) and 1437f(o)(13)(F)). As in the tenant-based voucher program, a PHA must inspect 100 percent of project-based voucher units before entering into the HAP contract, and may only enter into a HAP contract for units that fully comply with the HQS. There is, however, a change in the annual HQS inspection requirements for the project-based voucher program. In the tenant-based program—where each unit is assisted under a separate HAP contract for each individual assisted family—the PHA must inspect each assisted unit annually. The new law provides that in the project-based voucher program, a PHA is not required to inspect each assisted unit in a project annually, thus allowing annual inspection of a representative sample of the project-based voucher units in a project.

• *Vacant units.* The new law permits a PHA, at its discretion, to continue providing assistance for a unit that becomes vacant (after commencement of assisted occupancy by a family) for up to a maximum of 60 days. Such payments may only be made if the vacancy is not the fault of the owner, and the owner takes "every reasonable action" to minimize the likelihood and extent of vacancies.

Section II. New Statutory Provisions That Are Non-Discretionary and Effective Immediately

This section provides guidance regarding implementation of provisions on project-basing in Section 232 of the Appropriations Act that are immediately effective. Except where this notice specifies otherwise, the present project-based regulations at 24 CFR part 983 continue to apply to newly constructed and substantially rehabilitated housing and now also apply to existing housing. Upon determination of good cause and subject to statutory limitations, HUD may waive any provision of this notice and the applicable project-based regulations in accordance with 5 CFR 5.110. Nothing in this notice affects the rights of owners and participants under existing contracts in HUD's Section 8 project-based certificate program. In the event of changes to this notice in future rulemaking concerning the project-based voucher program, HUD will take into account actions taken in compliance with this notice.

• *Authorization to provide project-based vouchers for existing housing.* Consistent with the project-based statute before amendment by Section 232, present regulations at 24 CFR part 983 only authorize project-based voucher assistance for newly constructed or rehabilitated units. Section 232 now also authorizes project-based assistance for existing housing. In accordance with the new law, a PHA may now enter HAP contracts that attach project-based voucher assistance to existing housing units that fully meet the housing choice voucher program HQS (see 24 CFR 982.401) but that would not have qualified for project-basing as newly constructed or rehabilitated units.

A housing unit will be considered an "existing unit" for purposes of the project-based voucher program if, at the time of the PHA's written notice of selection of the project for project-based assistance, the units require a maximum expenditure of less than $1,000 per assisted unit (including the unit's prorated share of any work to be accomplished on common areas or systems) to comply with the HQS.

A. Inapplicability of Certain Current Part 983 Regulations to New Commitments of Project-Based Vouchers

24 CFR 983.3 (c) and (d) of the present regulation, which are designed to assure that commitments of project-based assistance do not exceed amounts currently appropriated and available under the ACC, are inapplicable because the new law authorizes PHAs to enter into project-based HAP contracts for up to ten years, subject to the future availability of appropriations. In addition, the maximum percentage limit for project-based assistance has been raised to twenty percent of the baseline number of units in the PHA's voucher program.

24 CFR 983.4, HUD review of PHA plans to attach assistance to units, is inapplicable.

24 CFR 983.9(a) implemented the prior statutory prohibition of project-based assistance for units to be

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constructed or rehabilitated with U.S. Housing Act funds. This requirement is eliminated in the new law. Consequently section 983.9(a) is no longer applicable.

24 CFR 983.151(b) and (c), on term and renewal of HAP contracts, have been modified as described in this notice. The maximum potential term is now 10 years, subject to the future availability of appropriations and future availability of funding under the PHA's ACC. The PHA will determine the initial HAP contract term. The new law allows PHAs to determine the appropriate period for an extension, whereas previously (within the constraints imposed by available funding under a current ACC), HUD decided whether and for what period to approve renewals of expiring HAP contracts.

24 CFR 983.203(a)(6) is inapplicable, and 983.203(d)(3)'s declaration that a family that moves does not have any right to continued assistance is inapplicable.

B. Inapplicability of Certain Current Regulations to Project-Based Assistance for Housing in Existing Structures

The provisions of the present regulation that restrict assistance to newly constructed or rehabilitated units (see 24 CFR 983.7(b)(1) and (2)) do not apply to project-based voucher assistance for housing in an existing structure in accordance with Section 232 and this notice. In addition, the following regulatory provisions of 24 CFR part 983 do not apply to project-based assistance for housing in an existing structure:

Site and neighborhood standards at § 983.6;

- Rehabilitation requirements at section 983.8;
- Requirements for minimizing displacement because of rehabilitation in section 983.10(a);
- Subpart B—Owner Application Submission to Agreement, except 24 CFR 983.51, which is discussed further below; and
- Subpart C—Agreement and New Construction or Rehabilitation Period, except the provisions of paragraphs 983.103(d) regarding notification of vacancies and 983.104(c) regarding inspection to meet HQS.
- *Unit selection policy, advertising, and owner application requirements for existing housing with assistance attached to 25 percent or fewer of the units in a building.* For existing housing developments in the project-based voucher program, which have assistance attached to no more than 25 percent of the development's units, the PHA must advertise the availability of the project-based assistance. Such advertisements must meet standards comparable to those in 24 CFR 983.51(b); otherwise, section 983.51 does not apply to these projects.

Specifically, the PHA must advertise in a newspaper of general circulation that the PHA will accept applications for assistance for existing housing projects. The advertisement must be published once a week for three consecutive weeks; specify an application deadline of at least 30 days after the date the advertisement is last published; specify the number of units the PHA estimates that it will be able to assist under the funding the PHA is making available for this purpose; and state that only applications submitted in response to the advertisement will be considered. The PHA advertisement must also state the PHA's selection policies. In all cases, PHAs must maintain documentation of responses to advertisements or competitive proposals received in response to the PHA notice.

For existing housing developments with more than 25 percent project-based units (*i.e.*, at this time, for the elderly and special populations only, since the supportive services exception to the 25% cap is not implemented in this notice), and for newly constructed or rehabilitated units, the PHA must establish policies for public advertisement and competitive selection of units to be assisted with project-based voucher assistance. 24 CFR 983.51 is applicable.

C. 20 Percent Limit

Section 232 requires PHAs that participate in the project-based voucher program to comply with the statutory language that states that "[n]ot more than 20 percent of the funding available for tenant-based assistance under this section that is administered by the [public housing] agency may be attached to structures pursuant to this paragraph" [bracketed material added]. This language supersedes 24 CFR 983.3(b), and is effective immediately. Therefore, the total cumulative number of project-based units, including units previously placed under AHAP or HAP in the PHA's project-based certificate program, may not exceed 20 percent of the baseline number of units in the PHA's voucher program.

D. Consistency With PHA Plan

Until HUD issues further instructions, PHAs submitting PHA Plans that wish to use the project-based voucher program (as revised by Section 232) must include—as a required attachment to the PHA Plan template—a statement of the projected number of project-based units and general locations and how project basing would be consistent with their PHA Plans. If a PHA wishes to use the project-based voucher program before the anticipated approval date of the PHA's next PHA Plan, the PHA may do so by adding the information as an amendment to the PHA Plan and following the regulations and notices for such PHA Plan amendments.

As with all programs that are covered by the PHA Plan, the program must be carried out in conformity with the nondiscrimination requirements specified in the PHA Plan regulations, and must affirmatively further fair housing as required by the PHA Plan regulations.

E. Consistency With the Goals of Deconcentrating Poverty and Expanding Housing and Economic Opportunities

Section 232 requires, in addition to consistency with the PHA Plan, that a contract for project-basing under the voucher program be consistent with the goals of deconcentrating poverty and expanding housing opportunities. Until HUD issues further instructions, HUD will implement the deconcentration of poverty requirements in Section 232 by requiring that all new project-based assistance agreements or HAP contracts be for units in census tracts with poverty rates of less than 20 percent, unless HUD specifically approves an exception.

F. Partially Assisted Building Requirement

A PHA may not enter into an agreement or HAP contract or other binding commitment to provide project-based voucher assistance for more than 25 percent of the units in any one building, except for single-family dwellings and projects for elderly families and disabled families.

HUD is not implementing through this notice the exception for buildings for families receiving supportive services. HUD will address that exception through rulemaking, which will define "supportive services." In accordance with existing program usage, single family dwellings refer to 1–4 family dwellings.

If the PHA had entered into an agreement for project-based units prior to the effective date of this notice, section 232 provides that such buildings may have the assistance extended or renewed, notwithstanding this section on partially assisted buildings, 42 U.S.C. 1437f(o)(13)(D), as amended by the Appropriations Act.

G. Family Choice to Move With Continued Assistance

The new law provides that assisted families may move from the assisted building, and retain federal housing assistance. For the continued assistance option, Section 232, similar to existing 24 CFR 983.206(d)(2), requires for new HAP contracts that the owner permit the assisted tenants to move from the housing at any time after the family has occupied the dwelling unit with project-based voucher assistance for 12 months.

The law now provides that the PHA must provide the family with housing choice voucher assistance or such other tenant-based rental assistance that is subject to comparable income, assistance, rent contribution, affordability and other requirements. HUD will set the standards as to what may qualify as comparable assistance by regulation, but, for new HAP contracts incorporating this requirement, the PHA must in the interim use voucher assistance available under the ACC to provide tenant-based assistance for the family. If no such assistance is available at the time the family moves, the PHA must give the family priority to receive the next available tenant-based voucher. Vouchers under funding allocations targeted by HUD for special purposes (*e.g.*, family unification, mainstream disabled) are not available for this purpose, since they are required to be used only for the targeted purpose.

H. HAP Contract Term

The new law provides that, for HAP contracts entered after the effective date of the law, a HAP contract between a PHA and an owner of housing under this program may have a duration of up to 10 years (as determined by the PHA), subject to the future availability of sufficient appropriated funds under the PHA's consolidated ACC with HUD.

Upon expiration of the HAP contract term, the new law provides that the PHA may agree with the project-based housing owner to extend the HAP contract for such period as the PHA determines appropriate to expand housing opportunities (as well as an extension to assure long-term affordability of the housing, as provided under prior law). All HAP contract extensions must be contingent upon the future availability of appropriated funds.

I. Rent Limits

The new law provides that the HAP contract shall establish gross rents (rent to owner plus the allowance for tenant-paid utilities) that do not exceed 110 percent of the established Fair Market Rent ("FMR"), or any HUD-approved "exception payment standard" (*i.e.*, a payment standard amount that exceeds 110 percent of the published FMR) for the area where the housing is located.

If a unit has been allocated a low-income housing tax credit under the Internal Revenue Code of 1986 at 26 U.S.C. 42, but is not located in a "qualified census tract" as defined in the law, the rent to owner may be established at any level that does not exceed the rent charged for comparable units in the same building that receive the tax credit but do not have additional rental assistance.

Within the limitations mentioned above, the initial rent to the owner may differ from payment standard amounts in the payment standard schedule adopted for the PHA's tenant-based voucher program. However, just as in the regular tenant-based program and the project-based program under prior law, the initial and adjusted rent to owner must be reasonable in relation to rents charged in the private market for comparable unassisted units (see 42 U.S.C. 1437(f)(o)(10)(A).

J. Rent Adjustments During the Term of the HAP Contract

Section 232 provides that a housing assistance payments contract for project-based voucher assistance shall provide for rent adjustments and that the adjusted rent for any assisted unit shall be reasonable in comparison with rents charged for comparable dwelling units in the private, unassisted local market and may not exceed the maximum rent limits permitted under the statutory limitations summarized above. Determination of whether rent is reasonable in relation to comparable units shall be governed by 24 CFR 983.256.

The annual rent adjustment provisions at 983.254 and the special rent adjustment provisions at 983.255 shall only be applicable if the AHAP with the owner was executed before the effective date of this notice. These annual and special adjustment regulatory provisions do not apply to project-based assistance for existing housing pursuant to this notice, and do not apply if the Agreement for newly constructed or rehabilitated housing was executed on or after the effective date of this notice.

K. Family Share of Rent and Housing Assistance Payment

The housing assistance payment is calculated in accordance with 24 CFR 983.260 as the gross rent minus the total tenant payment. The family share is calculated in accordance with 24 CFR 983.261 by subtracting the amount of the HAP from the gross rent.

L. Tenant Selection

The PHA selection system for project-based units must comply with the requirements specified below, which in most respects (except for the income targeting provision) are a codification of present regulatory and contractual requirements:

- Income targeting. The requirements of 42 U.S.C. 1437n(b) and 24 CFR 982.201(b)(2) govern the selection of eligible families for this program, and generally provide that not less than 75 percent of families admitted annually to the PHA's combined tenant-based and project-based voucher program shall be families whose incomes do not exceed 30 percent of the area median, as determined by HUD.
- Applicants may only be selected from the PHA waiting list.
- A PHA may only maintain a separate project-based waiting list if all PHA tenant-based assistance applicants who seek project-based housing can be placed on this list upon request and without penalty to any other application for assisted housing they may have pending. Subject to its waiting list policies and selection preferences specified in the PHA administrative plan, the PHA may place a family referred by an owner of project-based voucher units on its waiting list.

If a PHA chooses to establish a separate waiting list for project-based assistance, the PHA must give all applicants currently on its waiting list for tenant-based assistance the opportunity to also have their names placed on the waiting list for project-based assistance in accordance with the PHA's established selection policies.

- As in the current project-based program, the PHA must refer families to housing units from the waiting list according to its regular applicant selection policies. If an applicant does not rent a unit with project-based assistance, or the owner turns an applicant down for admission to a project-based unit, the applicant may not be removed from the PHA's tenant-based assistance waiting list for that reason but must maintain its position on the list as though no offer of housing had been made.

Vacant units. A HAP contract must be in a form prescribed by HUD. The PHA may enter into such a contract that agrees to provide vacancy payments up to 60 days after a unit becomes vacant, in an amount not to exceed the rent to the owner as provided by the HAP contract on the day the family vacated.

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The PHA may only make such payments for a vacant unit if:

(1) The vacancy was not the owner's fault, and

(2) The PHA and owner take action to minimize the likelihood and length of any vacancy.

Reduction of contract units after vacancy. Except for units for which an AHAP was executed before the effective date of this notice, the new law supersedes 24 CFR 983.152(b) and (c). Instead, the following provisions apply:

If no eligible family rents a vacant unit within 120 days (commencing on the first day of the month when the vacancy occurs), the PHA may terminate its commitment to make any additional housing assistance payments for the unit for the balance of the HAP contract term. The PHA may use the amounts so saved to provide other voucher assistance.

The policy guidance and implementation directives of this notice remain in effect until the new project-based voucher changes in law have been fully implemented through a new regulation. HUD will endeavor to answer any questions PHAs may have that arise that are not anticipated in this notice.

HUD will soon issue a new required tenancy addendum and HAP contract for the project-based voucher program as implemented by this notice.

Dated: January 8, 2001.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 01–999 Filed 1–12–01; 8:45 am]

BILLING CODE 4210–33–P

INTER-AMERICAN FOUNDATION BOARD MEETING

Sunshine Act Meeting

TIME AND DATE: January 30, 2001, 10 a.m.–3 p.m.

PLACE: 901 N. Stuart Street, Tenth Floor, Arlington, Virginia 22203.

STATUS: Open session except for the portion specified as closed session as provided in 22 CFR Part 1004.4 (f).

MATTERS TO BE CONSIDERED:

- Approval of the Minutes of the November 30, 2000, Meeting of the Board of Directors
- Interim President's Report
- Congressional Activities and Plans for Fiscal Year 2001
- Expansion of the Advisory Council
- Review of Business Sector Participation in Foundation Grants
- Presentation of the Foundation's Results System and Indicators
- Review of a Sample of Successful Closed-Out Grants
- Closed Session To Discuss Personnel Issues. Closed session as provided in 22 CFR Part 1004.4 (f)

CONTACT PERSON FOR MORE INFORMATION: Carolyn Karr, General Counsel, (703) 306–4350.

Dated: January 11, 2001.

Carolyn Karr,

General Counsel.

[FR Doc. 01–1335 Filed 1–11–01; 12:49 pm]

BILLING CODE 7025–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Mud Island Addition to Wyandotte National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The Director of the U.S. Fish and Wildlife Service approved the expansion of the Wyandotte National Wildlife Refuge by accepting the donation of Mud Island, located in the Detroit River, adjacent to Ecorse, Michigan.

DATES: This action was effective on January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Thomas J. Larson, Chief, Ascertainment and Planning Branch, U.S. Fish and Wildlife Service, BHW Federal Building, 1 Federal Drive, Fort Snelling, MN 55111–4056. Telephone 612–713–5430

SUPPLEMENTARY INFORMATION: The authority to accept donation of real property is contained in the Fish and Wildlife Act of 1956 (16 U.S.C. 742f) as amended.

Mud Island will contribute toward the ecosystem goals of the Service by preserving valuable aquatic shoals for the benefit of migratory waterfowl, especially diving ducks, and potential spawning habitat for the lake sturgeon.

Based on the information contained in the decision document, a Categorical Exclusion was signed on November 30, 2000, by the Regional Director. We will expand the Wyandotte National Wildlife Refuge by accepting the donation of Mud Island.

Dated: January 5, 2001.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service, Washington, DC.

[FR Doc. 01–1181 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Application for Approval

The following applicant has applied for approval to conduct certain activities with birds that are protected in accordance with the Wild Bird Conservation Act of 1992. This notice is provided pursuant to Section 112(4) of the Wild Bird Conservation Act of 1992, 50 CFR 15.26(c).

Applicant: Mr. Jerry Jennings, Fallbrook, California, on behalf of the Toucan Preservation Center (CB006). The applicant wishes to amend approved cooperative breeding program CB006 to include Green aracari (*Pteroglossus viridis*), Black-necked aracari (*Pteroglossus aracari*), and Blue-headed macaw (*Ara couloni*). The Toucan Preservation Center maintains responsibility for oversight of this program.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with this application are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act,* by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: January 10, 2001.

Andrea Gaski,

Chief, Branch of CITES Operations, Division of Management Authority.

[FR Doc. 01–1246 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–090–01–1020PG]

Notice of Meeting

AGENCY: Lower Snake River District, Bureau of Land Management, Interior.

ACTION: Meeting notice.

SUMMARY: The Lower Snake River District Resource Advisory Council will meet in Boise. Potential agenda topics are off highway vehicle use, sage grouse habitat management, wild horse roundup and adoption and other resource management issues.

DATES: February 14, 2001. The meeting will begin at 9 a.m. Public comment periods will be held at 9:30 a.m. and 3:30 p.m.

ADDRESSES: The meeting will be held at the Lower Snake River District Office, located at 3948 Development Avenue, Boise, Idaho.

FOR FURTHER INFORMATION CONTACT: Mary Jones, Lower Snake River District Office (208–384–3305).

Dated: January 2, 2001.

Daryl L. Albiston,

Acting District Manager.

[FR Doc. 01–1130 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–66–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–025–1430–EU: G–01–0070]

Realty Action: Partial Cancellation of Sale of Public Land in Harney County, OR

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Partial cancellation of Notice of Realty Action—Sale of public land.

SUMMARY: The Notice of Realty Action—Sale of Public Land in Harney County, Oregon, published in the **Federal Register**, Volume 65, No. 222, on November 16, 2000, on Pages 69327–69329 is hereby cancelled as it relates to the sale of the following parcel only:

OR–55327—W.M., T. 27 S., R. 35E., Sec. 7, Lots 3, 4, NE¼SW¼; Sec. 18, Lots 1,2.

On December 19, 2000, in response to the Notice of Realty Action, a protest was filed concerning the sale of Parcel No. OR–55327. The parcel is being withdrawn from sale pending review of the merits of the protest. Upon resolution of the protest the parcel may be included in future offerings. All other provisions of the Notice of Realty Action remain in effect.

On January 16, 2001 this notice also opens the land to the discretionary land laws which include leases, licenses, permits, rights-of-way, and disposal of mineral or vegetative resources other than under the mining laws.

ADDRESSES: Comments should be submitted to the Three Rivers Resource Area Field Manager, HC 74–12533 Hwy 20 West, Hines, Oregon 97738.

FOR FURTHER INFORMATION CONTACT: Detailed information concerning this sale cancellation is available from Holly LaChapelle, Land Law Examiner, Three Rivers Resource Area at the above address, phone (541) 573–4501.

Dated: January 4, 2001.

Craig M. Hansen,

Three Rivers Resource Area Field Manager.

[FR Doc. 01–1129 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Lake Cascade Resource Management Plan; Draft Environmental Assessment

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public hearings.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Department of the Interior, Bureau of Reclamation (Reclamation) has prepared a draft environmental assessment (Draft EA) to evaluate alternatives to update the Lake Cascade Resource Management Plan (RMP). The updated RMP will serve as a blueprint for the future use, management, and site development of Reclamation lands and resources at the reservoir for the next 10 years.

DATES: Public hearings are scheduled from 7:30 to 9:30 p.m. on January 31, 2001 in Boise, ID and on February 1, 2001 in Cascade, ID. The formal public hearings will be preceded by open houses from 6 to 7 p.m., and a presentation describing the project from 7 to 7:30 p.m. Written comments on the Draft EA will be accepted through February 22, 2001.

ADDRESSES: The public hearings will be held at the following locations:

Bureau of Land Management, 1387 S. Vinnell Way, Boise, ID

American Legion Hall, 105 E. Mill Street, Cascade, ID

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

FOR FURTHER INFORMATION CONTACT: Those wishing to obtain a copy of the Draft EA or schedule time in advance to make oral comments at the hearing(s) may contact Ms. Carolyn Burpee-Stone at (208) 378–5395. Persons requiring any special services at the public hearing should contact Ms. Connie Wensman at (208) 378–5317 or TDD #1–800–377–3529, by January 22, 2001.

SUPPLEMENTARY INFORMATION: Speakers will be called in order of their requests. Requests to comment may also be made at each hearing and speakers will be scheduled to follow the advance requests. Comments will be limited to 3 minutes and will be recorded by a court stenographer to be included in the hearing record.

A planning process that included Federal, State, and local governments, Tribes and the public in developing alternatives to update the 1991 Lake Cascade RMP has occurred over the past two years. The Draft EA evaluates three action alternatives that combine various levels of recreation development and resource conservation. The Preferred Alternative emphasizes balanced recreation development and natural resource management. In addition to the action alternatives, the No Action Alternative of continuation of existing management practices was also evaluated. The Draft EA is available for viewing on the internet at *http://www.pn.usbr.gov/project/rmp/cascade_pub/news.htm* .

Dated: January 5, 2001.

J. William McDonald,

Regional Director, Pacific Northwest Region.

[FR Doc. 01–1229 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Pick-Sloan Missouri Basin Program, Eastern and Western Division Proposed Project Use Power Rate

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of extension of time for comments concerning the proposed Pick-Sloan Missouri Basin Program, Eastern and Western Division, Project Use Power rate adjustment.

SUMMARY: The Bureau of Reclamation (Reclamation) is proposing a rate adjustment (proposed rate) for Project

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Use Power for the Pick-Sloan Missouri Basin Program (P–SMBP), Eastern and Western Division. The proposed rate for Project Use Power is to recover all annual operating, maintenance, and replacement expenses. The analysis of the proposed Project Use Rate is included in a booklet available upon request. The proposed rate for Project Use Power will become effective April 1, 2001.

This notice provides the opportunity for public comment. After review of comments received, Reclamation will consider them, revise the rates if necessary, and recommend a proposed rate for approval to the Commissioner of the Bureau of Reclamation.

DATES: The comment period is being extended with the publication of this notice in the **Federal Register**. To be assured consideration, please submit comments on or before February 26, 2001.

ADDRESSES: Written comments should be sent to Jim L. Wedeward, GP–2020, Power O&M Administrator, Bureau of Reclamation, P.O. Box 36900, Billings MT 59107–6900.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

All booklets, studies, comments, letters, memoranda, and other documents made or kept by Reclamation for the purpose of developing the proposed rate for Project Use Power will be made available for inspection and copying at the Great Plains Regional Office, located at 316 North 26th Street, Billings, Montana 59107–6900.

FOR FURTHER INFORMATION CONTACT: Jim L. Wedeward (406) 247–7705, Internet: jwedeward@gp.usbr.gov

SUPPLEMENTARY INFORMATION: Power rates for the P–SMBP are established pursuant to the Reclamation Act of 1902 (43 U.S.C. 371 *et seq.*), as amended and supplemented by subsequent enactments, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)) and the Flood Control Act of 1944 (58 Stat. 887).

Beginning April 1, 2001, Reclamation proposes to:

(a) increase the energy charge from 2.5 mills/kWh to 10.76 mills/kWh

(b) the monthly demand charge will remain at zero.

The Project Use Power rate will be reviewed each time Western Area Power Administration (Western) adjusts the P–SMBP Firm power rate. Western will conduct the necessary studies and use the methodology identified in this rate proposal to determine a new rate.

The existing rate schedule MRB–P10 placed into effect on November 1, 1986, will be replaced by rate schedule MRB–P11.

In compliance with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq;* Council on Environmental Quality Regulations (40 CFR Parts 1500–1508); and Reclamation's Regulations (10 CFR Part 1021), Reclamation has determined that this action is categorically excluded from the preparation of an Environmental Assessment or Environmental Impact Statement.

Dated: January 9, 2001.

Gerald W. Kelso,

Assistant Regional Director, Great Plains Region, Bureau of Reclamation.

[FR Doc. 01–1166 Filed 1–12–01; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–652 (Review)]

In the Matter of Aramid Fiber Formed of Poly Para-Phenylene Terephthalamide From The Netherlands; Notice of Commission Determination To Conduct a Portion of The Hearing in Camera

AGENCY: U.S. International Trade Commission.

ACTION: Closure of a portion of a Commission hearing.

SUMMARY: Upon request of foreign producer Twaron Products bv and importer Twaron Products, Inc. ("Twaron"), the Commission has determined to conduct a portion of its hearing in the above-captioned investigation scheduled for January 9, 2001, *in camera*. *See* Commission rules 207.24(d), 201.13(m) and 201.36(b)(4) (19 CFR 207.24(d), 201.13(m) and 201.36(b)(4)). The remainder of the hearing will be open to the public. The Commission has determined that the seven-day advance notice of the change to a meeting was not possible. See Commission rule 201.35(a), (c)(1) (19 CFR 201.35(a), (c)(1)).

FOR FURTHER INFORMATION CONTACT: Karen V. Driscoll, Office of General Counsel, U.S. International Trade Commission, telephone 202–205–3092, e-mail *kdriscoll@usitc.gov*. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Commission's TDD terminal on 202–205–3105.

SUPPLEMENTARY INFORMATION: The Commission believes that Twaron has justified the need for a closed session. In this review, significant data for both the foreign and domestic industries are business proprietary. Twaron seeks a closed session in order to fully address the issues before the Commission without referring to business proprietary information. In making this decision, the Commission nevertheless reaffirms its belief that whenever possible its business should be conducted in public.

The hearing will begin with public presentations by E.I. DuPont de Nemours & Company ("DuPont"), domestic producer opposing revocation of the antidumping duty order, followed by foreign respondent Twaron in support of revocation. During the public session, the Commission may question the parties following their respective presentations. Next, the hearing will include a 20-minute *in camera* session for a confidential presentation by Twaron and for questions from the Commission relating to the BPI, followed by a 20-minute *in camera* rebuttal presentation by DuPont and questions from the Commission relating to the BPI. For any *in camera* session the room will be cleared of all persons except those who have been granted access to BPI under a Commission administrative protective order (APO) and are included on the Commission's APO service list in these investigations. See 19 CFR 201.35(b)(1), (2). The time for the parties' presentations and rebuttals in the *in camera* session will be taken from their respective overall time allotments for the hearing. All persons planning to attend the *in camera* portions of the hearing should be prepared to present proper identification.

Authority: The Assistant General Counsel for Antidumping and Countervailing Duty Investigations, acting for the General Counsel, has certified, pursuant to Commission Rule 201.39 (19 CFR 201.39) that a portion of the Commission's hearing in Aramid Fiber Formed of Poly Para-Phenylene Terephthalamide from the Netherlands, Inv.

No. 731–TA–652 (Review), may be closed to the public to prevent the disclosure of BPI.

By order of the Commission.

Issued: January 8, 2001.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–1221 Filed 1–12–01; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–444]

In the Matter of Certain Semiconductor Light Emitting Devices, Components Thereof, and Products Containing Same; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 15, 2000, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Rohm, Inc., of Japan. A supplement to the Complaint was filed on January 4, 2001. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain semiconductor light emitting devices, components thereof, and products containing same by reason of infringement of claims 1, 2, 4 and 6–45 of U.S. Letters Patent 6,084,899 and claims 1–5 and 9–23 of U.S. Letters Patent 6,115,399. The complaint further alleges that an industry in the United States exists and/or is in the process of being established as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

ADDRESSES: The complaint and supplement, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may be obtained by accessing its Internet server (*http://www.usitc.gov*).

FOR FURTHER INFORMATION CONTACT: Anne M. Goalwin, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2574.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR § 210.10 (2000).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on January 9, 2001, *Ordered That*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain semiconductor light emitting devices, components thereof, or products containing same by reason of infringement of claims 1, 2, 4, 6–44 or 45 of U.S. Letters Patent 6,084,899 or claims 1–5, 9–22 or 23 of U.S. Letters Patent 6,115,399, and whether an industry in the United States exists and/or is in the process of being established as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—

Rohm Co., Ltd., 21, Saiin Mizosaki-cho, Ukyo-ku, Kyoto, 615–8585, Japan

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Nichia Corporation, 491 Oka, Kaminaka-Cho, Anan, Tokushima, 774–8601, Japan

Nichia America Corporation, 3775 Hempland Road, Mountville, PA 17554

(c) Anne M. Goalwin, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, S.W., Room 401–P, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Sidney Harris is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR § 210.13. Pursuant to 19 CFR §§ 201.16(d) and 210.13(a), such responses will be considered by the Commission if received no later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and to authorize the administrative law judge and the Commission, without further notice to that respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against that respondent.

Issued: January 10, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–1222 Filed 1–12–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[A.G. Order No. 2353–2001]

Final Specification of Community Programs Necessary for Protection of Life or Safety Under Welfare Reform Legislation

AGENCY: Department of Justice.

ACTION: Notice of final order.

SUMMARY: This publication contains the final version of the Attorney General's Order that is issued pursuant to sections 401 and 411 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. The Order specifies the types of community programs, services, or assistance for which all aliens remain eligible. This publication also responds to comments submitted regarding the Order.

DATES: This Notice is effective January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Jessica Rosenbaum, Office of Policy

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Development, Department of Justice, 950 Pennsylvania Avenue, NW., Washington, DC 20530, telephone (202) 514–3737 for general information. For information regarding particular programs, contact the federal agency that administers the program.

SUPPLEMENTARY INFORMATION: On August 22, 1996, the President signed the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 ("Welfare Reform Act" or "the Act"). The Act, among other things, vests in the Attorney General the authority to specify certain types of community programs, services, or assistance for which all aliens remain eligible. Pursuant to the Act, the Attorney General issued an Order (AG Order No. 2049–96) ("the Order") implementing that authority, and making a "provisional specification" of such programs. The Order was published on August 30, 1996, at 61 FR 45985.

Under §§ 401 and 411 of the Act, aliens who are not "qualified aliens" (as defined in § 431 of the Act) are generally ineligible for federal, state, and local public benefits. However, there are a number of specified exceptions to those restrictions. Included in the list of statutory exceptions is a provision authorizing the Attorney General to identify programs, services, and assistance to which the Act's limitations on alien eligibility do not apply. Pursuant to §§ 401(b)(1)(D) and 411(b)(4), the Attorney General may specify only those types of programs, services, and assistance that meet all of the following three criteria: (1) Deliver in-kind services at the community level, including through public or private non-profit agencies; (2) do not condition the provision of assistance, the amount of assistance provided, or the cost of assistance provided on the individual recipient's income or resources; and (3) are necessary for the protection of life or safety. Any programs that are exempted under this provision of the Act must meet all three of the foregoing requirements. A program meeting only one or two of the criteria does not qualify for exemption under this section of the Act.

Discussion of Comments

On September 15, 1997, the Department published a notice requesting public comments on the Order (62 FR 48308). The comment period ended on November 14, 1997. The Department received 48 comments from a variety of sources including private, non-profit organizations, as well as city, state, and federal agencies. The Department also received four comments on the Order in response to the Attorney General's notice of proposed rule-making: "Verification of Eligibility for Public Benefits," which was published on August 4, 1998 (63 FR 41662). In developing this final Order, the Department of Justice also relied on the input of other appropriate federal agencies and departments. All comments have been considered in preparing this final Order. Any significant changes are discussed below.

Many commenters seemed to believe that unless the Attorney General exempted their program, they would be required to verify citizenship or immigration status of all applicants. While that is certainly true in some cases, a service provider should not assume that it must verify citizenship or immigration status simply because its program or service is not exempted by this Order. Service providers and other interested parties should refer to benefit-granting agencies' interpretations of the term "federal public benefit" as used in the Act in order to determine whether their program is a federal public benefit and therefore subject to the alienage restrictions of the Act. See, for example, the Department of Health and Human Services notice of interpretation of federal public benefit, 63 FR 41658 (Aug. 4, 1998) (identifying which of their programs provide "federal public benefits" subject to PRWORA's limitations on alien eligibility. HHS advises that HHS programs not listed in the notice, such as Community Health Centers, and HHS programs under the Ryan White CARE Act and the Older Americans Act, do not meet the statutory definition of "federal public benefit" and therefore do not have to verify the citizenship or immigration status of applicants or recipients under PRWORA.).

In the past, the Department of Justice has deferred to other benefit-granting agencies' interpretations of whether their programs fall within certain definitions under the Welfare Reform Act. *See, e.g.*, Department of Justice, Verification of Eligibility for Public Benefits, 63 FR 41662, 41664 (1998) (to be codified at 8 CFR pt. 104) (proposed Aug. 4, 1998) (in establishing proposed regulatory definition of "federal public benefit," Immigration and Naturalization Service intends to give "all appropriate deference to benefit granting agencies' application of the definition to the programs they administer"); Department of Justice, Interim Guidance on Verification of Citizenship, Qualified Alien Status and Eligibility under Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, 62 FR 61344, 61361 (1997) (directing interested parties with questions about the applicability of the Act to a benefit program to consult with the federal agency overseeing the program). Consistent with that practice, where commenters have raised questions about whether a particular program is a federal public benefit under the Act, the Department will grant all appropriate deference to the determination, if one has been made, by the benefit granting agency as to whether the program is a federal public benefit. Agencies and service providers should also note that section 432(d) of the Welfare Reform Act, which provides that nonprofit charitable organizations are not required to verify the immigration status of applicants for Federal, State, or local public benefits, may be applicable to their programs. For more information about this exemption, see Department of Justice, Verification of Eligibility for Public Benefits, 63 FR 41662, 41664 (1998) (to be codified at 8 CFR pt. 104) (proposed Aug. 4, 1998).

The majority of commenters emphasized the need for the Attorney General to exempt their particular services because they believed them to be necessary for the protection of life or safety. Many of those commenters, however, did not take account of the legal requirement that a program or service must satisfy all three prongs of the test set forth by Congress. Any service that is exempted by the Order not only must be necessary to protect life or safety and be delivered in-kind at the community level, but also must not condition the provision, amount, or cost of services on a client's income. With respect to the last requirement, in other words, if a state or community service provider charges fees that vary with the clients' income level, or determines the clients' eligibility for services based upon their income or ability to pay, the program at issue does not satisfy prong two of the test and therefore is not covered by the Order regardless of how necessary for life or safety the program, service, or assistance may be.

Twenty comments were received from community services providers, while the rest were from concerned citizens, members of Congress, and city, state, and federal agencies. Many comments addressed a variety of concerns, but more than twenty-eight concerned services provided to people with HIV/AIDS. The majority of those comments asked the Attorney General to exempt categorically all programs funded under the Ryan White CARE Act, Housing Opportunities for People Living with AIDS (HOPWA) and the McKinney Homeless Assistance Act due to the special nature of the AIDS epidemic. As already indicated, many of those programs may not be "federal public benefits" as determined by relevant benefit-granting agencies, and therefore an exemption under this Order is unnecessary. While the Act authorizes exemptions for "programs, services, or assistance" that meet the three-pronged test, the Attorney General has no authority to provide a blanket exemption for all programs authorized by a single statute. That is because one or more of those programs may fail to meet all of the requirements imposed by the statute. Agencies and service providers must assess each program individually to determine whether it meets the three-pronged test. While many, if not all, HIV/AIDS-related services are likely to meet the first and third prongs, any state or federally funded programs that are required as a condition of their funding to employ sliding scales, or that otherwise limit the access to services or the amount of such services according to a client's income or ability to pay would not qualify for exemption under the Attorney General's Order.

Thirteen comments were received concerning services for the elderly. The majority of those comments also sought categorical exemptions for services provided under a variety of statutes. Again, the Act does not give the Attorney General the authority to exempt groups of programs. For a program to be covered by the Order, it must meet all three prongs of the statutory test.

Twenty-three comments addressed the importance of shelter and safe housing. Those community programs cover a wide range of services from emergency shelter to lead paint abatement. While many shelter and housing programs are important to the protection of life or safety, each program must meet the requirements of the three-pronged test in order to be exempt under the Order. With respect to the specific issue of lead paint abatement programs, we note that HUD has determined that benefits under the Lead Hazard Control program are not federal public benefits within the meaning of section 401(c) of the Welfare Reform Act. In accordance with the Department's practice of deferring to the determinations of benefit granting agencies, we therefore note that there is no need to conduct any verification procedures with respect to the immigration status of individuals whose dwellings receive services under the Lead Hazard Control program. We therefore need not, at this time, consider whether such benefits should be exempted under section 401(b).

Nine comments emphasized the importance of access to health care in general. One commenter described health centers that have a sliding scale of costs for services. Such programs do not qualify for coverage under the Order as they fail to meet the prong of the Order related to means testing. However, another commenter explained that their health centers have a fundamental obligation to serve all patients regardless of their ability to pay. As stated above, where community-level health programs serve all eligible clients regardless of their ability to pay and do not administer any type of sliding scale fee schedule or other income or resource test, they are covered by the Attorney General's Order.

Some commenters argued that the administrative burden that would result from having to verify immigration status would outweigh any proposed savings that could be derived from denying benefits to unqualified aliens. It should be understood, however, that the decision to deny federal, state, and local public benefits to aliens not qualified to receive them was made by Congress. Title IV of the Act does provide several exceptions to this blanket denial, including the programs covered by this Order and an exception from verification for all non-profit charitable providers. See the Department of Justice, Proposed Rule, Verification of Eligibility for Public Benefits, 63 FR 41662, 41677 (Aug. 4, 1998). All programs and services covered by the Order are exempt from any requirement that verification be conducted, unless service providers are mandated to conduct such verification pursuant to federal, state, or local law other than the Welfare Reform Act.

A number of commenters sought clarification as to whether service providers were obligated to verify a benefit seeker's immigration status prior to providing services covered by the Order. The services exempted by the Order are one of several categories of services that were designated by Congress to remain available to all aliens regardless of their status as qualified or not qualified for welfare benefits. Accordingly, service providers are not obligated to verify immigration status before providing those services unless they are required to do so by a law other than the Welfare Reform Act.

The remaining comments addressed services to migrant farmers, the disabled, victims of domestic violence, child care, and mental health services. While all of those concerns are important to the protection of life or safety, each program must meet the requirements of the three-pronged test described above in order to be exempt under the Order.

Several providers of emergency shelter have expressed the concern that they may be barred from providing temporary housing to aliens not qualified for welfare benefits. The final Order, like the original Order, specifies that "short term shelter or housing assistance for the homeless, for victims of domestic violence, or for runaway, abused or abandoned children" are deemed to be necessary for the protection of life or safety. Accordingly, programs and services of that type that deliver in-kind services at the community level and do not condition the provision of assistance, or the amount or cost thereof, on the individual recipient's income or resources are exempt from any requirement that verification be conducted, unless service providers are mandated to conduct such verification pursuant to federal, state, or local law other than the Welfare Reform Act.

Final Specification of Community Programs Necessary for the Protection of Life or Safety Under the Welfare Reform Act

Preamble

(1) The types of programs, services, and assistance enumerated in this Order are ones that Congress authorized the Attorney General to except from limitations on the ban on the availability of federal, state, or local public benefits imposed by Title IV of the Act.

(2) The Attorney General has fully exercised the power delegated to her under §§ 401(b)(1)(D) and 411(b)(4) of the Welfare Reform Act (codified at 8 U.S.C. 1611(b)(1)(D) and 1621(b)(4)).

(3) Neither states nor other service providers may use the Act as a basis for prohibiting access of aliens to any programs, services, or assistance covered by this Order. Unless an alien fails to meet eligibility requirements provided by applicable law other than the Act, benefit providers may not restrict the access of any alien to the services covered by this Order, including, but not limited to, emergency shelters.

(4) Thus, unless required by some legal authority other than the Act, benefit providers who satisfy the requirements of this Order are not required to verify the citizenship, nationality, or immigration status of applicants seeking benefits.

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(5) If a benefit provider offers a number of services, only some of which are exempt from verification as a result of this Order, the benefit provider may conduct verification of the non-exempt programs or services as specified in the applicable portions of the "Interim Guidance on Verification of Citizenship, Qualified Alien Status and Eligibility Under Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996," 62 FR 61,344 (1997) or may be required to conduct verification as specified by any subsequent or superseding regulations.

(6) To the extent that it can be accomplished without undue administrative hardship, benefit providers should make every effort to provide information to all prospective benefit seekers about which benefits they qualify for and which benefits involve citizenship or immigration verification requirements.

Specification

Therefore, by virtue of the authority vested in me as Attorney General by law, including Title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, I hereby specify that:

1. I do not construe the Act to preclude aliens from receiving police, fire, ambulance, transportation (including paratransit), sanitation, and other regular, widely available services and, for that reason, I am not making specifications of such programs, services, or assistance. It is not the purpose of this Order, however, to define more specifically the scope of the public benefits that Congress intended to deny certain aliens either altogether or absent my specification, and nothing herein should be so construed.

2. The government-funded programs, services, or assistance specified in this Order are those that: deliver in-kind (non-cash) services at the community level, including through public or private non-profit agencies or organizations; do not condition the provision, amount, or cost of the assistance on the individual recipient's income or resources, as discussed in paragraph 3, below; and serve purposes of the type described in paragraph 4, below, for the protection of life or safety. Specified programs must satisfy all three prongs of this test.

3. The community-based programs, services, or assistance specified in paragraphs 2 and 4 of this Order are limited to those that provide in-kind (non-cash) benefits and are open to individuals needing or desiring to participate without regard to income or resources. Programs, services, or assistance delivered at the community level, even if they serve purposes of the type described in paragraph 4 below, are not within this specification if they condition on the individual recipient's income or resources:

(a) the provision of assistance;

(b) the amount of assistance provided; or

(c) the cost of the assistance provided on the individual recipient's income or resources.

4. Included within the specified programs, services, or assistance determined to be necessary for the protection of life or safety are:

(a) Crisis counseling and intervention programs; services and assistance relating to child protection, adult protective services, violence and abuse prevention, victims of domestic violence or other criminal activity; or treatment of mental illness or substance abuse;

(b) Short-term shelter or housing assistance for the homeless, for victims of domestic violence, or for runaway, abused, or abandoned children;

(c) Programs, services, or assistance to help individuals during periods of heat, cold, or other adverse weather conditions;

(d) Soup kitchens, community food banks, senior nutrition programs such as meals on wheels, and other such community nutritional services for persons requiring special assistance;

(e) Medical and public health services (including treatment and prevention of diseases and injuries) and mental health, disability, or substance abuse assistance necessary to protect life or safety;

(f) Activities designed to protect the life or safety of workers, children and youths, or community residents; and

(g) Any other programs, services, or assistance necessary for the protection of life or safety.

Dated: January 5, 2001.

Janet Reno,

Attorney General.

[FR Doc. 01–1158 Filed 1–12–01; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 2083–00]

Establishing an Immigration and Naturalization Service Data Management Improvement Act Task Force

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice establishing a Task Force.

SUMMARY: In accordance with the provisions of the Federal Advisory Committee Act, and Public Law 106–215, the Attorney General is establishing an Immigration and Naturalization Service Data Management Improvement Act Task Force. This notice advises Federal, State, and local agencies, and private sector representatives that the Immigration and Naturalization Service (Service) is soliciting members from interested groups, associations, or individuals who may wish to serve on the Task Force.

Purpose of Task Force

The Task Force will evaluate and make recommendations on:

(1) How the Attorney General, in consultation with the Secretaries of State, Treasury, and Commerce can efficiently and effectively implement an integrated entry and exit data system;

(2) How the United States can improve the flow of traffic at airports, seaports, and land border ports-of-entry through—

(a) Enhancing systems for data collection and data sharing, including the integrated entry and exit data system, by better use of technology, resources, and personnel;

(b) Increasing cooperation between the public and private sectors;

(c) Increasing cooperation among Federal agencies and among Federal and State agencies; and

(d) Modifying information technology systems while taking into account the different data systems, infrastructure, and processing procedures at airports, seaports, and land border ports-of-entry; and

(3) The cost of implementing each of the Task Force's recommendations.

Further, no later than December 31, 2002 and no later than December 31 of each subsequent year the Task Force is in existence, the Attorney General shall submit a report to Congress containing the findings, conclusions, and recommendations of the Task Force.

Composition of Task Force

The Task Force shall be composed of 17 members, including the Attorney General, private sector representatives of affected industries and groups, and representatives from Federal, State, and local agencies, who have an interest in: immigration and naturalization; travel and tourism; transportation; trade; law enforcement; national security; or the environment. Participation on the Task Force will not be remunerated, however, travel and associated expenses may be reimbursed or borne by the Government.

Qualification of Task Force members

Groups, associations, or individuals who wish to be considered for inclusion on this Task Force should have a background that reflects a good working knowledge of entry and exit procedures and business practices. Ideally, this knowledge should include all of the environments where inspections take place (*i.e.*, airports, northern and southern land borders ports, and seaports).

Additionally, it would be helpful for interested groups, associations, or individuals to understand modern data collection and matching processes in an automated environment and how the requirements of Public Law 106–215 can be best met given the business practices of ports-of-entry, and the competing goals of enforcing the Immigration and Nationality Act and facilitating the movement of travelers. For more information concerning the Task Force, see Public Law 106–215 on the Service's website at http://www.ins.usdoj.gov.

In considering what groups, associations, or individuals should serve on the Task Force, the Service will make every effort to balance both geographical interests to ensure the unique characteristics of each type of port-of-entry are considered and the needs of various industries that depend on the efficient operation of ports-of-entry.

Federal Advisory Committee Act

The Task Force will function solely as an advisory body in compliance with the provisions of the Federal Advisory Committee Act (FACA). Its charter will be filed in accordance with the provisions of that FACA.

Solicitation of Public Opinion Regarding Task Force Membership

The Department of Justice is seeking input from groups, associations or individuals to determine the optimal Task Force composition. Please send suggestions and a brief background or justification to the Immigration and Naturalization Service, Office of Inspections, 425 I Street, NW, Room 4064, Washington, DC 20536, Attn: Jennifer Sava. Please include a daytime phone number where a point of contact can be reached as well as an e-mail address, if available. Please submit information by February 16, 2001.

Once a group, association, or individual has been selected to serve on the Task Force, the Service will notify the point of contact and will provide further instruction.

Who Can Be Contacted If There Are Questions Concerning This Task Force?

For questions concerning this Task Force, please contact Jennifer Sava, Office of Inspections, Immigration and Naturalization Service, 425 I Street, NW, Room 4064, Washington, DC 20536; telephone (202) 514–3019.

Dated: January 3, 2001.

Mary Ann Wyrsch,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 01–1202 Filed 1–12–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Policy-Driven Responses to Parole Violations

AGENCY: National Institute of Corrections, Department of Justice.

ACTION: Solicitation for a cooperative agreement.

SUMMARY: The Department of Justice (DOJ), National Institute of Corrections (NIC) announces the availability of funds in FY 01 for a cooperative agreement to assist up to six paroling authorities through the "Policy-Driven Responses to Parole Violations" project. State releasing authorities have the legal responsibility for paroled, conditional released and some mandatory released offenders. Often times the actions taken by releasing authorities in their response to violations leads to revocation proceeding, which contributes to prison crowding. It is intended that through this solicitation paroling authorities will have an opportunity to develop policy guided responses in confronting violations. This is not an announcement for applicants to receive technical assistance. The purpose of this announcement is to select an awardee who will, in conjunction with the National Institute of Corrections, select the six paroling authorities, and plan and coordinate the work.

Background

The response to violations by offenders who are serving the remaining portion of their sentence in the community and under the control of a releasing authority has become a major correctional issue. Over all, commitment rates to prison for new offenses has leveled off or are declining, while at the same time prison populations continue to increase. Much of this increase has been the results of parole and probations violators coming to prison as the results of having their supervision period revoke by either a judge or a parole board. There appears to be a high reliance on incarceration or re-incarceration by decision makers in responding to the behaviors of the offender. There have been a variety of studies which seem to indicate that the appropriateness in responding to violations committed by the offender have a greater likelihood of success if the response is directly related the risk/need of that offender and incarceration in many instances may be the least effective response. Although, a complete analysis has not been done, the idea of equity, fairness and consistency in the revocation process should be explored to determine how and why and under what conditions certain decisions are made.

Project Objectives

This project will provide technical assistance to up to six paroling authorities that are committed to improving the effectiveness and efficiency of the way they respond to offenders who violate rules and/or conditions of parole, this includes both discretionary and mandatory release supervision. The project may also include enhancing policies governing rescission practices. (the cancellation of a presumptive release date) The intent of this project is to take into consideration the following:

1. The thorough analysis of current practice to determine the quantity and quality of data required/available for decision making information and the level of commitment of decision makers to use it.

2. Insure key decision makers are aware/knowledgeable of research evidence based on criminogenic need.

3. Provide key decision makers with information regarding program level/options for sanctioning/intervening in violation behavior based on assessed risk and responding to criminogenic need.

4. Forge/initiate working relationship with other criminal justice practitioners involved in the revocation process to attain common policy.

5. Articulate written policy on violation and revocation practices that the Board will consistently enforce/carry out with the assistance of other key community justice practitioners.

6. Implement data gathering regarding policy decisions.

Scope of Work

The response to violations involves the exercise of discretion by individuals from several organizations, and seldom

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has this complicated process been analyzed by individual states to fully understand its impact. The receipt must have the ability to work individually and jointly with parole boards, agency administrators, supervision staff, and treatment and service providers, in order to effectively manage policy development teams. The intent is that the recipient of this award will take into consideration the research and the practical knowledge of responding to violations, and from that knowledge base, assist states to develop policy driven practices for organizations to follow. The resulting effect should allow for a more rational utilization of prison space, staff allocation (both in the field and correctional facilities) and create a meaningful return on the investment the state makes in corrections.

The recipient of this cooperative agreement must prepare a proposal that describes their plan to meet the goals/objective which should include a schedule identifying benchmarks of significant tasks in chart form. Applicants must identify their key project staff and the relevant expertise of each. Also, the application should indicate how it will work with NIC on an announcement for marketing this project; develop selection criteria; and compile information on applicants making application. The proposal should present a methodology or approach that the applicant proposes to employ in providing technical assistance to 6 paroling authorities that would incorporate the following and other elements deemed appropriate to accomplishing the objectives of the project:

- The process for taking decision makers through analysis of past practices for parole violations including what data, information and decision making policies and practices should be identified, collected and analyzed.
- Develop descriptions of acceptable responses to a range of violation behaviors and identify the various sanctions and interventions strategies to consider.
- Develop future outcome or performance measures for a policy-driven parole violation process.
- Determine which dynamic screening, classification and assessment system(s) may contribute to improved violation decision-making and how and when such systems should be used.
- Develop a plan to design, implement and operate interventions consistent with the principles of effective interventions aimed at reducing risk by confronting parole violators criminogenic needs.

Authority: Public Law 93–415.

Funds Available: This is a cooperative agreement. A cooperative agreement is a form of assistance relationship through which the National Institute of Corrections is involved during the performance of the award. The award is made to an organization who, in concert with the Institute, will solicit and select participating jurisdictions and provide them with technical assistance. No funds are transferred to state or local government. The Community Corrections Division will provide the financial assistance in the form of a cooperative agreement to an agency or organization, who makes application. This initiative emphasizes policy development by paroling authorities in partnership with supervision staff and service delivery organizations. The award will be limited to $250,000 (direct and indirect cost) and project activity must be completed within 18 months of the date of award. Funds may not be used for construction, or to acquire or build real property. This project will be a collaborative venture with the NIC Community Correction Division.

Deadline for Receipt of Applications: Applications must be received by 4:00 p.m. on Thursday, February 28, 2001. They should be addressed to: Director, National Institute of Corrections, 320 First Street, NW, Room 5007, Washington, DC 20534. Hand delivered applications should be brought to 500 First Street, NW, Washington, DC 20534. The front desk will call Bobbi Tinsley at (202) 307–3106 extension 0 for pickup.

Addresses and Further Information: Request for application kit, which includes application forms and a copy of this announcement, should be directed to Judy Evens, Cooperative Agreement Control Office, National Institute of Corrections, 320 First Street, NW, Room 5007, Washington, DC 20534 or by calling 800–995–6423, ext. 159 or 202–307–3106, ext. 159, or email: *jevens@bop.gov*. A copy of this announcement and application forms may also be obtained through the NIC web site: http//www.nicic.org (click on "Cooperative Agreements"). All technical and/or programmatic questions concerning this announcement should be directed to Cranston J. Mitchell, Corrections Program Specialist at 320 First Street, NW, Room 5007, Washington, DC 20534 or by calling 800–995–6423, ext. 153 or 202–307–3106, ext. 153, or by email: *cjmitchell@bop.gov*.

Eligibility Applicants: An eligible applicant is any state or general unit of local government, public or private agency, educational institution, organization, team, or individual with the requisite skills to successfully meet the outcome objectives of the project.

Review Considerations: Applications received under this announcement will be subjected to an NIC 3 to 5 member review process.

Number of Awards: One (1).

Executive Order 12372: This program is subject to the provisions of Executive Order 12372. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Applicants (other than Federally-recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC), a list of which is included in the application kit, along with further instructions on proposed projects serving more than one state.

NIC Application Number: 01C06 This number should appear as a reference line in your cover letter and also in box 11 of Standard form 424.

Catalog of Federal Domestic Assistance Number: 16.603

Dated: January 9, 2001.

Morris L. Thigpen,

Director, National Institute of Corrections.

[FR Doc. 01–1209 Filed 1–12–01; 8:45 am]

BILLING CODE 4410–36–M

NATIONAL AERONAUTICS AND SPACE ADINISTRATION

[Notice 01–004]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of prospective patent license.

SUMMARY: NASA hereby gives notice that CJAB Associates, LLP, of Houston, TX, has applied for a partially exclusive license to practice the inventions described and claimed in U.S. Patent No. 5,153,132, entitled "Three-Dimensional Co-Culture Process;" U.S. Patent No. 5,153,133, entitled "Method for Culturing Mammalian Cells in a Horizontally Rotated Bioreactor;" U.S. Patent No. 5,155,034, entitled "Three-Dimensional Cell to Tissue Assembly Process;" U.S. Patent No. 5,155,035, entitled "Method for Culturing Mammalian Cells in a Perfused Bioreactor;" U.S. Patent No. 5,308,764, entitled "Multi-Cellular Three Dimensional Living Mammalian Tissue;" U.S. Patent No. 5,496,722, entitled "Method for Producing Non-Neoplastic, 3–Dimensional Mammalian Tissue and Cell Aggregates under Microgravity Culture Conditions and the Products Produced Thereby;" U.S. Patent No. 5,627,021, entitled "Multi-Cellular, Three-Dimensional Living Mammalian Tissue;" U.S.Patent No. 5,846,807, entitled "Media Compositions for Three-Dimensional Mammalian Tissue Growth Under Microgravity Culture Conditions;" U.S. Patent No. 5,858,783, entitled "Production of Normal Mammalian Organ Culture Using a Medium Containing Mem-Alpha, Leibovitz L–15, Glucose Galactose Fructose;" U.S. Patent No. 5,851,816, entitled "Cultured High-Fidelity Three Dimensional Human Urogenital Tract Carcinomas and Process;" and U.S. Patent No. 6,117,674, entitled "Horizontal Rotating-Wall Vessel Propagation in Vitro Human Tissue Models." Each of the above U.S. Patents is assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to the Johnson Space Center.

DATES: Responses to this notice must be received by March 19, 2001.

FOR FURTHER INFORMATION CONTACT: James Cate, Patent Attorney, NASA Johnson Space Center, Mail Stop HA, Houston, TX 77058–8452; telephone (281) 483–1001.

Dated: January 9, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1125 Filed 1–12–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Sunshine Act Meeting

AGENCY: Institute of Museum and Library Services.

ACTION: Notice of meeting of the National Museum Services Board.

SUMMARY: This notice sets forth the agenda of a forthcoming meeting of the National Museum Services Board. This notice also describes the function of the board. Notice of this meeting is required under the Government through the Federal Advisory Committee Act (5 U.S.C. App.) and regulations of the Institute of Museum and Library Services, 45 CFR 1180.84.

TIME/DATE: 9 am–12 pm on Friday, January 26, 2001.

STATUS: Open.

ADDRESS: Room M–07, The Old Post Office Building, 1100 Pennsylvania Avenue, NW, Washington, DC 20004, (202) 606–4649.

FOR FURTHER INFORMATION CONTACT: Elizabeth Lyons, Special Assistant to the Director, Institute of Museum and Library Services, 1100 Pennsylvania Avenue, NW, Room 510, Washington, DC 20506, (202) 606–4649.

SUPPLEMENTARY INFORMATION: The National Museum Services Board is established under the Museum Services Act, Title II of the Arts, Humanities, and Cultural Affairs Act of 1976, Public Law 94–462. The Board has responsibility for the general policies with respect to the powers, duties, and authorities vested in the Institute under the Museum Services Act.

The meeting on Friday, January 26, 2001 will be open to the public. If you need special accommodations due to a disability, please contact: Institute of Museum and Library Services, 1100 Pennsylvania Avenue, NW, Washington, DC 20506—(202) 606–8536—TDD (202) 606–8636 at least seven (7) days prior to the meeting date.

Agenda; 80th Meeting of the National Museum Services Board in Room M–07 at The Old Post Office Building, 1100 Pennsylvania Avenue, NW, Washington, DC 20004, on Friday, January 26, 2001

9 am–12 pm

I. Chairman's Welcome
II. Approval of Minutes
III. Director's Report
IV. Staff Reports:
Office of Management and Budget
Office of Public and Legislative Affairs
Office of Technology and Research: The Role of the Technology Officer; Barbara Smith
Office of Museum Services
Office of Library Services
V. Old Business
- Report from the 21st Century Learner Steering Committee
- Review and Approval of Conservation Action Plan

VI. New Business
- IMLS and the New Congress: Special Guest
- Reauthorization Update: Review of the Legislation
- General Operating Support Grants: Analysis and Discussion

Dated: January 9, 2001.

Linda Bell,

Director of Policy, Planning and Budget, National Foundation on the Arts and Humanities, Institute of Museum and Library Services.

[FR Doc. 01–1356 Filed 1–11–01; 2:11 pm]

BILLING CODE 7063–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301]

Nuclear Management Company, LLC; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Nuclear Management Company, LLC (the licensee) to withdraw its October 5, 1999, application for proposed amendment to Facility Operating License Nos. DPR–24 and DPR–27 for the Point Beach Nuclear Plant, Units 1 and 2, located in Town of Two Creeks, Manitowoc County, Wisconsin.

The proposed amendment would have revised the Technical Specifications (TSs) to eliminate inconsistencies, principally related to decay heat removal. The amendment is no longer necessary because the inconsistencies are being corrected as part of a separate application dated November 15, 1999, to convert Point Beach's current TSs to improved TSs. The November 15, 1999, application is currently being reviewed by the staff of the Commission.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on November 17, 1999 (64 FR 62717). However, by letter dated December 19, 2000, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated October 5, 1999, as supplemented May 19, 2000, and the licensee's letter dated December 19, 2000, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this 5th day of January 2001.

For the Nuclear Regulatory Commission.

Beth A. Wetzel,

Senior Project Manager, Section 1, Project Directorate III, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–1174 Filed 1–12–01; 8:45 am]

BILLING CODE 7590–01–U

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NUCLEAR REGULATORY COMMISSION

[NRC License No. 29–30458–01]

SteriGenics International, Somerset, NJ: Exemption From 10 CFR 36.23(a); Environmental Assessment, Finding of No Significant Impact, and Notice of Opportunity for a Hearing

AGENCY: Nuclear Regulatory Commission.

ACTION: SteriGenics International, Somerset, NJ: Exemption from 10 CFR 36.23(a); Environmental Assessment, Finding of No Significant Impact, and Notice of Opportunity for a Hearing.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering authorizing SteriGenics International, Inc. (SteriGenics or the licensee) an exemption to use a cell door which prevents an individual in the radiation room from leaving.

SUPPLEMENTARY INFORMATION:

Proposed Action

SteriGenics is licensed by the NRC to irradiate materials, except explosives, flammables, and corrosives using cobalt-60 in a panoramic wet-source-storage irradiator. The licensee requested, in a letter dated September 26, 2000, that the NRC grant an exemption from 10 CFR 36.23(a) to use a cell door which prevents an individual in the radiation room from leaving. SteriGenics has been conducting irradiations using this cell door since the license was issued on February 1, 1999. The NRC staff has determined during an inspection of the facility, that the cell door does not meet 10 CFR 36.23(a) which requires that doors and barriers not prevent an individual in the radiation room from leaving.

Need for the Proposed Action

Part 36 irradiators use high activity sealed sources of radioactive material in a facility constructed so that the sealed sources and material being irradiated are contained in a shielded volume (radiation room). In many units, sources are stored under water (wet-source-storage). Irradiator facilities typically incorporate the use of a shielded "maze" which allows an individual to move to a shielded area within the radiation room and a door to the radiation room which allows an individual to exit the radiation room at any time.

The exemption is needed so that SteriGenics can carry out its business of irradiating materials in this irradiator. The door to the radiation room of this irradiator serves as an integral part of the shielding and must be closed prior to exposing the radioactive sources to conduct an irradiation. The design of the irradiator control system does not allow the radioactive sources to be raised unless the door is closed. Once closed, an individual located in the radiation room cannot open the door and, therefore, is unable to leave the radiation room as required by 10 CFR 36.23(a). An individual in the radiation room with the door closed can prevent the sources from rising by pulling a cord on the room wall and thereby prevent radiation exposure.

SteriGenics has proposed modifications which provide a level of safety equivalent to that which is provided by compliance with 10 CFR 36.23(a). Currently, there are two pull cords inside the radiation room. One runs the length of two of the room walls, the second the length of the third. The fourth wall is covered by equipment. The presence of equipment in the radiation room forces individuals in the radiation room to be near one of these cords. Both of these cords must be actuated as part of the irradiator startup sequence. This actuation assures that the cords are functional and that the operator has searched the cell prior to beginning an irradiation. Once the startup sequence has been completed, the pull cords change function and pulling either cord will prevent the sources from rising or cause them to return to the shielded position if they have begun to rise. SteriGenics proposes to modify the irradiator control circuit logic so that if an individual pulls one of these cords twice, in addition to the sources returning to the shielded position, the cell door will open after a short delay. The control system logic will assure that the door does not open until and unless the sources are in the fully "down" position and radiation levels in the room are normal. The delay is caused by the operation of this logic and the fact that it takes between 15 and 30 seconds for the door to open.

SteriGenics will also relocate the "set-up" key switch to the far corner inside the radiation room. Currently, this switch is located outside the cell door. Inserting the key and turning this switch begins the sequence which eventually allows moving the sources. Within 90 seconds of turning the switch, the operator must search the radiation room, pull each cord once, exit the room and close the shield door. The operator must then place the key in the control console and may then move the sources. Placing the switch in the room forces the operator to bring the key which is used to move the sources (as required by 10 CFR 36.31(a)) into the radiation room during the "set-up" process. This increases the assurance that this requirement will be met by substituting an active control for the current administrative control (the operator is required by existing procedure to take the key into the room). Taking the key into the room during "setup" assures that no one other than that operator can move the sources.

Environmental Impacts of the Proposed Action

No radioactive material is released into the environment, all of the radioactive material is wholly contained within the shielded irradiator and there will be no changes to radiation dose rates outside the irradiator. The radiation dose rate outside this irradiator meets regulatory requirements and is similar to the dose rate outside traditional panoramic wet-source-storage irradiators which meet the requirement in 36.23(a). Therefore, the modification will not result in any significant environmental impacts.

Alternatives to the Final Action

As required by Section 102(2)(E) of NEPA (42 U.S.C. 4322(2)(E)), the staff has considered alternatives to the final action including denying the exemption or requiring that SteriGenics comply with 10 CFR 36.23(a). These options were not adopted because they would provide no gain in protection of the human environment and they would be significantly detrimental to SteriGenics. Denying the exemption request would result in SteriGenics ceasing all irradiations and either redesigning and substantially modifying the physical facility or disposing of the radioactive sources and decommissioning the facility. In order for SteriGenics to comply with 10 CFR 36.23(a) they need to extensively modify the existing irradiator to incorporate a shield maze. This would be expensive and would prevent the use of the existing conveyor system, requiring additional expenditures for modifications.

Alternative Use of Resources

Alternative use of resources was considered as stated above.

Agencies and Persons Consulted

Agencies or persons outside the U.S. Nuclear Regulatory Commission were not consulted because there will be no significant impact on the environment from the proposed activity.

Identification of Sources Used

Letters from SteriGenics to the U.S. Nuclear Regulatory Commission, Region I, dated:

1. January 5, 2000 (ML003676755)
2. February 4, 2000 (ML003684178)
3. September 26, 2000 (ML003754079)

Finding of No Significant Impact

Based on the above EA, the Commission has concluded that environmental impacts that would be created by the proposed action would not have a significant effect on the quality of the human environment and a Finding of No Significant Impact is appropriate. Accordingly, the preparation of an Environmental Impact Statement is not warranted.

Documents

Documents submitted by SteriGenics are available for public inspection from the Publicly Available Records (PARS) component of the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room). Assistance with the Public Electronic Reading Room may be obtained by calling (800) 397–4209. The accession numbers for the licensee's documents referred to in this Assessment are listed next to the document date above.

Opportunity for a Hearing

Any person whose interest may be affected by the issuance of this action may file a request for a hearing. Any request for hearing must be filed with the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the publication of this notice in the **Federal Register**; be served on the NRC staff (Executive Director for Operations, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852), and on the licensee (SteriGenics International, 210 Clyde Road, Somerset, NJ 08873); and must comply with the requirements for requesting a hearing set forth in the Commission's regulations, 10 CFR part 2, subpart L, "Information Hearing Procedures for Adjudications in Materials Licensing Proceedings."

These requirements, which the request must address in detail, are:

1. The interest of the requestor in the proceeding;
2. How that interest may be affected by the results of the proceeding (including the reasons why the requestor should be permitted a hearing);
3. The requestor's areas of concern about the licensing activity that is the subject matter of the proceeding; and
4. The circumstances establishing that the request for hearing is timely—that is, filed within 30 days of the date of this notice.

In addressing how the requestor's interest may be affected by the proceeding, the request should describe the nature of the requestor's right under the Atomic Energy Act of 1954, as amended, to be made a party to the proceeding; the nature and extent of the requestor's property, financial, or other (*i.e.*, health, safety) interest in the proceeding; and the possible effect of any order that may be entered in the proceeding upon the requestor's interest.

Dated at King of Prussia, Pennsylvania, this 4th day of January 2001.

For the Nuclear Regulatory Commission.

John D. Kinneman,

Chief, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety Region I.

[FR Doc. 01–1173 Filed 1–12–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–28641, License No. 42–23539–01AF Department of the Air Force; Docket No. 030–29462, License No. 45–23645–01NA, Department of the Navy; Docket No. 040–08767, License No. SUC–1380, Department of the Army]

Notice of Issuance of Director's Decision Under 10 CFR 2.206

Notice is hereby given that the Director, Office of Nuclear Material Safety and Safeguards, has issued a director's decision with regard to a petition dated June 1, 2000, filed by Doug Rokke, Ph.D., hereinafter referred to as the "petitioner." The petition concerns the use of depleted uranium (DU) by the U.S. Department of Defense and all services.

The petition requested that the U.S. Nuclear Regulatory Commission (Commission or NRC) hold a hearing to consider "the revocation of the master DU [depleted uranium] license for the U.S. Department of Defense and all services, implementation of substantial fines and consideration of personal criminal liability." As the basis for this request, the petitioner stated that "the continuing deliberate use of DU munitions during battle and during peacetime is resulting in serious health and environmental consequences."

By letter dated September 8, 2000, and addressed to the petitioner, the NRC staff acknowledged receiving the petition, and stated that pursuant to 10 CFR 2.206 the petition was referred to the Office of Nuclear Material Safety and Safeguards for action, and that it would be acted upon within a reasonable time.

The NRC staff requested the U.S. Department of the Air Force, the U.S. Department of the Army, and the U.S. Department of the Navy to respond to the petition. The licensees responded on October 30, 2000, and the information provided was considered by the staff in its evaluation of the petition.

The Director of the Office of Nuclear Material Safety and Safeguards has determined that the request to hold a hearing to consider the revocation of the military licenses authorizing the use of DU, implementation of substantial fines, and consideration of personal criminal liability, should be denied. The reasons for this decision are explained in the director's decision pursuant to 10 CFR 2.206 [DD–01–01], the complete text of which is available in ADAMS for inspection at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and via the NRC's Web site (*http://www.nrc.gov*) on the World Wide Web, under the "Public Involvement" icon.

A copy of the director's decision will be filed with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206 of the Commission's regulations. As provided for by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision, unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Dated at Rockville, Maryland, this 9th day of January 2001.

For the Nuclear Regulatory Commission.

William F. Kane,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 01–1175 Filed 1–12–01; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application To Withdraw From Listing and Registration; (Bitwise Designs, Inc., Common Stock, $.001 Par Value) File No. 0–20190

January 9, 2001.

Bitwise Designs, Inc., a Delaware corporation ("Company"), has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934

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("Act")[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock, $.001 par value ("Security"), from listing and registration on the Pacific Exchange, Inc. ("PCX").

The Company's Security has been approved for quotation on the National Market of the Nasdaq Stock Market, Inc. ("Nasdaq National Market"). Trading in the Security on the Nasdaq National Market began in April 2000. As a result, the Company has determined to withdraw its Security from listing and registration on the PCX in the belief there are no additional benefits to either the Company or its shareholders in maintaining such listing. In effecting such withdrawal, the Company will avoid the direct and indirect costs incurred in maintaining the PCX listing.

The Company has stated in its application that it has complied with the rules of the PCX governing the withdrawal of an issue from listing and registration and that the PCX has in turn indicated that it will not oppose such withdrawal. The Company's application relates solely to the withdrawal of the Security from listing on the PCX and registration under section 12(b) of the Act[3] and shall have no effect upon the Security's continuing quotation on the Nasdaq National Market or on its obligation to be registered under section 12(g) of the Act.[4]

Any interested person may, on or before January 31, 2001, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1190 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

[5] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of application To Withdraw From Listing and Registration; (Signal Technology Corporation, Common Stock, $.01 Par Value) File No. 1–13282

January 9, 2001.

Signal Technology Corporation, a Delaware corporation ("Company"), has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Common Stock, $.01 par value ("Security"), from listing and registration on the American Stock Exchange LLC ("Amex").

The Company's Security has been approved for quotation on the national Market of the Nasdaq Stock Market, Inc. ("Nasdaq National Market"). Trading in the Security on the Nasdaq National Market commenced at the opening of business on Friday, April 7, 2000, and was simultaneously suspended on the Amex. The Company made the decision to transfer the trading of its Security from the Amex to the Nasdaq National Market based on its evaluation of the comparative marketing advantages available to companies quoted through the dealer network of the Nasdaq National Market.

The Company has stated in its application that it has complied with the rules of the Amex governing the withdrawal of an issue from listing and registration. The Company's application relates solely to the withdrawal of the Security from listing on the Amex and registration under section 12(b) of the Act[3] and shall have no effect upon the Security's continuing quotation on the Nasdaq National Market or on its obligation to be registered under Section 12(g) of the Act.[4]

Any interested person may, on or before January 31, 2001, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulations, pursuant to delegated authority.[5]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1189 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(b).

[4] 15 U.S.C. 78*l*(g).

[5] 17 CFR 200.30–3(a)(1).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24821; 812–12388]

Nicholas-Applegate Fund, Inc., et al.; Notice of Application

January 9, 2001.

AGENCY: Securities and Exchange Commission ("SEC"or the "Commission").

ACTION: Notice of application under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from section 15(f)(1)(A) of the Act.

SUMMARY OF APPLICATION: The order would exempt the applicants from section 15(f)(1)(A) of he Act in connection with the proposed change in control of Nicholas-Applegate Capital Management ("NACM"). Without the requested exemption, Nicholas-Applegate Fund, Inc. (the "Company") would have to reconstitute its board of directors (the "Board") to meet the 75 percent non-interested director requirement of section 15(f)(1)(A) of the Act in order for NACM to rely upon the safe harbor provisions of section 15(f).

Applicants: The Company and NACM.

FILING DATE: The application was filed on January 8, 2001.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 31, 2001, and should be accompanied by proof of service on applicants, in the from of an affidavit, or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

[5] 17 CFR 200.30–3(a)(1).

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants: Nicholas-Applegate Capital Management, 600 West Broadway, San Diego, CA 92101; Nicholas-Applegate Fund, Inc., 100 Mulberry Street, Newark, NJ 07102.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegal, Senior Counsel, at (202) 942–0567, or Nadya B. Roytblat, Assistant Director, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicants' Representations

1. The Company is registered under the Act as an open-end management investment company, NACM, a California limited partnership, serves as the subadviser to the Company pursuant to a subadvisory agreement among NACM, the Company, and Prudential Investments Fund Management LLC (the successor to Prudential Mutual Fund Management, Inc.) ("Prudential"). Prudential serves as the manager and administrator of the Company. Each of NACM and Prudential is registered as an investment adviser under the Investment Advisers Act of 1940.[1]

2. Nicholas-Applegate Capital Management Holdings LP ("NACM Holdings LP") is the general partner of, and Nicholas-Applegate Capital Management Global Holding Co. LP ("Global Holding LP") is the sole limited partner of NACM. Their combined partnership interests comprise 100% ownership of NACM.

3. Allianz of America, Inc. ("Allianz of America") is a holding company that owns several insurance and financial service companies and is, in turn, a wholly owned subsidiary of Allianz AG. On October 17, 2000, NACM, NACM Holdings LP, Global Holding LP, and certain of their affiliates,[2] and Allianz of America and its wholly owned subsidiary, MacIntosh LLC, entered into a Merger Agreement under which Allianz of America agreed to acquire NACM (the "Transaction"). As a result of the Transaction, NACM will become an indirect wholly owned subsidiary of Allianz of America and Allianz of America will control NACM and its affiliates. Applicants expect that the Transaction will be consummated in January, 2001.

4. Consummation of the Transaction will result in a change of control of NACM within the meaning of section 2(a)(9) of the Act and, consequently, will result in an assignment of the current subadvisory agreement among NACM, the Company, and Prudential within the meaning of section 2(a)(4) of the Act. As required by section 15(a)(4) of the Act, the subadvisory agreement will automatically terminate in accordance with the terms of the agreement. In connection with the Transaction, NACM has determined to seek to comply with the "safe harbor" provisions of section 15(f) of the Act.

Applicants' Legal Analysis

1. Section 15(f) of the Act is a safe harbor that permits an investment adviser to a registered investment company (or an affiliated person of the investment company (or an affiliated person of the investment adviser) to realize a profit on the sale of its business if certain conditions are met. One of these conditions is set forth in section 15(f)(1)(A). This conditions provides that, for a period of three years after the sale, at least 75 percent of the board of directors of the investment company may not be "interested persons" with respect to either the predecessor or successor adviser of the investment company. Section 2(a)(19)(B) of the Act defines an "interested person" of an investment adviser to include, among others, any broker or dealer registered under the Securities Exchange Act of 1934 or any affiliated person of the broker or dealer. Rule 2a19–1 of the Act provides an exemption from the definition of interested person for directors who are registered as brokers or dealers, or who are affiliated persons of registered brokers or dealers, provided certain conditions are met.[3]

2. Upon consummation of the Transaction, it is proposed that the Board will consist of seven directors, four of whom are not interested persons of NACM within the meaning of section 2(a)(19)(B) of the Act ("Disinterested Directors"), and three of whom may be considered interested persons of NACM ("Interested Directors"). Two of the Interested Directors may be considered inferested persons of NACM within the meaning of section 2(a)(19)(B)(v) of the Act by virtue of their relationship to a registered broker-dealer. Applicants state that the exemption provided by rule 2a19–1 will not be available with respect to these two Interested Directors because the broker-dealers with which they are affiliated may engage in transactions with other members of the Company's complex.[4] The remaining interested Director is the managing partner of NACM and thus, is an interested person of NACM. With the exception of this director, upon consummation of the Transaction, none of the members of the Board will be affiliated persons within the meaning of section 2(a)(3) of the Act of any party to the Transaction.

3. Without the requested exemption, the Company would have to reconstitute its Board to meet the 75 percent non-interested director requirement of section 15(f)(1)(A).[5] Section 6(c) of the Act permits the SEC to exempt any person or transaction from any provision of the Act, or any rule or regulation under the Act, if the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the

[1] Applicants state that each of Prudential and NACM is acting as an "investment adviser" within the meaning of section 2(a)(20) of the Act under a contract subject to section 15 of the Act.

[2] These affiliates are Nicholas-Applegate LLC, Nicholas-Applegate Securities and Nicholas-Applegate Securities International LDC.

[3] The rule generally provides that the exemption is available only if: (a) The broker or dealer does not execute any portfolio transactions for, engage in principal transactions with, or distribute shares for, the investment company complex, as defined in the rule, (b) the investment company's board determines that the investment company will not be adversely affected if the broker or dealer does not effect the portfolio or principal transactions or distribute shares of the investment company, and (c) no more than a minority of the investment company's directors are registered brokers or dealers of affiliated persons thereof.

[4] With respect to one of these Interested Directors, applicants state that the exemption provided by the rule is also unavailable because the broker-dealer with which the Interested Director is affiliated acts as distributor for the Company. Applicants further state that the same Interested Director is treated as an interested person of NACM in keeping with section 2(a)(19)(B)(vi) of the Act, although the Company has not received a Commission order. Section 2(a)(19)(B)(vi) of the Act includes within the definition of interested person any individual whom the Commission by order has determined to be an interested person because of a material business or professional relationship with the investment adviser or principal underwriter of an investment company, or with any principal executive officer or controlling person of such entity.

[5] The Company filed a definitive proxy statement with the Commission on December 27, 2000 (the "Proxy Statement"). One of the proposals in the Proxy Statement solicits shareholder votes on the re-election of the seven directors who serve on the Board and the election of two additional Disinterested Directors. In the event exemptive relief has not been obtained by the earlier of February 28, 2001 or the time the Transaction closes, one of the Board's Interested Directors would resign and the election of the two additional Disinterested Directors would become effective. Thus, the total number of directors on the Board would be eight and the ratio of Interested Directors to total directors would be 2:8 (25). The Company would then be compliant with section 15(f)(1)(A).

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purposes fairly intended by the policy and provisions of the Act.

4. applicants request an exemption under section 6(c) from section 15(f)(1)(A). Applicants submit that the reconstitution of the Board as contemplated by the Proxy Statement would serve no public interest and, in fact, would not be in the best interests of the shareholders of the Company. Applicants state that the resignation of the Interested Director would deprive the Company of a director who has important experience with the Company and its service providers and also has important macro-economic insights and perspective. Applicants also state that the addition of the two new Disinterested Directors would entail the additional expenses of directors' fees and potentially increased insurance and fidelity bond premiums, and the real, if intangible, costs of integrating two new board members into the decisional and operational affairs of the Company.

5. Applicants state that although directors who are affiliated persons of broker-dealers may be viewed as interested persons of NACM, these directors, and the broker-dealers with which they are affiliated are not affiliated persons of any party to the Transaction. Applicants assert that the requested exemption is consistent with the protection of investors. Applicants state that the Company will continue to treat the Interested Directors as interested persons of the Company and NACM for all purposes other than section 15(f)(1)(A) of the Act so long as the directors are "interested persons" as defined in section 2(a)(19) of the Act and are not exempted from that definition by any applicable rules or orders of the SEC.

6. Applicants also submit that the requested exemption is consistent with the purposes fairly intended by the policies and provisions of the Act. Applicants assert that the legislative history of section 15(f) indicates that Congress intended the SEC to deal flexibly with situations where the imposi9tion of the 75 percent requirement might pose an unnecessary obstacle or burden on an investment company. Applicants also state that section 15(f)(1)(A) was designed primarily to address the types of biases and conflicts of interest that might exist where an investment company's board of directors is influenced by a substantial number of interested directors to approve a transaction because the interested directors have an economic interest in the adviser. Applicants assert that these circumstances do not exist in the present case.

Applicants' Condition

Applicants agree that the order granting the requested relief will be subject to following condition:

If, within three years of the completion of the Transaction, it becomes necessary to replace any director of the Company, that director will be replaced by a director who is not an "interested person" of NACM within the meaning of section 2(a)(19)(B) of the Act, unless at least 75% of the directors at that time, after giving effect to the order granted pursuant to the application, are not interested persons of NACM for purposes of section 15(f) of the Act. This condition will not: (a) preclude replacement with or addition of a director who is an interested person of NACM solely by reason of being an affiliated person of a broker or dealer, provided that such broker or dealer is not an affiliated person of NACM, or (b) require replacement of a director if a change in the director's circumstances causes him to become an interested person of NACM solely by reason of becoming an affiliated person of a broker or dealer, provided that such broker or dealer is not an affiliated person of NACM.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1191 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43803; File No. SR–ISE–00–20]

Self Regulatory Organizations; Notice of Filing of Proposed Rule Change by the International Securities Exchange LLC Relating to Limitations on Orders

January 4, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule19b–4 thereunder,[2] notice is hereby given that on November 20, 2000, the International Securities Exchange LLC ("ISE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to amend Rule 717 to adopt a rule prohibiting the entry of more than one order for the same beneficial account within a fifteen second period and to allow Electronic Access Members ("EAMs") to enter orders on behalf of another member other than an order for an ISE market maker account. Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

717. Limitations on Orders

* * * * *

(g) Orders for the Account of Another Member.

Absent an exemption from an Exchange official designated by the Board, Electronic Access Members shall not cause the entry of orders for [another Member] *the account of an ISE market maker that is exempt from the provisions of Regulation T of the Board of Governors of the Federal Reserve System pursuant to Section 7(c)(2) of the Exchange Act.*

(h) Multiple Orders for Same Beneficial Account.

Members shall not cause the entry of more than one order every fifteen (15) seconds for the account of the same beneficial owner in options on the same underlying security; provided, however that this shall not apply to multiple orders in different series of options on the same underlying security if such orders are part of a spread.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Exchange market makers must be firm at their quotations for all orders, although they can set different sizes for customer and broker-dealer orders. When the sizes of a particular quote is exhausted, the Exchange's trading system automatically moves the quote to an inferior price according to parameters preset by the market maker. However, the system moves only the quotation in the options series in which there was a trade, leaving the market maker exposed to the risk that multiple orders may be executed nearly simultaneously in many series of the same option. This situation increases in ISE market maker's "delta risk" (the amount of underlying stock that would be necessary to hedge the options position), due to exposure across multiple series. This could result in ISE market makers providing more liquidity than may be available in the underlying stock.

The proposed rule change states that members shall not cause the entry of more than one order every fifteen seconds for the account of the same beneficial owner in options on the same underlying security. The Exchange represents that the proposed rule change is designed to reduce ISE market maker risk exposure by limiting the ability of a person to rapidly send in orders in the same series or multiple series of the same underlying security. The Exchange believes that fifteen seconds is sufficient to allow market makers to move quotations following an execution, while at the same time not unduly long as to place a burden on investors seeking execution on the Exchange.

The Exchange also proposes to amend paragraph (g) of ISE Rule 717, which currently prohibits an EAM from entering an order for any other member of the Exchange. The amendment will limit the scope of ISE Rule 717(g) to only prohibit EAMs from entering orders for ISE market maker accounts. The Exchange believes that this reflects the original intent of ISE Rule 717(g), which was to prevent market makers from entering orders through other members, thus disguising their trading in an attempt to avoid the requirements in ISE Rule 805 that they do a specified percentage of their volume in their assigned options classes. The proposed rule change recognizes that there are legitimate reasons why a member may enter orders on the Exchange through an EAM. These reasons vary. For example, some EAMs desire a temporary means of routing orders to the ISE until they are connected directly to the Exchange. In addition, a few members have clearing relationships with EAMs and therefore route orders through them. The ISE represents that in its experience to date, there is no regulatory reason why this type of order routing should be limited.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[4] in general, and furthers the objectives of Section 6(b)(5)[5] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange did not solicit or receive written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–ISE–00–20 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1152 Filed 1–12–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43815; File No. SR–NASD–00–81]

Self Regulatory Organizations; Notice of Filing of a Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Computer to Computer Interface Fees For non-NASD Members

January 8, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 26, 2000, the National Association of Securities Dealers, Inc. ("NASD") through its wholly owned subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items, I, II, and III below, which Items have been prepared by Nasdaq.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to amend NASD Rule 7010 to change the manner in which fees are assessed on non-NASD

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The ISE filed its proposed rule change on November 20, 2000. On December 18, 2000, the ISE field Amendment No. 1 that entirely replaced the original rule filing.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On December 26, 2000, Nasdaq filed Amendment No. 1 with the Commission. Amendment No. 1 noted that Nasdaq's Board of Directors approved the proposed rule change at its meeting on October 4, 2000, and the NASD Board of Governors reviewed the proposal at its meeting on October 5, 2000.

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members who use a Computer-to-Computer Interface ("CTCI") to access Nasdaq services. This new fee structure has been created to reflect Nasdaq's adoption of a new Transmission Control Protocol/Internet Protocol ("TCP/IP") standard for CTCI linkages that will allow transmission of CTCI data using Nasdaq's Enterprise Wide Network II ("EWNII"). Proposed new language is underlined, proposed deletions are in brackets. Nasdaq intends to impose these fees on a rolling basis on non-members as they are converted to the new protocol and T1 or 56kb lines.[4] Proposed new language is in italics; proposed deletions are in brackets.

7000 Charges for Services and Equipment

7010. System Services

(a) through (e) No Change.

(f) Nasdaq Workstation™ Service

(1) through (2) No Change.

(3) The following charges shall apply for each CTCT subscriber:

[Service Charge $200/month per CTCI circuit]

Options	*Price*
Option 1: Dual 56kb lines (one for redundancy) and single hub and router	*$1275/month*
Option 2: Dual 56kb lines (one for redundancy), dual hubs (one for redundancy), and dual routers (one for redundancy)	*$1600/month*
Option 3: Dual T1 lines (one for redundancy), dual hubs (one for redundancy), and dual routers (one for redundancy). Includes base bandwidth of 128kb	*$8000/month*
Disaster Recovery Option: Single 56kb line with single hub and router. (For remote disaster recovery sites only.)	*$975/month*
Bandwidth Enhancement Fee (for T1 subscribers only)	*$4000/month per 64kb increase above 128kb T1 base*
Installation fee	*$2000 per site for dual hubs and routers* *$1000 per site for single hub and router*
Relocation Fee (for the movement of TCP/IP—capable lines within a single location)	*$1700 per relocation*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is proposing to amend NASD Rule 7010 to change the manner in which fees are assessed on NASD members who use a CTCI to access Nasdaq services. This new fee structure has been created to reflect Nasdaq's adoption of a new TCP/IP standard for CTCI linkages that will allow transmission of CTCI data using Nasdaq's EWNII. The CTCI network is a point-to-point dedicated circuit connection from the premises of brokerages and service providers to Nasdaq's processing facilities in Trumbull, Connecticut. Through CTCI, firms are able to enter trade reports to Nasdaq's Automated Confirmation Transaction Service ("ACT") and orders to Nasdaq's ACES and Small Order Execution ("SOES") systems. CTCI processes SelectNet transaction confirmation reports.

In response to numerous requests from market participants that Nasdaq upgrade the speed and reliability of its current CTCI data transmission environment, Nasdaq has determined to sunset its existing CTCI X.25/bisysnch network.[5] This network currently operates using an X.25 transmission protocol over 19.2 kilo bits per second ("kb") transmission lines. This X.25 system will be replaced by linking current CTCI subscribers to Nasdaq's faster and more reliable EWNII. EWNII operates over new more powerful 56kb and T1 data lines and transmits electronic information using the industry-standard TCP/IP transmission protocol. Once the transition to EWNII is completed, Nasdaq will terminate its current X.25/bisynch network. This upgrade will require all current X.25/19.2kb users to install either 56kb or T1 lines. Nasdaq believes that, in return, these lines will provide a minimum data transmission capability of almost three times that of the current 19kb-based interface. Moreover, running a TCP/IP protocol over these faster 56Kb and T1 lines will allow Nasdaq to provide CTCI subscribers with linkages that are more robust, customizable, and efficient in the use of available network bandwidth.

2. Statutory Basis

Nasdaq believes that the proposed rule changes are consistent with Section 15A(b)(5) of the Act, which requires that the rules of the NASD provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Nasdaq did not solicit or receive written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

(A) by order approve such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–00–81 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1150 Filed 1–12–01; 8:45 am]

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[4] Nasdaq has filed a separate proposal to impose these same fees on NASD members who interact with Nasdaq through a CTCI. *See* Securities Exchange Act Release No. 43821 (January 8, 2001).

[5] Given the age of the current CTCI X.25 network, Nasdaq also anticipates deficiency in obtaining sufficient hardware to meet future CTCI needs using the X.25 infrastructure.

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43821; File No. SR–NASD–80]

Self Regulatory Organization; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Computer to Computer Interface Fees for NASD Members

January 8, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 26, 2000, the National Association of Securities Dealers, Inc. ("NASD") through its wholly owned subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to amend NASD Rule 7010 to change the manner in which fees are assessed on NASD members who use a Computer-to-Computer Interface ("CTCI") to access Nasdaq services. This new fee structure has been created to reflect Nasdaq's adoption of a new Transmission Control Protocol/Internet Protocol ("TCP/IP") standard for CTCI linkages that will allow transmission of CTCI data using Nasdaq's Enterprise Wide Network II ("EWNII"). Nasdaq intends to impose these fees on a rolling basis on members as they are converted to the new protocol and T1 or 56kb lines.[4] Proposed new language is in italics; proposed deletions are in brackets.

* * * * *

7000 Charges for Services and Equipment

7010. System Services

(a) through (e) No Change.

(f) Nasdaq Workstation™ Service

(1) through (2) No Change.

(3) The following charges shall apply for each CTCT subscriber:

[Service Charge $200/month per CTCI circuit]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On December 26, 2000, Nasdaq filed Amendment No. 1 with the Commission. Amendment No. 1 noted that Nasdaq's Board of Directors approved the proposed rule change at its meeting on October 4, 2000, and the NASD Board of Governors reviewed the proposal at its meeting on October 5, 2000.

[4] Nasdaq has filed a separate proposal to impose these same fees on non-members who interact with Nasdaq through a CTCI. *See* Securities Exchange Act Release No. 43815 (January 8, 2001).

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Options	Price
Option 1: *Dual 56kb lines (one for redundancy) and single hub and router:*	*$1275/month*
Option 2: *Dual 56kb lines (one for redundancy), dual hubs (one for redundancy), and dual routers (one for redundancy).*	*$1600/month*
Option 3: *Dual T1 lines (one for redundancy), dual hubs (one for redundancy), and dual routers (one for redundancy). Includes base bandwidth of 128kb*	*$8000/month*
Disaster Recovery Option: *Single 56kb line with single hub and router. (For remote disaster recovery sites only*	*$975/month*
Bandwidth Enhancement Fee (for T1 subscribers only)	*$4000/month per 64kb increase above 128kb T1 base.*
Installation Fee	*$2000 per site for dual hubs and routers* *$1000 per site for single hub and router*
Relocation Fee (for the movement of TCP/IP-capable lines within a single location)	*$1700 per relocation*

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is proposing to amend NASD Rule 7010 to change the manner in which fees are assessed on NASD members who use a CTCI to access Nasdaq services. This new fee structure has been created to reflect Nasdaq's adoption of a new TCP/IP standard for CTCI linkages that will allow transmission of CTCI data using Nasdaq's EWNII. The CTCI network is a point-to-point dedicated circuit connection from the premises of brokerages and service providers to Nasdaq's processing facilities in Trumbull, Connecticut. Through CTCI, firms are able to enter trade reports to Nasdaq's Automated Confirmation Transaction Service ("ACT") and orders to Nasdaq ACES and Small Order Execution ("SOES") systems. CTCI also processes SelectNet transaction confirmation reports.

In response to numerous requests from market participants that Nasdaq upgrade the speed and reliability of its current CTCI data transmission environment, Nasdaq has determined to sunset its existing CTCI X.25/bisynch network.[5] This network currently operates using an X.25 transmission protocol over 19.2 kilo bits per second ("kb") transmission lines. This X.25 system will be replaced by linking current CTCI subscribers to Nasdaq's faster and more reliable EWNII. EWNII operates over new more powerful 56kb and T1 data lines and transmits electronic information using the industry-standard TCP/IP transmission protocol. Once the transition to EWNII is completed, Nasdaq will terminate its current X.25/bisynch network. This upgrade will require all current X.25/19.2kb users to install either 56kb or T1 lines. Nasdaq believes that, in return, these lines will provide a minimum data transmission capability of almost three times that of the current 19kb-based interface. Moreover, running a TCP/IP protocol over these faster 56Kb and T1 lines will allow Nasdaq to provide CTCI subscribers with linkages that are more robust, customizable, and efficient in the use of available network bandwidth.

2. Statutory Basis

Nasdaq believes that the proposed rule changes are inconsistent with Section 15A(b)(5) of the Act, which requires that the rules of the NASD provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operates or controls.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[5] Given the age of the current CTCI X.25 network, Nasdaq also anticipates difficulty in obtaining sufficient hardware to meet future CTCI needs using the X.25 infrastructure.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Nasdaq did not solicit or receive written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[6] and Rule 19b–4(f)(2) thereunder,[7] in that it establishes or changes a due, fee, or other charge. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 17 CFR 240.19b–4(f)(2).

provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASD–00–80 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1151 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43813; File No. SR–NASD–00–75]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of a Proposed Rule Change and Amendment No. 1 by the National Association of Securities Dealers, Inc. to Extend the Effectiveness of the Pilot Injunctive Relief Rule

January 5, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 19, 2000, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its wholly-owned subsidiary NASD Dispute Resolution, Inc. ("NASD Dispute Resolution") filed with the Securities and Exchange Commission ("SEC" or "Commission") a proposed rule change as described in Items I and II below, which Items have been prepared by NASD Dispute Resolution. On January 4, 2001, NASD Dispute Resolution submitted Amendment No. 1 to the proposed rule change.[3] For the reasons discussed below, the Commission is publishing this notice to solicit comments on the proposed rule change and Amendment No. 1 and to approve the proposal and Amendment No. 1 on an accelerated basis.

[8] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See letter to Katherine A. England, Assistant Director, Division of Market Regulation, Commission, from Laura Leedy Gansler, Counsel, NASD Dispute Resolution, dated January 3, 2001 ("Amendment No. 1").

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASD Dispute Resolution is proposing to amend Rule 10335 of the Code of Arbitration ("Code") of the NASD, to extend the pilot injunctive relief rule for one year, pending Commission action on a pending rule filing, SR–NASD–00–02, to amend Rule 19335 and make it a permanent part of the code. Below is the text of the proposed rule change. Proposed new language is in italics; proposed delections are in brackets.

10335. Injunctions

(i) Effective Date. This Rule shall apply to arbitration claims filed on or after January 3, 1996. Except as otherwise provided in this Rule, the remaining provisions of the Code shall apply to proceedings instituted under this Rule. This rule shall expire on [January 5, 2000] *January 4, 2002,* unless extended by the Association's Board of Governors.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD Dispute Resolution included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. NASD Dispute Resolution prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Rule 10335, the NASD's pilot injunctive relief rule, provides procedures for obtaining interim injunctive relief in controversies involving member firms and associated persons in arbitration. The rule has primarily been used in "raiding cases," or cases involving the transfer of an employee from one firm to another firm. Rule 10335 took effect on January 3, 1996, for a one-year pilot period. The SEC has periodically extended the initial pilot period in order to permit the NASD to assess the effectiveness of the rule. The pilot rule is currently due to expire on January 5, 2001.[4]

NASD Dispute Resolution believes that it is in the interest of members and associated persons that the effectiveness of the pilot rule remain uninterrupted pending final Commission action on SR–NASD–00–02. Therefore, NASD Dispute Resolution believes that the pilot rule should be extended to January 4, 2002, or such earlier time as permitted by Commission action on the permanent rule filing, which makes clear that, if approved, the amended rule would supersede the pilot rule in its entirety.

2. Statutory Basis

NASD Dispute Resolution believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[5] which requires, among other things, that the Association's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD Dispute Resolution does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act.[6] Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth

[4] On January 12, 2000, NASD Regulation, Inc. filed a proposed rule filing, SR–NASD–00–02 to amend rule 10335 and to make it a permanent part of the Code. See Securities Exchange Act Release No. 42606 (April 3, 2000), 65 FR 18405 (April 7, 2000) (File No. NASD–00–02). Simultaneously with this rule filing, the NASD Dispute Resolution has filed a response to Comments and Amendment No. 3 to SR–NASD–00–02.

[5] 15 U.S.C. 780o–(b)(6).

[6] In reviewing this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f)

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Street, NW., Washington, DC. 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provision of the 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to File No. SR–NASA–00–75 and should be submitted by February 6, 2001.

IV. Commission Findings and Order Granting Accelerated Approval of Proposed Rule Change

NASD Dispute Resolution has requested that the Commission find good cause pursuant to Section 19(b)(2)[7] for approving the proposed rule change and Amendment No. 1 prior to the 30th day after publication in the **Federal Register**. The Commission finds that the proposed rule change and Amendment No. 1 are consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of Section 15A of the Act and the rules and regulations thereunder.[8] Rule 10335 is intended to provide a pilot system within the NASD arbitration forum to process requests for temporary injunctive relief. Rule 10335 is intended principally to facilitate the disposition of employment disputes, and related disputes, concerning members who file for injunctive relief, to prevent registered representatives from transferring their client accounts to their new firms.

The Commission finds good cause for approving the proposed rule change and Amendment No. 1 prior to the 30th day after the date of publication of notice of filing thereof in that accelerated approval will permit members to have the benefit of injunctive relief in arbitration pending Commission action on the rule filing proposing to amend Rule 10335 and make it a permanent part of the Code.[9] Amendment No. 1 makes several technical changes to the proposal and adds the statutory basis to the rule filing. The Commission believes, therefore, that granting accelerated approval of the proposed rule change, as amended, is consistent with Section 15A of the Act.[10]

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–NASD–00–75), as amended, is approved on an accelerated basis through January 4, 2002.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1155 Filed 1–12–01; 8:45 am]

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[7] 15 U.S.C. 78s(b)(2).

[8] 15 U.S.C. 78o-3.

[9] *See supra* note 4.

[10] 17 U.S.C. 78o-3.

[11] 15 U.S.C. 78s(b)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43814; File No. SR–NASD–00–79]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to EWN II Fees for NASD Members

January 8, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 21, 2000, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its wholly-owned subsidiary, the Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission" or "SEC", the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is filing this proposed rule to pass on costs associated with increasing the bandwidth of the Enterprise Wide Network II ("EWN II") to NASD members for the period December 1–12, 2000. Nasdaq previously filed under Section 19(b)(3)(A)(ii) a proposed rule change to increase the fees beginning December 13, 2000, which was immediately effective upon filing.[3] Nasdaq also filed a parallel rule filing to effect amendments to the EWN II fee structure to apply to non-NASD members.[4] Below is the text of the proposed rule change. Proposed new language is in italics; proposed deletions are in brackets.

7010. System Services

(a)–(e) No Change

(f) Nasdaq Workstation Service

(1) No Change

(2) The following charges shall apply to the receipt of Level 2 or Level 3 Nasdaq Service via equipment and communications linkages prescribed for the Nasdaq Workstation II Service:

Service Charge	$1.875/month per service delivery platform ("SDP") from December [13] *1*, 2000 through February 28, 2001 $2,035/month per SDP beginning March 1, 2001
Display Charge	$525/month per presentation device ("PD")
Additional Circuit/SDP Charge	$3,075/month from December [13] *1*, 2000 through February 28, 2001, and 3,225/month beginning March 1, 2001*

A subscriber that accesses Nasdaq Workstation II Service via an application programming interface ("API") shall be assessed the Service Charge for each of the subscriber's SDPs and shall be assessed the Display Charge for each of the subscriber's API linkages, including an NWII substitute or quote-update facility. API subscribers also shall be subject to the Additional Circuit/SDP Charge.

* No change to footnotes

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 43769 (December 22, 2000), 66 FR 826 (January 4, 2001).

[4] Securities Exchange Act Release No. 43768 (December 22, 2000), 66 FR 824 (January 4, 2001).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In the September/October 2000 issue of Nasdaq's *Subscriber Bulletin*,[5] Nasdaq announced that it had increased the bandwidth of its Enterprise Wide Network II from 128 kilobits ("kb") to 192 kb. This increased bandwidth provides Nasdaq with the ability to support increased share volume and net products and trading applications that will be introduced. A description of the history of EWN II and the recent bandwidth increase may be found in SR–NASD–00–73.[6] *Subscriber Bulletin* also announced that the increased cost of the expanded bandwidth ($375 per month per circuit) would be passed on to Nasdaq subscribers beginning December 1, 2000. Nasdaq absorbed all of the increased costs for the month of November 2000.

On December 13, 2000, the Commission received Nasdaq's proposed rule change to amend the subscriber fees for NASD members as described above.[7] Because the filing was made under Section 19(b)(3)(A)(ii), which makes the rule change immediately effective upon filing with the Commission, the fee increase became effective as of December 13, 2000. In this filing, Nasdaq seeks to recover the costs associated with the expanded bandwidth for the period of December 1–12, 2000, as announced in the *Subscriber Bulletin*.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act[8] which requires that the rules of the NASD provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the NASD operate or controls. Nasdaq provided its subscribers with ample advance notice of the fee increase, and has limited the fee increase to the additional cost that it is incurring as a result of the expanded bandwidth. Nasdaq did not pass on the costs of the expanded bandwidth to subscribers that Nasdaq incurred in November 2000. As such, Nasdaq believes that it is equitably allocating charges among members for the use of EWN II during the period of December 1–12, 2000.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will impose any burden on competition that it is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Nasdaq has not solicited or received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that maybe withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–00–79 and should be submitted by February 6, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[9]

Margarety H. McFarland,

Deputy Secretary.

[FR Doc. 01–1195 Filed 1–12–01; 8:45 am]

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[5] *Subscriber Bulletins* are mailed to Nasdaq Workstation II subscribers and also may be found at www.nasdaqtrader.com/trader/news/subscriberbulletins.

[6] Securities Exchange Act Release No. 43769 (December 22, 2000).

[7] *Id.*

[8] 15 U.S.C. 78o–3(b)(5).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43811; File No. SR–00–38]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Modifying its Options Trade-Related Transaction Charges and Changing its Firm Transaction Fee

January 5, 2001

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 16, 2000, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Schedule of Rates and Charges to create a new fee category in the transactions portion of the "PCX Options: Trade-Related Charges." The new fee category will be entitled "Broker-Dealer."[4] The PCX also seeks to change the fees charged for firm transactions.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange filed its proposed rule change on November 16, 2000. On December 15, 2000, however, the Exchange filed Amendment No. 1, which clarified that the proposed fee is comparable to the fee charged by the Philadelphia Stock Exchange, Inc. ("Phlx"). *See* Letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Susie Cho, Attorney, Division of Market Regulation ("Division"), Commission (December 15, 2000).

[4] The term "Broker-Dealer" as used in this rule filing will include transactions in which a market maker is trading for a customer account, any trade for a joint back officer ("JBO") account, all trades for a firms account, except trades in which the firm is trading with its own customer on contra side.

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Section A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Schedule of Rates and Charges to create a new fee category in the transactions portion of the "PCX Options: Trade-Related Charges." The new fee category will be entitled "Broker-Dealer." The PCX also seeks to change the fees charged for firm transactions.

Currently, the PCX Schedule of Rates and Charges contains tow categorized of transactions under its options trade related charges. These categories include market maker transactions and firm transactions. The market maker charge is $0.21 per contract. The firm charge consists of $0.85 per contract side where the premium is less than $1.00 per contract and a $0.115 per contract side where the premium is $1.00 or more per contract. This fee structure does not address those instances where a broker/dealer processes a transaction through a customer account of the market maker or through a firm account created through a JBO arrangement with a clearing firm. In these situations the broker/dealer pays no transaction fees (customer account) or pays the applicable firm fee.

The Exchange now proposes to modify its Schedule of Rates and Charges. First, the Exchange proposes to change its options trade-related transaction charges by creating a new category entitled "Broker-Dealer." The PCX believes that this modification is needed in order to create a billing category for broker-dealer activity that does not fall within the structure of the Schedule of Rates and Charges. This new category will cover transaction and comparison charges incurred by broker-dealer activity originating both on and off the PCX floor. This new fee consists of $0.19 per contract transaction charge and $0.05 per contract comparison charge. The fee will apply to broker-dealers who are routing orders through firm or customer accounts carried by member clearing firms. The broker-dealer fee does not apply to certain firm/proprietary orders that are included within the firm transaction charge.

The PCX believes that the propsed fee isreasonable. The Exchange alsorepresents that it is comparable to fees charged by the Phlx.[5] Like the broker-dealer charge applied by the Phlx, the PCX's proposed broker-dealer fee applies to ordersfor any account in which the holder of a beneficial interest is a broker-dealer or person associated with or employed by a broker-dealer, including JBO accounts.[6]

The Exchange also propooses tochange its firm transaction fee. The firm transaction fee applies to member firm proprietary trades that have a customer of that firm on the contra side of the transaction. The simplify billing, the Exchange proposes tochange the rate to a revenue neutral rate of $0.100 per contract regardless of premium size.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[7] in general, and furthers the objectives of Section 6(b)(4)[8] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The PCX does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange did not solicit or receive comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[9] and Rule 19b–4(f)(2) thereunder,[10] in that it establishes or changes a due, fee, or other charge imposed by the Exchange. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to the File No. SR–PCX–00–38 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1153 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

[5] *See* Securities Exchange Act Release No. 43558 (November 14, 2000), 65 FR 69984 (November 21, 2000).

[6] *Id.*

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43823; File No. SF–PCX–99–48]

Self-Regulatory Organizations; Notice of Filing of a Proposed Rule Change and Amendment No. 1 by the Pacific Exchange, Inc. Relating to Miscellaneous House-Keeping Amendments to Options Trading Rules

January 9, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and rule 19b–4 thereunder,[2] notice is hereby given that on November 5, 1999, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. Amendment No. 1 was filed on October 11, 2000.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX proposes to modify its rules on options trading by clarifying existing provisions, eliminating superfluous provisions, codifying current policies and procedures, and renumbering certain Option Floor Procedure Advices ("OPFAs"). The text of the proposed rule change is available at the Office of the Secretary, the PCX, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In this filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the Exchange made several technical changes to the proposed rule text to correct the numbering and lettering of certain sections of the rule text. *See* Letter to Heather L. Traeger, Attorney, Division of Market Regulation, SEC, from Cindy Sink, Senior Attorney, Regulatory Policy, PCX, dated October 10, 2000 ("Amendment No. 1").

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to make several changes to the text of the PCX rules on options trading. First, the Exchange proposes to amend its rule 6.86[4] by providing a cross-reference to rule 6.37(f).[5] The Exchange proposes that, when rule 6.86 does not apply because an order is for a broker/dealer; a fast market has been declared; or rule 6.86 has been suspended, then rule 6.37(f) will apply. The Exchange proposes this rule change to protect investors and to emphasize the obligations of Market Makers on the Options Floor.

In addition, the Exchange proposes to define and clarify the terms "executed" and "filled" in rule 6.86, Commentary .09. Specifically, the Exchange proposes that an order is considered "executed" and "filled" at the price that was agreed upon when the trade was consummated, *i.e.*, when "buy" or "sell" was vocalized in response to a request for a market and disclosure was made of the price and the quantity of the order.

Second, the Exchange is proposing that rule 7.3(a)(6) references to subparagraphs (d) and (e) be changed to correctly reference subparagraphs (4) and (5).

Third, the Exchange proposes to renumber OFPA B–13, Subject: Evaluation of Options Trading Crowd Performance as rule 6.100. The Exchange proposes to renumber OFPA B–13 to centralize specific obligations, responsibilities and procedures of the Options Allocation Committee with respect to the evaluation of Lead Market Makers ("LMM") and trading crowds. Specifically, the Exchange proposes to require that all procedures applicable to the Options Allocation Committee ("OAC") for review of LMM or trading crowd performance pursuant to OFPA B–13 be renumbered and incorporated, verbatim, as rule 6.100.

Fourth, the Exchange proposes to eliminate the statement in rule 10.13(g) which states that "[e]except as provided in rule 10.14 (Summary Sanction Procedures), the circumstances underlying the issuance of each floor citation shall be reviewed by a designated committee for a determination of whether the evidence is sufficient to find a violation of Exchange rules." The Exchange notes that this provision is inconsistent with rule 10.13(c), which provides, in part, that Exchange Regulatory Staff designated by the Exchange has the authority to impose a fine pursuant to rule 10.13.

Fifth, the Exchange proposes to adopt new rules 10.13(h)(13) and 10.13(k)(i)(13) to incorporate new rule 4.23 into the Minor Rule Plan and Recommend Fine Schedule.[6] Rule 4.23 states that a member or member organization must obtain Exchange approval in order to Exchange or maintain a telephonic or electronic communication between the Floor and another location, or between locations on the Floor. The proposed recommended fines, pursuant to proposed rule 10.13(k)(i)(13) of this rule are $250, $750 and $1,500 for first, second and third time violations, respectively.

Sixth, the Exchange proposes to adopt rule 10.13(h)(35) and 10.13(k)(i)(35) to incorporate new rule 6.35(d) into the Minor Rule Plan and Recommended Fine Schedule.[7] Rule 6.35(d) states that newly registered Market Makers have a grace period (60 days from the commencement of trading), during which time they may have, but are not required to have, a Primary Appointment Zone. At the completion of the grace period, the Market Maker must select a Primary Appointment Zone. Market Makers who fail to select a Primary Appointment Zone prior to the expiration of their grace periods will

[4] PCX rule 6.86 is the Exchange's "firm quote" rule for non-broker dealer customer orders.

[5] PCX rule 6.37(f), to be amended as follows in a pending PCX filing with the Commission states that: "The following rule applies if rule 6.86 does not apply because an order is for a broker-dealer, a fast market has been declared or rule 6.86 has otherwise been suspended. Whenever a Floor Broker enters a trading crowd and calls for a market in any class and series at that post, each Market Maker present at the post where the option is traded is obligated, at a minimum, to make a market for one contract on each Market Maker's quoted price or 'implied' price (*e.g.*, if a Market Maker provides a bid but not an offer, the Market Maker's offering price will be implied by the bid price plus the maximum bid/ask spread differential specified in rule 6.37(b)(1)). In the event a Floor Broker is unable to satisfy an order from bids and offers given in the crowd, the Order Book Official may assign one contract to every Market Maker present within the trading crowd to assist the Floor Broker in satisfying the order. If a Market Maker at the post either bids lower or offers higher than the established market, such, Market Maker will be obligated to trade one contract at the price quoted by the Market Maker. If a Market Maker at the post fails to provide a bid or offer after having a reasonable opportunity to do so, the Market Maker will be obligated to trade one contract at the best price quoted in the crowd, or if there are no prices quoted, at the disseminated price." *See* Securities Exchange Act Release No. 42035 (October 19, 1999), 64 FR 57681 (October 26, 1999) (File No. SR–PCX–99–13).

[6] *See* Securities Exchange Act Release No. 40852 (December 28, 1998), 64 FR 1058 (January 7, 1999) (File No. SR–PCX–98–16).

[7] *See supra* note 5.

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be subject to disciplinary action pursuant to rule 10.13. The proposed recommended fines, pursuant to proposed rule 10.13(k)(i)(35) of this rule are $500, $1000 and $1,500 for first, second and third time violations, respectively.

Seventh, the Exchange proposes to amend the text specifying the recommended fines for violations of the position limit rules pursuant to rule 10.13(k)(i)(21) of the Minor Rule Plan Recommended Fine Schedule. The Exchange proposes that position and exercise limit violations be the greater of $250.00 or $1 per contract over 5% of the applicable limit. The Exchange proposes this change so that it is obvious that the imposition of a monetary fine is recommended regardless of whether the applicable number of contracts is less than 5% over the designated position or exercise limit.

Eighth, the Exchange proposes to amend the text specifying the recommended fines for violations of the exercise limit rules pursuant to rule 10.13(k)(i)(22) of the Minor Rule Plan Recommended Fine Schedule. The Exchange proposes that position and exercise limit violations be the greater of $250.00 or $1 per contract over 5% of the applicable limit. The Exchange proposes this change so that it is obvious that the imposition of a monetary fine is recommended regardless of whether the applicable number of contracts is less than 5% over the designated position or exercise limit.

Ninth, the Exchange proposes to delete all references to OFPAs in rule 10.13(h) and (k), pertaining to the PCX Minor Rule Plan and to replace those references with the current rules. The Exchange proposes this change because it intends to renumber and incorporate all OFPAs pertaining to Options trading into the text of Rule 6.[8]

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b)(5) of the Act[9] because it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, and in general, to protest investors and the public interest. The proposal is also consistent with Section 6(b)(6),[10] which requires that members and persons associated with members be appropriately disciplined for violations of Exchange Rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Written comments were not solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. by order approve the proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–PCX–99–48 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1192 Filed 1–12–01; 8:45 am]

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[8] See Securities Exchange Act Release No. 42035 (October 19, 1999), 64 FR 57681 (October 26, 1999) (File No. SR–PCX–99–13); Release No. 43293 (September 14, 2000) 65 FR 57416 (September 22, 2000) (File No. SR–PCX–99–36); Release No. 43025 (July 12, 2000), 65 FR 44559 (July 18, 2000) (File No. SR–PCX–99–40); Release No. 43149 (August 11, 2000), 65 FR 51392 (August 23, 2000) (File No. SR–PCX 99–44); and Release No. 42861 (May 30, 2000), 65 FR 36489 (June 8, 2000) (File No. SR–PCX–99–45).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78f(b)(6).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43816; File No. SR–PCX–00–42]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Supervisory Procedures

January 8, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2000, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On December 28, 2000, the Exchange filed Amendment No. 1 to the proposed rule change.[3] On January 5, 2001, the Exchange filed Amendment No. 2 to the proposed rule change.[4] The proposed rule change, as amended, has become effective on filing pursuant to section 19(b)(3)(A) of the Act[5] and rule 19b–4(f)(6) thereunder.[6] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See Letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission (December 28, 2000) ("Amendment No. 1"). Amendment No. 1 corrected typographical errors that appeared in the proposed rule text.

[4] See Letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division, Commission (January 5, 2001) ("Amendment No. 2"). Amendment No. 2 further corrected typographical errors that appeared in the proposed rule text.

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to adopt a rule requiring all members to adopt and implement a supervisory system and written supervisory procedures. Below is the text of the proposed rule change. Additions are *italicized* and deletions are in brackets.

Supervision

* * * * *

Rule 4.25(a). Adherence to Law

No member or member organization may engage in conduct in violation of the federal securities laws, the Constitution or the Rules of the Exchange. Every member or member organization must supervise persons associated with the member or member organization so as to assure compliance therewith.

(b) *Supervisory System*

Each member or member organization for which the Exchange is the Designated Examining Authority ("DEA") must establish and maintain a system to supervise the activities of its associated persons and the operations of its business. Such system must be reasonably designed to ensure compliance with applicable federal securities laws and regulations and PCX Rules. Final responsibility for proper supervision will rest with the member or member organization. The member's or member organization's supervisory system must provide, at a minimum, for the following:

(1) *The establishment and maintenance of written procedures as required by paragraph (c) of this Rule.*

(2) *The designation of a person with authority to reasonably discharge his/her duties and obligations in connection with supervision and control of the activities of the associated persons of the member or member organization.*

(3) *The member or member organization must undertake reasonable efforts to determine that all supervisory personnel are qualified by virtue of experience or training to carry out their assigned responsibilities.*

(4) *Each member or member organization must designate and specifically identify to the Exchange one or more persons who will be responsible for such supervision.*

(c) *Written Procedures*

Each member or member organization must establish, maintain, and enforce written procedures to supervise the business in which it engages and to supervise the activities of its associated persons that are reasonably designed to ensure compliance with applicable federal securities laws and regulations, and with the PCX Rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

There are some PCX and Pacific Exchange Equities, Inc., ("PCXE") rules that relate to supervision of firm activity for those PCX member firms that conduct a public business. these include options rules such as, "Office Supervision"[7] "Account Supervision,"[8] "Conduct on the Floor,"[9] and equities rules such as, "Allied Persons & Approved Persons,"[10] "Office Supervision,"[11] and "Account Supervision."[12] The Exchange, however, does not currently have a comprehensive rule that directly addresses the obligation of every member or member organization, whether conducting a public business or a proprietary business, to properly supervise its business and employees. The Exchange believes that the proposed rule clarifies (1) the responsibility of the member or member firm for the acts of its employees; and (2) the requirement that each member must supervise those persons for which it is responsible.

The proposed rule has three distinct parts. The first section of the proposed rule change is a prohibition on engaging in conduct that violates the federal securities laws, the Constitution or the Rules of the Exchange. This section also informs members that they must supervise all associated persons in order to assure compliance.

Section two of the proposed rule change sets forth the responsibility of all members or member organizations to establish and maintain a system to supervise the activities of its employees. The proposed rule states that this system must be reasonably designed to achieve compliance with the federal securities laws and PCX rules. The final responsibility for proper supervision rests with the member or member organization. The supervisory system must, at a minimum, provide (1) the designation of a person responsible for carrying out the firm's supervisory obligations; (2) a requirement that the member or member organization must undertake reasonable efforts to determine that all supervisory personnel are qualified, by virtue of experience and training, to carry out their obligations; and (3) a requirement that the member or member organization must identify to the Exchange the person(s) who will be responsible for such supervision.

Section three of the proposed rule change states that each member or member organization must establish, maintain, and enforce written procedures to supervise the business in which it engages and to supervise the activities of its employees. These procedures must be reasonably designed to achieve compliance with the federal securities laws and the PCX rules.

The Commission approved a similar rule filing by the National Association of Securities Dealers, Inc.[13] The Exchange believes that the proposed rule change will serve to significantly strengthen the ability of the Exchange to carry out its oversight responsibilities as a self-regulatory organization. The proposed rule change should also help the Exchange to carry out its examination, compliance, and surveillance functions. Finally, the proposed rule change clarifies to member or member organizations supervisory obligations.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with section 6(b) of the Act,[14] in general, and furthers the objectives of section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, and protect investors and the public interest by setting forth member supervisory obligations.

[7] PCX Rule 9.1.

[8] PCX Rule 9.2(b).

[9] PCX Rule 6.2(b).

[10] PCXE Rule 2.14(d).

[11] PCXE Rule 9.1(c).

[12] PCXE Rule 9.1(d).

[13] See National association of Securities Dealers, Rule 3010.

[14] 15 U.S.C. 78f(b).

[15] U.S.C. 78f(b)(5).

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B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, and the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date, it has become effective pursuant to section 19(b)(3)(A) of the Act[16] and rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC. 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX.

All submissions should refer to File No. SR–PCX–00–42 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1193 Filed 1–12–01; 8:45 am]

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[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 200.30–2(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43817; File No. SR–PCX–00–43]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Supervisory Procedures for Pacific Exchange Equities, Inc.

January 8, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 1, 2000, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. On December 28, 2000, the Exchange filed an amendment to the proposed rule change.[3] On January 5, 2001, the Exchange filed Amendment No. 2 to the proposed rule change.[4] The proposed rule change, as amended, has become effective on filing pursuant to Section 19(b)(3)(A) of the Act[5] and Rule 19b–4(f)(6) thereunder.[6] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division of Market Regulation ("Division"), Commission (December 28, 2000) ("Amendment No. 1"). Amendment No. 1 corrected typographical errors that appeared in the proposed rule text.

[4] *See* Letter from Hassan Abedi, Attorney, Regulatory Policy, PCX, to Nancy J. Sanow, Assistant Director, Division, Commission (January 5, 2001) ("Amendment No. 2"). Amendment No. 2 further corrected typographical errors that appeared in the proposed rule text.

[5] 15 U.S.C. 78s(b)(3)(A).

[6] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to adopt a Pacific Exchange Equities, Inc. ("PCXE") rule requiring all ETP Holders, Equity ASAP Holders and ETP Firms to adopt and implement a supervisory system and written supervisory procedures. Below is the text of the proposed rule change. Additions are *italicized*, and deletions are in brackets.

Supervision

* * * * *

Rule 6.17(a). Adherence to Law

No ETP Holder, Equity ASAP Holder or ETP Firms may engage in conduct in violation of the federal securities laws, the Constitution or the Rules of the Corporation. Every ETP Holder, Equity ASAP Holder or ETP Firm must supervise persons associated with it so as to assure compliance therewith.

(b). Supervisory System

Each ETP Holder, Equity ASAP Holder or ETP Firm for which the Corporation is the Designated Examining Authority ("DEA") must establish and maintain a system to supervise the activities of its associated persons and the operation of its business. Such system must be reasonably designed to ensure compliance with applicable federal securities laws and regulations and PCXE Rules. Final responsibility for proper supervision will rest with the ETP Holder, Equity ASAP Holder or ETP Firm. The ETP Holder's, Equity ASAP Holder's or ETP Firm's supervisory system must provide, at a minimum, for the following:

(1) The establishment and maintenance of written procedures as required by paragraph (c) of this Rule.

(2) The designation of a person with authority to reasonably discharge his/her duties and obligations in connection with supervision and control of the activities of the associated persons of the ETP Holder, Equity ASAP Holder or ETP Firm.

(3) The ETP Holder, Equity ASAP Holder or ETP Firm must undertake reasonable efforts to determine that all supervisory personnel are qualified by virtue of experience or training to carry out their assigned responsibilities.

(4) Each ETP Holder, Equity ASAP Holder or ETP Firm must designate and specifically identify to the Corporation one or more persons who will be responsible for such supervision.

(c). Written Procedures

Each ETP Holder, Equity ASAP Holder or ETP Firm must establish, maintain, and enforce written procedures to supervise the business in which it engages and to supervise the activities of its associated persons that are reasonably designed to achieve compliance with applicable federal securities laws and regulations, and with the PCXE Rules.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

There are some PCX and PCXE rules that relate to supervision of firm activity for those PCX member firms and PCXE ETP Holders, Equity ASAP Holders and ETP Firms that conduct a public business. These include options rules such as, "Office Supervision,"[7] "Account Supervision,"[8] "Conduct on the Floor,"[9] and equities rules such as, "Allied Persons & Approved Persons,"[10] "Office Supervision,"[11] and "Account Supervision."[12] The Exchange, however, does not currently have a comprehensive rule that directly addresses the obligation of every member firm and ETP Holder, Equity ASAP Holder and ETP Firm, whether conducting a public business or a proprietary business, to properly supervise its business and employees. The proposed rule clarifies (1) the responsibility of the ETP Holders, Equity ASAP Holders and ETP Firms for the acts of its employees; and (2) the requirement that each ETP Holder, Equity ASAP Holder and ETP Firm must supervise those persons for which it is responsible.

The proposed rule has three distinct parts. The first section of the proposed rule change is a prohibition on engaging in conduct that violates the federal securities laws, the Constitution or the Rules of the Exchange and the PCXE. This section also informs ETP Holders, Equity ASAP Holders and ETP Firms that they must supervise all associated persons in order to assure compliance.

Section two of the proposed rule change sets forth the responsibility of all ETP Holders, Equity ASAP Holders and ETP Firms to establish and maintain a system to supervise the activities of their employees. The proposed rule states that this system must be reasonably designed to achieve compliance with the federal securities laws and PCXE rules. The final responsibility for proper supervision rests with the ETP Holder, Equity ASAP Holder and ETP Firm. The supervisory system must, at a minimum, provide (1) the designation of a person responsible for carrying out the firm's supervisory obligations; (2) a requirement that the ETP Holder, Equity ASAP Holder and ETP Firm must undertake reasonable efforts to determine that all supervisory personnel are qualified, by virtue of experience and training, to carry out their obligations; and (3) a requirement that the ETP Holder, Equity ASAP Holder and ETP Firm must identify to the PCXE the person(s) who will be responsible for such supervision.

Section three of the proposed rule change states that each ETP Holder, Equity ASAP Holder and ETP Firm must establish, maintain, and enforce written procedures to supervise the business in which it engages and to supervise the activities of its employees. These procedures must be reasonably designed to achieve compliance with the federal securities laws and the PCXE rules.

The Commission approved a similar rule filing by the National Association of Securities Dealers, Inc.[13] The Exchange believes that the proposed rule change will serve to significantly strengthen the ability of the Exchange to carry out its oversight responsibilities as a self-regulatory organization. The proposed rule change should also aid the Exchange in carrying out its examination, compliance, and surveillance functions. Finally, the proposed rule change clarifies ETP Holder's, Equity ASAP Holder's and ETP Firm's supervisory obligations.

[7] PCX Rule 9.1.

[8] PCX Rule 9.2(b).

[9] PCX Rule 6.2(b).

[10] PCXE Rule 2.14(d).

[11] PCXE Rule 9.1(c).

[12] PCXE Rule 9.1(d).

[13] *See* National Association of Securities Dealers, Rule 3010.

2. Statutory Basis

The Exchange believes that the proposed rule change, as amended, is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, prevent fraudulent and manipulative acts and practices, and protect investors and the public interest by setting forth member supervisory obligations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, and the Exchange provided the Commission with written notice of its intent to file the proposed rule change at least five business days prior to the filing date, it has become effective pursuant to Section 19(b)(3)(A) of the Act[16] and Rule 19b–4(f)(6) thereunder.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(6).

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Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the PCX.

All submissions should refer to File No. SR–PCX–00–43 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1194 Filed 1–12–01; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43812; File No. SR–Phlx–99–50]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Amending the Exchange's Certificate of Incorporation

January 5, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 23, 1999, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Phlx filed an amendment to the proposal on December 28, 2000.[3] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

a. The Original Filing

The Phlx proposes to amend its Certificate of Incorporation to add Article Nineteenth, relating to the leasing of memberships.[4] A complete copy of the text of Article Nineteenth is available at the Office of the Secretary, the Phlx, and at the Commission.

Proposed Article Nineteenth provides that, in addition to all other powers granted to the Board by law, the Certificate of Incorporation or otherwise, the Board shall have the power to determine whether, and under what terms and conditions, memberships may be leased, and to adopt by resolution or to set forth in the Rules of the Board such rules with respect to lease agreements, lessors and lessees as the Board may from time to time determine to be advisable. Such rules may include rules regulating and setting forth the rights and obligations of lessors and lessees, the required terms of lease agreements, and the fees, dues, and other charges required to be paid by lessors and lessees (or either of them) to the Exchange in connection with, and for the privilege of, leasing memberships. In addition, proposed Article Nineteenth provides that the Board shall have the power to adopt rules relating to the suspension or termination of any or all lease agreements with respect to memberships, to issue provisional trading privileges on such terms as the Board shall determine to members whose lease agreements are suspended or terminated, and to amend, alter, or repeal any or all of the Rules of the Board with respect to any of the foregoing matters.

b. Amendment No. 1

As a non-stock corporation organized under the Delaware General Corporation Law ("DGCL"), the Exchange represents that it has ample authority to adopt proposed Article Nineteenth. Because the Exchange's Certificate of Incorporation does not require member approval to adopt a charter amendment, proposed Article Nineteenth may be adopted by the Board of Governors without approval by the members of the Exchange (including lessees of memberships) or the owners of memberships (including lessors of memberships). 8 *Del. C.* § 242(b)93).[5] Therefore, the Exchange's Board adopted Article Nineteenth in accordance with Section 242.

Furthermore, Section 141(j) of the DGCL empowers the Board to direct the business and affairs of the Exchange, and the Exchange's by-laws give the Board broad power to adopt rules of the Exchange. 8 *Del. C.* § 141(j);[6] By-Law Art. IV, § 4–4. In addition, existing Article Third of the Phlx Certificate of Incorporation gives the Exchange authority to do all things necessary to run a national securities exchange.[7] Numerous provisions of the Exchange's by-laws and rules already address matters similar to those addressed by proposed Article Nineteenth.[8] Therefore, the adoption of Article Nineteenth falls within the broad authority expressly conferred by Delaware law and existing provisions under the Phlx Certificate of Incorporation.

[18] CFR 200.30–2(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See Letter from Cynthia Hoekstra, Counsel, Phlx, to Nancy Sanow, Assistant Director, Division of Market Regulation, Commission, dated December 27, 2000 ("Amendment No. 1"). In Amendment No. 1, the Phlx represented that the Phlx's Board has the authority to adopt Article Nineteen pursuant to Delaware corporate law, Pennsylvania contract law, and the Exchange's Certificate of Incorporation, by-laws, and rules.

[4] In connection with this proposed rule change, the Commission approved a propose rule change that adopted Article Twentieth. *See* Securities Exchange Act Release No. 42317 (January 5, 2000), 65 FR 2215 (January 13, 2000) (SR–Phlx–99–48). Article Twentieth provides, in part, that the Exchange's Board of Governors ("Board") shall have the power to assess such fees, dues, and other charges upon members, lessors and lessees of memberships and holders of permits (or any of them) as the Board may from time to time adopt by resolution or set forth in the Rules of the Board. On May 11, 2000 the Commission approved a proposed rule change, which amended Article Twentieth to include the words "owner" and "member organization" and to define the word "owner" to clarify the original intent of Article Twentieth. *See* Securities Exchange Act Release No. 42773 (May 11, 2000), 65 FR 31622 (May 18, 2000) (SR–Phlx–00–30).

[5] Section 242 of the DGCL permits the board of a non-stock corporation to adopt amendments to the corporation's Certificate of Incorporation.

[6] *See also* 8 *Del. C.* § 121(a) (providing that in addition to powers expressly granted by law or the Certificate of Incorporation, the corporation and its directors may exercise "any powers incidental thereto, so far as such powers and privileges are necessary or convenient to the conduct, promotion or attainment of the business or purposes set forth in its certificate of incorporation").

[7] Article Third states, in part, that the Exchange may operate as and perform all functions of a national securities exchange and engage in any lawful act or activity for which corporations may be organized under the DGCL.

[8] *See, e.g.*, By-Law Art. XV, § 15–1(a) (providing that a membership may be leased in accordance with such rules as the Board may adopt); Rule 930 (setting forth required terms of lease agreement and providing, among other things, that the Exchange may dispose of a membership subject to a lease agreement); Rule 960.1 (providing that all members, member organizations and any persons associated with any member are subject to expulsion, suspension, termination as to activities at the Exchange or any other fitting sanction for violation of the Rules of the Exchange); *see also* Certificate of Incorporation, Article 20th (giving Board plenary authority to assess fees, dues and other charges and to impose penalties, including cancellation of a membership and forfeiture of all rights as a lessor or lessee, for nonpayment).

Pursuant to Article Nineteenth, the Board would have the authority to make rules that impact lease arrangements, including adopting rules relating to the termination of lease agreements. As discussed, the Exchange's Certificate of Incorporation, by-laws and rules already include several provisions addressing such authority.[9] Moreover, the Exchange's by-laws require lessors and lessees (as members) to pledge to abide by the rules as they may be amended from time to time.[10]

Accordingly, under the DGCL and the Exchange's Certificate of incorporation, by-laws, and rules, the Exchange represents that its Board of Governors has the authority to adopt Article Nineteenth without approval thereof by members, or by owners, lessors, or lessees of memberships.

Proposed Article Nineteenth is also permissible as a matter of Pennsylvania contract law. The provisions of Article Nineteenth authorizing the adoption of rules affecting lease agreements between lessors and lessees are lawful because, under the terms of its relationships with both lessors and lessees, the Exchange has the right to adopt by-laws, rules, or regulations that affect those lessors and lessees. Pennsylvania law holds that a contracting party may lawfully exercise its own contractual rights against another party to the contract, even if doing so interferes with the terms of a separate agreement of the other party. Here, the potential suspension or termination of a lease agreement in accordance with the rules of the Exchange is permissible under the terms of the Exchange's separate agreements with each of the parties to the lease agreement.

Both lessors and lessees (as members) agree respectively as a condition of approval of the right to lease seats and as a condition of approval for membership that the Exchange may effectuate changes to their lease agreements, including termination. As a condition of the right to lease their seats, lessors agree "to abide by the [Exchange's] By-Laws as they have or shall be from time to time amended, and by all rules and regulations adopted pursuant to the By-Laws." *See* By-Law Art. XII, § 12–9(b). Lessees (as members) likewise make the same commitment. *See id.* at 12–9(a). By agreeing to abide by future by-laws, rules, and regulations, lessors and lessees necessarily grant permission to the Exchange to adopt rules pursuant to which their lease agreements may be suspended or terminated. Indeed, the Exchange has already repeatedly exercised its right to adopt rules and by-laws directly impacting lessors and lessees in a variety of rules, including Rule 930, which closely regulates the terms and conditions of lease agreements.[11] Accordingly, article Nineteenth, which would provide in express form the authorization for the adoption of rules suspending or terminating lease agreements, would simply authorize that which is countenanced by the terms of the Exchange's existing relationships with lessors and lessees, and is thereby permissible as a matter of Pennsylvania contract law.

Proposed Article Nineteenth was properly adopted by the Exchange Board under Delaware law and is permissible as a matter of Pennsylvania contract law. As a result, the Exchange believes it should take effect in accordance with its terms following SEC approval and the filing of Article Nineteenth with the Secretary of State of the State of Delaware.

II. Self-Regulatory Organization's Statement Regarding the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to amend the Exchange's Certificate of Incorporation to provide for specific authority regarding the regulation of leases, including the rights and obligations of lessors and lessees. Article Nineteen will enable the Board to adopt and oversee specific rules relating to the leasing of memberships to protect and promote the best interests of the Exchange.

The Exchange acknowledges that any such rules or resolutions, which are adopted by the Board, shall be filed with the Commission to the extent required pursuant to Section 19(b) of the Act[12] and Commission rules thereunder. Moreover, it is intended that such rules or resolutions proposed by the Exchange and related to the leasing of memberships, primarily in connection with the termination or suspension of lease agreements, shall delineate, if applicable, the notice and procedural requirements that address any potentially adversely affected party to be followed prior to terminating or suspending a lease agreement.

For these reasons, the Exchange believes that the proposed rule change is consistent with Section 6 of the Act,[13] in general, and with Section 6(b)(5),[14] in particular, in that it promotes just and equitable principles of trade and protects investors and the public interest by enabling the Board to determine whether, and under what terms and conditions, memberships may be leased.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change imposes no burden on competition.

c. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to

[9] *See, e.g.*, Certificate of Incorporation, article Thirteenth (lessor entitled to vote on compromise or arrangement); Certificate of incorporation, Article Seventeenth (lessor entitled to receive any distribution of assets upon liquidation); By-Law Article I, Section 1–1 defining lessor and lessee); By-Law Article XII, Section 12–8 (authorizing lessor application fee as fixed from time to time by the Board, lessor initiation fee and fee upon transfer of equitable title to a membership); and Rule 930 (setting forth required terms of lease agreements).

[10] *See* Exchange By-Law Article XII, Section 12–9. As a condition of the right to lease their seats, lessors agree "to abide by the [Exchange's] By-Laws as they have or shall be from time to time amended, and by all rules and regulations adopted pursuant to the By-Laws." Lessees, as members, likewise make the same commitment.

[11] Other examples include By-Law Art. I, § 1–1 (defining lessor and lessee); By-Law Art. XII, § 12–1 (a member conducts business on the Exchange); By-Law Art. XII, § 12–8 (authorizing lessor application fee, lessor initiation fee, and fees upon transfer of equitable title); By-Law Art. XIV, §§ 14–1, 14–2, 14–5 (the Exchange can impose charges on members, including penalties for non-payment of fees); By-Law Art. XV, § 15–1 (the Exchange approves lessors); Rule 931 (the Exchange approves lessees); Rule 960.1 *et seq.* (the Exchange may discipline members).

[12] 15 U.S.C. 78s(b).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

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90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which Phlx consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to File No. SR–Phlx–99–50 and should be submitted by February 6, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1154 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional "peg" rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 5.875 (5⅞) percent for the January–March quarter of FY 2001.

LeAnn M. Oliver,

Deputy Associate Administrator for Financial Assistance.

[FR Doc. 01–1200 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment

AGENCY: Office of the United States Trade Representative.

ACTION: Request for written submissions from the public.

SUMMARY: Section 182 of the Trade Act of 1974 (Trade Act) (19 U.S.C. § 2242), requires the United States Trade Representative (USTR) to identify countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. (Section 182 is commonly referred to as the "Special 301" provisions in the trade act.) In addition, the USTR is required to determine which of these countries should be identified as Priority Foreign Countries. Acts, policies or practices which are the basis of a country's identification as a priority foreign country are normally the subject of an investigation under the Section 301 provisions of the trade act. Section 182 of the Trade Act contains a special rule for the identification of actions by Canada affecting United States cultural industries.

USTR requests written submissions from the public concerning foreign countries' acts, policies, and practices that are relevant to the decision whether particular trading partners should be identified under Section 182 of the Trade Act.

DATES: Submissions must be received on or before 12:00 noon on Friday, February 16, 2001.

ADDRESSES: 600 17th Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Claude Burcky, Deputy Assistant U.S. Trade Representative for Intellectual Property (202) 395–6864; Kira Alvarez or John Desrocher, Directors for Intellectual Property (202) 395–6864, or Stephen Kho, Assistant General Counsel (202) 395–3851, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: Pursuant to Section 182 of the Trade Act, the USTR must identify those countries that deny adequate and effective protection for intellectual property rights or deny fair and equitable market access to U.S. persons who rely on intellectual property protection. Those countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies or practices have the greatest adverse impact (actual or potential) on relevant U.S. products are to be identified as Priority Foreign Countries. Acts, policies or practices that are the basis of a country's designation as a Priority Foreign Country are normally the subject of an investigation under the Section 301 provisions of the Trade Act.

USTR may not identify a country as a Priority Foreign Country if it is entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

In identifying countries that deny adequate and effective protection of intellectual property rights in 2001, USTR will continue to pay special attention to other countries' efforts to reduce piracy of optical media (music CDs, video CDs, CD–ROMs, and DVDs) and prevent unauthorized government use of computer software. USTR will also focus on countries' compliance with their WTO TRIPS obligations, which for developing country members came due on January 1, 2000.

Section 182 contains a special rule regarding actions of Canada affecting United States cultural industries. The USTR is obligated to identify any act, policy or practice of Canada which affects cultural industries, is adopted or expanded after December 17, 1992, and is actionable under Article 2106 of the North American Free Trade Agreement (NAFTA). Any such act, policy or practice so identified shall be treated the same as an act, policy or practice which was the basis for a country's identification as a Priority Foreign Country under Section 182(a)(2) of the Trade Act, unless the United States has already taken action pursuant to Article 2106 of the NAFTA.

USTR must make the above-referenced identifications within 30 days after publication of the National Trade Estimate (NTE) report, *i.e.*, no later than April 30, 2001.

Requirements for Comments

Comments should include a description of the problems experienced and the effect of the acts, policies and practices on U.S. industry. Comments should be as detailed as possible and should provide all necessary information for assessing the effect of the acts, policies and practices. Any comments that include quantitative loss claims should be accompanied by the methodology used in calculating such estimated losses. Comments must be in English and provided in twenty copies. A submitter requesting that information contained in a comment be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the submitter. Confidential business information must be clearly marked "business confidential" in a contrasting color ink at the top of each page of each copy. A non-confidential version of the comment must also be provided.

All comments should be sent to Sybia Harrison, Special Assistant to the Section 301 committee, Room 100A, 600 17th Street, NW., Washington, DC 20508, and must be received no later than 12:00 noon on Friday, February 16, 2001.

Public Inspection of Submissions

Within one business day of receipt, non-confidential submissions will be placed in a public file, open for inspection at the USTR reading room, in Room 101, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC. An appointment to review the file may be made by calling Brenda Webb, (202) 395–6186. The USTR reading room is open to the public from 10 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday.

Joseph S. Papovich,

Assistant USTR for Services, Investment and Intellectual Property.

[FR Doc. 01–1220 Filed 1–12–01; 8:45 am]

BILLING CODE 3190–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. WTO/D–217]

WTO Consultations Regarding The Continued Dumping and Subsidy Offset Act of 2000

AGENCY: Office of the United States Trade Representative.

ACTION: Notice; request for comments.

SUMMARY: The Office of the United States Trade Representative ("USTR") is providing notice that on December 21, 2000, Australia, Brazil, the European Communities ("EC"), India Indonesia, Japan, Korea, and Thailand, acting jointly and severally, requested consultations with the United States under the Understanding on Rules and Procedures Governing the Settlement of Disputes ("DSU"), the General Agreement Regarding Tariffs and Trade 1994 ("GATT 1994"), the Agreement on the Implementation of Article VI of GATT 1994 ("Antidumping Agreement") and the Agreement on Subsidies and Countervailing Duties ("SCM Agreement") regarding the Continued Dumping and Subsidy Offset Act of 2000 ("Offset Act"), Public Law No. 106–387. The requesting parties allege that the Offset Act is inconsistent with certain obligations of the United States under GATT 1994, the Antidumping Agreement and the SCM Agreement. Pursuant to Article 4.3 of the DSU, such consultations are to take place within a period of 30 days from the date of the request, or within a period otherwise mutually agreed between the United States and the requesting parties. USTR invites written comments from the public concerning the issues raised in this dispute.

DATES: although the USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before February 9, 2001, to be assured of timely consideration by USTR.

ADDRESSES: Submit comments to Sandy McKinzy, Monitoring and Enforcement Unit, Office of the General Counsel, Room 122, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC, 20508, Attn: Byrd Amendment, Telephone: (202) 395–3582.

FOR FURTHER INFORMATION CONTACT: Rhonda K. Schnare, Associate General Counsel, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC, (202) 395–3582.

SUPPLEMENTARY INFORMATION: Section 127(b) of the Uruguay Round Agreements Act (URAA) (19 U.S.C. 3537(b)(1)) requires that notice and opportunity for comment be provided after the United States receives a request for the establishment of a WTO dispute settlement panel. Consistent with this obligation, but in an effort to provide additional opportunity for comment, USTR is providing notice that consultations have been requested pursuant to the WTO Dispute Settlement Understanding. If such consultations should fail to resolve the matter and a dispute settlement panel is established pursuant to the DSU, such panel, which would hold its meetings in Geneva, Switzerland, would be expected to issue a report on its findings and recommendations within six to nine months after it is established.

Major Issues Raised by the Consultation Request

The Continued Dumping and Subsidy Offset Act of 2000 amends the Tariff Act of 1930 to provide that duties collected pursuant to an antidumping duty order, a countervailing duty order or a finding under the Antidumping Act of 1921 are to be annually distributed to the affected domestic producers for their qualifying expenses.

The consultation request alleges the Offset Act constitutes a specific action against dumping or subsidization that is not contemplated by GATT 1994, the Antidumping Agreement or the SCM Agreement. The request further alleges that the Offset Act prevents the reasonable and impartial administration of the U.S. laws implementing the provisions of the Antidumping Agreement and the SCM Agreement regarding standing determinations and undertakings. Specifically, the request alleges that the Offset Act is inconsistent with

Article 18.1 of the Antidumping Agreement, in conjunction with Article VI:2 of GATT 1994 and Article 1 of the Antidumping Agreement;

Article 32.1 of the SCM Agreement, in conjunction with Article VI:3 of GATT 1994 and Articles 4.10, 7.9 and 10 of the SCM Agreement;

Article X(3)(a) of GATT 1994;

Article 5.4 of the Antidumping Agreement and Article 11.4 of the SCM Agreement;

Article 8 of the Antidumping Agreement and Article 18 of the SCM Agreement; and

Article XVI:4 of the Marrakesh Agreement Establishing the World Trade Organization ("WTO Agreement"), Article 18.4 of the Antidumping Agreement and Article 32.5 of the SCM Agreement.

In addition, the request alleges that the offsets paid under the Act constitute specific subsidies with the meaning of Article 1 of the SCM Agreement which may cause adverse effects to the requesting parties' interests within the meaning of Article 5 of the SCM Agreement.

Finally, the request asserts that, whether or not in conflict with the cited agreements, the Offset Act may nullify or impair benefits accruing to the requesting parties in a manner described in Article XXIII:1(b) of GATT 1994.

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in the dispute. Comments must be in English and

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provided in fifteen copies. A person requesting that information contained in a comment submitted by that person be treated as confidential business information must certify that such information is business confidential and would not customarily be released to the public by the commenter. Confidential business information must be clearly marked "BUSINESS CONFIDENTIAL" in a contrasting color ink at the top of each page of each copy.

Information or advice contained in a comment submitted, other than business confidential information, may be determined by USTR to be confidential in accordance with section 135(g)(2) of the Trade Act of 1974 (19 U.S.C. 2155(g)(2)). If the submitter believes that information or advice may qualify as such, the submitter—

(1) Must so designate the information or advice;

(2) Must clearly mark the material as "SUBMITTED IN CONFIDENCE" in a contrasting color ink at the top of each page of each copy; and

(3) Is encouraged to provide a non-confidential summary of the information or advice.

Pursuant to section 127(e) of the URAA (19 U.S.C. 3537(e)), USTR will maintain a file on this dispute settlement proceeding, accessible to the public, in the USTR Reading Room: Room 101, Office of the United States Trade Representative, 600 17th Street, N.W., Washington, D.C. 20508. The public file will include a listing of any comments received by USTR from the public with respect to the proceeding; the U.S. submissions to the panel in the proceeding, the submissions, or non-confidential summaries of submissions, to the panel received from other participants in the dispute, as well as the report of the dispute settlement panel, and, if applicable, the report of the Appellate Body. An appointment to review the public file (Docket WTO/D-217, Byrd Amendment Dispute) may be made by calling Brenda Webb, (202) 395-6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday.

A. Jane Bradley,

Assistant United States Trade Representative for Monitoring and Enforcement.

[FR Doc. 01-1159 Filed 1-12-01; 8:45 am]

BILLING CODE 3190-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice for Waiver of Aeronautical Land-Use Assurance; Willoughby Lost Nation Municipal Airport, Willoughby, OH

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent of waiver with respect to land.

SUMMARY: The Federal Aviation Administration (FAA) is considering a proposal to change a portion of airport land from aeronautical use to non-aeronautical use and to authorize the lease of the airport property. The proposal consists of one parcel of land totaling approximately 12.903 acres for an outdoor soccer facility. Current use and present condition is vacant grassland. There are no impacts to the airport by allowing the airport to dispose of the property. The land was acquired under FAA Project Nos.: AIP-3-39-0090-0185 and AIP-3-39-0090-0589. Approval does not constitute a commitment by the FAA to financially assist in the lease of the subject airport property nor a determination that all measures covered by the program are eligible for Airport Improvement Program funding from the FAA. The disposition of proceeds from the lease of the airport property will be in accordance with the FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in the **Federal Register** on February 16, 1999. Together this proposal is for approximately 12.903 acres in total.

In accordance with section 47107(h) of title 49, United States Code, this notice is required to be published in the **Federal Register** 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose. The proposed land will be used for the development of soccer-specific facilities, which have proven to enhance the economy for many Ohio communities in recent years. With over 55,000 registered players in Ohio-North alone, the opportunity to bring major and minor events into the Willoughby area would be significant. This development will also aide in increasing the positive tax revenue stream to the City, and add to the vitality of the existing sports complex during the spring, summer & fall months.

The proceeds from the lease of the land will be used for airport improvements and operation expenses at Willoughby Lost Nation Municipal Airport.

DATES: Comments must be received on or before February 15, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Stephanie R. Swann, Federal Aviation Administration, Great Lakes Region, Detroit Airports District Office, DET ADO-670.5, Willow Run Airport, East, 8820 Beck Road, Belleville, Michigan 48111, (734) 487-7277. Documents reflecting this FAA action may be reviewed at this same location or at Willoughby Lost Nation Municipal Airport, Willoughby, Ohio.

SUPPLEMENTARY INFORMATION: Following are legal descriptions of the property:

Legal Description of a 12.903 Acre Parcel Being Part of Land of the City of Willoughby Who Claims Title Through Instrument Recorded in Volume 212, Page 908 of the Lake County Records

Situated in the City of Willoughby, County of Lake and State of Ohio and known as being part of Original Lot No. 6, Douglas Tract as is further bounded and described as follows:

Beginning at a monument in the center of the cul-de-sac of Jet Center Place, as recorded in Volume 16, Page 34 of the Lake County Map Records.

Thence North 14°02'00" East 68.50 feet to an iron pin found in the westerly line of a6.8187 acre parcel of land of the City of Willoughby recorded in Vol. 680, Page 252 of Lake County Official Records;

Thence North 1°14'52" East, along said line, 82.96 feet to an iron pin found at the northwesterly corner of said land and being the principal place of beginning;

Course 1: Thence North 1°44'30" East, along a line, 903.33 feet to an iron pin found at the southerly line of land conveyed to Lost Nation Parkway Ltd. by Document No. 980042081 of the Lake County Records;

Course II: Thence South 88°15'30" East, along said southerly line and its prolongation easterly, 623.50 feet to an iron pin set;

Course III: Thence South 1°44'30" West 899.57 feet to an iron pin found at the northeasterly corner of said land of the City of Willoughby;

Course IV: Thence North 88°36'14" West, along said land, 623.51 feet to the principal place of beginning and containing 12.903 acres of land according to a survey made in May, 2000 by Richard J. Bilski, Ohio Professional Surveyor No. 5244 of CT Consultants, Inc., 35000 Kaiser Court, Willoughby, Ohio 44094;

The bearing stated herein are based upon the recorded centerline of Jet Center Place. All the iron pins, either set or found are ⅝ iron rebar with yellow caps marked "CT Consultants, Inc."

Issued in Belleville, Michigan, December 8, 2000.

Irene Porter,

Manager, Detroit Airports District Office, Great Lakes Region

[FR Doc. 01-712 Filed 1-12-01; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA-2001-8620]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 19, 2001.

ADDRESSES: Comments must refer to the docket notice numbers cited at the beginning of this notice and be submitted to Docket Management, Room PL-401, 400 Seventh Street, S.W., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB clearance Number. It is requested, but not required, that 2 copies of the comment be provided. The Docket Section is open on weekdays from 10 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Mr. Ed Kosek, NHTSA 400 Seventh Street, SW, Room 6123,Washington, DC 20590. Mr. Kosek's telephone number is (202) 366-2589. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected;

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Compliance Labeling of Warning Devices in 49 CFR Section 571.125

Type of Request: Reinstatement of Clearance.

OMB Clearance Number: 2127-0506.

Form Number: This collection of information uses no standard forms.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: 49 U.S.C. 30111, 30112 and 30117 (Appendix 1) of the National Traffic and Motor Vehicle Safety Act of 1966, authorizes the issuance of Federal Motor Vehicle Safety Standards (FMVSS). The Secretary is authorized to issue, amend, and revoke such rules and regulations as she/he deems necessary.

Using this authority, the agency issued FMVSS No. 125, "Warning Devices" (Appendix 2), which applies to devices, without self contained energy sources, that are designed to be carried mandatorily in buses and trucks that have a gross vehicle weight rating (GVWR) greater than 10,000 pounds and voluntarily in other vehicles. These devices are used to warn approaching traffic of the presence of a stopped vehicle, except for devices designed to be permanently affixed to the vehicle.

Description of the need for the information and proposed use of the information: Each manufacturer of warning triangles must label each device to comply with Standard No. 125. This standard establishes requirements for devices, without self-contained energy sources. Without proper deployment and use, the effectiveness of the devices may be greatly diminished, and may lead to serious injuries due to rear end collisions between moving traffic and disabled vehicles.

The warning device shall be permanently and legibly marked and also provide instructions for its erection and display. Each device shall be labeled with; (a) the name of the manufacturer, (b) the month and year of manufacture, (c) the DOT symbol, or the statement that the warning device complies with all applicable FMVSS. The instructions for each device shall include a recommendation that the driver activate the vehicular hazard warning signal lamps before leaving the vehicle to erect the warning device. Also, the instructions shall include an illustration indicating recommended positioning.

Without these devices and instructions there could be more deaths and injuries caused by stopped or disabled motor vehicles.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): There are three manufacturers labeling approximately 2.85 million warning devices (triangles) per year for the last few years. Based on the estimated number of warning triangles produced per year, the frequency of response is estimated to be 2.85 million.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: For the 2.85 million warning triangles produced per year, the tooling to label them would be replaced after about 20 years of service being used to make about 200K devices per year. The machining each mold that would be replaced is about 8 hours at a cost of $37.50 per hour, or a cost of $300. Assuming that this past years production level of 2.85 million devices were built each year for the last twenty years (an over-estimate that ignores the long steady growth of the market), the total number of devices manufactured would be 57 million. The tooling needs to be replaced every 4 million uses; the total number of tools used in the last 20 years is 14.25. The machining for the

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labeling in each tool would be 14.25 times 8 hours divided by 57 million, or 0.000002 hour per device. Thus the current annual cost for the 2.85 million devices manufactured is 5.7 hours × $37.50 = $213.75.

Authority: 44 U.S.C. 3506(c); delegation of authority at 49 CFR 1.50.

Issued on: January 9, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1216 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2001–8618]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 19, 2001.

ADDRESSES: Comments must refer to the docket notice numbers cited at the beginning of this notice and be submitted to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB clearance Number. It is requested, but not required, that 2 copies of the comment be provided. The Docket Section is open on weekdays from 10 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Mr. Ed Kosek, NHTSA 400 Seventh Street, SW, Room 6123,Washington, DC 20590. Mr. Kosek's telephone number is (202) 366–2589. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected;

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Labeling of Retroreflective Materials for Heavy Trailer Conspicuity

Type of Request: Reinstatement of Clearance.

OMB Clearance Number: 2127–0569.

Form Number: This collection of information uses no standard forms.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: The permanent marking of the letters "DOT–C2", "DOT–C3" or "DOT–C4" at least 3mm high at regular intervals on retroreflective sheeting material is the information collection.

Description of the need for the information and proposed use of the information: Federal Motor Vehicle Safety Standard No. 108, "Lamps, Reflective Devices, and Associated Equipment," specifies requirements for vehicle lighting for the purposes of reducing traffic accidents and their tragic results by providing adequate roadway illumination, improved vehicle conspicuity, appropriate information transmission through signal lamps, in both day, night, and other conditions of reduced visibility. For certification and identification purposes, the Standard requires the permanent marking of the letters "DOT–C2," "DOT–C3," or "DOT–C4" at least 3mm high at regular intervals on retroreflective sheeting material having adequate performance to provide effective trailer conspicuity.

The manufacturers of new tractors and trailers are required to certify that their products are equipped with retroreflective material complying with the requirements of the standard. The Federal Highway Administration Office of Motor Carrier Safety enforces this and other standards through roadside inspections of trucks. There is no practical field test for the performance requirements, and labeling is the only objective way of distinguishing trailer conspicuity grade material from lower performance material. Without labeling, FHWA will not be able to enforce the performance requirements of the standard, and the compliance testing of new tractors and trailers will be complicated. Labeling is also important to small trailer manufacturers because it may help them to certify compliance. Because wider stripes of material of lower brightness also can provide the minimum safety performance, the marking system serves the additional role of identifying the minimum stripe width required for the retroreflective brightness of the particular material. Since the differences between the brightness grades of suitable retroreflective conspicuity material is not obvious from inspection, the marking system is necessary for tractor and trailer manufacturers and repair shops to assure compliance and for FHWA to inspect tractors and trailers in use.

Permanent labeling is used to identify retroreflective material having the minimum properties required for effective conspicuity of trailers at night. The information enables the FHWA to make compliance inspections, and it aids tractor and trailer owners and repair shops in choosing the correct repair materials for damaged tractors and trailers. It also aids small trailer manufacturers in certifying compliance of their products.

The FHWA will not be able to determine whether trailers are properly equipped during roadside inspections without labeling. The use of cheaper and more common reflective materials, which are ineffective for the application, would be expected in repairs without the labeling requirement.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): The respondents are likely to be manufacturers of the conspicuity material. The agency is aware of at least three. Based on the estimated number of feet of conspicuity material for a year's installation on new tractors and trailers, the number of imprints of the information is estimated to be 10 million.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: The cost to manufacturers of extending the label requirement is the maintenance and amortization of printing rollers and the additional dye or ink consumed. The labels are to be placed at intervals of about 18 inches on rolls of retroreflective conspicuity tape. The labels are printed during the normal course of steady flow manufacturing operations without a direct time penalty.

Two methods of printing the label are in use. One method uses the same roller that applies the dye to the red segments of the material pattern. The roller is resurfaced annually using a computerized etching technique. The "DOT–C2" label was incorporated in the software to drive the roller resurfacing in 1993, and there is no additional cost to continue the printing of the label. In fact, costs would be incurred to discontinue the label.

The second method uses a separate roller to apply the label. The manufacturer using this technique reports that these rollers have been in service for 5 years without detectable wear and predicts a service life of at least fifteen years. Four rollers costing about $2,500 each are used. A straight line depreciation of the rollers over 15 years equals $667 per year. With an annual allowance for $333 for additional dye, the annual total industry cost of maintaining the "DOT–C2" label is about $1,000.

Authority: 44 U.S.C. 3506(c); delegation of authority at 49 CFR 1.50.

Issued on: January 9, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards

[FR Doc. 01–1217 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket Number NHTSA–2000–8619]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 19, 2001.

ADDRESSES: Comments must refer to the docket notice numbers cited at the beginning of this notice and be submitted to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB clearance Number. It is requested, but not required, that 2 copies of the comment be provided. The Docket Section is open on weekdays from 10 a.m. to 5 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Mr. Ed Kosek, NHTSA 400 Seventh Street, SW., Room 6123,Washington, DC 20590. Mr. Kosek's telephone number is (202) 366–2589. Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected;

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks for public comments on the following proposed collections of information:

Replaceable Light Source Dimensional Information for 49 CFR Part 564

Type of Request: Reinstatement of Clearance.

OMB Clearance Number: 2127–0563.

Form Number: This collection of information uses no standard forms.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: The information to be collected is in response to 49 CFR Part 564; "Replaceable Light Source Dimensional Information." Persons desiring to use newly designed replaceable headlamp light sources are required to submit interchangeability and performance specifications to the agency. After a short agency review to assure completeness, the information is placed in a public docket for use by any person who would desire to manufacture headlamp light sources for highway motor vehicles. In Federal Motor Vehicle Safety Standard No. 108, "Lamps, reflective devices and associated equipment," Part 564 submissions are referenced as being the source of information regarding the performance and interchangeability information for legal headlamp light sources, whether original equipment or replacement equipment. Thus, the submitted information about headlamp light sources becomes the basis for certification of compliance with safety standards.

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Description of the need for the information and proposed use of the information: The information is to be placed in a public docket for the use by vehicle, headlamp and headlamp light source manufacturers for determining the interchangeability aspects of headlamp light sources for manufacturing purposes and for the design and manufacture of headlamps. In order for replacement light sources to be designated as acceptable replacements, the replacement light sources also are required to comply with the dimensional and performance information in the docket for its type. The Federal program for reducing highway fatalities, injuries and accidents would likely be adversely affected if the information was not collected, because the bulbs would, in fact, not be standardized for performance and interchangeability. If the interchangeability information were not available to manufacturers who normally provide original equipment and aftermarket parts, replacements could become significantly more costly to replace upon burnout, and ready availability would also likely diminish because the replacements would be available from only the vehicle's manufacturer or its dealer. As a potential adverse safety consequence, more and more vehicles would likely be on the highways at night with headlamps having one or more failed bulbs because of the higher expense and lower availability, and therefore reduce the roadway illumination and increase the risk of accident. In the event that the information collection were not reapproved, it is likely that the agency would have to reinstate headlamp light source information as part of the federal lighting standard and thus any new light source designs could be used only after a lengthy and costly rulemaking instead of this simple review and reference procedure.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): For the burdened parties, only those which develop a new or modified headlamp light source or other additional interchange information will have to submit information. Based on the last three years of Part 564 data collection, sixteen submissions have been received.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: The average estimated cost of the information submissions is estimated to be 4.2 hours per submission at $100 per hour for a cost of $420 each, thus at a rate of 16/3 submissions per year, the average annual cost is $2240 and the average annual hour burden is 22.9 hours.

Issued on: January 9, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1218 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

Advisory Board; Notice of Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. I) notice is hereby given of a meeting of the Advisory Board of the Saint Lawrence Seaway Development Corporation (SLSDC), to be held at 1 PM on Friday, January 26, 2001, by conference call in the Administrator's Office, room 5424, 400 7th Street, S.W. Washington, D.C. The agenda for this meeting will be as follows: Opening Remarks; Consideration of Minutes of Past Meeting; Review of Programs; New Business; and Closing Remarks.

Attendance at meeting is open to the interested public but limited to the space available. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact not later than January 22, 2001, Marc C. Owen, Advisory Board Liaison, Saint Lawrence Seaway Development Corporation, 400 Seventh Street, SW., Washington, DC 20590; 202–366–6823.

Any member of the public may present a written statement to the Advisory Board at any time.

Issued at Washington, D.C. on January 9, 2001.

Marc C. Owen,

Chief Counsel.

[FR Doc. 01–1176 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF THE TREASURY

Departmental Offices Privacy Act of 1974; System of Records

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of Alteration to a Privacy Act System of Records.

SUMMARY: The Department is altering its system of records, Treasury/DO .203—Public Transportation Incentive Program Records.

DATES: Comments must be received no later than February 15, 2001. The proposed system of records will be effective February 26, 2001, unless the Department receives comments that would result in a contrary determination.

ADDRESSES: Comments should be sent to Disclosure Services, Department of the Treasury, 1500 Pennsylvania Ave., NW., Washington DC, 20220.

FOR FURTHER INFORMATION CONTACT: Les Smith, Program Manager, Facilities Management Division, (202) 622–0989, fax (202) 622–5334.

SUPPLEMENTARY INFORMATION: The Department is altering its system of records notice pertaining to the public transportation incentive program to bring its format into conformance with the other Treasury-wide systems of records notices by adding the following Treasury bureaus to the notice: Bureau of Alcohol, Tobacco and Firearms (ATF); Office of the Comptroller of the Currency (OCC); United States Customs Service (CS); Federal Law Enforcement Training Center (FLETC); Internal Revenue Service (IRS); United States Secret Service (USSS); and Office of Thrift Supervision (OTS). The system location is revised by listing each bureau under "System Location."

The "System manager(s)" is revised to identify the official responsible for the program at each bureau. The "Categories of records in the system" has been expanded to include records relating to the incentives authorized under the Federal Workforce Transportation Program. The "Purpose(s)" statement and the "Notification procedures" are also being revised. Under "Authority for maintenance of the system," new authority citations are being added as needed by individual bureaus. Three new routine uses (routine uses 7, 8 and 9) are being added to the system notice and routine uses (2) and (6) are being amended. The entry under "Record source categories" is also being revised.

The records are used to administer the public transportation incentive or subsidy programs provided by the bureaus for eligible employees. The notice for the system of records was last published in its entirety on December 17, 1998, at 63 FR 69737.

The altered system of records report, as required by 5 U.S.C. 552a(r) of the Privacy Act, has been submitted to the Committee on Government Reform and Oversight of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix I to OMB Circular A–130, Federal Agency Responsibilities

for Maintaining Records About Individuals, dated February 8, 1996.

The system of records, "Public Transportation Incentive Program Records-Treasury/DO," is published in its entirety below.

Dated: January 3, 2001.

W. Earl Wright, Jr.,

Chief Management and Administrative Programs Officer.

SYSTEM NAME:

Public Transportation Incentive Program Records-Treasury/DO.

SYSTEM LOCATION:

Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. The locations at which the system is maintained by Treasury bureaus and their associated field offices are:

1. a. Departmental Offices (DO): 1500 Pennsylvania Ave., NW, Washington, DC 20220.

b. The Office of Inspector General (OIG): 740 15th Street, NW, Washington, DC 20220.

2. Bureau of Alcohol, Tobacco and Firearms (ATF): 650 Massachusetts Avenue, NW, Washington, DC 20226.

3. Office of the Comptroller of the Currency (OCC): 250 E Street, SW, Washington, DC 20219–0001.

4. United States Customs Service (CS): 1300 Pennsylvania Avenue, NW, Washington DC 20229.

5. Bureau of Engraving and Printing (BEP): 14th & C Streets, SW, Washington, DC 20228.

6. Federal Law Enforcement Training Center (FLETC): Glynco, Ga. 31524.

7. Financial Management Service (FMS): 401 14th Street, SW, Washington, DC 20227.

8. Internal Revenue Service (IRS): 1111 Constitution Avenue, NW, Washington, DC 20224.

9. United States Mint (MINT): 801 9th St. NW, Washington, DC 20220.

10. Bureau of the Public Debt (BPD): 200 Third Street, Parkersburg, WV 26101.

11. United States Secret Service (USSS): 950 H Street, NW, Washington, DC 20001.

12. Office of Thrift Supervision (OTS): 1700 G Street, NW, Washington, DC 20552.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees who have applied for or who participate in the Public Transportation Incentive Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Public Transportation Incentive Program application form containing the participant's name, last four digits of the social security number, place of residence, office address, office telephone, grade level, duty hours, previous method of transportation, costs of transportation, and the type of fare incentive requested. Incentives authorized under the Federal Workforce Transportation Program may be included in this program.

(2) Reports submitted to the Department of the Treasury in accordance with Treasury Directive 74–10.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 26 U.S.C. 132(f), and Public Law 101–509.

PURPOSE(S):

The records are used to administer the public transportation incentive or subsidy programs provided by Treasury bureaus for eligible employees. The system also enables the Department to compare these records with other Federal agencies to ensure that employee transportation programs benefits are not abused.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used to disclose information to:

(1) Appropriate Federal, state, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order or license;

(2) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, in response to a court-ordered subpoena where relevant or potentially relevant to a proceeding, or in connection with criminal law proceedings;

(3) A congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Unions recognized as exclusive bargaining representatives under the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and/or 7114;

(5) Agencies, contractors, and others to administer Federal personnel or payroll systems, and for debt collection and employment or security investigations;

(6) Other Federal agencies for matching to ensure that employees receiving PTI Program benefits are not listed as a carpool or vanpool participant, the holder of a parking permit; and to prevent the program from being abused;

(7) The Department of Justice when seeking legal advice, or when (a) the Department of the Treasury (agency) or (b) any component thereof, or (c) any employee of the agency in his or her official capacity, or (d) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or (e) the United States, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation;

(8) The Office of Personnel Management, the Merit Systems Protection Board, the Equal Employment Opportunity Commission, and the Federal Labor Relations Authority or other third parties when mandated or authorized by statute; and

(9) A contractor for the purpose of compiling, organizing, analyzing, programming, or otherwise refining records to accomplish an agency function subject to the same limitations applicable to U.S. Department of Treasury officers and employees under the Privacy Act.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM

STORAGE:

Paper records, file folders and/or electronic media.

RETRIEVABILITY:

By name of individual, badge number or office.

SAFEGUARDS:

Access is limited to authorized employees. Files are maintained in locked safes and/or file cabinets. Electronic records are password-protected. During non-work hours, records are stored in locked safes and/or cabinets in locked room.

RETENTION AND DISPOSAL:

Active records are retained indefinitely. Inactive records are held for three years and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

The system managers for the Treasury Bureaus are:

(1) a. Departmental Offices: Assistant Director, Parking, Safety and Farecard Office, Facilities Management Division, 1500 Pennsylvania Ave., NW, Washington, DC 20220.

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b. Office of Inspector General: Office of Assistant Inspector for Resources, Office of Administrative Services, Suite 510, 740 15th St. NW., Washington, DC 20220.

(2) ATF: Chief, Safety Program Branch, Administrative Programs Division, Office of Management, 650 Massachusetts Ave., NW., Washington, DC 20226.

(3) BEP: Chief, Office of Administrative Services, Bureau of Engraving and Printing, 14th and C Streets, SW., Washington, DC 20228.

(4) OCC: Building Manager, Building Services, Office of the Comptroller of the Currency, 250 E Street, SW, Washington, DC 20219–0001.

(5) CS: Chief, Headquarters Facilities Service Branch, 1300 Pennsylvania Avenue, NW., Suite 3.2C, Washington, DC 20229.

(6) FLETC: Associate Director for Planning & Resources Federal Law Enforcement Training Center, Glynco, GA 31524

(7) FMS: Director, Facilities Management Division, Financial Management Service, 3700 East West Hwy., Room 144, Hyattsville, MD 20782.

(8) IRS: Official prescribing policies and practices—Chief, National Office, Protective Program Staff, Director, Personnel Policy Division, 2221 S. Clark Street-CP6, Arlington, VA 20224. Officials maintaining the system—Supervisor of local offices where the records reside. (See IRS Appendix A for addresses.)

(9) Mint: Office of Management Services, 801 9th St. NW., Washington, DC 20220.

(10) BPD: Executive Director, Administrative Resources Center, 200 Third Street, Parkersburg, WV 26106.

(11) USSS: Assistant Director, Office of Administration, 950 H Street, NW., Washington DC 20373–5802.

(12) OTS: Director, Planning, Budget and Finance, Office of Thrift Supervision, Department of the Treasury, 1700 G Street, NW., Washington, DC 20552.

NOTIFICATION PROCEDURE:

Individuals seeking notification and access to any record contained in the system of records, or seeking to contest its content, may inquire in accordance with instructions given in the Appendix for each Treasury bureau appearing at 31 CFR Part 1, Subpart C.

RECORD ACCESS PROCEDURES:

See "Notification procedure" above.

CONTESTING RECORD PROCEDURES:

See "Notification procedure" above.

RECORD SOURCE CATEGORIES:

The source of the data are employees who have applied for the transportation incentive, the incentive program managers and other appropriate agency officials, or other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–1010 Filed 1–12–01; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Departmental Offices; Privacy Act of 1974; System of Records

AGENCY: Departmental Offices, Treasury.

ACTION: Notice of Proposed New Privacy Act System of Records Notices.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Department of the Treasury gives notice of a new proposed system of records, "Treasury/DO .003—Law Enforcement Retirement Claims Records."

DATES: The proposed system of records will be effective February 26, 2001, unless the Department receives comments that would result in a contrary determination.

ADDRESSES: Comments should be sent to Director, Office of Personnel Policy, Room 6018-Metropolitan Square, Department of the Treasury, Washington, DC 20220.

FOR FURTHER INFORMATION CONTACT: Anne Carlucci, Office of Personnel Policy, (202) 622–2855.

SUPPLEMENTARY INFORMATION: The Department of the Treasury makes determinations concerning requests by Treasury employees that the positions they hold in a law enforcement bureau qualify as a law enforcement position (5 U.S.C. 8336(c)(1) and 8412(d)).

The records are maintained and used by the Departmental Office of Personnel Policy because government-wide Office of Personnel Management regulations require that the determination of coverage in a law enforcement position be made by the agency head or a designee who must report directly to the agency head or his/her deputy.

The new system of records report, as required by 5 U.S.C. 552a(r) of the Privacy Act, has been submitted to the Committee on Government Reform of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget, pursuant to Appendix I to OMB Circular A–130, Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996.

This system of records, "Treasury/DO .003—Law Enforcement Retirement Claims Records," is published in its entirety below.

Dated: January 3, 2001.

W. Earl Wright, Jr.,

Chief Management and Administrative Programs Officer.

Treasury/DO .003

SYSTEM NAME:

Law Enforcement Retirement Claims Records.

SYSTEM LOCATION:

These records are located in the Office of Personnel Policy, Department of the Treasury, Washington, DC 20220.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current or former Federal employees who have submitted claims for law enforcement retirement coverage (claims) with their bureaus in accordance with 5 U.S.C. 8336(c)(1) and 5 U.S.C. 8412(d).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains records relating to claims filed by current and former Treasury employees under 5 U.S.C. 8336(c)(1) and 5 U.S.C. 8412(d). These case files contain all documents related to the claim including statements of witnesses, reports of interviews and hearings, examiner's findings and recommendations, a copy of the original and final decision, and related correspondence and exhibits.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 8336(c)(1), 8412(d), 1302, 3301, and 3302; E.O. 10577; 3 CFR 1954–1958 Comp., p. 218 and 1959–1963 Comp., p. 519; and E.O. 10987.

PURPOSE(S):

The purpose of the system is to make determinations concerning requests by Treasury employees that the position he or she holds qualifies as a law enforcement position for the purpose of administering employment and retirement benefits.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used:

(1) To disclose pertinent information to the appropriate Federal, state, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(2) To disclose information to any source from which additional information is requested in the course of processing a claim, to the extent necessary to identify the individual whose claim is being adjudicated, inform the source of the purpose(s) of the request, and identify the type of information requested;

(3) To disclose information to a Federal agency, in response to its request, in connection with the hiring or retention of an individual, the issuance of a security clearance, the conducting of a security or suitability investigation of an individual, the classifying of jobs, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to requesting the agency's decision on the matter;

(4) To provide information to a congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(5) To disclose information which is necessary and relevant to the Department of Justice or to a court when the Government is party to a judicial proceeding before the court;

(6) To provide information to the National Archives and Records Administration for use in records management inspections conducted under authority of 44 U.S.C. 2904 and 2908;

(7) To disclose information to officials of the Merit Systems Protection Board, the Office of the Special Counsel, the Federal Labor Relations Authority, the Equal Employment Opportunity Commission, or the Office of Personnel Management when requested in performance of their authorized duties;

(8) To disclose information to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing Counsel or witnesses in the course of civil discovery, litigation or settlement negotiations in response to a subpoena where relevant or potentially relevant to a proceeding, or in connection with criminal law proceedings; and

(9) To provide information to officials of labor organizations recognized under the Civil Service Reform Act when relevant and necessary to their duties of exclusive representation concerning personnel policies, practices, and matters affecting work conditions.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders and electronic media.

RETRIEVABILITY:

By the names of the individuals on whom they are maintained.

SAFEGUARDS:

Lockable metal filing cabinets to which only authorized personnel have access. Automated databases are password protected.

RETENTION AND DISPOSAL:

Disposed of after closing of the case in accordance with General Records Schedule 1, Civilian Personnel Records, Category 7d.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Personnel Policy, Room 6018-Metropolitan Square, Department of the Treasury, Washington, DC 20220.

NOTIFICATION PROCEDURE:

It is required that individuals submitting claims be provided a copy of the record under the claims process. They may, however, contact the agency personnel or designated office where the action was processed, regarding the existence of such records on them. They must furnish the following information for their records to be located and identified: (1) Name, (2) date of birth, (3) approximate date of closing of the case and kind of action taken, (4) organizational component involved.

RECORD ACCESS PROCEDURES:

It is required that individuals submitting claims be provided a copy of the record under the claims process. However, after the action has been closed, an individual may request access to the official copy of the claim file by contacting the system manager. Individuals must provide the following information for their records to be located and identified: (1) Name, (2) date of birth, (3) approximate date of closing of the case and kind of action taken, (4) organizational component involved.

CONTESTING RECORD PROCEDURES:

Review of requests from individuals seeking amendment of their records which have been the subject of a judicial or quasi-judicial action will be limited in scope. Review of amendment requests of these records will be restricted to determining if the record accurately documents the action of the agency ruling on the case, and will not include a review of the merits of the action, determination, or finding. Individuals wishing to request amendment to their records to correct factual errors should contact the system manager. Individuals must furnish the following information for their records to be located and identified: (1) Name, (2) date of birth, (3) approximate date of closing of the case and kind of action taken, (4) organizational component involved.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided: (1) By the individual on whom the record is maintained, (2) by testimony of witnesses, (3) by agency officials, (4) from related correspondence from organizations or persons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 01–1011 Filed 1–12–01; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Means Test Thresholds

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) is hereby giving notice of cost-of-living adjustments (COLA) for means test income limitations. These adjustments are based on the rise in the Consumer Price Index (CPI) during the one-year period ending September 30, 2000.

DATES: These rates are effective January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Roscoe Butler, Chief Policy and Operations, Health Administration Service, (10C3), Veterans Health Administration, VA, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–8302. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Title 38 United States Code 1722(c), requires that on January 1 of each year, the Secretary increase the means test threshold amounts by the same percentage the maximum rates of pension benefits were increased under 38 U.S.C. 5312(a) during the preceding calendar year. Under the provisions of 38 U.S.C 5312 and section 306 of Public Law 95–588, VA is required to increase the benefit rates and income limitations in the pension and parents' indemnity compensation (DIC) program by the same percentage, and effective the same date, as increases in the benefit amount

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payable under Title II of the Social Security Act.

On October 24, 2000, for the period beginning December 1, 2000, the Social Security Administration announced at 65 FR 63663 of the **Federal Register**, a 3.5 percent cost-of-living increase in Social Security Benefits under Title II of the Social Security Act. The Veteran Benefits Administration has indicated Pension benefits will be increased by a 3.5 percent cost-of-living increase effective December 1, 2000. Therefore, applying the same percentage and rounding up in accordance with 38 CFR 3.29, the following income limitations for the Means Test Thresholds will be effective January 1, 2001.

TABLE 1.—MEANS TEST THRESHOLDS

(1) Veterans with no dependents:	
(a) Means Test Co-payment Exempted Category	$23,688
(b) Means Test Co-payment Required Category	23,689
(2) Veterans with 1 dependent:	
(a) Means Test Co-payment Exempt Category	28,429
(b) Means Test Co-payment Required Category	28,430
(3) Veterans with 2 dependents:	
(a) Means Test Co-payment Exempt Category	30,015
(b) Means Test Co-payment Required Category	30,016
(4) Veterans with 3 dependents:	
(a) Means Test Co-payment Exempt Category	31,601
(b) Means Test Co-payment Required Category	31,602
(5) Veterans with 4 dependents:	
(a) Means Test Co-payment Exempt Category	33,187
(b) Means Test Co-payment Required Category	33,188
(6) Veterans with 5 dependents:	
(a) Means Test Co-payment Exempt Category	34,773
(b) Means Test Co-payment Required Category	34,774
(7) Child Income Exclusion is:	7,450
(8) The Medicare deductible is:	792
(9) Maximum annual Rate of Pension effective December 1, 2000 are:	
(a) The base rate is	9,304
(b) The base rate with one dependent is	12,186
(c) Add 1,586 each additional dependent.	

Approved: January 5, 2001.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

[FR Doc. 01–1180 Filed 1–12–01; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs.

ACTION: Report of New System of Records—Consolidated Data Information System—VA (97VA105).

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e)(4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their system of records. Notice is hereby given that VA is adding a new system of records entitled "Consolidated Data Information System—VA" (97VA105).

DATES: Comments on the establishment of the new system of records must be received no later than February 15, 2001. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the system will become effective February 15, 2001.

ADDRESSES: Comments may be submitted to Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Comments will be available for public inspection at the above address in the Office of Regulations Management, Room 1176, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration Privacy Act Officer (193B2), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (727) 320–1839.

SUPPLEMENTARY INFORMATION: Under Section 527 of Title 38, U.S.C., and the Government Performance and Results Act of 1993, Pub. L. 103–62, VA is required to measure and evaluate, on an ongoing basis, the effectiveness of VA benefit programs and services. In performing this required function, VA must collect, collate and analyze full statistical data regarding participation, provision of services, categories of beneficiaries, and planning of expenditures for all VA programs. For this reason, VA is establishing a new system of records, which combines information from several existing systems of records with information from non-VA sources. This combined database is necessary for VA to accurately and timely assess the current health care usage by the patient population served by VA, to forecast future demand for VA medical care by individuals currently eligible for service by VA medical facilities, and to understand the numerous implications of cross-utilization between VA and non-VA health care systems.

Records from the Patient Medical Record System (24VA136), the Patient Fee Basis Medical and Pharmacy Records (23VA136), Veterans and Beneficiaries Identification and Records Location Subsystem (38VA23), Compensation, Pension, Education and Rehabilitation Records (58VA21/22), and Automated Medication Processing Records (56VA119) will be incorporated into this new system of records. Specific request files will be created for use in submitting requests for veteran-specific data from the Health Care Financing Administration (HCFA), the Department of Defense (DoD), and other non-VA data sources including state Medicaid databases. The new database will be created by including Medicare data records on utilization and enrollment for all VA users, enrollees and special category veterans. Utilization and enrollment data will also be extracted from the DoD military personnel system of records in order to supplement VA's database. This system will not be used by VA to make any determinations as to individual veteran's benefits. Because the exchange of data among VA, HCFA, DoD, and any other non-VA agencies will be only for the purpose of identifying current health care usage and forecasting future health care usage by VA beneficiaries, the computer matching provision of the Privacy Act does not apply.

VA will maintain the system of records in electronic form at VA Management Science Group, Bedford, Massachusetts, and VA Information Resource Center, Hines, Illinois. Copies or parts of these records may be maintained at VA Automation Center, Austin, Texas, and VA Allocation Resource Center, Braintree, Massachusetts. Multiple sites are needed because VA data files will be drawn from multiple locations and merged data files will be very large. Data in the system of records will include names, social security numbers (SSNs), demographic and health services utilization data for all VHA users and special veteran populations; inpatient, outpatient, physician supplier, nursing home, hospice, home care, and durable medical equipment data form HCFA; and utilization and enrollment data from DoD. The new database will be used to produce reports for statistical analyses on, for example: (1) The number of Medicare-eligible users who obtain health care services from VA, Medicare, and both VA and Medicare providers (dual use); (2) the number of "dual use" veterans by specific disease categories; and (3) the inpatient, outpatient, and total costs associated with VA services and Medicare covered services by "dual use" veterans. Statistical reports will not contain individually identifiable health information.

We are proposing to establish the following routine use disclosures of information which will be maintained in the system:

1. To Federal, State, and local agencies for the purpose of better identifying the total current health care usage of the patient population by VA, to forecast future demand for VA medical care, and as part of statistical matching programs.

VA needs to obtain information from other agencies in order to collect full statistical data regarding participation and provision of services to the patient population served by VA as well as non-VA health care systems. The records may also be disclosed as part of statistical matching programs to accomplish these purposes.

2. To Federal, State and local government agencies and national health organizations in order to assist in the development of programs that will be beneficial to claimants and to protect their rights under law and assure that they are receiving all benefits to which they are entitled.

VA needs to obtain information from other agencies in order to measure and evaluate, on an ongoing basis, the effectiveness of VA benefit programs and services.

3. To a Federal, State, or local agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. The names and addresses of veterans may only be disclosed:

- To a Federal agency when it is relevant to a suspected violation or reasonably imminent violation of law; and
- To a State or local agency under a written request when it is relevant to a suspected violation or reasonably imminent violation of law concerning public health or safety.

VA must be able to comply with the requirements of agencies charged with enforcing the law, and investigations of violations or possible violations of law. VA must also be able to provide information to State or local agencies charged with protecting the public health as set forth in State law.

4. To epidemiological and other research facilities approved by the Under Secretary for Health for research purposes (disclosure excludes names and addresses).

VA must be able to disclose information for research purposes approved by the Under Secretary for Health.

5. To a Federal department or agency or to a contractor of a Federal department or agency in order to conduct Federal research necessary to accomplish a statutory purpose of an agency.

VA must be able to disclose information for research purposes needed to accomplish a statutory purpose of a Federal agency.

6. To the National Archives and Record Administration (NARA) in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

NARA is responsible for archiving old records no longer actively used, but which may be appropriate for preservation; they are responsible in general for the physical maintenance of the Federal government's records. VA must be able to turn records over to this agency in order to determine the proper disposition of such records.

7. To the Department of Justice or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear when the Agency, or any component thereof; or any employee of the Agency in his or her official capacity; where the Department of Justice or the Agency has agreed to represent the employee; or the U.S. when the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation, and has an interest in such litigation, and the use of such records by the Department of Justice or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that the disclosure is compatible with the purpose for which the records were collected.

Whenever VA is involved in litigation, or occasionally when another party is involved in litigation and VA policies or operations could be affected by the outcome of the litigation, VA would be able to disclose information to the court or parties involved. A determination would be made in each instance that, under the circumstances involved, the purpose served by the use of the information in the particular litigation is compatible with a purpose for which VA collects the information.

8. To individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

VA must be able to provide information to contractors or subcontractors with whom VA has a contract or agreement in order to perform the services of the contract or agreement.

Release of information from these records will be made only in accordance with the provisions of the Privacy Act of 1974 for investigative, judicial and administrative uses. The Privacy Act permits us to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which we collected the information. In all of the routine use disclosures described above, either the recipient of the information will use the information in connection with a matter relating to one of VA's programs, will use the information to provide a benefit to VA, or disclosure is required by law. VA has determined that release of information for these purposes is a necessary and proper use of information and that specific routine uses for transfer of this information are appropriate.

Approved: December 15, 2000.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

97VA105

SYSTEM NAME:

Consolidated Data Information System-VA.

SYSTEM LOCATION(S):

Records will be maintained at the following computer site locations: VA Management Science Group, 200 Springs Road, Bedford, Massachusetts 01730; and VA Information Resource Center, 5th Avenue & Roosevelt Road, Hines, Illinois 60141. Copies or parts of these records may be maintained at the following computer site locations: VA Automation Center, 1615 Woodward Street, Austin, Texas 78722; and VA Allocation Resource Center, 100 Grandview Road, Braintree, Massachusetts 02184.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records include information concerning active duty military personnel, veterans, their spouses and their dependents, and individuals who are not VA beneficiaries, but who receive health care services from VHA.

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CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records in the system will include veterans' names, addresses, dates of birth, VA claim numbers, SSNs, and military service information; medical benefit application and eligibility information; code sheets and follow-up notes; sociological, diagnostic, counseling, rehabilitation, drug and alcohol, dietetic, medical, surgical, dental, psychological, and/or psychiatric medical information; prosthetic, pharmacy, nuclear medicine, social work, clinical laboratory and radiology information; patient scheduling information; family information such as next of kin, spouse and dependents; names, addresses, social security numbers and dates of birth; family medical history, employment information; financial information; third-party health plan information; information related to ionizing radiation and Agent Orange; date of death; VA claim and insurance file numbers; travel benefits information; military decorations; disability or pension payment information; information on indebtedness arising from 38 U.S.C. benefits; medical and dental treatment in the Armed Forces and claim information; applications for compensation, pension, education and rehabilitation benefits; information related to incarceration in a penal institution; medication profile such as name, quantity, prescriber, dosage, manufacturer, lot number, cost and administration instruction; pharmacy dispensing information such as pharmacy name and address.

The records will include information on DoD military personnel from two categories of DoD files: (1) Utilization files that contain inpatient and outpatient records, and (2) eligibility files from the Defense Eligibility Enrollment Reporting System (DEERS) containing data on all military personnel including those discharged from the Armed Services since 1972.

The records will include information on Medicare beneficiaries from HCFA databases: Denominator file (identifies the population being studied); Standard Analytical files (inpatient, outpatient, physician supplier, nursing home, hospice, home care, durable medical equipment); and Group Health Plan.

The records include information on Medicaid beneficiaries' utilization and enrollment from state databases.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 527 of 38 U.S.C. and the Government Performance and Results Act of 1993, Pub. L. 103–62.

PURPOSE(S):

The purpose of this system of records is to conduct statistical studies and analyses which will support the formulation of Departmental policies and plans by identifying the total current health care usage of the VA patient population.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Information from this system of records may be disclosed in accordance with the following routine uses:

1. Disclosure of identifying information, such as names, SSNs, demographic and utilization data, may be made to Federal, State, local, or tribal agencies such as the DoD, HCFA, and Medicare Payment Advisory Commission (MedPAC), as part of statistical matching programs for the purpose of better identifying the total current health care usage of the patient population served by VA in order to forecast future demand for VA medical care by VA medical facilities.

2. Disclosure may be made to Federal, State, local, and tribal government agencies and national health organizations in order to assist in the development of programs that will be beneficial to claimants and assure that they are receiving all benefits to which they are entitled.

3. Disclosure may be made of information relevant to or indicating a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, to Federal, State, local, or tribal agencies charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order listed pursuant thereto.

4. Disclosure may be made, excluding name and address (unless name and address are furnished by the requestor) for research purposes determined to be necessary and proper, to epidemiological and other research facilities approved by the Under Secretary for Health.

5. In order to conduct Federal research necessary to accomplish a statutory purpose of an agency, at the written request of the recipient agency, the name (s) and address (s) of present or former personnel of the Armed Services and/or their dependents may be disclosed (a) To a Federal department or agency or (b) directly to a contractor of a Federal department or agency. When disclosure of this information is to be made directly to the contractor, VA may impose applicable conditions on the department, agency and/or contractor to insure the appropriateness of the disclosure to the contractor.

6. Disclosure may be made to National Archives and Records Administration (NARA), General Services Administration (GSA) in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

7. Records from this system of records may be disclosed to the Department of Justice or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear when: The Agency, or any component thereof; or any employee of the Agency in his or her official capacity; where the Department of Justice or the Agency has agreed to represent the employee; or the U.S. when the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation, and has an interest in such litigation, and the use of such records by the Department of Justice or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that the disclosure is compatible with the purpose for which the records were collected.

8. Disclosure may be made to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data are maintained on magnetic tape, disk, or laser optical media.

RETRIEVABILITY:

Records may be retrieved by name, name and one or more criteria (*e.g.*, dates of birth, death and service), SSN or VA claim number.

SAFEGUARDS:

1. Access to and use of these records is limited to those persons whose official duties require such access. Personnel screening is employed to prevent unauthorized disclosure.

2. Access to Automated Data Processing files is controlled at two levels: (1) Terminals, central processing units, and peripheral devices are generally placed in secure areas (areas that are locked or have limited access) or are otherwise protected; and (2) the system recognizes authorized users by means of an individually unique password entered in combination with an individually unique user identification code.

3. Access to automated records concerning identification codes and codes used to access various VA automated communications systems and records systems, as well as security profiles and possible security violations is limited to designated automated systems security personnel who need to know the information in order to maintain and monitor the security of VA's automated communications and veterans' claim records systems. Access to these records in automated form is controlled by individually unique passwords/codes. Agency personnel may have access to the information on a need to know basis when necessary to advise agency security personnel or for use to suspend or revoke access privileges or to make disclosures authorized by a routine use.

4. Access to VA facilities where identification codes, passwords, security profiles and possible security violations are maintained is controlled at all hours by the Federal Protective Service, VA or other security personnel and security access control devices.

RETENTION AND DISPOSAL:

Copies of back-up computer files will be maintained at VA Management Science Group, Bedford, Massachusetts, and VA Information Resource Center, Hines, Illinois.

Records will be maintained and disposed of in accordance with the records disposal authority approved by the Archivist of the United States, the National Archives and Records Administration, and published in Agency Records Control Schedules.

SYSTEM MANAGER AND ADDRESS:

Director, Management Science Group, VA Medical Center, 200 Springs Road, Bedford, Massachusetts 01730.

NOTIFICATION PROCEDURE:

Individuals wishing to inquire whether this system of records contains information about them should submit a signed written request to the Director, Management Science Group, VA Medical Center, 200 Springs Road, Bedford, Massachusetts 01730.

RECORDS ACCESS PROCEDURES:

An individual who seeks access to records maintained under his or her name or other personal identifier may write the System Manager named above and specify the information being contested.

CONTESTING RECORD PROCEDURES:

(See Records Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information may be obtained from the Patient Medical Records System (24VA136); Patient Fee Basis Medical and Pharmacy Records (23VA136); Veterans and Beneficiaries Identification and Records Location Subsystem (38VA23); Compensation, Pension, Education and Rehabilitation Records (58VA21/22); and Automated Medication Processing Records (56VA119); DoD utilization files and DEERS files; and HCFA Denominator file, Standard Analytical files (inpatient, outpatient, physician supplier, nursing home, hospice, home care, durable medical equipment) and Group Health Plan, and State Medicaid beneficiaries' utilization and enrollment databases.

[FR Doc. 01–1112 Filed 1–12–01; 8:45 am]

BILLING CODE 8320–01–M

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of New System of Records "Agent Orange Registry—VA".

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e)(4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is establishing a new system of records entitled, "Agent Orange Registry—VA" (105VA131).

DATES: Comments on the establishment of this system of records must be received no later than February 15, 2001. If no public comment is received, the new system will become effective February 15, 2001.

ADDRESSES: Written comments concerning the proposed new system of records may be submitted to the Office of Regulations management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Comments will be available for public inspection at the above address in the Office of Regulatory Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration Privacy Act Officer (193B2), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (727) 320–1839.

SUPPLEMENTARY INFORMATION:

1. Description of the Proposed Systems of Records.

The Agent Orange Registry located at the Austin Automation Center (AAC), Austin, Texas, is an automated integrated system containing demographic and medical data of registry examinations from 1988 until such time as the VA Secretary or Congress by law ends the registry program. These data were entered manually on code sheets by VA facility staff and copies sent to the AAC for entry into the Agent Orange Registry data set.

The purpose of this Agent Orange Registry system of records is to provide information about veterans who have had an Agent Orange Registry examination at a VA facility; to assist in generating hypotheses for research studies; provide management with the capability to track patient demographics; report birth defects among veteran's children; dioxin-related diseases; planning and delivery of health care services and associated costs; and with relation to claims for compensation may assist in the adjudication of claims possibly related to herbicide exposure although more comprehensive medical records are required for evaluation of subject claims.

II. Proposed Routine Use Disclosures of Data in the System

We are proposing to establish the following routine use disclosures of information which will be maintained in the system:

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member of staff person requests the record on behalf of, and at the written request of, that individual.

Individuals sometimes request the help of a member of Congress in resolving some issue relating to a matter before VA. The member of Congress then writes VA, and VA must be able to give sufficient information to be responsive to the inquiry.

2. Disclosure of records covered by this system, as deemed necessary and proper to named individuals serving as accredited service organization representatives and other individuals named as approved agents or attorneys for a documented purpose and period of time, to aid beneficiaries in the

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preparation and presentation of their cases during the verification and/or due process procedures and in the presentation and prosecution of claims under laws administered by VA.

3. A record containing the name(s) and address(es) of present or former members of the armed services and/or their dependents may be released from this system of records under certain circumstances:

(a) To any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under Title 38, and

(b) To any criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name(s) or address(es) be provided for a purpose authorized by law; provided, further, that the record (s) will not be used for any purpose other than that stated in the request and that the organization, agency or instrumentality is aware of the penalty provision of 38 U.S.C. 3301(f).

VA must be able to comply with the requirements of agencies charged with enforcing the law who are conducting investigations. VA must also be able to provide information to State or local agencies charged with protecting the public health as set forth in State law.

4. Disclosure may be made to the National Archives and Record Administration (NARA) in records management inspections conducted under authority of 44 United States Code.

NARA is responsible for archiving old records no longer actively used, but which may be appropriate for preservation; they are responsible in general for the physical maintenance of the Federal government's records. VA must be able to turn records over to these agencies in order to determine the proper disposition of such records.

5. Disclosure of information, excluding name and address (unless name and address is furnished by the requestor) for research purposes determined to be necessary and proper, to epidemiological and other research facilities approved by the Under Secretary for Health.

VA participates in various research programs and activities. VA must be able to disclose information for research purposes approved by the Under Secretary of Health.

6. In order to conduct Federal research necessary to accomplish a statutory purpose of an agency, at the written request of the head of the agency, or designee of the head of that agency, the name(s) and address(es) of present or former personnel or the Armed Services and/or their dependents may be disclosed.

(a) To a Federal department or agency or

(b) Directly to a contractor of a Federal department or agency. When a disclosure of this information is to be made directly to the contractor, VA may impose applicable conditions on the department, agency, and/or contractor to insure the appropriateness of the disclosure to the contractor.

VA must be able to disclose information for research purposes needed to accomplish a statutory purpose of a Federal agency. VA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. VA must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract.

7. In the event that a record maintained by VA to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, information may be disclosed to the appropriate agency whether Federal, State, local or foreign, charged with responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

8. For program review purposes and the seeking of accreditation and/or certification, disclosure may be made to survey teams of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists, American Association of Blood Banks, and similar national accreditation agencies or boards with whom Va has a contract or agreement to conduct such reviews but only to the extent that the information is necessary and relevant to the review.

VA health care facilities undergo certification and accreditation by several national accreditation agencies or boards to comply with regulations and good medical practices. VA must be able to disclose information for program review purposes and the seeking of accreditation and/or certification of health care facilities and programs.

9. Records from this system of records may be disclosed to the Department of Justice (DOJ) or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear when: The Agency, or any component thereof; or any employee of the Agency in his or her official capacity; where the DOJ or the Agency has agreed to represent the employee; or the U.S. when the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation, and has an interest in such litigation, and the use of such records by the DOJ or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that the disclosure is compatible with the purpose for which the records were collected.

Whenever VA is involved in litigation, or occasionally when another party is involved in litigation and VA policies or operations could be affected by the outcome of the litigation, VA would be able to disclose information to the court or parties involved. A determination would be made in each instance that, under the circumstances involved, the purpose served by the use of the information in the particular litigation is compatible with a purpose for which the VA collects the information.

III. Compatibility of the Proposed Routine Uses

The Privacy Act permits VA to disclose information about individuals without their consent for a routine use when the information will be used for a purpose that is compatible with the purpose for which we collected the information. In all of the routine use disclosures described above, either the recipient of the information will use the information in connection with a matter relating to one of VA's programs, we use the information to provide a benefit to VA, or disclosure is required by law.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of Office of Management and Budget (OMB) as required by 5 U.S.C. 552a (Privacy Act) and guidelines issued by OMB (61 FR 6428), February 20, 1996.

Approved: December 22, 2000.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

105VA131

SYSTEM NAME:

Agent Orange Registry–VA.

SYSTEM LOCATION:

Character-based data from Agent Orange Registry Code Sheets are maintained in a registry dataset at the Austin Automation Center, 1615 Woodward Street, Austin, Texas 78772.

CATEGORIES OF INDIVIDUALS COVERED BY THIS SYSTEM:

Veterans who may have been exposed to dioxin or other toxic substance in a herbicide or defoliant during active military service in the Republic of Vietnam between 1962 and 1975 and have had an Agent Orange Registry examination at a Department of Veterans Affairs (VA) medical facility.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records may contain the following information: Code sheet records recording VA facility code identifier where the veteran was examined or treated; veteran's name; address; social security number; military service serial number; claim number; date of birth; race/ethnicity; marital status; sex; branch of service; periods of service; areas of service in Vietnam; list of military units where veterans served; method of exposure to herbicides; veteran's self-assessment of health; date of registry examination; veteran's complaints/symptoms; reported birth defects among veteran's children; consultations; diagnoses; disposition (hospitalized, referred for outpatient treatment, etc.) and name and signature of examiner/physician coordinator, when available.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code (U.S.C.) secs. 1710(e)(1)(B) and 1710(e)(1)(B) and 1720E.

PURPOSE(S):

The purpose of this Agent Orange Registry system of records is to provide information about: veterans who have had an Agent Orange Registry examination at a VA facility; to assist in generating hypotheses for research studies; provide management with the capability to track patient demographics; reported birth defects among veterans' children; dioxin-related diseases; planning and delivery of health care services and associated costs; and with relation to claims for compensation which may assist in the adjudication of claims possibly related to herbicide exposure although more comprehensive medical records are required for evaluation of subject claims.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. The record of an individual who is covered by this system may be disclosed to a member of Congress or staff person acting for the member when the member or staff person requests the record on behalf of, and at the written request of, that individual.

2. Disclosure of records covered by this system, as deemed necessary and proper to named individuals serving as accredited service organization representatives and other individuals named as approved agents or attorneys for a documented purpose and period of time, to aid beneficiaries in the preparation and presentation of their cases during the verification and/or due process procedures and in the presentation and prosecution of claims under laws administered by VA.

3. A record containing the name(s) and address(es) of present or former members of the armed services and/or their dependents may be released from this system of records under certain circumstances:

(a) To any nonprofit organization if the release is directly connected with the conduct of programs and the utilization of benefits under Title 38, and

(b) To any criminal or civil law enforcement governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name(s) or address(es) be provided for a purpose authorized by law; provided, further, that the record(s) will not be used for any purpose other than that stated in the request and that the organization, agency or instrumentality is aware of the penalty provision of 38 U.S.C. 3301(f).

4. Disclosure may be made to the National Archives and Record Administration (NARA) in records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

5. Disclosure of information, excluding name and address (unless name and address is furnished by the requestor) for research purposes determined to be necessary and proper, to epidemiological and other research facilities approved by the Under Secretary for Health.

6. In order to conduct Federal research necessary to accomplish a statutory purpose of any agency, at the written request of the head of the Agency, or designee of the head of that agency, the name(s) and address(es) of present or former personnel or the Armed Services and/or their dependents may be disclosed.

(a) To a Federal department or Agency or

(b) Directly to a contractor of a Federal department or agency. When a disclosure of this information is to be made directly to the contractor, VA may impose applicable conditions on the department, agency, and/or contractor to insure the appropriateness of the disclosure to the contractor.

7. In the event that a record maintained by VA to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, information may be disclosed to the appropriate agency whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

8. For program review purposes and the seeking of accreditation and/or certification, disclosure may be made to survey teams of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists, American Association of Blood Banks, and similar national accreditation agencies or boards with whom VA has a contract or agreement to conduct such reviews but only to the extent that the information is necessary and relevant to the review.

9. Records from this system of records may be disclosed to the Department of Justice (DOJ) or in a proceeding before a court, adjudicative body, or other administrative body before which the Agency is authorized to appear when: the Agency, or any component thereof; or any employee of the Agency in his or her official capacity; where the DOJ or the Agency has agreed to represent the employee; or the U.S. when the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation, and has an interest in such litigation, and the use of such records by the DOJ or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that the

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disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic data are maintained on Direct Access Storage Devices at the Austin Automation Center (AAC), Austin, Texas. AAC stores registry tapes for disaster back up at an off-site location.

RETRIEVABILITY:

Records are retrieved by name of veteran and social security number.

SAFEGUARDS:

Access to records at VA Headquarters is only authorized to VA personnel on a "need to know" basis. Records are maintained in manned rooms during working hours. During non-working hours, there is limited access to the building with visitor control by security personnel. Registry data maintained at the AAC can only be updated by authorized AAC personnel. Read access to the data is granted through a telecommunications network to authorized VA Headquarters personnel. AAC reports are also accessible through a telecommunications network on a read-only basis to the owner (VA facility) of the data. Access is limited to authorized employees by individually unique access codes which are changed periodically. Physical access to the AAC is generally restricted to AAC staff, VA Headquarters employees, custodial personnel, Federal Protective Service and authorized operational personnel through electronic locking devices. All other persons gaining access to the computer rooms are escorted. Backup records stored off-site for both the AAC and VA Headquarters are safeguarded in secured storage areas.

RETENTION AND DISPOSAL:

Records will be maintained and disposed of in accordance with records disposition authority approved by the Archivist of the United States.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Environmental Agents Service (131), Office of Public Health and Environmental Hazards (clinical issues) and Management/Program Analyst, Environmental Agents Service (131) (administrative issues), VA Headquarters, 810 Vermont Avenue, NW., Washington, DC 20420.

NOTIFICATION PROCEDURE:

An individual who wishes to determine whether a record is being maintained in this system under his or her name or other personnel identifier, or wants to determine the contents of such record, should submit a written request or apply in person to the last VA facility where medical care was provided or submit a written request to the Director, Environmental Agents Service (131), Office of Public Health and Environmental Hazards or the Management/Program Analyst, Environmental Agents Service (131), VA Headquarters, 810 Vermont Avenue, NW., Washington, DC 20420. Inquiries should include the veteran's name, social security number and return address.

RECORD ACCESS PROCEDURES:

An individual who seeks access to records maintained under his or her name may write or visit the nearest VA facility or write to the Director, Environmental Agents Service (131) or the Management/Program Analyst, Environmental Agents Service (131), VA Headquarters, 810 Vermont Avenue, NW., Washington, DC 20420.

CONTESTING RECORDS PROCEDURES:

Refer to previous item "Record Access Procedures."

RECORD SOURCE CATEGORIES:

VA patient medical records, various automated record systems providing clinical and managerial support to VA health care facilities, the veteran, family members, and records from Veterans Benefits Administration, Department of Defense, Department of the Army, Department of the Air Force, Department of the Navy and other Federal agencies.

[FR Doc. 01–1113 Filed 1–12–01; 8:45 am]
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Federal Register

Tuesday,
January 16, 2001

Part II

Reader Aids

Cumulative List of Public Laws 106th Congress, Second Session

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CUMULATIVE LIST OF PUBLIC LAWS

This is the cumulative list of public laws for the 106th Congress, Second Session. Other cumulative lists (1993-1999) are available online at http://www.nara.gov/fedreg. Comments may be addressed to the Director, Office of the Federal Register, Washington, DC 20408 or send e-mail to info@nara.fedreg.gov.

The text of laws may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470). The text will also be made available on the Internet from GPO Access at http://www.acess.gpo.gov/nara/index.html. Some laws may not yet be available online or for purchase.

Public Law	Title	Approved	114 Stat.
106–171	Electronic Benefit Transfer Interoperability and Portability Act of 2000	Feb. 11, 2000	3
106–172	Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000	Feb. 18, 2000	7
106–173	Abraham Lincoln Bicentennial Commission Act	Feb. 25, 2000	14
106–174	Poison Control Center Enhancement and Awareness Act	Feb. 25, 2000	18
106–175	To authorize the President to award a gold medal on behalf of the Congress to John Cardinal O'Connor, Archbishop of New York, in recognition of his accomplishments as a priest, a chaplain, and a humanitarian.	Mar. 5, 2000	21
106–176	Omnibus Parks Technical Corrections Act of 2000	Mar. 10, 2000	23
106–177	To reduce the incidence of child abuse and neglect, and for other purposes	Mar. 10, 2000	35
106–178	Iran Nonproliferation Act of 2000	Mar. 14, 2000	38
106–179	Indian Tribal Economic Development and Contract Encouragement Act of 2000	Mar. 14, 2000	46
106–180	Open-market Reorganization for the Betterment of International Telecommunications Act	Mar. 17, 2000	48
106–181	Wendell H. Ford Aviation Investment and Reform Act for the 21st Century	Apr. 5, 2000	61
106–182	Senior Citizens' Freedom to Work Act of 2000	Apr. 7, 2000	198
106–183	To designate the United States Post Office building located at 680 U.S. Highway 130 in Hamilton, New Jersey, as the "John K. Rafferty Hamilton Post Office Building".	Apr. 13, 2000	200
106–184	To designate the United States post office located at 14071 Peyton Drive in Chino Hills, California, as the "Joseph Ileto Post Office".	Apr. 14, 2000	201
106–185	Civil Asset Forfeiture Reform Act of 2000	Apr. 25, 2000	202
106–186	Expressing the sense of Congress that the President of the United States should encourage free and fair elections and respect for democracy in Peru.	Apr. 25, 2000	226
106–187	To direct the Secretary of Agriculture to convey certain National Forest lands to Elko County, Nevada, for continued use as a cemetery..	Apr. 28, 2000	227
106–188	Bikini Resettlement and Relocation Act of 2000	Apr. 28, 2000	228
106–189	To direct the Secretary of the Interior to release reversionary interests held by the United States in certain parcels of land in Washington County, Utah, to facilitate an anticipated land exchange.	Apr. 28, 2000	229
106–190	To clarify the legal effect on the United States of the acquisition of a parcel of land in the Red Cliffs Desert Reserve in the State of Utah.	Apr. 28, 2000	230
106–191	To amend the Mineral Leasing Act to increase the maximum acreage of Federal leases for sodium that may be held by an entity in any one State, and for other purposes.	Apr. 28, 2000	231
106–192	Lamprey Wild and Scenic River Extension Act	May 2, 2000	233
106–193	Methane Hydrate Research and Development Act of 2000	May 2, 2000	234
106–194	To amend the Alaska Native Claims Settlement Act to restore certain lands to the Elim Native Corporation, and for other purposes.	May 2, 2000	239
106–195	Recognizing the 50th anniversary of the Korean War and the service by members of the Armed Forces during such war, and for other purposes.	May 2, 2000	244
106–196	To designate the United States courthouse located at 223 Broad Avenue in Albany, Georgia, as the "C.B. King United States Courthouse".	May 2, 2000	245
106–197	To exempt certain reports from automatic elimination and sunset pursuant to the Federal Reports Elimination and Sunset Act of 1995, and for other purposes.	May 2, 2000	246
106–198	Providing for the appointment of Alan G. Spoon as a citizen regent of the Board of Regents of the Smithsonian Institution.	May 5, 2000	249
106–199	Providing for the reappointment of Manuel L. Ibáñez as a citizen regent of the Board of Regents of the Smithsonian Institution.	May 5, 2000	250
106–200	Trade and Development Act of 2000	May 18, 2000	251
106–201	To amend the Endangered Species Act of 1973 to provide that certain species conservation reports shall continue to be required to be submitted.	May 18, 2000	307
106–202	Worker Economic Opportunity Act	May 18, 2000	308
106–203	To designate the Federal building and United States courthouse located at 1300 South Harrison Street in Fort Wayne, Indiana, as the "E. Ross Adair Federal Building and United States Courthouse".	May 22, 2000	310
106–204	To designate the Federal building located at 500 Pearl Street in New York City, New York, as the "Daniel Patrick Moynihan United States Courthouse".	May 23, 2000	311
106–205	Supporting the Day of Honor 2000 to honor and recognize the service of minority veterans in the United States Armed Forces during World War II.	May 26, 2000	312
106–206	To allow the Secretary of the Interior and the Secretary of Agriculture to establish a fee system for commercial filming activities on Federal land, and for other purposes.	May 26, 2000	314
106–207	Hmong Veterans' Naturalization Act of 2000	May 26, 2000	316
106–208	National Historic Preservation Act Amendments of 2000	May 26, 2000	318
106–209	To designate the facility of the United States Postal Service located at 9308 South Chicago Avenue, Chicago, Illinois, as the "John J. Buchanan Post Office Building".	May 26, 2000	320
106–210	Muhammad Ali Boxing Reform Act	May 26, 2000	321
106–211	To amend the Higher Education Act of 1965 to improve the program for American Indian Tribal Colleges and Universities under part A of title III.	May 26, 2000	330
106–212	American Institute in Taiwan Facilities Enhancement Act	May 26, 2000	332
106–213	To extend the deadline for commencement of construction of a hydroelectric project in the State of Alabama.	May 26, 2000	334

Public Law	Title	Approved	114 Stat.
106–214	To amend the law that authorized the Vietnam Veterans Memorial to authorize the placement within the site of the memorial of a plaque to honor those Vietnam veterans who died after their service in the Vietnam war, but as a direct result of that service.	June 15, 2000	335
106–215	Immigration and Naturalization Service Data Management Improvement Act of 2000	June 15, 2000	337
106–216	To authorize leases for terms not to exceed 99 years on land held in trust for the Torres Martinez Desert Cahuilla Indians and the Guidiville Band of Pomo Indians of the Guidiville Indian Rancheria.	June 20, 2000	343
106–217	To provide that land which is owned by the Lower Sioux Indian Community in the State of Minnesota but which is not held in trust by the United States for the Community may be leased or transferred by the Community without further approval by the United States.	June 20, 2000	344
106–218	To designate the Federal building located at 2201 C Street, Northwest, in the District of Columbia, currently headquarters for the Department of State, as the "Harry S Truman Federal Building".	June 20, 2000	345
106–219	To designate the Washington Opera in Washington, D.C., as the National Opera	June 20, 2000	346
106–220	Carlsbad Irrigation Project Acquired Land Transfer Act	June 20, 2000	347
106–221	Wellton-Mohawk Transfer Act	June 20, 2000	351
106–222	Freedom to E-File Act	June 20, 2000	353
106–223	To authorize the award of the Medal of Honor to Ed W. Freeman, James K. Okubo, and Andrew J. Smith.	June 20, 2000	356
106–224	Agricultural Risk Protection Act of 2000	June 20, 2000	358
106–225	To authorize the President to award posthumously a gold medal on behalf of the Congress to Charles M. Schulz in recognition of his lasting artistic contributions to the Nation and the world, and for other purposes.	June 20, 2000	457
106–226	To provide that the School Governance Charter Amendment Act of 2000 shall take effect upon the date such Act is ratified by the voters of the District of Columbia.	June 27, 2000	459
106–227	Recognizing the 225th birthday of the United States Army	June 28, 2000	460
106–228	To make technical corrections to the status of certain land held in trust for the Mississippi Band of Choctaw Indians, to take certain land into trust for that Band, and for other purposes.	June 29, 2000	462
106–229	Electronic Signatures in Global and National Commerce Act	June 30, 2000	464
106–230	To amend the Internal Revenue Code of 1986 to require 527 organizations to disclose their political activities.	July 1, 2000	477
106–231	To redesignate the Federal building located at 701 South Santa Fe Avenue in Compton, California, and known as the Compton Main Post Office, as the "Mervyn Malcolm Dymally Post Office Building".	July 6, 2000	484
106–232	To redesignate the Federal building located at 10301 South Compton Avenue, in Los Angeles, California, and known as the Watts Finance Office, as the "Augustus F. Hawkins Post Office Building".	July 6, 2000	485
106–233	To designate the facility of the United States Postal Service at 200 East Pinckney Street in Madison, Florida, as the "Captain Colin P. Kelly, Jr. Post Office".	July 6, 2000	486
106–234	To designate the building of the United States Postal Service located at 5 Cedar Street in Hopkinton, Massachusetts, as the "Thomas J. Brown Post Office Building".	July 6, 2000	487
106–235	To designate the United States Post Office located at 3675 Warrensville Center Road in Shaker Heights, Ohio, as the "Louise Stokes Post Office".	July 6, 2000	488
106–236	To designate the United States Post Office located at 125 Border Avenue West in Wiggins, Mississippi, as the "Jay Hanna 'Dizzy' Dean Post Office".	July 6, 2000	489
106–237	To designate the United States Post Office located at 713 Elm Street in Wakefield, Kansas, as the "William H. Avery Post Office".	July 6, 2000	490
106–238	To redesignate the facility of the United States Postal Service located at 100 Orchard Park Drive in Greenville, South Carolina, as the "Keith D. Oglesby Station".	July 6, 2000	491
106–239	To designate certain facilities of the United States Postal Service in South Carolina	July 6, 2000	492
106–240	To designate the facility of the United States Postal Service located at 8409 Lee Highway in Merrifield, Virginia, as the "Joel T. Broyhill Postal Building".	July 6, 2000	494
106–241	To designate the facility of the United States Postal Service located at 3118 Washington Boulevard in Arlington, Virginia, as the "Joseph L. Fisher Post Office Building".	July 6, 2000	495
106–242	To designate the facility of the United States Postal Service located at 1818 Milton Avenue in Janesville, Wisconsin, as the "Les Aspin Post Office Building".	July 6, 2000	496
106–243	To direct the Secretary of the Interior, the Bureau of Reclamation, to conduct a feasibility study on the Jicarilla Apache Reservation in the State of New Mexico, and for other purposes.	July 10, 2000	497
106–244	To amend title I of the Employee Retirement Income Security Act of 1974 to provide for the preemption of State law in certain cases relating to certain church plans.	July 10, 2000	499
106–245	Radiation Exposure Compensation Act Amendments of 2000	July 10, 2000	501
106–246	Making appropriations for military construction, family housing, and base realignment and closure for the Department of Defense for the fiscal year ending September 30, 2001, and for other purposes.	July 13, 2000	511
106–247	Neotropical Migratory Bird Conservation Act	July 20, 2000	593
106–248	To authorize the acquisition of the Valles Caldera, to provide for an effective land and wildlife management program for this resource within the Department of Agriculture, and for other purposes.	July 25, 2000	598
106–249	Griffith Project Prepayment and Conveyance Act	July 26, 2000	619
106–250	Pope John Paul II Congressional Gold Medal Act	July 27, 2000	622
106–251	To provide for the award of a gold medal on behalf of the Congress to former President Ronald Reagan and his wife Nancy Reagan in recognition of their service to the Nation.	July 27, 2000	624
106–252	Mobile Telecommunications Sourcing Act	July 28, 2000	626
106–253	Semipostal Authorization Act	July 28, 2000	634
106–254	Federal Law Enforcement Animal Protection Act of 2000	Aug. 2, 2000	638
106–255	Cross-Border Cooperation and Environmental Safety in Northern Europe Act of 2000	Aug. 2, 2000	639
106–256	Oceans Act of 2000	Aug. 7, 2000	644
106–257	Oregon Land Exchange Act of 2000	Aug. 8, 2000	650

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Public Law	Title	Approved	114 Stat.
106–258	To amend the Act establishing Women's Rights National Historical Park to permit the Secretary of the Interior to acquire title in fee simple to the Hunt House located in Waterloo, New York.	Aug. 8, 2000	655
106–259	Department of Defense Appropriations Act, 2001	Aug. 9, 2000	656
106–260	Tribal Self-Governance Amendments of 2000	Aug. 18, 2000	711
106–261	To designate Wilson Creek in Avery and Caldwell Counties, North Carolina, as a component of the National Wild and Scenic Rivers System.	Aug. 18, 2000	735
106–262	To name the Department of Veterans Affairs outpatient clinic in Rome, New York, as the "Donald J. Mitchell Department of Veterans Affairs Outpatient Clinic".	Aug. 18, 2000	736
106–263	Shivwits Band of the Paiute Indian Tribe of Utah Water Rights Settlement Act	Aug. 18, 2000	737
106–264	Global AIDS and Tuberculosis Relief Act of 2000	Aug. 19, 2000	748
106–265	To amend title 5, United States Code, to provide for the establishment of a program under which long-term care insurance is made available to Federal employees, members of the uniformed services, and civilian and military retirees, provide for the correction of retirement coverage errors under chapters 83 and 84 of such title, and for other purposes.	Sept. 19, 2000	762
106–266	To designate the Federal facility located at 1301 Emmet Street in Charlottesville, Virginia, as the "Pamela B. Gwin Hall".	Sept. 22, 2000	787
106–267	To designate the United States border station located in Pharr, Texas, as the "Kika de la Garza United States Border Station".	Sept. 22, 2000	788
106–268	To designate the Federal building located at 643 East Durango Boulevard in San Antonio, Texas, as the "Adrian A. Spears Judicial Training Center".	Sept. 22, 2000	789
106–269	To designate the United States courthouse located at 220 West Depot Street in Greeneville, Tennessee, as the "James H. Quillen United States Courthouse".	Sept. 22, 2000	790
106–270	Deschutes Resources Conservancy Reauthorization Act of 2000	Sept. 22, 2000	791
106–271	Corinth Battlefield Preservation Act of 2000	Sept. 22, 2000	792
106–272	Jackson Multi-Agency Campus Act of 2000	Sept. 22, 2000	797
106–273	To amend the Pacific Northwest Electric Power Planning and Conservation Act to provide for sales of electricity by the Bonneville Power Administration to joint operating entities.	Sept. 22, 2000	802
106–274	Religious Land Use and Institutionalized Persons Act of 2000	Sept. 22, 2000	803
106–275	Making continuing appropriations for the fiscal year 2001, and for other purposes	Sept. 29, 2000	808
106–276	To amend the Omnibus Crime Control and Safe Streets Act of 1968 to extend the retroactive eligibility dates for financial assistance for higher education for spouses and dependent children of Federal, State, and local law enforcement officers who are killed in the line of duty.	Oct. 2, 2000	812
106–277	To authorize the payment of rewards to individuals furnishing information relating to persons subject to indictment for serious violations of international humanitarian law in Rwanda, and for other purposes.	Oct. 2, 2000	813
106–278	To designate the Lackawanna Valley and the Schuylkill River National Heritage Areas, and for other purposes.	Oct. 6, 2000	814
106–279	Intercountry Adoption Act of 2000	Oct. 6, 2000	825
106–280	Security Assistance Act of 2000	Oct. 6, 2000	845
106–281	FHA Downpayment Simplification Extension Act of 2000	Oct. 6, 2000	865
106–282	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 6, 2000	866
106–283	Kake Tribal Corporation Land Transfer Act	Oct. 6, 2000	867
106–284	Beaches Environmental Assessment and Coastal Health Act of 2000	Oct. 10, 2000	870
106–285	To amend the Act entitled "An Act relating to the water rights of the Ak-Chin Indian Community" to clarify certain provisions concerning the leasing of such water rights, and for other purposes.	Oct. 10, 2000	878
106–286	To authorize extension of nondiscriminatory treatment (normal trade relations treatment) to the People's Republic of China, and to establish a framework for relations between the United States and the People's Republic of China.	Oct. 10, 2000	880
106–287	To grant the consent of the Congress to the Kansas and Missouri Metropolitan Culture District Compact.	Oct. 10, 2000	909
106–288	Granting the consent of the Congress to the Red River Boundary Compact	Oct. 10, 2000	919
106–289	To designate the United States Post Office located at 3813 Main Street in East Chicago, Indiana, as the "Lance Corporal Harold Gomez Post Office".	Oct. 10, 2000	920
106–290	To expand the boundaries of the Gettysburg National Military Park to include the Wills House, and for other purposes.	Oct. 10, 2000	921
106–291	Department of the Interior and Related Agencies Appropriations Act, 2001	Oct. 11, 2000	922
106–292	To authorize appropriations for the United States Holocaust Memorial Museum, and for other purposes.	Oct. 12, 2000	1030
106–293	Presidential Transition Act of 2000	Oct. 12, 2000	1035
106–294	Federal Prisoner Health Care Copayment Act of 2000	Oct. 12, 2000	1038
106–295	To designate the bridge on United States Route 231 that crosses the Ohio River between Maceo, Kentucky, and Rockport, Indiana, as the "William H. Natcher Bridge".	Oct. 13, 2000	1043
106–296	To designate the Federal building and United States courthouse located at 402 North Walnut Street in Harrison, Arkansas, as the "J. Smith Henley Federal Building and United States Courthouse".	Oct. 13, 2000	1044
106–297	Death in Custody Reporting Act of 2000	Oct. 13, 2000	1045
106–298	Lincoln County Land Act of 2000	Oct. 13, 2000	1046
106–299	Wekiva Wild and Scenic River Act of 2000	Oct. 13, 2000	1050
106–300	Red River National Wildlife Refuge Act	Oct. 13, 2000	1055
106–301	Utah West Desert Land Exchange Act of 2000	Oct. 13, 2000	1059
106–302	To extend the authorization for the Air Force Memorial Foundation to establish a memorial in the District of Columbia or its environs.	Oct. 13, 2000	1062
106–303	To make certain personnel flexibilities available with respect to the General Accounting Office, and for other purposes.	Oct. 13, 2000	1063
106–304	To designate the Federal building located at 1710 Alabama Avenue in Jasper, Alabama, as the "Carl Elliott Federal Building".	Oct. 13, 2000	1071
106–305	To designate the United States customhouse located at 101 East Main Street in Norfolk, Virginia, as the "Owen B. Pickett United States Customhouse".	Oct. 13, 2000	1072
106–306	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 13, 2000	1073
106–307	El Camino Real de Tierra Adentro National Historic Trail Act	Oct. 13, 2000	1074

Public Law	Title	Approved	114 Stat.
106–308	To designate the Federal courthouse at 145 East Simpson Avenue in Jackson, Wyoming, as the "Clifford P. Hansen Federal Courthouse".	Oct. 13, 2000	1077
106–309	Microenterprise for Self-Reliance and International Anti-Corruption Act of 2000	Oct. 17, 2000	1078
106–310	Children's Health Act of 2000	Oct. 17, 2000	1101
106–311	To increase the amount of fees charged to employers who are petitioners for the employment of H-1B non-immigrant workers, and for other purposes.	Oct. 17, 2000	1247
106–312	Truth in Regulating Act of 2000	Oct. 17, 2000	1248
106–313	To amend the Immigration and Nationality Act with respect to H-1B nonimmigrant aliens	Oct. 17, 2000	1251
106–314	Strengthening Abuse and Neglect Courts Act of 2000	Oct. 17, 2000	1266
106–315	To designate the building of the United States Postal Service located at 307 Main Street in Johnson City, New York, as the "James W. McCabe, Sr. Post Office Building".	Oct. 19, 2000	1275
106–316	To reauthorize the Junior Duck Stamp Conservation and Design Program Act of 1994.	Oct. 19, 2000	1276
106–317	To make technical corrections to title X of the Energy Policy Act of 1992	Oct. 19, 2000	1277
106–318	Taunton River Wild and Scenic River Study Act of 2000	Oct. 19, 2000	1278
106–319	Yuma Crossing National Heritage Area Act of 2000	Oct. 19, 2000	1280
106–320	To designate the facility of the United States Postal Service located at 424 South Michigan Street in South Bend, Indiana, as the "John Brademas Post Office".	Oct. 19, 2000	1286
106–321	To designate the facility of the United States Postal Service located at 757 Warren Road in Ithaca, New York, as the "Matthew F. McHugh Post Office".	Oct. 19, 2000	1287
106–322	To designate the United States post office located at 451 College Street in Macon, Georgia, as the "Henry McNeal Turner Post Office".	Oct. 19, 2000	1288
106–323	Effigy Mounds National Monument Additions Act	Oct. 19, 2000	1289
106–324	To dedicate the Big South Trail in the Comanche Peak Wilderness Area of Roosevelt National Forest in Colorado to the legacy of Jaryd Atadero.	Oct. 19, 2000	1291
106–325	To designate the facility of the United States Postal Service located at 4601 South Cottage Grove Avenue in Chicago, Illinois, as the "Henry W. McGee Post Office Building".	Oct. 19, 2000	1292
106–326	To redesignate the facility of the United States Postal Service located at 14900 Southwest 30th Street in Miramar, Florida, as the "Vicki Coceano Post Office Building".	Oct. 19, 2000	1293
106–327	To designate the facility of the United States Postal Service located at 600 Lincoln Avenue in Pasadena, California, as the "Matthew 'Mack' Robinson Post Office Building".	Oct. 19, 2000	1294
106–328	To designate the facility of the United States Postal Service located at 2000 Vassar Street in Reno, Nevada, as the "Barbara F. Vucanovich Post Office Building".	Oct. 19, 2000	1295
106–329	Black Hills National Forest and Rocky Mountain Research Station Improvement Act	Oct. 19, 2000	1296
106–330	Texas National Forests Improvement Act of 2000	Oct. 19, 2000	1299
106–331	Cahaba River National Wildlife Refuge Establishment Act	Oct. 19, 2000	1303
106–332	To clarify certain boundaries on the map relating to Unit NC-01 of the Coastal Barrier Resources System.	Oct. 19, 2000	1306
106–333	To designate the facility of the United States Postal Service located at 919 West 34th Street in Baltimore, Maryland, as the "Samuel H. Lacy, Sr. Post Office Building".	Oct. 19, 2000	1307
106–334	To designate the facility of the United States Postal Service located at 3500 Dolfield Avenue in Baltimore, Maryland, as the "Judge Robert Bernard Watts, Sr. Post Office Building".	Oct. 19, 2000	1308
106–335	To designate the facility of the United States Postal Service located at 1908 North Ellamont Street in Baltimore, Maryland, as the "Dr. Flossie McClain Dedmond Post Office Building".	Oct. 19, 2000	1309
106–336	To designate the facility of the United States Postal Service located at 500 North Washington Street in Rockville, Maryland, as the "Everett Alvarez, Jr. Post Office Building".	Oct. 19, 2000	1310
106–337	To designate the facility of the United States Postal Service located at 24 Tsienneto Road in Derry, New Hampshire, as the "Alan B. Shepard, Jr. Post Office Building".	Oct. 19, 2000	1311
106–338	To redesignate the facility of the United States Postal Service located at 114 Ridge Street, N.W. in Lenoir, North Carolina, as the "James T. Broyhill Post Office Building".	Oct. 19, 2000	1312
106–339	To redesignate the facility of the United States Postal Service located at 1602 Frankford Avenue in Philadelphia, Pennsylvania, as the "Joseph F. Smith Post Office Building".	Oct. 19, 2000	1313
106–340	To redesignate the facility of the United States Postal Service located at 3030 Meredith Avenue in Omaha, Nebraska, as the "Reverend J.C. Wade Post Office".	Oct. 19, 2000	1314
106–341	To designate the facility of the United States Postal Service located at 301 Green Street in Fayetteville, North Carolina, as the "J.L. Dawkins Post Office Building".	Oct. 19, 2000	1315
106–342	To redesignate the facility of the United States Postal Service located at 200 West 2nd Street in Royal Oak, Michigan, as the "William S. Broomfield Post Office Building".	Oct. 19, 2000	1316
106–343	To extend the deadline under the Federal Power Act for commencement of the construction of the Arrowrock Dam Hydroelectric Project in the State of Idaho.	Oct. 19, 2000	1317
106–344	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 20, 2000	1318
106–345	Ryan White CARE Act Amendments of 2000	Oct. 20, 2000	1319
106–346*	Making appropriations for the Department of Transportation and related agencies for the fiscal year ending September 30, 2001, and for other purposes.	Oct. 23, 2000	1356
106–347	To designate the post office and courthouse located at 2 Federal Square, Newark, New Jersey, as the "Frank R. Lautenberg Post Office and Courthouse".	Oct. 23, 2000	1357
106–348	To authorize the Disabled Veterans' LIFE Memorial Foundation to establish a memorial in the District of Columbia or its environs to honor veterans who became disabled while serving in the Armed Forces of the United States.	Oct. 24, 2000	1358
106–349	Carter G. Woodson Home National Historic Site Study Act of 2000	Oct. 24, 2000	1359
106–350	Golden Gate National Recreation Area Boundary Adjustment Act of 2000	Oct. 24, 2000	1361
106–351	Santa Rosa and San Jacinto Mountains National Monument Act of 2000	Oct. 24, 2000	1362
106–352	Rosie the Riveter/World War II Home Front National Historical Park Establishment Act of 2000.	Oct. 24, 2000	1370
106–353	Colorado Canyons National Conservation Area and Black Ridge Canyons Wilderness Act of 2000.	Oct. 24, 2000	1374
106–354	Breast and Cervical Cancer Prevention and Treatment Act of 2000	Oct. 24, 2000	1381
106–355	National Historic Lighthouse Preservation Act of 2000	Oct. 24, 2000	1385
106–356	Dayton Aviation Heritage Preservation Amendments Act of 2000	Oct. 24, 2000	1391
106–357	White Clay Creek Wild and Scenic Rivers System Act	Oct. 24, 2000	1393
106–358	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 26, 2000	1397
106–359	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 26, 2000	1398

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106–360	To direct the Secretary of the Interior to make technical corrections to a map relating to the Coastal Barrier Resources System.	Oct. 27, 2000	1399
106–361	To amend title 5, United States Code, to allow for the contribution of certain rollover distributions to accounts in the Thrift Savings Plan, to eliminate certain waiting-period requirements for participating in the Thrift Savings Plan, and for other purposes.	Oct. 27, 2000	1400
106–362	Ivanpah Valley Airport Public Lands Transfer Act	Oct. 27, 2000	1404
106–363	To extend and reauthorize the Defense Production Act of 1950	Oct. 27, 2000	1407
106–364	To amend the Revised Organic Act of the Virgin Islands to provide that the number of members on the legislature of the Virgin Islands and the number of such members constituting a quorum shall be determined by the laws of the Virgin Islands, and for other purposes.	Oct. 27, 2000	1408
106–365	To provide for the placement at the Lincoln Memorial of a plaque commemorating the speech of Martin Luther King, Jr., known as the "I Have A Dream" speech.	Oct. 27, 2000	1409
106–366	To direct the Secretary of the Interior, through the Bureau of Reclamation, to convey to the Loup Basin Reclamation District, the Sargent River Irrigation District, and the Farwell Irrigation District, Nebraska, property comprising the assets of the Middle Loup Division of the Missouri River Basin Project, Nebraska.	Oct. 27, 2000	1410
106–367	National Police Athletic League Youth Enrichment Act of 2000	Oct. 27, 2000	1412
106–368	To authorize the Secretary of the Interior to enter into contracts with the Weber Basin Water Conservancy District, Utah, to use Weber Basin Project facilities for the impounding, storage, and carriage of nonproject water for domestic, municipal, industrial, and other beneficial purposes.	Oct. 27, 2000	1416
106–369	Cat Island National Wildlife Refuge Establishment Act	Oct. 27, 2000	1417
106–370	Duchesne City Water Rights Conveyance Act	Oct. 27, 2000	1421
106–371	To increase the amount authorized to be appropriated for the north side pumping division of the Minidoka reclamation project, Idaho.	Oct. 27, 2000	1424
106–372	To provide for a study of the engineering feasibility of a water exchange in lieu of electrification of the Chandler Pumping Plant at Prosser Diversion Dam, Washington.	Oct. 27, 2000	1425
106–373	Famine Prevention and Freedom From Hunger Improvement Act of 2000	Oct. 27, 2000	1427
106–374	To reauthorize grants for water resources research and technology institutes established under the Water Resources Research Act of 1984.	Oct. 27, 2000	1434
106–375	National Museum of the American Indian Commemorative Coin Act of 2000	Oct. 27, 2000	1435
106–376	To direct the Secretary of the Interior to convey certain water distribution facilities to the Northern Colorado Water Conservancy District.	Oct. 27, 2000	1439
106–377*	Making appropriations for the Departments of Veterans Affairs and Housing and Urban Development, and for sundry independent agencies, boards, commissions, corporations, and offices for the fiscal year ending September 30, 2001, and for other purposes.	Oct. 27, 2000	1441
106–378	To provide for the adjustment of status of certain Syrian nationals	Oct. 27, 2000	1442
106–379	Work Made For Hire and Copyright Corrections Act of 2000	Oct. 27, 2000	1444
106–380	Veterans' Oral History Project Act	Oct. 27, 2000	1447
106–381	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 27, 2000	1450
106–382	Fort Peck Reservation Rural Water System Act of 2000	Oct. 27, 2000	1451
106–383	To authorize the Smithsonian Institution to plan, design, construct, and equip laboratory, administrative, and support space to house base operations for the Smithsonian Astrophysical Observatory Submillimeter Array located on Mauna Kea at Hilo, Hawaii.	Oct. 27, 2000	1459
106–384	To amend chapter 36 of title 39, United States Code, to modify rates relating to reduced rate mail matter, and for other purposes.	Oct. 27, 2000	1460
106–385	To rename the National Museum of American Art	Oct. 27, 2000	1463
106–386	Victims of Trafficking and Violence Protection Act of 2000	Oct. 28, 2000	1464
106–387*	Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2001, and for other purposes.	Oct. 28, 2000	1549
106–388	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 28, 2000	1550
106–389	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 29, 2000	1551
106–390	Disaster Mitigation Act of 2000	Oct. 30, 2000	1552
106–391	National Aeronautics and Space Administration Authorization Act of 2000	Oct. 30, 2000	1577
106–392	To authorize the Bureau of Reclamation to provide cost sharing for the endangered fish recovery implementation programs for the Upper Colorado and San Juan River Basins.	Oct. 30, 2000	1602
106–393	Secure Rural Schools and Community Self-Determination Act of 2000	Oct. 30, 2000	1607
106–394	Federal Employees Health Benefits Children's Equity Act of 2000	Oct. 30, 2000	1629
106–395	Child Citizenship Act of 2000	Oct. 30, 2000	1631
106–396	Visa Waiver Permanent Program Act	Oct. 30, 2000	1637
106–397	District of Columbia Receivership Accountability Act of 2000	Oct. 30, 2000	1651
106–398*	To authorize appropriations for fiscal year 2001 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe personnel strengths for such fiscal year for the Armed Forces, and for other purposes.	Oct. 30, 2000	1654
106–399	Steens Mountain Cooperative Management and Protection Act of 2000	Oct. 30, 2000	1655
106–400	To rename the Stewart B. McKinney Homeless Assistance Act as the "McKinney-Vento Homeless Assistance Act".	Oct. 30, 2000	1675
106–401	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Oct. 30, 2000	1676
106–402	Developmental Disabilities Assistance and Bill of Rights Act of 2000	Oct. 30, 2000	1677
106–403	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 1, 2000	1741
106–404	Technology Transfer Commercialization Act of 2000	Nov. 1, 2000	1742
106–405	Commercial Space Transportation Competitiveness Act of 2000	Nov. 1, 2000	1751
106–406	International Patient Act of 2000	Nov. 1, 2000	1755
106–407	Southeast Federal Center Public-Private Development Act of 2000	Nov. 1, 2000	1758
106–408	Fish and Wildlife Programs Improvement and National Wildlife Refuge System Centennial Act of 2000.	Nov. 1, 2000	1762
106–409	Religious Workers Act of 2000	Nov. 1, 2000	1787
106–410	To amend title 44, United States Code, to authorize appropriations for the National Historical Publications and Records Commission for fiscal years 2002 through 2005.	Nov. 1, 2000	1788
106–411	Great Ape Conservation Act of 2000	Nov. 1, 2000	1789

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106–412	To authorize the exchange of land between the Secretary of the Interior and the Director of Central Intelligence at the George Washington Memorial Parkway in McLean, Virginia, and for other purposes.	Nov. 1, 2000	1795
106–413	Veterans' Compensation Cost-of-Living Adjustment Act of 2000	Nov. 1, 2000	1798
106–414	Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act	Nov. 1, 2000	1800
106–415	To amend the Hmong Veterans' Naturalization Act of 2000 to extend the applicability of that Act to certain former spouses of deceased Hmong veterans..	Nov. 1, 2000	1810
106–416	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 1, 2000	1811
106–417	Alaska Native and American Indian Direct Reimbursement Act of 2000	Nov. 1, 2000	1812
106–418	Lower Delaware Wild and Scenic Rivers Act	Nov. 1, 2000	1817
106–419	Veterans Benefits and Health Care Improvement Act of 2000	Nov. 1, 2000	1822
106–420	College Scholarship Fraud Prevention Act of 2000	Nov. 1, 2000	1867
106–421	Castle Rock Ranch Acquisition Act of 2000	Nov. 1, 2000	1870
106–422	To amend the Inspector General Act of 1978 (5 U.S.C. App.) to provide that certain designated Federal entities shall be establishments under such Act, and for other purposes.	Nov. 1, 2000	1872
106–423	Timbisha Shoshone Homeland Act	Nov. 1, 2000	1875
106–424	National Transportation Safety Board Amendments Act of 2000	Nov. 1, 2000	1883
106–425	Santo Domingo Pueblo Claims Settlement Act of 2000	Nov. 1, 2000	1890
106–426	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 3, 2000	1897
106–427	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 4, 2000	1898
106–428	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 4, 2000	1899
106–429*	Making appropriations for foreign operations, export financing, and related programs for the fiscal year ending September 30, 2001, and for other purposes.	Nov. 6, 2000	1900
106–430	Needlestick Safety and Prevention Act	Nov. 6, 2000	1901
106–431	Saint Helena Island National Scenic Area Act	Nov. 6, 2000	1905
106–432	Miwaleta Park Expansion Act	Nov. 6, 2000	1908
106–433	Social Security Number Confidentiality Act of 2000	Nov. 6, 2000	1910
106–434	To provide for the conveyance of a small parcel of public domain land in the San Bernardino National Forest in the State of California, and for other purposes.	Nov. 6, 2000	1912
106–435	2002 Winter Olympic Commemorative Coin Act	Nov. 6, 2000	1916
106–436	To designate the facility of the United States Postal Service located at 3695 Green Road in Beachwood, Ohio, as the "Larry Small Post Office Building".	Nov. 6, 2000	1919
106–437	To permit the payment of medical expenses incurred by the United States Park Police in the performance of duty to be made directly by the National Park Service, to allow for waiver and indemnification in mutual law enforcement agreements between the National Park Service and a State or political subdivision when required by State law, and for other purposes.	Nov. 6, 2000	1920
106–438	To designate the facility of the United States Postal Service located at 900 East Fayette Street in Baltimore, Maryland, as the "Judge Harry Augustus Cole Post Office Building".	Nov. 6, 2000	1922
106–439	To designate the facility of the United States Postal Service located at 1001 Frederick Road in Baltimore, Maryland, as the "Frederick L. Dewberry, Jr. Post Office Building".	Nov. 6, 2000	1923
106–440	To designate the facility of the United States Postal Service located at 2108 East 38th Street in Erie, Pennsylvania, as the "Gertrude A. Barber Post Office Building".	Nov. 6, 2000	1924
106–441	To designate the facility of the United States Postal Service located at 110 Postal Way in Carrollton, Georgia, as the "Samuel P. Roberts Post Office Building".	Nov. 6, 2000	1925
106–442	To amend the Omnibus Parks and Public Lands Management Act of 1996 to extend the legislative authority for the Black Patriots Foundation to establish a commemorative work.	Nov. 6, 2000	1926
106–443	To extend the authority of the Los Angeles Unified School District to use certain park lands in the City of South Gate, California, which were acquired with amounts provided from the land and water conservation fund, for elementary school purposes.	Nov. 6, 2000	1927
106–444	Freedmen's Bureau Records Preservation Act of 2000	Nov. 6, 2000	1929
106–445	United States Mint Numismatic Coin Clarification Act of 2000	Nov. 6, 2000	1931
106–446	To amend title 10, United States Code, to facilitate the adoption of retired military working dogs by law enforcement agencies, former handlers of these dogs, and other persons capable of caring for these dogs.	Nov. 6, 2000	1932
106–447	Indian Tribal Regulatory Reform and Business Development Act of 2000	Nov. 6, 2000	1934
106–448	To amend the Immigration and Nationality Act to provide a waiver of the oath of renunciation and allegiance for naturalization of aliens having certain disabilities..	Nov. 6, 2000	1939
106–449	To modify the date on which the Mayor of the District of Columbia submits a performance accountability plan to Congress, and for other purposes.	Nov. 6, 2000	1940
106–450	To amend the Fishermen's Protective Act of 1967 to extend the period during which reimbursement may be provided to owners of United States fishing vessels for costs incurred when such a vessel is seized and detained by a foreign country, and for other purposes.	Nov. 7, 2000	1941
106–451	Wartime Violation of Italian American Civil Liberties Act	Nov. 7, 2000	1947
106–452	To redesignate the facility of the United States Postal Service located at 2339 North California Avenue in Chicago, Illinois, as the "Roberto Clemente Post Office".	Nov. 7, 2000	1950
106–453	To redesignate the facility of the United States Postal Service located at 1568 South Green Road in South Euclid, Ohio, as the "Arnold C. D'Amico Station".	Nov. 7, 2000	1951
106–454	To designate the facility of the United States Postal Service located at 219 South Church Street in Odum, Georgia, as the *"Ruth Harris Coleman Post Office Building".	Nov. 7, 2000	1952
106–455	Glacier Bay National Park Resource Management Act of 2000	Nov. 7, 2000	1953
106–456	Spanish Peaks Wilderness Act of 2000	Nov. 7, 2000	1955
106–457	Estuaries and Clean Waters Act of 2000	Nov. 7, 2000	1957
106–458	Arizona National Forest Improvement Act of 2000	Nov. 7, 2000	1983
106–459	To amend the Colorado River Basin Salinity Control Act to authorize additional measures to carry out the control of salinity upstream of Imperial Dam in a cost-effective manner.	Nov. 7, 2000	1987
106–460	To direct the Secretary of the Interior to issue to the Landusky School District, without consideration, a patent for the surface and mineral estates of certain lots, and for other purposes.	Nov. 7, 2000	1988
106–461	Hoover Dam Miscellaneous Sales Act	Nov. 7, 2000	1989
106–462	Indian Land Consolidation Act Amendments of 2000	Nov. 7, 2000	1991
106–463	Coal Market Competition Act of 2000	Nov. 7, 2000	2010
106–464	Native American Business Development, Trade Promotion, and Tourism Act of 2000	Nov. 7, 2000	2012
106–465	Sand Creek Massacre National Historic Site Establishment Act of 2000	Nov. 7, 2000	2019

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106–466	Nampa and Meridian Conveyance Act	Nov. 7, 2000	2024
106–467	To authorize the Secretary of the Interior to enter into contracts with the Solano County Water Agency, California, to use Solano Project facilities for impounding, storage, and carriage of nonproject water for domestic, municipal, industrial, and other beneficial purposes.	Nov. 9, 2000	2026
106–468	Kristen's Act	Nov. 9, 2000	2027
106–469	Energy Act of 2000	Nov. 9, 2000	2029
106–470	Upper Housatonic National Heritage Area Study Act of 2000	Nov. 9, 2000	2055
106–471	To designate certain National Forest System lands within the boundaries of the State of Virginia as wilderness areas.	Nov. 9, 2000	2057
106–472	Grain Standards and Warehouse Improvement Act of 2000	Nov. 9, 2000	2058
106–473	Washington-Rochambeau Revolutionary Route National Heritage Act of 2000	Nov. 9, 2000	2083
106–474	National Recording Preservation Act of 2000	Nov. 9, 2000	2085
106–475	Veterans Claims Assistance Act of 2000	Nov. 9, 2000	2096
106–476	Tariff Suspension and Trade Act of 2000	Nov. 9, 2000	2101
106–477	To designate the United States courthouse located at 3470 12th Street in Riverside, California, as the "George E. Brown, Jr. United States Courthouse".	Nov. 9, 2000	2182
106–478	To designate the United States courthouse located at 1010 Fifth Avenue in Seattle, Washington, as the "William Kenzo Nakamura United States Courthouse".	Nov. 9, 2000	2183
106–479	To authorize the Frederick Douglass Gardens, Inc., to establish a memorial and gardens on Department of the Interior lands in the District of Columbia or its environs in honor and commemoration of Frederick Douglass.	Nov. 9, 2000	2184
106–480	To designate a building proposed to be located within the boundaries of the Chincoteague National Wildlife Refuge, as the "Herbert H. Bateman Education and Administrative Center".	Nov. 9, 2000	2186
106–481	Library of Congress Fiscal Operations Improvement Act of 2000	Nov. 9, 2000	2187
106–482	To authorize the Secretary of the Interior to acquire by donation suitable land to serve as the new location for the home of Alexander Hamilton, commonly known as the Hamilton Grange, and to authorize the relocation of the Hamilton Grange to the acquired land.	Nov. 9, 2000	2192
106–483	Recognizing that the Birmingham Pledge has made a significant contribution in fostering racial harmony and reconciliation in the United States and around the world, and for other purposes.	Nov. 9, 2000	2193
106–484	Bring Them Home Alive Act of 2000	Nov. 9, 2000	2195
106–485	To direct the Secretary of the Interior to convey certain land under the jurisdiction of the Bureau of Land Management in Washakie County and Big Horn County, Wyoming, to the Westside Irrigation District, Wyoming, and for other purposes.	Nov. 9, 2000	2199
106–486	To review the suitability and feasibility of recovering costs of high altitude rescues at Denali National Park and Preserve in the State of Alaska, and for other purposes.	Nov. 9, 2000	2201
106–487	Vicksburg Campaign Trail Battlefields Preservation Act of 2000	Nov. 9, 2000	2202
106–488	To improve Native hiring and contracting by the Federal Government within the State of Alaska, and for other purposes.	Nov. 9, 2000	2205
106–489	To amend title 46, United States Code, to provide equitable treatment with respect to State and local income taxes for certain individuals who perform duties on vessels.	Nov. 9, 2000	2207
106–490	To provide that the conveyance by the Bureau of Land Management of the surface estate to certain land in the State of Wyoming in exchange for certain private land will not result in the removal of the land from operation of the mining laws.	Nov. 9, 2000	2208
106–491	To amend the Act which established the Saint-Gaudens National Historic Site, in the State of New Hampshire, by modifying the boundary and for other purposes.	Nov. 9, 2000	2209
106–492	National Law Enforcement Museum Act	Nov. 9, 2000	2210
106–493	To provide for equal exchanges of land around the Cascade Reservoir	Nov. 9, 2000	2213
106–494	To provide for the conveyance of certain land to Park County, Wyoming	Nov. 9, 2000	2214
106–495	To permit the conveyance of certain land in Powell, Wyoming	Nov. 9, 2000	2216
106–496	Bend Feed Canal Pipeline Project Act of 2000	Nov. 9, 2000	2218
106–497	Indian Arts and Crafts Enforcement Act of 2000	Nov. 9, 2000	2219
106–498	Klamath Basin Water Supply Enhancement Act of 2000	Nov. 9, 2000	2221
106–499	To authorize the Secretary of the Interior to conduct a study to investigate opportunities to better manage the water resources in the Salmon Creek watershed of the Upper Columbia River.	Nov. 9, 2000	2223
106–500	To assist in establishment of an interpretive center and museum in the vicinity of the Diamond Valley Lake in southern California to ensure the protection and interpretation of the paleontology discoveries made at the lake and to develop a trail system for the lake for use by pedestrians and nonmotorized vehicles.	Nov. 9, 2000	2224
106–501	Older Americans Act Amendments of 2000	Nov. 13, 2000	2226
106–502	Fisheries Restoration and Irrigation Mitigation Act of 2000	Nov. 13, 2000	2294
106–503	To authorize appropriations for the United States Fire Administration, and for carrying out the Earthquake Hazards Reduction Act of 1977, for fiscal years 2001, 2002, and 2003, and for other purposes.	Nov. 13, 2000	2298
106–504	To amend the Organic Act of Guam, and for other purposes	Nov. 13, 2000	2309
106–505	Public Health Improvement Act	Nov. 13, 2000	2314
106–506	Lake Tahoe Restoration Act	Nov. 13, 2000	2351
106–507	To provide for the posthumous promotion of William Clark of the Commonwealth of Virginia and the Commonwealth of Kentucky, co-leader of the Lewis and Clark Expedition, to the grade of captain in the Regular Army.	Nov. 13, 2000	2359
106–508	To provide for increased penalties for violations of the Export Administration Act of 1979, and for other purposes.	Nov. 13, 2000	2360
106–509	Ala Kahakai National Historic Trail Act	Nov. 13, 2000	2361
106–510	Hawaii Volcanoes National Park Adjustment Act of 2000	Nov. 13, 2000	2363
106–511	To provide for equitable compensation for the Cheyenne River Sioux Tribe, and for other purposes.	Nov. 13, 2000	2365
106–512	Palmetto Bend Conveyance Act	Nov. 13, 2000	2378
106–513	National Marine Sanctuaries Amendments Act of 2000	Nov. 13, 2000	2381
106–514	Coastal Barrier Resources Reauthorization Act of 2000	Nov. 13, 2000	2394
106–515	America's Law Enforcement and Mental Health Project	Nov. 13, 2000	2399
106–516	Harriet Tubman Special Resource Study Act	Nov. 13, 2000	2404

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106–517	Bulletproof Vest Partnership Grant Act of 2000	Nov. 13, 2000	2407
106–518	Federal Courts Improvement Act of 2000	Nov. 13, 2000	2410
106–519	FSC Repeal and Extraterritorial Income Exclusion Act of 2000	Nov. 15, 2000	2423
106–520	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Nov. 15, 2000	2436
106–521	To authorize the enforcement by State and local governments of certain Federal Communications Commission regulations regarding use of citizens band radio equipment.	Nov. 22, 2000	2438
106–522	District of Columbia Appropriations Act, 2001	Nov. 22, 2000	2440
106–523	Military Extraterritorial Jurisdiction Act of 2000	Nov. 22, 2000	2488
106–524	To revise the boundary of Fort Matanzas National Monument, and for other purposes	Nov. 22, 2000	2493
106–525	Minority Health and Health Disparities Research and Education Act of 2000	Nov. 22, 2000	2495
106–526	Bend Pine Nursery Land Conveyance Act	Nov. 22, 2000	2512
106–527	To adjust the boundary of the Natchez Trace Parkway, Mississippi, and for other purposes	Nov. 22, 2000	2515
106–528	Airport Security Improvement Act of 2000	Nov. 22, 2000	2517
106–529	Saint Croix Island Heritage Act	Nov. 22, 2000	2524
106–530	Great Sand Dunes National Park and Preserve Act of 2000	Nov. 22, 2000	2527
106–531	Reports Consolidation Act of 2000	Nov. 22, 2000	2537
106–532	Dairy Market Enhancement Act of 2000	Nov. 22, 2000	2541
106–533	To amend the Congressional Award Act to establish a Congressional Recognition for Excellence in Arts Education Board.	Nov. 22, 2000	2545
106–534	Protecting Seniors From Fraud Act	Nov. 22, 2000	2555
106–535	To designate the facility of the United States Postal Service located at 431 North George Street in Millersville, Pennsylvania, as the "Robert S. Walker Post Office".	Nov. 22, 2000	2559
106–536	To amend the Immigration and Nationality Act to provide special immigrant status for certain United States international broadcasting employees.	Nov. 22, 2000	2560
106–537	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Dec. 5, 2000	2562
106–538	To establish the Las Cienegas National Conservation Area in the State of Arizona	Dec. 6, 2000	2563
106–539	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Dec. 7, 2000	2570
106–540	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Dec. 8, 2000	2571
106–541	Water Resources Development Act of 2000	Dec. 11, 2000	2572
106–542	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Dec. 11, 2000	2713
106–543	Making further continuing appropriations for the fiscal year 2001, and for other purposes	Dec. 15, 2000	2714
106–544	Presidential Threat Protection Act of 2000	Dec. 19, 2000	2715
106–545	ICCVAM Authorization Act of 2000	Dec. 19, 2000	2721
106–546	DNA Analysis Backlog Elimination Act of 2000	Dec. 19, 2000	2726
106–547	Enhanced Federal Security Act of 2000	Dec. 19, 2000	2738
106–548	To direct the Secretary of Agriculture to convey to the town of Dolores, Colorado, the current site of the Joe Rowell Park.	Dec. 19, 2000	2741
106–549	To authorize the Secretary of the Interior to contract with the Mancos Water Conservancy District to use the Mancos Project facilities for impounding, storage, diverting, and carriage of nonproject water for the purpose of irrigation, domestic, municipal, industrial, and any other beneficial purposes.	Dec. 19, 2000	2743
106–550	James Madison Commemoration Commission Act	Dec. 19, 2000	2745
106–551	Chimpanzee Health Improvement, Maintenance, and Protection Act	Dec. 20, 2000	2752
106–552	To redesignate the facility of the United States Postal Service located at 514 Express Center Road in Chicago, Illinois, as the "J.T. Weeker Service Center".	Dec. 20, 2000	2761
106–553*	Making appropriations for the government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 2001, and for other purposes.	Dec. 21, 2000	2762
106–554*	Consolidated Appropriations Act, 2001	Dec. 21, 2000	2763
106–555	Striped Bass Conservation, Atlantic Coastal Fisheries Management, and Marine Mammal Rescue Assistance Act of 2000.	Dec. 21, 2000	2765
106–556	To designate the facility of the United States Postal Service located at 200 South George Street in York, Pennsylvania, as the "George Atlee Goodling Post Office Building".	Dec. 21, 2000	2771
106–557	Shark Finning Prohibition Act	Dec. 21, 2000	2772
106–558	To amend the National Forest and Public Lands of Nevada Enhancement Act of 1988 to adjust the boundary of the Toiyabe National Forest, Nevada, and to amend chapter 55 of title 5, United States Code, to authorize equal overtime pay provisions for all Federal employees engaged in wildland fire suppression operations.	Dec. 21, 2000	2776
106–559	Indian Tribal Justice Technical and Legal Assistance Act of 2000	Dec. 21, 2000	2778
106–560	Interstate Transportation of Dangerous Criminals Act of 2000	Dec. 21, 2000	2784
106–561	Paul Coverdell National Forensic Sciences Improvement Act of 2000	Dec. 21, 2000	2787
106–562	To complete the orderly withdrawal of the NOAA from the civil administration of the Pribilof Islands, Alaska, and to assist in the conservation of coral reefs, and for other purposes.	Dec. 23, 2000	2794
106–563	Lincoln Highway Study Act of 2000	Dec. 23, 2000	2809
106–564	To establish a standard time zone for Guam and the Commonwealth of the Northern Mariana Islands, and for other purposes.	Dec. 23, 2000	2811
106–565	Jamestown 400th Commemoration Commission Act of 2000	Dec. 23, 2000	2812
106–566	To direct the Secretary of the Interior to conduct a study on the reclamation and reuse of water and wastewater in the State of Hawaii, and for other purposes.	Dec. 23, 2000	2818
106–567	Intelligence Authorization Act for Fiscal Year 2001	Dec. 27, 2000	2831
106–568	Omnibus Indian Advancement Act	Dec. 27, 2000	2868
106–569	American Homeownership and Economic Opportunity Act of 2000	Dec. 27, 2000	2944
106–570	Assistance for International Malaria Control Act	Dec. 27, 2000	3038
106–571	Federal Physicians Comparability Allowance Amendments of 2000	Dec. 28, 2000	3054
106–572	Computer Crime Enforcement Act	Dec. 28, 2000	3058
106–573	Installment Tax Correction Act of 2000	Dec. 28, 2000	3061
106–574	To authorize the addition of land to Sequoia National Park, and for other purposes	Dec. 28, 2000	3062
106–575	To authorize the Forest Service to convey certain lands in the Lake Tahoe Basin to the Washoe County School District for use as an elementary school site.	Dec. 28, 2000	3063
106–576	Lower Rio Grande Valley Water Resources Conservation and Improvement Act of 2000	Dec. 28, 2000	3065

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Public Law	Title	Approved	114 Stat.
106–577	To establish the California Trail Interpretive Center in Elko, Nevada, to facilitate the interpretation of the history of development and use of trails in the settling of the western portion of the United States, and for other purposes.	Dec. 28, 2000	3068
106–578	Internet False Identification Prevention Act of 2000	Dec. 28, 2000	3075
106–579	National Moment of Remembrance Act	Dec. 28, 2000	3078
106–580	National Institute of Biomedical Imaging and Bioengineering Establishment Act	Dec. 29, 2000	3088

*Note: Public Laws 106–346, 377, 387, 398, 429, 553, and 554 will contain appendixes which incorporate the text of certain bills that have been enacted into law by reference.

[FR Doc. 01–1999 Filed 1–12–01; 8:45 am]
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Federal Register

Tuesday,
January 16, 2001

Part III

Department of the Interior

Fish and Wildlife Service

Draft Policy on National Wildlife Refuge System: Mission, Goals, and Purposes; Notice

Draft Appropriate Refuge Uses Policy Pursuant to the National Wildlife Refuge System Improvement Act of 1997; Notice

Draft Wildlife-Dependent Recreational Uses Policy Pursuant to the National Wildlife Refuge System Improvement Act of 1997; Notice

Draft Wilderness Stewardship Policy Pursuant to the Wilderness Act of 1964; Notice

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[1018–AG46]

Draft Policy on National Wildlife Refuge System: Mission, Goals, and Purposes

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We propose to adopt a policy articulating the mission of the National Wildlife Refuge System (System), establishing its goals, and providing guidance for identifying or determining the purpose(s) of individual refuge units within the System. We propose that this policy be incorporated into the Fish and Wildlife Service Manual. The chapter will be consistent with the principles contained within the National Wildlife Refuge System Administration Act of 1966 (NWRSAA–1966), as amended by the National Wildlife Refuge System Improvement Act of 1997 (NWRSIA–1997), including recognizing the priority for management activities set forth in the NWRSIA–1997 (wildlife, wildlife-dependent uses, and other uses) in setting and achieving refuge goals and objectives.

The draft chapter also provides policy on how the purpose(s) of refuge additions relate to the original refuge purpose(s), and how wilderness designated under the Wilderness Act can affect a refuge's purpose(s). It also provides a decision-tree for how to determine refuge purpose(s) from existing documentation.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: Send comments concerning this draft policy via mail, fax, or email to: Barry Stieglitz, Acting Chief, Division of Conservation Planning and Policy, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Room 670, Arlington, Virginia, 22203; fax (703) 358–2248; email Mission_And_Goals_Policy_Comments@fws.gov.

FOR FURTHER INFORMATION CONTACT: Barry Stieglitz, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Telephone (703) 358–1744.

SUPPLEMENTARY INFORMATION: The NWRSIA–1997 (Pub. L. 105–57) amends and builds upon the NWRSAA–1966 (16 U.S.C. 668dd–668ee), providing an "Organic Act" for the System. It clearly establishes that wildlife conservation is the singular mission of the System and affirms the importance of refuge purposes as they relate to the broader System mission. It states that we shall manage each refuge to fulfill the mission of the System, as well as the specific purpose(s) for which that refuge was established.

The NWRSIA–1997 also provides a clear hierarchy of activities: wildlife conservation, wildlife-dependent recreational uses, and other uses. This chapter reinforces this hierarchy and allows us to articulate our goals for the System, given the direction this new legislation provides. We will incorporate this chapter in the Service Manual as 601 FW 1, replacing 2 RM 1 "Objectives of the National Wildlife Refuge System," which has been in effect since 1982. The complete text of the policy concludes this document, but the following is a overview of the chapter.

Overview of the Draft National Wildlife Refuge System: Mission, Goals, and Purposes Policy

Section 1.1 presents the purpose of the chapter.

Section 1.2 explains that this chapter applies to national wildlife refuges, waterfowl production areas, and coordination areas, which are all units of the System. It does not apply to administrative sites or national fish hatcheries.

Section 1.3 describes how the System mission and goals, and individual unit purposes relate to each other. It reiterates the NWRSIA–1997 language that clearly provides for a unit's purpose(s) to receive priority over the System mission, should there be a conflict between the two.

Section 1.4 describes the mission of the System.

Section 1.5 describes how the System mission relates to the Service mission. The network of lands and waters within the System clearly supports the Service mission of "* * * working with others, to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people."

Section 1.6 lists the goals of the System. These are:

A. To fulfill our statutory duty to achieve refuge purpose(s) and further the System mission;

B. Conserve, restore where appropriate, and enhance all species of fish, wildlife, and plants that are endangered or threatened with becoming endangered;

C. Perpetuate migratory bird, interjurisdictional fish, and marine mammal populations;

D. Conserve a diversity of fish, wildlife, and plants;

E. Conserve and restore as appropriate representative ecosystems of the United States, including the ecological processes characteristic of those ecosystems; and

F. To foster understanding and instill appreciation of native fish, wildlife, and plants, and their conservation, by providing the public with safe, high-quality, and compatible wildlife-dependent public use. Such use includes hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

Section 1.7 describes each of these goals in more detail and justification for why each goal is appropriate for the System.

Section 1.8 explains the relationship the identified goals have to our management priorities. It reiterates the priorities established in the NWRSIA–1997 to be: (1) Wildlife, (2) wildlife-dependent uses, and (3) other uses.

Section 1.9 discusses how we will use these System goals to provide the philosophical foundation of the System; to consider when developing wildlife population and habitat goals and objectives; to guide the land acquisition decision-making process; and in making determinations regarding appropriate uses and compatibility.

Section 1.10 describes what a "unit purpose" is, quoting from the NWRSIA–1997.

Section 1.11 discusses the importance of unit purposes.

Section 1.12 gives examples of unit purposes, and explains that some may be quite broadly written, while others may have a more narrow focus.

Section 1.13 gives the references where unit purposes can be found for each unit in the System.

Section 1.14 discusses how to determine which purpose(s) take priority over others, if a particular unit has multiple purposes associated with it.

Section 1.15 discusses the relationship of purposes for additions to existing units affect the original purpose(s) of the established unit(s), and vice versa.

Section 1.16 discusses how wilderness areas designated under the Wilderness Act (16 U.S.C. 1131–1136) affect a unit's purpose(s).

Section 1.17 provides a process for determining the purpose(s) of units of the System. It is a decision-tree that guides you through establishment/authorization methods and what other references you may need when purposes have not been clearly articulated in establishment/authorization documents. It also specifies that the Director of the Service must approve purposes in cases where establishing/authorizing documents do not articulate the purpose(s).

Comment Solicitation

If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to: Barry Stieglitz, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive—MS670, Arlington, VA 22203. You may comment via the Internet to: Mission_And_Goals_Policy_Comments@fws.gov. Please submit Internet comments as an ASCII file, avoiding the use of special characters and any form of encryption. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (703) 358–1744. You may also fax comments to: Barry Stieglitz, National Wildlife Refuge System, (703) 358–2248. Finally, you may hand-deliver comments to the address mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representative or officials of organizations or businesses, available for public inspection in their entirety.

We seek public comments on this draft policy and will take into consideration comments and any additional information received during the 60-day comment period.

We published a notice in the **Federal Register** on January 23, 1998 (63 FR 3583) notifying the public that we would be revising the Service Manual, establishing regulations as they relate to the NWRSIA–1997, and offering to send copies of specific draft Service Manual chapters to anyone who would like to receive them. We will mail a copy of this draft Service Manual chapter to those who requested one. In addition, this draft Service Manual chapter will be available on the Internet at http://www.fws.gov/directives/library/frindex.html during the 60-day comment period.

Required Determinations

Regulatory Planning and Review

In accordance with the criteria in Executive Order 12866, this document is not a significant regulatory action. The Office of Management and Budget (OMB) makes the final determination under Executive Order 12866.

a. This document will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit or full economic analysis is not required. This document is administrative and procedural in nature. This draft National Wildlife Refuge System policy provides for a hierarchy of activities and establishes the process for articulating the goals for the System. This policy will have the effect of providing priority consideration for wildlife conservation and wildlife-dependent recreational uses involving hunting, fishing, wildlife observation and photography, and environmental education and interpretation and other uses. Existing policy has been in place since 1982. The NWRSIA–1997 does not change this direction in public use, but provides legal recognition for the mission, goals, and purposes of the System. We expect this articulated policy will not cause a measurable economic effect to existing national wildlife refuge public use programs.

The appropriate measure of the economic effect of changes in recreational use is the change in the welfare of recreationists. We measure this in terms of willingness to pay for the recreational opportunity. We estimated total annual willingness to pay for all recreation at national wildlife refuges to be $372.5 million in Fiscal Year 1995 (Banking on Nature: The Economic Benefits to Local Communities of National Wildlife Refuge Visitation, DOI/FWS/Refuges 1997). We expect the policy implemented in this document will not affect public uses of the Refuge System. This does not mean that every refuge will have the same public uses. Public uses of a refuge are determined when a refuge is established and after public hearings are held. Only compatible uses with the purpose of the refuge are proposed for public review and comment. This policy will provide for a unit's purposes to receive priority over System mission should there be a conflict between the two.

This document will not make changes in the amounts of public activities occurring on national wildlife refuges. There will not be a change in the total benefits of permitted public uses activities on national wildlife refuges.

b. This document will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency since the document pertains solely to management of national wildlife refuges by the Service.

c. This document does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. There are no grants or other Federal assistance programs associated with public use of national wildlife refuges.

d. This document does not raise novel legal or policy issues; however, it does provide a hierarchy of activities pursuant to the NWRSIA–1997 provisions that ensure that wildlife conservation, wildlife-dependent recreational uses and other uses are the priority public uses of the System.

Regulatory Flexibility Act

We certify that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Congress created the National Wildlife Refuge System to conserve fish, wildlife, and plants and their habitats and facilitated this conservation mission by providing Americans opportunities to visit and participate in compatible wildlife-dependent recreation (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) as priority general public uses on national wildlife refuges and to better appreciate the value of, and need for, wildlife conservation.

This document is administrative and procedural in nature and provides for a hierarchy of activities on refuges: wildlife conservation, wildlife-dependent recreation and other uses. Since uses of a national wildlife refuge are determined with the establishment of the refuge, which includes public hearings, this policy will not affect public uses of refuges, and consequently, not affect any business establishments in the vicinity of any refuge.

National wildlife refuge visitation is a small component of the wildlife recreation industry as a whole. In 1996, 77 million U.S. residents over 15 years old spent 1.2 billion activity-days in wildlife-associated recreation activities. They spent about $30 billion on fishing, hunting, and wildlife watching trips (Tables 49, 54, 59, 63, 1996 National

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Survey of Fishing, Hunting, and Wildlife-Associated Recreation, DOI/FWS/FA, 1997). National wildlife refuges recorded about 29 million visitor-days that year (RMIS, FY1996 Public Use Summary). A study of 1995 national wildlife refuge visitors found their travel spending generated $401 million in sales and 10,000 jobs for local economies (Banking on Nature: The Economic Benefits to Local Communities of National Wildlife Refuge Visitation, DOI/FWS/Refuges, 1997). These spending figures include spending which would have occurred in the community anyway, and so they show the importance of the activity in the local economy rather than its incremental impact. Marginally greater recreational opportunities on national wildlife refuges will have little industry-wide effect.

There are no expected changes in expenditures as a result of this document. We expect there will not be a change in recreational opportunities so we do not expect the document to have a significant economic effect on a substantial number of small entities in any region or nationally.

Small Business Regulatory Enforcement Fairness Act

This document is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This document:

a. Does not have an annual effect on the economy of $100 million or more. These regulations will affect only visitors at national wildlife refuges. They may result in increased visitation at refuges and provide for minor changes to the methods of public use permitted within the National Wildlife Refuge System. Refer to response under Regulatory Flexibility Act.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. See response above.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. See response above.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

a. This document will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. See response to Regulatory Flexibility Act.

b. This document will not produce a Federal mandate of $100 million or greater in any year, *i.e.*, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. See response to Regulatory Flexibility Act.

Takings

In accordance with Executive Order 12630, the document does not have significant takings implications. A takings implication assessment is not required. These regulations may result in increased visitation at refuges and provide for minor changes to the methods of public use permitted within the National Wildlife Refuge System. Refer to response under Regulatory Flexibility Act.

Federalism

In accordance with Executive Order 13132, the document does not have significant federalism effects. This document will not have substantial direct effects on the States, in their relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, we have determined that this document does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the document does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The regulation will expand upon established regulations, and result in better understanding of the regulations by refuge visitors.

Paperwork Reduction Act

This document does not require an information collection from ten or more parties and a submission under the Paperwork Reduction Act of 1995 is not required.

National Environmental Policy Act

We ensure compliance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)) when developing national wildlife refuge Comprehensive Conservation Plans and public use management plans, and we make determinations required by NEPA before the addition of national wildlife refuges to the lists of areas open to public uses. The revisions to regulations as proposed in this document resolve a variety of issues concerning our administration of national wildlife refuge uses. In accordance with 516 DM 2, Appendix 1.10, we have determined that this document is categorically excluded from the NEPA process because it is limited to policies, directives, regulations and guidelines of an administrative, financial, legal, technical or procedural nature; or the environmental effects of which are too broad, speculative or conjectural to lend themselves to meaningful analysis. Site-specific proposals, as indicated above, will be subject to the NEPA process.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we have evaluated possible effects on federally recognized Indian tribes and have determined that there are no effects. In Alaska, this regulation would not apply to the development and use of Alaska Native Claims Settlement Act (ANCSA), 22(g) village lands in Alaska national wildlife refuges.

Primary Author

Brad Knudsen, Refuge Program Specialist, National Wildlife Refuge System, U.S. Fish and Wildlife Service, is the primary author of this notice.

Refuge Management—Part 601 National Wildlife Refuge System

Chapter 1 National Wildlife Refuge System Mission and Goals and Purposes 601 FW 1

1.1 *What is the purpose of this chapter?* This chapter reiterates the mission of the National Wildlife Refuge System, how it relates to the mission of the Fish and Wildlife Service, and explains the relationship of the System mission and goals, and the purpose(s) of each unit of the System. This chapter provides goals for the System and guidance for identifying or determining the purpose(s) of each unit within the System. This chapter also provides guidance on the use of goals and purposes in the administration and management of the System.

1.2 *What is the scope of this chapter?* This chapter applies to all units of the System. For purposes of this chapter, a unit of the System is defined as all lands, waters, and interests therein administered by the U.S. Fish and Wildlife Service as wildlife refuges, wildlife ranges, wildlife management areas, waterfowl production areas, coordination areas and other areas for the protection and conservation of fish

and wildlife including those threatened with extinction as determined in writing by the Director or so directed by Presidential or Secretarial order.

1.3 *How do the System mission, goals, and unit purpose(s) relate to each other?* Collectively, the System mission, goals, and unit purpose(s) define the duty of the U.S. Fish and Wildlife Service in the administration and management of any unit of the System. Ideally, the System mission, goals, and unit purpose(s) are viewed as symbiotic in nature; however, priority is given to achieving a unit's purpose(s) when conflicts with the System mission or a specific goal are identified. Unit purposes form the foundation for developing goals and objectives for units during Comprehensive Conservation Plan preparation, and provide the basis for determining the appropriateness and compatibility of existing and proposed uses on units.

1.4 *What is the mission of the National Wildlife Refuge System?* The National Wildlife Refuge System Administration Act of 1966 (NWRSAA–1966), as amended by the National Wildlife Refuge System Improvement Act of 1997 (NWRSIA–1997), states the following: "The mission of the National Wildlife Refuge System is to administer a national network of lands and waters for the conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats within the United States for the benefit of present and future generations of Americans."

1.5 *How does the mission of the System relate to the mission of the Service?* The mission of the Service set forth in National Policy Issuance 99–01 is: "Our mission is working with others, to conserve, protect and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people." To accomplish this mission, there is a clear need for a network of lands and waters representing the diversity of landscapes and ecosystems of the United States dedicated to the conservation of fish, wildlife, and plants. While the mission of the System and purposes of individual units are paramount, it is recognized that the System contributes a vital component to the Service mission.

1.6 *What are the goals of the System?* The administration, management, and growth of the System are guided by the following goals:

A. To fulfill our statutory duty to achieve refuge purpose(s) and further the System mission.

B. Conserve, restore where appropriate, and enhance all species of fish, wildlife, and plants that are endangered or threatened with becoming endangered.

C. Perpetuate migratory bird, interjurisdictional fish, and marine mammal populations.

D. Conserve a diversity of fish, wildlife, and plants.

E. Conserve and restore where appropriate representative ecosystems of the United States, including the ecological processes characteristic of those ecosystems.

F. To foster understanding and instill appreciation of native fish, wildlife, and plants, and their conservation, by providing the public with safe, high-quality, and compatible wildlife-dependent public use. Such use includes hunting, fishing, wildlife observation and photography, and environmental education and interpretation.

1.7 *What do these goals mean?* Goal A. The U.S. Fish and Wildlife Service is entrusted with the stewardship of America's National Wildlife Refuge System. Our first obligation in meeting that trust is the non-discretionary duty to fulfill refuge purpose(s). We may not discard that obligation in pursuit of other objectives. We may, in order to fulfill the broader System mission, and the further goals enumerated below, manage a refuge to achieve additional wildlife conservation purposes and needs, unforseen, unknown, or resulting from circumstances unanticipated at the time of refuge establishment. These additional efforts will be additive to the achievement of refuge purpose(s), which is our first and highest obligation.

Goal B. Threatened and endangered species are those listed as such by the Service or the National Marine Fisheries Service. As we manage to achieve unit purposes, we are mindful of our obligations under section 2(c)(1) of the Endangered Species Act and we strive to be a model for other Federal land management agencies in fulfilling that obligation. We protect and manage candidate and proposed species to enhance their status and help preclude the need for listing. Per Service policy [see Section 1.2(C) of the Service's "Section 7 Consultation Handbook", March 1998], we will consult or confer with Service Ecological Services staff on any actions authorized, funded, or carried out on System units that may affect listed, proposed, or candidate species or designated or proposed critical habitat.

Goal C. We strive to meet the needs of all migratory birds in our habitat strategies, especially those species which are rare, declining, or tied directly to a unit's purpose(s). We contribute to such efforts as the North American Bird Conservation Initiative, and continue to recognize the System's role in the perpetuation of the continent's waterfowl resource: more than 200 refuges and thousands of waterfowl production areas have been established for purpose of waterfowl or migratory bird conservation. We emphasize the conservation and management of those marine mammals for which the Service has been given primary management authority, including polar bears, walruses, sea otters, manatees, and dugongs, as well as the conservation of any marine mammal using System lands or waters. We emphasize the conservation and management of those fish populations using System waters and whose life-cycle movements cross international, State, or Tribal boundaries. Examples include anadromous species of salmon and free-roaming species endemic to large river systems, such as paddlefish and sturgeon.

Goal D. We sustain all native species of animals and plants that inhabit units of the System through our efforts to maintain the biological diversity, biological integrity, and environmental health of each unit. This does not preclude the consumptive use of some species when compatible with a unit's purpose(s) and the System mission, or the population management of some species to help achieve a unit's purpose(s). Some units were established primarily to protect populations of certain animal species that have a unique historic and cultural legacy in North America. We continue to emphasize the conservation of those native species tied directly to the establishment purpose(s) of units.

Goal E. Through our management and acquisition efforts, we assist states, Tribes, other agencies and conservation groups in preserving those ecosystems, plant communities, wetlands of national or international significance, and/or landscapes that are unique, rare, declining, or under-represented in existing conservation lands. We use existing and emerging classification systems that identify such ecosystems and/or resources to guide our preservation, restoration, and acquisition efforts. We care for our special designation lands such as wilderness, natural areas, wild and scenic rivers, national monuments, and national natural landmarks, and, where appropriate, expand these designations on existing and new units. We strive to establish and maintain a network of biological reserves to ensure preservation and genetic exchange of our Nation's diverse natural heritage in

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partnership with other Federal land management agencies, States, conservation organizations, and members of the public participating on a voluntary basis.

Goal F. We recognize that a higher awareness of, and appreciation for, the value of fish and wildlife conservation is gained in part by providing opportunities for people to engage in compatible wildlife-dependent recreation. This higher awareness and appreciation ultimately contributes to the mission of the System. Thus, we facilitate opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation that are compatible with a unit's purpose(s) and the System mission. Our interpretive and education programs also include historic and cultural resources found on units. We actively seek partnerships for our public use programs when a lack of funds or staff limit implementation.

1.8 *How do these goals relate to management priorities?* The NWRSAA–1966, as amended, sets forth the following priority for management activities: (1) Wildlife, (2) wildlife-dependent recreational uses, and (3) other uses. Thus, goals dealing with fish, wildlife, and plants, and the habitat or ecosystems on which they depend, take priority over wildlife-dependent uses or any other uses of System lands. Wildlife-dependent recreational uses in turn take priority over those uses which are not wildlife-dependent. Each unit contributes to one or more of the goals of the System, depending on the purpose(s) of the unit, a unit's geographic and ecological setting, and the unique characteristics, potential, or limitations of each unit.

1.9 *How will we use these goals of the System?* These goals help step down the System mission and statements on System management as written in the NWRSAA–1997, as amended. Collectively, these goals articulate the foundation for our stewardship of the System and define the unique niche it occupies among the various Federal land systems. We consider these goals in developing wildlife population and habitat goals and objectives at the System, regional, ecosystem, and unit level; in providing a frame of reference for Comprehensive Conservation Plans; to guide the land acquisition decision-making process; to assist managers in applying sound professional judgment to their decisions while carrying out the purpose(s) of their units and in determining whether proposed uses are appropriate and compatible; and as a guide when developing other policies on System administration and management.

1.10 *What is meant by the term "unit purpose?"* Unit purpose refers to the justification for the establishment of a unit of the System as a place owned by the American people and cared for on their behalf. The NWRSAA–1966, as amended, defines "purposes of the refuge" as the "purposes specified in or derived from the law, proclamation, executive order, agreement, public land order, donation document, or administrative memorandum establishing, authorizing, or expanding a refuge, refuge unit, or refuge subunit."

1.11 *Why are unit purposes important?* Purposes define the essential objective of our refuge stewardship. They constitute a non-discretionary obligation as the legislative, legal, and administrative foundations for the administration and management of a unit of the System. This includes planning, setting unit goals and objectives, and authorization of public uses, which must be shown to be appropriate and compatible with the purpose(s) of a unit and the System mission before they are allowed.

1.12 *What are some examples of purposes?* Units acquired under the authority of general conservation laws take on the purpose of the law. Examples of such laws include the Endangered Species Act of 1973, the Migratory Bird Conservation Act, the Fish and Wildlife Act of 1956, the Emergency Wetlands Resources Act, and the Alaska National Interest Lands Conservation Act. Executive Orders and refuge-specific legislation generally declare the purpose(s) of the unit, sometimes broadly ("as a preserve and breeding ground for native birds"), and sometimes very specifically ("to protect and preserve in the national interest the Key deer and other wildlife resources in the Florida Keys.").

1.13 *Where can the purpose(s) of each unit of the System be found?* The publication "Purposes for Refuges of the National Wildlife Refuge System" contains the official purpose(s) for each unit. This publication is updated annually to include new additions to the System, and can be found by using the "Search—databases" on the System web server at http://refuges.fws.gov.

1.14 *If a unit has multiple purposes, do some purposes take priority over others?* Unless otherwise indicated in the establishing law, order, or other document, purposes dealing with the conservation, management, and restoration of fish, wildlife, and plants, and the habitats on which they depend, take precedent over other purposes in the management and administration of any unit. Where a refuge has multiple purposes related to fish, wildlife and plant conservation, the more specific purpose will take precedent in instances of conflict. Designated wilderness assumes the purposes of the Wilderness Act of 1964 in addition and equal to other unit purposes, unless otherwise specified in the wilderness designation.

1.15 *How does the purpose(s) associated with acquiring new lands for existing units relate to the original purpose(s) of the existing units?* When an addition to a unit is acquired under an authority different from the authority used to establish the original unit, the addition also takes on the purpose(s) of the original unit, but the original unit does not take on the purpose(s) of the addition.

1.16 *How does the Wilderness Act affect a unit's purpose?* The purposes of the Wilderness Act become additional and equal purposes of units with designated wilderness, but apply only to those areas so designated. The purposes of the Wilderness Act include both the preservation of wilderness condition and character, and the use and enjoyment of wilderness.

1.17 *What is the process for determining purposes of units?* The purpose(s) of existing units may be found as described in section 1.13. We will use the decision process outlined in Exhibit 1 to determine the purpose(s) of a unit. This process can be applied to all System acquisitions, including excess military lands, land exchanges, or condemnations by focusing on the acquisition authority for the particular property. This process takes into account those rare cases where acquisition authority provides a vague purpose. This process should be used for each parcel or group of parcels included under different acquisition authorities, until the purpose for each authority has been determined.

Exhibit 1—Decision Process for Determining Unit Purposes

Step I. Was the unit established by an Executive Order, public land order, or Secretarial Order?

A. Yes.

1. The document specifies the purpose(s) for the unit—DONE.

2. The document does not specify a purpose:

What is the historical record of management, management plans, and the biological history of the area? Articulate the purpose(s) for Director's approval—DONE.

3. If any lands/waters at this unit were not included under any additional authorities—DONE.

4. If any lands/waters at this unit were included under additional authorities, go to Step II.

B. No. Go to Step II.

Step II. Was the unit established or authorized by unit-specific legislation?

A. Yes.

1. The legislation states the purpose(s) of the unit—DONE.

2. The legislation does not specify a purpose:

Further research is required including legislative history, agency testimony in the Congressional Record, or documents approved by the Director, or lacking these, the biological history of the area, resource inventories, or other resource-based documentation. Articulate the purpose(s) for Director's approval—DONE.

3. If any lands/waters at this unit were not included under any additional authorities—DONE.

4. If any lands/waters at this unit were included under additional authorities, go to Step III.

B. No. Go to Step III.

Step III. Was the unit established or acquired by the authority of one or more of the following 14 laws that grant the Service acquisition authority?

1. An Act Authorizing the Transfer of Certain Real Property
2. Bankhead-Jones Farm Tenant Act
3. Consolidated Farm and Rural Development Act
4. Colorado River Storage Act
5. Emergency Wetlands Resources Act of 1986
6. Endangered Species Act of 1973
7. Fish and Wildlife Act of 1956
8. Fish and Wildlife Coordination Act
9. Lea Act
10. Migratory Bird Conservation Act
11. Migratory Bird Hunting and Conservation Stamp Act
12. North American Wetlands Conservation Act
13. National Wildlife Refuge System Administration Act of 1966
14. Refuge Recreation Act

A. Yes.

1. The purpose for acquisition is stated in the law and becomes the purpose of the unit—DONE.

2. If any lands/waters at this unit were not included under any additional authorities—DONE.

3. If any lands/waters at this unit were included under additional authorities, go to Step IV.

B. No. Go to Step IV.

Step IV. Was the unit donated to the Service?

A. Yes.

1. Research is required, including legislation that grants authority for donations, any biological reports on the unit or adjacent area, a review of fish, wildlife, and plant species of significance using the unit, and any conditions set forth in the donation letter or memorandum that do not conflict with the mission of the System. Articulate the purpose(s) for Director's approval.

Dated: December 18, 2000.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 01–20 Filed 1–12–01; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[1018–AG18]

Draft Appropriate Refuge Uses Policy Pursuant to the National Wildlife Refuge System Improvement Act of 1997

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We propose to establish, in policy, a procedure for determining when uses other than the six priority wildlife-dependent recreational uses are appropriate or not appropriate on a unit of the National Wildlife Refuge System (System). The National Wildlife Refuge System Improvement Act of 1997 (NWRSIA–1997), that amends the National Wildlife Refuge System Administration Act of 1966 (NWRSAA–1966), defines and establishes that wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) are the priority general public uses of the System and, if found compatible, will receive enhanced and priority consideration in refuge planning and management over other general public uses. This draft policy describes how we will provide priority to these uses, and establishes a process for deciding when it is appropriate to allow other, non-priority uses to occur on national wildlife refuges. We propose to incorporate this policy as Part 603 Chapter 1 of the Fish and Wildlife Service Manual.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: You may submit comments on this draft appropriate refuge uses policy by mail, fax or e:mail: by mail to J. Kenneth Edwards, Refuge Program Specialist, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; by fax to (703) 358–2248; or by e:mail to Appropriate_Uses _Policy_ Comments@fws.gov.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Edwards, Refuge Program Specialist, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Telephone (703) 358–1744.

SUPPLEMENTARY INFORMATION: The NWRSIA–1997 amends and builds upon the NWRSAA–1966 providing an "Organic Act" for the System. The NWRSIA–1997 clearly establishes that wildlife conservation is the singular System mission, provides guidance to the Secretary of the Interior (Secretary) for management of the System, provides a mechanism for refuge planning, and gives refuge managers uniform direction and procedures for making decisions regarding wildlife conservation and uses of the System.

The NWRSIA–1997 identifies six wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) as the priority general public uses of the System. The NWRSIA–1997 also provides a set of affirmative stewardship responsibilities regarding our administration of the System. These stewardship responsibilities direct us to ensure that these six wildlife-dependent recreational uses are provided enhanced consideration and priority over other general public uses.

The Refuge Recreation Act of 1962 (RRA–1962) also authorizes us to regulate or curtail public recreational uses in order to insure accomplishment of our primary conservation objectives. The RRA–1962 also directs us to administer the System for public recreation when the use is an "appropriate incidental or secondary use."

The determination of appropriateness is the first step in deciding whether we will permit a proposed or existing use on a refuge. After we decide a use is appropriate, we then must determine that it would be compatible before allowing. The six wildlife-dependent recreational uses are the priority public uses of the System and, when compatible, have been determined to be appropriate by law. Uses which are necessary for the safe, practical, and effective conduct of a priority public use are also appropriate. We will evaluate all other uses under a screening process established by this policy to determine their relationship to the System's wildlife conservation mission, individual refuge purposes, and the six priority public uses. This screening process, the "appropriate use" test contained in this policy, is a decision process that refuge managers will use to quickly and systematically decide which uses are not appropriate on a national wildlife refuge. We then more thoroughly review uses, which we have

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determined to be appropriate, for compatibility before we allow them on a refuge. This appropriate use policy and our compatibility policy are key tools refuge managers use together to fortify our commitment to provide enhanced opportunities for the public to enjoy wildlife-dependent recreation while at the same time ensuring that no refuge uses compromise the System's wildlife conservation mission and the individual refuge purposes. Through careful planning, System-wide application of regulations and policies, diligent monitoring of the impacts of uses on natural resources, and by preventing or eliminating uses not appropriate to the System, we can achieve our wildlife conservation mission and individual refuge purposes while also providing people with lasting opportunities for the highest quality wildlife-dependent recreation.

Appropriate Refuge Uses Policy

To ensure the primacy of the System wildlife conservation mission, the individual refuge purposes and to be sure we afford priority to the six wildlife-dependent recreational uses within the System, we are proposing to establish an appropriate refuge uses policy. This policy will apply to all proposed and existing uses of national wildlife refuges when we have jurisdiction over these uses. The following is a summary of the key provisions of this policy.

The Refuge Manager will not further consider allowing a new use, nor renewing, extending, or expanding an existing use on a national wildlife refuge without determining the use to be an appropriate use. The Refuge Manager will halt, as expeditiously as practicable, existing uses determined to be not appropriate.

An appropriate use of a refuge is a proposed or existing use that meets at least one of the following three conditions:

1. The use is a priority public use or is necessary for the safe, practical, and effective conduct of a priority public use on the refuge;

2. The use contributes to fulfilling the System mission, or the refuge purposes, goals, or objectives as described in a refuge management plan approved after October 9, 1997, the date the NWRSIA–1997 was passed; or

3. The use has been determined to be appropriate in a documented analysis by the Refuge Manager, with the Refuge Supervisor's concurrence. This documented analysis will address the following 11 factors.

a. Does the use comply with applicable laws and regulations?

b. Is the use consistent with applicable Executive Orders and Department and Service policies?

c. Is the use consistent with refuge goals and objectives in an approved refuge management plan?

d. Has an earlier documented analysis not denied the use?

e. Is the use consistent with public safety?

f. Is the use manageable within available budget and staff?

g. Is the use consistent with other resource or management objectives?

h. Will the use be easy to control in the future?

i. Is the refuge the only place where this activity can reasonably occur?

j. Does the use contribute to the public's understanding and appreciation of the refuge's wildlife or cultural resources, or is the use beneficial to the refuge's wildlife or cultural resources?

k. Can the use be accommodated without impairing existing wildlife-dependent recreational uses or reducing the potential to provide quality wildlife-dependent recreation into the future?

If the answer is "no" to any of these questions, we will generally not allow the use. If the answers are consistently "yes" to these questions, or, if not, if there are compelling reasons why the Refuge Manager believes the use is appropriate on the refuge, the Refuge Manager then prepares a written justification, and obtains concurrence from the Refuge Supervisor. Requiring concurrence from the Refuge Supervisor will help us promote consistency within the System.

Uses determined to be appropriate are also reviewed for compatibility before they may be allowed on a refuge.

Some recreational activities, while wholesome and enjoyable, are not dependent on the presence of fish and wildlife, nor dependent on the expectation of encountering fish and wildlife. Many of these non-wildlife-dependent recreational activities are often disruptive or harmful to fish, wildlife or plants, or may interfere with the use and enjoyment of a refuge by others engaged in wildlife-dependent recreation. These uses may more appropriately be conducted on private land, or other public lands not specifically dedicated for wildlife conservation.

Purpose of This Draft Policy

The purpose of this draft policy is to modify the general guidance concerning proposed and existing uses of the System in compliance with the NWRSIA–1997. This policy establishes a procedure we will use for determining when uses are appropriate or not appropriate on a unit of the National Wildlife Refuge System, before we undertake assessing compatibility of the use.

Fish and Wildlife Service Directives System

Because many of our field stations are in remote areas across the United States, it is important that all employees have available and know the current policy and management directives that affect their daily activities. The Fish and Wildlife Service Directives System, consisting of the Fish and Wildlife Service Manual (Service Manual), Director's Orders, and National Policy Issuances, is the vehicle for issuing the standing and continuing policy and management directives of the Service. New directives are posted on the Internet upon approval, ensuring that all employees have prompt access to the most current guidance.

The Service Manual contains our standing and continuing directives with which our employees comply. We use it to implement our authorities and to "step down" our compliance with statutes, executive orders, and Departmental directives. It establishes the requirements and procedures to assist our employees in carrying out our authorities, responsibilities, and activities.

Director's Orders are limited to temporary policy, procedures, delegations of authority, emergency regulations, special assignments of functions, and initial functional statements on the establishment of new organizational units. All Director's Orders must be converted as soon as practicable to appropriate parts of the Service Manual or removed. Material appropriate for immediate inclusion in the Service Manual generally is not issued as a Director's Order.

National Policy Issuances promulgate the Director's national policies for managing the Service and its programs. These policies are necessarily broad and generally require management discretion or judgment in their implementation. They represent the Director's expectations of how the Service and its employees will act in carrying out their official responsibilities.

The Service Manual, Director's Orders, and National Policy Issuances are available on the Internet at http://www.fws.gov/directives/direct.html. When finalized, we will incorporate this appropriate refuge uses policy into the Service Manual as Part 603 Chapter 1.

Comment Solicitation

We seek public comments on this draft appropriate refuge uses policy and will take into consideration comments and any additional information received during the 60-day comment period. You may submit comments on this draft appropriate refuge uses policy by mail, fax or e:mail: by mail to J. Kenneth Edwards, Refuge Program Specialist, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; by fax to (703) 358–2248; or by e:mail to Appropriate_Uses_Policy_Comments@fws.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include: "Attn: 1018–AG18" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (703) 358–1744. Finally, you may hand-deliver comments to the address mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

We published a notice in the **Federal Register** on January 23, 1998 (63 FR 3583) notifying the public that we would be revising the Service Manual, establishing regulations as they relate to the NWRSIA–1997, and offering to send copies of specific draft Service Manual chapters to anyone who would like to receive them. We will mail a copy of this draft Service Manual appropriate refuge uses chapter to those who requested one. In addition, this draft Service Manual appropriate refuge uses chapter will be available on the Internet at http://www.fws.gov/directives/library/frindex.html during the 60-day comment period.

Required Determinations

Regulatory Planning and Review (E.O. 12866)

In accordance with the criteria in Executive Order 12866, this policy is not a significant regulatory action. The Office of Management and Budget (OMB) makes the final determination under Executive Order 12866.

(1) This policy will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit or full economic analysis is not required. This policy is administrative, legal, technical, and procedural in nature. This policy establishes the process for determining the appropriateness of proposed national wildlife refuge uses. This policy will have the effect of providing priority consideration for wildlife-dependent recreational uses involving hunting, fishing, wildlife observation and photography, and environmental education and interpretation. Existing policy has been in place since 1985 that encouraged the phase-out on refuges of non-wildlife-oriented recreation. The NWRSIA–1997 does not greatly change this direction in public use, but provides legal recognition of the priority we afford to wildlife-dependent recreational uses. We expect these new procedures to cause only minor modifications to existing national wildlife refuge public use programs. While we may curtail some non-priority refuge uses, we may provide new and expanded opportunities for priority public uses. We expect an overall small increase, at most a 5 percent annual increase, in the amount of public use activities allowed on refuges as a result of this policy.

The appropriate measure of the economic effect of changes in recreational use is the change in the welfare of recreationists. We measure this in terms of willingness to pay for the recreational opportunity. We estimated total annual willingness to pay for all recreation at national wildlife refuges to be $372.5 million in Fiscal Year 1995 (Banking on Nature: The Economic Benefits to Local Communities of National Wildlife Refuge Visitation, DOI/FWS/Refuges 1997). We expect the appropriate use determination process implemented in this policy to cause at most a 5 percent annual increase in recreational use System-wide. This does not mean that every refuge will have the same increase in public use. We will allow the increases only on refuges where increases in hunting, fishing, and other wildlife-dependent recreational visitation are compatible. Across the entire System, we expect an increase in hunting, fishing, and non-consumptive visitation to amount to no more than a 5 percent overall increase. If the full 5 percent increase in public use were to occur at national wildlife refuges, this would translate to a maximum additional willingness to pay of $21 million (1999 dollars) annually for the public. However, we expect the real benefit to be less than $21 million because we expect the final increase in public use to be smaller than 5 percent. Furthermore, if the public substitutes non-refuge recreation sites for refuges, then we would subtract the loss of benefit attributed to non-refuge sites from the $21 million estimate.

We measure the economic effect of commercial activity by the change in producer surplus. We can measure this as the opportunity cost of the change, i.e., the cost of using the next best production option if we discontinue production using the national wildlife refuge. National wildlife refuges use grazing, haying, timber harvesting, and row crops to help fulfill the System mission and refuge purposes. Congress authorizes us to allow economic activities on national wildlife refuges, and we do allow some. But, for all practical purposes (almost 100 percent), we invite the economic activities to help achieve a refuge purpose or the System mission. For example, we do not allow farming per se, rather we invite a farmer to farm on the national wildlife refuge under a Cooperative Farming Agreement to help achieve a national wildlife refuge purpose. This policy will likely have minor changes in the amounts of these activities occurring on national wildlife refuges. Information on profits and production alternatives for most of these activities is proprietary, so a valid estimate of the total benefits of permitting these activities on national wildlife refuges is not available.

(2) This policy will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency since the policy pertains solely to management of national wildlife refuges by the Service.

(3) This policy does not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. No grants or other Federal assistance programs are associated with public use of national wildlife refuges.

(4) This policy does not raise novel legal or policy issues; however, it does provide a new approach. It adds the NWRSIA–1997 provisions that ensure that wildlife-dependent recreational

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uses are the priority public uses of the System, and adds consistency in application of public use guidelines across the entire System.

Regulatory Flexibility Act

We certify that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Congress created the National Wildlife Refuge System to conserve fish, wildlife, and plants and their habitats and facilitated this conservation mission by providing Americans opportunities to visit and participate in compatible wildlife-dependent recreation (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) as priority general public uses on national wildlife refuges and to better appreciate the value of, and need for, wildlife conservation.

This policy is administrative, legal, technical, and procedural in nature and provides more detailed instructions for the determination of the appropriateness of public use activities than have existed in the past. This policy may result in more opportunities for wildlife-dependent recreation on national wildlife refuges, and may result in the reduction of some non-wildlife-dependent recreation. For example, more wildlife observation opportunities may occur at Florida Panther National Wildlife Refuge in Florida or more hunting opportunities at Pond Creek National Wildlife Refuge in Arkansas. Conversely, we may no longer allow some activities on some refuges. For example, some refuges may currently allow water skiing on refuge-controlled waters or the use of off-road vehicles; we would likely curtail some of these uses as we implement this policy. The overall net effect of these regulations is likely to increase visitor activity near the national wildlife refuge. To the extent visitors spend time and money in the area that would not otherwise have been spent there, they contribute new income to the regional economy and benefit local businesses.

National wildlife refuge visitation is a small component of the wildlife recreation industry as a whole. In 1996, 77 million U.S. residents over 15 years old spent 1.2 billion activity-days in wildlife-associated recreation activities. They spent about $30 billion on fishing, hunting, and wildlife watching trips (Tables 49, 54, 59, 63, 1996 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation, DOI/FWS/FA, 1997). National wildlife refuges recorded about 29 million visitor-days that year (RMIS, FY1996 Public Use Summary). A study of 1995 national wildlife refuge visitors found their travel spending generated $401 million in sales and 10,000 jobs for local economies (Banking on Nature: The Economic Benefits to Local Communities of National Wildlife Refuge Visitation, DOI/FWS/Refuges, 1997). These spending figures include spending which would have occurred in the community anyway, and so they show the importance of the activity in the local economy rather than its incremental impact. Marginally greater recreational opportunities on national wildlife refuges will have little industry-wide effect.

Expenditures as a result of this policy are a transfer and not a benefit to many small businesses. We expect the incremental increase of recreational opportunities to be marginal and scattered, so we do not expect the policy to have a significant economic effect on a substantial number of small entities in any region or nationally.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This policy is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This policy:

(1) Does not have an annual effect on the economy of $100 million or more. This policy will affect only visitors at national wildlife refuges. It may result in increased visitation at refuges and provide for minor changes to the methods of public use permitted within the System. Refer to response under Regulatory Flexibility Act.

(2) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(3) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

(1) This policy will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. See response to Regulatory Flexibility Act.

(2) This policy will not produce a Federal mandate of $100 million or greater in any year, i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. See response to Regulatory Flexibility Act.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this policy does not have significant takings implications. A takings implication assessment is not required. This policy may result in increased visitation at refuges and provide for minor changes to the methods of public use permitted within the System. Refer to response under Regulatory Flexibility Act.

Federalism Assessment (E.O. 13132)

In accordance with Executive Order 13132, this policy does not have significant federalism effects. This policy will not have substantial direct effects on the States, in their relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, we have determined that this policy does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Civil Justice Reform (E. O. 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this policy does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. This policy will expand upon established policies, and result in better understanding of the policies by refuge visitors.

Paperwork Reduction Act

This policy does not require an information collection from 10 or more parties and a submission under the Paperwork Reduction Act of 1995 is not required.

Section 7 Consultation

We are in the process of reviewing the potential of this policy to affect species subject to the Endangered Species Act of 1973 (16 U.S.C. 1531–1543). The findings of that consultation will be available as part of the administrative record for the final policy.

National Environmental Policy Act

We ensure compliance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)) when developing national wildlife refuge Comprehensive Conservation Plans and public use management plans, and we make determinations required by NEPA before the addition of national wildlife refuges to the lists of areas open to public uses. In accordance with 516 DM 2, Appendix 1.10, we have determined that this policy is categorically excluded from the NEPA process because it is limited to policies, directives, regulations and guidelines of an administrative, financial, legal, technical, or procedural nature; or the environmental effects of which are too broad, speculative, or conjectural to lend themselves to meaningful analysis. Site-specific proposals, as indicated above, will be subject to the NEPA process.

Available Information for Specific National Wildlife Refuges

Individual national wildlife refuge headquarters retain information regarding public use programs and the conditions that apply to their specific programs, and maps of their respective areas.

You may also obtain information from the Regional Offices at the addresses listed below:

- Region 1—California, Hawaii, Idaho, Nevada, Oregon, and Washington. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Eastside Federal Complex, Suite 1692, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181; Telephone (503) 231–6214; http://pacific.fws.gov.
- Region 2—Arizona, New Mexico, Oklahoma and Texas. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Box 1306, Albuquerque, New Mexico 87103; Telephone (505) 248–7419; http://southwest.fws.gov.
- Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio and Wisconsin. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111; Telephone (612) 713–5300; http://midwest.fws.gov.
- Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico and the Virgin Islands. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Room 324, Atlanta, Georgia 30345; Telephone (404) 679–7166; http://southeast.fws.gov.
- Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and West Virginia. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035–9589; Telephone (413) 253–8306; http://northeast.fws.gov.
- Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 134 Union Blvd., Lakewood, Colorado 80228; Telephone (303) 236–8145; http://www.r6.fws.gov.
- Region 7—Alaska. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, Alaska 99503; Telephone (907) 786–3545; http://alaska.fws.gov.

Primary Author

Tom C. Worthington, Refuge Program Specialist, Region 3, National Wildlife Refuge System, U.S. Fish and Wildlife Service, is the primary author of this notice.

Draft Appropriate Refuge Uses Policy

Fish and Wildlife Service

National Wildlife Refuge System Uses

Refuge Management—Part 603 National Wildlife Refuge System Uses

Chapter 1 Appropriate Refuge Uses—603 FW 1

1.1 What is the purpose of this chapter? This chapter establishes policy that refuge managers will apply when determining the appropriateness of proposed and existing uses of national wildlife refuges before they undertake assessing compatibility in accordance with 603 FW 2. Through this policy, we establish a procedure for determining when uses other than the six wildlife-dependent recreational uses are appropriate or not appropriate on a refuge. This policy clarifies and expands upon 603 FW 2.10(D), which describes when refuge managers should deny a proposed use without determining compatibility. This policy also underscores that the fundamental mission of the National Wildlife Refuge System (System) is wildlife conservation: "Wildlife First."

A. National wildlife refuges are first and foremost national treasures for wildlife. Through careful planning, System-wide application of regulations and policies, diligent monitoring of the impacts of uses on wildlife resources, and by preventing or eliminating uses not appropriate to the System, we can achieve our wildlife conservation mission while also providing the public with lasting opportunities to enjoy the highest quality wildlife-dependent recreation.

B. Through consistent application of this policy, we will establish an administrative record and build public understanding and consensus regarding the types of public uses that are legitimate and appropriate within the System.

1.2 What is the scope of this policy? This policy applies to all proposed and existing uses of national wildlife refuges when we have jurisdiction over these uses. In situations where reserved rights or legal mandates provide that we must allow certain uses, the requirements of this policy will not apply. For example, we will not apply this policy to proposed public uses of wetland or grassland easement areas of the System because the rights we have acquired on these areas generally do not extend to control over public uses.

1.3 What is the policy regarding the appropriateness of uses on a national wildlife refuge? At the initial stage of considering a use, Refuge Managers will not further consider allowing a new use on a national wildlife refuge, nor renewing, extending, or expanding an existing use on a national wildlife refuge, unless the Refuge Manager has determined the use to be an appropriate use. We will halt, as expeditiously as practicable, existing uses determined to be not appropriate.

1.4 What is our statutory authority for this policy? A. The National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, 16 U.S.C. 668dd–668ee (Refuge Administration Act). This law provides authority for establishing policies and regulations governing national wildlife refuge uses, including the authority to prohibit certain harmful activities. The Refuge Administration Act does not authorize any particular use but rather authorizes the Secretary to permit uses only when compatible and "under said regulations as he may prescribe." This law specifically identifies certain public uses that when compatible, are legitimate and appropriate uses within the System. The law states "* * * it is the policy of the United States that * * * compatible wildlife-dependent recreation is a legitimate and appropriate general public use of the [National Wildlife Refuge] System * * *; * * * compatible wildlife-dependent recreational uses are the priority general public uses of the [National Wildlife Refuge] System and shall receive priority consideration in national wildlife refuge planning and management; and * * * when the Secretary determines that a proposed wildlife-dependent recreational use is a compatible use within a national wildlife refuge, that activity should be facilitated * * * the Secretary shall

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* * * ensure that priority general public uses of the [National Wildlife Refuge] System receive enhanced consideration over other general public uses in planning and management within the [National Wildlife Refuge] System * * *" The law also states "In administering the [National Wildlife Refuge] System, the Secretary is authorized to take the following actions: * * * Issue regulations to carry out this Act." This policy fortifies the standards set in the Refuge Administration Act, by showing how we will assure that the priority public uses are provided enhanced consideration over other public uses.

B. The Refuge Recreation Act of 1962, 16 U.S.C. 460k (Refuge Recreation Act). This law authorizes the Secretary of the Interior to "* * *administer such areas [of the National Wildlife Refuge System] or parts thereof for public recreation when in his judgment public recreation can be an appropriate incidental or secondary use."

C. Activities on lands conveyed from the System pursuant to Section 22(g) of the Alaska Native Claims Settlement Act are not subject to this policy, but are subject to compatibility (see 603 FW 2).

D. When allowing off-road vehicle use on refuges we comply with Executive Order 11644 which requires that we: designate areas as open or closed to off-road vehicles in order to protect refuge resources, promote safety, and minimize conflict among the various refuge users; monitor the effects of these uses, once they are allowed; and amend or rescind any area designation on the basis of the information gathered. Furthermore, Executive Order 11989 requires that we close areas to these types of uses when we determine that the use causes or will cause considerable adverse effects on the soil, vegetation, wildlife, habitat, or cultural or historic resources.

1.5 What do these terms mean? A. *Appropriate use.* A proposed or existing use on a refuge that meets at least one of the following three conditions.

(1) The use is a priority public use or is necessary for the safe, practical, and effective conduct of a priority public use on the refuge.

(2) The use contributes to fulfilling the System mission, or the refuge purposes, goals, or objectives as described in a refuge management plan approved after October 9, 1997, the date the National Wildlife Refuge System Improvement Act of 1997 was passed.

(3) The use has been determined to be appropriate as specified in section 1.10 of this chapter.

B. *Native American.* American Indians in the conterminous United States, and Alaska Natives (including Aleuts, Eskimos, and Indians) who are members of federally recognized tribes.

C. *Priority public use.* A wildlife-dependent recreational use involving hunting, fishing, wildlife observation and photography, or environmental education and interpretation.

1.6 What are our responsibilities? A. *Director.* Provides national policy for determining the appropriateness of uses within the System to ensure that such determinations comply with all applicable authorities.

B. *Regional Director.* (1) Ensures that refuge managers follow laws, regulations, and policies when determining appropriateness.

(2) Notifies the Director regarding controversial or complex appropriateness determinations.

C. *Regional Chief.* (1) Makes the final decision on appropriateness determinations when the Refuge Supervisor does not concur with the Refuge Manager.

(2) Notifies the Regional Director regarding controversial or complex appropriateness determinations.

D. *Refuge Supervisor.* (1) Reviews the Refuge Manager's determination that an existing or proposed use is appropriate when that use is not a priority public use, or does not support a priority public use, or is not already described in a refuge management plan approved after October 9, 1997.

(2) Refers an appropriateness determination to the Regional Chief if the Refuge Supervisor does not concur with the Refuge Manager. Discusses non-concurrence with the Refuge Manager for possible resolution before referring to the Regional Chief.

(3) Notifies the Regional Chief regarding controversial or complex appropriateness determinations.

E. *Refuge Manager.* (1) Determines if a proposed or existing use is subject to this policy.

(2) Determines whether a use is appropriate or not appropriate.

(3) Documents all determinations under this policy as described in section 1.10 of this chapter in writing.

(4) Refers all findings of appropriateness for any proposed use which is not a priority public use, or which does not directly support a priority public use, or which is not already described in a refuge management plan approved after October 9, 1997 to the Refuge Supervisor for concurrence.

1.7 What is the relationship between appropriateness and compatibility? This policy describes the initial decision process the Refuge Manager follows when first considering whether to allow or not allow a proposed use on a refuge. This appropriateness decision occurs before the Refuge Manager undertakes a compatibility review of the use. This policy clarifies and expands upon 603 FW 2.10(D), which describes when refuge managers should deny a proposed use without determining compatibility. If we find a proposed use to be not appropriate, we will not allow the use, and there is no need to prepare a compatibility determination. By screening out proposed uses which are not appropriate to the System, the Refuge Manager avoids an unnecessary compatibility review. By following the process for determining the appropriateness of a use, we strengthen the System and help fulfill our wildlife conservation mission. We describe this appropriateness determination process in section 1.10 of this chapter. It is important to remember that although a refuge use may be determined to be both appropriate and compatible, the Refuge Manager retains the authority not to allow the use. For example, there may be occasions when two appropriate and compatible uses are in conflict with each other. In these situations, even though both uses are appropriate and compatible, the Refuge Manager may need to limit or entirely curtail one of the uses in order to optimize the greatest benefit to the public and to refuge resources. See 603 FW 2 for detailed policy on compatibility.

1.8 How are uses considered in the comprehensive conservation planning process? A. We will manage all refuges in accordance with an approved Comprehensive Conservation Plan (CCP). The CCP describes the desired future conditions of the refuge or refuge planning unit and provides long-range guidance and management direction to accomplish the purposes of the refuge and the System mission. The CCP is prepared with public involvement, and will include a review of the appropriateness and the compatibility of existing refuge uses and of any planned future uses. If during the CCP preparation we identify prior approved uses which we can no longer consider appropriate on the refuge, we will clearly explain to the public our reasons and describe how we will eliminate the use.

B. We prepare CCPs with full public involvement, and provide the public an opportunity to review and comment on our decisions about which uses we will allow. For proposed new uses which we did not consider during the CCP preparation process, we will apply the guidelines contained in this policy and make an appropriateness determination without additional public review and comment. However, if we determine that a proposed use is appropriate, the use must still pass the compatibility standard, which includes an opportunity for public review and comment. See 602 FW 1–4 for detailed policy on refuge planning.

1.9 What are the different types of refuge uses? For the purposes of this policy, there are five types of uses.

A. *Priority public uses.* These are uses involving hunting, fishing, wildlife observation and photography, and environmental education and interpretation. They are legitimate, appropriate, and are the first priority uses of the System. See 605 FW 1–7 for detailed policy on the priority public uses.

B. *Public uses that directly support a priority public use.* These are uses necessary for the safe, practical, and effective conduct of priority public uses. When determined to be compatible, these are the second priority uses of the System. Uses that directly relate to and facilitate one of the six priority public uses are generally appropriate. Typically, these activities occur at the same time and place as the priority public use and are used either as a practical mode of access, or as an effective way to support a priority public use. In these cases, the primary reason for this use is to enable a person to enjoy one of the priority public uses. For example, boating on a refuge lake may be necessary to enjoy fishing or birdwatching; in this case the boating is an appropriate support activity. Conversely, speed boating for the pleasure of traveling on the open water is not an activity that supports one of the priority public uses. As another example, horseback riding and camping on the Charles M. Russell National Wildlife Refuge in Montana may be appropriate in support of big game hunting. In this case, horseback riding is a practical mode of access to remote, roadless areas, and camping is a necessary part of hunting in the remote parts of this vast refuge. On this refuge, or on other large or remote refuges, both horseback riding and camping may directly and appropriately support other priority public uses. As a contrasting example, camping on Necedah National Wildlife Refuge in Wisconsin, even if part of a hunting program, is not appropriate because the size of the refuge is such that camping is not necessary for reasonable access to its hunt areas, and there are camping and lodging accommodations nearby off the refuge. In order to ensure accessibility to refuge programs and activities for people with disabilities, we may authorize specialized means of access that are not normally allowed. We will provide these accommodations on a case-by-case basis, depending on the nature of the individual's disability, and our needs to protect refuge resources. See 605 FW 1–7 for detailed policy on the priority public uses.

C. *Public uses not related to a priority public use.* These public uses are not necessary to support a priority public use. Public uses not directly related to the priority public uses or that do not contribute to the fulfillment of refuge purposes, goals or objectives as described in current refuge management plans are the lowest priority for refuge managers to consider. Because these uses are likely to divert refuge management resources from higher priority public uses, or away from our wildlife conservation activities, there is general presumption, in both law and policy, against allowing such uses within the System. Before we will allow these uses, regardless of their frequency or duration, we must first determine that these public uses are appropriate as defined in section 1.10 of this chapter.

D. *Specialized uses.* These are uses not usually allowed that require specific authorization from the Service, often in the form of a special use permit, letter of authorization, or other permit document. These uses do not include uses already granted by a prior existing right. We determine the appropriateness of specialized uses on a case-by-case basis. Before we will allow a specialized use, we must determine it to be appropriate as defined in section 1.10 of this chapter. Any person denied a request for a specialized use, or adversely affected by the Refuge Manager's decision relating to a person's permit, may appeal the decision by following the procedures outlined in 50 CFR 25.45, and in 50 CFR 36.41(i). The appeals process for the denial of a right-of-way application is found in 50 CFR 29.22. The appeals process for persons who believe they have been improperly denied rights with respect to providing visitor services on Alaska refuges is found in 50 CFR 36.37(g). Some common examples of specialized uses include the following.

(1) *Right-of-ways.* See 340 FW 3 and 603 FW 2 for detailed policy on right-of-ways.

(2) *Telecommunications facilities.* We process a request to construct a telecommunication facility on a refuge the same way as any other right-of-way request. The Telecommunications Act of 1996 does not supersede any existing laws, regulations, or policy relating to right-of-ways on refuges. The Refuge Manager should continue to follow the procedures found in 340 FW 3.

(3) *Military, NASA, border security, and other national defense uses.* The following guidelines apply to refuge lands owned in fee title by the Service or lands to which the Service has management rights that provide for the control of such uses.

(a) We will continue to honor existing, long-term written agreements such as Memorandum of Understanding (MOU) between the Service, the military, NASA, and other Federal agencies with national defense missions. Only the Director may approve any modification to existing agreements. We do not anticipate entering into any new agreements permitting military preparedness activities on national wildlife refuges. Where joint military/NASA—Service jurisdiction occurs by law, an MOU negotiated by the principal parties, and subject to the approval of the Director, will specify the roles and responsibilities, terms, and stipulations of the refuge uses. Wherever possible, we will work to find practical alternatives to the use of refuge lands, and to minimize the impacts to wildlife resources.

(b) For routine or continuous law enforcement and border security activities, an MOU between the Service and the specific enforcement agency will clearly define roles and responsibilities of the enforcing agency and will specify steps they must take to minimize impacts to refuge resources. For emergency or undercover operations, reasonable notification must be given to and approval must be received from the Refuge Manager.

(c) We consider military activities on refuge lands that directly benefit refuge purposes to be refuge management activities, and they are not subject to this policy. For example, in a case where a national guard unit is assisting the refuge with the construction of a water control structure, or helping to repair a refuge bridge, we consider these uses to be refuge management activities and do not consider them to be specialized uses.

(4) *Research.* As a leader in wildlife management, we actively encourage cooperative wildlife resource-related research activities that address our management needs. We also encourage research related to the management of priority public uses. Wildlife resource-related research activities are generally appropriate. Research that directly benefits refuge management has priority over other research. These uses must be determined to be appropriate as defined in section 1.10 of this chapter.

(5) *Public safety training.* We may assist local government agencies with

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health, safety, and rescue training operations on the refuge if we determine the use to be appropriate. Examples include fire safety training, search and rescue training, and boat operations safety training. General law enforcement training exercises usually are not appropriate. We will evaluate these requests on a case-by-case basis, considering the availability of other local sites and the nature of other local resources. To the extent practicable, we will develop written agreements with the requesting agencies. These uses must be determined to be appropriate as defined in section 1.10 of this chapter, although it is unlikely that this type of use will pass the 10 criteria listed there.

(6) *Native American ceremonial, religious, and traditional gathering of plants.* We will review specific requests and provide reasonable access to Native Americans to refuge lands and waters for gathering plants for ceremonial, religious, medicinal, and traditional purposes. We may issue use permits if the use is consistent with treaties, judicial mandates, or Federal and Tribal law. These uses must be determined to be appropriate as defined in section 1.10 of this chapter.

(7) *Natural resource extractions.* Although most refuges are withdrawn from the mining and mineral leasing laws (i.e., closed to mining activities), several are at least partially open. It is incumbent upon refuge managers to know if these laws affect their particular refuge. Where a refuge is closed, we will prohibit prospecting, exploration, development, extraction, or removal of leaseable (*e.g.*, oil, gas, coal) and locatable (hardrock) minerals (see 50 CFR 27.61 and .64). We only allow the extraction of certain mineral resources (such as gravel) that supports a refuge management activity when there is no practical alternative. We will not justify such activity by citing budgetary constraints, rather we will seek appropriate funding through our normal budgetary process for projects that require gravel or other such resources found on the refuge. In some instances, individual refuges may be subject to valid existing mineral rights reserved during the acquisition process or rights vested prior to our acquisition of the lands. The owners of valid mining rights have the right to extract the minerals, even if they do not own the surface, and we may not unduly interfere with this right. Activities or uses relative to prior existing rights are generally outside the scope of this chapter. In the case of reserved rights, the Refuge Manager should work with the owner of the property interest to develop stipulations in a special use permit or other access agreement to alleviate or minimize adverse impacts to the refuge (see 50 CFR 29.32). ANILCA provides specific guidance for oil and gas leasing on Alaska refuges.

(8) *Commercial uses.* Commercial uses on a refuge may be appropriate if they directly support a priority public use or are a refuge management economic activity. See 50 CFR 29.1 for additional information on economic uses of refuges. An example of an appropriate commercial use would be a concession-operated boat tour that facilitates wildlife observation and interpretation. All commercial uses are subject to appropriateness determinations. These uses must be determined to be appropriate as defined in section 1.10 of this chapter. The following is a list of references for more detailed policy on commercial uses.

(a) Administration of commercial and economic uses 604 FW 2.

(b) Administration of commercial guiding of wildlife observation, hunting and fishing 604 FW 2.

(c) Concession management 604 FW 2.

(d) Commercial audio-visual management 604 FW 7, and 43 CFR 5.

(e) Commercial visitor services on Alaska Refuges 43 CFR 36.37.

E. *Prohibited uses.* Regulations prohibiting certain activities on national wildlife refuges are listed in 50 CFR part 27.

1.10 *How do we determine the appropriateness of a use on a national wildlife refuge?* A. A refuge use is appropriate if the use meets at least one of the following three conditions.

(1) A use is appropriate if it is a priority public use or is necessary for the safe, practical, and effective conduct of a priority public use on the refuge. This finding does not require Refuge Supervisor concurrence.

(2) A use is appropriate if it contributes to fulfilling the System mission, or the refuge purposes, goals, or objectives as described in a refuge management plan approved after October 9, 1997, the date the National Wildlife Refuge System Improvement Act of 1997 was passed. This finding does not require Refuge Supervisor concurrence.

(3) A use is appropriate if the Refuge Manager documents in writing reasons why the use should be considered appropriate and obtains concurrence from the Refuge Supervisor (see Exhibit 1). The Refuge Manager will base this finding of appropriateness in consideration of the following 11 factors. If the answer is "no" to any of the following questions, we will generally not permit the use. If the answers are consistently "yes" to these questions, and if there are compelling reasons why the Refuge Manager believes the use is appropriate for the refuge, the Refuge Manager then prepares a written justification (Exhibit 1), and obtains the Refuge Supervisor's written concurrence before proceeding with preparation of a compatibility determination. Concurrence from the Refuge Supervisor will promote System consistency and will help us avoid establishing precedents that may be difficult to overcome in the future. Furthermore, refuge supervisors will usually consult with their Regional Chief as these decisions are made. This section specifically clarifies and expands upon 603 FW 2.10(D) Denying a proposed use without determining compatibility.

(a) Does the use comply with applicable laws and regulations? The proposed use must be consistent with all applicable laws and regulations (e.g., Wilderness Act, Endangered Species Act, Marine Mammal Protection Act, 50 CFR part 27). Uses that are prohibited by law are immediately rejected.

(b) Is the use consistent with applicable Executive Orders and Department and Service policies? If the proposed use conflicts with an applicable executive order, or Department or Service Policy then the use should be rejected.

(c) Is the use consistent with refuge goals and objectives in an approved refuge management plan? Refuge goals and objectives are documented in approved refuge management plans (e.g., Comprehensive Conservation Plans, comprehensive management plans, master plans, step-down management plans). If the proposed use, either directly or in combination with other uses or activities, conflicts with a refuge goal, objective or management strategy, the use should not be considered further. If a plan which addresses this use has not been developed or yet approved, refer to 1.10.A(1)(g) of this chapter.

(d) Has an earlier documented analysis not denied the use? If we have already considered the proposed use in a refuge planning process and rejected it as not appropriate, then the use should not be considered further. If circumstances have changed significantly, then we may consider the use further. If we did not raise the proposed use as an issue during a refuge planning process, we may further consider the use.

(e) Is the use consistent with public safety? If the proposed use creates an unreasonable level of risk to visitors or refuge staff, or if the use requires refuge staff to take unusual safety precautions to assure the safety of the public or other refuge staff, then the use should be rejected.

(f) Is the use manageable within available budget and staff? Priority public uses take precedence over other public uses. If a proposed use diverts management efforts or resources away from the proper and reasonable management of a priority use, or from a refuge management activity, the proposed use should be rejected.

(g) Is the use consistent with other resource or management objectives? If the Refuge Manager cannot articulate why a proposed use would be consistent with a stated wildlife conservation or other resource or public use management objective of the refuge, then the use should be rejected.

(h) Will the use be easy to control in the future? If the use would lead to recurring requests for the same or similar activities that will be difficult to control in the future, then the request should be rejected. If we can manage the use so that impacts to wildlife resources are minimal or inconsequential, or if we can establish clearly defined limits, then we may further consider the use.

(i) Is the refuge the only place this activity can reasonably occur? If there are other nearby public or private lands that can reasonably accommodate the use, then the use should be rejected. If the proposed use involves or commemorates a culturally or historically significant event or activity that has direct connection to the refuge, then we may further consider the use.

(j) Does the use contribute to the public's understanding and appreciation of the refuge's wildlife or cultural resources, or is the use beneficial to the refuge's wildlife or cultural resources? We generally will not allow other uses that are not beneficial to or which do not lead to greater public understanding or appreciation of the refuge's cultural or wildlife resources.

(k) Can the use be accommodated without impairing existing wildlife-dependent recreational uses or reducing the potential to provide quality wildlife-dependent recreation into the future?

B. If the Refuge Manager finds that a proposed use is not appropriate, the finding must be documented for the refuge files (Exhibit 1). This finding does not require Refuge Supervisor concurrence.

C. Following the issuance of this policy, refuge managers must review all existing uses for appropriateness within 1 year. If the Refuge Manager finds that an existing use is not appropriate, the use must be modified so it is appropriate, or it must be terminated or phased out as expeditiously as practicable. This finding must be documented for the refuge files (Exhibit 1). A finding of "not appropriate" does not require Refuge Supervisor concurrence. However, the decision to modify or terminate a use may be subject to the National Environmental Policy Act (NEPA). Refuge managers should consult with their Regional NEPA Coordinator to see if this decision would be subject to NEPA.

D. The System Headquarters will maintain a database of refuge uses. This database will include a refuge-by-refuge listing of all uses that have been approved and not approved by refuge managers. With this information, refuge managers will know when proposed uses have already been approved or denied at any other unit of the System. This information will help strengthen the System by reinforcing consistency and integrity in the way we consider refuge uses.

Determination of Appropriateness of a Proposed Refuge Use

Refuge Name: _____

Proposed Use: _____

This form is not required for priority public uses, uses that support a priority public use, or uses already described in a current CCP.

	Yes	No
The proposed refuge use:		
Does the use comply with applicable laws and regulations?		
Is the use consistent with applicable Executive Orders and Department and Service policies?		
Is the use consistent with refuge goals and objectives in an approved refuge management plan?		
Has an earlier documented analysis not denied the use?		
Is the use consistent with public safety?		
Is the use manageable within available budget and staff?		
Is the use consistent with other resource or management objectives?		
Will this use be easy to control in the future?		
Is the refuge the only place this activity can reasonably occur?		
Does the use contribute to the public's understanding and appreciation of the refuge's wildlife or cultural resources, or is the use beneficial to the refuge's wildlife or cultural resources?		
Can the use be accommodated without impairing existing wildlife-dependent recreational uses or reducing the potential to provide quality wildlife-dependent recreation into the future?		

If the answer to any of these questions is no, the proposed use is probably not appropriate and we should generally not consider it further. However, if there are compelling reasons why the Refuge Manager believes the use should be considered, the Refuge Manager must justify the use in writing on an attached sheet, and obtain the Refuge Supervisor's concurrence.

Based on an overall assessment of these factors, my summary conclusion is that the proposed use is:

Not Appropriate _____

Appropriate _____

Refuge Supervisor: _____

Date: _____

If determined to be Not Appropriate, the Refuge Supervisor does not need to sign concurrence:

If determined to be Appropriate, the Refuge Supervisor must sign concurrence:

Refuge Supervisor: _____

Date: _____

Compatibility determination is required before the use may be allowed.

Dated: December 18, 2000.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 01–19 Filed 1–12–01; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service 1018–AG20

[1018–AG20]

Draft Wildlife-Dependent Recreational Uses Policy Pursuant to the National Wildlife Refuge System Improvement Act of 1997

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We propose to adopt a policy that will explain how we will provide

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visitors with high quality hunting, fishing, wildlife observation and photography, and environmental education and interpretation opportunities on units of the National Wildlife Refuge System (System). The National Wildlife Refuge System Improvement Act of 1997 (NWRSIA–1997), that amends the National Wildlife Refuge System Administration Act of 1966 (NWRSAA–1966), defines and establishes that wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) are the priority general public uses of the System and, if found compatible, will receive enhanced and priority consideration in refuge planning and management over other general public uses. This draft policy describes how we will provide priority to these uses. We propose to incorporate this policy as Part 605 Chapters 1–7 of the Fish and Wildlife Service Manual.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: You may submit comments on this draft wildlife-dependent recreational uses policy by mail, fax or e:mail: by mail to Douglas Staller, Acting Chief, Division of Visitor Services and Communications, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; by fax to (703) 358–2248; or by e:mail to Wildlife__Dependent__Recreational__Uses__Policy__Comments@fws.gov.

FOR FURTHER INFORMATION CONTACT: Douglas Staller, Acting Chief, Division of Visitor Services and Communications, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Telephone (703) 358–1744.

SUPPLEMENTARY INFORMATION: The NWRSIA–1997 amends and builds upon the NWRSAA–1966 providing an "Organic Act" for the System. The NWRSIA–1997 clearly establishes that wildlife conservation is the singular System mission, provides guidance to the Secretary of the Interior (Secretary) for management of the System, provides a mechanism for refuge planning, and gives refuge managers uniform direction and procedures for making decisions regarding wildlife conservation and uses of the System.

The NWRSIA–1997 identifies six wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) as the priority general public uses of the System. The NWRSIA–1997 also provides a set of affirmative stewardship responsibilities regarding our administration of the System. These stewardship responsibilities direct us to ensure that these six wildlife-dependent recreational uses are provided enhanced consideration and priority over other general public uses.

The Refuge Recreation Act of 1962 (RRA–1962) authorizes us to administer the System for public recreation when the use is an "appropriate incidental or secondary use." The RRA–1962 also requires us to regulate or curtail public recreational uses in order to insure accomplishment of our primary conservation objectives.

The six wildlife-dependent recreational uses are the priority public uses of the System have been determined to be appropriate by law and, when compatible, are to be facilitated. This Draft Wildlife-Dependent Recreational Uses Policy, the Draft Appropriate Refuge Uses Policy published concurrently in the notice section of this **Federal Register** and our Final Compatibility Policy and Regulations published in the October 18, 2000 **Federal Register** are key tools refuge managers use together to fortify our commitment to provide enhanced opportunities for the public to enjoy wildlife-dependent recreation while at the same time ensuring that no refuge uses compromise the System's wildlife conservation mission and the individual refuge purpose(s). Through careful planning, consistent System-wide application of regulations and policies, diligent monitoring of the impacts of uses on natural resources, and by preventing or eliminating uses not appropriate to the System, we can achieve our wildlife conservation mission and individual refuge purposes while also providing people with lasting opportunities for the highest quality wildlife-dependent recreation.

Wildlife-Dependent Recreational Uses Policy

To ensure the primacy of the System wildlife conservation mission as well as the individual refuge purpose(s), and to be sure we afford priority to the six wildlife-dependent recreational uses within the System, we are proposing to establish a policy on wildlife-dependent recreational uses. Following is a summary of this policy.

Chapter 1 General Guidance provides Service policies, strategies, and requirements concerning the management of recreation programs within the System. National wildlife refuges are national treasures for wildlife and for people who enjoy the wonders of the outdoors. Wildlife-dependent recreation programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. To assure that the System's fish, wildlife, and plant resources endure, their needs must come first. Thus, we only allow recreational uses on a refuge after we determine that use to be appropriate and compatible. In addition, we manage recreation in accordance with applicable Federal, State, and Tribal laws (see Code of Federal Regulations (CFR), Title 50 subchapter C). We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges. The policy outlined in this chapter applies to all recreational use activities that occur within the System, including wildlife-dependent and other appropriate recreational uses. Our general policy is to provide the American public high-quality opportunities to take part in wildlife-dependent recreation, regardless of age, race, religion, color, sex, national origin, sexual orientation, or physical or mental ability. To accomplish this policy, we ensure consistency and professionalism in planning and implementing recreational use programs and activities on System lands. Wildlife-dependent recreational uses (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) are the priority general public uses of the System and, when determined to be compatible, will receive enhanced and priority consideration in refuge planning and management over all other general public uses.

Chapter 2 Hunting provides Service policy governing the management of recreational hunting within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies hunting as a priority public use of the System. Hunting programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. Hunting is also an integral part of a comprehensive wildlife management program. When determined to be compatible, refuge managers are strongly encouraged to provide to the public high-quality hunting opportunities. We plan hunting programs in consultation and cooperatively with appropriate State and Tribal agencies, and we conduct them, to the extent practicable, in accordance with applicable State and Tribal regulations. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Chapter 3 Fishing provides Service policy governing the management of recreational fishing within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies fishing as a priority public use of the System. Fishing programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. When determined to be compatible, refuge managers are encouraged to provide to the public high-quality fishing opportunities. We plan fishing programs in consultation and cooperatively with the appropriate State and Tribal agencies. We base fishing seasons on refuges on local conditions and biological objectives. These seasons must, where practicable, conform with appropriate Federal, State, and Tribal regulations. The Service's Division of Fish and Wildlife Management Assistance has many field offices with a broad range of expertise that are available to the Refuge Manager when planning and managing fishing programs. We encourage refuge managers to take advantage of this important resource. We also encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Chapter 4 Wildlife Observation provides Service policy governing the management of recreational wildlife observation within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies wildlife observation as a priority public use of the System. Wildlife observation programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. When determined to be compatible, refuge managers are encouraged to provide to the public high quality wildlife observation opportunities. Refuge managers are encouraged to coordinate refuge wildlife observation programs with applicable Federal, State and Tribal programs. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Chapter 5 Wildlife Photography provides Service policy governing the management of recreational wildlife photography within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies wildlife photography as a priority public use of the System. Wildlife photography programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. When determined to be compatible, refuge managers are encouraged to provide to the public high quality wildlife photography opportunities. Refuge managers are encouraged to coordinate wildlife photography programs with applicable State programs. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Chapter 6 Environmental Education provides Service policy governing the management of environmental education within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies environmental education as a priority public use of the System. Environmental education programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. When determined to be compatible, refuge managers are encouraged to provide to the public high quality environmental education opportunities. Refuge managers will work with local schools, citizen groups, and other organizations to provide these programs. We encourage refuge managers to coordinate refuge environmental education programs with applicable local, State and Federal programs. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Chapter 7 Interpretation provides Service policy governing the management of interpretation within the System. The NWRSAA–1966 as amended by the NWRSIA–1997 identifies interpretation as a priority public use of the System. Interpretation programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. When determined to be compatible, refuge managers are encouraged to provide to the public high quality interpretation opportunities. We encourage refuge staff to coordinate refuge interpretive programs and materials with applicable local, State, and Federal programs. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

Fish and Wildlife Service Directives System

Because many of our field stations are in remote areas across the United States, it is important that all employees have available and know the current policy and management directives that affect their daily activities. The Fish and Wildlife Service Directives System, consisting of the Fish and Wildlife Service Manual (Service Manual), Director's Orders, and National Policy Issuances, is the vehicle for issuing the standing and continuing policy and management directives of the Service. New directives are posted on the Internet upon approval, ensuring that all employees have prompt access to the most current guidance.

The Service Manual contains our standing and continuing directives with which our employees comply. We use it to implement our authorities and to "step down" our compliance with statutes, executive orders, and Departmental directives. It establishes the requirements and procedures to assist our employees in carrying out our authorities, responsibilities, and activities.

Director's Orders are limited to temporary policy, procedures, delegations of authority, emergency regulations, special assignments of functions, and initial functional statements on the establishment of new organizational units. All Director's Orders must be converted as soon as practicable to appropriate parts of the Service Manual or removed. Material appropriate for immediate inclusion in the Service Manual generally is not issued as a Director's Order.

National Policy Issuances promulgate the Director's national policies for managing the Service and its programs. These policies are necessarily broad and generally require management discretion or judgment in their implementation. They represent the Director's expectations of how the Service and its employees will act in carrying out their official responsibilities.

The Service Manual, Director's Orders, and National Policy Issuances are available on the Internet at http://www.fws.gov/directives/direct.html. When finalized, we will incorporate this

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wildlife-dependent recreational uses policy into the Service Manual as Part 605 Chapters 1–7.

Comment Solicitation

We seek public comments on this draft wildlife-dependent recreational uses policy and will take into consideration comments and any additional information received during the 60-day comment period. You may submit comments on this draft appropriate refuge uses policy by mail, fax or e:mail: by mail to Douglas Staller, Acting Chief, Division of Visitor Services and Communications, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; by fax to (703)358–2248; or by e:mail to Wildlife__Dependent__Recreational__Uses__Policy__Comments@fws.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include: "Attn: 1018–AG18" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (703)358–1744. Finally, you may hand-deliver comments to the address mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

We published a notice in the **Federal Register** on January 23, 1998 (63 FR 3583) notifying the public that we would be revising the Service Manual, establishing regulations as they relate to the NWRSIA–1997, and offering to send copies of specific draft Service Manual chapters to anyone who would like to receive them. We will mail a copy of these draft Service Manual wildlife-dependent recreational uses chapters to those who requested one. In addition, these draft Service Manual wildlife-dependent recreational uses chapters will be available on the Internet at http://www.fws.gov/directives/library/frindex.html during the 60-day comment period.

Required Determinations

We have analyzed the impacts of this final policy in concert with the draft appropriate refuge uses policy published concurrently in the today's issue of the **Federal Register**. For compliance with applicable laws and executive orders affecting the issuance of polices, see the **SUPPLEMENTARY INFORMATION** section of the draft appropriate refuge uses policy notice.

Available Information for Specific National Wildlife Refuges

Individual national wildlife refuge headquarters retain information regarding public use programs and the conditions that apply to their specific programs, and maps of their respective areas.

You may also obtain information from the Regional Offices at the addresses listed below:

- Region 1—California, Hawaii, Idaho, Nevada, Oregon, and Washington. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Eastside Federal Complex, Suite 1692, 911 N.E. 11th Avenue, Portland, Oregon 97232–4181; Telephone (503) 231–6214; http://pacific.fws.gov.
- Region 2—Arizona, New Mexico, Oklahoma and Texas. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Box 1306, Albuquerque, New Mexico 87103; Telephone (505) 248–7419; http://southwest.fws.gov.
- Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio and Wisconsin. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111; Telephone (612) 713–5300; http://midwest.fws.gov.
- Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico and the Virgin Islands. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Room 324, Atlanta, Georgia 30345; Telephone (404) 679–7166; http://southeast.fws.gov.
- Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and West Virginia. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, Massachusetts 01035–9589; Telephone (413) 253–8306; http://northeast.fws.gov.
- Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 134 Union Blvd., Lakewood, Colorado 80228; Telephone (303) 236–8145; http://www.r6.fws.gov.
- Region 7—Alaska. Regional Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, Alaska 99503; Telephone (907) 786–3545; http://alaska.fws.gov.

Primary Author

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Draft General Guidance Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 1 General Guidance 605 FW 1.1

1.1 *What is the purpose of this chapter?* This chapter provides Fish and Wildlife Service (Service) policies, strategies, and requirements concerning the management of recreation programs within the National Wildlife Refuge System (System).

1.2 *What is the System's general recreation management policy?* National wildlife refuges are national treasures for wildlife and for people who enjoy the wonders of the outdoors. To assure that the System's fish, wildlife, and plant resources endure, their needs must come first. Thus, we only allow recreational uses on a refuge after we determine that use to be appropriate and compatible. In addition, we manage recreation in strict accordance with applicable Federal, State, and Tribal laws [see Code of Federal Regulations (CFR), Title 50 subchapter C]. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges. The policy outlined in this chapter applies to all recreational use activities that occur within the System, including wildlife-dependent and other appropriate recreational uses. Our general policy is to provide the American public high-quality opportunities to take part in wildlife-dependent recreation, regardless of age, race, religion, color, sex, national origin, sexual orientation, physical or mental ability. To accomplish this policy, we ensure consistency and professionalism in planning and implementing recreational use programs and activities on System lands.

1.3 *What authorities allow recreation use to occur on the Refuge System?* The following are laws and executive orders that regulate recreational use on System lands:

A. Laws

(1) Alaska National Interest Lands Conservation Act of 1980 (16 U.S.C. 410 hh-3233 and 43 U.S.C. 1602–1784)
(2) Alaska Native Claims Settlement Act (43 U.S.C. 1601–1624)
(3) Antiquities Act of 1906 (16 U.S.C. 431-433)
(4) Archaeological Resources Protection Act of 1979 (16 U.S.C. 470aa-470mm)
(5) Fish and Wildlife Act of 1956 (16 U.S.C. 742a-742j) as amended.
(6) Fish and Wildlife Conservation Act (16 U.S.C. 2901–2911), as amended
(7) Fish and Wildlife Improvement Act of 1978 (16 U.S.C. 7421)
(8) Land and Water Conservation Fund [16 U.S.C. 460(l-4)-(l-11)],as amended.
(9) National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd-668ee), as amended
(10) Refuge Recreation Act of 1962 (16 U.S.C. 460k-460k-4) as amended
(11) Wild and Scenic Rivers Act (16 U.S.C. 1271–1287), as amended.
(12) Wilderness Act of 1964 (16 U.S.C. 1131–1136)
(13) Endangered Species Act of 1973 (16 U.S.C. 1531–1544)

B. Executive Orders

(1) 11593—Protection and Enhancement of the Cultural Environment
(2) 11644—Use of Off-road Vehicles on the Public Lands
(3) 12996—Management and General Public Use of the National Wildlife Refuge System
(4) 13007—Indian Sacred Sites
(5) 12962—Recreational Fisheries

1.4 *How do we define the following terms?* The following are definitions of terms used throughout this chapter.

A. Priority wildlife-dependent recreational use and priority wildlife-dependent recreation. The National Wildlife Refuge System Administration Act of 1966, as amended, specifies that there are six priority general public uses of the National Wildlife Refuge System. The uses are hunting (605 FW 2), fishing (605 FW 3), wildlife observation (605 FW 4), wildlife photography (605 FW 5), environmental education (605 FW 6) or environmental interpretation (605 FW 7).

B. Other recreational use. A recreational use of the System that is not one of the priority wildlife-dependent uses, but we may allow it if it is appropriate and compatible.

C. Public use. Any use of the System by the public, including, but not limited to, those recreational uses and priority wildlife-dependent uses described above.

1.5 *What tools can we use to help us implement and manage a recreational use program?* Refuge managers have various tools available to them to implement recreational use programs on refuges. These include, but are not limited to: building successful refuge support groups, building successful volunteer programs, implementing a user fee program, conducting meetings, highlighting refuge attributes through exhibits and brochures, hiring staff, training personnel, registering users, and issuing special use permits. We determine overall effectiveness of the programs by evaluating factors such as improved resource protection, the success of refuge support groups, the quality of the visitor's experience, and visitor compliance.

1.6 *How do we promote the mission of the System?* We can promote the mission of the System through special events on both a local and national scale to showcase the System's roles in conservation efforts. These events can enhance public understanding and appreciation for conservation, and encourage broader public enjoyment of natural resources. We encourage Refuge managers to host special events for National Wildlife Refuge Week, International Migratory Bird Day, National Hunting and Fishing Day, Youth Hunting Days, National Fishing Week, and celebrations on refuge anniversaries, where appropriate. We also encourage Refuge managers to look for ways to introduce new sectors of the public to the System during these celebrations. By reaching out to new sectors, we lay the foundation to expand support for the System, understanding of wildlife conservation and management, and participation in wildlife dependent recreation.

1.7 *What management techniques are available to help us administer recreation programs?* We will successfully administer recreational programs through the use of:

A. *Monitoring.* Refuge managers, with help and support from Regional Offices as well as the public, must adequately monitor recreational activities on System lands. Monitoring programs must focus on the impacts of recreational activities on wildlife, habitat, and the quality of experience for the public. By implementing successful monitoring techniques, we can evaluate and adaptively manage to meet established standards and ensure that activities continue to be appropriate and compatible.

B. *Resolving conflicts.* Refuge managers may establish use limits and/or zones for specific activities, disperse or restrict use, or use other means to minimize or eliminate conflict between uses that occur at refuges. We will ensure that non-priority uses, if allowed, do not interfere with or diminish the opportunity for or quality of priority wildlife-dependent recreational uses. Through the use of zones or the establishment of acceptable limits, we can generally provide a balanced recreation program and avoid favoring one priority recreational opportunity over another when both are compatible. We recognize, however that some refuges can support no public use; many refuges only support limited public use; and that not every priority use can be accommodated on every refuge.

C. *Closure of sensitive areas.* Once opened to public use, the Refuge Manager may make a determination to close all or part of a refuge for public health and human safety reasons or to protect fish, wildlife, or plant resources. During non-emergency closure situations, the public will be notified and have the opportunity to participate in the decision-making process. During emergency closures, we will make every effort to keep the public informed of management decisions and, where possible, the basis for the closure.

1.8 *How do we address special requests and temporary situations?* The System's recreational use policy must be flexible enough to address special requests or temporary situations. We accommodate these requests only if they are appropriate, compatible, and there are clear benefits to the Service for allowing the use. Provided the use is determined to be both appropriate (reference Appropriate Uses Chapter, 603 FW 1) and compatible, the Refuge Manager, with guidance from the Regional Office, may issue a one-time or short-term permit for recreational activities not generally allowed (*e.g.*, an overnight activity or use of an historic structure). We must keep written justification documenting the analysis on file for an adequate period of time.

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1.9 *What are the general recreation guidelines for the System?* Hunting, fishing, wildlife observation, wildlife photography, environmental education, and interpretation are priority wildlife-dependent recreational uses of the System. Refuge managers must facilitate wildlife/outdoor experiences that provide visitors with high quality experiences and help them understand and appreciate the value of the individual refuge and its role in the System. Refuge managers must analyze the effects of the priority wildlife-dependent recreational uses and must, unless there is a valid reason not to, provide for those priority uses determined to be compatible. Not all refuges will be able to support each, or even any, of the six priority wildlife-dependent recreational uses. If it is determined that a refuge can support one or more of these uses, the priority wildlife-dependent recreational use must receive preferential consideration in refuge planning and management before the Refuge Manager analyzes other appropriate recreational opportunities. These uses provide opportunities for visitors to become interested in and enjoy quality wildlife/outdoor experiences and learn about, understand, and support resource management programs. Refuge managers should produce programs that not only inform visitors about the System but emphasize the specific role of the individual refuge. Refuge managers should explore partnerships with Federal, State, Tribal, and local agencies to enhance wildlife-dependent recreation programs. Refuge managers should look for ways to encourage priority wildlife-dependent recreation uses, however, if little or no demand exists for a priority use, we do not require Refuge managers to provide that use. The following general guidelines apply to recreation management throughout the System:

A. *Recreational uses that enable priority wildlife-dependent recreational uses.* Refuge managers may allow (with written justification) other compatible recreational uses that are necessary to facilitate the priority wildlife-dependent recreational uses. We can allow non-wildlife-dependent activities when needed to provide access to, help implement, or sustain a priority use when no other way is practicable. Refuge managers must determine the appropriateness as well as compatibility of such uses before allowing them to occur on System lands. For example, camping may be necessary to facilitate hunting on large remote refuges but may not be necessary to facilitate hunting on refuges near developed areas where camping or other lodging is available.

B. After hours recreational use. We may, on occasion, allow activities to occur on a refuge at night if it is appropriate and compatible with the purpose(s) of the refuge and the System mission. An example might be night fishing. Allowing night activities on the refuge often requires increased management and law enforcement capability, and the manager must consider these factors in assessing the effect of the action on wildlife goals and objectives. A use should not be allowed simply because it is a historical use.

C. Non-priority recreational uses. When considering non-priority public uses, Refuge managers must refer to the Appropriate Uses Chapter (603 FW 1).

D. Access to sacred sites. Refuge managers will accommodate access to and ceremonial use of sacred sites by religious practitioners of recognized Native American Tribes and Native Hawaiians in accordance to Executive Order 13007 or 614 FW 1–5. Refuge managers, with help from their regional cultural resource staff, must familiarize themselves with Executive Order 13007, which clarifies and highlights procedures to execute this policy. Refuge managers should understand that these sites are sensitive, and allowing uncontrolled access by the general public to them is unacceptable. Refuge managers must ensure the physical integrity of the sites, including maintaining appropriate location confidentiality. Refuge managers will utilize formal agreements to outline the responsibilities of all parties involved in implementing the Executive Order.

1.10 *Are there general criteria that we can use to decide which recreational activities to allow?* The following general criteria will help Refuge managers decide what recreational activities to allow, encourage, or develop, and at what level. Refuge managers must eliminate, with adequate consultation, documentation and cooperation with affected Federal, State, Tribal, local authorities, and groups, programs that do not meet these criteria.

A. Ensure appropriateness. Refuge managers, in consultation with Regional Offices when deemed necessary, must first consider if a use is appropriate on System lands. Refuge managers must be able to show why the requested use supports the System mission and the purpose of the refuge before investing additional resources for a compatibility determination.

B. Ensure compatibility. Refuge managers must:

(1) Exercise sound professional judgment. Compatibility determinations are inherently complex and require the Refuge Manager to consider their field experiences and knowledge of a refuge's resources, particularly its biological resources, and make conclusions that are consistent with principles of sound fish and wildlife management and administration, available scientific information, and applicable laws.

(2) Consider the extent to which available resources (funding, personnel, and facilities) are adequate to develop, manage, and maintain the proposed use so as to ensure compatibility. The Refuge Manager must make reasonable efforts to ensure that the lack of resources is not an obstacle to permitting otherwise compatible wildlife-dependent recreational uses (hunting, fishing, wildlife observation, wildlife photography, environmental education, and interpretation).

(3) Under no circumstances (except emergency provisions necessary to protect the health and safety of the public or any fish or wildlife population) authorize any use not determined to be compatible.

C. Focus on wildlife. Wildlife conservation is the first priority of the System, and new and ongoing recreational use programs should help visitors focus on wildlife and other natural resources. Activities should make visitors aware of the most important resource issues at the refuge, be supportive of management plans that address those issues, and show how the refuge contributes to the mission of the System.

D. Tailor programs to refuge needs and ability to administer the program. Refuge Managers will determine and document:

(1) The design and scope of a refuge recreational use program after evaluating the wildlife-dependent uses that are appropriate, compatible, and practical at that refuge; the amount and type of visitation; constraints of the location; traditions/viewpoints of the local populace; legal commitments; other opportunities in the area; public interest; resource management concerns; and other criteria.

(2) A realistic demand for the activity. This is important because activities generally are harder to curtail or stop than to begin. Refuge Managers must have an eye to the future and be ready for possible changes in staffing, funding, or other program elements that may occur.

E. Follow an approved plan. Before administering priority uses or identifying and allowing mandated or non-priority uses at a refuge, the Refuge Manager should consult the refuge's CCP, visitor service management plan, and other applicable step-down plans. The documents will outline program objectives and other specific information that will provide the guidance needed to manage these activities.

F. Ensure adequate resources. Refuge managers will:

(1) Offer wildlife-dependent recreational use programs only to the extent that staff and funds are sufficient to develop, operate, and maintain the program to safe, high quality standards. Refuge managers should remember that, in general, the greater the scope and complexity of a program, the greater the need for staff and money. Where wildlife-dependent recreational uses cannot occur at a refuge due to insufficient resources, Refuge managers will try to facilitate these programs through user fee programs and cooperative efforts, including memorandums of understanding, cost share agreements, sharing personnel with nearby refuges, and others. Conservation partnerships or other groups can help Refuge managers more effectively finance and administer recreational use programs on refuges by providing labor, funds, or other types of support. Where available and appropriate, Refuge managers should work with cooperating associations, volunteers, contractors, businesses, local communities, educational institutions, State and Tribal governments, other Federal agencies, conservation groups, other organizations, and the public, to minimize or reduce the costs of conducting recreational use programs. The community relations benefits of such an approach are effective and far-reaching.

(2) Seek opportunities to develop formal agreements, contracts, cooperative ventures, and community sponsorships to fund equipment and supplies, maintain facilities, conduct training, provide technical assistance, and help with other aspects of a quality recreational use program. Refuge managers should not enter into agreements that unnecessarily encumber lands and facilities or hinder meeting resource management objectives at the refuge.

1.11 Have we identified visitor service requirements on refuges? Yes. Service employees, volunteers, concessionaires, and other cooperators should conform to the following standards in planning, conducting, and evaluating all visitor services activities and facilities at refuges. These standards replace those outlined in the *Public Use Minimum Requirements Handbook* adopted by the Service in 1984.

A. Requirement 1. Develop a Visitor Services Plan. Through CCP's and visitor services plans, we will set goals, determine measurable objectives, identify strategies, and establish evaluation criteria for all visitor services. Careful planning provides the visiting public with opportunities to enjoy and appreciate fish, wildlife, and plants and other resources. As a result, the visiting public will develop an understanding and will build an appreciation of each individual's role in the environment today and into the future.

B. Requirement 2. Welcome and Orient Visitors. We will assure that national wildlife refuges are welcoming, safe, and accessible. We should regularly schedule some refuge staff to work weekends, and holidays (except Thanksgiving, Christmas, and New Years Day) and other anticipated periods of high public recreational use. We will provide visitors with clear information so they can easily determine where they can go, what they can do, and how to safely and ethically engage in recreational and educational activities. Facilities will be high quality, clean, well-maintained, and accessible. We will treat visitors with courtesy and in a professional manner.

C. Requirement 3. Provide quality hunting opportunities. Hunting is an appropriate use of wildlife resources of the System when compatible. Hunting programs will be of the highest quality, conducted in a safe and cost-effective manner, and, to the extent practicable, carried out in accordance with State regulations. (Reference 605 FW 2).

D. Requirement 4. Provide quality fishing opportunities. Fishing is an appropriate use of wildlife resources on units of the National Wildlife Refuge System when compatible. Fishing programs will be of the highest quality, conducted in a safe and cost-effective manner, and, to the extent practicable, carried out in accordance with State regulations. (Reference 605 FW 3).

E. Requirement 5. Provide quality wildlife observation and wildlife photography opportunities. Wildlife observation and wildlife photography (reference 605 FW 4 and 605 FW 5 respectively) are appropriate wildlife-dependent recreational uses of System lands when compatible. Visitors of all ages and abilities will have an opportunity to observe and photograph key wildlife and habitat resources of the refuge. Viewing and photographing wildlife in natural or managed environments will foster a connection between visitors and natural resources.

F. Requirement 6. Develop and implement a quality environmental education program. Through formal, curriculum-based environmental education tied to national and State education standards, we will advance public awareness, understanding, appreciation, and knowledge of key fish, wildlife, plant, and resource issues. Each refuge staff person will assess their potential to work with schools in providing an appropriate level of environmental education. We may support environmental education through the use of facilities, equipment, educational materials, teacher workshops, and study sites that are safe and conducive to learning. (Reference 605 FW 6).

G. Requirement 7. Interpret key resources and issues. We will communicate the most important fish, wildlife, habitat and other resource issues to visitors of all ages and abilities through effective interpretation. We will tailor messages and delivery methods to specific audiences and present them in appropriate locations. Through heightened awareness, we will inspire visitors to take positive actions supporting refuge goals and the System mission. (Reference 605 FW 7).

H. Requirement 8. Manage for appropriate recreational opportunities. The National Wildlife Refuge System Administration Act as amended by the National Wildlife Refuge System Improvement Act of 1997 states that compatible wildlife-dependent recreational uses are the priority public uses of the National Wildlife Refuge System (hunting, fishing, wildlife observation, wildlife photography, environmental education, and interpretation) and will receive enhanced consideration over other general public uses. Volunteers, partners, recreation fees and concessions are tools available to assist us in managing these uses. We will only permit other uses when we determine that they are legally mandated, provide benefits to the Service, occur due to special circumstances, or facilitate one of the priority wildlife-dependent recreational uses. (Reference 605 FW 1).

I. Requirement 9. Communicate key issues with off-site audiences. Effective outreach depends on open and continuing communication between the refuge and the public. This communication involves determining and understanding the issues, identifying audiences, crafting messages, selecting the most effective delivery techniques, and evaluating effectiveness. Achieved results will further the mission of the System and purpose(s) of the refuges. See the National Outreach Strategy: A Master Plan for Communicating in the U.S. Fish

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and Wildlife Service, and America's National Wildlife Refuge System: 100 on 100 Outreach Campaign.

J. Requirement 10. Build volunteer programs and partnerships with refuge support groups. Volunteer and refuge support groups fortify refuge staffs with their gift of time, skills, and energy and are integral to the future of the System. Refuge staff will initiate and nurture relationships with volunteers and refuge support groups, and will continually support, monitor, and evaluate these groups with the goal of fortifying important refuge activities. The National Wildlife Refuge System Volunteer and Community Partnership Enhancement Act of 1998 (P.L. 105–242) strengthens the System's role in developing effective partnerships with various community groups. Whether through volunteers, refuge support groups, or other important partnerships in the community, refuge personnel will seek to make the refuge an integral part of the community, giving rise to a stronger System.

Draft Hunting Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 2 Hunting 605 FW 2.1

2.1 What is the purpose of this chapter? This chapter provides the Fish and Wildlife Service's (Service) policy governing the management of recreational hunting on units of the National Wildlife Refuge System (System or we).

2.2 To what programs does this chapter apply? The policies contained in this chapter apply to recreational hunting within the System. Refer to other chapters or regulations governing policies and procedures addressing related activities such as guiding (604 FW 7) and field trials (631 FW 5).

2.3 What is our policy on hunting on refuge lands? The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. We recognize hunting as a healthy, traditional outdoor pastime, deeply rooted in American heritage, and when managed appropriately, can instill a unique understanding and appreciation of wildlife, their behavior, and their habitat needs. Hunting also is an important wildlife management tool on refuges. Hunting is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will invest our resources and imagination in providing high-quality hunting experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide public hunting opportunities. Hunting programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. We rely on close cooperation and coordination with State fish and wildlife management agencies in managing hunting opportunities on refuges and in setting refuge population management goals and objectives. Regulations permitting hunting of resident wildlife within the System shall be, to the extent practicable, consistent with State fish and wildlife laws, regulations, and management plans. We encourage refuge staff to develop and take full advantage of opportunities to work with other partners who have an interest in helping us promote high quality hunting programs on refuges.

2.4 What are the objectives for our hunting programs? The objectives of the System hunting program are to promote public understanding of and increase public appreciation for America's natural resources, to manage wildlife populations at optimum levels, and to provide opportunities for high-quality recreational and educational experiences.

2.5 What are the authorities that allow hunting on the System? Refer to 605 FW 1 for laws that govern hunting on System lands.

2.6 Do we have common definitions for hunting terms? Yes. The following are definitions of terms used in reference to hunting.

A. Open to the public. Open to public hunting means we allow individuals who hold, if required, valid licenses, permits, stamps or other documents to enter and take specific wildlife species. Areas open to hunting may differ from areas open to the general public for other recreational activities. We note this distinction on signs and in outreach materials, such as general refuge or hunting brochures.

B. Quality hunting experience. A quality hunting experience is one that:

(1) Maximizes safety for hunters and other visitors;

(2) Encourages the highest standards of ethical behavior in taking or attempting to take wildlife;

(3) Is available to a broad spectrum of the hunting public;

(4) Contributes positively to or has no adverse affect on population management of resident or migratory species;

(5) Reflects positively on the individual refuge, the System, and the Service;

(6) Provides hunters uncrowded conditions by minimizing conflicts and competition among hunters;

(7) Provides reasonable challenges and opportunities for taking targeted species under the described harvest objective established by the hunting program. It also minimizes the reliance on motorized vehicles and technology designed to increase the advantage of the hunter over wildlife;

(8) Minimizes habitat impacts;

(9) Creates minimal conflict with other priority wildlife-dependent recreational uses or refuge operations; and

(10) Incorporates a message of stewardship and conservation in hunting opportunities.

C. Special weapons hunts. Special weapons hunts limit the choice of weapons individuals can use in the field to take big game (e.g., elk, deer). Bows, shotguns, and black powder guns may be classified as special weapons. We generally authorize special weapons hunts with appropriate conditions, such as "Archery Only," "Primitive Weapons Only," or "Shotgun Only," unless these hunts are spatially separated by season.

D. Inviolate sanctuaries. A national wildlife refuge, or portions thereof, acquired or established in one of the following ways:

(1) Acquired with the approval of the Migratory Bird Conservation Commission (MBCC) for the purpose of an inviolate sanctuary;

(2) Established by an instrument or document that states that we intend to manage the area as an "inviolate sanctuary for migratory birds" or to fulfill the purpose of the Migratory Bird Conservation Act.

E. Tournament hunting. A hunting competition for monetary or other prizes, such as a "Big Buck" contest.

2.7 When do we address the decision to allow hunting for proposed additions to the National Wildlife Refuge System? When lands and waters are under consideration for addition to the System, the Refuge Manager will make an interim compatibility determination on any existing priority public uses. The record of decision establishing or expanding hunting on the refuge must document the completion of such determinations. The results of these determinations are in effect until the completion of a Comprehensive Conservation Plan (CCP). It is during the development of the CCP and implementation of the National

Environmental Policy Act (NEPA) that we accept and incorporate public comments into the hunting decision on the refuge.

2.8 How do we open System lands to hunting? The decision to open a refuge to hunting depends on the provisions of laws and regulations applicable to the specific refuge and a determination by the Refuge Manager that opening an area to hunting will be compatible. This decision must also be consistent with the principles of sound wildlife management, applicable wildlife objectives, and otherwise be in the public interest (see 50 Code of Federal Regulations (CFR) 32.1).

A. Specific conditions. The following conditions apply to hunting on certain units of the System.

(1) Inviolate sanctuaries. We may allow hunting of migratory game birds on no more than 40 percent of the total area unless the Secretary finds that taking of any such species in more than 40 percent of such area would be beneficial to the species (NWRSAA). If we open only 40 percent of an inviolate sanctuary to migratory bird hunting, the opened area could conceivably contain 100 percent of the habitat for migratory birds and comply with the law. However, we must first determine if the proposal is compatible with the purposes of the refuge and the System mission. Before we can open more than 40 percent of an inviolate sanctuary to hunting, we must publish the reasons for doing so in the **Federal Register**. Because of this requirement, the Director, under delegation from the Secretary, must approve all proposals to open more than 40 percent of an inviolate sanctuary to migratory bird hunting. Regional Directors retain the authority to open more than 40 percent of areas on refuges that are not inviolate sanctuaries. Refuge managers must carefully evaluate all such proposals to ensure the proposed action will be compatible. Inviolate sanctuary classification imposes no limits on hunting non-migratory birds or other game species.

(2) Waterfowl Production Areas (WPAs). WPAs are open to hunting in accordance with State law (50 CFR 32.1) as long as it is compatible. A hunting plan or rulemaking document is not necessary to open these areas to hunting. We may restrict WPA hunting programs and under 50 CFR 32.1, we may also close WPAs to hunting and other public use if circumstances warrant.

(3) Wetland easements. We have no authority over hunting on wetland easements, which we most often acquire as part of the Small Wetland Acquisition Program, unless we purchased specific rights with the easements. For these easements, the landowner has usually retained all rights to control public access, including for hunting and other recreational uses.

(4) Easement refuges. The rights acquired with the individual easement refuge determines our control of hunting on easement refuges. The Regional Director is responsible for determining the extent of our control over hunting on these areas. If we control hunting, the Refuge Manager must follow all procedures required to open a refuge to hunting.

(5) Farm Service Agency Easements formerly Farmers Home Administration (FmHA)). We have no authority over hunting or other forms of public use on easements obtained through the various Farm Service Agency inventory property easement programs of 1985, 1990, and 1996. The landowner retains the right to control access for hunting and other recreational uses.

(6) National wildlife refuges in Alaska. The Alaska National Interest Lands Conservation Act (ANILCA) (16 U.S.C. 410hh-3233 and 43 U.S.C. 1602–1784) opens all national wildlife refuges in Alaska to hunting under applicable Federal and State law as long as it is compatible (50 CFR 36.32). A hunting plan or rulemaking document is not necessary to permit hunting on these refuges. We may prohibit or restrict the taking of wildlife only in conjunction with notices and hearings under the requirements of 50 CFR 36.42 regarding public participation and closure procedures. Local rural residents may hunt wildlife for subsistence uses in compliance with applicable Federal and State laws. Under ANILCA, non-wasteful subsistence use of wildlife by rural residents has priority over other consumptive uses permitted on national wildlife refuges in Alaska.

B. Evaluation criteria for hunting programs. We will use the following criteria and standards to evaluate hunting programs on units of the System:

(1) Compatibility. A hunting program must be compatible with the purpose(s) of the refuge and the System mission.

(2) Biological integrity, diversity, and environmental health. We maintain, or contribute to the maintenance of, populations of native species. We design our wildlife population management strategies to support accomplishing refuge purposes while maintaining or restoring biological integrity, diversity, and environmental health (see 601 FW 3). We formulate refuge goals and objectives for population management by considering natural densities, social structures, and population dynamics at the refuge level and population objectives set by national plans and programs—such as the North American Waterfowl Management Plan—in which the System is a partner.

(3) Relationship with other public use programs. An integrated approach to providing opportunities for compatible wildlife-dependent recreational uses will minimize conflicts between individuals participating in these uses. We will evaluate time and space scheduling and zoning as methods to ensure opportunities for quality experience among different user groups.

(4) Resources. Providing quality recreational experiences for the public requires appropriate funding, facilities, and staff. The House Report accompanying the House of Representatives version of the National Wildlife Refuge System Improvement Act of 1997 (H. Rpt. 105–106) encourages refuge managers to take reasonable steps to obtain outside assistance from States and other conservation interests, if adequate financial resources are not available to manage a priority use in a compatible manner. Refuge managers should work closely with State, community, and conservation partners to help obtain necessary resources to manage the priority wildlife-dependent recreational use programs. Potential sources of support include the following: hunting organizations, user fees for hunting; cooperating with State, local, or Tribal agencies; and assistance from refuge support groups or volunteers. We encourage refuge managers to seek and implement other opportunities to obtain additional resources as they become available.

(5) Evaluation and monitoring. Refuge managers must monitor and evaluate their hunting programs regularly. Refuge managers should evaluate both the quality of the recreation experience and the effects of the activity on refuge resources. A wide variety of evaluation tools exist, from simply asking the hunting public how they rate their experience to contracting with a university or private company to conduct a formal survey. If a Refuge Manager decides to use a survey to evaluate the hunting experience, he or she must receive approval from the Office of Management and Budget on the information collection process before conducting any public surveys.

C. Consultation and coordination. (1) Coordination with states. When a refuge, or portion thereof, is open to hunting, we allow hunting within the

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framework of applicable State regulations. We consult with the State, Tribes, and other appropriate authorities during the development of hunting programs and whenever we plan significant changes. Refuge regulations must be consistent with State regulations, to the extent practicable. The use of more restrictive regulations requires consultation with the State. We must list regulations that are more restrictive than State regulations, such as seasons and fishing hours as refuge-specific regulations in 50 CFR part 32. Refuge-specific regulations must not weaken existing State laws and regulations. We must justify deviations from State regulations in the refuge hunting plan or amendments to that plan.

(2) Endangered species consultation. We will review all hunting programs annually to determine if they may affect, adversely or beneficially, threatened or endangered species and their habitats. The Refuge Manager will initiate consultation as appropriate, under Section 7 of the Endangered Species Act and intra-Service consultation procedures.

(3) Public involvement. The appropriate level of public involvement must accompany new or significant changes to existing hunting programs. Refuge managers must plan efforts well in advance of the proposed changes in order to obtain as much involvement from groups and individuals as possible. A variety of methods are available for the Refuge Manager to use to involve and inform the public, including public meetings, workshops, news releases, and mailings to interested groups. We encourage refuge managers to continue to use these and other methods. We require an outreach plan developed in coordination with Regional External Affairs Offices for new hunting programs or any major changes affecting existing programs.

D. Documentation required to open a refuge to hunting. The Refuge Manager must submit the following documents to the appropriate staff in the Regional Office to open a refuge to hunting. The Regional Office then forwards a copy of these documents to the National Wildlife Refuge System Headquarters for preparation of a rulemaking document.

(1) Step-down hunting plan. This plan should be a step-down plan of the refuge's CCP which must include a compatibility determination on the hunting program. If the unit has not yet completed a CCP, the step-down hunting plan must contain a compatibility determination until the CCP is completed. The hunting plan should be an appendix to the overall plan for providing public uses on refuges. The plan will provide documentation of the hunting allowed on a refuge, including the relationship of hunting to refuge purpose(s), goals, and objectives and the System mission. The suggested format for a refuge hunting plan is labeled as Exhibit 1 in this chapter.

(2) Appropriate NEPA documentation.

(3) Appropriate decision documentation.

(4) Section 7 evaluation. (See Exhibit 2 for information on Section 7 evaluation.)

(5) Copies of letters requesting State, and, where appropriate, tribal involvement and the results of the request.

(6) Draft news release.

(7) Outreach plan. (We label a Directorate-approved outline for an Outreach Plan as Exhibit 3.)

2.9 Who prepares and reviews a refuge hunting plan? The Refuge Manager, with technical assistance as needed from the Regional Office and State and Tribal wildlife agencies, is responsible for preparation of the hunting plan. The Regional Director approves the plan before the rulemaking process begins. The Regional Office sends copies of the approved hunting plans to Headquarters (including the approved outreach plan) for concurrence. During the rulemaking process, Headquarters staff use the hunting plan as reference material and supporting documentation. The Refuge Manager must annually review hunting plans for each refuge where we allow hunting. The Refuge Manager must refer to this plan in the Refuge Public Use Plan or CCP and provide overall documentation of the hunting allowed on a refuge.

2.10 What information do we need for publication in the Federal Register? The Refuge Manager must submit information about what species we propose to open for hunting and the conditions of the proposed hunt once we determine the proposal to be compatible and document the results in an approved hunting plan. The Regional Liaison must forward copies of this information to the Federal Register Liaison at Headquarters for the development of the proposed and final refuge-specific regulations (codified in 50 CFR), which we publish in the **Federal Register**. If a Refuge Manager proposes to open more than 40 percent of an inviolate sanctuary to migratory game bird hunting, we must also publish the justification in the **Federal Register**.

2.11 What is the refuge-specific regulations process? The refuge-specific regulation process is outlined below:

A. Headquarters must publish in the **Federal Register**, proposed refuge-specific regulations pertaining to a refuge's hunting program that are necessary to conduct that program prior to them becoming effective. Refuge managers must forward all refuge-specific regulations through appropriate channels to Headquarters for clearance and submission to the **Federal Register**. The refuge is open to hunting officially after the effective date of the final rule. Hunting can begin concurrently with or after the opening of the State season.

B. Refuge managers must review these regulations and the refuge hunting plan annually to ensure compatibility and consistency of the hunting program with existing laws and regulations. Refuge managers must submit any amendments (additions, deletions, or modifications) each year to the designated regional hunting and fishing program coordinator who, in turn, sends that information to Headquarter's Federal Register Liaison for inclusion in the rulemaking documents for publication in the **Federal Register**. Headquarter's Federal Register Liaison must receive this information by January 31 each year to allow sufficient time for compilation and review by concerned program offices and the Solicitor, signature by the Assistant Secretary, and the Departmental review for both proposed and final rules. This includes a 30-day public comment period on the proposed rule. We cannot publish a refuge opening without the complete hunting package. If no amendments are necessary, refuge managers should submit a negative response to that effect to the Regional Office (to the attention of the hunting and fishing program coordinator). Refuge-specific regulations should be standard and consistent in format throughout the System. We include guidelines for preparing and submitting regulations and amendments in Exhibit 4.

2.12 How do we revise a hunting plan? The Refuge Manager may approve all revisions in hunting plans except major revisions. Major revisions in hunting plans (*e.g.*, addition of big game to a hunting program, designating hunts for special weapons use only) must occur as an amendment to the hunting plan unless the original plan included specific conditions under which that revision could occur. The preparation and approval of amendments follows the same guidelines as preparation and approval of the original plan. Submit only the revised portion of the plan for approval to the Regional Office. The Regional Director approves revisions only when Headquarters has already listed the refuge in 50 CFR as open to that particular category of hunting. Otherwise, refuge managers must submit the amended hunting plan for rulemaking. Opening a refuge to new categories requires the appropriate National Environmental Policy Act (NEPA) findings.

2.13 What are the guidelines for refuge hunting programs? We should plan, manage, conduct, and evaluate refuge hunting programs on a consistent basis in ways that ensure hunter and visitor safety, and promote positive values such as fair chase, high ethical standards, and respect for the resource. Hunting on refuges must have the attributes of a quality hunt as defined in section 2.6B. The following guidelines should help ensure quality opportunities are available.

A. Permits. We require hunters to have all applicable Federal, State, and Tribal licenses or stamps in their possession. We can issue refuge permits to limit participation or gather information. If we use refuge permits to limit hunter numbers, we will issue them on a random basis to the public. Refuge managers should avoid complicated application processes that require additional resources. Application processes should be flexible to provide an opportunity to all potential hunters. Under ANILCA, qualified rural subsistence hunters are given a preference to harvest game on Alaska refuges as outlined by the rules and regulations established by the Federal Subsistence Board. We should coordinate with Tribal and State application and lottery processes where practicable.

B. Fees. The Refuge Manager makes the decision to charge a fee in coordination with the Regional Office. We have the authority to charge fees for applications, refuge permits, and the use of facilities (*i.e.*, hunting blinds) under existing recreation fee programs. We use fees collected for visitor service enhancement projects, and resource protection. The authority under which we collect fees contains stipulations on how we may reinvest the monies. The Regional Fee Coordinator can assist with the approval of fees as well as provide information on the appropriateness of fund distribution.

C. Zoning recreational use. We desire a balanced hunting program that allows a variety of quality hunting opportunities. For example, designating areas for youth hunts, establishing areas that provide access for hunters with disabilities, establishing "special weapons" areas, designating areas for seasonal or daily closures for consumptive and non-consumptive use, designating areas for non-motorized boat use, and establishing areas where hunters use methods to reduce crippling loss, help us achieve a balanced hunting program and increase the quality of the experience. We can also use zoning to reduce conflicts between hunters and other users.

D. Law enforcement. Law enforcement is an important part of any hunting program. It is used to ensure legal and equitable utilization of fish and wildlife resources on refuges, as prescribed by law. Law enforcement is also used to obtain compliance with laws and regulations necessary for proper administration, management, and protection of the System. The effort invested should be sufficient to protect human safety, wildlife populations, and ensure compliance with regulations based on past experiences and current circumstances.

E. Hunter access and vehicle control. Refuge managers must carefully plan, manage, and evaluate access and vehicle control to retain high levels of undisturbed opportunities. Refuge managers should strongly encourage those opportunities not dependent upon the use of motorized vehicles. We can make exceptions to general access restrictions for hunters with disabilities when necessary to facilitate their experience, and when compatible with resource management objectives. For example, refuge managers may issue special use permits to hunters with certain disabilities for access to hunt blinds, or retrieval of downed game. Refuge managers could require specific physician's documentation before providing the disabled hunter a special use permit.

F. Camping. We may allow camping on refuges when it is necessary to support hunting opportunities. Camping is appropriate only when no reasonable (based on time, distance and expense) lodging opportunities are available off-refuge and when staff resources needed to manage camping do not detract from the quality of another priority wildlife-dependent recreational use. Large refuges in the western United States, refuges in Alaska, and some remote refuges allow camping under this criteria. See the Appropriate Refuge Uses chapter (603 FW 1) for additional information.

G. Hunting by service staff. Service employees are subject to the same rules and regulations as the general public. If only limited hunting opportunities exist, refuge managers should discuss with Service employees the need to be sensitive to the possibility of the public perception of conflict of interest. We never authorize Service employees to wear uniform components outside of their official capacity. When employees participate in off-duty hunting opportunities, they are not authorized and, therefore, should never wear uniform components (e.g., uniform ball caps, uniform jeans). When Service employees actively participate in assigning limited hunting permits, they will not participate in that particular hunt on those affected refuge lands. In addition, personnel may not use means of access to hunt in areas that are not available to the general public.

H. Communication materials. Professionally developed outreach materials will benefit refuge managers by providing clear and thorough information to hunters. Brochures must conform with the U.S. Fish and Wildlife Service Graphics Standards and be consistent with refuge-specific regulations. Contact your Regional Publications Coordinator for graphic standards. Refuge managers do not need to include regulations and dates that are identical to State seasons. Include information that encourages hunters to hunt safely and ethically. We encourage refuge managers to use electronic media, such as the Internet, to distribute information. Refuge managers should work with Regional Office staff to provide information on standards and guidelines for all communications materials.

I. Equipment. Refuge managers may place limits on certain equipment such as decoys, boats, tree stands, and type of firearm or ammunition if they determine that such limits reduce crippling loss, resource damage, hunter conflicts, or improve the quality of the hunt.

J. Boundary hunting. We discourage boundary hunting adjacent to closed areas of refuges. We can alter boundary lines or habitat, or eliminate parking areas and access roads, to distribute hunters or modify wildlife use patterns in ways that make boundary hunting less appealing. Refuge managers must use retrieval zones sparingly and only to prevent waste by allowing the retrieval of dead or crippled game. Prior to establishing these zones, managers should consider adjusting hunt boundaries as well as the cost of signing and enforcing restrictions. Limit the entry of hunters into closed areas wherever possible. Retrieval of big game may require entry, with permission, into closed areas.

K. Check stations. Use check stations only as a means to monitor the hunt, gather important information that we cannot obtain in a less expensive

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manner, or gather biological information about animal populations. Refuge managers should evaluate the continued use of check stations periodically to determine if there is a more cost-effective means of providing quality hunting services. Use permanent check stations only to control the hunting area access and not to enforce hunting regulations.

L. Data collection. Refuge managers should evaluate hunting programs to determine if we are meeting objectives. Refuge managers should consult with the State regarding data collection needs and survey methods.

M. Proficiency testing. Generally, we will not require mandatory testing or qualifications above State requirements. If a Refuge Manager wants to implement a proficiency test more restrictive than that required by the State, the Refuge Supervisor must approve the test. For example, if hunters were not allowed to take black ducks or mallard hens on a refuge but were permitted to take gadwalls, the hunter could be required to show proficiency in the identification of gadwalls and other waterfowl.

N. Hunting with dogs. The use of properly trained dogs is an important part of the American hunting tradition, enhances the quality of the hunting experience, and can reduce the loss of crippled game. We recognize the long relationship between dogs and hunters. However, in our effort to emphasize high-quality visitor experiences which minimize visitor use conflicts and wildlife disturbance, we must make distinctions between various uses of dogs for hunting. Not all uses of dogs for hunting will fit with System quality hunting experience goals.

We do not allow hunting dogs in areas closed to hunting or other public use and we only allow their use in the following circumstances:

(1) Retrievers. We encourage the use of trained retrieving dogs for waterfowl. Emphasize the value of trained retrievers in reducing the loss of downed birds in outreach materials promoting the hunting program.

(2) Pointing and flushing dogs. Typically, hunters use pointing and flushing dogs in pursuit of upland game birds. Well-trained pointing and flushing dogs enhance a hunting experience by creating more opportunities and finding and retrieving downed birds.

(3) Pursuit hounds. Refuge managers will carefully consider the impacts of the use of pursuit hounds on the refuge. When evaluating compatibility of hunting with pursuit hounds, a Refuge Manager will include the following discussion points in the compatibility determination:

(a) The likelihood of pursuit hounds injuring or annoying wildlife to such an extent as to significantly disrupt normal behavioral patterns of non target species;

(b) The likelihood of pursuit hounds interfering with the quality of the experience of other refuge visitors;

(c) The likelihood of pursuit hounds venturing out of open hunting areas and entering closed areas or adjacent private lands; and

(d) The effects of pursuit hounds ranging out of the hunter's control and being left on the refuge for an extended period of time.

O. Special weapons hunts. We offer hunting opportunities to as broad a spectrum of the public as possible. Consider special weapons hunts, as defined in section 2.6C, under some of the following conditions:

(1) Safety. Extremely dense cover, agricultural fields, or other vegetation characteristics may create situations where rifles are not appropriate. Configuration of hunt areas, such as long, narrow corridors or occupied inholdings, may also create situations where we should only allow specific weapons due to safety considerations.

(2) Limited harvest. In cases where there are relatively low populations or other limited harvest opportunities, offering special weapons hunts could be a method to provide hunting opportunities where they would otherwise not exist.

(3) State seasons for special weapons. In some States, the State designates separate seasons for specific weapons. When the State conducts archery, black powder, and other special seasons, it may be appropriate for refuge hunts to accommodate them. The decision as to whether a special weapons hunt approved by the State is compatible on the refuge lies with the Refuge Manager.

P. Falconry. If falconry is deemed appropriate and compatible on the refuge, it must be conducted under applicable Federal, State, and Tribal regulations. Refuge managers should consider:

(1) Will the refuge falconry hunting area provide a quality and safe falconry experience? For example, is the area large enough for a raptor to fly, stoop, and capture prey and be unobstructed by barbed wire fences or power lines?

(2) Will endangered or threatened species be harassed (see 50 CFR 17.11)?

(3) Will falconry negatively impact adjacent land uses (e.g., a nearby poultry farm) or will adjacent land uses affect the falconry on the refuge (e.g., a neighboring race track)?

Q. Nontoxic shot. Hunters may possess only nontoxic shot that conforms with the standards identified in 50 CFR 32.2(k) while hunting with shotguns or muzzle loaders on WPA's, or on certain other areas of the System. This regulation does not apply to turkey and deer hunters using buckshot or slugs, except as specifically limited by refuge-specific regulations.

R. Night hunting. We allow night hunting when it is appropriate and compatible with the purpose(s) of the refuge and the mission of the System. If a refuge is generally not open after sunset, refuge managers may make an exception and allow night hunting. Refuge managers must base the decision on specific refuge objectives and not historical use. Reference the General Recreation Guidance Chapter, 605 FW 1, for additional information about after-hours activities.

S. Tournament hunting. We prohibit this type of hunting on System lands and waters unless we make a specific determination that the event builds appreciation for and an understanding of fish and wildlife resources, does not reasonably interfere with other refuge visitors, and if prizes of only nominal value are awarded. Refer to the Appropriate Uses Chapter (603 FW 1) for additional discussions of competitive events.

T. Youth hunting. We encourage refuge managers to set aside areas or times to promote hunting by children or under represented groups. Experiencing hunting in a safe environment and exposure to proper hunting methods is important to developing life skills and public support for healthy ecosystems. Refuge managers should take advantage of these opportunities to educate young hunters and their parents about the importance of wildlife management.

2.14 How do we close a refuge to hunting? The Refuge Manager may close all or any part of a refuge that we have opened to hunting whenever necessary to protect the resources of the area or in the event of an emergency endangering life, property, or any population of wildlife, fish or plants (50 CFR 25.21).

A. Emergency closure. We do not require advance public notice for closure under emergency conditions. We will notify the public of such closures by signs, special maps, or other appropriate methods.

B. Non emergency closure. We will evaluate non-emergency closure of a refuge hunting program for impacts on wildlife populations, ecosystems, and priority recreation uses. If the impacts are likely to be major or controversial, we will prepare an environmental assessment and follow the public participation process identified in the National Environmental Policy Act (NEPA). We will evaluate the impacts of the decisions and give appropriate notification to the public. In Alaska, temporary closures or restrictions relating to the taking of wildlife will not be effective prior to the notice and hearing that we will conduct for an emergency closure in the vicinity of the affected area(s) and may not exceed 12 months.

Exhibit 1—Refuge Hunting Plan Format

I. Introduction

Include a general description of the refuge and information pertinent to the planned hunting program. If a Refuge Manager develops this hunting plan as a portion of an integrated public use plan, we may not require this information. Include non repetitive general information in the Comprehensive Conservation Plan.

II. Conformance with Statutory Authorities

Explain how the program will be compatible with the System mission, the goals and objectives of the refuge, and the purpose(s) for which the refuge was established. Include projections of the resources (staff and funding) needed to conduct the program and their sources. Include an explanation of how the program will address the requirements of applicable authorities.

III. Statement of Objectives

List the major refuge objectives and the specific objectives of the hunting program. Describe how hunting will impact the refuge objectives.

IV. Assessment

Evaluate the hunting resources on the refuge populations and habitats. Points to discuss include, but are not limited to, the following:

a. Will populations sustain hunting and still support other wildlife-dependent priority uses?

b. Do target species and other wildlife compete for habitat?

c. Do target species prey on other species at unacceptable levels?

V. Description

Describe the program in detail, using graphics as needed. The description should include:

a. Areas of the refuge that support target species.

b. Areas of the refuge to be opened to hunting.

c. Species designated for hunting and hunting periods.

c. Justification of permit system, if required.

d. Consideration of user fees.

e. Consultation and coordination procedures with States, including justification of refuge-specific regulations.

f. Methods of control and enforcement.

g. Staffing and funding needs.

h. Consideration of providing opportunities for hunters with disabilities.

VI. Measures Taken To Avoid Conflicts With Other Management Objectives

a. *Biological conflicts.* Include section 7 consultation, and other measures proposed to minimize or eliminate conflicts with endangered species or non target species.

b. *Social conflicts.* Include proposed measures that minimize or eliminate conflicts with other user groups.

VII. Hunt Specifics

a. Refuge-specific regulations.

b. Outreach plan.

c. Hunter application and registration procedures (if needed).

d. Description of hunter selection process (if needed).

e. Draft news release regarding the hunting program.

f. Description of hunter orientation, including pre hunt scouting opportunities.

g. Hunter requirements:

(1) State determined age requirement.

(2) Allowable equipment.

(3) Licensing and permits.

(4) Reporting requirements.

(5) Hunter training and safety.

(6) Other information (use of dogs, falconry, etc.)

VIII. Compatibility Determination

IX. Appropriate NEPA Documents

X. Evaluation

a. Monitoring and reporting use levels and trends.

b. Surveying needs of the hunting visitor.

c. Are we meeting program objectives?

d. Do we need to resolve any conflicts?

e. Refuge/Regional Office review schedule.

Exhibit 2—Priority Wildlife-Dependent Recreation (Hunting)

Use the following terminology for your Section 7 determination as to whether the opening of your refuge to hunting and/or fishing will affect the continued existence of any endangered or threatened species or result in the destruction or adverse modification of habitat of such species within the System.

Types of Effects

1. No effect: The appropriate conclusion when the Service determines that a proposed Service action will not affect a listed species or designated critical habitat.

2. Is not likely to adversely affect: The appropriate conclusion when effects on listed species are expected to be discountable, insignificant, or completely beneficial. Beneficial effects are contemporaneous positive effects without any adverse effects to the species. Insignificant effects relate to the size of the impact and should never reach the scale where take occurs. Discountable effects are those extremely unlikely to occur. Based on best judgment, a person would not (1) be able to meaningfully measure, detect, or evaluate insignificant effects; or (2) expect discountable effects to occur.

3. Is likely to adversely affect: The appropriate finding in a biological assessment (or conclusion during information consultation) if any adverse effect to listed species may occur as a direct or indirect result of the proposed Service action or its interrelated or interdependent actions, and the effect is not: discountable, insignificant, or beneficial (see definition of "is not likely to adversely affect"). In the event the overall effect of the proposed Service action is beneficial to the listed species but is also likely to cause some adverse effects, then the proposed Service action "is likely to adversely affect" the listed species. If incidental take is anticipated to occur as a result of the proposed action, an "is likely to adversely affect" determination should be made. This determination requires the initiation of formal intra-Service section 7 consultation (see definition of "informal intra-Service consultation").

4. May affect: The appropriate conclusion when a proposed action may pose *any* effects on listed species or designated critical habitat. When the Federal agency (in this case the Service) proposing the action determines that a "may affect" situation exists, then the Service must initiate formal consultation or seek written concurrence from the involved Service programs that the action "is not likely to adversely affect" listed species.

5. Is likely to jeopardize proposed or candidate species/adversely modify proposed critical habitat: The appropriate conclusion when the Service identifies situations where the proposed Service action is likely to jeopardize the continued existence of a species proposed for listing or a candidate species, or adversely modify an area proposed for designation as critical habitat. If this conclusion is reached, intra-Service conference is required.

Types of Consultation

1. Formal intra-Service consultation: A process between a Service program authorizing an action and another Service program affected by that action that: (1) Determines whether a proposed Service action is likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat; (2) begins with the Service program that authorizes the action providing a written request and submitting a complete initiation package to the affected Service program; and (3) concludes with the issuance of a biological opinion and incidental take statement by the affected Service program. If a proposed Service action may affect a listed species or designated critical habitat, formal intra-Service consultation is required (except when the involved Service programs concur, in writing, that a proposed action "is not likely to adversely affect" listed species or designated critical habitat). (50 CFR 402.02; 50 CFR 402.14)

2. Informal intra-Service consultation: An optional process that includes all discussions and correspondence between Service programs, prior to formal intra-Service consultation, to determine whether a proposed Service action may affect listed species or critical habitat. This process allows the Service to utilize its in-house expertise to evaluate a Service program's assessment of potential effects or to suggest possible modifications to the proposed action

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which could avoid potentially adverse effects. If a proposed Service action may affect listed species or designated critical habitat, formal intra-Service consultation is required (except when the involved Service programs concur, in writing, that a proposed action "is not likely to adversely affect" listed species or designated critical habitat). (50 CFR 402.02; 50 CFR 402.13)

Exhibit 3—Outreach Plan Summary

I. Issue: (State the issue in one or two sentences.)
II. Basic Facts About the Issue:
III. Communication Goals:
IV. Message:
V. Interested Parties:
VI. Key Date:
VII. Strategy:

Exhibit 4—Guidelines for Preparation of Refuge-Specific Hunting Regulations

Hunting regulations on national wildlife refuges accomplish three major purposes: They protect the resource, manage it, and ensure safety. State hunting regulations generally provide the framework for meeting these three criteria. When State regulations fall short of meeting these criteria, refuge-specific regulations are necessary. These regulations should focus primarily on management of the wildlife resource and should be enforceable. For example, if we require permits on a specific refuge, a statement that we require special refuge permits is all that is necessary. Details are not appropriate in the regulations. Address details in a leaflet or the permit application. Also, do not submit text for your refuge unless it represents a CHANGE to the existing language in part 32. If you are adding conditions to those already published, state that these are "adds" and indicate where you want them inserted in the text.

Duplications of existing 50 CFR provisions. When writing your regulations, check 50 CFR to avoid duplication. For example, in Part 27, Prohibited Acts, Section 27.31 restricts motor vehicles to "designated routes of travel. * * * delineated on maps by the Refuge Manager;" Section 27.81 adequately covers possession of alcohol; and Section 27.95 prohibits setting fires.

Duplication of State regulations. 50 CFR 32.2 (d) states "Each person shall comply with the applicable provisions of the laws and regulations of the State wherein any area is located unless further restricted by Federal law or regulation." Therefore, do not repeat State bag limits, seasons, etc., in the refuge-specific regulations. Indicate differences in a cover memo that justifies differences and deviations.

Preparation of refuge-specific regulations. List shell limits, bag limits, seasons, and hours that differ from the State's in the refuge-specific regulations.

Use the following as an example for your submission for modifications to existing text:

§

Section 32.42 Minnesota.

Big Stone National Wildlife Refuge

B. Upland Game Hunting.

Replace the preamble to read as follows:

You may hunt partridge, pheasant, wild turkey, gray and fox squirrel, cottontail and jack rabbit, red and gray fox, raccoon, and striped skunk on designated areas of the refuge subject to the following conditions:

Add new conditions B.2. and B.3. to read as follows:

B.2. You may hunt fox, raccoon, and striped skunk only during open seasons for other small game species. You may not use dogs while raccoon hunting.

B.3. You may hunt turkey only if you have a valid State turkey hunting permit in your possession.

Use the following example for an addition of a refuge to part 32:

Section 32.20 Alabama.

Grand Bay National Wildlife Refuge

A. Hunting of Migratory Game Birds. We allow hunting of geese, ducks, and coots on designated areas of the refuge subject to the following condition: We require a refuge permit.

B. Upland Game Hunting. We allow hunting of squirrel and rabbits on designated areas of the refuge subject to the following condition: We require a refuge permit.

C. Big Game Hunting. We allow hunting of white-tailed deer on designated areas of the refuge subject to the following conditions: We require a refuge permit.

D. Sport Fishing. [Reserved]

Draft Recreational Fishing Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 3 Recreational Fishing 605 FW 3.1

3.1 What is the purpose of this chapter? This chapter provides the Fish and Wildlife Service's (Service) policy governing the management of recreational fishing on units of the National Wildlife Refuge System (System or we).

3.2 To what programs does this chapter apply? The policies contained in this chapter apply to recreational fishing on national wildlife refuges, waterfowl production areas, and coordination areas, which are all units of the System.

3.3 What is our policy on fishing on refuge lands? The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. We recognize fishing as a traditional outdoor pastime that is deeply rooted in America's natural heritage. Fishing is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will especially invest our resources in providing high quality fishing experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide to the public fishing opportunities. Our fishing programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. The Service's Division of Fish and Wildlife Management Assistance and Habitat Restoration has many field offices with a broad range of expertise that are available to the Refuge Manager when planning and managing fishing programs. We encourage refuge managers to take advantage of this important resource. We rely on close cooperation and coordination with State fish and wildlife management agencies in managing fishing opportunities on refuges and in setting refuge population management goals and objectives. Regulations permitting fishing within the System shall be, to the extent practicable, consistent with State fish and wildlife laws, regulations, and management plans. We encourage refuge staff to take advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

3.4 What are the objectives for our fishing programs? The objectives of the System's fishing program are to: effectively maintain healthy and diverse fish population resources through the use of scientific management techniques; to promote public understanding of, and increase public appreciation for, America's natural resources and the Service's role in managing the System; to provide opportunities for high-quality recreational and educational experiences; and to minimize conflicts between anglers and other visitors.

3.5 What are the authorities that allow fishing on the System? Refer to 605 FW 1 for laws and Executive orders that govern fishing on System lands.

3.6 Do we have common definitions for fishing terms? The following are definitions of terms used in reference to fishing.

A. Open to the public. Open to the public for fishing means we allow fishing by any individual who holds, if required, a valid license, permit(s), stamp(s) or other document allowing the taking of a specific species of fish on System waters. Areas open to fishing may differ from areas open to the general public for other recreational activities. We note this distinction through the use of signs and outreach materials, such as general refuge brochures or fishing brochures.

B. Quality fishing experience. A quality fishing experience is one that contributes to management objectives and accomplishes the following:

(1) Maximizes safety for anglers and other visitors;

(2) Causes no adverse impact on populations of resident or migratory species, native species, threatened and endangered species, or habitat;

(3) Encourages the highest standards of ethical behavior in regard to catching, attempting to catch, and releasing fish;

(4) Is available to a broad spectrum of the public that visits, or potentially would visit, the refuge;

(5) Provides reasonable accommodations for individuals with disabilities to participate in refuge fishing activities;

(6) Reflects positively on the System;

(7) Provides uncrowded conditions;

(8) Creates minimal conflict with other priority wildlife-dependent recreational uses or refuge operation;

(9) Provides reasonable challenges and harvest opportunities; and

(10) Increases the visitors understanding and appreciation for the fisheries resource.

C. Native fisheries. Fish that, other than as a result of an introduction, historically occurred in a specific watershed. By "historically" we mean a period identified as time before European contact or settlement.

D. Tournament fishing. A fishing competition for monetary or other prizes.

E. Shellfish harvest. The recreational harvest of abalone, clams, crabs, crayfish, lobster, mussels, oysters, scallops, shrimp, or other marine and freshwater invertebrates.

F. Nontoxic tackle. A weighted tackle (jigs and sinkers) made of materials other than lead or lead alloys.

G. Nonnative/alien species. Any species, including its seeds, eggs, spores, or other biological material capable of propagating that species, that is not native to that ecosystem.

H. Set tackle. Any fishing hook(s), devices, or lines that are not hand held or not attached to a fishing rod, reel, or pool under the immediate control of the user (excludes rod and pole holders and ice fishing tip-ups). In general terms, set tackle is any fishing tackle designed, rigged, floating or tied off for the purposes of catching fish while "unattended" by the fishing visitor (*e.g.*, trotlines, setlines).

I. Natural bait. Any natural live aquatic organism used to catch target fish.

3.7 When do we address the decision to allow fishing for proposed additions to the System? When lands or waters are under consideration for addition to the System, the Refuge Manager will make an interim compatibility determination on any existing priority public use. The record of decision establishing fishing on the refuge must document the completion of such determinations. The results of these determinations are to be in effect until the completion of a Comprehensive Conservation Plan (CCP). It is during the development of the CCP and implementation of National Environmental Policy Act (NEPA) that we accept public comments and incorporate them into the decision to allow fishing on the refuge. Refer to the Comprehensive Conservation Planning Process Chapter (602 FW 3) for detailed information on this process.

3.8 What are the procedures for opening System waters to fishing? The decision to open a refuge to fishing depends on the provisions of laws and regulations applicable to the specific refuge and a determination by the Refuge Manager that opening the area to fishing or harvest of other aquatic species will be compatible. This decision must also be consistent with the principles of sound fishery management, applicable fisheries objectives, and otherwise be in the public interest (see 50 Code of Federal Regulations (CFR) 32.4).

A. Specific conditions. The following conditions apply to fishing on certain units of the System:

(1) Waterfowl Production Areas (WPAs). WPAs are open to fishing subject to State law (50 CFR 32.4) as long as it is compatible. A rulemaking document is not necessary to open these areas to fishing since they are open unless closed. We may restrict WPA fishing programs by following the procedures established for refuges. Under 50 CFR 32.4, we may also temporarily close WPAs to fishing and other public use if circumstances warrant.

(2) Wetland easements. We have no authority over fishing on wetland easements, which we most often acquire as part of the Small Wetland Acquisition Program, unless we purchased specific rights with the easements. For these easements, the landowners has usually retained all rights to control public access, including access for fishing and other recreational uses.

(3) Easement refuges. The rights acquired with the individual easement refuge determine our control over fishing on easement refuges. The Regional Director is responsible for determining the extent of control over fishing on these areas. If we control fishing, the Refuge Manager must follow all procedures required to open a refuge to fishing.

(4) Farm Service Agency Easements (formerly Farmers Home Administration (FmHA)). We have no authority over fishing or other forms of public use on easements obtained through the various Farm Service Agency inventory property easement programs of 1985, 1990, and 1996. The landowner retains the right to control access for fishing and other recreational uses.

(5) National wildlife refuges in Alaska. The Alaska National Interest Lands Conservation Act (16 U.S.C. 410hh–3233 and 43 U.S.C. 1602–1784) opens all national wildlife refuges in Alaska to fishing under applicable Federal and State law as long as it is compatible (50 CFR 36.32). A fishing plan or rulemaking document is not necessary to permit fishing on these refuges. We may prohibit or restrict the taking of fish only in conjunction with notices and hearings under the requirements of 50 CFR 36.42 regarding public participation and closure procedures. Local rural residents may fish and gather shellfish for subsistence uses in compliance with applicable Federal and State laws. Non-wasteful subsistence use of wildlife by local rural residents has priority over other consumptive uses permitted on national wildlife refuges in Alaska.

B. Evaluation criteria for fishing programs. We will use the following criteria and standards to evaluate fishing programs on units of the System:

(1) Compatibility. A fishing program must be compatible with the purpose(s) of the refuge and the System mission.

(2) Biological integrity, diversity, and environmental health. Fishing programs must maintain, or contribute to the maintenance of, viable populations of native species. We design our fishing programs to support accomplishing refuge purposes while maintaining or restoring biological integrity, diversity, and environmental health (see 601 FW 3). We will not establish fishing programs when there is a high potential to adversely affect a significant biological component of an existing native fish population, either by taking fish from that population or by introducing non-native species.

(3) Relationship with other public use programs. An integrated approach to providing opportunities for compatible wildlife-dependent recreational uses will minimize conflicts. The Refuge Manager will evaluate time and space scheduling and zoning as methods to ensure opportunities for a quality experiences among different user groups. In the case of conflicts between priority wildlife-dependent recreational

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use, the Refuge Manager will make the final decision on which use to allow and which to curtail.

(4) Resources. Providing quality recreational experiences for the public requires appropriate funding, facilities, and staff. The House Report accompanying the House of Representatives version of the National Wildlife Refuge System Improvement Act of 1997 (H. Rpt. 105–106) encourages refuge managers to take reasonable steps to obtain outside assistance from States and other conservation interests, if adequate financial resources are not available to manage a priority use in a compatible manner. Refuge managers should work closely with State, community, and conservation partners to help obtain necessary resources to manage the priority wildlife-dependent recreational use programs. Potential sources of support include the following: angling organizations, user fees for hunting; cooperating with State, local, or Tribal agencies; and assistance from refuge support groups or volunteers. We encourage refuge managers to seek and implement other opportunities to obtain additional resources as they become available.

(5) Evaluation and monitoring. Refuge managers must monitor and evaluate their fishing programs regularly. Refuge managers must evaluate both the quality of the recreation experience and the effects of the activity on refuge resources. A wide variety of evaluation tools exist, from simply asking the fishing public how they rate their experience to contracting with a university or private company to conduct a formal survey. If a Refuge Manager decides to use a survey to evaluate the fishing experience, he or she must receive approval from the Office of Management and Budget before conducting any public surveys.

C. Consultation and coordination.

(1) Coordination with states and tribes. When a refuge, or portion thereof, is open to fishing, we generally allow fishing within the framework of applicable State and Tribal regulations. We consult with the State, Tribes, and other appropriate authorities during the development of fishing programs and whenever we plan significant changes. Refuge regulations must be consistent with State and Tribal regulations, to the extent practicable. The use of more restrictive regulations requires consultation with the State or Tribe. We must list regulations that are more restrictive than State or Tribal regulations, such as seasons and fishing hours as refuge-specific regulations in 50 CFR part 32. Refuge-specific regulations must not weaken existing State or Tribal laws and regulations. We must justify deviations from State or Tribal regulations in the refuge fishing plan or amendments to that plan. Refuge managers should discuss refuge-specific regulations with peer-level State or Tribal administrators.

(2) Endangered species consultation. Refuge managers will review all fishing programs annually to determine if they may affect, adversely or beneficially, threatened or endangered species and their habitats. The Refuge Manager will initiate consultation, as appropriate, under Section 7 of the Endangered Species Act and intra-Service consultation procedures, consistent with the "Policy for Conserving Species Listed or Proposed for Listing Under the Endangered Species Act While Providing and Enhancing Recreational Fishing Opportunities," and Section 305 (b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Pub. L. 94–265) regarding effects on "essential fish habitat."

(3) Public involvement. The appropriate level of public involvement must accompany new or significant changes (*e.g.*, boundary change, change of species fished, bait restrictions) to existing fishing programs. We plan efforts well in advance of the proposed changes in order to obtain as much involvement from the public as possible. A variety of methods are available for the Refuge Manager to use to involve and inform the public, including public meetings, workshops, news releases, and mailings to targeted groups. We encourage refuge managers to continue to use these and other methods. We require an outreach plan for new fishing programs or any significant changes affecting existing programs. We develop these plans in coordination with Regional External Affairs Offices for new fishing programs or any major changes affecting existing programs.

D. Documentation required to open a refuge to fishing. The Refuge Manager must submit the following documents to the appropriate staff in the Regional Office. This individual then forwards a copy to the National Wildlife Refuge System Headquarters for preparation of a rulemaking document:

(1) Fishing plan. This plan should be a step-down plan of the refuge's CCP, which must include a compatibility determination on the fishing program. If the unit has not yet completed a CCP, the step-down fishing plan must contain a compatibility determination(s) until the CCP is completed. Cover fishing and shellfish harvest in separate compatibility determinations. The plan must provide overall documentation of the fishing allowed on a refuge, including the relationship of fishing to refuge purpose(s), goals, and objectives of the refuge and the System mission. We label a suggested format for a refuge fishing plan as Exhibit 1 in this chapter.

(2) Appropriate NEPA documentation.

(3) Appropriate decision documentation.

(4) Section 7 evaluation. (See Exhibit 2 for information on Section 7 evaluation.)

(5) Copies of letters requesting state, and where appropriate, tribal involvement and the results of the request.

(6) Draft news release.

(7) Outreach plan. (We label a Directorate-approved outline for an Outreach Plan as Exhibit 3).

3.9 Who prepares and reviews a refuge fishing plan? The Refuge Manager, with technical assistance as required from Service fisheries biologists, State wildlife agencies, and, where appropriate, Tribal governments, is responsible for preparation of the fishing plan. The Regional Director approves the plan before the rulemaking process begins. During the rulemaking process, Headquarter's staff reviews the fishing plan and supporting documents. The Refuge Manager will annually review the fishing plan on the refuge where we allow fishing.

3.10 *What information do we need for publication in the* **Federal Register**? The Refuge Manager will determine the compatibility of conducting a fishing program on the refuge and will document the results in an approved fishing plan. After the Refuge Manager determines that the proposal is compatible, he or she will submit information about whether a refuge will open for fishing and the conditions of that fishing proposal to the Federal Register Liaison at the Headquarters. We will use this information to develop the proposed and final refuge-specific regulations for publication in the **Federal Register** and for codification in 50 CFR.

3.11 *What is the refuge-specific regulation process?* The refuge-specific regulation process is outlined below:

A. The Headquarters must publish in the **Federal Register** any proposed and final refuge-specific regulations pertaining to a refuge's fishing program and that are necessary to conduct that program prior to them becoming effective. Forward all refuge-specific regulations and any changes to 50 CFR part 32 through appropriate channels to the Headquarter's Federal Register Liaison for clearance and submission to the **Federal Register**. The refuge is open to fishing officially after the effective date of the final rule. Fishing can begin concurrently or after the opening of the season under the published regulations.

B. Refuge managers must review these regulations and the refuge fishing plan annually to ensure compatibility and consistency of the fishing program with existing laws and regulations. Regional Offices must submit any amendments (additions, deletions, or modifications) each year to their designated regional hunting and fishing program coordinators who, in turn, send that information to the Headquarter's Federal Register Liaison for inclusion in the rulemaking documents for publication in the **Federal Register**. The Headquarter's Federal Register Liaison must receive this information by January 31 each year to allow sufficient time for compilation and review by concerned program offices and the Solicitor, signature by the Assistant Secretary, and the Departmental review for both proposed and final rules. This includes a 30-day public comment period on the proposed rule. We cannot publish a refuge opening without the complete fishing package. If no amendments are necessary, refuge managers should submit a negative response to that effect to the Regional Office. Refuge-specific regulations should be standard and consistent in format throughout the System. We include guidelines for preparing and submitting regulations and amendments in Exhibit 4.

3.12 *How do we revise a fishing plan?* The Refuge Manager may approve all revisions in fishing plans except major revisions. Major revisions in fishing plans (*e.g.*, addition of new bodies of water or new species available for taking to a fishing program) can occur only as an amendment to the fishing plan unless the original plan included specific conditions under which the revision could occur. Preparation and approval of amendments follow the same guidelines as preparation and approval of the plan. Refuge managers will submit only the revised portion of the plan for approval to the Regional Office. The Regional Director approves revisions only if we have already listed the Refuge in 50 CFR as open to fishing. Otherwise, the Regional Office will submit the amended fishing plan to Headquarters to begin the rulemaking process described in section 3.11.

3.13 *What are the guidelines for refuge fishing programs?* We should plan, manage, conduct, and evaluate refuge fishing programs on a consistent basis in ways that protect habitat, fish and wildlife, ensure angler and visitor safety, and promote positive values such as high ethical standards and respect for the resource. Fishing on refuges must have the attributes of a quality fishing program listed in section 3.6. The following guidelines should help ensure that quality opportunities are available.

A. Permits. We require anglers to have all applicable Federal, Tribal, and State licenses, permits, or stamps in their possession. We can issue refuge permits to limit access, regulate methods, or gather information. If we use refuge permits to limit angler numbers, we will issue them on a random basis to the public. Refuge managers should avoid complicated application processes that require additional resources. Application processes should be flexible to provide an opportunity to all potential anglers. We should coordinate with Tribal and State application and lottery processes where practicable.

B. Fees. We can charge fees for applications, refuge permits, and the use of facilities (*e.g.*, boat ramps) under existing recreation fee programs. We use fees collected to enhance visitor facilities, to protect resources, and to educate visitors. The Regional Fee Coordinator can assist with the approval of fees.

C. Zoning recreational use. We desire a balanced fishing program that allows a variety of angling opportunities and contributes to the quality of a fishing experience. We can use zoning of boat types and motor horsepower to help achieve a balance of allowed uses and to reduce conflicts between anglers and other users. We can also use zoning to provide less competition for youth fishing events, anglers with disabilities, and those using non motorized boats and/or methods that reduce fish mortality, such as catch and release.

D. Law enforcement. Law enforcement is an important part of any fishing program. The effort invested should be sufficient to protect human safety, fish populations, and ensure compliance with regulations based on past experiences and current circumstances.

E. Angler access and vehicle vessel control. Refuge managers should carefully plan, manage, and evaluate angler access and vehicle/vessel control to retain quality opportunities. We should balance "walk-in" and remote fishing opportunities with easily accessible fishing opportunities. We can make exceptions to general access restrictions for anglers with disabilities when necessary to facilitate their experience and when compatible with resource management objectives.

F. Camping. We may allow camping on refuges when we have determined it to be a secondary compatible use that is necessary to support fishing opportunities. Camping is only appropriate when no reasonable (based on time, distance, and expense) lodging opportunities are available off-refuge and when staff resources needed to manage camping do not detract from the quality of another priority wildlife-dependent recreational use (refer to the Appropriate Uses Chapter (603 FW1) for information on non priority uses). Large refuges in the western United States, refuges in Alaska, and some remote refuges allow camping under these criteria..

G. Fishing by service staff. Service employees are subject to the same rules and regulations as the general public. If only limited fishing opportunities exist, refuge managers should discuss with Service employees the need to be sensitive to the possibility of the public perception of conflict of interest. We never authorize Service employees to wear uniform components outside of their official capacity. When employees participate in off-duty fishing opportunities, they are not authorized and, therefore, should never wear uniform components (*e.g.*, uniform ball caps, uniform jeans). In addition, personnel may not use means of access to fish in areas that are not available to the general public. This policy does not apply to the collection of fish by refuge staff for the purpose of monitoring specific fish populations.

H. Communication materials. Professionally developed outreach materials will assist refuge managers by providing clear and thorough information to anglers. Brochures must conform to the U.S. Fish and Wildlife Graphics Standards and be consistent with refuge-specific regulations. Contact your Regional Publications Coordinator for graphic standards. Refuge managers do not need to include regulations and dates that are identical to State seasons. Include information that encourages anglers to fish safely and ethically, and use equipment that reduces injury to released fish (such as barbless hooks). If we develop informational signs, they will conform with the Service's Sign Manual.

I. Tournament fishing. We prohibit this type of fishing on System lands and waters unless we make a specific determination that the event builds appreciation for and an understanding of fish and wildlife resources, does not reasonably interfere with other refuge visitors, and if prizes of only nominal value are awarded. Refer to the Appropriate Uses Chapter (603 FW 1) for additional discussions of competitive events.

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J. Special fishing areas. Our policy is to offer fishing opportunities to as broad a spectrum of the general public as possible. Generally, fishing programs should consider any legal means of fishing, as defined by the State and is determined to be appropriate and compatible and not inconsistent with System policy.

K. Nonnative bait. We will allow no live, nonnative bait (defined, with respect to a particular ecosystem, any species, including its seeds, eggs, spores, or other biological material capable of propagating that species) on System waters where we have jurisdiction. We will generally refer to the individual State's definition of native on System waters.

L. Natural bait methods. Throw nets, minnow traps, and other means/methods of taking natural bait will be done under State regulations unless we list more restrictive regulations in the refuge-specific regulations. We will limit bait collection on refuges to the recreational harvest of natural bait for personal use only; we will allow no commercial harvest of natural bait in waters under the jurisdiction of the System.

M. Limited harvest. We may offer special opportunities to a limited number of anglers in cases where there is a relatively small area of water to fish or we have a relatively low number of fish that are available for harvest.

N. Youth fishing. We encourage refuge managers to set aside areas or times to promote fishing by children or under represented groups. Experiencing the thrill of the catch and exposure to proper fishing methods through programs such as "Pathways to Fishing" and National Fishing Week is important to developing life skills and public support for healthy ecosystems. Refuge managers should take advantage of these opportunities to educate young anglers and their parents about the importance of fisheries management, the need for slot sizes, consumptive and non consumptive fishing opportunities and quality fishing experiences.

O. Barbless hooks. We encourage the use of these devices in our fishing program and recognize the importance of this method in reducing mortality of fish not intended for consumption (e.g. fish outside of the slot size range). As more anglers raise concern over the state of America's fisheries, refuge managers should take the lead in introducing methods that not only promote the experience but educate the angler. By promoting the use of barbless hooks in our brochures and other information sheets, we can, in some cases, avoid the need for increasing seasonal closures.

P. Data collection. Refuge managers should consult with the Service's Fisheries Program Specialist, States, Tribes, and other appropriate entities regarding data collection needs and survey methods.

Q. Nontoxic tackle. Refuge managers may restrict the use of specific types of tackle (e.g., lead fishing weights) in System waters to protect certain species (e.g., loons).

R. Unattended tackle. The use of trotlines, setlines, gillnets, giglines, jug lines, soap lines, snaglines and other unattended tackle, may be allowed if authorized by State fishing regulations. We prohibit the use of unattended tackle by commercial operators on System waters under our jurisdiction except when used as a management tool. We must strictly monitor the unattended tackle program and document the results. The only exception to this policy is found in the Alaska National Interest Lands Conservation Act (ANILCA) under subsistence uses. We do not consider tip-ups used for ice fishing unattended tackle for the purpose of this policy.

S. Ice fishing. We recognize ice fishing as an appropriate fishing opportunity. Refuge managers should encourage this activity where it is compatible and can be conducted in a safe manner. We prohibit the use of long-term structures or structures suitable for overnight occupancy.

T. Night fishing. We allow night fishing when it is appropriate and compatible with the purpose(s) of the refuge and the System's mission. If a refuge generally is not open after sunset, refuge managers may make an exception and permit night fishing. Refuge managers must base the decision on specific refuge objectives and not historical use. Refer to the General Guidance Chapter, 605 FW 1, for additional information about after-hours activities.

3.14 How do we close a refuge to fishing? The Refuge Manager may close all or any part of a refuge that we have opened to fishing whenever necessary to protect the resources of the area or in the event of an emergency endangering life, property, or any population of fish, wildlife, or plants.

A. Emergency closure. We do not require advance public notice for closure under emergency conditions. We notify the public of such closures by signs, special maps, or other appropriate methods.

B. Non-emergency closure. We evaluate non-emergency closure of a refuge fishing program for impacts on wildlife populations, ecosystems, and priority recreation uses. If the impacts are likely to be major or controversial, we prepare an environmental assessment and follow the public participation process identified in the National Environmental Policy Act (NEPA). In Alaska, we do not implement temporary closures (not exceeding 12 months) or restrictions relating to the taking of wildlife prior to the notice and hearing that we will conduct an emergency closure in the vicinity of the affected area(s).

Exhibit 1—Refuge Fishing Plan Format

I. Introduction

Include a general description of the refuge and information pertinent to the planned fishing program. If refuge managers develop this fishing plan as a portion of an integrated public use plan, we do not require this information. Include non repetitive general information in the Comprehensive Conservation Plan.

II. Conformance with Statutory Authorities

Explain how the program will be compatible with the System mission and the purpose(s) for which the refuge was established. Include projections of the resources (staff and funding) needed to conduct the program and their sources. Include an explanation of how the program will address the requirements of applicable authorities.

III. Statement of Objectives

List the major refuge objectives and the specific objectives of the fishing program. Describe how fishing will impact the refuge objectives.

IV. Assessment

Evaluate the fishing resources on the refuge populations and habitat. Points to be discussed include, but are not limited to, the following:

a. A biological evaluation.

b. Will populations sustain fishing and still support other wildlife-dependent priority uses?

c. Do fished species and other wildlife compete for habitat?

d. Do fished species prey on other species at unacceptable levels?

V. Description

Describe the program in detail using graphics as needed. The description should include:

a. Areas of the refuge that support fished species.

b. Areas of the refuge you intend to open to fishing.

c. Species for which you will allow fishing and fishing periods.

d. Justification of permit system, if required.

e. Consideration of user fees.

f. Consultation and coordination procedures with States and Tribes, including justification of refuge-specific regulations.

g. Methods of control and enforcement.

h. Consideration of providing opportunities for anglers with disabilities and youth anglers.

VI. Measures Taken to Avoid Conflicts With Other Management Objectives

a. *Biological conflicts.* Include Section 7 consultation, and other measures proposed to minimize or eliminate conflicts with endangered species or nontarget species.

b. *Social Conflicts.* Include proposed measures that minimize or eliminate conflicts with other user groups.

VII. Program Specifics

a. Refuge-specific regulations.

b. Outreach plan.

c. Angler application and registration procedures (if needed).

d. Description of angler selection process (if needed).

e. Draft news release regarding the fishing program.

f. Angler requirements.

(1) Age of angler.

(2) Allowable equipment.

(3) Licensing and permits.

(4) Reporting requirements.

(5) Angler training and safety.

(6) Other information (use of boats, motors, etc.).

VIII. Compatibility Determination

IX. Appropriate NEPA Documents

X. Evaluation

a. Monitoring and reporting use levels and trends.

b. Surveying needs of the fishing visitor.

c. Are we meeting program objectives?

d. Do we need to resolve any conflicts?

e. Refuge/Regional Office review schedule.

Exhibit 2—Priority Wildlife-Dependent Recreation (Fishing)

Use the following terminology for your section 7 determination as to whether the opening of your refuge to hunting and/or fishing will affect the continued existence of any endangered or threatened species or result in the destruction or adverse modification of habitat of such species within the System.

Types of Effects

1. *No effect:* The appropriate conclusion when the Service determines that a proposed Service action will not affect a listed species or designated critical habitat.

2. *Is not likely to adversely affect:* The appropriate conclusion when effects on listed species are expected to be discountable, insignificant, or completely beneficial. Beneficial effects are contemporaneous positive effects without any adverse effects to the species. Insignificant effects relate to the size of the impact and should never reach the scale where take occurs. Discountable effects are those extremely unlikely to occur. Based on best judgment, a person would not (1) be able to meaningfully measure, detect, or evaluate insignificant effects; or (2) expect discountable effects to occur.

3. *Is likely to adversely affect:* The appropriate finding in a biological assessment (or conclusion during information consultation) if any adverse effect to listed species may occur as a direct or indirect result of the proposed Service action or its interrelated or interdependent actions, and the effect is not: discountable, insignificant, or beneficial (see definition of "is not likely to adversely affect"). In the event the overall effect of the proposed Service action is beneficial to the listed species but is also likely to cause some adverse effects, then the proposed Service action "is likely to adversely affect" the listed species. If incidental take is anticipated to occur as a result of the proposed action, an "is likely to adversely affect" determination should be made. Such a determination requires the initiation of formal intra-Service section 7 consultation (see definition of "informal intra-Service consultation").

4. *May affect:* The appropriate conclusion when a proposed action may pose *any* effects on listed species or designated critical habitat. When the Federal agency (in this case the Service) proposing the action determines that a "may affect" situation exists, then the Service must initiate formal consultation or seek written concurrence from the involved Service programs that the action "is not likely to adversely affect" listed species.

5. *Is likely to jeopardize proposed or candidate species/adversely modify proposed critical habitat:* The appropriate conclusion when the Service identifies situations where the proposed Service action is likely to jeopardize the continued existence of a species proposed for listing or a candidate species, or adversely modify an area proposed for designation as critical habitat. If this conclusion is reached, intra-Service consultation is required.

Types of Consultation

1. Formal intra-service consultation: A process between a Service program taking/authorizing an action and another Service program affected by that action that: (1) determines whether a proposed Service action is likely to jeopardize the continued existence of listed species or destroy or adversely modify designated critical habitat; (2) begins with the Service program taking the action providing a written request and submittal of a complete initiation package to the affected Service program; and (3) concludes with the issuance of a biological opinion and incidental take statement by the affected Service program. If a proposed Service action may affect a listed species or designated critical habitat, formal intra-Service consultation is required (except when the involved Service programs concur, in writing, that a proposed action "is not likely to adversely affect" listed species or designated critical habitat). [50 CFR 402.02; 50 CFR 402.14]

2. Informal intra-service consultation: An optional process that includes all discussions and correspondence between Service programs, prior to formal intra-Service consultation, to determine whether a proposed Service action may affect listed species or critical habitat. This process allows the Service to utilize its in-house expertise to evaluate a Service program's assessment of potential effects or to suggest possible modifications to the proposed action that could avoid potentially adverse effects. If a proposed Service action may affect listed species or designated critical habitat, formal intra-Service consultation is required (except when the involved Service programs concur, in writing, that a proposed action "is not likely to adversely affect" listed species or designated critical habitat). [50 CFR 402.02; 50 CFR 402.13]

Exhibit 3—Outreach Plan Summary

I. Issue: (State the issue in one or two sentences.)

II. Basic Facts About the Issue:

III. Communication Goals:

IV. Message:

V. Interested Parties:

VI. Key Date:

VII. Strategy:

Exhibit 4—Guidelines for Preparation of Refuge-Specific Fishing Regulations

Fishing regulations on national wildlife refuges accomplish three major purpose(s): They protect the resource, manage it, and ensure safety. State fishing regulations generally provide the framework for meeting these three criteria. When State regulations fall short of meeting these criteria, refuge-specific regulations are necessary. These regulations should focus primarily on management of the wildlife (fisheries) resource and should be enforceable. For example, if we require permits on a specific refuge, a statement that we require special refuge permits is all that is necessary. Details are not appropriate in the regulations. Address details in a leaflet or the permit application. Also, do not submit text for your refuge unless it represents a CHANGE to the existing language in part 32. If you are adding conditions to those already published, state that these are "adds" and indicate where you want them inserted in the text.

Duplication of existing 50 CFR provisions. When writing your regulations, check 50 CFR to avoid duplication. For example, in Part 27, Prohibited Acts, Section 27.31 restricts motor vehicles to "designated routes of travel. * * * delineated on maps by the Refuge Manager;" Section 32.2(j) adequately covers possession of alcohol; and Section 27.95 prohibits setting fires.

Duplication of State regulations. 50 CFR 32.2 states "(d) Each person shall comply with applicable provisions of the laws and regulations of the State wherein any area is located unless further restricted by Federal law or regulation." Therefore, do not repeat State creel limits, seasons, etc., in the refuge-specific regulations. Refuge managers will justify why refuge-specific regulations deviate from State laws and regulations in a cover memo to the appropriate regional office representative.

Preparation of refuge-specific regulations. List tackle limits, creel limits, seasons, and hours that differ from the State's in the refuge-specific regulations. Please use the following examples for your submission for changes or additions to part 32:

For modifications to existing text in part 32:

Section 32.32 Illinois.

Chautauqua National Wildlife Refuge

D. Sport Fishing.

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Replace condition D.1. with the following:

You may fish on Lake Chautauqua from January 15 through October 15. You may not fish in the Waterfowl Hunting Area during waterfowl hunting season.

Delete condition D.2.

Renumber conditions D.3., D.4., and D.5., to become D.2., D.3., and D.4., respectively.

To add a refuge that is opening for fishing for the first time:

Section 32.63 Texas

Lower Rio Grande Valley National Wildlife Refuge

D. Sport Fishing. We allow sport fishing on designated areas of the refuge subject to the following conditions:

1. We only allow fishing at the three designated access sites on the Boca Chica Tract.

2. You must adhere to all applicable State fishing regulations.

Draft Wildlife Observation Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 4 Wildlife Observation 605 FW 4.1

4.1 *What is the purpose of this chapter?* This chapter provides the Fish and Wildlife Service's (Service) policy governing the management of recreational wildlife observation on units of the National Wildlife Refuge System (System).

4.2 *What programs does this chapter apply to?* The policies contained in this chapter apply to recreational wildlife observation within the System.

4.3 *What is our policy regarding wildlife observation on refuge lands?* The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. Wildlife observation is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will especially invest our resources in providing high quality wildlife observation experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide to the public wildlife observation opportunities. Our wildlife observation programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. We encourage refuge staff to coordinate refuge wildlife observation programs with applicable local, State, and Federal programs. We also encourage refuge staff to take advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

4.4 *What are the objectives of our wildlife observation program?* The objectives of the System wildlife observation program are to promote public understanding of and increase public appreciation for America's natural resources and the System by providing safe, enjoyable, attractive and accessible wildlife viewing opportunities and facilities.

4.5 *What authorities allow us to support wildlife observation activities on National Wildlife Refuge System lands?* Reference 605 FW 1 for laws that govern wildlife observation on System lands.

4.6 *What are the elements that constitute quality wildlife observation opportunities?* Essential elements of a quality wildlife observation experience include the following:

A. Observations occur in a primitive setting or use safe facilities and provide an opportunity to view wildlife and its habitat in a natural environment;

B. Observation facilities or programs maximize opportunities to view the spectrum of wildlife species and habitats of the refuge.

C. Observation opportunities, in conjunction with interpretive and educational opportunities, promote public understanding of and increase public appreciation for America's natural resources and the role of the System in managing and protecting these resources;

D. Viewing opportunities are tied to interpretive and educational messages related to stewardship and key resource issues;

E. Most facilities blend with the natural setting, station architectural style, and provide viewing opportunities for all visitors, including persons with disabilities;

F. Design of observation facilities minimize disturbance to wildlife while facilitating the visitor's views of the spectrum of species found on the refuge;

G. Observers understand and follow procedures that encourage the highest standards of ethical behavior;

H. Viewing opportunities exist for a broad spectrum of the public; and

I. Observers have minimal conflict with other priority wildlife-dependent recreational uses or refuge operations.

4.7 *How do we address the quality of our wildlife observation programs when funding is an issue?* Limited funding and staff may affect the quality of the wildlife observation experience that a refuge is able to offer the public. Refuge managers must scrutinize the impacts that lack of resources will have on the ability to provide quality wildlife observation opportunities to the public. It is appropriate to concentrate resources on fewer, high quality opportunities or seek partnerships to provide opportunities rather than offer many wildlife viewing opportunities that lack quality. When a refuge accepts funding to improve wildlife observation opportunities from partnership organizations, the Refuge Manager must ensure that the opportunity is provided in the most appropriate location.

4.8 *How do we foster public stewardship in our wildlife observation programs?* Refuge managers provide opportunities for the public to observe wildlife in order to instill in them an appreciation for the value of and need for fish and wildlife habitat conservation. Refuges provide enhanced opportunities to view wildlife in their natural habitat by identifying viewing areas, providing platforms, viewing equipment, providing brochures and interpreters, and designing tour routes. Refuge managers should seek to develop partnerships with organizations that promote wildlife observation and take steps toward conserving such resources. We encourage Refuge managers to design local "hands-on" activities that inspire participants to become involved in habitat restoration and other outreach programs. These opportunities foster a sense of stewardship for the System, wildlife, and habitat resources through direct association.

4.9 *Is there a special need to provide safety and accessibility within our wildlife observation programs?* Key issues for providing a quality wildlife observation program include accessibility and public safety. They are two of our highest priorities when evaluating our programs.

A. The Refuge Manager will ensure wildlife observation opportunities are accessible to a broad spectrum of visitors. Refuge managers must locate and design wildlife observation facilities to meet the needs of visitors with different abilities. The wildlife observation program fulfills accessibility standards and requirements by adhering to the Architectural Barriers Act of 1968 (42 U.S.C. 51, Sec. 4151), the 1984 Uniform Federal Accessibility Standards (UFAS), and the Americans with Disabilities Act of 1990 (42 U.S.C. 126). These acts specify physical accessibility in all construction and renovation projects funded wholly or in part by the Federal government. Also, the Rehabilitation Act Amendments of 1998, (29 U.S.C. 791 et seq.), require accessibility for all programs receiving Federal funds.

B. Visitor safety at refuges is a high priority. The Refuge Manager will construct pullouts and overlooks to reduce vehicular hazards. The Refuge Manager will provide visitors information regarding specific hazards and animal behavior if there is a concern about visitor safety. We may also use environmental education and interpretive programs to alert visitors about safety issues.

4.10 *How should we address visitor conflicts?* Wildlife observation opportunities must be compatible with the purpose(s) of the refuge and the System mission. Increased visitation to refuges, in many cases, will cause user conflicts and may create unavoidable wildlife disturbances. The Refuge Manager may impose use limits or establish zones of use to reduce conflicts. The Refuge Manager determines which uses to allow when conflicts exist between priority recreation uses.

4.11 *What are some examples of tools we can use to support our wildlife observation program?* The following are examples of tools that we can use to support wildlife observation. The Refuge Manager should consider these as guidelines and continually use creativity and ingenuity when providing opportunities that highlight the uniqueness of a particular refuge.

A. Information. Information distribution is an invaluable management tool as well as a means to promote wildlife observation opportunities. Information, distributed through various media, should communicate what wildlife observation opportunities are available, best viewing times, techniques that emphasize respect for wildlife through the minimization of visitor impacts on wildlife, access point information, viewer etiquette, regulations, restrictions, management concerns, and management objectives. Examples of ways to provide information include bird/plant/mammal check lists, brochures, maps, books, watchable wildlife recreation symbols to help identify wildlife viewing opportunities, wildlife viewing guides, movies, slide shows, talks, guided walks, staffed information desks, roving interpreters, formal environmental education classes, teacher workshops, and interpretive exhibits. Distributing information is a way to direct public use to appropriate areas, provide managers with the opportunity to present the refuge, System, and Service messages to visitors, and foster public appreciation and stewardship.

B. Developed observation sites. Developing specific areas for visitors to view wildlife enhances wildlife observation and limits disturbances of wildlife and habitat. During the planning process, Refuge managers must consider constructing viewing areas at sites that are less sensitive to the impacts of visitors. Refuge managers may consider hardening sites (e.g., adding gravel, asphalt, wood chips, etc.) as a method of reducing impacts. Developed observation sites provide a centralized area for visitors to receive information and education needed to produce a safe, high quality experience. Examples of such developments include trails, boardwalks in wet areas, observation platforms, blinds, vehicle pullouts, information kiosks, identification signs, and automobile tour routes. When modifications to facilities to increase accessibility for people with disabilities will deleteriously impact the setting's appearance, environmental features or historic character, we will make efforts to permit people with disabilities alternative access to the activity.

C. Specialized tools. In cases where direct wildlife viewing would be detrimental to sensitive species or habitats, Refuge managers may develop methods that provide remote viewing opportunities. Spotting scopes provide viewing opportunities from a distance. Remote cameras allow for viewing during especially sensitive periods such as nesting. Pictures from remote cameras link with the System's electronic field trip programs and long-distance environmental learning projects. Videos shown in the visitor center highlight wildlife and the purpose of the refuge. The videos aid those who visit the refuge outside of the optimum viewing season. Photographs incorporated into interpretive signs show visitors wildlife and habitats they may encounter. We should consider specialized tools as supplements to and not replacements for direct viewing opportunities. Consider using these tools to provide opportunities that might otherwise be unavailable.

D. Habitat enhancements. There may be situations where it is not feasible for viewers to get to an area for viewing because of cost, remoteness, accessibility problems, safety concerns or sensitivity to disturbance. In such cases, simple enhancement techniques in suitable and more accessible locations may be a solution. Examples of these techniques include creating a pond or wetland environment or creating bird habitat by planting cover vegetation in places where wildlife viewing is more accessible. Refuge managers must adhere to appropriate National Environmental Policy Act procedures before artificially creating habitat. Refuge managers must weigh both the benefits of enhancements to wildlife viewing against the change or elimination of the existing habitat and the potential harm the enhancement activity may have on wildlife.

E. Partners. Partnerships with other Federal and State agencies, Tribes, organizations, industry, local communities and others produce significant contributions to our wildlife observation programs. Refuge managers should contact potential cooperators and demonstrate the advantages associated with being a refuge supporter. Partnerships can develop through the sharing of expertise, personnel, materials, or money, and includes the "sharing" of wildlife and habitat. Wildlife does not observe property lines or agency boundaries. Sharing viewing areas may reduce human pressure from one spot or eliminate uses from sensitive spots by providing them off-site on shared areas. Partnering is an excellent way of fostering a sense of ownership and stewardship of natural resources among a variety of groups.

F. Evaluations. Refuge managers must monitor and evaluate their wildlife observation programs regularly. Refuge managers should evaluate both the quality of the resource experience and the effects of the activity on refuge resources. A wide variety of evaluation tools exist, from simply asking visitors how they rate their viewing experience to contracting with a university or private company to conduct a formal survey. If a Refuge Manager decides to use a survey to evaluate the visitor's wildlife experience, he or she must receive approval from the Office of Management and Budget (OMB) before conducting any public surveys (use of an existing Fish and Wildlife Service OMB-approved customer service evaluation card does not require additional OMB approval). We should have the refuge wildlife observation program reviewed by others to determine the quality of the program, if the program is meeting the specific objectives, and if it is meeting the needs of visitors.

4.12 *Can we close a refuge to wildlife observation?* The Refuge Manager may close all or any part of a refuge that is open to the public whenever it is necessary to protect resources of the area, to prevent potential emergency situations, or in the event of an actual emergency endangering life or property (*i.e.*, severe weather conditions). These closures do not require advance public

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notice to be implemented. We notify the public of such closures by signs, special maps, or other appropriate methods. When considering possible long-term closures, Refuge managers must follow procedures for public involvement as identified in the National Environmental Policy Act (NEPA).

Draft Wildlife Photography Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 5 Wildlife Photography 605 FW 5.1

5.1 What is the purpose of this chapter? This chapter provides Service policy governing the management of recreational wildlife photography on units of the National Wildlife Refuge System.

5.2 What programs does this chapter apply to? The policies contained in this chapter apply to recreational wildlife photography within the System. Reference the guide chapter (604 FW 7) for policies and procedures related to activities such as professional guide services. Reference the Audio Visual Productions chapter (604 FW 10) for policies and procedures related to activities associated with commercial filming and news photography.

5.3 What is our policy regarding wildlife photography on refuge lands? The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. Wildlife photography is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will especially invest our resources in providing high quality wildlife photography experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide to the public wildlife photography opportunities. Our wildlife photography programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. We encourage refuge staff to coordinate refuge wildlife photography programs with applicable local, State, and Federal programs. We also encourage refuge staff to take advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

5.4 What are the objectives of our wildlife photography program? The objectives of the System wildlife photography program are to promote public understanding and increase public appreciation for America's natural resources by providing safe, attractive and accessible wildlife photography opportunities and facilities.

5.5 What authorities allow us to support wildlife photography opportunities on National Wildlife Refuge System lands? Reference 605 FW 1 for laws that govern wildlife photography on System lands.

5.6 Have we defined common photographic terms? Yes. The following are definitions of terms used in reference to wildlife photography.

A. Film. Film is still photographs, motion pictures, and videotapes in digital and analog formats.

B. Recreational photography. Recreational photography is any type of visual recording on film performed by amateur owner/operators of photographic equipment. Casual photography is considered recreational photography and follows this policy (*e.g.*, visitors taking photographs for their own use, non-commercial recreational photo contests).

C. News photography. News photography includes audio-visual productions for news and public affairs, stills, motion-pictures, video, records and audio tapes, such as those produced for television, newspapers, and magazines. News photography on System lands is for the benefit of the general public. Examples of news events are emergencies, special events, or appearances by public figures or other unusual, non-recurring natural phenomenon. News photography will not require a permit but some restrictions may be placed on the activity by the Refuge Manager to protect the resource and/or the individuals associated with the media. Refer to the audio-visual chapter for additional information on this subject (604 FW 10).

D. Commercial photography. Commercial photography is visual recordings by firms or individuals (other than news media representatives) who intend to distribute their photographic content for money or other consideration. We include the creation of educational, entertainment, or commercial enterprises in this category. We also include advertising audio-visuals for the purpose of paid product or services, publicity and commercially-oriented photo contests under this section. We cover commercial photography permit requirements under the audio-visual chapter of this manual (604 FW 10).

5.7 Have we defined a quality wildlife photography opportunity? Yes. The following are essential elements of a quality photographic opportunity and facility.

A. Photographic opportunities occur in or use safe facilities;

B. Photographic opportunities promote public understanding and increases public appreciation of America's natural resources and our role in managing and protecting these resources;

C. Photographic opportunities occur in places that have the least amount of disturbance to wildlife;

D. Photographers understand and follow procedures that encourage the highest standards of ethical behavior;

E. Opportunities are available to a broad spectrum of the photographing public;

F. Facilities, if provided, are fully accessible, reflect positively on us and blend with the natural setting;

G. Photographic opportunities incorporate a message of stewardship and conservation;

H. Photographic opportunities create minimal conflicts with other priority wildlife-dependent recreational uses or refuge operations.

5.8 How do we address the quality of our wildlife photography programs when funding is an issue? Limited funding and staff may affect the quality of the experience. Managers must scrutinize the impacts of lack of resources on quality. It is appropriate to concentrate resources on fewer, high quality opportunities or seek partnerships to provide opportunities rather than offer photographic experiences that are lower in quality.

5.9 How do we address public stewardship in our wildlife photography programs? We provide opportunities to the public in order to develop an appreciation for the value of, and need for, fish, plant and wildlife conservation. These opportunities should also foster a sense of stewardship for the System and its wildlife and habitat resources through direct association.

5.10 Is there a special need to provide safety and accessibility within our wildlife photography programs? Not only are public safety and accessibility key to a quality wildlife photography program, they must be two of our highest priorities when evaluating our programs. We construct pullouts and overlooks to reduce vehicular hazards to photographers. We give our visitors information regarding specific hazards and animal behavior if we have a concern about visitor safety. Environmental education and interpretive programs may also be used to bring safety concerns to the attention of photographers. We will make every effort to ensure wildlife photographic opportunities are accessible to a broad spectrum of visitors.

5.11 How should we address user conflicts? Wildlife photography opportunities must be compatible with the purpose of the refuge and the System mission. Increased visitation to refuges will cause user conflicts and may create unavoidable wildlife disturbances. Refuge managers may impose use limits or establish zones of use to reduce conflicts. As an example, casual wildlife observers may disturb photographers at a specific site that provides the best opportunity on the refuge to observe bald eagles. The Refuge Manager may work out a partnership with the State to provide a roadside viewing point just off the refuge along the highway for general observation. The Refuge Manager may then decide to limit the area within the refuge to photographers or those wanting to use photography blinds.

5.12 Can we close a refuge to photography? As long as a refuge is open to the public, we cannot close it specifically to photography. The Refuge Manager may close all or any part of a refuge that is open to the public whenever it is necessary to protect resources of the area or in the event of an emergency endangering life or property (*i.e.*, severe weather conditions). We do not require advance public notice for closure under emergency conditions. The public is notified of such closures by signs, special maps, or other appropriate methods. When considering possible long term closures, refuge managers must follow procedures for public involvement as identified in the National Environmental Policy Act (NEPA).

Draft Environmental Education Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 6 Environmental Education 605 FW 6

6.1 What is the purpose of this chapter? This chapter identifies Service policy and guidance governing environmental education (EE) as a priority wildlife-dependent use of the National Wildlife Refuge System.

6.2 What is the scope of this chapter? This chapter applies to Refuge System environmental education programs and services. Along with this policy guidance, we will use other documents including but not limited to *Connecting People to Wildlife, Environmental Education in the National Wildlife Refuge System*, an environmental education guidance document for the Refuge System (Appendix 1).

6.3 What is our policy for environmental education? The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. Environmental education is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will especially invest our resources in providing high quality environmental education experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide to the public environmental education opportunities. Our environmental education programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. We will work with local schools, citizen groups, and other organizations to provide programs and assistance that promote awareness, appreciation, and understanding of the role the System plays in the conservation of fish, wildlife, plants, and cultural and historical resources. We encourage refuge managers to coordinate refuge environmental education programs with applicable local, State and Federal programs. We also encourage refuge staff to take advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

6.4 What are our objectives for environmental education programs on refuges? Our environmental education programs:

A. Will provide appropriate materials, equipment, facilities, and study locations to support environmental education, where compatible;

B. Will allow program participants to demonstrate learning through refuge-specific stewardship tasks as well as projects that they can carry over into their everyday lives;

C. Will establish partnerships to support environmental education on refuges open to the public;

D. Will incorporate local, State, and national educational standards in our programs with an emphasis on wildlife conservation;

E. Will assist refuge staff and volunteers to attain the knowledge, skills, and abilities to support environmental education at the minimum or higher levels as defined in Section 6.7C(1) below;

F. Will teach awareness, understanding and appreciation of our trust resources: and

G. Will serve as a means by which refuge employees are seen as role models for environmental stewardship through a continually developing positive relationship with the community.

6.5 What is our legislative authority for environmental education? Reference 605 FW 1 for laws that govern environmental education on Refuge System lands.

6.6 What are some of the terms we use in this chapter? The following are definitions of terms used in this chapter.

A. Environmental education (EE). Activities that use a planned process to build knowledge, skills and abilities in students and others, about wildlife-related environmental topics. EE often follows sequential learning strategies to promote specific learning outcomes.

B. Educational assistance. Either on- or off-site, making EE expertise from Service staff available to schools and teachers, Service entities, government agencies, private groups, and individuals.

C. Outdoor classrooms. Sites of structured EE activities that:

(1) Focus on the natural environment;

(2) Come from an approved course of study with identified learner outcomes; and

(3) Are hands on, involving Refuge System lands.

6.7 How will we develop and implement this chapter? In this chapter we present guidance for planning, implementing, and evaluating EE programs within the Refuge System. Connecting People to Wildlife, the EE guidance document for the Refuge System, curriculum guides, and other documents created for regions or at refuges contain additional guidance.

A. Program support. The Office of the Chief, National Wildlife Refuge System, is responsible for overall guidance, implementation, and management of EE within the Refuge System. Regional Directors designate EE coordinators to assist refuges with education programs and products. The National

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Conservation Training Center (NCTC) offers several EE training courses and model programs as well as program support for our EE programs. Refuge managers plan, develop, and implement EE programs that increase public knowledge, understanding and support for refuge resources.

B. Program planning. Each field station designs its EE objectives and strategies when they develop their Comprehensive Conservation Plan (CCP) or step-down visitor services plan. Managers and staff analyze their EE program potential and determine their educational objectives and develop an interim program if they are not scheduled to develop a CCP within 2 years. In either of these planning processes, refuge staff :

(1) Determine if current or proposed educational sites, programs, and activities are compatible with the Refuge System mission, the purpose(s) of the refuge, and the goals and objectives established for the refuge;

(2) Identify staffing, funding, and other requirements for an EE program, enhancing our EE offerings by working with volunteers and through partnerships with educators;

(3) Identify ecosystem characteristics, endangered species, cultural resources, wilderness, and fish, wildlife, plants, cultural and historical resources that are key resource issues for each field station. Working with educators, we use this assessment to identify target audiences and look for creative ways to tie resource priorities to local educational needs and curricula;

(4) Collect and consistently update data identifying teachers, community resources, transportation constraints, and history of use by educational groups;

(5) Identify current or potential outdoor classroom facilities; and

(6) Identify educational needs and educational outreach opportunities for our staff, volunteers and partners, particularly activities involving nontraditional audiences.

C. Program development and priorities. Field stations establish educational program priorities based on their objectives and mandates, as well as local, State and national priorities. As part of our planning we evaluate educational programs and offer differing levels of EE based in part on the number of staff with public use duties as well as other available resources. Other factors that determine our level of involvement include demand for educational programs, the number of schools near a refuge, and their willingness to participate. We can place our environmental education programs in one of four levels of service. Each field station will use components of one, or a combination of these levels, to design their educational programs to meet local needs, and where possible will strive to include components from the next higher level.

(1) Refuges that have staffs of less than 5 FTEs, and do not have any positions solely dedicated to public use activities. At the minimum level, field station EE programs include:

(a) Creating or providing a lending library of materials and resources for teachers and other educators;

(b) Designating a trained staff contact person for EE;

(c) Designating a study site and providing stewardship opportunities;

(d) Helping local educators identify refuge resources and develop programs;

(e) Forming partnerships or recruiting and training volunteers including senior citizens and/or people with disabilities to conduct EE activities.

(2) Refuges that have staffs of approximately 5–9 FTEs, do not have any positions solely dedicated to public use, and have a Refuge Manager position at the GS 11–12 level. At the standard level, we encourage field stations to:

(a) Conduct and/or host teacher training workshops;

(b) Provide educators with refuge-specific curriculum, activities and lesson plans;

(c) Develop accessible outdoor classrooms;

(d) Establish formal partnerships with school districts and/or community groups to assist with development and implementation of refuge EE programming;

(e) Recruit and train volunteers to assist in developing and presenting EE programming;

(f) Conduct regular EE program evaluation;

(g) Provide opportunities to contribute to refuge management goals through learning and stewardship activities;

(h) Establish a lending library of educational materials, including but not limited to book, trunk, and multimedia resources;

(i) Conduct some on-site and occasional off-site EE programming; and

(j) Employ key staff who have acquired the skills to develop and conduct EE activities.

(3) Refuges that have staffs of approximately 10–14 FTEs with 1 position solely dedicated to public use, and have a Refuge Manager at the GS 12–13 level. At the enhanced level, we encourage field station EE programs to:

(a) Develop a multi-disciplinary EE program with integrated curricula meeting national and State educational standards;

(b) Adapt the refuge's program to increase participant learning and connect environmental health with quality of life;

(c) Develop multiple facilities or study sites, with materials and equipment, that support refuge goals and objectives;

(d) Seek to hire professionally trained refuge EE staff;

(e) Conduct refuge-specific workshops; special events; symposia, including day camps, after-school, and off-site programs; elder hostels; and extended learning opportunities;

(f) Provide EE training and mentoring opportunities for educators, Service staff, and others;

(g) Have an EE program that demonstrates student learning through measurable objectives;

(h) Create an extensive EE outreach program for reaching participants outside the local area;

(i) Allow our EE staff to continue to develop professionally by attending training;

(j) Use technology to interface with off-site participants through the Internet, distance learning and websites; and

(k) Establish partnerships beyond local communities.

(4) Refuges that have staffs of approximately 15 FTEs or more with 1 or more positions solely dedicated to public use, have a visitor center, and have a Refuge Manager at the GS 13–14 level. The "flagship" level applies to stations with EE as part of their purpose(s). Other stations with an enhanced EE program can operate at this level. In addition to items at the enhanced level, we encourage refuges at the flagship level to:

(a) Develop and pilot new programs with broad applications across the Refuge System;

(b) Host local, State or national events/projects such as State duck stamp contests;

(c) Serve as a development site for entry level employees, detailees, and Student Career Experience Program participants;

(d) Become a community or State leader in EE;

(e) Have staff present papers at national conferences;

(f) Have staff serve as mentors or instructors for EE courses and course development;

(g) Perform peer review of other stations' EE program;

(h) Have year-round facilities that support all aspects of the EE program;

(i) Become centers for distance learning;

(j) Develop interactive curricula on refuge/Service websites;

(k) Develop multi-cultural programs as needed; and

(l) Develop outreach and partnerships that have regional focus.

D. Refuge-specific guidelines for developing EE programs: We advance and support the National Wildlife Refuge System mission and goals by developing programs based on the following guidelines. EE programs in the Refuge System strive to:

(1) Connect people's lives to the health of the environment;

(2) Advance science literacy through an interdisciplinary educational approach;

(3) Strengthen the Refuge System through science learning;

(4) Help participants experience the wonder of fish, wildlife, plants, cultural and historical resources;

(5) Stress the role and importance of refuges and emphasize the relationship between wildlife and associated ecosystems;

(6) Be outcome-based, going beyond attending a program to resulting in something of value for both refuge resources and participants;

(7) Pursue outreach and partnership opportunities enhancing programs on and off refuges and expanding our levels of educational expertise and staffing;

(8) Include lesson plans and refuge activity guides that incorporate, complement and focus on local school curricula allowing participants to utilize refuges as living laboratories;

(9) Train educators, volunteers, and partners in resource issues in order to multiply our efforts across a broader spectrum of students;

(10) Establish, maintain, and promote environmental study sites and outdoor classrooms where they are compatible with refuge purpose(s), goals, and objectives;

(11) Involve under-served populations like urban or rural schools, Native Americans, non-English speaking populations, senior citizens, people with disabilities, and groups in the educational community other than K–12 such as colleges and universities;

(12) Expand our capability through technology such as web pages and electronic field trips; and

(13) Use appropriate formats for visitors with disabilities (learning, visual, hearing).

6.8 How do we evaluate EE programs? We evaluate environmental education programs in the following manner:

A. Refuge staff should annually evaluate the program and make necessary changes to strengthen it.

B. As part of our Refuge Management Information System (RMIS), each year we report the number of people taking part in four educational categories: teachers participating in workshops, students taught on-site by staff or volunteers, students taught off-site by staff or volunteers, and non-staff conducted EE. These statistics provide some information about program activity, and we can use the data to identify trends and give an indication of program involvement.

C. Regardless of the level of EE program involvement, we should develop evaluation tools to measure program effectiveness. One simple tool is a comment form given to the leader after an educational field trip. Another way may be to measure the instances of littering, vandalism, or poaching, or compliance with refuge regulations. Refuge staff may consider implementing more detailed evaluation tools to measure learning outcomes and concept retention. Regional or Washington Office staff can assist with developing and analyzing the results of these evaluation tools.

Draft Interpretation Policy

Fish and Wildlife Service

Priority Wildlife-Dependent Recreation

Part 605 Fish and Wildlife Service Manual

Chapter 7 Interpretation 605 FW 7

7.1 What is the purpose of this chapter? This chapter identifies Service policy and guidance governing interpretation as a priority wildlife-dependent use of the National Wildlife Refuge System.

7.2 What is the role of interpretation? As one of the six priority wildlife-dependent uses of the Refuge System, interpretation connects people (visitors) to resources providing opportunities for them to develop an understanding and appreciation for natural and cultural resources. Visitors will receive messages about Refuge System resources through a variety of media including interpretive trails and boardwalks, wildlife centers, talks and walks, audio-visual productions, publications, and exhibits that communicate to a wide spectrum of visitors.

7.3 What is our policy for interpretation? The overarching goal of our priority public use policies is to enhance opportunities and access to high quality visitor experiences on national wildlife refuges while not compromising wildlife conservation. Interpretation is a legitimate and appropriate public use of the System, and along with the five other priority public uses in the Refuge Improvement Act, will receive enhanced consideration over other uses. This means we will especially invest our resources in providing high quality interpretation experiences for refuge visitors. When determined to be compatible, refuge managers are strongly encouraged to provide to the public interpretation opportunities. Our interpretation programs will promote understanding and appreciation of natural and cultural resources and their management on all lands included in the System. We encourage refuge staff to coordinate refuge interpretive programs and materials with applicable local, State, and Federal programs. We also encourage refuge staff to take advantage of opportunities to work with other partners who have an interest in helping us promote high quality wildlife-dependent recreational programs on refuges.

7.4 What are our objectives for interpretive programs on refuges? We will develop and maintain interpretive programs on refuges to:

A. Increase public understanding and support for the Refuge System;

B. Develop a sense of stewardship leading to actions and attitudes that reflect concern and respect for wildlife resources, cultural resources, and the environment;

C. Provide an understanding of the management of our natural and cultural resources.

D. Provide safe, enjoyable, accessible, meaningful, and high quality experiences for visitors increasing their awareness, understanding, and appreciation of fish, wildlife, plants, and their habitats.

7.5 What is our legislative authority for interpretation? Reference 605 FW 1 for laws that govern interpretation on Refuge System lands.

7.6 Do we have common definitions for interpretive terms? Yes. The following are definitions of terms used in reference to interpretation.

A. Interpretive plans. Interpretive plans are documents (see Exhibit 1) outlining key resources, visitor profiles, facilities, budget needs, and development plans as part of a refuge Comprehensive Conservation Plan or visitor services plan. The documents include interpretive objectives, themes, and activities presented at a refuge.

B. Interpretive objectives. Desired, measurable outcomes of an interpretive activity.

C. Interpretive themes. Central messages we strive to communicate. All interpretive activities should have messages relating back to overall field station interpretive subjects or topics as well as Service and/or Refuge System themes.

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D. Interpretive activities/tools. The ways we convey interpretive messages to visitors, on-site or off-site, such as, but not limited to, tours, talks, slide presentations, brochures, self-guided trails, audio tapes, videos, and exhibits.

7.7 What are some standards and requirements for interpretive programs? When we develop interpretive programs, we will utilize the following:

A. Principles of interpretation. Our interpretive activities will utilize the principles included in published materials describing the art of interpretation such as Freeman Tilden's "Interpreting Our Heritage" or others. We link the resources of the Refuge System with the concepts and values visitors bring to our sites. Specifically, we strive to:

(1) Relate what we display or describe to each visitor's expectations and experience;

(2) Motivate and reveal;

(3) Inspire and develop curiosity, not solely instruct;

(4) Relate enough of the story to introduce concepts and ideas, pique visitor's interest, allow visitors to develop their own conclusions; and

(5) Organize activities around central themes with measurable objectives.

B. Interpretation as a management tool. Well-designed interpretive services can be our most effective and inexpensive resource management tool. For many visitors, taking part in one or more interpretive activities is their primary contact with refuge staff, their chance to find out about refuge messages, and could be their first contact with the refuge, conservation, and wildlife. Through these contacts, we have the opportunity to influence visitor's attitudes toward the Service and their behaviors when visiting units of the Refuge System. Interpretive planning and subsequent activities and products can:

(1) Help visitors understand the impacts of their actions, minimizing unintentional resource damage and wildlife disturbance;

(2) Communicate rules and regulations so they relate to visitors, solving or preventing potential management problems; and

(3) Help us make management decisions and build public support by providing insight into management practices.

C. Assuring highest levels of quality: We carefully consider personnel, locations, and types of programs and products in order to provide high quality interpretive services.

(1) Staff conducting interpretive services must have more than subject matter knowledge. For example, the skill required to write text for interpretive exhibits and brochures differs from technical writing skills. We strive to select dynamic people who enjoy interacting with visitors, demonstrate organizational and communications skills, and act professionally.

(2) Often, sensitive habitats are the most attractive places to visit and best places to interpret. To minimize impacts on sensitive habitats we: use staff and/or trained volunteers to lead activities; limit group size; select certain times of day for programs; design facilities and activities to minimize disturbance to wildlife and habitats; and close areas seasonally. Visitors can experience sensitive resource areas with minimal impact by using boardwalks, viewing blinds, remote camera views, exhibits, and telescopes. Other techniques may be the use of dioramas, interactive displays, and digital (*i.e.*, CD–ROM) interpretive methods. We can also separate areas devoted to wildlife observation and education from other programs such as fishing and hunting to preserve a high quality experience for all visitors.

(3) While refuge staff should try to reach as many individuals and interest groups as possible with our message, quantity is not the only measure of success. Program quality and effectiveness is crucial. Refuge managers strive for a balanced program with a variety of experiences for visitors with different levels of time, ability, and, interest. Refuge staff periodically review and evaluate programs to assess effectiveness.

D. Making interpretation accessible: We will meet accessibility standards and requirements by adhering to the Architectural Barriers Act of 1968 (42 U.S.C. 51, Sec. 4151), the 1984 Uniform Federal Accessibility Standards (UFAS), and the Americans with Disabilities Act of 1990 (42 U.S.C. 126). These acts specify physical accessibility in all construction and renovation projects funded wholly or in part by the Federal government. Also, the Rehabilitation Act Amendments of 1998, (29 U.S.C. 791 *et seq.*), require accessibility for all programs receiving Federal funds. Meeting accessibility requirements presents the challenge and opportunity to provide better interpretive activities for everyone. Creating media, facilities and programs that are more easily read and understood, paths that are level or have ramps and handrails, and exhibits that provide audio or tactile elements benefits everyone and provides multiple paths to learning.

7.8 Why should we do interpretive planning? We are involved in interpretive planning for the following reasons:

A. Interpretive plans help focus staff time, funding, and other resources on our primary interpretive messages and give focus and direction to exhibits, programs, and other interpretive activities. This planning can also help set field station and funding priorities and help locate sources of alternative funding. We can use elements from Comprehensive Conservation Plans, step-down management plans, and visitor service plans to develop a refuge interpretive plan.

B. When we develop interpretive plans, they become the basis for the development of future programs and services. New activities should always relate to and support the themes developed in the refuge interpretive plan. Exhibit 1 contains a general outline for interpretive plans.

7.9 What delivery methods do we use for interpretive activities? There are two broad categories of interpretive activities: self-guided and personal services. Self-guided interpretation includes brochures, exhibits, kiosks, audio-visual media (including computer programs), and self-guided trails. Personal services interpretation includes information desk duty, group presentations, guided talks and tours, and special events. We provide a variety of interpretive experiences that appeal to a broad spectrum of interests and learning styles. We strive for:

(1) High quality, self-guided services, since they reach a larger audience, are more readily available, and visitors can use them at their own pace;

(2) High quality personal contact to initiate conversation and answer questions; and

(3) A variety of interpretive experiences that appeal to varying visitor interests.

7.10 How should we produce interpretive media? The following are interpretive media available to us:

A. Self-guided products will maintain the highest level of quality and be designed as to be appropriate for the site and audience. Regional Public Use Coordinators can assist with planning, design, and contracting for production of self-guided products. Final approval for text and design of self-guided products comes from the Regional Offices.

B. We will design our brochures and publications following the "U.S. Fish and Wildlife Manual of Graphic Standards for Publications." The Government Printing Office (GPO) processes all of our printing and duplication. Regional Printing Coordinators must approve requests to use a commercial source other than GPO.

7.11 How do we evaluate our interpretive program? We evaluate our programs to assure that we are providing the highest level of service. By periodically reviewing programs, we determine program needs, initiate changes, and decide if we are meeting our goals and objectives. Some sources for evaluation methods are interpretation textbooks, other agencies or organizations, and professional associations like the National Association for Interpretation.

A. Performance evaluation. We evaluate individuals and services to improve delivery methods, messages, and the interpretive approach for future activities. Remember that surveys must follow OMB requirements and restrictions. Some methods used include:

(1) Supervisory feedback;

(2) Peer evaluation;

(3) Self-evaluation; and

(4) Audience evaluations.

B. Program evaluation. Evaluating overall programs helps keep our information up-to-date and current. Often, refuge staff use program attendance and cost to compare activities, but true program evaluation must go deeper. We can identify areas needing further attention by examining use trends, location and time variables, and environmental factors. Areas to consider include:

(1) Is program participation increasing, decreasing, or staying the same?

(2) Do visitors attend more than one program or move on to other sites? Do visitors return and revisit interpretive facilities or guided programs? Do they bring their friends?

(3) Have staffing levels changed?

(4) How much of the station budget are we devoting to interpretive programs? What are those dollars buying?

(5) If too many or too few people attend some programs, what can we do to get attendance to an optimal level?

(6) Should we change or drop the program/activity?

C. Visitor reactions. We use many methods to determine visitor reaction to interpretive activities. We can:

(1) Develop comment forms in a variety of alternative formats, if needed, and make them available at a variety of locations;

(2) Interview visitors in focus groups regarding what they liked or didn't like about our interpretive activities;

(3) Observe and record visitor actions at interpretive facilities (e.g., monitor how long visitors stay, which exhibits they approach, whether they leave early from exhibits, audio-visual, or presentations, or ask thoughtful questions);

(4) Get a fresh perspective by visiting and observing other sites and then critiquing our own facilities;

(5) Observe visitors and note their behaviors when they visit refuges. Record the instances of littering, vandalism, or poaching. Is there a change in compliance with posted regulations?; and

(6) Request a Regional Office visitor services' review or invite staff from other refuges to critique your program.

D. Quality and effectiveness. The impact an activity had on the participants is the most difficult element to evaluate. We can:

(1) Find some visitor impressions by using focus groups and individual interviews;

(2) Use testimonials and unsolicited comments to assess the relative value of programs to visitors; and

(3) Evaluate quality and effectiveness through formal research by working with local colleges and universities.

Exhibit 1—Interpretive Plan Outline

A. Define key resources: Start by deciding what makes the refuge special. Does it have biological significance for key species, the ecosystem, endangered species protection, or restoration? Are there unique habitats represented or notable seasonal natural events? Are there known cultural resources requiring protection or interpretation? Has human history in the area had an impact on resources? Are you conducting habitat or population management activities? You can use maps to show resource locations. To complement the maps you should define habitat sensitivity and, if data exists, acceptable levels of visitation.

B. Define key audiences: Who are our present and future visitors?

(1) Demographics: You can determine some visitor demographics by contacting the State department of tourism, a community visitor's bureau, and neighboring attractions. You can glean some information from visitor contact stations and trailhead registration books. Even parking lot license plate counts can help indicate trends. Formal surveys go more in depth, but contact your Regional Office regarding Office of Management and Budget clearance for information allocation requirements, types of questions you can use, and the best way to administer a survey. From this data you can develop lists of visitor groups, (urban, international, short-term, repeat, schools, families, retirees, special interests like birding, hunting, and others).

(2) Visitor Expectations and Perceptions: What will each group need or expect when they arrive? What part of your interpretive program will appeal to each visitor group?

(3) Use Patterns: Does your refuge have any special concerns relating to seasons, time of day, existing or potential traffic patterns or facility capacity. Do any of these use patterns need to change?

C. Define goals and objectives: We must establish interpretive goals (guiding statements) and objectives (measurable outcomes) in the Comprehensive Conservation Plan. You should refer to this plan when developing your program. Focus on resource priorities on the refuge.

(1) Management goals focus on ways to protect resources while providing visitor opportunities.

(2) Interpretive goals identify what you hope visitors will remember, feel, appreciate, or understand after taking part in an interpretive activity. Objectives are measurable and identify what visitors will be able to do after taking part in your program.

D. Develop interpretive themes: The major messages you want visitors to take with them are themes. They can focus on refuge management issues, ecosystem issues, Refuge System issues, or on the Service. We derive themes for specific interpretive activities from overall station themes. Themes should be resource-based and stated in complete sentences. Developing good themes is difficult. Sometimes, identifying topics first, such as, Wildlife, Ecosystems, Neotropical Migrants, or Endangered Species can help. Often the theme works much like a thesis, and you should develop the theme in a manner appropriate for your audience as you plan out the program.

E. Select interpretive activities: Based on available resources, determine methods and locations for delivering your messages. You should evaluate the pros and cons of each and try to find a balance between personal and self-guided services. One way to do this is to create a chart with headings like Themes, Activities, and Locations to show how and where you will deliver your messages.

F. Implementation: After you have developed activities for your station, you should define staffing, volunteer, facility and funding needs. Prioritize and indicate possible funding sources from within and outside the Service. Input these identified needs in the Refuge Operations System (RONS) and Maintenance Management System (MMS).

G. Evaluation: You should consider evaluation at each phase of the program, especially at the beginning. Using some of the evaluation tools mentioned above, find out if you meet your interpretive goals. Have your themes become a part of the overall station experience? Are you meeting group needs and expectations? What portion of your plan may you need to change?

Dated: December 22, 2000.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[1018-AG19]

Draft Wilderness Stewardship Policy Pursuant to the Wilderness Act of 1964

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We propose to modify our policy for implementing the Wilderness Act of 1964 and the National Wildlife Refuge System Administration Act of 1966 as amended, as Part 610 Chapters 1–7 of the Fish and Wildlife Service Manual. Congress calls for the establishment of a National Wilderness Preservation System to secure an "enduring resource of wilderness" for the American public. This policy updates guidance on administrative and public activities on wilderness within the National Wildlife Refuge System.

DATES: Comments must be received by March 19, 2001.

ADDRESSES: Send comments concerning this draft wilderness stewardship policy via mail, fax or email to: National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; fax (703)358–2248; e-mail Wilderness_Policy_Comments@fws.gov. See **SUPPLEMENTARY INFORMATION** for further information on submitting comments.

FOR FURTHER INFORMATION CONTACT: Elizabeth Souheaver, National Wildlife Refuge System, U.S. Fish and Wildlife Service, Telephone (703)358–1744.

SUPPLEMENTARY INFORMATION: The Wilderness Act of 1964 provides the basis for wilderness protection on the National Wildlife Refuge System (System). It clearly establishes that, as we carry out the Service's mission, the System mission and goals, and the individual refuge establishing purposes in areas designated as wilderness, we do it in a way that preserves wilderness character. This policy gives refuge managers uniform direction and procedures for making decisions regarding conservation and uses of the System wilderness areas.

Purpose of This Draft Policy

The purpose of this draft policy is to implement the Wilderness Act of 1964 within the System. When finalized, this policy will replace existing policy found in the Refuge Manual. It prescribes how the Federal land manager preserves the character and qualities of designated wilderness while managing for the refuge establishing purpose(s), maintains outstanding opportunities for solitude and a primitive and unconfined type of recreation, and conducts minimum requirements analyses before taking any action that may impact wilderness character.

This policy includes the following chapters.

Chapter 1 establishes responsibility for wilderness stewardship, defines terms, and establishes training requirements.

Chapter 2 describes the broad framework within which we manage wilderness, discusses the philosophical underpinnings of wilderness, requires refuges to fulfill the establishing purpose(s) of the refuge and the wildlife conservation mission of the System in ways that prevent degradation of the wilderness that otherwise comply with the requirements of the Wilderness Act, and establishes a process for conducting minimum requirements analyses.

Chapter 3 addresses the general administration of wilderness and natural and cultural resource management. It clarifies the circumstances under which generally prohibited uses (temporary roads, motor vehicles, motorized equipment, motorboats, mechanical transport, landing of aircraft, structures, and installations) may be necessary for wilderness protection. It addresses commercial uses, research, and public access. It confirms that we will generally not modify habitat, species population levels; or natural ecological processes in refuge wilderness unless doing so maintains or restores ecological integrity that has been degraded by human influence or is necessary to protect or recover threatened or endangered species.

Chapter 4 addresses public use management in wilderness. It explains that wilderness areas will emphasize providing opportunities for solitude and a primitive and unconfined type of recreation. Appropriate recreational uses in wilderness are compatible, wilderness-dependent, nonmotorized activities that involve no mechanical transport. This includes the six priority wildlife-dependent uses (hunting, fishing, wildlife observation, wildlife photography, environmental education, and environmental interpretation), if they are compatible. Special needs for persons with disabilities are also addressed.

Chapter 5 confirms that wildland fires are an ecological and evolutionary process of wilderness, and that we respond to such fires according to the refuge Fire Management Plan and in accordance with minimum requirements. We may use prescribed fire to maintain or restore ecological integrity that has been degraded by human influence or is necessary to protect or recover threatened or endangered species.

Chapter 6 provides guidance on developing Wilderness Management Plans.

Chapter 7 describes the three-part process for conducting wilderness reviews. An inventory identifies areas that meet the basic definition of wilderness; a study evaluates all the values, resources, and uses within the area; and the recommendation follows upon completion of an Environmental Impact Statement.

Fish and Wildlife Service Directives System

Because many of our field stations are located in remote areas across the United States, it is important that all employees have available and know the current policy and management directives that affect their daily activities. The Fish and Wildlife Service Directives System, consisting of the Fish and Wildlife Service Manual, Director's Orders, and National Policy Issuances, is the vehicle for issuing the standing and continuing policy and management directives of the Service. New directives are posted on the Internet upon approval, ensuring that all employees have prompt access to the most current guidance.

The Fish and Wildlife Service Manual contains our standing and continuing directives with which our employees must comply and has regulatory force and effect within the Service. We use it to implement our authorities and to set forth our means of compliance with statutes, executive orders, and Departmental directives. It establishes the requirements and procedures to assist our employees in carrying out our responsibilities and activities.

The Fish and Wildlife Service Manual, Director's Orders, and National Policy Issuances are available on the Internet at http://www.fws.gov/directives/direct.html. When finalized, we will incorporate this wilderness stewardship policy into the Fish and Wildlife Service Manual as Part 610 Chapters 1–7.

Authorities

Our authorities to manage wilderness include:

A. Wilderness Act of 1964 (16 U.S.C. 1131–1136)

B. Alaska National Interest Lands Conservation Act (ANILCA) of 1980 (16 U.S.C. 410 hh—3233, 43 U.S.C. 1602–1784),

C. National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–ee), as amended.

D. Specific Service Wilderness Area Authorities. Public Laws 90–532, 91–504, 92–364, 93–429, 93–550, 93–632, 94–557, 95–450, 96–487, 96–560, 97–211, 98–140, and 101–628.

Comment Solicitation

We seek public comments on this draft wilderness stewardship policy and will take into consideration comments and any additional information received during the 60-day comment period. If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to: National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203. You may comment via the Internet to: Wilderness_Policy_Comments@fws.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include: "Attn: 1018–AG19" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at (703)358–1744. You may also fax comments to: National Wildlife Refuge System, (703)358–2248. Finally, you may hand-deliver comments to the address mentioned above.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

This draft Fish and Wildlife Service Manual Wilderness Stewardship policy will be available on the National Wildlife Refuge System web site (http://refuges.fws.gov) during the 60-day comment period.

Required Determinations

1. *Regulatory Planning and Review.* In accordance with the criteria in Executive Order 12866, this document is not a significant regulatory action. The Office of Management and Budget (OMB) makes the final determination under Executive Order 12866.

a. This document will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of the government. A cost-benefit and full economic analysis is not required. The purpose of this document is to update the wilderness management policy implemented by the Wilderness Act of 1964 pursuant to the National Wildlife Refuge System Improvement Act of 1997. A large portion of the updated policy addresses administrative actions and procedures that will enhance the public's wilderness experience by better preserving wilderness character. The updated policy makes only minor modifications to existing refuge wilderness public use programs. These modifications include: encouraging the use of Leave No Trace techniques that will leave the wilderness unimpaired for subsequent users; prohibiting extreme sports (which currently rarely occur); emphasizing the importance of solitude, risk, and challenge in a wilderness experience; encouraging education programs to better inform the public about wilderness; monitoring public use and its physical and social effects; and addressing the special needs of persons with disabilities. The basic restrictions on public use have not changed from current policy: we limit public travel to nonmotorized, nonmechanized means; we allow only commercial uses necessary for realizing the recreational purposes of the wilderness; and we allow scientific studies that conform to minimum requirements.

The data are insufficient to provide more than broad estimates about the effects of this updated policy on public use of wilderness areas on national wildlife refuges. The Service expects that refuges that improve the quality of their wilderness areas, and thereby increase the opportunities for high-quality wilderness experiences, will see an increase in public use. The Service estimates that on balance there will be an increase of 10 percent in the public's use of wilderness areas on refuges.

Following a best-case scenario, three quantifiable outcomes would be attributable to the updating of the wilderness policy. First, if 75 percent of the refuges that currently have designated wilderness were to establish a quality wilderness experience, it would mean an estimated 297,929 user days with a higher level of consumer surplus (Table 1). Second, if an additional 10 percent participation rate in wilderness experiences took place, it would mean an additional 39,724 user days. Third, some of the former wilderness users would switch to sites that allow motorized entrance or some other prohibited mode in wilderness areas. This last effect would be offset by new entrants to the wilderness experience, therefore, we estimate only the additional consumer surplus from new entrants since we have no reason to believe a change in consumer surplus would occur for those users who choose alternative sites with characteristics similar to what they were accustomed.

Since 1991, the trend in wildlife-related activities away from home has been increasing at a slow but steady rate, so we have reason to believe that quality experiences will attract new participants. Using the value of the difference in the upper and lower bounds of the 95 percent confidence interval for average consumer surplus to represent the estimate of the increase in consumer surplus for higher quality fishing and hunting (Walsh, Johnson, and McKean, 1990) yields an estimated increase in consumer surplus of $7.1 million annually. The use of the 95 percent confidence interval will remove the results of outlier studies and will be an acceptable estimate of quality differences in the consumer surplus estimates. To this we add the increase in consumer surplus for an estimated 10 percent new participants, for a total of $8.6 million annually attributable to the updated policy on wilderness management.

The probability of upgrading all refuges with wilderness programs to true wilderness characteristics, as defined by Congress, is very low. Resource constraints have kept these refuges from upgrading wilderness experiences, and it is unlikely that this updated policy will cause all refuges with wilderness designation to upgrade their programs immediately. As a result, we do not expect that this document will increase consumer surplus by as much as $8.6 million annually. Consequently, this document will have a small measurable economic benefit on the U.S. economy but will not have an annual effect of $100 million or more needed for a determination as a significant rulemaking action.

b. This document will not create inconsistencies with other agencies' actions. This updated policy has been developed with the assistance of personnel versed in Federal wilderness

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policy, and is consistent with the wilderness policies of the U.S. Forest Service, National Park Service, and Bureau of Land Management. An interagency wilderness committee meets monthly to discuss and coordinate on wilderness issues. The committee received a copy of the draft policy update and identified no major inconsistencies.

c. This document will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. This updated policy prescribes the management of designated wilderness within the National Wildlife Refuge System. Access to wilderness will be consistent with the outstanding rights-of-way, easements of record, enabling legislation, or other rights granted by law. User fees will not be charged as a result of this policy.

d. This document will not raise novel legal or policy issues. This policy is a revision and clarification of similar policy finalized in May 1986 and, as such, does not present any significant opportunity for novel issues.

2. *Regulatory Flexibility Act.* We certify that this document will not have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). A Regulatory Flexibility Analysis is not required. Accordingly, a Small Entity Compliance Guide is not required.

This policy is administrative, legal, technical, and procedural in nature and provides updated instructions for the maintenance of wilderness areas on the National Wildlife Refuge System. This policy does not increase the types of recreation allowed on the Refuge System but establishes an emphasis on the characteristics desired for a wilderness experience. As a result, opportunities for wilderness experiences on national wildlife refuges may increase. The maintenance of wilderness characteristics are likely to increase visitor activity on the national wildlife refuge. But, as stated above, there is a slight increase in the trend for this activity so the increase may not be that of a substitute site for the activity. At least some, if not all, of the increase will be in participation rates for wilderness use. To the extent visitors spend time and money in the area of the refuge that they would not have spent there anyway, they contribute new income to the regional economy and benefit local businesses.

For purposes of analysis, we will assume that any increase in refuge visitation is a pure addition to the supply of the available activity. This will result in a best-case scenario and is expected to overstate the benefits to local businesses. The latest information on the distances traveled for fishing and hunting activities indicates that over 80 percent of the participants travel less than 100 miles (160 km) from home to engage in the activity. This indicates that participants will spend travel-related expenditures in their local economy. Since participation is scattered across the country, many small businesses benefit. Expenditures for food and lodging, transportation, and other incidental expenses are identified in the National Survey of Fishing, Hunting, and Wildlife Associated Recreation. Using the average expenditures for these categories for wildlife-related recreation away from home with the expected additional participation on the Refuge System yields the following estimates (Table 1).

TABLE 1.—ESTIMATION OF POSSIBLE WILDERNESS OPPORTUNITIES WITH NEW REFUGE POLICY

	Refuge surplus visits	Consumer per day	Without policy update (base)	With policy update change
Refuge Visits With:				
Lower Quality Wilderness	297,929	$12.62	$3,759,867	$7,126,468
High Quality Wilderness	99,310	36.54	3,628,778	
Total Refuge Wilderness Visits	397,239		7388,645	
Increased Wilderness Visits (10%)	39,724	36.54		1,451,511
Total Increase in Consumer Surplus				8,577,979

Using a national impact multiplier for wildlife-associated recreation developed for the report "1996 National and State Economic Impacts of Wildlife Watching" for the estimated increase in direct expenditures yields a total economic impact of $46.0 million (Table 2). Since we know that most of the fishing and hunting (and most likely other wildlife-dependent recreation activities) occurs within 100 miles (160 km) of a participant's residence, then it is unlikely that most of this spending would be "new" money coming into a local economy and, therefore, would be offset with a decrease in some other sector of the local economy. The net gain to the local economies would be no more than $46.0 million and most likely considerably less. Since 80 percent of the participants travel less than 100 miles (160 km) to engage in hunting and fishing activities (and we assume that a similar relationship would hold for other wildlife-dependent activities), their spending patterns would not add new money in the local economy and, therefore, the real impact would be on the order of $9.2 million annually.

TABLE 2.—ESTIMATED EXPENDITURES ASSOCIATED WITH ADDITIONAL REFUGE VISITATION

Total Refuge wilderness visits	397,239
A 10% increase in visits	39,724
Average Expenditures per trip	$397
Total direct expenditures	$15,770,428
National impact multiplier	2.92
Total impact	$46,049,650
80% of impact is a transfer	$36,839,720
20% of impact is new money benefit	$9,209,930

Many businesses (both large and small) may benefit from some increased wildlife refuge visitation. However, we expect that much of this benefit will go to small business because wilderness areas tend to be in rural areas where fewer large businesses locate. We expect that the incremental recreational opportunities will be scattered, and so we do not expect that the document will have a significant economic effect on a substantial number of small entities in any region or nationally.

3. *Small Business Regulatory Enforcement Fairness Act.* The document is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This document:

a. Does not have an annual effect on the economy of $100 million or more. The addition of some wilderness experience opportunities at refuges would generate expenditures by wilderness participants with an economic impact estimated at $9.2 million per year. Consequently, the maximum benefit of this document for businesses both small and large would not be sufficient to make this a major rule. The impact would be scattered across the country and would most likely not be significant in any local area.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. This document will have a small effect on the expenditures of new participants for wilderness opportunities of Americans. Under the assumption that all wilderness opportunities would be of high quality, participants would be attracted to the Refuge System. If the refuge were closer to the participant's residence than alternative sources of wilderness experiences, then a reduction in travel costs would occur and benefit the participant. The Service does not have information to quantify this reduction in travel cost but has to assume that since most people travel less than 100 miles (160 km) to hunt and fish, that the reduced travel cost would be small for the additional days of wilderness activities generated by this document. We do not expect this document to significantly affect the supply or demand for wilderness opportunities in the United States and, therefore, should not affect prices for equipment and supplies, or the retailers that sell equipment. Refuge System wilderness opportunities account for a small portion of the wilderness opportunities available in the contiguous United States.

c. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. Because this document represents such a small proportion of wildlife-related recreational spending, there will be no measurable economic effect on the wildlife-dependent industry, which has annual sales of equipment and travel expenditures of $72 billion nationwide. Refuge visitors made 397,239 visits to refuges for wilderness activities during 1999, compared to 34.9 million visitors for all activities on Refuge System lands. This document seeks to preserve wilderness characteristics for those participants who want this experience and is aimed at providing guidance to Federal managers in establishing quality programs, where the opportunity exists for wilderness programs. Refuges that have or establish wilderness programs may hire additional staff from the local community to assist with the programs, but this would not be a significant increase with a total of 66 refuges participating. Consequently, there is no significant employment or small business effects.

4. *Unfunded Mandates Reform Act.* In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, *et seq.*):

a. This document will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. See 1.a., above.

b. This document will not produce a Federal mandate of $100 million or greater in any year, i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

5. *Takings.* In accordance with Executive Order 12630, the document does not have significant takings implications. A takings implication assessment is not required. This policy will not change the ability of inholders to access their property, although it may affect the way in which they may access it. Depending on the specifics of the easements of record, outstanding rights-of-way, enabling legislation, or other rights granted by law, to disturb the fewest wilderness users we may require inholders to modify their: routes of entry so that access will be through a non-wilderness area; method of access, and use of nonmotorized means; or time of entry.

6. *Federalism.* This document does not have significant Federalism effects to warrant the preparation of a Federalism Assessment under Executive Order 13132. This document will not have substantial direct effects on the States, in the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

7. *Civil Justice Reform.* In accordance with Executive Order 12988, the Office of the Solicitor has determined that the document does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The policy will clarify established policy and result in better understanding of the policies by refuge wilderness visitors.

8. *Paperwork Reduction Act.* This policy does not require any information collection from 10 or more parties and a submission under the Paperwork Reduction Act of 1995 is not required.

9. *National Environmental Policy Act.* We have analyzed this document in accordance with the criteria of the National Environmental Policy Act and 318 DM 2.2(g) and 6.3(D). This document does not constitute a major Federal action significantly affecting the quality of the human environment. An environmental assessment is not required.

We will need to develop Wilderness Management Plans for all refuges with wilderness. We will either incorporate these plans directly into refuge Comprehensive Conservation Plans or as step-down management plans, pursuant to our refuge planning guidance in 602 FW 1–3. We prepare these plans in compliance with section 102(2)(C) of NEPA, and the Council on Environmental Quality's regulations for implementing NEPA in 40 CFR parts 1500–1508. We invite the affected public to participate in the review, development, and implementation of these plans.

10. *Government-to-Government Relationship with Tribes.* In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we have evaluated possible effects on Federally-recognized Indian tribes and have determined that there are no effects. We coordinate wilderness use on national wildlife refuges with Tribal governments having adjoining or overlapping jurisdiction.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 1—Authorities, Responsibilities, Definitions, and Training Requirements

610 FW 1.1

1.1 *What is the purpose of this chapter?* Our Wilderness Stewardship policy describes how we manage refuge wilderness to meet refuge purposes and accomplish the mission of the National Wildlife Refuge System (System), while protecting the enduring resource of wilderness. This chapter provides guidance for the implementation of the Wilderness Act of 1964 and the National Wildlife Refuge System Administration Act of 1966, as amended. This chapter states our authorities and responsibilities, describes wilderness character and related terms, and establishes training requirements.

1.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the

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Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

1.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management include:

A. Wilderness Act of 1964 (16 U.S.C. 1131–1136).

B. Alaska National Interest Lands Conservation Act (ANILCA) of 1980 (16 U.S.C. 410 hh–3233, 43 U.S.C. 1602–1784).

C. National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–ee) (NWRSAA01966), as amended.

D. Clean Air Act Amendments of 1990; Public Law 101–549.

E. Specific Service Wilderness Area Authorities. Public Laws 90–532, 91–504, 92–364, 93–429, 93–550, 93–632, 94–557, 95–450, 96–487, 96–560, 97–211, 98–140, and 101–628.

F. Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–712) as amended.

G. Endangered Species Act of 1973 (16 U.S.C. 1531–1544) as amended.

H. National Historic Preservation Act of 1966 as amended, 16 U.S.C. 470 *et seq.*

I. Archeological Resources Protection Act as amended, 16 U.S.C. 470aa–mm.

J. American Antiquities Act of 1906, 16 U.S.C. 431–433.

K. American Indian Religious Freedom Act of 1978, 42 U.S.C. 1996 and 1996a.

L. Americans with Disabilities Act of 1990, 42 U.S.C. 12207.

M. Native American Graves Protection and Repatriation Act of 1990, 25 U.S.C. 3001–3013.

N. National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321–4347, and the Council on Environmental Quality's (CEQ) Regulations for Implementing the Procedural Provisions of NEPA, 40 CFR 1500–1508.

1.4 *What are our responsibilities?* A. Director. The Director provides national policy for managing wilderness and designates a National Wilderness Coordinator.

B. Regional Director. The Regional Director oversees the Regional wilderness management program, designates a Regional Wilderness Coordinator, and assembles Regional Wilderness Review Teams consisting of the Refuge Manager, selected refuge staff, Refuge Supervisor, and the Regional Wilderness Coordinator to coordinate wilderness reviews.

C. Refuge Manager. The Refuge manager protects, manages, and monitors wilderness areas in accordance with Service policy and the unit's Wilderness Management Plan (WMP); ensures that the refuge Comprehensive Conservation Plan (CCP) addresses the management direction of the wilderness units, and determines the need for a WMP; develops and implements the WMP; conducts wilderness reviews; and provides annual information to the Regional Wilderness Coordinator on the status of ongoing inventories and research initiatives used to monitor wilderness areas. Refuge managers may make minimum requirement decisions (610 FW 2).

D. National Wilderness Coordinator. The National Wilderness Coordinator advises the Chief, National Wildlife Refuge System, on wilderness issues; coordinates wilderness management policies with other wilderness management agencies (Bureau of Land Management, National Park Service, and Forest Service); and coordinates and provides assistance to Regional and refuge offices concerning wilderness issues.

E. Regional Wilderness Coordinator. The Regional Wilderness Coordinator advises the Regional directorate, refuge supervisors, refuge managers, and refuge employees on wilderness issues; coordinates and approves wilderness reviews; reviews Wilderness Management Plans; maintains data on wilderness acreage and training requirements within the Region; and provides a Wilderness Acreage Report (See Exhibit 2) to the Chief, National Wildlife Refuge System, by October 1 of each year. The coordinator concurs on all minimum requirement/tool decisions requiring elevation and receives written copies of all minimum requirement decisions.

1.5 *How do we effectively coordinate with the States?* To the extent possible, we coordinate with States through the conduct of regular meetings to discuss cooperative management needs and approaches. Through the comprehensive conservation planning process, we encourage input from and strive for cooperation and coordination with State fish and wildlife agencies, non-government organizations, universities, and others in setting wilderness management goals and objectives. Our regulations allowing hunting of resident wildlife or fishing within the System shall be, to the extent practicable, consistent with State fish and wildlife laws, regulations, and management plans.

1.6 *What terms do we use in this policy?* A. Adequate Legal Access. The combination of routes and modes of travel that will have the least impact on the wilderness resource, consistent with the outstanding rights-of-way, easements of record, enabling legislation, or other rights granted by law.

B. Aldo Leopold Wilderness Research Institute. An institute located in Missoula, Montana, and established in 1993 to develop "the knowledge needed to improve management of wilderness and other natural areas." The Institute operates under an interagency agreement among the Bureau of Land Management, the National Park Service, the Fish and Wildlife Service, the Forest Service, and the Biological Resources Division of the U.S. Geological Survey.

C. Alien Species. With respect to a particular ecosystem, any species, including its seeds, eggs, spores, or other biological material capable of propagating that species, that is not native to that ecosystem.

D. Arthur Carhart National Wilderness Training Center. A training center, located in Missoula, Montana, established in 1993 to "foster interagency excellence in wilderness stewardship by cultivating knowledgeable, skilled and capable wilderness managers and by improving public understanding of wilderness philosophy, values, and processes." The Carhart Center offers training across the country using experts from all levels of the four Federal wilderness-managing agencies, and outside organizations. The Bureau of Land Management, the National Park Service, the Fish and Wildlife Service, and the Forest Service financially support the Carhart Center.

E. Commercial Photography and Filming. Visual and/or sound recording by a business or enterprise for a market audience such as for a documentary, promotional, television or feature film, advertisement, or similar project. It does not mean bona fide breaking news coverage or casual visitor use that does not adversely impact on resources or visitation.

F. Designated Wilderness Area. An area designated in legislation and that we manage as part of the National Wilderness Preservation System.

G. Emergency. A situation that requires immediate action because of imminent danger to the health and safety of persons within a wilderness area.

H. Generally Prohibited Use. Temporary roads, motor vehicles, motorized equipment, motorboats, mechanical transport, landing of aircraft, structures, and installations generally prohibited by the Wilderness Act Section 4 (c). We may allow them only "as necessary to meet minimum requirements for the administration of the area for the purpose of this Act (including measures required in emergencies involving the health and safety of persons within the area) * * *" or if provided for by the specific wilderness designation legislation for a particular wilderness.

I. Indigenous Species. This means, with respect to a particular ecosystem, a species that, other than as a result of an introduction, historically occurred or currently occurs in that ecosystem.

J. Invasive Species. This means an alien species whose introduction causes or is likely to cause economic or environmental harm or harm to human health.

K. Limits of Acceptable Change. A planning and management framework for establishing and maintaining acceptable and appropriate environmental and social conditions in recreation settings. It emphasizes the conditions we maintain or attain in an area, rather than how much use it can accommodate.

L. Mechanical Transport. Any contrivance for moving people or material on or over land, water, or air that has moving parts, provides a mechanical advantage to the user, and is powered by a living or nonliving power source. We include, but do not limit this to, sailboats, hang gliders, parachutes, bicycles, game carriers, carts, and wagons. We do not include wheelchairs when used by those whose disabilities require wheelchairs for locomotion. We also do not include skis, snowshoes, rafts, canoes, sleds, travois, or similar primitive devices without moving parts.

M. Minimum Requirement Analysis. A documented process used for determining the appropriateness of all actions affecting wilderness.

N. Minimum Tool. The least intrusive tool, equipment, device, force, regulation, or practice determined to be necessary to accomplish an essential task, that will also achieve the wilderness management objective.

O. Motorized Equipment. Machines that use a motor, engine, or other nonliving power source. We include, but do not limit this to, chain saws, aircraft, snowmobiles, generators, motor boats, and motor vehicles. We do not include small battery- or gas-powered devices such as shavers, wristwatches, flashlights, cameras, stoves, or other similar small equipment. We do not include motorized wheelchairs used as defined under mechanical transport.

P. Nondegradation. This concept specifies that, at the time of wilderness designation, the conditions prevailing in an area establish a benchmark of that area's naturalness and wildness. We will not allow degradation of these conditions. The presence of undesirable conditions in one wilderness does not set a precedent or standard that we can apply to other areas.

Q. Primitive Recreation. Nonmotorized activities that provide dispersed, undeveloped recreation which do not require facilities or mechanical equipment.

R. Primitive Tool. The equipment or methods that make use of the simplest available technology that relies on human or animal power.

S. Proposed Wilderness. An area of the Refuge System that the Secretary of the Interior (Secretary) has recommended to the President for inclusion in the National Wilderness Preservation System.

T. Roadless Area. A reasonably compact area of undeveloped Federal land that possesses the general characteristics of a wilderness and within which there is no improved road that is suitable for public travel by means of four-wheeled, motorized vehicles intended primarily for highway use. A route maintained solely by the passage of vehicles does not constitute a road.

U. Roadless Island. A roadless area that is surrounded by permanent waters or that is markedly distinguished from surrounding lands by topographical or ecological features such as precipices, canyons, thickets, or swamps.

V. Solitude. One of the key descriptors of wilderness in the Wilderness Act. Wilderness solitude is a state of mind, a mental freedom that emerges from settings where visitors experience nature essentially free of the reminders of society, its inventions, and conventions. Privacy and isolation are important components, but solitude also is enhanced by the absence of other distractions, such as large groups, mechanization, unnatural noise, signs, and other modern artifacts. It is a highly valued component of the visitor's experience because it is conducive to the psychological benefits associated with wilderness and one's free and independent response to nature.

W. Temporary Structure. Any structure that is easy to dismantle, could be removed completely from a site between periods of actual use, and must be removed at the end of each session of use if the intervening non-use period is greater than 30 days. In Alaska, we manage temporary structures in accordance with Section 1316(a) of the Alaska National Interest Lands Conservation Act.

X. Untrammeled. A key descriptor of wilderness in the Wilderness Act, untrammeled refers to the freedom of a landscape from the human intent to intervene, alter, control, or manipulate natural conditions or processes to provide particular benefits.

Y. Wheelchair. A device designed solely for the use by a mobility-impaired person for locomotion and that is suitable for use in an indoor pedestrian area.

Z. Wilderness Review. The process we use to determine if we should recommend System lands and waters to Congress for wilderness designation. The wilderness review process consists of three phases: inventory, study, and recommendation. The inventory is a broad look at the refuge to identify lands and waters that meet the minimum criteria for wilderness. The study evaluates all values (ecological, recreational, cultural, spiritual), resources (*e.g.*, wildlife, water, vegetation, minerals, soils), public uses, and management within the Wilderness Study Area. The findings of the study determine whether we will recommend the area for designation as wilderness.

AA. Wilderness Study Area. An area we are considering for wilderness designation. We establish it following the inventory component of a wilderness review. It includes all areas that are still undergoing the review process and areas recommended for wilderness designation by the Director of the U.S. Fish and Wildlife Service (Director) to the Secretary.

BB. Wilderness Values. Wilderness values are physical (wildlife, ecosystems, and natural processes), psychological (opportunity for solitude, i.e., avoid the sights, sounds, and evidence of humans), symbolic (national and natural remnants of American cultural and evolutionary heritage), and spiritual (connection with nature and primal forces).

1.7 *What are the training requirements for National Wildlife Refuge System staff?* A. National Wilderness Coordinator. The National Wilderness Coordinator will attend the next available Arthur Carhart National Wilderness Training Center National Wilderness Stewardship training course following appointment to the position, unless the individual has attended a previous national session, and at least every 2 years, a "Wilderness Issues" course, or another course designed by the Training Center to serve as a review of wilderness policy and an update of current wilderness issues.

B. National Wildlife Refuge System Office Staff. Other staff involved in wilderness planning, protection, management, budget, or recreation should attend a National or Regional

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Wilderness Stewardship training course or specialized wilderness courses offered by the Training Center.

C. Regional Wilderness Coordinators. The Regional Wilderness Coordinators will attend the next available National Wilderness Stewardship training course and Regional Wilderness Stewardship training course following their appointment to the position, unless they have attended a previous national or regional session and at least every 2 years, a "Wilderness Issues" course, or another course designed by the Training Center to serve as a review of wilderness policy and an update of current wilderness issues.

D. Refuge Supervisors. Refuge supervisors will attend the National Wilderness Stewardship training course within 2 years, following their appointment to the position, unless they have attended a previous national session and at least every 4 years, a "Wilderness Issues" course, or another course designed by the Training Center to serve as a review of wilderness policy and an update of current wilderness issues.

E. Refuge Managers. Refuge Managers (including complex and unit managers) of refuges containing designated wilderness or a Wilderness Study Area will attend the National Wilderness Stewardship training course within 1 year of their appointment to the position, unless they have attended a previous national session. Other Refuge Managers (including complex and unit managers) should attend the National Wilderness Stewardship training course.

F. Other Refuge Staff. We should train staff members and volunteers who contact visitors on a regular basis regarding wilderness areas in low-impact or "Leave-No-Trace" techniques and be able to help the public make good choices in applying the principles of outdoor ethics.

G. Regional Chiefs, National Wildlife Refuge System. Regional Chiefs, National Wildlife Refuge System, should attend the National Wilderness Stewardship training course within 2 years following their appointment to the position, unless they have attended a previous national session.

1.8 *What are the training requirements for Ecological Services and Fisheries staff?* A. Project Leaders. Project leaders with significant responsibility for Endangered Species Act consultations with wilderness managers or fisheries management in wilderness areas within the Service or with any other Federal agency will attend the National Wilderness Stewardship training course within 2 years of their appointment to the position, unless they have attended a previous national session.

B. Other Staff. We encourage other Ecological Services and Fisheries staff with significant involvement in issues that affect wilderness planning, protection, management, or recreation to attend a Regional Wilderness Stewardship training course or specialized wilderness courses offered by the Training Center.

1.9 *When should State employees attend wilderness training?* When space is available, the Service may recommend State wildlife managers for a Regional Wilderness Stewardship training course or specialized wilderness courses offered by the Training Center.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 2 General Overview

610 FW 2.1

2.1 *What is the purpose of this chapter?* This chapter provides an overview and policy foundation for implementation of the Wilderness Act of 1964 and the National Wildlife Refuge System Administration Act of 1966 as amended. This chapter states the principles of wilderness management, and clarifies the application of the minimum requirement concept.

2.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

2.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management, are contained in 610 FW 1.3.

2.4 *What is the broad framework within which we manage wilderness?* A wilderness overlay deepens and broadens our responsibility to the refuge landscape, compelling us to think beyond our obligation to manage the area for the purposes for which it was established. Wilderness itself is a resource that embodies intangible values as well as biophysical values. As a place "where the earth and its community of life are untrammeled by man," wilderness serves as a reservoir of biological diversity, biological integrity, and environmental health. Wilderness is also a setting for compatible recreation, restoration, and inspiration, and a touchstone to our heritage as Americans, and more universally, as members in the community of life. The convergence of these diverse values (ecological, experiential, and symbolic) into one evocative and encompassing concept is the sum and substance of wilderness—and the source of its power to connect a diversity of people to these remnant landscapes. Wilderness is a place of restraint, for managers as well as visitors.

2.5 *What is wilderness character?* A.

> * * * each agency administering any area designated as wilderness shall be responsible for preserving the *wilderness character* of the area and shall so administer such area for such other purposes for which it may have been established as also to preserve its *wilderness character.* (emphasis added)—Section 4 (b), The Wilderness Act of 1964

B. Preserving "wilderness character," referenced throughout the Act and throughout this policy, is one of our criteria for judging the appropriateness of potential management actions, public uses, and technologies in wilderness. Preserving wilderness character requires that we maintain the wilderness condition: the natural, scenic condition of the land, biological diversity, biological integrity, environmental health, and ecological and evolutionary processes. But the character of wilderness embodies more than a physical condition.

C. The character of wilderness refocuses our perception of nature and our relationship to it. It embodies an attitude of humility and restraint that lifts our connection to a landscape from the utilitarian, commodity orientation that often dominates our relationship with nature to the symbolic realm serving other human needs. We preserve wilderness character by our compliance with wilderness legislation and regulation, but also by imposing limits upon ourselves.

D. The legislative history of the Wilderness Act recognizes the encompassing nature of wilderness character:

> We deeply need the humility to know ourselves as the dependent members of a great community of life, and this can indeed be one of the spiritual benefits of a wilderness experience. Without the gadgets, the inventions, the contrivances whereby men have seemed to establish among themselves an independence of nature, without these distractions, to know the wilderness is to know a profound humility, to recognize one's littleness, to sense dependence and interdependence, indebtedness, and responsibility.—(See Zahniser, The Need for Wilderness Areas, 1956, Exhibit 8)

E. We uphold wilderness character with every decision concerning public uses, management techniques, or technologies that might degrade the wilderness condition. We strengthen wilderness character with every decision to forego actions that have no seeming physical impact, but would detract from the idea of wilderness as a place set apart, a place where our uses, convenience, and expediency do not dominate. As the role we assume shapes the character of wilderness, so it shapes our character as its stewards. (See Exhibit 3 for the complete description of wilderness character.)

2.6 *What are the principles for managing wilderness?* As stated in the Wilderness Act, the purposes of the Act are within and supplemental to the purposes of the lands we administer. We observe five key principles in managing wilderness:

A. Accomplish refuge purposes, the mission of the National Wildlife Refuge System (System), and the purposes of the Wilderness Act.

B. Secure "an enduring resource of wilderness" by maintaining the wilderness character, biological diversity, biological integrity, environmental health, and its community of life.

C. Administer wilderness areas in a manner that retains wilderness character, is compatible with all of the purposes of a refuge, and leaves them unimpaired for future use and enjoyment as wilderness.

D. Provide opportunities for primitive recreational experience, emphasizing activities that are wildlife and wilderness dependent. Maintain physical, social, and managerial settings that are conducive to maintaining the experience of solitude, inspiration, adventure, challenge, and other aspects of wilderness character.

E. Provide opportunities for and conduct wilderness-related research in a manner compatible with all of the refuge purposes and preserving the wilderness environment.

2.7 *What are the purposes of the Wilderness Act?* The purposes of the Wilderness Act are to secure an enduring resource of wilderness, to protect and preserve the wilderness character of areas within the National Wilderness Preservation System, and to administer this wilderness system for the use and enjoyment of the American people in a way that will leave them unimpaired for future use and enjoyment as wilderness.

2.8 *How do Refuge Managers accomplish both the establishing purposes of a refuge and the purposes of the Wilderness Act?* A. The National Wildlife Refuge System Improvement Act (NWRSIA) amendments to the NWRSAA state that the establishing purposes of a refuge "mean the purposes specified in or derived from the law, proclamation, executive order, agreement, public land order, donation document, or administrative memorandum establishing, authorizing, or expanding a refuge, refuge unit, or refuge subunit."

B. The Wilderness Act states that "The purposes of this Act are hereby declared to be within and supplemental to the purposes for which national forests and units of the national park and national wildlife refuge systems are established and administered * * *"

C. The NWRSIA House Report 105–106 says that "This policy serves to underscore that the fundamental mission of our Refuge System is wildlife conservation: wildlife and wildlife conservation must come first."

D. Our wildlife conservation mission is entirely consistent with our wilderness responsibilities. Healthy and natural populations of wildlife are an important component of wilderness. *In Fulfilling the Promise,* the Service's long-term vision document for the System, we recognize wilderness "is a reservoir of biodiversity and natural ecological and evolutionary processes."

E. Because the Wilderness Act purposes become within and supplemental to the purposes of refuges where there is designated wilderness, we modify our management strategies to accomplish both the purposes for which the refuge was established and the purposes of the Wilderness Act. We continue to fulfill the establishing purposes of the refuge and the wildlife conservation mission of the System using management strategies and techniques that prevent degradation of the wilderness resource and comply with the requirements of the Wilderness Act. We do not authorize uses of refuge wilderness that the Wilderness Act prohibits, except when the use is the minimum requirement for the administration of the area for the purpose of the Wilderness Act or in an emergency involving the health and safety of persons.

2.9 *What activities do we prohibit in wilderness?* Section 4 (c) of the Wilderness Act prohibits certain uses in wilderness. It refers to prohibited uses by the public as well as prohibited uses by the wilderness administrators. Section 4 (c) says:

> "Except as specifically provided for in this Act * * * there shall be no commercial enterprise and no permanent road within any wilderness area designated by this Act and, except as necessary to meet minimum requirements for the administration of the area for the purpose of this Act (including measures required in emergencies involving the health and safety of persons within the area), there shall be no temporary road, no use of motor vehicles, motorized equipment or motorboats, no landing of aircraft, no other form of mechanical transport, and no structure or installation within any such area."

A. The Wilderness Act allows for commercial enterprises or services in wilderness when they are "necessary for activities which are proper for realizing the recreational or other wilderness purposes of the areas."

B. Subsequent wilderness legislation may permit uses of individual wilderness areas that the Wilderness Act generally prohibits, and we comply with the provisions of those laws. In Alaska, ANILCA authorizes use of motorized boats and snowmobiles, and the landing of airplanes, for public access in wilderness.

2.10 *How do we determine if a generally prohibited use is the minimum requirement to administer the area for the purposes of the Wilderness Act?* We conduct and document a minimum requirement analysis for all administrative actions that involve one or more of those things generally prohibited by the Wilderness Act, or for any proposed administrative activity that may impact the wilderness resource and character. We authorize a generally prohibited use only if we demonstrate that it is necessary to meet the minimum requirements for the administration of the area in accordance with the Wilderness Act.

A. We will use the interagency guidelines included in Exhibit 4 as procedures for assessing proposed administrative activities, to the extent that they do not conflict with this policy. In essence, these procedures allow us to answer two questions:

(1) Do I need to take some action?

(2) How can I take the action and have the least impact?

B. The analysis helps to clearly weigh the benefits and impacts (including intangible effects on wilderness character) and the cumulative effects of the activity in conjunction with other actions and methods we are applying within the wilderness. We will document the minimum requirement analysis in writing.

2.11 *Can we use a minimum requirement analysis to allow any*

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administrative action in wilderness? No. We consider permanent roads and most commercial enterprises prohibited uses in wilderness, and unless specific legislation authorizes their use, we will not authorize their use. We may authorize a generally prohibited use, but only after documenting the minimum requirement analysis. Administrative approval of generally prohibited actions should be temporary and rare. Only those actions that preserve wilderness character and/or have localized, short-term adverse impacts will be acceptable.

A. In Alaska, ANILCA authorizes use of motorized boats and snowmobiles, and the landing of airplanes, for public access in wilderness. Therefore, we may use motorized boats and snowmobiles for access in Alaskan wilderness without conducting a minimum requirement analysis.

2.12 *Can refuge managers take management actions in wilderness to maintain and restore natural conditions if doing so involves uses generally prohibited by the Wilderness Act?* Yes, if we determine the action to be the minimum requirement necessary to administer the area for the purposes of the Wilderness Act. Wilderness character has components of both wildness ["A wilderness, in contrast with those areas where man and his works dominate the landscape, is hereby recognized as an area where the earth and its community of life are untrammeled by man * * *"; Wilderness Act Sec.2(c)] and naturalness ["* * * an area of undeveloped Federal land retaining its primeval character and influence, without permanent improvements or human habitation, which is protected and managed so as to preserve its natural conditions * * *"; Wilderness Act Sec.2(c)].

A. National wildlife refuges are places where we conserve wildlife and its habitat and we manage for a natural diversity of habitat and species within wilderness. If, for example, an alien species invades a refuge, it is appropriate to eliminate or control it to protect important wildlife habitat and restore biological diversity, biological integrity, and environmental health. In refuge wilderness, we use restraint and choose techniques that protect wildness by avoiding motorized methods, mechanical transport, or the use of permanent structures whenever possible. We also must assure that our management techniques are effective to protect the naturalness of the area. We do this by always conducting a minimum requirement analysis where we review the effects of proposed actions on both wildness and naturalness.

2.13 *What effect do emergencies have on the Wilderness Act's prohibition of uses?* In an emergency involving the health and safety of persons within the wilderness, or where we must traverse wilderness to reach such persons, we may use, or authorize, motorized vehicles and equipment and mechanized transport or land aircraft. We will not need a minimum requirement analysis but should take all steps possible to respond to the emergency without unnecessarily damaging or detracting from the area's wilderness character.

2.14 *When must we conduct a minimum requirement analysis?* A. If the refuge has an approved Wilderness Management Plan (WMP) no older than 15 years, and it includes a written minimum requirement analysis for each planned administrative action that may allow a generally prohibited use (*e.g.*, chainsaws, motorized vehicles, aircraft use, radio repeater sites, rock drills, patrol structures) or have the potential to impact wilderness resources and values, we may carry out those administrative actions explicitly as described in the plan.

The analysis in the WMP must include an estimate of how frequently each administrative action resulting in a generally prohibited use will take place. If circumstances significantly change, or we wish to allow the same nonconforming use in a different part of the wilderness, we must conduct another minimum requirement analysis. If a proposed administrative action was not identified in the WMP, and if it involves a generally prohibited use or impacts the wilderness character and resource, we must conduct a minimum requirement analysis before we allow the proposed action.

B. If the refuge does not have an approved WMP, or one older than 15 years, we must conduct a minimum requirement analysis once a year on each planned administrative action that may result in a generally prohibited use (*e.g.*, chainsaws, motorized vehicles, aircraft use, radio repeater sites, rock drills, patrol structures) or have the potential to impact wilderness resources and values, even if it is a recurring action.

2.15 *What should we consider to determine if an action poses a significant impact to wilderness?* We must consider the full range of wilderness values and character when determining whether or not an action will have an adverse impact on wilderness. These values include the preservation of natural conditions (including the lack of unnatural noises and lights: see Exhibit 5); cultural resource values; the assurance of outstanding opportunities for solitude; the assurance that the action will not diminish the potential for the public to have a primitive and unconfined type of recreational experience; and the assurance that we will preserve wilderness character in an unimpaired condition. Cost or convenience usually do not determine the minimum requirement.

2.16 *Who may make minimum requirement decisions?* Refuge Managers may make minimum requirement decisions only if they have attended the Arthur Carhart Wilderness Training Center national wilderness stewardship course. If managers lack this training, they must submit their written minimum requirement analyses to their supervisor for approval. If the supervisor lacks training, then the supervisor shall request review from an individual with training. In emergencies (see definition 610 FW 1.6G), Refuge Managers without the wilderness training may take appropriate action, but should take all steps possible to respond to the emergency without unnecessarily damaging or detracting from the area's wilderness character.

2.17 *How does the Leave-No-Trace Program affect our management practices?* We have adopted the interagency Leave-No-Trace (LNT) program as our standard regarding minimum impact practices for both the public and ourselves. We influence public ethics of minimum impact by the example we set in the way we conduct our business in the wilderness. We will apply LNT principles and practices to all forms of administrative actions within wilderness. See Exhibit 6 LNT Memorandum of Understanding.

2.18 *Are subsistence uses allowed in wilderness?* In Alaska, we allow subsistence uses by local, rural residents. They are the priority consumptive uses of renewable resources in refuge wilderness, per Title VIII of ANILCA.

2.19 *How will we achieve consistency in managing wilderness?* Four Federal agencies administer wilderness areas: the Fish and Wildlife Service, the Bureau of Land Management, the National Park Service, and the Forest Service. Together we administer the 104-million-acre (41.6-ha) National Wilderness Preservation System, established under the Wilderness Act "for the use and enjoyment of the American people in such manner as will leave them unimpaired for future use and enjoyment as wilderness."

A. We maintain effective intra-agency and interagency communications and cooperation, and encourage, sponsor, and participate in interagency training and workshops designed to promote the sharing of ideas, concerns, and techniques related to wilderness management. We support the Arthur Carhart National Wilderness Training Center and the Aldo Leopold Wilderness Research Institute.

B. We seek to achieve consistency in wilderness management objectives, techniques, and practices wherever possible. In areas where our wilderness adjoins wilderness administered by another land management agency, the Refuge Manager coordinates with adjacent wilderness units to achieve as much consistency as possible in the application of wilderness regulations and management techniques. Coordination can include, but is not limited to, programs and policy concerning the issuance of permits, group and party size, research projects, limits on campfires and pets, and other resource and visitor management issues. We encourage Refuge Managers to consider creating joint management plans with neighboring wilderness areas, where possible.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 3 Wilderness Administration and Natural and Cultural Resource Management in Wilderness

610 FW 3.1

3.1 *What is the purpose of this chapter?* This chapter provides specific direction and guidance on wilderness administration and natural and cultural resource management in wilderness.

3.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

3.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management, are contained in 610 FW 1.3.

3.4 *What is the general policy for administering wilderness and managing natural and cultural resources in wilderness?* We plan and conduct resource management activities in wilderness to conform with the Wilderness Act's purposes of securing "an enduring resource of wilderness" and providing opportunities for "solitude or primitive and unconfined types of recreation." We must document a minimum requirement analysis (see 610 FW 2) for all administrative actions that may diminish wilderness character, especially if they may involve any actions generally prohibited. We will maintain the biological diversity, biological integrity, and environmental health (see 601 FW 3) of wilderness areas. We will apply the principle of nondegradation to wilderness management, and we will measure and assess our actions against each wilderness area's own natural, unimpaired condition.

3.5 *What are the elements of wilderness administration?* A. Structures and Installations. Section 4(c) of the Wilderness Act generally prohibits structures and installations in wilderness areas.

(1) Existing structures and installations. After Congress has designated a wilderness area, we will make an inventory of all existing structures and installations. We may retain structures if we determine them to be of historic significance, essential to accomplish unit purposes, or required to ensure public safety. See 610 FW 3.7C for additional guidance regarding the management of historic structures.

(2) Removal. We will remove structures and installations that are not of historical value, not essential for wilderness administration, not essential to accomplish unit purposes, and not necessary for public safety or allow them to naturally deteriorate. If we decide to restore a site, we allow regeneration by natural succession if soil and climate conditions permit. If revegetation is necessary, we use indigenous plant species.

(3) Construction and maintenance. We will not construct or maintain an administrative structure or installation in wilderness unless it is essential to administering the area as wilderness and accomplishing refuge purposes. We will not construct or maintain structures for administrative convenience, economy of effort, or convenience to the public. Wilderness users should be self-supporting in terms of shelter. In all instances, we should design, construct, or maintain facilities using native materials that blend into the natural landscape. We may establish new structures and facilities identified in Section 1310 of ANILCA on wilderness areas in Alaska after consultation between the head of the requesting Federal agency and the Secretary, and in accordance with such terms and conditions as mutually agreed upon to minimize the adverse effects of such structures and facilities.

(4) Lighthouses. Wilderness status does not alter the U.S. Coast Guard's right to access and operate lighthouses; however, we may allow use of motorized vehicles only if we approve them after documenting a minimum requirement analysis.

B. Roads. Permanent roads are a prohibited use in wilderness [Wilderness Act, Section 4(c)]. We will evaluate all roads in existence at the time of wilderness designation in the unit's Comprehensive Conservation Plan or Wilderness Management Plan (WMP). We may convert roads within wilderness to trails for walking or nonmotorized, nonmechanized transportation or restore them to natural conditions. If we decide to restore a road, we allow regeneration by natural succession, if soil and climate conditions permit. If revegetation is necessary, we will use indigenous plant species.

C. Unpaved Trails. We may provide unpaved trails and trail bridges only where they are essential for resource protection or where significant safety hazards exist during normal use periods. We will design and locate trail improvements to fit into the wilderness landscape as unobtrusively as possible and construct them of native materials. We will determine the need for trail improvements and maintenance through minimum requirement analyses and include them in the WMP for the unit.

D. Motorized Vehicles, Motorized Equipment, and Mechanical Transport. We generally prohibit motorized vehicles and equipment and mechanical transport in wilderness areas [Wilderness Act, Section 4(c)]. We will not use or allow the use of motorized vehicles or equipment or mechanical transport in wilderness unless they are essential to administer the area as wilderness and accomplish refuge purposes, ensure public safety, or to conserve threatened or endangered species, as determined by a minimum requirement analysis. We will not use such equipment or transport for administrative convenience, economy of effort, or convenience to the public. The applicable provisions of ANILCA govern the use of motorized equipment by the public in wilderness areas in Alaska.

E. Public Access.

(1) Inholdings. We will provide adequate legal access to non-Federal land that is effectively surrounded by wilderness, using routes and modes of

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travel causing the least impact to the wilderness area while allowing for the reasonable purposes for which we hold or visitors use the inholding (see ANILCA and 43 CFR 36 for provisions specific to Alaska). If alternate access is available through nonwilderness lands, we will not allow access through wilderness (other than access generally available to the public). We will pursue voluntary land exchanges, purchases, or donations to consolidate ownership where access to inholdings would be detrimental to wilderness character or values.

(2) Alaska. On wilderness lands in Alaska, we will permit the use of snowmobiles, motorboats (excluding airboats), fixed-wing aircraft, and nonmotorized surface transportation methods for access to traditional activities and for travel to and from villages and homesites, subject to reasonable regulations to protect the land's natural and other values (Sections 811 and 1110 of ANILCA and 50 CFR § 36.12). We will issue appropriate notice and hold public hearings on restrictions on these forms of access in the vicinity of the affected area. Such rights are subject to reasonable regulations to protect resource values.

(3) Access for People With Disabilities. The Americans With Disabilities Act of 1990 (Section 507(c), 104 Stat. 327, 42 U.S.C. 12207) reaffirms that nothing in the Wilderness Act prohibits wheelchair use in a wilderness area by an individual whose disability requires the use of a wheelchair. Consistent with the Wilderness Act, we are not required to provide any form of special treatment or accommodation, to construct any facilities, or to modify any conditions of lands within a wilderness area to facilitate such use. In meeting the goal of accessibility, we will ensure that we will afford persons with disabilities experiences and opportunities with other visitors to the greatest extent practicable. We will also work with commercial guides and outfitters to ensure they meet accessibility standards when offering services in refuge wilderness.

F. Commercial Uses. Sections 4(c) and 4(d)(5) of the Wilderness Act prohibit commercial enterprises or services in wilderness, unless such activities are "necessary for activities which are proper for realizing the recreational or other wilderness purposes of the areas."

(1) Guiding and Outfitting. We may authorize wilderness-dependent commercial services, such as guiding and outfitting, if we determine that they are necessary for the public enjoyment of wilderness, provide opportunities for primitive and unconfined types of recreation, preserve the wilderness character of the land, are not in conflict with unit purposes, and are managed in concert with our policies (see 604 FW 2). We will ensure that commercial operators comply with established "Leave No Trace" protocols. We will allow only temporary structures and facilities necessary to support wilderness recreation. We prohibit the storing of permanent equipment and supply caches in wilderness areas by commercial operators. In Alaska, ANILCA authorizes the use of temporary campsites, tent platforms, shelters, and other temporary facilities related to the authorized taking of fish and wildlife if they are not detrimental to unit purposes or the wilderness character of the area. This includes temporary facilities used by guides, outfitters, commercial fishermen, and transporters. Permittees must construct, use, and maintain such facilities and equipment in a manner consistent with the protection of the wilderness character of the area, subject to provisions of ANILCA 1316 (b). Permittees must construct any new facilities with materials that blend with the landscape. We will manage such facilities through Special Use Permits.

(2) Grazing. We generally prohibit commercial livestock grazing in wilderness. We may permit livestock grazing in wilderness areas as a habitat management tool only when it is the minimum requirement to administer the area as wilderness [see 610 FW 2.9]. We prohibit the use of motorized vehicles, motorized equipment, or mechanical transport, except as provided for in 610 FW 2.8. For those wilderness areas where the establishing legislation permits continuation of an existing commercial livestock grazing program, grazing activity will not be curtailed or eliminated solely because the area is included in the wilderness system. In those instances, commercial livestock grazing programs will be managed to minimize impacts and to protect resource values.

(3) Photography and Filmmaking. We prohibit commercial filming and commercial photography in wilderness areas unless we determine it is necessary and proper for providing educational information about wilderness uses, resources or values, or other wilderness purposes. In cases where we allow commercial photography, we will manage it through an audiovisual productions permit. See 120 FW 1 and 2, 605 FW 5, and 43 CFR 5.1 for additional guidance.

G. Rights-of-Way. We will terminate or phase out granted or existing rights-of-way included in wilderness whenever possible. Where it is not possible, we may renew rights-of-way subject to our control only under conditions outlined in the refuge's WMP that protect wilderness character and resources and limit the use of motorized or mechanical equipment. We will not issue any new rights-of-way or expand any existing rights-of-way in wilderness, except in Alaska, as provided for under Title XI of ANILCA (see also 43 CFR 36).

H. Mineral Exploration and Development. We prohibit mineral exploration or development in wilderness, except where valid rights existed prior to wilderness designation. We should remove or extinguish mining claims and non-Federal mineral interests in wilderness through authorized processes including purchasing valid rights. We will not apply this policy to contravene or nullify valid rights vested in holders of mineral interest on our wilderness areas. All claimants must comply with reasonable conditions for the protection of wilderness values. Claimants must conduct mineral development or exploration activities without interfering with the administration of the wilderness or disturbing wildlife, or its habitat. Claimants must confine use and occupation of the area to the minimum necessary for conducting efficient mineral operations. Persons conducting mineral operations must comply with all applicable Federal and State laws and regulations. When claimants complete operations, they will restore the area to its previous condition, including removing all structures and equipment from the area.

(1) In Alaska, Section 1010 of ANILCA requires the Secretary to assess oil, gas, and other mineral potential on all public lands, including wilderness. The mineral assessment program may include, but is not limited to, techniques such as side-looking radar and core and test drilling but does not include exploratory drilling of oil and gas test wells. Any assessment activity must be determined to be compatible before it is permitted.

I. Geographic Naming in Wilderness. The attachment of official, permanent names to mountains and other natural features represents a human intention to influence and dominate how they are perceived—in a landscape that symbolically represents freedom from human influence and dominance. Since place names diminish this aspect of wilderness character, we will not propose to the U.S. Board of Geographic Names, nor support proposals by others, to apply names to geographic features within wilderness. We may name new

wilderness refuges and new wilderness areas within refuges, but we will neither propose nor support naming them after any person. See 040 FW 2 2.7 (C).

3.6 *How do we protect natural resources in wilderness?* A. Research. The scientific value of wilderness derives from its relatively undisturbed condition. Because such undisturbed natural areas increasingly are rare, wilderness areas often provide unique opportunities for scientific investigation. All persons associated with research in wilderness must know and understand the purposes, provisions, and values of wilderness. We will not allow or engage in research that significantly disrupts wilderness conditions or character.

(1) We may allow scientific research consistent with protecting wilderness character when:

(a) Suitable locations outside wilderness are not available;

(b) It furthers the management, scientific, and educational purposes of the area;

(c) The possible benefits outweigh the negative impacts on wilderness values; and

(d) It is carried out in a manner respectful of wilderness character and values.

(2) We will not allow the use of motorized equipment or vehicles, mechanical transport, structures, installations, or monitoring devices and methods, unless:

(a) Alternative methods are not available;

(b) They represent the minimum requirement;

(c) They are consistent with the unit's WMP; and

(d) They are compatible with the unit's purposes.

(3) We will evaluate research using a minimum requirement analysis. We must include research activities in the unit's WMP.

(a) We may use fixed-wing aircraft to conduct approved research and management surveys. We will allow the use of helicopters and the landing of aircraft only when supported by a minimum requirement analysis. However, we may immediately authorize aircraft or helicopter landings in emergencies related to health and safety. We should conduct our aircraft operations over wilderness areas at an altitude greater than 2,000 feet (600 m) above ground level whenever possible. We must be respectful of the area's wilderness character and minimize disturbance to wildlife and other users when using aircraft. We should consider time of day, season, route, and flight altitude when planning our activities.

(4) In Alaska: ANILCA authorizes motorized boats, snowmobiles, and the landing of fixed-wing aircraft for public access to wilderness (subject to reasonable regulations to protect the natural and other values of the unit.) We may use motorized boats, snowmobiles, and fixed-wing aircraft for access in Alaskan wilderness without conducting a minimum tool analysis. We select landing areas to avoid surface disturbance.

B. Inventory and Monitoring. Long-term wilderness management depends upon the inventory and monitoring of wilderness resources, including fish, wildlife, habitat, vegetation, air, water, archaeological resources, and public use. We should conduct baseline inventories for key wilderness resources and identify any threats to the wilderness area. Baseline data provides the frame of reference for the thresholds and indicators identified in the WMP that may trigger use limitations. Inventories also provide us with the information necessary to evaluate the effects of management actions, public uses, and external threats on wilderness resources. We should conduct inventories using a minimum requirement analysis and in accordance with 701 FW 2. We should include inventory and monitoring in the unit's WMP.

C. Habitat and Species Population Management. We manage refuge wilderness to maintain and restore the natural features and processes affecting the components of an area's ecological integrity: biological diversity, biological integrity, and environmental health. We manage refuge wilderness to maintain components of natural biological diversity such as wildlife populations with natural densities, social structures, and dynamics. Major ecosystem processes including wildfire, drought, flooding, windstorms, pest and disease outbreaks, and predator/prey fluctuations are natural ecological and evolutionary processes. We will not interfere with these processes or the wilderness ecosystem's response to such natural events. However, in some cases these processes may become unnatural, such as excess fuel loads from fire suppression activities, predator/prey relationships disrupted by the control of carnivores, or the invasion of alien species. In such cases, we encourage the restoration or maintenance of ecological integrity and wilderness character. All decisions to modify habitat, species levels, or natural processes by the methods or practices listed below must be necessary to accomplish the purposes of the refuge and the Wilderness Act; supported by a minimum requirement analysis; and documented in the WMP. Generally, we will modify habitat, species population levels, or natural ecological processes in refuge wilderness only when such actions: maintain or restore ecological integrity; correct or alleviate negative impacts to wilderness character caused by human influence; are necessary to protect or recover a threatened or endangered species; or address an emergency involving the health and safety of persons within or outside the wilderness.

(1) Fire. We may use fire in wilderness subject to the above criteria (see 610 FW 5 and 621 FW 1–3 for additional guidance).

(2) Grazing. We may permit livestock grazing in wilderness areas as a habitat management tool only when it is the minimum requirement to administer the area as wilderness and essential to accomplish refuge purposes.

(3) Transplanting, Reintroducing, or Stocking Fish and Wildlife. We will not transplant, introduce, or reintroduce any species into a wilderness area where they are not indigenous or into bodies of water that are naturally barren (see 601 FW 3). We will determine through consultation with the appropriate State agency which indigenous species we will use for stocking. We will use local genetic strains whenever possible. We will give preference to species extirpated by human-induced causes. We may continue to manage species traditionally stocked before wilderness designation only if they meet the criteria established above. We will not use fertilizers to artificially enhance fisheries or other wildlife resources.

(4) Control of Invasive Species, Pests, and Diseases Through Integrated Pest Management (IPM). Where invasive species pose a threat to the integrity of the wilderness ecosystem or where the lack of control would result in unacceptable impacts on other wilderness resources (including threatened or endangered species), we take steps to control them. Where pests and diseases pose a significant threat to the health of humans or wildlife as identified by the Centers for Disease Control, or where the lack of control would result in unacceptable impacts on other wilderness resources (including threatened or endangered species), we may take steps to control them. We will not control invasive species, pests, and diseases, including mosquitoes, for administrative convenience, economy of effort, or convenience to the public.

(5) We will use integrated pest management to prevent, control, or

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eradicate alien species, pests, and diseases subject to the criteria listed above. We will determine appropriate IPM procedures through a minimum requirement analysis and document them in the WMP. If the approved IPM plan determines that chemical or biological applications are necessary, we will only use agents that have the least impact on nontarget species and on the wilderness environment in compliance with 7 RM 14.1–8 and 7 RM 8.6–8. We may make an exception to 610 FW 3.6 Cc for approved nonindigenous biological control agents. We will conduct invasive species, pest, and disease control in wilderness in a manner consistent with protecting wilderness character and values and only if compatible with refuge purposes.

(6) Predator Control. Predators are a natural and important component of the wilderness ecosystem and should be free from unregulated human interference. Rarely, predator control may be necessary for the protection of threatened or endangered species. In such cases, we may control predators subject to the above criteria and only when strong evidence exists that the proposed action will correct or alleviate the problem. We will direct control at the individual animal(s) causing the problem using the method least likely to harm nontarget species and wilderness visitors.

D. Air Quality Protection. Maintaining the wilderness character and values of an area requires proper management of air resources.

(1) Clean Air Act (CAA). Congress passed the CAA to protect both human health and the environment and provide protection of air quality in wilderness areas by means of national standards for air quality and the Prevention of Significant Deterioration (PSD) program (see also 561 FW 2.1). The PSD program designated 21 of our wilderness areas as mandatory Class I air quality areas, including all wilderness areas over 5,000 acres (2,000 ha) in existence on August 7, 1977. The CAA gives Class I areas the highest level of protection from air pollutants. The CAA designates and protects other wilderness and nonwilderness areas as "Class II," but not to the extent of Class I areas. The CAA charges the Federal Land Manager (the Assistant Secretary of the Interior for Fish and Wildlife and Parks) and the Service with an "affirmative responsibility" to protect the air quality related values of Class I lands. Air pollution, including visibility, wildlife, vegetation, soil, water, and geological and cultural resources may adversely affect air quality related values (ARQV). We will identify the ARQV of each wilderness area and evaluate their sensitivity to air pollution in the WMP.

(2) Visibility. The CAA grants special protection to visibility in Class I areas. The CAA establishes a national goal of remedying any existing and preventing any future, human-caused visibility impairment in mandatory Class I areas. The Environmental Protection Agency (EPA) established the Regional Haze regulations as part of their strategy to meet this goal, requiring the States to make "reasonable progress" towards natural visibility conditions. We will work with the EPA and the States to identify natural visibility conditions and set reasonable progress goals for visibility improvement in Class I areas. We may conduct monitoring with samplers sited on adjacent nonwilderness land to characterize current visibility and air quality conditions in wilderness areas.

(3) External Pollution Sources. Sources outside the wilderness, including powerplants, industries, and automobiles, are the usual cause of air pollution in wilderness areas. To ensure the protection of ARQV from these external sources, we will participate in State and local planning and permitting processes, including the review of air pollution permit applications for major new sources or modifications of existing sources of air pollution. We will also review the National Environmental Policy Act documents for projects with the potential to affect wilderness areas. In consultation with the EPA, State, or local agencies, we will determine whether air pollutant emissions from a proposed action will adversely affect air quality-related wilderness values and work to minimize or eliminate such adverse impacts.

(4) Internal Pollution Sources. Emissions also can come from sources within wilderness areas, notably fire. We may use fire as a tool to restore and maintain healthy wilderness ecosystems. However, we must balance the use of fire with our responsibility to protect visibility and other ARQV in Class I areas and wilderness (see 610 FW 5, and 621 FW 1–3 for additional guidance).

3.7 *How do we protect cultural resources in wilderness?* Cultural resources, such as archaeological sites, historic trails and structures, and sacred sites are unique and nonrenewable parts of the wilderness resource. We follow policy and standards for identifying, evaluating, protecting, and managing cultural resources in the FWS Manual, Part 614 FW 1–5.

A. Burial and Sacred Sites. We may maintain burial sites or cemeteries located within a wilderness area, but we prohibit new interments unless authorized by Federal statute, existing reservations, or retained rights. We will identify and protect Native American sacred sites or religious areas. We will allow Native American practitioners access to these sites within wilderness areas for religious and traditional ceremonial purposes in accordance with wilderness access regulations and procedures and the Service's sacred sites protection policy.

(1) We will notify and consult appropriate tribal leaders as early as possible in planning for wilderness management decisions that may affect sacred sites and practice of Native American religion. The American Indian Religious Freedom Act of 1978, 42 U.S.C. 1996 and 1996a; Executive Order 13007, "Protection of Sacred Sites;" and Service policy mandates this consultation. We must coordinate consultation through the Regional Historic Preservation Officer and Regional Native American Liaison.

B. Research. We will encourage archeological research employing noninvasive and nondestructive survey and inventory methods. The Refuge Manager and the Regional Historic Preservation Officer will review proposals for archeological research. The Regional Director approves or denies archaeological research permits based upon the recommendation of the Refuge Manager and regional archeologist. We will only approve archeological research requiring digs, trenching, or other forms of excavation in wilderness when required to protect a threatened resource or when the applicant can demonstrate the need for important data. Such research is subject to a minimum requirement analysis.

C. Historic Buildings and Structures. We will comply with cultural resource management requirements and policies when maintaining, using, or removing historic buildings and structures and will support our decisions with a minimum requirement analysis. We must consult with the Regional Historic Preservation Officer and adhere to the requirements covered by Sections 106 and 110 of the National Historic Preservation Act, and the regulations in 36 CFR 800, for any work affecting historic buildings and structures. The Regional Preservation Officer is responsible for determining if such properties are listed in or eligible for the National Register of Historic Places and for performing consultation with the appropriate State Historic Preservation Officer and the Advisory Council on Historic Places. For buildings and structures that are eligible for or listed in the National Register, and which we choose to use or maintain, we will follow the minimum requirement policy and the Secretary of the Interior Standards for the Treatment of Historic Properties. See 610 FW 3.5.A above for additional information regarding structures and installations.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 4 Public Use Management

610 FW 4.1

4.1 *What is the purpose of this chapter?* This chapter provides specific direction and guidance on managing public use in wilderness. You can find additional guidance for general public use management in Appropriate Uses 603 FW 1 and Priority Wildlife-Dependent Recreation 605 FW 1.

4.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

4.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management, are contained in 610 FW 1.3.

4.4 *What are our general public use guidelines for wilderness?* We will provide opportunities for compatible use and enjoyment of wilderness areas in a manner that will preserve their wilderness character and that will "leave them unimpaired for future use and enjoyment as wilderness" [The Wilderness Act: Sec 2 (a)]. We may prescribe appropriate conditions or restrictions upon any authorized activity as necessary to preserve wilderness resources and character.

A. We will emphasize providing "opportunities for solitude or a primitive and unconfined type of recreation" [The Wilderness Act: Sec. 2 (c)]. Visitors whose experience depends on wilderness conditions have the fewest number of settings to accommodate their use, while those whose use is not dependent on wilderness conditions have a greater range of alternatives. Where use conflicts occur, or when we must limit the number of visitors, we will give preference to those uses most dependent on wilderness conditions. Uses that are both wildlife and wilderness-dependent will receive highest priority.

B. Priority for public uses on wilderness portions of a refuge are:

(1) Compatible, wildlife-dependent recreation (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) practiced so as to preserve wilderness character; and

(2) Other compatible and appropriate, wilderness-dependent recreation.

4.5 *What are appropriate recreational uses in wilderness?* Where compatible, the priority public uses of the System (hunting, fishing, wildlife observation and photography, and environmental education and interpretation) are appropriate in refuge wilderness. In refuge wilderness, these uses are nonmotorized activities which involve no mechanical transport.

A. Other forms of wilderness-dependent recreational activities, such as hiking, canoeing, or crosscountry skiing, allow visitors to experience and observe wildlife and its habitat in a wilderness context. These activities provide opportunities to experience the physical, psychological, symbolic, and spiritual values of wilderness under conditions that include risk and challenge that rewards self-reliance and a spirit of exploration with discovery and adventure. Such wilderness-dependent recreation may be appropriate in refuge wildernesses when we determine it to be compatible with the refuge purposes and when it does not conflict with the priority public uses of the System or other policies for managing public uses of the System.

4.6 *What activities have we identified to prohibit or otherwise specifically regulate in wilderness areas?* A. The Wilderness Act defines prohibited uses in Sec. 4. (c).

B. Extreme and Thrill Sports. We prohibit the various forms of hang gliding and other recently developed thrill-oriented activities that do not depend on a wilderness setting.

C. Grazing Packstock. We may authorize noncommercial grazing of trail stock incidental to recreational use of wilderness in accordance with the conditions, outlined in the Wilderness Management Plan (WMP), that ensure protection of wilderness resources such as requiring that "weed free and weed-seed free" supplemental feed accompany all overnight use of pack animals, or prohibiting certain types of feed which could introduce invasive species.

D. Competitive Events. We prohibit competitive events that are not consistent with wilderness character, that may intrude on solitude, or are not dependent on a wilderness setting. Prohibited events include animal, foot, or watercraft races, endurance contests, competitive trail rides, organized survival exercises, and war games. We may make exceptions for preexisting and historically significant events, like the Iditarod sled dog race in Alaska, as long they do not degrade wilderness resources.

E. Flightseeing. Aerial sightseeing, aerial wildlife viewing, and aerial photography (collectively referred to as "flightseeing") are activities at variance with the purpose of wilderness and often result in unacceptable wildlife disturbance. Although we lack jurisdiction over airspace, we will not encourage flightseeing and will work with the Federal Aviation Administration to encourage pilots to conduct overflights above 2,000 feet (600 m) above ground level. We will enforce provisions of the Airborne Hunting Act that prohibit harassment of wildlife by aircraft. Wilderness administrators should monitor and document low-level aircraft activity.

F. Other Public Uses. We will manage other public uses not specifically mentioned above in accordance with Service wilderness, compatibility, appropriate refuge uses and wildlife-dependent recreation policies and the National Wildlife Refuge System Administration Act, as amended. In Alaska, ANILCA covers subsistence use, and we address it in 610 FW 2.17.

G. Alaska. In Alaska, the public may continue to use previously existing public use cabins. We may construct, maintain, or replace public use cabins subject to restrictions necessary to preserve the area's wilderness character. ANILCA Section 1315(d) requires the Secretary to notify the House and the Senate authorizing committees of our intention to remove an existing or construct a new public use cabin or shelter in wilderness.

(1) The use of temporary campsites, tent platforms, shelters, other temporary facilities and equipment directly related to the taking of fish and wildlife may continue. We must construct new facilities of materials that blend and are compatible with the surrounding landscape. However, ANILCA Section 1316(b) provides that we may, after adequate notice, deny establishment and use of new facilities for these activities if we determine them to be a significant expansion of existing facilities or uses which would be detrimental to the unit's purposes, including wilderness values.

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4.7 *How can we best preserve a quality wilderness experience and the wilderness itself?* We should maximize the visitor's autonomy and isolation from the influences of the mechanized and settled outside world. Management actions, necessary facilities, and on-site presence shall be as unobtrusive and subtle as possible, consistent with the overriding criteria of maintaining wilderness condition and character. We generally prefer information and education over direct management approaches such as regimentation and regulation. However, permit systems, group size limitations, and other rules may be necessary to ensure protection of both the wilderness experience and wilderness resource. The WMP will evaluate the fragility of wilderness resources, estimate expected visitation and potential impacts, establish monitoring methods, describe desired conditions, and provide indicators that will trigger action to prevent impacts. For instance, the refuge should identify specific areas essential to wildlife species sensitive to human disturbances and initiate visitor-use controls in critical areas or during critical periods of the year when necessary.

4.8 *How should we manage for solitude?* We should strive to minimize the presence of modern artifacts of civilization, such as signs, bridges, facilities, and technology; large groups; and conflicting uses that tend to interfere with one's free and independent response to nature. We should employ survey methods to evaluate visitor experiences related to solitude and correct deficiencies where we have ability to improve that experience.

4.9 *How do we manage for visitor safety in wilderness?* The wilderness visitor has an increased responsibility for their own safety in wilderness areas. Where the wild has not been taken out of the wilderness, there are risks. We will not modify wilderness areas to eliminate risks normally associated with wilderness travel. We should provide visitors general information about the unpredictable nature of risks inherent in wilderness, including potential dangers related to isolation, terrain, water, wildlife, and weather. We should provide site-specific information with caution to avoid the implication that we have identified all potential hazards. Information on risks and recommended precautions will emphasize that safety is the visitor's responsibility and that the freedom, independence, and self-reliance of the wilderness experience requires proper mental, physical, and material preparation. We must remain prepared to respond appropriately to emergencies related to public safety, including conducting or assisting State or local agencies with search and rescue functions. However, we must not convey the impression that assistance is readily available in all situations.

4.10 *How do we inform and educate the public about wilderness?* Each refuge containing a wilderness area should develop an information and education program designed to increase awareness and appreciation of the full spectrum of wilderness values, without stimulating unacceptable demand for use. The program should focus on providing information that enhances the experience, describes the limitations of wilderness to accommodate use, encourages visitors to practice Leave-No-Trace (LNT) techniques, properly prepares potential visitors for wilderness challenges, and generally stimulates cultivation of a personal ethic based on a willingness to exercise self-restraint in the interest of other users and future generations. Implementation of thoughtful information materials and interpretive programs can be the most effective tool for protecting the wilderness. Where appropriate, we also should produce brochures and other interpretive and information materials for the non-visiting public who may want to learn about wilderness and simply finds pleasure in just knowing that it is there. Development of information and educational materials should be guided by the *Primary Interpretive Themes for Wilderness Education* adopted by the Service (Exhibit 7 Interpretive Themes), FWS Publications Guidelines, Environmental Education Policy (605 FW 6), and Interpretation Policy (605 FW 7). Wilderness education curriculum materials are available through the Arthur Carhart National Wilderness Training Center; and Leave No Trace (LNT) curriculum materials, skills and ethics guides, and training are available through LNT, Inc. We strongly influence public education and wilderness ethic formation by the way we conduct our business in the wilderness. We must always be aware of the message our activities convey about appropriate wilderness behavior, norms, and attitudes.

4.11 *How do we implement the Leave No Trace program?* A. The LNT program promotes and inspires responsible outdoor recreation through education, research, and partnerships. LNT, Inc., a nonprofit organization, manages the program. The National Outdoor Leadership School (NOLS) maintains the educational component of LNT. The four Federal wilderness management agencies have adopted the LNT program through a Memorandum of Understanding (Exhibit 6, LNT Memorandum of Understanding) as our standard regarding minimum impact practices for both the public and ourselves.

B. We apply LNT principles and practices to all forms of recreation management within wilderness, including commercial operations. As an educational program, the LNT program offers managers a tool for dealing with issues and impacts. We should limit interpretation of wilderness to off-site locations, except as needed to protect visitor health and safety or to protect the wilderness resource. However, we may conduct educational programs, such as LNT training or interpretative walks, inside the wilderness area when deemed appropriate to help foster a better understanding and appreciation of wilderness. Such programs should remain sensitive to the wilderness resource, wilderness character, and the experience of other users.

4.12 *How do we monitor public use in wilderness?* A. We will monitor those conditions and long-term trends of wilderness resources that are necessary to identify the effects of both public activities and management actions and the need for corrective actions. We will monitor to ensure that our actions and visitor impacts on wilderness resources and character do not exceed standards and conditions established in an approved WMP. As appropriate, wilderness monitoring programs may assess physical, biological, and cultural resources, social/psychological conditions, and wilderness user demographics. Monitoring programs may also need to assess the effect of actions that originate outside the wilderness in order to determine the nature, magnitude, and probable source of those impacts.

B. Limits of Acceptable Change (LAC) is one framework designed for establishing indicators, standards, and desired conditions. While we commonly use LAC to manage recreational use of wilderness, the concept applies to any factor that can influence or change desired conditions, including fire, grazing, mining, or impacts on air quality. [See Hendee, Stankey, and Lucas (1990) in Exhibit 8 References.] We discuss other means of monitoring visitor impacts in Priority Wildlife Dependent Recreation 605 FW 1–7 and will describe them in the refuge's approved CCP, WMP, or Public Use Plan.

4.13 *Do we allow public use structures and facilities in wilderness?* We prohibit permanent structures and facilities in wilderness unless they are:

A. The minimum requirement necessary to administer the area for the purposes of the Wilderness Act and accomplish refuge purposes;

B. Essential to protect the health and safety of visitors; or

C. Listed or eligible for listing in the National Register of Historic Places [See 610 FW 3.7C].

D. Bridges. We will select bridge locations to minimize their size and complexity. We must construct them of native or native-appearing materials that blend with the environment. We must also construct them according to our construction standards and maintain them for safety.

E. Campsites. Campsites may include a site marker, fire rings, tent sites, animal-resistant food-storage devices and primitive toilets when we need these facilities to protect wilderness resources or human health and safety. We may provide bear-resistant food containers in locations where bear encounters are likely. We place toilets only in locations where their presence will resolve health and sanitation problems or prevent serious resource impacts, especially where reducing or dispersing visitor use is impractical or has failed to alleviate the problem. We encourage the use of cooking stoves. We do not provide picnic tables in wilderness. We will consult the LNT Outdoor Skill and Ethics Guide appropriate for each wilderness habitat to determine the best campfire policy. If we allow campfires and the use of fuel wood from within the wilderness as authorized in a WMP, we will limit wood cutting to dead and down material.

F. Hunting and Photography Blinds. We may allow the use of simple screens made of dead and down natural material found in the locale, if the user dismantles them at the end of each use period. The user must carry in and out commercially built, artificial blinds. We prohibit permanent blinds.

G. Signs. We may use signs only if they meet the criteria listed above (4.13 A–C), to identify routes and distances. We will not use signs to mark streams, lakes, mountains, or other points of interest. Signs will be compatible with their surroundings and the minimum size. In waterways, signs will meet all Coast Guard or appropriate State requirements. We may also use signs to mark wilderness boundaries.

H. Trails and Trail Structure Maintenance. We should include an inventory of the wilderness trail system as an integral part of the wilderness management plan. We will maintain trails at levels and conditions identified within the plan. We will administer historic trails according to approved cultural resource plan requirements.

4.14 *How do we address special needs for persons with disabilities in wilderness?* A. Nothing in the Wilderness Act prohibits the use of a wheelchair in a wilderness area by an individual whose disability requires use of a wheelchair. No agency must provide any form of special treatment or accommodation, or construct any facilities or modify any conditions of lands within a wilderness area to facilitate such use. (Americans with Disabilities Act of 1990 (ADA): Section 507(c), 104 Stat. 327, 42 U.S.C. 12207).

B. The Service has legal obligations to make available equal opportunities for people with disabilities in all of our programs and activities. This requirement includes the opportunity to participate in wilderness experiences. Management decisions responding to requests for special consideration to provide for wilderness use by persons with disabilities must be in accord with the Architectural Barriers Act of 1968, the Rehabilitation Act of 1973 (amended in 1978) and Section 507(c) of the Americans with Disabilities Act of 1990. Such decisions should balance the intent of the access and wilderness laws and find a way to provide the highest level of access for the disabled with the lowest level of impact on the wilderness resource.

C. The Secretary of the Interior's regulations regarding "Nondiscrimination in Federally Assisted Programs in the Department of the Interior" (43 CFR part 17) require that the Service will operate all programs and activities so that they are accessible to and usable by persons with disabilities to the greatest extent practicable. However, 43 CFR 17.550 does not require agencies to take any actions or provide access that would result in a fundamental alteration in the nature of a program or activity. The agency subsequently has the burden of proving that compliance would result in a fundamental alteration.

D. While the Service is not required to provide any special treatment to provide access for persons with disabilities who use wheelchairs, managers should explore solutions for reasonable accommodations when not in conflict with the Wilderness Act (e.g., barrier-free trails, accessible campsites). Any facilities, built or altered, must meet current accessibility guidelines.

E. We allow wheelchairs in wilderness if they meet the definition in the ADA. The intent of this definition is that a wheelchair is a person's primary mode of locomotion, manual or electric, that is suitable for use in indoor pedestrian areas. This definition will also ensure that we reasonably accommodate persons using wheelchairs in wilderness without compromising the wilderness resource and its character.

F. A publication entitled "Wilderness Access Decision Tool" (available from the Arthur Carhart National Wilderness Training Center) provides further guidance in assisting managers in making appropriate, objective, and consistent decisions regarding the use of wilderness areas by persons with disabilities.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 5 Fire Management

610 FW 5.1

5.1 *What is the purpose of this chapter?* This Chapter establishes policy for fire management in wilderness areas.

5.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

5.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management, are contained in 610 FW 1.3.

5.4 *What is our general policy for managing wilderness fires?* All fires on our wildlands, including wilderness areas, are either wildland or prescribed fires. Wildland fires and their effects are inherent parts of the ecological and evolutionary processes of wilderness. We will not interfere with the wilderness ecosystem's recovery response to these effects. We manage prescribed and wildland fires to achieve wilderness objectives included in an approved Fire Management Plan (FMP). We will appropriately respond to all wildland fires in accordance with the minimum requirement concept (610 FW 2). We must identify and address wilderness character and values to be protected, desired fire regime, and specific fire management considerations in the Wilderness Management Plan.

A. Firefighter and public safety is always the first priority on all wildland fire operations. The Manual chapter on

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Fire Management (621 FW 1–3) contains specific guidance on fire management policy, fire management plans, and prescribed burning. The chapter on Emergency Operations (095 FW 3) contains policy on wildland fire suppression. The Fire Management Handbook contains detailed guidance on FMP development.

B. We will conduct fire management planning, preparedness, wildland and prescribed fire operations, monitoring, and research on an interagency basis with the involvement of all partners.

5.5 *How do we manage wildland fire?* A. The principal wildland fire use objective in wilderness is to allow fire to play its natural role in the ecosystem. We may use wildland fire to achieve resource objectives as long as we include prescriptive criteria for wildland fire use in an approved FMP.

B. If we decide to suppress the fire, we determine the appropriate management response by selecting the least-cost options for suppression that also preserve the wilderness character and values. Firefighter safety and the minimum requirement concept will be the guiding factors in determining the appropriate suppression response and strategy. We will identify the appropriate minimum impact suppression standards in the FMP and develop them in conjunction with the fire management officer.

5.6 *How do we manage prescribed fire?* A. We may use prescribed fire within the wilderness area to fulfill unit purposes and the System mission and goals where fire is a natural part of the ecosystem only if it:

(1) Corrects or alleviates adverse impacts to the wilderness character and ecological integrity caused by human influence; or

(2) Is necessary to protect or recover a threatened or endangered species; and

(3) Is supported by a minimum requirements analysis.

B. We must include prescribed fire use within the wilderness in an approved FMP, and we must develop a Prescribed Fire Plan for any prescribed fire. We will append the FMP to the Wilderness Management Plan.

C. We should plan prescribed fire to minimize impacts on visibility during periods of heavy visitor use as well as to avoid adverse effects on other air-quality-related values.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 6 Wilderness Management Planning

610 FW 6.1

6.1 *What is the purpose of this chapter?* This chapter provides guidance on developing Wilderness Management Plans.

6.2 *To what does this chapter apply?* This chapter applies to Congressionally designated wilderness. Where this management guidance conflicts with provisions of legislation establishing wilderness on refuges, (including the Alaska National Interest Lands Conservation Act (ANILCA) in Alaska), the provisions of the legislation establishing wilderness take precedence. (See Exhibit 1; National Wildlife Refuge System Designated Wilderness Areas).

6.3 *What are the authorities that directly affect wilderness management on our lands?* Our authorities to manage wilderness, or those which may affect wilderness management, are contained in 610 FW 1.3.

6.4 *What is a Wilderness Management Plan (WMP)?* The WMP guides the preservation, management, and use of a particular designated wilderness. The WMP describes goals, objectives, and management strategies for the wilderness area based on the refuge or unit's purpose(s), System mission, and wilderness management principles. It contains specific, measurable management objectives that address the preservation of wilderness-dependent cultural and natural resource values and conditions. The WMP must clearly show the strategies and actions we will use and implement to preserve the wilderness resource, and the linkage between those strategies and actions and the wilderness objectives. It also contains indicators, standards, conditions, or thresholds that define adverse impacts on the wilderness character and values and will trigger management actions to reduce or prevent them. We will develop WMPs in coordination with State wildlife agencies and with public involvement.

6.5 *How does the WMP relate to the Comprehensive Conservation Plan (CCP)?* The WMP is a form of step-down management plan (602 FW 1.6 and 602 FW 4). The WMP provides detailed strategies and implementation schedules for meeting the broader wilderness goals and objectives identified in the CCP. WMPs are developed following the planning process guidance in 602 FW 1 and 602 FW 3 (602 FW 4).

6.6 *Does every wilderness area need a WMP?* We will describe the management direction for each designated wilderness either in a WMP or as part of a CCP (602 FW 3). We should address each wilderness as a separate management area.

6.7 *What should a WMP contain?* The WMP should include, at a minimum (see Exhibit 9 for further guidance):

A. Management direction in accordance with the refuge purposes, the Wilderness Act of 1964, specific wilderness-establishing legislation, System mission, and ANILCA, as applicable.

B. Goals and objectives for the wilderness area and their relationship to the refuge's purposes and objectives, and System mission, goals, and objectives. We derive wilderness objectives from applicable laws, including the Wilderness Act, legislation establishing the wilderness, purpose(s) for which the unit was established, applicable Service goals, and continental, national, and regional plans.

C. A description of the current or baseline situation of the wilderness resource, including a description of the wilderness area, natural conditions, management activities, existing facilities, and public use levels and activities. The plan also establishes indicators of change in resource conditions; standards for measuring that change; and desired conditions, or thresholds, that will trigger management actions to reduce or prevent impacts on the wilderness. Limits of Acceptable Change (LAC) is one framework designed for establishing indicators, standards, and desired conditions. While LAC commonly is used to manage recreational use of wilderness, the concept applies to any factor that can influence or change desired conditions, including fire, livestock grazing, mining, or impacts on air quality and related values. (See Hendee, Stankey, and Lucas (1990) in Exhibit 8 References).

D. A description of management actions (administrative, natural and cultural resources, public recreation, and interpretation and education) and a schedule of implementation, including funding and staff required to adequately administer the area. The implementation schedule will include a list of specific actions needed to accomplish WMP objectives, general prioritization of the action items, and target dates for completion.

E. Research needs and monitoring requirements to determine whether we are meeting our wilderness management objectives.

F. Procedures for determining and documenting the minimum requirement for administrative actions we will take in wilderness that might require a generally prohibited use and all minimum requirement analyses.

G. Descriptions of how we are to administer valid existing rights and congressionally authorized uses to provide protection to wilderness values.

H. An explanation of how we will coordinate, as much as possible, with adjoining wilderness units so that visitors traveling from one wilderness to another can do so with minimal impediments. Examples include the criteria for issuance of permits, riding and packstock use programs, and group and party sizes.

I. A legal description and map depicting the legal description.

J. An approval page signed by the Regional Director.

6.8 *How will we involve the public in wilderness management planning?* We will provide opportunities for meaningful public involvement as we develop management guidance for our wilderness areas. Public involvement is required in preparation of both CCPs and step-down management plans (602 FW 3 and 602 FW 4.2). Public involvement is also a requirement of the procedural provisions of the National Environmental Policy Act (NEPA). We will develop a public involvement plan to identify the most appropriate means and methods to ensure meaningful public involvement in wilderness management planning. Methods may vary depending on the particular situation (see 110 FW 1, Public Participation).

6.9 *How will we manage wilderness areas without an approved WMP?* During WMP development, the wilderness management policy (610 FW 1–7) and the refuge CCP will guide the conduct of day-to-day activities.

6.10 *May we implement a WMP completed prior to development of the refuge CCP?* We may implement an individual WMP completed prior to the development of the unit's CCP if the WMP:

A. Is current and approved; and

B. Was prepared in accordance with the NEPA process including appropriate public involvement.

6.11 *How frequently should we revise WMPs?* We review the WMP during routine unit programmatic evaluations. We will review and revise WMPs (if necessary) by the refuge staff concurrently with the CCP at least every 15 years, but we should review them every 5 years. We revise WMPs when significant changes to assumptions and conditions warrant it, including natural catastrophes, legal requirements, or environmental conditions. Revision of wilderness management direction requires appropriate public involvement and conformance with NEPA.

6.12 *How do we develop WMPs if our wilderness adjoins wilderness of another Federal agency?* When a Service wilderness area adjoins lands administered by another Federal agency, we coordinate the wilderness area management planning, including public involvement, with the neighboring agency. We develop joint management plans with all involved agencies, if at all possible.

Fish and Wildlife Service

Wilderness Stewardship

Part 610

Chapter 7 Wilderness Review and Evaluation

610 FW 7.1

7.1 *What is the purpose of this chapter?* This chapter establishes policy for conducting wilderness reviews nationwide. It also establishes policy for managing Wilderness Study Areas (WSAs).

7.2 *To what does this chapter apply?* This chapter applies to all lands of the National Wildlife Refuge System (System) that are subject to wilderness review and not currently designated wilderness. If any provisions in this policy conflict with the provisions of Alaska National Interest Lands Conservation Act (ANILCA), the provisions of ANILCA will prevail for refuges in Alaska.

7.3 *What are the authorities that directly affect wilderness reviews and management of WSAs on our lands?* We review lands for wilderness suitability and manage WSAs consistent with the authorities listed in 602 FW 1.3.

7.4 *What is a wilderness review?* We conduct wilderness reviews in accordance with the Comprehensive Planning Process (CCP) outlined in 602 FW 3. The wilderness review process is conducted in three phases: inventory, study, and recommendation. We identify lands and waters that meet the minimum criteria for wilderness in the inventory phase of the review. We evaluate the resulting WSAs in the study to determine if they merit recommendation from the Director to the Secretary for inclusion in the National Wilderness Preservation System.

7.5 *When should we conduct a wilderness review?* Consistent with the planning guidance, we may conduct a wilderness review any time that significant new information becomes available or when we identify the need to do so. At a minimum, we will conduct wilderness reviews every 15 years through the CCP process. We generally conduct wilderness reviews within 2 years of acquiring acreage (for a new refuge or an expansion) that may qualify as wilderness. A review would be appropriate when we have restored significant acreage to its natural conditions sufficiently that it meets the definition of wilderness. In addition, Congress may direct the study of specific areas and provide other guidance on wilderness evaluations through legislation.

7.6 *How do wilderness reviews relate to acquisition planning?* When we inventory lands and resources of a proposed new refuge or expansion area during the land acquisition planning process and identify management problems, needs, and opportunities, we will also include a preliminary inventory of the wilderness resource (see 602 FW 1.7.C). We discuss potentially suitable areas in the Land Protection Plan and associated NEPA document.

7.7 *Can we conduct a wilderness review outside of the scheduled Comprehensive Conservation Planning or acquisition planning processes?* Yes. At any time before or after we have developed a CCP, if additional information becomes available, if we have acquired additional lands, or if restoration activities have significantly modified System lands, we may conduct a wilderness review. The review will be conducted following the process described in 602 FW 3 including public involvement and NEPA compliance. Existing CCPs should be revised or amended to incorporate the results of wilderness reviews [602 FW 3.4 C (8)].

7.8 *How do we identify WSAs in the wilderness inventory?* We inventory System lands and waters to identify areas that meet the definition of wilderness as defined in Section 2(c) of the Wilderness Act.

A wilderness, in contrast with those areas where man and his works dominate the landscape, is hereby recognized as an area where the earth and its community of life are untrammeled by man, where man himself is a visitor who does not remain. An area of wilderness is further defined to mean in this Act an area of undeveloped Federal land retaining its primeval character and influence, without permanent improvements or human habitation, which is protected and managed so as to preserve its natural

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conditions, and which: (1) generally appears to have been affected primarily by the forces of nature, with the imprint of man's work substantially unnoticeable; (2) has outstanding opportunities for solitude or a primitive and unconfined type of recreation; (3) has at least five thousand acres of land or is of sufficient size as to make practicable its preservation and use in an unimpaired condition; and (4) may also contain ecological, geological or other features of scientific, educational, scenic, or historical value."

Areas that meet the above criteria are identified as WSAs.

7.9 *How do we evaluate the size criteria for wilderness?* Determine if the area "* * * has at least five thousand acres of land or is of sufficient size as to make practicable its preservation and use in an unimpaired condition". The Wilderness Act does not specify a minimum size for roadless islands. The size criteria will be satisfied for areas under Service jurisdiction in the following situations:

A. An area with over 5,000 contiguous acres (2,000 ha). State and private land inholdings are not included in making this acreage determination.

B. A roadless island of any size. Refer to 610 FW 1.6 for a definition of roadless island.

C. An area of less than 5,000 contiguous acres that is of sufficient size as to make practicable its preservation and use in an unimpaired condition, and of a size suitable for wilderness management.

D. An area of less than 5,000 contiguous acres that is contiguous with a designated wilderness, recommended wilderness, or area of other Federal lands under wilderness review by the U.S. Forest Service (USFS), Bureau of Land Management (BLM), or National Park Service (NPS).

7.10 *How do we evaluate the naturalness criteria for wilderness?* Determine if the area or island "* * * generally appears to have been affected primarily by the forces of nature with the imprint of man's work substantially unnoticeable." To make this determination, it must be possible to observe the area as being generally natural. It must appear to have been affected primarily by the forces of nature, and people's work must be substantially unnoticeable. It must retain its "primeval character."

A. We make a distinction between an area's "apparent naturalness" and "natural conditions" in the context of our ecological integrity policy. Natural conditions refers to the presence or absence of ecosystems that existed prior to European settlement and the advent of the industrial era. Apparent naturalness refers to whether or not an area looks natural to the average visitor who is not familiar with natural conditions versus human-affected ecosystems in a given area. The presence or absence of apparent naturalness (i.e., do the works of humans appear to be substantially unnoticeable to the average visitor?) is the question to be addressed in the inventory phase of the wilderness review. An assessment of an area's existing levels of ecological integrity is an appropriate consideration in the study phase of the wilderness review.

B. We will avoid an overly pure approach to assessing naturalness. Congress did not intend to limit wilderness designation to only those areas judged pristine. Land that was once logged, used for agriculture, or otherwise significantly altered by humans may be eligible for wilderness designation if it has been restored, or is in the process of being restored, to a substantially natural appearance.

C. We will use caution in assessing the effects on naturalness that relatively minor human impacts create. An area may include some human impacts provided they are substantially unnoticeable in the unit as a whole. The presence of the following types of impacts in an area being inventoried for wilderness character should not result in a conclusion that the entire area lacks naturalness. Examples of man-made features that would not disqualify an area for consideration as a WSA include: trails, trail signs, bridges, fire towers, fire breaks, fire presuppression facilities, pit toilets, fisheries enhancement facilities (such as fish traps and stream barriers), fire rings, hitching posts, snow gauges, water quantity and quality measuring devices, research monitoring markers and devices, wildlife enhancement facilities, radio repeater sites, air quality monitoring devices, fencing, spring developments, and small reservoirs.

D. Significant man-caused hazards, when considered unsafe for public use, such as the existence of unexploded bombs and shells from military activity or contaminated sites would probably disqualify the affected portions of an area from consideration pending completion of remediation and restoration activities.

E. We will not disqualify areas from further wilderness study solely on the basis of the "sights and sounds" of civilization located outside the areas. Human impacts outside the area being inventoried will not normally be considered in assessing naturalness. However, if an outside impact of major significance exists, it should be noted and evaluated in the inventory conclusions. Human impacts outside the area should not automatically lead to a conclusion that an area lacks wilderness characteristics.

F. We will not disqualify areas from further wilderness study solely on the basis of established or proposed management practices that require the use of temporary roads, motor vehicles, motorized equipment, motorboats, mechanical transport, landing of aircraft, structures, and installations generally prohibited in designated wilderness (see definition of "generally prohibited use" in 610 FW1.6). The physical impacts of these practices should be the focus of the naturalness evaluation. Administrative and management needs are appropriate for consideration in the study phase of the wilderness review.

7.11 *How do we evaluate outstanding opportunities for solitude or a primitive and unconfined type of recreation?* The word "or" in this sentence means that an area only has to possess one or the other. It does not have to possess outstanding opportunities for both elements and does not need to have outstanding opportunities on every acre. There must be outstanding opportunities somewhere in the unit.

A. The Wilderness Act does not specify what was intended by "solitude or a primitive and unconfined type of recreation." In most cases, the two opportunities could be expected to go hand-in-hand. However, the outstanding opportunity for solitude may be present in an area offering only limited primitive recreation potential. Conversely, an area may be so attractive for recreation use that it would be difficult to maintain opportunity for solitude (e.g. around water).

B. We will assess each inventory area on its own merits as to whether an outstanding opportunity exists; there must be no comparison among areas. It is not permissible to use any type of rating system or scale—whether numerical, alphabetical, or qualitative (i.e., high-medium-low)—in making the assessment.

C. When an area is contiguous to designated wilderness, recommended wilderness, or an area of other Federal lands (*i.e.* USFS, BLM, or NPS) already determined to have wilderness character, no additional evaluation of outstanding opportunities is required.

7.12 *Must an area contain ecological, geological, or other features of scientific, educational, scenic, or historic value to qualify as a WSA?* These values are not required for wilderness but their presence should be documented where they exist.

7.13 *What do we consider in the wilderness study?* We study each WSA identified in the inventory to analyze all values (*e.g.*, ecological, recreational, cultural, economic, symbolic); resources (*e.g.*, wildlife, water, vegetation, minerals, soils); public uses; and management within the area. We conduct wilderness studies following the procedures outlined in the refuge planning policy (602 FW 3). These procedures ensure public involvement and compliance with NEPA.

A. An All Wilderness Alternative and a No Wilderness Alternative will be evaluated for each WSA. Partial Wilderness Alternatives may be developed to minimize resource conflicts or improve the capability of managing the area as wilderness. The environmental analysis will address benefits and impacts to wilderness values and other resources under each of the alternatives. The study will evaluate how each alternative will achieve the goals of the NWPS. The study will also evaluate how each alternative will affect achieving refuge or planning unit purpose(s); help fulfill the System mission; maintain and, where appropriate, restore the ecological integrity of each refuge and the System; and meet other mandates.

B. The findings of the study determine whether we will recommend the area for designation as wilderness. The information, analysis, and decisions in the CCP provide the basis for wilderness proposals. The Director must concur with wilderness study conclusions prior to publication of the draft CCP/environmental impact statement (EIS). The study provides data so that we can defend our conclusions, and serves as the basic source of information throughout the public, executive, and legislative review processes that follow.

C. When the findings of the wilderness study result in a proposal for wilderness recommendation, we will give public notice of the proposal; hold a public hearing; and advise the Governor of the State, the governing board of each county or borough, and interested Federal departments and agencies of our intent and invite comment.

7.14 *What are the steps in the recommendation phase of the wilderness review?* The Regional Director must notify the Director of the Region's recommendations on WSAs proposed for wilderness designation. A Wilderness Study Report must be submitted that summarizes the results of the study and wilderness recommendation. The Director will review the Wilderness Study Report and make the final Service recommendation to the Secretary.

7.15 *What should we include in the Wilderness Study Report?* The study report contains the following information:

A. The Regional Director's wilderness recommendation and rationale;

B. A general description and background history of the area;

C. An analysis of the area's values, resources, and uses;

D. Evidence of public notice of the proposal, including publication in the **Federal Register**, and notices in local newspapers;

E. Evidence that we notified the governor and other concerned officials (*e.g.*, State, local government, and tribal) at least 30 days before holding public hearings;

F. Summary and analysis of comments received plus the public hearing record;

G. Evidence of direct notification and request for comments from the State Historic Preservation Officer regarding the presence or absence of significant cultural resources;

H. A legal description and map showing the proposed wilderness boundary; and

I. An EIS.

7.16 *What additional documents do we need for Secretarial approval of the wilderness recommendation?* The Regional Director will transmit the following additional documentation in support of the Region's wilderness recommendation to the Director for review, in preparation of the Director's recommendation to the Secretary:

A. A draft letter from the Director to the Secretary;

B. A draft letter from the Secretary to the President;

C. A draft letter from the President to the House and Senate;

D. Draft legislative language;

E. A copy of the unit's CCP and final EIS; and

F. A communication strategy and implementation plan.

7.17 *What is the general policy for managing WSAs?* A. We will manage WSAs to maintain their wilderness character to the extent that it will not preclude fulfilling and carrying out refuge purposes and the System mission. Once an area is identified as a WSA, protection will consist of a case-by-case review of any proposed or new site-specific projects, administrative actions, or uses within the WSA. The review will include a minimum requirement analysis and NEPA compliance to assess potential impacts and identify mitigating measures to protect wilderness character. The analysis must consider the entire WSA, not just the specific project area.

B. When we determine that a proposed discretionary action could cause irreversible or irretrievable impacts to the wilderness resource, we will postpone the action pending completion of the wilderness study unless the proposed action is part of an existing management plan and the Regional Director makes a written determination that the action is integral to accomplishing the purposes of the refuge.

C. Other than those activities that exist when an area is identified as a WSA, activities that we will allow are generally temporary uses that create no new surface disturbance and do not involve placement of permanent structures. Valid existing rights must be recognized.

7.18 *What is our general policy for managing proposed wilderness?* Proposed wilderness has undergone a complete wilderness review process and full environmental compliance. We will therefore manage proposed wilderness consistent with guidance provided in the preceding chapters (610 FW 1–6) to the extent that it will not preclude fulfilling and carrying out refuge purposes and the System mission. We will describe the management direction for each proposed wilderness either as part of the CCP (602 FW 3) or in a WMP. The WMP is a form of step-down management plan (602 FW 1.6 and 602 FW 4) that provides detailed strategies and implementation schedules for meeting the broader wilderness goals and objectives identified in the CCP. WMPs are developed following the planning process guidance in 602 FW 1 and 602 FW 3 (602 FW 4). We will not abrogate Congress's prerogative for designating wilderness, so we will preserve the wilderness character of proposed wilderness until Congress takes action.

Exhibit 1.—U.S. Fish and Wildlife Service, National Wildlife Refuge (NWR) System

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DESIGNATED WILDERNESS AREAS

Refuge name	Wilderness area name	Class I air quality	Public law	Wilderness acres
Alaska:				
Alaska Maritime NWR	Aleutian Islands		96–487	1,300,000
Alaska Maritime NWR	Bering Sea	Yes	91–504	81,340
Alaska Maritime NWR	Bogoslof		91–504	175
Alaska Maritime NWR	Chamisso		93–632	455
Alaska Maritime NWR	Forrester Island		91–504	2,832
Alaska Maritime NWR	Hazy Island		91–504	32
Alaska Maritime NWR	Semidi		96–487	250,000
Alaska Maritime NWR	Simeonof	Yes	94–557	25,855
Alaska Maritime NWR	St. Lazaria		91–504	65
Alaska Maritime NWR	Tuxedni	Yes	91–504	5,566
Alaska Maritime NWR	Unimak		96–487	910,000
Arctic	Mollie Beattie		96–487	8,000,000
			104–167	
Becharof	Becharof		96–487	400,000
Innoko	Innoko		96–487	1,240,000
Izembek	Izembek		96–487	307,982
Kenai	Kenai		96–487	1,350,558
			104–333	
Koyukuk	Koyukuk		96–487	400,000
Selawik	Selawik		96–487	240,000
Togiak	Togiak		96–487	2,270,160
Yukon Delta	Andreafsky		96–487	1,300,000
Yukon Delta	Nunivak		96–487	600,000
Arizona:				
Cabeza Prieta	Cabeza Prieta		101–628	803,418
Havasu	Havasu		101–628	14,606
Imperial	Imperial		101–628	9,220
Kofa	Kofa		101–628	516,200
Arkansas: Big Lake	Big Lake		94–557	2,144
California:				
Farallon	Farallon		93–550	141
Havasu	Havasu		103–433	3,195
Imperial	Imperial		103–433	5,836
Colorado: Leadville Fish Hatchery	Mount Massive		96–560	2,560
Florida:				
Cedar Keys	Cedar Keys		92–364	379
Chassahowitzka NWR	Chassahowitzka	Yes	94–557	23,579
Great White Heron	Florida Keys		93–632	1,900
Island Bay	Island Bay		91–504	20
J.N. "Ding" Darling	J.N. "Ding" Darling		94–557	2,619
Key West	Florida Keys		93–632	2,019
Lake Woodruff	Lake Woodruff		94–557	1,066
National Key Deer	Florida Keys		93–632	2,278
Passage Key	Passage Key		91–504	36
Pelican Island	Pelican Island		91–504	6
St. Marks NWR	St. Marks	Yes	93–632	17,350
Georgia:				
Blackbeard Island	Blackbeard Island		93–632	3,000
Okefenokee NWR	Okefenokee	Yes	93–429	353,981
Wolf Island	Wolf Island	Yes	93–632	5,126
Illinois: Crab Orchard	Crab Orchard		94–557	4,050
Louisiana:				
Breton NWR	Breton	Yes	93–632	5,000
Lacassine	Lacassine		94–557	3,346
Maine:				
Moosehorn NWR	Baring Unit	Yes	93–632	4,680
Moosehorn NWR	Birch Islands Unit		91–504	6
Moosehorn NWR	Edmunds Unit		91–504	2,706
Massachusetts: Monomoy	Monomoy		91–504	2,420
Michigan:				
Huron	Huron		91–504	148
Michigan Islands	Michigan Islands		91–504	12
Seney NWR	Seney	Yes	91–504	25,150
Minnesota:				
Agassiz	Agassiz		94–557	4,000
Tamarac	Tamarac		94–557	2,180
Missouri: Mingo NWR	Mingo	Yes	94–557	7,730
Montana:				
Medicine Lake NWR	Medicine Lake	Yes	94–557	11,366
Red Rock Lakes NWR	Red Rock Lakes	Yes	94–557	32,350

DESIGNATED WILDERNESS AREAS—Continued

Refuge name	Wilderness area name	Class I air quality	Public law	Wilderness acres
UL Bend NWR	UL Bend	Yes	94–557	20,819
Nebraska: Fort Niobrara	Fort Niobrara		94–557	4,635
New Jersey:				
Edwin B. Forsythe NWR	Brigantine	Yes	93–632	6,681
Great Swamp	Great Swamp		90–532	3,660
New Mexico:				
Bitter Lake NWR	Salt Creek	Yes	91–504	9,621
Bosque del Apache NWR	Chupadera	Yes	93–632	5,289
Bosque del Apache NWR	Indian Well	Yes	93–632	5,139
Bosque del Apache NWR	Little San Pascual	Yes	93–632	19,859
North Carolina: Swanquarter	Swanquarter	Yes	94–557	8,785
North Dakota:				
Chase Lake	Chase Lake		93–632	4,155
Lostwood	Lostwood		93–632	5,577
Ohio: West Sister Island	West Sister Island		93–632	77
Oklahoma:				
Wichita Mountains	Charons Garden	Yes	91–504	5,723
Wichita Mountains NWR	North Mountain		91–504	2,847
Oregon:				
Oregon Islands	Oregon Islands		91–504	21
Oregon Islands	Oregon Islands		95–450	459
Oregon Islands	Oregon Islands		104–333	445
Three Arch Rocks	Three Arch Rocks		91–504	15
South Carolina: Cape Romain NWR	Cape Romain	Yes	93–632	29,000
Washington:				
Copalis	Washington Islands		91–504	81
Flattery Rocks	Washington Islands		91–504	125
Quillayute Needles	Washington Islands		91–504	300
San Juan Islands	San Juan Islands		94–557	353
Wisconsin:				
Gravel Island	Wisconsin Islands		91–504	27
Green Bay	Wisconsin Islands		91–504	2
Total				20,694,517

Exhibit 2.—Wilderness Acreage Report

Reports Control Symbol R610–5

The Regional Wilderness Coordinator will send this report to the Chief, National Wildlife Refuge System, by October 1 of each year. The report will include:

a. The units with designated wilderness, proposed wilderness, or Wilderness Study Areas and the acreage for each;

b. The total number of Refuge and Wildlife, Ecological Services, and Fisheries staff that have attended wilderness training;

c. A list of refuge managers, Ecological Service project leaders, or Fisheries project leaders at units with designated or proposed wilderness, or significant wilderness responsibilities that have not attended wilderness training; and

d. The recommended schedule for employee wilderness training for the next fiscal year.

Exhibit 3.—Wilderness Character

* * * each agency administering any area designated as wilderness shall be responsible for preserving the *wilderness character* of the area and shall so administer such area for such other purposes for which it may have been established as also to preserve its *wilderness character.* [emphasis added]—Section 4 (b), The Wilderness Act of 1964

Preserving "Wilderness character," referenced throughout the Act and throughout this policy, is one of our criteria for judging the appropriateness of potential management actions, public uses, and technologies in Wilderness. Thus, we need to know what it is. We need a sense of how tangible and intangible attributes of a landscape converge to shape wilderness character, and how our actions may diminish or enhance this elusive, but definitive quality.

The natural, scenic condition of the land, natural numbers and interactions of wildlife, the integrity of ecological processes: these are all essential characteristics of the wilderness condition. But at its core, wilderness character, like personal character, is much more than a physical condition. This is what the ness of wilderness conveys—an aura or essence that connects the physical entity to deeper meanings it has come to embody.

The character of wilderness is an unseen presence capable of refocusing our perception of nature and our relationship to it. It is that quality that lifts our connection to a landscape from the utilitarian, commodity orientation that dominates the major part of our relationship with nature to the symbolic realm serving other human needs.

This transcendent function of wilderness character is recognized in the legislative history written by the Wilderness Act's chief author, Howard Zahniser:

We deeply need the humility to know ourselves as the dependent members of a great community of life, and this can indeed be one of the spiritual benefits of a wilderness experience. Without the gadgets, the inventions, the contrivances whereby men have seemed to establish among themselves an independence of nature, without these distractions, to know the wilderness is to know a profound humility, to recognize one's littleness, to sense dependence and interdependence, indebtedness, and responsibility.—The Need for Wilderness Areas, 1956

Like a cathedral or shrine or memorial to which it is so often compared, wilderness serves an ancestral impulse—found throughout time and across cultures—to set some places apart as the embodiment of an ideal. The wilderness ideal, as Zahniser so eloquently stated, is the need for places where we can know ourselves as part of something beyond our modern society and its creations, something more timeless and universal.

Wilderness character is not preserved by our compliance with wilderness legislation and regulation alone. It emerges from the circumstances we impose upon ourselves. It emerges from the decisions we make that test our commitment to our ideals. Does our choice represent a willingness to compromise for convenience and expediency? Or does it represent our willingness to stand tall in the

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arena of controversy, the triumph of principle?

Every management decision against an action or technology that might degrade the wilderness condition serves to uphold and strengthen the character it is seen to have. Every decision to forgo actions, technologies, or conveniences that have no seeming physical impact but detract from our commitment to wilderness as a place set apart enhances wilderness and agency character more, because sacrifice for an ideal is the strongest gesture of respect.

The Wilderness Act provides guidance for such decisions. But beyond its listing of certain allowed and prohibited uses, much ambiguity remains. Like the stewards of the Saint Paul Cathedral, Arlington Cemetery, or the Viet Nam Memorial, we have few objective criteria, and no standard metric with which to quantify or evaluate actions that enhance or detract from the character of our nation's natural sacred places. This is the unique challenge of wilderness management, preserving what is unseen and unmeasurable.

But Zahniser's words suggest that chief among our criteria should be the purpose of the action, the spirit in which it is carried out, and the effect it will have on our way of thinking. Will the action reinforce the primacy of our uses and benefits, our convenience and expediency? Or will it serve to affirm our role as humble, respectful guests and servants of the landscape? As the criteria we choose shapes the character of wilderness, so it shapes our character as stewards.

Consider a proposed habitat modification. If its purpose is to aid the survival of an endangered species, the action is congruent with the character of wilderness. But the same action, intended to increase the population of a preferred game species, violates the idea of respect for natural processes. Similarly, use of a wheelchair by the disabled is within the spirit of wilderness use, while a mountain bike, at the same level of technology, is not.

Wallace Stegner called Wilderness America's "geography of hope"—the hope for an undiminished future. Nowhere is this stewardship ideal expressed more visibly, nowhere is it made more apprehensible than in those remnant landscapes we allow to be wild and free. Free of our tendency to dominate and bend nature to our purposes. Thus free to inspire thinking outside the context of our uses, and beyond the boundary of our life and lifetime.

This convergence of vision and restraint is the source and symbolism of wilderness character. It is that essential being of the land which evokes what Zahniser described as the spiritual benefit of the wilderness experience. It is that quality that transcends physical boundaries to touch the millions who will never come, but who find inspiration and hope just in knowing some places are—and will always be—wild and free.

Exhibit 4.—Minimum Requirement Decision Guide

Note: Exhibit 4 is not printed in the **Federal Register**. It is available on the internet at *http://www.wilderness.net/carhart/docs/min req dec guide.PDF* and by written request to: National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22003.

Exhibit 5.—Light and Noise Pollution

Protection of Dark Night Skies

Dark night skies, unpolluted by manmade light, are integral to the wilderness experience and allow visitors to fully appreciate the stars and planets. Dark night skies are essential to some wildlife. We will cooperate with neighbors and local government agencies to minimize the intrusion of artificial light in wilderness areas.

Noise Pollution

We will strive to preserve the natural quiet and the natural sounds associated with wilderness (for example, the sounds of the winds in the trees or the howl of a wolf). We should monitor activities causing excessive or unnecessary unnatural sounds in and adjacent to wilderness areas, including low-elevation aircraft overflights. We will take action to prevent or minimize unnatural sounds that adversely affect wilderness resources or values or visitors' enjoyment of them.

Exhibit 6.—Leave No Trace

Memorandum of Understanding

Note: Exhibit 6 is not printed in the **Federal Register**. It is available on the internet at *http://refuges.fws.gov/library/* or by written request to: National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22003.

Exhibit 7.—Primary Interpretive Themes for Wilderness

Interpretation provides opportunities for people to forge intellectual and emotional connections to the meanings inherent in wilderness resources. Interpretive themes communicate specific messages based upon the significance of the wilderness resource and experience to the American people. They are the stories through which we convey the values of wilderness to the public. These themes connect wilderness to larger ideas as well as universal meanings and values. They are the building blocks on which we base interpretive products and services for wilderness. The interpretive themes for wilderness areas are:

PRIMARY INTERPRETIVE THEMES FOR WILDERNESS EDUCATION

Theme A	The concept of wilderness, codified in law, originated in the United States with the conviction that some wild land resources are most valuable to Americans left in their natural state (e.g. social, scientific, economic, educational, recreational, and cultural value).
Theme B	As a foundation for healthy and diverse ecosystems, officially designated wilderness and other remaining wild lands provide critical habitat for rare and endangered species and play a significant role in the overall health of natural systems worldwide (e.g. watersheds, air quality).
Theme C	By law, we manage wilderness differently than other federal lands in order to retain its primeval character and preserve wilderness as a special place for humans to examine their relationship to the natural world.
Theme D	Wilderness offers opportunities for personal renewal, inspiration, artistic expression, pride of ownership of our shared heritage, and the prospect of hope for the future. Wilderness has inspired and continues to inspire a distinctive genre of literature and art, enriching millions of lives in the United States and around the world.
Theme E	Wilderness provides opportunities for physical and mental challenge, risk and reward, renewal, self-reliance, solitude, and serves as a haven from the pressures of modern society (e.g. exploration, discovery, and recreation).
Theme F	The survival of wilderness depends on individual and societal commitment to the idea of wilderness and on appropriate visitor use, behavior, and values (e.g. appreciation, values, skills).
Theme G	Wilderness provides a unique setting for teaching ecosystem stewardship as well as science, math, literature, art and other subjects using an interdisciplinary approach (e.g. civics, outdoor skills, music, and others).
Theme H	Wilderness contains primitive areas relatively undisturbed by human activities where scientific research may reveal information about natural processes and living systems that may have wide-ranging applications and may serve as global indicators of ecological change.
Theme I	Cultural and archeological sites found in wilderness can provide a more complete picture of human history and culture. (This includes indigenous peoples, conquests, colonialism and resistance, freedom, independence, and ingenuity, a sense of connectedness, stewardship, and human survival.)
Theme J	The Wilderness Act created a National Wilderness Preservation System that preserves some of the most unique ecological, geological, scientific, scenic, and historical values in the National Park System, the National Wildlife Refuge System, National Forest System, and in public lands administered by the Bureau of Land Management, and that the public and Congress have determined to require special protection.

PRIMARY INTERPRETIVE THEMES FOR WILDERNESS EDUCATION—Continued

Theme K	Wilderness visitors must accept certain inherent risks associated with weather, terrain, water, wildlife, and other natural elements. We cannot guarantee visitor safety, but we can enhance it with proper trip planning, appropriate skill, and responsible behavior.

Exhibit 8.—References

Hendee, John C., Stankey, George H., Lucas, Robert C., 1990, Wilderness Management, North American Press, Golden, Colorado, pp. 219–238.

Zahniser, Howard, 1956, "The Need for Wilderness Areas," The Living Wilderness, Winter-Spring 1956–57, No. 59, pp 37–43.

Exhibit 9.—Wilderness Management Plan Outline

I. Introduction.

A. Wilderness establishment, including contents of pertinent laws, date of establishment, any changes from Secretary's recommendation, pertinent committee report discussion, and special provisions.

B. Objectives for the wilderness area and their relationship to the refuge's purposes and objectives, and System mission, goals, and objectives, including protection of the air quality related values of Class I wilderness areas.

II. Description of the Wilderness Area.

A. Legal and narrative description of the area.

B. Map displaying Service land unit boundary and wilderness area boundary.

C. A description of the current or baseline situation of the wilderness resource, including a description of the wilderness area, natural conditions, management activities, existing facilities, and public use levels and activities.

III. Public Involvement. Describe public involvement activities and provide a summary and analysis of comments received and how the plan responds to them.

IV. Management.

A. Detailed discussions of existing and planned biological, public use, cultural resource, and administrative management activities and permitted uses.

B. Procedures for determining and documenting the minimum requirement for administrative actions we will take in wilderness that might require a generally prohibited use.

C. The minimum requirement analyses for anticipated application of a generally prohibited use.

D. Descriptions of how valid existing rights and congressionally authorized uses are to be administered to provide protection to wilderness values.

E. An explanation of how we will coordinate with adjoining wilderness units so that visitors traveling from one wilderness to another can do so with a minimum of bureaucratic impediments.

F. Indicators of change in resource conditions; standards for measuring that change; and desired conditions, or thresholds, that will trigger management actions to reduce or prevent impacts on the wilderness. Limits of Acceptable Change (LAC) is one framework designed for establishing indicators, standards and desired conditions. (See Hendee, Stankey, and Lucas (1990) in Exhibit 8 References).

V. Research. Describe any past and current research, and identify research needs.

VI. Funds and Personnel. Provide a discussion of staff and funds needed to manage the wilderness.

VII. Monitoring. Identify monitoring requirements and thresholds for action, including procedures for measuring baseline air quality.

VIII. Implementation Schedule. Provide a schedule of implementation, prioritization of action items, staff assignments, and funding requirements to adequately administer the area.

IX. Compatibility Determination

X. Review and Approval.

XI. Appendix.

A. A copy of the Wilderness Act.

B. A copy of the legislation establishing the wilderness.

C. Service wilderness regulations (50 CFR 35), except Alaska.

D. Wilderness study report for the wilderness.

E. NEPA documentation, if applicable.

F. Public hearing record from wilderness study.

G. Congressional hearing record.

H. Congressional committee report accompanying the authorizing legislation.

Dated: November 29, 2000.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 01–18 Filed 1–12–01; 8:45 am]

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January 16, 2001

Part IV

Securities and Exchange Commission

17 CFR Parts 239, 240, 270, and 274
Role of Independent Directors of Investment Companies; Final Rule

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239, 240, 270 and 274

[Release Nos. 33–7932; 34–43786; IC–24816; File No. S7–23–99]

RIN 3235–AH75

Role of Independent Directors of Investment Companies

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Commission is adopting amendments to certain exemptive rules under the Investment Company Act of 1940 to require that, for investment companies that rely on those rules: independent directors constitute a majority of their board of directors; independent directors select and nominate other independent directors; and any legal counsel for the independent directors be an independent legal counsel. We also are adopting amendments to our rules and forms to improve the disclosure that investment companies provide about their directors. These amendments are designed to enhance the independence and effectiveness of boards of directors of investment companies and to better enable investors to assess the independence of those directors.

DATES: *Effective Date:* February 15, 2001, except that the rescission of § 270.2a19–1 under the Investment Company Act will become effective May 12, 2001.

Compliance Date: Section III of this release contains information on compliance dates.

FOR FURTHER INFORMATION CONTACT: For information regarding the Investment Company Act rule amendments, contact Jaea F. Hahn, Attorney, Martha B. Peterson, Special Counsel, or C. Hunter Jones, Assistant Director, Office of Regulatory Policy, (202) 942–0690, or regarding the disclosure amendments, contact Kimberly Browning, Attorney, Peter M. Hong, Special Counsel, or Kimberly Dopkin Rasevic, Assistant Director, Office of Disclosure Regulation, (202) 942–0721, at the Division of Investment Management, Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549–0506.

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission (the "Commission") is adopting new rules 2a19–3 [17 CFR 270.2a19–3], 10e–1 [17 CFR 270.10e–1], and 32a–4 [17 CFR 270.32a–4] and amendments to rules 0–1 [17 CFR 270.0–1], 10f–3 [17 CFR 270.10f–3], 12b–1 [17 CFR 270.12b–1], 15a–4 [17 CFR 270.15a–4], 17a–7 [17 CFR 270.17a–7], 17a–8 [17 CFR 270.17a–8], 17d–1 [17 CFR 270.17d–1], 17e–1 [17 CFR 270.17e–1], 17g–1 [17 CFR 270.17g–1], 18f–3 [17 CFR 270.18f–3], 23c–3 [17 CFR 270.23c–3], 30d–1 [17 CFR 270.30d–1], 30d–2 [17 CFR 270.30d–2], and 31a–2 [17 CFR 270.31a–2] under the Investment Company Act of 1940 [15 U.S.C. 80a] ("Investment Company Act" or "Act"); amendments to Forms N–1A [17 CFR 274.11A], N–2 [17 CFR 274.11a–1], and N–3 [17 CFR 274.11b] under the Investment Company Act and the Securities Act of 1933 [15 U.S.C. 77a–aa] ("Securities Act"); and amendments to Schedule 14A [17 CFR 240.14a–101] under the Securities Exchange Act of 1934 [15 U.S.C. 78a–mm] ("Exchange Act"). The Commission also is rescinding rule 2a19–1 under the Investment Company Act [17 CFR 270.2a19–1].

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Executive Summary

The Commission is adopting new rules and amendments to rules and forms to enhance the independence and effectiveness of independent directors of investment companies ("funds"). First, we are adopting amendments to require, for funds relying on certain exemptive rules, that:

- Independent directors constitute a majority of the fund's board of directors;
- Independent directors select and nominate other independent directors; and
- Any legal counsel for the fund's independent directors be an independent legal counsel.

Second, the rules and amendments:

- Prevent qualified individuals from being unnecessarily disqualified from serving as independent directors;
- Protect independent directors from the costs of legal disputes with fund management;
- Permit us to monitor the independence of directors by requiring funds to keep records of their assessments of director independence;
- Temporarily suspend the independent director minimum percentage requirements if a fund falls below a required percentage due to an independent director's death or resignation; and
- exempt funds from the requirement that shareholders ratify or reject the directors' selection of an independent public accountant, if the fund establishes an audit committee composed entirely of independent directors.

Finally, we are requiring that funds provide better information about directors, including:

- Basic information about the identity and business experience of directors;
- Fund shares owned by directors;
- Information about directors that may raise conflict of interest concerns; and
- The board's role in governing the fund.

Together, these new rules and amendments are designed to reaffirm the important role that independent directors play in protecting fund investors, strengthen their hand in dealing with fund management, reinforce their independence, and provide investors with greater information to assess the directors' independence.

I. Background

Mutual funds are organized as corporations, trusts, or limited partnerships under state laws, and thus are owned by their shareholders, beneficiaries, or partners.[1] Like other types of corporations, trusts, or partnerships, a mutual fund must be operated for the benefit of its owners.[2] Unlike most business organizations, however, mutual funds are typically organized and operated by an investment adviser that is responsible for the day-to-day operations of the fund. In most cases, the investment adviser is separate and distinct from the fund it advises, with primary responsibility and loyalty to its own shareholders.[3] The "external management" of mutual funds presents inherent conflicts of interest and potential for abuses that the Investment Company Act and the Commission have addressed in different ways.[4]

One of the ways that the Act addresses conflicts between advisers and funds is by giving mutual fund boards of directors, and in particular the disinterested directors,[5] an important role in fund governance.[6] In relying on fund boards to represent fund investors and protect their interests, Congress avoided the more detailed regulatory provisions that characterize other regulatory schemes for collective investments.[7] The Commission has similarly relied extensively on independent directors in rules we have adopted that exempt funds from provisions of the Act.[8]

Millions of Americans are today invested in mutual funds, which have experienced a tremendous growth in popularity over the past twenty years.[9] In light of this growth, and our growing reliance on independent directors to protect fund investors, last year we undertook a review of the governance of investment companies, the role of independent directors, our rules that rely on oversight by independent directors, and the information that funds are required to provide to shareholders about their independent directors.

We held a Roundtable discussion at which independent directors, investor advocates, executives of fund advisers, academics, and experienced legal counsel offered a variety of perspectives and suggestions.[10] After evaluating the ideas and suggestions offered by Roundtable participants last year, we proposed a package of rule and form amendments that were designed to reaffirm the important role that independent directors play in protecting fund investors, strengthen their hand in dealing with fund management, reinforce their independence, and provide investors with better information to assess the independence of directors.[11]

We received 142 comment letters on our proposals, including 86 letters from independent directors.[12] Commenters generally commended our efforts to enhance the independence and effectiveness of fund directors, although many offered recommendations for improving portions of the proposals. Many of these letters were helpful to us in formulating the final rules and amendments, which we are today adopting.

We have reason to believe that our efforts to improve the governance of mutual funds on behalf of mutual fund investors have already borne fruit. Our Roundtable discussions and proposed rules have provoked a great deal of discussion among directors, advisers, counsel, and investors about governance practices and policies. After our Roundtable, an advisory group organized by the Investment Company Institute ("ICI") made recommendations regarding fund governance in a "best practices" report ("ICI Advisory Group Report").[13] Many boards, we understand, have adopted the recommendations set forth in the ICI Advisory Group Report. Some groups of independent directors have hired independent counsel for the first time. Director nomination and selection procedures have been revised.

During the last year, Commissioners and members of the staff began meeting with independent directors and sharing ideas and concerns regarding the governance of mutual funds.[14] Former Commission Chairman David Ruder established the Mutual Fund Directors Education Council, a broad-based group of persons interested in fund governance and operations,[15] whose purpose is to foster the development of educational activities designed to promote the efficiency, independence, and accountability of independent fund directors. The American Bar Association formed a task force to examine the role of counsel to independent directors, and the task force released a report offering guidance to counsel and fund directors

[1] For simplicity, this release focuses on mutual funds (*i.e.*, open-end funds). The amendments we are adopting, however, apply to all management investment companies, except where noted.

[2] *See generally* James M. Storey & Thomas M. Clyde, Mutual Fund Law Handbook § 7.2 (1998); Allan S. Mostoff & Olivia P. Adler, *Organizing an Investment Company—Structural Considerations, in* The Investment Company Regulation Deskbook § 2.4 (Amy L. Goodman ed., 1997).

[3] As a result of their extensive involvement, and the general absence of shareholder activism, investment advisers typically dominate the funds they advise. *See* Role of Independent Directors of Investment Companies, Investment Company Act Release No. 24082 (Oct. 14, 1999) [64 FR 59826 (Nov. 3, 1999)] ("Proposing Release") at n.10 and accompanying text.

[4] An investment adviser's shareholders often have an interest in a mutual fund that is quite different from the interests of the fund's own shareholders. For example, while fund shareholders ordinarily prefer lower fees (to achieve greater returns), shareholders of the fund's investment adviser might want to maximize profits through higher fees. *See* Proposing Release, *supra* note 3, at nn.11–25 and accompanying text, for a discussion of the comprehensive regulatory scheme established by the Act to address conflicts of interest between funds and their investment advisers.

[5] We refer to directors who are not "interested persons" of the fund as "independent directors" or "disinterested directors." *See* section 2(a)(19) of the Act [15 U.S.C. 80a–2(a)(19)](defining "interested person").

[6] The Investment Company Act establishes a system of "checks and balances," and relies on independent directors to "oversee the fund's operations so as to prevent abuses of investors." James M. Storey & Thomas M. Clyde, The Uneasy Chaperone 34 (2000). Directors also have broad responsibilities to monitor compliance with securities, corporate and other laws. Robert A. Robertson, *Board Oversight of Mutual Fund Compliance Operations*, Rev. Sec. & Comm. Reg., Oct. 24, 2000, at 1.

[7] For example, in Japan, funds may be structured only in the form of securities investment trusts, which are primarily subject to regulation under the Securities Investment Trust Law. There is no board of directors or board of trustees, and under the Securities Investment Trust Law, a "trustor company" manages the trust assets on behalf of the beneficiaries of the trust. The Japanese Ministry of Finance approves the terms and conditions of securities investment trusts, and plays a supervisory role in the day-to-day operations of the trusts. *See* Yoshiki Shimada et al., *Regulatory Frameworks for Pooled Investment Funds: A Comparison of Japan and the United States*, 38 Va. J. Int'l L. 191 (1998).

[8] *See* Proposing Release, *supra* note 3, at nn.24–25 and accompanying text.

[9] Approximately 82.8 million individuals in 48.4 million households in the United States invest in funds. Investment Company Institute, Mutual Fund Fact Book 41 (2000).

[10] *See* SEC, Notice of Sunshine Act Meetings (Feb. 18, 1999) [64 FR 8632 (Feb. 22, 1999)]; *see also* Transcripts from the Roundtable on the Role of Independent Investment Company Directors, Feb. 23–24, 1999 ("Roundtable Transcripts"). The Roundtable Transcripts are available to the public in the Commission's public reference room and the Commission's Louis Loss Library. They are also available on the Commission's Internet web site <http://www.sec.gov/offices/invmgmt/rountab.htm>.

[11] *See* Proposing Release, *supra* note 3.

[12] The comment letters and a summary of the comments prepared by Commission staff are available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. (File No. S7–23–99). The comment summary is also available on the Commission's Internet web site <http://www.sec.gov/rules/extra/brownin1.htm>.

[13] *See* Investment Company Institute, Report of the Advisory Group on Best Practices for Fund Directors: Enhancing a Culture of Independence and Effectiveness (June 24, 1999).

[14] *See, e.g.*, Arthur Levitt, Chairman, SEC, Remarks at the Mutual Fund Directors Education Council Conference (Feb. 17, 2000) (transcript available at <http://www.sec.gov/news/speeches/spch346.htm>); Paul Roye, Director, Division of Investment Management, SEC, What Does It Take To Be an Effective Independent Director of a Mutual Fund?, Address at the ICI Workshop for New Fund Directors (Apr. 14, 2000) (transcript available at <http://www.sec.gov/news/spoeches/spch364.htm>).

[15] Members of the Council include independent directors, corporate governance experts, investor advocates, academics, industry members, and investment management attorneys.

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regarding standards of independence for counsel, and guidelines for reducing potential conflicts of interest ("ABA Task Force Report").[10] All of these initiatives have focused attention on the important role of independent directors, and their importance in promoting and protecting the interests of fund shareholders.

II. Discussion

A. Amendments to Exemptive Rules To Enhance Director Independence and Effectiveness

We are amending ten rules that exempt funds and their affiliates from certain prohibitions of the Act (the "Exemptive Rules").[17] As discussed further below, the amendments add conditions to the Exemptive Rules to require that, for funds that rely on the rules, (i) independent directors constitute a majority of the board, (ii) independent directors select and nominate other independent directors, and (iii) any legal counsel for the independent directors be an independent legal counsel.[18]

Most commenters supported our goal of enhancing the independence and effectiveness of independent directors of funds that choose to rely on the Exemptive Rules.[19] Some commenters questioned the need to amend the rules, because each rule already requires independent directors to separately approve some of the fund's activities under the rule. We selected these rules because they require the independent judgment and scrutiny of independent directors in overseeing activities that are beneficial to funds and investors, but involve inherent conflicts of interest between the funds and their managers.[20] The amendments are designed to increase the ability of independent directors to perform their important responsibilities under each of these rules.

1. Independent Directors as a Majority of the Board

(a) Board Composition Requirements

We are amending the Exemptive Rules to require that the boards of funds relying on the rules have a majority of independent directors.[21] A majority requirement will permit, under state law, the independent directors to control the fund's "corporate machinery," *i.e.*, to elect officers of the fund, call meetings, solicit proxies, and take other actions without the consent of the adviser.[22] As a result, independent directors who comprise the majority of a board can have a more meaningful influence on fund management and represent shareholders from a position of strength.[23] In short, a board with a majority of independent directors can be more effective in representing investors than a board with a majority of "inside" directors.[24] Commenters were supportive of this proposal.[25]

We are allowing funds ample time to implement the new majority independence condition. The compliance date for the majority independence condition is July 1, 2002. Although most funds already have a majority of independent directors, the transition period will allow sufficient time for those that do not, to carry out the selection, nomination, and election of new independent directors in accordance with the amended rules.[26]

(b) Suspension of Board Composition Requirements

We are adopting new rule 10e–1, which temporarily suspends the board composition requirements of the Act and our rules, if a fund fails to meet those requirements because of the death, disqualification, or bona fide resignation of a director. For a fund that relies on one or more of the Exemptive Rules, rule 10e–1 will provide relief if the fund no longer has a majority of independent directors because of the sudden loss of one or more directors.[27]

Rule 10e–1 suspends the board composition requirements for 90 days if the board can fill a director vacancy, or 150 days if a shareholder vote is required to fill a vacancy.[28] We have extended the time period when only board action is required (from the 60 day period we proposed) in response to comments that additional time would be needed for independent directors to select and nominate candidates, and for the board to elect new directors.[29]

2. Selection and Nomination of Independent Directors

We are adopting, as a condition of the Exemptive Rules, a requirement that the independent directors of funds relying on those rules select and nominate[30] any other independent directors.[31] Commenters supported the proposal, and many specifically agreed that the self-selection and self-nomination of independent directors fosters an independent-minded board that focuses primarily on the interests of a fund's investors rather than its adviser.[32]

Several commenters asked that we clarify the extent to which fund shareholders or a fund's adviser may participate in the selection and nomination process under the amendments. Control of the selection and nomination process at all times should rest with a fund's independent directors.[33] These amendments are not intended to supplant or limit the ability of fund shareholders under state law to nominate independent directors. The adviser may suggest independent director candidates if the independent directors invite such suggestions, and the adviser may provide administrative assistance in the selection and nomination process. Independent directors, however, should not view participation by shareholders and investment advisers in this process as precluding or excusing the independent directors from the responsibility to canvass, recruit, interview, and solicit independent director candidates.

3. Independent Legal Counsel

We are adopting amendments to each of the Exemptive Rules to require that any legal counsel for the fund's independent directors be an "independent legal counsel."[34] We believe that the conflicts involved in the transactions and arrangements permitted by the Exemptive Rules make it critical that independent directors, when they seek legal counsel, be represented by persons who are free of significant conflicts of interest that might affect their legal advice.[35]

The Commission received many comments on this proposal. Most fund management companies, and a number of independent directors and their lawyers, opposed the proposed amendments. Many argued that the selection of counsel was a matter that should be left to independent directors. Some argued that the bar association rules of professional conduct are adequate to assure independence of counsel. Others argued that imposing the independent counsel requirement could deny independent directors competent counsel from larger law firms with many potential conflicts.

Given the vital role of independent directors in the resolution of conflicts between the fund and its investment adviser, it is important that they have access to counsel who is free from conflicting loyalties. This is particularly true when directors are called upon to exercise judgment in certain key areas of their responsibilities such as approving the advisory contract or a distribution plan, approving a merger, monitoring the allocation of fund brokerage, or valuing fund securities.[36] Yet, as we observed in the Proposing Release, some independent directors have relied on

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[10] ABA, Report of the Task Force on Independent Director Counsel, Subcommittee of Investment Companies and Investment Advisers, Committee on Federal Regulation of Securities, Section of Business Law: Counsel to the Independent Directors of Registered Investment Companies (Sept. 8, 2000).

[17] The Exemptive Rules are:

Rule 10f–3 (permitting funds to purchase securities in a primary offering when an affiliated broker-dealer is a member of the underwriting syndicate);

Rule 12b–1 (permitting use of fund assets to pay distribution expenses);

Rule 15a–4(b)(2) (permitting fund boards to approve interim advisory contracts without shareholder approval where the adviser or a controlling person receives a benefit in connection with the assignment of the prior contract);

Rule 17a–7 (permitting securities transactions between a fund and another client of the fund's adviser);

Rule 17a–8 (permitting mergers between certain affiliated funds);

Rule 17d–1(d)(7) (permitting funds and their affiliates to purchase joint liability insurance policies);

Rule 17e–1 (specifying conditions under which funds may pay commissions to affiliated brokers in connection with the sale of securities on an exchange);

Rule 17g–1(j) (permitting funds to maintain joint insured bonds);

Rule 18f–3 (permitting funds to issue multiple classes of voting stock); and

Rule 23c–3 (permitting the operation of interval funds by enabling closed-end funds to repurchase their shares from investors).

[18] We discuss each of these conditions below. *See infra* Sections II.A.1, II.A.2, and II.A.3.

[19] We have revised the amendments to rule 15a–4, which permits fund boards to approve interim advisory contracts without shareholder approval. Funds have relied on that rule when an advisory contract terminated in unforeseeable circumstances, such as the death of the fund's investment adviser. After we issued the Proposing Release, we amended rule 15a–4 to further permit interim advisory contracts in foreseeable circumstances, when an adviser or controlling person receives a benefit in connection with the termination of the prior advisory contract (*e.g.*, in the context of an adviser merger). *See* Temporary Exemption for Certain Investment Advisers, Investment Company Act Release No. 24177 (Nov. 29, 1999) [64 FR 68019 (Dec. 6, 1999)]. Three commenters argued that the availability of the rule in *unforeseeable* circumstances should not depend on the fund's compliance with the conditions that we proposed to add to the Exemptive Rules. In addition, one commenter further argued that funds that do not comply with the new conditions could be constrained from terminating an adviser because they are unable to enter into an interim advisory contract without obtaining an exemptive order. In light of these comments, we have determined to amend only the paragraph of rule 15a–4 that permits interim advisory contracts in foreseeable circumstances. *See* rule 15a–4(b)(2).

[20] As we noted in the Proposing Release, the Exemptive Rules provide exemptive relief that affords funds increased flexibility, cost reductions, and the ability to operate for the maximum benefit of investors. At the same time, these rules involve inherent conflicts of interest between funds and their managers, and therefore rely on independent directors to monitor those conflicts. While the Exemptive Rules have greatly expanded the responsibilities of fund boards, most have not contained conditions to enhance director independence and effectiveness. *See* Proposing Release, *supra* note 3, at n.30 and accompanying text. In the future we will be reluctant to issue exemptive orders premised on the oversight of independent directors, if the fund does not meet the new conditions we are today adopting.

[21] The independent directors thus would need to comprise more than half of the membership of the board. The Investment Company Act generally requires that independent directors constitute at least 40 percent of the board. Section 10(a) of the Act (15 U.S.C. 80a–10(a)). Section 10(b)(2) of the Act (15 U.S.C. 80a–10(b)(2)) requires, in effect, that independent directors comprise a majority of a fund's board if the fund's principal underwriter is an affiliate of the fund's adviser. Section 15(f)(1) of the Act (15 U.S.C. 80a–15(f)(1)) provides a safe harbor for the sale of an advisory business if directors who are not interested persons of the adviser constitute at least 75 percent of a fund's board for at least three years following the assignment of the advisory contract.

[22] *See* Proposing Release, *supra* note 3, at text following n.44.

[23] *See* Proposing Release, *supra* note 3, at nn.36–44 and accompanying text.

[24] *See Burks* v. *Lasker*, 441 U.S. 471, 484 (1979) (discussing the "independent watchdog" function of independent directors).

[25] In the Proposing Release, we proposed two alternative board composition standards: (i) a simple majority and (ii) a two-thirds supermajority, as recommended by the ICI Advisory Group Report. We are adopting a simple majority independence standard, which most commenters supported.

[26] *See infra* Section II.A.2 (Selection and Nomination of Independent Directors).

[27] Without the relief provided by rule 10e–1, the consequence of losing an independent director and failing to have a majority of independent directors would be significant and immediate because funds would lose the ability to rely on the Exemptive Rules.

[28] Section 10(e) of the Act [15 U.S.C. 80a–10(e)] currently suspends the Act's board composition requirements for 30 days, if a fund's board may fill a director vacancy, or 60 days, if a shareholder vote is required to fill a vacancy. Section 10(e) also authorizes the Commission to issue rules or orders prescribing longer periods for filling board vacancies.

[29] The time periods begin to run when the fund no longer meets the applicable board composition requirement, even if the fund is not yet aware that it no longer meets the requirement. Funds and directors should be mindful of their responsibilities to maintain the required percentage of independent directors, and should monitor director independence (and other composition issues) accordingly. A fund also could avoid problems posed by the time constraints of rule 10e–1 by maintaining a greater percentage of independent directors than the simple majority required by the Exemptive Rules. *See* ICI Advisory Group Report, *supra* note 13, at 10–12 (recommending as a best practice that funds have a two-thirds majority of independent directors).

[30] Selection and nomination refers to the process by which board candidates are researched, recruited, considered, and formally named.

[31] Rules 12b–1 and 23c–3 already require funds relying on those rules to commit the selection and nomination of independent directors to the discretion of those directors. We are amending rules 12b–1 and 23c–3 to conform their language regarding self-selection and nomination to the language of the other Exemptive Rules.

[32] *See* Kenneth E. Scott, *What Role Is There for Independent Directors of Mutual Funds?*, 2 Vill. J.L. & INV. MGMT. 1, 4 (2000) ("Independence [of a director] is a reflection of how you got on the board and how you can be taken off."). The self-selection and self-nomination condition applies prospectively, *i.e.*, to independent directors elected after the effective date of the rules. Thus, current independent directors who were not selected and nominated by other independent directors may continue to serve as independent directors until the end of their terms, but any new independent directors must be selected and nominated by the incumbent independent directors. *See* Proposing Release, *supra* note 3, at n.69 and accompanying text.

[33] *See* The Robinson Humphrey Co., Inc., SEC No-Action Letter (Sept. 4, 1976) (analyzing the term "selected and proposed for election" in section 16(b) of the Act (15 U.S.C. 80a–16(b)) and concluding that independent directors had not been properly selected by other independent directors).

[34] *See* amended rules 10f–3(b)(11)(ii); 12b–1(c)(2); 15a–4(b)(2)(vii)(B); 17a–7(f)(2); 17a–8(c)(2); 17d–1(d)(7)(v)(B); 17e–1(c)(2); 17g–1(j)(3)(ii); 18f–3(e)(2); and 23c–3(b)(8)(ii). We rely on the concept of "independence" both in this rule and in our auditor independence rule. *See* Revision of the Commission's Auditor Independence Requirements, Securities Act Release No. 7919 (Nov. 21, 2000) (65 FR 76008 (Dec. 5, 2000)) (adopting release); Revision of the Commission's Auditor Independence Requirements, Securities Act Release No. 7870 (June 30, 2000) (65 FR 43148 (July 12, 2000)) (proposing release). It is important to note, however, that we use the concept in distinct ways in these two rules. In adopting amendments to the auditor independence rule, our goal was to reduce the potential for conflicts of interest that impair the auditor's ability to conduct an objective and impartial audit. Under rules of professional responsibility, attorneys have an obligation zealously to represent their clients. *See* Model Code of Professional Responsibility EC 7–1; *see also* Model Rules of Professional Conduct ["ABA Model Rules"] Rules 1.2(d), 1.3 and 3.1 (1998). With respect to the independent counsel provisions in this rule, we use "independence" to refer to the limits on relationships with third parties that might affect counsel's capacity to provide zealous representation in advising and representing a fund's independent directors.

[35] The amendments we are today adopting do not *require* that independent directors retain an independent counsel, but only that any person who acts as legal counsel to the independent directors be an "independent legal counsel." We requested comment on whether to *require* independent counsel for independent directors. Some commenters supported a requirement while others argued that independent directors should decide for themselves whether they need counsel. We have determined that not requiring independent counsel is the appropriate course at this time. We continue to believe, however, that a likely result of our rule amendments will be that many fund directors seek independent counsel. *See* ABA Task Force Report, *supra* note 16, at 3 ("The complexities of the Investment Company Act, the nature of the separate responsibilities of independent directors and the inherent conflicts of interest between a mutual fund and its managers effectively require that independent directors seek the advice of counsel in understanding and discharging their special responsibilities.").

[36] We believe that independent directors' access to independent counsel is also of key importance when directors address questions of the appropriateness and legality (under sections 17(a) and 17(d) of the Act) of proposed transactions between the fund and its promoter, adviser, or principal underwriter (or any other affiliated person). These matters (and those described in the text above) go to the core of matters addressed by the Act and the relationship between the fund, its adviser, and shareholders and may require the directors to deny fund management's wishes. Independent counsel can assist directors in understanding management proposals, their legal implications, and the obligations of directors under the law. When a lawyer for the independent directors—however learned and well intentioned—also represents the fund's adviser, he may be reluctant to recommend courses of action to the directors that are opposed by the adviser.

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counsel who has simultaneously represented the fund's adviser, or who does substantial legal work for the adviser or its affiliates.[37] We continue to be concerned by these conflicts and how they affect the ability of directors to carry out their responsibilities under the Act and the Exemptive Rules.

Funds also should be concerned when counsel to the independent directors have these types of conflicts of interest. The appearance of a conflict undermines the confidence investors have in the independence of their fund's directors to represent *investors'* interests. Directors who accept these conflicts strengthen the argument that more drastic changes are necessary in the way mutual funds are governed.[38] Fund advisers also should be concerned when independent directors engage counsel with substantial conflicts, because the adviser and the funds may be denied a significant defense in any lawsuit charging that its advisory fee or other payments or transactions are excessive or inappropriate.[39]

While we are persuaded that Commission rulemaking is necessary, we appreciate the concerns that the independent directors expressed in their comment letters on the proposed amendments. Many were concerned that the proposal did not afford them sufficient flexibility in selecting counsel. Some misunderstood our proposal as permitting counsel to have conflicts that are only extremely small or remote. That was not our intention, which we have clarified in revising the proposed amendments.

Under the final rule amendments, reliance on each of the Exemptive Rules would be conditioned on any legal counsel for a fund's independent directors being an "independent legal counsel."[40] A person[41] is considered an independent legal counsel if (i) the independent directors determine that any representation of the fund's investment adviser, principal underwriter, administrator (collectively "management organizations") or their control persons[42] during the past two fiscal years is or was *sufficiently limited*[43] that it is unlikely to adversely affect the professional judgment of the person in providing legal representation,[44] and (ii) the independent directors have obtained an undertaking from the counsel to provide them information necessary for their determination, and to update promptly that information if the counsel begins, or materially increases, the representation of a management organization or control person.[45]

The final amendments rely on the independent directors to determine whether a person is an independent legal counsel. They must make this determination no less frequently than annually, and the basis for the determination must be recorded in the board's meeting minutes.[46] If the independent directors obtain information that their counsel has begun to represent a management organization or control person, they must determine whether this new representation—together with any other representations of management organizations and control persons—is unlikely to adversely affect the counsel's professional judgment.[47] In order to prevent the fund from losing the availability of the exemptions in these circumstances, the rule provides that counsel can still be considered "independent legal counsel" for up to three months, which will provide time for the independent directors to make a new determination about the counsel or to hire a new independent legal counsel.[48]

[37] *See* Proposing Release, *supra* note 3, at n.80 and accompanying text.

[38] *See* Letter from Phillip Goldstein, Independent Director, Clemente Strategic Value Fund, to Jonathan G. Katz, Secretary, SEC (Feb. 1, 2000), File No. S7–23–99 ("shareholders of open-end funds * * * derive no benefit from independent directors"); Letter from George W. Karpus, President, Karpus Investment Management, to Arthur Levitt, Chairman, SEC (Jan. 21, 2000), File No. S7–23–99 (independent directors are not really independent, they are "house" directors "rubberstamping" management decisions); Letter from Weechler, Harwood, Halebian & Feffer, to Jonathan G. Katz, Secretary, SEC, (Jan. 14, 2000), File No. S7–23–99 ("There does not appear to be any credible evidence to support the view that independent directors are cost effective from the standpoint of public investors."). *See also* Samuel S. Kim, Note, *Mutual Funds: Solving the Shortcomings of the Independent Director Response to Advisory Self-Dealing Through Use of the Undue Influence Standard*, 98 Colum. L. Rev. 474 (1998).

[39] When deciding excessive advisory fee cases, courts have cited directors' reliance on independent counsel as a factor evidencing director independence and conscientiousness. *See Schuyt v. Rowe Price Prime Reserve Fund, Inc.*, 663 F. Supp. 962, 985, 982, 986 (S.D.N.Y.) (noting that "[d]uring all relevant times, the independent directors * * * had their own counsel" who was an "important resource" and whose advice "the record indicates the directors made every effort to keep * * * in mind as they deliberated"), aff'd, 835 F.2d 45 (2d Cir. 1987); *Gartenberg v. Merrill Lynch Asset Management, Inc.*, 528 F. Supp. 1038, 1084 (S.D.N.Y. 1981) (noting that the "non-interested Trustees were represented by their own independent counsel * * * who acted to give them conscientious and competent advice"), *aff'd*, 694 F.2d 923 (2d Cir. 1982).

[40] As noted above, the amendments as adopted do not *require* that independent directors retain legal counsel, but only that any person who acts as legal counsel to the independent directors be an "independent legal counsel." *See supra* note 35 and accompanying text. An attorney "acts as legal counsel" if an attorney-client relationship is established between counsel and the independent directors. We do not view a counsel as representing a fund's investment adviser merely because the counsel accepts payment of fees from the adviser for legal services performed on behalf of the fund or its independent directors as permitted by relevant legal ethics rules. *See* Proposing Release, *supra* note 3, at n.87.

[41] We are adopting as proposed the definition of "person" as any natural person or a company (including a partnership or other association) as well as a partner, co-member, or employee of any person. Rule 0–1(a)(6)(iv)(A) [17 CFR 270.0–1(a)(6)(iv)(A)]. Thus, the independent directors should examine any conflicting representations of their individual attorney, as well as conflicting representations of that attorney's law firm, partners, and employees.

[42] We are adopting as proposed the definition of "control person—as any person—other than a fund—directly or indirectly controlling, controlled by, or under common control with any of the fund's management organizations. Rule 0–1(a)(6)(iv)(B) [17 CFR 270.0–1(a)(6)(iv)(B)].

[43] We have used the phrase "sufficiently limited" instead of "so limited," which we used in the proposal, to provide directors somewhat greater latitude than the proposal. It is our intent, therefore, that the scope of the rule be construed by reference to our discussion in this release and not the Proposing Release.

[44] Rule 0–1(a)(6)(i)(A) [17 CFR 270.0–1(a)(6)(i)(A)]. As we stated in the Proposing Release, because the interests of a fund, its shareholders, and its independent directors are nearly always aligned, the independent legal counsel condition does not require independent directors to assess a counsel's representation of the fund itself. *See* Proposing Release, *supra* note 3, at n.94 and accompanying text. We do not consider counsel to the fund or to the fund's adviser to be legal counsel to the independent directors by virtue of the independent directors receiving and relying on advice from such counsel. However, the independent directors should be aware that they do not have their own counsel in those circumstances.

[45] Rule 0–1(a)(6)(i)(B) [17 CFR 270.0–1(a)(6)(i)(B)]. A lawyer generally has an obligation to inform his or her client of changes in the nature of conflicts. *See* ABA Model Rules, Rule 1.7 (stating that a client may waive a conflict of interest only *after consultation*); *see also* ABA Comm. on Ethics and Professional Responsibility, Formal Op. 93–372 (1993) (a client's generic waiver of future conflicts would be invalid if the circumstances of a representation change so that the client's previous waiver was not fully informed when given); ABA Task Force Report, *supra* note 16 (providing specific guidance to independent directors of funds when selecting and using legal counsel, and to counsel who advise independent directors). However, a lawyer's obligations in this regard envision that the lawyer assess the effect of the potential conflict first before informing the client, *see* ABA Model Rules, Rule 1.7(a)(1), and in any event may vary among different jurisdictions. The provision in our final rule concerning counsel's undertaking is intended to enable the independent directors to obtain the information they need in order to make their *own* determination about the independence of their counsel.

[46] We would not expect that the board meeting minutes would include detailed information such as law firm billing records. We would, however, expect the minutes to include material information the board considered and relied on in making its determination.

[47] Rule 0–1(a)(6)(iii). This provision also would apply when conflicts arise as a result of a law firm merger, the hiring of a new partner or associate, the merger of two financial services firms, or as a result of a material increase in the scope or nature of the legal counsel's representation of a management organization.

[48] *Id.*

In determining whether a counsel is an "independent legal counsel" under the rule, the judgment of the directors is not unbounded; it must be reasonable.[49] The independent directors should consider all relevant factors in evaluating whether the conflicting representations are "sufficiently limited.[50] For example, independent directors should consider (i) whether the representation is current and ongoing; (ii) whether it involves a minor or substantial matter; (iii) whether it involves the fund, the adviser, or an affiliate, and if an affiliate, the nature and the extent of the affiliation; (iv) the duration of the conflicting representation; (v) the importance of the representation to counsel and his firm (including the extent to which counsel relies on that representation economically); (vi) whether it involves work related to mutual funds;[51] and (vii) whether the individual who will serve as legal counsel was or is involved in the representation.[52] Applying these factors, we do not believe that independent directors could ordinarily conclude that a lawyer whose firm simultaneously represents the fund's adviser and independent directors in connection with matters as important to fund shareholders as the negotiation of the advisory contract[53] or distribution plan, or other key areas of conflict between the fund and its adviser, is an "independent legal counsel."[54]

We admonish directors to consider that your decision in selecting an independent counsel is not merely a matter of personal preference (as some commenters suggested), but an important exercise of your business judgment as an independent director.[55] The final rule makes it clear, however, that you are entitled to rely on information provided by counsel in forming your judgment.[56]

B. Limits on Coverage of Directors Under Joint Insurance Policies

We are adopting an amendment to rule 17d–1(d), which permits funds to purchase "errors and omissions" joint insurance policies for their officers and directors.[57] Currently, many of these policies contain exclusions when parties sue each other. As a result, independent directors of funds may not be covered against lawsuits by the adviser and consequently may be reluctant to take actions necessary to protect fund investors, out of concern for personal liability. Under the amendment, which we are adopting as proposed, rule 17d–1(d) is available only if the joint insurance policy does not exclude coverage for litigation between the adviser and the independent directors.[58] Commenters supported the proposed amendments, and agreed that they would allow independent directors to faithfully carry out responsibilities without concern for personal financial security.

C. Independent Audit Committees

We are adopting new rule 32a–4 exempting funds from the Act's requirement that shareholders vote on the selection of the fund's independent public accountant if the fund has an audit committee composed wholly of independent directors.[59] The rule will permit continuing oversight of the fund's accounting and auditing processes by an independent audit committee, in place of the shareholder vote. Commenters agreed that the shareholder ratification has become largely perfunctory, and that an independent audit committee could exercise more meaningful oversight.

Under the new rule, a fund is exempt from having to seek shareholder approval of its independent public accountant, if (i) the fund establishes an audit committee composed solely of independent directors that oversees the fund's accounting and auditing processes,[60] (ii) the fund's board of directors adopts an audit committee charter setting forth the committee's structure, duties, powers, and methods of operation, or sets out similar provisions in the fund's charter or bylaws,[61] and (iii) the fund maintains a copy of such an audit committee charter.[62] Some commenters questioned whether the proposed rule would require the audit committee to supervise a fund's day-to-day management and operations. The rule does not require, nor did we intend, that an audit committee perform daily management or supervision of a fund's operations.[63]

[49] Rule 0–1(a)(6)(i).

[50] By adopting these rules, we do not intend to regulate the legal profession or to suggest that the existence of a professional relationship between the independent directors' counsel and a management organization would necessarily violate applicable codes of legal ethics. Moreover, we do not intend to create a presumption that a lawyer having such a professional relationship did not provide proper, objective legal advice, or that the board's reliance on its counsel was improper, or that any determination the board made based on counsel's advice was itself improper.

[51] Whether counsel's representation of a management organization (or control person) is *unrelated* to a fund is a relevant factor for independent directors to consider when determining if the counsel may provide impartial advice to the independent directors. However, it is not a conclusive factor. Even if legal services are unrelated to a fund, those services may be so substantial, significant, or integral to the business of the management organization (or control person) that the independent directors could determine that the counsel is not an "independent legal counsel."

[52] We do not intend this list of factors to be an exhaustive or mandatory list of factors the directors must consider. *See, e.g.*, ABA Task Force Report, *supra* note 16, at 5–9 (providing guidance on factors that boards may wish to consider when assessing the quality and independence of their counsel).

[53] After analyzing the factors, independent directors may, however, conclude that a counsel's representation of a fund's administrator or sub-adviser does not impede that counsel's ability to serve as an "independent counsel" to the independent directors. In evaluating whether representation of an administrator (or its control person) is "sufficiently limited" for the person to be an "independent counsel," we believe a board could differentiate between an administrator that merely performs ministerial tasks and one that has sponsored, organized, or promoted the fund. Independent directors could reach a similar conclusion regarding a sub-adviser. The Act does not distinguish an adviser from a sub-adviser. *See* section 2(a)(20) of the Act (15 U.S.C. 80a–2(a)(20)). However, we believe that independent directors, in evaluating a counsel's conflicts, could give consideration to the nature of a sub-advisory relationship.

[54] The ABA Task Force Report acknowledges that there are circumstances, such as litigation or other "obvious adversarial situations," in which joint or multiple representations may never be appropriate. ABA Task Force Report, *supra* note 16, at 8. We agree, but believe that there are additional circumstances, due to the unique conflicts that are inherent in the structure of investment companies, in which independent directors should not accept joint and multiple representations.

[55] As discussed below, the compliance date for the legal counsel provision is July 1, 2002. *See infra* Section III.

[56] *See* rule 0–1(a)(6)(ii). The independent directors are entitled to rely on that information unless they know or have reason to believe that the information is materially false or incomplete. *Id.* As a result, if counsel begins or materially increases the representation of a fund management organization but does not inform the independent directors, the independent directors can rely on the previous representation they received so that counsel's change in representation will not trigger the requirement that the independent directors make a new determination within three months. *See* rule 0–1(a)(6)(iii).

[57] Paragraph (d) of rule 17d–1 provides an exemption from paragraph (a) of the rule, which prohibits a fund affiliate from participating in any joint enterprise, joint arrangement, or profit sharing plan without first obtaining a Commission order.

[58] *See* rule 17d–1(d)(7)(iii). The amendments would prohibit exclusions for (i) bona fide (*i.e.*, non-collusive) claims made against any independent director by another person insured under the joint insurance policy, and (ii) claims in which the fund is a co-defendant with an independent director in a claim brought by a co-insured.

[59] *See* section 32(a)(2) of the Act [15 U.S.C. 80a–31(a)(2)].

[60] Rule 32a–4(a).

[61] Rule 32a–4(b).

[62] Rule 32a–4(c). Commenters suggested that we permit the audit committee provisions to be set forth in the charter or bylaws of the fund. The final rule permits the fund either to adopt an audit committee charter or to set forth audit committee provisions in the fund's charter or bylaws. Rule 32a–4(b).

[63] *See* Audit Committee Disclosure, Exchange Act Release No. 41987 (Oct. 7, 1999) [64 FR 55648 (Oct. 14, 1999)] at text following n.26 ("We recognize how audit committees function may vary from

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D. Qualification as an Independent Director

In addition to the amendments to enhance the independence of fund boards, we are adopting a new rule to prevent qualified individuals from being unnecessarily disqualified from being considered an independent director. We are also rescinding a rule that has become unnecessary.

1. Ownership of Index Fund Securities

We are adopting new rule 2a19–3, which conditionally exempts an individual from being disqualified as an independent director solely because he or she owns shares of an index fund that invests in the investment adviser or underwriter of the fund, or their controlling persons.[64] As proposed, the exemption would have been available if the value of securities issued by the adviser or underwriter (or controlling person) did not exceed five percent of the value of any index tracked by the index fund. The purpose of this condition was to assure that an independent director's indirect interest in the adviser's securities would not be substantial enough to impair his or her independence and create a conflict of interest.[65] In response to some commenters' concerns that monitoring the five percent limit would be very difficult, we revised the rule so that it provides relief if a fund's investment objective is to replicate the performance of one or more "broad-based" indices.[66]

2. Affiliation with a Broker-Dealer

We are rescinding rule 2a19–1, which provides relief from the section of the Act that defines when a fund director is considered to be independent.[67] We had proposed to amend that rule to permit a slightly greater percentage of fund independent directors to be affiliated with registered broker-dealers, under certain circumstances. After our proposal, however, Congress passed the Gramm-Leach-Bliley Act, which amended section 2(a)(19) of the Investment Company Act and established new standards for determining independence under the circumstances we addressed in our proposal.[68] These amendments to the Act obviate the need for the exemptive relief provided by rule 2a19–1, and therefore we are rescinding the rule.[69]

E. Disclosure of Information about Fund Directors

We believe that shareholders have a significant interest in knowing who the independent directors are, whether the independent directors' interests are aligned with shareholders' interests, whether the independent directors have any conflicts of interest, and how the directors govern the fund. This information helps a mutual fund shareholder to evaluate whether the independent directors can, in fact, act as an independent, vigorous, and effective force in overseeing fund operations.

In reevaluating our current disclosure requirements, we concluded that, while our fundamental approach has been sound, there are several gaps in the information that shareholders currently receive about directors. We therefore proposed amendments to close these gaps. The proposal would require funds to:

- Provide basic information about directors to shareholders annually so that shareholders will know the identity and experience of their representatives;
- Disclose to shareholders fund shares owned by directors to help shareholders evaluate whether directors' interests are aligned with their own;
- Disclose to shareholders information about directors that may raise conflict of interest concerns; and
- Provide information to shareholders on the board's role in governing the fund.

We are adopting the disclosure amendments with several modifications designed to tailor the amendments more closely to our goal of providing shareholders with better information to evaluate the independent directors.

1. Basic Information

We are adopting the requirement to disclose basic information about directors in an easy-to-read tabular format, as proposed.[70] The table will be required in three places: the fund's annual report to shareholders, SAI, and proxy statement for the election of directors. The table will require for each director: (1) Name, address, and age; (2) current positions held with the fund; (3) term of office and length of time served; (4) principal occupations during the past five years; (5) number of portfolios overseen within the fund complex; and (6) other directorships held outside of the fund complex.[71] The table also requires for each interested director, as defined in Section 2(a)(19) of the Investment Company Act, a description of the relationship, events, or transactions by reason of which the director is an interested person.

Commenters generally supported the proposal, although several commenters

company to company, and companies need flexibility to determine all of the specific duties and functions of their audit committees.").

[64] Section 2(a)(19) of the Act disqualifies an individual from being considered an independent director if he or she knowingly has any direct or *indirect* beneficial interest in a security issued by the fund's investment adviser or principal underwriter, or by a controlling person of the adviser or underwriter. If a fund seeks to replicate the performance of a securities market index that includes securities of the fund's adviser (or principal underwriter or a controlling person of the adviser or principal underwriter), an issue could arise whether the director knowingly has an indirect beneficial interest in the securities of the adviser (or principal underwriter or controlling person). *See* Proposing Release, *supra* note 3, at n.138 and accompanying text.

[65] The new rule does not address an independent director's ownership of securities of an *actively* managed fund that owns shares of the fund's adviser, underwriter or any of their controlling persons. As we discussed in the Proposing Release, we do not believe an independent director who owns shares of an actively managed fund would ordinarily "knowingly" have an indirect beneficial interest in the issuers of securities the fund holds, and thus ownership of such fund would not cause a director to be an "interested person" as defined by section 2(a)(19) of the Act. *See* Proposing Release, *supra* note 3, at n.140.

[66] As we stated in the context of Form N–1A, a "broad-based index" is an index that "provides investors with a performance indicator of the overall applicable stock or bond markets, as appropriate. An index would not be considered to be broad-based if it is composed of securities of firms in a particular industry or group of related industries." *See* Disclosure of Mutual Fund Performance and Portfolio Managers, Investment Company Act Release No. 19382 (Apr. 6, 1993) [58 FR 19050 (Apr. 12, 1993)] at n.21.

[67] Sections 2(a)(19)(A)(v) and (B)(v) of the Act provide that no person can be an independent director if he or she is, or is affiliated with, a registered broker-dealer.

[68] Section 213(a)(1) of the Gramm-Leach-Bliley Act incorporates the conditions of current rule 2a19–1(a)(1) under the Act. As amended, section 2(a)(19) now permits an independent director to be an affiliate of a broker-dealer, but not if the director or his or her affiliate has executed portfolio transactions for, engaged in principal transactions with, or distributed shares for the fund or certain related funds or accounts within the past six months. Pub. L. No. 106–102, § 213, 113 Stat. 1338, 1397–98 (1999), to be codified at 15 U.S.C. 80a–2(a)(19)(A)(v) and (B)(v).

[69] Under the Administrative Procedure Act [5 U.S.C. 553(b)], notice of proposed rulemaking is not required if the agency for good cause finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Section 213 of the Gramm-Leach-Bliley Act established new standards for determining independence under the circumstances addressed by rule 2a19–1, and the rule is no longer necessary. The Commission therefore finds that proposing the rescission of rule 2a19–1 for public comment is unnecessary.

[70] Item 22(b)(1) of Schedule 14A; Items 13(a) and 22(b)(5) of Form N–1A; Item 18.1 and Instruction 4.e. to Item 23 of Form N–2; Item 20(a) and Instruction 4(v) to Item 27 of Form N–3. For convenience in discussing the requirements, we are not specifically referring to nominees for election as directors. The requirements, however, are applicable to nominees in proxy statements for the election of directors. The disclosure requirements in Item 22 of Schedule 14A also are applicable to information statements prepared in accordance with Regulation 14C and Schedule 14C [17 CFR 240.14c–101].

[71] In response to privacy concerns raised by several commenters, we wish to clarify that a director may provide the address of the fund or the fund's adviser in the table and need not provide his personal address.

opposed as unnecessary the requirement to describe in the table the relationships, events, or transactions that make certain directors "interested persons." Funds are currently required to disclose this information in the proxy statement for the election of directors, and we are adopting this requirement as proposed.[72] We believe it is important that shareholders be provided with an explanation of why certain directors are "interested persons."[73]

2. Ownership of Equity Securities in Fund Complex

We are adopting with modifications the requirement to disclose the amount of equity securities of funds in a fund complex owned by each director.[74] Commenters generally agreed with the Commission that disclosure of this information would be useful to shareholders in assessing whether directors' interests are aligned with those of shareholders.

(a) Disclosure of Amounts Owned by Directors

Many commenters expressed concern about the proposed requirement that funds disclose the exact dollar amount of securities directors own in a fund complex. These commenters argued that this disclosure would discourage potential directors from agreeing to serve, in order to avoid intrusions into their privacy, and might cause existing directors to reduce or sell their holdings to avoid publicity about their investments. As an alternative, many suggested that we require funds to disclose directors' equity ownership using specified dollar ranges, rather than exact dollar amounts. These commenters noted that using dollar ranges would provide shareholders with sufficient information to assess whether directors' interests were aligned with their own, making disclosure of exact dollar amounts unnecessary.

We are persuaded by these comments and have modified the proposal to require disclosure of a director's holdings of securities using dollar ranges rather than an exact dollar amount. Funds will be required to disclose directors' equity ownership using the following ranges: None; $1–$10,000; $10,001–$50,000; $50,001–$100,000; or over $100,000. We believe that disclosure of directors' holdings using these dollar ranges will provide investors with significant information to use in evaluating whether directors' interests are aligned with their own, while protecting directors' legitimate privacy interests.

(b) "Beneficial Ownership"

We received a number of comments requesting clarification about the types of director holdings that would be disclosed under the proposal. Based on these comments, we reevaluated our proposal to require disclosure of securities owned beneficially and of record by each director. Under the proposal, "beneficial ownership" would have been determined in accordance with rule 13d–3 of the Exchange Act, which focuses on a person's voting and investment power.[75] In light of our objective of providing information about the alignment of directors' and shareholders' interests, we believe that disclosure of record holdings should not be required and that the focus of "beneficial ownership" should be on whether a director's economic interests are tied to the securities, rather than his ability to exert voting power or to dispose of the securities. Therefore, we are modifying the proposal to require disclosure of "beneficial ownership" in accordance with the definition contained in rule 16a–1(a)(2) under the Exchange Act.[76] This definition, consistent with our goal, emphasizes the economic incidence of ownership.

(c) Disclosure of Ownership in the Funds the Director Oversees within the Same "Family of Investment Companies"

We proposed to require aggregate disclosure of a director's holdings in a fund complex, rather than separate disclosure of a director's holdings in a particular fund. We were concerned that fund-specific information might have limited meaning because of the many reasons that a director could have for not holding shares of any specific fund, *e.g.*, that its investment objective did not fill a need in the director's portfolio. Several commenters recommended, however, that disclosure of a director's holdings should be made on a fund-by-fund basis, rather than a complex-wide basis, arguing that it would be more relevant to disclose to shareholders a director's ownership of the specific funds on whose board the director serves. Other commenters, agreed that disclosure of a director's holdings should be on an aggregate basis as proposed, but recommended that the disclosure be limited to a director's aggregate ownership in the funds overseen by a director within a fund complex. These commenters argued that disclosure in this manner is more useful to investors than complex-wide disclosure in assessing whether a director's interests are aligned with their own.

We are persuaded by these comments and have modified the proposal to require disclosure of: (1) Each director's ownership in each fund that he oversees; and (2) each director's aggregate ownership in any funds that he oversees within a fund family. We believe that a director's ownership in a particular fund provides the most direct indication of his alignment with the interests of shareholders in that fund. We continue to believe, however, that disclosure of a director's aggregate ownership will provide shareholders with relevant information about the director's alignment with shareholders. In addition, a director could have many reasons for not holding shares of a specific fund, *e.g.*, that its investment objectives do not match the director's. Disclosure of aggregate ownership will help prevent any inappropriate negative inference about fund management that a fund shareholder could draw from the fact that a director does not hold shares of a particular fund.

For purposes of determining a director's holdings in a fund complex, the Commission proposed to define "fund complex" as two or more funds that (1) hold themselves out to investors as related companies for purposes of investment and investor services; or (2) have a common investment adviser or an investment adviser that is an affiliated person of the investment

[72] Instruction 4 to Item 22(b)(1) of Schedule 14A; Instruction 2 to Item 13(a) of Form N–1A; Instruction 2 to Item 18.1 of Form N–2; Instruction 2 to Item 20(a) of Form N–3.

[73] As discussed below, however, we are excluding interested directors from the new conflicts of interest disclosure requirements which we proposed in order to give shareholders better information about independent directors. *See infra* note 84 and accompanying text.

[74] Item 22(b)(5) of Schedule 14A; Item 13(b)(4) of Form N–1A; Item 18.7 of Form N–2; Item 20(f) of Form N–3.

[75] 17 CFR 240.13d—3.

[76] 17 CFR 240.16a–1(a)(2). We also have modified the proposal requiring disclosure of securities owned by an independent director and his immediate family members in an investment adviser or principal underwriter and persons controlling, controlled by, or under common control with an investment adviser or principal underwriter. This requirement is intended to illuminate potential conflicts of interest, and we therefore believe that any record or beneficial securities ownership in these entities should be disclosed, whether the beneficial ownership results from voting power, investment power, or economic interests. Therefore, we have revised the proposal to require disclosure of securities owned if covered by the definition of "beneficial ownership" contained in either rule 13d–3 or rule 16a–1(a)(2). Item 22(b)(6) and Instruction 2 to Item 22(b)(6) of Schedule 14A; Item 13(b)(5) and Instruction 2 to Item 13(b)(5) of Form N–1A; Item 18.8 and Instruction 2 of Item 18.8 of Form N–2; Item 20(g) and Instruction 2 of Item 20(g) of Form N–3.

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adviser of any of the other funds.[77] Many commenters argued that this definition would result in disclosure of holdings in funds that are too remotely related to funds on whose board the director serves to demonstrate alignment with fund shareholders (*e.g.*, for a director serving on the board of a fund with a sub-adviser, the director's ownership in any other funds that the sub-adviser serves would be disclosed, regardless of whether the funds are otherwise related). These commenters recommended that the Commission adopt a narrower definition of "family of investment companies," which includes only funds that share the same investment adviser or principal underwriter and hold themselves out to investors as related companies for purposes of investment and investor services.[78] We agree with commenters that the proposed "fund complex" definition could result in disclosure of information having little bearing on a director's alignment with shareholders, and are adopting the narrower definition of "family of investment companies."[79]

(d) Date of Disclosure

The equity ownership information must be included in the SAI and any proxy statement relating to the election of directors. For the proxy statement, the equity ownership information must be provided as of the most recent practicable date, as proposed, in order to ensure that shareholders receive up-to-date information when they are asked to vote to elect directors.[80] For the SAI, we have modified the proposal to require that the equity ownership information be provided as of the end of the last completed calendar year.[81] We believe that this modified time period requirement facilitates our goal that investors receive equity ownership information to evaluate whether directors' interests are aligned with their own, while imposing less of a burden on directors, especially those who serve multiple funds with staggered fiscal years.

3. Conflicts of Interest

We are adopting our proposals on conflicts of interest disclosure, with modifications that tailor the requirements more closely to our goals and address commenters' concerns that some aspects of the proposal were overbroad.[82] We proposed to require funds to disclose in the proxy statement and SAI three types of circumstances that could affect the allegiance of fund directors to their shareholders: positions, interests, and transactions and relationships of directors and their immediate family members with the fund and persons related to the fund. The rules we adopt today follow this basic approach.

A number of commenters recommended alternatives to the proposed conflicts of interest disclosure requirements, including: (i) Requiring funds to maintain records of potential conflicts of interest of directors; (ii) permitting independent directors to determine for themselves whether or not conflicts of interest exist that affect the "independence" of other independent directors; and (iii) limiting conflicts of interest disclosure to the proxy statement for the election of directors. After careful consideration of these alternatives, we have determined that they would not constitute an adequate substitute for disclosure to shareholders.

We continue to believe that shareholders have a significant interest in information concerning circumstances that may affect the directors' allegiance to shareholders. None of the alternatives suggested by commenters would provide this information to shareholders on a regular basis. The first two alternatives would completely exclude shareholders from the process of evaluating the independence of directors. The third alternative, limiting conflicts of interest disclosure to the proxy statement for the election of directors, ignores the fact that the proxy statement has become an ineffective vehicle for communicating information to fund shareholders on a regular basis because funds generally are no longer required to hold annual meetings.[83]

(a) Modifications to Persons Covered

(1) Interested Directors

We are modifying our proposal to exclude interested directors from the conflicts of interest disclosure requirements in both the SAI and proxy statement.[84] We are persuaded by the commenters' arguments that if the purpose of the conflicts of interest disclosure is to allow investors and the Commission staff to better evaluate the true independence of independent directors, this goal will not be achieved by requiring disclosure of interested directors' potential conflicts of interest. As previously discussed, however, funds will be required to describe the relationships, events, or transactions that make a director an interested person.[85]

(2) Immediate Family Members

We are narrowing the scope of "immediate family members" covered by the disclosure requirements to a director's spouse, children residing in the director's household, and dependents of the director.[86] As proposed, "immediate family members" also included the director's parents, siblings, children not residing with the director, and in-laws.[87]

We received many comments on this definition, with the overwhelming majority of commenters arguing that the proposed extension of conflicts of interest disclosure to include a director's immediate family members, as defined in the proposal, was overly broad and too burdensome. Commenters noted that the definition, as proposed, would require directors to seek financial information from remote family members with whom they have little or no contact, and that the requirement could impose liabilities on directors without providing the means to enable directors to obtain the required information from reluctant relatives. We are persuaded by the commenters and have addressed their concerns by limiting the definition of "immediate family members" along the lines suggested by many commenters. The narrower definition ensures that disclosure will only be required with respect to family members from whom directors can reasonably be expected to obtain the required information.[88]

(3) Related Persons

The Commission proposed to require disclosure about circumstances involving directors, on the one hand, and the fund and persons related to the fund, on the other. We are modifying the proposal to exclude administrators from the persons related to the fund that are covered by the requirements. Several commenters expressed concern that inclusion of administrators that are not affiliated with the fund's adviser or principal underwriter would produce irrelevant and unnecessary information for shareholders because interactions between directors and unaffiliated administrators would not create conflicts of interest that could affect an independent director's judgment. We are persuaded by these commenters and note that administrators that control, are controlled by, or are under common control with the adviser or principal underwriter will be covered by the conflicts of interest disclosure.[89]

While some commenters also recommended excluding entities "under common control" with the adviser or principal underwriter, we believe that disclosure of interests, positions, and transactions and relationships with entities under common control is important and could highlight circumstances that potentially could affect the judgment of independent directors. We also note that the current proxy rules require disclosure with respect to commonly controlled entities.[90]

Although we are narrowing the scope of immediate family members and related persons in recognition of the overbreadth of our proposal in certain circumstances, we wish to emphasize that a fund's independent directors can vigilantly represent the interests of shareholders only when they are truly independent of those who operate and manage the fund. To that end, we encourage funds to examine any circumstances that could potentially impair the independence of independent directors, whether or not they fall within the scope of our disclosure requirements. There may, for example, be circumstances where an interest of a family member outside the ambit of our rules, or a director's interest in an administrator, impairs the director's ability to represent the interests of shareholders vigilantly.

(b) Other Modifications

(1) Threshold for Disclosure of Interests, Transactions, and Relationships

We are adopting a $60,000 threshold for disclosure of interests, transactions, and relationships.[91] Many commenters requested that the Commission establish a specific dollar threshold that would trigger the disclosure requirements to eliminate the need to make subjective "materiality" determinations. We are persuaded by these comments and are adopting the $60,000 threshold, a level recommended by many commenters and contained in the existing proxy rules.[92]

We have replaced a materiality test with the $60,000 threshold in order to facilitate compliance with the disclosure requirements that we adopt today. This change does not, however, reflect a determination that the $60,000 threshold may be equated with "materiality." We note that the antifraud provisions of the federal securities laws may obligate funds to disclose a material conflict of interest between a director and the fund or its shareholders without regard to the $60,000 threshold. For example, a transaction between a director and a fund's adviser may constitute a material conflict of interest with the fund or its shareholders that is required to be disclosed, regardless of the amount involved, if the terms and conditions of the transaction are not comparable to those that would have been negotiated at "arms-length" in similar circumstances.

(2) Time Periods

We are adopting, as proposed, a five-year time period for disclosure of positions and interests of directors and immediate family members in the proxy statement for the election of directors.[93] We are, however, reducing the time period for disclosure of positions and interests in the SAI to two calendar years.[94] We believe that, when a shareholder is asked to vote to elect directors, he is entitled to information about potential conflicts covering a significant period of time.[95] We recognize, however, that providing five years of information annually in the SAI, would, as suggested by commenters, increase fund compliance burdens without commensurate benefits to shareholders.

We are adopting, as proposed, the requirement to disclose material transactions and relationships since the beginning of the last two completed fiscal years in the proxy statement for the election of directors.[96] In the SAI, however, we have modified the proposal to require disclosure of transactions and relationships during the two most recently completed calendar years, rather than the last two

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[77] *Cf.* redesignated Item 22(a)(1)(vi) of Schedule 14A (definition of fund complex).

[78] *Cf.* Item H of Form N–SAR [17 CFR 274.101] (definition of "family of investment companies").

[79] Item 22(a)(1)(iv) of Schedule 14A; Instruction 1(a) to Item 13 of Form N–1A; Instruction 1.a to Item 18 of Form N–2; Instruction 1.a to Item 20 of Form N–3.

[80] Instruction 1 to Item 22(b)(5) of Schedule 14A.

[81] Instruction 1 to Item 13(b)(4) of Form N–1A; Instruction 1 to Item 18.7 of Form N–2; Instruction 1 to Item 20(f) of Form N–3.

[82] Items 22(b)(4), 22(b)(6), 22(b)(7), 22(b)(8), 22(b)(9), and 22(b)(10) of Schedule 14A; Items 13(b)(3), 13(b)(5), 13(b)(6), 13(b)(7), 13(b)(8), and 13(b)(9) of Form N–1A; Items 18.6, 18.8, 18.9, 18.10, 18.11, and 18.12 of Form N–2; Items 20(e), 20(g), 20(h), 20(i), 20(j), and 20(k) of Form N–3.

[83] *See* Proposing Release, *supra* note 3, at n.149 and accompanying text.

[84] Items 22(b)(4), 22(b)(6), 22(b)(7), 22(b)(8), 22(b)(9), and 22(b)(10) of Schedule 14A; Items 13(b)(3), 13(b)(5), 13(b)(6), 13(b)(7), 13(b)(8), and 13(b)(9) of Form N–1A; Items 18.6, 18.8, 18.9, 18.10, 18.11, and 18.12 of Form N–2; Items 20(e), 20(g), 20(h), 20(i), 20(j), and 20(k) of Form N–3.

[85] *See supra* 73 note and accompanying text. In addition, we are retaining the existing requirement that funds disclose positions held by interested directors with affiliated persons or principal underwriters of the fund. Item 22(b)(2) of Schedule 14A; Item 13(a)(2) of Form N–1A; Item 18.2 of Form N–2; Item 20(b) of Form N–3.

[86] Item 22(a)(1)(vii) of Schedule 14A; Instruction 1(c) to Item 13 of Form N–1A; Instruction 1.c to Item 18 of Form N–2; Instruction 1.c to Item 20 of Form N–3. The term "children" includes step and adoptive children. We are using the term "dependent" as defined in section 152 of the Internal Revenue Code. I.R.C. 152.

[87] Proposed Item 22(a)(vi) of Schedule 14A; Proposed Instruction 1(b) to Item 13 of Form N–1A; Proposed Instruction 1.b. to Item 18 of Form N–2; Proposed Instruction 1.b. to Item 20 of Form N–3.

[88] A number of commenters recommended that if the Commission adopted the proposed definition of "immediate family members," disclosure of potential conflicts of interest should be limited to those of which the director had actual knowledge. Since we are narrowing the definition of "immediate family member," incorporation of an actual knowledge standard is unnecessary.

[89] Items 22(b)(4)(iv), 22(b)(6)(ii), 22(b)(7)(ii), 22(b)(8)(vii), 22(b)(9), and 22(b)(10)(iii) of Schedule 14A; Items 13(b)(3)(iv), 13(b)(5)(ii), 13(b)(6)(ii), 13(b)(7)(vii), 13(b)(8), and 13(b)(9)(iii) of Form N–1A; Items 18.6(d), 18.8(b), 18.9(b), 18.10(g), 18.11, and 18.12(c) of Form N–2; Items 20(e)(iv), 20(g)(ii), 20(h)(ii), 20(i)(vii), 20(j), and 20(k)(iii) of Form N–3.

[90] *See* Item 22(b)(1) of Schedule 14A (requiring independent directors to disclose direct or indirect securities interests in any person *under common control* with fund's adviser); Item 22(b)(3) (requiring all directors to disclose material transactions to which the adviser, principal underwriter, administrator, any parent or subsidiary of such entities (other than another fund), or any subsidiary of the parent of such entities was or is to be a party).

[91] Items 22(b)(7), 22(b)(8), and 22(b)(9) of Schedule 14A; Items 13(b)(6), 13(b)(7), and 13(b)(8) of Form N–1A; Items 18.9, 18.10, and 18.11 of Form N–2; Items 20(h), 20(i), and 20(j) of Form N–3. In the case of transactions, the $60,000 threshold applies to the size of a transaction, and a materiality standard applies to the director's or immediate family member's interest in the transaction. Item 22(b)(8) of Schedule 14A; Item 13(b)(7) of Form N–1A; Item 18.10 of Form N–2; Item 20(i) of Form N–3. The materiality of the interest is to be determined based on the significance of the information to investors in light of all the circumstances. Instruction 8 to Item 22(b)(8) of Schedule 14A; Instruction 7 to Item 13(b)(7) of Form N–1A; Instruction 7 to Item 18.10 of Form N–2; Instruction 7 to Item 20(i) of Form N–3. This is similar to a provision of the current proxy rules. Item 404(a) of Regulation S–K.

[92] *Cf.* redesignated Item 22(b)(11) of Schedule 14A; Item 404(a) of Regulation S–K. In determining whether the $60,000 threshold is exceeded for interests and relationships, a director's interest is to be aggregated with those of his immediate family members. Instruction 2 to Item 22(b)(7) and Instruction 6 to Item 22(b)(9) of Schedule 14A; Instruction 2 to Item 13(b)(6) and Instruction 5 to Item 13(b)(8) of Form N–1A; Instruction 2 to Item 18.9 and Instruction 5 to Item 18.11 of Form N–2; Instruction 2 to Item 20(h) and Instruction 5 to Item 20(j) of Form N–3.

[93] Items 22(b)(4) and 22(b)(7) of Schedule 14A.

[94] Items 13(b)(3) and 13(b)(6) of Form N–1A; Items 18.6 and 18.9 of Form N–2; Items 20(e) and 20(h) of Form N–3.

[95] Several commenters recommended that the Commission limit all conflicts of interest disclosure to a two-year period. These commenters argued that a two-year time period is consistent with the time limit for material business or professional relationships in section 2(a)(19) of the Act. We note, however, that the five-year time period for disclosure of positions and interests is currently required in the proxy rules. In fact, when the amendments to the proxy rules were adopted in 1994, most of the commenters that addressed the issue of time periods recommended limiting the disclosure of past relationships to the preceding five-year period. *See* Investment Company Act Rel. No. 20614 (Oct. 13, 1994) [59 FR 52689 (October 19, 1994)].

[96] Items 22(b)(8) and 22(b)(9) of Schedule 14A.

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fiscal years as proposed.[97] Many commenters noted that a director may serve multiple funds with staggered fiscal years and that a requirement to disclose transactions and relationships for fiscal year time periods could require funds to obtain the information from directors as frequently as monthly, which would be overly burdensome. We have revised the proposal to require two calendar years of disclosure, rather than two fiscal years, in order to reduce this burden for funds with staggered fiscal years, while maintaining the requirement to include two years of disclosure.[98]

(3) Routine, Retail Transactions and Relationships

As proposed, the conflicts of interest disclosure provisions would not have required a fund to disclose routine, retail transactions and relationships, such as a credit card or bank or brokerage account, unless the director is accorded special treatment. At the request of commenters, we are clarifying that the exception for routine, retail transactions and relationships extends to residential mortgages and insurance policies.[99] We also note that the exception for routine, retail transactions and relationships is not limited to the specific transactions and relationships enumerated (credit cards, bank or brokerage accounts, residential mortgages, and insurance policies), but extends to other routine, retail transactions and relationships where the director is not accorded special treatment.

4. Board's Role in Fund Governance

We are adopting, as proposed, disclosure requirements in the proxy rules and the SAI relating to a fund's committees of the board of directors, which commenters generally supported.[100] We are also adopting, as proposed, the requirement to disclose in the SAI the board's basis for approving an existing investment advisory contract.[101]

A number of commenters argued that information about the board's basis for approving an existing advisory contract is not relevant to an investment decision and disclosure of this information will be "boilerplate" in nature. After careful consideration of these comments, we continue to believe that shareholders should receive information in the SAI to help them evaluate the board's basis for approving the renewal of an existing investment advisory contract. In approving an investment advisory contract, independent directors must review the level of fees charged. Mutual funds fees and expenses, including advisory fees, are extremely important to shareholders. We note that the United States General Accounting Office ("GAO"), in a recent report to Congress on mutual fund fees, stressed the importance of heightening "investors" awareness and understanding of the fees they pay.[102] We believe that the rules we adopt today, which will ensure that shareholders receive specific information on how directors evaluate and approve fees on a regular basis, will help to address the GAO's concerns. In implementing this disclosure requirement, we remind funds that "boilerplate" disclosure is not appropriate. Funds are required to provide appropriate detail regarding the board's basis for approving an existing investment advisory contract, including the particular factors forming the basis of this determination.

5. Separate Disclosure

We are adopting, as proposed, the requirement that funds present all disclosure for independent directors separately from disclosure for interested directors in the SAI, proxy statements for the election of directors, and annual reports to shareholders.[103] While several commenters argued that this requirement would confuse shareholders by overemphasizing the differences between independent and interested directors, we believe that the new disclosure format will assist shareholders in understanding information about directors, particularly in evaluating whether the independent directors can, in fact, act as an independent, vigorous, and effective force in overseeing fund operations.[104]

6. Technical and Conforming Amendments

The Commission is adopting, as proposed, the technical and conforming amendments to its schedules, forms, and rules.

F. Recordkeeping Regarding Director Independence

We are adopting as proposed the amendments to rule 31a–2, to require funds to preserve for a period of at least six years any record of: (i) The initial determination that a director qualifies as an independent director, (ii) each subsequent determination of whether the director continues to qualify as an independent director, and (iii) the determination that any person who is acting as legal counsel to the independent directors is an independent legal counsel.[105] The rule amendments, which commenters supported, are designed to permit the Commission staff to monitor a fund's assessment of the independence of directors, and to ascertain whether a fund's assessment reflects diligent efforts to evaluate relevant business and personal relationships that might affect each director's independent judgment.[106]

III. Effective Date; Compliance Dates

A. Effective Date

The new rules and amendments to rules and forms that the Commission is adopting today will become effective February 15, 2001. The rescission of rule 2a19–1 will become effective on May 12, 2001, the effective date of section 213 of the Gramm-Leach-Bliley Act.

[97] Items 13(b)(7) and 13(b)(8) of Form N–1A; Items 18.10 and 18.11 of Form N–2; Items 20(i) and 20(j) of Form N–3.

[98] We also have modified the proposal to require funds to disclose in the SAI cross-directorships held by independent directors and their immediate family members during the last two most recently completed calendar years, rather than the last two fiscal years as proposed. Item 13(b)(9) of Form N–1A; Item 18.12 of Form N–2; Item 20(k) of Form N–3.

[99] Instruction 11 to Item 22(b)(8) and Instruction 9 to Item 22(b)(9) of Schedule 14A; Instruction 10 to Item 13(b)(7) and Instruction 8 to Item 13(b)(8) of Form N–1A; Instruction 10 to Item 18.10 and Instruction 8 to Item 18.11 of Form N–2; Instruction 10 to Item 20(i) and Instruction 8 to Item 20(j) of Form N–3. We also note that sales load waivers granted to fund directors generally would not be required to be disclosed as "material" transactions or relationships, provided that such waivers are disclosed as otherwise required. *See* Instruction 3 to Item 18(c) of Form N–1A; Instruction 3 to Item 5.2 of Form N–2; Instruction to Item 23(b) of Form N–3 (requiring funds to provide explanations for any differences in the price at which securities are offered generally to the public and the prices at which securities are offered to any class of individuals).

[100] Items 7(e) and 22(b)(14) of Schedule 14A; Item 13(b)(2) of Form N–1A; Item 18.5 of Form N–2; Item 20(d) of Form N–3.

[101] Item 13(b)(10) of Form N–1A; Item 18.13 of Form N–2; Item 20(l) of Form N–3.

[102] United States General Accounting Office, Mutual Fund Fees: Additional Disclosure Could Encourage Price Competition (June 2000) at 97.

[103] Instruction 3 to Item 22(b) of Schedule 14A; Instruction 2 to Item 13 of Form N–1A; Instruction 2 to Item 18 of Form N–2; Instruction 2 to Item 20 of Form N–3.

[104] We reiterate that funds may present information regarding independent and interested directors in a single table or chart, so long as the information for independent and interested directors is provided in separate sections within the table or chart. *See* Proposing Release, *supra* note, at text accompanying and following n.226.

[105] *See* rule 31a–2(a)(4), (5).

[106] For a discussion of the Commission staff's views on the types of professional and business relationships that may be considered material for purposes of sections 2(a)(19)(A)(vi) and (B)(vi) of the Act, *see* Interpretive Matters Concerning Independent Directors of Investment Companies, Investment Company Act Release No. 24083 (Oct. 14, 1999) [64 FR 59877 (Nov. 3, 1999)].

B. Compliance Dates for Investment Company Act Rule Amendments

1. *February 15, 2001.* Persons may begin to rely upon new rules 2a19–3, 10e–1 and 32a–4 on February 15, 2001, the effective date of these rules.

2. *July 1, 2002.* After July 1, 2002: (i) persons may rely upon any of the Exemptive Rules (rules 10f–3, 12b–1, 15a–4(b)(2), 17a–7, 17a–8, 17d–1(d)(7), 17e–1, 17g–1(j), 18f–3, and 23c–3) only if they comply with each of the three new conditions for use of each rule; (ii) persons may rely upon rule 17d–1(d)(7) only if any joint insurance policy then in effect does not exclude coverage of litigation between the independent directors and another insured person under the amended rule;[107] and (iii) funds must begin to comply with the recordkeeping requirements of amended rule 31a–2.

C. Compliance Date for Disclosure Amendments

January 31, 2002. All new registration statements and post-effective amendments that are annual updates to effective registration statements, proxy statements for the election of directors, and reports to shareholders filed on or after January 31, 2002 must comply with the disclosure amendments. Based on the comments, we believe that this will provide funds with sufficient time to make the necessary changes to disclosure documents. We note that a post-effective amendment that is filed for any purpose other than those specifically enumerated in paragraph (b)(1) of rule 485 is required to be filed pursuant to rule 485(a).[108] We would not, however, object if existing funds file their first annual update complying with the amendments pursuant to rule 485(b), unless information is included in response to the new conflicts of interest disclosure requirements, provided that the post-effective amendment otherwise meets the conditions for immediate effectiveness under the rule.[109] Thereafter, funds must make their own determination as to whether their annual updates should be filed pursuant to rule 485(a) or may be filed pursuant to rule 485(b) under the Securities Act.[110]

III. Cost-Benefit Analysis

The Commission is sensitive to the costs and benefits imposed by its rules. In the Proposing Release, we requested comments and specific data regarding the costs and benefits of the proposed amendments to the Exemptive Rules[111] and the proposed new rules. Six commenters responded to our request for comments on the cost-benefit analysis. The commenters focused on a number of issues, particularly the independent counsel proposal and the disclosure proposals. These comments are addressed below.

A. Amendments to the Exemptive Rules

The Commission is adopting the proposed amendments to the Exemptive Rules and the proposed new rules, with certain changes (together, the "Amendments"). The Amendments require that, for funds relying on those rules: (i) independent directors constitute a majority of their boards; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the fund's independent directors be an independent legal counsel. The Amendments are designed to enhance the independence and effectiveness of independent directors, who are charged with overseeing the fund's activities and transactions under the Exemptive Rules. Boards that meet these conditions should be more effective at exerting an independent influence over fund management. Their independent directors should be more likely to have their primary loyalty to the fund's shareholders rather than the adviser, and should be better able to evaluate the complex legal issues that are often faced by fund boards with an independent and critical eye. The Amendments, therefore, should provide substantial benefits to shareholders by helping to ensure that independent directors are better able to fulfill their role of representing shareholder interests and supplying an independent check on management. While these benefits are not easily quantifiable in terms of dollars, we believe that they are real, and that the Amendments will strengthen the hand of independent directors to the advantage of shareholders.

The Amendments may impose some costs on funds that choose to rely on the Exemptive Rules. These costs are discussed below. Funds that do not rely on an Exemptive Rule, however, will not be subject to the new conditions and should not incur any costs associated with those conditions.[112]

Independent directors as a majority of the board. The Amendments require funds to have independent directors constitute a simple majority of their boards in order to rely on the Exemptive Rules. Because, as noted above, most mutual funds today have boards with independent majorities,[113] it appears that the Amendments will not impose substantial costs on funds as a group.

Funds that currently do not have a majority of independent directors on their boards and that would like to rely on the Exemptive Rules may incur some costs. The Commission, however, has no reasonable basis for estimating those costs. Those funds could come into compliance with the majority requirement of the Amendments in a number of ways. For example, funds could: (i) Decrease the size of their boards and allow some inside directors to resign; (ii) maintain the current size of their boards and replace some inside directors with independent directors; or (iii) increase the size of their boards and elect new independent directors.

If new independent directors are elected in order to comply with the Amendments, the fund would incur the costs of preparing a proxy statement and holding a shareholder meeting to elect those independent directors, as well as the costs of compensating those directors.[114] The Commission, however, has no reasonable basis for determining how many funds that currently do not have independent directors as a majority of their boards will choose to comply with the Amendments by electing new independent directors.

Independent director self-selection and self-nomination. The Amendments require independent directors to select and nominate any other independent directors. This change should not impose significant new costs on funds, because many funds already have adopted this practice.[115] Although some

[107] *See* rule 17d–1(d)(7)(iii).

[108] 17 CFR 230.485.

[109] 17 CFR 230.485(b). This also would apply to closed-end interval funds filing post-effective amendments pursuant to rule 486(b) under the Securities Act. 17 CFR 230.486(b).

[110] 17 CFR 230.485(a) and 230.485(b). Likewise, closed-end interval funds filing future post-effective amendments must determine whether they must file pursuant to rule 486(a) or may file pursuant to rule 486(b) of the Securities Act. 17 CFR 230.486(a) and 230.486(b).

[111] *See* Proposing Release, *supra* note , at text following n.33.

[112] One commenter stated that the Commission's proposed amendments and rules will increase the costs of relying on the Exemptive Rules, and that the "financial impact of the [Commission's] Proposal is underestimated." The commenter did not provide specific dollar figures to quantify what it believed were more accurate reflections of the possible costs of the Amendments. Moreover, whether a particular fund incurs additional costs, and the amount of those costs, will depend upon a number of factors specific to the fund.

[113] *See* Proposing Release, *supra* note , at n.39 and accompanying text.

[114] Under some circumstances a vacancy on the board may be filled by the board of directors. *See* section 16(a) of the Act. In those cases, the fund would not incur the costs of the proxy statement and shareholder meeting.

[115] *See* Proposing Release, *supra* note 3, at n.66 and accompanying text.

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independent counsel. We are unable to predict with any certainty how many independent directors will obtain new counsel because they determine that their current counsel is not "independent." Each evaluation of counsel will be fact-specific, and each board will have to make its own determination with respect to its counsel. Some independent directors may choose not to hire their own legal counsel. The costs of obtaining new counsel also may be partially offset by savings generated by reductions in payment to current counsel, once they cease providing their services to the independent directors.

C. Suspension of Board Composition Requirements

New rule 10e–1 will increase the periods for which the independent director minimum percentage requirements of the Act, and of the rules under the Act, are temporarily suspended if the death, disqualification, or bona fide resignation of an independent director causes the representation of independent directors on the board to fall below that required by the Act or our rules. The new rule will benefit funds by helping to ensure that if a fund's board falls below the independent director minimum percentage requirements in these circumstances, the fund will not immediately face the severe consequences of losing the availability of the Exemptive Rules.

One commenter stated its opinion that there will be significant costs imposed on funds if the time periods suggested in the Proposing Release were not increased. We extended one of the proposed time periods for rule 10e-1 in response to concerns voiced by commenters, and we believe that the periods for which the rule would suspend the independent director minimum percentage requirements are consistent with concerns for investor protection. As amended, the new rule appears not to have any costs for investors or funds.

D. Limits on Coverage of Directors under Joint Insurance Policies

Rule 17d–1(d)(7) under the Act permits funds to purchase joint liability insurance policies without first obtaining a Commission order permitting this joint arrangement, provided that certain conditions are met. The Commission is amending this rule to make it available only for joint liability insurance policies that do not exclude coverage for independent directors' litigation expenses in the event that they are sued by the fund's adviser. This change should benefit shareholders by making it possible for independent directors to engage in the good faith performance of their responsibilities under the Act and our rules without concern for their personal financial security. For the same reasons, the rule change also should benefit independent directors.

Because obtaining this type of coverage may cause the premiums charged by some insurance providers for joint liability insurance policies to increase, this amendment may have some costs for funds.[126] The Commission, however, has no reasonable basis for estimating the possible increase in premiums that may result from this proposal.

E. Independent Audit Committees

Section 32(a)(2) of the Act requires that the selection of a fund's independent public accountant be submitted to shareholders for ratification or rejection. New rule 32a–4 exempts a fund from this requirement if the fund has an audit committee consisting entirely of independent directors to oversee the fund's auditor. The new rule could provide significant benefits to shareholders. Many believe shareholder ratification of a fund's independent auditor has become a perfunctory process, with votes that are rarely contested. As a consequence, we believe that the ongoing oversight provided by an independent audit committee can provide greater protection to shareholders than shareholder ratification of the choice of auditor. In addition, funds that rely on section 32(a)(2) will no longer have to obtain shareholder ratification or rejection of their auditor on an annual basis, and this change should save some printing costs with respect to proxy materials.

New rule 32a–4 may impose certain costs on those funds that choose to rely on the exemption. It appears that these costs will likely be minimal and will be justified by the relief provided by the exemption. To rely on the exemption, among other things, a fund's board of directors must adopt an audit committee charter that sets forth the committee's structure, duties, powers, and methods of operation, or similar audit committee provisions must appear in the fund's charter or bylaws. The fund also must preserve that charter, and any modifications to the charter, permanently in an easily accessible place.[127] We estimate that there are approximately 3,490 investment companies that may rely on the proposed rule.[128] We assume that approximately 15 percent (524) of those funds are likely to rely on the exemption. For each of those funds, we estimate that the adoption of the audit committee charter would require, on average, 2 hours of director time and 2 hours of professional time,[129] for a total one-time burden of approximately 2,096 hours, and a total one-time cost of approximately $655,000.[130] We also estimate that each of the funds relying on the rule would be required to spend approximately 0.2 hours annually to comply with the proposed requirement that they preserve permanently their audit committee charters,[131] for an additional total annual hour burden of 105 hours, and an additional total annual cost of approximately $5,425.[132]

In addition, some funds pay their directors an extra fee for each committee on which they serve.[133] Those funds may incur the additional costs of audit committee fees if they establish an audit committee in order to rely on the proposed exemption. Of those funds likely to rely on the exemption, however, we have no basis for determining the number that would pay

[126] The ICI Mutual Insurance Company ("ICI Mutual"), which insures funds representing approximately 70 percent of all open-end fund assets, announced last year that it was making available to funds a standard policy endorsement that permits independent directors to recover defense costs, settlements, and judgments in "insured vs. insured" claims otherwise covered under the policy. *See* Proposing Release, *supra* note , at n.111. According to an ICI Mutual representative, that company is not charging funds any additional premiums for this coverage. It is possible, however, that other insurance providers might charge funds additional premiums for providing this type of coverage.

[127] These conditions are designed to enable the Commission staff to monitor the duties and responsibilities of an independent audit committee formed by a fund relying on the exemption.

[128] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[129] This estimate is based on a review of the estimated hour burdens currently associated with other rules under the Act that impose similar collection of information requirements.

[130] To calculate this one-time cost, the Commission staff used $500 per hour as the average cost of directors' time and $125 per hour as an average hourly wage for professionals ((2 hours × 524 funds × $500/hour) + (2 hours × 524 funds × $125/hour) = $655,000).

[131] This estimate is based on a review of the estimated hour burdens associated with other rules under the Act that impose similar collection of information requirements.

[132] To calculate the total annual cost of the proposed rule, the Commission staff assumed that one-third of the total annual hour burden (35 hours) would be incurred by professionals with an hourly wage rate of $125 per hour, and two-thirds of that annual hour burden (70 hours) would be incurred by clerical staff with an hourly wage rate of $15 per hour ((35 × $125/hour) + (70 × $15/hour) = $5,425).

[133] In some cases, funds pay these additional committee fees only if the committee meeting is held on a day when a board meeting is not scheduled.

funds do not currently follow this practice and will need to adopt it in order to rely on the Exemptive Rules, we are not aware of any costs that would result from requiring a fund's incumbent independent directors to select and nominate other independent directors.

Independent legal counsel. Lastly, the Amendments require any legal counsel to a fund's independent directors to be an independent legal counsel.[116] The Amendments do not require independent directors to retain legal counsel, but do require any person that acts as counsel to the independent directors to qualify as an independent legal counsel. Independent directors who are represented by counsel who does not meet the new definition of "independent legal counsel" thus may have to retain different counsel if their fund chooses to rely on any of the Exemptive Rules. If a substitution of counsel is necessary, it may lead to an increase in costs as described below.

B. Definition of Independent Legal Counsel

Rule 0–1 defines certain terms for purposes of the rules and regulations under the Investment Company Act. The Commission is amending this rule to add a definition of the term "independent legal counsel." Under the new definition, a person is an independent legal counsel if a majority of the fund's independent directors determine, in the exercise of their business judgment, based on information obtained from such person, that any representation of the fund's adviser, principal underwriter, administrator,[117] or any of their control persons[118] since the beginning of the fund's last two completed fiscal years is unlikely to adversely affect the professional judgment of the person in providing legal representation to the independent directors. The basis of the independent directors' determination is required to be recorded in the minutes of the directors' meeting.

The new definition of "independent legal counsel" should help to ensure that independent directors' counsel is able to provide objective legal advice concerning the complex legal issues faced by those directors. This change thus should benefit both shareholders and independent directors by helping those directors to better carry out their responsibilities as shareholder representatives. Shareholders also will benefit from the requirement that the independent directors' determinations be recorded in the minute books of the fund, because this requirement will enable the Commission staff to review independent directors' determinations that their counsel qualifies as independent legal counsel.

The new definition will impose costs on some funds that rely on the Exemptive Rules.[119] We assume that approximately 3,200 funds rely on at least one of the Exemptive Rules annually.[120] We further assume that the independent directors of approximately one-third of those funds (1,065) would be required to make the specified determination in order for their counsel to meet the definition of "independent legal counsel."[121] We estimate that each of these 1,065 funds would be required to spend, on average, 0.75 hours annually to comply with the proposed requirement that this determination be recorded in the fund's minute books,[122] for a total annual burden of approximately 799 hours. Based on this estimate, the total annual cost to funds of this new definition would be approximately $70,505.[123] We estimated in the Proposing Release that the cost of the new definition would be approximately $70,505, and one commenter argued that the actual cost of the proposed definition would "far exceed" that amount.[124] Another commenter stated that "there are likely to be substantial costs incurred by funds if they are forced to hire new counsel to independent directors because counsel has also represented the adviser."[125] We do not believe the cost will "far exceed" the estimated amount. The rule relies solely on the independent directors to make a good faith determination that a person is an

[116] As discussed above, we are amending rule 0–1 to include a definition of "independent legal counsel." *See* Proposing Release, *supra* note 3, at n.87 and accompanying text; *see also infra* notes 120–125 and accompanying text (discussing the costs and benefits of this proposed definition).

[117] In connection with this new definition, we also are amending rule 0–1 to define an "administrator" as any person who provides significant administrative or business affairs management services to a fund. This definition is substantially similar to the definition of administrator that is currently contained in Item 22(e)(1)(i) of Schedule 14A and Item 15(h)(1) of Form N–1A. Adding this definition to rule 0–1 should benefit funds by helping to clarify the scope of the definition of independent legal counsel. We are not aware of any costs that would be associated with this definition of administrator.

[118] We are amending rule 0–1 to define "control person" as any person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with a fund's investment adviser, principal underwriter, or administrator. This definition should benefit funds by helping to clarify the scope of the definition of independent legal counsel. We are not aware of any costs that would be associated with this definition.

[119] Among other things, the Amendments require that, for funds relying on those rules, any legal counsel for the independent directors of the fund be an "independent legal counsel."

[120] Based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998, we estimate that there are approximately 3,560 funds that could rely on one or more of the Exemptive Rules. Of those funds, we assume that approximately 90 percent (3,200) actually rely on at least one Exemptive Rule annually.

[121] We assume that the independent directors of the remaining two-thirds of those funds (2,135) will choose not to have counsel (but instead rely in some circumstances on counsel who does not represent them), so that no determination by the independent directors would be necessary.

[122] This estimate is based on a staff assessment of the burden associated with this proposed recordkeeping requirement in light of the estimated hour burdens currently associated with other rules under the Act that impose similar collection of information requirements.

[123] To calculate this total annual cost, the Commission staff assumed that two-thirds of the total annual industry hour burden (532 hours) would be incurred by professionals with an average hourly wage rate of $125 per hour, and one-third of that annual hour burden (267 hours) would be incurred by clerical staff with an average hourly wage rate of $15 per hour ((532 × $125/hour) + (267 × $15/hour) = $70,505).

[124] The commenter argued that, using the Commission's estimate, if the 1,065 funds that make a specific determination regarding "independent legal counsel" retain separate new counsel to represent them, the "total annual cost of the Commission's proposal will exceed $26 million" (assuming the average annual retainer for each separate counsel will be $25,000). While we agree that there may be additional costs imposed by rule 0–1 if a board finds its current counsel is not independent and wishes to retain new counsel, it is also likely that the cost of new counsel would be partially offset by the lower amount of fees to be paid to prior counsel. Some boards may decide against appointing counsel. Moreover, the amended rule is different from the proposed rule, and gives the independent directors sole discretion to determine whether their counsel is independent. Thus, the overall additional costs should be far less than those suggested by the commenter.

[125] This commenter suggested that there would be additional costs associated with new counsel, which would need to familiarize itself with the fund, its charter documents, its contracts, the service providers, and other information in order to effectively represent the fund's independent directors. Similarly, the commenter stated that as mergers and acquisitions of fund advisers accelerate, many fund boards will increasingly have to look to outside counsel as one of the few, if not the only, source of continuity and institutional knowledge. We agree that costs may be incurred if the independent directors retain new counsel. However, the Commission cannot predict with any certainty how often this will occur, or the fees charged by the new counsel. Moreover, as law firms experience their own mergers, acquisitions, and turnover of attorneys, new lawyers frequently must familiarize themselves with the fund and its operations. These are costs that law firms would and might pass on to funds whether or not we adopt the new rule.

The same commenter also expressed concern that the Proposing Release did not factor the costs of law firms to initially screen and thereafter continuously monitor legal work performed to ensure continued independence. Most law firms already screen and monitor any new matters for conflicts of interest. We do not believe that our rules will affect this screening and monitoring, nor do we believe law firms will have to establish new systems for the initial screening and continued monitoring of conflicts.

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their independent directors a separate fee for service on the audit committee, or the likely amount of those fees.[134]

F. Qualifications as an Independent Director

New rule 2a19–3 should benefit shareholders, funds, and independent directors by working to prevent qualified individuals from being unnecessarily disqualified from serving as independent directors. New rule 2a19–3 will benefit both funds and their independent directors by clarifying the status of independent directors who own shares of index funds.

The Commission is not aware of any costs to funds that would result from the new rule. There also should be no costs to investors because, consistent with concerns for investor protection, the new rule will not permit individuals who have affiliations or business interests that could impair their independence to serve as independent directors. The new rule applies to funds that replicate a broad-based index or indices, and does not include the five percent threshold of the proposed rule, and therefore funds will not have to monitor the percentage of an index that is made up of the securities of the fund's adviser, lead underwriter, or their controlling persons.[135]

G. Disclosure of Information about Fund Directors

In the Proposing Release, we analyzed the costs and benefits of our proposals and requested comment and data regarding the costs and benefits of the disclosure amendments. A few commenters specifically addressed the Commission's estimates, and they generally argued that the Proposing Release underestimated the costs to be incurred in connection with the proposed amendments. The commenters, however, did not provide specific cost or benefit data in response to the Proposing Release. As discussed above, after careful consideration of the comments we received in response to our Proposing Release, we have tailored the disclosure requirements to better achieve our goals and also addressed the concerns of commenters by modifying the scope of the proposed disclosure amendments.

The amendments to the proxy rules and Forms N–1A, N–2, and N–3 will provide fund investors with improved information about directors. Because independent directors are the shareholders' representatives and advocates, shareholders have a significant interest in knowing who the independent directors are, whether the independent directors' interests are aligned with shareholders' interests, whether the independent directors have any conflicts of interest, and how the directors govern the fund. This information will help a fund shareholder evaluate whether his designated representatives can, in fact, act as independent, vigorous, and effective representatives.

We believe that the amendments benefit investors in several ways. The requirement that mutual funds disclose basic information about directors in an easy-to-read tabular format in the fund's annual report to shareholders, SAI, and proxy statements for the election of directors benefits shareholders by ensuring that shareholders receive information about the identity and experience of their directors both annually and whenever they are asked to vote to elect directors. Moreover, this information benefits prospective investors who may obtain the information, without charge, upon request.

The amendments require that funds disclose: (1) Each director's ownership in each fund that he oversees; and (2) each director's aggregate ownership in any funds that he oversees within a fund family. This information benefits shareholders and prospective investors by making available in the SAI information that may show the alignment of director interests with those of shareholders. In addition, shareholders also benefit by receiving this information in the proxy statements whenever they are asked to vote to elect directors.

Our amendments regarding circumstances that may raise conflict of interest concerns for directors benefit investors by enabling investors to decide for themselves whether an independent director would be an effective advocate for shareholders. Disclosure of this type of information also results in its public dissemination, bringing these circumstances to the attention of fund shareholders, and encouraging the selection of independent directors who are independent in the spirit of the Act. Finally, this information assists the Commission in determining whether to exercise its authority under section 2(a)(19) of the Act to find that a person is an interested person of a fund by reason of having had, at any time since the beginning of the last two completed years of the fund, a material business or professional relationship with the fund and certain persons related to the fund.

The modifications to the disclosure requirements of matters related to the board's role in governing a mutual fund benefit shareholders by allowing them to determine more readily whether the directors are effectively representing shareholders' interests, independent of fund management.

The amendments impose certain costs on the fund industry. The costs associated with the proposed amendments include the resources expended by funds in collecting the information and preparing the disclosure documents.[136] Although we have tailored the proposal to better achieve our goals and to address the concerns of commenters, we do not believe that the overall cost burden of the amendments was materially affected.

Proxy Statements

The hour burden for preparing proxy statements at the time of the Proposal Release was 96.2 hours per proxy statement, and we estimated that approximately ⅓ of those hours—or 32 hours—are expended collecting and disclosing information about directors and nominees.[137] We estimated the additional burden hours that would be imposed by the proposed disclosure requirements to be 10 hours per proxy statement.[138]

We estimate the annual industry cost of the proposed amendments to the proxy statements to be 10,000 hours, or $1.25 million, based on an estimated 1,000 proxy statements that are filed annually.[139]

[134] We also have no basis for determining how many funds would choose to avoid those fees by scheduling audit committee meetings for the same day as a board meeting.

[135] *See supra* Section I.E.2.

[136] One commenter argued that the Commission failed to account for the costs to funds when potential and existing directors are discouraged from serving on fund boards due to the burdens of the proposed disclosure amendments. The commenter, however, failed to provide any quantifiable data to support the commenter's argument. Moreover, in tailoring the disclosure amendments to better achieve our goals, we have addressed the concerns of commenters regarding the scope of the disclosure requirements.

Another commenter noted that the Commission failed to account for the legal costs associated with increased litigation that would arise from the new disclosure requirements. Again, the commenter failed to provide any data for us to consider.

[137] This estimate was based on a staff assessment of the different types of information required in proxy statements.

[138] This estimate was based upon a staff assessment of the proposed amendments in light of the hour burden and reporting requirements at the time of the Proposal Release.

As stated above, the additional hours were based on the additional time funds would devote to determining what information needs to be disclosed, formulating queries for directors, and preparing the disclosure documents.

[139] The estimated number of proxy statements was based on the approximate number of proxy statements filed with the Commission in calendar year 1998. The total industry cost of the proposed amendments to the proxy statement is calculated by multiplying the annual number of proxy statements (1,000) by the additional hour burden imposed by the proposed amendments (10 hours) by the hourly wage rate ($125). The hourly wage rate is based upon consultations with a sample of filers and represents the Commission's estimate for an appropriate wage rate for the legal, financial, and accounting skills commonly used in preparation of registration statements, shareholder reports, and proxy statements.

[140] Our estimated hour burden would be high for those portfolios that are part of a fund complex in which multiple registered investment companies have the same board of directors because the burden of collecting and disclosing information about the common board would be spread over a larger number of portfolios.

[141] Although funds only have to update the information about current directors and add information about new directors, we anticipate that funds will incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure information.

Registration Statements

Because the information to be disclosed in the registration statements is the same as in the proxy statements, we believe that the hour burden for the amendments per registration statement will be approximately the current hour burden for collecting and disclosing director information under the current proxy rules plus the hour burden for the proposed amendments to the proxy rules. As stated above, we estimated the current hour burden for collecting and disclosing information about directors and nominees in proxy statements to be 32 hours per proxy statement and the burden hours for collecting and disclosing the enhanced information about directors and nominees to be 10 hours per proxy statement, for a total of 42 hours.

Form N–1A

The hour burden for Form N–1A is on a per portfolio basis and not per registration statement filed with the Commission. Based on the staff's experience with Form N–1A, we estimate that there are approximately 1.75 portfolios per registration statement filed on Form N–1A. The average hour burden per portfolio for disclosing the information about directors will be the hour burden per registration statement (42) divided by the average number of portfolios per registrant (1.75), or 24 hours per portfolio.[140] Because mutual funds only have to update information in post-effective amendments, we expect the hour burden to be ⅙ of the hours expended for the initial registration statement, or 4 hours per portfolio for post-effective amendments.[141]

In the Proposing Release, we estimated that 280 portfolios file initial registration statements and 7,875 portfolios file post-effective amendments annually on Form N–1A.[142] Thus, we estimate the annual industry cost of the amendments to Form N–1A to be 38,220 hours, or $4.78 million.[143]

Form N–2

The hour burden for Form N–2 is on a per registration statement basis because funds registering on Form N–2 register one portfolio per registration statement. Because the disclosure will be the same for Form N–2 as for Form N–1A, except that it would be for one portfolio per registration statement, we estimated the additional hour burden for the proposed amendments to be 42 hours for each initial registration statement. Because funds only have to update information in post-effective amendments, we expect that the hour burden to be approximately ⅙ of the hours expended for the initial registration statement, or 7 hours per post-effective amendment.[144]

In the Proposing Release, we estimated that 110 funds file initial registration statements and 20 file post-effective amendments annually on Form N–2.[145] Thus, we estimate the annual industry cost of the amendments to Form N–2 to be 4,760 hours, or $595,000.[146]

Form N–3

The hour burden for Form N–3 is on a per portfolio basis and not per registration statement filed with the Commission. Based on the Commission staff's experience with Form N–3, we estimate that there are approximately 4 portfolios per investment company registering on Form N–3. The average hour burden per portfolio for disclosing the information about directors will be the hour burden per registration statement (42) divided by the approximate number of portfolios per registrant (4), or 10.5 hours per portfolio. Because funds only have to update information in post-effective amendments, we expect that the hour burden would be ⅙ of the hours expended for the initial registration statement, or 1.75 hours per portfolio for post-effective amendments.[147]

In the Proposing Release, we estimated that 20 portfolios file initial registration statements and 40 portfolios file post-effective amendments annually on Form N–3.[148] Thus, we estimate the annual industry cost of the amendments to Form N–3 to be 280 hours, or $35,000.[149]

Shareholder Reports

Because the disclosure of basic tabular information, which is required in annual shareholder reports, is a subset of the information that would be required in the initial registration statement of a fund and any post-effective amendments, we expect that the annual burden for complying with the proposed amendments to the shareholder report requirements would be minimal. Based upon the amount of information to be disclosed, we estimate that the hour burden would be one-half hour per investment company for each annual shareholder report. In the Proposing Release, we estimated that there were 3,490 management investment companies that are subject to the annual report requirements.[150] Thus, we estimate the annual industry cost of the proposed amendments for annual shareholder reports to be 1,745 hours, or $218,125.[151]

H. Recordkeeping Regarding Director Independence

The Commission also is amending rule 31a–2 under the Act, which requires funds to preserve certain records for specified periods of time. The amendments to rule 31a–2 require funds to preserve for a period of at least six years any record of: (i) The initial determination that a director qualifies as

[142] These estimates were based on filings received in calendar year 1998.

[143] The total annual industry cost is calculated by multiplying the total annual industry hour burden ((280 portfolios x 24 hours) + (7,875 portfolios x 4 hours)) by the hourly wage rate of $125.

[144] Although funds only have to update the information about current directors and add information about new directors, we anticipate that funds will incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure information.

[145] These estimates were based on filings received in calendar year 1998.

[146] The total annual industry cost is calculated by multiplying the total annual industry hour burden ((110 funds x 42 hours) + (20 funds x 7 hours)) by the hourly wage rate of $125.

[147] Although funds would only have to update the information about current directors and add information about new directors, we anticipate that funds would incur some burden hours in regularly collecting information from directors, determining what information needs to be disclosed, and preparing the updated disclosure information.

[148] These estimates were based on filings received in calendar year 1998.

[149] The total annual industry cost is calculated by multiplying the total annual industry hour burden ((20 portfolios x 10.5 hours) + (40 portfolios x 1.75 hours)) by the hourly wage rate of $125.

[150] This estimate was based on statistics compiled by Division staff from January 1, 1997 through December 31, 1998.

[151] The industry cost of the proposed annual shareholder reporting requirements is calculated by multiplying the total annual hour burden for the industry (0.5 hours x 3,490 registered management investment companies) by the hourly wage rate of $125.

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an independent director; (ii) each subsequent determination of whether the director continues to qualify as an independent director; and (iii) the determination that any person who is acting as legal counsel to the independent directors is an independent legal counsel. These amendments should benefit both shareholders and the Commission by enabling the Commission's staff to monitor the independent directors' determination of whether their counsel is independent.

The amendments will impose certain minimal costs on funds. The Commission staff estimates that each fund currently spends about 27.8 hours per year complying with the record preservation requirements of rule 31a–2.[152] Approximately 3,490 funds would be affected by the proposal to amend the rule to require funds to preserve records regarding the independence of their directors.[153] The Commission staff estimates that each of those funds would be required to spend an additional 0.2 hours annually to comply with the proposed amendment,[154] for a total additional burden for all funds of approximately 698 hours. Based on this estimate, the total annual cost for all funds of the proposed amendment to rule 31a–2 would be $36,100.[155] The estimated costs related to the determination of counsel's independence are discussed above in section IV.B. The Commission is not aware of any other costs that would result from the proposed amendments to rule 31a–2.

V. Effects on Efficiency, Competition and Capital Formation

Section 2(c) of the Investment Company Act, section 2(b) of the Securities Act, and section 3(f) of the Exchange Act require the Commission, when engaging in rulemaking that requires it to consider or determine whether an action is consistent with the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation.[156] The Commission has considered these factors.

Independent directors have significant responsibilities under the Investment Company Act and the Exemptive Rules. The new rules and amendments are intended to enhance the independence and effectiveness of independent directors so that they can perform these responsibilities capably and well. The new rules and rule amendments should promote capital formation by bolstering investors' confidence in the ability of independent directors to represent their interests effectively. When investors are confident that their interests are duly considered by those responsible for the operation of the mutual funds in which they invest, they are more likely to continue to rely on mutual funds as a vehicle for savings and investment. The new rules and rule amendments should promote efficiency and competition by enhancing the ability of fund independent directors to scrutinize fund operations and protect funds from inefficiencies inherent when a fund is operated to promote the interests of persons other than those who have invested in the fund.

As discussed above, shareholders have a significant interest in knowing who the independent directors are, whether the independent directors' interests are aligned with shareholders' interests, whether the independent directors have any conflicts of interest, and how the directors govern the fund. This information helps a fund shareholder to evaluate whether the independent directors can, in fact, act as an independent, vigorous, and effective force in overseeing fund operations. The disclosure amendments were designed to ensure that shareholders have the information necessary to make such evaluations.

It is unclear whether the disclosure amendments will promote the efficiency of funds since the disclosure amendments do not change the operation of funds. The disclosure amendments, however, may promote competition among funds since shareholders will now be better equipped to evaluate the effectiveness of fund boards among various funds before making their investment decisions. The disclosure amendments also may promote capital formation as the disclosure amendments may provide potential investors greater confidence to invest in funds knowing that the interests of the independent directors overseeing the funds are aligned with their own.

VI. Paperwork Reduction Act

As explained in the Proposing Release, certain provisions of Forms N–1A, N–2, and N–3, and rules 0–1, 20a–1, 30e–1, 31a–2, and 32a–4 under the Investment Company Act, and Schedule 14A under the Exchange Act contain "collection of information" requirements within the meaning of the Paperwork Reduction Act of 1995 [44 U.S.C. 3501–3520.]. We published notice soliciting comments on the collection of information requirements in the Proposing Release and submitted these requirements to the Office of Management and Budget ("OMB") for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11.

As discussed above, we are adopting the disclosure amendments with several modifications designed to tailor the amendments more closely to our goal of providing shareholders with better information to evaluate the independent directors. Specifically, we are adopting disclosure amendments that will require funds to disclose: (1) Basic information about directors in an easy-to-read tabular format; (2) fund shares owned by directors; (3) conflicts of interest information regarding independent directors; and (4) information on the board's role in governing the fund.

A few commenters specifically addressed the burden hours the Commission estimated funds would incur to satisfy the proposed disclosure requirements, generally stating that these estimates were too low. These commenters, however, did not provide the Commission with any specific quantitative data regarding burden hours.[157] As discussed in the Proposing Release, the Commission staff estimated the burden hours that would be necessary under the proposed disclosure amendments by assessing a variety of factors.[158] After careful consideration of these comments, as well as the modifications made to the amendments as proposed, we continue to believe that our estimates are appropriate.[159]

The rule amendments we are adopting in this Release include amendments to the Exemptive Rules that are designed to enhance the independence and effectiveness of fund independent directors.[160] The changes also include new rules and rule amendments that will prevent qualified individuals from being unnecessarily disqualified from serving as independent directors, protect independent directors from the costs of legal disputes with fund management, permit the Commission to monitor the independence of directors by requiring funds to preserve records of their assessments of director independence, and temporarily suspend the independent director minimum percentage requirements if a fund falls below the required percentage due to an independent director's death or resignation. In addition, the Commission is exempting funds from the requirement that shareholders ratify or reject the directors' selection of an independent public accountant, if the fund establishes an audit committee composed entirely of independent directors.

In the Proposing Release, the Commission estimated the burden hours that would be necessary for the collection of information requirements under the proposed amendments to the rules under the Act. Although no commenters specifically addressed the burden estimates for the collection of information requirements, a few commenters responding to the cost-benefit analysis in the Proposing Release generally stated that we had underestimated the burden hours. These commenters, however, did not provide an estimate of the burden hours associated with the proposed rule changes. We continue to believe that the estimates of the burden hours contained in the Proposing Release are appropriate.[161]

OMB approved the collection requirements contained in the forms and rules. Forms N–1A (OMB Control No. 3235–0307), N–2 (OMB Control No. 3235–0026), and N–3 (OMB Control No. 3235–0316) were adopted pursuant to section 8(a) of the Investment Company Act [15 U.S.C. 80a–8] and section 5 of the Securities Act [15 U.S.C. 77e]. Rule 0–1 was adopted pursuant to section 38(a) of the Investment Company Act [15 U.S.C. 80a–37(a)]. Rule 20a–1 (OMB Control No. 3235–0158) and rule 30e–1 (OMB Control No. 3235–0025) were promulgated under sections 20(a) and 30(e) [15 U.S.C. 80a–20 and 80a–29], respectively, of the Investment Company Act. Rule 31a–2 (OMB Control No. 3235–0179) was adopted under sections 31 [15 U.S.C. 80a–30] and 38(a) of the Investment Company Act. Rule 32a–4 (Control No. 3235–0530) was adopted under sections 6(c) [15 U.S.C. 80a–6(c)] and 38(a) of the Investment Company Act.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. Compliance with the disclosure requirements is mandatory. Responses to the disclosure requirements will not be kept confidential.

VII. Summary of Final Regulatory Flexibility Analysis

A Final Regulatory Flexibility Analysis ("FRFA") has been prepared in accordance with 5 U.S.C. 604. The Commission proposed new rules 2a19–3, 10e–1 and 32a–4, and amendments to rules 0–1, 2a19–1, 10f–3, 12b–1, 15a–4, 17a–7, 17a–8, 17d–1, 17e–1, 17g–1, 18f–3, 23c–3, 30d–1, 30d–2, and 31a–2, and requested comments on the new rules and amendments in the Proposing Release. The Commission prepared an Initial Regulatory Flexibility Analysis ("IRFA") in accordance with 5 U.S.C. 603 in conjunction with the Proposing Release, which was made available to the public. The Proposing Release summarized the IRFA and solicited comments on it. No comments specifically addressed the IRFA.

A. Need for the Rules and Rule Amendments

1. Amendments to Exemptive Rules

Fund boards of directors have significant responsibilities to protect investors under state law, the Investment Company Act, and many of our rules. Independent directors, in particular, represent the interests of fund shareholders. They serve as "independent watchdogs," guarding investor interests. We are amending certain Exemptive Rules to require that, for funds relying on those rules:

- Independent directors constitute a majority of the fund's board of directors;
- Independent directors select and nominate other independent directors; and
- Any legal counsel for the fund's independent directors be an "independent legal counsel."[162]

We also are adopting rules and rule amendments that will prevent qualified individuals from being unnecessarily disqualified from serving as independent directors, protect independent directors from the costs of legal disputes with fund management, permit us to monitor the independence of directors by requiring funds to keep records of their assessments of director independence, and temporarily suspend the independent director minimum percentage requirements if a fund falls below the required percentage due to an independent director's death or resignation. In addition, we are exempting funds from the requirement that shareholders ratify or reject the directors' selection of an independent public accountant, if the fund

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[152] Commission staff surveyed representatives of several funds to determine the current burden hour estimate for rule 31a–2.

[153] This estimate is based on statistics compiled by Commission staff from January 1, 1997 through December 31, 1998.

[154] This estimate is based on a Commission staff assessment of the hour burden that would be imposed by the proposed amendment in light of the estimated hour burden currently imposed by the requirements of the rule.

[155] In calculating the total annual industry cost of the proposed amendment, the Commission staff assumed that one-third of the total annual industry hour burden (233 hours) would be incurred by professionals with an average hourly wage rate of $125 per hour, and two-thirds of that annual hour burden (465 hours) would be incurred by clerical staff with an average hourly wage rate of $15 per hour ((233 x $125/hour) + (465 x $15/hour) = $36,100).

[156] 15 U.S.C. 80a–2(c), 77b(b), and 78c(f).

[157] One commenter did assert that an additional 250 hours would be required to convert the new disclosure requirements into "plain English" in order for funds to obtain accurate information from directors. In light of the modifications to the disclosure requirements discussed above, which simplified the disclosure requirements, we believe that our estimates remain appropriate.

[158] For example, in determining the burden hour for preparing proxy statements, we explained that the then current hour burden for preparing proxy statements was 96.2 hours per proxy statement, and we estimated that approximately ⅓ of those hours—or 32 hours—were expended collecting and disclosing information about directors and nominees. We estimated that an additional 10 burden hours per proxy statement would be imposed by the proposed disclosure requirements. This estimate was based upon a Commission staff assessment of the proposed amendments in light of the then current hour burden and current reporting requirements. We explained that the additional hours were based on the additional time funds would devote to determining what information needs to be disclosed and preparing the disclosure documents.

[159] We note that since issuing the Proposing Release, the Commission issued a proposal on Disclosure of Mutual Fund After-Tax Returns, Investment Company Act Release No. 24339 (March 15, 2000) [65 FR 15500 (March 22, 2000)]. The proposal would result in an increase in burden hours of 109,591 for Form N–1A and 17,100 burden hours for rule 30e–1 due to the proposed amendments relating to after-tax disclosure.

[160] These amendments require that, for funds relying on any of the Exemptive Rules, (i) independent directors constitute a majority of the fund's board of directors; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the independent directors be an independent legal counsel. In connection with these amendments, we also are amending rule 0–1 under the Act to add definitions of the terms "independent legal counsel" and "administrator."

[161] The Commission continues to estimate that the addition of the definition of the term "independent legal counsel" to rule 0–1 will require the independent directors of approximately 1,065 funds to spend, on average, 0.75 hours annually to determine whether their counsel meets the definition of "independent legal counsel," for a total annual burden of approximately 799 hours. *See* Proposing Release, *supra* note 3, at nn.287–290 and accompanying text.

In addition, the Commission estimates that the amendments to rule 31a–2, which require funds to preserve records regarding the independence of their directors and counsel, will require approximately 3,490 investment companies to spend an additional 0.2 hours annually to comply with the collection of information requirements of rule 31a–2, for a total additional burden for all funds of approximately 698 hours. *See* Proposing Release, *supra* note 3, at nn.310–312 and accompanying text.

The Commission also estimates that new rule 32a–4, which provides an exemption from the requirement in section 32(a)(2) of the Act that the selection of a fund's independent public accountant be submitted to shareholders for ratification or rejection, will be relied upon by approximately 524 funds, for a total one-time burden of 2,096 hours and an additional annual hour burden of 105 hours. *See* Proposing Release, *supra* note 3, at nn.313–314 and accompanying text.

[162] In connection with the adoption of this requirement, we also are defining the term "independent legal counsel."

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establishes an audit committee composed entirely of independent directors.

2. Disclosure Requirements

In reevaluating our current disclosure requirements about fund directors, we concluded that, while our fundamental approach has been sound, there are several gaps in the information that shareholders currently receive about directors. We are, therefore, requiring that funds provide better information about directors, including:

- Basic information about the identity and business experience of directors;
- Fund shares owned by directors;
- Information about directors that may raise conflict of interest concerns; and
- The board's role in governing the fund.

We are adopting the disclosure amendments with several modifications designed to tailor the amendments more closely to our goal of providing shareholders with better information to evaluate the independent directors.

B. Significant Issues Raised by Public Comment

The Commission requested comment on the IRFA, but we received no comments specifically addressing the analysis. Several commenters, however, asserted that the financial costs of the amendments to the rules under the Act would have a greater impact on funds that are small entities. Those commenters did not, however, provide an estimate of the costs to small entities. A few commenters stated that the disclosure amendments, as proposed, would disadvantage smaller funds.

Two commenters argued that the proposed fund ownership disclosure would disadvantage directors of smaller funds as these funds are more likely to be stand-alone funds or part of a fund complex with fewer funds, thereby reducing the likelihood that such funds would meet directors' particular investment objectives. We have addressed this concern by modifying the proposal to require that funds disclose each director's ownership in each fund that he oversees and each director's aggregate ownership in any funds that he oversees within a his fund family. Although we understand that directors of smaller funds will still have fewer funds from which to choose, limiting fund ownership disclosure to those funds that a director oversees within the same complex should help reduces the disadvantage to directors of smaller funds and still provide investors with information to assess whether a director's interests are aligned with their own..

We also narrowed the scope of immediate family members and related persons in recognition of the overbreadth of our proposal in certain circumstances, which should alleviate concerns that the conflicts of interest disclosure requirements would discourage directors from serving on fund boards.

C. Small Entities Subject to the Rules

As of December 1999, approximately 299 funds met the Commission's definition of small entity for purposes of the Investment Company Act.[163]

The amendments to the Exemptive Rules will affect funds, including any small entities that rely on the Exemptive Rules and do not already meet the new conditions to those rules. Although it appears that funds may incur certain costs in complying with those conditions, the Commission does not have a reasonable basis for estimating those costs. Other rule amendments are not expected to have a significant economic impact on funds, including those that are small entities.

As discussed above, we are adopting the disclosure amendments with several modifications designed to tailor the amendments more closely to our goal of providing shareholders with better information to evaluate the independent directors. In doing so, we have narrowed the scope of the disclosure requirements that were proposed and that would have applied to small entities.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

1. Investment Company Act Rule Amendments

The amendment to rule 17d–1(d)(7), and new rules 10e–1 and 2a19–3, will not impose any new reporting, recordkeeping or compliance requirements. The amendments to the Exemptive Rules also will not impose any new reporting or recordkeeping requirements, but will impose three new compliance requirements. For funds relying on the Exemptive Rules, the amendments require that: (i) Independent directors constitute a majority of the fund's board of directors; (ii) independent directors select and nominate other independent directors; and (iii) any legal counsel for the fund's independent directors be an independent legal counsel. Although it appears that there may be certain costs to funds, including those that are small entities, associated with complying with these requirements, the Commission does not have a reasonable basis for estimating those costs.

2. Disclosure Amendments

As noted in our Paperwork Reduction Act Analysis, a few commenters argued that we had underestimated the costs of complying with the proposed rules and amendments.[164] In addition, several commenters stated that compliance with the proposed rules and amendments would have a greater impact on small entities. However, none of the commenters provided an estimate of the impact on small entities, and how it would differ from the impact on larger entities.

E. Agency Action to Minimize Effects on Small Entities

1. Investment Company Act Rule Amendments

With respect to the amendments to the rules under the Act, we believe that establishing different requirements that are applicable specifically to small entities is inconsistent with the protection of investors. We also believe that adjusting the new rules and rule amendments to establish different compliance requirements for small entities could undercut the purpose of the changes: to enhance the effectiveness of independent directors of all funds, and thus better enable those directors to fulfill their role of protecting shareholder interests.

2. Disclosure Amendments

With respect to the disclosure requirements, the Commission believes that special compliance or reporting requirements for small entities would not be appropriate or consistent with investor protection. The disclosure amendments give shareholders and the public greater access to information about directors. Different disclosure requirements for small entities, such as reducing the level of disclosure that small entities would have to provide shareholders, would create the risk that shareholders would not receive adequate information about their independent directors. The Commission believes it is important for shareholders and the public to receive this information about directors for all funds, not just for funds that are not considered small entities. Shareholders in small funds should have information about their directors and would benefit from this information as much as shareholders in larger funds.

Consolidating or simplifying compliance requirements for small entities or exempting small entities from any or all of the disclosure requirements would be inconsistent with the Securities Act, the Exchange Act, the Investment Company Act, and investor protection. If we do not require certain information for small entities, this could create the risk that investors in small funds might not receive important information about their directors. The Commission also notes that current disclosure requirements in the proxy statements and registration statements do not distinguish between small entities and other funds. In addition, the Commission believes it would be inappropriate to impose a different timetable on small entities for complying with the requirements.

The Commission believes that the amendments will not adversely affect small entities. The new disclosure requirements modify the existing disclosure requirements in proxy statements and registrations statements. In addition, the Commission believes that any additional impact on small entities will be outweighed by the benefits to shareholders and the public of having greater access to the information. Further consolidation or simplification of disclosure requirements for small entities, or use of performance standards to specify different requirements for small entities would not be consistent with the objectives of the Investment Company Act.

The FRFA is available for public inspection in File No. S7–23–99, and a copy may be obtained by contacting Peter M. Hong, Special Counsel, at (202) 942–0721, Office of Disclosure Regulation, Division of Investment Management, Securities and Exchange Commission, 450 5th Street, N.W., Washington, D.C. 20549–0506.

VIII. Statutory Authority

The Commission is adopting rules 2a19–3, 10e–1, and 32a–4, and amendments to rules 0–1, 2a19–1, 10f–3, 12b–1, 15a–4, 17a–7, 17a–8, 17d–1, 17e–1, 17g–1, 18f–3, 23c–3, 30d–1, 30d–2, and 31a–2 pursuant to authority set forth in sections 6(c), 10(e), 30(e), 31, and 38(a) of the Investment Company Act [15 U.S.C. 80a–6(c), 80a–10(e), 80a–29(e), 80a–30, 80a–37(a)]. The Commission is adopting amendments to Schedule 14A pursuant to authority set forth in sections 14 and 23(a)(1) of the Exchange Act [15 U.S.C. 78n, 78w(a)(1)] and sections 20(a) and 38 of the Investment Company Act [15 U.S.C. 80a–20(a), 80a–37]. The Commission is adopting amendments to Forms N–1A, N–2, and N–3 pursuant to authority set forth in sections 5, 6, 7, 10, and 19(a) of the Securities Act [15 U.S.C. 77e, 77f, 77g, 77j, 77s(a)] and sections 8, 24(a), 30, and 38 of the Investment Company Act [15 U.S.C. 80a–8, 80a–24(a), 80a–29, 80a–37].

List of Subjects

17 CFR Parts 239 and 240

Reporting and recordkeeping requirements, Securities.

17 CFR Parts 270 and 274

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Final Rules and Forms

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for Part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*(d), 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. Section 240.14a–101 is amended as follows:

a. Redesignating paragraphs (e) and (d) of Item 7 as paragraphs (d) and (e) of Item 7;

b. In newly redesignated paragraph (d)(1) of Item 7, removing the third and fourth sentence;

c. In newly redesignated paragraph (d)(3)(iv)(A)*(2)* of Item 7, revise the phrase "paragraph (e)(3)(iv)(A)(2)" to read "paragraph (d)(3)(iv)(A)*(2)*";

d. In newly redesignated paragraphs (d)(3)(v), (d)(3)(vi) and (d)(3)(vii) of Item 7, revise the phrase "paragraph (e)(3)" to read "paragraph (d)(3)";

e. Revising newly redesignated paragraph (e) of Item 7;

f. Revising Item 8(d), before the Instruction, revising "Item 22(b)(6)" to read "Item 22(b)(13)";

g. In the Instruction following Item 10(a)(2)(ii)(A), revising "Item 22(b)(6)" to read "Item 22(b)(13)";

h. In the Instruction following Item 10(b)(1)(ii), revising "Item 22(b)(6)(ii)" to read "Item 22(b)(13)";

i. Revising paragraph (a)(1)(i) of Item 22;

j. In Item 22, redesignating paragraphs (a)(1)(iv), (v), (vi), (vii), and (viii) as paragraphs (a)(1)(v), (vi), (ix), (x), and (xii);

k. In Item 22, adding new paragraphs (a)(1)(iv), (vii), (viii), and (xi);

l. In Item 22, revising newly designated paragraph (a)(1)(x); and

m. Revising paragraph (b) of Item 22.

These additions and revisions read as follows:

§ 240.14a–101 Schedule 14A. Information required in proxy statement.

* * * * *

Item 7. Directors and executive officers

* * * * *

(e) In lieu of paragraphs (a) through (d)(2) of this Item, investment companies registered under the Investment Company Act of 1940 (15 U.S.C. 80a) must furnish the information required by Item 22(b) of this Schedule 14A.

* * * * *

Item 22. Information required in investment company proxy statement.

(a) * * *

(1) * * *

(i) *Administrator.* The term "Administrator" shall mean any person who provides significant administrative or business affairs management services to a Fund.

* * * * *

(iv) *Family of Investment Companies.* The term "Family of Investment Companies" shall mean any two or more registered investment companies that:

(A) Share the same investment adviser or principal underwriter; and

(B) Hold themselves out to investors as related companies for purposes of investment and investor services.

* * * * *

(vii) *Immediate Family Member.* The term "Immediate Family Member" shall mean a person's spouse; child residing in the person's household (including step and adoptive children); and any dependent of the person, as defined in section 152 of the Internal Revenue Code (26 U.S.C. 152).

(viii) *Officer.* The term "Officer" shall mean the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

* * * * *

(x) *Registrant.* The term "Registrant" shall mean an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a) or a business development company as defined by section 2(a)(48) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(48)).

(xi) *Sponsoring Insurance Company.* The term "Sponsoring Insurance Company" of a Fund that is a separate account shall mean the insurance company that establishes and maintains the separate account and that owns the assets of the separate account.

* * * * *

(b) *Election of Directors.* If action is to be taken with respect to the election of directors of a Fund, furnish the following information in the proxy statement in addition to the information (and in the format) required by

[163] We note that few, if any, insurance company separate accounts registered on Form N–3 have assets of less than $50 million when separate account assets are aggregated with the assets of the sponsoring insurance company.

[164] *See supra* note and accompanying text.

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paragraphs (f) and (g) of Item 7 of Schedule 14A.

Instructions to introductory text of paragraph (b). 1. Furnish information with respect to a prospective investment adviser to the extent applicable.

2. If the solicitation is made by or on behalf of a person other than the Fund or an investment adviser of the Fund, provide information only as to nominees of the person making the solicitation.

3. When providing information about directors and nominees for election as directors in response to this Item 22(b), furnish information for directors or nominees who are or would be "interested persons" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)) separately from the information for directors or nominees who are not or would not be interested persons of the Fund. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors and nominees who are or would be interested persons and for directors or nominees who are not or would not be interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors or nominees who are or would be interested persons and the directors or nominees who are not or would not be interested persons.

4. No information need be given about any director whose term of office as a director will not continue after the meeting to which the proxy statement relates.

(1) Provide the information required by the following table for each director, nominee for election as director, Officer of the Fund, person chosen to become an Officer of the Fund, and, if the Fund has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age.	Position(s) Held with Fund.	Term of Office and Length of Time Served.	Principal Occupation(s) During Past 5 Years.	Number of Portfolios in Fund Complex Overseen by Director or Nominee for Director.	Other Directorships Held by Director or Nominee for Director

Instructions to paragraph (b)(1). 1. For purposes of this paragraph, the term "family relationship" means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. No nominee or person chosen to become a director or Officer who has not consented to act as such may be named in response to this Item. In this regard, see Rule 14a–4(d) under the Exchange Act (§ 240.14a–4(d)).

3. If fewer nominees are named than the number fixed by or pursuant to the governing instruments, state the reasons for this procedure and that the proxies cannot be voted for a greater number of persons than the number of nominees named.

4. For each director or nominee for election as director who is or would be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director or nominee is or would be an interested person.

5. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

6. Include in column (5) the total number of separate portfolios that a nominee for election as director would oversee if he were elected.

7. Indicate in column (6) directorships not included in column (5) that are held by a director or nominee for election as director in any company with a class of securities registered pursuant to section 12 of the Exchange Act (15 U.S.C. 78*l*), or subject to the requirements of section 15(d) of the Exchange Act (15 U.S.C. 78o(d)), or any company registered as an investment company under the Investment Company Act of 1940, (15 U.S.C. 80a), as amended, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same Fund Complex, identify the Fund Complex and provide the number of portfolios overseen as a director in the Fund Complex rather than listing each portfolio separately.

(2) For each individual listed in column (1) of the table required by paragraph (b)(1) of this Item, except for any director or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Fund.

Instruction to paragraph (b)(2). When an individual holds the same position(s) with two or more registered investment companies that are part of the same Fund Complex, identify the Fund Complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

(3) Describe briefly any arrangement or understanding between any director, nominee for election as director, Officer, or person chosen to become an Officer, and any other person(s) (naming the person(s)) pursuant to which he was or is to be selected as a director, nominee, or Officer.

Instruction to paragraph (b)(3). Do not include arrangements or understandings with directors or Officers acting solely in their capacities as such.

(4) Unless disclosed in the table required by paragraph (b)(1) of this Item, describe any positions, including as an officer, employee, director, or general partner, held by any director or nominee for election as director, who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), or Immediate Family Member of the director or nominee, during the past five years, with:

(i) The Fund;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund;

(iii) An investment adviser, principal underwriter, Sponsoring Insurance Company, or affiliated person of the Fund; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund.

Instruction to paragraph (b)(4). When an individual holds the same position(s) with two or more portfolios that are part of the same Fund Complex, identify the Fund Complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(5) For each director or nominee for election as director, state the dollar range of equity securities beneficially owned by the director or nominee as required by the following table:

(i) In the Fund; and

(ii) On an aggregate basis, in any registered investment companies overseen or to be overseen by the director or nominee within the same Family of Investment Companies as the Fund.

(1)	(2)	(3)
Name of Director or Nominee.	Dollar Range of Equity Securities in the Fund.	Aggregate Dollar Range of Equity Securities in All Funds Overseen or to be Overseen by Director or Nominee in Family of Investment Companies

Instructions to paragraph (b)(5). 1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. Determine "beneficial ownership" in accordance with rule 16a–1(a)(2) under the Exchange Act (§ 240.16a–1(a)(2)).

3. If action is to be taken with respect to more than one Fund, disclose in column (2) the dollar range of equity securities beneficially owned by a director or nominee in each such Fund overseen or to be overseen by the director or nominee.

4. In disclosing the dollar range of equity securities beneficially owned by a director or nominee in columns (2) and (3), use the following ranges: none, $1–$10,000, $10,001–$50,000, $50,001–$100,000, or over $100,000.

(6) For each director or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), and his Immediate Family Members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) An investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director or Nominee.	Name of Owners and Relationships to Director or Nominee.	Company	Title of Class	Value of Securities	Percent of Class

Instructions to paragraph (b)(6). 1. Information should be provided as of the most recent practicable date. Specify the valuation date by footnote or otherwise.

2. An individual is a "beneficial owner" of a security if he is a "beneficial owner" under either rule 13d–3 or rule 16a–1(a)(2) under the Exchange Act (§§ 240.13d–3 or 240.16a–1(a)(2)).

3. Identify the company in which the director, nominee, or Immediate Family Member of the director or nominee owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company, describe the company's relationship with the investment adviser, principal underwriter, or Sponsoring Insurance Company.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director (or nominee) and his Immediate Family Members.

(7) Unless disclosed in response to paragraph (b)(6) of this Item, describe any direct or indirect interest, the value of which exceeds $60,000, of each director or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), or Immediate Family Member of the director or nominee, during the past five years, in:

(i) An investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund.

Instructions to paragraph (b)(7). 1. A director, nominee, or Immediate Family Member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

2. The interest of the director (or nominee) and the interests of his Immediate Family Members should be aggregated in determining whether the value exceeds $60,000.

(8) Describe briefly any material interest, direct or indirect, of any director or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), or Immediate Family Member of the director or nominee, in any transaction, or series of similar transactions, since the beginning of the last two completed fiscal years of the Fund, or in any currently proposed transaction, or series of similar transactions, in which the amount involved exceeds $60,000 and to which any of the following persons was or is to be a party:

(i) The Fund;

(ii) An Officer of the Fund;

(iii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund;

(iv) An Officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the Investment Company Act of 1940 (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser, principal underwriter, or Sponsoring Insurance Company as the Fund or having an investment adviser, principal underwriter, or Sponsoring Insurance Company that directly or indirectly controls, is controlled by, or is under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund;

(v) An investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund;

(vi) An Officer of an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund;

(vii) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund; or

(viii) An Officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund.

Instructions to paragraph (b)(8). 1. Include the name of each director, nominee, or Immediate Family Member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director, nominee, or Immediate Family Member of the director or nominee without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the

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earliest date of any series covered by the proxy statement.

7. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed "material" within the meaning of paragraph (b)(8) of this Item where the interest of the director, nominee, or Immediate Family Member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item, and the transaction is not material to the company.

8. The materiality of any interest is to be determined on the basis of the significance of the information to investors in light of all the circumstances of the particular case. The importance of the interest to the person having the interest, the relationship of the parties to the transaction with each other, and the amount involved in the transaction are among the factors to be considered in determining the significance of the information to investors.

9. No information need be given as to any transaction where the interest of the director, nominee, or Immediate Family Member arises solely from the ownership of securities of a person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item and the director, nominee, or Immediate Family Member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

10. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the latest practicable date, and the rate of interest paid or charged.

11. No information need be given as to any routine, retail transaction. For example, the Fund need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item unless the director is accorded special treatment.

(9) Describe briefly any direct or indirect relationship, in which the amount involved exceeds $60,000, of any director or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), or Immediate Family Member of the director or nominee, that exists, or has existed at any time since the beginning of the last two completed fiscal years of the Fund, or is currently proposed, with any of the persons specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item;

(ii) Provision of legal services to any person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item;

(iii) Provision of investment banking services to any person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs (b)(9)(i) through (b)(9)(iii) of this Item.

Instructions to paragraph (b)(9). 1. Include the name of each director, nominee, or Immediate Family Member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director, nominee, or Immediate Family Member and the person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item as a result of the relationship since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the earliest date of any series covered by the proxy statement.

5. Disclose indirect, as well as direct, relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item may have an indirect relationship by reason of the position, relationship, or interest.

6. In determining whether the amount involved in a relationship exceeds $60,000, amounts involved in a relationship of the director (or nominee) should be aggregated with those of his Immediate Family Members.

7. In the case of an indirect interest, identify the company with which a person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item has a relationship; the name of the director, nominee, or Immediate Family Member affiliated with the company and the nature of the affiliation; and the amount of business conducted between the company and the person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item since the beginning of the last two completed fiscal years of the Fund or proposed to be done during the Fund's current fiscal year.

8. In calculating payments for property and services for purposes of paragraph (b)(9)(i) of this Item, the following may be excluded:

A. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

B. Payments that arise solely from the ownership of securities of a person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

9. No information need be given as to any routine, retail relationship. For example, the Fund need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (b)(8)(i) through (b)(8)(viii) of this Item unless the director is accorded special treatment.

(10) If an Officer of an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund, or an Officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser, principal underwriter, or Sponsoring Insurance Company of the Fund, serves, or has served since the beginning of the last two completed fiscal years of the Fund, on the board of directors of a company where a director of the Fund or nominee for election as director who is not or would not be an "interested person" of the Fund within the meaning of section 2(a)(19) of the Investment Company Act of 1940 (15 U.S.C. 80a–2(a)(19)), or Immediate Family Member of the director or nominee, is, or was since the beginning of the last two completed fiscal years of the Fund, an Officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii)The investment adviser, principal underwriter, or Sponsoring Insurance Company or person controlling, controlled by, or under common control with the investment adviser, principal underwriter, or Sponsoring Insurance Company where the individual named in paragraph (b)(10)(ii) of this Item holds or held office and the office held; and

(iv) The director of the Fund, nominee for election as director, or Immediate Family Member who is or was an Officer of the company; the office held; and the period of holding the office.

Instruction to paragraph (b)(10). If the proxy statement relates to multiple portfolios of a series Fund with different fiscal years, then, in determining the date that is the beginning of the last two completed fiscal years of the Fund, use the earliest date of any series covered by the proxy statement.

(11) Provide in tabular form, to the extent practicable, the information required by Items 401(f) and (g), 404(a) and (c), and 405 of Regulation S–K (§§ 229.401(f) and (g), 229.404(a) and (c), and 229.405 of this chapter).

Instruction to paragraph (b)(11). Information provided under paragraph (b)(8) of this Item 22 is deemed to satisfy the requirements of Items 404(a) and (c) of Regulation S–K for information about directors, nominees for election as directors, and Immediate Family Members of directors and nominees, and need not be provided under this paragraph (b)(11).

(12) Describe briefly any material pending legal proceedings, other than ordinary routine litigation incidental to the Fund's business, to which any director or nominee for director or affiliated person of such director or nominee is a party adverse to the Fund or any of its affiliated persons or has a material interest adverse to the Fund or any of its affiliated persons. Include the name of the court where the case is pending, the date instituted, the principal parties, a description of the factual basis alleged to underlie the proceeding, and the relief sought.

(13) For all directors, and for each of the three highest-paid Officers that have aggregate compensation from the Fund for the most recently completed fiscal year in excess of $60,000 ("Compensated Persons"):

(i) Furnish the information required by the following table for the last fiscal year:

COMPENSATION TABLE

(1)	(2)	(3)	(4)	(5)
Name of Person, Position.	Aggregate Compensation From Fund.	Pension or Retirement Benefits Accrued as Part of Fund Expenses.	Estimated Annual Benefits Upon Retirement.	Total Compensation From Fund and Complex Paid to Directors

Instructions to paragraph (b)(13)(i). 1. For column (1), indicate, if necessary, the capacity in which the remuneration is received. For Compensated Persons that are directors of the Fund, compensation is amounts received for service as a director.

2. If the Fund has not completed its first full year since its organization, furnish the information for the current fiscal year, estimating future payments that would be made pursuant to an existing agreement or understanding. Disclose in a footnote to the Compensation Table the period for which the information is furnished.

3. Include in column (2) amounts deferred at the election of the Compensated Person, whether pursuant to a plan established under Section 401(k) of the Internal Revenue Code (26 U.S.C. 401(k)) or otherwise, for the fiscal year in which earned. Disclose in a footnote to the Compensation Table the total amount of deferred compensation (including interest) payable to or accrued for any Compensated Person.

4. Include in columns (3) and (4) all pension or retirement benefits proposed to be paid under any existing plan in the event of retirement at normal retirement date, directly or indirectly, by the Fund or any of its Subsidiaries, or by other companies in the Fund Complex. Omit column (4) where retirement benefits are not determinable.

5. For any defined benefit or actuarial plan under which benefits are determined primarily by final compensation (or average final compensation) and years of service, provide the information required in column (4) in a separate table showing estimated annual benefits payable upon retirement (including amounts attributable to any defined benefit supplementary or excess pension award plans) in specified compensation and years of service classifications. Also provide the estimated credited years of service for each Compensated Person.

6. Include in column (5) only aggregate compensation paid to a director for service on the board and other boards of investment companies in a Fund Complex specifying the number of such other investment companies.

(ii) Describe briefly the material provisions of any pension, retirement, or other plan or any arrangement other than fee arrangements disclosed in paragraph (b)(13)(i) of this Item pursuant to which Compensated Persons are or may be compensated for any services provided, including amounts paid, if any, to the Compensated Person under any such arrangements during the most recently completed fiscal year. Specifically include the criteria used to determine amounts payable under any plan, the length of service or vesting period required by the plan, the retirement age or other event that gives rise to payments under the plan, and whether the payment of benefits is secured or funded by the Fund.

(iii) With respect to each Compensated Person, business development companies must include the information required by Items 402(b)(2)(iv) and 402(c) of Regulation S–K (§§ 229.402(b)(2)(iv) and 229.402(c) of this chapter).

(14) Identify the standing committees of the Fund's board of directors, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii) The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

* * * * *

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

3. The authority citation for Part 270 is amended by adding the following citations to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–34(d), 80a–37, 80a–39 unless otherwise noted;

* * * * *

Section 270.10e–1 is also issued under 15 U.S.C. 80a–10(e);

Section 270.17a–8 is also issued under 15 U.S.C. 80a–6(c) and 80a–37(a);

Section 270.17d–1 is also issued under 15 U.S.C. 80a–6(c), 80a–17(d), and 80a–37(a);

Section 270.17e–1 is also issued under 15 U.S.C. 80a–6(c), 80a–30(a), and 80a–37(a);

Section 270.17g–1 is also issued under 15 U.S.C. 80a–6(c), 80a–17(d), 80a–17(g), and 80a–37(a);

Section 270.30e–1 is also issued under 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78*l*, 78m, 78n, 78o(d), 78w(a), 80a–8, 80a–29, and 80a–37;

Section 270.31a–2 is also issued under 15 U.S.C. 80a–30.

* * * * *

§§ 270.17a–8, 270.17d–1, 270.17e–1 [Amended]

4. The authority citations following §§ 270.17a–8, 270.17d–1, 270.17e–1, 270.17g–1, 270.30d–1, and 270.31a–2 are removed.

5. Section 270.0–1 is amended by adding paragraphs (a)(5) and (a)(6) to read as follows:

§ 270.0–1 Definition of terms used in this part.

(a) * * *

(5) The term *administrator* means any person who provides significant administrative or business affairs management services to an investment company.

(6)(i) A person is an *independent legal counsel* with respect to the directors who are not interested persons of an investment company ("disinterested directors") if:

(A) A majority of the disinterested directors reasonably determine in the exercise of their judgment (and record the basis for that determination in the minutes of their meeting) that any representation by the person of the company's investment adviser, principal underwriter, administrator ("management organizations"), or any of their control persons, since the beginning of the fund's last two completed fiscal years, is or was sufficiently limited that it is unlikely to adversely affect the professional judgment of the person in providing legal representation to the disinterested directors; and

(B) The disinterested directors have obtained an undertaking from such person to provide them with information necessary to make their determination and to update promptly that information when the person begins to represent, or materially increases his representation of, a management organization or control person.

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(ii) The disinterested directors are entitled to rely on the information obtained from the person, unless they know or have reason to believe that the information is materially false or incomplete. The disinterested directors must re-evaluate their determination no less frequently than annually (and record the basis accordingly), except as provided in paragraph (iii) of this section.

(iii)After the disinterested directors obtain information that the person has begun to represent, or has materially increased his representation of, a management organization (or any of its control persons), the person may continue to be an independent legal counsel, for purposes of paragraph (a)(6)(i) of this section, for no longer than three months unless during that period the disinterested directors make a new determination under that paragraph.

(iv) For purposes of paragraphs (a)(6)(i)–(iii) of this section:

(A) The term *person* has the same meaning as in section 2(a)(28) of the Act (15 U.S.C. 80a–2(a)(28)) and, in addition, includes a partner, co-member, or employee of any person; and

(B) The term *control person* means any person (other than an investment company) directly or indirectly controlling, controlled by, or under common control with any of the investment company's management organizations.

* * * * *

§ 270.2a19–1 [Removed and reserved]

6. Section 270.2a19–1 is removed and reserved.

7. Section 270.2a19–3 is added to read as follows:

§ 270.2a19–3 Certain investment company directors not considered interested persons because of ownership of index fund securities.

If a director of a registered investment company ("Fund") owns shares of a registered investment company (including the Fund) with an investment objective to replicate the performance of one or more broad-based securities indices ("Index Fund"), ownership of the Index Fund shares will not cause the director to be considered an "interested person" of the Fund or of the Fund's investment adviser or principal underwriter (as defined by section 2(a)(19)(A)(iii) and (B)(iii) of the Act (15 U.S.C. 80a–2(a)(19)(A)(iii) and (B)(iii)).

8. Section 270.10e–1 is added to read as follows:

§ 270.10e–1 Death, disqualification, or bona fide resignation of directors.

If a registered investment company, by reason of the death, disqualification, or bona fide resignation of any director, does not meet any requirement of the Act or any rule or regulation thereunder regarding the composition of the company's board of directors, the operation of the relevant subsection of the Act, rule, or regulation will be suspended as to the company:

(a) For 90 days if the vacancy may be filled by action of the board of directors; or

(b) For 150 days if a vote of stockholders is required to fill the vacancy.

9. Section 270.10f–3 is amended by redesignating paragraph (b)(11) as paragraph (b)(12), and adding new paragraph (b)(11) to read as follows:

§ 270.10f–3 Exemption for the acquisition of securities during the existence of an underwriting or selling syndicate.

* * * * *

(b) * * *

(11) *Board Composition, Selection, and Representation:*

(i) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

10. Section 270.12b–1 is amended by revising paragraph (c) to read as follows:

§ 270.12b–1 Distribution of shares by registered open-end management investment company.

* * * * *

(c) A registered open-end management investment company may rely on the provisions of paragraph (b) of this section only if:

(1) A majority of the directors of the company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel;

* * * * *

11. Section 270.15a–4 is amended by:

a. Removing the word "and" at the end of paragraph (b)(2)(v);

b. Removing the period at the end of paragraph (b)(2)(vi)(C)(2) and adding in its place "; and"; and

c. Adding paragraph (b)(2)(vii) to read as follows:

§ 270.15a–4 Temporary exemption for certain investment advisers.

* * * * *

(b) * * *

(2) * * *

(vii)(A) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(B) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

12. Section 270.17a–7 is amended by:

a. Removing the "and" at the end of paragraph (e)(3);

b. Redesignating paragraph (f) as paragraph (g); and

c. Adding new paragraph (f) to read as follows:

§ 270.17a–7 Exemption of certain purchase or sale transactions between an investment company and certain affiliated persons thereof.

* * * * *

(f)(1) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel; and

* * * * *

13. Section 270.17a–8 is amended by:

a. Removing the ", and" at the end of paragraph (a)(2) and in its place adding a semi-colon;

b. Removing the period at the end of paragraph (b) and adding in its place "; and"; and

c. Adding new paragraph (c) to read as follows:

§ 270.17a–8 Mergers of certain affiliated investment companies.

* * * * *

(c)(1) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

14. Section 270.17d–1 is amended by:

a. Removing the word "and" at the end of paragraph (d)(7)(ii);

b. Redesignating paragraph (d)(7)(iii) as paragraph (d)(7)(iv);

c. Removing the period at the end of newly designated paragraph (d)(7)(iv) and adding in its place "; and"; and

d. Adding new paragraphs (d)(7)(iii) and (d)(7)(v) to read as follows:

§ 270.17d–1 Applications regarding joint enterprises or arrangements and certain profit-sharing plans.

* * * * *

(d) * * *

(7) * * *

(iii) The joint liability insurance policy does not exclude coverage for bona fide claims made against any director who is not an interested person of the investment company, or against the investment company if it is a co-defendant in the claim with the disinterested director, by another person insured under the joint liability insurance policy;

* * * * *

(v)(A) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(B) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

15. Section 270.17e–1 is amended by:

a. Removing the word "and" at the end of paragraph (b)(3);

b. Redesignating paragraph (c) as paragraph (d); and

c. Adding new paragraph (c) to read as follows:

§ 270.17e–1 Brokerage transactions on a securities exchange.

* * * * *

(c)(1) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel; and

* * * * *

16. Section 270.17g–1 is amended by revising paragraph (j) to read as follows:

§ 270.17g–1 Bonding of officers and employees of registered management investment companies.

* * * * *

(j) Any joint insured bond provided and maintained by a registered management investment company and one or more other parties shall be a transaction exempt from the provisions of section 17(d) of the Act (15 U.S.C. 80a–17(d)) and the rules thereunder, if:

(1) The terms and provisions of the bond comply with the provisions of this section;

(2) The terms and provisions of any agreement required by paragraph (f) of this section comply with the provisions of that paragraph; and

(3)(i) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

17. Section 270.18f–3 is amended by redesignating paragraph (e) as paragraph (f), and adding new paragraph (e) to read as follows:

§ 270.18f–3 Multiple class companies.

* * * * *

(e)(1) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(2) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

18. Section 270.23c–3 is amended by revising paragraph (b)(8) to read as follows:

§ 270.23c–3 Repurchase offers by closed-end companies.

* * * * *

(b) * * *

(8)(i) A majority of the directors of the investment company are not interested persons of the company, and those directors select and nominate any other disinterested directors of the company; and

(ii) Any person who acts as legal counsel for the disinterested directors of the company is an independent legal counsel.

* * * * *

§ 270.30d–1 [Redesignated as § 270.30e–1]

19. a. Redesignate § 270.30d–1 as § 270.30e–1;

b. In newly designated § 270.30e–1, in paragraph (a), revise "financial statements" to read "information"; and

c. Revise paragraph (d) to read as follows:

§ 270.30e–1 Reports to stockholders of management companies.

* * * * *

(d) An open-end company may transmit a copy of its currently effective prospectus or Statement of Additional Information, or both, under the Securities Act, in place of any report required to be transmitted to shareholders by this section, provided that the prospectus or Statement of Additional Information, or both, include all the information that would otherwise be required to be contained in the report by this section. Such prospectus or Statement of Additional Information, or both, shall be transmitted within 60 days after the close of the period for which the report is being made.

* * * * *

§ 270.30d–2 [Redesignated as § 270.30e–2]

20. Redesignate § 270.30d–2 as § 270.30e–2, and in newly designated § 270.30e–2:

a. Revise "§ 270.30d–1" in the first and second sentences of paragraph (a) to read "§ 270.30e–1"; and

b. Revise "§ 270.30d–1(f)" in paragraph (b) to read "§ 270.30e-1(f)".

21. Section 270.31a–2 is amended by removing the period at end of paragraph (a)(3) and in its place adding a semi-colon, and adding paragraphs (a)(4) and (a)(5) to read as follows:

§ 270.31a–2 Records to be preserved by registered investment companies, certain majority-owned subsidiaries thereof, and other persons having transactions with registered investment companies.

(a) * * *

(4) Preserve for a period not less than six years, the first two years in an easily accessible place, any record of the initial determination that a director is not an interested person of the investment company, and each subsequent determination that the director is not an interested person of the investment company. These records must include any questionnaire and any other document used to determine that a director is not an interested person of the company; and

(5) Preserve for a period not less than six years, the first two years in an easily accessible place, any materials used by the disinterested directors of an investment company to determine that a person who is acting as legal counsel to those directors is an independent legal counsel.

* * * * *

22. Section 270.32a–4 is added to read as follows:

§ 270.32a–4 Independent audit committees.

A registered management investment company or a registered face-amount certificate company is exempt from the requirement of section 32(a)(2) of the Act (15 U.S.C. 80a–32(a)(2)) that the selection of the company's independent public accountant be submitted for

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ratification or rejection at the next succeeding annual meeting of shareholders, if:

(a) The company's board of directors has established a committee, composed solely of directors who are not interested persons of the company, that has responsibility for overseeing the fund's accounting and auditing processes ("audit committee");

(b) The company's board of directors has adopted a charter for the audit committee setting forth the committee's structure, duties, powers, and methods of operation or set forth such provisions in the fund's charter or bylaws; and

(c) The company maintains and preserves permanently in an easily accessible place a copy of the audit committee's charter and any modification to the charter.

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

23. The authority citation for part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77z-2, 77sss, 78c, 78*l*, 78m, 78n, 78o(d), 78u-5, 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79*l*, 79m, 79n, 79q, 79t, 80a-8, 80a-24, 80a-29, 80a-30, and 80a-37, unless otherwise noted.

* * * * *

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

24. The authority citation for part 274 continues to read as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l*, 78m, 78n, 78o(d), 80a-8, 80a-24, and 80a-29, unless otherwise noted.

Note: The text of Form N-1A does not and these amendments will not appear in the *Code of Federal Regulations*.

25. Form N-1A (referenced in §§ 239.15A and 274.11A), is amended by:

a. In Item 13 by adding Instructions 1 and 2 before paragraph (a).

b. In Item 13 by removing paragraphs (a), (b), and (c) and adding paragraphs (a) and (b) in their place.

c. In Item 13 by redesignating paragraphs (d) and (e) as paragraphs (c) and (d).

d. In Item 13 by removing "executive" from the first sentence of newly redesignated paragraph (c).

e. In Item 22 by adding paragraphs (b)(5) and (b)(6).

These additions and revisions read as follows:

Form N-1A

* * * * *

Item 13. Management of the Fund

Instructions

1. For purposes of this Item 13, the terms below have the following meanings:

(a) The term "family of investment companies" means any two or more registered investment companies that:

(1) Share the same investment adviser or principal underwriter; and

(2) Hold themselves out to investors as related companies for purposes of investment and investor services.

(b) The term "fund complex" means two or more registered investment companies that:

(1) Hold themselves out to investors as related companies for purposes of investment and investor services; or

(2) Have a common investment adviser or have an investment adviser that is an affiliated person of the investment adviser of any of the other registered investment companies.

(c) The term "immediate family member" means a person's spouse; child residing in the person's household (including step and adoptive children); and any dependent of the person, as defined in section 152 of the Internal Revenue Code (26 U.S.C. 152).

(d) The term "officer" means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons of the Fund separately from the information for directors who are not interested persons of the Fund. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the directors who are not interested persons.

(a) *Management Information.*

(1) Provide the information required by the following table for each director and officer of the Fund, and, if the Fund has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, address, and age.	Position(s) held with fund.	Term of office and length of time served.	Principal occupation(s) during past 5 years.	Number of portfolios in fund complex overseen by director.	Other directorships held by director.

Instructions. 1. For purposes of this paragraph, the term "family relationship" means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person of the Fund, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Securities Exchange Act (15 U.S.C. 78l) or subject to the requirements of section 15(d) of the Securities Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the Investment Company Act, and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

(2) For each individual listed in column (1) of the table required by paragraph (a)(1) of this Item 13, except for any director who is not an interested person of the Fund, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Fund.

Instruction. When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

(3) Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction. Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

(b) *Board of Directors.*

(1) Briefly describe the responsibilities of the board of directors with respect to the Fund's management.

Instruction. A Fund may respond to this paragraph by providing a general statement as to the responsibilities of the board of directors with respect to the Fund's management under the applicable laws of the state or other jurisdiction in which the Fund is organized.

(2) Identify the standing committees of the Fund's board of directors, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii)The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

(3) Unless disclosed in the table required by paragraph (a)(1) of this Item 13, describe any positions, including as an officer, employee, director, or general partner, held by any director who is not an interested person of the Fund, or immediate family member of the director, during the two most recently completed calendar years with:

(i) The Fund;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a-3(c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Fund or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Fund;

(iii) An investment adviser, principal underwriter, or affiliated person of the Fund; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund.

Instruction. When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(4) For each director, state the dollar range of equity securities beneficially owned by the director as required by the following table:

(i) In the Fund; and

(ii) On an aggregate basis, in any registered investment companies overseen by the director within the same family of investment companies as the Fund.

(1)	(2)	(3)
Name of director	Dollar range of equity securities in the fund	Aggregate dollar range of equity securities in all registered investment companies overseen by director in family of investment companies.

Instructions. 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. Determine "beneficial ownership" in accordance with rule 16a-1(a)(2) under the Exchange Act (17 C.F.R. 240.16a-1(a)(2)).

3. If the SAI covers more than one Fund or Series, disclose in column (2) the dollar range of equity securities beneficially owned by a director in each Fund or Series overseen by the director.

4. In disclosing the dollar range of equity securities beneficially owned by a director in columns (2) and (3), use the following ranges: none, $1–$10,000, $10,001–$50,000, $50,001–$100,000, or over $100,000.

(5) For each director who is not an interested person of the Fund, and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) An investment adviser or principal underwriter of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director.	Company	Title of Class	Value of Securities	Percent of Class

Instructions. 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. An individual is a "beneficial owner" of a security if he is a "beneficial owner" under either rule 13d–3 or rule 16a–1(a)(2) under the Exchange Act (17 C.F.R. 240.13d–3 or 240.16a–1(a)(2)).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter, describe the company's relationship with the investment adviser or principal underwriter.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director and his immediate family members.

(6) Unless disclosed in response to paragraph (b)(5) of this Item 13, describe any direct or indirect interest, the value of which exceeds $60,000, of each director who is not an interested person of the Fund, or immediate family member of the director, during the two most recently completed calendar years, in:

(i) An investment adviser or principal underwriter of the Fund; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund.

Instructions. 1. A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

2. The interest of the director and the interests of his immediate family members should be aggregated in determining whether the value exceeds $60,000.

(7) Describe briefly any material interest, direct or indirect, of any director who is not an interested person of the Fund, or immediate family member of the director, in any transaction, or series of similar transactions, during the two most recently completed calendar years, in which the amount involved exceeds $60,000 and to which any of the following persons was a party:

(i) The Fund;

(ii) An officer of the Fund;

(iii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Fund or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Fund;

(iv) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Fund or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Fund;

(v) An investment adviser or principal underwriter of the Fund;

(vi) An officer of an investment adviser or principal underwriter of the Fund;

(vii) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund; or

(viii) An officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund.

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Instructions. 1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed "material" within the meaning of paragraph (b)(7) of this Item 13 where the interest of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13, and the transaction is not material to the company.

7. The materiality of any interest is to be determined on the basis of the significance of the information to investors in light of all the circumstances of the particular case. The importance of the interest to the person having the interest, the relationship of the parties to the transaction with each other, and the amount involved in the transaction are among the factors to be considered in determining the significance of the information to investors.

8. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

9. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the end of the most recently completed calendar year, and the rate of interest paid or charged.

10. No information need be given as to any routine, retail transaction. For example, the Fund need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 unless the director is accorded special treatment.

(8) Describe briefly any direct or indirect relationship, in which the amount involved exceeds $60,000, of any director who is not an interested person of the Fund, or immediate family member of the director, that existed at any time during the two most recently completed calendar years with any of the persons specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13;

(ii) Provision of legal services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13;

(iii) Provision of investment banking services to any person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs (b)(8)(i) through (b)(8)(iii) of this Item 13.

Instructions. 1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 as a result of the relationship during the two most recently completed calendar years.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. Disclose indirect, as well as direct, relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 may have an indirect relationship by reason of the position, relationship, or interest.

5. In determining whether the amount involved in a relationship exceeds $60,000, amounts involved in a relationship of the director should be aggregated with those of his immediate family members.

6. In the case of an indirect interest, identify the company with which a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business conducted between the company and the person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 during the two most recently completed calendar years.

7. In calculating payments for property and services for purposes of paragraph (b)(8)(i) of this Item 13, the following may be excluded:

A. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

B. Payments that arise solely from the ownership of securities of a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

8. No information need be given as to any routine, retail relationship. For example, the Fund need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (b)(7)(i) through (b)(7)(viii) of this Item 13 unless the director is accorded special treatment.

(9) If an officer of an investment adviser or principal underwriter of the Fund, or an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Fund, served during the two most recently completed calendar years, on the board of directors of a company where a director of the Fund who is not an interested person of the Fund, or immediate family member of the director, was during the two most recently completed calendar years, an officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii) The investment adviser or principal underwriter or person controlling, controlled by, or under common control with the investment adviser or principal underwriter where the individual named in paragraph (b)(9)(ii) of this Item 13 holds or held office and the office held; and

(iv) The director of the Fund or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

(10) Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of directors approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Fund such as soft dollar arrangements by which brokers provide research to the Fund or its investment adviser in return for allocating Fund brokerage.

Instruction. Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Fund and the investment advisory contract.

* * * * *

Item 22. Financial Statements

* * * * *

(b) * * *

(5) The management information required by Item 13(a)(1).

(6) A statement that the SAI includes additional information about Fund directors and is available, without charge, upon request, and a toll-free (or collect) telephone number for shareholders to call to request the SAI.

* * * * *

Note: The text of Form N–2 does not and these amendments will not appear in the *Code of Federal Regulations.*

26. Form N–2 (referenced in §§ 239.14 and 274.11a-1) is amended by:

a. In Item 18 by adding Instructions 1 and 2 before paragraph 1.

b. In Item 18 by revising paragraphs 1 and 2.

c. In Item 18 by redesignating paragraphs 3 and 4 as paragraphs 4 and 14.

d. In Item 18 by adding paragraphs 3 and 5 through 13.

e. In Item 18, in newly designated paragraph 14, removing "executive" from the first sentence.

f. In Instruction 4 to Item 23 by removing "and" from the end of paragraph c.

g. In Instruction 4 to Item 23 by removing the period at the end of paragraph d. and in its place adding a semi-colon.

h. In Instruction 4 to Item 23 by adding paragraphs e. and f.

These additions and revisions read as follows:

Form N–2

* * * * *

Item 18. Management

Instructions: 1. For purposes of this Item 18, the terms below have the following meanings:

a. The term "family of investment companies" means any two or more registered investment companies that:

(i) Share the same investment adviser or principal underwriter; and

(ii) Hold themselves out to investors as related companies for purposes of investment and investor services.

b. The term "fund complex" means two or more registered investment companies that:

(i) Hold themselves out to investors as related companies for purposes of investment and investor services; or

ii) Have a common investment adviser or have an investment adviser that is an affiliated person of the investment adviser of any of the other registered investment companies.

c. The term "immediate family member" means a person's spouse; child residing in the person's household (including step and adoptive children); and any dependent of the person, as defined in section 152 of the Internal Revenue Code (26 U.S.C. 152).

d. The term "officer" means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a-2(a)(19)) and the rules thereunder, separately from the information for directors who are not interested persons of the Registrant. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the directors who are not interested persons.

1. Provide the information required by the following table for each director and officer of the Registrant, and, if the Registrant has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, Address, and Age.	Position(s) Held with Registrant.	Term of Office and Length of Time Served.	Principal Occupation(s) During Past 5 years.	Number of Portfolios in Fund Complex Overseen by Director.	Other Directorships Held by Director.

Instructions: 1. For purposes of this paragraph, the term "family relationship" means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Exchange Act (15 U.S.C. 78*l*) or subject to the requirements of section 15(d) of the Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the 1940 Act (15 U.S.C. 80a), and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

2. For each individual listed in column (1) of the table required by paragraph 1 of this Item 18, except for any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Registrant.

Instruction: When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

3. Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction: Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

4. For each non-resident director or officer of the Registrant listed in column (1) of the table required by paragraph 1, disclose whether he has authorized an agent in the United States to receive notice and, if so, disclose the name and address of the agent.

5. Identify the standing committees of the Registrant's board of directors, and provide the following information about each committee:

(a) A concise statement of the functions of the committee;

(b) The members of the committee;

(c) The number of committee meetings held during the last fiscal year; and

(d) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

6. Unless disclosed in the table required by paragraph 1 of this Item 18, describe any positions, including as an officer, employee, director, or general partner, held by any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, during the two most recently completed calendar years with:

(a) The Registrant;

(b) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3 (c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Registrant or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Registrant;

(c) An investment adviser, principal underwriter, or affiliated person of the Registrant; or

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(d) Any person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant.

Instruction: When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

7. For each director, state the dollar range of equity securities beneficially owned by the director as required by the following table:

(1)	(2)	(3)
Name of Director	Dollar Range of Equity Securities in the Registrant.	Aggregate Dollar Range of Equity Securities in All Registered Investment Companies Overseen by Director in Family of Investment Companies

Instructions: 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. Determine "beneficial ownership" in accordance with rule 16a–1(a)(2) under the Exchange Act (17 CFR 240.16a–1(a)(2)).

3. In disclosing the dollar range of equity securities beneficially owned by a director in columns (2) and (3), use the following ranges: none, $1–$10,000, $10,001–$50,000, $50,001–$100,000, or over $100,000.

8. For each director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(a) An investment adviser or principal underwriter of the Registrant; or

(b) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director.	Company	Title of Class	Value of Securities	Percent of Class

Instructions: 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. An individual is a "beneficial owner" of a security if he is a "beneficial owner" under either rule 13d–3 or rule 16a–1(a)(2) under the Exchange Act (17 CFR 240.13d–3 or 240.16a–1(a)(2)).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter, describe the company's relationship with the investment adviser or principal underwriter.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director and his immediate family members.

9. Unless disclosed in response to paragraph 8 of this Item 18, describe any direct or indirect interest, the value of which exceeds $60,000, of each director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, during the two most recently completed calendar years, in:

(a) An investment adviser or principal underwriter of the Registrant; or

(b) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant.

Instructions: 1. A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

2. The interest of the director and the interests of his immediate family members should be aggregated in determining whether the value exceeds $60,000.

10. Describe briefly any material interest, direct or indirect, of any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, in any transaction, or series of similar transactions, during the two most recently completed calendar years, in which the amount involved exceeds $60,000 and to which any of the following persons was a party:

(a) The Registrant;

(b) An officer of the Registrant;

(c) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Registrant or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Registrant;

(d) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same investment adviser or principal underwriter as the Registrant or having an investment adviser or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with an investment adviser or principal underwriter of the Registrant;

(e) An investment adviser or principal underwriter of the Registrant;

(f) An officer of an investment adviser or principal underwriter of the Registrant;

(g) A person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant; or

(h) An officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant.

Instructions: 1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a transaction with one of the persons listed in paragraphs 10(a) through (h) of this Item 18 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed "material" within the meaning of paragraph 10 of this Item 18 where the interest of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs 10(a) through (h) of this Item 18, and the transaction is not material to the company.

7. The materiality of any interest is to be determined on the basis of the significance of the information to investors in light of all the circumstances of the particular case. The importance of the interest to the person having the interest, the relationship of the parties to the transaction with each other, and the amount involved in the transaction are among the factors to be considered in determining the significance of the information to investors.

8. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs 10(a) through (h) of this Item 18 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

9. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the end of the most recently completed calendar year, and the rate of interest paid or charged.

10. No information need be given as to any routine, retail transaction. For example, the Registrant need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs 10(a) through (h) of this Item 18 unless the director is accorded special treatment.

11. Describe briefly any direct or indirect relationship, in which the amount involved exceeds $60,000, of any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, that existed at any time during the two most recently completed calendar years, with any of the persons specified in paragraphs 10(a) through (h) of this Item 18. Relationships include:

(a) Payments for property or services to or from any person specified in paragraphs 10(a) through (h) of this Item 18;

(b) Provision of legal services to any person specified in paragraphs 10(a) through (h) of this Item 18;

(c) Provision of investment banking services to any person specified in paragraphs 10(a) through (h) of this Item 18, other than as a participating underwriter in a syndicate; and

(d) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs 11(a) through (c) of this Item 18.

Instructions: 1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs 10(a) through (h) of this Item 18 as a result of the relationship during the two most recently completed calendar years.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. Disclose indirect, as well as direct, relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs 10(a) through (h) of this Item 18 may have an indirect relationship by reason of the position, relationship, or interest.

5. In determining whether the amount involved in a relationship exceeds $60,000, amounts involved in a relationship of the director should be aggregated with those of his immediate family members.

6. In the case of an indirect interest, identify the company with which a person specified in paragraphs 10(a) through (h) of this Item 18 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business conducted between the company and the person specified in paragraphs 10(a) through (h) of this Item 18 during the two most recently completed calendar years.

7. In calculating payments for property and services for purposes of paragraph 11(a) of this Item 18, the following may be excluded:

a. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

b. Payments that arise solely from the ownership of securities of a person specified in paragraphs 10(a) through (h) of this Item 18 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

8. No information need be given as to any routine, retail relationship. For example, the Registrant need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs 10(a) through (h) of this Item 18 unless the director is accorded special treatment.

12. If an officer of an investment adviser or principal underwriter of the Registrant, or an officer of a person directly or indirectly controlling, controlled by, or under common control with an investment adviser or principal underwriter of the Registrant, served during the two most recently completed calendar years, on the board of directors of a company where a director of the Registrant who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, was during the two most recently completed calendar years, an officer, identify:

(a) The company;

(b) The individual who serves or has served as a director of the company and the period of service as director;

(c) The investment adviser or principal underwriter or person controlling, controlled by, or under common control with the investment adviser or principal underwriter where the individual named in paragraph 12(b) of this Item 18 holds or held office and the office held; and

(d) The director of the Registrant or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

13. Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of directors approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Registrant such as soft dollar arrangements by which brokers provide research to the Registrant or its investment adviser in return for allocating fund brokerage.

Instruction: Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Registrant and the investment advisory contract.

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Item 23. Financial Statements

* * * * *

Instructions

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4. * * *

e. the management information required by paragraph 1 of Item 18; and

f. a statement that the SAI includes additional information about directors of the Registrant and is available, without charge, upon request, and a toll-free (or collect) telephone number for shareholders to call to request the SAI.

* * * * *

Note: The text of Form N–3 does not and these amendments will not appear in the *Code of Federal Regulations*.

27. Form N–3 (referenced in §§ 239.17a and 274.11b) is amended by:

a. In Item 20 adding instructions 1 and 2 before paragraph (a).

b. In Item 20 by revising paragraphs (a) and (b).

c. In Item 20 by redesignating paragraph (c) as paragraph (m).

d. In Item 20 by adding paragraphs (c) through (l).

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e. In Item 20 by removing "executive" from the first sentence of newly designated paragraph (m).

f. In Instruction 4 to Item 27 by removing "and" from the end of paragraph (iii).

g. In Instruction 4 to Item 27 by removing the period at the end of paragraph (iv) and in its place adding a semi-colon.

h. In Instruction 4 to Item 27 by adding paragraphs (v) and (vi).

These additions, and revisions read as follows:

Form N–3

* * * * *

Item 20. Management

Instructions: 1. For purposes of this Item 20, the terms below have the following meanings:

a. The term "family of investment companies" means any two or more registered investment companies that:

(i) Share the same investment adviser or principal underwriter; and

(ii) Hold themselves out to investors as related companies for purposes of investment and investor services.

b. The term "fund complex" means two or more registered investment companies that:

(i) Hold themselves out to investors as related companies for purposes of investment and investor services; or

(ii) Have a common investment adviser or have an investment adviser that is an affiliated person of the investment adviser of any of the other registered investment companies.

c. The term "immediate family member" means a person's spouse; child residing in the person's household (including step and adoptive children); and any dependent of the person, as defined in section 152 of the Internal Revenue Code (26 U.S.C. 152).

d. The term "officer" means the president, vice-president, secretary, treasurer, controller, or any other officer who performs policy-making functions.

2. When providing information about directors, furnish information for directors who are interested persons of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, separately from the information for directors who are not interested persons of the Registrant. For example, when furnishing information in a table, you should provide separate tables (or separate sections of a single table) for directors who are interested persons and for directors who are not interested persons. When furnishing information in narrative form, indicate by heading or otherwise the directors who are interested persons and the directors who are not interested persons.

(a) Provide the information required by the following table for each member of the board of managers ("director") and officer of the Registrant, and, if the Registrant has an advisory board, member of the board. Explain in a footnote to the table any family relationship between the persons listed.

(1)	(2)	(3)	(4)	(5)	(6)
Name, address, and age.	Position(s) held with registrant.	Term of office and length of time served.	Principal occupation(s) during past 5 years.	Number of portfolios in fund complex overseen by director.	Other directorships held by director.

Instructions: 1. For purposes of this paragraph, the term "family relationship" means any relationship by blood, marriage, or adoption, not more remote than first cousin.

2. For each director who is an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe, in a footnote or otherwise, the relationship, events, or transactions by reason of which the director is an interested person.

3. State the principal business of any company listed under column (4) unless the principal business is implicit in its name.

4. Indicate in column (6) directorships not included in column (5) that are held by a director in any company with a class of securities registered pursuant to section 12 of the Exchange Act (15 U.S.C. 78*l*) or subject to the requirements of section 15(d) of the Exchange Act (15 U.S.C. 78o(d)) or any company registered as an investment company under the 1940 Act (15 U.S.C. 80a–2(a)(19)), and name the companies in which the directorships are held. Where the other directorships include directorships overseeing two or more portfolios in the same fund complex, identify the fund complex and provide the number of portfolios overseen as a director in the fund complex rather than listing each portfolio separately.

(b) For each individual listed in column (1) of the table required by paragraph (a) of this Item 20, except for any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, describe any positions, including as an officer, employee, director, or general partner, held with affiliated persons or principal underwriters of the Registrant.

Instruction: When an individual holds the same position(s) with two or more registered investment companies that are part of the same fund complex, identify the fund complex and provide the number of registered investment companies for which the position(s) are held rather than listing each registered investment company separately.

(c) Describe briefly any arrangement or understanding between any director or officer and any other person(s) (naming the person(s)) pursuant to which he was selected as a director or officer.

Instruction: Do not include arrangements or understandings with directors or officers acting solely in their capacities as such.

(d) Identify the standing committees of the Registrant's board of managers, and provide the following information about each committee:

(i) A concise statement of the functions of the committee;

(ii) The members of the committee;

(iii) The number of committee meetings held during the last fiscal year; and

(iv) If the committee is a nominating or similar committee, state whether the committee will consider nominees recommended by security holders and, if so, describe the procedures to be followed by security holders in submitting recommendations.

(e) Unless disclosed in the table required by paragraph (a) of this Item 20, describe any positions, including as an officer, employee, director, or general partner, held by any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, during the two most recently completed calendar years with:

(i) The Registrant;

(ii) An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, or principal underwriter as the Registrant or having an Insurance Company, investment adviser, or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant;

(iii) The Insurance Company or an investment adviser, principal underwriter, or affiliated person of the Registrant; or

(iv) Any person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant.

Instruction: When an individual holds the same position(s) with two or more portfolios that are part of the same fund complex, identify the fund complex and provide the number of portfolios for which the position(s) are held rather than listing each portfolio separately.

(f) For each director, state the dollar range of equity securities beneficially owned by the director as required by the following table:

(i) In the Registrant; and

(ii) On an aggregate basis, in any registered investment companies overseen by the director within the same family of investment companies as the Registrant.

(1)	(2)	(3)
Name of Director	Dollar Range of Equity Securities in the Registrant.	Aggregate Dollar Range of Equity Securities in All Registered Investment Companies Overseen by Director in Family of Investment Companies.

Instructions: 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. Determine "beneficial ownership" in accordance with rule 16a–1(a)(2) under the Exchange Act (17 CFR 240.16a–1(a)(2)).

3. If the SAI covers more than one sub-account, disclose in column (2) the dollar range of equity securities beneficially owned by a director in each sub-account overseen by the director.

4. In disclosing the dollar range of equity securities beneficially owned by a director in columns (2) and (3), use the following ranges: none, $1–$10,000, $10,001–$50,000, $50,001–$100,000, or over $100,000.

(g) For each director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, and his immediate family members, furnish the information required by the following table as to each class of securities owned beneficially or of record in:

(i) The Insurance Company or an investment adviser or principal underwriter of the Registrant; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant:

(1)	(2)	(3)	(4)	(5)	(6)
Name of Director	Name of Owners and Relationships to Director.	Company	Title of Class	Value of Securities	Percent of Class.

Instructions: 1. Information should be provided as of the end of the most recently completed calendar year. Specify the valuation date by footnote or otherwise.

2. An individual is a "beneficial owner" of a security if he is a "beneficial owner" under either rule 13d–3 or rule 16a–1(a)(2) under the Exchange Act (17 C.F.R. 240.13d–3 or 240.16a–1(a)(2)).

3. Identify the company in which the director or immediate family member of the director owns securities in column (3). When the company is a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter, describe the company's relationship with the Insurance Company, investment adviser, or principal underwriter.

4. Provide the information required by columns (5) and (6) on an aggregate basis for each director and his immediate family members.

(h) Unless disclosed in response to paragraph (g) of this Item 20, describe any direct or indirect interest, the value of which exceeds $60,000, of each director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, during the two most recently completed calendar years, in:

(i) The Insurance Company or an investment adviser or principal underwriter of the Registrant; or

(ii) A person (other than a registered investment company) directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant.

Instructions: 1. A director or immediate family member has an interest in a company if he is a party to a contract, arrangement, or understanding with respect to any securities of, or interest in, the company.

2. The interest of the director and the interests of his immediate family members should be aggregated in determining whether the value exceeds $60,000.

(i) Describe briefly any material interest, direct or indirect, of any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, in any transaction, or series of similar transactions, during the two most recently completed calendar years, in which the amount involved exceeds $60,000 and to which any of the following persons was a party:

(i) The Registrant;

(ii) An officer of the Registrant;

(iii)An investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, or principal underwriter as the Registrant or having an Insurance Company, investment adviser, or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant;

(iv) An officer of an investment company, or a person that would be an investment company but for the exclusions provided by sections 3(c)(1) and 3(c)(7) of the 1940 Act (15 U.S.C. 80a–3(c)(1) and (c)(7)), having the same Insurance Company, investment adviser, or principal underwriter as the Registrant or having an Insurance Company, investment adviser, or principal underwriter that directly or indirectly controls, is controlled by, or is under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant;

(v) The Insurance Company or an investment adviser or principal underwriter of the Registrant;

(vi) An officer of the Insurance Company or an investment adviser or principal underwriter of the Registrant;

(vii) A person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant; or

(viii) An officer of a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant.

Instructions: 1. Include the name of each director or immediate family member whose interest in any transaction or series of similar transactions is described and the nature of the circumstances by reason of which the interest is required to be described.

2. State the nature of the interest, the approximate dollar amount involved in the transaction, and, where practicable, the approximate dollar amount of the interest.

3. In computing the amount involved in the transaction or series of similar transactions, include all periodic payments in the case of any lease or other agreement providing for periodic payments.

4. Compute the amount of the interest of any director or immediate family member of the director without regard to the amount of profit or loss involved in the transaction(s).

5. As to any transaction involving the purchase or sale of assets, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost to the seller. Describe the method used in determining the purchase or sale price and the name of the person making the determination.

6. Disclose indirect, as well as direct, material interests in transactions. A person who has a position or relationship with, or interest in, a company that engages in a

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transaction with one of the persons listed in paragraphs (i) through (viii) of paragraph (i) of this Item 20 may have an indirect interest in the transaction by reason of the position, relationship, or interest. The interest in the transaction, however, will not be deemed "material" within the meaning of paragraph (i) of this Item 20 where the interest of the director or immediate family member arises solely from the holding of an equity interest (including a limited partnership interest, but excluding a general partnership interest) or a creditor interest in a company that is a party to the transaction with one of the persons specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20, and the transaction is not material to the company.

7. The materiality of any interest is to be determined on the basis of the significance of the information to investors in light of all the circumstances of the particular case. The importance of the interest to the person having the interest, the relationship of the parties to the transaction with each other, and the amount involved in the transaction are among the factors to be considered in determining the significance of the information to investors.

8. No information need be given as to any transaction where the interest of the director or immediate family member arises solely from the ownership of securities of a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 and the director or immediate family member receives no extra or special benefit not shared on a pro rata basis by all holders of the class of securities.

9. Transactions include loans, lines of credit, and other indebtedness. For indebtedness, indicate the largest aggregate amount of indebtedness outstanding at any time during the period, the nature of the indebtedness and the transaction in which it was incurred, the amount outstanding as of the end of the most recently completed calendar year, and the rate of interest paid or charged.

10. No information need be given as to any routine, retail transaction. For example, the Registrant need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 unless the director is accorded special treatment.

(j) Describe briefly any direct or indirect relationship, in which the amount involved exceeds $60,000, of any director who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family member of the director, that existed at any time during the two most recently completed calendar years, with any of the persons specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20. Relationships include:

(i) Payments for property or services to or from any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20;

(ii) Provision of legal services to any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20;

(iii) Provision of investment banking services to any person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20, other than as a participating underwriter in a syndicate; and

(iv) Any consulting or other relationship that is substantially similar in nature and scope to the relationships listed in paragraphs (j)(i) through (j)(iii) of this Item 20.

Instructions: 1. Include the name of each director or immediate family member whose relationship is described and the nature of the circumstances by reason of which the relationship is required to be described.

2. State the nature of the relationship and the amount of business conducted between the director or immediate family member and the person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 as a result of the relationship during the two most recently completed calendar years.

3. In computing the amount involved in a relationship, include all periodic payments in the case of any agreement providing for periodic payments.

4. Discloses indirect, as well as direct, relationships. A person who has a position or relationship with, or interest in, a company that has a relationship with one of the persons listed in paragraphs (i) through (viii) of paragraph (i) of this Item 20 may have an indirect relationship by reason of the position, relationship, or interest.

5. In determining whether the amount involved in a relationship exceeds $60,000, amounts involved in a relationship of the director should be aggregated with those of his immediate family members.

6. In the case of an indirect interest, identify the company with which a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 has a relationship; the name of the director or immediate family member affiliated with the company and the nature of the affiliation; and the amount of business conducted between the company and the person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 during the two most recently completed calendar years.

7. In calculating payments for property and services for purposes of paragraph (j)(i) of this Item 20, the following may be excluded:

a. Payments where the transaction involves the rendering of services as a common contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority; or

b. Payments that arise solely from the ownership of securities of a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received.

8. No information need be given as to any routine, retail relationship. For example, the Registrant need not disclose that a director has a credit card, bank or brokerage account, residential mortgage, or insurance policy with a person specified in paragraphs (i) through (viii) of paragraph (i) of this Item 20 unless the director is accorded special treatment.

(k) If an officer of the Insurance Company or an investment adviser or principal underwriter of the Registrant, or an officer of a person directly or indirectly controlling, controlled by, or under common control with the Insurance Company or an investment adviser or principal underwriter of the Registrant, served during the two most recently completed calendar years, on the board of directors of a company where a director of the Registrant who is not an interested person of the Registrant, as defined in Section 2(a)(19) of the 1940 Act (15 U.S.C. 80a–2(a)(19)) and the rules thereunder, or immediate family membef of the director, was during the two most recently completed calendar years, an officer, identify:

(i) The company;

(ii) The individual who serves or has served as a director of the company and the period of service as director;

(iii) The Insurance Company, investment adviser, or principal underwriter or person controlling, controlled by, or under common control with the Insurance Company, investment adviser, or principal underwriter where the individual named in paragraph (k)(ii) of this Item 20 holds or held office and the office held; and

(iv) The director of the Registrant or immediate family member who is or was an officer of the company; the office held; and the period of holding the office.

(l) Discuss in reasonable detail the material factors and the conclusions with respect thereto that formed the basis for the board of managers approving the existing investment advisory contract. If applicable, include a discussion of any benefits derived or to be derived by the investment adviser from the relationship with the Registrant such as soft dollar arrangements by which brokers provide research to the Registrant or its investment adviser in return for allocating fund brokerage.

Instruction: Conclusory statements or a list of factors will not be considered sufficient disclosure. The discussion should relate the factors to the specific circumstances of the Registrant and the investment advisory contract.

* * * * *

Item 27. Financial Statements

* * * * *

Instructions

* * * * *

4. * * *

(v) the management information required by paragraph (a) of Item 20; and

(vi) a statement that the SAI includes additional information about members of the board of managers of the Registrant and is available, without charge, upon request, and a toll-free (or collect) telephone number for contract owners to call to request the SAI.

* * * * *

By the Commission.

Dated: January 2, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–536 Filed 1–12–01; 8:45 am]

BILLING CODE 8010–01–P

Federal Register

Tuesday,
January 16, 2001

Part V

Environmental Protection Agency

40 CFR Parts 9, 141, and 142

Revisions to the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1DBPR), and Revisions to State Primacy Requirements To Implement the Safe Drinking Water Act (SDWA) Amendments; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[FRL–6925–7]

RIN 2040–AD43

Revisions to the Interim Enhanced Surface Water Treatment Rule (IESWTR), the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1DBPR), and Revisions to State Primacy Requirements To Implement the Safe Drinking Water Act (SDWA) Amendments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final action will make minor revisions to the Interim Enhanced Surface Water Treatment Rule (IESWTR) and the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) which were published December 16, 1998 and the Revisions to State Primacy Requirements to Implement Safe Drinking Water Act (SDWA) Amendments (Primacy Rule) published April 28, 1998. This final rule revises the compliance dates for the IESWTR and the Stage 1 DBPR so that they coincide with calendar quarters. This change will facilitate implementation of both rules. This action also extends the use of new analytical methods to compliance monitoring for long-standing drinking water regulations for total trihalomethanes. In addition, this document corrects typographical errors, replaces inadvertently deleted text, and clarifies some of the regulatory provisions found in the published rules. Lastly, this document contains minor corrections to the Primacy Rule. These regulations relate to the requirements and procedures for States to obtain primary enforcement authority (primacy) for the Public Water System Supervision (PWSS) program under the Safe Drinking Water Act as amended by the 1996 Amendments. At this time, EPA is not taking final action on the proposed changes to § 141.130(a)(1) (consecutive systems) and to § 141.174(b) (filtration sampling requirements). These changes will be considered in future rulemaking.

DATES: This regulation is effective on February 15, 2001. For judicial review purposes, this final rule is promulgated as of 1:00 p.m. EST on January 16, 2001.

ADDRESSES: Public comments, the comment/response document for the April 14, 2000 proposed rule, and applicable **Federal Register** documents are available for review at EPA's Drinking Water Docket: East Tower Basement, USEPA, 401 M Street, SW., Washington, DC 20460 from 9 a.m. to 4 p.m., EST, Monday through Friday, excluding legal holidays. The record for this rule has been established under docket number W–99–11. For access to docket materials, please call 202–260–3027 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: Jennifer Melch, Drinking Water Protection Division, Office of Ground Water and Drinking Water (MC–4606), U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Ave, NW., Washington DC 20460, (202) 260–7035. Information may also be obtained from the EPA Safe Drinking Water Hotline. Callers within the United States may reach the Hotline at (800) 426–4791. The Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. EST.

SUPPLEMENTARY INFORMATION:

Regulated Entities

The entities regulated by the IESWTR and Stage 1 DBPR, and thus by these revisions to those rules, are public water systems. These include community and noncommunity water systems. States are subject to the primacy rule requirements as revised.

Regulated categories and entities include the following:

Category	Examples of potentially regulated entities	SIC
State, Tribal, and Territorial Governments	States, Territories, and Tribes that analyze water samples on behalf of public water systems required to conduct such analysis; States, Territories, and Tribes that operate public water systems required to monitor under the IESWTR or Stage 1 DBPR.	9511
Industry	Private operators of public water systems required to monitor under the IESWTR or Stage 1 DBPR.	9511
Municipalities	Municipal operators of public water systems required to monitor under the IESWTR or Stage 1 DBPR.	9511

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.2, 141.70, 141.130, 141.170, 142.2, 142.3, and 142.10 of title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Abbreviations

CWS: Community water system
DBPR: Disinfectant and Disinfection Byproducts Rule
EPA: Environmental Protection Agency
GWUDI: Ground water under the direct influence of surface water
HAA5: Haloacetic Acids (monochloroacetic, dichloroacetic, trichloroacetic, monobromoacetic and dibromoacetic acids)
ICR: Information Collection Request
IESWTR: Interim Enhanced Surface Water Treatment Rule
MCL: Maximum contaminant level
MCLG: Maximum contaminant level goal
MRDL: Maximum residual disinfectant level
MRDLG: Maximum residual disinfectant level goal
NPDWR: National Primary Drinking Water Regulation
NTNCWS: Non-transient, non-community water system
OMB: Office of Management and Budget
Primacy: Primary enforcement responsibility
PWS: Public water system
RFA: Regulatory Flexibility Analysis
SDWA: Safe Drinking Water Act
TNCWS: Transient, non-community water system
TOC: Total organic carbon
TTHM: Total Trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform)
UMRA: Unfunded Mandates Reform Act

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J. Congressional Review Act

I. Background

On December 16, 1998, EPA published the final Interim Enhanced Surface Water Treatment Rule (IESWTR; 63 FR 69478) and Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR; 63 FR 69390). On April 28, 1998, EPA published the Revisions to State Primacy Requirements to Implement the SDWA Amendments (63 FR 23362). On April 14, 2000, EPA published revisions to the IESWTR, Stage 1 DBPR, and Primacy Rule as a direct final rule (65 FR 20304) and parallel proposed rule (65 FR 20314). On June 13, 2000, EPA withdrew the direct final rule (65 FR 37052) because of receipt of adverse comment and reopened the comment period on the proposed rule, at the request of numerous stakeholders, until July 13, 2000 (65 FR 37092).

IESWTR: The IESWTR was designed to improve control of microbial pathogens, including the protozoan *Cryptosporidium*, in drinking water and to address risk trade-offs with disinfection byproducts. The IESWTR builds upon the treatment technique requirements of the Surface Water Treatment Rule. Key provisions established in the final IESWTR include: a Maximum Contaminant Level Goal (MCLG) of zero for *Cryptosporidium*; 2-log *Cryptosporidium* removal requirements for systems that filter; strengthened combined filter effluent turbidity performance standards and individual filter turbidity monitoring provisions; disinfection benchmark provisions to assure continued levels of microbial protection while facilities take the necessary steps to comply with new disinfection byproduct standards; inclusion of *Cryptosporidium* in the definition of ground water under the direct influence of surface water (GWUDI) and additional avoidance criteria for unfiltered public water systems; requirements for covers on new finished water reservoirs; and sanitary surveys for all surface water and GWUDI systems regardless of size.

The IESWTR applies to public water systems that use surface water or GWUDI and serve 10,000 or more people, except that the rule requires primacy States to conduct sanitary surveys for all surface water and GWUDI systems regardless of size.

EPA believes that implementation of the IESWTR will significantly reduce the level of *Cryptosporidium* in finished drinking water supplies through improvements in filtration and reduce the likelihood of the occurrence of cryptosporidiosis outbreaks by providing an increased margin of safety against such outbreaks for some systems. In addition, the filtration provisions of the rule are expected to increase the level of protection from exposure to other pathogens (*i.e.*, *Giardia* or other waterborne bacterial or viral pathogens).

Stage 1 DBPR: The Stage 1 DBPR was designed to reduce the levels of disinfection byproducts in drinking water supplies. The DBPR established maximum residual disinfectant level goals (MRDLGs) for chlorine, chloramines, and chlorine dioxide; maximum contaminant level goals (MCLGs) for four trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), two haloacetic acids (dichloroacetic acid and trichloroacetic acid), bromate, and chlorite; and National Primary Drinking Water Regulations (NPDWRs) for three disinfectants (chlorine, chloramines, and chlorine dioxide), two groups of organic disinfection byproducts (total trihalomethanes (TTHM)—a sum of chloroform, bromodichloromethane, dibromochloromethane, and bromoform; and haloacetic acids (HAA5)—the sum of dichloroacetic acid, trichloroacetic acid, monochloroacetic acid and mono- and dibromoacetic acids), and two inorganic disinfection byproducts (chlorite and bromate). The NPDWRs consist of maximum residual disinfectant levels (MRDLs) for these disinfectants and maximum contaminant levels (MCLs) or treatment techniques for their byproducts. The NPDWRs also include monitoring, reporting, and public notification requirements for these compounds.

The Stage 1 DBPR applies to public water systems that are community water systems (CWSs) and nontransient noncommunity water systems (NTNCWSs) that treat water with a chemical disinfectant for either primary or residual treatment. In addition, certain requirements for chlorine dioxide apply to transient noncommunity water systems (TNCWSs).

The Stage 1 DBPR provides public health protection for households that were not previously covered by drinking water rules for disinfection byproducts. The rule adds coverage for CWSs and NTNCWSs serving fewer than 10,000 persons. In addition, the rule, for the first time, provides public health protection from exposure to haloacetic acids, chlorite (a major chlorine dioxide byproduct) and bromate (a major ozone byproduct).

Primacy Rule: This rule codified new statutory requirements under the 1996 Amendments to the Safe Drinking Water Act (SDWA) involving changes to the process and requirements for States to obtain or retain primary enforcement authority for the Public Water System Supervision program under section 1413 of the SDWA and to the definition of a "public water system" under section 1401 of the SDWA.

II. Today's Action

A. IESWTR and Stage 1 DBPR

This document revises the IESWTR and Stage 1 DBPR to move compliance dates to facilitate implementation, correct typographical errors identified in these rules, replace text inadvertently deleted, delete incorrect text, and clarify certain provisions in the final rules. The revisions include the following modifications:

1. Shifting Compliance Date of Rules

Today's rule finalizes provisions in the April 14, 2000 proposed rule that revise the compliance dates of both rules by extending them approximately

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two weeks. This shift will facilitate the implementation of the IESWTR and the Stage 1 DBPR as the monitoring periods for both rules will coincide with calendar quarters and consequently with the monitoring periods for other contaminants.

Summary of Comments and Response

There were no significant comments on shifting the compliance date of the rules and therefore EPA is finalizing this provision as proposed.

2. New Analytical Methods Use

Today's rule finalizes the proposed action modifying § 141.30 to extend the use of new analytical methods included in the DBPR § 141.131(b) for compliance monitoring for long-standing drinking water regulations at § 141.30 for total trihalomethanes.

Summary of Comments and Response

There were no significant comments on extending the use of analytical methods in the Stage 1 DBPR and therefore EPA is finalizing this provision as proposed.

3. Regulated Entities Compliance With Stage 1 DBPR

After evaluating the comments on the proposal, EPA is not taking final action at this time on the proposed changes to § 141.130(a). EPA proposed the change to § 141.130(a) to clarify which systems must meet the new MCLs and MRDLs under the Stage 1 DBPR. The current language specifies that systems which "add a chemical disinfectant to the water in any part of the drinking water treatment process" are responsible for complying with the rule. EPA proposed a clarification adding "or systems which provide water that contains a chemical disinfectant." EPA intended to include all consecutive systems in the original rule making and included them in the regulatory impact analyses for the original rule. EPA will consider this issue in the future. The September 2000 Stage 2 M–DBP Agreement in Principle contains a recommendation at section 3.1.c. on "Wholesale and Consecutive Systems" that states:

"The FACA (Federal Advisory Committee Act group) has considered the issues of consecutive systems and recommends that EPA propose that all wholesale and consecutive systems must comply with the provisions of the Stage 2 DBPR on the same schedule required of the wholesale or consecutive system serving the largest population in the combined distribution system.

Principles:

• Consumers in consecutive systems should be just as well protected as customers of all systems, and

• Monitoring provisions should be tailored to meet the first principle.

The FACA recognizes that there may be issues that have not been fully explored or completely analyzed and therefore recommends that EPA solicit comments."

Therefore, EPA plans to seek further comment on this issue in the proposal for the Stage 2 M–DBP rule making.

4. TTHM and HAA5 Monitoring and Compliance Provisions

The regulatory language addressing TTHM and HAA5 monitoring and compliance determination has been revised to clarify the intention of the regulatory requirements in § 141.132(b)(1). Sections a. through c. below discuss these revisions.

a. Criteria To Return to Routine Monitoring

This clarification specifies the criteria under which certain subpart H systems may return to routine monitoring from increased monitoring. The systems affected by this revision are those that use surface water or ground water under the direct influence of surface water serving <500 people and ground water systems serving <10,000 people on increased monitoring. Such systems are required to increase monitoring if the compliance sample or average of annual compliance samples, if more than one sample is taken, exceeds the MCL. The rule language in the 1998 Stage 1 DBPR omitted criteria that would govern returning to routine monitoring from increased monitoring. EPA proposed that systems on increased monitoring may return to routine monitoring if their TTHM annual average was 0.040 mg/L or less and their HAA5 annual average was 0.030 mg/L or less; these values are consistent with the criteria for reduced monitoring for other systems on quarterly monitoring. However, a number of commentors urged EPA to allow systems on increased monitoring to return to routine monitoring if their TTHM annual average is 0.060 mg/L or less and their HAA5 annual average is 0.045 mg/L or less; these values were discussed in the preamble to the 1998 rule. These are the same values that trigger systems to return to routine monitoring from reduced monitoring. EPA is persuaded by these commentors and is promulgating these criteria. A corresponding change is reflected in the table in § 141.132(b)(1). Also, the reference "paragraph c" in the third and fifth entries of the proposal will be replaced by "paragraph (b)(1)(iv)" in today's final rule.

b. MCL Exceedence Triggers Quarterly Monitoring

Today's rule finalizes the proposed action which clarifies the monitoring requirements for ground water systems serving <10,000 on reduced monitoring (one sample per plant every 3 years). As issued in 1998, there was concern that the Stage 1 DBPR language was ambiguous. The proposed rule clarified that in the situation where a sample collected during reduced monitoring exceeds the MCL, EPA's intention is to assure that the system would be triggered into quarterly monitoring immediately following the exceedence rather than first return to routine monitoring (one sample per plant per year).

Summary of Comments and Response

There were no significant comments on this clarification and therefore EPA is finalizing these revisions as proposed.

c. Compliance Criteria for Systems on Reduced Monitoring

EPA is finalizing the proposed clarification on compliance determination for TTHM and HAA5 in § 141.133(b)(1). The clarification deals specifically with systems monitoring less frequently than quarterly with TTHM or HAA5 sample results above the MCL. Compliance should not be calculated based solely on a sample taken at a frequency less than quarterly. The intention of the rule is that these systems should immediately begin quarterly monitoring. Compliance should be determined based on the results of four consecutive quarters of monitoring (averaging the sample results from the sample that triggered the increased monitoring and the following three quarters of monitoring). For systems with exceptionally high levels of DBPs, compliance could be calculated with fewer than four quarters of sampling results. (The exceptions to this are when the results of fewer than four quarters will cause the running annual average to exceed the MCL, or if the system fails to collect the four samples over four consecutive quarters, in which case the MCL is calculated based on the average of the available data for the four-quarter compliance period). This intent is clarified by deleting the last two sentences of § 141.133(b)(1)(i), revising paragraphs (b)(1) (ii) and (iii), and adding new paragraph (b)(1)(iv).

Summary of Comments and Responses

There were no significant comments on this clarification and therefore EPA is finalizing these revisions as proposed.

5. Chlorite Provisions

Today's rule finalizes the proposed revisions to two provisions addressing chlorite. First, EPA is correcting the general requirements for transient non-community water systems (TNCWS) in § 141.130 which incorrectly states that TNCWS must comply with chlorite requirements. This correction is accomplished by deletion of the chlorite reference in paragraph (b)(2).

Second, EPA is clarifying the monitoring provisions in § 141.131(b) for daily chlorite analysis. The Stage 1 DBPR of 1998 required analysis to be performed by a certified lab. Water system personnel, however, are capable of analyzing routine samples for chlorite using amperometric titration. Therefore, language has been added to allow public water system personnel to be approved for such monitoring. This change results in a reduction of the financial and operational burden on systems and will make data available immediately so that operational changes can be made on a more timely basis.

Summary of Comments and Response

There were no significant comments on modifications to the chlorite provisions and therefore EPA is finalizing these revisions as proposed.

6. Disinfection Byproduct Precursor Removal Provisions

This rule finalizes the proposed clarifications to the public notification requirements related to compliance with DBP precursor removal requirements under § 141.133. The revision to § 141.133(d) states that for systems required to meet Step 1 TOC removals, if the value calculated under § 141.135(c)(1)(iv) is less than 1.00, the system has a treatment technique violation and must notify the public.

Today's rule also finalizes proposed language clarifications regarding the Step 2 TOC removal requirements under § 141.135. The revision to the Step 2 TOC removal requirements clarifies that the submitted bench or pilot-scale tests must be used to determine the alternate enhanced coagulation level. In the table in § 141.135(b)(2), "≤60–120" is corrected to read ">60–120" in the heading of the second column and percentage signs—%—are added to all values while the word "percent" is deleted from the three column headings.

Summary of Comments and Response

There were no significant comments on the clarifications to the DBP precursors provisions in Stage 1 DBPR and therefore EPA is finalizing these revisions as proposed.

7. System Reporting and Recordkeeping

a. Reporting Requirement Added to the IESWTR

EPA is finalizing this provision as proposed. The revision adds system reporting requirements which were inadvertently omitted from § 141.175 of the IESWTR. These requirements mirror the reporting requirements in § 141.75 of the Surface Water Treatment Rule. Today's rule requires that when the combined filter effluent sample in a direct or conventional filtration system exceeds the maximum turbidity limit of 1 NTU, the system must inform the State no later than the end of the next business day. Similarly, when the combined filter effluent sample in a system using alternative filtration technologies exceeds the maximum turbidity level set by the State under § 141.173(b), the system must inform the State no later than the end of the next business day.

Summary of Comments and Response

While EPA received several comments supporting this revision, several other commentors disagreed with this correction and stated that the current reporting requirements were sufficient and that requiring systems to inform the State by the end of the next business day was excessive and unnecessary. Additionally, two commentors were unsure whether this requirement applied to individual or combined filter effluent samples.

After review of all comments, EPA has determined that the reporting requirement promulgated today is necessary and not an undue burden. Today's requirement simply parallels the Surface Water Treatment Rule's longstanding reporting requirement (5 NTU) but at the tighter maximum standard promulgated in the IESWTR. Also, a combined filter effluent turbidity above 1 NTU can be an indicator of significant operational or other problems in a water treatment plant. The State should be informed as quickly as possible so that action can be taken to minimize any threat to public health. The burden associated with today's reporting requirement is not expected to increase from the burden associated with the Surface Water Treatment Rule which is covered by the general PWSS program ICR (OMB No. 2040–0090). Even though § 141.175(c) alters (for large systems only) the level at which turbidity exceedences are reported, data indicate that large systems have high compliance rates and we do not expect a significant increase in violations and burden associated with this new level.

b. Clarification of Reporting Tables

Today's rule also adds clarifying text to the § 141.134 reporting tables. These changes will clarify a system's reporting requirements for the disinfectant byproducts, disinfectants, and disinfectant byproduct precursors and enhanced coagulation or enhanced softening.

In the section (b) table, all entries in the "You must report" column are revised to add the citation of the MCL and replace the word "exceeded" with "violated." In the second entry, under the second reporting requirement, the phrase "last quarter" is replaced with "last monitoring period," and in the fourth entry, the language in all four reporting requirements is revised. In the section (c) table, all entries in the "You must report" column are revised to add the citation of the MRDL and replace the word "exceeded" with "violated." In the section (d) table, the first entry is revised by deleting the phrase "prior to continuous disinfection" from the first reporting requirement.

Summary of Comments and Response

Several comments expressed concern that these table revisions change the table format, thus creating inconsistency among the existing tables in § 141.134. EPA agrees with this comment and will work with the **Federal Register** to ensure consistency.

8. Filtration Provisions

Under the 1998 IESWTR, § 141.174 states that if continuous turbidity monitoring equipment fails, the system must repair or replace the equipment within five working days. In the April 14, 2000 **Federal Register**, EPA proposed that if a system did not make this repair, it would be assessed a violation. After evaluating the comments on the proposal, EPA is not taking final action on the proposed change at this time. EPA will consider this issue in future microbial rulemaking.

B. Primacy Rule

EPA is finalizing all the primacy rule clarifications as proposed. The final primacy regulations subject to these corrections increase the time for a State to adopt new or revised Federal regulations from 18 months to two years. Inadvertently, this time increase was not reflected in § 142.12(d)(2) of the final regulations. This rule corrects that error.

In addition, this rule updates the interim primacy provision at § 142.12(b)(3)(i). Interim primacy gives States full responsibility for implementation and enforcement during

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the time that EPA reviews the complete and final primacy revision application, provided that States have full primacy for all prior National Primary Drinking Water Regulations. When extensions to the time frame for submission of primacy revision applications are granted, States must agree to conditions for rule implementation. These conditions are lifted when a State receives primacy. EPA believes that under the SDWA amendments, these conditions should also be lifted when a State receives interim primacy. Inadvertently, this intent was not reflected in the **Federal Register** of Tuesday, April 28, 1998 (63 FR 23362). Today's change to § 142.12(b)(3)(i) clarifies that the conditions that go with an extension are not necessary after a State receives interim primacy.

Summary of Comments and Response

There were no significant comments on corrections to the Primacy Rule and therefore EPA is finalizing these provisions as proposed.

III. Administrative Requirements

A. Executive Order 12866—Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

B. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866.

C. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule makes minor revisions and corrections to three SDWA regulations. EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

For the same reason, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

D. Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, information collection, reporting and recordkeeping requirements must be submitted to the Office of Management and Budget (OMB) for approval. Information Collection Request (ICR) documents for the original IESWTR, Stage 1DBPR and Primacy Rule were prepared by EPA and approved by OMB (OMB Nos. 2040–0205, 2040–0204, and 2040–0915 respectively) and copies may be obtained from Sandy Farmer by mail at OPPE Regulatory Information Division; U.S. Environmental Protection Agency (2137); 401 M St., SW., Washington, DC 20460, by e-mail at: farmer.sandy@epamail.epa.gov, or by calling: (202) 260–2740.

The system reporting requirements contained in § 141.175(c) are covered by the general PWSS program ICR (OMB No. 2040–0090). This ICR calculates the burden associated with reporting turbidity exceedences under § 141.75(a)(5). Although § 141.175(c) alters for large systems the level at which turbidity exceedences are reported, data indicate that such systems already have high compliance rates with the new levels and there would be no significant increase in violations and burden associated with this new level. The part 9 table is amended in this rule to reflect OMB approval of these reporting requirements.

E. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et. seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice-and-comment rulemaking requirement under the Administrative Procedure Act or any other statute unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small government jurisdictions. This rule makes only minor revisions, corrections, and clarifications to promulgated regulations that will facilitate the implementation of those regulations. This rule does not impose additional burden on any regulated small entity since impacts were included in the original rule analysis. The additional reporting requirements contained in today's rule apply only to systems that serve 10,000 or more people. Thus, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113 section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action extends the applicability of analytical methods established under the Stage 1 DBPR in the December 16, 1998 **Federal Register**. In developing the Stage 1 DBPR, EPA's process for selecting analytical test methods was consistent with section 12(d) of the NTTAA. EPA performed literature searches to identify analytical methods from industry, academia and voluntary consensus standards, and provided an opportunity for comment. For a more detailed discussion, refer to page 69457 of the Stage 1 DBPR (63 FR 69390, Dec. 16, 1998). Neither the IESWTR nor the Primacy Rule involve standards subject to this Act.

G. Executive Order 12898—Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898—"Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (February 11, 1994) focuses Federal attention on the environmental and human health conditions of minority populations and low-income populations with the goal of achieving environmental protection for all communities. Today's changes to the IESWTR, Stage 1 DBPR, and Primacy Rule will not diminish the health protection to minority and low-income populations.

H. Executive Order 13132—Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule makes only minor revisions, corrections and clarifications to three SDWA rules that were promulgated in 1998. The result of these revisions, corrections and clarifications will be to facilitate the implementation of these regulations at the State and local levels of government. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

I. Executive Order 13084—Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

This rule makes minor revisions, corrections and clarifications to promulgated regulations. It does not significantly or uniquely affect the communities of Indian tribal governments, nor does it impose substantial direct compliance costs on them. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it

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is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 15, 2001.

List of Subjects in 40 CFR Parts 9, 141, and 142

Environmental protection, Analytical methods, Drinking water, Intergovernmental relations, Public utilities, Reporting and recordkeeping requirements, Reservoirs, Utilities, Water supply, Watersheds.

Dated: December 22, 2000.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40 of the Code of Federal Regulations is amended as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735; 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by removing the entry for § 141.174–141.175 in the table and adding new entries in its place to read as follows:

§ 9.1 [Amended]

* * * * *

40 CFR citation	OMB control No.
* * * * *	
141.174(a)–(b)	2040–0205
141.175	2040–0205
141.175(a)–(b)	2040–0205
141.175(c)	2040–0090
* * * * *	

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

3. The authority citation for part 141 continues to read:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

§ 141.12 [Amended]

4. Section 141.12 is amended by revising "December 16, 2001" to read "December 31, 2001" and by revising the two occurrences of "December 16, 2003" to read "December 31, 2003".

§ 141.30 [Amended]

5. Amend § 141.30 by:

a. Revising the first sentence of paragraph (e); and

b. In paragraph (h), revising "December 16, 2001" to read "December 31, 2001", and revising the two occurrences of "December 16, 2003" to read "December 31, 2003".

§ 141.30 Total trihalomethanes sampling, analytical and other requirements.

* * * * *

(e) Sampling and analyses made pursuant to this section shall be conducted by one of the total trihalomethanes methods as directed in § 141.24(e), and the *Technical Notes on Drinking Water Methods*, EPA–600/R–94–173, October 1994, which is available from NTIS, PB–104766, or in § 141.131(b). * * *

* * * * *

§ 141.64 [Amended]

6. Amend § 141.64 by:

a. In paragraph (b)(1), revising "December 16, 2001" to read "January 1, 2002" and revising "December 16, 2003" to read "January 1, 2004"; and

b. In paragraph (b)(2), revising "December 16, 2003" to read "December 31, 2003".

§ 141.65 [Amended]

7. Section 141.65, paragraphs (b)(1) and (b)(2) are amended by revising "December 16, 2001" to read "January 1, 2002" and revising "December 16, 2003" to read "January 1, 2004", wherever they appear.

§ 141.71 [Amended]

8. Section 141.71(b)(6) is amended by revising the two occurrences of "December 17, 2001" to read "December 31, 2001".

§ 141.73 [Amended]

9. Amend § 141.73 by:

a. In paragraph (a)(3), revising "December 17, 2001" to read "January 1, 2002"; and

b. In paragraph (d), revising "December 17, 2001" to read "January 1, 2002".

§ 141.130 [Amended]

10. Amend § 141.130 by:

a. In paragraphs (b)(1) and (b)(2), revising "December 16, 2001" to read "January 1, 2002" and revising "December 16, 2003" to read "January 1, 2004"; and

b. In paragraph (b)(2), removing the phrase "and chlorite" from the first and second sentences.

§ 141.131 [Amended]

11. Amend § 141.131 by revising the first sentence of paragraph (b)(2) and adding paragraph (b)(3) to read:

§ 141.131 Analytical requirements.

* * * * *

(b) * * *

(2) Analysis under this section for disinfection byproducts must be conducted by laboratories that have received certification by EPA or the State, except as specified under paragraph (b)(3) of this section. * * *

(3) A party approved by EPA or the State must measure daily chlorite samples at the entrance to the distribution system.

* * * * *

§ 141.132 [Amended]

12. Amend § 141.132 by:

a. In paragraph (a)(2), revising the reference "§ 142.16(f)(5)" to read "§ 142.16(h)(5)";

b. In paragraph (b)(1)(i), revising the third and fifth entries and footnote 2 in the table;

c. In paragraph (b), revising the last two sentences in paragraph (b)(1)(iii), redesignating paragraph (b)(1)(iv) as (b)(1)(v), adding a new paragraph (b)(1)(iv); and

d. In paragraph (c), revising the first sentence after the heading in paragraph (c)(1)(i).

The addition and revisions read as follows:

§ 141.132 Monitoring requirements.

* * * * *

(b) * * *

(1) * * *

(i) * * *

ROUTINE MONITORING FREQUENCY FOR TTHM AND HAA5

Type of system	Minimum monitoring frequency	Sample location in the distribution system
* * *	* * *	* * *
Subpart H system serving fewer than 500 persons.	One sample per year per treatment plant during month of warmest water temperature.	Locations representing maximum residence time.[1] If the sample (or average of annual samples, if more than one sample is taken) exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter, taken at a point reflecting the maximum residence time in the distribution system, until the system meets criteria in paragraph (b)(1)(iv) of this section.
* * *	* * *	* * *
System using only ground water not under direct influence of surface water using chemical disinfectant and serving fewer than 10,000 persons.	One sample per year per treatment plant[2] during month of warmest water temperature.	Locations representing maximum residence time.[1] If the sample (or average of annual samples, if more than one sample is taken) exceeds the MCL, the system must increase monitoring to one sample per treatment plant per quarter, taken at a point reflecting the maximum residence time in the distribution system, until the system meets criteria in paragraph (b)(1)(iv) of this section.
* * *	* * *	* * *

[1] If a system elects to sample more frequently than the minimum required, at least 25 percent of all samples collected each quarter (including those taken in excess of the required frequency) must be taken at locations that represent the maximum residence time of the water in the distribution system. The remaining samples must be taken at locations representative of at least average residence time in the distribution system.

[2] Multiple wells drawing water from a single aquifer may be considered one treatment plant for determining the minimum number of samples required, with State approval in accordance with criteria developed under § 142.16(h)(5) of this chapter.

(ii) * * *

(iii) * * * Systems that do not meet these levels must resume monitoring at the frequency identified in paragraph (b)(1)(i) of this section (minimum monitoring frequency column) in the quarter immediately following the monitoring period in which the system exceeds 0.060 mg/L or 0.045 mg/L for TTHM or HAA5 respectively. For systems using only ground water not under the direct influence of surface water and serving fewer than 10,000 persons, if either the TTHM annual average is >0.080 mg/L or the HAA5 annual average is >0.060 mg/L, the system must go to the increased monitoring identified in paragraph (b)(1)(i) of this section (sample location column) in the quarter immediately following the monitoring period in which the system exceeds 0.080 mg/L or 0.060 mg/L for TTHMs or HAA5 respectively.

(iv) Systems on increased monitoring may return to routine monitoring if, after at least one year of monitoring their TTHM annual average is ≤0.060 mg/L and their HAA5 annual average is ≤0.045 mg/L.

* * * * *

(c) * * *

(1) * * *

(i) *Routine Monitoring.* Community and nontransient noncommunity water systems that use chlorine or chloramines must measure the residual disinfectant level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. * * *

* * * * *

13. Amend § 141.133 by:

a. In the first sentence of paragraph (a)(1), revising "system's failure" to read "system fails";

b. In paragraph (b), removing the last two sentences of paragraph (b)(1)(i), revising paragraphs (b)(1) (ii) and (iii), and adding new paragraph (b)(1)(iv);

c. In paragraph (c), removing the phrase "of quarterly averages" in the second sentence of paragraph (c)(1)(i) and adding the phrase "in addition to reporting to the State pursuant to § 141.134" to the end of the second and third sentences in paragraph (c)(2)(i) and the second and third sentences of paragraph (c)(2)(ii); and

d. In paragraph (d), revising the reference "§ 141.135(b)" in the first sentence to read "§ 141.135(c)" and adding a sentence to the end of the paragraph.

The additions and revisions as follows

§ 141.133 Compliance requirements.

* * * * *

(b) * * *

(1) * * *

(ii) For systems monitoring less frequently than quarterly, systems demonstrate MCL compliance if the average of samples taken that year under the provisions of § 141.132(b)(1) does not exceed the MCLs in § 141.64. If the average of these samples exceeds the MCL, the system must increase monitoring to once per quarter per treatment plant and such a system is not in violation of the MCL until it has completed one year of quarterly monitoring, unless the result of fewer than four quarters of monitoring will cause the running annual average to exceed the MCL, in which case the system is in violation at the end of that quarter. Systems required to increase monitoring frequency to quarterly monitoring must calculate compliance by including the sample which triggered the increased monitoring plus the following three quarters of monitoring.

(iii) If the running annual arithmetic average of quarterly averages covering any consecutive four-quarter period exceeds the MCL, the system is in violation of the MCL and must notify the public pursuant to § 141.32 or § 141.202, whichever is effective for your system, in addition to reporting to the State pursuant to § 141.134.

(iv) If a PWS fails to complete four consecutive quarters of monitoring, compliance with the MCL for the last four-quarter compliance period must be

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based on an average of the available data.

* * * * *

(d) * * * For systems required to meet Step 1 TOC removals, if the value calculated under § 141.135(c)(1)(iv) is less than 1.00, the system is in violation of the treatment technique requirements and must notify the public pursuant to § 141.32, in addition to reporting to the State pursuant to § 141.134.

14. Amend § 141.134 by:

a. In paragraph (b), revising the table;

b. In paragraph (c), revising the table; and

c. In paragraph (d), revising the first entry in the table, designating the second entry in the first column as (2), and redesignating its corresponding entries in the second column as (i) through (ix).

The revisions read as follows:

§ 141.134 Reporting and recordkeeping requirements.

* * * * *

(b) * * *

If you are a * * *	You must report * * *
(1) System monitoring for TTHMs and HAA5 under the requirements of § 141.132(b) on a quarterly or more frequent basis.	(i) The number of samples taken during the last quarter. (ii) The location, date, and result of each sample taken during the last quarter. (iii) The arithmetic average of all samples taken in the last quarter. (iv) The annual arithmetic average of the quarterly arithmetic averages of this section for the last four quarters. (v) Whether, based on § 141.133(b)(1), the MCL was violated.
(2) System monitoring for TTHMs and HAA5 under the requirements of § 141.132(b) less frequently than quarterly (but as least annually).	(i) The number of samples taken during the last year. (ii) The location, date, and result of each sample taken during the last monitoring period. (iii) The arithmetic average of all samples taken over the last year. (iv) Whether, based on § 141.133(b)(1), the MCL was violated.
(3) System monitoring for TTHMs and HAA5 under the requriements of § 141.132(b) less frequently than annually.	(i) The location, date, and result of each sample taken (ii) Whether, based on § 141.133(b)(1), the MCL was violated.
(4) System monitoring for chlorite under the requirements of § 141.132(b).	(i) The number of entry point samples taken each month for the last 3 months. (ii) The location, date, and result of each sample (both entry point and distribution system) taken during the last quarter. (iii) For each month in the reporting period, the arithmetic average of all samples taken in each three samples set taken in the distribution system. (iv) Whether, based on § 141.133(b)(3), the MCL was violated, in which month, and how many times it was violated each month.
(5) System monitoring for bromate under the requirements of § 141.132(b).	(i)The number of samples taken during the last quarter. (ii)The location, date, and result of each sample taken during the last quarter. (iii) The arithmetic average of the monthly arithmetic averages of all samples taken in the last year. (iv) Whether, based on § 141.133(b)(2), the MCL was violated.

[1] The State may choose to perform calculations and determine whether the MCL was exceeded, in lieu of having the system report that information

(c) * * *

If you are a * * *	You must report * * *
(1) System monitoring for chlorine or chloramines under the requirements of § 141.132(c).	(i) The number of samples taken during each month of the last quarter. (ii) The month arithmetic average of all samples taken in each month for the last 12 months. (iii) The arithmetic average of the monthly averages for the last 12 months. (iv) Whether, based on § 141.133(c)(1), the MRD was violated.
(2) System monitoring for chlorine dioxide under the requirements of § 141.132(c).	(i) The dates, result, and locations of samples taken during the last quarter. (ii) Whether, based on § 141.133(c)(2), the MRDL was violated. (iii) Whether the MRDL was exceeded in any two consecutive daily samples and whether the resulting violation was acuate or nonacute.

[1] The State may choose to perform calculations and determine whether the MRDL was exceeded, in lieu of having the system report that information.

(d) * * *

If you are a * * *	You must report * * *
(1) System monitoring monthly or quarterly for TOC under the requirements of § 141.132(d) and required to meet the enhanced coagulation or enhanced softening requirements in § 141.135(b)(2) or (3).	(i) The number of paired (source water and treated water) samples taken during the last quarter. (ii) The location, date, and results of each paired sample and associated alkalinity taken during the last quarter. (iii) For each month in the reporting period that paired samples were taken, the arithmetic average of the percent reduction of TOC for each paired sample and the required TOC percent removal. (iv) Calculations for determining compliance with the TOC prevent removal requirements, as provided in § 141.135(c)(1). (v) Whether the system is in compliance with the ehnanced coagulation or enhanced softening percent removal requirements in § 141.135(b) in § 141.135(b) for the last four quarters.

[1] The State may choose to perform calculations and determine whether the treatment technique was met, in lieu of having the system report taht information.

§ 141.135 [Amended]

15. Amend § 1A141.135 by:

a. In paragraph (a)(2)(iii), revising "as required by" in the first sentence to read "according to", and revising "June 16, 2005" in the third sentence to read "June 30, 2005";

b. In paragraph (b)(2), revising the table;

c. In paragraph (b)(4), removing the phrase "(as aluminum)" wherever it appears and revising the introductory text; and

d. In paragraph (c)(1), revising the table;

The revisions read as follows:

§ 141.135 Treatment technique for control of disinfection byproduct (DBP) precursors.

* * * * *

(b) * * *

(2) * * *

STEP 1 REQUIRED REMOVAL OF TOC BY ENHANCED COAGULATION AND ENHANCED SOFTENING FOR SUBPART H SYSTEMS USING CONVENTIONAL TREATMENT [1 2]

Source-water TOC, mg/L	Source-water alkalinity, mg/L as $CaCO_3$ (in precantages)		
	0–60	>60–120	>120 [3]
>2.0–4.0	35.0	25.0	15.0
>4.0–8.0	45.0	35.0	25.0
>8.0	50.0	40.0	30.0

[1] Systems meeting at least one of the conditions in paragraph (a)(2)(i)–(vi) of this section are not required to operate with enhanced coagulation.

[2] Softening system meeting one of the alternative compliance criteria in paragraph (a)(3) of this section are not required to operate with enhanced softening.

[3] System practicing softening must meet the TOC removal requirements in this column.

(3) * * *

(4) *Alternate minimum TOC removal (Step 2) requirements.* Applications made to the State by enhanced coagulation systems for approval of alternate minimum TOC removal (Step 2) requirements under paragraph (b)(3) of this section must include, at a minimum, results of bench- or pilot-scale testing conducted under paragraph (b)(4)(i) of this section. The submitted bench- or pilot-scale testing must be used to determine the alternate enhanced coagulation level.

* * * * *

(c) * * *

(1) Subpart H systems other than those identified in paragraph (a)(2) or (a)(3) of this section must comply with requirements contained in paragraph (b)(2) or (b)(3) of this section. * * *

* * * * *

§ 141.170 [Amended]

16. Section 141.170(a) is amended in the introductory text by revising "December 17, 2001" to read "January 1, 2002".

§ 141.172 [Amended]

17. Amend § 141.172 by:

a. In paragraph (a)(2)(iii)(A), revising "March 16, 2000" to read "March 31, 2000";

b. In paragraph (a)(5), revising "December 16, 1999" to read "December 31, 1999" wherever it appears;

c. In paragraph (a)(5)(iii), revising "March 16, 2000" to read "March 31, 2000";

d. In the introductory text of paragraph (b)(2), revising "March 16, 2000" to read "April 1, 2000";

e. In paragraph (b)(3)(i), revising "March 16, 2000" to read "March 31, 2000"; and

f. In paragraph (b)(4)(ii), revising the last sentence to read:

§ 141.172 Disinfection profiling and benchmarking.

* * * * *

(b) * * *

(4) * * *

(ii) * * * The $(CTcalc/CT_{99.9})$ value of each segment and $(\Sigma(CTcalc/CT_{99.9}))$ must be calculated using the method in paragraph (b)(4)(i) of this section.

* * * * *

§ 141.173 [Amended]

18.–19. In § 141.173, amend the introductory text by revising "December 17, 2001" to read "December 31, 2001".

§ 141.175 [Amended]

20. Amend § 141.175 by revising the two occurrences of "December 17, 2001" to read "January 1, 2002" in the introductory text and adding paragraph (c);

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§ 141.175 Reporting and recordkeeping requirements

* * * * *

(c) *Additional reporting requirements.*

(1) If at any time the turbidity exceeds 1 NTU in representative samples of filtered water in a system using conventional filtration treatment or direct filtration, the system must inform the State as soon as possible, but no later than the end of the next business day.

(2) If at any time the turbidity in representative samples of filtered water exceeds the maximum level set by the State under § 141.173(b) for filtration technologies other than conventional filtration treatment, direct filtration, slow sand filtration, or diatomaceous earth filtration, the system must inform the State as soon as possible, but no later than the end of the next business day.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

21. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

22. In § 142.12, revise paragraph (b)(3)(i) and the last sentence of (d)(2), to read as follows:

§ 142.12 Revision of state programs

* * * * *

(b) * * *

(3) * * *

(i) Informing public water systems of the new EPA (and upcoming State) requirements and that EPA will be overseeing implementation of the requirements until the State, if eligible for interim primacy, submits a complete and final primacy revision request to EPA, or in all other cases, until EPA approves the State program revision;

* * * * *

(d) * * *

(2) *Final request.* * * * Complete and final State requests for program revisions shall be submitted within two years of the promulgation of the new or revised EPA regulations, as specified in paragraph (b) of this section.

* * * * *

§ 142.15 [Amended]

23. In the first sentence of paragraph (c)(5), revise the reference "§ 141.16(b)(3)" to read "§ 142.16(b)(3)".

[FR Doc. 01–655 Filed 1–12–01; 8:45 am]

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Part VI

Environmental Protection Agency

40 CFR Parts 31 and 35
Environmental Program Grants for Tribes; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

Environmental Program Grants for Tribes

40 CFR Parts 31 and 35

[FRL–6929–5]

RIN 2030–AA56

Environmental Program Grants for Tribes

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This final rule revises and updates requirements in several Environmental Protection Agency (EPA) regulations governing grants to Indian Tribes and Intertribal Consortia. It creates a new Tribal-specific subpart which contains only the provisions for environmental program grants that apply to Tribes; simplifies, clarifies, and streamlines current provisions for environmental program grants to Tribes; and addresses the Performance Partnership Grant (PPG) program for Tribes. The rule includes results-oriented approaches to planning and managing environmental programs. The PPG program fosters EPA's continuing efforts to improve partnerships with its Tribal recipients by increasing flexibility in using environmental program funding. The regulation reflects efforts by EPA and its Tribal partners to increase administrative and programmatic flexibility for Tribes while moving toward improved environmental protection. (A regulation governing environmental program grants to State, interstate, and local government agencies published in the **Federal Register** of January 9, 2001.)

DATES: This regulation is effective February 15, 2001. This regulation applies to new grants awarded after February 15, 2001.

ADDRESSES: Although this regulation is final, comments may be submitted to the person identified in the section below at any time.

FOR FURTHER INFORMATION CONTACT: Michelle McClendon, Grants Policy, Information, and Training Branch (3903R), United States Environmental Protection Agency, 1200 Pennsylvania Ave., Washington, D.C. 20460, Telephone: 202–564–5357, McClendon.Michelle@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Regulated Entities

Entities eligible to receive the environmental grants listed in 40 CFR 35.501 are regulated by this rule. Regulated categories and entities include:

Category	Regulated Entities
Government	Federally recognized Indian Tribal Governments
Other Entities	Intertribal Consortia

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your organization is regulated by this action, you should carefully examine the definitions of Tribe and Intertribal Consortium in § 35.502 and in the program-specific rules found following § 35.540 of the rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Comments and Record

The record of this final rule includes copies of the proposed and final rule, comments received on the rule, EPA's responses to those comments, and other relevant documents that support the rule. It is available for inspection from 9 am to 4 pm (Eastern Time), Monday through Friday, excluding legal holidays, at the Water Docket, U.S. EPA Headquarters, 401 M Street, SW; East Tower Basement; Washington, DC 20460. For access to docket materials, please call (202) 260–3027 to schedule an appointment.

III. Background

EPA proposed a rule for environmental program grants for Indian Tribes on July 23, 1999 (64 FR 40084). EPA received 16 letters of comment on the proposed rule. A summary of the comments and EPA's response are included in this preamble. The preamble also summarizes a few changes to the rule EPA determined necessary to clarify various provisions. This publication makes the rule final.

The United States Government has a unique legal relationship with Tribal governments as set forth in the United States Constitution, treaties, statutes, executive orders, and court decisions. EPA recognized the uniqueness of Tribal governments by issuing and reaffirming its 1984 policy on the "Administration of Environmental Programs on Indian Reservations." Specifically, EPA recognizes the existence of the trust responsibility in Principle Number 5 of its Indian Policy, which states that the Agency will assure that Tribal concerns and interests will be considered when Agency actions may affect Tribal environments. Additionally, in 1994, the President of the United States issued a presidential memorandum for the heads of Executive Departments and Agencies reaffirming the government-to-government relationships with Native American Tribal Governments. Most recently, on May 14, 1998, the President issued Executive Order 13084, "Consultation and Coordination With Tribal Governments." The Executive Order addresses consultation and collaboration with Indian Tribal governments in developing regulatory policies on federal matters affecting their communities, reducing the imposition of unfunded mandates on Indian Tribal governments, and streamlining the application process and increasing the availability of statutory or regulatory waivers for Indian Tribal governments. Consistent with these principles, this regulation provides an easy-to-use Tribal-specific subpart to optimize the administration of Tribal assistance programs through increased flexibility and to remove procedural impediments to effective environmental programs for Indian Tribes.

In various program specific regulations in this subpart, we have used terms such as "treatment as a State" or "treatment in a manner similar to a State." We have used those terms because they are in many of the statutes authorizing grants to Tribes. EPA recognizes that Tribes are sovereign nations with a unique legal status and a relationship to the federal government that is significantly different than that of States. EPA believes that Congress did not intend to alter this relationship when it authorized treatment of Tribes "as States;" rather, the purpose was to reflect an intent that, insofar as possible, Tribes should assume a role in implementing the environmental statutes in Indian country comparable to the role States play outside of Indian country.

Generally, the administration of financial assistance to Tribes is the same as the administration of financial assistance to States. However, there are provisions in some assistance programs unique to Indian Tribes. For example, Indian Tribes currently compete with each other for limited financial resources in many of the Tribal environmental grant programs listed under § 35.501(a) of the rule. Thus, the stability of annual grant funding for

State, interstate, and local environmental program grants (see 40 CFR part 35, subpart A) is not shared by Tribes. Indian Tribes do not currently receive and cannot rely on continuity of funding from year to year. This uncertainty in financial assistance makes long-term environmental planning difficult. Therefore, the administration of these programs by EPA requires a different approach compared to the approach used when administering an environmental program for State, interstate, or local government agencies.

EPA and many Indian Tribal governments have forged partnerships on a government-to-government basis. An important mechanism to further support these relationships was established when EPA requested and received authorization for a PPG program for Indian Tribes and Intertribal Consortia. (Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. 104–134, 110 Stat. 1321, 1321–299 (1996); Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1998, Pub. L. 105–65, 111 Stat. 1344, 1373 (1997)). PPGs allow eligible Tribes and Intertribal Consortia to combine environmental program grants into a single grant in order to improve environmental performance, increase programmatic flexibility, achieve administrative savings, and strengthen the partnerships between Indian Tribes and EPA. Environmental program grants that may be included in PPGs are listed in 40 CFR 35.501(a) and funded under EPA's State and Tribal Assistance Grant (STAG) appropriation account.

This regulation will be codified in 40 CFR part 35, subpart B, as "Environmental Program Grants for Tribes." Subpart B incorporates administrative provisions for grants formerly included in 40 CFR part 35, subparts A and Q. This regulation supplements EPA's regulation, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments," contained in 40 CFR part 31, which will apply to grants awarded under this regulation (including grants to Intertribal Consortia as defined in § 35.502, regardless of whether the Consortia are organized as nonprofit corporations under State or Tribal law). We have used the terms "Tribe" and "Intertribal Consortium" to refer to the entities eligible to receive grants throughout this subpart. Those terms are defined in § 35.502 for environmental programs that do not include their own program-specific definitions. When the definition of either term is different in a specific program provision in §§ 35.540 through 35.718 of the rule, the specific definition will govern.

IV. Requirements for All Environmental Program Grants

Sections 35.500 through 35.518 apply to all environmental program grants covered by 40 CFR part 35, subpart B, including PPGs. This rule contains changes to foster Tribal-EPA partnerships, improve accountability for environmental and program performance, and streamline administrative requirements. Some of the rule's key features are discussed below.

Tribal-EPA partnerships. To foster joint planning and priority setting, the rule explicitly requires consideration of Tribal priorities along with national and regional guidance in negotiating all grant work plans. All Tribes are provided flexibility through the work plan negotiation process, and, in particular, through their ability to organize work plan components in whatever way fits the Tribe best. However, EPA must be able to link the grant work plans to EPA's Government Performance and Results Act Goal and Objective architecture. Where appropriate, the grant work plan will reflect both EPA and Tribal roles and responsibilities in carrying out work plan commitments and there will be a negotiated process for jointly evaluating performance. Tribes applying for PPGs will have still greater flexibility as described in the PPG discussion below. The EPA Regional Administrator must consult with the National Program Manager before agreeing to a PPG work plan that deviates significantly from national program guidance.

Core performance measures. Core performance measures for Tribal programs are still evolving and may be different from those negotiated by EPA National Program Managers (NPM) with the States. When EPA has negotiated these measures with the Tribes, they will be included in national program guidance and incorporated, as appropriate, into Tribal/EPA Environmental Agreements and grant work plans as the basis for reporting requirements. Until the Tribal core performance measures are further developed, the regions should use significant work plan goals, objectives or commitments for measuring performance, as appropriate.

Accountability. The rule includes results-oriented approaches to planning and managing environmental programs. Definitions and other aspects of the rule are compatible with GPRA and reflect efforts to establish goals and objectives as well as environmental and program performance measures at both the national and Tribal levels. The rule recognizes the need for a mix of outcome (results) and output (activity) measures for management purposes. The rule encourages Tribes and Intertribal Consortia to organize their work plans around goals and objectives to reflect the new GPRA requirements.

Administrative changes. Under the rule, Tribes can negotiate funding periods of more than one year with EPA, thereby improving stability in the programs. EPA recommends, however, that funding periods not exceed five years because it is difficult to account for funds and maintain records for longer periods. The funding period of a General Assistance Program (GAP) grant cannot exceed four years. (The term "funding period" used in this preamble and 40 CFR 31.23 has the same meaning as the term "budget period" on EPA's grant and cooperative agreement and amendment forms.)

The rule streamlines some requirements and eliminates other requirements associated with post-award changes to grant work plan commitments and budgets. It replaces the requirements regarding changes found in 40 CFR 31.30. Prior written approval from EPA is still required for significant changes in a recipient's work plan commitments. Written, but not prior, approval is required for work that will result in a need for increases in grant amounts and extensions of the funding period. However, recipients beginning such work without prior, written approval do so at their own financial risk. EPA approval is no longer required for other changes in the work plan, budget, key persons, or to carry out portions of the work through subgrants or contracts unless the Regional Administrator determines, on a case-by-case basis, that circumstances warrant imposing additional approval requirements on a particular recipient.

Pre-award costs. Pre-award costs may be reimbursed under the grants without prior approval so long as they are incurred within the funding period, identified in the approved grant application, and would have been allowable if incurred after the award.

Intertribal Consortia. Under this rule, EPA will treat a group of Tribes that applies for a grant (called an Intertribal Consortium in the rule) in the same manner as a single Tribe. Thus, in the absence of clear Congressional intent to the contrary, if a Tribe is eligible for a particular grant, EPA will also treat a group of individually eligible Tribes as

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eligible for the grant. EPA believes this approach is a practical, reasonable and prudent way to help interested Tribes strengthen environmental protection when limited funding is available to support Tribal environmental programs. Tribes that form Consortia may be able to use their limited resources more efficiently and address environmental issues more effectively than they could if each Tribe separately developed and maintained separate environmental programs. Accordingly, Intertribal Consortia as defined in § 35.502, will be eligible to receive grants under the programs listed in § 35.501.

For all grants except GAP grants, all members of an Intertribal Consortium must be eligible to receive the grant and must authorize the Consortium to apply for and receive the grant. This means, for example, that for a Consortium to be eligible for a Clean Water Act section 106 grant, each member of the Consortium must establish that it is a federally recognized Tribe and that it has met the requirement for treatment in a manner similar to a State, because that is required for individual Tribes seeking section 106 grants. If a grant authority does not require Tribes to establish eligibility for treatment in a manner similar to a State to receive a grant, then the authorizing members of a Consortium need not satisfy that prerequisite.

For GAP grants, an Intertribal Consortium will be eligible if (1) a majority of the Consortium's members meet the eligibility requirements for the grant; (2) all members that meet the eligibility requirements authorize the Consortium to apply for and receive the grant; and (3) only the members that meet the eligibility requirements will benefit directly from the grant project and the Consortium agrees to a grant condition to that effect. This means that a Consortium may receive a GAP grant even if the Consortium includes Tribal governments that are not recognized as eligible for the special services provided by the United States to Indians because of their status as Indians so long as the Consortium meets the three requirements specified above. EPA decided to impose somewhat less restrictive requirements on Intertribal Consortia seeking GAP grants because the Indian Environmental General Assistance Program Act of 1992, 42 U.S.C. 4368b (IEGAPA), explicitly authorizes GAP grants to an "Intertribal Consortium," which it defines as "a partnership of two or more Indian Tribal governments authorized by the governing bodies of those Tribes to apply for and receive assistance pursuant to this section." This definition may reasonably be interpreted to include a Consortium comprised of a majority of federally recognized Tribes and a few non-recognized Tribal governments. Such a Consortium would be a partnership of federally recognized Tribes, although it would not be a partnership consisting exclusively of federally recognized Tribes. In effect, the recipient of the GAP grant to such an Intertribal Consortium would be a subset of the original Consortium consisting only of those individually eligible Tribes. The Agency is adopting this approach to meet those very rare circumstances where awarding a GAP grant to such a Consortium would be consistent with the intent of the IEGAPA.

EPA believes this approach for making environmental program grants available to Intertribal Consortia is consistent with President Clinton's Executive Order 13084, which encourages agencies to adopt "flexible policy approaches" and to respect the principle of Indian self-government and sovereignty.

Preferences for Indians, Indian organizations, and Indian-owned economic enterprises. Section 450e(b) of the Indian Education, Assistance, and Self Determination Act, January 4, 1975 (25 U.S.C. 450 *et seq.*), provides:

Any contract, subcontract, grant, or subgrant pursuant to this Act, the Act of April 16, 1934 (48 Stat. 596), as amended (25 U.S.C. 452), or any other Act authorizing federal contracts with or grants to Indian organizations or for the benefit of Indians shall require to the extent feasible—

(1) Preferences and opportunities for training and employment in connection with the administration of such contracts or grants shall be given to Indians; and

(2) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77) (25 U.S.C. 1452).

EPA determined that these preference requirements of the Indian Self-Determination Act apply to the award of grants, contracts, subcontracts and subgrants under the grant programs covered by this subpart. In the proposed regulation, EPA asked for comments on implementing this provision, but received none. Since issuing the proposed rule, EPA has determined that the preference requirements of the Indian Self-Determination Act should apply to all grants awarded to Tribes by EPA because they are awarded to Tribes pursuant to statutes authorizing grants to Indian organizations, which includes Tribes and Intertribal Consortia, or for the benefit of Indians. Therefore, the regulations governing the award of all EPA grants to Tribes at 40 CFR part 31 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments) are amended in this rule to reflect the preference requirements of the Indian Self-Determination Act and no comparable provision is included in the final rule for 40 CFR part 35, subpart B. EPA is adding to 40 CFR part 31 a new § 31.38 which provides:

Any contract, subcontract, or subgrant awarded under an EPA grant by an Indian Tribe or Indian Intertribal Consortium that meets the definition and eligibility requirements at 40 CFR part 35, subpart B shall require to the extent feasible—

(1) Preferences and opportunities for training and employment in connection with the administration of such contracts or grants shall be given to Indians, as defined in the Indian Self-Determination Act (25 U.S.C. § 405b); and

(2) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77) (25 U.S.C. 1452).

In addition, the requirements for procurement under grants are amended to include a cross reference to the new preference provision at 40 CFR 31.38. Specifically, 40 CFR 31.36(b)(1) is amended to provide:

Procurement Standards. (1) Grantees and subgrantees will use their own procurement procedures which reflect applicable State and local laws and regulations, provided that the procurement actions conform to applicable federal law, the standards identified in this section, and, if applicable, 40 CFR 31.38.

V. Performance Partnership Grants

Sections 35.530 through 35.538 contain the requirements that apply only to PPGs to Tribes or Intertribal Consortia. In a PPG, the recipient can combine funds from two or more environmental program grants into a single grant under streamlined administrative requirements. Before a Tribe or Intertribal Consortium can include funds from an EPA environmental program in a PPG, it must meet the requirements for that program with a few specified exceptions. For example, if a program

requires treatment in a manner similar to a State, the Tribe or Tribal members of a Consortium must satisfy that requirement in order to include that program's funds in a PPG. The exceptions are requirements that restrict how a specific environmental program grant can be used after award. These requirements are not appropriate to be carried over to PPGs because after funds are awarded in a PPG, they may be used for cross-media activities or strategies and do not need to be accounted for in accordance with their original program sources. However, the source of the funds is considered by the Regional Administrator in negotiating a work plan with the applicant. See §§ 35.507(a) and 35.535. Key features of the PPG rule are discussed below.

Funds and activities eligible for inclusion in a PPG. Funds for any environmental program grant listed in § 35.501 may be included in a PPG if the funds for that grant were appropriated in the same specific appropriation as the funds for PPGs. EPA will announce any changes in its appropriation acts that affect the list of programs in § 35.501.

Unlike the rule governing PPGs to States, § 35.535 of this rule allows Tribes and Intertribal Consortia to use PPG funds for any environmental activity that is eligible under the environmental programs listed in § 35.501 (except EPA delegated, EPA approved, or EPA authorized activities, which still require delegation, approval or authorization), regardless of whether a Tribe applied for or was selected for funding for that particular activity, provided that the Regional Administrator consults with the appropriate NPMs. The NPM may expressly waive or modify the consultation requirement in national program guidance. For example, if EPA found that a Tribe was not eligible for a Clean Air Act section 105 grant, but the Tribe wanted to perform air program monitoring or inspections, the Tribe could pay for those activities with PPG funds, provided that: (1) The Regional Administrator consulted with the appropriate NPMs, including those NPMs for the sources of the PPG funds (unless waived in national program guidance) and (2) the activity was included in the approved PPG work plan. The Tribe would perform these air activities using Tribal authority. To implement an EPA delegated, approved, or authorized program under a PPG, a Tribe would need the delegations, approvals, or authorizations as required under § 35.535(a). Given the wide variety of environmental activities eligible under GAP (see §§ 35.540–35.548), this will allow Tribes, as determined by the Regional Administrator, to use funds from other programs that are put into a PPG for the same wide variety of activities that are eligible for funding under GAP. Furthermore, this will allow Tribes to use GAP funds included in a PPG, to carry out activities that are eligible for funding under any of the other grant programs covered by this subpart as long as the Tribe has any EPA delegation, approval, or authorization required under § 35.535(a).

Within the framework of EPA oversight established by §§ 35.507, 35.514(a), 35.535 and national program guidance, EPA is providing Tribes with flexibility to use PPG funds for a broad variety of activities. EPA believes this approach is appropriate because Tribes need to address a broad range of environmental issues, but do not have the same access to diverse funding sources as States and, generally, Tribes must compete annually for their funds while States do not. EPA believes this approach will help achieve a key purpose of the PPG program: to provide Tribes and Intertribal Consortia with the flexibility to direct resources where they are most needed to address environmental and public health priorities. EPA will retain sufficient programmatic control because § 35.535(b) requires the Regional Administrator to consult with the appropriate NPMs before agreeing to work plans that differ significantly from National Program Guidance. For example, if a Tribe or Intertribal Consortium was selected for funding in a competition based on its proposed work plan for that grant and the Tribe or Consortium proposed a PPG work plan that would significantly modify those proposed work plan activities, then the Regional Administrator would have to consult with the NPM associated with the funding source before approving the work plan (unless waived in national program guidance). Accordingly, the Regional Administrator will be responsible for ensuring that the Tribes and Intertribal Consortia meet the basic requirements of programs which provide funds for the PPG before the Tribes use funds for other important activities.

EPA intends to evaluate the flexibility provided under the rule regarding the activities eligible for funding under a PPG. After the third year of implementing the program, but before the end of the fifth year, the Agency will evaluate the environmental benefits of this flexibility as compared to the costs, which may include reduced accountability for funds and outcomes. Based on that evaluation, the Agency will determine whether to continue to allow Tribes to use PPG funds to perform activities under programs for which they are not eligible to receive a grant. If the Agency determines that a change in the regulation is appropriate, it will revise the regulations appropriately.

Administrative flexibility. A primary advantage of PPGs is the administrative flexibility provided to all PPG recipients. A PPG requires only a single application, work plan, and budget. Once funds are awarded in a PPG, the Tribe or Intertribal Consortium can direct the funds as needed to achieve work plan commitments and does not need to account for funds in accordance with their original program sources. However, EPA must be able to link the grant work plans to EPA's GPRA goal and objective architecture. These features also make it possible for Tribes to negotiate a work plan that includes cross-media or innovative strategies for addressing environmental problems.

Cost share. The PPG cost share is the sum of the cost shares required for all individual program grants included in the PPG in accordance with 40 CFR 35.536(b) and (c) for each individual program grant included in the PPG. EPA will not require Tribes and Intertribal Consortia to provide a PPG cost share for funds from programs which do not require cost shares, such as GAP. (Cost sharing requirements for individual programs are found under §§ 35.540 through 35.718.) For funds from programs with a cost share requirement of five percent or less under the provisions of §§ 35.540 through 35.718, the PPG cost share will be the same as the cost share for the individual programs, as identified in §§ 35.540 through 35.718. For funds from programs with a required cost share greater than five percent, EPA will require Tribes to provide a cost share of five percent; however, after the first two years, the Regional Administrator will determine through an objective assessment whether the Tribe or the members of an Intertribal Consortium meet socio-economic indicators that demonstrate the ability of the Tribe or the Intertribal Consortium to provide a cost share greater than five percent. If the Regional Administrator determines that the Tribe or members of the Intertribal Consortium meet such indicators, then the Regional Administrator will increase the required cost share up to a maximum of 10 percent. If the Regional Administrator determines that the Tribe or the members of the Intertribal Consortium do not meet such indicators, then the cost share will remain at five percent.

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(The required cost share for the Tribal Water Pollution Control Grant Program (Clean Water Act, section 106) is five percent; therefore, it is not one of the grant programs under which the cost share could be raised to 10 percent through the Regional Administrator assessment and determination process.)

Further, the Regional Administrator may waive the required PPG cost share at the request of the Tribe or Intertribal Consortium if the Regional Administrator determines, based on an objective assessment of socio-economic indicators, that fulfilling the cost share requirement would impose undue hardship on the Tribe or members of the Intertribal Consortium. EPA received several comments on the cost sharing provisions of the proposed rule. The comments are discussed in Section VII of this preamble.

In the preamble to the proposed rule, EPA invited suggestions for the socio-economic indicators for approval of the lower cost share and waiver of cost share, as well as suggestions for how the cost share for Intertribal Consortia should be calculated. EPA did not receive any recommendations for the socio-economic indicators.

VI. Indian Environmental General Assistance Program and Performance Partnership Grants

An important and unique environmental program available only to Tribes and Intertribal Consortia is the Indian Environmental General Assistance Program (GAP) (40 CFR 35.540 *et seq.*) This program was created to assist Indian Tribes in developing the capacity to manage their own environmental protection programs. GAP offers the opportunity for Tribes to develop integrated environmental programs, to develop capacity to manage specific programs that can be delegated by EPA, and to plan, develop, and establish a core program for environmental protection. It also provides the opportunity for Tribes to define and develop administrative and legal infrastructures, and to undertake additional activities to plan, develop, and establish environmental programs within a simplified administrative framework.

GAP funds can be used more flexibly than categorical environmental program funds. EPA recognizes the Tribes' need for flexibility in using limited resources available for protecting Tribal environments, but believes that this need for flexibility must be balanced with the Agency's goals of establishing a strong Tribal environmental presence in Indian country and of diversifying financial resources available to Tribes for the administration of comprehensive environmental programs. GAP funds are primarily available for and critical to the development of sustainable, integrated Tribal environmental programs. The long-term goal of developing and maintaining an adequate level of funding for Tribal environmental programs will be best served not by increasing the number of activities that are funded by GAP, but rather by expanding and diversifying the use of various categorical environmental programs funds, in addition to the use of GAP funds.

When Congress authorized the PPG program, it allowed GAP funds to be included in such a grant. However, to balance competing interests in the use of GAP funds, EPA encourages Tribes and Intertribal Consortia to continue to use GAP funds, at least in the first instance, for the development of Tribal capacity to manage environmental programs and not to use these funds for media-specific environmental activities. EPA believes that the overriding value of GAP lies in its ability to assist Tribes in the development of their environmental program capacity. This original and primary purpose of GAP has not been fully realized since some Tribes have not yet developed an environmental program capacity. Including a GAP grant in a PPG should not result in a reduction of EPA media-specific environmental program assistance available to Indian Tribes and Tribal Consortia.

VII. Response to Comments

EPA received 16 letters commenting on the proposed rule. In general, the comments supported the rule as written but suggested several changes. Specifically:

1. Three commenters addressed EPA's intention to include regulations for the Hazardous Waste and Underground Storage Tank programs in the final rule. One commenter asked that the programs be added to the rule immediately while two asked that the provisions for these programs be made available for public comment first.

EPA decided to include the Hazardous Waste and Underground Storage Tank Grant Programs in the final rule to provide Tribes with an expedited opportunity to include funds from these programs in a PPG and to allow Tribes to use PPGs for activities eligible for funding under these grant programs even if they do not include funds from these programs in a PPG (consistent with the limitations at § 35.535). EPA believes that giving Tribes the option, as soon as possible, of including Hazardous Waste and Underground Storage Tanks grants in a PPG provides Tribes with greater flexibility in building a partnership for environmental protection than not including the programs in subpart B at this time. Furthermore, as part of its regulation review process EPA provided copies of the draft final rule to many Tribal representatives including those who serve on the EPA Tribal Operations Committee (TOC), the National Tribal Environmental Council (NTEC) and the Tribal Association of Solid Waste and Emergency Response (TASWER). Finally, as noted above, comments on this rule, although final, may be submitted to the person identified above in the **FOR FURTHER INFORMATION** section above. Although EPA does not anticipate doing so, EPA could amend this rule in response to comments without having to go through a subsequent notice and comment rule making. This is because rules regarding the award and administration of grants are explicitly exempt from the notice and comment requirements of the Administrative Procedure Act APA (5 U.S.C. 553(a)(1)).

2. One commenter noted that Section VII of the Preamble included a reference to "State" work plans and it should refer to Tribal work plans.

EPA apologizes for any confusion this mistake may have caused. EPA will substitute the words Tribe, or Tribal for State in this paragraph.

3. Two commenters suggested the term "Tribal/EPA Environmental Agreement" (TEA) should not be defined in the rule because TEAs are not intended to bind Tribes to any particular substantive requirements. The commenters stated that the definition would tend to increase rather than streamline requirements.

EPA agrees that the decision whether to negotiate a TEA is discretionary. Nevertheless, EPA believes it is appropriate to include the definition since a TEA may be used as a work plan under § 35.507(c). EPA is today revising the definition of Tribal/EPA Environmental Agreement that was included in the proposed rule to be more consistent with Administrator Browner's 1994 Action Memorandum for the EPA Indian Program and the American Indian Environmental Office's template and guidance on TEAs which views these as dynamic rather than static documents. To the extent a TEA is used as the basis for a PPG work plan, the version used would be binding for the purposes of the agreement. For an explanation of EPA's work with Tribes to develop TEAs, please see Administrator Browner's July 12, 1994, Tribal Operations Action Memorandum and American Indian Environmental Office Director's July 1995 TEA Template. Both of these documents are available at: *http://www.epa.gov/indian*, or contact Bob Smith at EPA's American Indian Environmental Office at (202) 260–8202.

Including an appropriate definition for a TEA in the regulation does not impose any requirement for a Tribe to have a TEA, or add new requirements for the content of a TEA. Further, there is no requirement that a TEA be developed. The intention of § 35.507(c) is to provide added flexibility for EPA and a Tribe to agree to use a TEA or a portion of the TEA as the work plan or part of the work plan for an environmental program grant: (1) If they choose to do so; and (2) if the portion of the TEA that is to serve as the grant work plan clearly identifies and distinguishes work plan activities from other portions of the TEA and meets the work plan requirements in § 35.507(b). EPA reasoned that, in some cases, the development of a work plan could actually be made easier if parts of it had already been formulated when the Tribe developed its TEA.

4. Three commenters expressed concern about § 35.504 which will allow Intertribal Consortia to receive grants under all of the grant programs covered by this rule. The commenters maintain that EPA should not award grants to Consortia because it might jeopardize the autonomy of Tribes, conflict with an individual Tribe's proposals, or result in the duplication of activities or performance of activities that are not supported by all members of the Intertribal Consortium.

EPA understands these concerns and has modified the final rule to ensure that such consequences do not result from the award of grants to Intertribal Consortia. Section 35.502 defines Intertribal Consortium as "a partnership between two or more Tribes that is authorized by the governing bodies of those Tribes to apply for and receive assistance under one or more of the programs listed in § 35.501," and § 35.504(a) provides that "an Intertribal Consortium is eligible to receive a grant under the authorities listed in § 35.501 only if the Consortium demonstrates that all members of the Consortium * * * authorize the Consortium to apply for and receive assistance." The definition of Intertribal Consortium in the proposed rule also provided that "[a] Consortium must have adequate documentation of the existence of the partnership and the authorization to apply for and receive assistance." Thus, an Intertribal Consortium must be able to provide some documentary proof that a Tribe has authorized it to apply for and receive a specific grant on the Tribe's behalf.

To clarify the eligibility and documentation requirements, EPA made a number of changes in the final rule. First, EPA moved the documentation requirements from the definition of Intertribal Consortium to the section on eligibility requirements. In addition, EPA clarified that the documentation must show that all members of the Consortium (or all eligible members of the Consortium in the case of a GAP grant) authorize the Consortium to apply for and receive the grant for which the Intertribal Consortium has applied: The final rule also makes it clear that Intertribal Consortia must both "have" this documentation and submit it to EPA in order to be eligible for a grant award as a Consortium. The documentation of the member Tribes' authorization of the Consortium should specify the period of time for which the authorization is effective without further action by the authorizing Tribe and whether the authorization applies to particular grants or all grants for which the Consortium may apply. Members of a Consortium may impose other requirements on their Consortium to ensure that the Consortium cannot act on their behalf without their authorization. EPA believes that these provisions, as modified in the final rule, will ensure that grants to Consortia do not jeopardize the autonomy of a Tribe, conflict with a Tribe's own proposals, or involve activities not supported by all Tribes that are members of the Consortia. In addition, EPA's review of work plans will further reduce the possibility that Tribes and Intertribal Consortia carry out duplicative activities.

5. Three comments concerned the provisions related to changes in assistance agreements after award. One stated EPA should reduce the number of small changes required, especially in the GAP program with respect to the grant budget.

EPA believes this regulation will eliminate the need for frequent budget revisions for such small changes as unanticipated fluctuations in travel, lodging, or office equipment prices. Those changes will not have to be reported or require prior approval unless the Regional Administrator determines otherwise in specific cases. Section 35.514(c) states that recipients do not need to obtain approval for changes in budgets unless the Regional Administrator determines additional approval requirements should be imposed on a specific recipient for a specified period of time. Amendments to environmental program grant amounts and extensions of the budget period still, however, require approval from the Regional Administrator under § 35.514(b).

Two commenters suggested that EPA define "significant" as used in § 35.514(a) and explain the circumstances under which the Regional Administrator might determine that additional approval requirements should be imposed in § 35.514(c).

Section 35.514 requires recipients to obtain the Regional Administrator's prior written approval before making significant changes to the grant work plan or budget after the work plan has been negotiated. Under the Uniform Administrative Regulations for Grant and Cooperative Agreements to State and Local Governments (40 CFR part 31), Tribes and Intertribal Consortia would also be required to get EPA's prior written approval for "any revision of the scope or objectives of the project (regardless of whether there is an associated budget revision requiring prior approval)" (40 CFR 31.30(d)(1)). EPA believes that for the continuing environmental program grants covered by this rule, prior written approval for changes should be necessary only for significant changes, and that the grantee, with assistance from the EPA project officer, if necessary, is in the best position to distinguish significant from insignificant changes in the context of its particular work plan. Further, defining the term would reduce management discretion and flexibility which we believe are essential to the regulation. Accordingly, EPA has decided not to define "significant". If there is any question as to whether a post-award change in the work plan is significant, the grantee is encouraged to consult with the EPA project officer either during work plan negotiations or before making the change.

These commenters also asked EPA to explain the circumstances under which the Regional Administrator might determine that additional approval requirements should be imposed in § 35.514(c).

Section 35.514(c) provides that no approval is required for changes other than those changes described in § 35.514(a) and (b), unless the Regional Administrator determines that approval requirements should be imposed on a specific recipient for a specific period of time. Thus, § 35.514(c) eliminates requirements for that category of changes, but gives the Regional Administrator the authority to impose them on a case-by-case basis. There are a variety of circumstances which could lead EPA to impose such requirements.

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For example, the Regional Administrator might determine that additional approval requirements should be imposed when it is determined the additional requirements are necessary to ensure proper management of EPA grants because the recipient has had a history of poor performance and corrective actions directed by audits.

6. Two comments asked that EPA define "cumulative effectiveness" and "sufficient progress" as used in § 35.515.

Section 35.515 describes the process developed by the Regional Administrator and the Tribe or Intertribal Consortium for jointly evaluating a recipient's performance under the grant in accordance with § 35.515(a). Paragraph (b) of § 35.515 provides, in pertinent part, that "the evaluation process must provide for * * * a discussion of the cumulative effectiveness of the work performed under all work plan components". Paragraph (c) states that "if the joint evaluation reveals that the recipient has not made sufficient progress under the work plan, the Regional Administrator and the recipient will negotiate a resolution that addresses the issues". The phrase "cumulative effectiveness" in the context of § 35.515(b) refers to how effectively the recipient carried out the work under all of the work plan components, taken together. The phrase "sufficient progress" in the context of § 35.515(c) is a jointly agreed upon assessment of accomplishments as measured against the work plan commitments.

EPA believes that a regulatory definition of these terms would significantly restrict the flexibility afforded both Regional Administrators and applicants under § 35.515, particularly since the regulation contemplates a jointly developed process for jointly evaluating and reporting progress and accomplishments under the work plan.

7. Two commenters state the Administrator should not be able to use a guidance document to delete a program from coverage under a PPG.

Section 35.533 provides that the Administrator may in guidance or in regulation describe subsequent additions, deletions, or changes to the list of environmental programs eligible for inclusion in PPGs. EPA grant guidance may include rules (as "rule" is defined by the Administrative Procedure Act, which explicitly exempts grant related rules from notice and comment rule making requirements). There may be changes in the list of environmental programs eligible for inclusion in a PPG as a result of EPA's annual appropriation act and Tribes will need to know about those changes as soon as possible since they will take effect at the start of the fiscal year. Thus, EPA believes it is important to be able to inform grantees of such changes quickly in a guidance document rather than in a rule. Any changes in the list of environmental programs will be published in the **Federal Register**.

8. One commenter supported the cost sharing requirements included in the proposed regulation while several stated that EPA should reduce the cost share required under PPGs to zero (see § 35.536).

The formula will reduce the cost share from current levels for Tribes that move grants with matches greater than five percent into a PPG. EPA carefully considered the question of further reductions in the cost share for Tribal recipients and concluded that some investment by recipients is generally appropriate to expand the ability of EPA and its partners to protect public health and the environment from pollution. Section 35.536(d) also authorizes the Regional Administrator to waive the cost share requirement at any time upon request by the Tribe or Intertribal Consortium, if the Regional Administrator determines the cost share would impose undue hardship. EPA notes that PPGs and many of the Agency's grant programs allow for recipients to meet the cost share requirements with in-kind services (see 40 CFR 31.24).

9. One commenter expressed concern that PPGs do not work well for Tribes because Tribal grants are not awarded at the same time in a fiscal year, causing the Tribes and EPA to continually update the PPG. The commenter also expressed concern that certain grants are not eligible for the PPG, including solid waste and emergency response grants.

Finally, the commenter stated that: "It seems as though there is a[n] undercurrent of mistrust by Regional program offices, because of the newness of PPG's to Tribes, that fuels the conception that Tribes are not capable of this type of grant management." The commenter expressed concern that EPA is scrutinizing the grants management practices of Tribes more than those of States.

The concern raised by the commenter about the timing of grant awards is valid. EPA hopes that the opportunity to streamline administrative procedures in a PPG will provide an incentive for closer alignment of funding cycles in the Agency's grant programs.

Under the legislation authorizing the PPG program (Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. 104–134, 110 Stat. 1321, 1321–299 (1996); Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1998, Pub. L. 105–65, 111 Stat. 1344, 1373 (1997)), EPA has made as many environmental program grants as possible eligible for inclusion in a PPG. With this final rule, funds from all 17 environmental program grants available to Tribes in the Agency's earmark for multi-media or single media pollution prevention, control and abatement and related activities, which are in the "State and Tribal Assistance Grant" (STAG) appropriation account, may be included in PPGs. Only funds included in that particular earmark within the STAG account are available for inclusion in PPGs because the statutory authority to award a PPG is limited to those funds. Funds from other EPA appropriations, such as those for Superfund emergency response grants are not included in the earmark. The programs that are funded under this regulation are those listed in § 35.501. EPA does not currently have a grant program for continuing solid waste programs. Under this rule, however, Tribes may use GAP funds to develop and implement solid waste programs (see § 35.545).

EPA has traditionally received funding for its grant programs on a media-specific basis and reported to Congress on program accomplishments similarly. The concerns raised by the commenter regarding "additional scrutiny" and "an undercurrent of mistrust" may reflect the challenge (and growing pains) associated with adopting a new approach that allows funds appropriated by Congress on a media-specific basis to be merged into a PPG. The fact that, due to funding limitations, many EPA programs award grants to Tribes on a competitive basis, rather than through an allotment process, may compound the difficulty of moving from individual Tribal grants to PPGs.

EPA believes its requirements for State and Tribal grants administration are similar under subparts A and B. However, EPA has recognized that there are unique features to Tribal grant programs which make implementation of a PPG more challenging. For example, in addition to the competition for funds described above, an individual Tribe will generally have access to fewer EPA grants on an annual basis than EPA's State partners. Therefore, EPA has provided the opportunity for more flexibility in the use of Tribal grants funds. In particular, EPA is allowing Tribes and the Regional Administrator to develop a PPG work plan that may include activities that are eligible for funding under any of the PPG-eligible grant programs (within certain limitations), even if funds from certain grant programs were not included in the PPG. In contrast, EPA is requiring States to receive funding from a grant program in order to use PPG funds for activities under that program.

10. One commenter opposed award of GAP grants to Intertribal Consortia because GAP grants are "awarded to build capacity to administer environmental programs on Indian lands by providing general assistance to plan, develop and establish the capability to implement environmental programs in Indian Country." The commenter stated that such capacity building should be undertaken by individual Tribes, not by Consortia.

EPA disagrees. Because we have defined an Intertribal Consortium as a partnership between two or more Tribes (defined in this rule generally as Indian Tribal governments), GAP grants to Intertribal Consortia will assist those Tribes that are members of the Consortium to build capacity to administer environmental programs. Furthermore, the Indian Environmental General Assistance Program Act (42 U.S.C. 4368b) explicitly authorizes EPA to award grants to Intertribal Consortia. EPA prefers not to restrict the eligible recipients of GAP grants further than the statutory authority for GAP grants. Therefore, EPA has not changed the final rule in response to this comment.

11. Two commenters asked for clarification of what constituted "otherwise available funds" which would prevent funding under the Clean Air Act section 105 referenced in § 35.576(d). Section 35.576(d) provides that "[t]he Regional Administrator will not award section 105 funds unless the applicant provides assurance that the grant will not supplant non-federal funds that would otherwise be available for maintaining the section 105 program."

EPA intended § 35.576(d) to refer only to Tribes and Intertribal Consortia that are eligible for financial assistance under § 35.573(b) (for Tribes that have not established eligibility for treatment in a manner similar to a State) and it is a corollary to the maintenance of effort requirement applicable to such Tribes. It does not apply to Tribes that are eligible for a section 105 grant under § 35.573(a) (for Tribes that have established treatment as a State). Non-federal funds that would otherwise be available "for maintaining the section 105 program" would include Tribal funds in an amount equal to that which the Tribe expended on the Air 105 program in the previous year. To clarify that this section applies only to Tribes that establish eligibility under § 35.573(b), EPA added the phrase "For Tribes and Intertribal Consortia that are eligible for financial assistance under § 35.573(b) of this subpart" to the beginning of this paragraph. We also changed the numbering of the section as follows: Section 35.576(b) became § 35.576(a)(1); § 35.576(c) became § 35.576(a)(2) and § 35.576(d) became § 35.576(b).

12. Two commenters requested that the limit on administrative costs in the Nonpoint Source Program (§ 35.638(c)) be clarified. They asked, does the 10 percent limit apply to Tribal general administrative costs or to general and administrative costs associated with the program? If the former, they ask that a phrase, "unless the applicant has an indirect cost rate agreement," be added at the end of the sentence containing the limitation. If the latter, they express concern that this limitation is so severe as to result in an inability of the Tribes to administer the program at all.

EPA does not have the discretion to remove the limitation at § 35.638(c) from the award of grants under section 319 of the Clean Water Act because it is required by law. This limitation is a restatement of the statutory limitation established by section 319(h)(12) which provides that "administrative costs * * * charged against activities and programs carried out with a grant under this subsection shall not exceed 10 percent of the amount of the grant in such year, except that the costs of implementing enforcement and regulatory activities, education, training, technical assistance, demonstration projects, and technology transfer programs shall not be subject to this limitation." It applies to grants awarded under section 319 to both States and Tribes. The limitation does not apply to Tribal general administrative costs because general administrative costs that are not associated with a grant program cannot be charged to a grant. Only administrative costs, including allowable indirect costs, that are reasonable and necessary to carry out a grant program or project can be charged to that particular grant. However, it should be noted that section 319(h)(12) specifically exempts the costs of implementing enforcement and regulatory activities, education, training, technical assistance, demonstration projects, and technology transfer programs. The experience of States, Territories, and Tribes that have received section 319 grants is that this limitation, defined as it is in the statute, has not posed any significant obstacle to the use of section 319 funds.

13. Two comments strongly supported the increase in funding to be available to Tribes and Intertribal Consortia for drinking water programs (§ 35.673). The commenters agreed with the recent focus on achieving safe and clean drinking water throughout Indian Country and appreciate the recognition of capacity-building needs in respect to Tribal water systems. One commenter asked that the increase of up to seven percent in the Public Water System Supervision (PWSS) program Tribal reserve under § 35.673 be restated to provide for a fixed amount of seven percent. Two other comments strongly opposed the increase. They fear that increasing the Tribal reserve will cause a decrease in PWSS grants available to primacy States. In addition, they argue there should not be an increase in the Tribal reserve since State programs are currently underfunded.

EPA understands the concerns about the increase in the PWSS Tribal Reserve. However, we specifically asked Congress for additional PWSS funds to help Tribes build their capabilities in the PWSS program and to help Tribes meet new requirements that are needed to obtain Drinking Water Infrastructure Tribal Set-Aside grants. These new requirements, such as operator certification and capacity development, are necessary to successfully run a PWSS program as well as to obtain grants. Since Fiscal Year 1998 EPA has received an additional $3,780,500 in the PWSS Program for these purposes. For the past two years, EPA has deviated from the three percent regulatory limit on the amount of PWSS funds reserved for Tribes. We are increasing the regulatory limit on PWSS funds reserved for Tribes because Tribes need these funds to comply with new requirements imposed by the Safe Drinking Water Act Amendments of 1996.

Tribes do not have the same opportunity as States have to use a portion of their infrastructure funding to meet these new requirements. Thus far, States have set-aside more than $91 million from their Drinking Water State Revolving Fund capitalization grants for activities supporting drinking water programs (including PWSS, capacity development and operator certification programs) and are expected to set-aside more funds for these purposes in the future. The only additional funds that have been made available for Tribes is the $3,780,500 million that has been added to the PWSS grants.

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The increase in the funds reserved for Tribes is not intended to take funds away from States, but rather to continue to fund the Indian programs at the current level without the need to deviate from the regulations. EPA may not necessarily reserve seven percent of the annual appropriation for PWSS grants; the regulation only provides that "up to" seven percent of the PWSS funds shall be reserved for Tribes. This provides EPA flexibility to adjust the amount of the Tribal reserve upward or downward. Thus, for example, if Congress reduces the appropriation for PWSS grants in the future, then EPA may decide to reduce the Tribal reserve to balance it with the need for funding for the States. EPA will work with stakeholders, including States and Tribes, in establishing an equitable allocation.

14. Two commenters asked that the Agency make the regulation effective for Fiscal Years 2000 and 2001 and not retroactively.

EPA agrees. The regulation will apply to new grants awarded 30 days after the regulation is published. EPA will not apply this rule to grants that have already been awarded. A Tribe may, however, close out an existing grant and carry over funding to a new grant awarded under this subpart after the regulation is published.

15. One commenter expressed concern that the definition of "Indian country" in subpart B may limit the use of certain grant funds that could otherwise be available to address pollution threats to Usual and Accustomed Areas (areas where certain treaty-reserved fishing rights are exercised) and in ceded lands.

To avoid the appearance of unnecessarily limiting its grant authorities, EPA has reviewed the regulations and removed use of the term "Indian country" in four provisions: § 35.516 (Direct Implementation); § 35.540 (Purpose of the Indian Environmental General Assistance Program); § 35.545(b) (Eligible Activities); and § 35.570 (Air Pollution Control Grants). The change to § 35.516 makes this provision consistent with parallel language in the State rule. The changes to §§ 35.540 and 35.545(b) are consistent with the Indian Environmental General Assistance Program Act 42 U.S.C. 4368b. The change to § 35.570 is consistent with Clean Air Act provisions governing use of these grant funds.

16. One commenter stated that the boundaries of many Tribes are constantly being defined and redefined, and wanted to know whether the PPG is sufficiently flexible to accommodate these changes.

To the extent a Tribe or Intertribal Consortium must identify particular land areas in order to be eligible for a grant (either a single media grant or a PPG), and it wants to perform work in an area not identified in the original application, the Tribe or Intertribal Consortium will need to demonstrate that it continues to meet the requirements for receiving grant.

VIII. Other Changes in the Proposed Rule

EPA made a several changes to the proposed rule to clarify certain provisions even though the provisions were not the subject of comments.

1. There is no substantive difference between the definition of Tribe in the GAP provisions of the proposed rule (§ 35.542) and the definition of Tribe at 35.502 which applies to subpart B generally ("Definition of terms"). Section 35.542 of the proposed rule defined "Tribe" as "[a]ny Indian Tribe, band, nation, or other organized group or community including any Alaska Native village or regional or village corporation (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act (43 U.S.C. 1601, *et seq.*)), which is recognized as eligible for the special services provided by the United States to Indians because of their status as Indians." 64 FR 40084, 40097 (1999). This definition was in turn based on the definition of "Indian Tribal government" in the Indian Environmental General Assistance Program Act (IEGAPA), which authorizes GAP grants. 42 U.S.C. § 4368b(c)(1).

The definition of Tribe in § 35.502 of the proposed and final rules provided that "Except as otherwise defined in statute or this subpart, Indian Tribal Government (Tribe) means: any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village, which is recognized as eligible by the United States Department of the Interior for the special services provided by the United States to Indians because of their status as Indians."

The inclusion of Alaska Native regional or village corporations in the definition of Indian Tribal government in IEGAPA and the proposed rule has created some confusion because regional and village corporations are not governments, and they are not recognized as eligible for the special services provided by the United States to Indians because of their status as Indians. Since Alaska Native regional and village corporations are not federally recognized governments, they are not eligible for GAP grants.

In the proposed rule, the only difference between the definitions of Tribe in §§ 35.542 and 35.502 was the inclusion of Alaska native regional and village corporations in § 35.542. However, as discussed above, there is no substantive difference between the definitions because no Alaska native regional and village corporation is in fact eligible for a GAP grant as a "Tribe". As there is no need for a GAP-specific definition of Tribe, we have omitted the definition of Tribe for GAP grants at § 35.542, and the general definition at § 35.502 will apply instead.

Although Alaska Native regional and village corporations are not eligible for GAP grants, an Alaska Tribe receiving a GAP grant may award a subcontract or subgrant to a village or regional corporation (just as they could to any other organization), in accordance with EPA's regulations governing subcontracts and subgrants.

2. The regulation uses the term "Regional Administrator" throughout. However, grants subject to these provisions may also be approved and awarded by officials in EPA Heaquarters from time to time. Accordingly, the final rule has been modified by adding § 35.501(c) to clarify that this subpart applies and the phrase "Regional Administrator" means "Assistant Administrator in the case of grants awarded from EPA headquarters.

3. We revised § 35.576 to make it clear that while applications for Section 105 Air Pollution Grants must indicate recipients will meet the Maintenance of Effort (MOE) provision of the program (§§ 35.576(a)), recipients' actual expenditures must actually meet the MOE level. We have added section § 35.576(a)(2) to make clear the Regional Administrator must take action to recover the grant funds, if expenditures do not meet the required level.

4. We revised § 35.708(h) to make clear that Indoor Radon program grant funds under section 306 of TSCA may be used to cover the costs of Tribal and Intertribal Consortium proficiency rating programs, but not a federal one.

5. After publishing the proposed rule, EPA reevaluated the eligibility requirements for Intertribal Consortia seeking GAP grants (section 35.504). That provision is intended to allow a GAP grant to a Consortium that includes a majority of recognized and a minority of non-recognized Tribes (it was not intended to allow a GAP grant to a Consortium that includes non-Tribal organizations and businesses). While EPA reaffirms its determination to award GAP grants to Intertribal Consortia made up of a majority of federally recognized Tribes and a minority of non-federally recognized Tribes, EPA has modified the eligibility requirements for Intertribal Consortia seeking GAP grants in order to further ensure that only those members of an Intertribal Consortium that are federally recognized Tribes directly benefit from the grant.

6. The Clean Air Act prohibits the use of revenue collected under a Title V operating permit program to meet the cost share requirements of an air pollution program under section 105 of the Clean Air Act. We added a new paragraph (c) to § 35.575 to make this clear.

IX. Implementing GPRA

EPA has developed an integrated approach to implement GPRA, the Chief Financial Officers Act (CFOA), and the Federal Financial Management Improvement Act of 1996 (FFMIA). These laws provide EPA with a framework to demonstrate to Congress and the taxpayers the costs to the federal government of EPA's program accomplishments or outcomes. Tribes and Intertribal Consortia, by virtue of authorized or delegated program authorities and as recipients of EPA grant funds, play an integral part in achieving those goals and objectives. Thus EPA's reports of Agency resources associated with results-based outcomes will incorporate—at the GPRA goal, objective, and subobjective level—expenditures incurred in the form of payments to the Tribes under grants and cooperative agreements. In order to comply with the Paperwork Reduction Act and the federal government's general grant regulations, EPA also has a responsibility to minimize additional administrative reporting requirements and costs borne by the Tribes. In addition, under current regulations EPA generally may not impose accounting requirements on Tribes beyond those currently required by 40 CFR part 31.

EPA, therefore, will use the budget information that Tribes and Intertribal Consortia provide in grant applications as a basis for linking the Agency's actual expenditures with EPA's results-based accomplishments or outcomes. EPA will be able to rely on Tribal budget information sufficiently to determine the costs of EPA's results-based outcomes according to the requirements of this rule:

(1) Tribes and Intertribal Consortia provide the program budget information required as part of the application (see § 35.507(b)(2)(ii));

(2) EPA and the recipients explicitly define work plan goals, objectives, outcomes, and outputs, as well as the program flexibility contained in the work plan (see § 35.507(b)(2)(i)); and

(3) Recipients report back on work plan accomplishments (see § 35.515).

The rule will ensure these three requirements are met. Additionally, in accordance with § 35.514(a), recipients may make significant changes to the work plan commitments only after obtaining the Regional Administrator's prior written approval. The regional office, in consultation with the recipient, will document these revisions including budgeted amounts associated with the revisions. If necessary, the EPA funding office will make adjustments to original budget linking work plan components to EPA's goal and objective architecture. Once these requirements are met, they provide a reasonable basis for associating the costs of its grants with the Agency's results-based outcomes.

EPA in consultation with recipients, is responsible for cross-walking the Tribal budget information (grant application and work plan data) into the GPRA goal, objective, and subobjective architecture. If a grant is subsequently amended to reflect significant adjustments to work plan commitments, the region will consult with the Tribal government to develop an estimate of the budget associated with the revision so that it can be reflected in regional office GPRA reporting. Cross-walk information is developed by EPA during the work plan/PPA negotiations process with the Tribe or Intertribal Consotium.

X. Program Specific Provisions

Requirements applicable to each environmental grant program, such as the requirements regarding eligibility and cost share, are located in 40 CFR 35.540 through 35.718.

Programs not specifically available to Tribes. Sections 28 and 306 of the Toxic Substances Control Act (TSCA) and section 6605 of the Pollution Prevention Act (PPA) provide explicit authority for grants to States, but are silent regarding grants to Tribes. This rule reflects EPA's determination that those statutes may be interpreted to also authorize grants to Tribes for radon abatement (TSCA section 306) and toxic substances compliance monitoring programs (TSCA sections 28), and reaffirms EPA's determination that Tribes are eligible for Pollution Prevention Grants under section 6605 of the PPA (*see, e.g.*, 56 FR 11553 (1991)).

Previously, EPA determined that it has the authority to approve Tribal lead-based paint abatement certification and training programs and make grants to Tribes under section 404(g) of TSCA for the development and implementation of such programs even though TSCA makes no mention of Tribes. 61 FR 45778, 45805–808 (1996). The Agency reasoned that its interpretation of TSCA is governed by the principles of *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council*, 467 U.S. 837 (1984) and that because Congress has not explicitly stated its intent in adopting the statutory provision, the Agency could adopt an interpretation which in its expert judgment is reasonable in light of the goals and purposes of the statute. EPA opined further that since TSCA did not define a role for Tribes, there was an ambiguity in Congressional intent and therefore, the Agency's interpretation of TSCA to allow Tribes to apply for program authorization was permissible under *Chevron*. EPA reasoned further that this interpretation is consistent with Supreme Court precedent holding that limitations on Tribal sovereignty must be "unmistakably clear," *Montana* v. *Blackfeet Indian Tribe*, 471 U.S. 759 (1985), and that statutes are to be construed liberally in favor of the Indians, with ambiguous provisions interpreted for their benefit. *County of Yakima* v. *Yakima Indian Nation*, 502 U.S. 251, 268 (1992). Finally, EPA noted that allowing Tribes to apply for program authorization is consistent with the general principles of federal Indian law "encouraging Tribal independence," *Ramah Navaho Sch. Bd.* v. *Bureau of Revenue*, 458 U.S. 832, 846 (1985), and the Agency's Indian policy which states that environmental programs in Indian country will be implemented to the maximum extent possible by Tribal governments. In light of these principles, EPA reasoned that Tribes are also eligible for grants to develop and implement lead-based paint certification and training programs under section 404(g) of TSCA.

Consistent with the reasoning that warranted EPA's determination with respect to Tribal lead program approval and grant authority, EPA interprets sections 28 and 306 of TSCA and section 6605 of PPA to authorize grants to Tribes as well as States, even though there is no program approval or authorization associated with the grant programs for radon abatement, toxics substance compliance monitoring, or pollution prevention incentives. While Congress did not expressly provide a role for Tribes in either TSCA or PPA, both statutes were clearly intended to have comprehensive, nationwide coverage—including the provisions regarding financial assistance for these programs. EPA does not believe that

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Congress intended the Agency to provide grants exclusively to States and thereby leave Tribal lands without the benefit of grant assistance for these programs, since the problems and goals they address—toxic substances, radon abatement and pollution prevention—are relevant throughout the nation in both State and Tribal areas. Therefore, EPA has determined that it is appropriate to provide grants to Tribes for Radon Abatement programs under section 306 of TSCA, Toxics Substances Compliance Monitoring programs under section 28 of TSCA, and Pollution Prevention Grant programs under section 6605 of PPA.

In order to be eligible for a grant under TSCA section 28, TSCA section 306, or PPA section 6605, a Tribe or each member of an Intertribal Consortium must establish eligibility for treatment in a manner similar to a State by demonstrating that it:

(1) Is recognized by the Secretary of the Interior;

(2) Has an existing government exercising substantial governmental duties and powers;

(3) Has adequate authority to carry out the grant activities; and,

(4) Is reasonably expected to be capable, in the Regional Administrator's judgment, of administering the grant program.

If the Administrator has previously determined that a Tribe has met the prerequisites in paragraphs (1) and (2) for another EPA program, the Tribe need provide only that information unique to the particular program required by paragraphs (3) and (4).

Public water system supervision Tribal reserve. Until now, EPA's regulation (40 CFR 35.115(g)) has provided that EPA annually reserve up to three percent of each year's Public Water System Supervision (PWSS) funds for use on Indian lands. The Agency is increasing the limit to allow a reserve of up to seven percent. This increase will provide needed funds for the Tribal PWSS program without affecting States' current funding. (See also the response to comments on this issue.)

The Tribal reserve is used for two purposes: to allow EPA to directly implement the PWSS program on Tribal lands; and to assist Tribes with developing PWSS primacy programs. The three percent ceiling, established in 1988, was EPA's estimate of the amount that would be needed to achieve both of these purposes. Over the past 10 years, we have realized that three percent is not adequate to achieve both purposes. To date, only a small number of Tribes have taken steps toward PWSS primacy. We believe that there are more Tribes which may be interested in the program but have not yet voiced that interest because they do not have the capacity to develop an adequate program. We also believe more Tribes would take interest in the program if sufficient funds were available.

In addition, the current Tribal reserve is insufficient to cover basic direct implementation needs. Tribal systems have a high number of monitoring/reporting and maximum contaminant level violations. These same systems will need to abide by upcoming drinking water regulations and will be asked to partake in several new initiatives outlined in the revised SDWA, including source water protection, capacity development, and operator certification. Although Tribes are not required to apply for PWSS primacy, we believe that EPA, as the primary enforcement authority of non-primacy Tribal systems, should address these initiatives on Tribal lands. Additional Tribal funding can help EPA and Tribes respond to Tribal safe drinking water needs.

EPA requested Congress to provide for funding in excess of the amount necessary for the traditional three percent reserve in Fiscal Year 1998 and succeeding years to assist Tribes in developing capacity and maintaining their own PWSS programs, and to provide additional support to the Tribal PWSS Direct Implementation program. In Fiscal Years 1998, 1999, and 2000, EPA received an additional $3,780,500 for these purposes. In order to use those funds for Tribes, EPA needed to deviate from the regulation at 40 CFR 35.115(g), which limits EPA's Tribal PWSS reserve to three percent. Instead of continuing to deviate from the regulations, EPA is raising the ceiling of the annual Tribal reserve to up to seven percent. With the additional $3.78 million PWSS program appropriation, EPA was able to raise the funding ceiling for Tribes to 6.91 percent, the amount available to Tribes in Fiscal Year 2000, without reducing current State funding levels.

Safe Drinking Water Act and Alaska Native Villages. EPA is including a new interpretation of the definition of "Indian Tribe" in 42 U.S.C. 300f(14) that would include eligible Alaska Native Villages (ANVs) for purposes of PWSS and Underground Water Source Protection (also known as underground injection control (UIC)) grants under 42 U.S.C. 300j–2(a) and (b). It will also allow ANVs to be considered for primacy for the PWSS and UIC programs under 42 U.S.C. 300g–2, 300h–1 and 300h–4. Under this approach, a federally recognized Tribe in Alaska could seek to demonstrate that it is eligible for treatment in the same manner as a State according to the criteria established by Congress in 42 U.S.C. 300j–11 and in EPA's regulations at 40 CFR 142.72 and 145.52.

In 1988, EPA announced its interpretation that the term "Indian Tribe" in 42 U.S.C. 300(f)(14) does not include ANVs. 53 FR 37396, 37407. This interpretation was based on the Agency's interpretation of the legislative history of the Act. At the time, EPA reasoned that Congress would have explicitly mentioned ANVs if it intended to include ANVs in the definition of Indian Tribes. Since then, EPA has reconsidered that interpretation and now believes it is more consistent with Congressional intent and federal Indian law and policy to interpret the term "Indian Tribe" in 42 U.S.C. 300f(14) to include Indian Tribes located in Alaska (*i.e.*, ANVs) that otherwise meet the SDWA's definition of Indian Tribe.

Under the SDWA, the term "Indian Tribe" means "any Indian Tribe having a federally recognized governing body carrying out substantial governmental duties and powers over any area." 42 U.S.C. 300(f)(14). In 1993, the Department of the Interior (DOI) clarified that the Alaska Native entities listed on DOI's list of federally recognized Tribes have the same governmental status as other federally acknowledged Indian Tribes by virtue of their status as Indian Tribes with a government-to-government relationship with the United States; are entitled to the same protection, immunities, privileges as other acknowledged Tribes; have the right, subject to general principles of federal Indian law, to exercise the same inherent and delegated authorities available to other Tribes; and are subject to the same limitations imposed by law on other Tribes. 58 FR 54364, 54366 (1993).

Thus, because DOI has clarified that federally-recognized Tribes in Alaska have the same status as other federally-recognized Tribes, EPA believes that ANVs that otherwise meet the SDWA's definition of Indian Tribe should not be excluded from seeking PWSS and UIC program primacy or related program grants. This interpretation is consistent with the plain language of the SDWA's definition of "Indian Tribe" and EPA's policy that Indian Tribes are the appropriate entities to set environmental standards and manage their environments where they have the authority and capability to do so. *See* EPA's 1984 Indian Policy. It is also consistent with Supreme Court precedent holding that any statutory limitations on Tribal sovereignty must be stated explicitly, *Santa Clara Pueblo* v. *Martinez*, 436 U.S. 49 (1978); *Montana* v. *Blackfeet Indian Tribe*, 471 U.S. 759 (1985), and that statutes are to be construed liberally in favor of the Indians, with ambiguous provisions interpreted for their benefit. *County of Yakima* v. *Yakima Indian Nation*, 502 U.S. 251, 268 (1992).

While this change in interpretation would include ANVs that otherwise meet the SDWA's definition of Indian Tribe within the context of the PWSS and UIC programs, any ANV wishing to seek primacy, or a primacy development grant, for either the PWSS or UIC programs would still need to demonstrate that it meets the relevant statutory and regulatory eligibility criteria, including the jurisdictional requirements contained in 42 U.S.C. 300j–11; 40 CFR 142.72 and 145.52, 40 CFR 35.676 and 35.686 of this subpart. Furthermore, upon the request of an Alaska Tribe in an application for grant or primacy eligibility, EPA will evaluate whether the Alaska Tribe meets the criteria for program primacy or a related program grant. The State of Alaska currently has primacy for PWSS and UIC (Class II wells) for all areas in Alaska except Indian country. EPA is not amending the extent of the State's primacy through this notice.

In the 1996 amendments to the Safe Drinking Water Act, Congress added a sentence to the definition of Indian Tribe explicitly noting that the term "Indian Tribe" for purposes of the State Revolving Fund (SRF) program includes "any Native village." 42 U.S.C. 300f(14). EPA believes that, through this change, Congress only intended to ensure that all Native villages may receive SRF grants. EPA believes that this provision was not intended to mean that federally-recognized Tribes carrying out substantial governmental duties and powers in Alaska are excluded from the definition of Indian Tribe for purposes other than SRF.

Regulations for programs to manage hazardous waste and underground storage tanks. After the EPA workgroup reached closure on the proposed rule, Congress authorized the Agency to award grants to Tribes "for the development and implementation of programs to manage hazardous waste, and underground storage tanks." Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1999, Pub. L. 105–276, 112 Stat. 2461, 2499 (1998). EPA has included regulations for these programs in the final rule.

XI. Conclusion

This Tribal-specific subpart reflects EPA's regulatory and budgetary efforts to improve the continuity and stability of financial assistance for Tribal environmental programs. Recipients will benefit from the streamlined and simplified requirements of the regulation. In addition, it will provide Tribes and Intertribal Consortia choosing to participate in the PPG program with the flexibility to better use funds to address their environmental priorities.

Regulatory Flexibility Act

This final rule is not subject to the Regulatory Flexibility Act (RFA), which generally requires an agency to prepare a regulatory flexibility analysis for any rule that will have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which notice and comment rule making is required under the Administrative Procedure Act (APA) or any another statute. Grant award and administration matters, such as this rule, are explicitly exempt from the notice and comment requirements of the APA (5 U.S.C. 553(a)(1)) and are not required to undergo notice and comment rule making under any other statute.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, 2 U.S.C. 1501 *et seq.*, 109 Stat. 48 (1995), establishes requirements for federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "federal mandates" that may result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. This regulation contains no federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or Tribal governments or the private sector. The UMRA excludes from the definitions of "federal intergovernmental mandate" and "federal private sector mandates" duties that arise from conditions of federal assistance.

National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), requires EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impracticable. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used, the Act requires EPA to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

This rule does not involve any technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 applies to any rule that is determined to be: (1) "Economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

Executive Order 12866

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) a significant regulatory action is subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

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(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is a "significant regulatory action" under the terms of Executive Order 12866 because the Performance Partnership Grant authority is a new type of grant authority and therefore raises novel policy issues. As such, this action was submitted to the Office of Management and Budget (OMB) for review. Changes made in response to OMB suggestions and recommendations will be documented in the public record.

Paperwork Reduction Act

In keeping with the requirements of the Paperwork Reduction Act (PRA), as amended, 44 U.S.C. 3501 *et seq.*, the information collection requirements contained in this rule have been approved by OMB under information collection request number 0938.06 (OMB Control Number 2030–0020) and Quality Assurance Specifications and Requirements information request number 0866.05 (OMB Control Number 2080–0033). This rule does not contain any collection of information requirements beyond those already approved. Since this action imposes no new or additional information collection, reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, no information request has been or will be submitted to the Office of Management and Budget for review.

Executive Order 13132—Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This rule does not apply to States or local governments; it applies only to Tribes and Intertribal Consortia. Executive Order 13132 does not apply to Tribes and Intertribal Consortia. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian Tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

This rule may significantly or uniquely affect the communities of Indian Tribal governments, but it will not impose substantial direct compliance costs on such communities. This rule governs financial assistance to Tribes. Any costs associated with this regulation will be incurred by a Tribe as a result of its discretionary decision to seek financial assistance. Accordingly, the requirements of Executive order 13084 do not apply.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective thirty days after publication in the **Federal Register**.

List of Subjects

40 CFR Part 31

Environmental protection. Administrative practice and procedure, Grant programs, Indians, Intergovernmental relations, Loan programs, Reporting and recordkeeping requirements.

40 CFR Part 35

Environmental protection, Air pollution control, Coastal zone, Grant programs-environmental protection, Grant programs-Indians, Hazardous waste, Indians, Intergovernmental relations, Pesticides and pests, Reporting and recordkeeping requirements, Superfund, Waste treatment and disposal, Water pollution control, Water supply.

Dated: December 28, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth in this preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 31—[AMENDED]

1. EPA is amending 40 CFR part 31 by revising 40 CFR 31.36(b)(1) and adding a new 40 CFR 31.38 to read as follows:

§ 31.36 Procurement.

* * * * *

(b) *Procurement Standards.* (1) Grantees and subgrantees will use their own procurement procedures which reflect applicable State and local laws and regulations, provided that the procurements conform to applicable federal law, the standards identified in this section, and if applicable, § 31.38.

* * * * *

§ 31.38 Indian Self Determination Act.

Any contract, subcontract, or subgrant awarded under an EPA grant by an Indian Tribe or Indian Intertribal Consortium shall require to the extent feasible:

(a) Preferences and opportunities for training and employment in connection with the administration of such contracts or grants shall be given to Indians as defined in the Indian Self Determination Act (25 U.S.C. 450b); and

(b) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77) [25 U.S.C. 1452].

PART 35—[AMENDED]

2. EPA is removing 40 CFR part 35, subpart Q.

3. EPA is adding a new 40 CFR part 35, subpart B to read as follows.

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Subpart B—Environmental Program Grants for Tribes

Authority: 42 U.S.C. 7401 *et seq.*; 33 U.S.C. 1251 *et seq.*; 42 U.S.C. 300f *et seq.*; 42 U.S.C. 6901 *et seq.*; 7 U.S.C. 136 *et seq.*; 15 U.S.C. 2601 *et seq.*; 42 U.S.C. 13101 *et seq.*; Pub. L. 104–134, 110 Stat. 1321, 1321–299 (1996); Pub. L. 105–65, 111 Stat. 1344, 1373 (1997); Pub. L. 105–276, 112 Stat. 2461, 2499 (1988).

General—All Grants

§ 35.500 Purpose of the subpart.

This subpart establishes administrative requirements for all grants awarded to Indian Tribes and Intertribal Consortia for the environmental programs listed in § 35.501. This subpart supplements requirements in EPA's general grant regulations found at 40 CFR part 31. Sections 35.500–518 contain administrative requirements that apply

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to all environmental program grants included in this subpart. Sections 35.530 through 35.718 contain requirements that apply to specified environmental program grants. Many of these environmental programs also have programmatic and technical requirements that are published elsewhere in the Code of Federal Regulations.

§ 35.501 Environmental programs covered by the subpart.

(a) The requirements in this subpart apply to all grants awarded for the following programs:

(1) Performance Partnership Grants (1996 Omnibus Consolidated Rescissions and Appropriations Act of 1996, Pub. L. 104–134; 110 Stat. 1321, 1321–299 (1996) and Departments of Veterans Affairs, Housing and Urban Development, and Independent Agencies Appropriations Act of 1998, Pub. L. 105–65; 111 Stat. 1344, 1373 (1997)).

(2) The Indian Environmental General Assistance Program Act of 1992, 42 U.S.C. 4368b.

(3) Clean Air Act. Air pollution control (section 105).

(4) Clean Water Act.

(i) Water pollution control (section 106 and 518).

(ii) Water quality cooperative agreements (section 104(b)(3)).

(iii) Wetlands development grant program (section 104(b)(3)).

(iv) Nonpoint source management (section 319(h)).

(5) Federal Insecticide, Fungicide, and Rodenticide Act.

(i) Pesticide cooperative enforcement (section 23(a)(1)).

(ii) Pesticide applicator certification and training (section 23(a)(2)).

(iii) Pesticide program implementation (section 23(a)(1)).

(6) Pollution Prevention Act of 1990. Pollution prevention grants for Tribes (section 6605).

(7) Safe Drinking Water Act.

(i) Public water system supervision (section 1443(a)).

(ii) Underground water source protection (section 1443(b)).

(8) Toxic Substances Control Act.

(i) Lead-based paint program (section 404(g)).

(ii) Indoor radon grants (section 306).

(iii) Toxic substances compliance monitoring (section 28).

(9) Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1999 (Pub. L. 105–276; 112 Stat. 2461, 2499; 42 U.S.C. 6908a).

(i) Hazardous Waste Management Program Grants (Pub. L. 105–276; 112 Stat. 2461, 2499; 42 U.S.C. 6908a).

(ii) Underground Storage Tanks Program Grants (Pub. L. 105–276; 112 Stat. 2461, 2499; 42 U.S.C. 6908a).

(b) Unless otherwise prohibited by statute or regulation, the requirements in § 35.500 through § 35.518 of this subpart also apply to grants to Indian Tribes and Intertribal Consortia under environmental programs established after this subpart becomes effective, if specified in Agency guidance for such programs.

(c) In the event a grant is awarded from EPA headquarters for one of the programs listed in paragraph (a) of this section, this subpart shall apply and the term "Regional Administrator" shall mean "Assistant Administrator".

§ 35.502 Definitions of terms.

Terms are defined as follows when they are used in this regulation:

Consolidated grant. A single grant made to a recipient consolidating funds from more than one environmental grant program. After the award is made, recipients must account for grant funds in accordance with the funds' original environmental program sources. Consolidated grants are not Performance Partnership Grants.

Environmental program. A program for which EPA awards grants under the authorities listed in § 35.501. The grants are subject to the requirements of this subpart.

Federal Indian reservation. All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation.

Funding period. The period of time specified in the grant agreement during which the recipient may expend or obligate funds for the purposes set forth in the agreement.

Intertribal Consortium or Consortia. A partnership between two or more Tribes that is authorized by the governing bodies of those Tribes to apply for and receive assistance under one or more of the programs listed in § 35.501.

National program guidance. Guidance issued by EPA's National Program Managers for establishing and maintaining effective environmental programs. This guidance establishes national goals, objectives, and priorities as well as other information to be used in monitoring progress. The guidance may also set out specific environmental strategies, core performance measures, criteria for evaluating programs, and other elements of program implementation.

Outcome. The environmental result, effect, or consequence that will occur from carrying out an environmental program or activity that is related to an environmental or programmatic goal or objective. Outcomes must be quantitative, and they may not necessarily be achievable during a grant funding period. See "output."

Output. An environmental activity or effort and associated work products related to an environmental goal or objective that will be produced or provided over a period of time or by a specified date. Outputs may be quantitative or qualitative but must be measurable during a grant funding period. See "outcome."

Performance Partnership Grant. A single grant combining funds from more than one environmental program. A Performance Partnership Grant may provide for administrative savings or programmatic flexibility to direct grant resources where they are most needed to address public health and environmental priorities (see also § 35.530). Each Performance Partnership Grant has a single, integrated budget and recipients do not need to account for grant funds in accordance with the funds' original environmental program sources.

Planning target. The amount of funds that the Regional Administrator suggests a grant applicant consider in developing its application, including the work plan, for an environmental program.

Regional supplemental guidance. Guidance to environmental program grant applicants prepared by the Regional Administrator, based on the national program guidance and specific regional and applicant circumstances, for use in preparing a grant application.

Tribal Environmental Agreement (TEA). A dynamic, strategic planning document negotiated by the Regional Administrator and an appropriate Tribal official. A Tribal Environmental Agreement may include: Long-term and short-term environmental goals, objectives, and desired outcomes based on Tribal priorities and available funding. A Tribal Environmental Agreement can be a very general or specific document that contains budgets, performance measures, outputs and outcomes that could be used as part or all of a Performance Partnership Grant work plan, if it meets the requirements of section 35.507(b).

Tribe. Except as otherwise defined in statute or this subpart, Indian Tribal Government (Tribe) means: Any Indian Tribe, band, nation, or other organized group or community, including any

Alaska Native village, which is recognized as eligible by the United States Department of the Interior for the special services provided by the United States to Indians because of their status as Indians.

Work plan. The document which identifies how and when the applicant will use funds from environmental program grants and is the basis for management and evaluation of performance under the grant agreement to produce specific outputs and outcomes (see 35.507). The work plan must be consistent with applicable federal statutes; regulations; circulars; executive orders; and EPA delegations, approvals, or authorizations.

Work plan commitments. The outputs and outcomes associated with each work plan component, as established in the grant agreement.

Work plan component. A negotiated set or group of work plan commitments established in the grant agreement. A work plan may have one or more work plan components.

§ 35.503 Deviation from this subpart.

EPA will consider and may approve requests for an official deviation from non-statutory provisions of this regulation in accordance with 40 CFR 31.6.

§ 35.504 Eligibility of an Intertribal Consortium.

(a) An Intertribal Consortium is eligible to receive grants under the authorities listed in § 35.501 only if the Consortium demonstrates that all members of the Consortium meet the eligibility requirements for the grant and authorize the Consortium to apply for and receive assistance in accordance with paragraph (c) of this section, except as provided in paragraph (b) of this section.

(b) An Intertribal Consortium is eligible to receive a grant under the Indian Environmental General Assistance Program Act, in accordance with § 35.540, if the Consortium demonstrates that:

(1) A majority of its members meets the eligibility requirements for the grant;

(2) All members that meet the eligibility requirements authorize the Consortium to apply for and receive assistance; and

(3) It has adequate accounting controls to ensure that only members that meet the eligibility requirements will benefit directly from the grant project and will receive and manage grant funds, and the Consortium agrees to a grant condition to that effect.

(c) An Intertribal Consortium must submit to EPA adequate documentation of:

(1) The existence of the partnership between Indian Tribal governments, and

(2) Authorization of the Consortium by all its members (or in the case of the General Assistance Program, all members that meet the eligibility requirements for a General Assistance Program grant) to apply for and receive the grant(s) for which the Consortium has applied.

Preparing an Application

§ 35.505 Components of a complete application.

A complete application for an environmental program grant must:

(a) Meet the requirements in 40 CFR part 31, subpart B;

(b) Include a proposed work plan (§ 35.507 of this subpart); and

(c) Specify the environmental program and the amount of funds requested.

§ 35.506 Time frame for submitting an application.

An applicant should submit a complete application to EPA at least 60 days before the beginning of the proposed funding period.

§ 35.507 Work plans.

(a) *Bases for negotiating work plans.* The work plan is negotiated between the applicant and the Regional Administrator and reflects consideration of national, regional, and Tribal environmental and programmatic needs and priorities.

(1) *Negotiation considerations.* In negotiating the work plan, the Regional Administrator and applicant will consider such factors as national program guidance; any regional supplemental guidance; goals, objectives, and priorities proposed by the applicant; other jointly identified needs or priorities; and the planning target.

(2) *National program guidance.* If an applicant proposes a work plan that differs significantly from the goals and objectives, priorities, or performance measures in the national program guidance associated with the proposed work plan activities, the Regional Administrator must consult with the appropriate National Program Manager before agreeing to the work plan.

(3) *Use of existing guidance.* An applicant should base the grant application on the national program guidance in place at the time the application is being prepared.

(b) *Work plan requirements.* (1) The work plan is the basis for the management and evaluation of performance under the grant agreement.

(2) An approvable work plan must specify:

(i) The work plan components to be funded under the grant;

(ii) The estimated work years and estimated funding amounts for each work plan component;

(iii) The work plan commitments for each work plan component, and a time frame for their accomplishment;

(iv) A performance evaluation process and reporting schedule in accordance with § 35.515 of this subpart; and

(v) The roles and responsibilities of the recipient and EPA in carrying out the work plan commitments.

(3) The work plan must be consistent with applicable federal statutes; regulations; circulars; executive orders; and delegations, approvals, or authorizations.

(c) *Tribal Environmental Agreement as work plan.* An applicant may use a Tribal Environmental Agreement or a portion of the Tribal Environmental Agreement as the work plan or part of the work plan for an environmental program grant if the portion of the Tribal Environmental Agreement that is to serve as the grant work plan:

(1) Is clearly identified as the grant work plan and distinguished from other portions of the Tribal Environmental Agreement; and

(2) Meets the requirements in § 35.507(b).

§ 35.508 Funding period.

The Regional Administrator and applicant may negotiate the length of the funding period for environmental program grants, subject to limitations in appropriations and authorizing statutes.

§ 35.509 Consolidated grants.

Any applicant eligible to receive funds from more than one environmental program may submit an application for a consolidated grant. For consolidated grants, an applicant prepares a single budget and work plan covering all of the environmental programs included in the application. The consolidated budget must identify each environmental program to be included, the amount of each program's funds, and the extent to which each program's funds support each work plan component. Recipients of consolidated grants must account for grant funds in accordance with the funds' environmental program sources; funds included in a consolidated grant from a particular environmental program may be used only for that program.

EPA Action on Application

§ 35.510 Time frame for EPA action.

The Regional Administrator will review a complete application and either approve, conditionally approve,

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or disapprove it within 60 days of receipt. The Regional Administrator will award grants for approved or conditionally approved applications if funds are available.

§ 35.511 Criteria for approving an application.

(a) After evaluating other applications as appropriate, the Regional Administrator may approve an application upon determining that:

(1) The application meets the requirements of this subpart and 40 CFR part 31;

(2) The application meets the requirements of all applicable federal statutes; regulations; circulars; executive orders; and EPA delegations, approvals, or authorizations;

(3) The proposed work plan complies with the requirements of § 35.507 of this subpart; and

(4) The achievement of the proposed work plan is feasible, considering such factors as the applicant's existing circumstances, past performance, program authority, organization, resources, and procedures.

(b) If the Regional Administrator finds the application does not satisfy the criteria in paragraph (a) of this section, the Regional Administrator may either:

(1) Conditionally approve the application if only minor changes are required, with grant conditions necessary to ensure compliance with the criteria, or

(2) Disapprove the application in writing.

§ 35.512 Factors considered in determining award amount.

(a) After approving an application under § 35.511, the Regional Administrator will consider such factors as the amount of funds available for award to Indian Tribes and Intertribal Consortia, the extent to which the proposed work plan is consistent with EPA guidance and mutually agreed upon priorities, and the anticipated cost of the work plan relative to the proposed work plan components to determine the amount of funds to be awarded.

(b) If the Regional Administrator finds that the requested level of funding is not justified, the Regional Administrator will attempt to negotiate a resolution of the issues with the applicant before determining the award amount.

§ 35.513 Reimbursement for pre-award costs.

(a) Notwithstanding the requirements of 40 CFR 31.23(a) (Period of availability of funds), and OMB cost principles, EPA may reimburse recipients for pre-award costs incurred from the beginning of the funding period established in the grant agreement if such costs would have been allowable if incurred after the award. Such costs must be specifically identified in the grant application EPA approves.

(b) The applicant incurs pre-award costs at its own risk. EPA is under no obligation to reimburse such costs unless they are included in an approved grant application.

Post-Award Requirements

§ 35.514 Amendments and other changes.

The provisions of 40 CFR 31.30 do not apply to environmental program grants awarded under this subpart. The following provisions govern amendments and other changes to grant work plans and budgets after the work plan is negotiated and a grant awarded.

(a) *Changes requiring prior approval.* The recipient needs the Regional Administrator's prior written approval to make significant post-award changes to work plan commitments. EPA, in consultation with the recipient, will document approval of these changes including budgeted amounts associated with the revisions.

(b) *Changes requiring approval.* Recipients must request, in writing, grant amendments for changes requiring increases in environmental program grant amounts and extensions of the funding period. Recipients may begin implementing a change before the amendment has been approved by EPA, but do so at their own risk. If EPA approves the change, EPA will issue a grant amendment. EPA will notify the recipient in writing if the change is disapproved.

(c) *Changes not requiring approval.* Other than those situations described in paragraphs (a) and (b) of this section, recipients do not need to obtain approval for changes, including changes in grant work plans, budgets, or other parts of grant agreements, unless the Regional Administrator determines approval requirements should be imposed on a specific recipient for a specified period of time.

(d) *Office of Management and Budget (OMB) cost principles.* The Regional Administrator may waive, in writing, approval requirements for specific recipients and costs contained in OMB cost principles.

(e) *Changes in consolidated grants.* Recipients of consolidated grants under § 35.509 may not transfer funds among environmental programs.

(f) *Subgrants.* Subgrantees must request required approvals in writing from the recipient and the recipient shall approve or disapprove the request in writing. A recipient will not approve any work plan or budget revision which is inconsistent with the purpose or terms and conditions of the federal grant to the recipient. If the revision requested by the subgrantee would result in a significant change to the recipient's approved grant which requires EPA approval, the recipient will obtain EPA's approval before approving the subgrantee's request.

§ 35.515 Evaluation of performance.

(a) *Joint evaluation process.* The applicant and the Regional Administrator will develop a process for jointly evaluating and reporting progress and accomplishments under the work plan (see section 35.507(b)(2)(iv)). A description of the evaluation process and reporting schedule must be included in the work plan. The schedule must require the recipient to report at least annually and must satisfy the requirements for progress reporting under 40 CFR 31.40(b).

(b) *Elements of the evaluation process.* The evaluation process must provide for:

(1) A discussion of accomplishments as measured against work plan commitments;

(2) A discussion of the cumulative effectiveness of the work performed under all work plan components;

(3) A discussion of existing and potential problem areas; and

(4) Suggestions for improvement, including, where feasible, schedules for making improvements.

(c) *Resolution of issues.* If the joint evaluation reveals that the recipient has not made sufficient progress under the work plan, the Regional Administrator and the recipient will negotiate a resolution that addresses the issues. If the issues cannot be resolved through negotiation, the Regional Administrator may take appropriate measures under 40 CFR 31.43. The recipient may request review of the Regional Administrator's decision under the dispute processes in 40 CFR 31.70.

(d) *Evaluation reports.* The Regional Administrator will ensure that the required evaluations are performed according to the negotiated schedule and that copies of evaluation reports are placed in the official files and provided to the recipient.

§ 35.516 Direct implementation.

If funds for an environmental program remain after Tribal and Intertribal Consortia environmental program grants for that program have been awarded or because no grants were awarded, the Regional Administrator may, subject to any limitations contained in appropriation acts, use all or part of the funds to support a federal program required by law in the absence of an acceptable Tribal program.

§ 35.517 Unused funds.

If funds for an environmental program remain after Tribal and Intertribal Consortia grants for that program have been awarded or because no grants were awarded, and the Regional Administrator does not use the funds under § 35.516 of this subpart, the Regional Administrator may award the funds to any eligible Indian Tribe or Intertribal Consortium in the region (including a Tribe or Intertribal Consortium that has already received funds) for the same environmental program or for a Performance Partnership Grant, subject to any limitations in appropriation acts.

§ 35.518 Unexpended balances.

Subject to any relevant provisions of law, if a recipient's final Financial Status Report shows unexpended balances, the Regional Administrator will deobligate the unexpended balances and make them available, either to the same recipient or other Tribes or Intertribal Consortia in the region, for environmental program grants.

Performance Partnership Grants

§ 35.530 Purpose of Performance Partnership Grants.

(a) *Purpose of section.* Sections 35.530 through 35.538 govern Performance Partnership Grants to Tribes and Intertribal Consortia authorized in the Omnibus Consolidated Rescissions and Appropriations Act of 1996 (Pub. L. 104–134; 110 Stat. 1321, 1321–299 (1996)) and Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1998 (Pub. L. 105–65; 111 Stat. 1344, 1373 (1997)).

(b) *Purpose of program.* Performance Partnership Grants enable Tribes and Intertribal Consortia to combine funds from more than one environmental program grant into a single grant with a single budget. Recipients do not need to account for Performance Partnership Grant funds in accordance with the funds' original environmental program sources; they need only account for total Performance Partnership Grant expenditures. Subject to the requirements of this subpart, the Performance Partnership Grant program is designed to:

(1) Strengthen partnerships between EPA and Tribes and Intertribal Consortia through joint planning and priority setting and better deployment of resources;

(2) Provide Tribes and Intertribal Consortia with flexibility to direct resources where they are most needed to address environmental and public health priorities;

(3) Link program activities more effectively with environmental and public health goals and program outcomes;

(4) Foster development and implementation of innovative approaches, such as pollution prevention, ecosystem management, and community-based environmental protection strategies; and

(5) Provide savings by streamlining administrative requirements.

§ 35.532 Requirements summary.

(a) Applicants and recipients of Performance Partnership Grants must meet:

(1) The requirements in §§ 35.500 to 35.518 of this subpart which apply to all environmental program grants, including Performance Partnership Grants; and

(2) The requirements in §§ 35.530 to 35.538 of this subpart which apply only to Performance Partnership Grants.

(b) In order to include funds from an environmental program grant listed in § 35.501(a) of this subpart in a Performance Partnership Grant, applicants must meet the requirements for award of each environmental program from which funds are included in the Performance Partnership Grant, except the requirements at §§ 35.548(c), 35.638(b) and (c), 35.691, and 35.708 (c), (d), (e), and (g). These requirements can be found in this regulation beginning at § 35.540. If the applicant is an Intertribal Consortium, each Tribe that is a member of the Consortium must meet the requirements.

(3) Apply for the environmental program grant.

(4) Obtain the Regional Administrator's approval of the application for that grant.

(c) If funds from an environmental program are not included in a Performance Partnership Grant, an applicant is not required to meet the eligibility requirements for that environmental program grant in order to carry out activities eligible under that program as provided in § 35.535.

§ 35.533 Programs eligible for inclusion.

(a) *Eligible programs.* Except as provided in paragraph (b) of this section, the environmental program grants eligible for inclusion in a Performance Partnership Grant are listed in § 35.501(a)(2) through (9) of this subpart.

(b) *Changes in eligible programs.* The Administrator may, in guidance or regulation, describe subsequent additions, deletions, or changes to the list of environmental programs eligible for inclusion in Performance Partnership Grants.

§ 35.534 Eligible recipients.

(a) A Tribe or Intertribal Consortium is eligible for a Performance Partnership Grant if the Tribe or each member of the Intertribal Consortium is eligible for, and the Tribe or Intertribal Consortium receives funding from, more than one of the environmental program grants listed in § 35.501(a) in accordance with the requirements for those environmental programs.

(b) For grants to Tribes, a Tribal agency must be designated by a Tribal government or other authorized Tribal process to receive grants under each of the environmental programs to be combined in the Performance Partnership Grant.

§ 35.535 Activities eligible for funding.

(a) *Delegated, approved, or authorized activities.* A Tribe or Intertribal Consortium may use Performance Partnership Grant funds to carry out EPA-delegated, EPA-approved, or EPA-authorized activities, such as permitting and primary enforcement responsibility only if the Tribe or each member of the Intertribal Consortium receives from the Regional Administrator the delegations, approvals, or authorizations to conduct such activities.

(b) *Other program activities.* Except for the limitation in paragraph (a) of this section, a Tribe or Intertribal Consortium may use Performance Partnership Grant funds for any activity that is eligible under the environmental programs listed in § 35.501(a) of this subpart, as determined by the Regional Administrator. If an applicant proposes a Performance Partnership Grant work plan that differs significantly from any of the proposed work plans approved for funding that the applicant now proposes to move into a Performance Partnership Grant, the Regional Administrator must consult with the appropriate National Program Managers before agreeing to the Performance Partnership Grant work plan. National Program Managers may expressly waive or modify this requirement for consultation in national program guidance. National Program Managers also may define in national program guidance "significant" differences from a work plan submitted with a Tribe's or a Consortium's application for funds.

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§ 35.536 Cost share requirements.

(a) The Performance Partnership Grant cost share shall be the sum of the amounts required for each environmental program grant included in the Performance Partnership Grant, as determined in accordance with paragraphs (b) and (c) of this section, unless waived under paragraph (d) of this section.

(b) For each environmental program grant included in the Performance Partnership Grant that has a cost share of five percent or less under the provisions of §§ 35.540 through 35.718, the required cost share shall be that identified in §§ 35.540 through 35.718 of this subpart.

(c) For each environmental program grant included in the Performance Partnership Grant that has a cost share of greater than five percent under the provisions of §§ 35.540 through 35.718 of this subpart, the required cost share shall be five percent of the allowable cost of the work plan budget for that program. However, after the first two years in which a Tribe or Intertribal Consortium receives a Performance Partnership Grant, the Regional Administrator must determine through objective assessment whether the Tribe or the members of an Intertribal Consortium meet socio-economic indicators that demonstrate the ability of the Tribe or the Intertribal Consortium to provide a cost share greater than five percent. If the Regional Administrator determines that the Tribe or the members of Intertribal Consortium meets such indicators, then the Regional Administrator shall increase the required cost share up to a maximum of 10 percent of the allowable cost of the work plan budget for each program with a cost share greater than five percent.

(d) The Regional Administrator may waive the cost share required under this section upon request of the Tribe or Intertribal Consortium, if, based on an objective assessment of socio-economic indicators, the Regional Administrator determines that meeting the cost share would impose undue hardship.

§ 35.537 Application requirements.

An application for a Performance Partnership Grant must contain:

(a) A list of the environmental programs and the amount of funds from each program to be combined in the Performance Partnership Grant;

(b) A consolidated budget;

(c) A consolidated work plan that addresses each program being combined in the grant and which meets the requirements of § 35.507.

§ 35.538 Project period.

If the projected completion date for a work plan commitment funded under an environmental program grant that is added to a Performance Partnership Grant extends beyond the end of the project period for the Performance Partnership Grant, the Regional Administrator and the recipient will agree in writing as to how and when the work plan commitment will be completed.

Indian Environmental General Assistance Program (GAP)

§ 35.540 Purpose.

(a) *Purpose of section.* Sections 35.540 through 35.547 govern grants to Tribes and Intertribal Consortia under the Indian Environmental General Assistance Program Act of 1992 (42 U.S.C. 4368b.)

(b) *Purpose of program.* Indian Environmental General Assistance Program grants are awarded to build capacity to administer environmental programs for Tribes by providing general assistance to plan, develop, and establish environmental protection programs for Tribes.

§ 35.543 Eligible recipients.

The following entities are eligible to receive grants under this program:

(a) Tribes and

(b) Intertribal Consortia as provided in § 35.504.

§ 35.545 Eligible activities.

Tribes and Intertribal Consortia may use General Assistance Program funds for planning, developing, and establishing environmental protection programs and to develop and implement solid and hazardous waste programs for Tribes.

§ 35.548 Award limitations.

(a) Each grant awarded under the General Assistance Program shall be not less than $75,000. This limitation does not apply to additional funds that may become available for award to the same Tribe or Intertribal Consortium.

(b) The Regional Administrator shall not award a grant to a single Tribe or Intertribal Consortium of more than 10 percent of the total annual funds appropriated under the Act.

(c) The project period of a General Assistance Program award may not exceed four years.

(d) No award under this program shall result in reduction of total EPA grants for environmental programs to the recipient.

Air Pollution Control (Section 105)

§ 35.570 Purpose.

(a) *Purpose of section.* Sections 35.570 through 35.578 govern air pollution control grants to Tribes (as defined in section 302(r) of the Clean Air Act (CAA)) authorized under sections 105 and 301(d) of the Act and Intertribal Consortia.

(b) *Purpose of program.* Air pollution control grants are awarded to develop and administer programs that prevent and control air pollution or implement national air quality standards for air resources within the exterior boundaries of the reservation or other areas within the Tribe's jurisdiction.

(c) *Associated program regulations.* Refer to 40 CFR parts 49, 50, 51, 52, 58, 60, 61, 62, and 81 for associated program regulations.

§ 35.572 Definitions.

In addition to the definitions in § 35.502, the following definitions apply to the Clean Air Act's section 105 grant program:

Nonrecurrent expenditures are those expenditures which are shown by the recipient to be of a nonrepetitive, unusual, or singular nature such as would not reasonably be expected to recur in the foreseeable future. Costs categorized as nonrecurrent must be approved in the grant agreement or an amendment thereto.

Recurrent expenditures are those expenses associated with the activities of a continuing environmental program. All expenditures are considered recurrent unless justified by the applicant as nonrecurrent and approved as such in the grant award or an amendment thereto.

§ 35.573 Eligible tribe.

(a) A Tribe is eligible to receive section 105 financial assistance under §§ 35.570 through 35.578 if it has demonstrated eligibility to be treated as a State under 40 CFR 49.6. An Intertribal Consortium consisting of Tribes that have demonstrated eligibility to be treated as States under 40 CFR 49.6 is also eligible for financial assistance.

(b) Tribes that have not made a demonstration under 40 CFR 49.6 and Intertribal Consortia consisting of Tribes that have not demonstrated eligibility to be treated as States under 40 CFR 49.6 are eligible for financial assistance under sections 105 and 302(b)(5) of the Clean Air Act.

§ 35.575 Maximum federal share.

(a) For Tribes and Intertribal Consortia eligible under § 35.573(a), the Regional Administrator may provide financial assistance in an amount up to 95 percent of the approved costs of planning, developing, establishing, or improving an air pollution control program, and up to 95 percent of the approved costs of maintaining that program. After two years from the date of each Tribe's or Intertribal Consortium's initial grant award, the Regional Administrator will reduce the maximum federal share to 90 percent if the Regional Administrator determines that the Tribe or each member of the Intertribal Consortium meets certain economic indicators that would provide an objective assessment of the Tribe's or each of the Intertribal Consortiums member's ability to increase its share. For a Tribe or Intertribal Consortium eligible under § 35.573(a), the Regional Administrator may increase the maximum federal share if the Tribe or Intertribal Consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or within the member Tribes of the Intertribal Consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship.

(b) For Tribes and Intertribal Consortia eligible under § 35.573(b), the Regional Administrator may provide financial assistance in an amount up to 60 percent of the approved costs of planning, developing, establishing, or improving an air pollution control program, and up to 60 percent of the approved costs of maintaining that program.

(c) Revenue collected under a Tribal Title V operating permit program may not be used to meet the cost share requirements of this section.

§ 35.576 Maintenance of effort.

(a) For Tribes and Intertribal Consortia that are eligible for financial assistance under § 35.573(b) of this subpart, the Tribe or each of the Intertribal Consortium's members must expend annually, for recurrent Section 105 program expenditures, an amount of non-federal funds at least equal to such expenditures during the preceding fiscal year.

(1) In order to award grants in a timely manner each fiscal year, the Regional Administrator shall compare a Tribe's or each of the Intertribal Consortium's member's proposed expenditure level, as detailed in the grant application, to its expenditure level in the second preceding fiscal year. When expenditure data for the preceding fiscal year is complete, the Regional Administrator shall use this information to determine the Tribe's or Intertribal Consortium's compliance with its maintenance of effort requirement.

(2) If expenditure data for the preceding fiscal year shows that a Tribe or Intertribal Consortium did not meet the requirements of paragraph (a) of this section, the Regional Administrator will take action to recover the grant funds for that year.

(3) The Regional Administrator may grant an exception to § 35.576(a) if, after notice and opportunity for a public hearing, the Regional Administrator determines that a reduction in expenditures is attributable to a non-selective reduction of all the Tribe's or each of the Intertribal Consortium's member's programs.

(b) For Tribes and Intertribal Consortia that are eligible under § 35.573(b), the Regional Administrator will not award Section 105 funds unless the applicant provides assurance that the grant will not supplant non-federal funds that would otherwise be available for maintaining the Section 105 program.

§ 35.578 Award limitation.

The Regional Administrator will not disapprove an application for, or terminate or annul an award of, financial assistance under § 35.573 without prior notice and opportunity for a public hearing within the appropriate jurisdiction or, where more than one area is affected, within one of the affected areas within the jurisdiction

Water Pollution Control (Sections 106 and 518)

§ 35.580 Purpose.

(a) *Purpose of section.* Sections 35.580 through 35.588 govern water pollution control grants to eligible Tribes and Intertribal Consortia (as defined in § 35.502) authorized under sections 106 and 518 of the Clean Water Act.

(b) *Purpose of program.* Water pollution control grants are awarded to assist Tribes and Intertribal Consortia in administering programs for the prevention, reduction, and elimination of water pollution, including programs for the development and implementation of ground-water protection strategies.

(c) *Associated program requirements.* Program requirements for water quality planning and management activities are provided in 40 CFR part 130.

§ 35.582 Definitions.

Federal Indian reservation. All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation.

Tribe. Any Indian Tribe, band, group, or community recognized by the Secretary of the Interior, exercising governmental authority over a federal Indian reservation.

§ 35.583 Eligible recipients.

A Tribe, including an Intertribal Consortium, is eligible to receive a section 106 grant if EPA determines that the Indian Tribe or each member of the Intertribal Consortium meets the requirements for treatment in a manner similar to a State under section 518(e) of the Clean Water Act (see 40 CFR 130.6(d)).

§ 35.585 Maximum federal share.

(a) The Regional Administrator may provide up to 95 percent of the approved work plan costs for Tribes or Intertribal Consortia establishing a section 106 program. Work plan costs include costs of planning, developing, establishing, improving or maintaining a water pollution control program.

(b) The Regional Administrator may increase the maximum federal share if the Tribe or Intertribal Consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of an Intertribal Consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship.

§ 35.588 Award limitations.

(a) The Regional Administrator will only award section 106 funds to a Tribe or Intertribal Consortium if:

(1) All monitoring and analysis activities performed by the Tribe or Intertribal Consortium meets the applicable quality assurance and quality control requirements in 40 CFR 31.45.

(2) The Tribe or each member of the Intertribal Consortium has emergency power authority comparable to that in section 504 of the Clean Water Act and adequate contingency plans to implement such authority.

(3) EPA has not assumed enforcement as defined in section 309(a)(2) of the Clean Water Act in the Tribe's or any Intertribal Consortium member's jurisdiction.

(4) The Tribe or Intertribal Consortium agrees to include a discussion of how the work performed under section 106 addressed water quality problems on Tribal lands in the annual report required under § 35.515(d).

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(5) After an initial award of section 106 funds, the Tribe or Intertribal Consortium shows satisfactory progress in meeting its negotiated work plan commitments.

(b) A Tribe or Intertribal Consortium is eligible to receive a section 106 grant or section 106 grant funds even if the Tribe or each of the members of an Intertribal Consortium does not meet the requirements of section 106(e)(1) and 106(f)(1) of the Clean Water Act.

Water Quality Cooperative Agreements (Section 104(b)(3))

§ 35.600 Purpose.

(a) *Purpose of section.* Sections 35.600 through 35.604 govern Water Quality Cooperative Agreements to Tribes and Intertribal Consortia authorized under section 104(b)(3) of the Clean Water Act. These sections do not govern Water Quality Cooperative Agreements under section 104(b)(3) to organizations that do not meet the definitions of Tribe or Intertribal Consortium in § 35.502; such cooperative agreements generally are subject to the uniform administrative requirements for grants at 40 CFR part 30.

(b) *Purpose of program.* EPA awards Water Quality Cooperative Agreements for investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction, and elimination of water pollution. EPA issues guidance each year advising EPA regions and headquarters regarding appropriate priorities for funding for this program. This guidance may include such focus areas as National Pollutant Discharge Elimination System watershed permitting, urban wet weather programs, or innovative pretreatment programs and biosolids projects.

§ 35.603 Competitive process.

EPA will award water quality cooperative agreement funds through a competitive process in accordance with national program guidance. After the competitive process is complete, the recipient can, at its discretion, accept the award as a separate cooperative agreement or add the funds to a Performance Partnership Grant. If the recipient chooses to add the funds to a Performance Partnership Grant, the water quality work plan commitments must be included in the Performance Partnership Grant work plan.

§ 35.604 Maximum federal share.

The Regional Administrator may provide up to 100 percent of approved work plan costs.

Wetlands Development Grant Program (Section 104(b)(3))

§ 35.610 Purpose.

(a) *Purpose of section.* Sections 35.610 through 35.615 govern wetlands development grants to Tribes and Intertribal Consortia under section 104(b)(3) of the Clean Water Act. These sections do not govern wetlands development grants under section 104(b)(3) to organizations that do not meet the definitions of Tribe or Intertribal Consortium in § 35.502; such grants generally are subject to the uniform administrative requirements for grants at 40 CFR part 30.

(b) *Purpose of program.* EPA awards wetlands development grants to assist in the development of new, or the refinement of existing, wetlands protection and management programs.

§ 35.613 Competitive process.

Wetlands development grants are awarded on a competitive basis. EPA annually establishes a deadline for receipt of grant applications. EPA reviews applications and decides which grant projects to fund based on criteria established by EPA. After the competitive process is complete, the recipient can, at its discretion, accept the award as a wetlands development program grant or add the funds to a Performance Partnership Grant. If the recipient chooses to add the funds to a Performance Partnership Grant, the wetlands development program work plan commitments must be included in the Performance Partnership Grant work plan.

§ 35.615 Maximum federal share.

EPA may provide up to 75 percent of the approved work plan costs for the development or refinement of a wetlands protection and management program.

Nonpoint Source Management Grants (Sections 319(h) and 518(f))

§ 35.630 Purpose.

(a) *Purpose of section.* Sections 35.630 through 35.638 govern nonpoint source management grants to eligible Tribes and Intertribal Consortia under sections 319(h) and 518(f) of the Clean Water Act.

(b) *Purpose of program.* Nonpoint source management grants may be awarded for the implementation of EPA-approved nonpoint source management programs, including ground-water quality protection activities that will advance the approved nonpoint source management program.

§ 35.632 Definition.

Tribe. Any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a federal Indian reservation.

§ 35.633 Eligibility requirements.

A Tribe or Intertribal Consortium is eligible to receive a Nonpoint Source Management grant if EPA has determined that the Tribe or each member of the Intertribal Consortium meets the requirements for treatment in a manner similar to a State under section 518(e) of the Clean Water Act (see 40 CFR 130.6(d)).

§ 35.635 Maximum federal share.

(a) The Regional Administrator may provide up to 60 percent of the approved work plan costs in any fiscal year. The non-federal share of costs must be provided from non-federal sources.

(b) The Regional Administrator may increase the maximum federal share if the Tribe or Intertribal Consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or within each Tribe that is a member of the Intertribal Consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship. In no case shall the federal share be greater than 90 percent.

§ 35.636 Maintenance of effort.

To receive funds under section 319 in any fiscal year, a Tribe or each member of an Intertribal Consortium must agree that the Tribe or each member of the Intertribal Consortium will maintain its aggregate expenditures from all other sources for programs for controlling nonpoint source pollution and improving the quality of the Tribe's or the Intertribal Consortium's members' waters at or above the average level of such expenditures in Fiscal Years 1985 and 1986.

§ 35.638 Award limitations.

(a) *Available funds.* EPA may use no more than the amount authorized under the Clean Water Act section 319 and 518(f) for making grants to Tribes or Intertribal Consortia.

(b) *Financial assistance to persons.* Tribes or Intertribal Consortia may use funds for financial assistance to persons only to the extent that such assistance is related to the cost of demonstration projects.

(c) *Administrative costs.* Administrative costs in the form of salaries, overhead, or indirect costs for services provided and charged against activities and programs carried out with these funds shall not exceed 10 percent of the funds the Tribe or Intertribal Consortium receives in any fiscal year. The cost of implementing enforcement and regulatory activities, education, training, technical assistance, demonstration projects, and technology transfer programs are not subject to this limitation.

(d) The Regional Administrator will not award section 319(h) funds to any Tribe or Intertribal Consortium unless:

(1) *Approved assessment report.* EPA has approved the Tribe's or each member of the Intertribal Consortium's Assessment Report on nonpoint sources, prepared in accordance with section 319(a) of the Act;

(2) *Approved Tribe or Intertribal Consortium management program.* EPA has approved the Tribes's or each member of the Intertribal Consortium's management program for nonpoint sources, prepared in accordance with section 319(b) of the Act;

(3) *Progress on reducing pollutant loadings.* The Regional Administrator determines, for a Tribe or Intertribal Consortium that received a section 319 funds in the preceding fiscal year, that the Tribe or each member of the Intertribal Consortium made satisfactory progress in meeting its schedule for achieving implementation of best management practices to reduce pollutant loadings from categories of nonpoint sources, or particular nonpoint sources, designated in the Tribe's or each Consortium member's management program. The Tribe or each member of the Intertribal Consortium must develop this schedule in accordance with section 319(b)(2) of the Act;

(4) *Activity and output descriptions.* The work plan briefly describes each significant category of nonpoint source activity and the work plan commitments to be produced for each category; and

(5) *Significant watershed projects.* For watershed projects whose costs exceed $50,000, the work plan contains:

(i) A brief synopsis of the watershed implementation plan outlining the problems to be addressed;

(ii) The project's goals and objectives; and

(iii) The performance measures and environmental indicators that will be used to evaluate the results of the project.

Pesticide Cooperative Enforcement (Section 23(a)(1))

§ 35.640 Purpose.

(a) *Purpose of section.* Sections 35.640 through 35.645 govern cooperative agreements to Tribes and Intertribal Consortia authorized under section 23(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act for pesticide enforcement.

(b) *Purpose of program.* Cooperative agreements are awarded to assist Tribes and Intertribal Consortia in implementing pesticide enforcement programs.

(c) *Associated program regulations.* Refer to 19 CFR part 12 and 40 CFR parts 150 through 189 for associated regulations.

§ 35.641 Eligible recipients.

Eligible recipients of pesticide enforcement cooperative agreements are Tribes and Intertribal Consortia.

§ 35.642 Maximum federal share.

The Regional Administrator may provide up to 100 percent of the approved work plan costs.

§ 35.645 Basis for allotment.

The Administrator allots pesticide enforcement cooperative agreement funds to each regional office. Regional offices award funds to Tribes and Intertribal Consortia based on their programmatic needs and applicable EPA guidance.

Pesticide Applicator Certification and Training (Section 23(a)(2))

§ 35.646 Purpose.

(a) *Purpose of section.* Sections 35.646 through 35.649 govern pesticide applicator certification and training grants to Tribes and Intertribal Consortia under section 23(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act.

(b) *Purpose of program.* Pesticide applicator certification and training grants are awarded to train and certify restricted use pesticide applicators.

(c) *Associated program regulations.* Associated program regulations are found in 40 CFR parts 162, 170, and 171.

§ 35.649 Maximum federal share.

The Regional Administrator may provide up to 50 percent of the approved work plan costs.

Pesticide Program Implementation (Section 23(a)(1))

§ 35.650 Purpose.

(a) *Purpose of section.* Sections 35.650 through 35.659 govern Pesticide Program Implementation cooperative agreements to Tribes and Intertribal Consortia under section 23(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act.

(b) *Purpose of program.* Cooperative agreements are awarded to assist Tribes and Intertribal Consortia to develop and implement pesticide programs, including programs that protect workers, ground water, and endangered species from pesticide risks and other pesticide management programs designated by the Administrator.

(c) *Program regulations.* Refer to 40 CFR parts 150 through 189 and 19 CFR part 12 for associated regulations.

§ 35.653 Eligible recipients.

Eligible recipients of pesticide program implementation cooperative agreements are Tribes and Intertribal Consortia.

§ 35.655 Basis for allotment.

The Administrator allots pesticide program implementation cooperative agreement funds to each Regional Office. Regional Offices award funds to Tribes and Intertribal Consortia based on their programmatic needs and applicable EPA guidance.

§ 35.659 Maximum federal share.

The Regional Administrator may provide up to 100 percent of the approved work plan costs.

Pollution Prevention Grants (Section 6605)

§ 35.660 Purpose.

(a) *Purpose of section.* Sections 35.660 through 35.669 govern grants to Tribes and Intertribal Consortia under section 6605 of the Pollution Prevention Act.

(b) *Purpose of program.* Pollution Prevention Grants are awarded to promote the use of source reduction techniques by businesses.

§ 35.661 Competitive process.

EPA Regions award Pollution Prevention Grant funds to Tribes and Intertribal Consortia through a competitive process in accordance with EPA guidance. When evaluating a Tribe's or Intertribal Consortium's application, EPA must consider, among other criteria, whether the proposed program would:

(a) Make specific technical assistance available to businesses seeking information about source reduction opportunities, including funding for experts to provide onsite technical advice to businesses seeking assistance in the development of source reduction plans;

(b) Target assistance to businesses for whom lack of information is an impediment to source reduction; and

(c) Provide training in source reduction techniques. Such training may be provided through local

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engineering schools or other appropriate means.

§ 35.662 Definitions.

The following definition applies to the Pollution Prevention Grant program and to §§ 35.660 through 35.669:

(a) Pollution prevention/source reduction is any practice that:

(1) Reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal;

(2) Reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants; or

(3) Reduces or eliminates the creation of pollutants through:

(i) Increased efficiency in the use of raw materials, energy, water, or other resources; or

(ii) Protection of national resources by conservation.

(b) Pollution prevention/source reduction does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to and necessary for the production of a product or the providing of a service.

§ 35.663 Eligible recipients.

(a) The Regional Administrator will treat a Tribe or Intertribal Consortium as eligible to apply for a Pollution Prevention Grant if the Tribe or each member of the Intertribal Consortium:

(1) Is recognized by the Secretary of the Interior;

(2) Has an existing government exercising substantial governmental duties and powers;

(3) Has adequate authority to carry out the grant activities; and

(4) Is reasonably expected to be capable, in the Regional Administrator's judgment, of administering the grant program.

(b) If the Administrator has previously determined that an Indian Tribe has met the prerequisites in paragraphs (a)(1) and (2) of this section for another EPA program, the Tribe need provide only that information unique to the Pollution Prevention Grants program required by paragraphs (b)(3) and (4) of this section.

§ 35.666 Award limitation.

If the Pollution Prevention Grant funds are included in a Performance Partnership Grant, the Pollution Prevention work plan commitments must be included in the Performance Partnership Grant work plan.

§ 35.669 Maximum federal share.

The federal share for Pollution Prevention Grants will not exceed 50 percent of the allowable Tribe and Intertribal Consortium Pollution Prevention project cost.

Public Water System Supervision (Section 1443(a) and Section 1451)

§ 35.670 Purpose.

(a) *Purpose of section.* Sections 35.670 through 35.678 govern public water system supervision grants to Tribes and Intertribal Consortia authorized under sections 1443(a) and 1451 of the Safe Drinking Water Act.

(b) *Purpose of program.* Public water system supervision grants are awarded to carry out public water system supervision programs including implementation and enforcement of the requirements of the Act that apply to public water systems.

(c) *Associated program regulations.* Associated program regulations are found in 40 CFR parts 141, 142, and 143.

§ 35.672 Definition.

Tribe. Any Indian Tribe having a federally recognized governing body carrying out substantial governmental duties and powers over any area.

§ 35.673 Annual amount reserved by EPA.

Each year, EPA shall reserve up to seven percent of the public water system supervision funds for grants to Tribes and Intertribal Consortia under section 1443(a).

§ 35.675 Maximum federal share.

(a) The Regional Administrator may provide up to 75 percent of the approved work plan costs.

(b) The Regional Administrator may increase the maximum federal share if the Tribe or Intertribal Consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or Consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship, except that the federal share shall not be greater than 90 percent.

§ 35.676 Eligible recipients.

A Tribe or Intertribal Consortium is eligible to apply for a public water system supervision grant if the Tribe or each member of the Intertribal Consortium meets the following criteria:

(a) The Tribe or each member of the Intertribal Consortium is recognized by the Secretary of the Interior;

(b) The Tribe or each member of the Intertribal Consortium has a governing body carrying out substantial governmental duties and powers over any area;

(c) The functions to be exercised under the grant are within the area of the Tribal government's jurisdiction; and

(d) The Tribe or each member of the Intertribal Consortium is reasonably expected to be capable, in the Regional Administrator's judgment, of carrying out the functions to be exercised under the grant.

§ 35.678 Award limitations.

(a) *Initial grant.* The Regional Administrator will not make an initial award unless the Tribe or each member of the Intertribal Consortium has:

(1) Met the requirements of § 35.676 (Eligible recipients);

(2) Established an approved public water system supervision program or agrees to establish an approvable program within three years of the initial award and assumed primary enforcement responsibility within this period; and

(3) Agreed to use at least one year of the grant funding to demonstrate program capability to implement the requirements found in 40 CFR 142.10.

(b) *Subsequent grants.* The Regional Administrator will not make a subsequent grant, after the initial award, unless the Tribe or each member of the Intertribal Consortia can demonstrate reasonable progress towards assuming primary enforcement responsibility within the three-year period after initial award. After the three-year period expires, the Regional Administrator will not award section 1443(a) funds to an Indian Tribe or Intertribal Consortium unless the Tribe or each member of the Intertribal Consortia has assumed primary enforcement responsibility for the public water system supervision program.

Underground Water Source Protection (Section 1443(b))

§ 35.680 Purpose.

(a) *Purpose of section.* Sections 35.680 through 35.688 govern underground water source protection grants to Tribes and Intertribal Consortia under section 1443(b) of the Safe Drinking Water Act.

(b) *Purpose of program.* The Underground Water Source Protection grants are awarded to carry out underground water source protection programs.

(c) *Associated program regulations.* Associated program regulations are found in 40 CFR parts 124, 144, 145, 146, and 147.

§ 35.682 Definition.

Tribe. Any Indian Tribe having a federally recognized governing body carrying out substantial governmental duties and powers over any area.

§ 35.683 Annual amount reserved by EPA.

EPA shall reserve up to five percent of the underground water source protection funds each year for underground water source protection grants to Tribes under section 1443(b) of the Safe Drinking Water Act.

§ 35.685 Maximum federal share.

(a) The Regional Administrator may provide up to 75 percent of the approved work plan costs.

(b) The Regional Administrator may increase the maximum federal share if the Tribe or Intertribal Consortium can demonstrate in writing to the satisfaction of the Regional Administrator that fiscal circumstances within the Tribe or Consortium are constrained to such an extent that fulfilling the match requirement would impose undue hardship, except that the federal share shall not be greater than 90 percent.

§ 35.686 Eligible recipients.

A Tribe or Intertribal Consortium is eligible to apply for an underground water source protection grant if the Tribe or each member of the Intertribal Consortium meets the following criteria:

(a) The Tribe or each member of the Intertribal Consortium is recognized by the Secretary of the Interior;

(b) The Tribe or each member of the Intertribal Consortium has a governing body carrying out substantial governmental duties and powers over any area;

(c) The functions to be exercised under the grant are within the area of the Tribal government's jurisdiction; and

(d) The Tribe or each member of the Intertribal Consortium is reasonably expected to be capable, in the Regional Administrator's judgment, of carrying out the functions to be exercised under the grant.

§ 35.688 Award limitations.

(a) *Initial grants.* The Regional Administrator will not make an initial award unless the Tribe or each member of the Intertribal Consortium has:

(1) Met the requirements of § 35.676 (Eligible recipients); and

(2) Established an approved underground water source protection program or agrees to establish an approvable program within four years of the initial award.

(b) *Subsequent grants.* The Regional Administrator will not make a subsequent grant, after the initial award, unless the Tribe can demonstrate reasonable progress towards assuming primary enforcement responsibility within the four-year period after initial award. After the four-year period expires, the Regional Administrator shall not award section 1443(b) funds to an Indian Tribe unless the Tribe has assumed primary enforcement responsibility for the underground water source protection program.

Lead-Based Paint Program (Section 404(g))

§ 35.690 Purpose.

(a) *Purpose of section.* Sections 35.690 through 35.693 govern grants to Tribes and Intertribal Consortia under section 404(g) for the Toxic Substances Control Act .

(b) *Purpose of program.* Lead-Based Paint Program grants are awarded to develop and carry out authorized programs to ensure that individuals employed in lead-based paint activities are properly trained; that training programs are accredited; and that contractors employed in such activities are certified.

(c) *Associated program regulations.* Associated program regulations are found in 40 CFR part 745.

§ 35.691 Funding coordination.

Recipients must use the Lead-Based Paint program funding in a way that complements any related assistance they receive from other federal sources for lead-based paint activities.

§ 35.693 Eligible recipients.

(a) The Regional Administrator will treat a Tribe or Intertribal Consortium as eligible to apply for a Lead-Based Paint Program grant if the Tribe or each member of the Intertribal Consortium:

(1) Is recognized by the Secretary of the Interior;

(2) Has an existing government exercising substantial governmental duties and powers;

(3) Has adequate authority to carry out the grant activities; and

(4) Is reasonably expected to be capable, in the Regional Administrator's judgment, of administering the grant program.

(b) If the Administrator has previously determined that an Indian Tribe has met the prerequisites in paragraphs (a)(1) and (2) of this section for another EPA program, the Tribe need provide only that information unique to the Lead-Based Paint Program required by paragraphs (b)(3) and (4) of this section.

Indoor Radon Grants (Section 306)

§ 35.700 Purpose.

(a) *Purpose of section.* Sections 35.700 through 35.708 govern Indoor Radon Grants to Tribes and Intertribal Consortia under section 306 of the Toxic Substances Control Act.

(b) *Purpose of program.* (1) Indoor Radon Grants are awarded to assist Tribes and Intertribal Consortia with the development and implementation of programs that assess and mitigate radon and that aim at reducing radon health risks. Indoor Radon Grant funds may be used for the following eligible activities.

(i) Survey of radon levels, including special surveys of geographic areas or classes of buildings (such as public buildings, school buildings, high-risk residential construction types);

(ii) Development of public information and education materials concerning radon assessment, mitigation, and control programs;

(iii) Implementation of programs to control radon on existing and new structures;

(iv) Purchase, by the Tribe or Intertribal Consortium of radon measurement equipment and devices;

(v) Purchase and maintenance of analytical equipment connected to radon measurement and analysis, including costs of calibration of such equipment;

(vi) Payment of costs of Environmental Protection Agency-approved training programs related to radon for permanent Tribal employees;

(vii) Payment of general overhead and program administration costs;

(viii) Development of a data storage and management system for information concerning radon occurrence, levels, and programs;

(ix) Payment of costs of demonstration of radon mitigation methods and technologies as approved by EPA, including Tribal and Intertribal Consortia participation in the Environmental Protection Agency Home Evaluation Program; and

(x) A toll-free radon hotline to provide information and technical assistance.

(2) In implementing paragraphs (b)(1)(iv) and (ix) of this section, a Tribe or Intertribal Consortia should make every effort, consistent with the goals and successful operation of the Tribal Indoor Radon program, to give preference to low-income persons.

§ 35.702 Basis for allotment.

(a) The Regional Administrator will allot Indoor Radon Grant funds based on the criteria in EPA guidance in accordance with section 306(d) and (e) of the Toxic Substances Control Act.

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(b) No Tribe or Intertribal Consortium may receive an Indoor Radon Grant in excess of 10 percent of the total appropriated amount made available each fiscal year.

§ 35.703 Eligible recipients.

(a) The Regional Administrator will treat a Tribe or Intertribal Consortium as eligible to apply for an Indoor Radon Grant if the Tribe or each member of the Intertribal Consortium:

(1) Is recognized by the Secretary of the Interior;

(2) Has an existing government exercising substantial governmental duties and powers;

(3) Has adequate authority to carry out the grant activities; and,

(4) Is reasonably expected to be capable, in the Regional Administrator's judgment, of administering the grant program.

(b) If the Administrator has previously determined that a Tribe has met the prerequisites in paragraphs (a)(1) and (2) of this section for another EPA program, the Tribe need provide only that information unique to the radon grant program required by paragraphs (a)(3) and (4) of this section.

§ 35.705 Maximum federal share.

The Regional Administrator may provide Tribes and Intertribal Consortia up to 75 percent of the approved costs for the development and implementation of radon program activities incurred by the Tribe in the first year of a grant to the Tribe or Consortium; 60 percent in the second year; and 50 percent in the third and each year thereafter.

§ 35.706 Award limitations.

(a) The Regional Administrator shall consult with the Tribal agency which has the primary responsibility for radon programs as designated by the affected Tribe before including Indoor Radon Grant funds in a Performance Partnership Grant with another Tribal agency.

(b) No grant may be made in any fiscal year to a Tribe or Intertribal Consortium which did not satisfactorily implement the activities funded by the most recent grant awarded to the Tribe or Intertribal Consortium for an Indoor Radon program.

(c) The costs of radon measurement equipment or devices (see § 35.820(b)(1)(iv)) and demonstration of radon mitigation, methods, and technologies (see § 35.820(b)(1)(ix)) shall not, in aggregate, exceed 50 percent of a Tribe's or Intertribal Consortium's radon grant award in a fiscal year.

(d) The costs of general overhead and program administration (see § 35.820(b)(1)(vii)) of an indoor radon grant shall not exceed 25 percent of the amount of a Tribe's or Intertribal Consortium's Indoor Radon Grant in a fiscal year.

(e) A Tribe or Intertribal Consortium may use funds for financial assistance to persons only to the extent such assistance is related to demonstration projects or the purchase and analysis of radon measurement devices.

(f) Recipients must provide the Regional Administrator all radon-related information generated in its grant supported activities, including the results of radon surveys, mitigation demonstration projects, and risk communication studies.

(g) Recipients must maintain and make available to the public, a list of firms and individuals that have received a passing rating under the EPA proficiency rating program under section 305(a)(2) of the Act.

(h) Funds appropriated for section 306 may not be used to cover the costs of federal proficiency rating programs under section 305(a)(2) of the Act. Funds appropriated for section 306 and grants awarded under section 306 may be used to cover the costs of the Tribal proficiency rating programs.

Toxic Substances Compliance Monitoring (Section 28)

§ 35.710 Purpose.

(a) *Purpose of section.* Sections 35.710 through 35.715 govern Toxic Substances Compliance Monitoring grants to Tribes and Intertribal Consortia under section 28 of the Toxic Substances Control Act.

(b) *Purpose of program.* Toxic Substances Compliance Monitoring grants are awarded to establish and operate compliance monitoring programs to prevent or eliminate unreasonable risks to health or the environment associated with chemical substances or mixtures on Tribal lands with respect to which the Administrator is unable or not likely to take action for their prevention or elimination.

(c) *Associated program regulations.* Refer to 40 CFR parts 700 through 799 for associated program regulations.

§ 35.712 Competitive process.

EPA will award Toxic Substances Control Act Compliance Monitoring grants to Tribes or Intertribal Consortia through a competitive process in accordance with national program guidance.

§ 35.713 Eligible recipients.

(a) The Regional Administrator will treat a Tribe or Intertribal Consortium as eligible to apply for a Toxic Substances Compliance Monitoring grant if the Tribe or each member of the Intertribal Consortium:

(1) Is recognized by the Secretary of the Interior;

(2) Has an existing government exercising substantial governmental duties and powers;

(3) Has adequate authority to carry out the grant activities; and,

(4) Is reasonably expected to be capable, in the Regional Administrator's judgment, of administering the grant program.

(b) If the Administrator has previously determined that an Indian Tribe has met the prerequisites in paragraphs (a)(1) and (2) of this section for another EPA program, the Tribe need provide only that information unique to the Toxic Substances Compliance Monitoring grant program required by paragraphs (a)(3) and (4) of this section.

§ 35.715 Maximum federal share.

The Regional Administrator may provide up to 75 percent of the approved work plan costs.

§ 35.718 Award limitation.

If the Toxic Substances Compliance Monitoring grant funds are included in a Performance Partnership Grant, the toxic substances compliance monitoring work plan commitments must be included in the Performance Partnership Grant work plan.

Hazardous Waste Management Program Grants (P.L. 105–276)

§ 35.720 Purpose.

(a) *Purpose of section.* Sections 35.720 through 35.725 govern hazardous waste program grants to eligible Tribes and Intertribal Consortia under the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1999, P.L. 105–276, 112 Stat. 2461, 2499; 42 U.S.C. 6908a (1998).

(b) *Purpose of program.* Tribal hazardous waste program grants are awarded to assist Tribes and Intertribal Consortia in developing and implementing programs to manage hazardous waste.

§ 35.723 Competitive process.

EPA will award Tribal hazardous waste program grants to Tribes or Intertribal Consortia on a competitive basis in accordance with national program guidance. After the competitive process is complete, the recipient can, at its discretion, accept the award as a Tribal hazardous waste program grant or add the funds to a Performance Partnership Grant. If the recipient chooses to add the funds to a Performance Partnership Grant, the Tribal hazardous waste program work plan commitments must be included in the Performance Partnership Grant work plan.

§ 35.725 Maximum federal share.

The Regional Administrator may provide up to 100 percent of the approved work plan costs.

Underground Storage Tanks Program Grants (P.L. 105–276)

§ 35.730 Purpose.

(a) *Purpose of section.* Section 35.730 through 35.733 govern underground storage tank program grants to eligible Tribes and Intertribal Consortia under P.L. 105–276.

(b) *Purpose of program.* Tribal underground storage tank program grants are awarded to assist Tribes and Intertribal Consortia in developing and implementing programs to manage underground storage tanks.

§ 35.731 Eligible recipients.

Eligible recipients of underground storage tank program grants are Tribes and Intertribal Consortia.

§ 35.732 Basis for allotment.

The Administrator allots underground storage tank program grant funds to each regional office based on applicable EPA guidance. Regional offices award funds to Tribes and Intertribal Consortia based on their programmatic needs and applicable EPA guidance.

§ 35.735 Maximum Federal share.

The Regional Administrator may provide up to 100 percent of the approved work plan costs.

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Part VII

Department of the Interior

Fish and Wildlife Service

Policy on Maintaining the Biological Integrity, Diversity, and Environmental Health of the National Wildlife Refuge System; Notice

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

RIN 1018–AG47

Policy on Maintaining the Biological Integrity, Diversity, and Environmental Health of the National Wildlife Refuge System

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We (U.S. Fish and Wildlife Service) issue a final policy to guide personnel of the National Wildlife Refuge System (System) in implementing the clause of the National Wildlife Refuge System Improvement Act of 1997 (Refuge Improvement Act) directing Secretary of the Interior to ensure that the "biological integrity, diversity, and environmental health" of the System is maintained. This policy applies to all units of the System. The policy is an additional directive for refuge managers to follow while achieving refuge purpose(s) and System mission. It provides for the consideration and protection of the broad spectrum of fish, wildlife, and habitat resources found on refuges and associated ecosystems. Further, it provides refuge managers with an evaluation process to analyze their refuge and recommend the best management direction to prevent additional degradation of environmental conditions and, where appropriate in achieving refuge purpose(s) and System mission, restore lost or severely degraded components. Lastly, it provides guidelines for refuge managers to follow in dealing with external threats to biological integrity, diversity, and environmental health.

DATES: This notice is effective February 15, 2001.

FOR FURTHER INFORMATION CONTACT: Elizabeth Souheaver, Acting Chief, Division Natural Resources, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 670, Arlington, Virginia 22203; telephone (703) 358–1744. Please note that the full text of the policy appears at the end of this notice. In addition, the chapter will be available on the System web site *Http://refuges.fws.gov*, select link to "Administration: Federal Register Notices" * * * then click on "2001 Notices" to find "Biological Integrity, Diversity, and Environmental Health."

SUPPLEMENTARY INFORMATION:

Disposition

We published a notice in the **Federal Register** on January 23, 1998 (63 FR 3583) notifying the public that we would be revising the Fish and Wildlife Service Manual, establishing regulations as they relate to the Refuge Improvement Act, and offering to send copies of specific draft Fish and Wildlife Service Manual chapters to anyone who would like to receive them. We published a proposed policy notice in the **Federal Register** (65 FR 61356) on October 17, 2000 with a 45-day comment period ending on December 1, 2000. We extended that comment period to December 15, 2000 with a notice published in the **Federal Register** on December 4, 2000 (65 FR 75731).

The proposed policy was derived from Section 5(a)(4)(B) of the Refuge Improvement Act that the Secretary of the Interior "ensure that the biological integrity, diversity, and environmental health of the System are maintained * * *" The policy presented in this notice is a final policy that has been modified after consideration of public comment. The finalized policy will constitute part 601 Chapter 3 of the Fish and Wildlife Service Manual..

Purpose of This Policy

The purpose of the policy is to provide guidance for maintaining, and restoring where appropriate, the biological integrity, diversity, and environmental health of the National Wildlife Refuge System.

Response to Comments Received

The combined comment periods totaled 60 days. We received 106 comments from the following sources: Non-governmental organizations (36); State agencies or commissions (31); Federal agencies or facilities (9); local or county governmental agencies (3); and individuals (24). The key points raised by these comments fell into 10 general categories:

- Creation of the term "ecological integrity" and its definition:
- Definition of the term "natural conditions" and application of the concept in management;
- Impact of the policy on the ongoing refuge management activities;
- Impact of the policy on recreational use of refuges, primarily hunting and fishing;
- Concern that the policy would not meet specific refuge purpose(s) in favor of the System mission or some other management direction;
- Concern that the policy might adversely affect private property rights of refuge neighbors, and does not adequately recognize the State interests in how we manage refuges;
- Confusion regarding management for biological integrity, diversity, and environmental health at various landscape scales;
- Concern that the policy contains too many exceptions;
- General support either for the entire policy or significant elements of it; and
- A collection of other issues.

We read and addressed all the comments in the categories cited above. These comments, as well as any resulting changes to the policy, are cited below. Eight response letters included comments which were not relevant to the policy. These were not addressed.

Issue 1: The Term "Ecological Integrity"

Comment: Most of the commenters (9 of 14) who cited this term stated that it went beyond the Refuge Improvement Act by creating a term that was not contained in the law or legislative history. Another stated it provided managers too much latitude to threaten private landowners. Still others stated it was too academic and basically unnecessary to meet the requirements of the Refuge Improvement Act. One commenter supported the term but stated the definition needed further refinement pursuant to scientific literature and that we should provide more guidance as to how to measure it.

Response: We never intended for the term "ecological integrity" to be more than a convenient means of referencing the terms biological integrity, diversity and environmental health. We agree, however, that as we used the term throughout the policy it appeared to take on meaning beyond the reference to the three terms. We abandoned the term in the final policy and substitute its appearance with the three specific terms as they appear in the law.

Issue 2: The Definition of the Term "Natural Conditions" and Its Application in Management

Fifty-nine of 106 commenters made specific references to the definition of natural conditions. Of these, 14 generally favored the concept and the remainder expressed concern about the concept and/or its application in management. An additional 9 commenters indicated general support for the policy overall, thus indicating support for the concept as well. However, even the 14 commenters who specifically endorsed the concept did so with various qualifications or suggestions. Overall, the commenters raised the following concerns:

Comment: A reference period is unnecessary, since the Refuge Improvement Act merely requires us to maintain the biological integrity, diversity, and environmental health necessary to meet refuge purposes.

Response: We believe the use of a reference point is pivotal to compliance with the mandate of the Refuge Improvement Act to ensure the maintenance of biological diversity, integrity, and environmental health. To implement the Refuge Improvement Act mandate, we needed definitions for the three terms. We believe a reference period is a critical element in these definitions and thus critical to the assessment of current habitat and wildlife conditions.

Comment: A frame of reference from which to manage is a good idea, but as defined and proposed it is unworkable. Five commenters suggested referencing natural dynamics or processes rather than "conditions;" and four others suggested using "historic range of variability" instead of "natural conditions," as the U.S. Forest Service has done in its "National Forest System Land Resources Management Planning" rule. Several who expressed general disfavor with the policy qualified their comments by suggesting they might accept a more historical reference period rather than a 1,000-year period. Several simply stated we needed something more flexible, achievable, and open to interpretation.

Response: In using the term "natural conditions" relative to a specific period (*i.e.*, 800 to 1800 AD), we chose an approach with scientific underpinnings very similar to those of the Forest Service. We attempted to go a step further, however, by assigning a specific frame of reference from which to work. Our intent in using the period was not to suggest a return to some particular community or habitat but, in fact, to reference something within the historic range of variability as found within that time frame. Section 3.14 of the draft policy noted that we are interested in the "scale and frequency of processes," and managing or restoring a particular site could include any of a range of successional seres or stages that might have occurred on that site within the 1,000-year time frame. Notwithstanding, the way the draft policy presents this concept clearly created a catalyst for controversy among reviewers, and while nine commenters supported the concept with some variation, the great majority expressed strong concern. Thus, we agree that the term "natural conditions" and the implications for management in the framework we have described should be removed from the policy. Instead, we adopted the more general and open-ended term, "historic conditions," which we refer to as the condition of the landscape in a particular area before the onset of significant, human-caused change. See final policy Section 3.12. On that basis, we refined the definitions of biological integrity and environmental health to mean composition, structure and functioning of ecosystems "comparable to historic conditions." The intent is to emphasize not a particular point in time, but the range of ecosystem processes and functions that we believe would have occurred historically.

As developed in the final policy, this "historic" framework incorporates those comments that suggested one simply reflect conceptually on what used to be on the landscape before it underwent major change. In this regard, we have reworded language to clearly emphasize the use of the historic perspective as a starting point for assessing the condition of the landscape, the potential for restoration of habitats where appropriate, and the recognition of irrevocable changes that may preclude or greatly limit restoration. We note that where restoration is impractical, the historic perspective, coupled with the refuge purpose(s) and the System mission, may suggest appropriate and useful habitat management alternatives.

Comment: The time frame to be used as a baseline for natural conditions was arbitrarily chosen and speculative. Managing for natural conditions as proposed is effectively managing for a "snapshot" in time.

Response: We chose the time frame of 800–1800 in keeping with the Refuge Improvement Act, and it was the result of professional judgment with a scientific basis. We began with two premises: (1) "Integrity" and "health" suggest nondegraded conditions, and loss of integrity and health constitutes degradation; and (2) Assessing current degradation requires a benchmark or standard from which to measure. Some stated that the benchmarks for a refuge should be the conditions at time of acquisition, but we viewed that as unacceptable since we acquire many refuges in already extremely degraded condition. The point is to have a benchmark against which to assess such condition and that information will provide some suggestion to a refuge manager regarding a management direction as they attempt to repair such degradation. For our benchmark in the draft policy, we carefully chose a roughly 1000-year time frame during which ecological science tells us we could have expected the full historic range of variability to have occurred within the plant communities which form the basis of habitats for wildlife species. We intentionally chose a relatively modern starting point (800 AD) so as to preclude an argument for Pleistocene flora and fauna, and we carefully chose the end point to be somewhere between European settlement and the onset of the industrial era because that period marked the onset of significant and extensive change in landscapes within the continental United States. The period chosen was very recent in a geologic sense, yet encompassed a range of temperature extremes. This was critical since temperature is one of the most important factors determining ecological composition, structure, and functioning. Given the temperature extremes and time period, and the fact that virtually all modern vegetative communities are thought to have been established by then, 800 AD seemed a reasonable and objective choice to initiate the frame of reference. The relatively extensive and rapid environmental degradation so recognizable today began with the land-intensive practices of pre-industrial European settlers, and accelerated rapidly with the onset of the industrial era. Thus, the period between European settlement and the onset of an industrial era presented an objective endpoint to the frame of reference we chose. However, we recognize the confusion and distraction that this time period has caused, and we have abandoned a specific time period in the final policy. We are now using a more open-ended reference to historic conditions (see Section 3.12 in the final policy).

Comment: Managing for natural conditions, however defined, precludes or preempts managing for specific refuge purpose(s) OR in a related vein, because purposes come first and often entail maintenance of highly artificial conditions, the policy becomes one of exceptions.

Response: Despite the many commenters who inferred otherwise, the draft policy was not intended to be a mandate for refuges to give up current management practices and return to "natural conditions." (See Issue 3: Implications for Refuge Purpose(s) and System Mission below.) One of the difficulties of developing the proposed policy was reconciling the highly artificial and intensively managed nature of many refuges with the Refuge Improvement Act's mandate that we ensure the biological integrity, diversity and environmental health of such refuges. Given the historical needs and thus purpose(s) for which refuges were established, there are indeed a variety of management circumstances directing refuge management. This policy does

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not instruct managers to ignore refuge purpose(s). Rather, it says that when they select management actions that fulfill purpose(s), they should do so following as closely as possible the guidelines provided in this policy while still keeping their obligations to purpose(s) at the forefront. The final policy also emphasizes that much land on a refuge is not directly manipulated in pursuit of purpose(s) and thus managers often have much leeway to protect such tracts from further degradation and, where appropriate and feasible, to restore them as nearly as possible to communities and habitats that might reasonably be thought to have existed historically.

Ultimately, the final policy resolves much of this concern by using "historic conditions" rather than "natural conditions," and by emphasizing the historical perspective as primarily a starting point for choosing management directions and strategies. Also, in the final policy, we have changed any language which might mistakenly be interpreted as directing a return to natural conditions as a management mandate.

Comment: There is no quantitative ecological data available for the 1,000-year reference period. Thus managers would often manage from speculative, often undocumented accounts, and would have nothing quantitative from which to measure progress towards objectives.

Response: Most ecological information is a mixture of quality and quantity, and information on natural conditions is likewise. For example, qualitative information includes which types of plant communities existed in an area during the frame of reference, while quantitative information includes acreage estimates for such plant communities. The final policy continues to provide managers with suggested sources for historic information. However, managers will make the final decisions for determining historic conditions based on sound professional judgment.

Comment: Natural conditions, as defined, are simply not attainable in today's highly altered landscapes, particularly on intensively managed refuges.

Response: The intent of the draft policy was not to attain or re-create natural conditions, but to use natural conditions as a frame of reference for maintaining existing levels of biological integrity (including natural levels of biological diversity) and environmental health. The final policy clearly states our intent to prevent further degradation from historic conditions of biological integrity, diversity and environmental health. We indicate this in Section 3.7 D. of the final policy.

Comment: The policy discounts or ignores the role of humans, especially Native Americans, in shaping landscapes, and implies that there is no place for humans in modern landscapes restored to or managed for natural conditions.

Response: We see that the most natural, intact, and functioning systems are those that have not been impacted by extensive and intensive landscape alterations. Recognition of human impacts on the landscape demonstrates the difference between ecosystems functioning today versus those found prior to substantial landscape changes. We use this information to inform and encourage managers to reflect on the natural ecosystem functions and processes that are necessary to maintain or restore the most viable ecosystem function or processes, and especially those that are necessary to achieve refuge purposes and the System mission. Permanent human alterations to the landscape are a reality and may not be restored and must be managed to maintain the existing levels of biological integrity, diversity and environmental health.

Issue 3: Implications for Refuge Purposes and System Mission

Comment: We received several comments addressing concerns that this policy would have impacts on refuge purposes or affect the System mission. There were 17 comments that interpreted this policy as having a negative impact on refuge purposes; these ranged from some interpretations that this policy would replace refuge purposes to a concern that the policy does not clearly emphasize the priority of refuge purpose(s) over ecological integrity.

Response: In response, we changed the final policy Section 3.7 B. from "Maintaining Biological Integrity of the System and Accomplishing Refuge Purposes," to "Accomplishing Refuge Purposes and Maintaining Biological Integrity, Diversity, and Environmental Health of the System." Further, Section 3.7 B. clearly states the priorities for refuge purposes, System mission, and maintenance of biological integrity, diversity and environmental health.

Comment: One commenter felt that the Ecological Integrity Policy and Refuge Improvement Act should take precedence over, or replace refuge purpose(s).

Response: The fulfillment of refuge purpose(s) is a nondiscretionary statutory duty of the Service. However, the law also requires that we ensure that the biological integrity, diversity, and environmental health of the System is maintained, and therefore, this is an additional duty which we must fulfill as we endeavor to achieve refuge purpose(s) and System mission.

Comment: We received one comment concerning discrepancies between System mission and refuge purpose(s) which inquired as to how often we evaluate and change refuge purpose(s).

Response: Typically, the fulfillment of refuge purpose(s) is consistent with achieving the System mission, but where there are exceptions, refuge purpose(s) take precedence. We evaluate refuge purpose(s) prior to any significant actions proposed on a refuge, but refuge purpose(s) do not change.

Comment: There were two comments that perceived a conflict between the statement that "we may compromise the ecological integrity of a refuge for the sake of maintaining a higher level of ecological integrity at the System scale" and the statement that "conflicts will be resolved in a manner that first protects the refuge purpose(s)."

Reponse: This is a comparison of different issues. We have statutory obligations to fulfill refuge purpose(s) and to protect the biological integrity, diversity and environmental health of the System. Basically, the sentences are meant to convey that biological integrity, diversity and environmental health on an individual refuge may sometimes be compromised when a purpose requires alterations of the landscape to accommodate a broader System need (such as intensively managed feeding or resting areas for migratory waterfowl). In such a case, addressing the flyway needs of waterfowl provide diversity and integrity at a larger landscape.

Comment: Another comment was received expressing concern that promoting ecological integrity of the System might have impacts on ecological integrity for specific refuges.

Response: This is, in fact, the case as noted above. It may sometimes be necessary to compromise the biological integrity, diversity, and/or environmental health of a given refuge in favor of the greater resource needs at the System landscape scale. We will not, however, compromise the fulfillment of individual refuge purposes.

Issue 4: Impacts on Public Use, Especially Hunting and Fishing

We received 34 letters that addressed the relationship between the draft policy and its relationship to public uses on refuges and public use as mandated under Refuge Improvement Act.

Comment: More than half of these letters (17) were concerned that the policy, as drafted, would interfere with or eliminate hunting and fishing on refuges while another 13 letters were concerned that this policy would affect or find all public uses incompatible with ecological integrity.

Response: We did not write the draft policy with the intent or direction to eliminate hunting, fishing, or other priority public uses recognized by the Refuge Improvement Act. This draft policy rarely mentions public use, but where it does, the purpose is for refuge managers to consider impacts on wildlife and habitat (*i.e.*, biological integrity, diversity, and environmental health) when implementing public uses. The authority for this draft policy is the Refuge Improvement Act, which also clearly identifies hunting and fishing as priority public uses. Section 2.(6) of the Refuge Improvement Act states, "When managed in accordance with principles of sound fish and wildlife management and administration, fishing, hunting * * * in national wildlife refuges have been and are expected to continue to be generally compatible uses." In order to clearly address concerns over priority public uses, we have added Section 3.7 G. "Principles Underlying This Policy, Public Use", to the final policy. A summary of this section is as follows: The Service reiterates the importance of the public being able to utilize refuges for those priority public uses, including hunting and fishing. The six priority wildlife-dependent public uses identified in the Refuge Improvement Act are generally not in conflict with management for the biological integrity, diversity, and environmental health when compatible with refuge purpose(s). Restoration of historical landscapes as they appeared prior to significant disturbance does not generally mean exclusion of visitors. But we direct refuges to use spatial or temporal zoning to manage public visitation in a way that it complements efforts to protect and, where appropriate, restore historic habitats and wildlife populations. In addition, fishing programs on refuges will not be terminated in pursuit of biological integrity, diversity, and environmental health because managed fishing programs on refuges do not impact fish population viability.

Comment: A few letters specifically question the relationship between ecological integrity and compatibility determinations used for permitting hunting and fishing.

Response: We determine compatibility of a priority public use on a refuge by comparing that use to the purpose of the refuge and the mission of the System. If we determine a use to be compatible, then we facilitate it. However, that does not preclude administration of those public uses in such a way as to promote biological integrity, diversity, and environmental health, and the Refuge Improvement Act directs managers to do so. In such cases, a refuge may carefully plan the location, size, and use of structures for an environmental education program, for example, perhaps adopt hunting regulations (*e.g.*, antlerless deer hunts) more restrictive than those of a respective State. Because the use of the words "conflict with" confused this issue, we have deleted the sentence that contains it.

Comment: There also were a few letters that felt the policy will find public use structures such as boardwalks, roads, observation towers, and similar facilities in conflict with ecological integrity. The draft policy says that "Where feasible, we also pursue ecological integrity by eliminating unnatural biotic and abiotic features and processes not necessary to accomplish refuge purposes."

Response: The purpose of this section of the policy is for managers to consider ways to minimize impacts on biological integrity, diversity, and environmental health when planning structures and facilities by placing them in the most suitable location to allow quality public use while still ensuring biological integrity, diversity, and environmental health.

Comment: A few letters thought that hunting, fishing and trapping should not be permitted on refuges because they interfere with ecological integrity, while one letter wanted "trapping" added to Section 3.14 where hunting and fishing are encouraged in cooperation with State fish and wildlife management agencies.

Response: The six priority wildlife-dependent uses are given special status by the Refuge Improvement Act, which specifically recognizes hunting, fishing, wildlife observation, photography, interpretation, and environmental education. Refuges must facilitate these uses when compatible. The Refuge Improvement Act does not similarly recognize trapping.

Issue 5: Implications for States and Other Partnerships

Comment: Various States commented that the policy should place emphasis on cooperation and coordination with States in the management of wildlife populations on refuges.

Response: Strong partnerships with the respective States are an essential part of all refuge planning and management, including the maintenance of biological integrity, diversity, and environmental health of refuges. We encourage and expect managers to forge effective partnerships with States through cooperation and coordination in the management of wildlife habitats and populations found on refuges. We have changed the language in the final policy, Section 3.14, to more clearly state this expectation.

Issue 6: Implications for Private Property Rights

Comment: Several commenters were concerned that the policy was not mindful of the property rights of others and encouraged managers to seek resolutions to problems injuring resources on refuges through litigation.

Response: We changed Section 3.20 of the final policy to emphasize that the preferred course of action for managers in cases of injury to refuge resources from outside sources is first to seek cooperative resolution to such conflicts through neighborly discussion, negotiation, and consultation. This includes working with State or local agencies and other third party interests to seek solutions of mutual satisfaction. The revised policy offers several steps for a manager to take in this regard. Ultimately, however, and with full respect of private property rights, we recognize our responsibility to protect the property and resources of the American public, and state the responsibility to do so.

Issue 7: Implications for Wildlife and Habitat Management on Refuges

Comment: We received many comments which expressed concern about the role of active management on refuges under the proposed policy. These comments noted that active management is often necessary to achieve refuge purpose(s). Some felt management for natural conditions basically implied an absence of management and would, therefore, conflict with achieving refuge purpose(s). Comments also noted that numerous refuges are located in highly altered landscapes where active management is needed to maintain wildlife values of the refuge. A few comments identified that active management actions are required to maintain desirable wildlife populations where habitats surrounding the refuge have been degraded.

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Response: We acknowledge that active management is often critically important to achieve refuge purpose(s). We also acknowledge that at some refuges very intensive management actions are required to maintain high densities of some wildlife species. We will continue active management where needed. However, we will evaluate management practices on all refuges to ensure that we take appropriate management action to achieve refuge purpose(s), while at the same time addressing the guidelines identified in the final policy.

Comment: Numerous comments noted that identifying "natural conditions" during the time period 800 AD to 1800 AD and then managing for conditions identified during that period was inappropriate and was contrary to Service mandates to achieve refuge purpose(s) which necessitate active management.

Response: As noted throughout the policy and in above responses to comments (see Issue 3: Implications for Refuge Purpose(s) and System Mission), nothing in this chapter places management for biological integrity, diversity, and environmental health above refuge purpose(s). However, we still need a reference period to assess the condition of a refuge and to provide a management perspective. In the final chapter, we propose to use historic conditions to assess the status of refuges in relation to conditions present before man substantially altered the landscape. We will use this historic reference to identify appropriate ranges of habitats that may occur at a refuge, which species of wildlife should occur, and what processes that shaped these habitats still exist. We will maintain processes which are still extant. We will mimic processes which no longer exist or have been altered in our management actions or, where appropriate and feasible, restore them if possible. Due to the highly altered landscapes in which many refuges exist, we acknowledge that extensive active management actions are required to mimic these natural processes to achieve refuge purpose(s). We also acknowledge that numerous refuges have been so drastically altered that it may be infeasible to restore the historic conditions of biological integrity, diversity, and environmental health.

Comment: Other commenters were concerned that the extent and types of active management were left too much to the discretion of the Refuge Manager. They felt that such discretion would lead to inconsistencies in refuge management practices.

Response: The Refuge Manager is the first line manager responsible for all aspects of management of a refuge. The Refuge Manager is the individual most knowledgeable about conditions at each refuge. It is the manager's responsibility to identify appropriate management for the refuge. However, we acknowledge that inconsistencies do occur. To minimize this concern, we have instituted numerous review and approval processes for what managers propose. Examples of these review and approval processes are refuge management plans, Comprehensive Conservation Plans, National Environmental Policy Act guidelines, Endangered Species Act, Section 7 regulations and guidance, and individual refuge program reviews. All of these require some form of Regional Office oversight and/or public input and comment.

Comment: A few comments were concerned that refuges should not manage for natural densities, age structures, and sex ratios of large ungulates and other fish and wildlife populations mainly because this may not be in keeping with State management objectives and or may not be feasible.

Response: The final policy directs refuges to work cooperatively with the States devising appropriate harvest strategies to achieve these objectives, recognizing that the refuge management objectives may differ from those of the State. In such cases, refuges may implement regulations more restrictive than those of their respective States in pursuit of more natural sex and age structures. We will not take such actions without consulting State fish and wildlife management agencies.

Comment: A few comments identified concerns for public health, related to natural production of insects which are vectors of disease. It was proposed that management of vector populations should be included in this policy in a manner that is consistent with protection of the natural resources that exist within the refuge.

Response: We also are very much concerned about threats to human health. However, our mandate is to manage for "Wildlife First," and in numerous situations management to eliminate or reduce insect vectors will adversely impact the quality of food chains and wildlife habitats at a refuge, so we intend to continue to follow our current policy of taking action to reduce vector populations only when needed to address a Declared Human Health Emergency. We are working with agencies responsible for vector control to identify vector management practices, which we can use on refuges while not compromising the purpose(s) of the refuge or System mission. In emergency events, such as a Declared Human Health Emergency, the Service and responsible agencies will work together to address these situations.

Comment: One comment addressed the need to introduce large predators to maintain some wildlife populations.

Response: We agree that predators are an important component of System biological integrity and diversity. To this end, we have undertaken programs to reintroduce predators to some refuges where this action is feasible. At other refuges, efforts are being made to maintain declining populations of some predatory species. Where introductions of large predators may be feasible at a refuge, we would undertake a thorough public scoping process to identify how this action may impact local communities. In cases where key predator species cannot be feasibly reintroduced, we may employ management practices, including hunting programs, to both provide recreational opportunity and improve biological integrity by maintaining natural densities of certain wildlife prey species.

Issue 8: Implications of Policy at Different Landscape Scales

Comment: There were 12 letters that raised issues of scale and the definitions and references to landscapes.

Response: Use of the term "local landscape" in the draft policy caused some confusion among these commenters. We intended the term to describe the refuge and its immediate surroundings. In the final policy, we dropped the "landscape" part of the term and use "local scale" or "refuge scale" to refer to a refuge and the area around it.

Comment: The majority of other comments on this issue related to how integrity will be maintained at various scales.

Response: It is important to stress that this policy does not authorize or suggest that refuge staff will manage lands outside their boundaries. However, it does provide clear direction that refuge managers must examine the context of their management actions at the refuge scale and all scales up to the international scale. Within each refuge there is a certain amount of biological diversity, integrity, and environmental health that contribute to these conditions at a local scale. However, as part of larger systems, each refuge must examine its contributions to objectives that have been developed at larger scales through initiatives such as the North American Waterfowl Management Plan or Partners in Flight. Refuges must continually reassess their contributions in light of new information and new initiatives, such as the North American Bird Conservation Initiative. As noted throughout the policy, refuges must seek to identify their most important contributions to these higher levels. Sometimes this will mean sacrificing biological diversity and integrity at the local scale in order to contribute to diversity at a larger scale, while at all times managing for refuge purpose(s).

Comment: Two reviewers asked for definitions of landscapes within which refuges will operate.

Response: There is no single answer to this question. Refuges operate at many different scales, and landscapes are not always defined the same way. For example, we develop our ecosystem teams within major watersheds, while Bird Conservation Regions of the North American Bird Conservation Initiative are defined using ecoregions developed by the Commission for Environmental Cooperation. The continual challenge for refuge managers is to achieve refuge purpose(s) while evaluating the refuge's most significant contributions to regional, national, and international goals and objectives.

Comment: One reviewer observed that the System is not an ecological system.

Response: This is true. It is a System of lands that is administratively bound together and for which the Refuge Improvement Act has set certain standards for management. While not all refuges are connected ecologically, many refuges are, particularly those located along migratory bird pathways. This policy directs those refuges that are connected ecologically to examine their roles in the context of purpose(s), but also in the context of maintaining, and when appropriate, restoring biological integrity, diversity, and environmental health at all levels. In doing so, all refuges contribute to the maintenance of biological integrity and diversity, and environmental health, of the System.

Issue 9: Other Issues

Sixty-two commenters raised numerous "other" issues and concerns in addition to those major categories addressed above. Typically, any given concern was addressed by perhaps 10 or fewer commenters. We group these as "other" issues and address them below:

Comment: Seven commenters raised the concern that the policy will have a profound effect on local tax bases, local economies, and property rights through land protection and acquisition. They expressed fears about land acquisition and managers pursuing civil action against neighbors whose actions damage refuge resources. Three felt the policy constitutes a significant Federal action under NEPA and requires an environmental impact statement.

Response: We feel these fears are ungrounded. The policy will not accelerate the rate of land acquisition within the System. The policy creates no new authorities for refuge managers, nor do we expect it to create significant new conflicts among managers and private landowners. On the contrary, it emphasizes partnerships and similar cooperative avenues to resolve conflicts (See Issue 6: Implications for Private Property Rights). Section 3.20 of the final policy emphasizes that we will take any resolution of conflicts with full respect of private property rights. We will follow NEPA guidelines when refuge managers implement this policy in refuge Comprehensive Conservation Plans, compatibility determinations, and other interim management plans.

Comment: The definition of "sound professional judgment" is unnecessary or goes beyond the Refuge Improvement Act. Seven commenters made these remarks, including one who believed the concept of allowing individual managers to interpret management needs was unsafe because of their different backgrounds and biases. Another believes the policy should incorporate more oversight of refuge managers to address this concern and let comprehensive conservation planning (CCP) teams make judgments. Another wanted to know who a refuge manager might consult with outside the Service in making management decisions.

Response: We deleted the term "sound professional judgment" from the definitions of the final policy because we already defined it in the Compatibility chapter (see 603 FW 2). We maintained the term as integral to the final policy, which we believe is in keeping with the Refuge Improvement Act. We concur that refuge managers will make different interpretations of management needs in different situations, and there is value to group processes. However, we must still empower refuge managers to make the decisions inherent to administering a refuge. The refuge manager is the individual with the most holistic, on-the-ground knowledge of the circumstances surrounding management operations. It is typical for refuge managers to maintain close working relationships with State agencies, neighboring landowners, academics, conservation organizations, and/or local government, many of whose concerns are addressed in choosing management direction.

Comment: The policy is not properly presented in the context of the Refuge Improvement Act and other policies. Six commenters stated the policy inappropriately elevates the Refuge Improvement Act's mandate to "ensure * * * biological integrity, diversity and health" above thirteen other directives found in Section 5 of the Refuge Improvement Act. Some also felt we should explain how the policy will be interpreted in the context of other Service policies.

Response: The policy on biological integrity, diversity, and environmental health is a new policy which has not previously existed in other forms. We already address virtually all other directives of the Refuge Improvement Act in some form in existing policies, which we are updating as necessary to incorporate these directives. The policy is not intended to elevate biological integrity, diversity and environmental health above the other directives, though we do believe and state in Section 3.7 A. of the final policy that biological integrity, diversity and environmental health are "intrinsic and high priority components of wildlife conservation" and thus important to the "Wildlife first!" principle.

Comment: Two comments voiced the concern that we provide no direction for measuring and evaluating results.

Response: We provide ample guidance on management through goals and objectives and adaptive management in 602 FW 1–4 (policies related to comprehensive conservation planning) and the related Writing Refuge Management Goals and Objectives: A Handbook. Section 3.19 B. of the final policy specifies that we will develop goals and objectives for maintaining biological integrity, diversity, and environmental health into Comprehensive Conservation Plans.

Comment: Eight commenters expressed some variation of "The policy is unfocused, ambiguous, not achievable, and a catalyst for litigation."

Response: We feel the various changes to the policy incorporating such comments (*e.g.*, use of "historic conditions" rather than "natural conditions," modification of the frame of reference, etc.) have addressed this concern by simplifying and focusing the language.

Comment: One commenter held the view that this policy is unnecessary.

Response: We disagree based on the Refuge Improvement Act mandate.

Comment: One commenter commented on the use of prescribed fires and wildfires * * * that the policy might result in greater use of prescribed fire as a management tool, and noted

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that use of fire must include consideration of air quality impacts.

Response: Fire is already a much-used and significant management tool on refuges, and we do not anticipate a marked increase in its use as a result of this policy. Coordination of controlled burns with State air quality agencies is standard procedure for refuges, and that will not change under this policy.

Comment: One commenter stated we should avail ourselves of new technology, regardless of whether it mimics nature.

Response: We disagree that all new land management technology is appropriate for refuges. We encourage refuges to utilize the tools that are available and most efficient for accomplishing refuge objectives while remaining in compliance with existing policy.

Comment: One commenter held the view that the policy "second guesses" nature by promoting the creation of natural disasters like floods and fires.

Response: The policy promotes mimicking the results of such disasters through the application of prescribed fires and moist soil management. It does not advocate creating them on historic scales.

Comment: How do we deal with native but nonindigenous species that utilize the "artificial" habitats created by much of traditional refuge management? Two commenters noted that such species now utilize niches created in habitats that did not exist historically.

Response: We often create such habitats on refuges in order to accomplish a refuge-specific purpose (*e.g.*, creation of marsh habitat where none previously existed). As noted in various places throughout the draft and final policies, actions taken in pursuit of purpose(s)—and by implication the results of those actions—(*e.g.*, the population of new habitats by species which do not previously occur in an area) take precedence over any conflicting elements of this policy.

Comment: We received one comment that the Endangered Species Act is minimized in the policy and not elevated above other refuge priorities.

Response: We recognize several statutes, including the Endangered Species Act, that provide direction for management of national wildlife refuges. We expect refuge managers to follow all relevant environmental compliance statutes in the execution of this policy.

Comment: One commenter voiced the concern that Section 3.10 unnecessarily references "evolution" as part of the natural processes on refuges.

Response: We disagree because it does not detract from the policy, and we feel that it is relevant.

Comment: Relationship to the "Wildlife First!" principle: Four commenters addressed the relationship between biological integrity, diversity and environmental health and the "wildlife first" mandate of the Refuge Improvement Act. One wanted the "wildlife first" idea removed in favor of public uses. Others agreed with the "wildlife first" principle, but not to the diminution of public use.

Response: This would be in conflict with the purpose and mission of refuges and the Refuge Improvement Act that clearly place wildlife and habitat as the first priority on refuges. These concerns were addressed in the above section on public use (Section 6: Impacts on public use, especially hunting and fishing).

Comment: One commenter voiced the concern that the policy attempts to nullify important elements of the Alaska National Interest Lands Conservation Act (ANILCA), referencing two elements of the draft policy that seemed to imply this. First was the draft policy's heavy emphasis on "natural conditions," which the commenter interpreted as a "back to nature policy."

Response: While we believe the commenter misinterpreted the draft policy, we nevertheless abandoned the concept of "natural conditions" in favor of the more appropriate and open-ended "historic conditions" and clarified the way this frame of reference would be utilized in management. Second, the commenter felt the draft policy was anti-public use, and thus in opposition to ANILCA. We have clarified this by adding "recognizing public use as an underlying principle of biological integrity, diversity and environmental health" in Section 3.7 G. of the final policy. That section emphasizes the appropriateness of public use on refuges and clarifies the relationship between public use and biological integrity, diversity, and environmental health. In any case, Section 9 of the Refuge Improvement Act explicitly reiterates support for ANILCA by noting that any conflicts between the two Acts will be resolved in favor of ANILCA. The present policy cannot override the statutory language.

Comment: One commenter felt the biological integrity discussion is inadequate. Section 3.10A. of the draft policy should be expanded to include the "natural functioning of ecosystems" and the "spatial distribution of species within a landscape" and should also "incorporate ecosystem service provided by fully functioning natural ecosystems."

Response: We feel our discussion in the final policy implicitly and adequately includes these concepts as written. The same commenter felt we should recognize the value of recolonization by native species over physical reintroductions of such species. We concur with the commenter and favor recolonization where source populations are available; however, where no such source is available, we advocate reintroduction.

Comment: The policy needs to be simplified.

Response: We concur and incorporated significant changes into the final policy to accomplish this. Most notably, we modified the definition of "natural conditions" to "historic conditions" and deleted extensive sections of text in support of natural conditions. We simplified related definitions, and we added language to clarify the relationships among refuge purpose(s), public use, and "biological integrity, diversity, and environmental health."

Comment: What are the ramifications regarding State water rights, as well as State and local flood control projects? One commenter inquired as to how the policy might direct a manager to address water development upstream of a refuge that diverted water from a refuge. On a similar but opposite note, another commenter was concerned the policy would not allow diversion of flood waters onto refuges should the need arise as part of a local flood control effort.

Response: Nothing in either the draft or final policies is meant to suggest we will attempt to override or change the legitimate existing water rights of any party. However, if the actions of any party impinge on our legal water rights, we will take action to defend those rights as necessary. We expect refuge managers to review all controlling legal authorities, including appropriate statutes, establishing purposes, relevant Service policy, binding contracts and other legal considerations before entering into agreements regarding flood control and related issues. The present policy will not alone determine a course of action here, but rather the sum of all such considerations. Managers will undoubtedly take such action only in close consultation with their Regional solicitor.

Comment: In a comment concerning draft policy's emphasis of on-refuge research over off-refuge research, one letter believed Section 3.7G. ("Adaptive Management") of the draft policy inappropriately emphasized on-refuge research, and noted research off-refuge has value as well.

Response: We concur; however, in the final policy, we abbreviated the discussion of "Adaptive Management" and removed the references to research and other specific elements in the interest of brevity, so the question is moot.

Comment: Refuges should manage for as many species as possible once purposes are met. One commenter felt Section 3.11 of the draft policy should permit the introduction of as wide an array of species as possible on refuge, specifically any species that is in decline, whether or not it is listed.

Response: We disagree. Such an approach would produce diffuse and unfocused management, as well as defeat the intent of the present policy. Threatened and endangered species provide a clear, statutory responsibility not present with nonlisted species.

Comment: Several commenters felt that the draft policy ignored the role of humans in the ecosystems.

Response: Neither the draft nor final policy ignores the role of humans, but both imply that prior to European settlement and subsequent industrialization of the United States, humans existed in a somewhat steady state with the environment. While they indeed had a effect, smaller and more dispersed populations and lack of mechanized technology produced more of a harmony than we see today. The policy addresses the significant changes to landscapes that have occurred since European settlement.

Comment: One commenter felt the policy ignored ongoing significant ecological phenomena like glaciers.

Response: Section 3.14 of the draft policy states that we do not attempt to "correct" natural phenomena like volcanic eruptions and naturally impounded water. Both the draft and final policies recognize natural processes throughout without regard to scale.

Comment: One commenter felt that biological integrity, as the draft policy defines it, is not a major component of wildlife conservation.

Response: We disagree based on best available science.

Comment: Two commenters felt the policy should include a planning element to assure refuges address the practical considerations of meeting their purposes in the face of changing future conditions or to examine ways to balance the various management alternatives open to refuges under this policy.

Response: Other Service policies on comprehensive conservation planning (see 602 FW 1–4) provide a process for incorporating and reconciling refuge purposes with the requirements of this policy.

Comment: Several commenters expressed concern that refuges do not have adequate staff or funds to meet the requirements of this new policy. One felt the policy will distance staff from their basic, more important administrative functions.

Response: We believe such concerns reflect a misinterpretation of the policy. In some regards, managing pursuant to this policy may require more staff, funds, or planning time; however, other changes in management philosophy, direction, or strategies will reduce staff and funds being expended on existing efforts. We also believe implementation of this policy is integral to the basic administration of a refuge.

Comment: The System's contribution to conservation should be that of a laboratory and teaching facility rather than conservation area. One commenter suggested wildlife can only be "saved" on private lands, so refuges should be dedicated to research, teaching, and extension.

Response: We believe this view to be counter to statutory mandate for the System found in the Refuge Improvement Act, as well as contrary to the long history and institutional culture of individual refuges and the System overall. Virtually all refuges are facilities for research, teaching, and outreach; but they also fulfill a vital conservation role among the broad mosaic of wildlife and habitat conservation efforts throughout the United States.

Comment: Thirteen commenters suggested we either withdraw the policy altogether or else withdraw it unless we incorporate significant changes.

Response: The final policy incorporates significant revisions that were meant to address the extensive concerns voiced about natural conditions, public uses, and partnerships with States and private landowners. Given this, we feel the policy merits publication.

Comment: Issues not relevant to the policy: Many reviewers, while addressing various aspects of the policy, expressed concerns such as tribal rights, taking of endangered species, refuge funding and administration, etc.

Response: We do not believe these concerns were applicable to the policy.

Issue 10: General Support

Nineteen commenters expressed general support of the draft policy as written, although 12 individuals qualified their support in various ways, suggesting different treatment of "natural conditions," more specifics on public use, more clarity or language, etc. These supportive respondents were from a cross section of categories: four Federal agencies, five State agencies, four environmentally-oriented, non-governmental organizations, one sportsman's group, two academics, and three private individuals. One additional State natural resource agency specifically supported Section 3.7F. "Wildlife and Habitat Management." Additionally, several commenters specifically supported our proposal to manage ungulate populations for natural sex and age structure.

Supportive comments included the following: "* * * the draft policy was well written and understandable;" "* * * it establishes new and overdue philosophy;" "* * * it promotes wildlife first and active management when necessary;" "* * * it ensures consistency;" "* * * it is flexible;" "* * * it is scientifically credible and balanced;" "* * * it promotes landscape-scale conservation by allowing refuges to manage for habitats lost in other parts of the landscape, it allows for maintenance of a variety of habitat stages;" and "* * * it promotes cooperation with States, and it will help refuge managers implement the Refuge Improvement Act."

One supportive reviewer suggested that we expand the summary and clarify it to ensure that we emphasize the most important aspects of the policy. We revised the summary to incorporate this and other comments. Two reviewers suggested that the draft policy deals effectively with deer management issues. Two reviewers mentioned concerns about implementation but otherwise expressed general support.

Issue 11: Extension of Comment Period

Comments: Fourteen letters were received requesting an extension of the comment period, from 45 to 120 days. Four made open-ended extension requests, *i.e.*, with no extension period specified.

Response: We extended the period by 15 days, for a total comment period of 60 from the date of first publication.

The text of the final policy follows:

Fish and Wildlife Service

National Wildlife Refuge System

Refuge Management—Part 601 National Wildlife Refuge System

Chapter 3—Biological Integrity, Diversity, Environmental Health 601 FW 3

3.1 What Is the Purpose of This Chapter?

This chapter provides policy for maintaining, and restoring where

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appropriate, the biological integrity, diversity, and environmental health of the National Wildlife Refuge System.

3.2 What Is the Scope of This Policy?

This policy applies to all units of the System.

3.3 What Is the Biological Integrity, Diversity, and Environmental Health Policy?

The policy is an additional directive for refuge managers to follow while achieving refuge purpose(s) and System mission. It provides for the consideration and protection of the broad spectrum of fish, wildlife, and habitat resources found on refuges and associated ecosystems. Further, it provides refuge managers with an evaluation process to analyze their refuge and recommend the best management direction to prevent further degradation of environmental conditions; and where appropriate and in concert with refuge purposes and System mission, restore lost or severely degraded components.

3.4 What Are the Objectives of This Policy?

A. Describe the relationships among refuge purposes, System mission, and maintaining biological integrity, diversity, and environmental health.

B. Provide guidelines for determining what conditions constitute biological integrity, diversity, and environmental health.

C. Provide guidelines for maintaining existing levels of biological integrity, diversity, and environmental health.

D. Provide guidelines for determining how and when it is appropriate to restore lost elements of biological integrity, diversity, and environmental health.

E. Provide guidelines to follow in dealing with external threats to biological integrity, diversity, and environmental health.

3.5 What Are Our Authorities for This Policy?

A. National Wildlife Refuge System Administration Act of 1966 as amended by the National Wildlife Refuge System Improvement Act of 1997, 16 U.S.C. 668dd–668ee (Refuge Administration Act)

The authority for this policy is the National Wildlife Refuge System Administration Act of 1966, as amended by the National Wildlife Refuge System Improvement Act of 1997, 16 U.S.C. 668dd-668ee (Refuge Administration Act). Section 4(a)(4)(B) of this law states that "In administering the System, the Secretary shall * * * ensure that the biological integrity, diversity, and environmental health of the System are maintained for the benefit of present and future generations of Americans * * *." This is one of 14 directives to the Secretary contained within the Refuge Administration Act.

3.6 What Do These Terms Mean?

A. *Biological diversity.* The variety of life and its processes, including the variety of living organisms, the genetic differences among them, and communities and ecosystems in which they occur.

B. *Biological integrity.* Biotic composition, structure, and functioning at genetic, organism, and community levels comparable with historic conditions, including the natural biological processes that shape genomes, organisms, and communities.

C. *Environmental health.* Composition, structure, and functioning of soil, water, air, and other abiotic features comparable with historic conditions, including the natural abiotic processes that shape the environment.

D. *Historic conditions.* Composition, structure, and functioning of ecosystems resulting from natural processes that we believe, based on sound professional judgment, were present prior to substantial human related changes to the landscape.

E. *Native.* With respect to a particular ecosystem, a species that, other than as a result of an introduction, historically occurred or currently occurs in that ecosystem.

3.7 What Are the Principles Underlying This Policy?

A. Wildlife First

The Refuge Administration Act, as amended, clearly establishes that wildlife conservation is the singular National Wildlife Refuge System mission. House Report 105–106 accompanying the National Wildlife Refuge System Improvement Act of 1997 states "* * * the fundamental mission of our System is wildlife conservation: wildlife and wildlife conservation must come first." Biological integrity, diversity, and environmental health are critical components of wildlife conservation.

B. Accomplishing Refuge Purposes and Maintaining Biological Integrity, Diversity, Environmental Health of the System

The Refuge Administration Act states that each refuge will be managed to fulfill refuge purpose(s) as well as to help fulfill the System mission, and we will accomplish these purpose(s) and our mission by ensuring that the biological integrity, diversity, and environmental health of each refuge is maintained, and where appropriate, restored. We base our decisions on sound professional judgment.

C. Biological Integrity, Diversity, and Environmental Health in a Landscape Context

Biological integrity, diversity, and environmental health can be described at various landscape scales from refuge to ecosystem, national, and international. Each landscape scale has a measure of biological integrity, diversity, and environmental health dependent on how the existing habitats, ecosystem processes, and wildlife populations have been altered in comparison to historic conditions. Levels of biological integrity, diversity, and environmental health vary among refuges, and often within refuges over time. Individual refuges contribute to biological integrity, diversity, and environmental health at larger landscape scales, especially when they support populations and habitats that have been lost at an ecosystem, national, or even international scale. In pursuit of refuge purposes, individual refuges may at times compromise elements of biological integrity, diversity, and environmental health at the refuge scale in support of those components at larger landscape scales. When evaluating the appropriate management direction for refuges, refuge managers will consider their refuges' contribution to biological integrity, diversity, and environmental health at multiple landscape scales.

D. Maintenance and Restoration of Biological Integrity, Diversity, Environmental Health

We will, first and foremost, maintain existing levels of biological integrity, diversity, and environmental health at the refuge scale. Secondarily, we will restore lost or severely degraded elements of integrity, diversity, environmental health at the refuge scale and other appropriate landscape scales where it is feasible and supports achievement of refuge purpose(s) and System mission.

E. Wildlife and Habitat Management

Management, ranging from preservation to active manipulation of habitats and populations, is necessary to maintain biological integrity, diversity, and environmental health. We favor management that restores or mimics natural ecosystem processes or function to achieve refuge purpose(s). Some refuges may differ from the frequency and timing of natural processes in order to meet refuge purpose(s) or address biological integrity, diversity, and environmental health at larger landscape scales.

F. Sound Professional Judgment

Refuge managers will use sound professional judgment when implementing this policy primarily during the comprehensive conservation planning process to determine: The relationship between refuge purpose(s) and biological integrity, diversity, and environmental health; what conditions constitute biological integrity, diversity, and environmental health; how to maintain existing levels of all three; and, how and when to appropriately restore lost elements of all three. These determinations are inherently complex. Sound professional judgment incorporates field experience, knowledge of refuge resources, refuge role within an ecosystem, applicable laws, and best available science including consultation with others both inside and outside the Service.

G. Public Use

The priority wildlife-dependent public uses, established by the National Wildlife Refuge System Improvement Act of 1997, are not in conflict with this policy when determined to be compatible. The directives of this policy do not generally entail exclusion of visitors or elimination of public use structures, *e.g.*, boardwalks and observation towers. However, maintenance and/or restoration of biological integrity, diversity, and environmental health may require spatial or temporal zoning of public use programs and associated infrastructures. General success in maintaining or restoring biological integrity, diversity, and environmental health will produce higher quality opportunities for wildlife-dependent public use.

3.8 What Are Our Responsibilities?

A. Director

(1) Provides national policy, goals and objectives for maintaining and restoring the biological integrity, diversity, and environmental health of the System.

(2) Ensures that national plans and partnerships support maintaining and restoring the biological integrity, diversity, and environmental health of the System.

(3) Ensures that the national land acquisition strategy for the System is designed to enhance the biological integrity, diversity, and environmental health of the System at all landscape scales.

B. Regional Director

(1) Provides regional policy, goals and objectives for maintaining and restoring the biological integrity, diversity, and environmental health of the System, including guidance to resolve any conflicts with biological integrity, diversity, and environmental health at an individual refuge versus at the larger landscape scales.

(2) Ensures that regional and ecosystem plans, and regional partnerships support maintaining and restoring the biological integrity, diversity, and environmental health of the System.

(3) Resolves conflicts that arise between maintaining biological integrity, diversity, and environmental health at the refuge level landscape scale versus at larger landscape scales.

C. Regional Chief

(1) Ensures that individual refuge comprehensive conservation plans support maintaining and restoring the biological integrity, diversity, and environmental health of the System.

(2) Reviews and ensures those refuge management programs that occur on many refuges (*e.g.*, fire management) are consistent with this policy.

D. Refuge Manager

(1) Follows the procedure outlined in Section 3.9 of this chapter.

(2) Incorporate the principles of this policy into all refuge management plans and actions.

3.9 How Do We Implement This Policy?

The Director, Regional Directors, Regional Chiefs, and Refuge Managers will carry out their responsibilities specified in Section 3.8 of this chapter. In addition, refuge managers will carry out the following tasks.

A. Identify the refuge purpose(s), legislative responsibilities, refuge role within the ecosystem and System mission.

B. Assess the current status of biological integrity, diversity, and environmental health through baseline vegetation, population surveys and studies, and any other necessary environmental studies.

C. Assess historic conditions and compare them to current conditions. This will provide a benchmark of comparison for the relative intactness of ecosystems' functions and processes. This assessment should include the opportunities and limitations to maintaining and restoring biological integrity, diversity, and environmental health.

D. Consider the refuge's importance to refuge, ecosystem, national, and international landscape scales of biological integrity, diversity, and environmental health. Also, identify the refuge's roles and responsibilities within the Regional and System administrative levels.

E. Consider the relationships among refuge purpose(s) and biological integrity, diversity and environmental health, and resolve conflicts among them.

G. Through the comprehensive conservation planning process, interim management planning, or compatibility reviews, determine the appropriate management direction to maintain and, where appropriate, restore, biological integrity, diversity, and environmental health, while achieving refuge purpose(s).

H. Evaluate the effectiveness of our management by comparing results to desired outcomes. If the results of our management strategies are unsatisfactory, assess the causes of failure and adapt our strategies accordingly.

3.10 What Factors Do We Consider When Maintaining and Restoring Biological Integrity, Diversity, and Environmental Health?

We plan for the maintenance and restoration of biological integrity, diversity, and environmental health while considering all three in an integrated and holistic manner. The highest measure of biological integrity, diversity, and environmental health is viewed as those intact and self-sustaining habitats and wildlife populations that existed during historic conditions.

A. Biological Integrity

(1) We evaluate biological integrity by examining the extent to which biological composition, structure, and function has been altered from historic conditions. Biological composition refers to biological components such as genes, populations, species, and communities. Biological structure refers to the organization of biological components, such as gene frequencies, social structures of populations, food webs of species, and niche partitioning within communities. Biological function refers to the processes undergone by biological components, such as genetic recombination, population migration, the evolution of species, and community succession [see 602 FW 3.4 C (1)(e), Planning Area and Data Needs].

(2) Biological integrity lies along a continuum from a biological system extensively altered by significant human

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impacts to the landscape to a completely natural system. No landscape retains absolute biological integrity, diversity, and environmental health. However, we strive to prevent the further loss of natural biological features and processes, i.e., biological integrity.

(3) Maintaining or restoring biological integrity is not the same as maximizing biological diversity. Maintaining biological integrity may entail managing for a single species or community at some refuges and combinations of species or communities at other refuges. For example, a refuge may contain critical habitats for an endangered species. Maintaining that habitat (and, therefore, that species), even though it may reduce biological diversity at the refuge scale, helps maintain biological integrity and diversity at the ecosystem or national landscape scale.

(4) In deciding which management activities to conduct to accomplish refuge purpose(s) while maintaining biological integrity, we start by considering how the ecosystem functioned under historic conditions. For example, we consider the natural frequency and timing of processes such as flooding, fires, and grazing. Where it is not appropriate to restore ecosystem function, our refuge management will mimic these natural processes including natural frequencies and timing to the extent this can be accomplished.

(5) We may find it necessary to modify the frequency and timing of natural processes at the refuge scale to fulfill refuge purpose(s) or to contribute to biological integrity at larger landscape scales. For example, under historic conditions, an area may have flooded only a few times per decade. Migratory birds dependent upon wetlands may have used the area in some years, and used other areas that flooded in other years. However, many wetlands have been converted to agriculture or other land uses, the remaining wetlands must produce more habitat, more consistently, to support wetland-dependent migratory birds. Therefore, to conserve these migratory bird populations at larger landscape scales, we may flood areas more frequently and for longer periods of time than they were flooded historically.

B. Biological Diversity

(1) We evaluate biological diversity at various taxonomic levels, including class, order, family, genus, species, subspecies, and—for purposes of Endangered Species Act implementation—distinct population segment. These evaluations of biological diversity begin with population surveys and studies of flora and fauna. The System's focus is on native species and natural communities such as those found under historic conditions [see 602 FW 3.4 C (1)(e)]. The Natural Heritage Network databases for respective States should prove a valuable tool for this initial evaluation.

(2) We also evaluate biological diversity at various landscape scales, including refuge, ecosystem, national, and international. On refuges, we typically focus our evaluations of biological diversity at the refuge scale; however, these refuge evaluations can contribute to assessments at larger landscape scales.

(3) We strive to maintain populations of breeding individuals that are genetically viable and functional. We provide for the breeding, migrating, and wintering needs of migratory species. We also strive to maximize the size of habitat blocks and maintain connectivity between blocks of habitats, unless such connectivity causes adverse effects on wildlife or habitat (*e.g.*, by facilitating the spread of invasive species).

(4) At the community level, the most reliable indicator of biological diversity is plant community composition. We use the National Vegetation Classification System to identify biological diversity at this level.

C. Environmental Health

(1) We evaluate environmental health by examining the extent to which environmental composition, structure, and function have been altered from historic conditions. Environmental composition refers to abiotic components such as air, water, and soils, all of which are generally interwoven with biotic components (*e.g.*, decomposers live in soils). Environmental structure refers to the organization of abiotic components, such as atmospheric layering, aquifer structure, and topography. Environmental function refers to the processes undergone by abiotic components, such as wind, tidal regimes, evaporation, and erosion. A diversity of abiotic composition, structure, and function tends to support a diversity of biological composition, structure, and function [see 602 FW 3.4 C (1)(e), Planning Area and Data Needs].

(2) We are especially concerned with environmental features as they affect all living organisms. For example, at the genetic level, we manage for environmental health by preventing chemical contamination of air, water, and soils that may interfere with reproductive physiology or stimulate high rates of mutation. Such contamination includes carcinogens and other toxic substances that are released within or outside of refuges.

(3) At the population and community levels, we consider the habitat components of food, water, cover, and space. Food and water may become contaminated with chemicals that are not naturally present. Activities such as logging and mining or structures such as buildings and fences may modify security or thermal cover. Unnatural noise and light pollution may also compromise migration and reproduction patterns. Unnatural physical structures, including buildings, communication towers, reservoirs, and other infrastructure, may displace space or may be obstacles to wildlife migration. Refuge facility construction and maintenance projects necessary to accomplish refuge purpose(s) should be designed to minimize their impacts on the environmental health of the refuge.

3.11 How Do We Apply Our Management Strategies To Maintain and Restore Biological Integrity, Diversity, and Environmental Health?

A. We strive to manage in a holistic manner the combination of biological integrity, diversity, and environmental health. We balance all three by considering refuge purpose(s), System mission, and landscape scales. Considered independently, management strategies to maintain and restore biological integrity, diversity, and environmental health may conflict.

B. For example, physical structures and chemical applications are often necessary to maintain biological integrity and to fulfill refuge purpose(s). We may use dikes and water control structures to maintain and restore natural hydrological cycles, or use rotenone to eliminate invasive carp from a pond. These unnatural physical alterations and chemical applications would compromise environmental health if considered in isolation, but they may be appropriate management actions for maintaining biological integrity and accomplishing refuge purpose(s).

C. We may remove physical structures to promote endangered species recovery in some areas, or we may remove plants or animals to protect structures, depending upon refuge purpose(s). Unless we determine that a species was present in the area of a refuge under historic conditions, we will not introduce or maintain the presence of that species for the purpose of biological diversity. We may make exceptions where areas are essential for the conservation of a threatened or endangered species and suitable habitats are not available elsewhere. In such cases, we strive to minimize unnatural effects and to restore or maintain natural processes and ecosystem components to the extent practicable without jeopardizing refuge purpose(s).

3.12 How Do We Incorporate Information From Historic Conditions Into Our Management Decisions?

A. Maintaining biological integrity, diversity, and environmental health require an ecological frame of reference. A frame of reference allows us to contrast current conditions of our resources with historic conditions. The reference guides us in two ways. It provides information on how the landscape looked prior to changes in land use that destroyed and fragmented habitats and resulted in diminished wildlife populations and the extirpation or extinction of species. It also allows us to examine how natural ecosystems function and maintain themselves. We use these conditions as a frame of reference in which to develop goals and objectives.

B. We use historical conditions as the frame of reference to identify composition, structure, and functional processes that naturally shaped ecosystems. We especially seek to identify keystone species, indicator species, and types of communities that occurred during the frame of reference. We also seek to ascertain basic information on natural ecosystem structure such as predator/prey relationships and distribution of plant communities. Finally, we seek to identify the scale and frequency of processes that accompanied these components and structures, such as fire regimes, flooding events, and plant community succession. Where appropriate and feasible, we also pursue biological integrity, diversity, and environmental health by eliminating unnatural biotic and abiotic features and processes not necessary to accomplish refuge purpose(s).

C. We do not expect, however, to reconstruct a complete inventory of components, structures, and functions for any successional stage occurring during the frame of reference. Rather, we use sound professional judgment to fit the pieces to create a conceptual picture of our resources under historic conditions.

D. We ensure that our management activities result in the establishment of a community that fits within what we reasonably believe to have been the natural successional series, unless doing so conflicts with accomplishing refuge purpose(s). We may choose to maintain nonclimax communities pursuant to refuge purpose(s) or for maintaining biological integrity, diversity, and environmental health at the regional, national, or international landscape scale. We favor techniques such as fire or flooding that mimic or result in natural processes to maintain these nonclimax communities. However, where it will support fulfillment of refuge purpose(s), we allow or, if necessary, encourage natural succession to proceed.

3.13 Where Do We Get Information on Historic Conditions?

A. Information on historic conditions may be historical, archeological, or other. Historical information includes the written and, in some cases, the pictographic accounts of Native Americans, explorers, surveyors, traders, and early settlers. Archeological information comes from collections of cultural artifacts maintained by scientific institutions. We may obtain other data from a range of sources, including research, soil sediments, and tree rings.

B. We obtain information on historic conditions from our investigations and from partners in academia, conservation organizations, and other Federal, State, Tribal, and local government agencies. In many cases, we use historical vegetation maps to provide data. Such historical maps are usually drawn at relatively coarse scales, perhaps to the level of vegetation alliance. Generally a comprehensive historical list of plant and animal species is not available or necessary. We will base the determination of natural species and ecosystem composition on sound professional judgment. We periodically update our information on historic conditions with results from ongoing historical, archeological, and other studies.

3.14 How Do We Manage Populations To Maintain and Restore Biological Integrity, Diversity, and Environmental Health?

A. We encourage cooperation and coordination with State fish and wildlife management agencies in setting refuge population goals and objectives. To the extent practicable, our regulations pertaining to fishing or hunting of resident wildlife within the System are consistent with State fish and wildlife laws, regulations, and management plans.

B. We maintain, or contribute to the maintenance of, populations of native species. We design our wildlife population management strategies to support accomplishing refuge purpose(s) while maintaining or restoring biological integrity, diversity, and environmental health. We formulate refuge goals and objectives for population management by considering natural densities, social structures, and population dynamics at the refuge level, and population objectives set by national plans and programs—such as the North American Waterfowl Management Plan—in which the System is a partner.

C. Natural densities are relatively stable for some species and variable for others. We manage populations for natural densities and levels of variation, while assuring that densities of endangered or otherwise rare species are sufficient for maintaining viable populations. We consider population parameters such as sex ratios and age class distributions when managing populations to maintain and restore where appropriate biological integrity, diversity, and environmental health.

D. On some refuges, including many of those having the purpose of migratory bird conservation, we establish goals and objectives to maintain densities higher than those that would naturally occur at the refuge level because of the loss of surrounding habitats. We more closely approximate natural levels at larger landscape scales, such as flyways, by maintaining higher densities at the refuge level.

E. We do not, however, allow densities to reach excessive levels that result in adverse effects on wildlife and habitat. The effects of producing densities that are too high may include disease, excessive nutrient accumulation, and the competitive exclusion of other species. We use planning and sound professional judgment to determine prudent limits to densities.

F. Where practical, we support the reintroduction of extirpated native species. We consider such reintroduction in the context of surrounding landscapes. We do not introduce species on refuges outside their historic range or introduce species if we determine that they were naturally extirpated, unless such introduction is essential for the survival of a species and prescribed in an endangered species recovery plan, or is essential for the control of an invasive species and prescribed in an integrated pest management plan.

3.15 How Do We Manage Habitats To Maintain and Restore Biological Integrity, Diversity, Environmental Health?

A. We will, first and foremost, maintain existing levels of biological

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integrity, diversity, and environmental health at the refuge scale. Following that, we will restore lost or degraded elements of biological integrity, diversity, and environmental health at all landscape scales where it is feasible and supports fulfillment of refuge purposes.

B. Our habitat management plans call for the appropriate management strategies that mimic historic conditions while still accomplishing refuge objectives. For example, prescribed burning can simulate natural fire regimes or water level management can mimic natural hydrological cycles. Farming, haying, logging, livestock grazing, and other extractive activities are permissible habitat management practices only when prescribed in plans to meet wildlife or habitat management objectives, and only when more natural methods, such as fire or grazing by native herbivores, cannot meet refuge goals and objectives.

C. We do not allow refuge uses or management practices that result in the maintenance of non-native plant communities unless we determine there is no feasible alternative for accomplishing refuge purpose(s). For example, where we do not require farming to accomplish refuge purpose(s), we cease farming and strive to restore natural habitats. Where feasible and consistent with refuge purpose(s), we restore degraded or modified habitats in the pursuit of biological integrity, diversity, and environmental health. We use native seed sources in ecological restoration. We do not use genetically modified organisms in refuge management unless we determine their use is essential to accomplishing refuge purpose(s) and the Director approves the use.

3.16 How Do We Manage Non-Native Species To Maintain and Restore Biological Integrity, Diversity, and Environmental Health?

A. We prevent the introduction of invasive species, detect and control populations of invasive species, and provide for restoration of native species and habitat conditions in invaded ecosystems. We develop integrated pest management strategies that incorporate the most effective combination of mechanical, chemical, biological, and cultural controls while considering the effects on environmental health.

B. We require no action to reduce or eradicate self-sustaining populations of non-native, noninvasive species (*e.g.*, pheasants) unless those species interfere with accomplishing refuge purpose(s). We do not, however, manage habitats to increase populations of these species unless such habitat management supports accomplishing refuge purpose(s).

3.17 How Does This Policy Affect the Acquisition of Lands for the System?

A. We consider the mission, goals, and objectives of the System in planning for its strategic growth. We will take a proactive approach to identifying lands that are critical for maintaining or restoring the biological integrity, diversity, and environmental health of the System at all landscape scales. We will integrate this approach into all Service strategies and initiatives related to the strategic growth of the System. We incorporate the directives of this policy when evaluating an area's potential contribution to the conservation of the ecosystems of the United States.

B. We use the Land Acquisition Priority System to rank potential acquisitions once the Director approves significant expansions or new refuges. Our Land Acquisition Priority System includes components that gauge the contributions of refuges to maintaining and restoring biological integrity, diversity, and environmental health.

3.18 What Is the Relationship Between Biological Integrity, Diversity, and Environmental Health and Compatibility?

When completing compatibility determinations, refuge managers use sound professional judgment to determine if a refuge use will materially interfere with or detract from the fulfillment of the System mission or the refuge purpose(s). Inherent in fulfilling the System mission is protection of the biological integrity, diversity, and environmental health of the System. Specific policy for compatibility is found in 603 FW 2.

3.19 What Is the Relationship Between Biological Integrity, Diversity, and Environmental Health and Comprehensive Conservation Planning?

A. We integrate the principles of this policy into all aspects of comprehensive conservation planning, including pre-planning guidance [see 602 FW 3.4 C (1)(e)] as we complete plans to direct long-range refuge management and identify desired future conditions for proposed refuges (see 602 FW 1.7 D).

B. Refuge purpose(s) and the System mission serve as the basis for goals and objectives at all levels of the System (*e.g.*, System, Regional, ecosystem, and refuge level). When we develop refuge goals and objectives during the Comprehensive Conservation Plan process we include goals and objectives for maintaining and restoring the biological integrity, diversity, and environmental health of the refuge.

C. While developing Comprehensive Conservation Plans, we make management decisions based on sound professional judgment. We subsequently evaluate the effectiveness of these decisions by comparing results to desired outcomes. If the results are unsatisfactory, we assess the causes of failure and adapt our management decisions accordingly. In part, we base management decisions on natural resource-related research that has been conducted on refuges. This type of research adds to the general body of information related to natural resource management and aids us in continually adapting our management decisions. We generally encourage natural resource-related research on refuges.

3.20 How Do We Protect Biological Integrity, Diversity, and Environmental Health From Actions Outside of Refuges?

Events occurring off refuge lands or waters may injure or destroy the biological integrity, diversity, and environmental health of a refuge. Given their responsibility to the public resources with which they have been entrusted, refuge managers should address these problems. It is critical that they pursue resolution fully cognizant and respectful of legitimate private property rights, seeking a balance between such rights and the refuge manager's own responsibility to the public trust. While each situation will be different, the following is a suggested procedure which emphasizes our desire for cooperative resolutions. The time and effort expended, and the rate at which a refuge manager escalates the process, will depend on the severity of threat and the resources at risk.

A. We first seek resolution by directly contacting the landowner(s), corporation, agency or other entity from which the problem originates.

B. Where direct discussions fail, managers might seek resolution through collaborative discussions with State or local authorities or other organizations that can help in cooperative resolution of the problem.

C. An appropriate next step might be to pursue resolution at the local level through planning and zoning boards or other regulatory agencies at the city and county level. Failing that, the manager may seek avenues through State administrative and regulatory agencies. Regulatory solutions are a serious step, and a manager should take this route only after careful consideration and in close consultation with the Regional Offices.

D. If the above efforts fail, we may take action within the legal authorities available to the Service and with full respect to private property rights. In such cases, refuge managers will consult with the Office of the Solicitor for assistance in identifying appropriate remedies and obtain concurrence from the Regional Director.

Dated: January 8, 2001.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

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Part VIII

Office of Management and Budget

North American Industry Classification System—Revision for 2002; Notice

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OFFICE OF MANAGEMENT AND BUDGET

North American Industry Classification System—Revision for 2002

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of final decision.

SUMMARY: Under Title 44 U.S.C. 3504(e), the Office of Management and Budget (OMB) is announcing its final decision to adopt the North American Industry Classification System (NAICS) revisions for 2002 as recommended by the Economic Classification Policy Committee in OMB's notice for solicitation of comments in Part II of the April 20, 2000, **Federal Register** (65 FR 21241). In addition, OMB is adopting one change not included in the April 20, 2000, notice—the move of Map and Atlas Publishing from Industry 511199, All Other Publishing, to Industry 511130, Book Publishing.

In the April 20, 2000, notice, OMB's Economic Classification Policy Committee (ECPC) recommended a revision of the industry classification system to extend the three-country agreement level for the Construction sector and to recognize important changes in the Information sector. In addition, as an interim measure in the United States, the ECPC recommended restructuring the Wholesale Trade sector to reflect differences in production functions and to capture more accurately the rapidly-growing business-to-business electronic markets developing in the United States. For the Retail Trade sector, the United States is creating additional national level detail for department stores and nonstore retailers to create more meaningful, homogeneous industries for the United States. More details of this decision are presented in the **SUPPLEMENTARY INFORMATION** section below.

EFFECTIVE DATE: Federal statistical data published for reference years beginning on or after January 1, 2002, should be published using the 2002 NAICS United States codes. Agencies may adopt the 2002 NAICS earlier at their discretion. Publication of a 2002 NAICS United States Manual is planned for January 2002.

ADDRESSES: You should send correspondence about the adoption and implementation of 2002 NAICS as shown in the April 20, 2000, **Federal Register** notice, and modified by Attachments 1, 2, and 3 of this notice, to: Katherine K. Wallman, Chief Statistician, Office of Management and Budget, 10201 New Executive Office Building, Washington, DC 20503, telephone number: (202) 395–3093, FAX number: (202) 395–7245.

You should address inquiries about the content of industries or requests for electronic copies of the 2002 NAICS tables to: John Murphy, Assistant Division Chief for Classification Activities, Service Sector Statistics Division, Bureau of the Census, Room 2641–3, Washington, DC 20233, telephone number: (301) 457–2672, FAX number: (301) 457–1343.

Electronic Availability and Comments:

This document and the April 20, 2000, **Federal Register** are available on the Internet from the Census Bureau via WWW browser and E-mail. To obtain this document via WWW browser, connect to http://www.census.gov/naics. This WWW page also contains previous NAICS **Federal Register** notices and related documents.

FOR FURTHER INFORMATION CONTACT: Paul Bugg, 10201 New Executive Office Building, Washington, DC 20503, E-mail address: pbugg@omb.eop.gov, telephone number: (202) 395–3095, FAX number: (202) 395–7245.

SUPPLEMENTARY INFORMATION: The April 20, 2000, **Federal Register** notice (1) summarized the background for the proposed revisions to NAICS 1997 in Part I; (2) contained a summary of public comments in Part II; (3) detailed the structure changes agreed upon by the three countries in Part III; and (4) provided a comprehensive listing of changes for national industries and their links to NAICS 1997 industries in Part IV.

Subsequent to the release of the April 20 **Federal Register**, representatives from the statistical agencies of Mexico, Canada, and the United States who were working on a parallel three-country product classification system proposed to the three-country Steering Committee that Atlas and Map Publishers, currently in NAICS Industry 51119 Other Publishers, be moved to Industry 51113 Book Publishers. This proposal stemmed from the fact that the process of publishing atlases is similar to the publishing process for books such as reference books, and that the same industries often produce both atlases and maps. Informal discussions with these industries confirmed their support of this change. OMB's final decision regarding revision of NAICS for 2002 is to adopt the proposal contained in the April 20, 2000, **Federal Register**, with the one change to move Atlas and Map Publishers into Industry 51113. Attachments 1, 2, and 3 show the corrected lines for Tables 1, 2, and 3, as contained in the April 20 **Federal Register**.

After taking into consideration other comments submitted in direct response to the April 20, 2000, **Federal Register** notice, as well as benefits and costs, and after consultation with the Economic Classification Policy Committee (ECPC), Mexico's Instituto Nacional de Estadística, Geografiia e Informática (INEGI) and Statistics Canada, OMB made no other changes to the scope and substance of the April 20, 2000, **Federal Register** notice. The other comments that were received either supported proposed changes, or suggested changes that would be incompatible with the production-based foundation of NAICS or be incompatible with proposals that were accepted.

NAICS was jointly developed by Canada, Mexico, and the United States. For the 2002 revision the three countries focused on harmonizing and updating the Construction and Information sectors of NAICS. In the 1997 NAICS, the Construction sector was comparable among all three countries only at the highest levels of aggregation. Although new in 1997, the Information sector lacked finite categories related to important new and emerging industries, prompting the three countries to re-evaluate and restructure this sector. The United States will implement structural changes for the Wholesale Trade and Retail Trade sectors which will not impact the three country comparability for these sectors. It was not the intent of the ECPC to open for consideration all areas of NAICS that currently lack three-country comparability or to revise sectors other than those specifically listed above. Other sectors will be re-evaluated for future NAICS revisions.

Sally Katzen,

Deputy Director for Management.

Attachment 1—Revisions to Table 1 of the April 20, 2000, Federal Register Part II

TABLE 1.—2002 NAICS UNITED STATES MATCHED TO 1997 NAICS UNITED STATES

2002 NAICS code	2002 NAICS and U.S. description	Status code	1997 NAICS code	1997 NAICS description
51113	Book Publishers	R	*511199	All Other Publishers (atlas and map publishers, except Internet Publishing).
		R	*511130	Book Publishers (except Internet Publishing).

Attachment 2—Revisions to Table 2 of the April 20, 2000, Federal Register Part II

TABLE 2.—1997 NAICS MATCHED TO 2002 NAICS UNITED STATES

1997 NAICS code	1997 NAICS U.S. description	2002 NAICS code	2002 NAICS and U.S. description
511199	All Other Publishers:		
	Atlas and Map Publishers (except Internet Publishers)	511130	Book Publishers.
	Atlas and Map Publishers (Internet Publishers) and All Other Internet Publishers.	516110	Internet Publishers (pt.)
	All Other Publishers (except Internet Publishers)	511199	All Other Publishers.

Attachment 3—Revisions to Table 3 of the April 20, 2000, Federal Register Part II

TABLE 3.—2002 NAICS UNITED STATES MATCHED TO 1987 STANDARD INDUSTRIAL CLASSIFICATION

2002 NAICS code	2002 NAICS description	1987 SIC code	1987 SIC description
51113	Book Publishers:		
	Atlas and Map Publishers and Technical Book and Manual Publishers. (except Internet)	2741	Miscellaneous Publishing (atlases and books, technical books and manuals, except Internet publishing)
	Book Publishers (except Internet)	2731	Books: Publishing or Publishing and Printing (except music books and Internet book publishing).

[FR Doc. 01–1131 Filed 1–12–01; 8:45 am]

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Part IX

Office of Management and Budget

Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity; Notice

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OFFICE OF MANAGEMENT AND BUDGET

Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity

AGENCY: Executive Office of the President, Office of Management and Budget (OMB), Office of Information and Regulatory Affairs.

ACTION: Notice of availability and request for comments.

SUMMARY: OMB is announcing the availability of "Provisional Guidance for the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity," and soliciting public comment on any aspects of the document for a period of 60 days. The document is close to 200 pages and thus is not being reproduced in the **Federal Register**. It is available electronically on the OMB web site at the following address: http://www.whitehouse.gov/OMB/inforeg/index.html#SP—go to Data on Race and Ethnicity, or in paper form from OMB at the address below. This updated material supercedes and replaces the draft provisional guidance that OMB made available on its web site in February 1999.

DATES: Written comments should be received by OMB by March 19, 2001.

ADDRESSES: Please send comments to: Katherine K. Wallman, Chief Statistician, Office of Management and Budget, Room 10201 New Executive Office Building, 725 17th Street, N.W., Washington, DC 20503; fax: (202) 395–7245.

Electronic Availability and Addresses: This **Federal Register** Notice is available electronically from the OMB web site: http://www.whitehouse.gov/OMB/fedreg/index.html. **Federal Register** Notices also are available electronically from the U.S. Government Printing Office web site: http://www.access.gpo.gov/su_docs/aces/aces140.html.

FOR FURTHER INFORMATION CONTACT: Suzann Evinger at telephone 202–395–7315; or E-mail: sevinger@omb.eop.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** for October 30, 1997, OMB announced "Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity," which revised the standards originally adopted in 1977. (See 62 FR 58781—58790 for background on revisions that were adopted). This classification provides a minimum set of five categories for data on race (American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White) and two categories for data on ethnicity (Hispanic or Latino and Not Hispanic or Latino). In addition to changes in the categories and terminology, the 1997 standards require that agencies provide the opportunity for individuals to choose more than one racial category if they wish to reflect multiple racial heritages.

Since this change in policy that permits reporting of more than race was announced, considerable attention has been given to the question of how data on multiple race responses would be tabulated. Federal agencies and other users of data on race and ethnicity requested guidance on how to implement several aspects of the 1997 standards.

OMB issued some preliminary tabulation guidance as part of the October 30, 1997 **Federal Register** Notice. In addition, for the past several years the Tabulation Working Group of the Interagency Committee for the Review of Standards for Data on Race and Ethnicity has been considering tabulation and other implementation issues and working to develop additional guidance. This group of statistical and policy experts drawn from the Federal agencies that generate or use data on race and ethnicity produced draft provisional guidance that OMB issued on its web site in February 1999. The provisional guidance being announced today is a substantially updated version of the earlier guidance. It reflects public comments on the earlier draft as well as the Tabulation Working Group's further research and deliberations on the issues.

The guidance presented in this document is intended for any Federal agencies or organizational units that maintain, collect, or present data on race and ethnicity for Federal statistical purposes, program administrative reporting, or civil rights compliance reporting. To foster comparability across data collections carried out by various agencies, it is useful for those agencies to report responses of more than one race using some standardized tabulations or formats.

The guidance briefly explains why the tabulation guidelines are needed, reviews the general guidance issued when the standards were adopted in October 1997, and provides information on the criteria used in developing the guidelines. The guidance also addresses a larger set of implementation questions that have emerged during the working group's deliberations. Thus, the guidance addresses: collecting data on race and ethnicity using the 1997 standards, including sample questions; tabulating Census 2000 data as well as data on race and ethnicity collected in surveys and from administrative records; using data on race and ethnicity in applications such as legislative redistricting, civil rights monitoring and enforcement, and population estimates; and comparing data under the 1997 and the 1977 standards when conducting trend analyses. The 1997 standards are reproduced in Appendix A to the guidance. Appendix B provides OMB Bulletin No. 00–02, Guidance on Aggregation and Allocation of Data on Race for Use in Civil Rights Monitoring and Enforcement." Appendix C provides the full report with tables (85 pages) on how data collected under the 1997 standards might be meaningfully compared to data collected under the 1977 standards. Including the appendices, the full document is close to 200 pages.

This guidance is necessarily provisional pending the availability of data from Census 2000 and other data systems as the 1997 standards are implemented. The guidance provides a general framework and is not intended to cover every specific issue that agencies will encounter during their implementation of the 1997 standards. In some instances, for example, specific implementation issues are being addressed through OMB's review of data collections under the Paperwork Reduction Act. This guidance is expected to be reviewed and refined as Federal agencies and others gain experience with data collected under the 1997 standards and as agencies address implementation issues in their respective programs.

Below is the table of contents for the "Provisional Guidance on the Implementation of the 1997 Standards for Federal Data on Race and Ethnicity."

Table of Contents

Chapter 1. Background

A. Need for Tabulation Guidelines
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Chapter 4. Using Data on Race and Ethnicity Collected Under the 1997 Standards

A. Civil Rights Enforcement and Monitoring
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Chapter 5. Comparing Data Collected Under the 1997 and the 1977 Standards (Full Report at Appendix C)

A. Introduction
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F. Strategies for Users

Appendix A. Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (October 30, 1997)
Appendix B. OMB Bulletin No. 00–02, Guidance on Aggregation and Allocation of Data on Race for Use in Civil Rights Monitoring and Enforcement (March 9, 2000)
Appendix C. Bridge Report: Tabulation Options for Trend Analysis

OMB would appreciate receiving views and comments on any aspects of the provisional guidance for implementing the 1997 standards for Federal data on race and ethnicity.

Sally Katzen,

Deputy Director for Management.

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Part X

Department of Justice

Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against Origin Discrimination Affecting Limited English Proficient Persons; Notice

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DEPARTMENT OF JUSTICE

Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons

AGENCY: United States Department of Justice.

ACTION: Policy Guidance Document.

SUMMARY: The United States Department of Justice (DOJ) is publishing policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons.

DATES: This guidance is effective immediately. Comments must be submitted on or before March 19, 2001. DOJ will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

ADDRESSES: Interested persons should submit written comments to Ms. Merrily Friedlander, Chief, Coordination and Review Section, Civil Rights Division, Department of Justice, P.O. Box 66560, Washington, DC 20035–6560; Comments may also be submitted by facsimile at 202–307–0595.

FOR FURTHER INFORMATION CONTACT: Christine Stoneman or Sebastian Aloot at the Civil Rights Division, P.O. Box 66560, Washington, DC 20035–6560. Telephone 202–307–2222; TDD: 202–307–2678. Arrangements to receive the policy in an alternative format may be made by contacting the named individuals.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.* and its implementing regulations provide that no person shall be subjected to discrimination on the basis of race, color, or national origin under any program or activity that receives federal financial assistance.

The purpose of this policy guidance is to clarify the responsibilities of recipients of federal financial assistance from the U.S. Department of Justice (DOJ) ("recipients"), and assist them in fulfilling their responsibilities to limited English proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964 and implementing regulations. The policy guidance reiterates DOJ's longstanding position that in order to avoid discrimination against LEP persons on the grounds of national origin, recipients must take reasonable steps to ensure that such persons have meaningful access to the programs, services, and information those recipients provide, free of charge.

The policy guidance includes appendices. Appendix A provides examples of how this guidance would apply to DOJ recipients. Appendix B provides further information on the legal bases for the guidance. It also explains further who is covered by this guidance. The text of the complete guidance document, including appendices, appears below.

Dated: January 5, 2001.

Daniel Marcus,

Associate Attorney General, United States Department of Justice.

Guidance to Recipients of U.S. Department of Justice Federal Financial Assistance: Providing Meaningful Access to Individuals Who Are Limited English Proficient in Compliance With Title VI and Implementing Regulations ("LEP Guidance for DOJ Recipients")

I. Introduction

For most people living in the United States, English is their native language or they have learned to read, speak, and understand English. There are others for whom English is not their primary language. If they also have limited ability to read, speak, or understand English, then these people are limited English proficient, or "LEP." For them, language can be a barrier to accessing benefits or services, understanding and exercising important rights, or understanding other information provided by federally funded programs and activities.

This guidance ("Guidance") is based on Title VI of the Civil Rights Act of 1964 and regulations that implement Title VI. Title VI was intended to eliminate barriers based on race, color, and national origin in federally assisted programs or activities. In certain circumstances, failing to ensure that LEP persons can effectively participate in or benefit from federally assisted programs and activities or imposing additional burdens on LEP persons is national origin discrimination. Therefore, recipients must take reasonable steps to ensure meaningful access for LEP persons.

In August, 2000, the President signed Executive Order 13166. Under that order, every federal agency that provides financial assistance to non-federal entities must create guidance on how their recipients can provide meaningful access to LEP persons and therefore comply with the longstanding Title VI law and its regulations. DOJ is issuing this Guidance to comply with the Executive Order. The guidance document is new, but Title VI's meaningful access requirement is not.

This Guidance should help recipients of Department of Justice (DOJ) financial assistance understand how to comply with the law. Recipients have a great deal of flexibility in determining how to comply with the meaningful access requirement, and are not required to use all of the suggested methods and options listed. As always, recipients also have the freedom to and are encouraged to go beyond mere compliance and create model programs for LEP access.

Federal financial assistance includes grants, training, use of equipment, donations of surplus property, and other assistance. Recipients of DOJ assistance include, for example:

- Police and sheriffs' departments
- Departments of corrections
- Courts
- Certain nonprofit agencies with law enforcement missions.

When federal funds are passed through from one recipient to a subrecipient, the subrecipient is also covered by Title VI.

The LEP persons that are eligible to be served or encountered by these recipients include, but are not limited to:

- LEP persons who are in the custody of the recipient, including juveniles, detainees, wards, and inmates.
- LEP persons subject to or serviced by law enforcement activities, including, for example, suspects, violators, witnesses, victims, and community members.
- LEP persons who are not in custody but are under conditions of parole or probation.
- LEP persons who encounter the court system.
- Parents and family members of the above.

Title VI applies to the entire program or activity of a recipient of DOJ assistance. That means that Title VI covers all parts of a recipient's operations. This is true even if only one part of the agency uses the federal assistance.

Example: DOJ provides assistance to a state department of corrections to improve a particular prison facility. All of the operations of the entire state department of corrections—not just the particular prison—are covered by Title VI.

Technical Assistance

DOJ plans to continue to provide assistance and guidance in this important area. For example, DOJ plans to work with representatives of law enforcement, corrections, courts, and LEP persons to identify model plans and examples of best practices and share those with recipients.

DOJ Programs and Activities

At the same time as federal agencies are creating recipient guidance, Executive Order 13166 requires that they create LEP plans for their own agencies that are consistent with the standards for recipients. Therefore, DOJ will apply the standards in this guidance to its own activities.[1]

Appendices

There are two appendices to this guidance. Appendix A provides examples of how this guidance would apply to DOJ recipients.

Appendix B provides further information on the legal bases for the guidance. It also explains further who is covered by this guidance.

Both of these appendices should be considered part of this guidance.

State or Local "English-Only" Laws

State or local "English-only" laws do not change the fact that recipients cannot discriminate in violation of Title VI. Entities in states and localities with "English-only" laws do not have to accept federal funding. However, if they do, they still have to comply with Title VI, including its prohibition against national origin discrimination by recipients.

II. How Recipients Should Decide What Language Services They Should Provide

As mentioned in Executive Order 13166 and the DOJ Guidance issued in August, 2000, recipients should apply a four-factor test to decide what steps to take to provide meaningful access to their programs and activities for LEP persons. Once the recipient has chosen the services it will provide, the recipient should prepare a written policy on language assistance for LEP persons (an "LEP policy").

A. The Four-Factor Analysis

Recipients must take reasonable steps to ensure meaningful access to their services, programs, and activities. What "reasonable steps to ensure meaningful access" means depends on a number of factors. DOJ recipients should apply the following four factors to the various kinds of contacts that they have with the public to decide what reasonable steps they should take to ensure meaningful access for LEP persons. The results of this balancing test allow a recipient to decide what documents to translate, when oral translation is necessary, and whether language services must be made immediately available.

After applying the four-factor analysis, a recipient may conclude that different language assistance measures are needed for its different types of programs or activities. For instance, some of a recipient's activities will be more important than others and/or have greater impact on or contact with LEP persons, and thus require more in the way of language assistance.

(1) The Number or Proportion of LEP Persons Served or Encountered in the Eligible Service Population

One factor in determining what language services recipients should provide is the number or proportion of LEP persons eligible to be served or encountered by the recipient in carrying out its operations. Recipients should look to available data, such as the latest census data for the area served, data from school systems and from community organizations, and data collected by the recipient.[2] *The greater the number or proportion of LEP persons, the more likely language services are needed.*

(2) The Frequency With Which LEP Individuals Come in Contact With the Program

Recipients should assess, as accurately as they can, the frequency with which they have or should have contact with LEP language groups. The more frequent the contact, the more likely that language services are needed. The steps that are reasonable for a recipient that serves one LEP person a year may be very different than those expected from a recipient that serves several LEP persons each day. But even those that serve very few LEP persons on an infrequent basis should utilize this balancing analysis to determine what to do if an LEP individual seeks services under the program in question. This plan need not be intricate. It may be as simple as being prepared to use one of the commercially available language lines to obtain immediate interpreter services.

In applying this standard, recipients should take care to consider whether appropriate outreach to LEP persons could increase the frequency of contact with LEP language groups.

(3) The Nature and Importance of the Program, Activity, or Service Provided by the Program

The more important the activity, information, service, or program, or the greater the possible consequences of the contact to the LEP individuals, the more likely language services are needed. For example, the obligations to communicate rights to a person who is arrested or to provide medical services to an ill or injured inmate differ from those to provide bicycle safety courses or recreational programming. A recipient needs to determine if a denial or delay of access to services or information could have serious implications for the LEP individual. In addition, a decision by a federal, state, or local entity to make an activity compulsory, such as particular educational programs in a correctional facility or the communication of *Miranda* rights, serves as strong evidence of the program's importance.

(4) The Resources Available to the Recipient

A recipient's level of resources may have an impact on the nature of the steps it should take. Smaller recipients with more limited budgets are not expected to provide the same level of language services as larger recipients with larger budgets. Resource issues can sometimes be minimized by technological advances and sharing of resources and translations. Large entities should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance.

Applying the four factors, for example, a small police department with limited resources encountering very few LEP people has far fewer language assistance responsibilities than larger departments with more resources and large populations of LEP individuals.[3]

[1] DOJ has created, pursuant to the Executive Order, a separate plan for providing meaningful access to LEP persons in DOJ conducted activities.

[2] The focus of the analysis is on lack of English proficiency, not the ability to speak more than one language. Note that census data may indicate the most frequently spoken languages other than English and the percentage of people who speak that language who do not speak or understand English very well. Some of the most commonly spoken languages other than English may be spoken by people who are also overwhelmingly proficient in English. Thus, they may not be the languages spoken most frequently by limited English proficient individuals. When using census data, it is important to focus in on the languages spoken by those who are not proficient in English.

[3] As another example, under the four-part analysis, Title VI does not require recipients to translate documents requested under a state equivalent of the Freedom of Information Act or Privacy Act, or to translate all official state statutes or notices of rulemaking. The focus of the analysis is the nature of the information being communicated, the intended or expected audience, and the cost of providing translations. In virtually all instances, one or more of these criteria would lead to the conclusion that recipients need not translate these types of official documents. These criteria, however, may result in translation obligations where, for instance, laws are otherwise posted or summarized in waiting rooms, summarized or set forth in forms, applications, or

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B. Selecting Language Assistance Services

After applying the four-factor analysis, recipients have two main ways to provide language services, where needed: Oral interpretation and written translation. In deciding how to provide these services, recipients should consider the following information.

(1) Oral Language Services

Where oral interpretation is needed, recipients should develop procedures for providing competent interpreters in a timely manner. To do so, the recipient should consider some or all of the following options:

HIRING BILINGUAL STAFF For public contact positions. When particular languages are encountered often, hiring bilingual staff offers one of the best options. Recipients can, for example, fill public contact positions with staff who are bilingual and competent to communicate directly with LEP persons in their language. If bilingual staff are also used to interpret between English speakers and LEP persons, or to orally translate documents, they must be competent in the skill of interpreting. When bilingual staff cannot meet all of the language service obligations of the recipient, the recipient should turn to other options.

HIRING STAFF INTERPRETERS. Hiring interpreters may be most helpful where there is a frequent need for interpreting services in one or more languages.

CONTRACTING FOR INTERPRETERS. Contract interpreters may be a cost-effective option when there is no regular need for a particular language skill.

USING COMMUNITY VOLUNTEERS. Recipient-coordinated use of community volunteers may provide a cost-effective way to provide language services. It is often best to use community volunteers who are trained in the information or services of the program and can communicate directly with LEP persons in their language. Community volunteers used to interpret between English speakers and LEP persons, or to orally translate documents, must be competent in the skill of interpreting. It is best to make formal arrangements with volunteers. That way, the service is available more regularly and volunteers understand applicable confidentiality and impartiality rules.

USING TELEPHONE INTERPRETER LINES. Telephone interpreter service lines often offer speedy interpreting assistance in many different languages. Although they are useful in many situations, it is important to ensure that such services have interpreters who are able to interpret any legal terms or terms that are specific to a particular program when such terms may come up in the conversation. Also, sometimes it may be necessary to provide on-site interpreters to provide accurate and meaningful communication with an LEP person.

COMPETENCE OF INTERPRETERS. When providing oral assistance, recipients should ensure competency of the language service provider, no matter which of the above options they use. Competency requires more than self-identification as bilingual. Some bilingual staff and community volunteers, for instance, may be able to communicate effectively in a different language when communicating information directly in that language, but not be competent to interpret in and out of English.

Competency to interpret does not always mean formal certification as an interpreter. However, certification is helpful. When using interpreters, recipients should ensure that they:

- Demonstrate proficiency in both English and in the other language;
- Are bound to confidentiality and impartiality to the same extent the recipient employee they are interpreting for is so bound and/or to the extent their position requires;
- Have knowledge in both languages of any specialized terms or concepts peculiar to the entity's program or activity; and
- Demonstrate the ability to convey information in both languages, accurately;

Some recipients, such as courts, may have additional self-imposed requirements for interpreters.

Inappropriate Use of Family Members, Friends, Other Inmates, or Detainees. As a general rule, when language services are required, recipients should provide competent interpreter services free of cost to the LEP person. LEP persons should be advised that they may choose either to secure the assistance of an interpreter of their own choosing, at their own expense, or a competent interpreter provided by the recipient.[4] If the LEP person decides to provide his or her own interpreter, the provision of this notice and the LEP person's election should be documented in any written record generated with respect to the LEP person. In emergency situations that are not reasonably foreseeable, use of interpreters not provided by the recipient may be necessary. Proper recipient planning and implementation can help avoid such situations.

(2) Translation of Written Materials

An effective LEP policy ensures that vital written materials are translated into the language of each regularly encountered LEP group eligible to be served and/or likely to be affected by the recipient's program.

The term "vital documents" includes, for example:

- Consent and complaint forms
- Intake forms with the potential for important consequences
- Written notices of rights, denial, loss, or decreases in benefits or services, parole, and other hearings
- Notices of disciplinary action
- Notices advising LEP persons of free language assistance
- Prison rule books
- Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required
- Applications to participate in a recipient's program or activity or to receive recipient benefits or services.

Whether or not a document is "vital" also depends upon the importance of the program, information, encounter, or service involved. For instance, applications for bicycle safety courses would not generally be considered vital, whereas applications for drug and alcohol counseling in prison would generally be considered vital.

Many large documents have both vital and non-vital information in them. Written translation of only the vital information is usually sufficient.

It sometimes may be hard to tell the difference between vital and non-vital documents. This may be especially true for outreach materials like brochures or other information on rights and services.

vital outreach material, or special populations are provided with rules and regulations they must follow (e.g., in prisons, see Appendix A).

[4] While an LEP person may sometimes look to bilingual family members or friends or other persons with whom they are comfortable for language assistance, there are many situations where an LEP person might want to rely upon recipient-supplied interpretative services. For example, such individuals may not be available when and where they are needed, or may not have the ability to translate program-specific technical information. Alternatively, an individual may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing medical, law enforcement (e.g., sexual or violent assaults), family, or financial information to a family member, friend, or member of the local community. Similarly, there may be situations where a recipient's own interests justify the provision of an interpreter regardless of whether the LEP individual also provides his or her own interpreter. For example, where precise, complete and accurate translations of information and/or testimony are critical for law enforcement, adjudicatory or legal reasons, a recipient might decide to provide its own, independent interpreter, even if an LEP person wants to use their own interpreter as well.

In order to have meaningful access, LEP persons need to be aware of those rights and services. Of course, it would be impossible to translate every piece of outreach material into every language. However, sometimes lack of awareness that a particular program, right, or service exists may effectively deny LEP individuals meaningful access. Thus, recipients should regularly assess the needs of the populations frequently encountered or affected by the program or activity to determine whether certain critical outreach materials should be translated. Community organizations may be helpful in determining what outreach materials may be most helpful to translate.

Recent technological advances have made it easier for recipients to store and share translated documents. At the same time, DOJ recognizes that recipients in a number of areas, such as many large cities, regularly serve LEP persons from many different areas of the world who speak dozens and sometimes over 100 different languages. It would be too burdensome to demand that recipients in these circumstances translate all written materials into all of those languages. Nevertheless, well-substantiated claims of lack of resources to translate all vital documents into dozens of languages do not necessarily relieve the recipient of the obligation to translate those documents into at least several of the most frequently encountered languages, and to set benchmarks for continued translations over time. As a result, the extent of the recipient's obligation to provide written translations of documents will be determined on a case-by-case basis, looking at the totality of the circumstances.

One way for a recipient to know with greater certainty that it will be found in compliance with its obligation to provide written translations in languages other than English is for the DOJ recipient to meet the guidelines outlined in paragraphs (a) and (b) below.

Paragraphs (a) and (b) outline the circumstances that provide a "safe harbor" for recipients regarding the requirements for translation of written materials. A "safe harbor" means that if a recipient provides written translations under these circumstances, this will be considered strong evidence of compliance, in the area of written translations.

The failure to provide written translations under the circumstances outlined in paragraphs (a) and (b) will not necessarily mean non-compliance with Title VI. In such circumstances, DOJ reviews the totality of the circumstances to determine the recipient's obligation to provide written materials in languages other than English.

Example: Even if the safe harbors are not used, if written translation of a certain document(s) would be so burdensome as to defeat the legitimate objectives of its program, DOJ will not find the translation of written materials necessary for compliance with Title VI. Other ways of providing meaningful access, such as effective oral interpretation of vital documents, would be acceptable under such circumstances.

Safe Harbor. DOJ will consider a recipient to be in compliance with its Title VI obligation to provide written materials in non-English languages if:

(a) The DOJ recipient provides written translations of, at a minimum, vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other vital documents, if needed, can be provided orally; or

(b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral translation of those written materials, free of cost.

These safe harbor provisions apply to the translation of written documents only. They do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where oral language services are needed. For example, correctional facilities should ensure that prison rules have been explained to LEP inmates, at orientation, for instance, prior to taking disciplinary action against them.

The term "persons eligible to be served or likely to be affected or encountered" as used in paragraph (a) relates to the issue of identifying the DOJ recipient's service area for purposes of meeting its Title VI obligation. Because of the wide variety of recipient programs and activities, there is no "one size fits all" definition of what constitutes "persons eligible to be served or likely to be affected or encountered." Generally, the term means those persons who are in the geographic area that has been approved by a federal grant agency as the service area and who are either eligible for the recipient's services or otherwise might be affected or encountered by the recipient.

Where no service area has been approved, DOJ will consider the relevant service area as that approved by state or local authorities or designated by the recipient itself, provided that these designations do not themselves discriminatorily exclude certain populations. Appendix A provides examples of determining the relevant service area. When considering the number or proportion of LEP individuals in a service area, recipients need to consider LEP parent(s) when their English-proficient or LEP minor children and dependents encounter the legal system.

Just as with oral interpreters, translators of written documents must be competent. It is a good idea to build in a "check" on the translation. For instance, an independent translator could check the first translation. Or, one translator could translate the document, and a second, independent translator could translate it back into English. This is called "back translation."

Translators should understand the expected reading level of the audience. Sometimes direct translation of materials results in a translation that is written at a much more difficult level than the English language version. Community organizations may be able to help consider whether a document is written at a good level for the audience.

Finally, recipients will find it more effective and less costly if they try to maintain consistency in the words and phrases used to translate terms of art, legal, or other technical concepts. Creating or using already-created glossaries of commonly-used terms may be useful for LEP persons and translators, and cost effective for the recipient. Providing translators with examples of previous translations of similar material by the recipient, other recipients, or federal agencies may be helpful.

C. Elements of Effective Written Policy on Language Assistance for LEP Persons ("LEP Policy")

After completing the four-factor analysis and deciding what language assistance services are needed, the recipient should include those in a written LEP policy. The key to providing meaningful access is accurate and effective communication between the DOJ recipient and the LEP individual.

Although DOJ recipients have a great deal of flexibility in designing their policies, effective programs usually have five elements, discussed below. Failure to take all of the steps outlined in this section does not necessarily mean that a recipient has violated the law. Just as with all Title VI complaints, DOJ assesses each complaint on a case-by-case basis. DOJ applies the four factors in deciding whether the steps

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taken by a recipient provide meaningful access.

(1) Identifying LEP Individuals Who Need Language Assistance.

As noted above, the first two parts of the four-factor analysis of need include an assessment of the number or proportion of LEP individuals eligible to be served or encountered and the frequency of encounters. In addition, when developing a plan, recipients should develop a process for employees to identify the language of LEP persons encountered so that language services can be provided.

One way to determine the language of communication is to use language identification cards (or "I speak cards"), which invite LEP persons to identify their language needs to staff. Such cards, for instance, might say "I speak Spanish" in both Spanish and English, "I speak Vietnamese" in both English and Vietnamese, etc. When records are normally kept of past interactions with members of the public, the language of the LEP person should be included as part of the record. In addition to helping employees identify the language of LEP persons they encounter, this process will help in future application of the first two factors of the four-factor analysis.

(2) Language Assistance Measures

The LEP policy should include information about the ways in which language assistance will be provided. For instance, it should include information on at least the following:

- Types of language services available (see Section IIB, above).
- How staff can obtain those services.
- How to respond to LEP callers.
- How to respond to written communications from LEP persons.
- How to respond to LEP individuals who have in-person contact with recipient staff.
- How to ensure competency of interpreters and translation services.

(3) Training Staff

Staff need to know that they must provide meaningful access to information and services for LEP persons. Recipients should provide training to ensure that:

- Staff know about LEP policies and procedures.
- Staff having contact with the public (or those in a recipient's custody) are trained to work effectively with in-person and telephone interpreters.

It is important that this training be part of the orientation for new employees and that all employees in public contact positions (or having contact with those in a recipient's custody) be properly trained. Recipients have flexibility in deciding the way the training is provided. The more frequent the contact with LEP persons, the greater the need will be for in-depth training. Staff with little or no contact with LEP persons may only have to be aware of an LEP policy.

(4) Providing Notice to LEP Persons

Once an agency has decided, based on the four factors, that it will provide language services, it is important to let LEP persons know that those services are available and that they are free of charge. Recipients should provide this notice in a language LEP persons will understand. Examples of notification that recipients should consider include:

- Posting signs in intake areas and other entry points. When language assistance is needed to ensure meaningful access to information and services, the signs could state that LEP persons have a right to free language assistance. The signs should be translated into the most common languages encountered. They should explain how to get the language help.
- Stating in outreach documents that language services are available from the agency. Announcements could be in, for instance, brochures, booklets, and in outreach and recruitment information. These statements should be translated into the most common languages and could be "tagged" onto the front of common documents.
- Working with community-based organizations and other stakeholders to inform LEP individuals of the recipients' services, including the right to language services.
- Using a telephone voice mail menu. The menu could be in the most common languages encountered. It should provide information about available language assistance services and how to get them.
- Including notices in local newspapers in languages other than English.
- Providing notices on non-English-language radio stations about the available language assistance services and how to get them.

(5) Monitoring and Updating the LEP Policy

Recipients should always consider whether new documents, programs, services, and activities need to be made accessible for LEP individuals, and they should make any needed changes. They should then provide notice of any changes in services to the LEP public and to employees. In addition, DOJ recipients should evaluate their entire language policy at least every three years. One way to evaluate the LEP policy is to seek feedback from the community.

In their reviews, recipients should assess changes in:

- Current LEP populations in service area or population affected or encountered.
- Frequency of encounters with LEP language groups.
- Nature and importance of activities to LEP persons.
- Availability of resources, including technological advances and sources of additional resources.
- Whether existing assistance is meeting the needs of LEP persons.
- Whether staff knows and understands the LEP policy and how to implement it.
- Whether identified sources for assistance are still available and viable.

III. Application to Specific Types of Recipients

Appendix A of this Guidance provides examples of how the Title VI meaningful access requirement applies to law enforcement, corrections, courts, and other recipients of DOJ assistance.

A. State and Local Law Enforcement

Appendix A further explains how law enforcement recipients can apply the four factors to a range of encounters with the public. The responsibility for providing language services differs with different types of encounters.

Appendix A helps recipients identify the population they should consider when deciding the types of services to provide. It then provides guidance and examples of applying the four factors. For instance, it gives examples on how to apply this guidance to:

- Receiving and responding to requests for help
- Enforcement stops short of arrest and field investigations
- Custodial interrogations
- Intake/detention
- Community outreach

B. Departments of Corrections

Appendix A also helps departments of corrections understand how to apply the four factors. For instance, it gives examples of LEP access in:

- Intake
- Disciplinary action
- Health and safety
- Participation in classes or other programs affecting length of sentence
- English as a Second Language (ESL) Classes
- Community corrections programs

C. Other Types of Recipients

Appendix A also applies the four factors and gives examples for other types of recipients. Those include, for example:

- Courts
- Juvenile Justice Programs
- Domestic Violence Prevention/ Treatment Programs

Title VI Compliance Procedures

DOJ recipients have a great deal of flexibility in deciding how to comply with these obligations. DOJ will continue to use the same process for handling complaints based on LEP as it uses in any other Title VI complaint. That process emphasizes voluntary compliance. (*See* Appendix B for further information). In addition, DOJ will use this Guidance, including the appendices, in conducting investigations or reviews of a recipient's language services.

Appendix A—Application of LEP Guidance for DOJ Recipients to Specific Types of Recipients

While a wide range of entities receive federal financial assistance through DOJ, most of DOJ's assistance goes to law enforcement agencies, including state and local police and sheriffs' departments, and to state departments of corrections. Sections A and B below provide examples of how these two major types of DOJ recipients might apply the four-factor analysis. Section C provides examples for other types of recipients. The examples in this Appendix are not meant to be exhaustive.

The requirements of Title VI and its implementing regulations, as clarified by this Guidance, supplement, but do not supplant, constitutional and other statutory or regulatory provisions that may require LEP services. For instance, while application of the four-factor analysis may lead to a similar result, it does not replace constitutional or other statutory protections mandating warnings and notices in languages other than English in the criminal justice context. Rather, this Guidance clarifies the Title VI obligation to address, in appropriate circumstances and in a reasonable manner, the language assistance needs of LEP individuals beyond those required by the Constitution or statutes and regulations other than Title VI.

A. State and Local Law Enforcement

For the vast majority of the public, exposure to law enforcement begins and ends with interactions with law enforcement personnel discharging their duties while on patrol, responding to a request for services, talking to witnesses, or conducting community outreach activities. For a much smaller number, that exposure includes a visit to a station house. And for an important but even smaller number, that visit to the station house results in entry into the criminal justice, judicial, or juvenile justice systems.

The common thread running through these and other interactions between the public and law enforcement is the exchange of information. LEP individuals' encounters with police and sheriffs' departments are covered by Title VI if those departments receive federal financial assistance. This Guidance focuses on the requirements under Title VI to communicate effectively with persons who are LEP to ensure that they have meaningful access to the system, including, for example, understanding rights and accessing police assistance.

Many police and sheriffs' departments already provide language services in a wide variety of circumstances to obtain information effectively, to build trust and relationships with the community, and to contribute to the safety of law enforcement personnel. For example, many police departments have available printed *Miranda* rights in languages other than English.[1] In areas where significant LEP populations reside, law enforcement officials already may have forms and notices in languages other than English or they may employ bilingual law enforcement officers, intake personnel, counselors, and support staff. These experiences can form a strong basis for assessing need and implementing a plan in compliance with Title VI and its implementing regulations.

1. General Principles

The touchstone of the four-factor analysis is reasonableness based upon the specific purposes, needs, and capabilities of the law enforcement service under review and an appreciation of the nature and particularized needs of the LEP population served. Accordingly, the analysis cannot provide a single uniform answer on how service to LEP persons must be provided in all programs or activities in all situations. Knowledge of local conditions and community needs becomes critical in determining the type and level of language services needed. The more predictable the need for language services, the greater the responsibility under the four-factor analysis.

Before giving specific examples, several general points should assist law enforcement planners in correctly applying the analysis to the wide range of services employed in their particular jurisdictions.

a. Permanent Versus Seasonal Populations

In many communities, resident populations change over time or season. For example, in some resort communities, populations swell during peak vacation periods, many times exceeding the number of permanent residents of the jurisdiction. In other communities, primarily agricultural areas, transient populations of agricultural workers will require increased law enforcement services during the relevant harvest season. This dynamic demographic ebb and flow can also dramatically change the size and nature of the LEP community likely to come into contact with law enforcement personnel. Thus, law enforcement officials should not limit their analysis to numbers and percentages of permanent residents. In assessing factor one—the number or proportion of LEP individuals—police departments should consider any significant but temporary changes in a jurisdiction's demographics.

Example: A rural jurisdiction has a permanent population of 30,000, 7% of which is Hispanic. Based on census data and an information from the contiguous school district, of that number, only 15% are estimated to be LEP individuals. Thus, the total estimated permanent LEP population is 315 or approximately 1% of the total permanent population. Under the four-factor analysis, a sheriffs' department could reasonably conclude that the small number of LEP persons makes the affirmative translation of documents and/or employment of bilingual staff unnecessary. However, during the spring and summer planting and harvest seasons, the local population swells to 40,000 due to the influx of seasonal agricultural workers. Of this transitional number, about 75% are Hispanic and about 50% of that number are LEP individuals. This information comes from the schools and a local migrant worker community group. Thus, during the harvest season, the jurisdiction's LEP population increases to over 10% of all residents. In this case, the department should consider, under the safe harbor provisions of this Guidance, translating vital written documents into Spanish. In addition, the predictability of contact during those seasons makes it important for the jurisdiction to review its oral language services to ensure meaningful access for LEP individuals.

[1] DOJ's own Federal Bureau of Investigation makes written versions of those rights available in several different languages.

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b. Target Audiences

For most law enforcement services, the target audience is defined in geographic rather than programmatic terms. However, some services may be targeted to reach a particular audience (*e.g.*, elementary school children, elderly, residents of high crime areas, minority communities, small business owners/operators, etc.). Also, within the larger geographic area covered by a police department, certain precincts or portions of precincts may have concentrations of LEP persons. In these cases, even if the overall number or proportion of LEP individuals in the district is low, the frequency of contact may be foreseeably higher for certain areas or programs. Thus, the second factor—frequency of contact—should be considered in light of the specific program or the geographic area being served. The police department could then focus language services where they are most likely to be needed.

Example: A police department that receives funds from the DOJ Office of Justice Programs initiates a program to increase awareness and understanding of police services among elementary school age children in high crime areas of the jurisdiction. This program involves "Officer in the Classroom" presentations at elementary schools located in areas of high poverty. The population of the jurisdiction is estimated to include only 3% LEP individuals. However, the LEP population at the target schools is 35%, the vast majority of whom are Vietnamese speakers. In applying the four-factor analysis, the higher LEP language group populations of the target schools and the frequency of contact within the program with LEP students in those schools, not the LEP population generally, should be used in determining the nature of the LEP needs of that particular program. Further, because the Vietnamese LEP population is concentrated in one or two main areas of town, the police department should expect the frequency of contact with Vietnamese LEP individuals in general to be quite high in those areas, and it should plan accordingly.

c. Importance of Service/Information

Given the critical role law enforcement plays in maintaining quality of life and property, traditional law enforcement and protective services rank high on the critical/non-critical continuum. However, this does not mean that information about, or provided by, each of the myriad services and activities performed by law enforcement officials must be equally available in languages other than English. While clearly important to the ultimate success of law enforcement, certain community outreach activities do not have the same direct impact on the provision of core law enforcement services as the activities of 911 lines or law enforcement officials' ability to respond to requests for assistance while on patrol, to communicate basic information to suspects, etc. Nevertheless, with the rising importance of community partnerships and community-based programming as a law enforcement technique, the need for language services should be considered in such activities as well.

d. Interpreters

Just as with other recipients, law enforcement recipients have a variety of options for providing language services. As a general rule, when language services are required, recipients should provide competent interpreter services free of cost to the LEP person. LEP persons should be advised that they may choose either to secure the assistance of an interpreter of their own choosing, at their own expense, or a competent interpreter provided by the recipient.

If the LEP person decides to provide his or her own interpreter, the provision of this notice and the LEP person's election should be documented in any written record generated with respect to the LEP person. While an LEP person may sometimes look to bilingual family members or friends or other persons with whom they are comfortable for language assistance, there are many situations where an LEP person might want to rely upon recipient-supplied interpretative services. For example, such individuals may not be available when and where they are needed, or may not have the ability to translate program-specific technical information. Alternatively, an individual may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing medical, law enforcement (*e.g.*, sexual or violent assaults), family, or financial information to a family member, friend, or member of the local community. Similarly, there may be situations where a recipient's own interests justify the provision of an interpreter regardless of whether the LEP individual also provides his or her own interpreter. For example, where precise, complete and accurate translations of information and/or testimony are critical for law enforcement, adjudicatory or legal reasons, a recipient might decide to provide its own, independent interpreter, even if an LEP person wants to use their own interpreter as well.

In emergency situations that are not reasonably foreseeable, the recipient may have to temporarily rely on non-recipient-provided language services. Proper recipient planning and implementation can help avoid such situations.

While all language services need to be competent, the greater the potential consequences, the greater the need to monitor interpretation services for quality. For instance, it is important that interpreters in custodial interrogations be highly competent to translate legal and other law enforcement concepts, as well as be extremely accurate in their interpretation. It may be sufficient, however, for a desk clerk who is bilingual but not skilled at interpreting to help an LEP person figure out to whom he or she needs to talk about setting up a neighborhood watch.

2. Applying the Four-Factor Analysis Along the Law Enforcement Continuum

While all police activities are important, the Title VI analysis requires some prioritizing so that language services are targeted where most needed because of the nature and importance of the particular law enforcement activity involved. In addition, because of the "reasonableness" standard, and frequency of contact and resources factors, the obligation to provide language services increases where the importance of the activity is greater, the law enforcement activity is more focused, and/or the provision of language services is more "within the control" of the police department.

Under this framework, then, critical areas for language assistance include: 911 calls, custodial interrogation, and health and safety issues for persons within the control of the police. These activities should be considered the most important under the four-factor analysis. Systems for receiving and investigating complaints from the public are important; further, complaint forms and investigations/hearings are directly within the control of the department. Thus, forms, hearings, and other complaint procedures should be made accessible to LEP individuals. Often very important, but less focused and controlled are: Routine patrol activities, receiving non-emergency information regarding potential crimes, and ticketing. In these situations, the LEP plan should provide for a great deal of flexibility while at the same time ensuring that, wherever reasonable, language resources are available to officers and the LEP persons they encounter and that, when not available, the consequences to the LEP individuals are minimized. Community outreach activities are hard to categorize, but generally they do not rise to the same level of importance as the other activities listed. However, with the importance of community partnerships and community-based programming as a law enforcement technique, the need for language services should be considered in these activities as well. Police departments have a great deal of flexibility in determining how to best address their outreach to LEP populations.

a. Receiving and Responding to Requests for Assistance

LEP persons must have meaningful access to police services when they are victims of or witnesses to alleged criminal activity. Effective reporting systems transform victims, witnesses, or bystanders into assistants in law enforcement and investigation processes. Given the critical role the public plays in reporting crimes or directing limited law enforcement resources to time-sensitive emergency or public safety situations, efforts to address the language assistance needs of LEP individuals could have a significant impact on improving responsiveness, effectiveness, and safety.

All emergency service lines, or "911" lines, operated by agencies that receive federal financial assistance must be accessible to persons who are LEP. This will mean different things to different jurisdictions. For instance, in large cities with significant LEP communities, the 911 line may have operators who are bilingual and capable of accurately interpreting in high stress situations. Smaller cities or areas with small LEP populations should still have to have a plan for serving callers who are LEP, but the LEP policy and implementation may involve a telephonic language line that is fast enough and reliable enough to attend to the emergency situation, or include some other accommodation short of hiring bilingual operators.

Example: A large city provides bilingual operators for the most frequently encountered languages, and uses a commercial telephone language line when it receives calls from LEP persons who speak other languages. Ten percent of the city's population is LEP, and sixty percent of the LEP population speaks Spanish. In addition to 911 service, the city has a 311 line for non-emergency police services. The 311 Center has Spanish speaking operators available, and uses a language bank, staffed by the city's bilingual city employees who are competent translators, for other non-English-speaking callers. The city also has a campaign to educate non-English speakers when to use 311 instead of 911. Such services are consistent with Title VI principles.

b. Enforcement Stops Short of Arrest and Field Investigations

Field enforcement includes, for example, traffic stops, pedestrian stops, serving warrants and restraining orders, *Terry* stops, and crowd/traffic control. Because of the diffuse nature of these activities, the reasonableness standard allows for great flexibility in providing meaningful access, for example, in routine field investigations and traffic stops. Nevertheless, the ability of law enforcement personnel to discharge fully and effectively its enforcement and crime interdiction mission requires the ability to communicate instructions, commands, and notices. For example, a routine traffic stop can become a difficult situation if an officer is unable to communicate effectively the reason for the stop, the need for identifying or other information, and the meaning of any written citation. Requests for consent to search are meaningless if the request is not understood. Similarly, crowd control commands will be wholly ineffective where significant numbers of people in a crowd cannot understand the meaning of law enforcement commands.

Given the wide range of possible situations in which law enforcement in the field can take place, it is impossible to equip every officer with the tools necessary to respond to every possible LEP scenario. Rather, in applying the four factors to field enforcement, the goal should be to implement measures addressing the language needs of significant LEP populations in the most likely and common situations.

Example: A police department serves a jurisdiction with a significant number of LEP individuals residing in one or more precincts, and it is routinely asked to provide crowd control services at community events or demonstrations in those precincts. Consistent with the requirements of the four-factor analysis, the police department should assess how it will discharge its crowd control duties in a language-appropriate manner. Among the possible approaches are plans to assign bilingual officers, basic language training of all officers in common law enforcement commands, the use of devices that provide audio commands in the predictable languages, or the distribution of translated written materials for use by officers.

Field investigations include neighborhood canvassing, witness identification and interviewing, investigative or *Terry* stops, and similar activities designed to solicit and obtain information from the community. Encounters with LEP individuals will often be less predictable in field investigations. However, the jurisdiction should still assess the potential for contact with LEP individuals in the course of field investigations and investigative stops, identify the LEP language group(s) most likely to be encountered, and provide their officers with sufficient written or oral translation resources to ensure that lack of English proficiency does not impede otherwise proper investigations or unduly burden LEP individuals.

Example: A police department in a moderately large city includes a precinct that serves an area which includes significant LEP populations whose native languages are Spanish, Korean, and Tagalog. Law enforcement officials could reasonably consider the adoption of a policy assigning bilingual investigative officers to the precinct and/or creating a resource list of department employees competent to interpret and ready to assist officers by phone or radio. This could be combined with developing language-appropriate written materials, such as consents to searches or statements of rights, for use by its officers where LEP individuals are literate in their languages. In certain circumstances, it may also be helpful to have telephone language line access where other options are not successful and safety and availability of phone access permit.

c. Custodial Interrogations

Custodial interrogations of unrepresented LEP individuals trigger constitutional rights that this Guidance is not designed to address. Given the importance of being able to communicate effectively under such circumstances, recipients' ability to anticipate and plan for a need for language services, and the control over LEP and other individuals asserted by recipients in custodial interrogation situations, law enforcement recipients must ensure competent and free language services for LEP individuals in such situations. A clear written policy, understood and easily accessible by all officers, will assist the law enforcement agency in complying with this obligation. In formulating a written policy for effectively communicating with LEP individuals, agencies should consider whether law enforcement personnel themselves ought to serve as interpreters during custodial interrogation, or whether a qualified independent interpreter would be more appropriate.[2]

Example: A large city police department institutes an LEP plan that requires arresting officers to procure a qualified interpreter for any custodial interrogation, notification of rights, or taking of a statement, and any communication by an LEP individual in response to a law enforcement officer. When considering whether an interpreter is qualified, the LEP policy discourages use of police officers as interpreters in interrogations except under circumstances in which the reliability of the interpretation is verified, such as, for example, where the officer has been trained and tested in

[2] Some state laws prohibit police officers from serving as interpreters during custodial interrogation of suspects.

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interpreting and tape recordings are made of the entire interview. In determining whether an interpreter is qualified, the jurisdiction uses the analysis noted above. Such a plan is consistent with Title VI responsibilities.

d. Intake/Detention

State or local law enforcement agencies that arrest LEP persons should consider the inherent communication impediments to gathering information from the LEP arrestee through an intake or booking process. Aside from the basic information, such as the LEP arrestee's name and address, law enforcement agencies should evaluate their ability to communicate with the LEP arrestee about his or her medical condition. Because medical screening questions are commonly used to elicit information on the arrestee's medical needs, suicidal inclinations, presence of contagious diseases, potential illness, resulting symptoms upon withdrawal from certain medications, or the need to segregate the arrestee from other prisoners, it is essential that law enforcement agencies have the ability to communicate effectively with an LEP arrestee. In jurisdictions with few bilingual officers or in situations where the LEP person speaks a language not encountered very frequently, language lines may provide the most cost effective and efficient method of communication.

e. Community Outreach

Community outreach activities increasingly are recognized as important to the ultimate success of more traditional duties. Thus, an application of the four-factor LEP analysis to community outreach activities can play an important role in ensuring that the purpose of these activities (to improve police/community relations and advance law enforcement objectives) is not thwarted due to the failure to address the language needs of LEP persons.

Example: A police department initiates a program of domestic counseling in an effort to reduce the number or intensity of domestic violence interactions. A review of domestic violence records in the city reveals that 25% of all domestic violence responses are to minority areas and 30% of those responses involve interactions with one or more LEP persons, most of whom speak the same language. The department should take reasonable steps to make the counseling accessible to LEP individuals. In this case, the department successfully sought bilingual counselors (for whom they provided training in translation) for some of the counseling positions. In addition, the department has an agreement with a local university in which bilingual social work majors who are competent in interpreting, as well as language majors who are trained by the department in basic domestic violence sensitivity and counseling, are used as interpreters when the in-house bilingual staff cannot cover the need. Interpreters must sign a confidentiality agreement with the department. This would be consistent with Title VI responsibilities.

Example: A large city has initiated an outreach program designed to address a problem of robberies of Vietnamese homes by Vietnamese gangs. One strategy is to work with community groups and banks and others to help allay traditional fears in the community of putting money and other valuables in banks. Because a large portion of the target audience is Vietnamese speaking and LEP, the department contracts with a bilingual community liaison competent in the skill of translating to help with outreach activities. This would be consistent with Title VI responsibilities.

B. Departments of Corrections

All departments of corrections that receive federal financial assistance from DOJ must provide LEP prisoners [3] with meaningful access to benefits and services within the program. In order to do so, corrections departments, like other recipients, must apply the four-factor analysis.

1. General Principles

Departments of corrections also have a wide variety of options in providing translation services appropriate to the particular situation. Bilingual staff competent in translating, in person or by phone, pose one option. Additionally, particular prisons may have agreements with local colleges and universities, interpreter services, and/or community organizations to provide paid or volunteer competent translators under agreements of confidentiality and impartiality. Language lines may offer a prudent oral interpreting option for prisons with very few and/or infrequent prisoners in a particular language group. Reliance on fellow prisoners is generally not appropriate. Reliance on fellow prisoners should only be an option in unforeseeable emergency circumstances; when the LEP inmate signs a waiver that is in his/her language and in a form designed for him/her to understand; or where the topic of communication is not sensitive, confidential, important, or technical in nature and the prisoner is competent in the skill of interpreting.

In addition, a department of corrections that receives federal financial assistance would be ultimately responsible for ensuring that LEP inmates have meaningful access within a prison run by a private or other entity with which the department has entered into a contract. The department may provide the staff and materials necessary to provide required language services, or it may choose to require the entity with which it contracted to provide the services itself.

2. Applying the Four Factors Along the Corrections Continuum

As with law enforcement activities, critical and predictable contact with LEP individuals poses the greatest obligation for language services. Corrections facilities have somewhat greater abilities to assess the language needs of those they encounter, although inmate populations may change rapidly in some areas. Contact affecting health and safety, length of stay, and discipline present the most critical situations under the four-factor analysis.

a. Assessment

In order to create a plan for providing language services, each department of corrections that receives federal financial assistance should assess the number of LEP prisoners who are in the system, in which prisons they are located, and the languages he or she speaks. Each prisoner's LEP status, and the language he or she speaks, should be placed in his or her file. Although this Guidance and Title VI are not meant to address literacy levels, agencies should be aware of literacy problems so that LEP services are provided in a way that is meaningful and useful (*e.g.*, translated written materials are of little use to a nonliterate inmate). After the initial assessment, new LEP prisoners should be identified at intake or orientation, and the data should be updated accordingly.

b. Intake/Orientation

Intake/Orientation plays a critical role not merely in the system's identification of LEP prisoners, but in providing those prisoners with fundamental information about their obligations to comply with system regulations, participate in education and training, receive appropriate medical treatment, and enjoy recreation. Even if only one prisoner doesn't understand English, that prisoner should be given the opportunity to be informed of the rules, obligations, and opportunities in a manner designed effectively to communicate these matters. An appropriate analogy is the obligation to communicate effectively with deaf prisoners, which is most frequently accomplished through sign language interpreters or written materials. Not every prison will use the same method for providing language assistance. Prisons with large numbers of Spanish-speaking LEP prisoners, for example, will likely need to translate written rules, notices, and other important orientation material into Spanish, with oral instructions, whereas prisons with very few such inmates may choose to rely upon a language line or qualified community volunteers to assist.

Example: The department of corrections in a state with a 5% Haitian Creole-speaking LEP corrections population and an 8% Spanish-speaking LEP population receives federal financial assistance to expand one of its prisons. The department of corrections has developed an intake video in Haitian Creole and another in Spanish for all of the prisons within the department to use when orienting new prisoners who are LEP and speak one of those languages. In addition, the department provides inmates with an opportunity to ask questions and discuss intake information through either bilingual staff who are competent in interpreting who are present at the orientation or who are patched in by phone to act as interpreters. The department also has an agreement whereby some of its prisons house a small number of INS detainees. For those detainees or other inmates who are LEP and do not speak Haitian Creole or Spanish, the department has created a list of sources for interpretation, including department staff, contract interpreters, university resources, and a language line. Each person receives at least an oral explanation of the rights, rules, and opportunities. This orientation plan would be considered consistent with Title VI.

c. Disciplinary Action

When a prisoner who is LEP is the subject of disciplinary action, the prison must provide language assistance. That assistance must ensure that the LEP prisoner had adequate notice of the rule in question and is meaningfully able to understand and participate in the process afforded prisoners under those circumstances. As noted previously, fellow inmates cannot serve as interpreters in disciplinary hearings.

d. Health and Safety

Prisons providing health services should refer to Department of Health and Humans Services' guidance [4] regarding health care providers' Title VI obligations, as well as with this Guidance.

Health care services are obviously extremely important. LEP individuals must be provided with access to those services. How that access is provided depends upon the number or proportion of LEP individuals, the frequency of contact with those LEP individuals, and the resources available to the recipient. If, for instance, a prison serves a high proportion of LEP individuals who speak Spanish, then the prison health care provider should have available qualified bilingual medical staff or interpreters versed in medical terms. If the population of LEP individuals is low, then the prison may choose instead, for example, to rely on a local community volunteer program that provides qualified interpreters through a university. Due to the private nature of medical situations, only in unpredictable emergency situations or in non-emergency cases where the inmate has waived rights to an non-inmate interpreter would the use of other bilingual inmates be appropriate.

e. Participation Affecting Length of Sentence

If a prisoner's LEP status makes him/her unable to participate in a particular program, such a failure to participate cannot be used to adversely impact the length of stay or significantly affect the conditions of imprisonment. Prisons have options in how to apply this standard. For instance, prisons could: (1) Make the program accessible to the LEP inmate; or (2) waive the requirement.

Example: State law provides that otherwise eligible prisoners may receive early release if they take and pass an alcohol counseling program. Given the importance of early release, LEP prisoners must be provided access to this prerequisite in some fashion. *How* that access is provided depends on the three factors other than importance. If, for example, there are many LEP prisoners speaking a particular language in the prison system, the class could be provided in that language for those inmates. If there were far fewer LEP prisoners speaking a particular language, the prison will still need to ensure access to this prerequisite because of the importance of early release opportunities. Options include, for example, use of bilingual teachers, contract interpreters, or community volunteers to interpret during the class, reliance on videos or written explanations in a language the inmate understands, and/or modification of the requirements of the class to meet the LEP individual's ability to understand and communicate. Another possible option would be to waive the requirement for the LEP prisoners and allow early release without this prerequisite.

f. ESL Classes

States often mandate English-as-a-Second language (ESL) classes for LEP inmates. Nothing in this Guidance prohibits or requires such mandates. ESL courses often serve as an important part of a proper LEP plan in prisons because, as prisoners gain proficiency in English, fewer language services are needed. However, the fact that ESL classes are provided does not obviate the need to provide meaningful access for prisoners who are not yet English proficient.

g. Community Corrections

This guidance also applies to community corrections programs that receive, directly or indirectly, federal financial assistance. For them, the most frequent contact with LEP individuals will be with an offender, a victim, or the family members of either, but may also include witnesses and community members in the area in which a crime was committed.

As with other recipient activities, community corrections programs should apply the four factors and determine areas where language services are most needed. Important oral communications include, for example: interviews; explaining conditions of probations/release; developing case plans; setting up referrals for services; regular supervision contacts; outlining violations of probations/parole and recommendations; and making adjustments to the case plan. Competent oral language services for LEP persons are important for each of these types of communication. Recipients have great flexibility in determining how to provide those services.

Just as with all language services, it is important that language services be competent. Some knowledge of the legal system may be necessary in certain circumstances. For example, special attention should be given to the technical interpretation skills of interpreters used when obtaining information from an offender during pre-sentence and violation of probation/parole investigations or in other circumstances in which legal terms and the results of inaccuracies could impose an enormous burden on the LEP person.

In addition, just as with other recipients, corrections programs should identify vital written materials for probation and parole that should be translated when a significant number or proportion of LEP individuals that speak a particular language is encountered. Vital documents in this context could include, for instance: probation/parole department

[3] In this Guidance, the terms "prisoners" or "inmates" include all of those individuals, including immigration and Naturalization Service (INS) detainees and juveniles, who are held in a facility operated by a recipient. Certain statutory, regulatory, or constitutional mandates/rights may apply only to juveniles, such as educational rights, including those for students with disabilities or limited English proficiency. Because a decision by a recipient or a federal, state, or local entity to make an activity compulsory serves as strong evidence of the program's importance, the obligation to provide language services may differ depending upon whether the LEP person is a juvenile or an adult inmate.

[4] A copy of that guidance can be found on the HHS website at http://www.hhs.gov/ocr/lep/ and at http://www.usdoj.gov/crt/cor.

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descriptions and grievance procedures, offender rights information, the pre-sentence/release investigation report, notices of alleged violations, sentencing/release orders, including conditions of parole, and victim impact statement questionnaires.

C. Other Types of Recipients

DOJ provides federal financial assistance to many other types of entities and programs, including, for example, courts, juvenile justice programs, shelters for victims of domestic violence, and domestic violence prevention programs. Title VI and this Guidance apply to those entities. Examples involving some of those recipients follow:

1. Courts

Application of the four-factor analysis requires recipient courts to ensure that LEP parties and witnesses receive competent language services. At a minimum, every effort should be taken to ensure translations for LEP individuals during all hearings, trials, and motions during which the LEP individual must and/or may be present. When a recipient court appoints an attorney to represent an LEP defendant, the court should ensure that either the attorney is proficient in the LEP person's language or that a competent interpreter is provided during consultations between the attorney and the LEP person.

Many states have created certification procedures for interpreters. This is one way of meeting the Title VI requirement that recipients ensure competency of interpreters. Courts will not, however, always be able to find a certified interpreter, particularly for less frequently encountered languages.

Example: A state court receiving DOJ federal financial assistance has frequent contact with LEP individuals as parties and witnesses, but has experienced a shortage in certified interpreters in the range of languages encountered. State court officials work with training and testing consultants to broaden the number of certified interpreters available in the top several languages spoken by LEP individuals in the state. Because resources are scarce and the development of tests expensive, state court officials decide to partner with other states that have already established agreements to share proficiency tests and to develop new ones together. The state court officials also look to other existing state plans for examples of: Codes of professional conduct for interpreters; mandatory orientation and basic training for interpreters; interpreter proficiency tests in Spanish and Vietnamese language interpretation; a written test in English for interpreters in all languages covering professional responsibility, basic legal term definitions, court procedures, etc. They are considering working with other states to expand testing certification programs in coming years to include several other most frequently encountered languages. This type of assessment of need, planning, and implementation is consistent with Title VI principles.

Many individuals, while able to communicate in English to some extent, are still LEP. Courts should consider carefully whether a person will be able to understand and communicate effectively in the stressful role of a witness or party and in situations where knowledge of language subtleties and/or technical terms and concepts are involved.

Example: Judges in a county court receiving federal financial assistance have adopted a *voir dire* for determining a witness' need for an interpreter. The voir dire avoids questions that could be answered with "yes" or "no." It includes questions about comfort level in English, and questions that require active responses, such as: "How did you come to court today?" etc. The judges also ask the witness more complicated conceptual questions to determine the extent of the person's proficiency in English. Such a procedure is consistent with Title VI principles.

When courts experience low numbers or proportions of LEP individuals from a particular language group and infrequent contact with that language group, creation of a new certification test for interpreters may be overly burdensome. In such cases, other methods should be used to determine the competency of interpreters for the court's purposes.

Example: A witness in a county court in a large city speaks Urdu and not English. The jurisdiction has no court interpreter certification testing for Urdu language interpreters because very few LEP individuals encountered speak Urdu. However, a non-certified interpreter is available and has been given the standard English-language test on court processes and interpreter ethics. The judge brings in a second, independent, bilingual Urdu-speaking person from a local university, and asks the prospective interpreter to interpret the judge's conversation with the second individual. The judge then asks the second Urdu speaker a series of questions designed to determine whether the interpreter accurately interpreted their conversation. Given the infrequent contact, the low number and proportion of Urdu LEP individuals in the area, and the high cost of providing certification tests for Urdu interpreters, this "second check" solution is one appropriate way of ensuring meaningful access to the LEP individual.

Another key to successful use of interpreters in the courtroom is to ensure that everyone in the process understands the role of the interpreter.

Example: Judges in a recipient court administer a standard oath to each interpreter and make a statement to the jury that the role of the interpreter is to interpret, verbatim, the questions posed to the witness and the witness' response. The jury should focus on the words, not the non-verbals, of the interpreter. The judges also clarify the role of the interpreter to the witness and the attorneys. These are important steps in providing meaningful access to the court for LEP individuals.

Just as corrections recipients must take care to ensure that eligible LEP individuals have the opportunity to reduce the term of their sentence to the same extent that non-LEP individuals do, courts must ensure that LEP persons have access to programs that would give them the opportunity to avoid serving a sentence at all.

Example: An LEP defendant should be given the same access to alternatives to sentencing, such as anger management and alcohol abuse counseling, as is given to non-LEP persons in the same circumstances.

Courts have significant contact with the public outside of the courtroom. Providing meaningful access to the legal process for LEP individuals requires more than just providing interpreters in the courtroom. Recipient courts should assess the need for language services all along the process, particularly in areas with high numbers of unrepresented individuals, such as family and small claims courts.

Example: Only twenty thousand people live in a rural county. The county superior court receives DOJ funds but does not have a budget comparable to that of a more-populous urbanized county in the state. Over 1000 LEP Hispanic immigrants have settled in the rural county. The urbanized county also has more than 1000 LEP Hispanic immigrants. Both counties have "how to" materials in English helping unrepresented individuals negotiate the family court processes. The urban county has taken the lead in developing Spanish-language translations of materials that would explain the process. The rural county modifies these slightly and thereby benefits from the work of the urban county. Because this type of outreach material can be vital for an unrepresented person seeking access to a vital service of the court, such a translation is consistent with Title VI obligations and falls within the safe harbor. Creative solutions, such as sharing resources across jurisdictions, can help overcome serious financial concerns in areas with few resources.

Just as with police departments, courts and/or particular divisions within courts may have more contact with LEP individuals than an assessment of the general population would indicate. Recipients should consider that higher contact level when determining the number or proportion of LEP individuals in the contact population, and the frequency of such contact.

Example: A county has very few residents who are LEP. However, many Vietnamese-speaking LEP motorists go through a major freeway running through the county, which connects two areas with high populations of Vietnamese speaking LEP individuals. As a result, the Traffic Division of the county court processes a large number of LEP persons, but it has taken no steps to train staff or provide forms or other language access in that Division because of the small number of LEP individuals in the county. The Division should assess the number and proportion of LEP individuals processed by the Division and the frequency of such contact. With those numbers high, the Traffic Division may find that it needs to provide key forms or instructions in Vietnamese. It may also find, from talking with community groups, that many older Vietnamese LEP individuals do not read Vietnamese well, and that it should provide oral language services as well. The court may already have Vietnamese-speaking staff competent in interpreting in a different section of the court; it may decide to hire a Vietnamese-speaking employee who is competent in the skill of interpreting; or it may decide that a language line service suffices.

2. Juvenile Justice Programs

DOJ provides funds to many juvenile justice programs to whom this Guidance applies.

Example: A county coordinator for an anti-gang program operated by a DOJ recipient has noticed that increasing numbers of gangs have formed comprised primarily of LEP individuals speaking a particular foreign language. The coordinator should assess the number of LEP youths at risk of involvement in these gangs, so that she can determine whether the program should hire a counselor who is bilingual in the particular language and English, or provide other types of language services to the LEP youths.

3. Domestic Violence Prevention/ Treatment Programs

Several domestic violence prevention and treatment programs receive DOJ financial assistance and thus must apply this Guidance to their programs and activities.

Example: A shelter for victims of domestic violence is operated by a recipient of DOJ funds and located in an area where 15 percent of the women in the service area speak Spanish and are LEP. Seven percent of the women in the service area speak various Chinese dialects and are LEP. The shelter uses community volunteers to help translate vital outreach materials into Chinese (which is one written language despite many dialects) and Spanish. The shelter hotline has a menu providing key information, such as location, in English, Spanish, and two of the most common Chinese dialects. Calls for immediate assistance are handled by the bilingual staff. The shelter has one counselor and several volunteers fluent in Spanish and English. Some volunteers are fluent in different Chinese dialects and in English. The shelter works with community groups to access interpreters in the several Chinese dialects that they encounter. Shelter staff train the community volunteers in the sensitivities of domestic violence intake and counseling. Volunteers sign confidentiality agreements. The shelter is looking for a grant to increase its language capabilities despite its tiny budget. This program is consistent with Title VI principles.

D. Framework for Creating a Model Plan

The following is an example of a framework for a model LEP policy that is potentially useful for all recipients, but is particularly appropriate for recipients serving and encountering significant and diverse LEP populations. The framework for a model plan incorporates a variety of options and methods for providing meaningful access to LEP persons. Recipients should consider some or all of these options for their plans:

—A formal written LEP policy;
—Identification and assessment of the number or proportion of LEP persons likely to be encountered through a review of census, school district, community agency, recipient and/or other data. The data will clearly be more within the control of some recipients than others. For instance, corrections facilities will likely be able to obtain accurate data more easily than police departments. Nevertheless, police departments should take reasonable steps to identify the language needs of the population they serve.
—Identification of the frequency of contact with LEP language groups.
—Identification of important information, services, and encounters that may require language services.
—Identification of resources available to provide services.
—Posting of signs in waiting areas and public entry points, in several languages, informing people what interpreter services are available and inviting them to identify themselves as needing language assistance.
—Informing LEP suspects, detainees, inmates and others potentially subject to criminal or disciplinary action of their right to language assistance.
—Use of "I speak" cards by those who encounter the public in-person, in order to identify the language an LEP person speaks.
—If a record is normally kept on encounters with individuals, noting the language of the LEP person in his or her record.
—Employing bilingual staff in public contact positions such as police officers, 911 operators, guards, etc.
—Contracting with interpreting services that can provide competent interpreters in a variety of languages in a timely manner.
—Formal arrangements with community groups for competent and timely interpreter services by community volunteers.
—An arrangement with a telephone language interpreter line (these can be arranged by, for instance, contacting major telephone services and asking if they have language line services).
—Where certain LEP populations make up a significant number of the population in the recipient's target area and are frequently encountered by the recipient, translation of vital documents into the languages of those LEP populations.
—Notice and training to staff, particularly those with public contact, of the LEP policy and how to access language services.
—Outreach to the LEP population on available language services.
—Appointing a senior level employee to coordinate the language assistance program, and ensure that there is regular monitoring of the program.

As noted, these suggestions for a model plan are particularly appropriate for larger recipients encountering significant LEP populations. However, several of these steps will help smaller recipients prepare for and provide meaningful access when LEP individuals are encountered.

For smaller recipients with few LEP encounters, identifying the most important activities is critical, and determining how to provide language services in those critical areas should be a priority. This may be as simple as accessing a commercially available language line. Plans for such recipients should include monitoring and expanding services as needed.

Appendix B—Coverage and Legal Background

A. Who is Covered?

Title VI applies to every entity that manages or administers a program or activity receiving direct or indirect federal financial assistance from DOJ. The term "recipients," as used in this guidance, includes all covered entities. "Covered entities" include any state or local agency, private institution or organization, or any public or private individual that receives federal financial assistance from DOJ directly or through another DOJ recipient. Examples of covered entities include but are not

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limited to: Police departments; sheriffs' departments; state departments of corrections; courts; shelters for victims of domestic violence; community corrections programs; juvenile justice programs; and nonprofit organizations with law enforcement missions. DOJ operates over eighty different grant programs that provide funding to these and other different types of non-federal entities. Many of those grants are disbursed to subrecipients, which are also covered entities.

Grants are not the only type of "federal financial assistance" to which Title VI applies. Federal financial assistance includes, but is not limited to: Grants and loans of federal funds; grants or donations of federal surplus or real property; details of federal personnel; use of federal facilities; or any agreement, arrangement, or other contract which has as one of its purposes the provision of assistance. See 28 CFR 42.102(c). Training, equitable sharing of federally forfeited property, and use of FBI computers can also be considered federal financial assistance.[1]

In 1988, Congress clarified what constitutes a "program or activity" covered by Title VI when it enacted the Civil Rights Restoration Act of 1987 (CRRA). The CRRA provides that, in most cases, when a recipient receives federal financial assistance for a particular program or activity, all operations of the recipient are covered by Title VI, not just the part of the program that uses the federal assistance. Thus, Title VI covers all parts of the recipient's operations, even if only one part of the agency uses the federal assistance. For example, when DOJ provides federal financial assistance to a state department of corrections to improve a particular prison facility, all of the operations of the entire department of corrections—not just the particular prison—are covered by Title VI.[2]

The Department of Justice also has jurisdiction over enforcement of the antidiscrimination provisions of the Omnibus Crime Control and Safe Streets Act, as amended, 42 U.S.C. 3789d(c) (Safe Streets Act). The standards for compliance with Title VI's prohibition against national origin discrimination also apply to the prohibition against national origin discrimination by recipients of Safe Streets Act funds.

B. Legal Background and Authority

The Title VI requirement to provide meaningful access to LEP persons is not new. The Department's position with regard to written language assistance is articulated in 28 CFR 42.405(d)(1), which is contained in the DOJ Coordination Regulations, 28 CFR Part 42, subpart F, issued in 1976. These regulations "govern the respective obligations of Federal agencies regarding enforcement of Title VI." 28 CFR 42.405. Section 42.405(d)(1) addresses the prohibitions cited by the Supreme Court in *Lau* v. *Nichols*, 414 U.S. 563 (1974). Thus, this Guidance draws its authority from Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d, *et seq.*; 28 CFR Part 42, subpart C, (DOJ Title VI Regulations) and the Title VI regulations of other federal agencies; 28 CFR Part 42, subpart F. Further, this Guidance is issued pursuant to Executive Order 12250, *reprinted* at 42 U.S.C. 2000d, note; Executive Order 13166, 65 FR 50121 (August 16, 2000); and is consistent with the DOJ "Policy Guidance Document: on Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency (LEP Guidance)," reprinted at 65 FR 50123 (August 16, 2000).

For additional background on Title VI and its methods of enforcement, see the DOJ *Title VI Legal Manual* (September, 1998); DOJ's *Investigation Procedures Manual for the Investigation and Resolution of Complaints Alleging Violations of Title VI and Other Nondiscrimination Statutes* (September 1998); DOJ Guidelines for the Enforcement of Title VI, 28 CFR 50.3; the Attorney General's "Memorandum for Heads of Departments and Agencies that Provide Federal Financial Assistance Regarding the Use of the Disparate Impact Standard in Administrative Regulations Under Title VI of the Civil Rights Act of 1964" (July 14, 1994); and the Assistant Attorney General for Civil Rights' "Policy Guidance Document: Enforcement of Title VI and Related Statutes in Block Grant-Type Programs" (January 28, 1999).[3]

1. Existing State and Local Laws

State and local laws may provide additional obligations to serve LEP individuals, but such laws cannot compel recipients of federal financial assistance to violate Title VI. For instance, given our constitutional structure, state or local "English-only" laws do not relieve an entity that receives federal funding from its responsibilities under federal anti-discrimination laws. Entities in states and localities with "English-only" laws are certainly not required to accept federal funding—but if they do, they have to comply with Title VI, including its prohibition against national origin discrimination by recipients of federal assistance. Failing to make federally assisted programs and activities accessible to individuals who are LEP will, in certain circumstances, violate Title VI.

2. Basic Requirements Under Title VI

Title VI prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. Section 601 of Title VI, 42 U.S.C. 2000d, provides:

> No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.

The term "program or activity" is broadly defined. 42 U.S.C. 2000d–4a.

On its face, Title VI prohibits only intentional discrimination.[4] However, virtually every federal agency, including DOJ, that grants federal financial assistance has promulgated regulations implementing Title VI. Those regulations prohibit recipients from "restrict[ing] an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program" and "utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination" or have "the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin." 28 CFR 42.04(b)(2). The Supreme Court has consistently upheld agency regulations prohibiting unjustified discriminatory effects.[5]

[1] *See* Appendix A to Subpart C of the Department of Justice's regulations implementing Title VI of the Civil Rights Act of 1964 (Subpart C, 28 CFR 42.101–42.112).

[2] However, if a federal agency were to decide to terminate federal funds based on noncompliance with Title VI, only funds directed to the specific entity that is out of compliance—e.g., a particular prison—would be terminated. 42 U.S.C. 2000d–1.

[3] The documents referenced in this section are available for viewing or downloading at *http://www.usdoj.gov/crt/cor.*

[4] *Alexander* v. *Choate*, 469 U.S. 287, 293 (1985).

[5] *Id.* at 293–294; *Guardians Ass'n* v. *Civil Serv. Comm'n*, 463 U.S. 582, 584 n.2 (1983) (White, J.), 623 n.15 (Marshall, J.), 642–645 (Stevens, Brennan, Blackmun, JJ.); *Lau* v. *Nichols*, 414 U.S. at 568; *id.* at 571 (Stewart, J., concurring in result). Further, in a July 24, 1994, Memorandum to Heads of Departments and Agencies that Provide Federal Financial Assistance concerning Use of the Disparate Impact Standard in Administrative Regulations Under Title VI of the Civil Rights Act of 1964, the Attorney General stated that each agency "should ensure that the disparate impact provisions of your regulations are fully utilized so that all persons may enjoy equally the benefits of federally financed programs."

[6] 414 U.S. at 566. Congress manifested its approval of the *Lau* decision by enacting provisions in the Education Amendments of 1974, Pub. L. 93–380, secs. 105, 204, 88 Stat. 503–512, 515 codified at 20 U.S.C. 1703(f), and the Bilingual Education Act, 20 U.S.C. 7401, *et seq.*, which provided federal financial assistance to school districts to provide language services to LEP students.

[7] For cases outside the educational context, *see, e.g., Sandoval* v. *Hagan*, 7 F. Supp. 2d 1234 (M.D. Ala. 1998), *affirmed*, 197 F.3d 484, (11th Cir. 1999), *rehearing and suggestion for rehearing en banc denied*, 211 F.3d 133 (11th Cir. Feb. 29, 2000) (Table, No. 98–6536–II), *petition for certiorari granted, Alexander* v. *Sandoval* 121 S. Ct. 28 (Sept. 26, 2000) (No. 99–1908) (giving drivers' license tests only in English violates Title VI); and *Pabon* v. *Levine*, 70 F.R.D. 674 (S.D.N.Y. 1976) (summary judgment for defendants denied in case alleging failure to provide unemployment insurance information in Spanish violated Title VI).

In *Lau* v. *Nichols*, 414 U.S. 563 (1974), the Supreme Court interpreted similar U.S. Department of Education regulations to require recipients of federal financial assistance to ensure, in appropriate circumstances, that language barriers did not exclude LEP persons from effective participation in federally assisted programs or activities. In *Lau*, a recipient provided the same services—an education provided solely in English—for a group of students who did not speak English as it did for students who did speak English. In finding for the Chinese-American students, the Court held that, under these circumstances, the school's practice violated the Title VI regulations' prohibition against discrimination on the basis of national origin. The Court observed that "[i]t seems obvious that the Chinese-speaking minority receive fewer benefits than the English-speaking majority from respondents' school system which denies them a meaningful opportunity to participate in the educational program—all earmarks of the discrimination banned by" the Title VI implementing regulations.[6]

While *Lau* arose in the educational context, its core holding—that the failure to address limited English proficiency among beneficiary classes could constitute national origin discrimination in violation of Title VI—has equal vitality with respect to any federally assisted program or activity providing services to the public.[7]

The failure to provide language assistance has significant discriminatory effects on the basis of national origin. The Department of Justice has consistently adhered to the view that these effects place the treatment of LEP individuals comfortably within the ambit of Title VI and agencies' implementing regulations.[8] Also, existing language barriers may reflect underlying intentional or invidious discrimination of the type prohibited directly by Title VI itself.

Title VI does not require recipients to remove language barriers when English is an essential aspect of the program (such as providing civil service examinations in English when the job requires person to communicate in English, *see Frontera* v. *Sindell*, 522 F.2d 1215 (6th Cir. 1975)), or there is another non-pretextual "substantial legitimate justification for the challenged practice" and there is no comparably effective alternative practice with less discriminatory affects. *Elston* v. *Talladega County Bd. of Educ.*, 997 F.2d 1394, 1407 (11th Cir. 1993); *New York City Environmental Alliance* v. *Giuliani*, 214 F.3d 65, 72 (2nd Cir. 2000) (plaintiffs failed to show less discriminatory options available to accomplish defendant city's legitimate goal of building new housing and fostering urban renewal). Similar balancing tests are used in other nondiscrimination provisions that are concerned with effects of an entity's actions. For example, under Title VII of the Civil Rights Act of 1964, employers need not cease practices that have a discriminatory effect if they are job-related and "consistent with business necessity" and there is no equally effective "alternative employment practice" that is less discriminatory. 42 U.S.C. 2000e–2(k). Under Section 504 of the Rehabilitation Act, 29 U.S.C. 794, recipients do not need to provide access to persons with disabilities if such steps impose an undue burden on the recipient. *Alexander* v. *Choate*, 469 U.S. at 300. Thus, in situations where all of the factors identified in the text are at their nadir, it may be "reasonable" not to take affirmative steps to provide further access.

Executive Order 13166 reaffirms and clarifies the obligation to eliminate limited English proficiency as a barrier to full and meaningful participation in federally assisted programs and activities. 65 FR 50121 (August 16, 2000). That order states, in part:

> The Federal Government is committed to improving the accessibility of * * * services to eligible [limited English proficiency] persons, a goal that reinforces its equally important commitment to promoting programs and activities designed to help individuals learn English * * * [E]ach Federal agency shall * * * work to ensure that recipients of Federal financial assistance (recipients) provide meaningful access to their LEP applicants and beneficiaries * * *. [R]ecipients must take reasonable steps to ensure meaningful access to their programs and activities by LEP persons.[9]

The Executive Order requires each federal agency to develop agency-specific LEP guidance for recipients of federal financial assistance. As an aid in developing this Guidance, the Executive Order incorporates the Department of Justice's Policy Guidance Document: "Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency ('LEP Guidance')" issued contemporaneously with the Executive Order.[10] That general LEP Guidance "sets forth the compliance standards that recipients must follow to ensure that programs and activities they normally provide in English are accessible to LEP persons."[11] This LEP Guidance for DOJ Recipients represents the application of DOJ's general LEP Guidance to recipients of DOJ's federal financial assistance.

While the Department of Justice's Coordination Regulation, 28 CFR 42.405(d)(1),[12] expressly addresses requirements for provision of written language assistance, a recipient's obligation to provide meaningful opportunity is not limited to written translations.

Oral communication between recipients and beneficiaries, clients, customers, wards, or other members of the public often is a necessary part of the exchange of information. In some cases, "meaningful opportunity" to benefit from the program requires the recipient to take steps to assure that translation services are promptly available. In other circumstances, instead of translating all of its written materials, a recipient may meet its obligation by making available oral assistance, or by commissioning written translations on reasonable request.

[8] *See, e.g.*, 28 CFR 42.405(d)(1).

[9] Section 1, Executive Order 13166.

[10] LEP Guidance, 65 FR 50123.

[11] *See* Executive Order 13166 at Section 1.

[12] Section 42.405(d)(1) states: "Where a significant number or proportion of the population eligible to be served or likely to be affected by a federally assisted program (*e.g.*, affected by relocation) needs service or information in a language other than English in order effectively to be informed or to participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in appropriate languages to such persons. This requirement applies with regard to written material of the type which is ordinarily distributed to the public." This LEP Guidance for DOJ Recipients is intended to clarify obligations under this regulation and further obligations under Title VI to provide language services outside of the context of such written documents.

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Thus, a recipient that limits its language assistance to the provision of written materials may not be allowing LEP persons "effectively to be informed of or to participate in the program." This Guidance provides information to recipients on how to comply with the meaningful access requirement.

D. Explanation of Title VI Compliance Procedures

This Guidance, including appendices, is not intended to be exhaustive. DOJ recipients have considerable flexibility in determining how to comply with their legal obligations in the LEP setting, and are not required to use all of the suggested methods and options listed. However, DOJ recipients must establish and implement policies and procedures for providing language assistance sufficient to fulfill their Title VI responsibilities and provide LEP persons with meaningful access to services. DOJ encourages recipients to document efforts to comply with the provisions of this Guidance. DOJ will make assessments on a case-by-case basis and will consider the four factors in assessing whether the steps taken by a DOJ recipient provide meaningful access.

DOJ enforces Title VI through the procedures identified in the Title VI regulations. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance. In addition, aggrieved individuals may seek judicial relief.

The Title VI regulations provide that DOJ will investigate whenever it receives a complaint, report, or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, DOJ will inform the recipient in writing of this determination, including the basis for the determination. DOJ uses voluntary mediation to resolve most complaints. However, if a case is fully investigated and results in a finding of noncompliance, DOJ must inform the recipient of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance. It must attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, DOJ must secure compliance through the termination of federal assistance after the DOJ recipient has been given an opportunity for an administrative hearing, and/or by referring the matter to a DOJ litigation section to seek injunctive relief or pursue other enforcement proceedings.

DOJ engages in voluntary compliance efforts and provides technical assistance to recipients at all stages of an investigation. During these efforts, DOJ proposes reasonable timetables for achieving compliance and consults with and assist recipients in exploring cost-effective ways of coming into compliance by sharing information on potential community resources, by increasing awareness of emerging technologies, and by sharing information on how other recipient/covered entities have addressed the language needs of diverse populations.

In determining a recipient's compliance with Title VI, DOJ's primary concern is to ensure that the recipient's policies and procedures overcome barriers resulting from language differences that would deny LEP persons a meaningful opportunity to participate in and access programs, services, and benefits.

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Part XI

The President

Memorandum of March 3, 2000—
Delegation of Authority To Transmit Report on Cooperative Projects With Russia

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Presidential Documents

Title 3—

The President

Memorandum of March 3, 2000

Delegation of Authority To Transmit Report on Cooperative Projects With Russia

Memorandum for the Secretary of Defense

By authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, I hereby delegate to the Secretary of Defense the duties and responsibilities vested in the President by section 2705(d) of Division G of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999 (Public Law 105–277; 112 Stat. 2681–844). Such duties and responsibilities shall be exercised subject to the concurrence of the Secretary of State.

The reporting requirements delegated by this memorandum to the Secretary of Defense may be redelegated not lower than the Under Secretary level. The Department of Defense shall obtain clearance on the report from the Office of Management and Budget prior to its submission to the Congress.

Any reference in this memorandum to the provisions of any Act shall be deemed to be referenced to such Act or its provisions as may be amended from time to time.

You are authorized and directed to publish this memorandum in the **Federal Register**.

William J. Clinton

THE WHITE HOUSE,
Washington, March 3, 2000

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Note: The List of Public Laws for the 106th Congress, Second Session has been completed and will resume when bills are enacted into public law during the next session of Congress. A cumulative List of Public Laws appears in Part II of this issue.

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

A checklist of current CFR volumes comprising a complete CFR set, also appears in the latest issue of the LSA (List of CFR Sections Affected), which is revised monthly.

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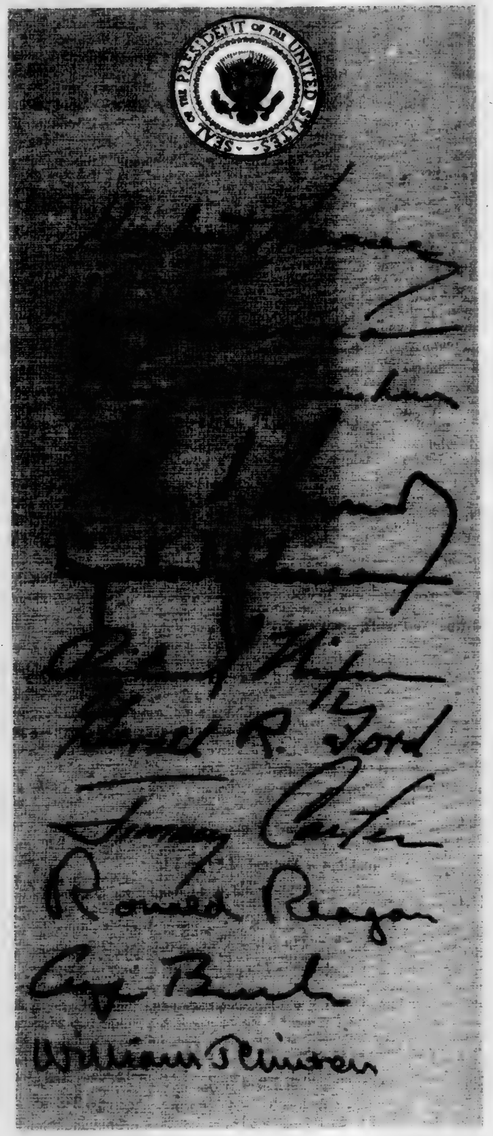
[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 1999, through January 1, 2000. The CFR volume issued as of January 1, 1999 should be retained.

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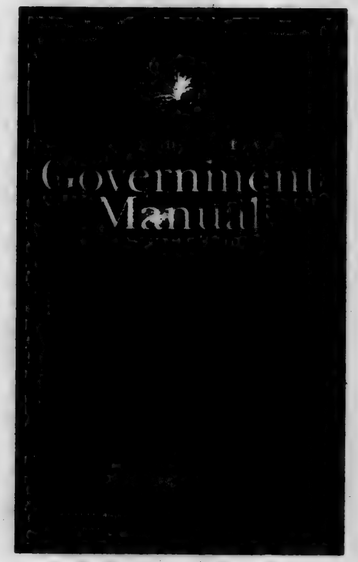
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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: January 24, 2001, from 9:00 a.m. to Noon (E.S.T.)

WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Presidential Documents

Title 3—

The President

Executive Order 13186 of January 10, 2001

Responsibilities of Federal Agencies To Protect Migratory Birds

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in furtherance of the purposes of the migratory bird conventions, the Migratory Bird Treaty Act (16 U.S.C. 703–711), the Bald and Golden Eagle Protection Acts (16 U.S.C. 668–668d), the Fish and Wildlife Coordination Act (16 U.S.C. 661–666c), the Endangered Species Act of 1973 (16 U.S.C. 1531–1544), the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4347), and other pertinent statutes, it is hereby ordered as follows:

Section 1. *Policy.* Migratory birds are of great ecological and economic value to this country and to other countries. They contribute to biological diversity and bring tremendous enjoyment to millions of Americans who study, watch, feed, or hunt these birds throughout the United States and other countries. The United States has recognized the critical importance of this shared resource by ratifying international, bilateral conventions for the conservation of migratory birds. Such conventions include the Convention for the Protection of Migratory Birds with Great Britain on behalf of Canada 1916, the Convention for the Protection of Migratory Birds and Game Mammals-Mexico 1936, the Convention for the Protection of Birds and Their Environment- Japan 1972, and the Convention for the Conservation of Migratory Birds and Their Environment-Union of Soviet Socialist Republics 1978.

These migratory bird conventions impose substantive obligations on the United States for the conservation of migratory birds and their habitats, and through the Migratory Bird Treaty Act (Act), the United States has implemented these migratory bird conventions with respect to the United States. This Executive Order directs executive departments and agencies to take certain actions to further implement the Act.

Sec. 2. *Definitions.* For purposes of this order:

(a) "Take" means take as defined in 50 C.F.R. 10.12, and includes both "intentional" and "unintentional" take.

(b) "Intentional take" means take that is the purpose of the activity in question.

(c) "Unintentional take" means take that results from, but is not the purpose of, the activity in question.

(d) "Migratory bird" means any bird listed in 50 C.F.R. 10.13.

(e) "Migratory bird resources" means migratory birds and the habitats upon which they depend.

(f) "Migratory bird convention" means, collectively, the bilateral conventions (with Great Britain/Canada, Mexico, Japan, and Russia) for the conservation of migratory bird resources.

(g) "Federal agency" means an executive department or agency, but does not include independent establishments as defined by 5 U.S.C. 104.

(h) "Action" means a program, activity, project, official policy (such as a rule or regulation), or formal plan directly carried out by a Federal agency. Each Federal agency will further define what the term "action" means with respect to its own authorities and what programs should be included

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in the agency-specific Memoranda of Understanding required by this order. Actions delegated to or assumed by nonfederal entities, or carried out by nonfederal entities with Federal assistance, are not subject to this order. Such actions, however, continue to be subject to the Migratory Bird Treaty Act.

(i) "Species of concern" refers to those species listed in the periodic report "Migratory Nongame Birds of Management Concern in the United States," priority migratory bird species as documented by established plans (such as Bird Conservation Regions in the North American Bird Conservation Initiative or Partners in Flight physiographic areas), and those species listed in 50 C.F.R. 17.11.

Sec. 3. *Federal Agency Responsibilities.* (a) Each Federal agency taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations is directed to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service (Service) that shall promote the conservation of migratory bird populations.

(b) In coordination with affected Federal agencies, the Service shall develop a schedule for completion of the MOUs within 180 days of the date of this order. The schedule shall give priority to completing the MOUs with agencies having the most substantive impacts on migratory birds.

(c) Each MOU shall establish protocols for implementation of the MOU and for reporting accomplishments. These protocols may be incorporated into existing actions; however, the MOU shall recognize that the agency may not be able to implement some elements of the MOU until such time as the agency has successfully included them in each agency's formal planning processes (such as revision of agency land management plans, land use compatibility guidelines, integrated resource management plans, and fishery management plans), including public participation and NEPA analysis, as appropriate. This order and the MOUs to be developed by the agencies are intended to be implemented when new actions or renewal of contracts, permits, delegations, or other third party agreements are initiated as well as during the initiation of new, or revisions to, land management plans.

(d) Each MOU shall include an elevation process to resolve any dispute between the signatory agencies regarding a particular practice or activity.

(e) Pursuant to its MOU, each agency shall, to the extent permitted by law and subject to the availability of appropriations and within Administration budgetary limits, and in harmony with agency missions:

(1) support the conservation intent of the migratory bird conventions by integrating bird conservation principles, measures, and practices into agency activities and by avoiding or minimizing, to the extent practicable, adverse impacts on migratory bird resources when conducting agency actions;

(2) restore and enhance the habitat of migratory birds, as practicable;

(3) prevent or abate the pollution or detrimental alteration of the environment for the benefit of migratory birds, as practicable;

(4) design migratory bird habitat and population conservation principles, measures, and practices, into agency plans and planning processes (natural resource, land management, and environmental quality planning, including, but not limited to, forest and rangeland planning, coastal management planning, watershed planning, etc.) as practicable, and coordinate with other agencies and nonfederal partners in planning efforts;

(5) within established authorities and in conjunction with the adoption, amendment, or revision of agency management plans and guidance, ensure that agency plans and actions promote programs and recommendations of comprehensive migratory bird planning efforts such as Partners-in-Flight, U.S. National Shorebird Plan, North American Waterfowl Management Plan, North American Colonial Waterbird Plan, and other planning efforts, as well as guidance from other sources, including the Food and Agricultural Organization's International Plan of Action for Reducing Incidental Catch of Seabirds in Longline Fisheries;

(6) ensure that environmental analyses of Federal actions required by the NEPA or other established environmental review processes evaluate the effects of actions and agency plans on migratory birds, with emphasis on species of concern;

(7) provide notice to the Service in advance of conducting an action that is intended to take migratory birds, or annually report to the Service on the number of individuals of each species of migratory birds intentionally taken during the conduct of any agency action, including but not limited to banding or marking, scientific collecting, taxidermy, and depredation control;

(8) minimize the intentional take of species of concern by: (i) delineating standards and procedures for such take; and (ii) developing procedures for the review and evaluation of take actions. With respect to intentional take, the MOU shall be consistent with the appropriate sections of 50 C.F.R. parts 10, 21, and 22;

(9) identify where unintentional take reasonably attributable to agency actions is having, or is likely to have, a measurable negative effect on migratory bird populations, focusing first on species of concern, priority habitats, and key risk factors. With respect to those actions so identified, the agency shall develop and use principles, standards, and practices that will lessen the amount of unintentional take, developing any such conservation efforts in cooperation with the Service. These principles, standards, and practices shall be regularly evaluated and revised to ensure that they are effective in lessening the detrimental effect of agency actions on migratory bird populations. The agency also shall inventory and monitor bird habitat and populations within the agency's capabilities and authorities to the extent feasible to facilitate decisions about the need for, and effectiveness of, conservation efforts;

(10) within the scope of its statutorily-designated authorities, control the import, export, and establishment in the wild of live exotic animals and plants that may be harmful to migratory bird resources;

(11) promote research and information exchange related to the conservation of migratory bird resources, including coordinated inventorying and monitoring and the collection and assessment of information on environmental contaminants and other physical or biological stressors having potential relevance to migratory bird conservation. Where such information is collected in the course of agency actions or supported through Federal financial assistance, reasonable efforts shall be made to share such information with the Service, the Biological Resources Division of the U.S. Geological Survey, and other appropriate repositories of such data (e.g, the Cornell Laboratory of Ornithology);

(12) provide training and information to appropriate employees on methods and means of avoiding or minimizing the take of migratory birds and conserving and restoring migratory bird habitat;

(13) promote migratory bird conservation in international activities and with other countries and international partners, in consultation with the Department of State, as appropriate or relevant to the agency's authorities;

(14) recognize and promote economic and recreational values of birds, as appropriate; and

(15) develop partnerships with non-Federal entities to further bird conservation.

(f) Notwithstanding the requirement to finalize an MOU within 2 years, each agency is encouraged to immediately begin implementing the conservation measures set forth above in subparagraphs (1) through (15) of this section, as appropriate and practicable.

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(g) Each agency shall advise the public of the availability of its MOU through a notice published in the **Federal Register**.

Sec. 4. *Council for the Conservation of Migratory Birds.* (a) The Secretary of Interior shall establish an interagency Council for the Conservation of Migratory Birds (Council) to oversee the implementation of this order. The Council's duties shall include the following: (1) sharing the latest resource information to assist in the conservation and management of migratory birds; (2) developing an annual report of accomplishments and recommendations related to this order; (3) fostering partnerships to further the goals of this order; and (4) selecting an annual recipient of a Presidential Migratory Bird Federal Stewardship Award for contributions to the protection of migratory birds.

(b) The Council shall include representation, at the bureau director/administrator level, from the Departments of the Interior, State, Commerce, Agriculture, Transportation, Energy, Defense, and the Environmental Protection Agency and from such other agencies as appropriate.

Sec. 5. *Application and Judicial Review.* (a) This order and the MOU to be developed by the agencies do not require changes to current contracts, permits, or other third party agreements.

(b) This order is intended only to improve the internal management of the executive branch and does not create any right or benefit, substantive or procedural, separately enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

William J. Clinton

THE WHITE HOUSE,
January 10, 2001.

[FR Doc. 01–1387
Filed 1–12–01; 8:45 am]
Billing code 3195–01–P

Presidential Documents

Executive Order 13187 of January 10, 2001

The President's Disability Employment Partnership Board

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to promote the employment of people with disabilities, it is hereby ordered as follows:

Section 1. *Establishment and Composition of the Board.* (a) There is hereby established the President's Disability Employment Partnership Board (Board).

(b) The Board shall be composed of not more than 15 members who shall be appointed by the President for terms of 2 years. The membership shall include individuals who are representatives of business (including small business), labor organizations, State or local government, disabled veterans, people with disabilities, organizations serving people with disabilities, and researchers or academicians focusing on issues relating to the employment of people with disabilities, and may include other individuals representing entities involved in issues relating to the employment of people with disabilities as the President finds appropriate.

(c) The President shall designate a Chairperson from among the members of the Board to serve a term of two years.

(d) Members and the Chairperson may be reappointed for subsequent terms and may continue to serve until their successors have been appointed.

Sec. 2. *Functions.* (a) The Board shall provide advice and information to the President, the Vice President, the Secretary of Labor, and other appropriate Federal officials with respect to facilitating the employment of people with disabilities, and shall assist in other activities that promote the formation of public-private partnerships, the use of economic incentives, the provision of technical assistance regarding entrepreneurship, and other actions that may enhance employment opportunities for people with disabilities.

(b) In carrying out paragraph (a) of this section, the Board shall:

(i) develop and submit to the Office of Disability Employment Policy in the Department of Labor a comprehensive written plan for joint public-private efforts to promote employment opportunities for people with disabilities and improve their access to financial institutions and commercial and business enterprises;

(ii) identify strategies that may be used by employers, labor unions, national and international organizations, and Federal, State, and local officials to increase employment opportunities for people with disabilities; and

(iii) coordinate with the Office of Disability Employment Policy in the Department of Labor in promoting the collaborative use of public and private resources to assist people with disabilities in forming and expanding small business concerns and in enhancing their access to Federal procurement and other relevant business opportunities. Public resources include those of the Department of Labor, the Small Business Administration, the Department of Commerce, the Department of Education, the Department of Defense, the Department of Treasury, the Department of Veterans Affairs, the Federal Communications Commission, and of executive departments and agency offices responsible for small, disadvantaged businesses utilization.

(c) The Board shall submit annual written reports to the President, who may apprise the Congress and other interested organizations and individuals

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on its activities, progress, and problems relating to maximizing employment opportunities for people with disabilities.

(d) The Chairperson of the Board shall serve as a member and Vice Chair of the National Task Force on Employment of Adults with Disabilities established under Executive Order 13078 of March 13, 1998.

Sec. 3. *Administration.* (a) The Board shall meet when called by the Chairperson, at a time and place designated by the Chairperson. The Chairperson shall call at least two meetings per calendar year. The Chairperson may form subcommittees or working groups within the Board to address particular matters.

(b) The Chairperson may from time to time prescribe such rules, procedures, and policies relating to the activities of the Board as are not inconsistent with law or with the provisions of this order.

(c) Members of the Board shall serve without compensation but shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Federal service. (5 U.S.C. 5701–5707).

(d) The Department of Labor shall provide funding and appropriate support to assist the Board in carrying out the activities described in section 2 of this order, including necessary office space, equipment, supplies, services, and staff. The functions of the President under the Federal Advisory Committee Act, as amended, except that of reporting to the Congress, that are applicable to the Commission, shall be performed by the Department of Labor in accordance with guidelines that have been issued by the Administrator of General Services.

(e) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Board such information as it may need for purposes of carrying out the functions described in section 2 of this order.

Sec. 4. *Prior Orders and Transition.* (a) Executive Order 12640 of May 10, 1988, as amended, relating to the establishment of the President's Committee on Employment of People with Disabilities, is hereby revoked. The employees, records, property, and funds of the Committee shall become the employees, records, property, and funds of the Department of Labor.

(b) Executive Order 13078 of March 13, 1998, is amended in sections 1(a) and (b) by striking "Chair of the President's Committee on Employment of People with Disabilities" and inserting "Chairperson of the President's Disability Employment Partnership Board."

William J. Clinton

THE WHITE HOUSE,
January 10, 2001.

[FR Doc. 01–1438
Filed 1–12–01; 8:45 am]
Billing code 3195–01–P

Rules and Regulations

Federal Register
Vol. 66, No. 11
Wednesday, January 17, 2001

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–83–AD; Amendment 39–12072; AD 2001–01–02]

RIN 2120–AA64

Airworthiness Directives; British Aerospace HP137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes that are equipped with certain nose landing gear units. This AD requires you to inspect the steering jack assembly to assure proper clearance between the bush heads on the steering plates and the shim on the steering jack trunnions and to assure that there is adequate lubrication at both trunnions and the eye end fitting. This AD also requires you to adjust the clearance and provide adequate lubrication, as necessary. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. The actions specified by this AD are intended to prevent cracked steering jack piston rods caused by inadequate clearance or inadequate lubrication of the steering jack pivot points. The condition could result in failure of the nose wheel steering system with consequent loss of airplane control.

DATES: This AD becomes effective on March 5, 2001.

The Director of the **Federal Register** approved the incorporation by reference of certain publications listed in the regulations as of March 5, 2001.

ADDRESSES: You may get the service information referenced in this AD from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 479888; facsimile: (01292) 479703. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–83–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD?

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. The CAA reports incidents where cracking has occurred at the base of the thread in the steering jack piston rod, part number 618212, in the nose landing gear unit. The condition could occur on the referenced airplanes that are equipped with nose landing gear unit 1873, B00A702852A, B00A703064A, or B00A703056A.

Inadequate clearance or inadequate lubrication of the steering jack pivot points can result in unusually high operational loads. These loads could result in such cracks in the steering jack piston rod.

What are the consequences if the condition is not corrected?

A cracked steering jack piston rod could result in failure of the nose wheel steering system with consequent loss of airplane control.

Has FAA taken any action to this point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes that are equipped with certain nose landing gear units. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 24, 2000 (65 FR 63553). The NPRM proposed to require you to inspect the steering jack assembly to assure proper clearance between the bush heads on the steering plates and the shim on the steering jack trunnions and to assure that there is adequate lubrication at both trunnions and the eye end fitting. The NPRM also proposed to require you to adjust the clearance and provide adequate lubrication, as necessary.

Accomplishment of the proposed action would be in accordance with APPH Ltd. Service Newsletter, Issue 2, Jetstream 31 Steering Jack Part Number 618200, as referenced in British Aerospace Mandatory Service Bulletin 32–JA 981043, dated March 5, 1999.

Was the public invited to comment?

Interested persons were afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

The FAA's Determination

What is FAA's Final Determination on this Issue?

After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

- Will not change the meaning of the AD; and
- Will not add any additional burden upon the public than was already proposed.

Cost Impact

How many airplanes does this AD impact?

We estimate that this AD affects 300 airplanes in the U.S. registry.

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What is the cost impact of this AD on owners/operators of the affected airplanes?

We estimate the following costs to accomplish the inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 workhour × $60 per hour	No parts required to accomplish the inspection.	$60	$18,000

We estimate the following costs to accomplish any necessary adjustments that are required based on the results of the inspections. We have no way of determining the number of airplanes that may need such adjustments:

Labor cost	Parts cost	Total cost per airplane
1 workhour × $60 per hour	No parts necessary for adjustment	$60

Regulatory Impact

Does this AD impact various entities?

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does this AD involve a significant rule or regulatory action?

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–01–02 British Aerospace: Amendment 39–12072; Docket No. 99–CE–83–AD.

(a) *What airplanes are affected by this AD?* This AD affects Models HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes, all serial numbers, that are:

(1) equipped with a nose landing gear unit 1873, B00A702852A, B00A703064A, or B00A703056A; and

(2) certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent cracked steering jack piston rods caused by inadequate clearance or inadequate lubrication of the steering jack pivot points. The condition could result in failure of the nose wheel steering system with consequent loss of airplane control.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Action	Compliance time	Procedures
(1) Inspect the steering jack assembly to assure proper clearance between the bush heads on the steering plates and the shim on the steering jack trunnions and to assure that there is adequate lubrication at both trunniions and the eye end fitting.	Within the next 200 hours time-in-service (TIS) after March 5, 2001, the effective date of this AD, unless already accomplished.	Accomplish in accordance with the instructions in APPH Ltd. Service Newsletter, Issue 2, Jetstream 31 Steering Jack Part Number 618200, as referenced in British Aerospace Mandatsory Service Bulletin 32–JA 981043, dated March 5, 1999.
(2) Adjust the clearance and provide adequate lubrication, as necessary.	Prior to further flight after the inspection required by paragraph (d)(1) of this AD.	Accomplish in accordance with the instructions in APPH Ltd. Service Newsletter, Issue 2, Jetstream 31 Steering Jack Part Number 618200, as referenced in British Aerospace Mandatory Service Bulletin 32–JA 981043, dated March 5, 1999.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Mr. Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with APPH Ltd. Service Newsletter, Issue 2, Jetstream 31 Steering Jack Part Number 618200, as referenced in British Aerospace Mandatory Service Bulletin 32–JA 981043, dated March 5, 1999. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on March 5, 2001.

Note 2: The subject of this AD is addressed in British AD 012–03–99.

Issued in Kansas City, Missouri, on January 4, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–916 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–48–AD; Amendment 39–12052; AD 2000–26–03]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A310, and Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600) Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in airworthiness directive (AD) 2000–26–03, which was published in the **Federal Register** on December 28, 2000 (65 FR 82262). The typographical error resulted in the misidentification of affected airplanes. This AD is applicable to Airbus Model A310, and Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600) series airplanes. This AD requires new wiring modifications for the engine and the fire detection system of the auxiliary power unit.

EFFECTIVE DATE: Effective February 1, 2001.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: Airworthiness Directive (AD) 2000–26–03, amendment 39–12052, was published in the **Federal Register** on December 28, 2000 (65 FR 82262). The AD requires new wiring modifications for the engine and auxiliary power unit (APU) fire detection system.

As published, AD 2000–26–03 incorrectly substituted a nonaffected group of airplanes for an affected group. Specifically, the AD substituted Model A300 B2 and B4 series airplanes for Model A310 series airplanes. The NPRM for this AD correctly identified the affected airplanes.

Since no other part of the regulatory information has been changed, the final rule is not being republished in the **Federal Register**.

The effective date of this AD remains February 1, 2001.

In AD 2000–26–03, amendment 39–12052, make the following corrections:

1. On page 82262, in the first column, the subject heading should read "Airworthiness Directives; Airbus Model A310 Series Airplanes, and Model A30A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600) Series Airplanes."

2. On page 82262, in the first column, under the heading **Summary**, in the fourth line, "A300 B2 and B4" should read "A310."

3. On page 82262, in the second column, under the heading **Cost Impact**, in the second line of the first paragraph, "A300 B2 and B4" should read "A310."

§ 39.13 [Corrected]

4. On page 82262, in the third column, the applicability of AD 2000–26–03 is corrected to read as follows:

* * * * *

Applicability: Model A310 series airplanes, and Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600) series airplanes; certificated in any category; except those on which Airbus Modifications 06267 and 07340 have been accomplished during production.

* * * * *

Issued in Renton, Washington, on January 8, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1231 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 103

RIN 1076–AD73

Loan Guaranty, Insurance, and Interest Subsidy

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior (DOI), Bureau of Indian Affairs (BIA) is revising the regulations that implement the Loan Guaranty, Insurance, and Interest Subsidy Program. This Program authorizes the Secretary of DOI to guaranty or insure loans made by private lenders to individual Indians and to organizations of Indians, and to assist qualified borrowers with a portion of their interest payments. The new regulations clarify prior regulatory language, in keeping with the "plain language" standard required by Executive Order 12866. They also reflect evolved BIA policies, and address several issues that prior regulations did not cover.

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EFFECTIVE DATE: These regulations take effect on February 16, 2001. They do not govern pre-existing loan guarantees. However, a lender may elect to have its pre-existing loan guarantees governed by the new regulations after the effective date by entering into a new loan guaranty agreement with BIA.

FOR FURTHER INFORMATION CONTACT: David B. Johnson, Division of Indian Affairs, Office of the Solicitor, 202–208–3401.

SUPPLEMENTARY INFORMATION: The Loan Guaranty, Insurance, and Interest Subsidy Program (Program) was established in the Act of April 12, 1974, as amended, 88 Stat. 79, 25 U.S.C. 1481 *et seq.* and 25 U.S.C. 1511 *et seq.* The Program has existed since 1974, and the regulations implementing it have existed since 1975. Until now, there has never been any extensive or significant revision of these regulations. The new regulations clarify part 103, reflect evolved BIA policies, address issues that have emerged over the years, and enhance some features of the Program. For example, BIA has overhauled the loan insurance feature of the Program to encourage lenders to reconsider its many advantages.

BIA published a proposed rule in the **Federal Register** on September 6, 2000 (65 FR 53948). BIA considered all comments received during the comment period, September 6, 2000 through November 6, 2000, in drafting this final rule.

Review of Public Comments

BIA received 133 comments during the comment period. Commenters generally liked the organization and approach of the proposed rule much better than the prior rule, and sought only to influence the effect or wording of particular sections. Nonetheless, while most comments were rather specific, some raised issues of greater impact than was apparently envisioned. Correspondingly, in some cases BIA had to rethink sections of the proposed rule other than the one cited by the commenter. Here is a detailed breakdown of the comments, and how they impacted the proposed rule:

Subpart A—General Provisions

Section 103.1What does this part do? There were no comments on this section.

Section 103.2 Who does the Program help? One commenter felt that the second sentence of proposed Section 103.2 was superfluous. BIA agrees. The final rule omits the sentence.

Section 103.3 Who administers the Program? Two commenters made three comments on this section, to the effect that BIA regional offices cannot and should not be the first point of contact for all applicants. BIA agrees. The final rule now has applicants contact "the BIA office serving the borrower's location."

Section 103.4 What kinds of loans will BIA guarantee or insure? Three commenters made five comments on this section, two of which were subsequently withdrawn. One comment stated that paragraph (a) should require a business to contribute to the economy of an Indian reservation, instead of to "an Indian tribe or its members." BIA agrees in part, and has changed the phrase in the final rule to "an Indian reservation or tribal service area recognized by BIA."

Another commenter stated that qualified loans should include individual housing loans, but should not include loans for refinancing. BIA disagrees with both of these comments. Individual housing loans are outside the apparent scope of statutory authority for the Program, whereas loans for refinancing Indian businesses are not. In BIA's experience, refinancing loans is occasionally required to meet Program objectives.

Section 103.5 What size loan will BIA guarantee or insure? Four commenters made five comments on this section. They generally questioned the concept of an "acceptable Indian business entity," and warned of the potential abuse of small partnerships seeking big loans. BIA disagrees with these comments. It is BIA's duty to determine when there is a reasonable prospect of loan repayment. No regulatory ceiling on the amount an Indian business entity can borrow, especially one dependent on the organizational structure of the borrower, is an acceptable substitute for BIA's exercise of its reasonable discretion on a case-by-case basis.

A comment on Section 103.6, however, resulted in a change to Section 103.5. The commenter pointed out that the proposed rule appeared to allow an individual Indian to apply for more than one loan in a manner that would enable the borrower to exceed the statutory limitation of $500,000 for an individual Indian. BIA agrees, and has added language to Section 103.5 to resolve this potential concern.

Section 103.6 To what extent will BIA guarantee or insure a loan? Two commenters made three comments on this section, one of which was subsequently withdrawn and one of which was actually addressed in Section 103.5. The remaining comment was to the effect that BIA should allow only one guaranteed loan at a time between a particular borrower and lender. BIA disagrees, and believes that the proposed rule offers a more workable balance between reasonable limits and flexibility.

Section 103.7 Must the borrower have equity in the business being financed? Two commenters made comments on this section. One comment was subsequently withdrawn, and the other merely expressed confusion over the proposed language. Upon review, BIA does not find any need to change this section.

Section 103.8 Is there any cost for a BIA guaranty or insurance coverage? There were no comments on this section.

Subpart B—How a Lender Obtains a Loan Guaranty or Insurance Coverage

Section 103.9 Who applies to BIA under the Program? Three commenters made four comments on this section, one of which was subsequently withdrawn. The remaining comments were to the effect that the last sentence of the proposed section was partly redundant, and partly unnecessary. BIA agrees, and has deleted it in the final rule.

Section 103.10 What lenders are eligible under the Program? Three commenters made five comments on this section. Two commenters felt that tribes should not qualify as lenders. BIA disagrees with this comment, but notes that paragraph (b) of the proposed rule is superfluous, and eliminating it would satisfy these commenters, at least in part. BIA has removed the former paragraph (b) in the final rule, and re-lettered the remaining provisions accordingly.

Another commenter suggested that BIA establish minimum ownership interests for those lenders who sell off portions of their guaranteed loans; the commenter suggested 25 percent. BIA agrees in part, and has established a minimum ownership interest of 10 percent. The final rule reflects this change in Section 103.28(a), not Section 103.10.

A commenter suggested that BIA insert a new section, between proposed §§ 103.10 and 103.11, to explain how a lender applies to BIA to become an approved lender under the Program. BIA disagrees. Historically, lenders interested in the Program have expressed no trouble getting channeled to BIA Regional Credit Officers, who in turn make the application process simple and expeditious in the vast majority of cases. BIA also has new, OMB-approved Loan Guaranty Agreement and Loan Insurance Agreement forms (BIA forms 5–4753 and 5–4754) that are designed to answer a number of questions and circumstances that prior forms bearing those numbers did not. In summary, the process is simple and is adequately explained in standard forms. There is no need to put the procedure in the rule itself.

A final comment was unclear to BIA, and did not result in any change in the final rule.

Section 103.11 How does BIA approve lenders for the Program? Six commenters made fifteen comments on this section. Five comments were directed at the need for three different levels of guaranteed lender approval, and how those levels are defined. BIA did not change the final rule as a result of these comments. The three levels of guaranteed lender approval are fully explained in BIA's new form 5–4753, Loan Guaranty Agreement.

Four comments noted a typographical error repeated in paragraphs (b) and (c), which previously used the phrase "loan agreement." BIA has corrected the phrase, which is now "loan guaranty agreement."

Four comments addressed the concern that a lender might think the suspension of its loan guaranty agreement and/or loan insurance agreement had an adverse impact on loan guarantees or insurance coverage already in effect. BIA has added a new paragraph (e) to clarify its intent.

One comment requested a grace period prior to the suspension of a lender's loan guaranty agreement and/or loan insurance agreement following a change in corporate structure or merger. BIA disagrees with this request. Suspension affects only the lender's ability to issue new guaranteed or insured loans, and can be quickly remedied when and if the lender has a new qualified loan to present.

One comment focused on the precise nature of the corporate changes that would trigger a suspension under this section. BIA agrees with the general comment, and has made changes in the final rule to clarify its intent. The changes appear in § 103.11(b)(2), and in the new paragraph (c). Correspondingly, BIA has renumbered the former paragraph (c) as paragraph (d). BIA also has added a new paragraph (g) in § 103.33, to conform with these changes.

Section 103.12 How does a lender apply for a loan guaranty? Four commenters made thirteen comments on this section, two of which were subsequently withdrawn. One comment suggested specifying that a lender should submit its application to the BIA Superintendent where the business is located. BIA's response to this comment already is incorporated in the changes made to Section 103.3.

One comment raised a question about the lender's role in providing a borrower with technical assistance, or even in evaluating the borrower's need for technical assistance. BIA agrees with this concern. BIA has reworded proposed paragraph (c) of this section—paragraph (d) in the final rule—to relieve the lender of these duties. BIA will bear primary responsibility for questions of technical assistance, to the extent it is able.

One comment suggested that in some cases obtaining a credit report on a natural person other than the borrower might violate the Fair Credit Reporting Act. BIA agrees that the law is not entirely clear. Accordingly, it has reworded proposed paragraph (d) of this section—paragraph (e) in the final rule.

One comment suggested that credit reports be more current than 90 days at the time of the application. BIA disagrees. The loan process can be lengthy, and BIA does not want to cause a borrower any unnecessary expense or a high number of credit report "inquiries," when the reason for a stale credit report may not even be the borrower's fault. Lenders still may require a more recent credit report if that is their ordinary procedure.

One comment said that lenders should not have to issue a commitment letter to a borrower until after BIA has approved the loan under the Program. BIA disagrees. A lender can avoid potential exposure by issuing its commitment letter subject to BIA approval under the Program. BIA, on the other hand, has no substitute for having before it the lender's blueprint for how it thinks a given loan will work.

One comment requested a stylistic change in proposed paragraph (f) of this section. Upon reflection, BIA slightly re-worded paragraph (f), but in a manner different from the suggested wording. The meaning remains the same.

One comment recommended establishing a standard for the maximum interest rate BIA would find acceptable. BIA disagrees, noting the historic volatility of interest rates.

Two comments noted that proposed paragraphs (e) and (h) of this section would require a borrower to make a substantial investment of time and money, very early in the overall application process. This investment may prove unwarranted, since some projects do not get even tentative approval before denial. BIA agrees. BIA has removed the requirements described in these proposed paragraphs, and made them conditions of closing in § 103.17 instead.

One comment displayed confusion over whether the proposed paragraph (h)—now, paragraph (d) in § 103.17—required each of the items in sub-paragraphs 1 through 4, or merely listed the items for convenience, should they apply in a given transaction. BIA has reworded the final rule to reduce the likelihood of confusion, and also to clarify the process for establishing that a proposed business will not be located in a special flood hazard area.

One comment stated that proposed §§ 103.12 and 103.26 are redundant. BIA agrees in part. BIA has eliminated the redundant features of these sections and placed their common components in § 103.17.

Section 103.13 How does a lender apply for loan insurance coverage? One commenter felt that lenders should always have to ask for BIA's approval, even to obtain loan insurance for a loan of under $100,000. BIA disagrees, noting the apparent intent of Congress in 25 U.S.C. 1484.

Section 103.14 Can BIA request additional information? There were no comments on this section.

Section 103.15 Are there any prohibited loan terms? Five commenters made seven comments on this section, one of which was subsequently withdrawn. One commenter felt that BIA should be flexible concerning balloon payments, with the understanding that BIA would normally avoid them in determining whether there was a reasonable prospect of loan repayment. BIA agrees, and has deleted proposed paragraph (e).

Two commenters recommended establishing a standard for the maximum interest rate BIA would find acceptable. BIA disagrees, noting the historic volatility of interest rates.

One commenter suggested that BIA limit interest rate adjustments to quarterly. BIA disagrees. BIA has no compelling reason to force lenders to use special interest rate change dates, which could be viewed by lenders as a disincentive to use the Program.

Two commenters questioned the late fee limitations in proposed paragraph (j)(3), now paragraph (i)(3). BIA agrees in part. It has removed the $100 cap on late fees.

Section 103.16 How does BIA approve or reject a loan guaranty or insurance application? One commenter made a comment on this section, then withdrew it.

Section 103.17 Must the lender follow any special procedures to close the loan? Three commenters made seven comments on this section, four of which were withdrawn. One commenter suggested that BIA require lenders to

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submit three copies of all loan closing documents. BIA disagrees. It has no compelling reason to force lenders to undertake large amounts of photocopying for BIA's convenience.

One commenter questioned whether BIA really needs copies of construction contracts and plans and specifications. BIA disagrees. BIA has experience with loans in which the absence of such documents has been disruptive.

One commenter felt that a lender should be given 90 days, not 60, within which to close a loan that BIA has approved under the Program. BIA agrees and correspondingly has changed proposed paragraph (c) of this section, which is paragraph (f) of this section in the final rule.

In addition, due to comments received with respect to proposed §§ 103.12 and 103.26, in the final rule BIA has taken requirements from those locations and placed them in § 103.17, specifically at paragraphs (c) and (d).

Section 103.18 How does BIA issue a loan guaranty certificate or confirm loan insurance? There were no comments on this section.

Section 103.19 When must the lender pay BIA the loan guaranty or insurance premium? One commenter made a comment on this section, then withdrew it.

Subpart C—Interest Subsidy

Section 103.20 What is interest subsidy? BIA received two comments on this section. One commenter asked BIA to adopt Robert Morris Associates as its standard for establishing industry norms for earnings. BIA disagrees. No single private source for such figures covers every circumstance that BIA encounters, and BIA typically avoids tying regulatory requirements to standards that are in the hands of a single private source.

A second commenter wanted BIA to delete the second sentence, effectively throwing interest subsidy open to every eligible borrower, regardless of their projected or historical earnings. BIA disagrees. The purpose and role of interest subsidy has evolved somewhat over the years, but at present policy considerations suggest that it should be available only in the limited circumstances BIA has proposed.

Section 103.21 Who applies for interest subsidy payments, and what is the application procedure? BIA received two comments on this section, one of which was subsequently withdrawn. One comment said that lenders should be required to submit interest subsidy applications at the same time they submit loan guaranty or loan insurance coverage applications. BIA disagrees. Prior regulations contained this requirement, and BIA found it too inflexible to adequately address the legitimate needs of borrowers.

Section 103.22 How does BIA determine the amount of interest subsidy? BIA received two comments on this section. One commenter requested that this section identify a more specific source of the "rate determined by the Secretary of the Treasury in accordance with 25 U.S.C. 1464." BIA disagrees. Periodically issued source documents have been known to change, whereas the underlying statute can be expected to remain more stable. Lenders are of course free at any time to consult BIA on the current source document in use.

Another comment suggested that BIA fix the interest subsidy amount as of the date of BIA approval. BIA agrees, and has modified the section accordingly.

Section 103.23 How does BIA make interest subsidy payments? There were no comments on this section.

Section 103.24 How long will BIA make interest subsidy payments? One commenter suggested that BIA offer interest subsidy payments for three years only, with no extensions. BIA disagrees. Experience shows that in many cases the fourth and fifth years of a loan are the critical years in which a borrower first becomes profitable. Absent interest subsidy payments, some borrowers would not survive to see that happen.

Subpart D—Provisions Relating to Borrowers

Section 103.25 What kind of borrower is eligible under the Program? Three commenters made six comments, two of which were withdrawn. One comment asked BIA to specify that its guaranty would automatically be revoked in the event a borrower's business entity became less than 51 percent Indian-owned. BIA disagrees. While that interpretation may arguably apply to prior regulatory language, BIA specifically intends that the final rule preserve for a lender the option of either pursuing default remedies under the Program, or else ignoring the default (thereby allowing BIA's loan guaranty or insurance to become void) and simply carrying the loan on the lender's books without the benefit of Program coverage. In other words, prior regulatory language suggests that a reduction in the borrower's ownership to less than 51 percent Indian would automatically void BIA's guaranty or insurance of the lender's loan—through no fault of the lender, and without giving the lender any time to react. The new rule at least gives the lender the option of pursuing a claim under its loan guaranty or insurance coverage, should such an event occur.

One comment requested that a lender have at least 45 days within which to exercise its remedies, should there be a default under the 51 percent Indian ownership requirement. BIA disagrees. A default under the 51 percent Indian ownership requirement triggers the same procedures, and the same deadlines, that apply for any other kind of default. See §§ 103.35 and 103.36. Those deadlines already provide 60 days for the lender to notify BIA of the default, and 90 days from the date of the default for the lender to elect a Program remedy.

One comment suggested that BIA define any ineligible businesses there may be, such as business activities involving gaming, currently made ineligible due to BIA policy. BIA disagrees. Policy considerations can change more rapidly than BIA can revise its regulations, and at present there is no other sort of business activity specifically prohibited under the Program.

One comment suggested that, in the event a borrower's business becomes less than 51 percent Indian owned, and the lender decides not to pursue a claim against BIA under the Program, the lender should be required at least to notify BIA of the default under the 51 percent Indian ownership requirement. This notification would permit BIA to remove the loan from its active recordkeeping system. BIA agrees. BIA has not modified this section to reflect the comment, however; it has instead made an addition to § 103.33.

Section 103.26 What must the borrower supply the lender in its loan application? Four commenters made thirteen comments on this section, one of which was subsequently withdrawn. Three comments suggested that a borrower should provide balance sheets and operating statements for the preceding three years, instead of two. BIA agrees, and has made the change in the final rule.

Two comments suggested that a borrower should provide three or more years of financial projections. BIA agrees, and the final rule reflects a requirement of three years.

Four comments pointed out that the borrower was being required to provide appraisals and proof of compliance with applicable law too early in the lending process, and that a borrower could unnecessarily suffer wasted time and expense pursuing these requirements for a loan without even tentative approval from a lender or BIA. BIA agrees. It has changed these requirements into conditions for closing, at § 103.17.

One comment displayed confusion over whether or not the borrower was required to supply the kinds of evidence outlined in proposed § 103.26(l), or whether the items listed at § 103.26(l)(1)–(4) were simply examples, to be used when applicable. BIA has slightly re-worded the language (now moved to § 103.17(d)) to reduce the likelihood of confusion.

One comment suggested that BIA establish standards for appraisals. BIA disagrees. In most cases, existing law or lender policy already establishes adequate appraisal standards, and BIA has no compelling need to add another system of requirements to what already is in place. Any BIA appraisal standards should in any event be designed for applicability far beyond the boundaries of the Program; it would be inappropriate to establish them for use solely within the Program.

One comment suggested that parts of § 103.12 and 103.26 are redundant. BIA agrees, and has removed the principal redundancies. The affected provisions have been combined and added to § 103.17.

Section 103.27 Can the borrower get help preparing its loan application or putting its loan funds to use? There were two comments on this section, both of which suggested revising the procedures for referring borrowers in need of technical assistance. One comment suggested that BIA refer borrowers to tribal business information centers. BIA disagrees. While tribal business information centers may be one potential source of help, they are not uniformly available and may not in some cases be the best available resource.

One comment noted that BIA does not always have technical assistance funding. It suggested revising the proposed regulation to eliminate the inference that BIA is obliged to provide free technical assistance to a borrower, when BIA has no funds for that purpose. BIA agrees, and has removed the last sentence of the proposed section in the final rule.

Changes to proposed §§ 103.17 and 103.26 also necessitated a conforming change in this section.

Subpart E—Loan Transfers

Section 103.28 What if the lender transfers part of the loan to another person? There were three comments on this section. One comment wanted BIA to permit the transfer of insured loans, in addition to guaranteed loans. BIA disagrees, due to the statutory prohibition implied by 25 U.S.C. 1485.

Two comments expressed confusion over transfers brought about through merger, and on the distinction between a lender's right to make new guaranteed loans or insured loans under a loan guaranty agreement or loan insurance agreement, and a lender's right to guarantee or insurance coverage on the asset transferred. BIA has clarified this section and Section 103.29 in response to these comments.

In addition, a comment on § 103.10 caused BIA to insert in this section a requirement that lenders maintain at least a 10 percent ownership interest in loans they maintain under the Program.

Section 103.29 What if the lender transfers the entire loan? BIA received four comments on this section. One comment suggested that BIA restrict transfers to eligible BIA lenders. BIA disagrees. Congress specifically expanded the universe of potential transferees when it enacted the current 25 U.S.C. 1485.

One comment wanted BIA to permit the transfer of insured loans, in addition to guaranteed loans. BIA disagrees, due to the statutory prohibition implied by 25 U.S.C. 1485.

Two comments expressed confusion over transfers brought about through merger, and on the distinction between a lender's right to make new guaranteed loans or insured loans under a loan guaranty agreement or loan insurance agreement, and a lender's right to guarantee or insurance coverage on the asset transferred. BIA has clarified this section and Section 103.28 in response to these comments.

Subpart F—Loan Servicing Requirements

Section 103.30 What standard of care must a lender meet? BIA received two comments on this section. One comment requested deleting the requirement of automatic bank account debiting. BIA disagrees. The requirement is a reasonable and prudent use of modern technology, and in any event is required only when feasible.

One comment suggested an additional place within BIA for recording lien instruments. BIA disagrees. The proposed wording covers all necessary contingencies, and does not require lenders to file any instrument with BIA more than once.

Section 103.31 What loan servicing requirements apply to BIA? BIA received one comment on this section. The commenter suggested deleting proposed paragraph (b), as unnecessary. BIA agrees. It has deleted the paragraph, and correspondingly re-designated the paragraphs of this section in the final rule.

Section 103.32 What sort of loan documentation does BIA expect the lender to maintain? There were no comments on this section.

Section 103.33 Are there reporting requirements? BIA received two comments on this section, one of which was subsequently withdrawn. The other commenter asked to reduce the number of lender's reports to once per annum. BIA disagrees. It needs quarterly updates to prepare accurate reports for the Department of the Treasury.

Also, due to comments received on §§ 103.11 and 103.25, BIA expanded this section to reflect two additional notices that a lender may be obliged to send BIA.

Section 103.34 What if the lender and the borrower decide to change the terms of the loan? There were no comments to this section. However, BIA made a minor change in paragraph (a)(7), to conform with a change in § 103.4.

Subpart G—Default and Payment by BIA

Section 103.35 What must the lender do if the borrower defaults on the loan? Three commenters made four comments on this section, one of which was subsequently withdrawn. One comment suggested a stylistic change in the standard for when a lender is required to send a borrower notice of its default. BIA disagrees, finding its proposed language more appropriate.

One comment wanted BIA to keep its former requirement of having lenders notify BIA of a borrower's default within 45 days. BIA disagrees. BIA has determined that giving lenders an additional 15 days, as in the final rule, can be of significant benefit to lenders without exposing BIA to any significant risk of an overall increase of Program losses.

One comment suggested that BIA accept service by overnight delivery service. BIA agrees, and has changed the final rule accordingly.

Section 103.36 What options and remedies does the lender have if the borrower defaults on the loan? Four commenters made five comments on this section, one of which was subsequently withdrawn. Two comments sought additional time for a lender that elects to negotiate a loan modification agreement with a borrower. BIA agrees in part. Rather than give an automatic 60 days, as one commenter suggested, BIA has added language enabling it to extend the 45 day period specified in the proposed rule.

One comment suggested that BIA accept service by overnight delivery

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service. BIA agrees, and has changed the final rule accordingly.

One comment suggested requiring lenders to liquidate collateral before submitting a claim for loss on a loan guaranty. BIA disagrees. Congress apparently wants lenders to have the option of making an immediate claim for loss without any prior efforts to enforce its other default remedies. See 25 U.S.C. 1491 and 1492.

Section 103.37 What must the lender do to collect payment under its loan guaranty certificate or loan insurance coverage? One commenter made three comments on this section. One comment suggested requiring lenders to submit claims for loss within 45 days of the borrower's default. BIA disagrees. Prior regulations gave the lender 60 days, and several lenders have had trouble complying with Program requirements within even that time period. BIA has determined that extending the required submission date for a claim for loss to 90 days will afford lenders the additional time they sometimes need, without unduly increasing BIA's potential exposure for overall Program losses.

One comment suggested requiring lenders to liquidate collateral before submitting a claim for loss on a loan guaranty. BIA disagrees. Congress apparently wants lenders to have the option of making an immediate claim for loss without any prior efforts to enforce its other default remedies. See 25 U.S.C. 1491 and 1492.

One comment observed an apparent inconsistency between allowing a lender up to 180 days following default to accrue interest while pursuing foreclosure remedies, and laws that require BIA to transfer a debt to the Department of the Treasury once it has been delinquent for 180 days. BIA disagrees. BIA is not obliged to send a debt to the Department of the Treasury until BIA has held the debt for at least 180 days, and in any event it need not forward any debt to Treasury that is in the process of foreclosure.

BIA made a change to paragraph (e) of this section, however, on the basis of a comment to Section 103.38. BIA has introduced a 90 day deadline for rendering a decision on a claim for loss.

Section 103.38 Is there anything else for BIA or the lender to do after BIA makes payment? BIA received two comments on this section, one of which was subsequently withdrawn. One comment asked BIA to adopt a 60 day deadline for making payment on a claim for loss. BIA agrees in part. It has added a 90 day deadline for rendering decision on a claim for loss. The change has been made in § 103.37(e).

Section 103.39 When will BIA refuse to pay all or part of a lender's claim? BIA did not receive any comments on this section.

Section 103.40 Will BIA make exceptions to its criteria for denying payment? BIA did not receive any comments on this section.

Section 103.41 What happens if a lender violates provisions of this part? BIA did not receive any comments on this section.

Section 103.42 How long must a lender comply with Program requirements? One commenter made two comments on this section. One comment suggested that BIA require either a shorter retention period, or else permit electronic data storage. BIA agrees. It has added appropriate language to the final rule.

One comment observed an apparent inconsistency between BIA's reservation of rights and applicable statutes of limitations. BIA disagrees. The final rule does not and cannot supercede Federal statutes of limitations.

Section 103.43 What must the lender do after repayment in full? BIA did not receive any comments on this section.

Subpart H—Definitions and Miscellaneous Provisions

Section 103.44 What certain terms mean in this part. Two commenters made four comments on this section, one of which was subsequently withdrawn. One comment suggested eliminating the phrase "when used as a noun," in the definition of "mortgage." BIA agrees. The change is in the final rule.

One comment suggested further restricting the definition of the word "Tribe" to those tribes recognized by the Federal government as eligible for services from BIA. BIA agrees. The change is in the final rule.

One comment suggested putting the definitions section at the beginning of the rule, rather than at the end. BIA disagrees. Current regulatory drafting theories suggest placing substantive provisions prominently at the beginning of a rule, and leaving reference materials towards the end.

Section 103.45 Information collection. BIA did not receive any comments on this section.

Other changes. In addition to the above comments, the final rule reflects a limited number of non-substantive, stylistic changes from the proposed rule. BIA added these for enhanced clarity, and in the case of a deletion in proposed § 103.30(e), to allow for conformity with another anticipated rulemaking. BIA also made a small number of conforming changes in definitions and paragraph designations, required due to the change, addition, or deletion of rule provisions based on public comments.

Regulatory Planning and Review

This document is not a significant rule and is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866.

This rule will not have an effect of $100 million or more on the economy. Current and foreseeable funding levels for the Program will permit at most $82 million in new loans per annum. The rule will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Program is designed to enhance, not hinder, productivity, competition, jobs, and the overall economy, and there is nothing inherent about the Program or the rule that will lead to adverse effects on the environment, public health or safety, or State, local, or tribal governments or communities.

This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. There is nothing in the rule to limit other efforts to encourage Indian economic development.

This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients. The Program does not create or limit any entitlement, has nothing to do with other grant or loan programs, and establishes no user fees.

This rule does not raise novel legal or policy issues. Part 103 has caused minimal legal review since 1975, and the new rule is in substance very similar to the existing rule.

Regulatory Flexibility Act

DOI certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The number of lenders who might be impacted by the changes in this document is limited by the relatively modest number of individual Indians and organizations of Indians whose loans can be guaranteed or insured under the Program.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of $100 million or more. Current and foreseeable funding levels for the Program will permit at most $82 million in new loans per annum.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The rule is designed to clarify the roles and duties of the persons it may impact, and should in fact result in administrative savings. Any additional requirements imposed by the rule are either very limited in scope, or else in the nature of assembling information that lenders typically gather anyway.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. To the contrary, the rule implements the Program in order to encourage investment in new Indian businesses, and thereby increase U.S.-based competition, employment, productivity, and innovation.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. It does not impose any mandates at all. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. Only a small segment of the private sector—the lending community—is directly affected by the rule, and the rule (1) is functionally very similar to existing law, and (2) relates to a Program that will permit at most $82 million in new loans per annum, based on current and foreseeable funding levels. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531, *et seq.*) is not required.

Takings

In accordance with Executive Order 12630, the rule does not have significant takings implications. The Program enhances the security available to lenders, and does not inherently involve any action that could deprive anyone of property without just compensation. A takings implication assessment is not required.

Federalism

In accordance with Executive Order 13132, this rule does not have federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State governments. The rule is directed at the relationship between lenders and the Federal Government, and does not impact States at all. This rule does not impose costs on States or localities, for the same reason.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

The Office of Management and Budget has reviewed and approved the information collections contained in this rule and assigned them number 1076–0020. The proposed rule was published on September 6, 2000 (65 FR 53948) and solicited comments on the information collection. OMB expressed no concerns with the information collection, and no comments were received from the public.

The information collection is required to obtain or retain a benefit. Information covered by the Privacy Act will be kept confidential as required by law. Please note that a Federal agency may not collect or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 is not required.

List of Subjects in 25 CFR Part 103

Indians—Insurance, Interest subsidy, and Loan guaranty.

For the reasons given in the preamble, BIA is revising part 103 in chapter I of title 25 of the Code of Federal Regulations as set forth below.

PART 103—LOAN GUARANTY, INSURANCE, AND INTEREST SUBSIDY

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103.40 Will BIA make exceptions to its criteria for denying payment?
103.41 What happens if a lender violates provisions of this part?
103.42 How long must a lender comply with Program requirements?
103.43 What must the lender do after repayment in full?

Subpart H—Definitions and Miscellaneous Provisions

103.44 What certain terms mean in this part.
103.45 Information collection.

Authority: 25 U.S.C. 1498, 1511.

Subpart A—General Provisions

§ 103.1 What does this part do?

This part explains how to obtain and use a BIA loan guaranty or loan insurance agreement under the Program, and who may do so. It also describes how to obtain and use interest subsidy payments under the Program, and who may do so.

§ 103.2 Who does the Program help?

The purpose of the Program is to encourage eligible borrowers to develop viable Indian businesses through conventional lender financing. The direct function of the Program is to help lenders reduce excessive risks on loans they make. That function in turn helps borrowers secure conventional financing that might otherwise be unavailable.

§ 103.3 Who administers the Program?

Authority for administering the Program ultimately rests with the Secretary, who may exercise that authority directly at any time. Absent a direct exercise of authority, however, the Secretary delegates Program authority to BIA officials through the U.S. Department of Interior Departmental Manual. A lender should submit all applications and correspondence to the BIA office serving the borrower's location.

§ 103.4 What kinds of loans will BIA guarantee or insure?

In general, BIA may guarantee or insure any loan made by an eligible lender to an eligible borrower to conduct a lawful business organized for profit. There are several important exceptions:

(a) The business must contribute to the economy of an Indian reservation or tribal service area recognized by BIA;

(b) The borrower may not use the loan for relending purposes;

(c) If any portion of the loan is used to refinance an existing loan, the borrower must be current on the existing loan; and

(d) BIA may not guarantee or insure a loan if it believes the lender would be willing to extend the requested financing without a BIA guaranty or insurance coverage.

§ 103.5 What size loan will BIA guarantee or insure?

BIA can guarantee or insure a loan or combination of loans of up to $500,000 for an individual Indian, or more for an acceptable Indian business entity, Tribe, or tribal enterprise involving two or more persons. No individual Indian may have an outstanding principal balance of more than $500,000 in guaranteed or insured loans at any time. BIA can limit the size of loans it will guarantee or insure, depending on the resources BIA has available.

§ 103.6 To what extent will BIA guarantee or insure a loan?

(a) BIA can guarantee up to 90 percent of the unpaid principal and accrued interest due on a loan.

(b) BIA can insure up to the lesser of:

(1) 90 percent of the unpaid principal and accrued interest due on a loan; or

(2) 15 percent of the aggregate outstanding principal amount of all loans the lender has insured under the Program as of the date the lender makes a claim under its insurance coverage.

(c) BIA's guaranty certificate or loan insurance agreement should reflect the lowest guaranty or insurance percentage rate that satisfies the lender's risk management requirements.

(d) Absent exceptional circumstances, BIA will allow no more than:

(1) Two simultaneous guarantees under the Program covering outstanding loans from the same lender to the same borrower; or

(2) One loan guaranty under the Program when the lender simultaneously has one or more outstanding loans insured under the Program to the same borrower.

§ 103.7 Must the borrower have equity in the business being financed?

The borrower must be projected to have at least 20 percent equity in the business being financed, immediately after the loan is funded. If a substantial portion of the loan is for construction or renovation, the borrower's equity may be calculated based upon the reasonable estimated value of the borrower's assets after completion of the construction or renovation.

§ 103.8 Is there any cost for a BIA guaranty or insurance coverage?

BIA charges the lender a premium for a guaranty or insurance coverage.

(a) The premium is:

(1) Two percent of the portion of the original loan principal amount that BIA guarantees; or

(2) One percent of the portion of the original loan principal amount that BIA insures, without considering the 15 percent aggregate outstanding principal limitation on the lender's insured loans.

(b) Lenders may pass the cost of the premium on to the borrower, either by charging a one-time fee or by adding the cost to the principal amount of the borrower's loan. Adding the premium to the principal amount of the loan will not make any further premium due. BIA will guarantee or insure the additional principal to the same extent as the original approved principal amount.

Subpart B—How a Lender Obtains a Loan Guaranty or Insurance Coverage

§ 103.9 Who applies to BIA under the Program?

The lender is responsible for determining whether it will require a BIA guaranty or insurance coverage, based upon the loan application it receives from an eligible borrower. If the lender requires a BIA guaranty or insurance coverage, the lender is responsible for completing and submitting a guaranty application or complying with a loan insurance agreement under the Program.

§ 103.10 What lenders are eligible under the Program?

(a) Except as specified in paragraph (b) of this section, a lender is eligible under the Program, and may be considered for BIA approval, if the lender is:

(1) Regularly engaged in the business of making loans;

(2) Capable of evaluating and servicing loans in accordance with reasonable and prudent industry standards; and

(3) Otherwise reasonably acceptable to BIA.

(b) The following lenders are not qualified to issue loans under the Program:

(1) An agency or instrumentality of the Federal Government;

(2) A lender that borrows money from any Federal Government source, other than the Federal Reserve Bank System, for purposes of relending;

(3) A lender that does not include the interest on loans it makes in gross income, for purposes of chapter 1, title 26 of the United States Code; and

(4) A lender that does not keep any ownership interest in loans it originates.

§ 103.11 How does BIA approve lenders for the Program?

(a) BIA approves each lender by entering into a loan guaranty agreement and/or a loan insurance agreement with it. BIA may provide up to three different levels of approval for a lender making guaranteed loans, depending on factors such as:

(1) The number of loans the lender makes under the Program;

(2) The total principal balance of the lender's Program loans;

(3) The number of years the lender has been involved with the Program;

(4) The relative benefits and opportunities the lender has given to Indian business efforts through the Program; and

(5) The lender's historical compliance with Program requirements.

(b) BIA will consider a lender's loan guaranty agreement and/or loan insurance agreement suspended as of:

(1) The effective date of a change in the lender's corporate structure;

(2) The effective date of a merger between the lender and any other entity, when the lender is not the surviving entity; or

(3) The start of any legal proceeding in which substantially all of the lender's assets may be subject to disposition through laws governing bankruptcy, insolvency, or receivership.

(c) A change in a lender's name, without any other change specified under paragraph (b) of this section, will not cause a suspension of the lender's loan guaranty agreement and/or loan insurance agreement. The lender should notify BIA of its name change as soon as possible.

(d) If a lender's loan guaranty agreement and/or loan insurance agreement is suspended under paragraph (b) of this section, the lender, or its successor in interest, must enter into a new loan guaranty agreement and/or loan insurance agreement with BIA in order to secure any new BIA loan guarantees or insurance coverage.

(e) The suspension of a loan guaranty agreement and/or loan insurance agreement does not affect the validity of any guaranty certificate or insurance coverage in effect before the date of the suspension. Any such certificate or insurance coverage will remain governed by applicable terms of the suspended loan guaranty agreement and/or loan insurance agreement.

§ 103.12 How does a lender apply for a loan guaranty?

To apply for a loan guaranty, a BIA-approved lender must submit to BIA a loan guaranty application request form, together with each of the following:

(a) A written explanation from the lender indicating why it needs a BIA guaranty for the loan, and the minimum loan guarantee percentage it will accept;

(b) A copy of the borrower's complete loan application;

(c) A description of the borrower's equity in the business being financed;

(d) A copy of the lender's independent credit analysis of the borrower's business, repayment ability, and loan collateral (including insurance);

(e) An original report from a nationally-recognized credit bureau, dated within 90 days of the date of the lender's loan guaranty application package, outlining the credit history of the borrower, and to the extent permitted by law, each co-maker or guarantor of the loan (if any);

(f) A copy of the lender's loan commitment letter to the borrower, showing at a minimum the proposed loan amount, purpose, interest rate, schedule of payments, and security (including insurance requirements), and the lender's terms and conditions for funding;

(g) The lender's good faith estimate of any loan-related fees and costs it will charge the borrower, as authorized under this part;

(h) If any significant portion of the loan will be used to finance construction, renovation, or demolition work, the lender's:

(1) Insurance and bonding requirements for the work;

(2) Proposed draw requirements; and

(3) Proposed work inspection procedures;

(i) If any significant portion of the loan will be used to refinance or otherwise retire existing indebtedness:

(1) A clear description of all loans being paid off, including the names of all makers, cosigners and guarantors, maturity dates, payment schedules, uncured delinquencies, collateral, and payoff amounts as of a specific date; and

(2) A comparison of the terms of the loan or loans being paid off and the terms of the new loan, identifying the advantages of the new loan over the loan being paid off.

§ 103.13 How does a lender apply for loan insurance coverage?

BIA-approved lenders can make loans insured under the Program in two ways, depending on the size of the loan:

(a) For loans in an original principal amount of up to $100,000 per borrower, the lender can make each loan in accordance with the lender's loan insurance agreement, without specific prior approval from BIA.

(b) For loans in an original principal amount of over $100,000, the lender must seek BIA's specific prior approval in each case. The lender must submit a loan insurance coverage application request form, together with the same information required for a loan guaranty under § 103.12, except for the information required by § 103.12(a).

(c) The lender must submit a loan insurance application package even for a loan of less than $100,000 if:

(1) The total outstanding balance of all insured loans the lender is extending to the borrower under the Program exceeds $100,000; or

(2) the lender makes a request for interest subsidy, pursuant to § 103.21.

§ 103.14 Can BIA request additional information?

BIA may require the lender to provide additional information, whenever BIA believes it needs the information to properly evaluate a new lender, guaranty application, or insurance application. After BIA issues a loan guaranty or insurance coverage, the lender must let BIA inspect the lender's records at any reasonable time for information concerning the Program.

§ 103.15 Are there any prohibited loan terms?

A loan agreement guaranteed or insured under the Program may not contain:

(a) Charges by the lender styled as "points," loan origination fees, or any similar fees (however named), except that if authorized in the loan agreement, the lender may charge the borrower a reasonable annual loan servicing fee that:

(1) Is not included as part of the loan principal; and

(2) Does not bear interest;

(b) Charges of any kind by the lender or by any third party except for the reasonable and customary cost of legal and architectural services, broker commissions, surveys, compliance inspections, title inspection and/or insurance, lien searches, appraisals, recording costs, premiums for required hazard, liability, key man life, and other kinds of insurance, and such other charges as BIA may approve in writing;

(c) A loan repayment term of over 30 years;

(d) Payments scheduled less frequently than annually;

(e) A prepayment penalty, unless the terms of the penalty are clearly specified in BIA's loan guaranty or loan insurance conditions;

(f) An interest rate greater than what BIA considers reasonable, taking into account the range of rates prevailing in the private market for similar loans;

(g) A variable interest rate, unless the rate is tied to a specific prime rate

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published from time to time by a nationally recognized financial institution or news source;

(h) An increased rate of interest based on default;

(i) A fee imposed for the late repayment of any installment due, except for a late fee that:

(1) Is imposed only after the borrower is at least 30 days late with payment;

(2) Does not bear interest; and

(3) Equals no more than 5 percent of the late installment;

(j) An "insecurity" clause, or any similar provision permitting the lender to declare a loan default solely on the basis of its subjective view of the borrower's changed repayment prospects;

(k) A requirement that the borrower take title to any real or personal property purchased with loan proceeds by a title instrument containing restrictions on alienation, control or use of the property, unless otherwise required by applicable law; or

(l) A requirement that a borrower which is a tribe provide as security a general assignment of the tribe's trust income. If otherwise lawful, a tribe may provide as loan security an assignment of trust income from a specific source.

§ 103.16 How does BIA approve or reject a loan guaranty or insurance application?

(a) BIA reviews each guaranty or insurance application, and may evaluate each loan application independently from the lender. BIA bases its loan guaranty or insurance decisions on many factors, including compliance with this part, and whether there is a reasonable prospect of loan repayment from business cash flow, or if necessary, from liquidating loan collateral. Lenders are expected to obtain a first lien security interest in enough collateral to reasonably secure repayment of each loan guaranteed or insured under the Program, to the extent that collateral is available.

(b) BIA approves applications by issuing an approval letter, followed by the procedures in § 103.18. If the guaranty or insurance application is incomplete, BIA may return the application to the lender, or hold the application while the lender submits the missing information. If BIA denies the application, it will provide the lender with a written explanation, with a copy to the borrower.

§ 103.17 Must the lender follow any special procedures to close the loan?

(a) BIA officials or their representatives may attend the closing of any loan or loan modification that BIA agrees to guarantee or insure. For guaranteed loans, and insured loans that BIA must individually review under this part, the lender must give BIA notice of the date of closing at least 5 business days before closing occurs.

(b) At or prior to closing, the lender must obtain appropriate, satisfactory title and/or lien searches for each asset to be used as loan collateral.

(c) At or prior to closing, the lender must obtain recent appraisals for all real property and improvements to be used as collateral for the loan, to the extent required by law.

(d) At or prior to closing, the lender must document that the lender and borrower have complied with all applicable Federal, State, local, and tribal laws implicated by financing the borrower's business, for example by securing:

(1) Copies of all permits and licenses required to operate the borrower's business;

(2) Environmental studies required for construction and/or business operations under NEPA and other environmental laws;

(3) Archeological or historical studies required by law; and

(4) Certification by a registered surveyor or appropriate BIA official indicating that the proposed business will not be located in a special flood hazard area, as defined by applicable law.

(e) The lender must supply BIA with copies of all final, signed loan closing documents within 30 days following closing. To the extent applicable, loan closing documents must include the following:

(1) Promissory notes;

(2) Security agreements, including pledge and similar agreements, and related financing statements (together with BIA's written approval of any assignment of specific tribal trust assets under § 103.15(l), or of any security interest in an individual Indian money account);

(3) Mortgage instruments or deeds of trust (together with BIA's written approval, if required by 25 U.S.C. 483a, or if the mortgage is of a leasehold interest in tribal trust property);

(4) Guarantees (other than from BIA);

(5) Construction contracts, and plans and specifications;

(6) Leases related to the business (together with BIA's written approval, if required under 25 CFR part 162);

(7) Attorney opinion letters;

(8) Resolutions made by a Tribe or business entity;

(9) Waivers or partial waivers of sovereign immunity; and

(10) Similar instruments designed to document the loan, establish the basis for a security interest in loan collateral, and comply with applicable law.

(f) Unless BIA indicates otherwise in writing, the lender must close a guaranteed or insured loan within 90 days of any approval provided under § 103.16.

§ 103.18 How does BIA issue a loan guaranty or confirm loan insurance?

(a) A loan is guaranteed under the Program when all of the following occur:

(1) BIA issues a signed loan guaranty certificate bearing a series number, an authorized signature, a guaranty percentage rate, the lender's name, the borrower's name, the original principal amount of the loan, and such other terms and conditions as BIA may require;

(2) The loan closes and funds;

(3) The lender pays BIA the applicable loan guaranty premium; and

(4) The lender meets all of the conditions listed in the loan guaranty certificate.

(b) A loan is insured under the Program when all of the following occur:

(1) The loan's purpose and terms meet the requirements of the Program and the lender's loan insurance agreement with BIA;

(2) The loan closes and funds;

(3) The lender notifies BIA of the borrower's identity and organizational structure, the amount of the loan, the interest rate, the payment schedule, and the date on which the loan closing and funding occurred;

(4) The lender pays BIA the applicable loan insurance premium;

(5) If over $100,000 or if the loan requires interest subsidy, BIA approves the loan in writing; and

(6) If over $100,000 or if the loan requires interest subsidy, the lender meets all of the conditions listed in BIA's written loan approval.

§ 103.19 When must the lender pay BIA the loan guaranty or insurance premium?

The premium is due within 30 calendar days of the loan closing. If not paid on time, BIA will send the lender written notice by certified mail (return receipt requested), or by a nationally-recognized overnight delivery service (signature of recipient required), stating that the premium is due immediately. If the lender fails to make the premium payment within 30 calendar days of the date of BIA's notice, BIA's guaranty certificate or insurance coverage with respect to that particular loan is void, without further action.

Subpart C—Interest Subsidy

§ 103.20 What is interest subsidy?

Interest subsidy is a payment BIA makes for the benefit of the borrower, to reimburse part of the interest payments the borrower has made on a loan guaranteed or insured under the Program. It is available to borrowers whose projected or historical earnings before interest and taxes, after adjustment for extraordinary items, is less than the industry norm.

§ 103.21 Who applies for interest subsidy payments, and what is the application procedure?

(a) An eligible lender must request interest subsidy payments on behalf of an eligible borrower, after determining that the borrower qualifies. Typically, the lender should include a request for interest subsidy at the time it applies for a guaranty or insurance coverage under the Program. A request for interest subsidy must be supported by the information required in §§ 103.12 and 103.13 (relating to loan guaranty and insurance coverage applications). BIA approves, returns, or rejects interest subsidy requests in the same manner indicated in § 103.16, based on the factors in § 103.20 and BIA's available resources.

(b) BIA's approval of interest subsidy for an insured loan may provide for specific limitations on the manner in which the lender and borrower can modify the loan.

§ 103.22 How does BIA determine the amount of interest subsidy?

Interest subsidy payments should equal the difference between the lender's rate of interest and the rate determined by the Secretary of the Treasury in accordance with 25 U.S.C. 1464. BIA will fix the amount of interest subsidy as of the date it approves the interest subsidy request.

§ 103.23 How does BIA make interest subsidy payments?

The lender must send BIA reports at least quarterly on the borrower's loan payment history, together with a calculation of the interest subsidy then due. The lender's reports and calculation do not have to be in any specific format, but in addition to the calculation the reports must contain at least the information required by § 103.33(a). Based on the lender's reports and calculation, BIA will send interest subsidy payments to the borrower in care of the lender. The payments belong to the borrower, but the borrower and lender may agree in advance on how the borrower will use interest subsidy payments. BIA may verify and correct interest subsidy calculations and payments at any time.

§ 103.24 How long will BIA make interest subsidy payments?

(a) BIA will issue interest subsidy payments for the term of the loan, up to 3 years. If interest subsidy payments still are justified, the lender may apply for up to two 1-year extensions of this initial term. BIA will make interest subsidy payments on a single loan for no more than 5 years.

(b) BIA will choose the date from which it calculates interest subsidy years, usually the date the lender first extends the loan funds. Interest subsidy payments will apply to all loan payments made in the calendar years following that date.

(c) Interest subsidy payments will not be due for any loan payment made after the corresponding loan guaranty or insurance coverage stops under the Program, regardless of the circumstances.

Subpart D—Provisions Relating to Borrowers

§ 103.25 What kind of borrower is eligible under the Program?

(b) A borrower is eligible for a BIA-guaranteed or insured loan if the borrower is:

(1) An Indian individual;

(2) An Indian-owned business entity organized under Federal, State, or tribal law, with an organizational structure reasonably acceptable to BIA;

(3) A tribe; or

(4) A business enterprise established and recognized by a tribe.

(b) To be eligible for a BIA-guaranteed or insured loan, a business entity or tribal enterprise must be at least 51 percent owned by Indians. If at any time a business entity or tribal enterprise becomes less than 51 percent Indian owned, the lender either may declare a default as of the date the borrower stopped being at least 51 percent Indian owned and exercise its remedies under this part, or else continue to extend the loan to the borrower and allow BIA's guaranty or insurance coverage to become invalid.

§ 103.26 What must the borrower supply the lender in its loan application?

The lender may use any form of loan application it chooses. However, the borrower must supply the lender the information listed in this section in order for BIA to process a guaranty or insurance coverage application:

(a) The borrower's precise legal name, address, and tax identification number or social security number;

(b) Proof of the borrower's eligibility under the Program;

(c) A statement signed by the borrower, indicating that it is not delinquent on any Federal tax or other debt obligation;

(d) The borrower's business plan, including resumes of all principals and a detailed discussion of the product or service to be offered, market factors, the borrower's marketing strategy, and any technical assistance the borrower may require;

(e) A detailed description of the borrower's equity in the business being financed, including the method(s) of valuation;

(f) The borrower's balance sheets and operating statements for the preceding 3 years, or so much of that period that the borrower has been in business;

(g) The borrower's current financial statement, and the financial statements of all co-makers and guarantors of the loan (other than BIA);

(h) At least 3 years of financial projections for the borrower's business, consisting of pro-forma balance sheets, operating statements, and cash flow statements;

(i) A detailed list of all proposed collateral for the loan, including asset values and the method(s) of valuation;

(j) A detailed list of all proposed hazard, liability, key man life, and other kinds of insurance the borrower will maintain on its business assets and operations;

(k) If any significant portion of the loan will be used to finance construction, renovation, or demolition work:

(1) Written quotes for the work from established and reputable contractors; and

(2) To the extent available, copies of all construction and architectural contracts for the work, plans and specifications, and applicable building permits;

(l) If the borrower is a tribe or a tribal enterprise, resolutions by the tribe and proof of authority under tribal law permitting the borrower to borrow the loan amount and offer the proposed loan collateral; and

(m) If the borrower is a business entity, resolutions by the appropriate governing officials and proof of authority under its organizing documents permitting the borrower to borrow the loan amount and offer the proposed loan collateral.

§ 103.27 Can the borrower get help preparing its loan application or putting its loan funds to use?

A borrower may seek BIA's assistance when preparing a loan application or

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when planning business operations, including assistance identifying and complying with applicable laws as indicated by § 103.17(d). The borrower should contact the BIA field or agency office serving the area in which the borrower's business is to be located, or if there is no separate field or agency office serving the area, then the borrower should contact the BIA regional office serving the area.

Subpart E—Loan Transfers

§ 103.28 What if the lender transfers part of the loan to another person?

(a) A lender may transfer one or more interests in a guaranteed loan to another person or persons, as long as the parties have in place an agreement that designates one person to perform all of the duties required of the lender under the Program and the loan guaranty certificate. Starting on the date of the transfer, only the person designated to perform the duties of the lender will be entitled to exercise the rights conferred by BIA's loan guaranty certificate, and will from that point forward be considered the lender for purposes of the Program. A lender under the Program must both service the guaranteed loan and own at least a 10 percent interest in the guaranteed loan. BIA will not consider more than one person at any given time to be the lender with respect to any loan guaranty certificate. If the person designated to perform the duties of the lender in an agreement among loan participants is not the original lender, then the provisions of § 103.29(a) will apply (relating to sale or assignment of guaranteed loans), and the person designated to perform the duties of the lender must give BIA notice of its interest in the loan. Failure to provide notice in accordance with § 103.29(a) will void BIA's loan guaranty certificate, without further action.

(b) Transferring any interest in an insured loan to another person will void the insurance coverage for that loan, except where the transfer is effected by a merger.

§ 103.29 What if the lender transfers the entire loan?

(a) A lender may transfer all of its rights in a guaranteed loan to any other person. The acquiring person must send BIA written notice of the transfer, describing the borrower, the loan, BIA's loan guaranty certificate number, and the acquiring person's name and address. Starting on the date of the transfer, only the acquiring person will be entitled to exercise the rights conferred by BIA's loan guaranty certificate, and will from that point forward be considered the lender for purposes of the Program. The acquiring person must service the guaranteed loan and otherwise perform all of the duties required of the lender under the Program and the loan guaranty certificate. Except when a transfer is effected by a merger, any failure by the acquiring person to send BIA proper notice of the transfer within 30 calendar days of the transfer date will void BIA's loan guaranty certificate, without further action.

(b) Transferring an insured loan to another person will void the insurance coverage for that loan, except where the transfer is effected by a merger.

(c) If a lender is not the surviving entity after a merger, the lender's successor must notify BIA in writing of the change within 30 calendar days of the merger. The lender also must re-apply to become an approved lender under the Program, as indicated in § 103.11.

Subpart F—Loan Servicing Requirements

§ 103.30 What standard of care must a lender meet?

Lenders must service all loans guaranteed or insured under the Program in a commercially reasonable manner, in accordance with standards and procedures adopted by prudent lenders in the BIA region in which the borrower's business is located, and in accordance with this part. If the lender fails to follow any of these standards, BIA may reduce or eliminate entirely the amount payable under its guaranty or insurance coverage to the extent BIA can reasonably attribute the loss to the lender's failure. BIA also may deny payment completely if the lender gets a loan guaranty or insurance coverage through fraud, or negligently allows a borrower's fraudulent loan application or use of loan funds to go undetected. In particular, and without limitation, lenders must:

(a) Check and verify information contained in the borrower's loan application, such as the borrower's eligibility, the authority of persons acting on behalf of the borrower, and the title status of any proposed collateral;

(b) Take reasonable precautions to assure that loan proceeds are used as specified in BIA's guaranty certificate or written insurance approval, or if not so specified, then in descending order of importance:

(1) BIA's written loan guaranty approval;

(2) The loan documents;

(3) The terms of the lender's final loan commitment to the borrower; or

(4) The borrower's loan application;

(c) When feasible, require the borrower to use automatic bank account debiting to make loan payments;

(d) Require the borrower to take title to real and personal property purchased with loan proceeds in the borrower's own name, except for real property to be held in trust by the United States for the benefit of a borrower that is a tribe;

(e) Promptly record all security interests and subsequently keep them in effect. Lenders must record all mortgages and other security interests in accordance with State and local law, including the laws of any tribe that may have jurisdiction. Lenders also must record any leasehold mortgages or assignments of income involving individual Indian or tribal trust land with the BIA office having responsibility for maintaining records on that trust land;

(f) Assure, to the extent reasonably practicable, that the borrower and any guarantor of the loan (other than BIA) keep current on all taxes levied on real and personal property used in the borrower's business or as collateral for the loan, and on all applicable payroll taxes;

(g) Assure, to the extent reasonably practicable, that all required insurance policies remain in effect, including hazard, liability, key man life, and other kinds of insurance, in amounts reasonably necessary to protect the interests of the borrower, the borrower's business, and the lender;

(h) Assure, to the extent reasonably practicable, that the borrower remains in compliance with all applicable Federal, State, local and tribal laws, including environmental laws and laws concerning the preservation of historical and archeological sites and data;

(i) Assure, to the extent reasonably practicable, that the borrower causes any construction, renovation, or demolition work funded by the loan to proceed in accordance with approved construction contracts and plans and specifications, which must be sufficient in scope and detail to adequately govern the work;

(j) Reserve for itself and BIA the right to inspect the borrower's business records and all loan collateral at any reasonable time;

(k) Promptly notify the borrower in writing of any material breach by the borrower of the terms of its loan, with specific instructions on how to cure the breach and a deadline for doing so;

(l) Participate in any probate, receivership, bankruptcy, or similar proceeding involving the borrower and any guarantor or co-maker of the borrower's debt, to the extent necessary to maintain the greatest possible rights to repayment; and

(m) Otherwise seek to avoid and mitigate any potential loss arising from the loan, using at least that level of care the lender would use if it did not have a BIA loan guaranty or insurance coverage.

§ 103.31 What loan servicing requirements apply to BIA?

Once a lender extends a loan that is guaranteed or insured under the Program, BIA has no responsibility for decisions concerning it, except for:

(a) Any approvals required under this part;

(b) Any decisions reserved to BIA under conditions of BIA's guaranty certificate or insurance coverage; and

(c) Decisions concerning a loan that the lender has assigned to BIA or to which BIA is subrogated by virtue of paying a claim based on a guaranty certificate or insurance coverage.

§ 103.32 What sort of loan documentation does BIA expect the lender to maintain?

For every loan guaranteed or insured under the Program, the lender must maintain:

(a) BIA's original loan guaranty certificate or insurance coverage approval letter, if applicable;

(b) Original signed and/or certified counterparts of all final loan documents, including those listed in § 103.17 (concerning documents required for loan closing), all renewals, modifications, and additions to those documents, and signed settlement statements;

(c) Originals or copies, as appropriate, of all documents gathered by the lender under §§ 103.12, 103.13 and 103.26 (concerning information submitted by the borrower in its loan application, and information supplied to BIA in the lender's loan guaranty or insurance coverage application);

(d) Originals or copies, as appropriate, of all applicable insurance binders or certificates, including without limitation hazard, liability, key man life, and title insurance;

(e) A complete and current history of all loan transactions, including dated disbursements, payments, adjustments, and notes describing all contacts with the borrower;

(f) Originals or copies, as appropriate, of all correspondence with the borrower, including default notices and evidence of receipt;

(g) Originals or copies, as appropriate, of all correspondence, notices, news items or other information concerning the borrower, whether gathered by the lender or furnished to it, containing material information about the borrower and its business operations;

(h) Originals or copies, as appropriate, of all advertisements, notices, title instruments, accountings, and other documentation of efforts to liquidate loan collateral; and

(i) Originals or copies, as appropriate, of all notices, pleadings, motions, orders, and other documents associated with any legal proceeding involving the lender and the borrower or its assets, including without limitation judicial or non-judicial foreclosure proceedings, suits to collect payment, bankruptcy proceedings, probate proceedings, and any settlement associated with threatened or actual litigation.

§ 103.33 Are there reporting requirements?

(a) The lender must periodically report the borrower's loan payment history so that BIA can recalculate the government's contingent liability. Loan payment history reports must be quarterly unless BIA provides otherwise for a particular loan. These reports can be in any format the lender desires, as long as they contain:

(1) The lender's name;

(2) The borrower's name;

(3) A reference to BIA's Loan Guaranty Certificate or Loan Insurance Agreement number;

(4) The lender's internal loan number; and

(5) The date and amount of all loan balance activity for the reporting period.

(b) If applicable, the lender must supply a calculation of any interest subsidy payments that are due, as indicated in § 103.23.

(c) If there is a transfer of any or all of the lender's ownership interest in the loan, the party receiving the ownership interest may be required to notify BIA, as indicated in §§ 103.28 and 103.29.

(d) If there is a default on the loan, the lender must notify BIA, as indicated in §§ 103.35 and 103.36.

(e) If the borrower ceases to qualify for a BIA-guaranteed or insured loan under § 103.25(b), the lender must promptly notify BIA even if the lender does not pursue default remedies under §§ 103.35 and 103.36. This notice allows BIA to eliminate the guaranty or insurance coverage from its active recordkeeping system.

(f) If the loan is prepaid in full, the lender must promptly notify BIA in writing so that BIA can eliminate the guaranty or insurance coverage from its active recordkeeping system.

(g) If a lender changes its name, it should notify BIA in accordance with § 103.11(c).

§ 103.34 What if the lender and borrower decide to change the terms of the loan?

(a) The lender must obtain written BIA approval before modifying a loan guaranteed or insured under the Program, if the change will:

(1) Increase the borrower's outstanding principal amount (if a term loan), or maximum available credit (if a revolving loan).

(i) BIA will approve or disapprove a loan increase based upon the lender's explanation of the borrower's need for additional funding, and updated information of the sort required under §§ 103.12, 103.13, and 103.26, as applicable.

(ii) Upon approval by BIA and payment of an additional guaranty or insurance premium in accordance with §§ 103.8 and 103.19 and this section, the entire outstanding loan amount, as modified, will be guaranteed or insured (as the case may be) to the extent BIA specifies. The lender must pay the additional premium only on the increase in the outstanding principal amount of the loan (if a term loan) or the increase in the credit limit available to the borrower (if a revolving loan).

(iii) Lenders may not increase the outstanding principal amount of a loan guaranteed or insured under the Program if a significant purpose of doing so would be to allow the borrower to pay accrued loan interest it otherwise would have difficulty paying.

(2) Permanently adjust the loan repayment schedule.

(3) Increase a fixed interest rate, convert a fixed interest rate to an adjustable interest rate, or convert an adjustable interest rate to a fixed interest rate.

(4) Allow any changes in the identity or organizational structure of the borrower.

(5) Allow any material change in the use of loan proceeds or the nature of the borrower's business.

(6) Release any collateral taken as security for the loan, except items sold in the ordinary course of business and promptly replaced by similar items of collateral, such as inventory.

(7) Allow the borrower to move any significant portion of its business operations to a location that is not on or near an Indian reservation or tribal service area recognized by BIA.

(8) Be likely to materially increase the risk of a claim on BIA's guaranty or insurance coverage, or materially reduce the aggregate value of the collateral securing the loan.

(9) Cure a default for which BIA is to receive notice under § 103.35(b).

(b) In the case of an insured loan, the amount of which will not exceed

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$100,000 when combined with all other insured loans from the lender to the borrower, the lender need not obtain BIA's prior approval to make any of the loan modifications indicated in § 103.34(a), except as provided in § 103.21(b). However, all loan modifications must remain consistent with the lender's loan insurance agreement with BIA, and in the event of an increase in the borrower's outstanding principal amount (if a term loan), or maximum available credit (if a revolving loan), the lender must send BIA an additional premium payment in accordance with §§ 103.8, 103.19 and this section. The lender must pay the additional premium only on the increase in the outstanding principal amount of the loan (if a term loan) or the increase in the credit limit available to the borrower (if a revolving loan). To the extent a loan modification changes any of the information supplied to BIA under § 103.18(b)(3), the lender also must promptly notify BIA of the new information.

(c) Subject to any applicable BIA loan guaranty or insurance coverage conditions, a lender may extend additional loans to a borrower without BIA approval, if the additional loans are not to be guaranteed or insured under the Program.

Subpart G—Default and Payment by BIA

§ 103.35 What must the lender do if the borrower defaults on the loan?

(a) The lender must send written notice of the default to the borrower, and otherwise meet the standard of care established for the lender in this part. The lender's notice to the borrower should be sent as soon as possible after the default, but in any event before the lender's notice to BIA under paragraph (b) of this section. For purposes of the Program, "default" will mean a default as defined in this part.

(b) The lender also must send written notice of the default to BIA by certified mail (return receipt requested), or by a nationally-recognized overnight delivery service (signature of recipient required) within 60 calendar days of the default, unless the default is fully cured before that deadline. This notice is required even if the lender grants the borrower a forbearance under § 103.36(a). One purpose of the notice is to give BIA the opportunity to intervene and seek assistance for the borrower, even though BIA has no duty, either to the lender or the borrower, to do so. Another purpose of the notice is to permit BIA to plan for a possible loss claim from the lender, under § 103.36(d). The lender's notice must clearly indicate:

(1) The identity of the borrower;

(2) The applicable Program guaranty certificate or insurance agreement number;

(3) The date and nature of all bases for default;

(4) If a monetary default, the amount of past due principal and interest, the date through which interest has been calculated, and the amount of any late fees, precautionary advances, or other amounts the lender claims;

(5) The nature and outcome of any correspondence or other contacts with the borrower concerning the default; and

(6) The precise nature of any action the borrower could take to cure the default.

§ 103.36 What options and remedies does the lender have if the borrower defaults on the loan?

(a) The lender may grant the borrower a temporary forbearance, even beyond any default cure periods specified in the loan documents, if doing so is likely to result in the borrower curing the default. However, BIA must approve in writing any forbearance or other agreement that:

(1) Permanently modifies the terms of the loan in any manner indicated by § 103.34(a);

(2) Would allow the borrower's default to extend beyond the deadline established in § 103.36(d) for the lender to elect a remedy; or

(3) Is not likely to result in the borrower curing the default.

(b) The lender may make precautionary advances on the borrower's behalf during the default, if doing so is reasonably necessary to ensure that loan recovery prospects do not significantly deteriorate. Items for which the lender may make precautionary advances include, for example:

(1) Hazard, liability, or key man life insurance premiums;

(2) Security measures to safeguard abandoned business assets;

(3) Real or personal property taxes;

(4) Corrective actions required by court or administrative orders; or

(5) Essential maintenance.

(c) BIA will guaranty or insure the amount of precautionary advances from the date of each advance to the same extent as other amounts due under the loan, if:

(1) The borrower has demonstrated its inability or unwillingness to make the payment or perform the duty that jeopardizes loan recovery, including by undue delay in making the payment or performing the duty;

(2) The total expense of all precautionary advances by the lender does not at the time of the advance exceed 10 percent of the outstanding principal balance of the loan;

(3) Where loan document provisions do not require the borrower to repay precautionary advances (however termed) when made by the lender, or where the total expense of all precautionary advances by the lender will exceed 10 percent of the outstanding principal balance of the loan when made, the lender secures BIA's prior written approval; and

(4) The lender properly claims and documents all precautionary advances, if and when it submits a claim for loss under § 103.37.

(d) If the default remains uncured, the lender must send BIA a written notice by certified mail (return receipt requested), or by a nationally-recognized overnight delivery service (signature of recipient required) within 90 calendar days of the default to select one of the following remedies:

(1) In the case of a guaranteed loan, the lender may submit a claim to BIA for its loss;

(2) In the case of either a guaranteed or insured loan, the lender may liquidate all collateral securing the loan, and upon completion, if it has a residual loss on the loan, it may submit a claim to BIA for that loss; or

(3) The lender may negotiate a loan modification agreement with the borrower to permanently change the terms of the loan in a manner that will cure the default. If the lender chooses this remedy, it may take no longer than 45 calendar days from the date BIA receives the notice of remedy selection to finalize a loan modification agreement and secure BIA's written approval of it, unless BIA specifically extends this deadline in writing. However, the lender may at any time before the expiration of the 45-day period (or any extension thereof) change its choice of remedy by sending BIA a notice otherwise complying with § 103.36(d)(1) or (2). If the lender fails to send BIA a notice changing its choice of remedy and does not finalize an approved loan modification agreement within the 45-day period (or any extension thereof), the lender's only permissible remedy under the Program will be to pursue the procedure specified in § 103.36(d)(2).

(e) Failure by the lender to provide BIA with notice of the lender's election of remedy within 90 calendar days of the default, as indicated in § 103.36(d), will invalidate BIA's loan guaranty certificate or insurance coverage for that particular loan, absent an express waiver of this provision by BIA. BIA may preserve the validity of a loan guaranty certificate or insurance coverage through waiver of this provision only when BIA determines, in its discretion, that:

(1) The lender consistently has acted in good faith, and

(2) The lender's failure to provide timely notice either:

(i) Has not caused any actual or potential prejudice to BIA; or

(ii) Was the result of the lender relying upon specific written advice from a BIA official.

§ 103.37 What must the lender do to collect payment under its loan guaranty certificate or loan insurance coverage?

(a) For guaranteed loans, the lender must submit a claim for its loss on a form approved by BIA.

(1) If the lender makes an immediate claim under § 103.36(d)(1), it must send BIA the claim for loss within 90 calendar days of the default by certified mail (return receipt requested), or by a nationally-recognized overnight delivery service (signature of recipient required). The lender's claim for loss may include interest that has accrued on the outstanding principal amount of the loan only through the date it submits the claim.

(2) If the lender elects first to liquidate the collateral securing the loan under § 103.36(d)(2), and has a residual loss after doing so, it must send BIA the claim for loss within 30 calendar days of completing all liquidation efforts. The lender must perform collateral liquidation as expeditiously and thoroughly as is reasonably possible, within the standards established by this part. The lender's claim for loss may include interest that has accrued on the outstanding principal amount of the loan only through the earlier of:

(i) The date it submits the claim;

(ii) The date the lender gets a judgment of foreclosure or sale (or the non-judicial equivalent) on the principal collateral securing the loan; or

(iii) One hundred eighty calendar days after the date of the default.

(b) For insured loans, after liquidating all loan collateral, the lender must submit a claim for its loss (if any) on a form approved by BIA. The lender must send BIA the claim for loss by certified mail (return receipt requested), or by a nationally-recognized overnight delivery service (signature of recipient required) within 30 calendar days of completing all liquidation efforts. The lender must perform collateral liquidation as expeditiously and thoroughly as is reasonably possible, within the standards established by this part. The lender's claim for loss may include interest that has accrued on the outstanding principal amount of the loan through the earlier of:

(1) The date it submits the claim;

(2) The date the lender gets a judgment of foreclosure or sale (or the non-judicial equivalent) on the principal collateral securing the loan; or

(3) One hundred eighty calendar days after the date of the default.

(c) Whenever the lender liquidates loan collateral under § 103.36(d)(2), it must vigorously pursue all reasonable methods of collection concerning the loan collateral before submitting a claim for its residual loss (if any) to BIA. Without limiting the generality of the preceding sentence, the lender must:

(1) Foreclose, either judicially or non-judicially, all rights of redemption the borrower or any co-maker or guarantor of the loan (other than BIA) may have in collateral under any mortgage securing the loan;

(2) Gather and dispose of all personal property pledged as collateral under the loan, in accordance with applicable law;

(3) Exercise all set-off rights the lender may have under contract or applicable law;

(4) Make demand for payment on the borrower, all co-makers, and all guarantors of the loan (other than BIA); and

(5) Participate fully in all bankruptcy proceedings that may arise involving the borrower and any co-maker or guarantor of the loan. Full participation might include, for example, filing a proof of claim in the case, attending creditors' meetings, and seeking a court order releasing the automatic stay of collection efforts so that the lender can liquidate affected loan collateral.

(d) BIA may require further information, including without limitation copies of any documents the lender is to maintain under § 103.32 and all documentation of liquidation efforts, to help BIA evaluate the lender's claim for loss.

(e) BIA will pay the lender the guaranteed or insured portion of the lender's claim for loss, to the extent the claim is based upon reasonably sufficient evidence of the loss and compliance with the requirements of this part. BIA will render a decision on a claim for loss within 90 days of receiving all information it requires to properly evaluate the loss.

§ 103.38 Is there anything else for BIA or the lender to do after BIA makes payment?

When BIA pays the lender on its claim for loss, the lender must sign and deliver to BIA an assignment of rights to its loan agreement with the borrower, in a document acceptable to BIA. Immediately upon payment, BIA is subrogated to all rights of the lender under the loan agreement with the borrower, and must pursue collection efforts against the borrower and any co-maker and guarantor, as required by law.

§ 103.39 When will BIA refuse to pay all or part of a lender's claim?

BIA may deny all or part of a lender's claim for loss when:

(a) The loan is not guaranteed or insured as indicated in § 103.18;

(b) The guarantee or insurance coverage has become invalid under §§ 103.28, 103.29, or 103.36(e);

(c) The lender has not met the standard of care indicated in § 103.30;

(d) The lender presents a claim for a residual loss after attempting to liquidate loan collateral, and:

(1) The lender has not made a reasonable effort to liquidate all security for the loan;

(2) The lender has taken an unreasonable amount of time to complete its liquidation efforts, the probable consequence of which has been to reduce overall prospects of loss recovery; or

(3) The lender's loss claim is inflated by unreasonable liquidation expenses or unjustifiable deductions from collateral liquidation proceeds applied to the loan balance; or

(e) The lender has otherwise failed in any material respect to follow the requirements of this part, and BIA can reasonably attribute some or all of the lender's loss to that failure.

§ 103.40 Will BIA make exceptions to its criteria for denying payment?

(a) BIA will not reduce or deny payment solely on the basis of §§ 103.39(c) or (e) when the lender making the claim for loss:

(1) Is a person to whom a previous lender transferred the loan under §§ 103.28 or 103.29 before maturity for value;

(2) Notified BIA of its acquisition of the loan interest as required by §§ 103.28 or 103.29;

(3) Had no involvement in or knowledge of the actions or circumstances that would have allowed BIA to reduce or deny payment to a previous lender; and

(4) Has not itself violated the standards set forth in §§ 103.39(c) or (e).

(b) If BIA makes payment to a lender under this section, it may seek reimbursement from the previous lender or lenders who contributed to the loss by violating §§ 103.39(c) or (e).

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§ 103.41 What happens if a lender violates provisions of this part?

In addition to reducing or eliminating payment on a specific claim for loss, BIA may either temporarily suspend, or permanently bar, a lender from making or acquiring loans under the Program if the lender repeatedly fails to abide by the requirements of this part, or if the lender significantly violates the requirements of this part on any single occasion.

§ 103.42 How long must a lender comply with Program requirements?

(a) A lender must comply in general with Program requirements during:

(1) The effective period of its loan guaranty agreement or loan insurance agreement; and

(2) Whatever additional period is necessary to resolve any outstanding loan guaranty or insurance claims or coverage the lender may have.

(b) Except as otherwise required by law, a lender must maintain records with respect to a particular loan for 6 years after either:

(1) The loan is repaid in full; or

(2) The lender accepts payment from BIA for a loss on the loan, pursuant to a guaranty certificate or an insurance agreement.

(c) At any time 2 years or more following one of the events specified in paragraphs (b)(1) or (2) of this section, a lender may convert its records for corresponding loans to any electronic format that is readily retrievable and that provides an accurate, detailed image of the original records. Upon converting its records in this manner, the lender may dispose of its original loan records.

(d) This section does not restrict any claims BIA may have against the lender or any other party arising from the lender's participation in the Program.

§ 103.43 What must the lender do after repayment in full?

The lender must completely and promptly release of record all remaining collateral for a guaranteed or insured loan after the loan has been paid in full. The release must be at the lender's sole cost. In addition, if the loan is prepaid the lender must notify BIA in accordance with § 103.33(f).

Subpart H—Definitions and Miscellaneous Provisions

§ 103.44 What certain terms mean in this part.

BIA means the Bureau of Indian Affairs within the United States Department of the Interior.

Default means:

(1) The borrower's failure to make a scheduled loan payment when it is due;

(2) The borrower's failure to meet a material condition of the loan agreement;

(3) The borrower's failure to comply with any other condition, covenant or obligation under the terms of the loan agreement within applicable grace or cure periods;

(4) The borrower's failure to remain at least 51 percent Indian owned, as provided in § 103.25(b);

(5) The filing of a voluntary or involuntary petition in bankruptcy listing the borrower as debtor;

(6) The imposition of a Federal, State, local, or tribal government lien on any assets of the borrower or assets otherwise used as collateral for the loan, except real property tax liens imposed by law to secure payments that are not yet due;

(7) Any default defined in the loan agreement, to the extent the definition is not inconsistent with this part.

Equity means the value, after deducting all debt, of the borrower's tangible assets in the business being financed, on which a lender can perfect a first lien security interest. It can include cash, securities, or other cash equivalent instruments, but cannot include the value of contractual options, the right to pay below market rental rates, or similar rights if those rights:

(1) Are unassignable; or

(2) Can expire before maturity of the loan.

Indian means a person who is a member of a tribe as defined in this part.

Loan agreement means the collective terms and conditions under which the lender extends a loan to a borrower, as reflected by the documents that evidence the loan.

Mortgage means a consensual lien on real or personal property in favor of the lender, given by the borrower or a co-maker or guarantor of the loan (other than BIA), to secure loan repayment. The term "mortgage" includes "deed of trust."

NEPA means the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*

Person means any individual or distinct legal entity.

Program means the BIA's Loan Guaranty, Insurance, and Interest Subsidy Program, established under 25 U.S.C. 1481 *et seq.*, 25 U.S.C. 1511 *et seq.*, and this part 103.

Reservation means any land that is an Indian reservation, California rancheria, public domain Indian allotment, pueblo, Indian colony, former Indian reservation in Oklahoma, or land held by an Alaska Native corporation under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688), as amended.

Secretary means the Secretary of the United States Department of the Interior, or his authorized representative.

Tribe means any Indian or Alaska Native tribe, band, nation, pueblo, rancheria, village, community or corporation that the Secretary acknowledges to exist as an Indian tribe, and that is eligible for services from BIA.

§ 103.45 Information collection.

(a) The information collection requirements of §§ 103.11, 103.12, 103.13, 103.14, 103.17, 103.21, 103.23, 103.26, 103.32, 103.33, 103.34, 103.35, 103.36, 103.37, and 103.38 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and assigned approval number 1076–0020. The information will be used to approve and make payments on Federal loan guarantees, insurance agreements, and interest subsidy awards. Response is required to obtain a benefit.

(b) The burden on the public to report this information is estimated to average from 15 minutes to 2 hours per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information collection. Direct comments regarding the burden estimate or any other aspect of this information collection to the Information Collection Control Officer, Bureau of Indian Affairs, MS 4613, 1849 C Street, NW., Washington, DC 20240.

Dated: December 26, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–1249 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 155

[USCG–1998–3417]

RIN 2115–AF80

Salvage and Marine Firefighting Requirements; Vessel Response Plans for Oil

AGENCY: Coast Guard, DOT.

ACTION: Final rule; partial suspension of regulation.

SUMMARY: Current vessel response plan regulations require the owners or operators of vessels carrying Groups I through V petroleum oil as a primary cargo to identify in their response plans a salvage company with expertise and equipment, and a company with firefighting capability that can be deployed to a port nearest to the vessel's operating area within 24 hours of notification (Groups I–IV) or a discovery of a discharge (Group V). On February 12, 1998, a notice of suspension was published in the **Federal Register**, suspending the 24-hour requirement scheduled to become effective on February 18, 1998, until February 12, 2001 (63 FR 7069). The Coast Guard has decided to extend this suspension period for another 3 years to allow us to complete the rulemaking that proposes to revise the salvage and marine firefighting requirements. The extension is necessary because the potential impact on small businesses from this new rulemaking requires us to prepare an initial regulatory flexibility analysis under the Small Business Regulatory Enforcement Fairness Act of 1996. This was not determined until a draft regulatory assessment was complete in November 2000. We expect to complete the analysis and publish a notice of proposed rulemaking this year. The extension of the suspension period will continue to relieve the affected industry from complying with the existing 24-hour requirements until the project is complete, and amendments to the salvage and marine firefighting requirements become final.

DATES: This extension is effective as of February 12, 2001. Termination of the suspension will be on February 12, 2004.

ADDRESSES: You may submit comments by one of the following methods:

(1) By mail to the Docket Management Facility, (USCG–1998–3417), U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web site for the Docket Management System at *http://dms.dot.gov.*

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For questions on this final rule partial suspension of regulations, call Lieutenant Douglas Lincoln, Office of Response, Response Operations Division, Coast Guard Headquarters, telephone 202–267–0448, or via e-mail: *dlincoln@comdt.uscg.mil.* For questions on viewing, or submitting material to, the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION:

Background and Regulatory History

Requirements for salvage and marine firefighting resources in vessel response plans have been in place since February 5, 1993 (58 FR 7424). The existing requirements are general. The Coast Guard did not originally develop specific requirements because each salvage and marine firefighting response for an individual vessel is unique, due to the vessel's size, construction, operating area and other variables. The Coast Guard's intent was to rely on the planholder to prudently identify contractor resources to meet their needs. The Coast Guard anticipated that the significant benefits of a quick and effective salvage and marine firefighting response would be sufficient incentive for industry to develop salvage and marine firefighting capability parallel to the development of oil spill removal organizations.

Early in 1997, it became apparent that there was disagreement among planholders, salvage and marine firefighting contractors, maritime associations, public agencies, and other stakeholders as to what constituted adequate salvage and marine firefighting resources. There was also concern as to whether these resources could respond to the port nearest to the vessel's operating area within 24 hours.

On June 24, 1997, a notice of meeting was published in the **Federal Register** (62 FR 34105) announcing a workshop to solicit comments from the public on potential changes to the salvage and marine firefighting requirements currently found in 33 CFR part 155.

A public workshop was held on August 5, 1997, to address issues related to salvage and marine firefighting response capabilities, including the 24-hour response time requirement, which was then scheduled to become effective on February 18, 1998. The participants uniformly identified the following three issues that they felt the Coast Guard needed to address:

(1) Defining the salvage and marine firefighting capability that is necessary in the plans.

(2) Establishing how quickly these resources must be on-scene.

(3) Determining what constitutes an adequate salvage and marine firefighting company.

Reason for Suspension

On February 12, 1998, a notice of suspension was published in the **Federal Register**, suspending the 24-hour requirement scheduled to become effective on February 18, 1998, until February 12, 2001 (63 FR 7069) so that the Coast Guard could address the issues identified at the public workshop through a rulemaking that would revise the existing salvage and marine firefighting requirements. The Coast Guard has decided to extend the suspension period for another 3 years. The extension is necessary because the potential impact on small businesses from this new rulemaking requires us to prepare an initial regulatory flexibility analysis under the Small Business Regulatory Enforcement Fairness Act of 1996. This was not determined until a draft regulatory assessment was complete in November 2000. We expect to complete the analysis and publish a notice of proposed rulemaking this year. The extension of the suspension period will continue to relieve the affected industry from complying with the existing 24-hour requirements until the project is complete, and amendments to the salvage and marine firefighting requirements become final.

Regulatory Evaluation

Although the final rule published in 1996 was a significant regulatory action under section 3(f) of Executive Order 12866, the Office of Management and Budget (OMB) does not consider this extension as a significant action. As a result, it does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040, February 26, 1979).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this extension will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their

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fields, and governmental jurisdictions with populations of less than 50,000.

This action will not have a significant economic impact on a substantial number of small entities because the original requirements did not have a significant effect on a substantial number of small entities. The extension on the suspension does not change those original requirements. Any future regulatory action on this issue will address any economic impacts, including impacts on small entities.

Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this extension to a suspension of a final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This action does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

We have analyzed this action under E.O. 13132 and have determined that it does not have implications for federalism under that Order. Because this action extends a suspension of a final rule, it does not preempt any state action.

Unfunded Mandates Reform Act

This action will not result in an unfunded mandate under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538).

Taking of Private Property

This action will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that preparation of an Environmental Impact Statement is not necessary. An Environmental Assessment and a Finding of No Significant Impact are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 155

Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

1. The authority citation for part 155 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j); 46 U.S.C. 3715, 3719; sec. 2, E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; 49 CFR 1.46, 1.46 (iii).

Sections 155.110–155.130, 155.350–155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), and 155.1065(g) also issued under 33 U.S.C. 1903(b); and §§ 155.1110–155.1150 also issued 33 U.S.C. 2735.

Note: Additional requirements for vessels carrying oil or hazardous materials appear in 46 CFR parts 30 through 36, 150, 151, and 153.

§ 155.1050 [Amended]

2. In § 155.1050, paragraph (k)(3) is suspended until February 12, 2004.

§ 155.1052 [Amended]

3. In § 155.1052, the last sentence in paragraph (f) is suspended until February 12, 2004.

Dated: January 10, 2001.

R.C. North,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety and Environmental Protection.

[FR Doc. 01–1205 Filed 1–11–01; 2:28 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICE

45 CFR Part 46

RIN 0925–AA14

Protection of Human Research Subjects

AGENCY: Department of Health and Human Services (DHHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (DHHS) is amending its human subjects protection regulations. These regulations provide additional protections for pregnant women and human fetuses involved in research and pertains to human in vitro fertilization. The rule continues the special protections for pregnant women and human fetuses that have existed since 1975. The rule enhances the opportunity for participation of pregnant women in research by promoting a policy of presumed inclusion, by permitting the pregnant woman to be the sole decision maker with regard to her participation in research, and by exempting from the regulations six categories of research. The rule also provides a mechanism for the Secretary of HHS to conduct or fund research not otherwise approvable after consultation with an expert panel and public review and comment.

DATES: Effective date: March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Susan Sherman, JD, Office for Human Research Protections (OHRP), 6100 Executive Blvd, Suite 3B01, Rockville, MD 20892–7507. Telephone 301–496–7005. Email: *ShermanS@od.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by the agency through regulations codified at Title 45, part 46, of the Code of Federal Regulations. Subpart B of 45 CFR part 46, promulgated on August 8, 1975, pertains to research involving fetuses, pregnant women, and human in vitro fertilization. The 1975 regulations were jointly published in the **Federal Register** with the report and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research on the Fetus (40 FR 33526). Subsequent changes were incorporated January 11, 1978 (43 FR 1758), November 3, 1978 (43 FR 51559), and June 1, 1994 (59 FR 28276). This preamble refers to these rules as the "1975 regulations."

Recent guidelines issued by components of DHHS have addressed the participation of women in research as follows:

- Food and Drug Administration 1993 Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs (58 FR 39406);
- National Institutes of Health 1994 Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (59 FR 14508); and
- Centers for Disease Control and Prevention 1995 Policy on the Inclusion of Women and Racial and Ethnic Minorities in Externally Awarded Research (60 FR 47947), and February 16, 1996 policy Inclusion of Women and Racial and Ethnic Minorities in Research.

These policies are all designed, in part, to improve the opportunity for women to be included as subjects in research.

A Committee on the Ethical and Legal Issues Relating to the Inclusion of Women in Clinical Studies of the Institute of Medicine issued a report in 1994 on Women and Health Research that included the recommendation that DHHS revise subpart B in accordance with the Committee's other recommendations. The Committee believed that women and men should have the opportunity to participate equally in the benefits and burdens of research, and many of the Committee's recommendations were aimed at enhancing the participation of women, including pregnant women, in clinical research.

The National Task Force on AIDS Drug Development and the Presidential Advisory Council on HIV/AIDS subsequently recommended that the lack of paternal consent should not disqualify a pregnant woman from participation in a federally funded clinical trial.

These guidelines and recommendations, and the lack of a formal review of subpart B for over two decades, led DHHS to determine that a substantive examination of subpart B was appropriate.

Based on this review the Department proposed to amend subpart B in a Notice of Proposed Rulemaking (NPRM) published on May 20, 1998 (63 FR 27794). The Department proposed that a policy of presumed opportunity for inclusion of pregnant women in research replace one of presumed exclusion. The Department also concurred with the recommendations of the National Task Force on AIDS Drug Development, the Presidential Advisory Council on HIV/AIDS, and the IOM Committee regarding paternal consent and proposed to modify the consent requirement to remove potential barriers to research that might provide a medical benefit to a fetus.

The exemptions in 45 CFR part 46, Subpart A, Basic DHHS Policy for Protection of Human Research Subjects, were proposed to apply to subpart B. These exemptions of certain categories of research (*e.g.*, survey research without subject identifiers) have applied since 1981 to research involving nonpregnant women.

In light of the 1993 legislative nullification of the regulatory requirement for ethical advisory board review of research involving in vitro fertilization of human ova (Public Law 103–43), the Department proposed a mechanism for the Secretary to modify or waive certain requirements of Subpart B, following consultation with experts and public input, in place of the provision that the Department have a standing ethical advisory board. Nonsubstantive technical, formatting, and clarifying changes were also proposed.

Discussion of Comments

During the public comment period that ended August 18, 1998, the Department received 13 public comments on the proposed rule from interested parties. The comments are summarized as follows:

General Comments

One commenter endorsed the NPRM in its entirety. One commenter suggested that there be three classes of research that mirror the categories in subpart D of part 46, Additional DHHS Protections for Children Involved as Subjects in Research. Those categories are: no greater than minimal risk, greater than minimal risk but presenting the prospect of direct benefit, and greater than minimal risk and no prospect of direct benefit. The Department finds that modification of the format of subpart B to parallel the categories of research in subpart D would not enhance the protection of women or fetuses and would likely cause confusion. Subpart B, since its inception in 1975 and in this final rule, requires that the risk to the fetus be the least possible risk for achieving the research objectives and any risk which is greater than minimal must hold out the prospect of direct benefit for the fetus or the woman.

One commenter objected to distinctions between "therapeutic" and "nontherapeutic" research as illogical, because, by definition, the purpose of research is always to contribute to generalizable knowledge. The commenter noted that this distinction confuses therapy with research. The Department concurs with this comment and has modified the final rule to eliminate language implying that the purpose of research is ever therapeutic. The final rule uses the phrases "* * * interventions or procedures that hold out the prospect of direct benefit * * *" and "* * * research [that] holds out the prospect of enhancing the probability of survival * * *" to describe research from which a subject may benefit (§ 46.204(b) and § 46.205(b)(1)(i)).

Applicability (Section 46.201)

The Department proposed that the exemptions at 45 CFR 46.101(b)(1)–(6) of subpart A apply to subpart B. These exemptions of six categories of research were promulgated in 1981, subsequent to the last substantive revision of subpart B, and have applied to research with nonpregnant subjects since that time. Two commenters endorsed the incorporation of the exemptions into subpart B. One commenter noted that pregnancy should not preclude women from participating in these types of research; one stated that pregnant women are autonomous decision makers and should not be treated as vulnerable or impaired because of their condition. Consistent with these comments, the exemptions are retained in the final rule (§ 46.201(b)).

The Department has retained in the final rule language specifying that the requirements of subpart B are in addition to those imposed under the other subparts of 45 CFR part 46, for purposes of clarity (§ 46.201(d)).

Definitions (Section 46.202)

The proposed definitions were substantively the same as those in the 1975 regulations.

The Department proposed the following simplified definition of "fetus:" "fetus means the product of conception during pregnancy until a determination is made after delivery that it is viable." One commenter noted that "product of conception" is generally understood to mean the associated placenta as well. The Department intends that research with the placenta prior to delivery be governed by 45 CFR 46.204, Research involving pregnant women or fetuses prior to delivery. For purposes of clarity, the definition of "fetus" in the final rule utilizes the phrase "from implantation," which is the same phrase used in the definition of "pregnancy."

Since 1975, subpart B has included the fetus *ex utero* until such time as

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viability of the fetus is determined. The Department proposed to replace the phrase "ex utero" with "after delivery." No comments were received on that proposal and the final rule retains the proposed language.

The Department also proposed the term "newborn," equating newborn with "fetus after delivery," because some persons may prefer one term to the other depending on the length of the gestation period. Two commenters found the introduction of this term confusing and inconsistent because after delivery there exists an entity that could be called either fetus or newborn. The Department concurs with these comments and has deleted the term "newborn" from the final rule.

One commenter noted that newborns can be of any species and believed that the term "child" should be used in place of "newborn." Another commenter stated that a viable fetus is generally understood to mean a fetus after the point of viability, generally at 5–6 months gestation. In response to these comments the Department has defined "viable" in the final rule and emphasized that, as it pertains to the fetus, "viable" means a fetus after delivery and the regulations at 45 CFR part 46, subpart D, are applicable (§ 46.202(h)).

Research Involving Pregnant Women or Fetuses Prior to Delivery (Section 46.204)

For purposes of clarity, the scope of § 46.204 has been narrowed in the final rule to research involving pregnant women or fetuses prior to delivery, and those provisions of proposed § 46.204 that are applicable to research involving fetuses after delivery have been repeated in section § 46.205 (see § 46.205(a)(1)–(6) and (b)(1)(i)).

The Department proposed to require, as a prerequisite to research on pregnant women or fetuses, preclinical and clinical studies, including studies on nonpregnant women, that provide data for assessing potential risks to pregnant women and fetuses. One commenter endorsed the increased specificity and noted that it would ensure that reproductive toxicity data are available. Another commenter found that to require pregnant women to wait until studies have been conducted on nonpregnant women is to neglect them as a population. The Department notes that preclinical and clinical studies are required only when scientifically appropriate. The final rule retains the proposed provision for preclinical and clinical studies (§ 46.204(a) and § 46.205(a)(1)).

To strengthen protections for the pregnant woman and fetus, the Department proposed a new informed consent provision: that the woman be fully informed regarding the reasonably foreseeable impact of the research on the fetus. No commenters objected to this provision. The final rule, at § 46.204(e), retains this requirement with the clarification that it also applies to the legally authorized representative. This provision is repeated in § 46.205(a)(2), so that the person whose informed consent is a prerequisite to participation in the research must be fully informed of the reasonably foreseeable impact of the research on the fetus.

One commenter stated that informed consent should highlight known or suspected risks and should incorporate unknown harms. The Department notes that provisions of subpart A at 45 CFR part 46.116(a)(2) and § 46.116(b)(1), respectively, also applicable to subpart B, address these concerns. The commenter further noted that researchers should work to ensure that the woman or her legally authorized representative understands the information that has been disclosed, that checks for understanding should be tailored according to the situation of particular women or representatives, and women should be encouraged to discuss research participation with their obstetrician before making a final decision about enrollment. The Department notes that ensuring that information is understood and checks for understanding tailored to particular situations are not precluded by the regulations, nor are they unique to research with pregnant women. Subpart A affords IRBs the opportunity and the authority to ensure the adequacy of informed consent and protections by imposing additional requirements or monitoring the research or the consent process. Similarly, with regard to the suggestion concerning encouragement of discussion with an obstetrician, the Department notes that the rules do not preclude encouragement to discuss participation with obstetricians or any other individuals and that subpart A requires that consent be sought only under circumstances that provide sufficient opportunity to consider participation (45 CFR 46.116).

The Department proposed to modify the consent requirements in the 1975 regulations by permitting research with pregnant women or fetuses prior to delivery based on the consent of the woman or her legally authorized representative. The Department recognizes and encourages paternal involvement in decisions affecting the pregnant woman and fetus prior to delivery. Nonetheless, in some cases the father's consent has been a barrier to participation in research of the woman or fetus prior to delivery. The recommendations of the National Task Force on AIDS Drug Development, the Presidential Advisory Council on HIV/AIDS, and the IOM Committee were unanimous that the consent of the father should not be a condition of the participation of a pregnant woman in research.

Ten commenters endorsed or applauded the proposal to modify the parental consent requirement, many describing specific research trials in which pregnant women were unable to participate in potentially beneficial research because of the requirement that the father's consent be secured. One commenter believed the consent of the father should continue to be required and that waivers from the Secretary should be sought if the father's consent is difficult to obtain. The Department concludes that the decision making authority for research participation of the pregnant woman or fetus prior to delivery should rest with the pregnant woman and has retained this provision in the final rule (§ 46.204(d)).

One commenter indicated that the rules are unclear whether a researcher may inform a pregnant woman of nonresearch alternatives. The Department notes that subpart B does not address alternatives to research, but that subpart A, at 45 CFR part 46.116(a)(4), also applicable to subpart B, requires disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

The Department has also decided to continue the use of the word "terminate" in sections 204 and 205 instead of utilizing the proposed change to the word "abort." The Department believes that the original language is clearer.

Research Involving Fetuses After Delivery (Section 46.205)

As indicated above, those provisions proposed in § 46.204 that are applicable to research involving fetuses after delivery are reiterated in the final rule under § 46.205(a) and (b)(1)(i).

One commenter requested that the Department explain why this section is separate from subpart D. As noted above, the 1975 regulations extended the definition of fetus to include the fetus *ex utero* until such time as a fetus is determined to be viable. The final rule continues this extension because nonviable fetuses, and fetuses whose viability has not yet been determined after delivery, require protection and are not covered by subpart D. Accordingly, subpart B permits research with fetuses of uncertain viability only if the research holds out the prospect of enhancing the probability of survival or there will be no risk resulting from the research and the purpose is the development of important biomedical knowledge that cannot be obtained by other means (§ 46.205(b)). Research with nonviable fetuses after delivery, which must be considered dying subjects, must meet the five criteria at § 46.205(c)(1)–(5), also intended to provide protection for such subjects.

Section 498(a), "Fetal Research," of the Public Health Service Act, 42 U.S.C. 289g(a), places statutory restrictions on research involving nonviable living fetuses ex utero or living fetuses ex utero for whom viability has not been ascertained. The statute permits research under either of the following two conditions: "the research * * * (1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or (2) will pose no added risk of suffering, injury, or death to the fetus and the purpose * * * is the development of important biomedical knowledge that cannot be obtained by other means." This rule exceeds those requirements for fetuses of uncertain viability by permitting research only if it either (1) holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, or (2) poses no risk to the fetus and the purpose is the development of important biological knowledge that cannot be obtained by other means. This rule also exceeds the statutory requirements for nonviable living fetuses ex utero by specifying that vital functions of the nonviable fetus may not be artificially maintained and the research may not terminate the heartbeat or respiration of the fetus.

The consent requirements for research involving fetuses of uncertain viability and nonviable fetuses at § 46.205(b)(2) and § 46.205(c)(5), respectively, also ensure protection of the fetus. Research involving fetuses of uncertain viability may proceed with the consent of either parent (or under certain circumstances the consent of a legally authorized representative), but the research must hold the prospect of enhancing the probability of survival of the fetus to the point of viability or pose no risk to the fetus. The Department recognizes that, in cases of uncertain viability, a decision regarding research participation must often be made very quickly, especially where the research presents the prospect of enhancing the probability of survival of the fetus. Thus, the consent of only one parent (or legally authorized representative) is required. However, if both parents are readily available at the time when a decision is needed, reasonable efforts should be made to provide all relevant information to both parents. The Department believes that research involving the nonviable fetus should only proceed with the consent of both parents (unless one is unavailable, incompetent, or temporarily incapacitated), and the consent of a representative is expressly prohibited. The individual(s) providing consent under § 46.205(b)(2) or (c)(5) must be fully informed regarding the reasonably foreseeable impact of the research on the fetus (§ 46.205(a)(2)).

Research after delivery, involving fetuses determined to be viable, is governed by Subpart D (§ 46.205(d)).

Research Not Otherwise Approvable That Presents Certain Opportunities section 46.207)

The Department proposed to replace the 1975 regulatory authority of the Secretary to modify or waive specific requirements with the approval of an ethical advisory board, with the authority to modify or waive requirements after consultation with appropriate experts and opportunity for public review and comment. The proposal would have required the Secretary to consider whether the risks to the subjects were so outweighed by the sum of the benefits to the subjects and the importance of the knowledge to be gained as to warrant modification or waiver. One commenter noted that the proposed waiver provision did not require IRB review, as does the similar section in subpart D (45 CFR 46.407). The commenter further noted that the proposed wording appeared to require that the overarching consideration be "beneficence" based, and that adopting the language in 45 CFR 46.407 would encompass all of the ethical principles in the Belmont Report and ensure consistency between subparts B and D. The Department concurs with these comments and the final rule, at § 46.207, is consistent with 45 CFR 46.407, with conforming and clarifying changes.

Under this provision the waiver authority is limited to the requirements of § 46.204 applicable to pregnant women and fetuses prior to delivery. The other requirements of subpart B, including those in § 46.205, cannot be waived. Even though the Secretary has the authority to waive the requirements of § 46.205 that exceed the statutory requirements of section 498(a), "Fetal Research," of the Public Health Service Act, 42 U.S.C. 289g(a) (see discussion of § 46.205 above), it was determined that the additional protections afforded by § 46.205 are essential and should not be waived under any circumstances.

Conclusion

After considering the comments, the Department is adopting the rule as proposed except for the changes noted above and editorial changes to clarify the intent of the regulation. Distinctions between therapeutic and nontherapeutic research are eliminated. The term "newborn" is deleted in the final rule for purposes of clarity, and the definition of "viable" as it pertains to the fetus is clarified. Section 46.207, regarding approval by the Secretary of research that would not otherwise be approvable under § 46.204, is modified consistent with the similar provision in subpart D. The Department has also incorporated additional nonsubstantive editorial and clarifying revisions in the final rule.

The rule is effective 60 days after publication to give Institutional Review Boards (IRBs) time to incorporate the regulations into their review of research protocols. All initial and ongoing projects reviewed after the effective date by IRBs under Multiple Project Assurances or other Assurances with the DHHS, Office for Human Research Protections, OHRP (formerly OPRR), must be reviewed in accordance with these rules.

Executive Order 12866

Executive Order 12866 requires that all regulatory actions reflect consideration of the costs and benefits they generate and that they meet certain standards, such as avoiding the imposition of unnecessary burdens on the affected public. If an action is deemed to fall within the scope of the definition of the term "significant regulatory action" contained in § 3(f) of the Order, a pre-publication review by the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) is necessary. OMB deemed this rule a "significant regulatory action," as defined by Executive Order 12866. Therefore, the rule was submitted to OIRA for review prior to its publication in the **Federal Register**.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. Chapter 6) requires that regulatory actions be analyzed to determine whether they create a significant impact on a substantial number of small entities. This rule primarily affects individual research

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subjects and institutions that receive funding from the Department of Health and Human Services for research involving human subjects. It will not have the effect of imposing significant additional costs on small research institutions that are within the definition of small entities. Therefore, the Secretary certifies that this rule will not have significant impact on a substantial number of small entities and that preparation of an initial regulatory flexibility analysis is not required.

Paperwork Reduction Act

This rule does not contain any new information collection requirements that are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

List of Subjects in 45 CFR Part 46

Health—clinical research, medical research.

Dated: September 21, 2000.

David Satcher,

Assistant Secretary for Health and Surgeon General.

Approved: October 30, 2000.

Donna E. Shalala,

Secretary of Health and Human Services.

Accordingly, the Department of Health and Human Services amends part 46 of the Regulations for the Protection of Human Subjects (45 CFR part 46), as follows:

1. authority citation for 45 CFR part 46 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

2. Supbart B of 45 CFR part 46 is revised to read as follows:

Subpart B—Additional Protections for Pregnant Women and Human Fetuses Involved in Research, and Pertaining to Human in Vitro Fertilization

Sec.

46.201 To what do these regulations apply?
46.202 Definitions.
46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization.
46.204 Research involving pregnant women or fetuses prior to delivery.
46.205 Research involving fetuses after delivery.
46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material.
46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses.

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women or human fetuses, and to all research involving the in vitro fertilization of human ova, conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of § 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in § 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Definitions.

The definitions in § 46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Dead fetus* means a fetus after delivery that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord. Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(b) *Fetus* means the product of conception from implantation until a determination is made after delivery that it is viable.

(c) *In vitro fertilization* means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

(d) *Nonviable fetus* means a fetus after delivery that, although living, is not viable.

(e) *Pregnancy* encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(f) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(g) *Viable* as it pertains to the fetus means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the **Federal Register** guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus after delivery is viable then it is a child as defined by § 46.402(a), and subpart D of this part is applicable.

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and human in vitro fertilization.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§ 46.204 Research involving pregnant women or fetuses prior to delivery.

Pregnant women or fetuses prior to delivery may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions of subpart A of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d);

(e) The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child;

(f) For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(g) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(h) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(i) Individuals engaged in the research will have no part in determining the viability of a fetus.

§ 46.205 Research involving fetuses after delivery.

(a) After delivery, fetuses may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses.

(2) The individual(s) providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or resultant child.

(3) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(4) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(5) Individuals engaged in the research will have no part in determining the viability of a fetus.

(6) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Fetuses of uncertain viability. After delivery, and until it has been ascertained whether or not a fetus is viable, a fetus may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the research, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the research; and

(2) The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d).

(c) Nonviable fetuses. After delivery, a nonviable fetus may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the fetus will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the fetus;

(3) There will be no risk to the fetus resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the fetus is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.

(d) Viable fetuses. A fetus, after delivery, that has been determined to be viable is a child as defined by § 46.402(a) and may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus, or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women or fetuses.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the **Federal Register**, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part, unless altered or waived in accord with § 46.101(i) or § 46.116(c) or (d).

[FR Doc. 01–1122 Filed 1–16–01; 8:45 am]
BILLING CODE 4140–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01–43, MM Docket No. 00–179, RM–9947]

Digital Television Broadcast Service; Arkadelphia, AR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Arkansas Educational Television Commission, licensee of noncommercial educational station KETG(TV), substitutes DTV *13 for DTV channel *46 at Arkadelphia. *See* 65 FR 59389, October 5, 2000. DTV channel *13 can be allotted to Arkadelphia in compliance with the principle community coverage requirements of Section 73.625(a) at reference coordinates (33–54–26 N. and 93–06–46 W.) with a power of 7.3, HAAT of 320.9 meters and with a DTV service population of 277 thousand. With is action, this proceeding is terminated.

DATES: Effective February 26, 2001.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Mass Media Bureau, (202) 418–1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report

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and Order, MM Docket No. 00–179, adopted January 10, 2001, and released January 11, 2001. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center 445 12th Street, SW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Services, Inc., (202) 857–3800, 1231 20th Street, NW, Washington, DC 20036.

List of Subjects in 47 CFR Part 73

Television, Digital television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

2. Section 73.622(b), the Table of Digital Television Allotments under Arkansas, is amended by removing DTV channel *46 and adding DTV channel *13 at Arkadelphia.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Services Division, Mass Media Bureau.

[FR Doc. 01–1185 Filed 1–16–01; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MM Docket No. 95–31, FCC 00–120]

Reexamination of Comparative Standards for Noncommercial Educational Applicants

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Commission adopted new rules for selecting among mutually exclusive applicants for noncommercial educational broadcast stations. Certain rules contained new and modified information collection requirements and were published in the **Federal Register** on June 8, 2000. This document announces the effective date of these published rules.

DATES: Effective August 1, 2000 with respect to the amendments to §§ 73.202, 73.3527, and 77.3572 published at 65 FR 36375 (June 8, 2000).

FOR FURTHER INFORMATION CONTACT: Irene Bleiweiss, Mass Media Bureau, Audio Services Division, (202) 418–2700.

SUPPLEMENTARY INFORMATION: On August 1, 2000, the Office of Management and Budget (OMB) approved the information collection requirements contained in Sections 73.202; 73.3527; and 73.3572 pursuant to OMB Control Nos. 3060–0948. Accordingly, the information collection requirements contained in these rules became effective on August 1, 2000.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. 01–1308 Filed 1–16–01; 8:45 am]

BILLING CODE 6712–01–U

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–99–6578]

RIN 2105–AAC49

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Correction

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule; correction.

SUMMARY: In its final drug and alcohol testing rule published on December 19, 2000, the Department made an editorial error in the numbering of a section in the complete new version regulation. This document corrects this error by inserting the proper numbering. In addition, the Department inadvertently omitted one item from its amendments to the existing regulation. This document adds this item, which concerns the responsibilities of the medical review officer in reviewing chain of custody documentation.

EFFECTIVE DATES: The correction to the amendments to the current 49 CFR Part 40 (i.e., the addition of § 40.227) is effective January 18, 2001. The correction to the revised 49 CFR Part 40 (i.e., corrected designation of § 40.33(f)) is effective August 1, 2001.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 400 7th Street, SW., Room 10424, Washington, DC 20590, at (202) 366–9306 (voice), (202) 366–9313 (fax), (202) 755–7687 (TDD), or bob.ashby@ost.dot.gov (e-mail).

SUPPLEMENTARY INFORMATION: In the December 19, 2000, **Federal Register** (65 FR 79462), the Department published a comprehensive revision to its drug and alcohol procedures testing regulation (49 CFR Part 40). This complete revision becomes effective August 1, 2001. In this revision, the Department made an error in numbering § 40.33(f). Following the introductory text of paragraph (f), the Department numbered three paragraphs (i), (ii), and (iii), respectively. They should have been numbered (1), (2), and (3). We are correcting this error.

In the same **Federal Register** document, we also published amendments to the existing 49 CFR Part 40, effective January 18, 2001. We inadvertently omitted from these amendments one provision we intended to make effective on this date. This provision concerns the responsibility of the medical review officer (MRO) to review the chain of custody documentation for a drug test. In § 40.123(b)(1) and § 40.129(a)(2) of the complete revision of Part 40, the Department specifies that MROs are not required to review the laboratory internal chain of custody documentation as part of this process, and that no one is authorized to cancel a test because the MRO does not review the internal laboratory chain of custody documentation.

These provisions of the complete revision of Part 40 are fully consistent with the Department's intent in, and interpretation of, the existing regulation. However, we learned last year that some parties have been confused about this point, and one state court decision—mistakenly, in our view—determined that MROs were required to review internal laboratory chain of custody documentation. We added the cited provisions to the complete revision of Part 40 to emphasize that MRO review of this documentation is not needed.

We intended to add the substance of these provisions to the amendments to the existing Part 40 that become effective January 18, 2001, lest there be any misunderstanding of this point in the interim before August 1, 2001. However, through editorial oversight, we failed to do so. We are correcting this omission by adding a new § 40.227 to Subpart E of the existing Part 40.

The Department finds that there is good cause to issue this correction without a prior notice and opportunity for comment. The underlying regulatory provisions were part of a rulemaking that was promulgated through the normal notice and comment provisions of the Administrative Procedure Act. The editorial correction to the numbering of § 40.33(f) has no substantive significance. The addition of a provision of the complete revision of Part 40 to the amendments to the existing Part 40 merely ensures that this restatement of the Department's understanding of MRO review responsibilities under the existing rule becomes part of the regulatory text in January as we intended, rather than in August.

The Department would not anticipate receiving any useful public comment on these matters. Therefore, the Department finds that it would be impracticable, unnecessary, and contrary to the public interest to go through a notice-and-comment process to fix a minor editorial mistake. For the same reason, we find good cause to make the correction with respect to MRO review responsibilities effective in less than 30 days.

This is a nonsignificant rule under both Executive Order 12866 and the Department's regulatory policies and procedures. The Department certifies, under the Regulatory Flexibility Act, that the rule will not have a significant economic effect on a substantial number of small entities. This is because we anticipate that this amendment will have no economic effect on anyone. It does not have Federalism impacts sufficient to warrant consultation or the preparation of a Federalism impact statement. It does not impose information collection requirements.

Issued this 4th Day of January 2000, at Washington, DC.

Rosalind A. Knapp,

Acting General Counsel.

Accordingly, in FR Doc. 00–31251, published in 65 FR 79462, December 19, 2000, make the following corrections:

PART 40—[CORRECTED]

1. On page 79521, in the second column, add § 40.227 to Subpart E, to read as follows:

§ 40.227 Is the MRO required to review laboratory internal chain of custody documentation?

(a) As the MRO, you are not required to review laboratory internal chain of custody documentation.

(b) No one is permitted to cancel a test because you have not reviewed this documentation.

§ 40.33 [Corrected]

2. Beginning on page 79533, in the third column, in § 40.33, correctly designate paragraphs (f)(i), (f)(ii), and (f)(iii) as paragraphs (f)(1), (f)(2), and (f)(3), respectively.

[FR Doc. 01–648 Filed 1–16–01; 8:45 am]

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Proposed Rules

Federal Register
Vol. 66, No. 11
Wednesday, January 17, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Public Workshop on Risk-Informed Regulation—Option 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of workshop.

SUMMARY: The Nuclear Regulatory Commission (NRC) will host a public workshop to provide an opportunity for discussion of topics raised from the advanced notice of proposed rulemaking on this subject, of the Nuclear Energy Institute's (NEI) guidelines for this issue, and possible alternative approaches to Option 2 in risk-informed regulations. The workshop is open to the public.

DATES: The workshop will be held on Wednesday, February 21, 2001 from 1:00 p.m. to 5:00 p.m. and on Thursday, February 22, 2001 from 8:30 a.m. through 4:00 p.m.

ADDRESSES: Two White Flint North Auditorium, 11545 Rockville Pike, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joe Golla, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415–1002 email: *JAG2@nrc.gov*.

SUPPLEMENTARY INFORMATION:

This workshop will provide an opportunity to discuss topics related to Option 2 in risk-informed regulations, as discussed in NRC documents SECY–99–256 and SECY–00–0194. The NRC is developing a rulemaking (referred to as Option 2) to revise, using a risk-informed categorization approach, the scope of structures, systems and components (SSC) that are subject to special treatment requirements. Such requirements include quality assurance, testing, qualification and other measures to provide a high degree of assurance that SSC will remain functional.

Based upon the comments received in response to the ANPR, other discussions with stakeholders, and staff views, the following presents the preliminary agenda and set of discussion topics. The discussion topics are tentative and subject to change. Anyone interested in providing a presentation on these or other related topic(s), please contact Joe Golla at (301) 415–1002.

Preliminary Agenda

2/21, 1:00 p.m.–1:30 p.m.; Introduction—purpose, agenda—NRC.

2/21, 1:30 p.m.–2 p.m.; Industry opening remarks—NEI/others?

2/21, 2:00 p.m.–2:30 p.m.; Keynote remarks by Frank Miraglia, Deputy Executive Director for Reactor Programs.

2/21, 2:30 p.m.–2:45 p.m.; Break.

2:45 p.m.–3:15 p.m.; Pilot activities (WOG, BWROG, CEOG).

3:15 p.m.–3:45 p.m.; ASME Code cases.

3:45 p.m.–4:15 p.m.; Industry Guidelines—NEI.

4:15 p.m.–5:00 p.m.; Other speakers?

2/22 8:30 a.m.–10:30 a.m.; SECY–00–194 topics.

8:30 a.m.–9:15 a.m.—Box chart (other categorization topics).

9:15 a.m.–9:30 a.m.—Candidate rules.

9:30 a.m.–10:00 a.m.—Selective implementation (systems).

10:00 a.m.–10:30 a.m.—Other topics as suggested by participants.

2/22 10:30 a.m. –10:45 a.m.; Break.

2/22 10:45 a.m.–12:00 noon—Detail, NRC review, change control.

2/22 12:00 noon–1:00 p.m.; Lunch.

2/22 1:00 p.m.–3:15 p.m.—Treatment requirements.

2/22 3:15 p.m.–3:30 p.m.; Break.

2/22 3:30 p.m.–4:00 p.m.; Closing Remarks/Adjourn.

Dated at Rockville, Maryland, this 7th day of January 2001.

For the Nuclear Regulatory Commission.

Cynthia A. Carpenter,

Chief, Generic Issues, Environmental, Financial and Rulemaking Branch, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 01–1365 Filed 1–16–01; 8:45 am]
BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–AEA–15]

Establishment of Class E Airspace; Seneca Falls, NY

AGENCY: Federal Aviation Administration [FAA], DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Seneca Falls, NY. An Area Navigation (RNAV) Standard Instrument Approach Procedure (SIAP) has been developed for Finger Lakes Regional Airport (0G7), Seneca Falls, NY. Controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain aircraft executing the approach. This action proposes to establish Class E airspace to Finger Lakes Regional Airport to contain aircraft executing the approach. The area would be depicted on aeronautical charts for pilot reference.

EFFECTIVE DATE: Comments must be received on or before February 16, 2001.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 00–AEA–15, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809.

The office docket may be examined in the Office of the Regional Counsel, AEA–7, F.A.A., Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A., Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 00–AEA–15". The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Regional Counsel, AEA–7, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class E airspace area at Seneca Falls, NY. An Area Navigation SIAP has been developed for Finger Lakes Regional Airport, Seneca Falls, NY. Controlled airspace extending upward from 700 feet AGL is needed to accommodate the approach. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979) and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration order 7400.9F dated September 1, 2000, and effective September 16, 2000, is proposed to be amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA NY E5, Seneca Falls, NY

Finger Lakes Regional Airport
(Lat. 4252.643 N-long 07646.885W)

That airspace extending upward from 700 feet above the surface within a 6 mile radius of Finger Lakes Regional Airport.

* * * * *

Issued in Jamaica, New York on January 2, 2001.

F.D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 01–1281 Filed 1–16–01; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–AWP–12]

Proposed Modification of Class E Airspace; Molokai, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to modify the Class E airspace area at Molokai, HI. The development of an Area Navigation (RNAV) Global Positioning System (GPS)–B Standard Instrument Approach Procedure (SIAP) to Kaunakakai/Molokai Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet above the surface is needed to contain aircraft executing the RNAV (GPS)–B SIAP to Kaunakakai/Molokai Airport. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Kaunakakai/Molokai Airport, Kaunakakai, HI.

DATES: Comments must be received on or before February 23, 2001.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP–520, Docket No. 00–AWP–12, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California, 90261.

The official docket may be examined in the Office of the Regional Counsel, Western-Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California, 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Jeri Carson, Air Traffic Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California, 90261, telephone (310) 725–6611.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis

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supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 00–AWP–12." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Airspace Branch, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Airspace Branch, 15000 Aviation Boulevard, Lawndale, California 90261. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to 14 CFR part 71 by modifying the Class E airspace area at Molokai, HI. The development of an RNAV (GPS)–B SIAP at Kaunakakai/Molokai Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet above the surface is needed to contain aircraft executing the RNAV (GPS)–B SIAP to Kaunakakai/Molokai Airport. The intended effect of this proposal is to provide adequate controlled airspace for aircraft executing the RNAV (GPS)–B SIAP at Kaunakakai/Molokai Airport, Kaunakakai, HI. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9H dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposed to amend 14 CFR part ~~71~~ as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP HI E5 Molokai, HI [Revised]

Kaunakakai/Molokai Airport, HI
(Lat. 21°09'11"N., long. 157°05'47"W
Molokai VORTAC
(Lat. 21°08'17"N., long. 157°10'03"W

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Kaunakakai/Molokai Airport and within 1.8 miles each side of the Molokai VORTAC 268° radial, extending from the 6.8-mile radius of Kaunkakai/Molokai Airport to 4.3 miles west of the Molokai VORTAC.

* * * * *

Issued in Los Angeles, California, on December 27, 2000.

John Clancy,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 01–1277 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106446–98]

RIN 1545–AW64

Relief From Joint and Several Liability

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to relief from joint and several liability under section 6015 of the Internal Revenue Code. The regulations reflect changes in the law made by the IRS Restructuring and Reform Act of 1998. The regulations provide guidance to married individuals filing joint returns who may seek relief from joint and several liability. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronically generated comments and requests to speak (with outlines of oral comments) at the public hearing scheduled for May 30, 2001, must be received by April 27, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–106446–98), room 5228, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–106446–98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax_regs/regslist.html*.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Bridget E. Finkenaur, 202–622–4940; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing, Guy Traynor, 202–622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O, Washington, DC 20224. Comments on the collection of information should be received by March 19, 2001. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.6015–5. Individuals may request relief from joint and several liability by timely filing Form 8857, "Request for Innocent Spouse Relief (And Separation of Liability and Equitable Relief)," or a written statement that contains the information required on Form 8857, that is signed under penalties of perjury. This collection of information is required in order for an individual to request relief from joint and several liability. This information will be used to carry out the internal revenue laws. The likely respondents are individuals.

The reporting burden contained in § 1.6015–5 is reflected in the burden of Form 8857. The estimated burden is: learning about the law or the form, 17 min.; preparing the form, 17 min.; and copying, assembling, and sending the form to the IRS, 20 min. The reporting burden contained in § 1.6015–5 for the statement signed under penalties of perjury is estimated as: learning about the law, 20 min.; preparing the statement signed under penalties of perjury, 30 min.; and copying, assembling, and sending the statement to the IRS, 20 min.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

Section 6013(d)(3) provides that spouses who file a joint Federal income tax return are jointly and severally liable for liabilities with respect to tax arising from that return. The term *tax* includes additions to tax, penalties, and interest. See sections 6665(a)(2) and 6601(e)(1). Joint and several liability allows the IRS to collect the entire liability from either spouse signing the joint return, without regard to whom the items of income, deduction, credit, or basis that gave rise to the liability are attributable. Before the enactment of the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105–206 (112 Stat. 685) (1998) (RRA), section 6013(e) provided the only relief from joint and several liability, and it only applied in very limited circumstances.

Section 3201 of the RRA repealed section 6013(e) and replaced it with section 6015. Section 6015 applies to liabilities that arise after July 22, 1998, and liabilities that arose prior to July 22, 1998, which remained unpaid as of that date. The provisions of section 6015 expand the relief available to spouses or former spouses who wish to be relieved from all or a portion of the joint and several liability arising from a joint individual Federal income tax return. Section 6015 makes the requirements for relief from joint and several liability, formerly in section 6013(e), less restrictive (section 6015(b)), and adds two other relief provisions. One provision, section 6015(c), permits the allocation of a deficiency between certain estranged spouses or former spouses in proportion to their respective erroneous items or in accordance with other allocation rules. The other provision, section 6015(f), gives the Secretary equitable discretion to grant relief from joint and several liability. The three relief provisions have different eligibility requirements and provide different types of relief.

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) that are necessary to carry out the provisions of section 6015. The proposed regulations provide detailed guidance on the three types of relief from joint and several liability under section 6015.

Explanation of Provisions

In General

To qualify for relief from joint and several liability, a *requesting spouse* (as defined in the regulations) must elect the application of section 6015(b) or 6015(c), or request equitable relief under section 6015(f), within 2 years of the first collection activity after July 22, 1998, with respect to the requesting spouse. Relief under section 6015 is only available for income taxes required under Subtitle A (including self-employment taxes). Relief is not available for other taxes reported on a taxpayer's income tax return (e.g., domestic services employment taxes under section 3510).

The proposed regulations define several terms, some of which are unique to specific provisions, and others of which are generally applicable to section 6015. One generally applicable term is an item. An item is generally defined as that which is required to be separately reported on an individual income tax return. However, amounts received from investments that are required to be separately reported on an individual income tax return and that are from the same source are aggregated and treated as one item. For example, assume an individual receives $700 in dividends and $1,000 in interest from X Co. Although dividends and interest are required to be separately reported on the individual's income tax return, they are considered one item for purposes of section 6015 because the dividends and interest are both from X Co. Items include, but are not limited to, gross income, deductions, credits, and basis. An erroneous item is defined as any item resulting in an understatement or deficiency in tax to the extent such item is omitted from, or improperly reported (including improperly characterized) on, an individual income tax return.

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Innocent Spouse Relief Under Section 6015(b)

In enacting section 6015, Congress focused, in part, on the limitations of section 6013(e). H.R. Conf. Rep. No. 599, 105th Cong., 2d Sess. 249 (1998). Thus, certain limitations under section 6013(e) have been eliminated in section 6015. For example, section 6013(e) required that there be a substantial understatement attributable to a grossly erroneous item, whereas section 6015(b) only requires that there be an understatement of an erroneous item. Another difference is that, unlike section 6013(e), section 6015(b) expressly provides for partial relief if a requesting spouse did not know, and had no reason to know, of only a portion of the understatement. One procedural difference is that a requesting spouse must now elect the application of section 6015(b).

Otherwise, section 6015(b) provides the same type of relief as was available under section 6013(e). In addition, as with section 6013(e), if a requesting spouse qualifies for relief under section 6015(b), refunds are available for amounts that the requesting spouse paid toward the liability for which relief was granted. Much of the language in section 6015(b) is identical to that of section 6013(e). Accordingly, the case law interpreting this language under section 6013(e) will be applied in interpreting the same language under section 6015(b).

The proposed regulations define *understatement* by reference to section 6662(d)(2)(A). Consistent with the interpretation of section 6013(e), the proposed regulations also clarify that "knowledge or reason to know" of an understatement exists only when either the requesting spouse actually knew of the erroneous item giving rise to the understatement, or a reasonable person in similar circumstances would have known of the item.

Allocation of Deficiency Under Section 6015(c)

Section 6015(c) is one of the new relief provisions added by section 3201 of the RRA. Section 6015(c) basically provides relief for an estranged or former spouse by allowing the requesting spouse to elect to limit the requesting spouse's liability for a deficiency to the portion of the deficiency allocated to the requesting spouse. As with section 6015(b), the relief under section 6015(c) must be elected. Unlike section 6015(b), refunds are not available under section 6015(c).

Of the three relief provisions in section 6015, section 6015(c) comes closest to being a mechanical test. Unlike the other two relief provisions, section 6015(c) does not require a determination that it would be inequitable to hold the requesting spouse liable in order for the requesting spouse to obtain relief. Several objective tests apply to determine whether a requesting spouse qualifies for relief. Among the requirements for relief under section 6015(c) is the requirement that the requesting spouse be divorced, widowed, or legally separated, or not have been a member of the same household as the nonrequesting spouse at any time during the 12-month period ending on the date an election for relief is filed. The proposed regulations provide rules for determining whether spouses are members of the same household in particular situations.

Relief under section 6015(c) is not available for the portion of a deficiency attributable to an erroneous item of the nonrequesting spouse if the Secretary demonstrates that the requesting spouse had actual knowledge of that item at the time the requesting spouse signed the joint return. If the requesting spouse had actual knowledge of only a portion of the erroneous item, partial relief may be available for the amount of the deficiency attributable to the portion of the item of which the requesting spouse did not have actual knowledge. Reason to know of an erroneous item or a portion thereof is not sufficient to disqualify a requesting spouse from relief under section 6015(c). Hence, it may be easier to qualify for relief under this provision than under section 6015(b).

Knowledge of an item means knowledge of the receipt or expenditure. It does not mean knowledge of the proper tax treatment of the item or how (or whether) it was actually reported on the return. This knowledge standard is consistent with the knowledge standard adopted by the United States Tax Court and other courts. See *Cheshire* v. *Commissioner*, 115 T.C. No. 15 (August 30, 2000) (knowledge requirement under section 6015(c) does not require requesting spouse to possess knowledge of the tax consequences arising from the erroneous item or that the item reported on the return is incorrect; rather the statute requires only a showing that the requesting spouse actually knew of the erroneous item); *Wiksell* v. *Commissioner*, 215 F.3d 1335 (9th Cir. 2000) (knowledge inquiry in section 6015(c) focuses on whether the taxpayer had knowledge of the erroneous item, not the tax consequences of that item). Also, under the proposed regulations, a requesting spouse could have actual knowledge of an erroneous item without necessarily knowing its source. Thus, if W knew that H received $1,000 of interest income, W would have actual knowledge of that item even if W thought that the interest was tax-exempt, or even if W did not know from whom the interest was received. Similarly, W would have actual knowledge of the item even if W had thought (incorrectly) that H had included the interest income on the return. A requesting spouse's failure to review a completed joint return will not negate a demonstration by the Secretary that the requesting spouse had actual knowledge of an item.

To demonstrate that a requesting spouse had actual knowledge of an erroneous item, the Secretary may rely upon all of the facts and circumstances. One relevant factor is whether the requesting spouse made an effort to be shielded from liability by deliberately avoiding learning about an item. Another relevant factor is whether the requesting spouse had an ownership interest in the property that gave rise to the item. The proposed regulations provide that joint ownership is a factor supporting a finding that the requesting spouse had actual knowledge of an erroneous item.

The proposed regulations also provide that the portion of the deficiency for which the requesting spouse remains liable is increased (up to the entire amount of the deficiency) by the value of any disqualified assets transferred to the requesting spouse by the nonrequesting spouse. Disqualified assets are defined as those assets transferred for the principal purpose of avoidance of tax or payment of tax. Any assets transferred during the period beginning 12 months before the mailing date of the first letter of proposed deficiency and continuing to the present are presumed to be disqualified assets. However, the requesting spouse can rebut the presumption by showing that the principal purpose of the transfer was not the avoidance of tax or payment of tax. In addition, the presumption does not apply to transfers of assets pursuant to a divorce or separate maintenance or child support agreement. The IRS and Treasury Department are particularly interested in receiving comments on whether there should be a de minimis exception to the presumption, and if so, the appropriate amount for such an exception.

If a requesting spouse qualifies to elect the application of section 6015(c), section 6015(d) generally provides that erroneous items are allocated between the spouses as if they had filed separate returns. In addition, section 6015(g) directs the Secretary to establish alternative methods of allocating erroneous items, other than the method in section 6015(d). Under the proposed regulations, erroneous income items are generally allocated to the spouse who earned the income or who owned the investment or business producing the income. If both spouses had an ownership interest in an investment or business, an erroneous income item from that investment or business is allocated between them in proportion to their respective ownership interests. Erroneous business or investment deductions are generally allocated to the spouse who owned the business or investment. If both spouses had an ownership in the business or investment, an erroneous deduction related to that business or investment is allocated between them in proportion to their respective ownership interests. Personal deductions are generally allocated 50% to each spouse, unless the evidence shows that a different allocation is appropriate.

Section 6015(d) also provides rules for allocating a deficiency. Under the proposed regulations, a portion of the deficiency is allocated under the "proportionate allocation method," that is, in proportion to each spouse's share of erroneous items. The proposed regulations provide additional rules regarding the allocation of other portions of the deficiency. First, any portion of the deficiency attributable to certain disallowed credits and taxes (other than income tax and alternative minimum tax) is allocated entirely to one spouse or the other. Second, any portion of the deficiency attributable to the liability of the child of the requesting or nonrequesting spouse is allocated under special rules. Third, any portion of the deficiency attributable to the alternative minimum tax under section 55 is allocated between the spouses in proportion to their individual shares of the total alternative minimum taxable income as defined under section 55(b)(2). Fourth, any portion of the deficiency attributable to accuracy-related penalties under section 6662 and fraud penalties under section 6663 is allocated to the spouse to whom the item giving rise to the penalty is allocable.

The proposed regulations provide one alternative allocation method, which must be used in place of the general allocation method when there are erroneous items taxed at different rates. This method ensures that the allocation of the liability is not skewed, for example, when the deficiency items consist of ordinary income items and capital gains.

Equitable Relief Under Section 6015(f)

Section 6015(f) is the other new relief provision that was added by section 3201 of the RRA. Section 6015(f) authorizes the Secretary to grant equitable relief from joint and several liability to requesting spouses who do not qualify for relief under section 6015(b) or 6015(c). The proposed regulations provide that the Secretary has the discretion to grant equitable relief and that the discretion may be exercised if it would be inequitable to hold the requesting spouse jointly and severally liable. Equitable relief is only available to requesting spouses who fail to qualify for relief under sections 6015(b) and 6015(c). However, section 6015(f) may not be used to circumvent the "no refund" rule of section 6015(c). Therefore, equitable relief under section 6015(f) is not available to refund liabilities already paid, for which the requesting spouse would otherwise qualify for relief under section 6015(c).

Section 6015(f) directs the Secretary to prescribe procedures regarding when equitable relief may be granted. These proposed regulations provide general information on section 6015(f) and refer individuals seeking more detailed guidance to the relevant revenue rulings, revenue procedures, or other published guidance issued on this topic. The detailed guidance on section 6015(f) is currently provided in Revenue Procedure 2000–15 (2000–5 I.R.B. 447).

Other Considerations

In addition to the three types of relief from joint and several liability, section 6015 has many provisions that are relevant when a requesting spouse elects relief under section 6015(b) or 6015(c), or requests relief under section 6015(f). The proposed regulations provide detailed guidance on these other provisions:

1. Types of Relief Considered

There are certain statutory consequences to electing the application of section 6015(b) or section 6015(c) (*e.g.*, suspension of the statute of limitations on collection). Therefore, the IRS will not automatically consider such relief unless the requesting spouse affirmatively elects the application of at least one of those sections. If a spouse requests relief under section 6015(f) alone, relief will only be considered under that section. However, if a requesting spouse elects the application of either section 6015(b) or 6015(c), the IRS will automatically consider whether the requesting spouse qualifies for relief under the other relief provisions of section 6015.

2. Time and Manner of Requesting Relief

Relief under section 6015 must be elected or requested within two years from the first *collection activity* (as defined in the proposed regulations) after July 22, 1998, against the requesting spouse with respect to the joint and several liability. In addition, relief may be elected or requested before the commencement of collection activity. However, the election may not be made, nor may relief be requested, before the taxpayer receives a notification of an audit or a letter or notice from the Secretary indicating that there may be an outstanding liability with regard to the joint return. The proposed regulations provide that the Secretary will not consider premature claims.

3. Determinations

The proposed regulations provide that a requesting spouse generally only receives one final determination of relief under section 6015. However, a second election under section 6015(c) may be considered, and a final determination may be rendered on that election, if, at the time of the second election, but not at the time of the first election, the requesting spouse is divorced, legally separated, widowed, or has not been a member of the same household as the nonrequesting spouse at any time during the 12-month period ending on the date the election was filed.

4. Community Property

Under section 6015 and the proposed regulations, the operation of community property law is not considered in determining to which spouse an erroneous item is allocable.

5. Duress

The proposed regulations amend § 1.6013–4 to clarify that if a spouse asserts and establishes that he or she signed a joint return under duress, then the return is not a joint return, and he or she is not jointly and severally liable for the liability arising from that return. Therefore, in such a case, relief from joint and several liability under section 6015 is not necessary and inapplicable.

Highlighted Issues

These proposed regulations contain detailed guidance on the three types of relief available under section 6015, as well as the other provisions contained in section 6015. Although public comment is sought on all of the issues in the proposed regulations, the IRS and Treasury Department are particularly interested in receiving comments on the issues highlighted below. These issues

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present the most challenge in administering section 6015(c).

1. *Knowledge:* The contrasting standards of the relief provisions are most evident in the respective knowledge limitations. Under section 6015(b), relief is not available unless the requesting spouse demonstrates that he or she had no knowledge or reason to know of the item giving rise to the understatement at the time the joint return was signed. In contrast, section 6015(c) provides that, assuming all of the qualifications are met, relief is available unless the Secretary demonstrates that the requesting spouse had actual knowledge of the item giving rise to the deficiency. Actual knowledge cannot be inferred from the requesting spouse's reason to know of the erroneous item. The Secretary bears the burden of proof with respect to the knowledge limitation of section 6015(c). In contrast, the requesting spouse bears the burden of proof with respect to the knowledge and reason to know limitations of section 6015(b). The IRS and Treasury Department are specifically seeking comments on the definition of *item*, because it is knowledge of an item that will disqualify a requesting spouse from receiving relief under sections 6015(b) and 6015(c).

2. *Alternative Allocation Methods:* Section 6015(g)(1) directs the Secretary to prescribe regulations providing alternative allocation methods, and the proposed regulations provide one that is discussed above. The proposed regulations also provide that additional alternative allocation methods may be provided in subsequent guidance. The IRS and Treasury Department are specifically interested in receiving comments about the alternative allocation method provided in the proposed regulations, and any other allocation methods that should be considered.

3. *Interests of the Nonrequesting Spouse:* It is anticipated that relief under section 6015 will be granted more frequently than it was under section 6013(e). Accordingly, section 6015 provides safeguards to protect nonrequesting spouses from erroneous determinations granting relief to their respective requesting spouses. The proposed regulations provide that the Secretary must give a nonrequesting spouse notice that the requesting spouse filed a claim for relief and an opportunity to participate in the determination of whether relief is appropriate.

In fashioning these safeguards, the IRS and Treasury Department are attempting to balance the rights and interests of both the requesting spouse and the nonrequesting spouse. A spouse who signs a joint return is jointly and severally liable for the entire liability, and the Secretary may collect the entire liability from either spouse. Therefore, a determination that one spouse is relieved of joint and several liability may have no legal effect on the amount of the other spouse's liability. However, a nonrequesting spouse does have a practical interest in the outcome of an innocent spouse determination because if the requesting spouse is relieved of liability, the IRS's only recourse is to collect that liability from the nonrequesting spouse. The IRS and Treasury Department recognize that Congress intended that the IRS take into account the nonrequesting spouse's views when it makes a determination of relief. See H.R. Conf. Rep. No. 599, 105th Cong., 2d Sess. 251, 255 (1998). In addition, information provided by a nonrequesting spouse is helpful in many cases to determine the appropriate amount of relief, if any.

Under the proposed regulations, a nonrequesting spouse will have an opportunity to participate in any administrative or judicial determination of relief. At the administrative level, the nonrequesting spouse may submit information relevant to the determination to the IRS employee making the determination. In addition, if the requesting spouse files a petition with the Tax Court, the nonrequesting spouse will be notified, and have an opportunity to become a party to the proceeding. See Interim Tax Court Rule 325.

Nonetheless, the IRS and Treasury Department recognize that some spouses may be reluctant to apply for relief from joint and several liability, or submit information regarding the other spouse's request for relief, due to privacy concerns or for fear of the other spouse's reprisal. To address this concern, the proposed regulations provide that, at the request of one spouse, the Secretary will omit from shared documents any information (*e.g.*, new name, address, employer) that would reasonably identify that spouse's location.

Special Analyses

It has been determined that these regulations are not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to the regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f), this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Comments and Public Hearing

Before the regulations are adopted as final regulations, consideration will be given to any written and electronic comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations, on how the proposed regulations can be made easier to understand, and on the highlighted issues. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 30, 2001, at 10 a.m., in the IRS Auditorium (7th Floor), Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed at the time to be devoted to each topic (signed original and eight (8) copies) by April 27, 2001.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of the regulations is Bridget E. Finkenaur of the Office of Associate Chief Counsel, Procedure and Administration (Administrative Provisions and Judicial Practice Division). However, other personnel from the IRS and Treasury Department participated in the development of the regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding the following entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.6015–1 also issued under 26 U.S.C. 6015(g).

§ 1.6015–2 also issued under 26 U.S.C. 6015(g).

§ 1.6015–3 also issued under 26 U.S.C. 6015(g).

§ 1.6015–4 also issued under 26 U.S.C. 6015(g).

§ 1.6015–5 also issued under 26 U.S.C. 6015(g).

§ 1.6015–6 also issued under 26 U.S.C. 6015(g).

§ 1.6015–7 also issued under 26 U.S.C. 6015(g).

§ 1.6015–8 also issued under 26 U.S.C. 6015(g).

§ 1.6015–9 also issued under 26 U.S.C. 6015(g). * * *

Par. 2. In § 1.6013–4, paragraph (d) is added to read as follows:

§ 1.6013–4 Applicable rules.

* * * * *

(d) *Return signed under duress.* If an individual asserts and establishes that he or she signed a return under legal duress, the return is not a joint return. The individual who signed such return under duress is not jointly and severally liable for the tax shown on the return or any deficiency in tax with respect to the return. The return is adjusted to reflect only the tax liability of the individual who voluntarily signed the return, and the liability is determined at the applicable rates in section 1(d). Section 6212 applies to the assessment of any deficiency in tax on such return.

Par. 3. Sections 1.6015–0 through 1.6015–9 are added to read as follows:

§ 1.6015–0 Table of contents.

This section lists captions contained in §§ 1.6015–1 through 1.6015–9.

§ 1.6015–1 Relief from joint and several liability on a joint return.

(a) In general.
(b) Duress.
(c) Prior closing agreement or offer in compromise.
(d) Fraudulent scheme.
(e) Res judicata and collateral estoppel.
(f) Community property laws.
(1) In general.
(2) Example.
(g) Definitions.
(1) Requesting spouse.
(2) Nonrequesting spouse.
(3) Item.
(4) Erroneous item.
(5) Election or request.
(h) Transferee liability.
(1) In general.
(2) Example.

§ 1.6015–2 Relief from liability applicable to all qualifying joint filers.

(a) In general.
(b) Understatement.
(c) Knowledge or reason to know.
(d) Inequity.
(e) Partial relief.
(1) In general.
(2) Example.

§ 1.6015–3 Allocation of liability for individuals who are no longer married, are legally separated, or are not members of the same household.

(a) Election to allocate liability.
(b) Definitions.
(1) Divorced.
(2) Legally separated.
(3) Not members of the same household.
(i) Temporary absences.
(ii) Separate dwellings.
(c) Limitations.
(1) No refunds.
(2) Actual knowledge.
(3) Disqualified asset transfers.
(i) In general.
(ii) Disqualified asset defined.
(iii) Presumption.
(4) Examples.
(d) Allocation.
(1) In general.
(2) Allocation of erroneous items.
(i) Benefit on the return.
(ii) Fraud.
(iii) Erroneous items of income.
(iv) Erroneous deduction items.
(3) Burden of proof.
(4) General allocation method.
(i) Proportionate allocation.
(ii) Separate treatment items.
(iii) Child's liability.
(iv) Allocation of certain items.
(A) Alternative minimum tax.
(B) Accuracy-related and fraud penalties.
(5) Examples.
(6) Alternative allocation methods.
(i) Allocation based on applicable tax rates.
(ii) Allocation methods provided in subsequent published guidance.
(iii) Example.

§ 1.6015–4 Equitable relief.

§ 1.6015–5 Time and manner for requesting relief.

(a) Requesting relief.
(b) Time period for filing a request for relief.
(1) In general.
(2) Definitions.
(i) Collection activity.
(ii) Date of levy or seizure.
(3) Requests for relief made before commencement of collection activity.
(4) Examples.
(5) Premature requests for relief.
(c) Effect of a final administrative determination.

§ 1.6015–6 Nonrequesting spouse's notice and opportunity to participate in administrative proceedings.

(a) In general.
(b) Information submitted.
(c) Effect of opportunity to participate.

§ 1.6015–7 Tax Court review.

(a) In general.
(b) Time period for petitioning the Tax Court.
(c) Restrictions on collection and suspension of the running of the period of limitations.
(1) Restrictions on collection under § 1.6015–2 or 1.6015–3.
(2) Suspension of the running of the period of limitations.
(i) Relief under § 1.6015–2 or 1.6015–3.
(ii) Relief under § 1.6015–4.
(3) Definitions.
(i) Levy.
(ii) Proceedings in court.
(iii) Assessment to which the election relates.

§ 1.6015–8 Applicable liabilities.

(a) In general.
(b) Liabilities paid on or before July 22, 1998.
(c) Examples.

§ 1.6015–9 Effective date.

§ 1.6015–1 Relief from joint and several liability on a joint return.

(a) *In general.* (1) An individual who qualifies and elects under section 6013 to file a joint Federal income tax return with another individual is jointly and severally liable for the joint Federal income tax liabilities for that year. However, a spouse or former spouse may be relieved of joint and several liability for any Federal income tax, self-employment tax, penalties, additions to tax, and interest for that year under the following three relief provisions:

(i) Innocent spouse relief under § 1.6015–2.

(ii) Allocation of deficiency under § 1.6015–3.

(iii) Equitable relief under § 1.6015–4.

(2) A requesting spouse may submit a single claim electing relief under both or either §§ 1.6015–2 and 1.6015–3, and requesting relief under § 1.6015–4. However, equitable relief under § 1.6015–4 is available only to a requesting spouse who fails to qualify for relief under §§ 1.6015–2 and 1.6015–3. If a requesting spouse elects the application of either § 1.6015–2 or 1.6015–3, the Secretary may consider

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whether relief is appropriate under the other elective provision and, to the extent relief is unavailable under either, under § 1.6015–4. If a requesting spouse seeks relief only under § 1.6015–4, the Secretary may not grant relief under § 1.6015–2 or 1.6015–3. A requesting spouse must affirmatively elect the application of § 1.6015–2 or 1.6015–3 in order for the Secretary to grant relief under one of those sections.

(3) Relief is not available for liabilities that are required to be reported on a joint Federal income tax return but are not income taxes imposed under Subtitle A of the Internal Revenue Code (e.g., domestic service employment taxes under section 3510).

(b) *Duress.* For rules relating to the treatment of returns signed under duress, see § 1.6013–4(d).

(c) *Prior closing agreement or offer in compromise.* A requesting spouse is not entitled to relief from joint and several liability under § 1.6015–2, § 1.6015–3, or § 1.6015–4 for any tax year for which the requesting spouse has entered into a closing agreement (other than an agreement entered into pursuant to section 6224(c) relating to partnership items) with the Commissioner that disposes of the same liability that is the subject of the claim for relief. In addition, a requesting spouse is not entitled to relief from joint and several liability under § 1.6015–2, § 1.6015–3, or § 1.6015–4 for any tax year for which the requesting spouse has entered into an offer in compromise with the Commissioner. For rules relating to the effect of closing agreements and offers in compromise, see sections 7121 and 7122, and the regulations thereunder.

(d) *Fraudulent scheme.* If the Secretary establishes that a spouse transferred assets to the other spouse as part of a fraudulent scheme, relief is not available under section 6015, and section 6013(d)(3) applies to the return.

(e) *Res judicata and collateral estoppel.* A requesting spouse is not entitled to relief from joint and several liability under § 1.6015–2 or 1.6015–3 for any tax year for which a court of competent jurisdiction has rendered a final determination on the requesting spouse's tax liability if the requesting spouse materially participated in the proceeding. A requesting spouse has not materially participated in a prior proceeding if, due to the effective date of section 6015, relief under section 6015 was not available in that proceeding. However, any final determinations made by a court of competent jurisdiction regarding issues relevant to § 1.6015–2, § 1.6015–3, or § 1.6015–4 are conclusive and may not be reconsidered, provided the requesting spouse materially participated in the prior court proceeding.

(f) *Community property laws*—(1) *In general.* In determining whether relief is available under § 1.6015–2, § 1.6015–3, or § 1.6015–4, items of income, credits, and deductions are generally allocated to the spouses without regard to the operation of community property laws. An erroneous item is attributed to the individual whose activities gave rise to such item. See § 1.6015–3(d)(2).

(2) *Example.* The following example illustrates the rule of this paragraph (f):

Example. (i) H and W are married and have lived in State A (a community property state) since 1987. On April 15, 2003, H and W file a joint Federal income tax return for the 2002 taxable year. In August 2005, the Internal Revenue Service proposes a $17,000 deficiency with respect to the 2002 joint return. A portion of the deficiency is attributable to $20,000 of H's unreported interest income from his individual bank account, the remainder of the deficiency is attributable to $30,000 of W's disallowed business expense deductions. Under the laws of State A, H and W each own ½ of all income earned and property acquired during the marriage.

(ii) In November 2005, H and W divorce and W timely elects to allocate the deficiency. Even though the laws of State A provide that ½ of the interest income is W's, for purposes of relief under this section, the $20,000 unreported interest income is allocable to H, and the $30,000 disallowed deduction is allocable to W. The community property laws of State A are not considered in allocating items for this purpose.

(g) *Definitions*—(1) *Requesting spouse.* A requesting spouse is an individual who filed a joint return and elects relief from Federal income tax liability arising from that return under § 1.6015–2 or § 1.6015–3, or requests relief from Federal income tax liability arising from that return under § 1.6015–4.

(2) *Nonrequesting spouse.* A nonrequesting spouse is the individual with whom the requesting spouse filed the joint return for the year for which relief from liability is sought.

(3) *Item.* An item is that which is required to be separately listed on an individual income tax return or any required attachments, subject to one exception: Amounts received from investments that are required to be separately reported on an individual income tax return and that are from the same source are aggregated and treated as a single item. Items include, but are not limited to, gross income, deductions, credits, and basis.

(4) *Erroneous item.* An erroneous item is any item resulting in an understatement or deficiency in tax to the extent that such item is omitted from, or improperly reported (including improperly characterized) on an individual income tax return. For example, unreported income from an investment asset resulting in an understatement or deficiency in tax is an erroneous item. Similarly, ordinary income that is improperly reported as capital gain resulting in an understatement or deficiency in tax is also an erroneous item. An erroneous item is also an improperly reported item that affects the liability on other returns (e.g., an improper net operating loss that is carried back to a prior year's return).

(5) *Election or request.* A qualifying election under § 1.6015–2 or § 1.6015–3, or request under § 1.6015–4, is the first timely claim for relief from joint and several liability for the tax year for which relief is sought. A qualifying election also includes a requesting spouse's second election to seek relief from joint and several liability for the same tax year under § 1.6015–3 when the additional qualifications of paragraph (g)(5) (i) and (ii) of this section are met—

(i) The requesting spouse did not qualify for relief under § 1.6015–3 when the Internal Revenue Service considered the first election because the qualifications of § 1.6015–3(a) were not satisfied; and

(ii) At the time of the second election, the qualifications for relief under § 1.6015–3(a) are satisfied.

(h) *Transferee liability*—(1) *In general.* The relief provisions of section 6015 do not negate liability that arises under the operation of other laws. Therefore, a requesting spouse who is relieved of joint and several liability under § 1.6015–2, § 1.6015–3, or § 1.6015–4 may nevertheless remain liable for the unpaid tax (including additions to tax, penalties, and interest) to the extent provided by Federal or state transferee liability or property laws. For the rules regarding the liability of transferees, see sections 6901 through 6904 and the regulations thereunder. In addition, the requesting spouse's property may be subject to collection under Federal or state property laws.

(2) *Example.* The following example illustrates the rule of this paragraph (h):

Example. H and W timely file their 1998 joint income tax return on April 15, 1999. H dies in March 2000, and the executor of H's estate transfers all of the estate's assets to W. In July 2001, the Internal Revenue Service assesses a deficiency for the 1998 return. The items giving rise to the deficiency are attributable to H. W is relieved of the liability under § 6015, and H's estate remains solely liable. The Internal Revenue Service may seek to collect the deficiency from W to the extent permitted under Federal or state transferee liability or property laws.

§ 1.6015–2 Relief from liability applicable to all qualifying joint filers.

(a) *In general.* A requesting spouse may be relieved of joint and several liability for tax (including additions to tax, penalties, and interest) from an understatement for a taxable year under this section if the requesting spouse elects the application of this section in accordance with §§ 1.6015–1(g)(5) and 1.6015–5, and—

(1) A joint return was filed for the taxable year;

(2) On the return there is an understatement attributable to erroneous items of the nonrequesting spouse;

(3) The requesting spouse establishes that in signing the return he or she did not know and had no reason to know of the item giving rise to the understatement; and

(4) It is inequitable to hold the requesting spouse liable for the deficiency attributable to the understatement.

(b) *Understatement.* The term *understatement* has the meaning given to such term by section 6662(d)(2)(A) and the regulations thereunder.

(c) *Knowledge or reason to know.* A requesting spouse has knowledge or reason to know of an erroneous item if he or she either actually knew of the item giving rise to the understatement, or if a reasonable person in similar circumstances would have known of the item giving rise to the understatement. For rules relating to a requesting spouse's actual knowledge, see § 1.6015–3(c)(2). All of the facts and circumstances are considered in determining whether a requesting spouse had reason to know of an erroneous item. The facts and circumstances that are considered include, but are not limited to, the nature of the item and the amount of the item relative to other items; the couple's financial situation; the requesting spouse's educational background and business experience; the extent of the requesting spouse's participation in the activity that resulted in the erroneous item; whether the requesting spouse failed to inquire, at or before the time the return was signed, about items on the return or omitted from the return that a reasonable person would question; and whether the erroneous item represented a departure from a recurring pattern reflected in prior years' returns (e.g., omitted income from an investment regularly reported on prior years' returns).

(d) *Inequity.* All of the facts and circumstances are considered in determining whether it is inequitable to hold a requesting spouse jointly and severally liable for an understatement. One relevant factor for this purpose is whether the requesting spouse significantly benefitted, directly or indirectly, from the understatement. A significant benefit is any benefit in excess of normal support. Evidence of direct or indirect benefit may consist of transfers of property or rights to property, including transfers that may be received several years after the year of the understatement. Thus, for example, if a requesting spouse receives property (including life insurance proceeds) from the nonrequesting spouse that is traceable to items omitted from gross income that are attributable to the nonrequesting spouse, the requesting spouse will be considered to have received significant benefit from those items. Other factors that may also be taken into account include the fact that the nonrequesting spouse has not fulfilled support obligations to the requesting spouse or the fact that the spouses have been divorced, legally separated, or not been members of the same household for at least the 12 months directly preceding the election. For more information on factors relevant to determining whether it is inequitable to hold a requesting spouse liable, see Rev. Proc. 2000–15 (2000–5 I.R.B. 447), or guidance subsequently published by the Secretary as described in § 1.6015–4(c).

(e) *Partial relief*—(1) *In general.* If a requesting spouse had no knowledge or reason to know of only a portion of an erroneous item, the requesting spouse may be relieved of the liability attributable to that portion of that item, if all other requirements are met with respect to that portion.

(2) *Example.* The following example illustrates the rules of this paragraph (e):

Example. H and W are married and file their 2004 joint income tax return in March 2005. In April 2006, H is convicted of embezzling $2 million from his employer during 2004. H kept all of his embezzlement income in an individual bank account, and he used most of the funds to support his gambling habit. However, each month during 2004, H transferred $10,000 from the individual account to H and W's joint bank account. W paid the household expenses using this joint account, and regularly received the bank statements relating to the account. W had no knowledge or reason to know of H's embezzling activities. However, W did have knowledge and reason to know of $120,000 of the $2 million of H's embezzlement income at the time she signed the joint return because that amount passed through the couple's joint bank account. Therefore, W may be relieved of the liability arising from $1,880,000 of the unreported embezzlement income, but she may not be relieved of the liability for the deficiency arising from $120,000 of the unreported embezzlement income of which she knew and had reason to know.

§ 1.6015–3 Allocation of deficiency for individuals who are no longer married, are legally separated, or are not members of the same household.

(a) *Election to allocate deficiency.* A requesting spouse may elect to allocate a deficiency if, as defined in paragraph (b) of this section, the requesting spouse is divorced, widowed, or legally separated, or has not been a member of the same household as the nonrequesting spouse at any time during the 12-month period ending on the date an election for relief is filed. Subject to the restrictions of paragraph (c) of this section, an eligible requesting spouse who elects the application of this section in accordance with §§ 1.6015–1(g)(5) and 1.6015–5 generally may be relieved of joint and several liability for the portion of any deficiency that is allocated to the nonrequesting spouse pursuant to the allocation methods set forth in paragraph (d) of this section. Relief may be available to both spouses filing the joint return if each spouse is eligible for and elects the application of this section.

(b) *Definitions*—(1) *Divorced.* A requesting spouse is divorced if the requesting spouse has a divorce decree that is recognized in the jurisdiction in which the requesting spouse resides.

(2) *Legally separated.* A requesting spouse is legally separated if the separation is recognized under the laws of the jurisdiction in which the requesting spouse resides.

(3) *Not members of the same household*—(i) *Temporary absences.* A requesting spouse and a nonrequesting spouse are considered members of the same household during either spouse's temporary absences from the household if it is reasonable to assume that the absent spouse will return to the household, and the household or a substantially equivalent household is maintained in anticipation of such return. Examples of temporary absences may include, but are not limited to, absence due to incarceration, hospitalization, business travel, vacation travel, military service, or education away from home.

(ii) *Separate dwellings.* A husband and wife who reside in the same dwelling are considered members of the same household. However, a husband and wife who reside in two separate

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dwellings, whether or not part of the same structure, are not considered members of the same household unless one is temporarily absent from the other's household within the meaning of paragraph (b)(3)(i) of this section.

(c) *Limitations*—(1) *No refunds.* Relief under this section is only available for unpaid liabilities resulting from understatements of liability. Refunds are not authorized under this section.

(2) *Actual knowledge.* (i) If the Secretary demonstrates that the requesting spouse had actual knowledge at the time the return was signed of an erroneous item that is allocable to the nonrequesting spouse, the election to allocate the deficiency attributable to that item is invalid, and the requesting spouse remains liable for the portion of the deficiency attributable to that item. For example, assume W received $5,000 of dividend income from her investment in X Co. but did not report it on the joint return. H knew that W received $5,000 of dividend income from X Co. that year. H had actual knowledge of the erroneous item (*i.e.*, $5,000 of unreported dividend income from X Co.), and no relief is available under this section for the deficiency attributable to the dividend income from X Co. If a requesting spouse had actual knowledge of only a portion of an erroneous item, then relief is not available for that portion of the erroneous item. For example, if H knew that W received $1,000 of dividend income and did not know that W received an additional $4,000 of dividend income, relief would not be available for the portion of the deficiency attributable to the $1,000 of dividend income of which H had actual knowledge. A requesting spouse's actual knowledge of the proper tax treatment of an item is not relevant for purposes of demonstrating that the requesting spouse had actual knowledge of an erroneous item. For example, assume H did not know W's dividend income from X Co. was taxable, but knew that W received the dividend income. Relief is not available under this provision. In addition, a requesting spouse's knowledge of how an erroneous item was treated on the tax return is not relevant to a determination of whether the requesting spouse had actual knowledge of the item. For example, assume that H knew of W's dividend income, but H failed to review the completed return and did not know that W omitted the dividend income from the return. Relief is not available under this provision.

(ii) Knowledge of the source of an erroneous item is not sufficient to establish actual knowledge. For example, assume H knew that W owned X Co. stock, but H did not know that X Co. paid dividends to W that year. H's knowledge of W's ownership in X Co. is not sufficient to establish that H had actual knowledge of the dividend income from X Co. In addition, a requesting spouse's actual knowledge may not be inferred when the requesting spouse merely had reason to know of the erroneous item. Even if H's knowledge of W's ownership interest in X Co. indicates a reason to know of the dividend income, actual knowledge of such dividend income cannot be inferred from H's reason to know.

(iii) To demonstrate that a requesting spouse had actual knowledge of an erroneous item at the time the return was signed, the Secretary may rely upon all of the facts and circumstances. One factor that may be relied upon in demonstrating that a requesting spouse had actual knowledge of an erroneous item is whether the requesting spouse made a deliberate effort to avoid learning about the item in order to be shielded from liability. This factor, together with all other facts and circumstances, may demonstrate that the requesting spouse had actual knowledge of the item. Another factor that may be relied upon in demonstrating that a requesting spouse had actual knowledge of an erroneous item is whether the requesting spouse and the nonrequesting spouse jointly owned the property that resulted in the erroneous item. Joint ownership is a factor supporting a finding that the requesting spouse had actual knowledge of an erroneous item. For purposes of this paragraph, a requesting spouse will not be considered to have had an ownership interest in an item based solely on the operation of community property law. Rather, a requesting spouse who resided in a community property state at the time the return was signed will be considered to have had an ownership interest in an item only if the requesting spouse's name appeared on the ownership documents, or there otherwise is an indication that the requesting spouse had a direct interest in the item. For example, assume H and W live in State A, a community property state. After their marriage, H opens a bank account in his name. Under the operation of the community property laws of state A, W owns ½ of the bank account. However, W does not have an ownership interest in the account for purposes of this paragraph (c)(2)(iii) because the account is not held in her name and there is no other indication that she has a direct interest in the item.

(3) *Disqualified asset transfers*—(i) *In general.* The portion of the deficiency for which a requesting spouse is liable is increased (up to the entire amount of the deficiency) by the value of any disqualified asset that was transferred to the requesting spouse. For purposes of this paragraph (c)(3), the value of a disqualified asset is the fair market value of the asset on the date of the transfer.

(ii) *Disqualified asset defined.* A disqualified asset is any property or right to property that was transferred from the nonrequesting spouse to the requesting spouse if the principal purpose of the transfer was the avoidance of tax or payment of tax (including additions to tax, penalties, and interest).

(iii) *Presumption.* Any asset transferred from the nonrequesting spouse to the requesting spouse during the 12-month period before the mailing date of the first letter of proposed deficiency (*e.g.*, a 30-day letter or, if no 30-day letter is mailed, a notice of deficiency) is presumed to be a disqualified asset. The presumption also applies to any asset that is transferred from the nonrequesting spouse to the requesting spouse after the mailing date of the first letter of proposed deficiency. However, the presumption does not apply if the requesting spouse establishes that the asset was transferred pursuant to a divorce decree or separate maintenance agreement. In addition, a requesting spouse may rebut the presumption by establishing that the principal purpose of the transfer was not the avoidance of tax or payment of tax.

(4) *Examples.* The following examples illustrate the rules in this paragraph (c):

Example 1. Actual knowledge of an erroneous item. (i) H and W file their 2001 joint Federal income tax return on April 15, 2002. On the return, H and W report W's self-employment income, but they do not report W's self-employment tax on that income. In August 2003, H and W receive a 30-day letter from the Internal Revenue Service proposing a deficiency with respect to W's unreported self-employment tax on the 2001 return. On November 4, 2003, H, who otherwise qualifies under paragraph (a) of this section, files an election to allocate the deficiency to W. The erroneous item is the self-employment income, and it is allocable to W. H knows that W earned income in 2001 as a self-employed musician, but he does not know that self-employment tax must be reported on and paid with a joint return.

(ii) H's election to allocate the deficiency to W is invalid because, at the time H signed the joint return, H had actual knowledge of W's self-employment income. The fact that H was unaware of the tax consequences of that income (i.e., that an individual is required to pay self-employment tax on that income) is not relevant.

Example 2. Actual knowledge not inferred from a requesting spouse's reason to know.

(i) H has long been an avid gambler. H supports his gambling habit and keeps all of his gambling winnings in an individual bank account, held solely in his name.

W knows about H's gambling habit and that he keeps a separate bank account, but she does not know whether he has any winnings because H does not tell her, and she does not otherwise know of H's bank account transactions. H and W file their 2001 joint Federal income tax return on April 15, 2002. On October 31, 2003, H and W receive a 30-day letter proposing a $100,000 deficiency relating to H's unreported gambling income. In February 2003, H and W divorce, and in March 2004, W files an election under section 6015(c) to allocate the $100,000 deficiency to H.

(ii) While W may have had reason to know of the gambling income because she knew of H's gambling habit and separate account, W did not have actual knowledge of the erroneous item (i.e., the gambling winnings). The Internal Revenue Service may not infer actual knowledge from W's reason to know of the income. Therefore, W's election to allocate the $100,000 deficiency to H is valid.

Example 3. Actual knowledge of return reporting position. (i) H and W are legally separated. In February 1999, W signs a blank joint Federal income tax return for 1998 and gives it to H to fill out. The return was timely filed on April 15, 1999. In September 2001, H and W receive a 30-day letter proposing a deficiency relating to $100,000 of unreported dividend income received by H with respect to stock of ABC Co. owned by H. W knew that H received the $100,000 dividend payment in August 1998, but she did not know whether H reported that payment on the joint return.

(ii) On January 30, 2002, W files an election to allocate the deficiency from the 1998 return to H. W claims she did not review the completed joint return, and therefore, she had no actual knowledge that there was an understatement of the dividend income. W's election to allocate the deficiency to H is invalid because she had actual knowledge of the erroneous item (dividend income from ABC Co.) at the time she signed the return. The fact that W signed a blank return is irrelevant. The result would be the same if W had not reviewed the completed return or if W had reviewed the completed return and had not noticed that the item was omitted.

(iii) Assume the same facts as in paragraph (i) of this *Example 3* except that, instead of receiving $100,000 of unreported dividend income, H received $50,000 of interest income from ABC Co. during the year (properly reported on the return) and $25,000 of dividend income from ABC Co. (omitted from the return). W knew that H received both dividend and interest income from ABC Co. but did not know the total was greater than $50,000. W's election to allocate to H the deficiency attributable to the omitted dividend income is valid. Although interest and dividend income are required to be separately stated on a joint Federal income tax return, they are one item in this case because the dividend and interest income are investment income received from the same source (ABC Co.). The erroneous item is the total dividend and interest income from ABC Co. W did not have actual knowledge of the erroneous item (combined dividend and interest income from ABC Co. greater than $50,000). Therefore, her election to allocate to H the deficiency attributable to the erroneous item is valid.

Example 4. Actual knowledge of an erroneous item of income. (i) H and W are legally separated. In June 2004, a deficiency is proposed with respect to H and W's 2002 joint Federal income tax return that is attributable to $30,000 of unreported income from H's plumbing business that should have been reported on a Schedule C. No Schedule C was attached to the return. At the time W signed the return, W knew that H had a plumbing business but did not know whether H received any income from the business. W's election to allocate to H the deficiency attributable to the $30,000 of unreported plumbing income is valid.

(ii) Assume the same facts as in paragraph (i) of this *Example 4* except that, at the time W signed the return, W knew that H received $20,000 of plumbing income. W's election to allocate to H the deficiency attributable to the $20,000 of unreported plumbing income (of which W had actual knowledge) is invalid. W's election to allocate to H the deficiency attributable to the $10,000 of unreported plumbing income (of which W did not have actual knowledge) is valid.

(iii) Assume the same facts as in paragraph (i) of this *Example 4* except that, at the time W signed the return, W did not know the exact amount of H's plumbing income. W did know, however, that H received at least $8,000 of plumbing income. W's election to allocate to H the deficiency attributable to $8,000 of unreported plumbing income (of which W had actual knowledge) is invalid. W's election to allocate to H the deficiency attributable to the remaining $22,000 of unreported plumbing income (of which W did not have actual knowledge) is valid.

(iv) Assume the same facts as in paragraph (i) of this *Example 4* except that H reported $26,000 of plumbing income on the return and omitted $4,000 of plumbing income from the return. At the time W signed the return, W knew that H was a plumber, but she did not know that H earned more than $26,000 that year. W's election to allocate to H the deficiency attributable to the $4,000 of unreported plumbing income is valid because she did not have actual knowledge that H received plumbing income in excess of $26,000.

(v) Assume the same facts as in paragraph (i) of this *Example 4* except that H reported only $20,000 of plumbing income on the return and omitted $10,000 of plumbing income from the return. At the time W signed the return, W knew that H earned at least $26,000 that year as a plumber. However, W did not know that, in reality, H earned $30,000 that year as a plumber. W's election to allocate to H the deficiency attributable to the $6,000 of unreported plumbing income (of which W had actual knowledge) is invalid. W's election to allocate to H the deficiency attributable to the $4,000 of unreported plumbing income (of which W did not have actual knowledge) is valid.

Example 5. Actual knowledge of a deduction that is an erroneous item. (i) H and W are legally separated. In February 2005, a deficiency is asserted with respect to their 2002 joint Federal income tax return. The deficiency is attributable to a disallowed $1,000 deduction for medical expenses H claimed he incurred. At the time W signed the return, W knew that H had not incurred any medical expenses. W's election to allocate to H the deficiency attributable to the disallowed medical expense deduction is invalid because W had actual knowledge that H had not incurred any medical expenses.

(ii) Assume the same facts as in paragraph (i) of this *Example 5* except that, at the time W signed the return, W did not know whether H had incurred any medical expenses. W's election to allocate to H the deficiency attributable to the disallowed medical expense deduction is valid because she did not have actual knowledge that H had not incurred any medical expenses.

(iii) Assume the same facts as in paragraph (i) of this *Example 5* except that the Internal Revenue Service disallowed $400 of the $1,000 medical expense deduction. At the time W signed the return, W knew that H had incurred some medical expenses but did not know the exact amount. W's election to allocate to H the deficiency attributable to the disallowed medical expense deduction is valid because she did not have actual knowledge that H had not incurred medical expenses (in excess of the floor amount under section 213(a)) of more than $600.

(iv) Assume the same facts as in paragraph (i) of this *Example 5* except that H claims a medical expense deduction of $10,000 and the Internal Revenue Service disallows $9,600. At the time W signed the return, W knew H had incurred some medical expenses but did not know the exact amount. W also knew that H incurred medical expenses (in excess of the floor amount under section 213(a)) of no more than $1,000. W's election to allocate to H the deficiency attributable to the portion of the overstated deduction of which she had actual knowledge ($9,000) is invalid. W's election to allocate the deficiency attributable to the portion of the overstated deduction of which she had no knowledge ($600) is valid.

Example 6. Disqualified asset presumption. (i) H and W are divorced. In May 1999, W transfers $20,000 to H, and in April 2000, H and W receive a 30-day letter proposing a $40,000 deficiency on their 1998 joint Federal income tax return. The liability remains unpaid, and in October 2000, H elects to allocate the deficiency under this section. Seventy-five percent of the net amount of erroneous items are allocable to W, and 25% of the net amount of erroneous items are allocable to H.

(ii) In accordance with the proportionate allocation method (see paragraph (d)(4) of this section), H proposes that $30,000 of the deficiency be allocated to W and $10,000 be allocated to himself. H submits a signed statement providing that the principal purpose of the $20,000 transfer was not the avoidance of tax or payment of tax, but he does not submit any documentation indicating the reason for the transfer. H has not overcome the presumption that the $20,000 was a disqualified asset. Therefore, the portion of the deficiency for which H is

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liable ($10,000) is increased by the value of the disqualified asset ($20,000). H is relieved of liability for $10,000 of the $30,000 deficiency allocated to W, and remains jointly and severally liable for the remaining $30,000 of the deficiency (assuming that H does not qualify for relief under any other provision).

Example 7. Disqualified asset presumption inapplicable. On May 1, 2001, H and W receive a 30-day letter regarding a proposed deficiency on their 1999 joint Federal income tax return relating to unreported capital gain from H's sale of his investment in Z stock. W had no actual knowledge of the stock sale. The deficiency is assessed in November 2001, and in December 2001, H and W divorce. According to the divorce decree, H must transfer ½ of his interest in mutual fund A to W. The transfer takes place in February 2002. In August 2002, W elects to allocate the deficiency to H. Although the transfer of ½ of H's interest in mutual fund A took place after the 30-day letter was mailed, the mutual fund interest is not presumed to be a disqualified asset because the transfer of H's interest in the fund was made pursuant to a divorce decree.

(d) *Allocation*—(1) *In general.* (i) An election to allocate a deficiency limits the requesting spouse's liability to that portion of the deficiency allocated to the requesting spouse pursuant to this section. Unless relieved of liability under § 1.6015–2 or § 1.6015–4, the requesting spouse remains liable for that portion of the deficiency allocated to the requesting spouse pursuant to this section.

(ii) Only a requesting spouse may receive relief. A nonrequesting spouse who does not also elect relief under this section remains liable for the entire amount of the deficiency, unless the nonrequesting spouse is relieved of liability under § 1.6015–2 or § 1.6015–4. If both spouses elect to allocate a deficiency under this section, there may be a portion of the deficiency that is not allocable, for which both spouses remain jointly and severally liable.

(2) *Allocation of erroneous items.* For purposes of allocating a deficiency under this section, erroneous items are generally allocated to the spouses as if separate returns were filed, subject to the following four exceptions:

(i) *Benefit on the return.* An erroneous item that would otherwise be allocated to the nonrequesting spouse is allocated to the requesting spouse to the extent that the requesting spouse received a tax benefit on the joint return.

(ii) *Fraud.* The Secretary may allocate any item appropriately between the spouses if the Secretary establishes that the allocation is appropriate due to fraud by one or both spouses.

(iii) *Erroneous items of income.* Erroneous items of income are allocated to the spouse who was the source of the income. Wage income is allocated to the spouse who performed the job producing such wages. Items of business or investment income are allocated to the spouse who owned the business or investment. If both spouses owned an interest in the business or investment, the erroneous item of income is generally allocated between the spouses in proportion to each spouse's ownership interest in the business or investment, subject to the limitations of paragraph (c) of this section. In the absence of clear and convincing evidence supporting a different allocation, an erroneous income item relating to an asset that the spouses owned jointly is generally allocated 50% to each spouse, subject to the limitations in paragraph (c) of this section and the exceptions in paragraph (d)(4) of this section. For information regarding the effect of community property laws, see § 1.6015–1(f) and paragraph (c)(2)(iii) of this section.

(iv) *Erroneous deduction items.* Erroneous deductions related to a business or investment are allocated to the spouse who owned the business or investment. If both spouses owned an interest in the business or investment, an erroneous deduction item is generally allocated between the spouses in proportion to each spouse's ownership interest in the business or investment. In the absence of clear and convincing evidence supporting a different allocation, an erroneous deduction item relating to an asset that the spouses owned jointly is generally allocated 50% to each spouse, subject to the limitations in paragraph (c) of this section and the exceptions in paragraph (d)(4) of this section. Personal deduction items are also generally allocated 50% to each spouse, unless the evidence shows that a different allocation is appropriate.

(3) *Burden of proof.* Except for establishing actual knowledge under paragraph (c)(2) of this section, the requesting spouse must prove that all of the qualifications for making an election under this section are satisfied and that none of the limitations (including the limitation relating to transfers of disqualified assets) apply. The requesting spouse must also establish the proper allocation of the erroneous items.

(4) *General allocation method*—(i) *Proportionate allocation.*

(A) The portion of a deficiency allocable to a spouse is the amount that bears the same ratio to the deficiency as the net amount of erroneous items allocable to the spouse bears to the net amount of all erroneous items. This calculation may be expressed as follows:

$$\frac{X}{\text{deficiency}} = \frac{\text{net amount of erroneous items allocable to the spouse}}{\text{net amount of all erroneous items}}$$

where X = the portion of the deficiency allocable to the spouse. Thus,

$$X = (\text{deficiency}) \times \frac{\text{net amount of erroneous items allocable to the spouse}}{\text{net amount of all erroneous items}}$$

(B) The proportionate allocation applies to any portion of the deficiency other than—

(1) Any portion of the deficiency attributable to erroneous items allocable to the nonrequesting spouse of which the requesting spouse had actual knowledge;

(2) Any portion of the deficiency attributable to separate treatment items (as defined in paragraph (d)(4)(ii) of this section);

(3) Any portion of the deficiency relating to the liability of a child (as defined in paragraph (d)(4)(iii) of this section) of the requesting spouse or nonrequesting spouse;

(4) Any portion of the deficiency attributable to alternative minimum tax under section 55;

(5) Any portion of the deficiency attributable to accuracy-related or fraud penalties;

(6) Any portion of the deficiency allocated pursuant to alternative allocation methods authorized under paragraph 6 of this section.

(ii) *Separate treatment items.* Any portion of a deficiency that is attributable to an item allocable solely to one spouse and that results from the disallowance of a credit, or a tax or an addition to tax (other than tax imposed by section 1 or section 55) that is required to be included with a joint return (a separate treatment item) is allocated separately to that spouse. Once the proportionate allocation is made, the liability for the requesting spouse's separate treatment items is added to the requesting spouse's share of the liability.

(iii) *Child's liability.* Any portion of a deficiency relating to the liability of a child of the requesting and nonrequesting spouse is generally allocated jointly to both spouses. However, if one of the spouses had sole custody of the child for the entire tax year for which the election relates, such portion of the deficiency is allocated solely to that spouse. For purposes of this paragraph, a child does not include the taxpayer's stepson or stepdaughter, unless such child was legally adopted by the taxpayer. If the child is the child of only one of the spouses, and the other spouse had not legally adopted such child, any portion of a deficiency relating to the liability of such child is allocated solely to the parent spouse.

(iv) *Allocation of certain items*—(A) *Alternative minimum tax.* Any portion of the deficiency attributable to alternative minimum tax under section 55 is allocated between the spouses in the same proportion as each spouse's share of the total alternative minimum taxable income, as defined in section 55(b)(2).

(B) *Accuracy-related and fraud penalties.* Any portion of the deficiency attributable to accuracy-related or fraud penalties under section 6662 or 6663 is allocated to the spouse whose item generated the penalty.

(5) *Examples.* The following examples illustrate the rules of this paragraph (d). In each example, assume that the requesting spouse or spouses qualify to elect to allocate the deficiency, that any election is timely made, and that the deficiency remains unpaid. In addition, unless otherwise stated, assume that neither spouse has actual knowledge of the erroneous items allocable to the other spouse. The examples are as follows:

Example 1. Allocation of erroneous items. (i) H and W file a 2003 joint Federal income tax return on April 15, 2004. On April 28, 2006, a deficiency is assessed with respect to their 2003 return. Three erroneous items give rise to the deficiency—

(A) Unreported interest income, of which W had actual knowledge, from H and W's joint bank account;

(B) A disallowed business expense deduction on H's Schedule C;

(C) A disallowed Lifetime Learning Credit for W's post-secondary education; and

(ii) H and W divorce in May 2006, and in September 2006, W timely elects to allocate the deficiency. The erroneous items are allocable as follows:

(A) The interest income would be allocated ½ to H and ½ to W, except that W has actual knowledge of it. Therefore, W's election to allocate the portion of the deficiency attributable to this item is invalid, and W remains jointly and severally liable for it.

(B) The business expense deduction is allocable to H.

(C) The Lifetime Learning Credit is allocable to W.

Example 2. Proportionate allocation. (i) W and H timely file their 2001 joint Federal income tax return on April 15, 2002. On August 16, 2004, a $54,000 deficiency is assessed with respect to their 2001 joint return. H and W divorce on October 14, 2004, and W timely elects to allocate the deficiency. Five erroneous items give rise to the deficiency—

(A) A disallowed $15,000 business deduction allocable to H;

(B) $20,000 of unreported income allocable to H;

(C) A disallowed $5,000 deduction for educational expense allocable to H;

(D) A disallowed $40,000 charitable contribution deduction allocable to W; and

(E) A disallowed $40,000 interest deduction allocable to W.

(ii) In total, there are $120,000 worth of erroneous items, of which $80,000 are attributable to W and $40,000 are attributable to H.

W's items		H's items
$40,000	charitable deduction	$15,000 business deduction
$40,000	interest deduction	$20,000 unreported income
$80,000		$ 5,000 education deduction
		$40,000

(iii) The ratio of erroneous items allocable to W to the total erroneous items is ⅔ ($80,000/$120,000). W's liability is limited to $36,000 of the deficiency (⅔ of $54,000). The Internal Revenue Service may collect up to $36,000 from W and up to $54,000 from H (the total amount collected, however, may not exceed $54,000). If H also made an election, there would be no remaining joint and several liability, and the Internal Revenue Service would collect $36,000 from W and $18,000 from H.

Example 3. Proportionate allocation with joint erroneous item. (i) On September 4, 2001, W elects to allocate a $3,000 deficiency for the 1998 tax year to H. Three erroneous items give rise to the deficiency—

(A) Unreported interest in the amount of $4,000 from a joint bank account;

(B) A disallowed deduction for business expenses in the amount of $2,000 attributable to H's business; and

(C) Unreported wage income in the amount of $6,000 attributable to W's second job.

(ii) The erroneous items total $12,000. Generally, income, deductions, or credits from jointly held property that are erroneous items are allocable 50% to each spouse. However, in this case, both spouses had actual knowledge of the unreported interest income. Therefore, W's election to allocate the portion of the deficiency attributable to this item is invalid, and W and H remain jointly and severally liable for this portion. Assume that this portion is $1,000. W may allocate the remaining $2,000 of the deficiency.

H's items	W's items
$2,000 business deduction	$6,000 wage income

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Total allocable items: $8,000

(iii) The ratio of erroneous items allocable to W to the total erroneous items is ¾ ($6,000/$8,000). W's liability is limited to $1,500 of the deficiency (¾ of $2,000) allocated to her. The Internal Revenue Service may collect up to $2,500 from W (¾ of the total allocated deficiency plus $1,000 of the deficiency attributable to the joint bank account interest) and up to $3,000 from H (the total amount collected, however, cannot exceed $3,000).

(iv) Assume H also elects to allocate the 1998 deficiency. H is relieved of liability for ¾ of the deficiency, which is allocated to W. H's relief totals $1,500 (¾ of $2,000). H remains liable for $1,500 of the deficiency (¼ of the allocated deficiency plus $1,000 of the deficiency attributable to the joint bank account interest).

Example 4. Separate treatment items (STIs). (i) On September 1, 2006, a $28,000 deficiency is assessed with respect to H and W's 2003 joint return. The deficiency is the result of 4 erroneous items—

(A) A disallowed Lifetime Learning Credit of $2,000 attributable to H;

(B) A disallowed business expense deduction of $8,000 attributable to H;

(C) Unreported income of $24,000 attributable to W; and

(D) Unreported self-employment tax of $14,000 attributable to W.

(ii) H and W both elect to allocate the deficiency.

(iii) The $2,000 Lifetime Learning Credit and the $14,000 self-employment tax are STIs totaling $16,000. The amount of erroneous items included in computing the proportionate allocation ratio is $32,000 ($24,000 unreported income and $8,000 disallowed business expense deduction). The amount of the deficiency subject to proportionate allocation is reduced by the amount of STIs ($28,000–$16,000 = $12,000).

(iv) Of the $32,000 of proportionate allocation items, $24,000 is allocable to W, and $8,000 is allocable to H.

W's share of allocable items	H's share of allocable items
3/4 ($24,000/$32,000)	1/4 ($8,000/$32,000)

(v) W's liability for the portion of the deficiency subject to proportionate allocation is limited to $9,000 (¾ of $12,000) and H's liability for such portion is limited to $3,000 (¼ of $12,000).

(vi) After the proportionate allocation is completed, the amount of the STIs is added to each spouse's allocated share of the deficiency.

W's share of total deficiency	H's share of total deficiency
$ 9,000 allocated deficiency	$3,000 allocated deficiency
$14,000 self-employment tax	$2,000 Lifetime Learning Credit
$23,000	$5,000

(vii) Therefore, W's liability is limited to $23,000 and H's liability is limited to $5,000.

Example 5. Allocation of the alternative minimum tax. (i) H and W file their 2004 joint Federal income tax return on April 15, 2005. During 2004, W's total alternative minimum taxable income was $120,000, and H's total alternative minimum taxable income was $30,000. All of H's income was from his business and was reported on Schedule C. Everything on the 2004 return was properly reported, and there was no alternative minimum tax liability. In 2005, H experienced a net operating loss of $25,000 for regular tax purposes. H did not have a net operating loss for alternative minimum tax purposes. In February 2006, H and W file an amended return for 2004 claiming the net operating loss that was carried back from 2005. The loss is a proper deduction, but it results in an alternative minimum tax liability, which H and W do not report on the amended return. In December 2007, a $5,500 deficiency is assessed on their 2004 joint Federal income tax return resulting from the unreported alternative minimum tax liability.

(ii) W and H divorce in January 2008, and W elects to allocate the deficiency.

W's AMT income for 2004: $120,000
H's AMT income for 2004: $ 30,000
Total AMT income for 2004: $150,000
W's share of AMT income for 2004: ⅘ ($120,000/$150,000)
H's share of AMT income for 2004: ⅕ ($30,000/$150,000)

(iii) W's liability is limited $4,400 (⅘ × $5,500). H remains liable for the entire deficiency because he did not make an election to allocate the deficiency.

Example 6. Requesting spouse receives a benefit on the joint return from the nonrequesting spouse's erroneous item. (i) In 2001, H earns gross income of $4,000 from his business, and W earns $50,000 of wage income. On their 2001 joint Federal income tax return, H deducts $20,000 of business expenses resulting in a net loss from his business of $16,000. H and W divorce in September 2002, and on May 22, 2003, a $5,200 deficiency is assessed with respect to their 2001 joint return. W elects to allocate the deficiency. The deficiency on the joint return results from a disallowance of all of H's $20,000 of deductions.

(ii) Since H used only $4,000 of the disallowed deductions to offset gross income from his business, W benefitted from the other $16,000 of the disallowed deductions used to offset her wage income. Therefore, $4,000 of the disallowed deductions are allocable to H and $16,000 of the disallowed deductions are allocable to W. W's liability is limited to $3,900 (¾ of $5,200). If H also elected to allocate the deficiency, H's election to allocate the $3,900 of the deficiency to W would be invalid because H had actual knowledge of the erroneous items.

Example 7. Calculation of requesting spouse's benefit on the joint return when the nonrequesting spouse's erroneous item is partially disallowed. Assume the same facts as in example 7, except that H deducts $18,000 for business expenses on the joint return, of which $16,000 are disallowed. Since H used only $2,000 of the $16,000 disallowed deductions to offset gross income from his business, W received benefit on the return from the other $14,000 of the disallowed deductions used to offset her wage income. Therefore, $2,000 of the disallowed deductions are allocable to H and $14,000 of the disallowed deductions are allocable to W. W's liability is limited to $4,550 (7/8 of $5,200).

(6) *Alternative allocation methods—*(i) *Allocation based on applicable tax rates.* If a deficiency arises from two or more erroneous items that are subject to tax at different rates (e.g., ordinary income and capital gain items), the deficiency is allocated after first separating the erroneous items into categories according to their applicable tax rate. After all erroneous items are categorized, a separate allocation is made with respect to each tax rate category using the proportionate allocation method of paragraph (d)(4) of this section.

(ii) *Allocation methods provided in subsequent published guidance.* The Secretary may prescribe alternative methods for allocating erroneous items under section 6015(c) in subsequent revenue rulings, revenue procedures, or other appropriate guidance.

(iii) *Example.* The following example illustrates the rules of this paragraph (d)(6):

Example. Allocation based on applicable tax rates. H and W timely file their 1998 joint Federal income tax return. H and W divorce in 1999. On July 13, 2001, a $5,100 deficiency is assessed with respect to H and W's 1998 return. Of this deficiency, $2,000 results from unreported capital gain of $6,000 that is attributable to W and $4,000 of capital gain that is attributable to H (both gains being subject to tax at the 20% marginal rate). The remaining $3,100 of the deficiency is attributable to $10,000 of unreported dividend income of H that is subject to tax at a marginal rate of 31%. H and W both timely elect to allocate the deficiency, and qualify under this section to do so. There are erroneous items subject to different tax rates; thus, the alternative allocation method of this paragraph (d)(6) applies. The three erroneous items are first categorized according to their applicable tax rates, then allocated. Of the total amount of 20% tax rate items ($10,000), 60% is allocable to W and 40% is allocable to H. Therefore, 60% of the $2,000 deficiency attributable to these items (or $1,200) is allocated to W. The remaining 40% of this portion of the deficiency ($800) is allocated to H. The only 31% tax rate item is allocable to H. Accordingly, H is liable for $3,900 of the deficiency ($800 + $3,100), and W is liable for the remaining $1,200.

§ 1.6015–4 Equitable relief.

(a) A requesting spouse who files a joint return for which a liability remains unpaid and who does not qualify for full relief under § 1.6015–2 or § 1.6015–3 may request equitable relief under this section. The Internal Revenue Service has the discretion to grant equitable relief from joint and several liability to a requesting spouse when, considering all of the facts and circumstances, it would be inequitable to hold the requesting spouse jointly and severally liable.

(b) This section may not be used to circumvent the limitation of § 1.6015–3(c)(1) (*i.e.*, no refunds under § 1.6015–3). Therefore, relief is not available under this section to refund liabilities already paid, for which the requesting spouse would otherwise qualify for relief under § 1.6015–3.

(c) The Secretary will provide the criteria to be used in determining whether it is inequitable to hold a requesting spouse jointly and severally liable under this section in revenue rulings, revenue procedures, or other published guidance.

§ 1.6015–5 Time and manner for requesting relief.

(a) *Requesting relief.* To elect the application of § 1.6015–2 or § 1.6015–3, or to request equitable relief under § 1.6015–4, a requesting spouse must file Form 8857, "Request for Innocent Spouse Relief (And Separation of Liability and Equitable Relief)"; submit a written statement containing the same information required on Form 8857, which is signed under penalties of perjury; or submit information in the manner as may be prescribed by the Secretary in relevant revenue rulings, revenue procedures, or other published guidance.

(b) *Time period for filing a request for relief—*(1) *In general.* To elect the application of § 1.6015–2 or § 1.6015–3, or to request equitable relief under § 1.6015–4, a requesting spouse must file Form 8857 or other similar statement with the Internal Revenue Service no later than two years from the date of the first collection activity against the requesting spouse after July 22, 1998, with respect to the joint tax liability.

(2) *Definitions—*(i) *Collection activity.* For purposes of this paragraph (b), collection activity means an administrative levy or seizure described by section 6331 to obtain property of the requesting spouse; an offset of an overpayment of the requesting spouse against a liability under section 6402; the filing of a suit by the United States against the requesting spouse for the collection of the joint tax liability; or the filing of a claim by the United States in a court proceeding in which the requesting spouse is a party or which involves property of the requesting spouse. Collection activity does not include a notice of intent to levy under sections 6330 and 6331(d); the filing of a Notice of Federal Tax Lien; or a demand for payment of tax. The term *property of the requesting spouse,* for purposes of this paragraph, means property in which the requesting spouse has an ownership interest (other than solely through the operation of community property laws), including property owned jointly with the nonrequesting spouse.

(ii) *Date of levy or seizure.* For purposes of this paragraph (b), if tangible personal property or real property is seized and is to be sold, a notice of seizure is required under section 6335(a). The date of levy or seizure is the date the notice of seizure is given. For more information on the rules regarding notice of seizure, see section 6502(b) and the regulations thereunder. For purposes of this paragraph (b), if a levy is made on cash or intangible personal property that will not be sold, the date of levy or seizure is the date the notice of levy is made. For more information on the rules regarding levy, see section 6331 and the regulations thereunder. For purposes of this paragraph (b), if a notice of levy is served by mail, the date of levy or seizure is the date of delivery of the notice of levy to the person on whom the levy is made. For more information on notices of levy served by mail, see § 301.6331–1(c) of this chapter.

(3) *Requests for relief made before commencement of collection activity.* An election or request for relief may be made before collection activity has commenced. For example, an election or request for relief may be made in connection with an audit or examination of the joint return, or pursuant to the pre-levy collection due process (CDP) hearing procedures pursuant to sections 6320 and 6330. For more information on the rules regarding pre-levy collection due process, see §§ 301.6320–1T(e)(1) and (2), and 301.6330–1T(e)(1) and (2) of this chapter. However, no request for relief may be made before the date specified in paragraph (b)(5) of this section.

(4) *Examples.* The following examples illustrate the rules of this paragraph (b):

Example 1. On January 11, 2000, a notice of intent to levy is mailed to H and W regarding their 1997 joint Federal income tax liability. The Internal Revenue Service levies on W's employer on June 5, 2000. The Internal Revenue Service levies on H's employer on July 10, 2000. W must elect or request relief by June 5, 2002, which is two years after the Internal Revenue Service levied on her wages. H must elect or request relief by July 10, 2002, which is two years after the Internal Revenue Service levied on his wages.

Example 2. The Internal Revenue Service levies on W's bank, in which W maintains a savings account, to collect a joint liability for 1995 on January 12, 1998. The bank complies with the levy, which only partially satisfies the liability. The Internal Revenue Service takes no other collection actions. On July 24, 2000, W elects relief with respect to the unpaid portion of the 1995 liability. W's election is timely because the Internal Revenue Service has not taken any collection activity after July 22, 1998; therefore, the two-year period has not commenced.

Example 3. Assume the same facts as in *Example 2,* except that the Internal Revenue Service delivers a second levy on the bank on July 23, 1998. W's election is untimely because it is filed more than two years after the first collection activity after July 22, 1998.

Example 4. H and W do not remit full payment with their timely filed joint Federal income tax return for the 1989 tax year. No collection activity is taken after July 22, 1998, until the United States files a suit against both H and W to reduce the tax assessment to judgment and to foreclose the tax lien on their jointly held residence on July 1, 1999. H elects relief on October 2, 2000. The election is timely because it is made within two years of the filing of a collection suit by the United States against H.

Example 5. W files a Chapter 7 bankruptcy petition on July 10, 2000. On September 5, 2000, the United States files a proof of claim for her joint 1998 income tax liability. W elects relief with respect to the 1998 liability on August 20, 2002. The election is timely because it is made within two years of the date the United States filed the claim in W's bankruptcy case.

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(5) *Premature requests for relief.* The Secretary will not consider premature claims for relief under § 1.6015–2, § 1.6015–3, or § 1.6015–4. A premature claim is a claim for relief that is filed for a tax year prior to the receipt of a notification of an audit or a letter or notice from the Secretary indicating that there may be an outstanding liability with regard to that year. Such notices or letters do not include notices issued pursuant to section 6223 relating to TEFRA partnership proceedings. A premature claim is not considered an election or request under § 1.6015–1(g)(5).

(c) *Effect of a final administrative determination*—(1) *In general.* A requesting spouse is entitled to only one final administrative determination of relief under § 1.6015–1 for a given assessment, unless the requesting spouse properly submits a second request for relief that is described in § 1.6015–1(g)(5).

(2) *Example.* The following example illustrates the rule of this paragraph (c):

Example. In January 2001, W invests in tax shelter P, and in February 2001, she starts her own business selling crafts, from which she earns $100,000 of net income for the year. H and W file a joint return for tax year 2001, on which they claim $20,000 in losses from their investment in P, and they omit W's self-employment tax. In March 2003, the Internal Revenue Service opens an audit under the provisions of subchapter C of chapter 63 of subtitle F of the Internal Revenue Code (TEFRA partnership proceeding) and sends H and W a notice under section 6223(a)(1). In September 2003, the Internal Revenue Service audits H and W's 2001 joint return regarding the omitted self-employment tax. H may file a claim for relief from joint and several liability for the self-employment tax liability because he has received a notification of an audit indicating that there may be an outstanding liability on the joint return. However, his claim for relief regarding the TEFRA partnership proceeding is premature under paragraph (b)(5) of this section. H will have to wait until the Internal Revenue Service sends him a notice of computational adjustment or assesses the liability from the TEFRA partnership proceeding on H and W's joint return before he files a claim for relief with respect to any such liability. The assessment relating to the TEFRA partnership proceeding is separate from the assessment for the self-employment tax; therefore, H's subsequent claim for relief for the liability from the TEFRA partnership proceeding is not precluded by his previous claim for relief from the self-employment tax liability under this paragraph (c).

§ 1.6015–6 Nonrequesting spouse's notice and opportunity to participate in administrative proceedings.

(a) *In general.* (1) When the Secretary receives an election under § 1.6015–2 or § 1.6015–3, or a request for relief under § 1.6015–4, the Secretary must send a notice to the nonrequesting spouse's last known address that informs the nonrequesting spouse of the requesting spouse's claim for relief. The notice must provide the nonrequesting spouse with an opportunity to submit any information that should be considered in determining whether the requesting spouse should be granted relief from joint and several liability. A nonrequesting spouse is not required to submit information under this section. The Secretary has the discretion to share with one spouse any of the information submitted by the other spouse. At the request of one spouse, the Secretary will omit from shared documents the spouse's new name, address, employer, telephone number, and any other information that would reasonably indicate the other spouse's location.

(2) The Secretary must notify the nonrequesting spouse of the Secretary's final determination with respect to the requesting spouse's claim for relief under section 6015. However, the nonrequesting spouse is not permitted to appeal such determination.

(b) *Information submitted.* The Secretary will consider all of the information (as relevant to each particular relief provision) that the nonrequesting spouse submits in determining whether relief from joint and several liability is appropriate, including information relating to the following—

(1) The legal status of the requesting and nonrequesting spouses' marriage;

(2) The extent of the requesting spouse's knowledge of the erroneous items or underpayment;

(3) The extent of the requesting spouse's knowledge or participation in the family business or financial affairs;

(4) The requesting spouse's education level;

(5) The extent to which the requesting spouse benefitted from the erroneous items;

(6) Any asset transfers between the spouses;

(7) Any indication of fraud on the part of either spouse;

(8) Whether it would be inequitable, within the meaning of §§ 1.6015–2(d) and 1.6015–4(b), to hold the requesting spouse jointly and severally liable for the outstanding liability;

(9) The allocation or ownership of items giving rise to the deficiency; and

(10) Anything else that may be relevant to the determination of whether relief from joint and several liability should be granted.

(c) *Effect of opportunity to participate.* The failure to submit information pursuant to paragraph (b) of this section does not affect the nonrequesting spouse's ability to seek relief from joint and several liability for the same tax year. However, information that the nonrequesting spouse submits pursuant to paragraph (b) of this section is relevant in determining whether relief from joint and several liability is appropriate for the nonrequesting spouse should the nonrequesting spouse also submit an application for relief.

§ 1.6015–7 Tax Court review.

(a) *In general.* Requesting spouses may petition the Tax Court to review the denial of relief under § 1.6015–1.

(b) *Time period for petitioning the Tax Court.* Pursuant to section 6015(e), the requesting spouse may petition the Tax Court to review a denial of relief under § 1.6015–1 within the 90-day period beginning on the date the final determination letter is mailed. If the Secretary does not mail the requesting spouse a final determination letter within 6 months of the date the requesting spouse files an election under § 1.6015–2 or § 1.6015–3, the requesting spouse may petition the Tax Court to review the election at any time after the expiration of the 6-month period, and before the expiration of the 90-day period beginning on the mailing date of the final determination letter. The Tax Court also may review a claim for relief if Tax Court jurisdiction has been acquired under section 6213(a) or 6330(d). For rules regarding petitioning the Tax Court under section 6213(a) or 6330(d), see §§ 301.6213–1, 301.6330–1T(f), and 301.6330–1T(g) of this chapter.

(c) *Restrictions on collection and suspension of the running of the period of limitations*—(1) *Restrictions on collection under § 1.6015–2 or 1.6015–3.* Unless the Secretary determines that collection will be jeopardized by delay, no levy or proceeding in court shall be made, begun, or prosecuted against a requesting spouse electing the application of § 1.6015–2 or § 1.6015–3 for the collection of any assessment to which the election relates until the expiration of the 90-day period described in paragraph (b) of this section, or if a petition is filed with the Tax Court, until the decision of the Tax Court becomes final under section 7481. Notwithstanding the preceding sentence, if the requesting spouse appeals the Tax Court's determination, the Internal Revenue Service may resume collection of the liability from the requesting spouse on the date of the Tax Court's determination unless the requesting spouse files an appeal bond pursuant to the rules of section 7485. For more information regarding the date on which a decision of the Tax Court becomes final, see section 7481 and the regulations thereunder. Jeopardy under this paragraph (c)(1) means conditions exist that would require an assessment under section 6851 or 6861 and the regulations thereunder.

(2) *Suspension of the running of the period of limitations*— (i) *Relief under § 1.6015–2 or 1.6015–3.* The running of the period of limitations in section 6502 on collection against the requesting spouse of the assessment to which an election under § 1.6015–2 or § 1.6015–3 relates is suspended for the period during which the Commissioner is prohibited by paragraph (c)(1) of this section from collecting by levy or a proceeding in court and for 60 days thereafter.

(ii) *Relief under § 1.6015–4.* If a requesting spouse seeks only equitable relief under § 1.6015–4, the restrictions on collection of paragraph (c)(1) of this section do not apply. The request for relief does not suspend the running of the period of limitations on collection.

(3) *Definitions*—(i) *Levy.* For purposes of this paragraph (c), levy means an administrative levy or seizure described by section 6331.

(ii) *Proceedings in court.* For purposes of this paragraph (c), proceedings in court means suits filed by the United States for the collection of Federal tax. Proceedings in court does not refer to the filing of pleadings and claims and other participation by the Commissioner or the United States in suits not filed by the United States, including Tax Court cases, refund suits, and bankruptcy cases.

(iii) *Assessment to which the election relates.* For purposes of this paragraph (c), the assessment to which the election relates is the entire assessment of the deficiency to which the election relates, even if the election is made with respect to only part of that deficiency.

§ 1.6015–8 Applicable liabilities.

(a) *In general.* Sections 6015(b), 6015(c), and 6015(f) apply to liabilities that arise after July 22, 1998, and to liabilities that arose prior to July 22, 1998, that were not paid on or before July 22, 1998.

(b) *Liabilities paid on or before July 22, 1998.* A requesting spouse seeking relief from joint and several liability for amounts paid on or before July 22, 1998, must request relief under section 6013(e) and the regulations thereunder.

(c) *Examples.* The following examples illustrate the rules of this section:

Example 1. H and W file a joint income tax return for 1995 on April 15, 1996. There is an understatement on the return attributable to an omission of H's wage income. On October 15, 1998, H and W receive a 30-day letter proposing a deficiency on the 1995 joint return. W pays the outstanding liability in full on November 30, 1998. In March 1999, W files Form 8857, requesting relief from joint and several liability under section 6015(b). Although W's liability arose prior to July 22, 1998, it was unpaid as of that date. Therefore, section 6015 is applicable.

Example 2. H and W file their 1995 joint income tax return on April 15, 1996. On October 14, 1997, a deficiency is assessed regarding a disallowed business expense deduction attributable to H. On June 30, 1998, the Internal Revenue Service levies on W's bank account in full satisfaction of the outstanding liability. On August 31, 1998, W files a request for relief from joint and several liability. The liability arose prior to July 22, 1998, and it was paid as of July 22, 1998. Therefore, section 6015 is not applicable and section 6013(e) is applicable.

§ 1.6015–9 Effective date.

Sections 1.6015–0 through 1.6015–9 are applicable for all elections under § 1.6015–2 or § 1.6015–3 or any request for relief under § 1.6015–4 filed on or after federal regulations are published in the **Federal Register**.

Charles Rossotti,

Commissioner of Internal Revenue.

[FR Doc. 01–8 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106030–98]

RIN 1545–AW50

Source of Income from Certain Space and Ocean Activities; Also, Source of Communications Income

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations under section 863(d) governing the source of income from certain space and ocean activities. It also contains proposed regulations under sections 863(a), (d), and (e) governing the source of income from certain communications activity. This document also contains proposed regulations under sections 863(a) and (b), amending the regulations in § 1.863–3 to conform those regulations with these proposed regulations. This document affects persons who conduct activities in space, or on or under water not within the jurisdiction of a foreign country, possession of the United States, or the United States (collectively, in international water). This document also affects persons who derive income from transmission of communications.

In addition, this document provides notice of a public hearing on these proposed regulations.

DATES: Comments and outlines of oral comments to be presented at the public hearing scheduled for March 28, 2001, at 10 a.m. must be received by March 7, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (Reg–106030–98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–106030–98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at: http://www.irs.ustreas.gov/tax_regs/regslist.html. The public hearing will be held in the auditorium, seventh floor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Anne Shelburne, (202) 874–1490; concerning submissions and the hearing, and/or to be placed on the building access list to attend the hearing, La Nita Van Dyke, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O, Washington, DC 20224. Comments on the collection of information should be received by March 19, 2001. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

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How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information requirements are in proposed § 1.863–8(g) and in § 1.863–9(g). This information is required by the IRS to monitor compliance with the federal tax rules for determining the source of income from space or ocean activities, or from transmission of communications. The likely respondents are taxpayers who conduct space or ocean activities, or who derive communications income. Responses to this collection of information are required to properly determine the source of a taxpayer's income from such transactions.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Estimated total annual reporting/recordkeeping burden: 1,200 hours. The estimated annual burden per respondent varies from 3 hours to 7 hours, depending on individual circumstances, with an estimated average of 5 hours.

Estimated number of respondents: 250.

Estimated annual frequency of responses: One time per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

Background

This document contains proposed regulations relating to the Income Tax Regulations (CFR part 1) under sections 863(a), (b), (d), and (e) of the Internal Revenue Code (Code). Congress enacted section 863(d) and section 863(e) as part of the Tax Reform Act of 1986 (Public Law 99–514, 100 Stat. 2085) (the 1986 Act). Section 863(d) governs the source of income derived from certain space and ocean activities. Section 863(e) governs the source of income derived from international communications activity.

Explanation of Provisions

These proposed regulations provide two sets of rules, one in § 1.863–8 for determining the source of income from space and ocean activities, the other in § 1.863-9 for determining the source of income from communications activity. Section 1.863–9 provides rules for both international communications income (ICI) and other communications income. The IRS and Treasury believe it is appropriate to provide source rules for both ICI and other communications income in a single regulation.

The IRS and Treasury are fully aware of the rapid technological evolution in the space and communications industries since Congress enacted sections 863(d) and (e) in 1986, and have attempted to take into account these changes as well as changes in the space and communications industries and business practices and business models. The IRS and Treasury recognize that these regulations address important issues for many different industries and have worked closely with the industries in drafting these rules. The IRS and Treasury are interested in receiving comments from these industries on how to accommodate issues arising from the use of new technologies, consistent with the language and purpose of the statutory provisions.

A. Space and Ocean Activity Under Section 863(d)

1. Scope of § 1.863–8 of the Proposed Regulations

Section 1.863–8 of the proposed regulations provides rules for sourcing income derived from space and ocean activity, notwithstanding other sections. Proposed regulations § 1.863–8(a) provides that a taxpayer derives income from a space or ocean activity only if the taxpayer conducts such activity directly. This is consistent with the approach that IRS and Treasury adopted in the § 1.863–3 regulations sourcing income from inventory sales.

2. Source of Gross Income From Space or Ocean Activity

a. *General.* Section 863(d)(1) states that, except as provided in regulations, any income derived from space or ocean activity by a U.S. person will be U.S. source income, and if derived by a foreign person, foreign source income. Proposed regulations § 1.863-8(b)(1) provides that a U.S. person's space or ocean income is U.S. source. Proposed regulations § 1.863–8(b)(1) also states the general rule that income derived by a foreign person from a space or ocean activity is foreign source income. However, the proposed regulations contain several exceptions to that general rule.

Proposed regulations § 1.863–8(b)(2) provides that if a foreign corporation is 50 percent or more owned by vote or value (directly, indirectly, or constructively) by U.S. persons and is not a controlled foreign corporation within the meaning of section 957 (CFC), all income derived by the corporation from space or ocean activity is U.S. source income. This rule reflects IRS and Treasury's concern that U.S. persons may use a foreign corporation (for example, by incorporating a 50/50 joint venture with a foreign person, thereby avoiding CFC status) to obtain results that are inconsistent with the purposes of this section. The IRS and Treasury believe Congress granted Treasury broad regulatory authority in section 863(d) to prevent taxpayers from circumventing the purposes of this section.

Proposed regulations § 1.863–8(b)(3) provides that if a foreign person is engaged in a U.S. trade or business, the foreign person's income derived from a space or ocean activity is presumed to be U.S. source income. The rule reflects IRS and Treasury's concern that a foreign person could engage in significant economic activities in the United States and avoid U.S. taxation of space or ocean income derived from such activities. For example, a foreign satellite company established in a no-tax jurisdiction could engage in substantial activity in the United States through launch facilities, yet pay no U.S. or foreign tax on income arising from leasing the satellites it launches. The IRS and Treasury believe Congress intended that a foreign person engaged in substantial U.S. business in the United States be subject to U.S. tax on related space or ocean activity.

The IRS and Treasury recognize that the presumption may be over-inclusive in certain cases. Therefore, the proposed regulations provide that if the foreign person can allocate gross space or ocean income between income from sources within the United States, space, or international water, and outside the United States and space and international water, to the satisfaction of the Commissioner, based on the facts and circumstances, which may include functions performed, resources employed, risks assumed, or other contributions to value, income from outside the United States and space and international water will be treated as foreign source income. When a foreign person is entitled to the benefits of a tax treaty with the United States, such person may elect to be taxed under the rules of that treaty, so that, for example, the United States would tax only income attributable to a permanent establishment of that foreign person, regardless of the amount of income considered effectively connected with a U.S. trade or business.

b. *Source Rules for Sales of Certain Property.* Taxpayers must apply the rules of section 863(d) and these proposed regulations to determine the source of income from sales of property purchased or produced by the taxpayer, either when production occurs in whole or in part in space or in international water, or when the sale occurs in space or in international water. The rules of sections 861, 862, 863(a) and (b), and 865, and the regulations thereunder apply only to the extent provided in proposed regulations § 1.863–8(b)(4).

Proposed regulations § 1.863–8(b)(4)(i) provides that income derived from the sale of purchased property in space or international water is sourced under paragraph (b)(1), (2), or (3) of this section. Proposed regulations § 1.863–8(d)(2)(iii) provides that a sale occurs in space or international water if either property is located in space or international water at the time the rights, title, and interests pass to the purchaser, or the property sold is for use in space or international water. This rule for determining if a sale takes place in space or in international water modifies for space and ocean activity the rule in § 1.861–7(c) for otherwise determining where a sale takes place. The IRS and Treasury believe this rule for determining the place of sale in the case of space or ocean activity is consistent with the legislative history of section 863(d), indicating Congress intended that space and ocean activity be broadly defined. See S. Rept. No. 313, 99th Cong., 2d Sess. 357 (1986) (Senate Report). It is also consistent with the language of the Senate Report stating that the committee did not intend to override the title passage rule for sales of property on the high seas. Consistent with this language, proposed regulations § 1.863–8(d)(1)(ii) excludes from the definition of ocean activity the sale of inventory on international water, and the source of income from such sales continues to be determined under § 1.861–7(c).

Proposed regulations § 1.863–8(b)(4)(ii) provides rules for income derived from the sale of property produced by the taxpayer. To determine the source of income derived from the sale of property produced by the taxpayer, proposed regulations § 1.863–8(b)(4)(ii)(A) provides that the taxpayer must divide gross income from such sale equally between production activity and sales activity. Thus, one-half of the taxpayer's gross income is attributed to production activity, and the other one-half of such gross income is attributed to sales activity.

Proposed regulations § 1.863–8(b)(4)(ii)(A) provides that income attributable to sales activity is sourced applying the rules applicable to the sale of purchased property. If the taxpayer sells such property in space or international water, the source of income attributable to sales activity is determined under paragraph (b)(1), (2), or (3). If the taxpayer sells such property outside space and outside international water, the source of income attributable to sales activity is determined under § 1.863–3(c)(2). Proposed regulations § 1.863–8(b)(4)(ii)(B) provides that income attributable to production activity, when production occurs only in space or in international water, is sourced under paragraphs (b)(1), (2), or (3). When production occurs only outside space and international water, income attributable to production activity is sourced under § 1.863-3(c)(1). When production activity occurs both in space or in international water and outside space and international water, proposed regulations § 1.863–8(b)(4)(ii)(C) splits the income attributed to production activity between production activities occurring in space or in international water, and production activities occurring outside space and international water. Gross income must be allocated to the satisfaction of the Commissioner, based on all relevant facts and circumstances, which may include functions performed, resources employed, risks assumed, and any other contributions to the value of the property. The source of gross income attributable to production activities in space or in international water is sourced under paragraphs (b)(1), (2), or (3). The source of gross income attributable to production activities outside space and international water is determined under § 1.863–3(c)(1).

c. *Special Rule for Determining the Source of Income from Services.* Proposed regulations § 1.863–8(b)(5) provides that income derived from the performance of services in space or in international water is sourced under paragraph (b)(1), (2), or (3). Proposed regulations § 1.863–8(d)(2)(ii)(A) provides that a performance of a service is a space or ocean activity when a part of the service, even if de minimis, is performed in space or in international water. The IRS and Treasury believe that Congress intended a broad range of activities be treated as space or ocean activities.

The IRS and Treasury recognize that this rule may be over-inclusive in certain cases. Therefore, proposed regulations § 1.863–8(b)(5) provides that the taxpayer can allocate gross income derived from the performance of the service between activities that occur in space or international water and activities that occur outside space and international water, to the satisfaction of the Commissioner, based on facts and circumstances, which may include functions performed, resources employed, risks assumed, or other contributions to value. Gross income allocated to activities occurring outside space and international water will be sourced under sections 861, 862, 863, and 865 of the Code.

d. *Special Rule for Determining the Source of Communications Income.* A communications activity, as defined in proposed regulations § 1.863–9(d), also can be a space or ocean activity. Pursuant to the authority granted in section 863(d)(1), proposed regulations § 1.863–8(b)(6) provides that income from communications activity that is also a space or ocean activity is sourced under proposed regulations § 1.863–9(b).

3. Taxable Income

When a taxpayer allocates gross income under paragraph (b)(3) (allocation for certain foreign persons), paragraph (b)(4)(ii)(C) (allocation between production occurring in space or international water and production occurring outside), or paragraph (b)(5) (allocation between services occurring in space or international water and those occurring outside) of this section, the taxpayer must allocate or apportion expenses, losses, and other deductions under §§ 1.861–8 through 1.861–14T of the regulations to the class of gross income, which must include the total income so allocated in each case. A taxpayer must then apply the rules of §§ 1.861–8 through 1.861–14T to properly allocate or apportion amounts of expenses, losses, and other deductions allocated or apportioned to such class of gross income between gross income from sources within the United States and without the United States.

When a taxpayer must allocate gross income to the satisfaction of the Commissioner based on the facts and circumstances, IRS and Treasury believe that such allocations would be based generally on section 482 principles. However, IRS and Treasury solicit comments on this approach, including specific comments and examples on

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alternative methods that could be used to make these allocations.

4. Definition of Space and Ocean Activity

a. *General Rules.* Section 863(d)(2) provides that space or ocean activity means any activity conducted in space, and any activity conducted in or under water not within the jurisdiction of the United States or a foreign country. Proposed regulations § 1.863–8(d)(1)(i) defines space as any area not within the jurisdiction (as recognized by the United States) of a foreign country, possession of the United States, or the United States, and not in international water.

Proposed regulations § 1.863–8(d)(1)(i) provides that space activity is any activity conducted in space, with certain exceptions. Space activity includes performance and provision of services in space, leasing of equipment or other property, including spacecraft (e.g., satellites) or transponders, located in space, licensing of technology or other intangibles for use in space, and the production, processing, or creation of property in space. Space activity includes the sale of property in space. Space activity also includes underwriting income from the insurance of risks on activities that produce income derived from space activity. The inclusion of such underwriting income is consistent with language in the Senate Report. See Senate Report at 357.

Proposed regulations § 1.863–8(d)(1)(ii) provides that ocean activity is any activity conducted in international water, with certain exceptions. Ocean activity includes performance and provision of services in international water, leasing of equipment or other property located in international water, licensing of technology or other intangibles for use in international water, and the production, processing, or creation of property in international water. Ocean activity includes the sale of property in international water, and the sale of inventory under international water, but does not include the selling of inventory if the sale takes place on international water. Thus, if property sold on international water is inventory property, income attributable to sales activity is sourced under § 1.861–7(c).

Ocean activity also includes underwriting income from the insurance of risks on activities that produce income derived from ocean activity. The inclusion of such underwriting income is consistent with language in the Senate Report. See Senate Report at 357.

Ocean activity also includes any activity performed in Antarctica. Ocean activity further includes the leasing of a vessel if such vessel does not transport cargo or persons for hire between ports-of-call. Thus, for example, income earned by a lessor of a vessel that is to engage only in research activities in international water is ocean income. Ocean activity also includes the leasing of drilling rigs, extraction of minerals, and performance and provision of services related thereto, to the extent the mines, oil and gas wells, or other natural deposits are not within the jurisdiction of the United States, U.S. possessions, or any foreign country (as defined in section 638).

Based on legislative history, the IRS and Treasury believe space and ocean activity should be broadly defined based on legislative history. The legislative history clearly indicates that Congress intended to characterize certain land based activity as space or ocean activity. See Senate Report at 357. Consistent with that determination, the proposed regulations provide that when activities occur both in space or in international water and outside space and international water, and constitute parts of a single transaction described in § 1.863–8(d)(1), the transaction will be characterized as space or ocean activity. Thus, for example, income from the lease of equipment located in space will be sourced in its entirety under section 863(d), even though certain functions associated with the transaction may be performed outside space and international water. The rules of this section for defining space or ocean activity by combining activities occurring both in space or in international water and outside space and international water simply reflect existing principles for characterizing a transaction, and are fully consistent with rules for characterizing income for purposes of other source rules. Taxpayers enjoy flexibility in structuring their transactions that will be characterized under existing principles. To ensure the statutory purpose is not circumvented, the Commissioner may treat parts of a transaction as separate transactions, or combine separate transactions as a single transaction.

Certain activities occurring in space or international water are not considered either space or ocean activity. Proposed regulations § 1.863–8(d)(3)(i) provides that space or ocean activity does not include any activity giving rise to transportation income as defined in section 863(c). Proposed regulations § 1.863–8(d)(3)(ii) provides that space or ocean activity also does not include any activity with respect to mines, oil and gas wells, or other natural deposits to the extent the mines or wells are located within the jurisdiction (as recognized by the United States) of any country, including the United States and its possessions (as defined in section 638). Proposed regulations § 1.863–8(d)(3)(iii) provides that space or ocean activity does not include any activity giving rise to international communications income as defined in proposed regulations § 1.863–9(d)(3)(ii). These exceptions are consistent with section 863(d)(2)(B) of the Code.

b. *Special Rules in Determining Space or Ocean Activity.* Proposed regulations § 1.863–8(d)(2)(ii)(A) provides that services are performed in space or in international water if functions are performed, resources employed, risks assumed, or other contributions to the value of the transaction occur in space or international water, whether such contributions are performed by personnel, or equipment, or otherwise. The IRS and Treasury believe that all contributions to a transaction's value, whether contributed by personnel, equipment, or otherwise, should be considered in determining whether services are performed in space or international water.

Proposed regulations § 1.863–8(d)(2)(ii)(A) provides that the performance of a service is treated as a space or ocean activity if a part of the service is performed in space or international water. The IRS and Treasury recognize that this rule may be over-inclusive in certain cases. Therefore, proposed regulations § 1.863–8(d)(2)(ii)(B) provides that the performance of a service will not be a space or ocean activity if the only activity of the taxpayer in space or in international water is to facilitate the taxpayer's own communications, as part of provision or delivery of a service by the taxpayer, and that service would not otherwise be in whole or in part a space or ocean activity. Several examples in the regulations illustrate this facilitation exception. The IRS and Treasury recognize that taxpayers may use communications services in conducting a business, and the fact that such communications may be routed through space or international water instead of by way of land should not produce differences in the source of the taxpayer's income derived from such service.

5. Treatment of Partnerships

Proposed regulations § 1.863–8(e) provides that for U.S. partnerships, section 863(d) and the regulations thereunder will be applied at the partnership level. The IRS and Treasury believe this rule is consistent with section 7701(a)(30)(B), which defines a U.S. person as a domestic partnership. For foreign partnerships, section 863(d) and the regulations thereunder will be applied at the partner level. The proposed regulations provide a different rule for foreign partnerships because IRS and Treasury are concerned that U.S. persons may use a foreign partnership to circumvent the purposes of this section. For example, two U.S. persons by the simple expediency of forming a foreign partnership can change significantly the U.S. tax consequences under section 863(d).

6. Reporting and Documentation Requirements

When a taxpayer allocates gross income to the satisfaction of the Commissioner under § 1.863–8(b)(3) (income of certain foreign persons), § 1.863–8(b)(4)(ii)(C) (certain production activity), or under § 1.863–8(b)(5) (services) of the proposed regulations, the taxpayer must do so by making the allocation on a timely filed original return (including extensions). An amended return does not qualify, and section 9100 relief will not be available. In all cases, a taxpayer must maintain contemporaneous documentation regarding the allocation of gross income, and allocation of expenses, losses, and other deductions, the methodology used, and the circumstances justifying use of that methodology. The taxpayer must produce such documentation within 30 days upon request.

B. Communications Activity Under Sections 863(a), (d), and (e)

1. Scope

Section 1.863–9 of the proposed regulations provides rules for sourcing income derived from communications activity, notwithstanding any other section. Pursuant to proposed regulations § 1.863–8, these source rules apply to communications activity that is also space or ocean activity.

2. Source of Gross Income Derived From Communications Activity

a. *International Communications Income.* Section 863(e)(1)(A) states that any international communications income of a U.S. person will be sourced 50 percent to the United States and 50 percent to foreign sources. Proposed regulations § 1.863–9(b)(2)(i) provides that international communications income of a U.S. person will be sourced 50 percent to the United States and 50 percent to foreign sources.

Section 863(e)(1)(B)(i) provides that any international communications income of a foreign person will be foreign source income except as provided in regulations or in section 863(e)(1)(B)(ii). Proposed regulations § 1.863–9(b)(2)(ii)(A) states the general rule that international communications income of a foreign person is foreign source income. However, the proposed regulations contain several exceptions to the general rule.

Proposed regulations § 1.863–9(b)(2)(ii)(B) states that if a foreign corporation is 50 percent or more owned by vote or value (directly, indirectly, or constructively) by U.S. persons, or is a controlled foreign corporation within the meaning of section 957, all international communications income is U.S. source income. This rule reflects IRS and Treasury's concern that U.S. persons may use a foreign corporation to obtain benefits that are inconsistent with the purposes of this section.

Section 863(e)(1)(B)(ii) provides that if a foreign person has a U.S. fixed place of business, international communications income attributable to the fixed place of business is U.S. source income. Consistent with section 863(e)(1)(B)(ii), proposed regulations § 1.863–9(b)(2)(ii)(C) states that if a foreign person, other than a foreign person described in paragraph (b)(2)(ii)(A), maintains an office or other fixed place of business in the United States, any international communications income attributable to the office or other fixed place of business is U.S. source income. The principles of section 864(c)(5) will apply to determine whether a foreign person has an office or fixed place of business in the United States. This rule does not apply if the foreign person is engaged in a U.S. trade or business.

Proposed regulations § 1.863–9(b)(2)(ii)(D) provides that if a foreign person is engaged in a U.S. trade or business, the foreign person's international communications income is presumed to be U.S. source income. The rule reflects IRS and Treasury's concern that a foreign person could avoid a U.S. fixed place of business under section 863(e)(1)(B)(ii), yet engage in significant communications activity in the United States.

The IRS and Treasury believe Congress intended that a foreign person engaged in substantial U.S. business in the United States be subject to U.S. tax on that communications activity.

The IRS and Treasury recognize that this rule may be over-inclusive in certain cases. Therefore, the proposed regulations provide that if the foreign person can allocate income to international communications activity outside the United States and space and international water, to the satisfaction of the Commissioner, based on the facts and circumstances, which may include functions performed, resources employed, risks assumed, or other contributions to value, then the income allocated to such communications activity outside the United States and space and international water will be foreign source income. When a foreign person is entitled to the benefits of a tax treaty with the United States, such person may elect to be taxed under the rules of that treaty, so that, for example, the United States would tax only income attributable to a permanent establishment of that foreign person, regardless of the amount of income considered effectively connected with a U.S. trade or business.

b. *Other Communications Income.* The proposed regulations also provide rules, for both U.S. and foreign persons, for determining the source of income from communications activity that does not qualify as international communications activity. The IRS and Treasury believe rules that address income from other communications activities are necessary based on the legislative history. See Senate Report at 357.

Proposed regulations § 1.863–9(b)(3) states that the source of income derived by either a U.S. or foreign person from U.S. communications activity is U.S. source income. Proposed regulations § 1.863–9(b)(4) states that the source of income derived by either a U.S. or foreign person from foreign communications activity is foreign source income. Proposed regulations § 1.863–9(b)(5) states that the source of income derived from space/ocean communications activity is determined under section 863(d) and the regulations thereunder.

3. Taxable Income

When a taxpayer allocates gross income under paragraph (b)(2)(ii)(D) (certain foreign persons), or (d)(1)(ii) (determining a communications activity), the taxpayer must allocate or apportion expenses, losses, and other deductions as prescribed in §§ 1.861–8 through 1.861–14T of the regulations to the class of gross income, which must include the total income so allocated in each case. A taxpayer must then apply the rules of §§ 1.861–8 through 1.861–14T of the regulations to properly allocate or apportion amounts of expenses, losses, and other deductions allocated or apportioned to such gross income between gross income from sources within the United States and without the United States. For amounts of expenses, losses, and other

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deductions allocated or apportioned to gross income derived from international communications activity, when the source of income is determined under the 50/50 method of paragraph (b)(2)(i), taxpayers must apportion expenses and other deductions between U.S. and foreign sources pro rata based on the relative amounts of U.S. and foreign source gross income. Research and experimental expenditures qualifying under § 1.861–17 are allocated under that section.

When a taxpayer must allocate gross income to the satisfaction of the Commissioner based on the facts and circumstances, IRS and Treasury believe that such allocations would be based generally on section 482 principles. However, IRS and Treasury solicit comments on this approach, including specific comments and examples on alternative methods that could be used to make these allocations.

4. Definition of Communications Activity and Income Derived From Communications Activity

a. *Communications Activity.* Proposed regulations § 1.863–9(d)(1) defines a communications activity as an activity consisting solely in the delivery by transmission of communications or data (communications). The definition of a communications activity is limited to the function of transmitting a particular communication from point A to point B. The delivery of communications by means other than transmission, for example, delivery of a letter is not a communications activity. The IRS and Treasury believe that this narrow definition of communications activity is consistent with the legislative history of section 863(e). See Senate Report at 357.

The provision of capacity to transmit communications or data is considered to be a communications activity. For example, the provision of satellite transponder capacity can qualify as a communications activity.

The provision of content or any other additional service will not be treated as a communications activity unless de minimis. For example, changes in the form of a voice communication when switching from analog technology to digital data for Internet telephony would be disregarded in determining whether there has been a transmission of communications within the meaning of proposed regulations § 1.863–9(d). However, payment for information from a data base sent electronically, or for income attributable to an entertainment event transmitted electronically, would not be income derived from a communications activity.

When the provision of content or any other services is de minimis, such content or services are ignored, and the transaction will be treated solely as the transmission of communications within the meaning of proposed regulations § 1.863–9(d)(1). The determination of whether the provision of content or other services is de minimis should be based on all the facts and circumstances. The IRS and Treasury believe the exclusion of content and other services is consistent with the legislative history of section 863(e). No evidence exists in the Congressional testimony or in the legislative history that content provided by transmission was to be considered a communications activity.

Proposed regulations § 1.863–9(d)(1)(ii) requires that a transaction encompassing non-de minimis communications activities and non-de minimis non-communications activities must be broken into parts and each part treated as a separate transaction. Proposed regulations § 1.863–9(d)(1)(ii) states that gross income derived from the activities must be allocated to each separate transaction, to the satisfaction of the Commissioner, based on all relevant facts and circumstances, which may include functions performed, resources employed, risks assumed, and any other contributions to the value of the respective transactions. For example, a payment by an advertiser to a TV broadcast station may be in part a payment for transmission of the advertisement, but could also be a payment for other property or services, for example the transmitter's ability to reach a particular market or audience. Such activities, if not de minimis, must be treated as non-communications activities under § 1.863–9(d)(1)(ii) of the proposed regulations.

To ensure the statutory purposes are not circumvented, the Commissioner may treat parts of a transaction as separate transactions, or construe separate transactions as a single transaction.

b. *Income Derived from Communications Activity.* Income derived from communications activity is defined in proposed regulations § 1.863–9(d)(2) as income derived from the transmission of communications, including income derived from the provision of capacity to transmit communications. There is no requirement that the income recipient perform the transmission function. This rule reflects IRS and Treasury's understanding that those providing communications services often use capacity owned or operated by others. However, income is derived from communications activity only if the taxpayer is paid to transmit, and bears the risk of transmitting, the communications.

c. *Character of Communications Activity.* Proposed regulations § 1.863–9(d)(3) provides rules for characterizing income derived from a communications activity for purposes of sourcing the income derived from such activity. The character of income derived from communications activity is determined by establishing the two points between which the taxpayer is paid to transmit, and bears the risk of transmitting, the communication. Under the paid-to-do rule, the path the communication takes between the two points is not relevant in determining the character of the transmission. If a taxpayer is paid to take a communication from one point to another point, income derived from the transmission is characterized based on the transmission between those two points, even though the taxpayer contracts out part of the transmission to another. This rule reflects IRS and Treasury's recognition that those providing communications often use the network owned or operated by others. Several examples in the proposed regulations illustrate the paid-to-do rule.

Proposed regulations § 1.863–9(d)(3)(ii) defines income derived from international communications activity as the transmission from a point in the United States and a point in a foreign country (or a possession of the United States). Proposed regulations § 1.863–9(d)(3)(iii) defines income derived from U.S. communications activity as the transmission between two points in the United States or a point in the United States and a point in space or international water.

Proposed regulations § 1.863–9(d)(3)(iv) defines income derived from foreign communications activity as the transmission between two points either in a foreign country or in foreign countries or a point in a foreign country and a point in space or international water. Proposed regulations § 1.863–9(d)(3)(v) defines income derived from space/ocean communications activity as the transmission between a point in space or international water and another point in space or international water. The IRS and Treasury believe these rules are consistent with the legislative history. See Senate Report at 357.

When the taxpayer cannot establish the two points between which the taxpayer is paid to transmit, the source of income derived from such activity, for either a U.S. or foreign person, is U.S. source income. Thus, for example, when a provider of communications services provides both local and international long distance along with cable services in one-price bundles for a set amount each month, tracing each transmission may not be possible or practical. In such cases, the source of income derived from communications activity is U.S. source income. The IRS and Treasury understand that many in the communications industry may not consider it practical or possible to prove the end points of the communications the taxpayer transmits. The IRS and Treasury solicit comments as to proposals for those situations when taxpayers cannot establish the points between which the taxpayer is paid to transmit the communications.

5. Treatment of Partnerships

Proposed regulations § 1.863–9(e) provides, in general, that for U.S. partnerships, section 863(e) and the regulations thereunder will be applied at the partnership level. The IRS and Treasury believe this rule is consistent with section 7701(a)(30)(B), which defines a U.S. person as a domestic partnership. For foreign partnerships, and in the case of a U.S. partnership in which 50 percent or more of the partnership interests are owned by foreign persons, section 863(e) and the regulations thereunder will be applied at the partner level. The proposed regulations provide a different rule for foreign partnerships and for U.S. partnerships with substantial foreign ownership because the IRS and Treasury are concerned that U.S. persons may use such partnerships to circumvent the purposes of this section.

6. Reporting Rules and Documentation Requirements

When a taxpayer allocates gross income to the satisfaction of the Commissioner under proposed regulations § 1.863–9(b)(2)(ii)(D) (certain foreign persons) or -(d)(1)(ii) (determining a communications activity), it does so by making the allocation on a timely filed original return (including extensions). An amended return does not qualify, and section 9100 relief will not be available. In all cases, a taxpayer must maintain contemporaneous documentation regarding the allocation of gross income, and allocation of expenses, losses and other deductions, the methodology used, and the circumstances justifying use of that methodology. The taxpayer must produce such documentation within 30 days upon request.

C. Amendment to the § 1.863–3 Regulations

These proposed regulations amend the regulations under § 1.863–3 for determining the source of income in certain inventory sales.

The regulations provide that in determining the source of income from sales of property when the property is either (i) produced in whole or in part in space or in international water, or (ii) sold in space or in international water, the rules of § 1.863–8 of the proposed regulations apply. The rules of sections 863 (a) and (b), and the regulations under those sections, do not apply to determine the source of income in such cases, except to the extent provided in § 1.863–8 of the proposed regulations. The proposed regulations in § 1.863–8(b)(4)(ii)(A) provide, however, that the source of income from sales of inventory on international water continues to be sourced under § 1.863–3(c)(2). The regulations in § 1.863–3(a)(1) and –3(c)(1)(i)(A) are amended to reflect these provisions.

The proposed regulations also amend § 1.863–3(c)(2) to provide that the place of sale will be presumed to be the United States, for purposes of that section, when property is produced in the United States and the property is sold to a U.S. resident for use, consumption, or disposition in space. See § 1.864–6(b)(3) for determining whether property is used in space and whether the sale is to a U.S. resident.

These rules reflect the views of Treasury and the IRS that sales of satellites or transponders by a U.S. resident in space should produce U.S. source income. These rules also reflect the view that sales of such property by a U.S. resident to a U.S. purchaser should produce U.S. source income. Treasury and the IRS believe that these provisions are consistent with Congress' intent in enacting section 863(d) to tax U.S. persons on a residency basis on income that is not likely to be subject to foreign tax by a foreign country. It is also consistent with the tax policy of the foreign tax credit that income not likely to be subject to foreign tax should not be treated as foreign source income, which would inappropriately allow taxpayers with excess foreign tax credits to shelter this income from U.S. tax.

Proposed Effective Dates

These regulations are proposed to apply for taxable years beginning on or after the date that is 30 days after the date of publication of final regulations in the **Federal Register**.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the rules of this section principally impact large multinationals who pay foreign taxes on substantial foreign operations and therefore the rules will impact very few small entities. Moreover, in those few instances where the rules of this section impact small entities, the economic impact on such entities is not likely to be significant. Accordingly, a regulatory flexibility analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely (in the manner described under the **ADDRESSES** caption) to the IRS. The IRS and Treasury specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for March 28, 2001, at 10 a.m., in the auditorium, seventh floor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit comments and an outline of topics to be discussed and the time to be devoted to each topic (in the manner described under the **ADDRESSES** caption of this preamble) by March 7, 2001.

A period of 10 minutes will be allotted to each person for making comments.

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An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Anne Shelburne, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.863–8 also issued under 26 U.S.C. 863(a), (b) and (d).

Section 1.863–9 also issued under 26 U.S.C. 863(a), (d) and (e). * * *

Par. 2 Section 1.863–3 is amended by:

1. Adding a sentence after the first sentence in paragraph (a)(1).

2. Adding a sentence at the end of paragraph (c)(1)(i)(A).

3. Adding three sentences, one after the current first sentence of paragraph (c)(2), and the other two sentences after the current second sentence of paragraph (c)(2).

The additions read as follows:

§ 1.863–3 Allocation and apportionment of income from certain sales of inventory.

(a) * * * (1) * * *To determine the source of income from sales of property produced by the taxpayer, when the property is either produced in whole or in part in space or on or under water not within the jurisdiction (as recognized by the United States) of a foreign country, possession of the United States, or the United States (in international water), or is sold in space or in international water, the rules of § 1.863–8 apply, and the rules of this section do not apply, except to the extent provided in § 1.863–8. * * *

* * * * *

(c) * * * (1) * * * (i) * * * (A) * * * For rules regarding the source of income when production takes place, in whole or in part, in space or in international water, the rules of § 1.863–8 apply, and the rules of this section do not apply except to the extent provided in § 1.863–8.

* * * * *

(c)(2) * * * Notwithstanding any other provision, for rules regarding the source of income when a sale takes place in space or in international water, the rules of § 1.863–8 apply, and the rules of this section do not apply except to the extent provided in § 1.863–8. * * * The place of sale will be presumed to be the United States under this rule when property is produced in the United States and the property is sold to a U.S. resident, who uses the property in space or in international water. In such cases, the property will be treated as sold for use, consumption, or disposition in the United States.

* * * * *

Par. 3 Section 1.863–8 and 1.863–9 are added to read as follows:

§ 1.863–8 Source of income from space and ocean activity under section 863(d).

(a) *In general.* Income of a U.S. or a foreign person derived from space or ocean activity (space or ocean income) is sourced under the rules of this section, notwithstanding any other provision, including sections 861, 862, 863, and 865. A taxpayer will not be considered to derive income from space or ocean activity, as defined in paragraph (d) of this section, if such activity is performed by another person, subject to the rules for the treatment of consolidated groups in section § 1.1502–13.

(b) *Source of gross income from space or ocean activity*—(1) *In general.* Income derived by a U.S. person from space or ocean activity is income from sources within the United States, except as otherwise provided in this paragraph (b). Income derived by a person other than a United States person from space or ocean activity is income from sources without the United States, except as otherwise provided in this paragraph (b).

(2) *Income derived by certain foreign corporations.* If a U.S. person or U.S. persons own 50 percent or more of the vote or value of the stock of a foreign corporation (directly, indirectly or constructively) that is not a controlled foreign corporation within the meaning of section 957, all income derived by that foreign corporation from space or ocean activity is U.S. source income.

(3) *Income derived by foreign persons engaged in a U.S. trade or business.* If a foreign person, other than a controlled foreign corporation within the meaning of section 957 or a foreign person described in paragraph (b)(2) of this section, is engaged in a U.S. trade or business, all income derived by that person from space or ocean activity is presumed to be U.S. source income. However, if the foreign person can allocate income between sources within the United States, or space, or international water, and sources outside the United States and space and international water, to the satisfaction of the Commissioner, based on the facts and circumstances, which may include functions performed, resources employed, risks assumed, or other contributions to value, then space or ocean income allocated to sources outside the United States and space and international water shall be treated as from sources outside the United States.

(4) *Source rules for income from certain sales of property*—(i) *Sales of purchased property.* When a taxpayer sells property in space or in international water, the source of gross income shall be determined under paragraph (b)(1), (2), or (3) of this section as applicable. However, if inventory, within the meaning of section 1221(1), is sold on international water, the source of income shall be determined under § 1.863–3(c)(2).

(ii) *Sales of property produced by the taxpayer*—(A) *General.* If the taxpayer both produces property and also sells such property, the taxpayer must divide gross income from such sales between production activity and sales activity under the 50/50 method as described in this paragraph (b)(4)(ii)(A). Under the 50/50 method, one-half of the taxpayer's gross income will be considered income attributable to production activity, and the source of that income will be determined under paragraphs (b)(4)(ii)(B) or (C) of this section. The remaining one-half of such gross income will be considered income attributable to sales activity and the source of that income will be determined under paragraph (b)(4)(i) of this section. However, if the taxpayer sells such property outside space and outside international water, the source of gross income attributable to sales activity will be determined under § 1.863–3(c)(2).

(B) *Production only in space or in international water, or only outside space and international water.* When production occurs only in space or in international water, income attributable to production activity is sourced under paragraph (b)(1), (2), or (3) of this section as space or ocean income. When production occurs only outside space and international water, income attributable to production activity is sourced under § 1.863–3(c)(1).

(C) *Production both in space or in international water and outside space and international water.* When property is produced in space or in international water and outside space and international water, gross income must be allocated to production occurring in space or in international water and production occurring outside space and international water, to the satisfaction of the Commissioner, based on all the facts and circumstances, which may include functions performed, resources employed, risks assumed, and any other contributions to value. The source of gross income allocated to space or international water is determined under paragraph (b)(1), (2), or (3) of this section. The source of gross income allocated outside space and international water is determined under § 1.863–3(c)(1).

(5) *Special rule for determining the source of gross income from services.* If a transaction characterized as the performance of services constitutes a space or ocean activity by reason of the performance of part of the service in space or in international water, as determined under paragraph (d)(2)(ii)(A) of this section, the source of all gross income derived from such transaction of which such performance is a part is determined under paragraph (b)(1), (2), or (3) of this section. However, if the taxpayer can allocate gross income between performance occurring outside space and international water, and performance occurring in space or international water, to the satisfaction of the Commissioner, based on the facts and circumstances, including functions performed, resources employed, risks assumed, or other contributions to value, then the source of income allocated to performance occurring outside space and international water shall be determined under sections 861, 862, 863, and 865.

(6) *Special rule for determining source of income from communications activity (other than income from international communications activity).* Space and ocean activity, as defined in paragraphs (d)(1) and (2) of this section, includes activity occurring in space or in international water that is characterized as a communications activity as defined in § 1.863–9(d). The source of gross income from space or ocean activity that is also a communications activity as defined in § 1.863–9(d) is determined under the rules of § 1.863–9(b), rather than under paragraph (b) of this section.

(c) *Taxable income.* When a taxpayer allocates gross income under paragraph (b)(3), (b)(4)(ii)(C), or (b)(5) of this section, to the satisfaction of the Commissioner, based on all the facts and circumstances, the taxpayer must allocate or apportion expenses, losses, and other deductions as prescribed in §§ 1.861–8 through 1.861–14T to the class of gross income, which must include the total income so allocated in each case. A taxpayer must then apply the rules of §§ 1.861–8 through 1.861–14T to properly allocate or apportion amounts of expenses, losses, and other deductions allocated or apportioned to such gross income between gross income from sources within the United States and without the United States.

(d) *Space and Ocean activity*—(1) *Definition*—(i) *Space activity.* In general, space activity is any activity conducted in space. Space activity includes performance and provision of services in space, as defined in paragraph (d)(2)(ii)(A) of this section, leasing of equipment located in space, including spacecraft (e.g., satellites) or transponders located in space, licensing of technology or other intangibles for use in space, and the production, processing, or creation of property in space, as defined in paragraph (d)(2)(i) of this section. Space activity includes activity occurring in space that is characterized as communications activity (other than international communications activity) under § 1.863–9(d). Space activity also includes underwriting income from the insurance of risks on activities that produce space income. Space activity includes the sale in space of property, as defined in paragraph (d)(2)(iii) of this section. For purposes of this section, space means any area not within the jurisdiction (as recognized by the United States) of a foreign country, possession of the United States, or the United States, and not in international water. For purposes of determining space activity, the Commissioner may separate parts of a single transaction into separate transactions or combine separate transactions as parts of a single transaction. Paragraph (d)(3) of this section lists exceptions to the general rule.

(ii) *Ocean activity.* In general, ocean activity is any activity conducted on or under water not within the jurisdiction (as recognized by the United States) of a foreign country, possession of the United States, or the United States (collectively, in international water). Ocean activity includes performance and provision of services in international water, as defined in paragraph (d)(2)(ii)(A) of this section, leasing of equipment located in international water, including underwater cables, licensing of technology or other intangibles for use in international water, and the production, processing, or creation of property in international water, as defined in paragraph (d)(2)(i) of this section. Ocean activity includes sales of property in international water, as defined in paragraph (d)(2)(iii) of this section, but ocean activity does not include the selling of inventory as defined in section 1221(1) on international water. Ocean activity includes activity occurring in international water that is characterized as communications activity (other than international communications activity) under § 1.863–9(d). Ocean activity also includes underwriting income from the insurance of risks on activities that produce ocean income. Ocean activity also includes any activity performed in Antarctica. Ocean activity further includes the leasing of a vessel if such vessel does not transport cargo or persons for hire between ports-of-call. Thus, for example, the leasing of a vessel that is to engage only in research activities in international water is an ocean activity. Except as provided in paragraph (d)(3)(ii) of this section, ocean activity also includes the leasing of drilling rigs, extraction of minerals, and performance and provision of services related thereto. For purposes of determining ocean activity, the Commissioner may separate parts of a single transaction into separate transactions or combine separate transactions as parts of a single transaction. Paragraph (d)(3) of this section lists exceptions to the general rule.

(2) *Determining a space or ocean activity*—(i) *Production of property in space or in international water.* For purposes of this section, production activity means an activity that creates, fabricates, manufactures, extracts, processes, cures, or ages property within the meaning of sections 864(a) and § 1.864–1.

(ii) *Special rule for performance of services*—(A) *General.* If a transaction is characterized as the performance of a service, then such service will be treated as a space or ocean activity when a part of the service, even if de minimis, is performed in space or in international water. Services are performed in space or in international water if functions are performed, resources employed, risks assumed, or other contributions to value occur in space or in international water, regardless of whether performed by personnel, or equipment, or otherwise.

(B) *Exception to the general rule—facilitating the taxpayer's own communications.* If a taxpayer's only activity in space or in international water is to facilitate the taxpayer's own communications as part of the provision or delivery of a service provided by the taxpayer, and that service would not otherwise be in whole or in part a space

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or ocean activity, such service will not be treated as either space or ocean activity because of such facilitation.

(iii) *Sale in space or in international water.* In applying § 1.861–7(c) to determine where a sale takes place, property will be sold in space or in international water if the property is located in space or in international water when rights, title and interest pass to the buyer (or when bare legal title is retained, at the time and place of passage of beneficial ownership and risk of loss), or if property is sold for use in space or in international water.

(3) *Exceptions to space or ocean activity.* Space or ocean activity does not include the following types of activities—

(i) Any activity giving rise to transportation income as defined in section 863(c); or

(ii) Any activity with respect to mines, oil and gas wells, or other natural deposits to the extent the mines or wells are located within the jurisdiction (as recognized by the United States) of any country, including the United States and its possessions; or

(iii) Any activity giving rise to international communications income as defined in § 1.863–9(d)(3)(ii).

(e) *Treatment of partnerships.* In the case of a U.S. partnership, this section will be applied at the partnership level. In the case of a foreign partnership, this section will be applied at the partner level.

(f) *Examples.* The following examples illustrate the rules of this section:

Example 1. Space activity—activity occurring on land and in space. (i) *Facts.* S owns satellites, and leases one of its satellites to A. S, as lessor, will not operate the satellite. Part of S's performance as lessor in this transaction occurs on land.

(ii) *Analysis.* The combination of S's activities is characterized as the lease of equipment. Since the equipment is located in space, the transaction is defined as space activity under paragraph (d)(1)(i) of this section. Income derived from the lease will be sourced in its entirety under paragraph (b) of this section.

Example 2. Space activity. (i) *Facts.* X is an Internet service provider, offering a service to personal computer users accessing the Internet. This service permits a customer, C, to make a call, initiated by a modem, routed to a control center, for connection to the World Wide Web. X transmits the requested information over its satellite capacity leased from S to C's personal computer. X charges its customers a flat monthly fee. Assume neither X nor S derive international communications income within the meaning of § 1.863–9(d)(3)(ii).

(ii) *Analysis.* In this case, X performs a service, and X's activity in space is not simply facilitation within the meaning of paragraph (d)(2)(ii)(B) of this section, because X's activity is not simply the facilitation of X's own communications and because X's activity is not just part of another service provided by X. Thus, X's activity constitutes space activity in its entirety under paragraph (d)(2)(ii)(A) of this section, and the source of X's income is determined under paragraph (b) of this section. To the extent X derives income from communications activity, within the meaning of § 1.863–9(d), the source of X's income is determined under § 1.863–9(b), as provided in paragraph (b)(6) of this section. S derives communications income within the meaning of § 1.863–9(d), and therefore the source of S's income is determined under § 1.863–9(b), as provided in paragraph (b)(6) of this section.

Example 3. Services as space activity—facilitation of communications. (i) *Facts.* R owns a retail outlet in the United States. R employs S to provide a security system for R's premises. S operates its security system by transmitting images from R's premises to a satellite, and from there to a group of S employees located in Country B, who then monitor the premises by viewing the transmitted images. O provides S with transponder capacity on O's satellite, which S uses to transmit those images.

(ii) *Analysis.* S derives income for providing monitoring services. Because, in this case, S uses O's satellite transponder to transmit images to facilitate S's own communications in space as part of its provision of a security service, S's activity in space is limited to facilitating communications as described in paragraph (d)(2)(ii)(B) of this section. Thus, S is not engaged in a space activity, and none of S's income is space income. Assuming O's provision of capacity is viewed as the provision of a service, O's activity in space is not simply the facilitation of communications as provided in paragraph (d)(2)(ii)(B) of this section, because O is not just facilitating its own communications. Thus, O's activity is characterized as space activity in its entirety under paragraph (d)(2)(ii)(A) of this section (unless O's activity in space qualifies as international communications activity). To the extent O derives income from communications activity, within the meaning of § 1.863–9(d), the source of O's income is determined under § 1863–9(b), as provided in paragraph (b)(6) of this section. On these facts, R does not derive any income from space activity.

Example 4. Space activity. (i) *Facts.* L, a U.S. company, offers programming and also certain services to customers located both in the United States and in foreign countries. Assume L's provision of programming and services in this case was viewed as the provision of a service, with no part of that service occurring in space. L uses satellite capacity acquired from S to deliver the service directly to customers' television sets, so that the delivery of the service occurs in space. Assume the delivery in this case is not considered de minimis. L also acquires programming from H, and L pays H a royalty for use of copyrighted material in the United States and in foreign countries. Customer, C, pays L for delivery of the service to C's residence in the United States. Assume S's provision of capacity in this case was viewed as the provision of a service, and also that S does not derive international communications income within the meaning of § 1.863–9(d)(3)(ii).

(ii) *Analysis.* On these facts, S's activity in space is not just the facilitation of its own communications within the meaning of paragraph (d)(2)(ii)(B) of this section, because S is facilitating the communications of others. To the extent S derives income from a space activity that is also a communications activity under § 1.863–9(d), the source of S's income is determined under § 1.863–9(b), as provided in paragraph (b)(6) of this section. On these facts, L is treated as providing a service and is paid to deliver that service to its customers, and each transaction, i.e., the provision of the service and the delivery of the service, constitutes a separate transaction. L's income derived from provision of the service is not income derived from space activity. L's income derived from delivery of the service is space activity. L's delivery of the service is not just the facilitation of L's own communications within the meaning of paragraph (d)(2)(ii)(B) of this section, because it is not just a part of the provision of a service, but instead the entire service. Since L derives communications income within the meaning of § 1.863–9(d), the source of L's income is determined under § 1.863–9(b), as provided in paragraph (b)(6) of this section. If on other facts, L provides a service and delivers that service, and L treats the provision of the service and the delivery of the service as one separate transaction, then L performs services in space under paragraph (d)(2)(ii)(A) of this section, because the delivery of the service occurs in space. However, L's activity in space would be limited to facilitating its own communications within the meaning of paragraph (d)(2)(ii)(B) of this section, because it is part of another service that would not otherwise be a space activity. As a result, L's provision of the service would not be a space activity under paragraph (d)(2)(ii)(A) of this section.

Example 5. Space activity—treatment of land activity. (i) *Facts.* S, a U.S. person, offers remote imaging products and services to its customers. In year 1, S uses its satellite's remote sensors to gather data on certain geographical terrain. In year 3, C, a construction development company, contracts with S to obtain a satellite image of an area for site development work. S pulls data from its archives and transfers to C the images gathered in year 1, in a transaction that is characterized as a sale of the data. Title to the data passes to C in the United States. Before transferring the images to C, S uses computer software to enhance the images so that the images can be used.

(ii) *Analysis.* The collection of data and creation of images in space is characterized as the creation of property in space. S's income is derived from production of property in part in space, and is, therefore, derived in part from space activity. The source of S's income from production and sale of property is, therefore, determined under paragraph (b)(4) of this section. Since production activity occurs both in space and on land, the source of S's production income is determined under paragraphs (b)(4)(ii)(A) and (C) of this section. The source of S's income attributable to sales activity is determined under paragraph (b)(4)(ii)(A) of this section and § 1.863–3(c)(2) as U.S. source income.

Example 6. Use of intangible property in space. (i) *Facts.* X acquires a license to use a particular satellite slot or orbit, which X sublicenses to C. C pays X a royalty.

(ii) *Analysis.* Since the royalty is paid for the right to use intangible property in space, the source of X's royalty is determined under paragraph (b) of this section.

Example 7. Performance of services. (i) *Facts.* E, a U.S. company, operates satellites with sensing equipment that can determine how much heat and light particular plants emit and reflect. Based on the data, E will provide F, a U.S. farmer, a report analyzing the data, which F will use in growing crops. E analyzes the data from U.S. offices.

(ii) *Analysis.* Assume E's combined activities are characterized as the performance of services. Because part of the service is performed in space, all income E derives from the transaction will be treated as derived from space activity under paragraph (d)(2)(ii)(A) of this section. The source of such income will be determined under paragraph (b)(5) of this section. If, however, E can allocate gross income, to the satisfaction of the Commissioner, as prescribed in paragraph (b)(5) of this section, then the source of gross income attributable to services performed outside space may be determined as provided in paragraph (b)(5) of this section.

Example 8. Separate transactions. (i) *Facts.* The same facts as *Example 7*, except that E provides the raw data to F in a transaction characterized as a sale of a copyrighted article, and in addition also provides an analysis in the form of a report to F, a U.S. farmer who uses the information in growing crops. The price F pays E for the raw data is separately stated.

(ii) *Analysis.* To the extent the provision of raw data and the analysis of the data are each treated as separate transactions, the source of income from the production and sale of data is determined under paragraph (b)(4) of this section. The provision of services would be analyzed in the same manner as in *Example 7*.

Example 9. Sale of property under international water. (i) *Facts.* T owns transatlantic cable lying under the ocean, which it purchased. T sells the cable to B.

(ii) *Analysis.* Because the property is sold under international water as provided in paragraph (d)(2)(iii) of this section, the transaction is ocean activity under paragraph (d)(1)(ii) of this section, and the source of income is determined under paragraph (b)(4)(i) of this section, by reference to paragraph (b)(1), (2), or (3) of this section.

Example 10. Sales of property in space. (i) *Facts.* S manufactures a satellite in the United States and sells it to a U.S. customer, with the rights, title, and interest passing to the customer when the satellite is located in space.

(ii) *Analysis.* The source of income derived from the sale of the satellite in space is determined under paragraph (b)(4) of this section, with the source of income attributable to production activity determined under paragraphs (b)(4)(ii)(A) and (B) of this section, and the source of income attributable to sales activity determined under paragraphs (b)(4)(ii)(A) and (b)(4)(i) of this section, by reference to paragraph (b)(1), (2), or (3) of this section.

Example 11. Sale of property located in space. (i) *Facts.* S has a right to operate from a particular position in space. S sells the right to operate from that satellite slot or orbit to P.

(ii) *Analysis.* Because the sale takes place in space, as provided in paragraph (d)(2)(iii) of this section, gain on the sale of the satellite slot or orbit is income derived from space activity under paragraph (d)(1)(i) of this section, and income from the sale is sourced under paragraph (b)(4)(i) of this section, by reference to paragraph (b)(1), (2), or (3) of this section.

Example 12. Source of income of a foreign person. (1) *Facts.* FP, a foreign company, not a controlled foreign corporation within the meaning of section 957, derives income from the operation of satellites. FP operates a ground station in the United States and in foreign country, FC.

(ii) *Analysis.* In this case, FP is engaged in a U.S. trade or business of operating the ground station. Thus, under paragraph (b)(3) of this section, all FP's income derived from space activity is presumed to be U.S. source income. However, if FP can allocate space income to contributions occurring outside the United States, space, and international water, as provided in paragraph (b)(3) of this section, for example, to the ground station located in FC, then such space income so allocated will be from sources outside the United States.

Example 13. Source of income of a foreign person. (i) *Facts.* FP, a foreign company, not a controlled foreign corporation within the meaning of Section 957, operates remote sensing satellites, collecting data and images in space for its customers. FP uses an independent agent, A, in the United States who provides marketing, order taking, and other customer service functions.

(ii) *Analysis.* In this case, FP is engaged in a U.S. trade or business on the basis of A's activities on its behalf in the United States. Therefore, under paragraph (b)(3) of this section, all of FP's income derived from space activity is presumed to be space income. However, if FP can allocate income to contributions occurring outside the United States, space, and international water, as provided in paragraph (b)(3) of this section, then such income so allocated will be from sources outside the United States.

(g) *Reporting and documentation requirements.* When a taxpayer allocates gross income, to the satisfaction of the Commissioner, under paragraph (b)(3), (b)(4)(ii)(C), or (b)(5) of this section, it does so by making the allocation on a timely filed original return (including extensions). An amended return does not qualify for this purpose, nor shall the provisions of § 301.9100–1 of this chapter and any guidance promulgated thereunder apply. In all cases, a taxpayer must maintain contemporaneous documentation in existence when such return is filed regarding the allocation of gross income and allocation or apportionment of expenses, losses and other deductions, the methodology used, and the circumstances justifying use of that methodology. The taxpayer must produce such documentation within 30 days upon request.

(h) *Effective date.* This section applies to taxable years beginning on or after the date that is 30 days after the date of publication of final regulations in the **Federal Register**.

§ 1.863–9 Source of income derived from communications activity under sections 863(a), (d), and (e).

(a) *In general.* Income of a U.S. or foreign person derived from communications activity is sourced under the rules of this section, notwithstanding any other provision including sections 861, 862, 863, and 865.

(b) *Source of gross income derived from communications activity*—(1) *In general.* The source of gross income derived from each type of communications activity, as defined in paragraph (d)(3) of this section, is determined under this paragraph (b). If a communications activity would qualify as space or ocean activity under section 863(d) and the regulations thereunder, the source of income derived from such communications activity is determined under this section, and not under section 863(d) and the regulations thereunder. See § 1.863–8(b)(6).

(2) *Source of international communications income*—(i) *Income derived by a U.S. person.* Under the 50/50 method of this paragraph (b)(2)(i), income derived by a U.S. person from international communications activity is one-half from sources within the United States and one-half from sources without the United States.

(ii) *Income derived by foreign persons*—(A) *General rule.* Income derived by a person other than a U.S. person from international communications activity is, except as otherwise provided in this paragraph (b), wholly from sources without the United States.

(B) *Income derived by certain foreign corporations.* If a foreign corporation, including a controlled foreign corporation within the meaning of section 957, is 50 percent or more owned by vote or value (directly,

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indirectly, or constructively) by U.S. persons, all income derived by that corporation from international communications activity is from sources within the United States.

(C) *Income derived by foreign persons with a U.S. fixed place of business.* If a foreign person (other than a foreign person described in paragraph (b)(2)(ii)(B) of this section) maintains an office or other fixed place of business in the United States, the foreign person's international communications income, as determined to the satisfaction of the Commissioner, attributable to the office or other fixed place of business is from sources within the United States. The principles of section 864(c)(5) apply in determining whether a foreign person has an office or fixed place of business in the United States. See § 1.864–6 and –7. This paragraph does not apply if the foreign person is engaged in a U.S. trade or business.

(D) *Income derived by foreign persons engaged in a U.S. trade or business.* If a foreign person (other than a foreign person described in paragraph (b)(2)(ii)(B) of this section) is engaged in a U.S. trade or business, all of the foreign person's international communications income is presumed to be from sources within the United States. However, if the foreign person can allocate income between sources within the United States, or space, or international water and sources outside the United States and space and international water, to the satisfaction of the Commissioner, based on the facts and circumstances, which may include functions performed, resources employed, risks assumed, or other contributions to value, then the income allocated to sources outside the United States and space and international water shall be treated as from sources without the United States.

(3) *Source of U.S. communications income.* The source of income derived by a U.S. or a foreign person from U.S. communications activity is from sources within the United States.

(4) *Source of foreign communications income.* The source of income derived by a U.S. or a foreign person from foreign communications activity is from sources without the United States.

(5) *Source of space/ocean communications income.* The source of income derived by a U.S. or a foreign person from space/ocean communications activity is determined under section 863(d) and the regulations thereunder, without regard to § 1.863–8(b)(6).

(6) *Source of communications income when taxpayer cannot establish the two points between which the taxpayer is paid to transmit the communication.* The income derived by a U.S. person or foreign person from communications activity, when the taxpayer cannot establish the two points between which the taxpayer is paid to transmit the communication as required in paragraph (d)(3)(i) of this section, is from sources within the United States.

(c) *Taxable income.* When a taxpayer allocates gross income under paragraph (b)(2)(ii)(D) or (d)(1)(ii) of this section, to the satisfaction of the Commissioner, based on all the facts and circumstances, the taxpayer must allocate or apportion expenses, losses, and other deductions as prescribed in §§ 1.861–8 through 1.861–14T to the class of gross income, which must include the total income so allocated in each case. A taxpayer must then apply the rules of §§ 1.861–8 through 1.861–14T to properly allocate or apportion amounts of expenses, losses, and other deductions allocated or apportioned to such gross income between gross income from sources within the United States and without the United States. For amounts of expenses, losses, and other deductions allocated or apportioned to gross income derived from international communications activity, when the source of income is determined under the 50/50 method of paragraph (b)(2)(i) of this section, taxpayers must apportion expenses, losses, and other deductions between sources within and sources without pro rata based on the relative amounts of gross income from sources within the United States and without the United States. Research and experimental expenditures qualifying under § 1.861–17 are allocated under that section, and are not allocated and apportioned pro rata under the method of paragraph (b)(2)(i) of this section.

(d) *Communications activity and income derived from communications activity*—(1) *Communications activity*—(i) *General rule.* For purposes of this part, communications activity consists solely of the delivery by transmission of communications or data (communications). Delivery of communications other than by transmission, for example, by delivery of physical packages and letters, is not communications activity within the meaning of this section. Communications activity also includes the provision of capacity to transmit communications. Provision of content or any other additional service provided along with, or in connection with, a non-de minimis communications activity must be treated as a separate non-communications activity unless de minimis.

(ii) *Separate transaction.* To the extent a taxpayer's transaction consists in part of non-de minimis communications activity and in part of non-de minimis non-communications activity, such parts of the transaction must be treated as separate transactions. Gross income must be allocated to each such transaction involving the communications activity and the non-communications activity to the satisfaction of the Commissioner, based on all relevant facts and circumstances, which may include functions performed, resources employed, risks assumed, and any other contributions to the value of the respective transactions. For purposes of determining whether income is derived from communications activity, the Commissioner may treat communications activity and non-communications activity, treated as a single transaction, as separate transactions, or combine separate communications activity and non-communications activity transactions into a single transaction.

(2) *Income derived from communications activity.* Income derived from communications activity (communications income) is income derived from the delivery by transmission of communications, including income derived from the provision of capacity to transmit communications. Income may be considered derived from a communications activity even if the taxpayer itself does not perform the transmission function, but in all cases, the taxpayer derives communications income only if the taxpayer is paid to transmit, and bears the risk of transmitting, the communications.

(3) *Determining the type of communications activity*—(i) *In general.* Whether income is derived from international communications activity, U.S. communications activity, foreign communications activity, or space/ocean communications activity is determined by identifying the two points between which the taxpayer is paid to transmit the communication. The taxpayer must establish to the satisfaction of the Commissioner the two points between which the taxpayer is paid to transmit, and bears the risk of transmitting, the communication. Whether the taxpayer contracts out part or all of the transmission function is not relevant.

(ii) *Income derived from international communications activity.* Income derived by a taxpayer from international communications activity (international communications income) is income derived from communications activity, as defined in paragraph (d)(1) of this section, when the taxpayer is paid to transmit between a point in the United States and a point in a foreign country (or a possession of the United States).

(iii) *Income derived from U.S. communications activity.* Income derived by a taxpayer from U.S. communications activity (U.S. communications income) is income derived from communications activity, as defined in paragraph (d)(1) of this section, when the taxpayer is paid to transmit—

(A) Between two points in the United States; or

(B) Between the United States and a point in space or in international water.

(iv) *Income derived from foreign communications activity.* Income derived by a taxpayer from foreign communications activity (foreign communications income) is income derived from communications activity, as defined in paragraph (d)(1) of this section, when the taxpayer is paid to transmit—

(A) Between two points in a foreign country or countries (or possession or possessions of the United States); or

(B) Between a foreign country (or a possession of the United States) and a point in space or in international water.

(v) *Income derived from space/ocean communications activity.* Income derived by a taxpayer from space/ocean communications activity (space/ocean communications income) is income derived from a communications activity, as defined in paragraph (d)(1) of this section, when the taxpayer is paid to transmit between a point in space or in international water and another point in space or in international water.

(e) *Treatment of partnerships*—(1) *General.* In the case of a U.S. partnership, this section will be applied at the partnership level. In the case of a foreign partnership, this section will be applied at the partner level.

(2) *Exception.* In the case of a U.S. partnership in which 50 percent or more of the partnership interests are owned by foreign persons, this section will be applied at the partner level.

(f) *Examples.* The following examples illustrate the rules of this section:

Example 1. Income derived from communications activity. (i) *Facts.* D provides its customers in various foreign countries with access to its data base. A customer, C, places a toll call to D's telephone number, and can then access D's data base to obtain certain information, such as C's customers' health care coverage.

(ii) *Analysis.* D is not paid to transmit communications and does not derive income solely from transmission of communications within the meaning of paragraph (d) of this section. D instead derives income from provision of content or provision of services to its customers.

Example 2. Income derived from U.S. communications activity. (i) *Facts.* Local telephone company (TC) receives access fees from an international carrier for picking up calls from a local telephone customer and delivering the call to a U.S. point of presence (POP) of the international carrier. The international carrier picks up the call from its U.S. POP and delivers the call to a foreign country.

(ii) *Analysis.* TC is not paid to carry the transmission between the United States and a foreign country. It is paid to transmit communications between two points in the United States. TC derives income from U.S. communications activity as defined in paragraph (d)(3)(iii) of this section, which is sourced under paragraph (b)(3) of this section as U.S. source income.

Example 3. Income derived from international communications activity. (i) *Facts.* TC, a U.S. company, owns an underwater fiber optic cable. Pursuant to three year contracts, TC makes capacity to transmit communications via the cable available to its customers. Such customers then solicit telephone customers and arrange for transmitting their calls. The cable runs in part through U.S. waters, through international waters, and in part through foreign country waters.

(ii) *Analysis.* TC derives income from communications activity under paragraph (d)(2) of this section. The income is derived from international communications activity as provided in paragraph (d)(3)(ii) of this section, since TC is paid to make available capacity to transmit between the United States and a foreign country, and vice versa. Since TC is a U.S. person, TC's international communications income is sourced under paragraph (b)(2)(i) of this section as one-half from sources within the United States and one-half from sources without the United States.

Example 4. Character of communications activity: the paid-to-do rule. (i) *Facts.* TC is paid to transmit communications from Toronto, Canada, to Paris, France. TC transmits the communication to New York. TC pays another communications company, IC, to transmit the communications from New York to Paris.

(ii) *Analysis.* Under the paid-to-do rule of paragraph (d)(3)(i) of this section, TC derives income from foreign communications activity under paragraph (d)(3)(iv) of this section, since it is paid to transmit communications between two foreign points, Toronto and Paris. Under paragraph (d)(3)(i) of this section, the character of TC's activity is determined without regard to the fact that TC pays IC to transmit the communication for some portion of the delivery path. IC has international communications income under paragraph (d)(3)(ii) of this section, because it is paid to transmit the communication between a point in the United States and a point in a foreign country.

Example 5. Income derived from international communications activity. (i) *Facts.* S, a U.S. satellite operator, owns satellites and the uplink facilities in Country X, a foreign country. B, a resident of Country X, pays S to deliver its programming from Country X to its downlink facility in the United States, owned by C, a customer of B.

(ii) *Analysis.* S derives communications income under paragraph (d) of this section. S's income is characterized as international communications income under paragraph (d)(3)(ii) of this section, because S is paid to transmit the communication between the beginning point in a foreign country to an end point in the United States. The source of S's international communications income is determined under paragraph (b)(2)(i) of this section as one-half from sources within the United States and one-half from sources without the United States.

Example 6. Character of income derived from communications activity: the paid-to-do rule. (i) *Facts.* TC is paid to take a call from North Carolina to Iowa, two points in the United States, but routes the call through Canada.

(ii) *Analysis.* Under paragraph (d)(3)(i) of this section, the character of the income derived from communications activity is determined by the two points between which the taxpayer is paid to transmit, and bears the risk of transmitting, the communications, without regard to the path of the transmission between those two points. Thus, under paragraph (d)(3)(iii) of this section, TC derives income from U.S. communications activity because it is paid to transmit between two U.S. points.

Example 7. Source of income derived from communications activity. (i) *Facts.* A, a U.S. company, is an Internet access provider. A charges C a lump sum, paid monthly, for Internet access. A transmits a call made by C in France to a recipient in England, over the public Internet. A does not maintain records as to the beginning and end points of the transmission.

(ii) *Analysis.* Although A derives income from communications activity as defined in paragraph (d)(1) of this section, the source of income is determined under paragraph (b)(6) of this section as income from sources within the United States, because A cannot establish the two points between which it is paid to transmit the communications.

Example 8. Income derived from communications and non-communications activity. (i) *Facts.* A, a U.S. company, offers customers local and long distance phone service, video, and Internet services. Customers pay one monthly fee, and in addition 10 cents a minute for all long-distance calls, including international calls.

(ii) *Analysis.* To the extent A derives income from communications activity, A must allocate income to its communications activity as provided in paragraph (d)(1)(ii) of this section. To the extent A can establish that it derives international communications income as defined in paragraph (d)(3)(ii) of this section, A would determine the source of such income under paragraph (b)(2)(i) of this section. If A cannot establish the points between which it is paid to transmit communications, as required in paragraph (d)(3)(i) of this section, the source of A's income must be determined under paragraph (b)(6) of this section as from within the United States.

Example 9. Income derived from communications activity. (i) *Facts.* T

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purchases capacity from TC to transmit telephone calls. T sells prepaid telephone calling cards, giving customers access to TC's lines, for a certain number of minutes.

(ii) *Analysis.* T derives income from communications activity, under paragraph (d)(2) of this section, because T makes capacity to transmit available to its customers. In this case, T cannot establish the points between which communications are transmitted. Therefore, the source of its income must be determined under paragraph (b)(6) of this section as U.S. source income.

Example 10. Income derived from communications and non-communications activity. (i) *Facts.* B, a U.S. company, transmits television programs using its satellite transponder, from the United States to downlink facilities in foreign country Y, owned by D, a cable system operator in Country Y. D receives the transmission, unscrambles the signals, and distributes the broadcast to customers in Country Y.

(ii) *Analysis.* B derives income both from communications activity as defined under paragraph (d)(1)(i) of this section, and from non-communications activity. Gross income must be allocated to the communications activity as required in paragraph (d)(1)(ii) of this section. Income derived by B for transmission to D is international communications income within paragraph (d)(3)(ii) of this section, because B is paid to transmit communications from the United States to a foreign country.

Example 11. Income derived from communications activity. (i) *Facts.* TC is paid for Internet access. TC replicates frequently requested sites on its servers, solely to speed up response time.

(ii) *Analysis.* On these facts, the replication service would be treated as de minimis under paragraph (d)(1)(i) of this section, so that TC derives income from communications activity. The type and source of TC's communications income depends on demonstrating the points between which TC is paid by its customer to transmit the communications, under paragraph (d)(3)(i) of this section.

Example 12. Income derived from foreign communications activity. (i) *Facts.* S leases capacity to B, a broadcaster located in Australia. B beams programming to the satellite, and S's satellite picks the communications up in space, and beams the programming over Southeast Asia.

(ii) *Analysis.* S derives income from communications activity under paragraph (d)(2) of this section. S's income is characterized as income derived from foreign communications activity under paragraph (d)(3)(iv) of this section, because S picks up the communication in space, and beams it to a footprint entirely covering a foreign area. The source of S's income is determined under paragraph (b)(4) of this section as from sources without the United States. If S were beaming the programming over a satellite footprint that covered area both in the United States and outside the United States, S would be required to allocate the income derived from the different types of communications activity.

(g) *Reporting rules and disclosure on tax return.* When a taxpayer allocates gross income to the satisfaction of the Commissioner under paragraph (b)(2)(ii)(D) or (d)(1)(ii) of this section, it does so by making the allocation on a timely filed original return (including extensions). An amended return does not qualify for this purpose, nor shall the provisions of § 301.9100–1 of this chapter and any guidance promulgated thereunder apply. In all cases, a taxpayer must maintain contemporaneous documentation in existence when such return is filed regarding the allocation of gross income, and allocation and apportionment of expenses, losses, and other deductions, the methodology used, and the circumstances justifying use of that methodology. The taxpayer must produce such documentation within 30 days of a request.

(h) *Effective date.* This section applies to taxable years beginning on or after the date that is 30 days after the date of publication of final regulations in the **Federal Register**.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–7 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–109481–99]

RIN 1545–AX34

Special Rules Under Section 417(e)(7) for Written Explanations Provided by Qualified Retirement Plans After Annuity Starting Dates

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the special rule added by the Small Business Job Protection Act of 1996 which permits the required written explanations of certain annuity benefits to be provided by qualified retirement plans to plan participants after the annuity starting date. These regulations affect administrators of, participants in, and beneficiaries of qualified retirement plans.

DATES: Written and electronic comments and requests for a public hearing must be received by April 17, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–109481–99), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–109481–99), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax_regs/regslist.html*.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Robert M. Walsh, (202) 622–6090; concerning submissions and delivery of comments, Sonya Cruse (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O, Washington, DC 20224. Comments on the collection of information should be received by March 19, 2001. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.417(e)–1(b)(3)(iv)(B) and § 1.417(e)–1(b)(3)(v)(A). This collection of information is required by the IRS to ensure that the participant and the participant's spouse consent to a form of distribution from a qualified retirement plan that may result in reduced periodic payments. This information will be used by the plan administrator to verify that the required consent has been given. The collection of information is required to obtain a benefit. The respondents are individuals who are entitled to receive certain types of distributions from a qualified retirement plan or who are married to individuals entitled to receive certain types of distributions from a qualified retirement plan.

Taxpayers provide the information to administrators of qualified retirement plans when a distribution with a retroactive annuity starting date is elected.

Estimated total annual reporting burden: 12,500 hours.

Estimated average annual burden hours per respondent: 0.25 hours.

Estimated number of respondents: 50,000.

The estimated annual frequency of responses is on occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains proposed amendments to 26 CFR Part 1 under section 417(a)(7) of the Internal Revenue Code (Code). Section 401(a)(11) provides that, subject to certain exceptions, all distributions from a qualified plan must be made in the form of a qualified joint and survivor annuity (QJSA). One such exception is provided in section 417, which allows a participant to elect to waive the QJSA in favor of another form of distribution. Section 417(a)(2) provides that, for the waiver to be valid, the participant's spouse must consent to the waiver. Section 417(a)(3)(A) requires a qualified plan to provide to each participant, within a reasonable period of time before the annuity starting date, a written explanation (QJSA explanation) that describes the QJSA, the right to waive the QJSA and the rights of the participant's spouse. Under section 417(d), a participant's spouse who has not been married to the participant throughout the 1-year period preceding the annuity starting date is not required to be treated as the spouse for purposes of entitlement to the QJSA. Section 417(a)(2)(B) provides that spousal consent is not required to waive the QJSA if it is established to the satisfaction of a plan representative that such consent may not be obtained because there is no spouse, because the spouse cannot be located, or because of such other circumstances as the Secretary may by regulations prescribe.

Section 417(a)(7), which was added to the Code by section 1451(a) of the Small Business Job Protection Act of 1996, Public Law 104–188 (110 Stat. 1755) (SBJPA), creates an exception to the rules of section 417(a)(3)(A), effective for plan years beginning after December 31, 1996. Section 417(a)(7)(A) provides that, notwithstanding any other provision of section 417(a), a plan may furnish the QJSA explanation after the annuity stating date, as long as the applicable election period is extended for at least 30 days after the date on which the explanation is furnished. Thus, section 417(a)(7)(A) allows the annuity starting date to be a date that is earlier than the date the QJSA explanation is provided, thereby allowing the retroactive payment of benefits that are attributable to the period before the QJSA explanation is provided. Section 417(a)(7)(A)(ii) provides that the Secretary may limit the application of the provision permitting the selection of a retroactive annuity starting date by regulations, except that the regulations may not limit the period of time by which the annuity starting date precedes the furnishing of the written explanation other than by providing that the retroactive annuity starting date may not be earlier than termination of employment.

Section 205(c)(8) of the Employee Retirement Income Security Act of 1974, Public Law 93–406 (88 Stat. 829) (ERISA), provides a parallel rule to section 417(a)(7) of the Code that applies under Title I of ERISA, and authorizes the Secretary of the Treasury to issue regulations limiting the application of the general rule. Thus, Treasury regulations issued under section 417(a)(7) of the Code apply as well for purposes of section 205(c)(8) of ERISA.

On December 18, 1998, final regulations were published in the **Federal Register** (63 FR 70009) which amended § 1.417(e)–1(b)(3)(ii) of the Income Tax Regulations, relating to the timing for the QJSA explanation and the participant waiver of a QJSA form of distribution. The regulations finalized an earlier set of proposed regulations that were issued in 1995. The regulations specified that the QJSA explanation must be provided before the annuity starting date, except as otherwise provided by section 417(a)(7) for plan years beginning after December 31, 1996, but the regulations did not further address section 417(a)(7).

Explanation of Provisions

In accordance with section 417(a)(7)(A), these proposed regulations would provide that the QJSA explanation may be furnished on or after the annuity starting date under certain circumstances. The proposed regulations refer to the annuity starting date in such cases as the "retroactive annuity starting date", define how payments are made in the case of a retroactive annuity starting date, and set conditions for the use of retroactive annuity starting dates.

Under the proposed regulations, a retroactive annuity starting date could be used only if the plan provides for it and the participant elects to use the retroactive annuity starting date. The election under the proposed regulations would place the participant in approximately the same situation he or she would have been in had benefit payments actually commenced on the retroactive annuity starting date. Accordingly, the proposed regulations would provide that future periodic payments for a participant who elects a retroactive annuity starting date must be the same as the periodic payments that would have been paid to the participant had payments actually commenced on the retroactive annuity starting date and that the participant must also receive a make-up amount to reflect the missed payments (with an appropriate adjustment for interest from the date the payments would have been made to the date of actual payment).

In addition, because the purpose of a retroactive annuity starting date is to place the participant in approximately the same situation that he or she would have been in had benefits commenced on the retroactive date, the retroactive benefit payments would be required to be based upon the terms of the plan in effect as of the retroactive annuity starting date (taking into account plan amendments executed after the retroactive annuity starting date, but made effective on or before that date). Accordingly, the retroactive annuity starting date could not be earlier than the date the participant could have started receiving benefits if the payments had commenced at the

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earliest date permitted under the terms of the plan (*e.g.*, the retroactive annuity starting date could not be before the earlier of the date of the participant's termination of employment or attainment of normal retirement age), and the amount of the benefit must satisfy sections 415 and 417 as of the retroactive annuity starting date.

These proposed regulations would not require plans to provide for a retroactive annuity starting date. Instead, plans could continue to provide that the QJSA explanation is to be provided before the annuity starting date under the rules of section 417(a) without regard to section 417(a)(7)(A). Moreover, if a plan is amended to provide for a retroactive annuity starting date, the plan could impose additional restrictions on availability not imposed under these proposed regulations, provided that the additional restrictions did not violate any of the rules applicable to qualified plans. For example, plans that generally provide benefit options that include annuities and lump sum payments could provide that retroactive annuity starting dates are available only for participants who elect annuities.

These proposed regulations make it clear that the notice, consent, and election rules of section 417(a)(1), (2), and (3), and the regulations thereunder, would apply to the retroactive payment of benefits but with several modifications. These modifications generally reflect the fact that the existing timing rules relating to notice and consent are generally tied to an annuity starting date that is after the furnishing of the QJSA explanation.[1]

Section 417(a)(7)(A) specifically permits the QJSA explanation to be made after the annuity starting date and modifies the participant election period in these situations. These regulations would make a comparable adjustment for the timing rules applicable to spousal consent by providing generally that, for retroactive payments under section 417(a)(7), the first date of actual payment is substituted for the annuity starting date in applying the timing rules for notice and consent. These modifications are intended to ensure that the notice and election are generally contemporaneous with the commencement of benefits, but the modifications recognize the need for flexibility in the timing to take into account administrative delays. In furtherance of that goal, these proposed regulations would modify the general timing rule applicable to the furnishing of notices, and to participant elections and spousal consent. The proposed regulations would provide that the participant's election to waive the QJSA under section 417(a)(1)(A)(i) and the spouse's consent under section 417(a)(2) must generally be made before the annuity starting date, but permits a later election if the distribution commences no more than 90 days after the QJSA explanation required by section 417(a)(3)(A) is furnished to the participant. This modification would apply without regard to the retroactivity of annuity starting dates, but would include an exception for reasonable administrative delay in the distribution of benefits.

Pursuant to the regulatory authority provided in section 417(a)(7)(A)(ii), these proposed regulations include a special spousal consent rule in addition to those rules applicable under section 417(a). Under this special rule, if the spouse's survivor annuity under a QJSA with an annuity starting date after the date the QJSA explanation was provided would be greater than the spouse's survivor annuity pursuant to the participant's election of a retroactive annuity starting date, the participant could not elect a retroactive annuity starting date unless the participant's spouse (determined at the time distributions actually commence) consents to the distribution. This special rule applies even if the form of benefit that the participant elects as of the retroactive annuity starting date is a QJSA. Thus, for example, where a QJSA that begins after the QJSA explanation is furnished would provide $1,000 monthly to the participant with a survivor annuity of $500 monthly to the spouse, and a QJSA with a retroactive annuity starting date would provide $900 monthly to the participant with a survivor annuity of $450 monthly to the spouse, together with a $20,000 make-up payment to the participant, the spouse would be required to consent in order for the participant to elect the retroactive annuity starting date. Spousal consent under this special rule would not be required in this example if the spouse's survivor annuity under the retroactive annuity starting date election is at least $500 per month.

These proposed regulations would also provide that, pursuant to section 417(a)(2)(B), the consent of the participant's spouse as of the retroactive annuity starting would not be required if that spouse is not the participant's spouse as of the date distributions commence, unless otherwise provided in a qualified domestic relations order (as defined in section 414(p)).

The proposed regulations would impose an additional condition on the availability of a retroactive annuity starting date, regarding the permissible amount of the distribution under sections 417(e)(3) (if applicable) and 415. To satisfy this condition, the distribution would be required to be adjusted, if necessary, to satisfy the requirements of sections 417(e)(3) (if applicable) and 415 if the date the distribution commences is substituted for the annuity starting date.

Proposed Effective Date

These regulations are proposed to be applicable for plan years beginning on or after January 1, 2002.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations require the collection of plan participants' written elections requesting qualified retirement plan distributions, and written spousal consent to these distributions, under limited circumstances. It is anticipated that most small businesses affected by these regulations will be sponsors of qualified retirement plans. Since these written participant elections and written spousal consents are required to be collected only for certain distributions, and since, in the case of a small plan, there will be relatively few distributions per year (and even fewer that are subject to these requirements), small plans that provide distributions for which this collection of information is required will only have to collect a small number of participant elections and spousal consents as a result of these regulations. Accordingly, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and 8 copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these regulations are Robert M. Walsh and Linda S. F. Marshall, Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.417(e)–1 is amended by:

1. Revising paragraph (b)(3)(i).
2. Revising paragraph (b)(3)(ii) introductory text.
3. Revising paragraph (b)(3)(ii)(C).
4. Redesignating paragraphs (b)(3)(iii) and (b)(3)(iv) as paragraphs (b)(3)(viii) and (b)(3)(ix), respectively.
5. Adding new paragraphs (b)(3)(iii) through (b)(3)(vii).

The additions and revisions read as follows:

§ 1.417(e)–1 Restrictions and valuations of distributions from plans subject to sections 401(a)(11) and 417.

* * * * *

(b)* * *

(3)* * *

(i) Written consent of the participant and the participant's spouse to the distribution must be made not more than 90 days before the annuity starting date, and, except as otherwise provided in paragraphs (b)(3)(iii) and (b)(3)(iv) of this section, no later than the annuity starting date.

(ii) A plan must provide participants with the written explanation of the QJSA required by section 417(a)(3) no less than 30 days and no more than 90 days before the annuity starting date, except as provided in paragraph (b)(3)(iv) of this section regarding retroactive annuity starting dates. However, if the participant, after having received the written explanation of the QJSA, affirmatively elects a form of distribution and the spouse consents to that form of distribution (if necessary), a plan will not fail to satisfy the requirements of section 417(a) merely because the written explanation was provided to the participant less than 30 days before the annuity starting date, provided that the following conditions are met:

* * * * *

(C) The annuity starting date is after the date that the explanation of the QJSA is provided to the participant.

* * * * *

(iii) The plan may permit the annuity starting date to be before the date that any affirmative distribution election is made by the participant (and before the date that distribution is permitted to commence under paragraph (b)(3)(ii)(D) of this section), provided that, except as otherwise provided in paragraph (b)(3)(vii) of this section regarding administrative delay, distributions commence not more than 90 days after the explanation of the QJSA is provided.

(iv) *Retroactive annuity starting dates.* (A) Notwithstanding the requirements of paragraphs (b)(3)(i) and (ii) of this section, pursuant to section 417(a)(7), a defined benefit plan is permitted to provide benefits based on a retroactive annuity starting date if the requirements described in paragraph (b)(3)(v) of this section are satisfied. A defined benefit plan is not required to provide for retroactive annuity starting dates. If a plan does provide for a retroactive annuity starting date, it may impose conditions on the availability of a retroactive annuity starting date in addition to those imposed by paragraph (b)(3)(v) of this section, provided that imposition of those additional conditions does not violate any of the rules applicable to qualified plans. For example, a plan that includes a single sum payment as a benefit option may limit the election of a retroactive annuity starting date to those participants who do not elect the single sum payment. A defined contribution plan is not permitted to have a retroactive annuity starting date.

(B) For purposes of this section, a "retroactive annuity starting date" is an annuity starting date affirmatively elected by a participant that occurs on or before the date the written explanation required by section 417(a)(3) is provided to the participant. In order for a plan to treat a participant as having elected a retroactive annuity starting date, future periodic payments with respect to a participant who elects a retroactive annuity starting date must be the same as the future periodic payments, if any, that would have been paid with respect to the participant had payments actually commenced on the retroactive annuity starting date. The participant must receive a make-up payment to reflect any missed payment or payments for the period from the retroactive annuity starting date to the date of the actual make-up payment (with an appropriate adjustment for interest from the date the missed payment or payments would have been made to the date of the actual make-up payment). Thus, the benefit determined as of the retroactive annuity starting date must satisfy the requirements of sections 417(e)(3), if applicable, and section 415 with the applicable interest rate and applicable mortality table determined as of that date. Similarly, a participant is not permitted to elect a retroactive annuity starting date that precedes the date upon which the participant could have otherwise started receiving benefits (e.g., the earlier of the participant's termination of employment or the participant's normal retirement age) under the terms of the plan in effect as of the retroactive annuity starting date. A plan does not fail to treat a participant as having elected a retroactive annuity starting date as described in this paragraph (b)(3)(iv)(B) merely because the distributions are adjusted to the extent necessary to satisfy the requirements of paragraph (b)(3)(v)(B) of this section relating to sections 415 and 417(e)(3).

(C) If the participant's spouse as of the retroactive annuity starting date would not be the participant's spouse determined as if the date distributions commence were the participant's annuity starting date, consent of that former spouse is not needed to waive the QJSA with respect to the retroactive annuity starting date, unless otherwise provided under a qualified domestic relations order (as defined in section 414(p)).

(D) A distribution payable pursuant to a retroactive annuity starting date election is treated as excepted from the present value requirements of paragraph (d) of this section under paragraph (d)(6) of this section if the distribution form would have been described in paragraph (d)(6) of this section had the distribution

[1] For example, section 417(a)(1) provides that a participant may elect to waive the QJSA within the "applicable election period" which is defined by section 417(a)(6) as the 90-day period ending on the annuity starting date. Similarly, § 1.417(e)–1(b)(3)(i) provides that the written consent of the plan participant and the participant's spouse must be made no more than 90 days before the annuity staring date. Also, § 1.417(e)–1(b)(3)(ii) provides that the QJSA explanation must generally be provided no less than 30 days and no more than 90 days before the annuity starting date.

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actually commenced on the retroactive annuity starting date.

(v) *Requirements applicable to retroactive annuity starting dates.* A distribution is permitted to have a retroactive annuity starting date with respect to a participant's benefit only if the following requirements are met:

(A) The participant's spouse (including an alternate payee who is treated as the spouse under a qualified domestic relations order (QDRO), as defined in section 414(p)), determined as if the date distributions commence were the participant's annuity starting date, consents to the distribution in a manner that would satisfy the requirements of section 417(a)(2). The spousal consent requirement of this paragraph (b)(3)(v)(A) is satisfied if such spouse consents to the distribution under paragraph (b)(2)(i) of this section. The spousal consent requirement of this paragraph (b)(3)(v)(A) does not apply if the amount of such spouse's survivor annuity payments under the retroactive annuity starting date election is no less than the amount that the payments to such spouse would have been under a QJSA with an annuity starting date after the date that the explanation was provided.

(B) The distribution (including appropriate interest adjustments) provided based on the retroactive annuity starting date would satisfy the requirements of sections 417(e)(3), if applicable, and section 415 if the date the distribution commences is substituted for the annuity starting date for all purposes, including for purposes of determining the applicable interest rate and the applicable mortality table.

(vi) *Timing of notice and consent requirements in the case of retroactive annuity starting dates.* In the case of a retroactive annuity starting date, the date of the first actual payment of benefits based on the retroactive annuity starting date is substituted for the annuity starting date for purposes of satisfying the timing requirements for giving consent and providing an explanation of the QJSA provided in paragraphs (b)(3)(i) and (ii) of this section, except that the substitution does not apply for purposes of paragraph (b)(3)(iii) of this section. Thus, the written explanation required by section 417(a)(3)(A) must generally be provided no less than 30 days and no more than 90 days before the date of the first payment of benefits and the election to receive the distribution must be made after the written explanation is provided and on or before the date of the first payment. Similarly, the written explanation may also be provided less than 30 days prior to the first payment of benefits if the requirements of paragraph (b)(3)(ii) of this section would be satisfied if the date of the first payment is substituted for the annuity starting date.

(vii) *Administrative delay.* A plan will not fail to satisfy the 90-day timing requirements of paragraphs (b)(3)(iii) and (vi) of this section merely because, due solely to administrative delay, a distribution commences more than 90 days after the written explanation of the QJSA is provided to the participant.

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–132 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–104876–00]

RIN 1545–AY66

Taxable Years of Partner and Partnership; Foreign Partners

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations on the taxable year of a partnership with foreign partners. The proposed regulations affect partnerships and their partners. This document also contains a notice of public hearing on these proposed regulations.

DATES: Written comments must be received by April 17, 2001. Requests to speak (with outlines of oral comments) at the public hearing scheduled for June 6, 2001, at 10 a.m., must be submitted by May 16, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–104876–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–104876–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option of the IRS Home Page or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/tax_regs/regslist.html. The public hearing will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Dan Carmody, (202) 622–3080; concerning specific international issues, Ronald M. Gootzeit, (202) 622–3860; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, LaNita VanDyke, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: This document proposes to amend section 706 of the Income Tax Regulations (26 CFR part 1) regarding partnership taxable years.

Background

Section 706 governs the taxable years for a partnership and its partners. The partners and the partnership each have their own taxable years, which may or may not coincide. Under section 706(a), for a partner's taxable year, the partner must include in taxable income the partner's share of any income, gain, loss, deduction, or credit of the partnership for the partnership's taxable year that ends within or with the partner's taxable year. Section 706(b) provides rules for determining a partnership's taxable year.

Prior to the Tax Reform Act of 1986, it was possible for partners to create income deferral opportunities through arranging divergent taxable years for a partnership and its partners. For example, under certain circumstances, a partnership could elect a June 30 taxable year while its partners were calendar year taxpayers. Under such an arrangement, the partners would include partnership income earned from July 1, Year 1, to June 30, Year 2, in Year 2, when the partnership's taxable year ended, even though six months of income was generated during Year 1. To prevent this potential for income deferral, Congress amended section 706(b). See generally Staff of the Joint Committee on Taxation, *General Explanation of the Tax Reform Act of 1986, 533–39 (1986).*

Section 706(b) provides that, unless the partnership establishes a business purpose for a different taxable year, a partnership cannot have a taxable year other than: (i) the majority interest taxable year; (ii) if there is no majority interest taxable year, the taxable year of all the principal partners of the partnership; or (iii) if there is no taxable year described in (i) or (ii), the calendar year unless the Secretary by regulation prescribes another period. Section 1.706–1T(a)(1) and (2) provides that if neither (i) nor (ii) is applicable, the partnership's taxable year will be the taxable year that results in the least aggregate deferral of partnership income.

Additionally, § 1.706–3T(a) provides that under certain circumstances, a tax-exempt partner will be disregarded for purposes of section 706(b).

Explanation of Provisions

I. Treatment of Foreign Partners

Currently, foreign partners are taken into consideration when determining a partnership's taxable year under section 706(b). In some circumstances, this could allow the taxable year of a partnership to be determined for Federal tax purposes by reference to the taxable year of one or more partners who may not be subject to U.S. taxation on income earned through the partnership. For instance, assume that a foreign partner owns a majority interest in a partnership that generates only foreign source income that is not effectively connected with a trade or business conducted within the United States. The minority partners are domestic persons subject to tax in the United States on income earned through the partnership. If the taxable year or years of the domestic partners are different from that of the majority partner, the majority partner's taxable year would determine the partnership's taxable year, which would affect the timing of the domestic partners' inclusion of partnership income. Thus, by conforming the partnership's taxable year to the taxable year of foreign partners, the mechanical application of section 706(b) can create deferral for those partners who are subject to tax in the United States on income earned through the partnership, while having no impact on the majority foreign partners who are not subject to tax in the United States on such income. The IRS and the Treasury do not believe that such a result is consistent with the intent of the statute.

A. Disregard Certain Foreign Partners

The proposed regulations generally require foreign partners who are not subject to U.S. taxation on a net basis on income earned through the partnership to be disregarded for purposes of applying section 706(b). For these purposes a foreign partner will be considered subject to Federal income tax only if the partner is allocated gross income of the partnership that is effectively connected (or treated as effectively connected) with the conduct of a trade or business within the United States (effectively connected income or ECI). In the case of a foreign partner claiming benefits under a U.S. income tax treaty, a foreign partner will be disregarded unless it is allocated gross income that is attributable to a permanent establishment in the United States.

A foreign partner also may be subject to U.S. Federal income tax on its distributive share of fixed or determinable annual or periodic income (FDAP income) from U.S. sources. In certain circumstances, the timing for imposing United States withholding tax on FDAP income earned through a partnership may be affected by the partnership's taxable year. See, e.g., § 1.1441–5(b)(2)(i) (providing the timing for withholding under section 1441 in the case of a domestic partnership that has received, but not distributed, FDAP income that is includible in the distributive share of a foreign partner). The IRS and Treasury believe that the withholding provisions of section 1441 provide a more appropriate mechanism than section 706 for addressing timing issues for these partners. Additionally, the IRS and Treasury are concerned that the ability of a partnership to earn small amounts of FDAP income, and thereby alter the determination of its taxable year, may permit inappropriate manipulation of the rule under section 706(b) for the domestic partners. Accordingly, under these proposed regulations, the taxable year of a foreign partner would be disregarded for purposes of section 706(b) if that partner is subject to Federal income tax solely due to the presence of U.S. source income earned through the partnership that is not ECI. In addition, it is irrelevant, for purposes of the proposed regulations, whether the foreign partner is subject to tax in the United States with respect to income other than income earned by the partnership.

The rule for foreign partners provided in these proposed regulations generally is consistent with the present rule under § 1.706–3T for the treatment of partners that are exempt from taxation under section 501(a). The taxable years of tax-exempt partners are not considered for purposes of section 706(b) unless those partners are subject to tax on income from the partnership. One difference between the rules for foreign partners and the rules for tax-exempt partners is that foreign partners will be included in determining a partnership's taxable year where the foreign partner is allocated gross income that is effectively connected with a U.S. trade or business, but actually has a net loss from the partnership for the taxable year (i.e., the foreign partners are not actually subject to tax on their allocable portion of the partnership's income). By contrast, a tax-exempt partner is disregarded where its allocable share of the partnership's tax items produces a net loss for the taxable year even though, if the foreign partner were allocated net income for the taxable year, the tax-exempt entity would have been subject to tax on such income. The IRS and Treasury are considering modifying the tax-exempt rule to conform with the proposed rule for foreign partners and request comments in this regard.

Finally, for purposes of these rules, the proposed regulations generally define a foreign partner as a partner that is not a U.S. person (as defined in section 7701(a)(30)), but provide that controlled foreign corporations (CFCs) and foreign personal holding companies (FPHCs) are not treated as foreign partners. These entities are not treated as foreign for purposes of determining a partnership's taxable year under section 706 because the U.S. owners of such entities may be subject to Federal income taxation on a current basis with respect to income earned by the entities.

The IRS and Treasury also considered, but did not include, a similar rule for passive foreign investment companies (PFICs). The proposed regulations do not include a similar rule for PFICs because, unlike the rules for CFCs and FPHCs, which require that a majority of the ownership be concentrated in a small group of U.S. persons, the PFIC rules apply without regard to the level of ownership of the individual, or of all U.S. owners in the aggregate. Additionally, in most instances where a PFIC does have substantial U.S. ownership, it will also be a CFC or a FPHC.

B. Minority Interest Rule

The IRS and Treasury recognize that requiring a partnership taxable year to be determined without regard to certain foreign partners may present difficulties for minority partners in some cases. If the taxable years of certain foreign partners are disregarded for purposes of section 706(b), it is possible that the taxable year of a partnership may be determined solely by reference to the taxable year of one or more small minority domestic partners. This could create significant administrative burdens for minority partners if the partnership maintains its books and records on a taxable year selected by significant foreign partners that is different from the taxable year of the minority partner or partners.

In order to provide relief in this situation, the proposed regulations contain an exception providing that foreign partners will not be disregarded

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for purposes of section 706(b) if the partnership's taxable year would be determined by reference to partners that individually hold less than a 10-percent interest, and in the aggregate hold less than a 20-percent interest, in the capital and profits of the partnership. For purposes of this rule, a partner's interest will include interests held directly and interests held by related partners. In determining whether the minority interest rule applies, the proposed regulations take into account the ownership of tax-exempt entities that are disregarded under § 1.706–3T(a).

Where a domestic tax-exempt entity (or entities) owns a relatively small interest in the partnership, but enough to cause the minority interest rule not to apply, the result may be anomalous, given that the tax-exempt entity has no real interest in a particular taxable year and thus has no incentive to convince significant foreign partners to cause the partnership to determine its taxable year by reference to the domestic partners. However, where such a tax-exempt entity (or entities) owns a majority interest in the partnership, the result may be more appropriate because the domestic partners are more likely to have significant bargaining power regarding the taxable year vis-a-vis the foreign partners. An appropriate solution may be to exclude tax-exempt entities from both the numerator and denominator in applying the de minimis rule. The IRS and Treasury request comments regarding how tax-exempt entities should be treated for purposes of the minority interest rule.

C. Transitional Relief

Under current law, a partnership may have adopted a taxable year that creates deferral by reference to the taxable year of a foreign partner not subject to U.S. net income taxation. In such instances, compliance with these regulations could result in a change in the partnership taxable year which would cause a "bunching" of more than 12 months of partnership income into a single taxable year of the partners subject to Federal income tax.

For example, consider a partnership that has a June 30 taxable year because of the presence of a 60-percent foreign partner that is not subject to U.S. net income taxation on income earned through the partnership. This taxable year creates six months of deferral for the 40-percent domestic partner, who is on the calendar year. In the year that these proposed regulations become effective, two partnership taxable years (the taxable year concluding on June 30 and the initial short calendar year concluding December 31) would close during the domestic partner's taxable year. Thus, section 706(a) would require the domestic partner to recognize its distributive share of 18 months of partnership income during a single taxable year. While the historic taxable year of the partnership in this example is inconsistent with the intent of section 706(b), the IRS and Treasury recognize that the potential bunching of income caused by changing to an appropriate taxable year might present an undue hardship for some taxpayers.

In order to alleviate such a hardship, the proposed regulations would permit adversely affected taxpayers to apply the four-year spread provisions of § 1.702–3T. This transitional rule will have limited application; it is intended only to provide relief for bunching of income that occurs in the first taxable year beginning on or after the effective date of these proposed regulations.

II. Application of § 1.701–2

The mechanical rules of section 706(b) operate to limit partners' opportunities to defer the recognition of partnership income. Where partners have different taxable years, eliminating or limiting deferral for one partner may result in increasing deferral for another partner. Such deferral is an anticipated result of section 706(b). However, an application of the mechanical rules of section 706(b) and these proposed regulations remains subject to the anti-abuse rule of § 1.701–2.

For example, assume that these proposed regulations would disregard the taxable year of a 76-percent foreign partner and require the partnership (which only has foreign operations, and therefore does not earn ECI) to adopt the taxable year of the 24-percent domestic partner. Conceivably the partners could attempt to avoid this result by forming a tiered structure where the foreign partner would own a 95-percent interest in an upper-tier domestic partnership that would hold, as its only asset, an 80 percent interest in the lower-tier operating partnership (the domestic partner would own the remaining 5 percent of the upper-tier partnership and the remaining 20 percent of the lower-tier partnership). In substance, this is the same arrangement as the single partnership except that the minority interest rule would generally require the upper-tier partnership to adopt the taxable year of the foreign partner (because the domestic partner owns less than a 10-percent interest in the upper-tier partnership). The upper-tier domestic partnership's taxable year would then be considered the majority interest taxable year of the lower-tier partnership under section 706(b)(1)(B)(i). In these circumstances, the Commissioner may determine that in order to achieve a tax result that is consistent with the intent of section 706, § 1.701–2 should apply. In such event, the Commissioner may disregard the upper-tier partnership and treat the assets thereof (in this case, the interest in the lower-tier partnership) as being owned directly by its partners, with the result that the foreign partner would be disregarded in determining the taxable year of the lower-tier partnership under section 706(b) and these proposed regulations.

III. Finalization of Prior Proposed Regulations

The current temporary regulations under section 706 are the product of three separate Treasury decisions. The text of these Treasury decisions, TD 7991 (adopted November 29, 1984), TD 8169 (adopted December 23, 1987), and TD 8205 (adopted May 24, 1988), were also contemporaneously promulgated as proposed regulations, LR–183–84 (published in the **Federal Register** on November 30, 1984), LR–101–86 (published in the **Federal Register** on December 29, 1987), and LR–53–880 (published in the **Federal Register** on May 27, 1988). These proposed regulations have not been withdrawn, and it is likely that they will be finalized in conjunction with the finalization of the regulations proposed by this document. The IRS and Treasury expect that the finalization of these previously proposed regulations will be accompanied by the withdrawal of the existing temporary regulations. Comments previously received in connection with the prior proposed regulations will be considered as well as new or additional comments with respect to such regulations.

IV. Effective Date

These regulations are proposed to apply to partnership taxable years beginning on or after the date final regulations are published in the **Federal Register**. For example, if the final regulations were published on November 1, 2001, a partnership that historically has determined its taxable year by reference to a 75-percent foreign partner with a March 31 taxable year end rather than by reference to a 25-percent domestic partner that uses the calendar year would be required to change to the calendar year as of April 1, 2002 (the partnership year beginning after the date final regulations were published). This would result in a short taxable year from April 1, 2002, to December 31, 2002.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (preferably a signed original and eight (8) copies) that are submitted timely to the IRS. The IRS and Treasury specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for June 6, 2001, beginning at 10 a.m., in room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons that wish to present oral comments at the hearing must submit timely written comments and must submit an outline of the topics to be discussed and the time to be devoted to each topic (preferably a signed original and eight (8) copies) by May 16, 2001.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Dan Carmody, Office of Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.706–4 is added to read as follows:

§ 1.706–4 Certain foreign partners disregarded.

(a) *General rule*—(1) *Foreign partners not claiming benefits under a U.S. income tax treaty.* In determining the taxable year (the current taxable year) of a partnership under section 706(b) and the regulations thereunder, a foreign partner shall be disregarded unless such partner is allocated any gross income of the partnership that was effectively connected (or treated as effectively connected) with the conduct of a trade or business within the United States during the partnership's taxable year immediately preceding the current taxable year. However, if a foreign partner was not a partner during the partnership's immediately preceding taxable year, such partner will be disregarded for the current taxable year if the partnership reasonably believes that the partner will not be allocated any gross income generated by the partnership during the current taxable year that is effectively connected with the conduct of a trade or business within the United States.

(2) Foreign partners claiming benefits under a U.S. income tax treaty. In the case of a foreign partner claiming benefits under an income tax treaty between the United States and another jurisdiction, a foreign partner will be disregarded under this paragraph (a) unless such partner was allocated any gross income that was attributable to a permanent establishment in the United States during the partnership's taxable year immediately preceding the current taxable year (or, if such partner was not a partner during the immediately preceding taxable year, the partnership reasonably believes that such partner will be allocated such income during the current taxable year).

(b) *Minority interest rule.* If the partners that are not disregarded by paragraph (a) of this section (absent the application of this paragraph (b)) individually hold less than a 10-percent interest, and in the aggregate hold less than a 20-percent interest, in the capital and profits of the partnership, paragraph (a) of this section will not apply. For purposes of determining ownership in the partnership after application of paragraph (a) of this section, the constructive ownership rules of section 318 shall apply, and the attribution rules of section 267(c) also shall apply to the extent they attribute ownership to persons to whom section 318 does not attribute ownership. However, "10 percent" shall be substituted for "50 percent" in section 318(a)(2)(C) and (3)(C). For purposes of determining if partners hold less than a 20-percent interest in the aggregate, the same interests will not be considered as being owned by more than one partner.

(c) *Definition of foreign partner.* For purposes of this section, a foreign partner is any partner that is not a U.S. person (as defined in section 7701(a)(30)), except that a partner that is a controlled foreign corporation (as defined in section 957(a)) or a foreign personal holding company (as defined in section 552) shall not be treated as a foreign partner.

(d) *Example.* The provisions of this section may be illustrated by the following example:

Example. Partnership B is owned by two partners, F, a foreign corporation that owns a 95-percent interest in the capital and profits of partnership B, and D, a domestic corporation that owns the remaining 5-percent interest in the capital and profits of partnership B. Partnership B is not engaged in the conduct of a trade or business within the United States, and, accordingly, partnership B does not earn any income that is effectively connected with a U.S. trade or business. F uses a March 31 fiscal year, and causes partnership B to maintain its books and records on a March 31 fiscal year as well. D is a calendar year taxpayer. Under paragraph (a) of this section, F would be disregarded and partnership B's taxable year would be determined by reference to D. However, because D owns less than a 10-percent interest in the capital and profits of partnership B, the minority interest rule of paragraph (b) of this section applies, and

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partnership B must adopt the March 31 fiscal year.

(e) *Effective date*—(1) *Generally.* The provisions of this section are applicable for partnership taxable years that begin on or after the date final regulations are published in the **Federal Register**.

(2) *Transition rule.* Partners of a partnership that is required to change its taxable year as of the beginning of its first taxable year after the date final regulations are published in the **Federal Register** may apply the provisions of § 1.702–3T if the change in taxable year occurs in the first taxable year following the date final regulations are published in the **Federal Register**.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–270 Filed 1–16–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[Reg–107175–00]

RIN 1545–AY19

Definition of Disqualified Person

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations to narrow the definition of the term disqualified person for section 1031 like-kind exchanges. The regulations are in response to recent changes in the federal banking law, especially the repeal of section 20 of the Glass-Steagall Act of 1933. The regulations will affect the eligibility of certain persons to serve as escrow holders of qualified escrow accounts, trustees of qualified trusts, or as qualified intermediaries. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by April 17, 2001. Requests to speak and outlines of topics to be discussed at the public hearing scheduled for June 5, 2001, at 10 a.m. must be received by May 15, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–107175–00), room 5226, Internal Revenue Service, Post Office Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–107175–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.ustreas.gov/tax_regs/regslist.html*. The public hearing will be held in room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, J. Peter Baumgarten, at (202) 622–4950; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Treena Garrett, at (202) 622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) for the definition of disqualified person under section 1.1031(k)–1(k).

An exchange of property, like a sale, usually results in the current recognition of gain or loss. Section 1031(a) provides an exception to the general rule. Under section 1031(a), no gain or loss is recognized if property held for productive use in a trade or business or for investment is exchanged solely for property of a like kind that is to be held either for productive use in a trade or business or for investment.

Taxpayers may use a qualified escrow account, qualified trust, or qualified intermediary (or any combination of the three) to facilitate a like-kind exchange. A requirement common to qualified escrow accounts, qualified trusts, and qualified intermediaries is that the escrow holder, trustee, or intermediary may not be the taxpayer or a disqualified person.

Section 1.1031(k)-1(k) defines a disqualified person to include a person that is an agent of the taxpayer at the time of the transaction. An agent includes a person that has acted as the taxpayer's employee, attorney, accountant, investment banker or broker, or real estate agent or broker within two years of the taxpayer's transfer of relinquished property. However, in determining whether a person is a disqualified person, services provided by such person for the taxpayer with respect to section 1031 exchanges of property and routine financial, title insurance, escrow, or trust services provided to the taxpayer by a financial institution, title insurance company, or escrow company are not taken into account. A person that is related to a disqualified person, determined by using the attribution rules of sections 267(b) and 707(b) but substituting 10 percent for 50 percent, is also considered a disqualified person.

Under section 20 of the Banking Act of 1933 (12 U.S.C. 377) (the Glass-Steagall Act), banks generally were proscribed from affiliation with any corporation, association, business trust, or other similar organization engaged principally in the issue, flotation, underwriting, public sale, or distribution at wholesale or retail or through syndicate participation of stocks, bonds, debentures, notes, or other securities. However, last year Congress enacted the Gramm-Leach-Bliley Act, Public Law 106–102 (November 12, 1999), 113 Stat. 1341 (the GLB Act). Section 101 of the GLB Act repeals section 20 of the Glass-Steagall Act. In addition, section 103 of the GLB Act amends section 4 of the Bank Holding Company Act of 1956 (12 U.S.C. 1843) by adding new subsection (k). Subsection (k) specifically authorizes qualifying financial institutions to engage in activities that are financial in nature, such as (1) providing financial, investment, or economic advisory services, including advising an investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3)); (2) issuing and selling instruments representing interests in pools of assets permissible for a bank to hold directly; and (3) underwriting, dealing in, and making a market in securities.

As a consequence of the GLB Act (and other changes in policy by the Federal Reserve System in recent years), many banks and bank holding companies are, or are in the process of becoming, members of controlled groups that include investment banking and brokerage firms. This, in turn, may cause the banks, bank holding companies, and their subsidiaries to be disqualified persons for purposes of section 1031 by virtue of the related party rule of § 1.1031(k)–1(k)(4).

Treasury and the Service believe that, in general, banks should be permitted to serve as qualified intermediaries, escrow holders, or trustees. Banks, as regulated institutions, have historically acted in this role as neutral or independent holders of funds. These regulations permit banks to continue in this role despite recent legislative and regulatory changes.

In order to account for changes in the banking industry, the proposed regulations generally provide that a bank that is a member of a controlled group that includes an investment banking or brokerage firm as a member will not be a disqualified person merely because the investment banking or brokerage firm has provided services to an exchange customer within a two-year period ending on the date of the transfer of the relinquished property by that customer.

Proposed Effective Date

The regulations are applicable for transfers of property made by a taxpayer on or after January 17, 2001.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the merits of the proposed regulations and how the proposed regulations can be made clearer and easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for June 5, 2001, beginning at 10 a.m. in room 4718 of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the main Constitution Avenue entrance between 10th and 12th Streets, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments and an outline of the topics to be discussed and the time to be devoted to each topic by May 15, 2001. A period of ten (10) minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving the outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is J. Peter Baumgarten of the Office of Associate Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendment to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1031(k)–1 is amended by adding a sentence to the end of paragraph (k)(4) to read as follows:

§ 1.1031(k)–1 Treatment of deferred exchanges.

* * * * *

(k) * * *

(4) * * * However, with respect to transfers of relinquished property made by a taxpayer on or after the date on which these regulations are published as final regulations, this paragraph (k)(4) does not apply to a bank (as defined in section 581) that is a member of a controlled group (as determined under section 267(f)(1), substituting "10 percent" for "50 percent" where it appears), where a person described in paragraph (k)(2) of this section is an investment banker or broker that has provided investment banking or brokerage services to the taxpayer within the 2-year period and also is a member of the controlled group.

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–624 Filed 1–16–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 31

[REG–126100–00]

RIN 1545–AY62

Guidance on Reporting of Deposit Interest Paid to Nonresident Aliens

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that provide guidance on the reporting requirements for interest on deposits maintained at the U.S. office of certain financial institutions and paid to nonresident alien individuals. These proposed regulations affect persons making payments of interest with respect to such a deposit. This document also provides a notice of public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by February 27, 2001. Requests to speak (with outlines of oral comments to be discussed) at the public hearing scheduled for 10 a.m. on March 21, 2001, must be received by February 27, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–126100–00), Room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions also may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–126100–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax-regs/regslist.html*. The public hearing will be held in Room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations,

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Kate Y. Hwa, (202) 622–3840 (not a toll free number); concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Lanita Vandyke, (202) 622–7180 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O, Washington, DC 20224. Comments on the collections of information should be received by March 19, 2001. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper operation of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

The collection of information in these proposed regulations is in §§ 1.6049–4(b)(5)(i), 1.6049–6(e)(4) (i), and (ii). This information is required to determine if taxpayers have properly reported amounts received as income. The collection of information is mandatory. The likely respondents are businesses and other for-profit institutions.

The estimated average annual burden per respondent and/or recordkeeper required by §§ 1.6049–4(b)(5)(i), 1.6049–6(e)(4) (i), and (ii) will be reflected in the burdens of Forms W–8, 1042, 1042–S, and the income tax return of a foreign person.

Further, the estimated average annual burden per respondent and/or recordkeeper for the statement required by § 1.6049–6(e)(4)(i) is as follows:

Estimated total annual reporting burden: 500 hours.

Estimated average annual burden per respondent: 15 minutes.

Estimated number of respondents: 2,000.

Estimated annual frequency of responses: annually.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law.

Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background and Explanation of Provisions

The IRS previously determined that information concerning interest paid on deposits from U.S. bank accounts to nonresident alien individuals who are residents of Canada would be significant in furthering its compliance efforts. Consequently, § 1.6049–8(a) requires the reporting of such interest on a Form 1042–S.

The proposed regulations extend the information reporting requirement for bank deposit interest paid to nonresident alien individuals who are residents of other foreign countries. This extension is appropriate for two reasons. First, requiring routine reporting to the IRS of all bank deposit interest paid within the United States will help to ensure voluntary compliance by U.S. taxpayers by minimizing the possibility of avoidance of the U.S. information reporting system (such as through false claims of foreign status). Second, several countries that have tax treaties or other agreements that provide for the exchange of tax information with the United States have requested information concerning bank deposits of individual residents of their countries. Because of the importance that the United States attaches to exchanging tax information as a way of encouraging voluntary compliance and furthering transparency, see e.g. S. Exec. Rep. No. 106–8, at 15 (1st Sess. 1999), Treasury and the IRS believe it is important for the United States to facilitate, wherever possible, the effective exchange of all relevant tax information with our treaty partners.

In addition to extending the information reporting requirement for interest paid on deposits maintained at a bank's office within the United States to all nonresident alien individuals, the proposed regulations also make the following minor changes and clarifications.

Section 1.6049–6 provides that a copy of Form 1042–S must be furnished to the recipient for interest paid on deposits maintained at a bank's office within the United States. Paragraph (e)(4)(i) of that section has been revised to clarify that the payor or middleman can satisfy this requirement by furnishing a copy of Form 1042–S either in person or to the last known address of the recipient.

A new paragraph (e)(4)(ii) has been added to § 1.6049–6 to provide guidance on the manner in which a Form 1042–S is furnished when there are joint account holders. Specifically, if any joint account holder is a U.S. non-exempt recipient, the payor or middleman must report the entire payment to that person. If all joint account holders are foreign persons, the payor or middleman must report the payment to the nonresident alien individual that is a resident of a country with which the United States has an income tax treaty or a tax information exchange agreement (TIEA). If more than one of the joint account holders is a foreign person and is a resident of a country with which the United States has an income tax treaty or a TIEA, the payor or middleman must report the payment to the person that is the primary account holder. The payor or middleman must, however, furnish a Form 1042–S to any account holder who requests it.

Section 1.6049–8(a) provides that interest paid with respect to a deposit maintained at an office within the United States to individuals who are Canadian residents must be reported. The payor or middleman may rely on the permanent address found on Form W–8 to make the determination of whether the nonresident alien individual resides in Canada. However, the regulation also provides that a payor or middleman may rely on its actual knowledge of the individual's residence address in Canada, even if a valid Form W–8 has not been provided, to make such a determination. This "actual knowledge of the individual's residence address" rule has been eliminated because it creates a result that is contrary to the presumption rules contained in § 1.1441–1(b)(3)(iii) (and made applicable to reportable payments by § 1.6049–5(d)(2)). Accordingly, § 1.6049–8(a) has been clarified to provide that, while amounts described in § 1.6049–8(a) generally are not subject to backup withholding under section 3406, the payor must report the payment on a Form 1099 as made to a U.S. non-exempt recipient in accordance with the presumption rules of §§ 1.6049–5(d)(2) and 1.1441–1(b)(3)(iii) if the payor or middleman does not have either a valid Form W–8 or valid Form W–9. Further, such payment is subject to backup withholding under section 3406.

Proposed Effective Date

These regulations are proposed to apply to payments made after December 31 of the year in which they are published as final regulations in the **Federal Register**.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely (in the manner described in the **ADDRESSES** portion of this preamble) to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for March 31, 2001, beginning at 10 a.m. in Room 4718, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** portion of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments must submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight (8) copies) by February 27, 2001. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for reviewing outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of the regulations is Kate Y. Hwa, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 31 are proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In section 1.6049–4, paragraph (b)(5) is revised to read as follows:

§ 1.6049–4 Return of information as to interest paid and original issue discount includible in gross income after December 31, 1962.

* * * * * *

(b) * * *

(5) *Interest payments to nonresident alien individuals*—(i) *General rule.* In the case of interest aggregating $10 or more paid to a nonresident alien individual (as defined in section 7701(b)(1)(B)) that is reportable under § 1.6049–8(a), the payor shall make an information return on Form 1042–S for the calendar year in which the interest is paid. The payor or middleman shall prepare and file Form 1042–S at the time and in the manner prescribed by section 1461 and the regulations under that section and by the form and its accompanying instructions. See §§ 1.1461–1(b) (rules regarding the preparation of a Form 1042) and 1.6049–6(e)(4) (rules for furnishing a copy of the Form 1042–S to the payee). To determine whether an information return is required for original issue discount, see §§ 1.6049–5(f) and 1.6049–8(a).

(ii) *Effective date.* Paragraph (b)(5)(i) of this section shall be effective for payments made after December 31 of the year in which the final regulations are published in the **Federal Register** with respect to a Form W–8 (Certificate of Foreign Status) furnished to the payor or middleman after that date. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see § 1.6049–4(b)(5) as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * * *

Par. 3. Section 1.6049–6 is amended as follows:

1. Paragraph (e)(4) is revised.

2. In paragraph (e)(5), the first sentence is revised and a new sentence is added at the end of the paragraph.

The addition and revisions read as follows:

§ 1.6049–6 Statements to recipients of interest payments and holders of obligations for attributed original issue discount.

* * * * * *

(e) * * *

(4) *Special rule for amounts described in § 1.6049–8(a)*—(i) *In general.* In the case of amounts described in § 1.6049–8(a) (relating to payments of deposit interest to nonresident alien individuals) paid after December 31 of the year in which the final regulations are published in the **Federal Register**, any person who makes a Form 1042–S under section 6049(a) and § 1.6049–4(b)(5) shall furnish a statement to the recipient either in person or by first-class mail to the recipient's last known address. The statement shall include a copy of the Form 1042–S required to be prepared pursuant to § 1.6049–4(b)(5) and a statement to the effect that the information on the form is being furnished to the United States Internal Revenue Service and may be furnished to the government of the foreign country where the recipient resides.

(ii) *Joint account holders.* In the case of joint account holders, a payor or middleman must report the entire amount of interest as paid to any joint account holder that provides a valid Form W–9, or, if any account holder has not furnished a Form W–8 or Form W–9, any account holder that is presumed to be a U.S. non-exempt recipient under § 1.6049–5(d)(2) and 1.1441–1(b)(3)(iii). If all of the joint account holders are

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foreign persons, then the payor or middleman must report the payment to the nonresident alien individual that is a resident of a country with which the United States has an income tax treaty or a tax information exchange agreement. If more than one of the joint account holders is a foreign person and is a resident of a country with which the United States has an income tax treaty or a tax information exchange agreement, then the payor or middleman may report the interest as paid to any such account holder that is treated as the primary account holder under § 31.3406(h)–2(a) of this chapter. If, however, any account holder requests its own Form 1042–S, the payor or middleman must furnish a Form 1042–S to the account holder who requests it.

(5) *Effective date.* Paragraph (e)(4) is effective for payee statements due after December 31 of the year in which the final regulations are published in the **Federal Register**, without regard to extensions. * * * (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see § 1.6049–6(e)(4) as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * *

Par. 4. In section 1.6049–8, the section heading and paragraph (a) are revised to read as follows:

§ 1.6049–8 Interest and original issue discount paid to nonresident alien individuals.

(a) *Interest subject to reporting requirement.* For purposes of §§ 1.6049–4, 1.6049–6, and this section and except as provided in paragraph (b) of this section, the term *interest* means interest paid to a nonresident alien individual after December 31 of the year in which the final regulations are published in the **Federal Register**, where the interest is described in section 871(i)(2)(A) with respect to a deposit maintained at an office within the United States. For purposes of the regulations under section 6049, a nonresident alien individual is a person described in section 7701(b)(1)(B). The payor or middleman may rely upon a valid Form W–8 to determine whether the payment is made to a nonresident alien individual. Generally, amounts described in this paragraph (a) are not subject to backup withholding under section 3406. See § 31.3406(g)–1(d) of this chapter. However, if the payor or middleman does not have either a valid Form W–8 or valid Form W–9, the payor or middleman must report the payment as made to a U.S. non-exempt recipient if it must so treat the payee under the presumption rules of §§ 1.6049–5(d)(2) and 1.1441–1(b)(3)(iii) and must also backup withhold under section 3406. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see § 1.6049–8(a) as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * *

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Par. 5. The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 6. In § 31.3406(g)–1, paragraph (d) is revised to read as follows:

§ 31.3406(g)–1 Exceptions for payments to certain payees and certain other payment.

* * * * *

(d) *Reportable payments made to nonresident alien individuals.* A payment of interest that is reported on Form 1042–S as paid to a nonresident alien individual under § 1.6049–8(a) of this chapter is not subject to withholding under section 3406. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see § 31.3406(g)–1(d) as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–250 Filed 1–16–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF TREASURY

Internal Revenue Service (IRS)

26 CFR Parts 1 and 54

[REG–130477–00; REG–130481–00]

RIN 1545–AY69, 1545–AY70

Required Distributions from Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to required minimum distributions from qualified plans, individual retirement plans, deferred compensation plans under section 457, and section 403(b) annuity contracts, custodial accounts, and retirement income accounts. These regulations will provide the public with guidance necessary to comply with the law and will affect administrators of, participants in, and beneficiaries of qualified plans; institutions that sponsor and individuals who administer individual retirement plans, individuals who use individual retirement plans for retirement income, and beneficiaries of individual retirement plans; and employees for whom amounts are contributed to section 403(b) annuity contracts, custodial accounts, or retirement income accounts and beneficiaries of such contracts and accounts.

DATES: Written and electronic comments must be received by April 17, 2001. Outlines of topics to be discussed at the public hearing scheduled for June 1, 2001, at 10 a.m. must be received by May 11, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–130477–00/REG130481–00) room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–130477–00/REG–130481–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option of the IRS Home Page, or by submitting comments directly to the IRS Internet site at: *http://www.irs.gov/tax_regs/reglist.html.* The public hearing on June 1, 2001, will be held in the IRS Auditorium (7th Floor), Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Cathy A. Vohs, 202–622–6090; concerning submissions and the hearing, and/or to be placed on the building access list to attend the hearing, Guy Traynor, 202–622–7180 (not toll-free numbers).

Paperwork Reduction Act

The collections of information contained in these proposed regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–0996, in conjunction with the notice of proposed rulemaking published on July 27, 1987, 52 FR 28070, REG–EE–113–82, Required Distributions From Qualified Plans and Individual Retirement Plans, and control number 1545–1573, in conjunction with the notice of proposed rulemaking published on December 30, 1997, 62 FR 67780, REG–209463–82, Required Distributions from Qualified Plans and Individual Retirement Plans.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books and records relating to the collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) and to the Pension Excise Tax Regulations (26 CFR Part 54) under sections 401, 403, 408, and 4974 of the Internal Revenue Code of 1986. It is contemplated that proposed rules similar to those in these proposed regulations applicable to section 401 will be published in the near future for purposes of applying the distribution requirements of section 457(d). These amendments are proposed to conform the regulations to section 1404 of the Small Business Job Protection Act of 1996 (SBJPA) (110 Stat. 1791), sections 1121 and 1852 of the Tax Reform Act of 1986 (TRA of 1986) (100 Stat. 2464 and 2864), sections 521 and 713 of the Tax Reform Act of 1984 (TRA of 1984) (98 Stat. 865 and 955), and sections 242 and 243 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (96 Stat. 521). The regulations provide guidance on the required minimum distribution requirements under section 401(a)(9) for plans qualified under section 401(a). The rules are incorporated by reference in section 408(a)(6) and (b)(3) for individual retirement accounts and annuities (IRAs), section 408A(c)(5) for Roth IRAs, section 403(b)(10) for section 403(b) annuity contracts, and section 457(d) for eligible deferred compensation plans.

For purposes of this discussion of the background of the regulations in this preamble, as well as the explanation of provisions below, whenever the term *employee* is used, it is intended to include not only an employee but also an IRA owner.

Section 401(a)(9) provides rules for distributions during the life of the employee in section 401(a)(9)(A) and rules for distributions after the death of the employee in section 401(a)(9)(B).

Section 401(a)(9)(A)(ii) provides that the entire interest of an employee in a qualified plan must be distributed, beginning not later than the employee's required beginning date, in accordance with regulations, over the life of the employee or over the lives of the employee and a designated beneficiary (or over a period not extending beyond the life expectancy of the employee and a designated beneficiary).

Section 401(a)(9)(C) defines required beginning date for employees (other than 5-percent owners and IRA owners) as April 1 of the calendar year following the later of the calendar year in which the employee attains age 70 ½ or the calendar year in which the employee retires. For 5-percent owners and IRA owners, the required beginning date is April 1 of the calendar year following the calendar year in which the employee attains age 70 ½, even if the employee has not retired.

Section 401(a)(9)(D) provides that (except in the case of a life annuity) the life expectancy of an employee and the employee's spouse that is used to determine the period over which payments must be made may be redetermined, but not more frequently than annually.

Section 401(a)(9)(E) provides that the term *designated beneficiary* means any individual designated as a beneficiary by the employee.

Section 401(a)(9)(G) provides that any distribution required to satisfy the incidental death benefit requirement of section 401(a) is a required minimum distribution.

Section 401(a)(9)(B)(i) provides that, if the employee dies after distributions have begun, the employee's interest must be distributed at least as rapidly as under the method used by the employee.

Section 401(a)(9)(B)(ii) and (iii) provides that, if the employee dies before required minimum distributions have begun, the employee's interest must be either: distributed (in accordance with regulations) over the life or life expectancy of the designated beneficiary with the distributions beginning no later than 1 year after the date of the employee's death, or distributed within 5 years after the death of the employee. However, under section 401(a)(9)(B)(iv), a surviving spouse may wait until the date the employee would have attained age 70 ½ to begin taking required minimum distributions.

Comprehensive proposed regulations under section 401(a)(9) were previously published in the **Federal Register** on July 27, 1987, 52 FR 28070. Many of the comments on the 1987 proposed regulations expressed concerns that the required minimum distribution must be satisfied separately for each IRA owned by an individual by taking distributions from each IRA. In response, Notice 88–38 (1988–1 C.B. 524) provided that the amount of the required minimum distribution must be calculated for each IRA, but permitted that amount to be taken from any IRA. Amendments to the 1987 proposed regulations published in the **Federal Register** on December 30, 1997, 62 FR 67780, responded to comments on the use of trusts as beneficiaries. Notice 96–67 (1996–2 C.B. 235) and Notice 97–75 (1997–2 C.B. 337) provided guidance on the changes made to section 401(a)(9) by the SBJPA. The guidance in Notice 88–38, Notice 96–67, and Notice 97–75 is incorporated in these proposed regulations with some modifications.

Even though the distribution requirements added by TEFRA were retroactively repealed by TRA of 1984, the transition election rule in section 242(b) of TEFRA was preserved. Notice 83–23 (1983–2 C.B. 418) continues to provide guidance for distributions permitted by this transition election rule. These proposed regulations retain the additional guidance on the transition rule provided in the 1987 proposed regulations.

As discussed below, in response to extensive comments, the rules for calculating required minimum distributions from individual accounts under the 1987 proposed regulations have been substantially simplified. Certain other 1987 rules have also been simplified and modified, although many of the 1987 rules remain unchanged. In particular, due to the relatively small number of comments on practices with respect to annuity contracts, and the effect of the 1987 proposed regulations on these practices, the basic structure of the 1987 proposed regulation provisions with respect to annuity payments is retained in these proposed regulations. The IRS and Treasury are continuing to study these rules and specifically request updated comments on current practices and issues relating to required minimum distributions from annuity contracts.

Explanation of Provisions

Overview

Many of the comments on the 1987 proposed regulations addressed the rules for required minimum distributions during an employee's life, including calculation of life expectancy and determination of designated beneficiary. In particular, comments raised concerns about the default

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provisions, election requirements, and plan language requirements. In general, the need to make decisions at age 70½, which under the 1987 proposed regulations would bind the employee in future years during which financial circumstances could change significantly, was perceived as unreasonably restrictive. In addition, the determination of life expectancy and designated beneficiary and the resulting required minimum distribution calculation for individual accounts were viewed as too complex.

To respond to these concerns, these proposed regulations would make it much easier for individuals—both plan participants and IRA owners—and plan administrators to understand and apply the minimum distribution rules. The new proposed regulations would make major simplifications to the rules, including the calculation of the required minimum distribution during the individual's lifetime and the determination of a designated beneficiary for distributions after death. The new proposed regulations simplify the rules by

- Providing a simple, uniform table that all employees can use to determine the minimum distribution required during their lifetime. This makes it far easier to calculate the required minimum distribution because employees would
  —no longer need to determine their beneficiary by their required beginning date, sbull no longer need to decide whether or not to recalculate their life expectancy each year in determining required minimum distributions, and
  —no longer need to satisfy a separate incidental death benefit rule.
- Permitting the required minimum distribution during the employee's lifetime to be calculated without regard to the beneficiary's age (except when required distributions can be reduced by taking into account the age of a beneficiary who is a spouse more than 10 years younger than the employee).
- Permitting the beneficiary to be determined as late as the end of the year following the year of the employee's death. This allows
  —the employee to change designated beneficiaries after the required beginning date without increasing the required minimum distribution and
  —the beneficiary to be changed after the employee's death, such as by one or more beneficiaries disclaiming or being cashed out.
- Permitting the calculation of post-death minimum distributions to take into account an employee's remaining life expectancy at the time of death, thus allowing distributions in all cases to be spread over a number of years after death.

These simplifications would also have the effect of reducing the required minimum distributions for the vast majority of employees.

The Uniform Distribution Period

Under these proposed regulations and the 1987 proposed regulations, for distributions from an individual account, the required minimum distribution is determined by dividing the account balance by the distribution period. For lifetime required minimum distributions, these proposed regulations provide a uniform distribution period for all employees of the same age. The uniform distribution period table is the required minimum distribution incidental benefit (MDIB) divisor table originally prescribed in § 1.401(a)(9)-2 of the 1987 proposed regulations and now included in A–4 of § 1.401(a)-5 of the new proposed regulations. An exception applies if the employee's sole beneficiary is the employee's spouse and the spouse is more than 10 years younger than the employee. In that case, the employee is permitted to use the longer distribution period measured by the joint life and last survivor life expectancy of the employee and spouse.

These changes provide a simple administrable rule for plans and individuals. Using the MDIB table, most employees will be able to determine their required minimum distribution for each year based on nothing more than their current age and their account balance as of the end of the prior year (which IRA trustees report annually to IRA owners). Under the 1987 proposed regulations, some employees already use the MDIB table to determine required minimum distributions. Under the new proposed regulations, they would continue to do so. For the majority of other employees, required minimum distributions would be reduced as a result of the changes.

For years after the year of the employee's death, the distribution period is generally the remaining life expectancy of the designated beneficiary. The beneficiary's remaining life expectancy is calculated using the age of the beneficiary in the year following the year of the employee's death, reduced by one for each subsequent year. If the employee's spouse is the employee's sole beneficiary at the end of the year following the year of death, the distribution period during the spouse's life is the spouse's single life expectancy. For years after the year of the spouse's death, the distribution period is the spouse's life expectancy calculated in the year of death, reduced by one for each subsequent year. If there is no designated beneficiary as of the end of the year after the employee's death, the distribution period is the employee's life expectancy calculated in the year of death, reduced by one for each subsequent year.

The MDIB table is based on the joint life expectancies of an individual and a survivor 10 years younger at each age beginning at age 70. Allowing the use of this table reflects the fact that an employee's beneficiary is subject to change until the death of the employee and ultimately may be a beneficiary more than 10 years younger than the employee. The proposed regulations would allow lifetime distributions at a rate consistent with this possibility. Consistent with the requirements of section 401(a)(9)(A)(ii), the distribution period after death is measured by the life expectancy of the employee's designated beneficiary in the year following death, or the employee's remaining life expectancy if there is no designated beneficiary. This ensures that the employee's entire benefit is distributed over a period described in section 401(a)(9)(A)(ii), i.e., the life expectancy of the employee or the joint life expectancy of the employee and a designated beneficiary.

The approach in these proposed regulations allowing the use of a uniform lifetime distribution period addresses concerns raised in comments on the 1987 proposed regulations that the rules are too complex. It eliminates the use of two tables and the interaction of the multiple beneficiary and change in beneficiary rules. Finally, it generally eliminates the need to fix the amount of the distribution during the employee's lifetime based on the beneficiary designated on the required beginning date and eliminates the need to elect recalculation or no recalculation of life expectancies at the required beginning date.

Suggestions have been received that the life expectancy table used to calculate required minimum distributions should be revised to reflect recent increases in longevity. These proposed regulations instead provide authority for the Commissioner to issue guidance of general applicability revising the life expectancy tables and the uniform distribution table in the future if it becomes appropriate. While life expectancy has increased in the 14 years since the issuance of the section 72 life expectancy tables, those tables may already overstate the average life expectancy of the class of individuals who are subject to these required minimum distribution rules (qualified plan participants, IRA owners, et al.). That is because those existing section 72 tables were derived from the particular mortality experience of the select population of individuals who purchase individual annuities, as opposed to the population who are subject to the required minimum distribution rules. In any event, as noted earlier, the new proposed uniform distribution period—equal to the joint life expectancy of an individual and a survivor 10 years younger at each age—would lengthen the lifetime distribution period for most employees and beneficiaries. In fact, the new proposed regulations would lengthen that period more for many individuals than would an update to reflect recent increases in longevity. The IRS and Treasury believe that this lengthening of the distribution period for most employees provides further justification for retaining the existing life expectancy tables at this time.

Some commentators suggested that the calculation of required minimum distributions include credit for any distribution in a prior year that exceeded that year's required minimum distribution. However, such a "credit" carryforward would require significant additional data retention and would add substantial complexity to the calculation of required minimum distributions. By using the prior year's ending account balance for calculating required minimum distributions, distribution of amounts in excess of the required minimum distribution has the effect of reducing future required minimum distributions over the remaining distribution period to some extent. Accordingly, these proposed regulations do not provide for a credit carryforward.

Determination of the Designated Beneficiary

These proposed regulations provide that, generally, the designated beneficiary is determined as of the end of the year following the year of the employee's death rather than as of the employee's required beginning date or date of death, as under the 1987 proposed regulations. Thus, any beneficiary eliminated by distribution of the benefit or through disclaimer (or otherwise) during the period between the employee's death and the end of the year following the year of death is disregarded in determining the employee's designated beneficiary for purposes of calculating required minimum distributions. If, as of the end of the year following the year of the employee's death, the employee has more than one designated beneficiary and the account or benefit has not been divided into separate accounts or shares for each beneficiary, the beneficiary with the shortest life expectancy is the designated beneficiary, consistent with the approach in the 1987 proposed regulations.

This approach for determining the designated beneficiary following the death of an employee after the employee's required beginning date is simpler in several respects than the approach in the 1987 proposed regulations and responds to concerns raised with respect to the effects of beneficiary designation at the required beginning date. Under this approach, the determination of the designated beneficiary and the calculation of the beneficiary's life expectancy generally are contemporaneous with commencement of required distributions to the beneficiary. Any prior beneficiary designation is irrelevant for distributions from individual accounts, unless the employee takes advantage of a lifetime distribution period measured by the joint life expectancy of the employee and a spouse more than 10 years younger than the employee. Further, for an employee with a designated beneficiary, this approach provides the same rules for distributions after the employee's death, regardless of whether death occurs before or after an employee's required beginning date. Finally, in the case of an employee who elects or defaults into recalculation of life expectancy and who dies without a designated beneficiary, the requirement that the employee's entire remaining account balance be distributed in the year after an employee's death has been eliminated and replaced with a distribution period equal to the employee's remaining life expectancy recalculated immediately before death.

Default Rule for Post-Death Distributions

As requested by some commentators, these proposed regulations would change the default rule in the case of death before the employee's required beginning date for a nonspouse designated beneficiary from the 5-year rule in section 401(a)(9)(B)(ii) to the life expectancy rule in section 401(a)(9)(B)(iii). Thus, absent a plan provision or election of the 5-year rule, the life expectancy rule would apply in all cases in which the employee has a designated beneficiary. As in the case of death on or after the employee's required beginning date, the designated beneficiary whose life expectancy is used to determine the distribution period would be determined as of the end of the year following the year of the employee's death, rather than as of the employee's date of death (as would have been required under the 1987 proposed regulations). The 5-year rule would apply automatically only if the employee did not have a designated beneficiary as of the end of the year following the year of the employee's death. Finally, in the case of death before the employee's required beginning date, these proposed regulations allow a waiver, unless the Commissioner determines otherwise, of any excise tax resulting from the life expectancy rule during the first five years after the year of the employee's death if the employee's entire benefit is distributed by the end of the fifth year following the year of the employee's death.

Annuity Payments

These proposed regulations make several changes to the rules for determining whether annuity payments satisfy section 401(a)(9). The changes are designed to make these rules more administrable without adverse effects on the basic structure and application of the rules. The IRS and Treasury are continuing to study and evaluate whether additional changes would be appropriate for determining whether annuity payments satisfy section 401(a)(9). Some comments were received on the annuity rules in 1987, but updated comments that include a discussion of current industry practices, products, and concerns would be helpful.

These proposed regulations provide that the designated beneficiary for determining the distribution period for annuity payments generally is the beneficiary as of the annuity starting date, even if that date is after the required beginning date. Thus, if annuity payments commence after the required beginning date, the determination of the designated beneficiary is contemporaneous with the annuity starting date and any intervening changes in the beneficiary designation since the required beginning date are ignored. Second, as requested in comments, these regulations extend to all annuity payment streams the rule in the 1987 proposed regulations that allows a life annuity with a period certain not exceeding 20 years to commence on the required beginning date with no makeup for the first distribution calendar year. For this purpose, the regulations clarify that only accruals as of the end of the prior calendar year must be taken into account in calculating the amount of an annuity

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commencing on the required beginning date. Subsequent accruals are treated as additional accruals that must be taken into account in the next calendar year. Also as requested in comments, the regulations provide that, although additional accruals need to be taken into account in the first payment in the calendar year following the year of the accrual, actual payment in the form of a make-up payment need only be completed by the end of that calendar year.

The permitted increase in annuity payments to an employee upon the death of the survivor annuitant has been expanded to cover the elimination of the survivor portion of a joint and survivor annuity due to a qualified domestic relations order. Further, in response to comments, in the case of an annuity contract purchased from an insurance company, an exception to the nonincreasing-payment requirement in these proposed regulations has been added to accommodate a cash refund upon the employee's death of the amount of the premiums paid for the contract.

One of the rules in the 1987 proposed regulations that the IRS and Treasury are continuing to study and evaluate is the rule providing that if the distributions from a defined benefit plan are not in the form of an annuity, the employee's benefit will be treated as an individual account for purposes of determining required minimum distributions. The IRS and Treasury are continuing to consider whether retention of this rule is appropriate for defined benefit plans. Similarly, the IRS and Treasury are continuing to consider whether the rule permitting the benefit under a defined benefit plan to be divided into segregated shares for purposes of section 401(a)(9) is useful and appropriate for defined benefit plans.

Trust as Beneficiary

These proposed regulations retain the provision in the proposed regulations, as amended in 1997, allowing an underlying beneficiary of a trust to be an employee's designated beneficiary for purposes of determining required minimum distributions when the trust is named as the beneficiary of a retirement plan or IRA, provided that certain requirements are met. One of these requirements is that documentation of the underlying beneficiaries of the trust be provided timely to the plan administrator. In the case of individual accounts, unless the lifetime distribution period for an employee is measured by the joint life expectancy of the employee and the employee's spouse, the deadline under these proposed regulations for providing the beneficiary documentation would be the end of the year following year of the employee's death. This is consistent with the deadline for determining the employee's designated beneficiary. Because the designated beneficiary during an employee's lifetime is not relevant for determining lifetime required minimum distributions in most cases under these proposed regulations, the burden of lifetime documentation requirements contained in the previous proposed regulations is significantly reduced.

A significant number of commentators on the 1997 amendment to the proposed regulations requested clarification that a testamentary trust named as an employee's beneficiary is a trust that qualifies for the look-through rule to the underlying beneficiaries, as permitted in the 1997 proposed regulations. These proposed regulations provide examples in which a testamentary trust is named as an employee's beneficiary and the look-through trust rules apply. As previously illustrated in the facts of Rev. Rul. 2000–2, 2000–3 I.R.B. 305, the examples also clarify that remaindermen of a "QTIP" trust must be taken into account as beneficiaries in determining the distribution period for required minimum distributions if amounts are accumulated for their benefit during the life of the income beneficiary under the trust.

Rules for Qualified Domestic Relations Orders

These proposed regulations retain the basic rules in the 1987 proposed regulation for a qualified domestic relations order (QDRO). Thus, for example, the proposed regulations continue to provide that a former spouse to whom all or a portion of the employee's benefit is payable pursuant to a QDRO will be treated as a spouse (including a surviving spouse) of the employee for purposes of section 401(a)(9), including the minimum distribution incidental benefit requirement, regardless of whether the QDRO specifically provides that the former spouse is treated as the spouse for purposes of sections 401(a)(11) and 417. This rule applies regardless of the number of former spouses an employee has who are alternate payees with respect to the employee's retirement benefits. Further, for example, if a QDRO divides the individual account of an employee in a defined contribution plan into a separate account for the employee and a separate account for the alternate payee, the required minimum distribution to the alternate payee during the lifetime of the employee must nevertheless be determined using the same rules that apply to distribution to the employee. Thus, required minimum distributions to the alternate payee must commence by the employee's required beginning date. However, the required minimum distribution for the alternate payee will be separately determined. The required minimum distributions for the alternate payee during the lifetime of the employee may be determined either using the uniform distribution period discussed above based on the age of the employee in the distribution calendar year, or, if the alternate payee is the employee's former spouse and is more than 10 years younger than the employee, using the joint life expectancy of the employee and the alternate payee.

Election of Surviving Spouse To Treat an Inherited IRA as Spouse's Own IRA

These proposed regulations clarify the rule in the 1987 proposed regulations that allows the surviving spouse of a decedent IRA owner to elect to treat an IRA inherited by the surviving spouse from that owner as the spouse's own IRA. The 1987 proposed regulations provide that this election is deemed to have been made if the surviving spouse contributes to the IRA or does not take the required minimum distribution for a year under section 401(a)(9)(B) as a beneficiary of the IRA. These new proposed regulations clarify that this deemed election is permitted to be made only after the distribution of the required minimum amount for the account, if any, for the year of the individual's death. Further these new proposed regulations clarify that this deemed election is permitted only if the spouse is the sole beneficiary of the account and has an unlimited right to withdrawal from the account. This requirement is not satisfied if a trust is named as beneficiary of the IRA, even if the spouse is the sole beneficiary of the trust. These clarifications make the election consistent with the underlying premise that the surviving spouse could have received a distribution of the entire decedent IRA owner's account and rolled it over to an IRA established in the surviving spouse's own name as IRA owner.

These new proposed regulations also clarify that, except for the required minimum distribution for the year of the individual's death, the spouse is permitted to roll over the post-death required minimum distribution under section 401(a)(9)(B) for a year if the spouse is establishing the IRA rollover account in the name of the spouse as IRA owner. However, if the surviving spouse is age 70½ or older, the minimum lifetime distribution required under section 401(a)(9)(A) must be made for the year and, because it is a required minimum distribution, that amount may not be rolled over. These proposed regulations provide that this election by a surviving spouse eligible to treat an IRA as the spouse's own may also be accomplished by redesignating the IRA with the name of the surviving spouse as owner rather than beneficiary.

IRA Reporting of Required Minimum Distributions

Because these regulations substantially simplify the calculation of required minimum distributions from IRAs, IRA trustees determining the account balance as of the end of the year can also calculate the following year's required minimum distribution for each IRA. To improve compliance and further reduce the burden imposed on IRA owners and beneficiaries, under the authority provided in section 408(i), these proposed regulations would require the trustee of each IRA to report the amount of the required minimum distribution from the IRA to the IRA owner or beneficiary and to the IRS at the time and in the manner provided under IRS forms and instructions. This reporting would be required regardless of whether the IRA owner is planning to take the required minimum distribution from that IRA or from another IRA, and would indicate that the IRA owner is permitted to take the required minimum distribution from any other IRA of the owner. During year 2001, the IRS will be receiving public comments and consulting with interested parties to assist the IRS in evaluating what form best accommodates this reporting requirement, what timing is appropriate (e.g., the beginning of the calendar year for which the required amount is being calculated), and what effective date would be most appropriate for the reporting requirement. In this context, after thorough consideration of comments and consultation with interested parties, the IRS intends to develop procedures and a schedule for reporting that provides adequate lead time, and minimizes the reporting burden, for IRA trustees, issuers, and custodians in complying with this new reporting requirement while providing the most useful information to the IRA owners and beneficiaries.

The IRS and Treasury are also considering whether similar reporting would be appropriate for section 403(b) contracts.

Permitted Delays Relative to QDROs and State Insurer Delinquency Proceedings

The regulations permit the required minimum distribution for a year to be delayed to a later year in certain circumstances. Specifically, commentators requested a delay during a period of up to 18 months during which an amount is segregated in connection with the review of a domestic relations order pursuant to section 414(p)(7). Commentators also requested that a delay be permitted while annuity payments under an annuity contract issued by a life insurance company in state insurer delinquency proceedings have been reduced or suspended by reason of state proceedings. These proposed regulations allow delay in these circumstances.

Correction of Failures Under Section 401(a)(9)

The proposed regulations do not set forth the special rule relieving a plan from disqualification for isolated instances of failure to satisfy section 401(a)(9) because all failures for qualified plans and section 403(b) accounts under section 401(a)(9) are now permitted to be corrected through the Employee Plans Compliance Resolution System (EPCRS). See Rev. Proc. 2000–16 (2000–6 I.R.B. 518).

Amendment of Qualified Plans

These regulations are proposed to be effective for distributions for calendar years beginning on or after January 1, 2002. For distributions for calendar years beginning before the effective date of final regulations, plan sponsors can continue to rely on the 1987 proposed regulations, to the extent those proposed regulations are not inconsistent with the changes to section 401(a)(9) made by the Small Business Job Protection Act of 1996 (SBJPA) and guidance related to those changes. Alternatively, for distributions for the 2001 and subsequent calendar years beginning before the effective date of final regulations, plan sponsors are permitted, but not required, to follow these proposed regulations in the operation of their plans by adopting the model amendment set forth below.

The Treasury Department and the IRS are making the model amendment set forth below available to plan sponsors to permit them to apply these proposed regulations in the operation of their plans without violating the requirement that a plan be operated in accordance with its terms. Plan sponsors who adopt the model amendment will have reliance that, during the term of the amendment, operation of their plans in a manner that satisfies the minimum distribution requirements in these proposed regulations will not cause their plans to fail to be qualified. In addition, distributees will have reliance that distributions that are made during the term of the amendment that satisfy the minimum distribution requirements in these proposed regulations. The model amendment may be adopted by plan sponsors, practitioners who sponsor volume submitter specimen plans and sponsors of master and prototype (M&P) plans.

These proposed regulations permit plans to make distributions under either default provisions or under permissible optional provisions. A plan that has been amended by adoption of the model amendment will be treated as operating in conformance with a requirement of the proposed regulations that permits the use of either default or optional provisions if the plan is operated consistently in accordance with either the default rule or a specific permitted alternative, notwithstanding the plan's terms.

The Service will not issue determination, opinion or advisory letters on the basis of the changes in these proposed regulations until the publication of final regulations. Until such time, the IRS will continue to issue such letters on the basis of the 1987 proposed regulations and SBJPA. Although the IRS will not issue determination, opinion or advisory letters with respect to the model amendment, the adoption of the model amendment will not affect a determination letter issued for a plan whose terms otherwise satisfy the 1987 proposed regulations and SBJPA. Plan sponsors should not adopt other amendments to attempt to conform their plans to the changes in these proposed regulations before the publication of final regulations. The IRS intends to publish procedures at a later date that will allow qualified plans to be amended to reflect the regulations under section 401(a)(9) when they are finalized.

Qualified plans are required to be amended for changes in the plan qualification requirements made by GUST by the end of the GUST remedial amendment period under section 401(b), which is generally the end of the first plan year beginning on or after January 1, 2001, or, if applicable, a later date determined under the provisions of section 19 of Rev. Proc. 2000–20 (2000–6 I.R.B. 553). Many plans have been operated in a manner that reflects the changes to section 401(a)(9) made by SBJPA and will have to be amended for

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these changes by the end of the GUST remedial amendment period. The IRS intends that its procedures for amending qualified plans for the final regulations under section 401(a)(9) will generally avoid the need for plan sponsors, volume submitter practitioners and M&P plan sponsors to request another determination, opinion or advisory letter subsequent to their application for a GUST letter. In addition, to the extent such a subsequent letter is needed or desired, the IRS intends that its procedures will provide that the application for the letter will not have to be submitted prior to the next time the plan is otherwise amended or required to be amended.

The model amendment described above is set forth below:

With respect to distributions under the Plan made in calendar years beginning on or after January 1, 2000 (ALTERNATIVELY, SPECIFY A LATER CALENDAR YEAR FOR WHICH THE AMENDMENT IS TO BE INITIALLY EFFECTIVE), the Plan will apply the minimum distribution requirements of section 401(a)(9) of the Internal Revenue Code in accordance with the regulations under section 401(a)(9) that were proposed in January 2001, notwithstanding any provision of the Plan to the contrary. This amendment shall continue in effect until the end of the last calendar year beginning before the effective date of final regulations under section 401(a)(9) or such other date specified in guidance published by the Internal Revenue Service.

Amendment of IRAs and Effective Date

These regulations are proposed to be effective for distributions for calendar years beginning on or after January 1, 2002. For distributions for the 2001 calendar year, IRA owners are permitted, but not required, to follow these proposed regulations in operation, notwithstanding the terms of the IRA documents. IRA owners may therefore rely on these proposed regulations for distributions for the 2001 calendar year. However, IRA sponsors should not amend their IRA documents to conform their IRAs to the changes in these proposed regulations before the publication of final regulations. The IRS will not issue model IRAs on the basis of the changes in these proposed regulations until the publication of final regulations. Until such time, IRA owners can continue to use the current model IRAs which are based on the 1987 proposed regulations under section 401(a)(9). The IRS will publish procedures at a later date that will allow IRAs to be amended to reflect final regulations under section 401(a)(9).

Proposed Effective Date

The regulations are proposed to be applicable for determining required minimum distributions for calendar years beginning on or after January 1, 2002. For determining required minimum distributions for calendar year 2001, taxpayers may rely on these proposed regulations or on the 1987 proposed regulations. If, and to the extent, future guidance is more restrictive than the guidance in these proposed regulations, the future guidance will be issued without retroactive effect.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these proposed regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments (preferably a signed original and eight (8) copies) that are submitted timely to the IRS. In addition to the other requests for comments set forth in this document, the IRS and Treasury also request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for June 1, 2001, at 10 a.m. in the IRS Auditorium (7th Floor), Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by May 11, 2001.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these regulations are Marjorie Hoffman and Cathy A. Vohs of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 54

Excise taxes, Pensions, Reporting and recordkeeping requirements.

Adoption of Amendments of the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.401(a)(9)–1 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–2 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–3 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–4 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–5 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–6 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–7 is also issued under 26 U.S.C. 401(a)(9).

§ 1.401(a)(9)–8 is also issued under 26 U.S.C. 401(a)(9).* * *

§ 1.403(b)–2 is also issued under 26 U.S.C. 403(b)(10).* * *

§ 1.408–8 is also issued under 26 U.S.C. 408(a)(6) and (b)(3).* * *

Par. 2. Sections 1.401(a)(9)–0 through 1.401(a)(9)–8 are added to read as follows:

§ 1.401(a)(9)–0 Required minimum distributions; table of contents.

This table of contents lists the regulations relating to required minimum distributions under section 401(a)(9) of the Internal Revenue Code as follows:

§ 1.401(a)(9)–0 Required minimum distributions; table of contents.
§ 1.401(a)(9)–1 Required minimum distribution requirement in general.
§ 1.401(a)(9)–2 Distributions commencing before an employee's death.
§ 1.401(a)(9)–3 Death before required beginning date.
§ 1.401(a)(9)–4 Determination of the designated beneficiary.
§ 1.401(a)(9)–5 Required minimum distributions from defined contribution plans.
§ 1.401(a)(9)–6 Required minimum distributions from defined benefit plans.
§ 1.401(a)(9)–7 Rollovers and transfers.
§ 1.401(a)(9)–8 Special rules.

§ 1.401(a)(9)–1 Required minimum distribution requirement in general.

Q–1. What plans are subject to the required minimum distribution requirement under section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8?

A–1. All stock bonus, pension, and profit-sharing plans qualified under section 401(a) and annuity contracts described in section 403(a) are subject to the required minimum distribution rules in section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8. See § 1.403(b)–2 for the distribution rules applicable to annuity contracts or custodial accounts described in section 403(b), see § 1.408–8 for the distribution rules applicable to individual retirement plans, see § 1.408A–6 described for the distribution rules applicable to Roth IRAs under section 408A, and see section 457(d)(2)(A) for distribution rules applicable to certain deferred compensation plans for employees of tax exempt organizations or state and local government employees.

Q–2. Which employee account balances and benefits held under qualified trusts and plans are subject to the distribution rules of section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8?

A–2. The distribution rules of section 401(a)(9) apply to all account balances and benefits in existence on or after January 1, 1985. Sections 1.401(a)(9)–1 through 1.401(a)(9)–6 apply for purposes of determining required minimum distributions for calendar years beginning on or after January 1, 2002.

Q–3. What specific provisions must a plan contain in order to satisfy section 401(a)(9)?

A–3. (a) *Required provisions.* In order to satisfy section 401(a)(9), the plan must include several written provisions reflecting section 401(a)(9). First, the plan must generally set forth the statutory rules of section 401(a)(9), including the incidental death benefit requirement in section 401(a)(9)(G). Second, the plan must provide that distributions will be made in accordance with §§ 1.401(a)(9)–1 through 1.401(a)(9)–8. The plan document must also provide that the provisions reflecting section 401(a)(9) override any distribution options in the plan inconsistent with section 401(a)(9). The plan also must include any other provisions reflecting section 401(a)(9) as are prescribed by the Commissioner in revenue rulings, notices, and other guidance published in the Internal Revenue Bulletin. See § 601.601(d)(2)(ii)(b) of this chapter.

(b) *Optional provisions.* The plan may also include written provisions regarding any optional provisions governing plan distributions that do not conflict with section 401(a)(9) and the regulations thereunder.

(c) *Absence of optional provisions.* Plan distributions commencing after an employee's death will be required to be made under the default provision set forth in § 1.401(a)(9)–3 for distributions unless the plan document contains optional provisions that override such default provisions. Thus, if distributions have not commenced to the employee at the time of the employee's death, distributions after the death of an employee are to be made automatically in accordance with the default provisions in A–4(a) of § 1.401(a)(9)–3 unless the plan either specifies in accordance with A–4(b) of § 1.401(a)(9)–3 the method under which distributions will be made or provides for elections by the employee (or beneficiary) in accordance with A–4(c) of § 1.401(a)(9)–3 and such elections are made by the employee or beneficiary.

§ 1.401(a)(9)–2 Distributions commencing before an employee's death.

Q–1. In the case of distributions commencing before an employee's death, how must the employee's entire interest be distributed in order to satisfy section 401(a)(9)(A)?

A–1. (a) In order to satisfy section 401(a)(9)(A), the entire interest of each employee must be distributed to such employee not later than the required beginning date, or must be distributed, beginning not later than the required beginning date, over the life of the employee or joint lives of the employee and a designated beneficiary or over a period not extending beyond the life expectancy of the employee or the joint life and last survivor expectancy of the employee and the designated beneficiary.

(b) Section 401(a)(9)(G) provides that lifetime distributions must satisfy the incidental death benefit requirements.

(c) The amount required to be distributed for each calendar year in order to satisfy section 401(a)(9)(A) and (G) generally depends on whether a distribution is in the form of distributions under a defined contribution plan or annuity payments under a defined benefit plan. For the method of determining the required minimum distribution in accordance with section 401(a)(9)(A) and (G) from an individual account under a defined contribution plan, see § 1.401(a)(9)–5. For the method of determining the required minimum distribution in accordance with section 401(a)(9)(A) and (G) in the case of annuity payments from a defined benefit plan or an annuity contract, see § 1.401(a)(9)–6.

Q–2. For purposes of section 401(a)(9)(C), what does the term *required beginning date* mean?

A–2. (a) Except as provided in paragraph (b) of this A–2 with respect to a 5-percent owner, as defined in paragraph (c), the term *required beginning date* means April 1 of the calendar year following the later of the calendar year in which the employee attains age 70½, or the calendar year in which the employee retires from employment with the employer maintaining the plan.

(b) In the case of an employee who is a 5-percent owner, the term *required beginning date* means April 1 of the calendar year following the calendar year in which the employee attains age 70½.

(c) For purposes of section 401(a)(9), a 5-percent owner is an employee who is a 5-percent owner (as defined in section 416) with respect to the plan year ending in the calendar year in which the employee attains age 70½.

(d) Paragraph (b) of this A–2 does not apply in the case of a governmental plan (within the meaning of section 414(d)) or a church plan. For purposes of this paragraph, the term *church plan* means a plan maintained by a church for church employees, and the term *church* means any church (as defined in section 3121(w)(3)(A)) or qualified church-controlled organization (as defined in section 3121(w)(3)(B)).

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(e) A plan is permitted to provide that the required beginning date for purposes of section 401(a)(9) for all employees is April 1 of the calendar year following the calendar year in which the employee attained age 70½ regardless of whether the employee is a 5-percent owner.

Q–3. When does an employee attain age 70½?

A–3. An employee attains age 70½ as of the date six calendar months after the 70th anniversary of the employee's birth. For example, if an employee's date of birth was June 30, 1932, the 70th anniversary of such employee's birth is June 30, 2002. Such employee attains age 70½ on December 30, 2002. Consequently, if the employee is a 5-percent owner or retired, such employee's required beginning date is April 1, 2003. However, if the employee's date of birth was July 1, 1932, the 70th anniversary of such employee's birth would be July 1, 2002. Such employee would then attain age 70½ on January 1, 2003 and such employee's required beginning date would be April 1, 2004.

Q–4. Must distributions made before the employee's required beginning date satisfy section 401(a)(9)?

A–4. Lifetime distributions made before the employee's required beginning date for calendar years before the employee's first distribution calendar year, as defined in A–1(b) of § 1.401(a)(9)–5, need not be made in accordance with section 401(a)(9). However, if distributions commence before the employee's required beginning date under a particular distribution option, such as in the form of an annuity, the distribution option fails to satisfy section 401(a)(9) at the time distributions commence if, under terms of the particular distribution option, distributions to be made for the employee's first distribution calendar year or any subsequent distribution calendar year will fail to satisfy section 401(a)(9).

Q–5. If distributions have begun to an employee before the employee's death (in accordance with section 401(a)(9)(A)(ii)), how must distributions be made after an employee's death?

A–5. Section 401(a)(9)(B)(i) provides that if the distribution of the employee's interest has begun in accordance with section 401(a)(9)(A)(ii) and the employee dies before his entire interest has been distributed to him, the remaining portion of such interest must be distributed at least as rapidly as under the distribution method being used under section 401(a)(9)(A)(ii) as of the date of his death. The amount required to be distributed for each distribution calendar year following the calendar year of death generally depends on whether a distribution is in the form of distributions from an individual account under a defined contribution plan or annuity payments under a defined benefit plan. For the method of determining the required minimum distribution in accordance with section 401(a)(9)(B)(i) from an individual account, see A–5(a) of § 1.401(a)(9)–5 for the calculation of the distribution period that applies when an employee dies after the employee's required beginning date. In the case of annuity payments from a defined benefit plan or an annuity contract, see § 1.401(a)(9)–6.

Q–6. For purposes of section 401(a)(9)(B), when are distributions considered to have begun to the employee in accordance with section 401(a)(9)(A)(ii)?

A–6. (a) *General rule.* Except as otherwise provided in A–10 of § 1.401(a)(9)–6, distributions are not treated as having begun to the employee in accordance with section 401(a)(9)(A)(ii) until the employee's required beginning date, without regard to whether payments have been made before that date. For example, if employee A upon retirement in 2002, the calendar year A attains age 65½, begins receiving installment distributions from a profit-sharing plan over a period not exceeding the joint life and last survivor expectancy of A and A's beneficiary, benefits are not treated as having begun in accordance with section 401(a)(9)(A)(ii) until April 1, 2008 (the April 1 following the calendar year in which A attains age 70½). Consequently, if such employee dies before April 1, 2008 (A's required beginning date), distributions after A's death must be made in accordance with section 401(a)(9)(B)(ii) or (iii) and (iv) and § 1.401(a)(9)–4, and not section 401(a)(9)(B)(i). This is the case without regard to whether the plan has distributed the minimum distribution for the first distribution calendar year (as defined in A–1(b) of § 1.401(a)(9)–5) before A's death.

(b) If a plan provides, in accordance with A–2(e) of this section, that the required beginning date for purposes of section 401(a)(9) for all employees is April 1 of the calendar year following the calendar year in which the employee attains age 70½, an employee who dies after the required beginning date determined under the plan terms is treated as dying after the employee's required beginning date for purposes of A–5(a) of this section even though the employee dies before the April 1 following the calendar year in which the employee retires.

§ 1.401(a)(9)–3 Death before required beginning date.

Q–1. If an employee dies before the employee's required beginning date, how must the employee's entire interest be distributed in order to satisfy section 401(a)(9)?

A–1. (a) Except as otherwise provided in A–10 of § 1.401(a)(9)–6, if an employee dies before the employee's required beginning date (and, thus, generally before distributions are treated as having begun in accordance with section 401(a)(9)(A)(ii)), distribution of the employee's entire interest must be made in accordance with one of the methods described in section 401(a)(9)(B)(ii) or (iii). One method (the five-year rule in section 401(a)(9)(B)(ii)) requires that the entire interest of the employee be distributed within five years of the employee's death regardless of who or what entity receives the distribution. Another method (the life expectancy rule in section 401(a)(9)(B)(iii)) requires that any portion of an employee's interest payable to (or for the benefit of) a designated beneficiary be distributed, commencing within one year of the employee's death, over the life of such beneficiary (or over a period not extending beyond the life expectancy of such beneficiary). Section 401(a)(9)(B)(iv) provides special rules where the designated beneficiary is the surviving spouse of the employee, including a special commencement date for distributions under section 401(a)(9)(B)(iii) to the surviving spouse.

(b) See A–4 of this section for the rules for determining which of the methods described in paragraph (a) applies. See A–3 of this section to determine when distributions under the exception to the five-year rule in section 401(a)(9)(B)(iii) and (iv) must commence. See A–2 of this section to determine when the five-year period in section 401(a)(9)(B)(ii) ends. For distributions using the life expectancy rule in section 401(a)(9)(B)(iii) and (iv), see § 1.401(a)(9)–4 in order to determine the designated beneficiary under section 401(a)(9)(B)(iii) and (iv), see § 1.401(a)(9)–5 for the rules for determining the required minimum distribution under a defined contribution plan, and see § 1.401(a)(9)–6 for required minimum distributions under defined benefit plans.

Q–2. By when must the employee's entire interest be distributed in order to satisfy the five-year rule in section 401(a)(9)(B)(ii)?

A–2. In order to satisfy the five-year rule in section 401(a)(9)(B)(ii), the employee's entire interest must be distributed by the end of the calendar year which contains the fifth anniversary of the date of the employee's death. For example, if an employee dies on January 1, 2002, the entire interest must be distributed by the end of 2007, in order to satisfy the five-year rule in section 401(a)(9)(B)(ii).

Q–3. When are distributions required to commence in order to satisfy the life expectancy rule in section 401(a)(9)(B)(iii) and (iv)?

A–3. (a) *Nonspouse beneficiary.* In order to satisfy the life expectancy rule in section 401(a)(9)(B)(iii), if the designated beneficiary is not the employee's surviving spouse, distributions must commence on or before the end of the calendar year immediately following the calendar year in which the employee died. This rule also applies to the distribution of the entire remaining benefit if another individual is a designated beneficiary in addition to the employee's surviving spouse. See A–2 and A–3 of § 1.401(a)(9)–8, however, if the employee's benefit is divided into separate accounts (or segregated shares, in the case of a defined benefit plan).

(b) *Spousal beneficiary.* In order to satisfy the rule in section 401(a)(9)(B)(iii) and (iv), if the sole designated beneficiary is the employee's surviving spouse, distributions must commence on or before the later of—

(1) The end of the calendar year immediately following the calendar year in which the employee died; and

(2) The end of the calendar year in which the employee would have attained age 70½.

Q–4. How is it determined whether the five-year rule in section 401(a)(9)(B)(ii) or the life expectancy rule in section 401(a)(9)(B)(iii) and (iv) applies to a distribution?

A–4. (a) *No plan provision.* If a plan does not adopt an optional provision described in paragraph (b) or (c) of this A–4 specifying the method of distribution after the death of an employee, distribution must be made as follows:

(1) If the employee has a designated beneficiary, as determined under § 1.401(a)(9)–4, distributions are to be made in accordance with the life expectancy rule in section 401(a)(9)(B)(iii) and (iv).

(2) If the employee has no designated beneficiary, distributions are to be made in accordance with the five-year rule in section 401(a)(9)(B)(ii).

(b) *Optional plan provisions.* The plan may adopt a provision specifying either that the five-year rule in section 401(a)(9)(B)(ii) will apply to certain distributions after the death of an employee even if the employee has a designated beneficiary or that distribution in every case will be made in accordance with the five-year rule in section 401(a)(9)(B)(ii). Further, a plan need not have the same method of distribution for the benefits of all employees.

(c) *Elections.* A plan may adopt a provision that permits employees (or beneficiaries) to elect on an individual basis whether the five-year rule in section 401(a)(9)(B)(ii) or the life expectancy rule in section 401(a)(9)(B)(iii) and (iv) applies to distributions after the death of an employee who has a designated beneficiary. Such an election must be made no later than the earlier of, the end of the calendar year in which distribution would be required to commence in order to satisfy the requirements for the life expectancy rule in section 401(a)(9)(B)(iii) and (iv) (see A–3 of this section for the determination of such calendar year), or the end of the calendar year which contains the fifth anniversary of the date of death of the employee. As of the date determined under the life expectancy rule, the election must be irrevocable with respect to the beneficiary (and all subsequent beneficiaries) and must apply to all subsequent calendar years. If a plan provides for the election, the plan may also specify the method of distribution that applies if neither the employee nor the beneficiary makes the election. If neither the employee nor the beneficiary elects a method and the plan does not specify which method applies, distribution must be made in accordance with paragraph (a).

Q–5. If the employee's surviving spouse is the employee's designated beneficiary and such spouse dies after the employee, but before distributions have begun to the surviving spouse under section 401(a)(9)(B)(iii) and (iv), how is the employee's interest to be distributed?

A–5. Pursuant to section 401(a)(9)(B)(iv)(II), if the surviving spouse dies after the employee, but before distributions to such spouse have begun under section 401(a)(9)(B)(iii) and (iv), the five-year rule in section 401(a)(9)(B)(ii) and the life expectancy rule in section 401(a)(9)(B)(iii) are to be applied as if the surviving spouse were the employee. In applying this rule, the date of death of the surviving spouse shall be substituted for the date of death of the employee. However, in such case, the rules in section 401(a)(9)(B)(iv) are not available to the surviving spouse of the deceased employee's surviving spouse.

Q–6. For purposes of section 401(a)(9)(B)(iv)(II), when are distributions considered to have begun to the surviving spouse?

A–6. Distributions are considered to have begun to the surviving spouse of an employee, for purposes of section 401(a)(9)(B)(iv)(II), on the date, determined in accordance with A–3 of this section, on which distributions are required to commence to the surviving spouse, even though payments have actually been made before that date. See A–11 of § 1.401(a)(9)–6 for a special rule for annuities.

§ 1.401(a)(9)–4 Determination of the designated beneficiary.

Q–1. Who is a designated beneficiary under section 401(a)(9)(E)?

A–1. A designated beneficiary is an individual who is designated as a beneficiary under the plan. An individual may be designated as a beneficiary under the plan either by the terms of the plan or, if the plan so provides, by an affirmative election by the employee (or the employee's surviving spouse) specifying the beneficiary. A beneficiary designated as such under the plan is an individual who is entitled to a portion of an employee's benefit, contingent on the employee's death or another specified event. For example, if a distribution is in the form of a joint and survivor annuity over the life of the employee and another individual, the plan does not satisfy section 401(a)(9) unless such other individual is a designated beneficiary under the plan. A designated beneficiary need not be specified by name in the plan or by the employee to the plan in order to be a designated beneficiary so long as the individual who is to be the beneficiary is identifiable under the plan as of the date the beneficiary is determined under A–4 of this section. The members of a class of beneficiaries capable of expansion or contraction will be treated as being identifiable if it is possible, as of the date the beneficiary is determined, to identify the class member with the shortest life expectancy. The fact that an employee's interest under the plan passes to a certain individual under applicable state law does not make that individual a designated beneficiary unless the individual is designated as a beneficiary under the plan.

Q–2. Must an employee (or the employee's spouse) make an affirmative election specifying a beneficiary for a person to be a designated beneficiary under section 401(a)(9)(E)?

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A–2. No. A designated beneficiary is an individual who is designated as a beneficiary under the plan whether or not the designation under the plan was made by the employee. The choice of beneficiary is subject to the requirements of sections 401(a)(11), 414(p), and 417.

Q–3. May a person other than an individual be considered to be a designated beneficiary for purposes of section 401(a)(9)?

A–3. (a) No. Only individuals may be designated beneficiaries for purposes of section 401(a)(9). A person that is not an individual, such as the employee's estate, may not be a designated beneficiary, and, if a person other than an individual is designated as a beneficiary of an employee's benefit, the employee will be treated as having no designated beneficiary for purposes of section 401(a)(9). However, see A–5 of this section for special rules which apply to trusts.

(b) If an employee is treated as having no designated beneficiary, for distributions under a defined contribution plan, the distribution period under section 401(a)(9)(A)(ii) after the death of the employee is limited to the period described in A–5(a)(2) of § 1.401(a)(9)–5 (the remaining life expectancy of the employee determined in accordance with A–5(c)(3) of § 1.401(a)(9)–5). Further, in such case, except as provided in A–10 of § 1.401(a)(9)–6, if the employee dies before the employee's required beginning date, distribution must be made in accordance with the 5-year rule in section 401(a)(9)(B)(ii).

Q–4. When is the designated beneficiary determined?

A–4. (a) *General rule.* Except as provided in paragraph (b) and § 1.401(a)(9)–6, the employee's designated beneficiary will be determined based on the beneficiaries designated as of the last day of the calendar year following the calendar year of the employee's death. Consequently, except as provided in § 1.401(a)(9)–6, any person who was a beneficiary as of the date of the employee's death, but is not a beneficiary as of that later date (*e.g.*, because the person disclaims entitlement to the benefit in favor of another beneficiary or because the person receives the entire benefit to which the person is entitled before that date), is not taken into account in determining the employee's designated beneficiary for purposes of determining the distribution period for required minimum distributions after the employee's death.

(b) *Surviving spouse.* As provided in A–5 of § 1.401(a)(9)–3, in the case in which the employee's spouse is the designated beneficiary as of the date described in paragraph (a) of this A–5, and the surviving spouse dies after the employee and before the date on which distributions have begun to the spouse under section 401(a)(9)(B)(iii) and (iv), the rule in section 401(a)(9)(B)(iv)(II) will apply. Thus, the relevant designated beneficiary for determining the distribution period is the designated beneficiary of the surviving spouse. Such designated beneficiary will be determined as of the last day of the calendar year following the calendar year of surviving spouse's death. If, as of such last day, there is no designated beneficiary under the plan with respect to that surviving spouse, distribution must be made in accordance with the 5-year rule in section 401(a)(9)(B)(ii) and A–2 of § 1.401(a)(9)–3.

(c) *Multiple beneficiaries.* Notwithstanding anything in this A–4 to the contrary, the rules in A–7 of § 1.401(a)(9)–5 apply if more than one beneficiary is designated with respect to an employee as of the date on which the designated beneficiary is to be determined in accordance with paragraphs (a) and (b) of this A–4.

Q–5. If a trust is named as a beneficiary of an employee, will the beneficiaries of the trust with respect to the trust's interest in the employee's benefit be treated as having been designated as beneficiaries of the employee under the plan for purposes of determining the distribution period under section 401(a)(9)?

A–5. (a) Only an individual may be a designated beneficiary for purposes of determining the distribution period under section 401(a)(9). Consequently, a trust is not a designated beneficiary even though the trust is named as a beneficiary. However, if the requirements of Paragraph (b) of this A–5 are met, the beneficiaries of the trust will be treated as having been designated as beneficiaries of the employee under the plan for purposes of determining the distribution period under section 401(a)(9).

(b) The requirements of this paragraph (b) are met if, during any period during which required minimum distributions are being determined by treating the beneficiaries of the trust as designated beneficiaries of the employee, the following requirements are met:

(1) The trust is a valid trust under state law, or would be but for the fact that there is no corpus.

(2) The trust is irrevocable or will, by its terms, become irrevocable upon the death of the employee.

(3) The beneficiaries of the trust who are beneficiaries with respect to the trust's interest in the employee's benefit are identifiable from the trust instrument within the meaning of A–1 of this section.

(4) The documentation described in A–6 of this section has been provided to the plan administrator.

(c) In the case of payments to a trust having more than one beneficiary, see A–7 of § 1.401(a)(9)–5 for the rules for determining the designated beneficiary whose life expectancy will be used to determine the distribution period. If the beneficiary of the trust named as beneficiary is another trust, the beneficiaries of the other trust will be treated as having been designated as beneficiaries of the employee under the plan for purposes of determining the distribution period under section 401(a)(9)(A)(ii), provided that the requirements of paragraph (b) of this A–5 are satisfied with respect to such other trust in addition to the trust named as beneficiary.

Q–6. If a trust is named as a beneficiary of an employee, what documentation must be provided to the plan administrator?

A–6. (a) *Required minimum distributions before death.* In order to satisfy the documentation requirement of this A–6 for required minimum distributions under section 401(a)(9) to commence before the death of an employee, the employee must comply with either paragraph (a)(1) or (2) of this A–6:

(1) The employee provides to the plan administrator a copy of the trust instrument and agrees that if the trust instrument is amended at any time in the future, the employee will, within a reasonable time, provide to the plan administrator a copy of each such amendment.

(2) The employee—

(i) Provides to the plan administrator a list of all of the beneficiaries of the trust (including contingent and remaindermen beneficiaries with a description of the conditions on their entitlement);

(ii) Certifies that, to the best of the employee's knowledge, this list is correct and complete and that the requirements of paragraphs (b)(1), (2), and (3) of A–5 of this section are satisfied;

(iii) Agrees that, if the trust instrument is amended at any time in the future, the employee will, within a reasonable time, provide to the plan administrator corrected certifications to the extent that the amendment changes any information previously certified; and

(iv) Agrees to provide a copy of the trust instrument to the plan administrator upon demand.

(b) *Required minimum distributions after death.* In order to satisfy the documentation requirement of this A–6 for required minimum distributions after the death of the employee, by the last day of the calendar year immediately following the calendar year in which the employee died, the trustee of the trust must either—

(1) Provide the plan administrator with a final list of all beneficiaries of the trust (including contingent and remaindermen beneficiaries with a description of the conditions on their entitlement) as of the end of the calendar year following the calendar year of the employee's death; certify that, to the best of the trustee's knowledge, this list is correct and complete and that the requirements of paragraph (b)(1), (2), and (3) of A–5 of this section are satisfied; and agree to provide a copy of the trust instrument to the plan administrator upon demand; or

(2) Provide the plan administrator with a copy of the actual trust document for the trust that is named as a beneficiary of the employee under the plan as of the employee's date of death.

(c) *Relief for discrepancy between trust instrument and employee certifications or earlier trust instruments.* (1) If required minimum distributions are determined based on the information provided to the plan administrator in certifications or trust instruments described in paragraph (a)(1), (a)(2) or (b) of this A–6, a plan will not fail to satisfy section 401(a)(9) merely because the actual terms of the trust instrument are inconsistent with the information in those certifications or trust instruments previously provided to the plan administrator, but only if the plan administrator reasonably relied on the information provided and the required minimum distributions for calendar years after the calendar year in which the discrepancy is discovered are determined based on the actual terms of the trust instrument.

(2) For purposes of determining the amount of the excise tax under section 4974, the required minimum distribution is determined for any year based on the actual terms of the trust in effect during the year.

§ 1.401(a)(9)–5 Required minimum distributions from defined contribution plans.

Q–1. If an employee's benefit is in the form of an individual account under a defined contribution plan, what is the amount required to be distributed for each calendar year?

A–1. (a) *General rule.* If an employee's accrued benefit is in the form of an individual account under a defined contribution plan, the minimum amount required to be distributed for each distribution calendar year, as defined in paragraph (b) of this A–1, is equal to the quotient obtained by dividing the account (determined under A–3 of this section) by the applicable distribution period (determined under A–4 of this section). However, the required minimum distribution amount will never exceed the entire vested account balance on the date of the distribution. Further, the minimum distribution required to be distributed on or before an employee's required beginning date is always determined under section 401(a)(9)(A)(ii) and this A–1 and not section 401(a)(9)(A)(i).

(b) *Distribution calendar year.* A calendar year for which a minimum distribution is required is a distribution calendar year. If an employee's required beginning date is April 1 of the calendar year following the calendar year in which the employee attains age 70½, the employee's first distribution calendar year is the year the employee attains age 70½. If an employee's required beginning date is April 1 of the calendar year following the calendar year in which the employee retires, the calendar year in which the employee retires is the employee's first distribution calendar year. In the case of distributions to be made in accordance with the life expectancy rule in § 1.401(a)(9)–3 and in section 401(a)(9)(B)(iii) and (iv), the first distribution calendar year is the calendar year containing the date described in A–3(a) or A–3(b) of § 1.401(a)(9)–3, whichever is applicable.

(c) *Time for distributions.* The distribution required to be made on or before the employee's required beginning date shall be treated as the distribution required for the employee's first distribution calendar year (as defined in paragraph (b) of this A–1). The required minimum distribution for other distribution calendar years, including the required minimum distribution for the distribution calendar year in which the employee's required beginning date occurs, must be made on or before the end of that distribution calendar year.

(d) *Minimum distribution incidental benefit requirement.* If distributions are made in accordance with this section, the minimum distribution incidental benefit requirement of section 401(a)(9)(G) will be satisfied.

(e) *Annuity contracts.* Instead of satisfying this A–1, the required minimum distribution requirement may be satisfied by the purchase of an annuity contract from an insurance company in accordance with A–4 of § 1.401(a)(9)–6 with the employee's entire individual account. If such an annuity is purchased after distributions are required to commence (the required beginning date, in the case of distributions commencing before death, or the date determined under A–3 of § 1.401(a)(9)–3, in the case of distributions commencing after death), payments under the annuity contract purchased will satisfy section 401(a)(9) for distribution calendar years after the calendar year of the purchase if payments under the annuity contract are made in accordance with § 1.401(a)(9)–6. In such a case, payments under the annuity contract will be treated as distributions from the individual account for purposes of determining if the individual account satisfies section 401(a)(9) for the calendar year of the purchase. An employee may also purchase an annuity contract for a portion of the employee's account under the rules of A–2(c) of § 1.401(a)(9)–6

Q–2. If an employee's benefit is in the form of an individual account and, in any calendar year, the amount distributed exceeds the minimum required, will credit be given in subsequent calendar years for such excess distribution?

A–2. If, for any distribution calendar year, the amount distributed exceeds the minimum required, no credit will be given in subsequent calendar years for such excess distribution.

Q–3. What is the amount of the account of an employee used for determining the employee's required minimum distribution in the case of an individual account?

A–3. (a) In the case of an individual account, the benefit used in determining the required minimum distribution for a distribution calendar year is the account balance as of the last valuation date in the calendar year immediately preceding that distribution calendar year (valuation calendar year) adjusted in accordance with paragraphs (b) and (c) of this A–3.

(b) The account balance is increased by the amount of any contributions or forfeitures allocated to the account balance as of dates in the valuation calendar year after the valuation date. Contributions include contributions made after the close of the valuation calendar year which are allocated as of dates in the valuation calendar year.

(c)(1) The account balance is decreased by distributions made in the

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valuation calendar year after the valuation date.

(2)(i) The following rule applies if any portion of the required minimum distribution for the first distribution calendar year is made in the second distribution calendar year (*i.e.*, generally, the distribution calendar year in which the required beginning date occurs). In such case, for purposes of determining the account balance to be used for determining the required minimum distribution for the second distribution calendar year, distributions described in paragraph (c)(1) shall include an additional amount. This additional amount is equal to the amount of any distribution made in the second distribution calendar year on or before the required beginning date that is not in excess (when added to the amounts distributed in the first calendar year) of the amount required to meet the required minimum distribution for the first distribution calendar year.

(ii) This paragraph (c)(2) is illustrated by the following example:

Example. (i) Employee X, born October 1, 1931, is an unmarried participant in a qualified defined contribution plan (Plan Z). After retirement, X attains age 70½ in calendar year 2002. X's required beginning date is April 1, 2003. As of the last valuation date under Plan Z in calendar year 2001, which was on December 31, 2001, the value of X's account balance was $25,300. No contributions are made or amounts forfeited after such date which are allocated in calendar year 2001. No rollover amounts are received after such date by Plan Z on X's behalf which were distributed by a qualified plan or IRA in calendar years 2001, 2002, or 2003. The applicable distribution period from the table in A–4(a)(2) for an individual age 71 is 25.3 years. The required minimum distribution for calendar year 2002 is $1,000 ($25,300 divided by 25.3). That amount is distributed to X on April 1, 2003.

(ii) The value of X's account balance as of December 31, 2002 (the last valuation date under Plan Z in calendar year 2002) is $26,400. No contributions are made or amounts forfeited after such date which are allocated in calendar year 2002. In order to determine the benefit to be used in calculating the required minimum distribution for calendar year 2003, the account balance of $26,400 will be reduced by $1,000, the amount of the required minimum distribution for calendar year 2002 made on April 1, 2003. Consequently, the benefit for purposes of determining the required minimum distribution for calendar year 2003 is $25,400.

(iii) If, instead of $1,000 being distributed to X, $20,000 is distributed on April 1 2003, the account balance of $26,400 would still be reduced by $1,000 in order to determine the benefit to be used in calculating the required minimum distribution for calendar year 2003. The amount of the distribution made on April 1, 2003, in order to meet the required minimum distribution for 2002 would still be $1,000. The remaining $19,000 ($20,000—$1,000) of the distribution is not the required minimum distribution for 2002. Instead, the remaining $19,000 of the distribution is sufficient to satisfy the required minimum distribution requirement with respect to X for calendar year 2003. The amount which is required to be distributed for calendar year 2003 is $1,040.10 ($25,400 divided by 24.4, the applicable distribution period for an individual age 72). Consequently, no additional amount is required to be distributed to X in 2003 because $19,000 exceeds $1,040.10. However, pursuant to A–2 of this section, the remaining $17,959.90 ($19,000 − $1,040.10) may not be used to satisfy the required minimum distribution requirements for calendar year 2004 or any subsequent calendar years.

(d) If an amount is distributed by one plan and rolled over to another plan (receiving plan), A–2 of § 1.401(a)(9)–7 provides additional rules for determining the benefit and required minimum distribution under the receiving plan. If an amount is transferred from one plan (transferor plan) to another plan (transferee plan), A–3 and A–4 of § 1.401(a)(9)–7 provide additional rules for determining the amount of the required minimum distribution and the benefit under both the transferor and transferee plans.

Q–4. For required minimum distributions during an employee's lifetime, what is the applicable distribution period?

A–4. (a) *General rule*—(1) *Applicable distribution period.* Except as provided in paragraph (b) of this A–4, the applicable distribution period for required minimum distributions for distribution calendar years up to and including the distribution calendar year that includes the employee's date of death is determined using the table in paragraph (a)(2) for the employee's age as of the employee's birthday in the relevant distribution calendar year.

(2) *Table for determining distribution period*—(i) *General rule.* The following table is used for determining the distribution period for lifetime distributions to an employee.

Age of the employee	Distribution period
70	26.2
71	25.3
72	24.4
73	23.5
74	22.7
75	21.8
76	20.9
77	20.1
78	19.2
79	18.4
80	17.6
81	16.8
82	16.0
83	15.3
84	14.5
85	13.8
86	13.1
87	12.4
88	11.8
89	11.1
90	10.5
91	9.9
92	9.4
93	8.8
94	8.3
95	7.8
96	7.3
97	6.9
98	6.5
99	6.1
100	5.7
101	5.3
102	5.0
103	4.7
104	4.4
105	4.1
106	3.8
107	3.6
108	3.3
109	3.1
110	2.8
111	2.6
112	2.4
113	2.2
114	2.0
115 and older	1.8

(ii) *Authority for revised table.* The table in A–4(a)(2)(i) of this section may be replaced by any revised table prescribed by the Commissioner in revenue rulings, notices, or other guidance published in the Internal Revenue Bulletin. See § 601.601(d)(2)(ii)(b) of this chapter.

(b) *Spouse is sole beneficiary.* If the sole designated beneficiary of an employee is the employee's surviving spouse, for required minimum distributions during the employee's lifetime, the applicable distribution period is the longer of the distribution period determined in accordance with paragraph (a) of this A–4 or the joint life expectancy of the employee and spouse using the employee's and spouse's attained ages as of the employee's and the spouse's birthdays in the distribution calendar year. The spouse is sole designated beneficiary for purposes of determining the applicable distribution period for a distribution calendar year during the employee's lifetime if the spouse is the sole beneficiary of the employee's entire interest at all times during the distribution calendar year.

Q–5. For required minimum distributions after an employee's death, what is the applicable distribution period?

A–5. (a) *Death on or after the employee's required beginning date.* If an employee dies on or after

distribution has begun as determined under A–6 of § 1.401(a)(9)–2 (generally after the employee's required beginning date), in order to satisfy section 401(a)(9)(B)(i), the applicable distribution period for distribution calendar years after the distribution calendar year containing the employee's date of death is either—

(1) If the employee has a designated beneficiary as of the date determined under A–4 of § 1.401(a)(9)–4, the remaining life expectancy of the employee's designated beneficiary determined in accordance with paragraph(c)(1) or (2) of A–5; or

(2) If the employee does not have a designated beneficiary as of the date determined under A–4(a) of § 1.401(a)(9)–4, the remaining life expectancy of the employee determined in accordance with paragraph (c)(3) of this A–5.

(b) *Death before an employee's required beginning date.* If an employee dies before distribution has begun as determined under A–5 of § 1.401(a)(9)–2 (generally before the employee's required beginning date), in order to satisfy section 401(a)(9)(B)(iii) or (iv) and the life expectancy rule described in A–1 of § 1.401(a)(9)–3, the applicable distribution period for distribution calendar years after the distribution calendar year containing the employee's date of death is the remaining life expectancy of the employee's designated beneficiary, determined in accordance with paragraph(c)(1) or (2) of this A–5.

(c) *Life expectancy*—(1) *Nonspouse designated beneficiary.* The applicable distribution period measured by the beneficiary's remaining life expectancy is determined using the beneficiary's age as of the beneficiary's birthday in the calendar year immediately following the calendar year of the employee's death. In subsequent calendar years the applicable distribution period is reduced by one for each calendar year that has elapsed since the calendar year of the employee's death.

(2) *Spouse designated beneficiary.* If the surviving spouse of the employee is the employee's sole beneficiary, the applicable period is measured by the surviving spouse's life expectancy using the surviving spouse's birthday for each distribution calendar year for which a required minimum distribution is required after the calendar year of the employee's death. For calendar years after the calendar year of the spouse's death, the spouse's remaining life expectancy is the life expectancy of the spouse using the age of the spouse as of the spouse's birthday in the calendar year of the spouse's death. In subsequent calendar years, the applicable distribution period is reduced by one for each calendar year that has elapsed since the calendar year immediately following the calendar year of the spouse's death.

(3) *No designated beneficiary.* The applicable distribution period measured by the employee's remaining life expectancy is the life expectancy of the employee using the age of the employee as of the employee's birthday in the calendar year of the employee's death. In subsequent calendar years the applicable distribution period is reduced by one for each calendar year that has elapsed since the calendar year of death.

Q–6. What life expectancies must be used for purposes of determining required minimum distributions under section 401(a)(9)?

A–6. (a) *General rule.* Unless otherwise prescribed in accordance with paragraph (b) of this A–6, life expectancies for purposes of determining required minimum distributions under section 401(a)(9) must be computed using of the expected return multiples in Tables V and VI of § 1.72–9.

(b) *Revised expected return table.* The expected return multiples described in paragraph (a) of this A–6 may be replaced by revised expected return multiples prescribed for use for purposes of determining required minimum distributions under section 401(a)(9) by the Commissioner in revenue rulings, notices, and other guidance published in the Internal Revenue Bulletin. See § 601.601(d)(2)(ii)(b) of this chapter.

Q–7. If an employee has more than one designated beneficiary, which designated beneficiary's life expectancy will be used to determine the applicable distribution period?

A–7. (a) *General rule.* (1) Except as otherwise provided in paragraph (c) of this A–7, if more than one individual is designated as a beneficiary with respect to an employee as of any applicable date for determining the designated beneficiary, the designated beneficiary with the shortest life expectancy will be the designated beneficiary for purposes of determining the distribution period. However, except as otherwise provided in A–5 of § 1.401(a)(9)–4 and paragraph (c)(1) of this A–7, if a person other than an individual is designated as a beneficiary, the employee will be treated as not having any designated beneficiaries for purposes of section 401(a)(9) even if there are also individuals designated as beneficiaries.

(2) See A–2 of § 1.401(a)(9)–8 for special rules which apply if an employee's benefit under a plan is divided into separate accounts (or segregated shares in the case of a defined benefit plan) and the beneficiaries with respect to a separate account differ from the beneficiaries of another separate account.

(b) *Contingent beneficiary.* Except as provided in paragraph (c)(1) of this A–7, if a beneficiary's entitlement to an employee's benefit is contingent on an event other than the employee's death or the death of another beneficiary, such contingent beneficiary is considered to be a designated beneficiary for purposes of determining which designated beneficiary has the shortest life expectancy under paragraph (a) of this A–7.

(c) *Death contingency.* (1) If a beneficiary (subsequent beneficiary) is entitled to any portion of an employee's benefit only if another beneficiary dies before the entire benefit to which that other beneficiary is entitled has been distributed by the plan, the subsequent beneficiary will not be considered a beneficiary for purposes of determining who is the designated beneficiary with the shortest life expectancy under paragraph (a) of this A–7 or whether a beneficiary who is not an individual is a beneficiary. This rule does not apply if the other beneficiary dies prior to the applicable date for determining the designated beneficiary.

(2) If the designated beneficiary whose life expectancy is being used to calculate the distribution period dies on or after the applicable date, such beneficiary's remaining life expectancy will be used to determine the distribution period whether or not a beneficiary with a shorter life expectancy receives the benefits.

(3) This paragraph (c) is illustrated by the following examples:

Example 1. Employer L maintains a defined contribution plan, Plan W. Unmarried Employee C dies in calendar year 2001 at age 30. As of December 31, 2002, D, the sister of C, is the beneficiary of C's account balance under Plan W. Prior to death C has designated that, if D dies before C's entire account balance has been distributed to D, E, mother of C and D, will be the beneficiary of the account balance. Because E is only entitled, as a beneficiary, to any portion of C's account if D dies before the entire account has been distributed, E is disregarded in determining C's designated beneficiary. Accordingly, even after D's death, D's life expectancy continues to be used to determined the distribution period.

Example 2. (i) Employer M maintains a defined contribution plan, Plan X. Employee A, an employee of M, died in 2001 at the age of 55, survived by spouse, B, who was 50 years old. Prior to A's death, M had

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established an account balance for A in Plan X. A's account balance is invested only in productive assets. A named the trustee of a testamentary trust (Trust P) established under A's will as the beneficiary of all amounts payable from the A's account in Plan X after A's death. A copy of the Trust P and a list of the trust beneficiaries were provided to the plan administrator of Plan X by the end of the calendar year following the calendar year of A's death. As of the date of A's death, the Trust P was irrevocable and was a valid trust under the laws of the state of A's domicile. A's account balance in Plan X was includible in A's gross estate under § 2039.

(ii) Under the terms of Trust P, all trust income is payable annually to B, and no one has the power to appoint Trust P principal to any person other than B. A's children, who are all younger than B, are the sole remainder beneficiaries of the Trust P. No other person has a beneficial interest in Trust P. Under the terms of the Trust P, B has the power, exercisable annually, to compel the trustee to withdraw from A's account balance in Plan X an amount equal to the income earned on the assets held in A's account in Plan X during the calendar year and to distribute that amount through Trust P to B. Plan X contains no prohibition on withdrawal from A's account of amounts in excess of the annual required minimum distributions under section 401(a)(9). In accordance with the terms of Plan X, the trustee of Trust P elects, in order to satisfy section 401(a)(9), to receive annual required minimum distributions using the life expectancy rule in section 401(a)(9)(B)(iii) for distributions over a distribution period equal to B's life expectancy. If B exercises the withdrawal power, the trustee must withdraw from A's account under Plan X the greater of the amount of income earned in the account during the calendar year or the required minimum distribution. However, under the terms of Trust P, and applicable state law, only the portion of the Plan X distribution received by the trustee equal to the income earned by A's account in Plan X is required to be distributed to B (along with any other trust income.)

(iii) Because some amounts distributed from A's account in Plan X to Trust P may be accumulated in Trust P during B's lifetime for the benefit of A's children, as remaindermen beneficiaries of Trust P, even though access to those amounts are delayed until after B's death, A's children are beneficiaries of A's account in Plan X in addition to B and B is not the sole beneficiary of A's account. Thus the designated beneficiary used to determine the distribution period from A's account in Plan X is the beneficiary with the shortest life expectancy. B's life expectancy is the shortest of all the potential beneficiaries of the testamentary trust's interest in A's account in Plan X (including remainder beneficiaries). Thus, the distribution period for purposes of section 401(a)(9)(B)(iii) is B's life expectancy. Because B is not the sole beneficiary of the testamentary trust's interest in A's account in Plan X, the special rule in 401(a)(9)(B)(iv) is not available and the annual required minimum distributions from the account to Trust M must begin no later than the end of the calendar year immediately following the calendar year of A's death.

Example 3. (i) The facts are the same as Example 2 except that the testamentary trust instrument provides that all amounts distributed from A's account in Plan X to the trustee while B is alive will be paid directly to B upon receipt by the trustee of Trust P.

(ii) In this case, B is the sole beneficiary of A's account in Plan X for purposes of determining the designated beneficiary under section 401(a)(9)(B)(iii) and (iv). No amounts distributed from A's account in Plan X to Trust P are accumulated in Trust P during B's lifetime for the benefit of any other beneficiary. Because B is the sole beneficiary of the testamentary trust's interest in A's account in Plan X, the annual required minimum distributions from A's account to Trust P must begin no later than the end of the calendar year in which A would have attained age 70½, rather than the calendar year immediately following the calendar year of A's death.

(d) *Designations by beneficiaries.* (1) If the plan provides (or allows the employee to specify) that, after the end of the calendar year following the calendar year in which the employee died, any person or persons have the discretion to change the beneficiaries of the employee, then, for purposes of determining the distribution period after the employee's death, the employee will be treated as not having designated a beneficiary. However, such discretion will not be found to exist merely because a beneficiary may designate a subsequent beneficiary for distributions of any portion of the employee's benefit after the beneficiary dies.

(2) This paragraph (d) is illustrated by the following example:

Example. The facts are the same as in *Example 1* in paragraph (c)(3) of this A–7, except that, as permitted under the plan, D designates E as the beneficiary of any amount remaining after the death of D rather than C making this designation. E is still disregarded in determining C's designated beneficiary for purposes of section 401(a)(9).

Q–8. If a portion of an employee's individual account is not vested as of the employee's required beginning date, how is the determination of the required minimum distribution affected?

A–8. If the employee's benefit is in the form of an individual account, the benefit used to determine the required minimum distribution for any distribution calendar year will be determined in accordance with A–1 of this section without regard to whether or not all of the employee's benefit is vested. If any portion of the employee's benefit is not vested, distributions will be treated as being paid from the vested portion of the benefit first. If, as of the end of a distribution calendar year (or as of the employee's required beginning date, in the case of the employee's first distribution calendar year), the total amount of the employee's vested benefit is less than the required minimum distribution for the calendar year, only the vested portion, if any, of the employee's benefit is required to be distributed by the end of the calendar year (or, if applicable, by the employee's required beginning date). However, the required minimum distribution for the subsequent distribution calendar year must be increased by the sum of amounts not distributed in prior calendar years because the employee's vested benefit was less than the required minimum distribution (subject to the limitation that the required minimum distribution for that subsequent distribution calendar year will not exceed the vested portion of the employee's benefit). In such case, an adjustment for the additional amount distributed which corresponds to the adjustment described in A–3(c)(2) of this section will be made to the account used to determine the required minimum distribution for that calendar year.

§ 1.401(a)(9)–6 Required minimum distributions as annuity payments.

Q–1. How must annuity distributions under a defined benefit plan be paid in order to satisfy section 401(a)(9)?

A–1. (a) In order to satisfy section 401(a)(9), annuity distributions under a defined benefit plan must be paid in periodic payments made at intervals not longer than one year (payment intervals) for a life (or lives), or over a period certain not longer than a life expectancy (or joint life and last survivor expectancy) described in section 401(a)(9)(A)(ii) or section 401(a)(9)(B)(iii), whichever is applicable. The life expectancy (or joint life and last survivor expectancy) for purposes of determining the length of the period certain will be determined in accordance with A–3 of this section. Once payments have commenced over a period certain, the period certain may not be lengthened even if the period certain is shorter than the maximum permitted. Life annuity payments must satisfy the minimum distribution incidental benefit requirements of A–2 of this section. All annuity payments (life and period certain) also must either be nonincreasing or increase only as follows:

(1) With any percentage increase in a specified and generally recognized cost-of-living index;

(2) To the extent of the reduction in the amount of the employee's payments to provide for a survivor benefit upon death, but only if the beneficiary whose life was being used to determine the

period described in section 401(a)(9)(A)(ii) over which payments were being made dies or is no longer the employee's beneficiary pursuant to a qualified domestic relations order within the meaning of section 414(p);

(3) To provide cash refunds of employee contributions upon the employee's death; or

(4) Because of an increase in benefits under the plan.

(b) The annuity may be a life annuity (or joint and survivor annuity) with a period certain if the life (or lives, if applicable) and period certain each meet the requirements of paragraph (a) of this A–1. For purposes of this section, if distribution is permitted to be made over the lives of the employee and the designated beneficiary, references to life annuity include a joint and survivor annuity.

(c) Distributions under a variable annuity will not be found to be increasing merely because the amount of the payments varies with the investment performance of the underlying assets. However, the Commissioner may prescribe additional requirements applicable to such variable life annuities in revenue rulings, notices, and other guidance published in the Internal Revenue Bulletin. See § 601.601(d)(2)(ii)(b) of this chapter.

(d)(1) Except as provided in (d)(2) of this A–1, annuity payments must commence on or before the employee's required beginning date (within the meaning of A–2 of § 1.401(a)(9)–2). The first payment which must be made on or before the employee's required beginning date must be the payment which is required for one payment interval. The second payment need not be made until the end of the next payment interval even if that payment interval ends in the next calendar year. Similarly, in the case of distributions commencing after death in accordance with section 401(a)(9)(B)(iii) and (iv), the first payment that must be made on or before the date determined under A–3(a) or (b) (whichever is applicable) of § 1.401(a)(9)–3 must be the payment which is required for one payment interval. Payment intervals are the periods for which payments are received, *e.g.*, bimonthly, monthly, semi-annually, or annually. All benefit accruals as of the last day of the first distribution calendar year must be included in the calculation of the amount of the life annuity payments for payment intervals ending on or after the employee's required beginning date.

(2) In the case of an annuity contract purchased after the required beginning date, the first payment interval must begin on or before the purchase date and the payment required for one payment interval must be made no later than the end of such payment interval.

(3) This paragraph (d) is illustrated by the following example:

Example. A defined benefit plan (Plan X) provides monthly annuity payments of $500 for the life of unmarried participants with a 10-year period certain. An unmarried participant (A) in Plan X attains age 70 ½ in 2001. In order to meet the requirements of this paragraph, the first payment which must be made on behalf of A on or before April 1, 2002, will be $500 and the payments must continue to be made in monthly payments of $500 thereafter for the life and 10-year certain period.

(e) If distributions from a defined benefit plan are not in the form of an annuity, the employee's benefit will be treated as an individual account for purposes of determining the required minimum distribution. See § 1.401(a)(9)–5.

Q–2. How must distributions in the form of a life (or joint and survivor) annuity be made in order to satisfy the minimum distribution incidental benefit (MDIB) requirement of section 401(a)(9)(G)?

A–2. (a) *Life annuity for employee.* If the employee's benefit is payable in the form of a life annuity for the life of the employee satisfying section 401(a)(9), the MDIB requirement of section 401(a)(9)(G) will be satisfied.

(b) *Joint and survivor annuity, spouse beneficiary.* If the employee's sole beneficiary, as of the annuity starting date for annuity payments, is the employee's spouse and the distributions satisfy section 401(a)(9) without regard to the MDIB requirement, the distributions to the employee will be deemed to satisfy the MDIB requirement of section 401(a)(9)(G). For example, if an employee's benefit is being distributed in the form of a joint and survivor annuity for the lives of the employee and the employee's spouse and the spouse is the sole beneficiary of the employee, the amount of the periodic payment payable to the spouse may always be 100 percent of the annuity payment payable to the employee regardless of the difference in the ages between the employee and the employee's spouse. However, the amount of the payments under the annuity must be nonincreasing unless specifically permitted under A–1 of this section.

(c) *Joint and survivor annuity, nonspouse beneficiary*—(1) *Explanation of rule.* If distributions commence under a distribution option that is in the form of a joint and survivor annuity for the joint lives of the employee and a beneficiary other than the employee's spouse, the MDIB requirement will not be satisfied as of the date distributions commence unless the distribution option provides that annuity payments to be made to the employee on and after the employee's required beginning date will satisfy the conditions of this paragraph. The periodic annuity payment payable to the survivor must not at any time on and after the employee's required beginning date exceed the applicable percentage of the annuity payment payable to the employee using the table below. Thus, this requirement must be satisfied with respect to any benefit increase after such date, including increases to reflect increases in the cost of living. The applicable percentage is based on the excess of the age of the employee over the age of the beneficiary as of their attained ages as of their birthdays in a calendar year. If the employee has more than one beneficiary, the applicable percentage will be the percentage using the age of the youngest beneficiary. Additionally, the amount of the annuity payments must satisfy A–1 of this section.

(2) *Table.*

Excess of age of employee over age of beneficiary	Applicable percentage
10 years or less	100
11	96
12	93
13	90
14	87
15	84
16	82
17	79
18	77
19	75
20	73
21	72
22	70
23	68
24	67
25	66
26	64
27	63
28	62
29	61
30	60
31	59
32	59
33	58
34	57
35	56
36	56
37	55
38	55
39	54
40	54
41	53
42	53
43	53
44 and greater	52

(3) *Example.* This paragraph (c) is illustrated by the following example:

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Example. Distributions commence on January 1, 2001 to an employee (Z), born March 1, 1935, after retirement at age 65. Z's daughter (Y), born February 5, 1965, is Z's beneficiary. The distributions are in the form of a joint and survivor annuity for the lives of Z and Y with payments of $500 a month to Z and upon Z's death of $500 a month to Y, i.e., the projected monthly payment to Y is 100 percent of the monthly amount payable to Z. There is no provision under the option for a change in the projected payments to Y as of April 1, 2006, Z's required beginning date. Consequently, as of January 1, 2001, the date annuity distributions commence, the plan does not satisfy the MDIB requirement in operation because, as of such date, the distribution option provides that, as of Z's required beginning date, the monthly payment to Y upon Z's death will exceed 60 percent of Z's monthly payment (the maximum percentage for a difference of ages of 30 years).

(d) *Period certain and annuity features.* If a distribution form includes a life annuity and a period certain, the amount of the annuity payments payable to the employee must satisfy paragraph (c) of this A–2, and the period certain may not exceed the period determined under A–3 of this section.

Q–3. How long is a period certain under an annuity contract permitted to extend?

A–3. (a) *Distributions commencing during the employee's life*—(1) *Spouse beneficiary.* If an employee's spouse is the employee's sole beneficiary as of the annuity starting date, the period certain for annuity distributions commencing during the life of an employee with an annuity starting date on or after the employee's required beginning date is not permitted to exceed the joint life and last survivor expectancy of the employee and the spouse using the age of the employee and spouse as of their birthdays in the calendar year that contains the annuity starting date.

(2) *Nonspouse beneficiary.* If an employee's surviving spouse is not the employee's sole beneficiary as of the annuity starting date, the period certain for any annuity distributions during the life of the employee with an annuity starting date on or after the employee's required beginning date is not permitted to exceed the shorter of the applicable distribution period for the employee (determined in accordance with the table in A–4(a)(2) of § 1.401(a)(9)–5) for the calendar year that contains on the annuity starting date or the joint life and last survivor expectancy of the employee and the employee's designated beneficiary, determined using the designated beneficiary as of the annuity starting date and using their ages as of their birthdays in the calendar year that contains the annuity starting date. See A–10 for the rule for annuity payments with an annuity starting date before the required beginning date.

(b) *Life expectancy rule.* (1) If annuity distributions commence after the death of the employee under the life expectancy rule (under section 401(a)(9)(iii) or (iv)), the period certain for any distributions commencing after death cannot exceed the applicable distribution period determined under A–5(b) of § 1.401(a)(9)–5 for the distribution calendar year that contains the annuity starting date.

(2) If the annuity starting date is in a calendar year before the first distribution calendar year, the period certain may not exceed the life expectancy of the designated beneficiary using the beneficiary's age in the year that contains the annuity starting date.

Q–4. May distributions be made from an annuity contract which is purchased from an insurance company?

A–4. Yes. Distributions may be made from an annuity contract which is purchased with the employee's benefit by the plan from an insurance company and which makes payments that satisfy the provisions of this section. In the case of an annuity contract purchased from an insurance company, there is also an exception to the nonincreasing requirement in A–1(a) of this section for an increase to provide a cash refund upon the employee's death equal to the excess of the amount of the premiums paid for the contract over the prior distributions under the contract. If the payments actually made under the annuity contract do not meet the requirements of section 401(a)(9), the plan fails to satisfy section 401(a)(9).

Q–5. In the case of annuity distributions under a defined benefit plan, how must additional benefits which accrue after the employee's required beginning date be distributed in order to satisfy section 401(a)(9)?

A–5. (a) In the case of annuity distributions under a defined benefit plan, if any additional benefits accrue after the employee's required beginning date, distribution of such amount as a separate identifiable component must commence in accordance with A–1 of this section beginning with the first payment interval ending in the calendar year immediately following the calendar year in which such amount accrues.

(b) A plan will not fail to satisfy section 401(a)(9) merely because there is an administrative delay in the commencement of the distribution of the separate identifiable component, provided that the actual payment of such amount commences as soon as practicable but not later than by the end of the first calendar year following the calendar year in which the additional benefit accrues, and that the total amount paid during such first calendar year is not less than the total amount that was required to be paid during that year under A–5(a) of this section.

Q–6. If a portion of an employee's benefit is not vested as of the employee's required beginning date, how is the determination of the required minimum distribution affected?

A–6. In the case of annuity distributions from a defined benefit plan, if any portion of the employee's benefit is not vested as of December 31 of a distribution calendar year (or as of the employee's required beginning date in the case of the employee's first distribution calendar year), the portion which is not vested as of such date will be treated as not having accrued for purposes of determining the required minimum distribution for that distribution calendar year. When an additional portion of the employee's benefit becomes vested, such portion will be treated as an additional accrual. See A–5 of this section for the rules for distributing benefits which accrue under a defined benefit plan after the employee's required beginning date.

Q–7. If an employee retires after the calendar year in which the employee attains age 70½, for what period must the employee's accrued benefit under a defined benefit plan be actuarially increased?

A–7. (a) *Actuarial increase starting date.* If an employee (other than a 5-percent owner) retires after the calendar year in which the employee attains age 70½, in order to satisfy section 401(a)(9)(C)(iii), the employee's accrued benefit under a defined benefit plan must be actuarially increased to take into account any period after age 70½ in which the employee was not receiving any benefits under the plan. The actuarial increase required to satisfy section 401(a)(9)(C)(iii) must be provided for the period starting on April 1 following the calendar year in which the employee attains age 70½.

(b) *Actuarial increase ending date.* The period for which the actuarial increase must be provided ends on the date on which benefits commence after retirement in an amount sufficient to satisfy section 401(a)(9).

(c) *Nonapplication to plan providing same required beginning date for all employees.* If as permitted under A–2(e) of § 1.401(a)(9)–2, a plan provides that the required beginning date for purposes of section 401(a)(9) for all employees is April 1 of the calendar year following the calendar year in which the employee attained age 70½ (regardless of whether the employee is a 5-percent owner) and the plan makes distributions

in an amount sufficient to satisfy section 401(a)(9) using that required beginning date, no actuarial increase is required under section 401(a)(9)(C)(iii).

(d) *Nonapplication to defined contribution plans.* The actuarial increase required under this A–7 does not apply to defined contribution plans.

(e) *Nonapplication to governmental and church plans.* The actuarial increase required under this A–7 does not apply to a governmental plan (within the meaning of section 414(d)) or a church plan. For purposes of this paragraph, the term *church plan* means a plan maintained by a church for church employees, and the term *church* means any church (as defined in section 3121(w)(3)(A)) or qualified church-controlled organization (as defined in section 3121(w)(3)(B)).

Q–8. What amount of actuarial increase is required under section 401(a)(9)(C)(iii)?

A–8. In order to satisfy section 401(a)(9)(C)(iii), the retirement benefits payable with respect to an employee as of the end of the period for actuarial increases (described in A–7 of this section) must be no less than: the actuarial equivalent of the employee's retirement benefits that would have been payable as of the date the actuarial increase must commence under A–7(a) of this section if benefits had commenced on that date; plus the actuarial equivalent of any additional benefits accrued after that date; reduced by the actuarial equivalent of any distributions made with respect to the employee's retirement benefits after that date. Actuarial equivalence is determined using the plan's assumptions for determining actuarial equivalence for purposes of satisfying section 411.

Q–9. How does the actuarial increase required under section 401(a)(9)(C)(iii) relate to the actuarial increase required under section 411?

A–9. In order for any of an employee's accrued benefit to be nonforfeitable as required under section 411, a defined benefit plan must make an actuarial adjustment to an accrued benefit the payment of which is deferred past normal retirement age. The only exception to this rule is that generally no actuarial adjustment is required to reflect the period during which a benefit is suspended as permitted under section 203(a)(3)(B) of the Employee Retirement Income Security Act of 1974 (ERISA). The actuarial increase required under section 401(a)(9) for the period described in A–7 of this section is generally the same as, and not in addition to, the actuarial increase required for the same period under section 411 to reflect any delay in the payment of retirement benefits after normal retirement age. However, unlike the actuarial increase required under section 411, the actuarial increase required under section 401(a)(9)(C) must be provided even during the period during which an employee's benefit has been suspended in accordance with ERISA section 203(a)(3)(B).

Q–10. What rule applies if distributions commence to an employee on a date before the employee's required beginning date over a period permitted under section 401(a)(9)(A)(ii) and the distribution form is an annuity under which distributions are made in accordance with the provisions of A–1 (and if applicable A–4) of this section?

A–10. (a) *General rule.* If distributions irrevocably (except for acceleration) commence to an employee on a date before the employee's required beginning date over a period permitted under section 401(a)(9)(A)(ii) and the distribution form is an annuity under which distributions are made in accordance with the provisions of A–1 (and, if applicable, A–4) of this section, the annuity starting date will be treated as the required beginning date for purposes of applying the rules of this section and § 1.401(a)(9)–3. Thus, for example, the designated beneficiary distributions will be determined as of the annuity starting date. Similarly, if the employee dies after the annuity starting date but before the annuity starting date determined under A–2 of § 1.401(a)(9)–2, after the employee's death, the remaining portion of the employee's interest must continue to be distributed in accordance with this section over the remaining period over which distributions commenced (single or joint lives and, if applicable, period certain). The rules in § 1.401(a)(9)–3 and section 401(a)(9)(B)(ii) or (iii) and (iv) do not apply.

(b) *Period certain.* If as of the employee's birthday in the year that contains the annuity starting date, the age of the employee is under 70, the following rule applies in applying the rule in paragraph (a)(2) of A–3 of this section. The applicable distribution period for the employee (determined in accordance with the table in A–4(a)(2) of § 1.401(a)(9)–5) is 26.2 plus the difference between 70 and the age of the employee as of the employee's birthday in the year that contains the annuity starting date.

Q–11. What rule applies if distributions commence irrevocably (except for acceleration) to the surviving spouse of an employee over a period permitted under section 401(a)(9)(B)(iii)(II) before the date on which distributions are required to commence and the distribution form is an annuity under which distributions are made as of the date distributions commence in accordance with the provisions of A–1 (and if applicable A–4) of this section,

A–11. If distributions commence irrevocably (except for acceleration) to the surviving spouse of an employee over a period permitted under section 401(a)(9)(B)(iii)(II) before the date on which distributions are required to commence and the distribution form is an annuity under which distributions are made as of the date distributions commence in accordance with the provisions of A–1 (and if applicable A–4) of this section, distributions will be considered to have begun on the actual commencement date for purposes of section 401(a)(9)(B)(iv)(II). Consequently, in such case, A–5 of § 1.401(a)(9)–3 and section 401(a)(9)(B)(ii) and (iii) will not apply upon the death of the surviving spouse as though the surviving spouse were the employee. Instead, the annuity distributions must continue to be made, in accordance with the provisions of A–1 (and if applicable A–4) of this section over the remaining period over which distributions commenced (single life and, if applicable, period certain).

§ 1.401(a)(9)–7 Rollovers and Transfers.

Q–1. If an amount is distributed by one plan (distributing plan) and is rolled over to another plan, is the benefit or the required minimum distribution under the distributing plan affected by the rollover?

A–1. No. If an amount is distributed by one plan and is rolled over to another plan, the amount distributed is still treated as a distribution by the distributing plan for purposes of section 401(a)(9), notwithstanding the rollover.

Q–2. If an amount is distributed by one plan (distributing plan) and is rolled over to another plan (receiving plan), how are the benefit and the required minimum distribution under the receiving plan affected?

A–2. If an amount is distributed by one plan (distributing plan) and is rolled over to another plan (receiving plan), the benefit of the employee under the receiving plan is increased by the amount rolled over. However, the distribution has no impact on the required minimum distribution to be made by the receiving plan for the calendar year in which the rollover is received. But, if a required minimum distribution is required to be made by the receiving plan for the following calendar year, the rollover amount must be considered to be part of the

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employee's benefit under the receiving plan. Consequently, for purposes of determining any required minimum distribution for the calendar year immediately following the calendar year in which the amount rolled over is received by the receiving plan, in the case in which the amount rolled over is received after the last valuation date in the calendar year under the receiving plan, the benefit of the employee as of such valuation date, adjusted in accordance with A–3 of § 1.401(a)(9)–5, will be increased by the rollover amount valued as of the date of receipt. For purposes of calculating the benefit under the receiving plan pursuant to the preceding sentence, if the amount rolled over is received by the receiving plan in a different calendar year from the calendar year in which it is distributed by the distributing plan, the amount rolled over is deemed to have been received by the receiving plan in the calendar year in which it was distributed by the distributing plan.

Q–3. In the case of a transfer of an amount of an employee's benefit from one plan (transferor plan) to another plan (transferee plan), are there any special rules for satisfying the required minimum distribution requirement or determining the employee's benefit under the transferor plan?

A–3. (a) In the case of a transfer of an amount of an employee's benefit from one plan to another, the transfer is not treated as a distribution by the transferor plan for purposes of section 401(a)(9). Instead, the benefit of the employee under the transferor plan is decreased by the amount transferred. However, if any portion of an employee's benefit is transferred in a distribution calendar year with respect to that employee, in order to satisfy section 401(a)(9), the transferor plan must determine the amount of the required minimum distribution with respect to that employee for the calendar year of the transfer using the employee's benefit under the transferor plan before the transfer. Additionally, if any portion of an employee's benefit is transferred in the employee's second distribution calendar year but on or before the employee's required beginning date, in order to satisfy section 401(a)(9), the transferor plan must determine the amount of the required minimum distribution requirement for the employee's first distribution calendar year based on the employee's benefit under the transferor plan before the transfer. The transferor plan may satisfy the required minimum distribution requirement for the calendar year of the transfer (and the prior year if applicable) by segregating the amount which must be distributed from the employee's benefit and not transferring that amount. Such amount may be retained by the transferor plan and distributed on or before the date required.

(b) For purposes of determining any required minimum distribution for the calendar year immediately following the calendar year in which the transfer occurs, in the case of a transfer after the last valuation date for the calendar year of the transfer under the transferor plan, the benefit of the employee as of such valuation date, adjusted in accordance with A–3 of § 1.401(a)(9)–5, will be decreased by the amount transferred, valued as of the date of the transfer.

Q–4. If an amount of an employee's benefit is transferred from one plan (transferor plan) to another plan (transferee plan), how are the benefit and the required minimum distribution under the transferee plan affected?

A–4. In the case of a transfer from one plan (transferor plan) to another (transferee plan), the general rule is that the benefit of the employee under the transferee plan is increased by the amount transferred. The transfer has no impact on the required minimum distribution to be made by the transferee plan in the calendar year in which the transfer is received. However, if a required minimum distribution is required from the transferee plan for the following calendar year, the transferred amount must be considered to be part of the employee's benefit under the transferee plan. Consequently, for purposes of determining any required minimum distribution for the calendar year immediately following the calendar year in which the transfer occurs, in the case of a transfer after the last valuation date of the transferee plan in the transfer calendar year, the benefit of the employee under the receiving plan valued as of such valuation date, adjusted in accordance with A–3 of § 1.401(a)(9)–5, will be increased by the amount transferred valued as of the date of the transfer.

Q–5. How are a spinoff, merger or consolidation (as defined in § 1.414(l)–1) treated for purposes of determining an employee's benefit and required minimum distribution under section 401(a)(9)?

A–5. For purposes of determining an employee's benefit and required minimum distribution under section 401(a)(9), a spinoff, a merger, or a consolidation (as defined in § 1.414(l)–1) will be treated as a transfer of the benefits of the employees involved. Consequently, the benefit and required minimum distribution of each employee involved under the transferor and transferee plans will be determined in accordance with A–3 and A–4 of this section.

§ 1.401(a)(9)–8 Special rules.

Q–1. What distribution rules apply if an employee is a participant in more than one plan?

A–1. If an employee is a participant in more than one plan, the plans in which the employee participates are not permitted to be aggregated for purposes of testing whether the distribution requirements of section 401(a)(9) are met. The distribution of the benefit of the employee under each plan must separately meet the requirements of section 401(a)(9). For this purpose, a plan described in section 414(k) is treated as two separate plans, a defined contribution plan to the extent benefits are based on an individual account and a defined benefit plan with respect to the remaining benefits.

Q–2. If an employee's benefit under a plan is divided into separate accounts (or segregated shares in the case of a defined benefit plan), do the distribution rules in section 401(a)(9) and these regulations apply separately to each separate account (or segregated share)?

A–2. (a) Except as otherwise provided in paragraphs (b) and (c) of this A–2, if an employee's account under a defined contribution plan plan is divided into separate accounts (or if an employee's benefit under a defined benefit plan is divided into segregated shares in the case of a defined benefit plan) under the plan, the separate accounts (or segregated shares) will be aggregated for purposes of satisfying the rules in section 401(a)(9). Thus, except as otherwise provided in paragraphs (b) and (c) of this A–2, all separate accounts, including a separate account for nondeductible employee contributions (under section 72(d)(2)) or for qualified voluntary employee contributions (as defined in section 219(e)), will be aggregated for purposes of section 401(a)(9).

(b) If, for lifetime distributions, as of an employee's required beginning date (or the beginning of any distribution calendar year beginning after the employee's required beginning date), or in the case of distributions under section 401(a)(9)(B)(ii) or (iii) and (iv), as of the end of the year following the year containing the employee's (or spouse's, where applicable) date of death, the beneficiaries with respect to a separate account (or segregated share in the case of a defined benefit plan) under the plan differ from the beneficiaries with respect to the other separate accounts (or segregate shares)

of the employee under the plan, such separate account (or segregated share) under the plan need not be aggregated with other separate accounts (or segregated shares) under the plan in order to determine whether the distributions from such separate account (or segregated share) under the plan satisfy section 401(a)(9). Instead, the rules in section 401(a)(9) may separately apply to such separate account (or segregated share) under the plan. For example, if, in the case of a distribution described in section 401(a)(9)(B)(iii) and (iv), the only beneficiary of a separate account (or segregated share) under the plan is the employee's surviving spouse, and beneficiaries other than the surviving spouse are designated with respect to the other separate accounts of the employee, distribution of the spouse's separate account (or segregated share) under the plan need not commence until the date determined under the first sentence in A–3(b) of § 1.401(a)(9)–3, even if distribution of the other separate accounts (or segregated shares) under the plan must commence at an earlier date. In the case of a distribution after the death of an employee to which section 401(a)(9)(B)(i) does not apply, distribution from a separate account (or segregated share) of an employee may be made over a beneficiary's life expectancy in accordance with section 401(a)(9)(B)(iii) and (iv) even through distributions from other separate accounts (or segregated shares) under the plan with different beneficiaries are being made in accordance with the five-year rule in section 401(a)(9)(B)(ii).

(c) A portion of an employee's account balance under a defined contribution plan is permitted to be used to purchase an annuity contract with a remaining amount maintained in the separate account. In that case, the separate account under the plan must be distributed in accordance with § 1.401(a)(9)–5 in order to satisfy section 401(a)(9) and the annuity payments under the annuity contract must satisfy § 1.401(a)(9)–6 in order to satisfy section 401(a)(9).

Q–3. What is a separate account or segregated share for purposes of section 401(a)(9)?

A–3. (a) For purposes of section 401(a)(9), a separate account in an individual account is a portion of an employee's benefit determined by an acceptable separate accounting including allocating investment gains and losses, and contributions and forfeitures, on a pro rata basis in a reasonable and consistent matter between such portion and any other benefits. Further, the amounts of each such portion of the benefit will be separately determined for purposes of determining the amount of the required minimum distribution in accordance with § 1.401(a)(9)–5.

(b) A benefit in a defined benefit plan is separated into segregated shares if it consists of separate identifiable components which may be separately distributed.

Q–4. Must a distribution that is required by section 401(a)(9) to be made by the required beginning date to an employee or that is required by section 401(a)(9)(B)(iii) and (iv) to be made by the required time to a designated beneficiary who is a surviving spouse be made notwithstanding the failure of the employee, or spouse where applicable, to consent to a distribution while a benefit is immediately distributable?

A–4. Yes. Section 411(a)(11) and section 417(e) (see §§ 1.411(a)(11)–1(c)(2) and 1.417(e)–1(c)) require employee and spousal consent to certain distributions of plan benefits while such benefits are immediately distributable. If an employee's normal retirement age is later than the required beginning date for the commencement of distributions under section 401(a)(9) and, therefore, benefits are still immediately distributable, the plan must, nevertheless, distribute plan benefits to the participant (or where applicable, to the spouse) in a manner that satisfies the requirements of section 401(a)(9). Section 401(a)(9) must be satisfied even though the participant (or spouse, where applicable) fails to consent to the distribution. In such a case, the plan may distribute in the form of a qualified joint and survivor annuity (QJSA) or in the form of a qualified preretirement survivor annuity (QPSA) and the consent requirements of sections 411(a)(11) and 417(e) are deemed to be satisfied if the plan has made reasonable efforts to obtain consent from the participant (or spouse if applicable) and if the distribution otherwise meets the requirements of section 417. If, because of section 401(a)(11)(B), the plan is not required to distribute in the form of a QJSA to a participant or a QPSA to a surviving spouse, the plan may distribute the required minimum distribution amount required at the time required to satisfy section 401(a)(9) and the consent requirements of sections 411(a)(11) and 417(e) are deemed to be satisfied if the plan has made reasonable efforts to obtain consent from the participant (or spouse if applicable) and if the distribution otherwise meets the requirements of section 417.

Q–5. Who is an employee's spouse or surviving spouse for purposes of section 401(a)(9)?

A–5. Except as otherwise provided in A–6(a) (in the case of distributions of a portion of an employee's benefit payable to a former spouse of an employee pursuant to a qualified domestic relations order), for purposes of section 401(a)(9), an individual is a spouse or surviving spouse of an employee if such individual is treated as the employee's spouse under applicable state law. In the case of distributions after the death of an employee, for purposes of determining whether, under the life expectancy rule in section 401(a)(9)(B)(iii) and (iv), the provisions of section 401(a)(9)(B)(iv) apply, the spouse of the employee is determined as of the date of death of the employee.

Q–6. In order to satisfy section 401(a)(9), are there any special rules which apply to the distribution of all or a portion of an employee's benefit payable to an alternate payee pursuant to a qualified domestic relations order as defined in section 414(p) (QDRO)?

A–6. (a) A former spouse to whom all or a portion of the employee's benefit is payable pursuant to a QDRO will be treated as a spouse (including a surviving spouse) of the employee for purposes of section 401(a)(9), including the minimum distribution incidental benefit requirement, regardless of whether the QDRO specifically provides that the former spouse is treated as the spouse for purposes of sections 401(a)(11) and 417.

(b)(1) If a QDRO provides that an employee's benefit is to be divided and a portion is to be allocated to an alternate payee, such portion will be treated as a separate account (or segregated share) which separately must satisfy the requirements of section 401(a)(9) and may not be aggregated with other separate accounts (or segregated shares) of the employee for purposes of satisfying section 401(a)(9). Except as otherwise provided in paragraph

(b)(2) of this A–6, distribution of such separate account allocated to an alternate payee pursuant to a QDRO must be made in accordance with section 401(a)(9). For example, in general, distribution of such account will satisfy section 401(a)(9)(A) if required minimum distributions from such account during the employee's lifetime begin not later than the employee's required beginning date and the required minimum distribution is determined in accordance with § 1.401(a)(9)–5 for each distribution calendar year using an applicable distribution period determined under A–4 of § 1.401(a)(9)–5 using the age of the employee in the distribution calendar year for purposes of using the

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table in A–4(a)(2) of § 1.401(a)(9)–5 if applicable or ages of the employee and spousal alternate payee if their joint life expectancy is longer than the distribution period using that table. The determination of whether distribution from such account after the death of the employee to the alternate payee will be made in accordance with section 401(a)(9)(B)(i) or section 401(a)(9)(B)(ii) or (iii) and (iv) will depend on whether distributions have begun as determined under A–5 or § 1.401(a)(9)–2 (which provides, in general, that distributions are not treated as having begun until the employee's required beginning date even though payments may actually have begun before that date). For example, if the alternate payee dies before the employee and distribution of the separate account allocated to the alternate payee pursuant to the QDRO is to be made to the alternate payee's beneficiary, such beneficiary may be treated as a designated beneficiary for purposes of determining the required minimum distribution required from such account after the death of the employee if the beneficiary of the alternate payee is an individual and if such beneficiary is a beneficiary under the plan or specified to or in the plan. Specification in or pursuant to the QDRO will also be treated as specification to the plan.

(2) Distribution of the separate account allocated to an alternate payee pursuant to a QDRO satisfy the requirements of section 401(a)(9)(A)(ii) if such account is to be distributed, beginning not later than the employee's required beginning date, over the life of the alternate payee (or over a period not extending beyond the life expectancy of the alternative payee). Also, if the plan permits the employee to elect whether distribution upon the death of the employee will be made in accordance with the five-year rule in section 401(a)(9)(B)(ii) or the life expectancy rule in section 401(a)(9)(B)(iii) and (iv) pursuant to A–4(c) of § 1.401(a)(9)–3, such election is to be made only by the alternate payee for purposes of distributing the separate account allocated to the alternate payee pursuant to the QDRO. If the alternate payee dies after distribution of the separate account allocated to the alternate payee pursuant to a QDRO has begun (determined under A–5 of § 1.401(a)(9)–2) but before the employee dies, distribution of the remaining portion of that portion of the benefit allocated to the alternate payee must be made in accordance with the rules in § 1.401(a)(9)–5 or § 1.401(a)(9)–6 for distributions during the life of the employee. Only after the death of the employee is the amount of the required minimum distribution determined in accordance with the rules that apply after the death of the employee.

(c) If a QDRO does not provide that an employee's benefit is to be divided but provides that a portion of an employee's benefit (otherwise payable to the employee) is to be paid to an alternate payee, such portion will not be treated as a separate account (or segregated share) of the employee. Instead, such portion will be aggregated with any amount distributed to the employee and will be treated as having been distributed to the employee for purposes of determining whether the required minimum distribution requirement has been satisfied with respect to that employee.

Q–7. Will a plan fail to satisfy section 401(a)(9) where it is not legally permitted to distribute to an alternate payee all or a portion of an employee's benefit payable to an alternate payee pursuant to a QDRO within the period specified in section 414(p)(7)?

A–7. A plan will not fail to satisfy section 401(a)(9) merely because it fails to distribute a required amount during the period in which the issue of whether a domestic relations order is a QDRO is being determined pursuant to section 414(p)(7), provided that the period does not extend beyond the 18-month period described in section 414(p)(7)(E). To the extent that a distribution otherwise required under section 401(a)(9) is not made during this period, this amount and any additional amount accrued during this period will be treated as though it is not vested during the period and any distributions with respect to such amounts must be made under the relevant rules for nonvested benefits described in either A–8 of § 1.401(a)(9)–5 or A–6 of § 1.401(a)(9)–6.

Q–8. Will a plan fail to satisfy section 401(a)(9) where an individual's distribution from the plan is less than the amount otherwise required to satisfy section 401(a)(9) under § 1.401(a)(9)–5 or § 1.401(a)(9)–6 because distributions were being paid under an annuity contract issued by a life insurance company in state insurer delinquency proceedings and have been reduced or suspended by reasons of such state proceedings?

A–8. A plan will not fail to satisfy section 401(a)(9) merely because an individual's distribution from the plan is less than the amount otherwise required to satisfy section 401(a)(9) under § 1.401(a)(9)–5 or § 1.401(a)(9)–6 because distributions were being paid under an annuity contract issued by a life insurance company in state insurer delinquency proceedings and have been reduced or suspended by reasons of such state proceedings. To the extent that a distribution otherwise required under section 401(a)(9) is not made during the state insurer delinquency proceedings, this amount and any additional amount accrued during this period will be treated as though it is not vested during the period and any distributions with respect to such amounts must be made under the relevant rules for nonvested benefits described in either A–8 of § 1.401(a)(9)–5 or A–6 of § 1.401(a)(9)–6.

Q–9. Will a plan fail to qualify as a pension plan within the meaning of section 401(a) solely because the plan permits distributions to commence to an employee on or after April 1 of the calendar year following the calendar year in which the employee attains age 70½ even though the employee has not retired or attained the normal retirement age under the plan as of the date on which such distributions commence?

A–9. No. A plan will not fail to qualify as a pension plan within the meaning of section 401(a) solely because the plan permits distributions to commence to an employee on or after April 1 of the calendar year following the calendar year in which the employee attains age 70½ even though the employee has not retired or attained the normal retirement age under the plan as of the date on which such distributions commence. This rule applies without regard to whether or not the employee is a 5-percent owner with respect to the plan year ending in the calendar year in which distributions commence.

Q–10. Is the distribution of an annuity contract a distribution for purposes of section 401(a)(9)?

A–10. No. The distribution of an annuity contract is not a distribution for purposes of section 401(a)(9).

Q–11. Will a payment by a plan after the death of an employee fail to be treated as a distribution for purposes of section 401(a)(9) solely because it is made to an estate or a trust?

A–11. A payment by a plan after the death of an employee will not fail to be treated as a distribution for purposes of section 401(a)(9) solely because it is made to an estate or a trust. As a result, the estate or trust which receives a payment from a plan after the death of an employee need not distribute the amount of such payment to the beneficiaries of the estate or trust in accordance with section 401(a)(9)(B). However, pursuant to A–3 of § 1.401(a)(9)–4, distribution to the estate must satisfy the five-year rule in section 401(a)(9)(B)(iii) if the distribution to the employee had not begun (as defined in A–6 of § 1.401(a)(9)–2) as of the employee's date of death, and pursuant to A–3 of § 1.401(a)(9)–4, an estate may not be a designated beneficiary. See A–5 and A–6 of § 1.401(a)(9)–4 for provisions under which beneficiaries of a trust with respect to the trust's interest in an employee's benefit are treated as having been designated as beneficiaries of the employee under the plan.

Q–12. Will a plan fail to satisfy section 411 if the plan is amended to eliminate benefit options that do not satisfy section 401(a)(9)?

A–12. Nothing in section 401(a)(9) permits a plan to eliminate for all participants a benefit option that could not otherwise be eliminated pursuant to section 411(d)(6). However, a plan must provide that, notwithstanding any other plan provisions, it will not distribute benefits under any option that does not satisfy section 401(a)(9). See A–3 of § 1.401(a)(9)–1. Thus, the plan, notwithstanding section 411(d)(6), must prevent participants from electing benefit options that do not satisfy section 401(a)(9).

Q–13. Is a plan disqualified merely because it pays benefits under a designation made before January 1, 1984, in accordance with section 242(b)(2) of the Tax Equity and Fiscal Responsibility Act (TEFRA)?

A–13. No. Even though the distribution requirements added by TEFRA were retroactively repealed by the Tax Reform Act of 1984 (TRA of 1984), the transitional election rule in section 242(b) was preserved. Satisfaction of the spousal consent requirements of section 417(a) and (e) (added by the Retirement Equity Act of 1984) will not be considered a revocation of the pre-1984 designation. However, sections 401(a)(11) and 417 must be satisfied with respect to any distribution subject to those sections. The election provided in section 242(b) of TEFRA is hereafter referred to as a section 242(b)(2) election.

Q–14. In the case in which an amount is transferred from one plan (transferor plan) to another plan (transferee plan), may the transferee plan distribute the amount transferred in accordance with a section 242(b)(2) election made under either the transferor plan or under the transferee plan?

A–14. (a) In the case in which an amount is transferred from one plan to another plan, the amount transferred may be distributed in accordance with a section 242(b)(2) election made under the transferor plan if the employee did not elect to have the amount transferred and if the amount transferred is separately accounted for by the transferee plan. However, only the benefit attributable to the amount transferred, plus earnings thereon, may be distributed in accordance with the section 242(b)(2) election made under the transferor plan. If the employee elected to have the amount transferred, the transfer will be treated as a distribution and rollover of the amount transferred for purposes of this section.

(b) In the case in which an amount is transferred from one plan to another plan, the amount transferred may not be distributed in accordance with a section 242(b)(2) election made under the transferee plan. If a section 242(b)(2) election was made under the transferee plan, the amount transferred must be separately accounted for. If the amount transferred is not separately accounted for under the transferee plan, the section 242(b)(2) election under the transferee plan is revoked and section 401(a)(9) will apply to subsequent distributions by the transferee plan.

(c) A merger, spinoff, or consolidation, as defined in § 1.414(l)–1(b), will be treated as a transfer for purposes of the section 242(b)(2) election.

Q–15. If an amount is distributed by one plan (distributing plan) and rolled over into another plan (receiving plan), may the receiving plan distribute the amount rolled over in accordance with a section 242(b)(2) election made under either the distributing plan or the receiving plan?

A–15. No. If an amount is distributed by one plan and rolled over into another plan, the receiving plan must distribute the amount rolled over in accordance with section 401(a)(9) whether or not the employee made a section 242(b)(2) election under the distributing plan. Further, if the amount rolled over was not distributed in accordance with the election, the election under the distributing plan is revoked and section 401(a)(9) will apply to all subsequent distributions by the distributing plan. Finally, if the employee made a section 242(b)(2) election under the receiving plan and such election is still in effect, the amount rolled over must be separately accounted for under the receiving plan and distributed in accordance with section 401(a)(9). If amounts rolled over are not separately accounted for, any section 242(b)(2) election under the receiving plan is revoked and section 401(a)(9) will apply to subsequent distributions by the receiving plan.

Q–16. May a section 242(b)(2) election be revoked after the date by which distributions are required to commence in order to satisfy section 401(a)(9) and this section of the regulations?

A–16. Yes. A section 242(b)(2) election may be revoked after the date by which distributions are required to commence in order to satisfy section 401(a)(9) and this section of the regulations. However, if the section 242(b)(2) election is revoked after the date by which distributions are required to commence in order to satisfy section 401(a)(9) and this section of the regulations and the total amount of the distributions which would have been required to be made prior to the date of the revocation in order to satisfy section 401(a)(9), but for the section 242(b)(2) election, have not been made, the trust must distribute by the end of the calendar year following the calendar year in which the revocation occurs the total amount not yet distributed which was required to have been distributed to satisfy the requirements of section 401(a)(9) and continue distributions in accordance with such requirements.

Par. 3–4. Section 1.403(b)–2 is added to read as follows:

§ 1.403(b)–2 Required minimum distributions from annuity contracts purchased, or custodial accounts or retirement income accounts established, by a section 501(c)(3) organization or a public school.

Q–1. Are section 403(b) contracts subject to the distribution rules provided in section 401(a)(9)?

A–1. (a) Yes. Section 403(b) contracts are subject to the distribution rules provided in section 401(a)(9). For purposes of this section the term *section 403(b) contract* means an annuity contract described in section 403(b)(1), custodial account described in section 403(b)(7), or a retirement income account described in section 403(b)(9).

(b) For purposes of applying the distribution rules in section 401(a)(9), section 403(b) contracts will be treated as individual retirement annuities described in section 408(b) and individual retirement accounts described in section 408(a) (IRAs). Consequently, except as otherwise provided in paragraph (c), the distribution rules in section 401(a)(9) will be applied to section 403(b) contracts in accordance with the provisions in § 1.408–8.

(c)(1) The required beginning date for purposes of section 403(b)(9) is April 1, of the calendar year following the later of the calendar year in which the employee attains 70½ or the calendar year in which the employee retires from employment with the employer maintaining the plan. The concept of 5-percent owner has no application in the case of employees of employers described in section 403(b)(1)(A).

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(2) The rule in A–5 of § 1.408–8 does not apply to section 403(b) contracts. Thus, the surviving spouse of an employee is not permitted to treat a section 403(b) contract of which the spouse is the sole beneficiary as the spouse's own section 403(b) contract.

Q–2. To what benefits under section 403(b) contracts, do the distribution rules provided in section 401(a)(9) apply?

A–2. (a) The distribution rules provided in section 401(a)(9) apply to all benefits under section 403(b) contracts accruing after December 31, 1986 (post-'86 account balance). The distribution rules provided in section 401(a)(9) do not apply to the balance of the account balance under the section 403(b) contract valued as of December 31, 1986, exclusive of subsequent earnings (pre-'87 account balance). Consequently, the post-'86 account balance includes earnings after December 31, 1986 on contributions made before January 1, 1987, in addition to the contributions made after December 31, 1986 and earnings thereon. The issuer or custodian of the section 403(b) contract must keep records that enable it to identify the pre-'87 account balance and subsequent changes as set forth in paragraph (b) of this A–2 and provide such information upon request to the relevant employee or beneficiaries with respect to the contract. If the issuer does not keep such records, the entire account balance will be treated as subject to section 401(a)(9).

(b) In applying the distribution rules in section 401(a)(9), only the post-'86 account balance is used to calculate the required minimum distribution required for a calendar year. The amount of any distribution required to satisfy the required minimum distribution requirement for a calendar year will be treated as being paid from the post-'86 account balance. Any amount distributed in a calendar year in excess of the required minimum distribution requirement for a calendar year will be treated as paid from the pre-'87 account balance. The pre-'87 account balance for the next calendar year will be permanently reduced by the deemed distributions from the account.

(c) The pre-'86 account balance and the post-'87 account balance have no relevance for purposes of determining the amount includible in income under section 72.

Q–3. Must the value of the account balance under a section 403(b) contract as of December 31, 1986 be distributed in accordance with the minimum distribution incidental benefit requirement?

A–3. Distributions of the entire account balance of a section 403(b) contract, including the value of the account balance under the contract or account as of December 31, 1986, must satisfy the minimum distribution incidental benefit requirement. However, distributions attributable to the value of the account balance under the contract or account as of December 31, 1986 is treated as satisfying the minimum distribution incidental benefit requirement if such distributions satisfy the rules in effect as of July 27, 1987, interpreting 1.401–1(b)(1)(i).

Q–4. Is the required minimum distribution from one section 403(b) contract of an employee permitted to be distributed from another section 403(b) contract in order to satisfy section 401(a)(9)?

A–4. Yes. The required minimum distribution must be separately determined for each section 403(b) contract of an employee. However, such amounts may then be totaled and the total distribution taken from any one or more of the individual section 403(b) contracts. However, under this rule, only amounts in section 403(b) contracts that an individual holds as an employee may be aggregated. Amounts in section 403(b) contracts that an individual holds as a beneficiary of the same decedent may be aggregated, but such amounts may not be aggregated with amounts held in section 403(b) contracts that the individual holds as the employee or as the beneficiary of another decedent. Distributions from section 403(b) contracts or accounts will not satisfy the distribution requirements from IRAs, nor will distributions from IRAs satisfy the distribution requirements from section 403(b) contracts or accounts.

Par. 5. Section § 1.408–8 is added to read as follows:

§ 1.408–8 Distribution requirements for individual retirement plans.

The following questions and answers relate to the distribution rules for IRAs provided in sections 408(a)(6) and 408(b)(3).

Q–1. Are individual retirement plans (IRAs) subject to the distribution rules provided in section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8 for qualified plans?

A–1. (a) Yes. Except as otherwise provided in this section, IRAs are subject to the required minimum distribution rules provided in section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8 for qualified plans. For example, whether the five year rule or the life expectancy rule applies to distribution after death occurring before the IRA owner's required beginning date will be determined in accordance with § 1.401(a)(9)–3, the rules of § 1.401(a)(9)–4 apply for purposes of determining an IRA owner's designated beneficiary, the amount of the required minimum distribution required for each calendar year from an individual account will be determined in accordance with § 1.401(a)(9)–5, and whether annuity payments from an individual retirement annuity satisfy section 401(a)(9) will be determined under § 1.401(a)(9)–6. For this purpose the term IRA means an individual retirement account or annuity described in section 408(a) or (b).

(b) For purposes of applying the required minimum distribution rules in §§ 1.401(a)(9)–1 through 1.401(a)(9)–8 for qualified plans, the IRA trustee, custodian, or issuer is treated as the plan administrator, and the IRA owner is substituted for the employee

Q–2. Are employer contributions under a simplified employee pension (defined in section 408(k)) or a SIMPLE IRA (defined in section 408(p)) treated as contributions to an IRA?

A–2. Yes. IRAs that receive employer contributions under a simplified employee pension (defined in section 408(k)) or a SIMPLE plan (defined in section 408(p)) are treated as IRAs for purposes of section 401(a) and are, therefore, subject to the distribution rules in this section.

Q–3. In the case of distributions from an IRA, what does the term *required beginning date* mean?

A–3. In the case of distributions from an IRA, the term *required beginning date* means April 1 of the calendar year following the calendar year in which the individual attains age 70½.

Q–4. When is the amount of a distribution from a IRA not eligible for rollover because the amount is a required minimum distribution?

A–4. The amount of a distribution that is a required minimum distribution from an IRA and thus not eligible for rollover is determined in the same manner as provided in Q&A–7 of § 1.402(c)–2 for distributions from qualified plans. For example, if a required minimum distribution is required for a calendar year, the amounts distributed during a calendar year from an IRA are treated as required minimum distributions under section 401(a)(9) to the extent that the total required minimum distribution for the year under section 401(a)(9) for that IRA has not been satisfied. This requirement may be satisfied by a distribution from the IRA or, as permitted under A–8 of this section, from another IRA.

Q–5. May an individual's surviving spouse elect to treat such spouse's entire interest as a beneficiary in an individual's IRA upon the death of the individual (or the remaining part of such interest if distribution to the spouse has commenced) as the spouse's own account?

A–5. (a) The surviving spouse of an individual may elect in the manner described in paragraph (b) of this A–5 to treat the spouse's entire interest as a beneficiary in an individual's IRA (or the remaining part of such interest if distribution thereof has commenced to the spouse) as the spouse's own IRA. This election is permitted to be made at any time after the distribution of the required minimum amount for the account for the calendar year containing the individual's date of death. In order to make this election, the spouse must be the sole beneficiary of the IRA and have an unlimited right to withdrawal amounts from the IRA. This requirement is not satisfied if a trust is named as beneficiary of the IRA even if the spouse is the sole beneficiary of the trust. If the surviving spouse makes such an election, the surviving spouse's interest in the IRA would then be subject to the distribution requirements of section 401(a)(9)(A) applicable to the spouse as the IRA owner rather than those of section 401(a)(9)(B) applicable to the surviving spouse as the decedent IRA owner's beneficiary. Thus, the required minimum distribution for the year of the election and each subsequent year would be determined under section 401(a)(9)(A) with the spouse as IRA owner and not section 401(a)(9)(B).

(b) The election described in paragraph (a) of this A–5 is made by the surviving spouse redesignating the account as the account in the name of the surviving spouse as IRA owner rather than as beneficiary. Alternatively, a surviving spouse eligible to make the election is deemed to have made the election if, at any time, either of the following occurs:

(1) Any required amounts in the account (including any amounts that have been rolled over or transferred, in accordance with the requirements of section 408(d)(3)(A)(i), into an individual retirement account or individual retirement annuity for the benefit of such surviving spouse) have not been distributed within the appropriate time period applicable to the surviving spouse as beneficiary under section 401(a)(9)(B); or

(2) Any additional amounts are contributed to the account (or to the account or annuity to which the surviving spouse has rolled such amounts over, as described in (1) above) which are subject, or deemed to be subject, to the distribution requirements of section 401(a)(9)(A).

(c) The result of an election described in paragraph (b) of this A–5 is that the surviving spouse shall then be considered the IRA owner for whose benefit the trust is maintained for all purposes under the Code (*e.g.* section 72(t)).

Q–6. How is the benefit determined for purposes of calculating the required minimum distribution from an IRA?

A–6. For purposes of determining the required minimum distribution required to be made from an IRA in any calendar year, the account balance of the IRA as of the December 31 of the calendar year immediately preceding the calendar year for which distributions are being made will be substituted in A–3 of § 1.401(a)(9)–5 for the account of the employee. The account balance as of December 31 of such calendar year is the value of the IRA upon close of business on such December 31. However, for purposes of determining the required minimum distribution for the second distribution calendar year for an individual, the account balance as of December 31 of such calendar year must be reduced by any distribution (as described in A–3(c)(2) of § 1.401(a)(9)–5) made to satisfy the required minimum distribution requirements for the individual's first distribution calendar year after such date.

Q–7. What rules apply in the case of a rollover to an IRA of an amount distributed by a qualified plan or another IRA?

A–7. If the surviving spouse of an employee rolls over a distribution from a qualified plan, such surviving spouse may elect to treat the IRA as the spouse's own IRA in accordance with the provisions in A–5 of this section. In the event of any other rollover to an IRA of an amount distributed by a qualified plan or another IRA, the rules in § 1.401(a)(9)–3 will apply for purposes of determining the account balance for the receiving IRA and the required minimum distribution from the receiving IRA. However, because the value of the account balance is determined as of December 31 of the year preceding the year for which the required minimum distribution is being determined and not as of a valuation date in the preceding year, the account balance of the receiving IRA need not be adjusted for the amount received as provided in A–2 of § 1.401(a)(9)–7 in order to determine the required minimum distribution for the calendar year following the calendar year in which the amount rolled over is received, unless the amount received is deemed to have been received in the immediately preceding year, pursuant to A–2 of § 1.401(a)(9)–7. In that case, for purposes of determining the required minimum distribution for the calendar year in which such amount is actually received, the account balance of the receiving IRA as of December 31 of the preceding year must be adjusted by the amount received in accordance with A–2 of § 1.401(a)(9)–7.

Q–8. What rules apply in the case of a transfer from one IRA to another?

A–8. In the case of a transfer from one IRA to another IRA, the rules in A–3 or A–4 of § 1.401(a)(9)–7 will apply for purposes of determining the account balance of, and the required minimum distribution from, the IRAs involved. Thus, the transferor IRA must distribute in the year of the transfer any amount required determined without regard to the transfer. For purposes of determining the account balance of the transferee IRA and the transferor IRA, the account balance need not be adjusted for the amount transferred as provided in A–4(a) of § 1.401(a)(9)–7 in order to calculate the required minimum distribution for the calendar year following the calendar year of the transfer, because the account balance is determined as of December 31 of the calendar year immediately preceding the calendar year for which the required minimum distribution is being determined.

Q–9. Is the required minimum distribution from one IRA of an owner permitted to distributed from another IRA in order to satisfy section 401(a)(9)?

A–9. Yes. The required minimum distribution must be calculated separately for each IRA. However, such amounts may then be totaled and the total distribution taken from any one or more of the individual IRAs. However, under this rule, only amounts in IRAs that an individual holds as the IRA owner may be aggregated. Amounts in IRAs that an individual holds as a beneficiary of the same decedent may be aggregated, but such amounts may not be aggregated with amounts held in IRAs that the individual holds as the IRA owner or as the beneficiary of another decedent. Distributions from section 403(b) contracts or accounts will not satisfy the distribution requirements from IRAs, nor will distributions from IRAs satisfy the distribution requirements from section 403(b) contracts or accounts. Distributions from Roth IRAs (defined in section 408A) will not satisfy the distribution requirements applicable to IRAs or section 403(b) accounts or contracts and distributions from IRAs or section 403(b) contracts or accounts will not

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satisfy the distribution requirements from Roth IRAs.

Q–10. Is the trustee of an IRA required to report the amount that is required to be distributed from that IRA?

A–10. Yes. The trustee of an IRA is required to report to the Internal Revenue Service and to the IRA owner the amount required to be distributed from the IRA for each calendar year at the time and in the manner prescribed in the instructions to the applicable Federal tax forms, as well as any additional information as required by such forms or such instructions.

PART 54—PENSION EXCISE TAXES

Par. 6. The authority citation for part 54 is amended by adding the following citation to read as follows:

Authority: 26 U.S.C. 7805 * * *.

§ 54.4974–2 is also issued under 26 U.S.C. 4974.

Par. 7. Section after § 54.4974–2 is added to read as follows:

§ 54.4974–2 Excise tax on accumulations in qualified retirement plans.

Q–1. Is any tax imposed on a payee under any qualified retirement plan or any eligible deferred compensation plan (as defined in section 457(b)) to whom an amount is required to be distributed for a taxable year if the amount distributed during the taxable year is less than the required minimum distribution?

A–1. Yes. If the amount distributed to a payee under any qualified retirement plan or any eligible deferred compensation plan (as defined in section 457(b)) for a calendar year is less than the required minimum distribution for such year, an excise tax is imposed on such payee under section 4974 for the taxable year beginning with or within the calendar year during which the amount is required to be distributed. The tax is equal to 50 percent of the amount by which such required minimum distribution exceeds the actual amount distributed during the calendar year. Section 4974 provides that this tax shall be paid by the payee. For purposes of section 4974, the term *required minimum distribution* means the required minimum distribution amount required to be distributed pursuant to section 401(a)(9), 403(b)(10), 408(a)(6), 408(b)(3), or 457(d)(2), as the case may be, and the regulations thereunder. Except as otherwise provided in Q&A–6, the required minimum distribution for a calendar year is the required minimum distribution amount required to be distributed during the calendar year. Q&A–6 provides a special rule for amounts required to be distributed by an employee's (or individual's) required beginning date.

Q–2. For purposes of section 4974, what is a qualified retirement plan?

A–2. For purposes of section 4974, each of the following is a qualified retirement plan—

(a) A plan described in section 401(a) which includes a trust exempt from tax under section 501(a);

(b) An annuity plan described in section 403(a);

(c) An annuity contract, custodial account, or retirement income account described in section 403(b);

(d) An individual retirement account described in section 408(a);

(e) An individual retirement annuity described in section 408(b); or

(f) Any other plan, contract, account, or annuity that, at any time, has been treated as a plan, account, or annuity described in (a) through (e) of this A–2, whether or not such plan, contract, account, or annuity currently satisfies the applicable requirements for such treatment.

Q–3. If a payee's interest under a qualified retirement plan is in the form of an individual account, how is the required minimum distribution for a given calendar year determined for purposes of section 4974?

A–3. (a) *General rule.* If a payee's interest under a qualified retirement plan is in the form of an individual account and distribution of such account is not being made under an annuity contract purchased in accordance with A–4 of § 1.401(a)(9)–6, the amount of the required minimum distribution for any calendar year for purposes of section 4974 is the required minimum distribution amount required to be distributed for such calendar year in order to satisfy the required minimum distribution requirements in § 1.401(a)(9)–5 as provided in the following (whichever is applicable)—

(1) Section 401(a)(9) and §§ 1.401(a)(9)–1 through 1.401(a)(9)–8 in the case of a plan described in section 401(a) which includes a trust exempt under section 501(a) or an annuity plan described in section 403(a));

(2) Section 403(b)(10) and § 1.403(b)–2 (in the case of an annuity contract, custodial account, or retirement income account described in section 403(b)); or

(3) Section 408(a)(6) or (b)(3) and § 1.408–8 (in the case of an individual retirement account or annuity described in section 408(a) or (b)).

(b) *Default provisions.* Unless otherwise provided under the qualified retirement plan (or, if applicable, the governing instrument of the qualified retirement plan), the default provisions in A–4(a) of § 1.401(a)(9)–3 apply in determining the required minimum distribution for purposes of section 4974.

(c) *Five year rule.* If the five-year rule in section 401(a)(9)(B)(ii) applies to the distribution to a payee, no amount is required to be distributed for any calendar year to satisfy the applicable enumerated section in paragraph (a) of this A–3 until the calendar year which contains the date five years after the date of the employee's death. For the calendar year which contains the date five years after the employee's death, the required minimum distribution amount required to be distributed to satisfy the applicable enumerated section is the payee's entire remaining interest in the qualified retirement plan.

Q–4. If a payee's interest in a qualified retirement plan is being distributed in the form of an annuity, how is the amount of the required minimum distribution determined for purposes of section 4974?

A–4. If a payee's interest in a qualified retirement plan is being distributed in the form of an annuity (either directly from the plan, in the case of a defined benefit plan, or under an annuity contract purchased from an insurance company), the amount of the required minimum distribution for purposes of section 4974 will be determined as follows:

(a) *Permissible annuity distribution option.* A permissible annuity distribution option is an annuity contract (or, in the case of annuity distributions from a defined benefit plan, a distribution option) which specifically provides for distributions which, if made as provided, would for every calendar year equal or exceed the required minimum distribution amount required to be distributed to satisfy the applicable section enumerated in paragraph (a) of A–2 of this section for every calendar year. If the annuity contract (or, in the case of annuity distributions from a defined benefit plan, a distribution option) under which distributions to the payee are being made is a permissible annuity distribution option, the required minimum distribution for a given calendar year will equal the amount which the annuity contract (or distribution option) provides is to be distributed for that calendar year.

(b) *Impermissible annuity distribution option.* An impermissible annuity distribution option is an annuity contract (or, in the case of annuity distributions from a defined benefit plan, a distribution option) under which distributions to the payee are being made that specifically provides for distributions which, if made as provided, would for any calendar year be less than the required minimum distribution amount required to be distributed to satisfy the applicable section enumerated in paragraph (a) of A–2 of this section. If the annuity contract (or, in the case of annuity distributions from a defined benefit plan, the distribution option) under which distributions to the payee are being made is an impermissible annuity distribution option, the required minimum distribution for each calendar year will be determined as follows:

(1) If the qualified retirement plan under which distributions are being made is a defined benefit plan, the required minimum distribution amount required to be distributed each year will be the amount which would have been distributed under the plan if the distribution option under which distributions to the payee were being made was the following permissible annuity distribution option:

(i) In the case of distributions commencing before the death of the employee, if there is a designated beneficiary under the impermissible annuity distribution option for purposes of section 401(a)(9), the permissible annuity distribution option is the joint and survivor annuity option under the plan for the lives of the employee and the designated beneficiary which provides for the greatest level amount payable to the employee determined on an annual basis. If the plan does not provide such an option or there is no designated beneficiary under the impermissible distribution option for purposes of section 401(a)(9), the permissible annuity distribution option is the life annuity option under the plan payable for the life of the employee in level amounts with no survivor benefit.

(ii) In the case of distributions commencing after the death of the employee, if there is a designated beneficiary under the impermissible annuity distribution option for purposes of section 401(a)(9), the permissible annuity distribution option is the life annuity option under the plan payable for the life of the designated beneficiary in level amounts. If there is no designated beneficiary, the five-year rule in section 401(a)(9)(B)(ii) applies. See paragraph (b)(3) of this A–4. The determination of whether or not there is a designated beneficiary and the determination of which designated beneficiary's life is to be used in the case of multiple beneficiaries will be made in accordance with § 1.401(a)(9)–4 and A–7 of § 1.401(a)(9)–5. If the defined benefit plan does not provide for distribution in the form of the applicable permissible distribution option, the required minimum distribution for each calendar year will be an amount as determined by the Commissioner.

(2) If the qualified retirement plan under which distributions are being made is a defined contribution plan and the impermissible annuity distribution option is an annuity contract purchased from an insurance company, the required minimum distribution amount required to be distributed each year will be the amount which would have been distributed in the form of an annuity contract under the permissible annuity distribution option under the plan determined in accordance with paragraph (b)(1) of this A–4 for defined benefit plans. If the defined contribution plan does not provide the applicable permissible annuity distribution option, the required minimum distribution for each calendar year will be the amount which would have been distributed under an annuity described below in paragraph (b)(2)(i) or (ii) of this A–4 purchased with the employee's or individual's account used to purchase the annuity contract which is the impermissible annuity distribution option.

(i) In the case of distributions commencing before the death of the employee, if there is a designated beneficiary under the impermissible annuity distribution option for purposes of section 401(a)(9), the annuity is a joint and survivor annuity for the lives of the employee and the designated beneficiary which provides level annual payments and which would have been a permissible annuity distribution option. However, the amount of the periodic payment which would have been payable to the survivor will be the applicable percentage under the table in A–2(b) of § 1.401(a)(9)–6 of the amount of the periodic payment which would have been payable to the employee or individual. If there is no designated beneficiary under the impermissible distribution option for purposes of section 401(a)(9), the annuity is a life annuity for the life of the employee with no survivor benefit which provides level annual payments and which would have been a permissible annuity distribution option.

(ii) In the case of a distribution commencing after the death of the employee, if there is a designated beneficiary under the impermissible annuity distribution option for purposes of section 401(a)(9), the annuity option is a life annuity for the life of the designated beneficiary which provides level annual payments and which would have been permissible annuity distribution option. If there is no designated beneficiary, the five year rule in section 401(a)(9)(B)(ii) applies. See paragraph (b)(3) of this A–4. The amount of the payments under the annuity contract will be determined using the interest rate and actuarial tables prescribed under section 7520 determined using the date determined under A–3 of 1.401(a)(9)–3 when distributions are required to commence and using the age of the beneficiary as of the beneficiary's birthday in the calendar year that contains that date. The determination of whether or not there is a designated beneficiary and the determination of which designated beneficiary's life is to be used in the case of multiple beneficiaries will be made in accordance with § 1.401(a)(9)–3 and A–7 of § 1.401(a)(9)–5.

(3) If the five-year rule in section 401(a)(9)(B)(ii) applies to the distribution to the payee under the contract (or distribution option), no amount is required to be distributed to satisfy the applicable enumerated section in paragraph (a) of this A–4 until the calendar year which contains the date five years after the date of the employee's death. For the calendar year which contains the date five years after the employee's death, the required minimum distribution amount required to be distributed to satisfy the applicable enumerated section is the payee's entire remaining interest in the annuity contract (or under the plan in the case of distributions from a defined benefit plan).

Q–5. If there is any remaining benefit with respect to an employee (or IRA owner) after any calendar year in which the entire remaining benefit is required to be distributed under section, what is the amount of the required minimum distribution for each calendar year subsequent to such calendar year?

A–5. If there is any remaining benefit with respect to an employee (or IRA owner) after the calendar year in which the entire remaining benefit is required to be distributed, the required minimum distribution for each calendar year subsequent to such calendar year is the entire remaining benefit.

Q–6. If a payee has an interest under an eligible deferred compensation plan (as defined in section 457(b)), how is the required minimum distribution for a given taxable year of the payee determined for purposes of section 4974?

A–6. If a payee has an interest under an eligible deferred compensation plan (as defined in section 457(b)), the required minimum distribution for a given taxable year of the payee

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determined for purposes of section 4974 is determined under section 457(d).

Q–7. With respect to which calendar year is the excise tax under section 4974 imposed in the case in which the amount not distributed is an amount required to be distributed by April 1 of a calendar year (by the employee's or individual's required beginning date)?

A–7. In the case in which the amount not paid is an amount required to be paid by April 1 of a calendar year, such amount is a required minimum distribution for the previous calendar year, *i.e.*, for the employee's or the individual's first distribution calendar year. However, the excise tax under section 4974 is imposed for the calendar year containing the last day by which the amount is required to be distributed, *i.e.*, the calendar year containing the employee's or individual's required beginning date, even though the preceding calendar year is the calendar year for which the amount is required to be distributed. Pursuant to A–2 of § 1.401(a)(9)–5, amounts distributed in the employee's or individual's first distribution calendar year will reduce the amount required to be distributed in the next calendar year by the employee's or individual's required beginning date. There is also a required minimum distribution for the calendar year which contains the employee's required beginning date. Such distribution is also required to be made during the calendar year which contains the employee's required beginning date.

Q–8. Are there any circumstances when the excise tax under section 4974 for a taxable year may be waived?

A–8. (a) *Reasonable cause.* The tax under section 4974(a) may be waived if the payee described in section 4974(a) establishes to the satisfaction of the Commissioner the following—

(1) The shortfall described in section 4974(a) in the amount distributed in any taxable year was due to reasonable error; and

(2) Reasonable steps are being taken to remedy the shortfall.

(b) *Automatic Waiver.* The tax under section 4974 will be automatically waived, unless the Commissioner determines otherwise, if—

(1) The payee described in section 4974(a) is an individual who is the sole beneficiary and whose required minimum distribution amount for a calendar year is determined under the life expectancy rule described in § 1.401(a)(9)–3 A–3 in the case of an employee's death before the employee's required beginning date; and

(2) The employee's or individual's entire benefit to which that beneficiary is entitled is distributed by the end of the fifth calendar year following the calendar year that contains the employee's date of death.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 601

[REG–129608–00]

RIN 1545–AY68

Notice to Interested Parties

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the notice to interested parties. Before the IRS can issue an advance determination regarding the qualification of a retirement plan, a plan sponsor must provide evidence that it has notified all persons who qualify as interested parties that an application for an advance determination will be filed. These proposed regulations set forth standards by which a plan sponsor may satisfy the notice to interested parties requirement. The proposed regulations affect retirement plan sponsors, plan participants and other interested parties with respect to an application for a determination letter, and certain representatives of interested parties.

DATES: Written or electronic comments and requests for a public hearing must be received by April 17, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–129608–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–129608–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/tax_regs/reglist.html*.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, contact Pamela R. Kinard, (202) 622–6060; concerning the submission of comments, contact LaNita VanDyke, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR parts 1 and 601) under section 7476 of the Internal Revenue Code of 1986 (Code).

Section 7476(b)(2) provides that, with respect to a pleading filed by a petitioner for a request for a determination on the qualified status of a retirement plan under section 7476(a), the Tax Court may find the pleading to be premature unless the petitioner establishes to the satisfaction of the court that he has complied with the requirements prescribed by the regulations of the Secretary regarding the notice to interested parties.

On May 21, 1976, Final Income Tax Regulations (TD 7421) under section 7476 were published in the **Federal Register** (41 FR 20874). The final regulations provide guidance on the nature and method of giving notice to interested parties. Existing § 1.7476–1(a)(1) provides that in order to receive a determination on the qualified status of a retirement plan, the applicant must provide evidence that individuals who qualified as interested parties received notification of the determination letter application. In general, interested parties are defined in § 1.7476–1(b)(1) as all present employees of the employer eligible to participate in the plan, and all other present employees whose principal place of employment is the same as the principal place of employment of the employees eligible to participate. For plan terminations, § 1.7476–1(b)(5) defines interested parties as all present employees with accrued benefits, all former employees with vested benefits, and all beneficiaries of deceased former employees currently receiving benefits under the plan.

Existing § 1.7476–2(b) provides that the notice must be given in writing, must contain the information in § 601.201(o)(3) (Statement of Procedural Rules) and must be given in the manner prescribed in § 1.7476–2(c). For present employees, § 1.7476–2(c)(1) provides that the notice must be given in person, by mailing, by posting, or by printing it in a publication of the employer or an employee organization that is reasonably available to employees. For interested parties who are in a unit of employees covered by a collective-bargaining agreement, the notice must also be given in person or by mail to the collective-bargaining representative of the interested parties. For former employees and beneficiaries who qualify as interested parties, § 1.7476–2(c)(2)(i) provides that notice shall be given in person or by mail to the last known address of the interested party.

On February 8, 2000, the IRS and Treasury published Final Income Tax Regulations (TD 8873) in the **Federal Register** (65 FR 6001) that provide safe harbor methods for plan sponsors and administrators using electronic media to transmit notices and consents required under sections 402(f), 411(a)(11), or 3405(e)(10)(B). Notice 99–1 (1999–2 I.R.B. 8) and Announcement 99–6 (1999–4 I.R.B. 24) also provide guidance on the use of electronic media by retirement plans.

In order to continue to advance the goal of permitting plan sponsors to use electronic media in administering their retirement plans, this amendment to the regulations eliminates the writing requirement for the notice to interested parties. Instead, the proposed regulations set forth new standards for satisfying the notice requirement that would ensure that interested parties will receive timely and adequate notice.

Explanation of Provisions

This notice of proposed rulemaking would amend §§ 1.7476–2 and 601.201 regarding the nature and method of giving notices to interested parties. The proposed regulations do not change the information that the notice must contain or the time period in which the notice must be given. These regulations continue to provide that the notice to interested parties must contain the information and be given within the time period prescribed in § 601.201(o)(3) (Statement of Procedural Rules). The proposed regulations would set forth new standards for providing the notice to interested parties. These new standards permit greater flexibility in the manner in which the notice may be provided.

The proposed regulations provide that, in the case of a present employee, former employee, or beneficiary who is an interested party, the notice may be provided by any method that reasonably ensures that all interested parties will receive the notice. The method used must be reasonably calculated to provide timely and adequate notice to all interested parties. In addition, the proposed regulations provide that if an interested party who is a present employee is in a unit of employees covered by a collective-bargaining agreement between employee representatives and one or more employers, notice shall also be given to the collective-bargaining representative of such interested party by any method that reasonably ensures that the collective-bargaining representative will receive the notice. The proposed regulations also provide if the notice to interested parties is delivered using an electronic medium under a system that satisfies the requirements of Q&A–5 of § 1.402(f)–1, the notice will be deemed to be provided in a manner that satisfies the notice to interested parties requirement.

The proposed regulations provide that whether the notice to interested parties is given in a manner that satisfies the requirements under these regulations will be determined on the basis of all the facts and circumstances. These regulations further provide that since the facts and circumstances will differ depending on the interested party, it is possible that more than one method of delivery (including nonelectronic writing) must be used in order to ensure timely and adequate notice to all interested parties.

The proposed regulations also revise § 601.201 (Statement of Procedural Rules) to conform to the changes in § 1.7476–2.

Proposed Effective Date

These regulations are proposed to be effective with respect to applications made on or after the date they are published in the **Federal Register** as final regulations. Plan sponsors may rely on these proposed regulations for guidance pending the issuance of final regulations. If, and to the extent, future guidance is more restrictive than the guidance in these proposed regulations, the future guidance will be applied without retroactive effect.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these proposed regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury specifically request comments on the clarity of the proposed rule and how it may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing may be scheduled if requested in writing by a person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is Pamela R. Kinard of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.7476–2 is amended as follows:

1. Paragraphs (b) and (c) are revised.

2. Paragraph (d) is redesignated as paragraph (e) and a new paragraph (d) is added.

3. Paragraph (e)(1) is revised.

The revisions and additions read as follows:

§ 1.7476–2 Notice to interested parties.

* * * * *

(b) *Nature of notice.* The notice required by this section shall —

(1) Contain the information and be given within the time period prescribed in § 601.201(o)(3) of this chapter (Statement of Procedural Rules); and,

(2) Be given in a manner prescribed in paragraph (c) of this section.

(c) *Method of giving notice.* (1) In the case of a present employee, former employee, or beneficiary who is an interested party, the notice may be provided by any method that reasonably ensures that all interested parties will

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receive timely and adequate notice. If an interested party who is a present employee is in a unit of employees covered by a collective-bargaining agreement between employee representatives and one or more employers, notice shall also be given to the collective-bargaining representative of such interested party by any method that satisfies this paragraph. Whether the notice is provided in a manner that satisfies the requirements of this paragraph will be determined on the basis of all the facts and circumstances. Because the facts and circumstances will differ depending on the interested party, it is possible that more than one method of delivery must be used in order to ensure timely and adequate notice to all interested parties.

(2) If the notice to interested parties is delivered using an electronic medium under a system that satisfies the requirements of Q&A–5 of § 1.402(f)–1, the notice will be deemed to be provided in a manner that satisfies the requirements of paragraph (c)(1) of this section.

(d) *Examples.* The principles of this section are illustrated by the following examples:

Example 1. (i) Employer A is amending Plan C and applying for a determination letter. Plan C is not maintained pursuant to one or more collective-bargaining agreements and is not being terminated. As part of the determination letter application process, Employer A provides the notice required under this section to interested parties. For present employees, Employer A provides the notice by posting the notice at those locations within the principal places of employment of the interested parties which are customarily used for employer notices to employees with regard to labor-management relations matters.

(ii) In this *Example 1,* Employer A satisfies the notice to interested parties requirement described in this section.

Example 2. (i) Employer B is amending Plan D and applying for a determination letter. As part of the determination letter application process, Employer B provides the notice required under this section to interested parties.

(ii) Employer B has multiple worksites. Employer B's employees located at worksites 1 through 4 have access to computers at their workplace. However, Employer B's employees located at worksite 5 do not have access to computers.

(iii) For present employees with access to computers (worksites 1 through 4), Employer B provides the notice by posting the notice on Employer B's web site (Internet or intranet). Employer B customarily posts employer notices to employees at worksites 1 through 4 with regard to labor-management relations matters on its web site. For present employees without access to computers (worksite 5), Employer B provides the notice by posting the notice at worksite 5 in a location that is customarily used for employer notices to employees with regard to labor-management relations matters.

(iv) Employer B also sends the notice by e-mail to each collective-bargaining representative of interested parties who are present employees of Employer B covered by a collective-bargaining agreement between employee representatives and Employer B, using the e-mail address previously provided to Employer B by such collective-bargaining representative.

(v) In this *Example 2,* Employer B satisfies the notice to interested parties requirement described in this section.

Example 3. (i) Employer C is terminating Plan E and applying for a determination letter as to whether the plan termination affects the continuing qualification of Plan E. As part of the determination letter application process, Employer C provides the notice required under this section to interested parties.

(ii) All of Employer C's employees have access to computers. Each employee has an e-mail address where he or she can receive messages from Employer C. Employer C has set up kiosks for employees' use. The kiosks are located within the principal places of employment of the employees and are customarily used for employer notices to employees with regard to labor-management relations matters.

(iii) For present employees, Employer C provides the notice by sending the notice by e-mail.

(iv) Employer C also sends the notice by e-mail to each collective-bargaining representative of interested parties who are present employees of Employer C covered by a collective-bargaining agreement between employee representatives and Employer C, using the e-mail address previously provided to Employer C by such collective-bargaining representative.

(v) In addition, Employer C sends the notice by e-mail to each interested party who is a former employee or beneficiary, using the e-mail address previously provided to Employer C by such interested party. For any former employee or beneficiary who did not provide an e-mail address, Employer C sends the notice by regular mail to the last known address of such former employee or beneficiary.

(vi) In this *Example 3,* Employer C satisfies the notice to interested parties requirement described in this section.

(e) *Effective date.* (1) The provisions of this section shall apply to applications referred to in paragraph (a) of § 1.7476–1 made on or after the date the regulations are published in the **Federal Register** as final regulations.

PART 601—STATEMENT OF PROCEDURAL RULES

Paragraph 1. The authority citation for part 601 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 601.201 is amended as follows:

1. In paragraph (o)(3)(xv), the first sentence is replaced by two new sentences.

2. In paragraph (o)(3)(xvi), introductory text is revised.

The revisions read as follows:

§ 601.201 Rulings and determination letters.

* * * * *

(o) * * * (3) * * *

(xv) When the notice referred to in paragraph (o)(3)(xiv) of this section is given in the manner set forth in § 1.7476–2(c), the following time limitations for providing the notice apply. When the notice is given other than by mailing, it should be given not less than 7 days nor more than 21 days prior to the date that the application for a determination is made. * * *

(xvi) The notice referred to in paragraph (o)(3)(xiv) of this section shall be given in the manner prescribed in § 1.7476–2 and shall contain the following information:

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–131 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG–110374–00]

RIN 1545–AY21

Interest-free adjustments with respect to underpayments of employment taxes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains a proposed amendment to the regulations relating to interest-free adjustments with respect to underpayments of employment taxes. The proposed amendment reflects changes to the law made by the Taxpayer Relief Act of 1997. The proposed amendment affects employers that are the subject of IRS examinations involving determinations by the IRS that workers are employees for purposes of subtitle C or that the employers are not entitled to relief from employment taxes under section 530 of the Revenue Act of 1978 (section 530).

DATES: Written and electronic comments and requests for a public hearing must be received by April 17, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–110374–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: Unit CC:M&SP:RU (REG–110374–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.gov/taxregs/reglist.html.*

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Lynne Camillo of the Office of Associate Chief Counsel (Tax Exempt and Government Entities), (202) 622–6040.

SUPPLEMENTARY INFORMATION:

Background

This document contains a proposed amendment to the Employment Tax Regulations (26 CFR part 31) under section 6205. Section 6205 allows employers that have paid less than the correct amount of employment taxes to make adjustments without interest, provided the error is reported and the taxes are paid by the last day for filing the return for the quarter in which the error was ascertained. However, no interest-free adjustments are permitted pursuant to section 6205 after receipt of notice and demand for payment thereof based upon an assessment. § 31.6205–1(a)(6).

The Taxpayer Relief Act of 1997, Public Law 105–34 (111 Stat. 788), effective August 5, 1997, created new section 7436 of the Internal Revenue Code (Code), which provides the Tax Court with jurisdiction to review determinations by the IRS that workers are employees for purposes of subtitle C, or that the employer is not entitled to relief from employment taxes under section 530. Section 7436 resulted in a change in the way employment tax examinations involving worker classification and section 530 issues are conducted insofar as notice and demand for payment of an employment tax underpayment based upon an assessment cannot be made until after the taxpayer under examination receives notice of the IRS's determination and has been given an opportunity to file a petition in the Tax Court contesting such determination.

Explanation of Provisions

This document contains a proposed amendment to the regulations under section 6205. The proposed amendment clarifies the period for adjustments of employment tax underpayments without interest under section 6205 following the expansion of Tax Court review to certain employment tax determinations.

As a general rule, under section 6601, all taxpayers who fail to pay the full amount of a tax due under the Code must pay interest at the applicable rate on the unpaid amount from the last date prescribed for payment of the tax until the date the tax is paid. However, section 6205 allows employers that have paid less than the correct amount of certain employment taxes [1] with respect to any payment of wages or compensation to make adjustments to returns without interest pursuant to the regulations. The employment tax regulations under section 6205 generally allow employers to make adjustments to returns without interest until the last day for filing the return for the quarter in which the error was ascertained. An error is ascertained when the employer has sufficient knowledge of the error to be able to correct it. § 31.6205–1(a)(4). Section 31.6205–1(a)(6) provides that no interest-free adjustments can be made after receipt of a statement of notice and demand for payment based upon an assessment.

In Revenue Ruling 75–464 (1975–2 C.B. 474), the IRS further clarified the time for adjustments under section 6205. The ruling clarifies that employers can still make interest-free adjustments where the underpayment is discovered during an audit or examination (i.e., where the employer has not independently ascertained the underpayment). The ruling sets forth situations illustrating when an error is ascertained with respect to returns under audit by the IRS. Under the facts in the revenue ruling, an error is ascertained when the employer signs an "Agreement to Adjustment and Collection of Additional Tax", Form 2504, either at the examination level or the appeals level, when the taxpayer pays the full amount due so as to file a refund claim (if paid prior to notice and demand), or at the conclusion of internal IRS appeal rights if no agreement is reached. Under the factual situations in Revenue Ruling 75–464, the employment taxes can be paid free of interest at the time the employer signs Agreement Form 2504 or at the time it pays the tax preparatory to filing a claim to contest the liability in court, after having exhausted all appeal rights within the IRS, provided the payment is made before the taxpayer receives notice and demand for payment.

The Taxpayer Relief Act of 1997, Public Law 105–34 (111 Stat. 788), created new section 7436 of the Code which provides the Tax Court with jurisdiction to review determinations by the IRS that workers are employees for purposes of subtitle C of the Code, or that the organization for which services are performed is not entitled to relief from employment taxes under section 530. Section 7436(a) requires that the determination involve an actual controversy and that it be made as part of an examination. Subsequent to enactment of section 7436 of the Code, the IRS created a standard notice, the "Notice of Determination Concerning Worker Classification Under Section 7436" (notice of determination) to serve as the "determination" that is a prerequisite to invoking the Tax Court's jurisdiction under section 7436. Notice 98–43 (1998–33 I.R.B. 13).

Section 7436(d)(1) provides that the suspension of the limitations period for assessment in section 6503(a) applies in the same manner as if a notice of deficiency had been issued. Thus, pursuant to section 6503(a), the mailing of the notice of determination by certified or registered mail will suspend the statute of limitations for assessment of taxes attributable to the worker classification and section 530 issues. Generally, the statute of limitations for assessment of taxes attributable to the worker classification and section 530 issues is suspended for the 90-day period during which the taxpayer can begin a suit in Tax Court, plus an additional 60 days thereafter. Moreover, if the taxpayer does file a timely petition in the Tax Court, the statute of limitations for assessment of taxes attributable to the worker classification and section 530 issues is suspended under section 6503(a) during the Tax Court proceedings, and for sixty days after the Tax Court decision becomes final.

Current IRS guidance provides for interest-free adjustments under section 6205 prior to assessment and notice and demand. Because of the prohibition on assessment for cases pending in the Tax Court, this creates a potential for inconsistent application of interest depending upon whether an employer files a claim in the Tax Court or in

[1] Section 6205 applies to underpayments of taxes under the Federal Insurance Contributions Act (FICA), the Railroad Retirement Tax Act (RRTA), and income tax withholding. Section 6205 does not apply to underpayments of taxes under Federal Unemployment Tax Act (FUTA), as such underpayments are not subject to interest under section 6601(i).

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another court of Federal jurisdiction. The legislative history of section 7436 shows no intent to create an advantage for taxpayers who choose to litigate their cases in Tax Court as opposed to another court of Federal jurisdiction. H.R. No. 105–148, 105th Cong., 1st Sess., at 639–640 (1997). Taxpayers who choose to petition the Tax Court under section 7436 still have the benefit of all of the inherent advantages of litigating in the Tax Court, including the ability to obtain judicial review without prior payment of the additional tax the IRS has determined to be due.

Judicial and administrative precedents provide that an error is ascertained for purposes of section 6205 (ending the period for interest-free adjustments) when the taxpayer has exhausted all internal appeal rights with the Service. *Eastern Investment Corp.* v. *United States*, 49 F. 3d 651 (10th Cir. 1995); Rev. Rul. 75–464 (1975–2 C.B. 474). In the context of refund litigation, where a taxpayer whose erroneous underpayment of employment taxes is discovered during an examination pays only the required divisible portion of employment tax prior to filing a claim for refund in order to satisfy the jurisdictional requirements for filing suit in district court, interest continues to accrue on the unpaid portion of employment tax from the date upon which the tax is assessed after the taxpayer has exhausted all appeal rights within the IRS until the date such tax is paid. *See Eastern Investment Corp., supra* (rejecting taxpayer's argument that the error could not have been "ascertained" until a decision was made by the court and the liability was no longer being contested). Moreover, in Tax Court deficiency proceedings that do not involve employment taxes, unless the taxpayer makes a deposit to stop the running of interest, interest continues to accrue on the deficiency during the course of the Tax Court proceeding. Rev. Rul. 56–501 (1956–2 C.B. 954).

In employment tax examinations that do not involve worker classification or section 530 issues, the taxpayer has exhausted all internal appeal rights by the time a notice and demand for payment thereof based upon an assessment is received. Similarly, in employment tax examinations involving worker classification or section 530 issues, the taxpayer has already had the benefit of all of the same internal appeal rights by the time a notice of determination is received.

These proposed regulations provide that, in employment tax examinations involving worker classification or section 530 issues, as in other types of employment tax examinations, the error is ascertained for purposes of section 6205 when the employer has exhausted all internal appeals within the IRS. The fact that notice and demand for payment based upon an assessment cannot be made in cases involving worker classification and section 530 issues until the suspension of the statute of limitations is lifted, following issuance of a notice of determination, does not result in an extension of the period during which interest-free adjustments can be made under section 6205. Accordingly, in order to clarify that the error is ascertained for purposes of section 6205 once a taxpayer has exhausted all internal appeal rights with the IRS, the existing regulations would be modified by prohibiting interest-free adjustments after receipt of the notice of determination.

However, if, prior to receipt of a notice of determination, a taxpayer makes a remittance which is equal to the amount of the proposed liability, the IRS considers the remittance a payment and assesses it. Rev. Proc. 84–58 (1984–2 C.B. 501). In such a situation, no notice of determination would be sent to the taxpayer. If a taxpayer wants to stop the running of interest and contest the adjustment in the Tax Court, the taxpayer may make a remittance, designating it in writing as a deposit in the nature of a cash bond. If the taxpayer makes such a deposit, the IRS does not consider the remittance a payment. Id. at § 4.02. The deposit stops the running of interest and, if the taxpayer does not waive the restrictions on assessment, the IRS will send the taxpayer a notice of determination, thus permitting the taxpayer the option of Tax Court review.

In order to provide a mechanism for taxpayers to make a remittance to stop the accrual of interest, yet still receive a notice of determination and retain the right to petition the Tax Court, these proposed regulations would further modify the existing regulations to provide that, prior to receipt of a notice of determination, the taxpayer may, in lieu of making a payment, make a cash bond deposit which would have the effect of stopping the accrual of any interest, but would not deprive the taxpayer of its right to receive a notice of determination and to petition the Tax Court under section 7436.

Proposed Effective Date

These regulations are proposed to be applicable with respect to notices of determination issued on or after March 19, 2001. Interest will be computed under the rule in this regulation on any claims for refund of interest pending on January 12, 2001. No inference is intended that the rule set forth in these proposed regulations is not current law. Taxpayers may rely on these proposed regulations for guidance pending the issuance of final regulations. If, and to the extent, future guidance is more restrictive than the guidance in the proposed regulations, the future guidance will be applied without retroactive effect.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and, because these regulations do not impose on small entities a collection of information requirement, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic and written comments that are submitted timely to the IRS. The IRS and Treasury Department specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Lynne Camillo, Office of the Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social Security, Unemployment compensation.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 31 is proposed to be amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

Paragraph 1. The authority for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In § 31.6205–1, paragraph (a)(6) is revised to read as follows:

§ 31.6205–1 Adjustments of underpayments.

(a) * * *

(6) No underpayment shall be reported pursuant to this section after the earlier of the following—

(i) Receipt from the Commissioner of notice and demand for payment thereof based upon an assessment; or

(ii) Receipt from the Commissioner of a Notice of Determination Concerning Worker Classification Under Section 7436 (Notice of Determination). (Prior to receipt of a Notice of Determination, the taxpayer may, in lieu of making a payment, make a cash bond deposit which would have the effect of stopping the accrual of any interest, but would not deprive the taxpayer of its right to receive a Notice of Determination and to petition the Tax Court under section 7436).

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–273 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–110659–00]

RIN 1545–AY16

Amendment, Check the Box Regulations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance relating to elective changes in entity classification. The proposed regulations apply to subsidiary corporations that elect to change their classification for Federal tax purposes from a corporation to either a partnership or disregarded entity.

DATES: Written or electronic comments, or requests for a public hearing must be received by February 2, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–110659–00), room 5226, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–110659–00), Courier's desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at *http://www.irs.ustreas.gov /tax—regs/regslist.html*.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, David J. Sotos, (202) 622–3050; concerning submissions of comments, or to request a hearing, Sonya Cruse, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On November 29, 1999, Treasury and the IRS published final regulations (TD 8844) describing the transactions that are deemed to occur when an entity elects to change its classification for Federal tax purposes. Those regulations did not address certain requirements of section 332 as applied to the deemed liquidation incident to an association's election to be classified as a partnership or to be disregarded as an entity separate from its owner. This amendment to the final regulations addresses those requirements.

On January 20, 2000, Treasury and the IRS issued final regulations relating to qualified subchapter S subsidiaries. In order to permit the deemed transaction resulting from a QSub election to comply with the requirement of section 332 that a plan of liquidation have been adopted at the time of a liquidating distribution, the final regulations provide that a plan of liquidation is deemed adopted immediately before the deemed liquidation incident to the QSub election, unless a formal plan of liquidation that contemplates the filing of a QSub election is adopted on an earlier date. The preamble to the QSub regulations provided that Treasury and the IRS intend to amend the section 7701 regulations regarding elective changes in entity classification to provide a similar rule concerning the timing of the plan of liquidation.

Explanation of Provisions

A. In General

Section 301.7701–3(g)(1) describes how elective changes in the classification of an entity will be treated for tax purposes. Section 301.7701–3(g)(1)(ii) provides that an elective conversion of an association to a partnership is deemed to have the following form: the association distributes all of its assets and liabilities to its shareholders in liquidation of the association, and immediately thereafter, the shareholders contribute all of the distributed assets and liabilities to a newly formed partnership. Section 301.7701–3(g)(1)(iii) provides that an elective conversion of an association to an entity that is disregarded as an entity separate from its owner is deemed to have the following form: the association distributes all of its assets and liabilities to its single owner in liquidation of the association.

Section 332 may be relevant to the deemed liquidation of an association if it has a corporate owner. Under section 332, no gain or loss is recognized on the receipt by a corporation of property distributed in complete liquidation of another corporation if the requirements of section 332(b) are satisfied. Those requirements include the adoption of a plan of liquidation at a time when the corporation receiving the distribution owns stock of the liquidating corporation meeting the requirements of section 1504(a)(2) (i.e., 80 percent of vote and value). The elective changes from association to a partnership and to a disregarded entity result in a constructive liquidation of the association for Federal tax purposes. Formally adopting a plan of liquidation for the entity, however, is potentially incompatible with an elective change under § 301.7701–3, which allows the local law entity to remain in existence while liquidating only for Federal tax purposes. Accordingly, to provide tax treatment of an association's deemed liquidation that is compatible with the requirements of section 332, the proposed regulations state that, for purposes of satisfying the requirement of adoption of a plan of liquidation under section 332(b), a plan of liquidation is deemed adopted immediately before the deemed liquidation incident to an elective change in entity classification, unless a formal plan of liquidation that contemplates the filing of the elective change in entity classification is adopted on an earlier date.

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B. Proposed Effective Dates

These regulations are proposed to apply to elections occurring on or after the date final regulations are published in the **Federal Register**; however, it is also proposed that taxpayers may elect to apply the amendments retroactively.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. It also has been determined that section 533(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) that are submitted timely to the IRS. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet Site at *http://www.irs.ustreas.gov/tax—regs/comments.html*. All comments will be available for public inspection and copying. The Treasury Department and IRS specifically request comments on the clarity of the proposed regulations and how they may be made easier to understand. A public hearing may be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are David J. Sotos, and Jeanne M. Sullivan of Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and IRS participated in their development.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 301 is proposed to be amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

Paragraph 1. The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 301.7701–3 is amended as follows:

1. Redesignating the text of paragraph (g)(2) as paragraph (g)(2)(i) and adding a heading for paragraph (g)(2)(i).
2. Adding a new paragraph (g)(2)(ii).
3. Revising the first sentence of paragraph (g)(4).

The addition and revision read as follows:

§ 301.7701–3 Classification of certain business entities.

* * * * *

(g) * * *

(2) *Effect of elective changes*—(i) *In general.* * * *

* * * * *

(ii) *Adoption of plan of liquidation.* For purposes of satisfying the requirement of adoption of a plan of liquidation under section 332, unless a formal plan of liquidation that contemplates the election to be classified as a partnership or to be disregarded as an entity separate from its owner is adopted on an earlier date, the making, by an association, of an election under paragraph (c)(1)(i) of this section to be classified as a partnership or to be disregarded as an entity separate from its owner is considered to be the adoption of a plan of liquidation immediately before the deemed liquidation described in paragraph (g)(1)(ii) or (iii) of this section. This paragraph (g)(2)(ii) applies to elections effective on or after the date these regulations are published as final regulations in the **Federal Register**. Taxpayers may apply this paragraph (g)(2)(ii) retroactively to elections filed before these regulations are published as final regulations in the **Federal Register** if the corporate owner claiming treatment under section 332 and its subsidiary making the election take consistent positions with respect to the Federal tax consequences of the election.

* * * * *

(4) *Effective date.* Except as otherwise provided in paragraph (g)(2)(ii) of this section, this paragraph (g) applies to elections that are filed on or after November 29, 1999. * * *

* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue Service.

[FR Doc. 01–272 Filed 1–16–01; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket 99–67; DA 00–2826]

911 Requirements for Satellite Services

AGENCY: Federal Communications Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: In this public notice, the Chief of the FCC's International Bureau invites public comment in answer to a series of questions pertaining to implementation of emergency-calling services for people using commercial mobile radio services provided via satellite. The purpose for issuing the public notice is to elicit information that will help the Commission determine whether it would serve the public interest to adopt rules to require or facilitate provision of such services to mobile satellite-service customers.

DATES: Comments due on or before February 19, 2001. Reply Comments due on or before March 6, 2001.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: William Bell, Satellite Policy Branch, (202) 418–0741.

SUPPLEMENTARY INFORMATION:

Background

In 1996, the Commission adopted rules for the provision of basic and Enhanced 911 (E911) service by terrestrial commercial mobile radio service (CMRS) carriers. Basic 911 is the delivery of emergency 911 calls to a Public Safety Answering Point (PSAP).[1] E911 includes additional features, including automatically reporting the caller's location and telephone number. The Commission concluded that requiring wireless carriers to provide these 911 services helped implement its statutory mandate to "promot[e] safety of life and property through the use of wire and radio communication."[2] Specifically, the Commission adopted rules requiring cellular licensees, broadband PCS licensees, and other terrestrial wireless carriers providing two-way voice communication via interconnection with the public switched telephone network to offer basic 911 and E911 under a phased schedule.[3]

In the 1996 Order, the Commission exempted providers of Mobile Satellite Service (MSS) from these rules. While the Commission expressed its belief that the public interest will ordinarily require that providers of real time two-way voice services offer emergency service, it reasoned that adding specific regulatory requirements to MSS at that time might impede development of a service then in early development stages.[4] Further, the Commission agreed with commenters who maintained that emergency-service requirements for global MSS systems should be developed in an international forum in the first instance. The Commission stated that it expected that CMRS voice MSS carriers would eventually provide appropriate access to emergency services, however, and it urged carriers and other interested parties to do so as soon as feasible.[5]

In 1999, Congress enacted the Wireless Communications and Public Safety Act of 1999, with the purpose of "facilitat[ing] the prompt deployment * * * of a seamless, ubiquitous, and reliable end-to-end infrastructure for communications, including wireless communications, to meet the Nation's public safety * * * needs." To implement parts of this Act, the Commission has designated 911 as the universal emergency telephone number in the United States for both wireline and wireless telephone service and requested comment, inter alia, on what actions to take to encourage and support coordinated statewide deployment plans for wireless emergency communications networks that include E911 service.[6] The Act also contains provisions granting liability protection or immunity to wireless carriers, and to users of wireless 911 services, not less than that granted to providers and users of wireline services.[7]

The Commission revisited the subject of emergency-call service for MSS users in the current rulemaking in IB Docket No. 99–67, which primarily concerns adoption of rules to facilitate and promote international circulation of customer-operated satellite earth terminals used for Global Mobile Personal Communications by Satellite (GMPCS). In the initial Notice of Proposed Rulemaking in that proceeding, issued last year, the Commission sought comment as to whether, in light of recent technological developments, it should require MSS providers to implement 911 features, subject to transitional measures to avert adverse impact on systems already in operation or at an advanced stage of development.[8]

In the Notice of Proposed Rulemaking proposing licensing and service rules for the 2 GHz MSS, the Commission more narrowly inquired as to whether it should require licensees in that particular MSS service to implement basic and/or enhanced 911 capabilities.[9] In the *2 GHz Report and Order*, the Commission acknowledged that 911 services can save lives and that significant strides had been made in developing location technology, but found that the information in the record was insufficient to support adoption of specific 911 requirements in the 2 GHz MSS service rules proceeding. Therefore, the Commission decided that it would be better to address issues concerning 911 requirements for 2 GHz MSS in the more-general 911 inquiry conducted in the *GMPCS* proceeding.[10] To that end, the Commission directed the International Bureau to issue a public notice in the *GMPCS* proceeding requesting additional information "regarding the technological, regulatory, and international aspects of Basic 911 and E911 for satellite services."[11]

Request for Further Comment

In accordance with the Commission's instruction in the *2 GHz Report and Order*, and in order to obtain a more substantial record, we seek additional comment from interested parties and members of the general public in response to the following questions. We also encourage commenters to identify and discuss any other issues relevant to the implementation of 911 services by MSS licensees.

General Considerations

The general issues on which we seek comment and information are: first, whether it would improve public safety and promote the overall public interest to eliminate the exception allowed to MSS carriers under the wireless 911 rules and require MSS carriers to provide 911 emergency services; and, second, if rules are warranted, what the terms of those rules should be, including relevant implementation time frames.

We recognize that there are operational differences between MSS systems and terrestrial wireless systems that may have a bearing on resolution of these issues. MSS can provide voice service at locations where no terrestrial service is available, for instance, such as in maritime environments and remote areas. Cellular carriers interconnect with local wireline carriers at many points throughout their service areas and can generally make use of existing facilities to route 911 calls directly to local PSAPs in the areas where the calls are placed. MSS carriers, on the other hand, interconnect with the public switched telephone network at only a few points in the United States and do not interconnect directly with most local wireline carriers. Routing emergency MSS calls to the appropriate local emergency service providers may therefore present special challenges. To route MSS calls automatically to the

[1] "PSAP" is a point that has been designated to receive 911 calls and route them to emergency service personnel. A "Designated PSAP" is a PSAP that is designated by the local or state entity that has the authority and responsibility to designate the PSAP to receive wireless 911 calls. We use the term in this notice to refer to any local facility performing such functions, whether or not pursuant to a state-government mandate. See 47 CFR 20.3.

[2] Section 1 of the Communications Act, 47 U.S.C. 151.

[3] Revision of the Commission's Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems (First Report and Order and Further Notice of Proposed Rulemaking), 11 FCC Rcd 18676 (1996), 61 FR 40374 and 40348 (August 2, 1996) ("Wireless E911 Order"), on recon., 12 FCC Rcd 22665 (1997), 63 FR 2631 (January 16, 1998) ("Wireless E911 Recon Order"), on further recon., 14 FCC Rcd 20850 (1999), 64 FR 72951 (December 29, 1999) ("Wireless E911 Second Recon Order"). See, also, Second Report and Order, 14 FCC Rcd 10954 (1999), 64 FR 34564 (June 8, 1999); and Third Report and Order, 14 FCC Rcd 17388 (1999), 64 FR 60126 (November 4, 1999), on recon. FCC 00–326, released Sept. 8, 2000, 65 FR 58657 (October 2, 2000). For further information on the wireless 911 proceeding and rules, see www.fcc.gov/e911.

[4] Wireless E911 Order at paragraph 83; Wireless E911 Recon Order at paragraph 87.

[5] Wireless E911 Recon Order at paragraph 88.

[6] Wireless Communications and Public Safety Act of 1999, 113 Stat 1286, amending 47 U.S.C. 222 and 251(e); see also Implementation of 911 Act (Fourth Report and Order and Notice of Proposed Rulemaking), FCC 00–327, 65 FR 56751 (September 19, 2000).

[7] Wireless Communications and Public Safety Act of 1999, at Section 4.

[8] Amendment of Parts 2 and 25 to Implement the Global Mobile Personal Communications by Satellite (GMPCS) Memorandum of Understanding and Arrangements; Petition of the National Telecommunications and Information Administration to Amend Part 25 of the Commission's Rules to Establish Emissions Limits for Mobile and Portable Earth Stations Operating in the 1610–1660.5 MHz Band, 14 FCC Rcd 5871 (1999), at paragraph 98.

[9] Establishment of Policies and Service Rules for the Mobile Satellite Service in the 2 GHz Band, 14 FCC Rcd 4843, 4885 (1999), paragraph 94 ("2 GHz NPRM").

[10] Establishment of Policies and Service Rules for the Mobile Satellite Service in the 2 GHz Band, Report and Order, 1B Docket No. 99–81, paragraph 125, FCC 00–302, (rel. Aug. 25, 2000), 65 FR 59140 (October 4, 2000) ("2 GHz Report and Order").

[11] *Id.* Paragraph 125.

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most appropriate PSAP may require location information for each call and a national database to correlate callers' geographic positions with the service areas of local PSAPs and identify locations where no PSAP operates. Alternatively, emergency MSS calls might be routed to central operators, who could redirect the calls to the appropriate emergency response agencies in the caller's area. In some cases, public safety needs may best be met by routing MSS emergency calls to someone other than a local PSAP, for instance to the Coast Guard.

For terrestrial wireless emergency 911 calls, several technologies are being developed to identify the caller's location, including solutions that employ equipment in the wireless network and technologies employing upgraded handsets, with features such as Global Positioning System (GPS) capability.[12] Location solutions relying on facilities in terrestrial networks may not be available for MSS providers, however, and incorporation of handset-based position determination might affect MSS providers and terrestrial services differently with regard to such matters as handset performance, bulk, weight, battery life, cost, and price.

The National Telecommunications and Information Administration (NTIA) and the National Emergency Number Association (NENA) have recommended that we seek input on these issues from an ad hoc fact-finding committee. We request comment on this suggestion and, if this approach appears useful, how it might best be implemented.[13] For example, would it be more productive to postpone consideration of information gathered from this Public Notice until after such a group has provided a report to the Commission identifying or addressing relevant issues? We note that a Consensus Agreement that helped form the basis of the wireless 911 rules was developed by a voluntary ad hoc group with representatives of both the public safety and the wireless communities.

Specific Issues

Scope. The 911 rules for terrestrial wireless systems apply only to commercial mobile radio service involving provision of "real-time, two-way switched voice service * * * utiliz[ing] an in-network switching facility which enables the subscriber to reuse frequencies and accomplish seamless handoffs of subscriber calls."[14] Should 911 rules for satellite services, if adopted, be limited to the same extent? Are any MSS services analogous to the maritime and aeronautical services that are exempt from the 911 requirements for terrestrial wireless systems?[15] Does the rationale for exempting "SMR licensees offering mainly dispatch services to specialized customers in a more localized, non-cellular system configuration"[16] apply to any MSS providers?

If the Commission were to adopt 911 rules for MSS, should it adopt uniform requirements for all covered MSS, or should it develop varying requirements for different types of MSS systems or services? Should the rules distinguish, for instance, between provision of service to callers with single-mode MSS terminals and service to callers equipped with dual-mode terminals incorporating cellular or PCS transceivers?

Are there safety needs that MSS systems are uniquely or especially capable of meeting? How do MSS providers currently serve those or other public safety needs, or plan to serve them?[17] Are there relevant differences in the public safety needs that different MSS services and providers provide?

Basic 911 issues. Would it serve the public interest to require MSS licensees to provide basic 911 service[18] at this time? If not, please explain in detail why the public interest would not be served. If so, should MSS licensees be required to route 911 calls directly to PSAPs in the caller's vicinity, or should they have the option of initially routing the calls to special operators at central emergency-call bureaus for relay to PSAPs based on information obtained from the callers? What would be the impact, if any, of requiring basic 911 automatic routing on the cost and price of, and demand for, MSS?

Has a nationwide database been developed that emergency-call operators could use to ascertain which PSAP to contact in any given instance? If so, does the database include long-distance telephone numbers for contacting emergency-call handlers at each PSAP?[19]

If the Commission were to adopt a basic 911 requirement for MSS, how much lead time would be needed for compliance? How much more lead time, if any, would MSS providers need for achieving compliance with a rule requiring provision of basic 911 by automatic routing to PSAPs than with a rule permitting implementation by means of operator-assisted connection?

E911 issues. Should the Commission require MSS licensees to implement Automatic Number Identification (ANI)[20] for 911 calls and, if so, by what date? Would compliance with such a requirement be more problematic for MSS providers than for terrestrial wireless carriers subject to the ANI requirement in Section 20.18(d) of the Commission's rules and, if so, why? How much lead-time would be appropriate?

Is there any reason why implementation of *handset-based* Automatic Location Identification (ALI)[21] would be more problematic for MSS licensees than for terrestrial wireless carriers? Has handset-based ALI technology been developed for terrestrial wireless systems that is readily adaptable for use in MSS systems? Is it likely that such technology would be available to MSS licensees from competing commercial suppliers at prices comparable to prices charged for supplying equivalent technology to terrestrial carriers?

To what extent would incorporation, either internal or external (*e.g.*, GPS), of components for reception and correlation of satellite radiolocation signals affect the size, weight, battery life, and/or per-unit cost of new MSS handsets? What expenses, if any, aside from additional handset costs, would ALI implementation entail for MSS providers? How would implementation of ALI affect market demand for MSS and the commercial viability of MSS?

Is it feasible for some MSS systems to provide ALI without installing separate satellite radiolocation receivers (*e.g.*, GPS) in user terminals?[22] If so, what degree of accuracy can be achieved by this means, expressed in terms allowing comparison with the accuracy specifications for terrestrial wireless systems in section 20.18 of the Commission's rules? How would the cost of implementing ALI by this means compare with the cost of implementation based on reception of satellite radionavigation signals?

Would it serve the public interest to adopt a flexible rule requiring MSS providers to make their systems ALI-capable and offer ALI-capable terminals for sale or lease to customers who want them without barring continued provision of non-ALI-capable terminals to customers who prefer them? How would adoption of such a rule affect the cost, price, and demand for MSS?

How much lead-time should the Commission allow for meeting a flexible or other E911 ALI requirement for MSS, if adopted?

Compliance with other 911 and E911 rules and policies. If the Commission were to adopt 911 rules for GMPCS, would there be any need to devise special regulatory policies regarding any of the matters listed below, or should uniform policies apply alike to GMPCS and terrestrial wireless 911 services in these respects?

- Call priority (discussed in Wireless E911 Order at paragraphs 117–19)
- Calls from unauthorized and unidentified users (see Wireless E911 Recon Order at paragraphs 13–41)
- ALI interoperability (see Wireless E911 Third Report and Order at paragraphs 59–61)
- Compliance verification (*see id.* paragraphs 83–85 and OET Bulletin No. 71, *Guidelines for Testing and Verifying the Accuracy of E911 Location Systems, http://www.fcc.gov/oet/info/documents/bulletins)*
- Coordination with LECs and PSAPs (see Wireless E911 Second Recon Order at paragraphs 75–103 and Public Notice, DA 00–1875, in Docket No. 94–102 (released August 16, 2000), 65 FR 51831 (August 25, 2000).
- TTY access
- Waivers (see Wireless E911 Fourth Memorandum Opinion and Order[23] at paragraphs 42–45)
- Cooperation with the Coast Guard.[24]

Consumer notification. Should the Commission adopt a disclosure rule requiring manufacturers or sellers of GMPCS terminals that cannot be used for 911 emergency calls or with full E911 features to apprise users and potential purchasers of the functional limitations? If so, should the Commission require the notice to be affixed to the equipment or would another means of notification suffice?[25]

International issues. Three years ago, the Commission urged the public safety community and participants in the MSS industry "to continue their efforts to develop and establish . . . standards [for emergency calling] along with the international standards bodies."[26] What pertinent efforts, if any, have interested parties put forth, and with what result? What remains to be done, and how might the Commission promote its accomplishment?

What specific effect(s), if any, would FCC adoption of 911 requirements for MSS systems, including a requirement allowing operator-assisted connection, have on the use of U.S.-certified GMPCS terminals for calling in other countries and on the use of terminals imported from other countries for emergency calling in the U.S.? How likely would it be that other countries will adopt inconsistent emergency calling requirements or different protocols for ALI signals, and, if so, what issues and difficulties would be raised? Would it be feasible, in that event, to achieve systemwide ALI compatibility in a global or regional MSS system by means of processing at the gateway stations? How might such regulatory divergence affect handset design and marketing and what bearing would it have on domestic enforcement of technical and/or legal requirements for GMPCS handsets?

Would there be any need for special provisions pertaining to emergency MSS calls placed from within the U.S. but routed via foreign gateway stations?

Procedural Matters

Pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested persons may file Supplemental Comments limited to the issues addressed in this Public Notice no later than February 26, 2001. Supplemental Comments should reference IB Docket No. 99–67 and the DA number shown on this Public Notice. Supplemental Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).[27] Supplemental Comments filed through the ECFS can be sent as an electronic file via Internet to *http://www.fcc.gov/e-file/ecfs.html.* In completing the ECFS transmittal screen, parties responding should include their full name, mailing address, and the applicable docket number, IB Docket No. 99–67.

The Commission presented an Initial Regulatory Flexibility Analysis, as required by the Regulatory Flexibility Act (RFA),[28] in the Notice of Proposed Rulemaking in IB Docket 99–67, 64 FR 16687 (April 6, 1999).[29] If commenters believe that the proposals discussed in this Public Notice require additional RFA analysis, they may state their reasons for concluding so in their Supplemental Comments.

For *ex parte* purposes, this proceeding continues to be a "permit-but-disclose" proceeding, in accordance with section 1.1200(a) of the Commission's rules, and is subject to the requirements set forth in section 1.1206(b) of the Commission's rules.

For further information, please contact: William Bell, Satellite Policy Branch, (202) 418–0741.

Federal Communications Commission.

Shirley Suggs,

Chief, Publications Group.

[FR Doc. 01–1087 Filed 1–16–01; 8:45 am]

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[12] The Global Position System (GPS) is a network of U.S. government satellites that transmit signals that can be used to calculate the location of receivers.

[13] Comments of National Emergency Number Association in IB Docket No. 99–67, filed May 3, 1999 at page 2; Reply Comments of the National Telecommunications and Information Administration in IB Docket No. 99–67, filed July 21, 1999, at page 10.

[14] 47 CFR 20.18(a).

[15] Wireless E911 Order, at paragraph 82.

[16] *Id.* at paragraph 81.

[17] Although the Coast Guard has provided information on these points in previous comments, we would welcome additional comments in this regard, particularly from service providers. *See* Comments of the United States Coast Guard in IB Docket No. 99–67, Attachment 1 ("Search and Rescue Disaster Support MSS Capabilities Comparison Developed by the ISCAR CMSS Working Group"), filed June 21, 1999.

[18] See 47 CFR 20.18(b).

[19] In earlier comments, The Association of Public-Safety Communications Officials International, Inc. (APCO) and the National Emergency Number Association (NENA) have acknowledged that development of a national PSAP database is necessary to enable GMPCS licensees to provide 911 services. In reply comments filed in July 1999 NENA reported that it was compiling a national PSAP database but had not finished the task.

[20] ANI, *i.e.*, Automatic Number Identification, in this context, means automatic transmission of a callback number that a call-handler at a PSAP could dial to re-establish contact with a 911 caller in the event of a broken connection. See 47 CFR 20.3.

[21] ALI, *i.e.*, Automatic Location Identification, means automatic transmission of information specifying the caller's location.

[22] Orbcomm, a Little LEO licensee, has reported that it can automatically ascertain the location of a user terminal that has remained stationary for ten minutes within a 500-meter error radius 95% of the time, using calculations based on Doppler variations in the signals received from its low-orbit satellites. Comments of Orbital Communications Corporation in IB Docket No. 99–67, filed May 3, 1999. Globalstar, L.P. asserted that its Big LEO system has inherent position-location capability with an error radius of approximately 10 kilometers and that it expects to improve positioning accuracy over time. Comments of Globalstar, L.P. in IB Docket No. 99–81, filed July, 26, 1999.

[23] FCC 00–326 (released September 8, 2000) 65 FR 58657 (October 2, 2000).

[24] The Coast Guard has recommended adoption of a rule requiring providers of two-way mobile radio services to furnish coverage maps on request showing the areas where they provide emergency-calling service in order to facilitate enforcement of certain Coast Guard regulations. Comments of the U.S. Coast Guard in IB Docket No. 99–67, filed June 21, 1999.

[25] Compare Establishment of Policies and Service Rules for the Mobile Satellite Service in the 2 GHz Band, FCC 00–302 (released August 25, 2000) at paragraph 126, 65 FR 59140 (October 4, 2000) (imposing interim requirement to affix notification stickers to 2 GHz GMPCS handsets without 911 capability) with Wireless E911 Recon Order, supra, at paragraph 80 (allowing affected carriers to choose among various ways of notifying dispatch customers that their 911 calls will not be directly routed to PSAPs).

[26] Wireless E911 Recon Order, at paragraph 89.

[27] *See* Electronic Filing of Documents in Rulemaking Proceeding, 63 FR 24121 (May 1, 1998).

[28] *See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. § 601 *et seq.* seq., has been amended by the Contract With America Advancement Act of 1996, Public Law No. 104–121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

[29] 14 FCC Rcd at 5871, paragraph 101.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AG23

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for 12 Species of Picture-wing Flies From the Hawaiian Islands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose endangered status pursuant to the Endangered Species Act of 1973, as amended (Act), for 12 species of Hawaiian picture-wing flies—*Drosophila aglaia, D. differens, D. hemipeza, D. heteroneura, D. montgomeryi, D. mulli, D. musaphilia, D. neoclavisetae, D. obatai, D. ochrobasis, D. substenoptera, and D. tarphytrichia*. These species are found on one or more of the following Hawaiian Islands: Kaua'i, O'ahu, Moloka'i, Mau'i, and Hawai'i. These 12 species face substantial threats from one or more of the following: habitat degradation, loss of host plants, biological pest control, and predation from alien arthropods. Due to the restricted distributions and small populations, three species (*D. heteroneura, D. mulli, and D. neoclavisetae*) are in danger of extinction from naturally occurring random events. This proposal, if made final, would implement the protection provisions provided by the Act for these Hawaiian picture-wings.

DATES: Comments from all interested parties must be received by March 19, 2001. Requests for public hearings must be received by March 5, 2001.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods.

(1) You may submit written comments to the Field Supervisor, U.S. Fish and Wildlife Service, Pacific Islands Office, P.O. Box 50088, Honolulu, HI 96850–0001.

(2) You may send comments by e-mail to pwflies_pr@fws.gov (see **SUPPLEMENTARY INFORMATION** for file formats and other information about electronic filing); or

(3) You may hand-deliver comments to our Pacific Islands Office at 300 Ala Moana Blvd., Room 3–122, Honolulu, HI.

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Paul Henson, Field Supervisor, at the above address (telephone 808/541–3441, facsimile 808/541–2756).

SUPPLEMENTARY INFORMATION:

Background

Many of the major ecological zones of the earth are represented in Hawai'i, from coral reef systems through rain forests to high alpine deserts, in less than 10,800 square kilometers (6,500 square miles) of land. The range of topographies creates a great diversity of climates. Windward (northeastern) slopes can receive up to 1,000 centimeters (cm) (400 inches (in.)) of rain per year, while some leeward coasts that lie in the rain shadow of the high volcanoes are classified as deserts, receiving as little as 25 cm (10 in.) of rain annually. This topographic and climatic regime has given rise to a rich diversity of plant communities, including coastal, dryland, montane, subalpine, and alpine; dry, mesic, and wet; and herblands, grasslands, shrublands, forests, and mixed communities (Gagne and Cuddihy 1990). These habitats and plant communities in turn support one of the most unique arthropod faunas in the world, with an estimated 10,000 endemic species (Howarth 1990). Unusual characters of the arthropod fauna of Hawai'i include the presence of relict species; the absence of social insects, such as ants and termites; endemic genera; extremely small geographic ranges; adaptation of species to very specific conditions or environments; novel ecological shifts; flightlessness; and loss of certain antipredator behaviors (Zimmerman 1948, 1970, Simon *et al.* 1984, Howarth 1990).

Perhaps the most remarkable group of Hawaiian insects, and that which most typifies insect evolution in Hawai'i, is the flies in the family Drosophilidae (Williamson 1981). To date, 511 species of Hawaiian Drosophilidae have been named and described. An additional 250–300 species are already in the collection at the University of Hawai'i and await identification and description, and new species are still being discovered from localities not previously sampled. It is estimated that as many as 1,000 species may be present in native Hawaiian ecosystems (Kaneshiro 1993). The Drosophilidae family in Hawai'i represents one of the most remarkable cases of specific adaption to local conditions that has been found in any group of animals over the entire world (Hardy and Kaneshiro 1981). They are distributed throughout the high islands of the Hawaiian archipelago, each species displaying not only a highly characteristic trait of being found only on a single island, but also extraordinary physical diversity and adaptations that show their intimate ecological relationship to the native flora (Carson and Yoon 1982).

Drosophilidae are similar in structure to other flies in that adults have three main body parts: a head, thorax, and abdomen. A pair of antennae arises from the front of the head, between the eyes. The single pair of wings and three pairs of legs are attached to the thorax. The abdomen is composed of multiple segments. The general life cycle of Hawaiian Drosophilidae is typical of that of most flies: after mating, females lay eggs from which larvae (immature stage) hatch; as larvae grow they molt (shed their skin) through three successive stages (instars); when fully grown, the larvae change into pupae (a resting form) in which they metamorphose and emerge as adults.

The Hawaiian Drosophilidae have also developed and adapted ecologically to a tremendous diversity of ecosystems ranging from desert-like habitats where the soil is powdery dry, to rain forests with lush, tree-fern jungles, and in swampland perpetually shadowed by rain clouds and with vegetation burdened with dripping, moss-laden branches. While the larval stages of most species are saprophytic (feeding on decaying vegetation, such as rotting leaves, bark, flowers, and fruits), some have become highly specialized, being carnivorous on egg masses of spiders, or feeding on green algae growing underwater on boulders in streams. As a group, the Hawaiian Drosophilidae appear to be widespread and can be found in most of the natural communities in Hawai'i.

Unlike most Hawaiian insects that remain obscure, typically known only from their original taxonomic descriptions, most aspects of Hawaiian Drosophilidae biology have been researched, including their internal and external morphology, behavior, ecology, physiology, biochemistry, the banding sequence of giant chromosomes, as well as detailed analyses of the structure of the DNA molecules. More than 80 research scientists and over 350 undergraduates, graduate students, and post-doctoral fellows have participated in research on the Hawaiian Drosophilidae, resulting in over 600 scientific publications on the biology of these flies. The Hawaiian Drosophilidae is arguably the most intensively studied group of all terrestrial Hawaiian organisms.

Research on Hawaiian Drosophilidae has resulted in the development and testing of new theories of evolutionary biology (Bradley *et al.* 1991, Carson 1971, 1982a, Kaneshiro 1976, 1980, 1987, 1989). Ideas on the development of species and island evolution developed from studies on Hawaiian Drosophilidae are now referenced in most modern textbooks of biology and evolution (*e.g.*, Ridley 1993). These flies have also been the subject of numerous television programs produced by the BBC (British Broadcasting Corporation), NOVA, National Geographic Society, and other educational film makers. The BBC, in conjunction with the Open University in England, has also produced several programs focused on the research of the Hawaiian Drosophilidae, and these programs are being used in educational courses about evolution.

The Hawaiian Drosophila Project at the University of Hawai'i has coordinated and cooperated in most of the research on the Hawaiian Drosophilidae. It has also maintained extensive collection records of these species. These records form the basis for much of the data used to develop this proposed rulemaking. Three decades of collection work are maintained in permanent files of the Hawaiian Drosophila Project within the University of Hawai'i's Center for Conservation Research and Training. Also, collection notes of the individual researchers on the project contain extensive records of host plant associations of most of these species. Understanding the host plant association is important due to the fact that all of these flies appear to be closely linked with one or more particular host plant species. These host plant species provide necessary habitat requirements for the flies, including shelter, food, and areas for courtship. The host plants, and suitable habitat for the host plants, are absolutely essential for the flies' survival and recovery.

Biologists have observed a general decline of the Hawaiian Drosophilidae along with other components of the native ecosystem. As noted by Spieth (1980), during the early part of the century, the Tantalus area behind the city of Honolulu was the major spot for collecting *Drosophila* species. By 1963, the majority of the native *Drosophila* species in this area had been exterminated, apparently due to intrusion of exotic vegetation and predation by ants. Quantitative sampling since 1971 has demonstrated dramatic declines in the abundance of some species and in other cases local extirpations (Foote and Carson 1995). A review of the data collected by the Hawai'i Drosophila Project and assessment of the threats to remaining populations suggests that at least 12 species of these flies are presently threatened with extinction.

All 12 species in this proposed rulemaking belong to the species group commonly known as the picture-wings *Drosophila*. This group consists of 106 known species, most of which are large with elaborate markings on otherwise clear wings of both sexes, the pattern of which varies among species (Hardy and Kaneshiro 1981, Carson 1992). The picture-wing *Drosophila* have been referred to as the "birds of paradise" of the insect world because of the males' extremely elaborate and spectacular courtship displays and territorial defense behavior. Males occupy territories that serve as mating arenas to which receptive females are attracted for mating. The males fight among themselves for the best territories and establish a dominance hierarchy like some birds and mammals. Native Hawaiians apparently did not differentiate among the different species, but referred to flies collectively as *nalo*. Recognizing that some or all of these species may belong in the genus *Idiomyia* (Grimaldi 1990), we accept the most recent taxonomic description of the Hawaiian taxa as *Drosophila* (Nishida 1994) and will refer to the species in this proposed rule collectively as "Hawaiian picture-winged *Drosophila*," or "Hawaiian picture-wings." There has also been no traditional Hawaiian or European use of common names for individual species of Hawaiian picture-wings.

Each species of Hawaiian picture-wing in this proposed rulemaking is found only on a single island, and each breeds only in a single or a few related species of plants (see Table 1).

TABLE 1.—SUMMARY OF ISLAND DISTRIBUTION OF THE PROPOSED SPECIES

Species	Kaua'i	O'ahu	Moloka'i	Mau'i	Hawai'i	Primary host plants
Drosophila aglaia	.....	current	.....	.....	.....	*Urera glabra* (ōpuhe)
Drosophila differens.	.....	current	.....	.....	*Clermontia* spp. ('ōhā wai).	
Drosophila hemipeza.	.....	current	.....	.....	.....	*Urera* spp. (ōpuhe) and *Lobelia* spp. (ōhā)
Drosophila heteroneura.	.....	.....	.....	.....	current	*Clermontia* spp., *Delissea* spp., and *Cheirodendron* spp. (ōlapa)
Drosophila montgomeryi.	.....	current	.....	.....	.....	*Urera Ka'ala e* (ōpuhe)
Drosophila mulli ..	.....	.....	.....	.....	current	*Pritchardia beccariana* (loulu)
Drosophila musaphilia.	current	.....	.....	.....	.....	*Acacia koa* (koa)
Drosophila neoclavisetae.	.....	.....	.....	current	.....	*Cyanea* spp. (hāhā)
Drosophila obatai	.....	current	.....	.....	.....	*Pleomele forbesii* (hala pepe)
Drosophila ochrobasis.	.....	.....	.....	.....	current	*Myrsine* spp. (kōlea), *Marattia* spp. and *Clermontia* spp.
Drosophila substenoptera.	.....	current	.....	.....	.....	*Cheirodendron* spp. and *Tetraplasandra* spp. ('ohe mauka)
Drosophila tarphytrichia.	.....	current	.....	.....	.....	*Charpentiera* spp. (pāpala)

current = population observed within the past 20 years.

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Discussion of the 12 Species Proposed for Listing

Drosophila aglaia

Drosophila aglaia was first collected in 1946 on Mount Ka'ala on the island of O'ahu, and described by Elmo Hardy in 1965 (Hardy 1965). *Drosophila aglaia* is a small species, 4.0 mm (0.15 in.) in length, with wings 5.0 mm (0.2 in.) long. It has a yellow head that is approximately one-third wider than long. The eyes are brown, and the antennae are yellow, tinged with brown. The thorax is clear yellow with three broad brown stripes on the top, and the legs are yellow. The abdomen is brown with a large yellow spot on each of the hind corners. The wings are predominantly clear with irregular but characteristic brown markings, and are about two and three-quarter times longer than wide.

Drosophila aglaia is known only from six localities in the Wai'anae Mountains of O'ahu. It has been recorded on land owned by the State of Hawai'i Department of Land and Natural Resources (DLNR) at Makaleha Valley, Peacock Flats Trail, and Pu'u Kaua. Additionally, this species is known from private land holdings at Palikea Ridge, Pu'u Kaua, and Kalua'a gulch, and is also found on Federal land owned by the United States Army at Pu'u Pane. The occurrence of *D. aglaia* is restricted to the patchy distribution of its host plant, *Urera glabra*), a small endemic tree. The larvae of *D. aglaia* develop in the bark and stem of *U. glabra*. This tree does not form large stands, but is scattered throughout slopes and valley bottoms in mesic and wet forest habitat on all the main islands. In the Wai'anae Mountains on O'ahu, this tree occurs infrequently in mesic forest. Because *D. aglaia* is reliant on an infrequently occurring host plant, it is difficult to estimate the size of the land area on which this species occurs. Each site is probably less than several acres. The major threats to *D. aglaia* are predation by ants and habitat degradation from feral ungulates, alien plants, and fire.

Drosophila differens

Drosophila differens was described by Elmo Hardy and Kenneth Kaneshiro (1975) from specimens collected at South Hanalilolilo, Moloka'i, in 1972. Previous to the description, *D. differens* was referred to as "*Idiomyia planitibia* from Moloka'i." This species is large, approximately 7.0 mm (0.3 in.) in length, with wings 8.3 mm (0.33 in.) long. *Drosophila differens* looks very similar to *D. planitibia* of Mau'i, but can be differentiated from *D. planitibia* by its entirely or predominantly yellow face. There is also a difference in the markings found on the leading edge of the wings. In *D. planitibia* males, the marking extends about two-thirds the distance to the tip of the wings, while in *D. differens* males, it extends nearly to the marking at the tip of the wing. Hybridization experiments have demonstrated that *D. planitibia* from Mau'i and *D. differens* from Moloka'i represent distinct species as they are incapable of inter-breeding (Kaneshiro and Kaneshiro 1995). Crosses have been done in both directions and have resulted in fertile females, but sterile males. Other than differences in color, no morphological characters separate these species, and they are, therefore, considered to be sibling species.

Drosophila differens is restricted to the island of Moloka'i where it is known from three populations on private land: Kaunu O Hua, Pu'u Kolekole, and south Hanalilolilo where it was last observed on July 22, 1986. Montgomery (1975) found *D. differens* to breed in the bark, stems, and leaves of *Clermontia* spp. in wet rainforest habitat. This species is endangered by habitat degradation from feral ungulates and alien weeds, and predation by ants and alien wasps.

Drosophila hemipeza

Elmo Hardy (1965) described Drosophila hemipeza from specimens collected at Pūpūkea, O'ahu, in 1952. Drosophila hemipeza is most closely related to *D. planitibia* and *D. differens*. The key differences among these species is in the color of the face, which in *D. hemipeza* is pale yellow and densely covered with white fuzz. The thorax of *D. hemipeza* is predominantly yellow with two brown stripes on the top, and the legs are entirely yellow. This species is 5.0 mm (0.2 in.) long; the front legs are very slender with short straight bristles; and the wings are 6.0 mm (0.2 in.) in length, slender, and somewhat pointed.

Drosophila hemipeza is restricted to the island of O'ahu where it is known from six localities. In the Wai'anae Mountains, it is known from privately owned land at Palikea Ridge, Kalua'a Gulch, and Mauna Kapu. The species is also known from State of Hawai'i DLNR land in Makaleha and Wai'anae Valleys as well as from City and County of Honolulu holdings in Wai'anae Valley. The only occurrence of this species in the Ko'olau Range is from City and County of Honolulu property at Pauoa Flats on Mt. Tantalus.

Montgomery (1975) determined that *Drosophila hemipeza* utilizes several different mesic forest plants as larval breeding substrates. It breeds in the bark of *Urera kaalae*, a Federal endangered species (56 FR 55770), in the stems of *Lobelia* spp., and in the bark and stems of *Cyanea* spp., in mesic forest habitat. This Hawaiian picture-wing is endangered by habitat degradation from feral ungulates, alien weeds, and fire, and predation by ants and alien wasps.

Drosophila heteroneura

R.C.L. Perkins described *Idiomyia heteroneura*, based on specimens from 'Ōla'a on Hawai'i island (Perkins 1910). This taxon was later transferred to the genus *Drosophila* (Hardy 1969), forming its presently accepted name, *D. heteroneura*. *Drosophila heteroneura* has very large spots on the bases of the wings. However, the most characteristic feature of this species is the broad head of the male with the eyes situated laterally, thus giving it a hammer-head appearance. The hammer-head and entirely yellow face differentiate it from the closely related species, *D. silvestris*. The thorax is predominantly yellow with several black streaks and markings on top. The legs are yellow except for slight tinges of brown on the ends of the middle and hind femora and tibiae. The wings are hyaline (transparent) and are very similar in markings and venation to those of *D. silvestris*, except that the marking in the front margin of the wing of *D. heteroneura* extends nearly to the marking at the end of the wing. The abdomen is shining black with a large yellow spot on the top of each segment. This species is about 5.7 mm (0.22 in.) in length with wings approximately 7.0 mm (0.3 in.) long.

Drosophila heteroneura is restricted to the island of Hawai'i where it was historically known from 16 localities, on 4 of the island's 5 volcanoes (Hualālai, Mauna Kea, Mauna Loa, and Kīlauea). This species has never been found on the Kohala Mountains. The species was believed to be extinct in the late 1980s, until it was rediscovered on private acreage at Hualālai Volcano in 1993. The remaining population is extremely small, with a 90 percent reduction from historical abundance (Kaneshiro and Kaneshiro 1995).

Drosophila heteroneura breeds primarily in the bark and stems of *Clermontia* spp. and *Delissea* spp., but it is also known to utilize *Cheirodendron* spp. in open rain forest habitat. This Hawaiian picture-wing is endangered by habitat degradation from ungulates and alien weeds, predation by ants and alien wasps, and an extremely small remaining population.

Drosophila montgomeryi

Named after Dr. Steven L. Montgomery in honor of his work on Hawaiian picture-wings, *Drosophila montgomeryi* was described by Elmo Hardy and Kenneth Kaneshiro (1971) from specimens collected in the Wai'anae Mountains of O'ahu in 1970. This species morphologically appears to be most closely related to *D. pisonia* from the island of Hawai'i. It can be distinguished by the narrow, pale brown stripe on each side of the top of the thorax, the long hairs on the front legs, and the second antennal segment, which is yellow, tinged with brown on the top.

Drosophila montgomeryi is restricted to the Wai'anae Mountains on the island of O'ahu, where it is known from private holdings at Pu'u Kaua and Kalua'a Gulch, and State of Hawai'i DLNR property at Pu'u Kaua and Alaiheihe Gulch. Montgomery (1975) reported that the larvae of this species feed in the decaying bark of *Urera kaalae*, which grows on slopes and in gulches of diverse mesic forest. This Hawaiian picture-wing is endangered by habitat degradation from feral ungulates, alien weeds, and fire, and predation by ants and alien wasps.

Drosophila mulli

Drosophila mulli was described by William Perreira and Kenneth Kaneshiro (1990) and named for the eminent Hawaiian naturalist, William P. Mull, who first discovered this species. The head of *D. mulli* is yellow on the front, covered with a light, silvery grey fuzz. The face of the male is characteristically white, while that of the female is brown. The top of the thorax is brownish yellow and lacks conspicuous markings or stripes. The legs are predominantly yellow, and the front legs of males bear three distinct rows of long, curled hairs. The wings are two and one-half times longer than wide with distinct brown markings at the base and the tip. The length of the body is 4.3–5.0 mm (0.17–0.2 in.), and the wings are 4.3–4.8 mm (0.17–0.19 in.) long.

Drosophila mulli is restricted to the island of Hawai'i and is known only from the State of Hawai'i DLNR-owned 'Ōla'a Forest Reserve at an elevation of 985 meters (m) (3,200 feet (ft)). Adults are found only on the undersides of leaves of *Pritchardia beccariana*, an endemic fan palm, but the larval feeding site is still unknown. Attempts to rear this species from decaying parts of *P. beccariana* have been unsuccessful (W.P. Mull, Volcano, Hawai'i, pers. comm., 1995). However, because of the extremely localized population within a relatively small patch of *P. beccariana*, that a strong association between *D. mulli* and this plant is likely. This Hawaiian picture-wing is endangered by habitat degradation from feral pigs and alien weeds, limited numbers, and predation by ants and alien wasps.

Drosophila musaphilia

Elmo Hardy (1965) formally described *Drosophila musaphilia* from specimens at Kōke'e, Kaua'i, in 1952. Although Hardy (1965) indicated that D. musaphilia is very similar to *D. villosipedis*, based on both chromosomal data, as well as comparison of the male genitalia, *D. musaphilia* is clearly most closely related to *D. hawaiiensis* (Kaneshiro et al. 1995).

Drosophila musaphilia is characterized by a predominantly black thorax with gray fuzz and a very narrow gray stripe extending down the top. The legs are dark brown to yellow, with the front tibia devoid of ornamentation, and the tips of the legs have abundant long black hairs on top. The wings are three times longer than wide with characteristic markings of the *D. hawaiiensis* group. The abdomen is dark brown to black and densely covered with brown fuzz. The body length is about 5.0 mm (0.2 in.) and the wings 5.25 mm (0.207 in.) long.

Drosophila musaphilia is restricted to the island of Kaua'i where it is known from State of Hawai'i DLNR-owned land at Alexander Reservoir, Kōke'e State Park, and Halemanu. This species is extremely rare and has been observed only five times in the last 25 years. Montgomery (1975) determined that the host plant for *D. musaphilia* is *Acacia koa*. The females lay their eggs, and the larvae develop in the sap seeping from injured trees. This Hawaiian picture-wing is endangered by habitat degradation from feral ungulates, alien weeds, hurricanes, and fire, and predation by ants and alien wasps.

Drosophila neoclavisetae

Drosophila neoclavistae was described by William Perreira and Kenneth Kaneshiro (1990) from specimens collected at Pu'u Kukui, West Mau'i, in 1969. The species appears to be restricted to a ridge top at an elevation of 1,371 m (4,500 ft) (Kaneshiro and Kaneshiro 1995). It was named for its obvious affinities with *D. clavistae* from East Mau'i. Both species are similar in wing and thoracic markings as well as sharing one of the most bizarre courtship dances in the family. The male bends its abdomen up over its head, produces a bubble of liquid from its anal gland believed to be a sex pheromone, and then vibrates the abdomen; fanning the scent toward the female. Both *D. neoclavistae* and *D. clavistae* are members of the *D. adiastola* species group (Perreira and Kaneshiro 1990), and, while other species in this group perform similar mating behaviors, they are highly exaggerated in *D. clavistae* and *D. neoclavistae*.

Drosophila neoclavistae is between 6.0–6.4 mm (0.2–0.25 in.) in length, with wings 6.5–7.0 mm (0.26–0.3 in.) long. It is distinguished by its amber brown head and yellow face, with the middle portion raised to form a prominent ridge. The thorax is predominantly reddish brown with a distinct brown median stripe, bordered on each side by two brown stripes. The legs are yellow, with brown on the femora and a distinct brown band on the tips of the tibiae. The wings are broad and rounded, more than twice as long as wide, and with the front portion covered with brown markings and large clear spots tinged light yellow. It shares with *D. clavistae* an extra crossvein in the wing, which sets both these species apart from the other species of the *D. adiastola* species group. The abdomen is dark brown and black with numerous long hairs on the hind segments of the male.

Drosophila neoclavistae is restricted to the island of Mau'i where it is known only from State of Hawai'i DLNR property at Pu'u Kukui. The host plant of this species has not yet been confirmed, although it is believed to be associated with *Cyanea* sp.. All collections of this species have come from within a small patch of *Cyanea* spp., and many other species in the *D. adiastola* species group utilize these and other plants in the family Campanulaceae. This Hawaiian picture-wing is endangered by habitat degradation from feral ungulates and alien weeds, limited numbers, and predation by ants and alien wasps.

Drosophila obatai

Drosophila obatai was described by Elmo Hardy and Kenneth Kaneshiro in 1972, from specimens collected in the Wai'anae Mountains of O'ahu. This species was named for Mr. John Obata, who has made significant contributions to the study of Hawaiian *Drosophila* because of his knowledge of the native plants and habitats where these insects are found. *Drosophila obatai* resembles *D. sodomae* from Mau'i and Moloka'i, and is distinguished by small differences in wing markings and the black coloration of the abdomen.

Drosophila obatai is restricted to the island of O'ahu where it is known from State of Hawai'i DLNR-owned land at Makaleha Valley in the Mokul"ia Forest Reserve in the Wai'anae Mountains, and

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Wailupe Gulch located in the Honolulu Watershed Forest Reserve in the southern Ko'olau Mountains. This species is also known from Federal land owned by the Army at Pu'u Pane, and from City and County of Honolulu and private holdings at Wai'alae Nui. *Drosophila obatai* use *Pleomele forbesii* as a host plant (Montgomery 1975). This host plant, growing on slopes in dry forest and diverse mesic forest, occurs singly or in small clusters and does not form large stands of many individuals (Wagner et al. 1990). Threats to this Hawaiian picture-wing include habitat degradation from feral ungulates, alien weeds, and fire, and predation by ants and alien wasps.

Drosophila ochrobasis

Drosophila ochrobasis was originally described by Elmo Hardy and Kenneth Kaneshiro (1968) based on a specimen collected from Pu'u Hualâlai at an elevation of 1,692 m (5,550 ft). Based on chromosomal studies, D. ochrobasis appears to be most closely related to *D.setosimentum* (Kaneshiro *et al.* 1995).

Both the body and wings are approximately 4.6 mm (0.18 in.) in length. The head is yellow in front and brown on top, and the face is white with a prominent ridge running down the middle. The thorax is yellow except for a large brown spot on each side. The legs are yellow tinged with brown. In males, the basal three-fifths of the wing is predominantly clear to translucent with faint transverse streaks of brown. The outer two-thirds of the wing is dark brown with large clear spots similar to that portion of the wings in *Drosophila setosimentum*. The females of D. ochrobasis are virtually indistinguishable from those of *D.setosimentum* females.

Drosophila ochrobasis is restricted to the island of Hawai'i and has been found on State of Hawai'i DLNR property at Kīpuka and Alakahi Stream. It has also been observed at Kīpuka Pāhipa and Hualālai, both of which are privately owned. *Drosophila ochrobasis* was collected almost every year from 1967 to 1975, sometimes in large numbers, but has now virtually disappeared (Kaneshiro and Kaneshiro 1995). It was last observed at Kīpuka on February 14, 1986. This species has been reported to utilize several host plants, including *Myrsine* spp., *Clermontia* spp., and *Marattia* spp. (Montgomery 1975). Threats to this Hawaiian picture-wing include habitat degradation from ungulates and alien weeds, and predation by ants and alien wasps.

Drosophila substenoptera

Elmo Hardy described *Idiomyia substenoptera* in 1965. He then later determined the genus *Idiomyia* to be synonymous with Drosophila (Hardy 1969), thus creating the current name of *Drosophila substenoptera*. This species is closely related to *D. planitibia* and other closely related flies (Kaneshiro *et al.* 1995) but is quite distinctive from all the other species in this group because of characteristic markings on the wings, the narrow wing shape, and the complex structures of the male genitalia. *Drosophila substenoptera* is predominantly yellow with two black stripes extending down the entire length of the top surface of the thorax. The legs are yellow and lack long hairs on the dorsal surfaces. Body length is 4.35 mm (0.171 in.), and the wings are 5.0–5.3 mm (0.2–0.21 in.) long.

Drosophila substenoptera is restricted to the island of O'ahu where it is known from the following private holdings: Wiliwili Nui Ridge, Castle Trail, Hâlawa Ridge Trail, and Palikea Ridge. *Drosophila substenoptera* is also found on State of Hawai'i DLNR property at Mt. Ka'ala and the DuPont trail as well as on City and County of Honolulu owned acreage at Ka'au Crater. This species has never been abundant at any of these locations, but now appears to be extant only on the summit of Mt. Ka'ala , despite intensive efforts to relocate it at other sites. Montgomery (1975) determined that this Hawaiian picture-wing breeds in the bark of *Cheirodendron* spp. and *Tetraplasandra* spp. trees in wet forest habitat. Threats to this species include habitat degradation from feral ungulates and alien weeds, and predation by ants and alien wasps.

Drosophila tarphytrichia

Drosophila tarphytrichia was described by Elmo Hardy (1965) from specimens collected from Mānoa Falls on O'ahu, in 1949. This species is closely related to *D. vesciseta* based on the structure of the male genitalia (Kaneshiro *et al.* 1995), but can be differentiated by distinct wing markings and the ornamentation of the front legs of the male. The thorax is almost entirely yellow to red with a tinge of brown on the top. The legs are yellow, with the tip of the front leg strongly flattened laterally and with a dense clump of black hairs. This species is 3.70 mm (0.148 in.) long with wings 4.0 mm (0.2 in.) long.

Drosophila tarphytrichia is restricted to the island of O'ahu where it was historically known from both the Ko'olau and Wai'anae mountain ranges. It is now apparently extinct in the Ko'olau range and presently known from four localities in the Wai'anae Mountains. Three populations are found on privately owned lands at Mauna Kapu, Palikea ridge, and Kalua'a Gulch. The fourth is known from private and State of Hawai'i DLNR land at Pu'u Kaua. This species breeds on the stems and branches of *Charpentiera spp.* trees in mesic forest habitat (Montgomery 1975). Threats to this species include habitat degradation from feral ungulates and alien weeds, and predation by ants and alien wasps.

Previous Federal Action

Ten of these proposed species were classified as candidates for listing in the February 28, 1996, Notice of Review of Plant and Animal Taxa That Are Candidates for Listing as Endangered or Threatened Species (Notice of Review) (61 FR 7596). The remaining two species, *Drosophila differens* and *D. ochrobasis*, were classified as candidates for listing in the Notice of Review dated September 19, 1997 (62 FR 49398). Candidates are those taxa for which the Service has on file substantial information on biological vulnerability and threats to support preparation of listing proposals.

The processing of this proposed rule conforms with our Listing Priority Guidance published in the **Federal Register** on October 22, 1999 (64 FR 57114). The guidance clarifies the order in which we will process rulemakings. Highest priority is processing emergency listing rules for any species determined to face a significant and imminent risk to its well-being (Priority 1). Second priority (Priority 2) is processing final determinations on proposed additions to the lists of endangered and threatened wildlife and plants. Third priority (Priority 3) is processing new proposals to add species to the lists. The processing of administrative petition findings (petitions filed under section 4 of the Act) is the fourth priority (Priority 4). The processing of this proposed rule is a Priority 3 action.

Summary of Factors Affecting These Species

The procedures for adding species to the Federal Lists are found in section 4 of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and the accompanying regulations (50 CFR part 424). A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). Threats to these 12 species are summarized in Table 2.

TABLE 2. SUMMARY OF THREATS TO 12 HAWAIIAN PICTURE-WING FLIES

Species	Threats							
	Major alien plants	Feral animal activity				Fire	Alien insects	Limited numbers*
		Pigs	Goats	Deer	Cattle			
Drosophila aglaia	1,2,3,6	X	X			X	X	
Drosophila differens	2	X	X	X			X	
Drosophila hemipeza	1,2,3,5,6	X	X				X	
Drosophila heteroneura	2,4,8,9	X			X		X	X
Drosophila montgomeryi	1,2,3,6		X			X	X	
Drosophila mulli	2,8,9	X					X	X
Drosophila musaphilia	2,3,6,7,8	X	X	X		X	X	
Drosophila neoclavisetae	2,8	X					X	X
Drosophila obatai	1,2,3,5,6	X	X			X	X	
Drosophila ochrobasis	2,4,8,9	X			X		X	
Drosophila substenoptera	2,5,6	X					X	
Drosophila tarphytrichia	1,2,3,5,6	X	X				X	

[1] *-Schinus terebinthifolius* [2] *-Psidium cattleianum* [3] *-Melinus minutiflora* [4] *-Pennisetum setaceum* [5] *-Clidemia hirta* [6] *-Lantana camara* [7] *-Rubus argutus* [8] *-Passiflora mollissima* [9] *Rubus ellipticus*

* Fewer than three populations

The five factors and their application to *Drosophila aglaia, D. differens, D. hemipeza, D. heteroneura, D. montgomeryi, D. mulli, D. musaphilia, D. neoclavisetae, D. obatai, D. ochrobasis, D. substenoptera, and D. tarphytrichia* are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Native vegetation on all the main Hawaiian islands has undergone extreme alteration because of past and present land management practices, including ranching, deliberate introduction of alien plants and animals, and agricultural development (Cuddihy and Stone 1990). Some of the primary threats facing the 12 Hawaiian picture-wing species proposed for listing are ongoing and threatened destruction and adverse alteration of habitat by feral animals and alien plants.

All 12 of the proposed species are endangered by feral animals to various degrees. The early human inhabitants of the Hawaiian Islands introduced Polynesian pigs (*Sus spp.*), and more recently European settlers introduced more ungulate species, such as goats (*Capra hircus*), axis deer (*Axis axis*), black-tailed deer (*Odocoileus hemionus*), cattle (*Bos taurus*), and other domesticated pigs (*S. scrofa*), for food, commercial ranching activities, and hunting. Over the 200 years following the introduction of these animals, their numbers increased, and the adverse impacts of these feral ungulates on native vegetation have become increasingly apparent. Beyond the direct effect of trampling and grazing native plants, these feral ungulates have contributed significantly to the heavy erosion taking place on most of the main Hawaiian islands.

Pigs that were introduced to the Hawaiian Islands have escaped domestication and successfully established feral populations in wet and mesic forests and grasslands of Kaua'i, O'ahu, Moloka'i, Mau'i, and Hawai'i. Their presence on these islands threatens the existence of at least 11 of the proposed Hawaiian picture-wing species (see Table 2). Foote and Carson (1995) experimentally demonstrated the detrimental impact of feral pigs on Hawaiian picture-wings by showing that areas that had been fenced to exclude pigs supported higher numbers of flies and the plants they require for habitat. Conversely, areas of the same habitat that were not fenced were altered by pig-foraging activities resulting in the direct destruction of host plants. Furthermore, the foraging activities modified the habitat by making it more suitable for invasive plants that could crowd out host plants. While foraging, pigs root and trample the forest floor, encouraging the establishment of alien plants in the newly disturbed soil. Pigs also disperse alien plant seeds through their feces and on their bodies, accelerating the spread of alien plants through native forest (Cuddihy and Stone 1990, Stone 1985).

Goats native to the Middle East and India were first successfully introduced to the Hawaiian Islands in 1792. Feral goats now occupy a wide variety of habitats from lowland dry forests to montane grasslands on Kaua'i, O'ahu, Moloka'i, Mau'i, and Hawai'i, where they consume native vegetation, trample roots and seedlings, accelerate erosion, and promote the invasion of alien plants (Stone 1985, van Riper and van Riper 1982). Goats are significantly degrading the habitat of at least seven species proposed in this rule (see Table 2). On Kaua'i, goats contribute to the substantial decline of *Drosophila musaphilia*. On O'ahu, encroaching urbanization and hunting pressure tend to concentrate the goat population in the dry upper slopes of the Wai'anae Mountains, where populations of *D. aglaia, D. hemipeza, D. montgomeryi, D. obatai,* and *D. tarphytrichia* exist (Kaneshiro and Kaneshiro 1995). The goat population in the Wai'anae area is apparently increasing, becoming an even greater threat to the native habitat there. On Moloka'i, at least one population of *D. differens* at Pu'u Kolekole is presently endangered by goats.

Eight axis deer were introduced to the island of Moloka'i in 1868. By the turn of the century, their numbers had increased to thousands of animals (Tomich 1986). The herds had so damaged the vegetation on Moloka'i that professional hunters were hired to control their numbers (Tomich 1986). However, by then, the native vegetation had suffered irreparable damage from overgrazing by axis deer. These deer continue to degrade the habitat by trampling and overgrazing vegetation, which removes ground cover and exposes the soil to erosion. Activity of deer on Moloka'i has resulted in loss of habitat for *Drosophila differens*. The axis deer population is not presently managed by the State of Hawai'i DLNR or any other agency.

Black-tailed deer were first introduced to Kaua'i in 1961 for the purpose of sport hunting, and today probably number well over 500 animals. The deer are presently confined to the western side of the island, where they feed on a variety of native and alien

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plants (van Riper and van Riper 1982). The presence of these deer on Kaua'i is endangering some *Drosophila musaphilia* habitat.

Large-scale ranching of cattle in the Hawaiian Islands began in the middle of the 19th century on the islands of Kaua'i, O'ahu, Mau'i, and Hawai'i. Large ranches, tens of thousands of acres in size, developed on East Mau'i and Hawai'i (Cuddihy and Stone 1990) where most of the State's large ranches still exist today. Degradation of native forests used for ranching activities became evident soon after full-scale ranching began. The negative impact of cattle on Hawai'i's ecosystem is similar to that described for goats and deer (Cuddihy and Stone 1990, Stone 1985). Cattle grazing continues in several lowland regions in the northern portion of the Wai'anae Mountains of O'ahu. On Mau'i, cattle ranching is the primary agricultural activity in many areas and presently threatens populations of Drosophila heteroneura and D. ochrobasis.

Most of the plants that serve as breeding sites for these proposed Hawaiian picture-wings occur as understory vegetation beneath the canopy of the *Metrosideros polymorpha* (*'ohi'a*) and *Acacia koa*, and are affected by competition with alien weeds. All of the 12 Hawaiian picture-wing species being proposed for listing are endangered by loss of host plants due to competition with one or more alien plant species. The most significant of these alien plants appear to be *Schinus terebinthifolius* (Christmasberry), *Psidium cattleianum* (strawberry guava), *Melinus minutiflora* (molasses grass), *Pennisetum setaceum* (fountain grass), *Clidemia hirta* (Koster's curse), *Lantana camara* (lantana), *Passiflora mollissima* (banana poka), *Rubus argutus* (prickly Florida blackberry), and *R. ellipticus* (Himalayan raspberry).

Many noxious alien plants, such as *Schinus terebinthifolius*, have invaded the dry to mesic lowland regions of the Hawaiian Islands. Introduced to Hawai'i before 1911, *S. terebinthifolius* forms dense thickets that shade out and displace other plants (Cuddihy and Stone 1990). This fast-growing tree or shrub is found in lowland areas of the major Hawaiian Islands and is currently expanding its range (Smith 1985). *Schinus terebinthifolius* is now a major component of the mesic forests of the Wai'anae and Ko'olau mountains of O'ahu and currently threatens the habitat of *Drosophila aglaia*, *D. hemipeza*, *D. montgomeryi*, *D. obatai*, and *D. tarphytrichia*.

Psidium cattleianum, an invasive shrub or small tree native to tropical America, has become naturalized on all of the main Hawaiian islands. Like *Schinus terebinthifolius*, *P. cattleianum* is capable of forming dense stands that exclude other plant species (Cuddihy and Stone 1990). This alien plant grows primarily in mesic and wet habitats and provides food for several alien animal species, including feral pigs and game birds, which disperse the plant's seeds through the forest (Smith 1985, Wagner *et al.* 1985). Psidium cattleianum is considered one of the greatest alien plant threats to Hawai'i's rainforests. *Psidium cattleianum* is a major invader of forests in the Wai'anae and Ko'olau Mountains of O'ahu, where it often forms single-species stands. It poses a threat to all proposed species of Hawaiian picture-wings on O'ahu. *Psidium cattleianum* also threatens *D. musaphilia* on Kaua'i, *D. differens* on Moloka'i, *D. neoclavisetae* on Mau'i, and *D. heteroneura*, *D. mulli*, and *D. ochrobasis* on the island of Hawai'i.

First introduced to the Hawaiian Islands as cattle fodder, *Melinus minutiflora* (molasses grass) was later planted for erosion control (Cuddihy and Stone 1990). This alien grass quickly spread to dry and mesic forests previously disturbed by ungulates. *Melinus minutiflora* produces a dense mat capable of smothering plants (Smith 1985), essentially preventing seedling growth and native plant reproduction (Cuddihy and Stone 1990). Because it burns readily and often grows at the border of forests, this grass tends to carry fire into areas with woody native plants (Cuddihy and Stone 1990, Smith 1985). It is able to spread prolifically after a fire and effectively compete with less fire-adapted native plant species, ultimately creating a stand of alien grass where forest once stood. *Melinus minutiflora* is becoming a major threat to six of the proposed species on four islands. On Kaua'i it threatens the habitat of *Drosophila musaphilia*. In the Wai'anae Mountains of O'ahu, M. minutiflora threatens the habitat of *D. aglaia*, *D. hemipeza*, *D. montgomeryi*, *D. obatai*, and *D. tarphytrichia*.

Pennisetum setaceum has greatly increased fire risk in some regions, especially on the dry slopes of Hual'lai, K'lauea, and Mauna Loa volcanoes on the island of Hawai'i. The effects of *P. setaceum* invasion are similar to those discussed above for *Melinus minutiflora*. *Pennisetum setaceum* threatens the native vegetation on the leeward slopes of Hual'lai in a region where Drosophila heteroneura and *D. ochrobasis* occur.

Clidemia hirta, a noxious shrub native to tropical America, was first reported on O'ahu in 1941. It had spread through much of the Ko'olau Mountains by the early 1960s, and spread to the Wai'anae Mountains by 1970 (Cuddihy and Stone 1990). It poses a serious threat to *Drosophila hemipeza*, *D. obatai*, D. substenoptera, and *D. tarphytrichia* by displacing native plants used by these Hawaiian picture-wings as breeding sites.

Lantana camara, a native of the West Indies, became naturalized in dry to mesic forests and shrublands of the Hawaiian Islands before 1871 (Cuddihy and Stone 1990). This shrub often forms thick cover and produces chemicals that inhibit the growth of other plant species (Smith 1985). On Kaua'i, L. camara is a major component of the vegetation around the east and west rims of Waimea Canyon and the western ridges, and threatens the habitat of *Drosophila musaphilia*. It poses a threat to all proposed species of Hawaiian picture-wings on O'ahu.

Rubus argutus was introduced to the Hawaiian Islands in the late 1800s (Haselwood and Motter 1976). The fruit and seeds of this plant are easily spread by birds to open areas where this plant can form dense, impenetrable thickets (Smith 1985). On Kaua'i, the habitat of *Drosophila musaphilia* is endangered by this noxious weed.

Passiflora mollissima, a vine in the passionflower family, was introduced to the islands in the 1920s, probably as an ornamental. This vine is extremely detrimental to certain wet forest habitats of Kaua'i, Mau'i, and Hawai'i. Heavy growth of this vine can cause damage or death to the native trees by overloading branches, causing breakage, or by forming a dense canopy cover, intercepting sunlight and shading out native plants below. This weed threatens *Drosophila musaphilia* on Kaua'i, *D. neoclavisetae* on Mau'i, and *D. heteroneura*, *D. mulli*, and *D. ochrobasis* on the island of Hawai'i.

A recent introduction to the Hawaiian Islands, *Rubus ellipticus* is rapidly becoming a major weed pest in wet forests, pastures, and other open areas on the island of Hawai'i. It forms large thorny thickets and displaces native plants. Its ability to invade the understory of wet forests enables it to fill a niche presently unoccupied by any other major wet forest weed in Hawai'i. This has resulted in an extremely rapid population expansion of this alien plant in recent years. *Rubus ellipticus* threatens the habitat of Drosophila heteroneura, *D. mulli*, and *D. ochrobasis*.

Fire threatens species of Hawaiian picture-wings living in dry to mesic grassland, shrubland, and forests on two islands. On Kaua'i, fire is a significant threat to *Drosophila musaphilia*. Hurricane Iniki, in 1992, resulted in an enormous fuel load of downed woody debris and significantly raised the potential for serious fires on the western slopes of Kaua'i (Hawai'i DLNR-Department of Forestry and Wildlife 1993) . On O'ahu, fire is a potential threat to *D. montgomeryi*, *D. aglaia*, and *D. obatai* in the Wai'anae Mountains. The effects of fires on native Hawaiian vegetation are largely deleterious, tipping the competitive balance toward alien species. Unlike native plant species, many alien plant species recover quickly and increase in cover following fires (Cudihy and Stone 1990). Hawaiian picture-wing habitat that is damaged or destroyed by fire is likely to be invaded and revegetated by alien plants that cannot be used as host plants by picture-wings.

Two Hawaiian picture wings, *Drosophila obatai* and D. *aglaia*, occur on Federal property at Pu'u Pane, a part of the United States Army's Schofield Barracks Military Reservation. The gently sloping lands below Pu'u Pane are used as a live firing range, and ordnance-induced fires are a common occurrence. Although firebreak roads have been constructed around the perimeter of the firing range, uncontrollable fire still remains a threat to these species and their habitat.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overutilization is not a threat to any of the proposed Hawaiian picture-wings. While these and other species are valuable and popular as scientific research subjects, only a small number of researchers actively engage in field collections of these taxa. The individuals involved in this activity are professional biologists, knowledgeable and cognizant of the biology and conservation status of these animals. Because of the special collecting techniques involved, the use of these flies by more people for any purpose is highly unlikely. In addition, the collection of small numbers of adult flies would have little impact on the viability of a population, and such collection is necessary for accurate identification and conservation research.

C. Disease or Predation

Over 2,500 alien arthropods are now established in Hawai'i (Howarth 1990, Howarth *et al.* 1995, Nishida 1994), with a continuing establishment rate of 10-20 new species per year (Beardsley 1962, 1979). Many of these alien species have severe effects on the native Hawaiian insect fauna (Asquith 1995). Species of social Hymenoptera (ants and some wasps) and parasitic wasps pose the greatest threat to the Hawaiian picture-wings. Ants and other social insects frequently dominate the ecologies of tropical ecosystems and strongly influence the evolution of certain plants and animals. However, all of the native Hawaiian arthropods, including the Hawaiian picture-wings, evolved without the predation influence of ants or social wasps, and the subsequent arrival of these new groups to the Hawaiian islands has been devastating to the relatively defenseless native Hawaiian invertebrate flora.

Ants can be particularly destructive predators because of their high densities, recruitment behavior, aggressiveness, and broad range of diet (Reimer 1993). These attributes allow some ants to affect prey populations independent of prey density; thus ants can locate and destroy isolated populations and individuals (Nafus 1993). At least 36 species of ants are known to be established in the Hawaiian Islands, and particularly aggressive species have had severe effects on the native insect fauna (Zimmerman 1948). By the late 1870s, the big-headed ant (*Pheidole megacephala*) was present in Hawai'i, and its predation on native insects was noted by the early Hawaiian naturalist R.C.L. Perkins (1913), "It may be said that no native Hawaiian Coleoptera insect can resist this predator, and it is practically useless to attempt to collect where it is well established. Just on the limits of its range, one may occasionally meet with a few native beetles (e.g., species of *Plagithmysus*), often with these ants attached to their legs and bodies, but sooner or later they are quite exterminated from these localities." With few exceptions, native insects have been eliminated from areas where the big-headed ant is present (Perkins 1913, Gagne 1979, Gillespie and Reimer 1993), and it has been documented to completely exterminate populations of native insects.

The Argentine ant (*Iridomyrmex humilis*) was discovered on the island of O'ahu in 1940 and is now established on all the main islands. Unlike the big-headed ant, the Argentine ant is primarily confined to higher elevations (Reimer *et al.* 1990). This species has been demonstrated to reduce populations or even eliminate native arthropods at high elevations in Haleakala National Park on Mau'i (Cole *et al.* 1992). While this species does not disperse by flight, colonies are moved about with soil and construction material; a colony was recently discovered on an isolated peak on the island of O'ahu under a radio tower.

The long-legged ant (*Anoplolepis longipes*) appeared in Hawai'i in 1952 and now occurs on O'ahu, Mau'i, and Hawai'i (Reimer *et al.* 1990). It inhabits low-elevation (less than 600 m (2,000 ft)), rocky areas of moderate rainfall (less than 250 cm (100 in.) annually) (Reimer *et al.* 1990). Direct observations indicate that Hawaiian arthropods are susceptible to predation by this species (Gillespie and Reimer 1993), and Hardy (1979) documented the disappearance of most native insects from Kipahulu Stream on Mau'i after the area was invaded by the long-legged ant.

At least two species of fire ants, *Solenopsis geminita* and S. papuana, are also important threats (Reagan 1986; Gillespie and Reimer 1993) and occur on all the major islands (Reimer *et al.* 1990). *Solenopsis geminita* is known to be a significant predator on pest fruit flies (Diptera: Tephritidae) in Hawai'i (Wong and Wong 1988). *Solenopsis papuana* is the only abundant, aggressive ant that has invaded intact mesic forest above 600 m (2,000 ft) and is still expanding its range in Hawai'i (Reimer 1993).

Numerous other ant species are recognized as threats to native invertebrates, and additional species become established almost yearly. While the larvae of most of the Hawaiian picture-wings feed deep in the substrate of the host plant, they emerge and move away to pupate in the ground, thus exposing themselves to predation by ants. Upon newly emerging as adults, these flies are particularly susceptible to predation. Adult picture-wings have been observed with ants attached to their legs (Kaneshiro and Kaneshiro 1995).

Another group of social insects that are voracious predators and were originally absent from Hawai'i are yellowjacket wasps (Hymenoptera: Vespidae). In 1977, an aggressive race of the western yellowjacket (*Paravespula pennsylvanica*) became established in Hawai'i and is now abundant at most higher elevations (Gambino *et al.* 1990). In Haleakala National Park on Mau'i, yellowjackets were found to forage predominantly on native arthropods (Gambino *et al.* 1987, 1990, Gambino and Loope 1992). Overwintering yellowjacket colonies in Hawai'i can produce over half a million foragers that consume tens of millions of arthropods, and evidence exists for localized reduction in native arthropod abundance (Gambino and Loope 1992). Yellowjackets have been observed preying on Hawaiian picture-wings (Kaneshiro and Kaneshiro 1995), and

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the establishment of this species on the island of Hawai'i corresponded with a significant decline in several species of Hawaiian picture-wings (Carson 1982b, 1986, Foote and Carson 1995). Yellowjackets pose a serious threat to all Hawaiian picture-wing species in this proposed rulemaking.

Hawai'i also has a limited number of native parasitic Hymenoptera (wasps), with only species of Eucoiliidae recorded to utilize Hawaiian picture-wings as hosts. Several species of alien braconid wasps, *Diaschasmimorpha tryoni, D. longicaudatus, Opius vandenboschi, and Biosteres arisanus,* were purposefully introduced into Hawai'i to control several species of pest tephritid fruit flies (Funasaki *et al.* 1988). However, none of these parasitic wasps are specific to the pest flies, but are known to attack other species of flies, including native Hawaiian Tephritidae. While these wasps have not been recorded parasitizing Hawaiian picture-wings, and may not successfully develop in Drosophilidae, females will sting any fly larva available and can cause significant mortality (T. Duan, University of Hawai'i, pers. comm., 1995). Large extensive releases of these wasps or introductions of new species pose potential threats to Hawaiian picture-wings.

D. The Inadequacy of Existing Regulatory Mechanisms

Currently, no Federal, State, or local laws, treaties, and/or regulations specifically apply to the 12 proposed species of Hawaiian picture-wings. Some of the species may indirectly receive some protection under Federal and State laws because they utilize host plants that are protected under the Federal Endangered Species Act and the State of Hawai'i's Endangered Species Act. This indirect protection, however, is not sufficient since the species of Hawaiian picture-wings that utilize protected host plants may not be physically present on the host plants at all times and because some threats to these Hawaiian picture-wings can occur regardless of their presence on a protected host plant.

As stated above, alien parasitic wasps pose a threat to the Hawaiian picture-wings. Some alien wasp species have been introduced by Federal and State agencies for biological control of pest flies. The U.S. Environmental Protection Agency (EPA), under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), regulates biological control agents as pesticides. However, EPA only regulates microorganisms (*i.e.*, bacteria, fungi, protozoa, and viruses). EPA has exempted all other organisms from requirements of FIFRA, because it has determined that they are regulated by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA–APHIS). The State of Hawai'i requires that new introductions be reviewed by special committees before release (HRS Chapt. 150A), and current USDA–APHIS policy is to submit permit application materials, including an environmental assessment or environmental impact statement, to the Service's Pacific Islands Office for review under section 7 of the Act and National Environmental Policy Act (NEPA). However, predicting from laboratory studies the impacts introduced species may have on an ecosystem is difficult (Kauffman and Nechols 1992) and the purposeful release or augmentation of any Dipteran predator or parasitoid is a potential threat to these 12 species of Hawaiian picture-wing flies.

Federal listing would automatically invoke listing under Hawai'i State law, which prohibits taking and encourages conservation by State government agencies. Hawai'i's Endangered Species Act (HRS, Sect. 195D–4(a)) states, "Any species of aquatic life, wildlife, or land plant that has been determined to be an endangered species pursuant to the (Federal) Endangered Species Act shall be deemed to be an endangered species under the provisions of this chapter and any indigenous species of aquatic life, wildlife, or land plant that has been determined to be a threatened species pursuant to the (Federal) Endangered Species Act shall be deemed to be a threatened species under the provisions of this chapter." State regulations prohibit the removal, destruction, or damage of federally listed animals found on State lands (HRS, Sect. 195D–4(e)). Further, the State may enter into agreements with Federal agencies to administer and manage any area required for the conservation, management, enhancement, or protection of endangered species (HRS, Sect. 195D–5(c)). Funds for these activities could be made available under section 6 (Cooperation with the States) of the Act. Federal listing of these species will, therefore, trigger the protection available under State law.

E. Other Natural or Manmade Factors Affecting Its Continued Existence

The small number of populations of *Drosophila neoclavisetae, D. mulli,* and *D. heteroneura* puts these species at risk of extinction from naturally occurring, yet relatively common, events such as hurricanes and landslides. A hurricane could cause total population loss by causing direct mortality, habitat destruction or modification, and the spread of invasive alien plants. The continued existence of these picture-wings is further complicated by their limited habitat. *Drosophila mulli* is only found at one location on the island of Hawai'i within a localized patch of *Pritchardia beccariana.* Adults are found only on the undersides of this plant, and further associations between *D. mulli* and this host plant are likely. *Drosophila neoclavisetae* is restricted to a ridgetop on the island of Mau'i where it has been found only within a small patch of endemic *Cyanea* spp. *Drosophila heteroneura* was believed to be extinct until it was rediscovered on private acreage at Hualâlai Volcano in 1993. This remaining population is extremely small, with a 90 percent reduction from historical abundance (Kaneshiro and Kaneshiro 1995). Naturally occurring random events such as hurricanes or landslides may destroy vital *P. beccariana* or *Cyanea* spp., thus placing *D. mulli* and *D. neoclavisetae* at significant risk of extinction by eliminating the only habitat in which they have been found. Additionally, the destruction of native plants opens a niche for the establishment of introduced alien plant species. Once alien species are established, it is difficult for native plants, including host plants for *Drosophila* spp., to recover and thrive successfully.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by the 12 species in determining to propose this rule. Based on this evaluation, the proposed action is to list *Drosophila aglaia, D. differens, D. hemipeza, D. heteroneura, D. montgomeryi, D. mulli, D. musaphilia, D. neoclavisetae, D. obatai, D. ochrobasis, D. substenoptera,* and *D. tarphytrichia,* as endangered. All 12 species are endangered by one or more of the following: habitat degradation by pigs, goats, deer, cattle, and alien plants; habitat loss from fire; predation by ants and alien wasps; and biological pest control. Three species are known from less than three populations, making them susceptible to extinction from naturally occurring random events. Because these 12 species are in danger of extinction throughout all or a significant portion of their ranges, they fit the definition of endangered as defined in the Act. Therefore, the Service proposes to list these species as endangered.

Critical Habitat

In the last few years, a series of court decisions has overturned our

determinations regarding a variety of species that designation of critical habitat would not be prudent (*e.g., Natural Resources Defense Council* v. *U.S. Department of the Interior* 113 F. 3d 1121 (9th Cir. 1997); *Conservation Council for Hawaii* v. *Babbitt,* 2 F. Supp. 2d 1280 (D. Hawaii 1998)). Based on the standards applied in those judicial opinions, we have examined the question of whether critical habitat for the 12 species of *Drosophila* flies would be prudent.

Although the 12 species have small population sizes, they do not appear to be vulnerable to unrestricted collection, vandalism, or other intentional disturbance at this time. We remain concerned that these threats might be exacerbated by the publication of critical habitat maps and further dissemination of locational information. However, we have examined the evidence available and have not found specific evidence of taking, vandalism, collection, or trade of this species or any similarly situated species. Consequently, consistent with applicable regulations (50 CFR 424.12(a)(1)(i)) and recent case law, we do not expect that the identification of critical habitat will increase the degree of threat to this species of taking or other human activity.

In the absence of a finding that critical habitat would increase threats to a species, if any benefits would result from critical habitat designation, then a prudent finding is warranted. In the case of these species, some benefits may result from designation of critical habitat. The primary regulatory effect of critical habitat is the section 7 requirement that Federal agencies refrain from taking any action that destroys or adversely modifies critical habitat. While a critical habitat designation for habitat currently occupied by these species would not be likely to change the section 7 consultation outcome, because an action that destroys or adversely modifies such critical habitat would also be likely to result in jeopardy to the species, in some instances section 7 consultation might be triggered only if critical habitat is designated. Examples include unoccupied habitat or occupied habitat that may become unoccupied in the future. Designating critical habitat may also provide some educational or informational benefits. Therefore, we propose that critical habitat is prudent for *Drosophila aglaia, D. differens, D. hemipeza, D. heteroneura, D. montgomeryi, D. mulli, D. musaphilia, D. neoclavisetae, D. obatai, D. ochrobasis, D. substenoptera,* and *D. tarphytrichia.*

Critical habitat is not determinable when one or both of the following situations exist: the information needed to analyze the impacts of the designation is lacking, or the biological needs of the species are not sufficiently well known to permit identification of an area as critical habitat (50 CFR 424.12). Currently, we have found that critical habitat for the 12 *Drosophila* flies is not determinable based on our inadequate knowledge about the relationship of the flies to their primary and secondary host plant(s), the distributions of these host plant(s), the bacteria and fungal communities necessary for successful *Drosophila* larval development, and the relationship of these flies to other native and nonnative flies.

As discussed in the Background section of this proposed rule, each of the twelve species of *Drosophila* proposed for listing is restricted geographically to a single island; six species are reported from Oahu, three species are reported from the island of Hawaii, and one species, each, is reported from Kauai, Molokai, and Maui. All twelve species appear to have highly specialized breeding sites; they use small sections of fermenting or rotting areas on their host plant(s). The host plants are also, in many cases, "single-island endemics". Some, in fact, have already been independently listed as endangered or threatened and their locations are available through various government and privately-sponsored databases and from individual botanists. Unfortunately, information on the specific locations of other host plants may not be known, making determination of critical habitat difficult. In addition, we do not currently understand the relationship between the primary and the secondary host plant(s) and their associated *Drosophila* species. Factors that determine host suitability may include host plant size, the size and age of a rotting area upon which the larvae feed, the position of the rotting area with respect to the surrounding vegetation, soil moisture, relative humidity, frequency of rainfall and fog drip, and the presence or absence of other detritus (decaying organic matter) feeders, such as slugs and earthworms. However, it is not clear from currently available information which, or if all, of these factor(s) are essential for the long-term conservation of each *Drosophila* species.

We are also unable to determine critical habitat for these flies based on the lack of information on the bacteria and fungal communities necessary for successful *Drosophila* larval development. The larvae of all twelve *Drosophila* species are microbivores (fungus feeders) and little is known about their bacteria and fungal requirements or about the ability of host plant species to support them. This information is needed to determine what primary constituent elements are needed for fly larvae to survive.

Finally, we are currently unable to determine the inter-specific relationships between these species and other, more common species of *Drosophila,* introduced tipulids (crane flies), and other non-native fly species. Preliminary research strongly suggests that inter-generic competition is potentially an important limiting factor for the picture-wing *Drosophila* and may inhibit or limit their use of certain host plants. Additional information on these interrelationships will assist in determining what impacts these relationships have on the habitat requirements of these 12 flies.

When we find that critical habitat is not determinable, our regulations (50 CFR 424.17) provide that, within one year of the date of the final rule listing the species, we must publish a final rule designating critical habitat, based on the best information available at the time. Due to a limited listing budget, we plan to employ a priority system for deciding which outstanding critical habitat designations should be addressed first. We will focus our efforts on those designations that will provide the most conservation benefit, taking into consideration the efficacy of critical habitat designation in addressing the threats to the species, and the magnitude and immediacy of those threats. Therefore, if these species are listed, we will develop a proposal to designate critical habitat for the 12 species of *Drosophila* flies as soon as feasible, considering our workload priorities, as outlined in our priority system, and available funding.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages public awareness and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the State and requires that recovery actions be carried out for all listed species. Funding may be available through section 6 of the Act for the State to conduct recovery activities. The

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protection required of Federal agencies and the prohibitions against certain activities involving listed animals are discussed, in part, below.

Listing the 12 *Drosophila* species provides for the development and implementation of recovery plans for these species. These plans will bring together Federal, State, and regional agency efforts for the conservation of the species. Recovery plans will establish a framework for agencies to coordinate their recovery efforts. The plans will set recovery priorities and estimate the costs of the tasks necessary to accomplish the priorities. They will also describe the site-specific management actions necessary to achieve conservation and survival of these species.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer informally with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to insure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with us.

Federal agency actions that may require conference and/or consultation as described in the preceding paragraph include, but are not limited to: Army Corps of Engineers involvement in projects, such as the construction of roads, bridges, and dredging projects, subject to section 404 of the Clean Water Act (33 U.S.C. 1344 *et seq.*) and section 10 of the Rivers and Harbors Act of 1899 (33 U.S.C. 401 *et seq.*); U.S. Environmental Protection Agency authorized discharges under the National Pollutant Discharge Elimination System (NPDES); U.S. Department of Agriculture involved in release or permitting release of biological control agents under the Plant Pest Act; military training and activity carried out by the U.S. Department of Defense; and projects by the Natural Resources Conservation Service and U.S. Department of Housing and Urban Development.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. The prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.21 for endangered species, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these), import or export, ship in interstate or foreign commerce in the course of a commercial activity, or sell or offer for sale in interstate or foreign commerce any endangered wildlife species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 and 17.23. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in the course of otherwise lawful activities. Requests for copies of the regulations regarding listed wildlife and inquiries about permits and prohibitions may be addressed to the U.S. Fish and Wildlife Service, Endangered Species Permits, 911 Northeast 11th Avenue, Portland, Oregon 97232–4181 (telephone 503/231–6241; facsimile 503/231–6243).

As published in the **Federal Register** on July 1, 1994, (59 FR 34272), our policy is to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not be likely to constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of the listing on proposed and ongoing activities within a species' range. Likely activities that we believe could potentially result in a violation of section 9 of the Act include, but are not limited to, the following: road and firebreak construction; military troop movements; loss of habitat due to fire resulting from the use of military ammunition; intentional release or augmentation of biological control agents; introduction of other alien species; and collection of individuals for any purpose without a permit. Activities that we believe would not likely result in a violation of section 9 of the Act include, but are not limited to, non-destructive activities in areas occupied by these species, such as hiking, collecting non-host plants for cultural usage (e.g., hula halau), and hunting. Activities that occur under a valid incidental take permit or in accordance with a section 7 consultation would not violate section 9.

Questions regarding whether specific activities will constitute a violation of section 9 of the Act should be directed to the Manager of the Pacific Islands Ecoregion (see **ADDRESSES** section).

If these Hawaiian picture-wing flies are listed under the Act, the State of Hawai'i Endangered Species Act (HRS, Sect. 195D–4(a)) is automatically invoked, prohibiting taking and encouraging conservation by State government agencies. Further, the State may enter into agreements with Federal agencies to administer and manage any area required for the conservation, management, enhancement, or protection of endangered species (HRS, Sect. 195D–5(c)). Funds for these activities could be made available under section 6 of the Act (State Cooperative Agreements). Thus, the Federal protection afforded to these species by listing them as endangered species will be reinforced and supplemented by protection under State law.

Public Comments Solicited

We intend that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby sollcited. Comments particularly are sought concerning:

(1) Biological, commercial, or other relevant data concerning any threat (or lack thereof) to these species;

(2) The location of any additional populations of these species;

(3) Identification of habitat that should be designated as critical habitat and the reasons why this habitat should be determined to be critical habitat pursuant to section 4 of the Act or any reasons why critical habitat should not be designated;

(4) Additional information concerning the range, distribution, and population size of these species; and

(5) Current or planned activities in the subject area and their possible impacts on these species.

Final issuance of regulations on these species will take into consideration the comments and any additional information received by the Service, and such communications may lead to a final regulation that differs from this proposal. In accordance with interagency policy published on July 1, 1994 (59 FR 34270), upon publication of this proposed rule in the **Federal Register** we will solicit expert reviews by at least three specialists regarding pertinent scientific or commercial data and assumptions relating to the taxonomic, biological, and ecological information for the three species. The purpose of such a review is to ensure that listing decisions are based on scientifically sound data, assumptions, and analyses, including the input of appropriate experts. We will summarize the opinions of these reviewers in the final decision document. The final determination may differ from this proposal based upon the information we receive.

You may request a public hearing on this proposal. Your request for a hearing must be made in writing and filed within 45 days of the date of publication of this proposal in the **Federal Register**. Address your requests to the Field Supervisor (see **ADDRESSES** section).

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Electronic Access and Filing

You may send comments by e-mail to pwflies_pr@fws.gov. Please submit these comments as an ASCII file and avoid the use of special characters and any form of encryption. Please also include "Attn: 1018–AG23" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, contact us directly by calling our Pacific Islands Office at phone number 808–541–3441.

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

A complete list of all references and data cited herein, as well as others, is available upon request from Pacific Islands Ecoregion (see **ADDRESSES** section).

Author

The primary author of this document is Dr. Adam Asquith, U.S. Fish and Wildlife Service, Pacific Islands Ecoregion (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for Part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Section 17.11(h) is amended by adding the following, in alphabetical order under the family indicated, to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat
Common name	Scientific name					
INSECTS						
•	•	•	•	•	•	•
Fly, Hawaiian picture-wing	*Drosophila aglaia*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila differens*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila hemipeza*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila heteroneura*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila montgomeryi*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila mulli*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila musaphilia*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila neoclavisetae*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila obatai*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila ochrobasis*	U.S.A. (HI)	NA	E	NA	NA
Fly, Hawaiian picture-wing	*Drosophila substenoptera*	U.S.A. (HI)	NA	E	NA	NA

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Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat
Common name	Scientific name					
Fly, Hawaiian picture-wing	*Drosophila tarphytrichia* ...	U.S.A. (HI)	NA	E	NA	NA
•	•	•	•	•	•	•

Dated: December 15, 2000.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 01–1338 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–55–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[I.D. 010301D]

RIN 0648–AL95

Fisheries of the Exclusive Economic Zone Off Alaska; Amendments to Alaska Groundfish and Crab Fishery Management Plans to Revise the License Limitation Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of amendments to fishery management plans; request for comments.

SUMMARY: The North Pacific Fishery Management Council (Council) has submitted Amendment 60 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area, Amendment 58 to the Fishery Management Plan for Groundfish of the Gulf of Alaska and Amendment 10 to the Fishery Management Plan for the Commercial King and Tanner Crab Fisheries in the Bering Sea and the Aleutian Islands (FMPs). These plan amendments are necessary to implement changes to the License Limitation Program (LLP) as recommended by the Council and are intended to further the objectives of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the FMPs.

DATES: Comments on Amendments 60, 58, and 10 must be submitted by March 19, 2001.

ADDRESSES: Comments on the proposed plan amendments should be submitted to Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, P.O. Box 21668, Juneau, Alaska, 99802, Attn: Lori Gravel, or delivered to the Federal Building, 709 West 9th Street, Juneau, AK. Comments may also be sent by facsimile (fax) to 907-586-7465. Comments will not be accepted if submitted via e-mail or Internet. Copies of Amendments 60, 58, and 10 and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis prepared for the proposed plan amendments are available from the North Pacific Fishery Management Council, 605 West 4th Ave., Suite 306, Anchorage, AK 99501-2252; telephone 907-271-2809.

FOR FURTHER INFORMATION CONTACT: Jim Hale, 907-586-7228.

SUPPLEMENTARY INFORMATION:

Background

The Magnuson-Stevens Act requires that each Regional Fishery Management Council submit any fishery management plan or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, after receiving a fishery management plan or plan amendment, immediately publish a notice in the **Federal Register** that the fishery management plan or plan amendment is available for public review and comment. This action constitutes such notice for Amendments 60, 58, and 10 to the FMPs. NMFS will consider public comments received during the comment period in determining whether to approve these proposed plan amendments. To be considered, a comment must be received by the close of business on the last day of the comment period.

In June 1995, the Council recommended that NMFS implement the LLP to address concerns of excess capital in the groundfish and crab fisheries off Alaska. The LLP is the second stage of a multi-staged process to reduce capacity in the affected fisheries. The LLP will replace the Vessel Moratorium Program (VMP), a program implemented by NMFS on January 1, 1996, to impose a temporary moratorium on the entry of new capacity in the groundfish and crab fisheries off Alaska and to define the class of entities that would be eligible for licenses under the LLP. The VMP expired on December 31, 1999 (64 FR 3651). The final rule implementing the LLP specifies that fishing will begin under the LLP on January 1, 2000 (63 FR 52642, October 1, 1998).

If approved, Amendments 60, 58, and 10 would make several changes to the final rule implementing the LLP. First, the Council recommended that recent participation criteria be added to the eligibility requirements for a crab species license. Originally, a person applying for a crab species license had to demonstrate that documented harvests were made from a qualifying vessel during two periods, the general qualification period (GQP) and the endorsement qualification period (EQP). If approved, Amendment 10 would add a third period, the recent participation period (RPP), in which a person would have to demonstrate that documented harvests of crab were made from a qualifying vessel. The RPP was added to the eligibility requirements for a crab species license because of the Council's concern that a crab species license could be issued to a person whose eligibility was based on participation that has been inactive since 1995. These "latent licenses" could be transferred to persons who would become active in the fishery. Such transfers would be contrary to the purpose of the LLP because it would create the potential to increase fishing effort above the current levels in the crab fisheries. Except under specific exemptions provided in the FMP amendments, the RPP would require that a person demonstrate that at least one documented harvest of any crab species was made during the period beginning January 1, 1996, through February 7, 1998.

The Council's second recommendation is to require that the vessel designated on the LLP license be transferred with the LLP license, if that LLP license was issued based on documented harvests made from a vessel without a Federal Fisheries Permit. A Federal Fisheries Permit is required for any vessel that participates in a Federal groundfish fishery off Alaska. If a vessel did not participate in Federal groundfish fisheries off Alaska, its qualifying documented harvests must have occurred in waters of the State of Alaska or other waters shoreward of the exclusive economic zone (EEZ) off Alaska. Groundfish fisheries in state waters or other waters shoreward of the EEZ off Alaska will not be managed under the LLP. The Council reasoned that if a person is licensed to participate in a Federally managed fishery on the basis of participation in a State-managed fishery, certain restrictions should be placed on that license. Therefore, NMFS would restrict the transfer of a license issued to a vessel without a Federal Fishery Permit unless the licensed vessel is transferred with the license. The Council did not consider it a hardship to the license recipient to directly link the transfer of a license to the vessel, whether the recipient decides to keep or to transfer the license and vessel.

Third, the Council recommended that a gear designation be added to a groundfish license. The gear designation is intended to prevent movement between the trawl sector and the non-trawl sector. A license would be issued with a "trawl," "non-trawl," or "trawl/non-trawl" gear designation based on gear participation before June 17, 1995, with two exceptions. Under the first exception, a person could exercise a one-time option to switch gear designations if that person used a new gear between June 18, 1995, and February 7, 1998. For example, a person used only trawl gear before June 17, 1995. However, in 1997, that person used pot gear to catch Pacific cod. The use of a new gear in 1997 would allow the person to exercise a one-time option to change the gear designation from trawl gear to non-trawl gear. A person could not qualify for a trawl/non-trawl gear designation by use of this exception. Under the second exception, a person could request a gear designation change based on a significant financial investment. To qualify under the second exception, a person would have to (1) demonstrate that a significant financial investment was made in converting a vessel or purchasing fishing gear on or before February 7, 1998, and (2) demonstrate that a documented harvest was made from the qualifying vessel with the new gear type on or before December 31, 1998. A significant financial investment is defined as at least $100,000 toward vessel conversion or gear to change from a non-trawl to a trawl gear designation, or having acquired groundline, hooks or pots, and hauling equipment to change from a trawl to a non-trawl gear designation.

Fourth, the Council recommended that a community development quota (CDQ) vessel exemption, which originally had no ending date for eligibility, be limited to a specific time period (November 18, 1992, through October 9, 1998). The exemption was intended to facilitate the ability of CDQ organizations to enter and conduct groundfish fisheries through the purchase of new vessels that may not meet eligibility criteria. Concerns over excess capacity in the groundfish fisheries, and acknowledgment that CDQ organizations are integrating into the existing fishing industry at a reasonable pace, prompted the Council's recommendation. Further support for limiting this exemption came from public testimony that CDQ organizations did not use this exemption under the VMP.

Fifth, the Council recommended that limited processing ability, defined as 1 metric ton of round fish per day, be granted to a person deploying a vessel that is less that 60 ft (18.3 m) length overall, based on a groundfish license with a catcher vessel designation. This limited processing exemption is intended to assist small catcher vessels in exploiting niche markets not otherwise available.

Sixth, although not formally part of Amendments 60/58/10, the Council recommended that the name of the vessel to be deployed by the LLP license holder must be designated on the license. The Council recommended this change to address concerns about the movement of license holders among vessels contributing to excess capacity in the fisheries. The ability to move among vessels would have contributed to excess capacity by allowing a license holder to deploy a second vessel to fish while the first vessel was in port, or by allowing a license holder to alternate between vessels in different fisheries in different geographical locations. In both cases, a license holder could engage in uninterrupted fishing because breaks for unloading, vessel repairs, or running time could be eliminated through the use of another vessel. The Council recommended that NMFS make this change as a regulatory amendment.

Public comments will be accepted on these proposed amendments through the end of the comment period specified in this notification. A proposed rule that would implement the amendments may be published in the Federal Register for public comment following NMFS's evaluation under the Magnuson-Stevens Act procedures. All comments received by the end of the comment period specified in this notice, whether specifically directed to the amendments or to the proposed rule, will be considered in the decision to approve, disapprove, or partially approve these amendments.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 11, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1380 Filed 1–16–01; 8:45 am]

BILLING CODE: 3510-22-S

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Notices

Federal Register
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Wednesday, January 17, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Federal Invention Available for Licensing and Intent To Grant an Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of availability and intent.

SUMMARY: Notice is hereby given that a Federally owned invention, U.S. Patent Application No. 09/304,352 filed May 4, 1999, entitled "Chemical Compositions That Attract Arthropods," is available for licensing and the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to the University of Florida Research Foundation, Inc., of Gainesville, Florida, an exclusive license to this invention.

DATES: Comments must be received on or before April 17, 2001.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Room 4–1158, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5257.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights to this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within ninety (90) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,
Assistant Administrator.
[FR Doc. 01–1264 Filed 1–16–01; 8:45 am]
BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent to Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service (USDA), intends to grant to Viral Therapeutics of Ithaca, New York, an exclusive license to the invention disclosed in U.S. Patent No. 6,017,713 issued on January 25, 2000, entitled "Ferritin Formation as a Predictor of Iron Availability in Foods." Notice of Availability was published in the **Federal Register** on November 3, 1999.

DATES: Comments must be received on or before March 19, 2001.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Rm. 4–1158, Beltsville, Maryland 20705–5131.

FOR FURTHER INFORMATION CONTACT: June Blalock of the Office of Technology Transfer at the Beltsville address given above; telephone: 301–504–5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights in this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license the U.S. Government's rights in this invention as Viral Therapeutics has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty (60) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Richard M. Parry, Jr.,
Assistant Administrator.
[FR Doc. 01–1265 Filed 1–16–01; 8:45 am]
BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 00–091–2]

Secretary's Advisory Committee on Foreign Animal and Poultry Diseases; Solicitation for Membership

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent.

SUMMARY: We are giving notice that the Secretary anticipates reestablishing the Advisory Committee on Foreign Animal and Poultry Diseases for a 2-year period. The Secretary is soliciting nominations for membership for this Committee. This is the second notice calling for nominations. Previous nominations need not be resubmitted.

DATES: Consideration will be given to nominations received on or before March 5, 2001.

ADDRESSES: Nominations should be addressed to the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Dr. Joe Annelli, Chief Staff Veterinarian, Emergency Programs, VS, APHIS, 4700 River Road Unit 41, Riverdale, MD 20737–1231; (301) 734–8073.

SUPPLEMENTARY INFORMATION: The Secretary's Advisory Committee on Foreign Animal and Poultry Diseases (the Committee) advises the Secretary of Agriculture on actions necessary to keep foreign diseases of livestock and poultry from being introduced into the United States. In addition, the Committee advises on contingency planning and on maintaining a state of preparedness to deal with these diseases, if introduced.

The Committee Chairperson and Vice Chairperson shall be elected by the Committee from among its members.

Terms expired for the current members of the Committee in December 2000. We are soliciting nominations from interested organizations and individuals to replace members on the Committee. An organization may nominate individuals from within or outside its membership. This is a second notice soliciting nominations. Previous nominations need not be resubmitted. The Secretary will select members to obtain the broadest possible representation on the Committee, in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463) and U.S. Department of Agriculture (USDA) Regulation 1041–1. Equal opportunity practices, in line with USDA policies, will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by the Department, membership should include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Done in Washington, DC, this 10th day of January 2001.

Bobby R. Acord,
Acting Administrator, Animal and Plant Health Inspection Service.
[FR Doc. 01–1313 Filed 1–16–01; 8:45 am]
BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Forest Service

Pink Stone Fire Recovery; Kootenai National Forest, Lincoln County, MT

AGENCY: Forest Service USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: In August, 2000, two lightning-caused wildfires burned about 16,100 acres in the Pinkham and Sutton Creek drainages between 7 and 14 miles southwest of Eureka, Montana. The fires threatened private property and resulted in significant tree mortality and increased future fuel levels. Increases in spring-time peak water flows in a few streams are expected to approach maximum levels allowed by the Kootenai Forest Plan as a result of vegetation loss. The USDA Forest Service will prepare an Environmental Impact Statement (EIS) for the Pink Stone Fire Recovery Decision Area, which encompasses the two fire areas. The EIS will disclose the effects of fire recovery opportunities designed to meet the Purpose and Need for taking action, which is to (1) reduce existing and future fuel accumulations, the corresponding risk of reburn, and the risk to private property; (2) recover the economic value of fire-killed timber; (3) restore vegetative species diversity appropriate to the sites; and (4) restore affected watersheds to properly functioning conditions.

Fuel reduction and economic opportunities would be accomplished through salvage harvest of fire-killed timber and jackpot burning of harvest-created slash. Vegetation and watershed restoration opportunities would be accomplished through hand planting and natural regeneration in harvested, riparian and burned areas, and improving water drainage systems through road, ditch and culvert improvements. Additional fire recovery opportunities proposed include visual quality improvements using unit shapes and sizes designed to imitate patterns created by the fires, improvements to fire-affected trails, and provisions for adequate snag and coarse woody debris following recovery treatments.

The Proposed Action would reduce existing and future fuels and recover the economic value of burned timber on about 4,003 acres of land burned during the fires, producing about 89,488 hundred cubic feet (CCF), or 36.7 million board feet (MMBF), of forest product. Treatment types include about 1,663 acres of regeneration harvest, 1,522 acres of shelterwood harvest, 464 acres of seed tree harvest, and 354 acres of commercial thinning using tractor, cable and forwarded harvest systems. Jackpot burning would be used to reduce residual fuels. Watershed recovery actions would include about 315 acres of riparian planting, about 2,791 acres of hand planting in addition to expected natural regeneration, and roadside drainage improvements on approximately 76 miles of forest roads. Visual quality improvements involve unit size, shapes and treatments that imitate fire patterns and decrease the visual effect of previous unit edges and fire-killed trees. Fire-created trail hazards on three trials would be removed.

The Proposed Action would require Kootenai National Forest Plan project-specific exceptions to harvest in big game movement corridors and to temporarily exceed open road density standards in Management Area 12 (Big Game Summer Range with Timber Management). The Proposed Action would also create openings over 40 acres, which is allowable under catastrophic conditions such as large wildfires.

The proposed activities are considered together because they represent either connected or cumulative actions as defined by the Council on Environmental Quality (40 CFR 1508.23).

The EIS will tier to the Kootenai National Forest Land and Resource Management Plan, as amended, and the Final Environmental Impact Statement (FEIS), and Record of Decision (ROD) of September 1987, which provides overall guidance for forest management of the area.

DATES: Written comments and suggestions should be received on or before February 16, 2001.

ADDRESSES: The Responsible Official is Bob Castaneda, the Kootenai National Forest Supervisor, 1101 U.S. Highway 2 West, Libby, MT 59923. Written comments and suggestions concerning the scope of the analysis should be sent to Glen M. McNitt, District Ranger, Rexford Ranger District, 1299 U.S. Highway 93 N, Eureka, MT 59917.

FOR FURTHER INFORMATION CONTACT: Ron Komac, Acting NEPA Coordinator, Rexford Ranger District, Phone: (406) 296–2536.

SUPPLEMENTARY INFORMATION: The Decision Area is located on the Rexford Ranger District of the Kootenai National Forest in northwest Montana. Two fire areas, the Stone Hill Fire (10,960 acres) and the Lydia Fire (5,434 acres) make up the almost 16,200-acre Decision Area. All but some high-elevation ridgetops have favorable climate and good site conditions for forest vegetation. Proposed activities within the Decision Area include all or portions of T34–35N; R27–29W.

Average annual precipitation ranges from 14 to 100 inches. At higher elevations, most precipitation falls as snow. The Decision Area contains a combination of open-grown ponderosa pine and Douglas-fir in the lower elevations adjacent to Lake Koocanusa in the Store Hill fire area; upland areas in both fires that contain multistoried western larch/Douglas-fir intermixed with lodgepole pine; and mid to high to elevation areas in both fires that produce Englemann spruce, subalpine fir and lodgepole pine stands.

Some of the Stone Hill portion of the Decision Area is highly visible from a designated Scenic Byway (State Highway 37 and Forest Development Road #228) and from the Webb Mountain rental lookout.

The Kootenai National Forest Land and Resource Management Plan provides overall management objectives in individual delineated management areas (MAs). Almost all of the proposed fire recovery activities occur in MA 12 and 15. Briefly described, MA 12 is managed to maintain or enhance the summer range habitat effectiveness for big game species and produce a programmed yield of timber. MA 15

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focuses upon timber production using various silvicultural practices while providing for other resource values. Planting disease-resistant white-bark in suitable habitat and removing trail hazards along three trails are recovery activities proposed in MA 2 (non-motorized recreation, no timber harvest).

Purpose and Need

The Purpose and Need for taking action in the Decision Area is to (1) reduce existing and future fuel accumulations, the corresponding risk of reburn, and the risk to private property by removing dead and dying trees and jackpot burning residual fuels; (2) recover the economic value of fire-killed timber by harvesting merchantable trees; (3) restore vegetative species diversity by hand planting a variety of species appropriate to the sites in addition to natural regeneration; and (4) restore affected watersheds to properly functioning conditions by providing short- and long-term large woody debris recruitment, improving road-related drainage problems, and reducing the risk of additional watershed impacts from future reburns.

Proposed Activities

The Forest Service proposes to reduce existing and accumulating fuels and recover the economic value of burned timber on about 4,003 acres of fire-affected forest lands. About 1,663 acres of regeneration harvest would occur, where all trees would be harvested except about 5 moderately sized reserve trees. About 464 acres of seed tree harvest would occur, where 5–20 reserve trees would be retained to provide a seed source for natural regeneration. About 1,522 acres would be treated with a shelterwood harvest, where about 20–50 reserve trees per acre would be retained. Commercial thinning would occur on about 354 acres, with 30–100 trees per acre remaining. These treatments would recover an expected 89,488 CCF (36.7 MMBF) of commercial forest product from the fire-effected areas. A tractor harvest system would be used on about 1,270 acres where access and slope were favorable. On about 98 acres a cable system would be used, mostly due to steep slopes. A forwarded harvest system would be used on about 471 acres due to long skidding distances, steep slopes and soil concerns. Approximately 0.4 miles of temporary road would be needed to access one unit to be harvested with ground-based systems. This temporary road would be removed from the landscape after harvest activities were accomplished. No underburning is proposed due to the effects of the fires, however, residual fuels after the fires and harvest-generated fuels would be piled and burned as necessary (referred to as jackpot burning). Restoring vegetation as soon as possible would be supported by about 2,791 acres of hand planting western larch, western white pine and ponderosa pine in addition to expected natural regeneration. Selected sites over about 650 acres of high elevation land would be planted with disease-resistant white-barked pine. In addition to reforestation, watershed recovery actions would include providing species diversity and future large woody debris recruitment by planting aspen, black cottonwood, western redcedar, Englemann spruce and western hemlock up to 100 feet on both sides of about 13 mines of streams, or about 315 acres of riparian habitat; improving inadequate road-related drainage by upgrading roads to current Best Management Practices, increasing the size of stream crossing culverts, and improving road drainage; and reducing fuels in order to reduce the risk of additional impacts to watersheds from a future reburn. Visual quality improvements involve unit size, shapes and treatments that imitate fire patterns and decrease the visual effect of previous unit edges and fire-killed trees. Fire-created hazards on portions of three trails totaling about 7 miles would be removed.

The proposed activities were focused in high fire severity areas where large openings were created or will eventually be created by the fires. The Proposed Action contains 32 units that would exceed 40 acres and create immediate openings, ranging from 45 to 246 acres. Many are adjacent to other pre-fire openings or other Proposed Action units, and cumulatively with fire-affected stands could eventually result in very large openings exceeding 1,000 acres or more.

The proposal also includes 1.1 mile of permanent road construction, 0.4 miles of temporary road construction, and approximately 67 miles of reconstruction to meet Best Management Practices requirements. The temporary road would be obliterated following management actions.

Implementation of this proposal would require opening several miles of road currently restricted to public access. Depending on sale scheduling, some roads may be open to the public during activities. Restrictions for motorized access would be restored following the conclusion of the management activities.

Forest Plan Amendments

The proposed action includes several project-specific forest plan amendments and a programmatic amendment to meet the goals of the Kootenai National Forest Plan:

A project-specific amendment to MA 12 Wildlife and Fish Standard #7 and Timber Standard #2 would be needed to allow harvest adjacent to existing openings in big game movement corridors in MA 12. The wildfires burned around some pre-fire openings, removing cover in corridors and creating larger openings. The Proposed Action would remove much of the burned material that previously provided corridor cover. Surviving live trees and some snags and down woody material would be left to provide wildlife habitat and maintain soil productivity. In the larger openings, patches and corridors would be left to provide some level of security for big game movement through the fire areas.

A project-specific amendment to allow MA 12 open road densities would be needed to temporarily exceed the MA 12 Facilities Standard #3 of 1.15 miles/square mile (as previously amended by the Pinkham Timber Sale and Associated Activities Record of Decision, 1999). In order to recover forest products in a timely manner, several roads may be opened at the same time which would increase open road densities above the current standard. Open road densities would return to existing MA standards following activities.

Range of Alternatives

The Forest Service will consider a range of alternatives to the Proposed Action. One of these will be a "no action" alternative, in which none of the proposed activities would be implemented. Additional alternatives will be considered to achieve the project's purpose and need for action and to respond to specific resource issues and public concerns.

Preliminary Issues

Several issues of concern have been identified. These are briefly described below:

Future fire risk: The Lydia and Stone Hill fires killed many trees over large areas. Over the next 20 years most of these dead trees will fall over, creating high fuel levels. Reburns are anticipated with this kind of fuel load in intensities higher than what would normally be expected. In the aftermath of threats to private property this summer, public comments expressed concern over fuel loads and the potential for fires to again threaten private land ownership. There are also internal concerns that such a reburn would cause more severe effects to soils, watershed resources, vegetation and specialized habitat such as old-growth, snags and coarse woody debris.

Timber supply: Many preliminary public comments expressed concern that the value of burned timber will be lost if nothing is done to recover the area. Additional comments have voiced concern over the time frame proposed for addressing fire recovery, and expressed the urgency to recover the economic value of affected trees in a timely manner.

Water quality: Streams in or downstream of the fire areas have been impacted by past management and large wildfires. Several streams are nearing maximum allowable peak flow levels. Although the Proposed Action is expected to have long-term benefits, there are concerns that cumulative effects of past harvest, the fires and the Proposed Action may have short-term negative impacts to some watersheds.

Lynx habitat: Both fire areas impacted suitable habitat for Canada lynx. Coarse woody debris is an important component of denning habitat, and if a reburn does not occur, the fire areas are expected to produce denning and foraging habitat in about 15 years. Some comments expressed concern that post-fire recovery of timber products would reduce or remove important denning habitat.

Visual recovery: The Stone Hill fire is highly visible from a designated Scenic Byway and several scenic viewpoints. Preliminary comments have expressed concern over the visual appearance of burned landscapes, including blackened bark, red needles and large areas of dead and dying trees. Other comments expressed concern about the potential for management activities to create sharp lines or unnatural patterns and decrease visual quality.

Permanent road construction: The Lydia fire burned through a large area which currently has no suitable road access. About 1.1 mile of permanent road construction is proposed to provide reasonable access to the proposed treatment areas. There is a public concern that the Forest Service does not have enough funding to justify building a permanent road and maintaining it through time.

Decisions To Be Made

The Kootenai Forest Supervisor will decide the following:

- Whether or not to reduce existing and expected fuels create by the fires in order to reduce the risk of a reburn, and if so, identify the selection and site-specific location of such actions, and the fuel treatments necessary to reduce those fuels.
- Whether or not to recover the economic value of burned trees in a timely manner, and if so, identify the selection, site-specific location and timing of such actions, and appropriate timber management practices (silvicultural prescription, logging system, fuels treatment, and reforestation), road construction/reconstruction necessary to provide access, and appropriate mitigation measures.
- Whether or not hand planting should be used to supplement natural regeneration and increase diversity in burned, harvested and riparian areas, and if so, identify the selection and site-specific locations of such actions, and the appropriate species and reforestation methods needed.
- Whether or not short-term impacts to watersheds should be allowed in order to improve long-term watershed conditions.
- Whether or not watershed recovery activities (large woody debris recruitment provisions, improved road drainages, reduced risk of reburn) to improve long-term conditions should be implemented, and if so, identify the selection and site-specific locations of such actions.
- Whether or not project-specific Forest Plan exceptions are necessary to meet the specific purpose and need of this project, and whether those exceptions are significant under NFMA.
- What, if any, specific-project monitoring requirements would be needed to assure mitigation measures are implemented and effective.

Public Involvement and Scoping

In November, 2000 preliminary efforts were made to involve the public in considering management opportunities within the Pink Stone Fire Recovery Decision Area. Comments received prior to this notice will be included in the documentation for the EIS. The public is encouraged to take part in the process and is encouraged to visit with Forest Service officials at any time during the analysis and prior to the decision. The Forest Service will be seeking information, comments, and assistance from Federal, State, and local agencies, Indian tribes, individuals, and organizations who may be interested in, or affected by, the Proposed Action. The input will be used in preparation of the draft and final EIS.

The scoping process will assist in identifying potential issues, identifying major issues to be analyzed in depth, identifying alternatives to the proposed action, and identifying potential environmental effects of this project and alternatives (i.e., direct, indirect, and cumulative effects and connected actions).

Estimated Dates for Filing

While public participation in this analysis is welcome at any time, comments received within 30 days of the publication of this notice will be especially useful in the preparation of the Draft EIS. The Draft EIS is expected to be filed with the Environmental Protection Agency (EPA) and to be available for public review by April, 2001. At that time EPA will publish a Notice of Availability of the draft EIS in the **Federal Register**. The comment period on the draft EIS will be 45 days from the date the EPA publishes the Notice of Availability in the **Federal Register**.

The final EIS is scheduled to be completed by September, 2001. In the final EIS, the Forest Service is required to respond to comments and responses received during the comment period that pertain to the environmental consequences discussed in the draft EIS, and applicable laws, regulations, and policies considered in making a decision regarding the proposal.

Reviewer's Obligations

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions (*Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 [1978]). Also, environmental objections that could be raised at the draft environmental impact statement stage may be waived or dismissed by the courts (*City of Angoon* v. *Hodel*, 803, F.2d 1016, 1022 [9th Cir. 1986] and *Wisconsin Heritages, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 [E.D. Wis. 1980]). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 30-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider and respond to them in the final EIS.

To be most helpful in assisting the Forest Service to identify and consider issues and concerns on the Proposed Action, comments on the draft EIS

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should be as specific as possible and may address the adequacy of the statement or the merit of the alternatives discussed. Reference to specific pages or chapters of the draft EIS would also be helpful. Reviewers may wish to refer to the Council on Environmental Quality regulations (40 CFR 1503.3) for implementing the procedural provisions of the National Environmental Policy Act.

Responsible Official

As the Forest Supervisor of the Kootenai National Forest, 1101 U.S. Highway 2 West, Libby, MT 59923, I am the Responsible Official. As the Responsible Official I will decide if the proposed project will be implemented. I will document the decision and reasons for the decision in the Record of Decision. I have delegated the responsibility for preparing the EIS to Glen M. McNitt, District Ranger, Rexford Ranger District.

Dated: January 10, 2001.

Greg Kujawa,

Planning, Public Affairs, Recreation and Heritage Staff Officer, Kootenai National Forest.

[FR Doc. 01–1295 Filed 1–16–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent to Seek Approval to Extend an Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. No. 104–13) and Office of Management and Budget regulations at 5 CFR part 1320 (60 FR 44978, August 29, 1995), this notice announces the intent of the National Agricultural Statistics Service (NASS) to extend a currently approved information collection, the Milk and Milk Products Surveys.

DATES: Comments on this notice must be received by March 23, 2001 to be assured of consideration.

ADDITIONAL INFORMATION OR COMMENTS: Contact Rich Allen, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, Room 4117 South Building, 1400 Independence Avenue SW, Washington, D.C. 20250–2000, (202) 720–4333.

SUPPLEMENTARY INFORMATION:

Title: Milk and Milk Products Surveys.

OMB Control Number: 0535–0020.

Expiration Date of Approval: 03/31/01.

Type of Request: Intent to Seek Approval to Extend an Information Collection.

Abstract: The primary objective of the National Agricultural Statistics Service is to prepare and issue state and national estimates of crop and livestock production. The Milk and Milk Products Surveys obtain basic agricultural statistics on milk production and manufactured dairy products from farmers and processing plants throughout the nation. Data are gathered for milk production, dairy products, evaporated and condensed milk, manufactured dry milk, and manufactured whey products. Milk production and manufactured dairy products statistics are used by the U.S. Department of Agriculture to help administer programs and by the dairy industry in planning, pricing, and projecting supplies of milk and milk products. This is a request to extend approval for the information collection for 3 years, including the recent addition of cream/milkfat to the dairy product prices surveys.

These data will be collected under the authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by section 1770 of the Food Security Act of 1985, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 8 minutes per response.

Respondents: Farms and businesses.

Estimated Number of Respondents: 44,689.

Estimated Total Annual Burden on Respondents: 24,223 hours.

Copies of this information collection and related instructions can be obtained without charge from Ginny McBride, the Agency OMB Clearance Officer, at (202) 720–5778.

Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to: Ginny McBride, Agency OMB Clearance Officer, U.S. Department of Agriculture, Room 5336A South Building, 1400 Independence Avenue SW., Washington, DC 20250–2009 or gmcbride@nass.usda.gov.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, D.C., January 2, 2001.

Rich Allen,

Associate Administrator.

[FR Doc. 01–1266 Filed 1–16–01; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF COMMERCE

[I.D. 011001C]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Licensing of Private Land Remote-Sensing Space Systems.

Form Number(s): None.

OMB Approval Number: 0648-0174.

Type of Request: Regular submission.

Burden Hours: 314.

Number of Respondents: 13.

Average Hours Per Response: 40 hours for a license application, 10 hours for a license amendments, 2 hours for a notification of a foreign agreement, 1 hour for an executive summary, 2 hours for a notification of the demise of a systems or of a decision to discontinue operations, 2 hours for a notification of any operational deviation, 5 hours for a submission of a data collection restriction plan, 3 hours for submission of an operational plan for restricting collection or dissemination of information of Israeli territory, 3 hours for submission of a data flow diagram, 1 hour for submission of satellite subsystem drawings, 3 hours for submission of final imaging system specifications, 2 hours for submission of spacecraft operational information, 2 hours for notification of a disposition/orbital debris change, 2 hours for notification of planned purges of information, 3 hours for an operational quarterly report, 8 hours for an annual compliance audit, and 10 hours for an annual operational audit.

Needs and Uses: NOAA has established requirements for the licensing of private operators of remote-sensing space systems. The information in applications and subsequent reports is needed to ensure compliance with the Land remote-Sensing Policy Act of 1992 and with the national security and international obligations of the United States.

Affected Public: Business and other for-profit organizations.

Frequency: On occasion, quarterly, annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Forms Clearance Officer, (202) 482-3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at MClayton@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: January 9, 2001.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–1372 Filed 1–16–01; 8:45am]

BILLING CODE 3510–HR–S

DEPARTMENT OF COMMERCE

[I.D. 011001D]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Applications and Reporting Requirements for Small Takes of Marine Mammals by Specified Activities Under the Marine Mammal Protection Act.

Form Number(s): None.

OMB Approval Number: 0648-0151.

Type of Request: Regular submission.

Burden Hours: 7,512.

Number of Respondents: 44.

Average Hours Per Response: 483 hours for a request for new or renewal of regulations, 25.8 hours for an application for a Letter of Authorization, 200 hours for an application for Incidental Harassment Authorizations, 120 hours for a report for Incidental Harassment, and 93.6 hours for a report under a Letter of Authorization.

Needs and Uses: The taking by harassment, injury, or mortality of marine mammals is prohibited by the Marine Mammal Protection Act (MMPA) unless exempted or authorized by permit. The small-take program authorized the taking of marine mammals incidental to maritime activities (military, oil industry, shipping). It is the responsibility of the activity to determine if it might have a "taking" and, if it does, to apply for an authorization. Applications are necessary for NMFS to know that an authorization is needed and to determine whether authorization can be made under the MMPA. Reporting requirements are mandated by the MMPA and are necessary to ensure that determinations made in regard to the impact on marine mammals are valid.

Affected Public: Business and other for-profit organization, not-for-profit institutions, Federal government, and State, Local, or Tribal government.

Frequency: On occasion, annual, 90 days.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Forms Clearance Officer, (202) 482-3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at MClayton@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: January 9, 2001

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–1373 Filed 1–16–01; 8:45am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995, Public Law 104–13.

Bureau: International Trade Administration.

Title: Information for Certification Under FAQ 6 of the Safe Harbor Privacy Principles..

Agency Form Number: N/A.

OMB Number: 0625–0239.

Type of Request: Regular Submission.

Burden: 550 hours.

Number of Respondents: 1500.

Avg. Hours Per Response: 20–40 minutes.

Needs and Uses: In response to the European Commission Directive on Data Protection that restricts transfers of personal information from Europe to countries whose privacy practices are not deemed "adequate," the U.S. Department of Commerce has developed a "safe harbor" framework that will allow U.S. organizations to satisfy the European Directive's requirements and ensure that personal data flows to the United States are not interrupted. In this process, the Department of Commerce repeatedly consulted with U.S. organizations affected by the European directive and interested non-government organizations. On July 27, 2000, the European Commission issued its decision in accordance with Article 25.6 of the Directive that the Safe Harbor Privacy Principles provide adequate privacy protection. The safe harbor framework bridges the differences between the European Union (EU) and U.S. approaches to privacy protection. Under the safe harbor privacy framework, information is being collected in order to create a list of the organizations that have self-certified to the Principles. Organizations that have signed up to this list are deemed "adequate" under the Directive and do not have to provide further documentation to European officials. This list will be used by European Union organizations to determine whether further information and contracts will be needed for a U.S. organization to receive personally identifiable information. The decision to enter the safe harbor is entirely voluntary. Organizations that decide to participate in the safe harbor must comply with the safe harbor's requirements and publicly declare that they do so. To be assured of safe harbor

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benefits, an organization needs to self certify annually to the Department of Commerce in writing that it agrees to adhere to the safe harbor's requirements, which includes elements such as notice, choice, access, and enforcement. It must also state in its published privacy policy statement that it adheres to the safe harbor. This list will be used by European Union organizations to determine whether further information and contracts will be needed by a U.S. organization to receive personally identifiable information. It will be used by the European Data Protection Authorities to determine whether a company is providing "adequate" protection, and whether a company has requested to cooperate with the Data Protection Authority. The list will also be accessed when there is a complaint logged in the EU against a U.S. organization, and used by the Federal Trade Commission and the Department of Transportation to determine whether a company is part of the safe harbor. It will be accessed if a company is practicing "unfair and deceptive" practices and has misrepresented itself to the public. In addition, the list will be used by the Department of Commerce and the European Commission to determine if organizations are signing up to the list on a regular basis.

Affected Public: Businesses or other for-profit.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: David Rostker, (202) 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Forms Clearance Officer, (202) 482–3129, Department of Commerce, Room 6086, 14th and Constitution, NW., Washington, DC 20230 (or via the Internet at MClayton@doc.gov.

Written comments and recommendations for the proposed information collection should be sent to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503 within 30 days of the publication of this notice in the **Federal Register**.

Dated: January 11, 2001.

Madeleine Clayton,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–1386 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 1–2001]

Foreign-Trade Zone 82—Mobile, AL; Application for Subzone Status Austal USA, LLC (Shipbuilding and Repair)

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Mobile, Alabama, grantee of FTZ 82, requesting special-purpose subzone status for the shipbuilding facility of Austal USA LLC (Austal) [an Austal Holdings, Inc. (of Australia)/Bender Shipbuilding, Inc. joint venture] in Mobile, Alabama. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 9, 2001.

The Austal shipyard (13 acres, 200,000 sq.ft.) is located at 100 Dunlap Drive in Mobile, Alabama. The facility (150 employees) is used for the construction of aluminum commercial and military vessels for domestic and international customers. Foreign components that may be used at the Austal shipyard (representing up to 9% of vessel value) include propulsion units, engines and control systems, generators, pumps, air-conditioning systems, pipes, iron and steel mill products, aluminum bars/rods/profiles/plates/sheets/wire/tanks/containers, solenoids, valves, multimeters, signaling equipment, articles of rubber, twine, glass, prefabricated structures, stoves/ranges, electric motors, navigation and electronic equipment, propellers, transmission shafts, lighting and electrical equipment, panels, consoles, printed circuit assemblies, regulating/controlling equipment, and telephonic apparatus (2000 duty rate range: free—14.9%, *ad valorem*).

FTZ procedures would exempt Austal from Customs duty payments on the foreign components (except steel mill products) used in export activity. On its domestic sales, the company would be able to choose the duty rate that applies to finished oceangoing vessels (duty free) for the foreign-origin components noted above. The manufacturing activity conducted under FTZ procedures would be subject to the "standard shipyard restriction" applicable to foreign-origin steel mill products (*e.g.*, angles, pipe, plate), which requires that Customs duties be paid on such items. The application indicates that the savings from FTZ procedures would help improve the facility's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and three copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 19, 2001. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period (to April 3, 2001).

A copy of the application will be available for public inspection at the following locations:

Office of the Port Director, U.S. Customs Service, Suite 3004, 150 North Royal Street, Mobile, AL 36602

Office of the Executive Secretary, Foreign-Trade Zones Board, room 4008, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230

Dated: January 9, 2001.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 01–1384 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 2–2001]

Foreign-Trade Zone 29—Louisville, KY; Application for Subzone ISP Chemicals Inc. (Chemical Plant) Calvert City, KY

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Louisville & Jefferson County Riverport Authority, grantee of FTZ 29, requesting special-purpose subzone status for the chemical plant facilities of ISP Chemicals Inc., located in Calvert City, Kentucky. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 9, 2001.

The facility is located on Highway 95, Calvert City, Kentucky. The application is requesting the use of zone procedures only for the portion of the facility that processes butanediol (B1D) into butyrolactone (BLO). This portion of the facility (4 acres, 525 employees) has the capacity to produce 210,000 pounds per day of BLO (HTS 2932.29.50 and 3824.90.47; duty rate 3.7%). Some 60 percent of the B1D is sourced from abroad (HTS 2905.39.10; duty rate 7.9%).

FTZ procedures would exempt ISP from Customs duty payments on the foreign components used in export production. Some 35 percent of the BLO produced from the imported B1D in 1999 was exported. On its domestic sales, ISP would be able to choose the duty rates during Customs entry procedures that apply to BLO (3.7%) for the foreign input noted above. The request indicates that the savings from FTZ procedures would help improve the plant's international competitiveness.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 19, 2001. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to April 3, 2001.

A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce, Export Assistance Center, 601 West Broadway, Room, 634B, Louisville, KY 40202

Office of the Executive Secretary, Foreign-Trade Zones Board, Room 4008, U.S. Department of Commerce, 14th and Pennsylvania Avenue, NW., Washington, DC 20230

Dated: January 10, 2001.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 01–1385 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1135]

Expansion of Foreign-Trade Zone 46, Cincinnati, OH Area

Pursuant to its authority under the Foreign-Trade Zones Act (the Act) of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

WHEREAS, the Greater Cincinnati Foreign Trade Zone, Inc. (GCFTZ), grantee of FTZ 46, submitted an application to the Board for authority to expand FTZ 46—Site 3 (Clermont County Industrial Park) to include three additional parcels (FTZ Doc. 44–2000, filed 7–27–00);

WHEREAS, notice inviting public comment was given in the **Federal Register** (64 FR 47712, 8–3–00) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

WHEREAS, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the Act and the Board's regulations are satisfied, and that the proposal is in the public interest;

NOW, THEREFORE, the Board hereby authorizes the grantee to expand its zone as requested in the application, subject to the Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 29th day of December 2000.

Richard W. Moreland,

Acting Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Pierre V. Duy,

Acting Executive Secretary.

[FR Doc. 01–1383 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–428–817]

Certain Cut-to-Length Carbon Steel Plate from Germany; Final Results of Countervailing Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Countervailing Duty Administrative Reviews.

SUMMARY: On September 8, 2000, the Department of Commerce (the Department) published in the **Federal Register** its preliminary results of administrative reviews of the countervailing duty order on certain cut-to-length carbon steel plate from Germany for the periods calendar year 1997 and calendar year 1998 (65 FR 54496). The Department has now completed these administrative reviews in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). For information on the net subsidy for each reviewed company, and for all non-reviewed companies, please see the "Final Results of Review" section of this notice. We will instruct the U.S. Customs Service (Customs) to assess countervailing duties as detailed in the "Final Results of Review" section of this notice.

EFFECTIVE DATE: January 17, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Copyak, Office of AD/CVD Enforcement VI, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 CFR 351.213(b), these administrative reviews cover only those producers or exporters of the subject merchandise for which the administrative reviews were specifically requested. Accordingly, these administrative reviews cover exporter Novosteel SA and producer Reiner Brach GmbH and Co. KG. We received timely allegations of additional subsidies, including allegations of upstream subsidies. We initiated examinations of three of these alleged subsidy programs and determined not to initiate examinations of the alleged upstream subsidy programs. *See* memorandum to Melissa G. Skinner, Director, Office of AD/CVD Enforcement VI, from Team, entitled *1997 and 1998 Administrative Reviews of the Countervailing Duty Order on Certain Cut-to-Length Carbon Steel Plate from Germany: Memorandum Regarding Affiliation, Cross-ownership, Upstream Subsidy Allegations, and Other Subsidy Allegations*, dated August 23, 2000. (This memorandum is on file in public version form in the public file room of room B–099 of the main Commerce building.) These administrative reviews cover 39 programs and the periods calendar year 1997 and calendar year 1998.

On September 8, 2000, the Department published in the **Federal Register** its preliminary results of administrative reviews. *See Certain Cut-to-Length Carbon Steel Plate From Germany; Preliminary Results of Countervailing Duty Administrative Reviews*, 65 FR 54496 (*Preliminary Results*). We invited interested parties to comment on the *Preliminary Results*. We received comments on October 10, 2000, and on October 27, 2000.

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions of the Act, as amended by the Uruguay Round Agreements Act (URAA) effective January 1, 1995. The

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Department is conducting these administrative reviews in accordance with section 751(a) of the Act. In addition, unless otherwise indicated, all citations to the Department's regulations reference 19 CFR part 351 (1999).

Scope of the Review

The merchandise subject to these administrative reviews includes hot-rolled carbon steel universal mill plates (*i.e.*, flat-rolled products rolled on four faces or in a closed box pass, of a width exceeding 150 millimeters but not exceeding 1,250 millimeters and of a thickness of not less than 4 millimeters, not in coils and without patterns in relief), of rectangular shape, neither clad, plated nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances; and certain hot-rolled carbon steel flat-rolled products in straight lengths, of rectangular shape, hot rolled, neither clad, plated, nor coated with metal, whether or not painted, varnished, or coated with plastics or other nonmetallic substances, 4.75 millimeters or more in thickness and of a width which exceeds 150 millimeters and measures at least twice the thickness, as currently classifiable in the HTSUS under item numbers (7208.40.3030), (7208.40.3060), (7208.51.0030), (7208.51.0045), (7208.51.0060), (7208.52.0000), (7208.53.0000), (7208.90.0000), (7210.70.3000), (7210.90.9000), (7211.13.0000), (7211.14.0030), (7211.14.0045), (7211.90.0000), (7212.40.1000), (7212.40.5000), (7212.50.0000). Included in these administrative reviews are flat-rolled products of non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process (*i.e.*, products which have been "worked after rolling")—for example, products which have been beveled or rounded at the edges. Excluded from these reviews is grade X–70 plate. Also excluded from these administrative reviews is certain carbon cut-to-length steel plate with a maximum thickness of 80 mm in steel grades BS 7191, 355 EM, and 355 EMZ, as amended by Sable Offshore Energy Project specification XB MOO Y 15 0001, types 1 and 2.

Analysis of Programs

Programs Determined To Be Not Used

We examined the following programs and determined, based on the questionnaire responses, that the producer and/or exporter of the subject merchandise did not apply for or receive benefits under these programs during the periods of review:

1. Capital Investment Grants
2. Investment Premium Act
3. Joint Scheme: Improvement of Regional Economic Structure—GA Investment Grants and Other GA Subsidies
4. Ruhr District Action Program
5. Aid for Closure of Steel Operations
6. Joint Program: Upswing East
7. Freight Programs under the Special Subsidies for Companies in the Zonal Border Area
8. Loan Guarantees under Treuhandanstalt Subsidies
9. Long-term Loans from the Kreditanstalt fur Wiederaufbau (KfW)
10. Tax Programs under Special Subsidies for Companies in the Zonal Border Area
11. Structural Improvement Aids
12. ECSC Article 54 Loans
13. ECSC Article 54 Interest Rebates
14. ECSC Redeployment Aid Under Article 56(2)(b)
15. ECSC Article 54 Loans
16. ECSC Article 54 Interest Rebates
17. Loans with Reduced Interest Rates under the Steel Restructuring Plan
18. Federal and State Government Loan Guarantees under the Steel Restructuring Plan
19. Special Ruhr Plan
20. Zukunftsinitiative Montaregionen (ZIM)
21. Kreditanstalt fur Wiederaufbau (KfW) Investment Loans for Eastern Germany
22. Deutsche Ausglechsbank Investment Loans for Eastern Germany
23. European Recovery Program Loans for Eastern Germany
24. Loan Guarantee Program Loans for Eastern Germany
25. Peine-Salzgitter Profit Transfer Agreement and Other Operation Loss Subsidies
26. Elimination of Duisburg Harbor Tolls
27. Export Credits at Preferential Rates
28. Miscellaneous Tax Subsidies
29. Loans from the Government of Nordrhein-Westphalen
30. Tax Subsidies for Eastern Germany
31. European Investment Bank Loans and Loan Guarantees
32. New Community Instrument Loans
33. European Regional Development Fund Aid
34. Nordrhein-Westphalen's Air Pollution Control Program
35. ECSC Article 54 Loan Guarantees
36. ECSC Article 56 Conversion Loans
37. European Social Funds Grants
38. Assistance Measures for the Companies within the Steel Industry to Partially Compensate for Costs of the Social Plans
39. Social Aid for the Workers in the Coal and Steel Industries

Analysis of Comments Received

The comments submitted by interested parties are addressed in the "Issues and Decision Memorandum" (Decision Memorandum) from Holly A. Kuga, Acting Deputy Assistant Secretary, Import Administration, to Troy H. Cribb, Assistant Secretary for Import Administration, dated January 8, 2000, which is hereby adopted by this notice. A list of the issues addressed is attached to this notice as Appendix I. The Decision Memorandum is a public document which is on file in room B–099 of the Main Commerce Building and can be accessed via the internet at the website *http://ia.ita.doc.gov/frn* and under the heading "Germany." The paper copy and electronic version of the Decision Memorandum are identical in content.

Final Results of Administrative Reviews

In accordance with 19 CFR 351.221(b)(5), we calculated an individual subsidy rate for the producer/exporter subject to these administrative reviews. For the periods calendar year 1997 and calendar year 1998, we determine the net subsidy for Novosteel SA/Reiner Brach GmbH and Co. KG to be 0.00 percent *ad valorem*.

As provided for in the Act and 19 CFR 351.106(c)(1), any rate less than 0.5 percent *ad valorem* in an administrative review is *de minimis*. Accordingly, no countervailing duties will be assessed. The Department will instruct Customs to liquidate, without regard to countervailing duties, shipments of the subject merchandise from Novosteel SA produced by Reiner Brach GmbH and Co. KG, exported on or after January 1, 1997 through December 31, 1997 and January 1, 1998 through December 31, 1998. Also, the cash deposits for this producer will be zero.

Because the URAA replaced the general rule in favor of a country-wide rate with a general rule in favor of individual rates for investigated and reviewed companies, the procedures for establishing countervailing duty rates, including those for non-reviewed companies, are now essentially the same as those in antidumping cases, except as provided for in section 777A(e)(2)(B) of the Act. The requested review will normally cover only those companies specifically named. *See* 19 CFR 351.213(b). Pursuant to 19 CFR 351.212(c), for all companies for which a review was not requested, duties must be assessed at the cash deposit rate, and cash deposits must continue to be collected, at the rate previously ordered. As such, the countervailing duty cash deposit rate applicable to a company can no longer change, except pursuant to a request for a review of that company. *See Federal-Mogul Corporation and The Torrington Company* v. *United States*, 822 F.Supp. 782 (CIT 1993) and *Floral Trade Council* v. *United States*, 822 F.Supp. 766 (CIT 1993) (interpreting 19 CFR 353.22(e), the prior antidumping regulation on automatic assessment, which was identical to 19 CFR 355.22(g)). Therefore, the cash deposit rates for all companies except those covered by these reviews will be unchanged by the results of these reviews.

We will instruct Customs to continue to collect cash deposits for non-reviewed companies at the most recent company-specific or country-wide rate applicable to the company. Accordingly, the cash deposit rates that will be applied to non-reviewed companies covered by this order will be the rate for that company established in the most recently completed administrative proceeding conducted under the URAA. If such a review has not been conducted, the rate established in the most recently completed administrative proceeding pursuant to the statutory provisions that were in effect prior to the URAA amendments is applicable. *See Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Germany*, 58 FR 37315 (July 9, 1993). This rate shall apply to the non-reviewed companies until a review of a company assigned these rates is requested. In addition, for the periods calendar year 1997 and calendar year 1998, the assessment rates applicable to all non-reviewed companies covered by this order are the cash deposit rates in effect at the time of entry.

This notice serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These administrative reviews and this notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 8, 2001.

Troy H. Cribb,

Assistant Secretary for Import Administration.

APPENDIX 1—Issues Discussed in Decision Memorandum

Analysis of Comments

1. Upstream Subsidy Allegations
2. Need to Conduct Verification
3. Attribution of Subsidies

[FR Doc. 01–1382 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 011001A]

Small-craft Facility Questionnaire

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Proposed information collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 19, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Forms Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington, DC 20230 (or via Internet at MClayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lyn Preston, Chief, Nautical Data Branch, Marine Chart Division, N/CS26, Room 7350, 1315 East-West Highway, Silver Spring, MD 20910-3282 (phone 301-713-2737, ext. 123 or e-mail Lyn.Preston@noaa.gov).

SUPPLEMENTARY INFORMATION:

I. Abstract

NOAA's National Ocean Services produces nautical charts to ensure safe navigation. Small-craft charts are designed for recreational boaters and include information on local marine facilities and the services they provide (fuel, repairs, etc.). Information must be gathered from marinas to update the information provided to the public.

II. Method of Collection

Forms are sent to marinas when the relevant chart is to be updated. Forms are also made available at boat shows.

III. Data

OMB Number: 0648-0021.
Form Number: NOAA Form 77-1.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 1,600.
Estimated Time Per Response: 8 minutes.
Estimated Total Annual Burden Hours: 213.
Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 9, 2001

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–1370 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–JT–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 011001B]

Observer Workshop Survey

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Proposed information collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing

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effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 19, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Forms Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington, DC 20230 (or via Internet at MClayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Vicki Cornish or Margaret Toner, NMFS, F/ST1, 1315 East-West Highway; Silver Spring, MD 20910 (phone 301-713-2328, ext. 163).

SUPPLEMENTARY INFORMATION:

I. Abstract

NOAA Fisheries hosted two observer workshops, in 1998 and 2000, which brought together managers and scientists from the United States, Canada and other countries to share ideas and resolve key issues of common interest regarding fishery observer programs. In 2002, NOAA Fisheries will be hosting another observer workshop. The purpose of the collection is to gather information from participants in the previous workshops and from new potential participants in order to plan the format and content for the next observer workshop such that it will provide the greatest benefit to the performance of the NOAA Fisheries observer program.

II. Method of Collection

The information will be collected by having a survey form available on a NOAA web site.

III. Data

OMB Number: None.

Form Number: None.

Type of Review: Regular submission.

Affected Public: State, local, or tribal government; business and other for-profit organizations; not-for-profit institutions, individuals.

Estimated Number of Respondents: 350 (every two years).

Estimated Time Per Response: 15 minutes.

Estimated Total Annual Burden Hours: 44.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 9, 2001.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–1371 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 011001E]

Coast Pilot Report

AGENCY: National Oceanic and Atmospheric Administration (NOAA).

ACTION: Proposed information collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 19, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Forms Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue NW, Washington DC 20230 (or via Internet at MClayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Oren Stembel, N/CS51, Room 7532, 1315 East-West Highway, Silver Spring, MD 20910-3282 (phone 301-713-2750, ext. 204; e-mail Oren.Stembel@noaa.gov).

SUPPLEMENTARY INFORMATION:

I. Abstract

NOAA produces the U.S. Coast Pilot, a series of nine books that supplement marine nautical charts. The Coast Pilot contains information essential to navigators in U.S. coastal and intra-coastal waters but that cannot be shown graphically on charts. The Coast Pilot Report form is offered to the public as a means for recommending changes to the publication.

II. Method of Collection

A paper form is used.

III. Data

OMB Number: 0648-0007.

Form Number: NOAA Form 77-6.

Type of Review: Regular submission.

Affected Public: Individuals or households.

Estimated Number of Respondents: 100.

Estimated Time Per Response: 30 minutes.

Estimated Total Annual Burden Hours: 50.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 9, 2001.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 01–1374 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–JT–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010901C]

Marine Mammals: Draft Environmental Assessment on Allocating Gray Whales to the Makah Tribe for the years 2001 and 2002

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability and request for comments.

SUMMARY: NMFS announces the availability of a Draft Environmental Assessment (EA) that examines the environmental consequences of issuing the International Whaling Commission (IWC) quota for gray whales to the Makah Tribe for the years 2001 and 2002. NMFS has not identified a preferred alternative in this draft EA and is soliciting comments on the draft EA. The Draft EA considers four alternatives regarding the issuance of the IWC quota to the Makah Tribe.

DATES: Comments on the EA must be received by February 16, 2001. A public hearing on this draft EA will be held in Seattle, WA on Thursday, February 1, 2001, at 6:00 p.m. The public hearing will be held at the Sand Point Magnuson Park Auditorium, 74th Street Entrance, 7400 Sand Point Way NE, Seattle, Washington.

ADDRESSES: Comments on the draft EA should be addressed to Cathy E. Campbell, NOAA/NMFS, Office of Protected Resources, 13th Floor, 1315 East-West Hwy, Silver Spring, MD 20910. Mark the outside of the envelope with "Comments on Makah EA." Comments received over the Internet or by electronic mail will not be accepted. Copies of the EA and directions to the public hearing may be obtained over the internet at http://www.nmfs.noaa.gov/prot—res/prot—res.html under "New Arrivals".

FOR FURTHER INFORMATION CONTACT: Cathy Campbell, 301–713–2322.

SUPPLEMENTARY INFORMATION: Prior to the 1997 Annual International Whaling Commission (IWC) Meeting, NMFS formally analyzed the environmental impacts of a decision to support or not support whaling, and to determine whether an annual subsistence quota of up to five Eastern Pacific gray whales would significantly affect the quality of the human environment. A draft EA was distributed for public comment on August 22, 1997. After reviewing and addressing the comments received, NMFS issued a final EA and Finding of No Significant Impact on October 17, 1997.

At its 1997 annual meeting, the IWC approved a quota of 620 gray whales for an aboriginal subsistence harvest during the years 1998 through 2002. The basis for the quota was a joint request by the Russian Federation (for a total of 600 whales) and the United States (for a total of 20 whales). In 1998 and 1999, NOAA granted an allocation of up to five whales a year to the Makah Indian Tribe, whose subsistence and ceremonial needs had been the foundation of the U.S. request to the IWC.

U.S. Congressman Jack Metcalf, Breach Marine Protection, and several other plaintiffs brought a lawsuit, *Metcalf* v. *Daley*, in October 1997, alleging that the U.S. Government had violated the National Environmental Policy Act (NEPA), the Whaling Convention Act, and other statutes. In September 1998, the U.S. District Court for the Western District of Washington ruled in favor of the U.S. Government on all issues.

On June 9, 2000, the Ninth Circuit Court of Appeals overturned one aspect of that decision, ruling that the 1997 EA should have been completed before the U.S. and the Makah Tribe entered into a cooperative agreement. That agreement had provided that, if the Tribe prepared an adequate needs statement documenting a cultural and subsistence need to harvest gray whales, NOAA would request a quota of gray whales from the IWC. Two judges on a three-judge panel held that the timing of the EA, which was completed after the 1996 agreement was signed and before the 1997 annual meeting of the IWC, may have predisposed the preparers to find that the whaling proposal would not significantly affect the environment. The Court ordered NOAA to set aside that finding and comply with NEPA under circumstances that would ensure an objective evaluation of the environmental consequences of the gray whale harvest.

Following the Court action, NOAA rescinded its cooperative agreement with the Makah Tribe on August 11, 2000. NOAA subsequently set the gray whale quota for 2000 at zero (65 FR 75186, December 1, 2000), pending completion of its NEPA analysis.

The National Environmental Policy Act (NEPA) requires that federal agencies conduct an environmental analysis of their actions to determine if the actions may affect the environment. Accordingly, NMFS prepared a draft EA that explores the environmental consequences of four alternatives: (1) Granting the Makah Tribe the IWC quota with restrictions to target the hunt on migrating whales (similar to the 1999 regime); (2) Granting the Makah Tribe the IWC quota with restrictions that would allow a limited hunt on the gray whale summer feeding aggregation; (3) Granting the Makah Tribe the IWC quota without time-area restrictions; and (4) (No Action) - not granting the Makah Tribe the IWC quota.

The draft EA was prepared in accordance with NEPA and implementing regulations at 40 CFR parts 1500 through 1508 and NOAA guidelines concerning implementation of NEPA found in NOAA Administrative Order 216–6.

NMFS is soliciting public comments on this draft EA. Oral and written comments may be presented at the public hearing [see **DATES** and **ADDRESSES**]. Written comments on the draft EA may also be sent to the previously listed address by February 16, 2001. Further details or a copy of the EA can be obtained from the internet address above [see **ADDRESSES**].

Special Accommodations

The public hearing will be physically accessible to those with disabilities. Requests for sign language interpretation or other aids should be directed to C. Campbell at least 10 days prior to the hearing date (see **ADDRESSES**).

Dated: January 10, 2001.

Wanda L. Cain,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 01–1354 Filed 1–11–01; 3:33 pm]

BILLING CODE: 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 120400B]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Fishery Management Plan for the Dolphin and Wahoo Fishery of the Atlantic, Caribbean, and Gulf of Mexico

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

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Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of intent to prepare a draft environmental impact statement (DEIS); request for comments.

SUMMARY: The South Atlantic Fishery Management Council (South Atlantic Council) intends to prepare a DEIS to assess the impacts on the natural and human environment of the dolphin and wahoo fishery and of the management measures proposed for this fishery under the draft Fishery Management Plan for the Dolphin and Wahoo Fishery of the Atlantic, Caribbean and Gulf of Mexico. The purpose of this notice is to solicit public comments on the scope of the issues to be addressed in the DEIS.

ADDRESSES: Written comments on the scope of the DEIS and requests for additional information on the management measures proposed for the management of dolphin and wahoo in the Atlantic Ocean, Caribbean Sea, and Gulf of Mexico should be sent to the South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407-4699; phone: 843-571-4366; fax: 843-769-4520.

DATES: Written comments on the scope of the issues to be addressed by the DEIS should be received by the Council by February 16, 2001.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, 843-571-4366, or Steve Branstetter, 727-570-5305.

SUPPLEMENTARY INFORMATION: The South Atlantic Council is jointly preparing with the Gulf of Mexico Fishery Management Council (Gulf of Mexico Council) and the Caribbean Fishery Management Council (Caribbean Council) a draft Fishery Management Plan for the Dolphin and Wahoo Fishery of the Atlantic, Caribbean and Gulf of Mexico (FMP) The New England Fishery Management Council and the Mid-Atlantic Fishery Management Council are also cooperating in the FMP preparation.

The South Atlantic, Gulf of Mexico, and Carribean Councils intend that the FMP take a precautionary approach in conserving the dolphin and wahoo fishery resources throughout their range in the exclusive economic zone (EEZ) of the Atlantic, Gulf of Mexico, and Caribbean Sea. The FMP would have management objectives for the achievement of optimum yield from the dolphin and wahoo resources and the maintenance of current allocations among user groups. A draft environmental impact statement (DEIS) will be integrated into the draft FMP document.

The DEIS will describe the FMP's proposed management measures and their reasonable alternatives and will assess the environmental impacts of these proposed and alternative measures. Based on considerable previous public input (see reference below to public hearings held to date on a preliminary draft of the FMP/DEIS), the South Atlantic, Gulf of Mexico, and Caribbean Councils have already identified a number of proposed FMP measures and their alternatives. The proposed management units for dolphin and wahoo would be defined as the populations of each species throughout their full management range in the Atlantic, Gulf of Mexico, and Caribbean EEZ. Alternative management units considered will include the establishment of three separate units for each species based on each Council's geographical area of jurisdiction. The DEIS will assess the environmental impacts of the FMP's considered options for requiring dealer, vessel, and operator permits to participate in the fishery as well as the effects of any qualifying criteria, such as prior levels of participation in the fishery, for obtaining and maintaining permits. The DEIS will also evaluate the environmental impacts of the FMP's considered alternatives for reporting requirements. The DEIS will assess the impacts of the FMP's proposed and alternative biologically acceptable values, based on either biomass or fishing mortality rates, that define maximum sustainable yield, optimum yield, and overfishing and overfished conditions. The FMP and DEIS will identify and describe essential fish habitat (EFH) and EFH Habitat Areas of Particular Concern (EFH HAPCs) for dolphin and wahoo. The DEIS will assess the environmental impacts associated with the proposed and alternative EFH and EFH HAPCs; EFH/EFH HAPCs alternatives considered may include specific locales that are important to the continued health of the dolphin and wahoo stocks or areas of importance to a critical life stage of these species.

The FMP would establish a framework procedure allowing the South Atlantic, Gulf of Mexico, and Caribbean Councils to recommend new management measures and adjustments for existing measures, within specified limits, that could be approved and implemented (under the framework procedure) without having to amend the FMP. Also, the South Atlantic, Gulf of Mexico, and Caribbean Councils intend that the FMP provide each Council with the authority to recommend independently the establishment of harvesting restrictions for its respective area of jurisdiction. Such area-specific measures generally would be proposed, approved, and implemented under the FMP's framework procedure. The environmental impacts of measures proposed later under the framework procedure would be assessed at the time of proposal.

To maintain healthy stocks of both dolphin and wahoo in the Atlantic, the South Atlantic Council intends that the FMP initially propose commercial trip limits, recreational bag and boat limits, minimum size limits, and allowable gears for the dolphin and wahoo fishery within its area of the EEZ. The Gulf of Mexico Council is considering several measures that would apply only to the Gulf of Mexico EEZ; these include establishment of specific dates for the fishing year and prohibition of the sale of recreationally caught fish. The DEIS will assess the environmental impacts of all of the FMP's proposed area-specific measures and their considered alternatives.

The DEIS will evaluate the impacts of the FMP's proposed allocation of the majority of the catch to the recreational sector. This allocation is intended to preserve the historical contribution of the recreational sector to the total fishery. To ensure economic stability for the established commercial fishery, the FMP would propose a restriction on or a prohibition of the sale of fish caught in the recreational fishery.

Based on input received during 17 public hearings held to date on a preliminary draft of the FMP/DEIS, the South Atlantic Council intends to prepare a revised draft FMP and to finalize the DEIS covering its environmental impacts. Because of the previous considerable opportunities for public input, the South Atlantic Council has scheduled no specific scoping meetings for the DEIS. However, the South Atlantic Council is requesting written comments on the scope of the issues to be addressed in the DEIS.

Once the South Atlantic Council completes the DEIS, it will submit it to NMFS for filing with the Environmental Protection Agency (EPA). EPA will publish in the **Federal Register** a notice of availability of the DEIS for public comment. This procedure is pursuant to the Council on Environmental Quality's regulations for implementing the procedural provisions of The National Environmental Policy Act (NEPA; 40 CFR Parts 1500–1508) and to NOAA's Administrative Order 216-6 regarding NOAA's compliance with NEPA.

The South Atlantic, Gulf of Mexico, and Caribbean Fishery Management Councils intend to consider public comments received on the DEIS before adopting final management measures for a final FMP. The South Atlantic Council intends to prepare a final environmental impact statement (FEIS) in support of the final FMP. The three Councils would then submit the final FMP/FEIS to NMFS for Secretarial review, approval, and implementation under the Magnuson-Stevens Act. During Secretarial review, NMFS will file the FEIS with EPA for announcement of a final comment period on the FEIS (again, through publication of a notice in the **Federal Register**). This comment period will be concurrent with the Secretarial review period, during which NMFS will invite public comment on the final FMP and proposed implementing regulations (Secretarial review comment periods are announced through publication in the **Federal Register**). NMFS will consider all public comment received during the Secretarial review period, whether on the FMP, FEIS, or proposed regulations, prior to taking final agency action to approve, disapprove, or partially approve the FMP.

Copies of the draft FMP may be obtained by contacting Kim Iverson at the Council (see **ADDRESSES**).

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 10, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1378 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 000202023-1001-02; I.D. No.110200C]

RIN 0648-ZA78

Announcement of Funding Opportunity to Submit Proposals for the Coastal Ecosystem Research Project in the Northern Gulf of Mexico

AGENCY: Center for Sponsored Coastal Ocean Research/Coastal Ocean Program (CSCOR/COP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Announcement of funding opportunity for financial assistance for project grants and cooperative agreements.

SUMMARY: The purpose of this document is to advise the public that CSCOR/COP is soliciting 1-year and 2-year proposals for modeling, monitoring and retrospective studies of coastal ecosystem research in the Northern Gulf of Mexico (N-GOMEX). Funding is contingent upon the availability of Federal appropriations. It is anticipated that projects funded under this announcement will have an August 1, 2001, start date.

DATES: The deadline for receipt of proposals at the COP office is 3 p.m, EST, March 14, 2001. Note that late-arriving applications provided to a delivery service, on or before, March 13, 2001, with delivery guaranteed before 3 p.m.,EST, on March 14, 2001, will be accepted for review if the applicant can document that the application was provided to the delivery service with delivery to the address listed below (see **ADDRESSES**) guaranteed prior to the specified closing date and time; and in any event, the proposals are received in the COP office by 3 p.m. EST, no later than two business days following the closing date.

ADDRESSES: Submit the original and 10 copies of your proposal to Coastal Ocean Program Office (N-GOMEX 2001), SSMC3, 9th Floor, Station 9700, 1315 East-West Highway, Silver Spring, MD 20910. NOAA and COP Standard Form Applications with instructions are accessible on the COP Internet site (http://www.cop.noaa.gov) under the COP Grants Support Section, Part D, Application Forms for Initial Proposal Submission. Forms may be viewed, and in most cases, filled in by computer. All forms must be printed, completed, and mailed to CSCOR/COP with original signatures. Blue ink for original signatures is recommended but not required. If you are unable to access this information, you may call CSCOR/COP at 301-713-3338 to leave a mailing request.

FOR FURTHER INFORMATION CONTACT: Technical Information: Kenric Osgood, N-GOMEX 2001 Program Manager, COP Office, 301-713-3338/ext 135, Internet: Kenric.Osgood@noaa.gov

Business Management Information: Leslie McDonald, COP Grants Administrator, 301-713-3338/ext 137, Internet: Leslie.McDonald@noaa.gov

See **SUPPLEMENTARY INFORMATION** under the heading, ELECTRONIC ACCESS, for a listing of web sites pertaining to period hypoxia in the northern Gulf of Mexico.

SUPPLEMENTARY INFORMATION:

Electronic Access

The following web sites furnish results of studies concerning the periodic hypoxia associated with the northern Gulf of Mexico: http://www.aoml.noaa.gov/ocd/necop/, for results from the Nutrient Enhanced Coastal Ocean Productivity (NECOP) study and, http://www.nos.noaa.gov/Products/pubs—hypox.html for Gulf of Mexico hypoxia reports produced by the Committee on Environment and Natural Resources (CENR). Hard copies of reports from these studies can be obtained from the COP office.

A workshop report, U.S. GLOBEC report No. 19, is available from the following address or homepage: U.S. GLOBEC Coordinating Office, UMCES, Chesapeake Biological Laboratory, P.O. Box 38, Solomons, MD 20688; Phone: 410-326-7370; Fax: 410-326-7341; Internet: fogarty@usglobec.org and http://www.usglobec.org.

A listing of ongoing projects in the northern Gulf of Mexico funded by the COP are provided within the COP Internet Site at http://www.cop.noaa.gov/projects/GMX.htm

Background

Program Description

For complete Program Description and Other Requirements for the COP, see the General Grant Administration Terms and Conditions of the Coastal Ocean Program published in the **Federal Register** (65 FR 62706, October 19, 2000) and at the COP home page.

Coastal regions dominated by large rivers are disproportionately important to the biological production of the world's oceans, primarily because these rivers carry large amounts of "new" nitrogen. An important river-dominated coastal ecosystem in the U.S., which supports high primary and secondary production, is the one dominated by the Mississippi River in the northern Gulf of Mexico. Approximately 20 percent of the U.S. commercial fishery landings by dollar value are from the northern Gulf. Major recreational fisheries also exist in this region.

There is a strong relationship between riverine inputs (especially nutrients) and primary production, followed in turn by zooplankton production and fish production in a classic nutrient-phytoplankton-zooplankton-fish (NPZF) food web. Anthropogenic nitrogen loadings from the Mississippi River to the Gulf of Mexico have increased dramatically during the past several decades, which has led to changes in the ecosystem of the northern Gulf, including (1) an initial increase in overall biological production; (2) the annual development of an extensive zone of bottom water hypoxia during the summer stratified period; and (3) an apparent shift from a balanced pelagic/

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demersal fish community to one significantly more dominated by pelagic fisheries.

Several past and present programs have studied the seasonal hypoxia associated with the northern Gulf of Mexico. Notably, from 1990 to 1997, the COP supported a study on Nutrient Enhanced Coastal Ocean Productivity (NECOP); and the Committee on Environment and Natural Resources (CENR) recently completed an integrated assessment of Gulf of Mexico hypoxia. Results and reports of these studies can be found on the web sites or obtained from CSCOR/COP as listed under "Electronic Access" in the SUPPLEMENTARY INFORMATION section of this document.

A workshop was held in January 1999 to discuss relationships between the Mississippi River, the production of marine populations, and ecosystem parameters in the Gulf of Mexico; and to discuss how these relationships might be affected by changes in weather and climate. A report of the workshop, U.S. GLOBEC report No. 19, is available from the address or homepage provided under "Electronic Access" in the SUPPLEMENTARY INFORMATION section of this document

This solicitation for proposals will augment the initial phase of a program, started in fiscal year 2000, to examine the inter-relationships driving the Mississippi River-dominated Gulf of Mexico ecosystem. Abstracts of ongoing studies funded by CSCOR/COP in the northern Gulf of Mexico are available on the COP internet site that is provided in this document under "Electronuc Access" in the SUPPLEMENTARY INFORMATION section of this document. The planned suite of studies will enable improved predictions about future effects of nutrient loading, eutrophication, hypoxia, and climate change on the Gulf of Mexico ecosystem.

In order to fully develop a predictive capability, a more intensive 5-7 year program is being planned when additional funding becomes available. This complete program will include monitoring, retrospective studies, modeling and process field studies to identify relationships among ecosystem constituents.

The process studies will be nested within monitoring efforts which identify and measure important ecosystem components, and retrospective and modeling efforts which will place the field measurements into broader temporal and theoretical context.

The overall goal of the entire program is to understand and ultimately predict how changes in the physical, chemical and biological environment, including changes in climate, nutrient loading and hypoxia, will affect populations of marine animal species, especially economically and ecologically important species, in the northern Gulf of Mexico. The projects conducted as a result of this current solicitation for proposals will help guide the evolution of the future program.

Structure of the Research Program

CSCOR/COP intends to expand the initial research program, which was initiated in fiscal year 2000, with additional projects. Possible types of new projects include, in priority order, modeling, monitoring and retrospective studies. Subsequent announcements may solicit further proposals in these areas and for process field studies in the region, depending on the outcome of the proposed research solicited here and the levels of future appropriated funding.

Modeling studies are needed to provide a framework for studies in the northern Gulf of Mexico. Modeling activities will be used to guide further program development and identify important processes for the extensive fieldwork anticipated to follow this preliminary phase. Modeling studies may include: models that simulate impacts of varying nutrient flux on productivity and trophic response in the northern Gulf of Mexico ecosystem, including impacts to and responses of commercially and recreationally important fisheries; NPZF models; physical-biological coupled models of processes in the Gulf ecosystem influenced by the Mississippi River discharge, including transport and population dynamics of key zooplankton and fishery populations; models of oceanographic and climate influences on nutrients and their impact on Gulf productivity; models of biogeochemical cycling of nutrients within the Gulf and its relationship to the dynamics of organic carbon flux in the Gulf; and models of water column stability and hypoxic zone dynamics.

It is desirable for the modeling studies to be integrative or designed so that they can be fitted with other models to form an integrative whole. The goal is to build a predictive capability for the northern Gulf of Mexico ecosystem.

Proposed monitoring studies should provide calibration and validation data for modeling activities, but not duplicate ongoing activities. Monitoring studies could include shipboard surveys, multi-disciplinary mooring observations, drifters, and analysis of regional satellite data. Possible monitoring activities responsive to this announcement include physical or chemical observations or biological observations of distribution and abundance of key species, and their relation to hypoxia.

Proposed retrospective analyses should provide quantitative and detailed information on issues relevant to the objectives listed in the recent CENR reports. Examples include retrospective analyses of biological data concerning key animal populations; retrospective analyses of the coupling between transport and population dynamics of key species; and retrospective analyses of coupling between climate, drainage basin, and shelf oceanography. A better definition of the past, current, and potential impacts of hypoxia on both commercially and ecologically important species and ecosystems is needed.

Part I: Schedule and Proposal Submission

This announcement requests full proposals only. The provisions for proposal preparation provided here are mandatory. Proposals received after the published deadline or proposals that deviate from the prescribed format will be returned to the sender without further consideration. Information regarding this announcement, additional background information, and required Federal forms are available on the COP home page.

Full Proposals

Applications submitted in response to this announcement require an original proposal and 10 proposal copies at time of submission. This includes color or high-resolution graphics, unusually-sized materials (not 8.5" x 11" or 21.6 cm x 28 cm), or otherwise unusual materials submitted as part of the proposal. For color graphics, submit either color originals or color copies. The stated requirements for the number of proposal copies provide for a timely review process. Facsimile transmissions and electronic mail submission of full proposals will not be accepted.

Required Elements

All recipients must follow the instructions in the preparation of the CSCOR/COP application forms referenced later in this document in Part II: Further Supplementary Information, (10) Application forms. Each proposal must also include the following seven elements:

(1) *Signed summary title page*: The title page should be signed by the Principal Investigator (PI) and the institutional representative. The Summary Title page identifies the project's title starting with the acronym N-GOMEX 2001, a short title (less than 50 characters), and the lead PI's name and affiliation, complete address, phone, FAX, and E-mail information. The requested budget for each fiscal year should be included on the Summary Title page. Multi-institution proposals must include signed Summary Title pages from each institution.

(2) *One-page abstract/project summary*: The Project Summary (Abstract) Form, which is to be submitted at time of application, must include an introduction of the problem, rationale, scientific objectives and/or hypotheses to be tested, and a brief summary of work to be completed. The prescribed COP format for the Project Summary Form can be found on the COP Internet site under the COP Grants Support section, Part D.

The summary should appear on a separate page, headed with the proposal title, institution(s), investigator(s), total proposed cost, and budget period. It should be written in the third person. The summary is used to help compare proposals quickly and allows the respondents to summariz e these key points in their own words.

(3) *Statement of work/project description*: The proposed statement of work/project must be completely described, including identification of the problem, scientific objectives, proposed methodology, relevance to the program goals, and its scientific priorities. The project description section (including Relevant Results from Prior Support) should not exceed fifteen pages. Page limits are inclusive of figures and other visual materials, but exclusive of references and milestone chart.

Project management should be clearly identified with a description of the functions of each PI within a team. Environmental data must be submitted to the NOAA National Oceanographic Data Center. It is important to provide a full scientific justification for the research; do not simply reiterate justifications presented in this document. This section should also include:

(a) The objective for the period of proposed work and its expected significance;

(b) The relation to the present state of knowledge in the field and relation to previous work and work in progress by the proposing principal investigator(s);

(c) A discussion of how the proposed project lends value to the program goals, and

(d) Potential coordination with other investigators.

(e) References cited: Reference information is required. Each reference must include the name(s) of all authors in the same sequence in which they appear in the publications, the article title, volume number, page numbers, and year of publications. While there is no page limitation, this section should include bibliographic citations only and should not be used to provide parenthetical information outside of the 15-page project description.

(4) *Milestone chart*: Provide time lines of major tasks covering the duration of the proposed project, up to 24 months.

(5) *Budget and Application Forms*: Both NOAA and COP-specific application forms may be obtained at the COP Grants website. Forms may be viewed, and in most cases, filled in by computer. All forms must be printed, completed, and mailed to CSCOR/COP; original signatures in blue ink are encouraged. If applicants are unable to access this information they may call the CSCOR/COP grants administrator listed in the section FOR FURTHER INFORMATION CONTACT.

At time of proposal submission, all applicants must submit the Standard Form, SF-424 (Rev 7-97) Application for Federal Assistance, to indicate the total amount of funding proposed for the whole project period. Applicants must also submit a COP Summary Proposal Budget Form for each fiscal year increment. Multi-institution proposals must include a Summary Proposal Budget Form for each institution. Use of this budget form will provide for a detailed annual budget and for the level of detail required by the COP program staff to evaluate the effort to be invested by investigators and staff on a specific project. The COP budget form is compatible with forms in use by other agencies that participate in joint projects with COP and can be found on the COP home page under COP Grants Support, Part D. All applications must include a budget narrative and a justification to support all proposed budget categories. Ship time needs should be identified in the proposed budget. The SF-424A, Budget Information (Non-Construction) Form, will be requested only from those applicants subsequently recommended for award.

(6) *Biographical sketch*: Abbreviated curriculum vitae, two pages per investigator, must be included with each proposal. Include a list of up to five publications most closely related to the proposed project and up to five other significant publications. A list of all persons (including their organizational affiliation), in alphabetical order, who have collaborated on a project, book, article, or paper within the last 48 months must be included. If there are no collaborators, this should be so indicated. Students, post-doctoral associates, and graduate and postgraduate advisors of the PI must also be disclosed. This information is needed to help identify potential conflicts of interest or bias in the selection of reviewers.

(7) *Proposal format and assembly*: The original proposal should be clamped in the upper left-hand corner, but left unbound. The 10 copies can be stapled in the upper left-hand corner or bound on the left edge. The page margin must be one inch (2.5 cm) at the top, bottom, left and right, and the type face standard 12 points size must be clear and easily legible.

Part II: Further Supplementary Information

(1) *Program authorities*: For a list of all program authorities for the Coastal Ocean Program, see General Grant Administration Terms and Conditions of the Coastal Ocean Program published in the Federal Register (65 FR 62706, October 19, 2000) and at the COP home page. The specific authority cited for this announcement is 33 U.S.C. 1442.

(2) *Catalog of Federal Domestic Assistance Number*: 11.478 Coastal Ocean Program and 47.050 for the Directorate for Geosciences, National Science Foundation.

(3) *Program description*: For complete COP program descriptions, see General Grant Administration Terms and Conditions of the Coastal Ocean Program published in the **Federal Register** (65 FR 62706, October 19, 2000).

(4) *Funding availability*: Funding is contingent upon the availability of Federal appropriations. It is estimated that approximately $400,000 per fiscal year will be available for supporting studies proposed by submissions to this announcement. Priority for these funds will be given to proposals that promote balanced coverage of the science objectives stated under SUPPLEMENTARY INFORMATION, Structure of the Research Program.

If an application is selected for funding, NOAA has no obligation to provide any additional prospective funding in connection with that award in subsequent years. Renewal of an award to increase funding or extend the period of performance is based on satisfactory performance and is at the total discretion of the funding agency.

Publication of this document does not obligate the COP to any specific award or to any part of the entire amount of funds available. Recipients and

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subrecipients are subject to all Federal laws and agency policies, regulations, and procedures applicable to Federal financial assistance awards.

(5) *Matching requirements*: None.

(6) *Type of funding instrument*: Project Grants for non-Federal applicants; interagency transfer agreements or other appropriate mechanisms other than project grants or cooperative agreements for Federal applicants.

(7) *Eligibility criteria*: For complete eligibility criteria for the COP, see COP's General Grant Administration Terms and Conditions annual document in the **Federal Register** (65 FR 62706, October 19, 2000) and the COP home page. Eligible applicants are institutions of higher education, not-for-profit institutions, international organizations, state, local and Indian tribal governments and Federal agencies. COP will accept proposals that include foreign researchers as collaborators with a researcher who is affiliated with a U.S. academic institution, Federal agency, or other non-profit organization.

Applications from non-Federal and Federal applicants will be competed against each other. Proposals selected for funding from non-Federal applicants will be funded through a project grant or cooperative agreement under the terms of this notice. Proposals selected for funding from NOAA employees shall be effected by an intra-agency fund transfer. Proposals selected for funding from a non-NOAA Federal agency will be funded through an inter-agency transfer. PLEASE NOTE: Before non-NOAA Federal applicants may be funded, they must demonstrate that they have legal authority to receive funds from another Federal agency in excess of their appropriation. Because this announcement is not proposing to procure goods or services from applicants, the Economy Act (31 USC 1535) is not an appropriate legal basis.

(8) *Award period*: Full proposals should cover a project period of up to 2 years, with a start date of August 1, 2001. Multi-year project period funding may be funded incrementally on an annual basis; but once awarded, multi-year projects will not compete for funding in subsequent years. Each award shall require a Statement of Work which represents substantial accomplishments that can be easily separated into annual increments if prospective funding is not made available, or is discontinued.

(9) *Indirect costs*: If indirect costs are proposed, the total dollar amount of the indirect costs proposed in an application must not exceed the indirect cost rate negotiated and approved by a cognizant Federal agency prior to the proposed effective date of the award.

(10) *Application forms*: For complete information on application forms for the COP, see COP's General Grant Administration Terms and Conditions document in the Federal Register (65 FR 62706, October 19, 2000); the COP home page; and the information given under *Required Elements*, paragraph (5) Budget.

(11) *Project funding priorities*: For description of project funding priorities, see COP's General Grant Administration Terms and Conditions document in the **Federal Register** (65 FR 62706, October 19, 2000) and at the COP home page.

(12) *Evaluation criteria*: For complete information on evaluation criteria, see COP's General Grant Administration Terms and Condition document in the **Federal Register** (65 FR 62706, October 19, 2000) and at the COP home page.

(13) *Selection procedures*: For complete information on selection procedures, see COP's General Grant Administration Terms and Conditions Document in the **Federal Register** (65 FR 62706, October 19, 2000) and at the COP home page. All proposals received under this specific Document will be evaluated and ranked individually in accordance with the assigned weights of the above evaluation criteria by independent peer mail review.

(14) *Other requirements*: For a complete description of other requirements, see COP's General Grant Administration Terms and Conditions document in the **Federal Register** (65 FR 62706, October 19, 2000) and at the COP home page.

(15) *Pursuant to Executive Orders 12876, 12900 and 13021, the Department of Commerce, National Oceanic and Atmospheric Administration (DOC/NOAA) is strongly committed to broadening the participation of Historically Black Colleges and Universities, Hispanic Serving Institutions and Tribal Colleges and Universities in its educational and research programs. The DOC/NOAA vision, mission and goals are to achieve full participation by Minority Serving Institutions (MSI) in order to advance the development of human potential, to strengthen the nation's capacity to provide high-quality education, and to increase opportunities for MSIs to participate in, and benefit from, Federal financial assistance programs.* DOC/NOAA encourages all applicants to include meaningful participation of MSIs.

(16) Applicants are hereby notified that they are encouraged, to the greatest practicable extent, to purchase American-made equipment and products with funding provided under this program.

(17) Intergovernmental Review: Applications under this program are not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

(18) This notification involves collection-of-information requirements subject to the Paperwork Reduction Act (PRA). The use of Standard Forms 424, 424A, 424B, and SF-LLL has been approved by the Office of Management and Budget (OMB) under control numbers 0348-0043, 0348-0044, 0348-0040 and 0348-0046.

The following requirements have been approved by OMB under control number 0648-0384; a Summary Proposal Budget Form (30 minutes per response), a Project Summary Form (30 minutes per response), a standardized format for the annual Performance Report (5 hours per response), a standardized format for the Final Report (10 hours per response), and the submission of up to 20 copies of proposals (10 minutes per response). The response estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these requirements and the burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden, to Leslie.McDonald@noaa.gov. Copies of these forms and formats can be found on the COP home page under Grants Support sections, Parts D and F.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act, unless that collection displays a currently valid OMB control number.

Dated: January 10, 2001.

John Oliver

Director, Management and Budget Office, National Ocean Service.

[FR Doc. 01–1381 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–JS–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010901G]

Mid-Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Black Sea Bass Advisors and other members of the commercial fishing industry will hold a public meeting.

DATES: The meeting will be held on Thursday, February 1, 2001, from 10 a.m. until 4 p.m.

ADDRESSES: This meeting will be held at the Sheraton International Hotel, BWI Airport, 7032 Elm Road, Baltimore, MD; telephone: 410-859-3300.

Council address: Mid-Atlantic Fishery Management Council, Room 2115, 300 S. New Street, Dover, DE 19904.

FOR FURTHER INFORMATION CONTACT: Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council; telephone: 302-674-2331, ext. 19.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to discuss the problems and possible solutions associated with the commercial management system for black sea bass.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Joanna Davis at the Mid-Atlantic Council Office at least 5 days prior to the meeting date.

Dated: January 10, 2001.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1377 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010901F]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Council) Groundfish Management Team (GMT) will hold a working meeting which is open to the public.

DATES: The GMT working meeting will begin Tuesday, February 6, 2001 at 8 a.m. and may go into the evening until business for the day is completed. The meeting will reconvene from 8 a.m. to 5 p.m. Wednesday, February 7 and Thursday, February 8, from 8 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Council office, Conference Room, 2130 SW Fifth Avenue, Suite 224, Portland, OR; telephone: 503-326-6352.

Council address: Pacific Fishery Management Council, 2130 SW Fifth Avenue, Suite 224, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: Jim Glock, Groundfish Fishery Management Coordinator; telephone: (503) 326-6352.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT meeting is to review the groundfish management measures in place for the summer months and prepare recommendations for Council consideration, respond to assignments relating to implementation of the Council's groundfish strategic plan, and address other assignments relating to the groundfish management. The following specific items comprise the draft agenda (1) evaluate 2001 trip limits and other management measures; (2) assignments relating to the groundfish strategic plan, which may include limited entry for the open access fishery and permit stacking for limited entry trawl vessels; (3) complete and/or review rebuilding plans for canary rockfish, cowcod, lingcod, Pacific Ocean perch; (4) begin preparation of widow and darkblotched rockfish rebuilding plans; (5) evaluate management options for 2001; (6) review the fixed gear sablefish permit stacking proposal and analysis; (7) elect chair and vice chair for 2001; and (8) prepare a draft work plan for 2001.

Although non-emergency issues not contained in this agenda may come before the GMT for discussion, those issues may not be the subject of formal GMT action during this meeting. GMT action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the GMT's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 326-6352 at least 5 days prior to the meeting date.

Dated: January 10, 2001.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1376 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 010901D]

South Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a meeting of its Marine Reserves Committee in Charleston, SC.

DATES: The Marine Reserves Committee will meet February 6, 2001, from 7 p.m until 9 p.m., on February 7, from 8:30 a.m. until 5 p.m., and on February 8, from 8:30 a.m. until 10:30 a.m.

ADDRESSES: These meetings will be held at the Town and Country Inn, 2008 Savannah Highway, Charleston, SC 29407; telephone: 843-571-1000.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer;

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telephone: (843) 571-4366; fax: (843) 769-4520; email: kim.iverson@noaa.gov.

SUPPLEMENTARY INFORMATION: The Marine Reserves Committee will meet to develop recommendations to send to the full Council. The Committee will review the Council's current definition of a marine reserve, review the Council's goals for marine reserves, establish criteria necessary to meet the goals and draft an outline for the scoping document that will be used in the next phase of the process for utilizing marine reserves.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) by February 1, 2001.

Dated: January 10, 2001.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1375 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–22–S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Amendment of Coverage of Import Limits for Certain Part-Categories Produced or Manufactured in the People's Republic of China and Uruguay

January 10, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending coverage for import limits.

EFFECTIVE DATE: December 1, 2000.

FOR FURTHER INFORMATION CONTACT: Lori E. Mennitt, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

Certain tariff and statistical annotations have been amended in the Harmonized Tariff Schedule of the United States (HTS) in implementing Title V of the Trade and Development Act of 2000 (Public Law 106–2000). To facilitate implementation of the Uruguay Round Agreement on Textiles and Clothing and other textile agreements based upon the HTS, the tariff numbers in part-Category 410 B, which apply to imports from China and Uruguay, are being changed, as is a number in Category 440–M, which applies to imports from China. This change applies to imports entered for consumption or withdrawn from warehouse for consumption on and after December 1, 2000, regardless of the date of export.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to amend import controls for 2000 and 2001 for China and Uruguay and the current visa arrangement for China.

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 10, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directives issued to you on December 6, 1999, and December 20, 2000, by the Chairman, Committee for the Implementation of Textile Agreements, which established import controls for the People's Republic of China for agreement years 2000 and 2001, respectively. This directive also amends, but does not cancel, the directive issued to you on March 27, 1997, by the Chairman, Committee for the Implementation of Textile Agreements. That directive established an export visa arrangement for certain silk apparel, cotton, wool, man-made fiber, silk blend, and other vegetable fiber textiles and textile products, produced or manufactured in the People's Republic of China.

In addition, this directive amends, but does not cancel, the directives issued to you on October 21, 1999, and on November 2, 2000, by the Chairman, Committee for the Implementation of Textile Agreements, which established import controls for Uruguay for agreement years 2000 and 2001, respectively.

Effective on December 1, 2000, you are directed to make the changes shown below in the aforementioned directives for products entered in the United States for consumption or withdrawn from warehouse for consumption on and after December 1, 2000, for part-Categories 410–B and 440–M, regardless of the date of export:

Category	HTS change
410–B	
.....	Delete 5112.11.2030 and replace with 5112.11.3030 and 5112.11.3060.
.....	Delete 5112.11.2060 and replace with 5112.11.6030 and 5112.11.6060.
.....	Delete 5112.19.9010 and replace with 5112.19.6010 and 5112.19.9510.
.....	Delete 5112.19.9020 and replace with 5112.19.6020 and 5112.19.9520.
.....	Delete 5112.19.9030 and replace with 5112.19.6030 and 5112.19.9530.
.....	Delete 5112.19.9040 and replace with 5112.19.6040 and 5112.19.9540.
.....	Delete 5112.19.9050 and replace with 5112.19.6050 and 5112.19.9550.
.....	Delete 5112.19.9060 and replace with 5112.19.6060 and 5112.19.9560.
440–M	Delete 6203.21.0030 and replace with 6203.21.9030.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–1314 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DR–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Amendment of Coverage of an Import Limit and Visa and Certification Requirements for a Certain Part-Category Produced or Manufactured in the People's Republic of China

January 10, 2001.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending coverage for an import limit and visa and certification requirements.

EFFECTIVE DATE: January 1, 2001.

FOR FURTHER INFORMATION CONTACT: Lori E. Mennitt, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

To facilitate implementation of the Bilateral Textile Memorandum of Understanding dated February 1, 1997 between the Governments of the United States and the People's Republic of China (see 64 FR 69228, published on December 10, 1999) and the export visa arrangement dated February 1, 1997 (see 62 FR 15465, published on April 1, 1997) based upon the Harmonized Tariff Schedule (HTS), a certain HTS classification number is being changed for products in part-Category 666–C which are entered into the United States for consumption or withdrawn from warehouse for consumption on and after January 1, 2001, regardless of the date of export.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to amend all import controls and all visa and certification requirements for products exported from China in part-Category 666–C.

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 10, 2001.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 6, 1999 by the Chairman, Committee for the Implementation of Textile Agreements, which includes man-made fiber textile products in part-Category 666–C, produced or manufactured in China and imported into the United States on and after January 1, 2001, regardless of the date of export.

Also, this directive amends, but does not cancel, the directive issued to you on March 27, 1997 establishing visa and certification requirements for part-Category 666–C.

Effective on January 1, 2001, you are directed to make the changes shown below in the aforementioned directives for products entered in the United States for consumption or withdrawn from warehouse for consumption on and after January 1, 2001 for part-Category 666–C, regardless of the date of export:

Category	HTS change
666 C	Replace 6303.92.2000 with 6303.92.2010 and 6303.92.2020.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C.553(a)(1).

Sincerely,

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 01–1315 Filed 1–16–01; 8:45 am]

BILLING CODE 3510–DR–F

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 01–C0003]

Tensor Corporation, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Consumer Product Safety Act in the **Federal Register** in accordance with the terms of 16 CFR § 1118.20. Published below is a provisionally-accepted Settlement Agreement with Tensor Corporation, continuing a civil penalty of $125,000.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by February 1, 2001.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 01–C0003, Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: William J. Moore, Jr., Trial Attorney, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0626, 1348.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: January 10, 2001.

Sadye E. Dunn,

Secretary.

Settlement Agreement and Order

1. This Settlement Agreement, made by and between the staff ("the staff") of the U.S. Consumer Product Safety Commission (the "Commission") and Tensor Corporation ("Tensor"), a corporation, in accordance with 16 CFR 1118.20 of the Commission's Procedures for Investigations, Inspections, and Inquiries under the Consumer Product Safety Act ("CPSA"), is a settlement of the staff allegations set forth below.

The Parties

2. The Commission is an independent federal regulatory agency responsible for the enforcement of the Consumer Product Safety Act, 15 U.S.C. 2051–2084.

3. Tensor is a corporation organized and existing under the laws of the Commonwealth of Massachusetts. Its principal office is located at 100 Everett Avenue, Chelsea, Massachusetts.

Staff Allegations

4. Section 15(b) of the CPSA, 15 U.S.C. 2064(b), requires a manufacturer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that such product contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death, to immediately inform the Commission of the defect or risk.

5. Between May 1993 and December 1996, Tensor manufactured and sold throughout the United States approximately 600,000 "Halogen Floor Lamps, models LT609A, LT609N, and LT609P," equipped with 500 watt halogen light bulbs (hereinafter "halogen lamps").

6. A halogen lamp is a "consumer product" and Tensor is a "manufacturer" of a "consumer product", which is "distributed in commerce" as those terms are defined in Sections 3 (a)(1),(4), (11) and (12) of the CPSA, 15 U.S.C. 2052 (a)(1),(4), (11) and (12).

7. The halogen lamps are defective because the 500 watt halogen bulbs contained therein can spontaneously explode during normal use, creating a risk of fire, serious injury and death.

8. Between late 1993 and December 1996, Tensor received approximately 330 incidents of exploding halogen bulbs, some causing extensive property damage and personal injuries.

9. Not until June 1996, after receiving a letter from the staff requesting information about bulb explosion incidents, did Tensor provide any information about the exploding halogen lamp bulbs. The information initially provided by Tensor was very limited however.

10. Tensor's acts and omissions constitute a violation of its duty under Section 15(b) of the CPSA, 15 U.S.C. 2064(b), to report information that its lamps contained defects which could

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create a substantial product hazard and that said lamps created an unreasonable risk of serious injury or death. Tensor thereby committed a prohibited act under Section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4).

11. The staff alleges this violation, this prohibited act, was committed "knowingly" as that term is defined in Section 20 (d) of the CPSC, 15 U.S.C. 2069 (d), and Tensor is subject to civil penalties under Section 19 of the CPSA, 15 U.S.C. 2068.

Allegations of Tensor

12. Tensor denies all the staff allegations numbered four through eleven above. It denies that the halogen lamps contained a defect that created a substantial product hazard or an unreasonable risk of serious injury or death pursuant to Section 15 of the CPSA, 15 U.S.C. 2064.

13. Tensor further denies that it violated the reporting requirements of Section 15(b) of the CPSA, 15 U.S.C. 2064(b), or that it committed a prohibited act, knowingly or otherwise, as defined in Sections 19(a)(4) and 20(d) of the CPSA, 15 U.S.C. 2068(a)(4) and 2069(d). Tensor alleges, among other things, that it had no duty to report the halogen lamps but that it did report information in a timely and appropriate manner.

Agreement of the Parties

14. The Commission has jurisdiction over this matter and over Tensor under the CPSA, 15 U.S.C. 2051 *et seq.*

15. This Settlement Agreement and Order is in resolution of all staff's allegations concerning Tensor's failure to report any incidents or defects associated with exploding or shattering halogen bulbs through March 27, 2000, the date on which the staff examined documents at Tensor's headquarters. This Settlement Agreement and Order does not constitute an admission by Tensor that the law has been violated.

16. Tensor agrees to pay a civil penalty in the amount of one hundred twenty-five thousand and no/dollars ($125,000.00), payable to the "U.S. Treasury" and delivered to the attention of William J. Moore, Jr. as follows: if hand delivered, to Office of Compliance, Legal Division, 4330 East West Highway, Bethesda, MD 20814; if by U.S. Mail, to CPSC, Washington, DC 20207. Tensor shall pay sixty-two thousand five hundred dollars ($62,500.00) within 10 calendar days of receiving service of the final Settlement Agreement and Order, and sixty-two thousand five hundred dollars ($62,500.00) to be paid no later than one year from the date on which this Settlement Agreement and Order became final. If Tensor fails to make a full payment on schedule, the unpaid balance of the entire civil penalty shall be due and payable immediately and interest on the unpaid balance shall accrue and be paid at the federal legal rate of interest under the provisions of 28 U.S.C. 1961 (a) and (b), from the date the payment was due under the terms of this Settlement Agreement and Order.

17. Tensor knowingly, voluntarily and completely waives any rights it may have in the above captioned case (1) to the issuance of a Complaint in this matter; (2) to an administrative or judicial hearing with respect to the staff allegations cited herein; (3) to judicial review or other challenge or contest of the validity of the Settlement Agreement or the Commission's Order; (4) to a determination by the Commission as to whether a violation of Section 15(b) of the CPSA, 15 U.S.C. 2064(b), has occurred, and (5) to a statement of findings of fact and conclusions of law with regard to the staff allegations.

18. Upon provisional acceptance of this Settlement Agreement and Order by the Commission, this Settlement Agreement and Order shall be placed on the public record and shall be published in the **Federal Register** in accordance with 16 CFR 1118.20. If the Commission does not receive any meritorious written request not to accept the Settlement Agreement and Order within 15 days, the Settlement Agreement and Order shall be deemed finally accepted on the 16th day after the date it is published in the **Federal Register**, in accordance with 16 CFR 1118.20(f).

19. The Settlement Agreement and Order becomes effective upon its final acceptance by the Commission.

20. The Commission may publicize the terms of the Settlement Agreement and Order.

21. Tensor agrees to the entry of the attached Order, which is incorporated herein by reference, and agrees to be bound by its terms.

22. The Commission's Order in this matter is issued under the provisions of the CPSA, 15 U.S.C. 2051 *et seq.* and a violation of this Order may subject Tensor to appropriate legal action.

23. This Settlement Agreement and Order is binding upon Tensor, its parent and each of its assigns or successors.

24. Agreements, understandings, representations, or interpretations made outside this Settlement Agreement and Order may not be used to vary or to contradict its terms.

25. If, after the effective date hereof, any provision of this Settlement Agreement and Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Settlement Agreement and Order, such provision shall be fully severable. The rest of the Settlement Agreement and Order shall remain in full effect, unless the Commission and Tensor determine that severing the provision materially impacts the purpose of the Settlement Agreement and Order.

26. This Settlement Agreement and Order shall not be waived, changed, amended, modified, or otherwise altered, except in writing executed by the party against whom such amendment, modification, alteration, or waiver is sought to be enforced and approved by the Commission.

27. This Settlement Agreement may be used in interpreting the Order. Agreements, understandings, representations, or interpretations made outside of this Settlement Agreement and Order may not be used to vary or contradict its terms.

Dated: September 22, 2000.
Tensor Corporation.

Roger Sherman,
President.

The U.S. Consumer Product Safety Commission.

Alan H. Schoem,
Assistant Executive Director, Office of Compliance.

Eric L. Stone,
Director, Legal Division, Office of Compliance.

Dated: September 19, 2000.

William J. Moore, Jr.,
Trial Attorney.

Belinda V. Mitchell,
Trial Attorney, Legal Division, Office of Compliance.

Order

Under consideration of the Settlement Agreement entered into between Tensor Corporation, a corporation, and the staff of the U.S. Consumer Product Safety Commission; and the Commission having jurisdiction over the subject matter and Tensor Corporation, and it appearing that the Settlement Agreement and Order is in the public interest, it is

Ordered, that the Settlement Agreement be, and hereby is, accepted, and it is

Further Ordered, That Tensor Corporation, shall pay the Commission a civil penalty in the amount of *One Hundred Twenty-Five Thousand and 00/100* dollars, ($125,000.00) payable to the U.S. Treasury as follows: delivered to the Commission, sixty-two thousand five hundred dollars ($62,500.00) within 10 calendar days of the service of the Final Order upon Tensor Corporation and sixty-two thousand five hundred dollars ($62,500.00) to be paid one year from the date on which this Settlement Agreement and Order became final.

Upon failing to make a payment or upon making a payment that is at least five days late, the outstanding balance of the civil penalty shall become due and payable by Tensor Corporation, and the interest on the outstanding balance shall accrue and be paid at the federal legal rate under the provisions of 27 U.S.C. sections 1961 (a) and (b).

In the Matter of Tensor Corporation

[CPSC DOCKET NO. 01–C0003]

Provisionally accepted and Provisional Order issued on the 10th day of January, 2001.

By Order of the Commission.

Sadye E. Dunn,
Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 01–1252 Filed 1–16–01; 8:45 am]
BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Proposed Collection; Comment Request

AGENCY: Department of Defense, Office of the Under Secretary of Defense (Acquisition, Technology, and Logistics)/Defense Technical Information Center.

ACTION: Notice.

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Under Secretary of Defense (Acquisition, Technology, and Logistics)/Defense Technical Information Center (DTIC), announces the proposed extension of a currently approved collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by March 19, 2001.

ADDRESSES: Interested parties should submit written comments and recommendations on the proposed information collection to: ATTN: DTIC–BC, Defense Technical Information Center, 8725 John J. Kingman Road, Suite 0944, Fort Belvoir, VA 22060–6218; E-mail comments submitted via the Internet should be addressed to: laxe@dtic.mil.

FOR FURTHER INFORMATION CONTACT: To request further information on this proposed information collection, or to obtain a copy of the proposal and associated collection instrument, please write to the above address or call Ms. Linda Axe at (703) 767–8194.

Title, Associated Form, and OMB Number: Registration for Scientific and Technical Information Services, DD Form 1540, OMB Control Number 0704–0264.

Needs and Uses: The data that the Defense Technical Information Center handles is controlled, either because of distribution limitations or security classification. For this reason, all potential users are required to register for service. DODI 3200.14, Principles and Operational Parameters of the DOD Scientific and Technical Information Program, mandates the registration procedure. Federal Government agencies and their contractors are required to complete the DD Form 1540, Registration for Scientific and Technical Information Services (OMB Number 0704–0264). The contractor community completes a separate DD Form 1540 for each contract or grant and registration is valid until the contract expires.

Affected Public: Businesses or other for-profit; Small Businesses or organizations; Non-profit institutions.

Annual Burden Hours: 833.

Number of Annual Respondents: 2,000.

Annual Responses to Respondent: 1.

Average Burden Per Response: 25 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

The DOD Scientific and Technical Information Program (STIP) requires the exchange of scientific and technical information within and among Federal Government agencies and their contractors. The DD Form 1540 serves as a registration tool for Federal Government agencies and their contractors to access DTIC services. The contractors, subcontractors, and potential contractors are required to obtain certification from designated approving officials. Federal Government agencies need certification from approving officials and security offices only when requesting access to classified data. All collected information is verified by DTIC's Marketing and Registration Division.

Dated: January 10, 2001.

Patricia L. Toppings,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1316 Filed 1–16–01; 8:45 am]
BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense will submit to OMB for emergency processing, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title and OMB Number: Foreign Sourcing for Defense Application; OMB Number 0704—[To Be Determined].

Type of Request: New Collection; Emergency processing requested with a shortened public comment period ending February 7, 2001. An approval date by February 15, 2001 has been requested.

Number of Respondents: 3,205.

Responses Per Respondent: 1.

Annual Responses: 3,205.

Average Burden Per Response: 5 hours.

Annual Burden Hours: 16,025.

Needs and Uses: The information is required for the Department of Defense (DoD) to evaluate, for certain defense programs, the: (1) Extent of foreign sourcing within the defense products; (2) impact such foreign sourcing has on military readiness and the related domestic industrial infrastructure; and, (3) extent to which DoD or contractor policies, procedures, practices, or actions encourage or discourage consideration of foreign sources for defense products. The evaluation is required by section 831 of the National Defense Authorization Act for Fiscal Year 2001. Section 831 requires the Secretary of Defense to conduct a study analyzing the impact that foreign sources have on six specific defense systems to include the AH–64D Apache helicopter, F/A–18E/F aircraft, M1A2 Abrams tank, AIM 120 AMRAAM missile, Patriot missile ground station, and Hellfire missile. To ensure it can address emerging foreign sourcing issues, DoD will also evaluate foreign

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sourcing on the Joint Direct Attack Munition and the Advanced Amphibious Assault Vehicle. Section 831 requires that the information to be analyzed shall be collected from prime contractors and first and second tier subcontractors.

Affected Public: Business or Other For-Profit.

Frequency: One-Time.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Lew Oleinick. Written comments and recommendations on the proposed information collection should be sent to Mr. Oleinick at the Office of Management and Budget, Desk Officer for Acquisitions (DoD), Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302, or by fax at (703) 604–6270.

Dated: January 8, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1318 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form, and OMB Number: Application for Department of Defense Common Access Card—DEERS Enrollment; DD Form 1172–2; OMB Number 0704–0415.

Type of Request: Extension.

Number of Respondents: 300,000.

Responses Per Respondent: 1.

Annual Responses: 300,000.

Average Burden Per Response: 20 minutes.

Annual Burden Hours: 100,000.

Needs and Uses: This information collection is needed to obtain the necessary data to establish eligibility for the DoD Common Access Card for those individuals not pre-enrolled in the DEERS, and to maintain a centralized database of eligible individuals. This information is used to establish eligibility for the DoD Common Access Card for individuals either employed by or associated with the Department of Defense; is used to control access to DoD facilities and systems; and it provides a source of data for demographic reports and mobilization dependent support.

Affected Public: Individuals or Households.

Frequency: On Occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Mr. Edward C. Springer. Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: January 10, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1317 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form Number, and OMB Number: Civil Aircraft Landing Permit System; DD Form 2400, 2401, 2402; OMB Number 0701–0050.

Type of Request: Reinstatement.

Number of Respondents: 3,600.

Responses per Respondent: 1.

Annual Responses: 3,600.

Average Burden Per Response: 30 minutes.

Annual Burden Hours: 1,800.

Needs and Uses: The information collection requirement is necessary to ensure that the security and operational integrity of military airfields are maintained; to identify the aircraft operator and the aircraft to be operated; to avoid competition with the private sector by establishing the purpose for use of military airfields; and to ensure the U.S. Government is not held liable if the civil aircraft becomes involved in an accident or incident while using military airfields, facilities, and services.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions; Individuals or Households.

Frequency: On Occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Mr. Edward C. Springer. Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: January 8, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 01–1319 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form Number, and OMB Number: Description of Vessels, Description of Operations; ENG Form 3931, 3932; OMB Number 0710–0009.

Type of Request: Revision.

Number of Respondents: 2,500.

Responses Per Respondent: 1.

Annual Responses: 2,500.

Average Burden Per Response: 48 minutes.

Annual Burden Hours: 2,000.

Needs and Uses: The data collected provide information on vessel operators and their American Flag vessels operating or available for operation on the inland waterways of the United States in the transportation of freight and passengers. The information provides accurate U.S. Flag fleet statistics for use by the Army Corps of Engineers and other agencies, such as the U.S. Coast Guard and Federal and State agencies involved in transportation.

Affected Public: Business or Other For-Profit.

Frequency: Annually.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Mr. Jim Laity. Written comments and recommendations on the proposed information collection should be sent to Mr. Laity at the Office of Management and Budget, Desk Officer for the U.S. Army Corps of Engineers, Room 10202, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: January 8, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1320 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Form, and OMB Number: Personnel Security Clearance Change Notification; DISCO Form 562; OMB Number 0704–[To Be Determined].

Type of Request: New Collection.

Number of Respondents: 11,290.

Responses Per Respondent: 20.

Annual Responses: 225,800.

Average Burden Per Response: 12 minutes.

Annual Burden Hours: 45,160.

Needs and Uses: The DISCO Form 562 is used by contractors participating in the National Industrial Security Program to report various changes in employee personnel clearance status or identification information. The execution of the form is a factor in making a determination as to whether a contractor employee is eligible to have a security clearance.

Affected Public: Business or Other For-Profit; Not-For-Profit Institutions.

Frequency: On Occasion.

Respondents Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. Robert Cushing. Written requests for copies of the information collection proposal should be sent to Mr. Cushing, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202–4302.

Dated: January 8, 2001.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1321 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Intelligence Agency, Science and Technology Advisory Board Closed Panel Meeting

AGENCY: Defense Intelligence Agency, Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of subsection (d) of section 10 of Public Law 92–463, as amended by section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the DIA Science and Technology Advisory Board has been scheduled as follows:

DATES: January 9, and 10, 2001 (800 am to 1600 pm).

ADDRESSES: The Defense Intelligence Agency, 200 MacDill BLVD, Washington, DC, 20340.

FOR FURTHER INFORMATION CONTACT: Victoria J. Prescott, Executive Secretary, DIA Science and Technology Advisory Board, Washington, DC 20340–1328 (202) 231–4930.

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(l), title 5 of the U.S. Code, and therefore will be closed to the public. The Board will receive briefings on and discuss several current critical intelligence issues and advise the Director, DIA, on related scientific and technical matters.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1274 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Intelligence Agency, Science and Technology Advisory Board Closed Panel Meeting

AGENCY: Defense Intelligence Agency, Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of subsection (d) of section 10 of Public Law 92–463, as amended by section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the DIA Science and Technology Advisory Board has been scheduled as follows:

DATES: January 30, 2001 (0800 am–1600 pm).

ADDRESSES: The Defense Intelligence Agency, 200 MacDill Blvd, Washington, DC 20340.

DATES: January 31 2001 (0800 am–1600 pm).

ADDRESSES: National Reconnaissance Office (NRO) Headquarters, 14675 Lee Road, Chantilly, VA.

FOR FURTHER INFORMATION CONTACT: Ms. Victoria J. Prescott, Director/Executive Secretary, DIA Science and Technology Advisory Board, Washington, D.C.20340–1328 (202) 231—4930.

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(1), title 5 of the U.S. Code, and therefore will be closed to the public. The Board will receive briefings on and discuss several current critical intelligence issues and advise the Director, DIA, on related scientific and technical matters.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1275 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Advisory Group on Election Devices, Department of Defense.

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ACTION: Notice.

SUMMARY: The DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Tuesday, February 13, 2001.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. Eliot Cohen, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The AGED meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The agenda for this meeting will include programs on Radiation Hardened Devices, Microwave Tubes, Displays and Lasers. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended (5 U.S.C. App. § 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: January 10, 2001.

L.M. Bynum,

Alternate, OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1270 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Advisory Group on Electron Devices, Department of Defense.

ACTION: Notice.

SUMMARY: Working Group A (Microwave Devices) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Thursday, February 15, 2001.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, Inc. 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: David Cox, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency (ARPA) and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave devices, electronic warfare devices, millimeter wave devices, and passive devices. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended (5 U.S.C. App. § 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1271 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Meeting of the DOD Advisory Group on Electron Devices

AGENCY: Advisory Group on Electron Devices, Department of Defense.

ACTION: Notice.

SUMMARY: Working Group C (Electro-Optics) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Wednesday, January 31, 2001.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Elise Rabin, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director of Defense Research and Engineering (DDR&E), and through the DDR&E to the Director, Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective and economical research and development program in the area of electron devices.

The Working Group C meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This opto-electronic device area includes such programs as imaging device, infrared detectors and lasers. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App. 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1272 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Change in Meeting Date of the DOD Advisory Group on Electron Devices

AGENCY: Advisory Group on Electron Devices, Department of Defense.

ACTION: Notice.

SUMMARY: Working Group B (Microelectronics) of the DoD Advisory Group on Electron Devices (AGED) announces a change to a closed session meeting.

DATES: The meeting will be held at 0900, Wednesday, February 14, 2001.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 1745 Jefferson Davis Highway, Suite 500, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Elise Rabin, AGED Secretariat, 1745 Jefferson Davis Highway, Crystal Square Four, Suite 500, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide advice to the Under Secretary of Defense for Acquisition and Technology, to the Director Defense Research and Engineering (DDR&E), and through the DDR&E, to the Director Defense Advanced Research Projects Agency and the Military Departments in planning and managing an effective research and development program in the field of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military proposes to initiate with industry, universities or in their laboratories. The microelectronics area includes such programs on semiconductor materials, integrated circuits, charge couple devices and memories. The review will include classified program details throughout.

In accordance with section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App. 10(d) (1994)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly, this meeting will be closed to the public.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1273 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Department of Defense Wage Committee; Notice of Closed Meetings

Pursuant to the provisions of section 10 of Public Law 92–463, the Federal Advisory Committee Act, notice is hereby given that closed meetings of the Department of Defense Wage Committee will be held on February 6, 2001; February 13, 2001; February 20, 2001; and February 27, 2001, at 10:00 a.m. in Room A105, The Nash Building, 1400 Key Boulevard, Rosslyn Virginia.

Under the provisions of section 10(d) of Public Law 92–463, the Department of Defense has determined that the meetings meet the criteria to close meetings to the public because the matters to be considered are related to internal rules and practices of the Department of Defense and the detailed wage data to be considered were obtained from officials of private establishments with a guarantee that the data will be held in confidence.

However, members of the public who may wish to do so are invited to submit material in writing to the chairman concerning matters believed to be deserving of the Committee's attention.

Additional information concerning the meetings may be obtained by writing to the Chairman, Department of Defense Wage Committee, 4000 Defense Pentagon, Washington, DC 20301–4000.

Dated: January 10, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1269 Filed 1–16–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF ENERGY

Energy Employees Occupational Illness Compensation Act of 2000; List of Covered Facilities

AGENCY: Department of Energy.

ACTION: Notice of listing of covered facilities.

SUMMARY: The Energy Employees Occupational Illness Compensation Act of 2000 ("Act"), Public Law 106–398, establishes a program to provide compensation to individuals who developed illnesses as a result of their employment in nuclear weapons production-related activities and at certain federally-owned facilities in which radioactive materials were used. On December 7, 2000, the President issued Executive Order 13179 ("Order") directing the Department of Energy ("Department" or "DOE") to list covered facilities in the **Federal Register**. This notice responds to both the Act and the Order.

FOR FURTHER INFORMATION CONTACT: Office of Worker Advocacy, 1–877–447–9756.

ADDRESSES: The Department welcomes comments on this list. Individuals who wish to suggest additional facilities for inclusion on the list, indicate why one or more facilities should be removed from the list, or provide other information may contact: Office of Worker Advocacy (EH–8), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, email: worker_advocacy@eh.doe.gov, toll-free: 1–877–447–9756.

SUPPLEMENTARY INFORMATION:

Purpose: The Energy Employees Occupational Illness Compensation Act of 2000 ("Act"), Public Law 106–398, establishes a program to provide compensation to individuals who developed illnesses as a result of their employment in nuclear weapons production-related activities and at certain federally-owned facilities in which radioactive materials were used. On December 7, 2000, the President issued Executive Order 13179 ("Order") directing the Department of Energy ("Department" or "DOE") to list covered facilities in the **Federal Register**. Section 2. c. vii of the Order instructs the Department to list three types of facilities:

(1) Atomic weapons employer facilities, as defined in section 3621 (4) of the Act;

(2) Department of Energy facilities, as defined by section 3621 (12) of the Act; and

(3) Beryllium vendors, as defined by section 3621 (6) of the Act.

Compensation options and mechanisms are defined differently for each of these facility categories. The atomic weapons employer category includes facilities in which the primary work was not related to atomic weapons, and consequently these facilities are not commonly known as atomic weapons facilities. Their inclusion in this list is consistent with the Act, and is not intended as a classification for any other purpose.

The list at the end of this notice represents the Department's best efforts to date to compile a list of facilities in these three categories. Reconstructing the operational history of the nuclear weapons system over a sixty-year period is a complex and sometimes imprecise undertaking. Some list entries are based on records that contain the names and addresses of companies and facilities at the time work was performed for the Department and its predecessor federal agencies. The list may identify a corporate headquarters facility as a production location, or may contain some inadvertent duplication because of changes in names, ownership, and addresses. Similarly, attempts to minimize duplication may have resulted in the inadvertent omission of subsidiaries and satellite locations that should be included. Accordingly, the

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Department is continuing its research efforts in order to better understand past production activities, and DOE intends to update this list at least once annually so long as new information becomes available. The public is invited to comment on the list and to provide additional information.

In addition to continuing its research efforts, the Department is developing information dissemination mechanisms to make facility-specific data available to the public, including a publicly accessible database of site-related information. This database will help ensure that the Department keeps track of facilities involved in atomic weapons and other work potentially resulting in contamination or exposure. The site database will include, among other information, the type of nuclear weapons-related production work done, the dates such work occurred, and available health and safety data concerning the facility. The listing of facility name and location in this notice represents only a first step in providing information to the public.

The Act does not cover workers involved in uranium mining and milling, or those who worked in support of naval nuclear propulsion programs. Consequently, facilities associated with this type of work are not listed in this notice. Some workers who became ill as a result of their employment at these facilities may be covered by other programs such as the Radiation Exposure Compensation Act (RECA), the Federal Exposure Compensation Act (FECA), or other jurisdictions' worker compensation programs.

Introduction to the Covered Facility List

The list that follows covers the three categories of employers defined by the Act: atomic weapons employers ("AWE"), Department of Energy facilities ("DOE"), and beryllium vendors ("BE"). Some facilities fall into more than one category. For example, if a private contractor facility handled both radioactive materials and beryllium, it will have "AWE" and "BE" in the "facility type" column. For another example, a facility will have both "DOE" and "AWE" codes if ownership changed between the DOE and another entity. The Department intends to provide facility-specific explanations of the applicability of these categories through the database mentioned above.

Each of the categories is defined below:

1. Atomic Weapons Employers

Section 3621 (4) of the Act defines an atomic weapons employer as "an entity that—

(A) processed or produced, for the use by the United States, material that emitted radiation and was used in the production of an atomic weapon, excluding uranium mining and milling; and

(B) is designated as an atomic weapons employer for purposes of this title by the Secretary of Energy."

Most facilities listed as an AWE conducted nuclear weapons-related work for a limited period of time or in certain select areas of the plant. For example, some sites worked with radioactive materials to evaluate processing machinery that was being considered for use in atomic weapons production. Radioactive materials may not have been used as a routine part of the facility's operations. The Act covers those workers who became sick as a consequence of their work in support of nuclear weapons production activities, and was not intended to cover all workers at each site named.

The lines between research, atomic weapons production, and non-weapons production are often difficult to draw. For the purposes of this notice, and as directed by the Act, only those facilities whose work involved radioactive material that was connected to the weapons production chain are included. Available information about many of these facilities is incomplete or unclear, and the Department welcomes comments or additional information regarding facilities that may have supported atomic weapons production that are not on this list, as well as information that clarifies the work done at facilities named below.

2. Department of Energy Facilities

Section 3621 (12) of the Act defines a DOE facility as "any building, structure, or premise, including the grounds upon which such building, structure, or premise is located—

(A) in which operations are, or have been, conducted by, or on behalf of, the Department of Energy (except for buildings, structures, premises, grounds, or operations covered by Executive Order 12344, pertaining to the Naval Nuclear Propulsion Program); and

(B) with regard to which the Department of Energy has or had—

(i) A proprietary interest; or

(ii) Entered into a contract with an entity to provide management and operation, management and integration, environmental remediation services, construction, or maintenance services."

Consistent with this definition, the Department has taken a broad view of where operations have been conducted by DOE or its predecessor agencies. The list includes any facility handling radioactive materials or beryllium in which the Department had management and operations, management and integration, environmental remediation, or construction and maintenance contracts. This broad definition includes many facilities which are not generally thought of as Departmental facilities, as well as facilities which are not necessarily involved with weapons-related work. For example, some universities and private companies are included because the Department contracted for environmental remediation services at these sites, even though the Department did not own the facility. Also, some DOE-owned laboratories are included because they do work involving radioactive materials, even though that work is not related to nuclear weapons production.

The Act covers production workers at the gaseous diffusion plants at Paducah, KY and Piketon, OH. Production workers at these facilities are covered for work conducted until July 28, 1998, when the facilities were privatized under the control of the United States Enrichment Corporation (USEC, Inc.)

The listing of Department of Energy facilities is only intended for the context of implementing this Act and does not create or imply any new Departmental obligations or ownership at any of the facilities named on this list.

3. Beryllium Vendors

Section 3621(6) of the Act defines beryllium vendor as the following:

"(A) Atomics International.

(B) Brush Wellman, Incorporated, and its predecessor, Brush Beryllium Company.

(C) General Atomics.

(D) General Electric Company.

(E) NGK Metals Corporation and its predecessors, Kawecki-Berylco, Cabot Corporation, BerylCo, and Beryllium Corporation of America.

(F) Nuclear Materials and Equipment Corporation.

(G) StarMet Corporation, and its predecessor, Nuclear Metals, Incorporated.

(H) Wyman Gordan, Incorporated.

(I) Any other vendor, processor, or producer of beryllium or related products designated as a beryllium vendor for purposes of this title under Section 3622."

Beryllium metal has been an important material for atomic weapons production, and it was used at many places throughout the production system. The list indicates private firms that processed, produced, or provided beryllium metal for the Department, as defined by the Act. This information is drawn from a variety of historical documents, and much data remains incomplete. The Department welcomes comments or additional information about its beryllium vendors.

Covered Facility List

Jurisdiction	Facility name	Location	Facility type
AL	Southern Research Institute	Sylacauga	AWE
AL	Speed Ring Experimental & Tool Company	Culman	BE
AL	Tennessee Valley Authority	Muscle Shoals	AWE
AK	Amchitka Island Nuclear Explosion Site	Amchitka Island	DOE
AK	Project Chariot Site	Cape Thompson	DOE
CA	Arthur D. Little Co.	San Francisco	AWE
CA	Atomics International	Canoga Park	BE
CA	Burris Park Field Station	Kingsburg	AWE
CA	Ceradyne, Inc.	Santa Ana	BE
CA	Dow Chemical Co.	Walnut Creek	AWE
CA	Electro Circuits, Inc.	Pasadena	AWE
CA	Energy Technology Engineering Center	Santa Susana	DOE
CA	General Atomics	La Jolla	AWE/BE/DOE
CA	General Electric Vallecitos	Pleasanton	AWE
CA	Hunter Douglas Aluminum Corp.	Riverside	AWE
CA	Laboratory for Energy-Related Health Research	Davis	DOE
CA	Laboratory of Biomedical and Environmental Sciences	Los Angeles	DOE
CA	Laboratory of Radiobiology and Environmental Health	San Francisco	DOE
CA	Lawrence Berkeley National Laboratory	Berkeley	DOE
CA	Lawrence Livermore National Laboratory	Livermore	DOE
CA	Sandia Laboratory, Salton Sea Base	Imperial County	DOE
CA	Sandia National Laboratories—Livermore	Livermore	DOE
CA	Stanford Linear Accelerator Center	Palo Alto	DOE
CA	Stauffer Metals, Inc.	Richmond	AWE
CA	University of California	Berkeley	AWE/DOE
CO	Coors Porcelain	Golden	BE
CO	Project Rio Blanco Nuclear Explosion Site	Rifle	DOE
CO	Project Rulison Nuclear Explosion Site	Grand Valley	DOE
CO	Rocky Flats Plant	Golden	DOE
CO	Shattuck Chemical	Denver	AWE
CO	University of Denver Research Institute	Denver	AWE/BE
CT	American Chain and Cable Co.	Bridgeport	AWE
CT	Anaconda Co.	Waterbury	AWE
CT	Bridgeport Brass Co., Havens Lab.	Bridgeport	AWE
CT	Combustion Engineering	Windsor	AWE/DOE
CT	Connecticut Aircraft Nuclear Engine Lab. (CANEL)	Middletown	BE/DOE
CT	Dorr Corp.	Stamford	AWE
CT	Fenn Machinery Co.	Hartford	AWE
CT	New England Lime Co.	Canaan	AWE
CT	Seymour Specialty Wire	Seymour	AWE/DOE
CT	Sperry Products, Inc.	Danbury	AWE
CT	Torrington Co.	Torrington	AWE
DE	Allied Chemical and Dye Corp.	North Claymont	AWE
DC	National Bureau of Standards, Van Ness Street	Washington	AWE
DC	Naval Research Laboratory	Washington	AWE/DOE
FL	American Beryllium Co.	Sarasota	BE
FL	Armour Fertilizer Works	Bartow	AWE
FL	C.F. Industries, Inc.	Bartow	AWE
FL	Gardinier, Inc.	Tampa	AWE
FL	International Minerals and Chemical Corp	Mulberry	AWE
FL	Pinellas Plant	Clearwater	DOE
FL	University of Florida	Gainesville	AWE
FL	Virginia-Carolina Chemical Corp	Nichols	AWE
FL	W.R. Grace Co., Agricultural Chemical Div	Ridgewood	AWE
ID	Argonne National Laboratory—West	Scoville	DOE
ID	Idaho National Engineering Laboratory	Scoville	DOE
IL	Allied Chemical Corp.	Metropolis	AWE
IL	American Machine and Metals, Inc.	E. Moline	AWE
IL	Argonne National Laboratory-East	Argonne	DOE
IL	Armour Research Foundation	Chicago	AWE
IL	Blockson Chemical Co	Joliet	AWE
IL	C–B Tool Products Co.	Chicago	AWE
IL	Crane Co.	Chicago	AWE
IL	ERA Tool and Engineering Co.	Chicago	AWE
IL	Fansteel Metallurgical Corp.	North Chicago	BE
IL	Fermi National Accelerator Laboratory	Batavia	DOE
IL	Granite City Steel	Granite City	AWE/DOE
IL	Great Lakes Carbon Corp.	Chicago	AWE
IL	GSA 39th Street Warehouse	Chicago	AWE

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Jurisdiction	Facility name	Location	Facility type
IL	International Register	Chicago	AWE
IL	Kaiser Aluminum Corp.	Dalton	AWE
IL	Lindsay Light and Chemical Co.	W. Chicago	AWE
IL	Madison Site (Speculite)	Madison	AWE/DOE
IL	Midwest Manufacturing Co.	Galesbury	AWE
IL	Museum of Science and Industry	Chicago	AWE
IL	National Guard Armory	Chicago	AWE/DOE
IL	Podbeliniac Corp.	Chicago	AWE
IL	Precision Extrusion Co.	Bensenville	AWE
IL	Quality Hardware and Machine Co.	Chicago	AWE
IL	R. Krasburg and Sons Manufacturing Co.	Chicago	AWE
IL	Sciaky Brothers, Inc.	Chicago	AWE
IL	Swenson Evaporator Co.	Harvey	AWE
IL	University of Chicago	Chicago	AWE/DOE
IL	W.E. Pratt Manufacturing Co.	Joliet	AWE
IL	Wycoff Drawn Steel Co.	Chicago	AWE
IN	American Bearing Corp.	Indianapolis	AWE
IN	Dana Heavy Water Plant	Dana	DOE
IN	General Electric Plant	Shelbyville	AWE
IN	Joslyn Manufacturing and Supply Co	Ft. Wayne	AWE
IN	Purdue University Van der Graaf Lab	Lafayette	AWE
IN	Washrite	Indianapolis	AWE
IA	Ames Laboratory	Ames	DOE
IA	Iowa Ordnance Plant	Burlington	DOE
IA	Titus Metals	Waterloo	AWE
KS	Spencer Chemical Co., Jayhawks Works	Pittsburg	AWE
KY	Paducah Gaseous Diffusion Plant	Paducah	DOE
MR*	Eniwetok Test Site	Marshall Islands	DOE
MD	Armco-Rustless Iron & Steel	Baltimore	AWE
MD	W.R. Grace and Company	Curtis Bay	AWE/DOE
MA	American Potash & Chemical	West Hanover	AWE
MA	C.G. Sargent & Sons	Graniteville	AWE
MA	Chapman Valve	Indian Orchard	AWE/DOE
MA	Edgerton Germeshausen & Grier, Inc.	Boston	AWE
MA	Fenwal, Inc.	Ashland	AWE
MA	Franklin Institute	Boston	BE
MA	Heald Machine Co.	Worcester	AWE
MA	La Pointe Machine and Tool Co.	Hudson	AWE
MA	Massachusetts Institute of Technology	Cambridge	AWE/BE
MA	Metals and Controls Corp.	Attleboro	AWE
MA	National Research Corp.	Cambridge	AWE
MA	Norton Co.	Worcester	AWE/BE
MA	Nuclear Metals, Inc.	Concord	AWE/BE
MA	Reed Rolled Thread Co.	Worcester	AWE
MA	Shpack Landfill	Norton	AWE/DOE
MA	Ventron Corporation	Beverly	AWE/DOE
MA	Winchester Engineering and Analytical Center	Winchester	DOE
MA	Woburn Landfill	Woburn	AWE
MA	Wyman Gordon Inc.	Grayton, North Grafton	BE
MI	AC Spark Plug	Flint	BE
MI	Baker-Perkins Co.	Saginaw	AWE
MI	Carboloy Co.	Detroit	AWE
MI	Extruded Metals Co.	Grand Rapids	AWE
MI	General Motors	Adrian	AWE/DOE
MI	Gerity-Michigan Corp.	Adrian	BE
MI	Mitts & Merrel Co.	Saginaw	AWE
MI	Oliver Corp.	Battle Creek	AWE
MI	Revere Copper and Brass	Detroit	AWE/BE
MI	Speed Ring Experimental & Tool Company	Detroit	BE
MI	Star Cutter Corp.	Farmington	AWE
MI	University of Michigan	Ann Arbor	AWE
MI	Wolverine Tube Division	Detroit	AWE
MN	Elk River Reactor	Elk River	DOE
MS	Salmon Nuclear Explosion Site	Hattiesburg	DOE
MO	Kansas City Plant	Kansas City	DOE
MO	Latty Avenue Properties	Hazelwood	AWE/DOE
MO	Mallinckrodt Chemical Co., Destrehan St. Plant	St. Louis	AWE/DOE
MO	Medart Co.	St. Louis	AWE
MO	Roger Iron Co.	Joplin	AWE
MO	Spencer Chemical Co.	Kansas City	AWE
MO	St. Louis Airport Site	St. Louis	AWE/DOE
MO	Tyson Valley Powder Farm	St. Louis	AWE
MO	United Nuclear Corp.	Hematite	AWE
MO	Weldon Spring Plant	Weldon Spring	DOE

Jurisdiction	Facility name	Location	Facility type
NE	Hallam Sodium Graphite Reactor	Hallam	DOE
NV	Nevada Test Site	Mercury	DOE
NV	Project Faultless Nuclear Explosion Site	Central Nevada Test Site	DOE
NV	Project Shoal Nuclear Explosion Site	Fallon	DOE
NV	Yucca Mountain Site Characterization Project	Yucca Mountain	DOE
NJ	Aluminum Co. of America (Alcoa)	Garwood	AWE
NJ	American Peddinghaus Corp.	Moonachie	AWE
NJ	Baker and Williams Co.	Newark	AWE
NJ	Bell Telephone Laboratories	Murray Hill	AWE
NJ	Bloomfield Tool Co.	Bloomfield	AWE
NJ	Bowen Lab.	North Branch	AWE
NJ	Callite Tungsten Co.	Union City	AWE
NJ	Chemical Construction Co.	Linden	AWE
NJ	Du Pont Deepwater Works	Deepwater	AWE/DOE
NJ	International Nickel Co., Bayonne Laboratories	Bayonne	AWE
NJ	J.T. Baker Chemical Co.	Phillipsburg	AWE
NJ	Kellex/Pierpont	Jersey City	AWE/DOE
NJ	Maywood Chemical Works	Maywood	AWE/DOE
NJ	Middlesex Municipal Landfill	Middlesex	AWE/DOE
NJ	Middlesex Sampling Plant	Middlesex	DOE
NJ	National Beryllia	Haskell	BE
NJ	New Brunswick Laboratory	New Brunswick	DOE
NJ	Picatinny Arsenal	Dover	AWE
NJ	Princeton Plasma Physics Laboratory	Princeton	DOE
NJ	Rare Earths/ W.R. Grace	Wayne	AWE/DOE
NJ	Standard Oil Development Co. of NJ	Linden	AWE
NJ	Tube Reducing Co.	Wallington	AWE
NJ	U.S. Pipe and Foundry	Burlington	BE
NJ	United Lead Co.	Middlesex	AWE
NJ	Vitro Corp. of America	West Orange	AWE
NJ	Westinghouse Electric Corp.	Bloomfield	AWE
NJ	Wykoff Steel Co.	Newark	AWE
NM	Chupadera Mesa	Chupadera Mesa	DOE
NM	Los Alamos Medical Center	Los Alamos	DOE
NM	Los Alamos National Laboratory	Los Alamos	DOE
NM	Lovelace Respiratory Research Institute	Albuquerque	DOE
NM	Project Gasbuggy Nuclear Explosion Site	Farmington	DOE
NM	Project Gnome Nuclear Explosion Site	Carlsbad	DOE
NM	Sandia National Laboratories	Albuquerque	DOE
NM	South Albuquerque Works	Albuquerque	DOE
NM	Trinity Nuclear Explosion Site	White Sands Missile Range.	DOE
NM	Waste Isolation Pilot Plant	Carlsbad	DOE
NY	Allegheny-Ludlum Steel	Watervliet	AWE
NY	American Machine and Foundry	Brooklyn	AWE
NY	Ashland Oil	Tonawanda	AWE/DOE
NY	Baker and Williams Warehouses	New York	AWE/DOE
NY	Bethlehem Steel	Lackawana	AWE
NY	Bliss & Laughlin Steel	Buffalo	AWE/DOE
NY	Brookhaven National Laboratory	Upton	DOE
NY	Burns & Roe, Inc.	Maspeth	BE
NY	Colonie Site (National Lead)	Colonie	AWE/DOE
NY	Columbia University	New York City	AWE/DOE
NY	Electro Metallurgical	Niagara Falls	AWE
NY	General Astrometals	Yonkers	BE
NY	Hooker Electrochemical	Niagara Falls	AWE
NY	International Rare Metals Refinery, Inc	Mt. Kisko	AWE
NY	Ithaca Gun Co.	Ithaca	AWE
NY	Lake Ontario Ordnance Works	Niagara Falls	DOE
NY	Ledoux and Co.	New York	AWE
NY	Linde Air Products	Buffalo	AWE
NY	Linde Ceramics Plant	Tonawanda	AWE/DOE
NY	New York University	New York	AWE
NY	Peek Street Facility**	Schenectady	DOE
NY	Radium Chemical Co.	New York	AWE
NY	Rensselaer Polytechnic Institute	Troy	AWE
NY	Sacandaga Facility**	Glenville	DOE
NY	Seaway Industrial Park	Tonawanda	AWE/DOE
NY	Seneca Army Depot	Romulus	AWE
NY	Separations Process Research Unit (at Knolls Lab.)**	Schenectady	DOE
NY	Simonds Saw and Steel Co.	Lockport	AWE
NY	Staten Island Warehouse	New York	AWE
NY	Sylvania Corning Nuclear Corp.	Hicksville	AWE/DOE
NY	Sylvania Products Corp.	Bayside	AWE/BE

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Jurisdiction	Facility name	Location	Facility type
NY	Titanium Alloys Manufacturing	Niagara Falls	AWE
NY	Trudeau Foundation	Saranac Lake	BE
NY	University of Rochester Medical Laboratory	Rochester	AWE/DOE
NY	Utica St. Warehouse	Buffalo	AWE
NY	West Valley Demonstration Project	West Valley	DOE
NC	Beryllium Metals and Chemical Corp	Bessemer City	BE
NC	University of North Carolina	Chapel Hill	BE
OH	Air Force Plant 38	Evandale	AWE
OH	Ajax Magnathermic Corp.	Youngstown	AWE
OH	Alba Craft	Oxford	AWE/DOE
OH	Associated Aircraft Tool and Manufacturing Co	Fairfield	AWE/DOE
OH	B & T Metals	Columbus	AWE/DOE
OH	Baker Brothers	Toledo	AWE/DEL
OH	Battelle Columbus Laboratories	Columbus	AWE
OH	Battelle Memorial Institute	Columbus	AWE/BE/DOE
OH	Beryllium Production Plant (Brush)	Luckey	BE/DOE
OH	Brush Beryllium Co.	Elmore	AWE/BE
OH	Brush Beryllium Co.	Cleveland	AWE/BE
OH	Brush Beryllium Co.	Loraine	AWE/BE
OH	Cincinnati Milling Machine Co.	Cincinnati	AWE
OH	Clifton Products Co.	Clifton	BE
OH	Clifton Products Co.	Painesville	BE
OH	Copperweld Steel	Warren	AWE
OH	Du Pont-Grasselli Research Laboratory	Cleveland	AWE
OH	Extrusion Plant	Ashtabula	DOE
OH	Feed Materials Production Center	Fernald	DOE
OH	General Electric Company	Cincinnati/Evendale	AWE/BE/DOE
OH	Gruen Watch	Norwood	AWE
OH	Harshaw Chemical Co.	Cleveland	AWE
OH	Herring-Hall Marvin Safe Co.	Hamilton	AWE/DOE
OH	Horizons, Inc.	Cleveland	AWE
OH	Kettering Laboratory, University of Cincinnati	Cincinnati	BE
OH	Magnus Brass Co.	Cincinnati	AWE
OH	McKinney Tool and Manufacturing Co.	Cleveland	AWE
OH	Mitchell Steel Co.	Cincinnati	AWE
OH	Monsanto Chemical Co.	Dayton	AWE
OH	Mound Plant	Miamisburg	DOE
OH	Painesville Site (Diamond Magnesium Co.)	Painesville	AWE/DOE
OH	Piqua Organic Moderated Reactor	Piqua	DOE
OH	Portsmouth Gaseous Diffusion Plant	Piketon	DOE
OH	R. W. Leblond Machine Tool Co.	Cincinnati	AWE
OH	Tech-Art, Inc.	Milford	AWE
OH	Tocco Induction Heating Div.	Cleveland	AWE
OH	Vulcan Tool Co.	Dayton	AWE
OK	Kerr-McGee	Guthrie	AWE
OR	Albany Research Center	Albany	AWE/DOE
OR	Wah Chang	Albany	AWE
PA	Aeroprojects, Inc.	West Chester	AWE
PA	Aliquippa Forge	Aliquippa	AWE/DOE
PA	Aluminum Co. of America (Alcoa)	New Kensington	AWE
PA	Babcock & Wilcox	Parks Township	AWE
PA	Beryllium Corp. of America	Hazleton	BE
PA	Beryllium Corp. of America	Reading	BE
PA	Birdsboro Steel & Foundry	Birdsboro	AWE
PA	C.H. Schnoor	Springdale	AWE/DOE
PA	Carnegie Mellon Cyclotron Facility	Saxonburg	AWE
PA	Carpenter Steel Co.	Reading	AWE
PA	Chambersburg Engineering Co.	Chambersburg	AWE
PA	Foote Mineral Co.	East Whiteland Twp.	AWE
PA	Frankford Arsenal	Philadelphia	AWE
PA	Heppenstall Co.	Pittsburgh	AWE
PA	Jessop Steel Co.	Washington	AWE
PA	Koppers Co., Inc.	Pittsburgh	AWE
PA	Landis Machine Tool Co.	Waynesboro	AWE
PA	McDaniel Refractory Co.	Beaver Falls	BE
PA	Nuclear Materials and Equipment Corp.	Apollo	AWE/BE
PA	Penn Salt Co.	Philadelphia	AWE
PA	Philadelphia Naval Yard	Philadelphia	AWE
PA	Shippingport Atomic Power Plant	Shippingport	DOE
PA	Superior Steel Co.	Carnegie	AWE
PA	U.S. Steel Co., National Tube Division	McKeesport	AWE
PA	Vitro Manufacturing	Cannonsburg	AWE/BE
PA	Westinghouse Atomic Power Development Plant	East Pittsburgh	AWE
PR	BONUS Reactor Plant	Punta Higuera	DOE

Jurisdiction	Facility name	Location	Facility type
PR	Puerto Rico Nuclear Center	Mayaguez	DOE
RI	C.I. Hayes, Inc.	Cranston	AWE
SC	Savannah River Site	Aiken	DOE
TN	Clarksville Facility	Clarksville	DOE
TN	Oak Ridge Gaseous Diffusion Plant (K–25)	Oak Ridge	DOE
TN	Oak Ridge Hospital	Oak Ridge	DOE
TN	Oak Ridge Institute for Science Education	Oak Ridge	DOE
TN	Oak Ridge National Laboratory (X–10)	Oak Ridge	DOE
TN	Vitro Corp. of America	Chattanooga	AWE/BE
TN	W. R. Grace	Erwin	AWE
TN	Y–12 Plant	Oak Ridge	DOE
TX	AMCOT	Forth Worth	AWE
TX	Mathieson Chemcial Co	Pasadena	AWE
TX	Medina Facility	San Antonio	DOE
TX	Pantex Plant	Amarillo	DOE
TX	Sutton, Steele and Steele Co.	Dallas	AWE
TX	Texas City Chemicals, Inc.	Texas City	AWE
VA	Babcock & Wilcox Co.	Lynchburg	AWE
VA	Thomas Jefferson National Accelerator Facility	Newport News	DOE
VA	University of Virginia	Charlottesville	AWE
WA	Hanford	Richland	DOE
WA	Pacific Northwest National Laboratory	Richland	DOE
WV	Huntington Pilot Plant	Huntington	AWE/DOE
WI	Allis-Chalmers Co.	West Allis, Milwaukee	AWE
WI	Besley-Wells	South Beloit	AWE
WI	LaCrosse Boiling Water Reactor	LaCrosse	DOE
WI	Ladish Co.	Cudahy	BE

*Marshall Islands.
**Consistent with the Act, coverage is limited to activities not performed under the responsibility of the Naval Nuclear Propulsion program.

Issued in Washington, D.C. January 10, 2001.

David M. Michaels,

Assistant Secretary, Environment, Safety and Health.

[FR Doc. 01–1329 Filed 1–16–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–544–001]

Carnegie Interstate Pipeline Company; Notice of Compliance Filing

January 10, 2001.

Take notice that on November 13, 2000, Carnegie Interstate Pipeline Company (CIPCO) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets, with an effective date of October 1, 2000:

Second Revised Sheet No. 76
Second Revised Sheet No. 87

CIPCO states that the purpose of this filing is to comply with the Commission's Order issued on October 26, 2000.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before January 17, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1258 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL01–27–000]

Dominion Retail, Inc., Complainant, vs. FirstEnergy Corp., Cleveland Electric Illuminating Company, Ohio Edison Company, Toledo Edison Company, and American Transmission Systems, Inc., Respondent; Notice of Complaint

January 10, 2001.

Take notice that on January 9, 2001, the above listed entity, Dominion Retail, Inc. (Dominion Retail or Complainant), tendered for filing a complaint under the Federal Energy Regulatory Commission's (Commission) fast-track procedures against FirstEnergy Corp., Cleveland Electric Illuminating Company, Ohio Edison Company, Toledo Edison Company and American Transmission Systems, Inc. (FirstEnergy).

Complainant has requested that the Commission: (1) find that this complaint merits Fast Track Processing as provided by Section 206(h) of the Commission's Rules of Practice and Procedures; (2) find that the exclusion of FirstEnergy's marketing affiliates from the conditions contained in Paragraph V of the Stipulation and Recommendation is in violation of Section 205 of the Federal Power Act; and of the Commission's Rules related

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to affiliated entities, and of FirstEnergy's Code of Conduct as filed with and approved by this Commission; (3) find that the conditions imposed upon affiliated marketers in Paragraph V of the Stipulation and Recommendation is in violation of Section 205 of the Federal Power Act, or in the alternative, that FirstEnergy's interpretation and application of those conditions so as to disqualify Dominion Retail from qualifying to receive an allocation of MSG power is in violation of Section 205 of the Federal Power Act; and (4) provide such other and further relief as may be appropriate under the circumstances.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before January 29, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222) for assistance. Answers to the complaint shall also be due on or before January 29, 2001. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1259 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–337–001]

Kern River Gas Transmission Company; Notice of Proposed Pro Forma Changes in FERC Gas Tariff

January 10, 2001.

Take notice that on January 5, 2001, Kern River Gas Transmission Company (Kern River) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following pro forma tariff sheets:

Sheet No. 76, Sheet No. 106, Sheet No. 125, Sheet No. 125–A, Sheet No. 126, Sheet No. 135, Sheet No. 147, Sheet No. 148, Sheet No. 200, Sheet No. 201, Sheet No. 202, Sheet No. 501, Sheet No. 601, Sheet No. 701, Sheet No. 815, Sheet No. 825, Sheet No. 826, and Sheet No. 901

Kern River states that the purpose of this filing is to submit pro forma tariff sheets reflecting a proposed segmentation policy to be added to Kern River's tariff.

Kern River states that it has served copy of this filing upon each person designated on the official service list compiled by the Secretary in this proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before January 19, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1257 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–372–001]

New England Power Company; Notice of Filing

January 10, 2001.

Take notice that on December 29, 2000, New England Power Company (NEP), pursuant to section 205 of the Federal Power Act, 16 U.S.C. 824d (1994) and section 35.13 of the Commission's Rules and Regulations, 18 CFR 35.13, withdraws its service agreement filed with the Commission on November 6, 2000 in Docket No. ER01–372–000, and submits for filing a First Revised Service Agreement No. 124 between NEP and ANP Bellingham Energy Company for Firm Local Generation Delivery Service under NEP's Open Access Transmission Tariff, FERC Electric Tariff, Original Volume No. 9.

Copies of the filing were served upon ANP Bellingham Energy Company and regulators in the Commonwealth of Massachusetts.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 19, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–1312 Filed 1–16–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–904–000]

North Carolina Power Holdings, LLC; Notice of Filing

January 10, 2001.

Take notice that on January 8, 2001, North Carolina Power Holdings, LLC (NCPH), tendered for filing an application for waivers and blanket approvals under various regulations of the Commission and for an order accepting NCPH's FEFC Electric Rate Schedule No. 1 and accompanying Code of Conduct.

NCPH requests waiver of the 60-day prior notice requirement to permit NCPH's Rate Schedule and Code of Conduct to be effective January 19, 2001.

NCPH intends to engage in electric power and energy transactions as a marketer. In transactions where NCPH sells electric energy, it proposes to make such sales on rates, terms and conditions to be mutually agreed to with the purchasing party. NCPH's proposed Rate Schedule also permits it to reassign transmission capacity.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on or before January 18, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 01–1311 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–63–000]

Trunkline LNG Company; Notice of Application

January 10, 2001.

Take notice that on January 5, 2001, Trunkline LNG Company (Trunkline LNG), P.O. Box 4967, Houston, Texas 77210–4967, filed an application with the Commission in Docket No. CP01–63–000 pursuant to section 7 of the Natural Gas Act (NGA) for a certificate of public convenience and necessity requesting authorization to perform minor modifications to its liquefied natural gas (LNG) terminal near Lake Charles, Louisiana, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us/online/htm* (call 202–208–2222 for assistance).

Specifically, Trunkline LNG requests authorization to install approximately 80 feet of 16-inch insulated stainless steel by-pass piping and valve actuator around the existing recondenser to increase the LNG throughput to the second stage pumps; modify the seven vaporizer air blowers and motors by replacing the existing air blowers with new air blowers and removing the existing 359 HP motors, installing new 500 HP motors to increase the air capabilities and, installing new burner nozzles and NO_X controls on vaporizers to reduce emissions. Trunkline LNG states that the proposed modifications will eliminate operational bottlenecks in the re-gasification process and permit the terminal to increase the daily sendout capability from 700 MMscf/d to 1 Bscf/d at an estimated cost of approximately $1.25 million.

Any questions regarding this application should be directed to William W. Grygar, Vice President of Rates and Regulatory Affairs, 5444 Westheimer Road, Houston, Texas 77056–5306 at (713) 989–7000.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before January 31, 2001, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the Trunkline LNG and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the Trunkline LNG and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the Trunkline LNG, on other pipelines in the area, and on landowners and communities. For example, the Commission considers the extent to which the Trunkline LNG may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(ii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of

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the Commission's review process, a final Commission order approving or denying a certificate will be issued.

David P. Boergers,

Secretary.

[FR Doc. 01–1255 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–381–007]

Wyoming Interstate Company, Ltd.; Notice of Compliance Filing

January 10, 2001.

Take notice that on January 5, 2001, Wyoming Interstate Company, Ltd. (WIC) tendered for filing as part if its FERC Gas Tariff, Second Revised Volume No. 2, the sheets listed on Appendix A and Appendix B to the filing, to become effective on the dates indicated on each sheet.

WIC asserts that the purpose of this filing is to comply with the Commission's order issued September 27, 2000 in Docket No. RP99–381 approving settlement and granting interlocutory appeal. Specifically, this filing reflects the transportation rates from January 1, 2000 forward for consenting and contesting parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1256 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–34–000, et al.]

Delmarva Power & Light Company, et al.; Electric Rate and Corporate Regulation Filings

January 9, 2001.

Take notice that the following filings have been made with the Commission:

1. Delmarva Power & Light Company and Conectiv Energy Supply, Inc.

[Docket No. EC01–34–000]

Take notice that on January 5, 2001, Delmarva Power & Light Company (Delmarva) and Conectiv Energy Supply, Inc. (CESI) (collectively Applicant) submitted Exhibit H to supplement their application under the provisions of Section 203 of the Federal Power Act involving the assignment of Delmarva's rights and obligations under certain wholesale power sales agreements (Agreements) to CESI. Exhibit H includes the executed assignment and assumption agreement between Delmarva and CESI.

The Applicants state that copies of this joint application have been served upon Delmarva's counterparties in the Agreements and the pertinent state regulatory commissions.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Calumet Energy Team, LLC

[Docket No. EG01–26–000]

Take notice that on December 15, 2000, Calumet Energy Team, LLC, c/o Wisvest Corporation, N16 W23217 Stone Ridge Drive, Suite 100, Waukesha, WI 53188, filed with the Federal Energy Regulatory Commission an amended application for determination of exempt wholesale generator status pursuant to section 32(a)(1) of the Public Utility Holding Company Act of 1935. The applicant is a limited liability company organized under the laws of the State of Delaware that is engaged directly and exclusively in developing, owning, and operating a gas-fired, nominally 300 MW simple-cycle peaking power plant in Chicago, Illinois. The applicant's power plant will be an eligible facility.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. City of Kechikan, Alaska

[Docket No. EL01–26–000]

Take notice that on January 2, 2001, the City of Ketchikan, Alaska, d/b/a Ketchikan Public Utilities (Petitioner or Ketchikan), submitted an Application for Limited Waiver of Regulations Implementing PURPA § 210, or in the Alternative, Request for Confirmation of Treatment of Avoided Cost, pursuant to Section 402 of the Commission's Regulations under Sections 201 and 210 of the Public Utility Regulatory Policies Act of 1978 (PURPA). Ketchikan is seeking a limited waiver of any obligation that it may have under PURPA to displace purchases from the Four Dam Pool Initial Project, with purchases from a project certified under PURPA as a qualifying facility. Alternatively, Ketchikan requests that the Commission confirm that a proper calculation of "avoided costs" under PURPA reflect the avoided costs of the Four Dam Pool Initial Project Joint Action Agency, and any waivers necessary to permit the requested confirmation of the avoided cost calculation.

Comment date: February 8, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. ISO New England Inc.

[Docket No. EL00–62–016]

Take notice that on December 28, 2000, ISO New England Inc. submitted an Interim Report of Compliance in response to the Commission's June 28, 2000 Order in this proceeding.

Copies of said filing have been served upon all parties to this proceeding and upon the utility regulatory agencies of the six New England States.

Comment date: February 8, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. ISO New England Inc.

[Docket Nos. EL00–62–017 and EL00–62–018]

Take notice that on January 2, 2001, ISO New England Inc. made a compliance filing as required in the Commission's December 15, 2000 Order in these proceedings. Copies of said filing have been served upon all parties to this proceeding, upon NEPOOL Participants, as well as upon the utility regulatory agencies of the six New England States.

Comment date: February 8, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Potomac Electric Power Company

[Docket No. ER00–3727–002]

Take notice that on December 22, 2000, Potomac Electric Power Company (Pepco), tendered for filing an executed Service Agreement No. 20 under Pepco's FERC Electric Tariff, First Revised Volume No. 5 with Southern Company Energy Marketing L.P. (SCEM). The unexecuted service agreement had been previously accepted for filing by the Commission in Potomac Electric Power Company, et al, 93 FERC ¶ 61,240 (2000).

The service agreement became effective on December 19, 2000.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Cinergy Services, Inc.

[Docket No. ER01–500–001]

Take notice that on December 27, 2000, Cinergy Services, Inc. (Cinergy), tendered for filing a Service Agreement under Cinergy's Resale, Assignment or Transfer of Transmission Rights and Ancillary Service Rights Tariff (Tariff) entered into between Cinergy and Wabash Valley Power Association, Inc.

Comment date: January 19, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Outback Power Marketing Inc.

[Docket No. ER01–297–001]

Take notice that on January 5, 2001, Outback Power Marketing Inc. (OPMI), tendered for filing with the Federal Energy Regulatory Commission a compliance filing pursuant to the Commission's order in OPMI Docket No ER01–297–000 (Letter Order issued December 12, 2000).

Outback Power Marketing Inc. stated that it served a copy of its filing upon each person designated on the official service list compiled by the Secretary in this proceeding.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Fulton Cogeneration Associates, L.P.

[Docket No. ER01–324–001]

Take notice that on January 4, 2001, Fulton Cogeneration Associates, L.P. (Fulton), tendered for filing First Revised Sheet No. 1, FERC Electric Tariff, Original Volume No. 1.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Mississippi Power Company

[Docket No. ER01–866–000]

Take notice that on January 2, 2001, Mississippi Power Company (Mississippi), tendered for filing a request for a waiver of certain requirements of the Fuel Adjustment Clause of its FERC Electric Tariff, First Revised Volume I (Tariff), to allow Mississippi Power to pass through the fuel adjustment clause its displaced energy cost instead of the cost of test energy from its new combined cycle units, Plant Daniel 3 & 4.

Copies of the filing were served on all customers taking service under the Tariff and on the Mississippi Public Service Commission and the Mississippi Public Utilities Staff.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Indeck Pepperell Power Associates

[Docket No. ER01–867–000]

Take notice that on January 2, 2001, Indeck Pepperell Power Associates, Inc. (Indeck Pepperell), tendered for filing with the Federal Energy Regulatory Commission a Power Purchase and Sale Transaction (Transaction) between Indeck Pepperell and Calpine Energy Services, L.P. (Calpine), dated January 28, 2000, for service under Rate Schedule FERC No. 1.

Indeck Pepperell requests that the Service Agreement be made effective as of January 1, 2001.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Western Resources, Inc.

[Docket No. ER01–868–000]

Take notice that on January 2, 2001, Western Resources, Inc.(WR), tendered for filing a Service Agreement between WR and East Kentucky Power Cooperative (EKPC). WR states that the purpose of this agreement is to permit EKPC to take service under WR's Market Based Power Sales Tariff on file with the Commission.

This agreement is proposed to be effective December 5, 2000.

Copies of the filing were served upon EKPC and the Kansas Corporation Commission.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Geothermal Properties, Inc.

[Docket No. ER01–869–000]

Take notice that on January 2, 2001, Geothermal Properties, Inc. (GPI), petitioned the Commission for acceptance of GPI Rate Schedule FERC No. 1; the granting of certain blanket approvals, including the authority to sell electricity at market-based rates; and the waiver of certain Commission Regulations.

GPI intends to engage in wholesale electric power and energy purchases and sales as a marketer through a wholly-owned, special purpose vehicle. GPI is not currently in the business of generating or transmitting electric power, however, GPI intends to continue the exploration and development of its geothermal leases within the Coso KGRA with a view towards developing 10 MW of capacity by December 2002 and a minimum of 40 MW of capacity by December 2004. GPI is an affiliate of the Grace Family (Grace), which has been involved in geothermal projects in The Geysers area of California having total capacity of 240 MW.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Alliant Energy Corporate Services, Inc.

[Docket No. ER01–870–000]

Take notice that on January 2, 2001, Alliant Energy Corporate Services, Inc. (Alliant Energy) on behalf of IES Utilities Inc. (IESU) and Wisconsin Power & Light (WPL), tendered for filing a Negotiated Capacity Transaction (Agreement) between IESU and WPL for the period January 1, 2001 through January 31, 2001. The Agreement was negotiated to provide service under the Alliant Energy System Coordination and Operating Agreement among IES Utilities Inc., Interstate Power Company, Wisconsin Power & Light Company and Alliant Energy.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Cabrillo Power I LLC and Cabrillo Power II LLC

[Docket No. ER01–887–000]

Take notice that on January 3, 2001, Cabrillo Power I LLC and Cabrillo Power II LLC, tendered for filing their Reliability Must Run (RMR) Agreements conformed to the terms of the Second Stipulation in Docket No. ER98–445, et al., and the Commission's Order No. 614.

This filing has been served on the California ISO, San Diego Gas & Electric Company, the California Electricity Oversight Board and the California Public Utilities Commission.

Pursuant to the terms of the Second Stipulation, these changes should be made effective as of June 1, 1999.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

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16. California Independent System Operator Corporation

[Docket No. ER01–871–000]

Take notice that on January 3, 2001, the California Independent System Operator Corporation (ISO), tendered for filing and acceptance a Utility Distribution Company Operating Agreement (UDC Operating Agreement) between the ISO and the City of Vernon, California (Vernon).

The ISO requested waiver of the Commission's 60-day prior notice requirement to allow the UDC Operating Agreement to be made effective as of January 1, 2001, the date on which Vernon has requested to become a Participating TO.

The ISO states that this filing has been served upon all parties in this proceeding.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Central Maine Power Company

[Docket No. ER01–872–000]

Take notice that on January 3, 2001, Central Maine Power Company (CMP), tendered for filing a service agreement for Long Term Firm Local Point-to-Point Transmission Service entered into with Regional Waste System, Inc. Service will be provided pursuant to CMP's Open Access Transmission Tariff, designated rate schedule CMP—FERC Electric Tariff, Original Volume No. 3, as supplemented.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Entergy Services, Inc.

[Docket No. ER01–873–000]

Take notice that on January 3, 2001, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc., (collectively, the Entergy Operating Companies) tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement and a Short-Term Firm Point-To-Point Transmission Service Agreement both between Entergy Services, Inc., as agent for the Entergy Operating Companies, and The Legacy Energy Group, LLC.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. California Independent System Operator Corporation

[Docket No. ER01–889–000]

Take notice that on January 4, 2001, the California Independent System Operator Corporation (ISO), tendered for filing Amendment No. 36 to the ISO Tariff. The ISO states that Amendment No. 36 is intended to provide a temporary exemption from creditworthiness requirements for Schedule Coordinators that had an Approved Credit Rating on January 3, 2001, and are either Original Participating Transmission Owners or schedule on behalf of Original Participating Transmission Owners. The ISO will extend the temporary exemption on a day to day basis, but in no event beyond March 3, 2001.

The ISO states that this filing has been served on the California Public Utilities Commission, the California Electricity Oversight Board and all California ISO Scheduling Coordinators.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/ online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1254 Filed 1–16–01; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–959; FRL–6589–5]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–959, must be received on or before February 16, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–959 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–959. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–959 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *"opp-docket@epa.gov,"* or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–959. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 2, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

Petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical method available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Gowan Company

PP 7F4879

EPA has received a pesticide petition (PP 7F4879) from Gowan Company, P.O. Box 5569, Yuma, AZ 85366–5569 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of dicloran (2,6-dichloro-4-nitroaniline) in or on the raw agricultural commodities peanuts at 3 parts per million (ppm), in peanut oil at 6 ppm. EPA received an amendment for two additional tolerances. The existing tolerances for dicloran on carrots is limited to residues resulting from post-harvest use only and the existing tolerance for dicloran on tomatoes is

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limited to residues from pre-harvest use only. Gowan has proposed to expand the tolerances to permit residues resulting from pre-harvest use on carrots and post-harvest use on tomatoes. No numerical change in the current tolerance of 10 ppm on carrots and 5 ppm on tomatoes is proposed. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of dicloran in peaches, lettuce and potatoes has been studied. Parent compound and numerous metabolites derived by hydroxylation and acetylation of the nitro group, along with deamination and hydroxylation of the amino group, were seen in all crops. Glutathione conjugation with simultaneous removal of one or both chlorine atoms was shown to occur.

2. *Analytical method.* An adequate analytical method (EC GLC) is available for enforcement purposes. Parent compound is the only analyte in the tolerance expression.

3. *Magnitude of residues.* Twenty-five residue trials were conducted over 4 years. Average residues of 0.61 ppm were observed in peanuts and the highest average residue observed was 2.85 ppm. An average concentration factor of 1.6X in refined peanut oil was observed.

Five pre-harvest and three combined pre-harvest plus post-harvest carrot residue trials were conducted. Residues from the proposed pre-harvest use pattern were in all cases well below the existing post-harvest tolerance of 10 ppm.

Post-harvest tomato residue studies were conducted. Variables including dilution rates, application techniques and the composition and concentration of various wax emulsions were investigated. It was concluded that the proposed post-harvest use pattern will result in residues which are below the existing tolerance of 5 ppm for pre-harvest use.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD_{50} of technical dicloran is greater than 10,000 milligrams/kilograms (mg/kg), the acute dermal LD_{50} is greater than 2,000 mg/kg, and the 4-hour acute inhalation LC_{50} is greater than 2 milligrams/liter (mg/L). Dicloran is not a dermal irritant but is a sensitizer. Dicloran is a mild eye irritant.

2. *Genotoxicity.* The following genotoxicity tests were conducted: gene mutation (Ames tests), structural chromosome aberration (*in vivo* cytogenetic assay using human lymphocytes) and unscheduled DNA synthesis using rat hepatocytes. Results were generally negative; however, some Ames tests with the bacterium *S. typhimurium* showed a positive response. Ames tests with *E. coli* were negative. In view of the results of mammalian chronic, oncogenic and developmental studies, however, it is considered that the results of the positive Ames tests are not relevant to human toxicity.

3. *Reproductive and developmental toxicity.* In a rabbit developmental toxicity study, the maternal no observed adverse effect level (NOAEL) was 8 mg/kg/day and the maternal lowest observed adverse effect level (LOAEL) as 20 mg/kg/day. The developmental NOAEL was greater than or equal to 50 mg/kg/day, the highest dose tested.

In a rat developmental toxicity study, the maternal and embryotoxic NOAEL was 100 mg/kg/day, and the maternal and embryotoxic LOAEL was 200 mg/kg/day. The teratological NOAEL was greater than or equal to 400 mg/kg/day, the highest dose tested (HDT).

In a 2-generation rat reproduction study, the NOAEL for systemic toxicity was 250 ppm (21 mg/kg/day) on the basis of reduced bodyweight gain and increased liver and kidney weights. The NOAEL for reproductive and developmental toxicity was also 250 ppm on the basis of reduced pup weights. No other reproductive or developmental parameters were affected at any treatment level. The highest dose tested was 1,250 ppm (110 mg/kg/day).

4. *Subchronic toxicity.* In 90-day rat studies, the NOAEL was determined to be 500 ppm in the diet (44 mg/kg/day), and the LOAEL was based upon increased liver weights in both sexes and centrilobular hepatocyte enlargement in males. Similar effects, as well as an increase in blood cholesterol concentration, were observed in 90-day mouse studies, and the NOAEL was 15 mg/kg/day.

5. *Chronic toxicity.* EPA has established the reference dose (RfD) for dicloran at 0.025 mg/kg/day. The RfD for dicloran is based on a 2-year dog feeding study with a NOAEL of 2.5 mg/kg/day and an uncertainty factor of 100. The effect of concern was increased liver weight and histological changes in hepatocytes.

6. *Animal metabolism.* Dicloran is rapidly excreted by rats, goats, and hens. Numerous metabolites derived by reduction, acetylation, hydroxylation, deamination and dechlorination were observed.

7. *Carcinogenicity.* In an 80-week mouse study, dicloran was not oncogenic when administered at dose levels up to 600 ppm (103 mg/kg/day). Heptotoxicity indicated this to be the approximate maximum tolerance dose. In a 2-year rat study, dicloran was not oncogenic when administered at 1,000 ppm (59 mg/kg/day for males and 71 mg/kg/day for females).

8. *Endocrine disruption.* Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication of any effects on endocrine function related to development and reproduction. Subchronic and chronic treatment did not induce any morphological changes in endocrine organs and tissues.

C. Aggregate Exposure

1. *Dietary exposure*— i. *Chronic exposure.* In a theoretical maximum residue concentration (TMRC) worse-case analysis, it was assumed that dicloran is used on 100% of the acreage of all crops on which it is registered, and that residues on these crops are equal to the tolerance levels. It was calculated that the chronic dietary exposure to the general U.S. population would be 0.0265 mg/kg/day, or 106% of the chronic RfD. For non-nursing infants, the most highly exposed subgroup, the chronic dietary exposure from all crops is calculated to be 409% of the RfD.

Actual dietary chronic exposure is known to be much lower. The U.S. Department of Agriculture, the U.S. Food and Drug Administration, and California have monitored residues of dicloran in foods, and tens of thousands of analyses have been performed. These databases are readily examined using the Agency's own dietary exposure software, DEEM. It is concluded that the current actual chronic dietary exposure to dicloran from all foods is less than 0.002 mg/kg/day (less than 8% of the RfD) for non-nursing infants, the most highly exposed subgroup, and less than 0.001 mg/kg/day (less than 4% of the RfD) for the general U.S. population and all other subgroups.

Novigen Sciences DEEM software was used to perform a theoretical maximum residue concentration (TMRC) analysis for peanuts, carrots, and tomatoes. Actual results of peanut and tomato processing studies with dicloran were incorporated. Dietary exposure was calculated to be equivalent to 24% of the RfD for the U.S. population, 14% for non-nursing infants and 49% for children 1–6, the most heavily-exposed population subgroup. Given these assumptions, the total dietary exposure from all current and proposed uses would be equivalent to no more than 28% of the RfD for the U.S. population, 22% for non-nursing infants and 53% for children 1–6. These levels of exposure are acceptable.

ii. *Acute exposure.* No developmental or reproductive effects have been observed which indicate special perinatal sensitivity. Therefore, an analysis of acute exposure has not been conducted.

a. *Food.* Dicloran is registered for use on apricots, snap beans, carrots, celery, sweet cherries, cucumbers, endive, garlic, grapes, lettuce, nectarines, onions, peaches, plums, potatoes, rhubarb, sweet potatoes and tomatoes. (See 40 CFR 180.200 for specific tolerances.) The metabolism of dicloran in plants and animals is adequately understood for the purposes of these tolerances. There is a practical analytical method for detecting and measuring levels of dicloran in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance.

b. *Drinking water.* Dicloran was not reported in the Agency's survey of pesticides in ground water from 1971–1991, nor in the Agency's 1988–1990 survey of pesticides in drinking water wells. The compound has not been reported in surface water. A small scale prospective ground water study suggests that the average residue in ground water is well below 0.001 ppm. The Agency has not conducted a detailed analysis of potential exposure to dicloran via drinking water; however, it is believed that chronic exposure from this source is very small.

2. *Non-dietary exposure.* Dicloran has no aquatic, lawn or residential uses.

D. Cumulative Effects

At this time the Agency has not reviewed available information concerning the potentially cumulative effects of dicloran and other substances that may have a common mechanism of toxicity. For purposes of this petition only, the Agency is considering only the potential risks of dicloran in its aggregate exposure.

E. Safety Determination

1. *U.S. population—Chronic risk.* If it is assumed that all crops on which dicloran is registered are treated, and if all residues on crops are assumed to be equal to the tolerance levels, then it can be calculated that the theoretical maximum residue concentration (TMRC) is equal to 106% of the RfD for the general U.S. population and 408% of the RfD for non-nursing infants, the most highly exposed group.

Actual chronic risk is known to be much lower. Using anticipated residue concentrations, it was concluded that chronic dietary exposure to dicloran will be no more than 28% of the RfD. Exposures from drinking water and all other routes is expected to be negligible.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of dicloran, EPA considered data from developmental toxicity studies in the rat and rabbit and reproduction studies in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

No teratological effects have been observed with dicloran. The lowest embryotoxic NOAEL in these studies was 100 mg/kg/day, compared to a chronic NOAEL of 2.5 mg/kg/day. There is no indication of special perinatal sensitivity in the absence of maternal toxicity and thus no suggestion of special sensitivity of infants and children. It is concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to dicloran residues.

F. International Tolerances

There are no Codex, Canadian or Mexican maximum residue levels for dicloran in peanuts. Although no numerical revisions of existing tolerance levels are proposed for carrots or tomatoes, it is noted that Canadian MRL's of 5 ppm exist for both carrots and tomatoes. Codex MRL's of 10 ppm for carrots and 0.5 ppm for tomatoes exist.

[FR Doc. 01–1352 Filed 1–16–01; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–986; FRL–6755–1]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–986, must be received on or before February 16, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–961 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sharlene Matten, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0514; e-mail address: matten.sharlene@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–986. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–986 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: "opp-docket@epa.gov", or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–986. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 5, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

EPA has received a pesticide petition PP 0F6191 from Platte Chemical Company, j419 18th Street, Greeley, CO 80632–0667, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the microbial pesticide *Alternaria destruens.*

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Platte Chemical Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Platte Chemical Company and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

Platte Chemical Company

PP 0F6191

A. Product Name and Proposed Use Practices

Alternaria destruens is a naturally occurring fungus that is pathogenic to *Cuscuta* spp., often referred to as dodder, swamp dodder, largeseed dodder, field dodder or small seed dodder. The active ingredient will infect and suppress dodder at early stages of growth. Dodder is a leafless, rootless weed that is parasitic on cranberries and other crops, directly reducing vigor. Dodder generally germinates in late spring, twining stems around the host to derive its nutrients from that plant.

Two formulations of *Alternaria destruens* are proposed, one for the control of emerging dodder and one for the control of dodder that has attached to and infested the host plant. Smolder L G, a granular product, is proposed for use on known sites of dodder infestation, as it emerges in the spring, to suppress dodder growth and seed production. Smolder L WP, a sprayable product, is proposed for use on growing dodder, as spot or area treatment to control further growth. Use sites include vegetables, fruits, field crops and non-agricultural areas such as uncultivated rights-of-way, roadsides and fallow areas.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues. Alternaria destruens* is a naturally occurring fungus that is pathogenic to *Cuscuta* spp., often referred to as dodder, swamp dodder, largeseed dodder, field dodder or small seed dodder. The active ingredient will infect and suppress dodder at early stages of growth. *Alternaria destruens* requires adequate moisture and temperature during the infection period (3 to 4 hours). In very dry or drought conditions, when dew is absent, the onset of the infection process might be delayed until moisture conditions return. *Alternaria destruens* has been shown to survive in nature only on live or dead tissue of the host weed species. Survival on soil or non-susceptible plant tissue would be limited.

2. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable. The use of *Alternaria destruens* calls for application to field crops at an early stage for control of dodder species. Consequently, there is a considerable time lag between application and harvesting of crops. Since survival of the organism is in part dependent on existence of the host plant, it is unlikely that application will result in the presence of *Alternaria destruens* in food crops. Residues of *Alternaria destruens* are not expected on agricultural commodities.

C. Mammalian Toxicological Profile

The active ingredient *Alternaria destruens* has been evaluated for toxicity through oral, dermal, pulmonary, intraperitoneal, and eye routes of exposure. The results of the studies have indicated there are no significant human health risks.

For the active ingredient, acute oral toxicity/pathogenicity in rats is greater than 1 X 10^7 cfu/animal, acute pulmonary toxicity/pathogenicity in rats is greater than 5 X 10^5 cfu/animal, and acute intraperitoneal toxicity/pathogenicity in rats is greater than 9.6 X 10^6 cfu/animal. No pathogenic or infective effects were observed in the studies. For the end-use wettable powder formulation, acute dermal toxicity in rats is greater than 5,000 mg/kg (Toxicity Category IV), acute inhalation toxicity in rats is greater than 2.03 mg/l (Toxicity Category IV), minimal eye irritation in rabbits was observed at a dose of 0.1 ml (Toxicity Category III) and no skin irritation in rabbits was observed at a dose of 0.5 ml (Toxicity Category IV). Since its discovery, no incidents of hypersensitivity have been reported by researchers, manufacturers or users.

D. Aggregate Exposure

1. *Dietary exposure—i. Food.* Dietary exposure from use of *Alternaria destruens*, as proposed, is minimal. The use of *Alternaria destruens* calls for application to field crops at an early stages for control of dodder species. Consequently, there is a considerable time lag between application and harvesting of crops. Since survival of the organism is in part dependent on existence of the host plant, it is unlikely that application will result in the presence of *Alternaria destruens* in food crops. Residues of *Alternaria destruens* are not expected on agricultural commodities.

ii. *Drinking water.* Similarly, exposure to humans from residues of *Alternaria destruens* in consumed drinking water would be unlikely. *Alternaria destruens* is a naturally-occurring microorganism known to exist in terrestrial habitats in the presence of a host plant, it is not known to grow or thrive in aquatic environments.

2. *Non-dietary exposure.* The potential for non-dietary exposure to the general population, including infants and children, is unlikely as the proposed use sites are agricultural settings. However, non-dietary exposures would not be expected to pose any quantifiable risk due to a lack of residues of toxicological concern.

Person Protective Equipment (PPE) mitigates the potential for exposure to applicators and handlers of the proposed products, when used in agricultural settings.

E. Cumulative Exposure

It is not expected that, when used as proposed, *Alternaria destruens* would result in residues that would remain in human food items.

F. Safety Determination

1. *U.S. population. Alternaria destruens* is not pathogenic or infective to mammals. There have been no reports of toxins or secondary metabolites associated with the organism, and acute toxicity studies have shown that *Alternaria destruens* is non-toxic, non-pathogenic, and non-irritating. Residues of *Alternaria destruens* are not expected on agricultural commodities, and therefore, exposure to the general U.S. population, from the proposed uses, is not anticipated.

2. *Infants and children.* As mentioned above, residues of *Alternaria destruens* are not expected on agricultural commodities. There is a reasonable certainty of no harm for infants and children from exposure to *Alternaria destruens* from the proposed uses.

G. Effects on the Immune and Endocrine Systems

Alternaria destruens is a naturally-occurring microorganism. To date there is no evidence to suggest that *Alternaria destruens* functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

H. Existing Tolerances

There is no U.S. EPA Tolerance for *Alternaria destruens.*

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I. International Tolerances

A Codex Alimentarium Commission Maximum Residue Level (MRL) is not required for *Alternaria destruens.*

[FR Doc. 01–1353 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50873; FRL–6740–2]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits (EUPs) to the following pesticide applicants and amended certain previously granted EUPs. An EUP permits use of a pesticide for experimental or research purposes only in accordance with the limitations in the permit.

FOR FURTHER INFORMATION CONTACT: By mail: Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

In person or by telephone: Contact the designated person at the following address at the office location, telephone number, or e-mail address cited in each EUP: 1921 Jefferson Davis Hwy., Arlington, VA.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who conduct or sponsor research on pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this action, consult the designated contact person listed for the individual EUP.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

You may obtain electronic copies of this document from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

II. EUPs

EPA has issued the following EUPs: *524–EUP–90, 524–EUP–92,* and *524–EUP–93.* Issuance. Monsanto Company, 700 Chesterfield Parkway North, St. Louis, MO 63198. The issuance of these EUPs allows the use of the plant-pesticides *Bacillus thuringiensis* Cry3Bb protein and the genetic material necessary for its production (vector ZMIR14L) in corn, *Bacillus thuringiensis* Cry3Bb protein and the genetic material necessary for its production (vector ZMIR12L) in corn, and *Bacillus thuringiensis* Cry3Bb protein and the genetic material necessary for its production (vector ZMIR13L) in corn, respectively . A notice of receipt for these EUPs was published in the **Federal Register** on December 8, 1999 (64 FR 68681) (FRL–6398–3). The EUPs were granted on April 6, 2000 and amended on May 15, 2000. *524–EUP–90* allows the planting of 1,343 acres of corn to test and evaluate genetically modified corn that has been developed to provide control of corn rootworm (*Diabrotica spp.*). The program is authorized only in the States of California, Colorado, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Kansas, Michigan, Minnesota, Missouri, North Carolina, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin. *524–EUP–92* allows the planting of 416 acres of corn to test and evaluate genetically modified corn that has been developed to provide control of corn rootworm (*Diabrotica spp.*). The program is authorized only in the States of California, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Kansas, Michigan, Minnesota, Missouri, North Carolina, Nebraska, Oklahoma, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin. *524–EUP–93* allows the planting of 1,092 acres of corn to test and evaluate genetically modified corn that has been developed to provide control of corn rootworm (*Diabrotica spp.*). The program is authorized only in the States of California, Colorado, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Kansas, Michigan, Minnesota, Missouri, North Carolina, Nebraska, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Virginia, and Wisconsin. These EUPs are effective from April 6, 2000 to April 31, 2001. These permits are issued with the limitation that all treated crops will be genetically contained and destroyed or used for research purposes only. Nine comments were received in reply to the **Federal Register** notice announcing receipt of these applications. Non-target insect risks, ecological effects of biopesticides, the need for a transparent and scientifically rigorous process for setting conditions for registration and use of independent expert advice, insect resistance management, contamination levels of neighboring crops, and the participation of land grant university corn IPM experts in the EUP were concerns expressed during the comment period. Health, environmental, and agricultural benefits of corn rootworm protected Bt corn were also noted.

Insect resistance management and non-target organism research will be part of the testing taking place under these EUPs. Researchers will be looking at field and population levels for a wide variety of soil and surface dwelling organisms, including all major coleopteran species that are found in corn systems. This will include work on insects like collembola, carabids, and other soil invertebrates like earthworms. Land grant university researchers are involved in many of these investigations. Testing is not permitted in the vicinity of endangered beetle habitats. Based on the information submitted, no significant or irreversible hazards from Cry3Bb corn to non-target organisms are anticipated for the duration of these limited acreage programs. These EUPs are crop destruct and genetically contained. (Mike Mendelsohn; Rm. 910W16, Crystal Mall #2; telephone number: (703) 308–8715; e-mail address: mendelsohn.mike@epa.gov).

68467–EUP–2. Extensions/Amendments. Mycogen Seeds c/o Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The amendments and extensions to this EUP allow the use of the plant–pesticide *Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999) in corn plants. Notice of the original issuance of the EUP was published in the **Federal Register** on May 5, 1999 (64 FR 24161) (FRL–6078–2). Notices of receipt for several amendments were published in the **Federal Register** on February 25, 2000 (65 FR 10081) (FRL–6492–1) and on March 3, 2000 (65 FR 11575) (FRL–6495–8). On May 11, 1999, the EUP was amended to modify the containment provisions. On June 18, 1999, the EUP was amended to switch acreage between different protocols in the program at the same sites. On January 27, 2000, the EUP was amended to permit the planting of 55 acres in Puerto Rico for agronomic observation and Liberty herbicide tolerance studies. On February 4, 2000, the EUP was amended to permit the planting of 5 acres in Hawaii for agronomic observation studies. Planting dates for all amendments mentioned above remained the same as permitted in the original EUP issuance and genetic isolation and crop destruct provisions still applied. On March 31, 2000, the EUP was extended/amended to allow the planting of 145 acres of field corn to evaluate the control of European corn borer, Southwestern corn borer, fall armyworm and black cutworm; to perform agronomic and herbicide tolerance observations; and to do breeding and observation. The program is authorized only in the States of Colorado, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Missouri, North Carolina, Nebraska, North Dakota, Pennsylvania, Ohio, Puerto Rico, South Dakota, Tennessee, Texas, and Wisconsin. This amendment/extension of the EUP is effective from March 31, 2000 to March 31, 2001. This amendment/extension to the permit is issued with the limitation that all treated crops will be genetically contained and destroyed or used for research purposes only. On April 21, 2000, the EUP was extended/amended to allow the planting of an additional 947 acres of field corn to evaluate the control of European corn borer, Southwestern corn borer, fall armyworm and black cutworm; to perform agronomic and herbicide tolerance observations; to do hybrid production, breeding and observation; to study anthesis length; and to study insect resistance management. Additional acreage under this amendment/extension to the program is authorized only in the States of Hawaii, Iowa, Minnesota, and Nebraska. This amendment/extension of the EUP is effective from April 21, 2000 to March 31, 2001. This amendment/extension to the permit is issued with the limitation that all treated crops will be genetically contained and destroyed or used for research purposes only. Thirteen comments were received in reply to the **Federal Register** notice announcing receipt of this amendment/extension. Comments raised concerns about the labeling of food resulting from Bt corn, food safety, pollen shed/drift contamination of adjacent organic crops, the development of resistance to foliar Bt, the impact of testing on the Hawaiian environment, the impact on Bt corn on farmers in Puerto Rico, and the impact to non-target insects. Based on the information submitted, no significant or irreversible hazards from Cry1F corn to non-target organisms are anticipated for the duration of this limited acreage program. This EUP and the extension/amendments are crop destruct and genetically contained. (Mike Mendelsohn; Rm. 910W16, Crystal Mall #2; telephone number: (703) 308–8715; e-mail address: mendelsohn.mike@epa.gov).

Persons wishing to review these EUPs are referred to the designated contact person. Inquiries concerning these permits should be directed to the persons cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Experimental use permits.

Dated: January 10, 2001.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 01–1351 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6833–5]

Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information; Development of Read-Only Information Technology System and Qualified Researcher System

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability.

SUMMARY: The Environmental Protection Agency (EPA) is developing two systems for providing access to information about the potential off-site consequences of accidental chemical releases from industrial facilities. One system would provide the public with "read-only" access to the information in electronic database form. The other system would provide qualified researchers with access to the information in paper or electronic database form. Both systems are required by section 112(r) of the Clean Air Act, as revised by the Chemical Safety Information, Site Security and Fuels Regulatory Relief Act (CSISSFRRA) of 1999. In this document we describe draft plans for these systems and request public comment on the plans and related issues.

DATES: Comments should be submitted by March 19, 2001.

ADDRESSES: Comments should be mailed to: Environmental Protection Agency, Office of Air and Radiation, Docket and Information Center, Ariel Rios Building, M6102, 1200 Pennsylvania Avenue, NW., Washington DC, 20460, Attn: Docket No. A–2000–58. By Federal Express or Courier: Waterside Mall, Room M1500, 401 M Street, SW, Washington DC 20460, Attn: Docket No. A–2000–58. Comments may be submitted on a disk in Wordperfect or Word formats. Please submit comments in duplicate. The draft plan for a qualified researcher system and supporting information used to develop that plan and the draft plan for a "read-only" information system are contained in Docket No. A–2000–58. The docket is available for public inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday (except government holidays), at Waterside Mall, Room M1500, 401 M Street, S.W., Washington, DC 20460. A reasonable fee may be charged for copying. The draft qualified researcher plan and the supporting information are also available on the Internet at http://www.epa.gov/ceppo or by calling the Emergency Planning and Community Right-to-Know Hotline at (800) 424–9346 (in the Washington, DC metropolitan area, (703) 412–9810).

FOR FURTHER INFORMATION CONTACT: Dorothy McManus, Program Analyst, (202) 564–8606, or Vanessa Rodriguez, Chemical Engineer, (202) 564–7913, Chemical Emergency Preparedness and Prevention Office, Environmental Protection Agency (5104), 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

I. Background

Section 112(r)(7) of the Clean Air Act (CAA) establishes a program for the prevention and mitigation of industrial chemical accidents that could harm the surrounding community and environment. Facilities subject to the program are required to prepare risk management plans (RMPs) that include an analysis of the potential off-site consequences of hypothetical worst-case and alternative scenario chemical releases.

Under section 112(r)(7) as originally enacted, RMPs—including the off-site

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consequence analysis (OCA) portions—were to be available to the public. However, concerns were raised that potential Internet distribution of the OCA portions of RMPs would pose law enforcement and national security risks. In response to these concerns, CSISSFRRA was enacted in 1999. CSISSFRRA amended the Clean Air Act by adding a new subparagraph (H) to section 112(r)(7).

Under CAA section 112(r)(7)(H)(ii), EPA assessed the benefits of public access to the OCA portions of the RMPs and EPA's database compiled from those portions ("OCA information"), while the Department of Justice (DOJ) assessed the risks of Internet dissemination of the same information. Based on the assessments, both agencies issued a rule on August 4, 2000, governing the distribution of paper copies of OCA information (65 FR 48108) to the public.

The rule, which is fully described and explained in the **Federal Register** notice cited above, provides two ways for the public to obtain limited access to paper copies of OCA information. First, at 50 or more federal reading rooms located across the country, any member of the public may view a paper copy of the OCA information for the facilities located in the jurisdiction of the Local Emergency Planning Committee (LEPCs) where the person lives or works. (LEPCs are established under the federal Emergency Planning and Community Right-to-Know Act (EPCRA) and generally cover one or more counties.) In addition, a member of the public may see a paper copy of the OCA information for up to 10 facilities per month without regard to where the facility is located. Reading rooms may allow the public to read and take notes from, but not remove or mechanically copy, the paper copies of OCA information.

The rule's second avenue for the public to obtain paper copies of OCA information is through state and local agencies. The rule authorizes LEPCs and related local and state agencies to provide the public with read-only access to a paper copy of the OCA information for local facilities.

Apart from the rule, CSISSFRRA provides several other avenues for the public to access OCA information. In particular, CAA section 112(r)(7)(H)(viii) requires EPA, "[i]n consultation with the Attorney General and the heads of other appropriate Federal agencies, [to] establish an information technology system that provides for the availability to the public of off-site consequence analysis information by means of a central data base under the control of the Federal Government that contains information that users may read, but that provides no means by which an electronic or mechanical copy of the information may be made." This provision, in short, calls on EPA to provide public access to OCA information for all facilities in electronic, read-only form.

CSISSFRRA also includes a provision for making OCA information available to "qualified researchers." CAA section 112(r)(7)(H)(vii) requires EPA , "[i]n consultation with the Attorney General, [to] develop and implement a system for providing [OCA] information, including facility identification, to any qualified researcher, including a qualified researcher from industry or any public interest group." That section further provides that "[t]he system shall not allow the researcher to disseminate, or make available on the Internet, the [OCA] information, or any portion of the [OCA] information, received" under the system.

II. Draft System for Public Information Technology System

A. Description of Draft System

After consulting with DOJ and other appropriate agencies, EPA is considering an information technology (IT) system that would provide the public with read-only access to OCA information in electronic form by means of stand-alone or restricted computers. The computers would contain a database compiled from all of the RMPs submitted to EPA. The database would include the OCA portions of RMPs along with information about facilities' accident prevention programs, accident history and emergency response plans.

An IT system computer would provide no more than read-only access by having all of its external communication ports and disk drives removed or physically disabled so that there would be no way to attach the computer to a printer or other external device. Essentially, the only items on the computer would be a monitor, hard disk, and CD–ROM reader. There also would be locks on the case of the computer so that the hard drive could not be removed and stolen, and the case would be bolted to the desk or located in a locked room, so that the computer could not be stolen.

The same precautions would maintain EPA control of the IT system's database. That database would not be connected to EPA's central database because of the potential for hacking. However, EPA would periodically update the IT system's database to keep it reasonably current.

To make the IT system user-friendly, EPA would equip it with software that would allow users to query on various types of information, such as chemical name and industry sector. For example, users could ask the system to pull up the RMPs, including OCA information, for facilities that use a particular chemical or belong to the same industry sector. At the same time, the software would not allow queries on any OCA data elements.

EPA would introduce the IT system in one location at EPA Headquarters in Washington, D.C. That location would be open to the public during normal working hours on Mondays through Fridays. Currently, members of the public visiting EPA's headquarters must sign in and show identification to gain entry to the building. The same would be true for users of the IT system.

B. Facility Identification Issue

An important remaining issue in EPA's development of an IT system is whether the system should identify facilities by providing the name and address. The system would include all of the data in the OCA sections of RMPs (sections 2 through 5). It would also include the information in RMPs about prevention programs, accident history and emergency response plans. Members of the public using the system would thus be able to view OCA information in the context of a facility's overall risk management program. They would also be allowed to view an unlimited number of facilities' information. The issue is whether the system should reveal the names or locations of facilities.

As noted above, EPA and DOJ issued a rule that provides any member of the public with read-only access to paper copies of OCA information for facilities in the LEPC jurisdiction where the person lives or works and for up to 10 facilities per month regardless of where the facility is located. The agencies based the rule on assessments of the risks and benefits of broad public dissemination of OCA information, including facility identification. The agencies concluded that posting of a large OCA database on the Internet would pose a significant national security and law enforcement risk, while public access to OCA information would provide significant chemical safety benefits. The agencies thus decided to reduce the risk of Internet posting while preserving the public availability of OCA information by providing any member of the public with read-only access to paper copies of OCA information for a limited number of facilities.

In light of the rule and assessments underlying it, EPA is considering whether the IT system should include facility identification information. A database including that information would provide users with an efficient means of identifying and learning about facilities that may put them at risk. At the same time, such a database could undercut the security purposes that the rule's limits on public access to paper copies of OCA information are intended to serve. A database excluding the information, while not permitting users to access RMPs for named facilities, could allow users to identify and study trends in chemical safety among facilities using the same chemical or process. It could also allow users to identify facilities similar to ones for which the user had obtained read-only access to OCA information in paper form. Comparing similar facilities would allow members of the public to assess a particular facility's chemical safety practices.

EPA requests comment on the issue of whether the IT system should include facility identification information and how useful such a system would be without that information. EPA also requests comment on whether we could address any security concerns raised by an IT system with facility identification information by limiting the number of outlets for the system and adequately securing those outlets.

III. Draft System for Qualified Researcher Access to OCA Information

A. Description of Draft System

EPA has developed draft guidance, in consultation with DOJ, for implementing a qualified researcher (QR) system. The draft guidance describes the background of the RMP program, CSISSFRRA and the QR provision, the factors EPA considered relevant to developing a QR system, and the potential terms of the system itself.

As noted above, CSISSFRRA requires that the QR system not allow researchers to disseminate the OCA information, or any portion of the OCA information, they receive under the system. This restriction reflects the fact that under the system, qualified researchers are to receive the most comprehensive and manipulable form of OCA information—EPA's OCA database containing OCA data and identification information for all covered facilities. QR access to EPA's OCA database thus entails some risk of a large OCA database becoming broadly available, the same risk the rule for public access is designed to address. Consequently, EPA has sought to develop a system that would adequately screen applicants to identify only bona fide researchers and preclude the release of OCA information in a form or to an extent that could pose that same risk.

The system described in the draft QR guidance contains potential criteria for identifying a QR, including experience in conducting research in relevant subject matter areas and ability to protect OCA information from dissemination. The draft system also calls for any QR to sign a consent agreement acknowledging that dissemination of OCA information except as authorized by law is a crime and committing the QR to protect OCA information from unauthorized dissemination. The draft consent agreement provides for significant financial penalties for failure to meets its terms.

A copy of the draft guidance is contained in Docket No. A–2000–58 and may be viewed at EPA's website or obtained by calling the EPCRA Hotline. The addresses and numbers for these outlets are provided in the "Addresses" section of this notice.

B. Facility Identification Issue

Like the IT system, the QR system raises an issue related to facility identification. As noted above, a QR will have access to OCA information, including facility identification information. A QR will also be subject to the prohibition in CSISSFRRA and the public access rule against distributing OCA information except as authorized by the law and regulations. The question EPA must still address is whether a QR should be allowed to publish OCA data, as distinct from "OCA information," for identified facilities.

"OCA information" is defined by CSISSFRRA and the public access rule as the OCA portions of RMPs and any EPA database derived from those portions. CSISSFRRA and the rule make clear that while OCA information may not be disseminated to the public except in specified ways, there is no restriction on the dissemination of the data reported in the OCA portions of RMPs so long as the data is conveyed in a format different than the OCA portions of RMPs or EPA's OCA database. (The rule captures this distinction by defining a new term, "OCA data elements," to refer to OCA data in a format other than the restricted RMP and EPA database formats.) The distinction reflects that fact that the RMP and EPA database formats are relatively easy to post on the Internet and thus pose the greatest risk of broad dissemination of a large OCA database.

At the same time, the QR provision in CSISSFRRA provides that the system "shall not allow the researcher to disseminate * * * the [OCA] information, or any portion of the [OCA] information," the researcher receives under the system. There is also concern that a QR could potentially defeat the purpose of the statutory and regulatory limits on the dissemination of "OCA information" by publishing OCA data for a large number of identified facilities. We are thus considering whether the QR system should place limits on a QR's ability to publish OCA data for identified facilities. Among the limits being considered are a bar on publication of OCA data for identified facilities and a numerical limit on the number of identified facilities for which OCA data could be published. Under either of these alternatives, there would be no limit on the amount of OCA data that a QR could publish *without* facility identification. We are also considering the alternative of not restricting the publication of OCA data for identified facilities.

We request comment on this issue and the alternatives being considered for addressing it. In particular, we would like to know why researchers might find it necessary to publish OCA data for identified facilities and the number of facilities that might be involved. Our review of past publications on chemical safety indicates that much useful research on chemical safety has been published without naming the facilities that were studied. We are aware, however, that some researchers, especially those affiliated with public interest groups, are interested in identifying facilities in an industry or geographical area that have notably good or bad safety records or programs. We are therefore interested in receiving comments on how useful a QR system would be if it were to include one or the other of the restrictions being considered.

In considering this question, it should be noted that CSISSFRRA and the rule prohibit "covered persons," including a QR, from publishing statewide or national rankings of RMP facilities based on OCA information. This prohibition is likely to lead researchers themselves to limit the number of facilities they identify, with or without OCA data. It is also worth noting that the draft QR system defines "research" as more than regurgitation or reformatting of available information. Consequently, a QR applicant must show that he or she needs OCA information to learn something new, such as industry averages and ranges. In short, an applicant cannot obtain OCA

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information merely to publicize OCA data. We welcome comments on whether the QR system should include restrictions on publication of OCA data for identified facilities and, if so, what those restrictions should be. We also welcome comment on any other aspect of the draft guidance.

Dated: December 28, 2000.

Timothy Fields, Jr.,

Assistant Administrator for Solid Waste and Emergency Response.

[FR Doc. 01–1349 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–34191A FRL–6756–8]

PR Notice on Worker Risk Mitigation for Organophosphate Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of a Pesticide Registration (PR) Notice describing EPA's approach for managing risk to workers who may be exposed to organophosphate (OP) pesticide products by mixing, loading, applying, flagging, or otherwise handling OP pesticides, or are exposed to residues of these pesticides while performing tasks in recently treated areas. This approach generally provides for basic protective measures such as closed mixing and loading systems, enclosed cab equipment, or personal protective equipment, as well as increased restricted-entry intervals for occupational situations where revised risk assessments indicate that they are necessary and where these measures are feasible. Further, this PR Notice outlines the steps that EPA intends to take to address situations where baseline mitigation measures are not feasible, or situations where maximum feasible mitigation is still inadequate to protect workers.

FOR FURTHER INFORMATION CONTACT: Jacqueline Gwaltney, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6792; fax number: (703) 308–8041; e-mail address: gwaltney.jackie@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to environmental, human health, agricultural, and agricultural worker advocates; pesticide users; and persons who are or may be required to conduct testing of chemical substances under Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations," " Regulations and Proposed Rules," and then look up the entry for this document under the **Federal Register**—Environmental Documents. You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

The OP worker risk mitigation PR notice is available on the Home Page for the Office of Pesticide Programs at http://www.epa.gov/PR—Notices/pr2000-9.pdf. EPA's response to public comments received on the August 6, 1999, draft PR notice is available at http://www.epa.gov/PR—Notices/draftprworker-response.htm . You may access information about the organophosphate pesticides at http://www.epa.gov/pesticides/op.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–34191A. EPA previously established an official record under docket control number OPP–34191 when the Agency published an FR notice on August 6, 1999 (64 FR 41934) (FRL–6093–8), announcing the availability of the draft OP worker risk mitigation PR notice for public comment. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. What Action is the Agency Taking?

This notice announces the availability of Pesticide Registration (PR) Notice 2000–9, which presents EPA's approach for managing risks from organophosphate (OP) pesticides to occupational users. The approach described in this PR Notice applies to workers who may be exposed to OP pesticide products by mixing, loading, applying, flagging, or otherwise handling them, or by performing tasks in recently treated areas. The PR Notice outlines the six steps that EPA will follow in assessing and managing the human health risks of an OP pesticide, to evaluate risks to workers and mitigate risks of concern. It explains the protective measures that the Agency is recommending to reduce OP worker risk including use of personal protective equipment; use of engineering controls such as closed mixing and loading systems and enclosed cabs and cockpits; application modifications such as reducing the rate or frequency of pesticide applications; mechanical harvesting; and longer Restricted Entry Intervals. The PR Notice also addresses situations where the maximum feasible mitigation still is inadequate to protect workers, or where the baseline risk mitigation measures are not feasible.

The guidance set forth in this PR Notice is intended to inform manufacturers, formulators, and users of the type of risk management decisions EPA is likely to develop for the OP pesticides. These chemicals are being reviewed by the Agency as part of the larger process of implementing the Food Quality Protection Act of 1996 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Implementation of the FQPA amendments has been the subject of a joint effort by EPA, USDA, and interested stakeholders known as the Tolerance Reassessment Advisory Committee (TRAC), recently replaced by the Committee to Advise on Reassessment and Transition (CARAT). Among other initiatives, TRAC established a process for public participation in the review and refinement of risk assessments for the OP pesticides and for developing risk management options. USDA, stakeholders, and the public have the opportunity to participate by submitting comments on EPA's preliminary and revised risk assessments and by providing risk management proposals. During the final phase of this process, EPA prepares an Interim Reregistration Eligibility Decision (IRED) or a Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision (TRED) document for each OP pesticide, to implement interim risk management measures. Worker risk mitigation is but one aspect of the comprehensive mitigation strategy that is developed in concluding each individual OP assessment.

In a number of cases, the OP risk assessments show that, even with maximum feasible personal protective equipment and engineering controls, including all provisions required by the Worker Protection Standard (WPS), risks to workers still exceed EPA's levels of concern. Although each OP risk management decision and any associated mitigation measures will be implemented on a case-by-case basis, the Agency is outlining its decision process in the PR Notice because early notification to registrants will help to ensure that occupational risk management decisions for the OPs will be approached consistently and implemented quickly and equitably. EPA encourages registrants to demonstrate stewardship of their OP pesticides by adopting the protective measures described in this PR Notice prior to the Agency's completion of IRED and TRED documents for the OP chemicals, and to develop new packaging and application technologies that reduce worker exposure to pesticides. Further mitigation may be needed when the Agency issues its final, cumulative decision on the OP class of chemicals.

The PR Notice does not impose binding obligations on registrants or the Agency. The measures described will be implemented as appropriate based on chemical-specific reviews, including risk/benefit balancing where necessary, through pesticide reregistration and other decision-making processes. EPA is proposing specific worker risk mitigation measures for individual OP pesticides in completing interim risk management decisions for these chemicals, and will implement these measures shortly thereafter. The Agency envisions managing risks to workers exposed to other classes of pesticides posing similar risks, such as the carbamates, in a similar manner.

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: January 8, 2001.

Lois Rossi,

Director, Special Review and Reregistration Division.

[FR Doc. 01–1201 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00652A; FRL–6761–8]

First Aid Statements on Pesticide Product Labels, Pesticide Registration Notice; Update to Guidance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces an update to EPA guidance regarding the format and content of first aid statements on all federally regulated pesticide product labels. This notice addresses what the Agency believes is the appropriate first aid language for pesticide product labels to ensure that they continue to adequately protect the public. This notice supersedes Pesticide Registration Notice 2000–3, published in the **Federal Register** on April 19, 2000.

FOR FURTHER INFORMATION CONTACT: Amy Breedlove, Field and External Affairs Division (7506C), Policy and Regulatory Services Branch, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9069; fax number: (703) 305–5884; e-mail address: breedlove.amy@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to people who are responsible for developing, reviewing, or approving first aid information on pesticide labels. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. You may also obtain copies of the PR Notice by going directly to the Home Page for the Office of Pesticide Programs at http://www.epa.gov/pesticides. Under "What's New," select "Draft PR Notices," then select PR Notice 2000–1 "First Aid Statements on Pesticide Product Labels."

2. *Fax on Demand.* You may request a faxed copy of the PR Notice titled "First Aid Statements on Pesticide Product Labels," by using a faxphone to call (202) 401–0527 and selecting item 6135. You may also follow the automated menu.

3. *In person.* The Agency has previously established an official record for this action under docket control number OPP–00652. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

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holidays. The PIRIB telephone number is (703) 305–5805.

II. What Action is the Agency Taking?

The Agency is publishing guidance for appropriate first aid language for pesticide product labels. The Agency has received updated information for first aid statements and believes current pesticide product labels should be revised to reflect this information. The Agency, as a result of comments submitted in response to an earlier PR notice published in the **Federal Register** on April 19, 2000 (65 FR 20978) (FRL–6552–2), has extended the deadline until October 1, 2003, for when the Agency expects to see these revised statements and has made other changes to clarify the Agency's intent.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, First aid, Labeling, Pesticides and pests.

Dated: December 28, 2000.

Marcia E. Mulkey

Director, Office of Pesticide Programs.

[FR Doc. 01–1053 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6633–7]

Ward Transformer Superfund Site Notice of Prospective Purchaser Agreement Raleigh, Wake County, NC

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: Under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency (EPA) proposes to enter into a "Prospective Purchaser Agreement" (P.A.) concerning property that has been potentially contaminated by releases from the Ward Transformer Superfund Site (Ward Site) in Raleigh, Wake County, North Carolina (P.A. Property). EPA proposes to enter into the P.A. with Brier Creek Commons LP (Brier Creek LP). The P.A. obligates Brier Creek LP to cooperate fully with any response action EPA may take on the P.A. Property. The P.A. resolves Brier Creek LP's potential liability for the Existing Contamination at the Ward Site and/or the P.A. Property which may otherwise result from it obtaining an easement across the P.A. Property and constructing a roadway. This protection is contingent upon Brier Creek LP fulfilling its obligations under the P.A. EPA will consider public comments on the proposed settlement for thirty (30) days.

EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from: Ms. Paula V. Bachelor, Waste Management Division, U.S. EPA, Region 4, Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, Georgia 30303–3104, 404/562–8887.

Written comments may be submitted to Ms. Bachelor at the address noted above within thirty (30) calendar days of the date of this publication.

Dated: December 27, 2000.

James T. Miller,

Acting Chief, CERCA Program Services Branch, Waste Management Division.

[FR Doc. 01–1348 Filed 1–16–01; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

Office for Civil Rights; Title VI of the Civil Rights Act of 1964; Limited English Proficiency Policy Guidance for Recipients of Federal Financial Assistance

AGENCY: Office of Civil Rights, GSA.

ACTION: Notice of policy guidance with request for comment.

SUMMARY: The General Services Administration (GSA) is publishing policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons. GSA provides this policy guidance for its recipients of Federal financial assistance to ensure meaningful access to federally assisted programs and activities for persons with Limited English Proficiency (LEP). This policy guidance does not create new obligations, but rather, clarifies existing responsibilities under Title VI of the Civil Rights Act of 1964, as amended, its implementing regulations and relevant case law.

DATES: This guidance is effective immediately. Comments must be submitted on or before March 20, 2001. The Office of Civil Rights (OCR) will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

ADDRESSEES: Interested persons should submit written comments to Office of Civil Rights (AK), Room 5127, General Services Administration, 1800 F Street, NW., Washington, DC 20405. Comments may also be submitted by e-mail at evelyn.britton@gsa.gov.

FOR FURTHER INFORMATION CONTACT: James M. Taylor or K. Evelyn Britton, Office of Civil Rights, Room 5127, General Services Administration, 1800 F Street, NW., Washington, DC 20405, telephone 202–501–0767 or 1–800–662–6376; TDD 1–888–267–7660. Arrangements to receive the policy guidance in an alternative format may be made by contacting the named individuals.

Dated: January 10, 2001.

Madeline Caliendo,

Associate Administrator, Office of Civil Rights, General Services Administration.

Policy Guidance

1. *Subject.* Limited English proficiency policy guidance for recipients of Federal financial assistance.

2. *Purpose.* General Services Administration (GSA) provides this policy guidance for its recipients of Federal financial assistance to ensure meaningful access to federally assisted programs and activities for persons with Limited English Proficiency (LEP). This policy guidance does not create new obligations, but rather, clarifies existing responsibilities under Title VI of the Civil Rights Act of 1964, as amended, its implementing regulations and relevant case law.

3. *Dates:* This guidance is effective immediately. Comments are welcome and must be submitted on or before sixty (60) days from the date of this publication. GSA will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

4. *Policy.* To improve access to federally assisted programs and activities for persons who, as a result of national origin, are limited in their English proficiency.

5. *Action Required.* All recipients of Federal financial assistance from GSA are to develop an effective plan, in writing, for ensuring meaningful access to their programs and activities by LEP persons, consistent with this guidance.

6. *Background Information.* English is the predominant language of the United States. According to the 1990 Census, English is spoken by 95% of its residents. Of those U.S. residents who speak languages other than English at home, the 1990 Census reports that 57% above the age of four speak English "well to very well."

The United States is also home to millions of national origin minority individuals who are LEP. That is, their primary language is not English and they cannot speak, read, write or understand the English language at a level that permits them to interact effectively with recipients of Federal financial assistance. Because of language differences and the inability to effectively speak or understand English, persons with LEP may be subject to exclusion from programs or activities, experience delays or denials of services/benefits, or receive care and services/benefits from recipients of Federal financial assistance based on inaccurate or incomplete information.

Executive Order 13166 (65 FR 50119) dated August 11, 2000 and policy guidance issued by Department of Justice (DOJ) on August 11, 2000 (65 FR 50123), address the responsibility of all recipients of Federal financial assistance to ensure meaningful access for persons with LEP. GSA refers to and incorporates DOJ's policy guidance for recipients as part of this policy guidance, and for the purpose of determining compliance with this policy guidance, within the scope of Title VI of the Civil Rights of 1964, as amended, its implementing regulations and relevant case law.

This policy guidance establishes a four-step process that recipients should follow in developing an effective LEP assistance plan. A key element in this process is stakeholder input. Therefore, recipients should coordinate with local community-based organizations (i.e., stakeholders) that represent populations of LEP persons. These organizations can provide valuable input and assistance in identifying and addressing the LEP needs of the serviced population. This coordinated effort will assist in developing a practical approach in providing appropriate LEP assistance that is reasonable and cost-effective.

Some organizations representing LEP persons may include the National Council of La Raza (NCLR), the League of United Latin American Citizens (LULAC), the National Council of Asian Pacific Americans (NCAPA), the Organization of Chinese Americans (OCA), the National Congress of American Indians (NCAI), the National Urban League (NUL), the National Association for the Advancement of Colored People (NAACP), Mexican American Legal Defense and Educational Fund, Arab American Anti-Discrimination Committee and National Coalition for Haitian Rights. This is not meant to be an exhaustive listing, and different community-based or national origin minority organizations may be available in a recipient's serviced area.

7. *Legal Authority.* The legal authority for OCR's enforcement actions is Title VI of the Civil Rights Act of 1964, GSA's implementing regulations, and a consistent body of case law, and is further described below.

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. Section 2000d et. seq. states: "No person in the United States shall on the ground of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."

State and local laws may provide additional obligations to serve LEP individuals, but cannot compel recipients of Federal financial assistance to violate Title VI. For instance, given our constitutional structure, State or local "English-only" laws do not relieve an entity that receives Federal funding from its responsibilities under Federal anti-discrimination laws. Entities in States and localities with "English-only" laws are certainly not required to accept Federal funding—but if they do, they have to comply with Title VI, including its prohibition against national origin discrimination by recipients of Federal assistance. Thus, failing to make federally assisted programs and activities accessible to individuals who are LEP will, in certain circumstances, violate Title VI.

GSA's implementation regulations provide, in part, at 41 CFR 101–6.204–1:

No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program to which this subpart applies.

Specific discriminatory actions prohibited are addressed at 41 CFR 101–6.204–2:

(a)(1) In connection with any program to which this subpart applies, a recipient may not, directly or through contractual or other arrangements, on the ground of race, color, or national origin:

(i) Deny an individual any services/benefits, financial aid, or other benefit provided under the program;

(ii) Provide any service, financial aid, or other benefit to any individual which is different, or is provided in a different manner, from that provided to others under the program;

(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;

(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;

(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;

(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise, or afford him an opportunity to do so which is different from that afforded others under the program * * *

Furthermore, the DOJ coordination regulations for Title VI, located at 28 CFR 42.405(d)(1), provide that:

(1) Where a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program (e.g., affected by relocation) needs service or information in a language other than English in order effectively to be informed of or to participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in appropriate languages to such persons. This requirement applies with regard to written material of the type which is ordinarily distributed to the public.

Extensive case law affirms the obligation of recipients of Federal financial assistance to ensure that persons with LEP can meaningfully access federally assisted programs. Specifically, in the case of *Lau* v. *Nichols*, 414 U.S. 563 (1974), the U.S. Supreme Court ruled that a public school system's failure to provide English language instruction to students of Chinese ancestry who do not speak English denied the students a meaningful opportunity to participate in a public educational program in violation of Title VI of the Civil Rights Act of 1964.

More recently, the Eleventh Circuit in *Sandoval* v. *Hagan*, 197 F.3d 484 (11th Cir. 1999), cert. granted sub. Nom., *Alexander* v. *Sandoval*, 147 L. Ed. 2d 1051 (U.S. Sept. 26, 2000) (No. 99–1908), held that the State of Alabama's policy of administering a driver's license examination in English only was a facially neutral practice that had an adverse effect on the basis of national origin, in violation of Title VI. Title VI regulations prohibit both intentional discrimination and policies and practices that appear neutral but have a discriminatory effect. Thus, a recipient's policies or practices regarding the provision of benefits and services to persons with LEP need not be

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intentional to be discriminatory, but may constitute a violation of Title VI where they have an adverse effect on the ability of national origin minorities to meaningfully access programs and services.

The DOJ states in its policy guidance that Title VI does not require recipients to remove language barriers when English is an essential aspect of the program, or there is another "substantial legitimate justification for the challenged practice." See Footnote 13 of DOJ's policy guidance.

8. *Federal Financial Assistance Programs.* GSA administers two major Federal financial assistance programs, in addition to other programs of Federal financial assistance, such as the direct transfer of personal property and the allotment of space in GSA buildings. The two major programs of Federal financial assistance are the Federal Surplus Personal Property Donation Programs and the Disposal of Federal Surplus Real Property for Public Use.

a. *Federal Surplus Personal Property Donation Program.* Enables certain non-Federal agencies, institutions, organizations and certain small businesses to obtain property that the Federal Government no longer needs. The personal property includes all types and categories of property, such as hand and machine tools, office machines and supplies, furniture, appliances, medical supplies, hardware, clothing, motor vehicles, boats, airplanes, construction equipment, textiles, communications and electronic equipment and gifts or decorations given to Government officials by foreign dignitaries.

(1) Federal surplus personal property may be donated to nonprofit educational and public health activities exempt from taxation under Section 501 of the Internal Revenue Code. The property must be used to aid education or public health, and includes programs for the homeless. Eligible recipients include nonprofit educational and public health activities, such as medical institutions, hospitals, clinics, health centers, and drug abuse treatment centers; schools, colleges and universities; schools for persons with mental or physical disabilities; child care centers; educational radio and televisions licensed by the Federal Communications Commission; museums attended by the public; and libraries. Nonprofit, tax-exempt organizations that provide food, shelter, or support services to homeless people may also be eligible to receive surplus property through the donation program (i.e., soup kitchens, day centers for the homeless, food banks, shelters for battered spouses, half-way houses).

(2) Additionally, public agencies involved in such activities as conservation, economic development, education, park and recreation programs, public safety, public health, programs for the elderly, and programs for the homeless may be eligible for donations of surplus personal property. Public agencies generally include States, their departments, divisions and other instrumentalities; political subdivisions of States, including cities, counties, and other local Government units and economic development districts; instrumentalities created by compact or other agreement between State or political subdivisions; and Indian tribes, bands, groups, pueblos, or communities located on State reservations.

b. *Disposal of Federal Surplus Real Property for Public Use.* Under existing Federal law, States and local government bodies and certain nonprofit institutions may acquire Federal surplus real property at discounts of up to 100% for various types of public use. These uses include: homeless services, airports/ports, correctional, educational, historic monument, parks/recreation, public health and wildlife conservation. These disposals are usually accomplished in coordination with other Federal agencies (i.e., Department of Education (DOE), Department of Health and Human Services (DHHS), Department of Transportation (DOT), Department of Interior (DOI), Department of Housing and Urban Development (HUD).

c. *GSA Personal Property Utilization Program.* Government regulations mandate that Federal agencies, to the fullest extent practicable, use excess personal property as the first source of supply in meeting their requirements. However, certain laws provide Federal agencies with the ability to directly transfer certain excess property to non-Federal entities. For example, Executive Order 12999 (61 FR 17227, 3 CFR, 1996 comp., p. 180) provides that all Federal agencies, to the extent permitted by law, shall give highest preference to schools and nonprofit organizations, including community-based educational organizations, in the transfer of educationally useful Federal equipment. Thus, GSA recipients in this program include schools and certain community-based educational organizations.

d. *Allotment of Space.* Under existing Federal law, GSA may allot space for little or no costs to Federal Credit Unions, vending stands operated by blind persons and child care centers.

9. *Definition of Terms.* The following definitions are provided for reference.

a. *Federal financial assistance.* Grants and loan of Federal funds; grants or donation of Federal property and interests in property; detail of Federal personnel; sale and lease of, and the permission to use (on other than a casual or transient basis) Federal property or any interest in the property without consideration or at a nominal consideration, or at a consideration which is reduced for the purposes of assisting the recipient, or in recognition of the public interest to be served by the sale or lease to the recipient; or any Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

b. *Recipient:* Any State or political subdivision, any instrumentality of a State or political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient, except that such term does not include any ultimate beneficiary of the assistance.

c. *Person with Limited English Proficiency:* A person whose primary language is not English and whose ability to speak, read, write or understand the English language does not permit effective interaction with recipients of Federal financial assistance.

d. *Vital Documents:* A document or information will be considered vital if it contains information that is critical for accessing the recipient's program(s) and/or activities, or is required by law. Thus, vital documents include, for example, applications; consent forms; letters and notices pertaining to the reduction, denial or termination of services or benefits; and letters or notices that require a response from the beneficiary or client. Generally, entire web sites need not be translated. Only the vital information or documents within the web site should be translated. See subparagraph 11b(3) below for further discussion about web sites.

e. *Beneficiary:* Individuals and/or entities that directly or indirectly receive an advantage through the operation of a Federal program, (i.e., one who is within the serviced population of the recipient of Federal financial assistance and who ultimately benefits from those services.)

10. *LEP Procedures and Guidelines:* Executive Order 13166 (65 FR 50119) provides for a flexible standard stating that recipients of Federal financial assistance are to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. Thus, it is important that all recipients take the following steps in determining their LEP responsibilities and providing appropriate LEP assistance. These four steps are more fully explained below, and include: (1) Conduct an assessment of the serviced population, (2) develop written LEP assistance plans, (3) implement the LEP plan, and (4) monitor the effectiveness of the LEP plan.

a. *Step 1.* Conduct an assessment of the serviced population. This assessment includes identifying the types of service(s) being provided by the recipient and determining the serviced population (i.e., individuals served by the recipient's program(s) and activities).

b. *Step 2.* Develop written LEP assistance plans. These plans should address the recipient's LEP responsibilities and the types of LEP assistance that the recipient will provide, consistent with this policy guidance. Recipients are to develop a written plan based on a balanced analysis of the following four factors, to ensure meaningful access for eligible LEP persons.

(1) *Factor 1: Number or Proportion of LEP Persons.* One factor in determining the reasonableness of a recipient's efforts in providing LEP assistance is the number or proportion of people who will be excluded from the benefits or services absent efforts to remove language barriers. The key here is to focus on persons who are eligible to access the recipient's program or activity.

The steps reasonable for a recipient that serves one LEP person a year may be different than those expected of a recipient that serves several LEP persons per day. However, those who serve a few are still subject to the requirements of Title VI of the Civil Rights Act of 1964 and Executive Order 13166 (65 FR 50119). This plan need not be intricate, and may be as simple as being prepared to use one of the commercially available language lines to obtain interpreter services within a reasonable period of time.

Methods of obtaining estimates of serviced LEP population include taking a census of contacts with LEP persons over a given period of time or using demographic data of the service area. The 1990 U. S. Census information may be found at a local library or on the Internet at www.Census.gov. The 2000 Census data may not be available until the 2001–02 timeframe. In addition to the U. S. Census, other potential resources include State and local government offices; the Mayor's office; the local school superintendent's office; the State education department; the State social services department, and local hospitals; or other elected officials offices. Combining these methods will probably result in the most realistic and accurate estimates.

Local or State Yellow Pages may also be helpful in identifying organizations that serve or represent particular language minority populations. Local national origin minority organizations may be able to provide, or assist in obtaining, certain demographic information regarding LEP populations in the local area. The information that can be obtained and the network established in coordinating this type of effort with members of local and State government offices and minority organizations may prove to be valuable resources for recipients into the future.

(2) *Factor 2: Frequency of Contact with the Program.* Frequency of contacts between the recipient's program or activity and LEP persons is another factor to be weighed. For example, if LEP persons must access the program or activity on a daily basis, the recipient has a greater LEP responsibility than if such contact is unpredictable or infrequent.

Recipients should take into account local or regional conditions when determining frequency of contact.

Although past experience may be helpful in determining the frequency of contact, it should not be used as the exclusive criteria since the lack of prior LEP notice and assistance may have contributed to such minimal or non-existent contact.

(3) *Factor 3: Nature and Importance of the Program.* The importance of the services or benefits provided to the beneficiaries will affect the determination of the reasonable steps required. More affirmative steps are required in those programs where the denial or delay of access may have life or death implications than in programs that are not as crucial to one's day-to-day existence. For example, fire protection services are of more importance to the serviced population than access to a museum.

Recipients must also consider the importance of the program or activity to the eligible LEP population, both immediately, as well as the long-term. (i.e., what is the short-term and long-term impact to the LEP population if translation assistance is not provided?)

(4) *Factor 4: Resources Available.* The resources available to a recipient of Federal financial assistance may impact the steps that recipients take. For example, a small recipient with limited resources may not need to take the same steps as a larger recipient to provide LEP assistance in programs that have a limited number of eligible LEP persons or where the contact is infrequent. However, small recipients are still subject to this policy guidance, although the type of LEP mitigation measures may differ from that of larger recipients. Claims of limited resources from larger entities should be well substantiated.

A recipient that has limited resources may consider exploring whether State and local government offices provide translation assistance. These offices may provide resources for the recipient's use. Also, recipients may consider contacting local minority organizations for possible translation assistance.

c. *Step 3:* Implement the LEP plan. The key to successful implementation of an effective LEP assistance plan is to ensure that the serviced population is notified regarding the availability of free LEP assistance. Also, it is important that a recipient's staff is aware of LEP responsibilities and the recipient's LEP assistance plan.

(1) Notice of LEP assistance to be provided. Each recipient of Federal financial assistance is to notify the public of available LEP assistance at no cost to the LEP person. This may be done through a brochure or poster in the language(s) identified in the location(s) where the recipient's federally assisted service(s) and/or benefits are being provided. Posters should be placed in a conspicuous place to ensure LEP persons will see it. It may also include posting such notice on the recipient's internet site(s). Sample language to use for such notice is as follows: "Language assistance is available upon request if you cannot speak or write English very well."

(2) Ensure staff is aware of LEP responsibilities. Recipients are to ensure that GSA's policy regarding LEP responsibilities is communicated to all staff members whose duties may bring them in contact with LEP persons accessing the services and/or benefits of the recipient. This communication should ensure an understanding of the types of LEP assistance being offered by the recipient, and the mechanisms in place for the staff to use when a request for LEP assistance is made.

d. *Step 4:* Monitor the effectiveness of the LEP plan. LEP assistance requirements may change over a period of time. Therefore, it is important to regularly monitor, and when appropriate, adjust the LEP procedures to ensure meaningful access for persons with LEP. New programs, activities, forms, outreach documents, etc. should be considered for translation services as they arise. In addition, to be effective, it is crucial for recipients to re-assess language assistance services at least every three years to determine the effectiveness of existing assistance. This

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assessment should include a review of LEP policies and procedures (i.e., the LEP plan) with the recipient's staff. Feedback from LEP persons and community-based organizations will also provide helpful insights into the effectiveness of LEP assistance procedures.

11. *Translation Requirements.* In determining what is reasonable, the analysis should address the appropriate mix of written and oral language assistance. This includes information provided using the Internet, video and audio. When applying the four factors as outlined above, decisions should be made regarding which documents must be translated, when is oral translation necessary and whether such assistance (i.e., oral or written translation) should be immediately available or provided within a reasonable period of time.

a. *Oral Communication:* Depending on the need, options for providing oral language assistance range from hiring bilingual staff or on-staff interpreters to contracting for interpreter services as needed, engaging community volunteers, or contracting with a telephone interpreter services. Oral communication between recipients and beneficiaries often is a necessary part of the exchange of information. Proper analysis should include looking at what kind of communication (oral or written) you normally provide to an English speaking person in order to fully communicate the program to them. Thus, there may be instances where simply providing written translation may not be providing meaningful access to persons with LEP in the same manner as that provided to non-LEP beneficiaries.

b. *Written Communication:* As part of its overall language assistance program, a recipient's LEP assistance plan should provide for the translation of certain written materials in languages other than English, where a significant number or percentage of the population eligible to be served or likely to be directly affected by the program, needs services or information in a language other than English to communicate effectively. See 28 CFR 42.405(d)(1).

(1) In determining what should be translated, identify vital documents and non-vital documents. Vital documents must be translated when a significant number or percentage of the population eligible to be served, or likely to be directly affected by the recipient's program(s) or activities, seeks services or information in a language other than English to communicate effectively. For many larger documents, translation of vital information contained within the document will suffice and the documents need not be translated in their entirety. Non-vital documents/information need not be translated.

(2) OCR recognizes that it may sometimes be difficult to draw a distinction between vital and non-vital documents, particularly when considering outreach or awareness documents. Although meaningful access to a program or activity requires an awareness of the program's existence, OCR recognizes that it would be impossible, from a practical and cost-based perspective, to translate every piece of outreach material into every language. Title VI does not require this of its recipients. However, lack of awareness regarding the existence of a particular program may effectively deny LEP persons meaningful access. Thus, it is important that recipients continually survey and assess the needs of the eligible serviced populations in order to determine whether certain critical outreach materials should be translated into other languages.

(3) The same analysis is to be used in determining the translation of web site information, forms, etc. The decision to place a document or information on the Internet will not affect whether the document or information must be translated. For example, placement on the web site should not change the recipient's original assessment regarding the number or proportion of LEP persons that comprise the intended audience for that document or information. Generally, entire web sites need not be translated. Only the vital information or documents within the web site should be translated. The four-factor analysis as outlined above determines the appropriate language(s) for translation. If the four-factor analysis determines that written information or a document should be translated, the same written document or information should be translated on the recipient's web site—if the recipient's English version of the information or document is on the web site. A notice regarding the presence of a translated document or information on the web site should be posted at an initial entry point onto the site (usually the homepage).

(4) Oral translation assistance will be provided to those persons with LEP whose language does not exist in written form. This oral translation assistance will explain the contents of vital documents.

c. *Reliability of Translation Resources and Interpretive Services:* In order to provide effective services to LEP persons, it is important to ensure the use of competent interpreters. Although it is not a requirement, membership in or accreditation by the American Translators Association (ATA) is one indicator regarding the reliability and professionalism of language assistance vendors. However, competency does not necessarily mean formal certification as an interpreter, although certification is helpful. Yet, competency refers to more than being bilingual. It refers to demonstrated proficiency in both English and the other language, orientation and training that includes the skills and ethics of interpreting (i.e., issues of confidentiality), fundamental knowledge in both languages of terms or concepts peculiar to the program or activity, and sensitivity to the LEP person's culture.

It is also important to note that in some circumstances, verbatim translation of materials may not accurately and appropriately convey the substance of what is contained in the written language. An effective way to address this concern is to reach out to community-based organizations to review translated materials to ensure that the translation is accurate and easily understood by LEP persons.

It is recommended that a different contractor conduct a second review of a translated document, when such document is of a highly technical or complex nature. Another method of ensuring reliability of such documents is to have the document translated back into English to determine if the source document lost important meaning in its foreign translation.

Generally, it is not acceptable for recipients to rely upon an LEP individual's family members or friends to provide the interpreter services. The recipient should meet its obligations under Title VI by supplying competent language services free of cost. In rare emergency situations, the recipient may have to rely on an LEP person's family members or other persons whose language skills and competency in interpreting have not been established. Proper planning by recipients is important in order to ensure that those situations rarely occur. Therefore, it is not acceptable to rely upon an LEP person to provide his/her own interpreter, unless the LEP person requests the use of his/her own interpreter or in the case of an emergency.

12. *Examples.* The following examples are being provided to facilitate the assessment, planning and implementation of a successful LEP plan.

a. *Examples of problem areas include:* Providing services and/or benefits to LEP persons that are more limited in scope or lower in quality than those provided to other individuals; subjecting LEP persons to unreasonable delays; limiting participation in a recipient's program(s) or activities on the basis of English proficiency; providing services and/or benefits to LEP persons that are not as effective as those provided to persons proficient in English; failing to inform LEP persons of the right to receive free interpreter services; or requiring LEP persons to provide their own interpreter.

b. *Examples of satisfactory LEP assistance include:* Having policies and procedures in place for identifying and assessing the language needs of the recipient's serviced LEP population; providing a range of oral language assistance options, appropriate to each of the recipient's circumstances; providing notice to LEP persons of the right to free language services; communicating LEP responsibilities and available services to staff members; program monitoring; establishing a plan for providing written materials in languages other than English where a significant number or percentage of the affected population needs services or information in a language other than English.

c. *Examples of applying the 4 factors:* The following are examples of how meaningful access will be assessed by OCR:

(1) *Example 1.* A small child care center has three LEP parents (two who are Chinese and one who is Cuban) whose English-speaking children attend its child care center on a regular basis. The center has a staff of six, and has limited financial resources to afford to hire bilingual staff, contract with a professional interpreter service, or translate written documents. To accommodate the language needs of their LEP parents, the Center made arrangements with a Chinese and a Hispanic community organization for trained and competent volunteer interpreters, and with a telephone interpreter language line, to interpret during parent meetings and to orally translate written documents. There have been no client complaints of inordinate delays or other service related problems with respect to LEP clients.

Application of the 4 factors to Example 1: Factor 1: The center has three LEP parents (a small number); Factor 2: The frequency of contact is every day, but mostly for greeting; Factor 3: The nature and importance of the recipient's program to the serviced population relates to the health, safety and welfare of their children (i.e., child care); Factor 4: The child care center has limited resources and a small staff.

The assistance that the child care center is providing will probably be considered appropriate, given the center's resources, the size of staff, and the size of the LEP population. Thus, OCR would find the center in compliance with Title VI.

(2) *Example 2.* A county social service program has a large budget and serves 500,000 beneficiaries. Of the beneficiaries eligible for its services/benefits, 3,500 are LEP Chinese persons, 4,000 are LEP Hispanic persons, 2000 are LEP Vietnamese persons and about 400 are LEP Laotian persons. The county frequently encounters an LEP client, but has no policy regarding language assistance to LEP persons other than telling LEP clients to bring their own interpreters. LEP clients are provided with application and consent forms in English and, if unaccompanied by their own interpreters, must solicit the help of other clients or must return at a later date with an interpreter.

Application of the 4 factors to Example 2: Factor 1: The eligible LEP population is significant; Factor 2: The frequency of contact is frequent; Factor 3: The nature and importance of the county's program relates to the social welfare of the community it serves; Factor 4: The county has a large budget.

Given the size of the county program, its resources, the size of the eligible LEP population, the frequency of contact and the nature of the program, OCR would likely find the county in violation of Title VI and would require it to develop a comprehensive language assistance program.

d. The intent of this guidance is to provide recipients with information regarding the requirements of Title VI and its implementing regulations for providing meaningful access for LEP persons to federally assisted services and/or benefits. The examples and framework outlined above are not intended to be exhaustive. Thus, recipients have considerable flexibility in determining how to comply with their legal obligation in meeting their LEP responsibilities, and are not required to use all of the suggested methods and options listed. However, recipients must establish and implement policies and procedures for providing language assistance sufficient to fulfill their Title VI responsibilities.

13. *Compliance.* All recipients must take reasonable steps (consistent with this policy guidance) to overcome language differences that result in barriers and provide the language assistance needed to ensure that persons with LEP have meaningful access to services and benefits.

a. The failure to take all of the steps as outlined herein will not necessarily mean that a recipient has failed to provide meaningful access to LEP persons. OCR will make assessments on a case by case basis and will consider several factors in determining whether the steps taken by a recipient provide meaningful access. (i.e., nature and importance of recipient's services to the serviced population, recipient's size, availability of financial and other resources, and frequency of contact with LEP persons).

b. Those factors include the size of the recipient and the eligible LEP population, the nature of the program or service, the objectives of the program, the total resources available, the frequency with which particular languages are encountered, and the frequency with which LEP persons come into contact with the recipient's program.

c. There are instances where recipients of Federal financial assistance from GSA may also be recipients of Federal financial assistance from other Federal agencies. For instance, hospitals and health clinics may receive financial assistance from the Department of Health and Human Services (DHHS); schools and universities may receive financial assistance from the Department of Education (DOE); police departments and other law enforcement agencies/organizations may receive financial assistance from Department of Justice (DOJ). In order to avoid the potential for confusion with such recipient organizations as to their LEP responsibilities, OCR will apply, where appropriate, the Federal agency's LEP guidance that is more specific and/or stringent regarding LEP responsibilities and assistance.

14. *Enforcement.* OCR will enforce Title VI, and the recipient's responsibility to establish LEP procedures and provide appropriate LEP assistance, consistent with enforcement procedures as provided in Title VI regulations. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance.

GSA's Title VI regulations provide that OCR will investigate whenever it receives a complaint, report or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, OCR will inform the recipient in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, OCR will inform the recipient of the noncompliance through a Letter of Findings that identifies the areas of noncompliance and the steps that must be taken to correct the noncompliance,

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and will attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, the procedure for effecting compliance as described at 41 CFR 101–6.211–2, et. seq. will be followed.

15. *Technical Assistance.* A program of language assistance should provide for effective communication between the recipient and the person with LEP so as to facilitate participation in, and meaningful access to the services and/or benefits provided by the recipient. The key to ensuring meaningful access for LEP persons is effective communication.

OCR is available to provide assistance to recipients seeking to ensure that they operate an effective language assistance program. In addition, during its investigative process, OCR is available to provide technical assistance to enable recipients to come into voluntary compliance. OCR may be reached at 202–501–0767 or toll free 1–800–662–6376, or by mail at General Services Administration, Office of Civil Rights, Title VI, 1800 F Street NW, Suite 5127, Washington, DC, 20405, for further assistance. Arrangements to receive this policy guidance in alternative format may be made by contacting OCR.

[FR Doc. 01–1268 Filed 1–16–01; 8:45 am]
BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–01–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluating CDC Funded Health Department HIV Prevention Programs—New—The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), proposes a collection of standardized HIV evaluation data from health department grantees to ensure delivery of the best possible HIV prevention services. The CDC needs standardized evaluation data from health department grantees for the following reasons: (1) To determine the extent to which HIV prevention efforts have contributed to a reduction in HIV transmission, (2) to improve programs to better meet that goal, (3) to help focus technical assistance and support and (4) to be accountable to stakeholders by informing them of progress made in HIV prevention nationwide.

CDC and its prevention partners have specifically identified the types of standardized evaluation data they need to be accountable for the use of federal funds and to conduct systematic analysis of HIV prevention to improve policies and programs. Generally, evaluation data that are needed (but not yet available at the national level) include the types and quality of HIV prevention interventions provided by CDC health department grantees and their grantees, the characteristics of clients targeted and reached by the interventions, and the effects of interventions on client behavior and HIV transmission.

The annual burden hours are estimated to be 1248.

Respondents	No. of respondents	No. of forms per jurisdiction	No. of responses per respondent (per yr.)	Average burden per response (in hrs.)
Health Department Grantees	65	16	1	1.2

Dated: January 10, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1297 Filed 1–16–01; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–06–01]

Agency Forms Undergoing Paperwork Reduction Act Review; Correction

A notice announcing Jail STD Prevalence Monitoring System was published in the **Federal Register** on November 6, 2000, (65 FR 66546). This notice is a correction.

On page 66546, in the third column of the notice, the last line of the last paragraph, the burden hours should be changed from 1248 to 3296.

On page 66546, at the end of the notice, the burden table should be replaced with the following table:

Respondents	No. of respondents	Avg. No. of forms/respondent	No. of responses/respondent	Avg. burden/response (in hrs.)
State/local health departments ...		4 datasets/year		
A. With access to electronic data	A. 8 health departments		A. 3/dataset	A. 96
B. Without access to electronic data.	B. 8 health departments		B. 100/dataset	B. 3,200

All other information and requirements of the November 6, 2000, notice remain the same.

Dated: January 10, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1296 Filed 1–16–01; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of January 2001.

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry

Date and Time: January 31, 2001; 8:30 a.m.–5:30 p.m.

Place: The Hilton Washington Embassy Row, 2015 Massachusetts Avenue, NW., Washington, D.C. 20036.

The meeting is open to the public.

Purpose: The Advisory Committee shall (1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning activities under section 747 of the Public Health Service Act; and (2) prepare and submit to the Secretary, the Committee on Health, Education, Labor and Pensions (formerly the Committee on Labor and Human Resources) of the Senate, and the Committee on Commerce of the House of Representatives a report describing the activities of the Advisory Committee, including findings and recommendations made by the Committee concerning the activities under section 747 of the PHS Act. The Advisory Committee will meet twice each year and submit its first report to the Secretary and the Congress by November 2001.

Agenda: Discussion of the focus of the programs and activities authorized under section 747 of the Public Health Service Act. Review of the work completed to date by the two workgroups will be reviewed. Funding issues and recommendations for the future will be addressed. There will be finalization of an outline and specific content areas to be included in the Committee's first report.

Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Dr. Stan Bastacky, Deputy Executive Secretary, Advisory Committee on Training in Primary Care Medicine and Dentistry, Parklawn Building, Room 9A–21, 5600 Fishers Lane, Rockville, Maryland 20857, phone (301) 443–6326, e-mail sbastacky@hrsa.gov. The web address for the Advisory Committee is http://158.72.83.3/bhpr/dm/new_advisory_committee_on_primar.htm.

Dated: January 9, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1248 Filed 1–16–01; 8:45 am]
BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Evaluation of the CMHS/CSAT Collaborative Program On Homeless Families: Women With Psychiatric, Substance Use, Or Co-Occurring Disorders and Their Dependent Children, Phase II—New—SAMHSA's Center for Mental Health Services (CMHS) and Center for Substance Abuse Treatment (CSAT), through a set of cooperative agreements, proposes to conduct a longitudinal, multi-site evaluation study assessing mental health, substance abuse, and trauma interventions received by homeless mothers with psychiatric, substance use, or co-occurring disorders and their dependent children. The study will advance knowledge on appropriate and effective approaches to improving families residential stability, overall functioning, and ultimate self-sufficiency.

Data collection will be conducted over a 33-month period. A total of 2,000 participants will be recruited from eight to ten sites. At each site, a documented treatment intervention will be tested in comparison to an alternative treatment condition. Participants will be interviewed at baseline (within two weeks of entering a program) as well as three additional times (3 months after program entry, 9 months after program entry, and 15 months after program entry). Trained interviewers will administer the interviews to participating mothers. Information on the children will be obtained from the mother.

Key outcomes for the mothers are increased residential stability, decreased substance use, decreased psychological distress, improved mental health functioning, increased trauma recovery, improved health, improved functioning as a parent, and decreased personal violence. Outcomes for the children are reduced emotional/behavioral problems and improved school attendance.

To reduce burden and increase uniformity across the study sites, a central Coordinating Center will develop and administer common data entry and tracking computer programs. A variety of quality control procedures will also be implemented to ensure the integrity and uniformity of the data collected. Data will be submitted to the Coordinating Center via electronic means. Training and technical assistance will be provided to all sites on data submission. Sites will be asked to follow uniform procedures for submitting their data.

The estimated response burden is as follows:

Interview	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden horus
Baseline	2,000	1	1.58	3,160
Follow-Up 1 (3 months)	2,000	1	1.25	2,500
Follow-Up 2 (9 months)	2,000	1	1.25	2,500

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Interview	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden horus
Follow-Up 3 (15 months)	2,000	1	1.25	2,500
Total	2,000			10,660
3-yr annual average	2,000			3,553

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 10, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–1298 Filed 1–16–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

State Prevention Needs Assessments: Alcohol and Other Drugs—(OMB No. 0930–0185, Extension)—SAMHSA's Center for Substance Abuse Prevention (CSAP) has awarded contracts to eight States in Cohorts III and IV of the State Prevention Needs Assessment Program to collect data to assess the nature and extent of substance abuse prevention services needs. The family of prevention needs assessment studies applies a core set of measures, instruments, and methodologies developed and standardized under prior State needs assessment state contracts. These needs assessment studies will permit cross-State comparison of risk and protection variables to assist State services planning and allocation of State Block Grant funds.

CSAP is seeking a one year extension of OMB approval for the Virginia student survey to allow the second administration of the student survey and for completion of the Hawaii Community Resource Assessment survey. The annual response burden for this extension is as follows:

Respondent	Number of respondents	Average number of responses/respondent	Average burden/response (hours)	Total burden hours
Currently approved:				
Student Survey	27,120	1	.75	20,340
Young Adult Surveys	5,870	1	.50	2,935
Community Resource Assessment Studies	851	1	10	851
Special Population Studies	1,800	1	.50	900
Current Total	35,641			25,026
Virginia Student Survey Continuation	3,400	1	.75	2,550
Hawaii Community Resource Assessment	190	1	1.00	190
New Total	3,590			2,740

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Stuart Shapiro, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 10, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–1299 Filed 1–16–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application.

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Permit Number TE839777

Applicant: Don R. Helms, Bellevue, Iowa

The applicant requests a permit to take (capture, handle and release) the following federally listed unionid mussel species in Illinois, Indiana, Iowa, Kentucky, Minnesota, Missouri, Ohio, West Virginia, and Wisconsin: Fanshell (*Cyprogenia stegaria*), Fat pocketbook (*Potamilus capax*), Higgins' eye pearlymussel (*Lampsilis higginsi*), Scaleshell mussel (*Leptodea leptodon*), and Winged mapleleaf mussel (*Quadrula fragosa*), Clubshell (*Pleurobema clava*), Cracking pearlymussel (*Hemistena lata*), Northern riffleshell (*Epioblasma torulosa rangiana*), Orange-footed pimpleback pearlymussel (*Plethobasus cooperianus*), Pink mucket pearlymussel (*Lampsilis orbiculata*), Ring pink mussel (*Obovaria retusa*), Rough pigtoe (*Pleurobema plenum*), Tubercled-blossom pearlymussel (*Epioblasma torulosa torulosa*), Purple cat's paw pearlymussel (*Epioblasma obliquata obliquata*), White cat's paw pearlymussel (*Epioblasma obliquata perobliqua*), and White wartyback pearlymussel (*Plethobasus cicatricosus*). The applicant requests the permit to collect the threatened and endangered mussel species in all areas located within the Upper Mississippi, Illinois, and Ohio River watersheds. Activities are proposed for studies to identify populations of listed mussel species, develop methods to minimize or avoid project related impacts to those populations, and to identify new populations of listed unionid species. The scientific research is aimed at enhancement of survival of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with this application are available for review by any party who requests a copy of such documents from the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, peter—fasbender@fws.gov, telephone (612) 713–5343, or FAX (612) 713–5292.

Dated: January 8, 2001.

Charlie Wooley,

Assistant Regional Director, Ecological Services, Region 3, Fort Snelling, Minnesota.

[FR Doc. 01–1300 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan

Notice of availability of an environmental assessment/habitat conservation plan and receipt of an application for a permit for the incidental take of the Houston toad (*Bufo houstonensis*) during construction of one single-Family residence on approximately 0.5 acres of the 10.02-Acre property out of the Daniel M. Wisaman survey, abstract no. A–341, Bastrop County, Texas (Vasquez).

SUMMARY: Arturo and Yolanda Vasquez (Applicants) have applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to section 10(a) of the Endangered Species Act (Act). The Applicants have been assigned permit number TE–037190–0. The requested permit, which is for a period of 5 years, would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result of the construction of one single-family residence on approximately 0.5 acres of the 10.02-acre property out of the Daniel M. Wisaman Survey, Abstract No. A–341, Bastrop County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take application. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made until at least 30 days from the date of publication of this notice. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before February 16, 2001.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 4102, Albuquerque, New Mexico, 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Tannika Engelhard, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490–0057, Ex. 242). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCP should be submitted to the Supervisor, U.S. Fish and Wildlife Service, Austin, Texas, at the above address. Please refer to permit number TE–037190–0 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Tannika Engelhard at the above U.S. Fish and Wildlife Service, Austin Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the "taking" of endangered species such as the Houston toad. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicant: Arturo and Yolanda Vasquez plan to construct a single-family residence on approximately 0.5 acres of the 10.02-acre property out of the Daniel M. Wisaman Survey, Abstract No. A–341, Bastrop County, Texas. This action will eliminate 0.5 acres or less of Houston toad habitat and result in indirect impacts within the lot. The Applicants propose to compensate for this incidental take of the Houston toad by providing $2,000.00 to the National Fish and Wildlife Foundation for the specific purpose of land acquisition and management within Houston toad habitat, as identified by the Service.

Bryan Arroyo,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 01–1301 Filed 1–16–01; 8:45 am]

BILLING CODE 4510–55–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan

Notice of availability of an environmental assessment/habitat conservation plan and receipt of an application for a permit for the incidental take of the Houston toad (*Bufo houstonensis*) during construction of one single-family residence on approximately 0.5 acres of the 15.245-acre property on McBride Lane, Bastrop County, Texas (Wirries).

SUMMARY: James and Bernice Wirries (Applicants) have applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to section 10(a) of the Endangered Species Act (Act). The Applicants have been assigned permit number TE–037191–0. The requested permit, which is for a period of 7 years, would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result of the construction and occupation of one single-family residence on approximately 0.5 acres of the 15.245-acre property on McBride Lane, Bastrop County, Texas.

The Service has prepared the Environmental Assessment/Habitat Conservation Plan (EA/HCP) for the incidental take application. A

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determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made until at least 30 days from the date of publication of this notice. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application should be received on or before February 16, 2001.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 4102, Albuquerque, New Mexico, 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Clayton Napier, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas, 78758 (512/490–0057). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCP should be submitted to the Supervisor, U.S. Fish and Wildlife Service, Austin, Texas, at the above address. Please refer to permit number TE–037191–0 when submitting comments.

FOR FURTHER INFORMATION CONTACT: Clayton Napier at the above U.S. Fish and Wildlife Service, Austin Office.

SUPPLEMENTARY INFORMATION: Section 9 of the Act prohibits the "taking" of endangered species such as the Houston toad. However, the Service, under limited circumstances, may issue permits to take endangered wildlife species incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for endangered species are at 50 CFR 17.22.

Applicants: James and Bernice Wirries plan to construct a single-family residence on approximately 0.5 acres of the 15.245-acre property on McBride Lane, Bastrop County, Texas. This action will eliminate 0.5 acres or less of Houston toad habitat and result in indirect impacts within the property. The Applicants propose to compensate for this incidental take of the Houston toad by providing $2,000.00 to the National Fish and Wildlife Foundation for the specific purpose of land acquisition and management within Houston toad habitat, as identified by the Service.

Bryan Arroyo,

Acting Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 01–1302 Filed 1–16–01; 8:45 am]

BILLING CODE 4510–55–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of a Draft Environmental Assessment and Preliminary Finding of No Significant Impact, and Receipt of an Application for an Incidental Take Permit for Gopher Tortoises by the Board of Water and Sewer Commissioners of the City of Mobile, Mobile County, Alabama

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

The Board of Water and Sewer Commissioners of the City of Mobile ("Board" or "Applicant") has requested an incidental take permit (ITP) pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 (U.S.C. 1531 *et seq.*), as amended (Act). The Applicant anticipates taking the threatened gopher tortoise (*Gopherus polyphemus*) over the next 99 years. The proposed taking is incidental to the establishment of a conservation bank to mitigate take of up to 128 tortoises for residential, commercial and other development by private property owners throughout Mobile County. Under the proposed plan, the Board will sell mitigation credits to private landowners seeking incidental take of occupied gopher tortoise habitat in Mobile County. The private landowners will pay a mutually agreeable mitigation fee to the Board and allow for the relocation of the affected tortoises to the conservation bank. For each tortoise taken, private landowners will be required to cover costs associated with protecting, managing, and monitoring 1.5 acres of habitat at the conservation bank.

A more detailed description of the mitigation and minimization measures to address the effects of the Project to the gopher tortoise is provided in the Applicant's habitat conservation plan (HCP), the Service's draft Environmental Assessment (EA), and in the **SUPPLEMENTARY INFORMATION** section below.

The Service announces the availability of a draft EA and HCP for the incidental take application. Copies of the draft EA and/or HCP may be obtained by making a request to the Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice also advises the public that the Service has made a preliminary determination that issuing the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969, as amended (NEPA). The preliminary Finding of No Significant Impact (FONSI) is based on information contained in the draft EA and HCP. The final determination will be made no sooner than 60 days from the date of this notice. This notice is provided pursuant to section 10 of the Act and NEPA regulations (40 CFR 1506.6).

The Service specifically requests information, views, and opinions from the public via this Notice on the federal action, including the identification of any other aspects of the human environment not already identified in the Service's draft EA. Further, the Service specifically solicits information regarding the adequacy of the HCP as measured against the Service's ITP issuance criteria found in 50 CFR Parts 13 and 17.

If you wish to comment, you may submit comments by any one of several methods. Please reference permit number TE035340–0 in such comments. You may mail comments to the Service's Regional Office (see **ADDRESSES**). You may also comment via the internet to "david_dell@fws.gov". Please submit comments over the internet as an ASCII file avoiding the use of special characters and any form of encryption. Please also include your name and return address in your internet message. If you do not receive a confirmation from the Service that we have received your internet message, contact us directly at either telephone number listed below (see **FURTHER INFORMATION**). Finally, you may hand deliver comments to either Service office listed below (see **ADDRESSES**). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the administrative record. We will honor such requests to the extent allowable by law. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. We will not; however, consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

DATES: Written comments on the ITP application, draft EA, and HCP should be sent to the Service's Regional Office (see **ADDRESSES**) and should be received on or before March 19, 2001.

ADDRESSES: Persons wishing to review the application, HCP, and EA may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or Field Supervisor, U.S. Fish and Wildlife Service, P. O. Drawer 1190, Daphne, Alabama 36526. Written data or comments concerning the application, or HCP should be submitted to the Regional Office. Please reference permit number TE035340–0 in requests of the documents discussed herein.

FOR FURTHER INFORMATION CONTACT: Mr. David Dell, Regional HCP Coordinator, (see **ADDRESSES** above), telephone: 404/679–7313, facsimile: 404/679–7081; or Ms. Barbara Allen, Fish and Wildlife Biologist, Daphne Field Office, Alabama (see **ADDRESSES** above), telephone: 334/441–5181.

SUPPLEMENTARY INFORMATION: The gopher tortoise was listed in 1987 as a threatened species in the western part of its geographic range, west of the Tombigbee and Mobile Rivers in Alabama, Mississippi and Louisiana. The gopher tortoise is a burrowing animal that historically inhabited fire-maintained longleaf pine communities on moderately well drained to xeric soils in the Coastal Plain. These longleaf pine communities consisted of relatively open fire-maintained forests, without a closed overstory, with a well developed herbaceous plant layer of grasses and forbs. About 80% of the original habitat for gopher tortoises was lost by the time the species was listed due to conversions to urban and agricultural land use. On remaining forests, management practices converting longleaf pine to densely planted pine stands for pulpwood production, fire exclusion, and infrequently prescribed fire further reduced the open forest with grasses and forbs that tortoises need for burrowing, nesting, and feeding. Over 19,000 gopher tortoises have been estimated to occur in the listed range. The tortoise, however, is a long-lived animal with low reproductive rates. Remaining populations, though relatively widespread, are individually small, fragmented, and usually in poor habitat without adequate reproduction for a self-sustaining viable population.

In Mobile County, Alabama, development and fragmentation of tortoise habitat are a significant threat to the remaining tortoise population of the project area. The Applicant proposes to establish a conservation bank on land owned by the Board to benefit the federally threatened gopher tortoise. This HCP provides a mechanism to address development threats to the tortoise, to provide private landowners in Mobile County with viable gopher tortoise mitigation alternatives, and to provide the Board with a financial incentive to manage its lands for the benefit of this species.

Under section 9 of the Act and its implementing regulations, "taking" of endangered and threatened wildlife is prohibited. However, the Service, under limited circumstances, may issue permits to take such wildlife if the taking is incidental to and not the purpose of otherwise lawful activities. The Applicant has prepared an HCP as required for the incidental take permit application.

Under this HCP, the Board is applying for a 10(a)(1)(B) permit which would then be extended to private landowners who have tortoises on their property through a Certificate of Inclusion. Those landowners would purchase mitigation credit(s) from the Board after review and approval by the Service. After allowing for the relocation of affected tortoises onto Board property, they would have authorization to develop their property. The 222-acre conservation bank site occurs on lands (over 7,000 acres in total) owned by the Board that are permanently protected from development and that surround Big Creek Land in western Mobile County. A significant proportion of the site contains mature longleaf pine forest on well-drained, sandy soils. The site is in need of management activities that restore more open, longleaf-pine canopy conditions, reduce hardwood encroachment, reduce invasive exotic species, and restore more natural fire regimes. In addition, the resident tortoise population is significantly depleted, thus requiring translocation of tortoises to the site in order to establish a viable population. Should conservation banking prove to be a viable strategy for the Board and conservation of the tortoise, the Board is open to considering devoting more of the remaining 7,000 acres to serve as a gopher tortoise conservation bank.

The EA considers the environmental consequences of 5 alternatives, including the proposed action and no-action alternatives. The proposed action alternative is the issuance of a permit under section 10(a) of the Act that would authorize incidental take of up to 128 gopher tortoises from private landowners who would be required to obtain a certificate of inclusion from the Board. The proposed action would require the Applicant to implement their Habitat Conservation Plan which requires that for each tortoise taken, 1.5 acres of longleaf pine habitat at the conservation bank is restored, protected, and managed for a period of 99 years. Under the no-action alternative, the Incidental Take Permit would not be issued. There will be no concerted effort to restore, enhance, or maintain longleaf pine forest at the conservation bank owned by the Board. There is no legal obligation under the ESA for private property owners to actively manage their property for the benefit of the gopher tortoise. In the absence of this proposed ITP, much of the occupied habitat in Mobile County will be lost to benign neglect as the canopy becomes too dense to support gopher tortoises. The third alternative is to offer financial incentives to protect existing gopher tortoise habitat on private lands. This would be a useful approach for those landowners with sizeable tracts of fire-maintained longleaf pine that contain occupied habitat or habitat that is readily restorable. For this reason, in part, the Service maintains the ability to deny Certificates of Inclusion under this HCP when the agency deems that large tracts of occupied, suitable gopher tortoise habitat in Mobile County can and should be addressed through other appropriate means. The fourth alternative is to require on-site mitigation by issuing individual HCPs to landowners in Mobile county, requiring each to mitigate such take on the property where take occurs.

As stated above, the Service has made a preliminary determination that the issuance of the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of NEPA. This preliminary information may be revised due to public comment received in response to this notice and is based on information contained in the draft EA and HCP.

The Service will also evaluate whether the issuance of a section 10(a)(1)(B) ITP complies with section 7 of the Act by conducting an intra-Service section 7 consultation. The

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results of the biological opinion, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP.

Dated: January 9, 2001.

Sam D. Hamilton,

Regional Director.

[FR Doc. 01–1303 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Approved Tribal-State Compact.

SUMMARY: Pursuant to Section 11 of the Indian Gaming Regulatory Act of 1988 (IGRA), Pub. L. 100–497, 25 U.S.C. 2710, the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III gaming activities on Indian lands. The Assistant Secretary—Indian Affairs, Department of the Interior, through his delegated authority, has approved the Second Amendment between the Eastern Band of Cherokee Indians and the State of North Carolina, which was executed on November 14, 2000.

DATES: This action is effective January 17, 2001.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Office of Indian Gaming Management, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: December 28, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–1260 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Approved Tribal-State Compact.

SUMMARY: Pursuant to Section 11 of the Indian Gaming Regulatory Act (IGRA), Pub. L. 100–497, 25 U.S.C. 2710, the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III gaming activities on Indian lands. The Assistant Secretary—Indian Affairs, Department of the Interior, through his delegated authority, has approved the Tribal-State Compact for Class III Gaming Between the Hoh Indian Tribe and the State of Washington, which was executed on May 25, 2000.

DATES: This action is effective January 17, 2001.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Office of Indian Gaming Management, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: December 22, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–1263 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Approved Tribal-State Compact.

SUMMARY: Pursuant to Section 11 of the Indian Gaming Regulatory Act of 1988 (IGRA), Pub. L. 100–497, 25 U.S.C. 2710, the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III gaming activities on Indian lands. The Assistant Secretary—Indian Affairs, Department of the Interior, through his delegated authority, has approved the Tribal-State Compact Extension Between the Tunica-Biloxi Tribe of Louisiana and the State of Louisiana, which was executed on November 9, 2000.

DATES: This action is effective upon date of publication.

FOR FURTHER INFORMATION CONTACT: George T. Skibine, Director, Office of Indian Gaming Management, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4066.

Dated: December 27, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–1262 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–962–1410–HY–P]

Notice for Publication; F–14870–A; Alaska Native Claims Selection

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of section 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1613(a), will be issued to Kaktovik Inupiat Corporation for 60,000 square feet (1.3774 acres). The lands, located within T. 9 N., R. 34 E., Umiat Meridian, Alaska, are more particularly described as: Lot 6, Block 1, U.S. Survey No. 4234, Townsite of Kaktovik, Alaska.

Notice of the decision will be published once a week, for four (4) consecutive weeks, in the *Arctic Sounder.* Copies of the decision may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599 ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decision, an agency of the Federal government or regional corporation, shall have until February 16, 2001 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, subpart E, shall be deemed to have waived their rights.

Ronald E. Royer,

Land Law Examiner, Branch of ANCSA Adjudication.

[FR Doc. 01–1304 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–029–1610–DH CBMP]

Extension of Scoping Period, Montana

AGENCY: Bureau of Land Management, Miles City and Billings Field Offices, Interior.

ACTION: Notice.

SUMMARY: The BLM issued a Notice of Intent to Plan in a December 19, 2000 **Federal Register** notice. This notice is to inform the public that the scoping period has been extended to January 31, 2001.

BLM is preparing an Oil and Gas Resource Management Plan (RMP) Amendment and Environmental Impact Statement (EIS) jointly with the State of Montana (State). The planning area for the BLM will be the BLM-administered oil and gas estate within the Powder River and Billings RMP areas. The planning area for the State will be potential coal bed methane development areas around the state. The RMP Amendment will be based on the existing statutory requirements and will meet the requirements of the Federal Land Policy and Management Act (FLPMA) of 1976. The RMP Amendment will guide BLM's oil and gas decisions within the Powder River and Billings RMP areas and help the State evaluate effects of further oil and gas permit applications. The Draft EIS and RMP Amendment is scheduled for completion by September 2001. The Final EIS and Proposed RMP Amendment is scheduled for March 2002.

The public has been asked to help BLM and the State identify issues, concerns and alternatives. Draft Planning Criteria to help guide the effort have also been developed for public comment.

DATES: Any issues, concerns, or alternatives should be submitted to BLM on or before January 31, 2001.

ADDRESSES: All submissions should be sent to the following address: BLM, Mary Bloom, BLM Project Leader, 111 Garryowen Road, Miles City, Montana, 59301.

FOR FURTHER INFORMATION CONTACT: Mary Bloom, BLM Project Leader, (406) 233–3649.

SUPPLEMENTARY INFORMATION: Supplementary information is described in **Federal Register** Notice of Intent to Plan dated December 19, 2000, Volume 65, Number 244, pages 79422–79423.

The BLM and the State are seeking information from individuals, organizations, and agencies that may be affected by the plan. Specifically, we request any issues, concerns or alternatives that should be addressed in the plan amendment.

This notice meets the requirements of 40 CFR 1501.7 and 43 CFR 1610.2(c).

Dated: January 3, 2001.

Aden L. Seidlitz,

Associate Field Manager.

[FR Doc. 01–1355 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 6, 2001. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, 1849 C St. NW, NC400, Washington, DC 20240. Written comments should be submitted by February 1, 2001.

Carol D. Shull,

Keeper of the National Register.

ALASKA

Anchorage Borough-Census Area

Gill, Oscar, House, 1344 W. 10th Ave., Anchorage, 01000022

Kenai Peninsula Borough-Census Area

Thorn—Stingley House, 1660 E. End Rd., Homer, 01000023

Southeast Fairbanks Borough-Census Area

Rapids Roadhouse, Mile 227.4 Richardson Hwy., Delta, 01000021

Valdez-Cordova Borough-Census Area

Gakona Historic District, Mile 2, Tok Cutoff—Glenn Hwy, Gakona, 01000024

CALIFORNIA

Alameda County

Horner, William, House, 3101 Driscoll Rd., Fremont, 01000026

San Bernardino County

Atchison, Topeka and Santa Fe Railway Passenger and Freight Depot, 1170 W. 3rd St., San Bernardino, 01000025

San Diego County

Lindstrom House, 4669 E. Talmadge Dr., San Diego, 01000027

San Francisco County

Coffin—Redington Building, 301 Folsom St. and 300 Beale St., San Francisco, 01000028

COLORADO

Denver County

Midland Savings Building, 444 17th St., Denver, 01000030

Ray Apartments Buildings, 1550 and 1560 Ogden St., Denver, 01000029

Jefferson County

Bradford House II, N of Killdeer Ln., Littleton, 01000031

Park County

Colorado Salt Works, 3858 US 285, Hartsel, 01000033

Salt Works Ranch,

(Ranching Resources of South Park, Colorado) 3858 US 285, Hartsel, 01000032

FLORIDA

Alachua County

Waldo Historic District, Roughly bounded by NW 1st Ave., Main St., SW 5th Blvd., and SW 4th St., Waldo, 01000034

GEORGIA

Chatham County

Bonaventure Cemetery, Bonaventure Rd., 1 mi. N of US 80, Savannah, 01000035

MISSOURI

St. Louis Independent city

City Hospital Historic District, Roughly bounded by Lafayette Ave., Grattan St.,

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Carroll St., Dillon St., St. Ange St., 14th St., and Carroll St., St. Louis (Independent City), 01000036

MONTANA

Flathead County

Lincoln Creek Snowshoe Cabin, (Glacier National Park MPS) US 2, Glacier National Park, W. Glacier, 01000037

Powell County

Charter Oak Miner and Mill, Forest Rd. 227 B–1, Helena National Forest, USDA Forest Service, Elliston, 01000038

NEW JERSEY

Atlantic County

St. Nicholas of Tolentine Church, 1409 Pacific Ave., Atlantic City, 01000039

Burlington County

Red Dragon Canoe Club, 221 Edgewater Ave., Edgewater Park, 01000041

Salem County

Lawson, James and Mary, House, 209 N. Main St., Woodstown Borough, 01000042

NEW YORK

Broome County

Johnson City Square Deal Arch, Main St., W of Floral Ave., Johnson City, 01000044

Clinton County

Peru Community Church, 12 Elm St., Peru, 01000054

Erie County

Trico Plant #1, 817 Washinton St., Buffalo, 01000053

Oswego County

Mount Adnah Cemetery, 706 East Broadway, Fulton, 01000046

Sullivan County

Rialto Theatre, Broadway, Monticello, 01000043

Ulster County

Ulster Heights Synagogue, Ulter Heights Rd. and Beaver Dam Rd., Ulster Heights, 01000045

NORTH CAROLINA

Washington County

Garrett's Island House, 1445 Garrett's Island Rd., Plymouth, 01000047

OHIO

Butler County

Notre Dame Academy and Notre Dame High School, 926 Second St., Hamilton, 01000048

Clark County

Thomas Manufacturing Company Warehouse, 360 S. Limestone St., Springfield, 01000055

Cuyahoga County

Kundtz, Theodor, Company Building, 2249 Elm St., Cleveland, 01000051

Montgomery County

East Third Street Historic District, (Webster Station Area, Dayton, Ohio MPS) 424–520 East Third St. (S side only), Dayton, 01000049

McCormick Manufacturing Company Building, (Webster Station Area, Dayton, Ohio MPS) 434–438 E. First St., Dayton, 01000050

Scioto County

Anderson Brothers Department Store, (Boneyfiddle MRA) 301–307 Chillicothe St., Portsmouth, 01000052

Stark County

Clearview Golf Club, 8410 Lincoln St. SE, East Canton, 01000056

PENNSYLVANIA

Chester County

White Horse Historic District, Jct. of Goshen and Providence Rds., Willistown Township, 01000058

Lancaster County

Columbia Wagon Works, 920 Plane St., Columbia Borough, 01000057

Schuylkill County

Tamaqua Historic District, Roughly bounded by the Odd Fellows Cemetery, Rowe & Mauch Sts., East End Ave., Mountain Ave., and West Cottage Ave., Tamaqua, 01000059

TEXAS

Atascosa County

Lyons, Frederick and Sallie, House, 801 Live Oak St., Pleasanton, 01000061

Polk County

Polk County Courthouse and 1905 Courthouse Annex, Washington at Church St., Livingston, 01000060

VIRGINIA

Richmond Independent city

Tuckahoe Apartments, 5621 Cary Street Rd., Richmond (Independent City), 01000065

WASHINGTON

Spokane County

City of Cheney, Roughly bounded by Fifth St., C St., Front St., and F St., Cheney, 01000062

Millwood Historic District, Roughly bounded by Argonne and Sargent Rds., and by Euclid and Liberty Aves., Millwood, 01000064

Whatcom County

Sehome Hill Historic District, Portions of Jersey, Key, Liberty, Mason, Newell, E. Myrtle, E. Laurel, and E. Maple Sts., Sehome, 01000063

WEST VIRGINIA

Mason County

Maplewood, 1951 US 35, Pliny, 01000066

A Request for REMOVAL for Procedural Error has been made for the following resource:

COLORADO

El Paso County

North End Historic District, Roughly bounded by Monument Valley Wood, Nevada Ave., Madison and Unitah Sts., Colorado Springs, 82001017

[FR Doc. 01–1327 Filed 1–16–01; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Extension of Existing Collection: Summary of Sentenced Population Movement Annual Data Collection National Prisoner Statistics.

Office of Management and Budget approval is being sought for the information collection listed below. This proposed collection was previously published in the **Federal Register** on October 19, 2000, Vol. 65, page 62751, allowing for a 60-day public comment period.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for "thirty days" until February 16, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points;

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Overview of this Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Summary of Sentenced Population Movement—National Prisoner Statistics.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* NPS–1. Bureau of Justice Statistics.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Federal, State, and Local or Tribal Government. The National Prisoner Statistics—1 form is the only national source of information on the number of persons under jurisdiction or in custody at midyear and yearend; the number and type of admissions and releases; the number of inmate deaths by cause; counts by sex, race and Hispanic origin; number of inmates with HIV/AIDS, and prison capacity and jail backups due to crowding.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* the estimated total number of respondents is 52.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated total number of annual burden hours for this collection is 338.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instruction, or additional information, please contact Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, 1331 Pennsylvania Ave. NW, National Place Building, Washington, DC 20530.

Dated: January 10, 2001.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 01–1309 Filed 1–16–01; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF JUSTICE

Office of Justice Programs

Bureau of Justice Statistics; Agency Information Collection Activities: Extension of a Currently Approved Collection; Comment Request

ACTION: Notice of Information Collection; Extension of a currently approved collection; Capital punishment report of inmates under sentence of death.

The Department of Justice, Bureau of Justice Statistics has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. Office of Management and Budget (OMB) approval is being sought for the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 19, 2000, at 65 FR 62752–62753, allowing for a 60-day public comment period on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for "thirty days" until February 16, 2001. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn.: Department of Justice Desk Officer, Office of Management and Budget, Washington, DC 20530. Additionally, comments may be submitted to OMB via facsimile to 202–395–7285.

If you have additional comments, suggestions, or additional information, please write Jan M. Chaiken, Director, Bureau of Justice Statistics, 810 Seventh St. NW, Washington, DC 20531. If you need a copy of the collection instrument with instructions, or have additional information, please contact Tracy L. Snell at 202–616–3288, or via facsimile at 202–514–1757.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) enhance the quality, utility and clarity of the information to be collected; and

(4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses.

Overview of this Information Collection

(1) *Type of information collection:* Extension of a currently approved collection.

(2) *The title of the Form/Collection:* Capital Punishment Report of Inmates Under Sentence of Death.

(3) *The agency form number and the applicable component of the Department sponsoring the collection. Form:* NPS–8 Report of Inmates Under Sentence of Death; NPS–8A Update Report of Inmates Under Sentence of Death; NPS–8B Status of Death Penalty—No Statute in Force; and NPS–8C Status of Death Penalty—Statute in Force. Corrections Unit, Bureau of Justice Statistics, Office of Justice Programs, United States Department of Justice.

(4) *Affected public who will be asked to respond, as well as a brief abstract:* Primary: State Departments of Corrections and Attorneys General. Others: The Federal Bureau of Prisons. Approximately 104 respondents (two from each State, the District of Columbia, and the Federal Bureau of Prisons) responsible for keeping records on inmates under sentence of death in their jurisdiction and in their custody will be asked to provide information for the following categories: condemned inmates' demographic characteristics, legal status at the time of capital offense, capital offense for which imprisoned, number of death sentences imposed, criminal history information, reason for removal and current status if no longer under sentence of death, method of execution, and cause of death by other than by execution. The Bureau of Justice Statistics uses this information in published reports and for the U.S. Congress, Executive Office of the President, State officials, international organizations, researchers, students, the media, and others interested in criminal justice statistics.

(5) *An estimate of the total number of responses and the amount of time estimated for an average response:* 292 responses at 30 minutes each for the NPS–8; 3,452 responses at 30 minutes each for the NPS–8A; and 52 responses at 15 minutes each for the NPS–8B or NPS–8C. The 44 respondents for the NPS–8/8A and the 52 respondents for NPS–8B/8C totals 96 respondents for this data collection.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,885 annual burden hours.

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If additional information is required contact: Ms. Brenda E. Dyer, Deputy Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Suite 1220, National Place Building, 1331 Pennsylvania Ave. NW, Washington, DC 20530.

Dated: January 10, 2001.

Brenda E. Dyer,

Department Deputy Clearance Officer, United States Department of Justice.

[FR Doc. 01–1310 Filed 1–16–01; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 2001–01; Exemption Application Nos. D–10713, D–10714, D–10715, D–10716, and D–10717 et al.]

Grant of Individual Exemptions; General Motors Hourly-Rate Employees Pension Plan; General Motors Retirement Program for Salaried Employees; Saturn Individual Retirement Plan for Represented Team Members; Saturn Personal Choices Retirement Plan for Non-Represented Team Members; Employees' Retirement Plan for GMAC Mortgage Group; Delphi Hourly-Rate Employees Pension Plan; and Delphi Retirement Program for Salaried Employees (Collectively, the Plans)

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Grant of Individual Exemptions.

SUMMARY: This document contains exemptions issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Notices were published in the **Federal Register** of the pendency before the Department of proposals to grant such exemptions. The notices set forth a summary of facts and representations contained in each application for exemption and referred interested persons to the respective applications for a complete statement of the facts and representations. The applications have been available for public inspection at the Department in Washington, D.C. The notices also invited interested persons to submit comments on the requested exemptions to the Department. In addition the notices stated that any interested person might submit a written request that a public hearing be held (where appropriate). The applicants have represented that they have complied with the requirements of the notification to interested persons. No public comments and no requests for a hearing, unless otherwise stated, were received by the Department.

The notices of proposed exemption were issued and the exemptions are being granted solely by the Department because, effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed to the Secretary of Labor.

Statutory Findings

In accordance with section 408(a) of the Act and/or section 4975(c)(2) of the Code and the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990) and based upon the entire record, the Department makes the following findings:

(a) The exemptions are administrativsly feasible;

(b) They are in the interests of the plans and their participants and beneficiaries; and

(c) They are protective of the rights of the participants and beneficiaries of the plans.

General Motors Hourly-Rate Employees Pension Plan; General Motors Retirement Program for Salaried Employees; Saturn Individual Retirement Plan for Represented Team Members; Saturn Personal Choices Retirement Plan for Non-Represented Team Members; Employees' Retirement Plan for GMAC Mortgage Group; Delphi Hourly-Rate Employees Pension Plan; and Delphi Retirement Program for Salaried Employees (Collectively, the Plans) Located in New York, New York

[Prohibited Transaction Exemption 2001–01; Exemption Application Nos. D–10713; D–10714; D–10715; D–10716; and D–10717]

Exemption

The restrictions of section 406(a) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (D) of the Code, shall not apply to (1) the past and continuing lease (the Lease) by the Plans to CB Richard Ellis, Inc. (CB Richard Ellis), a party in interest with respect to the Plans, of commercial space in a certain office building; and (2) the exercise, by CB Richard Ellis, of an option to renew the Lease for one additional term, provided that the following conditions are met:

(a) All the terms and conditions of the Lease, including those providing CB Richard Ellis with an option to renew the Lease, are at least as favorable to the Plans as terms and conditions the Plans could have obtained in an arm's length transaction with an unrelated party;

(b) The interests of the Plans for all purposes under the Lease, including any renewal thereof, are represented by a qualified, independent fiduciary;

(c) The rent paid by CB Richard Ellis under the Lease, including any renewal thereof, is, at all times, no less than the fair market rental value of the leased space; and

(d) The independent fiduciary monitors the Lease, and any renewal thereof, on behalf of the Plans, and takes whatever actions necessary to safeguard the interests of the Plans and their participants and beneficiaries.

EFFECTIVE DATE: This exemption is effective as of December 17, 1998, the date on which CB Richard Ellis entered into the Lease.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption (the Notice) published on October 19, 2000 at 65 FR 62761.

Notice to Interested Persons: The applicant was unable to notify interested persons within the time period specified in the Notice. However, the applicant stated that interested persons, including the appropriate fiduciaries of the Plans, were notified in the manner and time agreed to by the Department, by November 18, 2000. Interested persons were informed that they had 30 days to submit any written comments regarding the Notice to the Department. No written comments were received by the Department.

FOR FURTHER INFORMATION CONTACT: Ms. Karin Weng of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Care Services Employees' 401(k) Profit Sharing Plan and Trust (the Plan) Located in Beachwood, OH

[Prohibited Transaction Exemption 2001–02; Exemption Application No. D–10771]

Exemption

The restrictions of sections 406(a) and 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the (1) cash sale by the Plan, occurring on December 30, 1997, of certain assets (the Assets), to Mr. Warren L. Wolfson, a party in interest with respect to the Plan; and (2) the prospective cash resale of the Assets by the Plan to Mr. Wolfson.

This exemption is subject to the following conditions:

(a) Each sale of the Assets was or will be a one-time transaction for cash.

(b) The Plan received or will receive no less than the fair market value of the Assets at the time of each sale.

(c) The sales price for each Asset was determined or will be determined by a qualified, independent appraiser at the time of each sale transaction.

(d) The terms of the past and prospective sales transactions were or will be no less favorable to the Plan than those obtainable in similar transactions negotiated at arm's length with unrelated parties.

(e) The Plan did not incur any fees or commissions in connection with the past sale of the Assets nor will it incur any fees or commissions expenses with respect to the prospective sale of such Assets.

(f) Within 60 days of the publication, in the **Federal Register**, of the notice granting this proposed exemption, Mr. Wolfson will file a Form 5330 with the Internal Revenue Service and pay all appropriate excise taxes that may be due and owing with respect to prohibited transactions arising in connection with certain of the Assets.

EFFECTIVE DATE: This exemption is effective as of December 30, 1997 with respect to the initial sale of the Assets by the Plan to Mr. Wolfson. In addition, this exemption is effective as of the date of the grant with respect to the resale of the Assets by the Plan to Mr. Wolfson.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on October 31, 2000 at 65 FR 65011.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady, Department of Labor, telephone (202) 219–8881. (This is not a toll-free number.)

IRAs for Eldon Nysether and Mark Nysether (the IRAs) Located in Seattle, Washington

[Prohibited Transaction Exemption 2001–03; Exemption Application Nos. D–10901 and D–10902]

Exemption

The sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the IRAs of their interests in certain improved real property (the Property) to Sea-Land Development Corporation, a disqualified person with respect to the IRAs,[1] provided that the following conditions are satisfied: (1) The sale is a one-time transaction for cash; (2) the IRAs pay no commissions nor other expenses relating to the sale; and (3) the sale price received by the IRAs equals the Property's fair market value, as of the date of the sale, as established by a qualified, independent appraiser.

For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on December 6, 2000 at 65 FR 76292.

FOR FURTHER INFORMATION CONTACT: Ms. Karin Weng of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions to which the exemptions does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) These exemptions are supplemental to and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transactional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(3) The availability of these exemptions is subject to the express condition that the material facts and representations contained in each application accurately describes all material terms of the transaction which is the subject of the exemption.

[1] Pursuant to 29 CFR 2510.3–2(d), the IRAs are not within the jurisdiction of Title I of the Act. However, there is jurisdiction under Title II of the Act, pursuant to section 4975 of the Code.

Signed at Washington, D.C., this 10th day of January, 2001.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 01–1196 Filed 1–16–01; 8:45 am]

BILLING CODE 4510–29–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Sunshine Act Meeting

January 10, 2001.

TIME AND DATE: 2:00 p.m., Wednesday, January 10, 2001.

PLACE: Room 6005, 6th Floor, 1730 K Street, NW., Washington, DC.

STATUS: Closed [Pursuant to 5 U.S.C. 552b(c)(10)].

MATTERS TO BE CONSIDERED: It was determined by a unanimous consent vote of the Commission that the Commission consider and act upon the following in closed session:

1. Disciplinary Matter, Docket No. D 2000–1.

2. Disciplinary Matter, Docket No. D 2001–1.

No earlier announcement of the meeting was possible.

CONTACT PERSON FOR FURTHER INFORMATION: Jean Ellen (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Jean H. Ellen,

Chief Docket Clerk.

[FR Doc. 01–1482 Filed 1–12–01; 12:40 pm]

BILLING CODE 6735–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–005]

Aerospace Safety Advisory Panel (ASAP); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the Aerospace Safety Advisory Panel.

DATES: Thursday, February 8, 2001, 1:00 p.m. to 2:30 p.m.

ADDRESSES: National Aeronautics and Space Administration, 300 E Street, SW., Room 9H40, Washington, DC 20546.

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FOR FURTHER INFORMATION CONTACT: Mr. David M. Lengyel, Aerospace Safety Advisory Panel Executive Director, Code Q–1, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–0391, if you plan to attend.

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel will present its annual report to the National Aeronautics and Space Administration Administrator. This is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The major subjects covered will be the National Space Transportation System, International Space Station, Aeronautical Operations, and Workforce Issues. The Aerospace Safety Advisory Panel is chaired by Mr. Richard D. Blomberg and is composed of nine members and eight consultants. The meeting will be open to the public up to the capacity of the room (approximately 60 persons including members of the Panel).

Dated: January 11, 2001.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–1307 Filed 1–16–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–003]

5th Digital Earth Community Meeting

AGENCY: National Aeronautics and Space Administration (Lead Agency).

ACTION: Notice of meeting.

SUMMARY: The Federal Interagency Digital Earth Working Group will hold the 5th Digital Earth Community Meeting that will focus on accomplishments thus far, and the future of Digital Earth. The intent of this meeting is to continue the efforts of enabling and facilitating the evolution of Digital Earth, a digital representation of the planet that will allow people to access and apply geo-spatial data from multiple resources. Federal, state, and local government along with private industry, academia and others will participate in presentations, workshops and panel discussions. Together we will educate and empower each other to continue to develop the Digital Earth environment.

DATES: Wednesday, January 31, 2001 from 8:00 AM to 5:00 PM. Registration beginning at 7:30 AM.

ADDRESSES: Capitol Union Building, Penn State University at Harrisburg, 777 W. Harrisburg Pike, Middletown, PA 17057.

FOR FURTHER INFORMATION CONTACT: To register for the meeting, please contact PSU Continuing Education at 717–948–6505 or e-mail: pshcsweb@psu.edu. If you would like to be present at this meeting, please contact Dr. Todd Bacastow at 814–863–0049 or e-mail bacastow@psu.edu. The deadline for registration is Wednesday, January 24, 2001. This is an outreach service of the College of Earth and Mineral Sciences.

SUPPLEMENTARY INFORMATION:

Format: The one day session will concentrate on presentations, workshops, and panel discussions. The status of The National Digital Earth Initiative, What is Digital Earth and its Community, Using Digital Earth Guidelines, Developing Applications, Involving Students, and Data Accessibility will all be discussed. Upcoming conferences, organizational committees and collaborative efforts will be addressed as well. There will be space available for personal demonstrations—and discussions throughout the day. Although the meeting is open to all interested parties, time availability for presentations and demonstrations is limited and will be allocated on a first come basis. All interested parties must contact Dr. Todd Bacastow by January 17, 2001.

Web Information: Additional details on the Community Meeting will be posted to *www.digitalearth.gov* in the near future.

Dated: January 2, 2001.

Thomas S. Taylor,

NASA Digital Earth Program Manager.

[FR Doc. 01–786 Filed 1–16–01; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Meetings

TIME AND DATE: 10:00 a.m., Thursday, January 18, 2001

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428

STATUS: Open.

MATTTERS TO BE CONSIDERED:

1. Request from a Federal Credit Union to Convert to a Community Charter.
2. Washington Member Business Loan Rule.
3. Request from a Corporate Credit Union for a Waiver under Part 704, NCUA's Rules and Regulations.
4. Final Rule: Amendments to Part 748, NCUA's Rules and Regulations, Guidelines for Safeguarding Member Information.

RECESS: 11:15 a.m.

TIME AND DATE: 11:30 a.m., Thursday, January 18, 2001

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, VA 22314–3428

STATUS: Closed.

MATTER TO BE CONSIDERED:

1. One (1) Personnel Matter. Closed pursuant to exemptions (2) and (6).

FOR FURTHER INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone 703–518–6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 01–1414 Filed 1–11–01; 4:58 pm]

BILLING CODE 7535–01–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–277 and 50–278]

In the Matter of PECO Energy Company, PSEG Nuclear LLC, Delmarva Power and Light Company, Atlantic City Electric Company (Peach Bottom Atomic Power Station, Units 2 and 3); Order Approving Transfer of Licenses and Conforming Amendments

I

PECO Energy Company (PECO), PSEG Nuclear LLC, Delmarva Power and Light Company (DP&L), and Atlantic City Electric Company (ACE) are the joint owners of the Peach Bottom Atomic Power Station, Units 2 and 3 (Peach Bottom), located in York County, Pennsylvania. They hold Facility Operating Licenses Nos. DPR–44 and DPR–56 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) on October 25, 1973, and July 2, 1974, respectively, pursuant to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR Part 50). Under these licenses, PECO (currently owner of 42.49 percent of each Peach Bottom unit) is authorized to possess, use, and operate the Peach Bottom units. The current nonoperating ownership interests of the other joint owners for each Peach Bottom unit are as follows: PSEG Nuclear LLC, 42.49 percent; DP&L, 7.51 percent; and ACE, 7.51 percent.

II

By an Order dated April 21, 2000, the NRC approved the transfer of the subject Peach Bottom licenses from DP&L and ACE to PECO and PSEG Nuclear LLC. Conforming license amendments were also approved. The April 21, 2000, Order was in response to an application dated December 21, 1999, as supplemented February 11, March 2, and March 16, 2000, and was based in part on the DP&L and ACE interests in the licenses and in the facility being transferred simultaneously, as well as the accumulated decommissioning funds of DP&L and ACE being transferred collectively to the decommissioning trusts of PECO and PSEG Nuclear LLC. The April 21, 2000, Order, with respect to the DP&L and ACE license transfers that were proposed to PECO, was issued in the context of PECO then existing as a stand-alone electric utility, and did not expressly approve the DP&L and ACE license transfers to PECO as it now exists as a subsidiary of Exelon Corporation. Further, the Order did not approve DP&L and ACE license transfers to Exelon Generation Company LLC (EGC), which is to be formed as an indirect subsidiary of Exelon Corporation. The NRC did, however, issue Orders dated August 3, 2000, and October 5, 2000, that respectively approved the direct transfer of the Peach Bottom licenses, to the extent now held by PECO, to EGC, and the indirect transfer of the Peach Bottom licenses, again to the extent now held by PECO, to Exelon Corporation (which indirect transfer occurred on October 20, 2000, by reason of PECO becoming at that time a wholly-owned subsidiary of Exelon Corporation).

By application dated October 10, 2000, PECO, PSEG Nuclear LLC, DP&L, and ACE requested approvals as necessary to allow the Peach Bottom licenses, to the extent now held by DP&L and ACE, to be transferred to PECO (as a subsidiary of Exelon Corporation), to EGC (whether the transferor(s) are DP&L, ACE, or PECO), and to PSEG Nuclear LLC, at two different times, namely, the DP&L transfers first, and the ACE transfers second, if at all. The October 10, 2000, application also requested that the NRC extend the effectiveness of the April 21, 2000, Order to December 31, 2001. No physical changes or changes in the management or operations of the Peach Bottom units are proposed in the application. The application also requested the approval of conforming license amendments to reflect the license transfers that are the subject of the application. The proposed amendments would delete references in the licenses to DP&L and ACE as licensees, as each respective interest is transferred, and add EGC to the licenses at the appropriate time.

Approval of the transfers encompassed by the October 10, 2000, application and conforming license amendments was requested pursuant to 10 CFR 50.80 and 50.90. A notice of the license transfer application and the conforming amendment request, and an opportunity for a hearing was published in the **Federal Register** on November 27, 2000 (65 FR 70740). No hearing requests or written comments were filed.

Pursuant to 10 CFR 50.80, no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. After reviewing the information submitted in the October 10, 2000, application, the Orders referenced above dated April 21, August 3, and October 5, 2000, and the underlying applications and safety evaluations regarding those Orders, and other information before the Commission, the NRC staff has determined that PSEG Nuclear LLC is qualified to hold, in addition to the interests in the licenses it presently holds, (1) one-half of the interest in the Peach Bottom licenses now held by DP&L, and (2) one-half of the interest in the Peach Bottom licenses now held by ACE; that PECO, as it presently exists as a subsidiary of Exelon Corporation, is qualified to hold, in addition to the interests in the licenses it presently holds, (1) one-half of the interest in the Peach Bottom licenses now held by DP&L, and (2) one-half of the interest in the Peach Bottom licenses now held by ACE; and that EGC is qualified to hold, in addition to the interests in the licenses that it may hold by virtue of transfers from PECO previously and separately approved by the August 3, 2000, Order, (1) one-half of the interest in the Peach Bottom licenses now held by DP&L, which one-half interest may be first transferred to PECO and then to EGC or may be directly transferred to EGC from DP&L, and (2) one-half of the interest in the Peach Bottom licenses now held by ACE, which one-half interest may be first transferred to PECO and then to EGC or may be directly transferred to EGC from ACE; and that each transfer of the licenses, as described, is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission, subject to the conditions described herein. The NRC staff has further found that the application for the proposed license amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations set forth in 10 CFR Chapter I; the facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission; there is reasonable assurance that the activities authorized by the proposed license amendments can be conducted without endangering the health and safety of the public and that such activities will be conducted in compliance with the Commission's regulations; the issuance of the proposed license amendments will not be inimical to the common defense and security or to the health and safety of the public; and the issuance of the proposed license amendments will be in accordance with 10 CFR Part 51 of the Commission's regulations and all applicable requirements have been satisfied. These findings are supported by a safety evaluation dated December 27, 2000.

III

Accordingly, pursuant to Sections 161b, 161i, and 184 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2201(b), 2201(i), and 2234; and 10 CFR 50.80, *It Is Hereby Ordered* that each license transfer described in Section II of this Order is approved, subject to the following conditions:

1. DP&L shall transfer to the PECO or EGC decommissioning trusts for Peach Bottom, as appropriate to the transferee, and to the PSEG Nuclear LLC decommissioning trusts for Peach Bottom at the time DP&L's interests in the Peach Bottom licenses are transferred to PECO or EGC and to PSEG Nuclear LLC, all of DP&L's accumulated decommissioning trust funds for Peach Bottom Units 2 and 3, divided equally between the PECO or EGC trusts, as appropriate to the transferee, and the PSEG Nuclear LLC trusts. Immediately following such transfer, the amounts in the PECO or EGC and PSEG Nuclear LLC decommissioning trusts combined with the additional payments from ACE that would be owed to PECO or EGC and to PSEG Nuclear LLC under the respective contractual commitments referenced in the application, which contractual commitments shall be in force and effect at the time of the transfer, and that in turn would be contributed to the respective decommissioning trusts as represented

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in the application must, with respect to the interests in Peach Bottom Units 2 and 3 transferred from DP&L that PECO or EGC and PSEG Nuclear LLC would then hold, be at a level no less than the formula amounts under 10 CFR Section 50.75.

2. ACE shall transfer to the PECO or EGC decommissioning trusts for Peach Bottom, as appropriate to the transferee, and to the PSEG Nuclear LLC decommissioning trusts for Peach Bottom at the time ACE's interests in the Peach Bottom licenses are transferred to PECO or EGC and to PSEG Nuclear LLC, all of ACE's accumulated decommissioning trust funds for Peach Bottom Units 2 and 3. Immediately following such transfer, the amounts in the PECO or EGC and PSEG Nuclear LLC decommissioning trusts must, with respect to the interests in Peach Bottom Units 2 and 3 transferred from DP&L and ACE that PECO or EGC and PSEG Nuclear LLC would then hold, be at a level no less than the formula amounts under 10 CFR Section 50.75.

3. The decommissioning trust agreements for Peach Bottom Units 2 and 3, with respect to decommissioning trust funds held by EGC and PSEG Nuclear LLC shall provide or continue to provide essentially that:

a. The agreement must be in a form acceptable to the NRC.

b. Investments in the securities or other obligations of the respective parent of the respective licensee, i.e., EGC or PSEG Nuclear LLC, affiliates thereof, or their successors or assigns, shall be prohibited. In addition, except for investments tied to market indexes or other non-nuclear sector mutual funds, investments in any entity owning one or more nuclear power plants shall be prohibited.

c. No disbursements or payments from the trust, other than for ordinary administrative expenses, shall be made by the trustee until the trustee has first given the NRC 30 days prior written notice of the payment. In addition, no disbursements or payments from the trust shall be made if the trustee receives prior written notice of objection from the Director, Office of Nuclear Reactor Regulation.

d. The trust agreement shall not be modified in any material respect without prior written notification to the Director, Office of Nuclear Reactor Regulation.

e. The trustee, investment advisor, or anyone else directing the investments made in the trust shall adhere to a "prudent investor" standard, as specified in 18 CFR 35.32(a)(3) of the Federal Energy Regulatory Commission's regulations.

4. With respect to each transfer approved by this Order, after receipt of all required regulatory approvals, the relevant transferor and transferee shall inform the Director, Office of Nuclear Reactor Regulation, in writing of such receipt and of the date of closing of the transfer no later than 1 business day before the date of closing. If any transfer approved by this Order is not completed by December 31, 2001, this Order shall become null and void with respect to such transfer; provided, however, on application and for good cause shown, such date may be extended.

It Is Further Ordered that, consistent with 10 CFR 2.1315(b), license amendments that make changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the Peach Bottom licenses to reflect the subject transfers are approved. Such amendments as appropriate to the particular license transfer occurring shall be issued and made effective at the time the proposed corresponding license transfer is completed.

It Is Further Ordered that to the extent the previous Order, issued April 21, 2000, related to the license transfers approved by this Order, is inconsistent with this Order, the April 21, 2000, Order is hereby superseded. Also, condition 2 of the April 21, 2000, Order is modified to supplement the reference to PECO with a reference to EGC in the alternative, as appropriate to the actual transferee. In addition, for good cause shown in the application, namely, the delay in receiving other necessary regulatory approvals, the approval of any concurrent transfer of one-half of the DP&L interests and one-half of the ACE interests in the Peach Bottom licenses to PSEG Nuclear LLC shall remain effective until December 31, 2001, under the applicable terms and conditions set forth in the April 21, 2000, Order.

This Order is effective upon issuance.

For further details with respect to this Order, see the application dated October 10, 2000, and the related safety evaluation issued with this Order. Also see the application dated December 21, 1999, and supplements thereto dated February 11, March 2, and March 16, 2000, and the Orders and related safety evaluations dated August 3, and October 5, 2000, pertaining to related Peach Bottom license transfers involving EGC and PECO, which may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One WhiteFlint North, 11555 Rockville Pike (first floor), Rockville, MD, and are accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site *http://www.nrc.gov*.

Dated at Rockville, Maryland, this 27th day of December 2000.

For the Nuclear Regulatory Commission.

Jacqueline E. Silber,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 01–1364 Filed 1–16–01; 8:45 am]

BILLING CODE 7590–01–P

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Sunshine Act Meeting

Board Votes to Close January 10, 2001, Meeting

In person and by telephone on January 10, 2001, a majority of the Board of Governors of the United States Postal Service voted to close to public observation its meeting held in Washington, DC, via teleconference. The Board determined that prior public notice was not possible.

ITEM CONSIDERED:

1. Business Initiative.

PERSONS EXPECTED TO ATTEND:

Governors Ballard, Daniels, del Junco, Dyhrkopp, Fineman, Kessler, McWherter, Rider and Walsh; Postmaster General Henderson, Deputy Postmaster General Nolan, Secretary to the Board Hunter, and General Counsel Gibbons.

GENERAL COUNSEL CERTIFICATION: The General Counsel of the United States Postal Service has certified that the meeting was properly closed under the government in the Sunshine Act.

CONTACT PERSON FOR MORE INFORMATION: Requests for information about the meeting should be addressed to the Secretary of the Board, David G. Hunter, at (202) 268–4800.

David G. Hunter,

Secretary.

[FR Doc. 01–1411 Filed 1–11–01; 4:58 pm]

BILLING CODE 7710–12–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act; Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of January 15, 2001.

A closed meeting will be held on Thursday, January 18, 2001, at 11:00 a.m.

Commissioner Hunt, as duty officer, determined that no earlier notice thereof was possible.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(A) and (10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will be:

- Institution and settlement of injunctive actions; and
- Institution and settlement of administrative proceedings of an enforcement nature.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: the Office of the Secretary at (202) 942–7070.

Dated: January 12, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1470 Filed 1–12–01; 11:38 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before February 16, 2001. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer*, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer*, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION:

Title: 8(a) SDB Applications.

No's: 1010, 1010B's and 1010C.

Frequency: On Occasion.

Description of Respondents: 8(A) Companies.

Annual Responses: 6,103.

Annual Burden: 21,460.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 01–1322 Filed 1–16–01; 8:45 am]

BILLING CODE 8025–01–U

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3315]

State of Arkansas; Amendment #1

In accordance with a notice received from the Federal Emergency Management Agency, dated January 8, 2001, the above-numbered Declaration is hereby amended to establish the incident period for this disaster as beginning on December 12, 2000 and continuing through January 8, 2001.

All other information remains the same, i.e., the deadline for filing applications for physical damage is February 27, 2001 and for economic injury the deadline is October 1, 2001.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: January 10, 2001.

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. 01–1325 Filed 1–16–01; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3316]

State of Oklahoma

As a result of the President's major disaster declaration on January 5, 2001, I find that the following Counties in the State of Oklahoma constitute a disaster area due to damages caused by a severe winter ice storm beginning on December 25, 2000 and continuing: Adair, Atoka, Bryan, Carter, Cherokee, Choctaw, Cleveland, Coal, Cotton, Creek, Garvin, Grady, Haskell, Hughes, Jefferson, Johnston, Latimer, LeFlore, Lincoln, Love, Marshall, McClain, McCurtain, McIntosh, Murray, Muskogee, Okfuskee, Oklahoma, Okmulgee, Pittsburg, Pontotoc, Pottawatomie, Pushmataha, Seminole, Sequoyah, Stephens, Tulsa, Wagoner and Washington Counties. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on March 6, 2001, and for loans for economic injury until the close of business on October 5, 2001 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 3 Office, 4400 Amon Carter Blvd., Suite 102, Fort Worth, TX 76155.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Caddo, Canadian, Comanche, Delaware, Kingfisher, Logan, Mayes, Nowata, Osage, Pawnee, Payne, Rogers, and Tillman in Oklahoma; Benton, Crawford, Little River, Polk, Scott, Sebastian, Sevier and Washington in Arkansas; Chautauqua and Montgomery in Kansas; Bowie, Clay, Cooke, Fannin, Grayson, Lamar, Montague, Red River and Wichita in Texas.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	7.000
Homeowners Without Credit Available Elsewhere	3.500
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	7.000
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 331611. For economic injury the numbers are 9K3300 for Oklahoma, 9K3400 for Arkansas, 9K3500 for Kansas, and 9K3600 for Texas.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

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Dated: January 9, 2001.
Herbert L. Mitchell,
Associate Administrator for Disaster Assistance.
[FR Doc. 01–1324 Filed 1–16–01; 8:45 am]
BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3317]

State of Texas

As a result of the President's major disaster declaration on January 8, 2001, I find that the following Counties in the State of Texas constitute a disaster area due to damages caused by a severe winter ice storm beginning on December 12, 2000 and continuing: Bowie, Cass and Red River Counties. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on March 9, 2001, and for loans for economic injury until the close of business on October 9, 2001 at the address listed below or other locally announced locations: U.S. Small Business Administration, Disaster Area 3 Office, 4400 Amon Carter Blvd., Suite 102, Fort Worth, TX 76155.

In addition, applications for economic injury loans from small businesses located in the following contiguous counties may be filed until the specified date at the above location: Delta, Franklin, Hopkins, Lamar, Marion, Morris and Titus Counties in Texas; Caddo County in Louisiana; Choctaw and McCurtain Counties in Oklahoma.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	7.000
Homeowners without credit available elsewhere	3.500
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.000
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 331711. For economic injury the numbers are 9K3700 for Texas, 9K3800 for Louisiana, 9K3900 for Oklahoma.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: January 10, 2001.
Herbert L. Mitchell,
Associate Administrator for Disaster Assistance.
[FR Doc. 01–1323 Filed 1–16–01; 8:45 am]
BILLING CODE 8025–01–U

DEPARTMENT OF STATE

[Public Notice 3540]

Bureau of Educational and Cultural Affairs Request for Grant Proposals: Benjamin A. Gilman International Scholarship Program—International Academic Opportunity Act of 2000

SUMMARY: The Office of Global Educational Programs of the Bureau of Educational and Cultural Affairs announces an open competition for the Benjamin A. Gilman International Scholarship Program. Public and private non-profit organizations meeting the provisions described in IRS regulation 26 CFR 1.501(c) may submit proposals for the purpose of carrying out a scholarship program for academic study outside of the United States.

Program Information

This program establishes grants for U.S. citizen or national undergraduate students of limited financial means from the United States to enable such students to pursue academic studies abroad. Such foreign study is intended to better prepare U.S. students to assume significant roles in an increasingly global economy.

Overview

This program provides an assistance award not to exceed $1,500,000 for the purpose of issuing grants of up to $5,000 to individuals who meet the eligibility requirements listed below, toward the cost of up to one academic year of undergraduate study abroad. Subject to the availability of funding and to satisfactory performance of the awardee, this assistance award may be renewable for two subsequent fiscal years.

The Presidential Memorandum on International Education of April 19, 2000 directs the Department of State to support the efforts of schools and colleges to improve access to high-quality international educational experiences by increasing the number of diversity of students who study and intern abroad. In support of this Memorandum and pursuant to the authorizing legislation for the Benjamin A. Gilman International Scholarship Program, this program is intended to broaden the student population that participates in study outside the U.S. by focusing on those students who might not otherwise study abroad due to financial constraints.

The Presidential Memorandum also directs the Department to encourage students and institutions to choose nontraditional study-abroad locations and to help underrepresented U.S. institutions offer and promote study-abroad opportunities for their students. These secondary objectives should also be addressed in grant proposals.

Guidelines

The administering organization should be prepared to solicit applications immediately upon receipt of grant notification and to award scholarships to allow study programs to begin in the 2001/2002 academic year.

Student Eligibility: To apply for a scholarship, an applicant must;

(1) Be a student in good standing at an institution of higher education in the United States (as defined in section 101(a) of the Higher Education Act of 1965);

(2) Have been accepted for up to one academic year of study on a program of study abroad approved for credit by the student's home institution;

(3) Be receiving any need-based student assistance under title IV of the Higher Education Act of 1965; and

(4) Be a citizen or national of the United States.

Application and Selection: (1) Scholarship application and selection shall be carried out through accredited institutions of higher education in the United States or a combination of such institutions.

(2) In considering applications for scholarships:

(A) consideration of financial need shall include the increased costs of study abroad; and

(B) priority consideration shall be given to applicants who are receiving Federal Pell Grants under title of the Higher Education Act of 1965.

(C) in ranking eligible applicants, consideration should also be given to academic excellence, and diversity of the applicant pool, fields of study, destinations, and type and location of home institutions of higher education.

Reporting: The grantee organization will submit quarterly reports on the number of applicants, the number of selectees, the names of the institutions of higher education in the United States that applicants and selectees attended at the time of application, name of institutions sponsoring the study program abroad, the names and locations of the institutions of higher education outside the United States which participants attended during their study abroad, the fields of study of participants, and attrition rates. Additionally, the Bureau of Educational and Cultural Affairs may request other periodic and ad hoc reports.

Budget Guidelines

Grants awarded to eligible organizations with less than four years of experience in conducting international exchange programs are limited by Bureau policy to $60,000. The bureau intends to make one award not to exceed $1,500,000. Accordingly, institutions with less than five years experience are not encouraged to apply. The Bureau encourages applicants to provide maximum levels of cost-sharing and funding from private sources in support of its programs.

Applicants must submit a comprehensive budget for the entire program. Of the total grant, a maximum of 10% (up to $150,000) may be spent on administrative and overhead costs. There must be a summary budget as well as breakdowns reflecting both administrative and program budgets. Applicants may provide separate sub-budgets for each program component, phase, location, or activity to provide clarification.

Allowable costs for the program include the following:

(1) Administrative: Salaries and benefits and other direct administrative expenses such as postage, phone, printing and office supplies.

(2) Program: Participant expenses, which may include institutional fees, travel expenses, tuition; expenses related to review panels, including travel and perdiem.

Please refer to the Solicitation Package for complete budget guidelines and formatting instructions.

Announcement Title and Number

All correspondence with the Bureau concerning this RFGP should reference the above title and number *ECA/A/S/A–01–14.*

FOR FURTHER INFORMATION, CONTACT: The Office of Global Educational Programs, Educational Information and Resources Branch (ECA/A/S/A), Room 349, U.S. Department of State, 301 4th Street, SW., Washington, DC 20547; telephone 202–619–5434; fax 202–401–1433; e-mail advise@pd.state.gov to request a Solicitation Package. The Solicitation Package contains detailed award criteria, required application forms, specific budget instructions, and standard guidelines for proposal preparation. Please specify Bureau Program Officer Amy Forest on all other inquiries and correspondence.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

To Download a Solicitation Package Via Internet

The entire Solicitation Package may be downloaded from the Bureau's website at http://exchanges.state.gov/education/RFGPs. Please read all information before downloading.

Deadline for Proposals

All proposal copies must be received at the Bureau of Educational and Cultural Affairs by 5 p.m. Washington, DC time on Friday, February 23, 2001. Faxed documents will not be accepted at any time. Documents postmarked on the due date but received on a later date will not be accepted. Each applicant must ensure that the proposals are received by the above deadline.

Applicants must follow all instructions in the Solicitation Package. The original and 15 copies of the application should be sent to: U.S. Department of State, SA–44, Bureau of Educational and Cultural Affairs, Ref.: *ECA/A/S/A–01–14,* Program Management, ECA/EX/PM, Room 534, 301 4th Street, SW., Washington, DC 20547.

Applicants must also submit the "Executive Summary" and "Proposal Narrative" sections of the proposal on 3.5" diskette, formatted for DOS. These documents must be provided in ASCII text (DOS) format with a maximum line length of 65 characters.

Diversity, Freedom and Democracy Guidelines

Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social, and cultural life. "Diversity" should be interpreted in the broadest sense and encompass differences including, but not limited to ethnicity, race, gender, religion, geographic location, socio-economic status, and physical challenges. Applicants are strongly encouraged to adhere to the advancement of this principle both in program administration and in program content. Please refer to the review criteria under the 'Support for Diversity' section for specific suggestions on incorporating diversity into the total proposal. Public Law 104–319 provides that "in carrying out programs of educational and cultural exchange in countries whose people do not fully enjoy freedom and democracy," the Bureau "Shall take appropriate steps to provide opportunities for participation in such programs to human rights and democracy leaders of such countries." Public Law 106–113 requires that the governments of the countries described above do not have inappropriate influence in the selection process. Proposals should reflect advancement of these goals in their program contents, to the full extent deemed feasible.

Review Process

The Bureau will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines stated herein and in the Solicitation Package. All eligible proposals will be reviewed by the program office, as well as the Public Diplomacy section overseas, where appropriate. Eligible proposals will be subject to compliance with Federal and Bureau regulations and guidelines and forwarded to Bureau grant panels for advisory review. Proposals may also be reviewed by the Office of the Legal Adviser or by other Department elements. Final funding decisions are at the discretion of the Department of State's Assistant Secretary for Educational and Cultural Affairs. Final technical authority for assistance awards (grants or cooperative agreements) resides with the Bureau's Grants Officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the criteria stated below. These criteria are not rank ordered and all carry equal weight in the proposal evaluation:

1. Quality of the Program Idea: Proposals should exhibit originality, substance, precision, and relevance to the Bureau's mission.

2. Program Planning: Detailed agenda and relevant work plan should demonstrate substantive undertakings and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above. The work plan should specify target dates for objectives such as application deadlines, notifications, and provision of funds to participants.

3. Ability to Achieve Program Objectives: Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

4. Multiplier Effect/Impact: Proposed programs should strengthen long-term mutual understanding, including

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maximum sharing of information and establishment of long-term institutional and individual linkages.

5. Support of Diversity: Proposals should demonstrate substantive support of the Bureau's policy on diversity. Achievable and relevant features should be cited in both program administration and program content. Proposals should demonstrate the recipient's commitment to promoting the awareness and understanding of diversity, including but not limited to diversity in applicant pool, type and location of home institution, study destinations, and fields of study.

6. Institutional Capacity: Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals. Applicants should demonstrate prior experience or the capacity to negotiate with academic institutions to achieve significant cost sharing. Electronic databases should be compatible with the Bureau's systems.

7. Institution's Record/Ability: Proposals should demonstrate an institutional record of successful exchange programs, including responsible fiscal management and full compliance with all reporting requirements for past Bureau grants as determined by Bureau Grant Staff. The Bureau will consider the past performance of prior recipients and the demonstrated potential of new applicants.

8. Follow-on Activities: Proposals should provide a plan for continued follow-on activity such as alumni tracking and programming.

9. Project Evaluation: Proposals should include a plan to evaluate the activity's success, both as the activities unfold and at the end of the program. A draft survey questionnaire or other technique plus description of a methodology to use to link outcomes to original project objectives is recommended. Successful applicants will be expected to submit intermediate reports after each project component is concluded or quarterly, whichever is less frequent.

10. Cost-effectiveness: The overhead and administrative components of the proposal, including salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate.

11. Cost-Sharing: Proposals should maximize cost-sharing through other private sector support as well as institutional direct funding contributions.

Authority

Overall grant making authority for this program is contained in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended, also known as the Fulbright-Hays Act. The purpose of the Act is "to enable the Government of the United States to increase mutual understanding between the people of the United States and the people of other countries . . . ; to strengthen the ties which unite us with other nations by demonstrating the educational and cultural interests, developments, and achievements of the people of the United States and other nations . . . and thus to assist in the development of friendly, sympathetic and peaceful relations between the United States and the other countries of the world." The funding authority for the program above is provided through the International Academic Opportunity Act of 2000.

Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements.

Notification

Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal Bureau procedures.

Dated: January 9, 2001.

William B. Bader,

Assistant Secretary for Educational and Cultural Affairs, U.S. Department of State.

[FR Doc. 01–1363 Filed 1–16–01; 8:45 am]

BILLING CODE 4710–05–U–M

DEPARTMENT OF STATE

[Public Notice 3639]

Imposition of Nonproliferation Measures Against a North Korean Entity, Including Ban on U.S. Government Procurement

AGENCY: Bureau of Nonproliferation, Department of State.

ACTION: Notice.

SUMMARY: A determination has been made that a North Korean entity has engaged in activities that require the imposition of measures pursuant to section 3 of the Iran Nonproliferation Act of 2000.

EFFECTIVE DATE: January 2, 2001.

FOR FURTHER INFORMATION CONTACT: On general issues: Vann H. Van Diepen, Office of Chemical, Biological and Missile Nonproliferation, Bureau of Nonproliferation, Department of State, (202–647–1142). On U.S. Government procurement ban issues: Gladys Gines, Office of the Procurement Executive, Department of State (703–516–1691).

SUPPLEMENTARY INFORMATION: Pursuant to sections 2 and 3 of the Iran Nonproliferation Act of 2000 (Pub. L. 106–178), the U.S. Government determined on January 2, 2001, that the measures authorized in section 3 of the Act shall apply to the following foreign entity identified in the report submitted pursuant to section 2(a) of the Act:

Changgwang Sinyong Corporation (North Korea) and any successor, sub-unit, or subsidiary thereof.

Accordingly, pursuant to the provisions of the Act, the following measures are imposed on this entity:

1. No department or agency of the United States Government may procure, or enter into any contract for the procurement of, any goods, technology, or services from the foreign person.

2. No department or agency of the United States Government may provide any assistance to the foreign person, and that person shall not be eligible to participate in any assistance program of the United States Government;

3. No United States Government sales to the foreign person of any item on the United States Munitions List (as in effect on August 8, 1995) are permitted, and all sales to that person of any defense articles, defense services, or design and construction services under the Arms Export Control Act are terminated; and,

4. No new individual licenses shall be granted for the transfer to the foreign person of items, the export of which is controlled under the Export Administration Act of 1979 or the Export Administration Regulations, and any existing such licenses are suspended.

These measures shall be implemented by the responsible departments and agencies of the United States Government and will remain in place until April 6, 2002, except to the extent that the Secretary of State may subsequently determine otherwise. The Secretary of State will make a new determination in the event that circumstances change in such a manner as to warrant a change in the duration of sanctions.

Dated: January 10, 2001.

Robert J. Einhorn,

Assistant Secretary of State for Nonproliferation, U.S. Department of State.

[FR Doc. 01–1362 Filed 1–16–01; 8:45 am]

BILLING CODE 4710–25–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Advisory Circular 25.335–1A, Design Dive Speed

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of issuance of advisory circular.

SUMMARY: This notice announces the issuance of Advisory Circular (AC) 25.335–1A, Design Dive Speed. This AC sets forth an acceptable means, but not the only means, of demonstrating compliance with the airworthiness standards for transport category airplanes related to the minimum speed margin between design cruise speed and design dive speed for transport category airplanes. Like all ACs, it is not regulatory but is to provide guidance for applicants in demonstrating compliance with the objective safety standards set forth in the rule.

DATES: Advisory Circular 25.335–1A was issued by the Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100, on September 29, 2000.

How to Obtain Copies: A paper copy of AC 25.335–1A may be obtained by writing to the U.S. Department of Transportation, Subsequent Distribution Office, DOT Warehouse, SVC–121.23, Ardmore East Business Center, 3341Q 75th Ave., Landover, MD 20785, telephone 301–322–5377, or faxing your request to the warehouse at 301–386–5394. The AC also will be available on the Internet at *http://www.faa.gov/avr/air/airhome.htm*, at the link titled "Advisory Circulars" under the "Available Information" down-drop menu.

Issued in Renton, Washington, on January 8, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 01–1287 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Advisory Circular; Damage Tolerance for High Energy Turbine Engine Rotors

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of issuance of final advisory circular (AC) on damage tolerance for high energy turbine engine rotors.

SUMMARY: This notice announces the issuance of Advisory Circular (AC) No. 33.14–1, Damage Tolerance for High Energy Turbine Rotors.

DATES: Advisory Circular No. 33.14.1, was issued by the New England Aircraft Certification Service, Engine and Propeller Directorate on January 8, 2001.

FOR FURTHER INFORMATION CONTACT: Tim Mouzakis, Engine and Propeller Standards Staff, ANE–110, at the above address, telephone (781) 238–7114, fax (781) 238–7199. A copy of the subject AC may also be obtained electronically by writing to the following Internet address: "tim.mouzakis@faa.gov". Additionally, you may obtain a copy of the AC directly from the internet at the following address: "http://www.faa.gov/avr/air/acs/achome.htm".

SUPPLEMENTARY INFORMATION: This advisory circular (AC) provides guidance and information on acceptable methods, but not the only methods of compliance with § 33.14 of the Federal Aviation Regulations, Title 14 of the Code of Federal Regulations. Section 33.14 contains requirements of life management requirements applicable to the design and life management of titanium alloy high energy rotating parts of aircraft engines. Although this AC does refer to regulatory requirements that are mandatory, this ACT is not, in itself, mandatory. This AC neither changes any regulatory requirement nor authorizes changes in or deviations from the regulatory requirements.

This advisory circular would be published under the authority granted to the Administrator by 49 U.S.C. 106(g), 40113, 44701–44702, 44704, provides guidance for Damage tolerance for high energy turbine engine rotors.

Issued in Burlington, Massachusetts, on January 8, 2001.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01–1285 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Advisory Circular 25.491–1, Taxi, Takeoff and Landing Roll Design Loads

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of issuance of advisory circular.

SUMMARY: This notice announces the issuance of Advisory Circular (AC) 25.491–1, Taxi, Takeoff and Landing Roll Design Loads. This AC sets forth acceptable methods of compliance with the provision of part 25 of the Federal Aviation Regulations (FAR) dealing with the certification requirements for taxi, takeoff and landing roll design loads. Guidance information is provided for showing compliance with § 25.491 of the FAR, relating to structural design for airplane operation on paved runways and taxiways normally used in commercial operations. Other methods of compliance with the requirements may be acceptable.

DATES: Advisory Circular 25.491–1 was issued by the Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100, on October 30, 2000.

How to Obtain Copies: A paper copy of AC 25.491–1 may be obtained by writing to the U.S. Department of Transportation, Subsequent Distribution Office, DOT Warehouse, SVC–121.23, Ardmore East Business Center, 3341Q 75th Ave., Landover, MD 20785, telephone 301–322–5377, or faxing your request to the warehouse at 301–386–5394. The AC also will be available on the Internet at *http://www.faa.gov/avr/air/airhome.htm*, at the link titled "Advisory Circulars" under the "Available Information" down-drop menu.

Issued in Renton, Washington, on January 8, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM–100.

[FR Doc. 01–1286 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Gerald R. Ford International Airport, Grand Rapids, MI

AGENCY: Federal Aviation Administration, DOT.

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ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by Kent County Department of Aeronautics for Gerald R. Ford International Airport, Grand Rapids, Michigan under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and 14 CFR Part 150 are in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure maps is December 27, 2000.

FOR FURTHER INFORMATION CONTACT: Ernest P. Gubry, Willow Run Airport, East, 8820 Beck Road Belleville, MI, 48111, (734) 487–7280.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Gerald R. Ford International Airport, Grand Rapids, MI are in compliance with applicable requirements of Part 150, effective December 27, 2000.

Under section 103 of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing non-compatible uses and for the prevention of the introduction of additional non-compatible uses. The FAA has completed its review of the noise exposure maps and related descriptions submitted by Kent County Department of Aeronautics. The specific maps under consideration are Figure 6–1, "2000 Noise Exposure Map", and Figure 6–2 "2005 Noise Exposure Map" noise map in Volume 1 of 3 of the submission. The FAA has determined that these maps for Gerald R. Ford International Airport, Grand Rapids, Michigan are in compliance with applicable requirements. This determination is effective on December 27, 2000. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport. Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Belleville, Michigan, on December 27, 2000.

Irene Porter,

Manager, Detroit Airports District Office, Great Lakes Region.

[FR Doc. 01–1282 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–01]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 5, 2001.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, DC, on January 10, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: FAA–2000–8157.

Petitioner: Petroleum Helicopters, Inc.

Section of 14 CFR Affected: 14 CFR § 135.152(a).

Description of Relief Sought/Disposition: To permit PHI to operate three Bell 212 helicopters (Registration Nos. N1074C, N5009N, and N5736D; Serial Nos. 30989, 30915, and 31135, respectively), two Bell 214ST helicopters (Registration Nos. N59805 and N59806, Serial Nos. 28141 and 28140, respectively), three Bell 412 helicopters (Registration Nos. N2014K, N2258F, and N3893L; Serial Nos. 33020, 33073, and 33006, respectively), and one Bell 421SP helicopter (Registration No. N142PH, Serial No. 33150) under part 135 without an approved digital flight data recorder installed on each helicopter.

Grant, 12/15/2000, Exemption No. 6713E

Docket No.: FAA–2000–8430.

Petitioner: Rocky Mountain Holdings, L.L.C.

Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).

Description of Relief Sought/Disposition: To permit RMH to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed in the aircraft.

Grant, 12/13/2000, Exemption No. 5774E

Docket No.: FAA–2000–8533.

Petitioner: Israel Aircraft Industries.

Section of 14 CFR Affected: 14 CFR § 61.77(a).

Description of Relief Sought/Disposition: To permit IAI to obtain special purpose pilot authorizations for its pilot employees for the purpose of performing: (1) Ferry/delivery flights of U.S.-registered ASTRA Galaxy airplanes from Israel to the United States for its U.S. customers; (2) Ferry/delivery flights of U.S.-registered ASTRA Galaxy airplanes from Israel to other countries for its U.S. customers; and (3) For performing test and acceptance flights of U.S.-registered ASTRA Galaxy airplanes for its U.S. customers.

Grant, 01/13/1999, Exemption No. 7406

Docket No.: FAA–2000–8497.

Petitioner: America West Airlines.

Section of 14 CFR Affected: 14 CFR § 91.205(b)(12).

Description of Relief Sought/Disposition: To permit AWX to operate it's aircraft over water without at least one pyrotechnic signaling device on board.

Denial, 12/18/2000, Exemption No. 7409

Docket No.: FAA–2000–8096.

Petitioner: Vinay M. Gidwani.

Section of 14 CFR Affected: 14 CFR § 61.83(a).

Description of Relief Sought/Disposition: To permit Mr. Gidwani to obtain a student pilot certificate for operation of an aircraft other than a glider or balloon.

Denial, 12/18/2000, Exemption No. 7408

Docket No.: FAA–2000–8491.

Petitioner: Lifeport, Inc.

Section of 14 CFR Affected: 14 CFR §§ 25.562 and 25.785(b).

Description of Relief Sought/Disposition: To permit certification of medical stretchers for transport of persons whose medical condition dictates such accommodation. The exemption is for an installation on a Learjet Model 45 airplane.

Grant, 12/07/2000, Exemption No. 7393

[FR Doc. 01–1288 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–02]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 5, 2001.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to *http://dms.dot.gov*. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85 and 11.91.

Issued in Washington, D.C., on January 10, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: FAA–2000–8165.

Petitioner: The Jet Center, Garret Aviation Services.

Section of 14 CFR Affected: 14 CFR 25.813(e).

Description of Relief Sought: To permit the Jet Center, Garret Aviation Services, to install doors in partitions between passenger compartments on Bombardier Model BD–700–1A10 airplanes used for corporate transportation.

[FR Doc. 01–1289 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–03]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions

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for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or ommission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 5, 2001.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029 Office of Rulemaking (ARM–1), Federal Avaiation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to § 11.85 and § 11.91.

Issued in Washington, D.C., on January 10, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: 30151.
Petitioner: Lufthansa Technik.
Section of the 14 CFR Affected: 14 CFR § 25.785(b)
Description of Relief Sought/Disposition: To permit relief from the general occupant protection requirements for multiple place side-facing seats on a Boeing Model 777–2AN airplane, serial number 29953.
Grant, 12/11/00, Exemption No. 7392

Docket No.: 30081.
Petitioner: Kodiak Expediting, Inc.
Section of the 14 CFR Affected: 14 CFR § 61.133(b)(1)
Description of Relief Sought/Disposition: To permit KEI to conduct passenger-carrying operations on cross-country flights in excess of 50 nautical miles without holding an instrument rating in the same category and class of aircraft listed on your commercial pilot certificate.
Denial, 12/18/00, Exemption No. 7407

Docket No.: 30052.
Petitioner: Airbus Industrie
Section of the 14 CFR Affected: 14 CFR § 25.807(f)(4)
Description of Relief Sought/Disposition: To permit an interior arrangement on an Airbus Model A340–600 that does not provide 60 feet or less between passenger emergency exists in the side of the fuselage.
Denial, 12/11/00, Exemption No. 7404

[FR Doc. 01–1290 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Use a Passenger Facility Charge (PFC) at Bradley International Airport, Windsor Locks, Connecticut

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to use a PFC at Bradley International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal aviation regulations (14 CFR part 158).

DATES: Comments must be received on or before February 16, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Ms. Priscilla Scott, PFC Program Manager, Federal Aviation Administration, Airport Division, 12 New England Executive Park, Burlington, Massachusetts 01803.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Robert Juliano, A.A.E., Bureau Chief, State of Connecticut, Department of Transportation, Bureau of Aviation and Ports at the following address: 2800 Berlin Turnpike, P.O. Box 317546, Newington, CT. 06131–7546.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the State of Connecticut under section 158.23 of Part 158 of the Federal Aviation Regulations.

FOR FURTHER INFORMATION CONTACT: Priscilla A. Scott, PFC Program Manager, Federal Aviation Administration, Airports Division, 12 New England Executive Park, Burlington, Massachusetts 01803, (781) 238–7614. The application may be reviewed in person at 16 New England Executive Park, Burlington, Massachusetts.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to use a PFC at Bradley International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On December 29, 2000, the FAA determined that the application to use a PFC submitted by the State of Connecticut was substantially complete within the requirements of section 158.25 of Part 158 of the Federal Aviation Regulations. The FAA will approve or disapprove the application, in whole or in part, no later than April 9, 2001.

The following is a brief overview of the use application.

PFC Project #: 01–13–U–00–BDL.
Level of the proposed PFC: $3.00.
Charge effective date: March 9, 2000.
Charge expiration date: April 11, 2000.
Estimated total PFC revenue: $4,400,000.
Brief description of project: Reconstruction of Taxiway "S".

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: On demand Air Taxi/Commercial Operators (ATCO).

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Connecticut Department of Transportation Building, 2800 Berlin Turnpike, Newington, Connecticut 06131–7546.

Issued in Burlington, Massachusetts on January 2, 2001.

Vincent A. Scarano,

Manager, Airports Division, New England Region.

[FR Doc. 01–1284 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Manchester Airport, Manchester, NH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Manchester Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 16, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address:

Priscilla Scott, PFC Program Manager, Federal Aviation Administration, Airports Division, 12 New England Executive Park, Burlington, Massachusetts 01803.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Kevin Dillon, Airport Director for Manchester Airport at the following address: Manchester Airport, One Airport Road, Suite 300, Manchester, New Hampshire 03103.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the City of Manchester under section 158.23 of part 158 of the Federal Aviation Regulations.

FOR FURTHER INFORMATION CONTACT: Priscilla A. Scott, PFC Program Manager, Federal Aviation Administration, Airports Division, 12 New England Executive Park, Burlington, Massachusetts 01803 (781) 238–7614. The application may be reviewed in person at 16 New England Executive Park, Burlington, Massachusetts.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Manchester Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 28, 2000, the FAA determined that the application to impose and use the revenue from a PFC submitted by the City of Manchester was substantially complete within the requirements of section 158.25 of part 158 of the Federal Aviation Regulations. The FAA will approve or disapprove the application, in whole or in part, no later than April 6, 2001.

The following is a brief overview of the impose and use application.

PFC Project #: 01–09–C–00–MHT.
Level of the proposed PFC: $3.00.
Proposed charge effective date: April 1, 2017.
Estimated charge expiration date: June 1, 2017.
Estimated total net PFC revenue: $700,000.
Brief description of project: Acquire Airport Rescue and Fire Fighting Vehicle.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Air Taxi/Commercial Operators (ATCO).

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Manchester Airport, One Airport Road, Suite 300, Manchester, New Hampshire 03103.

Issued in Burlington, Massachusetts on January 2, 2001.

Vincent A. Scarano,

Manager, Airports Division, New England Region.

[FR Doc. 01–1283 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Policy Statement Number ACE–00–23.777–01]

Proposed Issuance of Policy Memorandum, Automatic Pilot (Control Wheel Steering) Applications for Part 23/CAR 3 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of policy statement; request for comments.

SUMMARY: This document proposes to adopt new policy for certification of normal, utility, acrobatic, and commuter category turbine powered airplanes with automatic pilot (autopilot) (control wheel steering) applications.

DATES: Comments sent must be received by February 16, 2001.

ADDRESSES: Send all comments on this proposed policy statement to the individual identified under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT:

Sending comments: Bill Marshall, Federal Aviation Administration (FAA), Small Airplane Directorate, Regulations and Policy Branch, ACE–111, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4116; fax (816) 329–4090; email: <Bill.Marshall@faa.gov>.

Asking technical questions: Jon Hannan, FAA, Small Airplane Directorate, Regulations and Policy Branch, ACE–111, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone (816) 329–4127; fax (816) 329–4090; email: <Jon.Hannan@faa.gov>.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on the proposed policy? We invite your comments on this proposed policy statement, ACE–00–23.777–01. You may send whatever written data, views, or arguments you choose. We will consider all comments received by the closing date. We may change the proposals contained in this notice because of the comments received.

Please send comments using the following Internet address: Bill.Marshall@faa.gov. Comments sent using the Internet must contain "Comments to Policy Statement ACE–00–23.777–01" in the subject line. Writers should format in Microsoft Word 97 or ASCII any file attachments that are sent using the Internet.

Send comments using the following format:

- Organize comments issue-by-issue. For example, discuss a comment about the automatic pilot control panel and a comment about primary flight controls as two separate issues.
- For each issue, state what specific change you are requesting to the proposed policy memorandum.
- Include justification (for example, reasons or data) for each request. If sending your comments using the Internet will cause you extreme hardship, you may send comments using the U.S. Mail, overnight delivery, or facsimile machine. You should mark your comments, "Comments to Policy Statement ACE–00–23.777–01" and send two copies to the above address in the section "**FOR FURTHER INFORMATION CONTACT:** Sending comments."

What would be the general effect of this proposed policy? The FAA is

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presenting this information as a set of guidelines suitable for use. However, we do not intend for this proposed policy to become a binding norm; it does not form a new regulation, and the FAA would not apply or rely on it as a regulation.

The FAA Aircraft Certification Offices (ACO's) and Flight Standards District Offices (FSDO's) that certify changes in type design and approve alterations in normal, utility, and acrobatic category airplanes should try to follow this policy when appropriate. Also, as with all advisory material, this statement of policy identifies one means, but not the only means, of compliance.

Because this proposed general statement of policy only announces what the FAA seeks to establish as policy, the FAA considers it to be an issue for which public comment is appropriate. Therefore, the FAA requests comments on the following proposed general statement of policy relevant to compliance with § 23.777 of the Federal Aviation Regulations (14 CFR 23.777), and other related regulations.

Background

How does part 23 address the automatic pilot (autopilot) and control wheel steering? The guidance on autopilots used in part 23 airplanes does not specifically address Control Wheel Steering (CWS). Before 1996, CWS was a term used by industry to describe a momentary autopilot interrupt mode. Holding the CWS switch depressed temporarily disconnected the autopilot pitch and roll servos so the airplane could be maneuvered. When the CWS switch was released, the autopilot servos would reengage in the same mode as previously selected.

One minor exception was where an autopilot dropped the vertical axis from the reengagement. But in no case was there a change to a mode that had not been selected.

What recent developments have led to this proposed policy? More recently, there have been some autopilots certificated that could be engaged from a CWS mode switch on the primary flight controls. Additionally, some autopilots were certificated that changed modes from what had been previously selected by depressing the CWS switch.

In some cases, these two installations could lead to inadvertent autopilot engagement or mode changes during critical phases of flight such as liftoff, approach, and landing flare. Inadvertent operation could then lead to confusion and a misperception of a flight control problem or an unintended loss of approach coupling.

Although not specifically pertinent to autopilot controls, § 23.777 of the Federal Aviation Regulations (14 CFR 23.777) requires that each cockpit control "be located . . . to provide convenient operation and to prevent confusion and inadvertent operation."

The Proposed Policy

In order to comply with the intent of § 23.777 of the Federal Aviation Regulations (14 CFR 23.777) as applicable to automatic pilots (autopilots) installed in part 23 airplanes, autopilots should be evaluated in accordance with the following:

Note: These characteristics are not applicable to "go around" mode switches which are allowed on throttles.

- The automatic pilot (autopilot) should not be engaged from a switch on the primary flight controls, unless that switch is protected so inadvertent engagement is not possible. Guards covering the switch, which can be moved to provide access to the switch, may be acceptable in some cases.
- Mode changes should not be made by using a switch on the primary flight controls unless some reliable means is provided to prevent unsafe conditions caused by inadvertent mode changes. Refer to § 23.1329(h) of the Federal Aviation Regulations (14 CFR 23.1329(h)).
- The autopilot disengage button should be the color red and be of different design from nearby switches so it is distinguishable by touch.

Issued in Kansas City, Missouri on January 2, 2001.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1276 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2001–8669]

Crowley Maritime Corporation; Notice of Application for Written Permission Under Section 805(a) of the Merchant Marine Act, 1936, as Amended

AGENCY: Maritime Administration, Transportation.

ACTION: Notice of Application.

SUMMARY: Crowley Maritime Corporation (Crowley), by letter dated January 4, 2001, requests written permission under section 805(a) of the Merchant Marine Act, 1936, as amended (Act), to allow Marine Transport Corporation's (MTC) vessels CHEMICAL EXPLORER and CHEMICAL TRADER to continue to receive operating-differential subsidy (ODS) after MTC becomes a subsidiary of Crowley. This section 805(a) permission is necessary for these vessels to continue to receive ODS because Crowley, through its subsidiaries, owns and operates vessels engaged in the domestic inter-coastal or coastwise service.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than close of business (5 p.m. est) on January 31, 2001.

ADDRESSES: Your comments should refer to docket number MARAD–2001–8669. You may submit your comments in writing to: Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 7th Street, SW, Washington, DC 20590. You may also submit them electronically via the internet at *http://dmses.dot.gov/submit/*. You may call Docket Management at (202) 366–9324 and visit the Docket Room from 10 a.m. to 5 p.m., EST., Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: You may call Edmond J. Fitzgerald, Director, Office of Insurance and Shipping Analysis, (202) 366–2400. You may send mail to Edmond J. Fitzgerald, Director, Office of Insurance and Shipping Analysis, Room 8117, Maritime Administration, 400 Seventh St., SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Comments

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments. We encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments. Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelop containing your comments. Docket Management will return the postcard by mail.

How do I submit confidential business information? If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, Maritime Administration, at the address given above under **FOR FURTHER INFORMATION CONTACT**. You should mark "CONFIDENTIAL" on each page of the original document that your would like to keep confidential. In addition, you should submit two copies, from which your have deleted the claimed confidential business information, to Docket Management at the address given under **ADDRESSES**. When you send comments containing information claimed to be confidential business information, you should include a cover letter setting forth with specificity the basis for any such claim.

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

How Can I Read Comments Submitted by Other People?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket Room are indicated above in the same location. You may also see the comments on the Internet. To read the comments on the Internet, take the following steps: Go to the Docket Management System (DMS) Web page of the Department of Transportation (http//dmses.dot.gov/), click on the box labeled "Search". The docket number for this document is MARAD–2001–8669. After typing in the last four-digits of the docket number, click on "search." On the next page, which contains the docket summary information for the docket you selected, click on the desired comments. You may download the comments.

Application Request

Crowley and its wholly owned subsidiary, Shiloh Acquisition, Inc. (Shiloh), entered into an Agreement of Merger with MTC dated December 20, 2000. As part of the process, Shiloh will make a Tender Offer to purchase all the shares of MTC on January 5, 2001, which offer will expire on February 5, 2001, at which time Crowley expects to have control of MTC and subsequently thereafter effect a complete merger between Shiloh and MTC, with MTC being the surviving corporation as a direct subsidiary of Crowley.

MTC, through its subsidiaries, Frances ODS Corporation and Julius ODS Corporation, has two operating-differential subsidy agreements with the Maritime Administration dated as of September 30, 1998, Contract No. MA/MSB–442 and Contract No. MA/MSB–440, respectively. Pursuant to these agreements, Frances ODS Corporation receives ODS for the SMT CHEMICAL EXPLORER and Julius ODS Corporation receives ODS for SMT CHEMICAL TRADER. The agreement for SMT CHEMICAL EXPLORER will terminate by its terms on September 18, 2001 and the agreement for SMT CHEMICAL TRADER will terminate by its terms on March 25, 2001. Frances ODS Corporation receives approximately $8,500 per day pursuant to the agreement for the SMT CHEMICAL EXPLORER and Julius ODS Corporation receives approximately $8,100 per day pursuant to the agreement for SMT CHEMICAL TRADER.

Crowley, through its subsidiaries, owns and operates vessels engaged in the domestic inter-coastal or coastwise service, and has provided as an attachment to its application: Schedule A—the fleet of tugs and barges operating on the West Coast and Alaska and the Gulf; Schedule B—the fleet of tugs and barges operating in the U.S.-Puerto Rico trade; Schedule C—the fleet of tugs and barges operating on the East Coast and Gulf; and , Schedule D—the fleet of oil tankers operating throughout the Jones Act trading areas. These schedules show the horsepower of the tugs, capacity of the barges and tankers as well as the general itineraries. Interested parties may review these schedules by reading the application which is part of the docket and is accessible electronically via the internet, or personally at the DOT Docket Room, as described above under how to read comments submitted by other people.

In connection with these domestic services, Crowley requests written permission of the Secretary of Transportation, pursuant to section 805(a) of the Act to allow the MTC subsidiaries to continue to receive ODS pursuant to the subsidy contracts referred to above after MTC becomes a wholly owned subsidiary of Crowley.

In deciding whether to grant Crowley's application for a waiver pursuant to section 805(a) of the Act, Crowley requests the Maritime Administration to consider the following:

First, continued receipt by the two subsidiaries of MTC of ODS will not leak to Crowley. The subsidy dollars received by the two MTC subsidiaries will be used for the purposes set forth in the section 603 of the Act, as financial aid for the operation of the two vessels, the CHEMICAL EXPLORER and CHEMICAL TRADER. Thus, the ODS payments will remain with and be used by the ODS contractors, Frances ODS Corporation and Julius ODS Corporation.

Second, the continued receipt of ODS will be for (i) a relatively small amount of money and (ii) for a very short period of time. Crowley expects to have control of and complete the merger process by early February 2001. If this timetable holds firm, it would mean that Juluis ODS Corporation will receive subsidy for approximately one and a half months and Frances ODS Corporation will receive subsidy for approximately six and a half months. During this short period of time, the subsidy payments will be used by the ODS contractors and not leaked to Crowley.

Third, Crowley has been an operator in the Jones Act trades for over 100 years and, operates a wide range of vessels throughout the entire Jones Act trade area. Receipt of (i) a relatively small amount of ODS, (ii) for a short period of time; and (iii) earmarked for use by the Julius ODS Corporation and Frances ODS Corporation in the operation of the CHEMICAL TRADER and CHEMICAL EXPLORER will not leak to any of Crowley's wide range of Jones Act operations. In addition, it should be noted that by reason of the Title XI Reserve Fund and Financial Agreement between MARAD and the Julius ODS Corporation and the Frances ODS Corporation, those companies are prohibited from dividending any monies to their corporate parent and will continue to be so restricted through the date of the last ODS payment on September 18, 2001. Thus, there is no way for MTC to leak the ODS payments to Crowley.

For the reasons set forth above, Crowley believes that the grant of the requested section 805(a) waiver will not result in unfair competition to any person, firm, or corporation operating exclusively in the coastwise or inter-coastal service or that it would be prejudicial to the objects and policy of the Act and a hearing on the matter is not needed.

Any person, firm, or corporation having any interest (within the meaning of section 805(a)) in Crowley's request and desiring to submit comments

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together with petition for leave to intervene should do so in accordance with the above instructions for submitting comments. The petition should state clearly and concisely the grounds of interest, and the alleged facts relied on for relief.

If no petition for leave to intervene is received with the specified time or if it is determined that petitions filed do not demonstrate sufficient interest to warrant a hearing, the Maritime Administration will take such action as may be deemed appropriate.

In the event petitions regarding the relevant section 805(a) issues are received from parties with standing to be heard, a hearing will be held, the purpose of which will be to receive evidence under section 805(a) relative to whether the proposed operations: (a) could result in unfair competition to any person, firm, or corporation operating exclusively in the coastwise or inter-coastal service, or (b) would be prejudicial to the objects and policy of the Act relative to domestic trade operations.

(Catalog of Federal Domestic Assistance Programs No. 20.805 Operating-Differential Subsidies)

By Order of the Maritime Administrator.
Dated: January 11, 2001.

Joel C. Richard,

Secretary.

[FR Doc. 01–1359 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2000–8666]

ALASKA ROSE, BERING ROSE, and SEA WOLF—Applicability of Preferred Mortgage, Ownership and Control Requirements to Obtain a Fishery Endorsement

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a petition requesting MARAD to issue a determination that the ownership and control requirements and the preferred mortgage requirements of the American Fisheries Act of 1998 and 46 CFR Part 356 are in conflict with an international investment agreement.

SUMMARY: The Maritime Administration (MARAD, we, our, or us) is soliciting public comments on a petition from the owners and mortgagees of the vessels ALASKA ROSE—Official Number 610984, BERING SEA—Official Number 609823, and SEA WOLF—Official Number 609823 (hereinafter the "Vessels"). The petition requests that MARAD issue a decision that the American Fisheries Act of 1998 ("AFA"), Division C, Title II, Subtitle I, Pub. L. 105–277, and our regulations at 46 CFR Part 356 (65 Fed. Reg. 44860 (July 19, 2000)) are in conflict with the U.S.-Japan Treaty and Protocol Regarding Friendship, Commerce and Navigation, 206 UNTS 143, TIAS 2863, 4 UST 2063 (1953) ("U.S.-Japan FCN" or "Treaty"). The petition is submitted pursuant to 46 CFR 356.53 and 213(g) of AFA, which provide that the requirements of the AFA and the implementing regulations will not apply to the owners or mortgagees of a U.S.-flag vessel documented with a fishery endorsement to the extent that the provisions of the AFA conflict with an existing international agreement relating to foreign investment to which the United States is a party. This notice sets forth the provisions of the international agreement that the Petitioner alleges are in conflict with the AFA and 46 CFR Part 356 and the arguments submitted by the Petitioner in support of its request. If MARAD determines that the AFA and MARAD's implementing regulations conflict with the U.S.-Japan FCN, the requirements of 46 CFR Part 356 and the AFA will not apply to the extent of the inconsistency. Accordingly, interested parties are invited to submit their views on this petition and whether there is a conflict between the U.S.-Japan FCN and the requirements of both the AFA and 46 CFR Part 356. In addition to receiving the views of interested parties, MARAD will consult with other Departments and Agencies within the Federal Government that have responsibility or expertise related to the interpretation of or application of international investment agreements.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than February 16, 2001.

ADDRESSES: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted by mail to the Docket Clerk, U.S. DOT Dockets, Room PL–401, Department of Transportation, 400 7th St., S.W., Washington, D.C. 20590–0001. You may also send comments electronically via the Internet at http://dms.dot.gov/submit/. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal Holidays. An electronic version of this document and all documents entered into this docket are available on the World Wide Web at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: John T. Marquez, Jr. of the Office of Chief Counsel at (202) 366–5320. You may send mail to John T. Marquez, Jr., Maritime Administration, Office of Chief Counsel, Room 7228, MAR–222, 400 Seventh St., S.W., Washington, D.C., 20590–0001 or you may send e-mail to John.Marquez@marad.dot.gov.

SUPPLEMENTARY INFORMATION:

Background

The AFA was enacted in 1998 to give U.S. interests a priority in the harvest of U.S.-fishery resources by increasing the requirements for U.S. Citizen ownership, control and financing of U.S.-flag vessels documented with a fishery endorsement. MARAD was charged with promulgating implementing regulations for fishing vessels of 100 feet or greater in registered length while the Coast Guard retains responsibility for vessels under 100 feet.

Section 202 of the AFA, raises, with some exceptions, the U.S.-Citizen ownership and control standards for U.S.-flag vessels that are documented with a fishery endorsement and operating in U.S.-waters. The ownership and control standard was increased from the controlling interest standard (greater than 50%) of 2(b) of Shipping Act, 1916 ("1916 Act"), as amended, 46 App. U.S.C. 802(b), to the standard contained in 2(c) of the 1916 Act, 46 App. U.S.C. 802(c), which requires that 75 percent of the ownership and control in a vessel owning entity be vested in U.S. Citizens. In addition, section 204 of the AFA repeals the ownership grandfather "savings provision" in the Anti-Reflagging Act of 1987, Pub. L. 100–239, 7(b), 101 Stat 1778 (1988), which permits foreign control of companies owning certain fishing vessels.

Section 202 of the AFA also establishes new requirements to hold a preferred mortgage on a vessel with a fishery endorsement. State or federally chartered financial institutions must now comply with the controlling interest standard of 2(b) of the 1916 Act in order to hold a preferred mortgage on a vessel with a fishery endorsement. Entities other than state or federally chartered financial institutions must either meet the 75% ownership and control requirements of 2(c) of the 1916 Act or utilize an approved U.S.-Citizen Trustee that meets the 75% ownership and control requirements to hold the preferred mortgage for the benefit of the non-citizen lender.

Section 213(g) of the AFA provides that if the new ownership and control provisions or the mortgagee provisions are determined to be inconsistent with an existing international agreement relating to foreign investment to which the United States is a party, such provisions of the AFA shall not apply to the owner or mortgagee on October 1, 2001, with respect to the particular vessel and to the extent of the inconsistency. MARAD's regulations at 46 CFR 356.53 set forth a process wherein owners or mortgagees may petition MARAD, with respect to a specific vessel, for a determination that the implementing regulations are in conflict with an international investment agreement. Petitions must be noticed in the **Federal Register** with a request for comments. The Chief Counsel of MARAD, in consultation with other Departments and Agencies within the Federal Government that have responsibility or expertise related to the interpretation of or application of international investment agreements, will review the petitions and, absent extenuating circumstances, render a decision within 120 days of the receipt of a fully completed petition.

The Petitioners

Alaska Rose L.P., Bering Rose, L.P. and Kendrick Bay, L.P. (each a "Vessel Owner" and collectively, the "Vessel Owners"), are the owners, respectively, of the fishing vessels ALASKA ROSE, BERING ROSE and SEA WOLF (each a "Vessel" and collectively, the "Vessels"). Wards Cove Packing Company ("Wards Cove"), Gravina Fisheries, Inc., Flag Point, L.P., Duke Point, L.P., Island Point Corporation, Maruha Corporation ("Maruha"), Western Alaska Fisheries, Inc. ("WAF") and WAFBO, Inc., are owners of direct or indirect interests in the Vessel Owners and indirect interests in the Vessels. Alyeska Seafoods, Inc. ("Alyeska") is the owner of direct and indirect interests in the Vessel Owners and indirect interests in the Vessels and is the mortgagee under preferred mortgages on the Vessels. The parties identified above, including the shareholders and the Japanese Bank Lenders identified below are hereinafter referred to as the "Petitioner" or "Petitioners."

Petitioner's Entry Into and Participation In U.S. Fisheries

The Petitioner provided the following background on its entry into and participation in the fisheries of the United States.

"In 1985, Wards Cove, Maruha and Marubeni Corporation ("Marubeni") formed Alyeska to acquire, construct and operate a large seafood processing facility at Dutch Harbor, Alaska. Alyeska purchased an existing processing facility in 1985 and constructed a surimi processing plant and fish meal plant at the site in 1986 and 1987 to process pollock. Alyeska's total investment in its processing plant and equipment is approximately $70 million.

"The Alyeska processing facility is one of the largest fish processing facilities in the state of Alaska. Alyeska employs approximately 400 people at its Dutch Harbor processing facility and processes in excess of 125 million pounds of seafood annually. In order to secure a stable supply of raw material to this processing facility, Alyeska, Maruha and its subsidiaries, and Wards Cove, Alyeska's U.S. Citizen shareholder, have made investments in and provided financing for a number of fishing vessels, including the Vessels. By investing in the Vessel Owners, Alyeska, Maruha and Wards Cove also sought to realize the potential profits that could accrue to the Vessel Owners from sales to Alyeska. The Vessel Owners were organized and the Vessels were acquired by the Vessel Owners in 1996.

"Alyeska assisted in financing the acquisition of the Vessels by the Vessel Owners in return for the agreement of the Vessel Owners that fish harvested by the Vessels would be sold exclusively to Alyeska and in reliance on the assured revenue stream which sales to Alyeska would provide to the Vessel Owners. Such financing is a common and traditional means in the Alaska fishing industry by which fishing vessel owners secure financing for the acquisition, improvement or operation of their vessels and seafood processors secure supply commitments from fishing vessel owners. Each of the Vessels is 100 feet or greater in registered length. Each of the Vessels was designed and constructed or rebuilt for operation in the U.S. fisheries of the North Pacific Ocean and Bering Sea.

"As a result of the enactment of Section 208(a) of the American Fisheries Act, the fishing vessels eligible to catch and deliver pollock to Alyeska's Dutch Harbor facility are limited to vessels meeting specified criteria, including prior deliveries of certain quantities of pollock to Alaskan onshore processing plants. Accordingly, there is a fixed, limited number of vessels, including the Vessels, which are permitted by law to deliver to the Alyeska facility."

Ownership and Mortgage Structure of the Vessels

The ownership and mortgage structure is substantially the same for each of the Vessels and is summarized as follows:

A. Ownership Structure

Alaska Rose, L.P., and Bering Rose, L.P., are Washington limited partnerships that were formed in 1996 for the purpose of acquiring and operating the vessels ALASKA ROSE and BERING ROSE, respectively. From the time of formation through the present date, Alaska Rose L.P. and Bering Rose, L.P. have been owned by Duke Point, L.P. ("Duke Point"), as sole general partner, and Alyeska Seafoods, Inc., as sole limited partner, in the following percentages: Duke Point—75%; Alyeska—25%.

Duke Point is a Washington limited partnership. At all times since the acquisition of the Vessels by Alaska Rose, L.P. and Bering Rose L.P., Duke Point has been owned by Flag Point, L.P. ("Flag Point"), as sole general partner, and Alyeska, as sole limited partner, in the following percentages: Flag Point—75%; Alyeska—25%.

Flag Point is a Washington limited partnership. Flag Point is owned by Gravina Fisheries, Inc., a Washington corporation, as sole general partner; and Island Point Corporation, a Washington corporation, and Alyeska, as limited partners, in the following percentages: Gravina Fisheries, Inc.—50%; Island Point Corp.—25%; Alyeska—25%.

Gravina Fisheries, Inc. is a wholly owned subsidiary of Wards Cove, an Alaska corporation. Petitioners state that all of the capital stock of Wards Cove is owned by United States Citizens, as defined in 46 C.F.R. Part 356. All of the capital stock of Island Point Corporation is owned by Alec W. Brindle, Winn F. Brindle and Harold A. Brindle, each an individual United States Citizen.

Wards Cove is a 100% U.S. Citizen-owned fish processing company which has been engaged in processing salmon and other fish and shellfish species in Alaska since 1912. In 1928, Wards Cove was acquired by two brothers, A. W. Brindle and Harold A. Brindle, and continues to be owned by the Brindle family or entities owned and controlled by them. All of the officers and directors of Wards Cove, Gravina Fisheries, Inc., and Island Point Corporation are U.S. Citizens.

Alyeska is an Alaska corporation, formed in 1985 to acquire, construct and operate a large seafood processing facility at Dutch Harbor, Alaska. All of the capital stock of Alyeska is owned by

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Wards Cove, Maruha, WAF and Marubeni. Maruha and Marubeni are publicly traded Japanese corporations. WAF is a wholly-owned U.S. subsidiary of Maruha. Maruha, WAF and Marubeni collectively own more than 25% of the capital stock of Alyeska. Accordingly, Alyeska does not qualify as a U.S. Citizen under the standards of the AFA and MARAD's implementing rules and is therefore a "Non-Citizen," as defined in 46 CFR 356.3(0).

The SEA WOLF is owned by Kendrick Bay, L.P. ("Kendrick Bay"), a Washington limited partnership formed in 1996 for the purpose of acquiring and operating the SEA WOLF. At the time of its formation through the present date, Kendrick Bay has been owned by Duke Point, as sole general partner, and WAFBO, Inc., as sole limited partner, in the following percentages: Duke Point—75%, WAFBO, Inc.—25%,

The ownership structure of Duke Point is described above in connection with the discussion of the ownership of Alaska Rose, L.P. and Bering Rose, L.P. WAFBO, Inc. is a Washington corporation wholly owned by WAF. WAF is an Alaska corporation wholly owned by Maruha. Prior to the acquisition of the SEA WOLF by Kendrick Bay, the SEA WOLF was owned by Sea Wolf Limited Partnership, a Washington limited partnership in which WAF held a 25% limited partnership interest. Sea Wolf Limited Partnership distributed undivided interests in the SEA WOLF to its partners in proportion to their interests in the partnership prior to the acquisition of the Vessel by Kendrick Bay. WAFBO, Inc. is an entity which satisfies the requirements of 46 U.S.C. 12102(a), commonly referred to as a "Documentation Citizen," and was formed by WAF to hold WAF's undivided 25% interest in the SEA WOLF prior to transfer of the entire Vessel to Kendrick Bay. The former partners in Sea Wolf Limited Partnership with the exception of WAFBO, Inc. sold their undivided interests in the Vessel—totaling 75%—to Duke Point, which transferred this 75% interest in the SEA WOLF to Kendrick Bay as a capital contribution. WAFBO, Inc. transferred its undivided 25% interest in the SEA WOLF directly to Kendrick Bay as a capital contribution in return for a 25% limited partnership interest in Kendrick Bay.

The ownership structure of the Vessels was reviewed and approved by the U.S. Coast Guard under the standards applicable to fishing vessels and coastwise qualified vessels in a letter ruling dated December 11, 1996.

B. Mortgage Structure

Permanent financing for the acquisition of the Vessels was provided by three Japanese banks, Mitsubishi Trust and Banking Corporation, The Industrial Bank of Japan, Limited and The Dai-Ichi Kangyo Bank, Limited (collectively, the "Japanese Bank Lenders"), pursuant to a Term Loan Agreement dated March 27, 1997 (the "Alyeska Loan Agreement"). Pursuant to the Alyeska Loan Agreement, the Japanese Bank Lenders made loans to Alyeska (collectively, the "Alyeska Loan") for use by Alyeska for loans and capital contributions to the Vessel Owners and related entities to finance the acquisition by the Vessel Owners of the fishing vessels BERING ROSE, ALASKA ROSE and SEA WOLF.

Simultaneously with the Alyeska Loan transaction, Alyeska provided permanent financing to Alaska Rose, L.P. (the "Alaska Rose Loan") and Bering Rose, L.P. (the "Bering Rose Loan") for the purchase of the ALASKA ROSE and the BERING ROSE, respectively. In addition, permanent financing for the acquisition of the SEA WOLF was provided by the Japanese Bank Lenders through the Alyeska Loan transaction to Duke Point (the "Duke Point Loan") for Duke Point's purchase of an undivided 75% interest in the SEA WOLF. Alaska Rose, L.P., Bering Rose, L.P. and Duke Point executed Loan Agreements, Promissory Notes and Preferred Ship Mortgages in favor of Alyeska with respect to the loans. In consideration of the loans, Alaska Rose, L.P., Bering Rose, L.P., and Kendrick Bay also executed Nonrecourse Guaranties in favor of Mitsubishi Trust and Banking Corporation, as agent for the Japanese Bank Lenders (hereafter referred to as "MTBC, as agent"), limited to the amount of the loans outstanding from time to time plus applicable interest, together with the following documents:

(a) Preferred Ship Mortgages on the Vessels in favor of MTBC, as agent, securing the Nonrecourse Guaranties; and

(b) Assignments of Insurance Proceeds in favor of MTBC, as agent, securing the Nonrecourse Guaranties.

C. Exclusive Marketing Agreement

The Petitioners state that Alyeska financed the purchase of the Vessels in order to ensure a stable supply of fish to Alyeska's Dutch Harbor facility and in reliance on the assured revenue stream which sales to Alyeska would generate for the Vessel Owner. Accordingly, Section 5(A) of the loan agreement for each Vessel provides:

So long as there remains any outstanding balance on the Loan, Borrower agrees that the Vessel's sole market shall be Alyeska Seafoods, Inc. for any and all products regularly processed by Alyeska Seafoods, Inc., and for any and all species of catch processed by Alyeska Seafoods, Inc. Exceptions to this requirement are specified (1) on a delivery-by-delivery basis, where Alyeska informs the partnership that it lacks capacity to process the delivery; and (2) where Alyeska and [Vessel Owner] agree that the vessel may sell into other markets. Section 5(B) of the [Vessel Loan Agreement] provides that, in return for this marketing commitment, Alyeska will pay [Vessel Owner] a substantial annual "commitment fee."

Requested Action

The Petitioners have requested a consolidated filing for the Vessels. MARAD's regulations require at 46 CFR 356.53(c) that a separate petition be filed for each vessel for which the owner or mortgagee is requesting an exemption unless the Chief Counsel authorizes a consolidated filing. The Chief Counsel hereby authorizes the consolidated filing by Petitioners relating to the three Vessels.

The Petitioners seek a determination from MARAD under 213(g) of the Act and 46 CFR 356.53 that they are exempt from the requirements of sections 202, 203 and 204 of the AFA and 46 CFR Part 356 on the ground that the requirements of the AFA and 46 CFR Part 356, as applied to Petitioners with respect to the Vessels, conflict with U.S. obligations under U.S.-Japan FCN. The Petitioners request a determination that the restrictions placed on foreign ownership, foreign financing and foreign control of U.S.-flag vessels documented with a fishery endorsement contained in 46 C.F.R. Part 356 and sections 202, 203 and 204 of the AFA do not apply to Petitioners with respect to:

(1) the existing ownership interests in the Vessels held, directly or indirectly, by the Vessel Owners and their Non-Citizen Investors; [1]

(2) the existing preferred mortgage interests in the Vessels held by Alyeska and the Japanese Bank Lenders identified below, including existing exclusive marketing agreements and other contract rights and interests ancillary to such financing arrangements; and

(3) future loan, financing and other transactions between the Non-Citizen Investors or the Japanese Bank Lenders,

[1] As used herein, the term "Non-Citizen" means a person or entity which is not a U.S. Citizen, as defined at 46 CFR § 356.3(e). The "Non-Citizen Investors" are Alyeska, Maruha, WAF, Marubeni Corporation, WAFBO, Inc., and Duke Point, L.P.

on the one hand, and the Vessel Owners, on the other, with respect to the Vessels.

Petitioner's Description of the Conflict Between the FCN Treaty and Both 46 CFR Part 356 and the AFA

MARAD's regulations at 46 CFR 356.53(b)(3) require Petitioners to submit a detailed description of how the provisions of the international investment agreement or treaty and the implementing regulations are in conflict. The entire text of the FCN Treaty is available on MARAD's internet site at *http://www.marad.dot.gov*. The description submitted by the Petitioner of the conflict between the FCN Treaty and both the AFA and MARAD's implementing regulations forms the basis on which the Petitioners request that the Chief Counsel issue a ruling that 46 CFR Part 356 does not apply to Petitioners with respect to the Vessels. The Petitioner's description of how the provisions of the U.S.-Japan FCN are in conflict with both the AFA and 46 CFR Part 356 is as follows:

A. The AFA's Limitations and Restrictions on Foreign Involvement in the U.S. Fishing Industry Are Inconsistent With U.S. Obligations Under the U.S.-Japan FCN.[3]

1. The AFA's Restrictions on Foreign Ownership Violates Article VII

(a) *The AFA's Restrictions on Foreign Investment Impair Petitioners' Existing Ownership Interests.* The AFA's new restrictions on foreign investment in fishing vessels will prohibit the Vessel Owners from employing their Vessels in the U.S. fisheries on and after October 1, 2001, because the extent of Japanese investment in the Vessel Owners exceeds the maximum permitted by the AFA.

Dept. verify hwer ref. & ft**FOOTNOTES** [1]: [3]:

A vessel cannot lawfully be employed in the fisheries of the United States unless it is documented as a vessel of the United States with a fishery endorsement issued by the U.S. Coast Guard pursuant to 46 U.S.C. Chapter 121. 46 U.S.C. Chapter 121 sets out the requirements which must be met for a vessel to be eligible for documentation with a fishery endorsement, including requirements related to the citizenship of vessel owners.

The Vessels are fishing vessels, designed and constructed or rebuilt for use in the U.S. fisheries and operated in the U.S. fisheries of the North Pacific Ocean and Bering Sea. Each of the Vessel Owners is eligible to own a vessel with a fishery endorsement under the current standards of 46 U.S.C. Chapter 121 and each of the Vessels is documented as a vessel of the United States with a fishery endorsement.

However, the Vessel Owners will be prohibited from owning or operating the Vessels in the U.S. fisheries on and after October 1, 2001 under the new restrictions on foreign investment in fishing vessels imposed by the AFA and MARAD's implementing rules, codified at 46 CFR Part 356 (65 Fed. Reg. 44860 *et seq.*, July 19, 2000). The aggregate of the ownership interests held, directly or indirectly, in the Vessel Owners by Alyeska (in the case of the SEA WOLF, by Alyeska and WAFBO, Inc.) exceeds 25%—the maximum percentage interest permitted to be held by Non Citizens under Section 202(a) of the AFA, effective on and after October 1, 2001 (see 46 U.S.C. 12102(c)(1), as amended).[4] The AFA requires MARAD to revoke the fishery endorsement of any fishing vessel whose owner does not comply with this new requirement. AFA Section 203(e). Accordingly, unless exempted from the AFA's new requirements, the Vessel Owners will no longer be permitted to own and operate their Vessels in the U.S. fisheries as of October 1, 2001. As a result, the Vessel Owners will be deprived of income from their Vessels; will be driven into insolvency and will default under the terms of their Guaranties in favor of the Japanese Bank Lenders and their Loan Agreements with Alyeska, and Alyeska, in turn, will be forced into default under the terms of its loan agreement with the Japanese Bank Lenders. Alternatively, the Vessel Owners would be forced to sell the Vessels or their Non-Citizen Investors would be forced to sell their interests in the Vessel Owners, assuming a buyer could be found. In either case, if Alyeska loses access to the fish that would otherwise be harvested by the Vessels and delivered to its Dutch Harbor processing facility, the $70 million investment which Alyeska and its shareholders have made in that facility and the jobs of its employees would be jeopardized.

(b) *The Impairment of Petitioners' Existing Ownership Interests Violates Article VII.1 and the Grandfather Provision of Article VII.2* The impairment of Petitioners' existing ownership interests in the Vessels violates their right to "national treatment" under Article VII. 1 and the grandfather provision of Article VII.2 of the U.S.-Japan FCN.

The U.S.-Japan FCN was one of a series of similar Friendship, Commerce and Navigation ("FCN") Treaties entered into by the United States with various countries after World War II, based on a standard State Department treaty text. All of these treaties reflect U.S. post-war policy to encourage and protect international trade and investment. Herman Walker, Jr., the principal author of the standard FCN treaty text and one of the principal State Department negotiators during this period, has described the FCN treaties as "concerned with the protection of persons, natural and juridical, and of the property interests of such persons." Herman Walker, Jr., "Modern Treaties of Friendship, Commerce and Navigation," 42 Minn. L. Rev. 805, 806 (1958) (hereinafter, "Modern Treaties").

Article VII.1 of the U.S.-Japan FCN guarantees broad "national treatment" for the nationals and enterprises of the U.S. and Japan when doing business within the jurisdiction of the other country. Article XXII.1 of the U. S.-Japan FCN defines "national treatment" as "treatment accorded within the territories of a Party upon terms no less favorable than the treatment accorded therein, in like situations, to nationals, companies, products, vessels or other objects, as the case may be, of such Party." The principle of national treatment is the central principle of all of the post-war FCN treaties. National treatment requires that each State Party must treat nationals of the other in the same way that it treats its own nationals. The treaties focus on business and investment. "The right of corporations to engage in business on a national-treatment basis may be said to constitute the heart of the treaty." Herman Walker, Jr., "The Post-War Commercial Treaty Program of the United States," 73 Pol. Sci. Q. 57, 67 (1958). In a case involving interpretation of the U.S.-Japan FCN, the United States Supreme Court noted that the purpose

[3] The text of the relevant provisions of the U.S.-Japan FCN cited herein is found at Attachment 1 to the Annex I of Authorities (hereinafter "Annex"), filed herewith.

[4] The AFA makes two primary changes to the existing limitation on foreign ownership of fishing vessels: (1) The required percentage of U.S. Citizen ownership is increased from "a majority" to 75%; (2) this new test is to be applied both "at each tier of ownership and in the aggregate," whereas the existing standard is applied solely at each tier of ownership, allowing foreign interests "in the aggregate" to exceed 50%, so long as U.S. Citizen ownership is maintained "at each tier." *See* 46 CFR 221.3(c) (a U.S. Citizen is a Person who "at each tier of ownership" satisfies the requisite ownership standard). *Compare*, 46 U.S.C. 12102(c), as now in effect, and 46 CFR 67.31(c), with 46 U.S.C. 12102(c)(1), as amended by Section 202(a) of the Act, and 46 CFR 356.9. The Vessels are owned by U.S. Citizens (as defined at 46 CFR 356.3(e)) at each "tier" of ownership but the "aggregate" U.S. citizen ownership is less than 75%. In addition, Section 204 of the AFA repeals a provision of prior law which permits 100% foreign owned corporations to own certain vessels.

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of the FCN treaties was "to assure [foreign corporations] the right to conduct business on an equal basis without suffering discrimination based on their alienage." *Sumitomo Shoji America* v *Avagliano*, 457 U.S. 176, 187–88 (1982). "[N]ational treatment of corporations means equal treatment with domestic corporations." Id. at 188 n. 18.

The preamble of the U.S.-Japan FCN provides that guaranteeing nationals of each Party "national * * * treatment unconditionally" is one of the two general principles upon which the U.S.-Japan FCN was based. Use of the word "unconditionally" in this context clearly demonstrates the strength of the drafters' general intent. Accordingly, the exceptions to the principle of national treatment stated in the U.S.-Japan FCN must be narrowly construed.

The AFA's retroactive prohibition of ownership interests acquired by Alyeska and WAFBO, Inc. in compliance with existing law clearly denies national treatment to them and to the Vessel Owners. The AFA's new limitation on foreign ownership of fishing vessels is thus inconsistent with the most fundamental principle of the U.S.-Japan FCN.

The first sentence of Article VII.2 of the U.S.-Japan FCN provides a limited exception to the principle of national treatment for enterprises engaged in "the exploitation of land or other natural resources." Even in that context, however, the second sentence of Article VII.2 (referred to as the "grandfather" provision of Article VII.2) prohibits application of new restrictions and limitations to Japanese nationals or enterprises which have previously "acquired interests" in enterprises owning U.S. fishing vessels or have previously engaged in the business activities now to be restricted. Article VII.2 provides in pertinent part:

> Each Party reserves the right to limit the extent to which aliens may within its territories establish, acquire interests in, or carry on * * * enterprises engaged in * * * the exploitation of land or other natural resources. *However, new limitations imposed by either Party upon the extent to which aliens are accorded national treatment, with respect to carrying on such activities within its territories, shall not be applied as against enterprises which are engaged in such activities therein at the time such new limitations are adopted and which are owned or controlled by nationals and companies of the other Party*

Emphasis added. The grandfather provision of Article VII.2 thus provides that any new limitations on national treatment placed on alien participation in the sectors covered by the first sentence of Article VII.2 shall not apply to existing enterprises engaged in business within those sectors at the time such new limitations are adopted.

A study commissioned by the State Department of its past interpretations of the FCN treaties notes that, under the grandfather provision of Article VII.2, "protection is afforded to any privilege granted * * * prior to a change in national treatment; hence at a minimum these foreign enterprises are guaranteed the maintenance of their existing operations." Ronny E. Jones, "State Department Practices Under U.S. Treaties of Friendship, Commerce, and Navigation" (1981) (hereinafter "Jones Study") at 57.[5] "[R]egulations that force divestiture of interests already acquired or established prior to promulgation of such regulation * * * raise Art. VII questions." *Id.* at 107. Herman Walker, Jr. stated the purpose of the Article VII.2 grandfather provision clearly: "The aim is to * * * guarantee duly established investors against subsequent discrimination. The failure to find a welcome as to entry is of much less importance than would be a failure, once having entered and invested in good faith, to be protected against subsequent harsh treatment." Modern Treaties at 809. In describing the import of the phrase "new limitations," another State Department study states,

> The net effect [of the second sentence of Article VII.2 is that, although not obligated to allow alien interests to become established in those fields of activity, *rights which have been extended in the past shall be respected and exempted from the application of new restrictions.*

Charles H. Sullivan, "State Department Standard Draft Treaty of Friendship, Commerce and Navigation" (undated) (hereinafter "Sullivan Study") at 149 (emphasis added). "the second sentence of Article VII(2) is a grandfather clause intended in the interest of fairness to protect legitimately established alien enterprises against retroactive impairment." *Id.* at 148.

Both State Parties placed great importance on the grandfather provision of Article VII.2 because they recognized that it would not only protect existing property rights but would entitle foreign-owned enterprises to continue to operate in the same manner as before, notwithstanding later limitations placed on the rights of foreign-owned entities to engage in such business activities. It was a "principal negotiating point" of the U.S. side to ensure that the reservations in Article VII.2 would not permit retroactive application of any new limits to companies already engaged in relevant business activities.[6]

The U.S. negotiators therefore resisted efforts to modify the grandfather provision of Article VII.2, despite strong Japanese efforts to restrict its application. As an indication of the importance the Japanese negotiators attached to the provision, the Japanese Embassy at one point late in the negotiations indicated that the Ministry of Finance might be persuaded to withdraw "all other objections" to the draft treaty if the sentence granting grandfather rights to existing businesses were deleted.[7] Eventually, the Japanese negotiators accepted the language in Article VII.2 without any change after the U.S. agreed to the language appearing in the second sentence of Paragraph 4 of the Protocol. The U.S. State Department agreed to the Protocol language only on the understanding that it in no way undermined the prohibition against application of discriminatory laws to existing enterprises in the second sentence of Article VII.2.[8]

As adopted, the second sentence of Article VII.2 follows the standard treaty text developed by the State Department and used as the basis for more than a dozen FCN treaties. The Sullivan Study notes the breadth of the protection this sentence affords existing companies otherwise subject to VII.2. The Sullivan Study indicates that an enterprise protected by the Article VII.2 grandfather provision is not only protected as to existing property interests or contract rights, but "is able to enjoy what may be considered normal business growth in terms of acquiring new customers and increasing the dollar volume of its business, but it cannot claim expanded privileges. * * *" Sullivan Study at 150.

In short, the protections afforded existing investments and existing businesses by the second sentence of Article VII.2 were seen by the U.S. as a key part of the U.S.-Japan FCN and similar FCN treaties, providing substantial protections to foreign investors and businesses. The provision affords Alyeska and WAFBO, Inc. the right to continue to hold their direct and indirect investments in the Vessel Owners and, more generally, to continue to transact business with the

[5] Petitioners presume that MARAD has access to the Jones Study and the Sullivan Study referenced below. Petitioners will provide copies of these studies to MARAD on request.

[6] Annex, Attachment 2, Department of State Incoming Telegram dated March 20, 195, p. 1.

[7] Annex, Attachment 3, Memorandum from Frank A. Waring, Counselor of U.S. Embassy for Economic Affairs undated excerpt).

[8] Annex, Attachment 2 Department of State Incoming Telegram dated March 20, 1953, p. 1, and Attachment Office Memorandum dated March 23, 1953, pp. 1–2.

Vessel Owners on the same basis as permitted prior to passage of the AFA. Similarly, the Article VII.2 grandfather provision guarantees the Vessel Owners the right to own and operate the Vessels in the U.S. fisheries on equal terms with wholly domestic enterprises.

Maruha and Marubeni are clearly entitled to protection as Japanese enterprises which, at the time the AFA was adopted, were "engaged in * * * activities" within the United States which the AFA but for Section 213(g), would prohibit, limit or restrict. Alyeska, WAF, WAFBO, Inc. and the Vessel owners likewise come within the protection of the Article VII.2 grandfather provision by reason of the direct and indirect ownership interests in them held by Maruha and/or Marubeni. Thus, the Article VII.2 grandfather provision protects the ownership interests of Maruha, WAF and Marubeni in Alyeska, the ownership interests of Alyeska and WAFBO, Inc. in the Vessel Owners and the Vessel Owners' right to continue to own and operate the Vessels in the U.S. fisheries.

However, as noted above, the Article VII.2 grandfather provision not only protects preexisting rights and interests acquired, directly or indirectly, by Japanese nationals prior to a discriminatory change in the law, but protects *existing enterprises* from such changes. Accordingly, the Article VII.2 grandfather provision, together with Section 213(g) of the AFA, exempts the Vessel Owners and their Non-Citizen Investors from the new restrictions of Section 202, 203 and 204 of the AFA and 46 CFR Part 356 with respect to (a) the Non-Citizen Investors' existing direct and indirect ownership interests in the Vessel Owners and the Vessels, (b) the continued operations of the Vessels by the Vessel Owners in the U.S. fisheries, and (c) future transactions between the Non-Citizen Investors and the Vessel Owners to further or protect the existing rights and interests of the Non-Citizen Investors in the Vessels and the Vessel Owners, such as the refinancing of existing loans, the making of new loans, the modification of existing mortgages, the taking of new mortgages or other security and the conclusion of other contractual arrangements ancillary to such financing activities.

2. The AFA's Restrictions on Foreign Financing of Fishing Vessels Violate Article VII.

(a) *The AFA's Restrictions on Foreign Financing of Fishing Vessels Impair Petitioners' Rights and Interests With Respect to Vessel Financing.* The AFA will nullify the preferred mortgage interests in the Vessels currently held by Alyeska and the Japanese Bank Lenders, impair their rights and interests under existing financing documents and prevent them from protecting their established businesses and interests by entering into future financing and related business transactions with the Vessel Owners.

Current law permits wholly or partly Japanese-owned lenders, including the Japanese Bank Lenders, Alyeska and the other Non-Citizen Investors, to finance U.S. fishing vessels and to hold preferred mortgage interests in U.S. fishing vessels to secure their loans. *See* 46 USC 31322. A "preferred mortgage" is a creature of federal statute and gives the mortgagee a lien on the mortgaged vessel, enforceable in U.S. District Court under a priority scheme that protects the mortgagee from most maritime liens. *See, generally*, 46 USC Chapter 313. 46 USC 31326(b)(1) gives the preferred mortgage lien priority over all maritime liens arising after filing of the mortgage except a limited number of "preferred" maritime liens listed at 46 USC 31301(5) and provides that a sale of the vessel by order of the District Court terminates all liens or other claims against the vessel, thus ensuring the purchaser clear title and allowing the mortgagee to realize maximum value for its security. Since maritime liens arise in favor of suppliers, materialmen, repairmen and others in the course of the ordinary operations of the vessel, protection against such liens is essential to the mortgagee's security, as is the ability to terminate those liens on foreclosure and to sell the vessel "free and clear" of liens. Absent preferred mortgage status, a mortgage provides little or no security for the lender. Thus, the preferred mortgages which Alyeska and the Japanese Bank Lenders hold in the Vessels are valuable property interests in the Vessels.

The AFA will prohibit Alyeska and the Japanese Bank Lenders from continuing to hold their existing preferred mortgages on the Vessels unless, in the case of the Japanese Bank Lenders, their mortgages are transferred to a qualified Mortgage Trustee (*see* AFA Section 202(b), amending 46 USC 31322, and 46 CFR 356.19) *and* the terms of the financing documents are approved by a MARAD under the AFA's new "control" standards (see AFA Section 202(a), adding 46 USC 12102(c)(4)(A), and 46 CFR 356.15(d) and 356.21(d)). The AFA contains a new definition of impermissible Non-Citizen "control" (AFA Section 202(a), codified at 46 USC 12102(c)(2)) and requires transfers of "control" of fishing vessels to be "rigorously scrutinized" by MARAD under this new standard (AFA Section 203(c)(2)). MARAD has implemented the AFA's new "control" standard by adopting a host of new restrictions and limitations on contractual and other business arrangements between fishing vessel owners and Non-Citizens. *See, generally*, 46 CFR 356.11–356.13–15, 356.21–25, 356.39–45. Unless MARAD reviews and approves the terms of the loan agreements, preferred mortgages and other financing documents previously executed by the Vessel Owners in favor of the Alyeska and the Japanese Bank Lenders prior to October 1, 2001 under these new standards, the Vessels will lose their fishery endorsements and the Vessel Owners will no longer be permitted to own or operate the Vessels in the U.S. fisheries. See 46 CFR 356.15(d), 356.21(d). This, in turn, will destroy the value of the Vessels as security under the mortgages held by Alyeska and the Japanese Bank Lenders and destroy the ability of the Vessel Owners to pay the debts which the mortgages secure. By prohibiting Alyeska and the Japanese Bank Lenders from continuing to hold their existing preferred mortgages on the Vessels, imposing new conditions and restrictions on the terms of their existing financing documents, including a new requirement of administrative review and approval of those financing documents under AFA's new "control" standards, the AFA and MARAD's implementing regulations will impair the contractual rights and mortgage interests of Alyeska and the Japanese Bank Lenders under their existing preferred mortgages and related financing documents.

In the case of Petitioner Alyeska's mortgages, *MARAD has made clear that there is no way that Alyeska can preserve its mortgage interests under the AFA.* MARAD has interpreted the AFA's requirements to prohibit Non-Citizen fish processors, such as Alyeska, from holding mortgages or other security interests in fishing vessels, even if the mortgage is held by a qualified Mortgage Trustee and the loan and mortgage terms are otherwise acceptable to MARAD. 65 Fed. Reg. at 44871 c.2 (July 19, 2000) ("[A]dvancements of funds from Non-Citizen processors will not be permitted where the security for the loan is a security interest in the vessel"). Thus, in the case of Alyeska, the AFA's requirements will nullify Alyeska's existing preferred mortgage interests in the Vessels. If Alyeska's mortgages are not released, the Vessels will lose their fishery endorsements, destroying the

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value of the Vessels as collateral for Alyeska's loans and destroying the Vessel Owners' ability to pay their debts.

Further, even if Alyeska's *existing* financial interests in the Vessel Owners were found to be exempt from the requirements of the AFA and MARAD's implementing rules, the AFA's restrictions on *future* financing transactions between Alyeska or its Japanese shareholders and the Vessel Owners will substantially impair the rights and interests of Alyeska and its Japanese shareholders in violation of Article VII.1. The AFA's restrictions on foreign financing of fishing vessels will prevent Alyeska and its Japanese shareholders from protecting their investments in Alyeska's Dutch Harbor processing facility and their existing investments in and loans to the Vessel Owners by offering the Vessel Owners financing, secured by mortgages on the Vessels or otherwise, for vessel repairs or improvements which may become necessary to permit the Vessel Owners to operate profitably—or at all. If alternative financing from a financial institution is unavailable to the Vessel Owners, the ability of Alyeska to make loans to support the Vessels' continuing operations may be the only means available to protect the Vessel Owners from insolvency and default on their existing loans from Alyeska—triggering a default by Alyeska under its loan agreement with the Japanese Bank Lenders. Thus, the AFA's restrictions on the ability of Alyeska or its Japanese shareholders to make new loans to the Vessel Owners and to take security in the Vessels jeopardize the existing financial interests of Alyeska and its Japanese shareholders in the Vessel Owners and the Vessels, as well as Alyeska's own financial health.

Finally, the new restrictions imposed by the AFA and MARAD's regulations on the ability of Alyeska to make loans to fishing vessel owners will disrupt Alyeska's ability to secure a reliable supply of fish to its processing facility. Alyeska's ability to offer financing for the construction, acquisition or improvement of fishing vessels is a necessary means to secure a stable supply of fish to its processing plant. A processor's agreement to provide financing on favorable terms to qualified U.S. vessel owners in return for the vessel owner's agreement to sell the vessel's catch exclusively to the processor is a customary means by which vessel owners finance the acquisition, repair or improvement of their vessels and processors secure a reliable supply of fish to their plants. Such arrangements between vessel owners and processors, both wholly domestic and Non-Citizen processors, are common and traditional in the Alaska fishing industry. Non-Citizen processors, such as Alyeska, which have invested many millions of dollars in shore-based processing plants in remote locations in Alaska, must have the ability, like their wholly domestic competitors, to secure a reliable supply of fish to their plants by financing the acquisition or improvement of fishing vessels on normal commercial terms in return for the vessel owner's agreement to sell exclusively to that processor during the term of the loan. Just as their existing ownership and mortgage interests are protected by the Treaty; Alyeska, its Japanese shareholders and the Japanese Bank Lenders must also be able to modify and restructure their loans and related security arrangements with the Vessel owners and make new loans to the Vessel Owners with respect to the Vessels in order to further and protect their existing investments, mortgages and business interests, as circumstances may require.

(b) *The Restrictions on Foreign Financing of Fishing Vessels Imposed by the AFA and MARAD's Implementing Rules Violate Article VII.1.*

The new restrictions on foreign financing of fishing vessels imposed by the AFA and MARAD's implementing regulations violate Article VII.1's national treatment guaranty by (1) depriving Alyeska and the Japanese Bank Lenders of existing preferred mortgage interests securing existing loans; (2) subjecting the terms of their existing loan documents to a new requirement of administrative review and approval by MARAD under the new "control" standards of the AFA and MARAD's implementing rules; (3) depriving Alyeska and the Japanese Bank Lenders of the value of their collateral and the income stream from operations on which they relied in making their loans; and (4) preventing Alyeska, its shareholders or the Japanese Bank Lenders from refinancing existing loans, making new loans to the Vessel Owners, taking new mortgages on the Vessels or entering into other contractual arrangements with respect to the Vessels or the Vessel Owners necessary to further or protect their existing financial and business interests.

Article VII.1 extends full national treatment protection "with respect to engaging in *all types* of commercial, industrial, *financial* and other business *activities*." The negotiating history of the U.S.-Japan FCN leaves no doubt that loans and lending by foreign-owned lenders are entitled to full national treatment under the first sentence of Article VII.1.

At the fourth informal meeting of the U.S. and Japanese negotiators, the Japanese negotiators argued that foreign-owned banks should be denied national treatment, as well as most-favored-nation protection. One reason given was that their loans could result in the foreign-owned bank lender controlling key industries.[9] For this and other reasons, Japan suggested rewriting Article VII.1, and among other changes deleting "financial" from the activities provided national treatment in the first sentence of the provision.

A cable from U.S. State Department headquarters in Washington noted that the Japanese proposal, and in particular its interest in denying national treatment to bank loans, reflected an attitude that creates a "difficulty going to heart of treaty.[10] The State Department opposed any change that would delete the word *financial* from the first sentence of Article VII.1. Subsequently, the Japanese side suggested instead adding the word "lending" to the exception provided in the first sentence of Article VII.2, so the phrase would have read "banking involving depository, lending or fiduciary functions." In response, the State Department reiterated its opposition to any change that would deny foreign lenders the right to full national treatment under Article VII.1.

A Department cable explained why the exception to national treatment provided by the first sentence of the U.S. draft of Article VII.2 was limited to only the depository and fiduciary functions of banks.[11] The cable states: "Mr. Otabe is incorrect in supposing that the U.S. reservation for banking is based on the reason he alleges. The reservation has to do with receiving and keeping custody of deposits from the public at large; that is, the safekeeping of other people's money, a function of particular trust. It does not have to do with the lending activities of a bank; and the Department does not feel that a reservation is either appropriate or necessary as to a bank's lending its own money." Id. During the second round of informal meetings, the U.S. negotiators continued to oppose adding loans to the banking functions excluded from full national treatment by the first sentence of Article VII.2, and the Japanese

[9] Annex, Attachment 5, Memorandum of Conversation dated March 4, 1952, pp. 2–3.

[10] Annex, Attachment 6, Dept. of State Outgoing Telegram dated March 10, 1952, p. 1.

[11] Annex, Attachment 7, Dept. of State Outgoing Telegram dated May 21, 1952, p. 3.

government eventually agreed to withdraw its proposed change.[12]

The exception to national treatment for certain banking functions in the first sentence of Article VII.2 is the same as in the standard FCN treaty text. The Sullivan Study notes that "this reservation is stated in terms intended to circumscribe it as much as possible, thereby maximizing the extent to which the banking business remains subject to the rule [of national treatment] set forth in Article VII(1)." Sullivan Study at 144. The Sullivan Study notes that the two areas reserved, depositary and fiduciary functions, involve the custody and management of other people's money, and therefore are the most sensitive areas of banking.

It is clear, therefore, that the reference in the first sentence of Article VII.2 to "banking involving depository or fiduciary functions" does not include the lending activities of the Japanese Bank Lenders or Alyeska. Both the U.S. and Japanese negotiators were in full agreement as to the meaning of this phrase. Thus, the financing activities of banks and other lenders are entitled to the full national treatment under Article VII.1.[13]

The provisions of the AFA and MARAD's implementing rules which restrict the right of Japanese-owned entities to make loans secured by mortgages on U.S. vessels or to make such loans without prior MARAD approval of the loan terms are inconsistent with the guaranty of national treatment in Article VII.1. The rationale that such loan activities may be restricted on the grounds that they could result in a degree of control over sensitive industries was specifically considered by the U.S. negotiators and rejected as a valid reason for limiting the Treaty's protections for such lending activities. The control argument presented by Japan at that time is the same argument used to justify the restrictions of the AFA. Although the negotiating history deals largely with banking, the language of Article VII.1 extends the protections of national treatment broadly to "all types of * * * financial * * * activities." Under Article VII.1, neither State Party may restrict loans by foreign-owned entities secured by vessels of their national flag.

The AFA and MARAD's implementing rules impose new restrictions on the ability of Alyeska and the Japanese Bank Lenders, going forward, to protect their existing financial interests in the Vessel Owners and the Vessels by, *e.g.*, re-financing existing loans, advancing new loans for repair or improvement of the Vessels or entering into other financing or contractual arrangements with the Vessel Owners. These restrictions are not permitted by Article VIII of the Treaty. Article VIII extends the Treaty's protection both to loans, mortgages and other financing arrangements that are now outstanding under the terms of existing financing documents and to future financing activities by Alyeska, its shareholders or the Japanese Bank Lenders involving the Vessels or the Vessel Owners.

Application of the AFA's new "control" standards to restrict the ability of Alyeska to do business with the Vessel Owners that supply fish to its processing plant, as it has done in the past and on the same terms as its U.S. Citizen competitors, would deny national treatment to Alyeska and its Japanese shareholders. The State Department has recognized that the exception to the requirement of national treatment that may apply with respect to the ownership of fishing vessels under the first sentence of Article VII.2 does not apply to fish processors.[14] Article VII.1 applies, and it extends the protection of full and unconditional national treatment to fish processors with Japanese ownership, such as Alyeska. The discriminatory restrictions imposed under the AFA on Alyeska's ability to enter into future financing and other contractual arrangements with the Vessel Owners to ensure a stable supply of fish to Alyeska's Dutch Harbor processing facility clearly violate Article VII.1.

For these reasons, Petitioners seek a determination by MARAD that Sections 202, 203 and 204 of the AFA and MARAD's implementing regulations do not apply to Petitioners with respect to (a) existing preferred mortgages and associated loan and security documents previously executed by the Vessel owners in favor of Alyeska or the Japanese Bank Lenders, including the exclusive marketing agreements contained in Alyeska's loan agreements with the Vessel Owners (or, in the case of the SEA WOLF, with the Vessel Owner's general partner); or (b) fixture financing and ancillary contractual arrangements between Alyeska or the Japanese Bank Lenders and the Vessel Owners, including exclusive marketing agreements.

3. Application of the AFA and MARAD's Implementing Rules to Petitioners Would Result in a "Taking" in Violation of Article VI.3

The first sentence of Article VI.3 of the Treaty states that "[p]roperty of nationals and companies of either Party shall not be taken within the territories of the other Party except for a public purpose, nor shall it be taken without the prompt payment of just compensation." This "takings" provision precludes expropriations and other measures that substantially impair a Japanese national's direct and indirect property rights. Applying the AFA's new restrictions to prohibit the Non-Citizen Petitioners from holding their pre-existing ownership interests, mortgage interests and contract rights would deprive them of their property in violation of Article VI.3.

The term "property" in Article VI.3 includes not simply direct ownership but also a wide variety of property interests, such as those which the Non-Citizen Petitioners have in the Vessel Owners and in the Vessels. The Protocol to the U.S.-Japan FCN explicitly states that "[t]he provisions of Article VI, paragraph 3 * * * shall extend to interests held directly *or indirectly* by nationals and companies of either Party in property which is taken within the territories of the other Party." Protocol, ¶ 2 (emphasis added). As the United States delegates made clear during the negotiation of the Treaty, the phrase "interests held directly or indirectly" is intended to extend to every type of right or interest in property which is capable of being enjoyed as such, and upon which it is practicable to place a monetary value. These direct and indirect interests in property include not only rights of ownership, but [also] * * * lease hold interest[s], easements, contracts, franchises, and other tangible and intangible property rights.[15] In short, "all property interests are contemplated by the provision."[16] This necessarily includes the direct and indirect ownership interests which

[12] Annex, Attachment 8, Memorandum of Conversation dated October 15, 1952, p. 15.

[13] To the extent that it could be argued that the first sentence of Article VII.2 might permit restrictions on foreign financing of fishing vessels, the grandfather provision of Article VII.2 would clearly protect Alyeska, its shareholders and the Japanese Bank Lenders with respect to their existing rights and interests, as the holders of ownership and debt interests in the Vessel Owners and mortgage interests in the Vessels, and with respect to future financing activities undertaken to further or protect those interests. Alyeska, WAFBO, Inc., their Japanese shareholders and the Japanese Bank Lenders clearly "acquired interests" in the Vessel Owners prior to enactment of the AFA and are thus entitled to national treatment in future dealings with the Vessel Owners.

[14] Annex, Attachment 9, Letter to the Chairman of the House of Representatives Committee on Merchant Marine and Fisheries from Robert Lee, August 17, 1964.

[15] Annex, Attachment 10, Memorandum of Conversation dated April 15, 1952 at p. 3.

[16] *Id.*

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Petitioners have in the Vessel Owners and in the Vessels and the preferred mortgage interests which Alyeska and the Japanese Bank Lenders have in the Vessels, together with ancillary contract rights granted in their loan documents.

The concept of a taking in this context is broad and "is considered as covering, in addition to physical seizure, a wide variety of whole or partial sequestrations *and other impairments of interests in or uses of property.*" Sullivan Study at 116 (emphasis added). Here, the AFA's new restrictions on foreign investment and foreign financing will prohibit the Vessel Owners from using their Vessels in the U.S. fisheries. In effect, the AFA will either deprive the Petitioners of the economic value of their interests in the Vessels by prohibiting their productive use or force divestiture. The impairment of the presently existing rights of the Vessel Owners to use their Vessels in the U.S. fisheries—and the rights of the other Petitioners to hold their existing direct and indirect ownership interests in the Vessel Owners and mortgage interests in the Vessels—is a sufficient impairment of those rights and interests as to constitute a violation of Article VI.3.

Further, a taking is permitted under the Treaty only for a "public purpose," and it is clear that application of the AFA's ownership restrictions to the Vessel Owners so as to force a divestiture of the interests of Alyeska or WAFBO, Inc. to a private party which qualifies as a U.S. Citizen would not satisfy the "public purpose" requirement of the U.S.-Japan FCN. Even if such a forced sale to a private party could be characterized as having a "public purpose," the AFA makes no provision for the "prompt payment of just compensation," as required by Article VI.3. The fact that the AFA and 46 CFR Part 356 fail to provide any compensation scheme—let alone "adequate provision * * * at or prior to the time of taking for the determination and payment thereof"—is another basis for concluding that the AFA's retroactive limitations on foreign ownership and foreign financing of fishing vessels are inconsistent with Article VI.3 of the U.S.-Japan FCN.

4. The AFA and MARAD's Implementing Rules Impair Petitioners' Legally Acquired Rights in Violation of Article V

The new restrictions imposed by the AFA and MARAD's implementing rules on foreign involvement in the U.S. fishing industry are "unreasonable or discriminatory measures" that impair the legally acquired rights and interests of Petitioners in violation of Article V of the Treaty.

Article V provides that "[n]either Party shall take unreasonable or discriminatory measures that would impair the legally acquired rights or interests within its territories of nationals and companies of the other Party in the enterprises which they have established. * * *" The provision follows the standard FCN treaty language, except that the language was moved from Article VI.3 in the standard text to a new Article V and certain additional language, not relevant here, was added. According to the Sullivan Study, the provision "offers a basis in rather general terms for asserting protection against excessive governmental interference in business activities or particular activities not specifically covered by the treaty." Sullivan Study at 115. Herman Walker observed that this language is designed "to account for the possibility of injurious governmental harassments short of expropriation or sequestration." Herman Walker, Jr., "Treaties for the Encouragement and Protection of Foreign Investment: Present United States Practice," 5 Am. T. Comp. Law at 236 (1956). A State Department memorandum to Congress, discussing language very similar to Article V in another treaty, noted that the language "affords one more ground, in addition to all the other grounds set forth in the treaty, for contesting foreign actions which appear to be injurious to American interests."[17]

The negotiating history confirms that Article V was intended as a general provision prohibiting discrimination against foreign-owned entities not subject to other provisions of the U.S.-Japan FCN. During the negotiations, Japan proposed-adding language prohibiting the denial "of opportunities and facilities for the investment of capital." The proposal was not adopted after the U.S. opposed it on the grounds that Article VII fully addressed investment activities and that the additional language was not appropriate in Article V, which addresses issues not limited to investment.[18]

Thus, Article V was intended as a general prohibition of discriminatory restrictions not covered by other provisions of the U.S.-Japan FCN and of restrictions that do not rise to the level of a "taking." Article V prohibits deprivations of both most-favored nation treatment and national treatment. Sullivan Study at 115. Thus, it would apply to the variety of discriminatory prohibitions and restrictions that the AFA and MARAD's implementing regulations impose on Petitioners' existing ownership and mortgage interests and other contract rights and on Petitioners' ongoing ability to protect those rights and interests by entering into future transactions with the Vessel Owners.

The intrusive and discriminatory restrictions imposed by the AFA and MARAD's implementing rules on transactions between Non-Citizen lenders, such as Alyeska and the Japanese Bank Lenders, and U.S. fishing vessel owners place the Non-Citizen lenders at a significant competitive disadvantage. U.S. Citizen processors and other lenders are free to make loans and to enter into contracts with fishing vessel owners without restriction. U.S. Citizen processors remain free to obtain a reliable supply of fish by financing fishing vessel acquisitions, conversions and improvements in return for exclusive marketing relationships while Non-Citizen processors are prohibited from making similar arrangements. As previously noted, MARAD has stated that Non-Citizen processors will be flatly prohibited from taking security in fishing vessels to secure loans to vessel owners. Under 46 CFR 356.45, a Non-Citizen lender is not even permitted to make an *unsecured* loan to a fishing vessel owner, if (a) the loan exceeds the annual value of the vessel's catch (where an exclusive marketing agreement is involved—see § 356.45(a)(2)(i)); or (b) the lender is "affiliated with any party with whom the owner * * * has entered into a mortgage, long-term or exclusive sales or purchase agreement, or other similar contract * * *" (see § 356.45(b)(1)). Under these standards, Alyeska's existing loans to the Vessel Owners would not have been permitted and Alyeska will not be permitted to make future loans to the Vessel Owners, secured or unsecured, to protect its existing interests. Further, the requirement of MARAD review and approval is itself an unreasonable and discriminatory burden, particularly in the absence of coherent standards. The AFA and MARAD's rules thus impose "unreasonable or discriminatory measures" on Non-Citizen fish processors and other lenders with Japanese ownership, such as Alyeska and the Japanese Bank Lenders, impairing their legally acquired rights and interests and their ongoing ability to protect those interests in violation of Article V of the U.S.-Japan FCN.

[17] Annex, Attachment 11, Department of State Instruction dated February 15, 1954, p. 2. (discussing the applicability of Article V of the U.S.-Japan FCN to American lawyers doing business in Japan, and citing May, 1952 memorandum to U.S. Committee on Foreign Relations).

[18] Annex, Attachment 12; Department of State Division of Communications & Records Outgoing Airgram dated October 28, 1952, p. 2.

5. Article XIX 6 Does Not Authorize the Provisions of the AFA and MARAD's Implementing Rules Which Are Otherwise in Violation of the U.S.-Japan FCN

Article XIX.6 provides that notwithstanding any other provision of the Treaty, "each Party may reserve exclusive rights and privileges to its own vessels with respect to the * * * national fisheries.* * *" This provision does not authorize the discriminatory limitations on Japanese investment and financing contained in the AFA and MARAD's implementing rules.

Even if Article XIX. 6 is interpreted as applying to fishing vessels,[19] it would be irrelevant to the issues presented here with respect to the AFA. Consistent with the Treaty text authorizing a Party to reserve exclusive rights to "its own vessels," the State Department has interpreted Article XIX.6 merely to permit the U.S. to reserve the right to catch or land fish in the U.S. national fisheries to "U.S. flag vessels."[20] The text of Article XIX.6 says nothing about and certainly does not authorize restrictions on foreign ownership or financing of U.S. flag fishing vessels or the ability of foreign-owned enterprises to do business with the owners of U.S. flag fishing vessels—restrictions that otherwise clearly violate Article VII of the Treaty.

The historical record of the negotiations provides further evidence that Article XIX.6 was not intended to override Article VII's national treatment requirements with respect to foreign investment in or financing of U.S. flag fishing vessels or other dealings between foreign-owned enterprises and fishing vessel owners. At one point, the Japanese negotiators proposed rewriting Article XIX.6 to provide that the national treatment provisions of the Treaty would not extend to *"nationals companies and vessels* of the other Party any special privileges reserved to national fisheries." *See* Memorandum of Conversation dated April 3, 1952, at 5.[21] The State Department understood the Japanese suggestion as an attempt to obtain a blanket exception from the entire Treaty for national fisheries. *See* U.S. Dept. of State, Outgoing Airgram to U.S. Embassy in Tokyo (June 12, 1952), at 1–2 (noting that a clearer way to effect the Japanese intent would be by adopting a single comprehensive exception stating that "[t]he provisions of the present Treaty shall not apply with respect to the national fisheries of either Party, or to the products of such fisheries").[22] The U.S. rejected the Japanese proposal and the language of Article XIX.6 remained unchanged. The issue of Japanese investment in and other dealings with enterprises owning or operating U.S. flag fishing vessels was left to Article VII.

Subsequent practice of the State Department confirms this reading of Article XIX.6. In 1964, the State Department reaffirmed the narrow scope of Article XIX.6 in a letter to the House Committee on Merchant Marine and Fisheries. The letter makes clear that the provision merely permits the United States to reserve the right to catch or land fish to U.S. flag vessels?[23]

This reading of Article XIX.6 in the U.S.-Japan FCN also comports with the State Department's reading of this same language in other FCN treaties to which the U.S. is a party. The Sullivan Study explicitly states that "[t]he crucial element in Article XIX is that it relates to the treatment of *vessels* and to the treatment of their cargoes. *It is not concerned with the treatment of the enterprises which own the vessels* and the cargoes." Sullivan Study at 284 (emphasis added).

Thus, the text, negotiating history and subsequent State Department practice and understanding all explicitly confirm that Article XIX.6 is irrelevant to laws restricting foreign ownership and control of fishing vessel *owners* and thus does not override the other provisions of the U.S.-Japan FCN dealing with foreign investment and business activity. Article XIX.6 does not exempt the AFA's foreign ownership, financing and control restrictions, from Articles V, VI.3, VII or IX.2, each of which bars application of those restrictions to Petitioners with respect to the Vessel Owners and the Vessels.

6. Broad Interpretation of the Treaty's Protections is in the U.S. Interest

The terms of the U.S.-Japan FCN and the other FCN treaties which share the same language are reciprocal—that is, the principle of "national treatment" applies not only to protect the investments of foreign nationals in the United States but also to protect the investments of U.S. nationals in Japan and other countries. Thus, any interpretation of the U.S.-Japan FCN adopted by MARAD in the present context will also define the rights of U.S. nationals doing business in Japan and other countries, now and in the future. A narrow interpretation of the U.S.-Japan FCN's protections for Japanese enterprises and their investments in the present context will effectively limit the rights of U.S. investors and U.S. businesses in Japan and other countries with which the United States has concluded similar FCN treaties.

For this reason, the State Department has interpreted the national treatment requirement of the FCN treaties broadly in the past. *See, generally,* Jones Study. The U.S. interest in protecting U.S. nationals doing business abroad, as well as the State Department's historical practice in interpreting the FCN treaties, requires an interpretation of the U.S.-Japan FCN which will protect the interests of foreign enterprises and the U.S. companies in which they have invested from the retroactive and discriminatory prohibitions and restrictions of the AFA and 46 C.F.R. Part 356.

B. AFA Section 213(g) Exempts Japanese Enterprises and U.S. Enterprises With Japanese Investment From The AFA's Limitations and Restrictions on Foreign Ownership, Foreign Financing and Foreign "Control" of U.S. Fishing Vessels

Sections 202, 203 and 204 of the AFA and the implementing regulations published by MARAD on July 19, 2000, codified at 46 C.F.R. Part 356, impose a host of new limitations and restrictions on foreign ownership of fishing vessels, foreign financing of fishing vessels and contractual arrangements between foreign enterprises or U.S. companies with substantial foreign ownership and U.S. fishing vessel owners. As demonstrated above, if applied to Petitioners, these new limitations and restrictions would deprive Petitioners and the Japanese Bank Lenders of valuable existing ownership, mortgage and contract rights and interests in violation of the U.S.-Japan FCN. Application of the new restrictions to bar Petitioner Alyeska or its Japanese shareholders from entering into future transactions with the Vessel Owners, particularly financing and ancillary contractual arrangements, such as exclusive marketing agreements, would also violate the U.S.-Japan-FCN by substantially impairing the ability of Alyeska and its shareholders to protect

[19] Article XIX.7 defines "vessel" to exclude "fishing vessels" for purposes of Article XIX.6.

[20] Annex, Attachment 9, Letter to the Chairman of the House of Representatives Committee on Merchant Marine and Fisheries from Robert Lee, August 17, 1964.

[21] Annex, Attachment 13, Memorandum of Conversation dated April 3, 1952.

[22] Annex, Attachment 14, Department of State Outgoing Airgram dated June 12, 1952.

[23] *See* fn. 21. *See also,* Jones Study at 80–81.

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their existing rights and interests and to carry on their existing lawful business in the United States in conformity with past practice and on an equal footing with U.S. Citizens.

To avoid these results, Congress included a provision in the AFA to ensure that the Act would not contravene U.S. treaty obligations. Section 213(g) provides in pertinent part:

> In the event that any provision of section 12102(c) or section 31322(a) of title 46, United States Code, as amended by this Act, is determined to be inconsistent with an existing international agreement relating to foreign investment to which the United States is a party with respect to the owner or mortgagee on October 1, 2001 of a vessel with a fishery endorsement, such provision shall not apply to that owner or mortgagee with respect to such vessel to the extent of any such inconsistency * * *.

Section 213(g) makes clear that its reach is intended to extend to every "owner" or "mortgagee" holding an ownership or mortgage interest on October 1, 2001, when Sections 202, 203 and 204 of the AFA become effective. Section 213(g) provides explicitly that the exemption does not apply to "subsequent owners and mortgagees" who acquire their interests *after* October 1, 2001 or "to the owner [of the vessel] on October 1, 2001 if any ownership interest in that owner is transferred to or otherwise acquired by a foreign individual or entity *after such date* (emphasis added).

Petitioners are "owners" and "mortgagees" who acquired their interests in the Vessels prior to October 1, 2001, and who intend to continue to hold those interests on and after October 1, 2001. The inconsistency between the provisions of the AFA and MARAD's implementing regulations and the requirements of the U.S.-Japan FCN is demonstrated above. Accordingly, under Section 213(g) of the Act, the provisions of Sections 202, 203 and 204 "shall not apply" to Petitioners "to the extent of the inconsistency."

The exemption provided by Section 213(g) is not limited to existing property rights, mortgage interests or investment interests in existence on October 1, 2001, but rather applies to an "owner" or "mortgagee" on October 1, 2001 "to the extent of the inconsistency" between the Act and the Treaty. Petitioners qualify as "owners" and "mortgagees." Petitioners are, therefore, exempt from the requirements of the AFA "to the extent of the inconsistency" between the AFA and the Treaty. As demonstrated above, the "inconsistency" between the AFA and the Treaty is two-fold: (1) The Treaty protects the existing ownership and mortgage interests of Petitioners and the Japanese Bank Lenders in the Vessels and related contract rights, which the AFA would prohibit or restrict; and (2) the Treaty protects future transactions between Alyeska, its Japanese shareholders or the Japanese Bank Lenders and the Vessel Owners, which the AFA would prohibit or restrict, including future loans, preferred mortgages and other financing and contractual arrangements, which Petitioners may deem necessary or appropriate to protect their existing businesses and their existing interests in the Vessels and the Vessel Owners. Thus, Section 213(g) exempts Petitioners from the restrictions and limitations of Sections 202, 203 and 204 of the AFA and MARAD's implementing rules.

IV. Conclusion

For the reasons stated above, Sections 202, 203 and 204 of the AFA and 46 CFR Part 356 are inconsistent with the U.S.-Japan FCN and therefore may not be applied to Petitioners with: respect to the Vessels or the Vessel Owners.

This concludes the analysis submitted by Petitioner for consideration.

Dated: January 11, 2001.
By Order of the Maritime Administrator.
Joel Richard,
Secretary, Maritime Administration.

[FR Doc. 01–1357 Filed 1–16–01; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2001–8665]

ARICA—Applicability of Ownership and Control Requirements to Obtain a Fishery Endorsement to the Vessel's Documentation

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a petition requesting MARAD to issue a determination that the ownership and control requirements and the preferred mortgage requirements of the American Fisheries Act of 1998 and 46 CFR Part 356 are in conflict with an international investment agreement.

SUMMARY: The Maritime Administration ("MARAD") is soliciting public comments on a petition from the owners and mortgagees of the vessel ARICA—Official Number 550139 (hereinafter the "Vessel"). The petition requests that MARAD issue a decision that the American Fisheries Act of 1998 ("AFA" or "Act"), Division C, Title II, subtitle I, Pub. L. 105–277, and the implementing regulations at 46 CFR part 356 (65 FR 44860 (July 19, 2000)) are in conflict with the Agreement Between the United States of America and Denmark Regarding Friendship, Commerce and Navigation, 421 UNTS 105, TIAS: 4797,12 UST 908951 (1961) ("Denmark Treaty" or "FCN"). The petition is submitted pursuant to 46 CFR 356.53 and 213(g) of AFA, which provide that the requirements of the AFA and the implementing regulations will not apply to the owners or mortgagees of a U.S.-flag vessel documented with a fishery endorsement to the extent that the provisions of the AFA conflict with an existing international agreement relating to foreign investment to which the United States is a party. This notice sets forth the provisions of the international agreement that the Petitioner alleges are in conflict with the AFA and 46 CFR part 356 and the arguments submitted by the Petitioner in support of its request. If MARAD determines that the AFA and MARAD's implementing regulations conflict with the Denmark Treaty, the requirements of 46 CFR Part 356 and the AFA will not apply to the extent of the inconsistency. Accordingly, interested parties are invited to submit their views on this petition and whether there is a conflict between the Denmark Treaty and the requirements of both the AFA and 46 CFR Part 356. In addition to receiving the views of interested parties, MARAD will consult with other Departments and Agencies within the Federal Government that have responsibility or expertise related to the interpretation of or application of international investment agreements.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than February 16, 2001.

ADDRESSES: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted by mail to the Docket Clerk, U.S. DOT Dockets, Room PL–401, Department of Transportation, 400 7th St., SW, Washington, DC 20590–0001. You may also send comments electronically via the Internet at http://dms.dot.gov/submit/. All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except Federal Holidays. An electronic version of this document and all documents entered into this docket are available on the World Wide Web at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: John T. Marquez, Jr. of the Office of Chief Counsel at (202) 366–5320. You may send mail to John T. Marquez, Jr., Maritime Administration, Office of Chief Counsel, Room 7228, MAR–222, 400 Seventh St., SW, Washington, DC, 20590–0001 or you may send e-mail to John.Marquez@marad.dot.gov.

SUPPLEMENTARY INFORMATION:

Background

The AFA was enacted in 1998 to give U.S. interests a priority in the harvest of U.S.-fishery resources by increasing the requirements for U.S. Citizen ownership, control and financing of U.S.-flag vessels documented with a fishery endorsement. MARAD was charged with promulgating implementing regulations for fishing vessels of 100 feet or greater in registered length while the Coast Guard retains responsibility for vessels under 100 feet.

Section 202 of the AFA, raises, with some exceptions, the U.S.-Citizen ownership and control standards for U.S.-flag vessels that are documented with a fishery endorsement and operating in U.S.-waters. The ownership and control standard was increased from the controlling interest standard (greater than 50%) of § 2(b) of Shipping Act, 1916 ("1916 Act"), as amended, 46 App. U.S.C. 802(b), to the standard contained in § 2(c) of the 1916 Act, 46 App. U.S.C. 802(c), which requires that 75 percent of the ownership and control in a vessel owning entity be vested in U.S. Citizens. In addition, section 204 of the AFA repeals the ownership grandfather "savings provision" in the Anti-Reflagging Act of 1987, Pub. L. 100–239, § 7(b), 101 Stat 1778 (1988), which permits foreign control of companies owning certain fishing vessels.

Section 202 of the AFA also establishes new requirements to hold a preferred mortgage on a vessel with a fishery endorsement. State or federally chartered financial institutions must now comply with the controlling interest standard of § 2(b) of the 1916 Act in order to hold a preferred mortgage on a vessel with a fishery endorsement. Entities other than state or federally chartered financial institutions must either meet the 75% ownership and control requirements of § 2(c) of the 1916 Act or utilize an approved U.S.-Citizen Trustee that meets the 75% ownership and control requirements to hold the preferred mortgage for the benefit of the non-citizen lender.

Section 213(g) of the AFA provides that if the new ownership and control provisions or the mortgagee provisions are determined to be inconsistent with an existing international agreement relating to foreign investment to which the United States is a party, such provisions of the AFA shall not apply to the owner or mortgagee on October 1, 2001, with respect to the particular vessel and to the extent of the inconsistency. MARAD's regulations at 46 CFR 356.53 set forth a process wherein owners or mortgagees may petition MARAD, with respect to a specific vessel, for a determination that the implementing regulations are in conflict with an international investment agreement. Petitions must be noticed in the **Federal Register** with a request for comments. The Chief Counsel of MARAD, in consultation with other Departments and Agencies within the Federal Government that have responsibility or expertise related to the interpretation of or application of international investment agreements, will review the petitions and, absent extenuating circumstances, render a decision within 120 days of the receipt of a fully completed petition.

The Petitioners

Arica Fishing Company Limited Partnership ("Arica Fishing Co.") is the owner of the Vessel. Arica Fishing Co. is owned by JOMM Enterprises, Inc, the General Partner, and limited partners Royal Greenland Inc.-USA, JZ, Ltd., Kenneth Morrison, and Robert F. Allen. Royal Greenland Inc.-USA directly owns 47% of Arica Fishing Co. and indirectly owns an additional percentage through its participation in both JOMM Enterprises, Inc. and JZ, Ltd.. Royal Greenland, Inc.-USA is a Washington State Corporation that holds an aggregate interest at all tiers of the partnership ownership structure of approximately 54%.

Royal Greenland, Inc.-USA is a subsidiary of Royal Greenland Trading ApS, a Danish company registered in Denmark. In 1994, Royal Greenland Trading ApS was approached to invest in U.S. fishing operations on the West coast of the United States. The following year Royal Greenland agreed to make these investments through a U.S. subsidiary, Royal Greenland Inc.-USA. Arica Fishing Co, Royal Greenland, Inc.-USA, Royal Greenland Trading ApS, JOMM Enterprises, Inc. and JZ, Ltd are hereafter collectively referred to as the "Petitioner" or "Petitioners."

Requested Action

The Petitioners seek a determination from MARAD under § 213(g) of the AFA and 46 CFR 356.53 that they are exempt from the U.S. citizen ownership and control requirements of the AFA and 46 CFR part 356 on the grounds that the requirements of the AFA and 46 CFR part 356, as applied to Petitioners with respect to the Vessel, conflict with U.S. obligations under the Denmark Treaty. Specifically, the Petitioners request that MARAD determine that the ownership and control restrictions do not apply to Royal Greenland Trading ApS, its wholly-owned subsidiary Royal Greenland, Inc.-USA, or its equity ownership in the Vessel, through its ownership interest in Arica Fishing Company Limited Partnership, JOMM Enterprises, Inc., and JZ, Ltd.

Petitioner's Description of the Conflict Between the FCN Treaty and Both 46 CFR Part 356 and the AFA

MARAD's regulations at 46 CFR 356.53(b)(3) require Petitioners to submit a detailed description of how the provisions of the international investment agreement or treaty and the implementing regulations are in conflict. The entire text of the Denmark Treaty is available on MARAD's internet site at *http://www.marad.dot.gov*. The description submitted by the Petitioner of the conflict between the Denmark Treaty and both the AFA and MARAD's implementing regulations forms the basis on which the Petitioner requests that the Chief Counsel issue a ruling that 46 CFR part 356 does not apply to Petitioner with respect to the Vessel. The Petitioner's description of how the provisions of the Denmark Treaty are in conflict with both the AFA and 46 CFR Part 356 is as follows:

Summary of Argument

The ownership and control provisions of the AFA are directly inconsistent with the U.S-Denmark Treaty of Friendship, Commerce and Navigation (the "Denmark Treaty"), an existing international agreement relating to foreign investments to which the United States is a party. The issue is relevant because there is investment by Royal Greenland Trading, a Danish company, in the U.S. flag fishing vessel Arica that would be directly impaired by the AFA. Specifically, the AFA's unambiguous, retroactive discrimination against fishing companies with foreign ownership interests, for the benefit of super-majority U.S. owned fishing companies—as applied to Danish investment in such companies—is directly at odds with the Denmark Treaty.

The purpose of the Denmark Treaty is to encourage investment between the United States and Denmark. The Treaty prohibits the impairment of rights legally acquired by Danish investors in U.S. enterprises. The Denmark Treaty also explicitly accords Danish investors national treatment—treatment by the U.S. government as if such investors were U.S. nationals, with respect to their investments in the United States. Most plainly, the Denmark Treaty explicitly forbids interference with Danish investors'

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rights to manage enterprises which they have established or acquired.

Therefore, under Section 213(g) of the Act, the irreconcilable conflict between the investment protection provisions of the Denmark Treaty and the AFA's retroactive impairment of Royal Greenland Trading's investment rights requires Marad to grant this petition to exempt from the U.S. citizen ownership and control requirements of the AFA Royal Greenland Trading's equity ownership in the Arica (through its ownership interest in Arica Fishing Company Limited Partnership, JOMM Enterprises, Inc., and JZ, Ltd.).

The U.S. Treaties of Friendship, Commerce and Navigation Are a Class of International Agreements Protecting Bilateral Investment

The Denmark Treaty was one of a group of post-World War II treaties designed to create open-door investment between the U.S. and nearly twenty other countries. Unlike previous agreements, these "Friendship, Commerce and Navigation" treaties dealt explicitly with corporate investment between countries.

The purpose of the FCN treaties in the post-war period was to provide a stable environment for private international investment.[14] The FCN treaties sought "national treatment,"[15] and were intended to create an "open door" for foreign investment.[16] After the war, the United States "took the lead in developing [a liberal] international investment regime, and began to negotiate a series of Friendship, Commerce and Navigation treaties, a major purpose of which was to protect U.S. investment abroad."[17]

Federal courts recognized the FCN treaties as "the medium through which the U.S. and other nations could provide for the rights of each country's citizens, their property and their interests, in the territories of the other."[18] The treaties were the means by which nationals of each country could "manage their investment in the host country."[19]

These FCN treaties "define the treatment each country owes the nationals of the other; their rights to engage in business and other activities within the boundaries of the former; and the respect due them, their property and their enterprises."[20] Foreign investment issues were a centerpiece of the Treaties' purpose:

"[The FCN treaties] preoccupation with [national treatment issues] has been especially responsive to the contemporary need for a code of private foreign investment; and their adaptability for use as a vehicle in the forwarding of an investment aim follows from their historical concern with establishment matters."[21]

The FCN Treaties reached after World War II, had:

"a new consideration * * * which lent special impetus to the program following World War II, [that consideration] was the need for encouraging and protecting foreign investment, responsively to the increasing investment interests of American business abroad and to the position the United States has now reached as principal reservoir of investment capital in a world which has become acutely "economic development" conscious."[22]

It is also important to note that the FCN Treaties, including the Denmark Treaty, are self-executing treaties, that is, they are binding domestic law of their own accord, without the need for implementing legislation.[23] Such treaties are the supreme law of the land, and even federal statutes "ought never to be construed to violate the law of nations if any other possible construction remains."[24] Only when Congress clearly intends to depart from the obligations of a treaty will inconsistent federal legislation govern.[25]

The U.S.-Denmark Treaty of Friendship, Commerce and Navigation Protects Danish Investment in U.S. Companies and is Clearly Inconsistent with the American Fisheries Act

The Denmark Treaty contains 26 Articles, several of which contemplate, and expressly prohibit, retroactive limitations on foreign investment in U.S. companies, such as those imposed by the AFA.[26]

A. Proclamation: Encouraging International Investment

The first provision of the Denmark Treaty, entitled "A Proclamation," contains broad language relevant to an understanding of the subsequent Treaty Articles relating to bilateral investment. The Proclamation states:

"The United States of America and the Kingdom of Denmark, desirous of strengthening the bonds of peace and friendship traditionally existing between them and of encouraging closer economic and cultural relations between their people, and *being cognizant of the contributions which may be made toward these ends by arrangements encouraging mutually beneficial investments*, promoting mutually advantageous commercial intercourse and otherwise establishing mutual rights and privileges, have resolved to conclude a Treaty of Friendship, Commerce and Navigation, based in general upon the principles of national and of most-favored-nation treatment unconditionally accorded * * *" (emphasis added).

By emphasizing the importance of international investments, the Proclamation provides the Denmark Treaty's context for interpreting its investment protection provisions.[27] In entering into this Treaty, the United States recognized, and accepted as "consideration," the advantages provided by

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[14] Walker, Modern Treaties of Friendship, Commerce and Navigation, 42 Minn. L. Rev. 805 (1958). Herman Walker, Jr., the chief commentator on the purpose of the Friendship, Commerce and Navigation ("FCN") treaties, served, at the time of the drafting of the Treaty as Adviser on Commercial Treaties at the State Department and was responsible for formulation of the postwar form of the FCN Treaty, negotiating several of the treaties for the Untied States. See *Sumitomo Shoji America Inc.* v. *Avagliano et al.*, 457 U.S. 176, 182 (1982).

[15] Walker, *Modern Treaties of Friendship, Commerce and Navigation*, 42 Minn. L. Rev. 817 (1958).

[16] "National Treaties" is defined by Article XXII of the Denmark Treaty as "treatment accorded within the territories of a Party upon terms no less favorable than the treatment accorded therein, in like situations, to nationals, companies, products, vessels or other objects, as the case maybe, of such parties." National treatment in to be accorded automatically and without condition of reciprocity (*Sullivan Report* at page 64; see, infra at p.5 fn. 19.)

Harold F. Lidner, Deputy Assistant Secretary of State for Economic Affairs, testified before the Senate during hearings on ratification of the Denmark Treaty (among others) and corrected U.S. Senator Sparkman at this hearing on his misapprehension that "national treatment" meant treatment of U.S. nationals in a foreign nation in the same way foreign nations were treated in the United States, clarifying that it meant, instead, treatment of foreign nationals in the U.S. exactly as U.S. citizens are treated. Hearing Subcommittee on Commercial Treaties and Consular Conventions, at p. 7, 82nd Cong. (May 9, 1952).

[17] Vandevelde, *Sustainable Liberalism and The International Investment Regime*, 19 Mich. J. Int'l L. 373 (1998).

[18] *Spiess* v. *C. Itoh and Co. (Am.) Inc.*, 643 F.2d 353, 361 (5th Cir. 1981), vacated on other grounds, 457 U.S. 1128 (1982), quoting Walker, *Treaties for the Encouragement and Protection of Foreign Investment: Present Untied States Practice 5 Am J. Comp. L. 229 (1956).*

[19] *Lemnitzer* v. *Philippine Airlines*, 783 F. Supp. 1238 (N.D. Cal. 1991), quoting *Spiess*, supra at 361.

[20] *Wickes* v. *Olympic Airways*, 745 F.2d 363 (6th Cir. 1984), quoting Walker, *Modern Treaties of Friendship Commerce and Navigation*, 42 Minn. L. Rev. 805, 806 (1958).

[21] Walker, *Modern Treaties of Friendship, Commerce and Navigation*, 42 Minn. L. Rev. 805, 806 1958).

[22] *Wickes* v. *Olympic Airways*, 745 F.2d 363 (6th Cir. 1984), quoting Walker, *The Post-War Commercial Treaty Program of the United States*, 73 Pol. Sci. Q. 57, 59 (1957); *See also*, Waldek, Note, Proposals for Limiting Foreign Investment Risk Under the Exon-Florio Amendment, 42 Hastings L.J. 1175, 1235 (1991).

[23] *See e.g., Zenith Radio Corp.* v. *Matsushita Electric Industrial Co. Ltd.*, 494 F. Supp. 1263, 1266 (E.D. Pa. 1980).

[24] *McCulloch* v. *Sociedad Nacional de Marineros de Honduras*, 372 U.S. 10, 21 (1963).

[25] Id. *See also Sumitomo Shoji America, Inc.* v. *Avagliano et. al.*, 457 U.S. 176 (1982).

[26] The conflict between the AFA and certain international treaties has been recognized by one of the principal authors of the Act. Senator Slade Gorton (R–WA), one of the chief sponsors of the final legislation, was quoted in the press shortly after the Act passed questioning the validity of the new ownership provisions in relation to these investment treaties: 'Another provision [of the American Fisheries Act] requires vessels operating in this fishery to have at least 75 percent U.S. ownership three years after the law goes into effect, but [Senator Slade] Gorton said *this "Americanization" feature "may very well be found invalid" under U.S. trade agreements if challenged by foreign ownership interests. Marine Digest and Transportation News* at p. 29 November 1998) (emphasis added).

[27] The Sullivan Report is an Article-by-Article discussion of the standard draft treaty of Friendship, Commerce and Navigation, based on the record of negotiation, State Department messages providing instructions, and internal memoranda dealing with issues raised in the course of negotiations, that was completed in November, 1973. The Sullivan Report states that the standard FCN Treaty Preamble (designated "Proclamation" in the Denmark Treaty "does have legal effect, for the courts rely on it at as a guide to interpretation concerning the applicability of the operative articles." *Sullivan Report* at 62.

foreign investment in this country and protection of U.S. investments abroad.[28] The national treatment benefits of the Danish Treaty are "to be accorded automatically and without condition of reciprocity."[29]

B. Article VIII: Managing Commercial Enterprises

Paragraph 1 of Article VIII of the Denmark Treaty states that nationals of each signatory Nation shall be permitted to:

"constitute companies for engaging in commercial,[30] manufacturing, processing [and] financial * * * activities, and to *control and manage enterprises which they have been permitted to establish or acquire*[31] * * * *for the foregoing and other purposes.*" (emphasis added).

Royal Greenland Trading owns Royal Greenland Inc.-USA, a U.S. entity owning interests through a variety of entities in the fishing vessel Arica. There is no question that Royal Greenland Inc.-USA engages in commercial activities directly or through related entities: the sale of fish harvested by the fishing vessel Arica, and the fish processing undertaken aboard the vessel Arica.[32] Royal Greenland Inc.-USA is also directly engaged in financial activities: e.g., the investment of funds in the U.S. fishing industry.

The AFA would force Royal Greenland Trading to *divest itself of its current ownership and control of Royal Greenland, Inc.—USA*, requiring the sale of *75%* of that company's equity in order for it to be able to maintain its investment in Arica Fishing Company Limited Partnership.[33] Forced divestiture is facially inconsistent with the control and management protections required by Article VIII of the Denmark Treaty, above.

The clear conflict between Article VII.1 of the Denmark Treaty and the AFA can be seen from the stated purpose of the original bill that was eventually enacted as the AFA:

"*to prevent foreign ownership and control of United States flag vessels* employed in the fisheries in the navigable waters and exclusive economic zone of the United States * * *" (emphasis added).[34]

One additional point regarding Paragraph 1 of Article VIII is worthy of note. Article VIII states that it protects the control only of enterprises which a Danish entity has "been permitted to establish or acquire." That is, only retroactive limitations, such as the one here at issue, are forbidden.

2. Paragraph 2: National Treatment

Paragraph 2 of Article VIII states:

"Companies, *controlled by nationals and companies of either Party* and constituted under the applicable laws and regulations within the territories of the other Party for engaging in the activities listed in paragraph 1 of the present Article, *shall be accorded national treatment therein with respect to such activities.*" (emphasis added).

Under the definition of national treatment,[35] paragraph 2 of Article VIII requires that duly constituted companies controlled by Danish entities shall be treated precisely as if they were U.S. investors. Such an obligation can hardly be met by requiring the transfer of ownership and control of a company from Danish investors to U.S. investors.

The U.S. State Department has repeatedly recognized this interpretation of Article VIII. For example, in 1971, the State Department opposed legislation in Guam requiring that 50% of the voting stock of corporations doing business in Guam be owned by U.S. citizens. The State Department took the position that such legislation was inconsistent with Article VII of the Japan FCN Treaty, which, (as do Articles VII and VIII of the Denmark Treaty), establishes a right to national treatment of non-U.S. companies and nationals engaged in business activity.[36]

In sum, the provisions of the AFA requiring retroactive divestment of Danish ownership of a business entity in the United States are facially inconsistent with both paragraphs of Article VIII of the Denmark Treaty that explicitly protect foreign investors engaged in the control of U.S. companies.

C. Article VI, Paragraph 4: Impairment of Interest in Supplied Capital Is Prohibited

Paragraph 4 of Article VI of the Denmark Treaty prohibits:

"*unreasonable or discriminatory measures that would impair the legally acquired rights or interests* within its territories of nationals and companies of the other Party *in the enterprises which they have established, or in the capital*, skills, arts or technology *which they have supplied.*" (emphasis added).

The explicit purpose and effect of the AFA is to discriminate against foreign nationals and companies. The Act's ownership provisions require divestment of substantial equity in U.S. fishing vessels and the loss of future profits from the enterprise. On their face, these provisions directly "impair the legally acquired interests" of Danish investors both "in the enterprises which they have established," and "in their capital * * * which they have supplied."

It is clear from the expressed purposes of the FCN treaties, and from this provision in particular, that their central goal was to encourage capital investment between treaty signatories by protecting potential investors from the fear that government action would retroactively impair equity ownership rights in that investment. It was only in this context of mutually understood and guaranteed investment rights that open invitations to foreign capital to develop the U.S. fishing fleet could be, and was, successful.

Thus, the retroactive forced divestment of owned equity imposed on Danish investors by the AFA directly violates Article VI of the Denmark Treaty, and as such is inconsistent with the Treaty as contemplated under Section 213(g) of the Act.

D. Article VII: National Treatment Required

Paragraph 1 of Article VII of the Denmark Treaty states:

"Nationals and companies of either party shall be accorded * * * national treatment with respect to engaging in all types of commercial * * * [and] * * * financial activities."

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[28] Harold F. Linder, Deputy Assistant Secretary of State for Economic Affairs, testified before the Senate during hearings on ratification of the Denmark Treaty (among others) as follows: ". . . These treaties are not one-sided. They are drawn up in mutual terms, in keeping with their character as freely negotiated instruments between sovereign equals. Rights assured to Americans in foreign countries are assured in equivalent measure to foreigners in this country. Hearing, Subcommittee on Commercial Treaties and Consular Conventions, May 9, 1952 at p. 6

[29] *Sullivan Report* at 64. Although the Denmark Treaty requires investment protection without the requirement of reciprocity, it may be useful to note that a review of the *Jones Study, infra* p. 7 at fn. 23 shows no incidents of State Department conflicts with Denmark under the Denmark Treaty).

[30] The Minutes of interpretation appended to the Denmark Treaty state: "The word "commercial" as used in Article VII, paragraph 1 and Article VIII paragraph 1, does not extend to the fields of navigation and aviation. The word "commercial" "relates primarily but not exclusively to the buying and selling of goods and activities incidental thereto." Royal Greenland Inc. -USA is chiefly concerned with the sale of fishery products and activities incidental thereto. It is also important to note that the term "navigation" does not include commercial fishing. First, the Danish Treaty mentions "national fisheries," and "inland navigation" as separate, independent activities under paragraph 3, Article XIX. "Navigation" is generally defined as "the act of sailing a vessel on water." Black's Law Dictionary, 7th ed. West Publishing, 1999. Finally, it may be important to note that in the Denmark Treaty, the word navigation is represented by the Danish word "sofort," which means transportation activity on sea and would not include fishing or fish processing. Had fishing or fish Processing been intended, the appropriate word would have been "fiskrei."

[31] This provision as well as others found in Article VII of the standard draft treaty examined by the Sullivan Report, is considered "the heart of the treaty." *Sullivan Report* at 124.

[32] See, *e.g.* State Department opposition to H.R. 12275 (expanding the definition of fisheries to include processing activities) as contrary to U.S.-Japan FCN treaty; processing activities under the FCN are entitled even to prospective national treatment, Aug. 17, 1964. *Jones Study* at 80 (citation infra at p. 7 fn 29).

[33] Alternatively, Royal Greenland USA would be forced to sell its direct investment in the Arica Fishing Company, L.P., which would have the same impact on its parent company, Royal Greenland Trading.

[34] S. 1221, 105th Cong. (preamble) (1997).

[35] See supra at p. 3, fn. 9.

[36] The State Department's position on this and other FCN issues are reviewed in the "Jones Study," prepared by Ronny E. Jones for the U.S. State Department, and is a compilation of post-World War II State Department positions on FCN Treaties through 1981. See e.g. State Department position re: Letter to A. Papa (U.S. Attorney General's office) from F.R. Brown (Legislative Counsel of 11th Legislature of Guam), Sept. 27, 1971, *Jones Study* at 76. See also, State Department position concluding under the French FCN Treaty that control and national treatment provisions "bar new discriminatory limitations from being applied to established or authorized operations and rights of a protected foreign company" (differentiating from permissible prospective limitations on ownership), *Jones Study* at 54; State Department position opposing Korean government's restricting foreign majority ownership of companies in certain industries, October, 1972, *Jones Study* at 86; State Department position opposing Thai government's restrictions on majority ownership of companies in some industries. 1972 *Jones Study* at 104–106.

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As set forth above, the AFA directly affects Danish nationals and their companies that are "engaging in * * * commercial and other business activities." Royal Greenland Trading engages in commercial and financial investment activities through a subsidiary, Royal Greenland Inc.-USA. The Denmark Treaty requires that Royal Greenland Trading's commercial and investment activities be accorded national treatment, and as demonstrated above, the AFA's explicit discrimination against non-U.S. citizens violates this national treatment provision when applied to Danish investment.

Paragraph 2 of Article VII *also* requires most-favored-nation treatment with respect to "organizing, participating in and operating companies of [the United States]." Most-favored-nation treatment is defined by Article XXII of the Denmark Treaty as "treatment accorded * * * upon terms no less favorable than the treatment accorded therein, in like situations, to nationals, companies, products, vessels or other objects, as the case may be, of any third country. Thus, it is important to note that *if nationals of any other country are afforded protection under section 213(g) of the Act failure to provide the same protection to Danish nationals would also be inconsistent with Article VII.*

E. Article IX: Protection of Movable Property

Article IX of the Denmark Treaty explicitly applies the protections afforded by the rest of the Treaty, and in particular those protections secured by Articles VII and VIII, to the purchase, ownership and disposition of property.

Paragraph 4 of Article IX sets out the only conditions under which nationals and companies of either party may be required to dispose of property they have acquired.[37] Subparagraph a, Paragraph 4 of Article IX permits such a requirement for movable property so *long as such a requirement conforms to Article VIII, paragraph 1 and all other provisions of the Denmark Treaty.* As set forth above and below, the retroactive equity divestment requirements of the AFA do not conform with Article VIII and the other provisions of the Denmark Treaty. Article IX of the Denmark Treaty, in effect, repeats that ownership of movable property may not be subject to forced retroactive divestiture.[38]

[37] "Nationals and companies of either Party shall be accorded national treatment within the territories of the other Party with respect to acquiring * * * and with respect to owning movable property of all kinds . . . subject to the right of such other Party to limit or prohibit, *in a manner that does not impair rights and privileges secured by Article VIII, paragraph 1,* [See discussion at pp. 58 supra] or by other provisions of the present treaty, alien ownership of particular materials that are dangerous from the standpoint of public safety and alien ownership of interests in enterprises carrying on particular types of activities." (emphasis added).

[38] "The term "discriminatory" as used in this context would comprehend denials of either national or most-favored-nation treatment, or both . . . *the intent is to protect against retroactive impairment of vested rights if the acquisition of such rights was lawful* * * *" (emphasis added). *Sullivan Report* at 115.

F. Article I: Equitable Treatment Required for Danish Interests

Article I of the Denmark Treaty states:

"Each Party shall at all times accord equitable treatment to the persons, property, enterprises and other interests of nationals and companies of the other Party."

This Article was intended to provide a fail safe mechanism in the Treaty to ensure that fair and equitable treatment be afforded to nationals of both countries.[39] The forced divestiture of investments and/or sale of assets cannot be viewed as equitable treatment under any logical reading of Article I. Nevertheless, if this Article has any meaning whatsoever, at the very least, it cannot mean forcing a sale of valuable assets, such as the equity interest in a fishing company.

G. Article VI, Paragraph 3: Taking of Property Requires Just Compensation

Paragraph 3 of Article VI of the Denmark Treaty requires that the U.S. government cannot take property belonging to Danish nationals:

"without the prompt payment of just compensation. Such compensation shall be in an effectively realizable form and shall represent the full equivalent of the property taken; and adequate provision shall have been made at or prior to the time of taking for the determination and payment thereof * * * "

There is no practical difference between forcing a sale of property to the U.S. government and forcing such a sale to American nationals.[40] Thus, to the extent that a forced sale of property (1) diminishes the value of the asset for the company by virtue of the AFA's passage; or (2) results in a below-market sale of assets, the AFA violates Article VI,[41] as it makes no provision for compensation of Danish investors.[42] [43]

H. Article XIX: Vessels Flying the U.S. Flag are Deemed U.S. Vessels For Purposes of Access to U.S. Fisheries

Paragraph 4 of Article XIX of the Denmark Treaty states:

"each Party may reserve exclusive rights *and privileges to its own vessels* with respect to * * *. *national fisheries.*" (emphasis added).

This provision allows the U.S. and Denmark to reserve exclusive rights and privileges to "its own vessels" operating in the fisheries of their respective countries. The national identity of a vessel is determined by the country in which the vessel is documented, *i.e.* by the flag that it flies. The national identity of a vessel is not determined by the nationality of the investor in the owning entity.[44]

The Arica is a U.S. vessel documented under the laws of the United States. The U.S. entity owning this U.S. flag vessel—like General Motors, Ford Motor Company and Coca-Cola—has foreign investors. The purpose of this provision in the Treaty was to allow the United States and Denmark the opportunity to restrict fisheries to vessels each country could control. That control, historically, has always been through the flag of the vessel, subjecting the vessel to our environmental, labor and tax laws—not to

[39] This Article "provides a basis for making representation against actions detrimental to [a signatory's] interests that may not be covered by any specific legal rule in the treaty, as, for example, a measure that is superficially nondiscriminatory but is so framed as to harm only some [signatory's] interest * * *. the construction leading to a just or equitable result is to be preferred." *Sullivan Report* at 67. See also, Webster's New Universal Unabridged Dictionary, Barnes and Noble Books, 1996, "Equitable: Characterized by equity or fairness; just and right; fair; reasonable: *equitable treatment of all citizens*"; Black's Law Dictionary, 7th ed. West Publishing, 1999, "Equitable: just; conformable to principles of justice and right."

[40] The rule of just compensation covers partial takings. In such cases, the compensation should be a full approximation of the amount by which the taking impaired the value of the property." *Sullivan Report* at 117.

[41] At the very least, paragraph 3 of Article VI requires application of a standard similar to that under the 5th Amendment to the United States Constitution. Paragraph 5 of Article VI requires that Danish citizens "shall in no case be accorded * * * less than national treatment * * * with respect to the matters set forth" in paragraph 3. No federal court would permit the government to force a sale of assets by a U.S. citizen, thus denying that citizen any use of that property in the future, without requiring just compensation. Further, the Danish Protocol 2 appended to the Denmark Treaty requires that the provision of Article VI for payment of just compensation shall extend to interests held directly or indirectly by nationals and companies of either party.

[42] "The intent of this requirement [that provision is made for the determination and payment of compensation] is to afford protection against *ex post facto* proceedings that could work to the disadvantage of the person whose property is taken." *Sullivan Report* at 119.

[43] Even with respect to the forced sale of "materials dangerous from the standpoint of public safety," permitted under Article IX of the Treaty, the Danish Treaty requires that "a term of at least five years shall be allowed in which to effect such disposition." Subparagraph b, Paragraph 4, Article IX.

[44] In order to be documented under the U.S. flag, for example, a vessel must be owned by a U.S. citizen corporation, partnership or other entity. There is no limitation on the citizenship of the investment for the basic documentation. 42 U.S.C. 12102(a). Should the vessel be used in specific trades, such as coastwise or fisheries, there may be limitation on the citizenship of the investors. 46 U.S.C. 12106; 12108. It is significant to note that *at the time the Denmark Treaty was signed there was no such limitation on fishing vessels.* It was not until 1988 that a *prospective* limitation was imposed on the citizenship of the investors in an entity owning a vessel with a fisheries endorsement. See, *The Commercial Fishing Industry Vessel Anti-Reflating Act of 1987;* Section 7(b) of Public Law 100–239.

allow the foreign investment capital to be taken.

This issue is further clarified by Paragraph 2 of Article XIX, which states explicitly:

"Vessels under the flag of either Party * * * shall be deemed to be vessels of that Party * * *"

Thus, the United States has the full authority to reserve exclusive rights and privileges to the U.S. flag vessel Arica, ever since Royal Greenland Trading made its first investment in the Vessel. What the United States has not had the right to do under the Denmark Treaty is to take away that investment once it was made. Article XIX does not permit the United States to reserve rights or privileges under the Denmark Treaty for some of "its vessels" (those with super-majority U.S. investment) as against others of "its vessels" (those that include some Danish investment). On the contrary, it guarantees U.S. fishing vessels with Danish investment equal access to U.S. fisheries.

I. Article XXI: Restrictions on the Rights of "Third Country" Nationals Are Not Applicable to the Danish Citizens of Greenland

Greenland is a legal territory of Denmark, not an independent country.[45] Residents of Greenland are Danish citizens. The Danish Constitution of 1953 covers all parts of Denmark, including Greenland. Subsequent to this constitution, Greenland was administered as a department directly under the central Danish government authority. In 1978, a parliamentary statute established Greenlandic "home-rule" effective May 1, 1979 for some internal legal areas. However, Greenland remains a legal part of the sovereign nation, Denmark, and is subject to Danish statutes, such as the "Companies Act."

As stated earlier,[46] Royal Greenland Trading, the Danish company with investment in Arica Fishing Company Limited Partnership, is owned by investors in the Territory of Greenland. Article XXI, Paragraph 1(d) of the Denmark Treaty denies:

"to any company in the ownership or direction of which nationals of any *third country or countries* have directly or indirectly a controlling interest, the advantages of the present Treaty, except with respect to recognition of juridical status and with respect to access to courts." (emphasis added).

This reservation is a provision to permit piercing the corporate veil when nationals of non-signatories seek to "obtain rights under the treaty through the device of obtaining and exercising interests in companies of the treaty partner * * * *Absent such a provision, such corporate interests could take advantage of the definition of "companies" [in the Treaty], which establishes place of incorporation as the sole test of the nationality of a corporation.*[47] (emphasis added).

Greenland is not a "third country" within the meaning of this provision. Greenland is a territory of Denmark, dependent upon it for foreign policy determinations. It is also facially evident that no "device" to gain the benefits of the Treaty has taken place. The ownership arrangements for Royal Greenland Inc.-USA were completed long before enactment of the AFA. The duly constituted Danish company Royal Greenland Trading has the right to expect the protection afforded all incorporated Danish companies under the Denmark Treaty.

J. Article XXIII: Restriction on the Denmark Treaty's Application to Greenland Does Not Apply to Greenlandic Investment in a Duly Constituted Danish Company

Article XXIII of the Denmark Treaty states:

"The territories to which the present Treaty extends shall comprise all areas of land and water under the sovereignty or authority of each of the Parties, other than Greenland, the Panama Canal Zone and trust Territory of the Pacific. "

As set forth above, Royal Greenland Trading is a duly incorporated Danish company, subject to Danish government authority and chartered by the Danish Crown. Royal Greenland Trading is located at Langerak 15, 9220 Aalborg, Denmark. Overall, Royal Greenland Trading's affiliated companies have several hundred employees in Denmark. Article XXII, Paragraph 3 states:

"* * * Companies constituted under the applicable laws and regulations within the territories of either Party shall be deemed companies thereof and shall have their juridical status recognized within the territories of the other 'party.'"

Thus, the Denmark Treaty is absolutely explicit that:

"*the place of charter or incorporation [i]s the sole fact determining the nationality of the company.* This test is in contrast to the so-called 'seat' test favored in some European countries where the location of the real center of management of the company or the place or places where its principal activities are carried on are looked to as determining its nationality, even though its incorporation may be in another country. Under the test of place of incorporation, there is no specific requirement of a substantial de facto contact of the company with the chartering country other than the issuance of the charter * * * Adoption of the single test of place of incorporation was based in part on the practical consideration that it makes the nationality of a company simple and easy to determine."[48] (emphasis added).

The only exception to this "place of charter or incorporation" rule, is that set forth in Article XXI of the Denmark Treaty discussed in Section I above. As discussed, Danish citizen investors residing in Greenland do not fall within the narrow exception for third country nationals seeking by device to take advantage of another nation's favorable trade relations. Therefore, Royal Greenland Trading must be afforded the protections for Danish companies under the Denmark Treaty.

In addition, it is important to recognize that Article XXIII was not intended to preclude protection for the Danish nationals of Greenland and their companies, to which Danish law applies. It appears clear that this exception was intended to protect areas having special territorial, commonwealth or merely military relationships with their home countries, such as the Panama Canal Zone and the U.S. Trust Territory of the Pacific Islands. Such policy rationales are not applicable to investments by the Danish citizens of Greenland in their host country.

V. Conclusion: Royal Greenland Trading is Entitled to an Exemption Under Section 213(g) of the American Fisheries Act Because the Act's Retroactive Ownership and Control Provisions are Inconsistent With the Denmark Treaty.

The Danish Treaty clearly contemplates the very category of investment restrictions here at issue. It is important to recognize that should the United States or Denmark have wished to exclude investment in the fishing industry vessels of one party on behalf of the nationals or companies of the other, they could easily have done so. For example, Article XIV of the Treaty relates to prohibitions and restrictions on imports. Paragraph 4 of Article XIV explicitly excludes from the protections of the Article "advantages accorded * * * products of [each country's] national fisheries." Similarly, Paragraph 4 of Article XIX reserves exclusive rights and privileges to each signatory's own vessels with respect to national fisheries. The Treaty simply does not permit forced divestment of investment—or a prohibition on management of that investment—in U.S. companies operating in the national fisheries.

The overlapping, self-reinforcing investment protections provided by the several Articles analyzed in this petition were clearly intended to prohibit the category of coerced retroactive investment divestiture required by the AFA. The Treaty's explicit agreement as to a national's right to control interests in companies they have established in each Treaty partner's territory, its requirement for the highest possible degree of investment protection—national treatment, and its prohibition of the impairment of equity rights gained by supplied capital, are all, singly and in the aggregate, at odds with the AFA's ownership provisions.

If the investment of Royal Greenland Trading is not protected, the implications would be significant and the economic climate fostered by the Treaty damaged. Forcing the sale of Danish nationals' assets in the industry they helped to create would likely make more far reaching free trade agreements difficult. The United States has long been a champion worldwide of free market investment, often decrying other governments' actions in restricting their import markets, currencies and venture capital opportunities. To interpret the Treaty

[45] "Greenland first came under Danish rule in 1380. In the revision of the Danish Constitution in 1953, Greenland became part of the Kingdom and acquired the representation of two members in the Danish Folketing * * * Greenland is part of the Kingdom of Denmark, and the Danish Government remains responsible for foreign affairs, defense and justice." *The Europa World Year Book* 1999, Europe Publications Ltd. (1999); Volume I at pp 1203–04.

[46] See *Exhibit A* and discussion accompanying supra at p.2 fn. 6.

[47] *Sullivan Report* at 308.

[48] *Sullivan Report* at 318–20.

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so as to permit enforced, retroactive loss of assets, and the expulsion of Danish nationals overseeing their own investments from their corporate positions may seriously weaken the standing of the U.S. to continue in its leadership role.

Marad should therefore grant Royal Greenland Trading's petition pursuant to Section 213(g) of the AFA and 46 C.F.R. 356.53 promulgated thereunder, and rule that the citizen ownership and control restrictions in the Act and those portions of 46 C.F.R. Part 356 that implement those restrictions do not apply to Royal Greenland Trading ApS (or its wholly-owned subsidiary) with respect to its ownership equity in the vessel Arica (O.N. 550139), through its ownership interest in Arica Fishing Company Limited Partnership, JOMM Enterprises, Inc., and JZ, Ltd.

This concludes the analysis submitted by Petitioner for consideration.

Dated: January 11, 2001.

By Order of the Maritime Administrator.

Joel Richard,

Secretary, Maritime Administration.

[FR Doc. 01–1358 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

Marine Transportation System National Advisory Council

ACTION: National Advisory Council Public Meeting.

SUMMARY: The Notice of Marine Transportation System National Advisory Council Public Meeting which was published in the January 12, 2001 issue of the **Federal Register** contains an error. The meeting, scheduled for Friday, February 2, 2001, will begin at 8:30 a.m., not 9:00 a.m., as originally stated.

FOR FURTHER INFORMATION CONTACT: Raymond Barberesi, (202) 366–4357; Maritime Administration, MAR 830, Room 7201, 400 Seventh St., SW., Washington, DC 20590; Raymond.Barberesi@marad.dot.gov.

(Authority: 5 U.S.C. App 2, Sec. 9(a)(2); 41 CFR 101–6. 1005; DOT Order 1120.3B)

Dated: January 11, 2001.

Murray A. Bloom,

Acting Secretary, Maritime Administration.

[FR Doc. 01–1415 Filed 1–16–01; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33990]

C & C Railroad, Inc.—Operation Exemption—Centerpoint Properties, L.L.C.

C & C Railroad, Inc. (C & C), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire the operating authority on eight rail lines (lines) owned by Centerpoint Properties, L.L.C. (Centerpoint), and leased to The Custom Companies, Inc. (previously Custom Cartage, Inc.). The lines total about 1.71 miles and they connect with track located in the Union Pacific Global Two Intermodal Yard, near Union Pacific milepost 3.0. The lines are located in an office, warehouse, and dock facility at 317 West Lake Street in Northlake, IL.[1]

The transaction is expected to be consummated on the effective date of the exemption. The earliest the exemption can be consummated is January 9, 2001, the effective date of the exemption (7 days after the exemption was filed).[2]

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to reopen the proceeding to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33990, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Michael A. Abramson, Esq., 120 S. Riverside Plaza, Suite 1200, Chicago, IL 60606.

Board decisions and notices are available on our website at "WWW.STB.DOT.GOV."

Decided: January 9, 2001.

Vernon A. Williams,

Secretary.

[FR Doc. 01–1331 Filed 1–16–01; 8:45 am]

BILLING CODE 4915–00–P

[1] Pursuant to an agreement with The Custom Company, Inc., C & C will acquire the right to operate the lines for the purpose of shuttling cars solely on Centerpoint's property.

[2] On January 8, 2001, a petition to stay the effective date of the exemption was filed by Joseph C. Szabo, on behalf of United Transportation Union-Illinois Legislative Board. The petition for stay was denied in *C & C Railroad, Inc.—Operation Exemption—Centerpoint Properties, L.L.C.*, STB Finance Docket No. 33990 (STB served Jan. 8, 2001).

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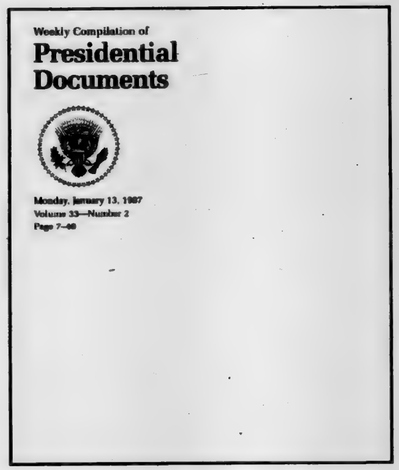
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Federal Register

Wednesday,
January 17, 2001

Part II

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

21 CFR Part 291

42 CFR Part 8

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Service Administration

21 CFR Part 291

42 CFR Part 8

[Docket No. 98N–0617]

RIN 0910–AA52

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction;

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services and the Substance Abuse and Mental Health Services Administration (SAMHSA) are issuing final regulations for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. This final rule repeals the existing narcotic treatment regulations enforced by the Food and Drug Administration (FDA), and creates a new regulatory system based on an accreditation model. In addition, this final rule shifts administrative responsibility and oversight from FDA to SAMHSA. This rulemaking initiative follows a study by the Institute of Medicine (IOM) and reflects recommendations by the IOM and several other entities to improve opioid addiction treatment by allowing for increased medical judgment in treatment.

DATES: This final rule will become effective on March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), SAMHSA, Rockwall II, 5600 Fishers Lane, Rm 12–05, Rockville, MD 20857, 301–443–0457, email: nreuter@samhsa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 22, 1999, (64 FR 39810, July 22, 1999, hereinafter referred to as the July 22, 1999, notice or July 22, 1999, proposal) SAMHSA, FDA, and the Secretary, Health and Human Services (HHS), jointly published a Notice of Proposed Rulemaking (NPRM) to revise the conditions for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. The agencies also proposed the repeal of the existing narcotic treatment regulations enforced by the FDA, the creation of a new regulatory system based on an accreditation model under new 42 CFR part 8, and a shift in administrative responsibility and oversight from FDA to SAMHSA.

The July 22, 1999, notice traced the history of Federal regulatory oversight of Opioid Treatment Programs ("OTPs," also known as narcotic treatment programs, or, methadone programs), focusing on Federal regulations enforced by FDA since 1972. The July 22, 1999, notice summarized the periodic reviews, studies, and reports on the Federal oversight system, culminating with the 1995 Institute of Medicine (IOM) Report entitled, *Federal Regulation of Methadone Treatment* (Ref. 1). As noted in the July 22, 1999, proposal, the IOM report recommended that the existing FDA process-oriented regulations should be reduced in scope to allow more clinical judgment in treatment and greater reliance on guidelines. The IOM report also recommended designing a single inspection format, having multiple elements, that would (1) provide for consolidated, comprehensive inspections conducted by one agency (under a delegation of Federal authority, if necessary), which serves all agencies (Federal, State, local) and (2) improve the efficiency of the provision of methadone services by reducing the number of inspections and consolidating their purposes.

To address these recommendations, SAMHSA proposed a "certification" system, with certification based on accreditation. Under the system, as set forth in the July 22, 1999, proposal, a practitioner who intends to dispense opioid agonist medications in the treatment of opiate addiction must first obtain from SAMHSA, a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from a private nonprofit entity, or from a State agency, that has been approved by SAMHSA to accredit OTPs. Accreditation bodies would base accreditation decisions on a review of an application for accreditation and on surveys (on site inspections) conducted every three years by addiction treatment experts. In addition, accreditation bodies will apply specific opioid treatment accreditation elements that reflect "state-of-the-art" opioid treatment guidelines. Moreover, accreditation standards will require that OTPs have quality assurance systems that consider patient outcomes.

As noted in the July 22, 1999, proposal, this new system would replace the existing FDA regulatory system. The existing system provides for FDA "approval" of programs, with direct government inspection in accordance with more detailed process-oriented regulations. These process-oriented regulations are less flexible and prescribe many aspects of treatment. The existing regulations do not require that programs have quality assurance systems. Finally, under the existing system, programs are not subject to periodic certification and there is no set schedule for inspections.

Proposed Subpart A addressed accreditation and included steps that accreditation bodies will follow to achieve approval to accredit OTPs under the new system. It also set forth the accreditation bodies' responsibilities, including the use of accreditation elements during accreditation surveys. Proposed Subpart B established the sequence and requirements for obtaining certification. This section addressed how and when programs must apply for initial certification and renewal of their certification. Finally, Subpart C of proposed part 8 established the procedures for review of the withdrawal of approval of the accreditation body or the suspension and proposed revocation of an OTP certification.

In addition to proposing an entirely new oversight system, the July 22, 1999, proposal included several other new provisions. For example, the Federal opioid treatment standards were significantly reduced in scope to allow more flexibility and greater medical judgment in treatment. Certain restrictions on dosage forms were eliminated so that OTPs may now use solid dosage forms. Under the previous rules, OTPs were limited to the use of liquid dosage forms. Several reporting requirements and reporting forms were eliminated, including the requirements for physician notifications (FDA Reporting Form 2633) and the requirement that programs obtain FDA approval prior to dosing a patient above 100 milligrams. The proposal included a more flexible schedule for medications dispensed to patients for unsupervised use, including provisions that permit up to a 31-day supply. Under the current regulations, patients are limited to a maximum 6-day supply of medication. Many of these regulatory requirements had been in place essentially unchanged for almost 30 years.

SAMHSA distributed the July 22, 1999, notice to each OTP listed in the current FDA inventory, each State Methadone Authority, and to other interested parties. Interested parties were given 120 days, until November 19, 1999, to comment on the July 22, 1999, proposal. In addition, on November 1, 1999, SAMHSA, FDA, the Office of National Drug Control Policy (ONDCP), the Drug Enforcement Administration (DEA), and other Federal agencies convened a Public Hearing on the proposal. The Public Hearing was announced in the **Federal Register** published October 19, 1999, (64 FR 59624, October 19, 1999), and was held in Rockville, MD. On January 31 and May 10, 2000, the SAMHSA/CSAT National Advisory Council Subcommittee on Accreditation met to assist SAMHSA/CSAT in its review of data and information from SAMHSA/CSAT's ongoing accreditation project. The SAMHSA/CSAT National Advisory Council convened to discuss the opioid accreditation project on May 12, 2000. The May 12, 2000, Council meeting provided an opportunity for comments from the public (65 FR 25352, May 1, 2000).

II. Comments and Agency Response

In response to the July 22, 1999, proposal, SAMHSA received almost 200 submissions, each containing one or more comments. The comments were from government, industry, industry trade associations, academia, health professionals, professional organizations, patient advocacy organizations, and individual patients.

A. General Comments

1. Many comments agreed in principle that the shift to an accreditation-based system will encourage OTPs to use individualized, clinically determined treatment plans that are guided by current, best-practice medical and clinical guidelines and to evaluate clinical outcomes. Other comments noted that the accreditation proposal recognizes that opiate addiction is a medical condition. Several comments affirmed that a major segment of the healthcare system in the United States is being reviewed through accreditation systems. As such, these comments stated that applying accreditation requirements to OTPs provides the potential for mainstream medicine to embrace opioid treatment.

While not opposing the proposal, some comments stated there should be no Federal regulations in this area. Other comments expressed concerns about additional costs to OTPs and, ultimately patients, for accreditation and duplicative assessments, noting that some States will continue to enforce process-oriented regulations, supported by considerable licensing fees. Based upon these "uncertainties," these comments suggest that SAMHSA wait for the results of further study before implementing new regulations.

The Secretary agrees that the SAMHSA-administered accreditation-based regulatory system will encourage the use of best-practice clinical guidelines and require quality improvement standards with outcome assessments. As set forth below, the Secretary does not agree that comments on the uncertainty about accreditation costs or State regulatory activities warrant additional study before implementing these new rules.

2. Several comments addressed the costs associated with accreditation and challenged the estimates provided in the July 22, 1999, proposed rule. One comment included the results from a survey of OTPs with accreditation experience to indicate the indirect costs of accreditation will be considerable. According to the comment, these OTPs have had to spend considerable sums to hire consultants and additional staff, upgrade computers, develop infection control manuals, and make physical plant improvements. In some cases these costs were reported to approach $50,000. Some of these comments suggested that SAMHSA await the completion of the "accreditation impact study" to obtain additional information on costs, before proceeding. Other comments stated that accreditation can lead to increased treatment capacity, but only if additional funds are provided. One comment suggested that SAMHSA create a capital improvement fund, while another suggested that SAMHSA allow block grant funds to be used to pay for accreditation.

The Secretary believes that the estimated costs as set forth in the July 22, 1999, notice remain reasonably accurate. As discussed in greater detail below, information on accreditation developed under the accreditation impact study, together with other ongoing SAMHSA technical assistance programs, indicates that the accreditation system will not produce an excessive burden to programs to warrant delaying the implementation of this final rule.

There are many components to SAMHSA's accreditation project that have been proceeding concurrently with this rulemaking. In April 1999, SAMSHA's Center for Substance Abuse Treatment (CSAT) issued "Guidelines for the Accreditation of Opioid Treatment Programs." These guidelines are up-to-date best-practice guidelines that are based upon the Federal opioid treatment standards set forth under proposed section 8.12 as well as SAMHSA/CSAT's Treatment Improvement Protocols (TIPs) that address opiate addiction treatment. Two accreditation bodies, the Commission for the Accreditation of Rehabilitation Facilities (CARF) and the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), under contract to SAMHSA/CSAT, used these guidelines to develop "state-of-the-art" accreditation elements. These two accreditation bodies have surveyed dozens of programs with these new accreditation standards.

The July 22, 1999, proposal described an ongoing accreditation impact study. Under the accreditation impact study, CARF and JCAHO trained over 170 participating OTPs. In addition, more than 50 OTPs have been accredited under this system with technical assistance provided through a contract funded by SAMHSA/CSAT. None of the accredited programs have had to incur the kind of "physical plant" and other costly expenses predicted by some of the comments previously discussed. This direct and up-to-date information indicates that the cost estimates in the July 22, 1999, notice are up-to-date and reasonable. On the other hand, the survey discussed above that was submitted with one comment reflected accreditation surveys performed over 10 years ago. And, in some cases, the accreditation experiences discussed in these comments reflect accreditation of psychiatric hospitals, not OTPs.

The accreditation-based system which is the subject of this rule includes safeguards to reduce the risk of unnecessary and overly burdensome accreditation activities relating to OTPs. For example, SAMHSA will approve each accreditation body after reviewing its accreditation elements, accreditation procedures, and other pertinent information. SAMHSA will convene periodically an accreditation subcommittee, as part of the SAMHSA/CSAT National Advisory Council. The subcommittee will review accreditation activities and accreditation outcomes and make recommendations to the full SAMHSA/CSAT Council, and ultimately to SAMHSA on accreditation activities and guidelines. Finally, SAMHSA/CSAT has been providing technical assistance to OTPs in the accreditation impact study that has helped programs in achieving accreditation. SAMHSA/CSAT intends to continue providing technical assistance on accreditation during the 3–5 year transition period and possibly longer.

The Secretary does not agree that it is necessary to establish a special fund to help programs pay for accreditation fees and indirect "physical plant" improvements in order for OTPs to be

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able to achieve accreditation. As noted above, the Secretary believes that the estimates in the July 22, 1999, proposal for the cost of accreditation are reasonably accurate (approximately $4–5 million per year, $5400 per OTP per year, $39 per patient per year). Nonetheless, the Secretary has taken steps to minimize the potential effects of this burden to OTPs, especially to OTPs that are small businesses or that operate in under-served communities. First, the Secretary has determined that States could use funds provided by SAMHSA under their Substance Abuse Prevention and Treatment (SAPT) Block Grants to offset costs of accreditation for programs qualified to receive assistance under the State's SAPT block grant. Second, SAMSHA has included in its budget, a plan to continue funding accreditation. Finally, SAMHSA will continue to provide technical assistance which will aid those programs that need help in achieving accreditation.

3. One OTP that is participating in the accreditation impact study, while commending the accreditation experience and accreditation in general, commented that the proposed change is premature. Some comments suggested that SAMHSA postpone implementation for an indefinite period to allow for an unspecified number of CARF and JCAHO accreditation results. Another comment stated that the first series of surveys will determine the utility of the first generation of standards, noting that the process can be focused and modified in response to results from the impact study. A few comments questioned whether all providers can make the transition.

On the other hand, many comments stated that the field has been subject to regulatory neglect long enough, and that SAMHSA should minimize the delay in finalizing rules. One comment submitted the results of a survey that suggested that as many as 155 OTPs currently need technical assistance in order to provide treatment in accordance with standards and regulations.

The Secretary does not believe that these final regulations should be delayed until the completion of the accreditation impact study. As stated in the July 22, 1999, proposal, the Department of Health and Human Services (HHS) has determined that accreditation is a valid and reliable system for providing external monitoring of the quality of health care—including substance abuse and methadone treatment. The SAMHSA/CSAT study is designed to provide additional information on the processes, barriers, administrative outcomes, and costs associated with an accreditation-based system. In addition, the study is expected to provide important information to allow SAMHSA to keep its guidelines, and its accreditation program, as responsive and up-to-date as possible. Among other things, the study will allow HHS to continuously monitor the monetary costs of accreditation, to ensure that successful OTPs are not precluded from operating by the costs of accreditation, and that patients are not denied treatment based on costs. The full study, which compares a representative sample of OTPs 6 months following accreditation to their baseline status across several variables, will require a few years to complete. Regulations can be modified at any time. If SAMHSA believes that the results of the study merit changes in the regulations, then such changes will be the subject of a future rulemaking.

The Secretary has reviewed preliminary results from the accreditation study by two accreditation bodies, CARF and JCAHO, of almost 10 percent (approximately 80 OTPs) of the entire inventory of approved outpatient OTPs. Well over 90 percent of the OTPs surveyed achieved accreditation under the "methadone specific" accreditation standards. Only a very few programs required a follow-up survey to achieve accreditation. And, to date, only one OTP failed to achieve accreditation. These accreditation outcome results are comparable to the historical compliance rate under the previous FDA process-oriented regulatory system. In addition, these rates correspond to the assumed accreditation resurvey rate stated in the July 22, 1999, proposal for estimating the indirect costs of accreditation.

These accreditation outcome results have been analyzed and presented to SAMHSA/CSAT's National Advisory Council's Accreditation Subcommittee (NACAS). As discussed in the July 22, 1999, proposal, SAMHSA/CSAT augmented NACAS with consultants representing OTPs (both large and small programs), medical and other substance abuse professionals, patients, and State officials. The subcommittee has met twice, on January 31 and May 10, 2000, and the public was provided an opportunity to participate in this advisory process. On May 12, 2000, the SAMHSA/CSAT National Advisory Council urged SAMHSA/CSAT to move expeditiously to finalize the July 22, 1999, proposal.

The Secretary believes that the interim results from the accreditation impact study confirm that the accreditation guidelines, along with the accreditation process itself, are a valid and reliable method for monitoring the quality of care provided by OTPs. The results indicate that most OTPs can achieve accreditation and that treatment capacity has not declined as a result. While SAMHSA intends to continue the study to fulfill its objectives, the Secretary does not believe that it is appropriate or necessary to delay implementation of these new rules until the full study is complete.

4. Many comments, especially from current and past OTP patients, questioned the impact of revised Federal regulations in light of State regulations. These comments contend that State regulations are much more restrictive on medical and clinical practices than Federal regulations, and that State regulatory authorities have expressed little or no interest in changing their regulations or the way State regulations are enforced. Comments from OTP sponsors stated that accreditation costs would add to State licensing fees, which, in some States, exceed several thousand dollars annually.

The Secretary shares the concerns expressed in these comments about State regulations and licensing requirements. Indeed, the July 22, 1999, proposal discussed State licensure and regulatory issues. The proposal also noted that there was considerable variation in the nature and extent of oversight at the State level. Some States have regulations and enforcement programs that exceed Federal regulations. Others have relied exclusively upon FDA and DEA regulatory oversight. An increasing number of States rely on accreditation, by nationally recognized accreditation bodies, for all or part of their healthcare licensing functions.

The Secretary believes that SAMHSA's ongoing coordination activities with States will minimize the impact of Federal-State regulatory disparities upon OTPs. One objective of these activities is to increase State authorities' acceptance of the new accreditation-based system. First, SAMHSA/CSAT's OTP accreditation guidelines were developed by a consensus process that included representation from State Methadone Authorities. In addition, some State officials have accompanied CARF and JCAHO accreditation survey teams to observe site visits. Finally, SAMHSA/CSAT has distributed information on accreditation to each State. This information includes the SAMHSA/CSAT OTP accreditation guidelines, the CARF OTP accreditation standards and the JCAHO OTP accreditation standards. SAMHSA/CSAT convened three national meetings of State officials between 1997 and 2000 and intends to continue coordinating activities with State authorities and national organizations such as the National Association of State Alcohol and Drug Abuse Directors (NASADAD).

This final rule includes provisions that would permit any State to apply for approval as an accreditation body and, if approved, accredit OTPs under the new Federal opioid treatment standards. Based on the above, the Secretary expects that many states will consider OTP accreditation and Federal certification requirements as sufficient to fulfill all or a substantial part of their licensing requirements. Taken together, the Secretary believes that these measures will minimize significantly the existing disparity between Federal and State regulation of OTPs.

5. Office-Based Treatment. The July 22, 1999, proposal discussed the concept of "office-based opioid treatment" and specifically solicited comments on how the Federal opioid treatment standards might be modified to accommodate office-based treatment and on whether a separate set of Federal opioid treatment standards should be included in this rule for office-based treatment.

The Secretary received many diverse comments on the office-based treatment issue. Several comments from patients and individual physicians believed that office-based treatment provided an excellent opportunity to expand opioid agonist treatment. These comments reference opioid treatment delivery systems in other countries and suggest that the U.S. should adopt similar systems. A few comments recommended that community pharmacies be encouraged to dispense methadone and LAAM as "medication units" as a way to make treatment more convenient for patients.

While many comments suggested separate standards for office-based treatment, others feared that different standards would result in a two-tiered system of treatment. Overall many comments stated that existing and proposed rules do not facilitate the development of the office-based practice model. As such, accreditation and certification would be prohibitively expensive for individual physicians.

On the other hand, many comments expressed concerns with the concept of "office-based" treatment and prescribing methadone and LAAM. Many of these comments reflected concern about the lack of trained and experienced practitioners. One comment referenced literature reports that described experiences in Australia and the United Kingdom with deaths from iatrogenic methadone toxicity associated with patients early in treatment. The experiences in these two countries were associated with an accelerated rate of patient admissions and the involvement of new, inexperienced practitioners. One comment cited research on methadone medical maintenance that indicated that approximately 15 percent of the patients treated in physicians offices were referred back to OTPs after "relapsing" to illicit opiate use.

Generally, most comments on this issue stated that there was not enough information on office-based practice. These comments suggest that based on the available information, office-based treatment warrants a gradual, step-wise approach, along with more use of medication units. This approach would serve to "diffuse opioid agonist maintenance treatment into traditional settings."

After carefully considering the diverse comments, as well as other legal and regulatory factors, the Secretary is not including in this rule specific standards that would permit physicians to prescribe methadone and LAAM in office-based settings without an affiliation with an OTP. Instead, until additional information is generated, the Secretary is announcing administrative measures to facilitate the treatment of patients under a "medical maintenance" model.

Current regulations enfonced by DEA do not permit registrants to prescribe narcotic drugs, including opioid agonist medications such as methadone and LAAM for the treatment of narcotic addiction (see 21 CFR 1306.07(a)). In addition, the Secretary agrees that, at the present time, there should be some linkage between OTPs and physicians who treat stable patients with methadone and LAAM in their offices to address patients' psychosocial needs in the event of relapse. The Secretary agrees with the comments about the lack of trained and experienced practitioners to diagnose, admit, and treat opiate addicts who are not sufficiently stabilized, without the support of an OTP.

The Secretary has taken steps to facilitate "medical maintenance," that will result in more patients receiving treatment with methadone and LAAM in an office-based setting. Medical maintenance refers to the treatment of stabilized patients with increased amounts of take-home medication for unsupervised use and fewer clinic visits for counseling or other services. First, the "take home" provisions in these rules have been revised from the previous regulations under 21 CFR § 291.505 to permit stabilized patients up to a one-month supply of treatment medication. In addition, SAMHSA/CSAT has developed treatment guidelines and training curricula for practitioners to increase the information and education for practitioners in this area. Finally, SAMHSA/CSAT has issued announcements to the field explaining how patients and treatment programs can obtain authorizations for medical maintenance. These authorizations were developed to address program-wide exemptions under 21 CFR 291.505; however, SAMHSA/CSAT envisions a similar approach will be used under the program-wide exemption provisions of 42 CFR 8.11(h).

Under the medical maintenance model, office-based physicians maintain formal arrangements with established OTPs. Typically, patients who have been determined by a physician to be stabilized in treatment may be referred to office-based physicians. It has been estimated that over 12,000 current patients would be eligible for medical maintenance treatment. The Secretary believes that this is a reasonable approach that will expand treatment capacity gradually while additional information and experience is developed to evaluate and refine office-based treatment models.

B. Comments on Subpart A—Definitions and Accreditation

Proposed subpart A sets forth definitions as well as procedures, criteria, responsibilities and requirements relating to accreditation.

1. A comment from a State authority suggested that the treatment plan definition under § 8.2 should be modified to require a reference to the services determined necessary to meet the goals identified in the plan. The Secretary agrees with this suggestion and has revised the treatment plan definition accordingly.

2. One comment suggested that the proposed definition of detoxification treatment specifies agonist and therefore precludes the use of mixed agonist or agonists in combination with other drugs. The Secretary has announced plans to develop new rules specifically for partial agonist medications for the treatment of opiate addiction (See 65 FR 25894, May 4, 2000). Therefore, use of the term "agonist" is appropriate in this context.

The use of "other drugs" (interpreted to mean non-narcotic substances) in combination with methadone and LAAM are not subject to the regulatory requirements of this rule.

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3. Several comments were submitted on the proposed definition of opiate addiction. Some comments suggested that the definition should be revised to remove behavior-oriented concepts and rely on medical constructs only. One comment suggested substituting the definition of opiate addiction contained in the recent NIH consensus panel report. The Secretary concurs, and has revised the definition of opiate addiction to be more consistent with the recent NIH Consensus panel's recommendations.

4. A few comments were concerned that there would be only two accreditation bodies, CARF and JCAHO. In addition, these comments reflect concern that accreditation would be an additional requirement on top of existing FDA regulations.

As proposed in the July 22, 1999, notice (section 8.3(a)) any private nonprofit organization, State governmental entity, or political subdivision thereof, capable of meeting the requirements of subpart A is eligible to apply to become an accreditation body under the new rules. As discussed elsewhere in this final rule, some State authorities have contacted SAMHSA and expressed interest in becoming an accreditation body under subpart A. In addition, a number of non-governmental entities have expressed similar interest. Accordingly, the Secretary believes that there will be more than two accreditation bodies that seek and obtain approval to become an accreditation body under these rules.

The requirements for accreditation and SAMSHA certification under this final rule will replace the requirements for FDA approval of OTPs under previous regulations. The previous regulations in place under 21 CFR 291.505 will be rescinded on March 19, 2001.

5. The Secretary received a considerable number of diverse comments from State authorities, OTPs, and patients on the provision proposed under section 8.3(a) that would permit States to serve as accreditation bodies under the new rules. The preamble to the July 22, 1999, notice emphasized the need for States to consider serving as accreditation bodies. This emphasis was based upon the recommendation in the IOM Report that strongly suggested that the Federal Government design a consolidated inspection system that reduces the burden on OTPs from multiple (Federal, State, local) inspections.

State authorities provided a mixed response in their comments on this issue. As discussed below, several States expressed an interest in becoming accrediting bodies under the new rules but believed that they were ineligible because they could not accredit 50 OTPs a year under proposed section 8.3. On the other hand, many States indicated that they were not interested in becoming accreditation bodies, while several indicated that they were undecided and would await additional information.

Comments from OTPs, for the most part, reflect a longstanding cooperative relationship with State regulatory authorities. OTPs, in general, did not appear to oppose the concept of State authorities serving as accreditation bodies under the proposed new system. Indeed, some OTPs, located within States that assess extensive licensing fees, commented that it would be imperative that States take on the role of accreditation bodies under the new system in order to eliminate the financial impact of licensing and accreditation fees.

Comments from patients on this issue suggested caution. Many patients sensed that State regulators would retain strict, "process-oriented" regulations or philosophies. These comments urged that if SAMHSA permitted States to serve as accreditation bodies then the agency should carefully monitor accreditation standards and practices to assure that they conform with the Federal opioid treatment standards.

After considering the comments on this issue, the Secretary is retaining the provision that allows States to serve as accreditation bodies under the new rules. The Secretary acknowledges that many States will choose not to participate as accreditation bodies. Some of these States already accept accreditation by recognized accreditation bodies for licensing purposes. It is expected that more States, especially States with relatively few OTPs, will also choose to accept accreditation as meeting State licensure requirements in time. Indeed, legislation enacted recently in New Hampshire to allow methadone maintenance treatment incorporated a requirement for CARF accreditation (Ref. 2). Finally, some States will apply accreditation reviews and findings to complement their licensing activities. The Secretary recognizes that the States' role in adapting to the new system will change over time as additional information on accreditation is developed.

The Secretary believes that there are adequate safeguards to address patient concerns about overly restrictive State regulations and oversight. Under section 8.3(b)(3), SAMHSA will review each applicant accreditation body's proposed accreditation standards. As part of this review, SAMHSA will determine the extent to which the accreditation standards are consistent with the Federal opioid treatment standards. In addition, under section 8.5, SAMHSA will evaluate periodically the performance of accreditation bodies by inspecting a selected sample of the OTPs accredited by the accreditation body. As part of this effort SAMHSA may also consider follow-up inspections in cases where accreditation activities identify public health, public safety, and patient care issues.

The Secretary continues to believe, as outlined in the July 22 proposal, that there are benefits to States serving as accreditation bodies under this rule. This feature provides the potential to reduce the overall number of OTP inspections. It also permits the use and application of the vast expertise available within many State oversight agencies.

6. A number of State authorities and an accreditation body questioned the restriction under proposed section 8.3(b)(3) that would require accreditation bodies to be able to survey no less than 50 OTPs annually. Some comments contend that this would unfairly and inappropriately exclude smaller States or States with fewer OTPs from participating. These comments suggested that other requirements should be considered and applied or a waiver provision added. One accreditation body commented that accreditation bodies recognized by the Health Care Financing Administration are not subject to such arbitrary limitations. Other comments suggested that the 50 survey per year minimum was not necessary to achieve its stated purpose—to ensure the quality of accreditation services and minimize the variability of accreditation standards.

The Secretary concurs with these comments. The provisions of section 8.3(b)(3) (submission and review of proposed accreditation standards) and section 8.5 (periodic evaluation of accreditation bodies) are adequate to enable SAMHSA to ensure the quality of accreditation services and minimize the potential variability in accreditation standards. Accordingly, section 8.3(b) has been modified to remove this requirement.

7. A few comments suggested that State authorities and patient advocates should be permitted to participate in the approval of accreditation bodies under the new rules and in the accreditation process in general. These comments believe that they can make substantial contributions to the process.

The Secretary agrees that patients and State authorities can contribute substantially to the successful operation of the new system. State authorities and patients have participated in the committees that have developed SAMHSA/CSAT's Accreditation Guidelines. In addition, representatives from both these groups have served on the Accreditation Subcommittee of the SAMHSA/CSAT National Advisory Council. Accreditation standards include several provisions designed to solicit and consider individual patient views regarding treatment planning and other areas. Some, though not all, accreditation bodies also have patient hotlines that allow patients to convey concerns directly to accreditation bodies. Finally, SAMHSA and State authorities will continue to consult and interact under the new rules. The Secretary believes that these measures are adequate to assure the appropriate level of State authority and patient input into the accreditation process.

8. Several comments addressed proposed section 8.3(b)(6), pertaining to the qualifications of accreditation body personnel and proposed section 8.4(h) on accreditation teams. One State authority objected that the requirement that there be a licensed physician on the accreditation body staff was an unnecessary expense to accreditation bodies. Another comment recommended that accreditation teams should include a physician certified for dispensing opioids. Some patients advocated that the accreditation team should include a current patient.

The Secretary believes the requirements for accreditation personnel and accreditation teams as set forth in the July 22, 1999, proposal are sufficient. It is not clear that every OTP would benefit from having a physician or opioid agonist patient on the accreditation team. The Secretary has reviewed the results of accreditation surveys under the SAMHSA/CSAT methadone accreditation project. Based on these reviews, the requirements set forth under section 8.4(h) are adequate to assure that accreditation bodies carefully consider the qualifications of accreditation surveyors and accreditation teams.

9. A considerable number of comments were submitted, mostly by State authorities, concerning the absence of a definition for State authority. These comments suggested that adding a definition for state authority could reduce confusion in States that serve as accreditation bodies. In addition, these comments reflect a belief that this change would help clarify the Federal-State consultation process set forth in the proposed rule. The Secretary agrees with these comments and has added a definition of State Authority. This definition tracks closely with the definition contained in the previous regulations under section 21 CFR 291.505.

C. Subpart B—Certification

Subpart B establishes the criteria and procedures for the certification of OTPs. This section also addresses the conditions for certification and the interaction between the Federal Government and State authorities under the new rules.

1. Many comments from State regulators noted that there was no reference to a requirement that OTPs obtain a license or permit from States before receiving certification from the Federal Government. These comments reflect a concern that SAMHSA may certify a program in a State where no methadone authority exists, or without the knowledge of the State authority. Other comments urged Federal certification to pre-empt State licensing, noting that "initial State approval will remain a de facto requirement."

The Secretary believes that the conditions for certification as set forth in the July 22, 1999, proposal, including the provisions relating to State licensure, are adequate and appropriate to fulfill the objectives of this rule. The Secretary's role in the oversight of narcotic treatment is to set standards for the appropriate use of narcotic drugs in the treatment of addiction, and then to ensure compliance with those standards. The States, on the other hand, have a broader set of responsibilities, including regional and local considerations such as the number and distribution of treatment facilities, the structural safety of each facility, and issues relating to the types of treatment services that should be available. Nothing in this part is intended to restrict State governments from regulating the use of opioid drugs in the treatment of opioid addiction. The Secretary notes that many States exercise this authority by choosing not to authorize methadone treatment at all.

The Secretary does not believe that OTPs will open and begin treating patients without State notification, review, and approval. The Secretary has been careful to state throughout this rule that OTPs (including medication units) must comply with all pertinent State and local laws as a condition of Federal certification. As such, OTPs will also be responsible for assuring that they have the necessary approvals and licensure at the State. Moreover, OTPs must obtain DEA registration prior to accepting opioid addiction treatment drugs for the treatment of opiate addiction. DEA registration is explicitly contingent upon State authority approval. Importantly, as noted below, there will be extensive consultation, coordination, and cooperation between SAMHSA and relevant State authorities.

2. One State regulator requested that the regulation be modified at section 8.11(c)(1) to add a requirement that SAMSHA notify the State upon receipt of applications for certification as well as approval and withdrawal. This comment was based upon a concern that provisionally certified programs could operate without a State's knowledge.

The Secretary agrees that it is imperative for States to be notified of significant certification activities, including new program applications, program suspensions and withdrawals. SAMHSA intends to notify States of all such developments under the provisions of section 8.11(c)(1). The Secretary believes that the rules are sufficiently clear on this point.

3. Some State authorities suggested revising proposed section 8.11(h), which states that SAMHSA "may" consult with State authorities prior to granting exemptions from a requirement under sections 8.11 or 8.12.

Section 8.11(h) permits OTPs to request exemptions from the requirements set forth under the regulation. This represents a continuation of a long-standing provision from the previous regulation under 21 CFR 291.505. The Secretary anticipates that most exemption requests under the new rule will be to permit variations from the treatment standards, including program-wide exemptions for medical maintenance. The Secretary agrees that it is appropriate and necessary to consult with State authorities on requests for variations from existing standards. Accordingly, section 8.11(h) is revised to require consultation with the State authority prior to granting an exemption.

4. Several comments from patients suggested that Federal regulations should prevent States from imposing additional regulatory requirements beyond the Federal regulations. Many of these comments contend that State regulations prevent treatment expansion, hinder accountability for quality treatment, limit patient access, and lead to patient abuses.

As noted above, the Secretary acknowledges the authority within State government to regulate the practice of medicine. This rule does not pre-empt States from enacting regulations necessary to carry out these important responsibilities.

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Many State regulations closely resemble the previous Federal regulations under 21 CFR 291.505. In addition, many States are currently reevaluating their regulations to determine if modifications are necessary to reflect the changes in Federal rules. The Secretary encourages States to consider the new information on changes in the opioid addiction treatment field, including phases of treatment, measuring accountability for improving the quality of patient care, and modern medication dosing practices, as States proceed in revising their regulations.

The Secretary also invites States to continue to enhance their partnership with Federal authorities in this area. As noted above, the final rule includes a new feature—the opportunity for States to serve as accreditation bodies. This new activity adds to existing partnership opportunities, such as the participation in the SAPT Block Grant program and its related technical assistance program. The Secretary hopes that these actions collectively will continue the regulatory reform started with the July 22, 1999, proposal.

5. A few comments expressed concern about proposed section 8.11(e), which permits provisional certification for one year, while a program obtains accreditation. These comments believe that one year was "too long for a program to go without accreditation."

The Secretary believes that the maximum 1-year term (not including the 90-day extension allowed under section 8.11(e)(2)) for provisional certification is reasonable and customary with accreditation in other areas of healthcare. The purpose of this provision is to permit new OTPs to initiate operations and generate patient records to aid in the accreditation application, survey, and review process. It should be noted that OTPs will be subject to SAMHSA, DEA, and State oversight during the tenure of provisional accreditation. These OTPs must comply with Federal opioid treatment regulations and are subject to compliance actions at any time.

6. Section 8.11(i)(2) proposed that certification as an OTP would not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than addiction. One comment noted that, as written, patients admitted to hospitals for cocaine or alcohol addiction would not be eligible for treatment under this provision. The comment suggested that adding the word "opioid" before "addiction" would help to clarify this issue. The Secretary concurs and the section 8.11(i)(2) has been changed to reflect this change.

D. Subpart B—Treatment Standards

1. A number of comments were submitted on proposed section 8.12 in general. These comments stated that the Federal Opioid Treatment standards are vague and lack specificity. As such, these comments contend that the standards are unenforceable as regulations. One comment suggested that the SAMHSA/CSAT Accreditation Guidelines be incorporated as regulations.

The Secretary believes that the Federal Opioid Treatment Standards are enforceable, and do not need to be modified to accomplish their purpose under the new rules. The July 22, 1999, proposal noted that in the past, HHS has attempted to write all facets of treatment, including required services, into regulation. In addition, the proposal acknowledged that it is now accepted that (a) different patients, at different times, may need vastly different services, and (b) the state of the clinical art has changed, to reflect scientific developments and clinical experience, and is likely to continue to change and evolve as our understanding of more effective treatment methods increases. Accordingly, the Secretary proposed a more flexible approach with a greater emphasis on performance and outcome measurement. With guidance from SAMHSA, the accreditation bodies will develop the elements needed to determine whether a given OTP is meeting patient needs for required services. SAMHSA will review these elements as part of the accreditation body's initial and renewal applications to ensure that accreditation bodies have incorporated the Federal opioid treatment standards into their accreditation elements. SAMHSA will also review accreditation body elements to ensure that the elements do not exceed Federal expectations in terms of opioid agonist treatment. Incorporating accreditation guidelines into regulations would subvert this approach.

As noted in the July 22, 1999, proposal, the Secretary believes that the standards are "enforceable regulatory requirements that treatment programs must follow as a condition of certification (64 FR 39810, July 22, 1999)." While the new regulations increase the flexibility and clinical judgement in the way OTPs meet the regulatory requirements, they are set forth under section 8.12 as the services, assessments, procedures, etc., that OTPs "must" and "shall" provide. As such, the new standards are as enforceable as the previous regulations under 21 CFR 291.505. OTPs that do not substantially conform with the Federal Opioid Treatment standards set forth under section 8.12 will risk losing SAMHSA certification.

2. One comment recommended that proposed section 8.12(b) should be modified to require a standard that OTPs should have adequate facilities. The comment stated that this provision existed in the previous regulation. The Secretary agrees and has added a requirement that OTP's must maintain adequate facilities. The Secretary notes, however, that SAMHSA/CSAT accreditation guidelines and accreditation standards used in the SAMHSA accreditation impact study, address the adequacy of the OTP's facility. These accreditation standards, in conjunction with treatment outcomes, will help determine whether facilities are adequate under the new rules.

3. One comment addressed proposed section 8.12(b), stating that rules should expressly require compliance with civil rights laws, not just "pertinent" Federal laws. As such, the comment suggests that the standards should require detailed patient grievance procedures, including appeals to neutral parties. The Secretary believes that it is not necessary to modify the rule to reflect civil rights laws specifically. These laws are included under the requirement as written. In addition, SAMHSA/CSAT Accreditation Guidelines, as well as the accreditation standards developed from them include provisions for accepting and acting upon patient grievances.

4. A number of respondents commented on proposed section 8.12(d) which addresses OTP staff credentials. Under the July 22, 1999, proposal, the Secretary proposed that each person engaged in the treatment of opiate addiction must have sufficient education, training, or experience or any combination thereof, to enable that person to perform the assigned functions. Further, all licensed professional care providers must comply with the credentialing requirements of their professions. The proposal encouraged, but did not require, that treatment programs retain credentialed staff.

Some comments requested that this standard be clarified to require American Society of Addiction Medicine (ASAM)-certified medical professionals. Another comment questioned whether personnel had to be licensed in the State where the treatment program is located. Another comment from a State Authority, recommended that the regulations specify the license, training, experience, as well as the number of licensed counselors in a program, including a minimum counselor-to-patient ratio. On the other hand, an OTP medical director commented that none of the cited credentials "conferred competence in dealing with opioid dependent patients, per se." According to this comment, SAMHSA/CSAT should instead develop curricula for medical directors and other care givers.

Except for the requirements of section 8.12(h), which relate to the qualifications for practitioners who administer or order medications, the Secretary does not believe that it is appropriate to further prescribe the qualifications for health professionals in this regulation. Under sections 8.12(b), (d), (e), (f) services must be provided by professionals qualified by education and training. The Secretary does not believe that one credentialing organization should be specified as a requirement for qualifications. Instead, the Secretary intends to rely on guidelines and accreditation standards together with patient outcome assessments to determine the adequacy of training and education level of professionals in OTPs. SAMHSA/CSAT is actively developing model training curricula in this area.

5. A few comments suggested that the regulations specify the outcome measures for quality assessment plans under section 8.12(c)(1). Similarly, some comments suggested that diversion control plans, which OTPs are required to develop under section 8.12(c)(2), should also be spelled out in regulations.

The Secretary believes that the regulation as proposed provides sufficient detail on outcome measures and diversion control plans. In keeping with the intent of the regulation reform, these general requirements are elaborated in best-practice guidelines and in "state-of-the-art" accreditation standards. Indeed, following a review of the accreditation standards that are based upon SAMHSA/CSAT's opioid treatment accreditation guidelines, the Secretary has determined that they are adequate to ensure that OTPs will be able to develop meaningful outcome assessment and diversion control plans. In addition, these SAMHSA/CSAT accreditation guidelines and accreditation standards reflect the latest research findings in this area. Unlike the Federal regulations, these guidelines and standards will be updated periodically to reflect new research and clinical experience.

6. The Secretary received a considerable number of comments on the proposed definition and the standards for short-and long-term detoxification treatment. Most of these comments suggested that the word "detoxification" is a pejorative non-medical term and does not constitute treatment, because few, if any, patients can be stabilized in such a short period of time. These comments suggested that all references to detoxification should be deleted from the regulations, or at least renamed.

These comments fail to recognize the distinction between opiate dependence, for which detoxification treatment is appropriate, and opiate addiction, for which maintenance treatment is appropriate. The Narcotic Addiction Treatment Act of 1974 (NATA) and regulations have long recognized these distinctions. While a majority of the available treatment research, including recent studies, concludes that maintenance treatment is much more effective than detoxification regimens, the Secretary believes that it is still necessary to retain distinct standards for maintenance and detoxification treatment (Ref. 3).

7. Several comments were submitted in response to the Secretary's specific request for comments on proposed section 8.12(e)(4) which set forth minimum requirements for detoxification treatment. The July 22, 1999, proposal retained the requirement from the existing regulation that "a patient is required to wait no less than 7 days between concluding one detoxification episode before beginning another." Essentially, while sympathetic to the need for limits on detoxification treatment, all the comments on this item opposed continuing any waiting period between detoxification episodes. These respondents believe that seven days is "artificial * * * or more time than is needed." In addition, these comments indicate that OTPs often request and are granted exemptions from the waiting period requirement under the existing regulation, creating an unnecessary paperwork burden for OTPs, as well as State and Federal regulators. Instead, the comments suggested a limit on the number of unsuccessful detoxification episodes in one year before the patient is assessed for opioid agonist maintenance or other treatment. In addition, these comments recommended that an unsuccessful detoxification attempt be defined to include any relapse to abuse.

The Secretary agrees with the recommendations that the intent of the restrictions on detoxification can be accomplished without a mandated time interval between detoxification admissions. The standards for detoxification treatment set forth under section 8.12(e)(2) and (4) have been revised to state that patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. This change is consistent with SAMHSA/CSAT accreditation guidelines which also elaborate on unsuccessful detoxification treatment attempts.

8. A considerable number of diverse comments addressed proposed section 8.12(f) relating to required services. This section of the July 22, 1999, proposal requires that "adequate medical, counseling, vocational, educational and assessment services are fully and reasonably available to patients enrolled in an OTP."

Two comments strongly recommended that the regulation require integrated, simultaneous treatment by specially cross-trained staff, for co-occurring opioid treatment and mental illness. These respondents believe that integrated services for persons with an addiction(s) and a psychiatric disorder are crucial. These dually-diagnosed patients represent 50–80 percent of substance dependent populations.

The Secretary agrees with the importance of providing adequate integrated services for opiate-addicted patients who also suffer from psychiatric disorders. Indeed, the SAMHSA/CSAT Accreditation Guidelines, along with the accreditation standards developed by CARF and JCAHO all address the need to evaluate patients for co-occurring illnesses, including mental illness. CARF Opioid Treatment Program Accreditation Standards state that services for co-occurring illness should be provided on site or by referral. However, the same standards note that "coexisting conditions, especially in persons from disenfranchised populations, are most effectively treated at a single site." The Secretary takes note that these provisions for co-occurring disorders under these new rules will be a vast improvement over the previous regulatory system, which did not address co-occurring opiate addiction and psychiatric disorders at all. As such, under the new rules, patients' access to effective treatment for co-occurring disorders will be enhanced substantially. However, the Secretary believes that it would be prohibitively expensive to require every OTP to hire and retain specialists in the treatment of co-occurring disorders.

Other comments on this section stated that the regulations should specify a schedule for services. Some comments

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recommended that the regulations require OTPs to document that patients actually receive services when they are referred to off-site providers. Other comments suggested that accreditation bodies should monitor the extent to which services are provided as part of their periodic onsite surveys. Still other comments, mostly from patients, suggested the requirement for services be eliminated, maintaining that medication is all they needed.

The Secretary believes that the requirements for services as stated in the July 22, 1999, proposal, together with the accreditation process, provide adequate assurance that patients enrolled in OTPs receive the services that they have been assessed to need. The July 22, 1999, proposal emphasized the need for these services as an essential part of treatment. However, in shifting to an accreditation approach with an emphasis on performance outcomes, the Secretary was no longer attempting to "write all facets of these required services into regulation." OTPs must initially and periodically assess each patient and ensure that adequate services are available to patients determined to need them. SAMHSA/CSAT Accreditation Guidelines and accreditation standards will elaborate on the standards for services. OTPs will be accountable through the accreditation process to assure that patients receive the appropriate services they need for successful treatment outcomes; for some patients, medication services may be sufficient to produce positive outcomes.

9. A number of respondents submitted comments on proposed section 8.12(f)(2), which requires a complete medical examination within the first 30 days following admission. Some of these comments noted that this provision, as proposed, permitted patients to enter treatment while tests, some of which required several days, are completed. Others commented that the 30 days was too long to wait for a medical exam to be completed, noting that information from the exam is crucial to the first few days of treatment. Finally, some comments suggested that regulations should specify the contents of the medical exam.

The intent of proposing 30 days for the completion of the physical exam was to allow patients into treatment while OTPs wait for the results of serology and other tests that require, in some cases, several days to complete. Section 8.12(f)(2) has been revised to clarify the requirement for a physical exam upon admission, with serology and other tests results completed w/in 14 days. The Secretary does not agree that regulations should specify the contents of the medical examination. Instead, the Secretary believes that accreditation guidelines should express the state-of-the-art content for a medical exam appropriate for the treatment of opiate addiction.

10. The July 22, 1999, notice proposed that OTPs conduct at least eight random drug abuse tests per year for each patient. Many comments suggested that the Federal standards specify more frequent drug abuse tests, including weekly testing, to balance the more flexible proposed take-home schedule. Other comments suggested that Federal regulations should specify measures to prevent adulteration. On the other hand, some comments suggested that quarterly drug abuse testing is appropriate. Moreover, one comment recommended substituting an "honor system" because patients can corrupt the testing process and falsify results.

After considering the comments on this issue, the Secretary is retaining the requirement for a minimum of eight random drug abuse tests per year for maintenance treatment. The Secretary believes that this is an adequate and balanced standard for drug abuse testing. There is extensive discussion on drug abuse testing issues in the SAMHSA/CSAT Treatment Improvement Protocols and the SAMHSA/CSAT Accreditation Guidelines. In addition, these guidelines elaborate on measures to address the corruption and falsification of results. Finally, as the Federal standard is a minimum, OTPs can require more frequent tests if desired.

11. The Secretary received many comments on proposed section 8.12(g)(2) which requires OTPs to determine and document that patients are not enrolled in other programs. Most respondents question how such determinations could be made without a patient registry. One comment stated that multiple enrollments are attributable to inadequate medication dosing practices.

The July 22, 1999, proposal retained the provisions relating to multiple enrollments from the previous regulations under 21 CFR 291.505. In proposing to retain the requirement, the Secretary noted that there have been cases of patients enrolling in more than one treatment program; however, the extent of this practice is undetermined but not considered to be widespread. The intent of this provision is for OTPs to make a good faith effort, using available resources and mechanisms to ascertain whether or not a prospective patient was currently enrolled in another OTP. Some individual States with OTPs concentrated within a community have established a patient registry and require OTPs to report new patients and patients who have discontinued in treatment. In other jurisdictions, patient registries are developed and maintained voluntarily by OTPs. OTPs also often contact other OTPs in the vicinity to determine if the patient is currently enrolled in an OTP, or they ask the patient. If used, these mechanisms must be used in accordance with the provisions at 42 CFR 2.34, regarding disclosures to prevent multiple enrollments. The Secretary acknowledges that none of these mechanisms can determine with complete certainty whether or not a patient is enrolled in more than one OTP. Accordingly, the Secretary expects that OTPs will document in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled in any other OTP. Section 8.12(g)(2) has been revised accordingly.

12. The Secretary received many comments on proposed section 8.12(j), relating to interim methadone maintenance. Most of these comments were from patients who suggested interim maintenance as a model for long standing patients who have been stabilized in treatment. As such, these comments suggested that the term for interim methadone maintenance be extended beyond 120 days.

These comments reflect a misunderstanding of interim methadone maintenance. Interim methadone maintenance was mandated by the ADAMHA Reorganization Act of 1992 as a measure to address shortages in treatment capacity and documented waiting lists (Pub. L. 102–321, See also 58 FR 495, January 5, 1993). The legislation included several restrictions which were incorporated and retained into Federal regulations. Although very few programs have applied for authorization to provide interim methadone maintenance, the Secretary does not at this time believe it is necessary or appropriate to change the standards. Instead, as discussed elsewhere in this notice, the Secretary believes that medical maintenance provides a more reasonable approach for expanding treatment capacity.

13. The Secretary received comments on proposed section 8.11(h), which provides for exemptions from treatment standards or certification requirements. One comment suggested that the examples in the previous regulation for exemptions, be retained in the final new regulations. The comment suggests that this would encourage individual physicians, pharmacists, or both to

provide methadone treatment in rural areas where methadone treatment is scarce or unavailable. Another comment suggested that SAMHSA streamline the exemption process and do more to publicize the availability of such regulatory options. The Secretary accepts both of these suggestions, and section 8.11(h) has been revised accordingly. In addition, SAMHSA has already taken steps to streamline the exemption process and publicize the availability of certain exemptions (Ref. 4).

14. Most comments strongly supported the provisions in proposed section 8.12(h)(3)(i) which permits OTPs to use solid dosage forms. Some patients reported spoilage and decomposition problems with 14-day supplies of liquid dosage form. Other comments suggested that the use of solid medication will reduce treatment cost modestly by eliminating the need for dosage bottles for solutions. The Secretary agrees that permitting OTPs to use solid medication will reduce treatment costs and increase treatment convenience to patients.

15. The Secretary received many comments on proposed section 8.11(h)(3)(iii) that would have required the program physician to justify in the patient record all doses above 100 mg. Most comments viewed this requirement as an inappropriate "value judgement" that hampers clinical judgement. The Secretary agrees that the requirement to justify a dose above 100 mg, which is a modification of a requirement under the previous regulation, is not necessary to reduce the risk of medication diversion. Accordingly, this requirement has been eliminated from the final rule.

16. The Secretary specifically requested and received comments on proposed changes to the requirements under section 8.12(i) pertaining to medications dispensed for unsupervised use (hereinafter "take-homes"). The July 22, 1999, proposal set forth four options for addressing take-homes. These options ranged from retaining the previous requirements to a scheme based on a maximum dose. Option number 2 was discussed as the option preferred by HHS and endorsed by DEA. This option resembles the requirement under the previous regulations and retains the 8-point take-home criteria. However, option number 2 permitted patients in stable treatment for one year to receive up to a 31-day supply of medication, while the previous regulation included a maximum take-home supply of 6 days.

Most comments supported proposed option 2, with modifications. In supporting option 2, current patients stated that less frequent clinic attendance will make treatment much more convenient. In addition, Option 2 will eliminate travel hardships and facilitate employment commitments, ultimately increasing retention in treatment and rehabilitation. Option 1, which encompassed the take-home schedule from the previous regulation, was viewed by many comments as too restrictive. Many comments opposed option 3, which proposed a set 2-week maximum milligram amount for take-homes, because it unfairly penalized patients receiving higher doses.

On the other hand, a form letter circulated and submitted by several treatment programs stated that no patients should be eligible for a 31-day take-home supply. According to these comments, all patients must report to clinics often so that their rehabilitation can be monitored appropriately. In addition, these comments stated that allowing any patient a 31-day take-home supply presents an unacceptable risk of diversion.

The Secretary does not agree with these comments. Indeed, there is considerable evidence that many patients can responsibly handle supplies of take-home medications beyond the 6-day maximum allowed under the previous regulations. In addition, FDA has permitted hundreds of patients to receive monthly take-home supplies of methadone through exemptions or Investigational New Drug Applications. These investigations have been analyzed and reported in scientific literature and indicate that patients successfully continue in rehabilitation (Ref. 5). Moreover, these cases indicate that rehabilitation is enhanced through these "medical maintenance" models. Accordingly, and in response to an increased interest in this issue, FDA and SAMHSA/CSAT issued a "Dear Colleague" letter on March 30, 2000, that advised the field on procedures for obtaining OTP exemptions for medical maintenance, which include a provision for up to a 31-day supply of take-home medication (Ref 4).

The Secretary notes that many comments provided suggestions on refining the basic schedule for take-home eligibility outlined in proposed option 2. For example, many comments suggested that one year of stable treatment was still too short a period of time to evaluate whether patients can responsibly handle a 31-day supply of take-home medication. These comments suggested an interim step that permits a 14-day take-home supply after one year of stable treatment before a patient is eligible for a 31-day supply.

The Secretary concurs with these comments. The 2-year time in treatment requirement is more consistent with the studies and exemptions for medical maintenance granted to date under the previous rules. In addition, this schedule is more consonant with the schedule set forth in the SAMHSA/CSAT Accreditation Guidelines and the accreditation body standards. Accordingly, section 8.12(i)(3) has been revised to reflect a 14-day take-home step after one year of stable treatment and to reflect that patients are eligible for a take-home supply up to 31 days after two years of stable treatment. The language in other parts of section 8.12(i)(3) has been modified slightly for clarity to lengthen the duration of the steps within the first year of treatment, and to remove some requirements for observed ingestion.

17. Comments overwhelmingly supported the proposal to permit take-home use of LAAM and suggest that the Secretary apply the same schedule as methadone, *e.g.* option 2. A comment from a practitioner who has treated over 500 patients, stated that patients dislike being switched from LAAM to methadone when necessary for travel purposes. Most comments suggested that diversion of LAAM is no more likely than the diversion of methadone which generally is not problematic. One comment submitted the results of a 149-patient study on LAAM take-home use. Patients were randomized into take-home and clinic only groups. As part of the study, 545 take-home doses of LAAM were distributed to patients, and patients were subject to random "callbacks." There was no evidence of tampering, diversion, or interest in obtaining LAAM take-home supplies illicitly. In addition, there were no differences between the two groups in the measured outcome variables. The investigator concluded that methadone and LAAM should be subject to the same take-home requirements. The Secretary concludes that LAAM should be available for take-home use under this rule.

18. A comment submitted by a physician discussed his successful experience using LAAM for detoxification treatment, finding LAAM to be superior to methadone for detoxification with some patients. The comment suggested that the regulations should be modified to permit the use of LAAM for detoxification.

Although previous **Federal Register** notices may have suggested that LAAM was not available for use in detoxification treatment (58 FR 38704, July 20, 1993), the July 22, 1999, proposal does not prohibit the use of

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methadone or LAAM for detoxification treatment. Indeed, the current FDA approved labeling for LAAM discusses and provides guidance on withdrawing patients from LAAM therapy:

> ORLAAM is indicated for the management of opiate dependence * * * There is a limited experience with detoxifying patients from ORLAAM in a systematic manner, and both gradual reduction (5 to 10% a week) and abrupt withdrawal schedules have been used successfully. The decision to discontinue ORLAAM therapy should be made as part of a comprehensive treatment plan.

The Secretary believes that the regulations are adequately clear on this point.

19. A few respondents commented upon the proposed implementation plan and whether OTPs could be expected to comply with the timetables for achieving accreditation. Under proposed section 8.11(d), treatment programs approved under the previous regulations are deemed certified under the new rules. This "transitional certification" would expire on June 18, 2001 unless the OTPs certify with a written statement signed by the program sponsor that they will apply for accreditation within 90 days of the date SAMHSA approves the first accreditation body. Transitional certification, in that case, will expire on March 19, 2003. SAMHSA may extend transitional certification on a case-by-case basis for up to one year under certain conditions. The comments questioned whether SAMHSA had empirical evidence that OTPs could meet this timetable.

The Secretary believes that the timetables proposed in the July 22, 1999, notice remain reasonable. A significant number of OTPs have already had experience with accreditation. This includes programs located in Department of Veterans Affairs Medical Centers, as well as OTPs located in the several States that require accreditation of OTPs (Maryland, Indiana, North Carolina, Georgia, South Carolina, and Michigan). Moreover, as discussed previously, as part of SAMHSA/CSAT's accreditation implementation plan, two accreditation bodies conducted accreditation surveys of OTPs and accredited over 50 OTPs in just a few months. SAMHSA/CSAT has planned additional training and technical assistance to enable OTPs to understand and comply with the new regulations. In addition, the regulations have been streamlined with fewer reporting and recordkeeping requirements. OTPs have had ample opportunity to prepare for this final rule, and the SAMHSA/CSAT Accreditation Guidelines as well as the CARF and JCAHO accreditation standards have been widely available for years. Taken together, these factors provide the Secretary with reasonable confidence that OTPs can apply for and achieve accreditation within two years from the effective date of this rule.

The Secretary is sensitive to concerns about OTPs contacting accreditation bodies and scheduling accreditation reviews in a convenient manner. Therefore, while not changing the timetables for achieving accreditation under the final rule, the Secretary has modified section 8.11(d) to state that programs will agree to apply for accreditation within 90 days from the date SAMSHA announces the approval of the second accreditation body. The Secretary believes that tying this certification for OTPs to apply from the date SAMHSA announces the approval of the first accreditation body to the date SAMHSA announces approval of the second accreditation body will facilitate OTPs contacting and achieving accreditation under the final rule.

20. A few comments requested that OTPs that have been previously accredited by JCAHO and CARF should be "grandfathered" somehow under the new final regulations.

There are no provisions in the final rule to accept accreditation by accreditation bodies that have not been approved by SAMHSA under section 8.3(d). These accreditation bodies did not develop and apply accreditation standards that were based upon the opioid agonist treatment standards set forth under section 8.12. SAMHSA, however, will consider on a case-by-case basis, whether OTPs that achieved accreditation under the SAMHSA/CSAT implementation initiative can be exempted from re-accreditation under this final rule, pursuant to section 8.11(h).

E. Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

1. One comment recommended that subpart C should be revised to add discovery provisions. This would enable OTPs to obtain crucial information on how "accreditation bodies conducted their investigation." The Secretary believes that the provisions of subpart A that require that accreditation bodies have appeals procedures in their accreditation decision-making process is adequate to assure that OTPs can obtain the information they need on accreditation activities.

2. One comment suggested that subpart C should be revised to allow applicant OTPs to appeal decisions to deny approval of an initial application. The Secretary does not agree and points out that OTPs will be able to appeal denials of accreditation by accreditation bodies under § 8.3(b)(4)(vii).

3. Response times in § 8.26(a), (b) and (c) have been lengthened, as have the oral presentation timeframes in § 8.27(d), and expedited procedures in § 8.28(a) and (d).

F. Conclusion and Delegation of Authority

After considering the comments submitted in response to the July 22, 1999, proposal, along with the information presented during the November 1, 1999, Public Hearing, the Secretary has determined that the administrative record in this proceeding supports the finalization of new rules under 42 CFR part 8.

In a notice to be published in a future issue of the **Federal Register**, the Secretary will announce the delegation of authority to the Administrator of SAMHSA, with the authority to redelegate, responsibility for the administration of 42 CFR part 8.

III. Analysis of Economic Impacts

The Secretary has examined the impact of this rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). According to Executive Order 12866, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. While this rule is not a significant economic regulation, the Secretary finds that this rule is a significant regulatory action as defined by Executive Order 12866. As such, this rule has been reviewed by the Office of Management and Budget (OMB) under the provisions of that Executive Order. In addition, it has been determined that this rule is not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

A. Introduction

As noted in the July 22, 1999, proposal, approximately 900 OTPs provide opioid agonist treatment to approximately 140,000 patients in the U.S. For almost 30 years, FDA has applied process-oriented regulations with periodic inspections to approve and monitor these OTPs. This final rule establishes an accreditation-based regulatory system, administered by SAMHSA, to carry out these responsibilities. In addition, this final rule includes changes that will make the regulations more flexible, and provide the opportunity to increase treatment capacity. OTPs will incur additional costs under the new accreditation-based system, but these additional costs are modest, and the Secretary believes are offset by benefits set forth under the new rules.

The additional costs under these new rules are attributable to the costs of accreditation. FDA did not assess fees for inspections under the previous regulations. Under the new rules, private not-for-profit accreditation bodies will assess accreditation survey fees, and if necessary, reinspection fees. The July 22, 1999, proposal estimated that the direct and indirect costs of accreditation at $4.9 million per year. These annual cost equal approximately $5,400 per facility and $39 per patient. The cost estimates were based on discussions with three accreditation bodies. Overall, the net costs of the new system over the existing FDA system, factoring in SAMHSA's estimated annual oversight costs of $3.4 million, was $4.4 million. The July 22, 1999, proposal noted that additional information on accreditation costs would be derived from SAMHSA/CSAT ongoing accreditation implementation project and requested specific comments on the estimates provided.

As discussed above, although a number of comments submitted in response to the July 22, 1999, proposal predicted that accreditation costs could be higher, these predictions were based upon accreditation experiences in the past, not associated with the specific accreditation standards set forth under the new system. The results from approximately 50 accreditation surveys under the SAMHSA accreditation impact study suggest that the costs, as estimated in the July 22, 1999, proposal, are reasonably accurate.

The July 22, 1999, proposal discussed the benefits of the proposed rule in terms of the advantages of accreditation and in terms of relapse rates as a function of retention in treatment. Although difficult to quantify, the Secretary believes that the accreditation-based system will provide more frequent quality surveys of OTPs and allow greater flexibility in the delivery of opioid treatment. In addition, patients have commented that the increased flexibility of the new regulations, particularly in the standards for medications dispensed for unsupervised use, will increase patient convenience, increase patient satisfaction, and increase patient retention in treatment. Importantly, changes in the regulations will facilitate and expand medical maintenance treatment freeing resources to expand treatment capacity. As noted in the July 22, 1999, proposal, increasing retention in treatment and increasing the number of patients in treatment will lead to decreases in mortality and morbidity associated with opiate addiction, decrease health expenditures, and decrease criminal activity. These benefits are likely to be significantly greater than the costs of these new regulations.

B. Small Entity Analysis

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. SAMHSA included such an analysis in the July 22, 1999, proposal.

1. Description of Impact

The July 22, 1999, proposal provided an extensive description of the industry, and concluded that, although the regulations were streamlined under the proposal with fewer forms and reporting requirements, the proposed rule constituted a significant impact on a substantial number of small entities. This impact is attributable to the requirement that all OTPs, regardless of size, must be accredited and maintain accreditation in order to continue to treat patients. Overall, the July 22, 1999, proposal estimated that the cost per patient for a "small" OTP (defined as an OTP treating 50 or fewer patients) would increase slightly more than the industry average ($50 compared to $39).

2. Analysis of Alternatives

The July 22, 1999, notice included a brief discussion of alternatives to the proposed accreditation-based regulatory scheme. In the analysis set forth initially in the July 22, 1999 notice, the Department discussed but dismissed the alternative of continuing the existing direct, FDA monitored, regulatory system because of the findings and criticisms of that system identified in the Institute of Medicine Report and elsewhere. In addition, the alternative of allowing self-certification was discussed, but rejected due to concerns about diversion and insufficient enforceability.

The preamble to the proposed rule also included a brief discussion of alternatives that would minimize the economic impact of the new regulations on small businesses and other small entities. For example, the notice discussed the alternative of exempting small facilities from some requirements. It was also noted that small facilities could seek arrangements with larger facilities that could lower costs with economy-of-scale features.

The issues in this initial analysis were highlighted for specific comment, and the notice itself was sent to every OTP identified in the FDA inventory of approved programs. Except to say that small programs should not have to close under the new rules, or that small programs should be exempt from accreditation, very few comments addressed the issue specifically, or provided information on alternatives. Therefore, this initial analysis does not require changing and is adopted as the final regulatory flexibility analysis.

3. Response to Comments From Small Entities

These issues were highlighted for specific comment, and the notice itself was sent to every OTP identified in the FDA inventory of approved programs. Except to say that small programs should not have to close under the new rules, or that small programs should be exempt from accreditation, very few comments addressed the issue specifically, or provided information on alternatives.

As discussed above, SAMHSA has evaluated the results of accreditation surveys of OTPs conducted pursuant to the proposed Federal opioid treatment standards. As such, SAMHSA has a better understanding of how accreditation will work in both large and small OTPs. Moreover, SAMHSA has provided technical assistance to participating programs to help them achieve accreditation. SAMHSA expects to continue providing technical assistance to programs during and after the transition to the new system.

The accreditation-based system, the subject of these new rules, includes flexibility measures for small OTPs. The Secretary anticipates that there will be a number of approved accreditation bodies to choose from, including those

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that will adjust accreditation fees on a sliding scale tied to the patient census. In addition, SAMHSA will retain the authority to certify programs without accreditation and could apply this provision, if necessary, to address burdens to OTPs with low patient censuses. SAMHSA prefers this case-by-case approach to a blanket exemption from accreditation requirements for programs below an arbitrary size. Such a blanket exemption would not be consistent with the intent of this regulatory initiative—to enhance the quality of opioid agonist treatment. The Secretary believes that, taken together, these considerations can mitigate the impact on small entities, while still meeting the objectives of this rulemaking.

C. Unfunded Mandates Reform Act of 1995

The Secretary has examined the impact of this rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). This rule does not trigger the requirement for a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by State, local, and tribal governments in the aggregate, or by the private sector, in any one year.

IV. Environmental Impact

The Secretary has previously considered the environmental effects of this rule as announced in the proposed rule (64 FR 39810 at 39825). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

V. Executive Order 13132: Federalism

The Secretary has analyzed this final rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, "policies that have federalism implications" refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

The Secretary is publishing this final rule to set forth treatment regulations that provide for the use of approved opioid agonist treatment medications in the treatment of opiate addiction. The Narcotic Addict Treatment Act (the NATA, Pub. L. 93–281) modified the Controlled Substances Act (CSA) to establish the basis for the Federal control of narcotic addiction treatment by the Attorney General and the Secretary. Because enforcement of these sections of the CSA is a Federal responsibility, there should be little, if any, impact from this rule on the distribution of power and responsibilities among the various levels of government. In addition, this regulation does not preempt State law. Accordingly, the Secretary has determined that this final rule does not contain policies that have federalism implications or that preempt State law.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence; Repeal of Current Regulations and Adoption of New Regulations.

Description: The Secretary is issuing regulations to establish an accreditation-based regulatory system to replace the current system that relies solely upon direct Federal inspection of treatment programs for compliance with process-oriented regulations.

These new rules are intended to enhance the quality of opioid treatment by allowing increased clinical judgment in treatment and by the accreditation process itself with its emphasis on continuous quality assessment. As set forth in this final rule, there will be fewer reporting requirements and fewer required forms under the new system. The total reporting requirements are estimated at 2,071 hours for treatment programs, and 341 hours for accrediting organizations as outlined in Tables 1 and 2.

The regulation requires a one-time reporting requirement for transitioning from the old system to the new system. The estimated reporting burden for "transitional certification" is approximately 475 hours. The proposal also requires ongoing certification on a 3-year cycle, with an estimated reporting burden of approximately 300 hours.

Description of Respondents: Business or other for-profit; Not-for-profit institutions; Federal Government; State, local or tribal government.

No comments were submitted in response to the Secretary's invitation in the July 22, 1999, proposal to comment on the information collection requirements.

TABLE 1.—ANNUAL REPORTING BURDEN FOR TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.11(b)	New programs approval (SMA–162)	75	1	1.50	112.50
8.11(b)	Renewal of approval (SMA–162) [1]	300	1	1.00	300.00
8.11(b)	Relocation of program (SMA–162)	35	1	1.17	40.83
8.11(d)	Application for transitional certification (SMA–162) [2]	300	1	1.58	475.00
8.11(e)(1)	Application for provisional certification	75	1	.50	37.50
8.11(e)(2)	Application for extension of provisional certification	30	1	.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change	60	1	.33	20.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	2	2.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12.	800	3	.438	1050.00

TABLE 1.—ANNUAL REPORTING BURDEN FOR TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units.	3	1	.25	.75
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	1	.33	.33
8.24	Contents of Appellant Request for Review of Suspension.	2	1	.25	.50
8.25(a)	Informal Review Request	2	1	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	1.00	2.00
8.28(c)	Appellant's Review File and Written Statement	2	1	5.00	10.00
Total					2,070.91

[1] Applications for renewal of certification are required every 3 years.
[2] Transitional Certification is a one-time requirement and will be included in the total annualized burden but averaged over the 3-year period of the OMB collection activity approval.

The final rule does not increase the estimated annualized burden. Certain reporting requirements have been eliminated, such as submissions for authorizations to use LAAM, the requirement to submit a physician responsibility statement (FDA Form 2633), and elimination of the requirement to obtain Federal approval for take-home doses of methadone in excess of 100 mg that exceed a 6-day supply. The new rule adds a one-time requirement for existing programs to apply for transitional certification, and a requirement to apply for certification renewal every third year. The annualized burdens associated with these new reporting requirements offset the burdens eliminated, resulting in no estimated net change.

Accreditation bodies will also require treatment programs to submit information as part of the standard operating procedures for accreditation. As mentioned earlier in this notice, accreditation bodies, under contract to SAMHSA, have accredited existing OTPs as part of an initiative to gain more information on the accreditation of OTPs. SAMHSA prepared a separate OMB Paperwork Reduction notice and analysis for that information collection activity (63 FR 10030, February 27, 1998, OMB approval number 0930–0194).

TABLE 2.—ANNUAL REPORTING BURDEN FOR ACCREDITATION ORGANIZATIONS

42 CFR citation	Purpose	No. of respondents	Responses/ respondent	Hours/ response	Total hours
8.3 (b) (1–11)	Initial approval (SMA–163)	10	1	3.0	30.0
8.3 (c)	Renewal of approval (SMA-163)	3	1	1.0	3.0
8.3 (e)	Relinguishment notification	1	1	0.5	0.5
8.3 (f) (2)	Non-renewal notification to accredited OTP's	1	90	0.1	9.0
8.4 (b) (1) (ii)	Notification to SAMHSA for serious noncompliant programs.	2	2	1.0	4.0
8.4 (b) (1) (iii)	Notification to OTP for serious noncompliance	2	2	1.0	4.0
8.4 (d) (1)	General document and information to SAMHSA upon request.	10	2	0.5	10.0
8.4 (d) (2)	Accrediation survey to SAMHSA upon request	10	6	0.2	12.0
8.4 (d) (3)	List of surveys, surveyors to SAMHSA upon request.	10	6	0.2	12.0
8.4 (d) (4)	Less than full accrediation report to SAMHSA	10	7.5	0.5	37.5
8.4 (d) (5)	Summaries of Inspections	10	30	0.5	150.0
8.4 (e)	Notifications of Compliants	10	1	0.5	5.0
8.6 (a) (2) and (b) (3)	Revocation notification to Accredited OTP's	1	90	0.3	27.0
8.6 (b)	Submission of 90-day Corrective plan to SAMHSA	1	1	10	10.0
8.6 (b) (1)	Notification to accredited OTP's of Probationary Status.	1	90	0.3	27.0
Total		82			341

Note: Because some of the numbers underlying these estimates have been rounded, figures in this table are approximate. There are no maintenance and operation costs nor start up and capital costs.

Recordkeeping—The recordkeeping requirements for OTPs set forth in sec. 8.12 include maintenance of the following: A patient's medical evaluation and other assessments when admitted to treatment, and periodically throughout treatment Sec. 8.12(f)(4)); the provision of needed services, including any prenatal support provided the patient (Sec. 8.12(f)(3) and (f)(4)) justification of exceptional initial doses; changes in a patient's dose and dosage schedule; justification for variations from the approved product labeling for LAAM and future medications (Sec. 8.12(h)(4)); and the rationale for decreasing a patient's clinic attendance (Sec. 8.12(i)(3)).

In addition, sec. 8.4(c)(1) will require accreditation bodies to keep and retain for 5 years certain records pertaining to their respective accreditation activities.

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These recordkeeping requirements for OTPs and accreditation bodies are customary and usual practices within the medical and rehabilitative communities, and thus impose no additional response burden hours or costs.

Disclosure—This final rule retains requirements that OTPs and accreditation organizations disclose information. For example, sec. 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the new rules require under sec. 8.4(i)(1) that each accreditation organization shall make public its fee structure. The Secretary notes that the preceding section of this notice contains publicly available information on the fee structure for each of three accreditation bodies. This type of disclosure is standard business practice and is not considered a burden in this analysis.

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to: SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The information collection provisions in this final rule have been approved under OMB control number 0930–0206. This approval expires 09/30/2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services, Administration.

Dated: January 5, 2001.

Donna E. Shalala,

Secretary of Health and Human Services.

VII. References

The following references have been placed on display at SAMHSA/CSAT Reading Room (7–220), 5515 Security Lane, Rockville, MD 20852.

1. Institute of Medicine, Federal Regulation of Methadone Treatment, National Academy Press, 1995.

2. "New Hampshire Legislature Allows Methadone Treatment," Copyright 2000, Alcoholism & Drug Abuse Weekly, Manisses Communications Group, Inc., Vol. 12, No. 23, Monday, June 5, 2000.

3. Sees, K.L., D.O., et al., "Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence, A Randomized Controlled Trial," Journal of the American Medical Association, Vol 283, No. 10 p1303–1310, March 8, 2000.

4. Clark, H. Westly, M.D., Lepay, David, M.D., "Dear Colleague Letter on Medical Maintenance", March 30, 2000.

5. Schwartz, M.D., et al., "A 12-Year Follow-Up of a Methadone Medical Maintenance Program, Am J Addiction, Vol. 8, pp 293–299, 1999.

List of Subjects

21 CFR Part 291

Health professions, Methadone, Reporting and recordkeeping requirements.

42 CFR Part 8

Health professions, Levo-Alpha-Acetyl-Methadol (LAAM), Methadone, Reporting and recordkeeping requirements.

Therefore, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Controlled Substances Act as amended by the Narcotic Addict Treatment Act of 1974, the Public Health Service Act, and applicable delegations of authority thereunder, titles 21 and 42 of the Code of Federal Regulations are amended as follows:

21 CFR Chapter I

PART 291—[REMOVED]

1. Under authority of sections 301(d), 543, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290dd–2, 300y–11); 38 U.S.C. 7332, 42 U.S.C. 257a; and section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), amend title 21 of the Code of Federal Regulations by removing part 291.

42 CFR Chapter I

2. Amend 42 CFR Chapter I by adding part 8 to subchapter A to read as follows:

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

Subpart A—Accreditation

Sec.

8.1 Scope.
8.2 Definitions.
8.3 Application for approval as an accreditation body.
8.4 Accreditation body responsibilities.
8.5 Periodic evaluation of accreditation bodies.
8.6 Withdrawal of approval of accreditation bodies.

Subpart B—Certification and Treatment Standards

8.11 Opioid treatment program certification.
8.12 Federal opioid treatment standards.
8.13 Revocation of accreditation and accreditation body approval.
8.14 Suspension or revocation of certification.
8.15 Forms.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

8.21 Applicability.
8.22 Definitions.
8.23 Limitation on issues subject to review.
8.24 Specifying who represents the parties.
8.25 Informal review and the reviewing official's response.
8.26 Preparation of the review file and written arguments.
8.27 Opportunity for oral presentation.
8.28 Expedited procedures for review of immediate suspension.
8.29 Ex parte communications.
8.30 Transmission of written communications by reviewing official and calculation of deadlines.
8.31 Authority and responsibilities of the reviewing official.
8.32 Administrative record.
8.33 Written decision.
8.34 Court review of final administrative action; exhaustion of administrative remedies.

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

Subpart A—Accreditation

§ 8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for opiate addiction treatment with an opioid agonist treatment medication.

§ 8.2 Definitions.

The following definitions apply to this part:

Accreditation means the process of review and acceptance by an accreditation body.

Accreditation body means a body that has been approved by SAMHSA under § 8.3 to accredit opioid treatment programs using opioid agonist treatment medications.

Accreditation body application means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body, as described in § 8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an accreditation body and approved by SAMHSA.

Accreditation survey means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in § 8.12.

Accredited opioid treatment program means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under § 8.3(d).

Certification means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards.

Certification application means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in § 8.11(b).

Certified opioid treatment program means an opioid treatment program that is the subject of a current, valid certification under § 8.11.

Comprehensive maintenance treatment is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

Federal opioid treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

For-cause inspection means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

Interim maintenance treatment means maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

Long-term detoxification treatment means detoxification treatment for a period more than 30 days but not in excess of 180 days.

Maintenance treatment means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid addiction.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

Medical and rehabilitative services means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

Medication unit means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Opiate addiction is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

Opioid agonist treatment medication means any opioid agonist drug that is approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opiate addiction.

Opioid drug means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

Opioid treatment means the dispensing of an opioid agonist treatment medication, along with a comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

Opioid treatment program or "OTP" means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication.

Patient means any individual who undergoes treatment in an opioid treatment program.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Registered opioid treatment program means an opioid treatment program that is registered under 21 U.S.C. 823(g).

Short-term detoxification treatment means detoxification treatment for a period not in excess of 30 days.

State Authority is the agency designated by the Governor or other appropriate official designated by the

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Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opiate addiction with an opioid drug.

Treatment plan means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

§ 8.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State governmental entities, or political subdivisions thereof, capable of meeting the requirements of this part may apply for approval as an accreditation body.

(b) *Application for initial approval.* Three copies of an accreditation body application form [SMA–163] shall be submitted to SAMHSA at rm. 12–105, 5600 Fishers Lane, Rockville, MD 20857, and marked ATTENTION: OTP Certification Program. SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. Accreditation body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the accreditation body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.*, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State governmental entity or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decisionmaking process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

(v) Policies and procedures for suspending or revoking an OTP's accreditation;

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by SAMHSA; and

(vii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions.

(5) Policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the applicant's staff;

(7) A description of the applicant's training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body; and

(11) Any other information SAMHSA may require.

(c) *Application for renewal of approval.* An accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to SAMHSA for renewal, or notify SAMHSA of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an accreditation body's term of approval, the body shall inform SAMHSA in writing of its intent to seek renewal.

(2) SAMHSA will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the accreditation body's term of approval, the applicant shall furnish to SAMHSA three copies of a renewal application containing the information, materials, and supporting documentation requested by SAMHSA under paragraph (c)(2) of this section.

(4) An accreditation body that does not intend to renew its approval shall so notify SAMHSA at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) SAMHSA will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the accreditation body requirements of this subpart.

(2) If SAMHSA determines that the applicant does not substantially meet the requirements set forth in this subpart. SAMHSA will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of SAMHSA within the 90-day time period, the body will be approved as an accreditation body. If the deficiencies have not been resolved to the satisfaction of SAMHSA within the 90-day time period, the application for approval as an accreditation body will be denied.

(3) If SAMHSA does not reach a final decision on a renewal application before the expiration of an accreditation body's term of approval, the approval will be deemed extended until SAMHSA reaches a final decision, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An accreditation body that intends to relinquish its accreditation approval before expiration of the body's term of approval shall submit a letter of such intent to SAMHSA, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An accreditation body that does not apply for renewal of approval, or is denied such approval by SAMHSA, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by SAMHSA to a location, including another accreditation body, and according to a schedule approved by SAMHSA; and

(2) Notify, in a manner and time period approved by SAMHSA, all OTPs accredited or seeking accreditation by the body that the body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An accreditation body's term of approval is for a period not to exceed 5 years.

(h) *State accreditation bodies.* State governmental entities, including political subdivisions thereof, may establish organizational units that may act as accreditation bodies, provided such units meet the requirements of this section, are approved by SAMHSA under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support opioid treatment services.

§ 8.4 Accreditation body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation bodies shall conduct routine accreditation surveys for initial, renewal, and continued accreditation of each OTP at least every 3 years.

(2) Accreditation bodies must agree to conduct for-cause inspections upon the request of SAMHSA.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved accreditation body application.

(b) *Response to noncompliant programs.* (1) If an accreditation body receives or discovers information that suggests that an OTP is not meeting Federal opioid treatment standards, or if survey of the OTP by the accreditation body otherwise demonstrates one or more deficiencies in the OTP, the accreditation body shall as appropriate either require and monitor corrective action or shall suspend or revoke accreditation of the OTP, as appropriate based on the significance of the deficiencies.

(i) Accreditation bodies shall either not accredit or shall revoke the accreditation of any OTP that substantially fails to meet the Federal opioid treatment standards.

(ii) Accreditation bodies shall notify SAMHSA as soon as possible but in no case longer than 48 hours after becoming aware of any practice or condition in an OTP that may pose a serious risk to public health or safety or patient care.

(iii) If an accreditation body determines that an OTP is substantially meeting the Federal opioid treatment standards, but is not meeting one or more accreditation elements, the accreditation body shall determine the necessary corrective measures to be taken by the OTP, establish a schedule for implementation of such measures, and notify the OTP in writing that it must implement such measures within the specified schedule in order to ensure continued accreditation. The accreditation body shall verify that the necessary steps are taken by the OTP within the schedule specified and that all accreditation elements are being substantially met or will be substantially met.

(2) Nothing in this part shall prevent accreditation bodies from granting accreditation, contingent on promised programmatic or performance changes, to OTPs with less substantial violations. Such accreditation shall not exceed 12 months. OTPs that have been granted such accreditation must have their accreditation revoked if they fail to make changes to receive unconditional accreditation upon resurvey or reinspection.

(c) *Recordkeeping.* (1) Accreditation bodies shall maintain records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the accreditation body.

(2) Accreditation bodies shall establish procedures to protect confidential information collected or received in their role as accreditation bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to SAMHSA or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that SAMHSA shares with the accreditation body concerning an OTP shall not be further disclosed except with the written permission of SAMHSA.

(d) *Reporting.* (1) Accreditation bodies shall provide to SAMHSA any documents and information requested by SAMHSA within 5 days of receipt of the request.

(2) Accreditation bodies shall make a summary of the results of each accreditation survey available to SAMHSA upon request. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation bodies shall provide SAMHSA upon request a list of each OTP surveyed and the identity of all individuals involved in the conduct and reporting of survey results.

(4) Accreditation bodies shall submit to SAMHSA the name of each OTP for which the accreditation body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to SAMHSA under paragraphs (d)(1) through (d)(4) of this section, each accreditation body shall submit to SAMHSA semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to SAMHSA at the address specified in § 8.3(b).

(e) *Complaint response.* Accreditation bodies shall have policies and procedures to respond to complaints from SAMHSA, patients, facility staff, and others, within a reasonable period of time but not more than 5 days of the receipt of the complaint. Accreditation bodies shall also agree to notify SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (*i.e.*, noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An accreditation body survey team shall consist of healthcare professionals with

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expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

§ 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTPs accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

§ 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTPs that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart B—Certification and Treatment Standards

§ 8.11 Opioid treatment program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.

(2) To obtain certification from SAMHSA, an OTP must meet the Federal opioid treatment standards in § 8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA.

(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.

(b) *Application for certification.* Three copies of an application for certification must be submitted by the OTP to the address identified in § 8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the control of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding; and

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (f) of this section.

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(c) *Action on application.* (1) Following SAMHSA's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

(2) SAMHSA may deny the application if SAMHSA determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal opioid treatment standards established under § 8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Transitional certification.* OTPs that before March 19, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR Parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such 'transitional certification' will expire on June 18, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before June 18, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on March 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (*e.g.*, within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with § 8.14.

(e) *Provisional certification.* (1) OTPs that have no current certification from SAMHSA, but have applied for accreditation with an accreditation body, are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP shall submit the information required by paragraph (b) of this section to SAMHSA along with a statement identifying the accreditation body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

(2) An extension of provisional certification may be granted in extraordinary circumstances or otherwise to protect public health. To apply for a 90-day extension of provisional certification, an OTP shall submit to SAMHSA a statement explaining its efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTPs shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of opioid drugs in the treatment of opioid addiction. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of opioid agonist treatment medications are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). Federally-sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee

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of SAMHSA to have access to and to copy all records on the use of opioid drugs in accordance with the provisions of 42 CFR part 2.

(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II, and must be registered by the DEA before administering or dispensing opioid agonist treatment medications.

(7) OTPs must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(g) *Conditions for interim maintenance treatment program approval.* (1) Before a public or nonprofit private OTP may provide interim maintenance treatment, the program must receive the approval of both SAMHSA and the chief public health officer of the State in which the OTP operates.

(2) Before SAMHSA may grant such approval, the OTP must provide SAMHSA with documentation from the chief public health officer of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim maintenance treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(iii) The authorization of the OTP to provide interim maintenance treatment will not otherwise reduce the capacity of comprehensive maintenance treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) The State certifies that each individual enrolled in interim maintenance treatment will be transferred to a comprehensive maintenance treatment program no later than 120 days from the date on which each individual first requested treatment, as provided in section 1923 of the Public Health Service Act (21 U.S.C. 300x-23).

(3) SAMHSA will provide notice to the OTP denying or approving the request to provide interim maintenance treatment. The OTP shall not provide such treatment until it has received such notice from SAMHSA.

(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms "hospital" and "long-term care facility" as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

§ 8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current "Diversion Control Plan" or "DCP" as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) *Patient admission criteria.*—(1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) Maintenance treatment for persons under age 18. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) Maintenance treatment admission exceptions. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) Detoxification treatment. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services.*—(1) General. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) Special services for pregnant patients. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) Initial and periodic assessment services. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) Counseling services. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) Drug abuse testing services. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application

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under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone; and

(ii) Levomethadyl acetate (LAAM).

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) Unsupervised or "take-home" use. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, *e.g.*, drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the following restrictions apply:

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91–601 (15 U.S.C. 1471 *et seq.*)).

(j) *Interim maintenance treatment.* (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or "take-home" use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

§ 8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with § 8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under § 8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA–162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA–163—Application for Becoming an Accreditation Body under § 8.3.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) SAMHSA has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that SAMHSA proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

(c) SAMHSA has notified an accreditation body of an adverse action taken regarding withdrawal of approval of the accreditation body under the regulations in subpart A of this part; and

(d) The accreditation body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

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§ 8.22 Definitions.

The following definitions apply to this subpart C.

(a) *Appellant* means:

(1) The treatment program which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation, or

(2) The accreditation body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

(b) *Respondent* means SAMHSA.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more HHS officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts the regulations, in the subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's responses.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the accreditation body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an accreditation body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation.*—(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) Burden of proof/standard of proof. In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) Admission of evidence. The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of §§ 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

§ 8.29 Ex parte communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart C, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

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§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

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Federal Register

Wednesday,
January 17, 2001

Part III

Department of Transportation

Federal Railroad Administration

49 CFR Parts 229, 231, and 232
Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-of-Train Devices; Final Rule

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DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Parts 229, 231, and 232

[FRA Docket No. PB–9; Notice No. 17]

RIN 2130–AB16

Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-of-Train Devices

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Final Rule.

SUMMARY: FRA is issuing revisions to the regulations governing the power braking systems and equipment used in freight and other non-passenger railroad train operations. The revisions are designed to achieve safety by better adapting the regulations to the needs of contemporary railroad operations and facilitating the use of advanced technologies. These revisions are being issued in order to comply with Federal legislation, to respond to petitions for rulemaking, and to address areas of concern derived from experience in the application of existing standards governing these operations.

EFFECTIVE DATE: April 1, 2001. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of April 1, 2001.

ADDRESSES: Any petition for reconsideration should reference FRA Docket No. PB–9, Notice 17, and be submitted in triplicate to FRA Docket Clerk, Office of Chief Counsel, RCC–10, 1120 Vermont Avenue, Mail Stop 10, Washington, DC 20590.

FOR FURTHER INFORMATION, CONTACT: Leon Smith, Deputy Regional Administrator—Region 3, FRA Office of Safety, RRS–14, 1120 Vermont Avenue, Stop 25, Washington, DC 20590 (telephone 404–562–3800), or Thomas Herrmann, Trial Attorney, Office of the Chief Counsel, RCC–10, 1120 Vermont Avenue, Stop 10, Washington, DC 20590 (telephone 202–493–6053).

SUPPLEMENTARY INFORMATION:

I. Background

In 1992, Congress amended the Federal rail safety laws by adding certain statutory mandates related to power brake safety. *See* 49 U.S.C. 20141. These amendments specifically address the revision of the power brake regulations by adding a new subsection which states:

(r) POWER BRAKE SAFETY.—(1) The Secretary shall conduct a review of the Department of Transportation's rules with respect to railroad power brakes, and not later than December 31, 1993, shall revise such rules based on such safety data as may be presented during that review.

(2) In carrying out paragraph (1), the Secretary shall, where applicable, prescribe standards regarding dynamic brake equipment. * * *

Pub. L. 102–365, section 7; codified at 49 U.S.C. 20141, superseding 45 U.S.C. 431(r).

In response to the statutory mandate, the various recommendations and petitions for rulemaking, and due to its own determination that the power brake regulations were in need of revision, FRA published an Advance Notice of Proposed Rulemaking (ANPRM) on December 31, 1992 (57 FR 62546), and conducted a series of public workshops in early 1993. The ANPRM provided background information and presented questions on various subjects including the following: the use and design of end-of-train (EOT) telemetry devices; the air flow method of train brake testing; the additional testing of train air brakes during extremely cold weather; the training of employees to perform train brake tests and inspections; computer-assisted braking systems; the operation of dynamic brakes on locomotives; and other miscellaneous subjects relating to conventional brake systems as well as information regarding high speed passenger train brakes. The questions presented in the ANPRM on the various topics were intended as fact-finding tools and were meant to elicit the views of those persons outside FRA charged with ensuring compliance with the power brake regulations on a day-to-day basis.

Based on the comments and information received, FRA published a Notice of Proposed Rulemaking (1994 NPRM) regarding revisions to the power brake regulation. *See* 59 FR 47676 (September 16, 1994). In the 1994 NPRM, FRA proposed a comprehensive revision of the power brake regulations which attempted to preserve the useful elements of the current regulatory system in the framework of an entirely new document. FRA attempted to delineate the requirements for conventional freight braking systems from the more diverse systems for various categories of passenger service. In developing the NPRM, FRA engaged in a systems approach to the power brake regulations. FRA considered all aspects of a railroad operation and the effects that the entire operation had on the train and locomotive power braking systems. Therefore, the proposed requirements not only addressed specific brake equipment and inspection requirements, but also attempted to encompass other aspects of a railroad's operation which directly affect the quality and performance of the braking system, such as personnel qualifications; maintenance requirements; written procedures governing operation, maintenance, and inspection; record keeping requirements; and the development and integration of new technologies.

Following publication of the 1994 NPRM in the **Federal Register**, FRA held a series of public hearings in 1994 to allow interested parties the opportunity to comment on specific issues addressed in the NPRM. Public hearings were held in Chicago, Illinois on November 1–2; in Newark, New Jersey on November 4; in Sacramento, California on November 9; and in Washington, DC on December 13–14, 1994. These hearings were attended by numerous railroads, organizations representing railroads, labor organizations, rail shippers, and State governmental agencies. Due to the strong objections raised by a large number of commenters at these public hearings, FRA announced by notice published on January 17, 1995 that it would defer action on the NPRM and permit the submission of additional comments prior to making a determination as to how it would proceed in this matter. *See* 60 FR 3375. Although the comment period officially closed April 1, 1995, FRA continued to receive comments on the NPRM as well as other suggested alternatives well into October 1995.

Furthermore, beginning in mid-1995, FRA internally committed to the process of establishing the Railroad Safety Advisory Committee (RSAC). The determination to develop the RSAC was based on FRA's belief that the continued use of ad hoc collaborative procedures for appropriate rulemakings was not the most effective means of accomplishing its goal of a more consensual regulatory program. FRA believed that the establishment of an advisory committee to address railroad safety issues would provide the best opportunity for creating a consensual regulatory program to benefit the Administrator in the conduct of her statutory responsibilities. FRA envisioned that the RSAC would allow representatives from management, labor, FRA, and other interested parties to cooperatively address safety problems by identifying the best solutions based on agreed-upon facts, and, where regulation appears necessary, by identifying regulatory options to implement these solutions. The process of establishing the RSAC was not complete until March 1, 1996, and on March 11, 1996, FRA published a notice

in the **Federal Register** that the Committee had been established. *See* 61 FR 9740.

In the interim, based on these considerations and after review of all the comments submitted, FRA published a notice in the **Federal Register** on February 21, 1996, stating that, in order to limit the number of issues to be examined and developed in any one proceeding, FRA would proceed with the revision of the power brake regulations via three separate processes. *See* 61 FR 6611. In light of the testimony and comments received on the 1994 NPRM, emphasizing the differences between passenger and freight operations and the brake equipment utilized by the two, FRA decided to separate passenger equipment power brake standards from freight equipment power brake standards. As passenger equipment power brake standards are a logical subset of passenger equipment safety standards, it was determined that the passenger equipment safety standards working group would assist FRA in developing a second NPRM covering passenger equipment power brake standards. *See* 49 U.S.C. 20133(c). In addition, in the interest of public safety and due to statutory as well as internal commitments, FRA determined that it would separate the issues related to two-way EOTs from both the passenger and freight issues, address them in a public regulatory conference, and issue a final rule on the subject as soon as practicable. A final rule on two-way EOTs was issued on December 27, 1996. *See* 62 FR 278 (January 2, 1997). Furthermore, it was announced that a second NPRM covering freight equipment power brake standards would be developed with the assistance of RSAC. At the Committee's inaugural meeting on April 1–2, 1996, the RSAC officially accepted the task of assisting FRA in development of revisions to the regulations governing power brake systems for freight equipment. *See* 61 FR 29164.

Members of RSAC nominated individuals to be members of the Freight Power Brake Working Group (Working Group) tasked with making recommendations regarding revision of the power regulations applicable to freight operations. The Working Group was comprised of thirty-one voting members as well as a number of alternates and technical support personnel. The following organizations were represented by a voting member and/or an alternate on the Working Group:

Association of American Railroads (AAR)
The American Short Line Railroad Association (ASLRA)
Brotherhood of Locomotive Engineers (BLE)
The Burlington Northern and Santa Fe Railway Company (BNSF)
Canadian National Railroads (CN)
Canadian Pacific Rail Systems (CP)
Consolidated Rail Corporation (CR)
CSX Transportation, Incorporated (CSX)
Illinois Central Railroad Company (IC)
International Association of Machinists & Aerospace Workers (IAMAW)
National Transportation Safety Board (NTSB)(Advisor)
National Association of Regulatory Commissioners (NARUC)
California Public Utilities Commission (CAPUC)
Norfolk Southern Corporation (NS)
Railway Progress Institute (RPI)
Sheet Metal Workers International Association (SMWIA)
Southern Pacific Lines (SP)
Transportation Communications International Union/Brotherhood of Railway Carmen (TCU/BRC)
Transport Workers Union of America (TWU)
Union Pacific Railroad Company (UP)
United Transportation Union (UTU)

The Working Group held seven multi-day sessions in which all members of the working group were invited. These sessions were held on the following dates:

May 15–17, 1996 in Washington D.C.;
June 11–13, 1996 in Chicago, Illinois;
July 31, 1996 in Chicago, Illinois;
August 21–23, 1996 in Annapolis, Maryland;
September 26–27, 1996 in Washington D.C.;
October 29–30, 1996 in Washington D.C.; and
December 4, 1996 in St. Louis, Missouri.

General minutes of each of these meetings are contained in FRA Docket PB–9 and are available for public inspection during the times and at the location noted previously. In addition to these meetings, there were numerous meetings conducted by smaller task force groups designated by the Working Group to further develop various issues. All of these smaller task forces were made up of various members of the Working Group or their representatives, with each task force being represented by management, labor, FRA, and other interested parties. The Working Group designated smaller task forces to address the following issues: Dry air; dynamic brakes; periodic maintenance and testing; electronically controlled locomotive brakes; and inspection and testing requirements. These task forces were assigned the job of developing the issues related to the broad topics, presenting reports to the larger Working Group, and if possible making recommendations to the Working Group for addressing the issues.

Although the Working Group discussed, debated, and attempted to reach consensus on various issues related to freight power brakes, consensus could not be reached. However, the working group in conjunction with the various task forces developed a wealth of information on various issues and further clarified the parties' positions regarding how the issues could or should be addressed in any regulation. The major cluster of issues, upon which resolution of many of the other issues rested, were the requirements related to the inspection and testing of brake equipment. The inspection and testing task force met on numerous occasions and gathered and reviewed data, and the labor and rail management representatives to the task force drafted various proposals and options related to the inspection and testing of freight brake equipment. The Working Group discussed the proposals and investigated many of the costs and benefits related to the various proposals as well as the safety implications; however, the Working Group could not reach any type of consensus position. Consequently, FRA declared that an impasse had been reached and announced, at the December 4, 1996 meeting of the Working Group, that FRA would proceed unilaterally with the drafting of the NPRM.

Subsequent to December 4, 1996, several members of the Working Group, including representatives from both rail management and labor, continued informal discussions of some of the issues related to the inspection and testing of freight equipment. These representatives informed FRA that a consensus proposal might be possible, provided that the Working Group were permitted to continue deliberations. Consequently, FRA agreed to reconvene the Working Group, and in April 1997 three additional meetings were conducted on the following dates:

April 2–3 in Kansas City, Missouri;
April 10–11 in Phoenix, Arizona; and
April 23 in Jacksonville, Florida.

Representatives of both rail management and rail labor presented the Working Group with inspection and testing proposals for consideration and review both before and during this period. Although the proposals were discussed and deliberated, the Working Group was once again unsuccessful in

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reaching consensus on any of the freight power brake inspection and testing issues. Consequently, by letter dated May 29, 1997, FRA informed the members of the Working Group that FRA would be withdrawing the freight power brake task from the Working Group at the next full RSAC meeting on June 24, 1997. FRA provided this notice to avoid any misunderstanding regarding the process by which the proposed rule would be drafted. FRA also informed the members of the Working Group that it would not invest further time in attempting to reach consensus unless all other members of the Working Group jointly indicated that they have reached consensus on a proposal and wanted to discuss it with FRA. FRA noted that if that were to occur prior to June 24, 1997, it would reconsider withdrawing the task from RSAC. As no consensus proposal was presented to FRA prior to June 24, 1997, FRA withdrew the task from the Working Group and informed the members of RSAC that FRA would proceed independently in the drafting of a freight power brake NPRM.

FRA carefully considered the information, data, and proposals developed by the Freight Power Brake Working Group as well as all the oral and written comments offered by various parties regarding the 1994 NPRM on power brakes when developing a revised power brake NPRM. On September 9, 1998, an NPRM (1998 NPRM) was published in the **Federal Register** proposing brake system safety standards for freight trains and equipment. *See* 63 FR 48294 (September 9, 1998).

As evidenced by the preceding discussion, FRA spent years developing the 1998 proposed power brake regulations. During that time, FRA instituted rulemakings to address passenger and commuter operations and equipment and two-way end-of-train devices, and developed a channel of communication to address tourist and excursion operational concerns. Consequently, the 1998 proposal focused solely on freight and other non-passenger operations. FRA did not, for the most part, attempt to include provisions related to the inspection and maintenance of locomotive braking systems or to the performance of other mechanical inspections that are currently addressed by other parts of the regulations. FRA believed that although those requirements are interrelated to the inspection, testing, and maintenance of freight power brakes, they are adequately addressed in other regulations and would only add to the complexity of the proposal, causing confusion and misunderstanding by members of the regulated community.

When developing the 1998 NPRM, FRA determined that the proposal would closely track the existing requirements related to the inspection, testing, and maintenance of the braking systems used in freight operations. Although FRA recognized that the current regulatory scheme tended to create incentives to "overlook" defects or fail to conduct vigorous inspections, FRA also believed that the current regulatory scheme is an effective and proven method of ensuring safety and that many of the "negative incentives" could be greatly reduced by strict and aggressive enforcement coupled with moderate revisions to address specific concerns raised by interested parties. Furthermore, representatives of both rail labor and rail management indicated that if a consensus proposal could not be developed then FRA should proceed on its own with developing a proposal which tracks the current requirements, and that FRA should strictly enforce those requirements.

The 1998 NPRM proposed a moderate, although comprehensive, revision of the existing requirements related to the inspection, testing, and maintenance of brake equipment used in freight operations. The proposal attempted to balance the concerns of rail labor and management and increase the effectiveness of the regulation. In the 1998 NPRM, FRA attempted to reorganize, update, and clarify the existing regulations related to freight power brakes and eliminate potential loopholes created by the existing regulatory language. Furthermore, completely new requirements were proposed to address the qualifications of those individuals conducting brake inspections and tests. FRA also proposed requirements related to the movement of freight equipment with defective or inoperative brakes which were consistent with existing statutory requirements and other federal regulations addressing the movement of defective freight equipment. The 1998 NPRM also attempted to codify existing maintenance requirements related to the brake system and its components and prevent unilateral changes to those provisions by the very party to which they apply. Moreover, the proposal also contained specific requirements related to dynamic brakes and requirements aimed at increasing the quality of air introduced into brake systems by yard air sources.

In addition to the above, the 1998 proposal also contained various incentives to the railroads to encourage the performance of quality brake inspections, particularly at locations where trains originate. These included incentives to use qualified mechanical forces to conduct brake system tests at major terminals where long-distance trains originate in order to move these trains greater distances between brake inspections than existing regulations permitted. Consequently, the 1998 proposal retained the basic inspection intervals and requirements contained in the existing regulations and preserved the useful elements of the existing system, but also proposed additions, clarifications, and modifications that FRA believed would increase the safety, effectiveness, and enforceability of the regulations.

Following publication of the 1998 NPRM, FRA held two public hearings and a public technical conference to allow interested parties the opportunity to comment on specific issues addressed in the NPRM. The public hearings were held in Kansas City, Missouri on October 26 and in Washington, DC on November 13, 1998. The public technical conference was conducted in Walnut Creek, California on November 23 and 24, 1998. The hearings and technical conference were attended by numerous railroads, organizations representing railroads, labor organizations, rail shippers, and State governmental agencies. During the hearings and technical conference a vast amount of oral information was presented, and a considerable number of issues were raised and discussed in detail.

Subsequent to conducting these public hearings and technical conference, FRA issued a notice extending the comment period on the NPRM from January 15, 1999 to March 1, 1999. *See* 64 FR 3273. This extension was provided based on the requests of several interested parties for more time in which to develop their responses. At the public hearings and technical conference conducted in relation to the NPRM and in written comments submitted subsequent to the public hearings and technical conference, concerns were raised regarding the data discussed by FRA in the NPRM. The comments raised concerns regarding FRA's collection of data related to FRA's inspection activity and the number of conditions not in compliance with Federal regulations found during that inspection activity. The comments and correspondence received alleged that there were substantial problems with FRA's database, that there had been substantial overreporting of the number of units inspected, and that there had been a systematic deflation of power brake defect ratios.

As the allegations and concerns raised were general in nature, FRA believed it prudent and necessary to allow interested parties to fully explain and discuss their concerns. Therefore, FRA conducted a public meeting on May 27, 1999 to permit the exchange of information and concerns regarding FRA's database and the information developed from that database. *See* 64 FR 23816 (May 4, 1999). The purpose of the meeting was to allow FRA to provide information regarding its internal review of the data and address some of the concerns raised as well as to allow interested parties to further develop and articulate the issues and concerns they had with regard to the data gathered and presented by FRA in the NPRM.

FRA has carefully considered all the information, data, and proposals submitted in relation to FRA Docket PB–9 when developing this final rule. This includes: the information, data and proposals developed by the RSAC Freight Power Brake Working Group; all oral and written comments submitted in relation to the 1994 NPRM on power brakes; and all oral and written comments submitted regarding the 1998 NPRM on freight power brakes. In addition to the preceding information, FRA's knowledge and experience with enforcing the existing power brake regulations were also relied upon when developing this final rule.

II. Overview of Comments and General FRA Conclusions

The following discussions are grouped by major themes and issues addressed in the 1998 NPRM and the oral and written comments submitted in relation to that document. In each of the major issue areas, FRA has attempted to outline the significant portions of the proposal, discuss the comments received on the proposal and any alternative approach recommended, and provide a general idea of how FRA has decided to address the issues or approaches.

A. Accident/Incident History and Defective Equipment

The 1998 NPRM contained a detailed discussion regarding the accident/incident data which FRA considered when developing the proposal. In that discussion, FRA noted that it considers a variety of factors in attempting to determine the relative condition of the industry as it relates to the safety of train power brake systems. Two of the factors considered when making this assessment are the number of recent brake-related incidents and the amount of defective brake equipment recently discovered operating over the railroad system, both of which provide some indication as to the potential or likelihood of future brake-related incidents. Due to concerns raised in both written comments and at the public meeting conducted on May 27, 1999, regarding the accident/incident data and power brake defect ratio data discussed above, FRA believes it is necessary to further explain how these data were used in developing this final rule.

1. Accident/Incident Data

In order to determine the potential quantifiable safety benefits to be derived from the provisions proposed in the NPRM and either retained or modified in this final rule, FRA conducted a review of all accidents/incidents reported to FRA to determine which incidents/accidents could potentially have been prevented had the provisions of the rule been in place. For purposes of the NPRM, FRA identified a brake-related incident as being an incident reported to FRA as being caused by one of the following: brake rigging down or dragging; air hose uncoupled or burst; broken brake pipe or connections; other brake components damaged, worn, broken or disconnected; brake valve malfunction (undesired emergency); brake valve malfunction (stuck brake); hand brake broken or defective; hand brake linkage and/or connections broken or defective. For purposes of the NPRM, FRA did not consider brake pipe obstruction-related incidents because FRA believed they had been fully considered at the time that FRA promulgated the final rule relating to the use of two-way end-of-train devices.

In written comments and at the public meeting held in conjunction with the NPRM, several labor representatives raised concerns regarding FRA's reliance on accident/incident information which is essentially reported to FRA by the railroads. These representatives contend that railroads have an economic incentive to report accidents/incidents as being due to human factors rather than to mechanical problems or deficiencies. Thus, they contend that the potential safety benefits identified by FRA in the NPRM are inaccurate and underestimated because the data used to determine those benefits are developed by the railroads. FRA tends to agree with the concerns raised by these commenters and raised this concern in its discussion of the accident/incident data in the NPRM.

In the NPRM, FRA acknowledged that the presented brake-related incidents most likely did not accurately reflect the total number of incidents that were potentially linked, in some part, to brake-related causes and did not provide a complete picture of the costs associated with the identified incidents. *See* 63 FR 48297. FRA recognized that the information on most incidents is provided by the railroads which generally identify the direct cause of an incident but may not sufficiently identify all of the contributory causes in a manner to permit FRA to conclude that the brake system played a part in the incident. Thus, FRA acknowledged that there may be numerous incidents which occurred in the industry which were at least partially due to brake-related problems, but which were ultimately more closely linked to human error or other mechanical problems and thus, were reported to FRA under different cause codes. However, as it is extremely difficult to identify those accidents/incidents that may have been in some part related to a brake problem, FRA elected to include only those accidents specifically identified as brake-related in its quantified safety benefits and included other potential incidents as qualitative safety benefits in the NPRM. FRA also recognized that the damage costs provided to FRA by the railroads for the incidents identified in the NPRM failed to consider all of the costs associated with an accident such as: loss of lading; wreck clearance; track delay; environmental clean-up; removal of damaged equipment; evacuations; or the impact on local traffic patterns. *See* 63 FR 48297. Thus, for purposes of the NPRM, the property damages reported by the railroads were multiplied by a factor of 1.5625 in an effort to capture these non-reported damages. *See* 63 FR 48297.

In calculating the potential quantifiable safety benefits to be derived from this final rule, FRA has slightly expanded the criteria for determining the accidents/incidents which are addressed by this final rule. Thus, for purposes of this final rule the quantified safety benefits include a percentage of certain types of accidents reported as being due to human error or other than a brake-related mechanical problem. The quantified safety benefits for this final rule also include a percentage of those incidents which are considered brake pipe obstruction-related. Although these accidents were considered in relation to the two-way EOT final rule, FRA believes that this final rule will prevent an additional percentage of those incidents that were not captured by the two-way EOT final rule.

Table 1 below contains a compilation of the relevant incidents that FRA

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considers to be preventable that have been reported to FRA from 1994 through 1998. The incidents included in this table contain incidents reported to FRA as being caused by one of the following: Brake rigging down or dragging; air hose uncoupled or burst; broken brake pipe or connections; other brake components damaged, worn, broken or disconnected; brake valve malfunction (undesired emergency); brake valve malfunction (stuck brake); hand brake broken or defective; hand brake linkage and/or connections broken or defective. Table 1 also contains incidents reported as being related to brake pipe obstructions and certain brake-related human factor incidents which include: runaway cuts of cars; train handling; and improper use of brakes. FRA believes that various provisions of this final rule have the potential of preventing a certain percentage of the incidents reported as being due to these causes. However, in developing the cost/benefit analysis for this final rule, FRA used a very conservative effectiveness rate of .2 for incidents with these reported causes. The Regulatory Impact Analysis prepared in connection with this final rule provides a detailed discussion of how certain human factor and brake pipe obstruction incidents were utilized when evaluating this rule.

It should be noted that the damage costs noted in Table 1 for the identified incidents are based on the damage to railroad property or equipment. Thus, the damages presented fail to consider the costs associated with the injuries and fatalities involved. These costs are calculated in detail in the Regulatory Impact Analysis prepared in connection with this final rule. The costs presented in Table 1 also do not consider such things as: loss of lading; wreck clearance; track delay; environmental clean-up; removal of damaged equipment; evacuations; or the impact on local traffic patterns. Consequently, the railroad property damages have been multiplied by a factor of 1.5625 in an effort to capture some of these non-reported damages.[1]

TABLE 1.—BRAKE-RELATED INCIDENTS

Year	Number of accidents	Injuries	Fatalities	Damages *
1994	99	24	1	$11,414,346
1995	121	65	0	9,431,582
1996	112	44	3	20,637,986
1997	98	8	0	9,651,569
1998	121	3	0	10,791,626
Total	551	140	4	61,927,107

* Increased by 56.25% to reflect unreported damages.

2. Use of Power Brake Defect Data

A second factor that is considered by FRA, to some extent, in determining the relative condition of the industry in regard to the safety of power brake equipment is the percentage of equipment found with defective brakes during FRA inspections and special projects. As noted in the preceding discussions, the method for calculating and determining the percentage of equipment with defective brakes was a contentious subject within the RSAC Power Brake Working Group prior to the issuance of the NPRM and at the public hearings and meetings conducted subsequent to the issuance of the NPRM. In the NPRM, FRA provided a lengthy discussion regarding the data it had available regarding power brake defect ratios and the limitations regarding the use of such data. *See* 63 FR 48298. In that discussion, FRA explained that data on brake defects is collected by FRA inspectors as they do rail equipment inspections and during special projects conducted under the Safety Assurance and Compliance Program (SACP). The NPRM made clear that the data collected during these activities is not suitable for use in any statistical analysis of brake defects.

In order to perform a statistically valid analysis, either all cars and locomotives must be inspected (prohibitively expensive), or a statistically valid sample must be collected. For the sample to be valid for the purpose of statistical analysis, the sample must be randomly selected so that it will represent the same characteristics as the universe of data. Random samples have several unique characteristics. They are unbiased, meaning that each unit has the same chance of being selected. Random samples are independent, or the selection of one unit has no influence on the selection of other units. Most statistical methods depend on independence and lack of bias. Without a randomized sample design there can be no dependable statistical analysis, and no way to measure sampling error, no matter how the data is modified. Random sampling "statistically guarantees" the accuracy of the results.

The sampling method used for regular FRA inspections is not random. It is more of a combination between a *judgement* sample and an opportunity sample. The opportunity sample basically just takes the first sample population that comes along, while the judgement sample is based on "expert" opinion. The sampling method used for SACP inspections is also a judgement sample, where FRA is focusing its inspections on a specific safety concern. This method is extremely prone to bias, as FRA is typically investigating known problem areas. Furthermore, some SACP inspections are joint inspections with labor. Consequently, it is unknown whether the final reports reflect only FRA defects, as many of the joint inspections had both AAR and FRA defects recorded.

Neither the regular FRA inspections nor the SACP inspections were designed for random data collection. Although both are very useful to FRA, they were not designed for this purpose and the data should be used carefully. FRA believes that data collected during routine inspections are the most likely data to accurately reflect the condition of the fleet. However, both FRA inspection data and SACP data lack any measuring device, a defect is a defect and no distinction is made between a critical defect versus a minor defect. Furthermore, the estimated correlation coefficients between defects and

[1] AAR surveyed its members and reported that, on average, these other costs constitute an additional 56.25 percent of the reported damages.

accidents were not found to be statistically significant. This does not mean that defects cannot lead to collisions or derailments as the lack of correlation could easily be a result of non-random sampling. Therefore, the data collected both during routine FRA inspections and under SACP cannot be used as a proxy for data collected by means of a random sample for the purpose of statistical analysis. The sample is not random, so no dependable statistical analysis may be performed. Consequently, FRA did not and will not use the data regarding power brake defects for the purpose of conducting any type of statistical analysis.

In the NPRM, FRA provided brake defect ratio's for the years 1993 through 1997 based upon the data contained in its database. *See* 63 FR 48298, Table 2. The average brake defect ratio for this five year period was 3.84 percent. The NPRM also noted that the available SACP data (which focuses on known problem areas) indicated brake defect ratios as high as 35 percent at some locations. FRA stated that the SACP data in all likelihood indicates that there are localized areas of concern and that some railroads have particular yards or operations with persistent problems. The NPRM attempted to make clear that FRA believes that brake defects are in all likelihood higher than that indicated by FRA's database and that the reality of power brake defects lies somewhere between the 3.84 percent represented in FRA's database and the 35 percent found at certain locations. FRA noted that actual power brake defect ratios are probably closer to the percentage reflected in FRA's database because FRA examines almost ½ million freight cars and locomotives annually. Thus, contrary to the assertions of certain commenters, FRA did not assert or contend that the power brake defect ratios represented by its database were an accurate or precise reflection as to the relative condition of the industry. In fact, as evidenced by the preceding discussion, FRA attempted to point out the limited usefulness of the data contained in its database. Furthermore, review of the defect data submitted by the BRC at the technical conference in Walnut Creek, California, as discussed below, appears to support FRA's conclusions regarding power brake defect ratios.

The NPRM made clear that the power brake defect ratios indicated in FRA's database were specifically relied on only to calculate the cost of the requirement to conduct retests on cars found with brakes that are not applied during the performance of the various required brake tests. Power brake defect ratios were not specifically relied on when developing any provision contained in the NPRM or in this final rule. Although power brake defect ratios were considered, they were not used as the basis for any of the provisions proposed in the NPRM or contained in this final rule. They were generally used to aid FRA in identifying problem areas, which in turn helped FRA identify brake issues and practices that needed to be addressed. For example, the existence of high power brake defect ratios at a particular location or on a particular railroad likely indicate the existence of certain practices or procedures that create or contribute to the high defect levels. As is evident from the discussions of the various requirements contained in both the NPRM and in this final rule, FRA considered a massive amount of information when developing this rule. These included accident/incident data; information and data provided in relation to the 1994 NPRM, the RSAC Power Brake Working Group, and the 1998 NPRM as well as FRA's experience in the enforcement of existing regulations and the expertise and knowledge of FRA's field inspectors.

Although the data regarding defect ratios contained in FRA's database has limited usefulness in the context of developing a regulation, the data is very useful to FRA in other ways. The data is useful in measuring a railroad's general compliance level and aids in identifying problem areas or locations. This information aids FRA in allocating its inspections forces and permits FRA to focus its enforcement on locations or issues which are in the greatest need of such scrutiny. By focusing its enforcement in this manner FRA is able to make the best use of its limited resources.

3. Discussion of Concerns Regarding FRA's Collection of Power Brake Defect Data

Although the NPRM and the preceding discussion detail the limitations of using the data collected by FRA regarding power brake defects when developing a regulation, FRA believes that a more detailed discussion of FRA's collection of power brake defect data is needed in order to address the issues raised by various commenters subsequent to the issuance of the NPRM. As noted above, FRA conducted a public meeting on May 27, 1999 in order to address general concerns raised by various parties regarding the accuracy of the brake defect data presented in the NPRM and to provide interested parties the opportunity to develop the issues they generally raised in oral and written comments regarding that data. At this public meeting, representatives of several labor organizations raised issues regarding the accuracy and use of the power brake defect data complied by FRA. These commenters generally allege that the method by which FRA collects defect data results in the underreporting of defects which in turn results in a systematic deflation of power brake defect ratios.

Specific issues raised at this public meeting and in subsequent written comments include: the overreporting of units inspected during FRA inspections; the calculation and deflation of the power brake defect ratio; the inspection procedures used by FRA that tend to exclude certain categories of power brake defects; potential discrepancies in the input data relative to the activity codes from FRA field inspection reports to FRA's database; the performance of power brake inspections by FRA inspectors on cars that are not properly charged or connected to a source of compressed air; FRA's reliance on the railroads for the total number of cars inspected; and the wide variance between FRA inspectors and FRA regions in the number of units inspected, the number of defects reported, and the resulting defect ratios.

In order to understand some of the issues raised, it is necessary to understand how inspection data developed by an FRA inspector are entered into FRA's database. FRA Motive Power & Equipment (MP&E) inspectors conduct inspections of railroad freight equipment pursuant to various parts of the Federal regulations contained in chapter 49 of the Code of Federal Regulations. Principally, these include inspections under the following: Part 215—Freight Car Safety Standards; part 229—Locomotive Safety Standards; part 231—Safety Appliance Standards; and part 232—Power Brakes and Drawbars. When performing an inspection under each of these parts, an FRA inspector will fill out the appropriate inspection form which indicates the number of units inspected under each part as well as the number of defective conditions found on those units. In the context of performing power brake inspections under part 232, an inspection of a car means a unit count of one. When this type of inspection is conducted, inspectors inspect various brake-related car components such as: Foundation brake rigging, air hoses, angle cocks, brake shoes, and, where possible, piston travel. When an inspector performs an inspection of a brake test required under part 232, the unit count for such a test

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is the train consist, block of cars, or car being tested. For example, when an inspector observes the performance of an initial terminal brake test, the entire train would constitute one unit count.

Certain labor representatives raised various issues regarding FRA's calculation of power brake defect ratios. Several of these concerns involve the potential overreporting of the number of units inspected which then results in the deflation of power brake defect ratios. One concern addressed the practice of counting a single car or locomotive as a unit count under each of the MP&E regulations that it is inspected under. For example, a freight car could be considered a unit count under part 215, part 231, and part 232 if an FRA inspector were to inspect that freight car under each of those provisions. Thus, one freight car could be represented as three unit counts. It is claimed that this practice inflates the number of units inspected and thus, deflates defect ratios. This concern would be valid if FRA were to attempt to express a defect ratio for combined parts of the CFR. For example, if FRA were to attempt to express an MP&E defect ratio (a combination of parts 215, 229, 231, and 232) then the method by which FRA collects data would result in an inflation of the number of units inspected and the resulting defect ratio would be skewed. For purposes of analysis, FRA's database is constructed so that defect ratios are expressed only in terms of each separate part of the CFR. Therefore, the power brake defect ratios discussed in the NPRM were calculated based solely on the units inspected by FRA under the provisions contained in part 232.

A second concern involves the potential of duplicate inspection reports being submitted by different FRA inspectors when engaged in team inspections. Certain labor representatives allege that FRA inspectors are significantly inflating the number of power brake units being inspected by submitting duplicate reports for the same inspection activity when groups of FRA inspectors perform inspections at the same location. In an effort to investigate this concern, FRA designed a computer program to search for potentially duplicate inspection reports submitted during the years of 1995 through 1998. Table 2 displays the figures regarding power brake inspections conducted by FRA for the years of 1995 through 1998 that is contained in FRA's database.

TABLE 2.—POWER BRAKE INSPECTIONS AND DEFECT RATIOS: 1995 THROUGH 1998*

Calendar year	Power brake units	Power brake defective units	All railroads power brake defect ratios	Class I RRs power brake defect ratios
1995	611,824	24,387	.03986	.0369
1996	646,140	28,795	.04456	.0419
1997	582,685	26,004	.04463	.045
1998	585,663	26,286	.04488	N/A

*Note: Class I Railroads Power Brake Defect Ratios column information comes from the Regulatory Impact Analysis (RIA) for the 1998 NPRM on freight power brakes. No defect ratio was used in the report for calendar year 1998 because the RIA was finalized in August of 1998.

In order to identify potential duplicate reports the computer program identified inspection reports in which two or more FRA inspectors were in the same county, on the same day, on the same railroad, and in which at least one unit-count code matched. Table 3 displays the results of this search, showing the number of potential duplicate reports that were submitted from 1995 through 1998 and showing the potential number of over reported units.

TABLE 3.—POTENTIAL DUPLICATE POWER BRAKE INSPECTIONS 1995 THROUGH 1998

Calendar year	Inspection reports with more than one matching unit	Units	Potential duplicate units (half of units)
1995	39	1,965	983
1996	154	12,646	6,323
1997	342	19,482	9,741
1998	182	8,692	4,346

Table 4 and Table 5 display the impact of the potential duplicate reports on the calculation of power brake defect ratios. FRA believes that the data contained in Tables 4 and Table 5 establish that the impact of potential duplicate reports on the defect ratios presented in the NPRM is insignificant when considered in the context of nationwide data.

TABLE 4.—REVISED POWER BRAKE DATA CONSIDERING POTENTIAL DUPLICATE REPORTS 1995 THROUGH 1998

Calendar year	Power brake units	Potential duplicate units	Units minus potential duplicate units	Defective units	Defect ratios after adjusting for potential duplicate units
1995	611,824	983	610,841	24,387	.03992
1996	646,140	6,323	639,817	28,795	.04501
1997	582,685	9,741	572,944	26,004	.04539
1998	585,663	4,346	581,317	26,286	.04522

TABLE 5.—AFFECT OF POTENTIAL DUPLICATE REPORTS ON POWER BRAKE DEFECT RATIOS 1995 THROUGH 1998

Calendar year	Defect ratios before adjustment	Defect ratios after adjustment	Difference
1995	.03986	.03992	.00006
1996	.04456	.04501	.00045
1997	.04463	.04539	.00076
1998	.04488	.04522	.00034

It should be noted that the numbers presented in Tables 3 through Table 5 overstate the actual impact of potential duplicate inspection reports. For the year 1998, FRA conducted an in-depth analysis of the potential duplicate reports found by the computer program. The computer program identified 393 potential duplicate inspection reports for the year 1998. However, included in this grouping were unique inbound inspection reports, outbound inspection reports and split inspection reports. In addition, there were inspection reports from inspectors who worked in the same county, but at different locations. Each of these reports was removed from the 393 potentially duplicate inspection reports identified by the computer program based on a report-by-report analysis of each of the reports by FRA MP&E specialists. This analysis left 182 potential duplicate reports for 1998, which were used to calculate the figures presented in Tables 3 through 5 for 1998. Although these tables note 182 potential duplicate inspection reports involving 8,692 units (4,346 duplicates), a further analysis of the reports by FRA found that only 54 of the inspection reports were actually found to be duplicative. These 54 duplicate inspection reports involved the over-reporting of just 3,073 units rather than the 4,346 units identified in Table 4. As an in-depth analysis was not performed on the potential duplicate inspection reports identified by the computer program for the years of 1995 through 1997, the figures provided for those years in all likelihood greatly overstate the actual number of duplicate claims submitted in each of those years. Thus, the actual impact of duplicate inspection reports is even less than the small percentages indicated in Table 5 above.

Although the impact of duplicate inspection reports is insignificant, FRA believes that a brief discussion of how these duplicate inspection reports happened is necessary in order to assure interested parties that such occurrences are rare and that FRA has taken steps to avoid these inaccuracies. In 1994, FRA had four inspection forms for the Agency's five inspection disciplines. The Operating Practices and Hazardous Materials disciplines shared the same form. FRA also had a Quality Improvement Plan (QIP) daily activity report form to help the Agency track resource allocations, including the amount of time required to perform certain inspections. When "team inspections" occurred, one inspector completed the inspection report for the entire team. However, each inspector on the team was also required to complete a separate QIP report to receive credit for the inspection. On January 1, 1995, a newly developed single inspection form (FRA 6180.96) for all disciplines became operational. Furthermore, in May of 1995, FRA discontinued the collection of QIP-time data based on FRA's conclusion that it had adequate information from previous QIP reports regarding the time it takes to conduct various inspections. In addition, the new inspection form incorporated many of the previous QIP codes. In August 1995, FRA converted to a data collection system using personal computers.

After conducting the analysis discussed above, it was determined that 26 FRA MP&E inspectors inadvertently prepared all of the involved duplicate inspection reports. Furthermore, FRA was not aware that the new computer system did not filter out duplicate inspection reports. After becoming aware of these problems based on reports from its field personnel, FRA specifically addressed the issue of inspection reporting at FRA's multi-regional conference conducted in 1998. At this conference, FRA's Office of Safety management provided specific guidance on preparing reports that would eliminate potential duplicate reporting. During this same period, FRA also changed its computer software to give inspectors credit for inspections while at the same time preventing potential duplicate reporting. Furthermore, on March 5, 1999, FRA re-issued reporting procedures designed to prevent duplicate inspection reports when team inspections are conducted. These procedures were issued to all Federal and State inspection personnel and to all FRA Regional Administrators and Deputy Regional Administrators.

Subsequent to the public meeting conducted in May of 1999, FRA made two modifications to the summary data produced by its database in order to clarify the meaning of the data and to avoid misunderstanding by outside parties. The first modification relates to safety appliance inspections conducted under 49 CFR part 231. The summary data previously contained the heading "SA & PB (cars and locomotives)." This heading may have caused some confusion because the heading suggests that it applies to both safety appliance and power brake inspections when in reality the data captured under this heading only concerns safety appliance inspections under part 231. This heading has been modified to read "SA (cars and locomotives)" to more accurately reflect the information contained under this heading. FRA has also modified the summary data by eliminating the calculation of an MP&E defect ratio. As discussed above, FRA believes that the calculation of a composite MP&E defect ratio is inappropriate based on the way FRA collects the information contained in its database and would result in a deflation of MP&E defect ratios. Therefore, defect ratios will only be presented for each separate MP&E CFR part.

In response to the issue raised regarding FRA's practice of conducting brake inspections under part 232 while cars are not connected to a source of compressed air or not completely charged with air, FRA has developed a separate reporting code for brake inspections conducted in this manner. This reporting code will become effective in mid-2000 and will indicate when brake inspections are conducted on cars or trains that are not charged with compressed air. Although FRA agrees that the most thorough brake inspection is performed when a car or train is charged, a large majority of the brake components on a car can be inspected for abnormalities without the actual application of the air brakes. For example, cut-out air brakes, brake connection pins missing, brake rigging down or dragging, brake shoes worn to the extent that the backing plate comes in contact with the tread of the wheel,

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angle cocks missing or broken, retainer valves broken or missing, and air brake piping bent or broken can all be discovered regardless of whether a car or train is charged with air. When FRA inspectors conduct train air brake tests, they inspect all of the components noted above as well as the operation of the train air brakes while under the required air pressures. FRA has conducted inspections of brake equipment in this manner for decades and will continue to conduct brake inspections under part 232 on equipment that is both on and off a source of compressed air. FRA believes that the addition of a code to identify those inspections conducted while equipment is not connected to a source of compressed air will provide a more accurate assessment of defective brake system components.

Two other issues raised by various individuals at the May 27, 1999, public meeting concerned FRA's reliance on railroads to determine the number of cars inspected and the wide disparity between FRA inspectors and regions with regard to the number of units inspected and defects reported. FRA acknowledges that FRA inspectors frequently rely on information provided by the railroad regarding car counts when initially conducting an inspection, which is sometimes higher than the actual number of cars being inspected. However, in most instances FRA inspectors request a copy of the consist prior to finalizing their inspection reports to ensure a proper unit count. FRA has issued guidance to its inspectors to ensure that the unit counts on all inspections are accurate.

Although FRA acknowledges that the number of brake inspections conducted varies somewhat from inspector to inspector and from region to region, FRA contends that these variances are the result of competing priorities and varying workloads within each region. FRA makes every effort to standardize its inspection activities by providing substantial training to each of its inspectors. This training is comprised of both classroom and on-the-job training. Classroom training conducted at least once a year at the Regional or Multi-Regional conferences, and through training provided by General Electric, General Motors-EMD, and Westinghouse Air Brake Company. Many regions also conduct discipline specific conferences with training on new regulations and issues provided by various subject matter experts. On-the-job training is provided through Regional Specialists and journeyman inspectors. These individuals will work one-on-one with the inspectors on the various types of inspections that the inspector is required to conduct. FRA also frequently issues enforcement guidance to its inspectors in the form of technical bulletins in order to ensure consistent enforcement of the regulations.

4. Review of Defect Data Submitted by the Brotherhood of Railway Carmen (BRC)

After issuance of the 1998 NPRM, FRA conducted a technical conference in Walnut Creek, California, on November 23 and 24, 1998. At this technical conference individuals representing the BRC submitted a vast amount of data collected either by its members at various locations or through joint labor and FRA inspection activities conducted at various locations. The data provided by BRC representatives addressed defective equipment found in various trains at seven different locations across the country during various time periods from October of 1997 to November of 1998. The BRC submitted this data in order to establish that the power brake defect ratios developed based on the information contained in FRA's database were inaccurate.

FRA conducted an in-depth review of the data submitted by BRC representatives. Although the BRC attempted to summarize the data for many of the locations addressed, FRA's review of the data discovered that the BRC's summaries counted defects that were not power brake defects, failed to summarize all the data for all the trains covered by the supporting documentation, and double counted some brake defects when calculating the number of defective cars. It should also be noted that approximately 80–90 percent of the defective conditions noted on the supporting documentation merely listed the defective condition as being "brake shoes." This notation does not make clear whether the defective brake shoe was defective under the federal regulations or defective under AAR industry standards. However, in order to assess the data in a manner that is most favorable to the party submitting the data, FRA assumed that all defects noted as "brake shoes" were defective under Federal requirements. In conducting its analysis of the data submitted, FRA only considered power brake defects, whereas, BRC's summary data appear to consider other mechanical and safety appliance defects which are not the subject of this proceeding.

Table 6 contains a summary of FRA's in-depth analysis of the data submitted. FRA's analysis determined that the data submitted by the BRC establish a power brake defect ratio of approximately 4.96 percent, which is less than 1 percent higher than the power brake defect ratios developed based on the information contained in FRA's database for the years of 1996 and 1997, discussed in the 1998 NPRM. *See* 63 FR 48298. The analysis of the data submitted by the BRC indicates that some locations and some trains have power brake defect ratios in excess of 11 and 12 percent, which is consistent with the findings made and reported by FRA during various SACP inspections as noted in the preceding discussion and in the 1998 NPRM.

TABLE 6.—ANALYSIS OF DEFECT DATA SUBMITTED BY THE BRC

Location	Total trains inspected	Total cars inspected	Cars with power brake defect	Power brake defect ratio (percent)
North Platte, Nebraska	1,625	150,926	8,136	5.39
Hinkle Yard, Oregon	151	13,455	425	3.15
Oak Island-Newark, New Jersey	13	618	72	11.65
Kansas City, Missouri	180	11,917	159	1.33
Clovis, Alliance, Temple Yards—Texas	16	1,419	41	2.88
Sparks Yard—Sacramento, California	8	781	30	3.84
Various Locations, Mississippi	4	296	37	12.5
Totals	1,997	179,412	8,900	4.96

B. Inspection and Testing Requirements

As noted in the preceding discussions and in the 1998 NPRM, the issues related to the inspection and testing of the brake equipment on freight trains are some of the most complex and sensitive issues with which FRA deals on a daily basis. Consequently, the requirements related to the inspection and testing of freight power brakes must be viewed as the foundation on which the rest of the requirement contained in this final rule are based.

1. Brake Inspections—General

In the 1998 NPRM, FRA fully discussed the information and proposals submitted in response to the 1994 NPRM, as well as the proposals developed as part of the RSAC process. *See* 63 FR 48298–304 (September 9, 1998). Based on its review of that information and those proposals and based upon its experience in the enforcement of the current power brake regulations, FRA provided a detailed discussion as to why those alternatives were not viable models upon which a revision of the freight power brake requirements could be based. *See* 63 FR 48301–304. Rather than reiterate those discussions, FRA refers interested parties to the discussions contained in the 1998 NPRM noted above. In developing the inspection requirements contained in the NPRM, FRA determined that the proposed requirements should closely track the existing inspection requirements and intervals as they have proven themselves effective in ensuring the safety of railroad operations. FRA believed that moderate modifications to the existing requirements were necessary to ensure clarity, eliminate potential loopholes, incorporate current best practices of the industry, and enhance enforcement while providing some flexibility to the railroads to utilize new technologies and recognize contemporary railroad operations.

The current regulations are primarily designed around the following four different types of brake system inspections: Initial terminal; 1,000-mile; intermediate terminal; and brake pipe continuity check. *See* 49 CFR 232.12 and 232.13. These brake system inspections differ in complexity and detail based on the location of the train or on some event that affects the composition of the train. Each of the inspection provisions details specific actions that are to be performed and identifies the items that are to be observed by the person performing the inspection.

The initial terminal inspection described in § 232.12(c)–(j) is intended to be a comprehensive inspection of the brake equipment and is primarily required to be performed at the location where a train is originally assembled. This inspection requires the performance of a leakage test and an in-depth inspection of the brake equipment to ensure that it is properly secure and does not bind or foul. Piston travel must be checked during these inspections and must be adjusted to a specified length if found not to be within a certain range of movement. The brakes must also be inspected to ensure that they apply and release in response to a specified brake pipe reduction and increase. FRA recently issued enforcement guidance to its field inspectors clarifying that both sides of a car must be observed sometime during the inspection process in order to verify the condition of the brake equipment as required when performing an initial terminal inspection.

The current regulations require an intermediate brake inspection at points not more than 1,000 miles apart. These inspections are far more limited than the currently required initial terminal inspections in that the railroad is required only to determine that brake pipe leakage is not excessive, the brakes apply on each car, and the brake rigging is secure and does not bind or foul. *See* 49 CFR 232.12(b). In the 1982 revisions to the power brake rules, FRA extended the distance between these inspections from 500 miles to 1,000 miles.

The existing regulations also mandate the performance of an intermediate terminal brake inspection on all cars added to a train after it leaves its initial terminal, en route to its destination, unless they have been previously given an initial terminal inspection. This inspection requires the performance of a leakage test and verification that the brakes on each car added to the train and the rear car of the train apply and release. *See* 49 CFR 232.13(d). Railroads are permitted to use a gauge or device at the rear of the train to verify changes in brake pipe pressure in lieu of performing an application and release on the rear car. The current regulations also require that if cars that are given an intermediate terminal brake inspection and have not previously been provided an initial terminal inspection and are then added to a train, then the added cars must be given an initial terminal inspection at the next location where facilities are available for performing such an inspection.

The current regulations also require the performance of a brake pipe continuity test whenever minor changes to a train consist occur. This inspection requires that a brake pipe reduction be made and verification that the brakes on the rear car apply and release. Railroads are permitted to use a gauge or device at the rear of the train to verify changes in brake pipe pressure in lieu of visually verifying the rear car application and release. This inspection is to be performed when a locomotive or caboose is changed, when one or more consecutive cars are removed from the train, and when previously tested cars are added to a train.

In the 1998 NPRM, FRA noted that in its opinion railroads have not conducted the excellent initial terminal inspections that were contemplated in 1982, when FRA extended the 500-mile inspection interval to 1,000 miles. FRA also contended that many initial terminal brake inspections are being performed by individuals who are not sufficiently qualified or trained to perform the task. FRA recognized that since 1982 new technology and improved equipment have been developed that allow trains to operate for longer distances with fewer defects. However, the key to achieving this improved capability is to ensure the proper operation and condition of the equipment at the location where the train is initially assembled.

Although FRA agreed that many of the initial terminal inspections conducted by train crews are not of the quality anticipated in 1982 when the inspection interval was increased from 500 miles to 1,000 miles, FRA also conceded that properly trained and qualified train crew personnel can perform certain brake inspections and have been performing such inspections for many years. FRA stated that it did not believe that a reversion to a 500-mile inspection interval restriction on trains inspected by train crews, as sought by some commenters, would adequately address the concerns regarding the safety of those trains and would impose an economic burden on the railroads that could not be justified. In FRA's view, two of the major factors in ensuring the quality of brake inspections are the proper training of the persons performing the inspections and adequate enforcement of the requirements. Therefore, FRA proposed that the current 1,000-mile inspection interval be retained but that general training requirements for persons conducting brake inspections be established. The proposed training requirements included general provisions requiring both classroom and "hands-on" training, general testing requirements, and annual refresher training provisions. FRA also proposed that various training records be

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maintained by the railroads in order for FRA to determine the basis for a railroad's determination that a particular person is qualified to perform a brake inspection, test, or repair. FRA believed that the proposed general training and recordkeeping requirements would provide some assurances that qualified people were conducting brake system inspections and tests. (See discussion below titled "Training and Qualification of Personnel.")

In addition to proposing general training requirements, FRA also noted its intent to enhance and increase its enforcement activities with regard to the performance of the brake inspections and tests eventually finalized in this rule, particularly those performed by train crews. FRA made clear that it would make a concerted effort to focus on the qualifications of train crew members and would strictly scrutinize the method and length of time spent by these individuals in the performance of the required inspections. FRA also committed to focus its inspection activities to ensure that train crews are provided the proper equipment necessary to perform many of the required inspections.

In addition to focusing its enforcement and to aid in that initiative, FRA proposed various clarifications, modernizations, and modifications of the current inspection requirements in order to close what are perceived to be existing loopholes and to incorporate what FRA believed to be the best practices existing in the industry while updating the requirements to recognize existing technology. FRA believed, and many representatives of rail labor and management agreed, that the current inspection requirements are very good for the most part and are sufficient to ensure a high level of safety, but that they need to be strictly enforced, clarified, and updated to recognize existing and new technology. Therefore, as noted above, FRA did not propose an extensive revision of the basic brake inspection intervals or requirements. Rather, FRA proposed a moderate revision of the requirements, with the intent of tightening, expanding, or clarifying those inspection or testing requirements that have created enforcement problems or inconsistencies in the past. FRA recognized some of the technological improvements made in the industry such as the use of two-way EOTs during the brake tests and use of the air flow method of qualifying train air brake systems. FRA also recognized that some trains are capable of moving extended distances between inspections provided that comprehensive inspections are performed at the locations where the trains are originated. (See discussion below titled "Extended Haul Trains.")

In order to clarify the requirements regarding where and when various brake inspections and tests were to be performed, FRA proposed modification of the terminology related to the power brake inspection and testing requirements contained in the current regulations, which is generally based on the locations where the inspections and tests must be performed (*e.g.*, "initial terminal" and "intermediate terminal"). Instead, FRA proposed various "classes" of inspections based on the duties and type of inspection required, such as: Class I; Class IA; and Class II. This is similar to the approach taken by FRA in the 1994 NPRM and in the final rule on passenger equipment safety standards. *See* 64 FR 25682–83. FRA believed that this type of classification system would avoid some of the confusion that currently arises regarding when and where a certain brake inspection must be performed.

Currently, the brake system inspection and testing requirements are interspersed within §§ 232.12 and 232.13 and are not clearly delineated. Therefore, FRA proposed a reorganization of the major types of brake inspections into separate and distinct sections in order to provide the regulated community with a better understanding as to when and where each inspection or test would be required. Although FRA proposed a change in the terminology used to describe the various power brake inspections and tests, the requirements of these inspections and tests mirrored the current requirements and were not intended to change or modify any of the voluminous case law that had been developed over the years regarding the inspections. Consequently, FRA proposed four different types of brake inspections that were to be performed by freight railroads some time during the operation of the equipment. FRA proposed the terms "Class I," "Class IA," "Class II," and "Class III" to identify the four major types of brake inspections required by this proposal.

The proposed Class I brake test, currently known as the "initial terminal" test, generally contained the requirements currently contained in § 232.12(a) and (c)–(j). *See* 63 FR 48362–63. The requirements were reorganized to clearly delineate when and how the inspection was to be performed based on current interpretations and comments received since the 1994 NPRM. The requirements were also modified to require written notification that the test was performed and that the notification was to be retained in the train until it reached its destination. The proposed revisions also acknowledged the use of the air flow method for qualifying train brake systems and permitted the use of end-of-train devices in the performance of the test. The proposal also provided some latitude to trains received in interchange that had a pre-tested car or solid block of cars added at the interchange point or that were to be moved less than 20 miles after being received in interchange by permitting these types of trains to continue without the performance of a comprehensive Class I brake test.

The proposed Class IA brake test clarified the requirements for performing 1,000-mile brake inspections currently contained in § 232.12(b). *See* 63 FR 48363. The proposal made clear that the most restrictive car or block of cars in the train would determine when the inspection was to be performed on the entire train. FRA also proposed that railroads designate the locations where these inspections would be conducted and did not permit a change in those designations without 30-day notice to FRA or the occurrence of an emergency situation. The proposed Class II and Class III brake tests essentially clarified the intermediate terminal inspection requirements currently contained in § 232.13(c) and (d) regarding the performance of brake system inspections when cars were added to the train en route or when the train consist was slightly altered en route. *See* 63 FR 48364.

In addition to the modifications and clarifications proposed with regard to the four major types of brake system inspections, FRA's proposal also retained, with clarification and elaboration, the basic inspection requirements related to transfer trains currently contained at § 232.13(e) as well as the requirements for performing brake system inspections using yard air sources currently contained at § 232.12(i). *See* 63 FR 48365. The proposal also retained the requirements related to the inspection and testing of locomotives when used in double heading and helper service currently contained at § 232.15 and proposed additional inspection requirements of locomotives when used in helper service or in distributed power operations to ensure the proper functioning of the brakes on these locomotives as these types of inspections are not adequately addressed in the existing regulation. *See* 63 FR 48365. Furthermore, the proposal recognized that trains, if properly inspected, could safely travel greater

than 1,000 miles between brake inspections. (See discussion below titled "Extended Haul Trains.")

FRA received numerous comments in response to the 1998 NPRM from representatives of rail labor and rail management, various private car owners, the NTSB, manufacturers of rail equipment, and one state public utility commission relating to these proposed provisions. These individuals and representatives submitted comments addressing the qualifications of individuals conducting the proposed inspections, the methods by which the proposed inspections are to be conducted, the frequency with which the proposed inspections should be required, and various other specific aspects of the language used in the proposed inspection requirements.

Several labor representatives objected to the proposed change in the names of the specific required inspections. These commenters believe that the proposed new terminology of Class I, Class IA, Class II, and Class III would result in a number of problems including confusion among those individuals responsible for performing the inspections as the existing terminology has been used for decades, imposition of additional training costs on the railroads as workers will need to be reeducated, and the risk of upsetting years of case law dealing with the various inspections.

Certain labor representatives also objected to the language used in connection to the proposed inspections that would permit a qualified person to perform many of the required inspections. Various labor organizations and their representatives reiterated their concerns that such an approach would continue to allow untrained and unqualified train crew personnel to perform the required inspections. These commenters continued to assert that FRA should mandate that carmen, or persons similarly trained and experienced, perform all of the required brake inspections except for the cursory train line continuity inspections covered by the proposed Class III brake test. It is their belief that only carmen possess the necessary training, skill, and experience to properly perform the other brake inspections contained in the proposal. These commenters contend that FRA is ignoring the commitment made by rail management in 1982, when the regulations were revised to permit trains to travel up to 1,000 miles between brake inspections, to conduct high quality inspections at a train's initial terminal. They contend that the 1982 revisions were intended to require that these brake inspections be performed only by carmen. Several labor representatives also contend that since the railroads have failed to live up to the commitment made in 1982, to conduct high quality initial terminal inspections, that FRA should reconsider its proposals to permit trains to travel 1,000 miles or more between brake inspections. These commenters recommended that FRA reduce the inspection interval to 500 miles.

Conversely, representatives of rail management and private car owners suggest that FRA failed to adequately consider the industry's safety record in proposing the inspection requirements. Several of these commenters recommended that FRA reconsider performance standards similar to those provided by the AAR in response to the 1994 NPRM. *See* 63 FR 48300. These individuals assert that based upon the industry's excellent safety record there is no need for the command and control type of regulations proposed in the 1998 NPRM. Several railroad representatives also commented that the proposed training requirements for designating an individual as a qualified person are onerous and not justified in light of the industry's safety record. They contend that the industry's safety record is evidence of the sufficiency of the training currently provided to its inspection forces. (See discussion below regarding the "Training and Qualification of Personnel.")

Many railroad and private car owner representatives also contend that there is no justification for continuance of the 1,000-mile inspection requirement. They contend that if a car is properly inspected at its point of origin it can be safely moved to destination and that very few cars are found defective at 1000-mile inspections. As support for these contentions, they cite to various studies, which included: a 1994 study conducted by the Illinois Institute of Technology Research Institute, which concluded that brake shoes could last up to 4,000 miles; a 1993 study conducted by BNSF at Havre, Montana, which found that less than ⅓ of 1 percent of the cars inspected at 1,000 miles had any kind of brake defect; and data submitted in 1985 by the AAR related to cars operating 3,000 miles between brake inspections. These commenters also rely on the fact that Canada eliminated its intermediate brake inspection requirement in 1994. Consequently, these commenters contend that the 1,000-mile inspection serves no useful purpose from a safety standpoint, creates unnecessary delays, and should be eliminated.

Commenters representing certain labor organizations also recommended that FRA establish step-by-step procedures for conducting the proposed inspections which specifically include a requirement that both sides of a train be given a walking inspection during both the set and the release of the brakes. These commenters contend that the language proposed in the 1998 NPRM regarding the inspection of both sides of a train is unclear and creates uncertainty as to how a proper inspection is to be conducted. They further recommend that roll-by inspections of the brake release not be permitted and that a walking inspection of the release be required. They also object to the proposed requirement permitting the use of an end-of-train device in lieu of a visual inspection of the pressure at the rear car in the train or in lieu of a set and release on such car as such a practice does not ensure actual application and release of that rear car.

Representatives of railroads and private car owners also believe that FRA should clarify the method by which certain inspections are to be performed. However, these commenters seek to clarify that both sides of the equipment do not have to be inspected during either the application or release of the brakes when conducting a Class I brake test and that both sides of the equipment do not have to be inspected when conducting Class IA brake tests. They contend that there is no reason to observe both sides of the equipment during either the set or release as long as the brake rigging and equipment is inspected to ensure it is in proper condition prior to or at the same time that the application or release of the brakes is conducted. If the brakes are applied or released on one side of the equipment then, due to the design of the equipment, the brakes on the other side of the equipment will be similarly applied or released in virtually every instance. Therefore, it is contended that there is no justification to require observation of the set and release from each side of the equipment. These commenters also contend that FRA needs to clarify that both sides of the equipment do not need to be observed during the performance of a Class IA inspection. They assert that such a requirement would be contrary to the current 1,000-mile inspection requirements and would increase the burden on railroads when conducting this inspection.

The CAPUC submitted comments on the proposed inspection requirements recommending that each side of the car be inspected during both the application and release of the brakes. This commenter also recommend that FRA

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require the proposed Class I brake tests to be performed by individuals designated as "qualified mechanical inspectors" pursuant to the proposal. The CAPUC believes that only these individuals possess sufficient knowledge and ability to adequately perform the inspection. The NTSB also submitted comments on the proposed inspection requirements suggesting that FRA modify the requirements regarding the pressure at which trains are tested to require that trains be tested at the pressure at which they will be operated. The NTSB believes that such a requirement would preclude attempts to qualify trains that have excessive leakage by testing them at a pressure that is lower than the train's operating pressure and thus, lower the amount of leakage that exists on the train.

Some labor commenters again objected to FRA's inclusion of the air flow method as an alternative to the leakage test when qualifying a train's brake system. They contend that the air flow method disguises serious leaks and allows greater leakage in a train's brake system than the currently required leakage test. The AAR and other railroad representatives endorsed the allowance of the air flow method as an alternative to the leakage test for qualifying a train's brake system. They believe that the air flow method is superior to the leakage test and is an appropriate alternative for all trains, regardless of length, provided the 15 psi brake pipe gradient is maintained.

Certain labor representatives expressed concern over the proposed provision permitting yard air tests to be conducted at a pressure that is lower than the operating pressure of the train. These commenters suggested that such a practice could permit trains to depart with excess leakage since the required leakage test would be performed at the lower pressure and thus, mask the potential leakage of the train. The AAR and some of its member railroads also expressed concern regarding the proposed requirements related to the performance of brake tests using yard air. These commenters objected to the requirement that brake tests performed with yard air be performed at 80 psi. They recommended that such test be permitted to be performed at 60 psi as currently required because the proposal permits yard and transfer trains to operate at such pressure and that to test at higher pressure creates the potential for overcharge conditions. They also argue the practical difficulties of an 80 psi requirement in that many older yard plants and rental compressors are not capable of supplying 80 psi of air pressure. These commenters further contend that FRA should permit yard air to be connected to other than the front of the consist provided that procedures are taken to prevent overcharge conditions. The commenters also provided recommended language to clarify the calibration requirements for devices and gauges used to conduct yard air brake tests.

Several labor representatives also commented on the proposed written notification requirement related to the performance of Class I brake tests. These commenters supported the written notification requirement and recommended that the information remain with the train if the motive power is changed. One labor organization also recommended that the proposed requirements related to the designation of 1,000-mile inspections are insufficient. This commenter recommended that the designation be filed with FRA and that the designations specifically identify the trains that will be inspected at each location. Representatives of rail management objected to the proposed requirement that locomotive engineers be notified in writing by a person performing the test as to the successful completion of a Class I brake test. These commenters did not object to notifying the locomotive engineer of the results of the test but believe that the notification could be provided orally or electronically by a person with knowledge of the test as long as the locomotive engineer made a record of the notification and necessary information. These commenters also sought clarification of the proposed requirements regarding the designation of locations where 1,000-mile inspections would be conducted. These commenters did not object to the designation requirement provided that it is not required on a train by train basis. They contend that to require that specific trains have 1,000-mile inspections performed at specific locations would create substantial burdens and would eliminate flexibility needed to operate trains in a timely and efficient manner.

The AAR and other railroad commenters also raised concern over the requirement that trains in captive service be required to receive a Class I brake test every 3,000 miles. They recommended that a train of this type that travels in excess of 3,000 miles between cycles be permitted to complete its cycle prior to receiving a Class I brake test. They contend that to require a Class I brake test on these types of cycle trains on a 3,000 mile basis will require the reallocation of manpower and equipment to locations not currently equipped to perform such inspections.

Several railroad representatives also objected to the definition of "solid block of cars" contained in the proposal. This definition is important because FRA proposed that if more than a solid block of cars is removed from or added or a train, the entire train would have to receive a Class I brake test. As the proposed definition limits a "solid block of cars" to a group of cars that are removed from only one other train and that remain coupled together, these commenters contend that the definition is much more restrictive than the current interpretation of the language and would significantly increase the need to perform Class I brake tests. These commenters contend that the current interpretation of the language permits a "solid block of cars" to be made up of cars from several different trains provided the block of cars is added to a train as one unit without triggering the requirement to perform a new initial terminal brake test on the entire train. These commenters also noted that a literal reading of the proposed provisions for when a Class I brake test would be required does not allow a railroad to remove defective equipment without triggering a Class I brake test on the entire train. They contend that this authority needs to be recognized and is currently permitted.

FRA Conclusions. After consideration of the comments submitted and based upon its experience in the enforcement of the current power brake regulations, FRA continues to believe that the general approach to brake inspections contained in the 1998 NPRM represents the most effective method of ensuring the continued safety and proper operation of brake systems currently used in the railroad industry without creating an unnecessary burden to the railroads. Therefore, the final rule is a moderate revision of the current inspection requirements, similar to that proposed, with certain minor changes made to address the comments and recommendations submitted on the NPRM.

The final rule adopts the proposed classifications identifying the various types of brake inspections based on the duties and tasks that are required to be performed. These include: Class I; Class IA; Class II; and Class III brake tests. Contrary to the contentions of some commenters, FRA does not believe that this classification of the brake inspections in any way impacts previous case law regarding the various inspections. Although the final rule changes the terminology used to describe the various brake inspections, the underlying inspection requirements have remained generally consistent with the existing requirements, and the final rule is not intended to change or modify any of the voluminous case law that has developed over the years regarding the inspections. Furthermore, the final rule retains the monikers that have traditionally been attached to the various inspections so as to limit any confusion that may exist. For example, the section containing the requirements for conducting Class I brake tests is entitled, "Class I brake test-initial terminal inspection." FRA believes that the classifications proposed in the NPRM and retained in this final rule clearly delineate what is required at each inspection, better clarify when each inspection is to be performed, and avoid the potential confusion caused by the terminology used in the present regulations.

As discussed in detail in the 1998 NPRM, FRA continues to believe that the performance standard recommended by the AAR in response to the 1994 NPRM and suggested again by some commenters does not provide a viable method for establishing the frequency of brake inspections. *See* 63 FR 48301–02. The performance standard proposed by the AAR is based upon the number of mechanically-caused accidents per million train miles. Therefore, the standard is based upon the rate of occurrence of accidents—accident history—rather than on a factor that could measure a railroad's performance prior to an accident occurring. The suggested performance standard would also be very difficult to calculate on a railroad-by-railroad basis, and the standard itself is a very subjective factor as many accidents are due to a variety of causes only a part of which may be a mechanical or brake-related cause. Thus, the determination of what constitutes a mechanically-caused accident would be difficult if not impossible to make in some circumstances and would be a determination made by the railroad; thus, opening the potential for data manipulation. FRA also notes that the AAR's performance standard contains certain provisions that are contrary to existing statutory requirements regarding the movement of defective equipment.

The final rule retains the requirement to perform 1,000-mile brake inspections as proposed with a few minor revisions discussed below and in the section-by-section analysis of that section. Although FRA agrees that many of the initial terminal brake inspections currently conducted by train crews and other personnel are not of the quality anticipated in 1982, when the inspection interval was increased from 500 miles to 1,000 miles, FRA continues to believe that properly trained and qualified train crew personnel can perform most of the inspections required by this final rule and have been performing such inspections for many years. Furthermore, FRA continues to believe that a reversion to a 500-mile inspection interval on trains inspected by train crews, as suggested by some commenters, does not address the concerns regarding the safety of these trains and would impose an economic burden on the railroads that cannot be justified. Rather than simply increasing the frequency at which inspections are performed, FRA believes that the proper approach is to enhance the quality of the inspections being performed in order to further improve safety. FRA believes that the training and designation requirements contained in this final rule will increase the quality of the brake inspections being performed by ensuring that those individuals responsible for conducting the inspections are provided adequate and continuing training to properly perform the task. The final rule contains general training provisions which include: classroom and experiential "hands-on" training; general testing requirements; and periodic refresher training. The final rule also mandates that training records be maintained by the railroads in order for FRA to ascertain the basis for a railroad's determination that a particular person is considered qualified to perform the inspection or test he or she is assigned. FRA believes these training requirements will provide the necessary assurances that the people conducting the required inspections and tests are qualified.

FRA recognizes that since 1982 new technologies and improved equipment have been developed that allow trains to operate longer distances with fewer defects. The data submitted by AAR, noted above, appears to support this assertion, and FRA does not dispute the potential capability of certain equipment to travel distances in excess of 1,000 miles without becoming defective. However, the capability of the equipment to travel extended distances is contingent on the condition of the equipment when it begins operation and on the nature of the operation in which it is to be engaged. FRA believes that in order for brake equipment to travel extended distances between brake inspections, the condition and planned operation of the equipment must be thoroughly assessed at the beginning of a train's journey through high quality inspections. As noted above, FRA believes that railroads are not conducting high quality initial terminal inspections at many locations because the railroads are utilizing employees who are not sufficiently qualified or trained to perform the inspections. Therefore, FRA believes that the 1,000-mile brake inspection interval continues to be necessary and important to ensure the safe operation of trains inspected by qualified personnel pursuant to this final rule. Furthermore, no trains operated in the United States are currently permitted to travel greater than 1,000 miles between brake inspections. Consequently, FRA is not willing to permit trains to travel in excess of 1,000 miles between brake inspections, except in the limited, controlled situations where data on the equipment can be gathered. (See discussion below titled "Extended Haul Trains.") FRA notes that Canada eliminated intermediate inspections in 1994. However, Canada has different inspection requirements than those contained in this final rule and vastly different operating conditions and environments than those prevalent on most American railroads, operating conditions and environments that are more conducive to the inspection regimen imposed by that country.

The final rule also generally retains the proposed provisions detailing the items that must be inspected during the various inspections and the minimum procedures for performing the inspections. Contrary to the assertions of some commenters, FRA believes that the proposed methods of inspection sufficiently detailed how the various inspections were to be performed while providing flexibility for railroads to conduct the inspections in a manner most conducive to their operations. The methods of inspection proposed in the 1998 NPRM incorporated current practices and technical guidance previously issued by FRA. To require that all inspections be performed by walking the train would impose a huge financial and operational burden on the railroads and would ignore the various different methods by which inspections are currently performed and have been performed for years. FRA does not intend to mandate specific methods for how the various inspections are to be performed. FRA believes that each railroad is in the best position to determine the method of inspection that best suits its operations at different locations. FRA has never mandated specific step-by-step procedures for conducting brake inspections but

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merely requires that, whichever method is used, it must ensure that all of the components required to be inspected will be so inspected.

The proposed rule made clear that when performing a Class I brake test of a train the inspector must take positions on each side of each car in the train sometime during the inspection process. This provision is retained in the final rule. This is intended to mean that at a minimum both sides of the equipment must be inspected. The provision does not require that both sides be observed during the application or during the release of the brakes. However, at a minimum at least one side of the car must be inspected while the brakes on the car are applied or if the brakes do not apply, while an effort is made to apply the brakes on the car. FRA continues to believe that if the various brake components are inspected to ensure they are properly secure and in proper condition then, due to the design of the equipment, if an application or release is observed from one side it can be assumed that in virtually every case there is an application or release of the brake occurring on the other side of the equipment. The final rule also retains the proposed requirement that the piston travel on each piece of the equipment must be inspected while the brakes are applied. Furthermore, the final rule retains the provision that permits a roll-by inspection of the release of the brake but prohibits the roll-by inspection from being considered an inspection of that side of the equipment.

FRA also finds the comments of AAR and other railroad representatives contending that both sides of the equipment should not be required to be inspected at Class IA brake tests to be lacking. The Class IA brake test basically incorporates the current 1,000-mile brake inspection, which FRA believes requires an inspection of both sides of the equipment during the inspection process. The current 1,000-mile inspection requires that brake rigging be inspected to ensure it is properly secure and does not bind or foul and that the brakes apply on each car in the train. *See* 49 CFR 232.12(b). In order to make these inspections properly, FRA believes that both sides of the equipment must be observed sometime during the inspection process and, to FRA's knowledge, railroads currently conduct these inspections in this manner. Thus, the NPRM and the final rule merely clarify what is required to be performed under the current regulations to properly perform a 1,000-mile inspection. Therefore, contrary to the contentions of certain commenters, retention of this current requirement does not impose any additional burden on the railroads.

The final rule retains the provisions granting railroads the ability to utilize the air flow method (AFM) to qualify a train's brake system in lieu of the traditional leakage test. FRA believes that if a train contains a locomotive equipped with 26L freight locomotive brake equipment and the train is equipped with an EOT device, that train should be allowed to be qualified using the AFM. The AFM of qualifying train air brake systems has been allowed in Canada as an alternative to the leakage test since 1984. In addition, several railroads in the United States have been using the AFM since 1989 when FRA granted the AAR's petition for a waiver of compliance to permit the AFM as an alternative to the leakage test. FRA recognizes the concerns of several labor organization commenters opposing the adoption of the AFM; however, FRA believes these commenters' apprehension is based on their unfamiliarity with the method. As FRA pointed out in the ANPRM, the 1994 NPRM, and the 1998 NPRM, the AFM is a much more comprehensive test than the leakage test. *See* 57 FR 62551, 59 FR 47682–47683, 63 FR 48305–06. The AFM tests the entire brake system just as it is used, with the pressure-maintaining feature cut in. FRA believes the AFM is an effective and reliable alternative method of qualifying train brakes. In the 1998 NPRM, FRA expressed some concern regarding the use of the AFM on short trains. However, based on consideration of the comments received and FRA's experiences in observing the use of the AFM, FRA agrees that the AFM should be permitted as an alternative on any train provided the 15 psi gradient is maintained on the train.

The final rule changes some of the provisions related to the conduct of brake tests utilizing yard air sources that were proposed in the NPRM. Rather than requiring yard air tests to be performed at 80 psi as was proposed, the final rule reduces the required pressure to 60 psi at the end of the consist as is currently required. FRA recognizes that many yard air sources and rental compressors are not capable of producing 80 psi of air pressure. However, to address the concerns raised regarding the inadequacy of conducting a leakage or air flow test at this lower pressure, the final rule includes provisions to require those tests to be conducted at the operating pressure of the train. Thus, if the yard air is not capable of producing the pressure that the final rule requires, then the leakage or air flow test is to be conducted when the locomotives are attached. The final rule also permits the yard air test device to be connected at other than the end of the consist nearest the controlling locomotive, provided that the railroad adopts and complies with written procedures to ensure that overcharge conditions do not occur. Many yards across the country currently conduct the test in this manner, and FRA believes it is necessary to acknowledge the viability of these operations.

The final rule also modifies the notification requirement related to Class I brake tests from that proposed in the NPRM. In the NPRM, FRA proposed that the engineer be informed in writing of the successful completion of the Class I brake test. The intent of this requirement was to ensure that the locomotive engineer was adequately informed of the results of the inspection; however, FRA recognizes that a requirement to provide the information in writing ignores technological advances and operational efficiencies. Consequently, the final rule will permit the notification in whatever format the railroad deems appropriate; provided that the notification contains the proper information and a record of the notification and the requisite information is maintained in the cab of the controlling locomotive. FRA believes these changes are consistent with the intent and purpose of the proposed requirement for written notification and ensure necessary information is relayed to the operator of the train.

FRA also realizes that the proposed requirement for designating locations where Class IA inspections will be performed was somewhat unclear and may have caused confusion. The intent of the requirement was to ensure that FRA was informed of those locations where a railroad intends to perform Class IA brake inspections and that FRA had the information with which to hold the railroad responsible for conducting the inspections at those locations. FRA was not intending to require that a railroad separately identify a specific Class IA inspection location for each train it operates. Consequently, the final rule makes clear that the designation required is for locations where such inspections will be performed and permits deviance from those locations only in emergency situations.

The final rule retains the proposed requirement that unit or cycle trains receive a Class I brake test every 3,000 miles. FRA has added a definition of "unit train" and "cycle train" to the final rule in order to clarify the applicability of the requirement.

Historically, these trains operate for extended periods of time with only a series of brake inspections similar to Class IA brake inspections. FRA believes that the proposed 3,000-mile limitation is appropriate as it represents the approximate distance that a train would cover when traveling from coast to coast. In addition the 3,000 mile requirement is consistent with the interval for performing Class IA brake tests and would equate to every third inspection being a Class I brake test rather than a Class IA brake test. Furthermore, AAR does not seek a moderate extension of a couple hundred miles so a few trains could complete their cycle, but seeks to extend the distance to more than 4,500 miles in many instances. FRA is not willing to modify the proposed requirement to that extent and believes that the 3,000-mile interval for these types of trains provides sufficient flexibility to the railroads to perform periodic Class I brake tests on these trains in a cost-efficient manner.

The definition of "solid block of cars" has been modified from that proposed in the NPRM. Although FRA believes the definition it proposed is consistent with current interpretations and enforcement of the requirement, FRA agrees with some of the commenters that the definition may have been too narrow and does not directly address FRA's primary concern, the block of cars itself. FRA's primary concern is the condition of the block of cars being added to the train especially when the block of cars is made up of cars from more than one train. Thus, the final rule will permit a solid block of cars to be added to a train without triggering a requirement to perform a Class I brake test on the entire train. However, depending on the make-up of that block of cars, certain inspections will have to be performed on that block of cars at the location where it is added to the train.

FRA believes that limits have to be placed on the addition of blocks of cars being added to a train in order to ensure that cars are being inspected in a timely manner and in accordance with the intent of the regulations. Some commenters suggest that a block of cars should be permitted to be added to a train with no inspection other than a continuity test regardless of the number of different trains the cars making up the block came from provided all the cars received a Class I brake test at their point of origin. Other commenters suggest that any number of blocks of cars should be permitted to be added to a train at a single location. FRA believes that to accept either of these positions would be tantamount to eliminating initial terminal and intermediate inspections and would drastically reduce the safety of freight trains being operated across the country. In FRA's view, both of the positions noted above are merely means to circumvent inspections and are akin to a practice known as "block swapping" in the mechanical inspection context, a practice that FRA does not permit. In FRA's opinion, the ability to add multiple blocks of cars to a train at one location or add a single block of cars to a train that is composed of cars from numerous different trains without inspecting the cars in those blocks, would essentially allow railroads to assemble new trains without performing any direct inspection of any of the cars in the train. Furthermore, if cars are permitted to be moved in and out of trains at will, the ability to track when and where Class IA brake tests are to be performed on trains will be impossible.

Based on a review of the comments submitted, two other minor modifications to the proposed inspection requirements have been made in this final rule. The final rule contains an additional caveat that will permit the removal of defective equipment at locations where other cars are added or removed without triggering the requirement to perform a Class I brake test on the entire train. FRA currently permits this practice, and it is consistent with the requirements aimed at having defective equipment repaired as quickly as possible. The final rule also modifies the language used in the proposed provisions related to the air pressure at which the brake tests are to be conducted based on a comment submitted by the NTSB. The NTSB noted that the language used by FRA in the NPRM to describe the air pressure settings for conducting the required brake tests would permit some road trains to be tested at a lower pressure than that at which the train would be operated. The NTSB contends that although most road freight trains operate at 90 psi, some road freight trains are operated at 100 psi and the proposal would permit them to be tested at 90 psi. FRA agrees with NTSB's suggestion that a trains brake system should be tested at the pressure at which the train will operate and has modified the language of the final rule accordingly.

2. Extended Haul Trains

In developing the provisions regarding extended haul trains proposed in the 1998 NPRM, FRA relied on several basic beliefs developed from the information and comments submitted and upon its experience in enforcing the current regulations. FRA believed that if a train was properly and thoroughly inspected, with as many defective conditions being eliminated as possible, then the train would be capable of traveling much more than 1,000 miles between brake inspections. By this, FRA contended that not only must the brake system be in quality condition but that the mechanical components of the equipment must be in equally prime condition. FRA believed that as the distance a train is allowed to travel increases, the mechanical condition of the equipment is a key factor in ensuring the proper and safe operation of the train brake system throughout the entire trip. FRA also stated that the best place to ensure the proper conduct of these inspections and to ensure that the train's brake system and mechanical components are in the best condition possible is at a train's point of origin (initial terminal).

In the 1994 NPRM, FRA proposed a set of requirements that had to be met by a railroad in order to move a train up to 1,500 miles without performing additional brake inspections. The requirements included such features as low defect ratios, maintenance programs, and the performance of quality brake and mechanical inspections at a train's point of origin. *See* 59 FR 47735. In the 1998 NPRM, FRA agreed with several commenters that some of the 1994 proposed requirements were overly burdensome and were partially predicated on potentially subjective standards. However, FRA continued to believe that many of the inspection requirements and movement restrictions proposed in 1994 were valid conditions that should be met in order to operate trains for extended distances between brake inspections. These included: the performance of a quality, in-depth brake inspection by a highly qualified inspector; the performance of a quality mechanical inspection by a person qualified under 49 CFR 215.11; and a restriction on the number of set-outs and pick-ups occurring en route. FRA also believed that these extended haul trains had to be closely monitored to ensure that both the brake system and mechanical components remain safely intact throughout the train's journey.

In the 1998 NPRM, FRA proposed that certain designated trains be permitted to move up to 1,500 miles between brake and mechanical inspections provided the railroad met various inspection and monitoring requirements. *See* 63 FR 48343, 48364–65. As no trains were currently permitted to travel in excess of 1,000 miles between inspections, FRA was not willing to propose more than

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1,500 miles between such inspections until appropriate data is developed that establish that equipment moved under the proposed criteria remains in proper condition throughout the train's trip. FRA believed that the proposed provision requiring the performance of an inbound inspection at destination or at 1,500 miles and the requirement that carriers maintain records of all defective conditions discovered on these trains would create the bases for developing such data.

In order to ensure the accuracy of the data as well as ensure the proper and safe operation of these extended haul trains, FRA also proposed that the trains have 100 percent operative brakes and contain no cars with mechanical defects at their initial terminal point and at the time of departure from the 1,500-mile point, if moving an additional 1,500 miles from that location between brake inspections. FRA further proposed that these trains not conduct any pick-ups or set-outs en route, except for the removal of defective equipment, in order to minimize the disruptions made to the integrity of the train's brake system and reduce mechanical damage that might occur during switching operations. In addition, as there was no reliable tracking system currently available to FRA to ensure that cars added to the train en route have been inspected in accordance with the proposed requirements, FRA believed that the number of cars added to these trains had to be limited.

As noted earlier in the discussion, FRA believed that in order for a train to be permitted to travel 1,500 miles between inspections, the train must receive inspections that ensure the optimum condition of both the brake system and the mechanical components at the location where the train originates. In order to ensure that quality inspections were performed, FRA proposed that they be performed by highly qualified and experienced inspectors. As FRA intended that the proposed Class I brake test performed on these trains at their initial terminal be as in-depth and comprehensive as possible, FRA believed that the inspections should be performed by individuals possessing the knowledge not only to identify and detect a defective condition in all of the brake equipment required to be inspected, but also to possess the basic knowledge to recognize the interrelational workings of the equipment and the ability to trouble-shoot and repair the equipment. Therefore, FRA proposed the term "qualified mechanical inspector" to identify and describe those individuals it believed would possess the necessary knowledge and experience to perform the proposed Class I brake tests on these extended haul trains.

In the 1998 NPRM, a "qualified mechanical inspector" was defined as a person with training or instruction in the troubleshooting, inspection, testing, maintenance, or repair of the specific train brake systems the person is assigned responsibility and whose primary responsibilities include work generally consistent with those functions. (See § 232.5 of the section-by-section analysis for a more detailed discussion of "qualified mechanical inspector.") FRA also proposed that these same highly qualified inspectors be the type of individuals performing the proposed inbound inspection on these extended haul trains in order to ensure that all defective conditions are identified at the train's destination or 1,500-mile location. Similarly, FRA proposed that all of the mechanical inspections required to be performed on these trains be conducted by inspectors designated pursuant to 49 CFR 215.11 in order to ensure that all mechanical components are in proper condition prior to the train's departure.

The AAR and various private car owners submitted a number of comments objecting to the proposed requirements regarding extended haul trains contained in the 1998 NPRM. These commenters believe that the 1,500-mile limitation on the movement of these trains between brake inspections is insufficient considering the restrictions placed on the trains. They recommend that these trains be permitted to operate to its destination or at a minimum be permitted 2,000 miles between brake inspections. They contend that the 1,500-mile limitation results in little or no benefit to the railroads because in order to take advantage of the flexibility provided, railroads would have to establish new facilities and add more manpower at 1,500-mile points to conduct the more stringent inspections required at those locations. They contend that a limitation at the 2,000-mile point would be logically consistent with existing inspection requirements, based on 1,000-mile increments, and would allow a greater number of trains to utilize the provisions because railroads could use existing facilities and manpower. They recommend that FRA reconsider the estimates provided regarding the benefits derived from the extended haul train provisions, claiming that the benefits estimated in the NPRM's Regulatory Impact Analysis are overstated. Several private car owners also suggested that even if FRA were not to extend the proposed distance for the entire industry, it should allow certain private car owners greater distances due to their superior safety record and maintenance practices.

Many of these same commenters also object to the proposed requirement that extended haul trains not be permitted to make any pick-ups or set-outs en route. These commenters contend that this restriction severely limits the actual flexibility of the proposal. They assert that the prohibition on pick-ups and set-outs would eliminate nearly one-half of the trains that could potentially be operated under the proposed provisions. Several commenters also objected to the proposed notification requirements for extended haul trains. These commenters state that the proposed provision requiring advance notification to FRA of the trains to be operated under the extended haul provision would seriously limit the number of trains utilizing the provisions as many trains are unscheduled with unknown train symbols and would be excluded. They recommend that the notification requirements be reduced in some manner to allow unscheduled trains to be identified as extended haul trains. One commenter also objects to the proposed requirement that extended haul trains not depart their initial terminals with any part 215 defects entrained. This commenter asserts that there was no rationale for this restriction and that it merely creates an additional burden for railroads.

Several rail labor representatives also object to the proposed provisions permitting trains to be operated as extended haul trains; however, these commenters oppose allowing any train to operate more than 1,000 miles between brake inspections. These commenters contend that when the distance between intermediate brake inspections was increased in 1982, the railroads made a commitment to conduct quality initial terminal brake inspections in exchange for the increased mileage, but that has not occurred and FRA should not provide the railroads with an increase in mileage when the previous agreement has not been honored. They contend that the proposed extension would merely allow defective equipment to be moved further distances without repair. They further contend that the proposed increase in distance between brake tests is not justified from a safety standpoint and, thus, violates 49 U.S.C. 20302(d)(2), which permits a change in the existing power brake regulations "only for the purpose of achieving safety." These commenters oppose any extension in the distance between brake inspections unless stringent

requirements are placed on the trains, one such requirement being that carmen or similarly trained individuals perform all the inspections and tests required to be performed on the trains. They also contend that the proposed standard for revoking a railroad's ability to designate extended haul trains is too high.

FRA Conclusions. FRA continues to believe that if a train is properly and thoroughly inspected, with as many defective conditions being eliminated as possible, then the train is capable of traveling much greater than 1,000 miles between brake inspections. Therefore, the final rule retains the provisions permitting railroads to designate trains as extended haul trains and allowing such trains to be operated up to 1,500 miles between brake inspections. Although FRA recognizes that retention of the 1,500-mile limitation may limit the utility of the provision on some railroads, FRA is not willing to increase the proposed mileage restriction at this time. Currently, no train is permitted to travel more than 1,000 miles without receiving an intermediate brake inspection. Therefore, FRA does not believe it would be prudent to immediately double or triple the currently allowed distance without evaluating the safety and operational effects of an incremental increase in the distance. Consequently, until sufficient information and data are collected on trains operating under the provisions proposed in the NPRM and retained in this final rule, FRA is not willing to permit trains to travel the distances suggested by some commenters without additional brake inspections. FRA continues to believe that the requirement for performing inbound inspections and the requirement to maintain records of all defective conditions discovered on these trains provides the basis for developing the information and data necessary to determine the viability of allowing greater distances between brake inspections.

After consideration of the comments submitted, FRA agrees that the benefits estimated in the NPRM in association with the extended haul provisions may have been overstated. FRA realizes that the retention of the 1,500-mile limitation may eliminate certain trains from being operated pursuant to the extended haul provisions and reduce the benefits estimated at the NPRM stage of the proceeding. (See detailed discussion in the Regulatory Impact Analysis portion of the preamble below.) However, in order to increase the viability of the extended haul provisions, the final rule provides some flexibility for designating extended haul trains and allows for the limited pick-up and set-out of equipment.

Several commenters noted that the proposed provisions regarding the advance designation of extended haul trains would prohibit certain unscheduled trains from being operated as extended haul trains. In an effort to provide some flexibility in this area, the final rule has been modified to allow railroads to designate certain locations as locations where extended haul trains will be initiated and requires railroads to describe those trains that will be so operated rather than requiring specific identification of every train. FRA believes this modification will allow railroads to capture some of their unscheduled trains by identifying the trains by the locations where they are initiated.

The final rule will also permit extended haul trains to set out cars at one location or to pick up cars, or both, at the same or another location. This modification will provide railroads the flexibility to set-out a block of cars at one location and pick up a block of cars at another location. FRA believes that this limited ability provides the railroads with some flexibility to move equipment efficiently while minimizing the disruptions made to the train's brake system and ensuring that cars added to such trains can be adequately tracked and inspected. The final rule makes clear that any cars added to extended haul trains must be inspected in the same manner as the cars at the train's initial terminal. The final rule also makes clear that any car removed from the train must be inspected in the same manner as a car at the train's point of destination or 1,500-mile location.

Certain commenters have portrayed the provisions related to extended haul trains as merely being an extension of the current intermediate inspection distances. FRA objects to such a characterization. In FRA's view, the extended haul provisions contained in the NPRM and retained in this final rule constitute a completely new inspection regimen. The provisions related to the operation of extended haul trains contain stringent inspection requirements, both brake and mechanical, by highly qualified inspectors and establish stringent requirements whenever cars are added to or removed from such trains. The extended haul train requirements also contain a means to assess the safety of such operations by requiring that records be maintained of the defective conditions that develop on these trains while en route. Consequently, FRA believes that the requirements related to extended haul trains not only ensure the safe operation of the trains operated under them, but actually increase the safety of such operations over that which is provided in the current regulations.

3. Charging of Air Brake System

Present regulations for air brake testing basically require that cars that have previously been tested in accordance with the regulations either "be kept charged until road motive power is attached" or be retested. *See* 49 CFR 232.12(i). The current regulations also require the performance of an initial terminal brake test "where the train consist is changed other than by adding or removing a solid block of cars, and the train brake system remains charged. * * *" *See* 49 CFR 232.12(a)(ii). Based on longstanding administrative interpretation and practice, FRA currently presumes that a brake system is no longer adequately charged if disconnected from the charging device (supply of pressurized air) for more than two hours before coupling or recoupling of locomotives; otherwise, retesting is required.

In the 1994 NPRM, FRA proposed to permit trains to be removed from a continuous source of compressed air for up to four hours without requiring the re-performance of a comprehensive brake inspection. FRA received very few comments that directly addressed the safety implications of this proposal; thus, FRA proposed the four-hour time limitation in the 1998 NPRM. In the 1998 NPRM, FRA agreed that its longstanding administrative interpretation, that requires the retesting of cars disconnected from a charging device for longer than two hours, was established prior to the development of new equipment that has greatly reduced leakage problems, such as welded brake piping and fittings and ferrule-clamped air hoses. However, contrary to several railroads' assertions, FRA did not believe that cars should be allowed to be off air for extended periods of time without being retested. FRA believed that the longer cars sit without air attached, the greater the chances were that the integrity of the brake system would be compromised. Consequently, based on today's equipment, operating practices, and overriding safety concerns, FRA proposed that cars should not be disconnected from a continuous supply of pressurized air for longer than four hours without being retested. FRA also proposed that the source of compressed air must be sufficient to maintain the integrity of the brake system. Consequently, FRA proposed that the source of compressed

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air be maintained at a minimum level of 60 psi.

The AAR and several other parties commented that there is no reason to assume that once a train is charged and tested and then left standing without being provided with a source of compressed air that the brake system would become defective. These commenters assert that leaving equipment connected to a source of compressed air does nothing to ensure proper performance of the brake system, does not prevent vandalism, and does not prevent leakage due to adverse weather conditions. These parties suggest that leakage on standing trains has been greatly reduced through the use of welded brake piping and fittings and ferrule-clamped air hoses. These commenters believe that FRA's current interpretation of allowing trains to sit without air for only two hours is from an era when this new equipment was not used. They also contend that FRA's current interpretation and the proposed four-hour limitation costs the industry money, fuel, and time and creates pollution because trains must either be reinspected or left with a locomotive attached and idling in order to avoid performing a full Class I brake test. They further contend that the proposed four-hour rule exposes employees to various safety hazards due to the employees being required to perform inspections at locations that are not designed or equipped for such activity.

The AAR recommends that the proposed four-hour limitation be eliminated for the reasons noted above. They also noted that the Canadian rules do not contain an off-air requirement and that in Canada if cars are off air for any length of time, only a set-and-release continuity test is required. As an alternative to eliminating the off-air requirement completely, the AAR suggests that FRA adopt requirements which would allow cars to be removed from a source of compressed air for up to 48 hours without a car-by-car reinspection. They recommend that cars only be required to receive a continuity test when they have been off a source of compressed air for more than fours hours but less than 48 hours and that no retesting occur if equipment is off air for less than four hours.

Representatives of rail labor objected to the proposed increase in the amount of time that equipment could be removed from a source of compressed air. These commenters believe that the existing two-hour limitation is reasonable. Most of these commenters expressed concern for the integrity of the brake system if a consist were left standing for longer than two hours. These concerns were aimed at the effect that climate might have on the equipment and the increased possibility of vandalism to the equipment if consists or equipment were left off air for longer periods.

FRA Conclusions. The final rule retains the proposed requirement that equipment removed from a source of compressed air for longer than four hours be reinspected. FRA believes that this requirement is necessary to ensure not only the integrity of the brake system on equipment but to ensure that inspections are performed on equipment in a timely and predictable manner. FRA tends to agree that the amount of time equipment is left off a source of compressed air is not directly related to the operation of the brake system on that equipment. However, FRA does believe that in certain circumstances the length of time that equipment is removed from a source of compressed air can impact the integrity and operation of the brake system on a vehicle or train. Particularly in cold weather situations where freeze-ups in train brake systems can occur or in areas where the potential for vandalism is high due to the location where equipment is left standing. Moreover, FRA believes that the four-hour limitation is consistent with the intent of the existing regulations and is intended to ensure that equipment is regularly inspected.

The commenters objecting to the four-hour limitation proposed in the NPRM and retained in this final rule have ignored the intent and purpose of the existing two-hour allowance permitted by longstanding administrative interpretation. As discussed above, the existing power brake regulations, adopted by Congress in 1958, are based on the premise that if a train or equipment does not remain charged the equipment is to be retested. There is no provision in the existing regulations for allowing equipment to be removed from a source of compressed air for any length of time, such allowance was granted only through administrative interpretation. The original intent of the currently existing two-hour interpretation, which permits equipment to remain off-air for up to two-hours without being retested, was to allow trains to pick up or remove cars from their consists while en route without requiring a retest of the entire train. The two-hour limit was based on the amount of time it would take a train to make a switching move while en route. Thus, the current application of the two-hour rule to any and all equipment left off a source of compressed air is somewhat counter to the original intent of the interpretation when it was provided.

Although FRA recognizes that it has acquiesced and endorsed the expansion of the two-hour rule to all equipment, FRA believes that the underlying intent of the existing regulations must be recognized and maintained. The doubling of the existing two-hour interpretation to four hours is based on the fact that the average time needed for many trains to perform the switching they conduct while en route has increased. Thus, FRA's intent when proposing an expansion of the two-hour rule was not to alter the basic tenet that equipment should be retested when it is removed from a source of compressed air for any lengthy period of time. FRA believes that the four-hour allowance provided by this final rule gives the railroads flexibility to perform switching operations while trains are en route and provides flexibility to efficiently move cars from one train to another when necessary, yet retains the concept that equipment be retested when left disconnected from a source of compressed air for longer periods of time.

FRA further believes that a limitation on the amount of time that equipment may be off air is necessary for ensuring that equipment is inspected in a timely and predictable manner. If no time limit were imposed or if 48 hours were permitted, as suggested by some commenters, equipment could lawfully sit for days at various locations while en route to its destination and be switched in and out of numerous trains without ever being reinspected. Such an approach would drastically reduce the number of times that the brake systems on such equipment would ever be given a visual inspection from what is currently required and, in FRA's view, would seriously degrade the safety of the trains operating with such equipment in its consist. Furthermore, if equipment were allowed to be off-air for an excessive amount of time, it would be virtually impossible for FRA to ensure that equipment is being properly retested as it would be extremely difficult for FRA to determine how long a particular piece of equipment was disconnected from a source of compressed air. In order to make such a determination, FRA would have to maintain observation of the equipment for days at a time. Consequently, the final rule retains the proposed four-hour limit on the amount of time equipment can be disconnected from a source of compressed air as it maintains current levels of safety and provides an enforceable and verifiable time limit that FRA believes provides the railroads some additional benefit over what is currently required both in terms of operational efficiency and cost savings.

4. Retesting of Brakes

In the 1998 NPRM, FRA attempted to clarify language contained in the current regulation which requires that the brakes "apply." *See* 49 CFR 232.12(b), 232.12(d), 232.13(d), and 232.13(e). The current language has been misinterpreted by some to mean that if the piston applies in response to a command from a controlling locomotive or yard test device, and releases before the release signal is given, the brake system on that car is in compliance with the regulation because the brake simply applied. The intent of the regulation has always been that the brakes apply and remain applied until the release signal is initiated from the controlling locomotive or yard test device. Therefore, clarifying language was added to the proposed inspection requirements to eliminate all doubt as to what is required. In the 1998 NPRM, FRA made clear that the brakes on a car must remain applied until the appropriate release signal is given. The proposal required that cars with brakes that fail to remain applied either be removed from the train or repaired in the train and retested, and the proposal provided specific requirements for performing a retest on such equipment.

FRA recognized that some defective train air brake conditions found when performing a train air brake test, which may cause insufficient application of the brakes on a piece of equipment, are of such a nature that they can be quickly repaired in the train. For example, a brake connection pin might be missing, a slack adjuster might be disconnected, or some other minor part of the brake system might be defective. FRA realized that to mandate that equipment with these types of obvious defective conditions be removed from the train would potentially impose a tremendous burden on the railroads. Therefore, FRA sought to provide some relief to railroads by permitting cars with obvious brake defects to be repaired and retested while remaining in the train. However, FRA also believed that some consistency and guidance had to be provided regarding the performance of a retest on a car's brake system. Consequently, FRA proposed that the retesting of a car had to be conducted from the controlling locomotive or head end of the consist if a car is repaired in a train. Furthermore, FRA proposed that if a retest is conducted the brakes on the retested car must remain applied for a minimum of five (5) minutes. The proposed five-minute requirement was based on the leakage parameters established for locomotives contained at § 229.59(c).

The AAR and several other commenters object to the parameters contained in the proposed retesting provisions. Specifically, these commenters object to three of the requirements contained in the proposed retest provision, these include: the requirement that only cars with an obvious defect be retested, the requirement that the brakes remain applied for five minutes, and the requirement that the retest be conducted from the controlling locomotive or the head of the consist. These commenters contend that there is no reason to limit the retest provision to cars with readily identifiable defects. They claim that there are a number of conditions which might cause a car's brakes not to apply that are not readily identifiable thus, the retest may identify the problem and allow it to be repaired, or the reason for a no-set is unknown but the brakes operate properly upon being retested.

These commenters also believe that the proposed requirement to have the brakes remain applied for five minutes is impractical and unnecessary. They assert that it is only necessary to have the brakes remain applied for the period of time it takes an inspector to perform an inspection of the brakes and that it is impractical to require an employee to watch each retested car for five minutes. They also contend that FRA's reliance on the five-minute requirement related to the testing of locomotive brake cylinder leakage contained in § 229.59 is misplaced. They assert that there is no parallel between determining the brake cylinder leakage on a locomotive and the testing of the brakes on a freight car. One commenter suggests that a one-minute application is a sufficient period to ensure the proper operation of a car's brakes.

These commenters also object to the proposed requirement that the retest be conducted from the controlling locomotive or the head end of the consist. They contend that there is no safety hazard in performing the test with a test device positioned at one end of the car being retested. They assert that such a procedure would replicate the natural gradient of the train and, thus, avoid the possibility of overcharging the brake system, and would better facilitate retesting.

Representatives of rail labor generally supported the proposed retest provisions. These commenters did assert that any retest should be conducted from the head end of the consist or from the controlling locomotive. They claim that to perform the test from other than that location would provide no assurance that the brakes would apply in response to a brake pipe reduction from the controlling locomotive.

FRA Conclusions. FRA agrees that the proposed provisions regarding the retesting of cars may have been overly restrictive and is modifying the final rule based on FRA's review of the comments and recommendations submitted. The final rule has been modified to permit the retesting of any car the brakes of which were found not to be applied during a required inspection. FRA agrees that there are several circumstances that could occur where the reason for the failure of the brakes to apply is not readily apparent. FRA believes that permitting a retest on any car found not applying will not adversely affect safety since the car will be required to pass the retest in order to remain in the train or be handled for necessary repair.

The final rule also modifies the proposed provision that requires a retested car's brakes to remain applied for five minutes. FRA agrees that its reliance on the five-minute requirement applicable to the testing of locomotive brake cylinder leakage is not appropriate. However, rather than insert a subjective requirement for how long the brakes should remain applied, as suggested by some commenters, FRA believes that a definite time period should be established to ensure consistency in the performance of these retests. Thus, the final rule requires that the brakes on a retested car remain applied for at least three minutes. FRA believes that three minutes is consistent with the amount of time that it would take an individual to conduct a complete inspection of the retested car's brakes. The three minutes is based on the generally accepted period of one and one-half minutes it would take to perform a walking inspection on each side of an average size freight car. Requiring the brakes to remain applied for a period of at least three minutes also provides FRA with sufficient assurances that the brakes are operating properly and will remain applied for the duration of any brake application required during the train's journey.

The final rule also modifies the proposed requirement that the retest be conducted from the controlling locomotive or the head of the consist by permitting the retest to be conducted with a suitable test device positioned at one end of the car or cars being retested. FRA agrees that there is little or no safety rationale for requiring the retest to be performed from the controlling locomotive or head of the consist. Some

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commenters argue that if the retest is not conducted from the controlling locomotive, then there are no assurances that the brakes will apply in response to a brake reduction from the controlling locomotive. FRA finds that this argument ignores the various methods by which cars may be tested and assembled when air brake tests are conducted using yard air sources. FRA currently allows and this final rule continues to allow cars to be tested with yard test plants and allows such cars to be added to trains without requiring that each car be inspected to ensure it operates in response to the controlling locomotive.

One potential safety hazard with allowing cars to be retested with a device at the car is the potential for injury to the employees responsible for separating the train line between the charged cars. The train line between the car being retested and the car it is coupled to would have to be separated to perform the retest with a device. In many cases this train line will be under pressure at the time of the separation and could cause injury to the person separating the train line if caution is not used. The final rule recognizes this potential safety concern and requires that the compressed air in a car to be retested must be depleted prior to separating the air hoses and conducting the retest.

C. Movement of Equipment With Defective Brakes

The current regulations do not contain requirements pertaining to the movement of equipment with defective power brakes. The movement of equipment with these types of defects is currently controlled by a specific statutory provision originally enacted in 1910, and later amended which states:

> (a) GENERAL.—A vehicle that is equipped in compliance with this chapter whose equipment becomes defective or insecure nevertheless may be moved when necessary to make repairs, without a penalty being imposed under section 21302 of this title, from the place at which the defect or insecurity was first discovered to the *nearest available place at which the repairs can be made*—
>
> (1) On the railroad line on which the defect or insecurity was discovered; or
>
> (2) At the option of a connecting railroad carrier, on the railroad line of the connecting carrier, if not farther than the place of repair described in clause (1) of this subsection.
>
> 49 U.S.C. 20303(a) (emphasis added).

Although there is no limit contained in 49 U.S.C. 20303 as to the number of cars with defective equipment that may be hauled in a train, FRA has a longstanding interpretation which requires that, at a minimum, 85 percent of the cars in a train have operative brakes. FRA bases this interpretation on another statutory requirement which permits a railroad to use a train only if "at least 50 percent of the vehicles in the train are equipped with power or train brakes and the engineer is using the power or train brakes on those vehicles and on all other vehicles equipped with them that are associated with those vehicles in a train." 49 U.S.C. 20302(a)(5)(B). As originally enacted in 1903, section 20302 also granted the Interstate Commerce Commission (ICC) the authority to increase this percentage, and in 1910 the ICC issued an order increasing the minimum percentage to 85 percent. *See* 49 CFR 232.1, which codified the ICC order.

As virtually all freight cars are presently equipped with power brakes and are operated on an associated train line, the statutory requirement is in essence a requirement that 100 percent of the cars in a train have operative power brakes, unless being hauled for repairs pursuant to 49 U.S.C. 20303. Consequently, FRA currently requires that equipment with defective or inoperative air brakes makeup no more than 15 percent of the train and that if it is necessary to move the equipment from where the railroad first discovered it to be defective, the defective equipment be moved no farther than the nearest place on the railroad's line where the necessary repairs can be made or, at the option of the receiving carrier, to a location that is no farther than the location where the repairs could have been performed on the delivering line.

In addition to the general requirements relating to the movement of equipment with defective safety appliances, FRA currently requires 100-percent operative brakes on a train departing its initial terminal. The requirement for 100 percent at the initial terminal has been a standard by which the railroad industry has operated for decades and one which FRA and its predecessor agency, the Interstate Commerce Commission, have endorsed since the adoption of the power brake regulations. The requirement is founded on Congress' mandate that the ICC incorporate into the federal rail safety regulations the AAR's rules, standards, and instructions as of April 11, 1958, regarding the installation, inspection, maintenance, and repair of train brakes. In 1958, Congress amended a provision of the Safety Appliance Acts, then codified at 45 U.S.C. 9, by incorporating the inspection requirements of the AAR into the statute and permitting their change only for the purpose of achieving safety.[3] Based on a review of the legislative history surrounding that amendment, FRA believes it is clear that Congress interpreted the AAR standards as requiring 100 percent operative brakes on all trains prior to departure from an initial terminal. As the current regulations regarding the performance of an initial terminal inspection contained at 49 CFR 232.12(c)-(j) were basically an adoption of the AAR inspection and testing standards as they existed in 1958, FRA believes that the current regulations are intended and do require 100 percent operative brakes at initial terminals.

In developing the 1998 NPRM, FRA considered the various proposals discussed in the RSAC Working Group and the numerous comments provided subsequent to the issuance of the 1994 NPRM. A discussion of those comments and proposals was provided in the 1998 NPRM and will not be reiterated here. *See* 63 FR 48308–310. It is clear from that discussion that many of the proposals received by FRA since the issuance of the 1994 NPRM were in direct conflict with various statutory requirements related to the movement of equipment with defective brakes. As the RSAC Working Group was unable to reach a consensus on the inspection, testing, and maintenance requirements for freight train brake systems, FRA was not willing or able to propose provisions regarding the movement of equipment with defective brakes that would be contrary to existing statutory mandates. The 1998 NPRM contained proposals regarding the tagging of defective equipment, the placement of defective equipment in a train, and a method for consistently calculating the percentage of operative brakes on a train. Therefore, in addition to being consistent with the statutory requirements, the proposed requirements ensured the safe and proper movement of defective equipment and clarified the duties imposed on a railroad when moving such equipment.

FRA proposed that all cars or locomotives found with defective or inoperative brake equipment be tagged as bad ordered with a designation of the location where the necessary repairs

[3] In 1994, Congress revised, recodified, and enacted without substantive change, the federal railroad safety laws. Simultaneously, the then existing general and permanent federal railroad safety laws were repealed. 45 U.S.C. 9 of the Safety Appliance Acts is currently codified at 49 U.S.C. 20301 and 20302. The reference to the AAR rules, standards, and instructions was removed during the recodification as executed. *See* Pub. L. 103–272 (July 5, 1994) and H.R. Rep. No. 103–180, at 94 (1993).

would be effectuated. FRA attempted to expressly clarify the requirement that equipment with defective brakes not depart from, or be moved beyond, a location where the necessary repairs to the equipment could be performed. The 1998 proposal made clear that if a car or locomotive is found with defective brakes during any of the proposed brake inspections or while the piece of equipment is en route and the location where the defective equipment is discovered is a place where repairs of the type needed can be performed, then that car or locomotive may not be moved from that location until the necessary repairs are effectuated. However, if repairs to the defective condition cannot be performed at the location where the defect is discovered, or should have been discovered, the proposal made clear that the railroad is permitted to move the equipment with the defective condition only to the nearest location where the necessary repairs can be performed.

The preamble to the 1998 NPRM contained a lengthy discussion regarding FRA's views as to what constitutes the nearest location where the necessary repairs can be performed. *See* 63 FR 48309. In that discussion, FRA noted that its previous proposals regarding the use of mobile repair trucks and when locations serviced by those trucks would be considered locations where necessary repairs could be effectuated did not sufficiently address the issue and might lead to undesired consequences. Rather than attempt to develop a standard applicable to all situations, which FRA did not believe could be accomplished at the time, FRA intended to approach the issue of what constitutes the nearest location where necessary repairs could be made based on a case-by-case analysis of each situation. FRA noted that in making these determinations both the railroad as well as FRA's inspectors must conduct a multi-factor analysis based on the facts of each case. In the preamble, FRA provided a broad discussion, based on existing case law, setting out general guidelines and factors that should be considered when determining whether a particular location is a location where necessary repairs can be made or whether a location is the nearest location where the necessary repairs can be effectuated. *See* 63 FR 48309.

FRA also proposed continuation of the requirement to have 100 percent operative brakes on a train at its point of origin (initial terminal). FRA noted that this has been a requirement in the railroad industry for decades and that it was not only wise from a safety standpoint, as it ensures the proper operation of a train's brake system at least once during its life, but it also sets the proper tone for what FRA expects to be accomplished at these locations. Furthermore, requiring 100 percent operative brakes on a trains at its inception provides the railroads with a margin for failure of some brakes while the train is in transit (up to 15 percent) and tends to ensure that defective equipment is being repaired in a timely fashion. In addition, FRA stated that the 100-percent requirement is consistent not only with Congress' understanding of the AAR inspection standards that were adopted in 1958, but also with the intent of FRA, rail management, and rail labor as to what was to occur at initial terminals when the inspection interval was increased from 500 miles to 1,000 miles in 1982. At that time, carrier representatives committed to the performance of quality initial terminal inspections in exchange for an extension in the inspection interval, for which FRA intended to hold them accountable. Moreover, FRA believed that retention of the 100-percent requirement is consistent with the statutory requirements regarding the movement of defective equipment because a majority of the locations where trains are initiated have the capability of conducting virtually any brake system repair, and thus, under 49 U.S.C. 20303(a) the defective equipment may not be moved from those locations anyway.

In the preamble to the 1998 NPRM, FRA recognized that the 100-percent requirement at points of origin tends to be somewhat burdensome for some railroads at certain locations. *See* 63 FR 48309–10. However, FRA noted that the number of locations where the requirement is quite burdensome appears to be fairly low as FRA had made clear that railroads are free to petition for a waiver of this requirement, but as of the issuance of the NPRM no railroad had filed such a petition. Although FRA recognized that the requirement creates somewhat illogical scenarios at some locations, FRA was not willing to propose provisions permitting trains to depart locations with less than 100 percent operative brakes without fully considering the safety hazards or potential abuses which may accompany such an approach. Therefore, FRA sought comment from interested parties regarding the potential for permitting very limited flexibility in moving defective equipment from outlying initial terminals which lack the capability of effectuating brake system repairs. FRA also discussed various alternative approaches, with attendant restrictions, which might provide some flexibility at these outlying locations and sought comment on those approaches as well. *See* 63 FR 48310.

The AAR and several other railroad representative submitted a number of comments on the proposed requirements regarding the movement of defective equipment. The majority of the comments received from these parties addressed the proposed requirements regarding 100 percent operative brakes at a train's initial terminal, the identification of locations where brake repairs should be required, and the tagging of defective equipment.

These commenters recommend that FRA permit trains to operate from any location with a minimum percentage of its brakes inoperative. At a minimum, they recommend that this flexibility be provided at locations where repairs can not be performed. They suggest adoption of a 95-percent minimum operative brake requirement from such locations. They contend that the 100-percent requirement at initial terminals is outdated and does not take into consideration the numerous technological improvements made to brake systems over the last several decades. They also contend that it makes no sense to require 100-percent operative brakes on trains originating at a location yet allow a train originating at another location to pick-up defective equipment at the same location and haul it to the same place that it could have been hauled by the originating train. They further contend that the 100-percent requirement results in the unnecessary switching of cars and exposes employees to greater safety risks than if the equipment were permitted to depart in originating trains. Several commenters note that Canada has permitted trains to operate to destination with 95 percent operative brakes since June of 1994 and has experienced no compromise in safety. The AAR commented that railroads could live with a 95-percent operative brake requirement out of initial terminals provided that there were no mileage restrictions placed on the movement of such defective equipment as discussed in the NPRM. *See* 63 FR 48310. The ASLRA sought clarification as to the applicability of the 100-percent requirement to transfer trains. They contend that the language used in the NPRM suggests that all transfer trains must have 100-percent operative brakes from their initial terminal which is not what is required under the current regulations and would have a huge impact on small railroads.

A number of railroad representatives also provided comments and

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recommendations on how FRA addressed the issue of what constitutes a location where brake repairs are required to be performed. These commenters recommend that FRA clarify what constitutes the nearest location where repairs can be made. These parties do not believe that this determination should be left to the discretion of individual FRA inspectors. They claim that such an approach creates inconsistent enforcement from one region to another and makes it very difficult for railroads to comply as FRA is continually second guessing their good faith determinations.

The AAR and other commenters contend that Congress intended that only fixed repair facilities be considered locations where brake system repairs must be conducted and that such facilities provide safer working conditions than those encountered when using a mobile repair truck. They further contend that it is not in the public interest to require repair trucks to make repairs at every location where they can be moved. The AAR and several railroads recommend that FRA permit railroads to designate repair locations to FRA and permit modification of those designations each quarter.

The AAR and its member railroads also objected to some to the proposed tagging requirements associated with the movement of equipment with defective brakes. They objected to the requirement that any automated tracking system be approved by FRA prior to its implementation. These commenters suggested that such review and approval process would be very time consuming and that FRA would not easily grant the use of such systems. They also objected to the proposed requirement that the tag or card be retained for 90 days, contending that the requirement was merely to aid in FRA's enforcement and served no other purpose.

The AAR also recommended that FRA modify the proposed requirement regarding the placement of equipment with defective brakes. The AAR contends that FRA should permit the use of multi-unit articulated equipment provided that it has no more than two consecutive control valves cut out or inoperative rather than the proposed limitation prohibiting the use of such equipment with consecutive inoperative or cut-out control valves. They contend this is the current practice of many railroads in the United States and is currently allowed on trains operated in Canada.

A number of rail labor representatives also provided comments on the proposed provisions regarding the movement of equipment with defective brakes. These commenters as well as the CAPUC support the requirement that trains have 100-percent operative brakes at their initial terminals. They believe that any flexibility granted to railroads in this regard would reduce the incentive to conduct quality inspections and would result in railroads eliminating even more personnel at other outlying locations. These commenters also suggest that any inability of railroads to conduct repairs at outlying locations is due to their own actions in eliminating repair equipment and personnel from these locations. They also contend that properly equipped mobile repair trucks have the capability of conducting any repair that would be required at virtually any of the outlying locations operated by a railroad.

Several labor representatives also object to granting the railroads the ability to designate locations where brake system repairs will be conducted. They contend that this is merely an attempt by the railroads to eliminate existing locations where repairs can be conducted. They further object to the AAR's contention that only fixed repair facilities should be considered in determining where brake system repairs must be conducted. They claim that such an approach would lead to the closure of even more fixed repair shops so that railroads could further circumvent the requirement to make timely repairs at the nearest location. They assert that allowing railroads to designate locations where repairs will be made would violate 49 U.S.C. 20303(a) which requires repairs to be conducted at the nearest location where the necessary repairs can be made.

Parties representing rail labor generally support the proposed tagging requirements for moving defective equipment but noted their objection to the use of an automated tracking system. These commenters believe that an automated tracking system reduces the awareness of ground inspection forces as to the presence of defective equipment and would not ensure proper handling of such equipment. The required tag provides carmen and yard crews with the ability to visually identify defective equipment and take appropriate action. Furthermore, it is contended that automated tracking systems lack ready accessibility and do not provide sufficient accountability or security to prevent potential abuse by the railroads. Many of these commenters also recommend that the tags be retained for a period of at least one year rather than the proposed 90 days and that they be made available to FRA immediately rather than within the proposed 15 days. Allowing railroads 15 days to produce the document would merely frustrate FRA enforcement activity due to information delay.

Several labor commenters as well as the CAPUC also recommend that FRA modify the proposed requirements regarding the person responsible for making the determinations regarding the movement of defective brake equipment. They suggest that the rule require the person to be a carman or at a minimum a person meeting the proposed definition of a qualified mechanical inspector. They contend that only these individuals have the experience and knowledge to adequately assess the impact that a defective piece of equipment might have on a train's operation.

Several labor representatives also raised concerns regarding the proposed method for calculating the percentage of operative brakes. These commenters along with the NTSB recommend that the proposed method for calculating the percentage of operative brakes, based on the number of cut-out control valves, be modified because a control valve can be cut in but the brakes which it controls can be inoperative. Thus, the proposed method does not provide an accurate count of the number of defective brakes. Some labor representatives suggest that the computation be based on car count as it provides a much more simple, reliable, and enforceable method than the proposed control-valve method. Certain labor representatives also object to the proposed list of conditions that would not be considered an inoperative brake for purposes of calculating the percentage of operative brakes. They contend that cars containing any of the listed conditions should be considered to have inoperative brakes.

FRA Conclusions. The final rule generally retains the requirements regarding the movement of defective equipment proposed in the 1998 NPRM with minor modification in response to the comments submitted. The final rule modifies the language used in the proposed general provisions to accurately reflect the language contained in the existing statutory provisions pertaining to the movement of equipment with defective brakes. The final rule replaces the term "repair location" with the phrase "location where necessary repairs can be performed." FRA agrees that the proposed language could have been interpreted as being somewhat contrary to the language used in the existing statute, which was not FRA's intent.

The final rule also clarifies that the person required to make the determinations regarding the safe movement of defective equipment is to be a "qualified person" as defined in the final rule. The intent of FRA when issuing the NPRM was to require the determinations to be made by these individuals. FRA believes that the training requirements contained in the final rule for designating a person qualified to perform a specific task will ensure that the individual possesses the appropriate knowledge and skills to perform the assigned task. The determinations that are required to be made in the final rule are currently made by individuals which FRA believes will be trained and designated under the final rule as qualified persons.

The final rule also modifies the proposed method for calculating the percentage of operative brakes. The final rule retains the general method of calculating the percentage based on a control-valve basis. FRA believes that basing the calculation on control valves provides a much more accurate measurement than using a car basis because many types of freight equipment in use today can have the brakes cut out on a per-truck basis, and FRA expects this trend to continue as the technology is applied to new equipment. Thus, the method retained in this final rule more accurately reflects the true braking ability of a train as a whole and recognizes existing technology. However, FRA agrees with the comments of the NTSB and certain labor representatives that the method proposed in the NPRM did not take into consideration the possibility of a control valve being cut in when the brakes it controls are inoperative. Consequently, the final rule clarifies that a control valve will not be considered cut in if the brakes controlled by that valve are inoperative.

The final rule also retains the proposed list of conditions that are not to be considered inoperative power brakes for purposes of calculating the percentage of operative brakes. Contrary to the assertions of some commenters, the conditions listed do not render the brakes inoperative nor are the listed conditions ones that are outside the scope of the movement-for-repair provisions. Furthermore, many of the listed conditions are of such a nature that if found, they would constitute a violation under other provisions contained in the final rule and separate penalties are provided.

The final rule also modifies the proposed requirement regarding the placement of multi-unit articulated equipment with inoperative brakes. The final rule requires that such equipment shall not be placed in a train if it has more than two consecutive individual control valves cut out or if the brakes controlled by the valve are inoperative. FRA recognizes that the proposed requirement prohibiting the placement of such equipment with consecutive control valves cut out is more restrictive than current practice on many railroads. When proposing the requirement in the NPRM, FRA believed that the current practice on most railroads was to prohibit the placement of such equipment if it had consecutive control valves cut-out. Based on the comments received, it appears that the standard practice on most railroads prohibits placement of this equipment only if more than two consecutive control valves are cut-out. As it was FRA's intent to incorporate the current practices of railroads with regard to the placement of this equipment, the final rule has been modified accordingly.

The final rule retains FRA's position on the use of automated tracking systems in lieu of the required tagging of defective equipment. As an adequate automated system for tracking defective equipment does not currently exist on most railroads, FRA is not willing to permit the implementation of such a system without its approval. Furthermore, FRA does not believe it is prudent, from a safety perspective, to allow implementation of a tracking system for which FRA would not have a prior opportunity to assess to ensure the system's accessibility, security, and accuracy. Moreover, FRA agrees that the physical tagging of defective equipment provides a railroad's ground and operational forces the ability to visually locate and identify defective equipment at the time they see it rather than referring to an electronic database for such information. It should be noted that FRA is not intending to discourage the development of a viable automated tracking system, but believes that FRA must be provided the ability to review and approve any such system prior to its implementation. In fact, the final rule contains some new language regarding FRA's oversight of any automated tracking system that is approved by FRA to ensure the agency's ability to monitor such systems and potentially prohibit the use of the system if it is found deficient.

The final rule also retains the proposed requirement that a record or copy of each tag removed from a defective piece of equipment be retained for 90 days and made available to FRA within 15 days of request. FRA does not believe that the proposed time frames need to be expanded as suggested by some commenters. The provisions are identical to those contained in part 215 regarding freight car defects, and they have proven to be sufficient to meet the needs of FRA. FRA admits that the record keeping requirements are intended to aid FRA in its enforcement of the regulations. However, as the agency is able to inspect and oversee only a small portion of the railroad operations taking place across the country at any one time, the need for railroads to maintain records is essential for FRA carry out its mission of ensuring that all railroads are operating in the safest possible manner and comply with those regulatory provisions designed to ensure that safety.

After consideration of the comments provided, FRA believes it is essential to further clarify to the regulated community its position for determining whether a location is a place where brake repairs can be made. FRA does not agree that railroads should be permitted to unilaterally determine the locations FRA will consider capable of making brake system repairs. History shows that many railroads and FRA have widely different views on what should be considered a location where brake repairs can and should be effectuated. Furthermore, it is apparent to FRA that some railroads attempt to minimize or circumvent the requirements for conducting repairs for convenience or efficiency. However, FRA also recognizes that the emergence of mobile repair trucks creates an ability to perform repairs that did not exist when Congress enacted the statutory requirements related to the movement of defective equipment. FRA acknowledges that every location where a mobile repair truck is capable of making repairs should not be considered a location where repairs must be conducted. However, FRA also disagrees with the contentions of some commenters that Congress intended for only fixed repair facilities to be considered when determining locations where brake repairs are to be performed and that mobile repair trucks should not be considered. FRA is aware of numerous locations where mobile repair trucks are being used in lieu of a fixed facility or where a fixed facility was eliminated and the same repairs, that were being performed by the fixed facility, are now being performed at the same location by a fully equipped repair truck. Thus, FRA believes that locations where repair trucks are used in the same manner as a fixed facility should be considered when determining where the necessary repairs can be made.

As noted in the NPRM, the determination as to what constitutes the

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nearest location where necessary repairs can be performed is an issue that FRA has grappled with for decades. FRA continues to believe that the determination must be made on a case-by-case basis after conducting a multi-factor analysis. However, in an effort to better detail the items that will be considered by FRA in making a determination, the final rule contains general guidelines that FRA will consider when determining whether a location is one where at least some brake system repairs must be made. FRA would expect railroads to consider the guidance contained in the final rule when making their decisions on where equipment containing brake defects will be repaired. The guidance contained in the final rule is based upon the voluminous case law that establishes the guiding principles for determining whether a location constitutes the nearest location where the necessary repairs can be made, previous enforcement actions taken, and guidance provided by FRA regarding identification of repair locations. The final rule guidance incorporates the principles contained in the following discussion previously set out in the NPRM.

In determining whether a particular location is a location where necessary repairs can be made or whether a location is the nearest repair location, the accessibility of the location and the ability to safely make the repairs at that location are the two overriding factors that must be considered in any analysis. These two factors have a multitude of sub-factors which must be considered, such as: the type of repair required; the safety of employees responsible for conducting the repairs; the safety of employees responsible for getting the equipment to or from a particular location; the switching operations necessary to effectuate the move; the railroad's recent history and current practice of making repairs (brake and non-brake) at a particular location; and relevant weather conditions. Although the distance to a repair location is a key factor, distance alone is not the determining factor concerning whether a particular location is the nearest location for purposes of effectuating repairs and must be considered in conjunction with the factors noted above. Existing case law states that neither the congestion of work at a particular location or convenience to the railroad are to be considered when conducting this analysis.

Although FRA does not believe that railroads should be permitted to unilaterally designate locations where brake system repair will be conducted, FRA does believe that safety could be served and disputes avoided if a railroad in cooperation with its employees could develop a plan, subject to FRA's approval, which designates locations where brake system repairs will be effectuated. FRA believes such a plan would have to be consistent with the guidelines discussed above and contained in this final rule and that such plans would have to be approved by FRA prior to being implemented. Such a plan could serve safety well by making clear to all where repairs are to be made and by assuring in advance that the criteria set forth in the final rule are appropriately applied. Consequently, the final rule permits railroads and representatives of their employees to submit a joint proposal containing a plan which designates locations where brake system repairs will be conducted. The final rule makes clear that such proposals would have to be approved by FRA prior to being implemented.

The final rule also retains the proposed and current requirement that a train have 100-percent operative brakes when departing from a location where an initial terminal brake test is required to be performed on the train. This has been a requirement in the railroad industry for decades, and FRA is not willing to provide an exception on an industry-wide basis at this time. Contrary to the assertions made by some commenters, FRA believes there is adequate justification for retaining the 100-percent requirement. In the NPRM and in the preceding discussion, FRA provided a number of reasons why it believes there is a need for the 100-percent requirement and will not reiterate them here. *See* 63 FR 48309. Some commenters suggested that FRA should permit any and all trains that have 95-percent operative brakes to operate from their points of origin to destination and that Canada currently allows such operation. FRA believes that such an approach would be completely contrary to, and would violate, the existing statutory mandate regarding the movement of equipment with defective brakes. The existing statutory provisions regarding the movement of equipment require that such equipment be repaired at the nearest location where the necessary repairs can be performed. *See* 49 U.S.C. 20303(a). Consequently, trains that originate at or that operate through locations where the necessary brake repairs can be effectuated clearly are required by the statute to have 100-percent operative brakes prior to departing those locations and may not haul a car with inoperative brakes under the statutory hauling-for-repair provision.

Although FRA recognizes that the 100-percent requirement may be somewhat burdensome for some railroads at certain locations, FRA believes that the number of locations involved is relatively low and should be handled on a case-by-case basis through the existing waiver process. FRA agrees that many railroads have created their own problems by eliminating repair facilities and personnel at many of the outlying locations where the railroads now claim they lack the ability to make appropriate repairs. Furthermore, FRA believes that the best method of assessing the safety implications of permitting a location to operate trains with less than 100-percent operative brakes is for the railroad to provide information on how the railroad will handle the defective equipment based on the specific needs and operating characteristics of the railroad involved.

In the NPRM, FRA provided various approaches under which it would potentially consider allowing a railroad to operate a train from their initial terminal with less than 100-percent operative brakes. *See* 63 FR 48310. The methods suggested by FRA were rejected as being overly burdensome by several commenters noted in the preceding discussion. Therefore, FRA believes the burden falls on each railroad seeking relief from the 100-percent requirement at certain outlying locations to provide FRA with an operating plan that will ensure the safe operation of such trains and provide for the timely and certain repair of any defective equipment moved from those locations. Consequently, FRA believes that there are a few existing locations that may be candidates for receiving a waiver from the 100-percent requirement, and FRA is willing to consider waivers for such locations, however; the railroads applying for such waivers must be able to establish a true need for the exemption and must be willing to provide alternative operating procedures that ensure the safety of the trains being operated from those locations.

The final rule also clarifies that the 100-percent operative brake requirement is not intended to apply to transfer trains that originate at location where the necessary brake repairs cannot be effectuated. FRA agrees that the 100-percent requirement does not currently apply to such trains, and it was not FRA's intention when issuing the NPRM to extend its application to such trains. However, it should be noted that if a transfer train originates at a location where repairs to the equipment containing defective brakes can be effectuated, then the train would be required to have 100-percent operative brakes prior to departing that location.

D. Dynamic Brakes

The issue of dynamic brakes, and the extent to which FRA should impose regulatory requirements governing their use, if at all, is one which has prompted lengthy and animated debate among all affected parties since the issuance of the ANPRM in December 1992. Coincident with the drafting of the ANPRM, the Rail Safety Enforcement and Review Act amended section 202 of the Federal Railroad Safety Act of 1970 (recodified at 49 U.S.C. 20141), and mandated, in part, that FRA, "where applicable, prescribe regulations that establish standards on dynamic braking equipment." This specific mandate is derived largely from two NTSB recommendations to FRA concerning dynamic brakes following the Southern Pacific Transportation Company (SP) accident at San Bernardino, California on May 25, 1989.

In this accident, excessive tonnage and excessive speed cresting a 2.2-percent grade, complicated by the fact that the train crew had been provided erroneous information regarding available and operative dynamic brakes, led to a train that was out of control and was ultimately unable to stop before derailing. While the NTSB determined the primary cause of the accident to be the excessive weight of the train as compared to that reported to the train crew, a secondary cause was determined to be the fact that the engineer had far less operable dynamic braking available for use than expected. The combination of these two conditions likely led to flawed decision making by the train crew in developing train handling strategies for negotiating the grade safely. In its final report, the Safety Board issued the following recommendations to the FRA regarding dynamic brakes:

1. Study, in conjunction with the AAR, the feasibility of developing a positive method to indicate to the operating engineer in the cab of the controlling locomotive unit the condition of the dynamic brakes on all units in the train.

2. Revise regulations to require that if a locomotive unit is equipped with dynamic brakes that the dynamic brakes function. NTSB Recommendation R–90–24 (1990).

To reiterate the general explanation of the principles of dynamic braking, as provided in the ANPRM (57 FR 62546), the 1994 NPRM (59 FR 47676), and the 1998 NPRM (63 FR 48311), dynamic brakes were developed as a "free" by-product of the diesel-electric drive train. By engaging the dynamic brake, the normally powered traction motors on each axle are changed to generators, and the power generated is dissipated through resistance grids. The effect is similar to that of shifting an automobile to a lower gear when descending a steep grade. The additional hardware needed to outfit a locomotive with dynamic brakes includes the grids and the controls and switches.

The primary selling point of dynamic brakes has been the ability to reduce freight car brake shoe wear. The dynamic brake is also useful in controlling train slack in lieu of using the locomotive independent brake. Furthermore, use of the dynamic brake in controlling train speed in lieu of power braking, where the train brake is applied with the locomotive under power, is a major factor in fuel savings. Due to these benefits, railroads currently emphasize and encourage the use of dynamic brakes as evidenced through examination of numerous carriers' operating rules which dictate the use of dynamic braking as the preferred method of slowing or controlling a train, or both, especially in heavy-grade territory. Historically, dynamic brakes have been applied to locomotives at the individual railroad's option, primarily based on economic considerations. It is important to note that, at present, the vast majority of new locomotives procured by the railroads are equipped with dynamic brakes.

A wealth of information was gathered regarding the operation, testing, and maintenance of dynamic brakes prior to the issuance of the 1998 NPRM. In the 1998 NPRM, FRA provided an in-depth discussion of the various proposals and comments related to the operation and maintenance of dynamic brakes as well as potential technologies for providing information to the locomotive engineer regarding the operational status of the dynamic brakes in a train consist. *See* 63 FR 48310–313. After consideration of all the information submitted and developed, FRA proposed a set of standards for dynamic brakes that it believed were consistent with the statutory mandate, took into consideration NTSB recommendations, promoted progressive improvements in dynamic brake information systems through the phased introduction of technology, while avoiding excessive regulation that might discourage the use of dynamic brakes.

In the 1998 NPRM, FRA noted that RSAC Working Group and task force deliberations provided no rationale to warrant a reconsideration of FRA's stated position that dynamic brakes do not offer the technical capability to serve as a primary train braking system since: (i) They provide braking force only on powered locomotive axles and are incapable of controlling in-train forces in the same manner as the automatic braking system; (ii) they are effective only within a narrow speed range and have no capability to actually stop a train; (iii) they can fail without prior warning; and (iv) their failure mode is characterized by loss of braking force (as opposed to the automatic brake, which, properly employed, initiates an emergency brake application upon loss of system integrity and therefore is failsafe). Similarly, however, FRA asserted that the RSAC Working Group and task force deliberations reinforced FRA's belief that dynamic brakes have become, *de facto*, a second-order safety system where employed. Although from the point of view of logical priorities, dynamic brakes "back up" the automatic train brake system, in sequence of operational procedures the priority is reversed. Stated differently, either the proper functioning of these systems, or the provision of reliable information concerning degraded functioning of these systems, should prevent locomotive engineers from operating trains in a manner that might make recovery through use of the automatic brake impossible.

In considering all of the information available, FRA concluded that it was imperative for the locomotive engineer to be informed in writing as to the operational status of the dynamic brakes on all locomotives in the consist at the initial terminal or point of origin for a train or at other locations where a locomotive engineer first takes charge of a train. Therefore, FRA proposed that locomotive engineers be provided this information at these locations. This proposed provision directly addressed the foremost concern articulated by the NTSB following the San Bernardino accident. FRA also proposed provisions requiring visible identification of locomotive units with inoperative dynamic brakes. FRA also agreed that when locomotives are equipped with dynamic brakes, they should be in proper operating condition and be maintained on a regular basis. Therefore, FRA proposed that defective dynamic brakes be repaired within 30 days of being found defective or at the locomotive's next periodic inspection. FRA recognized that these maintenance requirements might be overly burdensome in some instances for railroads (primarily short lines) that do not utilize dynamic brakes in their

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respective operations, but yet own and operate locomotives equipped with dynamic brakes. Consequently, FRA proposed provisions for deactivating a locomotive's dynamic brakes without physically removing the components.

In addition to the information and maintenance requirements, FRA also proposed the development of operating rules and training programs to ensure the proper and safe use of dynamic brakes. For example, FRA proposed that railroads operating trains with brake systems that include dynamic brakes, develop and implement written operating rules governing safe train handling procedures for using these dynamic brakes under all operating conditions that are tailored to the specific equipment and territory of the railroad. The NPRM also proposed that the railroads provide training to their locomotive engineers on the prescribed operating rules, that at a minimum includes classroom, hands-on, and annual refresher training. More importantly, FRA also proposed a requirement that a railroad's operating rules be *based on the ability of friction brakes alone to safely stop the train under all operating conditions.* FRA believed that the establishment of these comprehensive operating rules and training plans was the most effective means by which to minimize the possibility of future incidents caused by excessive reliance on dynamic brakes by a train crew.

In the ANPRM (57 FR 62555), the 1994 NPRM (59 FR 47687), and the 1998 NPRM (63 FR 48314), FRA requested comments from the industry on possible methods of providing information regarding the status of dynamic brakes to the engineer in the cab of the controlling locomotive. The 1998 NPRM also contained a detailed discussion of various technologies available for providing information on the status of the dynamic brakes to the locomotive engineer. *See* 63 FR 48312–13. Although FRA recognized that the technology for dynamic brake displays with the ability to provide the type of information sought by FRA in the 1994 NPRM was not readily available at the time the 1998 NPRM was issued, several commenters suggested that the technology was under development. Consequently, FRA was not ready or willing to require the use of such indicators at that time. However, FRA noted that the benefit of such an indicator would be to alert engineers that they have diminished or excessive dynamic braking capabilities, thus permitting the engineers to control the braking of their trains in the safest possible manner. FRA indicated that it would continue to monitor the development of the technology and consider its application to locomotives used in the industry.

The AAR and its members, the NTSB, the CAPUC, and several representatives of rail labor provided numerous comments on the provisions related to dynamic brakes proposed in the 1998 NPRM. The AAR contends that the proposed requirement to provide written notification of the operational status of the dynamic brakes is overly burdensome. They recommend that the information be permitted to be transmitted in any manner, provided a record of the notification is maintained in the cab of the controlling locomotive. They also suggest that the notification only be required on an exception basis, when the dynamic brakes are inoperative. Conversely, representatives of rail labor contend that no locomotive with inoperative dynamic brakes should be permitted to be dispatched from a location with mechanical facilities capable of making the repairs. They further contend that if the locomotive's dynamic brakes cannot be repaired at the train's point of origin it should be allowed to be operated only as a trailing unit. These commenters support the requirement that the locomotive engineer be informed in writing as to the operational status of the dynamic brakes on all units in the consist and recommend that the lead locomotive of the consist be tagged to notify the engineer of the presence of a defective unit.

The AAR also objects to the proposed requirement that defective dynamic brakes be repaired within 30 days of being found defective. It claims that due to the reliability of dynamic brake systems they should be permitted to operate until the next periodic inspection. AAR asserts that a shorter repair cycle will reduce motive power availability and may result in shortages of motive power on some railroads. AAR also requests clarification of the term "ineffective" dynamic brake. The organization recommends that the term be eliminated, that the term "inoperative" dynamic brake be retained, and that a dynamic brake be considered "inoperative" when it is no longer capable of providing its designed retarding force on the train, similar to the proposed definition of "effective" brake.

Representatives of rail labor contend that locomotives with defective dynamic brakes should be required to be repaired within 15 days of being discovered. They contend that this is a more than sufficient time period for railroads to arrange for alternative power and get the locomotive to a location where it can be repaired. These commenters also recommend that a record of the repairs made to a locomotives dynamic brakes be retained for a period of one year rather than the 92 days proposed in the NPRM. These commenters also recommend that provisions be added to ensure that all dynamic brakes operate as intended and that the equipment not be altered or cut back in any manner.

The AAR also seeks clarification of the proposed training requirements contending that they should not be included in this rule unless FRA is willing to specify the knowledge, skills, and ability criteria needed pursuant to part 240. They also contend that the proposed requirement regarding the development of operating rules is unclear and should be eliminated if not clarified. The BLE asserted that the problem is not in the training of engineers on the use of dynamic brakes but in the prohibition on the use of the automatic brake in normal train operation, not just when the dynamic brakes fail. They assert that locomotive engineers should be permitted to use the automatic brake to control the train on a periodic basis to become familiar with its operation.

The AAR also objects to the requirement to stencil locomotives operating with deactivated dynamic brakes. The AAR asserts that defacing such locomotives is unnecessary and that a less intrusive means of identification should be used. The organization recommends that a locomotive with a deactivated dynamic brake should be treated no differently than a locomotive with an inoperative dynamic brake, in that the locomotive engineer should be notified of its presence. The AAR also recommends that railroads be permitted to use existing tags to identify locomotives with inoperative dynamic brakes.

The AAR and several locomotive manufacturers provided comments on the availability and use of dynamic brake indicators. These commenters make clear that there is currently no easy method of providing the available dynamic brake retarding force to the locomotive engineer. They also contend that the technology does not exist to show dynamic brake performance on distributed power units and that they should, therefore, be excluded from any indicator requirements. These commenters indicated that technology is not available to have most existing locomotives retrofitted with an indicator of some sort. They also assert that it is impossible to develop a device that will tell an engineer whether the dynamic brakes will operate prior to the engineer actually applying the brakes due to the unknown risk of failure. The AAR also recommends that if FRA adopts an indicator requirement then the proposed requirements related to the notification of the locomotive engineer of dynamic brake status and for repairing inoperative dynamic brakes should not be adopted since real-time information will be available to the locomotive engineer.

Numerous labor representatives, the NTSB, and the CAPUC contend that the technology does exist, at least for new locomotives, to provide locomotive engineers with real-time indicators of the operating status of the dynamic brakes on trailing units. These commenters believe that the information these indicators provide to an engineer is extremely important and would allow engineers to control and operate their trains in the safest manner possible. All of these commenters appear to support a requirement to require these indicators in new locomotives, and some recommend some sort of retrofit requirement for existing equipment.

Several parties responded to FRA's request regarding technical reasons for prohibiting a locomotive with inoperative dynamic brakes from functioning as the lead or controlling locomotive in a locomotive consist. The AAR responded that it found no technical reason to prohibit such use, provided the locomotive has the ability to control the dynamic brakes on trailing locomotives. The AAR contends that railroads currently operate in this manner and will use a non-equipped locomotive when the other locomotives in the consist are cabless. Several labor representatives asserted that a locomotive with inoperative dynamic brakes should not be permitted to operate as the controlling locomotive regardless of whether it can operate the dynamic brakes on trailing units. These commenters contend that the engineer is better able to feel the dynamic brakes operate if the controlling unit has operative dynamic brakes and that the engineer will at least know whether that unit has operable dynamic brakes. The CAPUC cites similar human factor reasons for contending that a locomotive with inoperative dynamic brakes should not be used as a controlling unit. Several labor representatives also contended that if a defective locomotive were in the controlling position, then the speed of the train should be limited to 30 mph and the train should not be permitted to operate over grades of one percent or greater until a locomotive with operative dynamic brakes is placed in the lead position.

The NTSB and the CAPUC recommend that FRA include a "mile-per-hour-overspeed-stop" rule into the final rule to ensure that the speed of a train does not exceed its braking capacity. Such a rule would require a train that exceeds an established speed limit by a specified amount to be placed in emergency. The NTSB recommends that the overspeed limit be 5 mph or less over the designated speed limit. The CAPUC claims that California uses a 5 mph rule but that the limit may vary for different operations and should be established through validated simulations that include brake fade and field tests and must be related to a safe base speed. Both commenters contend that although the overspeed rule is simple, it accomplishes a critical safety function and reduces the chances of a runaway occurring as it removes any discretion from the operator. The CAPUC also recommends that railroads be required to validate their operating rules to ensure that friction brakes alone are sufficient to stop a train on all grades operated by the railroad. The CAPUC recommends that this be accomplished through validated simulations and field test that take into account brake heat-fade.

FRA Conclusions. The intent of the proposed requirement to notify the locomotive engineer in writing as to the operational status of the dynamic brakes on the locomotives in a train's consist was to ensure that the engineer had timely information on the condition of the locomotives so he could operate the train in the safest possible manner based upon that information. Thus, the manner in which the information is provided to the engineer is not a major concern to FRA, provided the information is accurate and up-to-date. Therefore, the final rule will allow railroads to provide locomotive engineers with the required information by any means they deem appropriate. However, the final rule will require that a written or electronic record of the information provided be maintained in the cab of the controlling locomotive. This will ensure that on-coming engineers will have the information provided to the previous operator of the train. The final rule also clarifies that the information is to be provided to the locomotive engineer at the train's initial terminal and at other locations where an engineer "first begins operation" of the train rather than where the engineer "takes charge of the train." This clarification is in response to certain labor commenters to prevent possible misinterpretation or abuse of the requirement.

The final rule retains the proposed requirement to repair locomotives with inoperative dynamic brakes within 30 days of being found inoperative or at the locomotive's next periodic inspection, whichever occurs first. Due to the industry's reliance on these braking systems, as noted in the discussion above, FRA continues to believe they should be repaired as soon as possible after being found inoperative. FRA believes that a period of 30 days provides the railroads with sufficient time to get a locomotive to a location where the dynamic brakes can be repaired and allows for the reallocation of motive power when necessary so as to cause minimal disruption to a railroad's operation. FRA is not willing decrease the time period allowed to make repairs, as recommended by some commenters, because such a reduction could jeopardize a railroad's access to available motive power and could cause delay in the movement of freight which may create safety hazards themselves.

The final rule also eliminates the use of the term "ineffective" dynamic brakes and uses the term "inoperative" dynamic brake to include any dynamic brake that no longer provides its designed retarding force on the train, for whatever reason. FRA agrees that the use of only this term clarifies the applicability of the requirements related to dynamic brakes and prevents potential misunderstandings. The final rule also retains the proposed requirements related to the tagging of a locomotive found with inoperative dynamic brakes. Contrary to the comments of some parties, FRA does not believe that the tagging provisions require the development of new tags. The rule would allow the use of any type of tag, provided it is placed in a conspicuous location and contains the required information. The final rule also eliminates the requirement to stencil the outside of a locomotive declared to have deactivated dynamic brakes. FRA agrees that defacing the exterior of the locomotive is unnecessary and would do little to inform the locomotive engineer of the presence of the locomotive. FRA believes that the requirements to notify the locomotive engineer of the operational status of the locomotives and to have the cab of the locomotive clearly marked that the locomotive's dynamic brakes are deactivated provide sufficient notice to the locomotive engineer as to the status of that locomotive.

The final rule contains a requirement that an electronic or written record of repairs made to a locomotive's dynamic brakes be maintained and retained for a period of 92 days. Although this

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requirement was not proposed in the NPRM, FRA believes these records fall within the scope of the notice and are necessary to ensure that necessary repairs are conducted on a locomotive's dynamic brakes in a timely fashion. FRA also believes that such a record will provide a railroad with information regarding the operation of the dynamic brakes and will potentially permit railroads to identify a repeated problem with a locomotive's dynamic brakes to prevent future reoccurrences and, thus, increase the utilization of a locomotive's dynamic brakes.

The final rule also contains specific requirements related to the use of a locomotive with inoperative or deactivated dynamic brakes as a controlling locomotive. These requirements are based on FRA's review of the comments submitted in response to FRA's request regarding the positioning of such a locomotive made in the NPRM. *See* 63 FR 48314. FRA tends to agree that there are no technical reasons why a locomotive with inoperative dynamic brakes cannot function as the controlling locomotive provided it can control the dynamic brakes on trailing units in the locomotive consist. However, FRA also agrees that a locomotive engineer loses the physical sensation of the operation of the dynamic brakes when the unit where the engineer is riding loses dynamic brake capability, which, if present, provides the engineer with at least some assurance that the dynamic brakes on some of the units in the consist are operating. Thus, in addition to requiring that locomotives with inoperative or deactivated dynamic brakes have the capability of controlling the dynamic brakes on trailing units when operating as the controlling locomotive, the final rule also requires that such locomotives also have the capability of displaying to the locomotive engineer the deceleration rate of the train or the total train dynamic brake retarding force. This requirement will ensure that locomotive engineers have at least some information as to the operation of the dynamic brakes in the locomotive consist they are controlling. FRA intends that the information required by this provision be provided either by a device known as an "accelerometer" or a similar device or by a dynamic brake indicator capable of providing total train dynamic brake retarding force to the locomotive engineer.

The final rule also contains provisions requiring new and rebuilt locomotives to be equipped with some sort of dynamic brake indicator. Although FRA agrees that the technology does not currently exist to equip existing locomotives with dynamic brake indicators economically, FRA does believe that the technology exists or is sufficiently developed to provide new locomotives with the ability to test the electrical integrity of the dynamic brakes at rest and to display the total train dynamic brake retarding force at various speed increments in the cab of the controlling locomotive. FRA recognizes that the industry will require a little time to incorporate the existing technology into new locomotives. Therefore, the requirements related to dynamic brake indicators will only apply to locomotives ordered one and one-half years after the issuance of this final rule and to locomotives placed in service for the first time three years after the effective date of the final rule. FRA also recognizes that not all locomotives being rebuilt are designed, or have the capability of being redesigned, to have the capability to display the total train dynamic brake retarding force in the cab of the controlling locomotive. Thus, the final rule allows rebuilt locomotives to be designed to display the train deceleration rate (i.e., equipped with an accelerometer or similar device as discussed above) in lieu of being equipped with the dynamic brake indicator required on new locomotives. FRA believes that the information provided by these indicators is extremely useful to an engineer and will provide locomotive engineers with ready access to real-time information on the operation of the dynamic brakes in a locomotive consist and permit engineers to control and operate trains in the safest manner possible.

FRA also acknowledges that the information provided by dynamic brake indicators would eliminate the need to provide the locomotive engineers with information regarding the operational status of the dynamic brakes when the engineer first begins operation of a train. As the indicators would provide real-time information to the engineer on the operation of the dynamic brakes brake in the train consist, the information received by the engine when beginning operation would be unnecessary. Therefore, the final rule alleviates the need to inform locomotive engineers of the status of the dynamic brakes when all of the locomotives in the lead consist are equipped with dynamic brake indicators required for new locomotives. FRA believes that this allowance makes sense from a practical perspective but also provides some incentive for railroads to equip existing equipment with such indicators when the technology for doing so becomes economically feasible. It should be noted that there is no requirement that the dynamic brake status of distributed power units be provided in order to eliminate the need to provide dynamic brake information to the engineer. FRA agrees that the technology for transmitting that information to the engineer is not currently available in a cost effective and reliable manner.

The final rule retains the proposed provisions requiring railroads to develop and implement written operating rules governing the use of dynamic brakes and to incorporate training on those operating rules into the locomotive engineer certification program pursuant to 49 CFR part 240. Contrary to the assertions of some commenters, FRA does not believe these requirements are unclear. FRA intends for each railroad to develop appropriate operating rules regarding train handling procedures when utilizing dynamic brakes that cover the equipment and territory operated by the railroad. Many railroads already have these procedures in place and already provide training to their employees that adequately cover the requirements. FRA continues to believe that training on proper train handling procedures is essential to ensuring that locomotive engineers can properly handle their trains with or without dynamic brakes and in the event that these brake systems fail while the train is being operated. FRA also disagrees that the agency should specify the knowledge, skill, and ability criteria that a railroad must incorporate in its training program. FRA believes that each railroad is in the best position to determine what these criteria should be, given the railroad's equipment, physical characteristics and operating rules, and what training is necessary to provide that knowledge, skill, and ability to its employees.

The final rule also requires that the operating rules developed by railroads include a "miles-per-hour-overspeed-stop" requirement that requires a train to be immediately stopped if it exceeds the maximum authorized speed by more than 5 mph when descending a grade of one percent or greater. FRA agrees with both the NTSB and the CAPUC that this requirement accomplishes a critical safety function and reduces the potential for a runaway train as it establishes a clear rule for stopping a train and removes any discretion from the operator to continue operation of a train. FRA believes that the five-mph limitation is a good base limitation that should be reduced if so indicated by validated research and should be increased only with FRA approval. Moreover, the operating rules of most

Class I railroads already include a five-mph-overspeed-stop provision; thus, FRA's inclusion of the requirement in this final rule should impose little or no burden on the operations of most railroads.

E. Training and Qualifications of Personnel

Currently, the regulations contain no specific training requirements or standards for personnel who conduct brake system inspections. The regulations merely require that a "qualified person" perform certain inspections or tasks. *See* 49 CFR 232.12(a). Furthermore, the current regulations do not require that a railroad maintain any type of records or information regarding the training or instruction it provides to its employees to ensure that they are capable of performing the brake inspections or tests for which they are assigned responsibility. In several cases, FRA has found that a railroad's list of "qualified persons" is merely a roster of all of its operating and mechanical forces.

In the 1994 NPRM, FRA proposed a series of broad qualification standards addressing various types of personnel engaged in the inspection, testing, and maintenance of brake equipment. *See* 59 FR 47731–47732. These broad qualifications were separated into distinct subgroups that identified various types of personnel based on the type of work those individuals would be required to perform under the proposal. These included supervisors, train crew members, mechanical inspectors, and electronic inspectors. Although not proposed in the rule text of the 1994 NPRM, the preamble contained various guidelines regarding specific hours of classroom and "hands-on" training as well as guidelines regard the level of experience each of these types of employees would be required to possess or be provided. *See* 59 FR 47702–47703. The proposal also contained various requirements regarding the development and retention of records and information used by a railroad in determining the qualifications of such employees. See 59 FR 47732.

In the 1998 NPRM, FRA acknowledged that many railroads continue to improve the training they provide to individuals charged with performing brake system inspections, tests, and maintenance; however, FRA also acknowledged that it continued to believe that this training could be greatly improved and enhanced. The agency noted that although there had been a decline in the number of train incidents, derailments, fatalities, and injuries over the previous ten years, FRA believed that the number of these incidents could be further reduced if maintenance, inspections, and tests of the brake system were performed by individuals who have received proper training specifically targeting the activities for which the individual is assigned responsibility. FRA believed that one of the major factors in ensuring the quality of brake inspections and the proper operation of that equipment is the adequate training of those persons responsible for inspecting and maintaining that equipment.

In the 1998 NPRM, FRA proposed broad performance-based training and qualification requirements that would permit a railroad to develop programs specifically tailored to the type of equipment it operates and the employees designated by the railroad to perform the inspection, testing, and maintenance duties required in this proposal. FRA agreed that there is no reason for an individual who solely performs pre-departure air brake tests and inspections to be as highly trained as a carman since a carman performs many other duties which involve the maintenance and repair of equipment in addition to brake inspections. Therefore, FRA proposed training and qualification requirements which permit a railroad to tailor its training programs to ensure the capability of its employees to perform the tasks to which they are assigned. FRA also made clear that the proposed training and qualification requirements applied not only to railroad personnel but also to the personnel of railroad contractors and personnel in plants that build cars and locomotives that are responsible for brake system inspections, maintenance, or tests covered by this part.

Contrary to the 1994 NPRM, FRA did not issue specific guidelines on experience, classroom training, or "hands-on" training. FRA agreed that many of the guidelines contained in the preamble to that proposal were overly restrictive and might have impeded the implementation of certain training protocols capable of achieving similar results with less emphasis on solely the time spent in the training process. Furthermore, the 1994 proposed guidelines failed to consider the potentially narrow scope of training that might be required for some employees, particularly some train crew personnel, that perform very limited inspection functions on very limited types of equipment. Consequently, although the training and qualification requirements proposed in the 1998 NPRM continued to require that any training provided include classroom and "hands-on" training as well as verbal or written examinations and "hands-on" proficiency, they did not mandate a specific number of hours that the training must encompass as FRA realized that the time period should vary depending on the employee or employees involved. The 1998 proposal also contained provisions for conducting periodic refresher training and supervisor oversight of an employee's performance once training is provided.

FRA believed that the recordkeeping and notification requirements contained in the 1998 proposal were the cornerstone of the training and qualification provisions. As FRA was not proposing specific training curricula or specific experience thresholds, FRA believed that the recordkeeping provisions were vital to ensuring that proper training was being provided to railroad personnel. FRA intended the record keeping requirements to provide the means by which FRA would judge the effectiveness and appropriateness of a railroad's training and qualification program. The proposed recordkeeping provisions also provided FRA with the ability to independently assess whether the training provided to a specific individual adequately addresses the tasks that the individual is deemed capable of performing. Finally the proposed training mandates seemed most likely to prevent railroads from using insufficiently trained individuals to perform the necessary inspections, tests, and maintenance required by the proposal.

In the 1998 NPRM, FRA proposed to require that railroads maintain specific personnel qualification records for all personnel (including their contractors' personnel) responsible for the inspection, testing, and maintenance of train brake systems. FRA proposed that the records contain detailed information regarding the training provided as well as detailed information on the types of equipment the individual is qualified to inspect, test, or maintain and the duties the individual is qualified to perform. As an additional means of ensuring that only properly qualified individuals are performing only those tasks for which they are qualified, FRA proposed that railroads be required to promptly notify personnel of changes in their qualification status and specifically identify the date that the employee's qualification ends unless refresher training is provided.

FRA recognized that some railroads would be forced to place a greater emphasis on training and qualifications than they had in the past, and as a result would incur additional costs. However, FRA believed that the proposed rule

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allowed railroads the flexibility to provide only the training that an employee needs in order to perform a specific job. The 1998 proposed rule did not require an employee who performs only brake inspections while the train is en route (*i.e.*, Class II brake tests) to receive the intensive training needed for an employee who performs Class I brake tests or one who is charged with the maintenance or repair of the equipment. The training might be tailored to the specific needs of the railroad. Across the industry as a whole, the 1998 proposal would not have required extensive changes in the way most railroads currently operate, but it would have required some railroads to invest more time in the training of their personnel.

FRA recognized that the costs of the proposed training requirements were fairly substantial; however, FRA believed that most Class I railroads had already invested in training, routinely scheduled training for their employees, and offered training to other interested parties. On the other hand, FRA noted that most railroads did not engage in the "hands-on" training and testing contained in the proposal nor did most railroads maintain the records required in the proposal. FRA noted that many Class I railroads have participated in initiatives under the Safety Assurance and Compliance Program (SACP) with FRA and labor and that many of the proposed training requirements would already be met by those railroads that have completed the training required under the SACP.

In the 1998 NPRM, FRA recognized that the proposed training requirements would likely cause some impact to smaller railroads but believed that the impact of the requirements on these smaller operations would be somewhat reduced due to the training already provided by the railroads and due to the nature of the operations themselves. FRA noted that many smaller railroads, particularly Class II railroads, send their employees to other railroads for training, participate in ASLRA and FRA training, and have some form of on-the job training. Furthermore, Class III railroad employees are not likely to require extensive training on different types of brake equipment since most of the equipment used by Class III railroads have only one type of brake valve. Furthermore, the employees of these small railroads would likely not be required to receive any training in the areas of EPIC brakes, dynamic brakes, two-way EOT devices, or on some of the brake tests and maintenance mandated in the proposal due to the limited distances traveled by these trains, the low tonnages hauled, and because many of the maintenance functions are contracted out to larger railroads.

The AAR and its members, the ASLRA, and various private car owners submitted numerous comments regarding the proposed training requirements. Generally, these commenters believe that the significant costs being imposed by the proposed training requirements are not justified based on the industry's safety record over the last two decades. They contend that the industry's safety record is evidence that the current training provided by the railroads is sufficient. At a minimum, these commenters recommend that railroads be provided three years to implement any training requirements imposed. Such an approach would be consistent with the proposed three-year refresher training requirements and would prevent manpower shortages and ease the financial impact.

Several railroad representatives recommend that railroads not be responsible for the training of the contract personnel they employ as was proposed. They contend that railroads do not maintain records of the training or experience of these individuals and that the contractor should bear the burden of training its own employees. These commenters admit that railroads would work with contractors to help them train their employees but that the contractor should be held responsible for providing the necessary training. They assert that the contractor is in the best position to determine the training needs of its employees and that the proposed approach potentially intrudes and alters the employment relationship of contractors and railroads.

Representatives of various railroads also object to some of the administrative burdens imposed by the proposed training requirements. They contend that the requirement to identify all tasks related to the inspection, testing, and maintenance of brake systems and develop procedures for performing each task, is overly burdensome and unnecessary. They also object to the proposed requirement that the railroad's Chief Mechanical or Chief Operating Officer sign a statement for each employee attesting that the employee meets the minimum requirements. They contend that the requirement would inhibit the use of electronic records and that there is no benefit obtained by requiring such a signature. These commenters further object to the requirement that railroads implement formal internal audit programs, contending that these programs would waste scarce resources and that the effectiveness of a training program can be assessed through efficiency tests, supervisory spot checks, and other less burdensome methods.

The AAR also objects to the potential requirement that all existing employees be completely retrained. The AAR recommends that existing employees not be required to receive any new training because it is unnecessary and there has been no showing that current training is inadequate. They also suggest that there is no need for refresher training of these employees unless a new brake system is introduced. At a minimum, they recommend that the "hands-on" refresher training be eliminated as virtually every railroad conducts periodic efficiency testing or audits of its employees to ensure "hands-on" proficiency of personnel. They also contend that refresher training should only be required for those employees that repeatedly demonstrate a failure to properly perform their required duties.

Several railroad representatives also object to the proposed requirement that employees receive training and testing on each task they will be required to perform and that they be trained and tested on each type of equipment operated by the railroad. These commenters contend that these proposed requirements would be cost-prohibitive and time-consuming. They claim that it is impossible for a railroad to have every type of vehicle it operates available to train all of its employees. They recommend that the training be limited to the different brake systems operated by the railroad and that the training be required to impart the necessary skills and abilities to perform the required tasks.

The AAR and the ASLRA also object to the proposed record keeping provisions, claiming they are overly detailed and unnecessary. These commenters recommend that the record keeping burdens be reduced and that FRA should only require a list of qualified employees, the training courses completed by an employee, and the date that training was completed. They contend that each railroad is in the best position to determine the level of detail that their records should contain and that the level of detail proposed by FRA will have a significant cost burden on railroads.

Representatives of rail labor reiterate that the need for any training provisions could be greatly reduced if FRA would simply require many of the proposed inspections and tests to be conducted by qualified carmen. At a minimum, these commenters contend that any training provisions must include a requirement

for FRA approval. They assert that any training program developed by a railroad should be approved by FRA. Several labor representatives also contend that the proposed training requirements fail to adequately address supervisors charged with oversight and training instructors. They believe that specific qualifications of both supervisors and instructors should be included in any final rule developed. They further contend that the proposed requirements do not include a dispute resolution procedure which they believe is necessary to avoid potential abuses by railroads when designating qualified employees. Certain labor representatives recommend that the proposed language regarding the training on new equipment needs to be clarified to ensure that the training is provided before the new equipment is placed in service.

FRA Conclusions. FRA recognizes that there has been a significant decline in the number of brake-related derailments and other train accidents and incidents, and resulting property damage, fatalities, and injuries over the last ten years; however, FRA continues to believe these numbers can be even further reduced if the inspections and tests of brake systems are performed by individuals who have received training that specifically targets the activities which the individual is assigned responsibility to perform. FRA's experience in enforcing the existing power brake regulations supports the conclusion that the better trained a person is on how to perform a brake inspection the better that person can perform the inspection when required to do so. Many FRA field inspectors have discovered equipment with brake conditions having the potential of causing a derailment or accident that are not identified by railroad personnel because those persons responsible for finding the conditions are not sufficiently trained or equipped to conduct the inspections they are required to perform. FRA's field forces consistently find that the most comprehensive brake inspections are performed by those individuals who have received detailed training specifically related to the inspection being performed and who conduct such inspections on a consistent basis. Based on this experience, FRA believes that the training required in this final rule will enhance the quality of brake inspections, which will increase the discovery of brake conditions that have the potential of causing a derailment or other accident. Because an increased number of brake conditions having the potential of causing a derailment or other accident will be discovered prior to being used in a train, FRA expects that the training required by this rule will reduce the number of incidents caused by brake-related problems.

Furthermore, as discussed in the 1998 NPRM, railroads continue to consolidate mechanical work to fewer and fewer locations on their systems. This trend places an increasing premium on the ability of mechanical and operating forces to conduct meaningful inspections and tests of the power brake system. Increases in train speeds and increased pressure on operating personnel due to growing traffic density will continue to make it critical for operating and mechanical forces to discharge their duties with respect to the power brake system both diligently and effectively even under the most optimistic of scenarios. Technological change presents an additional reason for placing a strong emphasis on the training and qualifications of inspection personnel. Both operating and mechanical personnel are confronted with an increasing variety of power brake arrangements and features. Consequently, these trends and changes make the training required in this final rule a necessity in order to ensure and enhance the quality of brake inspections.

In addition to the safety benefits, both quantified and non-quantified, there are certain operational benefits derived from the training required by this final rule. This final rule allows an increase in the distance some trains may travel between brake inspections. These increases are premised on the condition that all of the inspection functions performed on these trains are conducted by highly trained and qualified personnel. The latitude provided to these trains will result in fewer inspections per miles traveled and will reduce the number of opportunities that exist for a serious defect to be found before it could result in a train incident. It is imperative, therefore, that each inspection performed on these trains be of uniformly high quality. FRA believes that the training required by this final rule is a key factor for ensuring such high quality inspections. FRA also believes that certain non-quantifiable operational benefits will be derived from the training required by this final rule, particularly in the areas of equipment utilization, reduced train delays, and repair costs.

FRA agrees that railroads have made significant improvements in the quality of training provided to their employees but believes that this training can be further improved. Furthermore, FRA believes that a number of railroads participating in the SACP process have already developed, or are in the process of developing, comprehensive training programs that meet many of the requirements proposed in the NPRM. Therefore, the final rule retains the basic structure and concepts that were proposed in the NPRM regarding the training of individuals responsible for conducting the inspections and tests required by the final rule. The proposed training requirements have been slightly revised in this final rule in order to clarify FRA's intent, to recognize existing training, and to reduce any unnecessary burden that may have been inadvertently created by the proposed requirements.

The final rule modifies the proposed provision that required a railroad to provide training to the personnel of a contractor to the railroad whom the railroad uses to perform the various tasks required by the rule. The final rule makes clear that the contractor is responsible for providing appropriate training to its employees. FRA agrees that railroads should not bear the burden of training the employees of a contractor. However, FRA notes that this change does not relieve the railroad from potential civil penalties for, *e.g.*, failure to perform a proper Class I brake test, if the employees of a contractor were found not to be qualified to perform the task for which they are assigned responsibility. As a contractor's employees are acting as an agent for the railroad when performing a task required by this regulation, both the railroad and the contractor would remain liable for potential civil penalties if the employees used to perform a particular task were not trained and qualified in accordance with the training requirements contained in this final rule.

The final rule retains the proposed requirement that railroads and contractors identify the tasks related to the inspection, testing, and maintenance of the brake system required to be performed by the railroad or contractor and identify the skills and knowledge necessary to perform each task. FRA believes that it is essential to developing a comprehensive training program for a railroad or contractor to go through the process of identifying the tasks they will be required to perform and determining the skills and knowledge that must be provided to perform those tasks. FRA believes that most railroads have already engaged in this activity and would merely need to revise existing data with changes made to existing requirements by this final rule. The final rule eliminates the requirement to

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develop written procedures for performing each task identified. Although FRA believes that each railroad or contractor should and will develop such procedures, FRA does not believe it is necessary to require their development as FRA believes they will either be developed in the required training curricula or are sufficiently detailed in the regulation itself.

The final rule also clarifies that the required training is intended to provide employees with the skills and knowledge necessary to perform the tasks required by this final rule. FRA does not believe it is necessary to train an employee on every different type of equipment that a railroad operates or on each and every task an employee will be required to perform. FRA's intent when issuing the NPRM was to ensure that the training received by an employee provided that individual with the knowledge and skills needed to perform the tasks he or she was assigned on the various types of equipment the railroad operated. Therefore, the final rule clarifies this intent by specifically stating that the training curriculum, the examinations, and the "hands-on" capability should address the skills and knowledge needed to perform the various required tasks rather than focusing strictly on the tasks themselves or on the specific types of equipment operated by the railroad. The final rule also clarifies that the training that an employee is required to receive need only address the specific skills and knowledge related to the tasks that the person will be required to perform under this part. Thus, a railroad or contractor may tailor its training programs to the needs of each of its employees based on the tasks that each of its employee will be required to perform. FRA tends to agree with several commenters that there is no reason for an individual who performs strictly brake inspections and tests to be as highly trained as a carman since carmen perform many other duties related to the maintenance and repair of equipment in addition to brake inspections.

The final rule also clarifies that previous training and testing received by an employee may be considered by the railroad. FRA did not intend to require the complete retraining of every employee performing a task required in this final rule. When proposing the training requirements, FRA intended for railroads to incorporate existing training regimens and curricula into the proposed training programs. Therefore, in order to clarify this intent, the final rule contains a specific provision which permits railroads to consider previous training and testing received by an employee when determining whether an employee is qualified to perform a particular task. However, the final rule also makes clear that any previous training or testing considered by a railroad or contractor must be documented as required in the final rule. Thus, previous training or testing which has not been properly documented cannot be considered. The final rule also makes clear that employees must be trained on the specific regulatory requirements contained in this final rule related to the tasks that the employee will be required to perform. Therefore, all employees performing tasks covered by this part will require at least some training which covers the specific requirements detailed in this final rule.

The final rule retains the proposed requirement regarding the performance of periodic refresher training and testing. The final rule retains the requirement that refresher training be provided at least once every three years and that it include both classroom and experiential "hands-on" training and testing. FRA continues to believe that periodic refresher training is essential to ensuring the continued ability of an employee to perform a particular task. FRA does not intend for such training to be as lengthy or as formal as the initial training originally provided, but believes that the training should reemphasize key elements of various tasks and focus on items or tasks that have been identified as being problematic or of poor quality by the railroad, contractor, or its employees through the periodic assessment of the training program. The final rule also makes clear that a railroad or contractor may use efficiency testing to meet the hands-on portion of the required refresher training provided such testing is properly documented. FRA agrees that such testing provides the necessary assurances that the individual continues to have the knowledge and skills necessary to perform the task for which the employee is being tested.

The final rule also modifies the proposed requirement that railroads develop an internal audit process to evaluate the effectiveness of their training. Although FRA agrees that a formal audit process may not be necessary, FRA continues to believe that railroads and contractors should periodically assess the effectiveness of their training programs. However, rather than require a formal internal audit, FRA believes that periodic assessments may be conducted through a number of different means and each railroad or contractor may have a need to conduct the assessment in a different manner. The final rule requires that a railroad or contractor develop a plan to periodically assess its training program and, as suggested by some commenters, permits the use of efficiency tests or periodic review of employee performance as methods for conducting such review. FRA agrees that many railroads, due to their small size, are capable of assessing the quality of the training their employees receive by conducting periodic supervisory spot checks or efficiency tests of their employees' performance.

The final rule also retains the record keeping requirements proposed in the NPRM with slight modification for consistency with the changes noted above regarding the application of the skills and knowledge necessary to perform a particular task. FRA continues to believe that the record keeping and designation requirements contained in this final rule are the cornerstone of the training requirements. Contrary to the views of some commenters, FRA believes that something more than mere lists of qualified employees is needed. Because the rule allows each railroad and contractor the flexibility to develop a training program that best fits its operation and does not impose specific curriculum or experience requirements, FRA continues to believe it is vital for railroads and contractors to maintain detailed records on the training they do provide. Such documentation will allow FRA to judge the effectiveness of the training provided and will provide FRA with the ability to independently assess whether the training provided to a specific individual adequately addresses the skills and knowledge required to perform the tasks that the person is deemed qualified to perform. Moreover, requiring these records will prevent railroads and contractors from circumventing the training requirements and prevent them from attempting to utilize insufficiently trained personnel to perform the inspections and tests required by this rule.

The final rule makes clear that the required records may be maintained either electronically or in writing. Many railroads currently maintain their training records in an electronic format, and FRA sees no reason not to permit such a practice if as the information can be provided to FRA in a timely manner upon request. The proposed provision requiring the railroad's chief mechanical or chief operating officer to sign a statement regarding each employee's qualifications has been modified in the final rule to merely require identification of the person or persons making the determination that the employee has completed the necessary training. This modification will permit the information to be maintained electronically and will still provide the accountability which FRA intended by the provision in the NPRM. FRA believes it is absolutely essential that those individuals making the determinations regarding an employee's qualification be identified in order to ensure the integrity of the training programs developed and prevent potential abuses by a railroad or contractor.

FRA also objects to the portrayal by some commenters that the records required to be maintained are overly burdensome. Virtually all of the items required to be recorded are currently maintained by most railroads in some fashion or another. Contrary to the concerns raised by some commenters, the rule does not require that the contents of each training program be maintained in each employee's file. Railroads are free to develop whatever type of cross-referencing system they desire, provided the contents of the training program are maintained in some fashion and can be readily retrieved. Furthermore, railroads currently maintain lists of individuals they deem to be qualified persons and inform those individuals as to their status to perform particular tasks. FRA believes this is a good practice and is necessary to ensure that individual employees do not attempt to perform, or are not asked to perform, tasks for which they have not been trained.

The final rule contains two provisions that were not specifically included in the NPRM but which were intended by FRA to be covered by the established training programs. The final rule requires that new brake systems be added to training programs prior to their introduction into revenue service. FRA believes this requirement is only logical and makes sense. FRA believes that prior to the introduction of any new brake system the employees responsible for inspecting and maintaining the equipment need to be specifically trained on the systems in order to adequately perform their required tasks. The final rule also requires railroads that operate trains under conditions that require their employees to set retaining valves to develop training programs which specifically address the use of retainers and provide such training to those employees responsible for using or setting retainers. This provision has been added in response to an NTSB recommendation which FRA supports. *See* NTSB Recommendation R–98–7.

FRA has not included provisions requiring FRA approval of the training programs developed by railroads or contractors as suggested by some commenters. FRA does not have the resources to implement such an approval process and does not believe such approval is necessary, given the records that will be required to be maintained. Furthermore, FRA believes that such a process would slow the implementation of training programs and, thus, slow the implementation of this final rule. An approval process would also seriously impede the ability of a railroad or contractor to make necessary and timely changes to its training program, which is necessary to ensure its currency. The final rule also does not contain a dispute-resolution provision regarding such programs. FRA believes that such matters are within the province of employee-employer relationships and are better addressed by established processes. The final rule also does not specifically address the training that must be provided to supervisors. Although some commenters recommended specific requirements, FRA believes that supervisors are sufficiently covered by the final rule requirements. FRA believes that in order for a supervisor to properly exercise oversight of an employee's work, the supervisor must be qualified to perform the tasks for which they have oversight responsibilities.

FRA realizes that many railroads will need time to bring their existing training programs up to the level required by this final rule. FRA also recognizes that the cost of the proposed training requirements is somewhat substantial and may prevent railroads from completing the necessary training in a short period of time. Moreover, FRA recognizes that railroads need time to provide the necessary training to their employees without causing manpower shortages in their operations. Therefore, the final rule allows railroads three years in which to develop and complete the required training. This period is consistent with the time requested by the AAR and other railroad commenters. It is also consistent with the requirement to provide refresher training at least every three years and will allow a railroad to have one-third of its inspection forces receive the necessary refresher training each year after the initial training is complete.

F. Air Source Requirements

In the 1998 NPRM, FRA again proposed a ban on the use of anti-freeze chemicals in train air brake systems, reiterating the position stated in the 1994 NPRM, in order to prevent untimely damage and wear to brake system components. *See* 59 FR 47728. At that time, FRA had not received any adverse comments on this issue in response to the 1994 NPRM, in which a similar requirement was proposed. Furthermore, statements and discussions provided at various RSAC Working Group meetings appeared to establish that both rail labor and rail management representatives believed that such a provision would be acceptable.

Based on information gathered throughout the RSAC process, previous comments by industry parties, and agency experience, FRA firmly believes that the presence of moisture in the train air brake system poses potential safety, operational, and maintenance issues that require attention in this rulemaking. After completion of detailed, instrumented testing on both locomotives and yard test plants performed as part of the task force activities, FRA determined that locomotives rarely contribute to moisture in the trainline. Consequently, FRA did not propose that air dryers be installed on new locomotives, as was proposed in the 1994 NPRM (59 FR 47729). A detailed discussion of the testing conducted by the RSAC Working Group members and recommendations regarding air dryers appears in the preamble of the 1998 NPRM. *See* 63 FR 48317–19.

In contrast, the results of the same testing clearly indicated to FRA that yard air plants often provide unacceptably high levels of moisture while charging the train air brake system due to the age of the system, improper design, inadequate maintenance, or a combination thereof. Working Group task force efforts also estimated that upwards of 80 percent of train air brake systems are charged using yard/ground air plants. However, FRA did not believe that simply requiring yard air sources to be equipped with air dryers would solve or address the problem. In order for air dryers to be effective on yard air sources, the air dryers must be properly placed to sufficiently condition the air source. FRA determined that many yard air sources are configured such that a single air compressor services several branch lines used to charge train air brake systems; therefore, multiple air dryers would be required to eliminate the introduction of moisture into the brake system. Consequently, FRA determined that requiring yard air sources to be equipped with air dryers would impose a significant and unnecessary cost burden on the railroads.

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Based on its determination that air dryers would not provide a cost effective or suitable solution, FRA considered other viable alternatives. In the 1998 NPRM, FRA proposed that each railroad develop and implement a system by which it would monitor all yard air sources to ensure that the air sources operate as intended and do not introduce contaminates into the brake system. FRA believed that the proposed monitoring program provided a method by which the industry might maximize the benefits to be realized through air dryer technology, which all parties acknowledge has been proven to reduce the level of moisture introduced into the trainline, at a cost that was commensurate with the potential benefits. The proposed monitoring program required railroads to take remedial action with respect to any yard air sources that were found not operating as intended, and established a retention requirement for records of the deficient units to facilitate the tracking and resolution of continuing problem areas. FRA also proposed that yard air reservoirs either be equipped with an operative automatic drain system or be manually drained at least once each day that the devices were used or when moisture was detected in the system. FRA believed that these proposed provisions, in concert with assurances that condensation is blown from the pipe or hose from which compressed air is taken prior to connecting the yard air line or motive power to the train, as currently prescribed in § 232.11(d), would significantly minimize the possibility of moisture being introduced into the train air brake system.

In the 1998 NPRM, FRA noted the recent issuance of a final rule mandating the incorporation of two-way end-of-train telemetry devices (two-way EOTs) on a variety of freight trains, specifically those operating at speeds of 30 mph or greater or in heavy grade territories. *See* 62 FR 278. Two-way EOTs provide locomotive engineers with the capability of initiating an emergency brake application that commences at the rear of the train in the event of a blockage or separation in the train's brake pipe that would prevent the pneumatic transmission of the emergency brake application throughout the entire train. FRA noted that the issuance of a final rule mandating the use of these devices was significant particularly in the context of air source requirements and air dryers. In the unlikely event that the proposed requirements regarding air sources fail to sufficiently eliminate moisture from the trainline, and a restriction or obstruction in the form of ice forms as the result of the freezing of this moisture during cold weather operations, the two-way EOT device becomes a first order safety device and will initiate an emergency application of the brakes from the rear of train. Therefore, many of the concerns associated with moisture in the trainline freezing in cold weather operations have been alleviated through the incorporation of this technology in most freight operations, thus reducing the need or desire to specifically require air dryers on air sources.

The AAR and its member railroads submitted various comments related to the proposed air source requirements. Although various railroads had previously indicated support for a requirement banning the use of alcohol in train brake system and stated that their railroad no longer used alcohol in its operation, they now object to the proposed requirement prohibiting the use of the such chemicals. These commenters now assert that there are instances in the industry where alcohol is used to unfreeze frozen trainlines. They contend that railroads should be permitted to continue this practice in order to move trains in certain circumstances and that the need to use alcohol would be rare but necessary. The AAR contends that the use of the term "chemical" is inappropriate, and, unless there is an alternative, the requirement should be deleted. They contend that frozen trainlines are a reality and railroads must be provided some method to deal with such occurrences other than waiting for warm weather which could take months.

These commenters also discussed the proposed requirements related the development and implementation of monitoring plans for yard air sources. The AAR contends that the railroads would need at least five years to comply with the proposed requirements and would incur costs of $41 million. These commenters object to the requirement for remedial action when a yard air source is found to have the "potential" of introducing contaminants into the equipment it services. They contend that such remedial action should be required only if the yard air source actually introduces such contaminants. These commenters also object to the requirement for a detailed assessment of the remedial actions taken as unnecessary and believe that the recordkeeping requirements merely increase a railroad's administrative burden and are merely included as enforcement traps.

Several representatives of rail labor and the NTSB support the proposed prohibition on the use of alcohol and object to any allowance of its use. Some labor representatives suggested that, if FRA were to allow the use of alcohol, then it needed to reinstate the requirements to perform periodic clean, oil, test, and stencilling (COT&S). These commenters recommend that the prohibition be extended to any device providing air to a train's brake system. The BRC again asserts that FRA should require that locomotives and air sources be equipped with air dryers, contending that they are the only way to ensure that moisture is not introduced into a train's brake system. Labor representatives also object to the proposed yard air monitoring plan requirements, contending that the proposed requirements fail to specify the frequency with which yard air sources are to be inspected. They recommend that such inspections should be more frequent at locations in cold climates. They also suggest that the monitoring plans should be subject to FRA approval prior to implementation.

FRA Conclusions. The final rule retains the basic requirements regarding yard air sources and cold weather operations that were proposed in the 1998 NPRM. The final rule generally retains the proposed requirement prohibiting the use of chemicals in a train air brake system. However, FRA agrees that the proposed prohibition of all chemicals may have been somewhat overbroad and contrary to FRA's actual intent. In proposing the prohibition, FRA intended to eliminate the use of chemicals, such as alcohol, which are known to degrade the rubber of a train's brake system. FRA agrees that there are chemicals that are currently available or that are in the process of being developed that do not cause the problems associated with the use of alcohol. In fact, FRA believes there are products currently available that do not degrade a brake system's rubber components like alcohol does. FRA believes that several railroads are currently testing or using these chemical alternatives. Consequently, the final rule slightly modifies the prohibition on the use of chemicals by imposing the prohibition on chemicals that are known to degrade or harm brake system components, such as alcohol.

The final rule also modifies some of the requirements related to the proposed yard air source monitoring plans. FRA agrees that the proposed requirements did not establish a frequency with which inspections of yard air sources should be conducted. In proposing the requirement, FRA hoped that various commenters would recommend frequencies for conducting these inspections. This did not occur. FRA agrees that a set frequency needs to be established that will ensure that yard air sources are inspected in a timely manner during various climatic conditions. Therefore, the final rule requires the that yard air sources be inspected at least twice each calendar year and that two of the inspections be no less than five months apart. FRA intends for this requirement to result in yard air sources being inspected each year during two different seasonal periods.

The final rule also clarifies that remedial action under the monitoring plans is required only on those yard air sources that are not operating as intended or that are found introducing contaminants into brake systems. Thus, the final rule removes the word "potential" as FRA agrees that the proposed language was unclear and may have been over-inclusive. The final rule also eliminates the requirement for railroads to conduct a detailed assessment of the remedial actions taken. FRA agrees that this requirement is unnecessary because railroads will be conducting regular inspections of the yard air sources on which they have conducted repairs or taken other remedial action and will be able to determine if the repairs were effective through those inspections. The final rule retains the other proposed record keeping requirements related to yard air monitoring plans but clarifies that the records may be maintained either electronically or in writing. FRA continues to believe that these records are necessary to ensure that railroads are properly conducting the required inspections and are taking timely and appropriate remedial action when a problem air source is detected.

The final rule does not contain provisions requiring FRA approval of the yard air source monitoring plans prior to their implementation as suggested by some commenters. FRA does not have the manpower or resources to review and approve the plan of each railroad and does not believe such approval is necessary given the specific requirements contained in the final rule and the records that are required to be maintained. The final rule also does not contain requirements regarding the use of air dryers on either locomotives or yard air sources. For the reasons noted in the discussion above and in the NPRM, FRA believes that requiring the use of air dryers on either locomotives or yard air sources would impose a significant cost burden on railroads and would not necessarily address the problem sought to be resolved. *See* 63 FR 48317–19. It should be noted that FRA advocates the use of air dryers when possible and agrees that they have proven effective in reducing the level of moisture introduced into the brake system; however, FRA believes that the railroad is in the best position to determine where these devices will provide the greatest benefit based on the railroad's operation.

FRA is somewhat skeptical of the AAR's contentions regarding both the time and the cost necessary to implement the required yard air source monitoring plans. FRA sees no reason why a railroad would need five years to implement a plan to inspect each of its yard air sources twice a year. These devices are used on a fairly regular, if not daily, basis and should not be that difficult to inspect. Therefore, FRA believes that railroads should easily be able to implement these monitoring plans within the three years allowed under the applicable date provided in this final rule.

G. Maintenance Requirements

Based on comments received in response to the 1994 NPRM, deliberations of the RSAC Working Group and task force, and field experience, FRA proposed a comprehensive set of maintenance requirements which were intended to be a codification of current best practices occurring within the industry. The preamble to the 1998 NPRM contains a detailed discussion of the issues raised, discussed, and considered prior to the issuance of the NPRM. *See* 63 FR 48320–22.

After consideration of all the information and comments submitted prior to the issuance of the 1998 NPRM, FRA remained confident that the "new" repair track test and single car test, which have been used industry-wide since January of 1992, are a much better and more comprehensive method of detecting and eliminating defective brake equipment and components than the old, time-based COT&S requirements. FRA continued to believe that performance of the repair track and single car test significantly reduces the number of defective components and dramatically increases the reliability of brake equipment. Accordingly, FRA proposed the incorporation of AAR Interchange Rule 3 and Chart A into the 1998 NPRM, thus codifying the repair track air test requirements per Chart A, such that a railroad would be required to perform a repair track brake test on freight cars in any of the following six circumstances: (i) When a freight car is removed from a train due to an air brake related defect; (ii) when a freight car has its brakes cut out when removed from a train or when placed on a shop or repair track; (iii) when a freight car is on a repair or shop track for any reason and has not received a repair track brake test within the previous 12 month period; (iv) when a freight car is found with missing or incomplete repair track brake test information; (v) when the brake reservoir(s), the control valve mounting gasket, and the pipe bracket stud are removed, repaired, or replaced; or (vi) when a freight car is found with a wheel with a built-up tread, a slid flat, or a thermal crack. FRA also proposed that each freight car receive a repair track air test no less frequently than every 5 years, and not less than 8 years from the date the car was built or rebuilt. Similarly, it was proposed that the single car test requirements of Chart A be codified, such that a railroad would perform a single car test on a freight car when the service portion, the emergency portion, or the pipe bracket or a combination of such components is removed, repaired, or replaced.

In the 1998 NPRM, FRA recognized that circumstances arise where the proposed repair track brake tests or single car tests could not always be performed at the point where repairs can be made that necessitate performance of the test. To address these circumstances, FRA proposed that a car would be allowed to be moved to the next forward location where the test could be performed after the necessary repairs were conducted. FRA attempted to make clear that the inability to perform a repair track brake test or a single car test did not constitute an inability to effectuate the necessary repairs. At the same time, however, FRA recognized rail labor's contention that some carriers often attempt to circumvent the requirements for single car and repair track testing through the elimination of repair tracks, by moving cars to "expediter" tracks for repair, or simply by making the repairs in the field. As a means to curtail these practices, FRA decided to impose extensive tagging requirements on freight cars that, due to the nature of the defective condition(s) detected, require a repair track brake test or single car test but that are moved from the location where repairs are performed prior to receiving the required test. As an alternative to the tagging requirements, FRA proposed that railroads be permitted to utilize an automated tracking system to monitor these cars and ensure they receive the requisite tests provided the automated system has been approved by FRA. FRA also proposed to require stencilling of cars with the location and date of the last

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repair track or single car test. Alternatively, FRA proposed that railroads could utilize an electronic record keeping system to accomplish this stencilling requirement, provided the system has been approved by FRA. FRA believed that the proposed tagging and stencilling requirements were necessary to ensure the timely performance of the tests. Without such information, there would be virtually no way for FRA to verify a railroad's compliance with the proposed repair track and single car test requirements.

FRA also proposed various requirements related to the testing of the devices used to perform the single car tests. Similar to the 1994 NPRM, the 1998 NPRM again proposed that single car testing devices be tested at least once a day and receive routine maintenance at least every 92 days. FRA also proposed that the mechanical and electronic test devices be regularly calibrated.

In the 1998 NPRM, FRA determined that any changes to the AAR standards incorporated into regulation should be reviewed and approved by all affected parties, including FRA and rail labor. Consequently, FRA proposed a special approval process, whereby the AAR would be required to submit any proposed changes to the FRA. FRA would review the proposed change to determine whether the change is "safety-critical." Such proposed changes include, but are not limited to the following: (i) Any changes to Chart A, (ii) changes to established maintenance intervals, and (iii) changes to UMLER reporting requirements. If the proposed change was deemed by FRA to be "non safety-critical," FRA would permit the change to be implemented immediately. If the proposed change was deemed "safety-critical," FRA would be required to publish a **Federal Register** notice, conduct a public hearing if necessary, and act based on the information developed and submitted in regard to these proceedings.

FRA proposed the special approval process in response to comments from several railroads and manufacturers that FRA needed to devise some sort of quick approval process in order to permit the industry to make modifications to existing standards or equipment based on the development of new technology. Thus, FRA attempted to propose an approval process it believed would speed the process for taking advantage of new technologies over that which is currently available under the waiver process. However, in order to provide an opportunity for all interested parties to provide input for use by FRA in its decision-making process as required by the Administrative Procedure Act, FRA determined that any special approval provision must, at a minimum, provide proper notice to the public of any significant change or action being considered by the agency with regard to existing regulations.

The AAR, its members, and various private car owners and brake manufacturers submitted numerous comments regarding the maintenance requirements proposed in the NPRM. The commenters object to the proposed incorporation of AAR's Rule 3, Chart A, and the incorporation of specific AAR standards for performing single car and repair track air brake tests. They contend that such incorporation would inhibit the ability of the industry to develop and implement new rules and procedures that would improve safety and hinder the ability of the industry to implement changes that improve brake performance. They contend that the current reference to AAR rules is sufficient and that oversight by FRA is not necessary. The AAR notes that there have been over 25 changes to the AAR maintenance requirements and test procedures over the last ten years and that many of these may not have been accomplished under the provisions proposed in the NPRM. The AAR also notes that the single car and repair track standards cited in the NPRM were changed in July of 1998 and were being revised again in 1999. These commenters recommend that any provisions requiring FRA approval of AAR standards should be eliminated. Alternatively, they recommend that AAR be permitted to implement changes subject to FRA revocation based on a finding that the change does not promote safety.

In addition to their general objections to any incorporation of AAR maintenance standards, these commenters provide several recommendations in the event that FRA should decide to retain the proposed requirements. They recommend that FRA eliminate the requirement to stencil equipment with the date of the last single car or repair track air brake test and allow the industry to use the UMLER tracking system to record and monitor such information. They believe that the industry should be permitted to implement an automated or electronic tracking system without prior FRA approval. They contend that the industry has been using the UMLER system to track this information for years and it has proven effective. They contend that the automated system currently used is no less secure or capable of manipulation than a manual stenciling requirement. They contend that there has been no evidence of falsification on the part of railroads using the UMLER system and that it should be permitted without FRA approval.

Several railroad representatives also object to the proposed requirement for performing a repair track air brake test whenever a car is removed from a train for a brake-related defect. They contend that the way the provision is proposed it would require repair track air brake tests whenever minor brake defects occur that have no relation to the actual operation of the brakes. They recommend that the requirement be tied to cars removed from trains for inoperative brakes as this is the intent of AAR's Rule 3, Chart A. These commenters also object to the proposed requirement to perform a set and release of the brakes and to check piston travel when a car is on a shop or repair track. They contend that AAR no longer requires this to be performed and assert that the brake tests required in the proposal are sufficient to determine piston travel and proper operation of the brakes. These commenters also contend that there is no need to retain the bad order tags required for moving equipment for testing because a record of the repair is maintained for a year pursuant to AAR rules. They also recommend that FRA should not require brake repairs at locations where single car or repair track tests cannot be performed. They contend that the test is necessary to determine the sufficiency of the repair. They believe that the inability to conduct these test should be considered an inability to conduct brake repairs.

The AAR and certain manufacturers of brake equipment also raise concerns over the proposed requirements related to the testing and calibration of devices used to perform single car and repair track air tests. These commenters generally object to the inclusion of these requirements in the proposal as they have always been part of AAR standard S–486 and feel they do not belong in federal regulations. These parties also contend that the proposed requirements regarding the testing and calibration of single car test devices are more restrictive than are currently required. The current existing industry requirements for testing single car test devices are based on the date on which the device is placed in service. Thus, the time for conducting the 92-day test does not begin to run until the device is placed in service. They contend that the "in service" date allows railroads flexibility in having spare devices when a primary device is being serviced as such a device is generally sent to a special location for calibration and cleaning. At a minimum, they recommend that the rule permit testing and calibration of single car test devices based on the in-service date of the device rather than a strict 92-day requirement.

Representatives of rail labor support the incorporation of AAR standards and contend that AAR should not be allowed unilateral discretion to change the incorporated standards. These commenters assert that railroads do not currently follow existing AAR standards and will not do so unless they are made part of a federal regulation. These commenters recommend that FRA develop specific, detailed maintenance requirements rather than reference AAR standards. They further contend that all maintenance should be required to be performed by a carman or at least by a QMI as defined in the NPRM. These commenters object to any type of automated tracking system as it is susceptible to abuse and manipulation by railroads.

Certain labor representatives provided specific comments on the proposed requirements related to conducting single car and repair track air brake tests. They recommend that FRA identify locations where single car and repair track air brake tests can be performed to prevent manipulation and circumvention of the requirements by railroads. These commenters contend that only a carman or a QMI should be permitted to perform a single car or repair track air brake test. They also contend that, since periodic COT&S has been eliminated, the need to conduct frequent repair track and single car tests is much greater in order to ensure the proper operation of the brake equipment. They assert that the intervals for conducting these tests need to be increased over those proposed and recommend that each car receive a repair track air brake every year and a single car test every four years.

FRA Conclusions. Although the final rule retains many of the proposed maintenance requirements, several modifications have been made in this final rule in response to comments received and based upon the current best practices occurring within the industry. FRA agrees that the proposed incorporation of AAR Rule 3, Chart A, is unnecessary as it would remove the determination of when certain maintenance is performed from the discretion of the railroads, and would make it difficult for railroads to change the requirements related to the performance of that maintenance. FRA believes that a railroad is in the best position to determine when and where it will perform various maintenance on its equipment and should not have its hands tied in this area by overly prescriptive federal requirements. Furthermore, FRA's primary intent when proposing incorporation of AAR Rule 3, Chart A, was to codify the existing requirements for performing single car and repair track air brake tests and eliminate the right of the industry to unilaterally change the frequency and method of performing these tests. As the final rule retains the requirements for when and how these tests are to be completed and retains certain inspections that are to be performed when equipment is on a shop or repair track, FRA believes that it is unnecessary to incorporate every maintenance procedure covered in AAR's Rule 3, Chart A. Consequently, the final rule does not incorporate AAR's Rule 3, Chart A, and continues to allow railroads some flexibility in determining appropriate maintenance practices.

Contrary to the assertions of some commenters, FRA continues to believe that certain maintenance procedures are critical to ensuring the safe and proper operation of the brake equipment on the nation's fleet of freight cars. FRA does not believe that the determination of what maintenance should be performed should be left solely to the discretion of the railroads operating the equipment in all circumstances. As periodic COT&S maintenance has been eliminated and replaced with the performance of single car and repair track tests, which FRA agrees is a better and more comprehensive method of detecting defective brake equipment and components, FRA believes that specific and determinable limits must be placed on the manner and frequency in which these tests are performed. Therefore, the final rule retains the proposed requirements regarding the performance of single car and repair track tests.

FRA recognizes that the procedures for performing single car and repair track tests proposed in the NPRM have been modified by the AAR since the issuance of the proposal. As it is FRA's intent to incorporate the most recent version of the single car and repair track air brake test procedures, the final rule incorporates the test procedures that were issued by the AAR in April of 1999. FRA recognizes that the industry may find it necessary to modify the test procedures from time to time in order to address new equipment or utilize new technology. Thus, the final rule permits railroads to seek approval of alternative procedures through the special approval process contained in the final rule. The special approval process is intended to speed FRA's consideration of a party's request to utilize an alternative procedure from the one identified in the rule itself. FRA believes that it is essential for FRA to approve any change made in the procedures for conducting these safety-critical tests in order to prevent unilateral changes and to ensure consistency in the method in which the tests are performed.

It should be noted that the incorporated procedures for performing single car and repair track air brake tests are the minimum requirements for performing such tests. The special approval process is required to be used only if the incorporated procedures are to be changed in some manner. For instance, if the industry were to elect to add a new test protocol to the incorporated procedures, there would be no need to seek approval of such an addition as long as the procedures contained in the incorporated standard are still maintained. This final rule is not intended to prevent railroads from voluntarily adopting additional or more stringent maintenance standards provided they are consistent with the standards incorporated.

The final rule also modifies one of the proposed conditions for when a repair track air brake test would be required to be performed. FRA agrees that the proposed requirement to perform a repair track air brake test on any car removed from a train for a brake-related defect is overly restrictive and inconsistent with the requirements of AAR's Rule 3, Chart A. FRA agrees that the proposed requirement would require the performance of the test when minor brake system repairs are conducted, which is not the intent of the AAR's rule. Therefore, the final rule modifies the proposed condition to require the performance of a repair track test on cars that have inoperative or cut-out air brakes when removed from a train.

The final rule also modifies the proposed requirements regarding the use of an automated tracking system in lieu of stenciling equipment with the date and location of the last single car or repair track test received. Since 1992, the industry has utilized the AAR's UMLER reporting system to electronically track the performance of single car and repair track air brake test as well as other repair information. Based on the performance and use of this system over the last seven years, FRA believes that the AAR's UMLER system has proven itself effective for tracking the information required in this final rule and ensuring the timely performance of single car and repair

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track air brake tests. Furthermore, FRA continues to believe that the information required to be tracked with regard to these tests is easily maintained through an electronic medium. Moreover, FRA has found no substantiated instances of railroads falsifying or altering the information monitored and tracked by AAR's UMLER system. Thus, the final rule permits railroad to utilize an electronic record keeping system to track single car and repair track air brake tests without obtaining prior FRA approval of the system. The final rule makes clear that FRA will monitor the performance of such systems and retains the right to revoke a railroad's authority to utilize the system if FRA finds that it is not properly secure, inaccessible to FRA or a railroad's employees, or fails to properly or adequately track and monitor the equipment.

The final rule does not increase the proposed frequency at which the single car or repair track air brake tests are to be performed as recommended by some commenters. As noted above, the primary intent of the proposed provisions was to codify the existing requirements regarding the performance of single car and repair track air brake tests and prevent any unilateral changes to those requirements. FRA believes that the frequency at which these tests are currently required to be performed under industry standards has proven to be sufficient and a substantial economic burden would be imposed if the frequency were increased. The final rule also retains the requirement that these tests be conducted by a qualified person. FRA believes that the person performing these tests must be specifically trained and tested on how the test is to be performed and be able to determine the appropriate actions that must be taken based on the results of the test. FRA does not believe that the mere fact that a person is a carman or a QMI is sufficient to consider that person qualified to perform single car or repair track air brake tests. FRA believes that the training requirements contained in this final rule ensure that a person deemed qualified to perform these tests has been specifically trained and tested on the performance of the tests prior to being considered qualified.

The final rule also retains the proposed provisions permitting cars to be moved from a location where necessary repairs are made to a location where a single car or repair track air brake test can be performed if it cannot be performed at the same location where the repairs are conducted. FRA disagrees with the assertion that air brake repairs should not be required at locations that lack the ability to perform single car or repair track air brake tests. FRA believes that position is not only contrary to the statutory mandates regarding the movement of equipment with defective brakes but would open the door to potential abuse by railroads. Furthermore, the operation of a car's brake system can generally be tested after a repair without performing a complete repair track air brake test. For the most part, single car and repair track air brake tests are intended to be maintenance requirements that attach based on a condition in which a car is found or on a repair that is required to be performed. If the condition of a car is such that a repair track air brake test is necessary to determine the defect, then the final rule would permit movement of the car to the nearest location where a repair track air brake test can be performed. However, FRA believes that most defective conditions can be easily determined without performing a repair track air brake test. Moreover, for years FRA has required the performance of repairs where they can be performed and has allowed such equipment to be moved to the next forward location for performance of a single car or repair track air brake test and has not found that such a practice has created any potential safety hazard.

The final rule retains the proposed requirements for tagging equipment which is being hauled for the performance of a single car or repair track air brake test after the appropriate repairs have been conducted. FRA believes that the tags are necessary not only to provide notice to a railroad's ground forces as to the presence of the car but to ensure that railroads are properly performing the tests at appropriate locations. Furthermore, many railroads currently move equipment in this fashion, and there has been no indication that safety has been compromised. The final rule also retains the requirement that a copy or record of the tag be retained for 90 days and made available to FRA upon request. Contrary to the objections of some commenters, FRA continues to believe that the record keeping requirements are necessary so that there is accountability on the part of the railroads to conduct these tests at the proper locations and that equipment is not moved for extended periods without receiving its required maintenance. It should be noted that the final rule clarifies that the record or copy of the tag may be maintained either electronically or in writing provided all the required information is recorded. The final rule does not define or require identification of locations that can or will perform single car or repair track air brake tests as suggested by some commenters. FRA does not believe that such a requirement is necessary as the rule specifically establishes when the tests are to be performed and it is in the railroad's best interests to perform the tests in a timely manner.

The final rule retains the proposed provisions requiring certain tests and inspections to be performed whenever a car is on a shop or repair track. Although the AAR asserts that it did away with the requirements to perform a set and release of the brakes and adjust piston travel on all cars on repair or shop tracks, the requirements are currently contained in power brake regulations separate and apart from any AAR requirements. *See* 49 CFR 232.17(a)(2)(ii), (iv). FRA believes that repair and shop tracks provide an ideal setting for railroads to conduct an individualized inspection on a car's brake system to ensure its proper operation and that such an inspection is necessary to reduce the potential of cars with excessive piston travel being overlooked when employees are performing the ordinary brake inspections required by this final rule. If any problems are detected at that location, the personnel needed to make any necessary corrections are already present. Furthermore, performing these inspections at this time ensures proper operation of the cars' brakes and eliminates the potential of having to cut cars out of an assembled train and, thus, should reduce inspection times and make for more efficient operations.

The final rule adds two items to the inspections that are to be conducted when a car is on a shop or repair track. They are an inspection of a car's hand brake and an inspection of the accuracy and operation of any brake indicators on cars so equipped. The final rule does not provide for the specific inspection of these items during any of the other required brake tests. Consequently, FRA believes this is an ideal time for the railroad to inspect these items while imposing the least burden on the railroad's inspection and repair forces.

As the final rule requires that certain inspections and tests be performed when a car is on a shop or repair track and because a repair track air brake test is required to be performed when a car is on a repair track and such a test has not been performed within the last twelve months, FRA believes it is necessary to clarify what constitutes a shop or repair track. This issue has become more prevalent over the last few years due to the growing use of mobile repair trucks and due to the requirements for conducting repair track air brake tests. For years, many railroads have conducted minor repairs on tracks called "expedite tracks." Generally, the types of repairs that were performed on these tracks were minor repairs that could be made quickly with a limited amount of equipment, and neither the railroads or FRA considered the tracks to be repair tracks. However, recently railroads have started performing virtually every type of repair on these expedite tracks. These tracks are no longer limited to minor repairs but are being used to perform heavy, complex repairs that require the jacking of entire cars or the disassembly and replacement of major portions of a car's truck or brake system. At many locations these expedite tracks are positioned next to operative repair shops. Furthermore, several railroads have closed previously existing repair shop facilities and are now using fully equipped mobile repair trucks to perform the same type of repairs that were previously performed in the shop or on established repair tracks and are attempting to call the tracks serviced by these mobile repair trucks "expedite tracks." Thus, the line between what constitutes a repair or shop track and what constitutes an "expedite track" has become unclear, if not, nonexistent.

FRA believes that the operational changes, noted above, are partly an attempt by the railroads to circumvent the requirements that currently apply when a car is on a shop or repair track. Currently, if a car is on a shop or repair track, it must have its brakes inspected, under 49 CFR 232.17(a)(2)(ii), (iv), and the car is to receive a repair track air brake test if it has not received one in the last twelve months under AAR Rule 3, Chart A. Some railroads contend that an expedite track is not a repair or shop track; therefore, the requirements of § 232.17(a)(2)(ii), (iv) do not apply. FRA finds this interpretation to be unacceptable and believes that railroads are abusing the concept of expedite tracks to avoid performing required maintenance. Therefore, the industry's own actions have caused the need for FRA to clarify what constitutes a shop or repair track. Consequently, the final rule includes a definition of what FRA will consider to be repair or shop tracks requiring the performance of certain tests and inspections.

The final rule makes clear that FRA will consider certain tracks to be repair or shop tracks based on the types of repairs that are made on the tracks, not necessarily the designation given by a railroad. The definition in the final rule also makes clear that it is the nature of the repairs being conducted on a certain track that is the determining factor not whether a mobile repair truck is being used to make the repairs. Due to the ability of mobile repair trucks to make virtually any type of repair necessary and due to their growing use, FRA does not believe that tracks regularly and continually serviced by these types of vehicles should be excepted from the definition of a repair track. FRA believes that if a track is designated by the railroad as an "expedite" track (*i.e.*, one where minor repairs will be conducted) then the railroad should ensure that only cars needing minor repairs be directed to that track for repair. The final rule does not eliminate the concept of expedite tracks but limits the use of such tracks to those types of repairs that are truly minor in nature and that require a limited amount of equipment to perform. At locations where a railroad conducts repairs of all types, either with fixed facilities or with mobile repair trucks, FRA would expect the railroad to designate certain trackage at the location as repair tracks and certain trackage as "expedite tracks" where only minor repairs would be conducted. In such circumstances, FRA would expect railroads to direct cars in need of heavier repairs, the kind that have been traditionally performed on a shop or repair track, to be directed to trackage designated at the location as a repair track.

The final rule places the burden on the railroad to designate those tracks it will consider repair tracks at locations where it performs both minor and heavy repairs, and makes the railroad responsible for directing the equipment in need of repair to the appropriate trackage. If the railroad determines that repairs of a heavy nature will be performed on certain trackage, then the track should be treated as a repair track, and any car repaired on that trackage should be provided the attention required by this final rule for cars on a shop or repair track. Further, if a railroad determines that minor repairs will be performed on certain trackage, then the railroad bears the burden of ensuring that only cars needing minor repairs are directed to that trackage. If the railroad fails to adequately distinguish the tracks performing minor repairs from those tracks performing heavy repairs or improperly performs heavy repairs on a track designated as an "expedite track," then the railroad will be required to treat all cars on the trackage at the time that the heavy repairs are being conducted as though they are on a repair or shop track.

It should be noted that the issue of what constitutes a repair or shop track for the purposes of 49 CFR 232.17(a)(2)(ii) and (iv) is completely separate and distinct from the issue of whether a location is a location where necessary repairs can be performed for purposes of 49 U.S.C. 20303. Although an outlying location might be considered a location where certain brake repairs can be conducted, that does not mean the track where those repairs are performed should be considered a repair track. FRA does not intend for trackage located at outlying locations or sidings which are occasionally or even regularly serviced by mobile repair trucks to be considered repair tracks. FRA believes that repair or shop tracks should exist at locations that have fixed repair facilities and at locations where repairs of all types are performed on a regular and consistent basis regardless of whether the repairs are performed in fixed facilities or by mobile repair vehicles.

The final rule also modifies some of the proposed provisions regarding the testing and calibration of single car test devices and other mechanical devices used to perform single car and repair track air brake tests. FRA's intent when proposing the requirements was to codify the current best practices of the industry. Thus, FRA did not intend to propose testing and calibration requirements that were more stringent that those currently imposed by AAR standards. Therefore, FRA agrees that the testing and calibration requirements for single car test devices should not be imposed until the devices are actually placed in service, which is consistent with current AAR requirements. FRA recognizes that the proposed calibration and testing requirements may have resulted the unnecessary acquisition of single car testing devices. Consequently, the final rule makes clear that the 92-day and the 365-day requirements related to single car test devices are to be calculated from the day on which the device is first placed in service.

III. Section-by-Section Analysis

Amendments to 49 CFR Part 229

The amendments to part 229 contained in this final rule concern the testing of electronic gauges commonly used in electronically controlled locomotive brake systems. Currently, there are two electronically controlled locomotive brake systems in use on the nation's railroads, the Electro-Pneumatic Integrated Control (EPIC) system supplied by Westinghouse Air Brake Company and the Computer Controlled Brake (CCB) system developed by New York Air Brake Company. At this time, there are thousands of locomotives in service that

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are equipped with either the CCB system or the EPIC system.

The final rule retains the proposed requirements extending the testing cycles for the electronic gauges used in these types of locomotive brake systems. The final rule retains the proposed increase of the testing interval for these electronic gauges from 92 days to one year. Although certain labor representatives objected to the proposed increase in the testing interval, contending that the interval should be reduced due to problems encountered by numerous locomotive engineers, FRA continues to believe that technology incorporated into the electronic gauges used in these locomotive brake systems has significantly increased their reliability over standard mechanical gauges. Furthermore, the objections raised were not based on the proper operation or performance of the electronic gauges.

The lengthening of the testing interval for these gauges is based on recommendations made by a committee formed to address issues related to the operation of electronically controlled locomotive brake systems as well as the training of those individuals using this new technology. In May of 1996, the RSAC Working Group decided to form a task force to consider issues related to electronically controlled locomotive brake systems. Rather than create an entirely new task force, the Working Group assigned the task to a group of individuals who were members of the previously established "New Technology Joint Information Committee." This task force, comprised of representatives from the railroad industry, rail labor, air brake manufacturers, and locomotive manufacturers, addressed several issues related to these braking systems including: design; training; inspection and testing; and maintenance. The task force concluded that additional regulation of these types of locomotive braking systems was unnecessary since the current regulations or waivers sufficiently address the training, inspection, and maintenance of these systems and any additional design requirement would most likely not enhance safety and would probably restrict the advancement of new technology. The task force recommended that part 229 be revised to increase the testing interval for these electronic gauges from 92 days to an annual cycle. The task force based this recommendation on its finding that the electronic gauges used in these brake system are much more reliable than standard mechanical gauges due to the following: the electronic components have longer life cycles than those in mechanical gauges; the accuracy and durability of the transducer have been extended; and internal computer diagnostics detect inaccuracies before gauges becoming defective under federal regulations. FRA continues to agree with these findings and has retained the proposed extension in this final rule.

The final rule does not include the proposed requirement that locomotive compressors be tested for capacity by orifice test during the annual test required by § 229.27. FRA agrees that the requirement for orifice testing of locomotive air compressors was eliminated from part 229 in 1980. See 45 FR 21097. At that time, FRA found that such a test was not useful in detecting a bad compressor and, thus, found no reason to retain the requirement. Although the requirement to perform orifice testing remained in § 232.10(c), FRA's elimination of the requirement from part 229 rendered the provision in part 232 meaningless. As no railroad has performed orifice testing since 1980 and because FRA is not aware of any safety hazard being created due to the elimination of such testing, FRA agrees that there is no justification for reinstating the requirement to perform such testing.

Amendments to 49 CFR Part 231

The final rule retains the proposed clarifying changes in the applicability section of this part. FRA received no comments objecting to the proposed modifications. The changes are intended to make the regulatory exceptions consistent with the exceptions contained in the statute. The added exceptions are taken directly from 49 U.S.C. 20301 (previously codified at 45 U.S.C. 6). It is noted that the words "freight and other non-passenger" have been added to the exceptions in order to remain consistent with Congress' intent when the statutory exceptions were created. At the time that Congress provided an exception from the requirements of the Safety Appliance Acts, Congress did not and could not envision that the equipment used in these operations would be modified for the purposes of hauling passengers, which FRA has discovered with regard to four-wheel coal cars. Consequently, the final rule makes clear that FRA will except only freight operations or other non-passenger operations that employ the types of equipment contained in these amendments.

The final rule also retains the proposed movement of the provisions related to drawbars from part 232, where they are currently contained, to this part. FRA believes that part 231 is a more logical place for the drawbar provisions to be located as they are not a brake system component but a generic safety appliance. Although the final rule adopts the drawbar provisions as proposed, the changes made to the language of those provisions when proposed in the NPRM were for clarity and readability and were not intended to change any of the basic drawbar requirements contained in part 232.

49 CFR Part 232

Subpart A—General

Section 232.1 Purpose and Scope

Paragraph (a) contains a formal statement of the final rule's purpose and scope. FRA intends the final rule to cover all brake systems and brake components used in all freight train operations and all other non-passenger train operations.

Paragraph (b) contains the dates upon which railroads covered by this part will be required to comply with the requirements contained in this final rule. FRA recognizes the interrelationship between the proper training of railroad personnel and implementation of many of the inspection, testing, and maintenance requirements contained in the final rule. FRA realizes that in order for railroads to comply with many of the requirements related to the inspection, testing, and maintenance of equipment and the requirements regarding the movement of defective equipment, the railroad and its contractors must first be provided sufficient time to assess its current training program and develop and implement a training program consistent with the requirements of this part. The railroad or contractor then needs time to provide the necessary training to its employees without causing manpower shortages in its operations. FRA also recognizes that the costs of the training requirements are somewhat substantial and may prevent a railroad or contractor from completing the necessary training in a short period of time. Therefore, this final rule provides railroads and contractors with three years to develop and implement the required training. This period is consistent with the time requested by the AAR and other railroads. It is also consistent with the requirement to provide refresher training at least every three years and will allow a railroad or contractor to have one-third of its inspection forces receive the necessary refresher training each year after the initial training period is complete. Consequently, FRA will require compliance with all the requirements contained in § 232.15, subpart B, subpart C, and subpart F of this final rule at the conclusion of the three-year period provided for conducting the required training.

This paragraph makes clear that the maintenance requirements contained in subpart D will become applicable to all railroads to which this part applies approximately six months after the issuance of this final rule. Virtually all of the requirements contained in this subpart are existing regulatory requirements or prevailing industry practice, and FRA sees no reason to significantly delay their implementation. FRA notes that this subpart requires certain tasks to be performed by a "qualified person'; however, FRA will not subject railroads to the qualification and training requirements contained in this final rule for individuals performing these tasks until the conclusion of the three-year period provided for conducting the required training.

This paragraph also clarifies that the general provisions contained in subpart A of this final rule regarding applicability, definitions, waivers, responsibility for compliance, penalties, preemptive effect, special approval procedures, availability of records, and information collection will become applicable approximately sixty days after the issuance of this final rule. Due to the enforcement implications connected with these provisions, it is both necessary and desirable to have the provisions become applicable as quickly as possible.

This paragraph also makes clear that the requirements related to end-of-train devices contained in subpart E become applicable to all trains operating on track which is part of the general system of transportation approximately sixty days after issuance of the final rule. As the requirements related to these devices have existed for a number of years and because this final rule modifies those requirement to a very limited extent, FRA believes that railroads should have no problem complying with the requirements in this subpart in the period of time provided. Furthermore, the requirements contained in this subpart apply to both freight and passenger trains that operate on the general system of transportation and are not contingent on the performance of additional training.

FRA also recognizes that there are certain aspects of this final rule that provide operational flexibility to the railroads. Due to this flexibility, FRA believes that some railroads will desire the authority to comply with the final rule as soon as their employees have been properly trained. Therefore, paragraph (c) contains a provision which allows a railroad to notify FRA in writing that it is willing to begin compliance with the requirements of the final rule sometime earlier than the three years provided. However, FRA wishes to make clear that it does not intend for railroads to take advantage of the flexibility provided under some of the provisions of the final rule unless the railroad is willing to comply with all the requirements contained in the final rule.

Paragraph (d) of this section clarifies that any railroad that operates on the general railroad system of transportation that is not operating pursuant to the requirements contained in this final rule or the requirements contained in the Passenger Equipment Safety Standards at 49 CFR part 238, shall continue to comply with the requirements contained in part 232 as it existed prior to the issuance of this final rule, which have been moved to Appendix B of the new part 232. Thus, a railroad will continue to be subject to the existing inspection, testing, and maintenance provisions contained in part 232 until the railroad is required to operate under the provisions of this final rule (*i.e.* three years for most requirements) or until the railroad voluntarily commits to operate under the provisions of this final rule, whichever comes first. FRA also intends for operations and trains which currently operate under the existing part 232 to continue to operate pursuant to those provisions if the operation is not addressed by either this final rule or part 238. It should be noted that FRA does not intend to extend the coverage of part 232 beyond the types of operations that are currently subject to the requirements of part 232. Thus, FRA has explicitly excluded railroads that operate only on track inside an installation that is not part of the general railroad system of transportation, rapid transit operations that are not connected with the general system, and operations specifically excluded by statute.

Section 232.3 Applicability

As a general matter, paragraph (a) of this section establishes that this final rule applies to all railroads that operate freight or other non-passenger train service on standard gage track which is part of the general railroad system of transportation. In paragraph (b) of this section, FRA makes clear that subpart E of this final rule applies to all trains that operate on the general system regardless of whether the train is a freight or passenger train, unless it is specifically excepted by the provisions contained in subpart E. Subpart E contains the requirements regarding the use of two-way end-of-train devices which were issued on January 2, 1997 and became effective on July 1, 1997. Although the final rule contains some minor changes to these requirements, principally for clarification, the provisions contained in Subpart E are very similar to the existing requirements.

Paragraph (c) of this section contains a listing of those operations and equipment to which FRA does not intend this final rule to apply. These include: rapid transit operations not connected to the general system; commuter, intercity, and other short-haul passenger operations; and tourist, scenic, historic, or excursion operations. In 1994, FRA issued a power brake NPRM in which FRA attempted to draft a proposal covering all railroad operations. FRA received a multitude of comments suggesting that similar treatment of passenger and freight operations was not a viable approach due to the significant differences in the operating environment and equipment used in these operations. Based on these comments, FRA decided to separate passenger and freight operations and FRA recently addressed the power brake issues related to passenger and commuter operations in a separate final rule specifically tailored to those types of operations. *See* 64 FR 25540. Similarly, the Federal Railroad Safety Authorization Act of 1994 directs FRA to examine the unique circumstances of tourist and historic railroads when establishing safety regulations. The Act, which amended 49 U.S.C. 20103, states that:

> In prescribing regulations that pertain to railroad safety that affect tourist, historic, scenic, or excursion railroad carriers, the Secretary of Transportation shall take into consideration any financial, operational, or other factors that may be unique to such railroad carriers. The Secretary shall submit a report to Congress not later than September 30, 1995, on actions taken under this subsection.

Pub. L. 103–440, § 217, 108 Stat. 4619, 4624, November 2, 1994.

In response to this mandate, FRA submitted a report to Congress on June 11, 1996, outlining FRA's efforts to tailor its rail safety requirements to tourist, historic, scenic, and excursion railroads. Notably, FRA has established a Tourist and Historic Railroads Working Group formed under RSAC to specifically address the applicability of FRA's regulations to these unique types of operations. Consequently, any requirements issued by FRA for these types of operations will be part of a separate rulemaking proceeding. However, this final rule makes clear that

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the provisions of part 232 as they existed prior to this issuance of this rule will continue to apply to such operations that are currently required to comply with the requirements in order to avoid regulatory gaps while power brake provisions for such service are finalized. Part 232 as it existed prior to the issuance of this final rule is contained as appendix B to this new part 232.

Similar to the amendments made to part 231, paragraphs (c)(6)–(c)(8) of this section also contain the express exceptions currently contained in the statute for certain coal cars and logging cars. These provisions are intended to make the regulatory exceptions consistent with the exceptions contained in the statute. The exceptions are taken directly from 49 U.S.C. 20301 (previously codified at 45 U.S.C. 6). As was done in these amendments to part 231, the words "freight and other non-passenger trains" have been added to the exceptions in order to remain consistent with Congress' intent when the statutory exceptions were created. At the time that Congress created an exception from the requirements of the Safety Appliance Acts, Congress did not and could not envision that the equipment used in these operations would be modified for the purposes of hauling passengers, which FRA has discovered with regard to four-wheel coal cars. Consequently, FRA will only except freight and other non-passenger operations which employ the types of equipment contained in these amendments.

Paragraph (d) of this section revokes the Interstate Commerce Commission Order 13528, of May 30, 1945, as amended (codified in existing § 232.3 and appendix B to part 232), and codifies some of the relevant provisions of that Order. Thus, paragraph (d) of this section contains a list of pieces of equipment that were excepted from the Order's specifications and requirements for operating power-brake systems for freight service. FRA believes that the Order is no longer completely relevant or necessary and believes that the relevant provisions should be incorporated into this section. In addition, FRA references current industry standards containing performance specifications for freight power brakes in other portions of this final rule which mirror the provisions contained in the Order. FRA notes that locomotives were removed from the listing as this final rule contains various requirements which address locomotives.

It should be noted that paragraph (a) of this section contains a specific reference to private cars and circus trains. As private cars are designed to carry passengers and are generally hauled in both freight and passenger trains, FRA intends that these types of cars be covered by both the recently issued Passenger Equipment Safety Standards and this final rule. For example, these types of cars will be subject to the maintenance and equipment standards applicable to passenger equipment but will be covered by the inspection requirements contained in this final rule when hauled in a freight train. With regard to circus trains, FRA intends for these operations to be covered by this final rule due to the unique nature of this equipment and operations. Although a circus train carries some employees, the majority of the train is composed of freight-type equipment and is operated in a manner similar to a freight train. Thus, for consistency purposes, FRA intends that this final rule apply to circus train operations.

Section 232.5 Definitions

This section contains an extensive set of definitions. FRA intends these definitions to clarify the meaning of important terms as they are used in the text of the final rule. The definitions are carefully worded in an attempt to minimize the potential for misinterpretation of the rule. The final rule retains most of the definitions proposed in the NPRM; however, based on the comments received a few new definitions have been added and other definitions previously included in the NPRM have been slightly modified for clarity. Several of the definitions introduce new concepts or new terminologies which require further discussion. The following discussion is arranged in the order in which the definitions appear in the rule text.

"Brake indicator" means a device, actuated by brake cylinder pressure, which indicates whether brakes are applied or released on a car. The use of brake indicators in the performance of brake tests is a controversial subject. Rail labor organizations correctly maintain that brake indicators are not fully reliable indicators of brake application and release on each car in the train. Further, railroads correctly maintain that reliance on brake indicators is necessary because inspectors cannot always safely observe brake application and release. FRA believes that brake indicators can serve an important role in the performance of brake tests, particularly in those instances where the design of the equipment requires inspectors to place themselves in potentially dangerous position in order to observe the brake actuation or release.

The definition of "effective brake" has been slightly modified from the definition proposed in the NPRM. The modification clarifies that a car's air brake will not be considered effective if its piston travel exceeds the specified limits or if it is not capable of producing its designed retarding force. FRA believes this clarifying language is necessary to address the concerns raised by certain commenters regarding the definitions of "bind" and "foul" contained in this final rule. The definitions of "bind" and "foul" have been retained as proposed in the NPRM. Contrary to the assertions made by some commenters, FRA believes that the definitions are sufficiently clear. Certain commenters contend that the definitions of these terms fail to address every possible condition that could affect the proper operation of a brake system. FRA believes that the conditions noted by several commenters as not being covered by these definitions are sufficiently covered by the clarified definition of "effective brake" contained in this final rule. Thus, even though a condition may not cause a brake to "bind" or "foul" the condition would cause the brake not to be an "effective brake" as defined in the final rule. Furthermore, FRA does not believe that the definitions of "bind" or "foul" are overly broad, as suggested by some commenters, since the restrictions addressed are ones which affect the intended movement of a component. Therefore, if the restriction is one that does not restrict the component's intended movement, then it should not be considered to "bind" or "foul."

The final rule also includes a definition of "inoperative dynamic brake" which was not specifically contained in the NPRM. This definition has been added in response to comments that the term "ineffective dynamic brake" contained in the NPRM was unclear and could lead to potential misunderstandings. These commenters contended that the rule should use the term "inoperative dynamic brake" and that its definition should be consistent with the definition of "inoperative brake." FRA agrees with these comments and thus, the final rule replaces the term "ineffective dynamic brakes" with the term "inoperative dynamic brake." The term "inoperative dynamic brake" means any dynamic brake that no longer provides its designed retarding force on the train, for whatever reason. FRA agrees that the use of only this term clarifies the applicability of the requirements related to dynamic brakes and prevents potential misunderstandings.

The final rule also defines the term "initial terminal" to mean the location where a train is originally assembled. This definition is consistent with the definition contained in the existing power brake regulations. Furthermore, the final rule eliminates the term "point of origin" proposed in the NPRM. FRA agrees that the proposed definition of this term was duplicative of the term "initial terminal" and merely created potential misunderstandings. Moreover, FRA agrees that the problems attempted to be addressed by the use of this term are sufficiently addressed by the various inspections required in this final rule when adding cars to a train.

The concept of "ordered date" or "date ordered" is vital to the correct application of this final rule. The terms mean the date on which notice to proceed is given by a procuring railroad to a contractor or supplier for new equipment. Some of the provisions of the final rule apply only to newly constructed equipment. When FRA applies a requirement only to equipment ordered on or after a specified date or placed in service for the first time on or after a specified date, FRA intends to exempt from the requirement, or "grandfather" any piece of equipment that is both ordered and placed in service for the first time before that date. FRA believes this approach will allow railroads to minimize, or avoid altogether, any costs associated with changing existing purchase orders and yet limit the delay in realizing the safety benefits of the requirements contained in this final rule.

The definitions of "qualified person" and "qualified mechanical inspector" are vital to understanding the inspection, testing, and maintenance provisions contained in this final rule. In order to ensure a proper understanding of these terms, the final rule clarifies FRA's intent regarding the necessary training these individuals are to receive and further clarifies the designation of such individuals. Although FRA disagrees with the assertions of some commenters that a "qualified person" should only be able to perform a limited number of tasks required by this final rule, FRA does agree that the definition of "qualified person" contained in the NPRM was overly vague and was susceptible to abuse and misunderstanding. Therefore, this final rule modifies the definition of a "qualified person" in order to more fully develop what is required by a railroad when designating a person as qualified to perform a particular task.

The definition of "qualified person" contained in this final rule makes clear that the person is to receive training pursuant to the training, qualification, and designation program required under § 232.203. The definition also makes clear that although a person may be deemed a "qualified person" for the performance of one task, that same person may or may not be considered a "qualified person" for the performance of another task. The rule requires that various tasks be performed by a "qualified person." For example, these tasks include the performance of brake inspections, the handling of defective equipment, and the performance of single car tests. FRA would expect employees performing these various tasks to have different levels of training. For example, a person receiving appropriate training to be deemed a "qualified person" for the purpose of performing Class II brake tests should not be deemed a "qualified person" for the purpose of moving defective equipment or performing single car or repair track air brake tests, unless specific training is provided that individual which specifically covers those tasks. The final rule stresses that the individual must have received appropriate training to perform the task for which the railroad is assigning the person responsibility.

Contrary to the assertions of certain commenters, FRA does not intend for term "qualified person" to be synonymous with the term train crew member. Although the NPRM discussed the fact that a train crew member could be considered a "qualified person" for performing many of the brake inspections required by the rule, FRA does not intend for a train crew member to be deemed a "qualified person" for performing every task covered by this final rule which is to be performed by a "qualified person." There are various tasks covered by this final rule (*i.e.*, single car and repair track air brake test) that must be performed by a "qualified person" which would require an individual to receive more specialized and in-depth training than that received by a person strictly performing brake inspections. For some tasks a "qualified person" may have to be an individual in the railroad's repair or mechanical department. The final rule makes clear that the railroad is responsible for determining that the person has the knowledge and skills necessary to perform the required function for which the person is assigned responsibility and for maintaining sufficient records documenting this knowledge and skill.

The final rule also retains the proposed definition of "qualified mechanical inspector" (QMI) with slight modification to ensure clarity and avoid potential misunderstanding. The final rule defines a QMI as a "qualified person" who as a part of the training, qualification, and designation program required under § 232.203 has received instruction and training that includes "hands-on" experience (under appropriate supervision or apprenticeship) in one or more of the following functions: trouble-shooting, inspection, testing, maintenance, or repair of the specific train brake components and systems for which the inspector is assigned responsibility. This person shall also possess a current understanding of what is required to properly repair and maintain the safety-critical brake components for which the person is assigned responsibility. Further, a QMI shall be a person whose primary responsibility includes work generally consistent with the above-referenced functions.

The definition contained in this final rule clarifies the intent of the NPRM by specifically stating that a QMI must be properly trained and have a primary responsibility in the function of trouble-shooting, inspection, testing, maintenance, or repair of the specific train brake systems for which the inspector is assigned responsibility. The definition also clarifies that a QMI must possess a current understanding of what is required to properly repair and maintain the safety-critical brake or mechanical components for which the person is assigned responsibility. The concept of QMI is premised on the idea that railroads will be permitted to move trains extended distances between brake inspections if the trains are inspected by highly qualified individuals. As no trains are currently permitted to move the distances between brake inspections permitted by this rule, FRA believes that the inspections these trains receive must be of very high quality and must be performed by individuals who can not only identify a particular defective condition but who have the knowledge and experience to know how the particular defective condition affects other parts of the brake system or mechanical components and who have an understanding of what might have caused a particular defective condition. FRA also believes that in order for a person to become highly proficient in the performance of a particular task that person must perform the task on a repeated and consistent basis. As it is almost impossible to develop and impose specific experience requirements, FRA believes that a requirement that the person's primary

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responsibility be in one or more of the specifically identified work areas and that the person have a basic understanding of what is required to properly repair and maintain safety-critical brake components is necessary to ensure the high quality inspections envisioned by the rule.

In order to clarify the meaning of "primary responsibility" as used in the definition of QMI, the final rule contains a definition of the term. As a rule of thumb FRA will consider a person's "primary responsibility" to be the task that the person performs at least 50 percent of the time. Therefore, a person who spends at least 50 percent of the time engaged in the duty of either inspecting, testing, maintaining, troubleshooting, or repairing train brakes systems may be designated as a QMI; provided, the person is properly trained to perform the tasks assigned and possesses a current understanding of what is required to properly repair and maintain the safety-critical brake components for which he or she is assigned responsibility. However, FRA will consider the totality of the circumstances surrounding an employee's duties in determining a person's "primary responsibility." For example, a person may not spend 50 percent of their day engaged in any one readily identifiable type of activity; in those situations FRA will have to look at the circumstances involved on a case-by-case basis.

The definition of QMI largely rules out the possibility of train crew members being designated as these highly qualified inspectors since the primary responsibility, as defined above, of virtually all current train crew personnel is the operation of trains and for the most part train crew personnel do not possess a current understanding of what is required to properly repair and maintain the safety-critical brake components that are inspected during the various required brake tests. FRA provides a clear definition of qualified mechanical inspector so that a differentiation can be made between the comprehensive knowledge and training possessed by a professional mechanical employee, and the more specialized training and general knowledge possessed by train crews. FRA intends the definition to allow the members of the trades associated with the testing and maintenance of equipment such as carmen, machinists, and electricians to become qualified mechanical inspectors. However, membership in labor organizations or completion of apprenticeship programs associated with these crafts is not required to be a qualified mechanical inspector. The two primary qualifications are possession of the knowledge required to do the job and a primary work assignment inspecting, testing, maintaining, troubleshooting, or repairing the equipment.

The definition of "solid block of cars" has been modified from that proposed in the NPRM. Although FRA believes the definition it proposed is consistent with current interpretations and enforcement of the existing requirement, FRA agrees with some of the commenters that the definition may have been too narrow and did not directly address FRA's primary concern, the block of cars itself. Rather than attempt to limit the addition of certain blocks of cars to a train by requiring that the entire train be reinspected if the block of cars is not composed of cars from only one other train, the final rule specifically addresses the inspection of a "solid block of cars" in the various inspection provisions based on the composition of the block. Thus, the final rule defines a "solid block of cars" as two or more freight cars consecutively coupled together and added to a train as a single unit. As FRA's primary concern is the condition of the block of cars being added to the train especially when the block of cars is made up of cars from more than one train, the final rule will permit a solid block of cars to be added to a train without triggering a requirement to perform a Class I brake test on the entire train. However, depending on the make-up of that block of cars, certain inspections will have to be performed on that block of cars at the location where it is added to the train. Therefore, the final rule places the emphasis on the inspection of the cars being added to the train rather than requiring a complete reinspection of the entire train.

The final rule also adds a definition of "unit train" and "cycle train" in order to clarify the requirement regarding the performance of a Class I brake test on such a train every 3,000 miles. Although the preamble to the NPRM made clear that this requirement was intended to apply to trains that are operated in captive service, the proposed rule text failed to specifically identify which trains were required to receive such attention. Thus, in order to remain consistent with FRA's intent, the final rule text has been modified to include the term "unit or cycle train." "Unit train" or "cycle train" means a train that, except for the changing of locomotive power and the removal or replacement of defective equipment, remains coupled as a consist and continuously operates from location A to location B and back to location A. These trains are also referred to as captive service trains as they basically operate in one continuous loop. Currently, trains which operate in this fashion can operate almost indefinitely on one initial terminal inspection and then a continuing series of 1,000-mile inspections. FRA believes that it is necessary for these trains to receive comprehensive brake inspections on a periodic basis in order to ensure their safe and proper operation.

The definitions of "transfer train" and "switching service" are somewhat interrelated since the determination as to whether, at a minimum, a transfer train brake test is required is based on whether the movement is a switching movement or a train movement. It is noted that the definition of "yard train" contained in the NPRM has been eliminated from this final rule. As the term was not used in the NPRM and has not been used in this final rule, FRA finds no need to retain the definition. Furthermore, the determination as to whether or not a yard train is required to be inspected and tested as a transfer train is based on whether the train is engaged in a train movement.

The final rule slightly modifies the proposed definition of "transfer train" to clarify that such a train may pick up and deliver freight equipment while en route to its destination. Such activity is currently conducted by these trains, and it was not FRA's intent when issuing the NPRM to prohibit these trains from being used in this fashion. The final rule also retains the definition of "switching service," which is defined as the classification of cars according to commodity or destination; assembling of cars for train movements; changing the position of cars for purposes of loading, unloading, or weighing; placing of locomotives or cars for repair or storage; or moving of rail equipment in connection with work service that does not constitute a train movement. Thus, a train engaged in switching service carries the potential of becoming a transfer train, subject to a transfer train's testing requirements, if the movement it will be engaged in is considered a "train movement" rather than a "switching movement." FRA's determination of whether the movement of cars is a "train movement," subject to the requirements of this section, or a "switching movement" is and will be based on the voluminous case law developed by various courts of the United States.

FRA's general rule of thumb as to whether a trip constitutes a "train movement" requires five or more cars coupled together that are hauled a distance of at least one mile without a stop to set off or pick up a car and not moving for the purpose of assembling or disassembling a train. However, FRA may consider movements of less than one mile "train movements" if various circumstances exist. In determining whether a particular movement constitutes a "train movement," FRA conducts a multi-factor analysis based upon the discussions contained in various court decisions on the subject. *See e.g. United States* v. *Seaboard Air Line R. R. Co.*, 361 U.S. 78 (1959); *Louisville & Jeffersonville Bridge Co.* v. *United States*, 249 U.S. 543 (1919). The following factors are taken into consideration by FRA: The purpose of the movement; the distance traveled without a stop to set out or pick up cars; the number of cars hauled; and the hazards associated with the particular route traveled (*e.g.*, the existence of public or private crossings with or without crossing protection, the steepness of the grade, the existence of curves, any other conditions that minimize the locomotive engineer's sight distance, and any other conditions that may create a greater need for power brakes during the movement). The existence of any of these hazards would tend to weigh towards the finding of a "train movement," since these are the types of hazards against which the power brake provisions of the Federal rail safety laws were designed to give protection.

Section 232.7 Waivers

This section sets forth the procedures for seeking waivers of compliance with the requirements of this rule. Requests for such waivers may be filed by any interested party. In reviewing such requests, FRA conducts investigations to determine if a deviation from the general criteria can be made without compromising or diminishing rail safety.

Section 232.9 Responsibility for Compliance

General compliance requirements are contained in this section. In accordance with the "use" or "haul" language previously contained in the Safety Appliance Acts (49 U.S.C. chapter 203), and with FRA's general rulemaking authority under the Federal railroad safety laws, the final rule retains the proposed requirement that any train, railroad car, or locomotive covered by this part will be considered "in use" prior to departure but after it receives or should have received the necessary tests and inspections required for movement. FRA will no longer necessarily wait for a piece of equipment with a power brake defect to be hauled before issuing a violation report and recommending a civil penalty, a practice frequently criticized by the railroads. FRA believes that this approach will increase FRA's ability to prevent the movement of defective equipment that creates a potential safety hazard to both the public and railroad employees. FRA does not feel that this approach increases the railroads' burden since equipment should not be operated if it is found in defective condition in the pre-departure tests and inspections, unless permitted by the regulations. In fact, this modification of FRA's perspectives as to when a piece of equipment will be considered "in use" was fully discussed by members of the Working Group and representatives of both rail labor and rail management supported this approach, agreeing that the current practice of waiting for a defective piece of equipment to depart from a location does very little to promote or ensure the safety of trains. FRA received no comments objecting to this approach in response to the NPRM.

FRA currently interprets the "use" or "haul" language previously contained in the Safety Appliance Acts narrowly to require that a train or car not in compliance with the power brake regulations actually engage in a train movement before a violation under the power brake regulations could be assessed against a railroad. Although this interpretation is in accordance with existing case law, FRA believes that a broader interpretation is possible based upon the case law interpreting the "use" language contained in the Safety Appliance Acts and based upon FRA's general rulemaking authority under the Federal railroad safety laws. Based upon both these authorities, FRA finds that it is not necessary to require that a train or car engaged in a train movement prior to FRA assessing a violation under the power brake regulations. The fact that the train or car is being used by a railroad, has been or should have been inspected by the railroad, and will be engaged in a train movement while in non-compliance with the requirements contained in this part is sufficient to allow a violation to be assessed.

This section also clarifies FRA's position that the requirements contained in these rules are applicable to any "person," as broadly defined in § 232.11, that performs any function required by the proposed rules. Although various sections of the final rule address the duties of a railroad, FRA intends that any person who performs any action on behalf of a railroad or any person who performs any action covered by the final rule is required to perform that action in the same manner as required of a railroad or be subject to FRA enforcement action. For example, private car owners and contract shippers that perform duties covered by these regulations would be required to perform those duties in the same manner as required of a railroad.

Paragraph (c) states that any "person" as broadly defined in § 232.11, that performs any function or task required by this part will be deemed to have consented to FRA inspection of the person's operation to the extent necessary to ensure that the function or task is being performed in accordance with the requirements of this part. This provision was contained in the NPRM, and FRA received no comments opposing the position. This provision is intended to put railroads, contractors, and manufacturers that elect to perform tasks required by this part on notice that they are consenting to FRA's inspection for rail safety purposes of that portion of their operation that is performing the function or task required by this part. In most cases, this function or task involves a contractor's performance of certain required brake inspections or the performance of specified maintenance on cars, such as conducting single car or repair track tests on behalf of a railroad. FRA believes that if a person is going to perform a task required by this part, FRA must have the ability to view the performance of such a task to ensure that it is conducted in compliance with federal regulations. Without such oversight, FRA believes that the requirements contained in this the regulation would become illusory and could be easily circumvented by some railroads. FRA believes that it has the statutory authority pursuant to 49 U.S.C. 20107 to inspect any facility or operation that performs functions or tasks required under this part, and this provision is merely intended to make that authority clear to all persons performing such tasks or functions.

Section 232.11 Penalties

This section identifies the penalties that may be imposed upon a person, including a railroad or an independent contractor providing goods or services to a railroad, that violates any requirement of this part. These penalties are authorized by 49 U.S.C. 21301, 21302, and 21304. The penalty provision parallels penalty provisions included in numerous other safety regulations issued by FRA. Essentially, any person who violates any requirement of this part or causes the violation of any such requirement will be subject to a civil penalty of at least $500 and not more than $11,000 per violation. Civil penalties may be

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assessed against individuals only for willful violations, and where a grossly negligent violation or a pattern of repeated violations creates an imminent hazard of death or injury to persons, or causes death or injury, a penalty not to exceed $22,000 per violation may be assessed. In addition, each day a violation continues will constitute a separate offense. It should be noted that, the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. 101–410 Stat. 890, 28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 Pub. L. 104–134, April 26, 1996 required agencies to adjust for inflation the maximum civil monetary penalties within the agencies jurisdiction. See 63 FR 11623. The resulting $11,000 and $22,000 maximum penalties noted in this section were determined by applying the criteria set forth in sections 4 and 5 of the statute to the maximum penalties otherwise provided for in the Federal railroad safety laws. Finally, paragraph (b) makes clear that a person may be subject to criminal penalties under 49 U.S.C. 21311 for knowingly and willfully falsifying reports required by these regulations. FRA believes that the inclusion of penalty provisions for failure to comply with the regulations is important in ensuring that compliance is achieved.

The final rule includes a schedule of civil penalties in appendix A to this part. Because such penalty schedules are statements of policy, notice and comment were not required prior to its issuance. See 5 U.S.C. 553(b)(3)(A).

Section 232.13 Preemptive Effect

This section informs the public as to FRA's intention regarding the preemptive effect of the final rule. While the presence or absence of such a section does not conclusively establish the preemptive effect of a final rule, it informs the public concerning the statutory provisions which govern the preemptive effect of the rule and FRA's intentions concerning preemption. Paragraph (a) points out the preemptive provision contained in 49 U.S.C. 20106, which provides that all regulations prescribed by the Secretary relating to railroad safety preempt any State law, regulation, or order covering the same subject matter, except a provision necessary to eliminate or reduce an essentially local safety hazard that is not incompatible with a Federal law, regulation, or order and that does not unreasonably burden interstate commerce. With the exception of a provision directed at an essentially local safety hazard that is not inconsistent with Federal law, regulation, or order and that does not unreasonably burden interstate commerce, 49 U.S.C. 20106 will preempt any State regulatory agency rule covering the same subject matter as the regulations contained in this final rule.

Paragraph (b) of this section also informs the public of the potential for preemption under various other statutory and constitutional provisions. These include: the Locomotive Inspection Act (now codified at 49 U.S.C. 20701–20703), the Safety Appliance Acts (now codified at 49 U.S.C. 20301–20304), and the Commerce Clause. FRA is not expressing positions as to whether or to what extent preemption exists with regard to any of the provisions noted above because doing so requires a lengthy analysis for each component which, in the aggregate, would be so long as to impair the usefulness of this document for most readers. As FRA lacks the authority to make binding preemption determinations, FRA's purpose in identifying these provisions is merely to inform the public of the existence of these provisions and that voluminous case law exists regarding preemption under each of the provisions.

Paragraph (c) further informs the public that FRA does not intend to preempt provisions of State criminal law that impose sanctions for reckless conduct that leads to actual loss of life, injury, or damage to property, whether such provisions apply specifically to railroad employees or generally to the public at large.

Section 232.15 Movement of Defective Equipment

This section contains the provisions regarding the movement of equipment with defective brakes without civil penalty liability. Except as noted in the discussion below, the provisions contained in this section are almost identical to the provisions proposed in the 1998 NPRM and incorporate the stringent conditions currently contained in 49 U.S.C. 20302, 20303, 21302, and 21304 (previously codified at 45 U.S.C. 13). The language used in some of the provisions has been slightly modified to ensure consistency with existing statutory requirements. As pointed out in the previous discussion, most of the alternative proposals received by FRA in response to the 1994 NPRM, the subsequent RSAC Working Group meetings, and the 1998 NPRM all contained provisions regarding the movement of equipment with defective brakes which are in direct conflict with the statutory requirements. *See* "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "Movement of Equipment with Defective Brakes." FRA continues to believe that the requirements related to the movement of equipment with defective brakes retained in this final rule are not only consistent with the statutory requirements, but also ensure the safe and proper movement of defective equipment and clarify the duties imposed on a railroad when moving such equipment.

Paragraph (a) of this section contains various parameters which must exist in order for a railroad to be deemed to be hauling a piece of equipment with defective brakes for repairs without civil penalty liability. The final rule modifies the language used in some of the proposed general provisions contained in this paragraph to accurately reflect the language contained in the existing statutory provisions pertaining to the movement of equipment with defective brakes. The final rule replaces the term "repair location" with the phrase "location where necessary repairs can be performed." FRA agrees with the comments of certain labor representatives that the proposed language could have been interpreted as being somewhat contrary to the language used in the existing statute, which was not FRA's intent.

The vast majority of the requirements contained in this paragraph should pose absolutely no additional burden to railroads as they are merely a codification of existing statutory requirements. The only requirement being retained from the 1998 NPRM in this paragraph that is not currently mandated is the requirement that all cars or locomotives found with defective or inoperative braking equipment be tagged as bad ordered with a designation of the location where the necessary repairs can and will be effectuated and that a qualified person determine the safety parameters for moving a piece of defective equipment. Although these are new requirements, most railroads already tag defective brake equipment upon discovery of the defect. It should be noted that the final rule clarifies that the person required to make the determinations regarding the safe movement of defective equipment is to be a "qualified person" as defined in the final rule. The intent of FRA when issuing the NPRM was to require the determinations to be made by these individuals. FRA believes that the training requirements contained in the final rule for designating a person qualified to perform a specific task will ensure that the individual possesses the appropriate knowledge and skills to perform the assigned task. Furthermore, the determinations that are required to be made in the final rule are currently made by individuals who FRA believes will be trained and designated under the final rule as qualified persons.

In paragraph (a), FRA retains the existing and proposed requirement that equipment with defective brakes shall not depart from or be moved beyond a location where the necessary repairs to the equipment can be performed. Therefore, if a car or locomotive is found with defective brakes during any of the proposed brake inspections or while the piece of equipment is en route and the location where the defective equipment is discovered is a place where repairs of the type needed can be performed, that car or locomotive shall not be moved from that location until the necessary repairs are effectuated. However, if repairs to the defective condition cannot be performed at the location where the defect is discovered, or should have been discovered, the final rule makes clear that the railroad is permitted to move the equipment with the defective condition only to the nearest location where the necessary repairs can be performed.

Paragraph (a) also retains the proposed codification and clarification of the statutory restrictions on the movement of equipment with defective brakes onto the line of a connecting railroad. Hence, the delivery of defective equipment in interchange is covered by these restrictions. In addition to fulfilling the other requirements set out in this section, a railroad seeking relief from civil penalty liability must show that the connecting railroad has elected to accept the non-complying equipment and that the point of repair on the connecting railroad's line, where the equipment will be repaired, is no further than the point where the repairs could have been made on the line where the equipment was first found to be defective.

Paragraph (b) of this section contains the specific requirements regarding the tagging of equipment found with defective brake components. The requirements contained in this paragraph are very similar to the tagging requirements proposed in the NPRM and those currently contained in part 215, regarding the movement of equipment not in compliance with the Freight Car Safety Standards, and are generally consistent with how most railroads currently tag equipment found with defective brakes. The final rule retains the proposed requirement that a record or copy of each tag removed from a defective piece of equipment be retained for 90 days and made available to FRA within 15 days of request. FRA does not believe that the proposed time frames need to be expanded as suggested by some commenters. The provisions are identical to those contained in part 215, regarding freight car defects and they have proven to be sufficient to meet the needs of FRA. The record keeping requirements are intended to aid FRA in its enforcement of the regulations. As the agency is able to inspect and oversee only a small portion of the railroad operations taking place across the country at any one time, the need for railroads to maintain records of such operations is essential for FRA to carry out its mission of ensuring that all railroads are operating in the safest possible manner and that they comply with those minimum Federal standards designed to ensure that safety.

Paragraph (b) also recognizes that the industry may attempt to develop some type of automated tracking system capable of retaining the information required by this section and tracking defective equipment electronically. Thus, this paragraph permits the use of an automated tracking system in lieu of directly tagging the equipment if the automated system is approved for use by FRA. Contrary to the recommendations of some commenters, FRA is not willing to permit the implementation of an automated tracking system without its approval. As an adequate automated system for tracking defective equipment does not currently exist on most railroads, FRA does not believe it is prudent, from a safety perspective, to allow implementation of a tracking system for which FRA would not have a prior opportunity to assess to ensure the system's accessibility, security, and accuracy. Furthermore, FRA tends to agree with the assertion of various labor representatives that the physical tagging of defective equipment provides a railroad's ground and operational forces the ability to visually locate and identify defective equipment at the time they see it rather than referring to an electronic database for such information.

This paragraph also contains language not previously included in the NPRM regarding FRA's oversight of an automated tracking system that is approved by FRA. FRA believes these provisions as necessary to ensure the agency's ability to monitor such systems and potentially prohibit the use of the system if it is found deficient. The provisions make clear that an automated tracking system approved for use by FRA be capable of being reviewed and monitored by FRA at any time. This paragraph also notifies the railroads that FRA reserves the right to prohibit the use of a previously approved automated tracking system if FRA subsequently finds it to be insecure, inaccessible, or inadequate. Such a determination would have to be in writing and include the basis for taking such action.

Paragraph (c) retains the proposed provision restricting the movement of a vehicle with defective brakes for the purpose of unloading or purging only if it is necessary for the safe repair of the car. This restriction is fully consistent with the statutory provisions regarding the movement of equipment with defective safety appliances.

Paragraph (d) retains with slight modification the method of calculating the percentage of operative power brakes (operative primary brakes) in a train that was proposed in the NPRM. This paragraph retains the general method of calculating the percentage on a control valve basis. However, FRA agrees with the comments of the NTSB and certain labor representatives that the method proposed in the NPRM did not take into consideration the possibility of a control valve being cut in when the brakes it controls are inoperative. Therefore, this final rule clarifies that a control valve will not be considered cut-in if the brakes controlled by that valve are inoperative. Although the statute discusses the percentage of operative brakes in terms of a percentage of vehicles, the statute was written nearly a century ago, and at that time the only way to cut out the brakes on a car or locomotive was to cut out the entire unit. *See* 49 U.S.C. 20302(a)(5)(B). Today, many types of freight equipment can have their brakes cut out on a per-truck basis, and FRA expects this trend to increase as the technology is applied to newly acquired equipment. This final rule merely adopts a method of calculating the percentage of operative brakes in a train based on the design of equipment used today and, thus, a means to more accurately reflect the true braking ability of the train as a whole. FRA believes that this method of calculation is consistent with the intent of Congress when it drafted the statutory requirement and simply recognizes the technological advancements made in braking systems over the last century.

Paragraph (d) also retains the proposed list of conditions that are not to be considered inoperative power brakes for purposes of calculating the percentage of operative brakes. Certain commenters recommended that FRA eliminate the proposed listing of conditions that would not be considered as rendering the brakes inoperative, contending that the listed conditions

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should not be excluded from consideration. FRA disagrees with these commenters. The purpose of the calculation is to determine the percentage of operative brakes, and the conditions listed in the proposal and retained in this final rule do not render the power brakes inoperative. Many of the listed conditions constitute a violation under other provisions contained in the final rule or another regulatory provision for which separate penalties are provided.

A cut-out or ineffective power brake is an inoperative power brake, but the failure or cutting out of a secondary brake system does not result in inoperative power brakes; for example, failure of the dynamic brake does not render the power brake inoperative. Furthermore, inoperative handbrakes or power brakes overdue for maintenance or stenciling do not render the power brakes inoperative on the car and should not be deemed inoperative power brakes for purposes of the calculation. The final rule and other regulations contain separate penalties for operating a car that has an inoperative handbrake, is overdue for maintenance, or lacks the proper stenciling or marking if not being properly hauled for repairs. In addition, although a car may be found with piston travel that exceeds the Class I brake test limits, such excess travel does not render the brakes inoperative until the piston travel exceeds the outside limits established for that particular type of piston design. However, piston travel that exceeds the applicable Class I brake test limits would be considered a defective condition if the piston travel were not adjusted at the time that a Class I brake test were performed, and the final rule contains an appropriate penalty for such a condition.

Paragraph (e) contains the requirements regarding the placement of cars in a train that have inoperative brakes. The requirements contained in this final rule are virtually identical to the requirements proposed in the NPRM. The restrictions contained in this paragraph are consistent with current industry practice and are part of almost every major railroad's operating rules. This paragraph prohibits the placing of a vehicle with inoperative brakes at the rear of the train. In addition, this paragraph retains the prohibition on the consecutive placing of more than two vehicles with inoperative brakes, as test track demonstrations have indicated that when three consecutive cars have their brakes cut-out it is not always possible to obtain an emergency brake application on trailing cars. However, as it was FRA's intent to incorporate current industry practice when proposing the requirements, the final rule slightly modifies the requirement regarding the placement of multi-unit articulated equipment. When proposing the restrictions regarding multi-unit articulated equipment, FRA extrapolated the restriction based on the requirements regarding the consecutive placing of defective cars. Based on its consideration of the comments, FRA has determined that the proposed requirement prohibiting the placement of such equipment with consecutive control valves cut out is more restrictive than current practice on many railroads, which was not FRA's intent when drafting the proposal. Consequently, in order to remain consistent with existing industry practice, the final rule requires that such equipment shall not be placed in a train if it has more than two consecutive individual control valves cut out or if the brakes controlled by the valve are inoperative.

Paragraph (f) contains guidelines that FRA will consider when determining whether a location is one where necessary brake repairs can be performed and whether a location is the nearest location where such repairs can be effectuated. The preamble to the NPRM contained an extensive discussion regarding what factors should be considered when determining whether a particular location is one where brake system repairs should be performed and discussed the difficulties and pitfalls associated developing a standard applicable to all situations. *See* 63 FR 48309. In the NPRM, FRA stated that the determinations as to what constitutes a location where necessary repairs can be performed had to be conducted on a case-by-case basis utilizing the criteria established in existing case law. A number of railroad representatives commented on this issue and recommended that FRA further clarify what constitutes a location where brake repairs must be conducted. These commenters claimed that leaving the determination solely to individual FRA inspectors creates inconsistent enforcement and makes it virtually impossible for railroads to comply. AAR and its members recommended that FRA allow railroads to designate locations where brake system repairs would be conducted. Conversely, representatives of rail labor objected to any approach that would permit railroads to designate repair locations, claiming that such an allowance would violate the statutory conditions regarding the movement of defective equipment.

After consideration of these comments, FRA believes it is essential to further clarify to the regulated community what the agency's position will be for determining whether a location is a place where brake repairs are to be conducted. FRA does not agree that a railroad should be permitted to independently determine the locations it will consider capable of making brake system repairs. History shows that many railroads and FRA have widely different views on what should be considered a location where brake repairs can and should be effectuated. Furthermore, it is apparent to FRA that some railroads attempt to minimize or circumvent the requirements for conducting repairs in the name of convenience or efficiency. However, FRA also recognizes that the emergence of mobile repair trucks creates an ability to perform repairs that did not exist when Congress originally enacted the statutory requirements related to the movement of defective equipment. FRA acknowledges that every location where a mobile repair truck is capable of making repairs should not be considered a location where repairs must be conducted. However, FRA also disagrees with the contentions of some commenters that Congress only intended for fixed repair facilities to be considered when determining locations where brake repairs are to be performed and that mobile repair trucks should not be considered. FRA is aware of numerous locations where mobile repair trucks are being used in lieu of a fixed facility or where a fixed facility was eliminated and the repairs that were being performed by the fixed facility are now being performed at the same location with a fully equipped repair truck. Thus, FRA believes that locations where repair trucks are used in virtually the same manner as a fixed facility should be considered when determining whether the location is capable of making the necessary repairs.

As noted in the NPRM, the determination as to what constitutes a location where necessary repairs can be performed is an issue that FRA has grappled with for decades. FRA continues to believe that the determination must be made on a case-by-case basis after conducting a multi-factor analysis. However, in an effort to better detail the items that will be considered by FRA in making a determination, paragraph (f) contains general guidelines that FRA will consider when determining whether a location is one which should be considered a location where at least some brake system repairs must be made. FRA would expect a railroad to consider the guidance contained in this paragraph when making its decisions on where equipment containing brake defects will be repaired. The guidance contained in this paragraph is based upon, and consistent with, the voluminous case law which exists that establishes the guiding principles for determining whether a location constitutes a location where the necessary repairs can be made as well as previous enforcement actions taken and guidance provided by FRA regarding such locations. The final rule guidance incorporates the principles discussed in the "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "Movement of Equipment with Defective Brakes."

Paragraph (g) provides a method by which a railroad may designate locations where various brake system repairs will be conducted. Although FRA does not believe that railroads should be permitted to unilaterally designate locations where brake system repair will be conducted, FRA does believe that a railroad in cooperation with its employees could potentially develop a plan that designates locations where brake system repairs will be effectuated. This paragraph makes clear that such a plan would have to be consistent with the guidelines contained in paragraph (f) and that such plans would have to be approved by FRA prior to being implemented. This paragraph also makes clear that for FRA to entertain a proposal containing a plan which designates locations where brake system repairs will be conducted a railroad and representatives of its employees must submit the proposal jointly . FRA does not intend to consider proposals nominally submitted pursuant to this provision that are not supported by a railroad's employees and their representatives.

Section 223.17 Special Approval Process

This section contains the procedures to be followed when seeking to obtain FRA approval of a pre-revenue service acceptance plan under § 232.505 for completely new brake system technologies or major upgrades to existing systems or when seeking approval of an alternative to the test standard incorporated in §§ 232.305 or 232.307. Several railroads and manufacturers contended, both in response to the 1994 NPRM and at the RSAC Working Group meetings, that FRA needed to devise some sort of quick approval process in order to permit the industry to make modifications to incorporated standards or existing equipment based on the emergence of new technology. Thus, FRA proposed an approval process it believed should speed the process for taking advantage of new technologies over that which is currently available under the waiver process. However, in order to provide an opportunity for all interested parties to provide input for use by FRA in its decision making process, as required by the Administrative Procedure Act, FRA believes that any special approval provision must, at a minimum, provide proper notice to the public of any significant change or action being considered by the agency with regard to existing regulations.

This section essentially retains the proposed special approval process. One private car owner commented that the procedures should require FRA to publish any petition received within 30 days of receipt and to rule on the petition within 30 days of receipt of the last comment. Certain representatives of rail labor asserted that the special approval procedures should be tightened to be consistent with the requirements for granting a waiver and that the comment period should be extended and expanded to provide adequate time for parties to prepare. As the special approval process only applies to pre-revenue testing plans and the procedures for conducting single car and repair track air brake tests and because the purpose of the process is to speed the decision making process, FRA does not believe it is necessary to further lengthen the comment periods proposed in the NPRM, and FRA thinks that the procedures provide an adequate opportunity for interested parties to comment. Furthermore, if the procedures for these special approvals are made overly burdensome then the speed intended to be gained through the process would be lost. However, FRA also does not believe that the proposed time frames provided for FRA's consideration of a petition should be reduced. FRA believes that the time frames included in the proposal for FRA consideration are necessary for FRA to fully consider all comments and information received.

Section 232.19 Availability of Records

This section makes clear that unless otherwise provided by this part, the records and plans required to be developed and maintained by this part shall be made available to representatives of FRA and States participating under part 212 of this chapter for inspection and copying upon request. FRA has added this section to the final rule in order to specifically clarify the availability of such records while increasing the readability of the rule and reducing the unnecessary repetition of the requirement throughout the text of the rule.

Section 232.21 Information Collection

This section indicates the provisions of this part that have been approved by the Office of Management and Budget for compliance with the Paperwork Reduction Act of 1995. *See* 44 U.S.C. 3501 *et seq.* A more detailed discussion of the information collection requirements contained in this part is provided in the "Regulatory Impact" portion of this preamble.

Subpart B—General Requirements

Section 232.101 Scope

This section contains a formal statement of the scope of this specific subpart of the final rule. This subpart is intended to establish general operating, performance, and design standards for railroads that operate freight or other non-passenger trains and further contains specific requirements for equipment used in these types of operations.

Section 232.103 General Requirements for All Train Brake Systems

This section contains general requirements that are applicable to all freight and non-passenger train brake systems. This section specifically includes certain basic train brake system practices and procedures that form the foundation for the safe operation of all types of trains. Some of these basic principles are so obvious that they have not been specifically included in past rules. For example, paragraphs (a)-(c) state the most basic safety requirements for all train brake systems, which include having the ability to stop a train within the existing signal spacing, maintaining and monitoring the integrity of the train brake communication line, and having the train brake system respond as intended to signals from the brake communication line. These basic requirements were proposed in the NPRM and have been retained in this final rule without change.

Paragraph (d) contains the provision requiring trains to have 100 percent operative and effective power brakes prior to use at, or departure, from certain locations and prohibiting the hauling of a car with inoperative or ineffective power brakes from certain under 49 U.S.C. 20303. Paragraph (d) has been slightly modified from that

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proposed in the NPRM in order to clarify that the requirement applies only to trains that are required to receive a Class I brake test at the location. This modification was made in order to specifically clarify that the 100 percent operative brake requirement is not intended to apply to transfer trains that originate at a location where the necessary brake repairs cannot be effectuated. FRA agrees with the concerns raised by various commenters that the proposed language could have been interpreted as applying to transfer trains. FRA agrees that the 100 percent requirement does not currently apply to such trains, and it was not FRA's intention when issuing the NPRM to extend its application to such trains. However, it should be noted that if a transfer train originates at a location where repairs to the equipment containing defective brakes can be effectuated, then the train would be required to have 100 percent operative brakes prior to being used or departing that location.

Contrary to the contentions of certain commenters, FRA continues to believe that there is adequate justification for retaining the 100 percent requirement. The requirement to have 100 percent operative brakes prior to departing a location where an initial terminal brake test is required to be performed has existed in the railroad industry for decades. FRA believes it is not only wise from a safety standpoint, as it ensures the proper operation of a train's brake system at least once during its existence, but the requirement sets the proper tone for what FRA expects to be accomplished at these locations. FRA believes that requiring 100 percent operative brakes on trains at their origin provides the railroads with a margin for failure of some brakes while the train is in transit (up to 15 percent) and tends to ensure that defective equipment is being repaired in a timely fashion. In addition, FRA believes that the 100 percent requirement is consistent not only with Congress' understanding of the AAR inspection standards that were adopted in 1958, but also with the intent of FRA, rail management, and rail labor as to what was to occur at initial terminals when the inspection interval was increased from 500 miles to 1,000 miles in 1982. At that time, carrier representatives committed to the performance of quality initial terminal inspections in exchange for an extension in the inspection interval, for which FRA intends to hold them accountable.

Some commenters recommended that FRA permit any and all trains that have 95 percent operative brakes to operate from their point of origin to destination and noted that Canada currently allows such operation. FRA believes that such an approach would be completely contrary to the existing statutory mandate regarding the movement of equipment with defective brakes. The existing statutory provision regarding the movement of equipment with defective brakes requires that such equipment be repaired at the nearest location where the necessary repairs can be performed. *See* 49 U.S.C. 20303. Consequently, trains that originate at or that operate through locations where the necessary brake repairs can be effectuated are clearly required by the statute to have 100 percent operative brakes prior to departing those locations.

FRA realizes that the 100 percent requirement creates a somewhat illogical situation at some locations by requiring certain trains to have 100 percent operative brakes prior to departing the location and yet allowing other trains to pick up defective equipment at the same location. However, FRA believes that various safety benefits are created by retaining the 100 percent requirement. The public is assured that a train's brake system is in near perfect condition at the beginning of its journey, train crews are more cognizant of the presence of defective cars in the train when they are picked up en route, railroads are more likely to perform repairs at a location where trains are initiated in order to avoid breaking up trains to set out defective cars once the trains are assembled, and FRA retains a clear and consistent enforcement standard that can be easily understood by its inspectors and railroad industry employees.

Although FRA recognizes that the 100 percent requirement may be somewhat burdensome for some railroads at certain locations, FRA believes that the number of locations involved is relatively low and should be handled on a case-by-case basis through the existing waiver process. FRA believes that many railroads have created their own problems by eliminating repair facilities and personnel at many of the outlying locations that the railroads now claim they lack the ability to make appropriate repairs. Furthermore, FRA believes that the best method of assessing the safety implications of permitting a location to operate trains with less than 100 percent operative brakes is for the railroad to provide information on how the railroad will handle the defective equipment based on the specific needs and operating characteristics of the railroad involved.

In the NPRM, FRA provided various approaches under which it would potentially consider allowing a railroad to operate trains from their initial terminals with less than 100 percent operative brakes. *See* 63 FR 48310. The methods suggested by FRA were rejected as being overly burdensome by several commenters. Therefore, FRA believes the burden falls on each railroad seeking relief from the 100 percent requirement at certain outlying locations to provide FRA with an operating plan that will ensure the safe operation of such trains and provide for the timely and certain repair of any defective equipment moved from those locations. Consequently, FRA believes that there are a few existing locations that may be candidates for receiving a waiver from the 100 percent requirement, and FRA is willing to consider waivers for such locations; however the railroads applying for such waivers must be able to establish a true need for the exception and must be willing to provide alternative operating procedures that ensure the safety of the trains being operated from those locations.

Paragraph (e) contains a clear and absolute prohibition on train movement if more than 15 percent of the cars in a train have their brakes cut out or have otherwise inoperative brakes. Although there is no explicit limit contained in the statute regarding the number of cars with inoperative brake equipment that may be hauled in a train, the 15-percent limitation is a longstanding industry and agency interpretation of the hauling-for-repair provision currently codified at 49 U.S.C. 20303, and has withstood the test of time. This interpretation is extrapolated from another statutory requirement which permits a railroad to use a train only if "at least 50 percent of the vehicles in the train are equipped with power or train brakes and the engineer is using the power or train brakes on those vehicles and on all other vehicles equipped with them that are associated with those vehicles in a train." 49 U.S.C. 20302(a)(5)(B). As originally enacted in 1903, section 20302 also granted the Interstate Commerce Commission (ICC) the authority to increase this percentage, and in 1910 the ICC issued an order increasing the minimum percentage to 85 percent. *See* 49 CFR 232.1, which codified the ICC order. One labor representative recommended that this requirement be eliminated as it creates confusion regarding the movement of defective equipment. FRA believes that if the rule is read in its entirety there should be no confusion as to the movement of defective equipment, and that this provision merely sets an outside limit on the percentage of cars that may be hauled in any train with inoperative brakes. Consequently, FRA believes the express prohibition is necessary and will continue to require that equipment with inoperative air brakes make up no more than 15 percent of any train.

As virtually all freight cars are presently equipped with power brakes and are operated on an associated trainline, the statutory requirement cited above is in essence a requirement that 100 percent of the cars in a train have operative power brakes, unless being hauled for repairs pursuant to 49 U.S.C. 20303. Therefore, paragraph (f) makes clear that a train's air brakes shall be in effective and operable condition unless a car is being hauled for repairs pursuant to the conditions contained in § 232.15. This section retains the proposed standard for determining when a freight car's air brakes are not in effective operating condition based on piston travel. The piston travel limits for standard 12-inch stroke brake cylinders are the same as currently required under § 232.11(c). Certain labor representatives asserted that the permissible piston travel for these brake cylinders should be reduced to 10 inches rather than the currently allowed 10½ inches. These commenters provided no technical data to support such a change, and FRA is not aware of any problems or unsafe conditions resulting from the current 10½ inch piston travel allowance on such brake cylinders. Consequently, the final rule retains the existing piston travel limits for standard 12-inch stroke brake cylinders.

Due to the proliferation of equipment with other than standard 12-inch stroke brake cylinders, FRA has found that mechanical forces and train crew members performing brake system inspections often do not know the acceptable range of brake piston travel for this non-standard equipment. In an attempt to improve this situation and to ensure the proper operation of a car's brakes after being inspected, FRA proposed that vehicles equipped with other than standard 12-inch stroke brake cylinders have either the badge plate for the vehicle or a stencil, sticker, or marker indicate the acceptable range of piston travel for the brake equipment on that vehicle. FRA also proposed that the information on the badge plate, sticker, stencil, or marker include both the permissible brake cylinder piston travel range for the vehicle at Class I brake tests and the lengths at which the piston travel renders the brake ineffective. Paragraph (g) generally retains these proposed requirements. FRA continues to believe that this information is essential in order for a person to properly perform the brake inspections contained in this final due to the growing number of cars with other than standard brake designs. The requirement has been slightly modified from that proposed to require that the outside piston travel limit need only be provided if it is different from the Class I brake test limit. FRA agrees with the contentions of certain commenters that such information would be unnecessarily redundant if the limits are the same. Thus, if there is no outside limit indicated on the badge plate, stencil, sticker, or marker the piston travel limits indicated for the Class I/ initial terminal brake test for the vehicle will be considered the outside piston travel limits for that vehicle.

The AAR recommends that, in addition to vehicles equipped with standard 12-inch stroke brake cylinders, FRA should also except vehicles equipped with WABCOPAC or NYCOPAC truck-mounted brake cylinders from the marking requirements contained in paragraph (g). The AAR contends that the stenciling or marking of the piston travel limits on these vehicles is unnecessary because the piston travel limits for these brake systems are well-known and nearly 30 percent of the fleet is equipped with them. FRA disagrees with this contention. Based on FRA's experience in monitoring the performance of various brake tests, FRA believes that many employees are not aware of the piston travel limits for the brake systems noted above. Furthermore, there are numerous truck-mounted brake cylinders currently in use that have piston travel limits which are different from those of the WABCOPAC and NYCOPAC truck-mounted systems. Thus, FRA believes all vehicles equipped with these brake systems need to be marked in order to avoid confusion by individuals inspecting the equipment and thus ensure the proper operation of the brakes on such cars. Moreover, FRA is aware that many vehicles equipped with the type of truck-mounted brake systems sought to be excepted by AAR, particularly privately owned vehicles, already have decals, stickers, or stencils containing the information required by this paragraph.

The AAR also recommends that railroads be provided eight years in which to implement the marking requirements contained in this paragraph in order to perform the work during the required periodic single car or repair track air brake tests. FRA believes such an allowance of time is unnecessary and excessive. The reason FRA is permitting the information to be marked on the car with either a decal, stencil, or sticker is to provide the railroads with relatively simple and easy methods for bring cars into compliance without requiring them to be placed in a maintenance facility or on a repair track to have the information affixed. FRA believes that the three-year applicability period provided by this final rule provides railroads with sufficient time to mark cars as required. Furthermore, many cars are already properly marked with the necessary information as noted in the previous discussion.

Paragraph (h) requires that all equipment ordered or placed in service for the first time on or after the specified dates, be designed not to require an inspector to place himself or herself on, under, or between components of the equipment to observe brake actuation or release. This paragraph allows railroads the flexibility of using a reliable indicator in place of requiring direct observation of the brake application or piston travel because the designs of some freight car brake systems make direct observation extremely difficult unless the inspector places himself or herself underneath the equipment. Indicators of brake system piston travel or piston cylinder pressure have been used with satisfactory results for many years. Although indicators do not provide 100 percent certainty that the brakes are effective, FRA believes that they have proven themselves effective enough to be preferable to requiring an inspector to assume a dangerous position. Some commenters recommended that the indicator alternative be eliminated and that railroads should not be allowed to rely on indicators. FRA believes that these commenters fail to recognize the need to provide some alternative to direct observation of the piston travel on certain equipment and fail to acknowledge the existence of new technologies available to the industry. Further, although the rule permits the use of an indicator for purposes of determining piston travel, the individual inspecting such equipment would be required to inspect all components of the brake system for proper operation.

This requirement stems primarily from the brake system design of double-stack equipment currently used by several larger freight operations. Several commenters have indicated that the functioning of the brakes on this type of equipment cannot be observed without

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inspectors placing themselves in potentially dangerous positions. In addition, a complete inspection of the brake equipment and systems used on double-stack equipment is time consuming. Consequently, inspectors are reluctant to conduct a complete brake inspection test on departing trains that contain this type of equipment. FRA thinks that double-stack equipment is becoming a mainstay of the freight railroad industry and that this design deficiency must be corrected. Thus, FRA has attempted to make this a performance requirement by simply specifying how the equipment must function and allowing the industry to determine the method of compliance.

Paragraph (i) retains the proposed requirement that an emergency brake application feature be available at any time and that it produce an irretrievable stop. This section merely codifies current industry practice and ensures that all equipment will continue to be designed with an emergency brake application feature. In the 1994 NPRM on power brakes, FRA proposed a requirement that all trains be equipped with an emergency application feature capable of increasing the train's deceleration rate a minimum of 15 percent. *See* 59 FR 47729. This proposed requirement merely restated the emergency specification currently contained in Appendix B to part 232. Comments received in response to that proposal indicated that some brake equipment currently in use or being developed could provide a deceleration rate with a full service application that is close to the emergency brake rate and that the proposed requirement would require the lowering of full service brake rates, thereby compromising safety and lowering train speeds. Consequently, the requirement proposed in the 1998 and retained in this final rule removes the 15-percent differential.

Paragraphs (j) and (k), which were proposed as paragraphs (k) and (l), impose on the railroads the responsibility for determining maximum air brake system working pressure and maximum brake pipe pressure. These provisions were contained in both the 1994 and 1998 NPRM, and FRA received no comments objecting to their inclusion. *See* 59 FR 47743. Thus, FRA intends to continue to allow individual railroads the wide latitude currently permitted in determining these pressures.

Paragraph (l), previously proposed as paragraph (m), provides that except as provided by other provisions of this part, all equipment used in freight or other non-passenger trains shall, at a minimum, meet the performance specification for freight brakes in AAR standard S–469–47. The AAR standard incorporated by reference in this paragraph contains all the provisions currently referenced in § 232.3 and contained in existing Appendix B to part 232. In the NPRM, FRA sought comments from interested parties as to the necessity of referencing these standards as well as any information on any updated standards related to the performance of freight equipment that is currently being used throughout the industry. Although one commenter generally asserted that the standards should merely be included as a reference and that their inclusion would require retroactive validation of proven designs, FRA finds little merit in this contention since any existing equipment should already be designed to the specifications as they are currently part of the existing regulations. Except as noted below, FRA received no comments seeking specific changes to the referenced specifications or other objections to their inclusion.

It should be noted that the provision previously proposed in paragraph (j) of this section requiring that the air brake components that control brake application and release be adequately sealed to prevent contamination by foreign material (63 FR 48359) has been removed due to its incorporation in another provision contained in this final rule. As the proposed requirement is contained in AAR standard S–469–47 as one of the general specification requirements, there is no reason to retain the specific requirement in this final rule. Thus, although the requirement has been specifically removed from the rule text, it is retained by its inclusion in the referenced AAR standard. Furthermore, FRA finds AAR's objection to this requirement somewhat hard to understand. FRA is not imposing a new requirement but merely sets forth an existing requirement contained in an AAR standard. Contrary to the concerns raised by AAR, FRA does not intend to change the existing standard of compliance for this requirement.

Paragraph (m), previously proposed as paragraph (n), retains the proposed requirement that if an en route train qualified by the Air Flow Method experiences a brake pipe air flow of greater than 60 CFM or brake pipe gradient of greater than 15 psi and the movable pointer does not return to those limits within a reasonable time the train must be stopped at the next available location and inspected for leaks in the brake system. This requirement one of the conditions of the general waiver granted to the AAR allowing the use of the air flow method to qualify train air brakes. FRA believes that this requirement is necessary to prevent trains with excessive leakage from continuing to operate. If a train has excessive leakage, the engineer may lack the ability to stop the train using the air brake system. Other than the general contention raised by certain labor representatives that the Air Flow Method not be allowed, FRA received no specific comments on the requirements contained in this paragraph.

Paragraph (n), previously proposed as paragraph (o), contains requirements regarding the setting and releasing of hand brakes on equipment that is left unattended. The requirements contained in this paragraph differ from those previously proposed in the NPRM. In the NPRM, FRA proposed various requirements for securing standing equipment. The requirements proposed in the NPRM were basically a reiteration of the guidance issued by FRA in Safety Advisory 97–2 on September 15, 1997. *See* 62 FR 49046. The securement guidance contained in Safety Advisory 97–2 was based upon FRA's review of an incident that occurred on August 20, 1997 near Fort Worth, Texas, and its awareness of other incidents involving the improper securement of rolling equipment. The Safety Advisory was issued in order to provide the industry with some assistance and guidance regarding securement procedures and to provide information on current practices of the industry related to the securement of rolling stock. Id.

The requirements proposed in the NPRM where also intended to address the practice known as "bottling the air" in a standing cut of cars, an issue related to improperly secured rail equipment. The practice of "bottling the air" occurs when a train crew sets out cars from a train with the air brakes applied and the angle cocks on both ends of the train closed, thus trapping the existing compressed air and conserving the brake pipe pressure in the cut of cars they intend to leave behind. This practice has the potential of causing, first, an unintentional release of the brakes on these cars and, ultimately, a runaway. Many railroad operating rules require that a 20-pound reduction in brake pipe pressure be made when stopping a train to remove a cut of cars from the train. Thus, if the trainman closes the angle cock where the cut is to be made before pressure equalizes in the trainline, an air wave action may form that can be of sufficient amplitude to initiate an unintentional release of the brakes.

Brake pipe gradient is another factor that makes bottling the air dangerous. "Normal gradient" is a term used to express the difference between the higher pressure on the front end of the train and the lower pressure on the rear end of the train, which is dependent upon brake pipe leakage and train length. Each train establishes its own normal gradient value. "Inverse gradients" and "False gradients" are temporary gradients that are a result of brake operations. Inverse gradients occur when a brake pipe reduction is made, temporarily making the brake pipe pressure higher on the rear of the train. The false gradient is created anytime the train brakes are set and released, thus temporarily resulting in a higher than normal pressure differential between the front and rear end of the train as the brake pipe charges. Therefore, if the engineer sets and releases a train's brakes a sufficient number of times prior to stopping to remove a cut of cars, a false gradient could be established. Even if the engineer made a 20-pound brake pipe reduction and listened for the air to stop exhausting at the automatic brake valve before giving the signal to the trainman to cut off the cars, the potential exists for an unintentional release of air brakes if the air on the cars is bottled. The false gradient could be of such magnitude that, as the trainline attempts to equalize, the higher pressure on the front end flowing to the rear will exceed the 1½ pound differential across the service piston and cause a release of air brakes. An inverse gradient can also create an unintentional release of brakes. As brake pipe pressure is reduced at the front of the train, the rear end temporarily has a higher pressure. As the trainline attempts to equalize, the pressure on the front end will rise. In some circumstances, this rise could be enough to initiate a release of air brakes.

On June 5, 1998, the NTSB issued the following recommendation to FRA:

> Issue a regulation that requires the brake pipe pressure to be depleted to zero and an angle cock to remain open on standing railroad equipment that is detached from a locomotive controlling the brake pipe pressure.

(R–98–17). This recommendation was the result of NTSB's investigation of an incident that occurred on January 27, 1997, on the Apache Railway near Holbrook, Arizona. The incident involved the runaway of 77 cars down a 1.7 percent grade for 14 miles resulting in the eventual derailment of 46 cars and the release of hazardous materials. Although there were no fatalities, 150 people were evacuated from nearby residential areas. The NTSB determined that the 77 cars rolled away unattended because the conductor of the train had trapped the air in the brake system, i.e., "bottled the air," which resulted in an undesired release of the brakes on the standing cars. In its recommendation the NTSB correctly noted that FRA statistics show that ten accidents occurred between 1994 and 1995 which were attributable to the practice of "bottling the air."

FRA received numerous comments from the AAR and various other representatives of the railroads objecting to the proposed provisions regarding the securement of standing equipment. Although these commenters generally agreed with the intended purpose of the proposed requirements, they believed that the proposed provisions were overbroad, increased certain safety hazards, and exposed railroad employees to higher risk of injury. These commenters contend that the goals of FRA could be accomplished in a less burdensome fashion while increasing safety and reducing the potential for employee injuries. After reviewing the comments submitted by these parties, FRA agrees with most of the recommendations provided. Consequently, the provisions contained in this paragraph have been modified to reflect those recommendations.

FRA agrees with the recommendation that the requirements contained in this paragraph should be applied only to unattended equipment rather than to standing equipment generally. FRA agrees that, if the train is attended, the setting of handbrakes serves no useful purpose and would result in an enormous cost to the industry. Therefore, paragraph (n) contains a definition of "unattended equipment" to clarify the applicability of the requirements contained in this paragraph. The term covers equipment left standing and unmanned in such a manner that the brake system of the equipment cannot be readily controlled by a qualified person.

FRA also agrees that the proposed requirement that railroads develop a matrix to determine the number of hand brakes that are to be applied may not be the best approach to ensure that a sufficient number of hand brakes have been applied to a specific cut of unattended equipment. FRA agrees that the number of hand brakes required to be applied depends on a wide variety of factors not easily captured in a matrix format and that a matrix approach might result in either too few or too many hand brakes being applied. Thus, paragraph (n)(1) eliminates the requirement for developing a matrix and is modified to include a performance-based requirement that a sufficient number of hand brakes be applied to hold the equipment and a requirement that railroads develop and implement a process or procedure to verify that the applied hand brakes will sufficiently hold the equipment when the air brakes are released. This requirement will permit a railroad to develop appropriate operating rules to verify the sufficiency of the handbrakes applied which can be tailored to the specific territory and equipment operated by the railroad. On some railroads and at some locations, these operating rules may include the use of a matrix or some other type of set calculation.

Paragraph (n)(2) addresses the issue of "bottling air" on unattended equipment. This paragraph requires that an emergency brake application be initiated on all equipment prior to its being left unattended. This paragraph no longer requires that the locomotive be detached to effectuate the emergency application as was proposed. FRA agrees with the concerns raised by certain parties that the proposed requirement to detach locomotives to allow an emergency application of the brakes is not appropriate or desirable in many circumstances. FRA agrees that it is not necessary to detach locomotives to initiate an emergency application, that it is safer to leave the locomotives attached due to redundant securement features on a locomotive, that an emergency application should not be made until it is known that the number of hand brakes set is sufficient, and that it would be very burdensome to detach locomotives every time a train is left unattended.

Paragraphs (n)(3) and (n)(4) contain the requirements for securing unattended locomotives. FRA agrees with the recommendations made by various commenters that the proposed requirements regarding locomotive securement were over broad by failing to distinguish among (i) locomotives in the lead consist of a train, (ii) distributed power locomotives, and (iii) locomotives within yard limits. FRA agrees that these securement requirements contained in this final rule should not apply to distributed power locomotives. Consequently, these paragraphs establish specific securement requirements that apply only to locomotives in the lead consist of a train and are based on the location of the locomotive or locomotive consist when it is being left unattended.

Paragraph (n)(5) retains the proposed and existing requirement that any hand brakes applied to secure unattended equipment not be released until it is

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known that the air brake system is properly charged.

It should be noted that paragraph (n) reflects FRA's agreement with the various concerns raised regarding the proposed requirements to use derails to secure unattended equipment and to chock and chain locomotives when left unattended on certain grades. FRA agrees that the use of derails, as proposed in the NPRM, could potentially create safety hazards if not properly removed and might expose employees to a greater potential for injury by increasing the handling and movement of derails. FRA also agrees that if handbrakes are properly applied on unattended locomotives there is little need to chock and chain locomotive wheels in most instances and such a requirement merely creates the potential of exposing railroad employees to unnecessary risks. Furthermore, FRA believes that the alternative approach submitted by the CAPUC regarding when and where derails should be applied is too complicated, requires further research, and might require unnecessary securement in many instances. Thus, the approach taken in this final rule is to provide requirements for the setting of hand brakes and require railroads to ensure the capability of those hand brakes to hold the equipment. If the applied hand brakes do not adequately hold the equipment, FRA would expect the railroad to utilize other methods of securement such as derails, skates, chains, and chocks.

Paragraph (o), previously proposed as paragraph (p), requires that air pressure regulating devices be adjusted in accordance with the air pressures contained in the chart contained in this paragraph. The chart is very similar to that proposed in the NPRM, but has been slightly modified in response to the comments received. The references to equipment used in passenger operations has been eliminated, and the pressure of the self-lapping portion for independent air brake has been modified to read "30 psi or less" rather than the proposed "30–72 psi."

Paragraph (p) contains the proposed provision regarding the joint responsibility of supervisors and inspectors to ensure the proper condition and functioning of train brake systems. The provision contained in this paragraph has been slightly modified in order to remain consistent with the existing requirement regarding such joint responsibility contained at § 232.11(a). These modifications clarify that joint responsibility exists to the extent that it is possible to detect defective equipment by the inspections and tests required by this part.

Section 232.105 General Requirements for Locomotives

For the most part, this section contains general provisions related to locomotives that are either currently contained in § 232.10 or that were previously proposed in the NPRM. As discussed in detail in the NPRM, FRA does not intend to include provisions in this final rule related to the inspection and maintenance of locomotive braking systems. FRA believes that these requirements are adequately addressed in part 229 and would only add to the complexity of this rule and potentially cause confusion or misunderstanding by members of the regulated community. Therefore, while many of the requirements currently contained in § 232.10 are no longer necessary as they are adequately addressed in part 229, paragraphs (a) and (c) are provisions currently contained in § 232.10 which FRA believes need to be retained. See 49 CFR 232.10(b) and (f)(2).

Paragraph (c) retains the proposed requirement that the hand or parking brake on a locomotive be inspected and repaired, if necessary, at least every 368 days. It should be noted that paragraph (c) has been slightly modified from that proposed in order to allow the date of the last inspection of the hand brake to be entered on Form FRA F 6180–49A in lieu of stenciling such information on the car. As the current regulation permits either the stenciling or tagging of a locomotive with this information and because many railroads currently record the information on the form noted above, FRA believes it is appropriate to continue to allow such a practice. FRA continues to believe that this inspection requirement will have little or no impact on railroads as this inspection is intended to coincide with the annual locomotive inspection required under § 229.27 and many railroads currently inspect these devices at this annual inspection. FRA also continues to believe that a thorough inspection of these devices on an annual basis is sufficient to ensure the proper and safe functioning of the devices.

Paragraph (b) retains the proposed requirement that locomotives ordered or placed in service for the first time after the specified dates be equipped with a hand or parking brake. Although the final rule retains the requirements that the hand or parking brake be capable of being set and released manually, the final rule modifies the requirement regarding the holding capability of such brakes. Rather than requiring that the brake be capable of holding the equipment on the maximum grade anticipated by the operating railroad, the final rule requires that the brake be capable of holding the equipment on a three-percent grade. Based on information provided by several locomotive manufacturers, FRA agrees that current locomotive hand and parking brakes are designed to achieve a three-percent holding capacity and that current operating practices are based on this capacity. Several manufacturers assert that if the holding capacity of these brakes had to be increased, then the cost of a locomotive would increase significantly as such an increase would require redesign of the foundation brake rigging. As the current designs have provided adequate safety and the enhanced design would be very expensive relative to the improvement in safety, this paragraph has been amended to require that the hand or parking brake be capable of holding the unit on a three percent grade.

A hand or parking brake is an important safety feature that prevents the rolling or runaway of parked locomotives. The requirements contained in this paragraph represent current industry practice. In the 1994 NPRM on power brakes, FRA proposed requiring that a hand brake be equipped on locomotives. See 59 FR 47729. FRA received several comments to that proposal suggesting that the term "parking brake" be added to the requirement since that is what is used on many newly built locomotives. A parking brake generally can be applied other than by hand, such as by spring pressure, by air pressure when the brake pipe air is depleted, or by an electrical motor. Parking brakes usually incorporate some type of manual application or release feature, although these features are generally more difficult to operate. FRA believes that parking brakes are the functional equivalent of a traditional hand brake and are capable of providing a similar level of security to stationary equipment. Consequently, FRA added the term "parking brake" to the 1998 NPRM and has retained the term in this final rule.

In paragraph (d), FRA requires that the leakage of air from equalizing reservoirs on locomotives and related piping be zero. The equalizing reservoir contains the controlling volume of air pressure, which is set to a desired pressure by the locomotive engineer by setting the regulating valve (also known as the "feed valve") on the automatic air brake system. When the automatic brake valve handle is moved to the release position, air supplied from the locomotive air compressor and the main air reservoirs is supplied to the equalizing reservoir through the

regulating valve. The brake pipe pressure will then be charged to the level of the air pressure contained in the equalizing reservoir. When an application of the train brakes is desired, the engineer moves the automatic brake valve handle into the application zone. The movement of the brake valve handle into the application zone shuts off the supply of air from the regulating valve to the equalizing reservoir, leaving the volume of air contained in the equalizing reservoir trapped in the equalizing reservoir. The pressure of the trapped air can then be reduced to a desired amount by movement of the automatic brake valve handle. This will result in the brake pipe pressure responding and being reduced to a pressure equal to the pressure contained in the equalizing reservoir. Furthermore, the air pressure in the brake pipe on most freight equipment will be maintained at the pressure in the equalizing reservoir due to the maintaining features of the brake system. Consequently, any leakage from the equalizing reservoir will affect the maintaining feature of the automatic air brake, causing the engineer to lose the ability to effectively maintain control of the brake pipe pressure and, thus, affecting the ability of the engineer to safely control the train in some circumstances.

One manufacturer of locomotives commented on the requirement contained in this paragraph, contending that the requirement should not be applied to locomotives utilizing electronic braking systems because such leakage is not detectable by the locomotive engineer. This commenter contends that on these types of braking systems a continuous demand is made on the compressor to offset any leakage and if the compressor cannot offset the leakage the engineer is notified and the train is automatically stopped if necessary. Thus, the systems are designed to be fail-safe in the event of excessive leakage. This commenter believes that FRA should recognize these types of designs and except them from the requirement contained in this paragraph.

FRA agrees that the electronic brake systems currently in use on some locomotives are designed to maintain equalizing reservoir pressure at a set limit. Because these systems are designed to offset equalizing reservoir leakage, the locomotive engineer would not experience any problem with the operation of the train's brakes if a minor leak occurs. However, if the leakage exceeds the ability of the system to maintain the pressure, a fault message would be displayed to the locomotive engineer and the train's brakes would be automatically applied, if necessary. Therefore, this section has been slightly modified from that proposed in the NPRM to allow locomotives that are equipped with these types of maintaining features to continue to operate with some leakage in the equalizing reservoir. However, this section makes clear that when such systems identify an equalizing reservoir leak, the railroad is to perform the repairs necessary to eliminate the leakage at the nearest forward location where such repairs can be made. Generally a leakage on these electronic braking systems will be discovered when maintenance personnel review the fault screen during routine inspections and tests. Therefore, if a locomotive is equipped with a braking system that has the ability to maintain equalizing reservoir pressure, with the automatic brake valve set in the freight position or direct release, an equalizing reservoir leak will generally not be required to be repaired until it is either identified by the inspection forces or until the locomotive engineer identifies the condition during the normal operation of the train.

In paragraph (e), FRA retains the proposed prohibition on the use of "feed or regulating valve braking," in which reductions and increases in the brake pipe pressure are effected by manually adjusting the feed valve. "Feed valve braking" has been recognized by both the railroad industry and FRA as an unsafe practice. Most railroads already have some type of operating rule prohibiting this type of braking. No comments were received objecting to the inclusion of this prohibition in response to the NPRM.

In paragraph (f), FRA also retains the proposed prohibition on the use of the "passenger" position on the locomotive brake control stand on conventional freight trains when the trailing equipment is not designed for graduated brake release. The "passenger" position was intended only for use with equipment designed for graduated brake release. Therefore, use of the "passenger" position with other equipment can lead to potentially dangerous situations where undesired release of the brakes can easily occur due to the slightest movement of the automatic brake valve. In FRA's view, the only situation when the use of the passenger position might become necessary to safely control a train is when equalizing reservoir leakage occurs en route. If such a situation arises, this paragraph makes clear that the train may move only to the nearest forward location where the equalizing reservoir leakage can be corrected. No objections were received by FRA in response to the NPRM with regard to these requirements.

Paragraph (g) contains an existing requirement which was inadvertently excluded from the NPRM. This paragraph makes clear that engineers must know that the brakes on locomotives of which they are taking charge are in operative condition. This requirement is currently contained at § 232.10(l). Thus, FRA is not imposing a new burden by incorporating this requirement into the final rule. Furthermore, FRA does not intend to create a new inspection requirement by including this provision, but intends for it to be applied and enforced in the same manner as the existing requirement. If a locomotive engineer relieves another engineer, the condition of the brakes could be determined, based on a conversation or report from the engineer being relieved. The railroad may also elect to have mechanical forces inspect the locomotive for proper operation of the brakes and have the locomotive engineer accept the locomotives based on the mechanical department's inspection. However, a locomotive engineer may have to conduct a cursory inspection and perform a running test of the brake system to satisfy this requirement, if a prior inspection has not been performed.

Section 232.107 Air Source Requirements

This section contains requirements directed at ensuring that freight brake systems are devoid, to the maximum extent practical, of water and other contaminates which could conceivably deteriorate components of the brake system and, thus, negatively impact the ability of the brake system to function as intended. The general preamble section of this rule provides a detailed discussion as to why FRA proposed many of the items contained in this paragraph. *See* discussion contained in "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "Air Source Requirements." Based on the work performed by and information gathered by the RSAC Working Group and based on FRA field experience, FRA continues to believe that requiring locomotives to be equipped with air dryers would provide minimal safety benefits and would impose an enormous and unwarranted cost burden on the railroads. Further, FRA continues to believe that simply requiring that yard air sources be equipped with air dryers may not necessarily effectuate the

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desired results unless the air dryers are appropriately placed to sufficiently condition the air source. Many yard air sources are configured such that a single air compressor services several branch lines used to charge train air brake systems and, therefore, multiple air dryers may be required to eliminate the introduction of wet air into the brake system. FRA believes that, as with locomotives, requiring yard air sources to be equipped with air dryers would likely impose a significant and unnecessary cost burden on the railroads.

This section retains the basic requirements regarding yard air sources and cold weather operations that were proposed in the NPRM with minor modification based on the comments submitted in response to the proposal. Paragraph (a) retains the provisions requiring railroads to adopt and comply with a plan to monitor all yard air sources to ensure that the yard air sources operate as intended, are in proper condition, and do not introduce contaminants into the brake system of freight equipment. FRA intends to make clear that the inspections required under this paragraph are to be thorough inspections of the entire yard air source. This inspection would include all compressors, piping, hoses, valves, and any other component or part of the yard air source to ensure it is in proper condition and operates as intended.

Paragraph (a) modifies some of the proposed requirements related to the yard air source monitoring plans. FRA agrees with the comments provided by several labor representatives that the proposed requirements did not establish a frequency with which inspections of yard air sources should be conducted. In proposing the requirement, FRA hoped that various commenters would recommend frequencies for conducting these inspections. This did not occur. FRA agrees that a set frequency needs to be established which will ensure that yard air sources are inspected in a timely manner during various climatic conditions. Therefore, paragraph (a)(2)(i) requires that the monitoring plan developed by a railroad ensure that each yard air source be inspected at least twice each calendar year and that two of the inspections be no less than five months apart. FRA intends for this requirement to result in yard air sources being inspected each year during two different seasonal periods.

Paragraph (a)(2)(ii) clarifies that remedial action under the monitoring plans is required only on those yard air sources that are not operating as intended or that are found introducing contaminants into brake systems. Thus, the final rule removes the word "potential" from the proposed language as FRA agrees that the proposed language was unclear and may have been over-inclusive. The final rule also eliminates the proposed requirement for railroads to conduct a detailed assessment of the remedial actions taken. FRA agrees with the assertions of AAR that this proposed requirement is unnecessary because railroads will be conducting regular inspections of the yard air sources on which they have conducted repairs or taken other remedial action and will be able to determine if the repair were effective through those inspections. Paragraph (a)(3) retains the other proposed record keeping requirements related to yard air monitoring plans but clarifies that the records can be maintained either electronically or in writing. FRA continues to believe that these records are necessary to ensure that railroads are properly conducting the required inspections and are taking timely and appropriate remedial action when a problem air source is detected.

The final rule does not contain provisions requiring FRA approval of the yard air source monitoring plans prior to their implementation as suggested by some commenters. FRA does not have the personnel or resources to review and approve the plan of each railroad and does not believe such approval is necessary given the specific requirements contained in the final rule and the records that are required to be maintained. Although the final rule does not contain requirements regarding the use of air dryers on either locomotives or yard air sources, FRA advocates the use of air dryers when possible and agrees that they have proven effective in reducing the level of moisture introduced into the brake system. However, FRA believes that a railroad is in the best position to determine where these devices will provide the greatest benefit based on the railroad's operation. FRA notes its disagreement with AAR's contentions regarding both the time and the cost necessary to implement the required yard air source monitoring plans. FRA sees no reason why a railroad would need five years to implement a plan to inspect each of its yard air sources twice a year. These devices are used on a fairly regular, if not daily, basis and should not be that difficult to inspect. Consequently, FRA believes that railroads should easily be able to implement these monitoring plans by the three-year effective date provided in this final rule.

Paragraphs (b) and (d) contain additional measures to minimize the possibility of moisture being introduced into the trainline. Paragraph (b) of this section reiterates the proposed and current requirement contained at § 232.11(d), which requires that condensation be blown from the pipe or hose from which compressed air is taken prior to connecting the yard air line or motive power to the train. As an additional precaution, paragraph (d) of this section retains the proposed requirement that yard air reservoirs be equipped with an operable automatic drain system, or be manually drained at least once each day that the devices are used or more often when moisture is detected in the system.

Paragraph (c) generally retains the proposed ban on the use of chemicals in a train air brake system. However, FRA agrees with the position asserted by several commenters that the proposed prohibition of all chemicals may have been somewhat overbroad and contrary to FRA's actual intent. In proposing the prohibition FRA intended to eliminate the use of chemicals, such as alcohol, which are known to degrade the rubber of a train's brake system. FRA agrees that there may be chemicals which are currently available or which are in the process of being developed which do not cause the problems associated with the use of alcohol. In fact, FRA believes there are products currently available which do not degrade a brake system's rubber components. FRA believes that several railroads are currently testing or using these chemical alternatives. Therefore, FRA believes that there are alternatives to using alcohol which currently exist or can be developed which would provide railroads the ability to address the rare instances where trainlines become frozen. Consequently, this paragraph slightly modifies the prohibition on the use of chemicals by imposing the prohibition on chemicals that are known to degrade or harm brake system components, such as alcohol.

It should be noted that FRA recently published a final rule mandating the incorporation of two-way EOTs on a variety of freight trains, specifically those operating at speeds of 30 mph or greater or in heavy grade territories. *See* 62 FR 278. Two-way EOTs provide locomotive engineers with the capability of initiating an emergency brake application that commences at the rear of the train in the event of a blockage or separation in the train's brake pipe that would prevent the pneumatic transmission of the emergency brake application from the front of the train through the rest of the train. These devices consist of a front unit, located in the cab of the controlling locomotive, and a rear unit, located in the rear of the train and attached to the brake pipe. Radio communication between the front and rear units is continually monitored and confirmed at regular intervals, and the rear unit is only activated when continuity of these radio transmissions is not maintained over a specified time interval. This discussion of two-way EOTs is particularly appropriate within the context of the air source requirements. In the unlikely event that compliance with the requirements contained in this section regarding dry air fails to sufficiently eliminate moisture from the trainline, and a restriction or obstruction in the form of ice develops as the result of freezing of this moisture during cold weather operations, the two-way EOT device becomes a first-order safety device and will initiate an emergency application of the brakes from the rear of train. As such, the vast majority of concerns associated with moisture in the trainline freezing during cold weather operations have been alleviated through the incorporation of this technology in most freight operations.

Paragraph (e) retains the proposed requirement that a railroad adopt and comply with detailed written operating procedures tailored to the equipment and territory of the railroad to promote safe train operations during cold weather situations. In 1990, the NTSB, in response to an accident which occurred in Helena, Montana, recommended that FRA amend the power brake regulations to require additional testing of air brake systems when operating in extreme cold, especially when operated in mountain grade territory. *See* NTSB Recommendation R–89–081 (February 12, 1990). In response to this recommendation and to various petitions for rulemaking requesting similar action, FRA in the 1994 NPRM proposed various requirements regarding cold weather operations, which included: use of two-way EOTs; prohibition on the use of alcohol in trainlines; air dryers on locomotives; and requirements for railroads to develop procedures for operating during cold weather and in mountain grade territories. As noted previously, a final rule regarding the use of two-way EOTs has been issued and is in effect. This final rule also prohibits the use of certain anti-freeze chemicals, contains other requirements to ensure that dry air is being added to brake systems, and retains the previously proposed requirement that railroads adopt and comply with operating requirements for cold weather and heavy-grade operations.

FRA recognizes that in the past there has been little support for mandating additional brake system testing during cold weather. FRA agrees that the development and use of welded pipe fittings, wide-lip hose couplings, and ferrule clamps have greatly reduced the effects of cold weather on the air brake system. However, FRA continues to believe that cold weather situations do involve added safety risks and need to be further addressed. FRA believes that requiring the development of written operating procedures will require railroads to go through the thought process necessary to analyze their operations during cold weather conditions in order to determine the inherent safety hazards involved and develop procedures to minimize those hazards. Due to the unique nature of each railroad and the difficulty in developing specific requirements that are applicable to all operations, FRA does not intend to mandate specific operating requirements at this time. However, FRA might consider mandating specific operating requirements that should be included in a railroad's cold weather operating practices if it is found that railroads do not develop sufficient requirements to address safe cold weather operations.

FRA recognizes that some railroads have already developed certain cold weather operating procedures which might be useful as models on other similarly situated railroads. For example, BNSF has unilaterally instituted a cold weather operating plan for certain trains at specific locations in Montana. This plan requires trains with greater than 100 tons per operative brake to be inspected or operated in a certain manner when temperatures fall below zero degrees. Part of the plan requires that after the performance of a 1,000-mile or initial terminal brake test on such trains, the brakes be reset and held for 30 minutes after which time the train is to be reinspected to ensure that 100 percent of the brakes remained applied. Brakes found not to have remained applied must be set out of the train or repaired. FRA believes that procedures such as these could greatly enhance the safety of the trains operated in cold weather conditions. FRA recognizes that there may be other types of operating or inspection criteria that could be implemented in extreme cold weather instead of, or in addition to, that noted above; such as, limits on the length or tonnage of such trains, limits on the use of yard air sources, or other enhanced inspection criteria. At this time, FRA continues to believe that railroads are in the best position to determine what procedures are best suited to their operations.

Section 232.109 Dynamic Brake Requirements

This section contains the operating requirements for trains equipped with dynamic brakes. Most, if not all, of the railroads participating in and commenting on this rulemaking have asserted that they do not consider dynamic brakes to be a safety device. However, these same commenters admit that they promote and encourage the use of dynamic brakes for purposes of fuel efficiency and to avoid wear to brake components. Due to this encouragement, dynamic brakes are relied on to control train speed and to provide assistance in controlling trains on heavy grades. Contrary to continued comments of several labor representatives, FRA does not feel that locomotives should be required to be equipped with dynamic brakes. FRA believes that the decision to equip a locomotive with dynamic brakes is mainly an economic one, best determined by each individual railroad. However, in order to prevent accidents and injuries that may result from an over-reliance on the dynamic brake, which may fail at any time, FRA believes that if the devices are available, engineers should be informed on their safe and proper use and be provided with information regarding the amount of dynamic braking power actually available on their respective trains. FRA continues to believe that by providing an engineer with as much information as possible on the status of the dynamic brakes on a train, a railroad better enables that engineer to operate the train in the safest and most efficient manner.

Paragraph (a) generally retains the proposed requirement that a locomotive engineer be informed of the operational status of the dynamic brakes on the locomotives the engineer will be required to operate. This paragraph makes clear that the information is to be provided to the locomotive engineer at a train's initial terminal and at other locations where a locomotive engineer first begins operation of a train. This paragraph slightly modifies the proposed method for providing this information to the locomotive engineer. The NPRM proposed that the locomotive engineer be provided the required information in writing. The intent of the proposed requirement to notify the locomotive engineer in writing as to the operational status of the dynamic brakes was to ensure that the engineer had timely information on

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the condition of the locomotives so he or she could operate the train in the safest possible manner based upon that information. Thus, FRA tends to agree with the comments of several railroads and their representatives that the manner in which the information is provided to the engineer should not be a major concern provided the information is accurate and up-to-date. Therefore, this paragraph allows railroads to provide a locomotive engineer with the required information by any means they deem appropriate. However, this paragraph also makes clear that a written or electronic record of the information provided shall be maintained in the cab of the controlling locomotive. This will ensure that relief or other oncoming engineer will have the information provided to the previous operator of the train.

This paragraph also clarifies that the information is to be provided to the locomotive engineer at the train's initial terminal and at other locations where an engineer "first begins operation" of the train rather than where the engineer "takes charge of the train." This clarification is in response to comments provided by certain labor representatives to prevent possible misinterpretation or abuse of the requirement since most railroads consider the conductor to be in charge of a train.

Paragraph (b) retains the proposed requirement to repair a locomotive with inoperative dynamic brakes within 30 days of its being found inoperative or at the locomotive's next periodic inspection, whichever occurs first. There are currently no requirements governing the maintenance and repair of dynamic brakes. Experience has shown that, since railroads do not consider dynamic brakes to be a critical safety item, repairs are typically effectuated when it is convenient and economical for the railroad, with little regard for timeliness. FRA believes that, as railroads have become increasingly dependent on the use of dynamic brakes as an integral part of their published safe train handling procedures, it is a reasonable expectation on behalf of locomotive engineers to have operable dynamic brakes on those locomotive units which are so equipped. Due to the industry's reliance on these braking systems, as noted in the discussion above, FRA continues to believe they should be repaired as soon as possible after being found inoperative. FRA agrees that there must be an appropriate balance between the operational considerations important to the locomotive engineer and the logistical and repair considerations that will be imposed on the railroads. FRA continues to believe that 30 days provides a railroad with sufficient time to get a locomotive to a location where the dynamic brakes can be repaired and allows for the reallocation of motive power when necessary so as to cause minimal disruption to a railroad's operation. Although certain commenters requested that the period allowed for repair be reduced to 15 days or less, FRA believes such a reduction is unwise as it might jeopardize a railroad's access to available motive power and could cause delay in the movement of freight, consequences that may create safety hazards themselves.

This paragraph also eliminates the use of the term "ineffective dynamic brake" and replaces it with the term "inoperative dynamic brake." The term "inoperative dynamic brake" is defined in § 232.5 of the final rule to mean any dynamic brake which no longer provides its designed retarding force on the train, for whatever reason. FRA agrees with the comment of the AAR that the use and meaning of the term "ineffective dynamic brake" in the proposal was unclear and had the potential of creating misunderstandings. Consequently, for clarity this section uses only the term "inoperative dynamic brake" to describe a defective dynamic brake.

Paragraph (c) retains the proposed requirements related to the tagging of a locomotive found with inoperative dynamic brakes. FRA believes that the tags required by this paragraph are necessary to ensure the prompt and timely repair of locomotives found with defective dynamic brakes and also provide locomotive engineers and a railroad's ground forces with specific knowledge of the presence of such a locomotive. Contrary to the comments of some parties, FRA does not believe that the tagging provisions contained in this paragraph would require the development of new tags. This paragraph would allow the use of any type of tag provided it is placed in a conspicuous location on the cab of the locomotive and contains the required information.

Paragraph (d) contains a requirement that an electronic or written record of repairs made to a locomotive's dynamic brakes be maintained and retained for a period of 92 days. Although this requirement was not proposed in the NPRM, FRA believes these records fall within the scope of the notice and are necessary to ensure that repairs are conducted on a locomotive's dynamic brakes in a timely fashion. FRA also believes that such a record will provide a railroad with information regarding the operation of the dynamic brakes and will potentially permit railroads to identify a repeated problem with a locomotive's dynamic brakes to prevent recurrences of the problem and thus, increase the utilization of a locomotive's dynamic brakes.

The final rule continues to acknowledge that some railroads, primarily short lines, may own locomotives that are equipped with dynamic brakes but due to the physical terrain over which the railroad operates or the operating assignments of the particular locomotive, the railroad rarely, if ever, has the need to employ the dynamic braking capabilities of the individual locomotive. In these instances, the maintenance requirements discussed above become unnecessarily burdensome. Therefore, FRA continues to believe that relief is warranted in these situations provided a specified set of parameters is developed and adhered to that prevents direct and intentional circumvention of the proposed repair requirements. Therefore, paragraph (e) retains the proposed provision permitting a railroad to declare a locomotive's dynamic brakes "deactivated" if the following requirements are met: (i) The locomotive is clearly marked with the words "dynamic brake deactivated" in a conspicuous location in the cab of the locomotive; and (ii) the railroad has taken appropriate action to ensure that the deactivated locomotive is incapable of utilizing dynamic braking effort to retard or control train speed. It should be noted that the final rule eliminates the requirement to stencil the outside of a locomotive declared to have deactivated dynamic brakes. FRA agrees with the comments submitted by the AAR and other railroad representatives that defacing the exterior of the locomotive is unnecessary and would do little to inform the locomotive engineer of the deactivation of the dynamic brake. FRA believes that the requirements to notify the locomotive engineer of the operational status of the locomotives and to have the cab of the locomotive clearly marked that the locomotive's dynamic brakes are deactivated provide sufficient notice to the locomotive engineer as to the status of that locomotive.

This paragraph does not prescribe the specific manner in which a locomotive is to be deactivated, so long as the unit is not physically capable of employing its dynamic brakes to aid in train handling. Although FRA does not envision a significant number of instances where a locomotive which has been declared "deactivated" would need to be "reactivated," FRA does recognize that some railroads may need to reactivate the dynamic brakes in some circumstances, such as changes in a locomotive's operating environment or situations where a locomotive with previously "deactivated" dynamic brakes is purchased by another railroad. However, FRA intends to interpret the provision for "*deactivating*" a locomotive's dynamic brakes rather literally to minimize contentions that railroads are merely playing a cat and mouse game with the required maintenance interval to avoid repairing the units. Furthermore, FRA would expect the dynamic brakes on a locomotive to be fully functional at the time the locomotive is considered reactivated.

Paragraph (f) contains specific requirements related to the use of a locomotive with inoperative, deactivated, or no dynamic brakes as a controlling locomotive. These requirements are based on FRA's review of the comments submitted in response to FRA's request regarding the positioning of such locomotives contained in the NPRM. *See* 63 FR 48314. FRA tends to agree that there are no technical reasons why a locomotive with inoperative dynamic brakes cannot function as the controlling locomotive provided it can control the dynamic brakes on trailing units in the locomotive consist. However, FRA also agrees that a locomotive engineer loses the physical sensation of the operation of the dynamic brakes when the unit the engineer is riding loses dynamic brake capability because the physical sensation of operating dynamic brakes provides the engineer with at least some assurance that the dynamic brakes on some of the units in the consist are operating. Thus, this paragraph makes clear that locomotives with inoperative, deactivated, or no dynamic brakes have the capability of controlling the dynamic brakes on trailing units when operating as the controlling locomotive, and that such locomotives also have the capability of displaying to the locomotive engineer the deceleration rate of the train or the total train dynamic brake retarding force. FRA believes this requirement will ensure that locomotive engineers have at least some information as to the operation of the dynamic brakes in the locomotive consist they are controlling. FRA intends that the information required by this provision be provided by a device known as an "accelerometer", "predictor", or a similar type of device; or by a dynamic brake indicator capable of providing total train dynamic brake retarding force to the locomotive engineer. An "accelerometer" or "predictor" is a device currently used in the industry that indicates the predicted speed in miles per hour of the locomotive 60 seconds from the present, based on the computed acceleration or deceleration rate. This would provide the engineer with an indication of the retarding performance of the dynamic brakes and the train.

Paragraph (g) contains provisions requiring new locomotives to be equipped with some sort of dynamic brake indicator. In the NPRM, FRA sought information and comments regarding the feasibility of dynamic brake indicators which continually monitor the operation of dynamic brakes in a train consist. *See* 63 FR 48334. The NTSB noted that the NPRM failed to address its recommendation resulting from its investigation of the January 12, 1997, freight train derailment near Kelso, California, that all locomotives equipped with dynamic brakes be equipped with a device in the cab of the controlling locomotive to indicate real-time condition of the dynamic brakes on each trailing unit. *See* NTSB Recommendation R–98–6. Based on a review of the comments and information provided, FRA continues to believe that the technology does not currently exist to economically equip existing locomotives with dynamic brake indicators. However, FRA does believe that the technology exists or is sufficiently developed to provide new locomotives with the ability to test the electrical integrity of the dynamic brakes at rest and to display the total train dynamic brake retarding force at various speed increments in the cab of the controlling locomotive. Consequently, this paragraph requires new locomotives to be equipped with such indicators. FRA recognizes that the industry will require a little time to incorporate the existing and developing technology into new locomotives. Therefore, the requirements contained in this paragraph will apply only to locomotives ordered one and one-half years after the issuance of this final rule and to locomotives placed in service for the first time three years after the effective date of the final rule.

Paragraph (h) contains requirements for equipping rebuilt locomotives with devices to provide locomotive engineers with additional information on the operation of dynamic brakes on other locomotives in the train consist. This paragraph recognizes that not all locomotives being rebuilt are designed, or have the capability of being redesigned to have the capability to display the total train dynamic brake retarding force in the cab of the controlling locomotive. Thus, this paragraph allows rebuilt locomotives to be designed to display the train deceleration rate (i.e., to be equipped with an accelerometer, predictor, or similar device as described above) in lieu of being equipped with the dynamic brake indicator required on new locomotives. FRA believes that the information provided by these indicators is extremely useful to an engineer, will provide the engineer with ready access to real-time information on the operation of the dynamic brakes in a locomotive consist, and will permit the engineer to control and operate trains in the safest manner possible.

Paragraph (i) acknowledges that the information provided to a locomotive engineer by a dynamic brake indicator would satisfy the need to provide the locomotive engineer with information regarding the operational status of the dynamic brakes when the engineer first begins operation of a train. As the indicators would provide real-time information to the engineer on the operation of the dynamic brakes in the train consist, a separate set of information received by the engineer when beginning operation would be unnecessary. Therefore, this paragraph carves out an exception to the requirement to inform locomotive engineers of the status of the dynamic brakes for situations when all of the locomotives in the lead consist are equipped with dynamic brake indicators of the type required for new locomotives. FRA believes that this exception makes sense from a practical perspective and also provides some incentive for railroads to equip existing equipment with such indicators where possible when the technology for doing so becomes economically feasible. It should be noted that there is no requirement that the dynamic brake status of distributed power units be provided in order to eliminate the need to provide dynamic brake information to the engineer. FRA agrees that the technology for transmitting that information to the engineer is not currently available in a cost effective and reliable manner.

Paragraphs (j) and (k) retain the proposed provisions requiring railroads to adopt and comply with written operating rules governing the use of dynamic brakes and to incorporate training on those operating rules into the locomotive engineer certification program pursuant to 49 CFR part 240. Contrary to the assertions of some commenters FRA does not believe these requirements are unclear. FRA intends for each railroad to develop appropriate operating rules regarding train handling

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procedures when utilizing dynamic brakes that cover the equipment and territory operated by the railroad. Many railroads already have these procedures in place and already provide training to their employees which adequately cover the requirements. FRA continues to believe that training on proper train handling procedures is essential to ensuring that locomotive engineers can properly handle their trains with or without dynamic brakes and in the event that these brake systems fail while the train is being operated. FRA also disagrees that it must specify the knowledge, skill, and ability criteria that a railroad must adopt into its training program. FRA believes that each railroad is in the best position to determine what these criteria should be and what training is necessary to provide that knowledge, skill, and ability to its employees.

FRA continues to believe that the establishment of these comprehensive operating rules and their incorporation into a railroad's training plans is the most effective means by which to minimize the possibility of future accidents caused by excessive reliance on dynamic brakes by a train crew as a method of controlling the speed of a train in its descent through a difficult grade, as was the case in the San Bernardino incident. FRA views as unfortunate the number of existing train handling and power brake instructions issued by freight railroads that emphasize the use of dynamic brakes but do not include prominent warnings that such systems may not be relied upon to provide the margin of safety necessary to stop short of obstructions and control points or to avoid overspeed conditions. FRA believes that such instructions, while not misleading to seasoned locomotive engineers, could lead to an excessive reliance on these systems. Given the ever-increasing weight and length of freight trains, and the severe grades that they are often required to negotiate en route, the need for locomotive engineers who are thoroughly trained and knowledgeable in all aspects of train handling is paramount for continued safety in the rail industry.

Paragraph (j)(2) requires that the operating rules developed by railroads under this section include a "miles-per-hour-overspeed" requirement that requires trains to be immediately stopped if they exceed the maximum authorized speed by more than 5 mph when descending grades of one percent or greater. The NTSB recommended that FRA adopt such a requirement as a result of its investigation of the freight train derailment near Kelso, California noted above. *See* NTSB Recommendation R–98–4. FRA agrees with NTSB's recommendation and also agrees with the comments provided by both the NTSB and the CAPUC that this requirement accomplishes a critical safety function and reduces the potential for runaways because it establishes a clear rule for stopping a train and removes any discretion from the operator to continue operation of a train. This paragraph makes clear that the five-mph limitation is a good base limitation which should be reduced by a railroad if it so desires or if a reduction is indicated by validated research. The five-mph limitation may only be increased with FRA approval. FRA notes that the operating rules of virtually every Class I railroad already include a five-mph-overspeed provision similar to that contained in this paragraph. Consequently, FRA's inclusion of the requirement in this final rule should impose little or no burden on the operations of most railroads.

Section 232.111 Train Information Handling

This section retains the proposed requirements regarding the handling of train information, with slight modification in response to the comments submitted by interested parties. The purpose of the train-information handling requirements contained in this section is to ensure that a train crew is provided accurate information on the condition of a train's brake system and other factors that affect the performance of a train's brake system when the crew assumes responsibility for a train. This section contains a list of the specific information railroads are to furnish train crew members about the train and the train's brake system at the time they take charge of the train. FRA continues to believe that train crews need this information in order to avoid potentially dangerous train handling situations and to be able to comply with various Federal safety standards. Many railroads already provide their train crews with most of the information required in this section or have a process set up that can transmit such information; thus, the impact of these requirements should be relatively minor.

Paragraph (a) has been slightly modified to clarify that the information required to be provided in this section may be provided by any means determined appropriate by the railroad, provided, that a record of the information is maintained in the cab of the controlling locomotive. This requirement does not constitute a change from what was proposed in the NPRM but is merely a clarification to resolve an apparent misunderstanding of some parties. In the NPRM, FRA noted that it intended to leave the method in which the required information would be conveyed to train crews to the discretion of each railroad. FRA believed that each individual railroad is in the best position to determine the method in which to dispense the required information based on the individual characteristics of its operations. However, FRA noted that the means for conveying the required information would have to be part of the written operating requirements, and railroads would be required to follow their own requirements.

Paragraphs (b)(1) and (b)(2) have also been slightly modified, for purpose of clarity, from what was proposed in the NPRM. Paragraph (b)(1) clarifies that train crews are to be provided the required information when "taking charge of a train" rather than when "coming on duty" as was proposed. FRA agrees with the comments of the AAR that the modified language better clarifies when the required information is to be provided. Paragraph (b)(2) has been modified to clarify that the weight and length information to be provided should be based on the best information available to the railroad. FRA agrees with the comments of the AAR and several railroads that it is impossible to provide the exact weight of each car in a train because the facilities to weigh each car do not exist. FRA also agrees that it would be cost prohibitive and unrealistic to require that each car be weighed prior to being moved in a train. Consequently, the final rule makes clear that the weight of the train can be estimated based on the best information available to the railroad. It should be noted that FRA has eliminated the proposed requirement that train crews be provided a record of train configuration changes since performance of the last Class I brake test. FRA agrees that such information is not necessary based on the other information that is required to be provided and has the potential of creating information overload for the train crews.

Subpart C—Inspection and Testing Requirements

Section 232.201 Scope

This section contains the general statement regarding the scope of this subpart, indicating that it contains the inspection and testing requirements for brake systems used in freight and other non-passenger trains. This section also indicates that this subpart contains the general training requirements for railroad and contract personnel who perform the inspections and tests required by this part.

Section 232.203 Training Requirements

This section contains the general training requirements for railroad employees and contractor employees that are used to perform the inspections required by this part. (See "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "V. Training and Qualifications of Personnel" for a detailed discussion pertaining to the provisions contained in this section.) This section retains the basic structure and concepts regarding the training and qualification of individuals performing inspections and tests required by this part that were proposed in the NPRM. The training requirements contained in this final rule have been slightly revised from those proposed in the NPRM in order to clarify FRA's intent, to recognize existing training, and to reduce some of the burden that may have been inadvertently created by the proposed requirements.

Paragraph (a) requires that each railroad and each contractor adopt and comply with a training, qualification, and designation program for railroad employees and contractor employees who perform air brake system tests, inspections and maintenance. This paragraph modifies the proposed provision that would have required a railroad to provide training to the personnel of a contractor whom the railroad uses to perform the various tasks required by the rule. This paragraph makes clear that the contractor is responsible for providing appropriate training to its employees and maintaining the required records and information. FRA agrees with the comments submitted on behalf of numerous railroads that asserted that railroads should not bear the burden of training the employees of a contractor. However, FRA notes that this change does not relieve the railroad from potential civil penalties for, e.g., failure to perform a proper Class I brake test, if the employees of a contractor are found not to be qualified to perform the task for which they are assigned responsibility. Both the railroad and the contractor would remain liable for potential civil penalties if the employees used to perform a particular task were not trained and qualified in accordance with the training requirements contained in this final rule.

For purposes of this section, a "contractor" is defined as a person under contract with a railroad or a car owner or an employee of a person under contract with a railroad or a car owner. FRA intends for the training and qualification requirements to apply not only to railroad personnel but also to contract personnel that are responsible for performing brake system inspections, maintenance, or tests required by this part. FRA believes that railroads and contractors are in the best position to determine the precise method of training that is required for the personnel they use to conduct required brake system inspections, tests, and maintenance. Although FRA provides railroads and contractors with broad discretion to develop training programs specifically tailored to their operations and personnel, FRA will expect railroads and contractors to fully comply with the training and qualification plans they adopt. A critical component of this training will be making employees aware of specific Federal requirements that govern their work. Currently, many railroad training programs fail to distinguish Federal requirements from company policy.

Paragraph (b) contains general requirements or elements which must be part of any training and qualification plan adopted by a railroad or contractor. FRA believes that the elements contained in this section are specific enough to ensure high quality training and broad enough to permit a railroad or contractor to adopt a training plan that is best suited to its particular operation. This paragraph retains the proposed requirement that the plan identify the tasks related to the inspection, testing, and maintenance of the brake system required to be performed by the railroad or contractor and identify the skills and knowledge necessary to perform each task. FRA believes that most railroads already have a training plan and would merely need to revise it to reflect changes made to existing requirements by this final rule. The final rule eliminates the proposed requirement to develop written procedures for performing each task identified. Although FRA believes that each railroad or contractor should and will develop such procedures, FRA does not believe it is necessary to require their development as FRA believes they will either be developed in the required training curricula or are sufficiently detailed in the regulation itself.

This paragraph also clarifies that the required training is intended to provide employees with the skills and knowledge necessary to perform the tasks required by this final rule. FRA does not believe it is necessary to train an employee on every different type of equipment that a railroad operates or on each and every task an employees will be required to perform. FRA's intent when issuing the NPRM was to ensure that the training received by an employee provides that individual with the knowledge and skills needed to perform the tasks he or she is assigned on the various types of brake systems on the equipment the railroad operates. Therefore, this paragraph clarifies this intent by specifically stating that the training curriculum, the examinations, and the "hands-on" capability should address the skills and knowledge needed to perform the various required tasks rather than focusing strictly on the tasks themselves or on the specific types of equipment operated by the railroad. However, FRA does intend for the training developed by the railroad or contractor to address the various types of brake systems the employee will be required to inspect, test, or maintain. For example, if an employee were trained on how to perform a Class I brake test and demonstrated hands-on capability to perform that task, FRA would not expect the employee to demonstrate hands-on capability to perform a Class IA or Class II brake test since the components of a Class I brake test cover these other inspections. However, FRA would expect the employee to receive classroom training on when these other inspections are required and the tasks that are involved in each.

This paragraph also clarifies that the training that an employee is required to receive need only address the specific skills and knowledge related to the tasks that the person will be required to perform under this part. Thus, a railroad or contractor may tailor its training programs to the needs of each of its employees based on the tasks that each of its employees will be required to perform. FRA tends to agree with several commenters that there is no reason for an individual who performs strictly brake inspections and tests to be as highly trained as a carman since carmen perform many other duties related to the maintenance and repair of equipment in addition to brake inspections.

This paragraph also clarifies that previous training and testing received by an employee may be considered by the railroad. FRA did not intend to require the complete retraining of every employee performing a task required in this final rule. When proposing the training requirements, FRA intended for railroads to incorporate existing training

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regimens and curricula into the proposed training programs. In order to clarify this intent, this paragraph permits railroads and contractors to incorporate an already existing training program, such as an apprenticeship program, and contains a specific provision which permits railroads and contractors to consider previous training and testing received by an employee when determining whether an employee is qualified to perform a particular task. Thus, railroads and contractors would most likely not need to provide much additional training, except training specifically addressing the new requirements contained in this part and possibly refresher training, to its carmen forces that have completed an apprentice program for their craft. However, the final rule also makes clear that any previous training or testing considered by a railroad or contractor must be documented as required in the final rule. Thus, previous training or testing which has not been properly documented cannot be considered. The final rule also makes clear that employees must be trained on the specific regulatory requirements contained in this final rule related to the tasks that the employee will be required to perform. Therefore, all employees will require at least some training which covers the specific requirements detailed in this final rule.

This paragraph retains the proposed requirements that any program developed must include experiential or "hands-on" training as well as classroom instruction. FRA believes that classroom training by itself is not sufficient to ensure that an individual has retained or grasped the concepts and duties explained in a classroom setting. In order to adequately ensure that an individual actually understands the training provided in the classroom, some sort of "hands-on" capability must be demonstrated. FRA believes that the "hands-on" portion of the training program would be an ideal place for a railroad to fully involve its labor force in the training process. Appropriately trained and skilled employees would be perfectly suited to provide much of the "hands-on" training envisioned by FRA. Consequently, FRA strongly suggests that railroads work in partnership with their employees to develop a training program which utilizes the knowledge, skills, and experience of the employees to the greatest extent possible.

This paragraph also retains, with modification for clarity, the proposed requirement that employees pass either a written or oral examination and demonstrate "hands-on" capability. This paragraph clarifies that the tests and demonstration of "hands-on" capability cover the skills and knowledge the employee will need to possess in order to perform the tasks required by this part that the employee will be responsible for performing rather than focusing strictly on the tasks themselves or on the specific types of equipment operated by the railroad. However, FRA does intend for the testing and "hands-on" demonstration to cover the various types of brake systems the employee will be required to inspect, test, or maintain. FRA continues to believe that in order for a person to be adequately trained to perform a task, the individual must not only possess the knowledge of what is required to be performed but also must possess the capability of applying that knowledge.

This paragraph also retains the proposed requirement regarding the performance of periodic refresher training and testing. The final rule retains the requirement that refresher training be provided at least once every three years and that it include both classroom and experiential "hands-on" training and testing. FRA continues to believe that periodic refresher training is essential to ensuring the continued ability of an employee to perform a particular task. FRA does not intend for such training to be as lengthy or as formal as the initial training originally provided, but believes that the training should reemphasize key elements of various tasks and focus on items or tasks that have been identified as being problematic or of poor quality by the railroad, contractor, or its employees through the periodic assessment of the training program. This paragraph makes clear that a railroad or contractor may use efficiency testing to meet the hands-on portion of the required refresher training provided such testing is properly documented and covers the necessary tasks to ensure retention of the knowledge and skill required to perform the employee's duties required by this part. FRA agrees that such testing provides the necessary assurances that the individual continues to have the knowledge and skills necessary to perform the task for which the employee is being tested.

This paragraph contains a provision that was not specifically included in the NPRM but which was intended by FRA to be covered by the established training programs. This paragraph requires that new brake systems be added to training programs prior to their introduction into revenue service. Several labor representatives recommended that this provision be explicitly added to the training provisions, and FRA believes this requirement is only logical and makes sense. FRA believes that, prior to the introduction of any new brake system, the employees responsible for inspecting and maintaining the equipment need to be specifically trained on the systems in order to adequately perform their required tasks.

This paragraph also retains the proposed requirement that supervisors exercise oversight to ensure that all identified tasks are performed in accordance with the railroad's procedures and the specific Federal regulatory requirements contained in this part. Although the final rule also does not specifically address the training that must be provided to supervisors as suggested by some commenters, FRA believes that supervisors are sufficiently covered by the requirements contained in this section. FRA believes that in order for a supervisor to properly exercise oversight of an employee's work, the supervisor must be trained and qualified to perform the tasks for which they have oversight responsibilities.

Paragraph (c) requires each railroad that operates trains required to be equipped with two-way EOTs and each contractor that maintains such devices adopt and comply with a training program which specifically addresses the testing, operation, and maintenance of the devices. The final rule requiring the use of two-way EOTs became effective on July 1, 1997. Since that time, FRA has discovered numerous operating and mechanical employees who do not fully understand when the devices are required or how the inspection and testing of the devices are to be accomplished. Furthermore, FRA believes that it is vital for those employees responsible for the use of the devices (e.g. engineers and conductors) to be intimately familiar with the use and operation of the devices to ensure that the full safety potential of the devices is utilized and available. Consequently, FRA believes that adequate training must be provided to those employees responsible for the inspection, testing, operation and use of two-way EOTs.

Paragraph (d) requires railroads that operate trains under conditions that require their employees to set retaining valves to develop training programs which specifically address the use of retainers and provide such training to those employees responsible for using or setting retainers. This provision has been added in response to an NTSB recommendation which FRA supports. *See* NTSB Recommendation R–98–7. The NTSB specifically suggested that an explicit requirement to provide this training be contained in the final rule. The NTSB had previously recommended such a requirement in early 1998 based on its investigation of the 1997 derailment of a freight train near Kelso, California. Many railroads are currently providing such training based on that recommendation and FRA believes that a specific requirement to provide such training will ensure that all railroads that require their employees to set retainers adequately train their employees responsible for performing the task on the use of retainers.

Paragraph (e) retains the record keeping requirements proposed in the NPRM with slight modification for consistency with the changes noted above regarding the application of the skills and knowledge necessary to perform a particular task. FRA continues to believe that the record keeping and designation requirements contained in this final rule are the cornerstone of the training requirements. Contrary to the views of some commenters, FRA believes that something more than mere lists of qualified employees is needed. Because the rule allows each railroad and contractor the flexibility to develop a training program that best fits its operation and does not impose specific curriculum or experience requirements, FRA continues to believe it is vital for railroads and contractors to maintain detailed records on the training they do provide. Such documentation will allow FRA to judge the effectiveness of the training provided and will provide FRA with the ability to independently assess whether the training provided to a specific individual adequately addresses the skills and knowledge required to perform the tasks that the person is deemed qualified to perform. Moreover, requiring these records will deter railroads and contractors from circumventing the training requirements and discourage them from attempting to utilize insufficiently trained personnel to perform the inspections and tests required by this rule.

This paragraph makes clear that the required records may be maintained either electronically or on paper. Many railroads currently maintain their training records in an electronic format, and FRA sees no reason not to permit such a practice if the information can be provided to FRA in a timely manner upon request. The proposed provision requiring the railroad's chief mechanical or chief operating officer to sign a statement regarding each employee's qualifications has been modified in the final rule to merely require identification of the person or persons making the determination that the employee has completed the necessary training. This modification will permit the information to be maintained electronically and will still provide the accountability which FRA intended by the provision in the NPRM. FRA believes it is absolutely essential that those individuals making the determinations regarding an employee's qualification be identified in order to ensure the integrity of the training programs developed and to prevent potential abuses by a railroad or contractor.

FRA also objects to the portrayal by some commenters that the requirement to maintain training records is overly burdensome. Virtually all of the items required to be recorded are currently maintained by most railroads in some fashion or another. Contrary to the concerns raised by some commenters, the rule does not require that the contents of each training program be maintained in each employee's file. Railroads are free to develop whatever type of cross-referencing system they desire, provided the contents of the training program are maintained in some fashion and can be readily retrieved. Furthermore, railroads currently maintain lists of individuals they deem to be qualified persons, and the companies inform those individuals as to their status to perform particular tasks. FRA believes this is a good practice and is necessary to ensure that individual employees do not attempt to perform, or are not asked to perform, tasks for which they have not been trained.

Paragraph (e) requires that each railroad or contractor adopt and comply with a plan to periodically assess the effectiveness of its training program. This paragraph modifies the proposed requirement that railroads develop an internal audit process to evaluate the effectiveness of their training. Although FRA agrees that a formal audit process may not be necessary, FRA continues to believe that railroads and contractors should periodically assess the effectiveness of their training programs. However, rather than require a formal internal audit, FRA believes that periodic assessments may be conducted through a number of different means and each railroad or contractor may have a need to conduct the assessment in a different manner. This paragraph requires that a railroad or contractor institute a plan to periodically assess its training program and, as suggested by some commenters, the paragraph permits the use of efficiency tests or periodic review of employee performance as methods for conducting such review. FRA agrees that many railroads, due to their small size, are capable of assessing the quality of the training their employees receive by conducting periodic supervisory spot checks or efficiency tests of their employees' performance. However, FRA continues to believe that on larger railroads the periodic assessment of a training program should involve all segments of the workforce involved in the training. FRA believes it is vital that labor be intrinsically involved in the assessment process, from beginning to end. For example, evaluation of training techniques might best be approached through a "team" method, where several observers, including labor representatives, periodically evaluate course or "hands-on" training content and presentation.

Section 232.205 Class I Brake Test-Initial Terminal Inspection

This section describes the circumstances that would mandate the performance of a Class I brake test and outlines the tasks that must be performed when performing this inspection. Most of the provisions contained in this section are currently contained in § 232.12(a) and (c)–(h) or were proposed in the 1998 NPRM in order to clarify existing requirements, to eliminate potential abuses, and to standardize certain provisions. Basically a Class I brake test is intended to be the functional equivalent to what is currently referred to as an "initial terminal brake inspection."

Paragraph (a) identifies those trains that are required to receive a Class I brake test prior to movement from a location. The provisions contained in this paragraph are virtually identical to those proposed in the NPRM, with slight modification for clarity. Paragraph (a)(1) requires that a train receive a Class I brake test at the location where it is originally assembled. It should be noted that the final rule eliminates the term "point of origin" proposed in the NPRM. FRA agrees that the proposed definition of this term was duplicative of the term "initial terminal" and merely created potential misunderstandings. Moreover, FRA agrees that the problems attempted to be addressed by the use of this term are sufficiently addressed by the various inspections required in this final rule when cars are added to a train.

Paragraph (a)(2) requires the performance of a Class I brake test when the train consist is changed other than by adding or removing a solid block of cars. Currently, there appears to be some confusion over what constitutes a "solid block of cars." In order to clarify the

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issue, FRA proposed a definition of "solid block of cars" in the NPRM. In response to numerous comments regarding the proposed definition and to further clarify the issue, FRA has modified the definition in this final rule and referenced that definition in this paragraph. Although FRA believes that the definition it proposed is consistent with current interpretations and enforcement of the requirement, FRA agrees with some of the commenters that the proposed definition may have been too narrow and did not directly address FRA's primary concern, the block of cars itself. FRA's primary concern is the condition of the block of cars being added to the train, especially when the block of cars is made up of cars from more than one train. Thus, the final rule will permit a solid block of cars to be added to a train without triggering a requirement to perform a Class I brake test on the entire train. However, depending on the make-up of that block of cars, certain inspections will have to be performed on that block of cars at the location where it is added to the train.

FRA believes that limits have to be placed on the number of blocks of cars being added to a train in order to ensure that cars are being inspected in a timely manner and in accordance with the intent of the regulations. Some commenters suggest that a block of cars should be permitted to be added to a train with no inspection other than a continuity test regardless of the number of different trains the cars making up the block came from provided all the cars received a Class I brake test at their point of origin. Other commenters suggest that any number of blocks of cars should be permitted to be added to a train at a single location. FRA believes that to accept either of these positions would be tantamount to eliminating initial terminal and intermediate inspections and would drastically reduce the safety of freight trains being operated across the country. In FRA's view, both of the positions noted above are merely means to circumvent inspections and are akin to a practice known as "block swapping" in the mechanical inspection context, a practice that FRA does not permit. In FRA's opinion, the authority to add multiple blocks of cars to a train at one location or add a single block of cars to a train that is composed of cars from numerous different trains without inspecting the cars in those blocks, would essentially allow railroads to assemble new trains without performing any direct inspection of any of the cars in the train. Furthermore, if cars are permitted to be moved in and out of a train at will, determining when and where a Class IA brake test must be performed on the train will be impossible.

This paragraph requires the performance of a Class I brake test at locations where more than one "solid block of cars" is added to or removed from a train. It should be noted that the final rule permits both the addition and the removal of a "solid block of cars" at a location without requiring the performance of a Class I brake test on the entire train. Although this practice is not permitted under the existing regulations, FRA believes that the inspection requirements contained in this final rule ensure the safety of cars being added and removed in this fashion. This paragraph also contains an additional caveat that will permit the removal of defective equipment at locations where other cars are added or removed without triggering the requirement to perform a Class I brake test on the entire train. FRA currently permits this practice, and it is consistent with the requirements aimed at having defective equipment repaired as quickly as possible.

Paragraph (a)(3) incorporates FRA's longstanding administrative interpretation which permits trains to remain disconnected from a source of compressed air ("off air") for a short length of time without having to be retested. Currently, FRA permits trains to remain "off air" only for a period of approximately two hours before an initial terminal brake inspection must be performed. This paragraph retains the proposed extension of the permissible time "off air" to four hours. A detailed discussion regarding FRA's retention of the proposed extension of the permissible time cars may be left "off-air" is contained in the preceding "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "II. C. Charging of Air Brake System."

Paragraph (a)(4) retains the proposed requirement that unit or cycle trains receive a Class I brake test every 3,000 miles. The final rule has been slightly modified from the provision contained in the NPRM to clarify that this requirement applies to unit or cycle trains. FRA has also added a definition of "unit train" and "cycle train" to the final rule in order to clarify the applicability of the requirement. Historically, these trains operate for extended periods of time with only a series of brake inspections similar to Class IA brake inspections. FRA believes that the proposed 3,000-mile limitation is appropriate as it represents the approximate distance that a train would cover when traveling from coast to coast. In addition, the 3,000-mile requirement is consistent with the interval for performing Class IA brake tests and would equate to every third inspection on these trains being a Class I brake test rather than a Class IA brake test. Furthermore, AAR does not seek a moderate extension of a couple hundred miles so a few trains could complete their cycle, but seeks to extend the distance to more than 4,500 miles in many instances. FRA is not willing to modify the proposed requirement to that extent and believes that a 3,000-mile interval for these types of trains provides sufficient flexibility to the railroads to perform periodic Class I brake tests on these train in a cost-effective manner.

Paragraph (a)(5) retains the proposed provisions for when trains received in interchange must receive a Class I brake test. These are similar to what is currently contained in § 232.12(a)(1)(iii); however, this paragraph retains two proposed provisions that are not contained in the existing regulations. The final rule will permit trains received in interchange to have a previously tested solid block of cars added to the train without requiring the performance of a Class I brake test. Currently, the addition of these types of cars to a train received in interchange would require the performance of an initial terminal inspection. As long as the added block of cars has been previously tested, FRA sees no safety hazard in permitting the cars to be added to a train at an interchange location. Furthermore, the final rule will permit a train that is received in interchange, and that will travel no more than 20 miles from the interchange location, to have its consist changed other than as provided in paragraph (a)(5) without being required to receive a Class I brake test; provided that, any cars added to the consist at the interchange location receive at least a Class II brake test pursuant to § 232.209. Historically, FRA has not had a problem with these shorter distance trains and believes that a Class II brake test on those cars added to the train is sufficient to ensure the safety of these operations.

Paragraph (b) details the required tasks comprising a Class I brake test. A proper Class I brake test ensures that a train is in proper working condition and is capable of traveling to its destination with minimal problems en route. The final rule retains virtually all of the provisions proposed in the NPRM regarding the specific tasks that are to be part of the Class I brake test, which include most of the tasks currently required by § 232.12(c)-(h) for an initial terminal brake test, with some modification in the interest of standardization and clarity.

The final rule retains a standardized brake-pipe reduction of 20 psi for virtually all brake inspections and tests as was proposed in the 1994 and 1998 NPRMs. FRA agrees with both labor and management commenters that a standard brake-pipe reduction will simplify train brake tests and will make it easier to train workers. The 20-psi standardized reduction was suggested by both labor and management representatives.

The brake-pipe leakage test will continue to be a valid method of qualifying brake systems. However, the final rule retains the air flow method of testing the condition of the brake pipe as an acceptable alternate to the brake-pipe leakage test. The air flow method (AFM) would be an alternative only for trains having a lead locomotive equipped with a 26-L brake valve or equivalent and outfitted with an EOT device. The maximum allowable flow would be 60 CFM. The AFM of qualifying train air brake systems has been allowed in Canada as an alternative to the leakage test since 1984. In addition, several railroads in the United States have been using the AFM since 1989 when FRA granted the AAR's petition for a waiver of compliance to permit the AFM as an alternative to the leakage test. FRA recognizes the concerns of several labor organization commenters opposing the adoption of the AFM; however, FRA believes these commenters' apprehension is based on their unfamiliarity with the method. As FRA pointed out in the ANPRM, the 1994 NPRM, and the 1998 NPRM, the AFM is a much more comprehensive test than the leakage test. *See* 57 FR 62551, 59 FR 47682–47683, 63 FR 48305–06. The AFM tests the entire brake system just as it is used, with the pressure-maintaining feature cut in. FRA believes the AFM is an effective and reliable alternative method of qualifying train brakes. In the 1998 NPRM, FRA expressed some concern regarding the use of the AFM on short trains. However, based on consideration of the comments received and FRA's experiences in observing the use of the AFM, FRA agrees that the AFM should be permitted as an alternative on any train provided the 15 psi gradient is maintained on the train.

The brake-pipe gradient of 15 psi has been retained for both the leakage and air flow method of train brake testing; however, the minimum rear-car pressure has been increased to at least 75 psi, which will require a locomotive brake-pipe pressure of at least 90 psi. FRA feels that the added margin of braking power justifies the increase in pressure. The final rule modifies the language used in the proposed provisions related to the air pressure at which the brake tests are to be conducted based on comments submitted by the NTSB. The NTSB noted that the language used by FRA in the NPRM to describe the air pressure settings for conducting the required brake tests would permit some road trains to be tested at a lower pressure than that at which the train would be operated. The NTSB contends that although most road freight trains operate at 90 psi, some road freight trains are operated at 100 psi and the proposal would permit them to be tested at 90 psi. FRA agrees with NTSB's suggestion that a train's brake system should be tested at the pressure at which the train will operate and has modified the language of the final rule accordingly. Consequently, the final rule requires that the brake system be charged to the pressure at which the train will be operated and that the rear car pressure be within 15 psi of that pressure and not less than 75 psi when conducting the required brake tests and inspections.

Based on FRA's experience over the last several years and based on numerous comments received by FRA verifying the high reliability of the rear-car pressure transducers used in reporting brake-pipe pressure by an end-of-train (EOT) device, FRA now feels comfortable and justified in allowing the use of EOT devices in establishing the rear car pressure for Class I brake tests. FRA currently has requirements in place for the inspection and testing of EOT devices at the time of installation, which have been incorporated into subpart E of this proposal. However, in using an EOT to verify rear car pressure during a Class I brake test, the reading of the rear car air pressure is only permitted from the controlling or hauling locomotive of the train. Under no circumstances may train air brake pressure be read from a remote highway vehicle, another locomotive not attached to the train, or at any other location such as a remote unit installed in an office or shop.

Paragraph (b)(2) retains the proposed language regarding the duties of individuals performing brake inspections contained in this final rule. The language in this paragraph is reiterated in the final rule provisions on both the Class IA and Class II brake tests in order to ensure the proper performance of brake inspections. Contrary to the assertions of some commenters, FRA believes that the proposed provisions sufficiently detailed how the various inspections were to be performed while providing flexibility for railroads to conduct the inspections in a manner most conducive to their operations. The methods of inspection proposed in the 1998 NPRM incorporated current practices and technical guidance previously issued by FRA.

Over the last few years there has been extensive debate concerning what constitutes a proper train air brake test under the current provisions contained in part 232, particularly relating to the positioning of the person performing the brake inspection. In early 1997, FRA issued a technical bulletin to its field inspectors in an attempt to clarify what must be done in order to properly perform a brake test. This technical bulletin stated that inspectors must position themselves in such a manner so as to be able to observe all of the movable parts of the brake system on each car. At a minimum, this requires that the inspector observe both sides of the equipment sometime during the inspection process. FRA continues to believe that both sides of the equipment must be observed sometime after the occurrence of activities that have the likelihood of compromising the integrity of the brake components of the equipment, such as: hump switching; multiple switching; loading; or unloading. FRA also agrees with the comments submitted by several railroad representatives that if one side of the equipment is inspected to ensure the proper attachment and condition of brake components and the proper condition of brake shoes on that side and the application of the brakes is observed from the other side of the equipment, then based on the design of brake systems today it can be safely assumed that in virtually every case an application of the brakes is occurring on the other side of the equipment. Consequently, FRA would like to again make clear that both sides of the equipment do not necessarily have to be inspected while the brakes are applied if an adequate inspection of the brake components was conducted on both sides of the equipment sometime during the inspection process. However, FRA also intends to make clear that the piston travel on each car must be inspected while the brakes are applied; thus, an inspector must take appropriate steps to make this observation.

As indicated in the NPRM, FRA does not intend to mandate specific methods for how the various inspections are to be performed. FRA believes that each

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railroad is in the best position to determine the method of inspection that best suits its operations at different locations. To require that all inspections be performed by walking the train, as suggested by several labor representatives, would impose a huge financial and operational burden on the railroads and would ignore the various different methods by which inspections are currently performed and have been performed for years. FRA has never mandated specific step-by-step procedures for conducting brake inspections but merely requires that, whichever method is used, it must ensure that all of the components required to be inspected will be so inspected.

Paragraph (b)(4) contains the requirements for ensuring that a proper application of a car's brakes is made during the performance of brake inspections and provides the procedures for retesting a car found not to be properly applied during the initial performance of a brake inspection. In proposing the requirements contained in this paragraph, FRA attempted to clarify language contained in the current regulation which requires that the brakes "apply." The existing language has been misinterpreted by some to mean that if the piston applies in response to a command from a controlling locomotive or yard test device, and releases before the release signal is given, the brake system on that car is in compliance with the regulation because the brake simply applied. The intent of the regulation has always been that the brakes apply and remain applied until the release signal is initiated from the controlling locomotive or yard test device. In order to eliminate any confusion, this paragraph requires that the brakes on a car must remain applied until the appropriate release signal is given. If the brakes on a car fail to do so, the car must either be removed from the train or repaired in the train and retested as discussed below.

This paragraph retains the general concepts for retesting cars with brakes that are found not to apply or not to remain applied that were proposed in the NPRM. However, some of the specific requirements for performing a retest have been modified from those proposed in the NPRM based on FRA's consideration of the comments submitted and its determination that the proposed retesting provisions may have been overly restrictive. This paragraph modifies the proposed retest requirements by permitting any car found with brakes not applied during a required inspections to be retested rather than just cars with obvious defective conditions. FRA agrees with the assertions of several commenters that there are a number of circumstances where the reason for the failure of the brakes to apply is not readily apparent. This paragraph reduces the amount of time that the brakes on a retested car must remain applied to three minutes from the proposed five minutes. The final rule makes clear that the brakes on a retested car remain applied until the release is initiated and that the release be initiated no less than three minutes after the application of the brakes. FRA believes three minutes is consistent with the amount of time it would take a person to conduct a complete inspection of the retested car's brakes. This paragraph also permits a car to be retested with the use of a suitable device positioned at the car being retested rather than from the head of the consist or from the controlling locomotive. When a retest is performed in this fashion, the final rule requires that the compressed air be depleted from the car being retested prior to separating the train line to perform the retest in order to prevent potential injury to employees conducting the retest. This paragraph also makes clear that any retest performed must be conducted at the air pressure at which the train will be operated. The modifications made to the retesting requirements in this paragraph are reiterated or referenced in the other types of brake inspections required in this subpart. A detailed discussion regarding the modifications made to the retesting provision is contained in the preceding "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "II. D. Retesting of Brakes."

Paragraph (b)(5) retains the proposed and current requirement that piston travel be adjusted during the performance of a Class I brake test if it is found outside the nominal limits established for standard 8½ inch and 10-inch diameter brake cylinder or outside the limits established for other types, which will be contained on a stencil, sticker, or badge plate. This provision is identical to that proposed in the NPRM and is similar to the provision currently contained at § 232.12(f). The major difference is that FRA has modified the existing provision to require that piston travel found to be less than 7 inches or more than 9 inches must be adjusted nominally to 7½ inches. This change is based on a request by AAR to change the adjustment to 7½ inches from 7 inches as its member railroads were finding it extremely difficult to adjust the piston travel to precisely 7 inches and that in some cases the adjustment would be marginally less than 7 inches, thus requiring a readjustment. Thus, AAR sought the extra ½ inch in order to provide a small measure for error when the piston travel is adjusted. As FRA believes that AAR's concerns are validly placed and would have no impact on safety, FRA has accommodated the request.

Paragraph (b)(7) retains the proposed provision which clarified that brake connection bottom rod supports will no longer be required on bottom connection rods secured with locking cotter keys. FRA recognizes that there is no need for bottom rod safety supports in these circumstances and intends to relieve railroads of this unnecessary expense, which will provide the industry a cost savings without compromising safety.

Paragraph (b)(8) retains the proposed provisions relating to the performance of "roll-by" inspections of the release of the brakes on the cars of the train. This method of inspection has been used for years even though there is nothing in the current regulation which specifically addresses the method. The authority to use this method of inspection of the brake release permits railroads to expedite the movement of trains and has not proven to create a safety hazard. Therefore, this paragraph is intended to clarify the authority of railroads to use such a method and to ensure that the inspection is performed properly. This paragraph makes clear that when a railroad is performing a "roll-by" inspection of the brake release the train's speed shall not exceed 10 mph, that the qualified person performing the "roll-by" inspection shall notify the engineer when and if the "roll-by" has been successfully completed, and that the operator of the train shall note successful completion of the release portion of the inspection on the written or electronic notification required by this final rule. FRA intends to make clear that the notification to the engineer may be made through a hand held radio, a cellular telephone, or communication with a train dispatcher but that such information must be provided to the engineer prior to the train's departure. Based on the rationale provided for permitting only one side of a train to be inspected during the application of the brakes, FRA intends to make clear that only one side of the train must be inspected during the release portion of a brake test. However, paragraph (b)(2) makes clear that a "roll-by" inspection of the brake release shall not constitute an inspection of that side

for purposes of inspecting both sides during the inspection.

Paragraph (c) generally retains the provision as it was proposed in the NPRM and as currently contained in § 232.12(a), with slight modification for clarity, stating that a carman alone will be considered a qualified person if a railroad's collective bargaining agreement (CBA) provides that carmen are to perform the inspections and tests required by this section. FRA received a number of comments from various labor representatives objecting to FRA's proposed modification of the provision that currently exists in § 232.12(a). These commenters contended that the proposed language would alter the meaning of the existing provision and effectively eliminate its enforceability. Particularly, they objected to the proposed addition of the word "only" in the first sentence of the provision and the proposed elimination of the phrase "existing or future collective bargaining agreement." They contend that no CBA provides that only a carman may perform the inspections and that it is unclear whether the provision will apply to future CBAs due to the elimination of the specific language to that effect. They also asserted that it is unnecessary to require that carmen be trained as a qualified person or a QMI since carmen were recognized as the craft qualified to perform the inspection in 1982.

FRA's intent in proposing this provision was to clarify the meaning of the provision and explain FRA's ability to enforce the existing provision. FRA's intent was neither to expand nor reduce the applicability of the provision. FRA recognizes that its proposed addition of the word "only" could have the effect of altering the provision in a way that was not intended as FRA agrees that many existing CBAs do not require that only a carman perform the inspections. Thus, the language of the provision in this final rule eliminates the word "only" from the proposed clause, "Where a railroad's collective bargaining agreement provides that only a carman is to perform the inspections and tests required by this section.

* * *" However, FRA does not agree that it is necessary to include the phrase "existing or future collective bargaining agreement," as suggested by some commenters. FRA intends for the reference to a collective bargaining agreement to include any existing or future CBA. FRA believes that the inclusion of the suggested phrase is unnecessary because the plain meaning of the text is the CBA that applies at the time the issue arises. FRA sees no way to read the provision contained in this final rule as not to include both existing and future CBAs.

FRA also believes that it is essential for railroads to ensure that the individuals required to perform the inspections covered by this provision are properly trained and qualified to perform the inspections. As the requirements contained in this final rule for performing these inspections differ somewhat from the existing regulation, FRA believes it is necessary for employees performing the inspections to be trained on these new requirements. This paragraph merely makes clear that, in circumstances where a collective bargaining agreement requires that a carman is to perform the inspections and tests required by this section, the railroad shall bear the responsibility of ensuring that the carman responsible for performing this task is properly trained and designated as qualified to perform the task. In these circumstances, FRA believes that the railroad must ensure that the employees with whom they have collectively bargained to perform the inspections and tests required by this section are properly trained and designated to perform the task. Furthermore, FRA believes that on virtually all railroads carmen will be sufficiently trained and experienced to be considered "qualified persons" and "qualified mechanical inspectors" as defined in this proposal, provided they receive some additional training on the specific requirements contained in this final rule.

The original provision was added to the regulations in 1982 when the distance between brake inspections was increased from 500 miles to 1,000 miles. The provision was included as part of an agreement between the railroads and rail labor for permitting the maximum distance between brake tests to be increased and was presented to FRA at the time. The language contained in that agreement was included in the 1982 regulatory revisions without change by FRA. Consequently, due to the circumstances under which this provision was added to the regulations and because it has existed for over 16 years, FRA feels compelled to retain the language in this final rule. FRA will continue to interpret the provision as it has always interpreted the provision. In circumstances where a railroad's collective bargaining agreement requires that a carman perform the inspections and tests required by this section, a carman alone will be considered a qualified person. This has been FRA's approach to the provision since its inception.

As FRA lacks the authority to issue binding interpretations of collective bargaining agreements, FRA lacks the authority to settle a dispute between a railroad and its employees as to which group of its employees is to perform what work. FRA intends to make clear, that in order for FRA to proceed with an enforcement action under the provision contained in this paragraph, one of the parties to the collective bargaining agreement would first have to obtain a decision from a duly authorized body interpreting the relevant agreement, specifically identifying the involved location, and adequately resolving all of the interpretative issues necessary for FRA to conclude that the work belongs to a particular group of employees.

Paragraph (d) contains the requirement regarding the notification to the locomotive engineer and train crew of the successful completion of a Class I brake test by a qualified person. This paragraph slightly modifies the notification requirement from that proposed in the NPRM. In the NPRM, FRA proposed that the engineer be informed in writing of the successful completion of the Class I brake test. The intent of this proposed requirement was to ensure that the locomotive engineer was adequately informed of the results of the inspection; however, FRA recognizes that a requirement to provide the information in writing ignores technological advances and operational efficiencies. Consequently, this paragraph permits the notification to be made in whatever format the railroad deems appropriate; provided that the notification contains the proper information and a record of the notification and the requisite information is maintained in the cab of the controlling locomotive. FRA believes these changes are consistent with the intent and purpose of the proposed requirement for written notification and ensure necessary information is relayed to the operator of the train.

Paragraph (f) retains the proposed and existing requirements relating to the adding of cars or blocks of cars while a train is en route. This paragraph informs railroads that cars picked up en route that have not been previously tested and kept connected to a source of compressed air are to receive a Class I brake test when added to the train. Alternatively, a railroad may elect to perform only a Class II brake test at the time that a car is added to the train en route, but FRA intends to make clear that if this option is elected then the cars added in this fashion must be given a Class I brake test at the next forward location where facilities are available for providing such attention.

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Section 232.207 Class IA Brake Tests—1,000-Mile Inspection

This section retains the proposed requirements related to the performance of a Class IA brake test. Many of the provisions contained in this section are currently contained at § 232.12(b) regarding the performance of 1,000-mile inspections. FRA has modified some of the existing requirements for purposes of clarity and has added a few additional requirements in order to make the inspection requirement more enforceable and to prevent some of the current abuses which FRA field inspectors have observed in their enforcement activities.

FRA recognizes that since 1982 new technologies and improved equipment have been developed that allow trains to operate longer distances with fewer defects. The data submitted by AAR appear to support this assertion, and FRA does not dispute the potential capability of certain equipment to travel distances in excess of 1,000 miles without becoming defective. However, the capability of the equipment to travel extended distances safely is contingent on the condition of the equipment when it begins operation and on the nature of the operation in which it is to be engaged. FRA believes that in order for brake equipment to travel extended distances between brake inspections, the condition and planned operation of the equipment must be thoroughly assessed at the beginning of a train's journey through high quality inspections. As noted in the general preamble discussion above, FRA believes that railroads are not conducting high quality initial terminal inspections at many locations because the railroads are utilizing employees who are not sufficiently qualified or trained to perform the inspections. Therefore, FRA believes that the 1,000-mile brake inspection interval continues to be necessary and important to ensure the safe operation of trains inspected by qualified personnel pursuant to this final rule. Furthermore, no trains operated in the United States are currently permitted to travel greater than 1,000 miles between brake inspections. Consequently, FRA is not willing to permit trains to travel in excess of 1,000 miles between brake inspections, except in the limited, controlled situations where data on the equipment can be gathered. (See discussion and provisions related to "Extended Haul Trains.") FRA notes that Canada eliminated intermediate inspections in 1994. However, Canada has different inspection requirements than those contained in this final rule and vastly different operating conditions and environments than those prevalent on most American railroads, operating conditions and environments that are more conducive to the inspection regimen imposed by that country.

Paragraph (a) provides that each train shall receive a Class IA brake test at a location that is not more than 1,000 miles from the point where any car in the train last received a Class I or Class IA brake test. FRA intends to make clear that the most restrictive car or block of cars in the train will determine the location where this test must be performed. For example, if a train departs point A and travels 500 miles to point B where it picks up a previously tested block of cars en route which has travelled 800 miles since its last Class I brake test and the crew does not perform a Class I brake test when entraining the cars, then the entire train must receive a Class IA brake test within 200 miles from point B even though that location is only 700 miles from point A.

Paragraph (b) contains the tasks which must be performed when conducting a Class IA brake test. These task are virtually identical to some of the tasks required to be performed during a Class I brake test. A leakage or air flow test must be performed. Thus, when locomotives are equipped with a 26–L brake valve or equivalent, FRA will permit the use of the air flow method as an alternative to the brake pipe leakage test. This paragraph makes clear that the brakes shall apply on each car in the train in response to a 20-psi brake pipe reduction and shall remain applied until a release is initiated. In addition, the paragraph reiterates the parameters for performing a retest of the brakes on those cars found not to have sufficiently applied, which are contained in the Class I brake test requirements. It should be noted that, defective equipment may be moved from or past a location where a Class IA brake test is performed only if all of the requirements contained in § 232.15 have been satisfied. The only change to the tasks contained in this paragraph from those proposed in the NPRM is the clarification that the brake system be charged to the pressure at which the train will be operated and that the rear car pressure be within 15 psi of that pressure and not less than 75 psi when conducting the required brake tests and inspections. This change is identical to the change made in the Class I brake test and is discussed in detail in that section.

This paragraph also makes clear that in order to properly perform a Class IA brake test under this section both sides of the equipment must be observed sometime during the inspection process. FRA finds the comments of AAR and other railroad representatives contending that both sides of the equipment should not be required to be inspected at Class IA brake tests to lack merit. The Class IA brake test basically incorporates the current 1,000-mile brake inspection, which FRA believes requires an inspection of both sides of the equipment during the inspection process. The current 1,000-mile inspection requires that brake rigging be inspected to ensure it is properly secure and does not bind or foul and that the brakes apply on each car in the train. *See* 49 CFR 232.12(b). In order to make these inspections properly, FRA believes that both sides of the equipment must be observed sometime during the inspection process and, to FRA's knowledge, railroads currently conduct these inspections in this manner. Thus, the NPRM and the final rule merely clarify what is required to be performed under the current regulations to properly perform a 1,000-mile inspection. Therefore, contrary to the contentions of certain commenters, retention of this current requirement does not impose any additional burden on the railroads.

Paragraph (c) retains the proposed provision which would require railroads to maintain a list of locations where Class IA inspections will be performed and that FRA be notified at least 30 days in advance of any change to that list of locations. Based on a review of the comments submitted, FRA recognizes that the proposed requirement for designating locations where Class IA inspections will be performed was somewhat unclear and may have caused confusion. The intent of the proposed requirement was to ensure that FRA was informed of those locations where a railroad intends to perform Class IA brake inspections and that FRA had the information with which to hold the railroad responsible for conducting the inspections at those locations. FRA was not intending to require that railroad separately identify a specific Class IA inspection location for each train it operates. Consequently, this paragraph has been slightly modified from that proposed in order to make clear that the designation required is for locations where such inspections will be performed and permits deviance from those locations only in emergency situations.

The current regulations merely require that railroads designate locations where intermediate 1,000-mile brake inspections will be performed but place no limitation on changing the locations. Therefore, FRA has found some railroads changing the locations where these intermediate inspections are to occur on a daily basis which prevents FRA from observing these inspections being performed or avoids full performance of the required inspection by mechanical forces. In order to ensure that these types of inspections are being properly performed, FRA must be able to determine where the railroad plans to conduct these types of inspections. This paragraph recognizes that there may be occurrences or emergencies, such as derailments, that make it impossible or unsafe for a train to reach a location that the railroad has designated as a Class IA inspection site. Consequently, this paragraph permits railroads to bypass the 30-day written notification requirement in these instances provided FRA is notified within 24 hours after a designation has been changed. This paragraph also makes clear that failure to perform a Class IA brake test at a designated location will constitute a failure to properly perform the inspection.

Section 232.209 Class II Brake Tests—Intermediate Inspection

This section contains the requirements related to the performance of Class II brake tests. The requirements contained in this section are similar to the proposed requirements and the requirements currently contained in § 232.13(d) but have been slightly modified for clarity and to address situations where solid blocks of cars are added to an en route train. Paragraph (a) identifies those cars that are required to receive a Class II brake test when added to a train. This paragraph has been modified to address situations when certain "solid blocks of cars" are added to a train. As discussed previously, the final rule modifies the definition of "solid block of cars" from that proposed in the NPRM. (See section-by-section analysis of § 232.5.) Although FRA believes the definition it proposed was consistent with current interpretations and enforcement of the requirement, FRA agrees with some of the commenters that the definition may have been too narrow and did not directly address FRA's primary concern, the block of cars itself. FRA's primary concern is the condition of the block of cars being added to the train especially when the block of cars is made up of cars from more than one train. Thus, the final rule permits a "solid block of cars" to be added to a train without triggering a requirement to perform a Class I brake test on the entire train. However, this paragraph identifies the situations when "solid blocks of cars" must be inspected when added to a train.

This paragraph makes clear that a car or a solid block of cars that has not previously received a Class I brake test or that has been off a source of compressed air for longer than four hours must, at a minimum, receive a Class II brake test when added to an en route train. This paragraph also makes clear that a Class II brake test is required to be performed on each "solid block of cars" added to a train which is composed of cars from more than one other train or that is composed of cars from only one other train but that have not remained continuously and consecutively coupled together. It should be noted that this paragraph specifically acknowledges that the removal of defective equipment from a solid block of cars will not result in the solid block of cars being considered not to be continuously and consecutively coupled together. FRA believes this approach is consistent with the intent of both FRA and Congress to have defective equipment repaired as quickly as possible.

Paragraph (b) retains the proposed tasks which must be performed when conducting a Class II brake test. The only changes to the tasks contained in this paragraph from those proposed in the NPRM is the clarification that the brake system be charged to the pressure at which the train will be operated and that the rear car pressure be within 15 psi of that pressure and not less than 75 psi when conducting the required brake tests and inspections and the procedures for performing retests on cars. These changes are identical to the changes made in the Class I and Class IA brake tests and are discussed in detail in those sections.

A Class II brake test is intended to ensure that the brakes on those cars added apply and release and that the added cars do not compromise the integrity of the train's brake system. Therefore, a leakage or air flow test must be performed when the cars are added to the train to ensure the integrity of the train's brake system. This paragraph makes clear that in order to properly perform an inspection under this section both sides of the equipment must be observed sometime during the inspection process. This paragraph also makes clear that the brakes shall apply on each car added to the train and remain applied until a release is initiated and reiterates the parameters that are contained in the Class I brake test requirements for performing a retest on those cars whose brakes were found not to have sufficiently applied. It should be noted that, defective equipment may be moved from or past a location where a Class II brake test is performed only if all of the requirements contained in § 232.15 have been satisfied. Paragraph (b) also requires that the release of the brakes on those cars added to the train and on the rear car of the train be verified and allows railroads to conduct "roll-by" inspections for this purpose.

Paragraph (c) continues to permit the proposed and existing alternative to the rear car application and release portion of this test. This alternative permits the locomotive engineer to rely on a rear car gauge or end-of-train device to determine that the train's brake pipe pressure is being reduced by at least 5 psi and then restored by at least 5 psi in lieu of direct observation of the rear car application and release. Although certain labor representatives contended that this practice should not be allowed and that it is in violation of the existing regulations, this alternative has been permitted for years under the current regulations (§ 232.13(c)(1), (d)(1)) without any degradation of safety, and thus, FRA intends to permit the practice to continue.

Paragraph (d) retains the proposed and existing requirements relating to the inspection of cars or blocks of cars added to a train while a train is en route. This paragraph makes clear that if cars are given a Class II brake test when added to a train then the cars added must receive a Class I brake test at the next forward location where the facilities are available for performing such an inspection.

Section 232.211 Class III Brake Tests—Trainline Continuity Inspection

This section contains the requirements related to the performance of Class III brake tests. The requirements contained in this section are generally the same as those proposed, which incorporated the requirements currently contained in § 232.13(c), but have been slightly modified for clarity and standardization with the changes made in other inspection requirements contained in this final rule. Some of the changes made in this section from that proposed clarify the need to perform a Class III brake test when a solid block of cars is added to a train which does not require the performance of either a Class I or Class II brake test. Paragraph (b) of this section has been modified to incorporate the clarification that the brake system be charged to the pressure at which the train will be operated and that the rear car pressure be within 15 psi of that pressure and not less than 75 psi when conducting the required inspection.

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The purpose of a Class III brake test is to ensure the integrity of the trainline when minor changes in the train consist occur. Basically, a Class III brake test ensures that the train brake pipe is properly delivering air to the rear of the train. FRA intends to make clear that this inspection is designed to be performed whenever the continuity of the brake system is broken or interrupted. For example, if a railroad disconnects a locomotive from a train consist to perform switching duties for a short period and then reattaches the locomotive to the consist, without any other change being made in the consist, the railroad would be required to perform a Class III brake test prior to the train's departure. Similarly, a Class III brake test would be required if a railroad disconnects a locomotive from the train and adds a different locomotive to the train, only to discover that the added locomotive is not operating properly, and thus, adds the original locomotive back into the consist. Because the continuity of the trainline was interrupted when the locomotive was removed and then placed back in the train, even though the same cars and locomotives remained in the consist, a Class III brake test must be performed.

Paragraphs (b) and (c) contain the tasks related to the performance of a Class III brake test. These paragraphs require that the brakes on the rear car of the train apply in response to a 20-psi brake pipe reduction and that the brakes subsequently release on the rear car of the train when the release is initiated. Similar to a Class II brake test, paragraph (c) permits an alternative to direct observation of the application and release of the rear car's brakes by permitting the operator to rely on a rear car gauge or end-of-train device to determine that the brake pipe pressure is being reduced and restored in response to the controlling locomotive.

Section 232.213 Extended Haul Trains

This section generally retains the proposed provisions, which permit an extension of the allowable maximum distance a train may travel between train brake system tests. After consideration of all the comments submitted on this matter, FRA continues to believe that if a train is properly and thoroughly inspected, with as many defective conditions being eliminated as possible, then the train is capable of traveling much greater than 1,000 miles between brake inspections. (A detailed discussion of the comments submitted on this issue is contained in the preceding "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "II. B. Extended Haul Trains.") Therefore, the final rule retains the provisions permitting railroads to designate trains as extended haul trains and allowing such trains to be operated up to 1,500 miles between brake inspections. Although FRA recognizes that retention of the 1,500-mile limitation may limit the utility of the provision on some railroads, FRA is not willing to increase the proposed mileage restriction at this time. Currently, no train is permitted to travel more than 1,000 miles without receiving an intermediate brake inspection. Therefore, FRA does not believe it would be prudent to immediately double or triple the currently allowed distance without evaluating the safety and operational effects of an incremental increase in the distance. Consequently, until sufficient information and data are collected on trains operating under the provisions contained in this final rule, FRA is not willing to permit trains to travel the distances suggested by some commenters without additional brake inspections. FRA continues to believe that the requirement for performing inbound inspections and the requirement to maintain records of all defective conditions discovered on these trains provides the basis for developing the information and data necessary to determine the viability of allowing greater distances between brake inspections.

After consideration of the comments submitted, FRA agrees that the benefits estimated in the NPRM in association with the extended haul provisions may have been overstated. FRA realizes that the retention of the 1,500-mile limitation may eliminate certain trains from being operated pursuant to the extended haul provisions and reduce the benefits estimated at the NPRM stage of the proceeding. (See detailed discussion in the Regulatory Impact Analysis portion of the preamble below.) In order to increase the viability of the extended haul provisions, the final rule provides some flexibility for designating extended haul trains and allows for the limited pick-up and set-out of equipment as discussed below.

Certain commenters have portrayed the provisions related to extended haul trains as merely being an extension of the current intermediate inspection distances. FRA objects to such a characterization. In FRA's view, the extended haul provisions contained in this section constitute a completely new inspection regimen. This section contains stringent inspection requirements, both brake and mechanical, by highly qualified inspectors and establishes stringent requirements whenever cars are added to or removed from such trains. This section also contains a means to assess the safety of such operations by requiring that records be maintained of the defective conditions that develop on these trains while en route. Consequently, FRA believes that the requirements related to extended haul trains not only ensure the safe operation of the trains operated under them, but actually increase the safety of such operations over that which is provided in the current regulations.

In paragraph (a), FRA generally retains the proposed provisions permitting railroads to designate specific trains that will move up to 1,500 miles between brake and mechanical inspections provided the railroad meets various stringent inspection and monitoring requirements, which FRA believes will ensure the safe and proper operation of these trains. FRA intends to make clear that a railroad must meet all of the requirements contained in this paragraph in order to designate a train as an extended haul train. Paragraph (a)(1) contains the requirements for designating trains a railroad intends to move in accordance with this section. Several commenters contended that the proposed provisions regarding the advance designation of extended haul trains would prohibit certain unscheduled trains from being operated as extended haul trains. In an effort to provided some flexibility in this area, this paragraph has been modified to allow railroads to designate certain locations as locations where extended haul trains will be initiated and requires railroads to describe those trains that will be so operated rather than requiring specific identification of every train. FRA believes this modification will allow railroads to capture some of their unscheduled trains by identifying the trains by the locations where they originate. This paragraph sets forth the information that must be provided to FRA in writing when designating a train or a location for such operation. The information required to be submitted is necessary to facilitate FRA's ability to independently monitor a railroad's operation of these extended haul trains.

FRA continues to believe that in order for a train to be permitted to travel 1,500 miles between inspections, the train must receive inspections that ensure the optimum condition of both the brake system and the mechanical components. In paragraphs (a)(2), (a)(3), and (a)(8), FRA retains the proposed requirement that these inspections be performed by highly qualified and experienced

inspectors in order to ensure that quality inspections are being performed. As FRA intends the Class I brake tests that are required to be performed on these trains to be as in-depth and comprehensive as possible, FRA continues to believe that these inspections must be performed by individuals possessing not only the knowledge to identify and detect a defective condition in all of the brake equipment required to be inspected but also the knowledge to recognize the interrelational workings of the equipment as well as a general knowledge of what is required to repair the equipment. Therefore, paragraphs (a)(2) and (a)(8) retain the use of the term "qualified mechanical inspector" to identify and describe those individuals it believes possess the necessary knowledge and experience to perform the required Class I brake tests on these trains. A "qualified mechanical inspector" is a person with training or instruction in the troubleshooting, inspection, testing, maintenance, or repair of the specific train brake systems for which the person is assigned responsibility and whose primary responsibilities include work generally consistent with those functions. (See § 232.5 of this section-by-section analysis for a more detailed discussion of "qualified mechanical inspector.") FRA also continues to believe these same highly qualified inspectors must be the individuals performing the required inbound inspection, contained in paragraph (a)(6) of this section, on these extended haul trains in order to ensure that all defective conditions are identified at the train's destination or 1,500 mile location. Similarly, in paragraph (a)(3), FRA requires that all of the mechanical inspections required to be performed on these trains be conducted by inspectors designated pursuant to 49 CFR 215.11, rather than train crew members, in order to ensure that all mechanical components are in proper condition prior to the trains departure.

As discussed in detail above, FRA is not willing to allow more than 1,500 miles between brake inspections until appropriate data are developed which establish that equipment moved under the criteria contained in this final rule remains in proper condition throughout the train's journey. FRA believes that the provisions contained in paragraphs (a)(6) and (a)(7), requiring the performance of an inbound inspection at destination or at 1,500 miles and requiring carriers to maintain records of all defective conditions discovered on these trains for a period of one year, create the basis for developing such data. FRA believes the information generated from these inbound inspections will be extremely useful in assessing the quality of a railroad's inspection practices and will help FRA identify any systematic brake or mechanical problems that may result in these types of operations. It should be noted that paragraph (a)(7) has been slightly modified from what was proposed in order to clarify that the required records may be maintained either electronically or on paper.

Paragraphs (a)(4) and (a)(8) retain the proposed requirements that these trains have 100 percent operative brakes and contain no cars with mechanical defects under part 215 at either the train's initial terminal or at the time of departure from a 1,500-mile point, if moving in excess of 1,000 miles from that location. FRA has modified the provision proposed in paragraph (a)(5) that restricted extended haul trains from conducting any pick-ups or set-outs en route, except for the removal of defective equipment. Paragraph (a)(5) is modified to permit extended haul trains the limited ability make one pick-up and one set-out while en route. This modification will provide railroads the flexibility to set out a block of cars at one location and pick up a block of cars at the same or another location. FRA believes that this limited ability provides the railroads with some flexibility to move equipment efficiently while minimizing the disruptions made to the train's brake system and ensuring that cars added to such trains can be adequately tracked and inspected. Paragraph (a)(5) makes clear that any cars added to extended haul trains must be inspected in the same manner as the cars at the train's initial terminal. This paragraph also makes clear that any car removed from the train must be inspected in the same manner as a car at the train's point of destination or 1,500-mile location.

Paragraph (b) is retained as proposed and makes clear that failure to comply with any of the restrictions contained in this section will be considered an improper movement of a designated extended haul train for which appropriate civil penalties may be assessed. FRA has included specific civil penalties in appendix A to this final rule pertaining to the improper movement of these types of trains. In addition to the imposition of civil penalties, this paragraph makes clear that FRA reserves the right to revoke a railroad's authority to designate any or all trains for repeated or willful noncompliance with any of the provisions contained in this section.

Section 232.215 Transfer Train Brake Tests

This section generally retains the proposed requirements related to the performance of transfer train brake tests. The final rule requirements have been slightly modified for consistency with other inspection requirements and to clarify when a transfer train brake test is to be performed. The requirements contained in this section generally incorporate the requirements currently contained in § 232.13(e). "Transfer train" is defined in § 232.5 of this final rule as a train that travels between a point of origin and a point of destination, located not more than 20 miles apart. The definition makes clear a transfer train may pick up or deliver freight equipment while en route to its destination. This final rule makes clear that the decision as to whether a particular consist is subject to the transfer train inspection requirements is primarily based on a determination that the movement the train is engaged in is considered a "train movement" rather than a "switching movement." FRA's determination of whether the movement of cars is a "train movement," subject to the requirements of this section, or a "switching movement" is and will be based on the voluminous case law developed by various courts of the United States. (See section-by-section analysis for § 232.5 for a detailed discussion of the terms "train movement" and "switching movement.")

FRA intends to make clear that a train will be considered a transfer train only if the train moves no more than 20 miles between its point of origin and its point of final destination. If the train will move greater than 20 miles between the point of origin and point of final destination, it cannot be considered a transfer train, and a Class I brake test must be performed on the train prior to departure from its point of origin. Although cars may be added to a transfer train while the train is en route, as discussed below, with a transfer train brake test being performed on the cars added, the train is limited to a total of 20 miles from its point of origin, not from the location where new cars are added. The distance the entire train will move between its point of origin and point of final destination is the determinative factor in determining whether the train is a transfer train, cars dropped-off or picked-up en route do not affect this distance.

Paragraph (a) retains the proposed tasks that are required to be performed when conducting a transfer train brake test. Due to the short distance these

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types of trains will travel, FRA will continue to permit the brake system to be charged to only 60 psi but will make clear that this must be verified by an accurate gauge or end-of-train device. Although the current regulations do not require the use of a gauge or device, FRA is at a loss to understand how an inspector can know the pressure in the brake system without getting a reading from the rear of the train. This paragraph also retains the requirement that the brakes apply in response to a 15-psi brake pipe reduction. FRA continues to believe that the reduced pressure at which this test is performed (i.e., 60 psi rather than 75 psi) requires that an application be obtained with a smaller pressure reduction than that required for other brake tests. This paragraph also makes clear that the brakes shall apply on each car added to the train and remain applied until a release is initiated and reiterates the parameters for performing a retest on those cars found not to have sufficiently applied that are contained in the Class I brake test requirements.

Paragraph (b) clarifies that cars may be added to a transfer train while it is en route to its destination. This activity is currently conducted by these trains, and it was not FRA's intent when issuing the NPRM to propose prohibiting these trains from being used in this fashion. This paragraph makes clear that when cars are added to a transfer train the added cars are to be inspected pursuant to the requirements contained in paragraph (a) of this section. This is generally consistent with what FRA currently requires when cars are added to a transfer train, and this paragraph has been added to clarify FRA's retention of the existing practice.

Section 232.217 Train Brake System Tests Conducted Using Yard Air

This section contains the requirements for performing train brake system tests when using yard air. The requirements contained in this section have been modified from those proposed in the NPRM in response to the comments and recommendations received. Paragraph (a) retains the proposed requirements regarding the use of an engineer's brake valve or a suitable test device capable of making any increase or decrease of brake pipe air pressure at the same, or slower, rate as an engineer's brake valve when conducting brake tests utilizing yard air. The requirement to use such a device also applies when retesting cars during Class I, Class IA, Class II, and transfer train brake tests.

Paragraph (b) generally retains the requirement to connect the air test device to the end of the cut of cars that will be nearest to the controlling locomotive. However, this paragraph permits the test device to be connected to other than the end nearest the controlling locomotive if a railroad has appropriate procedures in place to ensure the safety of such a practice. FRA recognizes that some currently existing yards are designed in such a manner so that performance of a test from the front of the consist is extremely difficult or impossible. FRA also recognizes that the safety concerns that arise when cars are charged from other than the head-end of the consist can be eliminated if proper procedures are in place to ensure that overcharge conditions do not occur. An "overcharge condition" describes a situation in which the brake equipment of cars, or locomotives, or both is charged to a higher pressure than the maximum brake pipe pressure that can normally be achieved in that part of the train; this may result in the locomotive engineer's lacking the ability to control the application or release of the brakes at the rear of the train. This paragraph recognizes that there are a number of operating or testing procedures which may be used to eliminate the existence of potential overcharge conditions. Rather than specify a procedure, this paragraph permits a railroad to adopt and comply with whatever procedure it determines is best suited to its operation. However, this paragraph makes clear that the procedure must be in writing and that the procedure must be followed by the railroad. Consequently, FRA will hold a railroad responsible for complying with whatever procedure it adopts.

Paragraph (c) modifies some of the provisions related to conducting brake tests utilizing yard air sources that were proposed in the NPRM. Rather than requiring yard air tests to be performed at 80 psi as was proposed, this paragraph reduces the required pressure to 60 psi at the end of the consist as is currently required. FRA recognizes that many yard air sources and rental compressors are not capable of producing 80 psi of air pressure. In order to address the concerns raised regarding the inadequacy of conducting a leakage or air flow test at this lower pressure, this paragraph includes a requirement that leakage and air flow tests be conducted at the operating pressure of the train. Thus, if the yard air is not capable of producing the air pressure at which the train will be operated, then the leakage or air flow test must be conducted when the locomotives are attached. This paragraph also retains the proposed requirement that a Class III brake test as proposed in § 232.211 must be performed on cars tested with yard air at the time that the road locomotive is attached. This paragraph also retains the proposed requirement for retesting cars that remain disconnected from a source of compressed air for more than four hours.

Paragraph (c) and (d) retain the proposed requirements regarding the calibration and accuracy of yard test devices and gauges with slight modification for clarity. Paragraph (c) requires that mechanical yard test devices and gauges be calibrated every 92 days and that electronic yard test devices and gauges be calibrated annually. Based on observations made by FRA's field inspectors, FRA has some concerns regarding the condition of many yard test devices and gauges. FRA has found numerous mechanical gauges the condition of which creates serious doubt as to the accuracy of the gauge. Mechanical gauges have been found with broken or missing glass which would allow moisture and other contaminates to be present in the gauge. As many of the yard test plants being used today are portable, they are exposed to a wide array of handling and environmental hazards while being transported from location to location. Therefore, this paragraph requires that mechanical devices and gauges be tested and calibrated every 92 days. On the other hand, electronic gauges and devices appear to have much less exposure to many of the hazards encountered by mechanical devices and gauges and tend to be much more reliable and accurate for a longer period of time. Consequently, this paragraph requires electronic yard test devices and gauges to be tested or calibrated, or both, on an annual basis. Paragraph (d) retains the proposed requirement that any yard air test device and any yard air test equipment used to test a train be accurate and function as intended. FRA will consider a device or gauge to be accurate if it is within the calibration parameters contained in paragraph (c) of this section.

Section 232.219 Double Heading and Helper Service

This section contains the requirements related to double heading and helper service. This section has been modified from that proposed in order to clarify that the requirements contained in this section do not apply to distributed power units and to remove unnecessary provisions. Thus, the second sentence of proposed paragraph (a) has been removed as the brake valve on distributed power units

are left cut in to accelerate response time. In addition, proposed paragraph (b) has been eliminated as it was originally intended to apply to passenger equipment and is not applicable to freight operations. Paragraph (a) retains the proposed clarification regarding the inspection that is to be performed when a controlling locomotive is changed. Paragraph (a) clearly identifies that a Class III brake test pursuant to § 232.211 must be performed when a new locomotive is placed in control of the train. FRA believes that the provisions retained in paragraph (a) are necessary and have been in place for years in order to ensure that locomotives taking control of a train have the ability to actually control the brakes on the train.

Paragraph (b), previously proposed as paragraph (c), retains the proposed requirement aimed at ensuring that the brake systems on helper locomotives respond as intended to brake commands from the controlling locomotive at the time it is placed in the train. Although the brake system on locomotives are required to be inspected on a daily basis, FRA continues to believe that a visual confirmation of the proper operation of a helper locomotive's brakes should be made at the time the locomotive is added to a train. Failure of a helper locomotive to respond to the command of the controlling locomotive could result in a very serious safety hazard in that a helper locomotive may continue to push the rear of the train while the brakes are applied, potentially resulting in a derailment or other incident. FRA intends to make clear in this paragraph that a helper locomotive found with inoperative or ineffective brakes is to be repaired prior to use or else removed from the train.

Paragraph (c) contains basic design and testing requirements for helper locomotives utilizing a Helper Link device or similar technology. The Helper Link device is an electronic device, mounted on the front end of the lead helper locomotive and is used to control the automatic air brakes on helper locomotive consists. When this device is used, the train's brake pipe is not connected between the rear car of the train being pushed and the helper locomotives. The end-of-train device, attached to the rear car of the train, sends a radio signal which is received by the Helper link device. The Helper Link device is connected to the brake pipe of the helper locomotives, and electronic commands from the EOT device cause the air pressure in the helper locomotive brake pipe to be reduced or increased, thus applying or releasing the brakes on the helper locomotives. A signal is transmitted from the EOT device to the Helper Link device at 10-second intervals to ensure communication. The Helper Link is also used to operate the uncoupling lever to detach the helper locomotives from the rear of the train without stopping the train.

Based on information currently available to FRA, it appears that when there is a loss of communication between the EOT device and the Helper Link device, the engineer of the helper locomotive consist is not immediately aware of the failure. If the communication between the EOT device and the Helper Link is not reestablished within the next 40-second communication cycle, the Helper Link device will automatically disable itself. Consequently, if the train experiences an emergency application of the air brakes while the Helper Link device is disabled, the brakes on the helper locomotives would not apply and would result in the helper locomotives continuing to push under power. Furthermore, in order for communications to be reestablished between the EOT and Helper Link, the engineer must leave the locomotive controls, exit the locomotive cab, and proceed to the front of the locomotive to manually press the reset buttons located on the Helper Link device itself. In addition, there are currently no regulations which address the use, testing, or calibration of these Helper Link devices.

On August 22, 1996, the UTU submitted a petition for rulemaking with FRA regarding Helper Link devices raising many of the concerns noted above. *See* Petition for Proposed Rulemaking, Docket 96–1. In order to address the UTU petition in this rulemaking and to address the concerns of FRA noted above, FRA sought information and comment from persons interested in the NPRM. *See* 63 FR 48345. A presentation and discussion regarding the use, operation, and design of Helper Link devices was engaged in at the technical conference conducted in Walnut Creek, California, on November 23 and 24, 1998. Written comments regarding the device were also submitted by the manufacturer of the device. Based on consideration of this information, FRA has determined that certain minimum design and testing requirements should be included in this final rule to ensure the safety of those trains utilizing Helper Link technology.

Paragraph (c) contains the design and testing requirements that FRA believes are appropriate when railroads utilize Helper Link devices or similar technology. This paragraph ensures that a locomotive engineer is notified by a distinctive alarm of any loss of communication for more than 25 seconds between the device and the two-way EOT. This paragraph also requires that the engineer be provided a method of resetting the device in the cab of the helper locomotive and that the device be tested and calibrated on an annual basis. Due to the limited number of Helper Link devices currently being used, FRA believes that the manufacturer of these devices can easily provide railroads utilizing the devices with the information and hardware to meet the requirements contained in this paragraph at a minimal cost to the railroad.

Subpart D—Periodic Maintenance and Testing Requirements

This subpart provides the periodic brake system maintenance and testing requirements for equipment used in freight and other non-passenger trains. As stated in the 1994 NPRM and 1998 NPRM, FRA firmly believes that the new repair track test and single car test, which have been used industry-wide since January of 1992, are a much better and more comprehensive method of detecting and eliminating defective brake equipment and components than the old, time-based COT&S requirements. FRA believes that performance of these tests has significantly reduced the number of defective components found and has dramatically increased the reliability of brake equipment. Through the implementation of the repair track and single car tests, the safety of both railroad employees and the public has greatly improved due to brake equipment being in better and safer condition. At the same time, however, FRA is cognizant that contentions by rail labor regarding the carrier's direct and intentional circumvention of these revised requirements through the elimination of repair tracks, by moving cars to expediter tracks for repair, or simply by making repairs in the field raise a legitimate concern that needs to be addressed to ensure that the industry fully benefits from the advantages of the improved tests.

Although this subpart retains many of the proposed maintenance requirements, several modifications have been made in this final rule in response to comments received and based upon the current best practices occurring within the industry. FRA agrees that the proposed incorporation of AAR Rule 3, Chart A, is unnecessary as it would remove the determination of when certain maintenance is performed from the discretion of the railroads, and

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would make it difficult for railroads to change the requirements related to the performance of that maintenance. FRA believes that a railroad is in the best position to determine when and where it will perform various maintenance on its equipment and should not have its hands tied in this area by overly prescriptive federal requirements. Furthermore, FRA's primary intent when proposing incorporation of AAR Rule 3, Chart A, was to codify the existing requirements for performing single car and repair track air brake tests and eliminate the ability of the industry to unilaterally change the frequency and method of performing these tests. As this subpart retains the requirements for when and how these tests are to be completed and retains certain inspections that are to be performed when equipment is on a shop or repair track, FRA believes that it is unnecessary to incorporate every maintenance procedure covered in AAR's Rule 3, Chart A. Consequently, the final rule does not incorporate AAR's Rule 3, Chart A, and continues to allow railroads some flexibility in determining appropriate maintenance practices. (A detailed discussion of the comments and recommendations submitted on the maintenance requirements contained in this subpart is contained in the preceding "Overview of Comments and General FRA Conclusions" portion of the preamble under the heading "VII. Maintenance Requirements.")

Section 232.303 General Requirements

This section contains the general requirements regarding the maintenance, repair, and testing of freight cars. Paragraph (a) contains various definitions for determining whether a particular track or facility constitutes a shop or repair track. The definitions contained in this paragraph were not previously proposed in the NPRM but are consistent with current FRA enforcement policies and are necessary to clarify when various tests and inspections required in this section are to be performed.

As the current regulations and this subpart require that certain inspections and tests are to be performed when a car is on a shop or repair track and because a repair track air brake test is required to be performed when a car is on a repair track and such a test has not been performed within the last twelve months, FRA believes it is necessary to clarify what constitutes a shop or repair track. This issue has become more prevalent over the last few years due to the growing use of mobile repair trucks and due to the requirements for conducting repair track air brake tests. For years, many railroads have conducted minor repairs on tracks called "expedite tracks." Generally, the types of repairs that were performed on these tracks were minor repairs that could be made quickly with a limited amount of equipment, and neither the railroads or FRA considered the tracks to be repair tracks. However, recently railroads have started performing virtually every type of repair on these expedite tracks. These tracks are no longer limited to minor repairs but are being used to perform heavy, complex repairs that require the jacking of entire cars or the disassembly and replacement of major portions of a car's truck or brake system. At many locations these expedite tracks are positioned next to operative repair shops. Furthermore, several railroads have closed previously existing repair shop facilities and are now using fully equipped mobile repair trucks to perform the same type of repairs that were previously performed in the shop or on established repair tracks and are attempting to call the tracks serviced by these mobile repair trucks "expedite" or "light repair" tracks. Thus, the line between what constitutes a repair or shop track and what constitutes an "expedite" or "light repair" track has become unclear or nonexistent.

Appendix A of AAR's Field Manual of Interchange Rules provides a definition of both "shop or repair track" and "expedite track." Although FRA does not consider these definitions to be controlling with regard to what constitutes a repair track under the current regulations, FRA does believe that AAR's definitions of the above terms have created confusion within the industry regarding what constitutes a repair track. If the AAR's definitions are read together they appear to exclude repairs made by mobile repair trucks, regardless of where they are made or the nature of the repairs conducted, from ever being considered as being performed on a repair track. FRA believes it is both illogical and inconsistent with the intent and meaning of the existing regulations and with the provisions proposed in the NPRM to exclude from the definition of "shop or repair track" tracks at locations where repairs of all types are regularly and consistently performed from merely because they are serviced by a mobile repair vehicle. Furthermore, it would be inconsistent with previous technical bulletins and enforcement guidance issued by FRA to allow major repair work to be performed on "expedite" or "light repair" tracks merely because the repairs are performed by a mobile repair vehicle.

FRA believes that the operational changes, noted above, are partly an attempt by the railroads to circumvent the requirements that currently apply when a car is on a shop or repair track. Currently, if a car is on a shop or repair track, it must have its brakes inspected, under 49 CFR 232.17(a)(2)(ii), (iv), and the car is to receive a repair track air brake test if it has not received one in the last twelve months under AAR Rule 3, Chart A. Some railroads contend that an expedite track is not a repair or shop track; therefore, the requirements of § 232.17(a)(2)(ii), (iv) and AAR Rule 3, Chart A, do not apply. FRA finds this practice and interpretation to be unacceptable and believes that railroads are abusing the concept of expedite tracks to avoid performing required maintenance. Therefore, the industry's own actions have caused the need for FRA to clarify what constitutes a shop or repair track. Consequently, paragraph (a) includes a definition of what FRA will consider to be repair or shop tracks requiring the performance of certain tests and inspections.

Paragraph (a) makes clear that FRA will consider certain tracks to be repair or shop tracks based on the frequency and types of repairs that are made on the tracks, not necessarily the designation given by a railroad. The definitions in this paragraph also make clear that it is the nature of the repairs being conducted on a certain track that is the determining factor not whether a mobile repair truck is being used to make the repairs. Due to the ability of mobile repair trucks to make virtually any type of repair necessary and due to their growing use, FRA does not believe that tracks regularly and continually serviced by these types of vehicles should be excepted from the definition of "repair track." FRA believes that if a track is designated by the railroad as an "expedite" track (i.e., one where minor repairs will be conducted) then the railroad should ensure that only cars needing minor repairs are directed to that track for repair. FRA does not intend to eliminate the concept of expedite tracks but limits the use of such tracks to those types of repairs that are truly minor in nature and that require a limited amount of equipment to perform. At locations where a railroad conducts repairs of all types on a regular and consistent basis, either with fixed facilities or with mobile repair trucks, FRA would expect the railroad to designate certain trackage at the location as repair tracks and certain trackage as "expedite tracks" where only minor repairs would be conducted. In such circumstances, FRA would expect railroads to direct cars in need of heavier repairs, the kind that have been traditionally performed on a shop or repair track, to be directed to trackage designated at the location as a repair track.

Paragraph (a) places the burden on the railroad to designate those tracks it will consider repair tracks at locations where it performs both minor and heavy repairs on a regular and consistent basis, and makes the railroad responsible for directing the equipment in need of repair to the appropriate trackage. If the railroad determines that repairs of a heavy nature will be performed on certain trackage, then the track should be treated as a repair track, and any car repaired on that trackage should be provided the attention required by this final rule for cars on a shop or repair track. Further, if a railroad determines that minor repairs will be performed on certain trackage, then the railroad bears the burden of ensuring that only cars needing minor repairs are directed to that trackage. If the railroad fails to adequately distinguish the tracks performing minor repairs from those tracks performing heavy repairs or improperly performs heavy repairs on a track designated as an "expedite track," then the railroad will be required to treat all cars on the trackage at the time that the heavy repairs are being conducted as though they are on a repair or shop track.

It should be noted that the issue of what constitutes a repair or shop track for the purposes of this subpart is completely separate and distinct from the issue of whether a location is a location where necessary repairs can be performed for purposes of 49 U.S.C. 20303 and § 232.15 of this final rule. Although an outlying location might be considered a location where certain brake repairs can be conducted, that does not mean the track where those repairs are performed should be considered a repair track. FRA does not intend for trackage located at outlying locations or sidings which are occasionally or even regularly serviced by mobile repair trucks to be considered repair tracks. FRA believes that repair or shop tracks should exist at locations that have fixed repair facilities and at locations where repairs of all types are performed on a regular and consistent basis regardless of whether the repairs are performed in fixed facilities or by mobile repair vehicles.

Paragraphs (b)–(d) retain the proposed provisions requiring certain tests and inspections to be performed whenever a car is on a shop or repair track. Although the AAR asserts that it did away with the requirements to perform a set and release of the brakes and adjust piston travel on all cars on repair or shop tracks, the requirements are currently contained in power brake regulations separate and apart from any AAR requirements. *See* 49 CFR 232.17(a)(2)(ii), (iv). FRA believes that repair and shop tracks provide an ideal setting for railroads to conduct an individualized inspection on a car's brake system to ensure its proper operation and that such an inspection is necessary to reduce the potential of cars with excessive piston travel being overlooked when employees are performing the ordinary brake inspections required by this final rule. If any problems are detected at that location, the personnel needed to make any necessary corrections are already present. Furthermore, performing these inspections at this time ensures proper operation of the cars' brakes and eliminates the potential of having to cut cars out of an assembled train and, thus, should reduce inspection times and make for more efficient operations.

Paragraph (b) retains the proposed requirement that a car on a shop or repair track be tested to determine that its air brakes apply and remain applied until a release is initiated. This paragraph requires that the air brakes remain applied until the release signal is initiated and is intended to maintain consistency with the requirement contained in § 232.205(b)(4). Paragraph (b)(4) is an attempt to clarify language contained in the current regulation which require that the brakes "apply." This language has been misinterpreted by some to mean that if the piston applies in response to a command from a controlling locomotive or yard test device, and releases before the release signal is given, the brake system on that car is in compliance with the regulation because the brake simply applied. The intent of the regulation has always been that the brakes apply and remain applied until the release signal is initiated from the controlling locomotive or yard test device. Therefore, clarifying language was proposed in this paragraph to eliminate all doubt as to what is required. Consequently, this paragraph makes clear that the brakes on a car must remain applied until the appropriate release signal is given. If it fails to do so, the car must be repaired and retested.

Paragraph (c) retains the proposed requirement that if piston travel is found to be less than 7 inches or more than 9 inches, it must be adjusted to nominally 7½ inches, which is a change from the 7 inches as currently required, in order to maintain consistency with the requirement proposed at § 232.205(b)(5). This change was proposed in the NPRM and is based on a request by AAR to change the adjustment to 7½ inches from 7 inches as its member railroads were finding it extremely difficult to adjust the piston travel to precisely 7 inches and that in some cases the adjustment would be marginally less than 7 inches, thus requiring a readjustment. Therefore, AAR sought the extra ½ inch in order to provide a small margin for error when the piston travel is adjusted. As FRA believes that AAR's concerns are validly placed and would have no impact on safety, FRA has accommodated the request.

Paragraph (d) retains the proposed listing of brake system components that are to be inspected prior to a car being released from a shop or repair track. Many of the items contained in this paragraph are currently required to be inspected pursuant to § 232.17(a)(2)(iv). It should be noted that the proposed requirement, retained in this final rule, regarding the proper functioning of angle cocks was modified in the NPRM from the existing requirement by clarifying that angle cocks must be inspected to ensure that they are properly positioned to allow maximum air flow. This is a clarification regarding the normal functioning of the angle cock, and should pose little, if any, additional inspection burden on the railroads. This paragraph adds two items to the inspections that are to be conducted when a car is on a shop or repair track. They are an inspection of a car's hand brake and an inspection of the accuracy and operation of any brake indicators on cars so equipped. As the final rule does not provide for the specific inspection of these items during any of the other required brake tests, FRA believes this is an ideal time for the railroad to inspect these items while imposing the least burden on the railroad's inspection and repair forces.

Paragraph (e) retains the proposed provisions permitting cars to be moved from a location where necessary repairs are made to a location where a single car or repair track air brake test can be performed if it cannot be performed at the same location where the repairs are conducted. FRA disagrees with the assertions of some commenters that air brake repairs should not be required at locations that lack the ability to perform single car or repair track air brake tests. FRA believes that position is not only contrary to the statutory mandates regarding the movement of equipment with defective brakes but would open the door to potential abuse by railroads.

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Furthermore, the operation of a car's brake system can generally be tested after a repair without performing a complete repair track air brake test. For the most part, single car and repair track air brake tests are intended to be maintenance requirements that attach based on a condition in which a car is found or on a repair that is required to be performed. If the condition of a car is such that a repair track air brake test is necessary to determine the defect, then the final rule would permit movement of the car to the nearest location where a repair track air brake test can be performed. However, FRA believes that most defective conditions can be easily determined without performing a repair track air brake test. Moreover, for years FRA has required the performance of repairs where they can be performed and has allowed such equipment to be moved to the next forward location for performance of a single car or repair track air brake test and has not found that such a practice has created any potential safety hazard.

Paragraph (e) also retains the proposed requirements for tagging equipment which is being hauled for the performance of a single car or repair track air brake test after the appropriate repairs have been conducted. FRA believes that the tagging requirements are necessary not only to provide notice to a railroad's ground forces as to the presence of the car but also to ensure that railroads are properly performing the tests at appropriate locations. Furthermore, many railroads currently move equipment in this fashion, and there has been no indication that safety has been compromised. The final rule also retains the requirement that a copy or record of the tag be retained for 90 days and made available to FRA upon request. Contrary to the objections of some commenters, FRA continues to believe that the record keeping requirements are necessary so that there is accountability on the part of the railroads to conduct these tests at the proper locations and that equipment is not moved for extended periods without receiving its required maintenance. It should be noted that the final rule clarifies that the record or copy of the tag may be maintained either electronically or in writing provided all the required information is recorded. This paragraph retains the proposed alternative to the tagging requirements, which permits a railroad to utilize an automated tracking system to monitor these cars and ensure they receive the requisite tests as prescribed in this section provided the automated system is approved by FRA. It should be noted that the final rule does not define or require identification of locations that can or will perform single car or repair track air brake tests as suggested by some commenters. FRA does not believe that such a requirement is necessary because the rule specifically establishes when the tests are to be performed and it is in the railroad's best interests to perform the tests in a timely manner.

Paragraph (f) contains the requirements for railroads to adequately track when single car or repair track air brake tests were last performed on a piece of equipment. This paragraph modifies the proposed requirements regarding the use of an automated tracking system in lieu of stenciling equipment with the date and location of the last single car or repair track test received. Since 1992, the industry has utilized the AAR's UMLER reporting system to electronically track the performance of single car and repair track air brake test as well as other repair information. Based on the performance and use of this system over the last seven years, FRA believes that the AAR's UMLER system has proven itself effective for tracking the information required in this paragraph and ensuring the timely performance of single car and repair track air brake tests. Furthermore, FRA continues to believe that the information required to be tracked in this paragraph with regard to these tests is easily maintained through an electronic medium. Moreover, FRA has found no substantiated instances of railroads falsifying or altering the information monitored and tracked by AAR's UMLER system. Thus, this paragraph permits railroads to utilize an electronic record keeping system to track single car and repair track air brake tests without obtaining prior FRA approval of the system. The final rule makes clear that FRA will monitor the performance of such systems and retains the right to revoke a railroad's authority to utilize the system if FRA finds that it is not properly secure, inaccessible to FRA or a railroad's employees, or fails to properly or adequately track and monitor the equipment.

Section 232.305 Repair Track Air Brake Tests and Section 232.307 Single Car Tests

These sections generally retain the proposed requirements related to the performance of single car and repair track air brake tests. Contrary to the assertions of some commenters, FRA continues to believe that certain maintenance procedures are critical to ensuring the safe and proper operation of the brake equipment on the nation's fleet of freight cars. FRA does not believe that the determination of what maintenance should be performed should be left solely to the discretion of the railroads operating the equipment in all circumstances. As periodic COT&S maintenance has been eliminated and replaced with the performance of single car and repair track tests, which FRA agrees is a better and more comprehensive method of detecting defective brake equipment and components, FRA believes that specific and determinable limits must be placed on the manner and frequency of performing these tests. Therefore, these sections generally retain the proposed requirements regarding the performance of single car and repair track brake tests.

FRA recognizes that the procedures for performing single car and repair track tests proposed in the NPRM have been modified by the AAR since the issuance of the proposal. As it is FRA's intent to incorporate the most recent version of the single car and repair track air brake test procedures, paragraph (a) of each section incorporates by reference the test procedures that were issued by the AAR in April of 1999. These test procedures are contained in AAR standard S–486–99, Sections 3.0 and 4.0, which are located in the AAR's "Manual of Standards and Recommended Practices, Section E" (April 1999). Both these sections recognize that the industry may find it necessary to modify the test procedures from time to time in order to address new equipment or utilize new technology. Thus, paragraph (a) of each section permits railroads to seek approval of alternative procedures through the special approval process contained in § 232.17 of this final rule. The special approval process is intended to speed FRA's consideration of a party's request to utilize an alternative procedure from the ones identified in the rule itself. FRA believes that it is essential for FRA to approve any change made in the procedures for conducting these safety-critical tests in order to prevent unilateral changes and to ensure consistency in the method in which the tests are performed.

It should be noted that the incorporated procedures for performing single car and repair track air brake tests are the minimum requirements for performing such tests. The special approval process is required to be used only if the incorporated procedures are to be changed in some manner. For instance, if the industry were to elect to add a new test protocol to the incorporated procedures, there would be no need to seek approval of such an addition as long as the procedures contained in the incorporated standard are still maintained. This final rule is not intended to prevent railroads from voluntarily adopting additional or more stringent maintenance standards provided they are consistent with the standards incorporated.

Both sections retain the proposed frequency at which single car and repair track air brake tests are to be performed. As noted in the preceding discussion, the primary intent of the proposed provisions was to codify the existing requirements regarding the performance of single car and repair track air brake tests and prevent any unilateral changes to those requirements. FRA believes that the frequency at which these tests are currently required to be performed under industry standards has proven to be sufficient and a substantial economic burden would be imposed if the frequency were increased. Both sections also retain the requirement that these tests be conducted by a qualified person. FRA continues to believe that the person performing these tests must be specifically trained and tested on how the test is to be performed and be able to determine the appropriate actions that must be taken based on the results of the test. FRA does not believe that the mere fact that a person is a carman or a QMI is sufficient to make that person qualified to perform single car or repair track air brake tests. FRA believes that the training and testing requirements required by this final rule ensures that a person is qualified to perform these tests.

Section 232.305(b) generally retains the proposed list of conditions that would require the performance of a repair track air brake test. However, two of the proposed conditions for when a repair track air brake test would be required to be performed have been slightly modified in order to make them consistent with the currently existing AAR requirements for performing these tests. FRA agrees that the proposed requirement to perform a repair track air brake test on any car removed from a train for a brake-related defect is overly restrictive and inconsistent with the requirements of AAR's Rule 3, Chart A. FRA agrees that the proposed requirement would require the performance of the test when minor brake system repairs are conducted, which is not the intent of the AAR's rule. Therefore, this paragraph modifies the proposed condition to require the performance of a repair track test on cars that have inoperative or cut-out air brakes when removed from a train. Furthermore, the proposed provisions requiring the performance of a repair track air brake test whenever a car is found with a wheel with built-up tread or slid flat have been slightly modified. Under the final rule, the test will not be required if the built-up tread or slid flat wheel is known to have been caused by a hand brake that was left applied. These modifications are consistent with what is currently required under AAR Rule 3, Chart A.

Paragraphs (c) and (d) of § 232.305 retain the proposed requirements that each freight car receive a repair track air test within eight years from the date the car was built or rebuilt, and within every five years thereafter. FRA strongly believes that these minimum attention periods are sufficient to ensure the safety of the freight car fleet when considered in conjunction with the increased attention that freight cars receive when these types of tests are performed.

Paragraph (c) of § 232.307 retains the proposed requirement that a single car test be conducted by a qualified person prior to a new or rebuilt car being placed in or returned to revenue service. FRA believes that it is essential for new and rebuilt cars to receive this test prior to being placed in revenue service in order to ensure the proper operation of the brake system on the vehicle. Most railroads already require this attention to be given to new and rebuilt cars; thus, the cost of this requirement is minimal and merely incorporates the best practices currently in place in the industry.

Section 232.309 Repair Track Test and Single Car Test Equipment and Devices

This section generally retains the proposed requirements for maintaining the equipment and devices used in performing repair track and single car air brake tests. This section modifies some of the proposed provisions regarding the testing and calibration of single car test devices and other mechanical devices used to perform single car and repair track air brake tests. FRA's intent when proposing the requirements contained in this section was to codify the current best practices of the industry. Thus, FRA did not intend to propose testing and calibration requirements that were more stringent that those currently imposed by AAR standards. Therefore, FRA agrees with the comments submitted by AAR that the testing and calibration requirements for single car test devices should not be imposed until the devices are actually placed in service, which is consistent with current AAR requirements. FRA recognizes that the proposed calibration and testing requirements may have resulted in the unnecessary acquisition of single car testing devices. Consequently, this section has been modified to clarify that the 92-day and the 365-day calibration and testing requirements related to single car test devices are to be calculated from the day on which the device is first placed in service. FRA continues to believes that the devices and equipment used to perform these single car and repair track air brake tests are safety-critical items. Consequently, FRA believes that these devices must be kept accurate and functioning properly in order to ensure that repair track and single car tests are properly performed.

Subpart E—End-of-Train Devices

This subpart incorporates the design, performance, and testing requirements relating to end-of-train devices (EOTs) that were issued on January 2, 1997, which became effective for all railroads on July 1, 1997, except for those for which the effective date was extended to December 1, 1997 by notice issued on June 4, 1997. *See* 62 FR 278 and 62 FR 30461. This subpart also incorporates the recent modifications made to the two-way EOT requirements to clarify the applicability of the requirements to certain passenger train operations where multiple units of freight-type equipment, material handling cars, or express cars are part of a passenger train's consist. *See* 63 FR 24130.

As noted in the discussion of the applicability provisions contained in § 232.3 of this final rule, this subpart applies to all trains unless specifically excepted by the provisions contained in this subpart. As the provisions contained in this subpart were just recently issued, there is little need to discuss these requirements in detail as they were fully discussed in the publications noted above. However, after their issuance, FRA discovered that a few of the provisions were in need of minor modification for clarification purposes and to address some valid concerns that have been raised both internally by FRA inspectors and by outside parties. Consequently, in the NPRM FRA proposed various changes to the provisions related to end-of-train devices and discussed other issues which might require modification of the existing provisions. *See* 63 FR 48347–49. This discussion is intended to focus on the proposed changes and address those issues discussed in the preamble to the NPRM as well as address the issues raised at the public hearings and in written comments.

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Section 232.405 Design and Performance Standards for Two-Way End-of-Train Devices

Paragraph (d) retains the proposed modification of the requirement relating to the diameter of the valve opening and hose on two-way EOTs, which is currently contained in § 232.21(d). The current regulation requires that the valve opening and hose have a minimum diameter of ¾ inch to effect an emergency application. FRA has discovered that sometime prior to the issuance of the final rule on two-way EOTs, Pulse Electronics began manufacturing its two-way EOT with the internal diameter of the hose being ⅝ inch. Testing of the devices manufactured with these smaller diameter hoses showed that they met all criteria for emergency application capability based on standards and guidelines set forth by the AAR. Furthermore, testing of the devices at the Westinghouse facility in Wilmerding, Pennsylvania, demonstrated that the ⅝ inch diameter hose permitted 14 consecutive 50-foot cars with cut-out control valves or 750 feet of brake pipe to be jumped. This is more than double the AAR standard for control valve requirements. Moreover, FRA's intent when issuing the two-way EOT design requirements was to incorporate designs that existed at the time the rule became effective. Consequently, paragraph (d) of this section is modified to permit the use of a ⅝ inch internal diameter hose in the design of the devices.

Paragraph (e) has been slightly modified, from what is currently required in § 232.21(e), to permit the manually operated switch capable of initiating an emergency brake command to the rear unit to be located either on the front unit itself or on the engineer control stand. Several railroads and a manufacturer of locomotives recommended that the provision regarding the placement of the manually operated switch be modified to recognize existing designs of the devices and the locomotives on which they are placed. These commenters stated that many front units do not have the switch located directly on the front unit itself but that the switch is located on the engineer's control stand. FRA agrees with this recommendation and currently does not take exception to locomotives designed in the manner described above. Consequently, this paragraph permits the manually operated switch to be located either on the front unit itself or on the engineer's control stand.

A new paragraph (f) has been added to this section which incorporates a recommendation from AAR and its member railroads that new locomotives be equipped with a means to automatically activate an emergency brake application from the rear unit whenever the locomotive engineer places the train air brakes in emergency. On June 1, 1998, FRA issued Safety Advisory 98–2, which recommended that railroads adopt a procedure to require activation of the rear unit to effectuate an emergency brake application either by using the manual toggle switch or through automatic activation, whenever it becomes necessary for a locomotive engineer to place the train air brakes in emergency using either the automatic brake valve or the conductor's emergency brake valve or whenever an undesired emergency application of the train air brakes occurs. *See* 63 FR 30808. FRA applauds the industry for taking the initiative to incorporate available technology on new locomotives and agrees with the representatives of the railroads that it is not economically feasible to require existing equipment to be retrofitted with this capability at this time. Furthermore, existing equipment is addressed in § 232.407(f)(3), which retains the proposed requirement for the engineer to manually activate an emergency application from the rear unit when the engineer initiates an emergency application in the controlling locomotive if the locomotive is not equipped to do so automatically.

FRA issued Safety Advisory 98–2 in response to several recent freight train incidents potentially involving the improper use of a train's air brakes, events that caused FRA to focus on railroad air brake and train handling procedures related to the initiation of an emergency air brake application, particularly as they pertain to the activation of the two-way EOT from the locomotive. The NPRM discussed four accidents in which a train was placed into emergency braking by use of the normal emergency brake valve handles on the locomotive, and although the train in each instance was equipped with an armed and operable two-way EOT, the device was not activated by the locomotive engineer. *See* 63 FR 48348. Preliminary findings indicate that in all of the incidents noted above, there was evidence of an obstruction somewhere in the train line, caused by either a closed or partially closed angle cock or a kinked air hose. This obstruction prevented an emergency brake application from being propagated throughout the entire train, front to rear, after such an application was initiated from the locomotive using either the engineer's automatic brake valve handle or the conductor's emergency brake valve. Furthermore, the locomotive engineers in each of the incidents stated that they did not think to use the two-way EOT, when asked why they failed to activate the device.

Section 232.407 Operations Requiring Use of Two-Way End-of-Train Devices; Prohibition on Purchase of Nonconforming Devices

Paragraph (e) generally retains the proposed modification of the provision, currently contained in § 232.23(e)(1), which excepts from the two-way EOT requirements trains operating with a locomotive capable of effectuating an emergency application located in the rear third of the train. In the NPRM, FRA proposed to modify this exception so that it would be applicable only to trains operating with a locomotive on the rear of the train. Data supplied by VOLPE demonstrates that stopping distances are greatly increased, and could potentially result in a runaway train or derailment depending on the length of the train, if an obstruction of the brake pipe were to occur directly behind a locomotive located in the rear third of the train. Therefore, FRA proposed that a train with a locomotive located in the rear third of the consist no longer be excepted from the two-way EOT requirements, unless the train qualifies for relief under one of the other specific exceptions contained in § 232.407(e). Although FRA received no objections to this specific change, several commenters did recommend that the exception contained in paragraph (e)(1) be modified to include locomotive consists at the rear of a train. These commenters asserted that the existing rule needed to recognize that some locomotives have fuel tenders attached. FRA finds this requested modification to be sensible and logical. Consequently, paragraph (e)(1) has been retained as proposed, with a slight modification to clarify that the exception extends to trains with either a locomotive or a locomotive consist located at the rear of the train.

A new exception to the two-way EOT requirements has been added at paragraph (e)(9) to address the practice of "doubling a hill." The practice of "doubling a hill" occurs in situations where a train must be divided in two in order to traverse a particularly heavy grade due to the lack of sufficient motive power to haul the entire train up the grade. This issue was discussed in the NPRM and at the public technical conference conducted subsequent to the issuance of the NPRM. Initially, FRA believed that the two-way EOT should

be connected to that portion of the train traversing the grade. However, such an approach creates a multitude of operational as well as safety concerns. Such an approach would require train crews to repeatedly switch the rear unit from one portion of the train to another, which would require these individuals to repeatedly walk sections of the train at locations where it may not be safe to do so. Alternatively, such an approach might require some trains to carry extra devices while in transit. At the public technical conference, there was universal agreement between all representatives at the conference that the device should remain on the rear unit of the train in these circumstances. Consequently, paragraph (e)(9) has been added to except trains from the two-way EOT requirements that must be divided into two sections in order to traverse a grade. This paragraph makes clear that the exception only applies to the extent necessary to traverse the grade and only while the train is divided into two to conduct that movement.

Paragraph (f)(1) has been slightly modified from what is currently contained § 232.23(f)(1) in order to clarify and address an issue related to the ability of a railroad to dispatch a train with an inoperative two-way EOT from a location where the device is installed. Section 232.23(f)(1) of the current regulations, § 232.407(f)(1) of the NPRM, requires that "the device shall be armed and operable from the time the train departs from the point where the device is installed until the train reaches its destination." Therefore, the existing regulations clearly require a train to be equipped with an armed and operable two-way EOT when dispatched from a location where the device is installed. When issuing this requirement, FRA intended railroads to install repeater stations at locations where communication problems are prevalent.

Several commenters, both at the public hearings and in written comments, assert that this requirement is impossible to meet at some locations regardless of whether repeater stations are installed. These commenters contend that certain locations have dead spots where it is impossible to establish communication between the front and rear unit. These parties recommend that some allowance be provided to permit trains at these locations to be moved a short distance to restore communication. FRA agrees that there are a few locations where dead spots exist which make it difficult if not impossible to establish communication between the two units when they are installed. Therefore, paragraph (f)(1) has been modified to allow a train that experiences a loss of communication or that fails to establish communication between the two units at the location where the device is installed to move up to one mile from that location in order to establish communication. FRA believes that this allowance should be sufficient at most locations to establish the required communication. Furthermore, if communication cannot be established within these limits, then FRA believes the railroad needs to install additional repeater stations. If additional repeater stations still fail to address the issue, then FRA believes that a railroad should be required to apply for a waiver of the requirement at a particular location, pursuant to the requirements of 49 CFR part 211. This approach will allow FRA to address the unique circumstances of each location on a case-by-case basis and ensure that the railroad implements other operational safeguards to ensure the safety of those trains dispatched without armed and operable devices.

Paragraph (f)(3) generally retains the proposed provision requiring the two-way EOT to be activated to effectuate an emergency brake application either by using the manual toggle switch or through automatic activation, whenever it becomes necessary for the locomotive engineer to initiate an emergency application of the train's air brakes using either the automatic brake valve or the conductor's emergency brake valve. As discussed previously in regard to the addition of § 232.405(f), the proposed requirement incorporates the recommendations contained in FRA's Safety Advisory 98–2, issued on June 1, 1998. *See* 63 FR 30808. FRA believes that the operational requirement contained in this paragraph must be stressed by the railroads when conducting the two-way EOT training required in § 232.203 of this final rule. FRA continues to believe that the likelihood of future incidents, such as the ones described in the NPRM, will be greatly reduced if the train handling procedure contained in this paragraph is made part of a train crew's training and followed by members of the crew in emergency situations. FRA believes that this additional procedure, together with the required training, will not only ensure that an emergency brake application is commenced from both the front and rear of the train in emergency situations, but will familiarize the engineer with the activation and operation of the devices and will educate the engineer to react in the safest possible manner whenever circumstances require the initiation of an emergency brake application.

FRA recognizes that a number of railroads have already adopted procedures similar to those required in this paragraph and commends such actions. Although this paragraph allows the device to be activated either manually or automatically, FRA intends to make clear that the front unit of the device or the engineer's control stand must be equipped with a manually operated switch. *See* § 232.405(e). Although some railroads have developed, and this final rule requires, new locomotives to be equipped with a means by which the rear unit is automatically activated when an engineer makes an emergency application with the brake handle, FRA believes that an engineer must also be provided a separate, manually operated switch which is independent of any automatic system in order to ensure the activation of the rear unit in the event that the automatic system fails.

It should be noted that the provision contained in paragraph (f)(3) has been slightly modified from that proposed in the NPRM. This final rule has eliminated the requirement to activate the rear unit when an undesired emergency brake application occurs to a train. FRA agrees with the assertions of various commenters that such a requirement might distract a locomotive engineer from performing other critical duties required to bring a train to a stop when an undesired emergency brake application occurs. As an undesired emergency brake application is not initiated by the locomotive engineer, such an event will usually take the engineer by surprise, and FRA agrees that the engineer's attention would be best focused on the activity of bringing the train to a stop in such circumstances. Furthermore, all of the instances where an engineer failed to activate the rear device that were discussed in the NPRM occurred in conjunction with an emergency brake application knowingly initiated by the engineer.

Based on the above discussion regarding paragraph (e)(1) of this section, paragraph (g)(1) retains the proposed modification of the requirements for operating a train that experiences an en route failure of the two-way EOT over a section of track with an average grade of two percent or greater over a distance of two continuous miles. In the NPRM, FRA proposed modification of the alternative measure, currently contained at § 232.23(g)(1)(iii), which permits the operation over such a grade if a radio-controlled locomotive is placed in the

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rear third of the train consist and under the continuous control of the engineer in the head end of the train. FRA proposed modification of this alternative measure to permit such operation only if the radio-controlled locomotive is placed at the rear of the train consist. This modification is retained in this final rule in order that the alternative methods of operation over a heavy grade remain consistent with the exception from the two-way EOT requirements contained in § 232.407(e)(1) as discussed in the preceding paragraph. Although some commenters suggested elimination of all of the requirements related to operating a train experiencing an en route failure of its two-way EOT over heavy grades, FRA believes that the alternative methods are necessary to ensure the safety of such a train when descending a heavy grade and ensure that railroads properly maintain the required devices.

Paragraphs (g)(1)(i)(A) and (B) have also been slightly modified to clarify the requirements that a train be stopped in certain situations where communication is lost between a helper locomotive and the controlling locomotive. The final rule makes clear that the stopping of trains in such circumstances should be in accordance with the railroad's operating rules. When issuing the two-way EOT requirements, FRA did not intend for engineers to place themselves in unsafe situations when they encounter an en route failure of the device when traversing a heavy grade. Although the existing rule prohibits the operation of a train over certain heavy grades when a failure of the device occurs en route, FRA did not intend that the train be immediately stopped when a failure of the device occurs while operating on a heavy grade. Rather, FRA intended for the locomotive engineer to conduct the movement in accordance with the railroad's operating rules for bringing the train safely to a stop at the first available location. Therefore, safety may require that the train continue down the grade or to a specific siding rather than come to an immediate halt. Consequently, the modifications contained in these paragraphs are intended to reflect FRA's expectations when issuing the two-way EOT regulations.

Paragraph (g) has also been slightly modified in order to clarify what constitutes a loss of communication between the front and the rear units on two-way EOTs. The 16 minutes 30 seconds time period for determining when a loss of communication between the front and the rear unit was adopted based on the design of the devices, which automatically checks communication between the front and rear units every ten minutes. If no response is received, the front unit automatically requests communication from the rear unit 15 seconds later; if no response is received to that request, another request is made six minutes later; and if there is still no response, the front unit makes another request 15 seconds later. If there is still no response, a message is displayed to the locomotive engineer that there is a communication failure. This has caused some confusion in the industry, in that many people believe the 16 minutes and 30 seconds time frame should start when the message is first displayed on the front unit. This is incorrect. Based on the design of the currently operating devices, the 16 minutes and 30 seconds has elapsed when the failure message is broadcast. This paragraph has been modified to explain this design feature. Thus, appropriate action should be taken immediately upon receiving the failure message on the front unit. FRA also realizes that there may be some time lapse when the requests are made and the message is displayed, therefore the manufacturers of the devices should take care to factor any time lag into the 16 minute and 30 second time frame designed into the devices.

Section 232.409 Inspection and Testing of End-of-Train Devices

Paragraph (c) of this section regarding the notification of the locomotive engineer when the device is tested by someone other than a train crew member has been slightly modified from that proposed in the NPRM. In the NPRM, FRA proposed that the locomotive engineer be notified in writing in such circumstances. FRA agrees that this proposed requirement may have been overly burdensome and believes that the intent of the proposed requirement can be met without specifically requiring written notification. FRA's intent in proposing the written requirement was to ensure that locomotive engineers are provided sufficient information to confirm that the devices are properly inspected and tested and to provide locomotive engineers with a measure of confidence that the devices will work as intended. FRA believes these goals can be accomplished by permitting the required information to be provided by any means a railroad deems appropriate. FRA believes that the information required to be provided to an engineer (the date and time of the test, the location where the test was performed, and the name of the person performing the test) will ensure that the proper tests and inspections are performed. The modifications made in this paragraph make clear that a written or electronic record of the required information must be maintained in the cab of the controlling locomotive.

Paragraph (d) retains the proposed changes to the language related to the annual calibration and testing of EOT devices currently contained at § 232.25(d). The regulation currently states that the devices shall be "calibrated" annually. FRA intends to make clear that it intended for railroads to perform whatever tests or checks are necessary to ensure that the devices are operating within the parameters established by the manufacturers of the devices. Several railroads have attempted to "sharp shoot," or narrowly interpret, the language currently contained in the regulation, claiming that the manufacturer states that front units do not need to be calibrated on an annual basis, in order to avoid doing any testing of the devices. Although FRA agrees that the front units may not have to be calibrated every year, the devices must be tested in some fashion to verify that they are operating within the manufacturer's specification with regard to radio frequency, signal strength, and modulation and do not require recalibration. FRA has been provided written instructions from the manufacturers of the devices which contain procedures for testing both the front and rear units. Furthermore, railroads using the devices in Canada acknowledge that the radio functions of the front and rear units are tested periodically. Consequently, this paragraph retains the proposed clarifying language in order to avoid any misconceptions as to what actions are required to be performed on these devices on an annual basis.

Paragraph (d) has also been slightly modified to require the ready accessibility of the information regarding the calibration and testing of a front unit, which the current regulation requires to be placed on a sticker or other marking device affixed to the exterior of the front unit. Recently, FRA has discovered that some railroads have locked the cabinets that house the front units and that there is no way for either FRA or railroad operating crews to inspect the marking devices and verify the information required to be maintained. In order for the marking device to serve its intended purpose, it must be readily capable of being inspected by both FRA and railroad operating crews. FRA intends to make clear that the required information regarding the date and location that the unit was last calibrated is to be easily accessible to both FRA and train crews for inspection either on the marking device attached to the outside of the front unit or, if the front unit is inaccessible, in a readily accessible location in the cab of the locomotive.

In the NPRM, FRA discussed the potential need to amend paragraph (c) of this section by including specific provisions in this final rule to address the performance of bench testing on the front and rear units of two-way EOTs. *See* 63 FR 48322. After consideration of the comments received, FRA believes that specific regulatory requirements for performing these tests are unnecessary. FRA believes that its existing guidance, FRA Technical Bulletin MP&E 97–8, regarding the performance of bench tests on two-way EOTs is sufficient at this time. Since the issuance of this guidance on July 28, 1997, FRA has discovered very few instances where the issued guidance was not being followed and has found no evidence indicating that bench tests have compromised the proper operation of the devices. Consequently, FRA will not issue specific regulations regarding the performance of bench test at this time. However, FRA will continue to monitor the performance of these tests and will continue to expect railroads to perform the tests in accordance with the guidance previously issued by FRA.

FRA issued Technical Bulletin MP&E 97–8 to its inspectors to clarify what is required when a railroad performs a bench test. In this guidance, FRA made clear that a bench test may be performed on both the front and rear units, independent of each other, if the test is performed within the yard limits or location where the unit will be installed on the train. In FRA's view, bench testing the rear unit requires applying air pressure to the device and then transmitting an emergency brake application from a front unit using the front unit manual switch; the individual performing the test would determine that the emergency valve functions properly either by observing the emergency indicator pop out or by observing brake pipe pressure at the rear device go to zero while hearing the exhaust of air from the device. On the other hand, bench testing the front unit would entail transmitting an emergency brake application from the front unit, using the front unit manual switch, and observing that a rear unit successfully receives the signal and activates the emergency air valve.

The guidance also indicated that both tests must be performed within a reasonable time period prior to the device being armed and placed on the train. To determine a reasonable time period, the environment where the device is stored and the conditions the device is subjected to after completing a successful bench test have to be considered. If the device is tested and stored in a controlled environment that is free from weather elements, excessive dust, grease, and dirt prior to the immediate installation on a train, then four to eight hours would be acceptable. If the device is tested and haphazardly thrown into a corner of a shop or are placed in the rear of a truck to be bounced around a yard, one hour would likely be considered reasonable before installation. The guidance also made clear that bench tests must be performed at the location or yard where the device will be installed on a train.

Subpart F—Introduction of New Brake System Technology

This subpart retains, without change, the proposed tests and procedures required to introduce new train brake system technology into revenue service. The technology necessary for the introduction of advanced braking systems is quickly developing. The new technology includes various forms of electronic braking systems, a variety of braking sensors, and computer-controlled braking systems. In order to allow and encourage the development of new technology, this subpart establishes tests and procedures for introducing new brake system technology. These provisions require the submission to FRA of a pre-revenue service acceptance testing plan.

FRA intends to make clear that this subpart applies only to new train brake system technology that complies with the statutory mandates contained in 49 U.S.C. 20102, 20301–20304, 20701–20703, 21302, and 21304, but that is not specifically covered by this final rule. Any type of new train brake system that requires an exemption from the Federal railroad safety laws in order to be operated in revenue service may not be introduced into service pursuant to this section. In order to grant a waiver of the Federal railroad safety laws, FRA is limited by the specific statutory provisions contained in 49 U.S.C. 20306 as well as any FRA procedural requirements contained in this chapter.

Section 232.503 Process to Introduce New Brake System Technology

This section retains the proposed procedural requirements which must be met when a railroad intends to introduce new brake system technology into its system. This section makes clear that the approval of FRA's Associate Administrator for Safety must be obtained by a railroad prior to the railroad's implementation of a pre-revenue service acceptance test plan and before introduction of new brake system technology into revenue service. This section requires that such approval be obtained pursuant to the special approval process contained in § 232.17 of this final rule. FRA believes the special approval process should speed the process for taking advantage of new technologies over that which is currently available under the waiver process. However, in order to provide an opportunity for all interested parties to provide comment for use by FRA in its decision making process, as required by the Administrative Procedure Act, FRA believes that any special approval provision must, at a minimum, provide proper notice to the public of any significant change or action being considered by the agency with regard to existing regulations.

Section 232.505 Pre-Revenue Service Acceptance Testing Plan

This section retains the proposed requirements for pre-revenue service testing of new brake system technology. These tests are extremely important in that they are intended to prove that the new brake system can be operated safely in its intended environment. For equipment that has not previously been used in revenue service in the United States, paragraph (a) requires the operating railroad to develop a pre-revenue service acceptance testing plan and obtain FRA approval of the plan under the procedures stated in § 238.17 before beginning testing. Previous testing of the equipment at the Transportation Test Center, on another railroad, or elsewhere will be considered by FRA in approving the test plan. Paragraph (b) requires the railroad to fully execute the tests required by the plan, to correct any safety deficiencies identified by FRA, and to obtain FRA's approval to place the equipment in revenue service prior to introducing the equipment in revenue service. Paragraph (c) requires the railroad to comply with any operational limitations imposed by FRA. Paragraph (d) requires the railroad to make the plan available to FRA for inspection and copying. Paragraph (e) enumerates the elements that must be included in the plan. FRA believes this set of steps and the documentation required by this section are necessary to ensure that all safety risks have been reduced to a level that permits the new brake system technology to be used in revenue service. In lieu of the requirements of paragraphs (a) through (e), paragraph (f) provides for an abbreviated testing procedure for new brake system technology that has previously been

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used in revenue service in the United States. The railroad need not submit a test plan to FRA; however, a description of the testing shall be maintained by the railroad and made available to FRA for inspection and copying.

IV. Regulatory Evaluation

A Executive Order 12866 and DOT Regulatory Policies and Procedures

This final rule has been evaluated in accordance with existing policies and procedures and is considered to be significant under both Executive Order 12866 and DOT policies and procedures (44 FR 11034; Feb. 26, 1979). FRA has prepared and placed in the docket a regulatory evaluation of this final rule. This evaluation estimates the costs and consequences of this final rule as well as its anticipated economic and safety benefits. It may be inspected and photocopied during normal business hours by visiting the FRA Docket Clerk at the Office of Chief Counsel, FRA, Seventh Floor, 1120 Vermont Avenue, NW., in Washington, DC. Photocopies may also be obtained by submitting a written request by mail to the FRA Docket Clerk at the Office of Chief Counsel, Federal Railroad Administration, 1120 Vermont Avenue, NW., Mail Stop 10, Washington, DC 20590.

FRA believes that this rule will produce net benefits to society. The estimated Net Present Value (NPV) of the total 20-year costs associated with this final rule is approximately $109 million. The total 20-year benefits (safety and economic) consist of quantified benefits estimated at between approximately $112 and $130 million and various non-quantified benefits discussed in detail below. The following tables contain the estimated 20-year quantified costs and quantified benefits associated with this final rule.

TABLE 3.—ESTIMATED COSTS

Category	NPV costs
Training	$61,221,156
Retest	8,276,574
Piston Travel Stickers	3,385,681
Air Quality	1,819,214
Dynamic Brake	11,657,846
Cycle Trains	16,012,217
Class I Brake Test Notification	4,414,173
Helper Locomotive Inspection	1,929,071
Helper Link	164,933
Total	108,880,865

TABLE 4.—ESTIMATED BENEFITS

Category	NPV benefits
Extended Haul	$29,590,556—$46,735,494
Safety Improvements	57,460,452
EOT Use at Class I Brake Test	22,070,863
Bottom Rod Safety Supports	3,239,650
Total	112,361,521—129,506,459

Although the quantified benefits of this final rule exceed the quantified costs of the rule, FRA believes that the quantified benefits significantly underestimate the total benefits of this rule for several reasons. The information available to FRA on the value of property damage significantly understates the true value of the damage in railroad accidents. The property damage estimate provided by the railroad(s) in the aftermath of an accident are only for "railroad property damage" (equipment, track, and structures). Although the numbers provided by the railroads regarding railroad property damage have been enhanced to account for chronic underestimation of these damages, the figures used by FRA do not include the costs of evacuations, individual (non-railroad employee) or community health expenses, environmental cleanup, the closure of adjacent roads, or any of the other potential costs which are borne by society after a railroad accident.

A review of recent incidents that involve a train that loses its ability to stop or decrease speed show that there is a significant risk that such an occurrence could result in the release of large amounts of hazardous materials which, if the incident occurred in a densely populated or environmentally sensitive area, could produce truly catastrophic results. The costs of evacuation and medical treatment for those near the accident site could be substantial, and associated road closures could also produce significant economic impact to travelers and the communities nearby. Should a hazardous material release impact a river or stream, the consequences to wildlife in the area could also be severe and lasting. Furthermore, because derailments or collisions of trains which lose the ability to stop or decrease speed often occur due to overturning on curves or entering congested areas, third party casualties and property damage can also be substantial. As the inspection, testing, and maintenance provisions of this final rule are intended to ensure that the brakes on a train are effective and operable and because this final rule will ensure that a locomotive engineer is provided information regarding the condition of the brakes on the train they are operating, FRA believes that this final rule will reduce the number of instances where a train loses its ability to stop or decrease speed that create the potential for catastrophic consequences.

An example of the catastrophic consequences that could result when a freight train loses the ability to stop or decrease speed occurred on February 1, 1996, in Cajon Pass in California. This accident resulted in two fatalities, 32 injuries (32 emergency responders required medical treatment due to inhalation of toxic chemicals), the release of hazardous materials, and the subsequent evacuation of the surrounding area. In addition, a 20 mile segment of Interstate 15, the main route between Los Angeles and Las Vegas, was closed for 5 days as a result of the hazardous materials release. The road closure forced 89,000 vehicles a day to use detours. This added approximately 2 hours to the travel time between Las Vegas and Los Angeles. The losses to the surface transportation sector due to road and track closure, revenue losses to businesses and tourism, and the costs of emergency response related to this incident were not included in the estimated $15 million damage figure used by FRA when including this incident in the regulatory impact analysis of the two-way end-of-train device final rule. *See* 62 FR 291. FRA recognizes that an exact figure cannot be placed on these costs, but believes that the figure would be in the tens, if not hundreds, of millions of dollars. As devastating and costly as this incident was, it is probable that the results of this particular incident could have been much more disastrous. An Amtrak passenger train passed 17 minutes ahead of the train involved in the incident. Had the Amtrak train been stopped on the tracks or otherwise delayed, the consequences of the incident would have been much more severe, with the potential for scores of fatalities. (As illustration of potential consequences, a freight-to-passenger train collision at Hinton, Alberta, on February 8, 1986, resulted in 29 fatalities.)

Other power-brake related accidents illustrate the potential for high severity when a heavy-tonnage freight train loses braking control. On May 12, 1989, a Southern Pacific Transportation Company train accelerated out of control descending a 2.2 percent grade into San Bernardino, California. Two employees were killed and three injured. The entire train was effectively

destroyed. The incident destroyed seven residences adjacent to the right-of-way, killing two residents and injuring a third. A 14-inch gasoline pipeline which may have been damaged in either the incident or the ensuing clean-up, ruptured 13 days later, resulting in the death of two additional residents, serious injuries to two residents, and minor injuries to 16 others. Eleven additional homes were destroyed, along with 21 motor vehicles.

On February 2, 1989, near Helena, Montana, freight cars from a Montana Rail Link train rolled eastward down a mountain grade and struck a helper locomotive consist, slightly injuring two crewmembers. Hazardous materials in the consist which included hydrogen peroxide, isopropyl alcohol, and acetone were later released. The release of these hazardous materials resulted in a fire and explosions necessitating the evacuation of approximately 3,500 residents of Helena for over two days. According to the National Transportation Safety Board, railroad and other property damage alone exceeded $6 million, and all of the buildings of Carroll College sustained damage. Furthermore, the City of Helena received 154 reports of property damage from residents within a three-mile radius of the incident. Consequently, FRA believes that the potential unquantified benefits derived from the prevention of just one accident similar to the Cajon Pass incident or the other incidents noted above would most likely outweigh the potential costs of this final rule.

In addition to the potential underestimation of the quantified safety benefits, there may also be significant non-quantified business benefits that may be available as a consequence of this rule. The quantified benefits from the extended haul provisions may be significantly understated. FRA's estimates for the number of trains eligible for this benefit, and the cost saving that it produces, were much higher in the NPRM than those supplied by AAR in response to the NPRM. While we have used the figures provided by AAR to develop a range for the benefits related to the extended haul provisions, FRA continues to believe that more potential benefits are available to the industry than have been quantified in the Regulatory Impact Analysis.

Another business benefit for which FRA has insufficient information to form a credible estimate relates to the provision permitting previously tested cars to be added to trains received in interchange and the allowance to conduct a Class II brakes test on only those cars added to trains received in interchange that will move less than 20 miles from the interchange location. Under the existing regulations the addition of cars to such trains would require the performance of either an initial terminal brake test or a transfer train brake test on the entire train. The industry may realize substantial cost savings by being permitted to add cars to such trains without inspection of the entire train. By permitting the addition of cars to trains received in interchange, FRA allows the railroads to save significant time (labor and train delay costs) by not having to inspect the entire train consist when such cars are added to these trains. Because FRA does not have information on the number of interchanged trains engaging in such activity (and none were provided in response to the NPRM), we have not estimated the extent of this potential benefit. Actual business benefits to be realized due to this rule, therefore, may be significantly understated.

Moreover, Congress mandated that FRA review and revise the existing power brake regulations where necessary and specifically required that FRA prescribe standards regarding dynamic brakes, where applicable. Consequently, FRA believes that this final rule produces a net benefit to society. The costs that have been quantified represent the maximum that this rule is expected to cost, and the quantified projected benefits are the minimum which should be realized.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires an assessment of the impacts of proposed and final rules on small entities. FRA has conducted a regulatory flexibility analysis of this rule's impact on small entities, and the assessment has been placed in the public docket for this rulemaking.

1. Why Action By the Agency Is Being Considered

In 1992, Congress amended the Federal rail safety laws by adding certain statutory mandates related to power brake safety. *See* 49 U.S.C. 20141. These amendments specifically address the revision of the power brake regulations by adding a new subsection which states:

(r) POWER BRAKE SAFETY.—(1) The Secretary shall conduct a review of the Department of Transportation's rules with respect to railroad power brakes, and not later than December 31, 1993, shall revise such rules based on such safety data as may be presented during that review.

(2) In carrying out paragraph (1), the Secretary shall, where applicable, prescribe standards regarding dynamic brake equipment. * * * Pub. L. No. 102–365, section 7; codified at 49 U.S.C. 20141, superseding 45 U.S.C. 431(r).

In addition to this statutory mandate, FRA received various recommendations and petitions for rulemaking, and determined on its own that the power brake regulations were in need of revision. FRA has been in the process of revising the power brake regulations since 1992. An ANPRM and two NPRMs revising the power brake regulations were previously issued on December 31, 1992, September 16, 1994, and September 9, 1998, respectively. *See* 57 FR 62546, 59 FR 47676, and 63 FR 48294. A detailed discussion of the history leading up to this final rule is contained in the preamble. The reasons for the actual provisions of the action considered by the agency are explained in the body of the preamble and the section-by-section analysis.

2. The Objectives and Legal Basis for the Rule

The objective of the rule is to enhance the safety of rail transportation, protecting both those people traveling and working on the system, and those people off the system who might be affected by a rail incident by revising the regulations related to the braking systems used and operated in freight and other non-passenger trains to address potential deficiencies in the existing regulations, better address the needs of contemporary railroad operations, and facilitate the use of advanced technologies. The legal basis for this action is reflected in the response to 1. above and in the preamble.

3. A Description of and an Estimate of the Number of Small Entities to Which the Final Rule Would Apply

The Small Business Administration (SBA) uses an industry wide definition of "small entity" based on employment. Railroads are considered small by SBA definition if they employ fewer than 1,500 people for line haul railroads, and 500 for switching and terminal railroads. An agency may establish one or more other definitions of this term, in consultation with the SBA and after an opportunity for public comment, that are appropriate to the agency's activities.

The classification system used in this analysis is that of the FRA. Prior to the SBA regulations establishing size categories, the Interstate Commerce Commission (ICC) developed a classification system for freight railroads as Class I, II, or III, based on annual operating revenue. A Class I railroad has

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operating revenue of $250 million or more, a Class II railroad has operating revenue greater than $20 million dollars but less than $250 million and a Class III railroad has operating revenue of $20 million or less. The Department of Transportation's Surface Transportation Board, which succeeded the ICC, has not changed these classifications. The ICC/STB classification system has been used pervasively by FRA and the railroad industry to identify entities by size. In the NPRM, FRA discussed these revenue thresholds in terms of the revenue levels actually achieved by these different classes of railroads rather than by the specific limits established in the Surface Transportation Board's regulations. See 49 CFR part 1201 1–1.

After consultation with the Office of Advocacy of the SBA and as explained in detail in the "Interim Policy Statement Concerning Small Entities Subject to the Railroad Safety Laws," published August 11, 1997 at 62 FR 43024, FRA has decided to define "small entity," on an interim basis, to include only those entities whose revenues would bring them within the Class III definition. In response to FRA's request for comments on its alternate definition, the American Short Line and Regional Railroad Association (ASLRRA) suggested that the definition include all Class II and Class III railroads. However, the ASLRRA offered no support for this request nor provided any rationale for why such a large number of railroads should be considered "small entities." Consequently, this final rule retains the alternate definition of "small entity" which includes only Class III railroads.

All of the small entities directly affected by this rule are Class III railroads. FRA certifies that this final rule is expected to have a significant impact on a substantial number of Class III railroads. Although FRA did not quantify the estimated annual cost or benefit to the average Class III railroad (of which there are approximately 600–650 at any given time), the Regulatory Impact Analysis contains discussions and cost estimates for certain specific provisions where the impact could be estimated for non-Class I and Class III railroads.

The only significant costs to Class III railroads imposed by this final rule are related to the training of employees. In the NPRM, FRA estimated that Class III railroads would absorb approximately 15 percent of the training costs being imposed on non-Class I railroads. This estimate was based on the fact that Class III railroads employ approximately 15 percent of the employees on non-Class I railroads and because virtually all of the training costs are related to the number and types of employees employed by a railroad. FRA received no specific comment from any interested party objecting to this estimate. The final rule has been modified to reduce the potential impact of the training requirements on these small railroads based on comments received, by eliminating the need to develop internal audit programs and by allowing efficiency tests to be utilized to assess the effectiveness of a railroad's training program. Moreover, as discussed above and below, the training that employees of Class III railroads will be required to receive is significantly less than the required training of many employees on Class I and Class II railroads. Thus, although FRA believes that the actual cost to Class III railroads will be much less than the 15 percent originally assigned, FRA will retain the very conservative cost estimate related to training for Class III railroads of 15 percent of the training costs for non-Class I railroads which results in an estimated impact of approximately $740,579, or less than $1,200 for the average Class III railroad. These cost will be apportioned among the 600 to 650 Class III railroads, and will vary according to the number of employees each railroad must train. This is a rough estimate based on the number of Class III employees as a percentage of total employees. Actual impact should be less, as discussed below.

4. A Description of the Projected Reporting, Recordkeeping and Other Compliance Requirements of the Final Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirements and the Type of Professional Skills Necessary for Preparation of the Report or Record

Other than the training requirements discussed above, this rule will have a *de minimus* impact on small entities. Most of the final rule provisions will not effect small railroad costs because of the nature and limits to their operations, or the small railroad costs are inseparable from the industry-wide costs. For example, small railroads do not generally operate helper locomotives, so they will not be subject to the costs associated with that new rule provision. In the case of provisions such as those requiring piston travel stickers, FRA has no basis for assigning to any particular segment of the industry the costs for equipping the entire fleet of non-standard piston travel cars with piston travel stickers. But in reality, it is unlikely that these costs will fall on the smaller railroads.

In various places in the Regulatory Impact Analysis, FRA has attempted to assign burdens to the smaller members of the industry based on some measure of their size relative to the rest of the industry. In those cases, FRA has probably overestimated the burden for the smaller carriers. A good example is the requirement regarding the repair and documentation of dynamic brake failures. While FRA has assigned these costs based on the total number of locomotives operated by each segment of the industry, the reality is that few small railroads operate locomotives equipped with operative dynamic brakes and they will not actually be subject to these costs. The costs shown in the Regulatory Impact Analysis should be viewed as a maximum. Similarly, smaller railroads perform a limited number of Class I brake tests, do not generally own and operate yard air sources, and do not usually perform the type of maintenance that will trigger the new record keeping requirements, thus the reporting and record keeping requirements related to those activities will be minimal or non-existent for these smaller carriers.

5. Federal Rules Which May Duplicate, Overlap, or Conflict With the Rule

None.

Significant Alternatives:

1. Differing compliance or reporting requirements or timetables which take into account the resources available to small entities:

2. Clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities:

3. Exemption from coverage of the rule, or any part thereof, for such small entities:

FRA considered the role that non-Class I railroads (Class II and III railroads) have in today's freight industry. FRA believes that the current marketplace requires Class I railroads and these smaller railroads to operate as an integrated system. Many of today's smaller railroads rely on Class I railroads for the training of their employees and the maintenance of their equipment. In addition, many non-Class I railroads and Class I railroads interchange and operate each other's equipment. Therefore, except in limited circumstances, it is impossible, from a regulatory standpoint, to separate these smaller railroads from the larger Class I railroads. Therefore, in order to ensure the safety and quality of train and locomotive power braking systems throughout the entire freight industry, this final rule generally imposes a consistent set of requirements on Class I, II, and III railroads as a group. Although FRA recognizes that many of the operational benefits created by this final rule are not available to many of the smaller operations, FRA feels that the integrated nature of the freight industry requires that universally consistent requirements be imposed on both Class I and non-Class I railroads.

Where possible, efforts were taken in this final rule to minimize the impact on non-Class I railroads. The dynamic brake provisions of this final rule provide railroads with the option of declaring the dynamic brake portion of a locomotive deactivated. Thus, smaller railroads which do not choose to utilize dynamic brakes are not required to incur the cost of maintaining the equipment. The final rule also eliminates the proposed requirement to stencil a locomotive with deactivated dynamic brakes which further reduces the cost to smaller railroads. The final rule permits railroads to perform Class II brake tests on cars added to a train received in interchange, if the train will travel a distance not to exceed 20 miles from the point at which it was received in interchange. The current regulations require the performance of at least a transfer train brake test on the entire train, rather than testing only those cars added. FRA believes this will provide a cost savings to smaller railroads as they generally move short distances from interchange points to destination.

Furthermore, virtually all of the inspection and testing requirements imposed by this final rule on Class III railroads reflect current practices on those operations.

The final rule also modifies some of the proposed training requirements in order to reduce the costs to smaller railroads based on comments received by the ASLRRA. The final rule eliminates the requirement that railroads develop an internal audit program to assess the effectiveness of their training programs and allows efficiency tests to be utilized to assess the effectiveness of such programs. This was a change requested by the ASLRRA and will reduce the impact of the training requirements by permitting smaller railroads to utilize existing supervisory oversight to assess the effectiveness of training. The final rule also clarifies that each employee need only be trained on the knowledge and skills necessary to perform the tasks they are required to perform. Because employees of Class III railroads generally are not required to perform many of the tasks covered by this final rule, these employees would not be required to be trained on those tasks. For example, Class III railroads generally do not operate a large variety of brake systems on their lines thus, their employees would only have to be trained on a limited number of different brake systems. In addition, the employees of Class III railroads generally will not be required to receive any training in the areas of EPIC brakes, dynamic brakes, two-way EOT devices, or on some of the brake tests and maintenance mandated in this final rule due to the limited distances traveled by trains on these operations, the low tonnages hauled, and because many of the maintenance functions on these smaller railroads are contracted out to larger railroads. Thus, the final rule has attempted to narrow the training requirements for employees of smaller railroads to only those tasks they are required to perform and thus, reduce the economic impact of the requirements.

4. Use of performance, rather than design standards:

Where possible, especially with regard to advanced technologies and certain brake system components, an attempt was made to tie the proposed requirements to performance.

C. Paperwork Reduction Act

The information collection requirements in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* The sections that contain the new information collection requirements and the estimated time to fulfill each requirement are as follows:

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost (dollars)
229.27—Annual tests	20,000 locomotives	18,000 tests	15 minutes	4,500 hours	157,500
231.31—Drawbars for freight cars—approval to operate on track with non-standard gage.	545 railroads	0 letters	N/A	N/A	N/A
232.1—Purpose and Scope—Requests for Earlier Application to comply with Subparts D through F.	545 railroads	4 requests/letters	60 minutes	4 hours	180
232.3—Applicability— Export, industrial, & other cars not owned by railroads-identification.	545 railroads	8 cards	10 minutes	1 hour	45
232.7—Waivers	545 railroads	10 petitions	40 hours	400 hours	18,000
232.11—Penalties—Knowing falsifying a record/report.	545 railroads	1 falsified recd/rpt	10 minutes	.20 hour	9
232.15—Movement of Defective Equipment:					
—Tags	1,620,000 cars	128,400 tags	2.5 minutes	5,350 hours	187,250
— Written Notification	1,620,000 cars	21,200 notices	3 minutes	1,060 hours	37,100
232.17—Special Approval Procedure:					
—Petitions for special approval of safety-critical revision.	545 railroads	4 petition	100 hours	400 hours	18,000
—Petitions for special approval of pre-revenue service acceptance plan.	545 railroads	2 petitions	100 hours	200 hours	9,000
—Service of petitions	545 railroads	6 petitions	40 hours	240 hours	10,800
—Statement of interest.	Public/railroads	20 statements	8 hours	160 hours	7,200
—Comments	Public/railroads	15 comments	4 hours	60 hours	2,700

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CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost (dollars)
232.103—Gen'l requirements—all train brake systems:	1,600,000 cars	246,886 stickers	10 minutes	41,144 hours	835,156
—Locomotives—1st Year—Procedures.	545 railroads	50 procedures	4 hours	200 hours	9,000
—Locomotives—Subsequent Years—Procedures.	25 new railroads	1 procedure	4 hours	4 hours	180
232.105—Gen'l requirements for locomotives-inspection.	545 railroads	20,000 insp. forms	5 minutes	1,667 hours	58,345
232.107—Air source requirements:.					
—1st Year	545 railroads	50 plans	40 hours	2,000 hours	90,000
—Subsequent Years	25 new railroads	1 plan	40 plans	40 hours	1,800
—Amendments to Plan.	50 existing plans	10 amendments	20 hours	200 hours	9,000
—Recordkeeping	50 existing plans	1,150 records	20 hours	23,000 hours	1,035,000
—Cold weather situations.	545 railroads	37 plans	20 hours	740 hours	33,300
232.109—Dynamic brake requirements:.					
—status	545 railroads	1,656,000 records	4 minutes	110,400 hours	3,864,000
—Inoperative dynamic brakes.	20,000 locomotives	6,358 repair recds	4 minutes	424 hours	14,840
—Tag bearing words "inoperative dynamic brakes".	20,000 locomotives	6,358 tags	30 seconds	53 hours	1,855
—Deactivated dynamic brakes—1st Year.	8,000 locomotives	2,800 stencilings	5 minutes	233 hours	8,155
—Subsequent Years	8,000 locomotives	20 stencilings	5 minutes	2 hours	70
—Displays to Locomotive Engineer-Deceleration rate.	8,000 locomotives	2,800,000 Disp.	.50 second	400 hours	0
—Operating rules—1st Year.	545 railroads	300 oper. rules	4 hours	1,200 hours	54,000
—Subsequent Years	5 new railroads	5 operating rules	4 hours	20 hours	900
—Amendments	545 railroads	15 amendments	1 hour	15 hours	675
—Miles-per-hour-overspeed-top rule in operating proc..	545 railroads	545 rules	60 minutes	545 hours	24,525
—Requests to increase 5 mph overspeed restriction.	545 railroads	5 requests/ltrs.	30 min. + 20 hrs.	103 hours	4,635
—Knowledge criteria—locomotive engineers—1st Year.	545 railroads	300 amendments	16 hours	4,800 hours	216,000
—Subsequent Years	5 new railroads	5 amendments	16 hours	80 hours	3,600
232.111—Train information handling:					
—1st Year	545 railroads	545 procedures	50 hours	27,250 hours	1,226,250
—Subsequent Years	10 new railroads	10 procedures	40 hours	400 hours	18,000
—Amendments	100 railroads	100 amendments	20 hours	2,000 hours	90,000
—Report requirements to train crew.	545 railroads	2,112,000 reports	10 minutes	352,000 hours	12,320,000
232.203—Training requirements—Tr. Prog.:					
—1st Year	545 railroads	300 programs	100 hours	30,000 hours	1,350,000
—Subsequent years	15 railroads	1 program	100 hours	100 hours	4,500
—Amendments to written program.	545 railroads	545 amendments	8 hours	4,360 hours	196,200
—Training records	545 railroads	67,000 records	8 minutes	8,933 hours	312,655
—Training notifications.	545 railroads	67,000 notific.	3 minutes	3,350 hours	117,250
—Audit program	545 railroads	545 plans	40 hours	21,800 hours	981,000
—Amendment to audit program.	545 railroads	50 amendments	20 hours	1,000 hours	45,000
232.205—Class 1 brake test—Notifications.	545 railroads	1,656,000 notific.	45 seconds	20,700 hours	724,500
232.207—Class 1A brake tests:	545 railroads	25 lists	30 minutes	13 hours	585
—1st Year	545 railroads	1 list	1 hour	1 hour	45
—subsequent years					
—Notification	545 railroads	5 amendments	1 hour	5 hours	225
232.209—Class II brake tests-intermediate inspection.	545 railroads	1,600,000 comnnt	3 seconds	1,333 hours	46,655
—Operator of train	545 railroads	1,600,000 comm.	2 seconds	689 hours	31,115
—Electronic communication link.	545 railroads	32,000 messages	2 seconds	18 hours	630

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total annual burden cost (dollars)
232.211—Class II brake test-trainline continuity insp..	545 railroads	500,000 commun.	5 seconds	694 hours	24,290
—Electronic communication link.	545 railroads	5,000 messages	5 seconds	7 hours	245
232.213—Extended haul trains.	84,000 long dist. mvmts.	70 letters	15 minutes	18 hours	810
—Record of all defective/inoperative brakes.	84,000 long dist. mvmts.	25,200 records	20 minutes	8,400 hours	294,000
232.303—Gen'l requirements—single car test.	1,600,000 frgt. cars	5,600 tags	5 minutes	467 hours	16,345
—Last repair track brake test/single car test.	1,600,000 frgt. cars	320,000 stncl.	5 minutes	26,667 hours	993,345
232.307—Single Car	545 railroads	Inc. under 232.17	Inc. under 232.17	Inc. under 232.17	Inc. under 232.17
232.309—Repair track brake test.	640 shops	5,000 tests	30 minutes	2,500 hours	87,500
232.403—Design stds—1 way end-of-train (EOTs) dev..	545 railroads	4 billion mess.	1/186,000 sec.	6 hours	0
—Unique Code	545 railroads	12 requests	5 minutes	1 hour	35
232.405—Design + Performance stds.—2 way EOTs.	545 railroads	8 billion mess.	1/186,000 sec.	12 hours	0
232.407—Operations 2-way EOTs.	545 railroads	50,000 comm.	30 seconds	417 hours	14,595
232.409—Insp. and Testing of EOTs.	245 railroads	450,000 comm.	30 seconds	3,750 hours	168,750
—Telemetry Equipment—Testing and Calibration.	245 railroads	32,708 units	1 minute	545 hours	24,525
232.503—Process to introduce new brake technology.	545 railroads	1 letter	1 hour	1 hour	45
—Special approval	545 railroads	1 request	3 hours	3 hours	135
232.505—Pre-revenue service accept. test plan:					
—1st Yr.	545 railroads	1 main. procedure	160 hours	160 hours	7,200
—Subsequent years	545 railroads	1 main. procedure	160 hours	160 hours	7,200
—Amendments	545 railroads	1 main. procedure	40 hours	40 hours	1,800
—Design description	545 railroads	1 petition	67 hours	67 hours	3,015
—Report to FRA Assoc. Admin.. for Safety.	545 railroads	1 report	13 hours	13 Hours	585
—Brake system technology testing.	545 railroads	5 descriptions	40 hours	200 hours	9,000

All estimates include the time for reviewing instructions; searching existing data sources; gathering or maintaining the needed data; and reviewing the information. For information or a copy of the paperwork package submitted to OMB contact Robert Brogan at 202–493–6292.

OMB is required to make a decision concerning the collection of information requirements contained in this final rule between 30 and 60 days after publication of this document in the **Federal Register**.

FRA cannot impose a penalty on persons for violating information collection requirements which do not display a current OMB control number, if required. This final rule has been assigned OMB control number 2130–0008.

D. Environmental Impact

FRA has evaluated this final rule in accordance with its "Procedures for Considering Environmental Impacts" (FRA Procedures)(64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this final rule is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c) of FRA's Procedures. Section 4(c) of FRA's Procedures identifies twenty classes of FRA actions that are categorically excluded from the requirements for conducting a detailed environmental review. FRA further considered this final rule in accordance with section 4(c) and (e) of FRA's Procedures to determine if extraordinary circumstances exist with respect to this final rule that might trigger the need for a more detailed environmental review.

After conducting this review, FRA has determined that extraordinary circumstances do not exist because this final rule: Is not judged to be environmentally controversial; is not inconsistent with Federal, State, or local laws, regulations, ordinances, or judicial or administrative determinations relating to environmental protection; will not have any significant adverse impact on any natural, cultural, recreational, or scenic environments; will not use protected properties, involve new construction in wetlands, or affect a base floodplain; and will not cause a significant short- or long-term increase in traffic congestion or other adverse environmental impact on any mode of transportation. As a result, FRA finds that this regulation is not a major Federal action significantly effecting the quality of the human environment.

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E. Federalism Implications

FRA believes it is in compliance with Executive Order 13132. This final rule will not have a substantial effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This final rule will not have federalism implications that impose substantial direct compliance costs on State and local governments. FRA notes that States involved in the State Participation Program, pursuant to 49 CFR part 212, may incur minimal costs associated with the training of their inspectors involved in the enforcement of this final rule. Meanwhile, State officials were consulted to a practicable extent through their participation in the RSAC, a federal advisory committee discussed earlier in the preamble. Although this rule was removed from the RSAC process prior to the issuance of the 1998 NPRM, representatives of state officials were represented in the RSAC Power Brake Working Group and the concerns and comments raised by these representatives during that process were fully considered during the development of both the 1998 NPRM and this final rule. Specifically, the National Association of Regulatory Commissioners, the American Association of State Highway and Transportation Officials, and the California Public Utilities Commission (CAPUC) were all represented when this rule was being considered by the RSAC Power Brake Working Group. The CAPUC submitted extensive comments in response to the 1998 NPRM which are detailed and addressed in the preamble to this final rule.

In any event, Federal preemption of a State or local law occurs automatically as a result of the statutory provision contained at 49 U.S.C. 20106 when FRA issues a regulation covering the same subject matter as a State or local law unless the State or local law is designed to reduce an essentially local safety hazard, is not incompatible with Federal law, and does not place an unreasonable burden on interstate commerce (see discussion in the section-by-section analysis of § 232.13). It should be noted that the potential for preemption also exists under various other statutory and constitutional provisions. These include: the Locomotive Inspection Act (now codified at 49 U.S.C. 20701–20703), the Safety Appliance Acts (now codified at 49 U.S.C. 20301–20304), and the Commerce Clause of the United States Constitution.

List of Subjects

49 CFR Part 229

Railroad locomotive safety, Railroad safety.

49 CFR Part 231

Railroad safety, Railroad safety appliances.

49 CFR Part 232

Incorporation by reference, Railroad power brakes, Railroad safety, Two-way end-of-train devices.

The Rule

In consideration of the following, FRA amends chapter II, subtitle B of title 49, Code of Federal Regulations as follows:

Part 229—[AMENDED]

1. The authority citation for part 229 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20137–20138, 20143, 20701–20703, 21301–21302, 21304; 49 CFR 1.49(c), (m).

2. Section 229.5 is amended by adding a new paragraph (p) to read as follows:

§ 229.5 Definitions.

* * * * *

(p) *Electronic air brake* means a brake system controlled by a computer which provides the means for control of the locomotive brakes or train brakes or both.

3. Section 229.25 is amended by revising paragraph (a) to read as follows:

§ 229.25 Tests: Every periodic inspection.

* * * * *

(a) All mechanical gauges used by the engineer to aid in the control or braking of the train or locomotive, except load meters used in conjunction with an auxiliary brake system, shall be tested by comparison with a dead-weight tester or a test gauge designed for this purpose.

* * * * *

4. Section 229.27 is amended by revising paragraph (b) to read as follows:

§ 229.27 Annual tests.

* * * * *

(b) The load meter shall be tested. Each device used by the engineer to aid in the control or braking of the train or locomotive that provides an indication of air pressure electronically shall be tested by comparison with a test gauge or self-test designed for this purpose. An error of greater than five percent or three pounds per square inch shall be corrected. The date and place of the test shall be recorded on Form FRA F 6180–49A, and the person conducting the test and that person's supervisor shall sign the form.

* * * * *

5. Section 229.53 is revised to read as follows:

§ 229.53 Brake gauges.

All mechanical gauges and all devices providing indication of air pressure electronically that are used by the engineer to aid in the control or braking of the train or locomotive shall be located so that they may be conveniently read from the engineer's usual position during operation of the locomotive. A gauge or device shall not be more than five percent or three pounds per square inch in error, whichever is less.

Part 231—[AMENDED]

6. The authority citation for part 231 is revised to read as follows:

Authority: 49 U.S.C. 20102–20103, 20107, 20131, 20301–20303, 21301–21302, 21304; 49 CFR 1.49(c), (m).

7. Section 231.0 is amended by adding paragraphs (b)(3) through (5) and paragraph (g) to read as follows:

§ 231.0 Applicability and penalties.

* * * * *

(b) * * *

(3) Freight and other non-passenger trains of four-wheel coal cars.

(4) Freight and other non-passenger trains of eight-wheel standard logging cars if the height of each car from the top of the rail to the center of the coupling is not more than 25 inches.

(5) A locomotive used in hauling a train referred to in paragraph (b)(4) of this section when the locomotive and cars of the train are used only to transport logs.

* * * * *

(g) Except as provided in paragraph (b) of this section, § 231.31 also applies to an operation on a 24-inch, 36-inch, or other narrow gage railroad.

8. Part 231 is further amended by adding § 231.31 to read as follows:

§ 231.31 Drawbars for freight cars; standard height.

(a) Except on cars specified in paragraph (b) of this section—

(1) On standard gage (56½-inch gage) railroads, the maximum height of drawbars for freight cars (measured perpendicularly from the level of the tops of the rails to the centers of the drawbars) shall be 34½ inches, and the minimum height of drawbars for freight cars on such standard gage railroads (measured in the same manner) shall be 31½ inches.

(2) On 36-inch gage railroads, the maximum height of drawbars for freight cars (measured perpendicularly from the level of the tops of the rails to the centers of the drawbars) shall be 26 inches, and the minimum height of drawbars for freight cars on such 36-inch gage railroads (measured in the same manner) shall be 23 inches.

(3) On 24-inch gage railroads, the maximum height of drawbars for freight cars (measured perpendicularly from the level of the tops of the rails to the centers of the drawbars) shall be 17½ inches, and the minimum height of drawbars for freight cars on 24-inch gage railroads (measured in the same manner) shall be 14½ inches.

(4) On railroads operating on track with a gage other than those contained in paragraphs (a)(1) through (a)(3) of this section, the maximum and minimum height of drawbars for freight cars operating on those railroads shall be established upon written approval of FRA.

(b) This section shall not apply to a railroad all of whose track is less than 24 inches in gage.

9. Appendix A of Part 231 is amended by adding an entry for § 231.31 to the end of the Schedule of Civil Penalties to read as follows:

Appendix A to Part 231—Schedule of Civil Penalties

FRA safety appliance defect code section	Violation	Willful violation
. . . . .		
231.31 Drawbars, standard height	2,500	5,000
. . . . .		

10. Part 232 is revised to read as follows:

PART 232—BRAKE SYSTEM SAFETY STANDARDS for FREIGHT and OTHER NON-PASSENGER TRAINS and EQUIPMENT; END-of-TRAIN DEVICES

Subpart A—General

Sec.
232.1 Scope.
232.3 Applicability.
232.5 Definitions.
232.7 Waivers.
232.9 Responsibility for compliance.
232.11 Penalties.
232.13 Preemptive effect.
232.15 Movement of defective equipment.
232.17 Special approval procedure.
232.19 Availability of records.
232.21 Information collection.

Subpart B—General Requirements

232.101 Scope.
232.103 General requirements for all train brake systems.
232.105 General requirements for locomotives.
232.107 Air source requirements and cold weather operations.
232.109 Dynamic brake requirements.
232.111 Train handling information.

Subpart C—Inspection and Testing Requirements

232.201 Scope.
232.203 Training requirements.
232.205 Class I brake tests—initial terminal inspection.
232.207 Class IA brake tests—1,000-mile inspection.
232.209 Class II brake tests—intermediate inspection.
232.211 Class III brake tests—trainline continuity inspection.
232.213 Extended haul trains.
232.215 Transfer train brake tests.
232.217 Train brake tests conducted using yard air.
232.219 Double heading and helper service.

Subpart D—Periodic Maintenance and Testing Requirements

232.301 Scope.
232.303 General requirements.
232.305 Repair track air brake tests.
232.307 Single car tests.
232.309 Repair track air brake test and single car test equipment and devices.

Subpart E—End-of-Train Devices

232.401 Scope.
232.403 Design standards for one-way end-of-train devices.
232.405 Design and performance standards for two-way end-of-train devices.
232.407 Operations requiring use of two-way end-of-train devices; prohibition on purchase of nonconforming devices.
232.409 Inspection and testing of end-of-train devices.

Subpart F—Introduction of New Brake System Technology

232.501 Scope.
232.503 Process to introduce new brake system technology.
232.505 Pre-revenue service acceptance testing plan.

Appendix A—Schedule of Civil Penalties

Appendix B—49 CFR part 232 prior to April 1, 2001

Authority: 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20301–20303, 20306, 21301–21302, 21304; 49 CFR 1.49(c), (m).

Subpart A—General

§ 232.1 Scope.

(a) This part prescribes Federal safety standards for freight and other non-passenger train brake systems and equipment. Subpart E of this part prescribes Federal safety standards not only for freight and other non-passenger train brake systems and equipment, but also for passenger train brake systems. This part does not restrict a railroad from adopting or enforcing additional or more stringent requirements not inconsistent with this part.

(b) Except as otherwise specifically provided in this paragraph or in this part, railroads to which this part applies shall comply with all the requirements contained in subparts A through C and subpart F of this part beginning on April 1, 2004. Sections 232.1 through 232.13 and 232.17 through 232.21 of this part will become applicable to all railroads to which this part applies beginning on April 1, 2001. Subpart D of this part will become applicable to all railroads to which this part applies beginning on August 1, 2001. Subpart E of this part will become applicable to all trains operating on track which is part of the general railroad system of transportation beginning on April 1, 2001.

(c) A railroad may request earlier application of the requirements contained in subparts A through C and subpart F of this part upon written notification to FRA's Associate Administrator for Safety. Such a request shall indicate the railroad's readiness and ability to comply with all of the requirements contained in those subparts.

(d) Except for operations identified in § 232.3(c)(1), (c)(4), and (c)(6) through (c)(8), all railroads which are part of the general railroad system of transportation shall operate pursuant to the requirements contained in this part 232 as it existed on April 1, 2001 and included as Appendix B to this part until they are either required to operate pursuant to the requirements contained in this part or the requirements contained in part 238 of this chapter or they elect to comply earlier than otherwise required with the requirements contained in this part or the requirements contained in part 238 of this chapter.

§ 232.3 Applicability.

(a) Except as provided in paragraphs (b) and (c) of this section, this part applies to all railroads that operate freight or other non-passenger train service on standard gage track which is part of the general railroad system of transportation. This includes the operation of circus trains and private cars when hauled on such railroads.

(b) Subpart E of this part, "End-of-Train Devices," applies to all trains operating on track which is part of the general railroad system of transportation unless specifically excepted in that subpart.

(c) Except as provided in § 232.1(d) and paragraph (b) of this section, this part does *not* apply to:

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(1) A railroad that operates only on track inside an installation that is not part of the general railroad system of transportation.

(2) Intercity or commuter passenger train operations on standard gage track which is part of the general railroad system of transportation;

(3) Commuter or other short-haul rail passenger train operations in a metropolitan or suburban area (as described by 49 U.S.C. 20102(1)), including public authorities operating passenger train service;

(4) Rapid transit operations in an urban area that are not connected with the general railroad system of transportation;

(5) Tourist, scenic, historic, or excursion operations, whether on or off the general railroad system;

(6) Freight and other non-passenger trains of four-wheel coal cars;

(7) Freight and other non-passenger trains of eight-wheel standard logging cars if the height of each car from the top of the rail to the center of the coupling is not more than 25 inches; or

(8) A locomotive used in hauling a train referred to in paragraph (c)(7) of this subsection when the locomotive and cars of the train are used only to transport logs.

(d) The provisions formerly contained in Interstate Commerce Commission Order 13528, of May 30, 1945, as amended, now revoked, are codified in this paragraph. This part is not applicable to the following equipment:

(1) Scale test weight cars.

(2) Locomotive cranes, steam shovels, pile drivers, and machines of similar construction, and maintenance machines built prior to September 21, 1945.

(3) Export, industrial, and other cars not owned by a railroad which are not to be used in service, except for movement as shipments on their own wheels to given destinations. Such cars shall be properly identified by a card attached to each side of the car, signed by the shipper, stating that such movement is being made under the authority of this paragraph.

(4) Industrial and other than railroad-owned cars which are not to be used in service except for movement within the limits of a single switching district (i.e., within the limits of an industrial facility).

(5) Narrow-gage cars.

(6) Cars used exclusively in switching operations and not used in train movements within the meaning of the Federal safety appliance laws (49 U.S.C. 20301–20306).

§ 232.5 Definitions.

For purposes of this part—

AAR means the Association of American Railroads.

Air brake means a combination of devices operated by compressed air, arranged in a system, and controlled manually, electrically, electronically, or pneumatically, by means of which the motion of a railroad car or locomotive is retarded or arrested.

Air Flow Indicator, AFM means a specific air flow indicator required by the air flow method of qualifying train air brakes (AFM). The AFM Air Flow Indicator is a calibrated air flow measuring device which is clearly visible and legible in daylight and darkness from the engineer's normal operating position. The indicator face displays:

(1) Markings from 10 cubic feet per minute (CFM) to 80 CFM, in increments of 10 CFM or less; and

(2) Numerals indicating 20, 40, 60, and 80 CFM for continuous monitoring of air flow.

Bind means restrict the intended movement of one or more brake system components by reduced clearance, by obstruction, or by increased friction.

Brake, dynamic means a train braking system whereby the kinetic energy of a moving train is used to generate electric current at the locomotive traction motors, which is then dissipated through resistor grids or into the catenary or third rail system.

Brake, effective means a brake that is capable of producing its required designed retarding force on the train. A car's air brake is not considered effective if it is not capable of producing its designed retarding force or if its piston travel exceeds:

(1) 10½ inches for cars equipped with nominal 12-inch stroke brake cylinders; or

(2) the piston travel limits indicated on the stencil, sticker, or badge plate for that brake cylinder.

Brake, hand means a brake that can be applied and released by hand to prevent or retard the movement of a locomotive.

Brake indicator means a device which indicates the brake application range and indicates whether brakes are applied and released.

Brake, inoperative means a primary brake that, for any reason, no longer applies or releases as intended.

Brake, inoperative dynamic means a dynamic brake that, for any reason, no longer provides its designed retarding force on the train.

Brake, parking means a brake that can be applied by means other than by hand, such as spring, hydraulic, or air pressure when the brake pipe air is depleted, or by an electrical motor.

Brake pipe means the system of piping (including branch pipes, angle cocks, cutout cocks, dirt collectors, hoses, and hose couplings) used for connecting locomotives and all railroad cars for the passage of compressed air.

Brake, primary means those components of the train brake system necessary to stop the train within the signal spacing distance without thermal damage to friction braking surfaces.

Brake, secondary means those components of the train brake system which develop supplemental brake retarding force that is not needed to stop the train within signal spacing distances or to prevent thermal damage to wheels.

Emergency application means an irretrievable brake application resulting in the maximum retarding force available from the train brake system.

End-of-train device, one-way means two pieces of equipment linked by radio that meet the requirements of § 232.403.

End-of-train device, two-way means two pieces of equipment linked by radio that meet the requirements of §§ 232.403 and 232.405.

Foul means any condition which restricts the intended movement of one or more brake system components because the component is snagged, entangled, or twisted.

Freight car means a vehicle designed to carry freight, or railroad personnel, by rail and a vehicle designed for use in a work or wreck train or other non-passenger train.

Initial terminal means the location where a train is originally assembled.

Locomotive means a piece of railroad on-track equipment, other than hi-rail, specialized maintenance, or other similar equipment, which may consist of one or more units operated from a single control stand—

(1) With one or more propelling motors designed for moving other railroad equipment;

(2) With one or more propelling motors designed to transport freight or passenger traffic or both; or

(3) Without propelling motors but with one or more control stands.

Locomotive cab means that portion of the superstructure designed to be occupied by the crew operating the locomotive.

Locomotive, controlling means the locomotive from which the engineer exercises control over the train.

Off air means not connected to a continuous source of compressed air of at least 60 pounds per square inch (psi).

Ordered date or date ordered means the date on which notice to proceed is given by a procuring railroad to a contractor or supplier for new equipment.

Piston travel means the amount of linear movement of the air brake hollow rod (or equivalent) or piston rod when forced outward by movement of the piston in the brake cylinder or actuator and limited by the brake shoes being forced against the wheel or disc.

Pre-revenue service acceptance testing plan means a document, as further specified in § 232.505, prepared by a railroad that explains in detail how pre-revenue service tests of certain equipment demonstrate that the equipment meets Federal safety standards and the railroad's own safety design requirements.

Previously tested equipment means equipment that has received a Class I brake test pursuant to § 232.205 and has not been off air for more than four hours.

Primary responsibility means the task that a person performs at least 50 percent of the time. The totality of the circumstances will be considered on a case-by-case basis in circumstances where an individual does not spend 50 percent of the day engaged in any one readily identifiable type of activity.

Qualified mechanical inspector means a qualified person who has received, as a part of the training, qualification, and designation program required under § 232.203, instruction and training that includes "hands-on" experience (under appropriate supervision or apprenticeship) in one or more of the following functions: troubleshooting, inspection, testing, maintenance or repair of the specific train brake components and systems for which the person is assigned responsibility. This person shall also possess a current understanding of what is required to properly repair and maintain the safety-critical brake components for which the person is assigned responsibility. Further, the qualified mechanical inspector shall be a person whose primary responsibility includes work generally consistent with the functions listed in this definition.

Qualified person means a person who has received, as a part of the training, qualification, and designation program required under § 232.203, instruction and training necessary to perform one or more functions required under this part. The railroad is responsible for determining that the person has the knowledge and skills necessary to perform the required function for which the person is assigned responsibility. The railroad determines the qualifications and competencies for employees designated to perform various functions in the manner set forth in this part. Although the rule uses the term "qualified person" to describe a person responsible for performing various functions required under this part, a person may be deemed qualified to perform some functions but not qualified to perform other functions. For example, although a person may be deemed qualified to perform the Class II/intermediate brake test required by this part, that same person may or may not be deemed qualified to perform the Class I/initial Terminal brake test or authorize the movement of defective equipment under this part. The railroad will determine the required functions for which an individual will be deemed a "qualified person" based upon the instruction and training the individual has received pursuant to § 232.203 concerning a particular function.

Railroad means any form of non-highway ground transportation that runs on rails or electromagnetic guideways, including:

(1) Commuter or short-haul railroad passenger service in a metropolitan or suburban area and commuter railroad service that was operated by the Consolidated Rail Corporation on January 1, 1979; and

(2) High speed ground transportation systems that connect metropolitan areas, without regard to whether those systems use new technologies not associated with traditional railroads. The term "railroad" is also intended to mean a person that provides transportation by railroad, whether directly or by contracting out operation of the railroad to another person. The term does not include rapid transit operations in an urban area that are not connected to the general railroad system of transportation.

Rebuilt equipment means equipment that has undergone overhaul identified by the railroad as a capital expense under the Surface Transportation Board's accounting standards.

Refresher training means periodic retraining required for employees or contractors to remain qualified to perform specific equipment troubleshooting, inspection, testing, maintenance, or repair functions.

Respond as intended means to produce the result that a device or system is designed to produce.

"Roll-by" inspection means an inspection performed while equipment is moving.

Service application means a brake application that results from one or more service reductions or the equivalent.

Service reduction means a decrease in brake pipe pressure, usually from 5 to 25 psi at a rate sufficiently rapid to move the operating valve to service position, but at a rate not rapid enough to move the operating valve to emergency position.

Solid block of cars means two or more freight cars consecutively coupled together and added to or removed from a train as a single unit.

State inspector means an inspector of a participating State rail safety program under part 212 of this chapter.

Switching service means the classification of freight cars according to commodity or destination; assembling of cars for train movements; changing the position of cars for purposes of loading, unloading, or weighing; placing of locomotives and cars for repair or storage; or moving of rail equipment in connection with work service that does not constitute a train movement.

Tourist, scenic, historic, or excursion operations are railroad operations that carry passengers, often using antiquated equipment, with the conveyance of the passengers to a particular destination not being the principal purpose.

Train means one or more locomotives coupled with one or more freight cars, except during switching service.

Train line means the brake pipe or any non-pneumatic system used to transmit the signal that controls the locomotive and freight car brakes.

Train, unit or *train, cycle* means a train that, except for the changing of locomotive power and the removal or replacement of defective equipment, remains coupled as a consist and continuously operates from location A to location B and back to location A.

Transfer train means a train that travels between a point of origin and a point of final destination not exceeding 20 miles. Such trains may pick up or deliver freight equipment while en route to destination.

Yard air means a source of compressed air other than from a locomotive.

§ 232.7 Waivers.

(a) Any person subject to a requirement of this part may petition the Administrator for a waiver of compliance with such requirement. The filing of such a petition does not affect that person's responsibility for compliance with that requirement while the petition is being considered.

(b) Each petition for waiver must be filed in the manner and contain the information required by part 211 of this chapter.

(c) If the Administrator finds that a waiver of compliance is in the public interest and is consistent with railroad safety, the Administrator may grant the waiver subject to any conditions the Administrator deems necessary. If a waiver is granted, the Administrator

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publishes a notice in the **Federal Register** containing the reasons for granting the waiver.

§ 232.9 Responsibility for compliance.

(a) A railroad subject to this part shall not use, haul, permit to be used or hauled on its line, offer in interchange, or accept in interchange any train, railroad car, or locomotive with one or more conditions not in compliance with this part; however, a railroad shall not be liable for a civil penalty for such action if such action is in accordance with § 232.15. For purposes of this part, a train, railroad car, or locomotive will be considered in use prior to departure but after it has received, or should have received, the inspection required for movement and is deemed ready for service.

(b) Although many of the requirements of this part are stated in terms of the duties of a railroad, when any person performs any function required by this part, that person (whether or not a railroad) is required to perform that function in accordance with this part.

(c) Any person performing any function or task required by this part shall be deemed to have consented to FRA inspection of the person's operation to the extent necessary to determine whether the function or task is being performed in accordance with the requirements of this part.

§ 232.11 Penalties.

(a) Any person (including but not limited to a railroad; any manager, supervisor, official, or other employee or agent of a railroad; any owner, manufacturer, lessor, or lessee of railroad equipment, track, or facilities; any employee of such owner, manufacturer, lessor, lessee, or independent contractor) who violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least $500, but not more than $11,000 per violation, except that: Penalties may be assessed against individuals only for willful violations, and, where a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to persons, or has caused death or injury, a penalty not to exceed $22,000 per violation may be assessed. Each day a violation continues shall constitute a separate offense. Appendix A to this part contains a schedule of civil penalty amounts used in connection with this rule.

(b) Any person who knowingly and willfully falsifies a record or report required by this part is subject to criminal penalties under 49 U.S.C. 21311.

§ 232.13 Preemptive effect.

(a) Under 49 U.S.C. 20106, issuance of the regulations in this part preempts any State law, rule, regulation, order, or standard covering the same subject matter, except for a provision necessary to eliminate or reduce a local safety hazard if that provision is not incompatible with this part and does not impose an undue burden on interstate commerce.

(b) Preemption should also be considered pursuant to the Locomotive Boiler Inspection Act (now codified at 49 U.S.C. 20701–20703), the Safety Appliance Acts (now codified at 49 U.S.C. 20301–20304), and the Commerce Clause based on the relevant case law pertaining to preemption under those provisions.

(c) FRA does not intend by issuance of the regulations in this part to preempt provisions of State criminal law that impose sanctions for reckless conduct that leads to actual loss of life, injury, or damage to property, whether such provisions apply specifically to railroad employees or generally to the public at large.

§ 232.15 Movement of defective equipment.

(a) *General provision.* Except as provided in paragraph (c) of this section, a railroad car or locomotive with one or more conditions not in compliance with this part may be used or hauled without civil penalty liability under this part only if *all* of the following conditions are met:

(1) The defective car or locomotive is properly equipped in accordance with the applicable provisions of 49 U.S.C. chapter 203 and the requirements of this part.

(2) The car or locomotive becomes defective while it is being used by the railroad on its line or becomes defective on the line of a connecting railroad and is properly accepted in interchange for repairs in accordance with paragraph (a)(7) of this section.

(3) The railroad first discovers the defective condition of the car or locomotive prior to moving it for repairs.

(4) The movement of the defective car or locomotive for repairs is from the location where the car or locomotive is first discovered defective by the railroad.

(5) The defective car or locomotive cannot be repaired at the location where the railroad first discovers it to be defective.

(6) The movement of the car or locomotive is necessary to make repairs to the defective condition.

(7) The location to which the car or locomotive is being taken for repair is the nearest available location where necessary repairs can be performed on the line of the railroad where the car or locomotive was first found to be defective or is the nearest available location where necessary repairs can be performed on the line of a connecting railroad if:

(i) The connecting railroad elects to accept the defective car or locomotive for such repair; and

(ii) The nearest available location where necessary repairs can be performed on the line of the connecting railroad is no farther than the nearest available location where necessary repairs can be performed on the line of the railroad where the car or locomotive was found defective.

(8) The movement of the defective car or locomotive for repairs is not by a train required to receive a Class I brake test at that location pursuant to § 232.205.

(9) The movement of the defective car or locomotive for repairs is not in a train in which less than 85 percent of the cars have operative and effective brakes.

(10) The defective car or locomotive is tagged, or information is recorded, as prescribed in paragraph (b) of this section.

(11) Except for cars or locomotives with brakes cut out en route, the following additional requirements are met:

(i) A qualified person shall determine—

(A) That it is safe to move the car or locomotive; and

(B) The maximum safe speed and other restrictions necessary for safely conducting the movement.

(ii) The person in charge of the train in which the car or locomotive is to be moved shall be notified in writing and inform all other crew members of the presence of the defective car or locomotive and the maximum speed and other restrictions determined under paragraph (a)(11)(i)(B) of this section. A copy of the tag or card described in paragraph (b) of this section may be used to provide the notification required by this paragraph.

(iii) The defective car or locomotive is moved in compliance with the maximum speed and other restrictions determined under paragraph (a)(11)(i)(B) of this section.

(12) The defective car or locomotive is not subject to a Special Notice for Repair under part 216 of this chapter, unless the movement of the defective car is made in accordance with the restrictions contained in the Special Notice.

(b) *Tagging of defective equipment.*

(1) At the place where the railroad first discovers the defect, a tag or card shall be placed on both sides of the defective equipment or locomotive and in the cab of the locomotive, or an automated tracking system approved for use by FRA shall be provided with the following information about the defective equipment:

(i) The reporting mark and car or locomotive number;

(ii) The name of the inspecting railroad;

(iii) The name and job title of the inspector;

(iv) The inspection location and date;

(v) The nature of each defect;

(vi) A description of any movement restrictions;

(vii) The destination of the equipment where it will be repaired; and

(viii) The signature, or electronic identification, of the person reporting the defective condition.

(2) The tag or card required by paragraph (b)(1) of this section shall remain affixed to the defective equipment until the necessary repairs have been performed.

(3) An electronic or written record or a copy of each tag or card attached to or removed from a car or locomotive shall be retained for 90 days and, upon request, shall be made available within 15 calendar days for inspection by FRA or State inspectors.

(4) Each tag or card removed from a car or locomotive shall contain the date, location, reason for its removal, and the signature of the person who removed it from the piece of equipment.

(5) Any automated tracking system approved by FRA to meet the tagging requirements contained in paragraph (b)(1) of this section shall be capable of being reviewed and monitored by FRA at any time to ensure the integrity of the system. FRA's Associate Administrator for Safety may prohibit or revoke a railroad's authority to utilize an approved automated tracking system in lieu of tagging if FRA finds that the automated tracking system is not properly secure, is inaccessible to FRA or a railroad's employees, or fails to adequately track and monitor the movement of defective equipment. FRA will record such a determination in writing, include a statement of the basis for such action, and provide a copy of the document to the railroad.

(c) *Movement for unloading or purging of defective cars.* If a defective car is loaded with a hazardous material or contains residue of a hazardous material, the car may not be placed for unloading or purging unless unloading or purging is consistent with determinations made and restrictions imposed under paragraph (a)(11)(i) of this section and the unloading or purging is necessary for the safe repair of the car.

(d) *Computation of percent operative power brakes.*

(1) The percentage of operative power brakes in a train shall be based on the number of control valves in the train. The percentage shall be determined by dividing the number of control valves that are cut-in by the total number of control valves in the train. A control valve shall not be considered cut-in if the brakes controlled by that valve are inoperative. Both cars and locomotives shall be considered when making this calculation.

(2) The following brake conditions not in compliance with this part are not considered inoperative power brakes for purposes of this section:

(i) Failure or cutting out of secondary brake systems;

(ii) Inoperative or otherwise defective handbrakes or parking brakes;

(iii) Piston travel that is in excess of the Class I brake test limits required in § 232.205 but that does not exceed the outside limits contained on the stencil, sticker, or badge plate required by § 232.103(g) for considering the power brakes to be effective; and

(iv) Power brakes overdue for inspection, testing, maintenance, or stenciling under this part.

(e) *Placement of equipment with inoperative brakes.*

(1) A freight car or locomotive with inoperative brakes shall not be placed as the rear car of the train.

(2) No more than two freight cars with either inoperative brakes or not equipped with power brakes shall be consecutively placed in the same train.

(3) Multi-unit articulated equipment shall not be placed in a train if the equipment has more than two consecutive individual control valves cut-out or if the brakes controlled by the valves are inoperative.

(f) *Guidelines for determining locations where necessary repairs can be performed.* The following guidelines will be considered by FRA when determining whether a location is a location where repairs to a car's brake system or components can be performed and whether a location is the nearest location where the needed repairs can be effectuated.

(1) The following general factors and guidelines will be considered when making determinations as to whether a location is a location where brake repairs can be performed:

(i) The accessibility of the location to persons responsible for making repairs;

(ii) The presence of hazardous conditions that affect the ability to safely make repairs of the type needed at the location;

(iii) The nature of the repair necessary to bring the car into compliance;

(iv) The need for railroads to have in place an effective means to ensure the safe and timely repair of equipment;

(v) The relevant weather conditions at the location that affect accessibility or create hazardous conditions;

(vi) A location need not have the ability to effectuate every type of brake system repair in order to be considered a location where some brake repairs can be performed;

(vii) A location need not be staffed continuously in order to be considered a location where brake repairs can be performed;

(viii) The ability of a railroad to perform repair track brake tests or single car tests at a location shall not be considered; and

(ix) The congestion of work at a location shall not be considered

(2) The general factors and guidelines outlined in paragraph (f)(1) of this section should be applied to the following locations:

(i) A location where a mobile repair truck is used on a regular basis;

(ii) A location where a mobile repair truck originates or is permanently stationed;

(iii) A location at which a railroad performs mechanical repairs other than brake system repairs; and

(iv) A location that has an operative repair track or repair shop;

(3) In determining whether a location is the nearest location where the necessary brake repairs can be made, the distance to the location is a key factor but should not be considered the determining factor. The distance to a location must be considered in conjunction with the factors and guidance outlined in paragraphs (f)(1) and (f)(2) of this section. In addition, the following safety factors must be considered in order to optimize safety:

(i) The safety of the employees responsible for getting the equipment to or from a particular location; and

(ii) The potential safety hazards involved with moving the equipment in the direction of travel necessary to get the equipment to a particular location.

(g) Based on the guidance detailed in paragraph (f) of this section and consistent with other requirements contained in this part, a railroad and the representatives of the railroad's

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employees may submit, for FRA approval, a joint proposal containing a plan designating locations where brake system repairs will be performed. Approval of such plans shall be made in writing by FRA's Associate Administrator for Safety and shall be subject to any modifications or changes determined by FRA to be necessary to ensure consistency with the requirements and guidance contained in this part.

§ 232.17 Special approval procedure.

(a) *General.* The following procedures govern consideration and action upon requests for special approval of an alternative standard under §§ 232.305 and 232.307; and for special approval of pre-revenue service acceptance testing plans under subpart F of this part.

(b) *Petitions for special approval of an alternative standard.* Each petition for special approval of an alternative standard shall contain:

(1) The name, title, address, and telephone number of the primary person to be contacted with regard to review of the petition;

(2) The alternative proposed, in detail, to be substituted for the particular requirement of this part;

(3) Appropriate data or analysis, or both, for FRA to consider in determining whether the alternative will provide at least an equivalent level of safety; and

(4) A statement affirming that the railroad has served a copy of the petition on designated representatives of its employees, together with a list of the names and addresses of the persons served.

(c) *Petitions for special approval of pre-revenue service acceptance testing plan.* Each petition for special approval of a pre-revenue service acceptance testing plan shall contain:

(1) The name, title, address, and telephone number of the primary person to be contacted with regard to review of the petition; and

(2) The elements prescribed in § 232.505.

(d) *Service.*

(1) Each petition for special approval under paragraph (b) or (c) of this section shall be submitted in triplicate to the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, SW., Washington, DC 20590.

(2) Service of each petition for special approval of an alternative standard under paragraph (b) of this section shall be made on the following:

(i) Designated employee representatives responsible for the equipment's operation, inspection, testing, and maintenance under this part;

(ii) Any organizations or bodies that either issued the standard incorporated in the section(s) of the rule to which the special approval pertains or issued the alternative standard that is proposed in the petition; and

(iii) Any other person who has filed with FRA a current statement of interest in reviewing special approvals under the particular requirement of this part at least 30 days but not more than 5 years prior to the filing of the petition. If filed, a statement of interest shall be filed with FRA's Associate Administrator for Safety and shall reference the specific section(s) of this part in which the person has an interest.

(e) *Federal Register notice.* FRA will publish a notice in the **Federal Register** concerning each petition under paragraph (b) of this section.

(f) *Comment.* Not later than 30 days from the date of publication of the notice in the **Federal Register** concerning a petition under paragraph (b) of this section, any person may comment on the petition.

(1) A comment shall set forth specifically the basis upon which it is made, and contain a concise statement of the interest of the commenter in the proceeding.

(2) The comment shall be submitted in triplicate to the Associate Administrator for Safety, Federal Railroad Administration, 400 7th Street, SW., Washington, DC 20590.

(3) The commenter shall certify that a copy of the comment was served on each petitioner.

(g) *Disposition of petitions.*

(1) If FRA finds that the petition complies with the requirements of this section and that the proposed alternative standard or pre-revenue service plan is acceptable and justified, the petition will be granted, normally within 90 days of its receipt. If the petition is neither granted nor denied within 90 days, the petition remains pending for decision. FRA may attach special conditions to the approval of any petition. Following the approval of a petition, FRA may reopen consideration of the petition for cause.

(2) If FRA finds that the petition does not comply with the requirements of this section and that the alternative standard or pre-revenue service plan is not acceptable or justified, the petition will be denied, normally within 90 days of its receipt.

(3) When FRA grants or denies a petition, or reopens consideration of the petition, written notice is sent to the petitioner and other interested parties.

§ 232.19 Availability of records.

Except as otherwise provided, the records and plans required by this part shall be made available to representatives of FRA and States participating under part 212 of this chapter for inspection and copying upon request.

§ 232.21 Information Collection.

(a) The information collection requirements of this part were reviewed by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) and are assigned OMB control number 2130–0008.

(b) The information collection requirements are found in the following sections: §§ 229.27, 231.31, 232.1, 232.3, 232.7, 232.11, 232.15, 232.17, 232.103, 232.105, 232.107, 232.109, 232.111, 232.203, 232.205, 232.207, 232.209, 232.211, 232.213, 232.303, 232.307, 232.309, 232.403, 232.405, 232.407, 232.409, 232.503, 232.505.

Subpart B—General Requirements

§ 232.101 Scope.

This subpart contains general operating, performance, and design requirements for each railroad that operates freight or other non-passenger trains and for specific equipment used in those operations.

§ 232.103 General requirements for all train brake systems.

(a) The primary brake system of a train shall be capable of stopping the train with a service application from its maximum operating speed within the signal spacing existing on the track over which the train is operating.

(b) If the integrity of the train line of a train brake system is broken, the train shall be stopped. If a train line uses other than solely pneumatic technology, the integrity of the train line shall be monitored by the brake control system.

(c) A train brake system shall respond as intended to signals from the train line.

(d) One hundred percent of the brakes on a train shall be effective and operative brakes prior to use or departure from any location where a Class I brake test is required to be performed on the train pursuant to § 232.205.

(e) A train shall not move if less than 85 percent of the cars in that train have operative and effective brakes.

(f) Each car in a train shall have its air brakes in effective operating condition unless the car is being moved for repairs in accordance with § 232.15. The air brakes on a car are not in effective

operating condition if its brakes are cut-out or otherwise inoperative or if the piston travel exceeds:

(1) 10½ inches for cars equipped with nominal 12-inch stroke brake cylinders; or

(2) The piston travel limits indicated on the stencil, sticker, or badge plate for the brake cylinder with which the car is equipped.

(g) Except for cars equipped with nominal 12-inch stroke (8½ and 10-inch diameters) brake cylinders, all cars shall have a legible decal, stencil, or sticker affixed to the car or shall be equipped with a badge plate displaying the permissible brake cylinder piston travel range for the car at Class I brake tests and the length at which the piston travel renders the brake ineffective, if different from Class I brake test limits. The decal, stencil, sticker, or badge plate shall be located so that it may be easily read and understood by a person positioned safely beside the car.

(h) All equipment ordered on or after August 1, 2002, or placed in service for the first time on or after April 1, 2004, shall have train brake systems designed so that an inspector can observe from a safe position either the piston travel, an accurate indicator which shows piston travel, or any other means by which the brake system is actuated. The design shall not require the inspector to place himself or herself on, under, or between components of the equipment to observe brake actuation or release.

(i) All trains shall be equipped with an emergency application feature that produces an irretrievable stop, using a brake rate consistent with prevailing adhesion, train safety, and brake system thermal capacity. An emergency application shall be available at all times, and shall be initiated by an unintentional parting of the train line or loss of train brake communication.

(j) A railroad shall set the maximum main reservoir working pressure.

(k) The maximum brake pipe pressure shall not be greater than 15 psi less than the air compressor governor starting or loading pressure.

(l) Except as otherwise provided in this part, all equipment used in freight or other non-passenger trains shall, at a minimum, meet the Association of American Railroads (AAR) Standard S–469–47, "Performance Specification for Freight Brakes," contained in the AAR *Manual of Standards and Recommended Practices, Section E* (April 1, 1999). The incorporation by reference of this AAR standard was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the incorporated document from the Association of American Railroads, 50 F Street, NW, Washington, DC. 20001. You may inspect a copy of the document at the Federal Railroad Administration, Docket Clerk, 1120 Vermont Avenue, NW, Suite 7000, Washington, DC or at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC 20408.

(m) If a train qualified by the Air Flow Method as provided for in subpart C of this part experiences a brake pipe air flow of greater than 60 CFM or brake pipe gradient of greater than 15 psi while en route and the movable pointer does not return to those limits within a reasonable time, the train shall be stopped at the next available location and be inspected for leaks in the brake system.

(n) *Securement of unattended equipment.* A train's air brake shall not be depended upon to hold equipment standing unattended on a grade (including a locomotive, a car, or a train whether or not locomotive is attached). For purposes of this section, "unattended equipment" means equipment left standing and unmanned in such a manner that the brake system of the equipment cannot be readily controlled by a qualified person. Unattended equipment shall be secured in accordance with the following requirements:

(1) A sufficient number of hand brakes shall be applied to hold the equipment. Railroads shall develop and implement a process or procedure to verify that the applied hand brakes will sufficiently hold the equipment with the air brakes released.

(2) Where possible, an emergency brake application of the air brakes shall be initiated prior to leaving equipment unattended.

(3) The following requirements apply to the use of hand brakes on unattended locomotives:

(i) All hand brakes shall be fully applied on all locomotives in the lead consist of an unattended train.

(ii) All hand brakes shall be fully applied on all locomotives in an unattended locomotive consist outside of yard limits.

(iii) At a minimum, the hand brake shall be fully applied on the lead locomotive in an unattended locomotive consist within yard limits.

(4) A railroad shall adopt and comply with a process or procedures to verify that the applied hand brakes will sufficiently hold an unattended locomotive consist. A railroad shall also adopt and comply with instructions to address throttle position, status of the reverse lever, position of the generator field switch, status of the independent brakes, position of the isolation switch, and position of the automatic brake valve on all unattended locomotives. The procedures and instruction required in this paragraph shall take into account winter weather conditions as they relate to throttle position and reverser handle.

(5) Any hand brakes applied to hold unattended equipment shall not be released until it is known that the air brake system is properly charged.

(o) Air pressure regulating devices shall be adjusted for the following pressures:

Locomotives	PSI
(1) Minimum brake pipe air pressure:	
Road Service	90
Switch Service	60
(2) Minimum differential between brake pipe and main reservoir air pressures, with brake valve in running position	15
(3) Safety valve for straight air brake	30–55
(4) Safety valve for LT, ET, No. 8–EL, No. 14 El, No. 6–DS, No. 6–BL and No. 6–SL equipment	30–68
(5) Safety valve for HSC and No. 24–RL equipment	30–75
(6) Reducing valve for independent or straight air brake	30–50
(7) Self-lapping portion for electro-pneumatic brake (minimum full application pressure)	50
(8) Self-lapping portion for independent air brake (full application pressure)	30 or less
(9) Reducing valve for high-speed brake (minimum)	50

(p) Railroad or contract supervisors shall be held jointly responsible with the inspectors and train crew members they supervise for the condition and proper functioning of train brake systems to the extent that it is possible

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to detect defective equipment by the inspections and tests required by this part.

§ 232.105 General requirements for locomotives.

(a) The air brake equipment on a locomotive shall be in safe and suitable condition for service.

(b) All locomotives ordered on or after August 1, 2002, or placed in service for the first time on or after April 1, 2004, shall be equipped with a hand or parking brake that is:

(1) Capable of application or activation by hand;

(2) Capable of release by hand; and

(3) Capable of holding the unit on a three (3) percent grade.

(c) On locomotives so equipped, the hand or parking brake as well as its parts and connections shall be inspected, and necessary repairs made, as often as service requires but no less frequently than every 368 days. The date of the last inspection shall be either entered on Form FRA F 6180–49A or suitably stenciled or tagged on the locomotive.

(d) The amount of leakage from the equalizing reservoir on locomotives and related piping shall be zero, unless the system is capable of maintaining the set pressure at any service application with the brakes control valve in the freight position. If such leakage is detected en route, the train may be moved only to the nearest forward location where the equalizing-reservoir leakage can be corrected. On locomotives equipped with electronic brakes, if the system logs or displays a fault related to equalizing reservoir leakage, the train may be moved only to the nearest forward location where the necessary repairs can be made.

(e) Use of the feed or regulating valve to control braking is prohibited.

(f) The passenger position on the locomotive brake control stand shall be used only if the trailing equipment is designed for graduated brake release or if equalizing reservoir leakage occurs en route and its use is necessary to safely control the movement of the train until it reaches the next forward location where the reservoir leakage can be corrected.

(g) When taking charge of a locomotive or locomotive consist, an engineer must know that the brakes are in operative condition.

§ 232.107 Air source requirements and cold weather operations.

(a) *Monitoring plans for yard air sources.*

(1) A railroad shall adopt and comply with a written plan to monitor all yard air sources, other than locomotives, to determine that they operate as intended and do not introduce contaminants into the brake system of freight equipment.

(2) This plan shall require the railroad to:

(i) Inspect each yard air source at least two times per calendar year, no less than five months apart, to determine it operates as intended and does not introduce contaminants into the brake system of the equipment it services.

(ii) Identify yard air sources found not to be operating as intended or found introducing contaminants into the brake system of the equipment it services.

(iii) Repair or take other remedial action regarding any yard air source identified under paragraph (a)(2)(ii) of this section.

(3) A railroad shall maintain records of the information and actions required by paragraph (a)(2). These records shall be maintained for a period of at least one year from the date of creation and may be maintained either electronically or in writing.

(b) Condensation and other contaminants shall be blown from the pipe or hose from which compressed air is taken prior to connecting the yard air line or motive power to the train.

(c) No chemicals which are known to degrade or harm brake system components shall be placed in the train air brake system.

(d) Yard air reservoirs shall either be equipped with an operable automatic drain system or be manually drained at least once each day that the devices are used or more often if moisture is detected in the system.

(e) A railroad shall adopt and comply with detailed written operating procedures tailored to the equipment and territory of that railroad to cover safe train operations during cold weather. For purposes of this provision, "cold weather" means when the ambient temperature drops below 10 degrees Fahrenheit (F) (minus 12.2 degrees Celsius).

§ 232.109 Dynamic brake requirements.

(a) Except as provided in paragraph (i) of this section, a locomotive engineer shall be informed of the operational status of the dynamic brakes on all locomotive units in the consist at the initial terminal or point of origin for a train and at other locations where a locomotive engineer first begins operation of a train. The information required by this paragraph may be provided to the locomotive engineer by any means determined appropriate by the railroad; however, a written or electronic record of the information shall be maintained in the cab of the controlling locomotive.

(b) Except as provided in paragraph (e) of this section, all inoperative dynamic brakes shall be repaired within 30 calendar days of becoming inoperative or at the locomotive's next periodic inspection pursuant to § 229.23 of this chapter, whichever occurs first.

(c) Except as provided in paragraph (e) of this section, a locomotive discovered with inoperative dynamic brakes shall have a tag bearing the words "inoperative dynamic brake" securely attached and displayed in a conspicuous location in the cab of the locomotive. This tag shall contain the following information:

(1) The locomotive number;

(2) The name of the discovering carrier;

(3) The location and date where condition was discovered; and

(4) The signature of the person discovering the condition.

(d) An electronic or written record of repairs made to a locomotive's dynamic brakes shall be retained for 92 days.

(e) A railroad may elect to declare the dynamic brakes on a locomotive deactivated without removing the dynamic brake components from the locomotive, only if all of the following conditions are met:

(1) The locomotive is clearly marked with the words "dynamic brake deactivated" in a conspicuous location in the cab of the locomotive; and

(2) The railroad has taken appropriate action to ensure that the deactivated locomotive is incapable of utilizing dynamic brake effort to retard or control train speed.

(f) If a locomotive consist is intended to have its dynamic brakes used while in transit, a locomotive with inoperative or deactivated dynamic brakes or a locomotive not equipped with dynamic brakes shall not be placed in the controlling (lead) position of a consist unless the locomotive has the capability of:

(1) Controlling the dynamic braking effort in trailing locomotives in the consist that are so equipped; and

(2) Displaying to the locomotive engineer the deceleration rate of the train or the total train dynamic brake retarding force.

(g) All locomotives equipped with dynamic brakes and ordered on or after August 1, 2002, or placed in service for the first time on or after April 1, 2004, shall be designed to:

(1) Test the electrical integrity of the dynamic brake at rest; and

(2) Display the available total train dynamic brake retarding force at various speed increments in the cab of the controlling locomotive.

(h) All rebuilt locomotives equipped with dynamic brakes and placed in service on or after April 1, 2004, shall be designed to:

(1) Test the electrical integrity of the dynamic brake at rest; and

(2) Display either the train deceleration rate or the available total train dynamic brake retarding force at various speed increments in the cab of the controlling (lead) locomotive.

(i) The information required by paragraph (a) of this section is not required to be provided to the locomotive engineer if all of the locomotives in the lead consist of a train are equipped in accordance with paragraph (g) of this section.

(j) A railroad operating a train with a brake system that includes dynamic brakes shall adopt and comply with written operating rules governing safe train handling procedures using these dynamic brakes under all operating conditions, which shall be tailored to the specific equipment and territory of the railroad. The railroad's operating rules shall:

(1) Ensure that the friction brakes are sufficient by themselves, without the aid of dynamic brakes, to stop the train safely under all operating conditions.

(2) Include a "miles-per-hour-overspeed-stop" rule. At a minimum, this rule shall require that any train, when descending a grade of 1 percent or greater, shall be immediately brought to a stop, by an emergency brake application if necessary, when the train's speed exceeds the maximum authorized speed for that train by more than 5 miles per hour. A railroad shall reduce the 5 mile per hour overspeed restriction if validated research indicates the need for such a reduction. A railroad may increase the 5 mile per hour overspeed restriction only with approval of FRA and based upon verifiable data and research.

(k) A railroad operating a train with a brake system that includes dynamic brakes shall adopt and comply with specific knowledge, skill, and ability criteria to ensure that its locomotive engineers are fully trained in the operating rules prescribed by paragraph (j) of this section. The railroad shall incorporate such criteria into its locomotive engineer certification program pursuant to Part 240 of this chapter,

§ 232.111 Train handling information.

(a) A railroad shall adopt and comply with written procedures to ensure that a train crew employed by the railroad is given accurate information on the condition of the train brake system and train factors affecting brake system performance and testing when the crew takes over responsibility for the train. The information required by this paragraph may be provided to the locomotive engineer by any means determined appropriate by the railroad; however, a written or electronic record of the information shall be maintained in the cab of the controlling locomotive.

(b) The procedures shall require that each train crew taking charge of a train be informed of:

(1) The total weight and length of the train, based on the best information available to the railroad;

(2) Any special weight distribution that would require special train handling procedures;

(3) The number and location of cars with cut-out or otherwise inoperative brakes and the location where they will be repaired;

(4) If a Class I or Class IA brake test is required prior to the next crew change point, the location at which that test shall be performed; and

(5) Any train brake system problems encountered by the previous crew of the train.

Subpart C—Inspection and Testing Requirements

§ 232.201 Scope.

This subpart contains the inspection and testing requirements for brake systems used in freight and other non-passenger trains. This subpart also contains general training requirements for railroad and contract personnel used to perform the required inspections and tests.

§ 232.203 Training requirements.

(a) Each railroad and each contractor shall adopt and comply with a training, qualification, and designation program for its employees that perform brake system inspections, tests, or maintenance. For purposes of this section, a "contractor" is defined as a person under contract with the railroad or car owner. The records required by this section may be maintained either electronically or in writing.

(b) As part of this program, the railroad or contractor shall:

(1) Identify the tasks related to the inspection, testing, and maintenance of the brake system required by this part that must be performed by the railroad or contractor and identify the skills and knowledge necessary to perform each task.

(2) Develop or incorporate a training curriculum that includes both classroom and "hands-on" lessons designed to impart the skills and knowledge identified as necessary to perform each task. The developed or incorporated training curriculum shall specifically address the Federal regulatory requirements contained in this part that are related to the performance of the tasks identified.

(3) Require all employees to successfully complete a training curriculum that covers the skills and knowledge the employee will need to possess in order to perform the tasks required by this part that the employee will be responsible for performing, including the specific Federal regulatory requirements contained in this part related to the performance of a task for which the employee will be responsible;

(4) Require all employees to pass a written or oral examination covering the skills and knowledge the employee will need to possess in order to perform the tasks required by this part that the employee will be responsible for performing, including the specific Federal regulatory requirements contained in this part related to the performance of a task for which the employee will be responsible for performing;

(5) Require all employees to individually demonstrate "hands-on" capability by successfully applying the skills and knowledge the employee will need to possess in order to perform the tasks required by this part that the employee will be responsible for performing to the satisfaction of the employee's supervisor or designated instructor;

(6) Consider training and testing, including efficiency testing, previously received by an employee in order to meet the requirements contained in paragraphs (b)(3) through (b)(5) of this section; provided, such training and testing can be documented as required in paragraph (e) of this section;

(7) Require supervisors to exercise oversight to ensure that all the identified tasks are performed in accordance with the railroad's written procedures and the specific Federal regulatory requirements contained in this part;

(8) Require periodic refresher training at an interval not to exceed three years that includes classroom and "hands-on" training, as well as testing. Efficiency testing may be used to meet the "hands-on" portion of this requirement; provided, such testing is documented as required in paragraph (e) of this section; and

(9) Add new brake systems to the training, qualification and designation program prior to its introduction to revenue service.

(c) A railroad that operates trains required to be equipped with a two-way

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end-of-train telemetry device pursuant to Subpart E of this part, and each contractor that maintains such devices shall adopt and comply with a training program which specifically addresses the testing, operation, and maintenance of two-way end-of-train devices for employees who are responsible for the testing, operation, and maintenance of the devices.

(d) A railroad that operates trains under conditions that require the setting of air brake pressure retaining valves shall adopt and comply with a training program which specifically addresses the proper use of retainers for employees who are responsible for using or setting retainers.

(e) A railroad or contractor shall maintain adequate records to demonstrate the current qualification status of all of its personnel assigned to inspect, test, or maintain a train brake system. The records required by this paragraph may be maintained either electronically or in writing and shall be provided to FRA upon request. These records shall include the following information concerning each such employee:

(1) The name of the employee;

(2) The dates that each training course was completed;

(3) The content of each training course successfully completed;

(4) The employee's scores on each test taken to demonstrate proficiency;

(5) A description of the employee's "hands-on" performance applying the skills and knowledge the employee needs to possess in order to perform the tasks required by this part that the employee will be responsible for performing and the basis for finding that the skills and knowledge were successfully demonstrated;

(6) A record that the employee was notified of his or her current qualification status and of any subsequent changes to that status;

(7) The tasks required to be performed under this part which the employee is deemed qualified to perform; and

(8) Identification of the person(s) determining that the employee has successfully completed the training necessary to be considered qualified to perform the tasks identified in paragraph (e)(7) of this section.

(9) The date that the employee's status as qualified to perform the tasks identified in paragraph (e)(7) of this section expires due to the need for refresher training.

(f) A railroad or contractor shall adopt and comply with a plan to periodically assess the effectiveness of its training program. One method of validation and assessment could be through the use of efficiency tests or periodic review of employee performance.

§ 232.205 Class I brake test-initial terminal inspection.

(a) Each train and each car in the train shall receive a Class I brake test as described in paragraph (b) of this section by a qualified person, as defined in § 232.5, at the following points:

(1) The location where the train is originally assembled ("initial terminal");

(2) A location where the train consist is changed other than by:

(i) Adding a single car or a solid block of cars;

(ii) Removing a single car or a solid block of cars;

(iii) Removing cars determined to be defective under this chapter; or

(iv) A combination of the changes listed in paragraphs (a)(2)(i) through (a)(2)(iii) of this section (See §§ 232.209 and 232.211 for requirements related to the pick-up of cars and solid blocks of cars en route.);

(3) A location where the train is off air for a period of more than four hours;

(4) A location where a unit or cycle train has traveled 3,000 miles since its last Class I brake test; and

(5) A location where the train is received in interchange if the train consist is changed other than by:

(i) Removing a car or a solid block of cars from the train;

(ii) Adding a previously tested car or a previously tested solid block of cars to the train;

(iii) Changing motive power;

(iv) Removing or changing the caboose; or

(v) Any combination of the changes listed in paragraphs (a)(5) of this section.

(A) If changes other than those contained in paragraph (a)(5)(i)–(a)(5)(v) of this section are made to the train consist when it is received in interchange and the train will move 20 miles or less, then the railroad may conduct a brake test pursuant to § 232.209 on those cars added to the train.

(B) Reserved.

(b) A Class I brake test of a train shall consist of the following tasks and requirements:

(1) Brake pipe leakage shall not exceed 5 psi per minute or air flow shall not exceed 60 cubic feet per minute (CFM).

(i) *Leakage Test.* The brake pipe leakage test shall be conducted as follows:

(A) Charge the air brake system to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, as indicated by an accurate gauge or end-of-train device at the rear end of train;

(B) Upon receiving the signal to apply brakes for test, make a 20-psi brake pipe service reduction;

(C) If the locomotive used to perform the leakage test is equipped with a means for maintaining brake pipe pressure at a constant level during a 20-psi brake pipe service reduction, this feature shall be cut out during the leakage test; and

(D) With the brake valve lapped and the pressure maintaining feature cut out (if so equipped) and after waiting 45–60 seconds, note the brake pipe leakage as indicated by the brake-pipe gauge in the locomotive, which shall not exceed 5 psi per minute.

(ii) *Air Flow Method Test.* When a locomotive is equipped with a 26-L brake valve or equivalent pressure maintaining locomotive brake valve, a railroad may use the Air Flow Method Test as an alternate to the brake pipe leakage test. The Air Flow Method (AFM) Test shall be performed as follows:

(A) Charge the air brake system to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, as indicated by an accurate gauge or end-of-train device at the rear end of train; and

(B) Measure air flow as indicated by a calibrated AFM indicator, which shall not exceed 60 cubic feet per minute (CFM).

(iii) The AFM indicator shall be calibrated for accuracy at periodic intervals not to exceed 92 days. The AFM indicator calibration test orifices shall be calibrated at temperatures of not less than 20 degrees Fahrenheit. AFM indicators shall be accurate to within ± 3 standard cubic feet per minute (CFM).

(2) The inspector shall position himself/herself, taking positions on each side of each car sometime during the inspection process, so as to be able to examine and observe the functioning of all moving parts of the brake system on each car in order to make the determinations and inspections required by this section. A "roll-by" inspection of the brake release as provided for in paragraph (b)(8) of this section shall not constitute an inspection of that side of the train for purposes of this requirement;

(3) The train brake system shall be charged to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, as indicated by an accurate gauge or end-of-train device at rear end of train;

(4) The brakes on each car shall apply in response to a 20-psi brake pipe service reduction and shall remain applied until a release of the air brakes has been initiated by the controlling locomotive or yard test device. The brakes shall not be applied or released until the proper signal is given. A car found with brakes that fail to apply or remain applied may be retested and remain in the train if the retest is conducted at the pressure the train will be operated from the controlling locomotive, head end of the consist, or a suitable test device, as described in § 232.217(a) of this part, positioned at one end of the car(s) being retested and the brakes remain applied until a release is initiated after a period which is no less than three minutes. If the retest is performed at the car(s) being retested with a suitable device, the compressed air in the car(s) shall be depleted prior to disconnecting the hoses between the car(s) to perform the retest;

(5) For cars equipped with 8½-inch or 10-inch diameter brake cylinders, piston travel shall be within 7 to 9 inches. If piston travel is found to be less than 7 inches or more than 9 inches, it must be adjusted to nominally 7½ inches. For cars not equipped with 8½-inch or 10-inch diameter brake cylinders, piston travel shall be within the piston travel stenciled or marked on the car or badge plate. Minimum brake cylinder piston travel of truck-mounted brake cylinders must be sufficient to provide proper brake shoe clearance when the brakes are released. Piston travel must be inspected on each freight car while the brakes are applied;

(6) Brake rigging shall be properly secured and shall not bind or foul or otherwise adversely affect the operation of the brake system;

(7) All parts of the brake equipment shall be properly secured. On cars where the bottom rod passes through the truck bolster or is secured with cotter keys equipped with a locking device to prevent their accidental removal, bottom rod safety supports are not required; and

(8) When the release is initiated by the controlling locomotive or yard test device, the brakes on each freight car shall be inspected to verify that it did release; this may be performed by a "roll-by" inspection. If a "roll-by" inspection of the brake release is performed, train speed shall not exceed 10 MPH and the qualified person performing the "roll-by" inspection shall communicate the results of the inspection to the operator of the train. The operator of the train shall note successful completion of the release portion of the inspection on the record required in paragraph (d) of this section.

(c) Where a railroad's collective bargaining agreement provides that a carman is to perform the inspections and tests required by this section, a carman alone will be considered a qualified person. In these circumstances, the railroad shall ensure that the carman is properly trained and designated as a qualified person or qualified mechanical inspector pursuant to the requirements of this part.

(d) A railroad shall notify the locomotive engineer that the Class I brake test was satisfactorily performed and provide the information required in this paragraph to the locomotive engineer or place the information in the cab of the controlling locomotive following the test. The information required by this paragraph may be provided to the locomotive engineer by any means determined appropriate by the railroad; however, a written or electronic record of the information shall be retained in the cab of the controlling locomotive until the train reaches its destination. The written or electronic record shall contain the date, time, number of freight cars inspected, and identify the qualified person(s) performing the test and the location where the Class I brake test was performed.

(e) Before adjusting piston travel or working on brake rigging, cutout cock in brake pipe branch must be closed and air reservoirs must be voided of all compressed air. When cutout cocks are provided in brake cylinder pipes, these cutout cocks only may be closed and air reservoirs need not be voided of all compressed air.

(f) Except as provided in § 232.209, each car or solid block of cars, as defined in § 232.5, that has not received a Class I brake test or that has been off air for more than four hours and that is added to a train shall receive a Class I test when added to a train. A Class III brake test as described in § 232.211 shall then be performed on the entire new train.

§ 232.207 Class IA brake tests—1,000-mile inspection.

(a) Except as provided in § 232.213, each train shall receive a Class IA brake test performed by a qualified person, as defined in § 232.5, at a location that is not more than 1,000 miles from the point where any car in the train last received a Class I or Class IA brake test. The most restrictive car or block of cars in the train shall determine the location of this test.

(b) A Class IA brake test of a train shall consist of the following tasks and requirements:

(1) Brake pipe leakage shall not exceed 5 psi per minute or air flow shall not exceed 60 cubic feet per minute (CFM). The brake pipe leakage test or air flow method test shall be conducted pursuant to the requirements contained in § 232.205(b)(1);

(2) The inspector shall position himself/herself, taking positions on each side of each car sometime during the inspection process, so as to be able to examine and observe the functioning of all moving parts of the brake system on each car in order to make the determinations and inspections required by this section;

(3) The air brake system shall be charged to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, as indicated by an accurate gauge or end-of-train device at rear end of train;

(4) The brakes on each car shall apply in response to a 20-psi brake pipe service reduction and shall remain applied until the release is initiated by the controlling locomotive. A car found with brakes that fail to apply or remain applied may be retested and remain in the train if the retest is conducted as prescribed in § 232.205(b)(4); otherwise, the defective equipment may only be moved pursuant to the provisions contained in § 232.15, if applicable;

(5) Brake rigging shall be properly secured and shall not bind or foul or otherwise adversely affect the operation of the brake system; and

(6) All parts of the brake equipment shall be properly secured.

(c) A railroad shall designate the locations where Class IA brake tests will be performed, and the railroad shall furnish to the Federal Railroad Administration upon request a description of each location designated. A railroad shall notify FRA's Associate Administrator for Safety in writing 30 days prior to any change in the locations designated for such tests and inspections.

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(1) Failure to perform a Class IA brake test on a train at a location designated pursuant to this paragraph constitutes a failure to perform a proper Class IA brake test if the train is due for such a test at that location.

(2) In the event of an emergency that alters normal train operations, such as a derailment or other unusual circumstance that adversely affects the safe operation of the train, the railroad is not required to provide prior written notification of a change in the location where a Class IA brake test is performed to a location not on the railroad's list of designated locations for performing Class IA brake tests, provided that the railroad notifies FRA's Associate Administrator for Safety and the pertinent FRA Regional Administrator within 24 hours after the designation has been changed and the reason for that change.

§ 232.209 Class II brake tests—intermediate inspection.

(a) At a location other than the initial terminal of a train, a Class II brake test shall be performed by a qualified person, as defined in § 232.5, on the following equipment when added to a train:

(1) Each car or solid block of cars, as defined in § 232.5, that has not previously received a Class I brake test or that has been off air for more than four hours;

(2) Each solid block of cars, as defined in § 232.5, that is comprised of cars from more than one previous train; and

(3) Each solid block of cars that is comprised of cars from only one previous train but the cars of which have not remained continuously and consecutively coupled together with the train line remaining connected, other than for removing defective equipment, since being removed from its previous train.

(b) A Class II brake test shall consist of the following tasks and requirements:

(1) Brake pipe leakage shall not exceed 5 psi per minute or air flow shall not exceed 60 cubic feet per minute (CFM). The brake pipe leakage test or air flow method test shall be conducted on the entire train pursuant to the requirements contained in § 232.205(b)(1);

(2) The air brake system shall be charged to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, as indicated by an accurate gauge or end-of-train device at the rear end of train;

(3) The brakes on each car added to the train and on the rear car of the train shall be inspected to ensure that they apply in response to a 20-psi brake pipe service reduction and remain applied until the release is initiated from the controlling locomotive. A car found with brakes that fail to apply or remain applied may be retested and remain in the train if the retest is conducted as prescribed in § 232.205(b)(4); otherwise, the defective equipment may only be moved pursuant to the provisions contained in § 232.15, if applicable;

(4) When the release is initiated, the brakes on each car added to the train and on the rear car of the train shall be inspected to verify that they did release; this may be performed by a "roll-by" inspection. If a "roll-by" inspection of the brake release is performed, train speed shall not exceed 10 MPH, and the qualified person performing the "roll-by" inspection shall communicate the results of the inspection to the operator of the train; and

(5) Before the train proceeds the operator of the train shall know that the brake pipe pressure at the rear of the train is being restored.

(c) As an alternative to the rear car brake application and release portion of the test, the operator of the train shall determine that brake pipe pressure of the train is being reduced, as indicated by a rear car gauge or end-of-train telemetry device, and then that the brake pipe pressure of the train is being restored, as indicated by a rear car gauge or end-of-train telemetry device. (When an end-of-train telemetry device is used to comply with any test requirement in this part, the phrase "brake pipe pressure of the train is being reduced" means a pressure reduction of at least 5 psi, and the phrase "brake pipe pressure of the train is being restored" means a pressure increase of at least 5 psi). If an electronic communication link between a controlling locomotive and a remotely controlled locomotive attached to the rear end of a train is utilized to determine that brake pipe pressure is being restored, the operator of the train shall know that the air brakes function as intended on the remotely controlled locomotive.

(d) Each car or solid block of cars that receives a Class II brake test pursuant to this section when added to the train shall receive a Class I brake test at the next forward location where facilities are available for performing such a test. A Class III brake test as described in § 232.211 shall then be performed on the entire train.

§ 232.211 Class III brake tests-trainline continuity inspection.

(a) A Class III brake test shall be performed on a train by a qualified person, as defined in § 232.5, to test the train brake system when the configuration of the train has changed in certain ways. In particular, a Class III brake test shall be performed at the location where any of the following changes in the configuration of the train occur:

(1) Where a locomotive or a caboose is changed;

(2) Where a car or a block of cars is removed from the train with the consist otherwise remaining intact;

(3) At a point other than the initial terminal for the train, where a car or a solid block of cars that is comprised of cars from only one previous train the cars of which have remained continuously and consecutively coupled together with the trainline remaining connected, other than for removing defective equipment, since being removed from its previous train that has previously received a Class I brake test and that has not been off air for more than four hours is added to a train;

(4) At a point other than the initial terminal for the train, where a car or a solid block of cars that has received a Class I or Class II brake test at that location, prior to being added to the train, and that has not been off air for more than four hours is added to a train; or

(5) Whenever the continuity of the brake pipe is broken or interrupted.

(b) A Class III brake test shall consist of the following tasks and requirements:

(1) The train brake system shall be charged to the pressure at which the train will be operated, and the pressure at the rear of the train shall be within 15 psi of the pressure at which the train will be operated, but not less than 75 psi, or 60 psi for transfer trains, as indicated at the rear of the train by an accurate gauge or end-of-train device;

(2) The brakes on the rear car of the train shall apply in response to a 20-psi brake pipe service reduction and shall remain applied until the release is initiated by the controlling locomotive;

(3) When the release is initiated, the brakes on the rear car of the train shall be inspected to verify that it did release; and

(4) Before proceeding the operator of the train shall know that the brake pipe pressure at the rear of freight train is being restored.

(c) As an alternative to the rear car brake application and release portion of the test, it shall be determined that the brake pipe pressure of the train is being reduced, as indicated by a rear car gauge or end-of-train telemetry device, and then that the brake pipe pressure of the train is being restored, as indicated by a rear car gauge or end-of-train telemetry device. If an electronic or radio communication link between a controlling locomotive and a remotely controlled locomotive attached to the rear end of a train is utilized to determine that brake pipe pressure is being restored, the operator of the train shall know that the air brakes function as intended on the remotely controlled locomotive.

§ 232.213 Extended haul trains.

(a) A railroad may be permitted to move a train up to, but not exceeding, 1,500 miles between brake tests and inspections if the railroad designates a train as an extended haul train. In order for a railroad to designate a train as an extended haul train, all of the following requirements must be met:

(1) The railroad must designate the train in writing to FRA's Associate Administrator for Safety. This designation must include the following:

(i) The train identification symbol or identification of the location where extended haul trains will originate and a description of the trains that will be operated as extended haul trains from those locations;

(ii) The origination and destination points for the train;

(iii) The type or types of equipment the train will haul; and

(iv) The locations where all train brake and mechanical inspections and tests will be performed.

(2) A Class I brake test pursuant to § 232.205 shall be performed at the initial terminal for the train by a qualified mechanical inspector as defined in § 232.5.

(3) A freight car inspection pursuant to part 215 of this chapter shall be performed at the initial terminal for the train and shall be performed by an inspector designated under § 215.11 of this chapter.

(4) All cars having conditions not in compliance with part 215 of this chapter at the initial terminal for the train shall be either repaired or removed from the train. Except for a car developing such a condition en route, no car shall be moved pursuant to the provisions of § 215.9 of this chapter in the train.

(5) The train shall have no more than one pick-up and one set-out en route, except for the set-out of defective equipment pursuant to the requirements of this chapter.

(i) Cars added to the train en route shall be inspected pursuant to the requirements contained in paragraphs (a)(2) through (a)(5) of this section at the location where they are added to the train.

(ii) Cars set out of the train en route shall be inspected pursuant to the requirements contained in paragraph (a)(6) of this section at the location where they are set out of the train.

(6) At the point of destination, if less than 1,500 miles from the train's initial terminal, or at the point designated by the railroad pursuant to paragraph (a)(1)(iv) of this section, not to exceed 1,500 miles, an inbound inspection of the train shall be conducted by a qualified mechanical inspector to identify any defective, inoperative, or ineffective brakes or any other condition not in compliance with this part as well as any conditions not in compliance with part 215 and part 231 of this chapter.

(7) The railroad shall maintain a record of all defective, inoperative, or ineffective brakes as well as any conditions not in compliance with part 215 and part 231 of this chapter discovered at anytime during the movement of the train. These records shall be retained for a period of one year and made available to FRA upon request. The records required by this section may be maintained either electronically or in writing.

(8) In order for an extended haul train to proceed beyond 1,500 miles, the following requirements shall be met:

(i) If the train will move 1,000 miles or less from that location before receiving a Class IA brake test or reaching destination, a Class I brake test shall be conducted pursuant to § 232.205 to ensure 100 percent effective and operative brakes. The inbound inspection required by paragraph (a)(6) of this section may be used to meet this requirement provided it encompasses all the inspection elements contained in § 232.205.

(ii) If the train will move greater than 1,000 miles from that location without another brake inspection, the train must be identified as an extended haul train for that movement and shall meet all the requirements contained in paragraphs (a)(1) through (a)(7) of this section. Such trains shall receive a Class I brake test pursuant to § 232.205 by a qualified mechanical inspector to ensure 100 percent effective and operative brakes, a freight car inspection pursuant to part 215 of this chapter by an inspector designated under § 215.11 of this chapter, and all cars containing non-complying conditions under part 215 of this chapter shall either be repaired or removed from the train. The inbound inspection required by paragraph (a)(6) of this section may be used to meet these inspection requirements provided it encompasses all the inspection elements contained paragraphs (a)(2) through (a)(4) of this section.

(9) FRA inspectors shall have physical access to visually observe all brake and freight car inspections and tests required by this section.

(b) Failure to comply with any of the requirements contained in paragraph (a) of this section will be considered an improper movement of a designated priority train for which appropriate civil penalties may be assessed as outlined in Appendix A to this part. Furthermore, FRA's Associate Administrator for Safety may revoke a railroad's ability to designate any or all trains as extended haul trains for repeated or willful noncompliance with any of the requirements contained in this section. Such a determination will be made in writing and will state the basis for such action.

§ 232.215 Transfer train brake tests.

(a) A transfer train, as defined in § 232.5, shall receive a brake test performed by a qualified person, as defined in § 232.5, that includes the following:

(1) The air brake hoses shall be coupled between all freight cars;

(2) After the brake system is charged to not less than 60 psi as indicated by an accurate gauge or end-of-train device at the rear of the train, a 15-psi service brake pipe reduction shall be made; and

(3) An inspection shall be made to determine that the brakes on each car apply and remain applied until the release is initiated by the controlling locomotive. A car found with brakes that fail to apply or remain applied may be retested and remain in the train if the retest is conducted as prescribed in § 232.205(b)(4); otherwise, the defective equipment may only be moved pursuant to the provisions contained in § 232.15, if applicable.

(b) Cars added to transfer trains en route shall be inspected pursuant to the requirements contained in paragraph (a) of this section at the location where the cars are added to the train.

(c) If a train's movement will exceed 20 miles or is not a transfer train as defined in § 232.5, the train shall receive a Class I brake test in accordance with § 232.205 prior to departure.

§ 232.217 Train brake tests conducted using yard air.

(a) When a train air brake system is tested from a yard air source, an engineer's brake valve or a suitable test device shall be used to provide any increase or reduction of brake pipe air pressure at the same, or slower, rate as an engineer's brake valve.

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(b) The yard air test device must be connected to the end of the train or block of cars that will be nearest to the controlling locomotive. However, if the railroad adopts and complies with written procedures to ensure that potential overcharge conditions to the train brake system are avoided, the yard air test device may be connected to other than the end nearest to the controlling locomotive.

(c) Except as provided in this section, when a yard air is used the train air brake system must be charged and tested as prescribed by § 232.205(b) and when practicable should be kept charged until road motive power is coupled to train, after which, a Class III brake test shall be performed as prescribed by § 232.211.

(1) If the cars are off air for more than four hours, these cars shall be retested in accordance with § 232.205(b) through (e).

(2) At a minimum, yard air pressure shall be 60 psi at the end of the consist or block of cars opposite from the yard test device and shall be within 15 psi of the regulator valve setting on yard test device.

(3) If the air pressure of the yard test device is less than the pressure at which the train will be operated, then a leakage or air flow test shall be conducted at the operating pressure of the train when the locomotives are attached in accordance with § 232.205(b)(1).

(d) Mechanical yard air test devices and gauges shall be calibrated every 92 days. Electronic yard test devices and gauges shall be calibrated annually. Mechanical and electronic yard air test devices and gauges shall be calibrated so that they are accurate to within ± 3 psi.

(e) If used to test a train, a yard air test device and any yard air test equipment shall be accurate and function as intended.

§ 232.219 Double heading and helper service.

(a) When more than one locomotive is attached to a train, the engineer of the controlling locomotive shall operate the brakes. In case it becomes necessary for the controlling locomotive to give up control of the train short of the destination of the train, a Class III brake test pursuant to § 232.211 shall be made to ensure that the brakes are operative from the automatic brake valve of the locomotive taking control of the train.

(b) When one or more helper locomotives are placed in a train, a visual inspection shall be made of each helper locomotive brake system to determine that the brake system operates as intended in response to a 20-psi reduction initiated from the controlling locomotive of the train. A helper locomotive with inoperative or ineffective brakes shall be repaired prior to use or removed from the train.

(c) If a helper locomotive utilizes a Helper Link device or a similar technology, the locomotive and device shall be equipped, designed, and maintained as follows:

(1) The locomotive engineer shall be notified by a distinctive alarm of any loss of communication between the device and the two-way end-of-train device of more than 25 seconds;

(2) A method to reset the device shall be provided in the cab of the helper locomotive that can be operated from the engineer's usual position during operation of the locomotive;

(3) The device shall be tested for accuracy and calibrated if necessary according to the manufacturer's specifications and procedures every 365 days. This shall include testing radio frequencies and modulation of the device. A legible record of the date and location of the last test or calibration shall be maintained with the device.

Subpart D—Periodic Maintenance and Testing Requirements

§ 232.301 Scope.

This subpart contains the periodic brake system maintenance and testing requirements for equipment used in freight and other non-passenger trains.

§ 232.303 General requirements.

(a) *Definitions.* The following definitions are intended solely for the purpose of identifying what constitutes a shop or repair track under this subpart.

(1) *Shop or repair track* means:

(i) A fixed repair facility or track designated by the railroad as a shop or repair track;

(ii) A fixed repair facility or track which is regularly and consistently used to perform major repairs;

(iii) track which is used at a location to regularly and consistently perform both minor and major repairs where the railroad has not designated a certain portion of that trackage as a repair track;

(iv) A track designated or used by a railroad to regularly and consistently perform minor repairs during the period when major repairs are being conducted on such a track; and

(v) The facilities and tracks identified in paragraphs (a)(1)(i) through (a)(1)(iv) shall be considered shop or repair tracks regardless of whether a mobile repair vehicle is used to conduct the repairs.

(2) *Major repair* means a repair of such a nature that it would normally require greater than four man-hours to accomplish or would involve the use of specialized tools and equipment. Major repairs would include such things as coupler replacement, draft gear repair, and repairs requiring the use of an air jack.

(3) *Minor repair* means repairs, other than major repairs, that can be accomplished in a short period of time with limited tools and equipment. Minor repairs would include such things as safety appliance straightening, handhold replacement, air hose replacement, lading adjustment, and coupler knuckle or knuckle pin replacement.

(b) A car on a shop or repair track shall be tested to determine that the air brakes apply and remain applied until a release is initiated.

(c) A car on a shop or repair track shall have its piston travel inspected. For cars equipped with 8½-inch or 10-inch diameter brake cylinders, piston travel shall be within 7 to 9 inches. If piston travel is found to be less than 7 inches or more than 9 inches, it must be adjusted to nominally 7½ inches. For cars not equipped with 8½-inch or 10-inch diameter brake cylinders, piston travel shall be within the piston travel stenciled or marked on the car or badge plate.

(d) Before a car is released from a shop or repair track, a qualified person shall ensure:

(1) The brake pipe is securely clamped;

(2) Angle cocks are properly located with suitable clearance and properly positioned to allow maximum air flow;

(3) Valves, reservoirs, and cylinders are tight on supports and the supports are securely attached to the car;

(4) Hand brakes are tested, inspected, and operate as intended; and

(5) Brake indicators, on cars so equipped, are accurate and operate as intended.

(e) If the repair track air brake test or single car test required in §§ 232.305 and 232.307 cannot be conducted at the point where repairs can be made to the car, the car may be moved after the repairs are effectuated to the next forward location where the test can be performed. Inability to perform a repair track air brake test or single car test does not constitute an inability to effectuate the necessary repairs.

(1) If it is necessary to move a car from the location where the repairs are performed in order to perform a repair track air brake test or a single car test required by this part, a tag or card shall be placed on both sides of the equipment, or an automated tracking system approved for use by FRA, with the following information about the equipment:

(i) The reporting mark and car number;

(ii) The name of the inspecting railroad;

(iii) The location where repairs were performed and date;

(iv) Indication whether the car requires a repair track brake test or single car test;

(v) The location where the appropriate test is to be performed; and

(vi) The name, signature, if possible, and job title of the qualified person approving the move.

(2) The tag or card required by paragraph (e)(1) of this section shall remain affixed to the equipment until the necessary test has been performed.

(3) An electronic or written record or copy of each tag or card attached to or removed from a car or locomotive shall be retained for 90 days and, upon request, shall be made available within 15 calendar days for inspection by FRA or State inspectors.

(4) The record or copy of each tag or card removed from a car or locomotive shall contain the date, location, and the signature or identification of the qualified person removing it from the piece of equipment.

(f) The location and date of the last repair track brake test or single car test required by §§ 232.305 and 232.307 of this part shall be clearly stenciled, marked, or labeled in two-inch high letters or numerals on the side of the equipment. Alternatively, the railroad industry may use an electronic or automated tracking system to track the required information and the performance of the tests required by §§ 232.305 and 232.307 of this part.

(1) Electronic or automated tracking systems used to meet the requirement contained in this paragraph shall be capable of being reviewed and monitored by FRA at any time to ensure the integrity of the system. FRA's Associate Administrator for Safety may prohibit or revoke the railroad industry's authority to utilize an electronic or automated tracking system in lieu of stenciling or marking if FRA finds that the electronic or automated tracking system is not properly secure, is inaccessible to FRA or railroad employees, or fails to adequately track and monitor the equipment. FRA will record such a determination in writing, include a statement of the basis for such action, and will provide a copy of the document to the affected railroads.

(2) [Reserved.]

§ 232.305 Repair track air brake tests.

(a) Repair track brake tests shall be performed by a qualified person in accordance with either Section 3.0, "Procedures for Repair Track Test for Air Brake Equipment," of the Association of American Railroads Standard S–486–99, "Code of Air Brake System Tests for Freight Equipment," contained in the AAR *Manual of Standards and Recommended Practices, Section E* (April 1, 1999) or an alternative procedure approved by FRA pursuant to § 232.17. The incorporation by reference of this AAR standard was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the incorporated document from the Association of American Railroads, 50 F Street, NW., Washington, DC 20001. You may inspect a copy of the document at the Federal Railroad Administration, Docket Clerk, 1120 Vermont Avenue, NW., Suite 7000, Washington, DC or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

(b) Except as provided in § 232.303(e), a railroad shall perform a repair track brake test on a car when:

(1) A car has its brakes cut-out or inoperative when removed from a train or when placed on a shop or repair track;

(2) A car is on a repair or shop track, as defined in § 232.303(a), for any reason and has not received a repair track brake test within the previous 12 month period;

(3) A car is found with missing or incomplete repair track brake test information;

(4) One or more of the following conventional air brake equipment items is removed, repaired, or replaced:

(i) Brake reservoir;

(ii) Control valve mounting gasket; or

(iii) Pipe bracket stud.

(5) A car is found with one or more of the following wheel defects:

(i) Built-up tread, unless known to be caused by hand brake left applied;

(ii) Slid flat wheel, unless known to be caused by hand brake left applied; or

(iii) Thermal cracks.

(c) Except as provided in paragraph (d) of this section, each car shall receive a repair track brake test no less than every 5 years.

(d) Each car shall receive a repair track brake test no less than 8 years from the date the car was built or rebuilt.

§ 232.307 Single car tests.

(a) Single car tests shall be performed by a qualified person in accordance with either Section 4.0, "Tests-Standard Single Capacity Freight Brake Equipment (Single Car Test)," of the Association of American Railroads Standard S–486–99, "Code of Air Brake System Tests for Freight Equipment," contained in the AAR *Manual of Standards and Recommended Practices, Section E* (April 1, 1999) or an alternative procedure approved by FRA pursuant to § 232.17. The incorporation by reference of this AAR standard was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the incorporated document from the Association of American Railroads, 50 F Street, NW., Washington, DC 20001. You may inspect a copy of the document at the Federal Railroad Administration, Docket Clerk, 1120 Vermont Avenue, NW., Suite 7000, Washington, DC or at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

(b) Except as provided in § 232.303(e), a railroad shall perform a single car test on a car when one or more of the following conventional air brake equipment items is removed, repaired or replaced:

(1) Service portion;

(2) Emergency portion; or

(3) Pipe bracket.

(c) A single car test pursuant to paragraph (a) of this section shall be performed on a new or rebuilt car prior to placing or using the car in revenue service.

§ 232.309 Repair track air brake test and single car test equipment and devices.

(a) Test equipment and devices used to perform repair track air brake tests or single car tests shall be tested for correct operation at least once each calendar day of use.

(b) Except for single car test devices, mechanical test devices such as pressure gauges, flow meters, orifices, etc. shall be calibrated once every 92 days.

(c) Electronic test devices shall be calibrated at least once every 365 days.

(d) Test equipment and single car test devices placed in service shall be tagged or labeled with the date its next calibration is due.

(e) Each single car test device shall be tested not less frequently than every 92 days after being placed in service and may not continue in service if more than one year has passed since its last 92-day test.

(f) Each single car test device shall be disassembled and cleaned not less frequently than every 365 days after being placed in service.

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Subpart E—End-of-Train Devices

§ 232.401 Scope.

This subpart contains the requirements related to the performance, operation, and testing of end-of-train devices. Unless expressly excepted in this subpart, the requirements of this subpart apply to all trains operating on track which is part of the general railroad system of transportation.

§ 232.403 Design standards for one-way end-of-train devices.

(a) *General.* A one-way end-of-train device shall be comprised of a rear-of-train unit (rear unit) located on the last car of a train and a front-of-train unit (front unit) located in the cab of the locomotive controlling the train.

(b) *Rear unit.* The rear unit shall be capable of determining the brake pipe pressure on the rear car and transmitting that information to the front unit for display to the locomotive engineer. The rear unit shall be—

(1) Capable of measuring the brake pipe pressure on the rear car with an accuracy of ±3 pounds per square inch (psig) and brake pipe pressure variations of ±1 psig;

(2) Equipped with a "bleeder valve" that permits the release of any air under pressure from the rear of train unit or the associated air hoses prior to detaching the rear unit from the brake pipe;

(3) Designed so that an internal failure will not cause an undesired emergency brake application;

(4) Equipped with either an air gauge or a means of visually displaying the rear unit's brake pipe pressure measurement; and

(5) Equipped with a pressure relief safety valve to prevent explosion from a high pressure air leak inside the rear unit.

(c) *Reporting rate.* Multiple data transmissions from the rear unit shall occur immediately after a variation in the rear car brake pipe pressure of ±2 psig and at intervals of not greater than 70 seconds when the variation in the rear car brake pipe pressure over the 70-second interval is less than ±2 psig.

(d) *Operating environment.* The rear unit shall be designed to meet the performance requirements of paragraphs (b) and (c) of this section under the following environmental conditions:

(1) At temperatures from −40°C to 60°C;

(2) At a relative humidity of 95% noncondensing at 50°C;

(3) At altitudes of zero to 12,000 feet mean sea level;

(4) During vertical and lateral vibrations of 1 to 15 Hz., with 0.5 g. peak to peak, and 15 to 500 Hz., with 5 g. peak to peak;

(5) During the longitudinal vibrations of 1 to 15 Hz., with 3 g. peak to peak, and 15 to 500 Hz., with 5 g. peak to peak; and

(6) During a shock of 10 g. peak for 0.1 second in any axis.

(e) *Unique code.* Each rear unit shall have a unique and permanent identification code that is transmitted along with the pressure message to the front-of-train unit. A code obtained from the Association of American Railroads, 50 F Street, NW., Washington, DC 20036 shall be deemed to be a unique code for purposes of this section. A unique code also may be obtained from the Office of Safety Assurance and Compliance (RRS–10), Federal Railroad Administration, Washington, DC 20590.

(f) *Front unit.* (1) The front unit shall be designed to receive data messages from the rear unit and shall be capable of displaying the rear car brake pipe pressure in increments not to exceed one pound.

(2) The display shall be clearly visible and legible in daylight and darkness from the engineer's normal operating position.

(3) The front device shall have a means for entry of the unique identification code of the rear unit being used. The front unit shall be designed so that it will display a message only from the rear unit with the same code as entered into the front unit.

(4) The front unit shall be designed to meet the requirements of paragraphs (d)(2), (3), (4), and (5) of this section. It shall also be designed to meet the performance requirements in this paragraph under the following environmental conditions:

(i) At temperatures from 0°C to 60°C;

(ii) During a vertical or lateral shock of 2 g. peak for 0.1 second; and

(iii) During a longitudinal shock of 5 g. peak for 0.1 second.

(g) *Radio equipment.* (1) The radio transmitter in the rear unit and the radio receiver in the front unit shall comply with the applicable regulatory requirements of the Federal Communications Commission (FCC) and use of a transmission format acceptable to the FCC.

(2) If power is supplied by one or more batteries, the operating life shall be a minimum of 36 hours at 0°C.

§ 232.405 Design and performance standards for two-way end-of-train devices.

Two-way end-of-train devices shall be designed and perform with the features applicable to one-way end-of-train devices described in § 232.403, except those included in § 232.403(b)(3). In addition, a two-way end-of-train device shall be designed and perform with the following features:

(a) An emergency brake application command from the front unit of the device shall activate the emergency air valve at the rear of the train within one second.

(b) The rear unit of the device shall send an acknowledgment message to the front unit immediately upon receipt of an emergency brake application command. The front unit shall listen for this acknowledgment and repeat the brake application command if the acknowledgment is not correctly received.

(c) The rear unit, on receipt of a properly coded command, shall open a valve in the brake line and hold it open for a minimum of 15 seconds. This opening of the valve shall cause the brake line to vent to the exterior.

(d) The valve opening shall have a minimum diameter of ¾ inch and the internal diameter of the hose shall be ⅝ inch to effect an emergency brake application.

(e) The front unit shall have a manually operated switch which, when activated, shall initiate an emergency brake transmission command to the rear unit or the locomotive shall be equipped with a manually operated switch on the engineer control stand designed to perform the equivalent function. The switch shall be labeled "Emergency" and shall be protected so that there will exist no possibility of accidental activation.

(f) All locomotives ordered on or after August 1, 2001, or placed in service for the first time on or after August 1, 2003, shall be designed to automatically activate the two-way end-of-train device to effectuate an emergency brake application whenever it becomes necessary for the locomotive engineer to place the train air brakes in emergency.

(g) The availability of the front-to-rear communications link shall be checked automatically at least every 10 minutes.

(h) Means shall be provided to confirm the availability and proper functioning of the emergency valve.

(i) Means shall be provided to arm the front and rear units to ensure the rear unit responds to an emergency command only from a properly associated front unit.

§ 232.407 Operations requiring use of two-way end-of-train devices; prohibition on purchase of nonconforming devices.

(a) *Definitions.* The following definitions are intended solely for the purpose of identifying those operations subject to the requirements for the use of two-way end-of-train devices.

(1) *Heavy grade* means:

(i) For a train operating with 4,000 trailing tons or less, a section of track with an average grade of two percent or greater over a distance of two continuous miles; and

(ii) For a train operating with greater than 4,000 trailing tons, a section of track with an average grade of one percent or greater over a distance of three continuous miles.

(2) *Train* means one or more locomotives coupled with one or more rail cars, except during switching operations or where the operation is that of classifying cars within a railroad yard for the purpose of making or breaking up trains.

(3) *Local train* means a train assigned to perform switching en route which operates with 4,000 trailing tons or less and travels between a point of origin and a point of final destination, for a distance that is no greater than that which can normally be operated by a single crew in a single tour of duty.

(4) *Work train* means a non-revenue service train of 4,000 trailing tons or less used for the administration and upkeep service of the railroad.

(5) *Trailing tons* means the sum of the gross weights—expressed in tons—of the cars and the locomotives in a train that are not providing propelling power to the train.

(b) *General.* All trains not specifically excepted in paragraph (e) of this section shall be equipped with and shall use either a two-way end-of-train device meeting the design and performance requirements contained in § 232.405 or a device using an alternative technology to perform the same function.

(c) *New devices.* Each newly manufactured end-of-train device purchased by a railroad after January 2, 1998 shall be a two-way end-of-train device meeting the design and performance requirements contained in § 232.405 or a device using an alternative technology to perform the same function.

(d) *Grandfathering.* Each two-way end-of-train device purchased by any person prior to July 1, 1997 shall be deemed to meet the design and performance requirements contained in § 232.405.

(e) *Exceptions.* The following types of trains are excepted from the requirement for the use of a two-way end-of-train device:

(1) Trains with a locomotive or locomotive consist located at the rear of the train that is capable of making an emergency brake application, through a command effected by telemetry or by a crew member in radio contact with the controlling locomotive;

(2) Trains operating in the push mode with the ability to effectuate an emergency brake application from the rear of the train;

(3) Trains with an operational caboose placed at the rear of the train, carrying one or more crew members in radio contact with the controlling locomotive, that is equipped with an emergency brake valve;

(4) Trains operating with a secondary, fully independent braking system capable of safely stopping the train in the event of failure of the primary system;

(5) Trains that do not operate over heavy grades and do not exceed 30 mph;

(6) Local trains, as defined in paragraph (a)(3) of this section, that do not operate over heavy grades;

(7) Work trains, as defined in paragraph (a)(4) of this section, that do not operate over heavy grades;

(8) Trains that operate exclusively on track that is not part of the general railroad system;

(9) Trains that must be divided into two sections in order to traverse a grade (*e.g.*, doubling a hill). This exception applies only to the extent necessary to traverse the grade and only while the train is divided in two for such purpose;

(10) Passenger trains in which all of the cars in the train are equipped with an emergency brake valve readily accessible to a crew member;

(11) Passenger trains that have a car at the rear of the train, readily accessible to one or more crew members in radio contact with the engineer, that is equipped with an emergency brake valve readily accessible to such a crew member; and

(12) Passenger trains that have twenty-four (24) or fewer cars (not including locomotives) in the consist and that are equipped and operated in accordance with the following train-configuration and operating requirements:

(i) If the total number of cars in a passenger train consist is twelve (12) or fewer, a car located no less than halfway through the consist (counting from the first car in the train) must be equipped with an emergency brake valve readily accessible to a crew member;

(ii) If the total number of cars in a passenger train consist is thirteen (13) to twenty-four (24), a car located no less than two-thirds (⅔) of the way through the consist (counting from the first car in the train) must be equipped with an emergency brake valve readily accessible to a crew member;

(iii) Prior to descending a section of track with an average grade of two percent or greater over a distance of two continuous miles, the engineer of the train shall communicate with the conductor, to ensure that a member of the crew with a working two-way radio is stationed in the car with the rearmost readily accessible emergency brake valve on the train when the train begins its descent; and

(iv) While the train is descending a section of track with an average grade of two percent or greater over a distance of two continuous miles, a member of the train crew shall occupy the car that contains the rearmost readily accessible emergency brake valve on the train and be in constant radio communication with the locomotive engineer. The crew member shall remain in this car until the train has completely traversed the heavy grade.

(f) *Specific requirements for use.* If a train is required to use a two-way end-of-train device:

(1) That device shall be armed and operable from the time the train departs from the point where the device is installed until the train reaches its destination. If a loss of communication occurs at the location where the device is installed, the train may depart the location at restricted speed for a distance of no more than one mile in order to establish communication. When communication is established, the quantitative values of the head and rear unit shall be compared pursuant to § 232.409(b) and the device tested pursuant to § 232.409(c), unless the test was performed prior to installation.

(2) The rear unit batteries shall be sufficiently charged at the initial terminal or other point where the device is installed and throughout the train's trip to ensure that the end-of-train device will remain operative until the train reaches its destination.

(3) The device shall be activated to effectuate an emergency brake application either by using the manual toggle switch or through automatic activation, whenever it becomes necessary for the locomotive engineer to initiate an emergency application of the air brakes using either the automatic brake valve or the conductor's emergency brake valve.

(g) *En route failure of device on a freight or other non-passenger train.* Except on passenger trains required to be equipped with a two-way end-of-train device (which are provided for in paragraph (h) of this section), en route failures of a two-way end-of-train device shall be handled in accordance with this paragraph. If a two-way end-of-train device or equivalent device fails en route (*i.e.*, is unable to initiate an emergency brake application from the rear of the train due to certain losses of communication (front to rear) or due to

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other reasons, the speed of the train on which it is installed shall be limited to 30 mph until the ability of the device to initiate an emergency brake application from the rear of the train is restored. This limitation shall apply to a train using a device that uses an alternative technology to serve the purpose of a two-way end-of-train device. With regard to two-way end-of-train devices, a loss of communication between the front and rear units is an en route failure only if the loss of communication is for a period greater than 16 minutes and 30 seconds. Based on the existing design of the devices, the display to an engineer of a message that there is a communication failure indicates that communication has been lost for 16 minutes and 30 seconds or more.

(1) If a two-way end-of-train device fails en route, the train on which it is installed, in addition to observing the 30-mph speed limitation, shall not operate over a section of track with an average grade of two percent or greater for a distance of two continuous miles, unless one of the following alternative measures is provided:

(i) Use of an occupied helper locomotive at the end of the train. This alternative may be used only if the following requirements are met:

(A) The helper locomotive engineer shall initiate and maintain two-way voice radio communication with the engineer on the head end of the train; this contact shall be verified just prior to passing the crest of the grade.

(B) If there is a loss of communication prior to passing the crest of the grade, the helper locomotive engineer and the head-end engineer shall act immediately to stop the train until voice communication is resumed, in accordance with the railroad's operating rules.

(C) If there is a loss of communication once the descent has begun, the helper locomotive engineer and the head-end engineer shall act to stop the train, in accordance with the railroad's operating rules, if the train has reached a predetermined rate of speed that indicates the need for emergency braking.

(D) The brake pipe of the helper locomotive shall be connected and cut into the train line and tested to ensure operation.

(ii) Use of an occupied caboose at the end of the train with a tested, functioning brake valve capable of initiating an emergency brake application from the caboose. This alternative may be used only if the train service employee in the caboose and the engineer on the head end of the train establish and maintain two-way voice radio communication and respond appropriately to the loss of such communication in the same manner as prescribed for helper locomotives in paragraph (g)(1)(i) of this section.

(iii) Use of a radio-controlled locomotive at the rear of the train under continuous control of the engineer in the head end by means of telemetry, but only if such radio-controlled locomotive is capable of initiating an emergency application on command from the lead (controlling) locomotive.

(2) [Reserved.]

(h) *En route failure of device on a passenger train.*

(1) A passenger train required to be equipped with a two-way end-of-train device that develops an en route failure of the device (as explained in paragraph (g) of this section) shall not operate over a section of track with an average grade of two percent or greater over a distance of two continuous miles until an operable two-way end-of-train device is installed on the train or an alternative method of initiating an emergency brake application from the rear of the train is achieved.

(2) Except as provided in paragraph (h)(1) of this section, a passenger train required to be equipped with a two-way end-of-train device that develops an en route failure of the device (as explained in paragraph (g) of this section) shall be operated in accordance with the following:

(i) A member of the train crew shall be immediately positioned in the car which contains the rearmost readily accessible emergency brake valve on the train and shall be equipped with an operable two-way radio that communicates with the locomotive engineer; and

(ii) The locomotive engineer shall periodically make running tests of the train's air brakes until the failure is corrected; and

(3) Each en route failure shall be corrected at the next location where the necessary repairs can be conducted or at the next location where a required brake test is to be performed, whichever is reached first.

§ 232.409 Inspection and testing of end-of-train devices.

(a) After each installation of either the front or rear unit of an end-of-train device, or both, on a train and before the train departs, the railroad shall determine that the identification code entered into the front unit is identical to the unique identification code on the rear unit.

(b) After each installation of either the front or rear unit of an end-of-train device, or both, on a train and before the train departs, the functional capability of the device shall be determined, after charging the train, by comparing the quantitative value of the air pressure displayed on the front unit with the quantitative value of the air pressure displayed on the rear unit or on a properly calibrated air gauge. The end-of-train device shall not be used if the difference between the two readings exceeds three pounds per square inch.

(c) A two-way end-of-train device shall be tested at the initial terminal or other point of installation to ensure that the device is capable of initiating an emergency power brake application from the rear of the train. If this test is conducted by a person other than a member of the train crew, the locomotive engineer shall be notified that a successful test was performed. The notification required by this paragraph may be provided to the locomotive engineer by any means determined appropriate by the railroad; however, a written or electronic record of the notification shall be maintained in the cab of the controlling locomotive and shall include the date and time of the test, the location where the test was performed, and the name of person conducting the test.

(d) The telemetry equipment shall be tested for accuracy and calibrated if necessary according to the manufacturer's specifications and procedures at least every 365 days. This shall include testing radio frequencies and modulation of the device. The date and location of the last calibration or test as well as the name of the person performing the calibration or test shall be legibly displayed on a weather-resistant sticker or other marking device affixed to the outside of both the front unit and the rear unit; however, if the front unit is an integral part of the locomotive or is inaccessible, then the information may be recorded on Form FRA F6180–49A instead, provided the serial number of the unit is recorded.

Subpart F—Introduction of New Brake System Technology

§ 232.501 Scope.

This subpart contains general requirements for introducing new brake system technologies. This subpart is intended to facilitate the introduction of new complete brake system technologies or major upgrades to existing systems which the current regulations do not adequately address (*i.e.*, electronic brake systems). This subpart is not intended for use in the introduction of a new brake component or material.

§ 232.503 Process to introduce new brake system technology.

(a) Pursuant to the procedures contained in § 232.17, each railroad shall obtain special approval from the FRA Associate Administrator for Safety of a pre-revenue service acceptance testing plan, developed pursuant to § 232.505, for the new brake system technology, prior to implementing the plan.

(b) Each railroad shall complete a pre-revenue service demonstration of the new brake system technology in accordance with the approved plan, shall fulfill all of the other requirements prescribed in § 232.505, and shall obtain special approval from the FRA Associate Administrator for Safety under the procedures of § 232.17 prior to using such brake system technology in revenue service.

§ 232.505 Pre-revenue service acceptance testing plan.

(a) *General; submission of plan.* Except as provided in paragraph (f) of this section, before using a new brake system technology for the first time on its system the operating railroad or railroads shall submit a pre-revenue service acceptance testing plan containing the information required by paragraph (e) of this section and obtain the approval of the FRA Associate Administrator for Safety, under the procedures specified in § 232.17.

(b) *Compliance with plan.* After receiving FRA approval of the pre-revenue service testing plan and before introducing the new brake system technology into revenue service, the operating railroad or railroads shall:

(1) Adopt and comply with such FRA-approved plan, including fully executing the tests required by the plan;

(2) Report to the FRA Associate Administrator for Safety the results of the pre-revenue service acceptance tests;

(3) Correct any safety deficiencies identified by FRA in the design of the equipment or in the inspection, testing, and maintenance procedures or, if safety deficiencies cannot be corrected by design or procedural changes, agree to comply with any operational limitations that may be imposed by the Associate Administrator for Safety on the revenue service operation of the equipment; and

(4) Obtain FRA approval to place the new brake system technology in revenue service.

(c) *Compliance with limitations.* The operating railroad shall comply with each operational limitation, if any, imposed by the Associate Administrator for Safety.

(d) *Availability of plan.* The plan shall be made available to FRA for inspection and copying upon request.

(e) *Elements of plan.* The plan shall include all of the following elements:

(1) An identification of each waiver, if any, of FRA or other Federal safety regulations required for the tests or for revenue service operation of the equipment.

(2) A clear statement of the test objectives. One of the principal test objectives shall be to demonstrate that the equipment meets the safety design and performance requirements specified in this part when operated in the environment in which it is to be used.

(3) A planned schedule for conducting the tests.

(4) A description of the railroad property or facilities to be used to conduct the tests.

(5) A detailed description of how the tests are to be conducted. This description shall include:

(i) An identification of the equipment to be tested;

(ii) The method by which the equipment is to be tested;

(iii) The criteria to be used to evaluate the equipment's performance; and

(iv) The means by which the test results are to be reported to FRA.

(6) A description of any special instrumentation to be used during the tests.

(7) A description of the information or data to be obtained.

(8) A description of how the information or data obtained is to be analyzed or used.

(9) A description of any criteria to be used as safety limits during the testing.

(10) A description of the criteria to be used to measure or determine the success or failure of the tests. If acceptance is to be based on extrapolation of less than full level testing results, the analysis to be done to justify the validity of the extrapolation shall be described.

(11) A description of any special safety precautions to be observed during the testing.

(12) A written set of standard operating procedures to be used to ensure that the testing is done safely.

(13) Quality control procedures to ensure that the inspection, testing, and maintenance procedures are followed.

(14) Criteria to be used for the revenue service operation of the equipment.

(15) A description of all testing of the equipment that has previously been performed, if any.

(f) *Exception.* For brake system technologies that have previously been used in revenue service in the United States, the railroad shall test the equipment on its system, prior to placing it in revenue service, to ensure the compatibility of the equipment with the operating system (track, signals, etc.) of the railroad. A description of such testing shall be retained by the railroad and made available to FRA for inspection and copying upon request.

Appendix A to Part 232—Schedule of Civil Penalties [1]

Section	Violation	Willful violation
Subpart A—General		
232.15 Movement of power brake defects:		
(a) Improper movement, general	(1)	(1)
(11) Failure to make determinations and provide notification of en route defect	$2,500	$5,000
(b) Complete failure to tag	2,500	5,000
(1) Insufficient tag or record	1,000	2,000
(2), (4) Improper removal of tag	2,000	4,000
(3) Failure to retain record of tag	2,000	4,000
(c) Improper loading or purging	2,500	5,000
(e) Improper placement of defective equipment	2,500	5,000
232.19 Availability of records	(1)	(1)
Subpart B—General Requirements		
232.103 All train brake systems:		
(a)–(c), (h)–(i) Failure to meet general design requirements	2,500	5,000
(d) Failure to have proper percentage of operative brakes from Class I brake test	5,000	7,500
(e) Operating with less than 85 percent operative brakes	5,000	7,500
(f) Improper use of car with inoperative or ineffective brakes	2,500	5,000
(g) Improper display of piston travel	2,500	5,000

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Section	Violation	Willful violation
(m) Failure to stop train with excess air flow or gradient	2,500	5,000
(n) Securement of unattended equipment:.		
(1) Failure to apply sufficient number of hand brakes; failure to develop or implement procedure to verify number applied	5,000	7,500
(2) Failure to initiate emergency	2,500	5,000
(3) Failure to apply hand brakes on locomotives	2,500	5,000
(4) Failure to adopt or comply with procedures for securing unattended locomotive	5,000	7,500
(o) Improper adjustment of air regulating devices	2,500	5,000
(p) Failure to hold supervisors jointly responsible	2,500	5,000
232.105 Locomotives:		
(a) Air brakes not in safe and suitable condition	1,000-	2,000-
	5,000	7,500
(b) Not equipped with proper hand or parking brake	5,000	7,500
(c)(1) Failure to inspect/repair hand or parking brake	2,500	5,000
(2) Failure to properly stencil, tag, or record	2,000	4,000
(d) Excess leakage from equalizing reservoir	2,500	5,000
(e) Improper use of feed or regulating valve braking	2,500	5,000
(f) Improper use of passenger position	2,500	5,000
(g) Brakes in operative condition	2,500	5,000
232.107 Air sources/cold weather operations:		
(a)(1), (2) Failure to adopt or comply with monitoring program for yard air sources	5,000	7,500
(3) Failure to maintain records	2,500	5,000
(b) Failure to blow condensation	2,500	5,000
(c) Use of improper chemicals	5,000	7,500
(d) Failure to equip or drain yard air reservoirs	2,500	5,000
(e) Failure to adopt or comply cold weather operating procedures	5,000	7,500
232.109 Dynamic brakes:		
(a) Failure to provide information	5,000	7,500
(b) Failure to make repairs	5,000	7,500
(c) Failure to properly tag	2,500	5,000
(d) Failure to maintain record of repair	2,000	4,000
(e) Improper deactivation	2,500	5,000
(f) Improper use of locomotive as controlling unit	2,500	5,000
(g) Locomotive not properly equipped with indicator	2,500	5,000
(h) Rebuilt locomotive not properly equipped	2,500	5,000
(j) Failure to adopt or comply with dynamic brake operating rules	5,000	7,500
(k) Failure to adopt or comply with training on operating procedures	5,000	7,500
232.111 Train handling information:		
(a) Failure to adopt and comply with procedures	5,000	7,500
(b) Failure to provide specific information	2,500	5,000
Subpart C—Inspection and Testing Requirements		
232.203 Training requirements:		
(a) Failure to develop or adopt program	7,500	11,000
(b)(1)–(9) Failure to address or comply with specific required item or provision of program	5,000	7,500
(c) Failure to adopt or comply with two-way EOT program	5,000	7,500
(d) Failure to adopt or comply with retaining valve program	5,000	7,500
(e) Failure to maintain adequate records	5,000	7,500
(f) Failure to adopt and comply with periodic assessment plan	7,500	11,000
232.205 Class I brake test—initial terminal inspection:		
(a) Complete failure to perform inspection	[1] 10,000	15,000
(b)(1)–(4), (6)–(8) Partial failure to perform inspection	5,000	7,500
(b)(5) Failure to properly adjust piston travel (per car)	2,500	5,000
(c) Failure to use carman when required	5,000	7,500
(d) Failure to provide proper notification	2,500	5,000
(e) Failure to void compressed air	2,500	5,000
(f) Failure to perform inspection on cars added	5,000	7,500
232.207 Class IA brake tests—1,000-mile inspection:		
(a) Complete failure to perform inspection	[1] 15,000	7,500
(b)(1)–(6) Partial failure to perform inspection	2,500	5,000
(c) Failure to properly designate location	5,000	7,500
(c)(1) Failure to perform at designated location	5,000	7,500
(c)(2) Failure to provide notification	2,500	5,000
232.209 Class II brake tests—intermediate inspection:		
(a) Complete failure to perform inspection	[1] 5,000	7,500
(b)(1)–(5), (c) Partial failure to perform inspection	2,500	5,000
232.211 Class III brake tests—trainline continuity inspection:		
(a) Complete failure to perform inspection	5,000	7,500
(b)(1)–(4), (c) Partial failure to perform inspection	2,500	5,000
232.213 Extended haul trains:		
(a)(1) Failure to properly designate an extended haul train	5,000	7,500
(a)(2)–(3), (5)(i), (8) Failure to perform inspections	[2]	[2]
(a)(4) Failure to remove defective car (per car)	2,000	4,000
(a)(5)(ii), (6) Failure to conduct inbound inspection	5,000	7,500
(a)(7) Failure to maintain record of defects (per car)	2,000	4,000

Section	Violation	Willful violation
232.215 Transfer train brake tests:		
(a) Failure to perform inspection	5,000	7,500
(b) Failure to perform on cars added	2,500	5,000
232.217 Train brake system tests conducted using yard air:		
(a) Failure to use suitable device	2,500	5,000
(b) Improper connection of air test device	5,000	7,500
(c) Failure to properly perform inspection	[2]	[2]
(d) Failure to calibrate test device	2,500	5,000
(e) Failure to use accurate device	2,500	5,000
232.219 Double heading and helper service:		
(a) Failure to perform inspection or inability to control brakes	2,500	5,000
(b) Failure to make visual inspection	2,500	5,000
(c) Use of improper helper link device	2,500	5,000
Subpart D—Periodic Maintenance and Testing Requirements		
232.303 General requirements:		
(b)–(d) Failure to conduct inspection or test when car on repair track	2,500	5,000
(e) Improper movement of equipment for testing	2,500	5,000
(e)(1) Failure to properly tag equipment for movement	2,000	5,000
(e)(2)–(4) Failure to retain record or improper removal of tag or card	2,000	4,000
(f) Failure to stencil or track test information	2,500	5,000
232.305 Repair track air brake tests:		
(a) Failure to test in accord with required procedure	2,500	5,000
(b)–(d) Failure to perform test	2,500	5,000
232.307 Single car tests:		
(a) Failure to test in accord with required procedure	2,500	5,000
(b)–(c) Failure to perform test	2,500	5,000
232.309 Repair track air brake test and single car test equipment and devices:		
(a)–(f) Failure to properly test or calibrate	2,500	5,000
Subpart E—End-of-Train Devices		
232.403 Design standards for one-way devices:		
(a)–(g) Failure to meet standards	2,500	5,000
232.405 Design standards for two-way devices:		
(a)–(i) Failure to meet standards	2,500	5,000
232.407 Operating requirements for two-way devices:		
(b) Failure to equip a train	5,000	7,500
(c) Improper purchase	2,500	5,000
(f)(1) Failure of device to be armed and operable	5,000	7,500
(f)(2) Insufficient battery charge	2,500	5,000
(f)(3) Failure to activate the device	2,500	5,000
(g) Improper handling of en route failure, freight or other non-passenger	5,000	7,500
(h) Improper handling of en route failure, passenger	5,000	7,500
232.409 Inspection and testing of devices:		
(a) Failure to have unique code	2,500	5,000
(b) Failure to compare quantitative values	2,500	5,000
(c) Failure to test emergency capability	5,000	7,500
(d) Failure to properly calibrate	2,500	5,000
Subpart F—Introduction of New Brake System Technology		
232.503 Process to introduce new technology:		
(b) Failure to obtain FRA approval	10,000	15,000
232.505 Pre-revenue service acceptance testing plan:		
(a) Failure to obtain FRA approval	5,000	7,500
(b) Failure to comply with plan	2,500	5,000
(f) Failure to test previously used technology	5,000	7,500

[1] A penalty may be assessed against an individual only for a willful violation. Generally when two or more violations of these regulations are discovered with respect to a single unit of equipment that is placed or continued in service by a railroad, the appropriate penalties set forth above are aggregated up to a maximum of $11,000 per day. An exception to this rule is the $15,000 penalty for willful violation of § 232.503 (failure to get FRA approval before introducing new technology) with respect to a single unit of equipment; if the unit has additional violative conditions, the penalty may routinely be aggregated to $15,000. Although the penalties listed for failure to perform the brake inspections and tests under § 232.205 through § 232.209 may be assessed for each train that is not properly inspected, failure to perform any of the inspections and tests required under those sections will be treated as a violation separate and distinct from, and in addition to, any substantive violative conditions found on the equipment contained in the train consist. Moreover, the Administrator reserves the right to assess a penalty of up to $22,000 for any violation where circumstances warrant. *See* 49 CFR part 209, appendix A.

Failure to observe any condition for movement of defective equipment set forth in § 232.15(a) will deprive the railroad of the benefit of the movement-for-repair provision and make the railroad and any responsible individuals liable for penalty under the particular regulatory section(s) concerning the substantive defect(s) present on the equipment at the time of movement.

Failure to provide any of the records or plans required by this part pursuant to § 232.19 will be considered a failure to maintain or develop the record or plan and will make the railroad liable for penalty under the particular regulatory section(s) concerning the retention or creation of the document involved.

Failure to properly perform any of the inspections specifically referenced in § 232.213 and § 232.217 may be assessed under each section of this part or this chapter, or both, that contains the requirements for performing the referenced inspection.

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Appendix B to Part 232—Part 232 Prior to April 1, 2001

PART 232—RAILROAD POWER BRAKES AND DRAWBARS

Sec.
232.0 Applicability and penalties.
232.1 Power brakes; minimum percentage.
232.2 Drawbars; standard height.
232.3 Power brakes and appliances for operating power-brake systems.
232.10 General rules; locomotives.
232.11 Train air brake system tests.
232.12 Initial terminal road train airbrake tests.
232.13 Road train and intermediate terminal train air brake tests.
232.14 Inbound brake equipment inspection.
232.15 Double heading and helper service.
232.16 Running tests.
232.17 Freight and passenger train car brakes.
232.19 End of train device.
232 App A Appendix A to Part 232
232 App B Appendix B to Part 232

Authority: 45 U.S.C. 1, 3, 5, 6, 8–12, and 16, as amended; 45 U.S.C. 431, 438, as amended; 49 app. U.S.C. 1655(e), as amended; Pub. L. 100–342; and 49 CFR 1.49(c), (g), and (m).

§ 232.0 Applicability and penalties.

(a) Except as provided in paragraph (b), this part applies to all standard gage railroads.

(b) This part does not apply to:

(1) A railroad that operates only on track inside an installation which is not part of the general railroad system of transportation; or

(2) Rapid transit operations in an urban area that are not connected with the general railroad system of transportation.

(c) As used in this part, carrier means "railroad," as that term is defined below.

(d) Railroad means all forms of non-highway ground transportation that run on rails or electromagnetic guideways, including (1) commuter or other short-haul rail passenger service in a metropolitan or suburban area, and (2) high speed ground transportation systems that connect metropolitan areas, without regard to whether they use new technologies not associated with traditional railroads. Such term does not include rapid transit operations within an urban area that are not connected to the general railroad system of transportation.

(e) Any person (including a railroad and any manager, supervisor, official, or other employee or agent of a railroad) who violates any requirement of this part or causes the violation of any such requirement is subject to a civil penalty of at least $250 and not more than $10,000 per violation, except that: Penalties may be assessed against individuals only for willful violations, and, where a grossly negligent violation or a pattern of repeated violations has created an imminent hazard of death or injury to persons, or has caused death or injury, a penalty not to exceed $20,000 per violation may be assessed. Each day a violation continues shall constitute a separate offense.

§ 232.1 Power brakes; minimum percentage.

On and after September 1, 1910, on all railroads used in interstate commerce, whenever, as required by the Safety Appliance Act as amended March 2, 1903, any train is operated with power or train brakes, not less than 85 percent of the cars of such train shall have their brakes used and operated by the engineer of the locomotive drawing such train, and all power-brake cars in every such train which are associated together with the 85 percent shall have their brakes so used and operated.

§ 232.2 Drawbars; standard Height.

Not included in this Appendix. Moved to 49 CFR part 231.

§ 232.3 Power brakes and appliances for operating power-brake systems.

(a) The specifications and requirement for power brakes and appliances for operating power-brake systems for freight service set forth in the appendix to the report on further hearing, of May 30, 1945, are hereby adopted and prescribed. (See appendix to this part for order in Docket 13528.)

Rules for Inspection, Testing and Maintenance of Air Brake Equipment

§ 232.10 General rules; locomotives.

(a) Air brake and hand brake equipment on locomotives including tender must be inspected and maintained in accordance with the requirements of the Locomotive Inspection and United States Safety Appliance Acts and related orders and regulations of the Federal Railroad Administrator (FRA).

(b) It must be known that air brake equipment on locomotives is in a safe and suitable condition for service.

(c) Compressor or compressors must be tested for capacity by orifice test as often as conditions require but not less frequently than required by law and orders of the FRA.

(d) Main reservoirs shall be subjected to tests periodically as required by law and orders of the FRA.

(e) Air gauges must be tested periodically as required by law and orders of the FRA, and whenever any irregularity is reported. They shall be compared with an accurate deadweight tester, or test gauge. Gauges found inaccurate or defective must be repaired or replaced.

(f)(1) All operating portions of air brake equipment together with dirt collectors and filters must be cleaned, repaired and tested as often as conditions require to maintain them in a safe and suitable condition for service, and not less frequently than required by law and orders of the FRA.

(2) On locomotives so equipped, hand brakes, parts, and connections must be inspected, and necessary repairs made as often as the service requires, with date being suitably stenciled or tagged.

(g) The date of testing or cleaning of air brake equipment and the initials of the shop or station at which the work was done shall be placed on a card displayed under transparent covering in the cab of each locomotive unit.

(h)(1) Minimum brake cylinder piston travel must be sufficient to provide proper brake shoe clearance when brakes are released.

(2) Maximum brake cylinder piston travel when locomotive is standing must not exceed the following:

	Inches
Steam locomotives:	
Cam type of driving wheel brake	3½
Other types of driving wheel brakes	6
Engine truck brake	8
Engine trailer truck brake	8
Tender brake (truck mounted and tender bed mounted)	8
Tender brake (body mounted)	9
Locomotives other than steam:	
Driving wheel brake	6
Swivel type truck brake with brakes on more than one truck operated by one brake cylinder	7
Swivel type truck brake equipped with one brake cylinder	8
Swivel type truck brake equipped with two or more brake cylinders	6

(i)(1) Foundation brake rigging, and safety supports, where used, must be maintained in a safe and suitable condition for service. Levers, rods, brake beams, hangars and pins must be of ample strength and must not bind or foul in any way that will affect proper operation of brakes. All pins must be properly applied and secured in place with suitable locking devices. Brake shoes must be properly applied and kept approximately in line with treads of wheels or other braking surfaces.

(2) No part of the foundation brake rigging and safety supports shall be closer to the rails than specified by law and orders of the FRA.

(j)(1) Main reservoir leakage: Leakage from main air reservoir and related piping shall not exceed an average of 3 pounds per minute in a test of three minutes' duration, made after the pressure has been reduced 40 percent below maximum pressure.

(2) Brake pipe leakage: Brake pipe leakage must not exceed 5 pounds per minute after a reduction of 10 pounds has been made from brake pipe air pressure of not less than 70 pounds.

(3) Brake cylinder leakage: With a full service application of brakes, and with communication to the brake cylinders closed, brakes must remain applied not less than five minutes.

(4) The main reservoir system of each unit shall be equipped with at least one safety valve, the capacity of which shall be sufficient to prevent an accumulation of pressure of more than 10 pounds per square inch above the maximum setting of the compressor governor fixed by the chief mechanical officer of the carrier operating the locomotive.

(5) A suitable governor shall be provided that will stop and start the air compressor within 5 pounds above or below the pressures fixed.

(6) Compressor governor when used in connection with the automatic air brake system shall be so adjusted that the compressor will start when the main reservoir pressure is not less than 15 pounds above the maximum brake-pipe pressure fixed by the rules of the carrier and will not stop the compressor until the reservoir pressure has increased not less than 10 pounds.

(k) The communicating signal system on locomotives when used in passenger service must be tested and known to be in a safe and suitable condition for service before each trip.

(l) Enginemen when taking charge of locomotives must know that the brakes are in operative condition.

(m) In freezing weather drain cocks on air compressors of steam locomotives must be left open while compressors are shut off.

(n) Air pressure regulating devices must be adjusted for the following pressures:

	Pounds
Locomotives:	
(1) Minimum brake pipe air pressure:	
Road Service	70
Switch Service	60
(2) Minimum differential between brake pipe and main reservoir air pressures, with brake valve in running position	15
(3) Safety valve for straight air brake	30–55
(4) Safety valve for LT, ET, No. 8–EL, No. 14 El, No. 6–DS, No. 6–BL and No. 6–SL equipment	30–68
(5) Safety valve for HSC and No. 24–RL equipment	30–75
(6) Reducing valve for independent or straight air brake	30–50
(7) Self-lapping portion for electro-pneumatic brake (minimum full application pressure)	50
(8) Self-lapping portion for independent air brake (full application pressure)	30–50
(9) Reducing valve for air signal	40–60
(10) Reducing valve for high-speed brake (minimum)	50
Cars:	
(11) Reducing valve for high-speed brake	58–62
(12) Safety valve for PS, LN, UC, AML, AMU and AB–1–B air brakes	58–62
(13) Safety valve for HSC air brake	58–77
(14) Governor valve for water raising system	60
(15) Reducing valve for water raising system	20–30

§ 232.11 Train Air Brake System Tests.

(a) Supervisors are jointly responsible with inspectors, enginemen and trainmen for condition of train air brake and air signal equipment on motive power and cars to the extent that it is possible to detect defective equipment by required air tests.

(b) Communicating signal system on passenger equipment trains must be tested and known to be in a suitable condition for service before leaving terminal.

(c) Each train must have the air brakes in effective operating condition, and at no time shall the number and location of operative air brakes be less than permitted by Federal requirements. When piston travel is in excess of 10½ inches, the air brakes cannot be considered in effective operating condition.

(d) Condensation must be blown from the pipe from which air is taken before connecting yard line or motive power to train.

§ 232.12 Initial Terminal Road Train Airbrake Tests.

(a)(1) Each train must be inspected and tested as specified in this section by a qualified person at points—

(i) Where the train is originally made up (initial terminal);

(ii) Where train consist is changed, other than by adding or removing a solid block of cars, and the train brake system remains charged; and

(iii) Where the train is received in interchange if the train consist is changed other than by—

(A) Removing a solid block of cars from the head end or rear end of train;

(B) Changing motive power;

(C) Removing or changing the caboose; or

(D) Any combination of the changes listed in (A), (B), and (C) of this subparagraph.

Where a carman is to perform the inspection and test under existing or future collective bargaining agreement, in those circumstances a carman alone will be considered a qualified person.

(2) A qualified person participating in the test and inspection or who has knowledge that it was made shall notify the engineer that the initial terminal road train air brake test has been satisfactorily performed. The qualified person shall provide the notification in writing if the road crew will report for duty after the qualified person goes off duty. The qualified person also shall provide the notification in writing if the train that has been inspected is to be moved in excess of 500 miles without being subjected to another test pursuant to either this section or § 232.13 of this part.

(b) Each carrier shall designate additional inspection points not more than 1,000 miles apart where intermediate inspection will be made to determine that—

(1) Brake pipe pressure leakage does not exceed five pounds per minute;

(2) Brakes apply on each car in response to a 20-pound service brake pipe pressure reduction; and

(3) Brake rigging is properly secured and does not bind or foul.

(c) Train airbrake system must be charged to required air pressure, angle cocks and cutout cocks must be properly positioned, air hose must be properly coupled and must be in condition for service. An examination must be made for leaks and necessary repairs made to reduce leakage to a minimum. Retaining valves and retaining valve pipes must be inspected and known to be in condition for service. If train is to be operated in electro-pneumatic brake operation, brake circuit cables must be properly connected.

(d)(1) After the airbrake system on a freight train is charged to within 15 pounds of the setting of the feed valve on the locomotive, but to not less than 60 pounds, as indicated by an accurate gauge at rear end of train, and on a passenger train when charged to not less than 70 pounds, and upon receiving the signal to apply brakes for test, a 15-pound brake pipe service reduction must be made in automatic brake operations, the brake valve lapped, and the number of pounds of brake pipe leakage per minute noted as

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indicated by brake pipe guage, after which brake pipe reduction must be increased to full service. Inspection of the train brakes must be made to determine that angle cocks are properly positioned, that the brakes are applied on each car, that piston travel is correct, that brake rigging does not bind or foul, and that all parts of the brake equipment are properly secured. When this inspection has been completed, the release signal must be given and brakes released and each brake inspected to see that all have released.

(2) When a passenger train is to be operated in electro-pneumatic brake operation and after completion of test of brakes as prescribed by paragraph (d)(1) of this section the brake system must be recharged to not less than 90 pounds air pressure, and upon receiving the signal to apply brakes for test, a minimum 20 pounds electro-pneumatic brake application must be made as indicated by the brake cylinder gage. Inspection of the train brakes must then be made to determine if brakes are applied on each car. When this inspection has been completed, the release signal must be given and brakes released and each brake inspected to see that all have released.

(3) When the locomotive used to haul the train is provided with means for maintaining brake pipe pressure at a constant level during service application of the train brakes, this feature must be cut out during train airbrake tests.

(e) Brake pipe leakage must not exceed 5 pounds per minute.

(f)(1) At initial terminal piston travel of body-mounted brake cylinders which is less than 7 inches or more than 9 inches must be adjusted to nominally 7 inches.

(2) Minimum brake cylinder piston travel of truck-mounted brake cylinders must be sufficient to provide proper brake shoe clearance when brakes are released. Maximum piston travel must not exceed 6 inches.

(3) Piston travel of brake cylinders on freight cars equipped with other than standard single capacity brake, must be adjusted as indicated on badge plate or stenciling on car located in a conspicuous place near the brake cylinder.

(g) When test of airbrakes has been completed the engineman and conductor must be advised that train is in proper condition to proceed.

(h) During standing test, brakes must not be applied or released until proper signal is given.

(i)(1) When train airbrake system is tested from a yard test plant, an engineer's brake valve or an appropriate test device shall be used to provide increase and reduction of brake pipe air pressure or electro-pneumatic brake application and release at the same or a slower rate as with engineer's brake valve and yard test plant must be connected to the end which will be nearest to the hauling road locomotive.

(2) When yard test plant is used, the train airbrakes system must be charged and tested as prescribed by paragraphs (c) to (g) of this section inclusive, and when practicable should be kept charged until road motive power is coupled to train, after which, an automatic brake application and release test of airbrakes on rear car must be made. If train is to be operated in electro-pneumatic brake operation, this test must also be made in electro-pneumatic brake operation before proceeding.

(3) If after testing the brakes as prescribed in paragraph (i)(2) of this section the train is not kept charged until road motive power is attached, the brakes must be tested as prescribed by paragraph (d)(1) of this section and if train is to be operated in electro-pneumatic brake operation as prescribed by paragraph (d)(2) of this section.

(j) Before adjusting piston travel or working on brake rigging, cutout cock in brake pipe branch must be closed and air reservoirs must be drained. When cutout cocks are provided in brake cylinder pipes, these cutout cocks only may be closed and air reservoirs need not be drained.

§ 232.13 Road train and intermediate terminal train air brake tests.

(a) *Passenger trains.* Before motive power is detached or angle cocks are closed on a passenger train operated in either automatic or electro-pneumatic brake operation, except when closing angle cocks for cutting off one or more cars from the rear end of train, automatic air brake must be applied. After recouping, brake system must be recharged to required air pressure and before proceeding and upon receipt of proper request or signal, application and release tests of brakes on rear car must be made from locomotive in automatic brake operation. If train is to be operated in electro-pneumatic brake operation, this test must also be made in electro-pneumatic brake operation before proceeding. Inspector or trainman must determine if brakes on rear car of train properly apply and release.

(b) *Freight trains.* Before motive power is detached or angle cocks are closed on a freight train, brakes must be applied with not less than a 20-pound brake pipe reduction. After recoupling, and after angle cocks are opened, it must be known that brake pipe air pressure is being restored as indicated by a rear car gauge or device. In the absence of a rear car gauge or device, an air brake test must be made to determine that the brakes on the rear car apply and release.

(c)(1)At a point other than an initial terminal where a locomotive or caboose is changed, or where one or more consecutive cars are cut off from the rear end or head end of a train with the consist otherwise remaining intact, after the train brake system is charged to within 15 pounds of the feed valve setting on the locomotive, but not less than 60 pounds as indicated at the rear of a freight train and 70 pounds on a passenger train, a 20-pound brake pipe reduction must be made and it must be determined that the brakes on the rear car apply and release. As an alternative to the rear car brake application and release test, it shall be determined that brake pipe pressure of the train is being reduced as indicated by a rear car gauge or device and then that brake pipe pressure of the train is being restored as indicated by a rear car gauge or device.

(2) Before proceeding it must be known that brake pipe pressure as indicated at rear of freight train is being restored.

(3) On trains operating with electro-pneumatic brakes, with brake system charged to not less than 70 pounds, test must be made to determine that rear brakes apply and release properly from a minimum 20 pounds electro-pneumatic brake application as indicated by brake cylinder gauge.

(d)(1) At a point other than a terminal where one or more cars are added to a train, after the train brake system is charged to not less than 60 pounds as indicated by a gauge or device at the rear of a freight train and 70 pounds on a passenger train. A brake test must be made by a designated person as described in § 232.12 (a)(1) to determine that brake pipe leakage does not exceed five (5) pounds per minute as indicated by the brake pipe gauge after a 20-pound brake pipe reduction has been made. After the test is completed, it must be determined that piston travel is correct, and the train airbrakes of these cars and on the rear car of the train apply and remain applied, until the release signal is given. As an alternative to the rear car brake application and release portion of the test, it shall be determined that brake pipe pressure of the train is being reduced as indicated by a rear car gauge or device and then that brake pipe pressure of the train is being restored as indicated by a rear car gauge or device. Cars added to a train that have not been inspected in accordance with § 232.12 (c) through (j) must be so inspected and tested at the next terminal where facilities are available for such attention.

(d)(2)(i) At a terminal where a solid block of cars, which has been previously charged and tested as prescribed by § 232.13 (c) through (j), is added to a train, it must be determined that the brakes on the rear car of the train apply and release. As an alternative to the rear car application and release test, it shall be determined that brake pipe pressure of the train is being reduced as indicated by a rear car gauge or device and then that brake pipe pressure of the train is being restored as indicated by a rear car gauge or device.

(d)(2)(ii) When cars which have not been previously charged and tested as prescribed by § 232.12 (c) through (j) are added to a train, such cars may either be given inspection and tests in accordance with § 232.12 (c) through (j), or tested as prescribed by paragraph (d)(1) of this section prior to departure in which case these cars must be inspected and tested in accordance with § 232.12 (c) through (j) at next terminal.

(3) Before proceeding it must be known that the brake pipe pressure at the rear of freight train is being restored.

(e)(1) Transfer train and yard train movements not exceeding 20 miles, must have the air brake hose coupled between all cars, and after the brake system is charged to not less than 60 pounds, a 15 pound service brake pipe reduction must be made to determine that the brakes are applied on each car before releasing and proceeding.

(2) Transfer train and yard train movements exceeding 20 miles must have brake inspection in accordance with § 232.12 (c)–(j).

(f) The automatic air brake must not be depended upon to hold a locomotive, cars or train, when standing on a grade, whether locomotive is attached or detached from cars or train. When required, a sufficient number of hand brakes must be applied to hold train, before air brakes are released. When ready to start, hand brakes must not be released until it is known that the air brake system is properly charged.

(g) As used in this section, device means a system of components designed and inspected in accordance with § 232.19.

(h) When a device is used to comply with any test requirement in this section, the phrase brake pipe pressure of the train is being reduced means a pressure reduction of at least five pounds and the phrase brake pipe pressure of the train is being restored means a pressure increase of at least five pounds.

§ 232.14 Inbound Brake Equipment Inspection.

(a) At points where inspectors are employed to make a general inspection of trains upon arrival at terminals, visual inspection must be made of retaining valves and retaining valve pipes, release valves and rods, brake rigging, safety supports, hand brakes, hose and position of angle cocks and make necessary repairs or mark for repair tracks any cars to which yard repairs cannot be promptly made.

(b) Freight trains arriving at terminals where facilities are available and at which special instructions provide for immediate brake inspection and repairs, trains shall be left with air brakes applied by a service brake pipe reduction of 20 pounds so that inspectors can obtain a proper check of the piston travel. Trainmen will not close any angle cock or cut the locomotive off until the 20 pound service reduction has been made. Inspection of the brakes and needed repairs should be made as soon thereafter as practicable.

§ 232.15 Double Heading and Helper Service.

(a) When more than one locomotive is attached to a train, the engineman of the leading locomotive shall operate the brakes. On all other motive power units in the train the brake pipe cutout cock to the brake valve must be closed, the maximum main reservoir pressure maintained and brake valve handles kept in the prescribed position. In case it becomes necessary for the leading locomotive to give up control of the train short of the destination of the train, a test of the brakes must be made to see that the brakes are operative from the automatic brake valve of the locomotive taking control of the train.

(b) The electro-pneumatic brake valve on all motive power units other than that which is handling the train must be cut out, handle of brake valve kept in the prescribed position, and air compressors kept running if practicable.

§ 232.16 Running Tests.

When motive power, engine crew or train crew has been changed, angle cocks have been closed except for cutting off one or more cars from the rear end of train or electro-pneumatic brake circuit cables between power units and/or cars have been disconnected, running test of train air brakes on passenger train must be made, as soon as speed of train permits, by use of automatic brake if operating in automatic brake operation or by use of electro-pneumatic brake if operating in electro-pneumatic brake operation. Steam or power must not be shut off unless required and running test must be made by applying train air brakes with sufficient force to ascertain whether or not brakes are operating properly. If air brakes do not properly operate, train must be stopped, cause of failure ascertained and corrected and running test repeated.

§ 232.17 Freight and passenger train car brakes

(a) *Testing and repairing brakes on cars while on shop or repair tracks.* (1) When a freight car having brake equipment due for periodic attention is on shop or repair tracks where facilities are available for making air brake repairs, brake equipment must be given attention in accordance with the requirements of the currently effective AAR Code of Rules for cars in interchange. Brake equipment shall then be tested by use of a single car testing device as prescribed by the currently effective AAR Code of Tests.

(2)(i) When a freight car having an air brake defect is on a shop or repair track, brake equipment must be tested by use of a single car testing device as prescribed by currently effective AAR Code of Tests.

(ii) All freight cars on shop or repair tracks shall be tested to determine that the air brakes apply and release. Piston travel on a standard body mounted brake cylinder which is less than 7 inches or more than 9 inches must be adjusted to nominally 7 inches. Piston travel of brake cylinders on all freight cars equipped with other than standard single capacity brake, must be adjusted as indicated on badge plate or stenciling on car located in a conspicuous place near brake cylinder. After piston travel has been adjusted and with brakes released, sufficient brake shoe clearance must be provided.

(iii) When a car is equipped for use in passenger train service not due for periodical air brake repairs, as indicated by stenciled or recorded cleaning dates, is on shop or repair tracks, brake equipment must be tested by use of single car testing device as prescribed by currently effective AAR Code of Tests. Piston travel of brake cylinders must be adjusted if required, to the standard travel for that type of brake cylinder. After piston travel has been adjusted and with brakes released, sufficient brake shoe clearance must be provided.

(iv) Before a car is released from a shop or repair track, it must be known that brake pipe is securely clamped, angle cocks in proper position with suitable clearance, valves, reservoirs and cylinders tight on supports and supports securely attached to car.

(b)(1) Brake equipment on cars other than passenger cars must be cleaned, repaired, lubricated and tested as often as required to maintain it in a safe and suitable condition for service but not less frequently than as required by currently effective AAR Code of Rules for cars in interchange.

(2) Brake equipment on passenger cars must be clean, repaired, lubricated and tested as often as necessary to maintain it in a safe and suitable condition for service but not less frequently than as required in Standard S–045 in the Manual of Standards and Recommended Practices of the AAR.

(3) Copies of the materials referred to in this section can be obtained from the Association of American Railroads, 1920 L Street, NW., Washington, DC 20036.

§ 232.19 through § 232.25 Provisions related to end-of-train devices.

Not included in this Appendix as they are contained in Subpart E of this rule.

Issued in Washington, DC, on January 4, 2001.

John V. Wells,

Acting Administrator, Federal Railroad Administration.

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Office of the Secretary

48 CFR Chapter 3
Acquistition Regulation Revision; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Chapter 3

Acquisition Regulation Revision

AGENCY: Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services is finalizing its acquisition regulation (HHSAR) to streamline and simplify it in accordance with the tenets of the National Performance Review. In doing so, the Department has eliminated procedural guidance which it believes is too encumbering for a simplified system and has empowered appropriate levels of management and contracting personnel with the authorities required for them to successfully accomplish their mission with the least amount of resistance and oversight.

EFFECTIVE DATE: January 17, 2001.

FOR FURTHER INFORMATION CONTACT: E. S. Lanham, Office of Acquisition Management, telephone (202) 690–7590.

SUPPLEMENTARY INFORMATION: The HHSAR was published as a proposed rule on January 8, 1999 (64 FR Vol 5 pps 1343—1390). Comments were received from several departmental contracting activities and one outside source. All comments have been analyzed and considered in the formulation of this final rule.

As a result of the publication of this regulation, the existing HHSAR at 48 CFR Chapter 3, including Appendix A, is canceled. Pertinent subject matter from Appendix A has been incorporated into this version of the HHSAR.

The Department reemphasizes that it is not making significant amendments to the existing HHSAR. The amendments being made to the HHSAR concern internal procedural matters which are administrative in nature, and will not have a major effect on the general public, or to contractors or offerors of the Department. The majority of the amendments eliminate procedural guidance no longer deemed necessary, or change contracting review and approval authorities to situate them at levels more appropriate to simplification, streamlining, and empowerment.

The Department of Health and Human Services certifies this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*); therefore, no regulatory flexibility statement has been prepared. Since this rule conveys existing acquisition policies or procedures and does not promulgate any new policies or procedures which would impact the public, it has been determined that this rule will not have a significant economic effect on a substantial number of small entities, and , thus, a regulatory flexibility analysis was not performed.

Furthermore, this document does not contain new information collection requirements needing approval by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing approvals cited in 48 CFR section 301.106 remain in effect. The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 486 (c).

List of Subjects in 48 CFR Parts 301 through 370

Government procurement.

Under the authority of 5 U.S.C. 301; 40 U.S.C. 486(c), the Department of Health and Human Services revises 48 CFR Chapter 3 as set forth below.

Dated: December 14, 2000.

John J. Callahan,

Assistant Secretary for Management and Budget.

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PART 301—HHS ACQUISITION REGULATION SYSTEM

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Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 301.1—Purpose, Authority, Issuance

301.101 Purpose.

(a) The Department of Health and Human Services Acquisition Regulation (HHSAR) is issued to establish uniform acquisition policies and procedures for the Department of Health and Human Services (HHS) which conform to the Federal Acquisition Regulation (FAR) System.

(b) The HHSAR implements and supplements the FAR. (Implementing material expands upon or indicates the manner of compliance with related FAR material. Supplementing material is new material which has no counterpart in the FAR.)

(c) The HHSAR contains all formal departmental policies and procedures that govern the acquisition process or otherwise control contracting relationships between the Department's contracting offices and contractors.

301.103 Authority.

(b) The HHSAR is prescribed by the Assistant Secretary for Management and Budget under the authority of 5 U.S.C. 301 and section 205(c) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 486(c)), as delegated by the Secretary.

(c) The HHSAR is issued in the Code of Federal Regulations (CFR) as Chapter 3 of Title 48, Department of Health and Human Services Acquisition Regulation. It may be referenced as "48 CFR Chapter 3."

301.106 OMB approval under the Paperwork Reduction Act.

(a) The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this chapter:

HHSAR segment	OMB control No.
315.4	0990–0139
324.70	0990–0136
342.7101	0990–0131
352.224–70	0990–0137
352.224–70	0990–0136
352.233–70	0990–0133
352.270–1	0990–0129
352.270–2	0990–0129
352.270–3	0990–0129
352.270–5	0990–0130
352.270–8	0990–0128
352.270–9	0990–0128
370.1	0990–0129
370.2	0990–0129

(b) The OMB control number "OMB No. 0990–0115" is to be included in the upper right corner of the first page of all solicitations, purchase orders, and contracts issued by departmental contracting activities. The number represents approval of the HHS acquisition process and covers recordkeeping and reporting requirements which are unique to individual acquisitions (*e.g.*, requirements contained in specifications, statements of work, etc.).

Subpart 301.2—Administration

301.270 Executive Committee for Acquisition.

(a) The Deputy Assistant Secretary for Grants and Acquisition Management has established the Executive Committee for Acquisition (ECA) to assist and facilitate the planning and development of departmental acquisition policies and procedures and to assist in responding to other agencies and organizations concerning policies and procedures impacting the Federal acquisition process.

(b) The ECA consists of members and alternates from the Office of Acquisition Management, Administration for Children and Families, Agency for Healthcare Research and Quality, Health Care Financing Administration, Program Support Center, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and Substance Abuse and Mental Health Services Administration. The ECA is chaired by the Director, Office of Acquisition Management. All meetings will be held at the call of the Chair, and all activities will be carried out under the direction of the Chair.

(c) The ECA, to facilitate the planning, development, and coordination of governmentwide and departmentwide acquisition policies and procedures, is to:

(1) Advise and assist the Chair concerning major acquisition policy matters;

(2) Review and appraise, at appropriate intervals, the overall effectiveness of existing policies and procedures; and

(3) Review and appraise the impact of new major acquisition policies, procedures, regulations, and development on current acquisition policies and procedures.

(d) The Chair will periodically issue a list of current members and alternates specifying the name, title, organization, address, and telephone number of each. The member organizations are responsible for apprising the Chair whenever a new member or alternate is to be appointed to the ECA, or an organizational change retitles the individual or organization.

Subpart 301.4—Deviations From the FAR

301.403 Individual deviations.

Requests for individual deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded through administrative channels to the Director, Office of Acquisition Management for review and approval.

301.404 Class deviations.

Requests for class deviations to either the FAR or HHSAR shall be prepared in accordance with 301.470 and forwarded through administrative channels to the Deputy Assistant Secretary for Grants and Acquisition Management for review and approval.

301.470 Procedure.

(a) When a contracting office determines that a deviation is needed, it shall prepare a deviation request in memorandum form and forward it through administrative channels to the official designated in 301.403 or 301.404. In an exigency situation, the contracting office may request a deviation verbally, through normal acquisition channels, but is required to confirm the request in writing as soon as possible.

(b) A deviation request shall clearly and precisely set forth the:

(1) Nature of the needed deviation;

(2) Identification of the FAR or HHSAR citation from which the deviation is needed;

(3) Circumstances under which the deviation would be used;

(4) Intended effect of the deviation;

(5) Period or applicability;

(6) Reasons which will contribute to complete understanding and support of the requested deviation. A copy of pertinent background papers such as a contractor's request should accompany the deviation request.; and

(7) Suggested wording for the deviation (if applicable).

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.602 Contracting officers.

301.602–3 Ratification of unauthorized commitments.

(b) *Policy.* (1) The Government is not bound by agreements or contractual commitments made to prospective contractors by persons to whom contracting authority has not been delegated. However, execution of otherwise proper contracts made by individuals without contracting authority, or by contracting officers in excess of the limits of their delegated authority, may be later ratified. The ratification must be in the form of a written document clearly stating that ratification of a previously unauthorized act is intended and must be signed by the head of the contracting activity (HCA).

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(2) The HCA is the official authorized to ratify an unauthorized commitment (but see paragraph (b)(3) of this section).

(3) Ratification authority for actions up to $25,000 may be redelegated by the HCA to the chief of the contracting office (CCO). No other redelegations are authorized.

(c) *Limitations.* (5) The concurrence of legal counsel concerning the payment issue is optional.

(e) *Procedures.* (1) The individual who made the unauthorized contractual commitment shall furnish the reviewing contracting officer all records and documents concerning the commitment and a complete written statement of facts, including, but not limited to: a statement as to why the contracting office was not used, a statement as to why the proposed contractor was selected, a list of other sources considered, a description of work to be performed or products to be furnished, the estimated or agreed contract price, a citation of the appropriation available, and a statement whether the contractor has commenced performance.

(2) The contracting officer will review the submitted material, and prepare the ratification document if he/she determines that the commitment may be ratifiable. The contracting officer shall forward the ratification document and the submitted material to the HCA or CCO with any comments or information which should be considered in evaluation of the request for ratification. If legal review is desirable, the HCA or CCO will coordinate the request for ratification with the Office of General Counsel, Business and Administrative Law Division.

(3) If ratification is authorized by the HCA or CCO, the file will be returned, along with the ratification document, to the contracting officer for issuance of a purchase order or contract, as appropriate.

301.603 Selection, appointment, and termination of appointment.

301.603–1 General.

(a) The appointment and termination of appointment of contracting officers shall be made by the head of the contracting activity (HCA). This authority is not delegable.

(b) The contracting officer appointment document for personnel in the GS–1101, 1102, and 1105 series, as well as personnel in any other series who will obligate the Government to the expenditure of funds in excess of the micro-purchase threshold, shall be the Standard Form (SF)—1402, Certificate of Appointment. The HCA may determine an alternative appointment document for appointments at or below that threshold. Changes to appointments shall be made by issuing a new appointment document. Each appointment document shall be prepared and maintained in accordance with FAR 1.603–1 and shall state the limits of the individual's authority.

(c) An individual must be certified at the appropriate level under the HHS Acquisition Certification Program as a prerequisite to being appointed as a contracting officer with authority to obligate funds in excess of the micro-purchase threshold (see 301.603–3(a)). The HCA will determine and require appropriate training for individuals appointed as contracting officers at lower dollar levels. An individual shall be appointed as a contracting officer only in instances where a valid organizational need can be demonstrated. Factors to be considered in assessing the need for an appointment of a contracting officer include volume of actions, complexity of work, and structure of the organization.

301.603–2 Selection.

Nominations for appointment of contracting officers shall be submitted to the HCA through appropriate organizational channels for review. The nomination package, which is usually initiated by the prospective contracting officer's immediate supervisor, shall normally include the nominee's current personal qualifications statement or job history, including the information required by FAR 1.603–2, a copy of his/her most recent performance appraisal, and a copy of the certificate issued under the HHS Acquisition Certification Program indicating the nominee's current certification level, if applicable. The HCA will determine the documentation required, consistent with FAR 1.603–2, when the resulting appointment and authority will not exceed the micro-purchase threshold.

301.603–3 Appointment.

(a) Contracting officer appointments shall be made at levels commensurate with nominees' certification levels as follows:

(1) Level I—Purchasing Agent—Required for all personnel in the GS–1102 and 1105 series having signature authority for simplified acquisitions, including orders from GSA sources over the micro-purchase threshold.

(2) Level II—Acquisition Official—Required for all personnel in the GS–1102 series. Sufficient for delegation of contracting officer authority up to $500,000.

(3) Level III—Senior Acquisition Official—Required for all personnel in the GS–1102 series for delegation of contracting officer authority above $500,000.

(4) Level IV—Acquisition Manager—Required for delegation of pre-award review and approval authority as specified in subpart 304.71.

(b) If it is essential to appoint an individual who does not fully meet the certification requirements of this section for the contracting officer authority sought, an interim appointment may be granted by the HCA. Interim appointments may not exceed one (1) year in total, and shall not be granted unless the individual can meet the certification requirements within one year from the date of appointment. If the certification requirements are not met by that date, the appointment will automatically terminate and cannot be renewed.

301.603–4 Termination.

Termination of contracting officer appointments shall be accomplished in accordance with FAR 1.603–4.

301.603–70 Delegation of contracting officer responsibilities.

(a) Contracting officer responsibilities which do not involve the obligation (or deobligation) of funds or result in establishing or modifying contractual provisions may be delegated by the contracting officer by means of a written memorandum which clearly delineates the delegation and its limits.

(b) Contracting officers may designate individuals as ordering officials to make purchases or place orders under blanket purchase agreements, indefinite delivery contracts, or other pre-established mechanisms. Ordering officials, including those under NIH's DELPRO, are not contracting officers.

(c) Project officers are required to complete the training specified in 307.170, while ordering officials and others should receive sufficient instruction from the contracting officer to ensure the appropriate exercise of the responsibilities and knowledge of their limitations.

PART 302—DEFINITIONS OF WORDS AND TERMS

Subpart 302.1—Definitions

Sec.
302.101 Definitions.

Subpart 302.2—Definitions Clause

302.201 Contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 302.1—Definitions

302.101 Definitions.

Chief of the contracting office (CCO) is a mid-level management official in charge of a contracting office who controls and oversees the daily contracting operation of an Operating Division (OPDIV) or major component of an OPDIV. The CCO is subordinate to the head of the contracting activity, and is located at a management level above other contracting personnel, usually as a branch chief or division director.

Head of the agency or *agency head,* unless otherwise specified, means the head of the Operating Division (OPDIV) for ACF, AHRQ, HCFA, PSC, CDCP, FDA, HRSA, IHS, NIH, and SAMHSA, or the Assistant Secretary for Management and Budget (ASMB) for the Office of the Secretary (OS).

Head of the contracting activity (HCA) is defined in terms of certain organizational positions within the Office of Grants and Acquisition Management (OGAM), Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), Program Support Center (PSC), Centers for Disease Control and Prevention (CDCP), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Metal Health Services Administration (SAMHSA), as follows:

OGAM–OS—Director, Office of Acquisition Management
ACF—Director, Division of Acquisition Management
AHRQ—Director, Division of Contracts Management
HCFA—Director, Acquisition and Grants Group
PSC—Director, Division of Acquisition Management
CDCP—Director, Procurement and Grants Office
FDA—Director, Policy, Evaluation and Support Staff, Office of Facilities, Acquisition, and Central Services
HRSA—Director, Division of Grants and Procurement Management
IHS—Director, Division of Acquisitions and Grants Management
NIH—Director, Office of Acquisition Management and Policy
SAMHSA—Director, Division of Contracts Management

In addition, the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM) is designated as an HCA. Each HCA is responsible for conducting an effective and efficient acquisition program. Adequate controls shall be established to assure compliance with applicable laws, regulations, procedures, and the dictates of good management practices. Periodic reviews shall be conducted and evaluated by qualified personnel, preferably assigned to positions other than in the contracting office being reviewed, to determine the extent of adherence to prescribed policies and regulations, and to detect a need for guidance and/or training. The HCA shall be certified, or be certifiable, at Level IV of the HHS Acquisition Certification Program. Individuals appointed as HCA's who do not meet the Level IV requirements shall have one year from the date of appointment to obtain Level IV certification. The heads of contracting activities may redelegate their HCA authorities to the extent that redelegation is not prohibited by the terms of their respective delegations of authority, by law, by the Federal Acquisition Regulation, by the HHS Acquisition Regulation, or by other regulations. However, HCA and other contracting approvals and authorities shall not be redelegated below the levels specified in the HHS Acquisition Regulation or, in the absence of coverage in the HHS Acquisition Regulation, the Federal Acquisition Regulation. To ensure proper control of redelegated acquisition authorities, HCA's shall maintain a file containing successive delegations of HCA authority through and including the contracting officer level. Personnel delegated responsibility for acquisition functions must possess a level of experience, training, and ability commensurate with the complexity and magnitude of the acquisition actions involved.

Subpart 302.2—Definitions clause

302.201 Contract clause.

The FAR clause, Definitions, at 52.202–1 shall be used as prescribed in FAR 2.201, except as follows:

(a) Paragraph (a) at 352.202–1 shall be used in place of paragraph (a) of the FAR clause.

(b) Paragraph (h), or its alternate, at 352.202–1 shall be added to the end of the FAR clause. Use paragraph (h) when a fixed-priced contract is anticipated; use the alternate to paragraph (h) when a cost-reimbursement contract is anticipated. This is an authorized deviation.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 303.1—Safeguards

Sec.
303.101 Standards of conduct.
303.101–3 Agency regulations.

Subpart 303.2—Contract Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

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303.303 Reporting suspected antitrust violations.

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303.704 Policy.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 303.1—Safeguards

303.101 Standards of conduct.

303.101–3 Agency regulations.

The Department of Health and Human Services' Standards of Conduct are prescribed in 45 CFR part 73.

Subpart 303.2—Contractor Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

Departmental personnel shall report suspected violations of the Gratuities clause in accordance with subpart M, Reporting Violations, of 45 CFR part 73. Refer to subpart B, Gifts from Outside Sources, (5 CFR 2635.201) for an explanation regarding what is prohibited and what is permitted.

Subpart 303.3—Reports of Suspected Antitrust Violations

303.303 Reporting suspected antitrust violations.

A copy of each report of suspected antitrust violations submitted to the Attorney General by the HCA shall also be submitted to the Director, Office of Acquisition Management.

Subpart 303.4—Contingent Fees

303.405 Misrepresentations or violations of the Covenant Against Contingent Fees.

(c) Reports shall be made promptly to the contracting officer.

(d)(4) Suspected fraudulent or criminal matters to be reported to the Department of Justice shall be prepared in letter format and forwarded through acquisition channels to the head of the contracting activity for signature. The letter must contain all pertinent facts

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and background information considered by the contracting officer and chief of the contracting office that led to the decision that fraudulent or criminal matters may be present. A copy of the signed letter shall be sent to the Director, Office of Acquisition Management.

Subpart 303.6—Contracts With Government Employees or Organizations Owned or Controlled by Them

303.602 Exceptions.

Approval of an exception to the policy stated in FAR 3.601 shall be made by the HCA (not delegable).

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

For purposes of implementing FAR subpart 3.7, the authorities granted to the "agency head or designee" shall be exercised by the HCA (not delegable).

PART 304—ADMINISTRATIVE MATTERS

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Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 304.6—Contracting Reporting

304.602 Federal Procurement Data System (FPDS).

The Departmental Contracts Information System (DCIS) represents the Department's implementation of the FPDS. All departmental contracting activities are required to participate in the DCIS and follow the procedures stated in the Enhanced Departmental Contracts Information System Manual and amendments to it. The HCA (not delegable) shall ensure that all required contract information is collected, submitted, and received into the DCIS on or before the 15th of each month for all appropriate contract and contract modifications award of the prior month.

Subpart 304.8—Government Contract Files

304.804–70 Contract closeout audits.

(a) Contracting officers shall rely, to the maximum extent possible, on non-Federal single audits to close physically completed cost-reimbursement contracts with colleges and universities, hospitals, non-profit firms, and State and local governments. In addition, where appropriate, a sample of these contractors may be selected for audit, in accordance with the decision-making process set forth in the following paragraph (b).

(b) Contracting officers shall request contract closeout audits on physically completed, cost-reimbursement, for-profit contracts in accordance with the following:

(1) Decisions on: The need for and allocation of contract audit resources and services; the selection of contracts or contractors to be audited; the identification of the audit agency to perform the audit; and the type or scope of closeout audit to be conducted, shall be made by the Office of Inspector General (OIG) and Office of Grants and Acquisition Management, in consultation with the Department's Contract Audit Users Work Group. These decisions shall be based upon the needs of the customer, risk analysis, return on investment, and the availability of audit resources. When an audit is warranted prior to closing a contract, the contracting officer shall submit the audit request to the OIG's Office of Audit via the appropriate OPDIV representative on the Contract Audit Users Work Group.

(2) Except where a contracting officer suspects misrepresentation or fraud, contract closeout field audits shall not be requested if the cost of performance is likely to exceed the potential cost recovery. Contracts that are not selected for a field audit may be closed on the basis of a desk review, subject to any later on-site audit findings. The release executed by the contractor shall contain the following statement:

> The Contractor agrees, pursuant to the clause in this contract entitled "Allowable Cost" or "Allowable Cost and Fixed Fee" (as appropriate), that the amount of any sustained audit exceptions resulting from any audit made after final payment shall be refunded to the Government."

Subpart 304.70—Acquisition Instrument Identification Numbering System

304.7000 Scope of subpart.

This subpart prescribes policy and procedures for assigning identifying numbers to contracts and related instruments, including solicitation documents, purchase orders, and delivery orders. The HCA (not delegable) is responsible for establishing the numbering system within the OPDIV.

304.7001 Numbering acquisitions.

(a) *Acquisitions which require numbering.* The following acquisitions shall be numbered in accordance with the system prescribed in paragraphs (b) and (c) of this section:

(1) Contracts, including letter contracts and task orders under basic ordering agreements, which involve the payment of $2,500 or more for the acquisition of personal property or nonpersonal services. (The number assigned to a letter contract shall be assigned to the superseding definitized contract).

(2) Contracts which involve the payment of $2,000 or more for construction (including renovation or alteration).

(3) Contracts which involve more than one payment regardless of amount.

(4) Requests for proposals and invitations for bids.

(5) Requests for quotations.

(6) Basic ordering agreements.

(b) *Numbering system for contracts.* All contracts which require numbering (paragraphs (a)(1) through (3) of this section) shall be assigned a number consisting of the following:

(1) The three digit identification code assigned to the contracting office by the Office of Grants and Acquisition Management (OGAM).

(2) A two digit fiscal year designation; and

(3) A four digit serial number. For example, the initial contract executed by the Office of Acquisition Management, OS, for fiscal year 1996 would be numbered 100–96–0001. While it is required that a different series of four digit serial numbers be used for each fiscal year, serial numbers assigned need not be sequential.

(c) *Numbering system for other acquisitions.* The HCA is responsible for developing a numbering system for the acquisitions other than contracts listed in paragraphs, (a)(4) through (a)(6) of this section, and any other types of acquisitions that may be used.

(d) *Assignment of identification codes.* Each contracting office of the Department shall be assigned a three digit identification code by the OGAM. Requests for the assignment of codes for newly established contracting offices shall be submitted by the headquarters acquisition staff office of the contracting activity to the OGAM. A listing of the contracting office identification codes currently in use is contained in the Enhanced Departmental Contracts Information System Manual.

Subpart 304.71—Review and Approval of Proposed Contract Awards

304.7100 Policy.

This subpart requires each HCA (not delegable) to establish review and approval procedures for proposed contracts actions to ensure that:

(a) Contract awards are in conformance with law, established policies and procedures, and sound business practices;

(b) Contractual documents properly reflect the mutual understanding of the parties; and

(c) The contracting officer is informed of deficiencies and items of questionable acceptability, and corrective action is taken.

304.7101 Procedures.

(a) All contractual documents, regardless of dollar value, are to be reviewed by the contracting officer prior to award.

(b) The HCA is responsible for establishing review and approval procedures and designating acquisition officials to serve as reviewers. Each HCA is responsible for determining the criterion (criteria) to be used in determining which contracts are to be reviewed, and that a sampling of proposed contracts not included in the "to be reviewed" group are reviewed and approved.

(c) Officials assigned responsibility for review and approval of contract actions must possess qualifications in the field of acquisition commensurate with the level of review performed, and, at a minimum, possess those acquisition skills expected of a contracting officer. However, if any official is to serve as the contracting officer and sign the contractual document, the review and approval function shall be performed by an appropriate official at least one level above.

PART 305—PUBLICIZING CONTRACT ACTIONS

Subpart 305.2—Synopsis of Proposed Contract Actions

Sec.
305.202 Exceptions.

Subpart 305.3—Synopsis of Contract Awards

305.303 Announcement of contract awards.

Subpart 305.5—Paid Advertisements

305.502 Authority.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 305.2—Synopsis of Proposed Contract Actions

305.202 Exceptions.

(b) When a contracting office believes that it has a situation where advance notice is not appropriate or reasonable, it shall prepare a memorandum citing all pertinent facts and details and send it, through normal acquisition channels, to the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM) requesting relief from synopsizing. The DASGAM shall review the request and decide whether an exception to synopsizing is appropriate or reasonable. If it is, the DASGAM shall take the necessary coordinating actions required by FAR 5.202 (b). Whatever the decision is on the request, the DASGAM shall promptly notify the contracting office when a determination has been made.

Subpart 305.3—Synopses of Contract Awards

305.303 Announcement of contract awards.

(a) *Public announcement.* Any contract, contract modification, or delivery order in the amount of $3 million or more shall be reported by the contracting officer to the Office of the Deputy Assistant Secretary for Legislation (Congressional Liaison), Room 406G, Hubert H. Humphrey Building. Notification shall be accomplished by providing a copy of the contract or award document face page to the referenced office prior to the day of award, or in sufficient time to allow for an announcement to be made by 5 p.m. Washington, DC time on the day of award.

Subpart 305.5—Paid Advertisements

305.502 Authority.

The contracting officer is authorized to publish advertisements, notices, and notices that proposals are being sought in newspapers and periodicals in accordance with the requirements and conditions referenced in FAR subpart 5.5.

PART 306—COMPETITION REQUIREMENTS

Subpart 306.2—Full and Open Competition After Exclusion of Sources

Sec.
306.202 Establishing or maintaining alternative sources.

Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.
306.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.
306.302–7 Public interest.
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306.304 Approval of the justification.

Subpart 306.5—Competition Advocates

306.501 Requirement.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 306.2—Full and Open Competition After Exclusion of Sources

306.202 Establishing or maintaining alternative sources.

(a) The reference to the agency head in FAR 6.202 (a) shall mean the appropriate competition advocate cited in 306.501.

(b)(1) The required determination and findings (D&F) shall be prepared by the contracting officer based on the data provided by program personnel, and shall be signed by the appropriate competition advocate. The D&F signatory is not delegable.

Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.

(a) (2) (ii) Follow-on contracts for the continuation of major research and development studies on long-term social and health programs, major research studies, or clinical trials may be deemed to be available only from the original source when it is likely that award to any other source would result in unacceptable delays in fulfilling the Department's or OPDIV's requirements.

(b) *Application.* (4) When the head of the program office has determined that a specific item of technical equipment or parts must be obtained to meet the activity's program responsibility to test and evaluate certain kinds and types of products, and only one source is available. (This criterion is limited to testing and evaluation purposes only and may not be used for initial outfitting or repetitive acquisitions. Project officers should support the use of this criterion with citations from their agency's legislation and the technical rationale for the item of equipment required.)

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306.302–7 Public interest.

(a) *Authority.* (2) Agency head, in this instance, means the Secretary.

(c) *Limitations.* An "approval package" must be prepared by the contracting officer and staffed through departmental acquisition channels to the Secretary. The package shall include a determination and findings for the Secretary to sign that contains all pertinent information to support justification for exercising the exemption to competition, and a letter for the Secretary to sign notifying Congress of the determination to award a contract under the authority of 41 U.S.C. 253(c)(7).

306.303 Justifications.

306.303–1 Requirements.

(b) Preliminary arrangements or agreements with the proposed contractor shall have no effect on the rationale used to support an acquisition for other than full and open competition.

(f) When a program office desires to obtain certain goods or services by contract without full and open competition, it shall, at the time of forwarding the requisition or request for contract, furnish the contracting office a justification explaining why full and open competition is not feasible. All justifications shall be initially reviewed by the contracting officer.

(1) Justifications in excess of the simplified acquisition threshold shall be in the form of a separate, self-contained document, prepared in accordance with FAR 6.303 and 306.303, and called a "JOFOC" (Justification for Other Than Full and Open Competition). Justifications at or below the simplified acquisition threshold may be in the form of a paragraph or paragraphs contained in the requisition or request for contract.

(2) Justifications, whether over or under the simplified acquisition threshold, shall fully describe what is to be acquired, offer reasons which go beyond inconvenience, and explain why it is not feasible to obtain competition. The justifications shall be supported by verifiable facts rather than mere opinions. Documentation in the justification should be sufficient to permit an individual with technical competence in the area to follow the rationale.

306.303–2 Content.

(a)(1) The program office and name, address, and telephone number of the project officer shall also be included.

(2) This item shall include project identification such as the authorizing program legislation, to include citations or other internal program identification data such as title, contract number, etc.

(3) The description may be in the form of a statement of work, purchase description, or specification. A statement is to be included to explain whether the acquisition is an entity in itself, whether it is one in a series, or part of a related group of acquisitions.

(c) Each JOFOC shall conclude with at least signature lines for the project officer, project officer's immediate supervisor, contracting officer, and approving official.

306.304 Approval of the justification.

(a)(2) The competition advocates are listed in 306.501. This authority is not delegable.

(3) The competition advocate shall exercise this approval authority, except where the individual designated as the competition advocate does not meet the requirements of FAR 6.304 (a)(3)(ii). This authority is not delegable.

(4) The senior procurement executive of the Department is the Assistant Secretary for Management and Budget.

(c) A class justification shall be processed the same as an individual justification.

Subpart 306.5—Competition Advocates

306.501 Requirement.

The Department's competition advocate is the Deputy Assistant Secretary for Grants and Acquisition Management. The competition advocates for the Department's primary contracting officers are as follows:

ACF—Director, Office of Management Services
HCFA—Director, Office of Internal Customer Support
OS—Deputy Assistant Secretary for Grants and Acquisition Management
PSC—Director, Administrative Operations Service
AHRQ—Executive Officer
CDCP—Director, Office of Program Support
FDA—Director, Office of Facilities, Acquisition, and Central Services
HRSA—Associate Administrator for Operations and Management
IHS—Director, Office of Management and Support
NIH—(R&D)—Director, Office of Extramural Research (Other than R&D)—Director, Office of Intramural Research
SAMHSA—Associate Administrator for Management

PART 307—ACQUISITION PLANNING

Subpart 307.1—Acquisition Plans

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307.104 General procedures.
307.105 Contents of written acquisition plans.
307.170 Program training requirements.
307.170–1 Policy exceptions.
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307.7107 Review.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 307.1—Acquisition Planning

307.104 General procedures.

(d) Each contracting activity shall prepare an Annual Acquisition Plan (AAP). The AAP is a macro plan, containing a list of anticipated contract actions over the simplified acquisition threshold and their associated funding, as well as the aggregate planned dollars for simplified acquisitions by quarter, developed for each fiscal year. The AAP shall conform to reasonable budget expectations and shall be reviewed at least quarterly and modified as appropriate. The chief of the contracting office (CCO) shall obtain this information from the program planning/budget office of the contracting activity and use the AAP to provide necessary reports and monitor the workload of the contracting office. For contract actions, the plan shall contain, at a minimum:

(1) A brief description (descriptive title, perhaps one or two sentences if necessary);

(2) Estimated award amount;

(3) Requested award date;

(4) Name and phone number of contact person (usually the project officer);

(5) Other information required for OPDIV needs.

(e) Once the AAP is obtained, the contracting officer/contract specialist shall initiate discussions with the assigned project officer for each planned negotiated acquisition over $100,000 except for:

(1) Acquisitions made under interagency agreements, and

(2) Contract modifications which exercise options, make changes authorized by the Changes clause, or add funds to an incrementally funded contract. (The HCA may prescribe procedures for contract actions not covered by this subpart.)

(f) The purpose of the discussions between the contracting and project officers is to develop an individual acquisition planning schedule and to address the things that will need to be covered in the request for contract (RFC), including clearances, acquisition strategy, sources, etc. The project officer must either have a statement of work (SOW) ready at this time or must discuss in more detail the nature of the services/supplies that will be required.

(g) Standard lead-times for processing various types of acquisitions and deadlines for submission of acceptable RFCs (that is, RFCs which include all required elements such as clearances, funding documents, and an acceptable SOW) for award in a given fiscal year shall be established by the HCA or designee not lower than the CCO.

(h) The outcome of the discussions referenced in paragraph (f) of this section between the project officer and the contracting officer/contracting specialist will be an agreement concerning the dates of significant transaction-specific acquisition milestones, including the date of submission of the RFC to the contracting officer. This milestone schedule document will be prepared with those dates and will be signed by the project officer and the contracting officer. The milestones cannot be revised except by mutual agreement of these same individuals. If the planning schedule indicates the need to obtain approval of a Justification for Other than Full and Open Competition, the CCO must sign the milestone agreement. This document shall be retained in the contract file. All other considerations that will affect the acquisition (technical, business, management) shall be addressed in the RFC (see 307.71).

307.105 Contents of written acquisition plans.

The written acquisition plan required by FAR 7.105 must be contained in the request for contract, as specified in subpart 307.71, and is the final product of the planning process.

307.170 Program training requirements.

(i) All program personnel selected to serve as project officers for HHS contracts shall have successfully completed either the Department's appropriate "Basic Project Officer" course, or an equivalent course (see paragraph (c) of this section).

(b) At least fifty percent of the HHS program personnel performing the function of technical proposal evaluator on a technical evaluation team or panel for any competitively solicited HHS contract shall have successfully completed the appropriate "Basic Project Officer" course, or an equivalent course (see paragraph (c) of this section). This requirement applies to the initial technical proposal evaluation and any subsequent technical evaluations that may be required.

(c) Determination of course equivalency shall be made by the HCA (not delegable) of the cognizant contracting activity. The contracting officer is responsible for ensuring that the project officer and technical proposal evaluators have successfully completed the required training discussed in 307.170–2.

307.170–1 Policy exceptions.

In the event there is an urgent requirement for a specific individual to serve as a project officer and that individual has not successfully completed the prerequisite training course, the HCA (not delegable) may waive the training requirement and authorize the individual to perform the project duties, provided that:

(a) The individual first meets with the cognizant contracting officer to review the DHHS Project Officers' Contracting Handbook," and to discuss the important aspects of the contracting—program office relationship as appropriate to the circumstances; and

(b) The individual attends the next scheduled and appropriate "Basic Project Officer" course.

307.170–2 Training course prerequisites.

(a) *Project officers.* (1) Newly appointed project officers, and project officers with less than three years experience and no previous related training, are required to take the appropriate "Basic Project Officer" course. (The grade level for project officers attending the course should be GS–7 and above.) All project officers are encouraged to take the appropriate "Writing Statements of Work" course.

(2) Project officers with more than three years experience, and project officers with less than three years experience who have successfully completed the appropriate basic course, are qualified (and encouraged) to take the "Advanced Project Officer" course.

(3) Additional information on prerequisites for attendance of these courses may be found in the "DHHS Acquisition Training and Certification Program Handbook."

(b) *Technical proposal evaluators.* Technical proposal evaluators, regardless of experience, are required to take the appropriate "Basic Project Officer" course or its equivalent. Upon successful completion of the basic course, it is recommended that they take the appropriate "Advanced Project Officer" course. Peer and objective reviewers are excluded from these requirements.

Subpart 307.3—Contractor Versus Government Performance

307.302 General.

(a) General Administration Manual (GAM) Chapter 18–10, Commercial-Industrial Activities of the Department of Health and Human Services Providing Products or Services for Government Use, assigns responsibilities for making method-of-performance decisions (contract vs. in-house performance) to various management levels within the Department depending on the dollar amount of capital investment or annual operating costs. It also requires that each operating division (OPDIV) and staff division (STAFFDIV) designate a "Commercial-Industrial Control Officer" (CICO) to be responsible for ensuring compliance with the requirements of the Chapter.

307.303 Determining availability of private commercial sources.

In accordance with the provisions of GAM Chapter 18–10, OPDIVs and STAFFDIVs must prepare and maintain a complete inventory of all individual commercial or industrial activities. They must also conduct periodic reviews of each activity and contract in the inventory to determine if the existing performance, in-house or by contract, continues to be in accordance with the policy guidelines of GAM Chapter 18–10.

307.304 Procedures.

Contracting officers shall ensure that no acquisition action involving a commercial-industrial activity is initiated unless it is in compliance with the requirements of GAM Chapter 18–10. The contracting officer must check each request for contract expected to result in a contract in excess of $100,000 to ensure that it contains a statement as to whether the proposed contract is or is not subject to review under GAM Chapter 18–10 requirements. If the contracting officer has any questions regarding the determination of applicability or nonapplicability, or if the required statement is missing, the

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program office submitting the request for contract should be contacted and the situation rectified. If the issue cannot be resolved with the program office, the contracting office shall refer the matter to the CICO for a final determination. The HCA is responsible for ensuring that contracting activities are in full compliance with FAR Subpart 7.3.

307.307 Appeals.

The review and appeals procedure discussed in FAR 7.307 are addressed in GAM Chapter 18–10.

Subpart 307.70—Considerations in Selecting an Award Instrument

307.7000 Scope of subpart.

This subpart provides guidance on the appropriate selection of award instruments consistent with 31 U.S.C. 6301–6308. This subpart explains the use of the contract as the award instrument for acquisition relationships, and the grant or cooperative agreement as the instrument for assistance relationships. This subpart provides guidance for determining whether to use the acquisition or assistance process to fulfill program needs.

307.7001 Distinction between acquisition and assistance.

(a) 31 U.S.C. 6301–6308 requires the use of contracts to acquire property or services for the direct benefit or use of the Government and grants or cooperative agreements to transfer money, property, services, or anything of value to recipients to accomplish a public purpose of support or stimulation authorized by Federal statute.

(b) A contract is to be used as the legal instrument to reflect a relationship between the Federal Government and a recipient whenever:

(1) The principal purpose of the instrument is the acquisition, by purchase, lease, or barter, of property or services for the direct benefit or use of the Federal Government; *or*

(2) The Department determines in a specific instance that the use of a type of contract is appropriate. That is, it is determined in a certain situation that specific needs can be satisfied best by using the acquisition process. However, this authority does not permit circumventing the criteria for use of acquisition or assistance instruments. Use of this authority is restricted to extraordinary circumstances and only with the prior approval of the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM).

(c) A grant or cooperative agreement is to be used as the legal instrument to reflect a relationship between the Federal Government and a recipient whenever the principal purpose of the relationship is the transfer of money, property, services, or anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute.

(1) A grant is the legal instrument to be used when no substantial involvement is anticipated between the Department and the recipient during performance of the contemplated activity.

(2) A cooperative agreement is the legal instrument to be used when substantial involvement is anticipated between the Department and the recipient during performance of the contemplated activity.

(d) As a general rule, contracts are to be used for the following purposes:

(1) Evaluation (including research of an evaluative nature) of the performance of Government programs or projects or grantee activity initiated by the funding agency for its direct benefit or use.

(2) Technical assistance rendered to the Government, or on behalf of the Government, to any third party, including those receiving grants or cooperative agreements.

(3) Surveys, studies, and research which provide specific information desired by the Government for its direct activities, or for dissemination to the public.

(4) Consulting services or professional services of all kinds if provided to the Government or, on behalf of the Government, to any third party.

(5) Training projects where the Government selects the individuals or specific groups whose members are to be trained or specifies the content of the curriculum (not applicable to fellowship awards.)

(6) Planning for Government use.

(7) Production of publications or audiovisual materials required primarily for the conduct of the direct operations of the Government.

(8) Design or development of items for Government use or pursuant to agency definition or specifications.

(9) Conferences conducted on behalf of the Government.

(10) Generation of management information or other data for Government use.

307.7002 Procedures.

(a) OPDIV program officials should use existing budget and program planning procedures to propose new activities and major changes in ongoing programs. It is the responsibility of these program officials to meet with the HCA and the principal grants management official, or their designees, to distinguish the relationships and determine whether award is to be made through the acquisition process or assistance process. This determination should be made prior to the time when the annual acquisition plan is reviewed and approved so that the plan will reflect all known proposed contract actions. The cognizant contracting officer will confirm the appropriateness of the use of the contract instrument when reviewing the request for contract.

(b) Shifts from one award instrument to another must be fully documented in the appropriate files to show a fundamental change in program purpose that unequivocally justifies the rationale for the shift.

(c) OPDIVs must ensure that the choice of instrument is determined in accordance with 31 U.S.C. 6301–6308 and applicable departmental policies. If, however, there are major individual transactions or programs which contain elements of both acquisition and assistance in such a way that they cannot be characterized as having a principal purpose of one or the other, guidance should be obtained from the DASGAM, through normal channels, before proceeding with a determination.

(d) Any public notice, program announcement, solicitation, or request for applications or proposals must indicate whether the intended relationship will be one of acquisition or assistance and specify the award instrument to be used.

Subpart 307.71—Requests for Contract

307.7100 Scope of subpart.

This subpart prescribes the format and contents of the request for contract (RFC) and provides procedures for its preparation and submission.

307.7101 General.

The program office's preparation of the RFC and submission to the contracting office completes the presolicitation phase of the acquisition planning process and commences the solicitation phase. The RFC is the formal document which initiates the preparation of the solicitation by the contracting office and sets the acquisition process in motion. It is the result of the planning by the project officer and contracting officer and contains much of the pertinent information necessary for the development of a sound, comprehensive solicitation.

307.7102 Procedures.

The program office should submit the RFC to the contracting office no later than the date agreed to by the contracting officer and the project officer in the milestone schedule (see 307.104(h)), unless a revised due date has been established by mutual agreement.

307.7103 Responsibilities.

(a) It is the responsibility of the project officer to prepare the RFC so that it complies with the requirements of this subpart and any OPDIV guidance issued in accordance with this subpart.

(b) Prior to the submission of the RFC to the contracting office, the head of the program office sponsoring the project shall review the RFC to ensure that all required information is provided in the prescribed format, and a technical review of the statement of work has been made. The level and extent of the technical review is to be commensurate with the estimated cost, importance, and complexity of the proposed acquisition, and must be thorough enough to ensure that vague and ambiguous language is eliminated, the statement of work is structured by phases or tasks, if appropriate, and methods are available for assessing the contractor's technical, cost, and delivery performance.

307.7104 Transmittal.

The RFC must be conveyed to the contracting office by use of a covering memorandum or other form of transmittal. The transmittal document must be signed by the head of the sponsoring program office and include both a statement attesting to the conclusiveness of the review described in 307.7103(b) and a list identifying all attachments to the RFC.

307.7105 Format and content.

The Department does not prescribe a standard format for the RFC. A format similar to what is in this section is recommended. However, any document or group of documents will be acceptable as an RFC as long as all of the required information (paragraph (a) of this section), and as much of the optional information (paragraph (b) of this section) as is relevant, is included.

(a) The RFC must include:

(1) *Purpose of the contract.* A brief, general description of the requirement, including the citation of the legislation which authorizes the program or project, and a statement as to the intended purpose/use of the proposed contract.

(2) *Period of performance.* The number of months (or other time period) required for total performance and, if applicable, for each phase of work indicated in the statement of work, as well as the proposed starting date.

(3) *Estimated cost and funds citation.* An estimate of the total cost of the proposed contract and, if applicable, the estimate for each phase indicated in the statement of work. The project officer must provide a cost breakdown of all contributing cost factors, an estimate of the technical staff hours, direct material, subcontracting, travel, etc., and may consult with contracting and cost advisory personnel in developing this information. This section must include the certification of funds availability for the proposed acquisition, along with the appropriation and accounting information citations. When funds for the proposed acquisition are not currently available for obligation but are anticipated, a statement of intent to commit funds from the financial management officer shall be included in lieu of the certification of funds availability. (Contracts cannot be awarded unless funds are available, but see FAR 32.703–2).

(4) *Specification, purchase description, or statement of work.* A description of the work to be performed that may be in the form of a specification, purchase description, or statement of work. Guidance concerning the statement of work and its contents is contained in 307.7106. Use of the specification is primarily limited to supply or service contracts where the material end item or service to be delivered is well defined by the Government. To the maximum extent possible, requirements should be defined as performance-based statements of work that focus on outcomes or results. If the RFC for a service contract is not utilizing a performance-based statement of work, with associated measures and a quality surveillance plan, the rationale for this determination must be documented. If a performance-based service contract is utilized, the RFC must detail the performance standards that must be met, the quality surveillance plan that will be implemented and the performance incentives to be used, if applicable.

(5) *Schedule of deliverables/reporting requirements.* A description of what is to be delivered, including, if applicable, technical and financial progress reports and any final report, and the required date of delivery for each deliverable. Reporting requirements should be tailored to the instant acquisition and should not be unnecessarily extensive or detailed. All delivery and reporting requirements shall include the quantities, the place of delivery, and time of delivery.

(6) *Sources for solicitation.* A list of known potential sources by name, size, type of ownership, and mailing address. The project officer is encouraged to use trade and professional journals and publications and conduct a thorough market research to identify new prospective sources to supplement the list of known sources. Efforts to identify set-aside possibilities, e.g., 8(a), HUBZone, and small business, and efforts to identify sources such as small disadvantaged and women-owned small businesses must be documented.

(7) *Project officer and alternate.* The project officer's name, title, organization, mailing address, and telephone number, along with the same data for the project officer's alternate, and a statement that these individuals have completed the Department's project officer training course (see 307.170)

(b) The RFC must include, if applicable to the acquisition:

(1) *Background and need.* The background, history, and necessity for the proposed contract. This section is to include prior, present, and planned efforts by the program office in the same or related areas, and a description of efforts by other departmental activities and Federal agencies in the same or related program areas, if known. In addition, specific project information, such as the relevance or contribution to overall program objectives, reasons for the need, priority, and project overlap are to be provided.

(2) *Reference materials.* A list, by title and description, of study reports, plans, drawings, and other data to be made available to prospective offerors for use in preparation of proposals and/or the contractor for use in performance of the contract. The project officer must indicate whether this material is currently available or when it will be available, and how it may be accessed by potential offerors.

(3) *Technical evaluation criteria and instructions.* Technical evaluation criteria, which have been developed based on the requirements of the specific project, and any instructions and information which will assist in the preparation of prospective offerors' technical proposals. Evaluation factors may include understanding of the problem, technical approach, experience, personnel, facilities, etc. Criteria areas discussed in the statement of work and the relative order of importance or weights assigned to each of these areas for technical evaluation purposes must be identified.

(4) *Special program clearances or approvals.* Any required clearance or approval. The following special program clearances or approvals should be reviewed for applicability to each

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acquisition. The ones which are applicable should be addressed during the planning discussions between the project officer and contracting officer/contract specialist (see 307.104(f)) and immediate action should be initiated by the project officer to obtain the necessary clearances or approvals. Comprehensive checklists of these and any OPDIV special approvals, clearances, and requirements shall be provided for reference purposes to program offices by the servicing contracting activity. If the approval or clearance has been requested and is being processed at the time of RFC submission, a footnote to this effect, including all pertinent details, must be included in this section.

(i) *Commercial activities.* (OMB Circular No. A–76). A request for contract (RFC) must contain a statement as to whether the proposed solicitation is or is not to be used as part of an OMB Circular No. A–76 cost comparison. (See General Administration Manual (GAM) Chapter 18–10; FAR subpart 7.3, subpart 307.3; OMB Circular No. A–76.)

(ii) *Printing.* The acquisition of printing and high volume duplicating by contract is prohibited unless it is authorized by the Joint Committee on Printing of the U.S. Congress. Procedures to be followed are contained in the "Government Printing and Binding Regulations" and the HHS Printing Management Manual and FAR subpart 8.8.

(iii) *Paperwork Reduction Act.* Under the Paperwork Reduction Act of 1995, a Federal agency shall not collect information or sponsor the collection of information from ten or more persons (other than Federal employees acting within the scope of their employment) unless, in advance, the agency has submitted a request for Office of Management and Budget (OMB) review, to the OMB, and the OMB has approved the proposed collection of information. Procedures for the approval may be obtained by contacting the OPDIV reports clearance officer. (See 5 CFR part 1320).

(iv) *Publications.* All projects that will result in contracts which include publications development (print products, electronic bulletin boards, posting on the internet) require review and approval by the Office of the Assistant Secretary for Public Affairs (OASPA). Form HHS–615, Publication Planning and Clearance Request, must be forwarded to OASPA through the OPDIV public affairs officer. Publications are defined in Chapter 5–00–15 of the Public Affairs Management Manual.

(v) *Public affairs services.* Projects for the acquisition of public affairs services in excess of $5,000 must be submitted to the Office of the Assistant Secretary for Public Affairs (OASPA) for review and approval on Form HHS–524, Request for Public Affairs Services Contract.

(vi) *Audiovisual.* All projects which will result in contracts which include audiovisuals, regardless of the audio, video, or audiovisual medium employed, require review and approval by the Office of the Assistant Secretary for Public Affairs (OASPA). Form HHS–524A, Publication Planning and Clearance Request, must be forwarded to OASPA through the OPDIV public affairs officer. Audiovisuals are defined in chapter 6–00–15 of the Public Affairs Management Manual.

(vii) *Privacy Act (5 U.S.C. 552a).* Whenever the Department contracts for the design, development, operation, or maintenance of a system of records on individuals on behalf of the Department to accomplish a departmental function, the Privacy Act is applicable. The program official, after consultation with the activity's Privacy Act Coordinator and the Office of General Counsel, as necessary, shall include a statement in the request for contract as to the applicability of the Act. Whenever an acquisition is subject to the Act, the program official prepares a "system notice" and has it published in the **Federal Register**. (See HHS Privacy Act regulation, 45 CFR part 5b; FAR subpart 24.1 and subpart 324.1.)

(viii) *Foreign research.* All foreign research contract projects to be conducted in a foreign country and financed by HHS funds (U.S. dollars) must have clearance by the Department of State with respect to consistency with foreign policy objectives. This clearance should be obtained prior to negotiation. Procedures for obtaining this clearance are set forth in the HHS General Administration Manual, Chapter 20–60.

(5) *Identification and disposition of data.* Identification of the data expected to be generated by the acquisition and an indication of whether the data are to be delivered to the Department or to be retained by the contractor is required. The project officer must also include information relative to the use, maintenance, disclosure, and disposition of data. The project officer must include a statement as to whether or not another acquisition, based upon the data generated by the proposed acquisition, is anticipated.

(6) *Government property.* If known, the type of Government property, individual items, and quantities of Government property to be furnished to, or allowed to be acquired by, the resultant contractor should be indicated. The project officer must specify when the Government property is to be made available.

(7) *Special terms and conditions.* Any suggested special terms and conditions not already covered in the statement of work or the applicable contract general provisions is required.

(8) *Justification for other than full and open competition.* If the proposed acquisition is to be awarded using other than full and open competition, a justification prepared in accordance with FAR subpart 6.3 and subpart 306.3 is required.

307.7106 Statement of work.

(a) *General.* A statement of work (SOW) differs from a specification and purchase description primarily in that it describes work or services to be performed in reaching an end result rather than a detailed, well defined description or specification of the end product. The SOW may enumerate or describe the methods (statistical, clinical, laboratory, etc.) that will be used. However, it is preferable for the offeror to propose the method of performing the work. The SOW should specify the desired results, functions, or end items without telling the offeror what has to be done to accomplish those results unless the method of performance is critical or required for the successful performance of the contract. The SOW should be clear and concise and must completely define the responsibilities of the Government and the contractor. The SOW should be worded so as to make more than one interpretation virtually impossible because it has to be read and interpreted by persons of varied backgrounds, such as attorneys, contracting personnel, cost estimators, accountants, scientists, educators, functional specialists, etc. The SOW must clearly define the obligations of both the contractor and the Government so as to protect the interests of both. Ambiguous statements of work can create unsatisfactory performance, delays, and disputes, and can result in higher costs.

(b) *Term (level of effort) vs. completion work statement.* Careful distinctions must be drawn between term (level of effort) SOWs, which essentially require the furnishing of technical effort and which may include a report thereof, and completion type work statements, which require development of tangible items designed to meet specific performance and/or design characteristics. (See FAR 16.306(d) for distinction).

(1) *Term (or level of effort).* A term or level of effort type SOW is appropriate for research where one seeks to discover the feasibility of later development, or to gather general information. A term or level of effort type SOW may only specify that some number of labor-hours be expended on a particular course of research, or that a certain number of tests be run, without reference to any intended conclusion.

(2) *Completion.* A completion type SOW is appropriate to development work where the feasibility of producing an end item is already known. A completion type SOW may describe what is to be achieved through the contracted effort, such as development of new methods, new end items, or other tangible results.

(c) *Phasing.* Individual research, development, or demonstration projects frequently lie well beyond the present state of the art and entail procedures and techniques of great complexity and difficulty. Under these circumstances, a contractor, no matter how carefully selected, may be unable to deliver the desired result. Moreover, the job of evaluating the contractor's progress is often difficult. Such a contract is frequently phased and often divided into stages of accomplishment, each of which must be completed and approved before the contractor may proceed to the next. Phasing makes it necessary to develop methods and controls, including reporting requirements for each phase of the contract and criteria for evaluation of the report submitted, that will provide, at the earliest possible time, appropriate data for making decisions relative to future phases. A phased contract may include stages of accomplishment such as research, development, and demonstration. Within each phase, there may be a number of tasks which should be included in the SOW. When phases of work can be identified, the SOW will provide for phasing and the request for proposals will require the submission of proposed costs by phases. The resultant contract will reflect costs by phases, require the contractor to identify incurred costs by phases, establish delivery schedules by phase, and require the written acceptance of each phase. The provisions of the Limitation of Cost clause shall apply to the estimated cost of each phase. Contractors shall not be allowed to incur costs for phases which are dependent upon successful completion of earlier phases until written acceptance of the prior work is obtained from the contracting officer.

(d) *Elements of the SOW.* The elements of the SOW will vary with the objective, complexity, size, and nature of the acquisition. In general, it should cover the following matters as appropriate.

(1) *A general description of the required objectives and desired results.* Initially, a broad, nontechnical statement of the nature of the work to be performed. This should summarize the actions to be performed by the contractor and the results that the Government expects.

(2) *Background information helpful to a clear understanding of the requirements and how they evolved.* Include a brief historical summary as appropriate and the relationship to overall program objectives.

(3) *A detailed description of the technical requirements.* A comprehensive description of the work to be performed to provide whatever details are necessary for prospective offerors to submit meaningful proposals.

(4) *Subordinate tasks or types of work.* A listing of the various tasks or types of work (it may be desirable in some cases to indicate that this is not all-inclusive). The degree of task breakout is directly dependent on the size and complexity of the work to be performed and the logical groupings. A single cohesive task should not be broken out merely to conform to a format. Indicate whether the tasks are sequential or concurrent for offeror planning purposes.

(5) *Reference material.* All reference material to be used in the conduct of the project that tells how the work is to be carried out must be identified. Applicability should be explained, and a statement made as to where the material can be obtained.

(6) *Level of effort.* When a level of effort is required, the number and type of personnel required should be stated. If known, the type and degree of expertise should be specified.

(7) *Special requirements.* (as applicable). An unusual or special contractual requirement, which would impact on contract performance, should be included as a separate section.

(8) *Deliverables reporting requirements.* All deliverables and/or reports must be clearly and completely described.

307.7107 Review.

Upon receipt of the RFC, the contracting officer shall review its contents to ensure that all pertinent information has been provided by the program office and that it includes an acceptable SOW. If pertinent information is missing or the SOW is inadequate, the contracting officer shall obtain or clarify the information as soon as possible so that the acquisition schedule can be met. If the program office delays furnishing the information or clarification, the contracting officer should notify the head of the sponsoring program office, in writing, of the possible slippage in the acquisition schedule and the need for an expeditious remedy. The contracting officer should also notify the chief of the contracting office. A program office's or project officer's continued failure to adhere to agreed on milestones should also be reported to the head of the contracting activity.

PART 309—CONTRACTOR QUALIFICATIONS

Subpart 309.4—Debarment, Suspension, and Ineligibility

Sec.

309.403 Definitions.
309.404 List of Parties Excluded from Federal Procurement and Nonprocurement Programs.
309.405 Effect of listing.
309.406 Debarment.
309.406–3 Procedures.
309.407 Suspension.
309.407–3 Procedures.
309.470 Reporting of suspected causes of debarment, suspension, or the taking of evasive actions.
309.470–1 Situations where reports are required.
309.470–2 Contents of reports.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 309.4—Debarment, Suspension, and Ineligibility

309.403 Definitions.

Acquiring agency's head or designee, as used in the FAR, shall mean, unless otherwise stated in this subpart, the head of the contracting activity. Acting in the capacity of the acquiring agency's head, the head of the contracting activity may make the required justifications or determinations, and take the necessary actions, specified in FAR 9.405, 9.406 and 9.407 for his or her respective activity, but only after obtaining the written approval of the debarring or suspending official, as the case may be.

Debarring official means the Assistant Secretary for Management and Budget, or his/her designee.

Initiating official means either the contracting officer, the head of the contracting activity, the Deputy Assistant Secretary for Grants and Acquisition Management, or the Inspector General.

Suspending official means the Assistant Secretary for Management and Budget, or his/her designee.

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309.404 List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

(c) The Office of Grants and Acquisition Management (OGAM) shall perform the actions required by FAR 9.404(c).

(4) OGAM shall maintain all documentation submitted by the initiating official recommending the debarment or suspension action and all correspondence and other pertinent documentation generated during the OGAM review.

309.405 Effect of listing.

(a) The head of the contracting activity (HCA) (not delegable) may, with the written concurrence of the debarring or suspending official, make the determinations referenced in FAR 9.405(a), regarding contracts for their respective activities.

(1) If a contracting officer considers it necessary to award a contract, or consent to a subcontract with a debarred or suspended contractor, the contracting officer shall prepare a determination, including all pertinent documentation, and submit it through acquisition channels to the head of the contracting activity. The documentation must include the date by which approval is required and a compelling reason for the proposed action. Some examples of circumstances that may constitute a compelling reason for the award to, or consent to a subcontract with, a debarred or suspended contractor include:

(i) The property or services to be acquired are available only from the listed contractor;

(ii) The urgency of the requirement dictates that the Department deal with the listed contractor; or

(iii) There are other compelling reasons which require business dealings with the listed contractor.

(2) If the HCA decides to approve the requested action, he/she shall request the concurrence of the debarring or suspending official and, if given, shall inform the contracting officer in writing of the decision within the required time period.

309.406 Debarment.

309.406–3 Procedures.

(a) *Investigation and referral.* Whenever an apparent cause for debarment becomes known to an initiating official, that person shall prepare a report incorporating the information required by 309.470–2, if known, and forward it through appropriate channels with a written recommendation, to the debarring official. Contracting officers shall forward their reports in accordance with 309.470–1. The debarring official shall initiate an investigation through such means as he/she deems appropriate.

(b) *Decisionmaking process.* The debarring official shall review the results of the investigation, if any, and make a written determination whether or not debarment procedures are to be commenced. A copy of the determination shall be promptly sent through appropriate channels to the initiating official, and the contracting officer, if necessary. If the debarring official determines to commence debarment procedures, he/she shall, after consultation with the Office of the General Counsel, notify the contractor in accordance with FAR 9.406–3(c). If the proposed action is not based on a conviction or judgement and the contractor's submission in response to the notice raises a genuine dispute over facts material to the proposed debarment, the debarring official shall arrange for fact-finding hearings and take the necessary action specified in FAR 9.406–3(b)(2). The debarring official shall also ensure that written findings of facts are prepared, and shall base the debarment decisions on the facts as found, after considering information and argument submitted by the contractor and any other information in the administrative record. The Office of the General Counsel shall represent the Department at any fact-finding hearing and may present witnesses for HHS and question any witnesses presented by the contractor.

309.407 Suspension.

309.407–3 Procedures.

(a) *Investigation and referral.* Whenever an apparent cause for suspension becomes known to an initiating official, that person shall prepare a report incorporating the information required by 309.470–2, if known, and forward it through appropriate channels, with a written recommendation, to the suspending official. Contracting officers shall forward their reports in accordance with 309.470–1. The suspending official shall initiate an investigation through such means as he/she deems appropriate.

(b) *Decisionmaking process.* The suspending official shall review the results of the investigation, if any, and make a written determination whether or not suspension should be imposed. A copy of this determination shall be promptly sent through appropriate channels to the initiating official and the contracting officer, if necessary. If the suspending official determines to impose suspension, he/she shall, after consultation with the Office of the General Counsel, notify the contractor in accordance with FAR 9.407–3(c). If the action is not based on an indictment, and, subject to the provisions of FAR 9.407–3(b)(2), the contractor's submission in response to the notice raises a genuine dispute over facts material to the suspension, the suspending official shall, after suspension has been imposed, arrange for fact-finding hearings and take the necessary actions specified in FAR 9.407–3(b)(2).

309.470 Reporting of suspected causes for debarment or suspension, or the taking of evasive actions.

309.470–1 Situations where reports are required.

A report incorporating the information required by 309.470–2 shall be forwarded, in duplicate, by the contracting officer through acquisition channels to OGAM when:

(a) A contractor has committed, or is suspected of having committed, any of the acts described in FAR 9.406–2 or FAR 9.407–2; or

(b) A contractor is suspected of attempting to evade the prohibitions of debarment or suspension imposed under this subject, or any other comparable regulation, by changes of address, multiple addresses, formation of new companies, or by other devices.

309.470–2 Contents of reports.

Each report prepared under 309.470–1 shall be coordinated with the Office of the General Counsel and shall include the following information, where available:

(a) Name and address of contractor.

(b) Name of the principal officers, partners, owners, or managers.

(c) All known affiliates, subsidiaries, or parent firms, and the nature of the affiliation.

(d) Description of the contract or contracts concerned, including the contract number, and office identifying numbers or symbols, the amount of each contract, the amount paid the contractor and the amount still due, and the percentage of work completed and to be completed.

(e) The status of vouchers.

(f) Whether contract funds have been assigned pursuant to the Assignment of Claims Act, as amended, (31 U.S.C. 3727, 41 U.S.C. 15), and, if so assigned, the name and address of the assignee and a copy of the assignment.

(g) Whether any other contracts are outstanding with the contractor or any affiliates, and, if so, the amount of the contracts, whether these funds have been assigned pursuant to the Assignment of Claims Act, as amended, (31 U.S.C. 3727, 41 U.S.C. 15), and the amounts paid or due on the contracts.

(h) A complete summary of all available pertinent evidence.

(i) A recommendation as to the continuation of current contracts.

(j) An estimate of damages, if any, sustained by the Government as a result of the action of the contractor, including an explanation of the method used in making the estimate.

(k) The comments and recommendations of the contracting officer and statements regarding whether the contractor should be suspended or debarred, whether any limitations should be applied to the action, and the period of any proposed debarment.

(l) As an enclosure, a copy of the contract(s) or pertinent excerpts therefrom, appropriate exhibits, testimony or statements of witnesses, copies of assignments, and other relevant documentation or a written summary of any information for which documentation is not available.

PART 313—SIMPLIFIED ACQUISITION PROCEDURES

Subpart 313.3—Simplified Acquisition Methods

Sec.
313.301 Governmentwide commercial purchase card.
313.303 Blanket purchase agreements (BPAs).
313.303–5 Purchases under BPAs.
313.305 Imprest funds and third party drafts.
313.305–1 General.
313.306 SF 44, Purchase Order—Invoice—Voucher.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 313.3—Simplified Acquisition Methods.

313.301 Governmentwide commercial purchase card.

(b) The Department has issued general guidance concerning the use of governmentwide commercial purchase cards, and has authorized the OPDIVs to establish procedures for the use, administrative and management controls, and training necessary to comply with FAR 13.301.

313.303 Blanket Purchase Agreements (BPAs).

313.303–5 Purchases under BPAs.

(e)(5) Delivery documents, invoices, etc., signed by the Government employee receiving the item or service will be forwarded to the fiscal office or other paying office as designated by the OPDIV. Payment will be made on the basis of the signed document, invoice, etc. Contracting offices will ensure that established procedures allowing for availability of funds are in effect prior to placement of orders.

313.305 Imprest funds and third party drafts.

313.305–1 General.

Requests to establish imprest funds shall be made to the responsible fiscal office. At larger activities where the cashier may not be conveniently located near the purchasing office, a Class C Cashier may be installed in the purchasing office. Documentation of cash purchases shall be in accordance with instructions contained in the HHS Voucher Audit Manual Part 1, Chapter 1–10.

313.306 SF 44, Purchase Order—Invoice—Voucher.

(d) Since the Standard Form (SF) 44 is an accountable form, a record shall be maintained of serial numbers of the form, to whom issued, and date issued. SF 44's shall be kept under adequate lock and key to prevent unauthorized use. A reservation of funds shall be established to cover total anticipated expenditures prior to use of the SF 44.

PART 314—SEALED BIDDING

Subpart 314.2—Solicitation of Bids

Sec.
314.202 General rules for solicitation of bids.
314.202–7 Facsimile bids.
314.213 Annual submission of representations and certifications.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.
314.404–1 Cancellation of invitations after opening.
314.407 Mistakes in bids.
314.407–3 Other mistakes disclosed before award.
314.407–4 Mistakes after award.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 314.2—Solicitation of Bids

314.202 General rules for solicitation of bids.

314.202–7 Facsimile bids.

If the head of the contracting activity (HCA) (not delegable) has determined that the contracting activity will allow use of facsimile bids and proposals, the HCA shall prescribe internal procedures, in accordance with the FAR, to ensure uniform processing and control.

314.213 Annual submission of representations and certifications.

Each HCA (not delegable) shall determine whether the contracting activity will allow use of the annual submission of representations and certifications by bidders.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.

314.404–1 Cancellation of invitations after opening.

The chief of the contracting office (CCO) (not delegable) shall make the determinations required to be made by the agency head in FAR 14.404–1.

314.407 Mistakes in bids.

314.407–3 Other mistakes disclosed before award.

(e) Authority has been delegated to the Departmental Protest Control Officer, Office of Acquisition Management, Office of Grants and Acquisition Management, to make administrative determinations in connection with mistakes in bid alleged after opening and before award. This authority may not be redelegated.

(f) Each proposed determination shall have the concurrence of the Chief, Business Law Branch, Business and Administrative Law Division, Office of General Counsel.

(i) Doubtful cases shall not be submitted by the contracting officer directly to the Comptroller General, but shall be submitted to the Departmental Protest Control Officer.

314.407–4 Mistakes after award.

(c) Authority has been delegated to the Departmental Protest Control Officer to make administrative determinations in connection with mistakes in bid alleged after award. This authority may not be redelegated.

(d) Each proposed determination shall have the concurrence of the Chief, Business Law Branch, Business and Administrative Law Division, Office of the General Counsel.

PART 315—CONTRACTING BY NEGOTIATION

Subpart 315.2—Solicitation and Receipt of Proposals and Information

Sec.
315.204 Contract format.
315.204–5 Part IV—Representations and instructions.
315.208 Submission, modification, revision, and withdrawal of proposals.
315.209 Solicitation provisions and contract clauses.

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Subpart 315.3—Source Selection

315.305 Proposal evaluation.
315.306 Exchanges with offerors after receipt of proposals.
315.307 Proposal revisions.
315.370 Finalization of details with the selected source.
315.371 Contract preparation and award.
315.372 Preparation of negotiation memorandum.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.
315.404–2 Information to support proposal analysis.
315.404–4 Profit.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.
315.606 Agency procedures.
315.606–1 Receipt and initial review.
315.609 Limited use of data.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 315.2—Solicitation and Receipt of Proposals and Information

315.204 Contract format.

315.204–5 Part IV—Representations and instructions.

(a) *Section K, Representations, certifications, and other statements of offerors.*

(1) This section shall begin with the following and continue with the applicable representations and certifications:

To Be Completed by the Offeror: (The Representations and Certifications must be executed by an individual authorized to bind the offeror.) The offeror makes the following Representations and Certifications as part of its proposal (check or complete all appropriate boxes or blanks on the following pages).

(Name of Offeror)

(RFP No.)

(Signature of Authorized Individual)

(Date)

(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

(c) *Section M, Evaluation factors for award.*

(1) *General.* (i) The evaluation factors must be developed by the project officer and submitted to the contracting officer in the request for contract (RFC) for inclusion in the request for proposal (RFP). Development of these factors and the assignment of the relative importance or weight to each require the exercise of judgment on a case-by-case basis because they must be tailored to the requirements of the individual acquisition. Since the factors will serve as a standard against which all proposals will be evaluated, it is imperative that they be chosen carefully to emphasize those considered to be critical in the selection of a contractor.

(ii) The finalized evaluation factors cannot be changed except by a formal amendment to the RFP issued by the contracting officer. No factors other than those set forth in the RFP shall be used in the evaluation of proposals.

(2) *Review of evaluation factors.*

(i) The evaluation factors should be reviewed by the contracting officer in terms of the work statement. This review is not intended to dictate technical requirements to the program office or project officer, but rather to ensure that the evaluation factors are clear, concise, and fair so that all potential offerors are fully aware of the bases for proposal evaluation and are given an equal opportunity to compete.

(ii) The project officer and the contracting officer should then review the evaluation factors together to ascertain the following:

(A) The factors are described in sufficient detail to provide the offerors (and evaluators) with a total understanding of the factors to be involved in the evaluation process;

(B) The factors address the key programmatic concerns which the offerors must be aware of in preparing proposals;

(C) The factors are specifically applicable to the instant acquisition and are not merely restatements of factors from previous acquisitions which are not relevant to this acquisition; and

(D) The factors are selected to represent only the significant areas of importance which must be emphasized rather than a multitude of factors. (All factors tend to lose importance if too many are included. Using too many factors will prove as detrimental as using too few.)

(3) *Examples of topics that form a basis for evaluation factors.* Typical examples of topics that form a basis for the development of evaluation factors are listed in the following paragraphs. These examples are intended to assist in the development of actual evaluation factors for a specific acquisition and should only be used if they are applicable to that acquisition. They are not to be construed as actual examples of evaluation factors to be included in the RFP.

(i) Understanding of the problem and statement of work:

(ii) Method of accomplishing the objectives and intent of the statement of work;

(iii) Soundness of the scientific or technical approach for executing the requirements of the statement of work (to include, when applicable, preliminary layouts, sketches, diagrams, other graphic representations, calculations, curves, and other data necessary for presentation, substantiation, justification, or understanding of the approach);

(iv) Special technical factors, such as experience or pertinent novel ideas in the specific branch of science or technology involved;

(v) Feasibility and/or practicality of successfully accomplishing the requirements (to include a statement and discussion of anticipated major difficulties and problem areas and recommended approaches for their resolution);

(vi) Availability of required special research, test, and other equipment or facilities;

(vii) Managerial capability (ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources, and to successfully manage the project, including subcontractor and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous experience);

(viii) Availability, qualifications, experience, education, and competence of professional, technical, and other personnel, to include proposed subcontractors and consultants (as evidenced by resumes, endorsements, and explanations of previous efforts);

(ix) Soundness of the proposed staff time or labor hours, propriety of personnel classifications (professional, technical, others), necessity for type and quantity of material and facilities proposed, validity of proposed subcontracting, and necessity of proposed travel;

(x) Quality of offeror's past performance on recent projects of similar size and scope; and

(xi) Extent of proposed participation of small disadvantaged business concerns in performance of the contract.

315.208 Submission, modification, revision, and withdrawal of proposals.

(b) When the head of the contracting activity (HCA) for a health agency determines that certain classes of biomedical or behavioral research and development acquisitions should be subject to conditions other than those specified in FAR 52.215–1(c)(3), the HCA may authorize the use of the provision at 352.215–70 in addition to the provision at FAR 52.215–1. This is an authorized deviation.

(2) When the provision at 352.215–70 is included in the solicitation and a proposal is received after the exact time specified for receipt, the contracting officer, with the assistance of cost and technical personnel, shall make a written determination as to whether the proposal meets the requirements of the provision at 352.215–70 and, therefore, can be considered.

315.209 Solicitation provisions and contract clauses.

(a) Paragraph (e) of the provision at 352.215–1 shall be used in place of that specified at FAR 52.215–1(e). This is an authorized deviation.

(g) If the head of the contracting activity (HCA)(not delegable) has determined that the contracting activity will allow the use of the annual submission of representations and certifications by offerors, the provisions of FAR 14.213 shall be followed.

Subpart 315.3—Source Selection

315.305 Proposal evaluation.

(a)(1) *Cost or price evaluation.* The contracting officer shall evaluate business proposals adhering to the requirements for cost or price analysis included in FAR 15.404. The contracting officer must determine the extent of analysis in each case depending on the amount of the proposal, the technical complexity, and related cost or price. The contracting officer should request the project officer to analyze items such as the number of labor hours proposed for various labor categories; the mix of labor hours and categories of labor in relation to the technical requirements of the project; the kinds and quantities of material, equipment, and supplies; types, numbers and hours/days of proposed consultants; logic of proposed subcontracting; analysis of the travel proposed including number of trips, locations, purpose, and travelers; and kinds and quantities of information technology. The project officer shall provide his/her opinion as to whether these elements are necessary and reasonable for efficient contract performance. Exceptions to proposed elements shall be supported by adequate rationale to allow for effective negotiations or award if discussions are not conducted. The contracting officer should also request the assistance of a cost/price analyst when considered necessary. In all cases, the negotiation memorandum must include the rationale used in determining that the price or cost is fair and reasonable.

(2) *Past performance evaluation.* When evaluating past performance, the contracting officer is responsible for conducting reference checks to obtain information concerning the performance history of offerors. The contracting officer may require the assistance of the project officer as well as other Government technical personnel in performing this function.

(3) *Technical evaluation.*

(i) Technical evaluation plan.

(A) A technical evaluation plan may be required by the contracting officer, at his/her discretion, when an acquisition is sufficiently complex as to warrant a formal plan.

(B) The technical evaluation plan should include at least the following:

(*1*) A list of recommended technical evaluation panel members, their organizations, a list of their major consulting clients (if applicable), their qualifications, and curricula vitae (if applicable);

(*2*) A justification for using non-Government technical evaluation panel members. (Justification is not required if non-Government evaluators will be used in accordance with standard contracting activity procedures or policies);

(*3*) A statement that there is no apparent or actual conflict of interest regarding any recommended panel member;

(*4*) A copy of each rating sheet, approved by the contracting officer, to be used to assure consistency with the evaluation criteria; and

(*5*) A brief description of the general evaluation approach.

(C) The technical evaluation plan must be signed by an official within the program office in a position at least one level above the project officer, or in accordance with contracting activity procedures.

(D) The technical evaluation plan should be submitted to the contracting officer for review and approval before the solicitation is issued. The contracting officer shall make sure that the significant factors and subfactors relating to the evaluation are reflected in the evaluation criteria when conducting the review of the plan.

(ii) Technical evaluation panel.

(A) *General.* (*1*) A technical evaluation panel is required for all acquisitions subject to this subpart which are expected to exceed $500,000 and in which technical evaluation is considered a key element in the award decision. The contracting officer has the discretion to require a technical evaluation panel for acquisitions not exceeding $500,000 based on the complexity of the acquisition.

(*2*) The technical evaluation process requires careful consideration regarding the size, composition, expertise, and function of the technical evaluation panel. The efforts of the panel can result in the success or failure of the acquisition.

(B) *Role of the project officer.* (*1*) The project officer is the contracting officer's technical representative for the acquisition action. The project officer may be a voting member of the technical evaluation panel, and may also serve as the chairperson of the panel, unless he/she is prohibited by law or contracting activity procedures to do so.

(*2*) The project officer is responsible for recommending panel members who are knowledgeable in the technical aspects of the acquisition and who are competent to identify strengths and weaknesses of the various proposals. The program training requirements specified in 307.170 must be adhered to when selecting prospective panel members (government employees).

(*3*) The project officer shall ensure that persons possessing expertise and experience in addressing issues relative to sex, race, national origin, and handicapped discrimination are included as panel members in acquisitions which address those issues. The intent is to balance the composition of the panel so that qualified and concerned individuals may provide insight to other panel members regarding ideas for, and approaches to be taken in, the evaluation of proposals.

(*4*) The project officer is to submit the recommended list of panel members to an official within the program office in a position at least one level above the project officer, or in accordance with contracting activity procedures. This official will review the recommendations and select the chairperson.

(*5*) The project officer shall arrange for adequate and secure working space for the panel.

(C) *Role of the contracting officer.* (*1*) The term "contracting officer," as used in this subpart, may be the contracting officer or his/her designated representative within the contracting office.

(*2*) The contracting officer shall not serve as a member of the technical evaluation panel but should be available to:

(*i*) Address the initial meeting of the technical evaluation panel;

(*ii*) Provide assistance to the evaluators as required; and

(*iii*) Ensure that the scores adequately reflect the written technical report comments.

(D) *Conflict of interest.* (*1*) If a panel member has an actual or apparent conflict of interest related to a proposal

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the evaluation. The contracting officer shall provide written guidance to the panel if he/she is unable to attend the initial panel meeting. The guidance should include:

(*1*) Explanation of conflicts of interest;

(*2*) The necessity to read and understand the solicitation, especially the statement of work and evaluation criteria, prior to reading the proposals;

(*3*) The need for evaluators to restrict the review to only the solicitation and the contents of the technical proposals;

(*4*) The need for each evaluator to review all the proposals;

(*5*) The need to watch for ambiguities, inconsistencies, errors, and deficiencies which should be surfaced during the evaluation process;

(*6*) An explanation of the evaluation process and what will be expected of the evaluators throughout the process;

(*7*) The need for the evaluators to be aware of the requirement to have complete written documentation of the individual strengths and weaknesses which affect the scoring of the proposals; and

(*8*) An instruction directing the evaluators that, until the award is made, information concerning the acquisition must not be disclosed to any person not directly involved in the evaluation process.

(v) Rating and ranking of proposals. The evaluators will individually read each proposal, describe tentative strengths and weaknesses, and independently develop preliminary scores in relation to each evaluation factor set forth in the solicitation. After this has been accomplished, the evaluators shall discuss in detail the individual strengths and weakness described by each evaluator and, if possible, arrive at a common understanding of the major strengths and weaknesses and the potential for correcting each offeror's weakness(es). Each evaluator will score each proposal, and then the technical evaluation panel will collectively rank the proposals. Generally, ranking will be determined by adding the numerical scores assigned to the evaluation factors and finding the average for each offeror. The evaluators should then identify whether each proposal is acceptable or unacceptable. Predetermined cutoff scores shall not be employed.

(vi) Technical evaluation report. A technical evaluation report shall be prepared and furnished to the contracting officer by the chairperson and maintained as a permanent record in the contract file. The report must reflect the ranking of the proposals and identify each proposal as acceptable or unacceptable. The report must also include a narrative evaluation specifying the strengths and weaknesses of each proposal, a copy of each signed rating sheet, and any reservations, qualifications, or areas to be addressed that might bear upon the selection of sources for negotiation and award. Concrete technical reasons supporting a determination of unacceptability with regard to any proposal must be included. The report should also include specific points and questions which are to be raised in discussions or negotiations.

315.306 Exchanges with offerors after receipt of proposals.

(d) *Exchanges with offerors after establishment of the competitive range.* The contracting officer and project officer should discuss the uncertainties and/or deficiencies that are included in the technical evaluation report for each proposal in the competitive range. Technical questions should be developed by the project officer and/or the technical evaluation panel and should be included in the technical evaluation report. The management, past performance and cost or price questions should be prepared by the contracting officer with assistance from the project officer and/or panel as required. The method of requesting offerors in the competitive range to submit the additional information will vary depending on the complexity of the questions, the extent of additional information requested, the time needed to analyze the responses, and the time frame for making the award. However, to the extent practicable, all questions and answers should be in writing. Each offeror in the competitive range shall be given an equitable period of time for preparation of responses to questions to the extent practicable. The questions should be developed so as to disclose the ambiguities, uncertainties, and deficiencies of the offeror.

315.307 Proposal revisions.

(b) Final proposal revisions are subject to a final evaluation of price or cost and other salient factors by the contracting officer and project officer with assistance from a cost/price analyst, and an evaluation of technical factors by the technical evaluation panel, as necessary. Proposals may be technically rescored and reranked by the technical evaluation panel and a technical evaluation report prepared. To the extent practicable, the evaluation shall be performed by the same evaluators who reviewed the original proposals. A final evaluation of past performance will be made by the contracting officer and project officer. The technical evaluation panel may be involved in the final evaluation of past performance if the panel is comprised solely of Government personnel.

315.370 Finalization of details with the selected source.

(a) After selection of the successful proposal, finalization of details with the selected offeror may be conducted if deemed necessary. However, no factor which could have any effect on the selection process may be introduced after the common cutoff date for receipt of final proposal revisions. The finalization process shall not in any way prejudice the competitive interest or rights of the unsuccessful offerors. Finalization of details with the selected offeror shall be restricted to definitizing the final agreement on terms and conditions, assuming none of these factors were involved in the selection process.

(b) Caution must be exercised by the contracting officer to insure that the finalization process is not used to change the requirements contained in the solicitation, nor to make any other changes which would impact on the source selection decision. Whenever a material change occurs in the requirements, the competition must be reopened and all offerors submitting final proposal revisions must be given an opportunity to resubmit proposals based on the revised requirements. Whenever there is a question as to whether a change is material, the contracting officer should obtain the advice of technical personnel and legal counsel before reopening the competition. Significant changes in the offeror's cost proposal may also necessitate a reopening of competition if the changes alter the factors involved in the original selection process.

(c) Should finalization details beyond those specified in paragraph (a) of this section be required for any reason, discussions must be reopened with all offerors submitting final proposal revisions.

(d) Upon finalization of details, the contracting officer should obtain a confirmation letter from the successful offeror which includes any revisions to the technical proposal, the agreed to price or cost, and, as applicable, a certificate of current cost or pricing data.

315.371 Contract preparation and award.

(a) The contracting officer must perform the following actions after finalization details have been completed:

under evaluation, he/she shall be removed from the panel and replaced with another evaluator. If a suitable replacement is not available, the panel shall perform the review without a replacement.

(*2*) For the purposes of this subpart, conflicts of interest are defined in the Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635), Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (5 CFR part 5501), and the Procurement Integrity Act. For outside evaluators serving on the technical evaluation panel, see paragraph (a)(3)(ii)(F) of this section.

(E) *Continuity of evaluation process.* (*1*) The technical evaluation panel is responsible for evaluating the original proposals, making recommendations to the chairperson regarding weaknesses and deficiencies of proposals, and, if required by the contracting officer, assisting the contracting officer during communications and discussions, and reviewing supplemental, revised and/or final proposal revisions. To the extent possible, the same evaluators should be available throughout the entire evaluation and selection process to ensure continuity and consistency in the treatment of proposals. The following are examples of circumstances when it would not be necessary for the technical evaluation panel to evaluate revised proposals submitted during the acquisition:

(*i*) The answers to questions do not have a substantial impact on the proposal;

(*ii*) Final proposal revisions are not materially different from the original proposals; or

(*iii*) The rankings of the offerors are not affected because the revisions to the proposals are relatively minor.

(*2*) The chairperson, with the concurrence of the contracting officer, may decide not to have the panel evaluate the revised proposals. Whenever this decision is made, it must be fully documented by the chairperson and approved by the contracting officer.

(*3*) When technical evaluation panel meetings are considered necessary by the contracting officer, the attendance of evaluators is mandatory. When the chairperson determines that an evaluator's failure to attend the meetings is prejudicial to the evaluation, the chairperson shall remove and/or replace the individual after discussing the situation with the contracting officer and obtaining his/her concurrence and the approval of the official responsible for appointing the panel members.

(*4*) Whenever continuity of the evaluation process is not possible, and either new evaluators are selected or a reduced panel is decided upon, each proposal which is being reviewed at any stage of the acquisition shall be reviewed at that stage by all members of the revised panel unless it is impractical to do so because of the receipt of an unusually large number of proposals.

(F) *Use of outside evaluators.* (*1*) The National Institutes of Health (NIH) and the Substance Abuse and Mental Health Services Administration (SAMHSA) are required to have a peer review of research and development contracts in accordance with Public Law 93–352 as amended by Public Law 94–63; 42 U.S.C. 289 a and 42 U.S.C. 290aa–3 respectively. This legislation requires peer review of projects and proposals, and not more than one-fourth of the members of a peer review group may be officers or employees of the United States. NIH and SAMHSA are therefore exempt from the provisions of 315.305(a)(3)(ii) to the extent that 42 U.S.C. 289a and 290aa–3 apply. Conflicts of interest are addressed at 42 CFR part 52h. Other agencies subject to statutory scientific peer review requirements are also exempt from the requirements of paragraph (a)(3)(ii) of this section to the extent that these requirements are inconsistent with their legislative requirements.

(*2*) In general, decisions to disclose proposals outside the Government for evaluation purposes shall be made by the official responsible for appointing panel members for the acquisition, after consultation with the contracting officer and in accordance with operating division procedures. The decision to disclose either a solicited or unsolicited proposal outside the Government for the purpose of obtaining an evaluation shall takes into consideration the avoidance of organizational conflicts of interest and any competitive relationship between the submitter of the proposal and the prospective evaluator(s).

(*3*) When it is determined to disclose a solicited proposal outside the Government for evaluation purposes, the following or similar conditions shall be included in the written agreement with evaluator(s) prior to disclosure:

Conditions for Evaluating Proposals

The evaluator agrees to use the data (trade secrets, business data, and technical data) contained in the proposal only for evaluation purposes.

The foregoing requirement does not apply to data obtained from another source without restriction.

Any notice or legend placed on the proposal by either the Department or the submitter of the proposal shall be applied to any reproduction or abstract provided to the evaluator or made by the evaluator. Upon completion of the evaluation, the evaluator shall return the Government furnished copy of the proposal or abstract, and all copies thereof, to the Departmental office which initially furnished the proposal for evaluation.

Unless authorized by the Department's initiating office, the evaluator shall not contact the submitter of the proposal concerning any aspects of its contents.

The evaluator is obligated to obtain commitments from its employees and subcontractors, as necessary, to effect the purposes of these conditions.

(iii) Receipt of proposals.

(A) After the closing date set by the solicitation for the receipt of proposals, the contracting officer will use a transmittal memorandum to forward the technical proposals to the project officer or chairperson for evaluation. The business proposals will be retained by the contracting officer for evaluation.

(B) The transmittal memorandum shall include at least the following:

(*1*) A list of the names of the organizations submitting proposals;

(*2*) A reference to the need to preserve the integrity of the source selection process;

(*3*) A statement that only the contracting officer is to conduct discussions.

(*4*) A requirement for a technical evaluation report in accordance with paragraph (a)(3)(vi) of this section; and

(*5*) The establishment of a date for receipt of the technical evaluation report.

(iv) Convening the technical evaluation panel.

(A) Normally, the technical evaluation panel will convene to evaluate the proposals. However, there may be situations when the contracting officer determines that it is not feasible for the panel to convene. Whenever this decision is made, care must be taken to assure that the technical review is closely monitored to produce acceptable results.

(B) When a panel is convened, the chairperson is responsible for the control of the technical proposals provided to him/her by the contracting officer for use during the evaluation process. The chairperson will generally distribute the technical proposals prior to the initial panel meeting and will establish procedures for securing the proposals whenever they are not being evaluated to insure their confidentiality. After the evaluation is complete, all proposals must be returned to the contracting officer by the chairperson.

(C) The contracting officer shall address the initial meeting of the panel and state the basic rules for conducting

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(1) Prepare the negotiation memorandum in accordance with 315.372;

(2) Prepare the contract containing all agreed to terms and conditions and clauses required by law or regulation;

(3) Include in the contract file the pertinent documents referenced in FAR 4.803; and

(4) Obtain the appropriate approval of the proposed contract award(s) in accordance with subpart 304.71 and contracting activity procedures.

(b) After receiving the required approvals, the contract should be transmitted to the prospective contractor for signature. The prospective contractor must be informed that the contract is not effective until accepted by the contracting officer.

(c) The contract shall not be issued until the finance office certifies that the funds are available for obligation.

315.372 Preparation of negotiation memorandum.

The negotiation memorandum or summary of negotiations is a complete record of all actions leading to award of a contract and is prepared by the contract negotiator to support the source selection decision discussed in FAR 15.308. It should be in sufficient detail to explain and support the rationale, judgments, and authorities upon which all actions were predicated. The memorandum will document the negotiation process and reflect the negotiator's actions, skills, and judgments in concluding a satisfactory agreement for the Government. Negotiation memorandums shall contain discussion of the following or a statement of nonapplicability; however, information already contained in the contract file need not be reiterated. A reference to the document which contains the required information is acceptable.

(a) *Description of articles and services and period of performance.* A description of articles and services, quantity, unit price, total contract amount, and period of contract performance should be set forth (if Supplemental Agreement—show previous contract amount as revised, as well as information with respect to the period of performance).

(b) *Acquisition planning.* Summarize or reference any acquisition planning activities that have taken place.

(c) *Synopsis of acquisition.* A statement as to whether the acquisition has or has not been publicized in accordance with FAR Subpart 5.2. A brief statement of explanation should be included with reference to the specific basis for exemption under the FAR, if applicable.

(d) *Contract type.* Provide sufficient detail to support the type of contractual instrument recommended for the acquisition. If the contract is a cost-sharing type, explain the essential cost-sharing features.

(e) *Extent of competition.* The extent to which full and open competition was solicited and obtained must be discussed. The discussion shall include the date of solicitation, sources solicited, and solicitation results. If a late proposal was received, discuss whether or not the late proposal was evaluated and the rationale for the decision.

(f) *Technical evaluation.* Summarize or reference the results presented in the technical evaluation report.

(g) *Business evaluation.* Summarize or reference results presented in the business report.

(h) *Past performance.* Summarize or reference results of past performance evaluation and reference checks.

(i) *Competitive range (if applicable).* Describe how the competitive range was determined and state the offerors who were included in the competitive range and the ones who were not.

(j) *Cost breakdown and analysis.* Include a complete cost breakdown together with the negotiator's analysis of the estimated cost by individual cost elements. The negotiator's analysis should contain information such as:

(1) A comparison of cost factors proposed in the instant case with actual factors used in earlier contracts, using the same cost centers of the same supplier or cost centers of other sources having recent contracts for the same or similar item.

(2) Any pertinent Government-conducted audit of the proposed contractor's record of any pertinent cost advisory report.

(3) Any pertinent technical evaluation inputs as to necessity, allocability and reasonableness of labor, material and other direct expenses.

(4) Any other pertinent information to fully support the basis for and rationale of the cost analysis.

(5) If the contract is an incentive type, discuss all elements of profit and fee structure.

(6) A justification of the reasonableness of the proposed contractor's estimated profit or fixed fee, considering the requirements of FAR 15.404–4 and HHSAR 315.404–4.

(k) *Cost realism.* Describe the cost realism analysis performed on proposals.

(l) *Government-furnished property and Government-provided facilities.* With respect to Government-furnished or Government-provided facilities, equipment, tooling, or other property, include the following:

(1) Where no property is to be provided, a statement to that effect.

(2) Where property is to be provided, a full description, the estimated dollar value, the basis of price comparison with competitors, and the basis of rental charge, if rental is involved.

(3) Where the furnishing of any property or the extent has not been determined and is left open for future resolution, a detailed explanation.

(m) *Negotiations.* Include a statement as to the date and place negotiations were conducted, and identify members of both the Government and contractor negotiating teams by area of responsibility. Include negotiation details relative to the statement of work, terms and conditions, and special provisions. The results of cost or price negotiations must include the information required by FAR 31.109 and 15.406–3. In addition, if cost or pricing data was required to be submitted, the negotiation record must also contain the extent to which the contracting officer relied upon the factual cost or pricing data submitted and used in negotiating the cost or price.

(n) *Other considerations.* Include coverage of areas such as:

(1) Financial data with respect to a contractor's capacity and stability.

(2) Determination of contractor responsibility.

(3) Details as to why the method of payment, such as progress payment, advance payment, etc., is necessary. Also cite any required D & F's.

(4) Information with respect to obtaining of a certificate of current cost or pricing data.

(5) Other required special approvals.

(6) If the contract represents an extension of previous work, the status of funds and performance under the prior contract(s) should be reflected. Also, a determination should be made that the Government has obtained enough actual or potential value from the work previously performed to warrant continuation with the same contractor. (Project officer should furnish the necessary information.)

(7) If the contract was awarded by full and open competition, state where the unsuccessful offerors' proposals are filed.

(8) State that equal opportunity provisions of the proposed contract have been explained to the contractor, and it is aware of its responsibilities. Also state whether or not a clearance is required.

(9) If the contract is for services, a statement must be made, in accordance with FAR 37.103, that the services to be acquired are nonpersonal in nature.

(o) *Terms and conditions.* Identify the general and special clauses and conditions that are contained in the contract, such as option arrangements, incremental funding, anticipatory costs, deviations from standard clauses, etc. The basis and rationale for inclusion of any special terms and conditions must be stated and, where applicable, the document which granted approval for its use identified.

(p) *Recommendation.* A brief statement setting forth the recommendations for award.

(q) *Signature.* The memorandum must be signed by the contract negotiator who prepared the memorandum.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.

315.404–2 Information to support proposal analysis.

(a)(2) When some or all information sufficient to determine the reasonableness of the proposed cost or price is already available or can be obtained by phone from the cognizant audit agency, contracting officers may request less-than-complete field pricing support (specifying in the request the information needed) or may waive in writing the requirement for audit and field pricing support by documenting the file to indicate what information is to be used instead of the audit report and the field pricing report.

(3) When initiating audit and field pricing support, the contracting officer shall do so by sending a request to the cognizant administrative contracting officer (ACO), with an information copy to the cognizant audit office. When field pricing support is not available, the contracting officer shall initiate an audit by sending, in accordance with agency procedures, two (2) copies of the request to the OIG Office of Audits' Regional Audit Director. In both cases, the contracting officer shall, in the request:

(i) Prescribe the extent of the support needed;

(ii) State the specific areas for which input is required;

(iii)Include the information necessary to perform the review (such as the offeror's proposal and the applicable portions of the solicitation, particularly those describing requirements and delivery schedules);

(iv) Provide the complete address of the location of the offeror's financial records that support the proposal;

(v) Identify the office having audit responsibility if other than the HHS Regional Audit Office; and

(vi) Specify a due date for receipt of a verbal report to be followed by a written audit report. (If the time available is not adequate to permit satisfactory coverage of the proposal, the auditor shall so advise the contracting officer and indicate the additional time needed.) One copy of the audit request letter that was submitted to the Regional Audit Director and a complete copy of the contract price proposal shall be submitted to OIG/OA/DAC. Whenever, an audit review has been conducted by the Office of Audits, two (2) copies of the memorandum of negotiation shall be forwarded to OIG/OA/DAC by the contracting officer.

315.404–4 Profit.

(b) *Policy.* (1) The structured approach for determining profit or fee (hereafter referred to as profit) provides contracting officers with a technique that will ensure consideration of the relative value of the appropriate profit factors described in paragraph (d) of this section in the establishment of a profit objective for the conduct of negotiations. The contracting officer's analysis of these profit factors is based on information available to him/her prior to negotiations. The information is furnished in proposals, audit data, assessment reports, preaward surveys and the like. The structured approach also provides a basis for documentation of this objective, including an explanation of any significant departure from this objective in reaching an agreement. The extent of documentation should be directly related to the dollar value and complexity of the proposed acquisition. Additionally, the negotiation process does not require agreement on either estimated cost elements or profit elements. The profit objective is a part of an overall negotiation objective which, as a going-in objective, bears a distinct relationship to the cost objective and any proposed sharing arrangement. Since profit is merely one of several interrelated variables, the Government negotiator generally should not complete the profit negotiation without simultaneously agreeing on the other variables. Specific agreement on the exact weights or values of the individual profit factors is not required and should not be attempted.

(ii) The profit-analysis factors set forth at FAR 15.404–4(d) shall be used for establishing profit objectives under the following listed circumstances. Generally, it is expected that this method will be supported in a manner similar to that used in the structured approach (profit factor breakdown and documentation of the profit objective); however, factors within FAR 15.404–4(d) considered inapplicable to the acquisition will be excluded from the profit objective.

(A) Contracts not expected to exceed $100,000;

(B) Architect-engineer contracts;

(C) Management contracts for operations and/or maintenance of Government facilities;

(D) Construction contracts;

(E) Contracts primarily requiring delivery of material supplies by subcontractors;

(F) Termination settlements; and

(G) Cost-plus-award-fee contracts (However, contracting officers may find it advantageous to perform a structured profit analysis as an aid in arriving at an appropriate fee arrangement). Other exceptions may be made in the negotiation of contracts having unusual pricing situations, but shall be justified in writing by the contracting officer in situations where the structured approach is determined to be unsuitable.

(c) *Contracting officer responsibilities.* A profit objective is that part of the estimated contract price objective or value which, in the judgment of the contracting officer, constitutes an appropriate amount of profit for the acquisition being considered. This objective should realistically reflect the total overall task to be performed and the requirements placed on the contractor. Development of a profit objective should not begin until a thorough review of proposed contract work has been made; a review of all available knowledge regarding the contractor pursuant to FAR subpart 9.1, including audit data, preaward survey reports and financial statements, as appropriate, has been conducted; and an analysis of the contractor's cost estimate and comparison with the Government's estimate or projection of cost has been made.

(d) *Profit—analysis factors* (1) *Common factors.* The following factors shall be considered in all cases in which profit is to be negotiated. The weight ranges listed after each factor shall be used in all instances where the structured approach is used.

Profit factors	Weight ranges (in percent)
Contractor effort:	
Material acquisition	1 to 5.
Direct labor	4 to 15.
Overhead	4 to 9.
General management (G&A).	4 to 8.

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Profit factors	Weight ranges (in percent)
Other costs	1 to 5.
Other factors:	
Cost risk	0 to 7.
Investment	−2 to +2.
Performance	−1 to +1.
Socioeconomic programs	−.5 to +.5.
Special situations..	

(i) Under the structured approach, the contracting officer shall first measure "Contractor Effort" by the assignment of a profit percentage within the designated weight ranges to each element of contract cost recognized by the contracting officer. The amount calculated for the cost of money for facilities capital is not to be included for the computation of profit as part of the cost base. The suggested categories under "Contractor Effort" are for reference purposes only. Often individual proposals will be in a different format, but since these categories are broad and basic, they provide sufficient guidance to evaluate all other items of cost.

(ii) After computing a total dollar profit for "Contractor Effort," the contracting officer shall then calculate the specific profit dollars assigned for cost risk, investment, performance, socioeconomic programs, and special situations. This is accomplished by multiplying the total Government Cost Objective, exclusive of any cost of money for facilities capital, by the specific weight assigned to the elements within the "Other Factors" category. Form HHS–674, Structured Approach Profit/Fee Objective, should be used, as appropriate, to facilitate the calculation of this profit objective. Form HHS–674 is illustrated in 353.370–674.

(iii) In making a judgment of the value of each factor, the contracting officer should be governed by the definition, description, and purpose of the factors together with considerations for evaluating them.

(iv) The structured approach was designed for arriving at profit objectives for other than nonprofit organizations. However, if appropriate adjustments are made to reflect differences between profit and nonprofit organizations, the structured approach can be used as a basis for arriving at profit objectives for nonprofit organizations. Therefore, the structured approach, as modified in paragraph (d)(1)(iv)(B) of this section, shall be used to establish profit objectives for nonprofit organizations.

(A) For purposes of this section, nonprofit organizations are defined as those business entities organized and operated exclusively for charitable, scientific, or educational purposes, no part of the net earnings of which inure to the benefit of any private shareholder or individual, and which are exempt from Federal income taxation under Section 501 of the Internal Revenue Code.

(B) For contracts with nonprofit organizations where profit is involved, an adjustment of up to 3 percentage points will be subtracted from the total profit objective percentage. In developing this adjustment, it will be necessary to consider the following factors;

(*1*) Tax position benefits;

(*2*) Granting of financing through advance payments; and

(*3*) Other pertinent factors which may work to either the advantage or disadvantage of the contractor in its position as a nonprofit organization.

(2) *Contractor effort.* Contractor effort is a measure of how much the contractor is expected to contribute to the overall effort necessary to meet the contract performance requirement in an efficient manner. This factor, which is apart from the contractor's responsibility for contract performance, takes into account what resources are necessary and what the contractor must do to accomplish a conversion of ideas and material into the final service or product called for in the contract. This is a recognition that within a given performance output, or within a given sales dollar figure, necessary efforts on the part of individual contractors can vary widely in both value and quantity, and that the profit objective should reflect the extent and nature of the contractor's contribution to total performance. A major consideration, particularly in connection with experimental, developmental, or research work, is the difficulty or complexity of the work to be performed, and the unusual demands of the contract, such as whether the project involves a new approach unrelated to existing technology and/or equipment or only refinements to these items. The evaluation of this factor requires an analysis of the cost content of the proposed contract as follows:

(i) *Material acquisition.* (Subcontracted items, purchased parts, and other material.) Analysis of these cost items shall include an evaluation of the managerial and technical effort necessary to obtain the required subcontracted items, purchased parts, material or services. The contracting officer shall determine whether the contractor will obtain the items or services by routine order from readily available sources or by detailed subcontracts for which the prime contractor will be required to develop complex specifications. Consideration shall also be given to the managerial and technical efforts necessary for the prime contractor to select subcontractors and to perform subcontract administration functions. In application of this criterion, it should be recognized that the contribution of the prime contractor to its purchasing program may be substantial. Normally, the lowest unadjusted weight for direct material is 2 percent. A weighting of less than 2 percent would be appropriate only in unusual circumstances when there is a minimal contribution by the contractor.

(ii) *Direct labor.* (Professional, service, manufacturing and other labor). Analysis of the various labor categories of the cost content of the contract should include evaluation of the comparative quality and quantity of professional and semiprofessional talents, manufacturing and service skills, and experience to be employed. In evaluating professional and semiprofessional labor for the purpose of assigning profit dollars, consideration should be given to the amount of notable scientific talent or unusual or scarce talent needed in contrast to nonprofessional effort. The assessment should consider the contribution this talent will provide toward the achievement of contract objectives. Since nonprofessional labor is relatively plentiful and rather easily obtained by the contractor and is less critical to the successful performance of contract objectives, it cannot be weighted nearly as high as professional or semiprofessional labor. Service contract labor should be evaluated in a like manner by assigning higher weights to engineering or professional type skills required for contract performance. Similarly, the variety of manufacturing and other categories of labor skills required and the contractor's manpower resources for meeting these requirements should be considered. For purposes of evaluation, categories of labor (*i.e.*, quality control, receiving and inspection, etc.) which do not fall within the definition for professional, service or manufacturing labor may be categorized as appropriate. However, the same evaluation considerations as outlined in this paragraph will be applied.

(iii) *Overhead and general management* (G&A). (A) Analysis of these overhead items of cost should include the evaluation of the makeup of these expenses and how much they contribute to contract performance. To the extent practicable, analysis should include a determination of the amount of labor within these overhead pools and how this labor should be treated if it were considered as direct labor under the contract. The allocable labor elements should be given the same profit considerations that they would receive if they were treated as direct labor. The other elements of these overhead pools should be evaluated to determine whether they are routine expenses, such as utilities and maintenance, and hence given lesser profit consideration, or whether they are significant contributing elements. The composite of the individual determinations in relation to the elements of the overhead pools will be the profit consideration given the pools as a whole. The procedure for assigning relative values to these overhead expenses differs from the method used in assigning values of the direct labor. The upper and lower limits assignable to the direct labor are absolute. In the case of overhead expenses, individual expenses may be assigned values outside the range as long as the composite ratio is within the range.

(B) It is not necessary that the contractor's accounting system break down overhead expenses within the classifications of research overhead, other overhead pools, and general administrative expenses, unless dictated otherwise by Cost Accounting Standards (CAS). The contractor whose accounting system reflects only one overhead rate on all direct labor need not change its system (if CAS exempt) to correspond with these classifications. The contracting officer, in an evaluation of such a contractor's overhead rate, could break out the applicable sections of the composite rate which could be classified as research overhead, other overhead pools, and general and administrative expenses, and follow the appropriate evaluation technique.

(C) Management problems surface in various degrees and the management expertise exercised to solve them should be considered as an element of profit. For example, a contract for a new program for research or an item which is on the cutting edge of the state of the art will cause more problems and require more managerial time and abilities of a higher order than a follow-on contract. If new contracts create more problems and require a higher profit weight, follow-ons should be adjusted downward because many of the problems should have been solved. In any event, an evaluation should be made of the underlying managerial effort involved on a case-by-case basis.

(D) It may not be necessary for the contracting officer to make a separate profit evaluation of overhead expenses in connection with each acquisition action for substantially the same project with the same contractor. Where an analysis of the profit weight to be assigned to the overhead pool has been made, that weight assigned may be used for future acquisitions with the same contractor until there is a change in the cost composition of the overhead pool or the contract circumstances, or the factors discussed in paragraph (d)(2)(iii)(C) of this section are involved.

(iv) *Other costs.* Analysis of this factor should include all other direct costs associated with contractor performance (*e.g.*, travel and relocation, direct support, and consultants). Analysis of these items of cost should include, the significance of the cost of contract performance, nature of the cost, and how much they contribute to contract performance. Normally, travel costs require minimal administrative effort by the contractor and, therefore, usually receive a weight no greater than 1%. Also, the contractor may designate individuals as "consultants" but in reality these individuals may be obtained by the contractor to supplement its workforce in the performance of routine duties required by contract. These costs would normally receive a minimum weight. However, there will be instances when the contractor may be required to locate and obtain the services of consultants having expertise in fields such as medicine or human services. In these instances, the contractor will be required to expend greater managerial and technical effort to obtain these services and, consequently, the costs should receive a much greater weight.

(3) *Other factors* (i) *Contract cost risk.* The contract type employed basically determines the degree of cost risk assumed by the contractor. For example, where a portion of the risk has been shifted to the Government through cost-reimbursement provisions, unusual contingency provisions, or other risk-reducing measures, the amount of profit should be less than where the contractor assumes all the risk.

(A) In developing the prenegotiation profit objective, the contracting officer will need to consider the type of contract anticipated to be negotiated and the contractor risk associated therewith when selecting the position in the weight range for profit that is appropriate for the risk to be borne by the contractor. This factor should be one of the most important in arriving at prenegotiation profit objective. Evaluation of this risk requires a determination of the degree of cost responsibility the contractor assumes; the reliability of the cost estimates in relation to the task assumed; and the complexity of the task assumed by the contractor. This factor is specifically limited to the risk of contract costs. Thus, risks on the part of the contractor such as reputation, losing a commercial market, risk of losing potential profits in other fields, or any risk which falls on the contracting office, such as the risk of not acquiring a satisfactory report, are not within the scope of this factor.

(B) The first and basic determination of the degree of cost responsibility assumed by the contractor is related to the sharing of total risk of contract cost by the Government and the contractor through the selection of contract type. The extremes are a cost-plus-a-fixed-fee contract requiring the contractor to use its best efforts to perform a task and a firm fixed-price contract for a service or a complex item. A cost-plus-a-fixed-fee contract would reflect a minimum assumption of cost responsibility, whereas a firm-fixed-price contract would reflect a complete assumption of cost responsibility. Where proper contract selection has been made, the regard for risk by contract type would usually fall into the following percentage ranges:

	Percent
Cost-reimbursement type contracts	0–3
Fixed-price type contracts	2–7

(C) The second determination is that of the reliability of the cost estimates. Sound price negotiation requires well-defined contract objectives and reliable cost estimates. Prior experience assists the contractor in preparing reliable cost estimates on new acquisitions for similar related efforts. An excessive cost estimate reduces the possibility that the cost of performance will exceed the contract price, thereby reducing the contractor's assumption of contract cost risk.

(D) The third determination is that of the difficulty of the contractor's task. The contractor's task can be difficult or easy, regardless of the type of contract.

(E) Contractors are likely to assume greater cost risk only if contracting officers objectively analyze the risk incident to proposed contracts and are willing to compensate contractors for it. Generally, a cost-plus-fixed fee contract will not justify a reward for risk in excess of 0.5 percent, nor will a firm fixed-price contract justify a reward of less than the minimum in the structured approach. Where proper contract-type selection has been made, the reward for risk, by contract type, will usually fall into the following percentage ranges:

(*1*) Type of contract and percentage ranges for profit objectives developed by using the structured approach for

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research and development and manufacturing contracts:

	Percent
Cost-Plus-fixed fee	0 to 0.5
Cost-plus-incentive fee:	
With cost incentive only	1 to 2
With multiple incentives	1.5 to 3
Fixed-price-incentive:	
With cost incentive only	2 to 4
With multiple incentives	3 to 5
Prospective price redetermination.	3 to 5
Firm fixed-price	5 to 7

(2) Type of contract and percentage ranges for profit objectives developed by using the structured approach for service contracts:

	Percent
Cost-plus-fixed-fee	0 to 0.5
Cost-plus-incentive fee	1 to 2
Fixed-price incentive	2 to 3
Firm fixed-price	3 to 4

(F) These ranges may not be appropriate for all acquisitions. For instance, a fixed-price-incentive contract that is closely priced with a low ceiling price and high incentive share may be tantamount to a firm fixed-price contract. In this situation, the contracting officer may determine that a basis exists for high confidence in the reasonableness of the estimate and that little opportunity exists for cost reduction without extraordinary efforts. On the other hand, a contract with a high ceiling and low incentive formula can be considered to contain cost-plus incentive-fee contract features. In this situation, the contracting officer may determine that the Government is retaining much of the contract cost responsibility and that the risk assumed by the contractor is minimal. Similarly, if a cost-plus-incentive-fee contract includes an unlimited downward (negative) fee adjustment on cost control, it could be comparable to a fixed-price-incentive contract. In such a pricing environment, the contracting officer may determine that the Government has transferred a greater amount of cost responsibility to the contractor than is typical under a normal cost-plus-incentive-fee contract.

(G) The contractor's subcontracting program may have a significant impact on the contractor's acceptance or risk under a contract form. It could cause risk to increase or decrease in terms of both cost and performance. This consideration should be a part of the contracting officer's overall evaluation in selecting a factor to apply for cost risk. It may be determined, for instance, that the prime contractor has effectively transferred real cost risk to a subcontractor and the contract cost risk evaluation may, as a result, be below the range which would otherwise apply for the contract type being proposed. The contract cost risk evaluation should not be lowered, however, merely on the basis that a substantial portion of the contract costs represents subcontracts without any substantial transfer of contractor's risk.

(H) In making a contract cost risk evaluation in an acquisition action that involves definitization of a letter contract, unpriced change orders, and unpriced orders under basic ordering agreements, consideration should be given to the effect on total contract cost risk as a result of having partial performance before definitization. Under some circumstances it may be reasoned that the total amount of cost risk has been effectively reduced. Under other circumstances it may be apparent that the contractor's cost risk remained substantially unchanged. To be equitable, the determination of profit weight for application to the total of all recognized costs, both those incurred and those yet to be expended, must be made with consideration to all attendant circumstances—not just the portion of costs incurred or percentage of work completed prior to definitization.

(I) Time and material and labor hour contracts will be considered to be cost-plus-a-fixed-fee contracts for the purpose of establishing profit weights unless otherwise exempt under paragraph (b)(1)(ii) of this section in the evaluation of the contractor's assumption of contract cost risk.

(ii) *Investment.* HHS encourages its contractors to perform their contracts with the minimum of financial, facilities, or other assistance from the Government. As such, it is the purpose of this factor to encourage the contractor to acquire and use its own resources to the maximum extent possible. The evaluation of this factor should include an analysis of the following:

(A) *Facilities.* (Including equipment). To evaluate how this factor contributes to the profit objective requires knowledge of the level of facilities utilization needed for contract performance, the source and financing of the required facilities, and the overall cost effectiveness of the facilities offered. Contractors who furnish their own facilities which significantly contribute to lower total contract costs should be provided with additional profit. On the other hand, contractors who rely on the Government to provide or finance needed facilities should receive a corresponding reduction in profit. Cases between these examples should be evaluated on their merits with either positive or negative adjustments, as appropriate, in profit being made. However, where a highly facilitized contractor is to perform a contract which does not benefit from this facilitization or where a contractor's use of its facilities has a minimum cost impact on the contract, profit need not be adjusted. When applicable, the prospective contractor's computation of facilities capital cost of money for pricing purposed under CAS 414 can help the contracting officer identify the level of facilities investment to be employed in contract performance.

(B) *Payments.* In analyzing this factor, consideration should be given to the frequency of payments by the Government to the contractor. The key to this weighting is to give proper consideration to the impact the contract will have on the contractor's cash flow. Generally, negative consideration should be given for advance payments and payments more frequent than monthly with maximum reduction being given as the contractor's working capital approaches zero. Positive consideration should be given for payments less frequent than monthly with additional consideration given for a capital turn-over rate on the contract which is less than the contractor's or the industry's normal capital turn-over rate.

(iii) *Performance.* (Cost-control and other past accomplishments.) The contractor's past performance should be evaluated in such areas as quality of service or product, meeting performance schedules, efficiency in cost control (including need for and reasonableness of cost incurred), accuracy and reliability of previous cost estimates, degree of cooperation by the contractor (both business and technical), timely processing of changes and compliance with other contractual provisions, and management of subcontract programs. Where a contractor has consistently achieved excellent results in these areas in comparison with other contractors in similar circumstances, this performance merits a proportionately greater opportunity for profit. Conversely, a poor record in this regard should be reflected in determining what constitutes a fair and reasonable profit.

(iv) *Federal socioeconomic programs.* This factor, which may apply to special circumstances or particular acquisitions, relates to the extent of a contractor's successful participation in Government sponsored programs such as small business, small disadvantaged business, women-owned small business, and energy conservation efforts. The contractor's policies and procedures which energetically support Government socioeconomic programs and achieve successful results should be given positive considerations. Conversely, failure or unwillingness on the part of the contractor to support Government socioeconomic programs should be viewed as evidence of poor performance for the purpose of establishing a profit objective.

(v) *Special situations* (A) *Inventive and developmental contributions.* The extent and nature of contractor-initiated and financed independent development should be considered in developing the profit objective, provided that the contracting officer has made a determination that the effort will benefit the contract. The importance of the development in furthering health and human services purposes, the demonstrable initiative in determining the need and application of the development, the extent of the contractor's cost risk, and whether the development cost was recovered directly or indirectly from Government sources should be weighed.

(B) *Unusual pricing agreements.* Occasionally, unusual contract pricing arrangements are made with the contractor wherein it agrees to cost ceilings, *e.g.*, a ceiling on overhead rates for conditions other than those discussed at FAR 42.707. In these circumstances, the contractor should receive favorable consideration in developing the profit objective.

(C) *Negative factors.* Special situations need not be limited to those which only increase profit levels. A negative consideration may be appropriate when the contractor is expected to obtain spin-off-benefits as a direct result of the contract (*e.g.*, products or services with commercial application).

(4) *Facilities capital cost of money.* When facilities capital cost of money (cost of capital committed to facilities) is included as an item of cost in the contractor's proposal, a reduction in the profit objective shall be made in an amount equal to the amount of facilities capital cost of money allowed in accordance with the Facilities Capital Cost-of Money Cost Principal. If the contractor does not propose this cost, a provision must be inserted in the contract that facilities capital cost of money is not an allowable cost.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.

(d) Certification by offeror—To ensure against contacts between Department employees and prospective offerors which would exceed the limits of advance guidance set forth in FAR 15.604 resulting in an unfair advantage to an offeror, the contracting officer shall ensure that the following certification is furnished to the prospective offeror and the executed certification is included as part of the resultant unsolicited proposal:

Unsolicited Proposal

Certification by Offeror

This is to certify, to the best of my knowledge and belief, that:

(a) This proposal has not been prepared under Government supervision.

(b) The methods and approaches stated in the proposal were developed by this offeror.

(c) Any contact with employees of the Department of Health and Human Services has been within the limits of appropriate advance guidance set forth in FAR 15.604.

(d) No prior commitments were received from departmental employees regarding acceptance of this proposal.

Date: _____

Organization: _____

Name: _____

Title: _____

(This certification shall be signed by a responsible official of the proposing organization or a person authorized to contractually obligate the organization.)

315.606 Agency procedures.

(a) The HCA is responsible for establishing procedures to comply with FAR 15.606(a).

(b) The HCA or his/her designee shall be the point of contract for coordinating the receipt and handling of unsolicited proposals.

315.606–1 Receipt and initial review.

(d) An unsolicited proposal shall not be refused consideration merely because it was initially submitted as a grant application. However, contracts shall not be awarded on the basis of unsolicited proposals which have been rejected for grant support on the grounds that they lack scientific merit.

315.609 Limited use of data.

The legend, Use and Disclosure of Data, prescribed in FAR 15.609(a) is to be used by the offeror to restrict the use of data for evaluation purposes only. However, data contained within the unsolicited proposal may have to be disclosed as a result of a request submitted pursuant to the Freedom of Information Act. Because of this possibility, the following notice shall be furnished to all prospective offerors of unsolicited proposals whenever the legend is provided in accordance with FAR 15.604(a)(7):

The Government will attempt to comply with the "Use and Disclosure of Data" legend. However, the Government may not be able to withhold a record (data, document, etc.) nor deny access to a record requested by an individual (the public) when an obligation is imposed on the Government under the Freedom of Information Act, 5 U.S.C. 552, as amended. The Government determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. Records which the offeror considers to be trade secrets and commercial or financial information and privileged or confidential must be identified by the offeror as indicated in the referenced legend.

PART 316—TYPES OF CONTRACTS

Subpart 316.3—Cost-Reimbursement Contracts

Sec.
316.307 Contract clauses.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.
316.603–3 Limitations.
316.603–70 Information to be furnished when requesting authority to issue a letter contract.
316.603–71 Approval for modifications to letter contracts.

Subpart 316.7—Agreements

316.770 Unauthorized types of agreements.
316.770–1 Letter of intent.
316.770–2 Memorandums of understanding.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 316.3—Cost-Reimbursement Contracts

316.307 Contract clauses.

(a) If the contract is with a hospital (profit or nonprofit) for research and development, modify the "Allowable Cost and Payment" clause at FAR 52.216–7 by deleting from paragraph (a) the words "Subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substituting "45 CFR Part 74 Appendix E."

(j) The contracting officer shall insert the clause at 352.216–72, Additional Cost Principles, in all solicitations and resultant cost-reimbursement contracts.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.

316.603–3 Limitations.

An official one level above the contracting officer shall execute the prescribed written statement.

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316.603–70 Information to be furnished when requesting authority to issue a letter contract.

The following information should be included by the contracting officer in any memorandum requesting approval to issue a letter contract:

(a) Name and address of proposed contractor.

(b) Location where contract is to be performed.

(c) Contract number, including modification number, if possible.

(d) Brief description of work and services to be performed.

(e) Performance or delivery schedule.

(f) Amount of letter contract.

(g) Estimated total amount of definitized contract.

(h) Type of definitive contract to be executed (fixed price, cost-reimbursement, etc.)

(i) Statement of the necessity and advantage to the Government of the use of the proposed letter contract.

(j) Statement of percentage of the estimated cost that the obligation of funds represents. In rare instances where the obligation represents 50 percent or more of the proposed estimated cost of the acquisition, a justification for that obligation must be included which would indicate the basis and necessity for the obligation (e.g., the contractor requires a large initial outlay of funds for major subcontract awards or an extensive purchase of materials to meet an urgent delivery requirement). In every case, documentation must assure that the amount to be obligated is not in excess of an amount reasonably required to perform the work.

(k) Period of effectiveness of a proposed letter contract. If more than 180 days, complete justification must be given.

(l) Statement of any substantive matters that need to be resolved.

316.603–71 Approval for modifications to letter contracts.

All letter contract modifications (amendments) must be approved one level above the contracting officer. Request for authority to issue letter contract modifications shall be processed in the same manner as requests for authority to issue letter contracts and shall include the following:

(a) Name and address of the contractor.

(b) Description of work and services.

(c) Date original request was approved and indicate approving official.

(d) Letter contract number and date issued.

(e) Complete justification as to why the letter contract cannot be definitized at this time.

(f) Complete justification as to why the level of funding must be increased.

(g) Complete justification as to why the period of effectiveness is increased beyond 180 days, if applicable.

(h) If the funding of the letter contract is to be increased to more than 50 percent of the estimated cost of the acquisition, the information required by 316.603–70(j) must be included.

Subpart 316.7—Agreements

316.770 Unauthorized types of agreements.

316.770–1 Letters of intent.

A letter of intent is an informal unauthorized agreement between the Government and a prospective contractor which indicates that products or services will be produced after completion of funding and/or other contractual formalities. Letters of intent are often solicited by prospective contractors or may be originated by Government personnel. Letters of intent are not authorized by the FAR and are prohibited for use by Department personnel.

316.770–2 Memorandums of understanding.

A "memorandum of understanding" is an unauthorized agreement, usually drafted during the course of negotiations, to modify mandatory FAR and HHSAR provisions in such a manner as to make them more acceptable to a prospective contractor. It may be used to bind the contracting officer in attempting to exercise rights given the Government under the contract, or may contain other matters directly contrary to the language of the solicitation or prospective contractual document. Use of memorandums of understanding is not authorized. Any change in a solicitation or contract shall be made by amendment or modification to that document. When a change to a prescribed contract clause is considered necessary, a deviation shall be requested.

PART 317—SPECIAL CONTRACTING METHODS

Subpart 317.2—Options

Sec.
317.201 Definition.

Subpart 317.71—Supply and Service Acquisitions Under the Government Employees Training Act.

317.7100 Scope of subpart.
317.7101 Applicable regulations.
317.7102 Acquisition of training.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 317.2—Options

317.201 Definitions.

An option must:

(a) Identify the supplies or services as a discrete option quantity in addition to the basic quantity of supplies or services to be delivered under the initial contract award;

(b) Establish a price or specify a method of calculation which will make the price certain;

(c) Be agreed to and included in the initial contract award; and

(d) Permit the Government the right to exercise the option unilaterally.

Subpart 317.71—Supply and Service Acquisitions Under the Government Employees Training Act

317.7100 Scope of subpart.

This subpart provides alternate methods for obtaining training under the Government Employees Training Act (GETA), 5 U.S.C. Chapter 41.

317.7101 Applicable regulations.

Basic policy, standards, and delegations of authority to approve training are contained in HHS Personnel Manual Instruction 410–1.

317.7102 Acquisition of training.

(a) Off-the-shelf training, whether for individuals or for groups of employees, shall be acquired under the GETA by officials delegated authority in HHS Transmittal 95.5, Personnel Manual (3/30/95).

(b) Training must be acquired through the contracting office if there are costs for training course development or for modification of off-the-shelf training courses.

PART 319—SMALL BUSINESS PROGRAMS

Subpart 319.2—Policies

Sec.
319.201 General policy.

Subpart 319.5—Set-Asides for Small Business

319.501 General.
319.506 Withdrawing or modifying set-asides.

Subpart 319.7—Subcontracting with Small Business, Small Disadvantaged Business and Women-Owned Small Business Concerns

319.705 Responsibilities of the contracting officer under the subcontracting assistance program.
319.705–5 Awards involving subcontracting plans.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 319.2—Policies

319.201 General policy.

(d) The functional management responsibilities for the Department's Small Business Program, (small, HUBZone, small disadvantaged, and women-owned small business programs) are delegated to the Director of the Office of Small and Disadvantaged Business Utilization (OSDBU).

(e) (1) The Department's Small Business Program shall be carried out by appointed small business specialists (SBS) at the OPDIV Level. Appointments, and termination of appointments, shall be made in writing by the head of the OPDIV after consultation and concurrence by the Director, OSDBU. The small business specialist shall be responsible directly to the appointing authority and shall be at an organizational level outside the direct acquisition chain of command, i.e., should report directly to the head of the OPDIV or designee. The Director, OSDBU will exercise functional management authority over small business specialists regarding the small business programs.

(2) The head of each OPDIV shall appoint a qualified full-time small business specialist (SBS) in the following activities: Administration for Children and Families (ACF), Agency for Healthcare Research and Quality (AHRQ), Health Care Financing Administration (HCFA), Substance Abuse and Mental Health Services Administration (SAMHSA), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDCP), and Program Support Center (PSC). A SBS shall also be appointed for the Office of the Secretary (OS). As deemed necessary, additional small business specialists may be appointed in larger contracting activities. When the volume of contracting does not warrant assignment of a full-time SBS, an individual shall be appointed as the specialist on a part-time basis. The responsibilities of this assignment shall take precedence over other responsibilities.

Subpart 319.5—Set-Asides For Small Business

319.501 General.

(d) Subsequent to the contracting officer's recommendation on Form HHS653, Small Business Set-Aside Review Form, the SBS shall review each proposed acquisition and either concur or non-concur with the contracting officer's recommendation. If the contracting officer disapproves the SBS's set-aside recommendation, the reasons must be documented on the Form HHS–653, and the form placed in the contract file. The contracting officer will make the final determination as to whether the proposed acquisition will be set-aside or not.

319.506 Withdrawing or modifying set-asides.

(d) Immediately upon notice from the contracting officer, the SBS shall provide telephone notification regarding all set-aside withdrawals to the OSDBU Director.

Subpart 319.7—Subcontracting with Small Business, Small Disadvantaged Business and Women-Owned Small Business Concerns

319.705 Responsibilities of the contracting officer under the subcontracting assistance program.

319.705–5 Awards involving subcontracting plans.

(a)(3) The SBA PCR shall be allowed a period of one to five working days to review the contract award package, depending upon the circumstances and complexity of the individual acquisition.

PART 323—ENVIRONMENT, CONSERVATION, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

Subpart 323.70—Safety and Health

Sec.
323.7000 Scope of subpart.
323.7001 Policy.
323.7002 Actions required.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 323.70—Safety and Health

323.7000 Scope of subpart.

This subpart prescribes the use of a safety and health clause in contracts involving hazardous materials or operations, and provides procedures for administering safety and health provisions.

323.7001 Policy.

Various statutes and regulations (e.g. Walsh-Healy Act; Service Contract Act) require adherence to minimum safety and health standards by contractors engaged in potentially hazardous work. The guidance contained in FAR subpart 23.3 shall be used for hazardous materials as the primary reference. When the guidance is judged insufficient or does not meet the safety and health situation in the instant acquisition, this subpart shall be followed.

323.7002 Actions required.

(a) *Contracting activities.* Contracting activities shall use the clause set forth in 352.223–70, or a clause reading substantially the same, in prospective contracts and subcontracts involving hazardous materials or operations for the following:

(1) Services or products;

(2) Research, development, or test projects;

(3) Transportation of hazardous materials; and

(4) Construction, including construction of facilities on the contractor's premises.

(b) *Safety officers.* OPDIV safety officers shall advise and assist initiators of acquisition requests and contracting officers in:

(1) Determining whether safety and health provisions should be included in a prospective contract;

(2) Evaluating a prospective contractor's safety and health programs; and

(3) Conducting post-award reviews and surveillance to the extent deemed necessary.

(c) *Initiators.* Initiators of acquisition requests for items described in paragraph (a) of this section shall:

(1) During the preparation of a request for contract, and in the solicitation, ensure that hazardous materials and operations to be used in the performance of the contract are clearly identified; and

(2) During the period of performance:

(i) Apprise the contracting office of any noncompliance with safety and health provisions identified in the contract; and

(ii) Cooperate with the safety officer in conducting review and surveillance activities.

PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 324.1—Protection of Individual Privacy

Sec.
324.100 Scope of subpart.
324.102 General.
324.103 Procedures.

Subpart 324.2—Freedom of Information Act

324.202 Policy.

Subpart 324.70—Confidentiality of Information

324.7001 General.
324.7002 Policy.
324.7003 Applicability.
324.7004 Required clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

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Subpart 324.1—Protection of Individual Privacy

324.100 Scope of subpart.

This subpart implements 45 CFR Part 5b, Privacy Act Regulations, and FAR Subpart 24.1, Protection of Individual Privacy, which implements the Privacy Act of 1974 (Public Law 93–579, December 31, 1974; 5 U.S.C. 552a) and OMB Circular No. A–108, July 9, 1975.

324.102 General.

(a) It is the Department's policy to protect the privacy of individuals to the maximum possible extent while permitting the exchange of records required to fulfill the Department's administrative and program responsibilities and its responsibilities for disclosing records to which the general public is entitled under the Freedom of Information Act (5 U.S.C. 552). The Privacy Act of 1974 and the Department's implementation under 45 CFR part 5b apply "when an agency provides by a contract for the operation by or on behalf of the agency of a system of records to accomplish any agency function* * *" The key factor is whether a departmental function is involved. Therefore, the Privacy Act requirements apply to a departmental contract when, under the contract, the contractor must maintain or operate a system of records to accomplish a departmental function.

(e) The program official, and, as necessary, the official designated as the activity's Privacy Act Coordinator and the Office of General Counsel, shall determine the applicability of the Act to each proposed acquisition. The program official is required to include a statement in the request for contract indicating whether the Privacy Act is or is not applicable to the proposed acquisition.

(f) Whenever the contracting officer is informed that the Privacy Act is not applicable, but the resultant contract will involve the collection of individually identifiable personal data by the contractor, the contracting officer shall include provisions to protect the confidentiality of the records and the privacy of individuals identified in the records (see subpart 324.70).

324.103 Procedures.

(a) All requests for contract shall be reviewed by the contracting officer to determine whether the Privacy Act requirements are applicable. If applicable, the contracting officer shall include the solicitation notification and contract clause required by FAR 24.104 in the solicitation, and the contract clause in the resultant contract. In addition, the contracting officer shall ensure that the solicitation notification, contract clause, and other pertinent information specified in this subpart are included in any contract modification which results in the Privacy Act requirements becoming applicable to a contract.

(b)(1) The contracting officer shall identify the system(s) of records on individuals in solicitations, contracts, and contract modifications to which the Privacy Act and the implementing regulations are applicable.

(2) The contracting officer shall include a statement in the contract notifying the contractor that the contractor and its employees are subject to criminal penalties for violations of the Act (5 U.S.C. 552a(i)) to the same extent as employees of the Department. The statement shall require that the contractor assure that each contractor employee knows the prescribed rules of conduct, and each contractor employee is aware that he/she can be subjected to criminal penalties for violations of the Act. The contracting officer shall provide the contractor with a copy of the rules of conduct and other requirements set forth in 45 CFR part 5b.

(c) The contracting officer shall include in the contract the disposition to be made of the system(s) of records on individuals upon completion of performance of the contract. For example, the contract may require the contractor to completely destroy the records, to remove personal identifiers, to turn the records over to the Department, or to keep the records but take certain measures to keep the records confidential and protect the individuals' privacy.

(d) Whenever an acquisition is determined to be subject to the Privacy Act requirements, a "system notice," prepared by the program official and describing the Department's intent to establish a new system of records on individuals, to make modifications to an existing system, or to disclose information in regard to an existing system, is required to be published in the **Federal Register**. A copy of the "system notice" shall be attached to the request for contract or purchase request. If a "system notice" is not attached, the contracting officer shall inquire about its status and shall obtain a copy from the program official for inclusion in the contract file. If a "system notice" has not been published in the **Federal Register**, the contracting officer may proceed with the acquisition but shall not award the contract until the "system notice" is published, and publication is verified by the contracting officer.

Subpart 324.2—Freedom of Information Act

324.202 Policy.

(a) The Department's regulation implementing the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, is set forth in 45 CFR part 5.

(b) The contracting officer, upon receiving a FOIA request, shall follow Department and operating division procedures. As necessary, actions should be coordinated with the cognizant Freedom of Information (FOI) Officer and the Business and Administrative Law Division of the Office of General Counsel. The contracting officer must remember that only the FOI Officer has the authority to release or deny release of records. While the contracting officer should be familiar with the entire FOIA regulation in 45 CFR part 5, particular attention should be focused on §§ 5.65 and 5.66; also of interest are §§ 5.32, 5.33, and 5.35.

Subpart 324.70—Confidentiality of Information

324.7001 General.

In performance of certain HHS contracts, it is necessary for the contractor to generate data, or be furnished data by the Government, which is about individuals, organizations, or Federal programs. This subpart and the accompanying contract clause require contractors to prudently handle disclosure of certain types of information not subject to the Privacy Act or the HHS human subject regulations set forth in 45 CFR part 46. This subpart and contract clause address the kinds of data to be generated by the contractor and/or data to be furnished by the Government that are considered confidential and how it should be treated.

324.7002 Policy.

It is the policy of HHS to protect personal interests of individuals, corporate interests of non-governmental organizations, and the capacity of the Government to provide public services when information from or about individuals, organizations, or Federal agencies is provided to or obtained by contractors in performance of HHS contracts. This protection depends on the contractor's recognition and proper handling of the information. As a result, the "Confidentiality of Information" contract clause was developed.

324.7003 Applicability.

(a) The "Confidentiality of Information" clause, set forth in 352.224–70, should be used in

solicitations and resultant contracts whenever the need exists to keep information confidential. Examples of situations where the clause may be appropriate include:

(1) Studies performed by the contractor which generate information or involve Government-furnished information that is personally identifiable, such as medical records, vital statistics, surveys, and questionnaires;

(2) Contracts which involve the use of salary structures, wage schedules, proprietary plans or processes, or confidential financial information of organizations other than the contractor's; and

(3) Studies or research which may result in preliminary or invalidated findings which, upon disclosure to the public, might create erroneous conclusions which, if acted upon, could threaten public health or safety.

(b) With regard to protecting individuals, this subpart and contract clause are not meant to regulate or control the method of selecting subjects and performing studies or experiments involving them. These matters are dealt with in the HHS regulation entitled "Protection of Human Subjects," 45 CFR Part 46. If a system of records under contract, or portions thereof, is determined to be subject to the requirements of the Privacy Act, in accordance with FAR 24.1 and 324.1 and Title 45 CFR part 5b, the procedures cited in those references are applicable and the Privacy Act contract clause shall be included in the contract. If the contract also involves confidential information, as described in this section, which is not subject to the Privacy Act, the contract shall include the "Confidentiality of Information" clause in addition to the Privacy Act clause.

324.7004 Required clause.

The clause set forth in 352.224–70 shall be included in any RFP and resultant contract(s) where it has been determined that confidentiality of information provisions may apply. Any RFP announcing the intent to include this clause in any resultant contract(s) shall indicate, as specifically as possible, the types of data which would be covered and requirements for handling the data.

PART 325—FOREIGN ACQUISITION

Subpart 325.1—Buy American Act—Supplies

Sec.
325.102 Policy.
325.108 Excepted articles, materials, and supplies.

Subpart 325.3—Balance of Payments Program

325.302 Policy.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 325.1—Buy American Act—Supplies

325.102 Policy.

(b) The head of the contracting activity (not delegable) shall make the determinations required by FAR 25.102(a)(1) through (5) and 25.102(b)(2).

325.108 Excepted articles, materials, and supplies.

(b) Articles, materials, and supplies not listed in FAR 25.108(d) may be excepted only after a written determination has been made by the head of the contracting activity (not delegable). These determinations are required only in instances where it has been determined that only suppliers of foreign source end items shall be solicited. However, approvals and determinations covering individual acquisitions in the following categories may be made by the contracting officer:

(1) Acquisition of spare and replacement parts for foreign manufactured items, if the acquisition must be restricted to the original manufacturer or its supplier; and

(2) Acquisition of foreign drugs when it has been determined, in writing, by the responsible program official, that only the requested foreign drug will fulfill the requirement.

Subpart 325.3—Balance of Payments Program

325.302 Policy.

All determinations addressed in FAR 25.302 shall be made by the head of the contracting activity (not delegable).

PART 328—BONDS AND INSURANCE

Subpart 328.3—Insurance

Sec.
328.301 Policy.
328.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.
328.311–2 Agency solicitation provisions and contract clauses.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 328.3—Insurance

328.301 Policy.

It is Department policy to limit the Government's reimbursement of its contractors' liability to third persons for claims not covered by insurance in cost-reimbursement contracts to the Limitation of Funds or Limitation of Cost clause of the contract. In addition, the amount of the Government's reimbursement will be limited to final judgments or settlements approved in writing by the Government.

328.311 Solicitation provision and contract clause on liability insurance under cost-reimbursement contracts.

328.311–2 Agency solicitation provisions and contract clauses.

The contracting officer shall insert the clause at 352.228–7, Insurance—Liability to Third Persons, in all solicitations and resulting cost-reimbursement contracts, in lieu of the clause at FAR 52.228–7 required by FAR 28.311–1. This is an authorized deviation.

PART 330—COST ACCOUNTING STANDARDS

Subpart 330.2—CAS Program Requirements

Sec.
330.201 Contract requirements.
330.201–5 Waiver.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 330.2—CAS Program Requirements

330.201 Contract requirements.

330.201–5 Waiver.

(c) The requirements of FAR 30.201–5 shall be exercised by the Director, Office of Acquisition Management (DOAM). Requests for waivers shall be forwarded through normal acquisition channels to the DOAM.

PART 332—CONTRACT FINANCING

Subpart 332.4—Advance Payments for Non-Commercial Items

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332.402 General.
332.403 Applicability.
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Subpart 332.9—Prompt Payment

332.902 Definitions.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

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Subpart 332.4—Advance Payments for Non-Commercial Items

332.402 General.

(e) The determination that the making of an advance payment is in the public interest (see FAR 32.402(c)(1)(iii)(A)) shall be made by the respective chief of the contracting office (CCO)(not delegable).

332.403 Applicability.

All contracts for research work with educational institutions located in the United States shall provide for financing by use of advance payments, in reasonable amounts, unless otherwise prohibited by law.

332.407 Interest.

(d) The HCA (not delegable) is authorized to make the determinations in FAR 32.407(d) and as follows. In addition to the interest-free advance payments for the types of contracts listed in FAR 32.407(d), advance payments without interest may be approved for nonprofit contracts which are without fee with educational institutions and other nonprofit organizations, whether public or private, which are for the performance of work involving health services, educational programs, or social service programs, including, but not limited to, programs such as:

(1) Community health representative services for an Indian Tribe or Band;

(2) Narcotic addict rehabilitative services;

(3) Comprehensive health care service program for Model Neighborhood programs;

(4) Planning and development of health maintenance organizations;

(5) Dissemination of information derived from educational research;

(6) Surveys or demonstrations in the field of education;

(7) Producing or distributing educational media for handicapped persons including captioned films for the hearing impaired;

(8) Operation of language or area centers;

(9) Conduct of biomedical research and support services;

(10) Research surveys or demonstrations involving the training and placement of health manpower and health professionals, and dissemination of related information; and

(11) Surveys or demonstrations in the field of social service.

332.409 Contracting officer action.

332.409–1 Recommendation for approval.

The information in FAR 32.409–1 (or FAR 32.409–2) shall be transmitted to the HCA in the form of a briefing memorandum.

Subpart 332.5—Progress Payments Based on Cost

332.501 General.

332.501–2 Unusual progress payments.

(a)(3) The approval of an unusual progress payment shall be made by the head of the contracting activity (HCA)(not delegable).

Subpart 332.7—Contract Funding

332.702 Policy.

An incrementally funded contract is a contract in which the total work effort is to be performed over multiple time periods and funds are allotted to cover discernible phases or increments of performance.

(a) Incremental funding may be applied to cost-reimbursement type contracts for the acquisition of research and development and other types of nonpersonal, nonseverable services. It shall not be applied to contracts for construction services, architect-engineer services, or severable services.Incremental funding allows nonseverable cost-reimbursement contracts, awarded for more than one year, to be funded from succeeding fiscal years.

(b) It is departmental policy that contracts for projects of multiple year duration be fully funded, whenever possible, to cover the entire project. However, incrementally funded contracts may be used when:

(1) A project, which is part of an approved program, is anticipated to be of multiple year duration, but funds are not currently available to cover the entire project;

(2) The project represents a valid need for the fiscal year in which the contract is awarded and of the succeeding fiscal years of the project's duration, during which additional funds may be obligated by increasing the allotment to the contract;

(3) The project is so significant to the approved program that there is reasonable assurance that it will command a high priority for proposed appropriations to cover the entire multiple year duration; and

(4) The statement of work is specific and is defined by separate phases or increments so that, at the completion of each, progress can be effectively measured.

332.703 Contract funding requirements.

332.703–1 General.

(b) The following general guidelines are applicable to incrementally funded contracts:

(1) The estimated total cost of the project (all planned phases or increments) is to be taken into consideration when determining the requirements which must be met before entering into the contract; i.e., justification for noncompetitive acquisition, approval or award, etc.

(2) The RFP and resultant contract are to include a statement of work which describes the total project covering the proposed multiple year period of performance and indicating timetables consistent with planned phases or increments and corresponding allotments of funds.

(3) Offerors will be expected to respond to RFPs with technical and cost proposals for the entire project indicating distinct break-outs of the planned phases or increments, and the multiple year period of performance.

(4) Negotiations will be conducted based upon the total project, including all planned phases or increments, and the multiple year period of performance.

(5) Sufficient funds must be obligated under the basic contract to cover no less than the first year of performance, unless the contracting officer determines it is advantageous to the Government to fund the contract for a lesser period. In that event, the contracting officer shall ensure that the obligated funds are sufficient to cover a complete phase or increment of performance representing a material and measurable part of the total project, and the contract period shall be reduced accordingly.

(6) Because of the magnitude of the scope of work and multiple year period of performance under an incrementally funded contract, there is a critical need for careful program planning. Program planning must provide for appropriate surveillance of the contractor's performance and adequate controls to ensure that projected funding will not impinge on the program office's ability to support, within anticipated appropriations, other equally important contract or grant programs.

(7) An incrementally funded contract must contain precise requirements for progress reports to enable the project officer to effectively monitor the contract. The project officer should be required to prepare periodic performance evaluation reports to facilitate the program office's ultimate decision to allot additional funds under the contract.

332.704 Limitation of cost or funds.

For detailed instruction regarding administrative actions in connection with anticipated cost overruns, see subpart 342.71

332.705 Contract clauses.

332.705–2 Clauses for limitation of costs or funds.

(c)(1) When using the Limitation of Funds clause (FAR 52.232–22) in the solicitation and resultant incrementally funded contract, the contracting officer shall insert the following legend between the clause title and the clause text:

(This clause supersedes the Limitation of Cost clause found in the General Provisions of this contract.)

(2) The contracting officer shall also include a clause reading substantially as that shown in 352.232–74 in the Special Provisions of the resultant incrementally funded contract.

(3) The request for proposals must inform prospective offerors of the Department's intention to enter into an incrementally funded contract. Therefore, the contracting officer shall include the provision at 352.232–75 in the request for proposals whenever the use of incremental funding is contemplated.

Subpart 332.9—Prompt Payment

332.902 Definitions.

Fiscal office means the office responsible for: determining whether interest penalties are due a contractor and, if so, the amount; determining whether an invoice offers a financially advantageous discount; maintaining records for and submission of prompt payment reports to the Deputy Assistant Secretary, Finance (DASF), ASMB, OS; and processing payments to the Treasury Department to allow for payment to a contractor when due. The fiscal office may fulfill the roles of the "designated billing office" and the "designated payment office."

PART 333—PROTESTS, DISPUTES, AND APPEALS

Subpart 333.1—Protests

Sec.

333.102 General.
333.103 Protests to the agency.
333.104 Protests to GAO.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.
333.209 Suspected fraudulent claims.
333.211 Contracting officer's decision.
333.212 Contracting officer's duties upon appeal.
333.212–70 Formats.
333.213 Obligation to continue performance.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 333.1—Protests

333.102 General.

(a) Contracting officers shall consider all protests or objections regarding the award of a contract, whether submitted before or after award, provided the protests are filed in a timely manner and are submitted by interested parties. To be considered timely, protests based on alleged improprieties in any type of solicitation which are apparent before bid opening or the closing date for receipt of proposals shall be filed prior to bid opening or the closing date for receipt of proposals. In the case of negotiated acquisitions, alleged improprieties which do not exist in initial solicitations, but which are subsequently incorporated by amendment, must be protested not later than the next closing date for receipt of proposals following the incorporation of the amendment. In other cases, protests shall be filed not later than ten (10) calendar days after the basis for protest is known or should have been known, whichever is earlier. Provided a protest has been filed initially with the contracting officer, any subsequent protest to the Secretary or GAO filed within ten (10) calendar days of notification of adverse action will be considered. Written confirmation of all oral protests shall be requested from protestants and must be timely filed.

(g)(1) The Office of Acquisition Management (OAM) has been designated as the headquarters office to serve as the liaison for protests lodged with GAO. Within the OAM, the Departmental Protest Control Officer (DPCO) has been designated as the individual to be contacted by GAO.

(2) Each contracting activity shall designate a protest control officer to serve as an advisor to the contracting officer and to monitor protests from the time of initial notification until the protest has been resolved. The protest control officer should be a senior acquisition specialist in the headquarters acquisition staff office. In addition, contracting activities should designate similar officials within their principal components to the extent practicable and feasible. A copy of each appointment and termination of appointment of protest control officers shall be forwarded to the Director, OAM.

333.103 Protests to the agency.

(f)(1) The contracting officer is authorized to make the determination, using the criteria in FAR 33.104(b), to award a contract notwithstanding the protest after obtaining the concurrence of the contracting activity's protest control officer and the Office of General Counsel—Business and Administrative Law Division (OGC–BAL). If the protest has been lodged with the Secretary, is addressed to the Secretary, or requests referral to the Secretary, approval shall also be obtained from the Director, OAM before making the award.

(2) The contracting officer shall require written confirmation of any oral protest. To be considered timely, the written confirmation must be filed in accordance with the applicable provisions in 333.102(a). In the following cases, written protests received by the contracting officer before award shall be forwarded, through acquisition channels, to the DPCO for processing. Files concerning these protests shall be submitted in duplicate, or as otherwise specified by the DPCO and sent in the most expeditious manner, marked "IMMEDIATE ACTION—PROTEST BEFORE AWARD", and contain the documentation referenced in 333.104(a)(3).

(i) The protestant requests referral to the Secretary of Health and Human Services;

(ii) The protest is known to have been lodged with the Comptroller General or the Secretary, or is addressed to either; or

(iii) The contracting officer entertains some doubt as to the proper action regarding the protest or believes it to be in the best interest of the Government that the protest be considered by the Secretary or the Comptroller General. Otherwise, protests addressed to the contracting officer may be answered by the contracting officer, with the concurrence of the contracting activity's protest control officer and OGC–BAL.

(3) Protests received after award shall be treated as indicated in FAR 33.103(b)(3).

333.104 Protests to GAO.

(a) *General procedures.* (3) Protests lodged with GAO, whether before or after award, shall be processed by the DPCO. Protest files shall be prepared by the contracting office and distributed as follows: two copies to the DPCO, one copy to the contracting activity's protest control officer, and one copy to OGC–BAL. Files shall include the following documentation:

(i) The contracting officer's statement of facts and circumstances, including a discussion of the merits of the protest, and conclusions and recommendations,

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including documentary evidence on which they are based.

(ii) A copy of the IFB or RFP.

(iii) A copy of the abstract of bids or proposals.

(iv) A copy of the bid or proposal of the successful offeror to whom award has been made or is proposed to be made.

(v) A copy of the bid or proposal of the protestant, if any.

(vi) The current status of award. When award has been made, this shall include whether performance has commenced, shipment or delivery has been made, or a stop work order has been issued.

(vii) A copy of any mutual agreement to suspend work on a no-cost basis, when appropriate (see FAR 33.104(c)(4)).

(viii) Copies of the notice of protest given offerors and other parties when the notice is appropriate (see FAR 33.104(a)(2)).

(ix) A copy of the technical evaluation report, when applicable, and a copy of each evaluator's rating for relevant proposals.

(x) A copy of the negotiation memorandum, when applicable.

(xi) The name and telephone number of the person in the contracting office who may be contacted for information relevant to the protest.

(xii) A copy of the competitive range memorandum. and

(xiii) Any document which is referred to in the contracting officer's statement of facts. The files shall be assembled in an orderly manner and shall include an index of enclosures.

(4) The DPCO is responsible for making the necessary distributions referenced in FAR 33.104 (a)(4).

(5) The contracting officer shall furnish the protest file containing the documentation specified in paragraph (a)(3) of this section, except the item in paragraph (a)(3)(i), to the DPCO within fourteen (14) calendar days from receipt of the protest. The contracting officer shall provide the documentation required by item (a)(3)(i) of this section to the DPCO within twenty-one (21) calendar days from receipt of the protest. Since the statute allows only a short time period in which to respond to protests lodged with GAO, the contracting officer shall handle each protest on a priority basis. The DPCO shall prepare the report and submit it and the protest file to GAO in accordance with FAR 33.104(a)(4)(i).

(6) Since the DPCO will furnish the report to GAO, the protestor, and other interested parties, comments on the report from the protestor and other interested parties will be requested to be sent to the DPCO.

(7) The Office of Acquisition Management (OAM) has been designated as the headquarters office, and the DPCO as the individual, that GAO should contact concerning all protests lodged with GAO.

(b) *Protests before award.* (1) To make an award notwithstanding a protest, the contracting officer shall prepare a finding using the criteria in FAR 33.104(b)(1), have it executed by the head of the contracting activity (HCA)(not delegable), and forward it, along with a written request for approval to make the award, to the Deputy Assistant Secretary for Grants and Acquisition Management (DASGAM).

(2) If the request to make an award notwithstanding the protest is approved by the DASGAM, the DPCO shall notify GAO. Whether the request is approved or not, the DPCO shall telephonically notify the contracting activity's protest control officer of the decision of the DASGAM, and the contracting activity's protest control officer shall immediately notify the contracting officer. The DPCO shall confirm the decision by memorandum to the contracting activity's protest control officer.

(4) The contracting officer shall prepare the protest file in accordance with paragraph (a)(3) of this section, and forward the required number of copies to the DPCO (see paragraph (a)(5) of this section).

(c) *Protests after award.* (2) If the contracting officer believes performance should be allowed to continue notwithstanding the protest, a finding shall be prepared by the contracting officer using the criteria in FAR 33.104(c)(2), executed by the HCA (not delegable), and forwarded, along with a written request for approval, to the Director, OAM. The same procedures for notification stated in paragraph (b)(2) of this section shall be followed.

(6) The contracting officer shall prepare the protest file in accordance with paragraph (a)(3) of this section, and forward the required number of copies to the DPCO (see paragraph (a)(5) of this section).

(d) *Findings and notice.* The contracting officer shall perform the actions required by FAR 33.104 (d); however, notification to GAO and other interested parties shall be made by the DPCO.

(g) *Notice to GAO.* The Deputy Assistant Secretary for Grants and Acquisition Management shall be the official to comply with the requirements of FAR 33.104 (g).

(i) *Express option.* When GAO invokes the express option, the contracting officer shall prepare the complete protest file as described in paragraph (a)(3) of this section, to include the item in paragraph (a)(3)(i), and deliver it (hand-carry, if necessary) to the DPCO in time to meet the submittal date established by GAO. The DPCO will notify the contracting officer of the submittal date after GAO has finalized its requirements.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.

(c) The Armed Services Board of Contract Appeals (ASBCA) has been designated by the Secretary as the authorized "Board" to hear and determine disputes for the Department.

333.209 Suspected fraudulent claims.

The contracting officer shall submit any instance of a contractor's suspected fraudulent claim to the Office of the Inspector General for investigation.

333.211 Contracting officer's decision.

(a)(2) The contracting officer shall refer a proposed final decision to the Office of General Counsel, Business and Administrative Law Division (OGC–BAL), for advice as to the legal sufficiency and format before sending the final decision to the contractor. The contracting officer shall provide OGC–BAL with the pertinent documents with the submission of each proposed final decision.

(a)(4)(v) When using the paragraph in FAR 33.211 (a)(4)(v), the contracting officer shall insert the words "Armed Services" before each mention of the term "Board of Contract Appeals".

(h) At any time within the period of appeal, the contracting officer may modify or withdraw his/her final decision. If an appeal from the final decision has been taken to the ASBCA, the contracting officer will forward his/her recommended action to OGC–BAL with the supplement to the contract file which supports the recommended correction or amendment.

333.212 Contracting officer's duties upon appeal.

(a) Appeals shall be governed by the rules set forth in the "Rules of the Armed Services Board of Contract Appeals", or by the rules established by the U.S. Court of Federal Claims, as appropriate.

(b) OGC–BAL is designated as the Government Trial Attorney to represent the Government in the defense of appeals before the ASBCA. A decision by the ASBCA will be transmitted by the Government Trial Attorney to the appropriate contracting officer for compliance in accordance with the ASBCA's decision.

(c) If an appeal is filed with the ASBCA, the contracting officer shall assemble a file within 30 days of receipt of an appeal, or advice that an appeal has been filed, that consists of all documents pertinent to the appeal, including:

(1) The decision and findings of fact from which the appeal is taken;

(2) The contract, including specifications and pertinent modifications, plans and drawings;

(3) All correspondence between the parties pertinent to the appeal, including the letter or letters of claim in response to which the decision was issued;

(4) Transcripts of any testimony taken during the course of proceedings, and affidavits or statements of any witness on the matter in dispute made prior to the filing of the notice of appeal with the Board; and

(5) Any additional information considered pertinent. The contracting officer shall furnish the appeal file to the Government Trial Attorney for review and approval. After approval, the contracting officer shall prepare four copies of the file, one for the ASBCA, one for the appellant, one for the Government Trial Attorney, and one for the contracting office.

(d) At all times after the filing of an appeal, the contracting officer shall render whatever assistance is requested by the Government Trial Attorney. When an appeal is set for hearing, the concerned contracting officer, acting under the guidance of the Government Trial Attorney, shall be responsible for arranging for the presence of Government witnesses and specified physical and documentary evidence at both the pre-hearing conference and hearing.

(e) If a contractor which has filed an appeal with the ASBCA elects to accept fully the decision from which the appeal was taken, or any modification to it, and gives written notification of acceptance to the Government Trial Attorney or the concerned contracting officer, the Government Trial Attorney will notify the ASBCA of the disposition of the dispute in accordance with Rule 27 of the ASBCA.

(f) If the contractor has elected to appeal to the U.S. Court of Federal Claims, the U.S. Department of Justice will represent the Department. However, the contracting officer shall still coordinate all actions through OGC–BAL.

333.212–70 Formats.

(a) The following format is suggested for use in transmitting appeal files to the ASBCA:

Your reference: _____
(Docket No.)
(Name)

Recorder, Armed Services Board of Contract Appeals

Skyline Six
5109 Leesburg Pike
Falls Church, Virginia 22041

Dear (Name):

Transmitted herewith are documents relative to the appeal under Contract No. _____ with the _____
(*Name of contractor*)
in accordance with the procedures under Rule 4. The Government Trial Attorney for this case is

_____

_____
(Insert Division of Business and Administrative Law, Office of General Counsel, Department of Health and Human Services, 330 Independence Avenue, SW., Washington, DC 20201).

The request for payment of charges resulting from the processing of this appeal should be addressed to:

_____
(Insert name and address of cognizant finance office.)

Sincerely yours,
Contracting Officer
Enclosures

(b) The following format is suggested for use in notifying the appellant that the appeal file was submitted to the ASBCA:

(Contractor Address)

_____

_____

Dear _____:

An appeal file has been compiled relative to the appeal under Contract No. _____, and has been submitted to the Armed Services Board of Contract Appeals (ASBCA). The enclosed duplicate of the appeal file is identical to that submitted to the Board, except that contract documents which you already have been excluded. You may furnish or suggest any additional information deemed pertinent to the appeal to the Armed Services Board of Contract Appeals according to their rules.

The ASBCA will provide you with further information concerning this appeal.

Sincerely yours,
Contracting Officer
Enclosure

333.213 Obligation to continue performance.

(a) The Disputes clause at FAR 52.233–1 shall be used without the use of Alternate I. However, if the contracting officer determines that the Government's interest would be better served by use of paragraph (i) in Alternate I, he/she must request approval for its use from the chief of the contracting office.

PART 334—MAJOR SYSTEM ACQUISITION

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

334.003 Responsibilities.

The Department's implementation of OMB Circular No. A–109 may be found in Chapter 1–150 of the General Administration Manual.

PART 335—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.

335.070 Cost-sharing.
335.070–1 Policy.
335.070–2 Amount of cost-sharing.
335.070–3 Method of cost-sharing.
335.070–4 Contract award.
335.071 Special determinations and findings affecting research and development contracting.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

335.070 Cost-sharing.

335.070–1 Policy.

(a) The use of cost-sharing type contracts should be encouraged to contribute to the cost of performing research where there is a probability that the contractor will receive present or future benefits from participation, such as, increased technical know-how, training to employees, acquisition of equipment, use of background knowledge in future contracts, etc. Cost-sharing is intended to serve the mutual interests of the Government and the performing organization by helping to assure efficient utilization of the resources available for the conduct of research projects and by promoting sound planning and prudent fiscal policies by the performing organization. Encouragement should be given to organizations to contribute to the cost of performing research under contracts unless the contracting officer determines that a request for cost-sharing would not be appropriate because of the following circumstances:

(1) The particular research objective or scope of effort for the project is specified by the Government rather than proposed by the performing organization. This would usually include any formal Government request for proposals for a specific project.

(2) The research effort has only minor relevance to the non-Federal activities of the performing organization, and the organization is proposing to undertake the research primarily as a service to the Government.

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(3) The organization has little or no non-Federal sources or funds from which to make a cost contribution. Cost-sharing should generally not be requested if cost-sharing would require the Government to provide funds through some other means (such as fees) to enable the organization to cost-share. It should be recognized that those organizations which are predominantly engaged in research and development and have little or no production or other service activities may not be in a favorable position to make a cost contribution.

(b) The responsibility for negotiating cost-sharing is that of the contracting office. Each research contract file should show whether the contracting officer considered cost-sharing appropriate for that particular contract and in what amount. If cost-sharing was not considered appropriate, the file must indicate the factual basis for that decision, e.g., "Because the contractor will derive no benefits from this award that can be applied to its commercial activities, cost-sharing is not considered appropriate." The contracting officer may wish to coordinate with the project officer before documenting this decision.

(c) If the contracting officer considers cost-sharing to be appropriate for a research contract and the contractor refuses to accept this type of contract, the award may be made without cost-sharing, if the contracting officer concludes that payment of the full cost of the research effort is necessary in order to obtain the services of that particular contractor.

335.070–2 Amount of cost-sharing.

When cost-sharing is determined to be appropriate, the following guidelines shall be utilized in determining the amount of cost participation by the contractor.

(a) The amount of cost participation should depend to a large extent on whether the research effort or results are likely to enhance the performing organization's capability, expertise, or competitive position, and the value of this enhancement to the performing organization. It should be recognized that those organizations which are predominantly engaged in research and development have little or no production or other service activities and may not be in a favorable position to derive a monetary benefit from their research under Federal agreements. Therefore, contractor cost participation could reasonably range from as little as 1 percent or less of the total project cost, to more than 50 percent of the total project cost. Ultimately, the contracting officer should bear in mind that cost-sharing is a negotiable item. As such, the amount of cost-sharing should be proportional to the anticipated value of the contractor's gain.

(b) If the performing organization will not acquire title or the right to use inventions, patents, or technical information resulting from the research project, it would generally be appropriate to obtain less cost-sharing than in cases in which the performer acquires these rights.

(c) A fee or profit will usually not be paid to the performing organization if the organization is to contribute to the cost of the research effort, but the amount of cost-sharing may be reduced to reflect the fact that the organization is foregoing its normal fee or profit in the research. However, if the research is expected to be of only minor value to the performing organization and if cost-sharing is not required by statute, it may be appropriate for the performer to make a contribution in the form of a reduced fee or profit rather than sharing costs of the project.

(d) The organization's participation may be considered over the total term of the project so that a relatively high contribution in one year may be offset by a relatively low contribution in another.

(e) A relatively low degree of cost-sharing may be appropriate if, in the view of the operating divisions or their subordinate elements, an area of research requires special stimulus in the national interest.

335.070–3 Method of cost-sharing.

Cost-sharing on individual contracts may be accomplished either by a contribution of part or all of one or more elements of allowable cost of the work being performed, or by a fixed amount or stated percentage of the total allowable costs of the project. Costs so contributed may not be charged to the Government under any other grant or contract (including allocations to other grants or contracts as part of any independent research and development program).

335.070–4 Contract award.

In consonance with the Department's objectives of competition and support of the small business program, award of contracts should not be made solely on the basis of ability or willingness to cost-share. Awards should be made primarily on the contractor's competence and only after adequate competition has been obtained among large and small business organizations whenever possible. The offeror's willingness to share costs should not be considered in the technical evaluation process but as a business consideration, which is secondary to selecting the best qualified source.

335.071 Special determinations and findings affecting research and development contracting.

OPDIV heads for health agencies shall sign individual and class determinations and findings for:

(a) Acquisition or construction of equipment or facilities on property not owned by the United States pursuant to 42 U.S.C. 241(a)(7); and

(b) Use of an indemnification provision in a research contract pursuant to 42 U.S.C. 241(a)(7).

PART 342—CONTRACT ADMINISTRATION

Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

Subpart 342.70—Contract Monitoring

Sec.
342.7001 Purpose.
342.7002 Contract monitoring responsibilities.
342.7003 Withholding of contract payments.
342.7003–1 Policy.
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342.7003–3 Withholding payments.

Subpart 342.71—Administrative Actions for Cost Overruns

342.7001 Scope of subpart.
342.7101 Contract administration.
342.7101–1 General.
342.7101–2 Procedures.
342.7102 Contract modifications.

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

The Director, Division of Cost Allocation of the Program Support Center within the servicing HHS regional office has been delegated the authority to establish indirect cost rates, research patient care rates, and, as necessary, fringe benefit, computer, and other special costing rates for use in contracts and grants awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

Subpart 342.70—Contract Monitoring

342.7001 Purpose.

Contract monitoring is an essential element of contract administration and the acquisition process. This subpart describes the Department's operating concepts regarding contract monitoring, performed jointly by the project officer and the contracting officer, to ensure that the required monitoring is performed, timely remedial action is taken when necessary, and a determination is made that contract objectives have been met.

342.7002 Contract monitoring responsibilities.

(a) Upon execution of the contract, the mutual obligations of the Government and the contractor are established by, and limited to, the written stipulations in the contract. Unless authorized by the contracting officer, HHS personnel shall not direct or request the contractor to assume any obligation or take any actions not specifically required by the contract. Only the contracting officer may impose a requirement which will result in a change to the contract. All contract changes must be directed in writing or confirmed in writing by the contracting officer.

(b) The contracting officer is responsible for assuring compliance with all terms of the contract, especially the statutory, legal, business, and regulatory provisions. Whether or not a postaward conference is held, the contracting officer shall inform the contractor by letter (if not already stipulated by contract provisions) of the authorities and responsibilities of the Government personnel with whom the contractor will be dealing throughout the life of the contract.

(c) The contracting officer must depend on program, technical, and other personnel for assistance and advice in monitoring the contractor's performance, and in other areas of postaward administration. The contracting officer must assure that responsibilities assigned to these personnel are understood and carried out. The individual roles and corresponding responsibilities typically involve, but are not limited to, the following:

(1) The role of program and technical personnel in monitoring the contract to assist or advise the contracting officer (or act as his/her representative when so designated by the contracting officer) in activities such as:

(i) Providing technical monitoring during contract performance, and issuing letters to the contractor and contracting officer relating to delivery, acceptance, or rejection in accordance with the terms of the contract;

(ii) Assessing contractor performance, including inspection and testing of products and evaluation of reports and data;

(iii) Recommending necessary changes to the schedule of work and period of performance in order to accomplish the objectives of the contract. This shall be accomplished by a written request to the contracting officer, together with an appropriate justification and funds availability citation;

(iv) Reviewing invoices/vouchers and recommending approval/disapproval action by the contracting officer, to include comments regarding anything unusual discovered in the review;

(v) Reviewing and recommending approval or disapproval of subcontractors, overtime, travel, and key personnel changes; and

(vi) Participating, as necessary, in various phases of the contract closeout process.

(2) The role of the project officer in performing required aspects of the contract monitoring process. In addition to those applicable activities set forth in paragraph (c)(1) of this section, the project officer shall:

(i) Submit periodic reports to the contracting officer that concisely explain the status of the contract, and include recommended actions for any problems reported. Provide the contracting officer with written notification of evaluation and approval/disapproval of contract deliverables and of completion of tasks or phases. The contracting officer will, in turn, provide the contractor with written notification of approval or disapproval unless the responsibility has been delegated by the contracting officer, in which case the person responsible for such action will notify the contractor and provide a copy to the contracting officer for inclusion in the contract file;

(ii) Monitor the technical aspects of the contractor's business and technical progress, identify existing and potential problems that threaten performance, and immediately inform the contracting officer of deviations from contract objectives, or from any technical or delivery requirements, so that remedial measures may be instituted accordingly;

(iii) Provide immediate notification to the head of the program office responsible for the program whenever it is determined that program objectives are not being met, together with specific recommendations of action to be taken. A copy of the project officer's report and recommendation shall be transmitted to the contracting officer for appropriate action;

(iv) Submit, within 120 days after contract completion, a final assessment report to the contracting officer. The report should include analysis of the contractor's performance, including the contract and program objectives achieved and missed. A copy of the final assessment report shall be forwarded to the head of the program office responsible for the program for management review and follow-up, as necessary; and

(v) Accompany and/or provide, when requested, technical support to the HHS auditor in the conduct of floor checks.

(3) The role of the contract administrator, auditor, cost analyst, and property administrator in assisting or advising the contracting officer in postaward administration activities such as:

(i) Evaluation of contractor systems and procedures, to include accounting policies and procedures, purchasing policies and practices, property accounting and control, wage and salary plans and rate structures, personnel policies and practices, etc.;

(ii) Processing of disputes under the Disputes clause and any resultant appeals;

(iii) Modification or termination of the contract; and

(iv) Determination of the allowability of cost charges to incentive or cost-reimbursement type contracts and progress payments under fixed-price contracts. This is especially important when award is made to new organizations or those with financial weaknesses.

(d) The contracting officer is responsible for assuring that contractor performance and contract monitoring are carried out in conformance with contract provisions. If performance is not satisfactory or if problems are anticipated, it is essential that the contracting officer take immediate action to protect the Government's rights under the contract. The contracting officer shall notify his/her immediate supervisor of problems that cannot be resolved within contract limitations and whenever contract or program objectives are not met. The notification shall include a statement of action being take by the contracting officer.

342.7003 Withholding of contract payments.

342.7003–1 Policy.

(a) All solicitations and resultant contracts shall contain the withholding of contract payments clause at 352.232–9, and an excusable delays clause, or a clause which incorporates the definition of excusable delays. The excusable delays clause at 352.249–14 shall be used when the solicitation and resultant contract (other than purchase orders) does not contain a default or other excusable delays clause.

(b) The transmittal letter used to convey the contract to each contractor shall contain a notice which highlights

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the contractor's agreement with the withholding of contract payments clause.

(c) No contract payment shall be made when any report required to be submitted by the contractor is overdue, or the contractor fails to perform or deliver work or services as required by the contract.

(d) The contracting officer shall issue a ten-day cure notice or initiate appropriate termination action for any failure in the contractor's performance as stated in paragraph (c) of this section.

342.7003–2 Procedures.

(a) The contracting officer is responsible for initiating immediate action to protect the Government's rights whenever the contractor fails to comply with either the delivery or reporting provisions of the contract. Compliance with the reporting provisions includes those reports to be submitted directly to the payment office. If such a report is not submitted on time, the contracting officer is to be notified promptly by the payment officer.

(b) When the contract contains a termination for default clause, the contractor's failure to either submit any required report when due or perform or deliver services or work when required by the contract is to be considered a default in performance. In either circumstance, the contracting officer is to immediately issue a formal ten-day cure notice pursuant to the default clause. The cure notice is to follow the format prescribed in FAR 49.607 and is to include a statement to the effect that contract payments will be withheld if the default is not cured or is not determined to be excusable.

(1) If the default is cured or is determined to be excusable, the contracting officer is not to initiate the withholding action.

(2) If the default is not determined to be excusable or a response is not received within the allotted time, the contracting officer is to initiate withholding action on all contract payments and is to determine whether termination for default or other action would be in the best interest of the Government.

(c) When the contract does not contain a termination for default clause, the contractor's failure to either submit any required report when due or perform or deliver services or work when required by the contract is to be considered a failure to perform. In either circumstance, the contracting officer is to immediately issue a written notice to the contractor specifying the failure and providing a period of ten days, or longer period as determined necessary by the contracting officer, in which the contractor is to cure the failure or establish an excusable delay. The contracting officer is to include a statement in the written notice to the effect that contract payments will be withheld if the failure is not cured or is not determined to be excusable.

(1) If the failure is cured or is determined to be excusable, the contracting officer is not to initiate the withholding action.

(2) If the failure is not determined to be excusable or a response is not received within the allotted time, the contracting officer is to initiate withholding action on all contract payments and is to determine whether termination for convenience or other action would be in the best interest of the Government.

(d) The contracting officer should consult FAR subpart 49.4 for further guidance before taking any of the actions described in this section.

342.7003–3 Withholding payments.

(a) When making the determination that contract payments should be withheld in accordance with the Withholding of Contract Payments clause, the contracting officer is to immediately notify the servicing finance office in writing of the determination to suspend payments. The notice of suspension is to contain all elements of information required by the payment office to properly identify the contract and the applicable accounts involved.

(b) The contracting officer is to immediately notify the contractor in writing that payments have been suspended until the default or failure is cured.

(c) When the contractor cures the default or failure, the contracting officer is to immediately notify, in writing, all recipients of the notice of suspension that the suspension is to be lifted and contract payments are to be resumed.

(d) When exercising actions regarding the withholding of payment procedures, the contracting officer must be careful not to waive any of the Government's rights when corresponding with the contractor or when taking any other actions.

Subpart 342.71—Administrative Actions for Cost Overruns

342.7100 Scope of subpart.

This subpart sets forth the procedures to be followed when a cost overrun is anticipated; i.e., the allowable actual cost of performing a cost-reimbursement type contract is expected to exceed the total estimated cost specified in the contract.

342.7101 Contract administration.

342.7101–1 General.

Upon receipt of information that a contractor's accumulated cost and projected expenditures will exceed the limit of funds obligated by the contract, the contracting officer shall coordinate immediately with the appropriate program office to determine whether the contract should be modified or terminated. If the contracting officer receives information from a source other than the contractor that a cost overrun is anticipated, the contracting officer shall verify the information with the contractor, and remind the contractor of the notification requirements of the Limitation of Cost clause.

342.7101–2 Procedures.

(a) Upon notification that a cost overrun is anticipated, the contracting officer shall inform the contractor to submit a request for additional funds which is to include:

(1) Name and address of contractor.

(2) Contract number and expiration date.

(3) Contract item(s) and amount(s) creating overrun.

(4) The elements of cost which changed from the original estimate (i.e., labor, material, travel, overhead, etc.) to be furnished in the following format:

(i) Original estimate,

(ii) Costs incurred to date,

(iii) Estimated cost to completion,

(iv) Revised estimate, and

(v) Amount of adjustment.

(5) The factors responsible for the increase, i.e., error in estimate, changed conditions, etc.

(6) The latest date by which funds must be available for commitment to avoid contract slippage, work stoppage, or other program impairment.

(b) When the contractor submits a notice of an impending overrun, the contracting officer shall:

(1) Immediately advise the appropriate program office and furnish a copy of the notice and any other data received;

(2) Request audit or cost advisory services, and technical support, as necessary, for evaluation of information and data received; and

(3) Maintain continuous follow-up with the program office to obtain a timely decision as to whether the work under the contract should be continued and additional funds provided, or the contract terminated. The decision of the program office must be supported by an appropriate written statement and funding authority, or a formal request for termination, when applicable. After a programming and funding decision is received from the program office, the contracting officer shall promptly notify the contractor in writing that:

(i) A specified amount of additional funds has been allotted to the contract by a contractual instrument; or

(ii) Work will be discontinued when the funds allotted to the contract have been exhausted, and that any work performed after that date is at the contractor's risk; or

(iii) The Government is considering whether additional funds should be allotted to the contract and will notify the contractor as soon as possible, but that any work performed after the funds then allocated to the contract have been exhausted is at the contractor's risk. Timely, formal notification of the Government's intention is essential in order to preclude loss of contractual rights in the event of dispute, termination, or litigation.

(c) If program requirements permit, contracting officers should refrain from issuing any contractual documents which will require new work or an extension of time, pending resolution of an overrun or additional fund request.

342.7102 Contract modifications.

(a) Modifications to contracts containing the Limitation of Cost clause shall include either:

(1) A provision increasing the estimated or ceiling amount referred to in the Limitation of Cost clause of the contract and stating that the clause will thereafter apply in respect to the increased amount; or

(2) A provision stating that the estimated or ceiling amount referred to in the contract is not changed by the modification and that the Limitation of Cost clause will continue to apply with respect to the amount in effect prior to the modification.

(b) A fixed-fee provided in a contract shall not be changed when funding a cost overrun. Changes in fixed-fee will be made only to reflect changes in the scope of work which justify an increase or decrease in fee.

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.2—Texts of Provisions and Clauses

Sec.
352.202–1 Definitions.
352.215–1 Instructions to offerors—Competitive acquisition.
352.215–70 Late proposals and revisions.
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352.223–70 Safety and health.
352.224–70 Confidentiality of information.
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352.270–1 Accessibility of meetings, conferences, and seminars to persons with disabilities.
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352.270–5 Key personnel.
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352.270–7 Paperwork Reduction Act.
352.270–8 Protection of human subjects.
352.270–9 Care of laboratory animals.

Authority: 5 U.S.C. 301, 40 U.S.C. 486(c).

Subpart 352.2—Texts of Provisions and Clauses

352.202–1 Definitions.

As prescribed in 302.201, the FAR Definitions clause at 52.202–1 is to be used as modified:

Definitions (Jan. 2001)

(a) Substitute the following as paragraph (a):

"(a) The term "Secretary" or "Head of the Agency" (also called "Agency Head") means the Secretary, Under Secretary, or any Assistant Secretary, Administrator or Commissioner of the Department of Health and Human Services; and the term "his/her duly authorized representative" means any person, persons, or board authorized to act for the Secretary."

(b) Add the following paragraph (h) or its alternate, as appropriate:

"(h) The term "Project Officer" means the person representing the Government for the purpose of technical monitoring of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the price of this contract or a change in the delivery dates or performance period of this contract."

or

Alternate:

"(h) The term "Project Officer" means the person representing the Government for the purpose of technical monitoring of contract performance. The Project Officer is not authorized to issue any instructions or directions which effect any increases or decreases in the scope of work or which would result in the increase or decrease of the cost of this contract or a change in performance period of this contract. In addition, the Project Officer is not authorized to receive or act upon the Contractor's notification of a revised cost estimate pursuant to the Limitation of Cost or Limitation of Funds clause of this contract."

352.215–1 Instructions to offerors—Competitive acquisition.

Insert the following paragraph (e) in place of paragraph (e) of the provision at FAR 52.215–1:

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or

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statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

352.215–70 Late proposals and revisions.

As prescribed in 315.208, the following provision may be included in the solicitation:

Late Proposals and Revisions (Nov. 1986)

Notwithstanding the procedures contained in FAR 52.215–1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

352.216–72 Additional cost principles.

As prescribed in 316.307(j), insert the following clause in all solicitations and resultant cost-reimbursement contracts:

Additional Cost Principles (Oct. 1990)

(a) *Bid and proposal costs.* (1) Bid and proposal costs are the immediate costs of preparing bids, proposals, and applications for potential Federal and non-Federal contracts, grants, and agreements, including the development of scientific, cost, and other data needed to support the bids, proposals, and applications.

(2) Bid and proposal costs of the current accounting period are allowable as indirect costs.

(3) Bid and proposal costs of past accounting periods are unallowable in the current period. However, if the organization's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable.

(4) Bid and proposal costs do not include independent research and development costs covered by the following paragraph, or preaward costs covered by paragraph 38 of Attachment B to OMB Circular A–122.

(b) *Independent research and development costs.* (1) Independent research and development is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.

(2) Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development.

(3) The cost of independent research and development, including its proportionate share of indirect costs, are unallowable.

(End of clause)

352.223–70 Safety and health.

The following clause, or one reading substantially the same, shall be used as prescribed in 323.7002:

Safety and Health (Jan. 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of Clause)

352.224–70 Confidentiality of information.

The following clause is covered by the policy set forth in subpart 324.70 and is to be used in accordance with the instructions set forth in 324.7004.

Confidentiality of Information (Apr. 1984)

(a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) In addition to the types of confidential information described in paragraph (a) of this clause, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

(c) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

(d) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(e) Confidential information, as defined in paragraph (a) of this clause, that is information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(f) Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research, which have the possibility of adverse effects on the public or the Federal agency, as described in paragraph (b) of this clause. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure. Disagreements not resolved by the Contractor and the Contracting Officer will be settled pursuant to the "Disputes" clause.

(g) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(h) Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

(i) The provisions of paragraph (e) of this clause shall not apply when the information is subject to conflicting or overlapping

provisions in other Federal, State or local laws.

(End of clause)

352.228–7 Insurance—Liability to third persons.

As prescribed in 328.311–2, contracting officers shall include the following clause in all cost-reimbursement contracts, in lieu of the clause at FAR 52.228–7:

Insurance—Liability to Third Persons (Dec. 1991)

(a)(1) Except as provided in paragraph (a)(2) immediately following, or in paragraph (h) of this clause (if the clause has a paragraph (h)), the Contractor shall provide and maintain workers' compensation, employer's liability, comprehensive general liability (bodily injury), comprehensive automobile liability (bodily injury and property damage) insurance, and such other insurance as the Contracting Officer may require under this contract.

(2) The Contractor may, with the approval of the Contracting Officer, maintain a self-insurance program; provided that, with respect to workers' compensation, the Contractor is qualified pursuant to statutory authority.

(3) All insurance required by this paragraph shall be in form and amount and for those periods as the Contracting Officer may require or approve and with insurers approved by the Contracting Officer.

(b) The Contractor agrees to submit for the Contracting Officer's approval, to the extent and in the manner required by the Contracting Officer, any other insurance that is maintained by the Contractor in connection with performance of this contract and for which the Contractor seeks reimbursement.

(c) Except as provided in paragraph (h) of this clause (if the clause has a paragraph (h)), the Contractor shall be reimbursed:

(1) For that portion of the reasonable cost of insurance allocable to this contract, and required or approved under this clause; and

(2) For certain liabilities (and expenses incidental to such liabilities) to third persons not compensated by insurance or otherwise within the funds available under the Limitation of Cost or the Limitation of Funds clause of this contract. These liabilities must arise out of the performance of this contract, whether or not caused by the negligence of the Contractor or the Contractor's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government. These liabilities are for:

(i) Loss of or damage to property (other than property owned, occupied, or used by the Contractor, rented to the Contractor, or in the care, custody, or control of the Contractor); or

(ii) Death or bodily injury.

(d) The Government's liability under paragraph (c) of this clause is limited to the amounts reflected in final judgements, or settlements approved in writing by the Government, but in no event to exceed the funds available under the Limitation of Cost or Limitation of Funds clause of this contract. Nothing in this contract shall be construed as implying that, at a later date, the Government will request, or the Congress will appropriate, funds sufficient to meet any deficiencies.

(e) The Contractor shall not be reimbursed for liabilities (and expenses incidental to such liabilities):

(1) For which the Contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract:

(2) For which the Contractor has failed to insure or to maintain insurance as required by the Contracting Officer; or

(3) That result from willful misconduct or lack of good faith on the part of the Contractor's directors, officers, managers, superintendents, or other representatives who have supervision or direction of:

(i) All or substantially all of the Contractor's business;

(ii) All or substantially all of the Contractor's operations at any one plant or separate location in which this contract is being performed; or

(iii) A separate and complete major industrial operation in connection with the performance of this contract.

(f) The provisions of paragraph (e) of this clause shall not restrict the right of the Contractor to be reimbursed for the cost of insurance maintained by the Contractor in connection with the performance of this contract, other than insurance required in accordance with this clause; *provided*, that such cost is allowable under the Allowable Cost and Payment clause of this contract.

(g) If any suit or action is filed or any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, and the risk of which is then uninsured or is insured for less than the amount claimed, the Contractor shall:

(1) Immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received;

(2) Authorize Government representatives to collaborate with counsel for the insurance carrier in settling or defending the claim when the amount of the liability claimed exceeds the amount of coverage; and

(3) Authorize Government representatives to settle or defend the claim and to represent the Contractor in or to take charge of any litigation, if required by the Government, when the liability is not insured or covered by the bond. The Contractor may, at its own expense, be associated with the Government representatives in any such claim or litigation.

(End of clause)

Alternate I (APR 1984). If the successful offeror represents in the offer that the offeror is *partially* immune from tort liability as a State agency, add the following paragraph (h) to the basic clause:

(h) Notwithstanding paragraphs (a) and (c) of this clause—

(1) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract; and

(2) The Contractor need not provide or maintain insurance coverage as required by paragraph (a) of this clause; provided, that the Contractor may obtain any insurance coverage deemed necessary, subject to approval by the Contracting Officer as to form, amount, and duration. The Contractor shall be reimbursed for the cost of such insurance and, to the extent provided in paragraph (c) of this clause, to liabilities to third persons for which the Contractor has obtained insurance coverage as provided in this paragraph, but for which such coverage is insufficient in amount.

(End of clause)

Alternate II (APR 1984). If the successful offeror represents in the offer that the offeror is totally immune from tort liability as a State agency, substitute the following paragraphs (a) and (b) for paragraphs (a) and (b) of the basic clause:

(a) The Government does not assume any liability to third persons, nor will the Government reimburse the Contractor for its liability to third persons, with respect to loss due to death, bodily injury, or damage to property resulting in any way from the performance of this contract or any subcontract under this contract.

(b) If any suit or action is filed, or if any claim is made against the Contractor, the cost and expense of which may be reimbursable to the Contractor under this contract, the Contractor shall immediately notify the Contracting Officer and promptly furnish copies of all pertinent papers received by the Contractor. The Contractor shall, if required by the Government, authorize Government representatives to settle or defend the claim and to represent the Contractor in or take charge of any litigation. The Contractor may, at its own expense, be associated with the Government representatives in any such claims or litigation

(End of clause)

352.232–9 Withholding of contract payments.

Insert the following clause in all solicitations and contracts other than purchase orders:

Withholding of Contract Payments (Apr. 1984)

Notwithstanding any other payment provisions of this contract, failure of the Contractor to submit required reports when due or failure to perform or deliver required work, supplies, or services, will result in the withholding of payments under this contract unless such failure arises out of causes beyond the control, and without the fault or negligence of the Contractor as defined by the clause entitled "Excusable Delays" or "Default", as applicable. The Government shall promptly notify the Contractor of its intention to withhold payment of any invoice or voucher submitted.

(End of clause)

352.232–74 Estimated cost and fixed fee-incrementally funded contract.

The following clause, or one reading substantially as it, shall be included in

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the Special Provisions of an incrementally funded contract:

Consideration-Estimated Cost and Fixed Fee (Apr. 1984)

(a) It is estimated that the total cost to the Government for full performance of this contract will be $_____, of which the sum of $_____ represents the estimated reimbursable costs and $_____ represents the fixed-fee.

(b) Total funds currently available for payment and allotted to this contract are $_____, of which $_____ represents the estimated reimbursable costs and $_____ represents the fixed-fee. For further provisions on funding, see the Limitation of Funds clause.

(c) It is estimated that the amount currently allotted will cover performance of Phase I which is scheduled to be completed by (date)_____.

(d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

(End of clause)

352.232–75 Incremental funding.

The following provision shall be included in all requests for proposals whenever the use of incremental funding is contemplated:

Incremental Funding (Jan. 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

352.233–70 Litigation and claims.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts:

Litigation and Claims (Apr. 1984)

The Contractor shall give the Contracting Officer immediate notice in writing of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled "Allowable Cost and Payment." Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent papers received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action. If the settlement or defense of an action or claim is undertaken by the Government, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by law or regulation or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Contractor shall not be reimbursed or indemnified by the Government for any liability loss, cost or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.242–71 Final decisions on audit findings.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts.

Final Decisions on Audit Findings (Apr. 1984)

For the purpose of issuing final decisions under the Disputes clause of this contract concerning monetary audit findings, the Contracting Officer shall be that person with ultimate responsibility for making that decision in accordance with Chapter 1–105, Resolution of Audit Findings, of the Department's Grants Administration Manual.

(End of clause)

352.249–14 Excusable delays.

Insert the following clause in all solicitations and resultant contracts other than purchase orders which do not have either a default or excusable delays clause, as prescribed in 342.7003–1(a):

Excusable Delays (Apr. 1984)

(a) Except with respect to failures of subcontractors, the Contractor shall not be considered to have failed in performance of this contract if such failure arises out of causes beyond the control and without the fault or negligence of the Contractor.

(b) Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, and unusually severe weather, but in every case the failure to perform must be beyond the control and without the fault or negligence of the Contractor. If the failure to perform is caused by the failure of a subcontractor to perform, and if such failure arises out of causes beyond the control of both the Contractor and subcontractor, and without the fault or negligence of either of them, the Contractor shall not be deemed to have failed in performance of the contract, unless: the supplies or services to be furnished by the subcontractor were obtainable from other sources, the Contracting Officer shall have ordered the Contractor in writing to procure such supplies or services from such other sources, and the Contractor shall have failed to comply reasonably with such order. Upon request of the Contractor, the Contracting officer shall ascertain the facts and extent of such failure and, if he/she shall determine that any failure to perform was occasioned by any one or more of the said causes, the delivery schedule shall be revised accordingly, subject to the rights of the Government under the termination clause hereof. (As used in this clause, the terms "subcontractor" and "subcontractors" mean subcontractor(s) at any tier.)

(End of clause)

352.270–1 Accessibility of meetings, conferences, and seminars to persons with disabilities.

The following clause is to be used in accordance with 370.102:

Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities (Jan. 2001)

The Contractor agrees as follows:

(a) *Planning.* The Contractor will develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR 36.101–36.500 and Appendix A: ADA Accessibility Guidelines (ADAAG). The plan shall be submitted to the project officer for approval prior to initiating action. (A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars may be submitted in lieu of separate plans.)

(b) *Facilities.* Any facility to be utilized for meetings, conferences, or seminars in performance of this contract shall be in compliance with 28 CFR 36.101–36.500 and Appendix A. The Contractor shall determine, by an on-site inspection, that the facility meets these requirements.

(1) *Parking.* Parking shall be in compliance with 28 CFR 36.101–36.500 and Appendix A.

(2) *Entrances.* Entrances shall be in compliance with 28 CFR 36.101–36.500 and Appendix A.

(3) *Meeting Rooms.* Meeting rooms, including seating arrangements, shall be in compliance with 28 CFR 36.101–36.500 and Appendix A. In addition, stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramp may not necessarily be independently negotiable if space does not permit. However, any slope over 1:12 must be approved by the Project Officer and the Contractor must provide assistance to negotiate access to the stage or platform.

(4) *Restrooms.* Restrooms shall be in compliance with 28 CFR 36.101–36.500 and Appendix A.

(5) *Eating Facilities.* Eating facilities in the meeting facility must also comply with 28 CFR 36.101–36.500 and Appendix A.

(6) *Overnight Facilities.* If overnight accommodations are required, the facility providing the overnight accommodations shall also comply with 28 CFR 36.101–36.500 and Appendix A.

(7) *Water Fountains.* Water fountains shall comply with 28 CFR 36.101–36.500 and Appendix A.

(8) *Telephones.* Public telephones shall comply with 28 CFR 36.101–36.500 and Appendix A.

(c) *Provisions of Services for Attendees with Sensory Impairments.*

(1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to persons with sensory impairments attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that persons with sensory impairments may contact a specific person(s), at a specific address and phone number(s), to make their service requirements known. The phone number(s) shall include a telecommunication device for the deaf (TDD).

(2) The Contractor shall provide, at no additional cost to the individual, those services required by persons with sensory impairments to insure their complete participation in the meeting, conference, or seminar.

(3) As a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For persons with hearing impairments, qualified interpreters. Also, the meeting rooms will be adequately illuminated so signing by interpreters can be easily seen.

(ii) For persons with vision impairments, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms will be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usable form for persons with sensory impairments. Readers, braille translations, large print text, and/or tape recordings are all acceptable. These materials shall be available to individuals with sensory impairments upon their arrival.

(4) The Contractor is responsible for making a reasonable effort to ascertain the number of individuals with sensory impairments who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no person with sensory impairment in attendance, the provision of those services under paragraph (c) of this clause for the nonrepresented group, or groups, is not required.

(End of clause)

352.270–2 Indian preference.

The following clause shall be used as prescribed in 370.202(a):

Indian Preference (Apr. 1984)

(a) The Contractor agrees to give preference in employment opportunities under this contract to Indians who can perform required work, regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. To the extent feasible and consistent with the efficient performance of this contract, the Contractor further agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts to the extent feasible and consistent with the efficient performance of this contract. The Contractor shall maintain statistical records as are necessary to indicate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide opportunities for training incident to such employment. Such training shall include on-the-job, classroom or apprenticeship training which is designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its employment and training opportunities after giving full consideration to Indians as required by this clause, those needs may be satisfied by selection of persons other than Indians in accordance with the clause of this contract entitled "Equal Opportunity."

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small business concerns, small disadvantaged business concerns, and women-owned small business concerns.

(e) As used in this clause:

(1) "Indian" means a person who is a member of an Indian Tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the Contractor shall grant the preference but shall require the individual to provide evidence within thirty (30) days from the Tribe concerned that the person is a member of the Tribe.

(2) "Indian Tribe" means an Indian Tribe, pueblo, band, nation, or other organized group or community, including Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601) which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(3) "Indian organization" means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451); and

(4) "Indian-owned economic enterprise" means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and that ownership shall encompass active operation and control of the enterprise.

(f) The Contractor agrees to include the provisions of this clause, including this paragraph (f) of this clause, in each subcontract awarded at any tier under this contract.

(g) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may impose any other sanctions authorized by law or by other provisions of the contract.

(End of clause)

352.270–3 Indian preference program.

The following clause shall be used as prescribed in 370.202(b):

Indian Preference Program (Apr. 1984)

(a) In addition to the requirements of the clause of this contract entitled "Indian Preference," the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work to be performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall:

(1) Designate a liaison officer who will maintain liaison with the Government and the Tribe(s) on Indian preference matters; supervise compliance with the provisions of this clause; and administer the Contractor's Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all advertisements for employment that Indian applicants will be given preference in employment and training incident to such employment.

(3) Not more than twenty (20) calendar days after award of the contract, post a written notice in the Tribal office of any reservations on which or near where the work under this contract is to be performed

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that sets forth the Contractor's employment needs and related training opportunities. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; the experience or special skills required for employment, if any; training opportunities available; and other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the Tribe(s) on or near whose reservation(s) the work is to be performed to provide assistance to the Contractor in filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact in regard to the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors and suppliers under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals only from Indian organizations or Indian-owned economic enterprises. The Contractor shall request assistance and information on Indian firms qualified as suppliers or subcontractors from the Tribe(s) on or near whose reservation(s) the work under the contract is to be performed. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to be contacted in regard to the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including: A clear description of the supplies or services required, including quantities, specifications, and delivery schedules which facilitate the participation of Indian firms; A statement indicating that preference will be given to Indian organizations and Indian-owned economic enterprises in accordance with section 7(b) of Public Law 93–638 (88 Stat. 2205; 25 U.S.C. 450e(b)); Definitions for the terms "Indian organization" and "Indian-owned economic enterprise" as prescribed under the "Indian Preference" clause of this contract; A statement to be completed by the bidder or offeror that it is an Indian organization or Indian-owned economic enterprise; and A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, no responsive bid or acceptable proposal is received, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference" clause of this contract. If one or more responsible bids or acceptable proposals are received, award shall be made to the low responsible bidder or acceptable offeror if the price is determined to be reasonable. If the low responsive bid or acceptable proposal is determined to be unreasonable as to price, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If a reasonable price cannot be agreed upon, the Contractor shall comply with the requirements of paragraph (d) of the "Indian Preference" clause of this contract.

(5) Maintain written records under this contract which indicate: The numbers of Indians seeking employment for each employment position available under this contract; The number and types of positions filled by Indians and non-Indians, and the total number of Indians employed under this contract; For those positions where there are both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Indian applicant was not selected; Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract; Reasons why preference was not given to Indian firms as subcontractors or suppliers for each requirement where it was determined by the Contractor that such preference would not be consistent with the efficient performance of the contract; and The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

(6) Submit to the Contracting Officer for approval a quarterly report which summarizes the Contractor's Indian preference program and indicates the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by the Government until expiration of one (1) year after final payment under this contract, or for such longer period as may be required by any other clause of this contract or by applicable law or regulation.

(b) For purposes of this clause, the following definitions of terms shall apply:

(1) The terms "Indian," "Indian Tribe," "Indian Organization," and "Indian-owned economic enterprise" are defined in the clause of this contract entitled "Indian Preference."

(2) "Indian reservation" includes Indian reservations, public domain Indian Allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*)

(3) "On or near an Indian Reservation" means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall be interpreted to preclude Indian Tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not conflict with any Federal statutory or regulatory requirement dealing with the award and administration of contracts.

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may impose any other sanctions authorized by law or by other provisions of the contract.

(End of clause)

352.270–4 Pricing of adjustments.

Insert the following clause in all solicitations and resultant fixed-priced contracts other than purchase orders.

Pricing of Adjustments (Jan. 2001)

When costs are a factor in determination of a contract price adjustment pursuant to the "Changes" clause or any provision of this contract, such costs shall be determined in accordance with the applicable cost principles and procedures set forth below:

Principles	Types of organizations
(a) Subpart 31.2 of the Federal Acquisition Regulation.	Commercial.
(b) Subpart 31.3 of the Federal Acquisition Regulation.	Educational.
(c) Subpart 31.6 of the Federal Acquisition Regulation.	State, local, and federally recognized Indian tribal governments.
(d) 45 CFR Part 74 Appendix E.	Hospitals (permforming research and development contracts only.
(e) Subpart 31.7 of the Federal Acquisition Regulation.	Other nonprofit institutions.

(End of clause)

352.270–5 Key personnel.

Insert the following clause in all solicitations and resultant cost-reimbursement contracts.

Key Personnel (Apr. 1984)

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

(End of clause)

352.270–6 Publications and Publicity.

Insert the following clause in all solicitations and resultant contracts.

Publications and Publicity (Jul. 1991)

(a) Unless otherwise specified in this contract, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

(End of clause)

352.270–7 Paperwork Reduction Act.

Insert the following clause in all solicitations and contracts.

Paperwork Reduction Act (Jan. 2001)

(a) In the event that it subsequently becomes a contractual requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties, the Paperwork Reduction Act of 1995 (Pub. L. 104–13) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single-time) may be used without first obtaining clearance from the Office of Management and Budget (OMB). Contractors and Project Officers should be guided by the provisions of 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall obtain the required OMB clearance through the Project Officer before expending any funds or making public contracts for the collection of data. The authority to expend funds and proceed with the collection of information shall be in writing by the Contracting Officer. The Contractor must plan at least 120 days for OMB clearance. Excessive delays caused by the Government which arises out of causes beyond the control and without the fault or negligence of the Contractor will be considered in accordance with the Excusable Delays or Default clause of this contract

(End of clause)

352.270–8 Protection of human subjects.

(a) The following provision shall be included in solicitations expected to involve human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (Jan. 2001)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1–6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OPRR, (telephone: 301–496–7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

(f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(b) The following clause shall be included in solicitations and resultant contracts involving human subjects:

Protection of Human Subjects (Jan. 2001)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH). The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgement or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during the performance of this contract, the Contracting officer determines, in consultation with the OPRR, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in a whole or in part, and the Contractor's name may be removed

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form the list of those contractors with approved Health and Human Services Human Subject Assurances.

(End of clause)

352.270–9 Care of laboratory animals.

(a) The following provision shall be included in solicitations expected to involve vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects (Sep. 1985)

The PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OPRR negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR may be contacted at NIH, Bethesda, Maryland 20892 (301–496–7041).

(End of provision)

(b) The following clause shall be included in all solicitations and resultant contracts involving research on vertebrate animals:

Care of Live Vertebrate Animals (Jan.2001)

(a) Before undertaking performance of any contract involving animal related activities, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1–2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of any live vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care of Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 *et seq.* and 9 CFR Subchapter A, Parts 1–4). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved PHS Animal Welfare Assurances.

Note: Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737.

(End of Clause)

PART 353—FORMS

Subpart 353.3—Illustrations of Forms

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 353.3—Illustrations of Forms

353.370–674 Form HHS 674, Structured Approach Profit/Fee Objective.

This form is available from local cost advisory personnel. For copies of the form, contact the Program Support Center at (301) 443–6740.

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

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Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 370.1—Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities

370.101 Policy.

(a) It is the policy of HHS that all meetings, conferences, and seminars be accessible to persons with disabilities. For the purpose of this policy, accessibility is defined as both physical access to meeting, conference, and seminar sites, and aids and services to enable individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

(b) In regard to acquisition, the policy is applicable to all contracts where the statement of work requires the contractor to conduct meetings, conferences, or seminars that are open to the public or involve HHS personnel, but not to ad hoc meetings that may be necessary or incidental to contract performance.

370.102 Responsibilities.

(a) The contracting officer shall include the clause in 352.270–1 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars in accordance with 370.101(b).

(b) The project officer shall be responsible for obtaining, reviewing, and approving the contractor's plan, which is to be submitted in response to

paragraph (a) of the contract clause in 352.270–1. A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars will be acceptable. The project officer, prior to approving the plan, should consult with the Office of Engineering Services serving the region where the meeting, conference, or seminar is to be held, to assure that the contractor's plan meets the accessibility requirements of the contract clause. The Office of Engineering Services should determine the adequacy of the contractor's plan, and notify the project officer, in writing, within ten (10) working days of receiving the request from the project officer.

Subpart 370.2—Indian Preference in Employment, Training, and Subcontracting Opportunities

370.201 Statutory requirements.

Section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, 88 Stat. 2205, 25 U.S.C. 450e(b), requires:

"Any contract, subcontract, grant, or subgrant pursuant to this Act, the Act of April 16, 1934 (48 Stat. 596), as amended, or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall require that to the greatest extent feasible:

(1) Preferences and opportunities for training and employment in connection with the administration of such contracts or grants shall be given to Indians; and

(b) Preference in the award of subcontracts and subgrants in connection with the administration of such contracts or grants shall be given to Indian organizations and to Indian-owned economic enterprises as defined in section 3 of the Indian Financing Act of 1974 (88 Stat. 77)."

370.202 Applicability.

The Indian Preference clause set forth in 352.270–2 and the Indian Preference Program clause set forth in 352.270–3 have been developed to implement section 7 (b) of Public Law 93–638 for all activities of the Department. The clauses shall be used by any affected departmental contracting activity as follows, except solicitations issued and contracts awarded pursuant to Title I of Public Law 93–638 (25 U.S.C. 450 et seq.) are exempted:

(a) The Indian Preference clause (352.270–2) shall be included in each solicitation and resultant contract, regardless of dollar amount:

(1) When the contract is to be awarded pursuant to an act specifically authorizing contracts with Indian organizations; or

(2) Where the work to be performed under the contract is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The Indian Preference Program clause (352.270–3) shall be included in each solicitation and resultant contract when:

(1) The dollar amount of the acquisition is expected to equal or exceed $50,000 for nonconstruction work or $100,000 for construction work;

(2) The Indian Preference clause is to be included in the solicitation and resultant contract; and

(3) The determination is made, prior to solicitation, that the work to be performed under the resultant contract will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the Indian Preference Program clause may be included in any solicitation and resultant contract below the $50,000 or $100,000 level for nonconstruction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section 370.202, and, in the opinion of the contracting activity, offer substantial opportunities for Indian employment, training, and subcontracting.

370.203 Definitions.

For purposes of this subpart 370.2, the following definitions shall apply:

(a) *Indian* means a person who is a member of an Indian Tribe. If the contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual to provide evidence within thirty (30) days from the Tribe concerned that the person is a member of the Tribe.

(b) *Indian Tribe* means an Indian Tribe, pueblo, band, nation, or other organized group or community, including any Alaska Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601) which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

(c) *Indian organization* means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77, 25 U.S.C. 1451).

(d) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*)

(f) *On or near an Indian Reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

370.204 Compliance enforcement.

(a) The concerned contracting activity shall be responsible for conducting periodic reviews to insure contractor compliance with the requirements of the clauses set forth in 352.270–2 and 352.270–3. These reviews may be conducted with the assistance of the Indian Tribe(s) concerned.

(b) Complaints of noncomplaince with the requirements of the clauses set forth in 352.270–2 and 352.270–3 which are filed in writing with the contracting activity shall be promptly investigated and resolved by the contracting officer.

370.205 Tribal preference requirements.

(a) Where the work under a contract is to be performed on an Indian reservation, the contracting activity may supplement the clause set forth in 352.270–3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The supplemental requirements shall be jointly developed for the contract by the contracting activity and the Tribe. Supplemental preference requirements must represent a further implementation of the requirements of section 7(b) of Public Law 93–638 and must be approved by the affected program director and approved for legal sufficiency by the Business and Administrative Law Division, OGC, or a regional attorney before being added to a solicitation and resultant contract. Any supplemental preference requirements to be added to the clause in 352.270–3 shall be included in the solicitation and clearly identified in order to insure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall be interpreted to preclude Tribes from independently developing and enforcing their own tribal preference requirements. Such independently

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developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart 370.2, and must not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all research and development activities involving human subjects conducted under contract (see 45 CFR 46.102(d) and (f)).

370.301 Policy.

It is the policy of the Department of Health and Human Services (DHHS) that no contract involving human subjects shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in DHHS regulations at 45 CFR 46.103. An applicable Multiple Project Assurance (MPA) or Single Project Assurance (SPA), approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of the contract. The OPRR, NIH, is responsible for negotiating assurances covering all DHHS-supported or DHHS-conducted activities involving human subjects. Contracting officers shall be guided by OPRR regarding nonaward or termination of a contract due to inadequate assurance or breach of assurance for protection of human subjects.

370.302 Types of assurances.

Assurances may be one of two types:

(a) *Multiple Project Assurance (MPA).* An MPA describes the oversight procedures applicable to all DHHS-supported human subjects activities within an institution having a significant number of concurrent projects. An MPA listed in OPRR's current "List of Institutions Which Have an Approved MPA" will be considered acceptable for purposes of this policy.

(b) *Single Project Assurance (SPA).* An SPA describes the oversight procedures applicable to a single DHHS-supported human subjects activity. SPAs may be approved in modified form to meet unusual requirements. SPAs are not solicited from institutions with OPRR approved MPAs. Copies of proposals selected for negotiation and requiring one or more SPAs shall be forwarded to the Human Subjects Assurance Branch, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible so that timely action may be taken to secure the SPA(s).

370.303 Notice to offerors.

(a) Solicitations shall contain the notice to offerors in 352.270–8(a) whenever contract performance is expected to involve human subjects.

(b) IRB approval of proposals submitted by institutions having an OPRR-approved MPA should be certified in the manner required by instructions for completion of the contract proposal; or by completion of a DHHS Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration; or by letter indicating the institution's OPRR-assigned MPA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) SPAs for contractors, subcontractors, or cooperating institutions generally will not be requested prior to determination that a contract proposal has been selected for negotiation. When an SPA is submitted, it provides certification for the initial contract period. No additional documentation is required. If the contract provides for additional years to complete the project, the noncompetitive renewal proposal shall be certified in the manner described in the preceding paragraph.

370.304 Contract clause.

The clause set forth in 352.270–8(b) shall be inserted in all solicitations and resultant contracts involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training and biological testing activities involving live vertebrate animals conducted under contract (see Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy), Rev. 1986, Repr. 1996).

370.401 Policy.

(a) It is the policy of the Department of Health and Human Services (DHHS) and the Public Health Service agencies that no contract involving live vertebrate animals shall be awarded until acceptable assurance has been given that the activity will be subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV. B. 6. and 7. An applicable Full Animal Welfare Assurance or Interinstitutional Agreement/Assurance, approved by the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), shall be required of each contractor, subcontractor, or cooperating institution having responsibility for animal care and use involved in performance of the contract (see PHS Policy II., IV. A., and V. B.).

(b) The OPRR, NIH, is responsible for negotiating assurances covering all DHHS/PHS-supported or DHHS/PHS-conducted activities involving the care and use of live vertebrate animals. Contracting officers shall be guided by OPRR regarding adequate animal care, and use, approval, disapproval, restriction, or withdrawal of approval of assurances (see PHS Policy V. A.).

370.402 Assurances.

(a) Assurances may be one of two types:

(1) *Full Animal Welfare Assurance (AWA).* An AWA describes the institution's complete program for the care and use of animals, including but not limited to the facilities, occupational health, training, veterinary care, IACUC procedures and lines of authority and responsibility. An AWA listed in OPRR's list of institutions which have an approved full AWA will be considered acceptable for purposes of this policy.

(2) *Interinstitutional Agreement/Assurance (IAA).* An IAA describes the arrangements between an offeror and usually a subcontractor where animal activities will occur. An IAA is limited to the specific award or single project.

(b) Copies of proposals selected for negotiation and requiring an assurance shall be forwarded to the Assurance Branch, Division of Animal Welfare, OPRR, NIH MSC 7507, 6100 Executive Blvd., Room 3B01, Rockville, Maryland 20892, as early as possible in order that timely action may be taken to secure the necessary assurances.

(c) A contractor providing animal care services at an assured entity, such as a Government-owned, contractor-operated (GOCO) site, does not need a separate assurance because the GOCO site normally covers the contractor services in the GOCO site assurance.

370.403 Notice to offerors.

Solicitations shall contain the notice to offerors in 352.270–9(a) whenever contract performance is expected to involve the use of live vertebrate animals.

(a) For offerors having a full AWA on file with OPRR, IACUC approval of the use of animals shall be submitted in the manner required by instructions for completion of the contract proposal, but prior to the technical review of the proposal. The date of IACUC review and approval must not be more than 36 months prior to the deadline for proposal submission.]

(b) Non-assured offerors are not required to submit assurances or IACUC approval with proposals. OPRR will contact contractors, subcontractors and cooperating institutions to negotiate necessary assurances and verify IACUC approvals when requested by appropriate DHHS/PHS staff.

370.404 Contract clause.

The clause set forth in 352.270–9(b) shall be included in all solicitations and resultant contracts involving the care and use of live vertebrate animals.

Subpart 370.5—Acquisitions Under the Buy Indian Act

370.500 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. Applicability of this subpart is limited to acquisitions made by or on behalf of the Indian Health Service of the Public Health Service.

370.501 Policy.

(a) The Indian Health Service will utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever the use of that authority is authorized and is practicable. The Buy Indian Act, 25 U.S.C. 47, prescribes the application of the advertising requirements of section 3709 of the Revised Statutes to the acquisition of Indian supplies. As set out in 25 U.S.C. 47, the Buy Indian Act provides as follows:

> So far as may be practicable Indian labor shall be employed, and purchases of the products (including, but not limited to printing, notwithstanding any other law) of Indian industry may be made in open market in the discretion of the Secretary of the Interior.

(b) The functions, responsibilities, authorities, and duties of the Secretary of the Interior for maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians are transferred to the Surgeon General of the United States under the supervision of the Secretary of Health and Human Services, 42 U.S.C. 2001 (a). Accordingly, the Secretary of Health and Human Services is authorized to use the Buy Indian Act in the acquisition of products of Indian industry in connection with the maintenance and operation of hospital and health facilities for Indians and for the conservation of the health of Indians. This authority has been delegated exclusively to the Indian Health Service and is not available for use by any other HHS component (unless that component is making an acquisition on behalf of the Indian Health Service).

(c) Use of the Buy Indian Act negotiation authority has been emphasized in subsequent legislation, particularly Public Law 94–437 and Public Law 96–537.

370.502 Definitions.

Buy Indian contract means any contract involving activities covered by the Buy Indian Act that is negotiated under the provisions of 41 U.S.C. 252(c) and 25 U.S.C. 47 between an Indian firm and a contracting officer representing the Indian Health Service.

Indian means a member of any tribe, pueblo, band, group, village or community that is recognized by the Secretary of the Interior as being Indian or any individual or group of individuals that is recognized by the Secretary of the Interior or the Secretary of Health and Human Services. The Secretary of Health and Human Services in making determinations may take into account the determination of the tribe with which affiliation is claimed.

Indian firm means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by one or more Indians (including, for the purpose of sections 301 and 302 of Public Law 94–437, former or currently federally recognized Indian tribes in the State of New York) or by an Indian firm; or a nonprofit firm organized for the benefit of Indians and controlled by Indians (see 370.503(a)).

Product of Indian industry means anything produced by Indians through physical labor or by intellectual effort involving the use and application of skills by them.

370.503 Requirements.

(a) *Indian ownership.* The degree of Indian ownership of an Indian firm shall be at least 51 percent during the period covered by a Buy Indian contract.

(b) *Joint ventures.* An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the joint venture must be approved by the contracting officer prior to the award of a contract under the Buy Indian Act.

(c) *Bonds.* In the case of contracts for the construction, alteration, or repair of public buildings or public works, performance and payment bonds are required by the Miller Act (40 U.S.C. 270a–270f) and FAR part 28. In the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe, bonds are not required. However, bonds are required when dealing with private business entities which are owned by an Indian tribe or members of an Indian tribe. Bonds may be required of private business entities which are joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe. A bid guarantee or bid bond is required only when a performance or payment bond is required.

(d) *Indian preference in employment, training and subcontracting.* Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act 25 U.S.C. 450e, which requires that preference be given to Indians in employment, training, and subcontracting. The Indian Preference clause set forth in 352.270–2 shall be included in all Buy Indian solicitations and resultant contracts. The Indian Preference Program clause set forth in 352.270–3 shall be used as specified in 370.202(b). All requirements set forth in subpart 370.2 which are applicable to the instant Buy Indian acquisition shall be followed by the contracting officer, e.g., sections 370.204 and 370.205.

(e) *Subcontracting.* Not more than 50 percent of the work to be performed under a prime contract awarded pursuant to the Buy Indian Act shall be subcontracted to other than Indian firms. For this purpose, work to be performed does not include the provision of materials, supplies, or equipment.

(f) *Wage rates.* A determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) shall be included in all contracts awarded under the Buy Indian Act for over $2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works,

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except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe. The wage rate determination is to be included in contracts with private business entities even if they are owned by an Indian tribe or a member of an Indian tribe and in connection with joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

370.504 Competition.

(a) Contracts to be awarded under the Buy Indian Act shall be subject to competition among Indians or Indian concerns to the maximum extent that competition is determined by the contracting officer to be practicable. When competition is determined not to be practicable, a Justification for Other than Full and Open Competition shall be prepared in accordance with 306.303 and subsequently retained in the contract file.

(b) Solicitations must be synopsized and publicized in the Commerce Business Daily and copies of the synopses sent to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian concerns and others having a legitimate interest. The synopsis should state that the acquisition is restricted to Indian firms under the Buy Indian Act.

370.505 Responsibility determinations.

(a) A contract may be awarded under the Buy Indian Act only if it is first determined that the project or function to be contracted for is likely to be satisfactorily performed under that contract and the project or function is likely to be properly completed or maintained under that contract.

(b) The determination called for by paragraph (a) of this section, to be made prior to the award of a contract, will be made in writing by the contracting officer reflecting an analysis of the standards set forth in FAR 9.104–1.

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Part V

Department of Commerce

National Oceanic and Atmospheric Administration

15 CFR Part 922

Florida Keys National Marine Sanctuary Regulations; Final Rule

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 000510129–1004–02]

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Florida Keys National Marine Sanctuary Regulations

AGENCY: National Marine Sanctuary Program (NMSP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule; notice of boundary expansion; supplemental management plan.

SUMMARY: By this document, NOAA expands the boundary of the Florida Keys National Marine Sanctuary (FKNMS or Sanctuary) in the remote westernmost portion of the Sanctuary by 96 square nautical miles (nm²) and establishes the Tortugas Ecological Reserve (Ecological Reserve or Reserve) (a 151 nm² no-take zone) in the expanded area and in 55 nm² of the existing Sanctuary, to protect important coral reef resources. This document publishes the boundary coordinates for the expansion area and for the Reserve, announces the availability of the Supplemental Management Plan (SMP) for the Reserve, and publishes the text of the Revised Designation Document for the Sanctuary. The SMP details the goals and objectives, management responsibilities, research activities, interpretive and educational programs, and enforcement, including surveillance activities, for the Reserve. By this document, NOAA also issues regulations to implement the boundary expansion and the establishment of the Reserve and to regulate activities in the Reserve consistent with the purposes of its establishment and to make minor revisions to the existing Sanctuary boundary and to the boundaries of various zoned areas within that boundary to correct errors, provide clarification, and reflect more accurate data. This action is necessary to comprehensively protect some of the healthiest and most diverse coral reefs in the Florida Keys. The intended effect of this rule is to protect the deep water coral reef community in this area from being degraded by human activities.

DATE: Pursuant to Section 304(b) of the National Marine Sanctuaries Act (NMSA) 16 U.S.C. 1434(b), the Revised Designation and regulations shall take effect and become final after the close of a review period of 45 days of continuous session of Congress, beginning on the day on which this document is published in the **Federal Register**, unless the Governor of the State of Florida certifies to the Secretary of Commerce that the Revised Designation or any of its terms is unacceptable, in which case the Revised Designation or any unacceptable term shall not take effect. Announcement of the effective date of the Final Regulations will be published in the **Federal Register**.

ADDRESSES: Copies of the Final Supplemental Environmental Impact Statement/Supplemental Management Plan (FSEIS/SMP) and the Record of Decision for the Tortugas Ecological Reserve are available upon request to the Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration, 1305 East-West Highway, 11th Floor, Silver Spring, MD, 20910, (301) 713–3125. The FSEIS/SMP is also available on the Internet at: http://www.fknms.nos.noaa.gov. Comments regarding the collection-of-information requirements contained in this rule should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20503 (Attention: Desk Officer for NOAA) and to Richard Roberts, NOAA, Work Station 8118, 1305 East-West Highway, 8th Floor, Silver Spring, MD, 20910.

FOR FURTHER INFORMATION CONTACT: Billy Causey, Sanctuary Superintendent, (305) 743–2437.

SUPPLEMENTARY INFORMATION:

I. Introduction

NOAA establishes the Tortugas Ecological Reserve (a no-take zone) in the Tortugas region (Tortugas or region) of the Florida Keys to protect nationally significant coral reef resources and to protect an area that serves as a source of biodiversity for the Sanctuary as well as for the southwest shelf of Florida. Establishment of the Reserve includes expansion of the Sanctuary boundary to ensure that the Reserve protects sensitive coral habitats lying outside the existing boundary of the Sanctuary.

With this expansion, the FKNMS, which was designated by the Florida Keys National Marine Sanctuary and Protection Act (FKNMSPA, Pub. L. 101–605) on November 16, 1990, consists of approximately 2900 nm² (9660 square kilometers) of coastal and oceanic waters, and the submerged lands thereunder, surrounding the Florida Keys and the Dry Tortugas.

NOAA expands the boundary of the FKNMS and establishes the Tortugas Ecological Reserve to protect the nationally significant coral reef resources of the Tortugas region. This action furthers the objectives of the National Marine Sanctuaries Act (NMSA, 16 U.S.C. 1431 *et seq.*) and the FKNMSPA and meets the objectives of E.O. 13089, Coral Reef Protection. With the addition of the Tortugas Ecological Reserve, the network of no-take zones in the FKNMS is increased to 24, two of which are ecological reserves (Western Sambo and Tortugas Ecological Reserves).

II. Background

The Tortugas region is located in the westernmost portion of the FKNMS approximately 70 miles west of Key West, a very strategic position oceanographically that makes it an ideal location for an ecological reserve. It contains the healthiest coral reefs found in the Sanctuary. Coral pinnacles as high as forty feet with the highest coral cover (>30%) found in the Keys jut up from the ocean floor. These coral formations are bathed by some of the clearest and cleanest waters found in the Florida Keys. This occurs where the tropical waters of the Caribbean mingle with the more temperate waters of the Gulf of Mexico.

Recent studies reveal that the Tortugas region is unique in its location and the extent to which oceanographic processes impact the area. The Tortugas plays a dynamic role in supporting marine ecosystems throughout south Florida and the Florida Keys. Larvae that are spawned from adult populations in the Tortugas are spread throughout the Keys and south and southwest Florida by a persistent system of currents and eddies that provide the retention and current pathways necessary for successful recruitment of both local and foreign spawned juveniles with larval stages remaining from hours for some coral species up to one year for spiny lobster. In addition, the upwellings and convergences of the current systems provide the necessary food supplies in concentrated frontal regions to support larval growth stages.

The Tortugas is located at the transition between the Gulf of Mexico and the Atlantic and is strongly impacted by two major current systems, the Loop Current in the eastern Gulf of Mexico and the Florida Current in the Straits of Florida, as well as by the system of eddies that form and travel along the boundary of these currents. Of particular importance to the marine communities of the Tortugas and Florida Keys is the formation of a large

counterclockwise rotating gyre (large eddy) that forms just south of the Tortugas where the Loop Current turns abruptly into the Straits of Florida. This gyre can persist for several months before it is forced downstream along the Keys decreasing in size and increasing in forward speed until its demise in the middle Keys. This gyre serves as a retention mechanism for local recruits and as a pathway to inshore habitats for foreign recruits. It may also serve as a potential food provider through plankton production and concentration.

The Tortugas is also located adjacent to two coastal current systems, including the wind-driven currents of both the Florida Keys coastal zone and the west Florida Shelf.

Persistent westward winds over the Keys create a downwelling system that drives a westward coastal countercurrent along the lower Keys to the Tortugas. The countercurrent provides a return route to the Tortugas and its gyre-dominated circulation, and onshore surface Ekman transport (a process whereby wind-driven upwelling bottom water is transported 45 degrees to the left of the actual wind direction in the northern hemisphere) provide a mechanism for larval entry into coastal habitats. Circulation on the west Florida shelf is strongly influenced by wind forcing, but there also appears to be a significant southward mean flow, possibly due to the Loop Current. The effect of these currents on the Tortugas is to provide a larval return mechanism to the Florida Bay nursery grounds during periods of southeast winds, as well as the transport mechanism for low-salinity shelf waters from the north when the mean southward flow is strong.

The combination of downstream transport in the Florida Current, onshore Ekman transport along the downwelling coast, upstream flow in the coastal countercurrent and recirculation in the Tortugas gyre forms a recirculating recruitment pathway stretching from the Dry Tortugas to the middle Keys that enhances larval retention and recruitment into the Keys coastal waters of larvae spawned locally or foreign larvae from remote upstream areas of the Gulf of Mexico and Caribbean Sea. Convergences between the Florida Current front and coastal gyres provide a mechanism to concentrate foreign and local larvae, as well as their planktonic food supply. Onshore Ekman transport and horizontal mixing from frontal instabilities enhance export from the oceanic waters into the coastal zone. A wind- and gyre-driven countercurrent provides a return leg to aid larval retention in local waters. Seasonal cycles of the winds, countercurrent and Florida Current favor recruitment to the coastal waters during the fall when the countercurrent can extend the length of the Keys from the Dry Tortugas to Key Largo, onshore Ekman transport is maximum and downstream flow in the Florida Current is minimum. The mix and variability of the different processes forming the recruitment conveyor provide ample opportunity for local recruitment of species with larval stages ranging from days to several months. For species with longer larval stages, such as the spiny lobster, which has a six to 12-month larval period, a local recruitment pathway exists that utilizes retention in the Tortugas gyre and southwest Florida shelf and return via the Loop Current and the Keys conveyor system. Return from the southwest Florida shelf could also occur through western Florida Bay and the Keys coastal countercurrent, due to a net southeastward flow recently observed connecting the Gulf of Mexico to the Atlantic through the Keys.

The Tortugas North portion of the Tortugas Ecological Reserve consists of coral reef communities that are unparalleled in the Florida Keys in their diversity and composition. Several carbonate banks of varying size and depth (30 feet to 75 feet) and low relief hardbottom habitats with patches of sand and rubble characterize Tortugas North. The most prominent features in the Tortugas North portion of the Reserve are Tortugas Bank and Sherwood Forest. Tortugas Bank crests at 66 feet and supports abundant attached reef organisms such as sponges, corals, and soft corals. North of Tortugas Bank, in an area previously believed to be composed only of sand, are several pinnacles covered with hard and soft corals and reef fish.

Sherwood Forest is an ancient stony coral forest exhibiting 30% or more bottom cover located along the western flank of Tortugas Bank (compared to 10% for the rest of the Florida Keys). The area's name was inspired by the bizarre mushroom-shaped coral heads that are an adaptation to the low light conditions. There seem to be indications that the mushroom shape is the result of a composite of two coral species. The coral reef is so well developed, that it forms a veneer over the true bottom approximately three feet below the reef. It is an area of low relief but high coral cover that rises to a depth of about 65 feet and covers an area of many acres. The area exhibits a complex habitat with various rock ledges, holes, and caves, providing hiding places for marine life. Unusual coral formations and previously unidentified coral species associations have been observed in this location. Gorgonians and black corals (Antipathies sp.), which are not common elsewhere in the Florida Keys, are also prolific. An abundance of groupers has been documented in Sherwood Forest as have sightings of uncommon and rare fish species such as jewfish, white-eyed goby, and orangeback bass.

The Tortugas South portion of the Reserve includes a wide range of deep water coral reef habitats that will protect and conserve many rare and unusual reef species, and incorporates sufficient area to provide a buffer to the critical coral reef community. The upper portion of Tortugas South includes the relatively shallow Riley's Hump area in less than 100 feet of water. Riley's Hump consists of attached algae, scattered small coral colonies, sand, and hardbottom habitats. It is also a known fish aggregating and spawning site for several snapper-grouper species.

Deep reef habitats with numerous soft corals but few stony corals are found in Tortugas South in depths from 200 to 400 feet. A series of small pinnacles that surround a larger seamount have been identified as part of an east-west running ledge that begins around 250 feet and drops to close to 400 feet in a nearly vertical profile. This is unlike any other coral reef habitat discovered within Sanctuary waters. These complex habitats support numerous fish species including streamer bass, yellowmouth grouper, snowy grouper, scamp, speckled hind, creole fish, bank butterflyfish, amberjack, and almaco.

The deepest portions (1,600 to 1,800 feet) of Tortugas South encompass limestone ledges where unusual deep-dwelling sea life such as lantern fish (myctophids), tilefish, golden crabs, and giant isopods have been observed. The sand bottom habitat has been observed to be teeming with unique deep sea species of shrimp, fish, sea cucumbers, anemones, and crabs.

These critical deep water communities of Tortugas South are vulnerable to a wide range of impacts from fishing gear including deep water trawls and traps, and impacts from anchoring. Fishing gear impacts have been observed on sand and limestone substrates in some deep water areas.

In order for the Reserve to be biologically effective and to ensure protection and conservation of the full range of coral reef habitats and species in the Tortugas region, it is critical that all of the various benthic habitats and their associated marine communities, from the shallowest to the greatest

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depths, be included within the boundary of the Reserve.

Despite its beauty and productivity, the Tortugas has been exploited for decades, greatly diminishing its potential as a source of larval recruits to the downstream portion of the Florida Keys and to itself. Fish and lobster populations have been significantly depleted thus threatening the integrity and natural dynamics of the ecosystem. Large freighters have been using Riley's Hump as a secure place to anchor between port visits. The several-ton anchors and chains of these ships have devastated large areas of fragile coral reef habitat that provide the foundation for economically important fisheries.

Visitation to the Tortugas region has increased dramatically over the past 10 years. Visitation in the DRTO increased 300% from 1984 through 1998. The population of South Florida is projected to increase from the current 6.3 million people to more than 12 million by 2050. With continued technological innovations such as global positioning systems (GPS), electronic fish finders, better and faster vessels, this increase in population will translate to more pressure on the resources in the Tortugas. By designating this area an ecological reserve, NOAA hopes to create a seascape of promise—a place where the ecosystem's full potential can be realized and a place that humans can experience, learn from and respect. This goal is consistent with E.O. 13089, Coral Reef Protection, and the U.S. Coral Reef Task Force's recommendations.

The FSEIS/SMP supplements the Final Environmental Impact Statement/ Final Management Plan (FEIS/MP) for the Sanctuary and fulfills the requirements of the National Environmental Policy Act of 1969 (NEPA) for the Sanctuary boundary expansion, the establishment of the Reserve, and the issuance of the regulations implementing the boundary expansion and the Reserve. Because establishment of the Tortugas Ecological Reserve includes a Sanctuary boundary expansion NOAA has followed the procedures and has complied with the requirements of section 304(a) of the NMSA, 16 U.S.C. 1434(a).

Other actions by various other jurisdictions are underway to ensure comprehensive protection of the unique resources of the Tortugas region:

- The National Park Service (NPS) is revising the General Management Plan for the Dry Tortugas National Park (DRTO) that will include as the preferred alternative a proposal to create a Research/Natural Area (RNA) within the Park. The proposed boundary and regulations for the RNA will be compatible with the establishment of the Tortugas Ecological Reserve.
- Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the Gulf of Mexico Fishery Management Council (GMFMC) has primary federal responsibility and expertise for the development of fishery management plans (FMPs) throughout the Gulf of Mexico. The GMFMC has developed an amendment for addressing Essential Fish Habitat requirements for the various Gulf of Mexico Fishery Management Plans (GMFMPs) which cover the area of the Tortugas Ecological Reserve. The GMFMPs are implemented by regulations promulgated by the National Marine Fisheries Service (NMFS) (50 CFR part 622). At the GMFMC's meeting on November 9, 1999, the NOS and NMFS requested that the GMFMC take steps to prohibit fishing, consistent with the purpose of the Tortugas Ecological Reserve. The GMFMC accepted this request and at its July 10–13, 2000 meeting, adopted the Generic Amendment for Addressing Essential Fish Habitat Requirements for Fishery Management Plans of the Gulf of Mexico. That amendment to the GMFMPs is consistent with the Tortugas Ecological Reserve and the regulations governing ecological reserves within the FKNMS, at 15 CFR 922.164(d).
- NMFS intends to issue regulations consistent with the no-take status of the Tortugas Ecological Reserve for the species covered by the GMFMPs and for Atlantic tunas, Swordfish, sharks, and Atlantic billfishes.
- The State of Florida is drafting regulations to prohibit fishing in those portions of Tortugas North that lie within State waters.

Combined with the establishment of the Tortugas Ecological Reserve, these actions would result in comprehensive protection for the nationally significant coral reef habitats from shallow to deep water extending from the DRTO into Sanctuary and GMFMC waters.

The process by which NOAA arrived at its proposal to establish the Tortugas Ecological Reserve is described in the preamble to the Proposed Rule published on May 18, 2000 (65 FR 31634). The five boundary alternatives and the four regulatory alternatives considered by NOAA are also set forth and described in the preamble to the Proposed Rule and in the FSEIS.

Consistent with the proposal, NOAA has selected Boundary Alternative III (the Preferred Boundary Alternative) (Figure 1) and expands the boundary of the Sanctuary by approximately 96 nm² to include two significant coral reef areas known as Sherwood Forest and Riley's Hump. The boundary of the Sanctuary in its northwesternmost corner is expanded by approximately 36 nm² to include Sherwood Forest and in its southwesternmost corner is expanded by adding a noncontiguous area of approximately 60 nm² to include Riley's Hump. By the final regulations issued with this document, NOAA establishes a Tortugas Ecological Reserve of approximately 151 nm². The Tortugas Ecological Reserve incorporates the expanded area and approximately 55 nm² of the existing Sanctuary in its northwest corner. The area of the Reserve surrounding Sherwood Forest encompasses approximately 91 nm² and is called Tortugas North; the area surrounding Riley's Hump is called Tortugas South.

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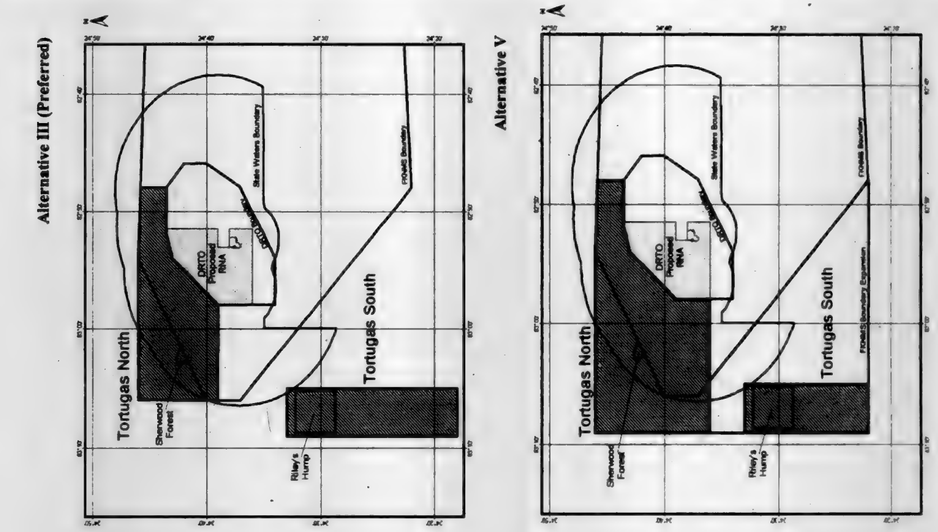


Figure 1. Boundary Alternatives II - V.

While NOAA proposed Regulatory Alternative C as its Preferred Regulatory Alternative, NOAA has selected Regulatory Alternative D and implements it by the final regulations issued with this document. The

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difference between Regulatory Alternatives C and D is that Regulatory Alternative D prohibits access in Tortugas South except for continuous transit, law enforcement, or for scientific research or educational activities pursuant to a sanctuary permit. Under Alternative C, which is less restrictive, access to Tortugas South would have been allowed and, except for continuous transit and law enforcement purposes, would have required a simple, no-cost permit and call-in for entering and leaving.

The GMFMC, at its July 10–13, 2000, meeting, took final action on its Generic Amendment Addressing the Establishment of Tortugas Marine Reserves, which would create the Council's own 60 nm² marine reserve in the same location as Tortugas South and in the 13 nm² portion of Tortugas North that is within the Council's jurisdiction. The GMFMC has proposed a prohibition on any fishing (consumptive activity) or anchoring by fishing vessels. The Council also requested that NOAA prohibit anchoring by all vessels in the reserve and that NOAA prohibit all diving in the areas of Tortugas North and Tortugas South that are subject to Council jurisdiction.

The GMFMC expressed concern that non-consumptive diving would make the no-take prohibitions difficult to enforce, particularly with regard to diving for lobsters and spearfishing. The Council believes that eliminating all diving activities would greatly simplify enforcement. In addition, the GMFMC stated that non-consumptive diving can impact and damage bottom habitat through the inadvertent contact with coral or by stirring up sand and silt on the bottom. The Council also expressed concern about the biological impact of diving on the behavior of reef fish populations. Tortugas South is a known spawning area for many fish including red snapper, yellow tail snapper, mutton snapper, mangrove snapper, snowy grouper, black grouper, red grouper, red hind, and rock hind. The Council believes that the potential for diver impact on fish spawning would be eliminated by the closure. In addition, other commentors expressed concern over the effects of non-consumptive diving on sensitive coral reef resources.

Based on the comments received, NOAA revised the Preferred Alternative in the FSEIS from the Preferred Alternative in the DSEIS to prohibit all diving in Tortugas South except for research or educational activities pursuant to a Sanctuary permit. Non-consumptive diving will still be allowed in Tortugas North. The resources of Tortugas North are not as sensitive to diver impacts as those in Tortugas South and permitting non-consumptive diving in Tortugas North with careful monitoring of the impacts of such diving will provide exceptional resource appreciation and public education benefits. Also, prohibiting diving in Tortugas South will provide a reference for assessing the impact of diving activities in Tortugas North.

Socio-economic impacts, determined by analyzing the costs and benefits of no-take regulations on various industries, indicate moderate impacts on fishermen, mostly lobster and handline fishermen, and some recreational charter operators, and minimal or small impacts on recreational fishermen, commercial shippers, and treasure salvors. The potential for benefits to non-consumptive users and the scientific community is high due to the educational and research value of a no-take ecological reserve. Positive effects to surrounding areas through long-term fisheries replenishment are also likely.

The action taken today adequately protects the nationally significant coral reef resources of the Tortugas region and fulfills the objectives of the FKNMSPA and the National Marine Sanctuaries Act (NMSA). The Tortugas Ecological Reserve established by this action is of sufficient size and the regulations impose adequate protective measures to achieve the goals and objectives of the FKNMSPA and the NMSA while not unduly impacting user groups.

III. Revised Designation Document

The Designation Document for the Sanctuary is revised to incorporate the coordinates for the expanded boundary of the Sanctuary, to authorize the regulation of entering or leaving specified areas of the Sanctuary, and to make necessary technical and editorial corrections of the Designation Document. The text of the Revised Designation Document follows:

REVISED DESIGNATION DOCUMENT FOR THE FLORIDA KEYS NATIONAL MARINE SANCTUARY

Article I. Designation and Effect

On November 16, 1990, the Florida Keys National Marine Sanctuary and Protection Act, Pub. L. 101–605 (16 U.S.C. 1433 note), became law. That Act designated an area of waters and submerged lands, including the living and nonliving resources within those waters, as described therein, as the Florida Keys National Marine Sanctuary (Sanctuary). By this revised Designation Document, the boundary of the Sanctuary is expanded to include important coral reef resources and resources in two areas known as Sherwood Forest and Riley's Hump, just beyond the westernmost portion of the statutory Sanctuary boundary.

Section 304 of the National Marine Sanctuaries Act (NMSA), 16 U.S.C. 1431 *et seq.*, authorizes the Secretary of Commerce to issue such regulations as are necessary and reasonable to implement the designation, including managing and protecting the conservation, recreational, ecological, historical, scientific, educational, cultural, archaeological or aesthetic resources and qualities of a national marine sanctuary. Section 1 of Article IV of this Designation Document lists activities of the type that are presently being regulated or may have to be regulated in the future, in order to protect Sanctuary resources and qualities. Listing in section 1 does not mean that a type of activity will be regulated in the future, however, if a type of activity is not listed, it may not be regulated, except on an emergency basis, unless section 1 is amended, following the procedures for designation of a sanctuary set forth in paragraphs (a) and (b) of section 304 of the NMSA, to include the type of activity.

Nothing in this Designation Document is intended to restrict activities that do not cause an adverse effect on the resources or qualities of the Sanctuary or on Sanctuary property or that do not pose a threat of harm to users of the Sanctuary.

Article II. Description of the Area

The Florida Keys National Marine Sanctuary boundary encompasses approximately 2900 nm² (9,800 square kilometers) of coastal and ocean waters, and the submerged lands thereunder, surrounding the Florida Keys in Florida. The easternmost point of the Sanctuary is the northeasternmost point of Biscayne National Park and the westernmost point is approximately 15 kilometers to the west of the western boundary of Dry Tortugas National Park, a linear distance of approximately 335 kilometers. The contiguous area boundary on the Atlantic Ocean side of the Florida Keys runs south from Biscayne National Park generally following the 300-foot isobath, curving in a southwesterly direction along the Florida Keys archipelago until south of the Dry Tortugas. The contiguous area boundary on the Gulf of Mexico side of the Florida Keys runs from this southern point in a straight line to the northwest and then when directly west of the Dry Tortugas in a straight line to the north. The boundary then turns to the east and slightly south and follows a straight line to just west of Key West and then turns to the northeast and follows a straight line parallel to the Florida Keys approximately five miles to the south, and then follows the Everglades National Park boundary until Division Point where the boundary then follows the western shore of Manatee Bay, Barnes Sound, and Card Sound. The boundary then follows the southern boundary of Biscayne National Park and up its eastern boundary until its northeasternmost point. Starting just to the east of the most western boundary line of the contiguous portion of the Sanctuary there is a vertical rectangular shape area of 60 nm² just to the south.

The shoreward boundary of the Sanctuary is the mean high-water mark except around the Dry Tortugas where it is the boundary of the Dry Tortugas National Park. The Sanctuary boundary encompasses the entire Florida coral reef tract, all of the mangrove islands of the Florida Keys, and some of the sea grass meadows of the Florida Keys. The precise boundary of the Sanctuary is set forth at the end of this Designation Document.

Article III. Characteristics of the Area That Give it Particular Value

The Florida Keys extend approximately 223 miles southwest from the southern tip of the Florida peninsula. Adjacent to the Florida Keys land mass are located spectacular unique, nationally significant marine environments, including sea grass meadows, mangrove islands, and extensive living coral reefs. These marine environments support rich biological communities possessing extensive conservation, recreational, commercial, ecological, historical, research, educational, and aesthetic values which give this area special national significance. These environments are the marine equivalent of tropical rain forests in that they support high levels of biodiversity, are fragile and easily susceptible to damage from human activities, and possess high value to humans if properly conserved. These marine environments are subject to damage and loss of their ecological integrity from a variety of sources of disturbance.

The Florida Keys are a limestone island archipelago. The Keys are located at the southern edge of the Florida Plateau, a large carbonate platform made of a depth of up to 7000 meters of marine sediments, which have been accumulating for 150 million years and which have been structurally modified by subsidence and sea level fluctuation. The Keys region is generally divided into five distinct areas: the Florida reef tract, one of the world's largest coral reef tracts and the only barrier reef in the United States; Florida Bay, described as an active lime-mud factory because of the high carbonate content of its silts and muds; the Southwest Continental Shelf; the Straits of Florida; and the Keys themselves.

The 2.5 million-acre Sanctuary contains one of North America's most diverse assemblages of terrestrial, estuarine, and marine fauna and flora, including, in addition to the Florida reef tract, thousands of patch reefs, one of the world's largest sea grass communities covering 1.4 million acres, mangrove fringed shorelines, mangrove islands, and various hardbottom habitats. These diverse habitats provide shelter and food for thousands of species of marine plants and animals, including more than 50 species of animals identified under Federal or State law, as endangered or threatened. The Keys were at one time a major seafaring center for European and American trade routes to the Caribbean, and the submerged cultural and historic resources (*i.e.*, shipwrecks) abound in the surrounding waters. In addition, the Sanctuary may contain substantial archaeological resources of pre-European cultures.

The uniqueness of the marine environment draws multitudes of visitors to the Keys. The major industry in the Florida Keys is tourism, including activities related to the Keys' marine resources, such as dive shops, charter fishing and dive boats and marinas, as well as hotels and restaurants. The abundance of the resources also supports a large commercial fishing employment sector.

The number of visitors to the Keys grows each year, with a concomitant increase in the number of residents, homes, jobs, and businesses. As population grows and the Keys accommodate ever-increasing resource-use pressures, the quality and quantity of Sanctuary resources are increasingly threatened. These pressures require coordinated and comprehensive monitoring and researching of the Florida Keys' region.

Article IV. Scope of Regulations

Section 1. Activities Subject to Regulation

The following activities are subject to regulation under the NMSA, either throughout the entire Sanctuary or within identified portions of it or, as indicated, in areas beyond the boundary of the Sanctuary, to the extent necessary and reasonable. Such regulation may include prohibitions to ensure the protection and management of the conservation, recreational, ecological, historical, scientific, educational, cultural, archaeological or aesthetic resources and qualities of the area. Because an activity is listed here does not mean that such activity is being or will be regulated. All listing means is that the activity can be regulated, after compliance with all applicable regulatory laws, without going through the designation procedures required by paragraphs (a) and (b) of section 304 of the NMSA, 16 U.S.C. 1434(a) and (b). Further, no regulation issued under the authority of the NMSA except an emergency regulation issued with the approval of the Governor of the State of Florida may take effect in the area of the Sanctuary lying within the seaward boundary of the State of Florida if the Governor of the State of Florida certifies to the Secretary of Commerce that such regulation is unacceptable within the forty-five-day review period specified in NMSA. Detailed definitions and explanations of the following "activities subject to regulation" appear in the Sanctuary Management Plan:

1. Exploring for, developing, or producing oil, gas, and/or minerals (*e.g.*, clay, stone, sand, gravel, metalliferous ores, nonmetalliferous ores) in the Sanctuary;

2. Touching, climbing on, taking, removing, moving, collecting, harvesting, injuring, destroying or causing the loss of, or attempting to take, remove, move, collect, harvest, injure, destroy or cause the loss of, coral in the Sanctuary;

3. Drilling into, dredging or otherwise altering the seabed of the Sanctuary, except incidental to allowed fishing and boating practices or construction activities permitted by county, state or federal regulatory agencies; or constructing, placing or abandoning any structure, material or other matter on the seabed of the Sanctuary, except as authorized by appropriate permits or incidental to allowed fishing practices;

4. Discharging or depositing, within or beyond the boundary of the Sanctuary, any material that subsequently enters the Sanctuary and injures a Sanctuary resource or quality;

5. Operating water craft in the Sanctuary

(a) in a manner that could injure coral, hardbottoms, seagrass, mangroves, or any other immobile organism attached to the seabed,

(b) in a manner that could injure or endanger the life of divers, fishermen, boaters or other users of the Sanctuary,

(c) in a manner that could disturb marine mammals, marine reptiles, or bird rookeries;

6. Diving or boating activities in the Sanctuary including anchoring that could harm Sanctuary resources, Sanctuary property, or other users of the Sanctuary;

7. Stocking within the Sanctuary or releasing within the Sanctuary or from beyond the boundary of the Sanctuary, native or exotic species of plant, invertebrate, fish, amphibian or mammals;

8. Defacing, marking, or damaging in any way or displacing, removing, or tampering with any markers, signs, notices, placards, navigational aids, monuments, stakes, posts, mooring buoys, boundary buoys, trap buoys, or scientific equipment in the Sanctuary;

9. Removing, injuring, preserving, curating, and managing historic resources within the Sanctuary without all required state and/or federal permits;

10. Taking, removing, moving, catching, collecting, harvesting, feeding, injuring, destroying, or causing the loss of, or attempting to take, remove, move, catch, collect, harvest, feed, injure, destroy or cause the loss of any marine mammal, marine reptile, or bird within the Sanctuary, without all required state and/or federal permits;

11. Possessing, moving, harvesting, removing, taking, damaging, disturbing, breaking, cutting, spearing, or otherwise injuring any marine invertebrate, fish, bottom formation, algae, seagrass or other living or dead organism, including shells, or attempting any of these activities in any area of the Sanctuary designated as an Existing Management Area, Wildlife Management Area, Ecological Reserve, Sanctuary Preservation Area, or Special-Use Area;

12. Carrying or possessing specified fishing gear in any area of the Sanctuary designated as an Existing Management Area, Wildlife Management Area, Ecological Reserve, Sanctuary Preservation Area, or Special-Use Area except for passage through without interruption;

13. Entering and leaving any Wildlife Management Area, Ecological Reserve, Sanctuary Preservation Area, or Special-Use Area except for passage through without interruption or for law enforcement purposes;

14. Harvesting marine life as defined and regulated by the State of Florida under its marine life rule;

15. Mariculture;

16. Possessing or using explosives or releasing electrical charges or substances poisonous or toxic to fish and other living marine resources within the Sanctuary or beyond the boundary of the Sanctuary (possession of ammunition shall not be considered possession of explosives);

17. Removing and disposing of lost, out-of-season, or illegal gear discovered within the Sanctuary; removing of vessels grounded, lodged, stuck or otherwise perched on coral

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reefs, hardbottom, or seagrasses within the Sanctuary; and removing and disposing of derelict or abandoned vessels or other vessels within the Sanctuary for which ownership cannot be determined or for which the owner takes no action for removal or disposal; and salvaging and towing of vessels abandoned or disabled within the Sanctuary vessels or of vessels within the Sanctuary otherwise needing salvaging or towing; and

18. Interfering with, obstructing, delaying or preventing an investigation, search, seizure or deposition of seized property in connection with enforcement of the NMSA or any regulation or permit issued under the NMSA.

Section 2. Emergency Regulation

Where necessary to prevent or minimize the destruction of, loss of, or injury to a Sanctuary resource or quality; or to minimize the imminent risk of such destruction, loss or injury, any activity, including any not listed in Section 1 of this article, is subject to immediate temporary regulation, including prohibition. However, no such regulation may take effect in any area of the Sanctuary lying within the seaward boundary of the State of Florida without the approval of the Governor of the State of Florida.

Article V. Effect on Leases, Permits, Licenses, and Rights

Pursuant to paragraph (c)(1) of section 304 of the NMSA, 16 U.S.C. 1434(c)(1), no valid lease, permit, license, approval or other authorization issued by any federal, State, or local authority of competent jurisdiction, or any right of subsistence use or access, may be terminated by the Secretary of Commerce, or his or her designee, as a result of a designation, or as a result of any sanctuary regulation, if such authorization or right was in effect on the effective date of the designation (November 16, 1990 with respect to the statutory Sanctuary boundary; _____, 2001 with respect to the revision to the Sanctuary boundary expansion made by this Revised Designation Document).

In no event may the Secretary of Commerce or his or her designee issue a permit authorizing, or otherwise approving: (1) the exploration for, development of, or production of oil, gas, or minerals within the Sanctuary; or (2) the disposal of dredged materials within the Sanctuary (except by certification in accordance with applicable National Marine Sanctuary Program regulations of valid authorizations in existence on the effective date of Sanctuary designation). Any purported authorizations issued by other authorities after the effective date of Sanctuary designation for any of these activities within the Sanctuary shall be invalid.

Article VI. Alteration of this Designation

The terms of designation, as defined in paragraph (a) of section 304 of the NMSA, 16 U.S.C. 1434(a), may be modified only by the procedures outlined in paragraphs (a) and (b) of section 304 of the NMSA, 16 U.S.C. 1434(a) and (b), including public hearings, consultation with interested federal, state, and local government agencies, review by the appropriate Congressional committees, review by the Governor of the State of Florida, and approval by the Secretary of Commerce, or his or her designee. No designation, term of designation, or implementing regulation may take effect in the area of the Sanctuary lying within the seaward boundary of the State of Florida if the Governor of the State of Florida certifies to the Secretary of Commerce that such designation or term of designation regulation is unacceptable within the forty-five-day review period specified in NMSA.

Florida Keys National Marine Sanctuary Boundary Coordinates (based on North American datum of 1983)

The boundary of the Florida Keys National Marine Sanctuary—

(a) begins at the northeasternmost point of Biscayne National Park located at a point approximately 25 degrees 39 minutes north latitude, 80 degrees 05 minutes west longitude, then runs eastward to the point located at 25 degrees 39 minutes north latitude, 80 degrees 04 minutes west longitude; and

(b) then runs southward and connects in succession the points at the following coordinates:

(i) 25 degrees 34 minutes north latitude, 80 degrees 04 minutes west longitude,

(ii) 25 degrees 28 minutes north latitude, 80 degrees 05 minutes west longitude,

(iii) 25 degrees 21 minutes north latitude, 80 degrees 07 minutes west longitude, and

(iv) 25 degrees 16 minutes north latitude, 80 degrees 08 minutes west longitude;

(c) then runs southwesterly and connects in succession the points at the following coordinates:

(i) 25 degrees 07 minutes north latitude, 80 degrees 13 minutes west longitude,

(ii) 24 degrees 57 minutes north latitude, 80 degrees 21 minutes west longitude,

(iii) 24 degrees 39 minutes north latitude, 80 degrees 52 minutes west longitude,

(iv) 24 degrees 30 minutes north latitude, 81 degrees 23 minutes west longitude,

(v) 24 degrees 25 minutes north latitude, 81 degrees 50 minutes west longitude,

(vi) 24 degrees 22 minutes north latitude, 82 degrees 48 minutes west longitude,

(vii) 24 degrees 37 minutes north latitude, 83 degrees 06 minutes west longitude,

(viii) 24 degrees 46 minutes north latitude, 83 degrees 06 minutes west longitude,

(ix) 24 degrees 46 minutes north latitude, 82 degrees 54 minutes west longitude,

(x) 24 degrees 44 minutes north latitude, 81 degrees 55 minutes west longitude,

(xi) 24 degrees 51 minutes north latitude, 81 degrees 26 minutes west longitude, and

(xii) 24 degrees 55 minutes north latitude, 80 degrees 56 minutes west longitude;

(d) then follows the boundary of Everglades National Park in a southerly then northeasterly direction through Florida Bay, Buttonwood Sound, Tarpon Basin, and Blackwater Sound;

(e) after Division Point, then departs from the boundary of Everglades National Park and follows the western shoreline of Manatee Bay, Barnes Sound, and Card Sound;

(f) then follows the southern boundary of Biscayne National Park to the southeasternmost point of Biscayne National Park; and

(g) then follows the eastern boundary of Biscayne National Park to the beginning point specified in paragraph (a).

The shoreward boundary of the Florida Keys National Marine Sanctuary is the mean high-water mark except around the Dry Tortugas where the boundary is conterminous with that of the Dry Tortugas National Park, formed by connecting in succession the points at the following coordinates:

(i) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude;

(ii) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 58 minutes 0 seconds west longitude;

(iii) 24 degrees 39 minutes 0 seconds north latitude, 82 degrees 58 minutes 0 seconds west longitude;

(iv) 24 degrees 43 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude;

(v) 24 degrees 43 minutes 32 seconds north latitude, 82 degrees 52 minutes 0 seconds west longitude;

(vi) 24 degrees 43 minutes 32 seconds north latitude, 82 degrees 48 minutes 0 seconds west longitude;

(vii) 24 degrees 42 minutes 0 seconds north latitude, 82 degrees 46 minutes 0 seconds west longitude;

(viii) 24 degrees 40 minutes 0 seconds north latitude, 82 degrees 46 minutes 0 seconds west longitude;

(ix) 24 degrees 37 minutes 0 seconds north latitude, 82 degrees 48 minutes 0 seconds west longitude; and

(x) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude.

The Florida Keys National Marine Sanctuary also includes the area located within the boundary formed by connecting in succession the points at the following coordinates;

(i) 24 degrees 33 minutes north latitude, 83 degrees 09 minutes west longitude,

(ii) 24 degrees 33 minutes north latitude, 83 degrees 05 minutes west longitude,

(iii) 24 degrees 18 minutes north latitude, 83 degrees 05 minutes west longitude,

(iv) 24 degrees 18 minutes north latitude, 83 degrees 09 minutes west longitude, and

(v) 24 degrees 33 minutes north latitude, 83 degrees 09 minute west longitude.

(End of Revised Designation Document.)

IV. Supplemental Management Plan

The Supplemental Management Plan (SMP) complements the existing Sanctuary Management Plan (MP) in several respects. Many of the strategies described in the MP that are now being implemented in the Sanctuary will be applied to the Tortugas Ecological Reserve. However, due to the unique characteristics of the Tortugas region (remoteness, deep water) some new strategies have been developed and will be implemented. Some of these strategies are described below. The SMP adds strategies to the Education and Outreach Action Plan, Enforcement Action Plan, Mooring and Boundary Buoy Action Plan, Research Monitoring Action Plan and adds an Administrative Action Plan.

Administrative Action Plan

The SMP adds an Administrative Action Plan to the Management Plan. It targets the development of a Memorandum of Understanding (MOU) to clearly define the roles and responsibilities of the various agencies responsible for resource management in the Tortugas region. The MOU will cover, at a minimum, the following activities: cooperative enforcement, research, and sharing of facilities. Management of the Reserve necessitates a high degree of coordination and cooperation between the affected agencies, particularly NOAA and the NPS. Both agencies have similar missions and responsibilities. Consequently, cooperation will not only save money but will also improve resource protection. The NPS has a variety of assets such as land, housing, and dockage that, under a workable agreement, could potentially be used to support management of the Reserve. An agreement on the use of these lands and facilities will be pursued by NOAA and NPS.

The State of Florida is the co-trustee for a significant portion of the waters and marine resources within the Reserve and will co-manage these resources with the NOAA.

NOAA's National Marine Fisheries Service (NMFS) has considerable expertise and some assets that could be utilized in managing the reserve, particularly in the areas of research and monitoring. The NMFS Office of Law Enforcement has responsibility for enforcing fishing regulations and has assets and technology that could potentially be used for enforcement.

The U.S. Coast Guard has responsibility for enforcing fishing regulations in federal waters of the Reserve. They have several large offshore patrol vessels based in Key West that could be used, in conjunction with Sanctuary patrol vessels, for enforcement of the reserve areas.

Strategy 1: Memorandum of Understanding (MOU)

Develop and enter into an MOU that clearly defines the roles and responsibilities of the various agencies responsible for resource management in the Tortugas region. The MOU should cover, at a minimum, the following activities: cooperative enforcement, research, and sharing of facilities and assets.

Education and Outreach Action Plan

The SMP supplements the Education and Outreach Plan in the MP by adding education and outreach strategies for the Reserve. These strategies are expected to have a significant effect on protecting and preserving the natural resources found in the Tortugas by enhancing the general public's understanding of this unique region and the regulations applicable to the reserve. These strategies were developed according to the Sanctuary Education and Outreach goals and outcomes identified in the MP.

Strategy E.13: Tortugas Site Brochure

To a large extent, marine reserves rely on visitor compliance and understanding in order for their regulations to be effective. This is even more critical when reserves like the Tortugas Ecological Reserve are remotely located or large in size. NOAA has learned from experience that an important tactic for increasing regulatory compliance is to provide appropriate educational products and information to visitors of protected areas. This strategy is to produce a site brochure which details the regulations and boundaries for the Reserve, how to obtain a permit to enter and visit Tortugas North area, the locations and numbers of mooring buoys, and the unique ecological features of the area. This product will complement the existing Sanctuary regional site brochures, and will interpret an area of the Sanctuary that is not currently covered in any existing products.

Activity 1—Design layout and content of brochure;

Activity 2—Identify partners to assist with brochure costs;

Activity 3—Print and distribute brochure.

Strategy E.14: Tortugas Ecological Reserve Exhibit, Garden Key

Most visitors to the Tortugas Ecological Reserve will stop at Fort Jefferson on Garden Key in the DRTO at some point during their visit. Garden Key provides a convenient anchorage for private pleasure boats, commercial fishing vessels, live-aboard dive vessels, recreational fishing guides, and ferries and seaplanes that bring campers and day visitors from Key West. This strategy involves the development and construction of an information kiosk at Fort Jefferson that will take advantage of this contact point to educate visitors about the Reserve. The exhibit will include practical information on reserve boundaries and regulations, as well as information on the habitats and marine life found in the reserve and the reasons for designating the Reserve. The exhibit will be visually appealing, educational and interesting for the general public, while still conveying necessary regulatory information for those visitors who may be entering the reserve.

Activity 1—Consult with National Park Service staff to determine size and location of kiosk. Review construction designs and materials of similar kiosks;

Activity 2—Design content and layout for kiosk;

Activity 3—Produce and install kiosk.

Strategy E.15: Interagency Visitor Center, Key West

Due to the geographical remoteness of the Tortugas area and considerable depths at which unique coral reef resources are located, it is important to provide educational opportunities for the over 2.5 million visitors to the Keys that will not see these special features first-hand. NOAA, working in conjunction with the NPS and the United States Fish and Wildlife Service, is establishing an interagency visitor center in Key West. This strategy will develop an exhibit for the visitor center in which the natural characteristics and habitats of the Tortugas region are featured. This exhibit will educate the visitor about natural resources while interpreting the multi-agency jurisdiction of the region. The development and designation of the Tortugas Ecological Reserve and the DRTO's Research Natural Area will also be explained.

Activity 1—Consult with National Park Service staff to determine content, design, and layout of exhibit;

Activity 2—Identify other possible agency or private partners for exhibit production;

Activity 3—Produce and install exhibit.

Strategy E.16: Tortugas Site Characterization

Several years ago a comprehensive site characterization of the FKNMS was produced. This 10 volume series is rich in biological, oceanographic, chemical, geological, and other scientific information. A similar, though less voluminous, site characterization of the Tortugas region was produced as a component of the Tortugas Ecological Reserve planning process. In order to heighten the Reserve users' awareness of the oceanographic and biological uniqueness of the Tortugas resources, a layperson's summary of the site characterization will be developed under this strategy. NOAA will seek to create a product in cooperation with the National Park Service that takes an

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ecosystem approach to interpretation, starting at the islands of the Park, and progressing through the deep-water environments of the Reserve. This product will be produced in both electronic and printed format to increase accessibility and reduce printing costs. The web site document will contain hyperlinks to the full site characterization document and to research data from the region, including GIS maps.

Activity 1—Obtain electronic versions of Tortugas Site Characterization document and upload to Sanctuary web site;

Activity 2—Write summary of Site Characterization and conduct review of summary by original authors;

Activity 3—Produce printed version of summary and post electronic version to web site;

Activity 4—Improve web site page by identifying and creating relevant links to data, photos, and GIS maps.

Strategy E.17: Tortugas Ecological Reserve Documentary

This strategy will produce a video documentary on the Tortugas Ecological Reserve to interpret the unique ecological resources of the reserve, explain the necessity of protection, summarize the use of marine zoning as an effective management tool, and explain the process by which the Reserve was created. NOAA has received and continues to receive multiple requests from national and international sources on the process used to create the Reserve. This documentary will convey the breadth of information associated with the reserve and its creation. The documentary will also be duplicated for use by the many agencies that have undertaken action within the Tortugas area relative to reserve designation (e.g., National Park Service, regional fishery management councils, the State of Florida).

Activity 1—Contract with videographer to produce documentary;

Activity 2—Produce duplicate copies of documentary and distribute as needed.

Strategy E.18: Traveling Exhibit on Marine Zoning

Sanctuary Education and Outreach staff participate in more than twenty-five community fairs, trade shows, scientific and management conferences, and related events annually. A variety of traveling exhibits and display materials are used to interpret Sanctuary resources, regulations, and special projects. This strategy involves the development and production of a traveling exhibit on marine zoning in the Sanctuary, including the Tortugas Ecological Reserve. Components of the exhibit will be interchangeable, focusing on a variety of topics such as zone designation, resources protected by various zone types, regulations, research and monitoring of zone performance, and the use of marine zoning in other national and international arenas.

Activity 1—Design content and layout for traveling exhibit;

Activity 2—Produce exhibit components.

Strategy E.19: Interpretive Wayside Exhibits on the Tortugas Ecological Reserve

Of the 2.5 million visitors to the Florida Keys annually, 14.4% participate in boating activities using private vessels. In recent years, visitation to the DRTO has increased from 18,000 visitors in 1984 to 72,000 in 1998. This strategy aims to educate private boaters traveling to the Tortugas by developing and installing interpretive wayside exhibits such as information signs at boat ramps, chambers of commerce, and other strategic locations. Exhibits will provide important information about the Tortugas waters, natural resources, and regulations for the new reserve. The signs will also display information on minimal impact usage and safety considerations for traveling to this remote area.

Activity 1—Identify number of exhibits needed and appropriate locations for exhibits. Prioritize exhibit placement;

Activity 2—Investigate production costs and possible partners for funding exhibits;

Activity 3—Design content and layout for wayside exhibits;

Activity 4—Produce and install exhibits by priority area as funding permits.

Enforcement Action Plan

The SMP supplements the Enforcement Action Plan in the MP by adding the goals of gaining the highest level of compliance by the public who enter and visit the Tortugas Ecological Reserve. This compliance can be achieved through several management actions including education and outreach and on the water presence of Sanctuary staff in programs such as Team OCEAN, where Sanctuary information is distributed along the waterfront or boat to boat by Sanctuary staff and volunteers.

The most effective management action that can be used to achieve compliance with Sanctuary regulations is an effective law enforcement program. Currently, the primary enforcement of Sanctuary regulations is accomplished through an enforcement agreement between NOAA/Office of National Marine Sanctuaries and the State of Florida Fish and Wildlife Conservation Commission. The enforcement efforts are consistent with the goals and objectives for enforcement described in the MP. The MP also calls for cross-deputization of other agency law enforcement personnel (*e.g.*, National Park Service Rangers) to accomplish law enforcement responsibilities within the Sanctuary. This approach to enforcement continues to remain an option.

The success of the Reserve will depend to a large extent on the level of enforcement resources dedicated to the Reserve. Several enforcement options are presently available and are being evaluated for deployment in the Reserve. These options include:

- Installation and monitoring of a long-range radar unit at the Dry Tortugas National Park. This would allow remote monitoring of vessels entering and leaving the Reserve.
- Place two 82' vessels into service for patrolling the Ecological Reserve.
- Cross-deputize and fund National Park Service Rangers to assist in enforcement in the Tortugas Ecological Reserve.

The SMP commits substantial enforcement resources for the Reserve. The SMP sets forth the law enforcement budget as follows:

Personnel

Law Enforcement Officers (4–6)
$50,000 per position
General Support $50,000

Vessels

82' Patrol Vessels (2) No Cost—Agency Property Transfer

NOAA will work with the FWC and other enforcement agencies to develop the enforcement resources that are necessary to assure the success of the Reserve.

Other Enforcement Factors

Because vessels are prohibited from stopping within the Tortugas South portion of the Tortugas Ecological Reserve, except for law enforcement or for scientific research or educational activities pursuant to a sanctuary permit, it will be possible to monitor vessel traffic remotely by radar and response will only be necessary when vessels without a permit stop within Tortugas South. Additionally, access to Tortugas North will be allowed only by permit. This will help Sanctuary managers monitor the level of visitor use in the reserve and will facilitate enforcement efforts.

Mooring and Boundary Buoy Action Plan

The SMP supplements the MP by revising the title to the Mooring Buoy Action to read Mooring and Boundary Buoy Action Plan and by adding several strategies specific to the Tortugas Ecological Reserve.

Tortugas Ecological Reserve Supplement

Strategy 1. Install and maintain boundary buoys for Tortugas North.

Strategy 2. Install and maintain an adequate number of mooring buoys in Tortugas North in appropriate locations.

Strategy 3. Determine whether buoys are appropriate for Tortugas South and, if so, determine the number, type, and locations of buoys.

Regulatory Action Plan

The SMP supplements the Regulatory Action Plan in the MP by calling for extensive coordination with other governmental entities, particularly the State of Florida, to ensure that all required regulations are put in place. The Plan calls for publication on NOAA nautical charts of the new boundaries for the Sanctuary and the reserve.

Research and Monitoring Action Plan

The SMP supplements the Regulatory Action Plan in the MP by identifying and describing research and monitoring strategies for the Tortugas Ecological Reserve. These strategies are expected to have significant effects on Sanctuary resources by providing the knowledge necessary to make informed decisions about protecting the biological diversity and natural ecosystem processes of the Tortugas region. These strategies were developed according to the Sanctuary Research and Monitoring goals and objectives identified in the MP.

Strategy T.1: Ecological Reserve Support Staff

This strategy involves hiring support staff to assist with regulatory implementation and interpretation of the Tortugas Ecological Reserve. This staff member will establish a permit issuance and tracking system for entrance into Tortugas North, answer inquiries from the general public while on-site at the reserve, and assist with research and other reserve issues as needed.

Activity 1—Review support staff logistics (office space, communications, lodging) with National Park Service personnel.

Activity 2—Advertise for and hire support staff.

Strategy T.2: Design and Implement Long-term Ecological Monitoring to Test the Efficacy and Ecological Integrity of the Tortugas Ecological Reserve

Ecological reserves are established within the Sanctuary to protect and enhance biodiversity and to provide natural spawning, nursery, and permanent residence areas for marine life. This strategy establishes monitoring activities that compare reserve areas before and after designation, as well as monitoring which captures changes occurring inside and outside the protected area, which is critical to gauge the effectiveness of ecological reserves as a management tool. This monitoring will also assist Sanctuary management in determining if the area's biodiversity, productivity, and ecological integrity are being adequately protected by the regulations in place.

Consistent with the existing Zone Monitoring Program, indicators for assessing ecosystem function and ecological integrity (such as changes in coral and fish diversity, trophic structure, and water quality) will be monitored. An important element will be monitoring diving impacts by comparing changes in gross habitat morphology in Tortugas South and Tortugas North, particularly around mooring buoys.

Activity 1—Assess existing Tortugas monitoring activities. Prioritize baseline monitoring data needs and provide support to existing monitoring programs to gather necessary data. Contract with additional researchers as needed to fill baseline data gaps.

Activity 2—Develop post-implementation monitoring plan for the Tortugas Ecological Reserve and adjacent areas of varying protection levels.

Activity 3—Convene annual or biannual meeting of Tortugas researchers to share monitoring data with Sanctuary management and review monitoring schedule.

Strategy T.3: Dry Tortugas Marine Laboratory and Research Support Feasibility Study

Historically, the Dry Tortugas have been a place of marine research, supporting early pioneers in the fields of coral reef biology, ecology, oceanography, and underwater photography. A remote marine research station supported by the Carnegie Institution existed in the late 1800's and early 1900's on Loggerhead Key. The Carnegie facility was closed and dismantled decades ago, and since that time research efforts in the region have been sporadic. This strategy undertakes a feasibility study for the re-establishment of this laboratory or a similar facility. Such a facility would address the growing interest in Tortugas research and support the collection of much-needed data to assist National Park Service and Sanctuary managers in future decisions about Tortugas resources. Additionally, the feasibility study will consider other logistical needs to support researchers working in the Dry Tortugas area, such as shore-based lodging.

Activity 1—Meet with NPS personnel to plan feasibility study and desired conditions of research station. Discuss funding options for feasibility study.

Activity 2—Conduct feasibility study and discuss results with NPS. Implement next steps as appropriate.

Strategy T.4: Wireless Data Transfer

This strategy will establish wireless data transfer capabilities using the existing Motorola two-way radio network.

Activity 1—Contact Motorola to determine wireless data transfer capabilities using the existing two way radio network.

Activity 2—If the existing network can be used to transfer data, procure needed software and hardware.

Activity 3—Train staff on wireless data transfer.

Activity 4—Maintain and upgrade system as needed.

Activity 5—If existing two way radio network will not permit data transfer, research additional options.

Strategy T.5: Automated Oceanographic Data Collection

Throughout the Sanctuary a series of automated, continuously functioning sensors mounted on remote platforms or structures (C–MAN Stations) collect physical oceanographic data and report this information real-time to the Internet. This strategy will expand the C–MAN network to include similar data collection at a remote location in the Tortugas. Additionally, instruments that continuously collect data on biological parameters will also be installed.

Activity 1—Assess existing remote data collection activities in the Dry Tortugas.

Activity 2—Contract with current C–MAN Station research team to install a new station in the Tortugas area. Develop maintenance plan.

Activity 3—Investigate instrument capabilities and costs to expand data collection to include biological parameters. Purchase and install necessary instrumentation.

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Strategy T.6: Tortugas Region Non-Use Valuation Study

In the development of the Sanctuary Final Management Plan, user attitude and economic values of the Sanctuary were established through a comprehensive socio-economic study. This strategy will complement the existing socio-economic studies of the Sanctuary by specifically identifying the non-use values that exist within the Tortugas region. Establishing these non-use values is critical for managers to accurately estimate the economic benefits and costs of newly designated reserve areas.

Activity 1—Discuss non-use valuation study requirements with Sanctuary economist.

Activity 2—Contract with economist to conduct study and publish results.

V. Summary of Final Regulations

The regulations applicable to the Reserve start with the current Sanctuary-wide regulations (15 CFR part 922, subpart P, in particular, § 922.163) and those additional regulations applicable to ecological reserves (15 CFR 922.164(d)). The Sanctuary-wide regulations prohibit mineral and hydrocarbon exploration; removal of, injury to, or possession of coral or live rock; alteration of, or construction on, the seabed; discharge or deposit of materials or other matter; operation of vessels in a manner that injures or endangers life, marine resources, or property; diving or snorkeling without flying a diver's down flag; releasing exotic species; damaging or removing markers; moving, removing, injuring, or possessing Sanctuary historical resources; taking or possessing protected wildlife; possessing or using explosives or electrical charges; harvesting or possessing marine life species not in accordance with the Florida Administrative Code; and interfering with law enforcement authorities.

The ecological reserve regulations prohibit the discharge or deposit of any material except cooling water or engine exhaust; taking, disturbing or injuring any dead or living organism; fishing; touching living or dead coral; and anchoring when a mooring buoy is available or on living or dead coral. Transit by vessels is allowed provided that all fishing gear is stowed away.

In addition to the Sanctuary-wide and ecological reserve regulations, the regulations for the Tortugas Ecological Reserve:

- Prohibit anchoring in, prohibit mooring by vessels more than 100 ft in length overall (LOA), and control access to Tortugas North, other than for continuous transit or for law enforcement purposes, via access permit and require permitted vessels to call-in prior to entering or when leaving.
- Prohibit anchoring in, prohibit mooring by vessels more than 100 ft in length overall (LOA), and restrict access to Tortugas South, other than for continuous transit with fishing gear stowed away or for law enforcement purposes, to research or educational purposes. A National Marine Sanctuary General Permit (see 15 CFR 922.166(a)) would be required for all research or educational activities.

The access permit for Tortugas North is free, no paperwork is required, and Sanctuary staff will be available year-round to handle requests. Applicants must call the Key West or Marathon Sanctuary office to request a permit and must radio into the Sanctuary staff person at Fort Jefferson (DRTO) prior to entering and upon leaving the reserve.

Applicants must furnish the following information:

1. Names, addresses, and telephone numbers of owner, captain, and applicant.
2. Vessel name and home port.
3. USCG documentation number, state license, or boat registration number.
4. Length of vessel and primary propulsion type (*i.e.*, motor or sail).
5. Number of divers.
6. Requested effective date and duration of permit.

The permit will be valid for the time the vessel is in the area, not to exceed two weeks. Vessels longer than 100 ft LOA exceed the capacity of the mooring buoys and are therefore prohibited from using them. Advance reservations will not be accepted more than one month in advance. Doubling-up on mooring buoys is permitted and leave and return privileges (dive during the day, stay at the park overnight) are allowed within the time period covered by the permit. Permit holders must notify FKNMS staff at Fort Jefferson by radio no less than 30 minutes and no more than six hours before entering the reserve and upon leaving.

The regulations issued today implement Regulatory Alternative D and amend 15 CFR 922.161 to expand the boundary of the FKNMS to be consistent with Boundary Alternative III. The revised Sanctuary boundary coordinates are set forth in Appendix I to Part 922 which is also revised to make minor revisions in the existing boundary to correct errors, provide clarification, and reflect more accurate data and, in the area of Biscayne National Park, to provide a fixed enforceable boundary. Appendix IV to Part 922 is also revised to make the area within the coordinates for Boundary Alternative III an ecological reserve, to provide clarification, and to remove no longer needed introductory text. Appendices II, V, VI, and VII are revised to correct errors, provide clarification, and reflect more accurate data.

The regulations prohibit anchoring in the Tortugas Ecological Reserve; entering the Tortugas North area of the Ecological Reserve without a valid access permit (except for continuous transit or law enforcement purposes); entering the Tortugas South area of the Ecological Reserve except for continuous transit or law enforcement, or for scientific research or educational activities pursuant to a sanctuary permit; or tying a vessel greater than 100 ft (30.48 meters) LOA to a mooring buoy in the Tortugas Ecological Reserve or tying more than one vessel (other than vessels carried on board a vessel), if the combined lengths would exceed 100 feet (30.48 meters) in length overall (LOA), to a mooring buoy or to a vessel tied to a mooring buoy in the ecological reserve. The reason for the length restriction is to prevent a buoy from being ripped off its mooring.

Because all anchoring is prohibited in the northern portion of the Tortugas Bank no-anchoring zone established by 15 CFR 922.164(g), the regulations revise the zone to be consistent. The existing zone is an area within the Sanctuary boundary where vessels 50 meters or greater in LOA are prohibited from anchoring. The northern portion of the zone overlaps the reserve.

The regulations add a new section to provide for permits for access to the Tortugas North area of the Ecological Reserve. A person with a valid access permit is allowed to enter the Tortugas North area of the Ecological Reserve. Access permits do not require written applications or the payment of any fee. Access permits must be requested at least 72 hours but no longer than one month before the date the permit would be effective. Permits may be requested via telephone or radio by contacting FKNMS at the Sanctuary offices at Key West or Marathon. Permit applicants must provide, as applicable, the following information: vessel name; the names, addresses, and telephone number of the owner, operator and applicant; USCG documentation, state license, or registration number; home port; length of vessel and propulsion type (*i.e.*, motor or sail); number of divers; and the requested effective date and duration of permit (two weeks, maximum). The Sanctuary Superintendent will issue a permit to the owner or to the owner's representative for the vessel when all applicable information has been provided. FKNMS will provide a permit number to the applicant and confirm the effective date and duration period of the permit. Written confirmation of permit issuance will be provided upon request. Permit holders must notify FKNMS staff at the Dry Tortugas National Park office by telephone or radio no less than 30 minutes and no more than six hours, before entering and upon leaving the Tortugas Ecological Reserve. Permit holders may leave and return to the Tortugas North area of the ecological reserve during the time their permit is effective.

Finally, the regulations add a new definition to 15 CFR 922.162, to define "length overall (LOA) or length of a vessel."

VI. Differences Between the Proposed and Final Regulations

There are two primary differences between the proposed and final regulations. The first is a prohibition on all activities in Tortugas South, including non-consumptive diving. The proposed regulations would have allowed non-consumptive activities in Tortugas South including diving. The second is that the prohibition on fishing does not exclude fishing in the Tortugas Ecological Reserve that might be authorized by NMFS under 50 CFR parts 622 and 635. The final regulation applies the existing ecological reserve regulations at § 922.164(d)(iii) to prohibit fishing in the Reserve. This is consistent with the Gulf of Mexico Fishery Management Council's recommendation for a total ban on all fishing in the Reserve. As discussed in the preamble, no-take protection for the critically important coral reef ecosystem of the Tortugas is necessary to preserve the richness of species and help the fish stocks in the Tortugas and throughout the Florida Keys. Preservation of the full biodiversity of the area cannot be accomplished if exceptions are made to the no-take prohibition. Additional changes to the regulations have been made to correct errors, provide clarification and reflect more accurate boundary coordinate data.

VII. Summary of Comments and Responses

More than 4,000 comments were received on the DSEIS/SMP and the proposed implementing regulations for the proposed Tortugas Ecological Reserve. All comments received were treated as being directed to both the DSEIS/SMP and the proposed regulations. Almost 3000 of the comments were form letters expressing general support for the creation of the Tortugas Ecological Reserve. Two hundred and forty-five persons commented by signing a petition. The substantive comments received are summarized below followed by the agency's responses. Multiple but similar comments have been treated as one comment for purposes of response. Comments merely stating personal support or opposition to the establishment of the proposed Tortugas Ecological Reserve and comments supporting the process employed or complimenting the many individuals who participated in that process, while certainly appreciated, do not require responses. Comments beyond the scope of the proposed action, such as establishment of an ecological reserve within the Dry Tortugas National Park, establishing more ecological reserves in the Sanctuary, or making the entire Sanctuary a "no-take" zone, are neither summarized nor responded to. No comments were received on the Initial Regulatory Flexibility Act Analysis (IFRA) per se. However, a number of the comments requested changes to the Preferred Alternative because of impacts on users, all of which are considered small entities for purposes of the Regulatory Flexibility Act. Comments 1, 3, 4, 9, 13, 16–19, 21–23, 36, 41–43, and 50 and the responses thereto summarize the significant issues raised by those comments and the assessment of the agency of such issues. Although changes were made to the proposed regulations, no changes were made as a result of those comments.

Comment 1: A commentor wrote on behalf of over 100 commercial fishermen who are opposed to ecological reserves in the Sanctuary. They believe that ecological reserves are unnecessary for stock or environmental preservation and that reserves are a "back-door" approach to the eventual elimination of all commercial fishing within the Sanctuary. They believe that the statement in the DSEIS that the Tortugas process was a joint effort with the commercial fishing industry is misleading and highly offensive to the rank and file fishermen who oppose the reserve. The commentor stated that he did not participate in the process because he believed that establishment of the Tortugas Ecological Reserve was a "done deal" from the beginning. He requested that the FSEIS not state that establishment of the Reserve was supported by the commercial fishing industry.

Response: NOAA disagrees. NOAA recognizes that some individual fishermen oppose reserves in the Sanctuary. However, NOAA worked with leaders in the commercial fishing industry who served on the Sanctuary Advisory Council, as well as the Tortugas 2000 Working Group. The commercial fishing representatives contacted other commercial fishermen for their input into the Tortugas 2000 process. Dozens of commercial fishermen participated in the process to draft the boundary alternatives for the proposed Tortugas Ecological Reserve. NOAA also worked cooperatively with the Gulf of Mexico Fishery Management Council in the development of the Reserve.

The successful use of ecological reserves or marine reserves as management tools to conserve, protect, and preserve stocks and marine environments is documented in the scientific literature. NOAA has its own positive experiences with the use of "no-take" reserves in the FKNMS since July 1997, as data from scientific research and monitoring of these areas supports the positive benefits of reserves. The Tortugas Ecological Reserve is proposed to protect remote areas that include varied habitats, exceptional coral reefs, and excellent water quality.

NOAA strongly disagrees that reserves are a "back-door" approach to the eventual elimination of commercial fishing in the Sanctuary. The proposal in no way represents an effort to eliminate commercial fishing from the rest of the Sanctuary. Including the Tortugas Reserve, approximately 6% of the total geographical area of the Sanctuary will be closed to fishing.

NOAA recognizes that some of the commercial fishing that formerly occurred in the Reserve will relocate to other areas within and outside the Sanctuary.

Comment 2: NOAA should select Boundary Alternative III (Preferred Boundary Alternative). This alternative provides distinct longitudinal and latitudinal boundary lines for both compliance and enforcement purposes; incorporates important benthic communities that serve as critical foraging areas for coral reef species; provides important buffer areas to the critical coral reef community; protects Riley's Hump, a known fish aggregating and fish spawning site; and protects a wide range of deep water coral reef habitats.

Response: NOAA agrees. Boundary Alternative III remains the Preferred Boundary Alternative. The protection of the diverse and productive benthic communities of the Tortugas region is consistent with the FKNMSPA and NMSA, and it is therefore critical that the full extent of coral reef and related

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habitats lying within Boundary Alternative III be included in the Tortugas Ecological Reserve. Expansion of the Sanctuary boundary as proposed in the Preferred Boundary Alternative is necessary to include unique coral structures and significant habitats lying outside the present boundary, such as Sherwood Forest and Riley's Hump. The on-going and immediate threat of anchor damage and other direct human impacts to the coral reef community outside the existing Sanctuary boundary further supports the Preferred Alternative.

The provision of buffer areas within the design of the Tortugas Ecological Reserve is necessary for several reasons. NOAA has learned from the Western Sambo Ecological Reserve and the Sanctuary Preservation Areas that fishermen will fish along the boundaries of these areas due to the success of no-take areas in increasing fish and other marine life abundance. Without an adequate buffer, traps and other fishing gear could become entangled in coral, threatening the effectiveness of the Ecological Reserve. Several different groups of scientists over the past two years have documented shrimp nets entangled on sensitive coral reef habitat in the proposed Tortugas North portion of the Reserve.

Scientists conducting research in the area of the proposed Tortugas Ecological Reserve have found that benthic primary production provides the base for the food web on this portion of the west Florida shelf. They also found that high levels of fishery production associated with the live bottom habitats are in fact directly supported by the surrounding open sand, algae and seagrass communities in the area. Buffer areas that include these habitat types will contribute to the overall functionality of the Ecological Reserve.

The Tortugas North portion of the Ecological Reserve as contained in Boundary Alternative III (Preferred Boundary Alternative) consists of coral reef communities that are unparalleled in the Florida Keys in their diversity and composition. Several carbonate banks of varying size and depth (30 feet to 75 feet) and low relief hardbottom habitats with patches of sand and rubble characterize Tortugas North. The most prominent features in the Tortugas North reserve are Tortugas Bank and Sherwood Forest. Tortugas Bank crests at 66 feet and supports abundant attached reef organisms such as sponges, corals, and soft corals. North of Tortugas Bank, in an area previously believed to be composed only of sand, are several pinnacles covered with hard and soft corals and reef fish.

Sherwood Forest is an ancient stony coral forest exhibiting 30% or more bottom cover located along the western flank of Tortugas Bank. The top of Sherwood Forest rises to a depth of about 65 feet and covers an area of many acres. The area exhibits a complex habitat with various rock ledges, holes, and caves, providing hiding places for marine life. Unusual coral formations and previously unidentified coral species associations have been observed in this location. Gorgonians and black corals (Antipathies sp.), which are not common elsewhere in the Florida Keys, are also prolific. An abundance of groupers has been documented in Sherwood Forest as have sightings of uncommon and rare fish species such as jewfish, white-eyed goby, and orangeback bass.

The Tortugas South portion of the Ecological Reserve as contained in Boundary Alternative III (Preferred Boundary Alternative) includes a wide range of deep water coral reef habitats that will protect and conserve many rare and unusual reef species, and incorporates sufficient area to provide a buffer to the critical coral reef community. The upper portion of Tortugas South includes the relatively shallow Riley's Hump area in less than 100 feet of water. Riley's Hump consists of attached algae, scattered small coral colonies, sand, and hardbottom habitats. It is also a known fish aggregating and spawning site for several snapper-grouper species.

During the 2000 Sustainable Seas Expedition (SSE), submersible pilots explored the lower (southern) portions of Tortugas South. Deep reef habitats with numerous soft corals but few stony corals were found in depths from 200 to 400 feet. A series of small pinnacles that surround a larger seamount were identified as part of an east-west running ledge that begins around 250 feet and drops to close to 400 feet in a nearly vertical profile. This is unlike any other coral reef habitat discovered within Sanctuary waters. These complex habitats support numerous fish species including streamer bass, yellowmouth grouper, snowy grouper, scamp, speckled hind, creole fish, bank butterflyfish, amberjack, and almaco.

The deepest portions (1,600 to 1,800 feet) of Tortugas South encompass limestone ledges where unusual deep-dwelling sea life such as lantern fish (myctophids), tilefish, golden crabs, and giant isopods have been observed by submersible pilots. Contrary to some opinions that these depths were devoid of life, the sand bottom habitat was observed to be teeming with unique deep sea species of shrimp, fish, sea cucumbers, anemones, and crabs.

These critical deep water communities of Tortugas South are vulnerable to a wide range of impacts from fishing gear including deep water trawls and traps, and impacts from anchoring. Fishing gear impacts have been observed on sand and limestone substrates in some deep water areas.

In order for the Ecological Reserve to be biologically effective and to ensure protection and conservation of the full range of coral reef habitats and species in the Tortugas region, it is critical that all of the various benthic habitats and their associated marine communities, from the shallowest to the greatest depths, be included within the boundary of the Tortugas Ecological Reserve.

Comment 3: NOAA should select the No-Action Alternative I. NOAA should not expand the FKNMS boundary or create an ecological reserve. The reserve "punishes the general public for the sins of commercial interests."

Response: NOAA disagrees. If the no-action alternative is selected and the Sanctuary boundary is not expanded to create the Tortugas Ecological Reserve as contained in the Preferred Alternative, significant coral reef resources would be left at risk to physical destruction by ship and boat anchors and other human impacts including fishing. If the Sanctuary boundary is not expanded to include the geographical extent of the Tortugas Ecological Reserve as proposed in the Preferred Boundary Alternative (III), some of this nation's most significant coral reef resources would be left vulnerable (see environmental description contained in Response to Comment 2).

The Sanctuary boundary established by Congress in the FKNMSPA in 1990 was based upon the very best information available at the time related to the coral reef resources located to the far-western extent of the Florida Keys. Over the last decade scientists and managers have learned and documented a considerable amount about the existence of extensive and unique coral reef resources that are located outside the boundary of the FKNMS. This new information regarding those significant coral reef resources and the threats to them emphasizes the critical need to take action and protect them.

The Tortugas Ecological Reserve is intended to preserve for all, including future generations, the critical coral reef ecosystem of the Tortugas and the extraordinary resources and qualities that are found there. Consumptive recreational activities have resource

impacts that are inconsistent with the protection needed for these resources. All consumptive commercial and recreational activities are being prohibited in the Reserve. Most of the data used in the analysis of the environmental consequences and socio-economic impacts in the DSEIS/SMP refer to commercial activities because commercial activities represent the majority of use of the Tortugas area and because commercial data are more readily available.

Comment 4: NOAA should adopt Boundary Alternative II.

Response: NOAA disagrees. The benthic community contained within the boundary of Alternative II does not include the significant and biologically diverse coral community known as Sherwood Forest. Unless this area is included within the Ecological Reserve, some of this nation's most significant coral reef resources will not be adequately protected for future generations. These unique coral reefs comprise some of the most biologically diverse coral reef communities and best water quality in the Florida Keys. Failure to protect these unique coral reefs will result in their decline from a variety of human impacts.

Additionally, Boundary Alternative II does not contain Riley's Hump, a known fish aggregating and spawning site, or its adjacent deep water shelf communities. Boundary Alternative II would not offer protection and preservation of these unique deep water habitats and their associated fish and invertebrate species (see description contained in Response to Comment 2).

Comment 5: NOAA should adopt Boundary Alternative IV.

Response: NOAA disagrees. While this alternative would protect a larger area than the Preferred Alternative and provide greater ecological benefits, the adverse socio-economic impacts of this alternative on various fishing activities such as recreational charter fishing, commercial fishing, and spearfishing, would be significantly greater because all of Tortugas Bank would be closed to consumptive activities. On balance, the benefits of the increased area protected would be outweighed by the greater socio-economic costs.

Comment 6: NOAA should adopt Boundary Alternative V.

Response: NOAA disagrees. While Alternative V would protect an even larger area than Alternative IV, it would not protect the full range of critical deep water habitat at the southern end of Tortugas South that would be protected by Alternatives III and IV (see description contained in Response to Comment 2). While it would expand protection to the west, the majority of the benthic communities located there are not as threatened from direct impact as those located within the boundary of the Preferred Alternative. Alternative V would not result in significant increased protection to coral reef communities located outside Alternative III, yet would have increased socio-economic costs.

Comment 7: Alternatives IV and V are more consistent than Alternative III with the goals that the Sanctuary has set for the ecological reserve, in addition to being more consistent with Executive Order 13089 by protecting nationally significant coral reef resources.

Response: NOAA disagrees. See Responses to Comments 2, 5 and 6. Boundary Alternative III is the Preferred Boundary Alternative because it will protect ecosystem integrity; protect biodiversity; enhance scientific understanding of marine ecosystems; facilitate human uses to the extent consistent with the other objectives; minimize socio-economic impacts to the extent consistent with the other objectives; and facilitate enforcement and compliance. The Preferred Alternative is of sufficient size, together with the Dry Tortugas National Park, to protect all known nationally significant coral reef resources of the Tortugas region and fulfill the objectives of the FKNMSPA and the NMSA, while not unduly impacting user groups, and is consistent with Executive Order 13089.

The Preferred Boundary Alternative (Alternative III) provides an appropriate balance of significant resource protection while leaving other areas of Tortugas Bank available for consumptive uses, including commercial and recreational fishing, and spearfishing. A detailed comparison of the alternatives and an explanation for the selection of the Preferred Alternative is set forth in the FSEIS. The Preferred Boundary Alternative is consistent with the criteria and objectives established for selecting a Preferred Alternative.

Comment 8: NOAA should adopt Regulatory Alternative D (Preferred Regulatory Alternative).

Response: NOAA agrees. Regulatory Alternative D (Preferred Regulatory Alternative) differs from Regulatory Alternative C (the Preferred Regulatory Alternative in the DSEIS) by prohibiting all activities in Tortugas South except for continuous transit, law enforcement, and, pursuant to a sanctuary permit, scientific research and educational activities. Both Regulatory Alternatives C and D would prohibit any take. The reasons that Alternative D is now the Preferred Regulatory Alternative are to more fully protect fish spawning aggregations found on Riley's Hump, to permit effective enforcement of Tortugas South, the most remote region of the Sanctuary, and to provide a reference area for comparison to gauge the impacts of non-consumptive activities in Tortugas North. Riley's Hump is a known fish spawning aggregation site for at least five species of snapper and several species of grouper. Riley's Hump is also one of the only known spawning aggregation sites for mutton snapper, a highly targeted species for commercial fisheries.

Comment 9: NOAA should adopt Regulatory Alternative C.

Response: NOAA disagrees. See Response to Comment 8.

Comment 10: The resources in the Tortugas area are in good shape overall and do not need the protection of an ecological reserve. The size and number of recreationally and commercially important species of fish remain healthy.

Response: The importance of the resources of the Tortugas region to the rest of the Florida Keys is documented throughout the DSEIS and FSEIS. Over the past few decades the Florida Keys have experienced a significant increase in visitation, particularly at Dry Tortugas National Park where visitation increased 300% from 1984 to 1998 (18,000 to 72,000 visitors). The current population of South Florida of approximately 6 million is expected to double by 2050. It is likely that population pressures, increase in tourism, and improved boating and fishing technology making it easier for more people to regularly visit the same remote sites, located well offshore, will result in greater visitation and pressure on the resources of the Tortugas area. By protecting the resources of the Tortugas area now, NOAA will be able to maintain them in a nearly pristine state, for the benefit of present and future generations. The protection of areas of the marine environment of special national significance due to their resource or human use values, such as the Tortugas region, is consistent with the FKNMSPA and NMSA.

Fisheries biologists have documented alarming declines in the size and abundance of commercially and recreationally important species of snapper, grouper, and grunts throughout the Florida Keys including the Tortugas region.

Comment 11: NOAA must provide an adequate number of mooring buoys in the Reserve. One commentor suggested that NOAA place at least 25 buoys in Tortugas North and a lesser number in

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Tortugas South. Several commentors suggested rotation of mooring buoys.

Response: NOAA agrees that an adequate number of mooring buoys will have to be provided in Tortugas North. It is not now known how many mooring buoys will be needed and where they should be installed. Some buoys will be installed at the more popular dive locations in Tortugas North prior to the effective date of the regulations. Non-consumptive users, such as dive charter operators, will be consulted to determine a desirable number and appropriate locations for buoys. The rotation of mooring buoys will be considered.

It has not yet been determined whether buoys will be installed in Tortugas South because, under the Preferred Alternative, diving will only be allowed for scientific research and educational purposes. Submerged moorings (*i.e.*, moorings located beneath the surface) are being considered as a means to facilitate scientific research activities in this portion of the Ecological Reserve.

Comment 12: Non-consumptive diving should be prohibited throughout the Reserve to prevent any disturbance to the ecosystem. Even non-consumptive diving activity can cause substantial damage to corals.

Response: Prohibiting non-consumptive diving in Tortugas North is not needed to protect the resources or their ecosystem. One of the basic tenets of the FKNMSPA, the NMSA and indeed the Designation Document for the FKNMS, is to allow activities in the Sanctuary that do not cause an adverse effect on the resources or qualities of the Sanctuary, or that do not pose a threat of harm to users of the Sanctuary. However, the resources of Tortugas South, particularly the spawning aggregation areas, are unique and warrant the additional protection of prohibiting diving. Enforcement surveillance in this remote part of the Reserve would be facilitated by prohibiting all activities in Tortugas South except for continuous transit, law enforcement, and, pursuant to a sanctuary permit, scientific research and educational activities. Additionally, prohibiting diving in Tortugas South will provide a baseline to gauge the effects of non-consumptive activities on the resources in Tortugas North.

Tortugas North is less remote and protection and conservation can be more easily afforded to it than to Tortugas South. Allowing non-consumptive diving that is carefully monitored in Tortugas North will provide significant educational and resource appreciation benefits. Further, prohibiting non-consumptive diving in Tortugas North would unnecessarily increase adverse socio-economic impacts on charter dive operators without providing corresponding resource protection. The permit system for Tortugas North will allow the level of diving activity to be monitored, and combined with the reference of Tortugas South, will allow the effects of non-consumptive diving on resources in Tortugas North to be determined.

Education and outreach programs are being implemented that will continue to raise the awareness of divers about the potential impact from their activity on coral reefs. The presence of "no-take" divers in the Reserve is viewed by marine reserve experts as important to help convey the message of the benefits of marine reserves.

Comment 13: NOAA should prohibit commercial fishing in the Tortugas Ecological Reserve but allow recreational fishing, especially catch-and-release fishing. Recreational spearfishing should be allowed in the Reserve because it has little impact on the fish populations of the Tortugas region.

Response: NOAA disagrees. No-take protection for the critically important coral reef ecosystem of the Tortugas is necessary to preserve the richness of species and health of fish stocks in the Tortugas and throughout the Florida Keys. Preservation of the full biodiversity of the area cannot be accomplished if exceptions are made to the "no-take" prohibition.

Even catch-and-release fishing can result in direct and indirect mortality. According to biologists, release mortality can be a significant contribution to total mortality depending on the intensity of fishing. Reef fishes are particularly vulnerable to catch-and-release mortality because of their behavior, long lives, and ecology. Fisheries biologists have reported mortalities ranging from 15–30% of fish that are caught and released. One study suggests high mortality for Barracuda that fight for an extended period.

Spearfishers tend to target the largest members of particular species. Scientists have demonstrated the impact spearfishing activities have of removing top predators in the food chain. The selective removal of the largest individuals of a fish species by spearfishing affects the over-all trophic structure of coral reef communities. Spearfishing charters in the Tortugas region, in particular, often target "trophy" fish for their customers. Research at the Looe Key National Marine Sanctuary between 1983 and 1985 demonstrated a marked increase in fish populations after spearfishing was prohibited. Continued spearfishing in the Tortugas Reserve would adversely affect fish populations and undermine the ecological integrity of the Reserve.

Impacts from commercial and recreational fishing activities are occurring in the Tortugas, where the average size of black grouper has decreased from 22.5 pounds to 9 pounds. The scientific literature as well as NOAA's own experience in the Sanctuary have shown that prohibiting fishing in select areas directly benefits species abundance, size and diversity. Prohibiting all consumptive activities, including commercial and recreational fishing, will greatly help the species within the Reserve achieve greater ecological and demographic potential. As described in the FSEIS, this should result in benefits to some fish populations outside the Reserve. Prohibiting all forms of take will also yield significant scientific benefits because the Reserve will more accurately reflect a natural system against which the effects of extractive human activities can be compared.

In addition, enforcement of the remote Tortugas Ecological Reserve would be complicated significantly if limited extractive activities such as catch and release fishing or spearfishing were not prohibited. NOAA's experience with the existing Sanctuary Preservation Areas is that no-take regulations are more easily enforced and gain more compliance and acceptance from visitors than areas that allow varying extractive activities.

Comment 14: Adequate law enforcement cannot be provided for the Tortugas Ecological Reserve. The 90+ square mile Oculina Marine Reserve off Fort Pierce is unenforceable and the Tortugas Reserve will be, also.

Response: NOAA disagrees. The proposed Tortugas Ecological Reserve is substantially different with respect to enforcement than the Oculina Marine Reserve. The Oculina Reserve is located in a remote area, well offshore of the east coast of Florida. It is not associated with an existing marine protected area and does not have the benefits of all the management programs that help increase the public's awareness of the reserve and the regulations with which they must comply. Education and outreach are important tools that help to gain the compliance of the general public, the majority of which are law-abiding citizens. The Management Plan commits substantial enforcement resources for the Reserve.

As set forth in the Enforcement Action Plan of the Supplemental Management Plan, one of the goals of

Sanctuary management is to gain the highest level of compliance by the public who enter and visit the Tortugas Ecological Reserve. This compliance can be achieved through several management actions including education and outreach and on-the-water presence of Sanctuary staff in programs such as Team OCEAN, where Sanctuary information is distributed along the waterfront or boat to boat by Sanctuary staff and volunteers.

The most effective management action that can be used to achieve compliance to Sanctuary regulations is an effective law enforcement program. Currently, the primary enforcement of Sanctuary regulations is accomplished through an enforcement agreement between NOAA/National Marine Sanctuary Program and the State of Florida Fish and Wildlife Conservation Commission. The enforcement efforts are consistent with the goals and objectives for enforcement described in the Final Management Plan for the FKNMS (July 1997). The Final Management Plan for the Sanctuary also calls for cross-deputization of other agency law enforcement personnel (*e.g.*, National Park Service Rangers) to accomplish law enforcement responsibilities within the Sanctuary. This approach to enforcement continues to remain an option.

A successful Ecological Reserve will depend to a large extent on the level of enforcement resources dedicated to the Reserve. Several enforcement options are presently available and are being evaluated for deployment in the Reserve. These options include:

- Installation and monitoring of a long-range radar unit at the Dry Tortugas National Park. This would allow remote monitoring of vessels entering and leaving the Reserve.
- Place two 82' vessels into service for patrolling the Ecological Reserve.
- Cross-deputize and fund National Park Service Rangers to assist in enforcement in the Tortugas Ecological Reserve.

Prohibiting vessels from stopping within Tortugas South except pursuant to a valid sanctuary permit for scientific research or educational activities will facilitate enforcement. This will make it possible to monitor vessel traffic remotely by radar and response will only be necessary when vessels without a permit stop within the reserve.

The permit system for Tortugas North will help Sanctuary managers monitor the level of visitor use in the reserve and facilitate enforcement efforts.

As set forth in the Management Plan for the Reserve, the law enforcement budget is as follows:

Personnel

Law Enforcement Officers (4–6) $50,000 per position
General Support $50,000

Vessels

82' Patrol Vessels (2) No Cost—Agency Property Transfer

Comment 15: The economic analysis contained in the DSEIS/SMP did not adequately consider activities of fishing clubs in the Tortugas Ecological Reserve Study Area. In public testimony, one fishing club estimated that its membership had 673 person-days of fishing in the Dry Tortugas National Park area in 1998 and was not contacted for input for the socio-economic analyses.

Response: The recreational use of the Tortugas region has been adjusted in the socio-economic impact analysis in the FSEIS/SMP to reflect this comment. In preparing the DSEIS/SMP, NOAA staff relied on directory assistance search to locate private fishing clubs. Only one was found, and that was in Miami. The president of that club indicated that very few if any of its members went to the Dry Tortugas region. He provided names of a few members who were knowledgeable of the region's fishing patterns. Phone calls to these contacts produced no new information and their names were not kept. Additionally, commercial operators who work in the Tortugas area were asked if they saw other boats in the Tortugas but outside the boundaries of the Dry Tortugas National Park. They consistently said that they did not. Some members of the club said they fished in the National Park, but not in the Tortugas Ecological Reserve Study Area (TERSA). NOAA was not able to identify any private households that did any activity in the TERSA.

Comment 16: Representatives of shrimping activities criticized the socio-economic impact analyses on the shrimp industry provided in Leeworthy and Wiley (October 1999). First, they claim that the total catch estimate of 58,374 pounds of shrimp from the area within the Preferred Boundary Alternative should be one million pounds instead. Second, they claim the prices for shrimp used were incorrect and a higher price should have been used. Third, they claim that the assumption that shrimp lost from the no-take areas could be caught elsewhere is incorrect.

Response: The use of the total catch estimate of 58,374 pounds of shrimp caught in the area within the Preferred Boundary Alternative is valid. The commentors offered no quantitative support to justify their assertion that the estimate should be one million pounds. The only information they offered was boat tracking data. No quantities of catch were offered, only that 30 percent of their fishing time was spent in the Tortugas North area. The sample of shrimp fishermen used in the socio-economic impact analysis accounted for 90 percent of the 58,374 pounds that was estimated. Non-sampled fishermen, including those that landed shrimp in counties other than Monroe and Lee (*i.e.*, Hillsborough, Pinellas and Franklin) accounted for the other 10 percent. If all the shrimp catch from the non-sampled population estimated in the TERSA were caught in the area within the Preferred Boundary Alternative, this would only amount to 71,500 pounds. If 30 percent of all the shrimp caught in the Florida Marine Research Institute (FMRI) areas 2.0 and 2.9 and landed in Hillsborough, Pinellas and Franklin counties (183,319 pounds) were caught from the area within the Preferred Boundary Alternative, this would only amount to 54,996 pounds. None of these estimates support an estimate of one million pounds. Not even all the shrimp catch estimated in the TERSA (715,500 pounds) is close to the one million pound estimate and the economists' sample accounted for 90 percent of all the shrimp caught in FMRI areas 2.0 and 2.9.

NOAA economists used an average price per pound at the ex-vessel level of $2.40. This estimate was derived from the NMFS landings and ex-vessel value reported for Monroe County for the year 1997. The landings for Monroe County were reported in a mix of heads-on and heads-off (tails). NOAA economists converted all weights to heads-on before deriving the price per pound (price per pound is equal to total ex-vessel value divided by total pounds of heads-on weight). Data provided by the commentors included a table showing pounds and ex-vessel value from the National Marine Fisheries Service (NMFS) and yields an average price of $4.31 per pound. Both of these prices are correct, however the commentors did not specify the geographic region or the species mix of the sample with which they calculated their price. Furthermore, the NMFS weights cited by the commentors are heads-off weight, whereas the socio-economic analysis used heads-on weight. Most of the shrimp caught in the TERSA was landed in either Monroe County (Stock Island) or in Lee County (Ft. Myers Beach). NOAA economists concluded that the Monroe County landings price per

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pound was the appropriate price to use in the analysis.

The commentors stated that lost catch cannot be replaced by catch from other areas. This presumes that they are fishing all areas as intensely as they can be fished. This is why the socio-economic study uses 58,374 pounds of shrimp as the upper bound estimate of maximum potential loss of from the Preferred Boundary Alternative.

Comment 17: Shrimping should not be prohibited in areas outside the 20 fathom contour at the western end of the Tortugas North because these are not areas of high environmental value or special ecological sensitivity. The eastern boundary of Tortugas North, above the DRTO, should be moved to the west from 82E 47′ to 82E 57′ to accommodate shrimping. Shrimpers are already prohibited from fishing within a 3 million acre Tortugas Shrimp Nursery year-round in State waters and seasonally in EEZ waters. Shrimpers cannot afford to be excluded from any additional areas in the Tortugas region.

Response: A substantial sand buffer area around the coral reef community is needed to provide foraging areas for reef inhabitants without the potential of capture by shrimp trawling. Additionally, the bycatch of shrimping activities is well-known and documented. Trawling outside the 20 fathom contour at the western end of Tortugas North or moving the eastern boundary of Tortugas North to the west would result in mortality of reef fish species and other reef inhabitants through bycatch. Other shrimp fishermen have questioned the need to move the eastern boundary of Tortugas North in light of the bathymetric profile in this area.

Scientists have discovered and documented the remains of shrimp nets entangled around living corals in the proposed Tortugas Ecological Reserve. It is well known and stated by shrimp trawlers that they do not trawl on coral reefs. However, they do trawl off the reefs. Prohibiting shrimping in the Reserve will eliminate the incidental impact of shrimping gear to the living coral reefs.

Preservation of the richness of the species and health of the fish stocks in the Tortugas region and throughout the Florida Keys, and indeed preservation of the biodiversity of the Tortugas region, cannot be accomplished if only the coral reefs are protected. The protection of diverse habitats including sand and other benthic habitats is essential. A recent scientific study has substantiated the importance of sand and other "barren" habitats to the ecology of the west shelf of Florida. Scientists conducting research in the proposed Tortugas Ecological Reserve have found that benthic primary production provides the base for the food web on this portion of the west Florida shelf. They also found that high levels of fishery production associated with the live bottom habitats are in fact directly supported by the surrounding open sand, algae and seagrass communities in the area.

Comment 18: Shrimpers were not, but should have been, represented on the Tortugas 2000 Working Group.

Response: Prior to the establishment of the Working Group, shrimpers stated that the 110 square mile area to the east of the Dry Tortugas National Park originally proposed for the ecological reserve should not be established because it would have an adverse economic impact on their shrimping. In response to them and to other fishers, NOAA did not include this area in the proposed ecological reserve.

Commercial fishing representatives on the Tortugas 2000 Working Group communicated with and received input from shrimpers regarding the proposal and reported this information back to the Working Group. Shrimpers, when shown the proposed boundaries, expressed no concern over the proposed Tortugas Ecological Reserve boundaries. No shrimper expressed an interest in participating in the Tortugas Working Group.

Additionally, 18 of the 28 shrimp operations known to fish in the area were interviewed by NOAA economists. These operations accounted for 65 of the 75 shrimp vessels and 193 of the 213 captains or crew that fish in the TERSA.

Comment 19: The following comments were provided by a charter spearfishing operation:

1. The majority of the reefs where the company takes passengers spearfishing are in the proposed Reserve area. Areas south of Fort Jefferson (not on Tortugas Bank) are not suitable for spearfishing because they are too deep and therefore unsafe, and have poor visibility. The Tortugas Bank area south of the proposed Reserve (south of 24E 30′) is mostly sand and low patch reef, with poor conditions for spearfishing.

2. The company provided detailed information to NOAA regarding the number of trips, days, and passengers the company takes. The survey that was done on the company in 1988 indicates 60 trips per year, 180 days with 550 divers. The information on pages 46 and 47 of the DSEIS is incorrect. The DSEIS does not reflect the company's information and it appears that deliberately falsified information was provided to the Working Group. The Working Group was provided incorrect information regarding the socio-economic impact on small businesses creating a false impression that small businesses would not be negatively impacted.

3. The commentor questioned the data attributed to one of the other two operators. The commentor requested the identity of the operator.

4. The company will go out of business and its employees will lose their jobs if it cannot conduct spearfishing charters in the area of the proposed Reserve, because 90% of the company's business is on the reefs north of latitude 24E 39′. South of that area are sandy patch reefs. A permit should be issued to the company allowing it to continue its business or the southern boundary of Tortugas North should be moved to 24E 40′ 50″N.

5. The DSEIS does not reflect that the company conducts approximately 30 spearfishing trips per year on Riley's Hump.

6. The commentor challenged specific conclusions regarding his business at pages 46, 47, and 123 of the DSEIS, which indicate a maximum potential loss of $13,700.00 of lost revenue and $5,580.00 of lost profits. The commentor claims that his business has grown significantly and that he now operates in the Tortugas more than 260 days per year. He states that he would lose $288,000.00 in revenues and experience a potential profit loss of $144,000.00. The real potential loss could be $460,000.

7. The figures on the Nitrox membrane system are not accurate. The amount should be increased by $10,000.

8. Statements about increased visits to Dry Tortugas National Park are misleading because most visitors only go to Garden Key because of the daily ferry boat service from Key West. These visitors never leave the island and do not impact the reefs.

Response: The DSEIS reports a total maximum potential adverse impact on spearfishing revenues of $66,816 for Boundary Alternatives II and III, $196,944 for Alternative IV, and $230,380 for Alternative V. The analysis and estimates of impacts were based upon survey data collected in 1998 and included information provided by three spearfishing operators. Data provided by the company submitting the above comment indicated that it operated in 48 one square nautical mile grid cells identified in the study area. Boundary Alternatives II and III would exclude the company from only 8 of those grid cells (16.67%). Alternative IV would exclude the company from 26 grid cells (54.17%) and Alternative V would exclude the company from 29 of the 48 grid cells (60.42%). The DSEIS and information provided to the Working Group accurately reflect the information that was reported by the three operators in response to the survey.

The impact estimates in the DSEIS are the maximum losses from displacement of the consumptive recreational activities. Based on the existing patterns of use provided by each of the three operators, it was concluded that they could relocate to other sites in the study area that they indicated they are using and completely offset their losses. While monitoring would be required to verify this conclusion, the estimates of maximum potential loss in the DSEIS represent the upper bound of potential losses based on the data collected in 1998. The FSEIS has been revised based on the assumed validity of the more recent data provided by the commentor. While it is hoped that the spearfishing operators will be able to shift to different locations and to different economic activities (such as non-consumptive dive charters), the need to protect the ecosystem of the Tortugas Ecological Reserve from the impacts of spearfishing justifies the adverse economic impacts on the operators. See also the Response to Comment 13.

NOAA accurately forwarded information to the Working Group. No information was falsified.

The laws governing the collection of business information by the government prevent the disclosure of proprietary information.

The cost estimate for the Nitrox system has been revised.

The overall trend in tourism at Dry Tortugas National Park suggests increased visitor use in the Tortugas area, particularly with the ability of larger, faster vessels from Key West to reach the Park and reef areas beyond the Park. See Response to Comment 10. One company has indicated that its business has increased in the Tortugas area in the last two years.

Comment 20: The National Marine Fisheries Service (NMFS) commented that it is incorrect to state, "the National Marine Fisheries Service (NMFS) is amending the Final Fishery Management Plan for Atlantic Tunas, Swordfish and Sharks (FMP) and its implementing regulations to be consistent with the no-take status of the proposed reserve."

Response: The FSEIS/SMP has been corrected to reflect this, as it is not necessary under that FMP's framework provision to amend the FMP.

Comment 21: NMFS stated that there is a lack of analyses of impacts on commercial and other fishermen and businesses from other counties who may be displaced by the proposed Reserve.

Response: The socio-economic analyses includes catch landed in Monroe, Collier and Lee Counties from each boundary alternative. Catch from the Tortugas that was landed in other counties was insignificant. The quantities and values cited by NMFS are irrelevant as far as impact, since the numbers referred to measure the total catch from FMRI areas 2.0 and 2.9. In Leeworthy and Wiley (October 1999), a set of steps are described showing how they estimated the proportion of this catch from the Tortugas Ecological Reserve Study Area (TERSA). The TERSA is a 1,020 nm² area and is a subset of the larger FMRI Areas 2.0 and 2.9. They estimated how much of the TERSA catch was caught in each boundary alternative. These are the relevant numbers for potential impact. They included all catch landed in all counties but only reported estimates of impact for Monroe, Collier and Lee counties because the catch in all other counties impacted was not significant. Below are summarized the steps used in estimating the impacts from shrimp catch since it was the most valuable portion of total catch, but the same procedures were followed for all species.

Steps in Estimating Economic Impact

Step 1. Examine Landings Data in FMRI Areas 2.0 and 2.9 FMRI areas 2.0 and 2.9 represent a large area generally referred to as the Tortugas, but also include the Marquesas. FMRI keeps landings and value information for this large statistical grid from Florida's trip ticket. The landings cited by NMFS for FMRI areas 2.0 and 2.9 are correct. But these values do not represent impact by the proposed Tortugas Ecological Reserve. Only a small portion of these landings are impacted by any of the proposed boundary alternatives.

Step 2. Examine Landings from the Tortugas Ecological Reserve Study Area (TERSA). Leeworthy and Wiley selected a portion of FMRI Areas 2.0 and 2.9 for the study area and a 1,020 nautical square mile area, called the Tortugas Ecological Reserve Study Area (TERSA). NOAA attempted to collect information on catch from all commercial fishermen that reported catch from FMRI areas 2.0 and 2.9. Thomas Murray and Associates limited the sample to those in Monroe, Dade, Collier and Lee counties for cost reasons and because the catch from FMRI areas 2.0 and 2.9 landed outside Monroe, Collier and Lee counties was only a small proportion of total catch. For example, 97.21 percent of the shrimp caught in FMRI areas 2.0 and 2.9 was landed in Monroe and Lee counties. The other 2.79 percent was landed in Hillsborough, Pinellas and Franklin counties which amounted to 183,319 pounds valued at $450,021.

The sample of shrimp fishermen included 18 of the 28 shrimp operations known to fish in FMRI areas 2.0 and 2.9. These 18 operations accounted for 65 of the 75 shrimp vessels and 193 of the 213 captain or crew shrimping in the area. The sample accounted for over 90 percent of the shrimp catch in FMRI areas 2.0 and 2.9.

The sample indicated they caught only 10 percent of all their catch from FMRI areas 2.0 and 2.9 in the TERSA. Using an average of 1997–1998 catch in FMRI areas 2.0 and 2.9, Leeworthy and Wiley estimated that 715,500 pounds of shrimp were caught from the TERSA. This amount includes those amounts landed in all counties of Florida, not just Monroe and Lee counties. NOAA used a factor of 1.10 to account for the non-sampled shrimp catch. This factor was applied to each one square mile grid cell to extrapolate sampled shrimp catch to the total population estimate of shrimp catch. See Leeworthy and Wiley (October 1999). The 715,000 pounds of shrimp caught in the TERSA still do not represent impacted catch, it simply represents the total amount estimated for the study area.

Step 3. Examine Landings Potentially Impacted by a Particular Boundary Alternative for the No-Take Area.

The spatial distribution of shrimp catch from our sample of shrimpers was used to derive the distribution of all shrimp catch for the TERSA. The Leeworthy and Wiley sample accounted for 665,500 pounds of the total of 715,500 pounds of shrimp catch estimated for the TERSA. The key assumption used was that the non-sampled catch had the same distribution as the sampled catch.

Catch within a boundary alternative was labeled maximum potential loss under the assumption that all catch within the no-take area could not be replaced. For the Preferred Boundary Alternative, they estimated the maximum potential loss of 58,374 pounds of shrimp. This amount includes catch landed in all counties of Florida including Monroe, Lee, Hillsborough, Pinellas and Franklin counties. Since 2.79 percent of the total shrimp catch from FMRI areas 2.0 and 2.9 was landed in Hillsborough, Pinellas and Franklin counties, this would imply that only 1,629 pounds of shrimp (.0279 times 58,374) valued at $3,910 would be lost from the three counties. Given the insignificance of this amount, they did not present separate estimates of this

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impact in Leeworthy and Wiley (October 1999). Actually, Leeworthy and Wiley included the amounts in the impacts for Monroe, Collier and Lee counties, thus slightly overstating the impacts in these counties. But again, these amounts are insignificant.

The same procedures were followed for finfish and all other species and are documented in Leeworthy and Wiley (October 1999). The document Proposed Tortugas 2000 Ecological Reserve, Draft Socio-economic Impact Analysis of Alternatives, October 1999 by Dr. Vernon R. (Bob) Leeworthy and Peter C. Wiley can be found at http://www-orca.nos.noaa.gov/projects/econkeys.econkeys.html.

Comment 22: NMFS stated that "the economic outcomes relative to private recreational fishing and diving do not appear to be addressed."

Response: Leeworthy and Wiley (October 1999) and the DSEIS documented that no information could be found to support private household use for any recreational activity in the TERSA. Leeworthy and Wiley identified the known population of charter/party operators in the TERSA. The Rod and Reel Club, Inc. in Miami, Florida, provided other contacts and which also reported no activity in the TERSA. Leeworthy and Wiley found that although some members of the club occasionally went to the Dry Tortugas National Park, they did not fish in the TERSA. In addition, each of the commercial operators that operated in the TERSA was asked whether s/he had seen any private household boats in the TERSA and all reported seeing each other, but no private household boats. Leeworthy and Wiley concluded that the private household boat usage, if it existed at all, was insignificant. In this case, usage was close enough to zero to be treated as zero.

Comment 23: NMFS stated that the DSEIS lacks an analysis of community impacts and should be analyzed at the City or Census Designated Place level.

Response: Leeworthy and Wiley had Thomas Murray and Associates go back to the data and assign FIPSCODES for City and Census Designated Places for where commercial fishermen live and where they landed their catch. They did the same for recreational charter boat operations.

Comment 24: The United States Environmental Protection Agency (EPA) rated the DSEIS as "EC–2" which means EPA has environmental concerns regarding the proposed Reserve, and believes more information is needed to fully assess the impacts. In particular, EPA stated further details are needed regarding measurable activities that could be used to manage natural resources in the Reserve, such as the number of permits NOAA plans to issue and the amount of visitor education/communication expected. Information should also be given regarding the frequency of ecological monitoring activities. It would also be helpful if the FSEIS included a map that showed the formerly proposed area that was in the Draft EIS and DMP for the FKNMS (1997) but that was later rejected, as compared to the Preferred Alternative in the DSEIS (2000), explaining how the Preferred Alternative protects the environment and prevents adverse economic impacts, as contrasted with the former proposal.

Response: At this time, there are no plans to limit the number of access permits for Tortugas North. However, as described in the Final Supplemental Management Plan, it will be possible to use the access permit system to determine the number of divers visiting Tortugas North annually and the areas in the vicinity of mooring buoys will be examined as primary sites for diver impact. This will enable sites to be monitored for impacts from diving. This information can then be used to determine whether it is necessary to limit the number of access permits for those who visit Tortugas North. The questions regarding public education and outreach and the frequency of ecological monitoring have also been addressed in the Education and Outreach Action Plan and Research and Monitoring Action Plan of the FSEIS/SMP. A map showing the previously considered site for the Reserve has not been added to the FSEIS because NOAA believes it would confuse the public with regards to the current Ecological Reserve proposal.

Comment 25: The United States Department of the Interior, Fish and Wildlife Service, commented that the importance of the Tortugas area as a spawning site and as a "source" reef for the fish communities found in the Key West and Great White Heron National Wildlife Refuges is just beginning to be understood scientifically. The ability of the Refuges to maintain a healthy ecosystem for the wildlife that inhabit them is directly dependent upon a healthy marine component. The avian resources of the Refuges feed upon the fish communities of the Refuges. Those fish communities depend upon a healthy "upstream" ecosystem, which includes the Tortugas region. Marine reserves are a viable tool for resource protection. The protection of marine resources in the Tortugas region will benefit the Refuges. Because of this, the USFWS endorses the Tortugas 2000 Preferred Alternative and proposed rules.

Response: The FSEIS has been revised to reflect the importance of the Tortugas area to the Key West and Great White Heron National Wildlife Refuges. It is recognized that the Tortugas Ecological Reserve will serve as important feeding grounds for many bird species that frequent the Key West and Great White Heron National Wildlife Refuges. Additionally, several threatened and endangered sea turtles that nest in the Key West National Wildlife Refuge spend a portion of their life cycle in the Tortugas Ecological Reserve region.

Comment 26: The Florida Fish and Wildlife Conservation Commission (FWC) was concerned that no limits were being placed on the level of non-consumptive diving that would be allowed. The FWC stated that non-consumptive diving results in some morbidity and mortality to coral reef habitat and asked that controls be placed on the number of divers and dive trips to assure minimal acceptable damage to the habitat. The FWC was also concerned over the adequacy of the enforcement resources. The FWC believes that the minimal enforcement resources needed to enforce the Reserve would be two vessels 50 feet or greater in length with a Lieutenant and two officers for each vessel. The FWC encourages NOAA to work with it to develop these enforcement resources in order to assure the success of the reserve.

Response: Regulatory Alternative D allowing non-consumptive diving in Tortugas North but closing Tortugas South to all diving except for scientific research or educational purposes, pursuant to a valid sanctuary permit, provides an appropriate degree of public access. See Response to Comment 12 regarding non-consumptive diving in the Reserve. If the monitoring of impacts from non-consumptive diving in Tortugas North demonstrates that its carrying capacity is being exceeded, limits can be imposed. See Response to Comment 14 regarding the Enforcement Action Plan for the Tortugas Reserve. NOAA will work with the FWC and its other enforcement partners to develop the enforcement resources that all agree are necessary to assure the success of the Reserve.

Comment 27: The Gulf of Mexico Fishery Management Council (GMFMC) requested that the Sanctuary Program use its authority to prohibit anchoring and all diving within the portions of Tortugas North and Tortugas South that are within the Council's jurisdiction (all of Tortugas South and 13 nm² of Tortugas North). Non-consumptive diving can impact and damage bottom habitat through the inadvertent touching of corals or the stirring up of sand and silt on the bottom. Non-consumptive diving can adversely affect sensitive habitats, the normal behavior of fish, and spawning activity. Anchoring and non-consumptive diving could also adversely affect essential fish habitat in the Reserve. In addition, if non-consumptive diving is allowed, it will be difficult to enforce prohibitions against spearfishing and the taking of lobster.

Response: Under the Preferred Alternative, all anchoring in Tortugas North and South would be prohibited as well as all activities in Tortugas South except for continuous transit, law enforcement, and, pursuant to a sanctuary permit, scientific research and educational activities. Non-consumptive diving will be allowed in all of Tortugas North. See Responses to Comments 8 and 12. NOAA does not anticipate that there will be significant non-consumptive diving in the area of Tortugas North within the GMFMC's jurisdiction because of the lack of coral reef formations.

Comment 28: Monroe County commented that the socio-economic section of the DSEIS seems to have been inserted out of context. This rather lengthy section should be reduced to some simpler explanations, tables and conclusions, then attach the larger document as an appendix.

Response: NOAA has retained the socio-economic section in the main body of the FSEIS/SMP but has revised it to make it clearer.

Comment 29: Monroe County commented that the FSEIS should provide some additional explanation concerning the table of benthic habitats in the DSEIS. It is not clear whether the 59% of unmapped acreage is a less significant area within the overall total (it should be noted if so). If it is not, then this area needs significant additional exploration.

Response: The benthic habitats categorized in Table 1 of the FSEIS represent those identified as the result of one mapping project based on aerial photographs and limited groundtruthing in the Tortugas region. Extensive characterization of the benthic communities within Dry Tortugas National Park has been completed (Agassiz 1883, Davis 1982, and Jaap 1998). Also, scientific exploration of benthic habitats within the proposed Tortugas Ecological Reserve area has occurred since the completion of the DSEIS (Miller, unpubl. data). However, NOAA agrees that additional mapping and exploration are needed to accurately assess the full extent of marine resources throughout the Tortugas region.

Comment 30: Monroe County commented that the FSEIS should include a table summarizing the regulatory alternatives.

Response: A table summarizing the regulatory alternatives has been added to the FSEIS.

Comment 31: The management plan should be designed to: (1) Protect ecosystem structure, function, and integrity; (2) improve fishery yields; (3) expand knowledge and understanding of marine systems; and (4) enhance non-consumptive opportunities.

Response: The regulations implementing the designation of the reserve are designed to protect ecosystem structure, function and integrity and should improve fishery yields outside of the closed areas. The management plan has been redesigned with many objectives including better understanding of marine systems as well as providing better opportunities for non-consumptive activities within the Tortugas North area of the Reserve.

Comment 32: The regulations concerning fishing in the Reserve should be issued pursuant to the National Marine Sanctuaries Act and the exception clause that would authorize fishing pursuant to regulations issued pursuant to the Magnuson-Stevens Fishery Conservation and Management Act at 50 CFR Parts 622 and 635 should be eliminated from the fishing prohibition.

Response: The fishing regulations will be issued under the National Marine Sanctuaries Act and have been revised to prohibit all fishing in the reserve without exception.

Comment 33: Fishing and other consumptive activities should be prohibited in the Reserve, including all forms of diving-related extraction. Carefully regulated non-consumptive diving should be allowed to continue to the extent consistent with resource protection.

Response: See Response to Comment 12. All consumptive activities are prohibited within the Reserve. As described in the FSEIS/SMP, the permit system for Tortugas North will allow NOAA to monitor the level of non-consumptive diving activity and its effect on resources in Tortugas North.

Comment 34: The Reserve should be permanent and should not be subject to sunset provisions.

Response: The only portion of the Tortugas Reserve that would be subject to termination would be the areas located in State waters. Pursuant to NOAA's Memorandum of Agreement with the State of Florida, the State has the right to review the portions of the Sanctuary located in State waters and the applicable regulations after 5 years. Based on its review, the Governor of the State may object to the designation of any portion of the Sanctuary in State waters and the continued application of the regulations.

Comment 35: NOAA should implement the Tortugas Reserve with strong enforcement, research and monitoring, education and outreach programs, and interagency cooperation to maximize the value of the Reserve.

Response: The Final Supplemental Management Plan so provides. See Response to Comment 14.

Comment 36: The economic analysis contains a bias toward hypothetical, short-term economic losses to a handful of consumptive users. Such losses are highly speculative in real-world terms and the quantitative analysis provided in the DSEIS lends them more weight than appears appropriate. The economic analysis also does not appear to account adequately for likely future migration of fishing economic activity to other economic sectors. The likelihood of continuing future reductions in fishing activities as a result of overfishing do not appear to be incorporated into the DSEIS' discussion.

Response: NOAA staff primarily analyzed data from users engaged in activities within the Tortugas Ecological Reserve Study Area. To assess maximum economic impacts, they assumed that the users could not replace their losses if the Tortugas Reserve were closed to consumptive activities. This is a very conservative assumption because, as stated in the DSEIS, many users will likely be able to relocate their activities outside of the Reserve. The protections afforded to the habitats in the Tortugas Reserve will also benefit displaced users by increasing production in areas outside of the Reserve. However, there is no hard data indicating the extent of mitigation or the likely future migration of fishing economic activity to other economic sectors.

Comment 37: The DSEIS does not describe clearly defined and scientifically justifiable goals. In particular, there are five fundamental objectives that are consistent with the overarching goal of maintaining the native biodiversity of a region in perpetuity: (1) represent all ecosystem types across their natural range or variation; (2) maintain or restore viable populations of all native species in natural patterns of abundance and distribution; (3) sustain ecological and evolutionary processes within their

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natural ranges of variability; (4) build a conservation network that is adaptable and resilient to short-term and long-term environmental change; and (5) regulate human uses that are consistent with conservation of native biodiversity, and eliminate those that are not.

The Plan should also consider additional criteria in order to protect endangered, threatened, rare or imperiled species, small populations, species with limited vitality, species with very specific habitat requirements, areas of high endemism, areas of productivity, areas of high diversity, and movement and migration corridors.

Response: Most of the five biodiversity goals are contained within the criteria for choosing the location and protection measures for the Ecological Reserve (see Part VI of this FSEIS). Specific subcriteria have been added to clarify what is contained in each criterion. Likewise, protecting endangered, threatened, rare, or imperiled species is included within the criterion "Protecting biodiversity, including the maintenance or restoration of viable populations of native species."

Part II of the FSEIS includes clear objectives for the Reserve. As stated, the goal for the Sanctuary zoning plan is to protect areas representing diverse Sanctuary habitats and areas important for maintaining natural resources and ecosystem functions. The objectives of the Reserve are to: protect ecosystem integrity; protect biodiversity including the maintenance or restoration of viable populations of native species; enhance scientific understanding of marine ecosystems; and facilitate human uses to the extent consistent with the other objectives. These are scientifically justifiable goals and objectives.

The goals listed by the commentor are essentially the goals and objectives that the establishment of the Reserve and issuance of the implementing regulations are designed to achieve. Likewise, the Supplemental Management Plan is designed to achieve the goals and objectives for which the reserve is being established and regulated.

Comment 38: The DSEIS does not define or identify indicators for assessing ecological integrity.

Response: Indicators for assessing ecological integrity have been incorporated in the Research and Monitoring Action Plan. These indicators include: changes in fish and coral diversity, changes in predation, herbivory and trophic structure, changes in water quality (nutrients and transmissivity), and changes in user activities.

Comment 39: The Draft Supplemental Management Plan is inadequate and needs to be more comprehensive. It should include:

- Specific goals and objectives;
- Performance measures with an implementation schedule;
- An estimate of management costs for implementing and maintaining the reserve;
- An expanded education plan;
- An expanded enforcement plan;
- A description of the permitting system with defined criteria and capacity limits;
- A mooring and boundary buoy component that includes criteria for placement and costs for placement and maintenance; and
- An expanded research and monitoring plan that includes a resource inventory, monitoring of ecological performance measures, cooperative research agreements, and database of research.

Response: See Response to Comment 37. The FSEIS/SMP includes:

- Specific goals and objectives;
- Estimate of management costs for implementing and maintaining the reserve;
- An expanded education plan;
- An expanded enforcement plan;
- A description of the permitting system;
- A mooring and boundary buoy component that includes costs for placement and maintenance; and
- An expanded research and monitoring plan that includes a resource inventory, monitoring of ecological performance measures for assessing ecological integrity, and cooperative research agreements.

Comment 40: NOAA should develop a broader research initiative including, at a minimum:

- Further identification and study of spawning aggregations including grouper, snapper and jewfish;
- Further studies of patterns of short- and long-distance larval dispersal;
- Complete inventories of biodiversity and habitat structure in the Reserve and Sanctuary waters in the region;
- Further documentation of the distribution and abundance of threatened, endangered, and rare species in the Reserve; and,
- Field experiments and comparative studies to test hypotheses generated by these studies.

Response: The Research and Monitoring Action Plan has been expanded to include long-term ecological monitoring to test the efficacy of the Reserve. As modified, the Plan will compare reserve areas before and after designation, as well as monitor changes occurring inside and outside the protected areas, in order to determine the overall effectiveness of the reserve. Over time, these efforts will examine larval dispersion and spawning aggregations. There should also be complete inventories of biodiversity and habitat structure in the Reserve, which would include more complete descriptions of the presence of endangered, threatened and rare species. Also the Plan has been expanded to monitor the effects of non-consumptive diving activities on the resources in Tortugas North using the reference provided by Tortugas South.

Comment 41: Scuba diving and underwater exploration in the Reserve should be permitted only in the company of a qualified guide.

Response: NOAA disagrees. It is not necessary to require that diving in the Reserve be conducted with a guide to adequately protect coral reef resources. As explained elsewhere (see Response to Comment 12) diving effects will be monitored to determine whether the Reserve's resources are being impacted. Also, a sufficient enforcement presence will be maintained to deter and detect violations of the no-take provisions.

Comment 42: Neither the Everglades National Park nor the Dry Tortugas National Park prohibit recreational fishing and they have the best fishery management system in the world. NOAA should not prohibit recreational fishing in the Tortugas Reserve.

Response: NOAA disagrees. See Responses to Comments 3 and 13. The Dry Tortugas National Park is proposing changes to its management plan that would prohibit recreational fishing in approximately 40% of the Park that would be adjacent to the Tortugas Reserve.

Comment 43: The United States Government does not have jurisdiction over the area that would be included in the proposed reserve.

Response: NOAA disagrees. The Tortugas Reserve is within the Exclusive Economic Zone and the authority of the United States to establish and manage the Reserve is well-established and consistent with international law. In 1983, President Ronald Reagan declared a 200 nautical mile Exclusive Economic Zone, in which the United States may conserve and manage natural resources, consistent with international law (Presidential Proclamation 5030, March 10, 1983). The NMSA expressly applies to the EEZ. In 1989, President Reagan extended the territorial sea to twelve nm (Presidential Proclamation 5928, December 27, 1988). In 1999, President William J. Clinton extended the contiguous zone from twelve to twenty-four nm, extending the jurisdiction of the United States over customs, fiscal, immigration, and sanitary laws (Presidential Proclamation 7219, August 2, 1999).

Comment 44: Sanctuary staff working at Dry Tortugas National Park should live and work aboard ships rather than increase environmental pressure on existing facilities at the Park.

Response: NOAA will work with the National Park Service so that Sanctuary personnel will be stationed at the Park in a manner that is consistent with environmental protection of the islands and waters in the Park.

Comment 45: NOAA's plan for a visitor center in Key West is redundant and would detract from other visitor centers in Key West dedicated to interpretation of the marine environment.

Response: NOAA disagrees. The creation of the visitor facility in Key West is not a part of this action. The facility has already been established and is located within the existing Dr. Nancy Foster Environmental Center at the Truman Annex. The visitor center complements existing interpretive centers in Key West. Among other things, the facility will present information derived from research conducted within the Sanctuary (including the Reserve) as well as describe ongoing research projects and other various activities related to the Sanctuary.

Comment 46: A nominal charge should be assessed for access permits to the Reserve.

Response: NOAA disagrees. As proposed, the access permit system will require minimal effort by users and will be relatively inexpensive for NOAA to operate. The system will be simple and reduce the time imposed on permit applicants. The cost to NOAA of administering the access permit system is expected to be small. If a fee were charged to offset the cost, the system would increase in complexity, increasing the cost that would need to be offset as well as increasing the burden on users applying for permits. In the interest of administrative efficiency and of not placing a burden on permit applicants, a permit fee is not being imposed.

Comment 47: The greatest threat to the marine resources of the area is pollution and degradation of water quality. Vessel discharges should not be permitted in the Reserve.

Response: Pollution and degradation of water quality is a serious threat to Sanctuary resources. Under the regulations applicable to ecological reserves, only engine cooling water and exhaust can be discharged in the Reserve.

Comment 48: Select a Preferred Alternative for the reserve that allows for fishing to the northwest of Loggerhead Key.

Response: The only alternative that would allow fishing to the northwest of Loggerhead Key is the No-Action Alternative (see Response to Comment 3).

Comment 49: Prohibit the use of motorized Personal Watercraft in the Ecological Reserve.

Response: While the use of Personal Watercraft has not been documented in the TERSA, Regulatory Alternative D will prohibit all activities in Tortugas South except for continuous transit, law enforcement, and pursuant to a Sanctuary permit, scientific research and educational activities. Should the use of motorized Personal Watercraft in Tortugas North be documented as a problem, NOAA will consider initiating appropriate rulemaking.

Comment 50: The Tortugas 2000 Working Group did not have a representative of the tourism industry and did not consider non-consumptive activities.

Response: Among its membership, the Tortugas 2000 Working Group had two non-consumptive diving representatives and one citizen-at-large representative. Additionally, the Working Group's proposal was recommended to Sanctuary managers by the Sanctuary Advisory Council which, among its members, has representatives of the tourism industry and other non-consumptive interests.

Comment 51: Several commentors addressed vessel discharge restrictions, pumpout facilities, and other public access issues related to the DRTO and surrounding Sanctuary waters. One commentor suggested that NOAA charts be updated to reflect any new regulatory changes in the Tortugas area.

Response: The NPS General Management Plan revisions are taking into consideration pressures and limitations on infrastructure and other Park resources. Sanctuary regulations will prohibit vessel discharges in the Tortugas Ecological Reserve, with the exception of engine cooling water and exhaust. NOAA nautical charts will be updated to include relevant information once regulations to implement the Ecological Reserve are issued and effective.

Comment 52: A number of commentors suggested various education, mooring buoy, research and monitoring, and enforcement programs for the Tortugas Ecological Reserve.

Response: The Final Supplemental Management Plan has been updated to reflect these comments and suggestions.

Comment 53: A commentor stated that it appeared that several disparate agency processes were going on with regard to an appropriate fishing regime for the Tortugas area and that no proposal should be adopted until all disparate processes are concluded.

Response: Providing comprehensive protection to the critical coral reef resources of the Tortugas must take precedence over awaiting the completion of the many other agency processes. However, NOAA has gathered input from the seven resource management agencies with jurisdiction in the TERSA with the ultimate goal of achieving a consensus to the extent consistent with requirements of the FKNMSPA, NMSA, and other applicable law. The Tortugas 2000 Working Group process, boundary and regulatory alternative development, and subsequent public hearings effectively brought all resource management entities to the table and ensured that federal and state regulations will be thoroughly integrated. This process has served as a model for interagency and stakeholder collaboration.

VIII. Miscellaneous Rulemaking Requirements

Marine Protection, Research, and Sanctuaries Act

Paragraph (b)(1) of section 304 of the NMSA, 16 U.S.C. 1434(b)(1), requires the Secretary, in designating a national marine sanctuary, to publish in the **Federal Register** a notice of the designation together with final regulations to implement the designation and any other matters required by law, and submit such notice to the Congress. The Secretary also is required to advise the public of the availability of the final management plan and the final environmental impact statement with respect to the Sanctuary. While this action does not designate a new national marine sanctuary, it revises the boundary and changes the terms of designation of an existing sanctuary, the FKNMS, and therefore must satisfy the requirements of section 304. In accordance with section 304, the public was advised on December 1, 2000 (65 FR 75285) of the availability of the FSEIS/SMP and this notice is being submitted to the Congress for its review.

Executive Order 12866

This action has been determined to be significant for purposes of E.O. 12866. That Order requires that the draft text of the final regulations, a reasonably

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detailed description of the need for the action, an explanation of how the action will meet that need, and an assessment of the potential costs and benefits, including an explanation of the manner in which the action is consistent with statutory mandates, and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions (referred to as a Regulatory Impact Review (RIR)) be prepared and be submitted to the Office of Management and Budget for review. In accordance with the requirements of the Executive Order, NOAA has prepared a RIR for this action and has submitted it to OMB for review. The RIR is contained in part V of the FSEIS/SMP.

Regulatory Flexibility Act

In accordance with the requirements of section 603(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a)), NOAA prepared an initial regulatory flexibility analysis (IFRA) describing the impact of the proposed action on small entities. No comments were received on the Initial Regulatory Flexibility Act Analysis (IFRA) per se. However, a number of the comments requested changes to the Preferred Alternative because of impacts on users, all of which are considered small entities for purposes of the Regulatory Flexibility Act. Comments 1, 3, 4, 9, 13, 16–19, 21–23, 36, 41–43, and 50 and the responses thereto summarize the significant issues raised by those comments and the assessment of the agency of such issues. Although changes were made to the proposed regulations, no changes were made as a result of those comments.

Section 604(b) (5 U.S.C. 604(b)) requires that NOAA prepare a final regulatory flexibility analysis (FRFA) for this action. The FRFA is required to contain: (1) A succinct statement of the need for and objectives of the rule; (2) a summary of the significant issues raised by the public comments in response to the IRFA, a summary of the assessment of the agency of such issues, a statement of any changes made to the proposed rule as a result of such comments; (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (4) a description of the projected reporting, record keeping and other compliance requirements of the regulations, including an estimate of the classes of small entities that will be subject to these requirements and the type of professional skills necessary to prepare any required report or record; and (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual policy and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

NOAA has prepared the required FRFA. The complete FRFA is contained in Parts I, IV, V, VI and Appendix H of the FSEIS/SMP. The following is a summary of the FRFA.

Statement of Need

As previously set forth in this regulatory preamble.

Goals, Objectives and Legal Basis

As previously set forth in this regulatory preamble.

Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, a Statement of Any Changes Made to the Proposed Rule as a Result of Such Comments

No comments were received on the IFRA per se. However, a number of the comments requested changes to the Preferred Alternative because of impacts on users, all of which are considered small entities for purposes of the Regulatory Flexibility Act. Comments 1, 3, 4, 9, 13, 16–19, 21–23, 36, 41–43, and 50 and the responses thereto appearing in Section VI Summary of Comments and Responses, above, summarizing the significant issues raised by those comments and the assessment of the agency of such issues. Although changes were made to the proposed regulations, no changes were made as a result of those comments.

Discussion of All Relevant State and Federal Rules Which May Duplicate, Overlap or Conflict with the Regulations

Under the Magnuson-Stevens Act, the GMFMC has primary federal responsibility and expertise for the development of FMPs throughout the Gulf of Mexico and has developed an Essential Fish Habitat Amendment for the various GMFMPs, which includes the area of the proposed Tortugas Ecological Reserve. The GMFMPs are implemented by regulations promulgated by the NMFS (50 CFR 622). At the GMFMC's meeting on November 9, 1999, the NOS and NMFS requested that the GMFMC take steps to prohibit fishing, consistent with the purpose of the proposed ecological reserve. The GMFMC accepted this request and at its July 10–13, 2000 meeting, adopted a Generic Amendment Addressing the Establishment of Tortugas Marine Reserves. That amendment to the GMFMPs is consistent with the no-take Tortugas Ecological Reserve proposed by NOAA and NOAA's regulations for ecological reserves in the FKNMS, at 15 CFR 922.164(d).

NMFS intends to issue regulations under the Magnuson-Stevens Act consistent with the no-take status of the Tortugas Ecological Reserve for the species covered by the GMFMPs and for Atlantic tunas, swordfish, sharks, and billfish. In federal waters, these regulations will duplicate and overlap, but not conflict, with the Sanctuary regulations prohibiting fishing in the Tortugas Ecological Reserve. Regulations issued under the Magnuson-Stevens Act must satisfy the requirements of that Act including the National Standards set forth in that Act. Sanctuary regulations including those governing fishing are issued under the NMSA. While some of the goals and objectives of the two Acts are similar, many of the goals and objectives of the two statutes are different.

The State of Florida may implement a no-fishing rule for the area of Tortugas North within State waters. In State waters, this rule could duplicate and overlap with the Sanctuary, but not conflict with the Sanctuary no-take rule for the Reserve. The State of Florida is co-manager of the Reserve with NOAA and Sanctuary regulations affecting State waters must have the approval of the State.

Description of the Projected Reporting, Record Keeping and Other Compliance Requirements of the Regulations, Including an Estimate of the Classes of Small Entities that Will be Subject to These Requirements and the Type of Professional Skills Necessary to Prepare Any Required Report or Record

The access permit application and call in requirements are described in the Summary of Final Regulations, above. Any entity desiring to enter Tortugas North for other than continuous transit or for law enforcement purposes will be subject to these requirements. It is anticipated that dive charters operators and individuals wishing to dive from private vessels will be the primary class of small entity subject to this requirement. No special skills will be necessary to comply with the permitting or call-in requirements.

Any entity desiring to conduct educational or scientific research activities in Tortugas South will be required to apply for a National Marine Sanctuary General Permit. Each permit applicant will be required to provide a detailed description of the proposed activity, including a timetable for completion of the activity and the equipment, personnel and methodology to be employed; the qualifications and experience of all personnel; a statement of the financial resources available to the applicant to conduct and complete the proposed activity; a statement as to why it is necessary to conduct the activity within the Sanctuary; a statement of the potential impacts of the activity, if any, on Sanctuary resources and qualities; and a statement of the benefit to be derived from the activity; and such other information as the Director may request. Copies of all other required licenses, permits, approvals, or other authorizations must be attached to the application. The application requirements for such a permit are set forth in 15 CFR 922.166(e). There will be additional reporting and record keeping requirements associated with a Sanctuary permit. These will include submitting interim reports on the status of the activity and final reports including relevant research findings.

It is anticipated that marine scientists affiliated with public and private research institutions, universities, and conservation organizations, and associated graduate students or assistants, will be the primary class of small entity subject to this requirement.

The skills necessary for preparing a permit application and subsequent reports are the same as those that are required to prepare research proposals, grant applications, and their associated activity reporting requirements.

A Description of the Steps the Agency has Taken to Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual Policy and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities was Rejected

In the DEIS/MP for the FKNMS, NOAA proposed a boundary for a 110 nm ² Replenishment Reserve (Ecological Reserve) in the Tortugas area to protect significant coral resources while minimizing or avoiding adverse impacts to users. NOAA postponed establishing a reserve in part because public comment identified serious adverse economic impacts on commercial fishers from the proposed boundary and the proposed no-take regulations.

Accepting these comments, NOAA went back to the drawing board by convening an ad hoc 25 member Working Group (WG) of the Sanctuary Advisory Council (SAC), that included key stakeholder representatives from the fishing, diving, and recreation industries, as well as eight SAC members, and government agency representatives with resource management authority in the Tortugas area to recommend a "Preferred Boundary Alternative" for the reserve.

The WG held five meetings in 1998 and 1999. In addition to ecological information, socio-economic data were gathered from the commercial and recreational users of the area. This was an unprecedented data collection effort spearheaded by Dr. Vernon R. (Bob) Leeworthy of NOAA. His contractors first determined that approximately 105–110 commercial fishermen used the area. They then collected information on catch, costs, and trips from 90 of the fishermen. These 90 fishermen caught over 90% of the total harvest from the Tortugas. The entire population of recreational charter users was interviewed and data on trips and costs were obtained. Through the help of the Florida Marine Research Institute, the commercial and recreational data were input into a GIS format and maps were produced showing intensity of use.

A critical aspect of this GIS data was the creation of maps at a consistent scale using the same grid cell framework so comparisons could be made between maps. The study area was partitioned into one minute by one minute (approximately one square nautical mile) grid cells which facilitated the collection and analysis of data and the creation of boundary alternatives.

In February 1999, the WG developed criteria for the ecological reserve that addressed ecological and socio-economic concerns. One of the objectives of these criteria was to try to choose an area and craft recommendations that would serve to minimize adverse socio-economic impacts on established users of resources in the area. The preferred alternative recommended by the WG (and that subsequently was selected by NOAA as its Preferred Alternative in the DSEIS/SMP) was selected, in part, because it provided environmental protection while leaving open significant fishing grounds for lobster and reef fish such as the southern half of Tortugas Bank, which is an important fishing area in the winter, and leaves open fishing areas for King mackerel.

The SAC unanimously adopted the WG's recommendation, recognizing that the WG's proposal for an ecological reserve would protect biodiversity and minimize impacts to users. The SAC that adopted the WG's recommendation included members from the fishing, diving, boating, and tourism industries. The geographical area for an ecological reserve and application of no-take regulations recommended by the SAC have been adopted by NOAA as the Preferred Alternative.

NOAA encouraged the public to comment on the alternatives contained in the DSEIS and held a series of public hearings throughout South Florida to accept comments. More than 4,000 comments were received and considered.

Approach to the Analysis of Alternatives

The analysis of the alternatives focuses on market economic impacts as measured by direct revenue, costs, and profits of the business firms directly affected by the "no-take" regulations. These impacts are then translated into the secondary or multiplier impacts on the local economy. For the recreational industry, the impact area is defined as Monroe County, Florida and, for the commercial fisheries the impact areas are Monroe County and Lee/Collier counties. For the commercial fisheries, the results presented here are an aggregation of the impacts on both Monroe and Lee/Collier Counties. The market economic impacts include estimates of output/sales, income and employment. The details by impacted area can be found in Leeworthy and Wiley (2000). Although the results are only presented for impacts on Monroe and Lee/Collier Counties, the impacts are based on catch landed in all counties. The results for Monroe and Lee/Collier counties are slightly overstated because they include the amounts landed in other counties, but for the boundary alternatives, these amounts are insignificant.

The approach begins by first analyzing the affects of the "no-take" regulation for each boundary alternative. Analyses are presented for the recreation industry (broken down into consumptive and non-consumptive), the commercial fisheries, commercial shipping, treasure salvors and then other benefits (non-users, scientific and education values). The next step is to analyze other regulations. Other regulations include the no anchoring/required mooring buoy use regulation, access restrictions, and sanctuary-wide regulations (for boundary alternatives that include areas outside current Sanctuary boundary). For most of the sanctuary-wide regulations, there is no additional or

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incremental impact over the "no-take" regulation.

The approach proceeds in two basic steps for the recreation industry and the commercial fisheries. First, the impacts are estimated under the assumption that all the activities displaced result in complete loss. This is done by summing all the activities within the geographic area defined by an ecological reserve boundary (i.e., the no-take area) and applying the appropriate economic parameters. Second, whether the results from step 1 are likely to occur is assessed by using a qualitative analysis. Mitigating and offsetting factors are taken into account and whether net benefits or costs exist in the short and longer terms is assessed. Over the long term, the ecological reserve is expected to generate replenishment effects to the fisheries. In the commercial reef fisheries, there may be some short term losses, however over the longer term, the expectation is that there would be long-term benefits even to commercial reef fishermen and related dependent businesses.

Results are presented in four sections. The first section addresses the recreation industry. Consumptive recreation is separated from non-consumptive recreation since consumptive recreation activities are displaced from the "no-take" areas and may potentially be negatively impacted, while non-consumptive activities would be beneficiaries of the "no-take" area in Tortugas North. The second section addresses the commercial fisheries which would all be displaced from the "no-take" areas and thus potentially negatively impacted. The third section addresses other potential benefits of the "no-take" areas including non-use economic values, scientific values, and education values. The fourth section addresses the costs of the management action to create the reserve. This analysis assumes that all entities impacted are small entities within the meaning of the Regulatory Flexibility Act.

Analysis of Alternatives

Definition of the Study Area

For purposes of this analysis, NOS examined a 1,020 nm² area called the Tortugas Ecological Reserve Study Area (TERSA) (Figure 2). All socio-economic information was collected and organized for the TERSA at a geographical resolution of one nm². Detailed descriptions of the data are included for the recreation industry and for the commercial fisheries. Four separate boundary alternatives were identified within the TERSA and analyzed using the information collected for the TERSA.

Boundary Alternatives (Figure 1)

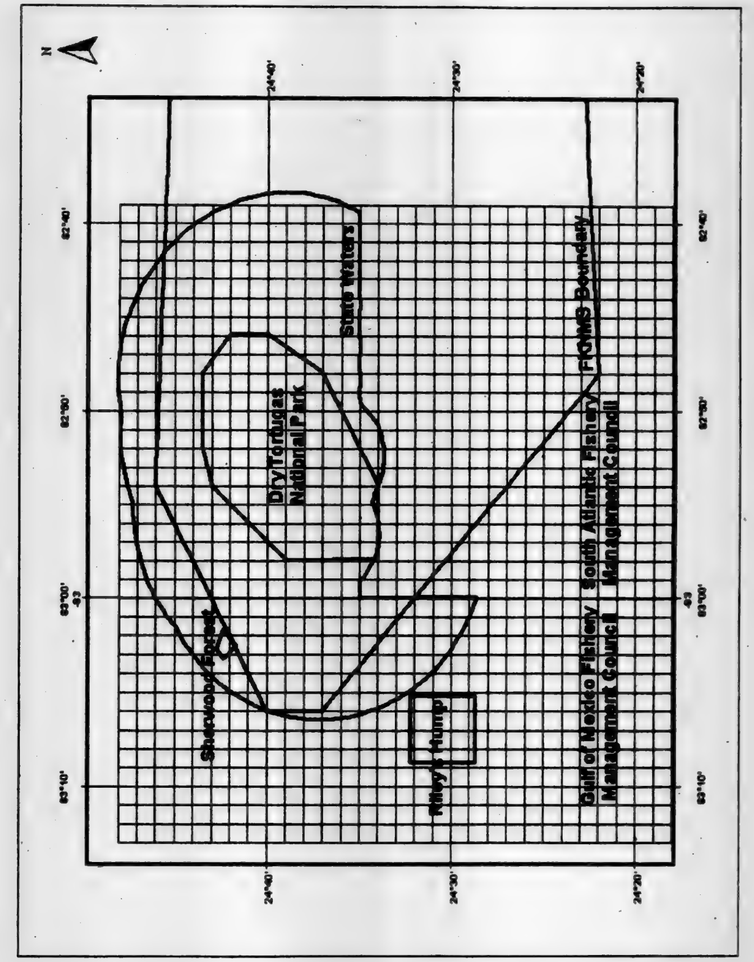


Figure 2. Tortugas Ecological Reserve Study Area (TERSA)

Boundary Alternative I. This alternative would be taking no-action, that is, not expanding the Sanctuary boundary and not establishing a Tortugas Ecological Reserve.

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Boundary Alternative II. This alternative would limit the reserve to the existing Sanctuary boundary for a total area of approximately 55 nm². This alternative includes a portion of Sherwood Forest and the coral pinnacles north of Tortugas Bank; it does not include Riley's Hump. It includes some coral and hardbottom habitat north of the DRTO.

Boundary Alternative III (Preferred Boundary Alternative). This alternative would expand the boundary of the Sanctuary and its westernmost corner by approximately 36 nm² to include Sherwood Forest. In addition, this alternative would expand the boundary by adding a non-contiguous area of approximately 60 nm² to include Riley's Hump. The Reserve would also incorporate approximately 55 nm² of the existing Sanctuary in its northern section, for a total area of approximately 151 nm². The area of the Reserve surrounding Sherwood Forest would be called Tortugas North and encompass approximately 91 nm²; the area surrounding Riley's Hump would be called Tortugas South and encompass approximately 60 nm².

Boundary Alternative IV. This alternative would increase the area of Tortugas North over that in Alternative III by an additional 23 nm² to make it conterminous with the DRTO's proposed Research/Natural Area for a total area of approximately 175 nm². It would involve the same boundary expansion as in Alternative III. The Tortugas South area would be the same as in Alternative III.

Boundary Alternative V. This alternative would expand the Sanctuary boundary to the west by 3 nm over Alternatives III and IV to make the boundary extend as far west as the western boundary of Tortugas South. The area of Tortugas North would be expanded over Alternatives III and IV to include the three nm boundary expansion. The area of Tortugas North would be approximately 145 nm². The area of Tortugas South would be approximately 45 nm², by reducing its southern extent over alternatives III and IV. Under Alternative V the overall area of the Reserve would be approximately 190 nm².

No-take Regulations

Recreation Industry

Boundary Analysis. The estimates from the geographic information system (GIS) analysis for the different boundary alternatives are the sum of each measurement within the boundaries of each alternative. The estimates therefore represent the maximum total potential loss from displacement of the consumptive recreational activities. This analysis ignores possible mitigating factors and the possibility of net benefits that might be derived if the proposed ecological reserve has replenishment effects. Although the extent of the mitigating factors or the potential benefits from replenishment is unknown, this analysis discusses these as well as other potential benefits of the proposed ecological reserve after the maximum potential losses from displacement of the current consumptive recreational uses are presented and discussed.

There are two types of potential losses identified and quantified in the analysis, non-market economic values and market economic values.

Non-Market Economic Values. There are two types of non-market economic values. The first is consumer's surplus, which is the amount an individual is willing to pay for a good or service over and above what he or she is required to pay for the good or service. It is a net benefit to the consumer and in the context of recreation use of natural resources, where the natural resources go unpriced in markets, this value is often referred to as the net user value of the natural resource. The second type of non-market economic value is one received by producers or owners of the businesses providing goods or services to the users of the natural resources. This is commonly referred to as producer's surplus. The concept is similar to consumer's surplus in that the businesses do not pay a price for the use of natural resources when providing goods or services to users of the resources. However, this concept is a little more complicated because, in "welfare economics", not all producer's surplus is considered a proper indicator in the improvement of welfare. Only that portion of producer's surplus called "economic rent" is appropriate for inclusion. Economic rent is the amount of profit a business receives over and above a normal return on investment (*i.e.*, the amount of return on investment that could be earned by switching to some alternative activity). Again, because businesses that depend on natural resources in the Tortugas do not have to pay for the use of them, there exists the possibility of earning above normal rates of return on investment or "economic rent". This like consumer's surplus, would be additional economic value attributable to the natural resources (*i.e.*, another user value).

Economic rents are different from consumer's surplus in that supply and demand conditions are often likely to lead to dissipation of the economic rents. This is generally true for most open access situations. As new firms enter the industry because of the lure of higher than normal returns on investment, the net effect is to eliminate most if not all of the economic rent. However, given the remoteness of the TERSA, it is likely that all economic rents would not be eliminated. Accounting profits are used as a proxy for economic rents in the analysis. The absolute levels of accounting profits are not a good proxy for economic rents, however, they are used here as an index for assessing the relative impacts across the different boundary alternatives.

The estimates for consumer's surplus were derived by combining estimates of person-days from all the operators in the TERSA with estimates of consumer's surplus per person-day from Leeworthy and Bowker (1997). The estimates were derived separately by season (see Leeworthy and Wiley 2000).

Market Economic Values. Revenues from the charter boat operations that provided service to the consumptive recreational users provide the basis for this portion of the analysis. Total output/sales, income and employment impacts on the Monroe County economy are then derived from these estimates. These impacts include the ripple or multiplier impacts. Total output/sales is equal to business revenue times the total output multiplier of 1.12 from English et al 1996. Income is then derived by taking the total output/sales impact and dividing by the total output-to-income ratio (2.63) from English et al. Total employment was derived by dividing the total income impact by the total income-to-employment ratio ($23,160) from English et al.

Boundary Alternative I: No Action

The no-action alternative is not establishing a reserve and not issuing the implementing regulations. The costs of imposing the no-take regulations, for any given alternative with no-take regulations, would be the benefits of the no-action alternative. That is, by not adopting the no-take regulations, the costs are avoided. Similarly, any benefits from imposing the no-take regulations, for any given alternative with no-take regulations, would be the costs of the no-action alternative. That is, by not adopting the no-take regulations, the costs are the benefits lost by not adopting the no-take regulations. Said another way, the costs are the opportunities lost. The impacts of the no-action alternative can only be understood by comparing it to one of the alternatives. Thus the impacts of the no-action alternative can be obtained by reading the impacts from any of the alternatives in reverse (Tables 1–8). Table 1 shows the 1997 baseline conditions.

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Table 1. Boundary Analysis Summary: TERSA - Consumptive Recreation

	Diving for Lobsters	Fishing	Spearfishing	Total
Within Fishery Boundary				
Person-Days	1,442	12,215	1,569	15,226
Revenue	$ 99,282	$ 579,143	$ 291,898	$ 970,323
Cost	$ 68,372	$ 471,657	$ 149,503	$ 689,532
Profit	$ 30,909	$ 107,497	$ 142,395	$ 280,801
Number of Firms	2	10	3	12 [1]
Consumer Surplus	$ 131,222	$ 996,744	$ 144,034	$ 1,272,000
Outside Fishery Boundary				
Person-Days	288	4,163	303	4,754
Revenue	$ 19,868	$ 257,597	$ 41,795	$ 329,260
Cost	$ 13,680	$ 217,794	$ 22,926	$ 254,400
Profit	$ 6,188	$ 49,804	$ 18,869	$ 74,861
Number of Firms	2	4	2	5 [1]
Consumer Surplus	$ 26,208	$ 339,619	$ 27,815	$ 393,642
Total				
Person-Days	1,730	16,378	1,872	19,980
Revenue	$ 119,150	$ 846,740	$ 333,693	$ 1,299,583
Cost	$ 82,052	$ 689,451	$ 172,429	$ 943,932
Profit	$ 37,097	$ 157,301	$ 161,264	$ 355,662
Number of Firms	2	10	3	12 [1]
Consumer Surplus	$ 157,430	$ 1,336,363	$ 171,850	$ 1,665,643

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.

Table 2. Boundary Analysis Summary: Alternative III Regulatory alternative D - Consumptive Recreation

	Diving for Lobsters[2]		Fishing[2]		Spearfishing[2]		Total[2]	
Within Fishery Boundary								
Person-Days	461	(31.97%)	200	(1.64%)	485	(30.91%)	1,146	(7.53%)
Revenue	$ 31,732	(31.96%)	$ 24,691	(4.26%)	$ 66,816	(22.89%)	$ 123,239	(12.70%)
Cost	$ 21,862	(31.98%)	$ 14,496	(3.07%)	$ 36,656	(24.52%)	$ 73,014	(10.59%)
Profit	$ 9,870	(31.93%)	$ 10,195	(9.48%)	$ 30,160	(21.18%)	$ 50,225	(17.89%)
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	9	(75.00%)
Consumer Surplus	$ 41,977	(31.99%)	$ 15,859	(1.59%)	$ 44,548	(30.93%)	$ 102,384	(8.05%)
Outside Fishery Boundary								
Person-Days	-	(0.00%)	-	(0.00%)	-	(0.00%)	-	(0.00%)
Revenue	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Cost	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Profit	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Number of Firms	-	(0.00%)	-	(0.00%)	-	(0.00%)	-	(0.00%)
Consumer Surplus	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Total								
Person-Days	461	(26.65%)	200	(1.22%)	485	(25.91%)	1,146	(5.74%)
Revenue	$ 31,732	(26.63%)	$ 24,691	(2.92%)	$ 66,816	(20.02%)	$ 123,239	(9.48%)
Cost	$ 21,862	(26.64%)	$ 14,496	(2.10%)	$ 36,656	(21.26%)	$ 73,014	(7.74%)
Profit	$ 9,870	(26.61%)	$ 10,195	(6.48%)	$ 30,160	(18.70%)	$ 50,225	(14.12%)
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	9	(75.00%)
Consumer Surplus	$ 41,977	(26.66%)	$ 15,859	(1.19%)	$ 44,548	(25.92%)	$ 102,384	(6.15%)
Private Boats								
Person-Days	-	n/a	673	(100.00%)	-	n/a	673	(100.00%)
Consumer's surplus	$ -	n/a	$ 53,392	(100.00%)	$ -	n/a	$ 53,392	(100.00%)

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.
2. Percent of TERSA (See Table 1) by activity and total in parentheses.
3. Private boat activity does not involve losses to commercial recreation operators, therefore the only impacts are in loss of person-days of activity and in consumer's surplus.
Lacking any information with regard to the distribution of the activity, the assumption was made that all of the activity takes place within the boundary alternative.

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Table 2. Boundary Analysis Summary: Alternative II/Regulatory alternative D - Consumptive Recreation

	Diving for Lobsters[2]		Fishing[2]		Spearfishing[2]		Total[2]	
Charter/Party Boat Operators								
Within FKNMS Boundary								
Person-Days	461	(31.97%)	200	(1.64%)	485	(30.91%)	1,146	(7.53%)
Revenue	$ 31,732	(31.96%)	$ 24,691	(4.26%)	$ 66,816	(22.89%)	$ 123,239	(12.70%)
Cost	$ 21,862	(31.98%)	$ 14,496	(3.07%)	$ 36,656	(24.52%)	$ 73,014	(10.59%)
Profit	$ 9,870	(31.93%)	$ 10,195	(9.48%)	$ 30,160	(21.18%)	$ 50,225	(17.89%)
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	9	(75.00%) [1]
Consumer Surplus	$ 41,977	(31.99%)	$ 15,859	(1.59%)	$ 44,548	(30.93%)	$ 102,384	(8.05%)
Outside FKNMS Boundary								
Person-Days	-	(0.00%)	-	(0.00%)	-	(0.00%)	-	(0.00%)
Revenue	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Cost	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Profit	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Number of Firms	-	(0.00%)	-	(0.00%)	-	(0.00%)	-	(0.00%) [1]
Consumer Surplus	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)	$ -	(0.00%)
Total								
Person-Days	461	(26.65%)	200	(1.22%)	485	(25.91%)	1,146	(5.74%)
Revenue	$ 31,732	(26.63%)	$ 24,691	(2.92%)	$ 66,816	(20.02%)	$ 123,239	(9.48%)
Cost	$ 21,862	(26.64%)	$ 14,496	(2.10%)	$ 36,656	(21.26%)	$ 73,014	(7.74%)
Profit	$ 9,870	(26.61%)	$ 10,195	(6.48%)	$ 30,160	(18.70%)	$ 50,225	(14.12%)
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	9	(75.00%)
Consumer Surplus	$ 41,977	(26.66%)	$ 15,859	(1.19%)	$ 44,548	(25.92%)	$ 102,384	(6.15%)
Private Boats[3]								
Person-Days	-	n/a	673	(100.00%)	-	n/a	673	(100.00%)
Consumer's surplus	$ -	n/a	$ 53,392	(100.00%)	$ -	n/a	$ 53,392	(100.00%)

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.
2. Percent of TERSA (See Table 1) by activity and total in parentheses.
3. Private boat activity does not involve losses to commercial recreation operators, therefore the only impacts are in loss of person-days of activity and in consumer's surplus. Lacking any information with regard to the distribution of the activity, the assumption was made that all of the activity takes place within the boundary alternative.

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Boundary Alternative II

Non-Market Economic Values. This alternative would displace over 26% of the total person-days of diving for lobsters, about 26% of the spearfishing, and just over 1% of the fishing. Across all three consumptive recreational activities just under 6% of the person-days would be displaced (Table 2). This alternative is entirely within the FKNMS boundary. Because of the way in which consumer's surpluses are calculated, they generally mirror the patterns in displaced use. Minor differences would be due to the distributions across activities by season. Only in the case of diving for lobsters are the impacts on person-days and profits equal. For spearfishing, the impacts on profits are lower than the affect on person-days (18.7% versus 25.9%), while for fishing the affect is greater on profits than on person-days (6.5% versus 1.2%). The GIS generated maps show why diving for lobsters and spearfishing are relatively more affected than fishing. The reason is that diving for lobsters and spearfishing are concentrated on Tortugas Bank, while relatively little fishing currently takes place on the Tortugas Bank. Private boat usage does not impact commercial recreational fishing operations, therefore the only impacts are the loss of person days and the non-market value (consumer's surplus) of the activity. During the public comment period it was noted that there were 673 person days of activity taking place in the TERSA. This translates to a maximum potential loss of $53,392 in consumer's surplus.

Market Economic Values. Presently, there are 12 charter boats operating within the TERSA, nine of which would be potentially affected by this alternative. Direct business revenue would include potential losses of 26.6% for diving for lobsters, 20% for spearfishing, and 3% for fishing. Across all three consumptive recreational activities, 9.5% of revenue would be potentially affected (Table 2).

Through the ripple or multiplier effects, 11–13% of output/sales, income and employment associated with all the consumptive recreational activities in the TERSA could potentially be lost (Table 7). Although these costs could have an effect on the nine firms operating in the TERSA, the effect would not likely be noticed in the Monroe County economy because the effect would amount to only a fraction of a percent of the total economy supported by recreating visitors to the Florida Keys (Table 8).

Boundary Alternative III (Preferred Boundary Alternative)

Non-Market Economic Values. Because the portion of this alternative that is within the FKNMS boundary is exactly the same as Alternative II, the analysis for these two activities is exactly the same for the two alternatives. This alternative would displace over 26% of the total person-days of diving for lobsters, about 26% of the spearfishing, and just over 3% of the fishing. Across all three consumptive recreational activities over 7% of the person-days would be displaced (Table 3). For fishing, 40% of the displaced activity would be from within the FKNMS boundary. Consumer's surpluses generally mirror patterns of displaced use. Again, minor differences would be due to the distributions across activities by season. Only in the case of diving for lobsters are the effects on person-days and profits equal. For spearfishing, the effects on profits is lower than the effect on person-days (18.7% versus 25.9%), while for fishing the effect is greater on profits than on person-days (10.02% versus 3.0%).

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Table 3. Boundary Analysis Summary: Alternative III/ Regulatory alternative D - Consumptive Recreation

	Fishing[2]		Spearfishing[2]		Diving for Lobsters[2]		Total[2]	
Charter Party Boat Operations								
Person-Days	200	(1.64%)	485	(30.91%)	461	(31.97%)	1,146	(7.53%)
Revenue	$ 24,691	(4.26%)	$ 66,816	(22.89%)	$ 31,732	(31.96%)	$ 123,239	(12.70%)
Cost	$ 14,496	(3.07%)	$ 36,656	(24.52%)	$ 21,862	(31.98%)	$ 73,014	(10.59%)
Profit	$ 10,195	(9.48%)	$ 30,160	(21.18%)	$ 9,870	(31.93%)	$ 50,225	(17.89%)
Number of Firms	8	(80.00%)	3	(100.00%)	2	(100.00%)	9	(75.00%)
Consumer Surplus	$ 15,859	(1.59%)	$ 44,548	(30.93%)	$ 41,976	(31.99%)	$ 102,383	(8.05%)
Other Party Boat Operations								
Person-Days	297	(7.13%)	-	(0.00%)	-	(0.00%)	297	(6.25%)
Revenue	$ 28,815	(10.77%)	$ -	(0.00%)	$ -	(0.00%)	$ 28,815	(8.75%)
Cost	$ 23,254	(10.68%)	$ -	(0.00%)	$ -	(0.00%)	$ 23,254	(9.14%)
Profit	$ 5,561	(11.17%)	$ -	(0.00%)	$ -	(0.00%)	$ 5,561	(7.43%)
Number of Firms	2	(50.00%)	-	(0.00%)	-	(0.00%)	2	(40.00%)
Consumer Surplus	$ 23,570	(6.94%)	$ -	(0.00%)	$ -	(0.00%)	$ 23,570	(5.99%)
Total								
Person-Days	497	(3.03%)	485	(25.91%)	461	(26.65%)	1,443	(7.22%)
Revenue	$ 53,506	(6.32%)	$ 66,816	(20.02%)	$ 31,732	(26.63%)	$ 152,054	(11.70%)
Cost	$ 37,750	(5.48%)	$ 36,656	(21.26%)	$ 21,862	(26.64%)	$ 96,268	(10.20%)
Profit	$ 15,756	(10.02%)	$ 30,160	(18.70%)	$ 9,870	(26.61%)	$ 55,786	(15.69%)
Number of Firms	8	(80.00%)	3	(100.00%)	2	(100.00%)	9	(75.00%)
Consumer Surplus	$ 39,429	(2.95%)	$ 44,548	(25.92%)	$ 41,976	(26.66%)	$ 125,953	(7.56%)
Private Boats								
Person-Days	673	(100.00%)	-	n/a	-	n/a	673	(100.00%)
Consumer's surplus	$ 53,392	(100.00%)	$ -	n/a	$ -	n/a	$ 53,392	(100.00%)

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.
2. Percent of TERSA (See Table 1) by activity and total in parentheses.
3. Private boat activity does not involve losses to commercial recreation operators, therefore the only impacts are in loss of person-days of activity and in consumer's surplus.
Lacking any information with regard to the distribution of the activity, the assumption was made that all of the activity takes place within the boundary alternative.

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Private boat usage does not impact commercial recreational fishing operations, therefore the only impacts are the loss of person days and the non-market value (consumer's surplus) of the activity. A total of 673 person days of private boat use takes place in the TERSA. This translates to a maximum potential loss of $53,392 in consumer's surplus.

Market Economic Values. Nine of the twelve charter boats operating within the TERSA would be potentially affected by this alternative. Direct business revenue would include potential losses of 26.6% for diving for lobsters, 20.0% for spearfishing, and 6.3% for fishing. Across all three consumptive recreational activities, 11.7% of revenue would be potentially affected (Table 3).

Through the ripple or multiplier effects, 16–17% of output/sales, income and employment associated with all the consumptive recreational activities in the TERSA could potentially be lost (Table 7). Although these costs could have an effect on the nine firms operating in the TERSA, the effect would not likely be noticed in the Monroe County economy because it would amount to only a fraction of a percent of the total economy supported by recreating visitors to the Florida Keys (Table 8).

Boundary Alternative IV

Non-Market Economic Values. This alternative would displace over 73% of the total person-days of diving for lobsters, just under 72% of the spearfishing, and over 6% of the fishing. Across all three consumptive recreational activities over 18% of the person-days would be displaced (Table 4). All the diving for lobsters and spearfishing activity displaced would be from within the FKNMS boundary. For fishing, 71% of the displaced activity would be from within the FKNMS boundary. Similarly to the other alternatives, consumer's surpluses mirror the patterns in displaced use because of the way in which they are calculated. Minor differences would be due to the distributions across activities by season. Again, profits are only equal to the effect on person-days for diving for lobsters. For spearfishing, the effects on profits is lower than the effect on person-days (56.2% versus 71.7%), while for fishing the effect is greater on profits than on person-days (17.6% versus 6.3%).

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Table 4. Boundary Analysis Summary: Alternative IV/ Regulatory alternative D - Consumptive Recreation

	Diving for Lobsters[2]		Fishing[2]		Spearfishing[2]		Total[2]	
Person-Days	1,269	(88.00%)	736	(6.03%)	1,343	(85.60%)	3,348	(21.99%)
Revenue	$ 87,361	(87.99%)	$ 196,944	(67.47%)	$ 344,566	(35.51%)		
Cost	$ 60,165	(88.00%)	$ 106,360	(71.14%)	$ 204,618	(29.67%)		
Profit	$ 27,196	(87.99%)	$ 90,584	(63.61%)	$ 139,948	(49.84%)	[1]	
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	10	(83.33%) [1]
Consumer Surplus	$ 115,449	(87.98%)	$ 123,271	(85.58%)	$ 297,221	(23.37%)		
Person-Days	-	(0.00%)	297	(7.13%)	-	(0.00%)	297	(6.25%)
Revenue	$ -	(0.00%)	$ 28,815	(10.77%)	$ -	(0.00%)	$ 28,815	(8.75%)
Cost	$ -	(0.00%)	$ 23,254	(10.68%)	$ -	(0.00%)	$ 23,254	(9.14%)
Profit	$ -	(0.00%)	$ 5,561	(11.17%)	$ -	(0.00%)	$ 5,561	(7.43%) [1]
Number of Firms	-	(0.00%)	2	(50.00%)	-	(0.00%)	2	(40.00%) [1]
Consumer Surplus	$ -	(0.00%)	$ 23,570	(6.94%)	$ -	(0.00%)	$ 23,570	(5.99%)
Person-Days	1,269	(73.35%)	1,033	(6.31%)	1,343	(71.74%)	3,645	(18.24%)
Revenue	$ 87,361	(73.32%)	$ 196,944	(59.02%)	$ 344,566	(35.51%)	$ 373,381	(28.73%)
Cost	$ 60,165	(73.33%)	$ 106,360	(61.68%)	$ 204,618	(29.67%)	$ 227,872	(24.14%)
Profit	$ 27,196	(73.31%)	$ 90,584	(56.17%)	$ 139,948	(49.84%)	$ 145,509	(40.91%) [1]
Number of Firms	2	(100.00%)	8	(80.00%)	3	(100.00%)	10	(83.33%) [1]
Consumer Surplus	$ 115,449	(73.33%)	$ 123,271	(71.73%)	$ 297,221	(23.37%)	$ 320,791	(19.26%)
Person-Days	-	n/a	-	n/a	-	n/a	673	(100.00%)
Consumer's surplus	$ -	n/a	$ -	n/a	$ -	n/a	$ 53,392	(100.00%)

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.
2. Percent of TERSA (See Table 1) by activity and total in parentheses.
3. Private boat activity does not involve losses to commercial recreation operators, therefore the only impacts are in loss of person-days of activity and in consumer's surplus.
Lacking any information with regard to the distribution of the activity, the assumption was made that all of the activity takes place within the boundary alternative.

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Private boat usage does not impact commercial recreational fishing operations, therefore the only impacts are the loss of person days and the non-market value (consumer's surplus) of the activity. A total of 673 person days of private boat use takes place in the TERSA. This translates to a maximum potential loss of $53,392 in consumer's surplus.

Market Economic Values. Ten of the twelve charter boats operating within the TERSA would be potentially affected by this alternative. Direct business revenue would include potential losses of 73.4% for diving for lobsters, 59.0% for spearfishing, and 10.5% for fishing. Across all three consumptive recreational activities, 28.7% of revenue would be potentially affected (Table 4).

Through the ripple or multiplier effects, 38–39% of output/sales, income and employment associated with all the consumptive recreational activities in the TERSA could potentially be lost (Table 7). Although these impacts could have significant effect on the ten firms operating in the TERSA, the effect would not likely be noticed in the Monroe County economy because the effect would amount to only a fraction of a percent of the total economy supported by recreating visitors to the Florida Keys (Table 8).

Boundary Alternative V

Non-Market Economic Values. This alternative would displace over 86% of the total person-days of diving for lobsters, over 84% of the spearfishing, and over 7% of the fishing. Across all three consumptive recreational activities over 21% of the person-days would be displaced (Table 5). For diving for lobsters 85% of the displaced activity would be from within the FKNMS boundary, 59% of the fishing, and 85% of the spearfishing. Because of the way in which consumer's surpluses are calculated, they generally mirror the patterns in displaced use. Minor differences would be due to the distributions across activities by season. Profits are only equal to the affect on person-days for diving for lobsters. For spearfishing, the effects on profits are lower than the affect on person-days (65.5% versus 84.7%), while for fishing the affect is greater on profits than on person-days (21.9% versus 7.6%).

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Table 5. Boundary Analysis Summary: Alternative V/Regulatory alternative D - Consumptive Recreation

	Diving for Lobsters[2]		Fishing[2]		Spearfishing[2]		Total[2]	
Person-Days	1,269	(88.00%)	736	(6.03%)	1,343	(85.60%)	3,348	(21.99%)
Revenue	$ 87,361	(87.99%)	$ 60,261	(10.41%)	$ 196,944	(67.47%)	$ 344,566	(35.51%)
Cost	$ 60,165	(88.00%)	$ 38,093	(8.08%)	$ 106,360	(71.14%)	$ 204,618	(29.67%)
Profit	$ 27,196	(87.99%)	$ 22,168	(20.62%)	$ 90,584	(63.61%)	$ 139,948	(49.84%)
Number of Firms	2	(100.00%)	10	(100.00%)	3	(100.00%)	10	(83.33%)
Consumer Surplus	$ 115,449	(87.98%)	$ 58,501	(5.87%)	$ 123,271	(85.58%)	$ 297,221	(23.37%)
Person-Days	231	(80.21%)	511	(12.27%)	243	(80.20%)	985	(20.72%)
Revenue	$ 15,894	(80.00%)	$ 48,832	(18.25%)	$ 33,436	(80.00%)	$ 98,162	(29.81%)
Cost	$ 10,944	(80.00%)	$ 36,495	(16.76%)	$ 18,341	(80.00%)	$ 65,780	(25.86%)
Profit	$ 4,950	(79.99%)	$ 12,337	(24.77%)	$ 15,095	(80.00%)	$ 32,382	(43.26%)
Number of Firms	2	(100.00%)	3	(75.00%)	2	(100.00%)	3	(60.00%)
Consumer Surplus	$ 20,992	(80.10%)	$ 40,617	(11.98%)	$ 22,277	(80.09%)	$ 83,886	(21.31%)
Person-Days	1,500	(86.71%)	1,247	(7.61%)	1,586	(84.72%)	4,333	(21.69%)
Revenue	$ 103,255	(86.66%)	$ 108,093	(12.88%)	$ 230,380	(68.04%)	$ 442,728	(34.07%)
Cost	$ 71,109	(86.66%)	$ 74,588	(10.82%)	$ 124,701	(72.32%)	$ 270,398	(28.65%)
Profit	$ 32,146	(86.65%)	$ 34,505	(21.94%)	$ 105,679	(65.53%)	$ 172,330	(48.45%)
Number of Firms	2	(100.00%)	10	(100.00%)	3	(100.00%)	11	(91.67%)
Consumer Surplus	$ 136,441	(86.67%)	$ 99,118	(7.42%)	$ 145,548	(84.69%)	$ 381,108	(22.88%)
Person-Days	-	n/a	673	(100.00%)	-	n/a	673	(100.00%)
Consumer's surplus	$ -	n/a	$ 53,392	(100.00%)	$ -	n/a	$ 53,392	(100.00%)

1. Number of firms does not add up to the total because individual firms may engage in more than one activity.
2. Percent of TERSA (See Table 1) by activity and total in parentheses.
3. Private boat activity does not involve losses to commercial recreation operations, therefore the only impacts are in loss of person-days of activity and h consumer's surplus.
Lacking any information with regard to the distribution of the activity, the assumption was made that all of the activity takes place within the boundary alternative.

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Private boat usage does not impact commercial recreational fishing operations, therefore the only impacts are the loss of person days and the non-market value (consumer's surplus) of the activity. A total of 673 person days of private boat use takes place in the TERSA. This translates to a maximum potential loss of $53,392 in consumer's surplus.

Market Economic Values. Eleven of the twelve charter boats operating within the TERSA would be potentially affected by this alternative. Direct business revenue would include potential losses of 86.7% for diving for lobsters, 69.0% for spearfishing, and 12.9% for fishing. Across all three consumptive recreational activities, 34.1% of revenue would be potentially affected (Table 5).

Through the ripple or multiplier effects, 45% of output/sales, income and employment associated with all the consumptive recreational activities in the TERSA could potentially be lost (Table 7). Although these effects could have significant affect on the ten firms operating in the TERSA, the affect would not likely be noticed in the Monroe County economy because the affect would amount to only a fraction of a percent of the total economy supported by recreating visitors to the Florida Keys (Table 8).

Table 8. Calculation of Maximum Potential Market Economic Losses: Consumptive Recreation

	TERSA	Alternative II	Preferred Alternative	Alternative IV		Alternative V	
Revenue[1]	$ 970,323	$ 123,239	(12.70%)	$ 344,586	(35.51%)	$ 344,586	(35.51%)
Output/Sales[2,5]	$ 1,086,762	$ 138,028	(12.70%)	$ 385,914	(35.51%)	$ 385,914	(35.51%)
Income[3,5]	$ 413,217	$ 52,482	(12.70%)	$ 146,735	(35.51%)	$ 146,735	(35.51%)
Employment[4,5]	18	2	(12.70%)	6	(35.51%)	6	(35.51%)
Revenue[1]	$ 329,260	$ -	(0.00%)	$ 28,815	(8.75%)	$ 98,162	(29.81%)
Output/Sales[2,5]	$ 368,771	$ -	(0.00%)	$ 32,273	(8.75%)	$ 109,941	(29.81%)
Income[3,5]	$ 140,217	$ -	(0.00%)	$ 12,271	(8.75%)	$ 41,803	(29.81%)
Employment[4,5]	6	0	(0.00%)	1	(8.75%)	2	(29.81%)
Revenue[1]	$ 1,299,583	$ 123,239	(9.48%)	$ 373,381	(28.73%)	$ 442,728	(34.07%)
Output/Sales[2,5]	$ 1,455,533	$ 138,028	(9.48%)	$ 418,187	(28.73%)	$ 495,855	(34.07%)
Income[3,5]	$ 553,435	$ 52,482	(9.48%)	$ 159,008	(28.73%)	$ 188,538	(34.07%)
Employment[4,5]	24	2	(9.48%)	7	(28.73%)	8	(34.07%)

1. Total Revenue from Tables 2-5.
2. Output is derived by multiplying Revenue by a multiplier of 1.12.
3. Income is calculated by dividing total output by the total output to total income ratio for Monroe County (2.48).
4. Employment is calculated by dividing total income by the total income to jobs ratio for Monroe County (23,160).
5. The multiplier, total output to total income ratio, and total income to jobs ratio are taken from English, et al., 1996

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Table 7. Summary of Maximum Total Potential Loss from Displacement: Summary: Consumptive Recreation

	TERSA	Alternative II	Preferred Alternative[1] III	Alternative IV	Alternative V
Market Impacts					
Output/Sales	$ 1,455,533	$ 138,028 (9.48%)	$ 170,300 (11.70%)	$418,187 (28.73%)	$ 495,855 (34.07%)
Income	$ 553,435	$ 52,482 (9.48%)	$ 64,753 (11.70%)	$159,006 (28.73%)	$ 188,538 (34.07%)
Employment	24	2 (8.37%)	3 (12.55%)	7 (29.29%)	8 (33.48%)
Non-market Impacts					
Consumer's Surplus	$ 1,665,643	$ 102,965 (6.18%)	$ 127,029 (7.63%)	$320,791 (19.26%)	$ 381,108 (22.88%)
Producer's Surplus (profit)	$ 355,662	$ 50,225 (14.12%)	$ 55,786 (15.69%)	$145,509 (40.91%)	$ 172,330 (48.45%)

1. Percent of TERSA in parentheses.

Table 8. Comparison to the Economic Contribution of Visitors to Florida Keys to Monroe County

	Monroe County	Alternative II	Preferred Alternative[1] III	Alternative IV	Alternative V
Output/Sales	$1,548,762,097	0.009%	0.011%	0.027%	0.032%
Income	$ 573,566,049	0.009%	0.011%	0.028%	0.033%
Employment	18,892	0.011%	0.016%	0.037%	0.042%

1. For year June 1997 - May 1998. Represents total impact of spending by recreating visitors (non-residents of Monroe County) on economy of Monroe County. See Leeworthy and Vanasse, 1999.

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Addendum to Economic Impact Estimates Based on One Commentor's Revised Input

Economic Impact Estimates Based on Commentor's Revised Input. In the course of the public comment period, several pieces of correspondence were received from a charter spearfishing operator indicating information and data that differ from that which he provided to us during our initial interview with him conducted on December 10, 1998. The following are the impact estimates based on the revised information received. These estimates are based on the assumption of a constant rate of profit, where no revised profit is indicated and a constant relationship between revenue and person-days of activity. The first column is the company's revised estimates, the second is the revised estimates for Spearfishing and the third is the revised estimates for Total Consumptive Recreational Activities.

The revised estimates indicate maximum potential impact on spearfishing and total consumptive recreational use based on the commentor's revised estimates. These estimates were submitted after the analysis based upon the alternative boundaries, including the Preferred Alternative, was complete.

Data from original survey—Revised Assumption: All activity takes place within Preferred Boundary Alternative (based on comments received in June 2000).

	Commentor	Spearfishing total	Total consumptive
Revenue	$214,000	$245,142	$301,565
Profit	$124,000	$130,160	$150,225
Person-days of activity	1,650	1,860	3,194
Total Output/Sales Impact	$239,680	$274,519	$337,713
Total Income Impact	$91,133	$104,395	$128,423
Total Employment Impact	4	4	5
Consumer's Surplus	$151,465	$170,743	$284,812

Revised Assumption: Revenue $288,000, Profit $144,000 and all activity takes place within Preferred Boundary Alternative (based on comments submitted in June 2000).

	Commentor	Spearfishing total	Total consumptive
Revenue	$288,000	$319,142	$375,565
Profit	$144,000	$150,160	$170,225
Person-days of activity	2,221	2,431	3,765
Total Output/Sales Impact	$322,560	$357,399	$420,593
Total Income Impact	$122,646	$135,908	$159,936
Total Employment Impact	5	5	6
Consumer's Surplus	$203,841	$223,119	$337,188

Revised Assumption: Revenue $416,000 and all activity takes place within Preferred Boundary Alternative (based on comments submitted in June 2000).

	Commentor	Spearfishing total	Total consumptive
Revenue	$416,000	$447,142	$503,565
Profit	$241,047	$247,207	$267,272
Person-days of activity	3,207	3,417	4,751
Total Output/Sales Impact	$465,920	$500,759	$563,953
Total Income Impact	$177,156	$190,418	$214,446
Total Employment Impact	8	8	9
Consumer's Surplus	$294,437	$313,715	$427,784

Revised Assumption: Revenue $460,000 and all activity takes place within Preferred Boundary Alternative (based on comments submitted in May 2000).

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	Commentor	Spearfishing total	Total consumptive
Revenue	$460,000	$491,142	$547,565
Profit	$266,542	$272,702	$292,767
Person-days of activity	3,547	3,757	5,091
Total Output/Sales Impact	$515,200	$550,039	$613,233
Total Income Impact	$195,894	$209,156	$233,184
Total Employment Impact	8	8	9
Consumer's Surplus	$325,579	$344,857	$458,926

Mitigating Factors—Are the Potential Losses Likely?

In the above GIS-based analysis, effects are referred to as "potential losses." The reason is that there are several factors that could mitigate these potential losses and further there is a possibility that there might not be any losses at all. It is quite possible that there might be actual benefits to even the current displaced users. These factors are referred to only in qualitative terms because it is not possible to quantify them. Below two possible mitigating factors, how likely they might mitigate the potential losses from displacement, and further how this might differ for each of the three alternatives, are discussed.

Substitution. If displaced users are simply able to relocate their activities, they may be able to fully or partially mitigate their losses. This of course depends on the availability of substitute sites and further depends on the substitute site qualities. Several scenarios are possible. Even when total activity remains constant (i.e., person-days remain the same as they simply go to other sites), if the quality of the site is lower there could be some loss in consumer's surplus. If it costs more to get to the substitute sites, there could still be increases in costs and thus lower profits. If there is not a completely adequate supply of substitute sites, then there could be losses in total activity and in all the non-market and market economic measures referenced in our above analysis of displaced use. The possibilities for substitution vary by alternative.

Long-term benefits from Replenishment Effects. Ecological reserves or marine reserves may have beneficial effects beyond the direct ecological protection for the sites themselves. That is, both the size and number of fish, lobster and other invertebrates both inside and outside the reserves may increase. The following quote from Davis (1998) summarizes the replenishment effect of reserves:

> [W]e found 31 studies that tested whether protected areas had an effect on the size, reproductive output, diversity, and recruitment of fish in adjacent areas. Fisheries targeted species were two to 25 times more abundant in no-take areas than in surrounding areas for fish, crustaceans, and mollusks on coral and temperate reefs in Australia, New Zealand, the Philippines, Japan, Kenya, South Africa, the Mediterranean Sea, Venezuela, Chile, and the United States (California, Florida and Rhode Island). Mean sizes of fished species protected in no-take zones were 12 to 200 percent larger than those in surrounding areas for all fishes studied and in 75 to 78 percent of the invertebrates. Eighty-six percent of the studies that tested fishery yields found that catches within three kilometers of the marine protected areas were 46 to 50 percent higher than before no-take zones were created. It is clear that fishers all over the world believe no-take zones increase yields because they fish as close to the boundaries as possible.

The long-term benefits from the reserve could offset any losses from displacement and may also result in long-term benefits and no costs to recreational users that are displaced by the proposed Tortugas Ecological Reserve. Again, this conclusion may still vary by alternative.

Boundary Alternative II

Substitution. Complete mitigation by substituting to alternative sites has a high probability for this alternative because over half of the Tortugas Bank would still be available for all consumptive recreation activities. Given the equal distribution of use for diving for lobsters and spearfishing on the Tortugas Bank, it is not likely that increased costs of relocation would occur or that there would be losses from users forced to go to sites of lower quality. Crowding effects, by pushing all the use currently spread over the whole Tortugas Bank onto half the bank, would also be unlikely given the small absolute amounts of activity. For fishing, only 1% of the activity would be displaced, so for this activity it would also be expected there would be no crowding effects and recreational fishermen would not likely suffer any losses.

Long-term Benefits from Replenishment Effects. Eight fish spawning areas have been identified in the western portion of the TERSA. One of these spawning areas is in the Alternative II boundary area. Alternative II is the portion of the Preferred Alternative that lies within the existing boundary of the Sanctuary. Therefore the long-term benefits to stocks derived from the portion of the Preferred Alternative that lies outside of the FKNMS boundary would not be realized. This alternative has the smallest area of those analyzed here and so the potential long-term benefits to stocks outside the protected area would be smaller than the other alternatives. But by the same token, the displaced activity to be mitigated is also much smaller and thus on net there is a high likelihood that there would be long-term benefits to all the consumptive recreational users in the TERSA.

Boundary Alternative III (Preferred Boundary Alternative)

Substitution. As with Alternative II, complete mitigation by substituting to alternative sites has a high probability for this alternative because of the small proportion of the Tortugas Bank included in the alternative. Given the equal distribution of use for diving for lobsters and spearfishing on the Tortugas Bank, it is not likely that increased costs of relocation would occur or that there would be losses from users forced to go to sites of lower quality. Crowding effects, again, would be unlikely given the small absolute amounts of activity. For fishing, only 3% of the activity would be displaced, so recreational fishermen would not likely suffer any losses.

Long-term Benefits from Replenishment Effects. Five of the eight fish spawning sites in the western portion of the TERSA are located within the boundary of this alternative. Because this alternative includes areas outside the Sanctuary, the potential long-term benefits to stocks outside the protected area would be comparatively larger than it would be for Alternative II. The mitigating effort required on the part of operators in the boundary alternative would also be comparatively larger, but as mentioned above, because of the small percentage of the active recreational area included in the alternative, the effect is likely to be very small. Therefore, there is a high likelihood that there would be long-term benefits to all the consumptive recreational users in the TERSA.

Boundary Alternative IV

Substitution. Under this alternative, about 73% of the diving for lobsters and 72% of the spearfishing would be displaced. The potential for substituting to other sites is greatly reduced as compared with Alternatives II and III. The reason is that under this alternative all of the Tortugas Bank falls within this boundary alternative. Some substitution is possible, but the probability of crowding effects rises considerably for diving for lobsters and spearfishing.

For fishing, substitution mitigating all the losses is still highly probable since only about 6% of the fishing activity would be displaced. This represents a relatively low amount of activity and given the wide distribution of this activity in the study area, crowding effects are still a low probability under this alternative.

Long-term Benefits from Replenishment Effects. Seven of the eight fish spawning sites in the western portion of the TERSA are located within the boundary of this alternative. For diving for lobsters and spearfishing, it is not clear whether there would be significant benefits offsite given that most of this activity currently takes place on the Tortugas Bank and none of the bank is available for the activity. Not much is currently known about other areas which might benefit from the stock effect and where they could relocate to reap these benefits. Whether those doing the activities displaced could find alternative sites where both the quantity and quality of activity could be maintained or enhanced seems less likely given the extent of displacement.

For fishing, however, the small amount of displacement relative to the entire area plus the wider distribution of fishing activity still makes it highly likely that the long-term benefits of replenishment would more than offset the potential losses from displacement resulting in net benefits to this group.

Boundary Alternative V

Substitution. This alternative displaces about 87% of the diving for lobsters and 85% of the spearfishing. Substitution possibilities for these activities are reduced even more, meaning that losses given in Table 7 are more likely to actually occur.

For fishing, mitigating all the losses through substitution is still highly probable since only about 8% of the fishing activity would be displaced. This again, represents a relatively low amount of activity and given the wide distribution of this activity in the study area, crowding effects are still a low probability under this alternative.

Long-term Benefits from Stock Effects. Seven of the eight fish spawning sites identified in the western portion of the TERSA are located within the boundary of this alternative. However, because the entire Tortugas Bank would be closed to diving for lobsters and spearfishing and the additionally large area encompassed by the proposed reserve, it is highly unlikely that these two user groups would benefit from the enhanced stocks of lobster and fish. Therefore, under this alternative, the maximum potential losses listed in Table 7 are highly likely to occur.

For fishing, however, the stock effects for the reserve could be substantial. Whether the benefits would be large enough to offset the displacement cannot immediately be determined. But given the past experience with reserves, it is still somewhat likely that the long-term benefits would offset the displacement costs yielding net benefits.

Benefits of the Tortugas Ecological Reserve to Recreational Users

Recreational Users on Entire Florida Keys Reef Tract. The possibility that consumptive recreational users could possibly benefit if there were long-term offsite impacts was discussed above. Given the work by Ault et al. (1998), Bohnsack and Ault (1996), Bohnsack and McClellan (1998), and Lee et al. (1994 and 1999), there is also the possibility that a protected area in the Tortugas could yield beneficial stock effects to a wide variety of species all along the entire Florida Keys reef tract and to species such as sailfish that are primarily offshore species. Even small increases in recreational tourist activities along the entire Florida Keys reef tract could more than offset the total displacements from the most extreme alternative analyzed here. Table 8 shows the total effects for each alternative relative to the total Florida Keys recreational visitor economic contribution. They are only fractions of a percent of the total recreational visitor economic contribution. One-tenth of one percent increase in the total recreational visitor contribution along the entire Florida Keys reef tract would more than offset the maximum potential losses from Alternative V (Table 7).

Non-consumptive Users (Divers) in Tortugas. Currently there is one operator that brings divers to the TERSA for non-consumptive diving. There were 1,048 person-days of non-consumptive diving which account for 4.98% of the total recreational activity in the TERSA (excluding the National Park). Of the total non-consumptive diving, 83.3% is currently done within the FKNMS boundary. Table 9 summarizes the information for non-consumptive divers. It is expected that this group would be benefited by Tortugas North. As the site improves in quality, it is expected that the demand for this site would increase and person-days, consumer's surplus, business revenues and profits would all increase. This would be expected to vary by alternative with the more protective alternatives having greater benefits.

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Table 9. Non-consumptive Diving

	TERSA	Alternative II	Preferred Alternative III	Alternative IV		Alternative V	
Person-Days	873	279 (31.96%)	279 (28.62%)	768 (87.97%)		768 (87.97%)	
Revenue	$ 95,123	$ 30,439 (32.00%)	$ 30,439 (28.67%)	$ 83,708 (88.00%)		$ 83,708 (88.00%)	
Cost	$ 58,157	$ 18,610 (32.00%)	$ 18,610 (28.67%)	$ 51,178 (88.00%)		$ 51,178 (88.00%)	
Profit	$ 36,966	$ 11,829 (32.00%)	$ 11,829 (28.67%)	$ 32,530 (88.00%)		$ 32,530 (88.00%)	
Number of Firms	1	1 (100.00%)	1 (100.00%)	1 (100.00%)		1 (100.00%)	
Consumer Surplus	$ 77,198	$ 24,710 (32.01%)	$ 24,710 (28.66%)	$ 67,954 (88.03%)		$ 67,954 (88.03%)	
Person-Days	175	- (0.00%)	- (0.00%)	- (0.00%)		140 (80.00%)	
Revenue	$ 19,025	$ - (0.00%)	$ - (0.00%)	$ - (0.00%)		$ 15,220 (80.00%)	
Cost	$ 11,631	$ - (0.00%)	$ - (0.00%)	$ - (0.00%)		$ 9,305 (80.00%)	
Profit	$ 7,393	$ - (0.00%)	$ - (0.00%)	$ - (0.00%)		$ 5,915 (80.01%)	
Number of Firms	1	- (0.00%)	- (0.00%)	- (0.00%)		1 (100.00%)	
Consumer Surplus	$ 15,475	$ - (0.00%)	$ - (0.00%)	$ - (0.00%)		$ 12,355 (79.84%)	
Person-Days	1,048	279 (26.62%)	279 (26.62%)	768 (73.28%)		908 (86.64%)	
Revenue	$ 114,148	$ 30,439 (26.67%)	$ 30,439 (26.67%)	$ 83,708 (73.33%)		$ 98,928 (86.67%)	
Cost	$ 69,788	$ 18,610 (26.67%)	$ 18,610 (26.67%)	$ 51,178 (73.33%)		$ 60,483 (86.67%)	
Profit	$ 44,359	$ 11,829 (26.67%)	$ 11,829 (26.67%)	$ 32,530 (73.33%)		$ 38,445 (86.67%)	
Number of Firms	1	1 (100.00%)	1 (100.00%)	1 (100.00%)		1 (100.00%)	
Consumer Surplus	$ 92,673	$ 24,710 (26.66%)	$ 24,710 (26.66%)	$ 67,954 (73.33%)		$ 80,309 (86.66%)	

Commercial Fishery

Boundary Analysis

Boundary Analysis Methodology. In performing the boundary analysis, for the each alternative, the impact estimates are broken out by "within the FKNMS boundary" and "outside the FKNMS boundary."

Commercial fishing is prohibited in the DRTO so these grid cells are "true" zeroes in the analysis. Before breaking out the impact, the status of each grid cell (i.e., inside or outside of the boundary) had to be determined. Two methods were considered to carry out this task: the "centroid method" and the "intersection method." The centroid method characterizes a grid cell as within a boundary if the center point of the cell is within the boundary. The intersection method characterizes a grid cell as within a boundary if any part of the cell is intersected by the boundary. The centroid method was selected because it was more consistent with how the data were collected (i.e., 1 nm^2 grid cells was the finest resolution).

The estimates from the geographic information system (GIS) analysis for the different boundary alternatives are the sum of each measurement within the boundary for each alternative. The estimates therefore represent the maximum total potential loss from displacement of the commercial fishing activities. This analysis ignores possible mitigating factors and the possibility of net benefits that might be derived if the proposed ecological reserve has replenishment effect. Although the extent of the mitigating factors or the potential benefits from replenishment cannot be quantified, these as well as other potential benefits of the proposed ecological reserve are discussed after presenting and discussing the maximum potential losses from displacement of the current commercial fisheries.

The boundary analysis is driven by the catch summed across grid cells within each boundary alternative. The set of relationships, measures and methods described in Leeworthy and Wiley (1999) are then used to translate catch into estimates of market and non-market economic values potentially affected. These estimates are broken-down by area both inside and outside FKNMS boundary and are done by species. Table 10 shows the results for catch for each alternative. Catch for the total TERSA is also presented to allow assessment of the proportion of the TERSA fishery potentially affected by each alternative.

Table 10. TERSA Catch Potentially Lost from Displacement. 1997

Alternative/Area	Species/Species Group (Pounds)/Percent					
	Lobster		Reef Fish		Shrimp	
TERSA	**937,952**		**574,642**		**715,500**	
Inside FKNMS	568,399	(60.60%)	293,374	(51.05%)	183,262	(25.61%)
Outside FKNMS	369,553	(39.40%)	281,268	(48.95%)	532,238	(74.39%)
Alternative II	**56,625**		**74,494**		**7,940**	
Inside FKNMS	56,625	(100.00%)	74,494	(100.00%)	7,940	(100.00%)
Outside FKNMS	-	(0.00%)	-	(0.00%)	-	(0.00%)
Preferred Alternative	**108,639**		**116,642**		**58,374**	
Inside FKNMS	56,802	(52.29%)	74,494	(63.87%)	7,940	(13.60%)
Outside FKNMS	51,837	(47.71%)	42,148	(36.13%)	50,434	(86.40%)
Alternative IV	**153,778**		**161,997**		**58,374**	
Inside FKNMS	101,940	(66.29%)	119,849	(73.98%)	7,940	(13.60%)
Outside FKNMS	51,838	(33.71%)	42,148	(26.02%)	50,434	(86.40%)
Alternative V	**164,908**		**169,907**		**73,427**	
Inside FKNMS	101,940	(61.82%)	119,849	(70.54%)	7,940	(10.81%)
Outside FKNMS	62,968	(38.18%)	50,058	(29.46%)	65,487	(89.19%)

Alternative/Area	King Mackerel	
TERSA	**96,346**	
Inside FKNMS	77,285	(80.22%)
Outside FKNMS	19,061	(19.78%)
Alternative II	**4,057**	
Inside FKNMS	4,057	(100.00%)
Outside FKNMS	-	(0.00%)
Preferred Alternative	**13,489**	
Inside FKNMS	4,057	(30.08%)
Outside FKNMS	9,432	(69.92%)
Alternative IV	**14,999**	
Inside FKNMS	5,568	(37.12%)
Outside FKNMS	9,431	(62.88%)
Alternative V	**14,999**	
Inside FKNMS	5,568	(37.12%)
Outside FKNMS	9,431	(62.88%)

1. Percents of catch inside and outside FKNMS in parentheses.

The boundary alternatives are ordered according to size and potential impact. Alternative I is the "No Action" alternative and is the least protective alternative. Alternative III is the "Preferred Alternative". Alternatives IV and V are the largest and "most protective" alternatives. For catch, generally the higher the alternative number the greater the potential affect on catch, except for King mackerel and shrimp. Potential affect on King mackerel catch is the same for both alternatives IV and V and, the potential affect on shrimp catch is the same for the Preferred Alternative (III) and alternative IV.

Both the market and non-market economic values potentially lost from displacement for each alternative, except the "No-action" Alternative (Boundary Alternative I), are summarized in Leeworthy and Wiley (2000), includes greater detail by species/species groups, and for the market economic values, separate estimates for Monroe and Collier/Lee counties. Although the impacts on only Monroe and Collier/Lee counties are presented, the catch impacted that is landed in other counties is included in the analyses. The result is that the impacts in Monroe and Collier/Lee Counties are slightly overstated. However, in the boundary alternative analyses only a small amount of catch is landed in other counties and the amounts are insignificant.

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Table 11. Maximum Potential Losses to the Commercial Fisheries from Displacement

Area/Measure	Total TERSA	Alternatives: Alternative II	Preferred Alternative	Alternative IV	Alternative V
Total					
Market[1]					
Harvest Revenue	$ 6,884,992	$ 411,632	$ 843,583	$ 1,126,237	$ 1,224,849
Total Output	$ 14,957,717	$ 865,819	$ 1,817,843	$ 2,400,730	$ 2,621,627
Total Income	$ 9,273,785	$ 536,808	$ 1,127,063	$ 1,488,453	$ 1,625,409
Total Employment	404	23	49	65	71
Non-market					
Consumer's Surplus[2]	$ 7,537,781	$ 473,097	$ 879,973	$ 1,103,808	$ 1,239,587
Producer's Surplus[3]	$ -	$ -	$ -	$ -	$ -
Return to Labor & Capital[4]	$ 1,926,162	$ 106,789	$ 221,968	$ 300,599	$ 326,880
Commercial					
Market					
Harvest Revenue	$ 3,476,456	$ 411,632	$ 411,632	$ 694,284	$ 694,284
Total Output	$ 7,292,387	$ 865,819	$ 865,819	$ 1,448,700	$ 1,448,700
Total Income	$ 4,521,280	$ 536,808	$ 536,808	$ 898,194	$ 898,194
Total Employment	197	23	23	39	39
Non-market					
Consumer's Surplus	$ 3,890,933	$ 473,097	$ 473,097	$ 696,932	$ 696,932
Producer's Surplus	$ -	$ -	$ -	$ -	$ -
Return to Labor & Capital	$ 1,029,118	$ 106,789	$ 106,789	$ 185,420	$ 185,420
Gray Snapper					
Market					
Harvest Revenue	$ 3,408,536	$ -	$ 431,951	$ 431,953	$ 530,565
Total Output	$ 7,665,330	$ -	$ 952,024	$ 952,030	$ 1,172,927
Total Income	$ 4,752,505	$ -	$ 590,255	$ 590,259	$ 727,215
Total Employment	207	-	26	26	32
Non-market					
Consumer's Surplus	$ 3,646,848	$ -	$ 406,876	$ 406,876	$ 542,655
Producer's Surplus	$ -	$ -	$ -	$ -	$ -
Return to Labor & Capital	$ 897,044	$ -	$ 115,179	$ 115,179	$ 141,460

1. Market economic measures include impacts on Monroe County and Collier/Lee counties. See Appendix A, Tables A.6 – A.11 in Leeworthy and Wiley (1999) for details by species and counties.
2. Maximum values from each species were used when range of estimates was generated multiple demand equations. See Appendix B in Leeworthy and Wiley (1999) for detailed calculations by species and alternatives.
3. Producer's surplus or economic rents were assumed to be zero for two reasons. First, all fisheries, except spiny lobsters, are open access fisheries and therefore economic would be zero i.e., firms are earning only normal rates of return on investment. Second, even using total return to labor & capital, which overstates return on investment, does not yield rates of return on investment above normal rates of return.
4. Return to Labor & Capital is not a non-market value but would include rent if it existed.

Boundary Alternative I: No Action

The no-action alternative is not establishing a reserve and not issuing the implementing regulations. The costs of imposing the no-take regulations, for any given alternative with no-take regulations, would be the benefits of the no-action alternative. That is, by not adopting the no-take regulations, the costs are avoided. Similarly, any benefits from imposing the no-take regulations, for any given alternative with no-take regulations, would be the costs of the no-action alternative. That is, by not adopting the no-take regulations, the costs are the benefits lost by not adopting the no-take regulations. Said another way, the costs are the opportunities lost. The impacts of the no-action alternative can only be understood by comparing it to one of the alternatives. Thus the effects of the no action alternative can be obtained by reading the effects from any of the proposed alternatives in reverse.

Boundary Alternative II

Market Economic Values. This alternative could potentially affect 4.2% of the catch of King mackerel, 6% of the lobster catch, 12.96% of the Reef Fish catch, and 1% of the shrimp catch in the TERSA. This would lead to a reduction in about $411 thousand in harvest revenue or 6% of the TERSA harvest revenue. This reduction in revenue would result in a reduction of 5.8% of total output, income and employment generated by the TERSA fishery. Since this alternative was restricted to reside within FKNMS current boundary, the effects are all inside FKNMS boundary. Although these effects may be significant to those firms that might potentially be affected, the overall affect on the local economies would be so small they would not be noticed. Harvest revenue potentially impacted was only 0.67% of all harvest revenue of catch landed in Monroe County. In addition, this lost revenue would translate (accounting for the multiplier effects) into only fractions of a percent of the total Monroe County economy; 0.035% of total output, 0.046% of total income and 0.045% of total employment.

Non-market Economic Values. For all species/species groups, this alternative could result in a potential loss of over $473 thousand in consumer's surplus. This is 6.28% of the consumer's surplus generated by the entire TERSA. Although producer's surplus or economic rents are estimated to be zero, about 5.54% of the return to labor and capital of the TERSA fishery is potentially affected by this alternative.

Boundary Alternative III (Preferred Boundary Alternative)

Market Economic Values. This alternative could potentially affect 14% of the catch of King mackerel, 11.58% of the lobster catch, 20.30% of the Reef Fish catch, and 8.16% of the shrimp catch in the TERSA. This would lead to a reduction in about $844,000 in harvest revenue or 12.26% of the TERSA harvest revenue. This reduction in revenue would result in a reduction of 12.16% of total output, income and employment generated by the TERSA fishery. The impacts are split almost evenly between the areas inside and outside the FKNMS boundary. Although these costs may be significant to those firms that might potentially be affected, the overall affect on the local economies would be so small they would not be noticed. Harvest revenue potentially affected was only 1.16% of all harvest revenue of catch landed in Monroe County. In addition, this lost revenue would translate (accounting for the multiplier effects) into only fractions of a percent of the total Monroe County economy; 0.0596% of total output, 0.0779% of total income and 0.0785% of total employment.

Non-market Economic Values. For all species/species groups, this alternative could result in a potential loss of about $880,000 in consumer's surplus. This was 11.7% of the consumer's surplus generated by the entire TERSA. Whereas the market economic values were almost evenly split inside and outside the FKNMS, 53.76% of the consumer's surplus potentially affected is from inside the FKNMS boundary. This is due to the distributions of lobster and reef fish catch where a higher proportion of the potentially affected catch come from inside the FKNMS boundary, whereas the distributions of shrimp and King mackerel come largely from outside the FKNMS boundary.

Although producer's surplus or economic rents are estimated to be zero, about 11.5% of the return to labor and capital of the TERSA fishery is potentially affected by this alternative. The distribution inside versus outside the FKNMS boundary follows that of the market economic values with 48% from catch inside the FKNMS boundary.

Boundary Alternative IV

Market Economic Values. This alternative could potentially affect 15.57% of the catch of King mackerel, 16.4% of the lobster catch, 28.19% of the Reef Fish catch, and 8.16% of the shrimp catch in the TERSA. This would lead to a reduction in about $1.126 million in harvest revenue or 16.45% of the TERSA harvest revenue. This reduction in revenue would result in a reduction of 16.05% of total output, income and employment generated by the TERSA fishery. About 61.65% of the harvest revenue and 60.34% of the output, income and employment impacts would come from catch displaced from within FKNMS boundary. Although the costs may be significant to those firms that might potentially be affected, the overall impact on the local economies would be so small they would not be noticed. Harvest revenue potentially affected was only 1.82% of all harvest revenue of catch landed in Monroe County. In addition, this lost revenue would translate (accounting for the multiplier effects) into only fractions of a percent of the total Monroe County economy; 0.0968% of total output, 0.127% of total income and 0.1281% of total employment.

Non-market Economic Values. For all species/species groups, this alternative could result in a potential loss of about $1.1 million in consumer's surplus. This is 14.64% of the consumer's surplus generated by the entire TERSA. Approximately 63.14% of the consumer's surplus potentially affected is from catch from inside the FKNMS boundary. This is due to the distributions of lobster and reef fish catch where a higher proportion of the potentially affected catch come from inside the FKNMS boundary, whereas the distributions of shrimp and King mackerel come largely from outside the FKNMS boundary.

Although producer's surplus or economic rents are estimated to be zero, about 15.6% of the return to labor and capital of the TERSA fishery is potentially affected by this alternative. The distribution inside versus outside the FKNMS boundary follows that of the market economic values with 61.68% from catch inside the FKNMS.

Boundary Alternative V

Market Economic Values. This alternative could potentially affect 15.57% of the catch of King mackerel, 17.58% of the lobster catch, 29.57% of the Reef Fish catch, and 10.26% of the shrimp catch in the TERSA. This would lead to a reduction in about $1.224 million in harvest revenue or 17.89% of the TERSA harvest revenue. This reduction in revenue would result in a reduction of 17.5% of total output, income and employment generated by the TERSA fishery. About 56.68% of the harvest revenue and 55.26% of the output, income and employment impacts would come from catch displaced from within the FKNMS boundary. Although the costs may be significant to those firms that might potentially be affected, the overall impact on the local economies would be so small they would not be noticed. Harvest revenue potentially affected was only 1.98% of all harvest revenue of catch landed in Monroe County. In addition, this lost revenue would translate (accounting for the multiplier effects) into only fractions of a percent of the total Monroe County economy; 0.106% of total output, 0.138% of total income and 0.1399% of total employment.

Non-market Economic Values. For all species/species groups, this alternative could result in a potential loss of about $1.24 million in consumer's surplus. This was 16.4% of the consumer's surplus generated by the entire TERSA. 56.2% of the consumer's surplus

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potentially affected is from catch from inside the FKNMS boundary. This is due to the distributions of lobster and reef fish catch where a higher proportion of the potentially affected catch come from inside the FKNMS boundary, whereas the distributions of shrimp and King mackerel come largely from outside the FKNMS boundary.

Although producer's surplus or economic rents are estimated to be zero, about 16.97% of the return to labor and capital of the TERSA fishery is potentially affected by this alternative. The distribution inside versus outside the FKNMS boundary follows that of the market economic values with 56.7% from catch inside the FKNMS boundary.

Profiles of Fishermen Potentially Affected

A profile of the approximately 110 fishermen using TERSA based on a sample of 90 was completed with a comparison with other commercial fishermen in Monroe County. The profiles of those potentially affected by each alternative were compared. The profiles are summarized in Table 12. Statistical tests were performed comparing the sample distributions for the groups that fished within each boundary alternative as compared with TERSA fishermen as a whole. Except for the number of fishing operations potentially affected, the only significant differences for all alternatives were in membership in organizations and in fish house usage.

Fishermen potentially affected by Boundary Alternative II were the only group that was significantly different for any other characteristics listed in Table 12. These fishermen had less experience fishing in Monroe County than the general TERSA fishermen, however they were not significantly different with respect to years fishing in the TERSA. Fishermen potentially affected by Boundary Alternative II also earned a significantly lower proportion of their income from fishing than the general TERSA fishermen; however, they earned a significantly higher proportion of their income from fishing within the TERSA than the general TERSA fishermen.

Fishermen potentially affected by Boundary Alternative II were also significantly different from the general TERSA fishermen in the distribution of their primary hauling port. A significantly higher proportion of those potentially affected by this alternative used Key West/Stock Island and Tavenier than the general TERSA fishermen, and they used Big Pine Key, Marathon and Naples/Ft. Myers significantly less than the general TERSA fishermen.

Fifty-one (51) or 57% of the sampled fishing operations could be potentially affected by Boundary Alternative II followed by 64 operations or 71% for Alternative III, and 65 operations or 72% for both Alternatives IV and V. Twenty-four (24) of the 28 or 86% of all the lobster operations could be potentially affected by Boundary Alternative II, while 27 of the 28 lobster operations or 96% are potentially affected by Boundary Alternatives III, IV, and V. Six (6) of the 18 or 33.3% of the shrimp operations are potentially affected by Alternative II, while Alternative III could potentially affect 15 of 18 or 83% of the shrimp operations. Boundary Alternatives IV and V could potentially affect 14 of the 18 or 78% of the shrimp operations. Fifteen (15) of the 16 King mackerel operations could be potentially affected by Boundary Alternative II, while Boundary Alternatives III, IV and V could potentially affect all 16 of the King mackerel operations. Thirty-seven (37) of the 42 or 88% of the reef fish operations could be potentially affected by Alternative II, while 40 or 95% of the reef fish fishing operations could be potentially affected by Alternative III. Boundary Alternatives IV and V could potentially affect all 42 reef fish operations.

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Table 12. Profile of TERSA Fishermen Compared to Other Keys Fishermen

	TERSA (%)	Alternative II	Preferred Alternative	Alternative IV	Alternative V
Age					
18-30	13.3	19.6	15.6	15.4	15.4
31-40	18.9	19.6	18.8	20.0	20.0
41-50	36.7	29.4	34.4	33.8	33.8
51-60	20.0	21.6	21.9	21.5	21.5
Over 60	11.1	9.8	9.4	9.2	9.2
Years of Fishing in Monroe					
Less than one year	1.1	**2.0**	1.6	1.5	1.5
1-5 years	6.7	**9.8**	7.8	7.7	7.7
6-10 years	12.4	**13.7**	12.5	12.3	12.3
11-20 years	16.9	**19.6**	17.2	18.5	18.5
21 or more years	62.9	**54.9**	60.9	60.0	60.0
Years of Fishing in TERSA					
1-5 years	10.1	9.8	10.9	10.8	10.8
6-10 years	25.8	25.5	20.3	21.5	21.5
11-20 years	16.9	17.6	17.2	18.5	18.5
21 or more years	47.2	47.1	51.6	49.2	49.2
Race/Ethnicity					
Anglo-American	76.7	74.5	78.1	78.5	78.5
Hispanic	21.1	25.5	20.3	20.0	20.0
African-American	2.2	0.0	1.6	1.5	1.5
Membership in Organizations					
Conch Coalition	7.0	**3.9**	**3.1**	**3.1**	**3.1**
OFF	12.0	**9.8**	**7.8**	**7.7**	**7.7**
MCCF	38.0	**23.5**	**21.9**	**21.5**	**21.5**
Environmental	2.0	**3.9**	**4.7**	**4.6**	**4.6**
Chambers of Commerce	303.0	**2.0**	**4.7**	**4.6**	**4.6**

Table 12. (Continued)

	TERSA (%)	Alternative II	Preferred Alternative IV	Alternative IV	Alternative V
Occupation					
Full-time Commercial Fishing	87.8	84.3	85.9	86.2	86.2
Part-time Commercial Fishing	1.1	2.0	1.6	1.5	1.5
Charter Boat (sell some catch)	11.1	13.7	12.5	12.3	12.3
Income					
Percent Income from Fishing	89.1	**84.3**	87.3	87.5	87.5
Percent Income from Fishing in TERSA	44.7	**51.2**	46.8	45.9	45.9
Family Members Supported					
1 (Myself)	19.3	17.0	15.5	16.9	16.9
2	28.9	27.7	29.3	27.1	27.1
3	22.9	29.8	27.6	28.8	28.8
4 or more	28.9	25.5	27.6	27.2	27.2
Primary Hauling Port					
Key West/Stock Island	74.4	**82.4**	75.0	72.3	72.3
Big Pine Key	4.4	**3.9**	4.7	4.6	4.6
Marathon	3.3	**0.0**	0.0	1.5	1.5
Tavernier	2.2	**3.9**	3.1	3.1	3.1
Naples/Ft. Myers	15.6	**9.8**	17.2	18.5	18.5
Fish House Usage (% Yes)	41.1	**35.3**	**35.9**	**36.9**	**36.9**
Number in Sample	90	51	64	65	65
Lobster Operations	28	24	27	27	27
Shrimp Operations	18	6	15	14	14
King Mackerel Operations	16	15	16	16	16
Reef Fish Operations	42	37	40	42	42

1. Numbers in bold identify statistically significant differences compared to total Kolgromov-Smirnoff two-sample test at 5 percent level of significance.

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Other Potential Costs and Mitigating Factors—Are the Potential Losses Likely?

In the above GIS-based analysis, the effects are referred to as "potential losses" or "maximum potential losses". There is the possibility that there could be an additional cost not discussed but which cannot be quantified, that is, crowding and the resulting conflicts among users forced to compete in a smaller area. There are also several factors that could mitigate all the potential losses and further there is a possibility that there might not be any losses at all. It is quite possible that there might be actual net benefits to even the current displaced users. Below the issue of crowding costs and the mitigating factors and potential for beneficial outcomes are discussed in qualitative terms because it is not possible for us to quantify them. Two mitigating factors, how likely they might mitigate the potential losses from displacement, and how this might differ for each of the alternatives are discussed.

Crowding. As shown above, each of the alternatives would result in a certain amount of displacement. Displacement of commercial fishing activity is a certainty under all boundary alternatives, except Alternative I, the No-action Alternative. If this displacement results in the activity being transferred to other sites, there is a potential for crowding effects. Crowding effects could raise the costs of fishing, both private costs to each fishing operation and social costs in resolving conflicts.

Crowding conflicts were one of the issues mentioned when the State of Florida created the lobster trap certificate program which was designed to reduce the number of lobster traps. If fishing stocks outside the protected area are already fished to their limits (i.e., limits of sustainable harvests), then displacement could also lead to adverse stock effects and a lower level of catch from all commercial fisheries. Crowding effects would represent a potential cost not accounted for in our above GIS-based analysis and the potential for the existence of crowding effects would vary by alternative. Whether crowding effects are experienced would depend on the status of the fisheries outside the proposed protected area, the extent of displacement, the current knowledge and fishing patterns of the displaced fishermen, and other potential regulations. The trap reduction program is an example where crowding effects could be mitigated by making room for the displaced traps.

Relocation. If displaced commercial fishermen are simply able to relocate their fishing effort and they are able to partially or completely replace their lost catch by fishing elsewhere, then there might be less or no effect. However, the possibility exists that displacement, even if it does not result in lower overall catch, may result in higher costs. This would result in lower profits to fishing operations. Whether fishermen are able to relocate to other fishing sites and replace lost catch or avoid cost increases would depend, like with the issue of crowding, on the status of the fisheries outside the proposed protected area, the extent of the displacement, the current knowledge and fishing patterns of the displaced fishermen, and other potential regulations.

Long-term benefits from Replenishment Effects. Ecological reserves or marine reserves may have beneficial effects beyond the direct ecological protection from the sites themselves. That is, both the size and number of fish, lobster, and other invertebrates both inside and outside the reserves may increase i.e., the replenishment effect. The following quote from Davis 1998 summarizes the replenishment effect of reserves:

[W]e found 31 studies that tested whether protected areas had an effect on the size, reproductive output, diversity, and recruitment of fish in adjacent areas. Fisheries targeted species were two to 25 times more abundant in no-take areas than in surrounding areas for fish, crustaceans, and mollusks on coral and temperate reefs in Australia, New Zealand, the Philippines, Japan, Kenya, South Africa, the Mediterranean Sea, Venezuela, Chile, and the United States (California, Florida and Rhode Island). Mean sizes of fished species protected in no-take zones were 12 to 200% larger than those in surrounding areas for all fishes studied and in 75 to 78% of the invertebrates. Eighty-six percent of the studies that tested fishery yields found that catches within three kilometers of the marine protected areas were 46 to 50% higher than before no-take zones were created. It is clear that fishers all over the world believe no-take zones increase yields because they fish as close to the boundary as possible.

The long-term benefits from the reserve could offset any losses from displacement and may also result in long-term benefits and no costs (net benefits) to commercial fishermen that would be displaced by a proposed reserve. Again, this conclusion may vary by alternative.

Boundary Alternative II

Crowding and Relocation. For the lobster fishery, it appears that the lobster trap reduction program could fully mitigate the potential for crowding costs. This boundary alternative would displace 2,228 traps. A ten percent reduction in traps in the TERSA would provide space for 3,690 traps. Further, lobster fishermen in the TERSA only catch 68% of their lobsters from the TERSA. Thus, lobster fishermen are knowledgeable about fishing in other areas of the Keys where they might move their displaced traps. Thus, under this boundary alternative there would be no crowding costs for lobsters and they would be able to replace catch from other areas. Thus, for lobsters, the potential economic losses identified in Table 11 are not likely to occur under Alternative II.

Crowding is not an issue for King mackerel because they are a pelagic species and thus move around and catching them elsewhere is highly likely without interfering with other fishermen. Shrimp fishermen currently only catch ten percent of their total shrimp catch from the TERSA. Displacement of shrimp catch under Boundary Alternative II would only be about one percent of their TERSA catch and less than one percent of their total shrimp catch. It would seem highly likely that there would be no crowding costs from displacement and given the small amounts of catch affected, it is highly likely that shrimp fishermen would be able to replace lost catch from other sites. However, some shrimp fishermen have said that they cannot replace lost catch from other sites. Thus, for King mackerel, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative II, but for shrimp the economic losses could range from zero to the maximum potential losses reported in Table 11.

Reef Fish fishermen comprise the largest group of TERSA fishermen. Under Boundary Alternative II, 37 of the sampled 42 fisherman would be affected. Reef fishermen are knowledgeable of other fishing locations outside the TERSA. In 1997, they caught 52% of their reef fish from areas in the Keys outside the TERSA. However, stocks of reef fish in the TERSA and throughout the Keys appear to be overfished. Alternative II displaces about 13% of the reef fish catch in the TERSA. Given the status of reef fish stocks, the losses identified in Table 11 are likely to occur in the short-term until the benefits of replenishment could off-set these losses in the longer-term.

Replenishment. No replenishment benefits to King mackerel or shrimp are expected. For lobsters and reef fish, replenishment benefits are expected. Davis (1998) provided an estimate that

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invertebrates and reef fish at other marine reserves had shown increases in yields of 46–50% within three kilometers of the protected areas. Eight fish spawning areas have been identified in the western portion of the TERSA. Only one of the eight fish spawning areas is located within the Alternative II boundary and would be protected, and to thus support the replenishment effect. For lobsters, long-term net benefits to the commercial fishery of the TERSA are expected. For reef fish, it is not clear whether the full 13% lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses expected to be less than the 13% reductions that are the basis for the losses calculated and presented in Table 11.

Boundary Alternative III (Preferred Boundary Alternative)

Crowding and Relocation. For the lobster fishery, there is some potential for crowding costs. This boundary alternative would displace 4,346 traps. A ten percent reduction in traps in the TERSA would provide space for 3,690 traps. However, if the remaining 656 traps are relocated to zones 1–3 in the Keys, there would be more than adequate space given the 10% reduction in traps that took place in Monroe County between 1997–98 and 1998–99 (475,094 to 428, 411). See FMRI, 1998. Lobster fishermen in the TERSA only catch 68% of their lobsters from the TERSA. Thus, lobster fishermen are knowledgeable about fishing in other areas of the Keys where they might move their displaced traps. Thus, under this alternative their would be no crowding costs for lobsters and it is expected that they would be able to replace catch from other areas. Thus, for lobsters, the potential economic losses identified in Table 11 are not likely to occur under this alternative.

Crowding is not an issue for King mackerel because they are a pelagic species and thus move around and catching them elsewhere is highly likely without interfering with other fishermen. Shrimp fishermen currently only catch ten percent of their total shrimp catch from the TERSA. Displacement of shrimp catch under Boundary Alternative III (Preferred Boundary Alternative) would only be about eight percent of their TERSA catch and less than one percent of their total shrimp catch. It would seem highly likely that there would be no crowding costs from displacement and given the small amounts of catch affected, it is highly likely that shrimp fishermen would be able to replace lost catch from other sites. However, some shrimp fishermen have said that they cannot replace lost catch from other sites. Thus, for King mackerel, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative III, but for shrimp the economic losses could range from zero to the maximum potential losses reported in Table 11.

Reef Fish fishermen comprise the largest group of TERSA fishermen. Under Boundary Alternative III (Preferred Boundary Alternative), 40 of the sampled 42 fishermen would be affected. Reef fishermen are knowledgeable of other fishing locations outside the TERSA. In 1997, they caught 52% of their reef fish from areas in the Keys outside the TERSA. However, stocks of reef fish in the TERSA and throughout the Keys appear to be overfished. Boundary Alternative III (Preferred Boundary Alternative) displaces 20% of the reef fish catch in the TERSA. Given the status of reef fish stocks, the losses identified in Table 11 are likely to occur in the short-term until the benefits of replenishment could offset these losses in the longer-term.

Replenishment. No replenishment benefits to King mackerel or shrimp are expected. For lobsters and reef fish, replenishment benefits are expected. Davis (1998) reports increases in yields of invertebrates and reef fish of 46–50% within three kilometers of the protected areas at other marine reserves. Five of the eight fish spawning areas identified in the western portion of the TERSA are located within the Alternative III boundary and would be protected, thus bolstering the replenishment effect. For lobsters, long-term net benefits would be expected under Boundary Alternative III (Preferred Boundary Alternative). For reef fish, it is not clear whether the full 20% lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses expected to be less than the 20% reductions that are the basis for the losses calculated and presented in Table 11.

Boundary Alternative IV

Crowding and Relocation. For the lobster fishery, there is some potential for crowding costs. It is estimated that this boundary alternative would displace 6,050 traps. A ten percent reduction in traps in the TERSA would provide space for 3,690 traps. However, if the remaining 2,360 traps are relocated to zones 1–3 in the Keys, there would be more than adequate space given the 10% reduction in traps that took place in Monroe County between 1997–98 and 1998–99 (475,094 to 428, 411). See FMRI, 1998. Lobster fishermen in the TERSA only catch 68% of their lobsters from the TERSA. Thus, lobster fishermen are knowledgeable about fishing in other areas of the Keys where they might move their displaced traps. Thus, under this alternative there would be no crowding costs for lobsters and fishermen would be able to replace catch from other areas. Thus, for lobsters, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative IV.

Crowding is not an issue for King mackerel because they are a pelagic species and thus move around and catching them elsewhere is highly likely without interfering with other fishermen. Shrimp fishermen currently only catch ten percent of their total shrimp catch from the TERSA. Displacement of shrimp catch under Boundary Alternative IV would only be about eight percent of their TERSA catch and less than one percent of their total shrimp catch. It would seem highly likely that there would be no crowding costs from displacement and given the small amounts of catch affected, it is highly likely that shrimp fishermen would be able to replace lost catch from other sites. However, some shrimp fishermen have said that they cannot replace lost catch from other sites. Thus, for King mackerel, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative IV, but for shrimp the economic losses could range from zero to the maximum potential losses reported in Table 11.

Reef fish fishermen comprise the largest group of TERSA fishermen. Under Boundary Alternative IV, all 42 of the sampled fishermen would be affected. Reef fishermen are knowledgeable of other fishing locations outside the TERSA. In 1997, they caught 52% of their reef fish from areas in the Keys outside the TERSA. However, stocks of reef fish in the TERSA and throughout the Keys appear to be overfished. Boundary Alternative IV displaces 28% of the reef fish catch in the TERSA. Given the status of reef fish stocks, the losses identified in Table 11 are likely to occur in the short-term until the benefits of replenishment could off-set these losses in the longer-term.

Replenishment. No replenishment benefits to King mackerel or shrimp are expected. For lobsters and reef fish, replenishment benefits are expected. Davis (1998) reports increases in yields of invertebrates and reef fish of 46–50% within three kilometers of the protected areas at other marine reserves. Seven of the eight fish spawning areas identified in the western portion of the TERSA are located within the Alternative IV boundary and would be protected, thus bolstering the replenishment effect. For lobsters, long-term net benefits to the commercial fishery of the TERSA are expected. For reef fish, it is not clear whether the full 28% lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses expected to be less than the 28% reductions that are the basis for the losses calculated and presented in Table 11.

Boundary Alternative V

Crowding and Relocation. For the lobster fishery, there is some potential for crowding costs. This boundary alternative would displace 6,487 traps. A ten percent reduction in traps in the TERSA would provide space for 3,690 traps. However, if the remaining 2,797 traps are relocated to zones 1–3 in the Keys, there would be more than adequate space given the 10% reduction in traps that took place in Monroe County between 1997–98 and 1998–99 (475,094 to 428,411). See FMRI, 1998. Lobster fishermen in the TERSA only catch 68% of their lobsters from the TERSA and they are knowledgeable about fishing in other areas of the Keys where they might move their displaced traps. Thus, under this boundary alternative there would be no crowding costs for lobsters and fishermen would be able to replace catch from other areas. Therefore, for lobsters, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative V.

Crowding is not an issue for King mackerel because they are a pelagic species and thus move around and catching them elsewhere is highly likely without interfering with other fishermen. Shrimp fishermen currently only catch ten percent of their total shrimp catch from the TERSA. Displacement of shrimp catch under Boundary Alternative V would only be about ten percent of their TERSA catch and about one percent of their total shrimp catch. It would seem highly likely that there would be no crowding costs from displacement and given the small amounts of catch affected, it is highly likely that shrimp fishermen would be able to replace lost catch from other sites. However, some shrimp fishermen have said that they cannot replace lost catch from other sites. Thus, for King mackerel, the potential economic losses identified in Table 11 are not likely to occur under Boundary Alternative V, but for shrimp the economic losses could range from zero to the maximum potential losses reported in Table 11.

Reef fish fishermen comprise the largest group of TERSA fishermen. Of the 90 TERSA fishermen sampled, 42 were reef fish fishermen. Under Boundary Alternative V, all 42 would be affected. Reef fishermen are knowledgeable of other fishing locations outside the TERSA. In 1997, they caught 52% of their reef fish from areas in the Keys outside the TERSA. However, stocks of reef fish in the TERSA and throughout the Keys appear to be overfished. Boundary Alternative V displaces 29% of the reef fish catch in the TERSA. Given the status of reef fish stocks, the losses identified in Table 11 are likely to occur in the short-term until the benefits of replenishment could off-set these losses in the longer-term.

Replenishment. No replenishment benefits to King mackerel or shrimp are expected. For lobsters and reef fish, replenishment benefits are expected. Davis (1998) reports increases in yields of invertebrates and reef fish of 46–50% within three kilometers of the protected areas at other marine reserves. Seven of the eight spawning areas identified in the western portion of the TERSA are located within the Alternative V boundary and would be protected, thus bolstering the replenishment effect. For lobsters, long-term net benefits under Alternative V are expected. For reef fish, it is not clear whether the full 29% lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses expected to be less than the 29% reductions that are the basis for the losses calculated and presented in Table 11.

Commercial Shipping

No effect for any of the alternatives.

Treasure Salvors

No expected effect for any of the alternatives. One permit for inventorying submerged cultural resources in Sanctuary waters was issued for the Tortugas area of the Sanctuary. There were no submerged cultural resources found on the Tortugas Bank. Whether there are any submerged cultural resources on Riley's Hump is unknown.

Other Potential Benefits

In both the recreation industry (fishing and diving) and the commercial fishery sections above, the potential benefits to recreational and commercial fisheries from the replenishment effect of an ecological reserve were discussed. Also discussed in the recreation industry section were the potential benefits to non-consumptive recreational users (divers). Below, some of the most important benefits of an ecological reserve—scientific values, and education values—are discussed.

Ecological reserves provide a multitude of environmental benefits. Sobel (1996) provides a long list of these benefits. Most of those benefits have been described above. Sobel (1996) categorizes scientific and education values into those things a reserve provides that increase knowledge and understanding of marine systems. Sobel provides the following lists of benefits:

Scientific Values:

- Provides long-term monitoring sites
- Provides focus for study
- Provides continuity of knowledge in undisturbed site
- Provides opportunity to restore or maintain natural behaviors
- Reduces risks to long-term experiments
- Provides controlled natural areas for assessing anthropogenic impacts, including fishing and other impacts

Education Values:

- Provides sites for enhanced primary and adult education
- Provides sites for high-level graduate education

Other Regulations

Each of the four regulatory alternatives (A–D) are analyzed for each boundary alternative (I–V).

Boundary Alternative I

This is the No-Action Alternative and would not result in the expansion of the Sanctuary boundary and would not establish a Tortugas Ecological Reserve. None of the regulatory alternatives would apply.

Boundary Alternative II

This alternative limits the reserve to the existing Sanctuary boundary for a total area of approximately 55 nm^2. (Figure 1). This alternative includes a portion of Sherwood Forest and the coral pinnacles north of Tortugas Bank; it does not include Riley's Hump. It includes some coral and hardbottom habitat north of the DRTO. Tortugas South would not exist under Boundary Alternative II. None of the regulatory alternatives would apply to the Tortugas South area.

Regulatory Alternative A: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South. The Sanctuary-wide regulations already

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apply to Tortugas North and the effects of the ecological reserve regulations have been analyzed under the no-take discussion above. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative B: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The Sanctuary-wide regulations already apply to Tortugas North and the effects of the ecological reserve regulations have been analyzed under the no-take discussion above. The existing ecological reserve regulations would prohibit fishing in the Tortugas Ecological Reserve consistent with 15 CFR 922.164(d) Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative C: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B). The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The Sanctuary-wide regulations already apply to Tortugas North and the effects of the ecological reserve regulations have been analyzed under the no-take discussion above. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

This regulatory alternative has no incremental impact on commercial fishing or recreational consumptive users since they are displaced by the "no-take" regulation. The dive operator servicing non-consumptive diving and currently operating in Tortugas North would be prohibited from anchoring. His vessel is less than 100 ft LOA and thus he would be unaffected by the prohibition on mooring. The location and availability of mooring buoys would constrain the number and choice of available dive sites. Whether this would have any impact on the future business volume of dive operators or the quality of the experience to non-consumptive divers is unknown. The extent of impact would be dependent on the number and locations of mooring buoys (to be determined).

This regulatory alternative would have little impact on commercial shipping because continuous transit would be allowed. Vessels 50m or greater in registered length are already prohibited from anchoring in 19.3% of Tortugas North. The main effect would be to ban such vessels from anchoring on the remainder of Tortugas North. There would be no incremental impact to treasure salvors since they would be displaced by the "no-take" regulation. The one dive operator servicing non-consumptive diving and currently operating in Tortugas North would be required to obtain Tortugas access permits. Any new dive operators would also be required to obtain permits. There would be minor time costs associated with obtaining a permit for calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out will not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit.

Regulatory Alternative D (Preferred Regulatory Alternative): Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); prohibit anchoring in and control access to Tortugas North via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B); and prohibit anchoring and restrict access to Tortugas South, other than for continuous transit or law enforcement purposes, to research or education activities only pursuant to a sanctuary permit. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The impacts of this regulatory alternative for this boundary alternative are the same as those described for Regulatory Alternative C, above. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Boundary Alternative III (Preferred Boundary Alternative)

This alternative would expand the boundary of the Sanctuary and its westernmost corner by approximately 36 nm^2 to include Sherwood Forest. In addition, this alternative would expand the boundary by adding a non-contiguous area of approximately 60 nm^2 to include Riley's Hump. The Reserve would also incorporate approximately 55 nm^2 of the existing Sanctuary in its northern section, for a total area of approximately 151 nm^2. The area of the Reserve surrounding Sherwood Forest would be called Tortugas North and encompass approximately 91 nm^2; the area surrounding Riley's Hump would be called Tortugas South and encompass approximately 60 nm^2. A small portion of Tortugas North and all of Tortugas South would be outside the existing Sanctuary boundary. (Figure 1).

Regulatory Alternative A: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South. Boundary Alternative III includes areas currently outside the Sanctuary boundary. The Sanctuary-wide regulations would become effective in the expansion areas of Tortugas North and South. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The effects of the ecological reserve regulations have been analyzed under the no-take discussion above. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative B: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy. The Sanctuary-wide regulations would become effective in the expansion areas of Tortugas North and South. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

The effects of the ecological reserve regulations have been analyzed under the no-take discussion above. The prohibition on anchoring would have no incremental impact on commercial fishing or recreational consumptive users since they are displaced by the "no-take" regulation. The one dive operator servicing non-consumptive diving and currently operating in Tortugas North would be prohibited from anchoring. There are no known recreational dive operators servicing Tortugas South. The location and availability of mooring buoys would constrain the number and choice of available dive sites. Whether this would have any impact on the future business volume of dive operators or the quality of the experience to non-consumptive divers is unknown. The extent of impact would be dependent on the number and locations of mooring buoys (to be determined). The prohibition on anchoring would impact commercial shipping in the boundary expansion areas, especially in Tortugas South. The prohibition on anchoring in Tortugas North is discussed under Boundary/Regulatory Alternative IIC above. Anchoring by large commercial vessels is known to occur in Tortugas South on Riley's Hump. The impact of this regulation on commercial vessel operators is expected to be small since other anchorages are available a short distance outside the Sanctuary boundary.

There would be no incremental impact on treasure salvors from the no-anchoring prohibition since they would be displaced by the "no-take" regulation. The permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations. There are no known non-consumptive dive operators currently operating in Tortugas South. Any non-consumptive dive operators operating in Tortugas South in the future would be required to obtain Tortugas access permits. It is not possible to gauge the extent of any such future activity. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit.

Regulatory Alternative C: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas North and South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B). The only difference between the impacts of this regulatory alternative from those discussed under Regulatory Alternative B would be those associated with the requirement to obtain a permit for other than continuous transit access to Tortugas North. The permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations. There is only one known non-consumptive dive operator currently operating in Tortugas North. He and any new non-consumptive dive operators operating in Tortugas North would be required to obtain Tortugas access permits. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative D (Preferred Regulatory Alternative): Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); prohibit anchoring in and control access to Tortugas North via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B); and prohibit anchoring and restrict access to Tortugas South, other than for continuous transit or law enforcement purposes, to research or education activities only pursuant to a sanctuary permit. The only difference between the impacts of this regulatory alternative from those discussed under Regulatory Alternative C would be those associated with limiting noncontinuous transit access to Tortugas South to research/educational purposes. For the commercial fisheries, salvors, and recreational consumptive users, there would be no incremental impacts since the "no-take" regulation would displace these user groups. There are no known non-consumptive dive operators currently operating in Tortugas South and no recreational diving is known to occur there. Under this alternative, none would be allowed in the future. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Boundary Alternative IV

Over Boundary Alternative III, this alternative would expand Tortugas North to the south by 23 nm^2 to be conterminous with the NPS's proposed Research/Natural Area within the DRTO. The total area of the Reserve would be approximately 175 nm^2. It also involves the same boundary expansion as Boundary Alternative III. A small portion of Tortugas North and all of Tortugas South would be outside the existing Sanctuary boundary. (Figure 1).

Regulatory Alternative A: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South. The Sanctuary-wide regulations would become effective in the expansion areas of Tortugas North and South. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/FSMP. The effects of the ecological reserve regulations which, under Boundary Alternative IV would apply to a larger area because of the southern expansion of Tortugas North, have been analyzed under the no-take discussion above. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

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Regulatory Alternative B: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy. The Sanctuary-wide regulations would become effective in the expansion areas of Tortugas North and South. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/FMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

The effects of the ecological reserve regulations which under Boundary Alternative IV would apply to a larger area because of the southern expansion of Tortugas North have been analyzed under the no-take discussion above. The prohibition on anchoring would have no incremental impact on commercial fishing or recreational consumptive users since they are displaced by the "no-take" regulation. There are no known recreational dive operators servicing Tortugas South. The location and availability of mooring buoys would constrain the number and choice of available dive sites. Whether this would have any impact on the future business volume of dive operators or the quality of the experience to non-consumptive divers is unknown. The extent of impact would be dependent on the number and locations of mooring buoys (to be determined).

The prohibition on anchoring would impact commercial shipping in the boundary expansion areas, especially in Tortugas South. The prohibition on anchoring in Tortugas North is discussed under Boundary/Regulatory Alternative IIC above. Anchoring by large commercial vessels is known to occur in Tortugas South on Riley's Hump. The impact of this regulation on commercial vessel operators is expected to be small since other non-coral reef anchorages outside the Sanctuary boundary are available a short distance away.

There would be no incremental impact on treasure salvors from the no-anchoring prohibition since they would be displaced by the "no-take" regulation.

The permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations. There are no known non-consumptive dive operators currently operating in Tortugas South. Any non-consumptive dive operators operating in Tortugas South in the future would be required to obtain Tortugas access permits. It is not possible to gauge the extent of any such future activity. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit.

Regulatory Alternative C: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas North and South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B). The only difference between the impacts of this regulatory alternative from those discussed under Alternative B would be those associated with the requirement to obtain a permit for other than continuous transit access to Tortugas North. Under this boundary alternative there are 2.75 more person-days of recreational non-consumptive use than under Boundary Alternatives II and III. While the area of Tortugas North would be increased by the expansion to the south, the permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations. There is only one known non-consumptive dive operator currently operating in Tortugas North. He and any new non-consumptive dive operators operating in Tortugas North would be required to obtain Tortugas access permits. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed ten minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative D (Preferred Regulatory Alternative): Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); prohibit anchoring in and control access to Tortugas North via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B); and prohibit anchoring and restrict access to Tortugas South, other than for continuous transit or law enforcement purposes, to research or education activities only pursuant to a sanctuary permit. The only difference between the impacts of this regulatory alternative from those discussed under regulatory Alternative C would be those associated with limiting non-continuous transit access to Tortugas South to research/educational purposes. For the commercial fisheries, salvors, and recreational consumptive users, there would be no incremental impacts since the "no-take" regulation would displace these user groups. There are no known non-consumptive dive operators currently operating in Tortugas South and no recreational diving is known to occur there. Under this alternative, none would be allowed in the future. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Boundary Alternative V

Over Boundary Altenative III, this alternative would expand the Sanctuary boundary to the west by three minutes ending at longitude 83°09′ instead of 83°06′ and would increase the reserve area to 190 nm². Tortugas North would be expanded to the west and Tortugas South would be shortened to the north. A small portion of Tortugas North and all of Tortugas South would be outside the existing Sanctuary boundary. (Figure 1).

Regulatory Alternative A: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South. The Sanctuary-wide regulations would become effective in the expansion area. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/FSMP. The effects of the ecological reserve regulations which, under Boundary Alternative V apply to a larger area because of the Sanctuary expansion, have been analyzed under the no-take discussion above. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative B: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); and prohibit anchoring in and control access to Tortugas South, other than for continuous transit or law enforcement purposes, via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy. The Sanctuary-wide regulations would become effective in the expansion area. The existing and proposed Sanctuary regulations and their impacts are summarized in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/FSMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

The effects of the ecological reserve regulations which, under Boundary Alternative V would apply to a larger area because of the Sanctuary expansion, have been analyzed under the no-take discussion above. The prohibition on anchoring would have no incremental impact on commercial fishing or recreational consumptive users since they are displaced by the "no-take" regulation. There are no known recreational dive operators servicing Tortugas South. The location and availability of mooring buoys would constrain the number and choice of available dive sites. Whether this would have any impact on the future business volume of dive operators or the quality of the experience to non-consumptive divers is unknown. The extent of impact would be dependent on the number and locations of mooring buoys (to be determined).

The prohibition on anchoring would impact commercial shipping in the boundary expansion area, especially in Tortugas South. Anchoring by large commercial vessels is known to occur in Tortugas South on Riley's Hump. The impact of this prohibition on commercial vessel operators would be small since other non-coral reef anchorages are available a short distance away outside the Sanctuary boundary.

There would be no incremental impact on treasure salvors from the no-anchoring prohibition since they would be displaced by the "no-take" regulation.

The permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations.

There are no known non-consumptive dive operators currently operating in Tortugas South. Any non-consumptive dive operators operating in Tortugas South in the future would be required to obtain Tortugas access permits. It is not possible to gauge the extent of any such future activity. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative C: Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South, other than for continuous transit or law enforcement purposes, to research or education activities only pursuant to a sanctuary permit. The only difference between the impacts of this regulatory alternative from those discussed under Regulatory Alternative B would be those associated with the requirement to obtain a permit for other than continuous transit access to Tortugas North. Under this boundary alternative there are 3.25 more person-days of recreational non-consumptive use than under Boundary Alternatives IV. While the area of Tortugas North would be increased by the expansion to the west, the permit requirements would have no incremental impact on fishermen or salvors because they would be displaced by the "no-take" regulations. There is one known non-consumptive dive operator currently operating in Tortugas North. He and any new non-consumptive dive operators operating in Tortugas North would be required to obtain Tortugas access permits. There would be minor time costs associated with obtaining a permit and calling-in and calling-out to access the reserve. It is expected that fulfilling all the permit requirements and calling-in and calling-out would not exceed 10 minutes of each permittee's time for each visit to the reserve. No special professional skills would be necessary to apply for a permit. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

Regulatory Alternative D (Preferred Regulatory Alternative): Apply existing Sanctuary-wide and existing ecological reserve regulations to Tortugas North and South (as described in Regulatory Alternative A); prohibit anchoring in and control access to Tortugas North via permit, require call-in for entering and leaving, and prohibit vessels longer than 100 ft LOA from using a mooring buoy (as described in Regulatory Alternative B); and prohibit anchoring and restrict access to Tortugas South, other than for continuous transit or law enforcement purposes, to research or education activities only pursuant to a sanctuary permit. The only difference between the impacts of this regulatory alternative from those discussed under Regulatory Alternative C would be those associated with limiting noncontinuous transit access to Tortugas South to research/educational purposes. For the commercial fisheries, salvors, and recreational consumptive users, there would be no incremental impacts since the "no-take" regulation would displace these user groups. There are no known non-consumptive dive operators currently operating in Tortugas South and no recreational diving is known to occur there. Under this alternative, none would be allowed in the future. The existing and proposed Sanctuary regulations and their impacts are presented in Table 13. More detailed descriptions of the regulations are included in Appendix C to the FSEIS/SMP. The existing ecological reserve regulations would prohibit fishing in the Reserve consistent with 15 CFR 922.164(d), Ecological Reserves and Sanctuary Preservation Areas.

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Table 13. Impacts on Small Businesses

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative II		
1. No Take					
(a) Possessing, moving, harvesting, removing, taking, damaging, disturbing, breaking, cutting, spearing, or otherwise injuring any coral, marine invertebrate, fish, bottom formation, algae, seagrass or other living or dead organism, including shells, or attempting any of these activities. However, fish, invertebrates, and marine plants may be possessed aboard a vessel in the ecological reserve provided such resources can be shown not to have been harvested within, removed from, or taken within, the ecological reserve, as applicable, by being stowed in a cabin, locker, or similar storage area prior to entering and during transit through	**A. Maximum Potential Loss** 51 of the 105 to 110 commercial fishing operations are potentially impacted. Some operations are multi-species fisheries. 24 lobster, 6 shrimp, 15 king mackerel, and 37 reef fish operations potentially impacted directly. About $411 thousand in harvest revenue potentially lost or 6 % of the harvest revenue from the TERSA. On average, about $8,000 per fishing operation. Additionally, potential losses to 10 fish houses and other small businesses through the multiplier impact.	**A. Maximum Potential Loss** 9 of 12 charter boat operations operating within the TERSA would be potentially impacted. Direct business revenue would include 26.6% for diving for lobsters, 20% for spear fishing, and 2.9% for fishing. Across all three recreation consumptive activities, 9.48% of revenue would be potentially impacted and about 14% of profits. On average, maximum potential losses are estimated to be about $13,700 of lost revenue and $5,580 of lost profits per operation. Additional potential losses to an unknown number of small firms through the multiplier	**A. Maximum Potential Loss** No losses. Potential gains to one charter boat dive operation providing services to non-consumptive divers. Indirect gains to several small businesses due to the multiplier impacts. Gains from improvements in quality of sites in terms of diversity, number and size of various sea life. Improvements in quality of experience leading to increase in demand for charter boat services and corresponding multiplier impacts on other small businesses.	**A. Maximum Potential Loss** No impact. **B. Mitigating Factors, Off-setting Factors and Net Impact** No impact.	**A. Maximum Potential Loss** No expected impact. One permit for inventorying submerged cultural resources in Sanctuary waters was issued for the Tortugas area of the Sanctuary. There were no submerged cultural resources found. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating factors or offsetting factors. Sanctuary will not issue permits for treasure salvaging in the ecological reserve. Since no submerged cultural resources were located on Tortugas Bank, no expected impact.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative II (continued)		
1. No Take (continued)					
such reserve, provided further that such vessel is in continuous transit through the ecological reserve. (b) Fishing by any means. (c) Touching living or dead coral, including but not limited to, standing on a living or dead coral formation.	**B. Mitigating Factors, Off-setting Factors and Net Impact** Relocation. For lobster fishing operations, the potential losses are not likely to occur because the State of Florida's trap reduction program and fishermen are knowledgeable of other fishing locations throughout the Sanctuary. For king mackerel operations, potential losses are not likely to occur because king mackerel is a pelagic species that is highly mobile and could be caught in other locations. For shrimp operations, losses are not likely to occur because shrimp caught in the proposed reserve are such a small percentage of total catch.	impacts. Only a fraction of a percent of the total tourist/recreation business in Monroe County. **B. Mitigating Factors, Off-setting Factors and Net Impact** Substitution. Complete mitigation with no losses is a high probability because only a small portion of the Tortugas Bank is included in the ecological reserve. All users can substitute to other sites on the southern half of Tortugas Bank. Long-term Benefits from Replenishment Effect. Net result is no short term losses and long-term gains to small businesses that are directly and indirectly dependent on recreational			

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative II (continued)				
1. No Take (continued)					
	For reef fish, the potential losses are likely to occur in the short term because reef fish stocks are overfished throughout the Sanctuary. Long-term Benefits from Replenishment. No expected benefits to king mackerel or shrimp operations. For lobster operations, expected net benefits from replenishment effect of ecological reserve. For reef fish operations, it is not clear whether the full 13 percent lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses to be less than the 13 percent reduction in the maximum loss case.	Consumptive use in the TERSA.			

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative II (continued)				
2. No Anchoring/Required Mooring Buoy Use/No Discharges or Deposits					
(a) Anchoring on coral. (b) Anchoring when mooring buoys or designated anchoring areas are available (c) Discharges or deposits except cooling water or engine exhaust.	No incremental impact since "no take" regulations already displace all commercial fishing.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	One charter operation that currently operates in Tortugas North potentially impacted. Mooring buoy use will constrain number and choice of available dive sites. It is unknown whether this will impact on future business of dive operators. Impact is dependent on the number and distribution (locations) of mooring buoys (to be determined). Prohibition against discharges or deposits will result in no incremental impact.	No impact.	No incremental impact since treasure salvaging displaced by "no take" regulations.
3. No Access					
Alternative A: Apply existing ecological reserve regulations to Tortugas North and South.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact since "no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative II (continued)				
3. No Access (continued)					
Alternative B: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas South via permit and require call-in, call-out. Use of mooring buoys by vessels 100' or less in length.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No incremental impact. See regulations 1 and 2 above. Tortugas South not in this boundary alternative.	No impact.	No incremental impact since "no take" regulations displaces treasure salvaging.
Alternative C: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas North and South via permit and require call-in, call-out (as described in Alternative B). Use of mooring buoys by vessels 100' or less in length.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Currently one charter dive operator operates in Tortugas North, while none operate in the South. Minor amount of time cost to charter operations in reporting to Sanctuary staffer to obtain permit and to notify when entering a leaving ecological reserve. None of the current operators have vessels over 100 feet in length. Time costs expected to be limited to less than 15 minutes to obtain permit and access permission per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative II (continued)				
3. No Access (continued)					
Alternative D (Preferred): Apply existing ecological reserve regulations to Tortugas North and Tortugas South (as described in Alternative A). Prohibit anchoring in Tortugas North and South and control accesss to Tortugas North via permit and require call-in, call-out (as described in Alternative B). Restrict access to Tortugas South to research or educational activities only. Use of mooring buoys by vessels 100' or less in length.	No incremental impact since commercial fishing is already displaced by "no take" regulations.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	Currently one dive operator operates in Tortugas North, none in Tortugas South. Minor time costs to dive charter operators in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve. Time cost is expected to be less than 15 minutes per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative III: Preferred		
1. No Take (a) Possessing, moving, harvesting, removing, taking, damaging, disturbing, breaking, cutting, spearing, or otherwise injuring any coral, marine invertebrate, fish, bottom formation, algae, seagrass or other living or dead organism, including shells, or attempting any of these activities. However, fish, invertebrates, and marine plants may be possessed aboard a vessel in the ecological reserve provided such resources can be shown not to have been harvested within, removed from, or taken within, the ecological reserve, as applicable, by being stowed in a cabin, locker, or similar storage area prior to entering and during transit through	**A. Maximum Potential Loss** 64 of the 105 to 110 commercial fishing operations are potentially impacted. Some operations are multi-species fisheries. 27 lobster, 15 shrimp, 16 king mackerel, and 40 reef fish operations potentially impacted directly. About $844 thousand in harvest revenue potentially lost or 12 % of the harvest revenue from the TERSA. On average, about $13,000 per fishing operation. Additionally, potential losses to 10 fish houses and other small businesses through the multiplier impact.	**A. Maximum Potential Loss** 9 of 12 charter boat operations operating within the TERSA would be potentially impacted. Direct business revenue would include 26.6% for diving for lobsters, 20% for spear fishing, and 6.3% for fishing. Across all three recreation consumptive activities, 11.7% of revenue would be potentially impacted and almost 16% of profits. On average, maximum potential losses are estimated to be about $13,700 of lost revenue and $5,580 of lost profits per operation. Additional potential losses to an unknown number of small firms through the multiplier impacts. Only a fraction	**A. Maximum Potential Loss** No losses. Potential gains to one charter boat dive operation providing services to non-consumptive divers. Indirect gains to several small businesses due to the multiplier impacts. Gains from improvements in quality of sites in terms of diversity, number and size of various sea life. Improvements in quality of experience leading to increase in demand for charter boat services and corresponding multiplier impacts on other small businesses. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating or off-setting factors. Net gains (see A above).	**A. Maximum Potential Loss** No impact. **B. Mitigating Factors, Off-setting Factors and Net Impact** No impact.	**A. Maximum Potential Loss** No expected impact. One permit for inventorying submerged cultural resources in Sanctuary waters was issued for the Tortugas area of the Sanctuary. There were no submerged cultural resources found. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating factors or offsetting factors. Sanctuary will not issue permits for treasure salvaging in the ecological reserve. Since no submerged cultural resources were located on Tortugas Bank, no expected impact.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative III: Preferred (continued)		
1. No Take (continued) such reserve, provided further that such vessel is in continuous transit through the ecological reserve. (b) Fishing by any means. (c) Touching living or dead coral, including but not limited to, standing on a living or dead coral formation.	**B. Mitigating Factors, Off-setting Factors and Net Impact** Relocation. For lobster fishing operations, the potential losses are not likely to occur because the State of Florida's trap reduction program and fishermen are knowledgeable of other fishing locations throughout the Sanctuary. For king mackerel operations, potential losses are not likely to occur because king mackerel is a pelagic species that is highly mobile and could be caught in other locations. For shrimp operations, losses are not likely to occur because shrimp caught in the proposed reserve are such a small percentage of total catch.	of a percent of the total tourist/recreation business in Monroe County. **B. Mitigating Factors, Off-setting Factors and Net Impact** Substitution. Complete mitigation with no losses is a high probability because only a small portion of the Tortugas Bank is included in the ecological reserve. All users can substitute to other sites on the southern half of Tortugas Bank. Long-term Benefits from Replenishment Effect. Net result is no short term losses and long-term gains to small businesses that are directly and indirectly dependent on			

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Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive**	**Commercial Shipping**	**Treasure Salvors**
			Boundary Alternative III: Preferred (continued)		
1. No Take (continued)	For reef fish, the potential losses are likely to occur in the short term because reef fish stocks are overfished throughout the Sanctuary. Long-term Benefits from Replenishment. No expected benefits to king mackerel or shrimp operations. For lobster operations, expected net benefits from replenishment effect of ecological reserve. For reef fish operations, it is not clear whether the full 20 percent lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses to be less than the 20 percent reduction in the maximum loss case.	recreational consumptive use in the TERSA.			

Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive**	**Commercial Shipping**	**Treasure Salvors**
			Boundary Alternative III: Preferred (continued)		
2. No Anchoring/Required Mooring Buoy Use/No Discharges or Deposits.					
(a) Anchoring on coral. (b) Anchoring when mooring buoys or designated anchoring areas are available (c) Discharges or deposits except cooling water or engine exhaust.	No incremental impact since "no take" regulations already displace all commercial fishing.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	One charter operation that currently operates in Tortugas North potentially impacted. Mooring buoy use will constrain number and choice of available dive sites. It is unknown whether this will impact on future business of dive operators. Impact is dependent on the number and distribution (locations) of mooring buoys (to be determined). Prohibition against discharges or deposits results in no incremental impact.	No impact.	No incremental impact since treasure salvaging displaced by "no take" regulations.
3. No Access					
Alternative A: Apply existing ecological reserve regulations to Tortugas North and South.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact since "no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
3. No Access (continued)					
Alternative B: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas South via permit and require call-in, call-out. Use of mooring buoys by vessels 100' or less in length.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.
Alternative C: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas North and South via permit and require call-in, call-out (as described in Alternative B). Use of mooring buoys by vessels 100' or less in length.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Currently one charter dive operator operate in Tortugas North, while none operate in the South. Minor amount of time cost to charter operations in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve. permission. None of the current operators have vessels over 100 feet in length. Time costs expected to be limited to less than 15 minutes to obtain permit and access permission per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
3. No Access (continued)					
Alternative D (Preferred): Apply existing ecological reserve regulations to Tortugas North and Tortugas South (as described in Alternative A). Prohibit anchoring in Tortugas North and South and control accesss to Tortugas North via permit and require call-in, call-out (as described in Alternative B). Restrict access to Tortugas South to research or educational activities only. Use of mooring buoys by vessels 100' or less in length.	No incremental impact since commercial fishing is already displaced by "no take" regulations.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	Currently one dive operator operates in Tortugas North, none in Tortugas South. Minor time costs to dive charter operators in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve. Time cost is expected to be less than 15 minutes per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.
4. Boundary Expansion Area: Additional Sanctuary-wide Regulations					
Prohibited Activities					
a. Mineral and hydrocarbon exploration, development and production.	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
b. Removal of, injury to, or possession of coral or live rock.	No impact because the commercial and personal taking of coral and live rock is currently illegal. Live rock aquaculture permits will not be issued and none are currently in existence.	No impact because the commercial and personal taking of coral and live rock is currently illegal.	Not applicable.	Not applicable.	Not applicable.
c. Alteration of, or construction on the seabed (exemptions are made for installation of nav aids & mooring buoys).	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
d. Discharge or deposit of materials or other matter except cooling water or engine exhaust.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No incremental impact since " no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
e. Operation of vessels that strike or injure coral or seagrass; anchoring on live coral in depths less than 40'; exceeding 4 knots or creating wakes in designated areas; injuring or taking birds or marine mammals.	No incremental impact because commercial fishing already displaced by "no take" regulations.	No incremental impacts because recreational consumptive users already displaced by "no take" regulations.	No impact expected because dive operators already operate in this manner. No firms currently operate in these areas.	No impact.	No incremental impact since " no take" regulation displaces treasure salvaging.
f. Conduct of diving/ snorkeling without a dive flag.	Not applicable.	No incremental impact because recreational consumptive users are already displaced by "no take" regulation.	No impact expected because use of flags is already required by other Federal and State regulations. No firms currently operate in these areas.	Not applicable.	Not applicable.
g. Release of exotic species.	No impact because release of exotic species is already prohibited by other laws and there are no known aquaculture operations in the areas.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No incremental impact since " no take" regulation displaces treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
h. Damage or removal of markers.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No Incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No incremental impact expected because such prohibitions already exist for markers placed by other governmental entities and the regulation only applies to Sanctuary markers. No firms currently operate in these areas.	No incremental impact expected because such prohibitions already exist for markers placed by other governmental entities and the regulation only applies to Sanctuary markers.	No incremental impact since " no take" regulation displaces treasure salvaging.
i. Movement of, removal of, injury to, or possession of Sanctuary historical resources.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	No incremental impact since " no take" regulations displace treasure salvaging.
j. Take or possession of protected wildlife.	No impact because wildlife is already protected by other applicable law.	No impact because wildlife is already protected by other applicable law.	Not applicable.	Not applicable.	Not applicable.
k. Possession or use of explosives or electrical discharges (intent is to apply to take of marine species).	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.	Not applicable.	Not applicable.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative III: Preferred (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
l. Harvest or possession of marine life species (effect is to extend current State law into Federal waters).	No incremental impact because commercial fishing is already displaced by "no take" regulations. Currently there are no marine life collectors operating in these areas.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.	Not applicable.	Not applicable.
m. Interference with law enforcement.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No impact expected because this provision is consistent with existing laws providing for penalties for interfering with law enforcement. No firms currently operate in these areas.	No impact expected because this provision is consistent with existing laws providing for penalties for interfering with law enforcement.	No incremental impact since " no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive Boundary Alternative IV**	**Commercial Shipping**	**Treasure Salvors**
1. No Take (a) Possessing, moving, harvesting, removing, taking, damaging, disturbing, breaking, cutting, spearing, or otherwise injuring any coral, marine invertebrate, fish, bottom formation, algae, seagrass or other living or dead organism, including shells, or attempting any of these activities. However, fish, invertebrates, and marine plants may be possessed aboard a vessel in the ecological reserve provided such resources can be shown not to have been harvested within, removed from, or taken within, the ecological reserve, as applicable, by being stowed in a cabin, locker, or similar storage area prior to entering and during transit through	**A. Maximum Potential Loss** 65 of the 105 to 110 commercial fishing operations are potentially impacted. Some operations are multi-species fisheries. 27 lobster, 14 shrimp, 16 king mackerel, and 42 reef fish operations potentially impacted directly. About $1.12 million in harvest revenue potentially lost or 16.45 % of the harvest revenue from the TERSA. On average, about $17,300 per fishing operation. Additionally, potential losses to 10 fish houses and other small businesses through the multiplier impact.	**A. Maximum Potential Loss** 10 of 12 charter boat operations operating within the TERSA would be potentially impacted. Direct business revenue would include 73.3% for diving for lobsters, 59% for spear fishing, and 10.5% for fishing. Across all three recreation consumptive activities, 28.7% of revenue would be potentially impacted and almost 41% of profits. On average, maximum potential losses are estimated to be about $37,380 of lost revenue and $14,500 of lost profits per operation. Additional potential losses to an unknown number of small firms through the multiplier impacts. Only a fraction	**A. Maximum Potential Loss** No losses. Potential gains to one charter boat dive operation providing services to non-consumptive divers. Indirect gains to several small businesses due to the multiplier impacts. Gains from improvements in quality of sites in terms of diversity, number and size of various sea life. Improvements in quality of experience leading to increase in demand for charter boat services and corresponding multiplier impacts on other small businesses. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating or offsetting factors. Net gains (see A above).	**A. Maximum Potential Loss** No impact. **B. Mitigating Factors, Off-setting Factors and Net Impact** No impact.	**A. Maximum Potential Loss** No expected impact. One permit for inventorying submerged cultural resources in Sanctuary waters was issued for the Tortugas area of the Sanctuary. There were no submerged cultural resources found. Currently, it is unknown whether there are any submerged cultural resources on Riley's Hump, located in Tortugas South. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating factors or offsetting factors. Sanctuary will not issue permits for treasure salvaging in the ecological reserve.

Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive Boundary Alternative IV (continued)**	**Commercial Shipping**	**Treasure Salvors**
1. No Take (continued) such reserve, provided further that such vessel is in continuous transit through the ecological reserve. (b) Fishing by any means. (c) Touching living or dead coral, including but not limited to, standing on a living or dead coral formation.	**B. Mitigating Factors, Off-setting Factors and Net Impact** Relocation. For lobster fishing operations, the potential losses are not likely to occur because the State of Florida's trap reduction program and fishermen are knowledgeable of other fishing locations throughout the Sanctuary. For king mackerel operations, potential losses are not likely to occur because king mackerel is a pelagic species that is highly mobile and could be caught in other locations. For shrimp operations, losses are not likely to occur because shrimp caught in the proposed reserve are such a small percentage of total	of a percent of the total tourist/recreation business in Monroe County. **B. Mitigating Factors, Off-setting Factors and Net Impact** **Substitution. Under this alternative, about 73% of diving for lobsters and 72% of spearfishing would be displaced. The potential for substituting to alternative sites is greatly reduced compared with Alternatives II and III. The reason is that under this alternative all of the Tortugas Bank falls within this boundary alternative. Some substitution is possible, but the probability of crowding effects rises considerably for diving for lobsters and spearfishing. For fishing, substitution mitigating all the losses is still highly**			Since no submerged cultural resources were located on Tortugas Bank, no expected impact.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative IV (continued)		
1. No Take (continued)	catch. For reef fish, the potential losses are likely to occur in the short term because reef fish stocks are overfished throughout the Sanctuary. Long-term Benefits from Replenishment. No expected benefits to king mackerel or shrimp operations. For lobster operations, expected net benefits from replenishment effect of ecological reserve. For reef fish operations, it is not clear whether the full 28 percent lost catch from displacement would be replaced from replenishment, but the	probable since only 6 percent of fishing activity would be displaced. This represents a relatively low amount of activity and given the wide distribution of this activity in the study area, crowding effects are still a low probability. Long-term Benefits from Replenishment Effect. For diving for lobsters and spearfishing, it is not clear whether there would be significant benefits offsite given that most of this activity currently takes place on the Tortugas Bank and none of the Bank is available for these activities. Not much is known about other areas that might benefit from the replenishment effect and where users could relocate to reap these benefits.			

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative IV (continued)		
1. No Take (continued)	costs of displacement would be mitigated and the losses to be less than the 28 percent reduction in the maximum loss case.	Whether the activities displaced could find alternative sites where both quantity and quality of activity could be maintained or enhanced seems less likely given the extent of displacement. For fishing, the small amount of displacement relative to the entire area plus the wide distribution of fishing activity still makes it highly likely that long-term benefits of replenishment will more than offset the potential losses from displacement with net benefits to this group. Net result is short term losses and low likelihood of long-term gains to small businesses that are directly and indirectly dependent on recreational consumptive use in the TERSA. For fishing, small amount of displacement not likely to result in short term losses and likely long-term gains.			

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
2. No Anchoring/Required Mooring Buoy Use/No Discharges or Deposits					
(a) Anchoring on coral. (b) Anchoring when mooring buoys or designated anchoring areas are available (c) Discharges or deposits except cooling water or engine exhaust.	No incremental impact since "no take" regulations already displaces all commercial fishing.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	One charter operation that currently operates in Tortugas North potentially impacted. Mooring buoy use will constrain number and choice of available dive sites. It is unknown whether this will impact on future business of dive operators. Impact is dependent on the number and distribution (locations) of mooring buoys (to be determined). Prohibition on discharges or deposits results in no incremental impact.	No impact.	No incremental impact since treasure salvaging displaced by "no take" regulations.
3. No Access					
Alternative A: Apply existing ecological reserve regulations to Tortugas North and South.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact since "no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
3. No Access (continued)					
Alternative B: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas South via permit and require call-in, call-out. Use of mooring buoys by vessels 100' or less in length.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No impact.	No incremental impact since "no take" regulations displaces treasure salvaging.
Alternative C: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas North and South via permit and require call-in, call-out (as described in Alternative B). Use of mooring buoys by vessels 100' or less in length.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Currently one charter dive operator operates in Tortugas North, while none operate in the South. Minor amount of time cost to charter operations in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve.. The current operator does not have vessels over 100 feet in length. Time costs expected to be limited to less than 15 minutes to obtain permit and access permission per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
3. No Access (continued)					
Alternative D (Preferred): Apply existing ecological reserve regulations to Tortugas North and Tortugas South (as described in Alternative A). Prohibit anchoring in Tortugas North and South and control accesss to Tortugas North via permit and require call-in, call-out (as described in Alternative B). Restrict access to Tortugas South to research or educational activities only. Use of mooring buoys by vessels 100' or less in length.	No incremental impact since commercial fishing is already displaced by "no take" regulations.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	Currently one dive operator operates in Tortugas North, none in Tortugas South. Minor time costs to the dive charter operator in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecoligcal reserve.. Time cost is expected to be less than 15 minutes per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations					
Prohibited Activities					
a. Mineral and hydrocarbon exploration, development and production.	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
b. Removal of, injury to, or possession of coral or live rock.	No impact because the commercial and personal taking of coral and live rock is currently illegal. Live rock aquaculture permits will not be issued and none are currently in existence.	No impact because the commercial and personal taking of coral and live rock is currently illegal.	Not applicable.	Not applicable.	Not applicable.
c. Alteration of, or construction on the seabed (exemptions are made for installation of nav aids & mooring buoys).	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
d. Discharge or deposit of materials or other matter except cooling water or engine exhaust.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No incremental impact since " no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
c. Operation of vessels that strike or injure coral or seagrass; anchoring on live coral in depths less than 40'; exceeding 4 knots or creating wakes in designated areas; injuring or taking birds or marine mammals.	No incremental impact because commercial fishing already displaced by "no take" regulations.	No incremental impacts because recreational consumptive users already displaced by "no take" regulations.	No impact expected because dive operators already operate in this manner. No firms currently operate in these areas.	No impact.	No incremental impact since " no take" regulations displace treasure salvaging.
f. Conduct of diving/ snorkeling without a dive flag.	Not applicable.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No impact expected because use of flags is already required by other Federal and State regulations. No firms currently operate in these areas.	Not applicable.	Not applicable.
g. Release of exotic species.	No impact because release of exotic species is already prohibited by other laws and there are no known aquaculture operations in the areas.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No incremental impact since " no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
h. Damage or removal of markers.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No Incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No incremental impact expected because such prohibitions already exist for markers placed by other governmental entities and the regulation only applies to Sanctuary markers. No firms currently operate in these areas.	No incremental impact expected because such prohibitions already exist for markers placed by other governmental entities and the regulation only applies to Sanctuary markers.	No incremental impact since " no take" regulations displace treasure salvaging.
i. Movement of, removal of, injury to, or possession of Sanctuary historical resources.	Not applicable.	Not applicable.	Not applicable.	Not applicable.	No incremental impact since " no take" regulations displace treasure salvaging.
j. Take of possession of protected wildlife.	No impact because wildlife is already protected by other applicable law.	No impact because wildlife is already protected by other applicable law.	Not applicable.	Not applicable.	Not applicable.
k. Possession or use of explosives or electrical discharges (intent is to apply to take of marine species).	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.	Not applicable.	Not applicable.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative IV (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
l. Harvest or possession of marine life species (effect is to extend current State law into Federal waters).	No incremental impact because commercial fishing is already displaced by "no take" regulations. Currently there are no marine life collectors operating in these areas.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.	Not applicable.	Not applicable.
m. Interference with law enforcement.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No impact expected because this provision is consistent with existing laws providing for penalties for interfering with law enforcement. No firms currently operate in these areas.	No impact expected because this provision is consistent with existing laws providing for penalties for interfering with law enforcement.	No incremental impact since " no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative V		
1. No Take (a) Possessing, moving, harvesting, removing, taking, damaging, disturbing, breaking, cutting, spearing, or otherwise injuring any coral, marine invertebrate, fish, bottom formation, algae, seagrass or other living or dead organism, including shells, or attempting any of these activities. However, fish, invertebrates, and marine plants may be possessed aboard a vessel in the ecological reserve provided such resources can be shown not to have been harvested within, removed from, or taken within, the ecological reserve, as applicable, by being stowed in a cabin, locker, or similar storage area prior to entering and during transit through	**A. Maximum Potential Loss** 65 of the 105 to110 commercial fishing operations are potentially impacted. Some operations are multi-species fisheries. 27 lobster, 14 shrimp, 16 king mackerel, and 42 reef fish operations potentially impacted directly. About $1.22 million in harvest revenue potentially lost or 17.9 % of the harvest revenue from the TERSA. On average, about $18,843 per fishing operation. Additionally, potential losses to 10 fish houses and other small businesses through the multiplier impact.	**A. Maximum Potential Loss** 11 of 12 charter boat operations operating within the TERSA would be potentially impacted. Direct business revenue would include 86.66% for diving for lobsters, 69% for spear fishing, and 12.88% for fishing. Across all three recreation consumptive activities, 34% of revenue would be potentially impacted and about 48% of profits. On average, maximum potential losses are estimated to be about $40,248 of lost revenue and $15,668 of lost profits per operation. Additional potential losses to an unknown number of small firms through the multiplier impacts. Only a fraction	**A. Maximum Potential Loss** No losses. Potential gains to one charter boat dive operation providing services to non-consumptive divers. Indirect gains to several small businesses due to the multiplier impacts. Gains from improvements in quality of sites in terms of diversity, number and size of various sea life. Improvements in quality of experience leading to increase in demand for charter boat services and corresponding multiplier impacts on other small businesses. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating or offsetting factors. Net gains (see A above).	**A. Maximum Potential Loss** No impact. **B. Mitigating Factors, Off-setting Factors and Net Impact** No impact.	**A. Maximum Potential Loss** No expected impact. One permit for inventorying submerged cultural resources in Sanctuary waters was issued for the Tortugas area of the Sanctuary. There were no submerged cultural resources found. Currently, it is unknown whether there are any submerged cultural resources on Riley's Hump, located in Tortugas South. **B. Mitigating Factors, Off-setting Factors and Net Impact** No mitigating factors or offsetting factors. Sanctuary will not issue permits for treasure salvaging in the ecological reserve.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative V (continued)		
1. No Take (continued) such reserve, provided further that such vessel is in continuous transit through the ecological reserve. (b) Fishing by any means. (c) Touching living or dead coral, including but not limited to, standing on a living or dead coral formation.	**B. Mitigating Factors, Off-setting Factors and Net Impact** Crowding and Relocation. For lobster fishing operations, there is some potential for crowding costs. However, the potential losses are not likely to occur because the State of Florida's trap reduction program and fishermen are knowledgeable of other fishing locations throughout the Sanctuary. For king mackerel operations, potential losses are not likely to occur because king mackerel is a pelagic species that is highly mobile and could be caught in other locations. For shrimp operations, losses are	of a percent of the total tourist/recreation business in Monroe County. **B. Mitigating Factors, Off-setting Factors and Net Impact** Substitution. This alternative displaces 87% of the diving for lobsters and 85% of the spearfishing. Substitution possibilities for these activities are extremely low given that this alternative eliminates access to the Tortugas Bank. Losses close to the maximum potential are more likely for these two activities. For fishing, mitigating all the losses through substitution is still highly probable since only 8% of the fishing activity would be displaced. This represents a low amount of activity and given the wide distribution of fishing activity throughout the study area, crowding effects are still a low probability.			Since no submerged cultural resources were located on Tortugas Bank, no expected impact.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
			Boundary Alternative V (continued)		
1. No Take (continued)	not likely to occur because shrimp caught in the proposed reserve are such a small percentage of total catch. For reef fish, the potential losses are likely to occur in the short term because reef fish stocks are overfished throughout the Sanctuary. Long-term Benefits from Replenishment. No expected benefits to king mackerel or shrimp operations. For lobster operations, expected net benefits from replenishment effect of	Long-term Benefits from Replenishment Effect. Although four of the five spawning sites identified in the western portion of the TERSA are within this boundary alternative, the displacement from the entire Tortugas Bank makes it highly unlikely that those diving for lobsters or spearfishing will benefit and will most likely suffer losses close to the maximum potential. For fishing, the stock effects or replenishment effect could be substantial. Whether the benefits would be large enough to offset displacement cannot be determined. But given the past experience with reserves, it is still somewhat likely that long-term benefits would offset			

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Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive**	**Commercial Shipping**	**Treasure Salvors**
			Boundary Alternative V (continued)		
1. No Take (continued)					
	ecological reserve. For reef fish operations, it is not clear whether the full 29 percent lost catch from displacement would be replaced from replenishment, but the costs of displacement would be mitigated and the losses to be less than the 29 percent reduction in the maximum loss case.	displacement costs yielding net benefits to fishing. Net result is short term losses and long-term losses to small businesses that are directly and indirectly dependent on recreational diving for lobsters and spearfishing in the TERSA. Possibility of small short term losses to fishing, but long-term gains from replenishment effect.			

Table 13. Impacts on Small Businesses (continued)

	Industries Impacted				
Regulation	**Commercial Fishing**	**Recreation Consumptive**	**Recreation Non-consumptive**	**Commercial Shipping**	**Treasure Salvors**
			Boundary Alternative V (continued)		
2. No Anchoring/Required Mooring Buoy Use/No Discharges or Deposits					
(a) Anchoring on coral. (b) Anchoring when mooring buoys or designated anchoring areas are available (c) Discharges or deposits except cooling water or engine exhaust.	No incremental impact since "no take" regulations already displace all commercial fishing.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	One charter operation currently operating in Tortugas North potentially impacted. Mooring buoy use will constrain number and choice of available dive sites. It is unknown whether this will impact on future business of dive operators. Impact is dependent on the number and distribution (locations) of mooring buoys (to be determined). Prohibition against discharges or deposits results in no incremental impact.	No impact.	No incremental impact since treasure salvaging displaced by "no take" regulations.
3. No Access					
Alternative A: Apply existing ecological reserve regulations to Tortugas North and South.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact since "no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative V (continued)				
3. No Access (continued)					
Alternative B: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas South via permit and require call-in, call-out. Use of mooring buoys by vessels 100' or less in length.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No incremental impact. See regulations 1 and 2 above.	No impact.	No incremental impact since "no take" regulations displace treasure salvaging.
Alternative C: Apply existing ecological reserve regulations to Tortugas North and South (as described in Alternative A). Prohibit anchoring in and control access to Tortugas North and South via permit and require call-in, call-out (as described in Alternative B). Use of mooring buoys by vessels 100' or less in length.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Currently one charter dive operator operates in Tortugas North, while none operate in the South. Minor amount of time cost to charter operations in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve. The current operator does not have vessels over 100 feet in length. Time costs expected to be limited to less than 15 minutes to obtain permit and access permission per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulations displaoe treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative V (continued)				
3. No Access (continued)					
Alternative D (Preferred): Apply existing ecological reserve regulations to Tortugas North and Tortugas South (as described in Alternative A). Prohibit anchoring in Tortugas North and South and control accesss to Tortugas North via permit and require call-in, call-out (as described in Alternative B). Restrict access to Tortugas South to research or educational activities only. Use of mooring buoys by vessels 100' or less in length.	No incremental impact since commercial fishing is already displaced by "no take" regulations.	No incremental impact since recreational consumptive users are already displaced by "no take" regulations.	Currently one dive operator operates in Tortugas North, none in Tortugas South. Minor time costs to the dive charter operator in reporting to Sanctuary staffer to obtain permit and to notify when entering and leaving ecological reserve. Time cost is expected to be less than 15 minutes per operation per visit to the reserve.	No impact.	No incremental impact since "no take" regulation displaces treasure salvaging.
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations					
Prohibited Activities					
a. Mineral and hydrocarbon exploration, development and production.	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).	No impact because the regulations only affect mineral and hydrocarbon firms (they are not small businesses).

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative V (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
b. Removal of, injury to, or possession of coral or live rock.	No impact because the commercial and personal taking of coral and live rock is currently illegal. Live rock aquaculture permits will not be issued and none are currently in existence.	No impact because the commercial and personal taking of coral and live rock is currently illegal.	Not applicable.	Not applicable.	Not applicable.
c. Alteration of, or construction on the seabed (exemptions are made for installation of nav aids & mooring buoys).	Not applicable.	Not applicable.	Not applicable.	Not applicable.	Not applicable.
d. Discharge or deposit of materials or other matter except cooling water or engine exhaust.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No impact. Other existing regulations already prohibit such discharges.	No incremental impact since " no take" regulations displace treasure salvaging.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted				
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive	Commercial Shipping	Treasure Salvors
	Boundary Alternative V (continued)				
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)					
Prohibited Activities (continued)					
e. Operation of vessels that strike or injure coral or seagrass; anchoring on live coral in depths less than 40'; exceeding 4 knots or creating wakes in designated areas; injuring or taking birds or marine mammals.	No incremental impact because commercial fishing already displaced by "no take" regulations.	No incremental impacts because recreational consumptive users already displaced by "no take" regulations.	No impact expected because dive operators already operate in this manner. No firms currently operate in these areas.	No impact.	No incremental impact since " no take" regulations displace treasure salvaging.
f. Conduct of diving/ snorkeling without a dive flag.	Not applicable.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No impact expected because use of flags is already required by other Federal and State regulations. No firms currently operate in these areas.	Not applicable.	Not applicable.
g. Release of exotic species.	No impact because release of exotic species is already prohibited by other laws and there are no known aquaculture operations in the areas.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No impact because release of exotic species is already prohibited by other laws.	No incremental impact since " no take" regulations displace treasure salvaging.

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Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted		
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)			
Prohibited Activities (continued)			
h. Damage or removal of markers.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No Incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No incremental impact expected because such prohibitions already exist for markers placed by other governmental entities and the regulation only applies to Sanctuary markers. One firm currently operates in these areas.
i. Movement of, removal of, injury to, or possession of Sanctuary historical resources.	Not applicable.	Not applicable.	Not applicable.
j. Take or possession of protected wildlife.	No impact because wildlife is already protected by other applicable law.	No impact because wildlife is already protected by other applicable law.	Not applicable.
k. Possession or use of explosives or electrical discharges (intent is to apply to take of marine species).	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.

Table 13. Impacts on Small Businesses (continued)

Regulation	Industries Impacted		
	Commercial Fishing	Recreation Consumptive	Recreation Non-consumptive
4. Boundary Expansion Areas: Additional Sanctuary-wide Regulations (continued)			
Prohibited Activities (continued)			
l. Harvest or possession of marine life species (effect is to extend current State law into Federal waters).	No incremental impact because commercial fishing is already displaced by "no take" regulations. Currently there are no marine life collectors operating in these areas.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	Not applicable.
m. Interference with law enforcement.	No incremental impact because commercial fishing is already displaced by "no take" regulations.	No incremental impact because recreational consumptive users are already displaced by "no take" regulations.	No incremental impact expected because this provision is consistent with existing laws providing for penalties for interfering with law enforcement. One firm currently operates in these areas.
	Not applicable.	Not applicable.	Not applicable.
	Not applicable.	Not applicable.	No incremental impact since " no take" regulations displace treasure salvaging.

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Selection of the Preferred Alternative

This section sets forth the Preferred Alternative and why it was selected as the Preferred Alternative.

Preferred Alternative

The Preferred Alternative is Boundary Alternative III (Figure 1) combined with Regulatory Alternative D.

General Rationale

Boundary Alternative III combined with Regulatory Alternative D has been selected as the Preferred Alternative because this combination achieves the objectives of all of the criteria listed below.

This Preferred Alternative is of sufficient size and imposes adequate protective measures to satisfy the selection criteria and to fulfill the goals and objectives of the FKNMSPA and the NMSA. Boundary Alternative III is consistent with the recommendations of the WG and SAC to NOAA and the State of Florida. While the WG and SAC recommended Regulatory Alternative A (application of the existing Sanctuary-wide and existing ecological reserve regulations), the more protective approach of Regulatory Alternative D is warranted because of the threat to coral reef resources posed by the anchoring of vessels, the threat to the sensitive resources of Tortugas South from non-consumptive activities, and the difficulty of enforcement in this remote area, particularly in Tortugas South. Extremely high coral cover and deep water in the Tortugas preclude anchoring without damaging coral.

The Preferred Regulatory Alternative in the DSEIS was Alternative C. The Preferred Regulatory Alternative in the FSEIS is Alternative D. Under Alternative D, Tortugas South will be accessible only for continuous transit and law enforcement or, pursuant to a sanctuary permit, for scientific research and educational purposes. This change was made because of comments received regarding the potential effects of non-consumptive activities, particularly non-consumptive diving. Alternative D will better protect resources in Tortugas South, such as the spawning aggregation areas, which are more sensitive to this activity than those in Tortugas North, and will enhance enforcement surveillance in this remote part of the Reserve. Leaving Tortugas North accessible to non-consumptive activities, including diving, will not only provide significant opportunities for resource appreciation and public education but will also allow the comparison of Tortugas North to Tortugas South over time to better understand and document the possible effects of non-consumptive diving in Tortugas North. The permit system for access to Tortugas North will provide information that will allow NOAA to determine the number of vessels and divers using the area and will assist in monitoring impacts.

The final regulations are revised from those proposed to make them consistent with Regulatory Alternative D. Also, the prohibition on fishing has been revised to prohibit all fishing in the Reserve without exception. This change was made in response to comments that the prohibition should be issued under the NMSA and that the exception clause that would have authorized fishing to the extent allowed under regulations issued pursuant to the Magnuson-Stevens Fishery Conservation and Management Act should be eliminated. Regulations issued under the Magnuson-Stevens Act must satisfy the requirements of that Act including the National Standards set forth in that Act. Sanctuary regulations including those governing fishing are issued under the NMSA. While some of the goals and objectives of the two Acts are similar, many of the goals and objectives of the two statutes are different.

Comparison of Alternatives

This section compares Boundary Alternatives II–V and Regulatory Alternatives A–D based on the selection criteria. Boundary Alternative I, the No-Action Alternative, is not compared because it would not be consistent with the goals of the FKNMSPA, the NMSA, the MP for the Sanctuary, and Executive Order 13089. Among other things, Part V of the FSEIS sets forth the environmental and socio-economic consequences of the No-Action Alternative. The selection criteria are: (1) protect ecosystem integrity; (2) protect biodiversity, including the maintenance or restoration of viable populations of native species; (3) enhance scientific understanding of marine ecosystems; (4) facilitate human uses to the extent consistent with meeting the other criteria; (5) minimize adverse socio-economic impacts to the extent consistent with meeting the other criteria; and (6) facilitate enforcement and compliance (Table 14). Subcriteria for and the goals and sources of each of the criteria are set forth in the table below. The criteria are consistent with the goals of the FKNMSPA, the NMSA, the MP, public scoping comments, design criteria developed by the Tortugas 2000 Working Group, Executive Order 13089 regarding Coral Reef Protection, the U.S. Coral Reef Task Force (CRTF) recommendations, and scientific literature on marine reserves. The criteria have been revised from those contained in the DSEIS based on comments received.

TABLE 14

Criteria	Objective	Rationale/Source
Protect ecosystem integrity. This includes the following sub-criteria: • Protect a wide range of contiguous habitats through deep water. • Maximize connectivity among habitats. • Protect unique coral formations and areas of high coral cover, including Sherwood Forest. • Provide adequate buffer areas. • Sustain ecological & evolutionary processes. • Protect against short and long-term environmental perturbations, and, • Encompass an area that is large enough and sufficiently protected that, when combined with existing protections, maintains the Tortugas region's contribution to the Florida Keys' ecosystem.	Choose an area and protection measures that protect a wide range of contiguous habitats, establish connectivity between those habitats, and protect unique structural formations.	FKNMSPA, NMSA, public comment, Working Group, CRTF, and literature
Protect biodiversity, including the maintenance or restoration of viable populations of native species. This includes the following sub-criteria: • Protect the full range of species. • Protect natural spawning, nursery, and permanent residence areas, including Riley's Hump. • Protect and enhance commercially and recreationally important fish species. • Protect species with specific habitat requirements. • Protect endangered, threatened, rare, or imperiled species. • Protect areas with physical oceanographic characteristics that will enhance larval dispersal. • Protect areas of high coral and fish diversity. • Protect areas of high productivity. • Protect foraging areas for seabird and endangered sea turtle populations, and, • Protect areas of high endemism.	Choose an area and protection measures that will protect areas of high biodiversity, known or reported spawning areas and habitats that support resident fish and other marine life.	Final Management Plan, public comment, Working Group, and literature
Enhance scientific understanding of marine ecosystems. This includes the following sub-criteria: • Provide a reference area to monitor the effects of both consumptive and non-consumptive activities on ecosystem structure and processes, and, • Provide a reference area to discriminate between human-caused and natural changes in the Florida Keys' marine ecosystem.	Choose an area and protection measures that will facilitate the monitoring of anthropogenic impacts and the evaluation of the efficacy of the ecological reserve for protecting coral reef health and biodiversity.	FKNMSPA, NMSA, public comment, Working Group, CRTF, and literature
Facilitate human uses to the extent consistent with the other criteria	Choose an area and protection measures that will allow uses and provide a range of habitats to observe and study, consistent with the attainment of the other objectives.	FKNMSPA, NMSA, Final Management Plan, public comment, Working Group, and literature
Minimize adverse socio-economic impacts to the extent consistent with the other criteria.	Choose an area and protection measures that meet the objectives of the other criteria but that do not unduly impact users.	FKNMSPA, NMSA, public comment, and Working Group
Facilitate enforcement and compliance	Choose an area and protection measures that facilitate enforcement of the ecological reserve and encourage compliance by users.	Working Group and literature

Protect ecosystem integrity. Boundary Alternative II does not encompass enough range of habitat or area to adequately protect the integrity of the ecosystem. Boundary Alternative II does not adequately protect the full range of habitats and species found in the Tortugas area. The unique and ancient coral formations of Sherwood Forest are not part of this alternative. Boundary Alternative II does not include contiguous habitats nor is connectivity between habitats maximized. Boundary Alternative II does not provide a reasonable buffer area for coral reef features. Alternative II includes no deep water habitats greater than approximately 200 feet. By not having two reserve components, Alternative II offers no insurance against the effects of a catastrophic event (*e.g.*, cold weather, low salinity) that could potentially damage resources of the area. Alternative II is not large enough to sustain local or regional ecological or evolutionary processes. Boundary Alternatives III, IV and V, when combined with existing protections in the region, are sufficient to protect ecosystem integrity in the Tortugas and that region's contribution to the Florida Keys ecosystem. Boundary Alternatives III–V include two replicate components that help to ensure against the effects of catastrophic events. Boundary Alternative III includes a sufficient range of essential habitats for many species life stages and includes adequate buffers. The increased area of Boundary Alternatives IV and V has negligible increased benefit to protecting ecosystem integrity compared to Alternative III. Boundary Alternative V does not capture additional significant habitat to the west of the

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Tortugas Bank and does not preserve the critical deep water habitat south of Riley's Hump. Regulatory Alternative A would not adequately protect ecosystem integrity because of the threat to coral reef resources by anchoring. Regulatory Alternative B would not adequately protect ecosystem integrity in Tortugas North and the Sherwood Forest area because of the threat to coral reef resources by anchoring. Regulatory Alternative C adequately protects ecosystem integrity by prohibiting anchoring and controlling access to Tortugas North and South via an access permit. Regulatory Alternative D increases protection of ecosystem integrity over Alternative C by prohibiting access to Tortugas South except by permit for research or educational reasons. This will virtually eliminate human degradation and protect the ecological integrity of the Tortugas region.

Protect biodiversity, including the maintenance or restoration of viable populations of native species. Boundary Alternative II does not protect the high coral species diversity of Sherwood Forest or the unique fish species richness of Tortugas South. Boundary Alternative II protects only one of eight known fish spawning aggregations and does not include Riley's Hump, which is an area of high endemism and a critical source area for larvae. Sherwood Forest, an important permanent residence area for a variety of species and area of high productivity, is not part of Alternative II. Boundary Alternative III protects 5 of the 8 known fish spawning areas as well as approximately 87% of the known coral reef habitat and 76% of the known hardbottom habitat. Boundary Alternative III also protects the habitat of several commercially important fish species and several uncommon species found in the deep water regions of Tortugas South. Boundary Alternatives III, IV, and V protect the high coral diversity of Sherwood Forest and they protect Riley's Hump and the deep habitat around it which are a critical source of larvae for downstream areas of the Florida Keys. In addition, they help protect important foraging areas for seabirds and sea turtles. Boundary Alternative IV encompasses 7 of the 8 known fish spawning sites as well as 100% of the known coral and hardbottom habitat. Boundary Alternative V encompasses 7 of the 8 known fish spawning sites and would protect all of the known coral and hardbottom habitat. Alternative V's expansion of Tortugas North to the west would provide increased protection for some additional habitats and associated species. However, its reduction in size of Tortugas South would provide less protection for critical deep water habitats and thereby has the least protection for associated species such as golden crab and snowy grouper. Regulatory Alternative A would not adequately preserve biodiversity and maintain viable populations because of the threat to associated habitats of many species by anchoring and the lack of protection for high diversity areas such as Sherwood Forest and Riley's Hump. Regulatory Alternative B would not adequately preserve biodiversity and maintain viable populations in Tortugas North because of the threat to associated habitats of many species by anchoring. Regulatory Alternative C would preserve biodiversity by prohibiting habitat destruction from anchoring. However, Regulatory Alternatives A, B, and C would not protect the several natural fish spawning aggregations in Tortugas South from disturbance. Regulatory Alternative D would adequately preserve biodiversity and maintain viable populations by protecting critical habitat in Tortugas North and Tortugas South from anchor damage and by minimizing disturbance to natural spawning aggregations in Tortugas South.

Enhance scientific understanding of marine ecosystems. Given the absence of unexploited areas in the Tortugas region, Boundary Alternatives II–V would all serve to increase our scientific understanding of marine ecosystems and their response to management of consumptive and non-consumptive activities, including their recovery from fishing impacts. Boundary Alternatives II–V would also facilitate scientific understanding by providing a reference area to gauge the broader changes occurring in the Florida Keys marine ecosystem. Boundary Alternatives III–V offer the added scientific benefit of protecting Riley's Hump, which would add to our knowledge of effective reserve design regarding networks and energy flow between marine reserves. The inclusion of Tortugas South will also significantly add to our knowledge of the importance of the Tortugas region in sustaining the Florida Keys ecosystem. Boundary Alternatives IV and V encompass all of Tortugas Bank and would compromise the study of fishing effects because there would be no comparable habitat for use as a reference site. Regulatory Alternatives A, B, and C would provide for essentially the same level of scientific understanding. Regulatory Alternative D will facilitate the most scientific understanding of human effects on ecosystem processes because it would create a research/education-only area in the Tortugas which could serve as a reference site from which to gauge the impacts of non-consumptive activities.

Facilitate human uses to the extent consistent with the other criteria. All of the alternatives would serve well in enhancing opportunities for non-consumptive activities such as education, photography, underwater wilderness exploration, and ecotourism. Boundary Alternatives III–V provide enhanced opportunities over Boundary Alternative II because of the addition of Tortugas South and the expansion of Tortugas North to include the unique coral reef region known as Sherwood Forest. Regulatory Alternatives A, B, and C would provide the same non-consumptive opportunities. Though Regulatory Alternative D will prohibit all consumptive and non-consumptive activities in Tortugas South other than research and education, the disallowance of these activities will establish Tortugas South as a critical reference area by which any impacts of the non-consumptive activities occurring in Tortugas North may be assessed.

Minimize adverse socio-economic impacts to the extent consistent with the other criteria. As stated in Part V of the FSEIS, all users are considered to be small entities within the meaning of the Regulatory Flexibility Act. Boundary Alternatives I and II and Regulatory Alternatives A, B, and C would have less of an adverse impact on users than the Preferred Alternative (Boundary Alternative III coupled with Regulatory Alternative D). Boundary Alternatives IV and V would have a greater adverse impact on users than the Preferred Boundary Alternative. Boundary Alternative III has moderate impacts on users, mostly lobster fishermen and handline fishermen. Alternatives IV and V have significantly greater impacts because they include the southern half of Tortugas Bank, which is heavily utilized by both recreational and commercial users. Alternative III offers a compromise because it allows for continued consumptive use of the southern half of Tortugas Bank including trolling for pelagic fish species. Ignoring the potential of such effects as replenishment that would result in a net economic benefit, Regulatory Alternative A has significant adverse socio-economic effects on users. There are 12 recreational charter operations that would be affected by this alternative and approximately 110 commercial fishing operations. Regulatory Alternative A would not provide a sufficient degree of protection to Tortugas resources. It would not protect coral reef resources from anchoring and from the possible effects of non-consumptive uses and would not provide the FKNMS with adequate notice to facilitate enforcement. Regulatory Alternative B would provide adequate protection from anchoring damage in Tortugas South and would provide adequate notification to FKNMS to facilitate enforcement there, but would not provide adequate protection to Tortugas North. It would also not protect the resources of Tortugas South from non-consumptive uses. Regulatory Alternative C would provide adequate protection from anchoring damage in Tortugas North and South and would provide adequate notification to FKNMS to facilitate enforcement with insignificant incremental costs to users. However, it would not protect the sensitive coral reef resources from the possible effects of non-consumptive uses. The Preferred Alternative (Boundary Alternative III/Regulatory Alternative D) could potentially impact, if one assumes no mitigating factors, 9 recreational charter users with total annual revenue losses of approximately $152,054, 64 commercial fishermen with total annual revenue losses of approximately $843,583, and 673 person days of recreational fishermen using private boats with a maximum potential loss of $53,392 in consumer's surplus. Though Regulatory Alternative D would prohibit use of Tortugas South except for continuous transit, for law enforcement purposes, or for research or education activities pursuant to a sanctuary permit, this alternative would provide an important reference area to facilitate the study of non-consumptive impacts in Tortugas North. Additionally, unlike in Tortugas North where a moderate amount of non-consumptive diving activities has been identified, little diving has been identified in Tortugas South and as such the socio-economic impacts of the more restrictive Regulatory Alternative D are not expected to be significant or substantial to this user group in Tortugas South.

Facilitate enforcement and compliance. Boundary Alternative II would be less likely to facilitate enforcement of and compliance by users of the ecological reserve due to its irregular boundary shape. Boundary Alternative III is the most likely to facilitate enforcement and compliance by users because the boundaries of Tortugas North and Tortugas South follow lines of latitude/longitude and share several of the existing boundaries and marked corners of the Dry Tortugas National Park. Boundary Alternatives IV and V would be less likely than Boundary Alternative III to facilitate compliance by users because the southern boundary of Tortugas North does not terminate at a marked corner of the Dry Tortugas National Park. Regulatory Alternative B would not adequately facilitate enforcement because it would not provide notice to FKNMS of the presence of users in the ecological reserve. Regulatory Alternative C adequately facilitates enforcement and compliance of Tortugas North but does not provide significant solutions for enforcing Tortugas South, the more remote portion of the ecological reserve. Regulatory Alternative D best facilitates enforcement and encourages compliance by limiting access to Tortugas South to continuous transit through the area with fishing gear stowed. Regulatory Alternative D will ease enforcement and provide additional environmental benefits by helping to control illegal spearfishing and lobster diving, as well as other illegal fishing and anchoring.

Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid control number issued by the Office of Management and Budget (OMB).

This rule contains collection-of-information requirements subject to review and approval by OMB under the PRA. The only additional record keeping or reporting requirements are the permit and call-in, call-out requirements for the Reserve previously described in the Preamble under Final Regulations. There are two classes of users that will be affected by these requirements: commercial dive boat operators and private boaters. The type of skills necessary to request an access permit (if not requested by telephone) and to provide notification when entering or leaving the Reserve is the ability to use marine radio equipment. The public reporting burden for these requirements is estimated to be 10 minutes per application for a permit and 2 minutes per call-in or call-out. These collection-of-information requirements have been approved by OMB under OMB control number 0648–0418.

Collection-of-information requirements for certification of preexisting leases, licenses, permits, approvals, or other authorizations in National Marine Sanctuaries, have been approved under OMB control number 0648–0141. The regulations apply the certification requirement of § 922.168 to holders of preexisting leases, licenses, permits, approvals, or other authorizations, in the boundary expansion area. The estimated response time for this requirement is 30 minutes.

These response estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send comments regarding these burden estimates, or any other aspect of these data collections, including suggestions for reducing the burden, to NOAA and OMB (See **ADDRESSES**).

E.O. 13132: Federalism

Executive Order 13132 sets forth Fundamental Federalism Principles (section 2) to guide federal agencies in formulating and implementing policies that have federalism implications and Policymaking Criteria (section 3) to adhere to, to the extent permitted by law, when formulating and implementing policies that have federalism implications. Since these final regulations do not preempt State law, the requirements of section 4 and section 6 (c) of the Executive Order do not apply.

Federalism Summary Impact Statement

In 1998, NOAA convened a 25-member Working Group (WG) of the Sanctuary Advisory Council (SAC) composed of key stakeholder representatives, eight SAC members, and government agency representatives with resource management authority in the Tortugas area to recommend a preferred boundary alternative for an ecological reserve. The WG included government agency representatives from the Florida Marine Patrol, the Florida Department of Environmental Protection and the Florida Marine Fisheries Commission.

Over a 13 month period, the WG met five times and built up a knowledge base on the Tortugas region using scientific information provided by Sanctuary staff and experts, personal knowledge, knowledge passed on by their constituents, and anecdotal information. All of the WG meetings were facilitated to ensure timely discussion of relevant issues and help build consensus.

On June 15, 1999, a presentation on the WG's process and recommendation for an ecological reserve was given to

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the SAC. The SAC included a member from Monroe County, and several representatives from the State of Florida attended SAC meetings to provide information and comment. The SAC voted unanimously to adopt the recommendation of the WG and forwarded it to NOAA and the State of Florida. County and State representatives were involved throughout the site selection process and development of regulatory recommendations, were present at all meetings and deliberations of the WG and SAC at which the proposal for an ecological was considered, and regularly communicated with NOAA.

NOAA adopted the recommendation of the SAC regarding the geographical area and the application of no-take regulations to the ecological reserve. NOAA held public hearings in conjunction with the State of Florida on the DSEIS and the proposed regulations and consulted with the State on the proposed boundary expansion, as required by section 303 of the National Marine Sanctuaries Act (NMSA), 16 U.S.C. 1431 *et seq.* In July 1999 and July 2000, NOAA provided to the Governor, Cabinet, and staff members a status report on the proposed ecological reserve.

The County and State also submitted comments to NOAA on the DSEIS/SMP and the proposed rule.

The Florida Fish and Wildlife Conservation Commission (FWC) was concerned that no limits were being placed on the level of non-consumptive diving that would be allowed. The FWC stated that non-consumptive diving results in some morbidity and mortality to coral reef habitat and asked that controls be placed on the number of divers and dive trips to assure minimal acceptable damage to the habitat. The FWC was also concerned over the adequacy of the enforcement resources. The FWC believes that the minimal enforcement resources needed to enforce the Reserve would be two vessels 50 feet or greater in length with a Lieutenant and two officers for each vessel. The FWC encourages NOAA to work with it to develop these enforcement resources in order to assure the success of the reserve.

The Final Regulations allow non-consumptive diving in Tortugas North but closes Tortugas South to all diving except for scientific research or educational purposes, pursuant to a valid sanctuary permit. This provides an appropriate degree of public access.

Prohibiting non-consumptive diving in Tortugas North is not needed to protect the resources or their ecosystem. One of the basic tenets of the FKNMSPA, the NMSA and indeed the Designation Document for the FKNMS, is to allow activities in the Sanctuary that do not cause an adverse effect on the resources or qualities of the Sanctuary, or that do not pose a threat of harm to users of the Sanctuary. However, the resources of Tortugas South, particularly the spawning aggregation areas, are unique and warrant the additional protection of prohibiting diving. Enforcement surveillance in this remote part of the Reserve will be facilitated by prohibiting all activities in Tortugas South except for continuous transit, law enforcement, and, pursuant to a sanctuary permit, scientific research and educational activities. Additionally, prohibiting diving in Tortugas South will provide a baseline to gauge the effects of non-consumptive activities on the resources in Tortugas North.

Tortugas North is less remote and protection and conservation can be more easily afforded to it than to Tortugas South. Allowing non-consumptive diving in Tortugas North that is carefully monitored will provide significant educational and resource appreciation benefits. Further, prohibiting non-consumptive diving in Tortugas North would unnecessarily increase adverse socio-economic impacts on charter dive operators without providing corresponding resource protection. The permit system for Tortugas North will allow the level of diving activity to be monitored, and combined with the reference of Tortugas South, will allow the effects of non-consumptive diving on resources in Tortugas North to be determined.

The SMP commits substantial enforcement resources for the Reserve. As set forth in the Enforcement Action Plan as supplemented by the SMP, one of the goals of Sanctuary management is to gain the highest level of compliance by the public who enter and visit the Reserve. This compliance can be achieved through several management actions including education and outreach and on-the-water presence of Sanctuary staff in programs such as Team OCEAN, where Sanctuary information is distributed along the waterfront or boat to boat by Sanctuary staff and volunteers.

The most effective management action that can be used to achieve compliance to Sanctuary regulations is an effective law enforcement program. Currently, the primary enforcement of Sanctuary regulations is accomplished through an enforcement agreement between NOAA/National Marine Sanctuary Program and the State of Florida Fish and Wildlife Conservation Commission. The enforcement efforts are consistent with the goals and objectives for enforcement described in the MP. The MP also calls for cross-deputization of other agency law enforcement personnel (e.g., National Park Service Rangers) to accomplish law enforcement responsibilities within the Sanctuary. This approach to enforcement continues to remain an option.

Prohibiting vessels from stopping within Tortugas South except pursuant to a valid sanctuary permit for scientific research or educational purposes will facilitate enforcement. This will make it possible to monitor vessel traffic remotely by radar and response will only be necessary when vessels without a permit stop within the reserve.

The permit system for Tortugas North will help Sanctuary managers monitor the level of visitor use in the reserve and facilitate enforcement efforts.

The success of the Reserve will depend to a large extent on the level of enforcement resources dedicated to the Reserve. Several enforcement options are presently available and are being evaluated for deployment in the Reserve. These options include:

- Installation and monitoring of a long-range radar unit at the Dry Tortugas National Park. This would allow remote monitoring of vessels entering and leaving the Reserve.
- Place two 82′ vessels into service for patrolling the Ecological Reserve.
- Cross-deputize and fund National Park Service Rangers to assist in enforcement in the Tortugas Ecological Reserve.

As set forth in the SMP, the law enforcement budget is as follows:

Personnel

Law Enforcement Officers (4–6)
$50,000 per position
General Support $50,000

Vessels

82′ Patrol Vessels (2) No Cost—Agency Property Transfer

NOAA will work with the FWC and other enforcement agencies to develop the enforcement resources that are necessary to assure the success of the Reserve.

Monroe County commented that the socio-economic section of the DSEIS seems to have been inserted out of context. This rather lengthy section should be reduced to some simpler explanations, tables and conclusions, then attach the larger document as an appendix. NOAA has retained the socio-economic section in the main body of the FSEIS/SMP but has revised it to make it clearer.

Monroe County commented that the FSEIS should provide some additional explanation concerning the table of benthic habitats in the DSEIS. It was not clear to the County whether the 59% of unmapped acreage is a less significant area within the overall total and, if so, that it should be noted. If it is not, the County believed that this area needs significant additional exploration.

The benthic habitats categorized in Table 1 of the FSEIS represent those identified as the result of one mapping project based on aerial photographs and limited groundtruthing in the Tortugas region. Extensive characterization of the benthic communities within Dry Tortugas National Park has been completed (Agassiz 1883, Davis 1982, and Jaap 1998). Also, scientific exploration of benthic habitats within the Tortugas Ecological Reserve area has occurred since the completion of the DSEIS (Miller, unpubl. data). However, NOAA agrees that additional mapping and exploration are needed to accurately assess the full extent of marine resources throughout the Tortugas region.

Monroe County commented that the FSEIS should include a table summarizing the regulatory alternatives. A table summarizing the regulatory alternatives has been added to the FSEIS.

Unfunded Mandates Reform Act of 1995

This rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA)) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Education, Environmental protection, Marine resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Research.

Dated: January 8, 2001.

Margaret A. Davidson,

Acting Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth in the preamble, 15 CFR part 922 is amended as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

1. The authority citation for part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

2. Section 922.161 is revised to read as follows:

§ 922.161 Boundary.

The Sanctuary consists of an area of approximately 2900 square nautical miles (9,800 square kilometers) of coastal and ocean waters, and the submerged lands thereunder, surrounding the Florida Keys in Florida. Appendix I to this subpart sets forth the precise Sanctuary boundary.

3. In § 922.162, definitions for "Length overall (LOA) or length," "Stem," and "Stern" are added alphabetically as follows:

§ 922.162 Definitions.

* * * * *

Length overall (LOA) or *length* means, as used in § 922.167 with respect to a vessel, the horizontal distance, rounded to the nearest foot (with 0.5 ft and above rounded upward), between the foremost part of the stem and the aftermost part of the stern, excluding bowsprits, rudders, outboard motor brackets, and similar fittings or attachments.

* * * * *

Stem means the foremost part of a vessel, consisting of a section of timber or fiberglass, or cast, forged, or rolled metal, to which the sides of the vessel are united at the fore end, with the lower end united to the keel, and with the bowsprit, if one is present, resting on the upper end.

Stern means the aftermost part of the vessel.

* * * * *

4. In § 922.164, paragraphs (d)(1)(v), (d)(1)(vi), and (g) are revised, and paragraphs (d)(1)(viii) and (ix) are added to read as follows:

§ 922.164 Additional activity regulations by Sanctuary area.

* * * * *

(d) * * *

(1) * * *

(v) Anchoring in the Tortugas Ecological Reserve. In all other Ecological Reserves and Sanctuary Preservation Areas, placing any anchor in a way that allows the anchor or any portion of the anchor apparatus (including the anchor, chain or rope) to touch living or dead coral, or any attached living organism. When anchoring dive boats, the first diver down must inspect the anchor to ensure that it is not touching living or dead coral, and will not shift in such a way as to touch such coral or other attached organism. No further diving shall take place until the anchor is placed in accordance with these requirements.

(vi) Except in the Tortugas Ecological Reserve where mooring buoys must be used, anchoring instead of mooring when a mooring buoy is available or anchoring in other than a designated anchoring area when such areas have been designated and are available.

* * * * *

(viii) Except for passage without interruption through the area, for law enforcement purposes, or for purposes of monitoring pursuant to paragraph (d)(2) of this section: entering the Tortugas South area of the Tortugas Ecological Reserve; or entering the Tortugas North area of the Tortugas Ecological Reserve without a valid access permit issued pursuant to § 922.167 or entering or leaving the Tortugas North area with a valid access permit issued pursuant to § 922.167 without notifying FKNMS staff at the Dry Tortugas National Park office by telephone or radio no less than 30 minutes and no more than 6 hours, before entering and upon leaving the Tortugas Ecological Reserve.

(ix) Tying a vessel greater than 100 feet (30.48 meters) LOA, or tying more than one vessel (other than vessels carried on board a vessel) if the combined lengths would exceed 100 feet (30.48 meters) LOA, to a mooring buoy or to a vessel tied to a mooring buoy in the Tortugas Ecological Reserve.

* * * * *

(g) *Anchoring on Tortugas Bank.* Vessels 50 meters or greater in registered length, are prohibited from anchoring on the portion of Tortugas Bank within the Florida Keys National Marine Sanctuary west of the Dry Tortugas National Park that is outside of the Tortugas Ecological Reserve. The boundary of the area closed to anchoring by vessels 50 meters or greater in registered length is formed by connecting in succession the points at the following coordinates (based on the North American Datum of 1983):

(1) 24 deg. 32.00′ N 83 deg. 00.05′ W

(2) 24 deg. 37.00′ N 83 deg. 06.00′ W

(3) 24 deg. 39.00′ N 83 deg. 06.00′ W

(4) 24 deg. 39.00′ N 83 deg. 00.05′ W

(5) 24 deg. 32.00′ N 83 deg. 00.05′ W

5. Revise the heading of § 922.166 to read as follows:

§ 922.166 Permits other than for access to the Tortugas Ecological Reserve-application procedures and issuance criteria.

§ 922.167 [Redesignated as § 922.168]

6. Redesignate § 922.167 as § 922.168 and revise it to read as follows:

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§ 922.168 Certification of preexisting leases, licenses, permits, approvals, other authorizations, or rights to conduct a prohibited activity.

(a) A person may conduct an activity prohibited by §§ 922.163 or 922.164 if such activity is specifically authorized by a valid Federal, State, or local lease, permit, license, approval, or other authorization in existence on July 1, 1997, or by any valid right of subsistence use or access in existence on July 1, 1997, provided that:

(1) The holder of such authorization or right notifies the Director, in writing, within 90 days of July 1, 1997, of the existence of such authorization or right and requests certification of such authorization or right; for the area added to the Sanctuary by the boundary expansion for the Tortugas Ecological Reserve, the holder of such authorization or right notifies the Director, in writing, within 90 days of the effective date of the boundary expansion, of the existence of such authorization or right and requests certification of such authorization or right.

(2) The holder complies with the other provisions of this § 922.168; and

(3) The holder complies with any terms and conditions on the exercise of such authorization or right imposed as a condition of certification, by the Director, to achieve the purposes for which the Sanctuary was designated.

(b) The holder of an authorization or right described in paragraph (a) of this section authorizing an activity prohibited by Secs. 922.163 or 922.164 may conduct the activity without being in violation of applicable provisions of Secs. 922.163 or 922.164, pending final agency action on his or her certification request, provided the holder is in compliance with this § 922.168.

(c) Any holder of an authorization or right described in paragraph (a) of this section may request the Director to issue a finding as to whether the activity for which the authorization has been issued, or the right given, is prohibited by Secs. 922.163 or 922.164, thus requiring certification under this section.

(d) Requests for findings or certifications should be addressed to the Director, Office of Ocean and Coastal Resource Management; ATTN: Sanctuary Superintendent, Florida Keys National Marine Sanctuary, P.O. Box 500368, Marathon, FL 33050. A copy of the lease, permit, license, approval, or other authorization must accompany the request.

(e) The Director may request additional information from the certification requester as he or she deems reasonably necessary to condition appropriately the exercise of the certified authorization or right to achieve the purposes for which the Sanctuary was designated. The information requested must be received by the Director within 45 days of the postmark date of the request. The Director may seek the views of any persons on the certification request.

(f) The Director may amend any certification made under this § 922.168 whenever additional information becomes available justifying such an amendment.

(g) Upon completion of review of the authorization or right and information received with respect thereto, the Director shall communicate, in writing, any decision on a certification request or any action taken with respect to any certification made under this § 922.168, in writing, to both the holder of the certified lease, permit, license, approval, other authorization, or right, and the issuing agency, and shall set forth the reason(s) for the decision or action taken.

(h) Any time limit prescribed in or established under this § 922.168 may be extended by the Director for good cause.

(i) The holder may appeal any action conditioning, amending, suspending, or revoking any certification in accordance with the procedures set forth in § 922.50.

(j) Any amendment, renewal, or extension made after July 1, 1997, to a lease, permit, license, approval, other authorization or right is subject to the provisions of § 922.49.

7. Add a new § 922.167 to read as follows:

§ 922.167 Permits for access to the Tortugas Ecological Reserve.

(a) A person may enter the Tortugas North area of the Tortugas Ecological Reserve other than for passage without interruption through the reserve, for law enforcement purposes, or for purposes of monitoring pursuant to paragraph (d)(2) of § 922.164 , if authorized by a valid access permit issued pursuant to § 922.167.

(b)(1) Access permits must be requested at least 72 hours but no longer than one month before the date the permit is desired to be effective. Access permits do not require written applications or the payment of any fee. Permits may be requested via telephone or radio by contacting FKNMS at any of the following numbers:

Key West office: telephone: (305) 292–0311

Marathon office: telephone: (305) 743–2437

(2) The following information must be provided, as applicable:

(i) Vessel name.

(ii) Name, address, and telephone number of owner and operator.

(iii) Name, address, and telephone number of applicant.

(iv) USCG documentation, state license, or registration number.

(v) Home port.

(vi) Length of vessel and propulsion type (*i.e.*, motor or sail).

(vii) Number of divers.

(viii) Requested effective date and duration of permit (2 weeks, maximum).

(c) The Sanctuary Superintendent will issue a permit to the owner or to the owner's representative for the vessel when all applicable information has been provided. The Sanctuary Superintendent will provide a permit number to the applicant and confirm the effective date and duration period of the permit. Written confirmation of permit issuance will be provided upon request.

8. Revise Appendices I, II, IV, V, VI, and VII to Subpart P of Part 922 to read as follows:

Appendix I to Subpart P of Part 922—Florida Keys National Marine Sanctuary Boundary Coordinates

(Appendix Based on North American Datum of 1983)

(1) The boundary of the Florida Keys National Marine Sanctuary—

(a) Begins at the northeasternmost point of Biscayne National Park located at approximately 25 degrees 39 minutes north latitude, 80 degrees 05 minutes west longitude, then runs eastward to the point at 25 degrees 39 minutes north latitude, 80 degrees 04 minutes west longitude; and

(b) Then runs southward and connects in succession the points at the following coordinates:

(i) 25 degrees 34 minutes north latitude, 80 degrees 04 minutes west longitude,

(ii) 25 degrees 28 minutes north latitude, 80 degrees 05 minutes west longitude, and

(iii) 25 degrees 21 minutes north latitude, 80 degrees 07 minutes west longitude;

(iv) 25 degrees 16 minutes north latitude, 80 degrees 08 minutes west longitude;

(c) Then runs southwesterly approximating the 300-foot isobath and connects in succession the points at the following coordinates:

(i) 25 degrees 07 minutes north latitude, 80 degrees 13 minutes west longitude,

(ii) 24 degrees 57 minutes north latitude, 80 degrees 21 minutes west longitude,

(iii) 24 degrees 39 minutes north latitude, 80 degrees 52 minutes west longitude,

(iv) 24 degrees 30 minutes north latitude, 81 degrees 23 minutes west longitude,

(v) 24 degrees 25 minutes north latitude, 81 degrees 50 minutes west longitude,

(vi) 24 degrees 22 minutes north latitude, 82 degrees 48 minutes west longitude,

(vii) 24 degrees 37 minutes north latitude, 83 degrees 06 minutes west longitude,

(viii) 24 degrees 46 minutes north latitude, 83 degrees 06 minutes west longitude,

(ix) 24 degrees 46 minutes north latitude, 82 degrees 54 minutes west longitude,

(x) 24 degrees 44 minutes north latitude, 81 degrees 55 minutes west longitude,

(xi) 24 degrees 51 minutes north latitude, 81 degrees 26 minutes west longitude, and

(xii) 24 degrees 55 minutes north latitude, 80 degrees 56 minutes west longitude;

(d) Then follows the boundary of Everglades National Park in a southerly then northeasterly direction through Florida Bay, Buttonwood Sound, Tarpon Basin, and Blackwater Sound;

(e) After Division Point, then departs from the boundary of Everglades National Park and follows the western shoreline of Manatee Bay, Barnes Sound, and Card Sound;

(f) then follows the southern boundary of Biscayne National Park to the southeasternmost point of Biscayne National Park; and

(g) then follows the eastern boundary of Biscayne National Park to the beginning point specified in paragraph (a).

(2) The shoreward boundary of the Florida Keys National Marine Sanctuary is the mean high-water mark except around the Dry Tortugas where the boundary is coterminous with that of the Dry Tortugas National Park, formed by connecting in succession the points at the following coordinates:

(a) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude;

(b) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 58 minutes 0 second west longitude;

(c) 24 degrees 39 minutes 0 seconds north latitude, 82 degrees 58 minutes 0 seconds west longitude;

(d) 24 degrees 43 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude;

(e) 24 degrees 43 minutes 32 seconds north latitude, 82 degrees 52 minutes 0 seconds west longitude;

(f) 24 degrees 43 minutes 32 seconds north latitude, 82 degrees 48 minutes 0 seconds west longitude;

(g) 24 degrees 42 minutes 0 seconds north latitude, 82 degrees 46 minutes, 0 seconds west longitude;

(h) 24 degrees 40 minutes 0 seconds north latitude, 82 degrees 46 minutes 0 seconds west longitude;

(i) 24 degrees 37 minutes 0 seconds north latitude, 82 degrees 48 minutes 0 seconds west longitude; and

(j) 24 degrees 34 minutes 0 seconds north latitude, 82 degrees 54 minutes 0 seconds west longitude.

(3) The Florida Keys National Marine Sanctuary also includes the area located within the boundary formed by connecting in succession the points at the following coordinates:

(a) 24 degrees 33 minutes north latitude, 83 degrees 09 minutes west longitude,

(b) 24 degrees 33 minutes north latitude, 83 degrees 05 minutes west longitude, and

(c) 24 degrees 18 minutes north latitude, 83 degrees 05 minutes west longitude;

(d) 24 degrees 18 minutes north latitude, 83 degrees 09 minutes west longitude; and

(e) 24 degrees 33 minutes north latitude, 83 degrees 09 minutes west longitude.

Appendix II to Subpart P of Part 922—Existing Management Areas Boundary Coordinates

(1) The boundary of each of the Existing Management Areas is formed by connecting in succession the points at the following coordinates:

National Oceanic and Atmospheric Administration

KEY LARGO-MANAGEMENT AREA

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.19′45″ N	80 deg.12′00″ W.
2	25 deg.16′02″ N	80 deg.08′07″ W.
3	25 deg.07′05″ N	80 deg.12′05″ W.
4	24 deg.58′03″ N	80 deg.19′08″ W.
5	25 deg.02′02″ N	80 deg.25′25″ W.
6	25 deg.19′45″ N	80 deg.12′00″ W.

LOOE KEY MANAGEMENT AREA

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.31′62″ N	81 deg.26′00″ W.
2	24 deg.33′57″ N	81 deg.26′00″ W.
3	24 deg.34′15″ N	81 deg.23′00″ W.
4	24 deg.32′20″ N	81 deg.23′00″ W.
5	24 deg.31′62″ N	81 deg.26′00″ W.

United States Fish and Wildlife Service

GREAT WHITE HERON NATIONAL WILDLIFE REFUGE

[Based on the North American Datum of 1983]

Point	Latitude	Longitude
1	24 deg.43.6′ N	81 deg.48.6′ W.
2	24 deg.43.8′ N	81 deg.37.2′ W.
3	24 deg.49.2′ N	81 deg.37.2′ W.
4	24 deg.49.2′ N	81 deg.19.8′ W.
5	24 deg.48.0′ N	81 deg.19.8′ W.
6	24 deg.48.0′ N	81 deg.14.4′ W.
7	24 deg.49.2′ N	81 deg.14.4′ W.
8	24 deg.49.2′ N	81 deg.08.4′ W.
9	24 deg.43.8′ N	81 deg.08.4′ W.
10	24 deg.43.8′ N	81 deg.14.4′ W.
11	24 deg.43.2′ N	81 deg.14.4′ W.

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GREAT WHITE HERON NATIONAL WILDLIFE REFUGE—Continued

[Based on the North American Datum of 1983]

Point	Latitude	Longitude
12	24 deg.43.2′ N	81 deg.16.2′ W.
13	24 deg.42.6′ N	81 deg.16.2′ W.
14	24 deg.42.6′ N	81 deg.21.0′ W.
15	24 deg.41.4′ N	81 deg.21.0′ W.
16	24 deg.41.4′ N	81 deg.22.2′ W.
17	24 deg.43.2′ N	81 deg.22.2′ W.
18	24 deg.43.2′ N	81 deg.22.8′ W.
19	24 deg.43.8′ N	81 deg.22.8′ W.
20	24 deg.43.8′ N	81 deg.24.0′ W.
21	24 deg.43.2′ N	81 deg.24.0′ W.
22	24 deg.43.2′ N	81 deg.26.4′ W.
23	24 deg.43.8′ N	81 deg.26.4′ W.
24	24 deg.43.8′ N	81 deg.27.0′ W.
25	24 deg.43.2′ N	81 deg.27.0′ W.
26	24 deg.43.2′ N	81 deg.29.4′ W.
27	24 deg.42.6′ N	81 deg.29.4′ W.
28	24 deg.42.6′ N	81 deg.30.6′ W.
29	24 deg.41.4′ N	81 deg.30.6′ W.
30	24 deg.41.4′ N	81 deg.31.2′ W.
31	24 deg.40.8′ N	81 deg.31.2′ W.
32	24 deg.40.8′ N	81 deg.32.4′ W.
33	24 deg.41.4′ N	81 deg.32.4′ W.
34	24 deg.41.4′ N	81 deg.34.2′ W.
35	24 deg.40.8′ N	81 deg.34.2′ W.
36	24 deg.48.0′ N	81 deg.35.4′ W.
37	24 deg.39.6′ N	81 deg.35.4′ W.
38	24 deg.39.6′ N	81 deg.36.0′ W.
39	24 deg.39.0′ N	81 deg.36.0′ W.
40	24 deg.39.0′ N	81 deg.37.2′ W.
41	24 deg.37.8′ N	81 deg.37.2′ W.
42	24 deg.37.8′ N	81 deg.37.8′ W.
43	24 deg.37.2′ N	81 deg.37.8′ W.
44	24 deg.37.2′ N	81 deg.40.2′ W.
45	24 deg.36.0′ N	81 deg.40.2′ W.
46	24 deg.36.0′ N	81 deg.40.8′ W.
47	24 deg.35.4′ N	81 deg.40.8′ W.
48	24 deg.35.4′ N	81 deg.42.0′ W.
49	24 deg.36.0′ N	81 deg.42.0′ W.
50	24 deg.36.0′ N	81 deg.48.6′ W.
51	24 deg.43.8′ N	81 deg.48.6′ W.

KEY WEST NATIONAL WILDLIFE REFUGE

[Based on the North American Datum of 1983]

Point	Latitude	Longitude
1	24 deg.40.0′ N	81 deg.49.0′ W.
2	24 deg.40.0′ N	82 deg.10.0′ W.
3	24 deg.27.0′ N	82 deg.10.0′ W.
4	24 deg.27.0′ N	81 deg.49.0′ W.
5	24 deg.40.0′ N	81 deg.49.0′ W.

(2) When differential Global Positioning Systems data becomes available, these coordinates may be publication in the **Federal Register** to reflect the increased accuracy of such data.

Appendix IV to Subpart P of Part 922—Ecological Reserves Boundary

Coordinates

(1) The boundary of the Western Sambo Ecological Reserve is formed by connecting in succession the points at the following coordinates:

WESTERN SAMBO

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.33.70′ N	81 deg.40.80′ W.
2	24 deg.28.85′ N	81 deg.41.90′ W.

WESTERN SAMBO—Continued

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
3	24 deg.28.50′ N	81 deg.43.70′ W.
4	24 deg.33.50′ N	81 deg.43.10′ W.
5	24 deg.33.70′ N	81 deg.40.80′ W.

(2) The Tortugas Ecological Reserve consists of two discrete areas, Tortugas North and Tortugas South.
(3) The boundary of Tortugas North is formed by connecting in succession the points at the following coordinates:

TORTUGAS NORTH

Point	Latitude	Longitude
1	24 deg.46.00′ N	83 deg.06.00′ W.
2	24 deg.46.00′ N	82 deg.54.00′ W.
3	24 deg.45.80′ N	82 deg.48.00′ W.
4	24 deg.43.53′ N	82 deg.48.00′ W.
5	24 deg.43.53′ N	82 deg.52.00′ W.
6	24 deg.43.00′ N	82 deg.54.00′ W.
7	24 deg.39.00′ N	82 deg.58.00′ W.
8	24 deg.39.00′ N	83 deg.06.00′ W.
9	24 deg.46.00′ N	83 deg.06.00′ W.

(4) The boundary of Tortugas South is formed by connecting in succession the points at the following coordinates:

TORTUGAS SOUTH

Point	Latitude	Longitude
1	24 deg.33.00′ N	83 deg.09.00′ W.
2	24 deg.33.00′ N	83 deg.05.00′ W.
3	24 deg.18.00′ N	83 deg.05.00′ W.
4	24 deg.18.00′ N	83 deg.09.00′ W.
5	24 deg.33.00′ N	83 deg.09.00′ W.

Appendix V to Subpart P of Part 922—Sanctuary Preservation Areas Boundary Coordinates

The boundary of each of the Sanctuary Preservation Areas (SPAs) is formed by connecting in succession the points at the following coordinates:

ALLIGATOR REEF

[Based on differential Global Positioning Systems data]

Point	Latitute	Longitude
1	24 deg.50.98′ N	80 deg.36.84′ W.
2	24 deg.50.51′ N	80 deg.37.35′ W.
3	24 deg.50.81′ N	80 deg.37.63′ W.
4	24 deg.51.23′ N	80 deg.37.17′ W.
5	24 deg.50.98′ N	80 deg.36.84′ W.

Catch and release fishing by trolling only is allowed in this SPA.

CARYSFORT/SOUTH CARYSFORT REEF

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.13.78′ N	80 deg.12.00′ W.
2	25 deg.12.03′ N	80 deg.12.98′ W.
3	25 deg.12.24′ N	80 deg.13.77′ W.
4	25 deg.14.13′ N	80 deg.12.78′ W.
5	25 deg.13.78′ N	80 deg.12.00′ W.

CHEECA ROCKS

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.54.42′ N	80 deg.36.91′ W.

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CHEECA ROCKS—Continued

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
2	24 deg.54.25′ N	80 deg.36.77′ W.
3	24 deg.54.10′ N	80 deg.37.00′ W.
4	24 deg.54.22′ N	80 deg.37.15′ W.
5	24 deg.54.42′ N	80 deg.36.91′ W.

COFFINS PATCH

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.41.47′ N	80 deg.57.68′ W.
2	24 deg.41.12′ N	80 deg.57.53′ W.
3	24 deg.40.75′ N	80 deg.58.33′ W.
4	24 deg.41.06′ N	80 deg.58.48′ W.
5	24 deg.41.47′ N	80 deg.57.68′ W.

CONCH REEF

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.57.48′ N	80 deg.27.47′ W.
2	24 deg.57.34′ N	80 deg.27.26′ W.
3	24 deg.56.78′ N	80 deg.27.52′ W.
4	24 deg.56.98′ N	80 deg.27.73′ W.
5	24 deg.57.48′ N	80 deg.27.47′ W.

Catch and release fishing by trolling only is allowed in this SPA.

DAVIS REEF

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.55.61′ N	80 deg.30.27′ W.
2	24 deg.55.41′ N	80 deg.30.05′ W.
3	24 deg.55.11′ N	80 deg.30.35′ W.
4	24 deg.55.34′ N	80 deg.30.52′ W.
5	24 deg.55.61′ N	80 deg.30.27′ W.

DRY ROCKS

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.07.59′ N	80 deg.17.91′ W.
2	25 deg.07.41′ N	80 deg.17.70′ W.
3	25 deg.07.25′ N	80 deg.17.82′ W.
4	25 deg.07.41′ N	80 deg.18.09′ W.
5	25 deg.07.59′ N	80 deg.17.91′ W.

GRECIAN ROCKS

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.06.91′ N	80 deg.18.20′ W.
2	25 deg.06.67′ N	80 deg.18.06′ W.
3	25 deg.06.39′ N	80 deg.18.32′ W.
4	25 deg.06.42′ N	80 deg.18.48′ W.
5	25 deg.06.81′ N	80 deg.18.44′ W.
6	25 deg.06.91′ N	80 deg.18.20′ W.

EASTERN DRY ROCKS

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.27.92′ N	81 deg.50.55′ W.
2	24 deg.27.73′ N	81 deg.50.33′ W.
3	24 deg.27.47′ N	81 deg.50.80′ W.
4	24 deg.27.72′ N	81 deg.50.86′ W.
5	24 deg.27.92′ N	81 deg.50.55′ W.

THE ELBOW

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.08.97′ N	80 deg.15.63′ W.
2	25 deg.08.95′ N	80 deg.15.22′ W.
3	25 deg.08.18′ N	80 deg.15.64′ W.
4	25 deg.08.50′ N	80 deg.16.07′ W.
5	25 deg.08.97′ N	80 deg.15.63′ W.

FRENCH REEF

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.02.20′ N	80 deg.20.63′ W.
2	25 deg.01.81′ N	80 deg.21.02′ W.
3	25 deg.02.36′ N	80 deg.21.27′ W.
4	25 deg.02.20′ N	80 deg.20.63′ W.

HEN AND CHICKENS

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.56.38′ N	80 deg.32.86′ W.
2	24 deg.56.21′ N	80 deg.32.63′ W.
3	24 deg.55.86′ N	80 deg.32.95′ W.
4	24 deg.56.04′ N	80 deg.33.19′ W.
5	24 deg.56.38′ N	80 deg.32.86′ W.

LOOE KEY

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.33.24′ N	81 deg.24.03′ W.
2	24 deg.32.70′ N	81 deg.23.85′ W.
3	24 deg.32.52′ N	81 deg.24.70′ W.
4	24 deg.33.12′ N	81 deg.24.81′ W.
5	24 deg.33.24′ N	81 deg.24.03′ W.

MOLASSES REEF

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	25 deg.01.00′ N	80 deg.22.53′ W.
2	25 deg.01.06′ N	80 deg.21.84′ W.
3	25 deg.00.29′ N	80 deg.22.70′ W.
4	25 deg.00.72′ N	80 deg.22.83′ W.
5	25 deg.01.00′ N	80 deg.22.53′ W.

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NEWFOUND HARBOR KEY

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.37.10′ N	81 deg.23.34′ W.
2	24 deg.36.85′ N	81 deg.23.28′ W.
3	24 deg.36.74′ N	81 deg.23.80′ W.
4	24 deg.37.00′ N	81 deg.23.86′ W.
5	24 deg.37.10′ N	81 deg.23.34′ W.

ROCK KEY

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.27.48′ N	81 deg.51.35′ W.
2	24 deg.27.30′ N	81 deg.51.15′ W.
3	24 deg.27.21′ N	81 deg.51.60′ W.
4	24 deg.27.45′ N	81 deg.51.65′ W.
5	24 deg.27.48′ N	81 deg.51.35′ W.

SAND KEY

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.27.58′ N	81 deg.52.29′ W.
2	24 deg.27.01′ N	81 deg.52.32′ W.
3	24 deg.27.02′ N	81 deg.52.95′ W.
4	24 deg.27.61′ N	81 deg.52.94′ W.
5	24 deg.27.58′ N	81 deg.52.29′ W.

Catch and release fishing by trolling only is allowed in this SPA.

SOMBRERO KEY

[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.37.91′ N	81 deg.06.78′ W.
2	24 deg.37.50′ N	81 deg.06.19′ W.
3	24 deg.37.25′ N	81 deg.06.89′ W.
4	24 deg.37.91′ N	81 deg.06.78′ W.

Catch and release fishing by trolling only is allowed in this SPA.

Appendix VI to Subpart P of Part 922—Special-Use Areas Boundary

Coordinates and Use Designations

The boundary of each of the Special-Use is formed by connecting in succession the points at the following coordinates:

CONCH REEF

(Research Only)—[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.56.83′ N	80 deg.27.26′ W.
2	24 deg.57.10′ N	80 deg.26.93′ W.
3	24 deg.56.99′ N	80 deg.27.42′ W.
4	24 deg.57.34′ N	80 deg.27.26′ W.
5	24 deg.56.83′ N	80 deg.27.26′ W.

EASTERN SAMBO

(Research Only)—[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.29.84′ N	81 deg.39.59′ W.
2	24 deg.29.55′ N	81 deg.39.35′ W.
3	24 deg.29.37′ N	81 deg.39.96′ W.

EASTERN SAMBO—Continued

(Research Only)—[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
4	24 deg.29.77′ N	81 deg.40.03′ W.
5	24 deg.29.84′ N	81 deg.39.59′ W.

LOOE KEY

(Research Only)—[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.34.17′ N	81 deg.23.01′ W.
2	24 deg.33.98′ N	81 deg.22.96′ W.
3	24 deg.33.84′ N	81 deg.23.60′ W.
4	24 deg.34.23′ N	81 deg.23.68′ W.
5	24 deg.34.17′ N	81 deg.23.01′ W.

TENNESSEE REEF

(Research Only)—[Based on differential Global Positioning Systems data]

Point	Latitude	Longitude
1	24 deg.44.77′ N	80 deg.47.12′ W.
2	24 deg.44.57′ N	80 deg.46.98′ W.
3	24 deg.44.68′ N	80 deg.46.59′ W.
4	24 deg.44.95′ N	80 deg.46.74′ W.
5	24 deg.44.77′ N	80 deg.47.12′ W.

Appendix VII to Subpart P of Part 922—Areas To Be Avoided Boundary

Coordinates

IN THE VICINITY OF THE FLORIDA KEYS

[Reference Charts: United States 11466, 27th Edition—September 1, 1990 and United States 11450, 4th Edition—August 11,1990]

Point	Latitude	Longitude
1	25 deg.45.00′ N	80 deg.06.10′ W.
2	25 deg.38.70′ N	80 deg.02.70′ W.
3	25 deg.22.00′ N	80 deg.03.00′ W.
4	25 deg.00.20′ N	80 deg.13.40′ W.
5	24 deg.37.90′ N	80 deg.47.30′ W.
6	24 deg.29.20′ N	81 deg.17.30′ W.
7	24 deg.22.30′ N	81 deg.43.17′ W.
8	24 deg.28.00′ N	81 deg.43.17′ W.
9	24 deg.28.70′ N	81 deg.43.50′ W.
10	24 deg.29.80′ N	81 deg.43.17′ W.
11	24 deg.33.10′ N	81 deg.35.15′ W.
12	24 deg.33.60′ N	81 deg.26.00′ W.
13	24 deg.38.20′ N	81 deg.07.00′ W.
14	24 deg.43.20′ N	80 deg.53.20′ W.
15	24 deg.46.10′ N	80 deg.46.15′ W.
16	24 deg.51.10′ N	80 deg.37.10′ W.
17	24 deg.57.50′ N	80 deg.27.50′ W.
18	25 deg.09.90′ N	80 deg.16.20′ W.
19	25 deg.24.00′ N	80 deg.09.10′ W.
20	25 deg.31.50′ N	80 deg.07.00′ W.
21	25 deg.39.70′ N	80 deg.06.85′ W.
22	25 deg.45.00′ N	80 deg.06.10′ W.

IN THE VICINITY OF KEY WEST HARBOR

[Reference Chart: United States 11434, 21st Edition—August 11, 1990]

Point	Latitude	Longitude
23	24 deg.27.95′ N	81 deg.48.65′ W.
24	24 deg.23.00′ N	81 deg.53.50′ W.
25	24 deg.26.60′ N	81 deg.58.50′ W.
26	24 deg.27.75′ N	81 deg.55.70′ W.

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IN THE VICINITY OF KEY WEST HARBOR—Continued

[Reference Chart: United States 11434, 21st Edition—August 11, 1990]

Point	Latitude	Longitude
27	24 deg.29.35' N	81 deg.53.40' W.
28	24 deg.29.35' N	81 deg.50.00' W.
29	24 deg.27.95' N	81 deg.48.65' W.

AREA SURROUNDING THE MARQUESAS KEYS

[Reference Chart: United States 11434, 21st Edition—August 11, 1990]

Point	Latitude	Longitude
30	24 deg.26.60' N	81 deg.59.55' W.
31	24 deg.23.00' N	82 deg.03.50' W.
32	24 deg.23.60' N	82 deg.27.80' W.
33	24 deg.34.50' N	82 deg.37.50' W.
34	24 deg.43.00' N	82 deg.26.50' W.
35	24 deg.38.31' N	81 deg.54.06' W.
36	24 deg.37.91' N	81 deg.53.40' W.
37	24 deg.36.15' N	81 deg.51.78' W.
38	24 deg.34.40' N	81 deg.50.60' W.
39	24 deg.33.44' N	81 deg.49.73' W.
40	24 deg.31.20' N	81 deg.52.10' W.
41	24 deg.28.70' N	81 deg.56.80' W.
42	24 deg.26.60' N	81 deg.59.55' W.

AREA SURROUNDING THE DRY TORTUGAS ISLANDS

[Reference Chart: United States 11434, 21st Edition—August 11, 1990]

Point	Latitude	Longitude
43	24 deg.32.00' N	82 deg.53.50' W.
44	24 deg.32.00' N	83 deg.00.05' W.
45	24 deg.39.70' N	83 deg.00.05' W.
46	24 deg.45.60' N	82 deg.54.40' W.
47	24 deg.45.60' N	82 deg.47.02' W.
48	24 deg.42.80' N	82 deg.43.90' W.
49	24 deg.39.50' N	82 deg.43.90' W.
50	24 deg.35.60' N	82 deg.46.40' W.
51	24 deg.32.00' N	82 deg.53.50' W.

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Federal Register

Wednesday,
January 17, 2001

Part VI

Department of Education

34 CFR Part 361
State Vocational Rehabilitation Services Program; Final Rule

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DEPARTMENT OF EDUCATION

34 CFR Part 361

RIN 1820–AB50

State Vocational Rehabilitation Services Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the State Vocational Rehabilitation Services Program. These amendments implement changes to the Rehabilitation Act of 1973 made by the Rehabilitation Act Amendments of 1998 that were contained in Title IV of the Workforce Investment Act of 1998 (WIA), enacted on August 7, 1998, and as further amended in 1998 by technical amendments in the Reading Excellence Act and the Carl D. Perkins Vocational and Applied Technology Education Act Amendments of 1998 (hereinafter collectively referred to as the 1998 Amendments).

DATES: These regulations are effective February 16, 2001. However, affected parties do not have to comply with the information collection requirements in §§ 361.10, 361.12, 361.13, 361.14, 361.15, 361.16, 361.17, 361.18, 361.19, 361.20, 361.21, 361.22, 361.23, 361.24, 361.25, 361.26, 361.27, 361.28, 361.29, 361.30, 361.31, 361.32, 361.34, 361.35, 361.36, 361.37, 361.38, 361.40, 361.41, 361.46, 361.47, 361.48, 361.49, 361.50, 361.51, 361.52, 361.53, 361.54, 361.55, 361.57, 361.60 and 361.62 until the Department of Education publishes in the **Federal Register** the control numbers assigned by the Office of Management and Budget (OMB) to these information collection requirements. Publication of the control numbers notifies the public that OMB has approved these information collection requirements under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Beverlee Stafford, U.S. Department of Education, 400 Maryland Avenue, SW., room 3014, Mary E. Switzer Building, Washington, DC 20202–2531. Telephone (202) 205–8831. If you use a telecommunications device for the deaf (TDD), you may call (202) 205–5538.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to Katie Mincey, Director, Alternate Formats Center, U.S. Department of Education, 400 Maryland Avenue, SW., room 1000, Mary E. Switzer Building, Washington, DC 20202–2531. Telephone (202) 260–9895. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The State Vocational Rehabilitation Services Program (VR program) is authorized by Title I of the Rehabilitation Act of 1973, as amended (Act) (29 U.S.C. 701–744). The VR program provides support to each State to assist it in operating a statewide comprehensive, coordinated, effective, efficient, and accountable State program, as an integral part of a statewide workforce investment system, to assess, plan, develop, and provide vocational rehabilitation (VR) services for individuals with disabilities so that those individuals may prepare for and engage in gainful employment consistent with their strengths, priorities, concerns, abilities, capabilities, interests, and informed choice.

On February 28, 2000, we published a notice of proposed rulemaking (NPRM) for this part in the **Federal Register** (65 FR 10620). In the preamble to the NPRM, we discussed on pages 10620 through 10630 the major changes proposed to the regulations in 34 CFR part 361 as a result of the 1998 Amendments. These included the following:

- Streamlining the regulatory requirements pertaining to the State plan for the VR program by changing several State plan descriptions or assurances to program requirements that need not be addressed in the State plan. These proposed changes were intended to reduce the paperwork burden associated with the development of the State plan.
- Amending the regulations to reflect the responsibilities of the designated state unit (DSU or State unit) as a required partner in the One-Stop service delivery system (One-Stop system) established under Title I of the WIA, Pub. L. 105–22. For example, we proposed amending § 361.4 to include among the regulations applicable to the VR program the One-Stop system requirements in 20 CFR part 662 and the civil rights requirements in 29 CFR part 37. In addition to these changes and, as noted later, amending other sections of the current regulations to reflect requirements in WIA, we discuss in some detail in the preamble to the NPRM (65 FR 10620 and 10621) the relationship between the VR program, the One-Stop system in general, and persons with disabilities. We suggest that you refer to that discussion for additional guidance in coordinating between One-Stop system components.
- Amending § 361.5 to include a new definition of the term "fair hearing board," a revised definition of "physical or mental impairment," a new definition of the term "qualified and impartial mediator," and several new statutory definitions found in WIA, including "local workforce investment board," "State workforce investment board," and "Statewide workforce investment system."
- Amending § 361.10 to require that each State submit its State plan for the VR program on the same date that it submits either a State plan under section 112 of WIA or a State unified plan under section 501 of that Act.
- Amending § 361.13 to expand the list of activities that are the responsibility of the DSU.
- Amending § 361.18(c) to require, as appropriate, DSUs to address in a written plan their retraining, recruitment, hiring, and other strategies to ensure that their personnel meet the statutory standards related to the comprehensive system of personnel development.
- Amending § 361.22 to reflect new statutory requirements that foster the transition of students from educational to VR services.
- Amending § 361.23 to reflect both the VR program's responsibilities as a partner of the One-Stop system under WIA and the requirements in the 1986 Amendments related to interagency coordination between the VR program and other components of the statewide workforce investment system under WIA.
- Amending § 361.26 to reflect the authority of States to use geographically earmarked funds without requesting a waiver of statewideness.
- Amending § 361.29 to guide States in developing a required comprehensive, forward-thinking plan for administering and improving their VR programs.
- Conforming § 361.30 solely to the requirement in the Act that DSUs provide VR services to eligible American Indians to the same extent as other significant populations of individuals with disabilities.
- Amending § 361.31 to conform to the requirement in the Act that the DSU establish cooperative agreements with private nonprofit VR service providers.
- Removing § 361.33 of the current regulations (regarding the use, assessment, and support of community rehabilitation programs) since these requirements are addressed in other regulatory sections and reserving this section for future use.
- Amending § 361.35 to reflect the requirement in section 101(a)(18) of the Act that the State reserve a portion of its allotment under section 110 of the Act to further innovation and expansion of its VR program.
- Amending § 361.36 to incorporate the requirement in the 1998 Amendments that individuals who do not meet the State's order of selection criteria for receiving services be provided access to the DSU's information and referral system under § 361.37.
- Amending § 361.37 to reflect new requirements in the Act for referring individuals, including eligible individuals who do not meet the State's order of selection criteria for receiving services, to those components of the statewide workforce investment system best suited to meet an individual's employment needs.
- Amending § 361.42 to implement new requirements in the Act regarding presumptive eligibility for Social Security recipients and beneficiaries and the use of trial work experiences as part of the assessment for determining eligibility, to revise regulatory requirements concerning extended evaluations, and to identify the type of personnel who must conduct eligibility determinations.
- Amending § 361.45 to implement new requirements in the Act that expand an eligible individual's options for developing the Individualized Plan for Employment (IPE), enable individuals to receive technical assistance in developing their IPEs, specify the information that the DSU must provide to the eligible individual during IPE development, and detail applicable procedural requirements.
- Amending § 361.47 to require the States to determine, with input from the State Rehabilitation Councils, the type of documentation that they will maintain for each applicant and eligible individual to meet the content items that must be included in each individual's record of services.
- Amending § 361.52 to implement the expanded authority in the Act requiring that applicants and eligible individuals be able to exercise informed choice throughout the rehabilitation process.
- Amending § 361.53 to require interagency agreements between the DSU and other appropriate public entities to ensure that eligible individuals with disabilities receive, in a timely manner, necessary services to which each party to the agreement has an obligation, or the authority, to contribute.
- Amending § 361.54 to expand the list of VR services exempt from State financial needs tests to include interpreter services for individuals who are deaf or hard of hearing, reader services for individuals who are blind, and personal assistant services. Also, this section was amended to prohibit States from applying financial needs tests to individuals receiving Supplemental Security Income (SSI) or Social Security Disability Insurance (SSDI).
- Re-titling and Amending § 361.56 to better reflect the requirements that must be met before the State unit can close the record of services for an individual who has achieved an employment outcome.
- Amending § 361.57 to implement new requirements in the 1998 Amendments regarding mediation and administrative review of disputes regarding the provision of VR services to applicants or eligible individuals.
- Amending § 361.60 to reflect the elimination of statutory authority for the innovation and expansion grant program and to implement new statutory provisions regarding the use of geographically limited earmarked funds as part of the State's non-Federal share.

These final regulations contain several significant changes from the NPRM. We fully explain each of these changes in the Analysis of Comments and Changes in the appendix at the end of these final regulations.

Analysis of Comments and Changes

In response to our invitation in the NPRM, 109 parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM is published as an appendix at the end of these final regulations.

We discuss substantive issues under the sections of the regulations to which they pertain. Generally, we do not address technical and other minor changes—and suggested changes that the law does not authorize the Secretary to make.

National Education Goals

The eight National Education Goals focus the Nation's education reform efforts and provide a framework for improving teaching and learning.

These regulations address the National Education Goal that every adult American, including individuals with disabilities, will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Executive Order 12866

We have reviewed these final regulations in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with the final regulations are those resulting from statutory requirements and those we have determined to be necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of these final regulations, we have determined that the benefits of the final regulations justify the costs.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Summary of Potential Costs and Benefits

We discussed the potential costs and benefits of these final regulations in the preamble to the NPRM (65 FR 10630 and 10631) and throughout the section-by-section analysis (65 FR 10621 through 10630). Our analysis of potential costs and benefits generally remains the same as in the NPRM, although we include additional discussion of potential costs and benefits in the Appendix to these final regulations titled Analysis of Comments and Changes.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. "Federalism implications" means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and

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respensibilities among the various levels of government.

These regulations implement various statutory changes to the State Vocational Rehabilitation Services Program. We do not believe that these regulations have federalism implications as defined in Executive Order 13132 or that they preempt State law. Accordingly, the Secretary has determined that these regulations do not contain policies that have federalism implications.

Assessment of Educational Impact

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Based on the response to the NPRM and our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

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(Catalog of Federal Domestic Assistance Number: 84.126 State Vocational Rehabilitation Services Program)

List of Subjects in 34 CFR Part 361

Reporting and recordkeeping requirements, State-administered grant program—education, Vocational rehabilitation.

Dated: December 7, 2000.

Richard W. Riley,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary amends title 34 of the Code of Federal Regulations by revising part 361 to read as follows:

PART 361—STATE VOCATIONAL REHABILITATION SERVICES PROGRAM

Subpart A—General

Sec.
361.1 Purpose.
361.2 Eligibility for a grant.
361.3 Authorized activities.
361.4 Applicable regulations.
361.5 Applicable definitions.

Subpart B—State Plan and Other Requirements for Vocational Rehabilitation Services

361.10 Submission, approval, and disapproval of the State plan.
361.11 Withholding of funds.

Administration

361.12 Methods of administration.
361.13 State agency for administration.
361.14 Substitute State agency.
361.15 Local administration.
361.16 Establishment of an independent commission or a State Rehabilitation Council.
361.17 Requirements for a State Rehabilitation Council.
361.18 Comprehensive system of personnel development.
361.19 Affirmative action for individuals with disabilities.
361.20 Public participation requirements.
361.21 Consultations regarding the administration of the State plan.
361.22 Coordination with education officials.
361.23 Requirements related to the statewide workforce investment system.
361.24 Cooperation and coordination with other entities.
361.25 Statewideness.
361.26 Waiver of statewideness.
361.27 Shared funding and administration of joint programs.
361.28 Third-party cooperative arrangements involving funds from other public agencies.
361.29 Statewide assessment; annual estimates; annual State goals and priorities; strategies; and progress reports.
361.30 Services to American Indians.
361.31 Cooperative agreements with private nonprofit organizations.
361.32 Use of profitmaking organizations for on-the-job training in connection with selected projects.
361.33 [Reserved.]
361.34 Supported employment State plan supplement.
361.35 Innovation and expansion activities.
361.36 Ability to serve all eligible individuals; order of selection for services.
361.37 Information and referral services.
361.38 Protection, use, and release of personal information.
361.39 State-imposed requirements.
361.40 Reports.

Provision and Scope of Services

361.41 Processing referrals and applications.
361.42 Assessment for determining eligibility and priority for services.
361.43 Procedures for ineligibility determination.
361.44 Closure without eligibility determination.
361.45 Development of the individualized plan for employment.
361.46 Content of the individualized plan for employment.
361.47 Record of services.
361.48 Scope of vocational rehabilitation services for individuals with disabilities.
361.49 Scope of vocational rehabilitation services for groups of individuals with disabilities.
361.50 Written policies governing the provision of services for individuals with disabilities.
361.51 Standards for facilities and providers of services.
361.52 Informed choice.
361.53 Comparable services and benefits.
361.54 Participation of individuals in cost of services based on financial need.
361.55 Annual review of individuals in extended employment or other employment under special certificate provisions of the Fair Labor Standards Act.
361.56 Requirements for closing the record of services of an individual who has achieved an employment outcome.
361.57 Review of determinations made by designated State unit personnel.

Subpart C—Financing of State Vocational Rehabilitation Programs

361.60 Matching requirements.
361.61 Limitation on use of funds for construction expenditures.
361.62 Maintenance of effort requirements.
361.63 Program income.
361.64 Obligation of Federal funds and program income.
361.65 Allotment and payment of Federal funds for vocational rehabilitation services.

Subpart D—[Reserved]

Subpart E—Evaluation Standards and Performance Indicators

361.80 Purpose.
361.81 Applicable definitions.
361.82 Evaluation standards.
361.84 Performance indicators.
361.86 Performance levels.
361.88 Reporting requirements.
361.89 Enforcement procedures.

Authority: 29 U.S.C. 709(c), unless otherwise noted.

Subpart A—General

§ 361.1 Purpose.

Under the State Vocational Rehabilitation Services Program (Program), the Secretary provides grants to assist States in operating statewide comprehensive, coordinated, effective, efficient, and accountable programs, each of which is—

(a) An integral part of a statewide workforce investment system; and

(b) Designed to assess, plan, develop, and provide vocational rehabilitation services for individuals with disabilities, consistent with their strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice, so that they may prepare for and engage in gainful employment.

(Authority: Section 100(a)(2) of the Act; 29 U.S.C. 720(a)(2))

§ 361.2 Eligibility for a grant.

Any State that submits to the Secretary a State plan that meets the requirements of section 101(a) of the Act and this part is eligible for a grant under this Program.

(Authority: Section 101(a) of the Act; 29 U.S.C. 721(a))

§ 361.3 Authorized activities.

The Secretary makes payments to a State to assist in—

(a) The costs of providing vocational rehabilitation services under the State plan; and

(b) Administrative costs under the State plan.

(Authority: Section 111(a)(1) of the Act; 29 U.S.C. 731(a)(1))

§ 361.4 Applicable regulations.

The following regulations apply to this Program:

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-profit Organizations), with respect to subgrants to entities that are not State or local governments or Indian tribal organizations.

(2) 34 CFR part 76 (State-Administered Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments), except for § 80.24(a)(2).

(6) 34 CFR part 81 (General Education Provisions Act—Enforcement).

(7) 34 CFR part 82 (New Restrictions on Lobbying).

(8) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(9) 34 CFR part 86 (Drug and Alcohol Abuse Prevention).

(b) The regulations in this part 361.

(c) 20 CFR part 662 (Description of One-Stop Service Delivery System under Title I of the Workforce Investment Act of 1998).

(d) 29 CFR part 37, to the extent programs and activities are being conducted as part of the One-Stop service delivery system under section 121(b) of the Workforce Investment Act of 1998.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

§ 361.5 Applicable definitions.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Department
EDGAR
Fiscal year
Nonprofit
Private
Public
Secretary

(b) *Other definitions.* The following definitions also apply to this part:

(1) *Act* means the Rehabilitation Act of 1973, as amended (29 U.S.C. 701 *et seq.*).

(2) *Administrative costs under the State plan* means expenditures incurred in the performance of administrative functions under the vocational rehabilitation program carried out under this part, including expenses related to program planning, development, monitoring, and evaluation, including, but not limited to, expenses for—

(i) Quality assurance;

(ii) Budgeting, accounting, financial management, information systems, and related data processing;

(iii) Providing information about the program to the public;

(iv) Technical assistance and support services to other State agencies, private nonprofit organizations, and businesses and industries, except for technical assistance and support services described in § 361.49(a)(4);

(v) The State Rehabilitation Council and other advisory committees;

(vi) Professional organization membership dues for designated State unit employees;

(vii) The removal of architectural barriers in State vocational rehabilitation agency offices and State-operated rehabilitation facilities;

(viii) Operating and maintaining designated State unit facilities, equipment, and grounds;

(ix) Supplies;

(x) Administration of the comprehensive system of personnel development described in § 361.18, including personnel administration, administration of affirmative action plans, and training and staff development;

(xi) Administrative salaries, including clerical and other support staff salaries, in support of these administrative functions;

(xii) Travel costs related to carrying out the program, other than travel costs related to the provision of services;

(xiii) Costs incurred in conducting reviews of determinations made by personnel of the designated State unit, including costs associated with mediation and impartial due process hearings under § 361.57; and

(xiv) Legal expenses required in the administration of the program.

(Authority: Section 7(1) of the Act; 29 U.S.C. 705(1))

(3) *American Indian* means an individual who is a member of an Indian tribe.

(Authority: Section 7(19)(A) of the Act; 29 U.S.C. 705(19)(A))

(4) *Applicant* means an individual who submits an application for vocational rehabilitation services in accordance with § 361.41(b)(2).

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(5) *Appropriate modes of communication* means specialized aids and supports that enable an individual with a disability to comprehend and respond to information that is being communicated. Appropriate modes of communication include, but are not limited to, the use of interpreters, open and closed captioned videos, specialized telecommunications services and audio recordings, Brailled and large print materials, materials in electronic formats, augmentative communication devices, graphic presentations, and simple language materials.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(6) *Assessment for determining eligibility and vocational rehabilitation needs* means, as appropriate in each case—

(i)(A) A review of existing data—

(*1*) To determine if an individual is eligible for vocational rehabilitation services; and

(*2*) To assign priority for an order of selection described in § 361.36 in the States that use an order of selection; and

(B) To the extent necessary, the provision of appropriate assessment activities to obtain necessary additional data to make the eligibility determination and assignment;

(ii) To the extent additional data are necessary to make a determination of the employment outcomes and the nature and scope of vocational

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rehabilitation services to be included in the individualized plan for employment of an eligible individual, a comprehensive assessment to determine the unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice, including the need for supported employment, of the eligible individual. This comprehensive assessment—

(A) Is limited to information that is necessary to identify the rehabilitation needs of the individual and to develop the individualized plan of employment of the eligible individual;

(B) Uses as a primary source of information, to the maximum extent possible and appropriate and in accordance with confidentiality requirements—

(*1*) Existing information obtained for the purposes of determining the eligibility of the individual and assigning priority for an order of selection described in § 361.36 for the individual; and

(*2*) Information that can be provided by the individual and, if appropriate, by the family of the individual;

(C) May include, to the degree needed to make such a determination, an assessment of the personality, interests, interpersonal skills, intelligence and related functional capacities, educational achievements, work experience, vocational aptitudes, personal and social adjustments, and employment opportunities of the individual and the medical, psychiatric, psychological, and other pertinent vocational, educational, cultural, social, recreational, and environmental factors that affect the employment and rehabilitation needs of the individual; and

(D) May include, to the degree needed, an appraisal of the patterns of work behavior of the individual and services needed for the individual to acquire occupational skills and to develop work attitudes, work habits, work tolerance, and social and behavior patterns necessary for successful job performance, including the use of work in real job situations to assess and develop the capacities of the individual to perform adequately in a work environment;

(iii) Referral, for the provision of rehabilitation technology services to the individual, to assess and develop the capacities of the individual to perform in a work environment; and

(iv) An exploration of the individual's abilities, capabilities, and capacity to perform in work situations, which must be assessed periodically during trial work experiences, including experiences in which the individual is provided appropriate supports and training.

(Authority: Section 7(2) of the Act; 29 U.S.C. 705(2))

(7) *Assistive technology device* means any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve the functional capabilities of an individual with a disability.

(Authority: Section 7(3) of the Act; 29 U.S.C. 705(3))

(8) *Assistive technology service* means any service that directly assists an individual with a disability in the selection, acquisition, or use of an assistive technology device, including—

(i) The evaluation of the needs of an individual with a disability, including a functional evaluation of the individual in his or her customary environment;

(ii) Purchasing, leasing, or otherwise providing for the acquisition by an individual with a disability of an assistive technology device;

(iii) Selecting, designing, fitting, customizing, adapting, applying, maintaining, repairing, or replacing assistive technology devices;

(iv) Coordinating and using other therapies, interventions, or services with assistive technology devices, such as those associated with existing education and rehabilitation plans and programs;

(v) Training or technical assistance for an individual with a disability or, if appropriate, the family members, guardians, advocates, or authorized representatives of the individual; and

(vi) Training or technical assistance for professionals (including individuals providing education and rehabilitation services), employers, or others who provide services to, employ, or are otherwise substantially involved in the major life functions of individuals with disabilities, to the extent that training or technical assistance is necessary to the achievement of an employment outcome by an individual with a disability.

(Authority: Sections 7(4) and 12(c) of the Act; 29 U.S.C. 705(4) and 709(c))

(9) *Community rehabilitation program.*

(i) *Community rehabilitation program* means a program that provides directly or facilitates the provision of one or more of the following vocational rehabilitation services to individuals with disabilities to enable those individuals to maximize their opportunities for employment, including career advancement:

(A) Medical, psychiatric, psychological, social, and vocational services that are provided under one management.

(B) Testing, fitting, or training in the use of prosthetic and orthotic devices.

(C) Recreational therapy.

(D) Physical and occupational therapy.

(E) Speech, language, and hearing therapy.

(F) Psychiatric, psychological, and social services, including positive behavior management.

(G) Assessment for determining eligibility and vocational rehabilitation needs.

(H) Rehabilitation technology.

(I) Job development, placement, and retention services.

(J) Evaluation or control of specific disabilities.

(K) Orientation and mobility services for individuals who are blind.

(L) Extended employment.

(M) Psychosocial rehabilitation services.

(N) Supported employment services and extended services.

(O) Services to family members if necessary to enable the applicant or eligible individual to achieve an employment outcome.

(P) Personal assistance services.

(Q) Services similar to the services described in paragraphs (A) through (P) of this definition.

(ii) For the purposes of this definition, the word *program* means an agency, organization, or institution, or unit of an agency, organization, or institution, that provides directly or facilitates the provision of vocational rehabilitation services as one of its major functions.

(10) *Comparable services and benefits* means—

(i) Services and benefits that are—

(A) Provided or paid for, in whole or in part, by other Federal, State, or local public agencies, by health insurance, or by employee benefits;

(B) Available to the individual at the time needed to ensure the progress of the individual toward achieving the employment outcome in the individual's individualized plan for employment in accordance with § 361.53; and

(C) Commensurate to the services that the individual would otherwise receive from the designated State vocational rehabilitation agency.

(ii) For the purposes of this definition, comparable benefits do not include awards and scholarships based on merit.

(*Authority:* Sections 12(c) and 101(a)(8) of the Act; 29 U.S.C. 709(c) and 721(a)(8))

(11) *Competitive employment* means work—

(i) In the competitive labor market that is performed on a full-time or part-time basis in an integrated setting; and

(ii) For which an individual is compensated at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals who are not disabled.

(*Authority:* Sections 7(11) and 12(c) of the Act; 29 U.S.C. 705(11) and 709(c))

(12) *Construction of a facility for a public or nonprofit community rehabilitation program* means—

(i) The acquisition of land in connection with the construction of a new building for a community rehabilitation program;

(ii) The construction of new buildings;

(iii) The acquisition of existing buildings;

(iv) The expansion, remodeling, alteration, or renovation of existing buildings;

(v) Architect's fees, site surveys, and soil investigation, if necessary, in connection with the construction project;

(vi) The acquisition of initial fixed or movable equipment of any new, newly acquired, newly expanded, newly remodeled, newly altered, or newly renovated buildings that are to be used for community rehabilitation program purposes; and

(vii) Other direct expenditures appropriate to the construction project, except costs of off-site improvements.

(*Authority:* Sections 7(6) and 12(c) of the Act; 29 U.S.C. 705(6) and 709(c))

(13) *Designated State agency* or *State agency* means the sole State agency, designated in accordance with § 361.13(a), to administer, or supervise the local administration of, the State plan for vocational rehabilitation services. The term includes the State agency for individuals who are blind, if designated as the sole State agency with respect to that part of the plan relating to the vocational rehabilitation of individuals who are blind.

(Authority: Sections 7(8)(A) and 101(a)(2)(A) of the Act; 29 U.S.C. 705(8)(A) and 721(a)(2)(A))

(14) *Designated State unit* or *State unit* means either—

(i) The State vocational rehabilitation bureau, division, or other organizational unit that is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of individuals with disabilities and that is responsible for the administration of the vocational rehabilitation program of the State agency, as required under § 361.13(b); or

(ii) The State agency that is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of individuals with disabilities.

(Authority: Sections 7(8)(B) and 101(a)(2)(B) of the Act; 29 U.S.C. 705(8)(B) and 721(a)(2)(B))

(15) *Eligible individual* means an applicant for vocational rehabilitation services who meets the eligibility requirements of § 361.42(a).

(Authority: Sections 7(20)(A) and 102(a)(1) of the Act; 29 U.S.C. 705(20)(A) and 722(a)(1))

(16) *Employment outcome* means, with respect to an individual, entering or retaining full-time or, if appropriate, part-time competitive employment in the integrated labor market to the greatest extent practicable; supported employment; or any other type of employment, including self-employment, telecommuting, or business ownership, that is consistent with an individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

(Authority: Sections 7(11), 12(c), 100(a)(2), and 102(b)(3)(A) of the Act; 29 U.S.C. 705(11), 709(c), 720(a)(2), and 722(b)(3)(A))

(17) *Establishment, development, or improvement of a public or nonprofit community rehabilitation program* means—

(i) The establishment of a facility for a public or nonprofit community rehabilitation program as defined in paragraph (b)(18) of this section to provide vocational rehabilitation services to applicants or eligible individuals;

(ii) Staffing, if necessary to establish, develop, or improve a community rehabilitation program for the purpose of providing vocational rehabilitation services to applicants or eligible individuals, for a maximum period of 4 years, with Federal financial participation available at the applicable matching rate for the following levels of staffing costs:

(A) 100 percent of staffing costs for the first year.

(B) 75 percent of staffing costs for the second year.

(C) 60 percent of staffing costs for the third year.

(D) 45 percent of staffing costs for the fourth year; and

(iii) Other expenditures related to the establishment, development, or improvement of a community rehabilitation program that are necessary to make the program functional or increase its effectiveness in providing vocational rehabilitation services to applicants or eligible individuals, but are not ongoing operating expenses of the program.

(Authority: Sections 7(12) and 12(c) of the Act; 29 U.S.C. 705(12) and 709(c))

(18) *Establishment of a facility for a public or nonprofit community rehabilitation program* means—

(i) The acquisition of an existing building and, if necessary, the land in connection with the acquisition, if the building has been completed in all respects for at least 1 year prior to the date of acquisition and the Federal share of the cost of acquisition is not more than $300,000;

(ii) The remodeling or alteration of an existing building, provided the estimated cost of remodeling or alteration does not exceed the appraised value of the existing building;

(iii) The expansion of an existing building, provided that—

(A) The existing building is complete in all respects;

(B) The total size in square footage of the expanded building, notwithstanding the number of expansions, is not greater than twice the size of the existing building;

(C) The expansion is joined structurally to the existing building and does not constitute a separate building; and

(D) The costs of the expansion do not exceed the appraised value of the existing building;

(iv) Architect's fees, site survey, and soil investigation, if necessary in connection with the acquisition, remodeling, alteration, or expansion of an existing building; and

(v) The acquisition of fixed or movable equipment, including the costs of installation of the equipment, if necessary to establish, develop, or improve a community rehabilitation program.

(Authority: Sections 7(12) and 12(c) of the Act; 29 U.S.C. 705(12) and 709(c))

(19) *Extended employment* means work in a non-integrated or sheltered setting for a public or private nonprofit agency or organization that provides compensation in accordance with the Fair Labor Standards Act and any needed support services to an individual with a disability to enable the individual to continue to train or otherwise prepare for competitive employment, unless the individual through informed choice chooses to remain in extended employment.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(20) *Extended services* means ongoing support services and other appropriate services that are needed to support and

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maintain an individual with a most significant disability in supported employment and that are provided by a State agency, a private nonprofit organization, employer, or any other appropriate resource, from funds other than funds received under this part and 34 CFR part 363 after an individual with a most significant disability has made the transition from support provided by the designated State unit.

(Authority: Sections 7(13) and 623 of the Act; 29 U.S.C. 705(13) and 795i)

(21) *Extreme medical risk* means a probability of substantially increasing functional impairment or death if medical services, including mental health services, are not provided expeditiously.

(Authority: Sections 12(c) and 101(a)(8)(A)(i)(III) of the Act; 29 U.S.C. 709(c) and 721(a)(8)(A)(i)(III))

(22) *Fair hearing board* means a committee, body, or group of persons established by a State prior to January 1, 1985 that—

(i) Is authorized under State law to review determinations made by personnel of the designated State unit that affect the provision of vocational rehabilitation services; and

(ii) Carries out the responsibilities of the impartial hearing officer in accordance with the requirements in § 361.57(j).

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(23) *Family member*, for purposes of receiving vocational rehabilitation services in accordance with § 361.48(i), means an individual—

(i) Who either—

(A) Is a relative or guardian of an applicant or eligible individual; or

(B) Lives in the same household as an applicant or eligible individual;

(ii) Who has a substantial interest in the well-being of that individual; and

(iii) Whose receipt of vocational rehabilitation services is necessary to enable the applicant or eligible individual to achieve an employment outcome.

(Authority: Sections 12(c) and 103(a)(17) of the Act; 29 U.S.C. 709(c) and 723(a)(17))

(24) *Governor* means a chief executive officer of a State.

(Authority: Section 7(15) of the Act; 29 U.S.C. 705(15))

(25) *Impartial hearing officer.*

(i) *Impartial hearing officer* means an individual who—

(A) Is not an employee of a public agency (other than an administrative law judge, hearing examiner, or employee of an institution of higher education);

(B) Is not a member of the State Rehabilitation Council for the designated State unit;

(C) Has not been involved previously in the vocational rehabilitation of the applicant or eligible individual;

(D) Has knowledge of the delivery of vocational rehabilitation services, the State plan, and the Federal and State regulations governing the provision of services;

(E) Has received training with respect to the performance of official duties; and

(F) Has no personal, professional, or financial interest that would be in conflict with the objectivity of the individual.

(ii) An individual is not considered to be an employee of a public agency for the purposes of this definition solely because the individual is paid by the agency to serve as a hearing officer.

(Authority: Section 7(16) of the Act; 29 U.S.C. 705(16))

(26) *Indian tribe* means any Federal or State Indian tribe, band, rancheria, pueblo, colony, or community, including any Alaskan native village or regional village corporation (as defined in or established pursuant to the Alaska Native Claims Settlement Act).

(Authority: Section 7(19)(B) of the Act; 29 U.S.C. 705(19)(B))

(27) *Individual who is blind* means a person who is blind within the meaning of applicable State law. (Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(28) *Individual with a disability*, except as provided in § 361.5(b)(29), means an individual—

(i) Who has a physical or mental impairment;

(ii) Whose impairment constitutes or results in a substantial impediment to employment; and

(iii) Who can benefit in terms of an employment outcome from the provision of vocational rehabilitation services.

(Authority: Section 7(20)(A) of the Act; 29 U.S.C. 705(20)(A))

(29) *Individual with a disability*, for purposes of §§ 361.5(b)(14), 361.13(a), 361.13(b)(1), 361.17(a), (b), (c), and (j), 361.18(b), 361.19, 361.20, 361.23(b)(2), 361.29(a) and (d)(5), and 361.51(b), means an individual—

(i) Who has a physical or mental impairment that substantially limits one or more major life activities;

(ii) Who has a record of such an impairment; or

(iii) Who is regarded as having such an impairment.

(Authority: Section 7(20)(B) of the Act; 29 U.S.C. 705(20)(B))

(30) *Individual with a most significant disability* means an individual with a significant disability who meets the designated State unit's criteria for an individual with a most significant disability. These criteria must be consistent with the requirements in § 361.36(d)(1) and (2).

(Authority: Sections 7(21)(E)(i) and 101(a)(5)(C) of the Act; 29 U.S.C. 705(21)(E)(i) and 721(a)(5)(C))

(31) *Individual with a significant disability* means an individual with a disability—

(i) Who has a severe physical or mental impairment that seriously limits one or more functional capacities (such as mobility, communication, self-care, self-direction, interpersonal skills, work tolerance, or work skills) in terms of an employment outcome;

(ii) Whose vocational rehabilitation can be expected to require multiple vocational rehabilitation services over an extended period of time; and

(iii) Who has one or more physical or mental disabilities resulting from amputation, arthritis, autism, blindness, burn injury, cancer, cerebral palsy, cystic fibrosis, deafness, head injury, heart disease, hemiplegia, hemophilia, respiratory or pulmonary dysfunction, mental retardation, mental illness, multiple sclerosis, muscular dystrophy, musculo-skeletal disorders, neurological disorders (including stroke and epilepsy), spinal cord conditions (including paraplegia and quadriplegia), sickle cell anemia, specific learning disability, end-stage renal disease, or another disability or combination of disabilities determined on the basis of an assessment for determining eligibility and vocational rehabilitation needs to cause comparable substantial functional limitation.

(Authority: Section 7(21)(A) of the Act; 29 U.S.C. 705(21)(A))

(32) *Individual's representative* means any representative chosen by an applicant or eligible individual, as appropriate, including a parent, guardian, other family member, or advocate, unless a representative has been appointed by a court to represent the individual, in which case the court-appointed representative is the individual's representative.

(Authority: Sections 7(22) and 12(c) of the Act; 29 U.S.C. 705(22) and 709(c))

(33) *Integrated setting.*—

(i) With respect to the provision of services, means a setting typically found in the community in which applicants or eligible individuals interact with non-disabled individuals other than non-disabled individuals who are providing services to those applicants or eligible individuals;

(ii) With respect to an employment outcome, means a setting typically found in the community in which applicants or eligible individuals interact with non-disabled individuals, other than non-disabled individuals who are providing services to those applicants or eligible individuals, to the same extent that non-disabled individuals in comparable positions interact with other persons.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(34) *Local workforce investment board* means a local workforce investment board established under section 117 of the Workforce Investment Act of 1998.

(Authority: Section 7(25) of the Act; 29 U.S.C. 705(25))

(35) *Maintenance* means monetary support provided to an individual for expenses, such as food, shelter, and clothing, that are in excess of the normal expenses of the individual and that are necessitated by the individual's participation in an assessment for determining eligibility and vocational rehabilitation needs or the individual's receipt of vocational rehabilitation services under an individualized plan for employment.

(Authority: Sections 12(c) and 103(a)(7) of the Act; 29 U.S.C. 709(c) and 723(a)(7))

(i) *Examples:* The following are examples of expenses that would meet the definition of maintenance. The examples are illustrative, do not address all possible circumstances, and are not intended to substitute for individual counselor judgment.

Example 1: The cost of a uniform or other suitable clothing that is required for an individual's job placement or job-seeking activities.

Example 2: The cost of short-term shelter that is required in order for an individual to participate in assessment activities or vocational training at a site that is not within commuting distance of an individual's home.

Example 3: The initial one-time costs, such as a security deposit or charges for the initiation of utilities, that are required in order for an individual to relocate for a job placement.

Example 4: The costs of an individual's participation in enrichment activities related to that individual's training program.

(ii) [Reserved]

(36) *Mediation* means the act or process of using an independent third party to act as a mediator, intermediary, or conciliator to assist persons or parties in settling differences or disputes prior to pursuing formal administrative or other legal remedies. Mediation under the program must be conducted in accordance with the requirements in § 361.57(d) by a qualified and impartial mediator as defined in § 361.5(b)(43).

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

(37) *Nonprofit*, with respect to a community rehabilitation program, means a community rehabilitation program carried out by a corporation or association, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual and the income of which is exempt from taxation under section 501(c)(3) of the Internal Revenue Code of 1986.

(Authority: Section 7(26) of the Act; 29 U.S.C. 705(26))

(38) *Ongoing support services*, as used in the definition of "Supported employment"

(i) Means services that are—

(A) Needed to support and maintain an individual with a most significant disability in supported employment;

(B) Identified based on a determination by the designated State unit of the individual's need as specified in an individualized plan for employment; and

(C) Furnished by the designated State unit from the time of job placement until transition to extended services, unless post-employment services are provided following transition, and thereafter by one or more extended services providers throughout the individual's term of employment in a particular job placement or multiple placements if those placements are being provided under a program of transitional employment;

(ii) Must include an assessment of employment stability and provision of specific services or the coordination of services at or away from the worksite that are needed to maintain stability based on—

(A) At a minimum, twice-monthly monitoring at the worksite of each individual in supported employment; or

(B) If under specific circumstances, especially at the request of the individual, the individualized plan for employment provides for off-site monitoring, twice monthly meetings with the individual;

(iii) Consist of—

(A) Any particularized assessment supplementary to the comprehensive assessment of rehabilitation needs described in paragraph (b)(6)(ii) of this section;

(B) The provision of skilled job trainers who accompany the individual for intensive job skill training at the work site;

(C) Job development and training;

(D) Social skills training;

(E) Regular observation or supervision of the individual;

(F) Follow-up services including regular contact with the employers, the individuals, the parents, family members, guardians, advocates or authorized representatives of the individuals, and other suitable professional and informed advisors, in order to reinforce and stabilize the job placement;

(G) Facilitation of natural supports at the worksite;

(H) Any other service identified in the scope of vocational rehabilitation services for individuals, described in § 361.48; or

(I) Any service similar to the foregoing services.

(Authority: Sections 7(27) and 12(c) of the Act; 29 U.S.C. 705(27) and 709(c))

(39) *Personal assistance services* means a range of services provided by one or more persons designed to assist an individual with a disability to perform daily living activities on or off the job that the individual would typically perform without assistance if the individual did not have a disability. The services must be designed to increase the individual's control in life and ability to perform everyday activities on or off the job. The services must be necessary to the achievement of an employment outcome and may be provided only while the individual is receiving other vocational rehabilitation services. The services may include training in managing, supervising, and directing personal assistance services.

(Authority: Sections 7(28), 102(b)(3)(B)(i)(I), and 103(a)(9) of the Act; 29 U.S.C. 705(28), 722(b)(3)(B)(i)(I), and 723(a)(9))

(40) *Physical and mental restoration services* means—

(i) Corrective surgery or therapeutic treatment that is likely, within a reasonable period of time, to correct or modify substantially a stable or slowly progressive physical or mental impairment that constitutes a substantial impediment to employment;

(ii) Diagnosis of and treatment for mental or emotional disorders by qualified personnel in accordance with State licensure laws;

(iii) Dentistry;

(iv) Nursing services;

(v) Necessary hospitalization (either inpatient or outpatient care) in connection with surgery or treatment and clinic services;

(vi) Drugs and supplies;

(vii) Prosthetic and orthotic devices;

(viii) Eyeglasses and visual services, including visual training, and the

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examination and services necessary for the prescription and provision of eyeglasses, contact lenses, microscopic lenses, telescopic lenses, and other special visual aids prescribed by personnel that are qualified in accordance with State licensure laws;

(ix) Podiatry;

(x) Physical therapy;

(xi) Occupational therapy;

(xii) Speech or hearing therapy;

(xiii) Mental health services;

(xiv) Treatment of either acute or chronic medical complications and emergencies that are associated with or arise out of the provision of physical and mental restoration services, or that are inherent in the condition under treatment;

(xv) Special services for the treatment of individuals with end-stage renal disease, including transplantation, dialysis, artificial kidneys, and supplies; and

(xvi) Other medical or medically related rehabilitation services.

(Authority: Sections 12(c) and 103(a)(6) of the Act; 29 U.S.C. 709(c) and 723(a)(6))

(41) *Physical or mental impairment* means—

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological, musculo-skeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin, and endocrine; or

(ii) Any mental or psychological disorder such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(Authority: Sections 7(20)(A) and 12(c) of the Act; 29 U.S.C. 705(20)(A) and 709(c))

(42) *Post-employment services* means one or more of the services identified in § 361.48 that are provided subsequent to the achievement of an employment outcome and that are necessary for an individual to maintain, regain, or advance in employment, consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

(Authority: Sections 12(c) and 103(a)(18) of the Act; 29 U.S.C. 709(c)) and 723(a)(18))

Note to paragraph (b)(42): Post-employment services are intended to ensure that the employment outcome remains consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice. These services are available to meet rehabilitation needs that do not require a complex and comprehensive provision of services and, thus, should be limited in scope and duration. If more comprehensive services are required, then a new rehabilitation effort should be considered. Post-employment services are to be provided under an amended individualized plan for employment; thus, a re-determination of eligibility is not required. The provision of post-employment services is subject to the same requirements in this part as the provision of any other vocational rehabilitation service. Post-employment services are available to assist an individual to maintain employment, *e.g.*, the individual's employment is jeopardized because of conflicts with supervisors or co-workers, and the individual needs mental health services and counseling to maintain the employment; to regain employment, *e.g.*, the individual's job is eliminated through reorganization and new placement services are needed; and to advance in employment, *e.g.*, the employment is no longer consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

(43) *Qualified and impartial mediator.*

(i) *Qualified and impartial mediator* means an individual who—

(A) Is not an employee of a public agency (other than an administrative law judge, hearing examiner, employee of a State office of mediators, or employee of an institution of higher education);

(B) Is not a member of the State Rehabilitation Council for the designated State unit;

(C) Has not been involved previously in the vocational rehabilitation of the applicant or eligible individual;

(D) Is knowledgeable of the vocational rehabilitation program and the applicable Federal and State laws, regulations, and policies governing the provision of vocational rehabilitation services;

(E) Has been trained in effective mediation techniques consistent with any State-approved or -recognized certification, licensing, registration, or other requirements; and

(F) Has no personal, professional, or financial interest that would be in conflict with the objectivity of the individual during the mediation proceedings.

(ii) An individual serving as a mediator is not considered to be an employee of the designated State agency or designated State unit for the purposes of this definition solely because the individual is paid by the designated State agency or designated State unit to serve as a mediator.

(Authority: Sections 12(c) and 102(c)(4) of the Act; 29 U.S.C. 709(c) and 722(c)(4))

(44) *Rehabilitation engineering* means the systematic application of engineering sciences to design, develop, adapt, test, evaluate, apply, and distribute technological solutions to problems confronted by individuals with disabilities in functional areas, such as mobility, communications, hearing, vision, and cognition, and in activities associated with employment, independent living, education, and integration into the community.

(Authority: Section 7(12)(c) of the Act; 29 U.S.C. 709(c))

(45) *Rehabilitation technology* means the systematic application of technologies, engineering methodologies, or scientific principles to meet the needs of, and address the barriers confronted by, individuals with disabilities in areas that include education, rehabilitation, employment, transportation, independent living, and recreation. The term includes rehabilitation engineering, assistive technology devices, and assistive technology services.

(Authority: Section 7(30) of the Act; 29 U.S.C. 705(30))

(46) *Reservation* means a Federal or State Indian reservation, public domain Indian allotment, former Indian reservation in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act.

(Authority: Section 121(c) of the Act; 29 U.S.C. 741(c))

(47) *Sole local agency* means a unit or combination of units of general local government or one or more Indian tribes that has the sole responsibility under an agreement with, and the supervision of, the State agency to conduct a local or tribal vocational rehabilitation program, in accordance with the State plan.

(Authority: Section 7(24) of the Act; 29 U.S.C. 705(24))

(48) *State* means any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(Authority: Section 7(32) of the Act; 29 U.S.C. 705(32))

(49) *State workforce investment board* means a State workforce investment board established under section 111 of the Workforce Investment Act of 1998.

(Authority: Section 7(33) of the Act; 29 U.S.C. 705(33))

(50) *Statewide workforce investment system* means a system described in section 111(d)(2) of the Workforce Investment Act of 1998.

(Authority: Section 7(34) of the Act; 29 U.S.C. 705(34))

(51) *State plan* means the State plan for vocational rehabilitation services submitted under § 361.10.

(Authority: Sections 12(c) and 101 of the Act; 29 U.S.C. 709(c) and 721)

(52) *Substantial impediment to employment* means that a physical or mental impairment (in light of attendant medical, psychological, vocational, educational, communication, and other related factors) hinders an individual from preparing for, entering into, engaging in, or retaining employment consistent with the individual's abilities and capabilities.

(Authority: Sections 7(20)(A) and 12(c) of the Act; 29 U.S.C. 705(20)(A) and 709(c))

(53) *Supported employment* means—

(i) Competitive employment in an integrated setting, or employment in integrated work settings in which individuals are working toward competitive employment, consistent with the strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice of the individuals with ongoing support services for individuals with the most significant disabilities—

(A) For whom competitive employment has not traditionally occurred or for whom competitive employment has been interrupted or intermittent as a result of a significant disability; and

(B) Who, because of the nature and severity of their disabilities, need intensive supported employment services from the designated State unit and extended services after transition as described in paragraph (b)(20) of this section to perform this work; or

(ii) Transitional employment, as defined in paragraph (b)(54) of this section, for individuals with the most significant disabilities due to mental illness.

(Authority: Section 7(35) of the Act; 29 U.S.C. 705(35))

(54) *Supported employment services* means ongoing support services and other appropriate services needed to support and maintain an individual with a most significant disability in supported employment that are provided by the designated State unit—

(i) For a period of time not to exceed 18 months, unless under special circumstances the eligible individual and the rehabilitation counselor or coordinator jointly agree to extend the time to achieve the employment outcome identified in the individualized plan for employment; and

(ii) Following transition, as post-employment services that are unavailable from an extended services provider and that are necessary to maintain or regain the job placement or advance in employment.

(Authority: Sections 7(36) and 12(c) of the Act; 29 U.S.C. 705(36) and 709(c))

(55) *Transition services* means a coordinated set of activities for a student designed within an outcome-oriented process that promotes movement from school to post-school activities, including postsecondary education, vocational training, integrated employment (including supported employment), continuing and adult education, adult services, independent living, or community participation. The coordinated set of activities must be based upon the individual student's needs, taking into account the student's preferences and interests, and must include instruction, community experiences, the development of employment and other post-school adult living objectives, and, if appropriate, acquisition of daily living skills and functional vocational evaluation. Transition services must promote or facilitate the achievement of the employment outcome identified in the student's individualized plan for employment.

(Authority: Section 7(37) and 103(a)(15) of the Act; 29 U.S.C. 705(37) and 723(a)(15))

(56) *Transitional employment*, as used in the definition of "Supported employment," means a series of temporary job placements in competitive work in integrated settings with ongoing support services for individuals with the most significant disabilities due to mental illness. In transitional employment, the provision of ongoing support services must include continuing sequential job placements until job permanency is achieved.

(Authority: Sections 7(35)(B) and 12(c) of the Act; 29 U.S.C. 705(35)(B) and 709(c)

(57) *Transportation* means travel and related expenses that are necessary to enable an applicant or eligible individual to participate in a vocational rehabilitation service, including expenses for training in the use of public transportation vehicles and systems.

(Authority: 103(a)(8) of the Act; 29 U.S.C. 723(a)(8))

(i) *Examples:* The following are examples of expenses that would meet the definition of transportation. The examples are purely illustrative, do not address all possible circumstances, and are not intended to substitute for individual counselor judgment.

Example 1: Travel and related expenses for a personal care attendant or aide if the services of that person are necessary to enable the applicant or eligible individual to travel to participate in any vocational rehabilitation service.

Example 2: The purchase and repair of vehicles, including vans, but not the modification of these vehicles, as modification would be considered a rehabilitation technology service.

Example 3: Relocation expenses incurred by an eligible individual in connection with a job placement that is a significant distance from the eligible individual's current residence.

(ii) [Reserved]

(58) *Vocational rehabilitation services*—

(i) If provided to an individual, means those services listed in § 361.48; and

(ii) If provided for the benefit of groups of individuals, also means those services listed in § 361.49.

(Authority: Sections 7(38) and 103(a) and (b) of the Act; 29 U.S.C. 705(38), 723(a) and (b))

Subpart B—State Plan and Other Requirements for Vocational Rehabilitation Services

§ 361.10 Submission, approval, and disapproval of the State plan.

(a) *Purpose.* For a State to receive a grant under this part, the designated State agency must submit to the Secretary, and obtain approval of, a State plan that contains a description of the State's vocational rehabilitation services program, the plans and policies to be followed in carrying out the program, and other information requested by the Secretary, in accordance with the requirements of this part.

(b) *Separate part relating to the vocational rehabilitation of individuals who are blind.* If a separate State agency administers or supervises the administration of a separate part of the State plan relating to the vocational rehabilitation of individuals who are blind, that part of the State plan must separately conform to all requirements under this part that are applicable to a State plan.

(c) *State unified plan.* The State may choose to submit the State plan for vocational rehabilitation services as part of the State unified plan under section 501 of the Workforce Investment Act of 1998. The portion of the State unified plan that includes the State plan for vocational rehabilitation services must meet the State plan requirements in this part.

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(d) *Public participation.* Prior to the adoption of any substantive policies or procedures governing the provision of vocational rehabilitation services under the State plan, including making any substantive amendment to those policies and procedures, the designated State agency must conduct public meetings throughout the State, in accordance with the requirements of § 361.20.

(e) *Duration.* The State plan remains in effect subject to the submission of modifications the State determines to be necessary or the Secretary may require based on a change in State policy, a change in Federal law, including regulations, an interpretation of the Act by a Federal court or the highest court of the State, or a finding by the Secretary of State noncompliance with the requirements of the Act or this part.

(f) *Submission of the State plan.* The State must submit the State plan for approval—

(1) To the Secretary on the same date that the State submits a State plan relating to the statewide workforce investment system under section 112 of the Workforce Investment Act of 1998;

(2) As part of the State unified plan submitted under section 501 of that Act; or

(3) To the Secretary on the same date that the State submits a State unified plan under section 501 of that Act that does not include the State plan under this part.

(g) *Annual submission.* (1) The State must submit to the Secretary for approval revisions to the State plan in accordance with paragraph (e) of this section and 34 CFR 76.140.

(2) The State must submit to the Secretary reports containing annual updates of the information required under §§ 361.18, 361.29, and 361.35 and any other updates of the information required under this part that are requested by the Secretary.

(3) The State is not required to submit policies, procedures, or descriptions required under this part that have been previously submitted to the Secretary and that demonstrate that the State meets the requirements of this part, including any policies, procedures, or descriptions submitted under this part that are in effect on August 6, 1998.

(h) *Approval.* The Secretary approves any State plan and any revisions to the State plan that conform to the requirements of this part and section 101(a) of the Act.

(i) *Disapproval.* The Secretary disapproves any State plan that does not conform to the requirements of this part and section 101(a) of the Act, in accordance with the following procedures:

(1) *Informal resolution.* Prior to disapproving any State plan, the Secretary attempts to resolve disputes informally with State officials.

(2) *Notice.* If, after reasonable effort has been made to resolve the dispute, no resolution has been reached, the Secretary provides notice to the State agency of the intention to disapprove the State plan and of the opportunity for a hearing.

(3) *State plan hearing.* If the State agency requests a hearing, the Secretary designates one or more individuals, either from the Department or elsewhere, not responsible for or connected with the administration of this Program, to conduct a hearing in accordance with the provisions of 34 CFR part 81, subpart A.

(4) *Initial decision.* The hearing officer issues an initial decision in accordance with 34 CFR 81.41.

(5) *Petition for review of an initial decision.* The State agency may seek the Secretary's review of the initial decision in accordance with 34 CFR part 81.

(6) *Review by the Secretary.* The Secretary reviews the initial decision in accordance with 34 CFR 81.43.

(7) *Final decision of the Department.* The final decision of the Department is made in accordance with 34 CFR 81.44.

(8) *Judicial review.* A State may appeal the Secretary's decision to disapprove the State plan by filing a petition for review with the United States Court of Appeals for the circuit in which the State is located, in accordance with section 107(d) of the Act.

(Authority: Sections 101(a) and (b), and 107(d) of the Act; 20 U.S.C. 1231g(a); and 29 U.S.C. 721(a) and (b), and 727(d))

§ 361.11 Withholding of funds.

(a) *Basis for withholding.* The Secretary may withhold or limit payments under section 111 or 622(a) of the Act, as provided by section 107(c) and (d) of the Act, if the Secretary determines that—

(1) The State plan, including the supported employment supplement, has been so changed that it no longer conforms with the requirements of this part or 34 CFR part 363; or

(2) In the administration of the State plan, there has been a failure to comply substantially with any provision of that plan or a program improvement plan established in accordance with section 106(b)(2) of the Act.

(b) *Informal resolution.* Prior to withholding or limiting payments in accordance with this section, the Secretary attempts to resolve disputed issues informally with State officials.

(c) *Notice.* If, after reasonable effort has been made to resolve the dispute, no resolution has been reached, the Secretary provides notice to the State agency of the intention to withhold or limit payments and of the opportunity for a hearing.

(d) *Withholding hearing.* If the State agency requests a hearing, the Secretary designates one or more individuals, either from the Department or elsewhere, not responsible for or connected with the administration of this Program, to conduct a hearing in accordance with the provisions of 34 CFR part 81, subpart A.

(e) *Initial decision.* The hearing officer issues an initial decision in accordance with 34 CFR 81.41.

(f) *Petition for review of an initial decision.* The State agency may seek the Secretary's review of the initial decision in accordance with 34 CFR 81.42.

(g) *Review by the Secretary.* The Secretary reviews the initial decision in accordance with 34 CFR 81.43.

(h) *Final decision of the Department.* The final decision of the Department is made in accordance with 34 CFR 81.44.

(i) *Judicial review.* A State may appeal the Secretary's decision to withhold or limit payments by filing a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, in accordance with section 107(d) of the Act.

(Authority: Sections 101(b), 107(c), and 107(d) of the Act; 29 U.S.C. 721(b), 727(c)(1) and (2), and 727(d))

Administration

§ 361.12 Methods of administration.

The State plan must assure that the State agency, and the designated State unit if applicable, employs methods of administration found necessary by the Secretary for the proper and efficient administration of the plan and for carrying out all functions for which the State is responsible under the plan and this part. These methods must include procedures to ensure accurate data collection and financial accountability.

(Authority: Sections 101(a)(6) and (a)(10)(A) of the Act; 29 U.S.C. 721(a)(6) and (a)(10)(A))

§ 361.13 State agency for administration.

(a) *Designation of State agency.* The State plan must designate a State agency as the sole State agency to administer the State plan, or to supervise its administration in a political subdivision of the State by a sole local agency, in accordance with the following requirements:

(1) *General.* Except as provided in paragraphs (a)(2) and (3) of this section, the State plan must provide that the designated State agency is one of the following types of agencies:

(i) A State agency that is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of individuals with disabilities; or

(ii) A State agency that includes a vocational rehabilitation unit as provided in paragraph (b) of this section.

(2) *American Samoa.* In the case of American Samoa, the State plan must designate the Governor.

(3) *Designated State agency for individuals who are blind.* If a State commission or other agency that provides assistance or services to individuals who are blind is authorized under State law to provide vocational rehabilitation services to individuals who are blind, and this commission or agency is primarily concerned with vocational rehabilitation or includes a vocational rehabilitation unit as provided in paragraph (b) of this section, the State plan may designate that agency as the sole State agency to administer the part of the plan under which vocational rehabilitation services are provided for individuals who are blind or to supervise its administration in a political subdivision of the State by a sole local agency.

(b) *Designation of State unit.*

(1) If the designated State agency is not of the type specified in paragraph (a)(1)(i) of this section or if the designated State agency specified in paragraph (a)(3) of this section is not primarily concerned with vocational rehabilitation or vocational and other rehabilitation of individuals with disabilities, the State plan must assure that the agency (or each agency if two agencies are designated) includes a vocational rehabilitation bureau, division, or unit that—

(i) Is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of individuals with disabilities and is responsible for the administration of the State agency's vocational rehabilitation program under the State plan;

(ii) Has a full-time director;

(iii) Has a staff, at least 90 percent of whom are employed full time on the rehabilitation work of the organizational unit; and

(iv) Is located at an organizational level and has an organizational status within the State agency comparable to that of other major organizational units of the agency.

(2) In the case of a State that has not designated a separate State agency for individuals who are blind, as provided for in paragraph (a)(3) of this section, the State may assign responsibility for the part of the plan under which vocational rehabilitation services are provided to individuals who are blind to one organizational unit of the designated State agency and may assign responsibility for the rest of the plan to another organizational unit of the designated State agency, with the provisions of paragraph (b)(1) of this section applying separately to each of these units.

(c) *Responsibility for administration.*

(1) At a minimum, the following activities are the responsibility of the designated State unit or the sole local agency under the supervision of the State unit:

(i) All decisions affecting eligibility for vocational rehabilitation services, the nature and scope of available services, and the provision of these services.

(ii) The determination to close the record of services of an individual who has achieved an employment outcome in accordance with § 361.56.

(iii) Policy formulation and implementation.

(iv) The allocation and expenditure of vocational rehabilitation funds.

(v) Participation as a partner in the One-Stop service delivery system under Title I of the Workforce Investment Act of 1998, in accordance with 20 CFR part 662.

(2) The responsibility for the functions described in paragraph (c)(1) of this section may not be delegated to any other agency or individual.

(Authority: Section 101(a)(2) of the Act; 29 U.S.C. 721(a)(2))

§ 361.14 Substitute State agency.

(a) *General provisions.*

(1) If the Secretary has withheld all funding from a State under § 361.11, the State may designate another agency to substitute for the designated State agency in carrying out the State's program of vocational rehabilitation services.

(2) Any public or nonprofit private organization or agency within the State or any political subdivision of the State is eligible to be a substitute agency.

(3) The substitute agency must submit a State plan that meets the requirements of this part.

(4) The Secretary makes no grant to a substitute agency until the Secretary approves its plan.

(b) *Substitute agency matching share.* The Secretary does not make any payment to a substitute agency unless it has provided assurances that it will contribute the same matching share as the State would have been required to contribute if the State agency were carrying out the vocational rehabilitation program.

(Authority: Section 107(c)(3) of the Act; 29 U.S.C. 727(c)(3))

§ 361.15 Local administration.

(a) If the State plan provides for the administration of the plan by a local agency, the designated State agency must—

(1) Ensure that each local agency is under the supervision of the designated State unit and is the sole local agency as defined in § 361.5(b)(47) that is responsible for the administration of the program within the political subdivision that it serves; and

(2) Develop methods that each local agency will use to administer the vocational rehabilitation program, in accordance with the State plan.

(b) A separate local agency serving individuals who are blind may administer that part of the plan relating to vocational rehabilitation of individuals who are blind, under the supervision of the designated State unit for individuals who are blind.

(Authority: Sections 7(24) and 101(a)(2)(A) of the Act; 29 U.S.C. 705(24) and 721(a)(2)(A))

§ 361.16 Establishment of an independent commission or a state rehabilitation council.

(a) *General requirement.* Except as provided in paragraph (b) of this section, the State plan must contain one of the following two assurances:

(1) An assurance that the designated State agency is an independent State commission that—

(i) Is responsible under State law for operating, or overseeing the operation of, the vocational rehabilitation program in the State and is primarily concerned with vocational rehabilitation or vocational and other rehabilitation services, in accordance with § 361.13(a)(1)(i);

(ii) Is consumer-controlled by persons who—

(A) Are individuals with physical or mental impairments that substantially limit major life activities; and

(B) Represent individuals with a broad range of disabilities, unless the designated State unit under the direction of the commission is the State agency for individuals who are blind;

(iii) Includes family members, advocates, or other representatives of individuals with mental impairments; and

(iv) Conducts the functions identified in § 361.17(h)(4).

(2) An assurance that—

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(i) The State has established a State Rehabilitation Council (Council) that meets the requirements of § 361.17;

(ii) The designated State unit, in accordance with § 361.29, jointly develops, agrees to, and reviews annually State goals and priorities and jointly submits to the Secretary annual reports of progress with the Council;

(iii) The designated State unit regularly consults with the Council regarding the development, implementation, and revision of State policies and procedures of general applicability pertaining to the provision of vocational rehabilitation services;

(iv) The designated State unit transmits to the Council—

(A) All plans, reports, and other information required under this part to be submitted to the Secretary;

(B) All policies and information on all practices and procedures of general applicability provided to or used by rehabilitation personnel providing vocational rehabilitation services under this part; and

(C) Copies of due process hearing decisions issued under this part and transmitted in a manner to ensure that the identity of the participants in the hearings is kept confidential; and

(v) The State plan, and any revision to the State plan, includes a summary of input provided by the Council, including recommendations from the annual report of the Council, the review and analysis of consumer satisfaction described in § 361.17(h)(4), and other reports prepared by the Council, and the designated State unit's response to the input and recommendations, including explanations of reasons for rejecting any input or recommendation of the Council.

(b) *Exception for separate State agency for individuals who are blind.* In the case of a State that designates a separate State agency under § 361.13(a)(3) to administer the part of the State plan under which vocational rehabilitation services are provided to individuals who are blind, the State must either establish a separate State Rehabilitation Council for each agency that does not meet the requirements in paragraph (a)(1) of this section or establish one State Rehabilitation Council for both agencies if neither agency meets the requirements of paragraph (a)(1) of this section.

(Authority: Sections 101(a)(21) of the Act; 29 U.S.C. 721(a)(21))

§ 361.17 Requirements for a state rehabilitation council.

If the State has established a Council under § 361.16(a)(2) or (b), the Council must meet the following requirements:

(a) *Appointment.*

(1) The members of the Council must be appointed by the Governor or, in the case of a State that, under State law, vests authority for the administration of the activities carried out under this part in an entity other than the Governor (such as one or more houses of the State legislature or an independent board), the chief officer of that entity.

(2) The appointing authority must select members of the Council after soliciting recommendations from representatives of organizations representing a broad range of individuals with disabilities and organizations interested in individuals with disabilities. In selecting members, the appointing authority must consider, to the greatest extent practicable, the extent to which minority populations are represented on the Council.

(b) *Composition.*

(1) *General.* Except as provided in paragraph (b)(3) of this section, the Council must be composed of at least 15 members, including—

(i) At least one representative of the Statewide Independent Living Council, who must be the chairperson or other designee of the Statewide Independent Living Council;

(ii) At least one representative of a parent training and information center established pursuant to section 682(a) of the Individuals with Disabilities Education Act;

(iii) At least one representative of the Client Assistance Program established under 34 CFR part 370, who must be the director of or other individual recommended by the Client Assistance Program;

(iv) At least one qualified vocational rehabilitation counselor with knowledge of and experience with vocational rehabilitation programs who serves as an ex officio, nonvoting member of the Council if employed by the designated State agency;

(v) At least one representative of community rehabilitation program service providers;

(vi) Four representatives of business, industry, and labor;

(vii) Representatives of disability groups that include a cross section of—

(A) Individuals with physical, cognitive, sensory, and mental disabilities; and

(B) Representatives of individuals with disabilities who have difficulty representing themselves or are unable due to their disabilities to represent themselves;

(viii) Current or former applicants for, or recipients of, vocational rehabilitation services;

(ix) In a State in which one or more projects are carried out under section 121 of the Act (American Indian Vocational Rehabilitation Services), at least one representative of the directors of the projects;

(x) At least one representative of the State educational agency responsible for the public education of students with disabilities who are eligible to receive services under this part and part B of the Individuals with Disabilities Education Act;

(xi) At least one representative of the State workforce investment board; and

(xii) The director of the designated State unit as an ex officio, nonvoting member of the Council.

(2) *Employees of the designated State agency.* Employees of the designated State agency may serve only as nonvoting members of the Council. This provision does not apply to the representative appointed pursuant to paragraph (b)(1)(iii) of this section.

(3) *Composition of a separate Council for a separate State agency for individuals who are blind.* Except as provided in paragraph (b)(4) of this section, if the State establishes a separate Council for a separate State agency for individuals who are blind, that Council must—

(i) Conform with all of the composition requirements for a Council under paragraph (b)(1) of this section, except the requirements in paragraph (b)(1)(vii), unless the exception in paragraph (b)(4) of this section applies; and

(ii) Include—

(A) At least one representative of a disability advocacy group representing individuals who are blind; and

(B) At least one representative of an individual who is blind, has multiple disabilities, and has difficulty representing himself or herself or is unable due to disabilities to represent himself or herself.

(4) *Exception.* If State law in effect on October 29, 1992 requires a separate Council under paragraph (b)(3) of this section to have fewer than 15 members, the separate Council is in compliance with the composition requirements in paragraphs (b)(1)(vi) and (b)(1)(viii) of this section if it includes at least one representative who meets the requirements for each of those paragraphs.

(c) *Majority.*

(1) A majority of the Council members must be individuals with disabilities who meet the requirements of § 361.5(b)(29) and are not employed by the designated State unit.

(2) In the case of a separate Council established under § 361.16(b), a majority of the Council members must be individuals who are blind and are not employed by the designated State unit.

(d) *Chairperson.* The chairperson must be—

(1) Selected by the members of the Council from among the voting members of the Council, subject to the veto power of the Governor; or

(2) In States in which the Governor does not have veto power pursuant to State law, the appointing authority described in paragraph (a)(1) of this section must designate a member of the Council to serve as the chairperson of the Council or must require the Council to designate a member to serve as chairperson.

(e) *Terms of appointment.*

(1) Each member of the Council must be appointed for a term of no more than 3 years, and each member of the Council, other than a representative identified in paragraph (b)(1)(iii) or (ix) of this section, may serve for no more than two consecutive full terms.

(2) A member appointed to fill a vacancy occurring prior to the end of the term for which the predecessor was appointed must be appointed for the remainder of the predecessor's term.

(3) The terms of service of the members initially appointed must be, as specified by the appointing authority as described in paragraph (a)(1) of this section, for varied numbers of years to ensure that terms expire on a staggered basis.

(f) *Vacancies.*

(1) A vacancy in the membership of the Council must be filled in the same manner as the original appointment, except the appointing authority as described in paragraph (a)(1) of this section may delegate the authority to fill that vacancy to the remaining members of the Council after making the original appointment.

(2) No vacancy affects the power of the remaining members to execute the duties of the Council.

(g) *Conflict of interest.* No member of the Council shall cast a vote on any matter that would provide direct financial benefit to the member or the member's organization or otherwise give the appearance of a conflict of interest under State law.

(h) *Functions.* The Council must, after consulting with the State workforce investment board—

(1) Review, analyze, and advise the designated State unit regarding the performance of the State unit's responsibilities under this part, particularly responsibilities related to—

(i) Eligibility, including order of selection;

(ii) The extent, scope, and effectiveness of services provided; and

(iii) Functions performed by State agencies that affect or potentially affect the ability of individuals with disabilities in achieving employment outcomes under this part;

(2) In partnership with the designated State unit—

(i) Develop, agree to, and review State goals and priorities in accordance with § 361.29(c); and

(ii) Evaluate the effectiveness of the vocational rehabilitation program and submit reports of progress to the Secretary in accordance with § 361.29(e);

(3) Advise the designated State agency and the designated State unit regarding activities carried out under this part and assist in the preparation of the State plan and amendments to the plan, applications, reports, needs assessments, and evaluations required by this part;

(4) To the extent feasible, conduct a review and analysis of the effectiveness of, and consumer satisfaction with—

(i) The functions performed by the designated State agency;

(ii) The vocational rehabilitation services provided by State agencies and other public and private entities responsible for providing vocational rehabilitation services to individuals with disabilities under the Act; and

(iii) The employment outcomes achieved by eligible individuals receiving services under this part, including the availability of health and other employment benefits in connection with those employment outcomes;

(5) Prepare and submit to the Governor and to the Secretary no later than 90 days after the end of the Federal fiscal year an annual report on the status of vocational rehabilitation programs operated within the State and make the report available to the public through appropriate modes of communication;

(6) To avoid duplication of efforts and enhance the number of individuals served, coordinate activities with the activities of other councils within the State, including the Statewide Independent Living Council established under 34 CFR part 364, the advisory panel established under section 612(a)(21) of the Individuals with Disabilities Education Act, the State Developmental Disabilities Planning Council described in section 124 of the Developmental Disabilities Assistance and Bill of Rights Act, the State mental health planning council established under section 1914(a) of the Public Health Service Act, and the State workforce investment board;

(7) Provide for coordination and the establishment of working relationships between the designated State agency and the Statewide Independent Living Council and centers for independent living within the State; and

(8) Perform other comparable functions, consistent with the purpose of this part, as the Council determines to be appropriate, that are comparable to the other functions performed by the Council.

(i) *Resources.*

(1) The Council, in conjunction with the designated State unit, must prepare a plan for the provision of resources, including staff and other personnel, that may be necessary and sufficient for the Council to carry out its functions under this part.

(2) The resource plan must, to the maximum extent possible, rely on the use of resources in existence during the period of implementation of the plan.

(3) Any disagreements between the designated State unit and the Council regarding the amount of resources necessary to carry out the functions of the Council must be resolved by the Governor, consistent with paragraphs (i)(1) and (2) of this section.

(4) The Council must, consistent with State law, supervise and evaluate the staff and personnel that are necessary to carry out its functions.

(5) Those staff and personnel that are assisting the Council in carrying out its functions may not be assigned duties by the designated State unit or any other agency or office of the State that would create a conflict of interest.

(j) *Meetings.* The Council must—

(1) Convene at least four meetings a year in locations determined by the Council to be necessary to conduct Council business. The meetings must be publicly announced, open, and accessible to the general public, including individuals with disabilities, unless there is a valid reason for an executive session; and

(2) Conduct forums or hearings, as appropriate, that are publicly announced, open, and accessible to the public, including individuals with disabilities.

(k) *Compensation.* Funds appropriated under Title I of the Act, except funds to carry out sections 112 and 121 of the Act, may be used to compensate and reimburse the expenses of Council members in accordance with section 105(g) of the Act.

(Authority: Section 105 of the Act; 29 U.S.C. 725)

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§ 361.18 Comprehensive system of personnel development.

The State plan must describe the procedures and activities the State agency will undertake to establish and maintain a comprehensive system of personnel development designed to ensure an adequate supply of qualified rehabilitation personnel, including professionals and paraprofessionals, for the designated State unit. If the State agency has a State Rehabilitation Council, this description must, at a minimum, specify that the Council has an opportunity to review and comment on the development of plans, policies, and procedures necessary to meet the requirements of paragraphs (b) through (d) of this section. This description must also conform with the following requirements:

(a) *Data system on personnel and personnel development.* The State plan must describe the development and maintenance of a system by the State agency for collecting and analyzing on an annual basis data on qualified personnel needs and personnel development, in accordance with the following requirements:

(1) Data on qualified personnel needs must include—

(i) The number of personnel who are employed by the State agency in the provision of vocational rehabilitation services in relation to the number of individuals served, broken down by personnel category;

(ii) The number of personnel currently needed by the State agency to provide vocational rehabilitation services, broken down by personnel category; and

(iii) Projections of the number of personnel, broken down by personnel category, who will be needed by the State agency to provide vocational rehabilitation services in the State in 5 years based on projections of the number of individuals to be served, including individuals with significant disabilities, the number of personnel expected to retire or leave the field, and other relevant factors.

(2) Data on personnel development must include—

(i) A list of the institutions of higher education in the State that are preparing vocational rehabilitation professionals, by type of program;

(ii) The number of students enrolled at each of those institutions, broken down by type of program; and

(iii) The number of students who graduated during the prior year from each of those institutions with certification or licensure, or with the credentials for certification or licensure, broken down by the personnel category for which they have received, or have the credentials to receive, certification or licensure.

(b) *Plan for recruitment, preparation, and retention of qualified personnel.* The State plan must describe the development, updating, and implementation of a plan to address the current and projected needs for personnel who are qualified in accordance with paragraph (c) of this section. The plan must identify the personnel needs based on the data collection and analysis system described in paragraph (a) of this section and must provide for the coordination and facilitation of efforts between the designated State unit and institutions of higher education and professional associations to recruit, prepare, and retain personnel who are qualified in accordance with paragraph (c) of this section, including personnel from minority backgrounds and personnel who are individuals with disabilities.

(c) *Personnel standards.*

(1) The State plan must include the State agency's policies and describe the procedures the State agency will undertake to establish and maintain standards to ensure that all professional and paraprofessional personnel needed within the designated State unit to carry out this part are appropriately and adequately prepared and trained, including—

(i) Standards that are consistent with any national or State-approved or -recognized certification, licensing, or registration requirements, or, in the absence of these requirements, other comparable requirements (including State personnel requirements) that apply to the profession or discipline in which that category of personnel is providing vocational rehabilitation services; and

(ii) To the extent that existing standards are not based on the highest requirements in the State, the steps the State is currently taking and the steps the State plans to take to retrain or hire personnel to meet standards that are based on the highest requirements in the State, including measures to notify State-unit personnel, the institutions of higher education identified under paragraph (a)(2)(i) of this section, and other public agencies of these steps and the timelines for taking each step. The steps taken by the State unit under this paragraph must be described in a written plan that includes—

(A) Specific strategies for retraining, recruiting, and hiring personnel;

(B) The specific time period by which all State unit personnel will meet the standards described in paragraph (c)(1)(i) of this section;

(C) Procedures for evaluating the State unit's progress in hiring or retraining personnel to meet applicable personnel standards within the time period established under paragraph (c)(1)(ii)(B) of this section; and

(D) In instances in which the State unit is unable to immediately hire new personnel who meet the requirements in paragraph (c)(1)(i) of this section, the initial minimum qualifications that the designated State unit will require of newly hired personnel and a plan for training those individuals to meet applicable requirements within the time period established under paragraph (c)(1)(ii)(B) of this section.

(2) As used in this section—

(i) *Highest requirements in the State applicable to that profession or discipline* means the highest entry-level academic degree needed for any national or State-approved or -recognized certification, licensing, registration, or, in the absence of these requirements, other comparable requirements that apply to that profession or discipline. The current requirements of all State statutes and regulations of other agencies in the State applicable to that profession or discipline must be considered and must be kept on file by the designated State unit and available to the public.

(ii) *Profession or discipline* means a specific occupational category, including any paraprofessional occupational category, that—

(A) Provides rehabilitation services to individuals with disabilities;

(B) Has been established or designated by the State unit; and

(C) Has a specified scope of responsibility.

(d) *Staff development.*

(1) The State plan must include the State agency's policies and describe the procedures and activities the State agency will undertake to ensure that all personnel employed by the State unit receive appropriate and adequate training, including a description of—

(i) A system of staff development for rehabilitation professionals and paraprofessionals within the State unit, particularly with respect to assessment, vocational counseling, job placement, and rehabilitation technology; and

(ii) Procedures for acquiring and disseminating to rehabilitation professionals and paraprofessionals within the designated State unit significant knowledge from research and other sources.

(2) The specific training areas for staff development must be based on the

needs of each State unit and may include, but are not limited to—

(i) Training regarding the Workforce Investment Act of 1998 and the amendments to the Rehabilitation Act of 1973 made by the Rehabilitation Act Amendments of 1998;

(ii) Training with respect to the requirements of the Americans with Disabilities Act, the Individuals with Disabilities Education Act, and Social Security work incentive programs, including programs under the Ticket to Work and Work Incentives Improvement Act of 1999, training to facilitate informed choice under this program, and training to improve the provision of services to culturally diverse populations; and

(iii) Activities related to—

(A) Recruitment and retention of qualified rehabilitation personnel;

(B) Succession planning; and

(C) Leadership development and capacity building.

(e) *Personnel to address individual communication needs.* The State plan must describe how the State unit—

(1) Includes among its personnel, or obtains the services of, individuals able to communicate in the native languages of applicants and eligible individuals who have limited English speaking ability; and

(2) Includes among its personnel, or obtains the services of, individuals able to communicate with applicants and eligible individuals in appropriate modes of communication.

(f) *Coordination with personnel development under the Individuals with Disabilities Education Act.* The State plan must describe the procedures and activities the State agency will undertake to coordinate its comprehensive system of personnel development under the Act with personnel development under the Individuals with Disabilities Education Act.

(Authority: Section 101(a)(7) of the Act; 29 U.S.C. 721(a)(7))

§ 361.19 Affirmative action for individuals with disabilities.

The State plan must assure that the State agency takes affirmative action to employ and advance in employment qualified individuals with disabilities covered under and on the same terms and conditions as stated in section 503 of the Act.

(Authority: Section 101(a)(6)(B) of the Act; 29 U.S.C. 721(a)(6)(B))

§ 361.20 Public participation requirements.

(a) *Conduct of public meetings.* The State plan must assure that prior to the adoption of any substantive policies or procedures governing the provision of vocational rehabilitation services under the State plan, including making any substantive amendments to the policies and procedures, the designated State agency conducts public meetings throughout the State to provide the public, including individuals with disabilities, an opportunity to comment on the policies or procedures.

(b) *Notice requirements.* The State plan must assure that the designated State agency, prior to conducting the public meetings, provides appropriate and sufficient notice throughout the State of the meetings in accordance with—

(1) State law governing public meetings; or

(2) In the absence of State law governing public meetings, procedures developed by the designated State agency in consultation with the State Rehabilitation Council.

(c) *Summary of input of the State Rehabilitation Council.* The State plan must provide a summary of the input of the State Rehabilitation Council, if the State agency has a Council, into the State plan and any amendment to the plan, in accordance with § 361.16(a)(2)(v).

(d) *Special consultation requirements.* The State plan must assure that the State agency actively consults with the director of the Client Assistance Program, the State Rehabilitation Council, if the State agency has a Council, and, as appropriate, Indian tribes, tribal organizations, and native Hawaiian organizations on its policies and procedures governing the provision of vocational rehabilitation services under the State plan.

(e) *Appropriate modes of communication.* The State unit must provide to the public, through appropriate modes of communication, notices of the public meetings, any materials furnished prior to or during the public meetings, and the policies and procedures governing the provision of vocational rehabilitation services under the State plan.

(Authority: Sections 101(a)(16)(A) and 105(c)(3) of the Act; 29 U.S.C. 721(a)(16)(A), and 725(c)(3))

§ 361.21 Consultations regarding the administration of the state plan.

The State plan must assure that, in connection with matters of general policy arising in the administration of the State plan, the designated State agency takes into account the views of—

(a) Individuals and groups of individuals who are recipients of vocational rehabilitation services or, as appropriate, the individuals' representatives;

(b) Personnel working in programs that provide vocational rehabilitation services to individuals with disabilities;

(c) Providers of vocational rehabilitation services to individuals with disabilities;

(d) The director of the Client Assistance Program; and

(e) The State Rehabilitation Council, if the State has a Council.

(Authority: Sections 101(a)(16)(B) of the Act; 29 U.S.C. 721(a)(16)(B))

§ 361.22 Coordination with education officials.

(a) *Plans, policies, and procedures.* (1) The State plan must contain plans, policies, and procedures for coordination between the designated State agency and education officials responsible for the public education of students with disabilities that are designed to facilitate the transition of students with disabilities from the receipt of educational services in school to the receipt of vocational rehabilitation services under the responsibility of the designated State agency.

(2) These plans, policies, and procedures in paragraph (a)(1) of this section must provide for the development and approval of an individualized plan for employment in accordance with § 361.45 as early as possible during the transition planning process but, at the latest, by the time each student determined to be eligible for vocational rehabilitation services leaves the school setting or, if the designated State unit is operating under an order of selection, before each eligible student able to be served under the order leaves the school setting.

(b) *Formal interagency agreement.* The State plan must include information on a formal interagency agreement with the State educational agency that, at a minimum, provides for—

(1) Consultation and technical assistance to assist educational agencies in planning for the transition of students with disabilities from school to post-school activities, including vocational rehabilitation services;

(2) Transition planning by personnel of the designated State agency and educational agency personnel for students with disabilities that facilitates the development and completion of their individualized education programs (IEPs) under section 614(d) of the Individuals with Disabilities Education Act;

(3) The roles and responsibilities, including financial responsibilities, of

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each agency, including provisions for determining State lead agencies and qualified personnel responsible for transition services; and

(4) Procedures for outreach to and identification of students with disabilities who are in need of transition services. Outreach to these students should occur as early as possible during the transition planning process and must include, at a minimum, a description of the purpose of the vocational rehabilitation program, eligibility requirements, application procedures, and scope of services that may be provided to eligible individuals.

(Authority: Section 101(a)(11)(D) of the Act; 29 U.S.C. 721 (a)(11)(D))

§ 361.23 Requirements related to the statewide workforce investment system.

(a) *Responsibilities as a partner of the One-Stop service delivery system.* As a required partner in the One-Stop service delivery system (which is part of the statewide workforce investment system under Title I of the Workforce Investment Act of 1998), the designated State unit must carry out the following functions consistent with the Act, this part, Title I of the Workforce Investment Act of 1998, and the regulations in 20 CFR part 662:

(1) Make available to participants through the One-Stop service delivery system the core services (as described in 20 CFR 662.240) that are applicable to the Program administered by the designated State unit under this part.

(2) Use a portion of funds made available to the Program administered by the designated State unit under this part, consistent with the Act and this part, to—

(i) Create and maintain the One-Stop service delivery system; and

(ii) Provide core services (as described in 20 CFR 662.240).

(3) Enter into a memorandum of understanding (MOU) with the Local Workforce Investment Board under section 117 of the Workforce Investment Act of 1998 relating to the operation of the One-Stop service delivery system that meets the requirements of section 121(c) of the Workforce Investment Act and 20 CFR 662.300, including a description of services, how the cost of the identified services and operating costs of the system will be funded, and methods for referrals.

(4) Participate in the operation of the One-Stop service delivery system consistent with the terms of the MOU and the requirements of the Act and this part.

(5) Provide representation on the Local Workforce Investment Board under section 117 of the Workforce Investment Act of 1998.

(b) *Cooperative agreements with One-Stop partners.* (1) The State plan must assure that the designated State unit or the designated State agency enters into cooperative agreements with the other entities that are partners under the One-Stop service delivery system under Title I of the Workforce Investment Act of 1998 and replicates those agreements at the local level between individual offices of the designated State unit and local entities carrying out the One-Stop service delivery system or other activities through the statewide workforce investment system.

(2) Cooperative agreements developed under paragraph (b)(1) of this section may provide for—

(i) Intercomponent training and technical assistance regarding—

(A) The availability and benefits of, and information on eligibility standards for, vocational rehabilitation services; and

(B) The promotion of equal, effective and meaningful participation by individuals with disabilities in the One-Stop service delivery system and other workforce investment activities through the promotion of program accessibility consistent with the requirements of the Americans with Disabilities Act of 1990 and section 504 of the Act, the use of nondiscriminatory policies and procedures, and the provision of reasonable accommodations, auxiliary aids and services, and rehabilitation technology for individuals with disabilities;

(ii) The use of information and financial management systems that link all of the partners of the One-Stop service delivery system to one another and to other electronic networks, including nonvisual electronic networks, and that relate to subjects such as employment statistics, job vacancies, career planning, and workforce investment activities;

(iii) The use of customer service features such as common intake and referral procedures, customer databases, resource information, and human services hotlines;

(iv) The establishment of cooperative efforts with employers to facilitate job placement and carry out other activities that the designated State unit and the employers determine to be appropriate;

(v) The identification of staff roles, responsibilities, and available resources and specification of the financial responsibility of each partner of the One-Stop service delivery system with respect to providing and paying for necessary services, consistent with the requirements of the Act, this part, other Federal requirements, and State law; and

(vi) The specification of procedures for resolving disputes among partners of the One-Stop service delivery system.

(Authority: Section 101(a)(11)(A) of the Act; 29 U.S.C. 721(a)(11)(A); Sections 121 and 134 of the Workforce Investment Act of 1998; 29 U.S.C. 2841 and 2864)

§ 361.24 Cooperation and coordination with other entities.

(a) *Interagency cooperation.* The State plan must describe the designated State agency's cooperation with and use of the services and facilities of Federal, State, and local agencies and programs, including programs carried out by the Under Secretary for Rural Development of the Department of Agriculture and State use contracting programs, to the extent that those agencies and programs are not carrying out activities through the statewide workforce investment system.

(b) *Coordination with the Statewide Independent Living Council and independent living centers.* The State plan must assure that the designated State unit, the Statewide Independent Living Council established under 34 CFR part 364, and the independent living centers established under 34 CFR part 366 have developed working relationships and coordinate their activities.

(c) *Cooperative agreement with recipients of grants for services to American Indians.*

(1) *General.* In applicable cases, the State plan must assure that the designated State agency has entered into a formal cooperative agreement with each grant recipient in the State that receives funds under part C of the Act (American Indian Vocational Rehabilitation Services).

(2) *Contents of formal cooperative agreement.* The agreement required under paragraph (a)(1) of this section must describe strategies for collaboration and coordination in providing vocational rehabilitation services to American Indians who are individuals with disabilities, including—

(i) Strategies for interagency referral and information sharing that will assist in eligibility determinations and the development of individualized plans for employment;

(ii) Procedures for ensuring that American Indians who are individuals with disabilities and are living near a reservation or tribal service area are provided vocational rehabilitation services; and

(iii) Provisions for sharing resources in cooperative studies and assessments, joint training activities, and other collaborative activities designed to improve the provision of services to American Indians who are individuals with disabilities.

(d) *Reciprocal referral services between two designated State units in the same State.* If there is a separate designated State unit for individuals who are blind, the two designated State units must establish reciprocal referral services, use each other's services and facilities to the extent feasible, jointly plan activities to improve services in the State for individuals with multiple impairments, including visual impairments, and otherwise cooperate to provide more effective services, including, if appropriate, entering into a written cooperative agreement.

(Authority: Sections 12(c) and 101(a)(11)(C), (E), and (F) of the Act; 29 U.S.C. 709(c) and 721(a)(11) (C), (E), and (F))

§ 361.25 Statewideness.

The State plan must assure that services provided under the State plan will be available in all political subdivisions of the State, unless a waiver of statewideness is requested and approved in accordance with § 361.26.

(Authority: Section 101(a)(4) of the Act; 29 U.S.C. 721(a)(4))

§ 361.26 Waiver of statewideness.

(a) *Availability.* The State unit may provide services in one or more political subdivisions of the State that increase services or expand the scope of services that are available statewide under the State plan if—

(1) The non-Federal share of the cost of these services is met from funds provided by a local public agency, including funds contributed to a local public agency by a private agency, organization, or individual;

(2) The services are likely to promote the vocational rehabilitation of substantially larger numbers of individuals with disabilities or of individuals with disabilities with particular types of impairments; and

(3) For purposes other than those specified in § 361.60(b)(3)(i) and consistent with the requirements in § 361.60(b)(3)(ii), the State includes in its State plan, and the Secretary approves, a waiver of the statewideness requirement, in accordance with the requirements of paragraph (b) of this section.

(b) *Request for waiver.* The request for a waiver of statewideness must—

(1) Identify the types of services to be provided;

(2) Contain a written assurance from the local public agency that it will make available to the State unit the non-Federal share of funds;

(3) Contain a written assurance that State unit approval will be obtained for each proposed service before it is put into effect; and

(4) Contain a written assurance that all other State plan requirements, including a State's order of selection requirements, will apply to all services approved under the waiver.

(Authority: Section 101(a)(4) of the Act; 29 U.S.C. 721(a)(4))

§ 361.27 Shared funding and administration of joint programs.

(a) If the State plan provides for the designated State agency to share funding and administrative responsibility with another State agency or local public agency to carry out a joint program to provide services to individuals with disabilities, the State must submit to the Secretary for approval a plan that describes its shared funding and administrative arrangement.

(b) The plan under paragraph (a) of this section must include—

(1) A description of the nature and scope of the joint program;

(2) The services to be provided under the joint program;

(3) The respective roles of each participating agency in the administration and provision of services; and

(4) The share of the costs to be assumed by each agency.

(c) If a proposed joint program does not comply with the statewideness requirement in § 361.25, the State unit must obtain a waiver of statewideness, in accordance with § 361.26.

(Authority: Section 101(a)(2)(A) of the Act; 29 U.S.C. 721(a)(2)(A))

§ 361.28 Third-party cooperative arrangements involving funds from other public agencies.

(a) The designated State unit may enter into a third-party cooperative arrangement for providing or administering vocational rehabilitation services with another State agency or a local public agency that is furnishing part or all of the non-Federal share, if the designated State unit ensures that—

(1) The services provided by the cooperating agency are not the customary or typical services provided by that agency but are new services that have a vocational rehabilitation focus or existing services that have been modified, adapted, expanded, or reconfigured to have a vocational rehabilitation focus;

(2) The services provided by the cooperating agency are only available to applicants for, or recipients of, services from the designated State unit;

(3) Program expenditures and staff providing services under the cooperative arrangement are under the administrative supervision of the designated State unit; and

(4) All State plan requirements, including a State's order of selection, will apply to all services provided under the cooperative program.

(b) If a third party cooperative agreement does not comply with the statewideness requirement in § 361.25, the State unit must obtain a waiver of statewideness, in accordance with § 361.26.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

§ 361.29 Statewide assessment; annual estimates; annual State goals and priorities; strategies; and progress reports.

(a) *Comprehensive statewide assessment.* (1) The State plan must include—

(i) The results of a comprehensive, statewide assessment, jointly conducted by the designated State unit and the State Rehabilitation Council (if the State unit has a Council) every 3 years describing the rehabilitation needs of individuals with disabilities residing within the State, particularly the vocational rehabilitation services needs of—

(A) Individuals with the most significant disabilities, including their need for supported employment services;

(B) Individuals with disabilities who are minorities and individuals with disabilities who have been unserved or underserved by the vocational rehabilitation program carried out under this part; and

(C) Individuals with disabilities served through other components of the statewide workforce investment system as identified by those individuals and personnel assisting those individuals through the components of the system; and

(ii) An assessment of the need to establish, develop, or improve community rehabilitation programs within the State.

(2) The State plan must assure that the State will submit to the Secretary a report containing information regarding updates to the assessments under paragraph (a) of this section for any year in which the State updates the assessments.

(b) *Annual estimates.* The State plan must include, and must assure that the State will annually submit a report to the Secretary that includes, State estimates of—

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(1) The number of individuals in the State who are eligible for services under this part;

(2) The number of eligible individuals who will receive services provided with funds provided under part B of Title I of the Act and under part B of Title VI of the Act, including, if the designated State agency uses an order of selection in accordance with § 361.36, estimates of the number of individuals to be served under each priority category within the order; and

(3) The costs of the services described in paragraph (b)(1) of this section, including, if the designated State agency uses an order of selection, the service costs for each priority category within the order.

(c) *Goals and priorities.*

(1) *In general.* The State plan must identify the goals and priorities of the State in carrying out the program.

(2) *Council.* The goals and priorities must be jointly developed, agreed to, reviewed annually, and, as necessary, revised by the designated State unit and the State Rehabilitation Council, if the State unit has a Council.

(3) *Submission.* The State plan must assure that the State will submit to the Secretary a report containing information regarding revisions in the goals and priorities for any year in which the State revises the goals and priorities.

(4) *Basis for goals and priorities.* The State goals and priorities must be based on an analysis of—

(i) The comprehensive statewide assessment described in paragraph (a) of this section, including any updates to the assessment;

(ii) The performance of the State on the standards and indicators established under section 106 of the Act; and

(iii) Other available information on the operation and the effectiveness of the vocational rehabilitation program carried out in the State, including any reports received from the State Rehabilitation Council under § 361.17(h) and the findings and recommendations from monitoring activities conducted under section 107 of the Act.

(5) *Service and outcome goals for categories in order of selection.* If the designated State agency uses an order of selection in accordance with § 361.36, the State plan must identify the State's service and outcome goals and the time within which these goals may be achieved for individuals in each priority category within the order.

(d) *Strategies.* The State plan must describe the strategies the State will use to address the needs identified in the assessment conducted under paragraph (a) of this section and achieve the goals and priorities identified in paragraph (c) of this section, including—

(1) The methods to be used to expand and improve services to individuals with disabilities, including how a broad range of assistive technology services and assistive technology devices will be provided to those individuals at each stage of the rehabilitation process and how those services and devices will be provided to individuals with disabilities on a statewide basis;

(2) Outreach procedures to identify and serve individuals with disabilities who are minorities and individuals with disabilities who have been unserved or underserved by the vocational rehabilitation program;

(3) As applicable, the plan of the State for establishing, developing, or improving community rehabilitation programs;

(4) Strategies to improve the performance of the State with respect to the evaluation standards and performance indicators established pursuant to section 106 of the Act; and

(5) Strategies for assisting other components of the statewide workforce investment system in assisting individuals with disabilities.

(e) *Evaluation and reports of progress.*

(1) The State plan must include—

(i) The results of an evaluation of the effectiveness of the vocational rehabilitation program; and

(ii) A joint report by the designated State unit and the State Rehabilitation Council, if the State unit has a Council, to the Secretary on the progress made in improving the effectiveness of the program from the previous year. This evaluation and joint report must include—

(A) An evaluation of the extent to which the goals and priorities identified in paragraph (c) of this section were achieved;

(B) A description of the strategies that contributed to the achievement of the goals and priorities;

(C) To the extent to which the goals and priorities were not achieved, a description of the factors that impeded that achievement; and

(D) An assessment of the performance of the State on the standards and indicators established pursuant to section 106 of the Act.

(2) The State plan must assure that the designated State unit and the State Rehabilitation Council, if the State unit has a Council, will jointly submit to the Secretary an annual report that contains the information described in paragraph (e)(1) of this section.

(Authority: Section 101(a)(15) of the Act; 29 U.S.C. 721(a)(15))

§ 361.30 Services to American Indians.

The State plan must assure that the designated State agency provides vocational rehabilitation services to American Indians who are individuals with disabilities residing in the State to the same extent as the designated State agency provides vocational rehabilitation services to other significant populations of individuals with disabilities residing in the State.

(Authority: Sections 101(a)(13) and 121(b)(3) of the Act; 29 U.S.C. 721(a)(13) and 741(b)(3))

§ 361.31 Cooperative agreements with private nonprofit organizations.

The State plan must describe the manner in which cooperative agreements with private nonprofit vocational rehabilitation service providers will be established.

(Authority: Sections 101(a)(24)(B); 29 U.S.C. 721(a)(24)(B))

§ 361.32 Use of profitmaking organizations for on-the-job training in connection with selected projects.

The State plan must assure that the designated State agency has the authority to enter into contracts with for-profit organizations for the purpose of providing, as vocational rehabilitation services, on-the-job training and related programs for individuals with disabilities under the Projects With Industry program, 34 CFR part 379, if the designated State agency has determined that for-profit agencies are better qualified to provide needed vocational rehabilitation services than nonprofit agencies and organizations.

(Authority: Section 101(a)(24)(A) of the Act; 29 U.S.C. 721(a)(24)(A))

§ 361.33 [Reserved]

§ 361.34 Supported employment State plan supplement.

(a) The State plan must assure that the State has an acceptable plan under 34 CFR part 363 that provides for the use of funds under that part to supplement funds under this part for the cost of services leading to supported employment.

(b) The supported employment plan, including any needed annual revisions, must be submitted as a supplement to the State plan submitted under this part.

(Authority: Sections 101(a)(22) and 625(a) of the Act; 29 U.S.C. 721(a)(22) and 795(k))

§ 361.35 Innovation and expansion activities.

(a) The State plan must assure that the State will reserve and use a portion of the funds allotted to the State under section 110 of the Act—

(1) For the development and implementation of innovative approaches to expand and improve the provision of vocational rehabilitation services to individuals with disabilities, particularly individuals with the most significant disabilities, consistent with the findings of the comprehensive, statewide assessment of the rehabilitation needs of individuals with disabilities under § 361.29(a) and the State's goals and priorities under § 361.29(c); and

(2) To support the funding of—

(i) The State Rehabilitation Council, if the State has a Council, consistent with the resource plan identified in § 361.17(i); and

(ii) The Statewide Independent Living Council, consistent with the plan prepared under 34 CFR 364.21(i).

(b) The State plan must—

(1) Describe how the reserved funds will be used; and

(2) Include, on an annual basis, a report describing how the reserved funds were used during the preceding year.

(Authority: Section 101(a)(18) of the Act; 29 U.S.C. 721(a)(18))

§ 361.36 Ability to serve all eligible individuals; order of selection for services.

(a) *General provisions.*

(1) The designated State unit either must be able to provide the full range of services listed in section 103(a) of the Act and § 361.48, as appropriate, to all eligible individuals or, in the event that vocational rehabilitation services cannot be provided to all eligible individuals in the State who apply for the services, include in the State plan the order to be followed in selecting eligible individuals to be provided vocational rehabilitation services.

(2) The ability of the designated State unit to provide the full range of vocational rehabilitation services to all eligible individuals must be supported by a determination that satisfies the requirements of paragraph (b) or (c) of this section and a determination that, on the basis of the designated State unit's projected fiscal and personnel resources and its assessment of the rehabilitation needs of individuals with significant disabilities within the State, it can—

(i) Continue to provide services to all individuals currently receiving services;

(ii) Provide assessment services to all individuals expected to apply for services in the next fiscal year;

(iii) Provide services to all individuals who are expected to be determined eligible in the next fiscal year; and

(iv) Meet all program requirements.

(3) If the designated State unit is unable to provide the full range vocational rehabilitation services to all eligible individuals in the State who apply for the services, the State plan must—

(i) Show the order to be followed in selecting eligible individuals to be provided vocational rehabilitation services;

(ii) Provide a justification for the order of selection;

(iii) Identify service and outcome goals and the time within which the goals may be achieved for individuals in each priority category within the order, as required under § 361.29(c)(5); and

(iv) Assure that—

(A) In accordance with criteria established by the State for the order of selection, individuals with the most significant disabilities will be selected first for the provision of vocational rehabilitation services; and

(B) Individuals who do not meet the order of selection criteria will have access to services provided through the information and referral system established under § 361.37.

(b) *Basis for assurance that services can be provided to all eligible individuals.*

(1) For a designated State unit that determined, for the current fiscal year and the preceding fiscal year, that it is able to provide the full range of services, as appropriate, to all eligible individuals, the State unit, during the current fiscal and preceding fiscal year, must have in fact—

(i) Provided assessment services to all applicants and the full range of services, as appropriate, to all eligible individuals;

(ii) Made referral forms widely available throughout the State;

(iii) Conducted outreach efforts to identify and serve individuals with disabilities who have been unserved or underserved by the vocational rehabilitation system; and

(iv) Not delayed, through waiting lists or other means, determinations of eligibility, the development of individualized plans for employment for individuals determined eligible for vocational rehabilitation services, or the provision of services for eligible individuals for whom individualized plans for employment have been developed.

(2) For a designated State unit that was unable to provide the full range of services to all eligible individuals during the current or preceding fiscal year or that has not met the requirements in paragraph (b)(1) of this section, the determination that the designated State unit is able to provide the full range of vocational rehabilitation services to all eligible individuals in the next fiscal year must be based on—

(i) Circumstances that have changed that will allow the designated State unit to meet the requirements of paragraph (a)(2) of this section in the next fiscal year, including—

(A) An estimate of the number of and projected costs of serving, in the next fiscal year, individuals with existing individualized plans for employment;

(B) The projected number of individuals with disabilities who will apply for services and will be determined eligible in the next fiscal year and the projected costs of serving those individuals;

(C) The projected costs of administering the program in the next fiscal year, including, but not limited to, costs of staff salaries and benefits, outreach activities, and required statewide studies; and

(D) The projected revenues and projected number of qualified personnel for the program in the next fiscal year;

(ii) Comparable data, as relevant, for the current or preceding fiscal year, or for both years, of the costs listed in paragraphs (b)(2)(i)(A) through (C) of this section and the resources identified in paragraph (b)(2)(i)(D) of this section and an explanation of any projected increases or decreases in these costs and resources; and

(iii) A determination that the projected revenues and the projected number of qualified personnel for the program in the next fiscal year are adequate to cover the costs identified in paragraphs (b)(2)(i)(A) through (C) of this section to ensure the provision of the full range of services, as appropriate, to all eligible individuals.

(c) *Determining need for establishing and implementing an order of selection.*

(1) The designated State unit must determine, prior to the beginning of each fiscal year, whether to establish and implement an order of selection.

(2) If the designated State unit determines that it does not need to establish an order of selection, it must reevaluate this determination whenever changed circumstances during the course of a fiscal year, such as a decrease in its fiscal or personnel resources or an increase in its program costs, indicate that it may no longer be able to provide the full range of services, as appropriate, to all eligible individuals, as described in paragraph (a)(2) of this section.

(3) If a DSU establishes an order of selection, but determines that it does not need to implement that order at the beginning of the fiscal year, it must continue to meet the requirements of paragraph (a)(2) of this section, or it must implement the order of selection

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by closing one or more priority categories.

(d) *Establishing an order of selection.*

(1) *Basis for order of selection.* An order of selection must be based on a refinement of the three criteria in the definition of "individual with a significant disability" in section 7(21)(A) of the Act and § 361.5(b)(31).

(2) *Factors that cannot be used in determining order of selection of eligible individuals.* An order of selection may not be based on any other factors, including—

(i) Any duration of residency requirement, provided the individual is present in the State;

(ii) Type of disability;

(iii) Age, gender, race, color, or national origin;

(iv) Source of referral;

(v) Type of expected employment outcome;

(vi) The need for specific services or anticipated cost of services required by an individual; or

(vii) The income level of an individual or an individual's family.

(e) *Administrative requirements.* In administering the order of selection, the designated State unit must—

(1) Implement the order of selection on a statewide basis;

(2) Notify all eligible individuals of the priority categories in a State's order of selection, their assignment to a particular category, and their right to appeal their category assignment;

(3) Continue to provide all needed services to any eligible individual who has begun to receive services under an individualized plan for employment prior to the effective date of the order of selection, irrespective of the severity of the individual's disability; and

(4) Ensure that its funding arrangements for providing services under the State plan, including third-party arrangements and awards under the establishment authority, are consistent with the order of selection. If any funding arrangements are inconsistent with the order of selection, the designated State unit must renegotiate these funding arrangements so that they are consistent with the order of selection.

(f) *State Rehabilitation Council.* The designated State unit must consult with the State Rehabilitation Council, if the State unit has a Council, regarding the—

(1) Need to establish an order of selection, including any reevaluation of the need under paragraph (c)(2) of this section;

(2) Priority categories of the particular order of selection;

(3) Criteria for determining individuals with the most significant disabilities; and

(4) Administration of the order of selection.

(Authority: Sections 12(d); 101(a)(5); 101(a)(12); 101(a)(15)(A), (B) and (C); 101(a)(21)(A)(ii); and 504(a) of the Act; 29 U.S.C. 709(d), 721(a)(5), 721(a)(12), 721(a)(15)(A), (B) and (C); 721(a)(21)(A)(ii), and 794(a))

§ 361.37 Information and referral services.

(a) *General provisions.* The State plan must assure that—

(1) The designated State agency will implement an information and referral system adequate to ensure that individuals with disabilities, including eligible individuals who do not meet the agency's order of selection criteria for receiving vocational rehabilitation services if the agency is operating on an order of selection, are provided accurate vocational rehabilitation information and guidance (which may include counseling and referral for job placement) using appropriate modes of communication to assist them in preparing for, securing, retaining, or regaining employment; and

(2) The designated State agency will refer individuals with disabilities to other appropriate Federal and State programs, including other components of the statewide workforce investment system.

(b) *Criteria for appropriate referrals.* In making the referrals identified in paragraph (a)(2) of this section, the designated State unit must—

(1) Refer the individual to Federal or State programs, including programs carried out by other components of the statewide workforce investment system, best suited to address the specific employment needs of an individual with a disability; and

(2) Provide the individual who is being referred—

(i) A notice of the referral by the designated State agency to the agency carrying out the program;

(ii) Information identifying a specific point of contact within the agency to which the individual is being referred; and

(iii) Information and advice regarding the most suitable services to assist the individual to prepare for, secure, retain, or regain employment.

(c) *Order of selection.* In providing the information and referral services under this section to eligible individuals who are not in the priority category or categories to receive vocational rehabilitation services under the State's order of selection, the State unit must identify, as part of its reporting under section 101(a)(10) of the Act and § 361.40, the number of eligible individuals who did not meet the agency's order of selection criteria for receiving vocational rehabilitation services and did receive information and referral services under this section.

(Authority: Sections 101(a)(5)(D) and (20) and 101(a)(10)(C)(ii) of the Act; 29 U.S.C. 721(a)(5)(D) and (20) and (a)(10)(C)(ii))

§ 361.38 Protection, use, and release of personal information.

(a) *General provisions.*

(1) The State agency and the State unit must adopt and implement written policies and procedures to safeguard the confidentiality of all personal information, including photographs and lists of names. These policies and procedures must ensure that—

(i) Specific safeguards are established to protect current and stored personal information;

(ii) All applicants and eligible individuals and, as appropriate, those individuals' representatives, service providers, cooperating agencies, and interested persons are informed through appropriate modes of communication of the confidentiality of personal information and the conditions for accessing and releasing this information;

(iii) All applicants or their representatives are informed about the State unit's need to collect personal information and the policies governing its use, including—

(A) Identification of the authority under which information is collected;

(B) Explanation of the principal purposes for which the State unit intends to use or release the information;

(C) Explanation of whether providing requested information to the State unit is mandatory or voluntary and the effects of not providing requested information;

(D) Identification of those situations in which the State unit requires or does not require informed written consent of the individual before information may be released; and

(E) Identification of other agencies to which information is routinely released;

(iv) An explanation of State policies and procedures affecting personal information will be provided to each individual in that individual's native language or through the appropriate mode of communication; and

(v) These policies and procedures provide no fewer protections for individuals than State laws and regulations.

(2) The State unit may establish reasonable fees to cover extraordinary costs of duplicating records or making extensive searches and must establish policies and procedures governing access to records.

(b) *State program use.* All personal information in the possession of the State agency or the designated State unit must be used only for the purposes directly connected with the administration of the vocational rehabilitation program. Information containing identifiable personal information may not be shared with advisory or other bodies that do not have official responsibility for administration of the program. In the administration of the program, the State unit may obtain personal information from service providers and cooperating agencies under assurances that the information may not be further divulged, except as provided under paragraphs (c), (d), and (e) of this section.

(c) *Release to applicants and eligible individuals.*

(1) Except as provided in paragraphs (c)(2) and (c)(3) of this section, if requested in writing by an applicant or eligible individual, the State unit must make all requested information in that individual's record of services accessible to and must release the information to the individual or the individual's representative in a timely manner.

(2) Medical, psychological, or other information that the State unit determines may be harmful to the individual may not be released directly to the individual, but must be provided to the individual through a third party chosen by the individual, which may include, among others, an advocate, a family member, or a qualified medical or mental health professional, unless a representative has been appointed by a court to represent the individual, in which case the information must be released to the court-appointed representative.

(3) If personal information has been obtained from another agency or organization, it may be released only by, or under the conditions established by, the other agency or organization.

(4) An applicant or eligible individual who believes that information in the individual's record of services is inaccurate or misleading may request that the designated State unit amend the information. If the information is not amended, the request for an amendment must be documented in the record of services, consistent with § 361.47(a)(12).

(d) *Release for audit, evaluation, and research.* Personal information may be released to an organization, agency, or individual engaged in audit, evaluation, or research only for purposes directly connected with the administration of the vocational rehabilitation program or for purposes that would significantly improve the quality of life for applicants and eligible individuals and only if the organization, agency, or individual assures that—

(1) The information will be used only for the purposes for which it is being provided;

(2) The information will be released only to persons officially connected with the audit, evaluation, or research;

(3) The information will not be released to the involved individual;

(4) The information will be managed in a manner to safeguard confidentiality; and

(5) The final product will not reveal any personal identifying information without the informed written consent of the involved individual or the individual's representative.

(e) *Release to other programs or authorities.*

(1) Upon receiving the informed written consent of the individual or, if appropriate, the individual's representative, the State unit may release personal information to another agency or organization for its program purposes only to the extent that the information may be released to the involved individual or the individual's representative and only to the extent that the other agency or organization demonstrates that the information requested is necessary for its program.

(2) Medical or psychological information that the State unit determines may be harmful to the individual may be released if the other agency or organization assures the State unit that the information will be used only for the purpose for which it is being provided and will not be further released to the individual.

(3) The State unit must release personal information if required by Federal law or regulations.

(4) The State unit must release personal information in response to investigations in connection with law enforcement, fraud, or abuse, unless expressly prohibited by Federal or State laws or regulations, and in response to an order issued by a judge, magistrate, or other authorized judicial officer.

(5) The State unit also may release personal information in order to protect the individual or others if the individual poses a threat to his or her safety or to the safety of others.

(Authority: Sections 12(c) and 101(a)(6)(A) of the Act; 29 U.S.C. 709(c) and 721(a)(6)(A))

§ 361.39 State-imposed requirements.

The designated State unit must, upon request, identify those regulations and policies relating to the administration or operation of its vocational rehabilitation program that are State-imposed, including any regulations or policy based on State interpretation of any Federal law, regulations, or guideline.

(Authority: Section 17 of the Act; 29 U.S.C. 714)

§ 361.40 Reports.

(a) The State plan must assure that the designated State agency will submit reports, including reports required under sections 13, 14, and 101(a)(10) of the Act—

(1) In the form and level of detail and at the time required by the Secretary regarding applicants for and eligible individuals receiving services under this part; and

(2) In a manner that provides a complete count (other than the information obtained through sampling consistent with section 101(a)(10)(E) of the Act) of the applicants and eligible individuals to—

(i) Permit the greatest possible cross-classification of data; and

(ii) Protect the confidentiality of the identity of each individual.

(b) The designated State agency must comply with any requirements necessary to ensure the accuracy and verification of those reports.

(Authority: Section 101(a)(10)(A) and (F) of the Act; 29 U.S.C. 721(a)(10)(A) and (F))

Provision and Scope of Services

§ 361.41 Processing referrals and applications.

(a) *Referrals.* The designated State unit must establish and implement standards for the prompt and equitable handling of referrals of individuals for vocational rehabilitation services, including referrals of individuals made through the One-Stop service delivery systems established under section 121 of the Workforce Investment Act of 1998. The standards must include timelines for making good faith efforts to inform these individuals of application requirements and to gather information necessary to initiate an assessment for determining eligibility and priority for services.

(b) *Applications.*

(1) Once an individual has submitted an application for vocational rehabilitation services, including applications made through common intake procedures in One-Stop centers established under section 121 of the Workforce Investment Act of 1998, an eligibility determination must be made within 60 days, unless—

(i) Exceptional and unforeseen circumstances beyond the control of the designated State unit preclude making an eligibility determination within 60 days and the designated State unit and

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the individual agree to a specific extension of time; or

(ii) An exploration of the individual's abilities, capabilities, and capacity to perform in work situations is carried out in accordance with § 361.42(e) or, if appropriate, an extended evaluation is carried out in accordance with § 361.42(f).

(2) An individual is considered to have submitted an application when the individual or the individual's representative, as appropriate—

(i)(A) Has completed and signed an agency application form;

(B) Has completed a common intake application form in a One-Stop center requesting vocational rehabilitation services; or

(C) Has otherwise requested services from the designated State unit;

(ii) Has provided to the designated State unit information necessary to initiate an assessment to determine eligibility and priority for services; and

(iii) Is available to complete the assessment process.

(3) The designated State unit must ensure that its application forms are widely available throughout the State, particularly in the One-Stop centers established under section 121 of the Workforce Investment Act of 1998.

(Authority: Sections 101(a)(6)(A) and 102(a)(6) of the Act; 29 U.S.C. 721(a)(6)(A) and 722(a)(6))

§ 361.42 Assessment for determining eligibility and priority for services.

In order to determine whether an individual is eligible for vocational rehabilitation services and the individual's priority under an order of selection for services (if the State is operating under an order of selection), the designated State unit must conduct an assessment for determining eligibility and priority for services. The assessment must be conducted in the most integrated setting possible, consistent with the individual's needs and informed choice, and in accordance with the following provisions:

(a) *Eligibility requirements.*

(1) *Basic requirements.* The designated State unit's determination of an applicant's eligibility for vocational rehabilitation services must be based only on the following requirements:

(i) A determination by qualified personnel that the applicant has a physical or mental impairment.

(ii) A determination by qualified personnel that the applicant's physical or mental impairment constitutes or results in a substantial impediment to employment for the applicant.

(iii) A determination by a qualified vocational rehabilitation counselor employed by the designated State unit that the applicant requires vocational rehabilitation services to prepare for, secure, retain, or regain employment consistent with the applicant's unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

(iv) A presumption, in accordance with paragraph (a)(2) of this section, that the applicant can benefit in terms of an employment outcome from the provision of vocational rehabilitation services.

(2) *Presumption of benefit.* The designated State unit must presume that an applicant who meets the eligibility requirements in paragraphs (a)(1)(i) and (ii) of this section can benefit in terms of an employment outcome unless it demonstrates, based on clear and convincing evidence, that the applicant is incapable of benefiting in terms of an employment outcome from vocational rehabilitation services due to the severity of the applicant's disability.

(3) *Presumption of eligibility for Social Security recipients and beneficiaries.*

(i) Any applicant who has been determined eligible for Social Security benefits under Title II or Title XVI of the Social Security Act is—

(A) Presumed eligible for vocational rehabilitation services under paragraphs (a)(1) and (2) of this section; and

(B) Considered an individual with a significant disability as defined in § 361.5(b)(31).

(ii) If an applicant for vocational rehabilitation services asserts that he or she is eligible for Social Security benefits under Title II or Title XVI of the Social Security Act (and, therefore, is presumed eligible for vocational rehabilitation services under paragraph (a)(3)(i)(A) of this section), but is unable to provide appropriate evidence, such as an award letter, to support that assertion, the State unit must verify the applicant's eligibility under Title II or Title XVI of the Social Security Act by contacting the Social Security Administration. This verification must be made within a reasonable period of time that enables the State unit to determine the applicant's eligibility for vocational rehabilitation services within 60 days of the individual submitting an application for services in accordance with § 361.41(b)(2).

(4) *Achievement of an employment outcome.* Any eligible individual, including an individual whose eligibility for vocational rehabilitation services is based on the individual being eligible for Social Security benefits under Title II or Title XVI of the Social Security Act, must intend to achieve an employment outcome that is consistent with the applicant's unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

(i) The State unit is responsible for informing individuals, through its application process for vocational rehabilitation services, that individuals who receive services under the program must intend to achieve an employment outcome.

(ii) The applicant's completion of the application process for vocational rehabilitation services is sufficient evidence of the individual's intent to achieve an employment outcome, and no additional demonstration on the part of the applicant is required for purposes of satisfying paragraph (a)(4) of this section.

(5) *Interpretation.* Nothing in this section, including paragraph (a)(3)(i), is to be construed to create an entitlement to any vocational rehabilitation service.

(b) *Interim determination of eligibility.*

(1) The designated State unit may initiate the provision of vocational rehabilitation services for an applicant on the basis of an interim determination of eligibility prior to the 60-day period described in § 361.41(b)(2).

(2) If a State chooses to make interim determinations of eligibility, the designated State unit must—

(i) Establish criteria and conditions for making those determinations;

(ii) Develop and implement procedures for making the determinations; and

(iii) Determine the scope of services that may be provided pending the final determination of eligibility.

(3) If a State elects to use an interim eligibility determination, the designated State unit must make a final determination of eligibility within 60 days of the individual submitting an application for services in accordance with § 361.41(b)(2).

(c) *Prohibited factors.*

(1) The State plan must assure that the State unit will not impose, as part of determining eligibility under this section, a duration of residence requirement that excludes from services any applicant who is present in the State.

(2) In making a determination of eligibility under this section, the designated State unit also must ensure that—

(i) No applicant or group of applicants is excluded or found ineligible solely on the basis of the type of disability; and

(ii) The eligibility requirements are applied without regard to the—

(A) Age, gender, race, color, or national origin of the applicant;

(B) Type of expected employment outcome;

(C) Source of referral for vocational rehabilitation services; and

(D) Particular service needs or anticipated cost of services required by an applicant or the income level of an applicant or applicant's family.

(d) *Review and assessment of data for eligibility determination.* Except as provided in paragraph (e) of this section, the designated State unit—

(1) Must base its determination of each of the basic eligibility requirements in paragraph (a) of this section on—

(i) A review and assessment of existing data, including counselor observations, education records, information provided by the individual or the individual's family, particularly information used by education officials, and determinations made by officials of other agencies; and

(ii) To the extent existing data do not describe the current functioning of the individual or are unavailable, insufficient, or inappropriate to make an eligibility determination, an assessment of additional data resulting from the provision of vocational rehabilitation services, including trial work experiences, assistive technology devices and services, personal assistance services, and any other support services that are necessary to determine whether an individual is eligible; and

(2) Must base its presumption under paragraph (a)(3)(i) of this section that an applicant who has been determined eligible for Social Security benefits under Title II or Title XVI of the Social Security Act satisfies each of the basic eligibility requirements in paragraph (a) of this section on determinations made by the Social Security Administration.

(e) *Trial work experiences for individuals with significant disabilities.*

(1) Prior to any determination that an individual with a disability is incapable of benefiting from vocational rehabilitation services in terms of an employment outcome because of the severity of that individual's disability, the designated State unit must conduct an exploration of the individual's abilities, capabilities, and capacity to perform in realistic work situations to determine whether or not there is clear and convincing evidence to support such a determination.

(2)(i) The designated State unit must develop a written plan to assess periodically the individual's abilities, capabilities, and capacity to perform in work situations through the use of trial work experiences, which must be provided in the most integrated setting possible, consistent with the informed choice and rehabilitation needs of the individual.

(ii) Trial work experiences include supported employment, on-the-job training, and other experiences using realistic work settings.

(iii) Trial work experiences must be of sufficient variety and over a sufficient period of time for the designated State unit to determine that—

(A) There is sufficient evidence to conclude that the individual can benefit from the provision of vocational rehabilitation services in terms of an employment outcome; or

(B) There is clear and convincing evidence that the individual is incapable of benefiting from vocational rehabilitation services in terms of an employment outcome due to the severity of the individual's disability.

(iv) The designated State unit must provide appropriate supports, including assistive technology devices and services and personal assistance services, to accommodate the rehabilitation needs of the individual during the trial work experiences.

(f) *Extended evaluation for certain individuals with significant disabilities.*

(1) Under limited circumstances if an individual cannot take advantage of trial work experiences or if options for trial work experiences have been exhausted before the State unit is able to make the determinations described in paragraph (e)(2)(iii) of this section, the designated State unit must conduct an extended evaluation to make these determinations.

(2) During the extended evaluation period, vocational rehabilitation services must be provided in the most integrated setting possible, consistent with the informed choice and rehabilitation needs of the individual.

(3) During the extended evaluation period, the designated State unit must develop a written plan for providing services necessary to make a determination under paragraph (e)(2)(iii) of this section.

(4) During the extended evaluation period, the designated State unit provides only those services that are necessary to make the determinations described in paragraph (e)(2)(iii) of this section and terminates extended evaluation services when the State unit is able to make the determinations.

(g) *Data for determination of priority for services under an order of selection.* If the designated State unit is operating under an order of selection for services, as provided in § 361.36, the State unit must base its priority assignments on—

(1) A review of the data that was developed under paragraphs (d) and (e) of this section to make the eligibility determination; and

(2) An assessment of additional data, to the extent necessary.

(Authority: Sections 7(2)(A), 7(2)(B)(ii)(I), 7(2)(C), 7(2)(D), 101(a)(12), 102(a)(1), 102(a)(2), 102(a)(3), 102(a)(4)(A), 102(a)(4)(B), 102(a)(4)(C), 103(a)(1), 103(a)(9), 103(a)(10) and 103(a)(14) of the Act; 29 U.S.C. 705(2)(A), 705(2)(B)(ii)(I), 705(2)(C), 705(2)(D), 721(a)(12), 722(a)(1), 722(a)(2), 722(a)(3), 722(a)(4)(A), 722(a)(4)(B), 722(a)(4)(C), 723(a)(1), 723(a)(9), 723(a)(10) and 723(a)(14))

Note to § 361.42: *Clear and convincing evidence* means that the designated State unit shall have a high degree of certainty before it can conclude that an individual is incapable of benefiting from services in terms of an employment outcome. The "clear and convincing" standard constitutes the highest standard used in our civil system of law and is to be individually applied on a case-by-case basis. The term *clear* means unequivocal. For example, the use of an intelligence test result alone would not constitute clear and convincing evidence. Clear and convincing evidence might include a description of assessments, including situational assessments and supported employment assessments, from service providers who have concluded that they would be unable to meet the individual's needs due to the severity of the individual's disability. The demonstration of "clear and convincing evidence" must include, if appropriate, a functional assessment of skill development activities, with any necessary supports (including assistive technology), in real life settings. (S. Rep. No. 357, 102d Cong., 2d. Sess. 37–38 (1992))

§ 361.43 Procedures for ineligibility determination.

If the State unit determines that an applicant is ineligible for vocational rehabilitation services or determines that an individual receiving services under an individualized plan for employment is no longer eligible for services, the State unit must—

(a) Make the determination only after providing an opportunity for full consultation with the individual or, as appropriate, with the individual's representative;

(b) Inform the individual in writing, supplemented as necessary by other appropriate modes of communication consistent with the informed choice of the individual, of the ineligibility determination, including the reasons for that determination, the requirements under this section, and the means by which the individual may express and seek remedy for any dissatisfaction, including the procedures for review of State unit personnel determinations in accordance with § 361.57;

(c) Provide the individual with a description of services available from a

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client assistance program established under 34 CFR part 370 and information on how to contact that program;

(d) Refer the individual to other training or employment-related programs that are part of the One-Stop service delivery system under the Workforce Investment Act; and

(e) Review within 12 months and annually thereafter if requested by the individual or, if appropriate, by the individual's representative any ineligibility determination that is based on a finding that the individual is incapable of achieving an employment outcome. This review need not be conducted in situations in which the individual has refused it, the individual is no longer present in the State, the individual's whereabouts are unknown, or the individual's medical condition is rapidly progressive or terminal.

(Authority: Sections 102(a)(5) and 102(c) of the Act; 29 U.S.C. 722(a)(5) and 722(c))

§ 361.44 Closure without eligibility determination.

The designated State unit may not close an applicant's record of services prior to making an eligibility determination unless the applicant declines to participate in, or is unavailable to complete, an assessment for determining eligibility and priority for services, and the State unit has made a reasonable number of attempts to contact the applicant or, if appropriate, the applicant's representative to encourage the applicant's participation.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

§ 361.45 Development of the individualized plan for employment.

(a) *General requirements.* The State plan must assure that—

(1) An individualized plan for employment (IPE) meeting the requirements of this section and § 361.46 is developed and implemented in a timely manner for each individual determined to be eligible for vocational rehabilitation services or, if the designated State unit is operating under an order of selection in accordance with § 361.36, for each eligible individual to whom the State unit is able to provide services; and

(2) Services will be provided in accordance with the provisions of the IPE.

(b) *Purpose.*

(1) The designated State unit must conduct an assessment for determining vocational rehabilitation needs, if appropriate, for each eligible individual or, if the State is operating under an order of selection, for each eligible individual to whom the State is able to provide services. The purpose of this assessment is to determine the employment outcome, and the nature and scope of vocational rehabilitation services to be included in the IPE.

(2) The IPE must—

(i) Be designed to achieve the specific employment outcome that is selected by the individual consistent with the individual's unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice; and

(ii) To the maximum extent appropriate, result in employment in an integrated setting.

(c) *Required information.* The State unit must provide the following information to each eligible individual or, as appropriate, the individual's representative, in writing and, if appropriate, in the native language or mode of communication of the individual or the individual's representative:

(1) *Options for developing an IPE.* Information on the available options for developing the IPE, including the option that an eligible individual or, as appropriate, the individual's representative may develop all or part of the IPE—

(i) Without assistance from the State unit or other entity; or

(ii) With assistance from—

(A) A qualified vocational rehabilitation counselor employed by the State unit;

(B) A qualified vocational rehabilitation counselor who is not employed by the State unit; or

(C) Resources other than those in paragraph (A) or (B) of this section.

(2) *Additional information.* Additional information to assist the eligible individual or, as appropriate, the individual's representative in developing the IPE, including—

(i) Information describing the full range of components that must be included in an IPE;

(ii) As appropriate to each eligible individual—

(A) An explanation of agency guidelines and criteria for determining an eligible individual's financial commitments under an IPE;

(B) Information on the availability of assistance in completing State unit forms required as part of the IPE; and

(C) Additional information that the eligible individual requests or the State unit determines to be necessary to the development of the IPE;

(iii) A description of the rights and remedies available to the individual, including, if appropriate, recourse to the processes described in § 361.57; and

(iv) A description of the availability of a client assistance program established under 34 CFR part 370 and information on how to contact the client assistance program.

(d) *Mandatory procedures.* The designated State unit must ensure that—

(1) The IPE is a written document prepared on forms provided by the State unit;

(2) The IPE is developed and implemented in a manner that gives eligible individuals the opportunity to exercise informed choice, consistent with § 361.52, in selecting—

(i) The employment outcome, including the employment setting;

(ii) The specific vocational rehabilitation services needed to achieve the employment outcome, including the settings in which services will be provided;

(iii) The entity or entities that will provide the vocational rehabilitation services; and

(iv) The methods available for procuring the services;

(3) The IPE is—

(i) Agreed to and signed by the eligible individual or, as appropriate, the individual's representative; and

(ii) Approved and signed by a qualified vocational rehabilitation counselor employed by the designated State unit;

(4) A copy of the IPE and a copy of any amendments to the IPE are provided to the eligible individual or, as appropriate, to the individual's representative, in writing and, if appropriate, in the native language or mode of communication of the individual or, as appropriate, the individual's representative;

(5) The IPE is reviewed at least annually by a qualified vocational rehabilitation counselor and the eligible individual or, as appropriate, the individual's representative to assess the eligible individual's progress in achieving the identified employment outcome;

(6) The IPE is amended, as necessary, by the individual or, as appropriate, the individual's representative, in collaboration with a representative of the State unit or a qualified vocational rehabilitation counselor (to the extent determined to be appropriate by the individual), if there are substantive changes in the employment outcome, the vocational rehabilitation services to be provided, or the providers of the vocational rehabilitation services;

(7) Amendments to the IPE do not take effect until agreed to and signed by the eligible individual or, as appropriate, the individual's representative and by a qualified vocational rehabilitation counselor employed by the designated State unit; and

(8) An IPE for a student with a disability receiving special education services is developed—

(i) In consideration of the student's IEP; and

(ii) In accordance with the plans, policies, procedures, and terms of the interagency agreement required under § 361.22.

(e) *Standards for developing the IPE.* The designated State unit must establish and implement standards for the prompt development of IPEs for the individuals identified under paragraph (a) of this section, including timelines that take into consideration the needs of the individuals.

(f) *Data for preparing the IPE.*

(1) *Preparation without comprehensive assessment.* To the extent possible, the employment outcome and the nature and scope of rehabilitation services to be included in the individual's IPE must be determined based on the data used for the assessment of eligibility and priority for services under § 361.42.

(2) *Preparation based on comprehensive assessment.*

(i) If additional data are necessary to determine the employment outcome and the nature and scope of services to be included in the IPE of an eligible individual, the State unit must conduct a comprehensive assessment of the unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice, including the need for supported employment services, of the eligible individual, in the most integrated setting possible, consistent with the informed choice of the individual in accordance with the provisions of § 361.5(b)(6)(ii).

(ii) In preparing the comprehensive assessment, the State unit must use, to the maximum extent possible and appropriate and in accordance with confidentiality requirements, existing information that is current as of the date of the development of the IPE, including—

(A) Information available from other programs and providers, particularly information used by education officials and the Social Security Administration;

(B) Information provided by the individual and the individual's family; and

(C) Information obtained under the assessment for determining the individual's eligibility and vocational rehabilitation needs.

(Authority: Sections 7(2)(B), 101(a)(9), 102(b)(1), 102(b)(2), 102(c) and 103(a)(1); 29 U.S.C. 705(2)(B), 721(a)(9), 722(b)(1), 722(b)(2), 722(c) and 723(a)(1))

§ 361.46 Content of the individualized plan for employment.

(a) *Mandatory components.* Regardless of the approach in § 361.45(c)(1) that an eligible individual selects for purposes of developing the IPE, each IPE must include—

(1) A description of the specific employment outcome that is chosen by the eligible individual that—

(i) Is consistent with the individual's unique strengths, resources, priorities, concerns, abilities, capabilities, career interests, and informed choice; and

(ii) To the maximum extent appropriate, results in employment in an integrated setting;

(2) A description of the specific rehabilitation services under § 361.48 that are—

(i) Needed to achieve the employment outcome, including, as appropriate, the provision of assistive technology devices, assistive technology services, and personal assistance services, including training in the management of those services; and

(ii) Provided in the most integrated setting that is appropriate for the services involved and is consistent with the informed choice of the eligible individual;

(3) Timelines for the achievement of the employment outcome and for the initiation of services;

(4) A description of the entity or entities chosen by the eligible individual or, as appropriate, the individual's representative that will provide the vocational rehabilitation services and the methods used to procure those services;

(5) A description of the criteria that will be used to evaluate progress toward achievement of the employment outcome; and

(6) The terms and conditions of the IPE, including, as appropriate, information describing—

(i) The responsibilities of the designated State unit;

(ii) The responsibilities of the eligible individual, including—

(A) The responsibilities the individual will assume in relation to achieving the employment outcome;

(B) If applicable, the extent of the individual's participation in paying for the cost of services; and

(C) The responsibility of the individual with regard to applying for and securing comparable services and benefits as described in § 361.53; and

(iii) The responsibilities of other entities as the result of arrangements made pursuant to the comparable services or benefits requirements in § 361.53.

(b) *Supported employment requirements.* An IPE for an individual with a most significant disability for whom an employment outcome in a supported employment setting has been determined to be appropriate must—

(1) Specify the supported employment services to be provided by the designated State unit;

(2) Specify the expected extended services needed, which may include natural supports;

(3) Identify the source of extended services or, to the extent that it is not possible to identify the source of extended services at the time the IPE is developed, include a description of the basis for concluding that there is a reasonable expectation that those sources will become available;

(4) Provide for periodic monitoring to ensure that the individual is making satisfactory progress toward meeting the weekly work requirement established in the IPE by the time of transition to extended services;

(5) Provide for the coordination of services provided under an IPE with services provided under other individualized plans established under other Federal or State programs;

(6) To the extent that job skills training is provided, identify that the training will be provided on site; and

(7) Include placement in an integrated setting for the maximum number of hours possible based on the unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice of individuals with the most significant disabilities.

(c) *Post-employment services.* The IPE for each individual must contain, as determined to be necessary, statements concerning—

(1) The expected need for post-employment services prior to closing the record of services of an individual who has achieved an employment outcome;

(2) A description of the terms and conditions for the provision of any post-employment services; and

(3) If appropriate, a statement of how post-employment services will be provided or arranged through other entities as the result of arrangements made pursuant to the comparable services or benefits requirements in § 361.53.

(d) *Coordination of services for students with disabilities who are receiving special education services.* The IPE for a student with a disability who is receiving special education services must be coordinated with the

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IEP for that individual in terms of the goals, objectives, and services identified in the IEP.

(Authority: Sections 101(a)(8), 101(a)(9), 102(b)(3), and 625(b)(6) of the Act; 29 U.S.C. 721(a)(8), 721(a)(9), 722(b)(3), and 795(k))

§ 361.47 Record of services.

(a) The designated State unit must maintain for each applicant and eligible individual a record of services that includes, to the extent pertinent, the following documentation:

(1) If an applicant has been determined to be an eligible individual, documentation supporting that determination in accordance with the requirements under § 361.42.

(2) If an applicant or eligible individual receiving services under an IPE has been determined to be ineligible, documentation supporting that determination in accordance with the requirements under § 361.43.

(3) Documentation that describes the justification for closing an applicant's or eligible individual's record of services if that closure is based on reasons other than ineligibility, including, as appropriate, documentation indicating that the State unit has satisfied the requirements in § 361.44.

(4) If an individual has been determined to be an individual with a significant disability or an individual with a most significant disability, documentation supporting that determination.

(5) If an individual with a significant disability requires an exploration of abilities, capabilities, and capacity to perform in realistic work situations through the use of trial work experiences or, as appropriate, an extended evaluation to determine whether the individual is an eligible individual, documentation supporting the need for, and the plan relating to, that exploration or, as appropriate, extended evaluation and documentation regarding the periodic assessments carried out during the trial work experiences or, as appropriate, the extended evaluation, in accordance with the requirements under § 361.42(e) and (f).

(6) The IPE, and any amendments to the IPE, consistent with the requirements under § 361.46.

(7) Documentation describing the extent to which the applicant or eligible individual exercised informed choice regarding the provision of assessment services and the extent to which the eligible individual exercised informed choice in the development of the IPE with respect to the selection of the specific employment outcome, the specific vocational rehabilitation services needed to achieve the employment outcome, the entity to provide the services, the employment setting, the settings in which the services will be provided, and the methods to procure the services.

(8) In the event that the IPE provides for services or an employment outcome in a non-integrated setting, a justification to support the non-integrated setting.

(9) In the event that an individual obtains competitive employment, verification that the individual is compensated at or above the minimum wage and that the individual's wage and level of benefits are not less than that customarily paid by the employer for the same or similar work performed by non-disabled individuals in accordance with § 361.5(b)(11)(ii).

(10) In the event that an individual obtains an employment outcome in an extended employment setting in a community rehabilitation program or any other employment under section 14(c) of the Fair Labor Standards Act, documentation of the results of the annual reviews required under § 361.55, the individual's input into those reviews, and the individual's or, if appropriate, the individual's representative's acknowledgement that those reviews were conducted.

(11) Documentation concerning any action or decision resulting from a request by an individual under § 361.57 for a review of determinations made by designated State unit personnel.

(12) In the event that an applicant or eligible individual requests under § 361.38(c)(4) that documentation in the record of services be amended and the documentation is not amended, documentation of the request.

(13) In the event an individual is referred to another program through the State unit's information and referral system under § 361.37, including other components of the statewide workforce investment system, documentation on the nature and scope of services provided by the designated State unit to the individual and on the referral itself, consistent with the requirements of § 361.37.

(14) In the event an individual's record of service is closed under § 361.56, documentation that demonstrates the services provided under the individual's IPE contributed to the achievement of the employment outcome.

(15) In the event an individual's record of service is closed under § 361.56, documentation verifying that the provisions of § 361.56 have been satisfied.

(b) The State unit, in consultation with the State Rehabilitation Council if the State has a Council, must determine the type of documentation that the State unit must maintain for each applicant and eligible individual in order to meet the requirements in paragraph (a) of this section.

(Authority: Sections 101(a)(6), (9), (14), (20) and 102(a), (b), and (d) of the Act; 29 U.S.C. 721(a)(6), (9), (14), (20) and 722(a),(b), and (d))

§ 361.48 Scope of vocational rehabilitation services for individuals with disabilities.

As appropriate to the vocational rehabilitation needs of each individual and consistent with each individual's informed choice, the designated State unit must ensure that the following vocational rehabilitation services are available to assist the individual with a disability in preparing for, securing, retaining, or regaining an employment outcome that is consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice:

(a) Assessment for determining eligibility and priority for services by qualified personnel, including, if appropriate, an assessment by personnel skilled in rehabilitation technology, in accordance with § 361.42.

(b) Assessment for determining vocational rehabilitation needs by qualified personnel, including, if appropriate, an assessment by personnel skilled in rehabilitation technology, in accordance with § 361.45.

(c) Vocational rehabilitation counseling and guidance, including information and support services to assist an individual in exercising informed choice in accordance with § 361.52.

(d) Referral and other services necessary to assist applicants and eligible individuals to secure needed services from other agencies, including other components of the statewide workforce investment system, in accordance with §§ 361.23, 361.24, and 361.37, and to advise those individuals about client assistance programs established under 34 CFR part 370.

(e) In accordance with the definition in § 361.5(b)(40), physical and mental restoration services, to the extent that financial support is not readily available from a source other than the designated State unit (such as through health insurance or a comparable service or benefit as defined in § 361.5(b)(10)).

(f) Vocational and other training services, including personal and vocational adjustment training, books, tools, and other training materials,

except that no training or training services in an institution of higher education (universities, colleges, community or junior colleges, vocational schools, technical institutes, or hospital schools of nursing) may be paid for with funds under this part unless maximum efforts have been made by the State unit and the individual to secure grant assistance in whole or in part from other sources to pay for that training.

(g) Maintenance, in accordance with the definition of that term in § 361.5(b)(35).

(h) Transportation in connection with the rendering of any vocational rehabilitation service and in accordance with the definition of that term in § 361.5(b)(57).

(i) Vocational rehabilitation services to family members, as defined in § 361.5(b)(23), of an applicant or eligible individual if necessary to enable the applicant or eligible individual to achieve an employment outcome.

(j) Interpreter services, including sign language and oral interpreter services, for individuals who are deaf or hard of hearing and tactile interpreting services for individuals who are deaf-blind provided by qualified personnel.

(k) Reader services, rehabilitation teaching services, and orientation and mobility services for individuals who are blind.

(l) Job-related services, including job search and placement assistance, job retention services, follow-up services, and follow-along services.

(m) Supported employment services in accordance with the definition of that term in § 361.5(b)(54).

(n) Personal assistance services in accordance with the definition of that term in § 361.5(b)(39).

(o) Post-employment services in accordance with the definition of that term in § 361.5(b)(42).

(p) Occupational licenses, tools, equipment, initial stocks, and supplies.

(q) Rehabilitation technology in accordance with the definition of that term in § 361.5(b)(45), including vehicular modification, telecommunications, sensory, and other technological aids and devices.

(r) Transition services in accordance with the definition of that term in § 361.5(b)(55).

(s) Technical assistance and other consultation services to conduct market analyses, develop business plans, and otherwise provide resources, to the extent those resources are authorized to be provided through the statewide workforce investment system, to eligible individuals who are pursuing self-employment or telecommuting or establishing a small business operation as an employment outcome.

(t) Other goods and services determined necessary for the individual with a disability to achieve an employment outcome.

(Authority: Section 103(a) of the Act; 29 U.S.C. 723(a))

§ 361.49 Scope of vocational rehabilitation services for groups of individuals with disabilities.

(a) The designated State unit may also provide for the following vocational rehabilitation services for the benefit of groups of individuals with disabilities:

(1) The establishment, development, or improvement of a public or other nonprofit community rehabilitation program that is used to provide vocational rehabilitation services that promote integration and competitive employment, including, under special circumstances, the construction of a facility for a public or nonprofit community rehabilitation program. Examples of "special circumstances" include the destruction by natural disaster of the only available center serving an area or a State determination that construction is necessary in a rural area because no other public agencies or private nonprofit organizations are currently able to provide vocational rehabilitation services to individuals.

(2) Telecommunications systems that have the potential for substantially improving vocational rehabilitation service delivery methods and developing appropriate programming to meet the particular needs of individuals with disabilities, including telephone, television, video description services, satellite, tactile-vibratory devices, and similar systems, as appropriate.

(3) Special services to provide nonvisual access to information for individuals who are blind, including the use of telecommunications, Braille, sound recordings, or other appropriate media; captioned television, films, or video cassettes for individuals who are deaf or hard of hearing; tactile materials for individuals who are deaf-blind; and other special services that provide information through tactile, vibratory, auditory, and visual media.

(4) Technical assistance and support services to businesses that are not subject to Title I of the Americans with Disabilities Act of 1990 and that are seeking to employ individuals with disabilities.

(5) In the case of any small business enterprise operated by individuals with significant disabilities under the supervision of the designated State unit, including enterprises established under the Randolph-Sheppard program, management services and supervision provided by the State unit along with the acquisition by the State unit of vending facilities or other equipment, initial stocks and supplies, and initial operating expenses, in accordance with the following requirements:

(i) "Management services and supervision" includes inspection, quality control, consultation, accounting, regulating, in-service training, and related services provided on a systematic basis to support and improve small business enterprises operated by individuals with significant disabilities. "Management services and supervision" may be provided throughout the operation of the small business enterprise.

(ii) "Initial stocks and supplies" includes those items necessary to the establishment of a new business enterprise during the initial establishment period, which may not exceed 6 months.

(iii) Costs of establishing a small business enterprise may include operational costs during the initial establishment period, which may not exceed 6 months.

(iv) If the designated State unit provides for these services, it must ensure that only individuals with significant disabilities will be selected to participate in this supervised program.

(v) If the designated State unit provides for these services and chooses to set aside funds from the proceeds of the operation of the small business enterprises, the State unit must maintain a description of the methods used in setting aside funds and the purposes for which funds are set aside. Funds may be used only for small business enterprises purposes, and benefits that are provided to operators from set-aside funds must be provided on an equitable basis.

(6) Other services that promise to contribute substantially to the rehabilitation of a group of individuals but that are not related directly to the individualized plan for employment of any one individual. Examples of those other services might include the purchase or lease of a bus to provide transportation to a group of applicants or eligible individuals or the purchase of equipment or instructional materials that would benefit a group of applicants or eligible individuals.

(7) Consultative and technical assistance services to assist educational agencies in planning for the transition of students with disabilities from school to post-school activities, including employment.

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(b) If the designated State unit provides for vocational rehabilitation services for groups of individuals, it must—

(1) Develop and maintain written policies covering the nature and scope of each of the vocational rehabilitation services it provides and the criteria under which each service is provided; and

(2) Maintain information to ensure the proper and efficient administration of those services in the form and detail and at the time required by the Secretary, including the types of services provided, the costs of those services, and, to the extent feasible, estimates of the numbers of individuals benefiting from those services.

(Authority: Sections 12(c), 101(a)(6)(A), and 103(b) of the Act; 29 U.S.C. 709(c), 721(a)(6), and 723(b))

§ 361.50 Written policies governing the provision of services for individuals with disabilities.

(a) *Policies.* The State unit must develop and maintain written policies covering the nature and scope of each of the vocational rehabilitation services specified in § 361.48 and the criteria under which each service is provided. The policies must ensure that the provision of services is based on the rehabilitation needs of each individual as identified in that individual's IPE and is consistent with the individual's informed choice. The written policies may not establish any arbitrary limits on the nature and scope of vocational rehabilitation services to be provided to the individual to achieve an employment outcome. The policies must be developed in accordance with the following provisions:

(b) *Out-of-State services.*

(1) The State unit may establish a preference for in-State services, provided that the preference does not effectively deny an individual a necessary service. If the individual chooses an out-of-State service at a higher cost than an in-State service, if either service would meet the individual's rehabilitation needs, the designated State unit is not responsible for those costs in excess of the cost of the in-State service.

(2) The State unit may not establish policies that effectively prohibit the provision of out-of-State services.

(c) *Payment for services.*

(1) The State unit must establish and maintain written policies to govern the rates of payment for all purchased vocational rehabilitation services.

(2) The State unit may establish a fee schedule designed to ensure a reasonable cost to the program for each service, if the schedule is—

(i) Not so low as to effectively deny an individual a necessary service; and

(ii) Not absolute and permits exceptions so that individual needs can be addressed.

(3) The State unit may not place absolute dollar limits on specific service categories or on the total services provided to an individual.

(d) *Duration of services.*

(1) The State unit may establish reasonable time periods for the provision of services provided that the time periods are—

(i) Not so short as to effectively deny an individual a necessary service; and

(ii) Not absolute and permit exceptions so that individual needs can be addressed.

(2) The State unit may not establish absolute time limits on the provision of specific services or on the provision of services to an individual. The duration of each service needed by an individual must be determined on an individual basis and reflected in that individual's individualized plan for employment.

(e) *Authorization of services.* The State unit must establish policies related to the timely authorization of services, including any conditions under which verbal authorization can be given.

(Authority: Sections 12(c) and 101(a)(6) of the Act and 29 U.S.C. 709(c) and 721(a)(6))

§ 361.51 Standards for facilities and providers of services.

(a) *Accessibility of facilities.* The State plan must assure that any facility used in connection with the delivery of vocational rehabilitation services under this part meets program accessibility requirements consistent with the requirements, as applicable, of the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990, section 504 of the Act, and the regulations implementing these laws.

(b) *Affirmative action.* The State plan must assure that community rehabilitation programs that receive assistance under part B of Title I of the Act take affirmative action to employ and advance in employment qualified individuals with disabilities covered under and on the same terms and conditions as in section 503 of the Act.

(c) *Special communication needs personnel.* The designated State unit must ensure that providers of vocational rehabilitation services are able to communicate—

(1) In the native language of applicants and eligible individuals who have limited English speaking ability; and

(2) By using appropriate modes of communication used by applicants and eligible individuals.

(Authority: Sections 12(c) and 101(a)(6)(B) and (C) of the Act; 29 U.S.C. 709(c) and 721(a)(6)(B) and (C))

§ 361.52 Informed choice.

(a) *General provision.* The State plan must assure that applicants and eligible individuals or, as appropriate, their representatives are provided information and support services to assist applicants and eligible individuals in exercising informed choice throughout the rehabilitation process consistent with the provisions of section 102(d) of the Act and the requirements of this section.

(b) *Written policies and procedures.* The designated State unit, in consultation with its State Rehabilitation Council, if it has a Council, must develop and implement written policies and procedures that enable an applicant or eligible individual to exercise informed choice throughout the vocational rehabilitation process. These policies and procedures must provide for—

(1) Informing each applicant and eligible individual (including students with disabilities who are making the transition from programs under the responsibility of an educational agency to programs under the responsibility of the designated State unit), through appropriate modes of communication, about the availability of and opportunities to exercise informed choice, including the availability of support services for individuals with cognitive or other disabilities who require assistance in exercising informed choice throughout the vocational rehabilitation process;

(2) Assisting applicants and eligible individuals in exercising informed choice in decisions related to the provision of assessment services;

(3) Developing and implementing flexible procurement policies and methods that facilitate the provision of vocational rehabilitation services and that afford eligible individuals meaningful choices among the methods used to procure vocational rehabilitation services;

(4) Assisting eligible individuals or, as appropriate, the individuals' representatives in acquiring information that enables them to exercise informed choice in the development of their IPEs with respect to the selection of the—

(i) Employment outcome;

(ii) Specific vocational rehabilitation services needed to achieve the employment outcome;

(iii) Entity that will provide the services;

(iv) Employment setting and the settings in which the services will be provided; and

(v) Methods available for procuring the services; and

(5) Ensuring that the availability and scope of informed choice is consistent with the obligations of the designated State agency under this part.

(c) *Information and assistance in the selection of vocational rehabilitation services and service providers.* In assisting an applicant and eligible individual in exercising informed choice during the assessment for determining eligibility and vocational rehabilitation needs and during development of the IPE, the designated State unit must provide the individual or the individual's representative, or assist the individual or the individual's representative in acquiring, information necessary to make an informed choice about the specific vocational rehabilitation services, including the providers of those services, that are needed to achieve the individual's employment outcome. This information must include, at a minimum, information relating to the—

(1) Cost, accessibility, and duration of potential services;

(2) Consumer satisfaction with those services to the extent that information relating to consumer satisfaction is available;

(3) Qualifications of potential service providers;

(4) Types of services offered by the potential providers;

(5) Degree to which services are provided in integrated settings; and

(6) Outcomes achieved by individuals working with service providers, to the extent that such information is available.

(d) *Methods or sources of information.* In providing or assisting the individual or the individual's representative in acquiring the information required under paragraph (c) of this section, the State unit may use, but is not limited to, the following methods or sources of information:

(1) Lists of services and service providers.

(2) Periodic consumer satisfaction surveys and reports.

(3) Referrals to other consumers, consumer groups, or disability advisory councils qualified to discuss the services or service providers.

(4) Relevant accreditation, certification, or other information relating to the qualifications of service providers.

(5) Opportunities for individuals to visit or experience various work and service provider settings.

(Authority: Sections 12(c), 101(a)(19); 102(b)(2)(B) and 102(d) of the Act; 29 U.S.C. 709(c), 721(a)(19); 722(b)(2)(B) and 722(d))

§ 361.53 Comparable services and benefits.

(a) *Determination of availability.* The State plan must assure that prior to providing any vocational rehabilitation services, except those services listed in paragraph (b) of this section, to an eligible individual, or to members of the individual's family, the State unit must determine whether comparable services and benefits, as defined in § 361.5(b)(10), exist under any other program and whether those services and benefits are available to the individual unless such a determination would interrupt or delay—

(1) The progress of the individual toward achieving the employment outcome identified in the individualized plan for employment;

(2) An immediate job placement; or

(3) The provision of vocational rehabilitation services to any individual who is determined to be at extreme medical risk, based on medical evidence provided by an appropriate qualified medical professional.

(b) *Exempt services.* The following vocational rehabilitation services described in § 361.48(a) are exempt from a determination of the availability of comparable services and benefits under paragraph (a) of this section:

(1) Assessment for determining eligibility and vocational rehabilitation needs.

(2) Counseling and guidance, including information and support services to assist an individual in exercising informed choice.

(3) Referral and other services to secure needed services from other agencies, including other components of the statewide workforce investment system, if those services are not available under this part.

(4) Job-related services, including job search and placement assistance, job retention services, follow-up services, and follow-along services.

(5) Rehabilitation technology, including telecommunications, sensory, and other technological aids and devices.

(6) Post-employment services consisting of the services listed under paragraphs (b)(1) through (5) of this section.

(c) *Provision of services.*

(1) If comparable services or benefits exist under any other program and are available to the individual at the time needed to ensure the progress of the individual toward achieving the employment outcome in the individual's IPE, the designated State unit must use those comparable services or benefits to meet, in whole or part, the costs of the vocational rehabilitation services.

(2) If comparable services or benefits exist under any other program, but are not available to the individual at the time needed to ensure the progress of the individual toward achieving the employment outcome in the individual's IPE, the designated State unit must provide vocational rehabilitation services until those comparable services and benefits become available.

(d) *Interagency coordination.*

(1) The State plan must assure that the Governor, in consultation with the entity in the State responsible for the vocational rehabilitation program and other appropriate agencies, will ensure that an interagency agreement or other mechanism for interagency coordination takes effect between the designated State vocational rehabilitation unit and any appropriate public entity, including the State entity responsible for administering the State medicaid program, a public institution of higher education, and a component of the statewide workforce investment system, to ensure the provision of vocational rehabilitation services (other than those services listed in paragraph (b) of this section) that are included in the IPE, including the provision of those vocational rehabilitation services during the pendency of any interagency dispute in accordance with the provisions of paragraph (d)(3)(iii) of this section.

(2) The Governor may meet the requirements of paragraph (d)(1) of this section through—

(i) A State statute or regulation;

(ii) A signed agreement between the respective officials of the public entities that clearly identifies the responsibilities of each public entity for the provision of the services; or

(iii) Another appropriate mechanism as determined by the designated State vocational rehabilitation unit.

(3) The interagency agreement or other mechanism for interagency coordination must include the following:

(i) *Agency financial responsibility.* An identification of, or description of a method for defining, the financial responsibility of the public entity for providing the vocational rehabilitation services other than those listed in paragraph (b) of this section and a provision stating the financial

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responsibility of the public entity for providing those services.

(ii) *Conditions, terms, and procedures of reimbursement.* Information specifying the conditions, terms, and procedures under which the designated State unit must be reimbursed by the other public entities for providing vocational rehabilitation services based on the terms of the interagency agreement or other mechanism for interagency coordination.

(iii) *Interagency disputes.* Information specifying procedures for resolving interagency disputes under the interagency agreement or other mechanism for interagency coordination, including procedures under which the designated State unit may initiate proceedings to secure reimbursement from other public entities or otherwise implement the provisions of the agreement or mechanism.

(iv) *Procedures for coordination of services.* Information specifying policies and procedures for public entities to determine and identify interagency coordination responsibilities of each public entity to promote the coordination and timely delivery of vocational rehabilitation services other than those listed in paragraph (b) of this section.

(e) *Responsibilities under other law.*

(1) If a public entity (other than the designated State unit) is obligated under Federal law (such as the Americans with Disabilities Act, section 504 of the Act, or section 188 of the Workforce Investment Act) or State law, or assigned responsibility under State policy or an interagency agreement established under this section, to provide or pay for any services considered to be vocational rehabilitation services (*e.g.*, interpreter services under § 361.48(j)), other than those services listed in paragraph (b) of this section, the public entity must fulfill that obligation or responsibility through—

(i) The terms of the interagency agreement or other requirements of this section;

(ii) Providing or paying for the service directly or by contract; or

(iii) Other arrangement.

(2) If a public entity other than the designated State unit fails to provide or pay for vocational rehabilitation services for an eligible individual as established under this section, the designated State unit must provide or pay for those services to the individual and may claim reimbursement for the services from the public entity that failed to provide or pay for those services. The public entity must reimburse the designated State unit pursuant to the terms of the interagency agreement or other mechanism described in paragraph (d) of this section in accordance with the procedures established in the agreement or mechanism pursuant to paragraph (d)(3)(ii) of this section.

(Authority: Sections 12(c) and 101(a)(8) of the Act; 29 U.S.C. 709(c) and 721(a)(8))

§ 361.54 Participation of individuals in cost of services based on financial need.

(a) *No Federal requirement.* There is no Federal requirement that the financial need of individuals be considered in the provision of vocational rehabilitation services.

(b) *State unit requirements.*

(1) The State unit may choose to consider the financial need of eligible individuals or individuals who are receiving services through trial work experiences under § 361.42(e) or during an extended evaluation under § 361.42(f) for purposes of determining the extent of their participation in the costs of vocational rehabilitation services, other than those services identified in paragraph (b)(3) of this section.

(2) If the State unit chooses to consider financial need—

(i) It must maintain written policies—

(A) Explaining the method for determining the financial need of an eligible individual; and

(B) Specifying the types of vocational rehabilitation services for which the unit has established a financial needs test;

(ii) The policies must be applied uniformly to all individuals in similar circumstances;

(iii) The policies may require different levels of need for different geographic regions in the State, but must be applied uniformly to all individuals within each geographic region; and

(iv) The policies must ensure that the level of an individual's participation in the cost of vocational rehabilitation services is—

(A) Reasonable;

(B) Based on the individual's financial need, including consideration of any disability-related expenses paid by the individual; and

(C) Not so high as to effectively deny the individual a necessary service.

(3) The designated State unit may not apply a financial needs test, or require the financial participation of the individual—

(i) As a condition for furnishing the following vocational rehabilitation services:

(A) Assessment for determining eligibility and priority for services under § 361.48(a), except those non-assessment services that are provided to an individual with a significant disability during either an exploration of the individual's abilities, capabilities, and capacity to perform in work situations through the use of trial work experiences under § 361.42(e) or an extended evaluation under § 361.42(f).

(B) Assessment for determining vocational rehabilitation needs under § 361.48(b).

(C) Vocational rehabilitation counseling and guidance under § 361.48(c).

(D) Referral and other services under § 361.48(d).

(E) Job-related services under § 361.48(l).

(F) Personal assistance services under § 361.48(n).

(G) Any auxiliary aid or service (e.g., interpreter services under § 361.48(j), reader services under § 361.48(k)) that an individual with a disability requires under section 504 of the Act (29 U.S.C. 794) or the Americans with Disabilities Act (42 U.S.C. 12101, *et seq.*), or regulations implementing those laws, in order for the individual to participate in the VR program as authorized under this part; or

(ii) As a condition for furnishing any vocational rehabilitation service if the individual in need of the service has been determined eligible for Social Security benefits under Titles II or XVI of the Social Security Act.

(Authority: Section 12(c) of the Act; 29 U.S.C. 709(c))

§ 361.55 Annual review of individuals in extended employment or other employment under special certificate provisions of the Fair Labor Standards Act.

The State plan must assure that the designated State unit—

(a) Annually reviews and reevaluates the status of each individual with a disability served under the vocational rehabilitation program who has achieved an employment outcome either in an extended employment setting in a community rehabilitation program or in any other employment setting in which the individual is compensated in accordance with section 14(c) of the Fair Labor Standards Act for 2 years after the individual achieves the employment outcome (and thereafter if requested by the individual or, if appropriate, the individual's representative) to determine the interests, priorities, and needs of the individual with respect to competitive employment or training for competitive employment;

(b) Enables the individual or, if appropriate, the individual's representative to provide input into the review and reevaluation and documents that input in the record of services, consistent with § 361.47(a)(10), with the individual's or, as appropriate, the individual's representative's signed acknowledgment that the review and reevaluation have been conducted; and

(c) Makes maximum efforts, including identifying and providing vocational rehabilitation services, reasonable accommodations, and other necessary support services, to assist the individuals identified in paragraph (a) of this section in engaging in competitive employment as defined in § 361.5(b)(11).

(Authority: Section 101(a)(14) of the Act; 29 U.S.C. 721(a)(14))

§ 361.56 Requirements for closing the record of services of an individual who has achieved an employment outcome.

The record of services of an individual who has achieved an employment outcome may be closed only if all of the following requirements are met:

(a) *Employment outcome achieved.* The individual has achieved the employment outcome that is described in the individual's IPE in accordance with § 361.46(a)(1) and is—

(1) Consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice; and (2) In the most integrated setting possible, consistent with the individual's informed choice.

(b) *Employment outcome maintained.* The individual has maintained the employment outcome for an appropriate period of time, but not less than 90 days, necessary to ensure the stability of the employment outcome, and the individual no longer needs vocational rehabilitation services.

(c) *Satisfactory outcome.* At the end of the appropriate period under paragraph (b) of this section, the individual and the qualified rehabilitation counselor employed by the designated State unit consider the employment outcome to be satisfactory and agree that the individual is performing well in the employment.

(d) *Post-employment services.* The individual is informed through appropriate modes of communication of the availability of post-employment services.

(Authority: Sections 12(c), 101(a)(6), and 106(a)(2) of the Act; 29 U.S.C. 711(c), 721(a)(6), and 726(a)(2))

§ 361.57 Review of determinations made by designated State unit personnel.

(a) *Procedures.* The designated State unit must develop and implement procedures to ensure that an applicant or eligible individual who is dissatisfied with any determination made by personnel of the designated State unit that affects the provision of vocational rehabilitation services may request, or, if appropriate, may request through the individual's representative, a timely review of that determination. The procedures must be in accordance with paragraphs (b) through (k) of this section:

(b) *General requirements.*

(1) *Notification.* Procedures established by the State unit under this section must provide an applicant or eligible individual or, as appropriate, the individual's representative notice of—

(i) The right to obtain review of State unit determinations that affect the provision of vocational rehabilitation services through an impartial due process hearing under paragraph (e) of this section;

(ii) The right to pursue mediation under paragraph (d) of this section with respect to determinations made by designated State unit personnel that affect the provision of vocational rehabilitation services to an applicant or eligible individual;

(iii) The names and addresses of individuals with whom requests for mediation or due process hearings may be filed;

(iv) The manner in which a mediator or impartial hearing officer may be selected consistent with the requirements of paragraphs (d) and (f) of this section; and

(v) The availability of the client assistance program, established under 34 CFR part 370, to assist the applicant or eligible individual during mediation sessions or impartial due process hearings.

(2) *Timing.* Notice described in paragraph (b)(1) of this section must be provided in writing—

(i) At the time the individual applies for vocational rehabilitation services under this part;

(ii) At the time the individual is assigned to a category in the State's order of selection, if the State has established an order of selection under § 361.36;

(iii) At the time the IPE is developed; and

(iv) Whenever vocational rehabilitation services for an individual are reduced, suspended, or terminated.

(3) *Evidence and representation.* Procedures established under this section must—

(i) Provide an applicant or eligible individual or, as appropriate, the individual's representative with an opportunity to submit during mediation sessions or due process hearings evidence and other information that supports the applicant's or eligible individual's position; and

(ii) Allow an applicant or eligible individual to be represented during mediation sessions or due process hearings by counsel or other advocate selected by the applicant or eligible individual.

(4) *Impact on provision of services.* The State unit may not institute a suspension, reduction, or termination of vocational rehabilitation services being provided to an applicant or eligible individual, including evaluation and assessment services and IPE development, pending a resolution through mediation, pending a decision by a hearing officer or reviewing official, or pending informal resolution under this section unless—

(i) The individual or, in appropriate cases, the individual's representative requests a suspension, reduction, or termination of services; or

(ii) The State agency has evidence that the services have been obtained through misrepresentation, fraud, collusion, or criminal conduct on the part of the individual or the individual's representative.

(5) *Ineligibility.* Applicants who are found ineligible for vocational rehabilitation services and previously eligible individuals who are determined to be no longer eligible for vocational rehabilitation services pursuant to § 361.43 are permitted to challenge the determinations of ineligibility under the procedures described in this section.

(c) *Informal dispute resolution.* The State unit may develop an informal process for resolving a request for review without conducting mediation or a formal hearing. A State's informal process must not be used to deny the right of an applicant or eligible individual to a hearing under paragraph (e) of this section or any other right provided under this part, including the right to pursue mediation under paragraph (d) of this section. If informal resolution under this paragraph or mediation under paragraph (d) of this section is not successful in resolving the dispute within the time period established under paragraph (e)(1) of this section, a formal hearing must be conducted within that same time period, unless the parties agree to a specific extension of time.

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(d) *Mediation.*

(1) The State must establish and implement procedures, as required under paragraph (b)(1)(ii) of this section, to allow an applicant or eligible individual and the State unit to resolve disputes involving State unit determinations that affect the provision of vocational rehabilitation services through a mediation process that must be made available, at a minimum, whenever an applicant or eligible individual or, as appropriate, the individual's representative requests an impartial due process hearing under this section.

(2) Mediation procedures established by the State unit under paragraph (d) must ensure that—

(i) Participation in the mediation process is voluntary on the part of the applicant or eligible individual, as appropriate, and on the part of the State unit;

(ii) Use of the mediation process is not used to deny or delay the applicant's or eligible individual's right to pursue resolution of the dispute through an impartial hearing held within the time period specified in paragraph (e)(1) of this section or any other rights provided under this part. At any point during the mediation process, either party or the mediator may elect to terminate the mediation. In the event mediation is terminated, either party may pursue resolution through an impartial hearing;

(iii) The mediation process is conducted by a qualified and impartial mediator, as defined in § 361.5(b)(43), who must be selected from a list of qualified and impartial mediators maintained by the State—

(A) On a random basis;

(B) By agreement between the director of the designated State unit and the applicant or eligible individual or, as appropriate, the individual's representative; or

(C) In accordance with a procedure established in the State for assigning mediators, provided this procedure ensures the neutrality of the mediator assigned; and

(iv) Mediation sessions are scheduled and conducted in a timely manner and are held in a location and manner that is convenient to the parties to the dispute.

(3) Discussions that occur during the mediation process must be kept confidential and may not be used as evidence in any subsequent due process hearings or civil proceedings, and the parties to the mediation process may be required to sign a confidentiality pledge prior to the commencement of the process.

(4) An agreement reached by the parties to the dispute in the mediation process must be described in a written mediation agreement that is developed by the parties with the assistance of the qualified and impartial mediator and signed by both parties. Copies of the agreement must be sent to both parties.

(5) The costs of the mediation process must be paid by the State. The State is not required to pay for any costs related to the representation of an applicant or eligible individual authorized under paragraph (b)(3)(ii) of this section.

(e) *Impartial due process hearings.* The State unit must establish and implement formal review procedures, as required under paragraph (b)(1)(i) of this section, that provide that—

(1) A hearing conducted by an impartial hearing officer, selected in accordance with paragraph (f) of this section, must be held within 60 days of an applicant's or eligible individual's request for review of a determination made by personnel of the State unit that affects the provision of vocational rehabilitation services to the individual, unless informal resolution or a mediation agreement is achieved prior to the 60th day or the parties agree to a specific extension of time;

(2) In addition to the rights described in paragraph (b)(3) of this section, the applicant or eligible individual or, if appropriate, the individual's representative must be given the opportunity to present witnesses during the hearing and to examine all witnesses and other relevant sources of information and evidence;

(3) The impartial hearing officer must—

(i) Make a decision based on the provisions of the approved State plan, the Act, Federal vocational rehabilitation regulations, and State regulations and policies that are consistent with Federal requirements; and

(ii) Provide to the individual or, if appropriate, the individual's representative and to the State unit a full written report of the findings and grounds for the decision within 30 days of the completion of the hearing; and

(4) The hearing officer's decision is final, except that a party may request an impartial review under paragraph (g)(1) of this section if the State has established procedures for that review, and a party involved in a hearing may bring a civil action under paragraph (i) of this section.

(f) *Selection of impartial hearing officers.* The impartial hearing officer for a particular case must be selected—

(1) From a list of qualified impartial hearing officers maintained by the State unit. Impartial hearing officers included on the list must be—

(i) Identified by the State unit if the State unit is an independent commission; or

(ii) Jointly identified by the State unit and the State Rehabilitation Council if the State has a Council; and

(2)(i) On a random basis; or

(ii) By agreement between the director of the designated State unit and the applicant or eligible individual or, as appropriate, the individual's representative.

(g) *Administrative review of hearing officer's decision.* The State may establish procedures to enable a party who is dissatisfied with the decision of the impartial hearing officer to seek an impartial administrative review of the decision under paragraph (e)(3) of this section in accordance with the following requirements:

(1) A request for administrative review under paragraph (g) of this section must be made within 20 days of the mailing of the impartial hearing officer's decision.

(2) Administrative review of the hearing officer's decision must be conducted by—

(i) The chief official of the designated State agency if the State has established both a designated State agency and a designated State unit under § 361.13(b); or

(ii) An official from the office of the Governor.

(3) The reviewing official described in paragraph (g)(2)(i) of this section—

(i) Provides both parties with an opportunity to submit additional evidence and information relevant to a final decision concerning the matter under review;

(ii) May not overturn or modify the hearing officer's decision, or any part of that decision, that supports the position of the applicant or eligible individual unless the reviewing official concludes, based on clear and convincing evidence, that the decision of the impartial hearing officer is clearly erroneous on the basis of being contrary to the approved State plan, the Act, Federal vocational rehabilitation regulations, or State regulations and policies that are consistent with Federal requirements;

(iii) Makes an independent, final decision following a review of the entire hearing record and provides the decision in writing, including a full report of the findings and the statutory, regulatory, or policy grounds for the decision, to the applicant or eligible individual or, as appropriate, the individual's representative and to the State unit within 30 days of the request for administrative review under paragraph (g)(1) of this section; and

(iv) May not delegate the responsibility for making the final decision under paragraph (g) of this section to any officer or employee of the designated State unit.

(4) The reviewing official's decision under paragraph (g) of this section is final unless either party brings a civil action under paragraph (i) of this section.

(h) *Implementation of final decisions.* If a party brings a civil action under paragraph (h) of this section to challenge the final decision of a hearing officer under paragraph (e) of this section or to challenge the final decision of a State reviewing official under paragraph (g) of this section, the final decision of the hearing officer or State reviewing official must be implemented pending review by the court.

(i) *Civil action.*

(1) Any party who disagrees with the findings and decision of an impartial hearing officer under paragraph (e) of this section in a State that has not established administrative review procedures under paragraph (g) of this section and any party who disagrees with the findings and decision under paragraph (g)(3)(iii) of this section have a right to bring a civil action with respect to the matter in dispute. The action may be brought in any State court of competent jurisdiction or in a district court of the United States of competent jurisdiction without regard to the amount in controversy.

(2) In any action brought under paragraph (i) of this section, the court—

(i) Receives the records related to the impartial due process hearing and the records related to the administrative review process, if applicable;

(ii) Hears additional evidence at the request of a party; and

(iii) Basing its decision on the preponderance of the evidence, grants the relief that the court determines to be appropriate.

(j) *State fair hearing board.* A fair hearing board as defined in § 361.5(b)(22) is authorized to carry out the responsibilities of the impartial hearing officer under paragraph (e) of this section in accordance with the following criteria:

(1) The fair hearing board may conduct due process hearings either collectively or by assigning responsibility for conducting the hearing to one or more members of the fair hearing board.

(2) The final decision issued by the fair hearing board following a hearing under paragraph (j)(1) of this section must be made collectively by, or by a majority vote of, the fair hearing board.

(3) The provisions of paragraphs (b)(1), (2), and (3) of this section that relate to due process hearings and of paragraphs (e), (f), (g), and (h) of this section do not apply to fair hearing boards under this paragraph (j).

(k) *Data collection.*

(1) The director of the designated State unit must collect and submit, at a minimum, the following data to the Commissioner of the Rehabilitation Services Administration (RSA) for inclusion each year in the annual report to Congress under section 13 of the Act:

(i) A copy of the standards used by State reviewing officials for reviewing decisions made by impartial hearing officers under this section.

(ii) The number of mediations held, including the number of mediation agreements reached.

(iii) The number of hearings and reviews sought from impartial hearing officers and State reviewing officials, including the type of complaints and the issues involved.

(iv) The number of hearing officer decisions that were not reviewed by administrative reviewing officials.

(v) The number of hearing decisions that were reviewed by State reviewing officials and, based on these reviews, the number of hearing decisions that were—

(A) Sustained in favor of an applicant or eligible individual;

(B) Sustained in favor of the designated State unit;

(C) Reversed in whole or in part in favor of the applicant or eligible individual; and

(D) Reversed in whole or in part in favor of the State unit.

(2) The State unit director also must collect and submit to the Commissioner of RSA copies of all final decisions issued by impartial hearing officers under paragraph (e) of this section and by State review officials under paragraph (g) of this section.

(3) The confidentiality of records of applicants and eligible individuals maintained by the State unit may not preclude the access of the RSA Commissioner to those records for the purposes described in this section.

(Authority: Section 102(c) of the Act; 29 U.S.C. 722(c))

Subpart C—Financing of State Vocational Rehabilitation Programs

§ 361.60 Matching requirements.

(a) *Federal share.*

(1) *General.* Except as provided in paragraph (a)(2) of this section, the Federal share for expenditures made by the State under the State plan, including expenditures for the provision of vocational rehabilitation services and the administration of the State plan, is 78.7 percent.

(2) *Construction projects.* The Federal share for expenditures made for the construction of a facility for community rehabilitation program purposes may not be more than 50 percent of the total cost of the project.

(b) *Non-Federal share.*

(1) *General.* Except as provided in paragraph (b)(2) and (3) of this section, expenditures made under the State plan to meet the non-Federal share under this section must be consistent with the provisions of 34 CFR 80.24.

(2) *Third party in-kind contributions.* Third party in-kind contributions specified in 34 CFR 80.24(a)(2) may not be used to meet the non-Federal share under this section.

(3) *Contributions by private entities.* Expenditures made from contributions by private organizations, agencies, or individuals that are deposited in the account of the State agency or sole local agency in accordance with State law and that are earmarked, under a condition imposed by the contributor, may be used as part of the non-Federal share under this section if the funds are earmarked for—

(i) Meeting in whole or in part the State's share for establishing a community rehabilitation program or constructing a particular facility for community rehabilitation program purposes;

(ii) Particular geographic areas within the State for any purpose under the State plan, other than those described in paragraph (b)(3)(i) of this section, in accordance with the following criteria:

(A) Before funds that are earmarked for a particular geographic area may be used as part of the non-Federal share, the State must notify the Secretary that the State cannot provide the full non-Federal share without using these funds.

(B) Funds that are earmarked for a particular geographic area may be used as part of the non-Federal share without requesting a waiver of statewideness under § 361.26.

(C) Except as provided in paragraph (b)(3)(i) of this section, all Federal funds must be used on a statewide basis consistent with § 361.25, unless a waiver of statewideness is obtained under § 361.26; and

(iii) Any other purpose under the State plan, provided the expenditures do not benefit in any way the donor, an individual to whom the donor is related by blood or marriage or with whom the donor has a close personal relationship,

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or an individual, entity, or organization with whom the donor shares a financial interest. The Secretary does not consider a donor's receipt from the State unit of a grant, subgrant, or contract with funds allotted under this part to be a benefit for the purposes of this paragraph if the grant, subgrant, or contract is awarded under the State's regular competitive procedures.

(Authority: Sections 7(14), 101(a)(3), 101(a)(4) and 104 of the Act; 29 U.S.C. 706(14), 721(a)(3), 721(a)(4) and 724))

Example for paragraph (b)(3): Contributions may be earmarked in accordance with § 361.60(b)(3)(iii) for providing particular services (*e.g.*, rehabilitation technology services); serving individuals with certain types of disabilities (*e.g.*, individuals who are blind), consistent with the State's order of selection, if applicable; providing services to special groups that State or Federal law permits to be targeted for services (*e.g.*, students with disabilities who are receiving special education services), consistent with the State's order of selection, if applicable; or carrying out particular types of administrative activities permissible under State law. Contributions also may be restricted to particular geographic areas to increase services or expand the scope of services that are available statewide under the State plan in accordance with the requirements in § 361.60(b)(3)(ii).

§ 361.61 Limitation on use of funds for construction expenditures.

No more than 10 percent of a State's allotment for any fiscal year under section 110 of the Act may be spent on the construction of facilities for community rehabilitation program purposes.

(Authority: Section 101(a)(17)(A) of the Act; 29 U.S.C. 721(a)(17)(A))

§ 361.62 Maintenance of effort requirements.

(a) *General requirements.*

(1) The Secretary reduces the amount otherwise payable to a State for a fiscal year by the amount by which the total expenditures from non-Federal sources under the State plan for the previous fiscal year were less than the total of those expenditures for the fiscal year 2 years prior to the previous fiscal year.

Example: For fiscal year 2001, a State's maintenance of effort level is based on the amount of its expenditures from non-Federal sources for fiscal year 1999. Thus, if the State's non-Federal expenditures in 2001 are less than they were in 1999, the State has a maintenance of effort deficit, and the Secretary reduces the State's allotment in 2002 by the amount of that deficit.

(2) If, at the time the Secretary makes a determination that a State has failed to meet its maintenance of effort requirements, it is too late for the Secretary to make a reduction in accordance with paragraph (a)(1) of this section, then the Secretary recovers the amount of the maintenance of effort deficit through audit disallowance.

(b) *Specific requirements for construction of facilities.* If the State provides for the construction of a facility for community rehabilitation program purposes, the amount of the State's share of expenditures for vocational rehabilitation services under the plan, other than for the construction of a facility for community rehabilitation program purposes or the establishment of a facility for community rehabilitation purposes, must be at least equal to the expenditures for those services for the second prior fiscal year. If a State fails to meet the requirements of this paragraph, the Secretary recovers the amount of the maintenance of effort deficit through audit disallowance.

(c) *Separate State agency for vocational rehabilitation services for individuals who are blind.* If there is a separate part of the State plan administered by a separate State agency to provide vocational rehabilitation services for individuals who are blind—

(1) Satisfaction of the maintenance of effort requirements under paragraphs (a) and (b) of this section are determined based on the total amount of a State's non-Federal expenditures under both parts of the State plan; and

(2) If a State fails to meet any maintenance of effort requirement, the Secretary reduces the amount otherwise payable to the State for that fiscal year under each part of the plan in direct relation to the amount by which expenditures from non-Federal sources under each part of the plan in the previous fiscal year were less than they were for that part of the plan for the fiscal year 2 years prior to the previous fiscal year.

(d) *Waiver or modification.*

(1) The Secretary may waive or modify the maintenance of effort requirement in paragraph (a)(1) of this section if the Secretary determines that a waiver or modification is necessary to permit the State to respond to exceptional or uncontrollable circumstances, such as a major natural disaster or a serious economic downturn, that—

(i) Cause significant unanticipated expenditures or reductions in revenue that result in a general reduction of programs within the State; or

(ii) Require the State to make substantial expenditures in the vocational rehabilitation program for long-term purposes due to the one-time costs associated with the construction of a facility for community rehabilitation program purposes, the establishment of a facility for community rehabilitation program purposes, or the acquisition of equipment.

(2) The Secretary may waive or modify the maintenance of effort requirement in paragraph (b) of this section or the 10 percent allotment limitation in § 361.61 if the Secretary determines that a waiver or modification is necessary to permit the State to respond to exceptional or uncontrollable circumstances, such as a major natural disaster, that result in significant destruction of existiag facilities and require the State to make substantial expenditures for the construction of a facility for community rehabilitation program purposes or the establishment of a facility for community rehabilitation program purposes in order to provide vocational rehabilitation services.

(3) A written request for waiver or modification, including supporting justification, must be submitted to the Secretary as soon as the State determines that an exceptional or uncontrollable circumstance will prevent it from making its required expenditures from non-Federal sources.

(Authority: Sections 101(a)(17) and 111(a)(2) of the Act; 29 U.S.C. 721(a)(17) and 731(a)(2))

§ 361.63 Program income.

(a) *Definition.* For purposes of this section, *program income* means gross income received by the State that is directly generated by an activity supported under this part.

(b) *Sources.* Sources of program income include, but are not limited to, payments from the Social Security Administration for assisting Social Security beneficiaries and recipients to achieve employment outcomes, payments received from workers' compensation funds, fees for services to defray part or all of the costs of services provided to particular individuals, and income generated by a State-operated community rehabilitation program.

(c) *Use of program income.*

(1) Except as provided in paragraph (c)(2) of this section, program income, whenever earned, must be used for the provision of vocational rehabilitation services and the administration of the State plan. Program income is considered earned when it is received.

(2) Payments provided to a State from the Social Security Administration for assisting Social Security beneficiaries and recipients to achieve employment outcomes may also be used to carry out programs under part B of Title I of the Act (client assistance), part B of Title VI of the Act (supported employment), and Title VII of the Act (independent living).

(3) The State is authorized to treat program income as—

(i) An addition to the grant funds to be used for additional allowable program expenditures, in accordance with 34 CFR 80.25(g)(2); or

(ii) A deduction from total allowable costs, in accordance with 34 CFR 80.25(g)(1).

(4) Program income cannot be used to meet the non-Federal share requirement under § 361.60.

(Authority: Section 108 of the Act; 29 U.S.C. 728; 34 CFR 80.25)

§ 361.64 Obligation of Federal funds and program income.

(a) Except as provided in paragraph (b) of this section, any Federal funds, including reallotted funds, that are appropriated for a fiscal year to carry out a program under this part that are not obligated by the State by the beginning of the succeeding fiscal year and any program income received during a fiscal year that is not obligated by the State by the beginning of the succeeding fiscal year remain available for obligation by the State during that succeeding fiscal year.

(b) Federal funds appropriated for a fiscal year remain available for obligation in the succeeding fiscal year only to the extent that the State met the matching requirement for those Federal funds by obligating, in accordance with 34 CFR 76.707, the non-Federal share in the fiscal year for which the funds were appropriated.

(Authority: Section 19 of the Act; 29 U.S.C. 716)

§ 361.65 Allotment and payment of Federal funds for vocational rehabilitation services.

(a) *Allotment.*

(1) The allotment of Federal funds for vocational rehabilitation services for each State is computed in accordance with the requirements of section 110 of the Act, and payments are made to the State on a quarterly basis, unless some other period is established by the Secretary.

(2) If the State plan designates one State agency to administer, or supervise the administration of, the part of the plan under which vocational rehabilitation services are provided for individuals who are blind and another State agency to administer the rest of the plan, the division of the State's allotment is a matter for State determination.

(b) *Reallotment.*

(1) The Secretary determines not later than 45 days before the end of a fiscal year which States, if any, will not use their full allotment.

(2) As soon as possible, but not later than the end of the fiscal year, the Secretary reallots these funds to other States that can use those additional funds during the current or subsequent fiscal year, provided the State can meet the matching requirement by obligating the non-Federal share of any reallotted funds in the fiscal year for which the funds were appropriated.

(3) Funds reallotted to another State are considered to be an increase in the recipient State's allotment for the fiscal year for which the funds were appropriated.

(Authority: Sections 110 and 111 of the Act; 29 U.S.C. 730 and 731)

Subpart D—[Reserved]

Subpart E—Evaluation Standards and Performance Indicators

§ 361.80 Purpose.

The purpose of this subpart is to establish evaluation standards and performance indicators for the Program.

(Authority: 29 U.S.C. 726(a))

§ 361.81 Applicable definitions.

In addition to those definitions in § 361.5(b), the following definitions apply to this subpart:

Average hourly earnings means the average per hour earnings in the week prior to exiting the vocational rehabilitation (VR) program of an eligible individual who has achieved a competitive employment outcome.

Business Enterprise Program (BEP) means an employment outcome in which an individual with a significant disability operates a vending facility or other small business under the management and supervision of a designated State unit (DSU). This term includes home industry, farming, and other enterprises.

Exit the VR program means that a DSU has closed the individual's record of VR services in one of the following categories:

(1) Ineligible for VR services.

(2) Received services under an individualized plan for employment (IPE) and achieved an employment outcome.

(3) Received services under an IPE but did not achieve an employment outcome.

(4) Eligible for VR services but did not receive services under an IPE.

General or combined DSU means a DSU that does not serve exclusively individuals with visual impairments or blindness.

Individuals from a minority background means individuals who report their race and ethnicity in any of the following categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, or Hispanic or Latino.

Minimum wage means the higher of the rate specified in section 6(a)(1) of the Fair Labor Standards Act of 1938, 29 U.S.C. 206(a)(1), (i.e., the Federal minimum wage) or applicable State minimum wage law.

Non-minority individuals means individuals who report themselves exclusively as White, non-Hispanic.

Performance period is the reporting period during which a DSU's performance is measured. For Evaluation Standards 1 and 2, performance data must be aggregated and reported for each fiscal year beginning with fiscal year 1999. However, DSUs that exclusively serve individuals with visual impairments or blindness must report each year the aggregated data for the 2 previous years for Performance Indicators 1.1 through 1.6; the second year must coincide with the performance period for general or combined DSUs.

Primary indicators means Performance Indicators 1.3, 1.4, and 1.5, which are specifically designed to measure—

(1) The achievement of competitive, self-, or BEP employment with earnings equivalent to the minimum wage or higher, particularly by individuals with significant disabilities; and

(2) The ratio between the average hourly earnings of individuals who exit the VR program in competitive, self-, or BEP employment with earnings equivalent to the minimum wage or higher and the State's average hourly earnings for all employed individuals.

RSA–911 means the Case Service Report that is submitted annually by a DSU as approved by the Office of Management and Budget (OMB).

Self-employment means an employment outcome in which the individual works for profit or fee in his or her own business, farm, shop, or office, including sharecroppers.

Service rate means the result obtained by dividing the number of individuals who exit the VR program after receiving one or more services under an IPE during any reporting period by the total number of individuals who exit the VR program (as defined in this section) during that reporting period.

State's average hourly earnings means the average hourly earnings of all persons in the State in which the DSU is located.

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(Authority: 29 U.S.C. 726(a))

§ 361.82 Evaluation standards.

(a) The Secretary establishes two evaluation standards to evaluate the performance of each DSU that receives funds under this part. The evaluation standards assist the Secretary and each DSU to evaluate a DSU's performance in serving individuals with disabilities under the VR program.

(b) A DSU must achieve successful performance on both evaluation standards during each performance period.

(c) The evaluation standards for the VR program are—

(1) *Evaluation Standard 1—Employment outcomes.* A DSU must assist any eligible individual, including an individual with a significant disability, to obtain, maintain, or regain high-quality employment.

(2) *Evaluation Standard 2—Equal access to services.* A DSU must ensure that individuals from minority backgrounds have equal access to VR services. (Approved by the Office of Management and Budget under control number 1820–0508.)

(Authority: 29 U.S.C. 726(a))

§ 361.84 Performance indicators.

(a) The performance indicators establish what constitutes minimum compliance with the evaluation standards.

(b) The performance indicators require a DSU to provide information on a variety of factors to enable the Secretary to measure compliance with the evaluation standards.

(c) The performance indicators are as follows:

(1) *Employment outcomes.*

(i) *Performance Indicator 1.1.* The number of individuals exiting the VR program who achieved an employment outcome during the current performance period compared to the number of individuals who exit the VR program after achieving an employment outcome during the previous performance period.

(ii) *Performance Indicator 1.2.* Of all individuals who exit the VR program after receiving services, the percentage who are determined to have achieved an employment outcome.

(iii) *Performance Indicator 1.3.* Of all individuals determined to have achieved an employment outcome, the percentage who exit the VR program in competitive, self-, or BEP employment with earnings equivalent to at least the minimum wage.

(iv) *Performance Indicator 1.4.* Of all individuals who exit the VR program in competitive, self-, or BEP employment with earnings equivalent to at least the minimum wage, the percentage who are individuals with significant disabilities.

(v) *Performance Indicator 1.5.* The average hourly earnings of all individuals who exit the VR program in competitive, self-, or BEP employment with earnings levels equivalent to at least the minimum wage as a ratio to the State's average hourly earnings for all individuals in the State who are employed (as derived from the Bureau of Labor Statistics report "State Average Annual Pay" for the most recent available year).

(vi) *Performance Indicator 1.6.* Of all individuals who exit the VR program in competitive, self-, or BEP employment with earnings equivalent to at least the minimum wage, the difference between the percentage who report their own income as the largest single source of economic support at the time they exit the VR program and the percentage who report their own income as the largest single source of support at the time they apply for VR services.

(2) *Equal access to services.*

(i) *Performance Indicator 2.1.* The service rate for all individuals with disabilities from minority backgrounds as a ratio to the service rate for all non-minority individuals with disabilities.

(Approved by the Office of Management and Budget under control number 1820–0508.)

(Authority: 29 U.S.C. 726(a))

§ 361.86 Performance levels.

(a) *General.*

(1) Paragraph (b) of this section establishes performance levels for—

(i) General or combined DSUs; and

(ii) DSUs serving exclusively individuals who are visually impaired or blind.

(2) The Secretary may establish, by regulations, new performance levels.

(b) *Performance levels for each performance indicator.*

(1)(i) The performance levels for Performance Indicators 1.1 through 1.6 are—

Performance indicator	Performance level by type of DSU	
	General/Combined	Blind
1.1	Equal or exceed previous performance period	Same.
1.2	55.8%	68.9%.
1.3	72.6%	35.4%.
1.4	62.4%	89.0%.
1.5	.52 (Ratio)	.59.
1.6	53.0 (Math. Difference)	30.4.

(ii) To achieve successful performance on Evaluation Standard 1 (Employment outcomes), a DSU must meet or exceed the performance levels established for four of the six performance indicators in the evaluation standard, including meeting or exceeding the performance levels for two of the three primary indicators (Performance Indicators 1.3, 1.4, and 1.5).

(2)(i) The performance level for Performance Indicator 2.1 is—

Performance indicator	Performance levels
2.1	.80 (Ratio).

(ii) To achieve successful performance on Evaluation Standard 2 (Equal access), DSUs must meet or exceed the performance level established for Performance Indicator 2.1 or meet the performance requirement in paragraph (2)(iii) of this section.

(iii) If a DSU's performance does not meet or exceed the performance level required for Performance Indicator 2.1, or if fewer than 100 individuals from a minority population have exited the VR program during the reporting period, the DSU must describe the policies it has adopted or will adopt and the steps it has taken or will take to ensure that individuals with disabilities from minority backgrounds have equal access to VR services.

(Authority: 29 U.S.C. 726(a))

§ 361.88 Reporting requirements.

(a) The Secretary requires that each DSU report within 60 days after the end of each fiscal year the extent to which the State is in compliance with the evaluation standards and performance indicators and include in this report the following RSA–911 data:

(1) The number of individuals who exited the VR program in each closure category as specified in the definition of "Exit the VR program" under § 361.81.

(2) The number of individuals who exited the VR program in competitive, self-, or BEP employment with earnings at or above the minimum wage.

(3) The number of individuals with significant disabilities who exited the VR program in competitive, self-, or BEP employment with earnings at or above the minimum wage.

(4) The weekly earnings and hours worked of individuals who exited the VR program in competitive, self-, or BEP employment with earnings at or above the minimum wage.

(5) The number of individuals who exited the VR program in competitive, self-, or BEP employment with earnings at or above the minimum wage whose primary source of support at the time they applied for VR services was "personal income."

(6) The number of individuals who exited the VR program in competitive, self-, or BEP employment with earnings at or above the minimum wage whose primary source of support at closure was "personal income."

(7) The number of individuals exiting the VR program who are individuals from a minority background.

(8) The number of non-minority individuals exiting the VR program.

(9) The number of individuals from a minority background exiting the VR program after receiving services under an IPE.

(10) The number of non-minority individuals exiting the VR program after receiving services under an IPE.

(b) In lieu of the report required in paragraph (a) of this section, a DSU may submit its RSA–911 data on tape, diskette, or any alternative electronic format that is compatible with RSA's capability to process such an alternative, as long as the tape, diskette, or alternative electronic format includes the data that—

(1) Are required by paragraph (a)(1) through (10) of this section; and

(2) Meet the requirements of paragraph (c) of this section.

(c) Data reported by a DSU must be valid, accurate, and in a consistent format. If a DSU fails to submit data that are valid, accurate, and in a consistent format within the 60-day period, the DSU must develop a program improvement plan pursuant to § 361.89(a). (Approved by the Office of Management and Budget under control number 1820–0508.)

(Authority: 29 U.S.C. 726(b))

§ 361.89 Enforcement procedures.

(a) If a DSU fails to meet the established performance levels on both evaluation standards as required by § 361.82(b), the Secretary and the DSU must jointly develop a program improvement plan that outlines the specific actions to be taken by the DSU to improve program performance.

(b) In developing the program improvement plan, the Secretary considers all available data and information related to the DSU's performance.

(c) When a program improvement plan is in effect, review of the plan is conducted on a biannual basis. If necessary, the Secretary may request that a DSU make further revisions to the plan to improve performance. If the Secretary establishes new performance levels under § 361.86(a)(2), the Secretary and the DSU must jointly modify the program improvement plan based on the new performance levels. The Secretary continues reviews and requests revisions until the DSU sustains satisfactory performance based on the current performance levels over a period of more than 1 year.

(d) If the Secretary determines that a DSU with less than satisfactory performance has failed to enter into a program improvement plan or comply substantially with the terms and conditions of the program improvement plan, the Secretary, consistent with the procedures specified in § 361.11, reduces or makes no further payments to the DSU under this program until the DSU has met one of these two requirements or raised its subsequent performance to meet the current overall minimum satisfactory level on the compliance indicators.

(Approved by the Office of Management and Budget under control number 1820–0508.)

(Authority: 29 U.S.C. 726(b) and (c))

Appendix

Analysis of Comments and Changes

Note: The following appendix will not appear in the Code of Federal Regulations.

Section 361.4—Applicable Regulations

Comments: Several commenters requested clarification of proposed § 361.4(c) and (d) that made applicable to the VR program the regulations implementing the One-Stop system under Title I of the WIA. In particular, these commenters requested that the Secretary assure in this section that the regulations governing the One-Stop system do not conflict with the regulations in part 361 and that the One-Stop system requirements would not apply if conflicts between regulatory provisions arise.

Discussion: Proposed § 361.4(c) listed the regulations in 20 CFR part 662 (Description of One-Stop Service Delivery System under Title I of WIA) among the regulations applicable to the VR program. Similarly, proposed § 361.4(d) identified the civil rights protections under 29 CFR part 37 (Implementation of the Nondiscrimination and Equal Opportunity Provisions of WIA) as applicable to VR program activities that are conducted as part of the One-Stop system. Citing these parts of Federal regulations is intended solely as a means of notifying State units of their regulatory obligations as One-Stop system partners.

Moreover, both Title I of WIA and its implementing regulations specify that partner programs, such as the VR program, are to participate in applicable One-Stop system activities in a manner that is consistent with the Federal law authorizing the individual partner program (see e.g., section 121(b)(1)(A)(ii) of WIA; 20 CFR 662.230(d)). We interpret this requirement to mean that the DSU administering the VR program in the State must partner with the other components of the One-Stop system in accordance with the requirements of both Title I of the Rehabilitation Act of 1973 and these final regulations. Given that condition on One-Stop system participation, and the fact that these regulations generally govern State conduct, we do not consider it appropriate to include in the regulations the assurances sought by the commenters. However, we emphasize that we have worked closely with the U.S. Department of Labor to ensure that the One-Stop system regulations do not conflict with VR program requirements. Despite these efforts, we urge State units and others to inform us of any apparent conflicts between regulatory provisions that arise so that we, along with the Department of Labor, can address any inconsistencies that might remain.

Changes: None.

Section 361.5(b)—Applicable Definitions

• *General*

Comments: Several commenters asked that additional terms be defined in the final regulations. One commenter requested that a definition of "informed choice" be added to the regulations. Other commenters asked that separate definitions of the terms "qualified vocational rehabilitation counselor" and "qualified vocational rehabilitation counselor employed by the designated State unit" be included among the regulatory definitions. Finally, some commenters asked that "rehabilitation engineering" be defined in the final regulations since that term is used in the definition of "rehabilitation technology," while others suggested that "mediation" be defined in the final regulations in order to clarify the scope of the mediation process.

Discussion: We do not believe it is necessary to define "informed choice" in the final regulations. Section 361.52 of both the proposed and final regulations, which tracks section 102(d) of the Act, enumerates the critical aspects of informed choice and reflects the statutory emphasis that individuals participating in the VR program must be able to exercise informed choice

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throughout the entire rehabilitation process. That section of the regulations also retains additional choice-related provisions from the current regulations, including, in § 361.52(c), the types of information that must be provided for an individual to exercise choice in selecting VR services and service providers. Thus, § 361.52, as a whole, contains a comprehensive list of requirements intended to ensure that individuals are given meaningful choices, and the opportunity to exercise those choices, in each aspect of their rehabilitation, as the Act intends.

For further discussion of our decision to not define "informed choice," please see the analysis of comments to § 361.52 in this appendix.

We agree that clarification is needed concerning the distinction between a "qualified vocational rehabilitation counselor" and a "qualified vocational rehabilitation counselor employed by the DSU." However, we do not believe that defining these terms would provide the necessary clarification since States can readily determine which counselors they employ. Rather, we think it would be more helpful to further explain the differences between the functions that must be performed by DSU and non-DSU counselors. That discussion can be found in the analysis of comments received under § 361.45.

We agree that retaining the current regulatory definition of "rehabilitation engineering" would be beneficial.

Finally, the 1998 Amendments introduced mediation as another means for individuals and State units to resolve disputes regarding the provision of VR services. Although mediation is new to the VR program, it has been used for years in other programs as a less adversarial process for resolving disputes than formal due process hearings or court litigation. The NPRM provided guidance to States in developing their systems of mediation by defining the statutory term "qualified and impartial mediator." However, we agree that defining "mediation" in the regulations would provide further clarification.

We believe it is important that the regulations give States sufficient flexibility to establish mediation procedures that best meet the needs of individuals with disabilities in the State and the needs of the State unit. At the same time, for efficiency purposes, we feel that the definition of "mediation" in the final regulations should allow for States to conduct mediations under the VR program in a manner that is consistent with those conducted by the State under similar programs. We believe that a definition that is based on relevant portions of the definition of "mediation" in the Federal regulations governing the Client Assistance Program (CAP) in 34 CFR 370.6(b) serves both of those purposes.

Changes: We have amended the proposed regulations to include definitions of the terms "mediation" and "rehabilitation engineering." These definitions are located in § 361.5(b)(36) and (b)(44), respectively, meaning that other definitions in the proposed regulations have been renumbered in the final regulations.

• *Administrative costs under the State plan*

Comments: One commenter asked why the listing of costs in the proposed definition of "administrative costs under the State plan" was preceded by the term "including" rather than "including, but not limited to," as in the current regulations. This same commenter also asked what is meant by "support services" to other entities, which was listed as an administrative cost under § 361.5(b)(2)(iv) of the proposed regulations.

Discussion: The proposed definition of "administrative costs under the State plan," which tracks the definition in section 7(1) of the Act, does not differ substantively from the previous regulatory definition. However, because we interpret the statutory definition to allow for "administrative costs" other than those listed in the Act, we agree with the commenter that the definition should specify that the scope of administrative costs is not limited to the costs listed in the definition.

"Support services to other State agencies, private nonprofit organizations, and businesses and industries," which is referenced in section 7(1)(D) of the Act, as well as in § 361.5(b)(2)(iv), can include activities such as training the staff of the One-Stop system on disability issues, providing organizations with materials and advice on auxiliary aids and services and other accessibility issues, reviewing employers' workplace policies and hiring practices, and other activities that would facilitate and promote the employment of individuals with disabilities. The scope of support services that a State unit may provide would differ depending upon the circumstances in that State.

Changes: We have amended the definition of "administrative costs under the State plan" to clarify that the scope of administrative costs under the program includes, but is not limited to, the costs listed in the definition.

• *Appropriate modes of communication*

Comments: Several commenters requested that we amend the proposed definition of "appropriate modes of communication" to include additional communication modes that are available for individuals who are deaf or hard of hearing.

Discussion: The definition of "appropriate modes of communication" in the proposed regulations, which was the same as the previous regulatory definition, was not intended as a comprehensive list of communication modes used by persons with disabilities. Accordingly, the definition specified that the scope of appropriate modes was not limited to the identified examples and allowed for other modes as they are needed.

Changes: None.

• Assessment for determining eligibility and vocational rehabilitation needs

Comments: One commenter asked that this proposed definition be amended to ensure that the information used in assessing eligibility, order of selection category, and vocational rehabilitation needs of an individual with a disability is provided by professionals with expertise in the individual's disabling condition or conditions. This commenter also asked that we revise the proposed regulations to require that appropriate modes of communication are used in the course of conducting assessments.

Discussion: The points made by the commenter relate to important elements of the assessment process. However, we believe those points are sufficiently addressed by other requirements in the regulations. For example, § 361.42(a) of both the proposed and final regulations requires that determinations of eligibility be made by qualified personnel. Similarly, § 361.18(e) requires that the State unit be able to communicate with applicants, as well as eligible individuals, through appropriate modes of communication. Because these requirements apply to the State unit as it conducts assessments and fulfills its other functions, we do not consider it necessary to amend the proposed definition as the commenter requested.

Changes: None.

• *Comparable services and benefits*

Comments: One commenter asked that the proposed definition be revised to specifically exclude the personal resources of the eligible individual from the scope of "comparable services and benefits" that the State unit must use before expending program funds in support of VR services.

In addition, a number of commenters asked whether a "ticket" issued to an individual with a disability under the Ticket to Work and Work Incentives Improvement Act of 1999, Pub. L. 106–170 (TWWIIA) constitutes a comparable service or benefit. Several other commenters stated that a Plan for Achieving Self-Support (PASS) issued by the Social Security Administration (SSA) should not be treated as a comparable service or benefit.

Discussion: The proposed regulatory definition of comparable services and benefits—services and benefits that are provided or paid for by other Federal, State or local public agencies, by health insurance, or by employee benefits—did not include the eligible individual's personal resources. Nonetheless, an individual may be asked to participate in the costs of certain VR services to the extent that the State unit uses a financial needs test that is consistent with the requirements in § 361.54 of the regulations.

Because Social Security recipients with disabilities are issued "tickets" under TWWIIA in order to receive training and employment-related services from an employment network as defined in that act, we believe that the ticket constitutes a comparable service and benefit under the VR program. Thus, to the extent that a ticket holder is receiving services from another entity that is serving as that individual's employment network, the DSU need not expend VR program funds on services that are comparable to the services the individual is already receiving. On the other hand, if the individual initially chooses the DSU as its employment network under TWWIIA, or otherwise transfers his or her ticket to the DSU, then the individual would be served solely by the DSU, and the ticket would not be considered a comparable service and benefit.

On a related point, we note that DSUs must accept a ticket as sufficient evidence that the ticket holder has a disability, is receiving Social Security benefits, and therefore is presumptively eligible under the VR program (see § 361.42(a)(3) of the final regulations).

Finally, we agree with the commenters' assertion that a PASS does not constitute a comparable service or benefit. Simply stated, a PASS is a mechanism made available to SSDI beneficiaries under the Social Security Act that enables its holder to conserve certain amounts of his or her own income or resources for purposes of supporting himself or herself in the future. Thus, because a PASS is not a source of support for VR services, we do not view it as a comparable benefit that the DSU can look to as an alternative to expending VR program funds.

Changes: None.

• *Competitive employment*

Comments: One commenter questioned the basis for the requirement that "competitive employment" be limited to employment outcomes in integrated settings. A second commenter asked that we broaden the definition of "competitive employment" in the proposed regulations to include employment under the Javits-Wagner-O'Day (JWOD) program if that employment is chosen by the eligible individual.

Discussion: The proposed definition of "competitive employment" was the same as that found in the previous regulations. Although the term is not defined in the Act, section 7(11), the statutory definition of "employment outcome" does refer to competitive employment in the integrated labor market. On that basis, and in light of the great emphasis that the Act places on maximizing the integration into society of persons with disabilities, it has been our longstanding policy to define "competitive employment" to mean employment in an integrated setting (at or above minimum wage). For further information on the integrated setting (and wage) components of the "competitive employment" definition, please refer to the relevant discussion in the preamble to the previous regulations (62 FR 6310 through 6311).

Whether an employment outcome meets the regulatory definition of "competitive employment" is to be determined on case-by-case basis. If a particular job, including a job secured under the JWOD program, is integrated (*i.e.*, the individual with a disability interacts with non-disabled persons to the same extent that non-disabled individuals in comparable positions interact with other persons; § 361.5(b)(33)(ii) of the final regulations) and the individual is compensated at or above the minimum wage (and not less than the customary wage and benefit level paid by the employer for the same or similar work performed by individuals who are not disabled; § 361.5(b)(11)(ii) of the final regulations), then that position would be considered competitive employment. In fact, we expect that many jobs secured under JWOD service contracts would meet these criteria. On the other hand, employment in a non-integrated setting such as a sheltered workshop would not qualify as competitive employment regardless of whether the position is obtained under a JWOD contract or another program or arrangement.

Changes: None.

• *Employment outcome*

Comments: A number of commenters recommended that we expand the definition of "employment outcome" in the proposed regulations (*i.e.*, entering or retaining full- or part-time competitive, supported, or other employment) to include "advancing in" appropriate employment. This change, the commenters believe, would encourage DSUs to look beyond entry-level employment options for eligible individuals.

Another commenter asked that we define "part-time employment" in the final regulations. This commenter expressed concern about DSUs expending resources on individuals who might work very few hours in the course of a week or a month.

Discussion: The chief purpose of the VR program is to assist eligible individuals with disabilities to achieve high-quality employment outcomes consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice. Because that standard is reflected in the definition of the term "employment outcome," we believe that the regulations sufficiently support the commenters' point that individuals with disabilities who are currently employed should be able to receive VR services in order to advance in their careers.

Additionally, the availability of VR services for purposes of "advancing in" employment is addressed in other parts of the regulations. For example, § 361.46(a)(1)(i)) of the final regulations also specifies that the employment outcome identified in the individualized plan for employment, *i.e.*, the employment goal the individual must pursue with the assistance of the State unit, must be consistent with the individual's unique strengths, resources, priorities, concerns, abilities, capabilities, career interests, and informed choice. That section requires that States look beyond options in entry-level employment for VR program participants who are capable of more challenging work. Specifically, the eligible individual should be assisted in pursuing the job that reflects his or her strengths, resources, abilities, and other employment factors previously listed. We suggest that you consult Rehabilitation Services Administration (RSA) Policy Directive 97–04 for a more complete discussion of the scope and selection of employment outcomes for eligible individuals.

We have not defined "part-time employment" as used in the proposed definition of "employment outcome." We note that most employers generally consider any job of less than 35 hours per week to be part-time. Yet, we do not believe that it would be appropriate to require a minimum number of hours for part-time work secured through the VR program.

Although we think that instances in which eligible individuals work only a handful of hours per week are limited, we do not want to discourage State units from serving potential part-time workers who, with the State unit's support, may increase their hours or even become employed full-time at a later date.

Changes: None.

• *Fair Hearing Board*

Comments: One commenter suggested modifying the proposed regulations to require a State's fair hearing board to include at least one individual with a disability.

Discussion: By defining "fair hearing board" in the proposed regulations, we intended to clarify past confusion about the scope of the fair hearing board exception to the due process requirements under section 102(c)(6)(A) of the Act. In particular, the proposed regulations specified in § 361.57(j) that for a State's pre-1985 fair hearing board to qualify under the exception, that board must be comprised of a group of persons that acts collectively when issuing final decisions to resolve disputes concerning the provision of VR services to applicants or eligible individuals.

These proposed requirements were intended to address instances in which some States had misinterpreted the exception as enabling a single administrative law judge or other official of a State office of hearing examiners to carry out hearings under § 361.57 without following the procedural requirements in that section. In response, we modeled the proposed definition after the actual State fair hearing board that served as the catalyst for the statutory exception in the 1986 Amendments to the Rehabilitation Act. Because those few States with hearing boards that qualify under the exception have long followed this authorized State process for resolving individual disputes under the VR program, we do not believe it is necessary or prudent to impose special membership requirements on those boards through regulations. We do, however, encourage the few fair hearing board States to consider qualified individuals with disabilities when vacancies on these boards arise.

Changes: None.

• *Maintenance*

Comments: Several commenters objected to the use of examples following this definition, stating that the information included in the examples should be placed in sub-regulatory guidance. Other commenters supported the use of the examples in the proposed regulations.

In addition, one commenter asked that we clarify the types of "enrichment activities" that would fall under the fourth example to the proposed definition, while another asked that we eliminate that example altogether.

Discussion: As we have stated in preambles to prior versions of the VR program regulations, we believe that the limited use of examples following the regulatory definition of "maintenance" is helpful in understanding the types of services that maintenance may include. The examples are purely illustrative and are not meant to limit or exclude other types of services that could be considered maintenance.

The fourth example to both the proposed and previous regulatory definition stated that maintenance can include the costs of an individual's "participation in enrichment activities" related to the individual's training. This example was added to the previous regulations in 1997 in response to the requests of public commenters who noted that some DSUs establish limits in

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maintenance budgets that preclude individuals from participating in enrichment activities (*e.g.*, student trips, visits to museums, supplemental lectures, etc.) that are often important components of a student's training program. The "enrichment" example was intended to encourage DSUs to factor in these extra costs when developing an individualized plan for employment (IPE) for a student so that the individual can take advantage of supplemental enrichment activities as appropriate.

Changes: None.

• *Personal assistance services*

Comments: One commenter asked us to point at which a State unit can provide personal assistance services to an individual with a disability.

Discussion: The proposed definition, which was the same as that in the previous regulations, specified that "personal assistance services" (*i.e.*, services designed to assist persons with disabilities in daily living activities) must be necessary to the achievement of an employment outcome and may be provided only while the individual is receiving other VR services. As long as those conditions are met, personal assistance services, as defined in § 361.5(b)(39) of the regulations, can be made available at any stage in the VR process, including during the assessment for determining the individual's eligibility and priority for VR services.

Changes: None.

• *Physical and mental restoration services*

Comments: One commenter asked us to require that all services listed in the proposed definition of "physical and mental restoration services" be provided by personnel who are qualified in accordance with applicable State licensure laws. Another commenter asked that the definition in the final regulations specifically refer to "assistive listening and alerting devices." Finally, one commenter asked that the regulations prohibit a State unit from providing physical or mental restoration services if other resources are available.

Discussion: The proposed regulations followed the scope of physical and mental restoration services specified in section 103(a)(6) of the Act, and we do not believe that it would be appropriate to apply, solely through regulations, State licensure requirements on the provision of additional restoration services. However, a State may, if it has not done so already, choose to establish licensure or other qualified personnel requirements for providers of physical and mental restoration services. Those States would need to address those requirements in its written policies on the nature and scope of services developed under § 361.50.

We do not believe it is necessary to list additional restoration services in the final regulatory definition. Additional medical or medically related services that an individual needs in order to achieve an employment outcome are authorized under § 361.5(b)(40)(xvi).

Similarly, the commenter's concerns about using other resources before expending VR funds in support of restoration services is fully addressed elsewhere in the regulations. Section 361.48(e) of both the proposed and final regulations, under which restoration services are authorized, specifies that those services can be made available only to the extent that financial support for the services is not available from other sources. The application of the more general comparable services and benefit requirements in § 361.53 produces the same result.

Changes: None.

• *Physical or mental impairment*

Comments: Several commenters questioned the proposed revision to the previous regulatory definition of "physical or mental impairment" to mirror the definition used in the regulations implementing section 504 of the Act (section 504) (34 CFR 104.3) and the Americans with Disabilities Act (ADA). The commenters stated that using the ADA or section 504 definition may create confusion, conflict with existing definitions in State law, and weaken the eligibility criteria of the VR program. Several other commenters supported the revised definition, stating that consistency across Federal disability laws leads to more effective administration of the VR and other programs.

Discussion: As noted in the preamble discussion of the changes to the definition of "physical or mental impairment" proposed in the NPRM (65 FR 10622), the revised definition does not impact on the employment-related eligibility criteria under the VR program. The changes to the definition in the previous regulations were proposed in an effort to make the VR program regulations more consistent with other Federal disability laws that define "physical or mental impairment." We agree with those commenters who indicated that consistency with the definition used in the ADA and section 504 regulations increases efficiency and actually lessens confusion by eliminating the need to duplicate efforts in assessing whether an individual has an impairment. Again, the changes address only whether an impairment exists; eligibility for VR services remains dependent on whether an individual also satisfies the eligibility criteria that are focused on employment (*i.e.*, the impairment results in a substantial impediment to employment and the other criteria in § 361.42(a)).

Also, we do not believe that the proposed definition restricted the scope of physical or mental impairments that satisfied the previous regulatory definition or that the proposed definition conflicted with definitions of the same term in State law. If such a conflict exists, we ask that the State seek technical assistance from RSA in modifying its requirements in order to ensure that the State does not employ additional or more restrictive eligibility criteria for individuals to receive VR services as compared to the criteria specified in these final regulations.

Changes: None.

• *Post-employment services*

Comments: One commenter requested that the proposed regulations be modified to eliminate the availability of post-employment services for purposes of "advancing" in employment.

Discussion: Although the term "post-employment services" is not defined in the Act, section 103(a)(18) of the Act specifically authorizes post-employment services that are necessary to assist an individual with a disability to retain, regain, or *advance* in employment. The proposed definition, which followed the definition in the previous regulations, supported the use of post-employment services to enable persons to "advance" in employment. As in the previous regulations, the note that followed the proposed definition offered additional guidance regarding the provision of post-employment services.

Changes: None.

• *Qualified and impartial mediator*

Comments: We received many comments on the proposed definition of "qualified and impartial mediator." First, several commenters stated that requiring mediators to be "trained in effective mediation techniques consistent with any State-approved or -recognized certification, licensing, registration, or other requirements* * *" establishes too restrictive a standard for mediators. Others sought additional guidance on how to implement this requirement if the State has not established applicable certification or other requirements. In addition, several commenters asked whether the prohibition on public agency employees serving as mediators under the proposed definition applies to those from a State Office of Dispute Resolution who conduct mediations across multiple State programs.

Aside from those issues, some commenters asked that we clarify whether a qualified and impartial mediator could also serve as an impartial hearing officer in resolving individual disputes that arise under the VR program. Other commenters voiced support for the proposed definition and for the emphasis given to mediation in the proposed regulations.

Discussion: In establishing the general guidelines that govern mediations, section 102(c)(4) of the Act requires that mediations be conducted by a "qualified and impartial mediator who is trained in effective mediation techniques." We defined "qualified and impartial mediator" in the proposed regulations as a means of providing guidance to the States in identifying or training available mediators.

As indicated previously, we are aware that many States already use mediation to resolve disputes arising under other authorities (*e.g.*, the Individuals with Disabilities Education Act (IDEA) or family law statutes) and that education, experience, or other qualification standards for mediators may vary from State to State. Thus, the proposed requirement that mediators under the VR program be trained consistent with applicable certification or other requirements was intended to ensure that mediators of disputes arising under the VR program are sufficiently qualified and that the State unit is able to use its State's existing pool of qualified mediators.

We fully agree that mediators in a State Office of Dispute Resolution or other similar office should be able to conduct mediations under the VR program, and we have modified the proposed definition to accommodate that situation. This change is analogous to the provision that enables administrative law judges and hearing examiners in the State to serve as impartial hearing officers even though those individuals are public employees (see the definition of "impartial hearing officer" in § 361.5(b)(25)).

In addition, although we believe that it is not generally the case, if there are no recognized credentialing or qualification standards for mediators in the State, then the Act and these final regulations require only that the State unit ensure that its mediators are trained in effective mediation techniques and meet the other components of the definition in § 361.5(b)(43).

It is critical that qualified and impartial mediators be neutral in facilitating the resolution of disputes regarding the provision of services to applicants or eligible individuals under the VR program. Therefore, we modeled the impartiality requirements in the proposed definition of "qualified and impartial mediator" after similar requirements in the previous definition of "impartial hearing officer." Nevertheless, we realize that many States, particularly rural States with relatively small populations, have difficulty maintaining an appropriate pool of individuals to serve as hearing officers. It is not unusual in these or other States for hearing officers also to be trained as mediators, and we interpret the Act as allowing individuals to serve as both mediators and hearing officers under the VR program, provided they meet the applicable qualifications for each position. However, we also interpret the statutory requirement that mediators and hearing officers be impartial (see section 102(c)(4)(B)(iii) of the Act in reference to mediators and sections 7(16) and 102(c)(5) of the Act in reference to hearing officers) to preclude the same individual from serving as both mediator and hearing officer in the same case.

Changes: We have revised the definition of "qualified and impartial mediator" to allow employees of a State office of mediators or similar office to serve as qualified and impartial mediators under the VR program.

• *Substantial impediment to employment*

Comments: One commenter suggested that "communication" be listed among the attendant factors in the definition that could indicate the existence of a "substantial impediment to employment," since communication plays a critical role in the individual's ability to function in the workplace. Other commenters requested that the proposed definition be revised to include examples of how the attendant medical factors are applied if medical measures are taken and result in mitigating functional limitations.

Discussion: We agree that communication competence is crucial to success in the workplace. Although the proposed and previous regulations stated explicitly that a "substantial impediment to employment" could be measured in terms of "other factors," we agree that "communication" should be added to the specific factors listed in the final regulatory term.

We suspect that those commenters who suggested that the final regulations explain how attendant medical factors indicating the existence of a "substantial impediment to employment" are assessed if medical measures that mitigate functional limitations (also referred to as "mitigating measures") are taken are questioning the application to the VR program of recent Supreme Court case law interpreting the ADA. The relevant cases require that any mitigating measures (*e.g.*, medication) that an individual is using to lessen the effects of that person's impairment be taken into account in determining whether the individual has a disability under the ADA (*i.e.*, an impairment that substantially limits one or more major life activities).

It is not clear, however, that the Court's decisions apply to the VR program eligibility criterion that an individual's impairment constitutes a substantial impediment to employment, since that provision and ADA language in question are not identical. Moreover, the purpose of the ADA, which is a civil rights statute, differs from that of the VR program, which provides Federal funding to assist individuals with disabilities enter into employment. We are not aware of any instances in which States, based on these cases, have altered their processes for assessing an individual's eligibility for the VR program; nor would we encourage them to do so.

Changes: None.

• *Supported employment*

Comments: Some commenters requested clarification of what it means to be "working toward competitive employment" for purposes of meeting the definition of "supported employment" in the proposed regulations. These commenters also asked whether the fact that an individual in supported employment is working toward competitive employment affects the 18-month limit on supported employment services provided by the State unit.

Discussion: The 1998 Amendments expanded the prior statutory definition of "supported employment" ("competitive work in an integrated setting with ongoing supports") to also include "employment in integrated settings in which individuals are working toward competitive work" in order to cover persons who are working in supported employment settings but are making less than the minimum wage. "Competitive employment," which we have long viewed as synonymous with the term "competitive work" used in the supported employment definition, generally refers to employment that is performed in an integrated setting for which the individual is compensated at or above the minimum wage. Thus, as long as an individual receiving ongoing support services while working in an integrated setting is also progressing or moving toward the minimum wage level, then the individual's job is considered "supported employment." We note, however, that an individual in supported employment working toward competitive employment would not be considered to have achieved a "competitive employment" outcome until the individual is earning at least the minimum wage consistent with the definition of "competitive employment" in § 361.5(b)(11).

We also note that the change to the statutory definition of "supported employment" does not affect the 18-month period for which the DSU can provide supported employment services. Once that 18 months has passed (and unless the special circumstances warrant an extension), ongoing services, if needed, must be provided by a provider of extended services (see § 361.5(b)(20) of the final regulations) regardless of whether the individual has yet to receive at least the minimum wage.

Changes: None.

• *Transportation*

Comments: Five commenters asked that the examples following the proposed definition of "transportation" be deleted. Another commenter supported specifically the example stating that the modification of a vehicle is a rehabilitation technology, rather than a transportation, service. Another commenter asked that we include in the final regulations specific authority for DSUs to pay for the repair and maintenance of vehicles.

Discussion: We have found that the examples following the previous regulatory definition of "transportation," which were largely the same as those included in the proposed regulations, were helpful to State agency personnel, individuals with disabilities, and others in clarifying the scope of transportation services authorized under the VR program. As we have always maintained, these examples are purely illustrative and are not meant to provide a comprehensive set of allowable transportation services.

Thus, because other authorized "transportation" services exist, and should be considered in light of the needs of the individual, we do not believe it is necessary to specify additional transportation costs in the regulations. We do note, however, that the second example to the proposed definition identifies the "purchase and repair" of vehicles as an example of an authorized transportation expense. We view the vehicle "repair and maintenance" expense identified by the commenter as covered by that example and, therefore, authorized. We would also instruct each DSU to include in its written policies governing the nature and scope of services under § 361.50(a) any additional transportation expenses that the DSU generally provides.

Changes: None.

Section 361.10 Submission, Approval, and Disapproval of the State Plan

Comments: Commenters expressed concern that the proposed regulations would require the State unit to hold public meetings throughout the State prior to adopting any new substantive policy or procedure concerning the provision of VR services or substantively amending an existing service-related policy or procedure. Consequently, many commenters viewed the provision as both burdensome and costly. Some of these commenters suggested that the State unit be permitted to adopt new policies and procedures (and make any amendments to existing policies) initially in accordance with applicable State laws and later invite public comment and input on those additions or changes during the State's public meetings on the State plan. Other commenters sought clarification of what constituted a "substantive" policy, procedure, or amendment and asked who would determine whether a policy is "substantive."

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Additional comments on this section of the proposed regulations reflected concerns about the different dates that govern the submission of the VR State plan. These commenters recommended that all States be required to submit updates and revisions to their State plans by the same date.

Discussion: Section 101(a)(16)(A) of the Act requires the State to hold public meetings prior to adopting policies or procedures governing the provision of services under the State plan. This requirement is essentially the same as the statutory requirements concerning public meetings that preceded the 1998 Amendments. Thus, we interpret the requirement in section 101(a)(16)(A) of the Act in the same manner as we have historically, i.e., the public is to be given the opportunity to comment on the State plan prior to the State unit adopting substantive policies and procedures (and any amendments thereto) governing the provision of vocational rehabilitation services under the plan. Typically, a State unit fulfills this requirement by taking comment on new policies during public meetings on State plan revisions and updates. Regardless of the timing of the State's public meetings, however, section 101(a)(16)(A) clearly requires that these meetings for receiving public input be held *prior* to States adopting new or revised policies affecting the provision of VR services. Implementing new policies in advance of the public meetings is not permitted.

We also note that section 101(a)(16)(B) of the Act and § 361.21 of both the previous and the proposed regulations required the designated State agency to consult with certain groups on matters of general policy arising in the administration of the State plan. In addition, a State unit that has a State Rehabilitation Council (Council), in accordance with section 101(a)(21)(A)(ii)(II) of the Act and § 361.16(a) of the regulations (again, both previous and proposed), must consult with the Council regarding the development, implementation, and revision of State policies and procedures of general applicability pertaining to the provision of vocational rehabilitation services. Each of the public comment or consultation requirements specified in the proposed regulations, and the resulting burden, was imposed by the Act, and each was intended to ensure that the State unit accounts for the diverse needs of its State's disability population before modifying its service-provision practices.

Nonetheless, in an effort to reduce the burden on the States, we incorporated into both the proposed and final regulations the term "substantive" to clarify that States need not hold public meetings on policy or procedural changes that are merely technical or do not affect the provision of VR services in any substantive manner. Longstanding RSA guidance (see PD–90–08 and PAC–90–05) provides additional information on the scope of this requirement. We note that the determination of whether a specific policy or procedure is sufficiently "substantive" to warrant public input is made by the State unit. Yet, we strongly urge State units to consult with their Councils in assessing whether proposed policy changes are "substantive" or in developing evaluative criteria for the State unit to use in making that assessment.

Section 101(a)(1)(A) of the Act requires the State to submit its State plan for the VR program on the same date that its submits its plan under section 112 of WIA. In addition, section 501 of WIA authorizes the State to submit a State unified plan in place of both a WIA section 112 plan and separate State plans for those WIA partner programs, including the VR program. We believe that in order to foster collaboration and cooperation between the VR program and other components of the One-Stop service delivery system, a State plan for the VR program that is not included in the State's unified plan should be submitted on the same date as that unified plan. That view is reflected in § 361.10(f)(3) of the proposed and the final regulations.

Changes: None

Section 361.16 Establishment of an Independent Commission or a State Rehabilitation Council

Comments: One commenter expressed concern that the proposed regulations failed to require the State unit to provide documents to the Council in alternative formats and in a timely manner. As a result, this commenter stated that Council members who are blind will not have sufficient opportunity to review and respond to information provided by the State unit.

Discussion: This section of the proposed regulations made only technical changes to the previous regulations in order to conform to statutory changes in the 1998 Amendments to the Act. We do not believe that a regulatory change to this provision is warranted based on the comment received. Providing information in appropriate formats to Council members with disabilities falls under the State unit's general responsibility under section 504(a) of the Act to not exclude, on the basis of disability, any individual from participating in programs or activities receiving Federal financial assistance. Moreover, Federal regulations at 34 CFR 104.4(b)(1)(vi) specify that a recipient's responsibility under section 504 of the Act extends to the participation of individuals with disabilities on advisory boards. Thus, as in many other instances in which it distributes written materials, the State unit must ensure that Council members who are blind or otherwise disabled are able to review information that the State unit transmits to the Council, as well as participate generally in Council activities.

Changes: None.

Section 361.17 Requirements for a State Rehabilitation Council

Comments: We received several comments regarding the composition requirements of the Council. One commenter requested clarification as to whether an entity that is a required member of the Council could select someone other than a member of that entity as its representative to the Council.

Several commenters suggested that the regulations specify that the "nonvoting" membership status of Council members who are employees of the designated State agency does not apply to the representative of the CAP. This change, the commenters assert, is necessary since the CAPs in some States are components of the designated State agency that administers the VR program. The commenters raised questions regarding the required Council membership of a representative of the directors of the American Indian VR services projects authorized under section 121 of the Act. Some of these commenters indicated that the Council should include members from each of the section 121 projects and that a single representative of all the directors could not adequately represent all American Indian VR service projects in the State. Other commenters described situations in which a section 121 project is "headquartered" in one State but has a service area that extends across State lines into another State and asked whether that project must be represented on the Council of each State that it serves.

One commenter questioned whether a Council member could be appointed to the State Workforce Investment Board (SWIB) under section 111 of WIA in order to satisfy the requirement in the proposed regulations that the Council include a member of the SWIB. This commenter stated that otherwise this requirement would be difficult to meet given the limited pool of persons interested in serving on the Council as evidenced by the difficulty Councils experience in filling vacancies as they occur.

Finally, we received several comments indicating that the proposed regulations failed to incorporate the new statutory requirement that the majority of members to a Council for a State agency for the blind must be individuals who are blind.

Discussion: Section 105(b) of the Act contains the membership requirements for the Council to ensure that various constituencies of the VR program have a voice in the conduct of the VR program in the State. Section 105(b)(3) requires that the Governor, after soliciting recommendations from organizations representing individuals with disabilities, appoint members to the Council in accordance with the membership criteria in section 105(b)(1) of the Act.

The question as to whether an entity can be represented on the Council by someone other than one of its own members or employees has been raised in the past. With few exceptions, the Council membership requirements in section 105(b)(1) of the Act state that a "representative" of an identified entity must serve on the Council. The Act does not require that the "representative" be an employee or member of the required entity. Thus, we interpret section 105(b) of the Act and § 361.17(b) of the regulations to allow an entity that is required to be represented on the Council to be represented by someone who is not an employee or member of that organization. Recommendations of appropriate representatives can be made by the organizations themselves, although final appointment authority rests with the Governor. Moreover, we would expect that such a Council member would be closely affiliated with and knowledgeable about the

organization or entity whose interests the individual is charged with representing.

We agree that the non-voting status of State agency or State unit employees under § 361.17(b)(2) of the proposed regulations does not apply to Council members representing the State's CAP pursuant to proposed § 361.17(b)(1)(iii).

Questions regarding Council representation of the section 121 project directors have been raised frequently since the passage of the 1998 Amendments to the Act. Moreover, the commenters' concerns as to whether one project director can sufficiently represent the interests of several independent projects serving different populations of American Indians have generated the most debate. Yet, the requirement in proposed § 361.17(b)(1)(ix) enabling one person to represent all section 121 project directors in the State came directly from section 105(b)(1)(ix) of the Act. This requirement appears to reflect an intent of Congress to minimize the burden on States and to ensure that the size of the Councils not be so large as to become unmanageable. Nevertheless, we urge the directors of section 121 projects in the same State to collaborate more extensively than they may have in the past and to work to ensure that their collective views are represented on the Council. We also note that neither the Act nor regulations prohibit the Governor from appointing to the Council more than one representative of the State's section 121 projects (or other groups) if warranted as long as the remaining composition requirements in the Act and regulations (*e.g.*, the requirement that a majority of Council members be individuals with disabilities) are met. As for section 121 projects that are "headquartered" in one State but serve those in another State, it is our understanding that to the extent this occurs, affected projects primarily serve American Indians with disabilities in the State in which the project is located and serve only a relatively small area in a neighboring State. We do not believe that the Council must include a representative of a section 121 project serving American Indians with disabilities in the State if that project is primarily located, and serves those, in another State. In that instance, § 361.17(b)(1)(ix) of the final regulations would apply only to the State in which the project is located. The Governor, however, always has the discretion to appoint to the Council a representative of an out-of-State project that also serves American Indians with disabilities in the Governor's State.

Since the time that the Council requirements came into effect, questions regarding whether the same individual can fulfill more than one role on the Council have been raised often. In response, we consistently have taken the position that an individual may represent only one entity on the Council even though that same individual may qualify under more than one of the composition requirements. We recognize that some States have difficulty maintaining a sufficient pool of qualified individuals to serve on statewide Councils and that the 1998 Amendments to the Act added three new required members to the Council. Nevertheless, section 105(b) of the Act establishes a minimum number of members for the Council, each of whom represents a specific component of the disability community. Because each member represents a different interest, sometimes one that is divergent from that of other members, we maintain that each organizational requirement must be met separately. Thus, a Council member who serves on the SWIB cannot represent both the SWIB and another organization on the Council.

We agree with the commenters who pointed out the discrepancy between the Act and the regulations regarding the membership requirements that apply to a Council for a separate State agency that administers the VR program for individuals who are blind. These commenters correctly noted that the proposed regulations did not specify, as does the statute, that the majority of members of these Councils must be individuals who are blind. This omission was inadvertent, and we agree that it needs to be corrected in the final regulations.

Changes: We have revised § 361.17(b)(2) of the proposed regulations to clarify that the CAP representative is, in all instances, a voting member of the Council. In addition, we have modified § 361.17(c) to reflect the requirement in section 105(b)(4)(B) of the Act that a majority of the members on a Council for a separate State agency for the blind must be individuals who are blind.

Section 361.18(c) Comprehensive System of Personnel Development—Personnel Standards

Comments: Some commenters expressed concern with the indication in the preamble to the NPRM that statewide "multi-tiered" personnel standards could be used by the State unit in establishing standards for its rehabilitation personnel. Other commenters suggested that the proposed regulations be revised to require that all rehabilitation counselors obtain a Master's degree consistent with the national certification standards for rehabilitation counselors.

In addition, a number of commenters sought waiver or "grandfather" provisions in the final regulations that would exempt current rehabilitation counselors and other professionals from the State's personnel standards. On a related point, some commenters asked whether currently employed rehabilitation counselors who do not meet the State unit's personnel standards can continue to serve as counselors while training to meet the standard.

Additionally, several commenters viewed the requirement in the proposed regulations that the State unit develop a written plan for retraining, recruiting, and hiring staff to meet applicable personnel standards as unduly burdensome. Other commenters supported this requirement and suggested that the written plan be developed with input from the Council.

Finally, several commenters suggested that RSA define the professional and paraprofessional disciplines for which a State unit must establish personnel standards, while others asked what standards the State unit should apply to professions or paraprofessions for which no certification or similar criteria exist.

Discussion: The preamble discussion in the NPRM concerning the ability of State units to use the same multi-tiered personnel standards as those applied by other State agencies to its rehabilitation staff was intended to clarify the level of flexibility the proposed regulations give State units in ensuring that its personnel are qualified within the meaning of the Act. Typically, multi-tiered certification systems require rehabilitation counselors to reach a certain academic level depending on the amount of experience the individual has had in that field. As we indicated in the NPRM (65 FR 10623), because the Act clearly allows State units to base their personnel standards on applicable State standards, it is permissible for a DSU to apply the multi-tiered counselor certification criteria of, for example, the State Workers' Compensation program to DSU counselors if the counselors of both agencies perform similar functions. The Act gives State units that discretion, and that same discretion also prohibits requiring by Federal regulations that all State unit counselors obtain a Master's degree consistent with the national rehabilitation counselor certification standards as sought by some commenters. Nonetheless, as we stressed in the preamble to the NPRM, we encourage each State unit to ensure that its personnel standards promote quality among its counselors and other staff, and we caution State units not to employ minimally qualified individuals by routinely substituting "equivalent experience" for higher-level degree criteria.

The Act does not authorize "grandfathering" or the waiving of personnel standards for current staff. Rather, section 101(a)(7)(B)(ii) of the Act compels the State unit, if its current personnel does not meet the "highest requirements in the State" (i.e., the highest entry-level academic degree needed for the applicable State or national certification, licensing, or registration requirements—*see* § 361.18(b)(2)(i) of the final regulations), to retrain existing staff, as well as recruit new employees, to meet the personnel standards applicable to each profession.

The written plan under § 361.18(c)(ii) that describes the retraining, recruitment, and other efforts of a State unit whose current personnel standards do not conform to the highest requirements in the State is based on the requirement in the Act that directs the State to provide this information in its State plan. More importantly, however, we believe that the limited components of the written plan (*e.g.*, retraining, recruiting, and hiring steps, timelines for those efforts, procedures for evaluating progress, etc.) are essential to ensuring that the State unit employs a fully qualified staff that is best able to meet the diverse needs of individuals with disabilities. Any burden associated with developing the plan, we believe, is caused by the intent of the Act. The narrow scope of required plan components is expected to provide States with a helpful framework for fulfilling their personnel development responsibilities and improving their service delivery capacity.

As we have stated in the past, we recognize the many constraints faced by State agencies in securing a fully qualified staff, not the least of which is the time that it takes to

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retrain existing staff. Thus, current counselors who, pursuant to the State unit's plan under § 361.18(c)(1)(ii), are working toward applicable qualification standards can continue to perform their counselor functions. The Act establishes an expectation that rehabilitation counselors and other staff will become qualified consistent with the highest applicable personnel standards in the State. Accordingly, the requirements in the regulations are intended to ensure that the State unit can continue to serve persons with disabilities while it progresses as rapidly as possible toward the point at which all of its staff, both current and new hires, meet the highest qualifications that the State applies to their professions.

We also emphasize the importance of the role of the Council in the area of personnel development. Section 361.18(a) of the final regulations requires that the Council, if it exists, have an opportunity to review and comment on the development of all plans, policies, and procedures necessary to meet the State unit's obligations under the comprehensive system of personnel development (CSPD). As with each of the Council's functions, we view the Council's input into the development of the State unit's personnel policies, procedures, and standards as vital toward ensuring that those efforts result in a State unit workforce that is fully capable of meeting the training and employment needs of persons with disabilities in the State.

We decline to define the professional and paraprofessional disciplines for which a State unit must establish personnel standards, as some commenters requested. While a State unit must apply to its staff the highest personnel requirements that exist in the State and that apply to each profession, determining the types of professionals and paraprofessionals needed to effectively administer its VR program and establishing the scope of functions for each job are the responsibility of the State unit. It is the State unit that can best judge its staffing needs and establish staffing arrangements that meet the particular needs of that agency's service recipients. In the preamble to the NPRM, however, we did provide some guidance on the categories of professional and paraprofessional disciplines most closely associated with the VR program for which the State unit should give priority in developing both specific job criteria and appropriate qualification standards. Those professions include rehabilitation counselors, vocational evaluators, job coaches for individuals in supported employment or transitional employment, job development and job placement specialists, and personnel who provide medical or psychological services to individuals with disabilities.

As a final matter, we note that if there are no State or national licensing, certification, or registration requirements for a given profession established by the State unit, then both the Act and the final regulations require the State to use other "comparable requirements" (such as State personnel requirements) for that profession or discipline. The scope of these "comparable requirements" (*e.g.*, degree criteria, work experience, etc.) that are applied to jobs for which no licensing or similar requirements exist is left to the reasonable judgement of the State unit.

Changes: None.

Section 361.22 Coordination With Education Officials

Comments: Some commenters opposed the requirement in the proposed regulations that the State unit complete the IPE for students eligible for VR services before they leave school. These commenters stated, for example, that the proposed requirement would be impracticable for State units to fulfill, would lead to rashly formulated IPEs, or would exceed applicable statutory requirements. Other commenters supported requiring completion of the IPE before the student leaves school and viewed the requirement in the proposed regulations as essential if transition planning is to prove effective.

In addition, one commenter requested that the proposed regulations be revised to require that the formal interagency agreement between the State unit and educational agencies specify both the manner and the time in which State unit staff will participate in transition planning for students with disabilities. Another commenter suggested that each agreement include provisions for resolving disputes regarding the agencies' financial responsibilities in paying for transition services and for enabling students to retain assistive technology provided by schools that the student needs following transition.

Discussion: The proposed requirement that State units provide for the development and completion of the IPE before students who are eligible for VR services leave the school setting was carried over from the previous regulations. As we have indicated from the time the previous regulations were published in 1997, we believe that requiring IPE completion before eligible students with disabilities leave school is entirely consistent with the emphasis on transition in both the Act and its legislative history (see Senate Report 102–357). That emphasis was only heightened by the requirement in the 1998 Amendments that State units increase their participation in transition planning and related activities. More importantly, requiring the IPE to be in place before the student exits school is essential toward ensuring a smooth transition process, one in which students do not suffer unnecessary delays in services and can continue the progress toward employment that they began making while in school. In fact, it is in support of that effort that we have made two clarifications in these final regulations: (1) that designated State agencies should be involved in the transition planning process as early as possible; and (2) that the IPE must be "approved" (i.e., agreed to and signed by the individual and the DSU) prior to the student leaving school, as opposed to simply "completed" as stated in the proposed regulations.

We have determined it necessary to clarify in the final regulations steps that the designated State agency must take, at a minimum, when conducting the statutorily required outreach to students with disabilities. It is essential for the designated State agency to inform these students of the purpose of the VR program, the application procedures, the eligibility requirements, and the potential scope of services that may be available. This information should be provided as early as possible during the transition planning process in order to enable students with disabilities to make an informed choice on whether to apply for VR services while still in school.

We are not aware that State units have had great difficulty in completing IPEs for students. As before, the final regulations require that if the State is operating under an order of selection, only the IPEs of those students that the State unit can serve under the order must be developed before the student leaves school. Moreover, we believe that State units will be even better prepared to fulfill this requirement as they become more active in transition planning for special education and other students with disabilities (*e.g.*, those students receiving services pursuant to section 504 of the Act or the IDEA) and in generally coordinating with school officials.

We believe, as did some commenters, that the extent to which the State unit should be involved in transition planning for individual students with disabilities should be based on the needs of the student. However, we also believe that it is important for the designated State agency to participate actively throughout the transition planning process, not just when the student is nearing graduation. Early involvement by the designated State agency can be very beneficial in terms of assisting the student to make the transition from school to employment. For this reason, these final regulations clarify that the designated State agency should become involved in the transition planning process as early as possible. The designated State agency and the State education agency should negotiate more specific provisions, as part of their interagency agreement, to ensure that the students' needs are met in a timely manner. Congress clearly envisioned that that approach be followed in developing the terms of the State's interagency agreement (*see e.g.*, Conference Report 105–659, page 354). Also left to local discretion is the scope of components, other than those limited components specified in the Act and clarified previously, that should be included in the agreement. Some of the additional agreement items identified by commenters may be considered in that regard.

However, in response to the commenter's suggestion that each agreement should include provisions for resolving disputes in paying for transition services, we note that State units are authorized to pay for only transition services for students who have been determined eligible under the VR program and who have an approved IPE. Thus, as long as those criteria have been met, and the IPE specifies those transition services necessary for the successful implementation of the IPE, we anticipate that disputes of the type raised by the commenter will not be prevalent.

Changes: We have amended § 361.22(a) of the proposed regulations to clarify that the IPE for a student determined to be eligible for vocational rehabilitation services must be developed and approved before the student leaves the school setting and as early as possible during the transition planning process. In addition, we have amended § 361.22(b)(4) of the proposed regulations to clarify information that must be provided by the designated State agency, at a minimum, when conducting outreach to students with disabilities, and we have clarified that outreach should begin as early as possible during the transition planning process.

Section 361.23 Requirements Related to the Statewide Workforce Investment System

Comments: We received a great many comments on this section of the proposed regulations that raise important policy issues and questions of interpretation that relate not only to the proposed regulations, but also to WIA and the regulations in 20 CFR part 662.

Most commenters requested more detail in the final regulations that elaborates on how the VR program is to fulfill the requirements in proposed § 361.23(a). For example, several commenters asked that we specify in the final regulations those core services under WIA that the VR program is expected to provide in accordance with proposed § 361.23(a)(1), while others asked that we explain which activities related to "creating and maintaining" the One-Stop system under § 361.23(a)(2) are allowable under the VR program.

Some of the commenters on this proposed section also urged us to identify in the final regulations certain restrictions in the Act (*e.g.*, the order of selection requirements under section 101(a)(5)) that may affect the extent to which State units can contribute to the cost of One-Stop system services or other One-Stop system activities. Of critical importance to the final regulations, most commenters stressed, is the need to address the responsibility of all WIA partner programs to serve individuals with disabilities.

Other commenters asked that we add to the One-Stop system responsibilities listed in proposed § 361.23(a) other items that are necessary for DSUs to effectively participate with other partner programs of the One-Stop system, including methods for allocating costs between programs, methods for ensuring proportionality between the partner's financial participation in the One-Stop system and the resulting benefits it receives, and methods for resolving disputes regarding funding that may arise between partner programs.

Several other commenters identified additional components that they suggested be included in the required cooperative agreements between the designated State agency and those entities administering other One-Stop system partner programs. In addition, some commenters asked whether the requirement that State units, through the cooperative agreements, promote participation by individuals with disabilities in the One-Stop system also requires that State units pay the cost of reasonable accommodations at the One-Stop system center or other locations.

Discussion: As we discussed at some length in the preamble to the NPRM (65 FR 10620, 10621, and 10624), we restated in § 361.23(a) of the proposed regulations the responsibilities of One-Stop system partners, including the VR program, that are described in the regulations implementing Title I of WIA (20 CFR part 662). That effort was intended solely to inform State units of the One-Stop system responsibilities to which they are subject under WIA. We also asked that commenters raise specific interpretive or policy questions related to these One-Stop system responsibilities so that we may address, through appropriate guidance, those most pressing matters that DSUs face as they participate in the One-Stop service delivery system. Most of the comments received on this section of the proposed regulations focus on those types of questions.

Although we anticipate addressing in future guidance materials, and in cooperation with other appropriate Federal agencies, the workforce policy questions posed by the commenters, we do note that many of the issues raised are impacted by a number of key One-Stop system principles embedded in WIA, its implementing regulations, and these final regulations.

First, participation by DSUs in the One-Stop system must be performed in a manner that is consistent with the legal requirements applicable to the VR program (*i.e.*, the Act and these final regulations). Thus, the DSUs' participation in the cost of core services or any other One-Stop system activities cannot, for example, result in expenditures for services to individuals who do not meet the priority for services in the order of selection under which a DSU is currently operating (although the DSU can participate, as appropriate, in the cost of intake and other expenditures that would normally be borne by the DSU prior to determining eligibility and the individual's priority category under the State's order of selection; see the discussion in the following section of this analysis of comments for further information on the relationship between order of selection requirements and participation in One-Stop system activities.) The fact that DSUs must comply with the Act and the VR program regulations in the course of participating in the One-Stop system, we believe, was made clear in the proposed regulations, as it is in Title I of WIA and the regulations implementing that title.

Compliance with the ADA and section 504 of the Act represents another key issue that directly impacts the One-Stop system. In sum, those laws obligate One-Stop system centers and their partners to make their services accessible to individuals with disabilities. Thus, we, along with the Department of Labor and many of the commenters, have emphasized that the legal responsibility for assisting persons with disabilities does not fall to the DSU alone. Consequently, individuals with disabilities are likely to receive services through a variety of arrangements (*e.g.*, through the One-Stop system center, through a combination of core services at the One-Stop system center and specialized VR services from the DSU, etc.) depending on the configuration and structure of the local One-Stop system. Nonetheless, because the universal access principles reflected in the ADA and section 504 relate to the responsibilities of non-DSU entities and because these final regulations establish requirements for designated State agencies and designated State units administering VR programs, we do not believe this section should be revised to address the application of the ADA and section 504 to the One-Stop system generally. Those responsibilities are fully addressed in WIA, particularly in section 188 of that act and its implementing regulations, 29 CFR part 37, which establish the civil rights protections that must be provided by the State and local workforce development systems.

Many of the commenters also raised important issues related to collaboration between the DSU and its One-Stop system partners. In response, we note that those issues can, and should, be addressed through the development of the memorandum of understanding (MOU) governing the operation of the One-Stop system referred to in § 361.23(a)(3) or through the cooperative agreements developed between these same parties under § 361.23(b). In fact, some of the suggested items, including the methods for funding One-Stop system costs among partner programs, are addressed in the regulations implementing title I of WIA (see MOU requirements in 20 CFR 662.300). Rather than specifying additional MOU or cooperative agreement components in these final regulations, we would urge DSUs and their One-Stop system partners to determine which components, other than those specified in the MOU requirements in 20 CFR part 662 and the agreement components in § 361.23(b) of these final regulations, would be most appropriate to address given State and local circumstances.

We do believe it is necessary, however, to clarify one technical item related to the cooperative agreement under § 361.23(b) that some commenters raised. The commenters appeared to interpret § 361.23(b)(2)(i)(B) as requiring DSUs to pay for reasonable accommodations, auxiliary aids, and other services for persons with disabilities participating in the One-Stop system. Yet, that proposed section, which comes directly from section 101(a)(11)(A)(i)(II) of the Act, states only that DSUs, in promoting meaningful participation by persons with disabilities in One-Stop system and other workforce investment activities through program accessibility, may provide training and technical assistance to its One-Stop system partners on how to provide reasonable accommodations and auxiliary aids and services. Neither the relevant statutory provision nor the proposed regulatory section questioned by commenters instructs DSUs to pay the costs of providing individuals with disabilities access to the One-Stop system. In fact, as previously noted, that responsibility falls to the One-Stop system pursuant to the ADA and section 504.

Changes: None.

Section 361.31 Cooperative Agreements With Private Nonprofit Organizations

Comments: None.

Discussion: We wish to clarify the relationship between these final regulations

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and potential agreements that DSUs may enter into with employment networks authorized under the recently enacted TWWIIA. In particular, we note that neither the Act nor the regulations, including the requirement in section 101(a)(24)(B) of the Act and § 361.31 of the regulations that the DSU enter into cooperative agreements under the VR program with private nonprofit VR service providers, are intended to limit or prohibit the establishment of a fee-for-service or other reimbursement type agreement between DSUs and employment networks. Typically, fee-for-service arrangements enable private service providers to purchase from the DSU services that are needed by an individual with a disability who is not a VR program participant.

On a related note, we also emphasize that nothing in the Act or these regulations would affect the ability of a DSU to serve as an employment network as authorized under TWWIIA.

Changes: None.

Section 361.36 Ability To Serve All Eligible Individuals; Order of Selection for Services

Comments: One commenter suggested that this section of the proposed regulations be strengthened to ensure that States preserve resources and provide needed services to individuals with significant disabilities, particularly as the State unit becomes more closely linked to, and participates in, the One-Stop system under WIA.

Discussion: As we discussed in the previous section, we agree that the policy behind the order of selection requirements in the Act and regulations—to preserve the fiscal and personnel resources of the DSU so that those with the most significant disabilities can receive the full range of VR services that they need to become appropriately employed—must be safeguarded. However, we believe those safeguards are in place. As a required partner in the One-Stop system, the State unit must participate toward the development and maintenance of an effective One-Stop system at the local level. Moreover, Title I of WIA and the regulations implementing that title clearly condition that participation on compliance with the Rehabilitation Act and these regulations. Thus, the order of selection requirements in section 101(a)(5) of the Act and these regulations, or any other statutory or regulatory requirement applicable to the VR program, must be followed in the course of participating in One-Stop system activities. If the State is operating on an order of selection because it cannot serve all eligible individuals given its current level of VR program resources, then the State unit can pay only for services (i.e., services beyond intake and assessment that are necessary to determine whether an individual is eligible under the program and, if so, to determine the individual's priority category under the order of selection) for the individuals who qualify for services under that order, regardless of whether those services are provided within or apart from the One-Stop system center. The severity of an individual's disability or the cost of the individual's program of services can have no bearing on the scope of services the individual receives.

Changes: We have made one clarifying change to § 361.36(c) of the proposed regulations that was not based on public comment. This proposed section has been revised to clarify that a DSU that has developed but not implemented an order of selection must continue to provide the full range of services, as appropriate, to all eligible individuals.

Section 361.42 Assessment for Determining Eligibility and Priority for Services

Comments: Several commenters recommended requiring in this section of the final regulations a written assessment for determining eligibility and priority for services by a qualified VR counselor employed by the DSU, as a means of emphasizing the importance of the professional opinion of the VR counselor. These commenters also proposed that this written assessment be included with the information given to the eligible individual during IPE development.

Some commenters opposed the eligibility provisions stated in proposed § 361.42(a)(i) and (ii) (i.e., determinations by qualified personnel that the applicant has a physical or mental impairment and the impairment constitutes or results in a substantial impediment to employment) on the basis that neither provision required that the applicable determination be made by a qualified employee of the DSU. These commenters stated that all eligibility-related determinations should be made by the DSU.

Several commenters opposed § 361.42(a)(3) of the proposed regulations, which implemented the statutory requirements regarding presumptive VR program eligibility for individuals receiving SSI or SSDI under the Social Security Act. These commenters stated that a categorical presumption of eligibility for this group of individuals could be misconstrued as creating an entitlement to VR services, could lead to efforts to extend presumptive eligibility inappropriately to other groups with common characteristics, and may undermine the individualized nature of the VR program. Some of the commenters asserted that a presumption of eligibility should be able to be rebutted by a showing that an individual receiving SSI or SSDI does not meet one or more of the eligibility criteria. Other commenters suggested that presumptive eligibility for these individuals should apply to only those Social Security recipients or beneficiaries seeking to earn wages as opposed to those intending to become homemakers.

On the other hand, several commenters supported the proposed requirements regarding presumptive VR program eligibility for individuals receiving SSI or SSDI. Some noted that the relevant statutory provision, section 102(a)(3) of the Act, already has been effective in reducing the time expended on eligibility determinations, thereby allowing counselors and individuals to focus on IPE development and initiating needed services.

Many commenters opposed the manner in which the proposed regulations implemented the passage in section 102(a)(3)(ii) of the Act that states that Social Security recipients are presumed eligible under the VR program "provided that the individual intends to achieve an employment outcome." Specifically, these commenters believed that completion of the application process, as described in the proposed regulations, is insufficient evidence of the individual's intent to achieve an employment outcome. They urged that the applicable paragraph in the proposed regulations be stricken on the basis that DSUs make eligibility-related decisions not only at the time of application but throughout the VR process.

Several commenters opposed authorizing DSUs, under § 361.42(b) of the proposed regulations, to make interim determinations of eligibility. Most of these commenters questioned the statutory authority for the proposed section or viewed the provision as unnecessary since all eligibility determinations must be completed within 60 days from the time the individual applies for VR services. On the other hand, many commenters supported the proposed interim eligibility authority and the fact that using it rests with the discretion of the DSU.

Several commenters supported proposed § 361.42(c)(1) that the DSU will not impose, as part of the eligibility determination process, a duration of residence requirement that excludes from services any applicant who is present in the State. Two commenters suggested that the proposed language more closely track the Act by applying the prohibition not only to applicants but to any individual who is present in the State. Other commenters supported retaining specific language stating that a requirement for an applicant to be present in the State cannot be used to circumvent an individual's choice of an out-of-State service provider.

We received many comments on proposed § 361.42(e), which implemented new statutory requirements regarding the use of trial work experiences as part of the process for determining eligibility for VR services. Several commenters responded to our request in the preamble to the NPRM that they identify examples of trial work experiences, other than supported employment and on-the-job training, that DSUs might employ. Suggestions included contract or production work in the individual's own home, internships, unpaid work experiences, on-the-job evaluations, job shadowing, structured volunteer experiences in real work settings, and community-based work assessments with supports, among others.

Many commenters suggested that the final regulations authorize a DSU to consider trial work that the individual performed previously, and that is documented, for purposes of meeting the requirement that it assess the individual's capacity to perform trial work before the individual is determined too severely disabled to achieve an employment outcome (and, therefore, ineligible). These commenters also recommended that the final regulations clarify that trial work experiences need not be used for all individuals with significant disabilities or in instances in which an individual's ability to achieve an employment outcome is not in question.

A number of commenters opposed the requirement in proposed § 361.42(e)(2)(i) that the DSU develop a written plan to assess the individual's capacity to perform in realistic

work settings. These commenters noted that the Act does not require a written plan and that the proposed provision could have the unintended effect of delaying services to the individual. Other commenters expressed concern that the trial work assessment for an individual appeared open-ended and, therefore, recommended that the regulations apply a specific time limit to the use of trial work for purposes of determining eligibility.

One commenter questioned the authority for the proposed regulatory requirement that DSUs provide appropriate supports, including assistive technology devices and services and personal assistance services, to accommodate the rehabilitation needs of an individual while performing trial work. In contrast, another commenter stated that it is vital for DSUs to provide the supports and assistive technology that are needed for an individual during the trial work period.

Several commenters recommended deleting proposed § 361.42(h), which authorized the continued use of extended evaluations in instances in which trial work experience options have been exhausted or cannot be used by the individual. These same commenters suggested that the 18-month time limit that applied to extended evaluation under the current regulations be applied to trial work experience options. Some of the commenters also questioned the authority for keeping the extended evaluation option in the regulations, while others suggested that since trial work experiences were available to most individuals with significant disabilities, the extended evaluation authority is no longer necessary or is inconsistent with the Act's preference for finding most applicants eligible for the VR program. In contrast, a number of commenters supported retaining the extended evaluation requirements.

Discussion: We agree that the professional opinion of the VR counselor is critical in assessing an individual's eligibility and priority for services. Both the Act and the regulations specify that qualified personnel must conduct assessments under the VR program. Although we suspect that most States develop written assessments, we do not think it is necessary to require by rulemaking that the assessment itself be in writing. Thus, State units may continue to require written eligibility assessments, or otherwise attest to an individual's eligibility and priority of service category under an existing order of selection, as they deem appropriate. We do note, however, that the DSU is required to document, in some fashion, support for determinations of eligibility as part of the record of services required under § 361.47 of the regulations. Whether that documentation is the assessment itself or some other combination of information, again, lies with the discretion of the DSU.

We believe that proposed § 361.42(a)(1)(i) and (ii) and the references to "qualified personnel" in each of the provisions are consistent with the Act. We interpret the requirements in section 103(a)(1) of the Act (requiring assessments for determining eligibility and rehabilitation to be conducted by "qualified personnel") and section 102(a)(6) of the Act (requiring eligibility determinations to be conducted by the designated State unit) the same as we have historically since neither statutory provision changed in the 1998 Amendments. Specifically, the Act authorizes qualified professionals, both DSU and non-DSU employees, to determine the existence of an impairment and to determine whether the impairment results in a substantial impediment to employment (*i.e.*, whether the first two eligibility criteria have been met.) The requirement in section 102(a)(4)(B) of the Act regarding the use of determinations made by officials of other agencies also supports this position. Assuming the DSU can confirm that a qualified professional has determined that the individual has met those criteria, the DSU counselor then assesses whether the individual requires VR services to obtain and retain work in the individual's chosen field that is appropriate to his or her abilities (*i.e.*, the third criterion of eligibility.) The individual is presumed to have met the fourth criterion—that the individual can benefit from VR services under § 361.42(a)(1)(iv). This framework, which we believe is required by the Act, is intended to ensure that the DSU controls the eligibility process at the same time that it facilitates more timely assessments that allow for existing information from other sources to be taken into account.

The 1998 Amendments specify that those who qualify for SSI or SSDI are presumed eligible for the VR program. As we discussed extensively in the preamble to NPRM (65 FR 10625 and 10626), we believe that this change was adopted in the 1998 Amendments to streamline eligibility and expedite necessary VR services for those Social Security recipients since each category of recipients already has met stringent disability criteria under the Social Security Act and clearly needs VR services in order to achieve appropriate employment. We do not believe that this presumption will be misconstrued as changing the nature of the VR program to a program under which individuals are entitled to services without pursuing a job. In fact, section 102(a)(3)(B) of the Act and § 361.42(a)(5) of these final regulations specify that nothing in the presumptive eligibility requirement creates an entitlement to VR services, meaning that individuals with disabilities are not automatically entitled to VR services but, rather, must expect to achieve an employment outcome as a result of receiving those services. The final regulations implement that expectation by ensuring that all applicants, including those receiving SSI or SSDI, are informed of the employment-related nature of the VR program during the application process.

We also disagree with the assertion that a categorical presumption of eligibility for individuals receiving SSI or SSDI will lead to categorical eligibility for other groups and undermine the individualized nature of the VR program. Prior to the 1998 Amendments, disabled SSI recipients were statutorily presumed to have a physical or mental impairment that constituted a substantial impediment to employment (*i.e.*, were presumed to have met the first two eligibility criteria in § 361.42(a)(1) of the regulations), as well as a severe disability. Section 102(a)(3) of the 1998 reauthorized Act expanded this presumption by giving presumptive VR program eligibility (*i.e.* a presumption that individuals meet all of the eligibility criteria under the VR program) to this same population. The presumption applies only to these persons and is not written to broadly cover other groups that do not qualify under the stringent disability-related criteria applied by the Social Security Administration. Also, the individualized nature of the VR program (*i.e.*, that services are provided under an IPE to meet an individual's rehabilitation needs and assist an individual to achieve an employment outcome) is unaffected by this requirement that only addresses eligibility for services.

As section 102(a)(3)(A)(ii) of the Act makes clear, a DSU can rebut the presumption that an SSI or SSDI recipient is eligible under the VR program if it can demonstrate by clear and convincing evidence that the individual is incapable of benefiting in terms of an employment outcome from VR services due to the severity of the individual's disability. In response to the commenter's contentions, we maintain that a presumption of eligibility can be rebutted only on this basis.

We also do not believe that presumptive eligibility for SSI or SSDI recipients should be restricted to those seeking certain types of employment outcomes. As we have long required, eligibility requirements are not to be applied with regard to the type of expected employment outcome that the applicant seeks (see § 361.42(c)(2)(ii)(B) of these final regulations). Thus, whether an individual seeks a self-employment, another wage-earning employment, a homemaker, or other outcome cannot be used as a factor in determining the individual's eligibility for VR services or affect the presumptive eligibility of an individual receiving SSI or SSDI.

We believe that completion of the application process after the DSU has informed the individual that he or she must seek an employment outcome to receive VR services is sufficient evidence that any individual, including SSI and SSDI recipients, "intends to achieve an employment outcome," as section 102(a)(3)(ii) specifies. While we understand that some commenters are concerned that disabled Social Security recipients in particular will seek VR services without intending to work, we find that concern unfounded. We referred in the preamble to the NPRM to an obvious fact—that all applicants for VR services, not only those who qualify for SSI or SSDI, must intend to work to receive VR services. Thus, ensuring that the DSU explains the employment-related nature of the VR program as part of the application process ensures that applicants understand what is expected of them before participating in the program. Thus, the proposed regulatory method of ensuring an individual's intent to work fulfills an expectation that applies to all applicants for VR services and streamlines, rather than hinders, the eligibility process for SSI and SSDI recipients, as the Act intends.

Additionally, we disagree with the contention that an individual's intent to

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achieve an employment outcome constitutes an additional eligibility-related criterion that must be applied throughout the VR process. Eligibility is assessed at the outset of the rehabilitation process, at a point when the final regulations require that the DSU apprise individuals of the nature of the program. As always, if an individual becomes too severely disabled to achieve an employment outcome (as supported by clear and convincing evidence) or, for whatever reason, stops participating in the VR program, then the DSU need not continue serving that individual. That approach applies no less to SSI recipients or SSDI beneficiaries than it does to any other participant in the VR program. Yet, as long as the individual continues to participate in the program, there exists a presumption that the individual intends to work.

We agree with those commenters who supported proposed § 361.42(b) that would allow DSUs to make interim determinations of eligibility for individuals who the DSU reasonably believes will be eligible for VR services at the end of the statutory 60-day period for making eligibility decisions. We emphasize that this provision is an option for DSUs to expedite further the delivery of services to individuals while the DSU awaits information to permit a final eligibility determination. DSUs are not required to implement provisions for interim determinations of eligibility.

We also agree with the commenters who stressed the importance of language in section 101(a)(12) of the Act that prohibits a State from establishing any residence requirement that excludes from services any individual who is present in the State. However, we believe that the proposed regulatory language sufficiently tracks the statutory requirement that was not changed by the 1998 Amendments. Again, we believe it is important to clarify, as explained in the Senate Committee Report on the Rehabilitation Act Amendments of 1998, that the requirement for an individual to be present in the State in order to be eligible to receive services should not be interpreted in any way to circumvent an individual's choice of an out-of-State provider (Senate Report 105–166, p. 13). The committee further stated that, with regard to out-of-State placements, the requirement that an individual be present in the State must be imposed at the time of the eligibility determination and may not be used as a means of denying the continuation of services that are being provided in an out-of-State setting.

As we explained more fully in the preamble to the NPRM (65 FR 10626 and 10627), the Act specifies that DSUs must explore an individual's abilities, capabilities, and capacity to perform in work settings through the use of trial work experiences before it can demonstrate that an individual is too severely disabled to benefit from VR services in terms of an employment outcome and, consequently, is ineligible under the program. We believe that this requirement establishes the fairest standard for assessing whether an individual with a significant disability is in fact capable of achieving employment. We also appreciate the trial work examples that commenters shared and note that these types of work options (*e.g.*, supported employment, on-the-job training, internships, job shadowing, structured volunteer experiences in real work settings, and community-based work assessments with appropriate supports) should be considered by others as they seek to expand the scope of trial work experiences available to applicants with significant disabilities. Nevertheless, we believe that § 361.42(e)(2)(ii) of the regulations is sufficiently broad to encompass each of these examples and that a change to that provision is not necessary.

In addition, we interpret the Act to clearly require DSUs to give individuals trial work experiences before deciding that an individual is ineligible under the VR program due to the severity of the individual's disability. Accordingly, a DSU cannot meet the requirement that it use trial work to assess eligibility by simply securing documentation that addresses the individual's success in performing work previously. Using documentation in that regard runs the risk of violating the scope of the mandate in section 102(a)(2)(B) of the Act, specifically that trial work options be sufficiently varied and take place over a sufficient period of time for the DSU to either conclude that the individual is eligible for VR services or (based on clear and convincing evidence) that the individual is incapable of benefiting from the provision of VR services in terms of an employment outcome. Given the State units' expertise in conducting assessments, and without knowing the validity of the documentation that exists or the circumstances that might have changed since the time the individual previously worked, we believe that it is appropriate to require that, before determining that an individual cannot benefit from VR services, the DSU give the individual a variety of trial work options regardless of the individual's past work history or assessments.

We do not believe that the written plan for providing trial work experiences as required in § 361.42(e)(2)(i) of the regulations is inconsistent with the Act or will cause delays in service delivery. On the contrary, we believe that requiring a written plan to assess an individual's abilities, capabilities, and capacities to perform in realistic work settings is a logical means of fulfilling the requirements in section 102(a)(2)(B) of the Act. The written plan will ensure that the assessment process is conducted in a deliberate and well-formulated manner, thus giving an individual a full opportunity to demonstrate his or her capabilities and enabling the DSU to accurately gauge whether the individual can achieve employment. Also, we feel that any burden or minor delay associated with developing the written plan is clearly justified given that the individual risks being found ineligible, and precluded from receiving services altogether, if trial work options are not well-planned and prove unsuccessful.

We recognize the concerns of those commenters who requested that time limits be included in the regulations to ensure that trial work opportunities do not extend beyond a reasonable length. Yet, we believe the timeframes that are the most reasonable and appropriate already were built into the proposed regulations. Specifically, § 361.42(e)(2)(iii) of the regulations requires that the DSU assess the individual's capacity to work in realistic work settings through the use of trial work experiences that are provided over a sufficient period of time for the DSU to determine either that the individual is eligible for VR services or that there exists clear and convincing evidence that the individual cannot benefit from VR services in terms of an employment outcome due to the severity of the individual's disability. Because trial work is intended to result in either a determination of eligibility or a determination of ineligibility that is sufficiently supported, trial work opportunities must be provided until the point that the DSU can reach one of these two conclusions. Thus, specific time periods that would serve to discontinue trial work requirements before the DSU has reached either result would serve to undermine the purpose behind those very same requirements.

We do not believe that the requirement in § 361.42(e)(2)(iv) of the regulations that the DSU provide individuals with appropriate support services, such as assistive technology devices and services and personal assistance services, during trial work falls beyond the scope of the Act. Section 102(a)(2)(B) of the Act states explicitly that trial work experiences are to be afforded "with appropriate supports provided by the designated State unit." Clearly, assistive technology devices and services and personal assistance services are authorized services available to individuals pursuing employment, including supported employment, through the VR program (see *e.g.*, section 102(b)(3)(B)(i)(I) of the Act). Accordingly, we believe it is entirely appropriate to interpret the DSU's responsibility to provide "necessary supports" during the trial work period to cover these same services.

We also disagree that the authority concerning extended evaluations should be deleted in the final regulations. Although the Act clearly places a priority on using trial work experiences in the course of assessments, Congress recognized the need to allow for extended evaluations in those limited instances in which a real work test is impossible or the State unit has exhausted its trial work options without reaching a determination of eligibility. That point is reflected in the legislative history to the trial work provisions in the Act, specifically in Senate Report 105–166, pages 9 and 10.

Changes: None.

Section 361.45 Development of the Individualized Plan for Employment

Comments: Several commenters recommended that the final regulations clarify that the DSU is not required to pay for the costs of technical assistance in IPE development that is provided by sources other than DSU personnel. On the other hand, other commenters suggested that the DSU be required to pay for the costs of the technical assistance provided by non-DSU sources, asserting that such a requirement would be consistent with the individual's opportunity to exercise informed choice in selecting DSU or non-DSU assistance for purposes of developing the individual's IPE.

Many commenters sought more explanatory information in the final regulations that details the role of the qualified VR counselor employed by the DSU in developing and approving the IPE and IPE amendments and in reviewing the IPE annually. These commenters indicated that the "diminished role for the DSU counselor" in the proposed regulations was inconsistent with the Act and other regulatory requirements. The commenters also stated that a DSU-employed counselor must conduct the required annual review of the IPE and assess the individual's progress toward achieving the identified employment outcome since the DSU is responsible for the proper delivery of services and the outcome of the individual's participation in the program. Other commenters suggested that we distinguish between the roles of the "qualified vocational rehabilitation counselor" and the "qualified vocational rehabilitation counselor employed by the designated State unit" by defining each term in the final regulations.

Some commenters suggested that this section of the proposed regulations be revised to prohibit VR counselors employed, or previously employed, by an agency or organization that may provide services under an individual's IPE from assisting the individual in developing the IPE. These commenters urged that a prohibition of this type be implemented in order to guard against conflicts of interest on the part of the counselor that could otherwise jeopardize the individual's ability to exercise informed choice in selecting services and service providers included in the IPE.

In addition, a number of commenters opposed § 361.45(e) of the proposed regulations, which required the DSU to establish and implement standards, including timelines, for the prompt development of IPEs. These commenters viewed this proposed section as beyond the scope of the Act. Other commenters recommended either requiring by regulations a specific time period governing IPE development and implementation (*e.g.*, 30 days from the date eligibility is determined) or defining the term "timely" as it applies to IPE development.

Discussion: Pursuant to section 102(b) of the Act and § 361.45(c) of the final regulations, the DSU must inform eligible individuals of the range of available options in obtaining assistance for purposes of developing the IPE (*e.g.*, developing the IPE with DSU assistance, with non-DSU assistance, or on one's own). Since IPE development assistance from non-DSU sources is authorized, the regulations do not prohibit the DSU from supporting the costs of that assistance. At the same time, however, we agree that the DSU need not pay the costs of assistance provided by non-DSU sources if it so chooses. Thus, it falls within the discretion of the DSU to determine whether, and under what circumstances, it will pay for technical assistance in IPE development from sources other than the DSU.

We believe that the proposed regulations accurately reflected the scope of functions that the Act reserves to the DSU, as well as the broad authority for non-DSU counselors to assist in the development and review of IPEs at the individual's discretion. As some commenters pointed out, a qualified VR counselor who is employed by the DSU must approve and sign the IPE and any amendments to the IPE (see section 102(b)(2)(C)(ii) and (b)(2)(E) of the Act). The proposed regulations followed the framework established by the Act, *i.e.*, by enabling individuals to receive assistance in IPE development from whichever source (if any) that they choose and ensuring that the DSU maintains final IPE approval authority as the Act requires. We do not believe that additional regulatory provisions in this area, including definitions, are needed.

While we note, as we did in the preamble to the NPRM, that the DSU also is responsible for ensuring that the individual's IPE is reviewed annually, we do not agree that that review must necessarily be conducted by a DSU counselor. As discussed in greater detail in the NPRM preamble (65 FR 10626 and 10627), Congress intended to distinguish between IPE functions that *must* be performed by a qualified VR counselor employed by the DSU and related functions that *may* be performed by a qualified VR counselor or other person who is not employed by the State unit. Thus, in addition to enabling individuals to secure assistance from outside the DSU in developing the IPE and IPE amendments, the DSU can meet its responsibility to ensure that the IPE is reviewed at least annually with the individual by conducting the review itself or, at the individual's discretion, by approving the results of a review appropriately conducted by a qualified VR counselor from outside the DSU.

At the same time, however, we do appreciate the commenters concerns regarding the potential conflicts of interest, including potential limits on the exercise of informed choice, that may arise if the counselor or other person assisting the individual in developing (or amending) the IPE is employed or otherwise affiliated with an organization that may provide services to the individual under that IPE. However, without information indicating whether that problem exists or the resulting effects that an existing problem has on participants in the program, we are not inclined to restrict, through these final regulations, the individual's choice of assistants in developing the IPE. Nonetheless, we emphasize that DSUs must ensure that individuals are given full opportunities to exercise informed choice in the selection of services and service providers consistent with the requirements of section 102(d) of the Act and § 361.52 of these final regulations. Accordingly, we would expect DSUs to address any situation, if it arises, in which it believes that a counselor employed by a service provider is unduly influencing an individual during IPE development to obtain services through that counselor's employer without providing the individual with sufficient choices.

We maintain that requirements in § 361.45(e) regarding DSU standards, including timelines, for the prompt development of IPEs are entirely consistent with the Act. In particular, section 101(a)(9) of the Act requires that the individual's IPE be developed and implemented "in a timely manner" subsequent to the determination of eligibility. In fact, both this regulatory requirement and the statutory provision on which it is based precede the 1998 Amendments. We continue to believe that the regulatory standards and timelines called for under § 361.45(e) of the regulations are necessary to guard against delays in service delivery that are, in turn, caused by delays in the IPE development process. We emphasize that DSUs need not meet this requirement by establishing an arbitrary time limit to apply to the development of all IPEs. Instead, State units are expected to develop general standards to guide the timely development of IPEs and, as part of those standards, flexible timelines that take into account the specific needs of the individual.

Changes: None.

Section 361.47 Record of Services

Comments: Some commenters generally supported the modifications to record of services requirements that we proposed in the NPRM. One commenter supported the new flexibility given to DSUs in determining the sources of documentation it will use to meet the required components of the record of services, but asked that RSA identify minimum documentation types in the final regulations. Several commenters opposed the expansion of the service record requirements beyond those in the previous regulations.

Several other commenters asked that we clarify the scope of § 361.47(a)(7) of the proposed regulations, which required documentation in the service record describing the extent to which the applicant or eligible individual exercised informed choice regarding assessment services and regarding the employment outcome, VR services, and other components of the IPE. Some commenters suggested that this proposed requirement be replaced by a provision requiring simply that the DSU document that the individual was provided an opportunity to exercise informed choice. Other commenters stated that it would be difficult to meet the proposed requirement in instances in which the DSU is not directly involved in the development of the IPE.

Many commenters opposed the newly proposed § 361.47(b), which would require that the DSU consult with the State Rehabilitation Council in determining the type of documentation that it will maintain for each applicant and eligible individual. These commenters believed that the proposed provision would expand the functions of the Council beyond those functions required by the Act. Due to the voluntary nature of the Council, the commenters asserted, it would be inappropriate to expect members of the Council to be involved in the DSU's day-to-day operations, including the setting of documentation requirements. Other commenters supported requiring the Council to be involved in establishing the DSU's documentation requirements.

Discussion: We revised § 361.47(a) of the previous regulations to identify minimum

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documentation standards that will enable DSUs to demonstrate that certain service delivery requirements, as they apply to applicants and eligible individuals participating in the VR program, have been met. While we identified in this proposed section those critical service delivery requirements that must be documented, we sought to provide greater flexibility to DSUs in determining the manner in which they would comply (*i.e.*, determining the types of documentation each would use to comply) with the stated requirements. We believe that the proposed regulations provided that flexibility, while identifying only those requirements of the rehabilitation process that are most necessary to address in the record of services. Those proposed requirements that were not drawn from the previous regulations represented important aspects of the 1998 Amendments that we believe the DSU, and we, must monitor to ensure the proper implementation of the program.

In addition, we believe that § 361.47(a)(7) of the proposed regulations established an appropriate standard for DSUs to meet in documenting compliance with a most critical aspect of the VR program—giving individuals the opportunity to exercise informed choice throughout the rehabilitation process. Accordingly, we do not believe that a simple statement that the applicant or eligible individual was provided an opportunity to exercise informed choice reflects either the scope or the importance of the choice-related requirements in the Act. Among those requirements, section 102(d) of the Act and § 361.52 of the final regulations specify that applicants and eligible individuals must be given opportunities to exercise informed choice in selecting assessment services and in selecting an employment outcome, the VR services needed to achieve that outcome, the entities providing services, and the methods used to secure the services. Thus, given the emphasis accorded choice under the Act, we believe it is appropriate and prudent to require documentation describing the extent to which the applicant or eligible individual exercised informed choice in accordance with the Act's requirements. As for those instances in which an individual elects to develop an IPE without the DSU's assistance, we would expect the DSU to inform individuals about the availability and opportunities to exercise informed choice (as it is required to do under section 102(d)(1) of the Act), obtain information from the individual on the extent to which he or she exercised choice during IPE development, and supplement that information with additional information available to the DSU in order to meet the documentation requirement in § 361.47(a)(7).

As we stated in the preamble to the NPRM, we think it is necessary that the DSU consult with the Council, if it has a Council, in determining the type of documentation that the DSU will maintain in the record of services for each applicant and eligible individual. Section 101(a)(16)(B)(v) of the Act requires the State unit to take into account, in connection with matters of general policy arising in the administration of the State plan, the views of the Council and other specified groups. The document types that will comprise the records of services maintained by the DSU relate directly to the DSU's ability to demonstrate its compliance with important service provision requirements in the law, as well as its ability to justify its decisions (e.g., eligibility determinations) regarding the individual's participation under the VR program. We maintain, therefore, that the DSU's documentation standards for fulfilling the record of services requirements in this section of the regulations constitute a policy of general applicability on which the Council's input is required. Moreover, we do not believe that the consultation required under this section of the regulations expands the Council's functions beyond the scope of the statute, particularly the broad scope of review, analysis, and advisory functions carried out by the Council under section 105(c)(1) of the Act.

Changes: None.

Section 361.48 Scope of Vocational Rehabilitation Services for Individuals With Disabilities

Comments: Several commenters requested that we revise § 361.48(j) of the proposed regulations to more clearly describe the type of interpreter and other communication access services that are authorized under the program. Other commenters requested clarification regarding the scope of assistance for eligible individuals seeking self-employment, telecommuting, or business ownership outcomes that is authorized under proposed § 361.48(s). One of these commenters requested guidance on how these services relate to the entrepreneurial services available through the State workforce investment system.

Discussion: We agree with the suggestion that the scope of authorized interpreter services under proposed § 361.48(j) needs to be clarified in the final regulations. In particular, we believe that we need to clarify that sign language interpreter and oral interpreter services are authorized under that section.

Regarding § 361.48(s), we have received several inquiries, in addition to the noted comments, asking us to clarify the scope of resources that are authorized to be provided through the statewide workforce investment system in order to clarify the extent of the State unit's obligation under proposed § 361.48(s). This provision restates section 103(a)(13) of the Act.

Section 112 of Title I of WIA requires that each participating State submit to the Department of Labor a State plan that describes its statewide workforce investment system and the employment and training activities that it will support with WIA Title I funds. The specific employment and training activities included in the plan are determined individually by each State, depending on the needs and economic conditions in that State. Therefore, the scope of resources authorized under the VR program for self-employed persons, telecommuters, and small business owners will depend on the extent to which the State's workforce development system, as described in the State plan under section 112 of WIA, provides support to individuals pursuing that type of work. Given the variances in workforce investment systems across the States, we do not believe that it is practical to revise the language in proposed § 361.48(s) that aligned the resources authorized under the VR program with those that the State makes available under WIA.

Finally, we believe it is important to note that the list of authorized services in this section of the regulations is not exhaustive and that § 361.48(t) specifically authorizes "other goods and services" that the DSU and individual determine to be necessary for the individual to achieve an employment outcome.

Changes: We have revised § 361.48(j) of the proposed regulations by referring specifically to sign language interpreter and oral interpreter services as included within the scope of authorized services for individuals who are deaf or hard of hearing.

Section 361.50 Written Policies Governing the Provision of Services for Individuals With Disabilities

Comments: One commenter requested changes to § 361.50(b)(1) of the proposed regulations, which authorized States to establish preferences for in-State services under certain conditions. The commenter contends that this provision, which was included in the previous regulations, has been subject to misuse and misinterpretation. In response, the commenter suggests restricting DSU preferences for in-State services to instances in which the in-State service is equivalent to and likely to have the same results as an out-of-State service.

Discussion: Section 361.50(b)(1) authorizes a DSU to establish a preference for in-State services in instances in which necessary services are available both within and outside the State. The preference (*i.e.*, the State not taking responsibility for the costs of an out-of-State service that exceeds the costs of the same service provided in-State) is dependent on the in-State service meeting the individual's rehabilitation needs. For that reason, we believe that the provision establishes an appropriate standard, one that has the same effect as that of requiring equivalency between in-State and out-of-State services.

Changes: None.

Section 361.51 Standards for Facilities and Providers of Services

Comments: Many commenters expressed concern about the omission in the proposed regulations of the designated State unit's current regulatory responsibility to issue minimum standards for facilities and service providers. The commenters believed that omitting these requirements from the final regulations will have the effect of holding community providers and facilities to a lower standard than that which must be met by the State agency administering the VR program. The concern was that VR program participants receiving services from private providers would be adversely affected. These commenters encouraged us to maintain the current regulatory standards in the final regulations.

The commenters on this section were concerned mostly about the proposed removal of the previous regulatory provisions requiring providers of vocational rehabilitation services to use qualified personnel. For example, one party stated that financial constraints on community facilities may reduce a facility's capacity to maintain the same qualified personnel standards that section 101(a)(7) of the Act imposes on State agencies; nevertheless, this commenter believed that regulatory requirements should be developed to ensure a reasonable level of professional qualifications at provider facilities. Other commenters stated that individuals who are blind or visually impaired in particular, and all individuals with disabilities generally, must be assured that private facilities and providers of services under the VR program have proper qualifications beyond native language skills and the ability to use appropriate modes of communication (two current standards that were retained in the proposed regulations). In addition, many of the commenters expressed concern that the proposed regulations, unlike the previous regulations, did not require VR service providers to have adequate and appropriate policies and procedures to prevent fraud, waste, and abuse.

Discussion: We had proposed to remove the regulatory requirements governing personnel and other standards for providers of VR services on the basis that the explicit statutory authority supporting those requirements was removed by the 1998 Amendments. Specifically, the 1998 Amendments removed provisions previously contained in section 12(e) of the Act that had required the Secretary to promulgate regulations pertaining to the selection of VR services and VR service providers. In accordance with the prior Act, § 361.51 of the previous regulations included procedures to prevent fraud, waste, and abuse among service providers and procedures to ensure that service providers complied with applicable standards, such as those related to qualified personnel. The requirements in § 361.51 of the proposed regulations that were retained from the previous regulations relating to the accessibility of facilities, affirmative action for qualified individuals with disabilities, and special communication needs personnel also were retained in the 1998 Amendments.

We have interpreted Congress' removal of standards governing personnel and fraud, waste, and abuse from the Act as intended to give States greater discretion in determining how best to ensure that service providers used by the DSU are capable of providing necessary VR services and meeting the needs of VR program participants. In other words, Congress determined that States could ensure the quality of personnel and administrative efficiency among the service providers it uses by following applicable State rules. We want to emphasize that removing this particular requirement from the final regulations does not absolve State units from ensuring that entities providing services under the VR program meet applicable State laws that impose personnel standards and other safeguards on parties providing services under State-administered programs. We believe that this responsibility of the DSU, as well as the DSU's general responsibilities under OMB Circular A–87 and the Education Department General Administrative Regulations (EDGAR) to administer the VR program and the expenditure of VR program funds efficiently and effectively, ensures that the removal of previous regulatory standards for service providers will not have an adverse impact on the program.

Changes: None.

Section 361.52 Informed Choice

Comments: As with proposed § 361.5(b) discussed previously, a number of commenters requested that we define the term "informed choice" in this section of the final regulations.

Another commenter suggested that this section of the proposed regulations be revised to ensure that participants in the VR program are able to exercise informed choice in selecting their vocational rehabilitation counselor. Specifically, the commenter suggested that participants, prior to selecting a counselor, be given a list of counselors in the local office of the State unit, a statement of the counselors' qualifications, and the opportunity to interview a number of counselors.

Other commenters suggested that DSUs make available to individuals information concerning the outcomes that individuals achieve in working with specific service providers. The commenters asked that this information be included in the scope of information that DSUs must provide individuals under § 361.52(c). Other commenters proposed revisions to § 361.52(d), which identifies sample methods or sources of information that the DSU may use to make available required information on services and service providers. Specifically, one commenter requested that DSUs make available to individuals information on nationwide services and service providers, as well as service-related information issued by national consumer groups.

Discussion: We have long been asked to define the term "informed choice" in regulations and have refrained on the basis that the current regulations establish appropriate guidelines governing the informed choice process, while leaving some discretion to DSUs, in conjunction with their Councils, if they have Councils, to determine how best to secure information and make that information available to participants so that they may exercise choice. The 1998 Amendments give even greater emphasis to informed choice, specifically in section 102(d), which identifies each of the stages at which choices must be given (essentially all stages of the rehabilitation process), requires the DSU to inform individuals about the availability of and the opportunity to exercise informed choice, and requires that the DSU assist individuals as is necessary so that they may make informed choices. We believe that this proposed section of the regulations sufficiently reflected the significant scope of the choice provisions in the Act and retained a number of key portions from the previous regulations that serve to guide DSUs in developing their choice-related policies. We again emphasize the crucial role that the Council must play in that regard.

Although we maintain that, at this point, defining "informed choice" in the regulations would not be appropriate, we have established additional guidance materials designed to facilitate the choice process, most notably as part of the RSA Monitoring Guide for FY 2000. We intend to develop additional policy directives that will also assist in that effort.

Section 361.45 of the regulations, which implements section 102(b)(1) of the Act, specifies the range of options available to individuals in securing assistance in developing their IPEs, including assistance provided by DSU or non-DSU counselors or from other sources. However, neither that provision nor the broad choice requirements in section 102(d) of the Act establish a basis for requiring DSUs to provide individuals with their choice of VR counselors. At the same time, we note that the Act and the final regulations do not prevent a State from giving individuals the opportunity to exercise informed choice in selecting counselors. RSA guidance to the States (Program Assistance Circular 88–03, dated June 7, 1988) underscores the importance of an effective counseling relationship between the applicant or eligible individual and the DSU counselor. Thus, we would urge DSUs, taking into account caseload levels and other staffing considerations, to assign counselors to individuals in a manner that they believe will result in a most effective match. Given the obvious effect that that match has on the successful rehabilitation of the individual, we also indicate in the guidance that, if an individual requests a change in counselor and the request is denied, the individual can appeal the determination through the DSU's due process procedures.

Section 361.52(c) of the proposed regulations listed the minimum scope of information that State units were required to provide to individuals, or assist the individual in acquiring, to enable the individual to make informed choices about the services, service providers, and outcome identified in the IPE. We agree with the commenter that the minimum information related to services and service providers specified in this section (e.g., cost, consumer satisfaction, qualifications, degree of integration, etc.) also should mention the types of outcomes that individuals have achieved in working with certain providers.

Section 361.52(d) identifies specific methods and sources of information that the DSU may use to provide individuals with sufficient information about services and service providers. Since this provision is not a comprehensive listing of methods and sources, we note that DSUs and individuals may use any other methods and sources of information that are available to enable the individual to exercise choice. We agree that participants and State units may benefit greatly by securing information from national consumer groups or other national organizations with specialized expertise in particular disabilities, rehabilitation methods, and services. In addition, methods involving experiences that participants may use to gain information about types of employment outcomes, services, and service providers may prove helpful. We encourage

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DSUs to assist individuals in obtaining useful information from many other appropriate sources.

Changes: We have revised § 361.52(c) of the proposed regulations to clarify that information and assistance provided under that section also must assist individuals in exercising informed choice among assessment services. In addition, we have included service provider outcomes in the scope of information relating to the selection of vocational rehabilitation services and service providers. We have deleted the terms "local" and "state and regional" from § 361.52(d) and have added references to methods involving visiting or experiencing various settings to the list of potential methods or sources of obtaining information.

Section 361.53 Comparable Services and Benefits

Comments: One commenter expressed concern that the requirement in the proposed regulations that DSUs provide services to an individual while waiting for identified comparable services and benefits to become available may serve as a disincentive for individuals to pursue the alternative benefits or services at the appropriate time. The commenter recommended that DSUs be able to discontinue services if an individual refuses to pursue the comparable benefits or services.

Another commenter noted that the proposed regulations did not include the statutory exemption in section 101(a)(8)(A)(ii) of the Act that states that awards and scholarships based on merit are not considered comparable services and benefits under the program.

Discussion: Both section 102(b)(3)(E)(ii) of the Act and § 361.46(a)(6)(ii)(C)) of the regulations require that the IPE identify the individual's responsibilities with regard to applying for and securing comparable services and benefits. Thus, the law anticipates that State units and individuals will work out the extent of those responsibilities through the IPE development process. For that reason, we do not believe that § 361.53(c)(2), which is unchanged from the previous regulations, would create the disincentive envisioned by the commenter as long as the individual is fully apprised of, and is assisted in fulfilling, his or her responsibilities in securing other services once they become available.

We recognize that this section of the proposed regulations did not refer to the statutory exception to comparable services and benefits for scholarships and awards based on merit. However, this exemption is addressed in the definition of the term "comparable services and benefits" in § 361.5(b)(10). We think the exception is best addressed in the definition itself since it is the definition that specifies the scope of comparable services and benefits under the program.

Changes: None.

Section 361.54 Participation of Individuals in Cost of Services Based on Financial Need

Comments: Many commenters supported the proposed expansion of those services that would be exempt from State financial needs tests, meaning that individuals could not be required to contribute to the cost of those services. One commenter suggested that the proposed exemption of interpreter services, reader services, and personal assistance services from financial needs tests be limited to the provision of those services during the assessment phase of the VR process. Another commenter supporting the proposal asked that we also emphasize that the DSU still must seek and use comparable services and benefits to pay for exempted services.

In addition, in response to our request for comments on the appropriate scope of services that should be exempted from financial needs tests, a number of commenters requested that the proposed listing be expanded to specifically include assistive communication devices, rehabilitation engineering services, and other access-type services.

Other commenters strongly opposed the proposed expansion of the list of services exempted from financial needs tests under the prior regulations. Some of these commenters stated that the proposed expansion would undermine the DSU's longstanding option of considering the financial need of program participants and would weaken the DSU's ability to conserve VR program funds.

In addition, many commenters supported the proposed prohibition in the NPRM on applying financial needs tests to eligible individuals receiving SSI or SSDI. Other commenters supported prohibiting the application of financial needs tests only to individuals receiving SSI since SSI eligibility is based on the individual's financial need as opposed to SSDI beneficiaries who may have assets that they could contribute to the cost of vocational rehabilitation services.

A significant number of commenters opposed the proposed exemption of SSI recipients and SSDI beneficiaries from the DSU's financial needs assessments on the basis that DSUs often consider the resources of the individual's entire household, as opposed to those of the individual only, in determining the level of resources the individual must contribute to the program of VR services. While these commenters agreed that DSUs could disregard an individual's actual SSI or SSDI cash payment, the commenters recommended that DSUs be able to consider the overall financial status of the individual and the individual's household when assessing the individual's financial need under the VR program.

Discussion: In the NPRM, we proposed to expand the scope of services exempt from State financial needs tests under the prior regulations to include certain services (*i.e.*, interpreter, reader, and personal assistance services) needed to participate in the VR program, as well as any service needed by a recipient of SSI or SSDI.

The purpose of the proposal to exempt from State financial needs tests interpreter, reader, and personal assistance services was to ensure *access* to the VR program. As we discussed in the preamble to the NPRM (65 FR.10629), the additional services that we proposed excluding from State financial needs tests enable individuals to participate in training or employment-related services that they are seeking through the VR program. Typically, individuals do not apply, nor are they determined eligible, under the VR program solely to receive these access-type services. Rather, these services are provided in conjunction with employment and training services sought by the individual participating in the VR program. In fact, the distinguishing feature of these access services is that participation in the VR program is not possible without these services being afforded. Thus, placing an additional burden on the individual to participate in the cost of accessing the VR program, in our view, is inappropriate and contrary to both the purpose of the VR program and the principles in section of 504 of the Act and the ADA, which safeguard participation by persons with disabilities in federally funded (under section 504) or public (under the ADA) programs.

As many of the commenters pointed out, we realize that access-type services other than the three additional services that the NPRM would have exempted from financial needs tests (*i.e.*, interpreter, reader, and personal assistance services) clearly exist and that individuals might need those services in order to participate in the VR program. In light of the extensive public comment we received on that point, and the fact that the limited scope of exempted services in the proposed regulations would not ensure that persons with certain disabilities are able to participate in the VR program, we have modified the proposed regulations to more clearly reflect the DSU's responsibility to ensure that all persons with disabilities do not incur the disability-related costs of accessing the VR program. Specifically, the final regulations prohibit the application of State financial needs tests to the provision of any auxiliary aid or service that would be necessary under section 504 of the Act or the ADA in order for an individual with a disability to participate in the VR program. Thus, the final regulations, in effect, ensure that individuals are able to receive, at no additional cost to themselves, aids and services to which they are already entitled under section 504 or the ADA.

We note that interpreter and reader services—two services proposed to be exempt from financial needs tests in the NPRM—generally would be covered under the section 504- and ADA-based standard in the final regulations if those services are needed in order for the individual to access other VR services. In addition, the final regulations, like the NPRM, identify personal assistance services as a separate category of services exempt from financial needs tests. While personal assistance services, as defined in the VR program regulations, might not necessarily be provided by public programs under section 504 or the ADA, those services are often critical for individuals with significant disabilities to be able to access employment and training under the VR program. As we indicated in the preamble to the NPRM, we believe it is important to exempt these services from financial needs tests as well. We also believe that retaining from the NPRM the exemption for personal assistance services will remove a significant disincentive toward pursuing

employment for those with the most significant disabilities.

We also note, however, that the final regulations do not alter the State unit's responsibility to seek comparable services and benefits that can meet the individual's interpreter, reader, personal assistant, or other access needs. Nor does it affect entities outside of the DSU from meeting their responsibilities under section 504 of the Act, the ADA, or other laws. In fact, we expect that some of those entities are likely to be public agencies with which the State unit is required to enter into an interagency agreement in order for both parties to fulfill their responsibilities toward individuals with disabilities (see § 361.53(d) of the final regulations).

With regard to the proposed prohibition on applying financial needs tests to individuals who receive SSI or SSDI, we continue to believe that it is appropriate to exempt those persons from DSU financial needs tests given the Act's emphasis on streamlining access to VR services for disabled Social Security recipients. Moreover, as we discussed in the preamble to the NPRM (65 FR 10629), this change to the prior regulations facilitates the primary goal behind referring SSI recipients and SSDI beneficiaries to the VR program—supporting their efforts (and reducing disincentives) to pursue gainful employment and no longer require Social Security support.

Our rationale for exempting individuals receiving SSI benefits, or a combination of SSI and SSDI benefits, from State-imposed financial needs tests is further supported by the fact that these persons already have gone through a rigorous, federally mandated financial needs test that is typically more restrictive than those tests employed at the State level. To qualify for SSI, individual recipients must have very limited, if any, monthly income—individual or household—or other assets. These individuals generally live at or below the federally established poverty level. Consequently, SSI recipients clearly have a limited ability to contribute to the costs of VR services. Requiring these same persons to undergo an additional financial needs test at the State level would serve only to unnecessarily delay the provision of VR services.

On the other hand, the rationale behind exempting from DSU financial needs tests individuals receiving SSDI benefits alone is based on three critical points. First, SSA, as a matter of policy, has deemed it necessary to award SSDI beneficiaries monthly cash assistance due to their inability to work. While it is true that SSDI benefits are awarded on the basis of earnings and years worked as opposed to extreme financial need, SSA has determined that these individuals can no longer work due to their disabilities and, therefore, cannot earn income to support themselves or their families. SSDI payments are intended to cover a person's living expenses. Once a person achieves an employment outcome earning sufficient wages, as determined by SSA, the individual would be removed from the SSDI rolls.

Second, many State and Federal agencies currently are working to remove as many disincentives as possible for individuals with disabilities, including individuals with significant disabilities receiving Social Security benefits, to return to work. For example, Congress has adopted changes to Social Security laws not to penalize persons (*i.e.*, not to eliminate or reduce Social Security benefits, including health care coverage) for working since individual's wages are often insufficient to cover costly medical and other living expenses. Previously, many individuals with disabilities chose to remain on SSDI, at Federal expense, rather than risk losing health care coverage. Imposing a financial needs test on this same population that is seeking VR services in order to achieve an employment outcome, in effect, creates an additional disincentive to work and could adversely affect the results sought through the revised Social Security laws and other reforms.

Third, it is important to note that SSA reimburses State VR agencies for the costs incurred in serving an SSI or SSDI recipient when that individual achieves an employment outcome (*i.e.*, substantial gainful activity under Social Security laws) for a specified period of time. Thus, as far as those SSI and SSDI recipients who successfully achieve employment outcomes under the VR program are concerned, there is ultimately little financial burden on the DSU in serving these persons to justify transferring that burden to individuals.

Changes: We have amended the proposed regulations to exempt from DSU financial needs tests any service that constitutes an auxiliary aid or service afforded the individual under section 504 of the Act or the ADA in order for the individual to participate in the VR program.

Section 361.56 Requirements for Closing the Record of Services of an Individual Who Has Achieved an Employment Outcome

Comments: Several commenters expressed concern about proposed § 361.56(a), which required, as a condition of closing the individual's record of services, that the employment outcome achieved by the individual be the same as that described in the individual's IPE. These commenters viewed the provision as inappropriate since amending the IPE to specify a new employment outcome is not always possible, for example when the individual is unavailable to sign an amended IPE.

Other commenters questioned § 361.56(c) of the proposed regulations, which required an agreement between the individual and the DSU counselor that the employment outcome is satisfactory and that the individual is performing well in the employment before the DSU can close the individual's record of services. These commenters suggested that the proposed provision might lead to differences of opinion between the counselor and the individual as to whether the outcome is "satisfactory" and thus preclude the State unit from appropriately closing the service record.

Discussion: We agree that in very limited instances it may be impractical for the DSU and the individual, together, to amend the individual's IPE to reflect the ultimate employment outcome that the individual obtains while participating in the VR program. Yet, we believe that in most instances necessary amendments to the IPE can be accomplished since the DSU and the individual need not approve and sign the amended IPE simultaneously. Moreover, the required consistency between the IPE and the individual's outcome, in our view, is warranted in order to preserve the usefulness of the IPE development process.

With respect to the comments on proposed § 361.56(c), we note that this provision in the NPRM was substantially the same as the previous regulatory provision. In addition, we are not aware of any reported problems regarding the implementation of this provision through RSA monitoring activities, referrals to the Client Assistance Program, or due process hearings. More importantly, given that employee and counselor satisfaction is a critical factor toward assessing the stability of the individual's job, we believe that the provision should be retained in the final regulations.

Changes: None

Section 361.57 Review of Determinations Made by Designated State Unit Personnel

Comments: One commenter suggested revising § 361.57(a) of the proposed regulations to require the State unit to provide in writing all agency decisions that result in a suspension, termination, or denial of services. This commenter explained that requiring written notification of service denials would be consistent with procedural safeguards in other Federal programs.

We received several comments regarding proposed § 361.57(b), the general requirements governing State due process procedures. Specifically, commenters expressed dissatisfaction with proposed § 361.57(b)(3)(ii) regarding representation during mediation sessions and formal due process hearings. One commenter suggested revising that paragraph to exclude the use of attorneys during mediation and to require the use of attorneys during the formal hearing process. The commenter expressed concern that the use of attorneys during mediation would alter the informal nature of that process. Conversely, the commenter explained, individuals who are not represented by attorneys during the formal hearing are at a distinct disadvantage since the State unit, in general, is represented in hearings by an attorney.

At least one commenter questioned whether mediation should be voluntary on the part of the State unit. The commenter suggested revising proposed § 361.57(d)(2)(i) to require the State unit to participate in good faith in the mediation process whenever mediation is requested by the individual.

Commenters suggested that § 361.57(d)(2)(ii) of the proposed regulations be modified to allow the mediator, in addition to the parties to the mediation, to terminate the mediation process. The commenters stated that it is common practice to give mediators that authority.

A few commenters raised concerns about proposed § 361.57(d)(2)(iii), which governs the manner in which mediators are assigned to a particular case and lists of qualified and

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impartial mediators are maintained. One commenter described the meticulous and thoughtful steps used in one State to assign the mediator who is most appropriate to each case. Another commenter suggested that the regulations require that the State unit and the Council agree to the list of mediators as they do for impartial hearing officers.

The final set of comments regarding the proposed mediation procedures pertain to the requirements governing mediation agreements under proposed § 361.57(d)(4). One commenter stated that mediators do not "issue" mediation agreements as that provision suggests. Several commenters urged us to make mediation agreements binding on all parties in order to create greater incentive to pursue mediation.

We received many comments regarding the requirement in proposed § 361.57(e)(1) that hearings generally be conducted within 45 days of an individual's request for review of a State unit decision that affects the provision of services to the individual. With one exception, all commenters indicated that it is overly burdensome to require the State unit to conduct informal reviews, mediation, and the formal hearing within the same 45-day period. Some suggested that the 45-day clock not begin until after an informal review and, if applicable, the mediation process are completed. Others suggested that the time period be extended by a certain number of days (e.g., 10 days) to allow for mediation to occur. Still others suggested that the regulations allow separate time periods for each phase of dispute resolution and that the time periods run consecutively.

Several commenters suggested that § 361.57(g)(3)(iii) of the proposed regulations be modified to eliminate the 30-day deadline by which a reviewing official must render a decision.

Finally, we received several comments asking that the final regulations include a time limit (e.g., 30 days) for the filing of civil actions under § 361.57(i) of the proposed regulations.

Discussion: The issue concerning requiring that all agency decisions that result in a suspension, termination, or denial of services be provided in writing has been brought to our attention many times since the adoption of the 1998 Amendments. Section 361.57(a) conforms to the statutory requirements in section 102(c) of the Act. The Act does not require a written decision in order for an individual to initiate an appeal under this section. An individual may appeal "any determination." Therefore, we do not require designated State unit personnel to issue decisions pertaining to the provision of services in writing, but we encourage the use of written decisions whenever practicable.

With respect to the comments pertaining to legal representation, we share the concern that individuals sometimes are at a disadvantage if they are not represented by an attorney during the formal hearing process, especially if the designated State unit is represented by an attorney. However, we do not share the concern that attorneys used during the mediation process necessarily change the nature of mediation. Nonetheless, the proposed requirements regarding representation during the mediation and hearing stages reflect the broad authority in section 102(c)(3)(B) of the Act for individuals to select the representative of their choice.

The 1998 Amendments to the Act added mediation as a new method of resolving disputes between individuals and the State unit. Thus, it is not surprising that many commenters sought further clarification of the requirements in the proposed regulations that impact the States' implementation of mediation procedures.

Section 361.57(d)(2)(i) conforms to the statutory language of section 102(c)(4)(B)(i) of the Act, which requires that the DSU's mediation procedures ensure that the mediation process "is voluntary on the part of the *parties*. . . ." (emphasis added). Therefore, Congress intended the mediation process to be voluntary on the part of both parties rather than giving only the individual the discretion to participate in mediation as one commenter suggested. We also believe that allowing mediation to be voluntary on the part of both parties is necessary since mediation is successful only if both parties participate willingly in an effort to resolve their dispute. We do note, however, that the State unit's decision to agree to pursue mediation should be made on a case-by-case basis. It is neither appropriate nor consistent with the intent of the Act for a DSU to follow a general policy of never participating in mediation.

Our intent behind § 361.57(d)(2)(ii) of the proposed regulations was to ensure that either party may change its mind about participating in mediation, even after the mediation process has begun, and at that point pursue a due process hearing. We sought to ensure that individuals in particular are never locked into a less formal dispute resolution process that they believe to be futile. Consistent with this approach, we also agree with the suggestion that mediators should be allowed to terminate the mediation process and that amending the regulations to reflect that point would not alter the intended effect of this proposed section.

We proposed a process in § 361.57(d)(2)(iii) of the proposed regulations that is similar to that which the Act applies to the selection of impartial hearing officers. In particular, we sought to ensure the same neutrality on the part of the mediators that exists for hearing officers. However, we believe that States with established processes for assigning mediators to a case should be allowed to continue appointing mediators in that fashion, provided that the process used ensures neutrality.

In response to the comments on proposed § 361.57(d)(2)(iii) and the development of the State's list of available mediators, we note that section 102(c)(4)(C) of the Act does not require the State to develop the list of mediators through the joint efforts of the State unit and the Council. Many States have developed an "Office of Dispute Resolution" or similar office to handle all mediations across multiple State agencies. These offices typically employ mediators or contract with private mediators to conduct mediations involving State-administered programs. The proposed regulations were intended to give States as much flexibility as possible in establishing mediation policies and using existing mediation processes.

Many individuals representing CAPs and DSUs have urged us to interpret section 102(c)(4) of the Act to require that a mediation agreement be binding on all parties. We believe that, if the outcome of mediation (i.e., a mediation agreement) were binding, then conceivably neither party could pursue a formal hearing afterward. That type of restriction would be contrary to the scope of due process procedures that are available under the Act.

In light of the overwhelming support for extending the 45-day period for holding due process hearings under proposed § 361.57(e)(1), we agree that the period should be extended to 60 days in the final regulations. We do not believe that the time period should be extended any longer since section 102(c) of the Act clearly envisions a due process system that is timely, quick, and equitable.

We believe that the 30-day period for an appropriate official to review a hearing officer's decision under proposed § 361.57(g)(3)(iii) is reasonable. This is the same time period that applied to the review of hearing decisions by the State unit director under the previous regulations. Although State-level review of hearing decisions, if established by the State, now must be conducted by an official of an entity overseeing the DSU, we see no reason for modifying the current time period.

We consider it inappropriate for us to establish a time limit for the filing of civil actions in disputes arising under the VR program. The State's Rules of Civil Procedure or the Federal Rules of Civil Procedure, depending on the appropriate forum, dictate the applicable deadline for filing an action in civil court.

Changes: We have made the following modifications to proposed § 361.57(d): authorizing mediators to terminate mediations (§ 361.57(d)(2)(ii)); authorizing States with an established method of assigning mediators to use that process in assigning mediators for the VR program provided the process ensures neutrality on the part of mediators (§ 361.57(d)(2)(iii)); and, in adopting a technical but important revision suggested by some commenters, clarifying that mediators assist in developing rather than "issue" mediation agreements (§ 361.57(d)(4)). We also have modified proposed § 361.57(e)(1) to require that hearings be conducted within 60, rather than 45, days from the individual's request for review of a DSU decision.

Section 361.60 Matching Requirements

Comments: One commenter wrote in support of the proposed change in § 361.60(b)(3)(ii) that would authorize a State to use funds that are earmarked for a particular geographic area within the State as part of its non-Federal share without obtaining a waiver of statewideness if the State determines and informs the RSA Commissioner that it cannot provide the full amount of its non-Federal share without using the earmarked funds. This commenter indicated that the provision was needed since many State legislatures appropriate most, but not all, of the funds needed to match the full amount of Federal funds available under the program.

Discussion: Although section 101(a)(4)(B) of the Act is intended to assist some States in meeting their matching obligations, we wish to reemphasize that statewideness requirements still apply to the Federal VR program funds that the State receives in return for contributing geographically limited earmarked funds to its non-Federal share. For further discussion of the effect of this change from the previous regulations, please refer to the preamble to the NPRM (65 FR 10630).

Changes: None.

Sections 361.80–361.89 Evaluation Standards and Performance Indicators

Comments: None.

Discussion: The Evaluation Standards and Performance Indicators for the VR program were published in the **Federal Register** on June 5, 2000 (65 FR 35792) and became effective on July 5, 2000. Because these performance measures are part of the regulations implementing the VR program (34 CFR 361), we have added the measures and their corresponding requirements to the final regulations in this publication. The Evaluation Standards and Performance Indicators are located in §§ 361.80 through 361.89 of Subpart E. For guidance in implementing the performance measures, we suggest you consult the preamble to the prior **Federal Register** publication of the measures (65 FR 35792).

Changes: We have amended the proposed regulations to include Subpart E, "Evaluation Standards and Performance Indicators," and the corresponding provisions in §§ 361.80 through 361.89 that were previously published. The requirements in these sections are the same as those published in the **Federal Register** on June 5, 2000.

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Part VII

Department of Agriculture

Food and Nutrition Service

7 CFR Parts 272 and 273

Food Stamp Program; Personal Responsibility Provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996; Final Rule

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 272 and 273

RIN 0584–AC39

Food Stamp Program: Personal Responsibility Provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final Rule.

SUMMARY: This rule finalizes the proposed rule of the same name which was published December 17, 1999. It implements 13 provisions of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA). Upon implementation, this rule will: Prohibit an increase in food stamp benefits when a household's income is reduced because of either a penalty imposed under a Federal, State, or local means-tested public assistance program for failure to perform a required action or for an act of fraud; allow State agencies to disqualify an individual from participation in the Food Stamp Program (Program) if the individual is disqualified from another means-tested program for failure to perform an action required by that program; specify that State agencies may not apply a food stamp sanction to Program households for failure to ensure their minor children attend school, or if the adults do not have (or are not working toward attaining) a secondary school diploma or its equivalent; make individuals convicted of drug-related felonies ineligible for food stamps; make fleeing felons and probation and parole violators ineligible for food stamps; require States to provide households' addresses, Social Security Numbers, or photographs to law enforcement officers to assist them in locating fugitive felons or probation or parole violators; allow States to require food stamp recipients to cooperate with child support agencies as a condition of food stamp eligibility; allow states to disqualify individuals who are in arrears in court-ordered child support payments; double the penalties for violating Program requirements; permanently disqualify individuals convicted of trafficking in food stamp benefits of $500 or more; make individuals ineligible for 10 years if they misrepresent their identity or residence in order to receive multiple Program benefits; and limit the Program participation of most able-bodied adults without dependents to three months in a three-year period during times the individual is not working or participating in a work program.

DATES: *Effective Dates:* This rule is effective no later than April 2, 2001, except for the amendment to 7 CFR 272.2(d)(1)(xiii) which is effective August 1, 2001.

Implementation Date: State agencies must implement the provision in this final rule no later than August 1, 2001.

FOR FURTHER INFORMATION CONTACT: Margaret Werts Batko, Assistant Branch Chief, Certification Policy Branch, Program Development Division, Food and Nutrition Service (FNS), USDA, 3101 Park Center Drive, Alexandria, Virginia, 22302, (703) 305–2516. Her Internet address is: Margaret.Batko@FNS.USDA.GOV.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be economically significant and was reviewed by the Office of Management and Budget in conformance with Executive Order 12866.

Executive Order 13132

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. FNS has considered the impact on State agencies. For the most part, this rule deals with changes required by law, and implemented by law in 1996. However, the Department has made discretionary changes to ensure client protections and access to the Program and to simply the administration of the requirements by the State agencies. These changes primarily affect food stamp recipients. The effects on State agencies are moderate. In some instances, the changes result in modest increases in administrative burdens. However, these changes are legislatively mandated and we have no discretion to minimize them. This rule is intended to have preemptive effect on any State law that conflicts with its provisions or that would otherwise impede its full implementation. Generally, PRWORA and other federal statutes required many of the changes made in this rule, and made most of them effective on enactment and all of them effective prior to the publication of this rule. FNS is not aware of any case where the discretionary provisions of the rule would preempt State law.

Prior Consultation With State Officials

Before drafting this rule, we received input from State agencies at various times. Because the Program is a State-administered, federally funded program, our regional offices have formal and informal discussions with State and local officials on an ongoing basis. These discussions involve implementation and policy issues. This arrangement allows State agencies to provide feedback that forms the basis for many discretionary decisions in this and other Program rules. In addition, FNS officials attend regional, national, and professional conferences to discuss issues and receive feedback from State officials at all levels. Lastly, the comments on the proposed rule from State officials were carefully considered in drafting this final rule. The nature of the concerns of the State and local officials who commented on the proposed rule, our position supporting the need to issue this final rule, and the extent to which the concerns expressed by the State and local officials have been met are discussed in detail in this preamble.

Executive Order 12372

The Food Stamp Program is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule in 7 CFR part 3015, Subpart V and related Notice (48 FR 29115), this Program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the DATES paragraph of this preamble. Prior to any judicial challenge to the provisions of this rule or the application of its provisions, all applicable administrative procedures must be exhausted.

Regulatory Flexibility Act

This rule has been reviewed with regard to the requirements of the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612). Shirley R. Watkins, Under Secretary, Food, Nutrition, and Consumer Services, has certified that this rule will not have a significant economic impact on a substantial number of small entities. State and local welfare agencies will be the most affected to the extent that they administer the Program.

Paperwork Reduction Act

The information collection burden associated with the provisions in this rule concerning eligibility, certification, and continued eligibility of food stamp recipients is approved under OMB 0584–0064. The information collection burden associated with the request for a waiver under the food stamp time limit in 7 CFR 273.24 is approved under OMB No. 0584–0479. The information collection burden associated with provisions in this rule which affect the regulations at 7 CFR 273.16, the Demand Letter for Over Issuance, is approved under OMB 0584–0492. The information collection burden that is associated with the provisions in this rule which affect the regulations at 7 CFR 272.2, the State Plan of Operations, is approved under OMB 0584–0083.

Unfunded Mandate Reform Act of 1995 (UMRA) Title II of UMRA establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, FNS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires FNS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, and tribal governments or the private sector of $100 million or more in any one year. This rule is, therefore, not subject to the requirements of sections 202 and 205 of the UMRA.

Civil Rights Impact Analysis

FNS has reviewed this final rule in accordance with the Department Regulation 4300–4, "Civil Rights Impact Analysis," to identify and address any major civil rights impacts the proposed rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, and the characteristics of food stamp households and individual participants, FNS has determined that there is no way to soften their effect on any of the protected classes. FNS has no discretion in implementing many of these changes. The changes required to be implemented by law have been implemented.

All data available to FNS indicate that protected individuals have the same opportunity to participate in the Food Stamp Program as non-protected individuals. FNS specifically prohibits the State and local government agencies that administer the Program from engaging in actions that discriminate based on race, color, national origin, gender, age, disability, marital or family status. Regulations at 7 CFR 272.6 specifically state that "State agencies shall not discriminate against any applicant or participant in any aspect of program administration, including, but not limited to, the certification of households, the issuance of coupons, the conduct of fair hearings, or the conduct of any other program service for reasons of age, race, color, sex, handicap, religious creed, national origin, or political beliefs. Discrimination in any aspect of program administration is prohibited by these regulations, the Food Stamp Act of 1977 (the Act), the Age Discrimination Act of 1975 (Pub. L. 94–135), the Rehabilitation Act of 1973 (Pub. L. 93–112, section 504), and title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d). Enforcement action may be brought under any applicable Federal law. Title VI complaints shall be processed in accord with 7 CFR part 15." Where State agencies have options, and they choose to implement a certain provision, they must implement it in such a way that it complies with the regulations at 7 CFR 272.6.

Regulatory Impact Analysis

Need for Action: On August 22, 1996 the President signed the PRWORA. This rule implements 13 provisions of the PRWORA. This rule (1) prohibits an increase in food stamp benefits when households' income is reduced because of a penalty imposed under a Federal, State, or local means-tested public assistance program for failure to perform a required action, (2) prohibits an increase in food stamp benefits when households' income is reduced because of an act of fraud under a Federal, State, or local means-tested public assistance program; (3) allows States to disqualify an individual from the Program if the individual is disqualified from another means-tested program for failure to perform an action required by that program; (4) clarifies that households who are receiving grants under a State's Temporary Assistance for Needy Families (TANF) Program and who are sanctioned because their minor children are not attending school, or if the adults do not have (or are not working toward attaining) a secondary school diploma or its equivalent, may not be sanctioned under the Program beyond those sanctions provided for in 7 CFR 273.11(k) and (l); (5) makes individuals convicted of drug-related felonies ineligible for food stamps; (6) makes fleeing felons and probation and parole violators ineligible for food stamps; (7) requires States to provide households' addresses, Social Security numbers, or photographs to law enforcement officers to assist them in locating fugitive felons or probation or parole violators; (8) allows states to require food stamp recipients to cooperate with child support agencies as a condition of food stamp eligibility; (9) allows states to disqualify individuals who are in arrears in court-ordered child support payments; (10) doubles the penalties for violating Program requirements; (11) permanently disqualifies individuals convicted of trafficking in food stamp benefits of $500 or more; (12) makes individuals ineligible for 10 years if they misrepresent their identity or residence in order to receive multiple food stamp benefits; and (13) limits the food stamp participation of most able-bodied adults without dependents (ABAWDs) to three months in a three-year period during times the individual is not working at least half-time or participating in a work program.

The changes in food stamp requirements made by the provisions in PRWORA addressed in this rule would reduce Program costs for fiscal year (FY) 1999–2003 by approximately $1.810 billion. For FY 1999–2003, the estimated yearly savings are (in millions) $525, $431, $348, $263, and $243, respectively. The majority of the savings are realized from Section 824 of PRWORA, time limited benefits for able-bodied adults without dependents. Smaller savings are realized from the following provisions: Section 819, comparable disqualifications; Section 822, cooperation with child support agencies; Section 823, disqualifications for child support arrears; and Section 829 and 911, no increase in benefits. The savings from the remaining provisions in the rule are negligible and, therefore, will not be discussed in this analysis.

Comparable Disqualifications—Section 819—This provision gives States the option to impose the same disqualification for food stamps as imposed on a household member for failure to take a required action under a Federal, State, or local law relating to a means-tested public assistance program. The rule provides that: (1) The

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program has to be authorized by Federal, State, or local law; (2) that a Federal means-tested program includes public and general assistance as defined in 7 CFR 271.2; (3) the provision may be applied selectively to programs since it is an optional provision; (4) the provision only applies if the person is disqualified while receiving the other assistance and food stamps; (5) the provision does not apply to time-limited benefits, exceeding the family cap, failing to complete the application process on time or failing to reapply; or to purely procedural requirements such as submitting a form; (6) only a household member may be disqualified; (7) the penalty must run concurrently with the penalty in the other program, and for the duration of the penalty in the other program, but not to exceed one year without review; (8) A State must shorten the disqualification period when it becomes aware that the person is ineligible for means-tested public assistance for another reason during that time frame; (9) all of the resources and all but pro rata share of the income of the ineligible member must be counted in accordance with 7 CFR 273.11(c)(2); (10) the household rather than the State agency will have to initiate the action of adding a person back to the household; (11) a disqualification may be imposed in addition to allotment reductions under section 829 of PRWORA; and (12) States that elect to implement this provision must include it in the Plan of Operation.

This provision affects participants to the extent States choose to implement this provision and to the extent individuals are disqualified or sanctioned under another Federal means-tested program. We estimate that 3,000 participants will be disqualified from food stamp benefits due to this provision in FY 1999. We estimate that the FY 1999 cost savings from this provision will be $5 million and the five-year cost savings for FY 1999 through FY 2003 will be $25 million.

As a proxy for the number of individuals disqualified from other means-tested programs, we used Department of Health and Human Services' Administration for Children and Families data regarding the average number of people sanctioned monthly from the JOBS program in May 1994. More recent data were not available. There were almost 13,000 monthly first sanctions, 1,876 monthly second sanctions and 375 monthly third sanctions. First sanctions were assumed to result in instant compliance and therefore last zero months in duration. Second sanctions were assumed to have an average duration of three months and third sanctions were assumed to have an average duration of six months.

The savings estimate was calculated as the sum of the products of the number of individuals sanctioned, an estimated average food stamp benefit per person ($73.74) and the duration of the sanction [*e.g.* (12,999 cases of first sanctions) times ($73.74 times 12 months for yearly benefits) times 0 months of sanction; (1,876 cases of second sanctions) times ($73.74 times 12 months for yearly benefits) times 3 months of sanction; (375 cases of third sanctions) times ($73.74 times 12 months for yearly benefits) times 6 months of sanction)].

Because Section 819 is optional, the estimate was adjusted to account for the proportion of food stamp households in States choosing to exercise this provision. State option data were based on the May 1998 FNS report, State Food Stamp Policy Choices Under Welfare Reform: Findings of 1997 50-State Survey, indicating which States have adopted the optional provisions of PRWORA as of the end of calendar year 1997. Thirteen States reported having adopted this optional provision: Arizona, California, Idaho, Illinois, Kansas, Maine, Michigan, Mississippi, North Dakota, Ohio, South Dakota, Tennessee and Wyoming. According to 1998 food stamp quality control data, these thirteen States account for approximately 30 percent of all food stamp public assistance households. The savings estimate was, therefore, adjusted to reflect 30 percent uptake by States. The estimate of the number of individuals disqualified because of the section 819 provision equals the total unrounded savings divided by an estimated average food stamp benefit.

Cooperation with Child Support Agencies—Section 822 of PRWORA—This provision allows States to require cooperation with child support agencies as a condition of food stamp eligibility. The provision is optional and can be waived for the custodial parent for good cause but not for the non-custodial parent. The rule requires: (1) States to refer appropriate individuals to the agency funded under IV–D for a determination of cooperation; (2) State agencies to adopt the IV–A or IV–D agency's standards for good cause, (3) the disqualification is for the individual and not the entire household; (4) States that elect to implement this provision to include it in the Plan of Operation; and (5) States to count all of the resources and all but pro-rata share of the income of the disqualified individual.

This provision affects participants to the extent States choose to implement this provision and to the extent they are a custodial or non-custodial parent with child support responsibilities and do not cooperate with child support agencies.

Custodial Parents

Using the fiscal year 2001 budget baseline, we estimate that in FY 1999 approximately 4,000 custodial parents will be disqualified due to sanctions for noncompliance and 68,000 custodial parents will have their benefits slightly reduced due to compliance and increased child support income as a result of this provision. We estimate the FY 1999 cost savings for the custodial parents to be $15 million and the five-year cost savings for FY 1999 through FY 2003 to be $85 million.

Because food stamp households receiving public assistance are already mandated to cooperate with child support agencies, the impact of this provision is expected to be realized among food stamp-only custodial-parent households. Based on the February 1995 FNS report, Participation in the Child Support Enforcement Program Among Non-AFDC Food Stamp Households, food stamp-only custodial households with child support needs that are not cooperating with the child support agencies account for roughly 2.8 percent of all participating food stamp households. According to the report, the response of these custodial parents to this provision was assumed to fall into three categories: (1) Those that comply and receive higher child support payments; (2) those that do not comply and face sanctions, and; (3) those that opt to leave the Program rather than comply.

First, in the 1995 report, custodial parents choosing to comply with the provision were found to account for approximately 8.5 percent of food stamp benefits and were expected to experience a decline in food stamp benefits of 2.0 percent as a result of higher child support payments. Savings from this group was calculated as the proportion of total food stamp benefits contributed to this group (8.5 percent) times the expected decline of 2.0 percent (0.085 times 0.02 = .00170 or 0.17 percent).

Second, to estimate the cost for households which are sanctioned for noncompliance, the report indicated that food stamp-only custodial households accounted for 7.0 percent of all food stamp households, and that approximately 2.1 percent of such households would choose to be sanctioned rather than comply with the provision. The total number of participating households was calculated by dividing a participation projection

from the fiscal year 2001 budget baseline by the average household size from 1998 food stamp quality control data (2.4 persons). The monthly benefit reduction for those sanctioned and leaving food stamps rather than comply was estimated to be the difference between the maximum allotment for a family of four and the maximum allotment for a family of three (difference =$90). The savings for this group was calculated as the product of total households, the proportion which are food stamp-only custodial households (7.0 percent), the proportion choosing to be sanctioned rather than comply with the provision (2.1 percent), and the annual value of the sanction (e.g., in FY 1999, 7,276 households times 7 percent times 2.1 percent times $90 times 12 months).

Third, the 1995 report indicated that of food stamp-only custodial households, 3.8 percent were expected to leave the Program rather than comply with the provision. The estimate of savings from the group of custodial parents choosing to leave food stamps rather than comply was calculated as the product of the number of total food stamp households, the proportion which are food stamp-only custodial households (7.0 percent), the proportion choosing to leave food stamps rather than comply (3.8 percent), and the annual value of the household benefit lost (*e.g.*, in FY 1999, 7,276 households times 7 percent times 3.8 percent times $221 benefit per month times 12 months).

The three group impacts were summed and the estimate was adjusted pursuant to assumptions regarding the proportion of food stamp recipients in States choosing to adopt this optional provision—10 percent in FY 1997 and growing to 20 percent by FY 2003. State option data were based on the May 1998 FNS report, *State Food Stamp Policy Choices Under Welfare Reform: Findings of 1997 50-State Survey*. Seven States reported having adopted this optional provision as of the end of calendar year 1997: Idaho, Kansas, Maine, Michigan, Mississippi, Ohio and Wisconsin. According to 1998 food stamp quality control data, these seven States account for approximately 10 percent of applicable food stamp households.

The estimate of the number of custodial parents disqualified for food stamp benefits from this provision (4,000 people) was calculated as the total unrounded savings ($10.6 million) attributable to the second and third groups of custodial parents—those continuing to not cooperate with child support agencies—divided by the annual value of their sanction ($221 times 12 months).

The estimate of the number of custodial parents receiving reduced benefits as a result of complying with this provision and receiving increased child support income (68,000 persons) was calculated as the difference between the total number of custodial parents affected by the provision (71,000 persons) and those being disqualified for noncompliance (4,000 people) rounded to the nearest thousand. The total number of custodial parents affected was estimated as the total target population of the provision—2.8 percent of all households according to the 1995 report—times the projected number of participants from the FY 2001 budget baseline, times the State option phase-in assumptions.

Non-Custodial Parents

Using the fiscal year 2001 budget baseline, we estimate that approximately 4,000 non-custodial parents will be disqualified by this provision in FY 1999. We estimate the FY 1999 cost savings for non-custodial parents to be $5 million and the five-year cost savings for FY 1999 through FY 2003 to be $25 million.

Estimates of the savings attributable to the non-custodial parents in this provision are based on information from a 1995 report, *Non-custodial Fathers: Can They Afford to Pay More Child Support*, by Elaine Sorenson at the Urban Institute. Data on non-custodial parents is extremely limited and this was the best available information. The number of non-custodial parents not cooperating with child support was estimated to be more than 78,000 in 1990. This estimate was based on the reported 5.9 million fathers in 1990 who were not paying support, adjusted by 75 percent to account for those at low-income levels, times the proportion estimated to represent non-custodial fathers receiving food stamps who had no child support order—a proxy for non-cooperation (1.77 percent which is derived from the 1995 Urban Institute report) (5.9 million times 0.75 times 0.0177 = 78,323). The estimate of the number of non-custodial parents not cooperating with their child support agency was inflated by 1.5 percent annually to account for growth in the child support system. This inflation factor is consistent with information from the Department of Health and Human Services on the child support system. The savings were estimated as the product of the number of non-custodial parents not cooperating and an estimated average food stamp benefit per person ($72.29 per month times 88,891 persons times 12 months).

The savings estimate for non-custodial parents was adjusted for the proportion of households in States choosing to adopt this optional provision and assumptions regarding the percent of non-cooperating non-custodial parents States are able to identify and sanction. The State option assumptions were based on the May 1998 FNS report, State Food Stamp Policy Choices Under Welfare Reform: Findings of 1997 50-State Survey. Three States reported having adopted this provision at the end of calendar year 1997: Maine, Mississippi, and Wisconsin. According to 1998 quality control data, these three States account for roughly 5 percent of all applicable households. Therefore, the savings estimate in FY 1997 assumes only these States implement this child support provision, thereby affecting 5 percent of all households that could be subject to this provision, and further assumes a gradual expansion of the States selecting this option so that 10 percent of all households are subject to this provision by FY 2003. The estimate was adjusted further based on the assumption that, operating at maximum effectiveness, States would only be able to correctly identify and sanction 75 percent of applicable offenders.

The estimate of the number of non-custodial parents disqualified for food stamp benefits from this provision was calculated as the total unrounded savings from non-custodial parents ($3 million) divided by an estimated average annual food stamp benefit ($867.48 = $72.29 times 12 months).

Summing together the estimates for both custodial and non-custodial parents, we estimate that 8,000 people will be disqualified as a result of these provisions in FY 1999. 68,000 custodial parents will have benefits reduced due to higher amounts of child support income as a result of this provision. We estimate the FY 1999 cost savings to be $20 million and the five-year cost savings for FY 1999 through FY 2003 to be $110 million.

Disqualification for Child Support Arrears—Section 823—This provision allows States to disqualify individuals for any month during which they are delinquent in any court-ordered child support payment. This provision is optional. The rule requires that: (1) The disqualification apply to the individual and not the entire household; (2) if the State later discovers that an individual was delinquent in paying child support, the State shall determine disqualification and establish a claim for the month's benefits; (3) States that

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elect to implement this provision must include it in the Plan of Operation; and, (4) the States must count all of the resources and all but a pro rata share of the income of disqualified individuals.

This provision affects participants to the extent States choose to implement this provision and to the extent they have court-ordered child support responsibilities and they are delinquent in their payments. We estimate that approximately 3,000 persons will be disqualified as a result of this provision in FY 1999. We estimate the FY 1999 cost savings to be $5 million and the five-year cost savings for FY 1999 through FY 2003 to be $25 million.

The estimate of savings for this provision was based on the 1995 report, Non-Custodial Fathers: Can They Afford to Pay More Child Support, by Elaine Sorenson at the Urban Institute. There were an estimated 825,000 custodial mothers participating in the child support system (in IV–D programs) with child support orders not receiving support in 1990. It was assumed that for every custodial mother with an order and without support, there was a non-custodial father in arrears. Estimating that almost 7 percent (the national average of 1 in 14 Americans receiving food stamps) of them were receiving food stamp benefits, it was calculated that in 1990 there were more than 56,000 non-custodial fathers receiving food stamps who were in arrears for court-ordered child support. This number was inflated by 1.5 percent per year to reflect growth in the child support system, consistent with information from the Department of Health and Human Services. The estimate of savings for this provision was based on an estimated average monthly benefit per person ($72.29). The total savings was calculated as the product of the number of non-custodial fathers in arrears for child support times the annual benefits they would lose due to disqualification (64,883 people times $72.29 per month times 12 months).

This product was adjusted for assumptions regarding the proportion of food stamp households in States choosing to implement this provision and the State's ability to identify and sanction the appropriate individuals. The State option assumptions were based on the May 1998 FNS report, State Food Stamp Choices Under Welfare Reform: Findings of 1997 50-State Survey, indicating that three States reported operating this provision at the end of 1997: Ohio, Oklahoma and Wisconsin. According to 1998 food stamp quality control data, these three States account for approximately 5 percent of all applicable households. The savings estimate was adjusted to reflect that 5 percent of the States would implement this provision in FY 1997, growing to 10 percent by FY 2003. The estimate was adjusted further based on the assumption that, operating at maximum effectiveness, States would only be able to correctly identify and sanction 75 percent of applicable offenders. In FY 1999, for example, the savings was calculated by taking the product of the 6 percent State phase-in and the assumption of 75 percent cooperation and multiplying it by the total savings. The estimate of the number of individuals disqualified for food stamp benefits from this provision was calculated as the total unrounded savings ($2.5 million) divided by an estimated average annual food stamp benefit ($867.48).

Able-Bodied Adults without Dependents—Section 824 of PRWORA—This provision limits the receipt of food stamps for certain able-bodied adults without dependents (ABAWDs) to 3-months in a 36 month period unless the individual is either working at least half-time or participating in an approved work or work training program for at least 20 hours per week. Individuals are exempt from the time limit if they are under 18 or 50 years or older, medically certified as physically or mentally unfit for employment, a parent or other household member with responsibility for a dependent child, or exempt from work registration under 6(d)(2) of the Act, or pregnant. Individuals can regain eligibility if they work 80 hours in a 30 day period, and they maintain eligibility as long as they are satisfying the work requirement. If individuals later lose their job, they can receive an additional 3 months of food stamps while not working. The additional 3 months must be consecutive, and begins on the date the individual notifies the State that he/she is no longer working. The Act allows waivers of the time limit for groups of individuals living in areas with an unemployment rate of more than 10 percent or where there are not a "sufficient number of jobs to provide employment for the individuals."

The rule: (1) Allows unpaid and work for in-kind services to count as "work;" (2) allows the State agency to determine good cause for missing work; (3) does not count partial months toward the 3 month limit; (4) makes verification of work hours mandatory; (5) makes participants report changes in work hours that bring the person below 20 hours a week; (6) counts all of the resources and all but a pro rata share of the income of the ineligible ABAWD as available to the household; (7) exempts individuals starting on their 50th birthday; (8) exempts all adults in a household where there is a child under 18; (9) prorates benefits back to the date the "cure" is complete for regaining eligibility (except in instances where individuals regain eligibility by doing workfare, at which point the benefits will be prorated back to the date of application); (10) requires States to submit unemployment data based on approved Bureau of Labor Statistics methodologies when applying for a waiver under the 10 percent criteria; (11) approves a waiver for a time period that bears some relationship to the documentation provided, but for no more than a year.

This provision affects participants to the extent they are able-bodied adults without dependents and to the extent they are not fulfilling the work requirement, exempt or covered by a waiver. The methodology used in this provision relies on current projections of participation in the Program and information on food stamp participants prior to PRWORA who match the ABAWD definition. We estimate that 345,000 individuals are subject to the time limit in FY 1999 due to this provision. We estimate that the FY 1999 cost savings from this provision will be $490 million. We estimate that the five-year cost savings for FY 1999 through FY 2003 will be $1.6 billion.

The caseload estimates were generated by identifying program participants in the 1996 food stamp quality control data who are likely to lose eligibility due to ABAWD work requirement provisions (those between the ages of 18 and 50 who have no dependents, are not disabled, who do not already have more earnings than that of a 20 hour-per week job, etc.). The size of this group of participants was then adjusted to reflect the decline in overall caseload between 1996 and 1999, resulting in a pool of just under 730,000 program participants who could have been considered to be subject to the ABAWD provisions in FY 1999. An adjustment was then made to account for the estimated number of ABAWDS who lived in waived areas and were exempt from the work requirement, which narrowed this pool down to approximately 523,000. An additional adjustment of just under 180,000 participants was then taken to account for persons who were able to retain eligibility through the Food Stamp Employment and Training (E&T) program. The estimated 345,000 participants who remain represent the final pool of ABAWDS in FY 99 who are expected to lose their eligibility due to the new work requirement. The cost

estimates for 1999 was then derived by first multiplying the 345,000 participants by the average monthly benefit for a single able-bodied Food Stamp recipient ($118), and then multiplying that amount by 12 to get the annual cost. Cost estimates for FY 2000–2003 also incorporated the expected decline in food stamp participation as well as the increased use of E&T funds to provide qualifying work opportunities.

Subsequent to the enactment of PRWORA, the Balanced Budget Act of 1997 and the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA) modified the ABAWD provisions of PRWORA. The Balanced Budget Act of 1997 increased funding to the Food Stamp Employment and Training Program to allow states to create qualifying work opportunities to help ABAWDs retain their Food Stamp eligibility, and permitted states to exempt up to 15 percent of their unwaived able-bodied caseload from the time limits. AREERA further modified the level of funding for Employment and Training Programs for ABAWDs. Taken together both of these laws will likely mitigate the effects of the ABAWD provisions of PRWORA. The effects of these more recent laws will be addressed in future rulemaking.

No increase for Penalties in other Programs—Section 829 and 911—Section 829 provides that if a household's benefits are reduced under a Federal, State, or local means-tested public assistance program for failure to perform a required action, the household may not receive an increased food stamp allotment as a result of the decrease in income due to the reduced public assistance payment. This applies to both intentional and unintentional failures to take a required action. In addition to not increasing allotments, States may reduce the Food Stamp allotment by up to 25 percent. The rule requires that: (1) Federal means-tested public assistance programs include public and general assistance as defined in 7 CFR 271.2; (2) "reduced" means denied, decreased, suspended, or terminated; (3) the penalty must be applied while the person is receiving other assistance; (4) it only applies if the other agency cooperates and it applies to overlapping provisions but runs concurrently; (5) States can prohibit an increase by several different means and reduce the allotment by up to 25 percent; (6) the whole household cannot be denied and the reduction cannot be more than 25 percent even if Title IV–A has a larger reduction; (7) States that elect to implement this 25 percent reduction must include it in the Plan of Operation; (8) the penalty will be for the same duration as the assistance penalty (but the State agency must review for appropriateness if the penalty is in effect after one year) and States must end the prohibition when it becomes aware that the person is ineligible for assistance in the other program for some other reason; and that the sanction goes with the person when they move within the State.

Section 911 prohibits an increase in food stamp benefits as the result of a decrease in Federal, State, or local means-tested assistance benefits because of fraud. The rule provides that this provision be treated the same as 829.

Participants will be affected by these provisions to the extent their benefits are reduced for failure to perform a required action or for fraud. The effect of the provisions also depends on the cooperation of other programs in notifying the food stamp agency. We estimate approximately 6,000 participants will be affected by these provisions. We estimate the FY 1999 cost saving to be $5 million and the five-year cost savings for FY 1999 through FY 2003 to be $40 million.

Food stamp savings from these provisions results from two sources: (1) A mandatory prohibition on increasing food stamp benefits when individuals receive lower benefits in other means-tested programs for failure to comply with a required action; and (2) an optional provision to decrease food stamp benefits by no more than 25 percent.

The estimate for savings from the mandatory prohibition on increasing benefits was based on the Department of Health and Human Services' Administration for Children and Families data regarding the average number of people sanctioned monthly from the JOBS program in May 1994. This serves as a proxy for the number of individuals that receive reduced benefits from a means-tested programs for failure to perform a required action or for fraud, and is the best available data. (Data on fraud in other programs is unavailable.) There were almost 13,000 monthly first sanctions, 1,876 monthly second sanctions and 375 monthly third sanctions. First sanctions were assumed to result in instant compliance and therefore last zero months in duration. This assumption is based on 1994 information from the Department of Health and Human Service, Administration on Children and Families (ACF). ACF does not have any more recent information. Second sanctions were assumed to have an average duration of three months and third sanctions were assumed to have an average duration of six months. The savings from the mandatory prohibition on increasing food stamp benefits was calculated as the sum of the products of the number of individuals sanctioned, the average AFDC benefit lost times the FSP benefit reduction rate of 30 percent, and the duration of the sanction. The average AFDC benefit reduction was taken from the average AFDC benefit per person reported in the 1996 Green Book and inflated over time. ((1,876 monthly second sanctions times 12 months times the 1999 estimated average AFDC benefit lost which equals $143 times 30 percent FSP benefit reduction times 3 months) plus (375 monthly third sanctions times 12 months times the average AFDC benefit lost which equals $143 times 30 percent FSP benefit reduction times 6 months))

The estimate for savings from the State option to decrease food stamp benefits by no more than 25 percent was based on an estimated average monthly food stamp benefit per person and the JOBS sanction data. The savings was calculated as the product of the number of individuals sanctioned, 25 percent of the average food stamp benefit per person and the duration of the sanction. This estimate was adjusted to account for the proportion of food stamp households in States expected to exercise this optional provision—10 percent in 1997 and growing to 20 percent by 2003. This was based on information provided in the May 1998 FNS report, *State Food Stamp Policy Choices Under Welfare Reform: Findings of 1997 50-State Survey*. Seven States reported having adopted this optional provision at the end of 1997: Connecticut, Iowa, Kentucky, Michigan, Mississippi, Montana and Tennessee. According to 1998 food stamp quality control data, these seven States account for approximately 10 percent of all food stamp cash assistance households.

The savings estimates for the mandatory and optional portions of the provisions were summed. The estimate of the number of individuals receiving a reduction in food stamp benefits due to these provisions was calculated as the total unrounded savings divided by an estimated average annual food stamp benefit. ((1,876 monthly second sanctions times 12 months times the average AFDC benefit lost which equals $143 times 30 percent Program benefit reduction times 3 months) plus (375 monthly third sanctions times 12 months times the average AFDC benefit lost which equals $143 times 30 percent Program benefit reduction times 6 months) plus the sum of (1,876 times 12 months times the average FSP benefit per AFDC household which equals

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$259.96 times .25 reduction times 3 months) and (375 times the average Program benefit per AFDC household which equals $259.96 times .25 reduction times 6 months))

Background

On August 22, 1996, the President signed the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. 104–193 (PRWORA). The PRWORA amended the Act by adding new Program eligibility requirements, increasing existing penalties for failure to comply with Program rules, and establishing a time limit for Program participation of three months in three years for able-bodied adults without children who are not working at least half time.

On December 17, 1999, we published a rule proposing to codify the personal responsibility provisions of PRWORA. The period for comment on the proposed rule ended February 17, 2000. We received comments from 28 State agencies, 37 advocate groups, 7 government entities, and 4 individuals. In this final rule, we will not address comments on provisions that are required by law and on which we have no discretion. We will not discuss comments that supported our proposals. We will not discuss comments that concerned merely technical corrections for inadvertent omissions, we have simply made the corrections. We will not discuss provisions on which we received no comments, and we will adopt these provisions as written. For a full understanding of the background of the provisions in this rule, see the proposed rulemaking, which was published in the **Federal Register** at 64 FR, 70920. With the exceptions noted above, in response to the comments made and for ease of reading we will discuss each provision and the comments made.

7 CFR 273.11—Action on Households with Special Circumstances

Ban on Increased Benefits for Failure To Take Required Action or Fraud—7 CFR 273.11(j)

Section 829 of PRWORA amended Section 8(d) of the Act, 7 U.S.C. 2017(d), to provide that, if the benefits of a household are reduced under a Federal, State, or local law relating to a means-tested public assistance program for the failure of a person to perform an action required under the law or program, then the household may not receive an increased food stamp allotment as the result of that decrease for the duration of the reduction. In addition, the State agency may reduce the household's food stamp allotment by not more than 25 percent. This provision applies when the act leading to the decrease in benefits was intentional or unintentional. If the reduction is the result of a failure to perform an action required under part A of title IV of the Social Security Act, 42 U.S.C. 601, *et seq.* (TANF), the State agency may use the rules and procedures that apply under part A of title IV to reduce the food stamp allotment.

Section 911 of PRWORA provides that if an individual's benefits under a Federal, State, or local law relating to a means-tested welfare or public assistance program are reduced because of an act of fraud by the individual under the law or program, the individual may not, for the duration of the reduction, receive increased food stamp benefits as a result of a decrease in income attributable to such reduction. Since cases of fraud generally involve a failure to take a required action in another program, we proposed to treat sections 829 and 911 similarly. We received no comments on this proposal. Therefoes, in this rule we continue to treat sections 829 and 911 similarly in 7 CFR 273.11(j).

We proposed to modify 7 CFR 273.11(k) to provide that a "means-tested public assistance program" for purposes of the restriction imposed by Section 829 of PRWORA would include any public or assisted housing under Title I of the United States Housing Act of 1937, 42 U.S.C. 1437 *et seq.*, any State program funded under part A of Title IV of the Social Security Act, and any program for the aged, blind, or disabled under Titles I, X, XIV, or XVI of the Social Security Act, and State and local general assistance as defined in 7 CFR 271.2. Title XIX of the Social Security Act was not included because Medicaid benefits are not counted as income for food stamp purposes. A final rule published November 21, 2000, redesignated paragraph (k) as paragraph (j). Therefore in this final, the paragraph concerning no increase in benefits will be referred to as paragraph (j). All subsequent paragraphs in 273.11 will be redesignated accordingly.

All but one of the comments we received opposed the definition of means-tested public assistance program. Most of the commenters opposed the inclusion of any public or assisted housing under Title I of the United States Housing Act of 1937. Commenters pointed out that including housing in this definition is administratively burdensome and error prone. In addition, as with Medicaid, we have never counted housing as income, and therefore, we should not include it in this definition. Finally, State agencies would not be aware if a reduction in housing was caused by a failure to comply with that program.

Several commenters opposed the inclusion of Supplemental Security Income (SSI) in the definition of "means-tested public assistance program." One commenter pointed out that historically it has been difficult to verify with the Social Security Agency (SSA) whether or not a person's SSI overpayment was the direct result of non-cooperation. Another commenter said that the SSA is not able to provide State agencies with this information because SSA considers all overpayments non-cooperation even if agency caused. For example, if the client reports a change, but the SSA does not act on the change timely or makes a computational error, the SSA would consider this non-cooperation.

Many commenters suggested that we restrict the definition of "means-tested public assistance program" to the current definitions of public assistance and general assistance found in 7 CFR 271.2. Some commenters suggested that we define "means-tested public assistance programs" as TANF only. One commenter suggested that we restrict the definition of "means-tested public assistance program" to TANF only, but allow State agencies the option of including general assistance in the definition.

Based on these comments, we have decided to modify the regulations at 7 CFR 273.11(j) to restrict the definition of "means-tested public assistance programs" to that of "public assistance" and "general assistance" as defined in 7 CFR 271.2. We decided not to adopt the one commenter's suggestion to modify the regulations further to give State agencies the option of including "general assistance" in the definition. General assistance is a means-tested State or local assistance program. We believe that not including it in the definition of "means-tested assistance program" would circumvent the law which specifically provides that this provision applies to " * * * State or local means-tested programs."

One commenter suggested we clarify that by "assistance" we mean "cash assistance" and not merely other benefits or services funded by TANF. While we agree, such non-cash benefits are not counted as income for food stamp purposes, and a reduction in these services due to failure to comply would not trigger an increase in food stamp benefits. Therefore, we do not believe that the regulations at 7 CFR 273.11(j) need to be clarified in this manner.

We proposed that the restriction imposed by section 829 of PRWORA only apply if assistance benefits are reduced for failure of a member of a household to perform a required action if the person was receiving assistance at the time the reduction was imposed. In other words, this provision would only apply to reductions imposed during the period benefits were originally authorized by the other program and to reductions imposed at the time of application for continued benefits if there is no break in participation, but not to reductions imposed at initial application. The majority of the commenters supported this proposal. Only three commenters opposed it. They suggested that the ban on increases apply to applicants of assistance programs as well as recipients. One commenter suggested that this be a State agency option. We are maintaining this provision as proposed at 7 CFR 273.11(j).

We proposed that if a reduction in the assistance benefits was in force at the time the individual applied for food stamps, the State agency would compute the benefits in a manner that would prevent a higher food stamp allotment as a result of the failure to take the required action. The majority of the commenters suggested that the ban on increases should only apply if the individual was receiving food stamps at the time he failed to take a required action in the other program. Several commenters said that the State agency cannot prevent an increase in food stamps if an individual is not receiving food stamps at the time he fails to perform a required action in the assistance program. In addition, several commenters stated that the State agency should advise individuals of the consequences of non-compliance in the assistance program before imposing a penalty in the Program. We agree with these comments. Therefore, we are modifying 7 CFR 273.11(j) to provide that the ban on increasing food stamps will only apply to individuals who are receiving food stamps at the time of the failure to perform a required action in a means-tested assistance program.

We proposed that this provision not apply to situations where individuals reach a time limit for benefits, have a child that is not eligible because of a family cap, or fail to comply with purely procedural requirements such as failure to submit a monthly report or failure to reapply for assistance. The majority of the commenters supported these proposals. One commenter opposed the exclusion of procedural requirements from those that would trigger a sanction because in many cases procedural requirements are in fact substantive. Several commenters suggested we clarify in the regulation what we consider "procedural" (which would not trigger a sanction) versus "substantive" (which would trigger a sanction). One commenter suggested we include an explicit definition of what is required for a public assistance sanction to trigger a disqualification under this provision. s

Since TANF policies vary substantially from State-to-State, and sometimes even within States, we are not confident that we could conclusively resolve this issue with a foolproof definition. However, based on these comments, we are clarifying the regulations at 7 CFR 273.11(j) to say that this provision does not apply to reaching a time limit for time-limited benefits, having a child that is not eligible because of a family cap, failing to reapply or complete the reapplication process for continued assistance under the other program, or failure to perform a purely procedural requirement. Further, in this section, we are providing the State agency with the flexibility to determine procedural versus substantive requirements within the following parameters: A procedural requirement, which would not trigger a food stamp sanction, is a step that an individual must take to continue receiving benefits in the program such as submitting a monthly report form or providing verification of circumstances. A substantive requirement, which would trigger a food stamp sanction, is a behavioral requirement designed to improve the well being of the recipient family, such as participating in job search activities or ensuring that children receive the proper vaccinations.

Several commenters suggested we clarify that the substantive action must be within the power of the individual in order to trigger a food stamp sanction. For example, an individual is required to attend parenting classes in order to continue receiving assistance. The individual is willing to take the class but the individual is unable to because the classes are full. We agree with this comment. Therefore, we are modifying 7 CFR 273.11(j) to provide that failing to perform an action because the individual is unable to perform, as opposed to refusing, shall not be considered failure to perform a required action.

One commenter suggested that the person not taking the required action must be a member of a certified food stamp household in order for the sanction to be imposed. In some instances, the TANF family unit and the food stamp household are not one and the same. If an individual who is not a member of the food stamp household (such as a roomer) fails to take a required action which precipitates a decrease in the TANF grant, the commenter believes the food stamp allotment should be allowed to rise. We agree with the commenter. Therefore, we are clarifying that in order for this provision to be effective, the individual must be a member of a food stamp household as defined in § 273.1, including ineligible household members such as students. If the individual is a non-household member, such as a roomer, a live-in attendant, or another individual who shares living quarters with the household but who does not purchase food and prepare meals together, this provision would not be effective.

Section 8(d)(1)(A) of the Act, as amended by section 829 of PRWORA, provides that the household may not receive an increase in food stamp benefits and section (8)(d)(1)(B) provides that State agencies may reduce the food stamp allotments by not more than 25 percent. Several commenters suggested we modify the regulations to provide that any percentage reduction in benefits should be calculated from the amount that the household would have received under the regular food stamp benefit formula, taking into account its actual (reduced) income. This would insure that the combination of preventing an increase and further reducing the food stamp allotments would not result in a household receiving an amount of food stamps that is more than 25 percent less than the amount the household would receive if the usual food stamp calculation formula were applied to the family's actual income. We agree with these commenters. Therefore, we are modifying the proposed regulations at 7 CFR 273.11(j) accordingly.

Section 829 of the PRWORA also amended section 8(d)(2) of the Act to provide that if benefits are reduced for a failure of an individual to perform an action required under a program under Title IV–A of the Social Security Act (TANF), the State agency may use the TANF rules and procedures to reduce the food stamp allotments. We interpreted the reference to use of TANF rules and procedures to apply only to procedural aspects such as budgeting and combined notices and hearings. A few commenters pointed out that budgeting procedures, such as use of prospective or retrospective budgeting, are substantive policies that could significantly change the scope and severity of the penalties. Since

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budgeting rules can routinely determine whether someone is eligible in a month, and what benefits an individual receives, budgeting procedures should be considered substantive and should not be imported from TANF. State agencies are currently mandated to use TANF budgeting procedures when determining eligibility for food stamp households/TANF households. Current regulations at 7 CFR 273.21(a)(2) provide that State agencies must "determine eligibility, either prospectively or retrospectively, on the same basis that it uses for its (TANF) program, unless it has been granted a waiver by FNS." Based on this, we are retaining the provision as written.

We proposed that the prohibition on increasing the food stamp allotment be for the duration of the reduction in the assistance program. At the same time we proposed that the maximum length of the food stamp sanction not exceed one year. Several commenters pointed out that there is a discrepancy between these two provisions. We believe that the prohibition on increasing benefits must be for the same months as the decrease in assistance to the extent possible, even if there is a break in participation. If the penalty in the other program is six months, then the food stamp sanction must be for the same six months, to the extent possible. We also believe that the prohibition on increasing food stamp benefits not be longer than a sanction for an Intentional Program Violation (IPV), and, therefore, we proposed that the prohibition not be longer than a year. The majority of the commenters supported the idea of a time limit on the penalty. Several suggested a shorter time frame, such as six months. Several suggested State agencies be allowed to set the time frame as long as it was less than one year. One commenter suggested the time frame for the sanction be the same as the food stamp certification period. A few commenters opposed the one-year limit because it was too short. These commenters suggested State agencies should be allowed to keep the food stamp sanction in place as long as the penalty in the other program is in effect and the assistance program remains open. The majority of the commenters supported the concept of a time limit. However, there was no consensus on how long that time limit should be. Our further legal review of the statutory authority resulted in a modification of the proposed rule. Therefore, we have provided that the sanction shall not exceed the sanction period in the other program. If at any time the State agency can no longer ascertain the amount of the reduction, then the State agency may terminate the food stamp sanction. If the sanction is still in effect at the end of one year, the State agency shall review the case to determine if the sanction continues to be appropriate. If, for example, the household is not receiving assistance, it would not be appropriate to continue the sanction. Sanctions extended beyond one year must be reviewed at least annually but may be ended by the State agency at any time. In the final rule at 7 CFR 273.11(j) we clarify that the ban on increasing food stamps is for the duration of the reduction in the assistance program. The State agencies may determine the length of the food stamp sanction providing it does not exceed the sanction in the other program, and does not exceed one year, without review.

We proposed that the State agency be allowed to shorten the prohibition on increasing benefits to less than one year if the individual becomes ineligible during the sanction period for some other reason. A few commenters suggested that State agencies be allowed to lift the sanction when the individual's case is closed in the other assistance program. Several commenters suggested that we require the State agencies to do this. Several commenters said that this would be administratively burdensome: how would the State agency know that the household was ineligible for some other reason since this isn't a reportable change? We agree that the individual should not be sanctioned when he is no longer eligible for the assistance program or when his case is closed. We believe the requirement to report a change in the amount of income will generally capture the instances when an individual whose assistance grant is reduced then becomes ineligible for another reason. However, we recognize that there are instances where food stamp reporting requirements won't capture this information. Therefore, we are modifying the regulations at 7 CFR 273.11(j) to provide that the State agency must lift the ban on increasing food stamp benefits when it becomes aware that the individual is ineligible during the sanction period for some other reason, or when his case is closed.

We proposed that if an individual fails to perform a required action in a State or local assistance program, and the individual moves within the State, the prohibition on increasing benefits goes with that person. We proposed that it be terminated if the person is ineligible for the assistance program for some other reason or if the individual moves out of State. We proposed that if an individual fails to perform a required action in a Federal program, and the individual moves, either interstate or intrastate, the State verify the status and continue the disqualification if appropriate. The majority of the commenters opposed tracking penalties, particularly from State-to-State because it is administratively burdensome and error prone. We agree with these comments. Therefore, we are removing the provision at 7 CFR 273.11(j) which requires tracking penalties from State-to-State. However, we believe if an individual moves intrastate, the State agency should be aware of penalties levied by Federal, State or local public assistance programs. Therefore, we are retaining the provision which provides if an individual moves within the State, the prohibition on increasing benefits shall be applied to the gaining household unless that person is ineligible for the assistance program for some other reason.

We proposed to remove the exception from 7 CFR 273.11(j) that the prohibition on increasing food stamp benefits did not apply in the case of individuals or households subject to the food stamp work sanction imposed pursuant to 7 CFR 273.7(g)(2). We believe the law allows the State agency to disqualify the individual for food stamp purposes and prohibit an increase in food stamps as the result of the reduction of assistance. We failed to mention in the preamble of the proposed rule that the law also permits the State agency to further reduce the food stamp allotment by up to 25 percent even if there is some overlap.

Several commenters opposed the proposal that the same conduct could be subject to multiple punishments. They pointed out that the subsequent penalty could be more severe than an IPV. One commenter suggested that the law did not authorize State agencies to "pile on" penalties, but gave them a choice among penalty systems. This commenter suggested that where both section 8(d) (no increase in benefits and or reduction by 25 percent) and section 6(i) (comparable disqualification), or section 6(d) (disqualification for failure to comply with TANF work requirements) of the Act apply to the same conduct, the household should receive the most severe of the penalties that apply in any given month, not the combined effect for them all, and the food stamp penalty should take precedence.

We consulted our legal authority and have determined that we do not have the discretion to limit the penalties the State agency may apply under sections 8(d) and sections 6(i) of the Act. The law clearly prohibits State agencies from increasing food stamp allotments and

gives them the option to further decrease the food stamp allotment by 25 percent. Separate and apart from these provisions, it gives them the option to disqualify individuals who are disqualified from a means-tested assistance program. There is no connection between the two penalties which can be construed as giving us the discretion to limit them. Therefore, we are not adopting the commenters' suggestions to limit the penalties by making only the most severe penalty apply. However, we urge the State agencies to carefully balance desires to support TANF policies with family food needs when choosing which optional provisions to apply.

We are retaining our proposal to remove the exception from 7 CFR 273.11(j) that the prohibition on increasing food stamp benefits did not apply in the case of individuals or households subject to the food stamp work sanction imposed pursuant to 7 CFR 273.7(g)(2). If an individual who is exempt from food stamp work registration is sanctioned under TANF for failing to comply with TANF work requirements, the individual must be disqualified from the Program. If we keep the exception in place, individual's food stamp benefits would rise in response to the decrease in income caused by the TANF sanction. One of the main thrusts of PRWORA was to help individuals become self sufficient by encouraging them to work if they are able. One of the main reasons behind these provisions (section 829 and 819 of PRWORA) was to support other programs' penalties. Individuals who fail to comply with a means-tested assistance program for any other reason and are subsequently disqualified from that program can be disqualified from the Program and have their food stamp benefits held constant. To make an exception for individuals who fail to comply with TANF work requirements is inconsistent with the spirit of the law. Therefore, we are removing the exception as proposed.

We emphasized in the preamble of the proposed rule that during the sanction the State agency must act on changes that would affect the household's benefits which are not related to the assistance violation. Several commenters pointed out that we left this out of the regulation language. This was an inadvertent error and we have corrected it in the final rule.

One commenter suggested that the rule should explicitly state that if the public assistance program determines that the reduction was not appropriate, any food stamps that the household was denied under this provision be restored. We agree that a household should not suffer if the public assistance program or the State agency administering the Program later determines that the reduction in the public assistance grant was not appropriate. At the same time, we cannot support the household's unduly benefiting. For example, if the public assistance program restores benefits, then the household would not be entitled to restored food stamp benefits. However, if the State agency chooses the option to further reduce the food stamp benefits by up to 25 percent and it is later determined that the reduction in the public assistance grant was inappropriate, then the household would be entitled to restored benefits. Currently, the regulations at 7 CFR 273.17 require the State agency to restore lost benefits if the loss was caused by an error by the State agency, an IPV which was reversed or if there is a statement elsewhere in the regulations specifically stating that the household is entitled to restoration of lost benefits. Instead of detailing all of these circumstances in the regulations, we have decided to modify 7 CFR 237.11(j) to provide that the State agency must restore lost benefits when necessary if it is later determined that the reduction in the public assistance program was not appropriate.

We proposed to revise 7 CFR 273.9(b)(5)(i) so that the total amount of welfare or public assistance, rather than the total amount minus the repayment amount, is counted as income for food stamps purposes when the overissuance in the PA program was caused by the household. The majority of the commenters opposed this proposal. Several commenters argued that this proposal is administratively complex and error prone. The State agency would have to contact the other program to determine if the overpayment was administrative or client caused. Several commenters argued that we should not assume all overpayments are the result of a failure to take a required action or even fraud, as many overpayments are either inadvertent household errors or errors caused by the program. Several commenters stated that this would result in a form of double jeopardy—we would count benefits as income in the usual manner, and again when they are recouped after the overpayment is found. A few commenters suggested we only count the amount of the repayment in the case of fraud. In light of these comments, we have decided not to make the proposed change at 7 CFR 273.9(b)(5)(i).

One commenter pointed out that we require State agencies to indicate in their State Plan of Operations if they are implementing optional provisions of this rule. However, we failed to require State agencies to indicate in their plans if they have chosen to implement the optional provision to reduce the food stamp allotments by up to 25 percent. This was an inadvertent error. We have modified 7 CFR 272.2 and 273.11(j) accordingly.

Comparable Disqualifications—7 CFR 273.11(k)

Section 819(a) of the PRWORA amended Section 6 of the Act, 7 U.S.C. 2015, to provide that if a disqualification is imposed on a member of a food stamp household for a failure of the member to perform an action required under a Federal, State, or local law relating to a means-tested public assistance program, the State agency may impose the same disqualification on the member of the household under the Food Stamp Program. In addition, the State agency may use the rules and procedures that apply under TANF to impose the same disqualification under the Food Stamp Program. Finally, after the disqualification period has expired, the member may apply for food stamp benefits and shall be treated as a new applicant.

We proposed to add a new section, 7 CFR 273.11(l) to codify this provision (now § 273.11(k)). Several of our proposals under this provision paralleled our proposals to implement section 829 and 911 of PRWORA at 7 CFR 273.11(j). For example, we proposed that neither of these provisions would apply to individuals who are initially applying for benefits from a means-tested assistance program. In general, the comments we received spoke to the parallel provisions. Where the provisions are similar we have discussed the comments and our rationale for our decisions in the previous discussion of section 829 and 911 of PRWORA, or 7 CFR 273.11(j). Therefore, we will not repeat the discussion here. However, we lay out our proposals and our decisions as they relate to this particular section. Where the provisions and our proposals differ, we provide a complete discussion of the provision, our proposal, the comments we received and our decision.

Parallel Provisions

(1) We proposed at 7 CFR 273.11(l) that the penalty applied only if an individual was receiving assistance at the time the disqualification was imposed by the other program and at the time of application for continued benefits if there was no break in participation. We proposed that this

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provision would not apply if the person was disqualified upon initially applying for an assistance program. We are maintaining this provision as written at 7 CFR 273.11(k).

(2) We proposed at §273.11(l) that if an individual was disqualified from an assistance program and the disqualification was still in effect when he initially applies for food stamps, then the State agency may disqualify him from food stamps at the initial application. We have revised this provision at 7 CFR 271.11(k) to provide that the individual must be receiving food stamps at the time of the disqualification in the other program in order to be disqualified from food stamps.

(3) We proposed at 7 CFR 273.11(l) that this provision not apply to reaching a time limit for time-limited benefits or having a child that is not eligible because of a family cap. In addition, we proposed that this provision not apply to purely procedural requirements such as a failure to submit a monthly report or failure to reapply for assistance. We are clarifying the regulations at 7 CFR 273.11(k) to provide that this provision does not apply to: (1) Reaching a time limit for time-limited benefits, (2) having a child that is not eligible because of a family cap, (3) failing to reapply or complete the reapplication process for continued assistance under the other program, (4) failing to perform an action that the individual is unable to perform as opposed to refusing to perform, or, (5) failing to perform a purely procedural requirement. We are providing that the State agency has the flexibility to determine procedural versus substantive requirements within the following parameters: (1) A procedural requirement, which would not trigger a sanction, is a step that an individual must take to continue receiving benefits in the program such as submitting a monthly report form or providing verification of circumstances; and (2) a substantive requirement, which would trigger a sanction, is a behavioral requirement designed to improve the well-being of the recipient family, such as participating in job search activities or ensuring that children receive the proper vaccinations.

(4) We proposed that the food stamp disqualification period be limited to the same period of time as the disqualification in the assistance program, to the extent possible. We also proposed that the maximum length of the food stamp disqualification in these circumstances be no more than one year. We are retaining the provision that the disqualification be concurrent to the extent possible with the disqualification in the other program. We are also providing that the State agency may determine the length of the disqualification as long as it does not exceed the disqualification in the other program. If the sanction is still in effect at the end of one year, the State agency shall review the case to determine if the sanction continues to be appropriate. If, for example, the household is not receiving assistance, it would not be appropriate to continue the sanction. Sanctions extended beyond one year must be reviewed at least annually but may be ended by the State agency at any time.

(5) We proposed at 7 CFR 273.11(l) that the State agency be allowed to shorten the food stamp disqualification period if the person becomes ineligible to participate in the other program for some other reason during that one-year time period. We are modifying the regulations at 7 CFR 273.11(k) to provide that a State agency must lift the food stamp disqualification when it becomes aware that the individual is ineligible for assistance for some other reason.

(6) We are modifying 7 CFR 237.11(k) to provide that the State agency must restore lost benefits when necessary if it is later determined that the reduction in the public assistance grant was not appropriate.

Provisions Unique to 7 CFR 273.11(k)

We proposed at 7 CFR 273.11(l) that the assistance program under which the disqualification was imposed, has to be authorized by Federal, State or local law, but that the specific disqualification penalty does not have to be specified in the law. Several commenters argued that in order for a State to sanction an individual under this provision, the action, not just the program, should be explicitly required by law. One commenter argued that the action should be required under law or formal written policy. We believe that the law provides that the program not the action must be specified in the law. Therefore, in the final rule at § 273.11(k) we are retaining the provision as proposed.

We interpreted the term, "means-tested public assistance program" to include any public or assisted housing under Title I of the United States Housing Act of 1937; any State temporary assistance for needy families funded under part A of Title IV of the Social Security Act; and any program for the aged, blind, or disabled under Titles I, X, XIV, or XVI of the Social Security Act; Medicaid under Title XX of the Social Security Act; and State and local general assistance as defined in 7 CFR 271.2. The majority of the commenters opposed this provision for the same reasons they opposed this definition for Section 829 of PRWORA. In addition, they opposed the inclusion of Medicaid in this definition. They suggested that the definition be restricted to the definition of "public assistance" and "general assistance" as defined in the food stamp regulations. Based on these comments, and in the interest of consistency with section 7 CFR 273.11(j), we have decided to modify the regulations at 7 CFR 273.11(k) to restrict the definition of "means-tested public assistance programs" to that of "public assistance" and "general assistance" as defined in 7 CFR 271.2

Since the law makes the comparable disqualification provision a State option, we proposed to allow State agencies the discretion to apply this provision to some, but not all, means-tested public assistance programs. Further, we proposed to allow State agencies to choose which disqualifications within a specific program it wants to impose for food stamp purposes. The majority of the comments we received supported this provision. Only one commenter opposed the provision that allows the State agency to apply it selectively. Because the majority of the commenters supported these provisions, and we believe that allowing State choice would further Program goals, we are retaining them as written at 7 CFR 273.11(k).

We proposed that for food stamp purposes only the individual can be disqualified, rather than the whole household. The majority of the commenters supported this provision. Therefore, we are retaining it as written.

We proposed that when a household member is disqualified from food stamp eligibility under section 6(a)(2) of the Act, the State agency count all of the member's resources and either all or a pro rata share of the income and deductible expenses as available to the household. The majority of the comments opposed allowing the State agencies the option of counting all of the individual's income as available to the household. They argue that this is too punitive. They contend that if a State agency chose to count all of the income as available to the household, it would be imposing the same penalty as for an IPV and that penalties comparable to IPVs should come at the direction of Congress as it did in the cases of drug felons and immigrants ineligible under section 6(f) of the Act. We agree with these comments and, accordingly, we have decided to modify

the regulations at 7 CFR 273.11(k) to provide that the State agency must count all of the resources and all but a pro-rata share of the income of the disqualified member as available to the household in accordance with 7 CFR 273.11(c)(2).

School Attendance—7 CFR 273.11(l)

Section 103 of PRWORA amended Part A of Title IV of the Social Security Act, 42 U.S.C. 601, *et seq.*, to provide for block grants to States for TANF. The title of Section 404 of the amended Part A of Title IV is "Use of Grants." Section 404(i) provides that a State to which a grant is made under section 403 shall not be prohibited from sanctioning a family that includes an adult who has received assistance under the Food Stamp Program, if such adult fails to ensure that the minor dependent children of such adult attend school as required by the law of the State in which the minor children reside. Section 404(j) provides that a State to which a grant is made under section 403 shall not be prohibited from sanctioning a family that includes an adult who is older than age 20 and younger than age 51 and who has received assistance under the Program, if such adult does not have, or is not working toward attaining, a secondary school diploma or its recognized equivalent unless such adult has been determined in the judgment of medical, psychiatric, or other appropriate professionals to lack the requisite capacity to successfully complete a course of study that would lead to a secondary school diploma or its recognized equivalent.

We interpreted these provisions to pertain to TANF sanctions only. We proposed that States may not apply a separate food stamp sanction to households based on sections 404(i) and (j). We included a reference to these provisions in 7 CFR 273.11, Action on Households with Special Circumstances. In addition, we proposed that if an individual was sanctioned under TANF, then the State agency must apply 7 CFR 273.11(j), prohibiting an increase in food stamp benefits as a result of a reduction in public assistance benefits, and it may apply 7 CFR 273.11(k), regarding comparable disqualifications. We also proposed that if a State agency elected the optional reduction, then it should include it in its State Plan of Operation. All of the comments we received supported our interpretation that these provisions applied to TANF sanctions only. One commenter stated that our regulations were unnecessarily long, and that a simple statement that these provisions do not provide independent authority for food stamp sanctions beyond any that may apply though sections 6(i) or 8(d) of the Act would be sufficient. One commenter questioned the necessity to include these provisions in the State Plan of Operation since they are already included under 7 CFR 273.11(j) and (k). We agree with both of these commenters. Therefore, we are combining these two provisions into a single provision at 7 CFR 273.11(l). We are providing that these provisions do not provide for a separate food stamp sanction beyond those that are provided for in 7 CFR 273.11(j) and (k). In addition, we are removing the requirement at 7 CFR 272.2 that State agencies include this in their State Plan of Operations. Finally, we are not including these individuals in the list of non-household members at 7 CFR 273.1(b).

Cooperation with Law-Enforcement Authorities—7 CFR 272.1(c)(1)(vii)

We proposed amending 7 CFR 272.1(c)(1) to implement section 837 of PRWORA which requires State agencies to disclose certain information regarding food stamp participants to law enforcement officers. Under proposed paragraph 7 CFR 272.1(c)(1)(vii), which essentially tracks the statutory language, a State agency, upon the written request (including the name of the household member) of a Federal, State, or local law enforcement officer, would be required to disclose the address, social security number and, if available, a photograph of any household member where the member is: (1) Fleeing to avoid prosecution, or custody or confinement after conviction, for a crime (or attempt to commit a crime) that, under the law of the place the member is fleeing, is a felony (or, in the case of New Jersey, a high misdemeanor); or (2) is violating a condition of probation or parole imposed under Federal or State law; or (3) has information that is necessary for the officer to conduct an official duty related to a member of the household who is fleeing to avoid prosecution or custody for a felony.

One commenter generally opposed the proposed provision based on the belief that it is unnecessary since State agencies are already free to cooperate with law enforcement agencies. Another commenter wanted to know if the State agency should withhold an eligibility determination if a law enforcement officer is seeking information regarding an applicant who may be fleeing from prosecution or custody for a felony or may have violated a condition of probation or parole. Other commenters requested clarification of some of the provisions in the proposed rule, specifically regarding information about a household member who is not a violator him or herself but who may have information regarding a violator. In response to these comments we are making the language of the final rule more specific. We are clarifying that a request from a law enforcement officer for information regarding a household member who may be fleeing to avoid prosecution or custody would not be sufficient to withhold an eligibility determination or to terminate the participation of such an individual. However, as provided by the amendment made by sections 115 and 821 of PRWORA (discussed below), documentation that the household member is, in fact, a fleeing felon, or is violating a condition of probation or parole, would be sufficient to terminate the eligibility or deny the application of the member. We are also clarifying that this provision authorizes law enforcement officers to obtain information regarding household members who, although not fleeing to avoid prosecution or custody themselves, have information regarding other members who are, in fact, fleeing felons. We are taking this opportunity to remind State agencies that this provision in no way requires them to collect photo IDs as a condition of eligibility. Though the regulations at 7 CFR 273.2(f) require State agencies to verify identity, they are very clear that any document which reasonably establishes the applicant's identity must be accepted. The State agency may not impose a requirement for a specific type of document such as a photo ID.

Finally, the rule notes that the State agency shall only disclose the information as is necessary to comply with a specific written request, which is authorized by the rule, of the law enforcement agency.

Verification of Criteria Related to the Commission of Crimes (Drug-related Felonies, Flight to Avoid Prosecution or Incarceration, and Violations of Parole or Probation)—7 CFR 273.2(f)(1)(ix)

Under section 115 of PROWRA, an individual convicted (under Federal or State law) of any offense which is classified as a felony by the law of the jurisdiction involved and which has as an element the possession, use, or distribution of a controlled substance (as defined in section 102(6) of the Controlled Substances Act, 21 U.S.C. 802(6)) is not eligible to participate in the Food Stamp Program unless the State agency through legislation elects to opt out of the disqualification provisions of the statute. Under section 6(k) of the Act, 7 U.S.C. 2015(k) as

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amended by section 821 of PRWORA, individuals who are fleeing to avoid prosecution, or custody or confinement after conviction, for a crime classified as a felony under the law of the place from which the individual is fleeing, or violating a condition of probation or parole imposed under a Federal or State law are ineligible to participate in the Program. We proposed amending 7 CFR 273.2(f)(1) to require that each State agency establish a system or systems to verify the status of food stamp applicants/recipients to determine if they would be subject to disqualification under section 115 or section 821 of PRWORA. One commenter expressed general support of the rule as written. A number of commenters expressed strong opposition to this proposal indicating that establishment of a system of verification would result in a significant burden on affected State agencies. Several State agencies indicated that since access to existing databases containing criminal records is generally limited to law enforcement agencies, State agencies would not be able to utilize such databases to determine whether an applicant would be subject to disqualification under section 115 or 821, making verification extremely difficult since there is no current nationwide database which is accessible to State welfare agencies.

Based on their experience, a number of State agencies expressed the opinion that a statement on the application form requiring individuals subject to disqualification based on convictions for drug related felonies to identify themselves as such would be sufficient to identify those individuals for the purposes of the Program. In response to these comments, we are eliminating the requirement that State agencies establish systems to verify whether an applicant has been convicted of a drug-related felony. With respect to verification of other criminal activity such as flight to avoid prosecution or custody, or violation of a condition of probation or parole, we feel that, based on the comments, it would be impracticable to mandate the establishment of State systems to verify such activity. We also believe that in the overwhelming majority of cases as soon as a household member is identified by a law enforcement agency as an individual who is fleeing to avoid prosecution or custody for a felony, or has violated a condition of parole or probation, that individual would be taken into custody, and as such, would no longer be a member of a household eligible to participate in the program. Based on these factors the final rule will not include a provision mandating the establishment of systems to verify whether applicants are fleeing to avoid prosecution or custody, or have violated a condition of probation or parole.

Applicability of SSI Categorical Eligibility to Individuals Subject to Disqualification Under Section 115 of PRWORA—7 CFR 273.2(j)(2)(vii)

Since publication of the proposed rule, it has come to our attention that it will be necessary to address the issue of whether section 115 of PRWORA (disqualification based on a conviction of a drug-related felony) applies to individuals who are categorically eligible to participate in the Program based on their eligibility to participate in the Supplemental Security Income (SSI) Program. Under 7 CFR 273.2(j)(2), households in which all persons receive or are authorized to receive SSI are considered categorically eligible to participate in the Program. Under 7 CFR 273.2(j)(2)(vii)), certain individuals who are statutorily ineligible based on nonfinancial eligibility criteria shall not be considered as part of an otherwise categorically eligible household. We believe that individuals who are ineligible to participate in the Program as the result of the operation of section 115 of PRWORA are similarly situated since their ineligibility is the result of a statutory provision unrelated to financial eligibility. Accordingly, we are amending 7 CFR 273.2(j)(2)(vii) by adding a new subparagraph (D) which specifically provides that an individual who is ineligible under 7 CFR 273.11(m) by virtue of a conviction for a drug-related felony shall not be included in a categorically eligible household. Although 7 CFR 273.2(j) also confers food stamp categorical eligibility on persons who are authorized to receive assistance under the TANF Program, it is not necessary to address the applicability of disqualification under section 115 of PRWORA to potentially categorically eligible TANF recipients convicted of drug-related felonies since section 115 of PRWORA also prohibits individuals convicted of drug-related felonies from participating in the TANF Program.

Disqualification Based on the Conviction of a Drug-Related Felony—7 CFR 273.11(m) and 273.11(c)(1)

Under Section 115 of PRWORA, an individual convicted (under Federal or State law) of any offense which is classified as a felony by the law of the jurisdiction involved and which has as an element the possession, use, or distribution of a controlled substance (as defined in section 102(6) of the Controlled Substances Act) is not eligible to participate in the Program unless the State agency through legislation elects to opt out of the disqualification provisions of the statute. Three commenters requested that we clarify the effective date of this provision. Although we addressed this issue in the implementation section of the preamble of the proposed rule, we have revised the language of 7 CFR 273.11(m) in the final rule to expressly provide that the disqualification provision only applies to convictions for crimes occurring subsequent to August 22, 1996. Some commenters also expressed the opinion that counting the resources and income of a person disqualified based on a drug-related felony conviction was unduly punitive. We are retaining the provision in the proposed rule since it is based directly on the statute (section 115(b)(2) of PRWORA) with no agency discretion. One commenter wanted to know if a conviction for a drug-related felony occurring during the certification period should be considered a reportable change. We are not mandating that the conviction be a reportable change although we anticipate that State agencies would act to disqualify a household member who is convicted of a drug-related felony during the certification period if the household voluntary reports such a change or if it becomes otherwise known to the State agency. We also believe that in most cases a conviction for a drug-related felony (as opposed to a misdemeanor) would result in the incarceration of the household member resulting in a reportable change based on household composition since the individual convicted and subsequently incarcerated would no longer be a household member. One commenter suggested that the regulation provide more detail regarding the treatment of the disqualified member's income and resources. Although we feel that the current regulations (including the proposed changes adding convicted drug felons) at 7 CFR 273.11(c) provide sufficient detail regarding the treatment of the income and resources of certain disqualified household members and that an expanded description of the applicable procedures is unnecessary, we have added a cross-reference to 7 CFR 273.11(c)(1) at 273.11(m).

For general information, the following 19 States have either opted out or limited the disqualification time period: Louisiana, Oklahoma, Illinois, Michigan, Minnesota, Ohio, Wisconsin, New Hampshire, New York, Vermont, New Jersey, North Carolina, Colorado, Iowa, Utah, Hawaii, Nevada, Oregon and Washington.

7 CFR 273.11(n)—Disqualification of Fleeing Felons and Probation/Parole Violators

Under section 821 of PRWORA, individuals who are fleeing to avoid prosecution, or custody or confinement after conviction, for a crime classified as a felony under the law of the place from which the individual is fleeing, or violating a condition of probation or parole imposed under a Federal or State law are ineligible to participate in the Program. One commenter expressed concern regarding the vagueness of the term, "violating a condition of probation or parole". Although we agree that the term is somewhat vague we do not believe that it would be possible to provide a definition with any specificity since conditions of probation or parole vary greatly among individuals. We also wish to note that, in most cases once a determination is made that an individual is violating a condition of probation or parole, the individual will be taken into custody and would be ineligible to participate in the Program on the basis that the individual is a resident of an institution rather than a member of the household. One commenter suggested that we clarify that once an individual is released from supervision he or she would no longer be considered in violation of a condition of probation or parole. We have considered the comment and have elected not to specifically address the issue in the regulatory language since we feel that the determination of whether an individual is considered to be violating a condition of parole or probation would be a determination of (State or Federal) courts and/or law enforcement authorities.

One commenter suggested we include a cross reference to 7 CFR 273.11(c)(1) regarding the treatment of income and resources of the ineligible member. We agree with the commenter and are making the change at § 273.11(n) to include the cross reference.

Cooperation With Child Support—7 CFR 273.11(o) and (p)

Section 822 of PRWORA amended section 6(l) of the Act (7 U.S.C. 2015(l)) to allow State agencies to disqualify a natural or adoptive parent or other individual (collectively referred to as "the individual") who is living with and exercising parental control over a child under the age of 18 if the custodial parent does not cooperate with the State agency administering the program established under Part D of Title IV of the Social Security Act (42 U.S.C. 651 *et seq.*,) (the State Child Support Agency) in establishing paternity and collecting support for the child and or the individual without good cause. The provision requires the Department, in consultation with the Department of Health and Human Services (DHHS), to develop standards for what will constitute "good cause" for refusal of a custodial parent to cooperate. Section 822 of PRWORA also amended Section 6 of the Act by adding subsection (m) to give State agencies the option to disqualify the non-custodial parent who refuses to cooperate with the State Child Support Agency in establishing the paternity of a child and providing support for the child.

One commenter suggested we define "custodial parent" versus "non-custodial parent" for purposes of these provisions. We agree that a definition is warranted. Therefore, for purposes of this provision, a custodial parent is one who lives with his or her child under the age of 18. A "non-custodial parent" is one who does not live with his or her child who is under the age of 18.

Several commenters suggested that we require the State agencies to notify applicants of the requirement to cooperate with the State Child Support Agency as a condition of eligibility. Without knowledge that a cooperation requirement exists and what will be required to comply, an individual cannot be expected to comply. We agree with these comments. Therefore, we are modifying both 7 CFR 273.11 (o) and (p) to require the State agency provide notification of this requirement in writing to applicants for initial benefits and for continued benefits.

Custodial Parent—7 CFR 273.11(o)

We proposed that the State agency make the cooperation and the good cause determination. Several commenters argued that we do not have the authority to determine if an individual is cooperating with the State Child Support Agency. A couple of commenters pointed out that the Social Security Act, as amended by section 5548 of Pub. L. 105–33, gives the State Child Support Agency the authority to make this determination. Section 454(29)(A) of the Social Security Act provides that the State Child Support Agency "shall make the determination (and redetermination at appropriate intervals) as to whether an individual who has applied for or is receiving assistance under * * * the Food Stamp Program * * * is cooperating in good faith with the State in establishing the paternity of, or in establishing, modifying or enforcing a support order for, any child of the individual by providing the State Child Support agency with the name of, and such other information as the State Child Support agency may require with respect to, the non-custodial parent of the child, subject to good cause and other exceptions * * *." Furthermore, section 454(4)(A)(IV) of the Social Security Act provides that the State Child Support Agency "* * * provide services relating to the establishment of paternity or the establishment, modification, or enforcement of child support obligations * * * with respect to each child for whom cooperation is required pursuant to section 2015(l)(1) of title 7 (the Food Stamp Program) * * *." One commenter suggested that our regulations simply clarify the process by which the State agency would be notified by the State Child Support Agency that the individual has failed to cooperate. Section 454(29)(E) provides that the IV–D agency must "promptly notify the individuals and the State agency administering * * * the Food Stamp Program * * * of each determination, and if non-cooperation is determined, and the basis thereof * * *."

When PRWORA was enacted in August of 1996, it did not include changes to the Social Security Act which addressed cooperation with the State Child Support Agency for food stamp recipients. However, the Balanced Budget Act of 1997 (Pub. L. 105–33) amended the Social Security Act to include references to the Food Stamp Program as detailed above. Subsequently, TANF has published final regulations implementing section 454 of the Social Security Act which also requires TANF applicants and recipients to cooperate with the State Child Support Agency as an eligibility requirement. Based on these developments, and on comments, we have decided to modify the proposed regulations at 7 CFR 273.11(o) to provide that if the State Agency chooses to implement this provision, it must refer the appropriate individuals to the State Child Support Agency.

The proposed definition of cooperation was based on wording used at the time by DHHS. We proposed that the individual must cooperate with the State agency in obtaining support by: (1) Establishing the paternity of a child born out of wedlock; (2) obtaining support payments for the child or the individual and the child; and (3) obtaining any other payments or property due the child or the individual and the child. We also proposed that the following actions be included in the definition: (1) Appearing at an office of

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the State or local agency or the child support agency to provide verbal or written information; (2) appearing as a witness at judicial or other hearings or proceedings; (3) supplying information in establishing paternity; and (4) paying to the child support agency any support payments received from the absent father. We received a number of comments on our proposed definition. Several commenters suggested that we refer to the final TANF regulations as an example. Several other commenters suggested changes to the proposed language defining cooperation. However, because it is the State Child Support Agency that makes the cooperation determination, and the definition of cooperation is embedded in section 454(29) of the Social Security Act, we have decided that it is not necessary to detail in our regulations the definition of cooperation beyond what is provided for in section 822 of PRWORA. Therefore, in this final rule at 7 CFR 273.11(o), we are deleting our proposed definition of cooperation and replacing it with an abbreviated version which is based on section 822 of PRWORA and section 454(29) of the Social Security Act. We provide that the individual must cooperate with the State Child Support Agency in establishing paternity, and in establishing, modifying, or enforcing a support order with respect to the child in accordance with section 454(29) of the Social Security Act.

A few commenters suggested that, if an individual is already participating in TANF, Medicaid or the State Child Support program, the individual would already be deemed as cooperating for food stamp purposes. We believe this would simplify the administration of this provision. Therefore, we are modifying 7 CFR 273.11(o) to provide accordingly.

Several commenters suggested that since this is an optional provision we allow the State agencies to apply this provision selectively, e.g. to parents but not other individuals. One commenter suggested we give State agencies the option to limit this provision to those groups of people who the State agency decides that child support cooperation requirements are appropriate. One commenter suggested that we define "other individual" as a "legally responsible adult." We believe that the State agency at a minimum should apply this provision to natural and adoptive parents. However, we agree that the State agency should have some latitude to apply this provision to those other individuals that it deems appropriate, whether or not those individuals are the "legally responsible adults." Therefore, we are modifying the regulations at 7 CFR 273.11(o) to provide that if the State agency chooses to implement this provision it must apply it to all natural and adoptive parents and, at State option, it may apply it to other individuals. This information must be included in the State Plan of Operation as required at 7 CFR 272.2

We proposed to adopt DHHS' provisions concerning good cause exceptions. We listed the circumstances under which cooperation may be against the best interests of the child and would not be required. Again, we received a multitude of comments on this subject. The commenters either suggested we be less prescriptive and let the State agencies define good cause, or more prescriptive, but adjust the wording to encompass more situations which would be considered good cause. One commenter said we should allow the State agencies to recognize additional situations in which cooperation would be contrary to the best interests of the child. A few commenters suggested we have a less onerous burden of good cause. For example, the emotional or physical harm should not have to be to the extent that it "reduces [the individual's] ability to care for the child adequately" or that the "emotional impairment * * * substantially affects the individual's functioning." Several commenters suggested that we go beyond that which is in the best interests of the child and take into consideration the best interests of the parent or other individual. Several commenters suggested that our good cause exemptions related to domestic violence are too narrowly drawn and would require the food stamp agencies to make impossible and dangerous judgments. Several commenters suggested we allow a good cause exemption based on the TANF exemption for victims of domestic violence. Finally, several commenters suggested that the inability to cooperate be considered good cause.

We have been advised by the DHHS that the definition and determination of good cause is left up to either the State Child Support Agency or the State TANF program. Based on the comments and our consultation with DHHS and in the interest of conforming to current TANF and Medicaid regulations, simplifying the administration of this provision, and reducing the potential for errors, we have decided to modify our regulations. Therefore, at 7 CFR 273.11(o) in this final rule, we provide that if a State agency chooses to implement this provision, it must, adopt the good cause criteria that its State TANF program or its State Child Support Agency uses, whichever agency defines good cause for non-cooperation. In addition, if those good cause provisions do not take into consideration the threat of domestic violence, State agencies must consider if cooperating with the State Child Support Agency would make it more difficult for individuals to escape domestic violence or unfairly penalize such individuals who are or have been victimized by such violence, or individuals who are at risk of further domestic violence. For purposes of this provision, the term "domestic violence" means the individual or child would be subject to physical acts that result in, or are threatened to result in, physical injury to the individual; sexual abuse; sexual activity involving a dependent child; being forced as the caretaker relative of a dependent child to engage in nonconsensual sexual acts or activities; threats of, or attempts at physical or sexual abuse; mental abuse; or neglect or deprivation of medical care.

Finally, we provide that the State agency may define additional good cause criteria in consultation with the State Child Support Enforcement Agency or the State TANF Program, whichever agency is appropriate, and identify the additional criteria in the State plan.

One commenter noted that good cause should address situations where a parent or caretaker may be willing but unable to pursue child support enforcement. For example, the parent or caretaker may lack information about the absent parent. Some custodial parents and other caretakers may simply not know the identity of a child's father. We agree with this commenter that there are instances where the individual cannot provide any information on the father. However, we believe this situation will be covered by the State Child Support or TANF agency's definition of good cause. As indicated above, the State agency must adopt the same criteria as the State Child Support or TANF agency uses for good cause. In the event that this situation is not covered by the State Child Support or TANF agency's definition of good cause, we urge State agencies to adopt the criteria that the inability to provide information about the father is considered good cause.

One commenter suggested that if the State TANF and Medicaid programs have already granted good cause then we should also do so for food stamp purposes. We agree with the commenter, especially since we are adopting the good cause provisions from the State TANF program or the State Child Support Agency. Therefore, we are modifying the regulations at 7 CFR 273.11(p), to provide that if the State TANF program or State Child Support Agency has already established that the individual has good cause for non-cooperation, then the State agency must accept that for food stamp purposes. If the State TANF program or the State Child Support Agency determines that the individual does not have good cause for refusing to cooperate, then the State agency must determine if the individual meets the good cause criteria for domestic violence or for any additional criteria the State agency has identified.

We proposed that the individual provide evidence to corroborate the claim of good cause. We received several comments regarding our proposal. All of the comments opposed our requirements as being too burdensome. A few commenters suggested that individuals be permitted to substantiate claims with a sworn statement. One commenter suggested we broaden our definition of good cause so those individuals should not have to offer additional proof that these circumstances would make the pursuit of child support against the best interests of the child.

Again we consulted with our counterparts at DHHS. Based on the comments and our discussions with DHHS, we have decided that the State agency must adopt the corroboration standards mandated by either the State Child Support Agency or the State TANF program, whichever agency in the State defines and determines good cause. We believe this will simplify administration of this provision and provide consistency with TANF, Medicaid and the State Child Support Agency. Therefore, we provide accordingly in this final rule at 7 CFR 273.11(o).

We proposed that if the State agency determines that the custodial parent has not cooperated without good cause, then that individual (and not the entire household) would be ineligible to participate in the Program. We received no comments on this provision and are adopting it as final at 7 CFR 273.11(o).

We proposed that the disqualification period be over as soon as it is determined that the individual is cooperating with the State Child Support Agency. An integral aspect of this requirement is that the State agency must have procedures in place to re-qualify an individual once cooperation has been established. We solicited comments on systems already in use. We received none. Therefore, we are adopting these provisions as final.

We proposed that the State agency count all of the disqualified individual's resources, but to give State agencies the option to count all or all but a pro rata share of the individual's income as available to the household. The majority of the comments we received on these provisions opposed allowing the State agencies the option to count all of the income as available to the household. They believe this is too punitive and is not in the best interest of the children. We agree. Therefore, in this final rulemaking we are amending 7 CFR 273.11(c) and 7 CFR 273.11(o) to provide that all but a pro rata share of the ineligible member's income is counted as available to the household.

Section 6(l) of the Act prohibits the payment of a fee or other cost for services provided under a Part D of Title IV, the Child Support Enforcement Program. Subsequently, section 454(6) of the Social Security Act (42 U.S.C. 654(6)) has been amended to prohibit the State Child Support Agency from charging application fees for furnishing such services if cooperation is required from the Food Stamp Program. All the comments we received on this provision were supportive. We are adopting this provision as final.

We proposed that if a State agency exercises its option to permit the disqualification of an individual who refuses to cooperate without good cause, the option must be included in its State Plan of Operation. We received no comments on this provision. We are adopting this provision as final at 7 CFR 272.2.

We proposed that prior to making a final determination of good cause for refusing to cooperate, the State agency would afford the State Child Support Agency the opportunity to review and comment on the findings and the basis of the proposed determination and consider any recommendation from the State Child Support Agency. We received no comments on this proposal. However, we have since been advised that it may not be the State Child Support Agency that defines and determines good cause. It could be the TANF agency. Accordingly, we are modifying the language at 7 CFR 273.11(o) to specify that the State agency will afford the State Child Support Agency or the agency which administers the program funded under Part A of the Social Security Act the opportunity to review and comment on the findings.

We proposed that the State agency will not deny, delay or discontinue assistance pending a determination of good cause for refusal to cooperate if the applicant or recipient has complied with the requirements to furnish corroborative evidence and information. We received several comments suggesting that we clarify that the 30-day processing standards still apply pending this determination. We agree with these comments and are, therefore, modifying this provision accordingly at 7 CFR 273.11(p).

Noncustodial Parent—7 CFR 273.11(p)

Section 822 of PRWORA also amended section 6 of the Act by adding subsection (m) to give State agencies the option to disqualify the non-custodial parent who refuses to cooperate with the State Child Support Agency in establishing the paternity of a child and providing support for the child.

We proposed to adopt DHHS' definition of cooperation. We also proposed that the State agency make the determination as to whether or not the individual is refusing to cooperate with the State Child Support Agency. We proposed that refusal to cooperate occurs if: (1) The non-custodial parent refuses to appear for an interview; (2) refuses to furnish requested documentation; (3) refuses DNA testing; or (4) fails to make payments to the State Child Support Agency.

One commenter argued that pursuant to section 454(29)(A) of the Social Security Act (42 U.S.C. 654(29)(A)), as amended by section 5548 of Pub. L. 105–33, the State Child Support Agency "shall make the determination (and redetermination at appropriate intervals) as to whether an individual who has applied or is receiving assistance under * * * the Food Stamp Program is cooperating in good faith * * *." This same commenter pointed out that this provision conflicts with section 6(l)(2) of the Food Stamp Act, 7 U.S.C. 2015(l)(2), which was added to the Act by section 822 of PRWORA which provides that the Secretary of Agriculture must, in consultation with the Secretary of Health and Human Services, " * * * develop guidelines on what constitutes a refusal to cooperate * * * and that the " * * * State agency shall develop procedures, using guidelines developed under (the preceding provision), for determining whether an individual is refusing to cooperate." Based on these two statutory provisions, this same commenter suggested that the State Child Support Agency make the determination of non-cooperation and that the food stamp State agency make the determination as to whether or not the non-cooperation constitutes a refusal to cooperate. We agree that this clear delineation of responsibilities better serves the program. Therefore, we

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are modifying the regulations at 7 CFR 273.11(p) to provide that if the State agency implements this option, it must refer non-custodial parents of a child under the age of 18 to the State Child Support Agency. If the State Child Support Agency determines that the individual is not cooperating in good faith, it must notify the State agency of this determination and the basis of its determination. The State agency must then determine whether this non-cooperation constitutes a refusal to cooperate.

Based on this modification, we have determined that there is no need to define in the regulations what constitutes cooperation, only what constitutes refusal. We received several comments suggesting we clarify that the non-custodial parent can only be disqualified for refusing to cooperate, as opposed to failing or being unable to cooperate. Therefore, we have decided to modify the regulations at 7 CFR 273.11(p) by deleting the definition of cooperation, and replacing it with a definition of refusal. The State agency must determine that an individual's non-cooperation with the State Child Support Agency is a refusal to cooperate if the individual demonstrates an unwillingness to cooperate as opposed to an inability to cooperate.

We proposed that the individual and not the entire household would be ineligible to participate in the Program. The comments we received were supportive. We adopting it as final at 7 CFR 273.11(p).

We proposed that the State agency count all of the disqualified individual's resources as available to the household, but that it may choose to count all or all but a pro rata share of the ineligible member's income as available to the household. The majority of the comments we received opposed this proposal as being potentially too punitive to the non-custodial parent's household. They suggested that we require the State agency to count all but a pro rata share of the income as available to the household. We agree with these comments. We are modifying the regulations at 7 CFR 273.11(p) and 7 CFR 273.11(c)(2) accordingly.

We proposed that the disqualification period be over as soon as it is determined that the individual is cooperating with the State Child Support Agency. The State agency must have procedures in place to re-qualify an individual once cooperation has been established. We solicited comments on those systems already in use. We received none. We are adopting this provision as final at 7 CFR 273.11(p).

Section 6(l) of the Act prohibits the payment of a fee or other cost for services provided under a Part D, Title IV, Child Support Enforcement Program. In addition, section 654(6) of the Social Security Act prohibits the State Child Support Agency from charging application fees for furnishing such services if cooperation is required from the Food Stamp Program. We proposed to prohibit the charging of such fees or costs. The comments we received on this provision were supportive. We are adopting this provision as final at 7 CFR 273.11(p)

Section 6 of the Act, as amended by section 822 of PRWORA also requires the State agency to provide safeguards to restrict the use of information collected by the State agency to purposes for which the information is collected. We proposed the State agency should have flexibility to establish the specific safeguards. We received no comments on this provision. Accordingly, we are adopting it as final at 7 CFR 273.11(p).

We proposed that if a State agency opts to disqualify the non-custodial parent who refuses to cooperate, it include this policy in its State Plan of Operation. In addition, we proposed to add a new section 7 CFR 272.2(d)(1)(xiv) to require that the States that elect to implement this provision include these safeguards in their Plan of Operation. We received no comments on these proposals. We are adopting them as final at 273.2(d)(xiii).

Disqualification for Child Support Arrears—7 CFR 273.11(q)

Section 823 of PRWORA amended section 6 of the Act by adding subsection (n) (7 U.S.C. 2015(n)) to give State agencies the option to disqualify a member of any household during any month that the individual is delinquent in any payment due under a court order for the support of the individual's child. The provision also specifies that if a court is allowing the individual to delay payment or the individual is complying with a payment plan approved by a court or the State Child Support Agency, the individual will not be disqualified. We proposed that the disqualification apply to the offending individual and not the entire household.

We proposed that for any month for which it later discovers that the individual was delinquent and should have been disqualified, the State agency must establish a claim against the household. We received several comments on this provision, both for and against this procedure. Several commenters opposed the provision in general because it was too punitive and further hampered individuals' ability to become self-sufficient and productive. Several commenters opposed it because it was too administratively burdensome. Several commenters suggest that the State agency be allowed to disqualify the individual the month after the month it learns that the individual has been delinquent in child support payments. Others suggested that State agencies be allowed to establish a grace period of several months. For example, if an individual has not paid child support after four months, the individual should be disqualified until the individual starts to comply. One commenter said that since this is not a reportable change, we have no authority to set up a claim. Several commenters supported our proposal as the only way to remain faithful to the statute. The statute provides that a State agency may disqualify an individual "* * * during any month the individual is delinquent in any payment * * *," and, therefore, we have no option but to set up a claim. Our analysis has determined that we have no discretion to permit the State agencies to implement the provision any other way than the way we proposed. The law is very clear that the individual is to be disqualified the month that he is delinquent. Therefore, we are adopting the provision as proposed at 7 CFR 273.11(q).

A few commenters suggested that we provide a good cause exception for this provision. One commenter suggested that this provision should only apply when an individual refuses to pay as opposed to being unable to pay. The Statute does provide exceptions to this provision: (1) If the court is allowing the individual to delay payment, or (2) the individual is complying with a payment plan approved by a court or the State Child Support Agency. However, since this is a State agency option, we have decided to give State agencies the option to identify additional good cause exemptions. We are adopting the provision at 7 CFR 273.11(q) accordingly.

One commenter suggested that this provision only apply to non-custodial parents. We believe that there are situations in which a custodial parent is still obligated to pay child support. For example, the parents are separated, and the non-custodial parent is required to pay child support. During the separation, the non-custodial parent does not comply with the support order for one reason or another. Even if the parents reunite, the former non-custodial parent is still obligated to pay for the period of time the parents were separated. However, we also recognize that some State agencies might view this as too punitive. Therefore, since this is a State agency option, we have decided to give State agencies the option to apply this provision to custodial or non-custodial parents.

We proposed that the State agency consider all of the disqualified individuals' resources, and at State agency option, either all or all but a pro rata share of the income as available to the household. All of the comments we received opposed this proposal as being too punitive to the household. Many of the commenters argued that if the State agency chose to count all of the income, the children in the household would suffer. We agree with these comments. Therefore, in this final rule at 7 CFR 237.11(q) and 7 CFR 273.11(c)(2) we are providing that if a State chooses this option, it must count all of the individuals' resources and all but a pro rata share of the income as available to the household.

We proposed that the State agency must disqualify the individual and not the whole household. All the comments we received on this provision were supportive. We are adopting the provision as proposed at 7 CFR 273.11(q).

7 CFR 273.16—Disqualification for Intentional Program Violation

The current regulations at 7 CFR 273.16 outline the procedures involved with Intentional Program Violations (IPVs) and IPV-related disqualifications. The proposed rule contained extensive revisions to this section of the regulations. These changes included the increased and additional IPV-related disqualification penalties brought about by sections 813, 814 and 820 of PRWORA. In addition, the proposed rule contained a change necessitated by a judicial decision on the imposition of disqualification periods. Clarification was also being provided in the proposed rule for a number of issues, including the definition of an IPV. Lastly, as part of an effort to streamline the regulatory requirements and to increase State agency flexibility in the area, the Department proposed to remove prescriptive language and some requirements in many discretionary areas concerning IPVs and the IPV disqualification process.

IPV Procedures and Rights of Individuals

With respect to this streamlining effort, the Department received numerous comments expressing concern about removing much of this prescriptive language. By doing so, according to the commenters, we are also omitting a number of protections necessary for ensuring fairness and due process for individuals facing the possibility of disqualification or criminal prosecution. The Department has found many of these arguments compelling. Although the Department believes the original goals of streamlining and increased State flexibility were worthy of the effort and may be revisited at some later date, we do not think such changes should come at the possible expense of the elimination of individuals' rights. Therefore, unless specifically addressed below, we are restoring in this final rule the language of the existing regulations as it pertained to discretionary areas concerning IPVs and the IPV disqualification process. Included in the restored language are such provisions as the Administrative Disqualification Hearing (ADH) and court referral process, notice requirements, waiver and consent forms, ADH decision format, and local level hearings. Finally, one commenter expressed concern that a significant number of innocent people, lacking adequate representation, are intimidated into signing ADH waivers. The commenter suggests that individuals may be threatened with criminal prosecution though the evidence against the individual is far from convincing. The Department in this preamble would like to clarify its position with respect to the use of false and/or misleading statements to obtain ADH waivers. While the Department believes strongly that those found guilty of IPVs should be removed from participation in the FSP, we would emphasize that the purpose of the FSP is to provide assistance to those in need. The use of investigative techniques that may lead to the disqualification of innocent participants is inconsistent with the intended purpose of the FSP. To this purpose, the current regulations provide for certain safeguards against intimidation, including a two-party review to ensure that evidence against an individual is sufficiently clear to merit an ADH before an ADH waiver is offered. The ADH waiver should not be used as a shortcut to the investigative process, but should only be offered after the investigation has yielded evidence adequate to bring before an ADH hearing official. Though the Department believes that no modification of the current regulations is necessary, we would emphasize our desire that these safeguards be observed.

Administrative Versus Criminal Pursuit—7 CFR 273.16(a)(1) and (e)(3)(iii)(H)

The Department received two comments in support of and four in opposition to our clarification that both an administrative disqualification hearing (ADH) and a criminal prosecution may be initiated simultaneously for the same offense. One of the opposing comments suggested that permitting simultaneous proceedings placed an enormous burden on individuals or their legal representatives to provide adequate representation in two separate proceedings. As a matter of fairness and to ensure that each individual has an appropriate opportunity to provide an adequate defense, the Department agrees with this argument and is clarifying in this final rule that both an ADH and a civil or criminal proceeding may be initiated by the State but not simultaneously. Further, the initiation of a civil or criminal proceeding is permitted regardless of the outcome of the ADH. This is not a change from our current policy as reflected in § 273.16(a) of this final rule.

Definition of an IPV—7 CFR 273.16(c)

The Department proposed updating this definition to provide a clarification on trafficking as well as to account for the improper acquisition and use of electronic benefit transfer (EBT) cards. One commenter suggested that we make the definition more consistent with section 6(b)(1) of the Act (7 U.S.C. 2035(b)(1)) by replacing "*relating to* the use, presentation" as it appears in the current regulations with "*for the purpose of* using, presenting" as it appears in the Act. We agree that this wording better reflects the appropriate intent and is reflected in Section 273.16(c) in this final rule.

PRWORA Section 813—Doubled Penalties for Violating FSP Rules

The proposed rule contained the provision in section 813 of PRWORA that increases the penalties twofold for the non-permanent offenses. Specifically, unless the offense falls under a specific category requiring a more stringent penalty, section 6(b)(1) of the Act (7 U.S.C. 2015(b)(1)) now requires that an individual be disqualified for one year for a first finding of IPV, and for two years for a second finding of IPV. The penalty for a third finding of IPV, permanent disqualification, remains the same. For convictions involving the trading of controlled substances for coupons, section 813 of PRWORA requires that an individual be disqualified for two years for the first offense.

The comments received by the Department concerning the doubling of the current disqualification penalties expressed general support. Since the

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Department is retaining the structure of the current rule, these changes will be reflected in § 273.16(b) of the final rule.

PRWORA Section 814—Disqualification of Individuals Convicted of Trafficking $500 or More

The proposed rule included the provision in section 814 of PRWORA that permanently disqualifies individuals from FSP participation if they are convicted of a trafficking offense of $500 or more.

The statutory language provides for this penalty to take effect where there is an actual *conviction*. The proposed rule extended the applicability of this penalty to include signed disqualification consent agreements in connection with deferred adjudications. The Department received two comments objecting to this extension of penalties. Specifically, the commenters believed that since there is no actual determination of guilt, there is no actual conviction as required by section 6(b) of the amended Act. This is a valid point. Therefore, the final rule adds language to permanently disqualify individuals from FSP participation if they are convicted of a trafficking offense of $500 or more. The proposed language specifying that this penalty also applies to deferred adjudications does not appear in the final rule.

This change does not affect our current long-standing policy in 7 CFR 273.16(b)(9) that allows the penalties associated with trading coupons for firearms, ammunition, explosives or controlled substances to be imposed using agreements obtained in deferred adjudications. The basis for the difference between this policy and the new trafficking penalty is the different respective requirements in the Act. As discussed above, Section 6(b)(1)(iii)(IV) of the Act (7 U.S.C. 2025 (b)(1)(iii)(IV)) requires a *conviction* for the new PRWORA trafficking penalty. Conversely, the existing firearms, ammunition, explosives and controlled substances penalties requires only a court *finding* (rather than a conviction) (7 U.S.C. 2025 (b)(1)). Therefore, the current policy regarding these long-standing penalties remain unchanged.

A number of comments were received regarding the $500 trafficking benchmark associated with this penalty. The preamble to the proposed rule (64 FR 70933) specified that, if the cumulative amount of the related infractions making up the IPV is greater than $500, then the individual would be subject to the increased trafficking penalty. Three of the comments were from State agencies expressing that it would be difficult to track dollar amounts of individual convictions. This is not our intention. Aggregating involves the accumulation of dollar amounts for separate but related trafficking *offenses* leading up to the prosecution of a *single IPV*. All evidence necessary for the prosecution of a case, regardless of the number of offenses, should include the dollar amounts for each. It should then be relatively simple to aggregate these amounts to determine whether the total reaches the $500 benchmark for permanent disqualification. Comparing or aggregating individual conviction amounts are not necessary (or even appropriate) in these instances.

The Department also received one comment indicating that the aggregating of the dollar amounts of individual trafficking offenses to reach the threshold of $500 is unfair to affected individuals and households. The commenter suggested that Congress intended to severely punish the more serious offenders while allowing the lesser offenders to learn from their mistakes. Therefore, according to the commenter, individual trafficking incidents should not be combined. While the Department does not disagree with the suggested intent, we believe that the trafficking of $500 or more, whether in an single transaction or in aggregate, is a serious offense and is deserving of the more serious penalty. Further, permanent disqualification is applicable, as clarified above, in such cases only when referred to the court and a conviction is obtained. The final determination will thus belong to the court. The Department would also like to point out that those individuals that receive less than $500 per month in food stamp benefits would have to participate in multiple intentional violations to reach the $500 benchmark for permanent disqualification. Without aggregating, these same individuals, though they be chronic serious offenders, would never be subject to the penalty intended by Congress. Conversely, without aggregating, the Department would be in the position of unfairly holding only those that receive $500 or more per month in food stamp benefits potentially liable for the more severe penalty. However, even this latter group could avoid ever receiving a permanent disqualification by intentionally limiting trafficking transactions to $499 or less. The Department does not believe that this is what Congress intended and the requirement concerning aggregating will be retained in the final rule.

PRWORA Section 820—Ten Year Disqualification for Multiple Participation

The proposed rule included the provision in section 820 of PRWORA which amended section 6 of the Act by adding paragraph (j), 7 U.S.C. 2015 (j), to provided for a ten year disqualification for making a fraudulent statement or misrepresentation in order to receive multiple benefits simultaneously duplicate participation.

Two of the commenters expressed general support for this provision and for the criteria used in determining duplicate participation. Two additional commenters suggested that there must be a dollar loss before duplicate participation is considered to have occurred. The Department disagrees. The amendment made by section 120 applies by its terms to fraudulent statements or representations with respect to identity or place of residence in order to receive multiple benefits simultaneously. It is not specified that such statements or representations must be successful in order for the 10-year disqualification to apply. As long as there is sufficient evidence that the individual made such statements or representations, it is not necessary to establish a dollar loss. Unsuccessful attempts to commit fraud through duplicate participation should be dealt with in the same manner as successful attempts. To do otherwise would undermine the integrity of the Program. The final rule at § 273.16(b)(5) remains unchanged.

Finally, one respondent asked for clarification on whether continuing to receive benefits in one State after moving to a second constitutes duplicate participation. If so, which State should pursue the IPV and establish the claim: the State the individual moved from or the State the individual moved to. In such cases, the State where the individual resides should initiate the IPV investigation and establish the claim.

Applicability of PRWORA Disqualification Penalties

The proposed rule discussed whether these new PRWORA IPV disqualification penalties should be applied to all ADHs, court hearings, and similar proceedings held subsequent to enactment of the law (regardless of when the actual offense occurred) or only to those cases in which the actual offense occurred subsequent to State agency implementation of the new legislation. PRWORA set the date of enactment, August 22, 1996, as the effective date for these provisions of the law. As a result, State agencies were permitted discretion as to whether the new or increased penalties should apply to offenses that occurred prior to State agency implementation of the new legislation. It was, therefore, impractical in the proposed rule for the Department to introduce standards on an issue for which action has already been taken.

The Department received two comments stating that offenses occurring prior to the date of enactment (August 22, 1996) should not trigger the new penalties. While we understand the commenters' position, the Department still believes that retroactively imposing new standards for an action that has already been taken would be an inappropriate burden to place on States. The final rule remains unchanged.

Another respondent asked the Department to specify which penalties apply when the offense occurs prior to August 22, 1996. Again, since State agencies have already used their discretion in implementing this provision, this will remain a State option and will not be regulated by the Department. We would add, however, that we expect that the penalties a State has decided to use in this circumstance, will be applied in all such cases.

Two respondents suggested that a second offense for the trafficking of a controlled substance that occurs after August 22, 1996 (the date of enactment of PRWORA) when the first offense occurred prior to that date should not trigger a permanent disqualification. While PRWORA required the doubling of the first offense for the trafficking of a controlled substance, the permanent disqualification for a second such offense existed prior to PRWORA. This provision was part of Section 13942 of the Mickey Leland Childhood Hunger Relief Act (Pub. L. 103–66). The Department already implemented this non-discretionary provision in regulations published on August 22, 1995 (60 FR 43513) and this provision is not changed in this final rule.

Imposition of Disqualification Penalties—7 CFR 273.16(a), (e), (f), (g) and (h)

In response to a lawsuit (*Garcia v. Concannon and Espy*, 67 F. 3d 256 (1995)), the Department proposed to require State agencies to impose a disqualification period for all IPV-related disqualifications as soon as administratively possible, regardless of eligibility. We received four comments supporting this change of policy. One commenter, however, believed that this change was too burdensome to implement since those that are no longer on the Program now need to have their disqualification periods tracked. We disagree. This policy adds no new requirements for State agencies, it actually eliminates one. State agencies have always been required to impose disqualifications immediately when the individual being disqualified remained otherwise eligible to participate in the Program. That will not change with this policy except that State agencies will no longer need to track pending disqualifications until the individual reapplies and is found eligible for benefits. The final rule retains the proposed provision. (See § 273.16(b)(13).)

ADH Timeframes

The current regulations at 7 CFR 273.16(e)(2) require that the State agency reach a decision and inform the individual within 90 days of the date the hearing is scheduled. The proposed rule required that the individual be notified within 180 days after the date of discovery of the suspected violation or within 60 days of the date of the hearing, whichever is sooner.

The Department received 12 comments opposing at least one aspect of this change. Most commenters thought 180 days was too short a period to properly develop evidence, build a case, hold the hearing and arrive at a decision. The commenters suggested retaining the current requirement of 90 days from the date of the initial notification to the individual. Given the general disagreement with the Department's proposal and support for retention of the current standard, we have decided to retain the existing 90-day standard as required in the current rule.

Local-Level ADHs

The proposed rule made clear our long-standing policy that either the affected individual or local agency must be given the opportunity to seek some form of an appellate review of a local-level decision. The Department received one comment disagreeing with this position. The commenter believed that State agencies should not be allowed to hold a second hearing on the same charge when the individual has already been "cleared." We disagree. The Department believes that there are instances in which a State appeal would be appropriate. We also believe that State agencies will not abuse this authority and only reserve these appeals for those instances in which policy is clearly misapplied. The current language in the existing regulations is retained without change.

Reporting Requirements—7 CFR 273.16(i)

The Department received one comment seeking clarification whether the Department's reporting system for disqualifications, DRS, would accept the new IPV disqualification penalties. DRS will currently accept a disqualification penalty of any length. The system does contain edits that alert the user when a non-standard penalty has been submitted, but this in no way prevents the system from accepting the disqualification record. The penalty for duplicate participation and the more severe penalties for trafficking will also trigger an alert. FNS is currently exploring ways to avoid this latter circumstance. State agencies should contact their FNS regional DRS Coordinator if they need further assistance.

7 CFR 273.24—Time Limit for Able-Bodied Adults Without Dependents (ABAWDs)

Section 824 of PRWORA amended section 6 of the Act by adding a new subsection (o) 7 U.S.C. 2015(o) that limits the receipt of food stamps for certain able-bodied adults to three months in a three-year period unless the individual is working 20 hours per week or participating in a work program 20 hours per week, or is participating in a workfare program. Individuals can regain eligibility, and may receive an additional three months of food stamps while not working in certain circumstances. Amended section 6(o) includes some exceptions, and receiving food stamps while exempt does not count towards an individual's time limit. In recognition that it may be difficult for individuals to find work in depressed labor markets, the statute authorizes waivers for individuals in areas in which the unemployment rate is above ten percent, or where there is a lack of sufficient jobs.

We proposed to codify the time limit for ABAWDs at 7 CFR 273.25. However, on Friday, September 3, 1999, we published an interim final rule called The Food Stamp Provisions of the Balanced Budget Act of 1997. This rule implemented the changes to the Food Stamp Act brought about by the Balanced Budget Act of 1997, which included a provision allowing the State agencies to exempt from the time limit up to 15 percent of "covered individuals." This provision was codified at 7 CFR 273.24. Because these two provisions are related, we have decided to merge the two. Therefore in this final rule, we have modified 7 CFR

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273.24 to include the time limit for ABAWDs.

We proposed that for purposes of this provision, 20 hours a week equals 80 hours a month. The majority of the commenters supported this proposal. A few commenters suggested that weekly earnings which equal the minimum wage times 20 should be the equivalent of working 20 hours a week. The statute refers specifically to "working 20 hours a week." In addition, it provides for an exception if an individual is exempt under section 6(d)(2) of the Act. One of the exemptions under section 6(d)(2) of the Act is if an individual's weekly earnings equal 30 times the minimum wage. We believe if Congress intended for 20 times the minimum wage to count as meeting the work requirement it would have specified so in the Act and not have referenced the section 6(d)(2) exemption. Therefore, we are not adopting the commenters' suggestion.

We proposed that for purposes of this provision unpaid work under standards established by the State agency, and work for in-kind services count as work. The majority of the commenters supported this proposal. Only one commenter opposed the provision as not consistent with the goal of self-sufficiency. Several commenters suggested that unpaid work be classified as comparable workfare so it would include worker protections and hour limitations. One commenter elaborated further saying this suggestion is consistent with congressional intent that persons working for no compensation other than the opportunity to receive food stamps should not be required to work more hours than the minimum wage divided into those benefits. Also, limiting the hours any individual recipient must volunteer would allow non-profits to create slots for more recipients. While we agree that individuals working for no compensation should not have to work more than their food stamp allotment divided by the minimum wage, we do not have the discretion to *require* State agencies to create a comparable workfare program in accordance with § 273.7(m)(10). We do encourage all State agencies to create comparable workfare programs in order to restrict the number of hours an individual has to work in a volunteer position in order not to be subject to the time limit. However, in those situations where State agencies do not have enough workfare slots or have not created a comparable workfare program, we believe individuals should have the opportunity to fulfill the work requirement by volunteering 20 hours a week averaged monthly. We also received several comments supporting this proposal. Therefore, we are adopting the provision as written at 7 CFR 273.24.

We proposed that work include unpaid work under standards established by the State agency. Several commenters suggested that we clarify in the regulations that the State agency may only set standards for verification of work, but they may not set standards for the work itself. One commenter pointed out that we allow in-kind work to count without referencing state-set standards and that we should allow the same for unpaid work. This same commenter stressed that any individual who can demonstrate that the individual is doing 20 hours of unpaid work a week, averaged monthly, should be able to receive food stamps. While we agree, we also believe that the State agency should have some control over unpaid work. We believe it should be able to require whatever verification it wants to in order to verify unpaid work. Therefore, we are modifying the regulation to provide that work means unpaid work, verified under standards set by the State agency.

Several commenters queried how the State agencies would determine the hourly value of in-kind work. One commenter suggested the State agencies be responsible for determining the value of in-kind work. We would like to reiterate that the State agency has to verify with the employer the number of hours an individual works, no matter what currency that individual is being paid in—money, commodities, or housing. If an individual is receiving housing in exchange for being the superintendent of the apartment complex, but the individual only works at that position 10 hours a week, then that individual is not fulfilling the work requirement, unless the total of all types of work and participation in work programs meet the 20 hours per week requirement. We believe we do not have to clarify the regulations any further.

A few commenters suggested counting all work experience programs as workfare programs. We do not have the discretion to do this. Workfare and work experience programs are two distinct programs governed by different provisions in the Act. Workfare is governed by section 20 of the Act, 7 U.S.C. 2029. Work experience programs are components of the Employment and Training Program (E&T Program) governed by section 6(d)(4) of the Act, 7 U.S.C. 2015(d)(4). Section 824 of PRWORA references both separately. Section 824 added paragraph (o) to section 6 of the Act to provide that the individual must participate and comply with a work program (which encompasses an E&T Program) 20 hours a week, or a workfare program under Section 20 of the Act. It does not reference an hourly requirement in the workfare program since everyone's workfare obligation is different. Therefore, we are not adopting the commenters' suggestion.

We proposed that someone who has missed work for good cause as determined by the State agency will be considered to be satisfying the work requirement if the absence from work is temporary and the individual retains the job. The majority of the commenters supported this provision. A few opposed it as administratively time consuming and error prone and feared that it would not be uniformly applied. A few commenters suggested we include in the regulations a non-exhaustive list of what constitutes good cause. We believe the State agencies are in a better position to define good cause for purposes of this provision. However, we also believe that the good cause provision for ABAWDS fulfilling the work requirements should parallel the good cause provisions for work registration and E&T Program requirements. Therefore, we are modifying the regulations at 7 CFR 273.24 to provide that good cause shall include circumstances beyond the member's control, such as, but not limited to, illness, illness of another household member requiring the presence of the member, a household emergency, or the unavailability of transportation.

A few commenters suggested that we extend this provision to workfare and employment and training (E&T). As mentioned above, the regulations at 7 CFR 273.7(i) already provide a good cause clause for work registration and E&T. We believe that putting it in the regulations at 7 CFR 273.24 would be redundant. Therefore, we are not adopting the commenter's suggestion.

We discussed in the preamble to the proposed regulation the merits of our proposal that a qualifying work program need not be an FNS E&T Program under 7 CFR 273.7(f). Section 6(o) only requires that a qualifying work program not be a job search or job search training program and that it meet standards approved by the Governor of the State. We proposed that we would not review plans for these programs, but cautioned State agencies to scrutinize these programs carefully so that they are not later determined through the quality control process to not meet the requirements of the statute. We received several comments voicing concern that this implied our quality control reviewers would be reviewing the programs themselves to ensure that they meet standards set by the Governor. We want to clarify that as part of our oversight duties we may evaluate, through our management evaluation process, and not our quality control process, these programs to ensure that they meet the requirements of the statute.

We proposed that a qualifying work program may contain job search as a subsidiary component but that the job search activity must be less than half of the requirement. The majority of the commenters supported this proposal. One commenter opposed the proposal as being too restrictive because many E&T programs are made up of job search and job search training activities. One commenter suggested we modify the wording so the job search component be "not more than half," that way the program could be 50 percent work and 50 percent job search. Section 824 of PRWORA specifically provides that participation in an E&T Program, OTHER THAN a job search or job search training program, would satisfy the work requirement. We acknowledge that prior to PRWORA the bulk of food stamp E&T Programs consisted of job search. We also acknowledge that job search and job search training are valuable aspects of the these programs. However, in amending Section 6 of the Act, Congress specifically prohibited E&T job search activities as fulfilling the work requirement. We decided to allow job search as a subsidiary component, but do not believe we have the discretion to allow it as an equal or dominant component. Therefore, we are not adopting the commenters' suggestions.

We proposed that an individual could combine work and participation in a work program to meet the 20 hours per week requirement. The majority of the commenters supported this proposal. One commenter suggested that we clarify in the regulations that time spent off-site preparing for E & T activities count towards meeting the requirements. This is up to the State agency. If the State Agency recognizes such activities for E & T purposes then the individual is fulfilling the work requirement.

We proposed that the State agencies have the option of how to measure and track the 36-month period. They may use a "fixed" or "rolling" 36-month "clock." The majority of the commenters supported this proposal. A few commenters suggested that we allow State agencies to switch back and forth from fixed to rolling at any time. Several State agencies switched from a rolling period to a fixed period in December 1999, the end of the first 36-months. Several other State agencies switched once they had solved their potential "Y2K" computer problems. We believe that switching back and forth frequently could negatively affect recipients. However, we also believe State agencies are in the best position to determine how to measure and track this period of time and should have the flexibility to change tracking systems if they determine it is necessary. We urge State agencies to choose which method they are going to use by the implementation date of this rule. After such time, we provide in this final rule at 7 CFR 273.24 that once the implementation date of this rule has passed, State agencies must inform us if they switch tracking methods for this time period.

We proposed that partial months not count towards the 3-month time limit. The majority of the commenters supported this proposal. One commenter suggested that we clarify that prorated months will not count as opposed to not counting the month of application. Another commenter suggested we clarify the regulations by saying ". . . after the first of the month." According to the regulations at 7 CFR 237.10, initial months' benefits are prorated from the date of application. This implies that, unless an individual applies on the first day of the issuance cycle, his benefits are prorated and are in effect for only part of the month, not the full month. While we believe our proposal that a countable month is one in which an individual receives a full month's benefit is clear, we will modify it to say that a countable month is one in which an individual receives a full month's benefit, and not benefits that are prorated in accordance to 7 CFR 273.10(a)(1)(ii).

We proposed that State agencies may opt to consider benefits erroneously received as having been received until they are repaid in full. Several of the commenters opposed the option of tracking benefits erroneously received as too complex. One commenter suggested that when determining the amount a client has to pay back on an overissuance, State agencies can exclude a month that was paid in error if that month was treated as a countable month for ABAWD purposes. A few commenters argued that benefits should count no matter what if they have been posted to an EBT account since the quality control system considers a case active and benefits received under this situation. One commenter suggested that State agencies be allowed to consider benefits to have been received unless or until it files a claim to recover the overissuance. The intent of this proposal was to give State agencies different options on how to treat benefits that are received in error. We believe that if an ABAWD receives benefits erroneously and then pays them back, that month should not be considered a countable month. Therefore, we are modifying the regulation to provide that State agencies must count benefits erroneously received as having been received for purposes of this provision, until the individual repays them in full.

We proposed that unreported work would "erase" a countable month. Only one commenter supported this proposal. The majority of the comments we received opposed it. They said it was complex, administratively burdensome and not consistent with income reporting requirements and regulations governing IPVs. One commenter said that it rewards a recipient who did not comply with the program requirement to report income. Another commenter argued that current rules state a household's benefit cannot be restored if the household fails to report the information and he questions why we should have different standards for ABAWDs. Another commenter said that as reinforcement to the reporting requirements the countable months should not be adjusted in this situation.

In light of these comments, we believe State agencies are in the best position to determine whether or not they should count an unreported job as "work" for purposes of this provision. We believe that if a State agency erases a countable month if it later determines the individual was in fact working in an unreported job, it will have acted within the law. However, we also realize from the comments that some State agencies would choose not to do this. Therefore, we are modifying the provision and giving State agencies the option to count unreported work as "work" for this provision.

We proposed at 7 CFR 273.2(f)(1)(xiv)(A) that State agencies must verify work hours for individuals subject to the time limit. Several commenters opposed mandating verification of work hours as overly prescriptive. One commenter suggested that the State agency only be required to verify that information if it is questionable. We understand that State agencies may see this requirement as burdensome. However, we believe it is necessary in order to ensure the proper implementation of a basic eligibility factor. Therefore, we are retaining this proposal as written.

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We proposed at 7 CFR 273.12 that individuals be required to report if their work hours fell below 20 hours a week, averaged monthly. The majority of the commenters opposed this provision. They said it was complicated, burdensome, not family friendly, and in contrast to reporting simplification measures of the President's July 1999 Initiative. One commenter suggested that individuals be required to report if their work hours fell below 80 hours a month. We believe that in order to be faithful to the law, we must require individuals subject to the time limit to report if their hours fall below 20 hours a week averaged monthly, or as defined earlier, 80 hours a month. However, we also recognize that State agencies have different kinds of reporting systems for different types of households. We do not want to prescribe the type of reporting system a State agency must assign a potential ABAWD. However, we want to emphasize that State agencies are required to adhere to the statutory requirement of time-limited benefits for individuals who are not fulfilling the work requirement. Therefore, we are modifying the regulations to provide that individuals are required to report when their number of hours worked fall below 20 hours a week, averaged monthly (80 hours a month). Regardless of the type of reporting system the State agency assigns to potential ABAWDs, the State agency must adhere to the statutory requirements of time-limited benefits for individuals who are not fulfilling the work requirement.

We proposed at 7 CFR 273.2(f)(8) that the State agency must verify the countable months an individual has used in another State if there is an indication that the individual participated in another State. We also proposed that the State agency may accept the other State's assertion as to the number of countable months the individual has used in the other State. The majority of the comments we received opposed this provision. Commenters argued that this proposal is complex, especially since State agencies have different tracking systems for the 36-month clock. A few commenters argued that this would delay application processing. Several commenters said that until a national database exists, they should not be required to verify this information. Some commenters suggested State agencies only verify this information if questionable. Other commenters indicated that they should not rely on other States' assertions as to the number of countable months since in fair hearings and IPV challenges, State agencies must obtain copies of all relevant supportive materials. To be faithful to the statute, we believe we must require State agencies to verify the number of countable months an individual has participated in another State where there is an indication that the individual has participated in another State. Because commenters have expressed concern that this may delay the application, we are reminding State agencies at 7 CFR 273.2(f) that the normal processing standards of 7 CFR 273.2(g) apply. In addition, and in an attempt to simplify and hasten this verification process, we have decided to retain in the regulations the provision that the State may accept another State's assertion as to the number of countable months an individual has used in another State. The other State's assertion will be acceptable for quality control review purposes.

We proposed that all of the resources and all but a pro rata share of the income of the ineligible ABAWD would be counted as available to the household. We received wide variety of comments. Several commenters argued that this proposal was too harsh, especially in light of the fact the ineligible ABAWD would not have much money or resources anyway. They suggested that none of the income and none of the resources be considered as available to the household. Other commenters said this was too lenient, and that the State agency should count all of the income and resources as available to the household. Other commenters suggested that this should be a State agency option. Since this is a mandatory provision, we do not believe we may give the State agency an option as to how to treat the income and resources of the ineligible ABAWD, especially since we are now mandating how the State agency treat it for individuals ineligible under optional provisions, such as comparable disqualification, cooperation with child support agencies, and disqualification for child support arrears. In addition, we do not believe we should be punitive and require the State agencies to count all of the income and resources of the individual since he has failed to meet his responsibilities. Finally, we do not believe we should require the State agency to ignore the income and resources of these individuals, given that they have not "complied" with a food stamp eligibility requirement. Therefore, we have decided to retain the language as written at 7 CFR 273.24 and 7 CFR 273.(11)(c)(2) and provide that the State agency must count all of the resources and all but a pro rata share of the income as available to the household. We believe this is the most equitable treatment.

Exemptions

We proposed in accordance with the section 6(o)(3)(A) of the Act, that an individual is exempt from this requirement if he is under 18 or older than 50 years of age. A few commenters suggested we clarify that an individual becomes exempt on his or her 50th birthday, in accordance with current policy. We agree with this comment. Therefore we are clarifying in the regulations that an individual is exempt if he is under 18 or 50 years or older.

We proposed that an individual is medically certified as physically or mentally unfit for employment if he provides a statement from a physician or a licensed or certified psychologist that he is physically or mentally unfit for employment. Several commenters supported our proposal of not requiring individuals to meet a more stringent definition of "disability." However, the majority of the commenters suggested that we let the eligibility worker certify the individual as physically or mentally unfit if the unfitness is obvious. A few commenters argued that it is too difficult and expensive for individuals to get a statement from a physician or a licensed or certified psychologist and that we allow a statement from a nurse, a nurse practitioner, or a designated staff member of the doctor's office to suffice. Several commenters suggested that we do away with this provision and rely solely on the regulations at 7 CFR 273.7(b). As explained in the preamble, we incorporated the "unfit for employment" exemption from 7 CFR 273.7(b) into the ABAWD provision except, in accordance with the statute, we required that for purposes of this provision, the medical certification be mandatory in all cases. However, our comment analysis has led us to believe that that this level of verification is not necessary. Therefore, we have decided to require a medical certification only in cases where the unfitness is not evident to the eligibility worker. In addition, we have decided that a statement from a nurse, nurse practitioner, designated representative at a doctor's office, social worker, or other medical personnel the State agency deems appropriate would suffice as a medical certification. We are modifying the regulations at 7 CFR 273.24 accordingly.

We proposed that an individual is exempt if the individual is a parent (natural, adoptive, or step) of a household member under the age of 18, or is living in a household where a member is under the age of 18. The majority of the commenters supported this proposal. A few commenters opposed the proposal as defeating the purpose of welfare reform. A couple of commenters suggested that only one parent should be exempt, not both, and that all the other adults in the house should work. A few commenters suggested that we clarify that even if the individual who is under 18 is not eligible for food stamps, the individual's presence in the house exempts those adults who are living in the household. As discussed in the preamble to the proposed rule, we believe it is administratively burdensome, and in this day and age virtually impossible, for the State agency to determine who is "responsible" for a dependent child. We believe that in many cases, more than one adult has responsibility for a dependent child. Therefore, we are retaining the provision as written. However, we are clarifying in the regulations that even if the household member who is under 18 is not eligible for food stamps, the other individuals in the household are still exempt from the time limit.

All the other comments concerning the proposals on the exemptions were supportive. Therefore, we are retaining them as written.

Regaining Eligibility

We proposed that an individual can regain eligibility if the individual works 80 hours in a 30-day period. For purposes of this provision, we proposed that a 30-day period be any 30 consecutive days. We received only a few comments on this proposal. One commenter opposed this provision and suggested that the 30-day period immediately precede application. One commenter suggested we clarify in the regulations that the 30-day period need not immediately precede application. One commenter suggested that we modify the language so that an individual can regain eligibility if the individual works 80 hours in a calendar month. Our proposal basically mirrored the language of the law which provides that individuals can regain eligibility if they work 80 hours during a 30-day period. As discussed in the proposed rule, the statute does not require that the 30-day period be a calendar month, nor does it require that the 30-day period immediately precede the date of application. Therefore, in order to afford flexibility and be faithful to the statute, we are retaining the proposal as written.

We proposed that the State agency have the option to prorate benefits from the date the "cure" is complete or back to the date of application for individuals that complete the cure by working or participating in a work program. One commenter said that it is burdensome to keep the application open and pending until an applicant completes the cure. Two commenters suggested that we allow State agencies to determine eligibility prospectively. For example, if an individual applies and has a job lined up to start the next week, which guarantees him the number of hours necessary to regain eligibility, the State agency should be allowed to determine that he has completed the cure. We agree with these comments. Therefore, we are modifying the regulations to provide that the State agency also has the option to determine eligibility for ABAWD purposes prospectively.

We proposed in the preamble that there be no limit to the number of times an individual could regain eligibility by working 80 hours in a 30-day period. Two commenters supported this proposal as written. One of these commenters suggested we codify this in the regulations. One commenter said that this proposal is too burdensome to track. This same commenter suggested that once an individual has regained eligibility, the individual should be eligible at any time he is meeting the work requirement. The individual should not have to work another 80 hours to regain eligibility. We recognize the complexity of this provision. However, we believe that the proper reading of the law requires that an individual who has lost eligibility must regain it by working 80 hours in a 30-day period. We agree that this needs to be codified in the regulations. Therefore, we are modifying the regulations at 7 CFR 273.24 to provide that there is no limit on the number of times an individual may regain and then maintain eligibility by fulfilling the work requirement.

We proposed that the window of eligibility for the second three-month period start on the day the State agency learns that an individual has lost his job. Several commenters argued that this is very difficult to administer, especially if someone notifies the State agency in the middle of the month. These commenters suggested that the window of eligibility start the month after the month in which the individual notifies the State agency that he has lost his job. The regulations already provide for this. According to the regulations at 7 CFR 273.10, benefits are prorated back to the date of application. In addition, according to the regulations at the newly designated §273.24, partial months are not countable months for ABAWD purposes. The individual would be entitled to benefits back to the date of application, but the first or partial month would not count for ABAWD purposes. The individual would still be entitled to three full consecutive countable months. We believe the regulations at 7 CFR 273.24(e) are clear when they state, "An individual * * * is eligible for three consecutive countable months (as defined in paragraph (b) of this section). * * *), emphasis added. Therefore, we are retaining the provision as written.

One commenter asked us to clarify if the "window of opportunity" opens whether or not an individual applies for benefits and if the State agency must take action if an individual does not apply for benefits. We believe in most cases, the State agency will be dealing with either current recipients or initial applicants. If an individual is a current food stamp recipient, the individual will notify the State agency in accordance with reporting requirements that the individual has lost his job and the window of eligibility starts then. Or, if the individual is a workfare participant, the State agency will become aware that the individual is no longer participating. However, if an individual is not a recipient, the individual probably will not notify the State agency that he has lost his job until he applies for benefits. At such time, the State agency must take action on the case. We believe it is very rare that a State agency is notified by a former recipient, or becomes aware that a former recipient is no longer employed, except at the time the former recipient is reapplying for benefits.

Several commenters disagreed with our proposal that when an individual "forfeits" the opportunity to use the three consecutive countable months (for example, due to a voluntary quit sanction), the individual may work another 80 hours in a 30-day period and regain eligibility again for the three consecutive countable months. These commenters argued that this is confusing and difficult to administer since the State agency does not track individuals' "window of eligibility." One commenter suggested that if an individual is not eligible for the three consecutive countable months because of a sanction, the individual may not regain eligibility for another three month period. One commenter suggested we include language that limits eligibility for the additional three months to those who lose a job or placement through no fault of their own, thus eliminating the confusion that would result from trying to reconcile the relationship between the voluntary quit sanction period and the additional three months of eligibility. Another commenter suggested that if the individuals were ineligible to receive

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benefits during those three months, they may "bank" the three months and then reapply for them once their sanction is over and not have to work 80 hours in a 30-day period again. We understand the tracking difficulties this provision implies. At the same time, we cannot ignore the fact that if an individual is under a sanction during the period the individual is eligible for benefits the three consecutive months, the individual does not "receive" food stamps. The language of the law states clearly that an "individual shall not receive benefits pursuant to clause (i) for more than a single 3-month period in any 36-month period." In addition, the law provides that if an individual loses eligibility the individual must regain it by working 80 hours in a 30-day period. If an individual does not "receive" the benefits for which the individual is eligible due to a sanction, the individual may regain eligibility and "receive" them in the future. We do not believe we have the discretion to limit this provision as suggested by the commenters. Therefore, we are retaining the provision as written.

One commenter suggested that we clarify that anyone who has lost eligibility can requalify, not just individuals who are denied benefits. We agree with this comment and are modifying the regulations to provide that an individual denied eligibility under paragraph (b) of this section, or who does not reapply for benefits because the individual is not meeting the work requirements of 7 CFR 273.7, can regain eligibility.

This same commenter suggested we clarify in the regulations that an individual can re-qualify by becoming exempt. We believe the regulations are clear that if a person meets one of the exemption criteria the person is exempt, and does not have to fulfill the work requirement, including regaining eligibility. However, we have modified the regulations at 7 CFR 273.24 to provide that an individual can requalify by becoming exempt.

Waivers

Section 824 of PRWORA amended section 6(o)(4) of the Act to allow the Secretary, at the request of a State agency, to waive the time limit for any group of individuals if the Secretary determines that the area in which the individuals reside has an unemployment rate of over ten percent, or "does not have a sufficient number of jobs to provide employment for the individuals."

On December 3, 1996, we published guidance which contained basic procedures for applying for a waiver, identified data sources which could be used to substantiate requests, and described some approaches that could support a request based on "lack of sufficient jobs." Because the guidance was extensive and detailed we proposed not to include it in the regulations. Instead, we proposed a general framework for waiver requests with the understanding that State agencies could submit requests with no limit on the supporting documentation, and every request would be weighed on its own individual merits. We received several comments suggesting we include all or some of the guidance in the regulations. Commenters argued that unless the guidance is incorporated into the regulations, a subsequent administration could abolish it without public comment. Based on these comments, we have decided to incorporate some of the more pertinent aspects of the guidance into the regulation. More specifically, we have modified the regulations at 7 CFR 273.24(f) to include a non-exhaustive list of the kinds of information a State agency may submit to support a claim of 10 percent unemployment or "lack of sufficient jobs." For example, a State agency could provide evidence that an area has 10 percent unemployment if it has: (1) A recent 12 month average unemployment rate over 10 percent which indicates a period of sustained high unemployment rates; (2) a recent three month average unemployment rate over 10 percent which indicates an early signal of a labor market with high unemployment; or (3) an historical seasonal unemployment rate of over 10 percent. States may submit evidence of a lack of sufficient jobs by submitting data that the area: (1) Was designated as a Labor Surplus Area by the Department of Labor's Employment and Training Administration (ETA); (2) was determined by the Department of Labor's Unemployment Insurance Service as qualifying for extended unemployment benefits; (3) has a low and declining employment-to-population ratio; (4) has a lack of jobs in declining occupations or industries; or (5) has a 24 month average unemployment rate 20 percent above the national average for the same period.

To facilitate the waiver process, we have decided to incorporate into the regulations a paragraph describing three types of waiver requests we currently approve and will continue to approve based on clear quantitative standards. Specifically, we provide that we will approve a waiver if a State agency submits and we confirm (1) data from the BLS or the BLS cooperating agency that shows an area has a most recent 12 month average unemployment rate over 10 percent; (2) data from the BLS or the BLS cooperating agency that an area has a 24 month average unemployment rate that exceeds the national average by 20 percent for any 24-month period no earlier than the same period the ETA uses to designate LSAs for the current fiscal year; or (3) evidence that the area has been designated a Labor Surplus Area by the ETA for the current fiscal year.

We proposed that States seeking waivers for areas with unemployment rates higher than 10 percent be required to submit data that relies on standard Bureau of Labor Statistics (BLS) data or methods. We also proposed that, to the extent that a "lack of sufficient jobs" waiver is based on labor force and unemployment data, States be required to submit data that relies on standard BLS data or methods. Several commenters opposed the mandate that State agencies be restricted to this data. One commenter pointed out that some states have already obtained waivers based on adverse employment-to-population ratios using BLS employment data and Census Bureau population estimates, or academic studies showing particularly severe employment barriers. We should weigh these requests on their own merits and not dismiss them out of hand. Other commenters suggested we consider data from the Bureau of Indian Affairs.

As discussed in the preamble, established Federal policy requires Federal executive branch agencies to use the most recent National, State or local labor force and unemployment data from the BLS for all program purposes. This policy is contained in Statistical Policy Directive No. 11, issued by the Office of Federal Statistical Policy Standards, Office of Management and Budget. This policy ensures the standardization of collection methods and the accuracy of data used to administer Federal programs. Therefore, we have no choice but to require State agencies that are submitting requests based on unemployment rates to submit the most recent data acquired from BLS or its cooperating agency in the State. This includes requests under the "lack of sufficient jobs" criteria which are using unemployment data as supporting evidence (e.g. low or declining employment-to-population ratios, or unemployment 20 percent above the national average for more than two years). As discussed above, this does not preclude any State agency from submitting other data to prove "lack of sufficient jobs" such as an academic study, designation of Labor Surplus Areas status, or data from the Bureau of Indian Affairs. Therefore, we are retaining the requirement as written.

We proposed that in areas for which the State certifies that data from BLS show an unemployment rate above 10 percent, the State may begin to operate the waiver at the time the waiver request is submitted, and that we would contact the State if the waiver needed to be modified. One commenter suggested that, in addition, we allow immediate implementation of waivers for areas where the Employment and Training Administration, U.S. Department of Labor (ETA), has designated such areas as Labor Surplus Areas (LSA), since our current policy defers to these designations in granting waivers. We agree with this comment. We are modifying the regulations at 7 CFR 273.24 accordingly.

We proposed that waivers would not be approved for more than one year. One commenter suggested we clarify that yearlong waivers are routinely available in order to reassure States that they will not be subject to more burdensome requirements. We agree with this comment. Therefore, we are modifying the regulations at 7 CFR 273.24 to provide that generally, we will approve waivers for one year. However, we reserve the right to approve waivers for a shorter period if the data is insufficient, or to approve waivers for longer periods if the reasons are compelling.

One commenter suggested we allow waivers to be granted retroactively at the request of a State agency where the data supports a waiver during the months in question. This commenter pointed out that it sometimes takes longer than anticipated for a State agency to get the necessary paperwork together and to get a waiver request cleared through the proper channels. States that know they have solid data in support of a waiver should be able to implement or continue implementing a waiver they are confident will be granted during these delays and while they await USDA's approval. We recognize that it may take time for the State agency to draft and clear its request, whether it be for an initial or extension requests. However, as already discussed above, States may begin operating a waiver immediately upon requesting one if it has data that indicates the area has a 12 month average unemployment rate above 10 percent or has been designated a LSA by the ETA. For all other requests, in the event a State agency submits a request to us in an untimely fashion due to circumstances beyond its control, we reserve the right to make a retroactive approval. However, we believe these decisions should be made on a case-by-case basis and not codified in regulations. We encourage State agencies to begin working on waiver requests (both initial and extensions) and submit them to us in a timely fashion, taking into consideration the amount of time it will take to get such a request cleared through the proper State channels, so that retroactive approval does not become an issue. We will continue to expedite the approval of these requests, and in those circumstances which warrant it, we will grant retroactive approval.

We proposed that State agencies have complete discretion to define the geographic areas covered by waivers so long as they provide data for the corresponding area. Most of the comments we received supported this proposal. We received one comment suggesting that State agencies may want to define areas that do not correspond with census tracts or the catchment areas of unemployment compensation offices, making a mismatch between data and areas. This commenter suggested we clarify in the regulations that this is permissible. For simplicity sake, we encourage States to define areas for which corresponding data exists. We believe this is very easily done, especially since unemployment data goes down to the census tract level. However, we also realize that there are situations where data does not correspond to already defined areas, such as Indian Reservations. In these situations, we suggest State agencies submit data that corresponds as closely to the area as possible. We will consider it and decide on a case-by-case basis whether or not to approve the request. In this final rule we are modifying the regulation at 7 CFR 273.24 to provide that if corresponding data does not exist, State agencies should submit data that corresponds as closely to the area as possible.

Implementation

This rule is effective no later than April 2, 2001, except for the amendment to 7 CFR 272.2(d)(1)(xiii) which is effective August 1, 2001. State agencies must implement the provisions in this final rule no later than August 1, 2001.

List of Subjects

7 CFR Part 272

Alaska, Civil rights, Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 273

Administrative practice and procedures, Claims Food stamps, Grant programs-social programs, Penalties, Reporting and recordkeeping, Social security, Students.

Accordingly, 7 CFR parts 272 and 273 are amended as follows:

1. The authority citation for parts 272 and 273 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

2. In § 272.1, add paragraph (c)(1)(vii) and paragraph (g)(165) to read as follows.

§ 272.1 General terms and conditions.

* * * * *

(c) * * *

(1) * * *

(vii) Local, State or Federal law enforcement officers, upon written request, for the purpose of obtaining the address, social security number, and, if available, photograph of any household member, if the member is fleeing to avoid prosecution or custody for a crime, or an attempt to commit a crime, that would be classified as a felony (or in the State of New Jersey, a high misdemeanor), or is violating a condition of probation or parole imposed under a Federal or State law. The State agency shall not require a household to present photographic identification as a condition of eligibility and must accept any document that reasonably establishes the applicant's identity. The State agency shall also provide information regarding a household member, upon the written request of a law enforcement officer acting in his or her official capacity, where such member has information necessary for the apprehension or investigation of another member who is fleeing to avoid prosecution or custody for a felony, or has violated a condition of probation or parole. If a law enforcement officer provides documentation indicating that a household member is fleeing to avoid prosecution or custody for a felony, or has violated a condition of probation or parole, the State agency shall terminate the participation of the member. A request for information absent documentation would not be sufficient to terminate the member's participation. The State agency shall disclose only such information as is necessary to comply with a specific written request of a law enforcement agency authorized by this paragraph.

* * * * *

(g) * * *

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(165) *Amendment No. 387*—This rule is effective no later than {insert the first day of the month 60 days after publication of the final rule, except for the amendment to 7 CFR 272.2(d)(1)(xiii) which is effective August 1, 2001. State agencies must implement the provisions in this final rule no later than August 1, 2001.

3. In § 272.2, new paragraph (d)(1)(xiii) is added to read as follows:

§ 272.2 Plan of operation.

* * * * *

(d) * * *

(1) * * *

(xiii) If the State agency chooses to implement the optional provisions specified in (273.11(k), (l), (o), (p), and (q) of this chapter, it must include in the Plan's attachment the options it selected, the guidelines it will use, and any good cause criteria under paragraph (o). For § 273.11(k) of this chapter, the State agency must identify which sanctions in the other programs this provision applies to. The State agency must also include in the plan a description of the safeguards it will use to restrict the use of information it collects in implementing the optional provision contained in § 273.11(p) of this chapter.

* * * * *

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

4. In § 273.1, new paragraphs (b)(7)(viii), (b)(7)(ix), (b)(7)(x), (b)(7)(xi), and (b)(7)(xii) are added to read as follows:

§ 273.1 Household concept.

* * * * *

(b) * * *

(7) * * *

(viii) Individuals who are ineligible under § 273.11(m) because of a drug-related felony conviction.

(ix) At State agency option, individuals who are disqualified in another assistance program in accordance with § 273.11(k).

(x) Individuals who are fleeing to avoid prosecution or custody for a crime, or an attempt to commit a crime, or who are violating a condition of probation or parole who are ineligible under § 273.11(n).

(xi) Individuals disqualified for failure to cooperate with child support enforcement agencies in accordance with § 273.11(o) or (p), or for being delinquent in any court-ordered child support obligation in accordance with § 273.11(q).

(xii) Persons ineligible under § 273.24, the time limit for able-bodied adults.

* * * * *

5. In § 273.2:

a. A new paragraph (f)(1)(xiv)is added.

b. Paragraph (f)(8)(i)(C) is redesignated as paragraph (f)(8)(i)(D), and a new paragraph (f)(8)(i)(C) is added.

c. Paragraph (j)(2)(vii)(D) is added.

The additions read as follows:

§ 273.2 Application processing.

* * * * *

(f) * * *

(1) * * *

(xiv) *Additional verification for able-bodied adults subject to the time limit.*

(A) *Hours worked.* For individuals subject to the food stamp time limit of § 273.24 who are satisfying the work requirement by working, by combining work and participation in a work program, or by participating in a work or workfare program that is not operated or supervised by the State agency, the individuals' work hours shall be verified.

(B) *Countable months in another state.* For individuals subject to the food stamp time limit of § 273.24, the State agency must verify the number of countable months (as defined in § 273.24(b)(1)) an individual has used in another State if there is an indication that the individual participated in that State. The normal processing standards of 7 CFR 273.2(g) apply. The State agency may accept another State agency's assertion as to the number of countable months an individual has used in another State.

* * * * *

(8) * * *

(i) * * *

(C) For individuals subject to the food stamp time limit of § 273.24 who are satisfying the work requirement by working, by combining work and participation in a work program, or by participating in a work program that is not operated or supervised by the State agency, the individuals' work hours shall be verified.

* * * * *

(j)* * *

(2) * * *

(vii)* * *

(D) Any member of that household is ineligible under § 273.11(m) by virtue of a conviction for a drug-related felony.

* * * * *

6. In § 273.11:

a. The introductory text of paragraph (c) is revised, and the heading and introductory text of paragraphs (c)(1) and (c)(2) are revised.

b. Paragraph (c)(4)(ii) is revised.

c. Paragraph (j) is revised.

d. Paragraphs (k), (l), (m), (n), (o), (p), and (q) are added.

The additions and revisions read as follows:

§ 273.11 Action on households with special circumstances.

* * * * *

(c) * * *

During the period of time that a household member cannot participate for the reasons addressed in this section, the eligibility and benefit level of any remaining household members shall be determined in accordance with the procedures outlined in this section.

(1) *Intentional Program violation, felony drug conviction, or fleeing felon disqualifications, and workfare or work requirement sanctions.* The eligibility and benefit level of any remaining household members of a household containing individuals determined ineligible because of a disqualification for an intentional Program violation, a felony drug conviction, their fleeing felon status, noncompliance with a work requirement of § 273.7, or imposition of a sanction while they were participating in a household disqualified because of failure to comply with workfare requirements shall be determined as follows:

* * * * *

(2) *SSN disqualifications, comparable disqualifications, child support disqualifications, and ineligible ABAWDs.* The eligibility and benefit level of any remaining household members of a household containing individuals determined to be ineligible for refusal to obtain or provide an SSN, for meeting the time limit for able-bodied adults without dependents or for being disqualified under paragraphs (k), (o), (p), or (q) of this section shall be determined as follows:

* * * * *

(4) * * *

(ii) *Disqualified or determined ineligible for reasons other than intentional Program violation.* If a household's benefits are reduced or terminated within the certification period for reasons other than an Intentional Program Violation disqualification, the State agency shall issue a notice of adverse action in accordance with § 273.13(a)(2) which informs the household of the ineligibility, the reason for the ineligibility, the eligibility and benefit level of the remaining members, and the action the household must take to end the ineligibility.

* * * * *

(j) *Reduction of public assistance benefits.* If the benefits of a household that is receiving public assistance are reduced under a Federal, State, or local means-tested public assistance program because of the failure of a food stamp household member to perform an action required under the assistance program or for fraud, the State agency shall not increase the household's food stamp allotment as the result of the decrease in income. In addition to prohibiting an increase in food stamp benefits, the State agency may impose a penalty on the household that represents a percentage of the food stamp allotment that does not exceed 25 percent. The 25 percent reduction in food stamp benefits must be based on the amount of food stamp benefits the household should have received under the regular food stamp benefit formula, taking into account its actual (reduced) income. However, under no circumstances can the food stamp benefits be allowed to rise. Reaching a time limit for time-limited benefits, having a child that is not eligible because of a family cap, failing to reapply or complete the application process for continued assistance under the other program, failing to perform an action that the individual is unable to perform as opposed to refusing to perform, or failing to comply with a purely procedural requirement, shall not be considered a failure to perform an action required by an assistance program for purposes of this provision. A procedural requirement, which would not trigger a food stamp sanction, is a step that an individual must take to continue receiving benefits in the assistance program such as submitting a monthly report form or providing verification of circumstances. A substantive requirement, which would trigger a food stamp sanction, is a behavioral requirement in the assistance program designed to improve the well being of the recipient family, such as participating in job search activities. The State agency shall not apply this provision to individuals who fail to perform a required action at the time the individual initially applies for assistance. The State agency shall not increase food stamp benefits, and may reduce food stamp benefits only if the person is receiving such assistance at the time the reduction in assistance is imposed or the reduction in assistance is imposed at the time of application for continued assistance benefits if there is no break in participation. The individual must be certified for food stamps at the time of the failure to perform a required action for this provision to apply. Assistance benefits shall be considered reduced if they are decreased, suspended, or terminated.

(1) For purposes of this provision a Federal, State or local "means-tested public assistance program" shall mean public or general assistance as defined in § 271.2 of this chapter, and is referred to as "assistance". This provision must be applied to all applicable cases. If a State agency is not successful in obtaining the necessary cooperation from another Federal, State or local means-tested welfare or public assistance program to enable it to comply with the requirements of this provision, the State agency shall not be held responsible for noncompliance as long as the State agency has made a good faith effort to obtain the information. The State agency, rather than the household, shall be responsible for obtaining information about sanctions from other programs and changes in those sanctions.

(2) The prohibition on increasing food stamp benefits applies for the duration of the reduction in the assistance program. If at any time the State agency can no longer ascertain the amount of the reduction, then the State agency may terminate the food stamp sanction. However, the sanction may not exceed the sanction in the other program. If the sanction is still in effect at the end of one year, the State agency shall review the case to determine if the sanction continues to be appropriate. If, for example, the household is not receiving assistance, it would not be appropriate to continue the sanction. Sanctions extended beyond one year must be reviewed at least annually but may be ended by the State agency at any time. It shall be concurrent with the reduction in the other assistance program to the extent allowed by normal food stamp change processing and notice procedures.

(3) The State agency shall determine how to prevent an increase in food stamp benefits. Among other options, the State agency may increase the assistance grant by a flat percent, not to exceed 25 percent, for all households that fail to perform a required action in lieu of computing an individual amount or percentage for each affected household.

(4) If the allotment of a household is reduced under Title IV–A of the Social Security Act, the State agency may use the same procedures that apply under Title IV–A to prevent an increase in food stamp benefits as the result of the decrease in Title IV–A benefits. For example, the same budgeting procedures and combined notices and hearings may be used, but the food stamp allotment may not be reduced by more than 25 percent.

(5) The State agency must lift the ban on increasing food stamp benefits if it becomes aware that the person has become ineligible for the assistance program during the disqualification period for some other reason, or the person's assistance case is closed.

(6) If an individual moves within the State, the prohibition on increasing food stamp benefits shall be applied to the gaining household unless that person is ineligible for the assistance program for some other reason. If such individual moves to a new State the prohibition on increasing benefits shall not be applied.

(7) The State agency must restore lost benefits when necessary in accordance with § 273.17 if it is later determined that the reduction in the public assistance grant was not appropriate.

(8) The State agency must act on changes which are not related to the assistance violation and that would affect the household's benefits.

(9) The State agency must include in its State Plan of Operations any options it has selected in this paragraph (j).

(k) *Comparable disqualifications.* If a disqualification is imposed on a member of a household for failure to perform an action required under a Federal, State or local means-tested public assistance program, the State agency may impose the same disqualification on the member of the household under the Food Stamp Program. The program must be authorized by a Federal, State, or local law, but the provision itself does not have to be specified in the law. A State agency may choose to apply this provision to one or more of these programs, and it may select the types of disqualifications within a program that it wants to impose on food stamp recipients. The State agency shall be responsible for obtaining information about sanctions from other programs and changes in those sanctions.

(1) For purposes of this section Federal, State or local "means-tested public assistance program" shall mean public and general assistance as defined in § 271.2 of this chapter.

(2) The State agency shall not apply this provision to individuals who are disqualified at the time the individual initially applies for assistance benefits. It may apply the provision if the person was receiving such assistance at the time the disqualification in the assistance program was imposed and to disqualifications imposed at the time of application for continued assistance benefits if there is no break in participation with the following exceptions: Reaching a time limit for time-limited benefits, having a child that is not eligible because of a family

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cap, failing to reapply or complete the application process for continued assistance, failing to perform an action that the individual is unable to perform as opposed to refusing to perform, and failing to perform purely procedural requirements, shall not be considered failures to perform an action required by an assistance program. A procedural requirement, which would not trigger a food stamp sanction, is a step that an individual must take to continue receiving benefits in the assistance program such as submitting a monthly report form or providing verification of circumstances. A substantive requirement, which would trigger a food stamp sanction, is a behavioral requirement in the assistance program designed to improve the well being of the recipient family, such as participating in job search activities. The individual must be receiving food stamps at the time of the disqualification in the assistance program to be disqualified from the Food Stamp Program under this provision.

(3) The State agency must stop the food stamp disqualification when it becomes aware that the person has become ineligible for assistance for some other reason, or the assistance case is closed.

(4) If a disqualification is imposed for a failure of an individual to perform an action required under a program under Title IV–A of the Social Security Act, the State may use the rules and procedures that apply under the Title IV–A program to impose the same disqualification under the Food Stamp Program.

(5) Only the individual who committed the violation in the assistance program may be disqualified for food stamp purposes even if the entire assistance unit is disqualified for Title IV–A purposes.

(6) A comparable disqualification for food stamp purposes shall be imposed concurrently with the disqualification in the assistance program to the extent allowed by normal food stamp processing times and notice requirements. The State agency may determine the length of the disqualification, providing that the disqualification does not exceed the disqualification in the other program. If the sanction is still in effect at the end of one year, the State agency shall review the case to determine if the sanction continues to be appropriate. If, for example, the household is not receiving assistance, if would not be appropriate to continue the sanction. Sanctions extended beyond one year must be reviewed at least annually but may be ended by the State agency at any time.

(7) If there is a pending disqualification for a food stamp violation and a pending comparable disqualification, they shall be imposed concurrently to the extent appropriate. For example, if the household is disqualified for June for a food stamp violation and an individual is disqualified for June and July for an assistance program violation, the whole household shall be disqualified for June and the individual shall be disqualified for July for food stamp purposes.

(8) The State agency must treat the income and resources of the disqualified individual in accordance with § 273.11(c)(2).

(9) After a disqualification period has expired, the person may apply for food stamp benefits and shall be treated as a new applicant or a new household member, except that a current disqualification based on a food stamp work requirement shall be considered in determining eligibility.

(10) A comparable food stamp disqualification may be imposed in addition to any coupon allotment reductions made in accordance with paragraph (j) of this section.

(11) State agencies shall state in their Plan of Operation if they have elected to apply comparable disqualifications, identify which sanctions in the other programs this provision applies to, and indicate the options and procedures allowed in paragraphs (k)(1), (k)(2), (k)(3), (k)(4), and (k)(10) of this section which they have selected.

(12) The State agency must act on changes which are not related to the assistance violation and that would affect the household's benefits.

(13) The State agency must restore lost benefits when necessary in accordance with 7 CFR 273.17 if it is later determined that the reduction in the public assistance grant was not appropriate.

(l) *School Attendance.* Section 404(i) of Part A of the Social Security Act, 42 U.S.C. 601, et seq., provides that any state receiving a TANF block grant cannot be prohibited from sanctioning a family that includes an adult who has received assistance financed with federal TANF dollars or provided from the food stamp program if such adult fails to ensure that the minor dependent children of such adult attend school as required by the law of the State in which the minor children reside. Section 404(j) of Part A of the Social Security Act, 42 U.S.C. 601, *et seq.*, provides that States shall not be prohibited from sanctioning a family that includes an adult who is older than 20 and younger than 51 and who has received assistance that is either financed with federal TANF funds or provided through the food stamp program if such adult does not have, or is not working toward attaining, a secondary school diploma or recognized equivalent. These provisions do not provide independent authority for food stamp sanctions beyond any that may apply through paragraphs (j) and (k) of this section.

(m) *Individuals convicted of drug-related felonies.* An individual convicted (under Federal or State law) of any offense which is classified as a felony by the law of the jurisdiction involved and which has as an element the possession, use, or distribution of a controlled substance (as defined in section 102(6) of the Controlled Substance Act, 21 U.S.C. 802(6)) shall not be considered an eligible household member unless the State legislature of the State where the individual is domiciled has enacted legislation exempting individuals domiciled in the State from the above exclusion. If the State legislature has enacted legislation limiting the period of disqualification, the period of ineligibility shall be equal to the length of the period provided under such legislation. Ineligibility under this provision is only limited to convictions based on behavior which occurred after August 22, 1996. The income and resources of individuals subject to disqualification under this paragraph (m) shall be treated in accordance with the procedures at paragraph (c)(1) of this section.

(n) *Fleeing felons and probation or parole violators.* Individuals who are fleeing to avoid prosecution or custody for a crime, or an attempt to commit a crime, that would be classified as a felony (or in the State of New Jersey, a high misdemeanor) or who are violating a condition of probation or parole under a Federal or State law shall not be considered eligible household members. The income and resources of the ineligible member shall be handled in accordance with (c)(1) of this section.

(o) *Custodial parent's cooperation with the State Child Support Agency.* For purposes of this provision, a custodial parent is a natural or adoptive parent who lives with his or her child, or other individual who is living with and exercises parental control over a child under the age of 18.

(1) *Option to disqualify custodial parent for failure to cooperate.* At the option of a State agency, subject to paragraphs (o)(2) and (o)(4) of this section, no natural or adoptive parent or, at State agency option, other individual (collectively referred to in this paragraph (o) as "the individual") who is living with and exercising parental control over a child under the age of 18 who has an absent parent shall be eligible to participate in the Food Stamp Program unless the individual cooperates with the agency administering a State Child Support Enforcement Program established under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*), hereafter referred to as the State Child Support Agency.

(i) If the State agency chooses to implement paragraph (o)(1) of this section, it must notify all individuals of this requirement in writing at the time of application and reapplication for continued benefits.

(ii) If the State agency chooses to implement paragraph (o)(1) of this section, it must refer all appropriate individuals to the State Child Support Agency.

(iii) If the individual is receiving TANF or Medicaid, or assistance from the State Child Support Agency, and has already been determined to be cooperating, or has been determined to have good cause for not cooperating, then the State agency shall consider the individual to be cooperating for food stamp purposes.

(iv) The individual must cooperate with the State Child Support Agency in establishing paternity of the child, and in establishing, modifying, or enforcing a support order with respect to the child and the individual in accordance with section 454(29) of the Social Security Act (42 U.S.C. 654(29)).

(v) Pursuant to Section 454(29)(E) of the Social Security Act (42 U.S.C. 654(29)(E) the State Child Support Agency will notify the individual and the State agency whether or not it has determined that the individual is cooperating in good faith.

(2) *Claiming good cause for non-cooperation.* Prior to requiring cooperation under paragraph (o)(1) of this section, the State agency will notify the household in writing at initial application and at application for continued benefits of the right to good cause as an exception to the cooperation requirement and of all the requirements applicable to a good cause determination. Paragraph (o)(1) of this section shall not apply to the individual if good cause is found for refusing to cooperate, as determined by the State agency:

(i) *Circumstances under which cooperation may be "against the best interests of the child."* The individual's failure to cooperate is deemed to be for "good cause" if:

(A) The individual meets the good cause criteria established under the State program funded under Part A of Title IV or Part D of Title IV of the Social Security Act (42 U.S.C. 601, *et seq*, or 42 U.S.C. 651, *et seq.*) (whichever agency is authorized to define and determine good cause) for failing to cooperate with the State Child Support Agency; or

(B) Cooperating with the State Child Support Agency would make it more difficult for the individual to escape domestic violence or unfairly penalize the individual who is or has been victimized by such violence, or the individual who is at risk of further domestic violence. For purposes of this provision, the term "domestic violence" means the individual or child would be subject to physical acts that result in, or are threatened to result in, physical injury to the individual; sexual abuse; sexual activity involving a dependent child; being forced as the caretaker relative of a dependent child to engage in nonconsensual sexual acts or activities; threats of, or attempts at physical or sexual abuse; mental abuse; or neglect or deprivation of medical care.

(C) The individual meets any other good cause criteria identified by the State agency. These criteria will be defined in consultation with the Child Support Agency or TANF program, whichever is appropriate, and identified in the State plan according to § 272.2(d)(xiii).

(ii) *Proof of good cause claim.* (A) The State agency will accept as corroborative evidence the same evidence required by Part A of Title IV or Part D of Title IV of the Social Security Act (42 U.S.C. 601, *et seq.* or 42 U.S.C. 651, *et seq.*) to corroborate a claim of good cause.

(B) The State agency will make a good cause determination based on the corroborative evidence supplied by the individual only after it has examined the evidence and found that it actually verifies the good cause claim.

(iii) *Review by the State Child Support or TANF Agency.* Prior to making a final determination of good cause for refusing to cooperate, the State agency will afford the State Child Support Agency or the agency which administers the program funded under Part A of the Social Security Act the opportunity to review and comment on the findings and the basis for the proposed determination and consider any recommendation from the State Child Support or TANF Agency.

(iv) *Delayed finding of good cause.* The State agency will not deny, delay, or discontinue assistance pending a determination of good cause for refusal to cooperate if the applicant or recipient has complied with the requirements to furnish corroborative evidence and information. In such cases, the State agency must abide by the normal processing standards according to § 273.2(g).

(3) *Individual disqualification.* If the State agency has elected to implement this provision and determines that the individual has not cooperated without good cause, then that individual shall be ineligible to participate in the Food Stamp Program. The disqualification shall not apply to the entire household. The income and resources of the disqualified individual shall be handled in accordance with paragraph(c)(2) of this section.

(4) *Fees.* A State electing to implement this provision shall not require the payment of a fee or other cost for services provided under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*)

(5) *Terminating the Disqualification.* The period of disqualification ends once it has been determined that the individual is cooperating with the State Child Support Agency. The State agency must have procedures in place for re-qualifying such an individual.

(p) *Non-custodial parent's cooperation with child support agencies.* For purposes of this provision, a "non-custodial parent" is a putative or identified parent who does not live with his or her child who is under the age of 18.

(1) *Option to disqualify non-custodial parent for refusal to cooperate.* At the option of a State agency, subject to paragraphs (p)(2) and (p)(4) of this section, a putative or identified non-custodial parent of a child under the age of 18 (referred to in this subsection as "the individual") shall not be eligible to participate in the Food Stamp Program if the individual refuses to cooperate with the State agency administering the program established under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*), hereafter referred to as the State Child Support Agency, in establishing the paternity of the child (if the child is born out of wedlock); and in providing support for the child.

(i) If the State agency chooses to implement paragraph (p)(1) of this section, it must notify all individuals in writing of this requirement at the time of application and reapplication for continued benefits.

(ii) If the individual is receiving TANF, Medicaid, or assistance from the State Child Support Agency, and has already been determined to be cooperating, or has been determined to have good cause for not cooperating,

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then the State agency shall consider the individual is cooperating for food stamp purposes.

(iii) If the State agency chooses to implement paragraph (p)(1) of this section, it must refer all appropriate individuals to the State Child Support Agency established under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*).

(iv) The individual must cooperate with the State Child Support Agency in establishing the paternity of the child (if the child is born out of wedlock), and in providing support for the child.

(v) Pursuant to Section 454(29)(E) of the Social Security Act (42 U.S.C. 654(29)(E)), the State Child Support Agency will notify the individual and the State agency whether or not it has determined that the individual is cooperating in good faith.

(2) *Determining refusal to cooperate.* If the State Child Support Agency determines that the individual is not cooperating in good faith, then the State agency will determine whether the non-cooperation constitutes a refusal to cooperate. Refusal to cooperate is when an individual has demonstrated an unwillingness to cooperate as opposed to an inability to cooperate.

(3) *Individual disqualification.* If the State agency determines that the non-custodial parent has refused to cooperate, then that individual shall be ineligible to participate in the Food Stamp Program. The disqualification shall not apply to the entire household. The income and resources of the disqualified individual shall be handled according to paragraph (c)(2) of this section.

(4) *Fees.* A State electing to implement this provision shall not require the payment of a fee or other cost for services provided under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*)

(5) *Privacy.* The State agency shall provide safeguards to restrict the use of information collected by a State agency administering the program established under Part D of Title IV of the Social Security Act (42 U.S.C. 651, *et seq.*) to purposes for which the information is collected.

(6) *Termination of disqualification.* The period of disqualification ends once it has been determined that the individual is cooperating with the child support agency. The State agency must have procedures in place for re-qualifying such an individual.

(q) *Disqualification for child support arrears.*

(1) *Option to disqualify.* At the option of a State agency, no individual shall be eligible to participate in the Food Stamp Program as a member of any household during any month that the individual is delinquent in any payment due under a court order for the support of a child of the individual. The State agency may opt to apply this provision to only non-custodial parents.

(2) *Exceptions.* A disqualification under paragraph (q)(1) of this section shall not apply if:

(i) A court is allowing the individual to delay payment;

(ii) The individual is complying with a payment plan approved by a court or the State agency designated under Part D of Title IV of the Social Security Act (42 U.S.C., 651 *et seq.*) to provide support of a child of the individual; or

(iii) The State agency determines the individual has good cause for non-support.

(3) *Individual disqualification.* If the State agency has elected to implement this provision and determines that the individual should be disqualified for child support arrears, then that individual shall be ineligible to participate in the Food Stamp Program. The disqualification shall not apply to the entire household. The income and resources of the disqualified individual shall be handled according to paragraph (c)(2) of this section.

(4) *Collecting claims.* State agencies shall initiate collection action as provided for in § 273.18 for any month a household member is disqualified for child support arrears by sending the household a written demand letter which informs the household of the amount owed, the reason for the claim and how the household may pay the claim. The household should also be informed as to the adjusted amount of income, resources, and deductible expenses of the remaining members of the household for the month(s) a member is disqualified for child support arrears.

7. In § 273.12, a new paragraph (a)(1)(viii) is added to read as follows:

§ 273.12 Reporting changes.

(a) * * *

(1) * * *

(viii) For able-bodied adults subject to the time limit of § 273.24, any changes in work hours that bring an individual below 20 hours per week, averaged monthly, as defined in § 273.24(a)(1)(i). An individual shall report this information in accordance with the reporting system for income to which he is subject.

* * * * *

8. In § 273.16

a. Remove the last sentence in paragraph (a)(1).

b. Revise paragraphs (b) and (c).

c. Revise paragraph (e)(8)(i).

d. Remove paragraph (e)(8)(iii) and redesignate paragraph (e)(8)(iv) as paragraph (e)(8)(iii).

e. Remove paragraph (f)(2)(iii) and redesignate paragraph (f)(2)(iv) as paragraph (f)(2)(iii).

f. Remove paragraph (g)(2)(ii) and redesignate paragraph (g)(2)(iii) as paragraph (g)(2)(ii).

g. Remove paragraph (h)(2)(ii) and redesignate paragraph (h)(2)(iii) as paragraph (h)(2)(ii).

The revisions read as follows:

§ 273.16 Disqualification for intentional Program violation.

* * * * *

(b) *Disqualification penalties.*

(1) Individuals found to have committed an intentional Program violation either through an administrative disqualification hearing or by a Federal, State or local court, or who have signed either a waiver of right to an administrative disqualification hearing or a disqualification consent agreement in cases referred for prosecution, shall be ineligible to participate in the Program:

(i) For a period of twelve months for the first intentional Program violation, except as provided under paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) of this section;

(ii) For a period of twenty-four months upon the second occasion of any intentional Program violation, except as provided in paragraphs (b)(2), (b)(3), (b)(4), and (b)(5) of this section; and

(iii) Permanently for the third occasion of any intentional Program violation.

(2) Individuals found by a Federal, State or local court to have used or received benefits in a transaction involving the sale of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) shall be ineligible to participate in the Program:

(i) For a period of twenty four months upon the first occasion of such violation; and

(ii) Permanently upon the second occasion of such violation.

(3) Individuals found by a Federal, State or local court to have used or received benefits in a transaction involving the sale of firearms, ammunition or explosives shall be permanently ineligible to participate in the Program upon the first occasion of such violation.

(4) An individual convicted by a Federal, State or local court of having trafficked benefits for an aggregate amount of $500 or more shall be permanently ineligible to participate in the Program upon the first occasion of such violation.

(5) Except as provided under paragraph (b)(1)(iii) of this section, an individual found to have made a fraudulent statement or representation with respect to the identity or place of residence of the individual in order to receive multiple food stamp benefits simultaneously shall be ineligible to participate in the Program for a period of 10 years.

(6) The penalties in paragraphs (b)(2) and (b)(3) of this section shall also apply in cases of deferred adjudication as described in paragraph (h) of this section, where the court makes a finding that the individual engaged in the conduct described in paragraph (b)(2) and (b)(3) of this section.

(7) If a court fails to impose a disqualification or a disqualification period for any intentional Program violation, the State agency shall impose the appropriate disqualification penalty specified in paragraphs (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5) of this section unless it is contrary to the court order.

(8) One or more intentional Program violations which occurred prior to April 1, 1983 shall be considered as only one previous disqualification when determining the appropriate penalty to impose in a case under consideration.

(9) Regardless of when an action taken by an individual which caused an intentional Program violation occurred, the disqualification periods specified in paragraphs (b)(2) and (b)(3) of this section shall apply to any case in which the court makes the requisite finding on or after September 1, 1994.

(10) For the disqualification periods in paragraphs (b)(1), (b)(5) or (b)(6) of this section, if the offense occurred prior to the implementation of these penalties, the State agency may establish a policy of disqualifying these individuals in accordance with the disqualification periods in effect at the time of the offense. This policy must be consistently applied for all affected individuals.

(11) State agencies shall disqualify only the individual found to have committed the intentional Program violation, or who signed the waiver of the right to an administrative disqualification hearing or disqualification consent agreement in cases referred for prosecution, and not the entire household.

(12) Even though only the individual is disqualified, the household, as defined in § 273.1, is responsible for making restitution for the amount of any overpayment. All intentional Program violation claims must be established and collected in accordance with the procedures set forth in § 273.18.

(13) The individual must be notified in writing once it is determined that he/she is to be disqualified. The disqualification period shall begin no later than the second month which follows the date the individual receives written notice of the disqualification. The disqualification period must continue uninterrupted until completed regardless of the eligibility of the disqualified individual's household.

(c) *Definition of intentional Program violation.* Intentional Program violations shall consist of having intentionally:

(1) made a false or misleading statement, or misrepresented, concealed or withheld facts; or

(2) committed any act that constitutes a violation of the Food Stamp Act, the Food Stamp Program Regulations, or any State statute for the purpose of using, presenting, transferring, acquiring, receiving, possessing or trafficking of coupons, authorization cards or reusable documents used as part of an automated benefit delivery system (access device).

* * * * *

(e) * * *

(8) * * *

(i) If the hearing authority rules that the individual has committed an intentional Program violation, the household member must be disqualified in accordance with the disqualification periods and procedures in paragraph (b) of this section. The same act of intentional Program violation repeated over a period of time must not be separated so that separate penalties can be imposed.

* * * * *

10. In § 273.24:

a. the section heading is revised.

b. paragraph (a) introductory text is revised.

c. paragraphs (a)(1) and (a)(2) are redesignated as paragraphs (a)(5) and (a)(6).

d. paragraphs (b), (c), (d), and (e) are redesignated as paragraphs (g), (h), (i) and (j).

e. the heading of the newly designated paragraph (g) is revised to read *"15 percent exemptions."*

f. paragraphs (a)(1) through (a)(4) and paragraphs (b) through (f) are added as follows.

§ 273.24 Time limit for able-bodied adults.

(a) *Definitions.* For purposes of the food stamp time limit, the terms below have the following meanings:

(1) *Fulfilling the work requirement* means:

(i) Working 20 hours per week, averaged monthly; for purposes of this provision, 20 hours a week averaged monthly means 80 hours a month;

(ii) Participating in and complying with the requirements of a work program 20 hours per week, as determined by the State agency;

(iii) Any combination of working and participating in a work program for a total of 20 hours per week, as determined by the State agency; or

(iv) Participating in and complying with a workfare program;

(2) *Working* means:

(i) Work in exchange for money;

(ii) Work in exchange for goods or services ("in kind" work); or

(iii) Unpaid work, verified under standards established by the State agency.

(iv) Any combination of paragraphs (a)(2)(i), (a)(2)(ii) and (a)(2)(iii) of this section.

(3) *Work Program* means:

(i) A program under the Workforce Investment Act (Pub. L. 105–220);

(ii) A program under section 236 of the Trade Act of 1974 (19 U.S.C. 2296); or

(iii) An employment and training program, other than a job search or job search training program, operated or supervised by a State or political subdivision of a State that meets standards approved by the Governor of the State, including a program under § 273.7(f). Such a program may contain job search or job search training as a subsidiary component as long as such component is less than half the requirement.

(4) *Workfare program* means:

(i) A program under § 273.22; or

(ii) A comparable program established by a State or political subdivision of a State.

* * * * *

(b) *General Rule.* Individuals are not eligible to participate in the Food Stamp Program as a member of any household if the individual received food stamps for more than three countable months during any three-year period, except that individuals may be eligible for up to three additional countable months in accordance with paragraph (e) of this section.

(1) *Countable months.* Countable months are months during which an individual receives food stamps for the full benefit month while not:

(i) Exempt under paragraph (c) of this section;

(ii) Covered by a waiver under paragraph (f) of this section;

(iii) Fulfilling the work requirement as defined in paragraph (a)(1) of this section; or

(iv) Receiving benefits that are prorated in accordance with § 273.10.

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(2) *Good cause.* As determined by the State agency, if an individual would have worked an average of 20 hours per week but missed some work for good cause, the individual shall be considered to have met the work requirement if the absence from work is temporary and the individual retains his or her job. Good cause shall include circumstances beyond the individual's control, such as, but not limited to, illness, illness of another household member requiring the presence of the member, a household emergency, or the unavailability of transportation.

(3) *Measuring the three-year period.* The State agency may measure and track the three-year period as it deems appropriate. The State agency may use either a "fixed" or "rolling" clock. If the State agency chooses to switch tracking methods it must inform FNS in writing. With respect to a State, the three-year period:

(i) Shall be measured and tracked consistently so that individuals who are similarly situated are treated the same; and

(ii) Shall not include any period before the earlier of November 22, 1996, or the date the State notified food stamp recipients of the application of Section 824 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193).

(4) *Treatment of income and resources.* The income and resources of an individual made ineligible under this paragraph (b) shall be handled in accordance with § 273.11(c)(2).

(5) *Benefits received erroneously.* If an individual subject to this section receives food stamp benefits erroneously, the State agency shall consider the benefits to have been received for purposes of this provision unless or until the individual pays it back in full.

(6) *Verification.* Verification shall be in accordance with § 273.2(f)(1) and (f)(8).

(7) *Reporting.* A change in work hours below 20 hours per week, averaged monthly, is a reportable change in accordance with § 273.12(a)(1)(viii). Regardless of the type of reporting system the State agency assigns to potential ABAWDs, the State agency must adhere to the statutory requirements of time-limited benefits for individuals who are subject to the work requirement. The State agency may opt to consider work performed in a job that was not reported according to the requirements of § 273.12 "work."

(8) *Applicability of Food Stamp Act.* Nothing in this paragraph (b) shall make an individual eligible for food stamp benefits if the individual is not otherwise eligible for benefits under the other provisions of these regulations and the Food Stamp Act of 1977, as amended.

(c) *Exemptions.* An individual is exempt from the time limit if he or she is;

(1) Under 18 or 50 years of age or older;

(2) Determined by the State agency to be medically certified as physically or mentally unfit for employment. An individual is medically certified as physically or mentally unfit for employment if he or she:

(i) Is receiving temporary or permanent disability benefits issued by governmental or private sources;

(ii) Is obviously mentally or physically unfit for employment as determined by the State agency; or

(iii) If the unfitness is not obvious, provides a statement from a physician, physician's assistant, nurse, nurse practitioner, designated representative of the physician's office, a licensed or certified psychologist, a social worker, or any other medical personnel the State agency determines appropriate, that he or she is physically or mentally unfit for employment.

(3) Is a parent (natural, adoptive, or step) of a household member under age 18, even if the household member who is under 18 is not himself eligible for food stamps;

(4) Is residing in a household where a household member is under age 18, even if the household member who is under 18 is not himself eligible for food stamps;

(5) Is otherwise exempt from work requirements under section 6(d)(2) of the Food Stamp Act, as implemented in regulations at § 273.7(b); or

(6) Is pregnant.

(d) *Regaining eligibility.* (1) An individual denied eligibility under paragraph (b) of this section, or who did not reapply for benefits because he was not meeting the work requirements under paragraph (b) of this section, shall regain eligibility to participate in the Food Stamp Program if, as determined by the State agency, during any 30 consecutive days, he or she:

(i) Worked 80 or more hours;

(ii) Participated in and complied with the requirements of a work program for 80 or more hours;

(iii) Any combination of work and participation in a work program for a total of 80 hours; or participated in and complied with a workfare program; or

(iv) At State agency option, verifies that the he or she will meet one of the requirements in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii), or (d)(1)(v) of this section, within the 30 days subsequent to application; or

(v) Becomes exempt.

(2) An individual regaining eligibility under paragraph (d)(1) of this section shall have benefits calculated as follows:

(i) For individuals regaining eligibility by working, participating in a work program, or combining hours worked and hours participating in a work program, the State agency may either prorate benefits from the day the 80 hours are completed or from the date of application, or

(ii) For individuals regaining eligibility by participating in a workfare program, and the workfare obligation is based on an estimated monthly allotment prorated back to the date of application, then the allotment issued must be prorated back to this date.

(3) There is no limit on how many times an individual may regain eligibility and subsequently maintain eligibility by meeting the work requirement.

(e) *Additional three-month eligibility.* An individual who regained eligibility under paragraph (d) of this section and who is no longer fulfilling the work requirement as defined in paragraph (a) of this section is eligible for a period of three consecutive countable months (as defined in paragraph (b) of this section), starting on the date the individual first notifies the State agency that he or she is no longer fulfilling the work requirement, unless the individual has been satisfying the work requirement by participating in a work or workfare program, in which case the period starts on the date the State agency notifies the individual that he or she is no longer meeting the work requirement. An individual shall not receive benefits under this paragraph (e) more than once in any three-year period.

(f) *Waivers.*

(1) *General.* On the request of a State agency, FNS may waive the time limit for a group of individuals in the State if we determine that the area in which the individuals reside:

(i) Has an unemployment rate of over 10 percent; or

(ii) Does not have a sufficient number of jobs to provide employment for the individuals.

(2) *Required data.* The State agency may submit whatever data it deems appropriate to support its request. However, to support waiver requests based on unemployment rates or labor force data, States must submit data that relies on standard Bureau of Labor Statistics (BLS) data or methods. A non-exhaustive list of the kinds of data a State agency may submit follows:

(i) To support a claim of unemployment over 10 percent, a State agency may submit evidence that an area has a recent 12 month average unemployment rate over 10 percent; a recent three month average unemployment rate over 10 percent; or an historical seasonal unemployment rate over 10 percent; or

(ii) To support a claim of lack of sufficient jobs, a State may submit evidence that an area: is designated as a Labor Surplus Area (LSA) by the Department of Labor's Employment and Training Administration (ETA); is determined by the Department of Labor's Unemployment Insurance Service as qualifying for extended unemployment benefits; has a low and declining employment-to-population ratio; has a lack of jobs in declining occupations or industries; is described in an academic study or other publications as an area where there are lack of jobs; has a 24-month average unemployment rate 20 percent above the national average for the same 24-month period. This 24-month period may not be any earlier than the same 24-month period the ETA uses to designate LSAs for the current fiscal year.

(3) *Waivers that are readily approvable.* FNS will approve State agency waivers where FNS confirms:

(i) Data from the BLS or the BLS cooperating agency that shows an area has a most recent 12 month average unemployment rate over 10 percent;

(ii) Evidence that the area has been designated a Labor Surplus Area by the ETA for the current fiscal year; or

(iii) Data from the BLS or the BLS cooperating agency that an area has a 24 month average unemployment rate that exceeds the national average by 20 percent for any 24-month period no earlier than the same period the ETA uses to designate LSAs for the current fiscal year.

(4) *Effective date of certain waivers.* In areas for which the State certifies that data from the BLS or the BLS cooperating agency show a most recent 12 month average unemployment rate over 10 percent; or the area has been designated as a Labor Surplus Area by the Department of Labor's Employment and Training Administration for the current fiscal year, the State may begin to operate the waiver at the time the waiver request is submitted. FNS will contact the State if the waiver must be modified.

(5) *Duration of waiver.* In general, waivers will be approved for one year. The duration of a waiver should bear some relationship to the documentation provided in support of the waiver request. FNS will consider approving waivers for up to one year based on documentation covering a shorter period, but the State agency must show that the basis for the waiver is not a seasonal or short term aberration. We reserve the right to approve waivers for a shorter period at the State agency's request or if the data is insufficient. We reserve the right to approve a waiver for a longer period if the reasons are compelling.

(6) *Areas covered by waivers.* States may define areas to be covered by waivers. We encourage State agencies to submit data and analyses that correspond to the defined area. If corresponding data does not exist, State agencies should submit data that corresponds as closely to the area as possible.

Dated: January 9, 2001.

Shirley R. Watkins,

Under Secretary, Food, Nutrition, and Consumer Services.

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Part VIII

Department of Energy

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430
Energy Conservation Program for Consumer Products: Energy Conservation Standards for Water Heaters; Final Rule

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DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket Number EE–RM–97–900]

RIN 1904–AA76

Energy Conservation Program for Consumer Products: Energy Conservation Standards for Water Heaters

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy (DOE).

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE or Department) has determined that revised energy conservation standards for water heaters will result in significant conservation of energy, are technologically feasible, and are economically justified. On this basis, the Department is today amending the existing energy conservation standards for water heaters.

EFFECTIVE DATES: The effective date of this rule and standard is January 20, 2004.

ADDRESSES: You may read copies of the Technical Support Document (TSD) at the DOE Freedom of Information Reading Room, U.S. Department of Energy, Forrestal Building, 1000 Independence Avenue, S.W., Washington, DC. 20585, (202) 586–3142, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. You may obtain copies of the TSD from the Codes and Standards Internet site at: http://www.eren.doe.gov/buildings/codes_standards/applbrf/waterheater.htm or from the U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Mail Station EE–41, 1000 Independence Avenue, S.W., Washington, D.C. 20585. (202) 586–9127.

FOR FURTHER INFORMATION CONTACT: Terry Logee, U.S. Department of Energy, EE–41, 1000 Independence Avenue, S.W., Washington, DC 20585–0121, (202) 586–9127, email: terry.logee@ee.doe.gov or Francine Pinto, Esq., U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, S.W., Washington, DC 20585, (202) 586–7432, email: francine.pinto@hq.doe.gov or Eugene Margolis, Deputy Assistant General Counsel, GC–72, at the same address, (202) 586–9507, email: eugene.margolis@hq.doe.gov.

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I. Introduction

The Energy Policy and Conservation Act, as amended (hereinafter referred to as EPCA or the Act), specifies that any new or amended energy conservation standard the Department of Energy (DOE) prescribes shall be designed to "achieve the maximum improvement in energy efficiency * * * which the Secretary determines is technologically feasible and economically justified." Section 325(o)(2)(A), 42 U.S.C. 6295(o)(2)(A). Furthermore, the amended standard must "result in significant conservation of energy." Section 325(o)(3)(B), 42 U.S.C. 6295(o)(3)(B).

In accordance with the statutory criteria discussed in this notice, DOE is amending the water heater energy efficiency standards, to go into effect on January 20, 2004.

A. Consumer Overview

The Table below summarizes the "vital statistics" of today's typical gas and electric water heater, as well as presenting the cost implications for the average consumer of water heaters after the 2004 water heater standards take effect.

VITAL STATISTICS OF TODAY'S TYPICAL WATER HEATERS

Current statistics	Gas	Electric
Average Price	$383	$380
Annual Utility Bill	$160	$256
Life Expectance	9 years	14 years
Energy Consumption	234 Therms/year	3,459 kWh/year
Statistics In Year 2004:		
Average New Water Heater Price*	$501	$486
Estimated Price Increase (Efficiency Only)	$58	$101
Annual Utility Bill Savings	$12.74	$13.05
Simple Payback Period	3.6 years	7.4 years
Average Net Saving Over Appliance Life	$30	$23
Energy Saving per Year	22 therms	188 kWh

*Includes expected price increases for non-energy efficiency regulations.

Currently, the average typical water heater costs, $380 for electric and $383 for gas. The average annual utility bill for an electric water heater is $256, while a gas water heater costs $160 a year to operate.

The water heater energy efficiency standards we are adopting today will have a positive impact on consumers. Consumers with electric water heaters would save $13.05 per year while those with natural gas water heaters would save about $12.74 per year on average. Of course these savings are not free, consumers will have to pay an average increase of $101 for electric and $58 for gas water heaters. Note that the total average increased cost for electric and gas water heaters are $105 and $118, respectively, due to the phase out of the current insulating foam blowing agent HCFC–141b and the compliance to resist ignition of flammable vapors on gas water heaters voluntarily agreed to between the manufacturers and the Consumer Product Safety Commission. The simple payback for cost increases due to efficiency standards is 7.4 years for electric and 3.6 years for gas water heaters. The lifetime owning cost or life-cycle costs are lower than life-cycle costs on current water heaters by $23 for electric and by $30 for gas water heaters.

The design improvements the Department considered are thicker insulation and heat traps on both gas and electric water heaters and an improved heat exchanger (flue baffle) on gas water heaters. These improvements result in a four percent increase in energy efficiency for electric and an eight percent increase in energy efficiency for gas water heaters. These kinds of improvements are already available on 26 percent of all water heater models. In energy terms, households with electric water heaters will save on average 188 kWh per year and households with gas water heaters will save 22 therms per year of natural gas or propane gas.

The benefits to the nation from this revised energy efficiency standard are also significant with energy savings of 4.6 quads of energy over 26 years. This is equivalent to the total energy consumption of all U.S. homes over a period of 2.8 months. By 2020, the standards will avoid the construction of nine 400 megawatt electric generating plants.

The amended standards in today's rule can be achieved by using HFC–134a, cyclopentane, or HFC–245fa as the blowing agent in the insulation. The 4.6 quads of energy savings will result in cumulative greenhouse gas emission reductions of 152 million metric tons (Mt) of carbon dioxide (CO_2) equivalent, or an amount equal to that produced by 3.9 million cars per year. Additionally, there will be a cumulative reduction of 273 thousand metric tons of nitrogen oxides (NO_X). In total, we estimate the national energy savings to have a positive net present value to American business and industry of $2.02 billion over 26 years.

B. Authority

Part B of Title III of the Energy Policy and Conservation Act, Pub. L. 94–163, as amended by the National Energy Conservation Policy Act, Pub. L. 95–619, the National Appliance Energy Conservation Act, Pub. L. 100–12, the National Appliance Energy Conservation Amendments of 1988, Pub. L. 100–357, and the Energy Policy Act of 1992, Pub. L. 102–486,[1] created the Energy Conservation Program for Consumer Products other than Automobiles. Water heaters are one of the consumer products subject to this program. Section 322(a)(4), 42 U.S.C. 6292(a)(4).

Under the Act, the program consists essentially of three parts: testing, labeling, and Federal energy conservation standards. The Department, with assistance from the National Institute of Standards and Technology (NIST), may amend or establish test procedures for each of the covered products. Section 323(b)(1)(A)–(B), 42 U.S.C. 6293(b)(1)(A)–(B). The test procedures measure the energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use. They must not be unduly burdensome to conduct. Section 323(b)(3), 42 U.S.C. 6929(b)(3). The water heater test procedure appears at Title 10 Code of Federal Regulations (CFR) Part 430, Subpart B, Appendix E.

The Federal Trade Commission (FTC) prescribes rules governing the labeling of covered products after DOE publishes test procedures. Section 324(a). At the present time, there are FTC rules requiring labels for water heaters.

The National Appliance Energy Conservation Act of 1987 prescribed Federal energy conservation standards for water heaters. Section 325(e). The Act provides that the Department shall determine whether amended standards to the existing requirements in Section 325(e) for water heaters are warranted, and issue a Final Rule. Such amendment shall apply to products manufactured three years on or after the date of this Final Rule. Section 325(e)(4)(A).

Any new or amended standard must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. Section 325(o)(2)(A), 42 U.S.C. 6295(o)(2)(A).

Section 325(o)(2)(B)(i), 42 U.S.C. 6295(o)(2)(B)(i) provides that before DOE determines whether a standard is economically justified, it must first ask for comments on a proposed standard. After reviewing comments on the proposal, DOE must determine that the benefits of the standard exceed its burdens, based, to the greatest extent practicable, on a weighing of the following seven factors:

(1) The economic impact of the standard on the manufacturers and on the consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products which are likely to result from the imposition of the standard;

(3) The total projected amount of energy or water savings likely to result directly from the imposition of the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the imposition of the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary considers relevant.

In addition, Section 325(o)(2)(B)(iii), 42 U.S.C. 6295(o)(2)(b)(iii), establishes a rebuttable presumption of economic justification in instances where the Secretary determines that "the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy, and as applicable, water, savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. * * *" The rebuttable presumption test is an

[1] Part B of Title III of the Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act, the National Appliance Energy Conservation Act, the National Appliance Energy Conservation Amendments of 1988, and the Energy Policy Act of 1992 is referred to in this notice as the "Act." Part B of title III is codified at 42 U.S.C. 6291 *et seq.* Part B of Title III of the Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act only, is referred to in this notice as the National Energy Conservation Policy Act.

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alternative path to establishing economic justification.

Section 327 of the Act, 42 U.S.C. 6297, addresses the effect of Federal rules on State laws or regulations concerning testing, labeling, and standards. Generally, all such State laws or regulations are superseded by the Act, unless specifically exempted in Section 327. The Department can grant a waiver of preemption in accordance with the procedures and other provisions of Section 327(d) of the Act. 42 U.S.C. 6297(d).

C. Background

1. *Current Standards.* The existing water heater efficiency standards have been in effect since 1991. Energy efficiency is measured in terms of an energy factor (EF), which measures overall water heater efficiency and is determined by the DOE test procedure. 10 CFR, Part 430, Subpart B, Appendix E. The current water heater efficiency standards are as follows:

- Electric: EF = 0.93–(0.00132 x rated volume)
- Gas-fired: EF = 0.62–(0.0019 x rated volume)
- Oil-fired: EF = 0.59–(0.0019 x rated volume)

where rated volume is the water storage capacity of a water heater in gallons, as specified by the manufacturer.

2. *History of Previous Rulemakings.* On September 28, 1990, DOE published an Advance Notice of Proposed Rulemaking announcing the Department's intention to revise the existing water heater efficiency standard. 55 FR 39624 (September 28, 1990). On March 4, 1994, DOE proposed a rule to revise the energy conservation standards for water heaters, as well as a variety of other consumer products. 59 FR 10464 (March 4, 1994). On January 31, 1995, we published a determination that we would issue a revised notice of proposed rulemaking (NOPR) for water heaters. 60 FR 5880 (January 31, 1995).

The Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1996 included a moratorium on proposing or issuing Final Rules for appliance efficiency standards for the remainder of Fiscal Year 1996. *See* Pub. L. 104–134. During the moratorium, the Department examined the appliance standards program and how it was working. Congress advised DOE to correct the standards-setting process and to bring together stakeholders (such as manufacturers and environmentalists) for assistance. Therefore, we consulted with energy efficiency groups, manufacturers, trade associations, state agencies, utilities and other interested parties to provide input to the process used to develop appliance efficiency standards. As a result, on July 15, 1996, the Department published a Final Rule: Procedures for Consideration of New or Revised Energy Conservation Standards for Consumer Products (referred to as the Process Rule) 61 FR 36974 (July 15, 1996), codified at 10 CFR Part 430, Subpart C, Appendix A.

The Process Rule states that for products, such as water heaters, for which DOE issued a proposed rule prior to August 14, 1996, DOE will conduct a review to decide whether any of the analytical or procedural steps already completed should be repeated. 61 FR 36974, 36982 (July 15, 1996). DOE completed this review and decided to use the Process Rule, to the extent possible, in the development of the revised water heater standards.

We developed an analytical framework for the water heater standards rulemaking for our stakeholders, which we presented during a water heater workshop on June 24, 1997. The analytical framework described the different analyses (e.g., life-cycle costs (LCC), payback, and manufacturing impact analyses (MIA)) to be conducted, the method for conducting them, the use of new LCC and national energy savings (NES) spreadsheets, and the relationship between the various analyses.

We held a workshop on November 9 and 10, 1998, to share the preliminary analysis results. We discussed our methodology for analyzing national energy savings, environmental inputs, consumer sub-group impacts and impacts on utilities including fuel switching. There was also a presentation of the water heater insulation testing by NIST. On July 23, 1999 we held another workshop to present the full results of our engineering and economic analysis. We discussed the comments from the November 1998 workshop and changes we made in our analysis as a result of these comments. On April 26, 2000 we published the notice of proposed rulemaking to amend water heater energy efficiency standards. 65 FR 25042 (April 28, 2000). We held the hearing/workshop to discuss comments to the proposed rule on June 20, 2000.

II. General Discussion

A. Test Procedures

The Act does not allow DOE to set energy standards for a product unless there is a test procedure in place for that product. The Department published a test procedure on May 11, 1998, that revised the first-hour rating of storage-type water heaters, added a new rating for electric and gas-fired instantaneous water heaters and amended the definition of a heat pump water heater. 63 FR 25996 (May 11, 1998). This revision did not change the test method for determining energy efficiency standards.

No one has petitioned DOE indicating the Department's test procedures are inadequate for testing water heaters. Accordingly the Department considers the current Federal test procedures applicable and appropriate for today's Final Rule.[2]

B. Technological Feasibility

The Act requires the Department, in considering any new or amended standards, to consider those that "shall be designed to achieve the maximum improvement in energy efficiency * * * which the Secretary determines is technologically feasible and economically justified." (Section 325 (o)(2)(A)). Accordingly, for each class of product considered in this rulemaking, a maximum technologically feasible (max tech) design option was identified and considered as discussed in the Proposed Rule. 65 FR 25042, 24045 (April 28, 2000).

However, DOE eliminated the heat pump water heater due to issues concerning the practicability to manufacture, install, and service on the scale necessary to serve the relevant market at the time of the effective date of the standard and product utility of these units. We eliminated heat pump water heaters after careful consideration of the current electric resistance and heat pump water heater markets and manufacturing technology, and after applying the factors to be considered in screening design options contained in the Process Rule. We also eliminated gas condensing water heaters because we determined they are not technologically feasible. 10 CFR 430, Subpart C, Appendix A(4)(a)(4) and (5)(b). There is a complete discussion of these conclusions in the proposed rule. 65 FR 25042, 25047–49 (April 28, 2000).

The Department has determined that the electric and gas water heaters considered in today's notice are technologically feasible as required by Section 325(o)(2)(A) of EPCA, as amended. There are some models of these water heaters in the market that meet the new standard levels. Thus, the design options DOE considered are technologically feasible.

[2] In August and September 2000, DOE conducted a certification review of high efficiency electric water heaters at five manufacturers. Based on the review of these manufacturers' laboratory procedures, we believe some clarifications to the water heater test procedure may be needed. We are planning to join GAMA and the manufacturers in their water heater test program to determine what needs to be clarified in the water heater test procedure.

C. Lessening of Utility or Performance of Products

This factor is not easily quantified. However, DOE has considered the effect of thicker insulation which might result in smaller capacity water heaters to be used in small existing spaces which could cause a reduction in first hour rating. A loss of first hour rating would reduce consumer utility. The discussion in the comments on size constraints explains how DOE dealt with this issue. Furthermore, if a certain type of water heater would no longer fit in spaces that it was designed for, we have considered a new class of products. We have included a discussion on new product classes to address this.

1. *Size Constraints.* We addressed size constraints in the proposed rule by estimating approximately 32 percent of electric water heating households and 27 percent of gas water heating households would need to remove the closet door for water heaters with 3 inch thick insulation. Then, we added a cost adjustment of $160 to install new water heaters in these households. Several stakeholders have commented on our estimates of costs and the number of households affected.

The American Gas Association (AGA) requests that DOE address size constraints consistently across electric and gas water heaters. It requested DOE to include the costs shown in the Battelle report that addresses space constraints. (AGA, No. 150 at 5). The Gas Appliance Manufacturers Association (GAMA) supports the Battelle analysis. (GAMA, No. 160 at 4). Battelle provided detailed comments on space constraints associated with larger gas water heaters. Based on a survey of 15 companies, covering areas within 24 states, it determined a range of space impacts on costs and the percentages of homes affected. (Battelle, No. 127 at C–1 to C–5).

Southern Gas Association stated that a survey of its members revealed that 18 percent of single family homes would be unable to fit a 2 inch larger diameter water heater into the existing space. (Southern Gas Association, No. 152 at 4). Alagasco indicated that many of its customers are renters in mid to low-income brackets. The proposed gas water heaters would cause space constraints in many of these homes. (Alagasco, No. 152 at 2). The National Propane Gas Association and Atlanta Gas Light Co. stated that an increase in storage tank size will cause significant and costly installation problems in water heater replacements. (National Propane Gas Association, No. 165 at 2 and Atlanta Gas Light Co., No. 178 at 1). The Oregon Office of Energy (OOE) claims that after installing tens of thousands of high efficiency water heaters in the Pacific Northwest, physically larger tanks do not impose higher installation costs. Drip pans are sized for the larger tanks and water connections are almost universally made with flexible copper tubing that easily accommodates a wide range of tank heights and alignments. (OOE, No. 174 at 3).

To account for size constraints in our revised analysis, we assume space constraints would only apply in those cases where the water heater is installed in a conditioned space, e.g., not in a garage or an unconditioned basement or attic. We also assume this will only apply to small houses or apartments. Therefore, we have excluded houses or apartments with a floor area of more than 1000 square feet. These assumptions are not intended to accurately identify every individual household that would face space constraints when replacing their water heater. Rather this estimate should roughly identify the number of households affected. Since this is based on the Residential Energy Consumption Survey (RECS) '97 data, we have a representative national sample of households. We believe using the RECS '97 database and the assumptions above will give us the best estimate of the impacts of increased water heater size.

In its comments, Battelle also assumed a large fraction of closets are smaller than 22 × 22 inches. Discussions with installers report this is a rare occurrence; they come upon this situation approximately once per month. We also checked the areas served by the gas utilities in the Battelle survey. We found that although 24 states are represented, usually the area served by the utility covered only a very small part of the state. Therefore, we do not believe that this survey is really representative of the entire United States. Consequently, we did not add any extra costs for small closets for gas water heaters. We assumed extra costs for removing and replacing closet doors and door frames for 32 percent of households with electric and 27 percent of households with gas water heaters with 3 inch insulation. See Chapter 9 of the TSD.

In the proposed rule, DOE asked for comments or suggestions to minimize the effects of smaller tanks either by increasing the electric element size from 4.5 kW to 6 kW or by increasing the thermostat setpoint. Several stakeholders opposed larger electric elements. There were no comments on increasing the thermostat setpoint.

The Electric Power Research Institute (EPRI) claims using 6 kW elements is not an option for smaller tanks to provide the consumer utility of larger tanks since these elements are only used in commercial water heaters. They state that it is generally not possible to use 6 kW elements in "residential" water heaters because standard household wiring circuits usually used for water heaters cannot carry a 6 kW continuous load with sufficient safety margin as required by the National Electrical Code. (EPRI, No. 104 at 3). Dominion concurs with EPRI, and states further that there are currently only two models listed in the latest GAMA directory with elements above 4.5 kW, and none greater than 5.5 kW. (Dominion, No. 145 at 4). The National Rural Electric Cooperative Association (NRECA) also opposes the use of larger heating elements. (NRECA, No. 126 at 1–2). Southern Co. and Dominion claim that increased element size will increase peak electric demand on electric utilities and could require new wiring and circuit breakers or electric panels in homes. (Southern Co., No. 142 at 3 and Dominion, No.145 at 3).

We are not including 6 kW elements as a means of compensating for downsized electric water heaters in today's Final Rule. Instead, we have increased the thermostat setpoint to meet the load in those cases where the downsized water heater would be too small to meet the particular requirements of a RECS '97 home. In addition to increasing the thermostat setpoint, we added $106 for the costs of tempering valves and check valves for about fifteen percent of electric and eight percent of the gas water heaters where we had to increase the thermostat setpoint above 140°F. (Generally, water temperatures above 140°F have the potential to cause scalding.) The detailed computer algorithm we used to determine when a tempering valve is needed can be found in the TSD in Chapter 9.

2. *New Product Classes.* During the hearing and in the comments, several comments claimed that tabletop and lowboy water heaters would be unable to fit into existing spaces if their size increased substantially beyond current dimensions. These comments suggested DOE create separate product classes for these water heaters.

GAMA requests DOE to establish a separate product class for lowboy and tabletop water heaters and not to increase the efficiency standards for these products. GAMA states that

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lowboy water heaters must be able to fit under a 36 inch high counter. Therefore, they are 34 inches high or shorter and have a jacket diameter less than 26 inches. GAMA defines tabletop water heaters as having typical dimensions of 36 inches high, 25 inches deep and 24 inches wide. Tabletop water heaters are designed to slide into a kitchen countertop space and provide additional countertop surface area. (GAMA, No. 160 at 4–5). Bradford White supports GAMA's request stating that elimination of these products will cost consumers substantial capital to convert and will impact the replacement market negatively. Lowboy electric models are limited to 34 inches in height and to 26 inches in diameter. (Bradford White, No.175 at 2 and No. 138 at 3). A.O. Smith also recommends a new product class for countertop-type (also known as tabletop) electric water heaters. (A.O. Smith, No.179 at 1). The American Council for an Energy-Efficient Economy (ACEEE) commented that it is not opposed to a new product class for tabletops and lowboys but recommended limiting these classes to a 30 gallon size. (ACEEE, No.170 at 7)

DOE has decided to establish a separate product class for tabletop water heaters due to strict size limitations for these products. However, we have concluded that lowboy water heaters do not have as stringent limitations on geometry as tabletop water heaters. For example, the diameter of the lowboys can be increased. We addressed these size constrained lowboy water heaters by adding extra installation costs, see Section II, General Discussion, Lessening of Utility or Performance of Products, "Size Constraints" in today's rule. GAMA data shows that lowboys make up 18 percent of the electric water heater market and that 38 percent of lowboy shipments are 30 gallon, 48 percent are 40 gallon, and 14 percent are 50 gallon tanks. (GAMA, No. 176 at 3).

In establishing classes of products and accounting for cost increases for a percentage of products which will require space modification, the Department does not believe any model of water heater will become unavailable as a result of thicker insulation. Therefore, DOE has eliminated any degradation of utility or performance in the products in today's Final Rule. In the application for tabletop water heaters, we established a new class with no change in standards because these models cannot be made any larger. In all other applications, we have determined from the GAMA directory, GAMA data on shipments, and from the RECS '97 data that sufficient types and sizes of water heaters exist in the market to satisfy any size constraints encountered.

D. Impact of Lessening of Competition

This factor seeks the views of the Attorney General to determine the potential impacts on competition resulting from the imposition of the proposed energy efficiency standards.

In order to assist the Attorney General in making such a determination, the Department provided the Attorney General with copies of the Proposed Rule and the Technical Support Document for review. In a letter responding to the Proposed Rule, the Department of Justice (DOJ) found only one area of concern regarding any lessening of competition. The area of concern involves the blowing agent for the foam insulation and the possibility that only one chemical, HFC–245fa, could be used and that it is a patented product with only one supplier. This situation led DOJ to conclude "that the proposed standards could have an adverse affect on competition because water heater manufacturers may have to use an input that will be produced by only one source." (DOJ, No. 143 at 1). The DOJ letter is printed at the end of today's rule.

To reduce heat loss from the stored reservoir of hot water, water heaters must have insulation. The choice of insulation is critical to achieving high water heater efficiency at a reasonable cost and essentially all water heaters use foam insulation. A blowing agent is needed to produce the foam insulation and currently all manufacturers are using the chemical HCFC–141b. Unfortunately, HCFC–141b is an ozone depleting chemical and will be phased out in January, 2003. Therefore, the water heater industry, like all other industries that use this chemical, must find and use a replacement chemical.

Options for non-ozone depleting blowing agents include HFC–245fa, HFC–134a, carbon dioxide (CO_2)/Water, pentane/cyclopentane and HFC 365mfc, as well as potential blends, or combinations, of these blowing agents. The U.S. Environmental Protection Agency's (EPA) Clean Air Act guides the U.S. appliance industry on replacement of HCFC/CFC blowing agents. The EPA's Significant New Alternatives Program (SNAP) approves chemicals and technologies that can be used to replace ozone depleting chemicals. Of the options listed above, all except HFC–365mfc have been approved by the EPA/SNAP.

Initially, the appliance industry, including water heater manufacturers, had leaned toward adopting HFC–245fa, which performs similarly to HCFC–141b but at a much higher material cost. HFC–245fa has a lower manufacturing conversion cost than some of the other alternatives, such as pentane/cyclopentane. Given the likelihood HFC–245fa would be adopted by manufacturers, the Department used the performance characteristics and increased material and manufacturing costs associated with HFC–245fa to estimate the impact the new blowing agent would have on consumers and manufacturers. This was not to imply HFC–245fa was the only path to meeting the standard and DOE believes that at least three alternative blowing agents are available to use in meeting the standards adopted in today's Final Rule. See the following section for the analysis we used to support our conclusion.

1. *Increased Costs Due to a Single Source of Supply for HFC–245fa.* In addition to the Attorney General's letter on the anti-competitive effects of the proposed rule, we received several comments from stakeholders. They were concerned about cost increases due to a single source supplier for HFC–245fa and about the unavailability of the material until July, 2002 or later.

The AGA position is that DOE should only consider water blown foams for its analytical baseline and standard level analysis. AGA pointed out that the blowing agent HFC–245fa has not yet been demonstrated in manufacture of water heaters in the U.S. AGA claimed that, due to uncertainty in availability to manufacturers and a sole source U.S. supplier, DOE should consider only those blowing agents that are available and proven for water heater manufacture. (AGA, No. 150 at 5–7).

To address concerns about the performance of alternative blowing agents, we tested three sets of four electric water heaters with different foam insulations. The purpose of these tests was to compare the performance of the current foam insulation, HCFC–141b, with water blown and HFC–245fa blown foam insulation. The results of the NIST tests showed that water heaters insulated with HFC–245fa had the same energy factors as those insulated with HCFC–141b. Water heaters insulated with water blown foam insulation had energy factors about two percent lower than tanks insulated with HCFC–141b. We believe the results of these tests demonstrate that the blowing agents HFC–245fa and water can be used to insulate water heaters and that the insulation performance is the same with HFC–245fa and only slightly reduced with water blown foam. (Performance Testing of Alternative Blowing Agents for Foam Insulation of Residential Water Heaters, Fanney et al., Proceedings of the AMC, 1999).

The DOJ urges DOE to account for the impact of a single source supplier on competition, and to consider altering the standard so manufacturers may meet the standard for all affected models using other blowing agents. DOJ further noted that some manufacturers have suggested that DOE underestimated the performance capabilities of alternative blowing agents. If this is true, manufacturers may in fact be able to comply with the proposed standard while using water-based blowing agents. (DOJ, No. 143 at 1–2).

Stepan is concerned that the proposed standards would require foam suppliers to use HFC–245fa as the blowing agent. This raises an issue about relying on a sole source supplier for an efficiency standard, since Honeywell maintains the exclusive North American rights to its manufacture and sale. (Stepan, No. 123 at 1–2). APGA claims the reliance on insulation technology licensed to a single company raises new issues and antitrust concerns and may be contrary to the statute. (APGA, No. 167 at 2).

To address these comments, we conducted additional engineering cost analyses with HFC–245fa, HFC–134a and cyclopentane as the blowing agent in the insulation. An April 7, 2000, Bayer press release states most appliance manufacturers in North America are considering either HFC–245fa or HFC–134a. Cyclopentane is not considered favorably because of the capital investment required to handle cyclopentane safely (cyclopentane is highly flammable). There are also high costs because the factory cannot produce water heaters while converting factory equipment to a cyclopentane system. However, appliance manufacturers are independently deciding which blowing agent to select. Switching to either HFC–245fa or HFC–134a involves capital costs. According to industry and Bayer research, HFC–245fa exhibits the best insulation value of the two blowing agents—roughly equal to HCFC–141b—though it is more costly per pound. HFC–134a demonstrates an insulation value approximately ten percent lower than HCFC–141b but has a lower per-pound cost than HFC–245fa.

We have examined, through the engineering analysis, the impact on product design and costs using two of the other blowing agent options, HFC–134a and cyclopentane, to achieve a similar energy factor as the proposed levels for HFC–245fa. See Table 1 below. We included the ten percent performance reduction for HFC–134a and an estimate of $7 per unit for the capitalization costs of cyclopentane in our engineering analyses. These analyses show that energy factors are the same for the three blowing agents. Costs for all design options are within a few dollars for HFC–245fa, HFC–134a and cyclopentane. While we have not examined every possible blowing agent option, we conclude that at least two additional options to HFC–245fa can be used to achieve similar performance for similar costs. The blowing agent performance characteristics and test results using HFC–245fa, HFC–134a and cyclopentane blown foam to evaluate design options can be found in Chapter 3.4.1 of the TSD.

Table 1 shows the trial standard levels, design options, energy factor and installed costs for the three alternative blowing agents, HFC–245fa, HFC–134a and cyclopentane. Note the energy factors are the same for all trial standard levels and all blowing agents. There are small differences in costs; HFC–245fa is the cheapest blowing agent, HFC–134a costs about $2/unit more than HFC–245fa, while cyclopentane is the most expensive blowing agent costing about $9 more per installed electric and $11 more per installed gas water heater.

TABLE 1.—ENGINEERING RESULTS FOR ALTERNATIVE BLOWING AGENTS

Trial standard level	Design options	Energy factor	Installed costs
HFC–245fa:			
1	Electric: Heat Traps + Tank Bottom Insulation	0.88	367.52
	Natural Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	431.57
2	Electric: Heat Traps + Tank Bottom Insulation + 2 Inch Insulation	0.89	403.69
	Gas: Heat Traps + Flue Baffles (78% RE) + 2.5 Inch Insulation	0.60	456.79
3	Electric: Heat Traps + Tank Bottom Insulation + 2.5 Inch Insulation	0.90	440.69
	Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	431.57
4	Electric: Heat Traps + 3 Inch Insulation + Plastic Tank	0.91	547.04
	Gas: Heat Traps + Flue Baffles (80% RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	0.71	751.31
HFC–134a:			
1	Electric: Heat Traps + Tank Bottom Insulation	0.87	363.06
	Natural Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	428.65
2	Electric: Heat Traps + Tank Bottom Insulation + 2 Inch Insulation	0.89	391.60
	Gas: Heat Traps + Flue Baffles (78% RE) + 2.5 Inch Insulation	0.60	454.39
3	Electric: Heat Traps + Tank Bottom Insulation + 2.5 Inch Insulation	0.90	428.01
	Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	428.65
4	Electric: Heat Traps + 3 Inch Insulation + Plastic Tank	0.91	531.45
	Gas: Heat Traps + Flue Baffles (80% RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	0.71	749.41
Cyclopentane:			
1	Electric: Heat Traps + Tank Bottom Insulation	0.88	368.11
	Natural Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	432.14
2	Electric: Heat Traps + Tank Bottom Insulation + 2 Inch Insulation	0.89	394.70
	Gas: Heat Traps + Flue Baffles (78% RE) + 2.5 Inch Insulation	0.60	456.10
3	Electric: Heat Traps + Tank Bottom Insulation + 2.5 Inch Insulation	0.90	428.79
	Gas: Heat Traps + Flue Baffles (78% RE) + 2 Inch Insulation	0.59	432.14
4	Electric: Heat Traps + 3 Inch Insulation + Plastic Tank	0.91	529.79
	Gas: Heat Traps + Flue Baffles (80% RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	0.72	749.25

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2. *Availability of HFC–245fa.* Bradford White said it has given careful consideration to all of the options available for blowing agents. However, since HCFC–141b may be in limited supply early in 2002 because of facility phase-outs and with the uncertainty in availability of HFC–245fa, Bradford White has no alternative but to pursue water blown insulation. (Bradford White, No. 175 at 1–2). Stepan has concerns about the overall availability of HFC–245fa. (Stepan, No. 123 at 1–2).

Honeywell indicated that over six years and $30 million has been invested in the development of HFC–245a. Honeywell has received all the necessary U.S. regulatory approvals and is constructing a commercial manufacturing facility at its Geismar, Louisiana location. The facility is expected to be online by July 1, 2002. Honeywell expects ample capacity to be available to water heater manufacturers. (Honeywell, No. 114 at 2).

The OOE claims adequate quantities of HFC–245fa are available now for optimizing production processes. (OOE, No. 174 at 3). The ACEEE states DOE has previously decided, in the refrigerator standard rulemaking, that HFC–245fa will be available and can be an energy-efficient and cost effective blowing agent. DOE should make the same decision here. ACEEE suggests DOE provide for manufacturers to petition for relief if HFC–245fa does not become available. (ACEEE, No. 170 at 8). Southern Company also asks why DOE made no provisions for an alternative if the blowing agent does not become available. (Southern Company, No. 142 at 3).

DOE has investigated the issue of the availability of HFC–245fa. Announcements in The Advocate, a Baton Rouge, LA newspaper (May 11, 2000 and October 6, 2000), indicate that Honeywell is proceeding to secure the necessary permits to build the HFC–245fa plant. Furthermore, Vulcan Chemicals is also planning to build a plant in Geismar, LA to make pentachloropropane, one of the chemicals used in the manufacture of HFC–245fa. DOE concludes that HFC–245fa will be available as planned and therefore does not believe it needs to make any provision in today's rule in the event of HFC–245fa unavailability. If Honeywell does not build its plant or if the plant is delayed, DOE believes there are still three or more alternative blowing agents for water heater manufacturers to use, *i.e.*, water, cyclopentane, HFC–134a or blends of these three.

E. Economic Justification

As noted earlier, Section 325(o)(2)(B)(i) of the Act provides seven factors to be evaluated in determining whether an energy conservation standard is economically justified. Since there were significant comments from the June 20, 2000, hearing, and new data from RECS '97 and AEO 2000, DOE has developed a revised water heater analysis. Specific revisions to our analysis methods are discussed in Section III, Methodology.

F. Other Factors

This provision allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to be relevant. Section 325(o)(2)(B)(i)(VI), 42 U.S.C. 6295(o)(2)(B)(i)(VI). The Secretary has decided that no other factors need to be considered in this rulemaking.

III. Methodology

DOE has made some minor changes to the engineering and LCC analysis for this Final Rule. We discuss these changes below in response to the comments on markup, the WATSIM computer model, blowing agents and blended fuel prices. Additionally, the household characteristics data used in the analysis were updated from the 1993 RECS data to the 1997 RECS data (except for oil-fired water heaters). We used the energy price projections from the AEO 2000 as well.

A. Engineering

DOE is continuing to use the WATSIM and TANK computer models in its analysis to evaluate the energy factor of water heaters with various design options. These models were discussed in the engineering methodology section of the proposed rule. 65 FR 25042, 25052–53 (April 28, 2000). We adjusted the manufacturers' costs and the installation costs to account for comments to the proposed rule. These changes resulted in reduced manufacturers' costs for gas water heaters and slightly higher retail costs for electric water heaters.

Further testing at NIST and reverse engineering of a water heater at the Lawrence Berkeley National Laboratory (LBNL) allowed DOE to fully validate WATSIM. These tests revealed that WATSIM and NIST results for the energy factor of a high efficiency electric water heater were the same. See the TSD, Chapter 8.2.4

1. *Water Heater Markup.* DOE's calculation of gas water heater markup was a major concern to stakeholders. There was wide spread criticism that the markup for gas water heaters we derived in the proposed rule was too low to support any manufacturer's production of that product.

The AGA claims DOE's approach to calculating markups has been roundly criticized by stakeholders throughout the development of the TSD and supporting analysis, and is unaware of any comments supporting DOE's analysis. AGA claims that DOE has provided no consistency checks for this and other markups to determine their validity, in spite of criticism it has received on its analytical results, and has failed to postulate a market mechanism or economic model to justify its numbers. Furthermore, AGA commented that manufactured cost and retail price are not independent random variables, and that DOE did not correlate its cost and price data. This resulted in 21 percent of the RECS '93 households being constrained to 0 markup. AGA believes DOE should adopt the Battelle markups. (AGA, No. 150 at 8–9). Laclede Gas claims DOE should not limit the markup algorithm to prevent negative markups. (Laclede Gas, No. 148 at 9).

To address the comments about correlating prices and costs, DOE has changed its LCC analysis to use correlated retail prices and manufacturer costs, *i.e.*, high prices correlate with high costs. This has eliminated the negative values of markup which occurred in the analysis for the proposed rule.

GAMA and Bradford White claim the markup for gas water heaters combines 4-inch flue model costs with 3-inch flue model prices. According to GAMA, using the DOE database and only 4-inch flue models, the markup increases from 1.22 to 1.5. (GAMA, No. 117 at 2–3 and Bradford White, No. 108 at 7). Dominion Virginia Power states that the DOE gas water heater base line assumes a 4 inch flue yet the typical 40 gallon gas water heater uses a 3 inch flue. (Dominion Virginia Power, No. 145 at 6).

We separated the retail prices for 3 inch and 4-inch flues on gas water heaters. We had our consultant estimate the incremental cost difference between manufacturing water heaters with 3 inch and 4 inch flues. We then subtracted this cost from the manufacturer cost supplied by GAMA for water heaters with 4 inch flues. Our analysis now accounts for these price and cost differences as recommended. Since the retail prices were not changed, this increased the markup on the baseline units in the LCC, as well as the markup applied to the various design options.

Southern Company and the Energy Market and Policy Analysis group claim

the price database is too limited for the type of analysis conducted by DOE. Specifically, Southern Company claims the database has a geographic bias, citing the high number of sample points from Washington and Oregon. It claims that over 23 percent of the sample points are from these two states, which represent slightly more than three percent of the U.S. population. Southern Company suggests using a combined markup for gas and electric water heaters. (Southern Company, No. 142 at 1–2 and Energy Market and Policy Analysis, No.151, at 5–6).

DOE's retail price database uses data points broadly distributed over the 10 Census regions of the U.S., and DOE does not believe the database has a geographic bias. Only 10.9 percent of the water heaters in the database are from the Pacific Region (see Table 5.3 in the TSD). The Department used a slightly higher proportion of water heaters from the northwest to ensure an adequate representation of high-efficiency units. DOE will not be using a combined markup, since each fuel type must be evaluated individually. The design option approach requires distinct costs for each fuel type.

Battelle estimated the cost of materials and labor for the design options under consideration and applied standard industry markup factors to determine the cost to the consumer. Battelle assumed standard industry markup factors were 1.5 for the manufacturer, 1.2 for the distributor, and 1.4 for the retailer. Thus, the overall markup factor is 2.52 (1.5 x 1.2 x 1.4 = 2.52). Therefore, to determine the cost to the consumer, the manufacturer's materials and labor costs for a design option are multiplied by 2.52.

To validate this standard approach for gas water heaters, Battelle conducted a tear down analysis on six water heaters varying in size among 30, 40, 50, and 75-gallon capacities. BDI Design for Manufacture software was used to catalog the components and estimate materials and labor costs for each water heater. The materials and labor costs for the 30, 40, 50, and 75-gallon baseline gas water heaters were $80.83, $86.06, $90.95, and $139.77, respectively. The 40-gallon gas water heater cost of $86.06 is in excellent agreement with the value of $87.51 supplied by GAMA to DOE. (Battelle, No. 106 at 1–2).

DOE compared its manufacturer markup to Battelle's standard markup factor. This is the total manufacturer cost divided by the sum of the materials and labor costs for 40 gallon gas-fired water heaters.

Battelle: $133.78/$86.06 = 1.55

DOE: $133.78/($75.07 + $10.74) = 1.56

Therefore the manufacturing markup is essentially identical.

The ACEEE claims the Battelle markups applied to the GAMA manufacturing costs yield incredibly high retail prices. ACEEE concludes the manufacturers' costs are too high and the markups may be too low on some water heaters. (ACEEE, No. 170 at 9). The OOE and the Northwest Power Planning Council (NWPPC) do not accept GAMA's manufacturing costs because the typical margins in the Pacific Northwest are $30–$40 for high efficiency water heaters. (OOE, No.174, at 2 and NWPPC, No.163, at 2).

In order to address the concerns about manufacturers' costs, DOE adjusted the higher range of the manufacturer's cost distribution, to match the average of the low range of the manufacturers' cost distribution. We also applied this correction to the incremental manufacturer costs for heat traps and increased insulation. We did this to bring manufacturers' costs in line with known appliance manufacturing costs, derived from publicly available SEC reports. It also ensures consistency within the data. Since the overall retail prices remain constant, the change eliminates the occurrences of unreasonably low markups on the baseline gas and electric water heaters. This reduced the average values of baseline costs for electric and gas water heaters by $9.55 and $6.22 respectively.

Battelle claims that when its baseline materials and labor costs were used in conjunction with the DOE database of retail water heater prices, the average overall markup factor for gas water heaters came out to be 2.44. This is in excellent agreement with the assumed standard markup factor of 2.52 stated previously. (Battelle, No. 106 at 1–2). Southern California Gas Co. agrees with Battelle's markup factor of 2.52. (Southern California Gas, No. 181, at 2). The American Public Gas Association (APGA) claims there is an obvious problem with the markup analysis. It suggests DOE approach this matter with real-world prices and manufacturers' costs. (APGA, No. 167 at 2).

In the DOE analysis, the overall markup factor consists of manufacturer markup and distributor/retailer markup. From the LCC analysis, we have an overall markup of 1.59 for gas and 1.94 for electric water heaters. These markups differ from the Battelle markups in an important respect. Battelle assumes that the water heater market is characterized by large distributors selling to retailers or plumbers. DOE has determined that less than 50 percent of the water heater market operates that way. Many water heaters are sold directly to retail by large cash and carry distributors or they are sold to builders or large plumbing companies by large distributors. Therefore, the standard markup factors are not correct for the residential water heater market.

2. *WATSIM Computer Model for Electric Water Heaters.* DOE received several comments about the WATSIM computer model for electric water heaters. Most comments stated that WATSIM does not predict the energy factor of electric water heaters accurately. Other comments asserted that DOE needed to test water heaters to compare actual performance to WATSIM predictions.

GAMA claims it has no confidence that WATSIM is properly predicting the energy factors resulting from the various insulation options. (GAMA, No.160 at 1–3). Dominion states that DOE should verify the accuracy of calculated energy factors for design options with results from commercially available products. (Dominion, No. 145 at 3). EPRI claims WATSIM can predict energy consumption of electric water heaters typically within 3–6 percent accuracy. For the type of analysis represented by DOE energy factor tests, the accuracy would typically be around the 3–4 percent range. (EPRI, No.104 at 1). Southern Company supports EPRI's remarks. (Southern Company, No. 142 at 2).

At the June 2, 1997, Water Heater Workshop, the Department sought comments on the selection of appropriate engineering models such as WATSIM and TANK to use in the Engineering Analysis. Most of the stakeholders' comments indicated no objections related to the use of the simulation models for the analysis. The following participants supported the use of WATSIM and TANK: C. Hiller (EPRI), J. Ranfone (AGA), J. Langmead (Water Heater Consortium), S. Nadel (ACEEE), R. Hemphill (Gas Technology Institute (GTI)). There were no comments that indicated WATSIM and TANK were incorrect to use.

Bradford White says DOE must test products to understand the actual performance of cavity increases and new blowing agents. (Bradford White, No.108 at 2–6). GAMA concurs, saying DOE has relied too heavily on computer modeling to establish insulation performance when actual testing of water heaters would have provided more precise results. GAMA further states that, "DOE is expected to test water heaters to exclude the energy-saving benefits of design options when

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the agency can do so at reasonable cost, rather then rely on computer modeling," 998 F. 2d 1041 (D.C. Cir. 1993). Bradford White further comments that DOE must test at least three storage capacities affected by the standard. (Bradford White, No.138 at 1).

We reviewed the court case that GAMA cited in its comments. The Court acknowledges that computer modeling is "a useful and often essential tool for performing the 'Herculean labors'" imposed by Congress. *Gas Appliance Manufacturers Association* v. *Department of Energy*, 998 F. 2d 1041, 1045 (D.C. Cir. 1993). The Court also stated that when computer modeling is used, an agency must sufficiently explain the assumptions and methodology so that there is a rational connection between the factual inputs, modeling assumptions, modeling results and conclusions drawn from these results. *Id.* at 1046. (GAMA, No. 160 at 1)

DOE provided a detailed explanation of the model, its assumptions, and its results in the proposed rule and accompanying Technical Support document. In the proposed rule, we stated that comparisons of the WATSIM prediction to the NIST test result for an electric water heater with an efficiency at the level proposed was within 0.002 EF. 65 FR 25042, 25053 (April 28, 2000). The detailed description of the WATSIM model and the assumptions DOE used to model electric water heaters are provided in the TSD for the proposed rule in Chapter 8.2.4.1.

In response to these comments on the proposed rule, LBNL tore down (reverse engineered) one of the American Water Heater Company's (American) 0.93 EF products to assess what design options were used. In addition, NIST tested the two units of the American model that LBNL tore down. Using the reverse engineering data in the WATSIM model and comparing to the NIST test results, we obtained results from WATSIM that were within 0.006 EF of the NIST results. Therefore, WATSIM has been validated at the efficiency levels and with the types of design options that our analysis is using. See Chapter 8.2.4.1 in the TSD. Consequently, we believe WATSIM correctly predicts the efficiency of electric water heaters.

DOE did not rely on computer modeling alone to demonstrate the performance of higher efficiency electric water heaters. In the fall of 1999, NIST tested five higher efficiency electric water heaters, one model from each manufacturer. In the fall of 2000, NIST tested six tanks, a sample of two tanks of three models of electric water heaters. None of these models achieved their rated efficiency as shown in the GAMA directory. However, several of these models performed at or above the standard level adopted in today's rule. Therefore, at this time, and while we are still examining this issue, we have concluded that the WATSIM model correctly accounts for the maximum technically feasible design options for electric resistance water heaters and continue to use it, without modification for this rulemaking. Furthermore, we believe we have performed sufficient testing to demonstrate that the minimum efficiency levels can be met.

3. *Pipe Insulation*. In our proposed rule, the Department did not consider insulation on water heater inlet and outlet pipes. In recent visits to the five water heater manufacturers, we discovered that four manufacturers ship the tanks with pipe insulation for their high efficiency water heaters. The DOE water heater test procedure allows water heaters to be tested with pipe insulation if the manufacturer ships the tank with pipe insulation. To determine the impact of pipe insulation on our analysis, we modeled water heaters with and without pipe insulation in WATSIM. These results showed that pipe insulation in combination with heat traps improves the energy factor by 0.005 EF. We performed tests at NIST with and without pipe insulation on three different models of electric water heaters equipped with heat traps, and the average increase in the energy factor with pipe insulation was 0.007. Since both the WATSIM computer model and NIST testing indicate the effects of pipe insulation combined with heat traps is small, we have not included the effects of pipe insulation in our analysis. Furthermore, since pipe insulation must be applied during water heater installation, we are not sure how often it is used. Information from a small survey of installers indicated that about 50 percent do not install the pipe insulation.

4. *Blowing Agent Conductivity*. Stepan believes HFC–245fa may not achieve the energy performance results predicted in the proposed rule, and that water blown foams may actually exceed modeled predictions. Stepan claims it measured initial k-factors for water blown foam as low as 0.175 BTU/hr-°F-in. (Stepan, No. 123 at 2–3). The NWPPC suggests DOE recalculate the LCC using the water blown foam k-factors given at the workshop. (NWPPC, No. 163 at 3–4).

For cost information, Honeywell, the licensee to manufacture HFC–245fa in the U.S., provided estimates of HFC–245fa costs. For efficiency data, we used published laboratory measurements of physical parameters but we derated these conductivities by eleven percent to account for losses of insulation effectiveness due to the foaming process and modeling assumptions. In order to keep the baseline efficiency (those with HCFC–141b insulation) and the energy use characteristics of water heaters with HFC–245fa insulation the same, we modeled them with appropriately thicker insulation. We also increased the amount and cost of steel used for the water heater jacket in addition to adding the extra volume and cost of insulation.

5. *Analytic Baseline*. The current baseline is for water heaters insulated with HCFC–141b and without any design to prevent the ignition of flammable vapors on gas water heaters. In order to analyze separately the effects of energy efficiency standards from the effects of EPA actions to phase out the HCFC–141b blowing agent or of the CPSC actions to make gas water heaters more resistant to ignition of flammable vapors, DOE has developed an "analytic baseline" concept. This concept assumes that by 2003 and before the energy efficiency standards become effective, the actions of these other Federal agencies will have taken effect. To meet these other agency's requirements, manufacturers will have created new designs and made other changes to the production of water heaters. The cost estimates of these production and design changes are included in the analytic baseline. Several comments state that DOE should have included different designs or production changes in its analytic baseline. The analytic baseline is used in the engineering and LCC analyses.

APGA claims manufacturers would use heat traps to meet the baseline standards in 2003. Furthermore, the DOE analytic baseline overstates the value of raising the standard. (APGA, No. 21 at 2 and No. 167 at 2). AGA suggests DOE should only consider water blown foam for its analytical baseline. AGA suggests that manufacturers will use heat traps to add the 0.01 EF needed to meet the current standards with water blown insulation after 2003. (AGA, No. 150 at 5). GTI claims DOE has defined a virtual baseline water heater that makes it easier to justify added insulation. (GTI, No. 141 at 4). The Southern Gas Association's experience with noisy heat traps led them to discontinue using heat traps when installers began removing the heat traps during water heater installation. (Southern Gas Association, No. 152 at 3).

DOE does not believe heat traps would be the only design option manufacturers might use to meet the current standard when the HCFC blowing agent is phased out. When asked, during the manufacturer interviews, none of the manufacturers indicated they were limited to heat traps as the only design option.

DOE also does not know what blowing agent any particular manufacturer would use. We believe that manufacturers will likely choose different blowing agents or use mixtures of blowing agents based on what they believe to be the best business decisions for them.

B. Life-Cycle Costs

As discussed in the proposed rule, DOE used new analytical tools in this rulemaking. We used a spreadsheet model to calculate LCC and payback. 65 FR 25042, 25059–64 (April 28, 2000). In the LCC spreadsheet model, we use Microsoft Excel for Windows 95, combined with Crystal Ball (a commercially available software program) so we can use actual distributions of input variables. The LCC outputs from this program are a range of LCCs and the fraction of the population that will benefit from energy efficiency standards.

1. *Blended Natural Gas and Propane Fuel Costs*. In the LCC analysis for the proposed rule, DOE used a gas price composed of approximately ten percent propane and 90 percent natural gas. Many gas utilities and a gas utility association objected to this approach.

AGA and GTI insist that we use natural gas costs when evaluating gas water heaters, not the blended fuel costs, because our blended fuel costs make natural gas prices ten percent higher. (AGA, No. 150 at 7 and GTI, No. 141 at 4). ACEEE claims a blended price is appropriate if the standard applies equally to both fuels. (ACEEE, No. 170 at 10). Dominion stated that a blended propane and natural gas price will artificially increase savings for natural gas equipment because propane has a higher price. (Dominion, No. 145 at 7).

DOE agrees that use of blended fuel costs is inappropriate when calculating gas water heater life-cycle-costs and national net present value, therefore, DOE has separated natural gas and propane water heaters and has considered each of these fuels separately in the LCC. To do this, DOE asked its consultant to develop a manufacturing cost for propane water heaters from the GAMA manufacturing cost data for natural gas water heaters. We estimated the retail price distribution for liquid petroleum gas water heaters from the manufacturers' costs and the markup for natural gas since there were not enough propane gas water heater prices in the price database.

During the time from the water heater hearing/workshop on the proposed rule until publication of this Final Rule, natural gas prices have risen dramatically for many consumers. DOE has investigated this increase to determine if these price increases might continue into the near future because increased gas prices would mean larger LCC savings and earlier paybacks for more energy efficient water heaters. The EIA has determined natural gas demand has increased in 2000 due to several factors including new gas-fired electric generators and new home construction. Natural gas prices will continue at higher levels than recent years but will return to more normal levels after the winter of 2000–2001 because the new gas wells should be in production by then. The AEO 2000 does not forecast any long term increase in gas prices.

2. *Percent of Consumers Benefitting from Standards*. EEI and Dominion claim the fraction of consumers benefitting from the standard level (74 percent for electric, 87 percent for natural gas) is too low for minimum efficiency standards. EEI and Dominion recommend DOE accept only those standard levels that will provide benefits to at least 90 percent of the population. (EEI, No.124 at 2 and Dominion, No. 145 at 2). Energy Market and Policy Analysis states that DOE overestimates the percentage of winners and underestimates the losers because it ignores some costs, uses high estimates of future electricity prices, and uses low discount rates. (Energy Market and Policy Analysis, No. 151 at 2).

Although ACEEE admits the two percent band of insignificance is arbitrary, it claims this is a very useful concept. ACEEE claims that life cycle costs probably must differ by $100 or $10/year before they are significant. (ACEEE, No. 170 at 11).

The Act requires the Department to consider life-cycle-cost as one of the seven factors in determining economic justification. In determining economic justification, the Secretary shall determine whether the benefits of a standard exceed the burdens. Life-cycle-cost is just one of the factors to be considered and there is no mathematical formula for weighing the benefits and burdens of the various factors. There are also no mathematical thresholds for life cycle cost as implied by EEI and the Energy Market and Policy Analysis. Furthermore, it can be argued that the Act, in requiring DOE to set national standards that maximize energy savings for appliances where there will obviously be regional differences in usage and energy costs, expected there would be some consumers with higher life cycle costs. Based on these arguments, the Department strongly disagrees with EEI and the Energy Market and Policy Analysis comments.

The Department has used the two percent band of insignificance as an indicator of the levels of LCC savings or costs where consumers could appreciate savings or suffer real loss. DOE uses the percent of households benefitting and the band of insignificance to help it weigh the LCC effects and in its consideration of the benefits and burdens of these amended standards.

C. Manufacturing Impact

We use the Government Regulatory Impact Model (GRIM) to determine the manufacturing impacts. The analysis methodology is discussed in the proposed rule and the TSD. 65 FR 25045, 25069–71 (April 28, 2000). The manufacturing impact analysis estimates the financial impact of standards on manufacturers, as well as the impacts on competition, employment, and manufacturing capacity. We used the GRIM spreadsheet model to perform an industry cash flow analysis.

D. Energy Savings and Net Present Value

DOE uses a variant of the Energy Information Administration (EIA)'s National Energy Modeling System, the National Energy Modeling System-Building Research and Standards, called NEMS-BRS, for the utility and environmental analyses, together with some scaling and interpolation calculations.[3] The NEMS-BRS permits the modeling of interactions among the various energy supply and demand sectors and the economy as a whole, so it produces a sophisticated picture of the effects of appliance standards. EEI claimed that DOE does not account for the effects of electricity deregulation in its analysis. (EEI, No. 124 at 2). The effects of deregulation are built into the NEMS-BRS 2000 model.

IV. Discussion of Comments

We received numerous comments from gas utilities and other gas

[3] For more information on NEMS, please refer to the National Energy Modeling System: An Overview 1998. DOE/EIA–0581 (98), February, 1998. DOE/EIA approves use of the name NEMS to describe only an official version of the model without any modification to code or data. Because our analysis entails some minor code modifications and the model is run under various policy scenarios that are variations on DOE/EIA assumptions, the name NEMS–BRS refers to the model as used here. BRs is DOE's Building Research and Standards office.

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consumers, supporting the AGA position and the Battelle analyses. We appreciate these comments and we believe we have covered their concerns in our responses to the comments from the Gas Technology Institute (GTI; formerly GRI), AGA, Battelle, and others in our responses to comments on markups, venting, and size constraints.

A. Venting of Gas Water Heaters

Venting of gas water heaters has been an issue throughout the water heater rulemaking. In our proposed rule, we advocated a standard level that included an increase in the recovery efficiency (RE) to 78 percent from the current 76 percent. Most gas utilities and manufacturers are concerned about the reduction in the margin of safety regarding venting system corrosion with this two percent increase in RE. To make this discussion about venting easier to follow, we have separated the issue into the following subtopics: safety, the National Fuel Gas Code (NFGC) venting tables, Type B vent connectors, costs, and direct vent applications.

1. *Safety.* AGA believes DOE is incorrect in its analysis concerning venting systems for water heaters with RE above 76 percent. AGA states DOE can resolve this issue of vent system modification by one of the following:

- By fully accounting for the vent system costs as reflected in the Battelle analysis;
- By determining that the comments concerning venting integrity and safety beyond its current analysis approach are without merit; and
- By determining that safety concerns are insignificant or the expected benefits of the standard outweigh this safety consideration as required under the process rule.

AGA further requests DOE to explicitly state its determination and its underlying rationale if the second or third option is chosen. AGA reiterates its position that DOE should not promulgate a standard that subjects consumers to a potential increase in safety risk. (AGA, No. 150 at 3–5). AGA and the Atlanta Gas Light Co. believe that DOE has not considered the retail cash and carry market where needed vent system upgrades are unlikely to occur. (AGA, No 150 at 4 and Atlanta Gas Light Co., No. 178 at 2).

Alagasco stated that the ability of gas water heaters to deliver outstanding economy, performance and environmental benefits is dependent on adequate margins of error in critical subsystems like venting, gas piping, combustion air and clearances. The overall utility of gas water heating is a function of proper installation. (Alagasco, No. 162 at 1). The New England Gas Association and Atlanta Gas Light Co. believe increased gas water heater efficiency from improved flue loss efficiency can lead to increased condensation and chimney degradation. (New England Gas Association, No. 139 at 2–3 and Atlanta Gas Light Co., No. 178 at 2). The NYSEB, National Propane Gas Association, Atlanta Gas Light Co, and Southern California Gas Co. state that DOE's proposal reduces the margin of error for installations of gas water heaters in retrofits. The National Propane Gas Association adds that existing vent systems are more likely to develop condensate problems and vent failures. (NYSEB, No. 164 at 1, National Propane Gas Association, No. 165 at 2, Atlanta Gas Light Co., No. 178 at 1; and Southern California Gas Co., No. 181 at 2).

ACEEE and OOE claim that there should be no safety concern at 78 percent RE because the Talbert study for GTI found that a single walled vent connector is acceptable at flue-loss efficiencies (FLE) up to 80 percent and 78 percent RE is equivalent to 79.75 percent FLE. (ACEEE, No. 170 at,3 and OOE, No. 174 at 2).

DOE did not raise the RE enough to create a safety concern if the venting system is correctly installed. DOE used the data from the GTI reports to estimate the impacts of 78 percent RE gas water heaters on venting systems. At 78 percent RE the flue loss efficiency is still below 80 percent, the level at which condensation begins. Since the increased RE may reduce the margin of error, DOE's analysis accounts for the cost of Type B vent connectors in eleven percent of households and for chimney relining in eight percent of households. Type B vent connector is a double walled vent connector that reduces cooling of the flue gasses and is more corrosion resistant than steel vent pipe.

Additionally, the California Energy Commission (CEC) in its comments, provided data about the number of models of gas water heaters that have energy factors at 76 percent RE and above that would comply with the gas water heater standards in the proposed rule. (The CEC maintains its own database of gas water heaters.) There are 170 distinct models of gas water heaters in the CEC database. A distinct model is a "discreet combination of manufacturer, input, volume, energy factor and recovery efficiency." Of these, 51 models or 30 percent of all distinct models have a RE of 76 or 77 percent. Furthermore, there are nearly an equal number of natural gas and propane gas water heaters in this category. (CEC, No. 171 at 3 and Attachment A). Since gas water heaters with a RE below 78 percent do not pose any safety threat and 30 percent of the models that can meet the standard are in this group, installers will have choices among lower RE models in those applications where there may be safety concerns. Therefore, DOE does not believe there is any application that will have a safety problem if the correct type of water heater and the proper installation procedures are followed.

2. *NFGC Venting Tables.* Bradford White claims the venting tables were developed around water heaters with a RE of approximately 75 percent. (Bradford White, No. 108 at 1–2). Southern Gas Association believes increasing RE to 78 percent would require retesting water heaters and rewriting the current venting tables because it claims the tables were based on 76 percent RE. (Southern Gas Association, No. 152 at 4). Battelle claims increasing RE to 78 percent will require a revision to the current venting tables. (Battelle, No. 127 at 26–27). GTI and Southern California Gas Company believe that DOE cannot make accurate cost estimates until venting codes are revised. (GTI, No. 141 at 3 and Southern California Gas Company, No. 181 at 2).

The NFGC does not limit its venting tables to any specific gas water heater recovery efficiency. The NFGC venting tables are based on specific conditions for each application such as water heater location and common venting with a furnace. We do agree with Battelle that the NFGC should revisit its venting tables and make whatever revisions are necessary to account for potential increases in recovery efficiencies. We also note that there are 37 models of gas water heaters with a recovery efficiency of 76 percent listed in the GAMA directory which can meet the standard levels adopted in today's rule. On that basis, we conclude there will be designs which can meet the new standard with 76 percent RE.

3. *Type B Vent Connectors.* GAMA and Bradford White claim each water heater manufacturer will change the installation instructions to require Type B vent connectors for all installations. Bradford White claims manufacturers will design to 80 percent RE in order to satisfy a 78 percent RE level. (GAMA, No. 117 at 2 and Bradford White, No. 108 at 1–2). Dominion claims DOE does not completely incorporate the additional cost for Type B vent connectors. (Dominion, No. 145 at 6). GTI states that DOE relied too heavily on data from an area of the country with atypical weather conditions. (GTI, No. 141 at 3) Battelle claims that increasing

RE to 78 percent will require Type B vent connectors in the 75 percent of installations that currently do not have them, which will add to the installed cost. (Battelle, No. 127 at 26–27) The New England Gas Association claims a majority of homes in New England are older with masonry chimneys which could require Type B vent connectors and chimney relining costing as much as $800. (New England Gas Association, No. 139 at 2–3).

ACEEE claims DOE overestimated the number of homes needing Type B vents at 78 percent RE because the AVISTA data applies to climates with 7000 heating degree days (HDDs) and the NFGC requires Type B vents in unconditioned spaces. (ACEEE, No. 170 at 2). The CEC summarizes its database of gas water heaters to show the number of models of gas water heaters with recovery efficiencies from 76 percent to 85 percent. There are 170 models which currently meet the standards. CEC also shows whether a vent connection modification or masonry chimney relining is needed. This data summary shows that a Type B vent connector is not needed until RE gets above 83 percent, and chimney relining is sometimes needed when RE gets above 78 percent. It is interesting to note there are 66 models or 39 percent of gas water heaters with recovery efficiencies at or below 78 percent which currently meet the standard and which do not need Type B vent connectors or chimney relining. (CEC, No. 171 at 3).

DOE does not agree manufacturers will specify that all installations with 78 percent RE gas water heaters will require Type B vent connectors. This is not current practice with gas water heaters with RE greater than 76 percent. Manufacturers have relied on the NFGC venting tables, and we believe they will continue to do so. We believe manufacturers should advise installers to use Type B vent connectors in climates where there are more than 5,000 HDD or some reasonably conservative level of heating degree days, and otherwise follow local codes and the NFGC requirements.

DOE uses HDD as an indicator for determining where venting systems may be subject to damage from the amount of time vent connectors may have condensate on their inside surfaces. This indicator considers both the effect of time and temperature. We use 5,000 HDD as a conservative approach since no incidence of vent system failures is associated with the installation of high efficiency gas water heaters in the Northwest, even in climates as cold as or colder than 7,000 HDD.

Given that there are 66 models of gas water heaters with RE at or below 78 percent, DOE believes a consumer has a choice between a lower RE and a higher RE with a Type B vent connector. At the lower RE, the consumer can continue to use a single wall vent connector whereas, at the higher RE levels, a consumer would be advised to use a Type B vent connector and/or chimney relining in those climate areas where condensation in the venting system is a concern.

4. *Vent System Costs.* AGA commented that DOE has underestimated the frequency of needed venting system upgrades. (AGA, No. 150 at 3). APGA claims DOE has underestimated venting costs. (APGA, No. 167 at 2). ACEEE claims DOE's cost for vent installations should not include a factor for the fraction of homes with gas water heaters. (ACEEE, No. 170 at 2).

DOE believes we have accounted for the installation costs associated with higher RE gas water heaters. We used installers' estimates to calculate the cost of installing Type-B vent connectors and to determine the cost to reline masonry chimneys. These estimates are slightly higher than the GTI estimates. Using information from comments and from an AGA survey in a GTI report, we estimated that eleven percent of households with gas-fired water heaters in regions with over 5,000 HDDs would need Type-B vent connectors for 78 percent RE gas-fired water heaters. (GRI–91/0298). DOE determined a cost of $134 for Type-B vent connectors based on the replacement market and installers' cost estimates for a typical installation. We also estimated that masonry chimney relining would cost $795 for eight percent of the households. This is nearly the same cost ($800) for chimney relining given by the New England Gas Association in its comments. See Appendix D–3 in the TSD.

DOE did not include a factor for the fraction of homes with gas water heaters in the vent installation cost calculation. The factor used in the vent installation cost calculation included the fraction of all homes with gas water heaters in the U.S. that are in the Northeast or Midwest. DOE was not double counting the number of gas water heaters as ACEEE states.

5. *Direct Vent Applications.* Dominion claims DOE does not account for the decreased vent length a 78 percent RE gas water heater will have for direct vent equipment. (Dominion, No. 145 at 6).

Dominion is correct; however, DOE notes this equipment accounts for less than two percent of the market. Only a small fraction of this market would be installed at the maximum length of vent allowed. This tiny fraction of the market could be served by a product that has not used the improved flue baffle to meet the standard or by a power vented unit.

B. Electric Water Heater Ratings

Issues concerning the efficiency ratings of electric water heaters with energy factors greater than 0.91 were raised in the workshops that the Department conducted prior to the proposed rule. Based on the Department's review of the GAMA certification test program, the Department noted the possibility that high efficiency electric water heaters, *i.e.*, with manufacturer rated energy factors greater than 0.91 EF, were overrated. Several stakeholders have requested that DOE take specific actions to avoid any future overrating.

ACEEE is concerned that manufacturers may be overrating electric water heaters and if this practice continues, some of the energy savings of the new standard will be lost. ACEEE stated that the apparent overrating affects not only the standards program, but also the efficacy of utility demand side management programs. (ACEEE, No. 170 at 1).

DOE has conducted a certification review of the five major water heater manufacturers and has found that there are incorrect energy factor ratings reported in the GAMA directory. All five major manufacturers use GAMA as their third party representative. Therefore, the GAMA directory contains manufacturers' certified ratings. We also found violations of DOE's record keeping requirements at several manufacturers. The Department has requested these manufacturers correct their ratings on these high efficiency electric water heaters, and the manufacturers have agreed. The corrected ratings will be published in the December, 2000 GAMA directory.

Some manufacturers' testing appears to show that some 50 gallon electric water heaters reach a 0.93 EF level. DOE acknowledges that recent tests of high efficiency electric water heaters at Intertek Testing Services (ITS) have shown several models with 0.92 or 0.93 EF. This testing was ordered by GAMA on a sample of four electric water heaters for each model. However, NIST has tested several of these models and has not been able to replicate the ITS test results.

Testing of 11 high efficiency electric water heaters at NIST has not demonstrated that electric water heaters can achieve a 0.93 EF. The difference

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between efficiency ratings listed in the GAMA Directory and NIST measured efficiencies ranged from 0.012 EF to 0.052 EF for an average difference of 0.029 EF. In other words, the average of the 11 tanks NIST tested was nearly 0.03 EF below the rated values from the manufacturer. We are continuing to evaluate additional units and the testing performed to understand why the NIST and ITS test results do not agree.

There may be numerous reasons why we cannot confirm the higher ratings. There could be an improper application of the DOE test procedure due to differences in interpretation of the requirements or due to selection of a different option for making some of the measurements. There could be problems in the sampling procedures used by GAMA or the manufacturers to obtain their sample tanks for testing. (The test procedure requires tanks for testing be representative of production.) There could be some design improvements in some of these high efficiency models that DOE did not consider in its analysis. Therefore, at this time we cannot determine if the difference in our testing and the manufacturers' rating is real or not.

C. Measured vs. Rated Volume

CEC, NWPPC, and ACEEE commented that DOE should use the measured volume of water heaters because manufacturers, by using the rated volume, can gain a 0.01 EF improvement by maximizing the tolerances allowed by UL (+/−10 percent for electric) or by ANSI Z21.10.1 (+/−5 percent for gas). (CEC, No. 171 at 4–5; NWPPC, No. 163 at 3; and ACEEE, No. 170 at 16–17). GAMA referred to its July 18, 1994, comments on the 1994 proposed rule, where it addressed this same issue, and suggested that DOE should continue to use rated volume because that is the basis of the extant standards set by NAECA. (GAMA, No. 160 at 5).

EPCA, as amended, by the 1987 NAECA amendment, uses the rated volume as the coefficient in the standard levels. Our analysis uses the rated tank volume to determine the performance of the design options. Therefore, DOE will continue to use the rated volume in its water heater standards.

D. Effective Date of Standards

Several stakeholders have taken the position that the effective date of today's rule should be five years from its publication. EPCA prescribes efficiency standards for water heaters manufactured on or after January 1, 1990, and requires two subsequent rulemakings to consider amendments to the water heater efficiency standards. The statute provides in effect that any amendment to the standards that results from the first rulemaking shall be effective three years after publication. For the second rulemaking cycle, to amend the standards then in effect, the statute provides an effective date five years after publication.

GAMA claims today's Final Rule should be effective 5 years after publication. GAMA believes the three year lead-time for the effective date applies only to a Final Rule published by January 1, 1992. (GAMA, No.113 at 2). Southern Co. and Dominion state that NAECA requires a 5 year implementation time. Southern Co. also suggests that refrigerant availability will become more manageable with two additional years. (Southern Co., No. 142 at 3 and Dominion, No. 145 at 3). On the other hand, ACEEE asserts the first revision has a three year effective date and since today's rule is the first amended standard, the three year effective date applies. ACEEE states this is the way the NAECA revisions have been interpreted. (ACEEE, No. 170 at 10–11).

DOE interprets the language in EPCA at 42 U.S.C. 6295(e)(4)(A) to mean that, where the schedule specified in the statute for the two required rulemakings has not been met, the first amendment to the standards should be effective three years after publication, and the second amendment to the standards, five years after publication. We believe that this interpretation is the one most consistent with the statutory scheme. DOE has the authority and responsibility to complete the two cycles of rulemakings mandated by Congress in the statute. We recognize that DOE has failed to implement the rulemaking schedule in EPCA, but we see no reason why such failure would justify a departure from the time periods the statute contemplates for an amendment to the standards to become effective. We believe we are adhering to the statutory scheme by making the effective date of today's rule, the first amended standard, conform to the amount of time the statute designates for the effective date after publication of the final rule. As ACEEE pointed out at the public hearing on June 20, 2000, in all the rulemakings where DOE has missed dates, it has used such an approach. (Transcript, No. 120FF at 295–296).

Moreover, the statute contemplated that the original efficiency standards specified in EPCA could be in effect for only five years before an amended standard would take effect. To date, the original standards have been in effect for 11 years. By making today's new standards effective in three years, it will be 14 years, not 5 years, before amended standards become effective. A five-year effective date would lengthen this period to 16 years, further delaying the benefits new standards will provide to consumers and the nation. Furthermore, the water heater industry never had an expectation that the original standards would be in effect so long. The original standards will have been in place 9 years longer than envisioned by the statute. For these reasons as well, a three-year effective date for today's rule is more consistent with the statutory scheme than the five-year period advocated by some commenters.

Accordingly, today's rule will become effective three years after the date of publication as originally proposed.

E. Water Heater Models Affected

GAMA commented that if the proposed standard levels were adopted, few current models listed in the GAMA directory would survive, and only a small percentage of current residential water heater shipments meet the proposed levels. (GAMA, No. 160 at 5). GAMA stated that 26 percent of the current models of gas and electric water heaters can meet the proposed standard. This number drops to 18 percent if only 30, 40 and 50 gallon models are considered. (GAMA, No. 176 at 1). Dominion suggests DOE should identify existing equipment that will meet the revised standards and designs it uses. Additionally, Dominion claims DOE should evaluate these models and provide data verifying the achievability of the proposed minimum efficiency standards using design options identified for the recommended standard level. (Dominion, No.145 at 3). The CEC claims that, based on its directory of certified water heaters, of the 170 models of gas water heaters listed, 51 meet the proposed standard. (CEC, No. 171 at 2). DOE's review of the April, 2000 GAMA Directory shows 37 gas-fired water heater models that could meet the proposed standards.

DOE recognizes that standards will eliminate current manufacturers' offerings which would affect the individual firms and industry's net present value. These effects are captured in the Manufacturer Impact Analysis. Furthermore, DOE rejects Dominion's comment that the Department should identify technologies that can be used to meet the standard. The standard is a performance standard, not a design standard. DOE's analysis identified a path, with different insulation blowing agents, which could be used to meet the standard. However, DOE believes there are a number of approaches individual manufacturers may elect to pursue to meet the standard. It is not up to the Department to mandate any one approach.

F. Instantaneous Water Heaters

Controlled Energy Corporation (Controlled Energy) claims instantaneous water heaters should not be included in the Final Rule without further analysis. (Controlled Energy, No. 125 at 1). The CEC claims NAECA clearly includes both storage and instantaneous water heaters, and DOE does not have any option to exempt this type of water heater since that would be equivalent to a reduction of energy efficiency. (CEC, No. 171 at 4). GAMA claims DOE should clearly state the proposed standards do not apply to instantaneous water heaters. GAMA claims the minimum energy factor for instantaneous water heaters has been inadvertently raised without any discussion or any analysis. Currently, instantaneous water heaters must meet a minimum of 0.62 EF. (GAMA, Transcript, No. 120 at 38 and 177–178.).

Since instantaneous water heaters make up a very small fraction of one percent of the water heater shipments, DOE did not include them in its analysis. Although the statutory definition includes instantaneous water heaters within the general definition of water heater, the statute does distinguish between storage and instantaneous water heaters based on input rate. The DOE regulations at 10 CFR 430 Subpart B, Appendix E(1.7), distinguish between the definition of storage water heaters and instantaneous gas water heaters by BTU input rates and storage capacity. However, EPCA, as amended, provides the same standards for instantaneous and storage water heaters. There is, moreover, a provision in EPCA, as amended, in Section 325(q), 42 U.S.C. 6295(q) for establishing a new class if the capacity or performance related features of a product justifies it. The volume ranges of storage water heaters are much larger and do not include the volumes of instantaneous water heaters as defined in DOE's regulation. Since DOE's current regulations use the capacity and input rate to define instantaneous water heaters, DOE is establishing a new class for instantaneous gas and electric water heaters and we will leave the standards at the current levels.

G. Fuel Switching

The New England Gas Association (NEGA) and Laclede Gas claim higher first costs for gas water heaters will encourage builders in new homes and consumers replacing gas water heaters to switch to electric water heaters. Laclede claims this is especially true when a consumer faces a $433 chimney relining cost. (NEGA, No. 139 at 3 and Laclede Gas, No. 148 at 3). AGA claims DOE needs to include a detailed analysis of fuel switching among gas and electric utilities in the environmental impacts analysis. (AGA, No. 150 at 10). OOE claims that the incremental costs for a 0.62 EF gas water heater are trivial compared to the costs of acquiring natural gas service where it does not exist, to buy a gas furnace, and in some cases to install a duct system where one does not exist. (OOE, No. 174 at 2).

The LCC analysis is one of the seven factors DOE is required by statute to consider when it makes its decision on standard levels. Included in the LCC analysis are the installed costs of electric and gas water heaters. These costs provide an indication of whether a particular standard level would cause fuel switching. Furthermore, in the NES, DOE estimates the shipments of each fuel type. These results are shown in Chapter 11 of the TSD. For example, DOE estimates that the standards adopted today will increase the total shipments of gas water heaters by 8 million and decrease the total shipments of electric water heaters by 7 million over the next 26 years. DOE has taken fuel switching into account in reaching its final decision. No further analysis is required.

V. Analytical Results and Conclusion

The choice of insulation blowing agent is critical to achieving high water heater efficiency at a reasonable cost. In the proposed rule, DOE based its analysis on HFC–245fa and water blown insulation. There were many comments from manufacturers, utilities and the DOJ that a standard based on HFC–245fa alone could be anti-competitive due to its single source of supply. There were also issues about venting system margin of error, size constraints for water heaters with thicker insulation, and the energy factor overrating of high efficiency electric water heaters. To determine whether there are alternative approaches to meet the standard level adopted by today's Final Rule, we evaluated two other blowing agents, HFC–134a and cyclopentane, that the proposed rule identified as potential alternatives for the HCFC–141.65 FR 25042, 25049–50 (April 28, 2000). This issue is briefly described in Section II, General Discussion, "Impact of Lessening of Competition" in today's rule.

We performed an engineering analysis on both of these alternative insulation blowing agents to determine if the standard could be met with these blowing agents and to estimate the relative manufacturer and consumer cost impacts. HFC–134a is a blowing agent that is less expensive per pound than HFC–245fa, but it also is ten percent less effective as an insulation material. Cyclopentane is a very inexpensive blowing agent, has similar insulation effectiveness to HFC–245fa, but it is flammable and would require expensive modifications to production facilities to meet the OSHA safety regulations. The engineering analyses for HFC–134a and cyclopentane show that water heater cost and performance is within two percent of the results for HFC–245fa. See Table 1 in Section II, General Discussion, "Impact of Lessening of Competition." Therefore, DOE believes that manufacturers have a choice among at least three blowing agents, water, HFC–134a and cyclopentane. When designing products to meet the new standard, manufacturers will be faced with a range of choices to consider. For example, water heaters with cyclopentane-blown foam insulation have lower material costs, as compared to HFC–245fa, however, the capital investment is significantly greater. In this scenario, they may weigh the investment costs and material costs to determine the approach that is cost-effective for them. Similarly, they may weigh either HFC–245fa and HFC–134a with water-blown foam. The HFC-blown foams have higher material costs, compared to water, but better insulation performance. Alternatively, at the standard levels adopted today, some manufacturers may find a design using other blowing agents or blends of these materials to be more cost effective. In summary, DOE believes there are a number of insulation blowing agents to meet today's standards. Manufacturers will, DOE believes, weigh the cost and efficiency trade-offs, as well as other factors, in selecting the insulation blowing material to use.

A. Economic Impacts on Consumers

1. *Life-Cycle-Cost.* To evaluate the economic impact on consumers, we conducted an LCC analysis for gas and electric water heaters. We included data and information from comments pertaining to installation costs for size constraints on fourteen percent of electric water heaters. This accounts for extra costs that consumers in small apartments and homes may have to pay for water heaters with thicker insulation. We also included

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information and costs for drip pans from the comments on gas water heaters. Table 2 shows the average LCC savings and percent of households benefitting for each of the trial standard levels for each fuel class. The average LCC savings for trial standard levels one, two and three are positive for gas-fired and electric water heaters with the HFC–245fa blowing agent. We do not show oil-fired water heaters because we are not making any revisions to the standards for that class.

Where LCC savings are positive for electric and gas-fired water heaters, the percent of households benefitting ranges from 59 percent to 90 percent for the trial standard levels analyzed. At trial standard level four, where the LCC savings are negative, 18–26 percent of households with electric or gas-fired water heaters will benefit.

TABLE 2.—LIFE-CYCLE-COST SAVINGS AND PERCENT BENEFITTING

[HFC–245fa blown insulation]

Trial standard level	Design options	Percent benefitting	Life-cycle cost savings ($)
1	Electric: Heat Traps + Tank Bottom Insulation	90	36
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	78	30
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	89	97
2	Electric: Heat Traps + Tank Bottom Insulation + 2 Inch Insulation	68	32
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2.5 Inch Insulation	64	11
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2.5 Inch Insulation	78	77
3	Electric: Heat Traps + Tank Bottom Insulation + 2.5 Inch Insulation	59	23
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	78	30
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	89	97
4	Electric: Heat Traps + 3 Inch Insulation + Plastic Tank	26	−82
	Natural Gas: Heat Traps + Flue Baffles (80 % RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	18	−244
	LP Gas: Heat Traps + Flue Baffles (80 % RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	37	−122

Another LCC analysis we conducted is the Consumer Subgroup analysis. This analysis examines the economic impacts on different groups of consumers by estimating the average change in LCC and by calculating the fraction of households that would benefit. We analyzed the potential effect of standards for households with low income levels and for senior-only households, two consumer subgroups of interest identified by DOE and supported by stakeholders. We present the results of the analysis in Table 3.

TABLE 3.—CONSUMER SUBGROUP LCC SAVINGS AND PERCENT OF HOUSEHOLDS BENEFITTING

Product class	Trial standard level	Total sample Delta LCC		Low-income Delta LCC		Senior-only Delta LCC	
		Ave. (1998$)	Fraction of population benefitting (%)	Ave. (1998$)	Fraction of population benefitting (%)	Ave. (1998$)	Fraction of population benefitting (%)
Electric	1	36	90	35	90	39	92
	2	32	68	28	67	39	72
	3	23	59	7	54	33	64
	4	−82	26	−105	22	−80	31
Natural Gas	1	30	78	30	78	34	82
	2	11	64	−1	55	17	68
	3	30	78	30	78	34	82
	4	−244	18	−268	15	−194	20
LPG	1	97	89	110	93	108	92
	2	77	78	88	80	87	80
	3	97	89	110	93	108	92
	4	−122	37	−53	37	−34	38

The two consumer subgroups show a similar trend in average LCC savings and percent of sample households benefitting as the total sample of households. In the case of electric water heaters, the low income consumer group has less benefit at all trial standard levels than the total sample of households while the senior-only consumer group has greater benefit at all trial standard levels than the total sample of households. In households with natural gas-fired water heaters, low income households have the same benefit for trial standard levels 1 and 3 and less benefit for trial standard levels 2 and 4 than the total sample of households. The senior-only households with natural gas water heaters have greater benefits at all trial standard levels than the total sample of households. Both low income and senior-only households have greater benefits at all trial standard levels with propane gas.

We have noted the LCC savings for the senior-only subgroup are similar to those of the general population. Since the elderly use 30 percent less hot water on average than the general population, one would expect their costs to be lower, and as a result, the LCC effect to be different. However, the standby losses of water heaters, which are not affected by hot water usage, are the same for the elderly and the general population. Therefore, since most of the design options considered affect standby losses and not water heating efficiency, we expect the distribution of LCC impacts for the elderly to be similar to the general population, which they were.

2. *Median Payback.* A part of the LCC analysis is the payback analysis. The LCC payback analysis considers all of the design option combinations for each fuel type and calculates a payback for each RECS household. We report the median payback from the distribution of paybacks for each trial standard level in Table 4. The median payback is the median number of years required to recover, in energy savings, the increased costs of the efficiency improvements.

TABLE 4.—MEDIAN AND TEST PROCEDURE PAYBACK (YEARS)

[HFC–245fa blown insulation]

Trial standard level	Design options	Median payback	Test procedure payback [1]
1	Electric: Heat Traps + Tank Bottom Insulation	2.9	1.5
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	3.6	3.4
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	2.8	
2	Electric: Heat Traps + Tank Bottom Insulation + 2 Inch Insulation	6.5	3.7
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2.5 Inch Insulation	5.0	4.9
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2.5 Inch Insulation	4.0	
3	Electric: Heat Traps + Tank Bottom Insulation + 2.5 Inch Insulation	7.4	5.2
	Natural Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	3.6	3.4
	LP Gas: Heat Traps + Flue Baffles (78 % RE) + 2 Inch Insulation	2.8	
4	Electric: Heat Traps + 3 Inch Insulation + Plastic Tank	14.4	9.8
	Natural Gas: Heat Traps + Flue Baffles (80 % RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID.	12.1	10.5
	LP Gas: Heat Traps + Flue Baffles (80 % RE) + 3 Inch Insulation + Side Arm Heater + Plastic Tank + IID	8.3	

[1] Electric—50 gallon; Gas—40 gallon

3. *Rebuttable Presumption.* The Act states that if the Department determines that the payback period is less than three years, as calculated with the DOE test procedure, there shall be a rebuttable presumption that such trial standard level is economically justified. In Table 4, we list the payback periods by fuel type (product class) and trial standard levels. The Act further states that if this three year payback is not met, this determination shall not be taken into consideration in deciding whether a standard is economically justified. Section 325(o)(2)(B)(iii), 42 U.S.C. 6295(o)(2)(B)(iii).

Only electric water heaters at trial standard level one satisfy the rebuttable presumption. Electric water heaters with heat traps and insulated tank bottoms have a 1.9 year payback calculated under the test procedure. There are no trial standard levels for natural gas water heaters that have a payback of three years or less.

4. *Economic Impact on Manufacturers.* We performed an MIA to determine the impact of standards on manufacturers. The complete analysis is in Chapter 13 of the TSD. In general, manufacturers stated they would be able to manufacture any of the design options with heat traps, thicker insulation, tank bottom insulation on electric and improved flue baffles on gas-fired water heaters. None of the manufacturers indicated they would leave the industry or go out of business as a result of standard levels that would require energy factors below plastic tanks or side-arm heaters (*i.e.*, trial standard levels one through three).

We conducted detailed interviews with four of the five major water heater manufacturers. (The fifth manufacturer declined to participate in our second interviews.) The five together supply more than 99 percent of the U.S. residential water heater market. The interviews provided valuable information used to evaluate the impacts of an amended standard on manufacturers' cash flows, manufacturing capacities and employment levels.

We analyzed the water heater industry using two business scenarios. The standards scenario represents the investments needed to meet the energy efficiency level of a trial standard level. The cumulative scenario includes the investments required for energy efficiency improvement, changes to a new blowing agent and the development and manufacture of a gas-fired water heater resistant to ignition of flammable vapors. Additionally, we examined the ability of manufacturers to recover the investments required for each of the scenarios and trial standard levels.

The potential value of the water heater industry, represented by the Industry Net Present Value (INPV) ($325 million in 1998 dollars), is directly related to the manufacturers' price to the dealer/distributor. Since all five of the major manufacturers produce both gas-fired and electric water heaters, the industry is highly competitive in terms of manufacturer's pricing. Manufacturer prices are expected to increase from the current average cost to the dealer/distributor of $157 to a range of $187–292 for trial standard levels one through four. Based on comments from the interviews, we assume manufacturers will raise prices enough to recover the costs of materials, labor and transportation and 75 percent of their investment. If manufacturers increased water heater distributor prices slightly more, from $0.13 for trial standard level one to $2.00 for trial standard level four, they would recover all of their investment. Table 5 shows the results of the cash flow analysis with these assumptions.

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TABLE 5.—MANUFACTURER IMPACT ANALYSIS

Trial std level	INPV ($ millions)	Change in INPV (%)	Change in INPV ($ millions)	Investment required ($ millions)
Standard Scenario, HFC–245fa blown insulation				
Base Case	325	0	0	0
1	317	−3	−8	33
2	310	−5	−15	60
3	310	−5	−15	59
4	268	−18	−57	229
Cumulative Scenario, HFC–245fa blown insulation				
Base Case	325	0	0	0
1	288	−12	−37	149
2	281	−14	−44	176
3	281	−14	−44	176
4	239	−27	−86	345

From Table 5, we note energy efficiency standards could result in losses of industry net present value from about $8 million to $57 million (3–18%), while requiring investments of $33 million to $229 million. However, even if DOE did not revise energy efficiency standards, other Federal regulatory actions that will take effect on or before January 1, 2003, will result in a $29 million loss (9%) in industry NPV. This loss exceeds any of DOE's trial standard levels except level four. As required by the Process Rule, 10 CFR Part 430, Subpart C, Appendix A 10(g)(1), DOE considered the cumulative impacts of other Federal regulatory actions on the trial standard levels, including the phase out of HCFC–141b and the CPSC initiative to prevent the ignition of flammable vapors on gas-fired water heaters. These cumulative losses range from $37 million to 86 million. The investments to prevent ignition of flammable vapors and for new blowing agents are $116 million. The investments for cumulative regulations are potentially large given the current after tax profitability of the water heater industry, estimated to be $45 million (1998) on revenues of $1.5 billion.

Based on DOE's interviews, manufacturers expect little impact on manufacturing capacity and expect to meet future demand since the revised standards are not based on side-arm gas-fired water heaters and plastic tank electric units. Currently, the U.S. industry has far more manufacturing capacity than the domestic market can absorb. Manufacturers estimated the industry is operating at approximately 80 percent of total capacity. Due to the phase-out of HCFC–141b insulation blowing agent and a requirement for a gas-fired water heater resistant to ignition of flammable vapors, it is likely that nearly every product line would have to be redesigned, retested and re-certified. Several manufacturers indicated a preference to retool for new blowing agents, energy-efficiency standards and flammable vapor-resistant designs at the same time, to avoid redundant efforts and limit costs.

We also used the manufacturers' interviews to assess employment impacts due to an amended energy efficiency standard. Manufacturers expected the impact of new blowing agents and flammable vapor resistant designs on labor to be minimal, neither increasing nor reducing employment levels by more than a few employees. Since the revised efficiency levels do not require the adoption of side arm heaters or plastic tanks, manufacturers do not anticipate significant changes in employment levels or training requirements. Additionally, we believe market growth of 2.5 percent per year for new homes and modest productivity gains ensure current employment levels for the foreseeable future. In our analysis, yearly water heater shipments range from 9.7 million in 2000 to 19.2 in 2030. Furthermore, a replacement market that increases by about 1/10th of the new home market each year ensures future demand.

B. Significance of Energy Savings

The Act prohibits the Department from adopting a standard for a product if that standard would not result in "significant" energy savings. Section 325(o)(3)(B), 42 U.S.C. 6295(o)(3)(B). While the term "significant" is not defined in the Act, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *Herrington*, 768 F.2d 1355, 1373 (D.C. Cir. 1985), concluded that Congressional intent in using the word "significant" was to mean "non-trivial." The energy savings for all of the trial standard levels considered in this rulemaking are non-trivial and therefore we consider them "significant" within the meaning of Section 325 of the Act.

1. *National Energy Savings.* To estimate the energy savings through the year 2030 due to amended standards, we compared the energy consumption of water heaters in the 2004 base case to the energy consumption of water heaters complying with the trial standard levels. DOE calculates these energy savings at the source using the NEMS–BRS distribution and generation losses. Table 6 shows these results for water heaters with HFC–245fa blown insulation.

TABLE 6.—SOURCE ENERGY SAVINGS WITH HFC–245FA BLOWN INSULATION (QUADS)

	Trial std 1	Trial std 2	Trial std 3	Trial std 4
Total quads saved	3.33	4.47	4.61	11.46
Total exajoules saved	3.51	4.72	4.86	12.09

All of the trial standard levels considered in this rulemaking have significant energy savings, ranging from 3.3 quads (3.5 Exajoules (EJ)) to 11.5 quads (12.1 EJ), depending on the trial standard level.

2. *National Net Present Value (NPV).* Additionally, we analyzed the economic impact on the nation to the year 2030. This is an NPV analysis using the AEO 2000 reference energy prices. Table 7 lists the NPV for HFC–245fa blown insulation. The NPV considers the combined discounted energy savings minus increased consumer costs of the four fuel types of equipment at a particular trial standard level. We base this calculation on all expenses and savings occurring between 2004 and 2030.

TABLE 7.—NATIONAL NET PRESENT VALUE

Trial standard level	NPV—HFC–245fa ($ billions)
1	1.20
2	−0.13
3	2.02
4	−24.94

The national NPV is positive for trial standard levels one and three and essentially 0 for trial standard level 2. In this analysis, a positive NPV means that the estimated energy savings are greater than the increased costs due to standards. Among the trial standard levels analyzed, trial standard level three has the highest NPV.

C. Lessening of Utility or Performance of Products

None of the trial standard levels reduces the performance of water heaters. Generally, the trial standard levels reduce heat losses and improve heat exchanger effectiveness. These changes improve energy and water heating performance and may increase the amount of water available in one hour, *i.e.*, the first hour rating.

However, to reduce heat losses, it may be necessary to use thicker insulation. At the trial standard level adopted in today's rule, DOE contemplates insulation thicknesses of 2–2.5 inches versus the 1–2 inches in common use today. This extra thickness of insulation will make water heaters larger and more difficult to squeeze into tight spaces when replacing a water heater. DOE added costs for tempering valves for a number of gas and electric water heaters where we believed there could be some loss of utility due to the need to downsize a water heater. Tempering valves allow the consumer to increase the setpoint, thus increasing the amount of cold water used to provide a comfortable and safe usable water temperature. The addition of cold water increases the first hour rating. Therefore, the consumer will not lose any utility or performance.

To eliminate the possibility of any water heater models becoming unavailable as a result of thicker insulation, we created a new class for tabletop water heaters based on the criteria in Section 325(q), 42 U.S.C. 6295(q) in the Act. These issues are discussed in Section II. General Discussion, "Lessening of Utility or Performance of Products."

D. Impact of Lessening of Competition

The Act directs the Department to consider any lessening of competition that is likely to result from standards. It further directs the Attorney General to determine the impact, if any, on competition likely to result from such standard and transmit such determination, not later than 60 days after the publication of a proposed rule to the Secretary, together with an analysis of the nature and extent of such impact. Section 325(o)(2)(B)(i)(V), 42 U.S.C. 6295(o)(2)(B)(i)(V).

In order to assist the Attorney General in making such a determination, the Department provided the Attorney General with copies of the Proposed Rule and the Technical Support Document for review. In a letter responding to the Proposed Rule, the Department of Justice (DOJ) found only one area of concern regarding any lessening of competition. The area of concern involves the blowing agent for the foam insulation and the possibility that only one blowing agent, HFC–245fa, could be used and that it is a patented product with only one supplier. This situation led DOJ to conclude "that the proposed standards could have an adverse affect on competition because water heater manufacturers may have to use an input that will be produced by only one source." (DOJ, No. 143 at 1).

DOE examined other possible blowing agents and concluded that at least four blowing agents are available to use in meeting the standards adopted in today's Final Rule. Therefore, the Department concludes there will be little to no impact on competition. See Section II, General Discussion, "Impact of Lessening of Competition" for the complete discussion of this topic.

E. Need of the Nation to Save Energy and Net National Employment

1. *Environmental Impacts.* Enhanced energy efficiency improves the Nation's energy security, strengthens the economy and reduces the environmental impacts of energy production. The energy savings from water heater standards result in reduced emissions of CO_2 and NO_X and aids in addressing global climate change and reducing air pollution. At the standard levels analyzed, the actual cumulative emission reductions to 2030 range from 149–354 Mt for carbon equivalent, 175–459 thousand metric tons (kt) for NO_X, and −3 to −64 kt for SO_2. The large reductions in CO_2 and NO_X at all standard levels are a positive benefit to the nation. The small increases (negative reductions) in SO_2 are due to small increases in the number of oil-fired water heaters from our shipment forecasts. We show actual cumulative emissions savings from 2004–2030 in Table 8.

TABLE 8.—ACTUAL CUMULATIVE EMISSIONS REDUCTIONS THROUGH 2030

Emission	Trial std level 1	Trial std level 2	Trial std level 3	Trial std level 4
Carbon (Mt)	149	139	152	354

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TABLE 8.—ACTUAL CUMULATIVE EMISSIONS REDUCTIONS THROUGH 2030—Continued

Emission	Trial std level 1	Trial std level 2	Trial std level 3	Trial std level 4
NO_X (kt)	175	215	273	459
SO_2 (kt)	**−3	**−11	**−13	**−64

** Results only include household SO_2 emissions reductions because SO_2 emissions from power plants are capped by clean air legislation. Thus, SO_2 emissions will only be negligibly affected by water heater standards.

The Department makes no effort to monetize the benefits of the actual emission reductions, but there may be time-related differences in the perceived value of the emissions depending on when they occur, as with monetized benefits that accumulate over time. Emission reductions that occur sooner are often more desirable than equivalent reductions that occur later. Like monetary benefits, the health, recreational and ecosystem benefits that result from emission reductions are often perceived to have a greater value if they occur sooner, rather than later. To the extent that the different trial standard levels have slightly different shipment distributions over time, some trial standard levels might have a slightly higher proportion of earlier emission reductions than another trial standard level.

To show the possible effect of the different timing patterns of the emissions, the Department is also presenting discounted emissions. We used the same seven percent discount rate for these calculations that we used for discounting monetized benefits. Since the discounted emission reductions in carbon shift slightly from trial standard level 3 to trial standard level 1, this indicates trial standard level 1 has a slight timing improvement in emission reductions. There is no similar shift in either the NO_X or SO_2 levels. We show the discounted cumulative emission savings from 2004–2030 in Table 9.

TABLE 9.—DISCOUNTED CUMULATIVE EMISSIONS REDUCTIONS THROUGH 2030

Emission	Trial std level 1	Trial std level 2	Trial std level 3	Trial std level 4
Carbon (Mt)	51	46	50	118
NO_X (kt)	53	67	90	131
SO_2 (kt)	**−1	**−3	**−4	**−17

** Results only include household SO_2 emissions reductions because SO_2 emissions from power plants are capped by clean air legislation. Thus, SO_2 emissions will only be negligibly affected by water heater standards.

2. *Net National Employment.* In the Process Rule, DOE committed to develop estimates of the employment impacts of revised standards in the economy in general. The standard adopted in today's rule will have a positive impact on employment. The results of the Department's analysis are shown in Chapter 15 of the TSD.

While both this input/output model and the direct use of Bureau of Labor Statistics (BLS) employment data suggest the revised water heater standards could increase the net demand for labor in the economy, the gains would most likely be very small relative to total national employment. For several reasons, however, even these modest benefits for national employment are in doubt:

- Unemployment is now at the lowest rate in 30 years. If unemployment remains very low during the period when the revised standards are put into effect, it is unlikely that the standards could result in any net increase in national employment levels.
- Neither the BLS data nor the input-output model used by DOE include the quality or wage level of the jobs. One reason that the demand for labor increases in the model may be that the jobs expected to be created pay less than the jobs being lost. The benefits from any potential employment gains would be reduced if job quality and pay are reduced.
- The net benefits from potential employment changes are a result of the estimated net present value of benefits or losses likely to result from the revised standards; it may not be appropriate to separately identify and consider any employment impacts beyond the calculation of net present value.

Taking into consideration these legitimate concerns regarding the interpretation and use of the employment impacts analysis, the Department concludes only that the proposed water heater standards are likely to produce employment benefits that are sufficient to offset fully any adverse impacts on employment in the water heater or energy industries.

F. Conclusion

1. *Comments on Standard Levels.* Several stakeholders made specific recommendations for standard levels during the workshops held prior to publication of the proposed rule or after publication of the proposed rule. We list these below to show the range of standard levels stakeholders believe are economically justified and technically feasible. In the formula for water heater standards, the letter "V" stands for rated volume as given in the statute.

The American Gas Association recommended EF =0.64—0.0019V for gas water heaters. (AGA, No. 110 at 2) ACEEE recommended EF =0.98—0.00132V for electric and EF =0.69—0.0019V for gas water heaters. (ACEEE, No. 71 at 9). The water heater manufacturer Bradford White recommended EF =0.94—0.0013V for electric, EF =0.65—0.0019V for gas and no change for oil-fired water heaters. (Bradford White, No. 108 at 7) The City of Palo Alto recommended EF =0.64—0.0019V for gas water heaters. (City of Palo Alto, No. 136 at 2) The Edison Electric Institute recommended EF =0.66—0.0019V for gas water heaters. (EEI, No. 105 at 3). The Electric Power Research Institute recommended EF =0.95—0.00132V for electric water heaters. (EPRI, No. 104 at 3). GAMA recommended EF =0.95—0.00132V for electric and EF =0.65—0.0019V for gas water heaters. (GAMA, No. 71 at 3 & 4). The Northwest Power Planning Council recommended EF =0.97—0.00132V for electric and EF =0.68—0.0019V for gas water heaters. (NWPPC, No. 163 at 4). The efficiency standards recommended in these comments are based on the analysis for the proposed rule and other information available to these organizations making recommendations.

2. *Proposed Revised Standard.* Section 325(o)(2)(A), 42 U.S.C. 6295(o)(2)(A), of the Act specifies that any new or amended energy conservation standard for any type (or class) of covered product shall be designed to achieve the maximum improvement in energy efficiency which the Secretary determines is technologically feasible and economically justified. In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens. Section 325(o)(2)(B)(i), 42 U.S.C. 6295(o)(2)(B)(i). The amended standard must "result in significant conservation of energy." Section 325(o)(2(B)(iii)(3)(B), 42 U.S.C. 6295(o)(B)(iii)(3)(B). The Secretary has eliminated the maximum technologically feasible levels for electric and gas-fired water heaters and has eliminated any revised standard levels for oil-fired water heaters based on the analysis in the proposed rule. All of the design options included in our analysis are technologically feasible since they are commercially available.

We consider the impacts of standards on gas and electric water heaters at each of four standard levels, beginning with the most efficient level, *i.e.*, standard level four. We then consider less efficient levels. Standard levels two and three are different combinations of efficiency levels for electric and gas water heater classes. For gas-fired water heaters, standard levels one and three are the same, though at lower efficiency than that found in standard level two. For electric water heaters, no standard levels are repeated and the efficiency of each succeeding standard level is higher. For oil fired water heaters, there are no changes from the current levels so this class is not shown but they were included in the analysis. By combining efficiency levels in this way, the Department is able to evaluate the impacts of different combinations of standard levels to make an informed decision on the merits of different efficiency combinations.

To aid the reader as we discuss the benefits or burdens of the trial standard levels we have included a summary of the analysis results in Table 10.

TABLE 10.—SUMMARY ANALYSIS RESULTS BASED ON HFC–245FA BLOWN INSULATION

	Trial Std 1	Trial Std 2	Trial Std 3	Trial Std 4
Total Quads Saved	3.	4.5	4.6	11.5
NPV ($Billion)	1.2	−0.1	2.0	−24.9
Emissions:				
Carbon Equivalent (Mt)	149	139	152	354
NO_X (kt)	175	215	273	459
SO_2 (kt)	**−3	**−11	**−13	**−64
Cumulative Change in INPV ($ Million)	−8	−15	−15	−57
Life Cycle Cost ($):				
Electric	36	32	23	−82
Natural Gas	30	11	30	−244
Propane Gas	97	77	97	−122

** Results only include household SO_2 emissions reductions because SO_2 emissions from power plants are capped by clean air legislation. Thus, SO_2 emissions will only be negligibly affected by possible water heater standards.

We first considered trial standard level four, the most efficient level for the two classes. Trial standard level four saves about 11.5 quads of energy, a significant amount. The emissions reductions of 354 Mt of carbon equivalent and 459 kt of NO_X are significant. There is a 64 kt increase in household emissions of SO_2 due to increased shipments of oil-fired water heaters. However, at this level, consumers experience negative LCC impacts. They would lose $82 with electric water heaters, $244 with natural gas water heaters and $122 with propane gas water heaters. Furthermore, the water heater industry would lose 27 percent of its value and the nation would have a loss in NPV of nearly $25 billion. The Department concludes the resulting energy savings and emission reductions at this level are outweighed by the negative economic impacts on the nation, consumers and manufacturers. Consequently, the Department concludes trial standard level four is not economically justified.

Next, we considered trial standard level three. This trial standard level saves about 4.6 quads of energy, a significant amount. The emissions reductions are significant: 152 Mt of carbon equivalent and 273 kt of NO_X. There is a 13 kt increase in household emissions of SO_2 due to a slight increase in shipments of oil-fired water heaters. The national NPV of trial standard level three is $2.0 billion from 2004–2030.

The economic benefits to consumers are significant. The average LCC savings for consumers with electric, natural gas and propane gas water heaters are $23, $30 and $97, respectively. In trial standard level three, 78 percent of households with natural gas-fired water heaters have LCC savings, for an average savings of $55, while 22 percent experience LCC losses, for an average loss of $54. In households with propane gas water heaters, the average LCC savings are $117 for 89 percent of the households while only eleven percent experience an average loss of $61. For households with electric water heaters, 59 percent have average LCC savings of $80, while 41 percent experience an average LCC loss of $59.

For electric water heaters, the analysis predicts that 41 percent of all consumers would experience no change or some net cost with more efficient electric water heaters. However, we believe that there are costs or savings near the point of zero change in LCC that consumers would be unable to distinguish in their yearly expenses. We have chosen ±2 percent of average baseline LCC as the band of no consumer impact. We believe this small percentage, regardless of the actual total LCC, is insignificant to the consumer because these LCC costs or savings are spread over monthly utility bills for the life of the water heater. By applying a two percent band of average LCC, we can clearly show the significant net savings and net costs associated with a trial standard level. This permits a more informed decision based on weighing the significant benefits and burdens in terms of consumer impact. The resulting ranges are shown in Figure 9.6.2 in the TSD.

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We will use ±2 percent of baseline LCC to indicate no impact, positively or negatively, on consumers. Therefore, only fifteen percent of consumers with electric water heaters or twelve percent of consumers with natural gas water heaters or five percent of consumers with propane gas water heaters sustain any significant net costs under standard level 3. Similarly, 30 percent of consumers with electric water heaters or 52 percent of consumers with natural gas water heaters or 69 percent of consumers with propane gas water heaters have significant net savings.

Two percent of average baseline LCC equals $56 for electric water heaters. Over the average life of 14 years for an electric water heater, this is less than $4 per year. For consumers with natural gas and propane gas water heaters, two percent of average baseline LCC is $31 and $47, respectively. Over the average life of 9 years for gas water heaters, this is less than $4 per year for natural gas and less than $6 per year for propane gas. We believe this is a small amount in terms of yearly expenditures and will not adversely impact consumers' purchase decisions about water heaters, or their financial positions. Additionally, low-income and senior-only consumer subgroups exhibit similar distributions of costs and savings. A similar small percentage of low-income or senior only consumers are affected by higher costs.

The industry will lose about five percent ($15 million) of its INPV due to energy efficiency standards. These losses are more than balanced by NPV gains to the nation of $2.0 billion, or 135 times the industry losses. Industry losses for trial standard level three due to all Federal actions (CPSC, EPA and DOE) are fourteen percent of its INP, or $44 million. Even this level of losses is offset by gains to the nation that are 46 times the industry losses.[4] Based on the manufacturer interviews, DOE believes there will not be any plant closures or employee layoffs.

In determining the economic justification of trial standard level three, the Department has weighed the benefits of energy savings, reduced average consumer LCC, significant and positive NPV, and emissions reductions and the burdens of a loss in manufacturer net present value, and consumer LCC increases for some households. After carefully considering the results of the analysis, DOE has determined the benefits of trial standard level three outweigh its burdens and is economically justified. The Department also concludes trial standard level three saves a significant amount of energy and is technologically feasible.[5] Therefore, the Department today adopts amended energy conservation standards for water heaters at trial standard level three.

VI. Procedural Issues and Regulatory Reviews

A. Review Under the National Environmental Policy Act

In issuing the March 4, 1994, Proposed Rule for energy efficiency standards for eight products, one of which was water heaters, the Department prepared an Environmental Assessment (DOE/EA–0819) that was published within the TSD for that Proposed Rule. (DOE/EE–0009, November 1993). We found the environmental effects associated with various standard levels for water heaters, as well as the other seven products, to be not significant, and we published a Finding of No Significant Impact (FONSI). 59 FR 15868 (April 5, 1994).

In conducting the analysis for the Proposed Rule upon which today's Final Rule is based, the DOE evaluated several design options suggested in comments to the screening document. As a result, the energy savings estimates and resulting environmental effects from revised energy efficiency standards for water heaters in that analysis differ somewhat from those presented for water heaters in the 1994 Proposed Rule. Nevertheless, the environmental effects expected from today's Final Rule fall within the ranges of environmental impacts from the revised energy efficiency standards for water heaters that DOE found in the 1994 FONSI not to be significant.

B. Review Under Executive Order 12866, "Regulatory Planning and Review's

The Department has determined today's regulatory action is an "economically significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review." 58 FR 51735 (October 4, 1993). Accordingly, today's action was subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

There were no substantive changes between the draft we submitted to OIRA and today's action. The draft and other documents we submitted to OIRA for review are a part of the rulemaking record and are available for public review in the Department's Freedom of Information Reading Room, 1000 Independence Avenue, SW, Washington, DC 20585, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays, telephone (202) 586–3142.

The proposed rule contained a summary of the Regulatory Impact Analysis (RIA), which focused on the major alternatives considered in arriving at the approach to improving the energy efficiency of consumer products. The reader is referred to the complete RIA, which is contained in the TSD, available as indicated at the beginning of this notice. It consists of: (1) a statement of the problem addressed by this regulation, and the mandate for government action; (2) a description and analysis of the feasible policy alternatives to this regulation; (3) a quantitative comparison of the impacts of the alternatives; and (4) the economic impact of the proposed standard.

The RIA calculates the effects of feasible policy alternatives to water heater energy efficiency standards, and provides a quantitative comparison of the impacts of the alternatives. We evaluate each alternative in terms of its ability to achieve significant energy savings at reasonable costs, and we compare it to the effectiveness of trial standard level 3 adopted by today's Final Rule.

We created the RIA using a series of regulatory scenarios (with various assumptions), which we used as input to the shipments model for water heaters. We used the results from the shipments model as inputs to the NES spreadsheet calculations.

DOE identified the following seven major policy alternatives for achieving consumer product energy efficiency. These alternatives include:

- No New Regulatory Action.
- Informational Action.
- Product Labeling.
- Consumer Education.
- Prescriptive Standards.
- Financial Incentives.

—Tax credits
—Rebates
—Low income and seniors subsidy

- Voluntary Energy Efficiency Targets (5 Years, 10 Years).
- Mass Government Purchases.
- The Proposed Approach (Performance Standards).

We have evaluated each alternative in terms of its ability to achieve significant energy savings at reasonable costs (Table 11), and have compared it to the effectiveness of this Final Rule.

TABLE 11.—ALTERNATIVES CONSIDERED

Policy alternatives	NPV $ in billions	Energy savings quads
Consumer Product Labeling	−$0.003	0.08
Consumer Education	0.40	0.49
Prescriptive Standards	0.99	0.74
Consumer Tax Credits	0.18	0.14
Consumer Rebates High Efficiency	0.18	0.14
Consumer Rebates Heat Pump	0.85	0.50
Low Income and Seniors Subsidy	0.05	0.37
Manufacturer Tax Credits	0.04	0.03
Voluntary Efficiency Target (5 year delay)	0.92	2.8
Voluntary Efficiency Target (10 year delay)	0.47	2.1
Mass Government Purchases	0.01	0.06
Performance Standards	2.0	4.6

NPV = Net Present Value (2003–2030, in billion 1998 $) (does not include government expenses)
Savings = Energy Savings (Source Quads)

For a complete discussion of the assumptions used to develop the alternative regulatory impacts, see the proposed rule. 65 FR 25042, 25080–25081 (April 28, 2000). All of these alternatives must be gauged against the performance standards in this Final Rule. The results in Table 11 above show that none of the alternative regulatory approaches meet or exceed the estimated national cost and energy savings from revised energy efficiency standards. Additionally, several of the alternatives would require new enabling legislation, since authority to carry out those alternatives does not exist presently.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612 requires an assessment of the impact of regulations on small businesses. The Small Business Administration's definition for a small business in the water heater industry is one that employs 500 or fewer employees.

The water heater industry is characterized by five firms accounting for nearly 99 percent of sales. Smaller businesses and firms, which make specialty water heaters and supply niche markets, share one percent of the market. We are aware of three small firms: Bock Water Heaters, Heat Transfer Products, and Vaughn.

Of the three small firms, Bock manufactures oil-fired water heaters that have not been affected by this rule. Therefore, Bock will not suffer any adverse impacts due to the rule. The other two firms, Heat Transfer and Vaughn, both make electric water heaters that are affected by this rule. In the GAMA directory, these firms only list electric water heaters that meet or exceed the standard level in this rule. Although the rule raises the standard level enough to impact their niche market for high efficiency electric water heaters, these manufacturers also manufacture very long life products that incorporate other features which will help them preserve their niche market. The Department has taken this into consideration in this rulemaking.

The Department prepared a manufacturing impact analysis that it shared with all the water heater manufacturers. The smaller manufacturers did not choose to discuss the impacts of the trial standard levels on their firms.

In view of the information discussed above, the Department has determined and hereby certifies pursuant to Section 605(b) of the Regulatory Flexibility Act that, for this particular industry, the standard levels in today's Final Rule will not "have a significant economic impact on a substantial number of small entities," and it is not necessary to prepare a regulatory flexibility analysis.

D. Review Under the Paperwork Reduction Act

No new information or record keeping requirements are imposed by this rulemaking that would require Office of Management and Budget clearance under the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.*

E. Review Under Executive Order 12988, "Civil Justice Reform"

With respect to the review of existing regulations and the promulgation of new regulations, Section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction.

With regard to the review required by Section 3(a), Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in Section 3(a) and Section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE reviewed today's Final Rule under the standards of Section 3 of the Executive Order and determined that, to the extent permitted by law, the final regulations meet the relevant standards.

F. "Takings" Assessment Review

The Department has determined pursuant to Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property

[4] As DOE has determined, the benefits of today's final rule outweigh the $15 million loss to the industry. To review the support for this determination, see the TSD at Chapters 12.5 and Table 12.1, 13.3.3.5 and Table 13.8, 13.3.4, and 13.3.5.

[5] The final standard is based on insulation blown with HFC–245fa. We also compared the engineering cost and performance for two alternative blowing agents, HFC–134a and cyclopentane. All three blowing agents are EPA–SNAP approved but there are concerns about availability and a single source supplier with HFC–245fa. However, since engineering results are within two percent of HFC–245fa, we conclude that the use of either of these alternative blowing agents would not change our decision.

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Rights," 53 FR 8859 (March 18, 1988) that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the United States Constitution.

G. Review Under Executive Order 13132, "Federalism"

Executive Order 13132, 64 FR 43255 (August 4, 1999) requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have "federalism implications." Policies that have federalism implications are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Under Executive Order 13132, DOE may not issue a regulation that has federalism implications, that imposes substantial direct costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the State and local governments, or DOE consults with State and local officials early in the process of developing the proposed regulation. DOE also may not issue a regulation that has federalism implications and that preempts State law unless it consults with State and local officials early in the process of developing the proposed regulations.

The statutory authority under which this Final Rule is being promulgated specifically addresses the effect of Federal rules on State laws or regulations concerning testing, labeling and standards. Section 327 of EPCA, as amended, 42 U.S.C. 6297. Generally all such State laws or regulations are superceded by EPCA, unless specifically exempted in Section 327. The Department can grant a waiver of preemption in accordance with the procedures and other provisions of Section 327(d) of the Act, as amended. 42 U.S.C. 6297(d). States can file petitions for exemption from preemption with the Secretary and have their request reviewed on a case-by-case basis.

DOE has examined today's Final Rule and has determined that although revised water heater standards would preempt State laws in this area, they would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

H. Review Under the Unfunded Mandates Reform Act of 1995

With respect to a proposed regulatory action that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year, Section 202(a) of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531 *et seq.*, requires a Federal agency to publish a written statement concerning estimates of the resulting costs, benefits and other effects on the national economy. 2 U.S.C. 1532(a), (b). UMRA also requires each Federal agency to develop an effective process to permit timely input by state, local, and tribal governments on a proposed significant intergovernmental mandate. The Department's consultation process is described in a notice published in the **Federal Register**. 62 FR 12820 (March 18, 1997). Today's Final Rule may impose expenditures of $100 million or more in a year in the private sector. It does not contain a Federal intergovernmental mandate.

Section 202 of UMRA authorizes an agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies this Final Rule. 2 U.S.C. 1532(c). The content requirements of Section 202(b) of UMRA relevant to the private sector mandate substantially overlap the economic analysis requirements that apply under Section 325(o) of EPCA, as amended, and Executive Order 12866. The Supplementary Information section of the Notice of Final Rulemaking and the analysis contained in the "Regulatory Impact Analysis" section of the TSD for this Final Rule respond to those requirements.

DOE is obligated by Section 205 of UMRA, 2 U.S.C. 1535, to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under Section 202 is required. From those alternatives, DOE must select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule, unless DOE publishes an explanation of why a different alternative is selected or the selection of such an alternative is inconsistent with law. As required by Section 325(o) of EPCA, as amended, 42 U.S.C. 6295(o), today's Final Rule establishes energy conservation standards for water heaters that are designed to achieve the maximum improvement in energy efficiency that DOE has determined is both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in the "Regulatory Impact Analysis" section of the TSD for this Final Rule.

I. Review Under the Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. No. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Today's Final Rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under the Plain Language Directives

Section 1(b)(12) of Executive Order 12866 requires that each agency draft its regulations so that they are simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty. Similarly, the Presidential memorandum directs the heads of executive departments and agencies to use plain language in all proposed and Final Rulemaking documents published in the **Federal Register**.63 FR 31883 (June 1, 1998).

Today's rule uses the following general techniques to abide by Section 1(b)(12) of Executive Order 12866 and the Presidential memorandum. 63 FR 31883 (June 1, 1998):

- Organization of the material to serve the needs of the readers (stakeholders).
- Use of common, everyday words.
- Shorter sentences and sections.

K. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of today's Final Rule prior to the effective date set forth at the outset of this notice. DOE also will submit the supporting analyses to the Comptroller General (GAO) and make them available to each House of Congress. The report will state that it has been determined that the rule is a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Energy conservation, Household appliances.

Issued in Washington, DC, on December 26, 2000.

Dan Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, Part 430 of Title 10, Code of Federal Regulations, is amended as set forth below.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

1. The authority citation for Part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309, 28 U.S.C. 2461 note.

2. Section 430, Appendix E to Subpart B of Part 430 is amended in Section 1 by adding paragraph 1.16 to read as follows:

Appendix E to subpart B of Part 430—Uniform Test Method for Measuring the Energy Consumption of Water Heaters

1. Definitions

* * * * *

1.16 *Tabletop water heater* means a water heater in a rectangular box enclosure designed to slide into a kitchen countertop space with typical dimensions of 36 inches high, 25 inches deep and 24 inches wide.

* * * * *

3. Section 430.32(d) of subpart C is amended by revising paragraph (d) to read as follows:

§ 430.32 Energy and water conservation standards and effective dates.

* * * * *

(d) *Water heaters.*

The energy factor of water heaters shall not be less than the following for products manufactured on or after the indicated dates.

Product class	Energy factor as of January 1, 1990	Energy factor as of of April 15, 1991	Energy factor as of January 20, 2004
1. Gas-fired Water Heater	0.62 – (.0019 × Rated Storage Volume in gallons).	0.62 – (.0019 × Rated Storage Volume in gallons).	0.67 – (0.0019 × Rated Storage Volume in gallons).
2. Oil-fired Water Heater	0.59 – (.0019 × Rated Storage Volume in gallons).	0.59 – (.0019 × rated Storage Volume in gallons).	0.59 – (0.0019 × Rated Storage Volume in gallons).
3. Electric Water Heater	0.95 – (0.00132 × Rated Storage Volume in gallons).	0.93 – (0.00132 × Rated Storage Volume in gallons.	0.97 – (0.00132 × Rated Storage Volume in gallons).
4. Tabletop Water Heater	0.95 – (0.00132 × Rated Storage Volume in gallons).	0.93 – (0.00132 × Rated Storage Volume in gallons).	0.93 – (0.00132 × Rated Storage Volume in gallons).
5. Instantaneous Gas-fire Water Heater.	0.62 – (0.0019 × Rated Storage Volume in gallons).	0.62 – (0.0019 × Rated Storage Volume in gallons).	0.62 – (0.0019 × Rated Storage Volume in gallons).
6. Instantaneous Electric Water Heater.	0.95 – (0.00132 × Rated Storage Volume in gallons).	0.93 – (0.00132 × Rated Storage Volume in gallons).	0.93 – (0.00132 × Rated Storage Volume in gallons).

Note: The Rated Storage Volume equals the water storage capacity of a water heater, in gallons, as specified by the manufacturer.

* * * * *

Appendix

[The following letter from the Department of Justice will not appear in the Code of Federal Regulations.]

Department of Justice,
Antitrust Division, Joel I. Klein Assistant Attorney General
Main Justice Building, *950 Pennsylvania Avenue, NW, Washington, DC 20530–0001, (202) 514–2401/(202) 616–2645 (f), Antitrust@justice.usdoj.gov*

July 10, 2000.

Mary Anne Sullivan,
General Counsel, Department of Energy, Washington, DC 20585

Dear General Counsel Sullivan: I am responding to your May 10, 2000 letter seeking the views of the Attorney General about the potential impact on competition of the proposed energy efficiency standards for water heaters, Docket No. EE–RM–97–900. Your request was submitted pursuant to Section 325(o)(2)(B)(i) of the Energy Policy and Conservation Act, 42 U.S.C. 6291, 6295, which requires the Attorney General to make a determination of the impact of any lessening of competition that is likely to result from the imposition of proposed energy efficiency standards. The Attorney General's responsibility for responding to requests from other departments about the effect of a program on competition has been delegated to the Assistant Attorney General for the Antitrust Division in 28 CFR 0.40 (g).

We have reviewed the proposed standards, the supplementary information published in the **Federal Register** notice, the Technical Support Document, and information from water heater manufacturers, their suppliers, and other interested parties. The Antitrust Division has concluded that the proposed standards could have an adverse effect on competition because water heater manufacturers may have to use an input that will be produced by only one source. We do not anticipate that the proposed standard will affect competition among water heater manufacturers. Rather, competition to provide heater manufacturers with blowing agents could be adversely affected, with resulting cost increases to consumers.

In the analysis of the proposed standard that the Department of Energy published in the **Federal Register**, the only design options for affected electric water heaters that meet the DOE's proposed standard require use of HFC–245fa as a blowing agent for insulation. Insulation is an essential part of a water heater, and HFC–245fa is a patented product that has only one supplier. DOE's published analysis further concludes that gas-fired water heaters have design options that would eliminate the need for HFC–245fa, but at significant added costs.

Water heater manufacturers have objected to the proposed standard on the grounds that their need to rely on a sole source will make them vulnerable to supply disruptions and monopoly pricing. Based on the analysis that DOE published, the concerns of water heater manufacturers regarding HFC–245fa, and our interviews with industry participants, the Antitrust Division has concluded that competition could be adversely affected by the adoption of the proposed standard.[1] The Department urges the Department of Energy to take into account this impact on competition in determining its final energy efficiency standard for water heaters and to consider altering the standard so that manufacturers may meet the standard for all affected models using blowing agents for insulation other than HFC–245fa without adding significantly to the costs of manufacturing water heaters.

Sincerely,

Joel I. Klein

[FR Doc. 01–1081 Filed 1–16–01; 8:45 am]

BILLING CODE 6450–01–P

[1] We note that some manufacturers have suggested that DOE underestimated the performance capabilities of alternative blowing agents. If these suggestions prove correct, water heater manufacturers may in fact be able to comply with the proposed standard for more models, while using water-based blowing agents. We also note that it's possible that manufacturers may in fact be able to engineer design options using water-based blowing agents with a greater performance capability or lower cost than they now anticipate.

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Federal Register

Wednesday,
January 17, 2001

Part IX

Environmental Protection Agency

40 CFR Part 372
Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[OPPTS–400140D; FRL–6722–4]

RIN 2070-AD38

Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is lowering the reporting thresholds for lead and lead compounds which are subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). The reporting thresholds are being lowered to 100 pounds. The lower reporting thresholds apply to lead and all lead compounds except for lead contained in stainless steel, brass, and bronze alloys. EPA is taking these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. Today's actions also include modifications to certain reporting exemptions and requirements for lead and lead compounds.

DATES: This rule shall take effect on February 16, 2001; with the first reports at the lower thresholds due on or before July 1, 2002, for the 2001 calendar year.

FOR FURTHER INFORMATION CONTACT: For technical information on this final rule contact: Daniel R. Bushman, Petitions Coordinator, Environmental Protection Agency, Mail Code 2844, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number 202-260-3882, e-mail address: bushman.daniel@epa.gov. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, Environmental Protection Agency, Mail Code 5101, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Toll free: 1-800-535-0202, in Virginia and Alaska: 703-412-9877 or Toll free TDD: 1-800-553-7672. Information concerning this action is also available on EPA's Web site at http://www.epa.gov/tri.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

You may be potentially affected by this action if you manufacture, process, or otherwise use lead or lead compounds. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Industry	SIC major group codes 10 (except 1011, 1081, and 1094), 12 (except 1241); or 20 through 39; or industry codes 4911 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4931 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4939 (limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce); or 4953 (limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. section 6921 *et seq.*); or 5169; or 5171; or 7389 (limited to facilities primarily engaged in solvent recovery services on a contract or fee basis)
Federal Government	Federal facilities

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding of **FOR FURTHER INFORMATION CONTACT** section.

B. How can I get additional information or copies of this document or other support documents?

1. *Electronically.* You may obtain electronic copies of this document from the EPA internet Home Page at http://www.epa.gov/. On the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the "**Federal Register**" listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPPTS–400140. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, North East Mall Rm. B-607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is (202) 260-7099.

II. What is EPA's Statutory Authority for Taking These Actions?

EPA is finalizing these actions under sections 313(f)(2), 313(g), 313(h), and 328 of EPCRA, 42 U.S.C. 11023(f)(2), 11023(g), 11023(h), and 11048; and section 6607 of PPA, 42 U.S.C. 13106. Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using a listed toxic chemical in amounts above reporting threshold levels, to report certain facility specific information about such chemicals, including the annual releases and other quantities entering each environmental medium. These reports must be filed by July 1 of each year for the previous calendar year. Such facilities also must report recycling and other waste management data and source reduction activities for such chemicals, pursuant to section 6607 of PPA.

A. What is EPA's Statutory Authority To Lower EPCRA Reporting Thresholds?

EPA is finalizing these actions pursuant to its authority under EPCRA section 313(f)(2) to revise reporting thresholds. EPCRA section 313 establishes default reporting thresholds, which are set forth in section 313(f)(1). Section 313(f)(2), however, provides that EPA:

> may establish a threshold amount for a toxic chemical different from the amount established by paragraph (1). Such revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this section. The amounts established by EPA may, at the Administrator's discretion, be based on classes of chemicals or categories of facilities.

This provision provides EPA with broad, but not unlimited, authority to establish thresholds for particular chemicals, classes of chemicals, or categories of facilities, and commits to EPA's discretion the determination that a different threshold is warranted. Congress also committed the determination of the levels at which to establish any alternate thresholds to EPA's discretion, requiring only that any "revised threshold shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements" of section 313. 42 U.S.C. 11023(f)(2).

For purposes of determining what constitutes a "substantial majority of total releases," EPA interprets the language in section 313(f)(2), "facilities subject to the requirements of [section 313]," to refer to those facilities that fall within the category of facilities described by sections 313 (a) and (b), i.e., the facilities currently reporting. Subsection (a) lays out the general requirement that "the owner or operator of facilities subject to the requirements of this section shall" file a report under EPCRA section 313. Subsection (b) then defines the facilities subject to the requirements of this section:

> [t]he requirements of this section shall apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20-39, . . . and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) of this section in excess of the quantity of that toxic chemical established under subsection (f) of this section during the calendar year for which a toxic chemical release form is required under this section.

Thus, in revising the reporting thresholds, EPA must ensure that, under the new thresholds, a substantial majority of releases currently being reported will continue to be reported. No further prerequisites for exercising this authority appears in the statute.

B. What is EPA's Statutory Authority for Making Modifications to Other EPCRA section 313 Reporting Requirements?

Today's actions also include modifications to certain reporting exemptions and requirements for lead and lead compounds. Congress granted EPA rulemaking authority to allow the Agency to fully implement the statute. EPCRA section 328 provides that the "Administrator may prescribe such regulations as may be necessary to carry out this chapter" (28 U.S.C. 11048).

III. Background Information

A. What is the General Background for this Action?

Under EPCRA section 313, Congress set the initial parameters of the Toxics Release Inventory (TRI), but also gave EPA clear authority to modify reporting in various ways, including authority to change the toxic chemicals subject to reporting, the facilities required to report, and the threshold quantities that trigger reporting. By providing this authority, Congress recognized that the TRI program would need to evolve to meet the needs of a better informed public and to refine existing information. EPA has, therefore, undertaken a number of actions to expand and enhance TRI. These actions include expanding the number of reportable toxic chemicals by adding 286 toxic chemicals and chemical categories to the EPCRA section 313 list in 1994. Further, a new category of facilities was added to EPCRA section 313 on August 3, 1993, through Executive Order 12856, which requires Federal facilities meeting threshold requirements to file annual EPCRA section 313 reports. In addition, in 1997 EPA expanded the number of private sector facilities that are required to report under EPCRA section 313 by adding seven new industrial groups to the list of covered facilities. At the same time, EPA has sought to reduce the burden of EPCRA section 313 reporting by actions such as delisting chemicals it has determined do not meet the statutory listing criteria and establishing an alternate reporting threshold of 1 million pounds for facilities with 500 pounds or less of production-related releases and other wastes. Facilities meeting the requirements of this alternate threshold may file a certification statement (Form A) instead of reporting on the standard EPCRA section 313 form, the Form R.

On October 29, 1999 (64 FR 58666), EPA finalized enhanced reporting requirements that focused on a unique group of toxic chemicals that persist and bioaccumulate in the environment. These chemicals are commonly referred to as persistent bioaccumulative toxic chemicals or PBT chemicals. Until that action, with the exception of the alternate threshold certification on Form A, EPA had not altered the statutory reporting threshold for any listed chemicals. However, as the TRI program has evolved over time and as communities identify areas of special concern, thresholds and other aspects of the EPCRA section 313 reporting requirements may need to be modified to assure the collection and dissemination of relevant, topical information and data. Toxic chemicals that persist and bioaccumulate are of particular concern because they remain in the environment for significant periods of time and concentrate in the organisms exposed to them. The October 29, 1999, PBT chemical final rule set forth criteria to be used by the EPCRA section 313 program for evaluating whether a listed toxic chemical persists or bioaccumulates in the environment. EPA has evaluated lead and lead compounds using these criteria, and has concluded that lead and lead compounds are PBT chemicals. Thus, as with the PBT chemical final rule, today's action further increases the utility of TRI to the public by lowering the reporting thresholds for lead and lead compounds. Lowering the reporting thresholds for lead and lead compounds will ensure that the public has important information on the quantities of these chemicals released or otherwise managed as waste, that would not be reported under the 10,000 and 25,000 pound/year thresholds that apply to most other listed toxic chemicals.

B. What Outreach Has EPA Conducted?

EPA has engaged in a comprehensive outreach effort relating to this action. This outreach served to inform interested parties, including industries and small businesses affected by the rule, state regulatory officials, environmental organizations, labor unions, community groups, and the general public of EPA's intention to lower the applicable EPCRA section 313 reporting thresholds for lead and lead compounds. EPA held three public meetings (in Los Angeles, CA (November 30, 1999); Chicago, IL (December 2, 1999); and Washington, DC (December 14, 1999)) during the comment period for the proposal. Participants included a range of industry representatives, trade associations (representing both small and large businesses), law firms representing industry groups, environmental groups, the general public, plus other groups and organizations. For state and tribal governments, EPA attended the regularly-held public meetings of the Forum on State and Tribal Toxics

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Action (FOSTTA) to discuss the proposed rule. EPA also received substantial public comment on the proposed rule, to which EPA is responding in this Final Rule and the Response to Comments document (Ref. 1). In response to the strong interest in the proposed rule, and to allow more individuals and groups to submit their comments, EPA extended the public comment period. The comment period was first extended from September 17 to November 1, 1999 (at 64 FR 51091, September 21, 1999) (FRL–6382–9) and then again from November 1 to December 16, 1999 (at 64 FR 58370, October 29, 1999) (FRL–6391–8) to allow commenters time to supplement or revise their comments in light of the decisions made in the final PBT chemical rulemaking (64 FR 58666). Additional information regarding EPA's outreach may be found in supporting documents included in the public version of the official record.

IV. Summary of Proposal

A. What Persistence and Environmental Fate Data were Presented for Lead and Lead Compounds?

A chemical's persistence refers to the length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes. The environmental media for which persistence is measured or estimated include air, water, soil, and sediment; however, water is the medium for which persistence values are most frequently available. It is important to distinguish between persistence in a single medium (air, water, soil, or sediment) and overall environmental persistence. Persistence in an individual medium is controlled by transport of the chemical to other media, as well as transformation to other chemical species. Persistence in the environment as a whole is a distinct concept. It is based on the observations that the environment behaves as a set of interconnected media, and that a chemical substance released to the environment will become distributed in these media in accordance with the chemical's intrinsic (physical/chemical) properties and reactivity. For overall persistence, only irreversible transformation contributes to net loss of a chemical substance.

Although metals and metal compounds, including lead and lead compounds, may be converted from the metal to a metal compound or from one metal compound to another in the environment, the metal cannot be destroyed. Thus, metals are obviously persistent in the environment in some form. The form of the metal that exists in the environment depends on its environmental fate. Environmental fate refers to the ultimate result of physical, chemical, and biological processes acting upon a metal or metal compound once it is released into the environment. The environmental fate determines the extent to which the metal or the metal from a metal compound will be available for exposure to organisms once released into the environment. The environmental fate of a metal or metal compound varies depending on the environmental conditions and the physical/chemical properties of the metal in question.

The information summarized in the proposed rule for the environmental fate of lead in each environmental medium represented the key elements influencing the transport, transformation, and bioavailability of lead in air, soil, water and sediments. This information, as well as a more extensive review of the existing data on the environmental fate of lead are contained in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) and in the references contained therein. Based on this information, EPA concluded that processes commonly observed in the environment can result in the release of available (ionic) lead where it can be bioaccumulated by organisms. These processes may occur in soil and aquatic environments with low pH and low levels of clay and organic matter. Under these conditions, the solubility of lead is enhanced and if there are no sorbing surfaces and colloids, lead ion can remain in solution for a sufficient period to be taken up by biota. Lead sorption to soil organic matter has been shown to be pH dependent. Decreasing pH can lead to increasing concentrations of lead in soil water; while increasing pH can lead to decreasing concentrations of lead in soil water.

The Agency's analysis of the environmental fate of lead and lead compounds showed that under many environmental conditions lead is available to express its toxicity and to bioaccumulate. In the EPCRA section 313 program, the issue of the environmental availability of metals from metal compounds is broader than just its implications for whether a chemical is a PBT. The issue of both the environmental availability and bioavailability has been addressed for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). This policy states that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity. If the intact metal compound is not toxic and the metal is not available from the metal compound then such a chemical is a potential candidate for delisting from the EPCRA section 313 list of toxic chemicals. EPA developed this petition policy specifically to address such circumstances.

B. What Aquatic Bioaccumulation Data was Presented for Lead and Lead Compounds?

Bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. The term bioaccumulation refers to uptake of chemicals by organisms both directly from water and through their diet (Ref. 3). EPA has defined bioaccumulation as the net accumulation of a substance by an organism as a result of uptake from all environmental sources (60 FR 15366). The nondietary accumulation of chemicals in aquatic organisms is referred to as bioconcentration, and may be described as the process through which a chemical is distributed between the organism and environment based on the chemical's properties, environmental conditions, and biological factors such as an organism's ability to metabolize the chemical (Ref. 4). EPA has defined bioconcentration as the net accumulation of a substance by an aquatic organism as a result of uptake directly from the ambient water through gill membranes or other external body surfaces (60 FR 15366). A chemical's potential to bioaccumulate can be quantified by measuring or predicting the chemical's bioaccumulation factor (BAF). EPA has defined the BAF as the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time (60 FR 15366). A chemical's potential to bioaccumulate can also be quantified by measuring or predicting the chemical's bioconcentration factor (BCF). EPA has defined the BCF as the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through water only and the ratio does not change substantially over time (60 FR 15366).

A review of the ecotoxicological literature indicates that bioconcentration values of lead and certain lead compounds (lead salts) in aquatic plants and animals are often above a bioconcentration/bioaccumulation factor of 1,000 and in some species at or greater than 5,000. Lead is bioaccumulated by aquatic organisms such as plants, bacteria, invertebrates, and fish. The principle form that is believed to be accumulated is divalent lead (i.e., lead in its plus 2 oxidation state (Pb +2)). It has been shown that fish held in water at a pH of 6.0 accumulate three times as much lead as fish held in water at a pH of 7.5 (Ref. 5), thus as pH decreases the availability of divalent lead increases. Older organisms usually have the highest body burdens, and lead accumulates in bony tissues to the greatest extent.

The bioaccumulation data reviewed concerning the extent (magnitude) of lead bioaccumulation found to occur in many aquatic plants and animals and the lead bioconcentration factors (BCF) determined or measured from laboratory studies conducted for certain durations using BCF test methods, can be found in the bioaccumulation support document (Ref. 6). Concentrations of lead monitored in various organisms were determined by comparing concentrations in the environment (water) with concentrations measured in the organisms. In general, bioconcentration values for four freshwater invertebrate species ranged from 499 to 1,700 (Ref. 7). BCFs for two species of freshwater fish were much lower, 42 and 45. However, certain fish tissues have much higher BCF values, e.g., the BCF value for the intestinal lipids in rainbow trout were as high as 17,300. Freshwater phytoplankton and both marine and freshwater algae accumulate or concentrate lead to very high levels (e.g., greater than 10,000x). BCF values for marine bivalve organisms were as high as 4,985 for blue mussels. Eastern oysters also had BCF values greater than 1,000. These data indicate that many of the BCF values and measured environmental concentration factors for lead are above 1,000 with several species having BCF or observed concentration factors at or above 5,000. The references cited for blue mussels include a range of values, the upper end of which is essentially 5,000 (i.e., 4,985). There are also a few fish tissues that have BCFs greater than 10,000, though most of the available fish data are below 5,000.

C. What Human Bioaccumulation Data was Presented for Lead and Lead Compounds?

There is a great deal of information available on the bioaccumulation of lead in humans and the effects that such accumulation can have (Refs. 8, 9, 10, and 11). The bioaccumulation of lead in humans is well documented. Although lead has no known biological function in humans, it is readily absorbed through the gut and can be absorbed by inhalation and, to some extent by dermal contact. Absorption of lead can occur as a result of exposure to air-borne forms of lead, as well as ingestion or contact with contaminated soil and dust. Children and developing fetuses are known to absorb lead more readily than adults and to excrete it at a lower total rate. These findings are especially significant since young children are most susceptible to the adverse effects associated with lead exposure. Lead absorption varies from very low levels (e.g., 5%) up to essentially 100%. Lead absorption appears to be linked to particle size, the chemical composition, and other factors (Refs. 12 and 13). Long-lasting impacts on intelligence, motor control, hearing, and neurobehavioral development of children have been documented at levels of lead that are not associated with clinical intoxication and were once thought to be safe. An analysis of human blood-lead level data collected from the most recent publicly available National Health and Nutrition Examination Surveys (see Ref. 9), showed that approximately 4.4% of the nation's children aged 1–5 years have blood-lead concentrations at or above 10 micrograms per deciliter (mg/ dL), which is the current action level established by the Centers for Disease Control. While this is a significant improvement over the 88% of children who had blood lead levels above this threshold in 1976, before the phase-out of lead in gasoline, it is still cause for concern because it indicates that nearly 900,000 children aged 1–5 have unacceptably high blood-lead levels.

Once lead is absorbed in the body, it is primarily distributed to the blood, soft tissues (kidney, bone marrow, liver, and brain) and to the mineralizing tissue (bones and teeth). In one study it was shown that in adults, following a single dose of lead, one-half of the lead absorbed from the original exposure remained in the blood for approximately 25 days after exposure, in soft tissues for about 40 days, and in bone for more than 25 years (Ref. 14). Once in the bone, lead can re-enter the blood and soft tissues. Under certain circumstances, such as pregnancy and lactation, lead can more readily re-enter blood and soft tissues. Thus, accumulation of lead in bone can serve to maintain elevated blood lead levels years after exposure. The total amount of lead in long-term bone retention can approach 200 mg for adult males 60–70 years old (and even higher with occupational exposure). For adults, up to 94% of the total amount of lead in the body is contained in the bones and teeth but for children only about 73% is stored in their bones. While the increase in bone lead level across childhood may appear modest, the total accumulation rate is actually 80-fold. The increase is 80-fold because children undergo a 40-fold increase in skeletal mass. While lead absorption rates are influenced by several parameters, including route of exposure, chemical speciation, the physical/chemical characteristics of the lead and the exposure medium, as well as the age and physiological states of the exposed individual, there is substantial documentation that a significant amount of lead can be absorbed and accumulated in humans. Such absorbed and accumulated lead can cause significant deleterious health effects, particularly in children.

D. What Proposed Conclusions did EPA Reach from Its Proposal Review of the Available Data on Lead and Lead Compounds?

EPA's review of the available information on lead and lead compounds led EPA to conclude that lead and lead compounds are highly persistent and at the least, bioaccumulative. The persistence of lead in the environment is not in question since, as a metal, lead cannot be destroyed in the environment. With respect to whether lead or lead compounds released to the environment will result in lead that is available, the data indicate that under many environmental conditions lead does become available. The conclusion that lead is available in the environment is confirmed by the data on the bioaccumulation of lead in aquatic organisms and in humans as a result of environmental exposures. As for lead's bioaccumulation potential, lead has been shown to bioaccumulate in laboratory studies, has been found to bioaccumulate in organisms observed in the environment, and has been found to bioaccumulate in humans. EPA noted in its proposal that these data indicate that many of the BCF values and measured environmental concentration factors for lead are above 1,000 with several species having BCF or observed concentration factors at or above 5,000. The references cited for blue mussels include a range of values, the upper end of which is essentially 5,000 (i.e., 4,985). In addition, EPA explained that "[t]he bioaccumulation and persistence of lead in humans is well documented" and requested comment on how such

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data should be regarded in classifying lead and lead compounds as highly bioaccumulative.

A high concern for the bioaccumulation potential for chemicals with BCF values above 1,000 is consistent with the discussion of BCF values in the proposed rule on PBT chemicals (January 5, 1999, 64 FR 688). In addition, there is considerable information on the accumulation of lead in humans, including children, who are the most susceptible to the toxic effects of lead. The data on lead's persistence and availability in the environment, the observed high bioaccumulation values in aquatic organisms, and lead's ability to accumulate in humans, provided the basis for EPA preliminarily concluding that lead and lead compounds are highly persistent and highly bioaccumulative.

E. What Changes to the Reporting Thresholds did EPA Propose for Lead and Lead Compounds?

In evaluating potential lower reporting thresholds for lead and lead compounds, EPA considered not only their persistence and bioaccumulation properties and the purposes of EPCRA section 313, but also the potential burden that might be imposed on the regulated community. Because PBT chemicals, including lead and lead compounds, persist and bioaccumulate in the environment, they have the potential to pose greater exposure to humans and the environment over a longer period of time. The nature of PBT chemicals, including lead and lead compounds, indicates that small quantities of such chemicals are of concern, which provides strong support for setting lower reporting thresholds than the current section 313 thresholds of 10,000 and 25,000 pounds. For determining how low reporting thresholds should be set for PBT chemicals, including lead and lead compounds, EPA adopted a two-tiered approach. Thus, EPA made a distinction between persistent bioaccumulative toxic chemicals and that subset of PBT chemicals that are highly persistent and highly bioaccumulative by setting lower reporting thresholds based on two levels of concern. As explained in the final PBT rule and in the proposed lead rule, this approach identifies as PBT chemicals those that are persistent (i.e., with half-lifes of at least 2 months) and those that are bioaccumulative (i.e., based on aquatic studies showing BAF/BCF values of at least 1,000 and/or human data showing evidence of bioaccumulation). Further, as also explained in the PBT rule and the proposed lead rule, highly PBT chemicals are identified as those that are highly persistent (i.e., with half-lifes of 6 months or greater) and those that are highly bioaccumulative (e.g., BAF/BCF values of 5,000 or greater). EPA preliminarily concluded that lead and lead compounds to be highly persistent and highly bioaccumulative toxic chemicals.

In determining the appropriate reporting thresholds to propose for lead and lead compounds, EPA started with the premise that low or very low reporting thresholds may be appropriate for these chemicals based on their persistence and bioaccumulation potentials only. EPA then considered the burden that would be imposed by lower reporting thresholds and the distribution of reporting across covered facilities. Using this approach and considering the factors described above and the purposes of EPCRA section 313, EPA proposed to lower the manufacture, process, and otherwise use thresholds to 10 pounds for lead and lead compounds. For purposes of section 313 reporting, threshold determinations for chemical categories, including lead compounds, are based on the total of all toxic chemicals in the category (see 40 CFR 372.25(d)).

F. What Other Reporting Issues Did EPA Consider for Lead and Lead Compounds?

1. *De minimis exemption.* In 1988, EPA promulgated the *de minimis* exemption because: (1) The Agency believed that facilities newly covered by EPCRA section 313 would have limited access to information regarding low concentrations of toxic chemicals in mixtures that are imported, processed, otherwise used or manufactured as impurities; (2) the Agency did not believe that these low concentrations would result in quantities that would significantly contribute to threshold determinations and release calculations at the facility (53 FR 4509, February 16, 1988); and (3) the exemption was consistent with information required by the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS). However, given that: (1) Covered facilities currently have several sources of information available to them regarding the concentration of PBT chemicals in mixtures; (2) even minimal releases of persistent bioaccumulative toxic chemicals may result in significant adverse effects and can reasonably be expected to significantly contribute to exceeding the proposed lower thresholds; and (3) the concentration levels chosen, in part, to be consistent with the OSHA HCS are inappropriately high for PBT chemicals, EPA's original rationale for the *de minimis* exemption does not apply to PBT chemicals. EPA therefore proposed to eliminate the *de minimis* exemption for lead and lead compounds based on their status as PBT chemicals. EPA did not propose, however, to modify the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)) because the Agency believed there was sufficient information available.

2. *Use of the Alternative threshold and Form A.* EPA stated its belief that use of the existing alternate threshold and reportable quantity for Form A would be inconsistent with the intent of expanded reporting for PBT chemicals such as lead and lead compounds. The general information provided in the Form A on the quantities of the chemical that the facility manages as waste is insufficient for conducting analyses on PBT chemicals and would be virtually useless for communities interested in assessing risk from releases and other waste management of PBT chemicals. EPA, therefore, proposed excluding lead and lead compounds from the alternate threshold of 1 million pounds.

3. *Proposed changes to the use of range reporting.* EPA stated its belief that use of ranges could misrepresent data accuracy for lead and lead compounds because the low or the high end range numbers may not really be that close to the estimated value, even taking into account any inherent error in reporting (i.e., errors in measurements and developing estimates). EPA believed this uncertainty would severely limit the applicability of release information where the majority of a facility's releases are within the amounts eligible for range reporting. Given EPA's belief that the large uncertainty that would be part of these data would severely limit their utility, EPA proposed to eliminate range reporting for lead and lead compounds.

4. *Proposed changes to the use of the half-pound rule and whole numbers.* EPA currently allows facilities to report whole numbers and to round releases of 0.5 pound or less to zero when reporting on EPCRA section 313 listed chemicals not designated as PBT chemicals in the October 29, 1999 final rule. EPA explained its concern that the combination of requiring the reporting of whole numbers and allowing rounding to zero would result in a significant number of facilities reporting their releases of lead and lead compounds as zero. EPA, therefore, proposed that all releases or other waste management quantities greater than 1/10 of a pound of lead and lead compounds be reported, provided that the appropriate activity threshold has been exceeded.

5. *Proposed exemption for the reporting of lead in certain alloys.* In the proposal, EPA proposed to defer making a final decision on lower reporting thresholds for lead contained in stainless steel, brass, and bronze alloys until the Agency could complete an ongoing scientific review of issues pertinent to the reporting of these types of alloys. This would result in no changes to the reporting requirements for lead contained in stainless steel, brass, and bronze alloys until EPA makes a final determination on whether there should be any changes to the reporting requirements for lead and other metals contained in these three types of alloys. EPA, therefore, proposed to include a qualifier to the listing for lead in 40 CFR 372.28. This qualifier would read "this lower threshold does not apply to lead when contained in a stainless steel, brass, or bronze alloy."

V. Summary of the Final Rule

A. What Threshold Has EPA Established for Lead and Lead Compounds?

EPA is finalizing manufacture, process, and otherwise use thresholds of 100 pounds for lead and lead compounds, with the first reports at this lower threshold due on or before July 1, 2002, for the 2001 calendar year. This lower reporting threshold does not apply to lead contained in stainless steel, brass, and bronze alloys nor do any of the other changes discussed below in Unit V.B. However, lead contained in stainless steel, brass, and bronze alloys remains reportable under the 25,000 pound manufacture and process reporting threshold and the 10,000 pound otherwise use reporting threshold.

B. What Exemptions and Other Reporting Issues is EPA Addressing for Lead and Lead Compounds?

EPA is eliminating the *de minimis* exemption for lead and lead compounds. However, this action will not affect the applicability of the *de minimis* exemption to the supplier notification requirements (40 CFR 372.45(d)(1)). In today's action, EPA is also excluding lead and lead compounds from eligibility for the alternate threshold of 1 million pounds and eliminating range reporting for on-site releases and transfers off-site for further waste management for lead and lead compounds. This will not affect the applicability of the range reporting of the maximum amount on-site as required by EPCRA section 313(g). EPA proposed to require reporting of all releases and other waste management quantities greater than 1/10 of a pound of lead and lead compounds. Also, EPA proposed that releases and other waste management quantities would continue to be reported to two significant digits. In addition, EPA proposed that for quantities of 10 pounds or greater, only whole numbers would be required to be reported. After reviewing all the comments on this issue, EPA is providing additional guidance on the level of precision at which facilities should report their releases and other waste management quantities of lead and lead compounds. Facilities should still report releases and other waste management quantities greater than 0.1 pound provided the accuracy and the underlying data on which the estimate is based supports this level of precision. Rather than reporting in whole numbers and to two significant digits, if a facility's release or other waste management estimates support reporting an amount that is more precise than whole numbers and two significant digits, then the facility should report that more precise amount. The Agency believes that, particularly for PBT chemicals such as lead and lead compounds, facilities may be able to calculate their estimates of releases and other waste management quantities to 1/10 of a pound and believes that such guidance is consistent with the reporting requirements of sections 313(g) and (h).

VI. Summary of Public Comments and EPA Responses

A. How is EPA Responding to Comments Relating to Generic Issues?

EPA received numerous comments relating to the generic issues raised and resolved in the first rulemaking on PBT chemicals, published on October 29, 1999 (64 FR 58666); for example, whether the Agency should select lower thresholds based on a risk assessment. Some commenters merely reiterate comments raised in the previous rulemaking. Other commenters rephrase, in terms of lead and lead compounds, comments that have been previously submitted on these generic issues, without presenting additional information or concerns specific to lead and lead compounds.

In its proposal to lower the thresholds for lead and lead compounds, EPA explicitly limited its request for comments to issues specific to lead and lead compounds, such as whether lead and lead compounds meet the EPCRA section 313 persistence and bioaccumulation criteria articulated in the PBT rule and proposed lead rule, and whether lead and lead compounds present such unique technical or policy issues that they merit different treatment than that established for either the class of PBT chemicals or the subset of highly persistent and highly bioaccumulative toxic chemicals (see 64 FR 42224 and 58666). Notwithstanding that EPA extended the comment period on this rulemaking to allow for an additional 48 days following publication of the final PBT chemical rule, commenters failed to present issues or information that persuades the Agency to revisit the decisions made with respect to generic issues in the PBT chemical rule, or that provides any basis for treating lead and lead compounds separately from how the Agency generally approachs PBT chemicals within the EPCRA section 313 program.

To the extent that commenters provide comments on the generic issues that were specific to lead and lead compounds, these comments are addressed in this preamble and in the Response to Comments (RTC) document for this final rule (Ref. 1). For responses to those comments on the generic issues that were not specific to lead and lead compounds the reader is referred to the PBT chemical final rule (64 FR 58666) and the associated Response to Comments document (Ref. 15). The remainder of this Unit contains responses to major comments on the issues of the EPCRA section 313 reporting thresholds for lead and lead compounds, the technical information regarding the persistence and bioaccumulation potential of lead and lead compounds, and the alloys reporting limitation for lead. Responses to major comments on EPA's economics analysis (Ref. 16) and regulatory assessment determinations are contained in Units VII and IX respectively. Additional responses to comments not addressed in this preamble are contained in the RTC document for this final rule (Ref. 1).

B. What Comments did EPA Receive on its Statutory Authority to Lower Reporting Thresholds for Lead and Lead Compounds?

Several commenters allege that under EPA's interpretation of EPCRA section 313(f)(2), Congress did not provide an "intelligible principle" for determining whether or how much to lower a statutory threshold, thereby rendering this provision unconstitutional as an improperly broad delegation of legislative power. The commenters raise several points in support of this contention; several commenters cite

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EPA's statement in the proposal that "Congress provided no prerequisites to the exercise of EPA's authority to lower [EPCRA section 313] thresholds" to demonstrate that EPA does not have the authority to lower the thresholds without violating the non-delegation doctrine. Other commenters support this allegation merely by reference to the fact that EPCRA section 313(f)(2) does not prohibit the Agency from establishing a threshold of "0." Another commenter contends that the unconstitutional delegation of authority is even more striking than it was in section 109(b)(1) of the Clean Air Act, which at least provided the Agency with the direction to set standards "requisite to protect the public health" and "with an adequate margin of safety." EPCRA, the commenter states, sets forth no standard for establishing reduced reporting thresholds. To support their assertions, several of these commenters specifically cite the decision in *American Trucking Association v. EPA*, 175 F.3d 1027 (D.C. Circuit, 1999) *cert. granted sub nom. Browner v. American Trucking Association*, 120 S.Ct 2003 (US May 22, 2000)(No. 99–1247).

EPA disagrees. As a preliminary matter, EPA disagrees with the interpretation of the non-delegation doctrine articulated in *American Trucking*, and has appealed that decision to the Supreme Court. Nonetheless, EPA believes that Congress has provided an "intelligible principle" sufficient for the delegation of authority contained in EPCRA section 313(f)(2).

The commenters appear to have fundamentally misunderstood EPA's explanation of its rationale for selecting the specific thresholds adopted in the final PBT chemical rule, and the implications these actions had for the selection of the thresholds for lead and lead compounds. As part of the discussion in the final PBT chemical rule, EPA noted that for several reasons, it was establishing "two sets of revised thresholds based on two classes of PBT chemicals," and stated its intention that "the revised thresholds establish a set of categories that would be generally applicable to future designated PBT chemicals." (64 FR 58689). Thus, the selection of the specific threshold for lead and lead compounds is governed by the analyses laid out in EPA's preamble to the final PBT chemical rule and in the proposed lead rule. See also EPA's rationale for the specific threshold chosen for lead and lead compounds, *infra* at Unit VI.E. Under this construct, taking into account the aquatic and human data available.

In the preamble to the final PBT chemical rule, and the associated Response to Comments Document (Ref. 15), EPA described at length the process by which it distilled Congressional guidance from various sources, such as the language and legislative history of EPCRA sections 313(f)(2) and (h), to guide its exercise of discretion in lowering the thresholds. See (e.g., (64 FR 58687–692). Specifically, EPA explained:

EPA relied on the language of EPCRA sections 313(f)(2) and (h), and the legislative history, to elicit the following principles to guide its exercise of discretion in lowering the thresholds, and in selecting the specific thresholds: (1) The purposes of EPCRA section 313; (2) the "verifiable, historical data" that convinces EPA of the need to lower the thresholds; (3) the chemical properties shared by the members of the class of toxic chemicals for which EPA is lowering the thresholds (i.e., the degree of persistence and bioaccumulation); and (4) the reporting burden imposed by revised thresholds to the extent that such consideration would not deny the public significant information from a range of covered industry sectors. Further, EPA believes that in the language of EPCRA § 313, and its legislative history, Congress provided direction on the appropriate weight to allocate to each of these considerations in implementing EPCRA section 313(f)(2). These considerations underlay the entire process by which EPA determined the appropriate thresholds. But the Agency's choice of revised thresholds was governed, and ultimately constrained, by EPCRA section 313's overriding purpose, which is to provide government agencies, researchers, and local communities, with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems. Id. at 58687.

EPA also disagrees with the analyses on which the commenters rely to support their assertions that Congress provided no intelligible principle to guide EPA's delegated authority under EPCRA section 313(f)(2). Whether the legislative guidance offered sufficiently constrains the discretion delegated to the Agency under EPCRA section 313(f)(2) must be evaluated against the actual "power to roam" that this provision confers on EPA. *Michigan v. EPA*, 213 F.3d 663, 680-81 (D.C. Cir. 2000). As discussed in Unit II.A., as EPA interprets the requirements in section 313(f)(2), the standard operates as an effective constraint when the Agency increases the thresholds, but as a practical matter, cannot provide the same level of constraint when the Agency decreases the thresholds. However, as previously explained, EPA relied on this standard to elicit factors to guide its exercise of discretion. See, 64 FR 58687–692.

But the mere fact that Congress provided neither explicit prerequisites in section 313(f)(2) to the Agency's determination that a lower threshold is warranted, nor a standard whose plain language effectively constrains EPA's discretion in selecting the appropriate lower threshold, does not necessarily render this provision unconstitutional. The issue is whether Congress granted the Agency too much discretion to *modify* the statutory thresholds—not merely whether Congress provided a standard to significantly constrain the Agency's discretion in lowering the thresholds. See *Michigan v. EPA*, 213 F.3d at 680; *International Union v. OSHA*, 37 F.3d 665 (D.C. Cir. 1994). Examination of the former issue demonstrates that in section 313(f)(2), EPA's "power to roam" is relatively narrow.

In section 313(f), Congress established thresholds as a baseline, and delegated authority to EPA to modify them provided that the "revised thresholds shall obtain reporting on a substantial majority of total releases of the chemical at all facilities subject to the requirements of this subsection." As previously explained, EPA interprets this to require that any revised threshold obtain reporting on a substantial majority of the total releases reported by facilities reporting under the existing, baseline thresholds. See, Unit II.A. *supra*, and 64 FR 58673–676. This standard effectively constrains EPA's ability to increase the thresholds, and thereby deprive government agencies, researchers, and local communities of information that would provide them with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems, contrary to EPCRA section 313's overriding purpose. The discretion exercised in this rule is EPA's discretion to establish thresholds between 0 and 10,000 pounds or 25,000 pounds; this can hardly be characterized as an "immense power to roam."

Moreover, the impact of any revised threshold is distinctly limited, which courts have recognized as a relevant factor in evaluating the degree of authority that Congress delegates to an Agency. See, e.g., *Michigan*, 2000 WL 180,650 ("a mass of cases in courts had upheld delegations of effectively standardless discretion, and distinguished them precisely on the ground of the narrower scope within which the agencies could deploy that discretion"); *American Trucking*, 175

F.3d at 1037 ("The standards in question affect the whole economy, requiring a more precise delegation than would otherwise be the case" (citations omitted)). Here, that means within the context of all of the other prerequisites Congress established for TRI reporting, and of the other relevant statutory provisions constraining the Agency's ability to modify those requirements. Irrespective of the modified threshold, a facility must still employ more than ten full-time employees; its primary SIC code must fall within one of the listed SIC codes; and it must be manufacturing, processing, or otherwise using one (or more) of the currently listed chemicals. 42 U.S.C. § 11023 (b). And far from granting EPA unfettered discretion to expand these requirements, Congress selectively granted EPA carefully qualified authority to adjust individual parameters. For example, section 313(l) explicitly limits the Agency's authority to modify the reporting frequency, ". . . but the Administrator may not modify the frequency to be any more often than annually." Similarly, Congress included no authority to amend the generally applicable employee threshold; thus facilities with fewer than ten employees are not subject to reporting under subsection 313(b)(1). In section 313(g)(2), Congress also specifically restricted the Agency's ability to require industry to collect data to report under TRI: "Nothing in [EPCRA section 313] requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment . . ." Accordingly, the scope within which EPA may deploy its discretion under EPCRA section 313(f)(2) is fairly narrow, and its impact limited.

In light of the above, EPA does not believe that the mere fact that the Agency is authorized to potentially select a threshold of "0," necessarily renders section 313(f)(2) unconstitutional. The issue underlying the non-delegation doctrine, as the DC Circuit has explained is "to make sure that the regulatory principles as applied have their origin in a judgement of the legislature," not whether Congress authorized the Agency to establish extremely low thresholds. *International Union* v. *OSHA*, 37 F.3d at 669 (citations omitted). Nor does the fact that Congress did not require the Agency to make specific findings to determine it was appropriate to increase or decrease section 313 reporting thresholds, necessarily demonstrate that Congress failed to provide the Agency with adequate guidance in delegating its authority under section 313(f)(2).

One commenter further alleged that the Agency has failed to identify an intelligible principle "to channel its application of these factors," quoting, *American Trucking Association v. EPA*. Another commenter asserts that EPA's reliance on the general purposes of EPCRA is insufficient, stating that "general purposes or factors cannot substitute for the constitutionally required "intelligible principle" by which to identify a stopping point" when setting levels or thresholds.

As noted above, the Supreme Court has granted EPA's request to review *American Trucking*. Nonetheless, EPA disagrees that EPCRA section 313(f)(2) falls afoul of the non-delegation doctrine, even as interpreted and applied in that case. As summarized above, in the preamble to the final PBT chemical rule, EPA identified and explained its application of the "intelligible principle" that Congress provided along with the delegation of authority in EPCRA section 313(f)(2). See, 64 FR 58687–692.

EPA also disagrees that its reliance on EPCRA section 313's general purposes to discern EPCRA section 313's overriding purpose, and thereby its intelligible principle, is insufficient. The DC Circuit upheld a broad delegation of legislative authority to OSHA based on the Agency's demonstration of legislative guidance found in the Act's "overriding purposes." There, the Court noted

> Were the six itemized criteria the full statement of OSHA's interpretation of its statutory mandate, we might have to vacate the rule, because the agency might still have too much freedom to "roam between the rigor of section 6(b)(5) standards and the laxity of unidentified alternatives. International Union I, 938 F.2d at 1317. **But OSHA has gone on to infer from various sections—that the Act's "overriding purpose" is "to provide a high degree of employee protection."** 58 FR 16, 614/3–15/1. Thus the Agency reads the Act to require it, once it has identified a "significant" safety risk to enact a safety standard that provides "a high degree of worker protection."Id. at 16, 615/1. It is not permitted to "do nothing at all", as we had earlier suggested. Id. (quoting International Union I, 938 F.2d at 1317). **Rather, OSHA reads the Act to permit it to deviate only modestly from the stringency required by section 6(b)(5) for health standards. Accordingly, as construed by OSHA, the Act guides its choice of safety standards enough to satisfy the demands of the nondelegation doctrine.** (citations omitted). *International Union v. OSHA*, 37 F.3d at 669 (emphasis added).

The Court also explained that the underlying purpose of non-delegation doctrine is "to make sure that the regulatory principles as applied have their origin in a judgement of the legislature." Id. (citations omitted). EPA believes that its application of EPCRA section 313(f)(2) in this rule, as well as in the PBT rule, similarly satisfy the demands of the nondelegation doctrine.

C. What Science Issues Were Raised by Commenters on the Persistence and Bioaccumulation Criteria?

Several commenters contend that the criteria articulated in the PBT chemical rule to characterize the persistence and bioaccumulation of toxic chemicals should not be applied to metals because the development of the persistence and bioaccumulation criteria (as discussed in the PBT chemical rulemaking, see 64 FR 688–729) was based largely on data pertaining to organic substances. Thus they contend it is inappropriate to use these criteria to determine whether inorganic substances, including inorganic metal compounds, should be classified as PBT chemicals.

The Agency disagrees with the commenters' statement that the PBT rule framework developed by EPA to assess the persistence and bioaccumulation of EPCRA section 313 listed toxic chemicals was designed only for organic substances and is being incorrectly applied to metals. The development of EPA's framework to assess persistence and bioaccumulation is described in detail in the PBT chemical rulemaking (see 64 FR 688–729) and in the proposed lead rule. This framework was not developed to assess only whether organic chemicals are persistent and/or bioaccumulative, but to assess whether *any* chemical substance is persistent and/or bioaccumulative, including metals and metal compounds. EPA notes that the public had the opportunity to comment on the applicability of the PBT rule criteria to metals in the PBT chemical rulemaking. Furthermore, in the PBT chemical rulemaking, the Agency applied these criteria to mercury and mercury compounds—a metal and metal compounds category. EPA also provided notice in the proposed PBT chemical rulemaking that it was continuing to evaluate the bioaccumulation data for lead and lead compounds, and for cobalt and cobalt compounds—also metals (64 FR 717). EPA made clear the PBT rule criteria were developed to apply to metals and metal compounds, as well as organic compounds and, in fact, has applied the criteria to metals and metal compounds in a previous notice and comment rulemaking. With respect to the half-life and BCF/BAF criteria, scientifically these criteria are quite applicable to metals. Finally in the

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lead proposed rule, EPA identified an additional factor for use in determining whether a chemical is, at the least, bioaccumulative. EPA explained that there is clear and convincing evidence that lead is bioaccumulative in humans. However, EPA requested comment on how such human data should be considered in determining whether a chemical should be classified in that subset of PBT chemicals that are highly bioaccumulative. Commenters argue that the human data should not be used to classify lead as bioaccumulative because the quantities of lead that might be reported, they believe, would not reduce human exposures to lead that are of concern. As explained elsewhere, EPA does not believe that human data showing the bioaccumulation nature of lead in humans should be ignored in any assessment of lead's bioaccumulation potential simply on the theory that the level of lead to which humans are exposed and the levels observed in humans may not correlate to the additional information on land release collected under this rule.

Persistence, bioaccumulation, and toxicity are three distinct, independent characteristics. Although in the PBT chemical rulemaking the experimental evidence used to derive the environmental half-life, BAF and BCF criteria were obtained largely from studies that involved organic substances, this does not preclude the application of these criteria to inorganic substances such as metals and metal compounds (including lead and lead compounds). The basis for the concern and reason for lowering thresholds is based on the ability of the chemical, whether it is an organic chemical or a metal compound, to persist and bioaccumulate. The Agency believes that these criteria should and must be applicable to *all* chemical substances, including metals and metal compounds. EPA provided a detailed response to the issue of metals as PBT chemicals in the PBT chemical rulemaking. Persistence and bioaccumulation are not dependent upon whether a substance contains carbon (i.e., is organic). Substances that are inorganic can persist and bioaccumulate. The underlying molecular properties that determine whether a substance can persist and bioaccumulate are fundamentally the same for organic chemicals as they are for inorganic chemicals, including metals and metal compounds. These properties, as with most chemical and biological properties of a substance, are more dependent on the electronic and steric characteristics of the atoms comprising a substance, the specific arrangement of the atoms within the substance's molecular structure and, with regard to bioaccumulation, the pharmacokinetics of the substance within the exposed organism and the sensitivity of the organism to the substance.

In addition, it is scientifically valid to establish generic criteria that are applicable to all substances provided that the endpoint or purpose for which the criteria are being established provides a common thread that is not dependent upon the unique elements comprising any given substance. For example, it would be legitimate to establish a category based on a type of arsenic toxicity and include within that category any substance that contains arsenic and exhibits that toxicity regardless of whether individual substances are organic or inorganic. In fact, it is common practice for scientific organizations and regulatory agencies to use generic criteria of this type. One example is the criteria established by the National Toxicology Program (NTP) for characterizing chemical carcinogens. The NTP is required by law to establish a list of all substances which either are known to cause cancer in humans, or may reasonably be anticipated to cause cancer in humans. A criterion used by the NTP to characterize chemicals as known or possible human carcinogens include, among others, tumor incidences in humans or experimental animals. While the vast majority of substances reviewed and tested by the NTP for carcinogenicity are organic substances, and the criterion established by NTP was based largely from toxicological observations pertaining to organic substances, the criterion used by the NTP is the same for inorganic substances as it is for organic substances. The NTP does not use different criteria when evaluating inorganic substances. This is because the ability of a substance to cause cancer is not dependent upon whether the substance is organic. In fact, NTP's current list of substances that are known to be human carcinogens contains both inorganic (including metallic) and organic substances. The carcinogenicity of all of these substances were characterized by the same generic criterion. A detailed discussion of the criteria used by the NTP is available (Ref. 17).

1. *What comments did EPA receive on the persistence of metals and metal compounds?* EPA defines a chemical's persistence as the length of time the chemical can exist in the environment before being destroyed by natural processes. Numerous commenters suggested that EPA adopt a different definition of persistence for metals and metal compounds. They assert that the definition of persistence as applied to metals and metal compounds should include the transformation of individual metal compounds in the environment. As discussed in detail in the following response to comments on this issue, EPA believes that these factors are irrelevant to the persistence of metals and metal compounds in the environment. The factors that the commenters contend should be considered are those which address the conversion of one metal compound to another, which is irrelevant in determining whether metal compounds are persistent. While these are factors which control the transformation of one metal compound to another compound of the same metal, they are not factors which result in the destruction of the metal. There are no environmental factors which can or will result in the destruction of the metal.

Some commenters disagree with EPA's definition of persistence. They contend that the definition of persistence should be based on the availability of the metal in various environments and the length of time the metal is retained in an organism. One of these commenters stated that "persistence is the length of time an element or compound is available to and/or is retained in an organism or an ecological community, and that the mobility of metals [such as lead] deposited in soils or aquatic sediments becomes an important question when discussing persistence, since they are not persistent in biota unless they reach those environmental compartments and are cleared more slowly than they accumulate."

EPA disagrees with the commenter's definition of persistence. In the PBT chemical rulemaking (64 FR 58666), EPA adopted a policy for use in classifying a toxic chemical as persistent under EPCRA section 313. In the proposed rule to lower the reporting thresholds of lead and lead compounds (64 FR 42222), EPA used this same policy to determine whether lead and lead compounds are persistent. Most of these comments address the issue of persistence generically rather than specifically to lead and lead compounds. EPA responded to these generic issues in the PBT chemical rulemaking (64 FR 58676) and in sections 2a–f of the associated Response to Comments document (Ref. 15). EPA is discussing these issues here as background for the individual issues specific to lead and lead compounds in order to assist in understanding EPA's responses. Persistence is the length of time a chemical can exist in the environment before being destroyed by natural processes (64 FR 698 and 64 FR 42227). The environmental media for which persistence is measured or estimated include air, water, soil, and sediment. It is important to distinguish between persistence in a single medium (air, water, soil or sediment) and overall environmental persistence. Persistence in an individual medium is controlled by transport of the chemical to other media. Persistence in the environment as a whole, however, is a distinct concept. It is based on observations that the environment behaves as a set of interconnected media, and that a chemical substance released to the environment will become distributed in these media in accordance with the chemical's intrinsic properties and reactivity. For overall persistence, only irreversible transformation contributes to net loss of a chemical substance. With regard to metals, although metals and metal compounds, such as lead and lead compounds, may be converted from the metal to a metal compound or from one metal compound to another in the environment, the metal itself cannot be destroyed. A metal by its very nature cannot be destroyed and, therefore, is persistent in the environment as the metal or a metal compound.

The primary purpose of the persistence criterion is to establish how long a chemical substance will remain in the environment. The greater the length of time a substance persists in the environment, the greater is the potential for all forms of life to be exposed to the substance. Persistence is not limited to the duration of time a chemical is present in an organism and EPA does not believe it would be appropriate to incorporate this concept into its definition of persistence. It should be noted that, unlike the commenter's definition of persistence, EPA's definition of persistence does not specifically address the longevity of a substance in an organism. Persistence of a substance in the environment as a whole, or even in a particular environmental medium, is fundamentally unrelated to the substance's biological persistence (i.e., length of time a chemical exists in an organism before being destroyed or excreted). Although there are a few factors (physicochemical factors; e.g., water solubility, reactivity) that have a similar influence on environmental persistence as they do on the biological persistence of a substance, there are a number of other factors that influence biological persistence but not environmental persistence. These other factors are organism specific, and are related to the anatomical and physiological characteristics of the organism. The Agency believes its environmental persistence criterion should not be extended to include biological persistence because the factors that influence the two persistence types are largely unrelated. Biological persistence in a given organism does not provide any information as to how long a substance will remain in the environment, and therefore is not relevant to the definition of persistence for EPCRA section 313.

One commenter claims that there is a serious flaw in the Agency's reasoning in characterizing all elements, including metals, as being persistent. Specifically, this commenter claims that this reasoning implies that because elements are non-destructible, then any compounds that contain a particular element is also non-destructible. The commenter acknowledges that EPA makes the statement in the proposed lead rule that "specific metal compounds may or may not be persistent, depending on the form of the metal and environmental conditions, but the elemental metal itself obviously meets the definition of persistence." The commenter claims that this statement begs the questions as to why EPA is not evaluating specific metal compounds when the Agency acknowledges that metal compounds differ in their "persistence" and also differ substantially with respect to toxicity and bioaccumulative potential. The commenter states that the above quoted statement could just as easily read ". . . specific *carbon* compounds may or may not be persistent, depending on the form of *carbon* and environmental conditions, but the elemental *carbon* itself obviously meets the definition of persistence." The commenter asserts that, according to EPA, this would mean that all organic compounds are persistent because they contain carbon and carbon is persistent. The commenter states that the Agency does not adopt such reasoning regarding elemental carbon because it would render the PBT chemical assessment methodology useless as an assessment tool. The commenter recommends that the Agency not apply the persistence assessment methodology to metals for the same reasons.

Another commenter believes that EPA's criteria for persistence as it applies to characterizing the persistence of metals is unfair. Specifically, this commenter interprets EPA's persistence assessment methodology as saying ". . . since any metal is persistent in the environment by definition, every compound of that metal is evaluated and regulated by EPA like the parent metal, even if there are no data on that compound's persistence, even if the persistence in the environmental medium of its concern is very short, and even if that compound's bioavailability is insignificant."

The Agency believes that both of these commenters have misinterpreted the PBT assessment methodology EPA applied to lead and lead compounds.

With respect to the commenter who questioned why EPA is not evaluating the persistence of compounds individually, EPA disagrees that it is either scientifically required, or necessary for purposes of EPCRA section 313, to evaluate the persistence of each lead compound individually. lead compounds are listed under EPCRA section 313 as a category; this means that all of the individual chemical compounds share common chemical characteristics, such that it is scientifically reasonable to conclude that lead compounds exhibit common toxicological properties/exhibit similar toxicity. For lead compounds, as for all metal compounds listed in an EPCRA section 313 metals category, the relevant common chemical property is the metal, because the toxic constituent is the metal itself, and this is what defines the category. Thus, in evaluating the persistence of lead compounds as an EPCRA section 313 chemical category, the relevant issue for purposes of EPCRA section 313 is the persistence of lead rather than the persistence of the other chemical constituents of the compounds in the category.

Similarly, EPA believes that this commenter's analogy to carbon and organic compounds is misguided. Organic compounds differ significantly from metal compounds in that the presence of carbon in a compound is not a controlling feature in the way that a metal contained in a metal compound is controlling. For example inorganic arsenic compounds are classified as known human carcinogens (Ref. 18). The toxicity is specific to the fact that the compounds contain arsenic and not to the other parts of the arsenic compounds. This is not the case with all groups of carbon compounds. For example, classes of organic chemicals that contain oxygen such as ketones, alcohols, ethers, and carboxylic acids exhibit significantly different physical and chemical properties and toxic effects. This is due to the differing arrangement of the carbon and oxygen within the compound. Even chemicals within the same class of organic chemicals, e.g., ketones, may not exhibit the same toxicity or similar physical

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chemical properties. Further, while one arsenic compound will be converted in the environment or *in vivo*, it will not be converted into a substance that does not contain arsenic. In the environment or *in vivo* degradation of one member of a group of organic chemicals, e.g., ketones, carboxylic acids, will not consistently be converted into another chemical of the same class. They will often be converted into a different class of organic chemical.

Thus, while the Agency agrees that elemental carbon is persistent, the Agency would not conclude that all organic substances are persistent simply because they contain carbon. This is because the toxic effects of organic compounds are attributable to the structure of the compounds and *not* the carbon contained in the compounds. Thus EPA would not list a chemical category consisting of carbon and all carbon containing compounds, nor would it make a determination using the PBT assessment methodology that such compounds are PBT chemicals because they contain carbon. The same is true for any other element that is not toxic.

This approach is consistent with the Agency's approach to listing chemical categories, where, in the absence of data on a particular member of the category, EPA adds a chemical category, such as a metal compound category, based on their common chemical characteristics, and without demonstrating separately that each individual member of the category meets the section 313(d)(2) criteria. The D.C. Circuit specifically upheld this approach with respect to listing categories, finding that EPA's action was reasonable (*Troy v. Browner*, 120 F.3d 277, 288-89 (D.C. Cir. 1997).

In addition, the commenters imply that in using the PBT rule assessment methodology EPA would conclude that all metals and their compounds are persistent and bioaccumulative, and therefore the Agency would require that all metals and their compounds that are listed on the EPCRA section 313 list of toxic chemicals have reduced reporting thresholds. The Agency would like to emphasize that while all metals persist, many metals and their compounds would not be characterized by EPA as bioaccumulative and toxic. For a listed toxic chemical to be considered a PBT chemical, the toxic chemical must be sufficiently persistent and sufficiently bioaccumulative.

Several commenters disagree with the Agency's rationale for characterizing all metals as being persistent, and believe that the issue of persistence has little or no relevance to metals.

The Agency disagrees with the commenters' statement that the issue of persistence has little or no relevance to metals. EPA believes that persistence is relevant to the hazard potential of metals such as lead for the same reason persistence is relevant to the hazard potential of organic chemicals: for a chemical that persists in the environment, there is a greater potential for exposure and, therefore, a greater potential for the chemical to cause toxicity in an exposed organism or individual. However, in this rulemaking the Agency did not rely on the property of persistence by itself in lowering reporting thresholds for lead and lead compounds, nor does persistence alone necessarily mean that a substance is or can be a hazard to human health and the environment. As stated above, to be classified as a PBT chemical, a chemical must: (1) Be an EPCRA section 313 listed toxic chemical; (2) be sufficiently persistent; and (3) be sufficiently bioaccumulative. In this rulemaking EPA is addressing lead and lead compounds which are EPCRA section 313 listed toxic chemicals and is also considering the bioaccumulation potential of these chemicals.

One of the commenters believes that metals do not necessarily persist, and that the definition of persistence in relation to metals should be qualified to mean how long a metal can remain in a particular form or species (e.g., oxidation state). This commenter also recommends that the Agency should examine data pertaining to certain properties of metals to assess persistence in accordance with this definition, and to allow for the identification of those metals and metal species which are the most/least resistant to change and which are the most or least bioavailable. The properties raised by the commenters include: transformation/dissolution, oxidation, corrosion, sulfide binding, and first hydrolysis constant.

EPA agrees with the commenter's statement that metals, including lead, can exist as different species and compounds. These different species pertain to the oxidation states or, more specifically, the number of electrons missing from the outer orbital of the metal atom. Lead, for example, can exist in a neutral species, Pb^0 (no electrons are missing from the outer electron orbital of the lead nucleus), or as lead compounds in one of two oxidation states: Pb^{+2} or Pb^{+4} (2 and 4 electrons are missing from the outer electron orbital, respectively). As stated in the proposed rule, these species can convert from one to another under certain, commonly encountered environmental conditions. See also Unit VI.C.5. of this preamble. While there may be a conversion from one lead compound to another lead compound or to metallic lead, or from metallic lead to a lead compound (either in the Pb^{+2} or Pb^{+4} oxidation states), there is no possible conversion either in the environment or *in vivo* that will convert (or degrade) metallic lead or any lead compound into a substance that does not contain lead. Any conversion will always result in the presence of lead or a compound that contains lead. Conversion of a metal atom from one oxidation state to another does not change the number of protons in the nucleus of the atom and, therefore, does not change the metal into another metal or element. In the case of lead, each species of lead (Pb^0, Pb^{+2}, and Pb^{+4}) is still lead because each contain the same number of protons (82) within their nuclei (See Refs. 19 and 20).

EPA disagrees with the commenter's assertion that the Agency consider transformation/dissolution, oxidation, corrosion, sulfide binding, and first hydrolysis constant in determining whether metal compounds are persistent. These are factors which address the conversion of one metal compound to another, which is irrelevant in determining whether metal compounds are persistent. While these are factors which control the transformation of one metal compound to another compound of the same metal, they are not factors which result in the destruction of the metal. There are no environmental factors which can or will result in the destruction of the metal. Therefore, EPA believes that the commenter's definition of persistence is not an appropriate alternative to EPA's definition.

One commenter who agrees with EPA's definition of persistence and, in particular the Agency's characterization of lead as being persistent states that the persistency of lead poses a significant threat to human health and the environment because this property allows lead to remain in the environment without being broken down by natural processes. This commenter disagrees with other commenters who claim that metals are not persistent or that persistence of toxic metals should not be of concern. This commenter believes that persistence enables a substance like lead to travel through ecosystems and through different media and, as such, threatens human health and the environment far beyond the geographic vicinity of the source from which it has been released.

The Agency agrees with the commenter's statement that lead is persistent. The Agency also agrees that

the persistence property of a substance contributes to the ability of the substance to be distributed through ecosystems and through different media to areas beyond the geographic vicinity from where the substance entered the environment. The property of persistence, however, pertains to longevity of a substance, and does not bestow an ability for the substance to partition throughout environmental media. However, the opportunity for exposure to a substance that is capable of partitioning throughout environmental media may be greater if the substance is also persistent, since the substance will remain in the environment for a longer period than a substance that is not persistent

2. *What comments did EPA receive on the availability and bioavailability of metal compounds?* Commenters suggest that EPA consider environmental availability (which they term "bioavailability") in lieu of bioaccumulation. Many of these commenters assert that unless a metal compound is readily available in the environment, it will not be bioavailable or bioaccumulate. Some attempt to take a risk-based approach to metals and metal compounds in the environment by arguing that when environmental availability is considered, metals and metal compounds will not be present at levels high enough to cause adverse effects.

As discussed in detail below, the level of environmental availability or bioavailability is not a surrogate for bioaccumulation. Even metal compounds that have limited availability or bioavailability can bioaccumulate. The extent of environmental availability or bioavailability will not affect whether bioaccumulation will occur. For example, lead from a sparing soluble compound and lead from a readily soluble compound will both bioaccumulate. This is in contrast to the commenters' implication that only the lead from the readily soluble lead compound will bioaccumulate. Further as discussed below, the presence of a soluble metal compound is not the only factor, or in many cases the determining factor, that controls the potential for the metal compound to bioaccumulate. A metal compound may undergo various transformations in the environment resulting in a different metal compound which has a much higher availability and/or bioavailability. While metals and metal compounds need to be environmentally available and/or bioavailable as a prerequisite to bioaccumulation, there is not a quantitative relationship between environmental availability and/or bioavailability and the degree of bioaccumulation. Therefore, EPA believes that availability and bioavailability are not appropriate substitutes for bioaccumulation.

Further, requiring a particular level environmental availability would effectively be establishing a risk-based approach to lowering thresholds which EPA believes is inappropriate for the following reasons. The availability of lead in the environment will vary depending upon environmental conditions. Choosing one level of environmental availability and applying that individually to each metal compound is neither practical nor scientifically supportable because: (1) As discussed above environmental availability is not necessarily reflective of bioavailability; and (2) the environmental availability of a metal compound depends upon local environmental conditions. There is no "best" or adequately representative set of national environmental conditions. Further, the TRI program is primarily a hazard based program. Risks that may be acceptable at the national level may not be acceptable at a regional or local level.

EPA considers availability in the environment and bioavailability for metal and metal compounds for purposes of bioaccumulation only to determine whether it is impossible for the metal and metal compounds to bioaccumulate, i.e., a compound that is both environmentally and biologically inert cannot bioaccumulate. EPA believes that there are data that indicate that lead and lead compounds are available in the environment, are bioavailable, and bioaccumulate, e.g., data in humans and fish advisories. However, several commenters contended at public meetings on EPA's PBT chemical rulemaking that metals and metal compounds, such as lead and lead compounds, are not available in the environment and thus, cannot bioaccumulate. To address these comments, EPA chose to conduct an environmental fate assessment to describe the environmental availability of lead and lead compounds. Qualitative environmental fate assessments are generally part of a hazard assessment for a chemical. The qualitative environmental fate assessment for lead and lead compounds, however, was not developed, nor was it intended, to be part of an exposure assessment or risk assessment.

Several commenters claim that EPA should consider bioavailability in its assessment of metals and metal compounds, such as lead and lead compounds. These commenters contend that not all metal compounds and lead compounds in particular are bioavailable. According to the commenters, unless a compound is in a form that is bioavailable, it will present little risk to human health and the environment. One commenter made the following statement:

> Because of metals' natural persistence, the weight of scientific opinion holds that bioavailability is a more appropriate criterion for assessing the environmental and health hazards associated with metals. While toxicity is obviously a relevant measure for assessing the hazard posed by a substance, the substance must be available for uptake [bioavailable] before it can exhibit an adverse effect. Bioavailability varies significantly among different species of metals, including lead compounds, and also is influenced by environmental media. Bioavailability can only occur if soluble metal compounds are released. Thus, the rate at which metals transform to soluble/bioavailable species is critical for hazard identification. Simply stated, the natural persistence of metals with toxic properties poses no special hazard if those metals generally are present in environmental media in forms that cannot be taken up by plants and animals.

Other commenters expressed similar views. These commenters believe that the availability of lead from lead compounds differs among lead compounds, and that lead is unavailable from certain lead compounds. Therefore, in the opinion of the commenters, lead compounds from which lead is not available and/or bioavailable cannot be PBT chemicals, and should not be included in this rulemaking.

The Agency disagrees with the commenters assertions that: (1) EPA did not consider bioavailability of lead in its assessment of lead and lead compounds as bioaccumulative substances; and (2) that bioavailability is only possible for released soluble metal compounds.

The basis for the Agency's disagreement with these comments concerns the commenters use of the terms "availability" and "bioavailability", which differs significantly from EPA's definition of these terms. The commenters are using the term bioavailability interchangeably with availability, when in fact these two terms have totally different meanings and cannot be used interchangeably. In addition, the commenters have incorrectly concluded that: (1) If lead is not available in the environment, it is not bioavailable and will not bioaccumulate or cause toxicity; (2) lead is only bioavailable when in its ionic oxidation state; and (3) only those lead compounds that are water soluble as released are bioavailable. To respond to

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these comments, the Agency needs to first clarify the distinction between "availability" of a metal, and "bioavailability" of a metal or metal compound, and the factors that influence availability and bioavailability of a metal or metal compound.

Availability of a metal is the extent to which a metal, in either its neutral (MG^0) or ionic (MG^{+x}) oxidation state, can reach a state of atomic disaggregation. Inorganic metal compounds that are water soluble will completely dissociate in aqueous media, liberating the metal in its ionic oxidation state. In aqueous solution the metal atoms of the molecules of these substances are completely disaggregated from the rest of their molecular constituents. In this disaggregated state the metal is completely available. Water solubility is not a prerequisite, however, for a metal to become available from a metal compound. In the environment a metal can become available from organometallic substances or inorganic metal compounds that are poorly soluble in water, by undergoing environmental transformations that cause the metal atoms to dissagregate and become available. Environmental transformations that cause metals to become available are summarized below, and discussed in greater detail in Unit V.A. of the proposed lead rule (64 FR 42227-42228), and in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2).

The extent to which a metal can become available from a metal compound in environmental media is dependent upon: (1) The physicochemical properties of the metal and the metal compound; (2) the structural characteristics of the metal compound; and (3) environmental factors, including, but not limited to: presence of aerobic or anaerobic bacteria, pH, moisture content, and organic matter content of soil or sediments. Some or all of these environmental factors can vary between specific terrestrial or aquatic environments. For different compounds that contain the same metal, the relative availability of the metal from each compound can vary within the same terrestrial or aquatic environment. It is also true that the availability of a metal from the same metal compound can vary between specific terrestrial or aquatic environments. Some metal compounds are more susceptible to environmental transformations and subsequent release of the metal than are other metal compounds.

Bioavailability is the extent to which a substance is absorbed by an organism, and distributed to an area(s) within the organism. This is important because the substance can then exert a toxic effect or accumulate. As with availability, the physicochemical and structural characteristics of a substance play an important role in determining whether the substance is bioavailable and the extent to which it is bioavailable. Unlike availability, however, whether a substance is bioavailable and the extent to which it is bioavailable in a given organism also depends upon the anatomy and physiology of the organism, the route of exposure, and the pharmacokinetics of the substance in the organism (i.e., the extent to which the substance is or can be absorbed by the organism from the exposure site, its distribution and metabolism within the organism, and its excretion from the organism). It is important to stress that bioavailability does not by itself mean that a substance is a hazard to human health or the environment. A substance that has 100% bioavailability does not pose a hazard to human health or the environment if it is not intrinsically toxic. Conversely, for substances that are intrinsically toxic it is not necessary for the substance to be 100% bioavailable to cause toxicity. Depending upon the extent of exposure, toxic potency, and the nature of the toxic effect, even substances that have low bioavailability can still pose a hazard to human health or the environment. Similarly, a substance does not have to have 100% bioavailability in order for it to bioaccumulate. For some compounds, even very limited bioavailability (that is a very small percentage is bioavailable) can result in concern if it is bioaccumulated. Lead and lead compounds are one example. Polychlorinated biphenyls (PCBs) are another (64 FR 706).

Absorption of a substance is a critical component of its bioavailability. Absorption is the movement of a chemical substance from its site of exposure on a terrestrial or aquatic life form into its systemic circulation (bloodstream) or, in the case of unicellular organisms such as algae, inside the cell comprising the organism. In any case, absorption of a substance from any exposure site involves its passage across the biological membranes that compose the exposure site. Chemicals can cross a cell membrane by several mechanisms. These are: (1) Passive permeation (diffusion) through the membrane; (2) passive transport through membrane channels or pores; (3) active transport; facilitated transport; or (4) phagocytosis (also pinocytosis and endocytosis) (Ref. 21). Whether a substance can or will be absorbed, and the degree to which it can be absorbed depends largely upon the physicochemical properties of the substance, the anatomical makeup of the exposed organism and the site of exposure (Ref. 21). Substances released to the environment that are not absorbable by terrestrial or aquatic species may be transformed in the environment to metabolites that are absorbable and, hence, bioavailable.

An important point to stress regarding the bioavailability of metals is that availability of a metal is not a prerequisite for its bioavailability. Metals can be bioavailable in either their neutral (MG^0) or ionic (MG^{+x}) oxidation states; or as part of an intact inorganic or organic compound. When in ionic oxidation states many metals are generally absorbed by active transport processes. Here, cellular membrane-bound proteins carry the metal across the cell membrane and into the cell. While it would seem that most metal ions are sufficiently small and water soluble to simply pass through membrane channels, their hydrated ionic radii are usually too large to permit their passage by this mechanism. Metals in their neutral or ionic oxidation states may be taken up by organisms by phagocytic processes as well. Organometallic substances are substances in which the metal is bonded to carbon-containing substituents. These substances can be absorbed intact by passive diffusion. The absorption of poorly water soluble inorganic metallic substances can occur via phagocytosis, or by other mechanisms. In terrestrial or aquatic life forms that have digestive systems that secrete strong acids, a poorly water soluble inorganic metallic substance or a metal in its neutral oxidation state can react (following oral exposure to the substance) with the acid to form a water soluble salt of the metal. Under these circumstances the metal is made available within the digestive system, and is absorbed in its ionic oxidation state. See Refs. 21, 22, 23, and 24.

The distribution, metabolism, and rate of excretion of a metal or metal compound depends upon the nature of the metal or metal compound, and the anatomy, physiology and genetic makeup of the organism. Metals absorbed in their neutral or ionic oxidation state be excreted unchanged or react with endogenous substances to form a metal compound *in vivo*. Organometallic substances are typically more lipid soluble than is the metal in its neutral or ionic oxidation state, and can be distributed more readily to areas of the organism that otherwise may be poorly accessible by the metal in its neutral or ionic oxidation state. Organometallic substances may also undergo metabolic transformations *in vivo* in which the metal is liberated from its organic constituents. The same is true for inorganic metallic substances absorbed intact. See Refs. 24, 25, and 26.

Generally the ionic oxidation states of metals are the most available and, for many life forms, the most bioavailable. For aquatic species the bioavailability of a metal is expected to be greater from those metal compounds in which the metal is readily available in aquatic environments than from metal compounds or complexes in which the metal is not readily available in aquatic environments. This is because the metal is in a completely disaggregated state and dissolved in the aqueous media of the aquatic environment, which favors uptake of the metal by aquatic organisms since they are typically immersed in the aqueous media. However, aquatic species can also absorb intact metal compounds (e.g., organometallic substances). Thus, metals may be bioavailable from metal compounds or metal complexes even where the metal is not available in aquatic environments. Many aquatic organisms such as mussels, clams, and oysters, for example, consume as food organic materials suspended in aqueous media. These molluscs use short, hairlike locomotory organelles (cilia) to take in suspended organic materials from the water. Water currents sweep the suspended organic materials into the open shells, where they become fastened to a film of mucus. The cilia sweep the mucus to the mouth of the mussel. Soft, fingerlike organs push the mucus and organic materials into the mouth of the mussel, where it is taken in and digested. As stated by EPA in the proposed rule regarding lead and lead compounds, and by many commenters, lead dissolved in aqueous media may be removed from solution through sorption to suspended organic matter. Although no longer available, the lead in these suspended complexes may still be *bioavailable* in aquatic life forms that consume solid organic materials as food. Another example is that fish can absorb organometallic substances (intact) via passive diffusion through their gill membranes. See Refs. 24, 27, and 28.

The availability of a metal from the *same* metal compound may vary in different terrestrial or aquatic locations. Differences in environmental conditions lead to differences in the environmental fate of the compound in different environments. In an aquatic environment that contains metal ions of the same metal, the bioavailability of the metal in different aquatic species may vary even though the availability of the metal to each species is the same (i.e., the concentration of the metal in its ionic oxidation state is the same throughout the aquatic environment). These differences in bioavailability in different aquatic species are due to the differences in anatomy, physiology, and pharmacokinetic differences among the species. For different compounds that contain the same metal, the bioavailability of the metal ion in a given organism within a particular terrestrial or aquatic location may vary among different compounds. For a given organism, differences in bioavailability of a metal among compounds that contain the metal may be ascribed to differences in the physicochemical properties of the metal compounds and pharmacokinetic differences.

As mentioned above, metals or metal compounds released to the environment from anthropogenic sources are affected by prevailing environmental conditions, meaning broadly the wide variety of physical, chemical and biological processes that act upon them. These processes collectively determine the metal compounds in which the metal can exist in the environment. Lead can enter the environment as available or bioavailable compounds, or as compounds that are not available or bioavailable. However, lead that enters the environment as compounds that are not available or bioavailable can be converted in the environment to compounds that are available or bioavailable. As mentioned above, the ionic oxidation states of metals are generally the most available and, for many organisms, the most bioavailable. Hence, environmental factors that affect the availability of a metal may indirectly affect the bioavailability of metal. It is therefore important to consider those factors that influence the availability of a metal in the environment, when assessing physical or biological properties of the metal. However, as also discussed above, availability of a metal is not a prerequisite for its bioavailability. Interconversion of inorganic metal compounds can be quite rapid and as a result the metal compound in which the metal is released may not be the predominant metal compound post-release. Availability of a metal from an organometallic compound or insoluble inorganic compound is affected by many factors and its determination is complex, but many of the more important variables are discussed below for lead. A detailed discussion of the environmental fate of lead, that is illustrative of many of the more important environmental variables that affect availability and bioavailability of metals in general is provided in Unit V.A. of the proposed rule (64 FR 42227-42228), in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2), and below.

In some instances, after deposition in the soil environment, lead may bind strongly by mechanisms such as the formation of insoluble complexes with organic material, clay minerals, phosphate, and iron-manganese oxides common in many soils. However, some of the lead in the soil environment (0.2 to 1%) may be water soluble. The extent of sorption appears to increase with increasing pH. Under acidic conditions, levels of lead in soil water can increase significantly. (The solubility of lead increases linearly in the pH range of 6 to 3.) Cation exchange capacity (CEC, related to soil clay content) and pH also influence the capacity of soil to immobilize lead. Using organic chelation as a model, the total capacity of soil to immobilize lead can be predicted by a linear relationship equation. Using this model to predict saturation capacity from CEC and pH it can be shown that a decrease in pH from 5.5 to 4.0 will reduce estimated soil capacity 1.5 times, thereby increasing the concentration of available lead in soil water (Ref. 2).

A number of field studies demonstrate the enhanced mobility of lead in soils under a range of environmental conditions. In all of these studies variables including pH, soil organic matter content and the chemical species of lead present played a significant role in increasing soil lead mobility. Limited data also indicate that organo lead compounds may be converted into water-soluble lead compounds in soil. Degradation products of tetramethyl and tetraethyl lead, the trialkyl lead oxides, are expected to be significantly more mobile in soils than the parent compounds (Ref. 2).

Levels of soluble lead in surface waters depend on the pH of the water and the dissolved salt content. Equilibrium calculations show that at a pH greater than 5.4 the total solubility of lead is approximately 30 micrograms per liter (μg/L) in hard water and approximately 500 μg/L in soft water. In soft water, sulfate ions limit the lead concentration in solution through the formation of lead sulfate. The lead carbonates limit lead in solution at a pH greater than 5.4 (Ref. 29). Concentrations as high as 330 μg/L could be stable in water at a pH near 6.5 and an alkalinity of about 25 milligrams (mg) bicarbonate ion per liter. Water

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having these properties is common in runoff areas of New York state and New England.

Lead also forms complexes with organic matter in water. The organic matter includes humic and fulvic acids that are the primary complexing agents in soils and widely distributed in surface waters. The presence of fulvic acid in water has been shown to increase the rate of solution of lead sulfide 10 to 60 times (Refs. 30 and 31). At pH levels near neutral (i.e., about 7.0), soluble lead-fulvic acid complexes are present in solution. As pH levels increase, the complexes are partially decomposed, and lead hydroxide and carbonate are precipitated.

At neutral pH lead generally moves from the dissolved to the particulate form with ultimate deposition in sediments. There is evidence that in anaerobic sediments, lead can undergo biological or chemical methylation. This process could result in the remobilization and reintroduction of transformed lead into the water column where it could be available for uptake by biota, and volatilization to the atmosphere. However, tetramethyl lead may be degraded in aerobic water before reaching the atmosphere.

It can be concluded that many processes commonly observed in the environment result in the release of lead ion, which is available and bioavailable lead. These processes may occur in soil and aquatic environments with low pH and low levels of organic matter. Under these conditions, the solubility of lead is enhanced and in the absence of sorbing surfaces and colloids, lead ion can remain in solution for a sufficient period to be taken up by biota. Lead sorption to soil organic matter has been shown to be pH dependent. A decrease in soil pH can cause sorbed lead to desorb, and increase lead availability in soil water.

A few commenters contend that bioavailability is only possible for released soluble metal compounds. This position is incorrect: EPA has concluded that metal compounds, including lead compounds, that are released as metal compounds that are not soluble or bioavailable may be converted in the environment into metal compounds that are available or bioavailable. Furthermore, as discussed above, a metal compound may not be soluble, but may, nonetheless, be bioavailable.

Several commenters contend that EPA should consider each member of a metal compounds category (such as lead compounds) individually because the availability will vary from metal compound to metal compound within a category and some metal compounds will not be available at all.

EPA disagrees. As discussed above in Unit VI.C.1. with respect to evaluating persistence for metal compound categories, the Agency believes that it is reasonable to evaluate metal compound categories, such as lead compounds, as a category rather than individually. Moreover, in the case of lead compounds, the bioavailability of a lead compound is not necessarily dependant upon the availability of lead from the compound. That is, the parent lead compound may be bioavailable as is or, if not itself bioavailable, could be converted in the environment into a compound that is bioavailable or from which lead is bioavailable. As EPA has discussed elsewhere in this preamble, the environmental fate assessment indicates that there are many conditions under which lead from lead compounds can become available in the environment. Further, most lead compounds provide bioavailable lead when ingested. In addition, regardless of the relative environmental availability of lead from one lead compound to another, the lead compounds all add to the environmental loading of lead. Thus, even if under the same environmental conditions the lead from compound A is 10 times less available than the lead from compound B, compound A would introduce the same amount of available lead if its releases are 10 times greater. If lead compounds are evaluated individually based on relative environmental availability then the additive effect of the loading of lead from these compounds would be ignored.

Two commenters criticize EPA for not using the latest tools for assessing the availability of metals, including those tools in which the Agency was or is involved with developing. These commenters mention several Agency efforts that pertain to availability and the assessment of metals. These include the Environmental Sediment Guidelines and the Biotic Ligand Model development for the Water Quality Criteria.

The environmental processes that determine the complexation, speciation, and ultimately the availability of lead in the environment have been considered and addressed elsewhere in this preamble. In conducting its assessment of the availability of lead in the environment, EPA reviewed the available documentation on both the simultaneously extracted metals/acid volatile sulfide (SEM/AVS) methodology and the Biotic Ligand Model (BLM). EPA believes that the SEM/AVS methodology as applied to the Environmental Sediment Guidelines, and the BLM as applied to water quality criteria show great promise for use in conducting *site-specific* assessments of those metals for which it has been validated. However, to date neither the SEM/AVS methodology nor the BLM have been validated for lead, nor have the substantive technical comments provided by the EPA Science Advisory Board been incorporated into these approaches. In addition, EPA does not believe that a means currently exists to incorporate these methodologies into the technical analysis supporting a *nationally* applied regulation such as this rulemaking. While at this stage of their development these methods may be useful in site-specific assessments, they cannot be applied to support national Agency programs such as the TRI Program because of the variability in environmental conditions throughout the United States. On the other hand, the PBT methodology, as used by EPA in the characterization of lead as a PBT chemical, can be used to provide technical support to national regulatory programs such as the TRI Program because this methodology incorporates the environmental processes that determine the complexation, speciation, and the availability of lead in the environment, but does not require site-specific input. EPA believes that the PBT model is an appropriate methodology for assessing the persistence of metals, including lead.

3. *What comments did EPA receive on the bioaccumulation of metals and metal compounds?* Numerous commenters suggest that for metals and metal compounds bioaccumulation is not a relevant endpoint of concern. They contend that for metals and metal compounds: (1) Bioaccumulation is mitigated by environmental factors; (2) that metals and metals compounds are often essential nutrients and thus organisms have developed mechanisms to control their accumulation; (3) that BCF values for metals are dependent upon the concentration of the metal; and (4) that metals do not bioaccumulate at the concentration levels associated with toxicity. As discussed in detail in the following comment responses, EPA does not believe that any of the issues raised by the commenters call into question EPA's scientific and policy reasons for considering bioaccumulation for lead and lead compounds. Not all metals are essential nutrients and even those that are can be accumulated to unsafe levels. In particular, lead is not an essential nutrient. While some metal BCF values

vary with metal concentration this does not change the fact that the metals do bioaccumulate. In addition, bioaccumulation does not need to occur at concentrations that cause toxicity to be of concern, and in fact testing of bioaccumulation should not be conducted at concentrations that are detrimental to the test organism. Moreover, where there is extensive human data showing significant bioaccumulation of a listed toxic chemical, such as here, the bioaccumulation of the metal is obviously of concern. Therefore, EPA believes that bioaccumulation potential is a relevant endpoint of concern for metals, especially for lead and lead compounds.

Several commenters contend that the extent to which a metal bioaccumulates in aquatic organisms is dependent upon the metal's concentration in the aqueous habitat of the organism. Specifically, this commenter states that the BAF or BCF of a substance is inversely related to its concentration in the surrounding aqueous medium: that is, BAFs and BCFs become larger as the external concentration of the substance decreases. Thus, according to the commenter, because a metal's BCF or BAF value in a given aquatic organism will vary depending upon concentration, a single BAF or BCF value cannot be used to define whether a metal bioaccumulates. In effect the commenter is disagreeing with EPA's definition of BCF and BAF since the definitions do not require that all concentrations of the chemical result in the same BCF or BAF.

The Agency is in general agreement with the commenters' position that for a substance that bioaccumulates in aquatic species the degree to which it does so (i.e., the BAF and BCF of the substance) is related in part to the external concentration of the substance. The Agency also believes, however, that external concentration is not the only factor that influences bioaccumulation. As discussed previously, the propensity of a substance to bioaccumulate in a species depends largely upon the pharmacokinetics of the substance in that species. For further discussion on pharmacokinetics and bioavailability and bioconcentration see Unit VI.C.2.

In addition, the Agency believes that when analyzing test data, the conclusion that bioaccumulation decreases as external concentration of a substance increases may be erroneous. It is quite possible that as the concentration of the test substance is increased, biochemical changes that are precursor events to toxicity are initiated. While the increased concentration may not be sufficient to cause death to the organism, the initiation of the precursor events may cause a stasis in cell growth or function, and interfere with the organism's ability to absorb the metal. In a species where this is the case, it would therefore incorrectly appear that the bioaccumulation of the metal decreases as external concentrations increase. Thus, the Agency is in general agreement with the commenter's position that, for a substance that bioaccumulates in aquatic species, the degree to which it does so is related to the external concentration of the substance. The Agency, however, does not agree that the relationship for metal is always truly inversely related: i.e., that as external concentration increases bioaccumulation decreases. This is not a general phenomenon for all metals and metal compounds in all organisms as suggested by the commenter.

When discussing BCF and BAF values, distinction needs to be made between BAF or BCF values that are measured in a laboratory from those that are measured in an actual environmental setting. The Agency's definition of BCF and BAF (64 FR 42229) pertain to determinations of BAF and BCF under controlled experimental conditions where exposure of the aquatic species to the chemical is kept relatively constant (i.e., external concentration of the substance remains relatively constant). Thus, assays performed in laboratories to determine BAFs and BCFs are conducted under controlled conditions, and any sources of variability in conditions are minimized or eliminated. In a laboratory assay the test concentration is usually set at some percentage below the acute LC_{50} (the concentration lethal to 50% of the test organisms following acute exposure); often $\frac{1}{10}$ of the LC_{50} of the metal is used. While there is no reason BCF tests cannot be conducted at other concentrations of the test chemical, it would serve no scientific purpose to use concentrations at which the test organism becomes stressed or dies before the test assay is completed or before the organism has the opportunity to bioaccumulate the test chemical. In an actual environmental setting, however, conditions can be variable. No commenter to this rule provided scientific data showing that these BCF values would not be found in the environment. Consequently, EPA believes that appropriately conducted bioaccumulation tests conducted at even at one concentration of lead are valid indicators of the potential for lead to bioaccumulate.

Two commenters claim that EPA dismisses the notion that bioavailable metals are often intentionally bioaccumulated as beneficial nutrients or are otherwise safely metabolized by plants and animals through biological mechanisms. One of the commenters states that while metals can bioaccumulate, the manner and rate at which they do so varies based upon the nutritional needs of the organism, external concentration of the metal, and speciation of the metal. The commenter also states that the bioaccumulation of metals is fundamentally different than the process by which organic compounds bioaccumulate.

EPA acknowledges that some metals are nutrients in some organisms, including humans, or are otherwise necessary for the subsistence of organisms. Thus, some metals need to be bioaccumulated by the organism. Clearly, such metals need to be bioavailable in the organisms that require these metals. As discussed in greater detail elsewhere in this document and as alluded to by one of the commenters, in many organisms the absorption or uptake of metals across cell membranes involves active (i.e., energy-requiring) processes, whereas absorption or uptake of organic substances is usually the result of passive diffusion across cell membranes. Active transport processes give the organism some ability to regulate the uptake of metals. It is also important to note that active transport across cell membranes is not the only means by which a metal can be absorbed. Organometallic substances, for example, are often absorbed by passive diffusion. Metals and metal containing substances may also be taken up by organisms through phagocytic processes. In addition, as one of the commenters states, metal speciation and concentration are factors that can influence uptake of metals into an organism.

While active transport processes are involved with the uptake of metals needed by the organisms, these processes do not always discriminate those metals that are needed by the organism from those metals that are harmful to the organism. Thus, organisms also have the ability to take up or absorb metals that are not nutrients and that are not necessary for subsistence. Thus, the processes that organisms use to absorb or take up needed metals do not necessarily prohibit or protect them from taking up toxic metals. In addition, even needed metals can be toxic to the organism if over exposure occurs. It is well established that metals that are not needed by an organism can be taken up by the organism, and bioaccumulated by the organism. lead and mercury, for

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example, are not known to be essential metals in any species. Yet the uptake and bioaccumulation of these metals by organisms, including humans, is well established. EPA has therefore determined, insofar as commenters are suggesting that EPA consider the nutrient value of metals in this rulemaking, that such comments are irrelevant because lead has no known nutritive value to any species. The results of the studies investigating the bioconcentration of lead and lead compounds in aquatic organisms summarized in Table 1 (64 FR 42230) of the proposed lead rule and the table in Reference 10 of the proposed rule show that lead is taken up and bioaccumulated by many different aquatic organisms. Also, as discussed in Unit VI.D.3., EPA's fish advisory data base demonstrates that many species of fish and shellfish from various aquatic environments in different regions of the country contain lead (see http://fish.rti.org) indicating that fish and shellfish bioaccumulate lead under realistic environmental conditions.

Two commenters stated that bioaccumulation of metals does not necessarily indicate the presence of, or a potential for adverse effects. At the outset, EPA stresses that lead and lead compounds are EPCRA section 313 listed toxic chemicals. Therefore, as stated in the proposed rule and elsewhere in this preamble, the toxicity of lead and lead compounds is not at issue in this rulemaking. These commenters state that bioaccumulation of a substance is not an indicator of hazard, and should not be used as a hazard assessment criterion.

The Agency agrees that the ability of a substance to bioaccumulate does not by itself necessarily indicate the presence of, or potential for adverse effects. The Agency believes, however, that the concept of bioaccumulation is relevant to the hazard characterization of metals for the same reasons that it is relevant to the hazard characterization of organic substances: that low-level or sub-toxic exposures to a toxic substance that bioaccumulates could eventually lead to exposures of concern in the organism that bioaccumulates it or increased exposure potential for predator species. The Agency would also like to emphasize that while bioaccumulation of lead in a given aquatic organism may not necessarily be toxic to the organism, the accumulated lead may serve as a source of lead exposure and toxicity to predator species, including humans.

Thus, the high bioaccumulation potential of lead, an EPCRA section 313 listed toxic chemical, within an organism is anticipated to contribute a greater total body burden relative to a chemical with lower bioaccumulation potential, thereby increasing any toxicity to the organism. High bioaccumulation also increases lead exposure to other organisms that are predators of the organism that has accumulated the lead.

4. *What comments did EPA receive on the relationship of its persistence and bioaccumulation criteria to international criteria?* Two commenters claim that numerous international organizations such as the Organization for Economic Cooperation and Development (OECD) have approached the classification of PBT chemicals in a manner that calls into question EPA's use of persistence and bioaccumulation criteria for accurately identifying the human and environmental health hazards of metals. One of the commenters claims that the OECD Advisory Group on Harmonization of Classification and Labeling (which includes EPA participants) has made the following conclusion: "...For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather, the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species." The commenter recommends that EPA reconsider its characterization of lead as a PBT chemical because, in the opinion of the commenter, there is a lack of scientific support for assessing a metal's PBT characteristics to determine its potential hazard to human health and the environment.

The Agency believes the commenter has misunderstood OECD's position on the applicability of general PBT criteria to metals. The quote is taken from the OECD document entitled *Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances.* (Ref. 32) The pronouncements on metals are contained in paragraphs 22 and 23 of that document. Paragraph 22 reads as follows:

For inorganic compounds and metals, the concept of degradability as applied to organic compounds has limited or no meaning. Rather the substance may be transformed by normal environmental processes to either increase or decrease the bioavailability of the toxic species. Equally, the use of bioaccumulation data should be treated with care. Specific guidance will be [but has not yet been] provided on how these data for such materials may be used in meeting the requirements of the classification criteria.

By "degradability as applied to organic compounds" OECD means molecular degradation, most often by microbial degradation and/or hydrolysis or other abiotic processes, to progressively simpler organic chemical structures, leading eventually to inorganic substances like carbon dioxide and water. It is important to note that paragraph 22 does not in any way suggest that metals are not persistent. Moreover, it does not suggest that OECD hazard classification criteria cannot be applied to metals, only that "care" (e.g., professional judgment) is required in the interpretation of data relative to the classification criteria. In fact, EPA agrees that in order for a metal to bioaccumulate in an organism it must either be environmentally available or bioavailable. In response to the allegations that lead is not environmentally available, as part of the proposed rule, the Agency analyzed information on the environmental fate of lead, and, as noted above, determined that lead has the potential to become available from lead compounds under commonly encountered environmental conditions. In addition, as explained in Unit VI.D.3, EPA determined that lead and lead compounds are bioavailable. Therefore, the Agency's assessment of lead as a PBT chemical is consistent with the OECD's intent.

EPA does not interpret the above quote to indicate that OECD's position is that its or any PBT chemical criteria are not applicable to lead. As the commenter correctly states, EPA is a member of the OECD Advisory Group on Harmonization of Classification and Labeling. OECD does not recommend that metals and metal compounds be *excluded* from consideration as PBT chemicals, as the commenter implies. More specifically, OECD has not concluded that metals and metal compounds have no potential to bioaccumulate because they are never released as bioavailable compounds; or cannot be converted to bioavailable compounds under any foreseeable circumstances. On the contrary, EPA believes that the preceding language indicates that OECD's position is that any substance judged to be potentially bioavailable, whether organic or inorganic, should not be excluded as a candidate from some form of regulatory action. As discussed in Units VI.C.2. and VI.D.1., it is realistic to expect that, in general, released metals such as lead can encounter conditions in which they are (or can become) available at levels sufficient to bioaccumulate. Therefore, the Agency's use of the PBT criteria in its assessment of lead is consistent with OECD's position on the general applicability of PBT criteria to metals.

5. *What comments did EPA receive on its metals policy?* Some commenters contend that EPA should not consider all members of the lead compounds category to be PBT chemicals because availability and bioavailability of the lead portion will vary among the compounds. These commenters further state that the toxicity can only be evaluated on a compound-by-compound basis and is dependent on bioavailability.

Members within the lead compounds category listed on the EPCRA section 313 list of toxic chemicals have a common moiety that bestows toxicity, i.e., lead. Consequently, it is reasonable to anticipate that once released into the environment: (1)The metal moiety in each member of the category will become available as a result of abiotic and/or biotic processes or (2) each member of the category will either be bioavailable or will convert into a compound that is bioavailable. For example, different inorganic lead compounds that are released into acidic surface waters will result in the formation of similar soluble inorganic lead compounds. Variation in the level of availability or bioavailability does not negate the consistency of effect across the members of the category.

EPA would like to remind the commenters that a mechanism already exists under EPCRA section 313 to address concerns for any metal compound for which the data show that the metal can never become available. Thus, the issue of availability, which is broader than the issue of a compound's potential to bioaccumulate, was addressed previously for EPCRA section 313 chemical assessments through EPA's policy and guidance concerning petitions to delist individual members of the metal compound categories listed under EPCRA section 313 (May 23, 1991, 56 FR 23703). If a petitioner has information demonstrating that a particular lead compound does not cause toxicity as the intact lead compound, and will not cause lead to be available in the environment to express its toxicity, they can submit a petition pursuant to EPCRA section 313(e)(1) to delete that specific lead compound from the EPCRA section 313 list of toxic chemicals. Under the metals policy EPA considers whether the metal from a metal compound can ever become bioavailable under abiotic or biotic conditions. An assessment of the availability and bioavailability of a lead compound would include processes such as: hydrolysis at various pHs; solubilization in the environment at various pHs; photolysis; aerobic transformations (both abiotic and biotic); anaerobic transformations (both abiotic and biotic); bioavailability when the compound is ingested (solubilization in and/or absorption from the gastrointestinal tract and solubilization in various organs); and bioavailability when the material is inhaled (solubilization in and/or absorption from lungs, especially taking into account the likelihood that the compound will lodge in the lungs and be converted a soluble compound by the lung's defense mechanism).

If the commenters have information demonstrating that a particular lead compound does not cause toxicity as the intact lead compound, and will not cause lead to be available in the environment to express the toxicity of the metal, the commenters can submit a petition pursuant to EPCRA section 313(e)(1) to delete that specific lead compound from the EPCRA section 313 list of toxic chemicals. EPA would address such a petition in accordance with the Agency's longstanding stated policy and guidance concerning petitions to delist individual members of the metal compounds categories (May 23, 1991, 56 FR 23703).

6. *What comments did EPA receive that pertain to natural vs. industrially produced lead and lead compounds?* Some commenters contend that natural forms of lead, as opposed to industrially produced lead compounds, should not be classified as PBT chemicals. Other commenters state that because lead occurs naturally, industrial activities involving lead do not change the total amount of lead in the earth: these activities only affect the form and location of the lead in the environment. These commenters believe that the forms of lead that are produced by industrial activity tend to be more hazardous and should be regulated more strictly than the natural forms, such as trace amounts of lead in natural minerals.

EPA disagrees that natural lead compounds should be treated differently than industrially produced lead compounds. While the comment was made specifically for lead it is general to all metals and metal compounds. Both naturally occurring and industrially produced lead and lead compounds, meet the persistence and bioaccumulation criteria. EPA's analysis of the environmental fate of lead demonstrates that it is reasonable to anticipate that under environmental conditions lead can become available from lead compounds, and that whether lead or lead compounds are obtained naturally or produced industrially does not change the potential for availability of lead. Whether a chemical comes directly from the ground or from a manufacturing plant will not affect whether the chemical is toxic, persistent, and bioaccumulative. These are the result of the inherent properties of the chemical, not from their origin (all other things being equal).

The Agency recognizes that lead and certain lead compounds occur naturally. EPA agrees that industrial activities involving lead do not change the total amount of lead in the earth, and that industrial activities involving lead only affect the type of lead compound and its location in the environment. The Agency believes, however, that while industrial activities do not increase the total quantity of lead in the earth, industrial activities transport lead and lead compounds from one environment to another environment in which the likelihood of exposure to lead in aquatic and terrestrial species, and humans is increased. As discussed in the PBT rulemaking (64 FR 688-729), environmental conditions can vary greatly among geographic locations, even those that are in close proximity to one another. There may be certain geographical areas in which the environmental conditions are such that lead availability from a naturally occurring lead compound may be equal to or greater than that from an industrially produced lead compound.

D. What Comments Did EPA Receive Concerning the Persistence and Bioaccumulation of Lead and Lead Compounds?

In the proposed rule to lower the thresholds of lead and lead compounds, EPA discussed its scientific basis for preliminarily characterizing lead and all lead compounds as highly persistent and highly bioaccumulative. To summarize, the data on lead's persistence in the environment, the observed high bioaccumulation values in aquatic organisms, and lead's ability to accumulate in humans were the basis for EPA's preliminary conclusion that lead and lead compounds are highly persistent and highly bioaccumulative. EPA has also evaluated the bioavailability of lead and lead compounds and has concluded that lead is bioavailable. In the proposed rule the Agency specifically requested public comment on its discussion of the scientific information concerning: (1) The fate, transport and availability of lead in the environment and how this information should be considered in classifying lead as a PBT chemical (Unit V.A.); (2) the bioaccumulation of lead in aquatic organisms, and how this

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information should be evaluated in assessing the bioaccumulative potential of lead and lead compounds (Unit V.B.); (3) the bioaccumulation of lead in humans, and how this information should be considered in classifying lead and lead compounds as highly bioaccumulative (Unit V.C.); and (4) abiotic factors (e.g. soil chemistry; pH; water hardness; presence of organic matter in aqueous media) that can diminish the bioavailability of lead in aquatic species.

The Agency received many comments regarding EPA's technical basis for preliminarily characterizing lead and lead compounds as highly persistent, and highly bioaccumulative. These comments were extensively reviewed and considered by the Agency in finalizing the rule. While some of the commenters agreed with the Agency's characterization of lead and lead compounds as highly persistent and highly bioaccumulative, the majority of the commenters disagreed. Most of the comments were similar in content, and pertained to general or specific issues dealing with persistence, bioaccumulation and toxicity, as well as EPA's use of persistence and bioaccumulation data pertaining to lead and lead compounds in characterizing these chemicals as PBT substances. Lead and lead compounds are included on the EPCRA section 313 list of toxic chemicals. EPA is not responding to comments on the toxicity of lead and lead compounds, because their inclusion on the EPCRA section 313 list of toxic chemicals is not at issue in this rulemaking. After consideration of all comments submitted in response to the proposed lead rule, EPA concludes that lead is highly persistent and, at the least, bioaccumulative and defers its determination as to whether lead is highly bioaccumulative. An explanation for EPA's conclusion that lead is at least bioaccumulative is provided below. The basis for EPA's conclusion that lead is highly persistent is provided elsewhere.

In the PBT chemical rulemaking, EPA described bioaccumulation as "the process by which organisms may accumulate chemical substances in their bodies" (64 FR 703) and defined the term as the "net accumulation of a substance by an organism as a result of uptake from all environmental sources." (64 FR 703) EPA has a concern for those toxic chemicals that are bioaccumulative and a particular concern for that subset of PBT chemicals that are highly bioaccumulative.

There are extensive, high quality human data (64 FR at 42230-31) that clearly indicate that lead and lead compounds bioaccumulate in humans, i.e., humans accumulate lead as a result of uptake from environmental sources. These data include bioaccumulation data on a number of subpopulations of humans, such as children, pregnant women, postmenopausal women, and men. Therefore, these human data support EPA's conclusion, as discussed below, that lead and lead compounds are bioaccumulative. EPA believes that these data would tend to support a finding that lead is also highly bioaccumulative because (1) the data are human data and (2) these data conclusively demonstrate that lead bioaccumulates in humans. EPA believes that these two factors are relevant to a determination that lead and lead compounds are highly bioaccumulative because human data are generally more compelling than animal data, particularly where there are multiple, high quality studies on a broad range of individuals. Thus, these data are sufficiently conclusive that there is no question that lead and lead compounds bioaccumulate in humans.

While evaluation of these data might affect EPA's conclusion as to whether lead and lead compounds are highly bioaccumulative, EPA recognizes that it did not clearly articulate in the proposed rule how human data would be used to distinguish between bioaccumulative and highly bioaccumulative chemicals. Because of this, EPA is deferring at this time the classification of lead and lead compounds as highly bioaccumulative solely on the basis of the extensive human data.

A number of industry commenters have contended that BCFs and BAFs measured for metals (including lead), and in particular essential elements, are not representative of the potential of these substances to bioaccumulate. They claim that the variability of the measured BCFs/BAFs with changing water concentration of the chemical makes it difficult to determine the most representative BCF/BAF value for a particular species. Specifically, these commenters contend that there is an inverse relationship between the measured BCF/BAF values and water concentration. Some commenters assert that only the values measured at higher water concentrations should be used, i.e., the lower BCF/BAF values. Other commenters contend that BCFs and BAFs are not meaningful measures for the bioaccumulation of metals and, therefore, cannot be used.

EPA disagrees that this is the best characterization of the bioaccumulation data for metals, including lead, in aquatic species. While this type of relationship may exist for some species and/or some metals, for other species and/or metals other relationships are observed: (1) Constant BCFs/BAFs with increasing water concentration; (2) increasing BCFs/BAFs with increasing water concentration; and (3) varying BCFs/BAFs values with constant water concentration.

EPA disagrees that the BCF/BAF data cannot be used to determine the potential for lead, which is not an essential element, to bioaccumulate. EPA recognizes that some data suggest that the relationship between bioaccumulation and water concentration of lead could be characterized as inverse for some organisms, such as fish, algae, and phytoplankton. Such a characterization, however, is incorrect for invertebrates such as snails and bivalves because there is little variation in BCF value with changing water concentration for these species. Further, EPA does not believe that even where the data suggest an inverse relationship, this precludes the use of BCFs and BAFs in assessing the bioaccumulative potential of lead. EPA notes that even for some species in which an inverse relationship is suggested (e.g., algae and phytoplankton), if EPA were to use the BCF or BAF at the highest water concentration measured (i.e., the lowest measured BCF/BAF value) the BCF/BAF values remain over 5,000.

EPA has determined that the data on oysters, snails, algae, phytoplankton, and blue mussels, as well as the human data, clearly support a conclusion that lead and lead compounds are bioaccumulative, and also believes that this information tends to support a finding that lead is highly bioaccumulative. However, during the public comment period and during inter-Agency review, questions were raised challenging the sufficiency of the data to support the conclusion that lead and lead compounds are highly bioaccumulative. Before determining whether lead and lead compounds are highly bioaccumulative, EPA believes that it would be appropriate to seek external scientific peer review from its Science Advisory Board, and EPA intends to do so. The external peer review would address the question of whether lead and lead compounds should be classified as highly bioaccumulative. The external peer review would address the issue of how lead and other, as yet unclassified, metals such as cadmium, should be evaluated using the PBT chemical framework, including which types of data (and which species) are most suitable for these determinations. After the completion of the external scientific peer review, EPA will consider and take appropriate action, which could include characterizing lead and lead compounds as highly bioaccumulative and lowering the reporting thresholds for lead and lead compounds to 10 pounds. Therefore, at this time, EPA concludes that lead is, at the least, bioaccumulative and defers its determination as to whether lead is highly bioaccumulative until further review.

1. *What comments did EPA receive on the environmental fate of lead and lead compounds?* In the lead proposed rule (64 FR 42227) the Agency provided a qualitative environmental fate assessment of lead and lead compounds. Qualitative environmental fate assessments are generally part of a hazard assessment for a chemical. The qualitative environmental fate assessment was not developed, nor was it intended, to be part of an exposure assessment or risk assessment.

An environmental fate assessment for a metal and metal compounds, such as lead and lead compounds, describes the physical, chemical, and biological processes acting upon the metal and metal compound in the environment and the result of these processes. The environmental fate of a metal or metal compound varies depending on the environmental conditions and the physical/chemical properties of the metal in question.

The Agency received many comments on its assessment of the environmental fate of lead and lead compounds and the influence of environmental fate on the environmental availability of lead and lead compounds. Commenters contend that normal environmental processes control the availability of lead and lead compounds in water, soil and sediments and concluded that under most environmental conditions lead from lead and lead compounds would not be available for uptake by organisms due to processes including the pH dependent formation and precipitation of insoluble lead compounds in surface waters, and sorption of lead to organic matter and inorganic constituents in soil, surface waters and sediments.

EPA disagrees with these commenters and concludes that processes commonly observed in the environment can result in the formation of available lead where it can be bioaccumulated by organisms. EPA believes that these processes may occur in soil environments with low pH and low levels of clay and organic matter. Lead sorption to soils has been shown to be pH dependent. Decreasing pH can result in increasing concentrations of lead in soil water with greater availability for uptake by biota. In acidic aquatic environments, low levels of suspended solids and dissolved organic matter can result in increased levels of lead ion in solution where it can be taken up by biota.

One commenter believes that the environmental fate data that EPA used and cites in the proposed rule falls short of what is necessary for a scientifically valid approach to assessing the transformation, specification, and availability of lead in the environment. The commenter argues that the data cited by EPA indicate that very little of the lead released to the environment is likely to be present in a "bioavailable form" (i.e., EPA concluded that less than 1% of lead in soil may be water soluble).

EPA disagrees with the commenter's characterization of EPA's assessment of the environmental fate of lead and lead compounds. EPA asserts that it used reliable data from a variety of credible sources in concluding that lead can be available for uptake by organisms in the environment and that lead is environmentally available. EPA refers the commenter to the discussions of the transformation, speciation, availability and bioavailability of lead in the environment provided in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) and elsewhere in the RTC document for this final rule (Ref. 1). EPA disagrees with the commenter's interpretation of the statement "EPA concludes that less than 1% of lead in soil may be water soluble" to mean or indicate that very little of the lead released into the environment is likely to be present in a "bioavailable form". Simple water solubility is not a prerequisite for a metal to become available from a metal compound. It is well established that certain environmental conditions can increase the solubility of a metal compound. Further, as discussed in Unit VI.C.2. of this preamble and in the RTC document (Ref. 1), availability of a metal is not a prerequisite for its bioavailability. Metals may be bioavailable from metal compounds or metal complexes that are not water soluble or in which the metal is not otherwise available. A classic example that illustrates these points are the well documented incidents of childrens' exposure to lead from consumption of soil that contains lead. While less than 1% of lead in soil is typically present as a lead compound that is water soluble (i.e., more than 99% is present as lead compounds that are water insoluble or bound to soils), the lead in soils is still bioavailable in humans.

EPA has concluded that lead released to the environment, whether under conditions where it is available or not, can reasonably be expected to be bioavailable in organisms. EPA's statement "that less than 1% of lead in soil may be water soluble" should not be interpreted to mean that the levels of lead in soils that is available are inconsequential or negligible. On the contrary, because exposure to even low levels of lead are expected to result in its bioaccumulation in many organisms, these levels are still of concern. It should be noted that if 1 percent of soil lead is soluble (i.e., available), this would mean that levels as high as 200 parts per billion (ppb) could be found in soil water (lead is present in many soils at 20 parts per million (Ref. 2) and one percent of this is 200 ppb.)

One commenter believes that the bioavailability of lead and lead compounds is only prevalent in those situations in which an organism would be exposed to continuous, localized influxes of lead compounds, such as near a lead smelter or a highway. The commenter believes that the proximity to sources of lead, such as smelters or highways (influenced by use of leaded fuels), is a prerequisite to high concentrations of the metal in the environment, and thus its potential to bioaccumulate. The commenter cites studies that provide data that show high levels of lead in waters and soils that are in close proximity to sources of lead releases (e.g., smelters, vehicular exhaust), and bioaccumulated lead in freshwater algae, invertebrates, and fish collected near industrialized areas, ponds with high numbers of lead shot, urban areas, lead mines and tailings ponds. The commenter states that although lead may be considered ubiquitous in the environment, its ecological impacts would appear to be significantly influenced by the proximity to sources of lead releases and the public should be aware of this. While the commenter used the term bioavailability, based on the context of the comment, EPA believes the commenter used the term interchangeably with the term environmental availability.

While the concentrations of lead in the environment are more likely to be higher in areas that are in close proximity to facilities that manufacture, process, or otherwise use lead and/or lead compounds, EPA disagrees with the commenter's contention that the availability of lead is only possible in such areas. EPA does not agree with the commenter's position that in order to be exposed to lead an organism needs to be in close proximity to points where lead

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is released into the environment. As discussed in Unit V.A. of the proposed rule (64 FR 42227), and in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2) many factors influence the mobility and disposition of lead in the environment. Under many environmental conditions lead may become mobile rather than remain stationary. Depending upon prevailing conditions and the method of environmental release, lead may travel within environmental media to areas that are not in close proximity to the point of release. Hence, EPA believes that the presence of lead in the environment, and therewith its availability, is not confined to the areas where lead is released from anthropogenic sources. In addition, any release of lead is important to local communities, because of lead's persistence and bioaccumulative properties. Although EPA disagrees with the commenter's conclusions, the commenter's statement that the ecological impacts of lead are influenced by the nearness to a source of release still provides support for the actions that EPA is taking in this rulemaking.

a. What comments did EPA receive on the abiotic factors that may affect the environmental availability of lead? Several commenters stated that EPA either did not, or should have considered speciation, transformation and bioavailability in its assessment of the persistence of lead and lead compounds. Some of the commenters contend that in most environments lead is either not available or is transformed into forms that are less available. A number of the commenters claimed that the environmental conditions in which lead is mobile or available are rare.

EPA disagrees with the commenters claim that the Agency did not consider speciation, transformation and bioavailability in its characterization of lead and lead compounds as PBT chemicals. As discussed in detail in: Unit V. of the proposed lead rule (64 FR 42222–42243); in *The Environmental Fate of Lead and Lead Compounds* (Ref. 2); elsewhere in this preamble; and in the RTC document (Ref. 1), EPA performed a comprehensive assessment of the environmental fate of lead. The environmental fate assessment embodied an analysis of the environmental variables that affect speciation, transformation, and the availability of lead. These environmental variables include: pH; redox conditions; water hardness; dissolved organic carbon content; and soil properties including cation exchange capacity, organic carbon content, iron and manganese oxide and phosphorus content. As discussed in Unit VI.D.3., EPA has evaluated the bioavailability of lead and lead compounds and has concluded that lead is bioavailable. From its analysis of the environmental fate of lead, EPA concluded that environmental conditions exist in the United States in which lead may become available or that can increase the availability of lead, even from compounds in which lead, as released into the environment, is not available. From its analysis of the bioavailability of lead, EPA concluded that lead is bioavailable in many aquatic species, and in humans. EPA also concluded that lead compounds that are not available or bioavailable as released may be converted to lead compounds that are available or bioavailable. Thus, after an evaluation of the available data, EPA has determined that the weight of scientific evidence indicates that it is reasonable to conclude that lead in the environment will be available and/or bioavailable from lead and lead compounds.

EPA disagrees with the commenters who claim that the environmental conditions in which lead is mobile or available for uptake are rare. As detailed in Unit VI.C. of this preamble and in the RTC document (Ref. 1), EPA conducted several analyses of large databases containing information on the properties of rivers, streams, lakes, and soils in the United States, with a focus on the properties known to contribute to the availability of lead. Acidity is a particularly important determinant of lead availability: acid conditions (pH < 7) increase lead availability. In water, the solubility and, hence, availability of lead increases linearly as acidity is increased (i.e., from pH 6 to 3). EPA determined that waters of sufficient acidity to favor lead availability, especially in the Mid-Atlantic region of the United States, are not rare. In fact, estimates indicated that almost 11,000 kilometers of streams could have a pH of < 5.5. In addition, as detailed elsewhere is this document, a query of EPA's STORET water quality database indicated that in 1998 pH values of between 5.5 and 5.1 were found in 52 watersheds in the United States. Finally, the commenter asserts that acidic soils in which lead is likely to be available are rare. EPA's analysis of the database of the Soil Survey Laboratory, National Soil Survey Center, discussed in Units VI.C.1. and VI.D.1. of this preamble, found more than 10,000 surface soil samples with low cation exchange capacity and pH values of less than 5.5.

One commenter supports EPA's concern for cross media transport of chemicals, but believes that it is misleading for EPA to imply that lead is predisposed to find the medium in which it will be transformed into forms that have the "greatest bioavailability (in) man". The commenter agrees that lead cannot be destroyed but, equates this attribute to most elements on the periodic table.

The commenter incorrectly asserts that EPA suggested that lead and lead compounds are released only to, or preferentially partitions to, those environments that are most favorable to enhancing availability or bioavailability of lead. EPA disagrees with the commenter. EPA has not made the claim that lead and lead compounds are released only into those environments where conditions are most favorable to the formation of the most soluble lead compounds. In EPA's discussion of the environmental fate of lead and lead compounds, EPA assessed the availability of the lead and lead compounds under a variety of conditions in water, sediments and soil. As discussed elsewhere, EPA believes that there are many environmental conditions in which lead and lead compounds will be available and/or bioavailable.

b. What comments did EPA receive on the availability of lead in surface waters and sediments. One commenter stated that there are many studies that indicate that lead does not persist in soluble and bioavailable forms in aquatic environments. The commenter cited work reported by May and McKinney (Ref. 33) which, according to the commenter, has shown that the majority of lead entering natural waters will be precipitated to sediments as carbonates or hydroxides (i.e., will be unavailable). The commenter states that even in acidic lake waters, "which according to EPA's own reports are rare", lead can precipitate out of the water, and cites work by White and Driscoll (Ref. 34) to support this position. Another commenter states that there is strong evidence to suggest that under conditions where organic material is present in the water column of an aquatic environment, the organic material will act to reduce the amount of potentially soluble and bioavailable lead. The commenter believes that the wide distribution of organic matter suggests that the potential for the reduction of soluble lead by complexation with organic material is high.

EPA disagrees with the argument that soluble and/or bioavailable lead compounds are irreversibly transformed into insoluble and un-bioavailable lead compounds. EPA discusses below and elsewhere that many lead compounds that form as a result of conditions in the aquatic environment (e.g., lead-organic matter complexes, inorganic precipitates, carbonates and hydroxides) are not necessarily permanently sequestered as a non-available lead compound, but are subject to processes that can result in their release back into solution. A review of the discussion of the fate of lead in natural waters in May and McKinney (Ref. 33) revealed a single sentence that says: "Upon entering natural waters, most lead is precipitated to the sediment bed as carbonates and hydroxides." While this statement is true for some surface waters in the United States, EPA has concluded for the reasons discussed below and elsewhere in this preamble and in the RTC document (Ref. 1) that lead solubility is greater and precipitation as carbonate and hydroxide is less in acidic waters with low hardness.

White and Driscoll (Ref. 34) observed temporal and spatial variations in the concentration and transport of lead in the acidic Darts Lake in the Adirondacks of New York. Deposition of particulate lead was strongly correlated with aluminum and organic carbon deposition. Increasing metals deposition was observed during periods of increasing pH. The flux of lead into the lake was related to stream hydrology, pH and lead concentration. Stream pH varied seasonally, with a steady pH of 5.1 until spring snowmelt, where pH levels dropped to a minimum of 4.8 in April/May. Increases in pH occurred throughout the summer reaching a maximum of 5.4 in August. High flow periods in the fall and spring were marked by increases in the concentration of dissolved lead in the inlet and outlet streams. Lead flux to and from the lake was greatest during spring and fall periods of high lead concentrations, elevated water discharge, and low pH. The authors explain that even in acidic lake water containing a variety of particle types, oxides and organic films may determine the surface properties of suspended particulate matter. The solid matrix in the lake was probably composed of inorganic hydrous oxides (coatings) and adsorbed or coprecipitated organic matter. The interaction of lead with this matrix appears to be pH sensitive. Changes in pH may affect lead partitioning between the solid and solution through a number of possible mechanisms: matrix formation/dissolution, sorption/desorption of organic complexes and inorganic complexes, and hydrogen ion exchange reactions.

Contrary to the commenter's interpretation, EPA believes that the study by White and Driscoll (Ref. 34) provides evidence that even in the presence of dissolved organic carbon, soluble lead may be present in the water column of acidic.waters, possibly through a process of sedimentation and decomposition of organic matter and/or dissolution of redox sensitive hydrous oxides.

Two commenters contend that the majority of lead entering aquatic systems will be removed from solution and become bound to sediments and/or suspended particulate matter. They believe that the lead that partitions to sediments is not expected to be readily bioavailable. The commenters contend that the availability of lead in sediments is controlled by several physicochemical factors including pH, organic carbon (particulate and dissolved), iron and manganese oxyhydroxides, and sulfides. In aerobic sediments, the main factors that drive the formation of insoluble lead are particulate organic carbon and iron/manganese oxyhydroxides. In anaerobic sediments, which represent the overwhelming majority of sediments, acid-volatile sulfides (AVS) are the main binding factor.

The commenter contends that if the concentration of AVS is greater than that of lead that is simultaneously extracted from the sediments, the lead will not be environmentally available. Further they state that EPA is currently considering using this concept to derive national sediment quality criteria for lead and other metals such as zinc, cadmium, and copper. In addition, the commenter contends that although events such as storms or dredging may cause a re-suspension of sediments (thus temporarily changing the physicochemical properties of the sediment), several studies have shown that these events do not have a large impact on the binding of metals such as lead to the sediments, and found that no significant release of lead occurred from dredged sediments being suspended in waters. The commenters claim that other studies have shown only a small portion of metals are released from sediment due to re-suspension and oxidation of the sediments.

EPA agrees that the environmental processes that determine the complexation, speciation, and ultimately the availability of lead in the environment should be considered in its present analysis and asserts that these have been considered. EPA believes that the AVS methodology shows great promise for use in conducting *site-specific* assessments of metals for which it has been validated. To date, the AVS methodology has not been validated for lead, nor have the generally favorable, albeit substantive technical comments provided by the EPA Science Advisory Board been incorporated into the methodology. Finally, EPA does not believe that a means currently exists to incorporate the AVS methodology into the technical analysis supporting a *nationally* applied regulation such as this rule.

EPA disagrees with the commenter's conclusions regarding sediment-bound metals, and the commenter's inference that once lead becomes bound to sediments it is no longer available. EPA has found that several researchers have investigated the impact of the oxidation of sediment constituents on the release of sediment-bound metals and found that metal availability can increase under these conditions. For example, Zhuang et al. (Ref. 35) found that the aeration of sediment resulted in the rapid oxidation of a major binding constituent, acid-volatile sulfide. In experiments conducted over a 1 month duration, the concentration of cadmium increased 200-400 percent. The oxidation of AVS occurred rapidly with a concomitant decrease in pH, and the release of cadmium from the solid to the liquid phase continued for approximately 2 weeks. The authors noted that aeration of sediments results in only a portion of the associated cadmium, and presumably other toxic metals, being released to water. Sedimentary iron and manganese are transformed to their oxyhydroxides by the oxidation of sulfide. Following the formation of iron and manganese oxyhydroxide, the binding of cadmium is transferred towards these solid phases. Approximately 50% of the cadmium bound in sediments is associated with the extractable iron and manganese components of the sediment following aeration. In addition, oxidation of the sulfidic phase releases other metals that compete with cadmium for available binding sites. EPA believes that it is important to note the following from the authors' conclusions:

Prediction of biological availability of metals in sediments based on the relationship between metal and AVS concentrations may be underestimated if the sediment is subject to aeration.

Thus, experimental data exist that indicate that cadmium, and presumably other toxic metals including lead, bound to sediments can become available. The data also suggest that contrary to what the commenter believes, the AVS methodology does not always provide an accurate estimate of lead availability

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when certain, realistic environmental conditions exist.

Other studies demonstrated the availability of lead in aquatic environments. Mahoney et al. (Ref. 36) examined the partitioning of metals, including lead, to organic carbon in 14 different freshwater sediment samples. The metal sorption due to acid volatile sulfide was subtracted from the total sorbed metal to determine the metal bound to other sediment phases (primarily organic carbon). The results indicated that organic carbon partition coefficients for lead were reduced by a factor of 10 with a decrease in pH from pH 7 to pH 6. The authors fit the sorption data to the Langmuir model. The results were consistent with a surface complexation model where binding sites are occupied by either protons (H^+) or metal ions. At lower pHs, the protons compete favorably for the sites, whereas at higher pHs where protons are fewer in number, free metal is removed from solution by organic carbon sorption. This study illustrates that in sediment water systems at pH values in the physiological range, lead can be available for uptake by organisms even in the presence of organic carbon.

Another commenter states organic matter, using as an example humic acids, present in freshwater and marine sediments and in the aqueous phases are capable of complexing variable amounts of metals. The commenter states that most lead entering natural waters is sorbed onto organic ligands and precipitated as insoluble complexes to the sediments as lead carbonate and hydroxide (Ref. 37). The commenter also states that the lead from these complexes may be mobilized and released back into the water column, but only when the pH is decreased suddenly or the ionic composition of the water changes. The commenter claims that both natural soluble organics (e.g., dicarboxylic and amino acids) and synthetic soluble organics (e.g., ethylene diaminetetraacectic acid (EDTA)) act as chelators (i.e., sequestering agents) of lead, and reduce the toxicity of heavy metals such as lead because chelated forms of metals are less toxic than their free, non-complexed forms. The commenter cites work by Canterford and Canterford (1980), which shows that EDTA reduced the toxicity of lead to the diatom, *Ditylum brightwellii*.

EPA believes that the data in Eisler (Ref. 37) cited by the commenter supports EPA's contention that lead can be available in the sediment/water environment under low pH conditions. EPA has discussed the role of organic matter and pH in decreasing the availability of lead and lead compounds in the aquatic environment elsewhere in this preamble (see also Ref. 2). EPA recognizes the important role of organic matter and pH on the availability of lead and lead compounds in the aquatic environment and the effect of pH on the sorptive behavior of organic matter. However, EPA has commented elsewhere that waters with low organic matter and low pH are widely distributed throughout the United States. EPA believes that lead can be available in such environments. In addition, while EPA believes that lead sorbed onto organic matter may be temporarily unavailable, EPA does not agree that lead sorbed onto organic matter is no longer *bioavailable*. Many aquatic species (e.g., mussels, fish) consume orally as part of their diet organic matter in their environment. Lead sorbed to organic matter may be bioavailable in organisms that consume the organic matter. The same holds true for terrestrial species. Lead sorbed to soils, for example, is bioavailable in humans (See Unit VI.D.2. of this preamble).

c. What comments did EPA receive on the availability of lead in soils. One commenter claims that EPA's data on the fate of lead in terrestrial environments do not support the Agency's conclusion that lead is expected to be bioavailable when in terrestrial environments. The commenter states that EPA fails to provide information about the probability of the natural occurrence of the conditions that could result in the formation of soluble/bioavailable lead species.

EPA believes that soils possessing properties that are conducive to the increased mobility of lead are by no means uncommon. In order to determine the extent to which soil samples collected across the United States possess such properties, EPA conducted a query of the database of the Soil Survey Laboratory (SSL), National Soil Survey Center. The database currently contains analytical data for more than 20,000 pedons of U. S. soils and about 1,100 pedons from other countries. Most of the data were obtained over the last 40 years. Of these, about 75 percent are less than 20 years old. Coverage is for all 50 states, Puerto Rico, Virgin Islands, Trust Territories, and some foreign nations. The search was designed to identify soils with a pH of less than 5.5 and a cation exchange capacity (CEC) of less than 10 milliequivalents (meq) /100 grams. The results of this search identified more than 10,000 samples that meet the criteria.

Many investigators have studied the speciation, mobility, and availability of lead in soils. The EPA concludes from this body of work that although lead binds to many soils, under many natural environmental conditions it will, or at least can be expected to be available for uptake by organisms. Reddy, et al. (Ref. 38) studied the speciation of lead in water extracts from soil samples from the Powder River Basin in Wyoming. Dissolved concentrations of lead were found to be 0.003 to 0.046 mg/L. Chemical speciation indicated that at near neutral pH, dissolved metal concentration in soil water extracts was dominated by dissolved organic carbon-metal complexes. At low pH, dissolved metal concentration in soil water extracts was dominated by free ionic oxidation states, (e.g., Pb^{+2}). The results suggest that as soil pH decreased, the availability and mobility of lead ions increased due to the lead compound in which the metal is present in soil solutions. Wang and Benoit (Ref. 39) investigated the mechanisms controlling the mobility of lead in soils of a northern hardwood forest ecosystem. The authors observed that about 50% of total filtrate lead (passing through a 0.45 um filter) was found to be in the colloidal form below the soil surface organic layer. Colloidal lead concentrations in deeper horizons were less than 10% of the concentrations in the surface layer. Less than 10% of the dissolved lead was found to be complexed to organic substances. A calculated distribution of inorganic lead species indicated that at the pH of the soil solutions tested (4.0 to 4.7), free, dissolved ionic Pb^{+2} dominated and other complexes and ligands were negligible. Low pH resulted in Pb^{+2} desorption from soil solids. However, because both colloidal and dissolved lead were effectively removed during transport down the soil profile, mobilized lead from the surface organic layer was retained in lower soil horizons. Although this study suggests that under the conditions investigated, lead does not migrate to an appreciable extent through the soil profile, EPA believes it gives a strong indication that lead may be available in the acidic organic surface horizon.

The effects of redox potential and pH on the solubility of lead in contaminated soil were investigated by Chuan et al. (Ref. 40). Lead was sparingly soluble at pH 8.0 and more soluble at pH 5.0; solubility increased considerably at pH 3.3. At the same pH, solubility increased as the redox potential decreased. However the effect of pH was more significant than redox potential. It was proposed that lead in soil was primarily adsorbed to iron-manganese (Fe-Mn) oxyhydroxides and the pH dependent adsorption and dissolution of the Fe-Mn oxyhydroxides under reducing conditions controlled the solubility of lead in soil. EPA believes that the indication of increased lead solubility at pH 5 suggests that in many soils lead could be available for uptake by organisms.

Murray *et al.* (Ref. 41) analyzed the distribution of lead in surface and subsurface soils at an outdoor shooting range in southeastern Michigan that had been in operation for 50 years. It was found that the distribution of lead in the subsurface corresponded to that in the surface soil horizon, suggesting that lead was mobilizing and migrating downward through the vadose zone. Mobilization of lead appeared to be occurring despite the clay-rich nature of the soils, and was thought to be due to the transformation of metallic lead into soluble lead carbonate and lead sulfate. Both compounds were found in crust material coating shot pellets found below a depth of about 5 cm at the site, thus implying a reaction between the metallic lead and the soil. The evidence of the apparent mobility of lead under conditions thought to decrease mobility further indicates that lead is available for uptake in soils.

Laperche *et al.* (Ref. 42) studied the use of soil phosphorous amendments as a means of reducing the availability of lead in contaminated soils. In this study soil contaminated with lead was treated with natural and synthetic phosphorous, and the bioavailability of lead in plants was determined in plant uptake studies with sudax (*Sorghum bicolor*). The lead content in the shoot tissue decreased as the quantity of added phosphorous increased, due to the formation of insoluble lead phosphate compound pyromorphite. However, lead and phosphorus contents in the roots increased as the quantity of added phosphorus increased. The formation of pyromorphite on root surfaces was also observed. It is important to note that in the absence of phosphorous amendments, lead content in the shoot was 170 mg lead/kg dry weight, whereas with the most effective phosphorus treatment, lead content in the shoot was 3 mg lead/kg dry weight. This strongly suggests that in soils with low phosphorus content, lead can be available for uptake by plants.

One commenter believes EPA does not adequately address the important role of cation exchange capacity of soils as it relates to the availability of lead and lead compounds. The commenter states that at pHs of 5 to 9, clays possess surfaces that are predominantly negative and to which charge-compensating cations are adsorbed. The commenter claims that these cations are not permanently bound to the clays and are being exchanged by other cations, including heavy metals such as lead, copper, and cadmium.

EPA has discussed the effects of pH and cation exchange capacity on the availability of lead in soils in Unit VI.C.2. of this preamble and in the RTC document (Ref. 1). EPA recognizes the important role of cation exchange capacity of soils in the availability of lead and lead compounds, and the effect of pH on the sorptive behavior of clays. The cation exchange capacity of soils is related to the clay content of the soil. Soils with low clay content and low cation exchange capacity are common and widely distributed. EPA has concluded that lead can be available in such soils.

A commenter summarized research results published by Zimdahl and Skogerboe (Ref. 43), and stated that the research showed that soils have a strong capacity to immobilize lead, and that lead tends to become associated with the organic fraction of soil particles. The commenter states that the authors concluded that this sorption is less likely to be affected by low pH (acidification) than would acid ion precipitates (carbonates, phosphates, sulfates, chlorides). The commenter also claims that these investigators concluded that plant uptake studies strongly support their conclusions about the immobilization of lead and its sorption to organic matter in the soil.

EPA reviewed the publication by Zimdahl and Skogerboe (Ref. 43). In the discussion section of this publication the authors provide the following overview regarding the behavior of lead in soils:

> * * * the movement of lead in the soil profile and its ultimate fate may be determined by one or more of several processes. These depend largely on the dissolution of the lead particles in the ground water. The lead dissolved may be leached through the soil profile if it remains in a soluble form. It may be immobilized by soil microorganisms, precipitation, sorption or ion-exchange interaction with soil entities (e.g., clays) or fixation by materials such as organic matter. It may also be taken up by plants, thereby entering the food chain. ... The significance of this possibility is reflected in the demonstrated toxicity of lead to corn, beans, lettuce, and radishes in lower concentrations in slightly acidic soil. These and other studies suggest that lead in soil can reach the soil plant root interface and be taken up by plants.

In their investigation of the factors controlling the mobility of lead in soils the authors developed a correlation function based on the soil properties determined to be most strongly correlated with soil immobilization of lead (pH and cation exchange capacity). Precipitation by carbonate and sorption by hydrous metal oxides appeared to be of secondary importance. They concluded that lead will be twice as mobile (i.e., available) in soil with a pH of 4.1 and a CEC of 13 meq/100 g as in a soil with a pH of 6.8 and a CEC of meq/100 g. EPA believes the findings of Zimdahl and Skogerboe do not conflict with EPA's environmental fate analysis of lead and lead compounds. EPA agrees that the authors determined that some soils have the capacity to decrease the mobility of lead, but equally as important, the study provided a means to estimate the effect that a soil's properties can have on decreasing its capacity to immobilize lead, thereby increasing availability.

One commenter disagrees with the contention of other commenters that lead and lead compounds should not be considered persistent because when released to the soils they will not be bioavailable. The commenter asserts that because metals released into the environment do not always immediately become bound to particles, nor do they remain bound given pH and other changes, and because metals bound to soil particles are ingested by young children, there are strong reasons to be concerned solely about the persistence of toxic metals.

EPA agrees with the commenter that lead released to the environment may not become immediately bound and that there are environmental conditions that will increase the availability of lead in soils. One example is the effect of pH on lead compounds. For example, lead when part of a compound which has low solubility at neutral to basic pH will be converted into soluble compounds when subject to acid mine drainage. The soluble lead compounds will be mobile and may travel through the environment. When these compounds experience higher pH their mobility will decrease and the availability will decrease. However, the availability in many cases will be greater than in the original lead compound. The lead may be part of a lead compound (e.g., carbonate) in which it is much more available than in the original lead compound, even if the pH is the same because the lead will be part of a different molecule and this molecule will react to the environment differently than the original lead compound.

Another commenter contended that EPA should have used the Multimedia Equilibrium Criterion (EQC) model to

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estimate overall environmental persistence and partitioning of lead. The commenter stated that in the PBT chemical rulemaking, the Agency discussed how it used this model to evaluate the overall environmental persistence of toxic chemicals subject to the proposal (64 FR 702–703). The commenter believes that the EQC model is ideally suited to model the environmental partitioning and persistence of lead.

The commenter is correct in stating that EPA used the EQC model to evaluate persistence and partitioning of toxic chemicals described in the PBT chemical rulemaking. EPA did not use the EQC model for metals in the PBT chemical rulemaking. EPA agrees that the EQC model is a valuable tool for determining the multimedia fate and transport of chemicals in the environment. As described in the PBT chemical rulemaking, however, the EQC model was only used to model environmental persistence and partitioning of organic chemicals, and not of metals. In the PBT chemical rulemaking, EPA based its determination of whether a toxic chemical is persistent based on half-lifes for specific media. For organic chemicals EPA used the EQC model to determine if it were possible that a toxic chemical that is persistent in one medium significantly partitions to another medium in which the toxic chemical rapidly degrades thus providing an overall environmental half-life less than the established criteria. The commenter is also correct in stating that the Agency did not use the EQC model to evaluate the environmental persistence and partitioning of lead and lead compounds. As EPA explained in both the PBT chemical rulemaking and the proposed lead rule, metals are persistent because the metal cannot be destroyed. While the EQC model can be used to model the partitioning of a metal and its compounds from one medium to another medium in the environment, it does not model the destruction of the metal because that *cannot* occur.

The Agency would like to point out, however, that Mackay et al. (Ref. 44) used lead as an example of a "class 2" (nonvolatile) substance for an EQC model run. Because lead is classified as a "class 2" chemical, the EQC model treats volatilization of lead from water to air and from soil to air as negligible. Mackay used an infinitely long degradation half-life for lead (i.e., lead is persistent and is not destroyed). When an infinitely long degradation half life is used (as was used by Mackay, et al. for lead in all media) only non-destructive removal processes such as loss from the air compartment by deposition of airborne particles to soil and water, soil runoff, advection in sediment (loss from the model environment by burial of sediment-bound lead), and transport of sediment bound lead particles out of the model environment are important. The overall environmental persistence of lead estimated by the model reflects the time necessary for lead to be physically transported from the model environment, not destroyed. Thus the model, in essence, provides information on the partitioning and movement of lead, but inevitably indicates that lead will be persistent in all media.

The EQC level III modeling results for lead showed the importance of deposition from the air compartment to soil and water, at a rate that exceeds the advection rate (rate of non-destructive transport out of the model environment). The main removal mechanism according to the model was advection (burial) in sediment, followed by soil runoff and advection in water. The buildup of the chemical in the model environment was about 1.7×10^{10} kg and its overall persistence was 5.6×10^{6} hours (634 years), which is essentially infinite duration. In addition, at steady state the model predicted that lead concentration in the water compartment of the model environment would be 4.27 ug/L. For lead the important transport parameters are those controlling atmospheric deposition and sediment-water exchange. EPA believes that, considering the results above and the discussion of the availability of lead in water, soil and sediments provided elsewhere in these responses to comments, the use of the EQC model would not have provided any information counter to EPA's position that lead and lead compounds are PBT chemicals. Thus, even if EPA had used the EQC model to estimate the environmental persistence and fate of lead, EPA would have drawn the same conclusions stated in the proposed rule. In addition, the Agency would like to emphasize that as discussed in the PBT chemical rulemaking the EQC model was only used as a secondary means to evaluate persistence and partitioning of organic chemical substances, and that unless all of the data inputs to the model were reliable it would not be used by the Agency to override persistence data from individual media.

2. *What comments did EPA receive on the bioaccumulation data for lead and lead compounds?* Some commenters contend that EPA failed to consider the results of more recent studies that indicate that the accumulation of lead in aquatic organisms is low and that the concentrations of lead found in the environment are lower than previously measured. Commenters also questioned the relevance of laboratory bioaccumulation studies on lead to the bioaccumulation of lead under environmental conditions claiming that under "realistic conditions" lead does not bioaccumulate significantly in organisms. As discussed in detail in this section, none of these issues change EPA's conclusions about the validity of the data. With regard to the results of more recent studies, these studies do not provide information that changes EPA's conclusions that lead and lead compounds are bioaccumulative. EPA also believes that the laboratory bioaccumulation studies for lead are relevant to the potential for lead to bioaccumulate, which is confirmed by the observed bioaccumulation of lead in the environment.

As discussed in Unit VI.B. of this preamble, bioaccumulation is a general term that is used to describe the process by which organisms may accumulate chemical substances in their bodies. The propensity of a substance to bioaccumulate in a species depends largely upon the pharmacokinetics of the substance in that species. That is, the extent to which a substance can bioaccumulate in an organism depends upon: (1) Whether the organism can absorb the substance; (2) the extent to which the substance is distributed and metabolized within the organism; and (3) how readily the organism can excrete the substance. The pharmacokinetics of a substance, and therefore the propensity for it to bioaccumulate, can (and often does) vary greatly among different species, even among species within the same trophic level. This is because species differ in their anatomy, physiology, and genetic makeup. These are important variables that govern the propensity for a substance to bioaccumulate, in addition to the substance's physicochemical and other properties. It is well established that a given substance can have different BAF (or BCF) values in different species. Data presented in Table 1 of the proposed rule (64 FR 42230) indicates that lead has different BAF (or BCF) values in different species.

In the proposed lead rule EPA preliminarily concluded that lead and lead compounds are highly bioaccumulative based upon the Agency's review of the bioaccumulation data for lead and lead compounds in aquatic species and in humans. Those who commented on EPA's assessment of the bioaccumulative properties of lead and lead compounds commented on the aquatic data used by EPA and did not comment on or refute the extensive data in humans. A number of commenters disagreed with the scientific basis that EPA used to support the use of bioaccumulation measurements for lead and lead compounds because they believe EPA's scientific basis: does not use relevant data; is insufficient; does not have a sound scientific foundation; or does not present a balanced view of the scientific literature. Other commenters address the issue of bioaccumulation generically, rather than specifically to lead and lead compounds. EPA responded to the generic issues in the earlier PBT chemical rulemaking (64 FR 58676) and in the associated Response to Comments document (Ref. 15). However, EPA is discussing some general issues here as background for the more specific issues related to lead and lead compounds in order to facilitate EPA's responses. Further, while some commenters agree that lead and lead compounds bioaccumulate, they contend that they are not highly bioaccumulative. A discussion of both the aquatic data and the human data used by EPA, and the issues raised by commenters on EPA's use of these data are provided below. As discussed earlier, after having reviewed and considered all the comments, EPA is finalizing this rule with a finding that lead and lead compounds are bioaccumulative, and is deferring its original conclusion that lead is highly bioaccumulative.

a. What comments did EPA receive on the aquatic bioaccumulation data for lead? Aquatic species have their own unique roles in ecosystems and are important for the subsistence of other species, including consumer and predator species. Thus, the propensity of lead to bioaccumulate in aquatic species is of concern. Among other things, aquatic species comprise components of the food chain that lead to humans. For example, green algae are primary producers in aquatic ecosystems in that, through photosynthesis, they produce oxygen and synthesize carbohydrates and other foodstuffs (Ref. 45). These substances are used by consumer species which in turn serve as the food source for predator species, including fish. Fish in turn, serve as a food source for wild mammals, birds, and man. The survival of a number of terrestrial species, including humans, is at least partially dependent upon aquatic organisms. The Agency for the purposes of EPCRA section 313 believes all aquatic organisms to be equally relevant when evaluating properties of chemicals to aquatic life forms: i.e., an alga is viewed just as important as an oyster or a fish.

EPA's scientific assessment of lead and lead compounds is based upon relevant data and has a sound scientific foundation. EPA believes that the scientific basis that the Agency used to support its conclusion that lead and lead compounds bioaccumulate in aquatic species is more than sufficient, and presents a balanced view of the scientific literature. The effects of lead and lead compounds on aquatic and terrestrial organisms has been studied extensively since the mid-1920s. A particularly active period for lead research was during the 1970s and 1980s, when dozens of studies were completed. In fact lead was one of the first chemicals extensively tested and monitored in water pollution and water quality studies. Thus, there are a plethora of studies available that investigated the environmental fate, availability, bioconcentration and bioaccumulation of lead and lead compounds. The Agency believes that these studies are relevant to an assessment of lead as a PBT substance, and many of these were reviewed by the Agency for the proposed rule. Each study reviewed by EPA in the development of this rule involving bioconcentration or bioaccumulation testing, was initially assessed by the Agency for quality. Not unexpectedly, the studies were found to vary in quality and test results to the subject organisms. Studies that were found to be most consistent with OPPT test guidelines were deemed valid and selected for use in the assessment. These studies covered a variety of different test species.

The results of EPA's assessment of the bioaccumulation of lead and lead compounds in aquatic organisms are summarized in Table 1 of the proposed rule and in references therein (64 FR 42230). As can be seen from Table 1, the BCF values from these studies range from 390 to over 12,000, additional information on BCF values for lead and lead compounds are contained in EPA's support document (Ref. 6). For a number of aquatic organisms that include: freshwater invertebrates such as mollusks, insects, and daphnid crustaceans; freshwater algae and phytoplankton; marine mollusks, a crustacean, and algae, lead and lead compounds bioconcentrate to levels above the baseline BCF criterion of 1,000 and, for some organisms, at or above 5,000. These values are viewed by the Agency as indicators of the potential for increased exposure due to significant bioaccumulation that could occur in other organisms in the environment that have not been tested. Based on these data EPA concludes that lead and lead compounds are bioaccumulative, and believes that these data tend to support a finding of highly bioaccumulative.

Where a range of lead BCF values was available for a specific organism, EPA evaluated the scientific validity of the studies reporting BCF values and relied upon those studies that were valid and scientifically sound. If valid BCF values meeting, or surpassing, the bioaccumulation criterion used by EPA in this rulemaking (i.e., BCF or BAF values greater than 1000) were identified for a species, EPA relied on these values as evidence that lead meets the EPCRA section 313 bioaccumulation criterion. Although some species may have a range of reported BCF values, in some cases crossing the bioaccumulation criterion, a study reporting a lower value does not invalidate scientifically sound studies reporting higher values.

The results of the majority of the studies that investigated the bioaccumulation of lead and lead compounds are in general agreement. Thus, although EPA did not review every published lead study as part of its assessment for the proposed rule, the scientific data EPA used to support its assessment of lead and lead compounds were valid, represented the majority of all available data on lead, and provided a representative sample of the available knowledge on lead.

One commenter notes EPA's definitions of BAF and BCF on page 42229 of the proposed lead rule. EPA defines BAF as "the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where both the organism and its food are exposed and the ratio does not change substantially over time." EPA defines BCF as "the ratio of a substance's concentration in tissue of an aquatic organism to its concentration in the ambient water, in situations where the organism is exposed through water only and the ratio does not change substantially over time." The commenter questions the portions of EPA's definitions of BCFs and BAFs that state that the ratios do not change substantially over time (64 FR 42229). Specifically, the commenter claims that "such ratios have little scientific relevance in themselves." The commenter states that available data indicate that the lead BCF may not be a constant for different exposures, species or trophic levels.

EPA agrees with the commenter's statement that a BCF may not be

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constant for different species or trophic levels. The Agency also agrees with the commenter's statement that the BAF and BCF of a substance measured in the same species can vary with the level of exposure (the concentration of the substance in ambient water). The Agency, however, believes the commenter has misunderstood the portions of its definitions of BCFs and BAFs that state that the "ratios do not change substantially over time" (64 FR 42229). The definitions of these terms pertain to determinations of BAF and BCF under controlled experimental conditions or field studies, where exposure of the aquatic species to the chemical is kept relatively constant. The phrase "ratios do not change substantially over time" does not refer to different experiments conducted at different concentrations of the test chemical. Thus, the fact that lead BCF values may not be constant for different exposures, species or trophic levels does not mean that lead does not bioaccumulate.

A number of commenters claim that EPA disregarded scientific data or did not use current scientific evidence in its assessment of the aquatic bioaccumulation potential of lead and lead compounds. Most of these commenters point out that EPA based its assessment of lead and lead compounds on studies published no later than the 1980s. These commenters are concerned that the studies EPA used are "out-of-date"; flawed; were not conducted using modern day analytical techniques; and assert that the data provided in these studies should not have been used by EPA in its assessment. These commenters also claim that environmental studies pertaining to lead and lead compounds published in the 1990s indicate that lead and lead compounds are not persistent or bioaccumulative in aquatic species.

While some commenters criticize the Agency for basing its assessment on the studies referenced in the **Federal Register** notice and in the technical support document entitled *Bioaccumulation/Bioconcentration Assessment for Lead and Lead Compounds* (Ref. 6), none of these commenters provide persuasive criticism of the studies used by EPA, or of a particular data point from a study used by EPA. In many cases it is not clear from their comments specifically which studies and data these commenters feel are untrustworthy. It is difficult, therefore, for EPA to provide specific responses to these commenters. In addition, although many of the commenters claim that EPA did not use current scientific evidence, very few of the commenters provide citations to specific studies that contain more current or more recent scientific data. The Agency recognizes that it did not use results from studies published during the 1990's in its assessment of lead and lead compounds. EPA disagrees with the commenters, however, that the studies used in its analysis are "out-of-date", or that the data are not sufficiently current such that they should not have been used in the assessment. As with all studies used by EPA, the studies EPA used in its assessment of lead and lead compounds were initially reviewed by EPA for scientific credibility, and found to be scientifically valid. Many of the current methods used for biological analyses and conducting ecotoxicity tests are essentially the same as those used in the studies cited by EPA in the proposed rule. In addition, on a more general level, the Agency does not believe that the quality of a study should be judged by the year it was published, or that the results of a more recently published study necessarily has greater scientific validity than a similar study published earlier. The Agency maintains its longstanding position that when conducting a scientific assessment it is scientifically unacceptable to discriminate between study results by the age of the study: the selection of studies for any scientific assessment must be based on scientific merit.

While the Agency did not rely on the specific results from the additional studies referenced and discussed by one commenter to assess the bioaccumulation of lead and lead compounds in developing the proposed rule, the studies published in the 1990s which were referenced by the commenters provide no significant additional information beyond the studies used by EPA in the proposed rule, nor do the results from these studies lead EPA to reconsider the characterization of lead and lead compounds as bioaccumulative.

One commenter claims that more recent aquatic bioaccumulation studies indicate that previously reported concentrations of metals in environmental waters are erroneously high due to sample contamination (i.e., that earlier studies on the concentration of lead in the environment over estimated the actual concentrations of lead in the environment). The commenter believes that this means that previously reported BAF and BCF values would appear lower than if the concentrations of lead had not been overestimated. The commenter states that because of the earlier "erroneous Pb measurements in water", researchers used higher lead levels in their bioaccumulation studies than they otherwise would have used. The commenter states that no experiments have been conducted at levels close to the actual lead concentrations in "natural waters." The commenter also stated that no data exists on actual lead concentrations for waters associated with highly contaminated sites where the results of the experiments conducted at concentrations above natural waters might apply. The commenter states that recent studies use lead concentrations 3 to 6 orders of magnitude above actual background lead concentrations and that although the data cited by EPA are from studies much closer to levels in natural waters they are still 2 to 4 orders of magnitude greater than typical values of lead in natural waters. According to the commenter this caused higher levels of lead to occur in the organism than would be observed under "actual concentrations of Pb in natural waters." The commenter tries to invalidate the concerns for bioaccumulation by claiming that, even though the BAFs/BCFs used by EPA are high, the absolute amount of lead that would bioaccumulate in organisms is low and does not pose a risk.

EPA disagrees with the commenter's argument that only BAF or BCF values measured at "actual concentrations of Pb in natural waters" are relevant to the bioaccumulation potential of lead and lead compounds. At its foundation the commenter's argument is flawed because under EPCRA section 313 the Agency is collecting data on releases of lead and lead compounds to the environment which are expected to raise lead concentrations above natural background levels. BCF studies that used lead concentrations above natural background levels are valid since they demonstrate that lead can bioaccumulate at lead concentrations that may result from industrial releases. Thus the fact that the experiments on bioaccumulation were conducted at lead levels in excess of those found in "natural waters" does not, in itself, invalidate the results of those studies. As noted in Unit VI.C.3., testing guidelines for bioaccumulation do not state that chemicals should be tested at natural background concentrations, only that the concentrations should be below a level that is detrimental to the test organism. Therefore, even if better data had been available on the background concentrations of lead that does not mean that bioaccumulation studies would have been conducted at those

concentrations. In addition, the commenter admits that higher bioaccumulation values would have been reported in earlier studies if better data on the concentration of lead in the water had been available. EPA fails to see how even higher bioaccumulation values undermine EPA's determination that lead and lead compounds are bioaccumulative. EPCRA section 313 is not a risk-based program, and the Agency is not required to demonstrate a specific risk in order to classify a substance as a PBT chemical. The EPCRA section 313 bioaccumulation criteria does not include a requirement that a chemical must bioaccumulate to some specific absolute amount within an organism in order to meet the criteria. Therefore, EPA disagrees that lead has not been shown to bioaccumulate to a level sufficient for inclusion as a PBT chemical. Even if such evidence were needed, it is available. EPA's database of Fish and Wildlife Advisories (http://fish.rti.org) contains 26 advisories for various fish and shellfish, see Unit VI.D.3. This indicates that lead and lead compounds can and do bioaccumulate in aquatic organisms to absolute levels that are of concern for human consumption.

Furthermore, the commenter's contention that previously reported lead concentrations in ambient waters may be erroneously high only serves to support the conclusion that lead and lead compounds are at least bioaccumulative. The commenter agrees that if the previously reported lead concentrations in ambient waters are in fact erroneously high, then the previously reported BAF and BCF values for lead and other metals are erroneously low (because the BAF and BCF values are determined by dividing tissue lead concentrations by environmental water concentrations). Thus, if the commenter's claim about the water concentrations is true, then the propensity for lead and lead compounds to bioaccumulate in aquatic species is actually greater than originally estimated. Based on the commenter's concern for the validity of the water concentrations and the BAF and BCF values reported for lead and lead compounds, EPA re-reviewed the studies it used in its original assessment of lead and lead compounds. EPA is satisfied that the lead water concentrations, BCF values, and BAF values reported in these studies are valid. However, as noted above, EPA is deferring on a final conclusion regarding the classification of lead as highly bioaccumulative based on the data in these studies, and is concluding in this rule that lead is bioaccumulative.

Two commenters contend that the extent to which a metal such as lead bioaccumulates is dependent upon its concentration in the aqueous habitat of the organism. The commenters state that in most cases where bioaccumulation was noted, the organisms were exposed to artificially elevated lead concentrations in laboratory settings, often where abiotic factors were manipulated to increase lead availability.

The Agency agrees that environmental transformations and the uptake of lead by biota are highly variable and complex. However, these variabilities and complexities can be minimized by testing in the laboratory using a valid method. As discussed in the proposed rule, valid laboratory BCF tests have shown that lead and lead compounds have BCF values in some species well over 1,000. In some of the lead assays, several of the tested species (e.g., mollusks, algae) have very high BAF or BCF values, i.e., 5,000 or greater, indicating that these organisms accumulate or concentrate lead to high levels and eliminate lead very slowly. Thus, in organisms such as these, it would seem logical that the BAF or BCF values obtained at different test chemical concentrations would probably not vary by much. Further, based on its assessment of lead and lead compounds the Agency has concluded that external concentration is only one of several factors that govern the propensity for these substances to bioaccumulate in a given species. As discussed in more detail Unit VI.C.3, pharmacokinetic factors are operative as well.

EPA does not believe that bioaccumulation of lead was documented mostly in cases where the concentrations of lead in the surrounding water were artificially elevated in laboratory settings. This was not the case, for example, in the freshwater and marine algal field studies where BAF or BCF values above 10,000 were documented in actual aquatic environments and the lead levels were not artificially controlled. In addition, the fish advisories discussed in Unit VI.D.3. were based on concerns for lead levels in fish and other species that did not occur as a result of artificially elevated lead concentrations in laboratory settings.

One commenter states that EPA's contention that relatively small releases of lead and lead compounds have the potential to bioaccumulate and cause significant adverse environmental impacts is not supported by the scientific literature. Another commenter stated that the preponderance of evidence shows that only under very limited conditions will lead and lead compounds be available to bioaccumulate and cause toxic impacts to ecosystems.

EPA disagrees. As discussed elsewhere in this document, there are many studies that show that there are several environmental factors (e.g., pH range of 3 to 6; soils that have low cation exchange capacity; low soil organic matter content) that increase the availability of lead and that, either individually or in combination, commonly exist throughout many geographical locations within the United States. However, even if the conditions under which lead is available were very limited this would not mean that lead would not bioaccumulate. Also, because lead and lead compounds are EPCRA section 313 listed toxic chemicals that EPA has determined are persistent and bioaccumulative, even small releases of lead and lead compounds into the environment persist and have the potential to bioaccumulate and cause significant adverse environmental impacts. Further, EPA notes the data on the bioaccumulation of lead and lead compounds in human (see Unit VI.D.2.b.) and the fish advisories for lead (see Unit VI.D.3.).

b. What comments did EPA receive on the human bioaccumulation data for lead and lead compounds? In Unit V.C. (pages 42230–42231) of the proposed rule, EPA provides a brief summary of available data on the pharmacokinetics of lead in humans. As stated in the proposed rule, EPA concluded that there is a substantial amount of evidence that shows that humans bioaccumulate lead. Unlike the assessment as to whether lead bioaccumulates in aquatic species, which was based on lead bioaccumulation factor (BAF) and bioconcentration factor (BCF) values measured in aquatic species in laboratory or field studies, the assessment of whether lead bioaccumulates in humans cannot be based on an analysis of BAF or BCF values because such values are not available for humans. The assessment of whether lead bioaccumulates in humans was based on the Agency's review of the references cited in Unit V.C. of the proposed rule, which provide a substantial amount of data and information regarding exposure of humans to lead, and the pharmacokinetics of lead in humans. From its review of these references, EPA concluded that humans, particularly

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children, bioaccumulate lead to a significant degree. The propensity of lead to bioaccumulate in humans is known to result in toxicity to humans, especially infants and children. While the EPCRA section 313 PBT chemical criteria does not require that toxicity must occur in the same species in which the substance bioaccumulates, or result from bioaccumulation of the substance, those chemicals that persist in the environment, bioaccumulate in humans, and are toxic to humans are particularly problematic in regard to human health. The following information on the accumulation of lead in humans is discussed in the references cited in the proposed rule (Refs. 8, 10, 11, 14, and 25).

Exposure of the general population to lead occurs primarily via the oral and inhalation routes, and data show that in humans lead is absorbed from the gastrointestinal tract and the lung. Absorption of lead from the gastrointestinal tract varies with age. Adults absorb approximately 10% of orally ingested lead, and usually retain less than 5% of what is absorbed. Children absorb up to 40% of ingested lead, and retain more than 5% of the absorbed quantity. Infants retain over 30% of the quantity absorbed following oral exposure. Research indicates that the differences in the extent to which lead is absorbed orally between adults and infants and children may be due to the increased need for calcium in infants and children. In infants, children, and adults, a transport mechanism is involved with the absorption of calcium from the gastrointestinal tract. Infants and children, because they are growing rapidly, utilize calcium for bone formation and growth. Dietary needs for calcium are therefore higher in infants and children than in adults and, consequently, calcium is more efficiently absorbed orally by infants and children than it is by adults. Evidence indicates that lead may be competing with calcium for the transport mechanism involved with absorption of calcium, which could explain why lead is absorbed from the gastrointestinal tract more efficiently in infants and children than it is in adults.

Following inhalation exposure, lead is well absorbed from the lung by all human subpopulations. About 90% of lead particles in ambient air that are deposited in the lung are small enough to be retained within the lung. Lead retained within the lung is essentially completely absorbed from the lung.

In humans, lead is known to bioaccumulate in bone. Following absorption, lead is distributed initially to the blood and soft tissues (especially the kidney, liver and bone marrow). The biological half-life of lead in blood is generally from 1 to 2 months. Some of the lead in the blood is excreted, predominately in the urine. The extent and rate of excretion is limited, however. Eventually, lead that is not excreted is redistributed from the blood to teeth and bone. Once in bone, the biological half-life of lead can extend beyond 20 years. Following daily exposure to lead, a steady state blood level of lead is achieved after about six months. (A steady state in blood lead is reached when the daily intake of lead approximates the amounts excreted in the urine and partitioned to bone.) Once steady state is reached, the blood level of lead remains essentially constant. However, because the rate and extent of urinary excretion of lead is limited, the concentration of lead in bone tends to continue to increase even though daily exposure remains constant. Also, if the amount of daily intake should increase, the time to accumulate higher levels of lead in the blood and soft tissues shortens disproportionately since renal excretion and deposition into bone occurs too slowly to prevent an accumulation in the blood and soft tissue.

The fraction of lead in bone increases with age from about 70% of total body lead in childhood to as high as 95% of the total body lead during old age. While lead bioaccumulates in bone, lead in bone can remobilize back to the blood. The extent to which lead in bone remobilizes to blood and other tissues is related to conditions that involve calcium resorption from bone. Any conditions that cause calcium to be resorbed from bone into the systemic circulation or other soft tissue will cause lead to resorb from bone. These conditions include: advanced age; osteoporosis; pregnancy; and lactation. Hence, lead stored in bone from exposures that occurred years, even decades, earlier may serve as an internal source of lead exposure later in life. lead previously accumulated in bone may contribute as much as 50% of blood lead.

Lead in maternal blood can enter the fetus. Lead in fetal tissue is proportional to maternal blood concentration. Inorganic lead (i.e., Pb^0, Pb^{+2}, Pb^{+4}) does not readily cross the blood brain barrier, and therefore only a small amount of inorganic lead accumulates in the brains of adult humans. Once in the central nervous system, however, lead accumulates in gray matter. The highest concentrations are in the hippocampus, followed by the cerebellum, cerebral cortex, and medulla. Fetuses, infants and children less than 4 years of age are more predisposed to accumulate inorganic lead in the brain than are adults because in these subpopulations the blood brain barrier is not completely formed. In addition to the ability of infants and children to absorb lead more efficiently from the gastrointestinal tract than adults, it is well established that infants and children are also more sensitive and susceptible than are adults to the neurotoxic effects caused by lead. Mobilization of lead from bone into the blood is of particular concern during pregnancy or lactation.

Based on EPA's findings that in humans lead bioaccumulates in bone, that the concentration of lead in bone tends to continue to increase over the course of a lifetime, and that lead stored in bone from exposures that occurred previously may serve as an internal source of lead exposure later in life, EPA has concluded that lead significantly bioaccumulates in humans. In the proposed rule EPA asked for public comment on the scientific information concerning the bioaccumulation of lead in humans, and how this information should be considered in classifying lead and lead compounds as highly bioaccumulative. Several organizations or individuals provided comments to EPA's request, however none of these comments addressed the scientific information presented by EPA concerning the bioaccumulation of lead in humans, or how this information should be considered in classifying lead and lead compounds as bioaccumulative much less as highly bioaccumulative. While EPA believes that it could have reached a determination of bioaccumulative based on the human data alone, EPA concludes that lead and lead compounds are clearly and properly categorized as bioaccumulative based on the aquatic and human data. EPA further believes that these data would tend to support a finding of highly bioaccumulative.

c. What other general comments did EPA receive on the bioaccumulation of lead? One commenter claimed that EPA's reasoning that lead bioaccumulates is based on many variables, and is not realistic. This commenter refers to EPA's frequent use of the words "may" or "can" throughout the proposal: "EPA believes that processes * * * can result in the release of bioavailable (ionic) lead where it can be bioaccumulated by organisms. These processes may occur in soil and aquatic environments with low pH and low levels of clay and organic matter."

The Agency disagrees with this commenter. As described above, EPA's characterization of lead as a highly bioaccumulative substance is based on the Agency's scientific assessment. Also, EPA's use of words such as "may" or "can" is justifiable. EPA's TRI program is a national program and is not limited to specific locations or regions of the country. As discussed in detail in the proposed rule and elsewhere in this document, environmental conditions have a direct influence on the availability of lead and, hence, an indirect influence on the bioavailability and bioaccumulation of lead in aquatic organisms. Environmental conditions vary substantially across the United States and hence the availability of lead in the environment is likely to vary accordingly. To encompass the fact that environmental conditions vary, and that this rulemaking decision will be implemented at the national level, EPA believes its use of words such as "can" or "may" in the proposed lead rule is an accurate characterization of the scientific data. Despite the variations in environmental conditions EPA has concluded that there are many conditions in the United States where lead is available to bioaccumulate. In addition, lead is bioavailable even under environmental conditions where the lead ion may not be readily available in the environment.

Further, there are sufficient experimental data in aquatic organisms, fish advisories, and extensive data in humans, all of which indicate that lead and lead compounds *do bioaccumulate*. Thus, EPA disagrees with the comment that the Agency's conclusion that lead bioaccumulates is unrealistic. To the contrary, EPA has concluded that the available evidence indicates that lead and lead compounds will bioaccumulate in many actual environments.

Several commenters state that there are numerous literature citations that show that lead does not biomagnify in aquatic food chains, and, in experimental trophic chains lead accumulated in decreasing concentration from the lowest to the highest trophic levels. One commenter concludes that bioaccumulation is not relevant unless lead is transferred up the food chain to humans, and that a concept more meaningful than BCF is needed to evaluate the potential risk from lead to public health from ingestion of fish.

EPA disagrees with the commenter's conclusion that bioaccumulation is not relevant unless lead is transferred up the food chain to humans and that BCFs [and BAFs] are not meaningful. "Transfer up the food chain" is really a biomagnification concern which EPA addressed in the final PBT chemical rule (64 FR 58682) and associated Response to Comment document (Ref. 15, section 2.d), stating that such a process is not relevant to the issue of whether a chemical bioaccumulates. Bioaccumulation is a concern for the organism that bioaccumulates it and any organism that eats such organisms. While available data may indicate that lead does not biomagnify, this has no bearing on the characterization of lead as a bioaccumulative substance because biomagnification is not required in order to have a concern for a chemical that bioaccumulates. While EPA does not have to make such a connection, the commenters' own information provides evidence of a transfer up the food chain. The commenter stated that about 60% of the lead in phytoplankton is assimilated by mussels and that mussels have high BCF values. EPA identified phytoplankton as having high bioaccumulation values so there is the potential for movement of lead in the food chain based on this information. In addition, EPA's database of Fish and Wildlife Advisories (http://fish.rti.org) contains 26 advisories for various aquatic organisms including shellfish.

3. What comments did EPA receive on the bioavailability of lead. Contrary to some commenters' claims that EPA did not consider relevant data regarding bioavailability, EPA emphasizes that the Agency **did** consider the bioavailability of lead in its evaluation of lead and lead compounds. In addition to the principles described above in Unit VI.C.2. that address the availability and bioavailability of metals, EPA also relied on empirical data regarding the availability and bioavailability of lead. EPA refers specifically to the test data cited in the proposed rule and in the references to the proposed rule that clearly show that lead is bioavailable (Table 1 of the proposed rule (64 FR 42230), and references therein). The fact that lead is detectable in the tissues of snails, algae, plankton, rainbow trouts, blue mussels, oysters, and lobsters exposed to lead provides compelling scientific evidence that lead is bioavailable in these species.

In addition to these test data, EPA examined its public National Listing of Fish and Wildlife Advisories database (see http://fish.rti.org/) to see whether lead has been detected in fish under actual environmental conditions. The individual states have the primary responsibility for protecting residents from the health risks of consuming contaminated noncommercially caught fish and wildlife. Individual counties monitor local fish and wildlife for the presence of chemical contaminants, including lead. Fish consumption advisories warn the public that high concentrations of chemical contaminants have been found or are suspected in fish from local waters and that consumption of these fish may pose health risks. The advisories may recommend to limit or avoid consumption of specific fish species, or to limit or avoid consumption of fish from specific water bodies. It is important to emphasize that while a single advisory has one geographic location (e.g., a portion of a river or lake), it can contain information about several fish species (e.g., carp, largemouth bass, shrimp), several pollutants (e.g., mercury and PCBs), and several "populations" (e.g., no consumption for at risk subpopulations such as pregnant women and/or restricted consumption for general populations). There are 26 reports that show that lead is or has been detected in different aquatic species located in various areas within the United States. The fact that lead is detected in fish shows that lead is bioavailable in fish under actual and varying environmental conditions. Being within the purview of state and local governments, there is some variation in fish advisory policies and procedures across the United States. Thus, not all counties monitor fish and wildlife for chemical contaminants, and some counties may not monitor for lead contamination. Therefore, there may be additional geographical locations within the United States, not listed in the National Listing of Fish and Wildlife Advisories database, where the fish are contaminated with lead.

Some commenters state that EPA should evaluate each individual member of the lead compounds category on a case-by-case basis because the availability of lead from lead compounds differs among lead compounds and lead is unavailable from certain lead compounds. As explained in Unit VI.C.1., the Agency has concluded that there is a scientific basis for evaluating lead compounds as a category rather than individually because the bioavailability of a lead compound is not necessarily dependent upon the availability of lead from the compound. That is, the parent lead compound may be bioavailable as is or, if not itself bioavailable, could be converted in the environment into a another lead compound that is bioavailable or from which lead is bioavailable. As discussed in Unit VI.D.1, EPA's environmental fate assessment indicates that there are

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many conditions under which lead from lead compounds can become available in the environment. Further, most lead compounds provide bioavailable lead when ingested. Thus, after an evaluation of the available data, EPA has determined that the weight of scientific evidence indicates that it is reasonable to conclude, based upon similarities between the compounds, that lead in the environment will be available and/or bioavailable from all lead compounds.

In addition, regardless of the relative environmental availability of lead from one lead compound to another, the lead compounds all add to the environmental loading of lead. Thus, even if under the same environmental conditions the lead from compound A is 10 times less available than the lead from compound B, compound A would introduce the same amount of available lead if its releases are 10 times greater. If lead compounds are evaluated individually based on relative environmental availability then the additive effect of the loading of lead from these compounds would be ignored.

E. What Comments Did EPA Receive on Its Proposed Threshold for Lead and Lead Compounds?

EPA received a range of comments on the thresholds proposed for lead and lead compounds similar to those it received on the thresholds proposed for the PBT chemicals in its earlier rulemaking. Many commenters contended that EPA should not consider burden in choosing thresholds. They believe that EPA should set a threshold of 1 pound for lead because it was proposed as falling within the subset of PBT chemicals that are both highly persistent and highly bioaccumulative. Numerous commenters believe that the threshold for reporting should be zero. Other commenters believe that burden should have been a greater consideration in EPA's choice of reporting thresholds. Many of these commenters also stated that EPA should set thresholds based on some percentage of releases that would be reported.

With few exceptions, the comments EPA received failed to take into account the analyses EPA laid out in the final PBT chemical rule. As explained in the preamble to that rule, the analyses in that rulemaking relied on the characteristics and policy considerations surrounding PBT chemicals in general. The analyses were not dependant on the specific chemical properties of the particular, individual chemicals addressed in that rulemaking, but were tied more closely to the overall characteristics of PBT chemicals generally. For example, as part of the explanation for the Agency's decision to establish two categories of thresholds an order of magnitude apart, EPA noted:

> EPA then considered the relative degree of persistence and bioaccumulation between the two classes of chemicals. EPA wanted to establish two sets of revised thresholds with the same approximate relationship to each other, as the relative exposure potentials of PBT chemicals to that subset of highly persistent and highly bioaccumulative PBT chemicals. Simply stated, chemicals with half-lifes of 6 months or greater and a BAF/BCF of 5,000 or greater have a higher exposure potential than chemicals with half-lifes of 2 months or greater and a BAF/BCF of 1,000 or greater. However, although, as discussed below, EPA could establish a qualitative relationship, the Agency could not reliably quantify the relative exposure potential across the board for all of the members of both classes. Therefore, in attempting to translate the qualitative exposure potential of PBT chemicals to that subset of PBT chemicals that are highly persistent and highly bioaccumulative into a qualitative *threshold* relationship, EPA considered both the attributes of these chemicals and factors specific to thresholds. 64 FR 58690.

And as EPA also explicitly noted in the preamble, EPA established the revised thresholds with the intention that they would be generally applicable to future members of the two PBT categories. See 64 FR 58691. Thus, absent some strong technical or policy concern to the contrary-a topic on which the public would have the opportunity to present information and otherwise provide comments—the revised thresholds were anticipated to be applicable to future candidate PBT chemicals. EPA requested commenters to submit such technical and policy concerns in its proposed rule for lead and lead compounds. See 64 FR 42224. This, the commenters have failed to do. In addition, in the proposed lead rule, EPA identified an additional factor for use in determining whether a chemical is, at the least, bioaccumulative. EPA explained that there is clear and convincing evidence that lead is bioaccumulative in humans. EPA also requested comment on the human data and on how such data should be considered in determining whether a chemical should be classified in that subset of PBT chemicals that are highly bioaccumulative. Therefore, consistent with the factors laid out in its previous rulemaking, and with its determination that lead and lead compounds are highly persistent and bioaccumulative toxic chemicals, EPA is setting the thresholds for lead and lead compounds at 100 pounds. As discussed elsewhere, following its review of the comments, EPA is deferring on its proposal to classify lead and lead compounds as highly bioaccumulative.

Consistent with EPA's approach to revise thresholds for PBT chemicals, EPA began with the premise that for lead and lead compounds, assuming no unique circumstances, a threshold of either 100 or 10 pounds would be warranted. The choice of threshold was dependent on whether the data indicated that lead and lead compounds were PBT chemicals, or fell within the subset of highly persistent and highly bioaccumulative toxic chemicals. In this rulemaking EPA has concluded, through application of PBT criteria as discussed in the PBT final rule and the proposed lead rule, that lead and lead compounds are highly persistent and bioaccumulative. At this time, EPA is deferring on a final conclusion as to whether lead and lead compounds are highly bioaccumulative, and is deferring on whether lead and lead compounds are appropriately classified in that subset of toxic chemicals that are highly persistent and highly bioaccumulative. Thus, based on EPA's conclusions, a 100 pound threshold for lead and lead compounds is warranted.

EPA has considered the same factors for lead and lead compounds that it had considered for the individual PBT chemicals included in its previous rulemaking. To determine whether the additional reporting burden associated with lowering the thresholds for lead and lead compounds presented any unique concerns, and to ensure that the 100 pound threshold would capture significant information from a range of covered industry sources, EPA analyzed the number of reports that would be submitted by each industry sector for the following potential thresholds: 1 pound, 10 pounds, 100 pounds, and 1,000 pounds.

EPA's analysis confirmed that 100 pound threshold achieves the appropriate balance of the various factors laid out in the preamble to the final PBT rule. EPA therefore finds that establishing the threshold at 100 pounds will not be unduly burdensome, and ensures that the resulting reporting will provide the public with information from a range of covered industry sectors, and that the information will contribute significantly to providing the public with a comprehensive picture of toxic chemical releases and potential exposures to humans and ecosystems.

F. What Comments Did EPA Receive on Its Proposed Treatment of Lead Contained in Stainless Steel, Brass, and Bronze Alloys?

The commenters on this issue generally agree with EPA's proposed limitation on the reporting of lead contained in stainless steel, brass, and bronze alloys, but felt that it should be expanded. Some commenters suggest that all alloys should be included, while others cited various types of alloys that they believed should also be included, e.g., aluminum, copper, zinc, tin, iron, all steels, carbon and low alloy steels, leaded steel, and galvanized and drawn steel wire. Some commenters also suggest that other metals be included in a broader alloy reporting exemption and that the exemption should be for all reporting, not just for the lower reporting thresholds. Some commenters claim that EPA's reasoning in drafting the alloys exemption is that lead incorporated into an alloy does not pose the same hazard as unincorporated lead, is not bioavailable, does not exert toxic effects, is not available for exposure, and that this reasoning holds true for lead contained in other alloys. Commenters also contend that alloys have significantly different bioavailability, bioaccumulation, and toxicity characteristics than other forms of metals, and thus should be treated separately. Some comments state that an alloys exemption would enhance the ability of TRI to provide meaningful information to the public regarding the risk associated with the release and handling of toxic materials. Several commenters requested an exemption for the use of lead and lead compounds in wire soldering operations. Some commenters state that lead contained in primary aluminum and aluminum alloys is incidental and that the concentrations are significantly lower than that found in stainless steel, bronze and brass alloys, which intentionally contain lead, and therefore lead in aluminum alloys should not be regulated any more stringently than those alloys. One commenter states that EPA failed to demonstrate that lead is bioavailable in any metal alloy and illegitimately provided a preferential exemption only to certain metal alloys. The commenter contends that EPA has failed to show any rational basis for excluding other metal alloys from such an exemption and that limiting the exemption to stainless steel, brass, and bronze alloys is arbitrary and capricious and should be expanded to all, metal alloys, including aluminum alloys.

EPA does not believe that it currently has any information that would support a decision to extend to other types of alloys, its deferral of a decision on a lower threshold for lead when contained in stainless steel, brass, and bronze alloys. EPA's proposed deferral was based on the fact that it is currently evaluating a previously submitted petition, as well as comments received in response to previous petition denials, that requested the Agency to revise the EPCRA section 313 reporting requirements for certain metals contained in stainless steel, brass, and bronze alloys. Contrary to the commenter's allegations, EPA has not determined that lead is neither toxic nor bioavailable when contained in these or any other alloys. Nor did EPA imply that lead or other metals contained in these or any other alloys are less hazardous than metals not contained in alloys, or that lead or other metals cannot exert toxic effects, or that lead or other metals are not available for exposure when contained in an alloy. Rather, the deferral is simply based on the fact that for stainless steel, brass, and bronze alloys, EPA is currently reviewing whether there should be any reporting changes. In light of that review, EPA has decided to maintain the status quo for lead when contained in these alloys until the review is complete.

Lead is an EPCRA section 313 listed toxic chemical, and lead contained in all alloys are therefore subject to the EPCRA section 313 reporting requirements. As discussed above, EPA did not illegitimately provide a preferential exemption only to stainless steel, brass, and bronze alloys. EPA is merely maintaining the status quo with respect to the alloys that are the subject of the pending review. Other alloys are not part of that review. Because the commenters have submitted no information or data that would allow the Agency to conclude that lead in all other alloys are similarly situated, in light of its scientific findings in this rule with respect to lead and lead compounds, EPA has no basis for extending its deferral.

With respect to the request for an exemption for lead soldering, EPA does not believe that the commenter's allegation that lead may not be released during these processes, such as wire soldering, provides an adequate basis for excluding that activity from threshold determinations and release reporting requirements. Under EPCRA section 313, whether an activity must be counted towards an EPCRA section 313 reporting threshold is based on whether the activities fall within the definition of manufacturing, processing, or otherwise use, not on whether the activity actually, or potentially, results in releases. Additionally, because even low amounts of releases are of concern for PBT chemicals like lead and lead compounds, it is not appropriate to exclude a reportable activity merely because releases from that activity may be relatively low.

In addition, this rulemaking is specific to lead and is not the appropriate forum to address the issue of limitations or exemptions for other metals contained in these or other alloys; nor was comment on such issues requested in the proposed rule. EPA will be issuing a report on its review of the data for stainless steel, brass, and bronze alloys and will be asking for comments on the report.

The comment that an alloys exemption would enhance the ability of TRI to provide meaningful information to the public regarding the risk associated with the release and handling of toxic materials is not relevant to the issue of whether or not there should be reporting changes for any alloys. As EPA has previously discussed (64 FR 58592), EPCRA section 313 is a hazard-based program, not a risk-based program. As such, EPCRA section 313 does not directly provide any risk information to its users, but rather provides basic release and other waste management information on chemicals that meet the criteria in EPCRA section 313(d)(2). Congress established these criteria as the sole standard for listing decisions. Therefore, any final determination on whether there should be changes to the reporting of alloys will be based on whether the alloys meet the criteria of EPCRA section 313(d)(2).

One commenter stated that EPA's limitation on the reporting of lead contained in alloys should apply to all alloys to be consistent with that proposed for cobalt and vanadium in the January 1999 proposal for other PBT chemicals.

EPA disagrees that it must extend its deferral to all lead alloys to be consistent with its past actions on cobalt and vanadium. With respect to cobalt, in the October 29, 1999 final PBT chemical rule (64 FR 58666), EPA only changed the reporting requirements for vanadium not cobalt. Regarding vanadium, the original vanadium listing contained the qualifier "fume or dust;" thus the status quo was that unless the vanadium alloy was converted to a fume or dust form, the vanadium in any alloy was not reportable. In the October 29, 1999 final rule, EPA added all forms of vanadium, except vanadium contained in alloys, to the list of TRI chemicals. EPA deferred its decision to add vanadium contained in alloys until it

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had resolved the pending petition. EPA explained its decision as follows: "At this time, while EPA is in the process of a scientific review of the issues pertinent to alloys, the Agency is not prepared to make a final determination on whether vanadium in vanadium alloys meet the EPCRA section 313(d)(2) toxicity criteria" (64 FR 58711).

At the time EPA made its determination with respect to vanadium, EPA chose not to add vanadium contained in any alloys to the EPCRA section 313 list of toxic chemicals. This decision excluded from a listing decision more than just the three classes of alloys specifically addressed in the alloys project out of concern that the project could be expanded to similar alloys. However, at the time of the lead proposal, EPA identified a potential concern with proposing a similarly broad deferral for lead since lead is used in many types of alloys that are not similar to stainless steel, brass, and bronze alloys. Because these other alloys, such as lead solder, are not being reviewed, and are currently subject to reporting under EPCRA section 313, EPA believes that the Agency has no basis to defer lowering thresholds for these other alloys. In light of the Agency's conclusions with respect to lead, EPA will review its October 29, 1999, vanadium decision and determine whether vanadium contained in alloys, other than the three classes of alloys currently under review by the Agency, should be added to the EPCRA section 313 list of toxic chemicals.

None of the commenters who supported a limitation for lead in other alloys submitted any data on which the Agency could rely to create such a limitation, or to extend the alloys review to encompass lead when contained in alloys other than stainless steel, brass, or bronze. As explained above, EPA believes that it has no basis to defer lowering thresholds for other alloys that are not currently being reviewed. If the commenter has data to support a revision to the reporting requirements for lead when contained in alloys other than stainless steel, brass, and bronze the commenter can submit it as part of a petition to delist lead contained in such alloys from the EPCRA section 313 list of toxic chemicals.

One commenter contends that EPA has exempted steel, brass and bronze alloys from reporting for lead with the implication being that these alloys do not yield sufficient lead to be a significant risk. The commenter stated that there are many products containing trace amounts of lead which are at least as stable as bronze or steel alloys. The commenter contends that EPA provides no explanation for why these other products were not also provided an exemption and that EPA sets forth an artificial and unfair distinction. The commenter cites colored plastics, vinyl siding, ceramics, paints and inks as examples of products that do not leach lead in sufficient quantity to pose a risk to the community. The commenter contends that there is an assumption implicit in the proposed rule, that steel alloys containing lead are sufficiently safe and non-toxic to avoid reporting under the TRI, while all other forms of lead, lead compounds and thousands of products which may contain trace quantities of lead and lead compounds are not and that this is unsubstantiated in the record for this rulemaking.

EPA is not providing an "exemption" to lead contained in stainless steel, brass and bronze alloys. As EPA discussed in other responses in these section, EPA is merely deferring a final decision on lowering thresholds for lead contained in these alloys until the scientific review of the alloys petition is complete. EPA has made no determination, implicit or otherwise, that lead contained in any alloy is safe, non-toxic, or without significant risk. Lead contained in other non-alloy products is currently reportable and since these other non-alloys are not part of the review of stainless steel, brass, and bronze alloys EPA did not include any similar deferral for these other products. With regard to these other lead containing products, if the commenter has data that indicate that the lead contained in these products cannot become available through any abiotic or biotic processes, then they may wish to provide these data in a petition to have the lead in such products delisted from the EPCRA section 313 listed toxic chemicals. In addition, under certain conditions, some of the products mentioned by the commenter (such as vinyl siding, colored plastics, and ceramics) may be eligible for the article exemption (see 40 CFR § 372.38 (b)) and thus would not be subject to reporting in any case.

Two commenters requested that lead and lead compounds contained in glass, ceramic enamels, and ceramicware be excluded from reporting. One commenter stated that EPA's limitation on the reporting of lead in stainless steel, brass, and bronze alloys, is apparently justified because alloys have significantly lower potential for bioavailability, bioaccumulation, and toxicity than other forms of metals and are less likely to affect organisms than non-alloy forms of metals and that these compounds are extremely stable and virtually unable to interact with organisms. The commenter contends that ceramic enamels share similar properties with alloys and that the way that they are manufactured and used results in little or no releases or exposures. The commenter stated that these enamels are as insoluble as possible and bind the lead compounds in such a way that their use in glazing and decorating ceramicware or glass would strictly limit the potential exposure of the community to releases from a glazing or decorating process.

As discussed in detail in the responses contained in the previous section, EPA has not determined that lead is neither toxic nor bioavailable when contained in these or any other alloys. Nor did EPA imply that lead or other metals contained in these or any other alloys are less hazardous than metals not contained in alloys, or that lead or other metals cannot exert toxic effects, or lead or other metals are not available for exposure. EPA is merely deferring a final decision on lead contained in these alloys until the Agency completes it current review of the alloys petition. The commenter has provided no data to support expanding its alloys review to these materials so the basis for the deferral for lead in certain alloys does not apply to these other materials. If the commenter has data to support such an extension, then they may wish to provide this data in a petition to have the lead in such products delisted from the EPCRA section 313 listed toxic chemicals. In addition, under certain conditions, glass and ceramic products may be eligible for the article exemption (see 40 CFR § 372.38 (b)) and thus would not be subject to reporting in any case.

VII. What Are the Results of EPA's Economic Analysis?

EPA has prepared an economic analysis of this action, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Lead and Lead Compounds Under EPCRA Section 313* (Ref. 46). This document is available in the public version of the official record for this rulemaking. The analysis assesses the costs, benefits, and associated impacts of the rule, including potential effects on small entities. The major findings of the analysis are briefly summarized here including responses to some of the major comments EPA received.

A. What Is the Need for the Rule?

Federal regulations exist, in part, to address significant market failures.

Markets fail to achieve socially efficient outcomes when differences exist between market values and social values. Two causes of market failure are externalities and information asymmetries. In the case of negative externalities, the actions of one economic entity impose costs on parties that are "external" to any market transaction. For example, a facility may release toxic chemicals without accounting for the consequences to other parties, such as the surrounding community, and the facility's decisions will fail to reflect those costs. The market may also fail to efficiently allocate resources in cases where consumers lack information. For example, where information is insufficient regarding toxic releases, individuals' choices regarding where to live and work may not be the same as if they had more complete information. Since firms ordinarily have little or no incentive to provide information on their releases and other waste management activities involving toxic chemicals, the market fails to allocate society's resources in the most efficient manner.

This action is intended to address the market failures arising from private choices about lead and lead compounds that have societal costs, and the market failures created by the limited information available to the public about the release and other waste management activities involving lead and lead compounds. Through the collection and distribution of facility-specific data on toxic chemicals, TRI overcomes firms' lack of incentive to provide certain information, and thereby serves to inform the public of releases and other waste management of lead and lead compounds. This information enables individuals to make choices that enhance their overall well-being. Choices made by a more informed public, including consumers, corporate lenders, and communities, may lead firms to internalize into their business decisions at least some of the costs to society relating to their releases and other waste management activities involving lead and lead compounds. In addition, by helping to identify areas of concern, set priorities and monitor trends, TRI data can also be used to make more informed decisions regarding the design of more efficient regulations and voluntary programs, which also moves society towards an optimal allocation of resources.

Certain facilities currently report TRI data on lead and lead compounds under the existing 10,000 and 25,000 pound reporting thresholds. In 1998, EPA received TRI data on the release and other waste management of over a billion pounds of lead and lead compounds from approximately 1,900 facilities. EPA believes that there are many additional facilities that do not currently report lead and lead compounds to TRI because they do not exceed current reporting thresholds for lead and lead compounds, and/or because the lead-containing materials they handle are currently covered by the *de minimis* exemption. EPA is not able to estimate the total multi-media releases or other waste management quantities from these additional facilities without additional TRI reporting. Since even small amounts or concentrations of lead and lead compounds are of concern, EPA believes that there is a need for reporting from these additional facilities.

If EPA were not to take this action, the market failure (and the associated social costs) resulting from the limited information on the release and disposition of lead and lead compounds would continue. EPA believes that today's action will improve the scope of multi-media data on releases and other waste management of lead and lead compounds. This, in turn, will provide information to the public, empower communities to play a meaningful role in environmental decision-making, and improve the quality of environmental decision-making by government officials. In addition, this action will serve to generate information that reporting facilities themselves may find useful in such areas as highlighting opportunities to reduce chemical use or release and thereby lower costs of production and/or waste management. EPA believes that these are sound rationales for lowering reporting thresholds for lead and lead compounds.

B. What are the Potential Costs of this Action?

This action will result in the expenditure of resources that, in the absence of the regulation, could be used for other purposes. The cost of the rule is the value of these resources in their best alternative use. Most of the costs of the rule will result from requirements on industry. Approximately 9,800 facilities are expected to submit additional Form R reports on an annual basis as a result of this action. The estimated composition of this reporting, by industry, is shown in Table 1. This table also displays the estimated costs for this action, which includes costs of compliance determination for all potentially affected facilities, and rule familiarization, report completion, and mailing/recordkeeping for facilities that are expected to file additional reports. Aggregate industry costs in the first year for the selected alternative are estimated to be $80 million; in subsequent years they are estimated to be $40 million per year. Industry costs are lower after the first year because facilities will be familiar with the reporting requirements, and many will be able to satisfy reporting requirements by updating or modifying information from the previous year's report. EPA is expected to expend $1.2 million in the first year, and $775,000 in subsequent years for programmatic, compliance assistance, and enforcement activities as a result of the rule.

TABLE 1. SUMMARY OF ESTIMATED ADDITIONAL REPORTING BY INDUSTRY

SIC Code—Industry	Estimated Number of Additional Reports	Estimated Industry Costs (thousand $ per year)	
		First Yr.	Sub. Yr.
10—Metal Mining	127	$756	$459
12—Coal Mining	314	$1,782	$1,163
20—Food	291	$2,857	$1,380
21—Tobacco	29	$170	$106
22—Textiles	184	$1,359	$761

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TABLE 1. SUMMARY OF ESTIMATED ADDITIONAL REPORTING BY INDUSTRY—Continued

SIC Code—Industry	Estimated Number of Additional Reports	Estimated Industry Costs (thousand $ per year)	
		First Yr.	Sub. Yr.
23—Apparel	16	$1,339	$371
24—Lumber	107	$1,998	$744
25—Furniture	60	$958	$377
26—Paper	211	$1,938	$894
27—Printing	41	$2,646	$755
28—Chemicals	497	$3,327	$1,968
29—Petroleum	95	$589	$364
30—Plastics	84	$1,685	$613
31—Leather	18	$185	$87
32—Stone/Clay/Glass	186	$1,889	$898
33—Primary Metals	1,945	$11,931	$7,049
34—Fabricated Metals	267	$3,865	$1,577
35—Machinery	53	$3,083	$892
36—Electrical Equipment	3,501	$25,957	$12,737
37—Transportation Equipment	347	$2,462	$1,409
38—Measure./Photo.	7	$723	$197
39—Miscellaneous	58	$1,103	$380
4911/4931/4939—Electric Utilities	574	$3,025	$2,069
4953—Refuse Systems	107	$561	$385
5169—Chemical Wholesale	0	$299	$75
5171—Bulk Petroleum	616	$3,539	$2,293
7389—Solvent Recovery Services	78	$417	$283
Total	9,813	$80,441	$40,287

A number of commenters contend that EPA's analysis of affected industry sectors for the proposed rule failed to include sectors that would be affected by the rule. These commenters suggest that the following industries would be affected by the rule: metalworkers; glaziers; lead crystal glassware manufacturers; animal feed producers; metal platers; brass and copper fabricators; stained glass manufacturers; organ makers and manufacturers of other musical instruments; dye makers and manufacturers of dye-containing products including businesses in the leather, garment, and textile industries; pigments and coatings companies; metal finishers; medical and dental equipment manufacturers; makers of sporting and recreational equipment; precision metal components, mirrors, stabilizers, fertilizer; and numerous ceramic decorative art manufacturers and studios; art pottery and art pottery supply firms; ink formulators; print shops; product painting/coating/refinishing businesses; and packaging or packaging coating firms, and other businesses that use or manufacture materials that contain small amounts of lead.

In the economic analysis for the proposed rule (Ref. 16), EPA estimated the additional TRI reporting that would be expected from a number of industry groups that are subject to EPCRA section 313 at four lower reporting thresholds considered for lead and lead compounds. EPA also identified other industry groups, which are also subject to EPCRA section 313, but for which EPA lacked sufficient information to generate quantitative estimates of additional reporting. In the proposed rule, and in a subsequent notice announcing public meetings, EPA solicited additional information to allow EPA to quantify the number of additional reports in all industry groups that are subject to EPCRA section 313. In response, EPA received comments that varied greatly in detail and utility for making quantitative estimates of additional reporting.

In some cases, in addition to asserting that an industry sector would be affected by the rule, commenters also provided detailed information on the activity in the industry sector associated with lead or lead compounds, the amount or concentration of lead associated with industrial materials, the lead usage per employee, the prevalence of the lead-related activity within the industry, or other information that allowed EPA to confirm the potential for additional reporting in that industry at the various proposed lower reporting thresholds. This information, in conjunction with additional research and industry contacts, allowed EPA to revise or generate estimates for many of the additional industry sectors that commenters identified. These sectors include galvanizers, stained glass manufacturers, metal finishers, animal feed producers, organ manufacturers, and other industry sectors described in Appendix A of the economic analysis of the final rule (Ref. 46).

In other cases, commenters asserted a potential impact on an industry without providing information that would allow EPA to confirm the potential for additional reporting as a result of the rule, or to make a quantitative estimate of additional reporting at any of the lower reporting threshold options that EPA considered. Table A-73 in the economic analysis of the final rule lists industries that may be affected by the rule, but for which existing data are inadequate to make a quantitative estimate of additional reporting.

EPA fully considered the information from the commenters on the potential for additional reporting from industries that were not identified in the economic analysis of the proposed rule, or for which EPA was unable to make quantitative estimates at the time of the proposal. As a result of the comments, EPA revised its estimates for a number of potentially affected industry groups. The revised estimates are described in Appendix A of the economic analysis of the final rule. While the estimates of additional reporting for some industry groups changed substantially as a result of the comments, the net effect on EPA's estimates of additional reporting was less pronounced because estimates for some industry sectors increased while others decreased. (Additional details are available in Appendix A of the economic analysis of the final rule.)

With regard to the potential for additional reporting, a number of commenters cite the following footnote to Table A-45 in Appendix A of the economic analysis of the proposed rule:

Zero facilities are predicted to report for lead due to natural gas combustion given the uncertainty regarding concentration data for lead in natural gas. Assuming available concentration data are accurate, an estimated 35,376 additional facilities would report at the proposed threshold.

The commenters note that this estimate for natural gas users would greatly increase the number of additional reports that EPA estimated for the proposed rule. Although one commenter notes that EPA explained that "concentration data for natural gas are considered unreliable," the commenters ask that EPA explain why it chose to reject the available concentration data for lead in natural gas, but not the data it used for lead in other fuels.

The footnote cited by the commenters reflects EPA's assessment of the quality of available information on the presence of lead as a trace contaminant in natural gas at the time of proposal. Because of uncertainties about the presence or absence of lead as a trace contaminant in natural gas, EPA did not include any reporting due solely to natural gas combustion in its quantitative estimates of additional lead and lead compound reporting at the lower reporting threshold options.

For the economic analysis of the proposed rule, EPA consulted two references for information on lead in natural gas: *Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds* (Ref. 47) and *Study of HAP Emissions from Electric Utility Steam Generating Units: Final Report to Congress* (Ref. 48). These references provided emission factors for lead from natural gas combustion based on a very limited number of observations. The observed emissions of lead do not necessarily indicate that lead was present as a trace contaminant in natural gas. For example, the lead measured in emissions from natural gas combustion may have originated from lead-containing oil residues in combined-cycle combustion units. In this case, the effect on additional reporting would have been captured in EPA's estimate of reporting due to lead levels in residual or distillate fuel oil. Due to this uncertainty about the origin of lead emissions from natural gas combustion, EPA estimated the potential number of additional reports based on the lead emission factor for natural gas, but did not include these reports in the quantitative estimate of additional reporting at the lower reporting threshold options. For other fuels, EPA was able to locate typical concentration values for lead contained in those fuels a trace contaminant. Therefore, for fuels other than natural gas, EPA included estimates of additional reporting due to fuel combustion at the lower reporting threshold options.

As a result of public comments on this issue, EPA sought additional information to verify if lead is found as a contaminant in natural gas. EPA located a report that characterizes the presence of hazardous air pollutants in natural gas (Ref. 49). According to this report, lead was not detected at a detection limit of 0.9 micrograms per cubic meter of natural gas. Assuming, as an illustrative example, that lead was present at the detection limit concentration, the facility at the 90th percentile of manufacturing facilities using natural gas would only have a lead throughput of 0.05 lbs per year based on natural gas throughput data presented in the economic analysis of the final rule. Because the currently available data reviewed by EPA on trace levels of lead and lead compounds in natural gas indicate that very few, if any, facilities would be affected by any of the lower reporting threshold options as a result of natural gas combustion, EPA has estimated in the economic analysis of the final rule that no additional reports on lead and lead compounds will be submitted solely as a result of natural gas combustion.

Commenters assert that EPA underestimated the burden associated with the proposed rule because they believe that EPA's estimates of burden consider only those facilities expected to file reports under the proposed lower reporting thresholds. The commenters state that many facilities will be affected by the rule because they will have to make threshold determinations, even though they will not exceed the reporting threshold. The commenters contend that these facilities will incur the unit costs that EPA has quantified in the *Economic Analysis* for compliance determination and rule familiarization. The commenters contend that because the proposed thresholds are very low and material use varies from year to year, these determinations would occur annually, not just in the first year.

In estimating the cost of the rule, EPA considered facilities that make threshold determinations but do not exceed the reporting threshold. EPA estimated the costs to facilities of determining whether a report must be filed for lead and/or lead compounds as part of "compliance determination." EPA agrees that a compliance determination will be made annually at all facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA section 313, and the economic analysis of the rule reflects this.

Compliance determination should occur annually at all facilities with 10 or more employees that are in SIC codes subject to reporting under EPCRA section 313. In this respect, compliance

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determination for lead and lead compounds is similar to compliance determination for all other EPCRA section 313 chemicals. However, lead and lead compounds are a small part of the list of over 600 EPCRA section 313 chemicals. Therefore, it is reasonable to expect that the typical *incremental* compliance determination costs specifically for lead and lead compounds at a lower reporting threshold would be less than current compliance determination costs for the entire list of EPCRA section 313 chemicals.

Compliance determination costs are described in Chapter 4 of the economic analysis. The economic analysis of the final rule estimates that compliance determination for the changes in TRI reporting will take an average of 1.6 hours in the first year of reporting and 0.4 hours in subsequent years. These estimates are incremental to the time currently required each year for compliance determination for other EPCRA section 313 chemicals. The lower burden hour estimate for subsequent years reflects the decline in burden hours after the necessary inputs to the threshold calculation are identified at each facility.

EPA does not agree that facilities will incur "rule familiarization" costs after the first year of reporting, especially if these facilities do not exceed any applicable reporting thresholds. Rule familiarization is related to the time that facilities spend learning how to fill out the reporting form. Once a facility determines that a report is not required, the subsequent costs of reporting (rule familiarization, report completion, and mailing/recordkeeping) are not incurred. Facilities are expected to incur costs of rule familiarization only if they are reporting under EPCRA section 313 for the first time. At a minimum, rule familiarization involves reading the instructions to the *Toxic Chemical Release Inventory Reporting Form R*, however, it may also involve consulting EPA guidance documents, attending a training course, and/or calling the EPCRA technical hotline. In subsequent years, staff are already familiar with the requirements that apply to their facility, apart from any minor changes to interpretive guidance that may occur in the intervening year.

C. What are the Potential Benefits of this Proposal?

In enacting EPCRA and PPA, Congress recognized the significant benefits of providing the public with information on toxic chemical releases and other waste management practices. EPCRA section 313 has empowered the Federal government, State governments, industry, environmental groups and the general public to participate in an informed dialogue about the environmental impacts of toxic chemicals in the United States. EPCRA section 313's publicly available data base provides quantitative information on toxic chemical releases and other waste management practices. Since the TRI program's inception in 1987, the public, government, and the regulated community have had the ability to understand the magnitude of chemical releases in the United States and to assess the need to reduce the uses and releases of toxic chemicals. TRI enables all interested parties to establish credible baselines, to set realistic goals for environmental progress over time, and to measure progress in meeting these goals over time. The TRI system is a neutral yardstick by which progress can be measured by all stakeholders.

The information reported under EPCRA section 313 increases knowledge of the amount of toxic chemicals released to the environment and the potential pathways of exposure, improving scientific understanding of the health and environmental risks of toxic chemicals; allows the public to make informed decisions on where to work and live; enhances the ability of corporate leaders and purchasers to more accurately gauge a facility's potential environmental liabilities; provides reporting facilities with information that can be used to save money as well as reduce emissions; and assists Federal, State, and local authorities in making better decisions on acceptable levels of toxic chemicals in the environment.

There are two types of benefits associated with reporting under EPCRA section 313: those resulting from the actions required by the rule (such as reporting and recordkeeping), and those derived from follow-on activities that are not required by the rule. Benefits of activities required by the rule include the value of improved knowledge about the release and waste management of toxic chemicals, which leads to improvements in understanding, awareness and decision-making. It is expected that this rule will generate such benefits by providing readily accessible information that otherwise would not be available to the public. The rule will benefit ongoing research efforts to understand the risks posed by lead and lead compounds and to evaluate policy strategies that address those risks.

The second type of benefit derives from changes in behavior that may result from the information reported under EPCRA section 313. These changes in behavior, including reductions in releases of and changes in the waste management practices for toxic chemicals may yield health and environmental benefits. These changes in behavior come at some cost, and the net benefits of the follow-on activities are the difference between the benefits of decreased chemical releases and transfers and the costs of the actions needed to achieve the decreases.

Commenters point out that EPA has not quantified the benefits of the proposed rule. The commenters assert that not quantifying the benefits of the rule severely inhibits the public's ability to evaluate and comment upon this proposed rule.

EPA notes that the state of knowledge about the economics of information is not highly developed. Because of the inherent uncertainty in the subsequent chain of events following TRI reporting, EPA has not attempted to predict the exact changes in behavior that result from the information, or the resultant monetized benefits. EPA does not believe that there are adequate methodologies to make reasonable monetary estimates of either the benefits of the activities required by the proposed rule, or the follow-on activities. The economic analysis of the proposed rule, however, does provide a qualitative discussion along with illustrative examples of how the proposed rule will improve the availability of information on lead and lead compounds. EPA described how consumers, industry, the financial and business community, academics, environmental groups, communities, and the media are expected to use the results of TRI reporting on lead and lead compounds. Based on the number and variety of comments, it appears that this information was adequate to allow the public to evaluate and comment on the benefits of the proposed rule.

A number of commenters request that EPA quantify the releases expected to be captured by the proposed rule and address whether a substantial majority of lead and lead compounds releases are already captured by current TRI reporting. Other commenters state that EPA cannot estimate the quantity of lead and lead compounds that are released or transferred without the additional data that would be collected by the rule. These commenters assert that estimates about releases or transfers would be "fundamentally flawed" due to a reliance on unsupported assumptions about facility operations, not on actual data. The commenters note that while it is possible to estimate how many facilities might be impacted

by having to report a particular substance, estimating quantities at a particular facility is extremely difficult because of differences in operations even among facilities in a narrowly-defined four-digit SIC code. The commenters express a concern that any release estimate made by EPA of an "average" facility is likely to be highly inaccurate and biased toward known sources of lead releases, and that those communities with large numbers of facilities with small releases would be adversely affected by this approach.

EPA agrees with the commenters who describe the practical difficulties in making reasonable, reliable estimates of the quantity of lead and lead compounds that are released or transferred without the additional reporting data that would be collected by the rule. EPA has not estimated the total national releases to all media for this rule (and in previous TRI rules) because EPA believes that there is insufficient information on the numerous processes and associated waste management techniques in the affected sectors to generate a comprehensive release estimate.

Existing data do not support estimates of releases and other waste management activities to multiple environmental media from the full range of facilities that may be affected by the rule because most of the data required for the analysis would only be available after the rule is in place. For the affected industry sectors, up-to-date multi-media release estimates for facilities that would be affected by the rule do not exist. Even where release estimates are available for an industry sector, most are derived from national activity levels and emission factors rather than from facility-level information. To the extent that release estimates are available, they tend to cover only a single medium such as air. EPA does not believe that there is sufficient information to make reasonable predictions of the multi-media releases and other waste management information that will be reported as a result of EPCRA section 313 rulemakings.

Historical attempts to estimate the releases expected to be reported to TRI prior to actual reporting have been imprecise to the point of being misleading, particularly in respect to estimates of releases per report or per facility. EPA notes that there were various reports and studies about air emissions of toxic chemicals prior to TRI, but the collection of facility-level data showed that actual releases were much different from what had been anticipated. EPA has not seen any evidence to indicate that the TRI releases that will be reported as a result of the this action can be predicted any more accurately now than the quantities reported as a result of the original TRI rule could have been predicted prior to 1987.

Aside from the general issue of uncertainty in the estimates of aggregate releases, predictions of releases per facility or per report (or dollars of reporting cost per pound of releases) are likely to be misleading due to the biases built into the estimates. The predicted number of reports (and thus costs) is generally an overestimate, since EPA's economic analyses use conservative estimates to avoid underestimating true costs. On the other hand, predictions of releases will tend to underestimate emissions, because while there may be information available on releases of some chemicals from some sectors, such estimates will not include other sources where releases are not identified until more detailed data (such as TRI data) are collected. Combining the two sets of estimates compounds the problem. Since estimated pounds of releases are underestimated and reports are overestimated, pounds per report are biased significantly downward. Likewise, estimates of dollars of reporting cost per pound of releases (which varies as the inverse of pounds per report) will be biased significantly upward.

EPA does not believe that inaccurate or incomplete estimates of releases and other waste management activities would aid the decision-making process for the rule. Therefore, EPA has not estimated the releases and other waste management activities that would be reported as a result of the rule.

Commenters assert that the cost of the rule would outweigh the benefits because the proposed 10 pound reporting threshold for lead and lead compounds will not capture "significant" amounts of releases, while substantially burdening thousands of facilities.

Although the reporting threshold for lead and lead compounds in this action is 100 pounds, EPA does not agree with the comment. The commenters do not define what constitutes "significant" amounts of releases of lead and lead compounds. Absent this definition, it is unclear what amount of unreported releases the commenters believe would justify the cost of additional reporting. The implication of the comment is that there is minimal benefit to any reporting that does not constitute a large proportion of total national releases. EPA does not agree. EPA notes that the inherent persistence, bioaccumulation, and toxicity of lead and lead compounds create concern about human health and environmental effects in even the smallest amounts or concentrations. EPA believes that information on small amounts of lead or lead compounds (either in absolute or relative terms) is important. Even if a single facility or industry is not responsible for a high percentage of total national loadings, the releases from that facility or industry may still be of concern to the public. The percentage of total national releases that an individual facility or industry represents does not reflect the potential human health and environmental effects of even small amounts of lead and lead compounds, especially when multiple facilities release lead and lead compounds that persist and bioaccumulate. EPA also believes that focusing exclusively on releases ignores the value of other data elements on TRI reporting form, such as quantities of waste otherwise managed on-site and transferred for off-site management and qualitative information on source reduction activities.

Aside from the issue of whether comprehensive release estimates for such a rulemaking can reliably be predicted, EPA notes that pounds of releases and other waste management activities (even if known) are not a reasonable proxy for the benefits of the information being provided. This is because the benefits of an informational regulation are not systematically related to the magnitude of the data elements being reported. For example, automobile manufacturers are required to provide information about fuel economy on the stickers for new cars. Assuming that the quantity reported is a direct measure of the value of the information would lead to the mistaken conclusion that there is 100 percent difference in the benefit of requiring the information to be provided on a car that gets 15 miles per gallon compared to another car that gets 30 miles per gallon. To use another example, nutritional labels are required on food packages. Assuming that the benefits of information provision are linearly related to the quantity that is reported would yield the conclusion that if one product has 6 grams of fat per serving and another has 2 grams, the benefit of the nutritional labeling requirement are three times higher for the former than the latter.

One of the central purposes of TRI data is to inform the public about releases and other waste management of EPCRA section 313 listed toxic chemicals in their community and nationally so that the public can form its own conclusions about risks. The amount of releases and other waste

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management activities that a community may find relevant or useful will vary depending on numerous factors specific to that community, such as the toxicity of the various chemicals, potential exposure to these toxic chemicals, and the number of other facilities in the area that release EPCRA section 313 listed toxic chemicals. Section 313(h) of EPCRA states that the data are "to inform persons about releases and other waste management activities of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes." Pounds of releases and other waste management activities reported does not measure how the data perform these functions, and thus is not a measure of benefits. EPA disagrees with the implicit assumption by commenters that the benefits of information from different facilities is strictly and systematically related to the quantity reported as being released. Finally, EPA notes that while the proposed reporting threshold for lead and lead compounds was 10 pounds, the final rule (and associated economic analysis) reflect a reporting threshold of 100 pounds. This further reduces the relevance of the comment.

D. What are the Potential Impacts of This Action on Small Entities?

In accordance with the Regulatory Flexibility Act (RFA) and the Agency's longstanding policy of always considering whether there may be a potential for adverse impacts on small entities, the Agency has evaluated the potential impacts of this rule on small entities.

This rule may affect both small businesses and small governments. No small non-profit organizations are expected to be affected by the rule. For the purpose of its small entity impact analysis for the final rule, EPA defined a small business using the small business size standards established by the Small Business Administration (SBA) at 13 CFR part 121. [On October 1, 2000, the new SBA size standards for small businesses based on the North American Industry Classification System (NAICS) took effect (65 FR 30836, May 15, 2000). These replaced the previous size standards established under the Standard Industrial Classification (SIC) system. EPA has concluded that the conversion to the new classification system will have no substantive impact on the conclusions of the Agency's small entity impact analysis for this action (Ref. 53)]. EPA defined small governments using the RFA definition of jurisdictions with a population of less than 50,000. EPA analyzed the potential cost impact of the rule on small businesses and governments separately in order to obtain the most accurate assessment for each. EPA then aggregated the analyses for the purpose of determining whether it could certify that the rule will not have a "significant economic impact on a substantial number of small entities." RFA section 605(b) provides an exemption from the requirement to prepare a regulatory flexibility analysis for a rule where an agency makes and supports this certification statement. EPA believes that the statutory test for certifying a rule and the statutory consequences of not certifying a rule all indicate that certification determinations should be based on an aggregated analysis of the rule's impact on all of the small entities subject to it.

Only those small entities that are expected to submit at least one report are considered to be "affected" for the purpose of the small entity analysis, although EPA recognizes that other small entities will conduct compliance determinations under lower thresholds. The number of affected entities will be smaller than the number of affected facilities, because many entities operate more than one facility. Potential small entity impacts were calculated for both the first year of reporting and subsequent years. First year costs are typically higher than continuing costs because firms must familiarize themselves with the requirements. Once firms have become familiar with how the reporting requirements apply to their operations, costs fall. EPA believes that subsequent year impacts present the best measure to judge the impact on small entities because these continuing costs are more representative of the costs firms face to comply with the rule.

The incremental burden of the additional reporting at the facility level is low. This burden is associated with labor that will be expended by facility staff to conduct the reporting activities to file one TRI report. By statutory requirement, the smallest possible facility that could be affected by this action must have the equivalent of at least 10 full-time employees. On a yearly basis, this means that there are at least 20,000 labor hours expended at the smallest potentially affected facility (10 FTEs x 50 wks/year/employee x 40 hours/wk = 20,000 labor hours/year). EPA estimates that typical reporting burdens as a result of this rule will be up to 110 hours per facility (in the first year of reporting for a first-time TRI reporter), and that in subsequent years typical reporting burden will be approximately 50 hours. Based on these reporting burdens, the average impact of TRI reporting ranges from 0.25 to 0.55 percent of available labor hours for the *smallest* facility affected by this rule. The impact would be even less for facilities with more than 10 full-time employees, or for facilities that take less than the average time to report.

EPA examined annual compliance costs as a percentage of annual company sales to assess the potential impacts of this rule on small businesses. Based on its estimates of additional reporting as a result of the rule, the Agency estimates that approximately 5,700 businesses will be affected by the rule, and that approximately 4,100 of these businesses are classified as "small" based on the applicable SBA size standards. EPA estimates that fewer than 250 small businesses (approximately 5% of all affected small businesses) will bear annual costs between 1–3% of annual revenues in the first reporting year, and that no small businesses will bear annual costs above 1% of annual revenues in subsequent reporting years. These results are not significantly different from those derived in the economic analysis of the proposed rule; the main difference is a "non-zero" result for the number of small businesses predicted to experience an annual cost impact above 1% of annual revenues in the first year of reporting. These estimates, and their derivation, are described in the economic analysis of the final rule (Ref. 46).

A number of commenters submitted comments on EPA's methodology for assessing small entity impacts in the economic analysis of the proposed rule. One commenter asserts that the Agency's analysis of potential impacts of the proposed rule on small business is lacking because it does not examine the large number of industrial sectors that may be affected by this reporting requirement. The commenter states that EPA's findings about the widespread and persistent nature of lead in the environment are not in accord with the "very limited effort" to identify affected sectors (especially small business sectors).

EPA disagrees with the commenter's characterization of the effort made to identify affected sectors. In the economic analysis for the proposed rule, EPA made quantitative estimates of the number of additional TRI reports that would be expected at four lower reporting thresholds for lead and lead compounds from industry groups that are subject to EPCRA section 313 and for which EPA could locate the information necessary to make quantitative estimates of facility level lead usage. EPA also identified a number of industry groups which are also subject to EPCRA section 313, but for which EPA lacked data on lead throughput to generate quantitative estimates of additional reporting.

In the proposed rule, and in a subsequent notice announcing public meetings, EPA solicited additional information to allow EPA to quantify the number of additional reports in all industry groups that are subject to EPCRA section 313. EPA fully considered information from the commenters on the potential for additional reporting from industries that were not identified in the economic analysis of the proposed rule, or for which EPA was unable to make quantitative estimates at the time of the proposal. As a result of the comments, EPA revised its estimates for a number of potentially affected industry groups. The revised estimates are described in Appendix A of the economic analysis of the final rule. While the estimates for some industry groups changed substantially as a result of the comments, EPA's estimate of the total number of additional reports remained relatively stable. At a 100 pound reporting threshold for lead and lead compounds, EPA estimates that approximately 9,800 facilities will submit additional reports.

EPA's economic analysis of the proposed rule modeled the revenue characteristics of affected firms to evaluate the potential impact on small businesses. Commenters assert EPA's analysis produced biased results by combining manufacturing industries (SIC codes 20–39) that are unrelated in most aspects. Commenters assert that EPA made faulty assumptions by "grouping together small business with large manufacturers." One commenter asserts that EPA's analysis considered the aggregate cost of the proposal to each industry group surveyed, ignoring individual businesses with costs above and below the aggregate value.

In the economic analysis of the proposed rule EPA modeled revenues for small firms with low, medium and high revenues in the manufacturing industries (i.e., SIC codes 20–39). EPA's RFA/SBREFA guidance states that "In assessing the impact of a rule on small businesses, it may be appropriate to analyze the rule's impact on each kind of business separately, particularly where the rule may impose significantly higher costs on some kinds of businesses than on others" (Ref. 50). However, there is no guidance as to the specific SIC code level that is appropriate (e.g., 2-digit vs. 3-digit vs. 4-digit vs. 5-digit, etc.). For the small entity analysis of the proposed rule, EPA analyzed impacts separately for the following "kinds of businesses": mining, manufacturing, electric utilities, commercial hazardous waste treatment, chemical and allied products-wholesale, petroleum bulk terminals, and solvent recovery services. EPA does not believe that this approach biased the results of the small entity impact analysis for the proposed rule.

EPA did not group small businesses together with large businesses in the manufacturing industry as the commenter asserts. EPA constructed separate revenue models for large firms and small firms. For small firms within each industry group, EPA compared typical reporting costs with the revenues available to small firms with low, medium, and high revenues. EPA's analysis was not based on an aggregate cost to each industry group, but rather on the cost to individual firms. For the economic analysis of the final rule, EPA developed revenue profiles at the 2-digit SIC code level (20, 21, 22, etc.) for small businesses within the manufacturing industries to provide for additional disaggregation. This approach was taken to address the comment that EPA would reach a different determination if impact estimates for the manufacturing SIC codes were presented at a greater level of disaggregation. Contrary to the comments on this issue, the disaggregated analysis does not change the ultimate conclusion about small entity impacts.

In the small entity impact analysis for the proposed rule, revenues of potentially affected small businesses were modeled using revenue data for small businesses that own or operate facilities that currently report to TRI on any chemical. EPA developed separate revenue profiles based on "small". current filers and "large" current filers. Within these profiles, EPA looked at companies with low, medium, and high revenues. Commenters contend that EPA's use of current TRI filers as a representative cohort for estimating the proposed rule's impacts on small businesses is flawed since current TRI filers may not be representative of facilities that report to TRI for the first time as a result of the rule. The commenters assert that facilities reporting as a result of this rule are very different in terms of size and revenues from their counterparts that currently use lead, or other EPCRA section 313 listed toxic chemicals, in amounts greater than 25,000 pounds. The commenters contend that current TRI filers are, for the most part, the largest members of their sectors with the highest revenues. As a result, the commenters contend that EPA underestimated the proposal's impact on small businesses. The commenters state a belief that an assessment of the rule's potential impact on small businesses should not be based upon its impact on current TRI filers. The commenters suggest an alternative methodology of assessing how the smallest facilities in each potentially impacted small business sector would be impacted by the proposed rule in order to make a SBREFA determination.

EPA disagrees that using small businesses that own current TRI filers as a representative cohort for estimating the proposed rule's impacts on small businesses is flawed methodology for assessing whether the rule would have a significant economic impact on a substantial number of small entities. First, it should be noted that current TRI filers span the range of employment, from companies with 10 employees to those with thousands of employees. As noted in the economic analysis for the proposed rule, almost 70 percent of current TRI reporters are small businesses. Therefore, small businesses have substantial representation in current TRI reporting. Second, additional reporting on lead and lead compounds will not be limited to small facilities, or to facilities filing their first TRI reports. Additional reporting on lead is expected to come from facilities with a mix of size characteristics, including large facilities that currently report other EPCRA section 313 chemicals but not lead. Third, current TRI filers in the manufacturing industries tend to be found in capital-intensive industries rather than in labor-intensive industries. Based on EPA's research, it appears that most facilities that file additional lead reports will also be from capital-intensive industries like the ones that predominate in current TRI reporting. Since additional lead reporting will come mainly from: (1) Current filers (who file on other chemicals) and (2) new filers in capital-intensive industries, EPA believes that it is valid to assume that first-time filers under this rule will be like current filers in terms of employment and revenue.

To evaluate the possibility that first-time TRI filers in the manufacturing sector would be so dissimilar to current TRI filers as to change EPA's small entity impact findings, EPA conducted a sensitivity analysis (Ref. 51) to estimate the potential impact on the smallest facilities in each potentially impacted small business sector for the proposed reporting threshold. This analysis estimated the average potential impact of the proposed rule on facilities

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in various employment size classes within each of the twenty 2-digit manufacturing SIC codes (and certain 4-digit SIC codes). The analysis revealed that average potential impacts are higher for facilities with fewer employees and lower annual revenues, but the potential cost impact is still less than 1 percent of average annual revenues for every employment size class in every manufacturing SIC code.

Even information submitted to EPA by industry does not indicate that a substantial number of small businesses would have costs above 1% of annual revenues. In an informal survey conducted by the IPC the Association Connecting Electronics Industries, IPC asked its member companies in the printed wiring board industry to indicate if the proposed rule would result in regulatory costs exceeding 1% of annual revenues (Ref. 52). IPC received 300 responses, of which 260 were from self-identified small businesses. Of these 260, only 5 claimed that the proposed rule would impose costs greater than 1% of their annual revenues. This survey indicates that less than 2% of affected small businesses in this sector believe that they would experience an economic impact of greater than 1% of annual revenues as a result of the proposed rule. Furthermore, IPC's survey was based on the proposed reporting threshold of 10 pounds. This final rule incorporates a reporting threshold of 100 pounds, which will result in less regulatory impact to facilities in this sector.

To further address the issue of differing revenue characteristics between current and first-time TRI filers, EPA revised its method for modeling the revenues of affected small businesses. In the small entity impact analysis for the final rule, EPA modeled revenues of small first-time filers using revenue data for small businesses that own facilities that do not currently file TRI reports. EPA modeled revenues of small current filers using revenue data on small businesses that own current TRI-filing facilities. Contrary to the comments on this issue, using this method to model revenues does not change the ultimate conclusion about small entity impacts.

A commenter asserts that EPA's conclusion about the impact of the rule on small businesses was based on an erroneous assumption about the percentage of additional reports that would be received from new filers. The commenter asserts that EPA "seriously" underestimated the number of first-time filers to TRI that would result from the proposed rule. The commenter notes that approximately 10% of printed wiring board facilities currently report to TRI and few of the facilities report for lead, but that this proposal would trigger lead reporting for virtually all companies. In this industry, approximately 80% to 90% would have to report to the TRI for the first time. The commenter notes that EPA estimated that first-time filers under the rule would comprise only 38.3% of affected manufacturing facilities.

The estimate for first-time TRI filers cited by the commenter is an average for the entire manufacturing sector. For individual SIC codes within manufacturing (such as printed wiring boards), the percentage of first-time TRI filers may be higher or lower. For the economic analysis of the final rule, the estimate of first-time filers was revised based on an SIC code-by-SIC code approach that assumes current TRI filers will file the first additional reports in each SIC code, and that the remaining additional reports will be filed by facilities that are new to TRI reporting (i.e., first-time filers). Rather than using an average number of new filers for manufacturers as a class, this approach estimates the number of new filers at the 2-, 3-, or 4-digit SIC code level. Using the revised approach, the total estimated percentage of first-time filers increased to approximately 40% of all affected facilities, with substantial variation at the 2-digit SIC code level as indicated by the commenters. Therefore, EPA does not believe that the number of first-time filers was "seriously" underestimated in the economic analysis of the proposed rule.

In assessing the potential impact of the rule on small entities, EPA searched for situations in which the annual cost of reporting for a business would exceed a small fraction of annual revenues. Commenters assert that 1% of annual sales (one of the indicator values used by EPA) is not a good measure of impacts on small businesses. The commenters assert that the 1% metric is arbitrary and argue that it may not be a good measure of impact across different industry sectors. The commenters state that some industries may have profits that are only a few percent of total revenue, in which case, costs that are close to one percent of revenue would be a very large percent of profit, while other industries may have profits that are a much higher percent of revenue.

Contrary to the commenters' claim, EPA did justify its choice of revenue-based impact metric for assessing small entity impacts. As EPA stated at 64 FR 42238, "EPA used annual compliance costs as a percentage of annual company sales to assess the potential impacts on small businesses of this proposed rule. EPA believes that this is a good measure of a firm's ability to afford the costs attributable to a regulatory requirement, because comparing compliance costs to revenues provides a reasonable indication of the magnitude of the regulatory burden relative to a commonly available measure of a company's business volume. Where regulatory costs represent a small fraction of a typical firm's revenue (for example, less than 1%, or not greater than 3%), EPA believes that the financial impacts of the regulation may be considered not significant."

The commenters suggest that EPA should use profits as a measure of impact. EPA, however, believes that there are several advantages to the use of revenue data. The advantage of using revenue to measure impacts is that it is a stable, easily accessible, and easily understood measure which provides a basis for comparing this rule to other rules. Unlike profit information, the definition is consistent and not subject to the widely varying accounting definitions and interpretations of terms that affect "profit" measures. Another advantage is that revenue data, unlike profit data, are widely available. The proportion of firms for which revenue data are available generally greatly exceeds the proportion of firms for which profit data are available. Many information sources, including the Census of Manufactures, collect and publish revenue data but not profit data.

Furthermore, revenue data are easily understood. For example, if the impact of compliance costs on a firm is 1% of revenue, a firm would need to raise its prices 1% to cover the costs of the regulation. This is a clear, easy to understand measure that can help decision-makers determine whether additional measures to reduce the impact of a regulation are warranted. In addition, EPA has a long history of using the relationship between the annual cost of compliance with a regulation and total annual revenue of the firm to determine whether a regulation may have a significant economic impact on substantial number of small entities.

EPA believes that the revenue-based impact calculation used in the analysis of this rule is preferable to a profit-based calculation because it is simple to apply and based on readily available data, which allows consistent application of the methodology from rule to rule. Although the commenters suggest other metrics such as profit margins, they do not provide any indication of how this data could be obtained or what impact levels would indicate a "significant" impact. The commenters note that profit margins are variable, but do not provide profit margin data for all affected industry sectors.

In addition to small businesses, the rule is also expected to affect certain small governments. To assess the potential impacts of the final rule on small governments, EPA used annual compliance costs as a percentage of annual government revenues to measure potential impacts. Similar to the methodology for small businesses, this measure was used because EPA believes it provides a reasonable indication of the magnitude of the regulatory burden relative to a government's ability to pay for the costs, and is based on readily available data. EPA estimates that 8 publicly owned electric utility facilities, operated by a total of 8 municipalities, may be affected by the rule. Of these, an estimated 7 are operated by small governments (i.e., those with populations under 50,000). It is estimated that none of these small governments will bear annual costs greater than 1% of annual government revenues in the first or subsequent reporting years. Therefore, the total number of small entities with impacts above 1% of revenues does not change when the results are aggregated for all small entities (i.e., small businesses, small governments, and small organizations) because only certain small businesses are expected to experience impacts above 1% of revenues in any year.

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IX. Regulatory Assessment Requirements

A. What is the Determination Under Executive Order 12866?

Under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), it has been determined that this is a "significant regulatory action". This action was submitted to the Office of Management and Budget (OMB) for review, and any substantive changes made during that review have been documented in the public version of the official record.

EPA's cost-benefit analysis for the proposed rule was contained in a document entitled *Economic Analysis of the Proposed Rule to Modify Reporting of Lead and Lead Compounds Under EPCRA Section 313 (Ref. 16).* The economic analysis contains a quantitative estimate of the costs and a qualitative discussion of the benefits of the proposed rule. This document, and its supporting documentation, were included in the public docket for review and comment. EPA has prepared an economic analysis of the impact of this final rule, which is contained in a document entitled *Economic Analysis of the Final Rule to Modify Reporting of Lead and Lead Compounds under EPCRA Section 313* (Ref. 42). This document is available as part of the public version of the official record for this action, and is briefly summarized in Unit VII.

Commenters assert that the proposed rule did not meet Executive Order 12866 requirements to consider costs and benefits, including the alternative of not regulating. The commenters assert that the Agency has not given adequate consideration to the baseline option of existing TRI reporting thresholds of 25,000 and 10,000 pounds, under which EPA has received reporting on release and other waste management of over one billion pounds of lead and lead compounds per year. The commenters assert that the alternative of the current reporting thresholds of 25,000 and 10,000 pounds is generally not included in the text and tables of the preamble and Economic Analysis.

EPA did consider the option of not regulating, and addressed what would happen in the absence of this rule. As EPA noted in the **Federal Register** notice for the proposed rule, "If EPA were not to take this proposed action to lower reporting thresholds, the market failure (and the associated social costs) resulting from the limited information on the release and disposition of lead and lead compounds would continue" (64 FR 42237). The discussion of costs and benefits in the economic analysis and preamble are all relative to the baseline of not regulating beyond the current reporting thresholds for lead and lead compounds. Chapter 6 of the economic analysis of the proposed rule contains a discussion of current reporting on lead and lead compounds at existing reporting thresholds, as well as a discussion of information that would be collected as a result of the proposed rule. Furthermore, current TRI reporting on lead and lead compounds was summarized in Tables A–3 and A–4 of the economic analysis of the proposed rule.

Commenters assert that EPA has not met requirements of Executive Order 12866 because EPA has not quantified benefits of the proposed rule and has not estimated the amount of releases expected to be reported.

EPA believes that the proposal is consistent with Executive Order 12866, because EPA proposed the regulation upon a reasoned determination that the benefits justify the costs. The commenters imply that EPA must quantify benefits to comply with Executive Order 12866. However, Executive Order 12866 recognizes that it may not be feasible to derive quantitative estimates of benefits in all cases. Section (1)(a) of Executive Order 12866 states that "Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider." The Executive Order goes on to state in section (1)(b)(6) that "Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." EPA's economic analysis has addressed the costs of the proposal in a quantified manner and the benefits in a qualitative manner. Because the state of knowledge about the economics of information is not highly developed, EPA has not attempted to quantify the benefits of the rule as monetized net benefits. EPA notes that Executive Order 12866 does not require that benefits be quantified for every regulation, or that agencies should predict the answers to a data collection (in this case, the "per facility" releases and other waste management of lead and lead compounds) prior to the actual collection of the data.

EPA notes that comparing the cost of the reporting to the quantity of releases that would be reported does not compare costs and benefits. Section 313(g) of EPCRA states that the data are intended to provide information to the Federal, State, and local governments and the public, including citizens of communities surrounding covered facilities, to inform persons about releases of toxic chemicals to the environment; to assist governmental agencies, researchers, and other persons in the conduct of research and data gathering; to aid in the development of appropriate regulations, guidelines, and standards; and for other similar purposes. The quantity of releases reported does not measure how well the data perform these functions, and thus releases are not a measure of benefits. The benefits of the rule include improvements in understanding, awareness, and decision making related to the provision of information. Even if reliable estimates of releases were possible, pounds of releases would not measure the value of the information provided. Improvements in understanding are not measured in pounds, nor are improvements in awareness or decision making.

While it is not possible to quantify the benefits of the rule with monetized estimates, EPA has qualitatively examined the benefits of the rule. Based on this review, EPA believes that the benefits provided by the information to be reported under this rule will significantly outweigh the costs. Upon review of this evidence, EPA has made a reasoned determination that the benefits of the regulation justify its costs. Therefore, EPA believes it has followed the principles and met the requirements of Executive Order 12866.

B. What is the Determination Under the Regulatory Flexibility Act?

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the EPA Administrator hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is presented in the small entity impact analysis prepared as part of the *Economic Analysis* for this final rule (Ref. 46), which is discussed in detail in Unit VII. and contained in the public version of the official record for this rule. Further support for this determination can be found in the sensitivity analysis (Ref. 51) that was conducted to assess the analytical methods used in the small entity impact analysis of the proposed rule. Information relating to this determination has been provided to the Chief Counsel for Advocacy of the Small Business Administration, and is included in the public version of the official record for this rulemaking. The following is a brief summary of the Agency's factual basis for this certification.

For the purpose of analyzing potential impacts on small entities, EPA used the RFA definition of small entities in section 601(6) of the RFA. Under this section, small entities include small businesses, small governments, and small non-profit organizations. [On October 1, 2000, the SBA size standards for small businesses based on the North American Industry Classification System (NAICS) took effect (65 FR 30836, May 15, 2000). These replaced the previous size standards established under the Standard Industrial Classification (SIC) system. EPA has concluded that the conversion to the new classification system will have no substantive impact on the conclusions of the Agency's small entity impact analysis for this action (Ref. 53)]. EPA defined a small business using the small business size standards established by the Small Business Administration (SBA), which are generally based on the number of employees or annual sales/revenue a business in a particular industrial sector has. EPA defined small governments using the RFA definition of jurisdictions with a population of less than 50,000. No small non-profit organizations are expected to be affected by this final rule.

EPA estimates that approximately 4,100 small businesses will be affected by the rule. The incremental burden of the additional reporting at the facility level is associated with labor that will be expended by facility staff to conduct reporting activities. Based on typical reporting burdens of approximately 110 hours (in the first year of reporting for a first-time TRI reporter) and 50 hours in subsequent years, the impact of this action ranges from 0.25 to 0.55 percent of available labor hours for the smallest affected facility. The impact would be even less for facilities with more than 10 full-time employees, or for those that take less than the average amount of time to report.

EPA estimates that the final rule would have an annual cost impact between 1–3% of annual revenues on fewer than 250 small businesses (approximately 5% of all affected small businesses) in the first year only. After the first year of reporting, the annual cost impact as a percentage of annual revenues is estimated to be below 1% for all affected small entities.

Commenters assert that this rule will have significant impacts on small businesses, and that EPA improperly certified the proposed rule. The commenters assert that a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel must be completed to determine the "true" impact of the proposed rule on small businesses.

EPA believes that its certification of the proposed rule as not having a significant economic impact on a substantial number of small entities was proper. In the **Federal Register** notice

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for the proposed rule, EPA described a quantitative small entity impact analysis that EPA placed in the official version of the public record. The results of this analysis indicated that the proposed rule would not have a significant economic impact on a substantial number of small entities. Based on public comments, EPA revised this quantitative analysis and arrived at the same conclusion for the final rule. Furthermore, EPA notes that while the proposed reporting threshold for lead and lead compounds was 10 pounds, this final rule incorporates a reporting threshold of 100 pounds. This threshold further reduces the potential regulatory impact on small entities as indicated in the economic analysis of the final rule.

EPA does not agree with the comment that a SBREFA panel must be completed to determine whether this, or any, proposed rule will have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act (RFA) to require EPA to convene a Small Business Advocacy Review Panel for any proposed rule for which EPA is required to prepare an initial regulatory flexibility analysis (IRFA). The RFA requires that EPA prepare an IRFA for all rules for which EPA is required by statute to publish a notice of proposed rulemaking unless the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." The panel is an additional means for small entities to participate in the rulemaking process, but the certification provision of the RFA as amended by SBREFA indicates that panels are not appropriate for every rulemaking. The panel requirement only applies to proposed rules that the Agency ultimately determines will not be certified under the RFA.

Commenters also assert that EPA failed to provide a "meaningful" opportunity for small businesses to participate in the rulemaking process. The commenters asserted than that EPA did not conduct outreach to small businesses prior to the proposal, and that any outreach after rule proposal is inadequate and cannot remedy EPA's "lack of outreach" to small entities early in the regulatory development process. The commenters assert that "EPA's failure to contact small business sectors early in the rulemaking process" led to "significant flaws" in EPA's SBREFA determination because it failed to consider "more than two dozen small business sectors that would be impacted by the proposed rule" and failed to consider the significance of the impact on small businesses. Specifically the commenters mention printed circuit board manufacturers, metal finishers, foundries, and dentists as affected sectors. As a result, the commenters contend that the Agency did not comply with SBREFA, and violated the analytical and outreach requirements of the RFA. The commenters also contend that EPA did not comply with the Agency's own internal guidance related to RFA/SBREFA compliance. One commenter contends that EPA's failure to conduct appropriate outreach misled the Agency to certify that the rule has no significant impact on small business. Therefore, the commenter suggests that the EPA conduct additional outreach with small business, followed by a thorough SBREFA panel process. The commenter contends that outreach to small business would have revealed that the proposed rule affects more than "two dozen small business sectors that the agency failed to consider." As one example, the commenter asserts that dentists would have to report because they accumulate lead in the form of used x-ray film backing that they store and recycle. The commenter also mentions metal finishing and the printed circuit board industry.

EPA complied with internal guidance and the requirements of the RFA as amended by SBREFA and conducted its analysis in accord with the Agency's internal guidance. EPA's actions provided a meaningful opportunity for small businesses to participate in the rulemaking process. EPA initially alerted the potentially affected community to EPA's intention to review lead and lead compounds for lower reporting thresholds in the proposed rule to lower the EPCRA section 313 reporting threshold for certain PBT chemicals that are subject to reporting under EPCRA section 313 (64 FR 688). That **Federal Register** notice stated that "EPA is aware of additional available data that may indicate that lead and/or lead compounds meet the bioaccumulation criteria discussed in this proposed rule. EPA intends to review these additional data to determine if lead and/or lead compounds should be considered PBT chemicals and whether it would be appropriate to establish lower reporting thresholds for these chemicals" (64 FR 717, January 5, 1999). As part of the PBT rulemaking process, EPA held three public meetings in San Francisco, CA; Chicago, IL; and Washington, DC. Numerous commenters on the PBT rule requested that EPA classify lead and lead compounds as PBT chemicals.

EPA published a notice of proposed rulemaking for lead and lead compounds on August 3, 1999. EPA requested comment on this rulemaking and provided an initial 45 day comment period. Subsequently, EPA extended the comment period twice for a total of 90 additional days. In addition, EPA held public meetings with special emphasis on potential small business impacts in Los Angeles, CA; Chicago, IL; and Washington, DC. EPA also met with representatives of small business trade organizations who expressed a desire for additional meetings.

EPA notes that a number of small businesses participated in the rulemaking process by attending public meetings and submitting comments on the proposed rule. EPA has considered these comments and updated its economic analysis with information provided by these commenters. EPA believes that these activities, along with the written public comment process, provided ample opportunities for small businesses to participate in the rulemaking process.

EPA does not agree that its rulemaking process led to significant flaws in EPA's certification that the proposed rule would not, if promulgated, have a significant economic impact on a substantial number of small businesses. EPA conducted an extensive economic analysis that included a quantitative small entity impact analysis. EPA made this analysis available as part of the public record for the rulemaking. The public comment process has provided an opportunity for small businesses to comment on this analysis, and to provide additional information to refine this analysis. Further, even though EPA extended the public comment period twice and held three public meetings, EPA did not receive additional information that would lead it to change its determination.

Although some commenters assert that EPA failed to identify certain potentially affected sectors leading to a flawed certification, EPA does not agree. EPA conducted an extensive economic analysis. Specifically, EPA did identify printed circuit board manufacturers, metal finishers, foundries, and other industries as potentially affected sectors in the economic analysis of the proposed rule. Dentists were not identified as potentially affected because they are not in a SIC code that is subject to TRI reporting. EPA cannot evaluate the accuracy of generic comments that assert EPA missed potentially affected industries when commenters do not identify these industries by name, or provide evidence to support the assertion for each additional identified industry. If EPA failed to identify certain sectors as potentially affected, this a reflection of the lack of publicly available information on lead and lead compounds. The lack of publicly available information on lead and lead compounds speaks more to the need for the rule than to the quality of EPA's analysis.

In conclusion, EPA believes that it has followed the requirements of the RFA and that it has properly certified that the rule will not have a significant impact on a substantial number of small entities.

C. What is the Determination Under the Paperwork Reduction Act?

The information collection requirements contained in this final rule have been submitted to OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), and in accordance with the procedures at 5 CFR 1320.11. OMB has approved the existing reporting and recordkeeping requirements for the EPA Toxic Chemical Release Inventory Form R (EPA Form No. 9350–1), supplier notification, and petitions under OMB Control No. 2070–0093 (EPA ICR No. 1363). EPA has prepared an amendment (EPA ICR No. 1363.11) to the existing Information Collection Request (ICR) to include the burden associated with lower reporting thresholds for lead and lead compounds. A copy may be obtained from Sandy Farmer, Office of Information Collections, U.S. Environmental Protection Agency (2137), 1200 Pennsylvania Ave., NW., Washington, DC 20460, by calling (202) 260–2740, or electronically by sending an e-mail message to "farmer.sandy@epa.gov."

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information subject to OMB approval under the PRA, unless a currently valid OMB control number is displayed. The OMB control numbers for EPA's regulations, after initial publication in the Federal Register, are maintained in a list at 40 CFR part 9. The information requirements contained in this final rule are not effective until OMB approves them.

EPCRA section 313 (42 U.S.C. 11023) requires owners or operators of certain facilities manufacturing, processing, or otherwise using any of over 600 listed toxic chemicals and chemical categories in excess of the applicable threshold quantities, and meeting certain requirements (i.e., at least 10 Full Time Employees or the equivalent), to report certain release and other waste management activities for such chemicals annually. Under PPA section 6607 (42 U.S.C. 13106), facilities must also provide information on recycling and other waste management data and source reduction activities. The regulations codifying the EPCRA section 313 reporting requirements appear at 40 CFR part 372. Respondents may designate the specific chemical identity of a substance as a trade secret, pursuant to EPCRA section 322 (42 U.S.C. 11042). Regulations codifying the trade secret provisions can be found at 40 CFR part 350. Under the rule, all facilities reporting to TRI on lead and lead compounds would have to use the EPA Toxic Chemical Release Inventory Form R (EPA Form No. 9350-1). OMB has approved the existing reporting and recordkeeping requirements related to Form R, supplier notification, and petitions under OMB Control No. 2070-0093 (EPA ICR No. 1363).

For Form R, EPA estimates the industry reporting burden for collecting this information (including recordkeeping) to average 74 hours per report in the first year (based on typical unit burden estimates for Form R completion and recordkeeping/mailing requirements), at an estimated cost of $5,079 per Form R. In subsequent years, the burden is estimated to average 52.1 hours per report, at an estimated cost of $3,557 per Form R. These estimates include the time needed to review instructions; search existing data sources; gather and maintain the data needed; complete and review the collection of information; and transmit or otherwise disclose the information. The actual burden on any specific facility may be different from this estimate depending on the complexity of the facility's operations and the profile of the releases at the facility.

This rule is estimated to result in additional reports from approximately 9,800 respondents. Of these, approximately 3,600 facilities are estimated to be reporting to TRI for the first time as a result of the rule, while the remainder are currently reporting facilities that will be submitting additional reports. The 9,800 respondents will each submit an additional Form R. This rule is estimated to result in a total burden of 1.2 million hours in the first year, and 0.6 million hours in subsequent years, at a total estimated industry cost of $80 million in the first year and $40 million in subsequent years. The existing ICR will be amended to add 790,000 burden hours (annual average burden for the first 3 years of ICR approval).

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes, where applicable, the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. EPA's burden estimates for the rule take into account all of the above elements, considering that under section 313, no additional measurement or monitoring may be imposed for purposes of reporting.

A commenter asserts that EPA failed to meet Paperwork Reduction Act requirements because it has not provided Form R reporting instructions for the proposed changes to the TRI reporting requirements for lead and lead compounds. The commenter contends that the proposed rule requires significant changes in the information submitted by regulated industry sectors on the Form R. The commenter asserts that OMB's Information Collection Review Handbook requires that materials submitted for review under the Paperwork Reduction Act must be accompanied by the documents to be used in the collection of information (i.e., forms, schedules, questionnaires, handbook, manual, interview plan or guide, rule, regulation, or other document), and any other explanatory material to be given or sent to prospective respondents. The commenter asserts that the current Form R reporting instructions do not provide the guidance necessary for reporting lead and lead compounds at the lower reporting thresholds with elimination of exemptions such as the *de minimis* exemption and changed rules for reporting. The commenter asserts that EPA has not issued guidance regarding how to comply under the proposed lower reporting thresholds, indicated what its plans are for issuing such guidance, or allowed formal opportunity for stakeholders to review and comment.

EPA disagrees with the commenter. EPA did not propose significant changes in the types of information to be reported by industry. EPA proposed using the existing Form R for reports that would be required under the lower reporting threshold. Since EPA did not propose to amend the Form R, and the existing Form R was already approved

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by OMB, EPA was not required to submit the Form R separately with the ICR amendment at the proposed rule stage. Nevertheless, the proposed ICR amendment that EPA submitted to OMB included a copy of the existing ICR approved by OMB, along with a copy of the Form R. The existing ICR also specifically describes all of the existing reporting elements on Form R.

EPA strongly disagrees with the suggestion that it has circumvented the notice and comment process. The preamble to the proposed rule, the economic analysis, and the proposed ICR amendment all specifically describe EPA's proposal to lower reporting thresholds, and to change the reporting requirements so as not to allow use of the *de minimis* exemption, range reporting or Form A for reports submitted under the lowered thresholds. The **Federal Register** provided public notice and specifically solicited public comments on the changes to reporting requirements and reporting instructions that were being considered, as well as on the Agency's associated burden estimates. The Agency provided a functional description of the changes in reporting that would result from his rule. Therefore, EPA was in compliance with the PRA and with OMB requirements.

D. What are the Determinations Under the Unfunded Mandates Reform Act and Executive Order 13084?

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action does not contain a "Federal mandate" that may result in expenditures of $100 million or more for the private sector in any 1 year, nor will it result in such expenditures for State, local, and tribal governments in the aggregate. The costs associated with this action are estimated in the economic analysis prepared for this final rule (Ref. 46), which is included in the public docket and summarized in Unit VII. of this preamble.

EPA has determined that it is not required to develop a small government agency plan as specified by section 203 of UMRA or to conduct prior consultation with State, local, or tribal governments under section 204 of UMRA, because the rule will not significantly or uniquely affect small governments and does not contain a significant Federal intergovernmental mandate.

Finally, EPA believes this rule complies with section 205(a) of UMRA. The objective of this rule is to expand the public benefits of the TRI program by exercising EPA's discretionary authority to lower reporting thresholds, thereby increasing the amount of information available to the public regarding the use, management, and disposition of listed toxic chemicals. In making additional information available through TRI, the Agency increases the utility of TRI data as an effective tool for empowering local communities, the public sector, industry, other agencies, and State and local governments to better evaluate risks to public health and the environment.

As described in Unit VI. of this preamble, EPA considered burden in the threshold selection. The rule also contains reporting requirements that will limit burden (e.g., reporting limitations for lead in certain alloys). In addition, existing burden-reducing measures (e.g., the laboratory exemption, and the otherwise use exemptions, which include the routine janitorial or facility grounds maintenance exemption, motor vehicle maintenance exemption, structural component exemption, intake air and water exemption and the personal use exemption) will apply to the facilities that file new reports as a result of this rule. EPA also will be assisting small entities subject to the rule, by such means as providing meetings, training, and compliance guides in the future, which also will ease the burdens of compliance. Many steps have been and will be taken to further reduce the burden associated with this rule, and to EPA's knowledge there is no available alternative to the rule that would obtain the equivalent information in a less burdensome manner. For all of these reasons, EPA believes the rule complies with UMRA section 205(a).

In addition, today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998) do not apply to this rule.

E. What are the Determinations Under Executive Orders 12898 and 13045?

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on environmental and health conditions in low-income populations and minority populations.

Since this is a significant regulatory action, additional OMB review is required under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). The Agency has, to the extent permitted by law and consistent with the agency's mission, identified and assessed the environmental health risks and safety risks that may disproportionately affect children.

By lowering the section 313 reporting thresholds for lead and lead compounds, EPA is providing communities across the United States (including low-income populations and minority populations) with access to data that may assist them in lowering exposures and consequently reducing chemical risks for themselves and their children. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the rule are expected to have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

F. What is the Determination under Executive Order 13132?

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implication" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This action is expected to have a limited impact on municipal governments that operate electric utilities that may be affected by this action. EPA estimates that there are only 13 publicly-owned electric utility facilities that are potentially affected by the rule. Of these 13 facilities, 8 are expected to file one additional report as a result of this action. Thus, the requirements of Section 6 of the Executive Order do not apply to this rule.

G. What are the Determinations under the National Technology Transfer and Advancement Act?

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards, nor did EPA consider the use of any voluntary consensus standards. In general, EPCRA does not prescribe technical standards for threshold determinations or completion of EPCRA section 313 reports. EPCRA section 313(g)(2) states that "In order to provide the information required under this section, the owner or operator of a facility may use readily available data (including monitoring data) collected pursuant to other provisions of law, or, where such data are not readily available, reasonable estimates of the amounts involved. Nothing in this section requires the monitoring or measurement of the quantities, concentration, or frequency of any toxic chemical released into the environment beyond that monitoring and measurement required under other provisions of law or regulation."

H. What are the Requirements of the Congressional Review Act?

The Congressional Review Act (5 U.S.C. 801 et seq.) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: January 8, 2001.

Carol M. Browner,

Administrator.

Therefore, 40 CFR part 372 is amended as follows:

PART 372—[AMENDED]

1. The authority citation for part 372 will continue to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

2. In § 372.28 by adding one chemical to paragraph (a)(1) alphabetically and to paragraph (a)(2) by alphabetically adding one category to read as follows:

§ 372.28 Lower thresholds for chemicals of special concern.

(a) * * *

(1) * * *

Chemical Name	CAS No.	Reporting Threshold
* * * * * * *		
Lead (this lower threshold does not apply to lead when contained in a stainless steel, brass or bronze alloy)	7439–92–1	100
* * * * * * *		

(2) * * *

Category Name	Reporting Threshold
* * * * * * *	
Lead Compounds	100
* * * * * * *	

* * * * *

[FR Doc. 01–1045 Filed 1–16–01; 8:45 am]

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Department of Defense

Department of the Army, Corps of Engineers

33 CFR Part 323

Environmental Protection Agency

40 CFR Part 232

Further Revisions to the Clean Water Act Regulatory Definition of Discharge of Dredged Material; Final Rule

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DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 323

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 232

[FRL–6933–2]

Further Revisions to the Clean Water Act Regulatory Definition of "Discharge of Dredged Material"

AGENCIES: Army Corps of Engineers, Department of the Army, DOD; and Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The U.S. Army Corps of Engineers (Corps) and the Environmental Protection Agency (EPA) are promulgating a final rule to amend our Clean Water Act (CWA) section 404 regulations defining the term "discharge of dredged material." Today's final action is being taken to follow-up on our earlier proposed rulemaking of August 16, 2000, in which we proposed to amend the regulations to establish a rebuttable presumption that mechanized landclearing, ditching, channelization, in-stream mining, or other mechanized excavation activity in waters of the U.S. result in more than incidental fallback, and thus involve a regulable discharge of dredged material.

As a result of the comments we received, today's final rule reflects several modifications from the proposal. In response to concerns raised by some commenters that the proposal would have shifted the burden of proof to the regulated community as to what constitutes a regulable discharge, we have revised the language to make clear that this is not the case. Additionally, we received numerous comments requesting that we provide a definition of "incidental fallback" in the regulatory language. In response, today's final rule does contain such a definition, which is consistent with past preamble discussions of that issue and is drawn from language contained in the relevant court decisions describing that term. Today's final rule will both enhance protection of the Nation's aquatic resources, including wetlands, and provide increased certainty and predictability for the regulated community. At the same time, it continues to allow for case-by-case evaluations as to whether a regulable discharge of dredged material results from a particular activity, thus retaining necessary program flexibility to address the various fact-specific situations that are presented.

EFFECTIVE DATE: February 16, 2001.

FOR FURTHER INFORMATION CONTACT: For information on today's rule, contact either Mr. Mike Smith, U.S. Army Corps of Engineers, ATTN CECW–OR, 441 "G" Street, NW, Washington, DC 20314–1000, phone: (202) 761–4598, or Mr. John Lishman, U.S. Environmental Protection Agency, Office of Wetlands, Oceans and Watersheds (4502F), 1200 Pennsylvania Avenue N.W., Washington, DC 20460, phone: (202) 260–9180.

SUPPLEMENTARY INFORMATION:

I. Potentially Regulated Entities

Persons or entities that discharge material dredged or excavated from waters of the U.S. could be regulated by today's rule. The CWA generally prohibits the discharge of pollutants into waters of the U.S. without a permit issued by EPA or a State approved by EPA under section 402 of the Act, or, in the case of dredged or fill material, by the Corps or an approved State under section 404 of the Act. Today's rule addresses the CWA section 404 program's definition of "discharge of dredged material," which is important for determining whether a particular discharge is subject to regulation under CWA section 404. Today's rule sets forth the agencies' expectations as to the types of activities that are likely to result in a discharge of dredged material subject to CWA section 404. Examples of entities potentially regulated include:

Category	Examples of potentially regulated entities
State/Tribal governments or instrumentalities	State/Tribal agencies or instrumentalities that discharge dredged material into waters of the U.S.
Local governments or instrumentalities	Local governments or instrumentalities that discharge dredged material into waters of the U.S.
Federal government agencies or instrumentalities	Federal government agencies or instrumentalities that discharge dredged material into waters of the U.S.
Industrial, commercial, or agricultural entities	Industrial, commercial, or agricultural entities that discharge dredged material into waters of the U.S.
Land developers and landowners	Land developers and landowners that discharge dredged material into waters of the U.S.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that are likely to be regulated by this action. This table lists the types of entities that we are now aware of that could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your organization or its activities are regulated by this action, you should carefully examine EPA's applicability criteria in section 230.2 of Title 40 of the Code of Federal Regulations, the Corps regulations at part 323 of Title 33 of the Code of Federal Regulations, and the discussion in section II of today's preamble. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

A. Plain Language

In compliance with President Clinton's June 1, 1998, Executive Memorandum on Plain Language in government writing, this preamble is written using plain language. Thus, the use of "we" in this action refers to EPA and the U.S. Army Corps of Engineers (Corps), and the use of "you" refers to the reader.

B. Overview of Previous Rulemaking Activities and Related Litigation

Section 404 of the CWA authorizes the Corps (or a State with an approved section 404 permitting program) to issue permits for the discharge of dredged or fill material into waters of the U.S. Two States (New Jersey and Michigan) have assumed the CWA section 404 permitting program. On August 25, 1993 (58 FR 45008), we issued a regulation (the "Tulloch Rule") that defined the

term "discharge of dredged material" as including "any addition, including any redeposit, of dredged material, including excavated material, into waters of the U.S. which is incidental to any activity, including mechanized landclearing, ditching, channelization, or other excavation that destroys or degrades waters of the U.S." The American Mining Congress and several other trade associations challenged the revised definition of the term "discharge of dredged material," and on January 23, 1997, the U.S. District Court for the District of Columbia ruled that the regulation exceeded our authority under the CWA because it impermissibly regulated "incidental fallback" of dredged material, and enjoined us from applying or enforcing the regulation. That ruling was affirmed on June 19, 1998, by the U.S. Court of Appeals for the District of Columbia Circuit. *American Mining Congress* v. *United States Army Corps of Engineers*, 951 F.Supp. 267 (D.D.C. 1997) ("*AMC*"); aff'd sub nom, *National Mining Association* v. *United States Army Corps of Engineers*, 145 F.3d 1339 (D.C.Cir. 1998) ("*NMA*").

On May 10, 1999, we issued a final rule modifying our definition of "discharge of dredged material" in order to respond to the Court of Appeals' holding in *NMA*, and to ensure compliance with the District Court's injunction (64 FR 25120). That rule made those changes necessary to conform the regulations to the courts' decisions, primarily by modifying the definition of "discharge of dredged material" to expressly exclude regulation of "incidental fallback."

The *NMA* court did not find that all redeposits are unregulable, and recognized that redeposits at various distances from the point of removal are properly the subject of regulation under the CWA. As explained in the preamble to the May 10, 1999, rulemaking, our determination of whether a particular redeposit of dredged material in waters of the U.S. requires a section 404 permit would be done on a case-by-case basis, consistent with our CWA authorities and governing case law. The preamble to that rulemaking also described and summarized relevant case law (see 64 FR 25121), for example, noting that the *NMA* decision indicates incidental fallback ". . . returns dredged material virtually to the spot from which it came" (145 F.3d at 1403) and also describes incidental fallback as occurring "when redeposit takes place in substantially the same spot as the initial removal." 145 F.3d at 1401. The *NMA* court also noted that "incidental fallback" occurs when a bucket used to excavate material from the bottom of a river, stream, or wetland is raised and soils or sediments fall from the bucket back into the water; the court further noted that "fallback and other redeposits" occur during mechanized landclearing, when bulldozers and loaders scrape or displace wetland soil as well as during ditching and channelization when draglines or backhoes are dragged through soils and sediments. 145 F.3d at 1403. The preamble also noted that the district court in *AMC* described incidental fallback as "the incidental soil movement from excavation, such as the soil that is disturbed when dirt is shoveled, or the back-spill that comes off a bucket and falls back into the same place from which it was removed." 951 F.Supp. at 270.

The *NMA* Court noted that the CWA "sets out no bright line between incidental fallback on the one hand and regulable redeposits on the other" and that "a reasoned attempt to draw such a line would merit considerable deference." (145 F.3d at 1405). The preamble to our May 10, 1999, rulemaking stated that we would be undertaking additional notice and comment rulemaking in furtherance of the CWA's objective to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."

Subsequent to our May 10, 1999, rulemaking the National Association of Homebuilders (NAHB) and others filed a motion with the district court that issued the *AMC* injunction to compel compliance with that injunction. The NAHB motion, among other things, asserted that the May 10, 1999, rule violated the court's injunction by asserting unqualified authority to regulate mechanized landclearing. A decision on that motion was still pending at the time we issued our August 16, 2000 proposal (65 FR 50108) to establish a rebuttable presumption that mechanized landclearing, ditching, channelization, in-stream mining, or other mechanized excavation activity in waters of the U.S. will result in regulable discharges of dredged material.

As explained in the preamble, the proposed rule set forth:

> * * * our expectation that, absent a demonstration to the contrary, the activities addressed in the proposed rule typically will result in more than incidental fallback and thus result in regulable redeposits of dredged material. It would not, however, establish a new formal process or new record keeping requirements, and Section 404 permitting and application requirements would continue to apply only to regulable discharges and not to incidental fallback.

65 FR 50113.

As with today's final rule, the proposal addressed only matters related to the "discharge of dredged material" under section 404 of the CWA. We note that other regulatory authorities may be applicable to activities in waters of the U.S., including stormwater permitting requirements under CWA section 402, and, in the case of "navigable waters of the U.S." (so-called navigable in fact waters), section 10 of the Rivers and Harbors Act of 1899. Readers should refer to the preamble of the proposal for further information on those authorities (65 FR 50114).

The proposed rule had a 60 day comment period, which ended on October 16, 2000. While that public comment period was still open, on September 13, 2000, the district court denied NAHB's motion to compel compliance with the *AMC* injunction, finding that our earlier May 10, 1999, rule was consistent with its decision and injunction, and the decision of the D.C. Circuit in *NMA*. *American Mining Congress* v. *U.S. Army Corps of Engineers*, Civil Action No. 93–1754 SSH (D.D.C. September 13, 2000) (hereafter referred to as "NAHB Motion Decision").

In that decision the court found that, "Inasmuch as this Court in *AMC*, and the Court of Appeals in *NMA*, invalidated the Tulloch Rule because it regulated incidental fallback, the Court's order enjoining the agencies from applying or enforcing the Tulloch Rule must be understood to bar the agencies from regulating incidental fallback." NAHB Motion Decision, slip op. at 8–9. The court then went on to determine that by making clear that the agencies may not exercise section 404 jurisdiction over redeposits of dredged material to the extent that the redeposits involve only incidental fallback, the May 10, 1999, rulemaking did not violate the court's injunction and is consistent with the decisions in *AMC* and *NMA*. Id. at 10–11.

C. Discussion of Final Rule

We received approximately 9,650 comments on the August 16, 2000, proposal (because the numbers given are rounded off, we refer to them as "approximate.") Approximately 9,500 were various types of individual or form letters from the general public expressing overall support for the rule or requesting it be strengthened. We received approximately 150 comments from various types of organizations, state or local agencies, or commercial entities, 75 of which provided detailed

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comments, with approximately 50 of these expressing opposition to the rule. Organizations opposing the rule were primarily construction and development interests, mining and commerce interests, as well as local agencies or water districts with agricultural, flood control, or utility interests. These commenters often expressed the view that the proposal was inconsistent with the *AMC* and *NMA* opinions and the CWA. These comments also often expressed concern that the rebuttable presumption would be difficult or impossible to rebut and should be removed from the rule, and also frequently stated that a definition of incidental fallback was necessary, with many expressing preference for a "brightline" definition.

Organizations supporting the proposal or its strengthening included state and local natural resource and environmental protection agencies and environmental organizations. In addition, one detailed letter from a group of wetland scientists associated with a variety of institutions was received, and expressed support for the proposed rule and its strengthening. Commenters favoring the rule or its strengthening generally believed that the proposed rule's presumption that mechanized landclearing, ditching, channelization, in-stream mining, or other mechanized excavation activity in waters of the U.S. result in more than incidental fallback, and thus involve a regulable discharge of dredged material, was appropriate. Many of these commenters, especially environmental organizations, requested that the rule be strengthened in a number of ways, particularly by identifying certain activities as always requiring a permit, and making clear that if chemical constituents are released into the water column or if material is moved in a way that permits its more ready erosion and movement downstream, a regulable discharge occurs. In addition, many of the commenters favoring the proposed rule or requesting that it be strengthened also expressed the view that it should define incidental fallback.

We have carefully considered all the comments received on the proposal in developing today's final rule. A detailed discussion of those comments and our responses is set out in section III of today's preamble.

Like the proposal, today's rule modifies our definition of "discharge of dredged material" in order to clarify what types of activities we believe are likely to result in regulable discharges. As described in the preamble to the proposed rule (65 FR 50111–50113), based on the nature of the equipment, we believe that the use of mechanized earth moving equipment to conduct landclearing, ditching, channelization, in-stream mining, or other mechanized excavation activity in waters of the U.S. is likely to result in regulable discharges of dredged material.

However, in response to comments we received expressing concern that the proposal would result in a shift in the burden of proof and impose undue burdens on project proponents to "prove a negative," we have made a number of changes to clarify that this is not our intent and will not be a result of this rule. Because these concerns primarily appeared to arise out of the proposed rule's use of a rebuttable presumption formulation, we have redrafted the rule language to eliminate use of a rebuttable presumption.

As we had explained in the proposed rule preamble, the proposal was intended to express our expectation that the activities in question typically result in regulable discharges, not to create a formal new process or record keeping requirements (65 FR 50113). The rule now provides that the agencies regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the U.S. as resulting in a discharge of dredged material unless project-specific evidence shows that the activity results in only incidental fallback

By no longer employing a rebuttable presumption, we believe it is more evident that we are not creating a new process or altering existing burdens under the CWA to show a regulable discharge of dredged material has occurred. To make this point unmistakably clear, we also have added a new sentence to the rule language that expressly provides the rule does not and is not intended to shift any burden in any administrative or judicial proceeding under the CWA. In addition, the rule language has been clarified to make it more evident that we will not look to project proponents alone to provide information that only incidental fallback results. Thus, the rule language now refers to "project-specific evidence show[ing] that the activity results in only incidental fallback." While this might consist in large part of information from project proponents, we also will look to all available information, such as that in agency project files or information gained from site visits, when determining if a discharge of dredged material results.

We also received a number of comments questioning how the presumption contained in the proposed rule might apply to particular equipment, or asserting that the presumption in the proposal was too broad. We thus are clarifying in the final rule language itself that we are addressing mechanized "earth-moving" equipment (*e.g.*, bulldozers, graders, backhoes, bucket dredges, and the like). Earth-moving equipment is designed to excavate or move about large volumes of earth, and we believe it is reasonable and appropriate for the agencies to view the use of such equipment in waters of the U.S. as resulting in a discharge of dredged material unless there is case specific information to the contrary. The administrative record of today's rule contains additional information on the nature of this equipment and its operation.

We received a large number of comments, both from those opposed to the proposed rule, as well as those supporting the proposal (or its strengthening), requesting us to provide a definition of "incidental fallback." The proposed rule had not done so, instead providing preamble discussion of the relevant case law addressing that term, as well as referring readers to the preamble to our earlier May 10, 1999, rule (65 FR 50109–50110; 64 FR 25121). Subsequent to the proposal, as many of the commenters opposed to the proposal noted, the court, in its decision on the NAHB motion to compel compliance with the *AMC* court's injunction, cautioned against parsing the *AMC* and *NMA* language to render an overly narrow definition of incidental fallback. NAHB Motion Decision, slip opinion 12–14.

In light of numerous comments requesting that a definition of incidental fallback be included in the regulations, and consistent with our preamble discussions of relevant case law and the more recent discussion in the court's NAHB Motion Decision, we have provided a descriptive definition in the final rule. That language, which is based on the *AMC* and *NMA*, cases and the NAHB Motion Decision, provides that:

> Incidental fallback is the redeposit of small volumes of dredged material that is incidental to excavation activity in waters of the United States when such material falls back to substantially the same place as the initial removal. Examples of incidental fallback include soil that is disturbed when dirt is shoveled and the back-spill that comes off a bucket when such small volume of soil or dirt falls into substantially the same place from which it was initially removed.

This language is fully consistent with the spirit and intent of those decisions. As noted in the *AMC* decision, incidental fallback involves "incidental soil movement from excavation" (951 F.Supp. 270); thus the definition in today's rule refers to the redeposit of small volumes of dredged material incidental to excavation activities. (See also *NMA*, 145 F.3d at 1404 (the statutory term "addition" does not cover the situation where material is removed "and a small portion of it happens to fall back")). The rule language refers to "incidental fallback" as returning dredged material to "substantially the same place" from which it came, a formulation consistent with the *AMC* and *NMA* decisions. AMC, 951 F.Supp. at 270; *NMA*, 145 F.3d. at 1403; see also, NAHB Motion Decision at 13. The examples of incidental fallback given in the rule's definition are drawn from the *AMC* decision. See, *AMC*, 951 F.Supp. at 270. We, therefore, believe the definition reflects an objective and good faith reading of the *AMC* and *NMA* decisions. See, NAHB Motion Decision, slip op. at 14.

We believe today's rule both ensures environmental protection consistent with CWA authorities and increases regulatory certainty in a manner fully consistent with the *AMC* and *NMA* decisions and the district court injunction. This has been accomplished through regulatory language that serves to put agency staff and the regulated community on notice that absent information to the contrary, it is our expectation that the use of mechanized earth moving equipment to conduct landclearing, ditching, channelization, in-stream mining, or other mechanized excavation activity in waters of the U.S. is likely to result in discharges of dredged material. In addition, in response to comments, and in order to provide a descriptive standard of what constitutes non-regulable incidental fallback, we have provided in the rule a descriptive definition of that term which we believe to be fully consistent with an objective and good faith reading of the *AMC*, *NMA*, and NAHB Motion decisions.

At the same time, today's rule is not unnecessarily prescriptive and still allows for the case-by-case consideration of whether a discharge results. In making that determination, the agencies will consider any available information on project plan or design, as well as other information, such as site visits or field observations, during and after project execution. Information which we will consider includes that from project proponents, as well as other available information.

In determining if a regulable discharge of dredged material occurs, we will carefully evaluate whether there has been movement of dredged material away from the place of initial removal. In doing so, we will look to see if earth-moving equipment pushes or relocates dredged material beyond the place of excavation, as well as whether material is suspended or disturbed such that it is moved by currents and resettles beyond the place of initial removal in such volume as to constitute other than incidental fallback, and thus be a regulable discharge. See e.g., *United States* v. *M.C.C. of Florida*, 722 F.2d 1501 (11th Cir. 1985), vacated on other grounds, 481 U.S. 1034 (1987), readopted in relevant part on remand, 848 F.2d 1133 (11th Cir. 1988) (resettling of material resulting from propeller rotation onto adjacent seagrass beds is jurisdictional). In appropriate situations, we also will include consideration of whether the operation results in the release of pollutants to the environment that were formerly physically or chemically bound up and sequestered from the environment prior to the dredging or excavation of the sediments. See e.g., *United States* v. *Deaton*, 209 F. 3d 331 (4th Cir. 2000) at 335–336 (discussing release of pollutants in determining sidecasting to be jurisdictional). In considering whether material is relocated, we will look at both horizontal and vertical relocation. For example, sidecasting, which involves horizontal relocation to the side of the ditch, is a regulable discharge. See e.g., *Deaton*, supra; NAHB Motion Decision at n. 3. Similarly, where activities involve the vertical relocation of the material, such as occurs in backfilling of trenches, a regulable discharge results. See e.g., (*United States* v. *Mango*, 997 F. Supp. 264, 285 (N.D.N.Y. 1998), affirmed in part, reversed in part on other grounds, 199 F.3d 85 (2d Cir. 1999); see, *Iroquois Gas Transmission System* v. *FERC*, 145 F.3d 398 at 402 (2nd Cir. 1998) (backfilling of trenches is jurisdictional).

We also will take into account the amount or volume of material that is redeposited. Incidental fallback at issue in *AMC* and *NMA* was the small-volume fallback from excavation. Similarly, today's rule defines incidental fallback as the "small volumes of dredged material" falling back to substantially the same place as the initial removal. Therefore, we will consider the volume redeposited in deciding whether the activity results in only incidental fallback.

Thus, the determination of whether an activity results in a regulable discharge of dredged material or produces only incidental fallback involves consideration of the location and the amount of the redeposit. Because of the fact-specific nature of the assessment of these factors, and their interrelated nature, we do not believe it to be feasible or appropriate to establish hard and fast cut-off points for each of these factors. Rather, the totality of the factors will be considered in each case.

Finally, we note that the proposed rule would have removed existing paragraph 3(iii) from the Corps' regulations at 33 CFR 323.2(d) and the counterpart EPA regulation at 40 CFR 232.2. Those paragraphs contained identical "grandfather" provisions for certain activities to be completed by August 24, 1995, and were proposed for deletion as being outdated. 65 FR 501211. Today's final rule, consistent with the original proposal, removes those paragraphs from the regulations.

III. Discussion of Comments

A. Legality of Proposal

1. Proposal as Inconsistent With NMA and Ruling on NAHB Motion to Compel

A number of commenters contended that the proposed rule conflicts with the rulings of the courts in *AMC*, *NMA*, and the NAHB Motion Decision. Among other things, they characterized the rule as an "end-run" around the nationwide injunction affirmed in *NMA;* "an attempt to re-promulgate [the 1993 Tulloch Rule];" and an effort to regulate the activities that the *NMA* court said were not regulable. In particular, these commenters characterized the *NMA* decision as holding that regulating any redeposit of dredged material during removal activities outruns the section 404 provisions of the CWA and that the agencies may only regulate activities that cause a net addition to waters of the U.S. They then argued that the rule is at odds with that holding. In addition, they asserted that the presumption would result in regulating effects as opposed to discharges and would make all excavation and landclearing activities regulated. Several commenters also noted that using a presumption does not address the *NMA* court's instruction that the agencies attempt to draw a bright line between what is a regulable redeposit versus non regulated incidental fallback.

As discussed in more detail in the sections below, we believe that the changes that we have made in today's rule address such concerns. Moreover, we do not agree with the legal analysis in many of the comments. In a number of respects, we believe the commenters have simply read the *NMA* decision too broadly. The court in *NMA* stated: "[W]e do not hold that the Corps may not legally regulate some forms of redeposit under its section 404 permitting authority. We hold only that by asserting jurisdiction over 'any

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redeposit,' including incidental fallback, the Tulloch Rule outruns the Corps' statutory authority." 145 F. 3d at 1405. Thus, the court explicitly recognized that some redeposits are regulable and indicated that the agencies' attempt to draw a line between incidental fallback and regulable redeposits would be entitled to deference. The court also acknowledged that sidecasting, the placement of removed soil in a wetland some distance from the point of removal, has always been regulated by the agencies; and finally, it recognized that removal of dirt and gravel from a streambed and its subsequent redeposit in the waterway after segregation of minerals constitutes an addition.

The court's acceptance of these principles undercuts the conclusion suggested by some that its statement that "incidental fallback represents a net withdrawal, not an addition" must be read to mean that activities that involve removal of material can never constitute a discharge. Similarly, the court's statement that "Congress could not have contemplated that the attempted removal of 100 tons [of dredged spoil] could constitute an addition simply because only 99 tons were actually taken away" must also be reconciled with the court's clear recognition that some redeposits constitute an addition.

In addition, the Court's NAHB Motion Decision supports the agencies' view that a more narrow reading of the *NMA* decision than some commenters are advocating is correct. The court stated:

> Inasmuch as this Court in *AMC*, and the Court of Appeals in *NMA*, invalidated the Tulloch Rule because it regulated incidental fallback, the Court's order enjoining the agencies from applying or enforcing the Tulloch Rule must be understood to bar the agencies from regulating incidental fallback [footnote omitted] * * * The May 10th Rule is facially consistent with the Court's injunction because it eliminates § 404 jurisdiction over incidental fallback, and removes the language asserting jurisdiction over "any" redeposit of dredged material. The rule makes clear that the agencies may not exercise § 404 jurisdiction over redeposits of dredged material *to the extent that the redeposits involve only incidental fallback* [citation omitted] (emphasis added).

Court's Denial of Motion to Compel, at 9–10.

Thus, the sweeping claims that "any redeposit" and all removal activities are beyond the scope of the CWA can not be substantiated based on *NMA* or other existing law. Today's rule provides a definition of "incidental fallback" that adheres to the judicial guidance provided in the *AMC* and *NMA* cases and the NAHB Motion Decision, while making clear to the public the types of activities that we believe are properly regulated.

a. *Excavation not covered.* The contention that excavation and other removal activities can never be regulated fails to recognize that "discharges of pollutants" can occur during removal activities even where the ultimate goal is withdrawal of material. That the CWA definition of "pollutants" does not include "incidental fallback from dredging operations" is of no significance, contrary to the suggestion of one commenter, because it does include "dredged spoil." Several commenters referenced dictionary definitions of "excavate" and "discharge" to buttress their view that a removal activity can not involve a discharge. One commenter, in particular, argued that "discharge" denotes an intentional act, and that redeposits from excavation activity may not be regulated because they do not involve an intentional act. These definitions, however, do not indicate whether, in a given situation, pollutants were added to waters of the U.S. within the meaning of the CWA, the only issue we are concerned with here. First, as indicated in section III. A. 4 of this preamble, there is no support under the CWA for the position that a discharge must be an intentional act. In addition, as indicated in the preamble to the proposed rule, as a general matter, excavation and other earth-moving activities that are undertaken using mechanized earth-moving equipment typically result in the addition of a pollutant to navigable waters because the nature of such equipment is to move large volumes of material within and around the excavation site.

The court in *NMA* also recognized that redeposits associated with earth-moving activities could be regulated. ("But we do not hold that the Corps may not legally regulate some forms of redeposit under its section 404 permitting authority." 145 F. 3d at 1405.). As described in the preamble to the proposed rule, the machinery used for excavation, mechanized landclearing, and other removal activities generally results in substantial soil movement beyond the area from which the material is being removed (See also section III D of today's preamble). This substantial soil movement and distribution of material makes the situations involving mechanized earth-moving equipment akin to the numerous cases in which the courts have found that the redeposit of material constituted the discharge of a pollutant. See e.g., *Avoyelles Sportsmen's League* v. *Marsh*, 715 F. 2d 897, 923 (5th Cir. 1983)(recognized that the term "discharge" covers the redepositing of materials taken from wetlands); *United States* v. *Mango*, 997 F. Supp. 264, 285 (N.D.N.Y. 1998), *affirmed in part, reversed in part on other grounds*, 199 F. 3d 85 (2d Cir. 1999)(found that backfilling of trenches with excavated material was a discharge); *United States* v. *M.C.C. of Florida, Inc.*, 772 F. 2d 1501 (11th Cir. 1985)(holding that redeposition of seabed materials resulting from propeller rotation onto adjacent sea grass beds was an "addition" of dredged spoil); *Slinger Drainage Inc.*, CWA Appeal No. 98–10 (EPA Environmental Appeals Board Decision (EAB)(holding that backfilling by a Hoes trenching machine is a regulable discharge of dredged material, not incidental fallback)(appeal pending); *United States* v. *Deaton*, 209 F. 3d 331 (4th Cir. 2000)(holding that sidecasting is a regulated discharge); *see also United States* v. *Huebner*, 752 F. 2d 1235 (7th Cir.), *cert denied*, 474 U.S. 817 (1985) (sidecasting materials along a ditch and then using a bulldozer to spread material over several acres constituted a discharge of dredged material).

We do recognize, however, that some excavation activities by using specialized techniques or precautions may be conducted in such a manner that no discharge of dredged material in fact occurs. Today's rule specifically provides for consideration of project-specific information as to whether only incidental fallback results in determining jurisdiction under section 404. For example, we acknowledge that some suction dredging operations can be conducted in such a manner that if the excavated material is pumped to an upland location or other container outside waters of the U.S. and the mechanized removal activity takes place without re-suspending and relocating sediment downstream, then such operations generally would not be regulated. Other examples of activities that would generally not be regulated include discing, harrowing, and harvesting where soil is stirred, cut, or turned over to prepare for planting of crops. These practices involve only minor redistribution of soil, rock, sand, or other surface materials. The use of K–G blades and other forms of vegetation cutting such as bush hogging or mowing that cut vegetation above the soil line do not involve a discharge of dredged material.

b. *Too narrow reading of "incidental fallback".* Several commenters incorrectly equate "incidental fallback" with all dredged spoil that is redeposited in regulated waters as a result of activities using mechanized equipment. As indicated, the *NMA* court made it clear that regulable redeposits could be associated with such activities and, to the extent that they were, the *NMA* decision did not preclude regulation. Today's rule explicitly excludes incidental fallback from the definition of discharge of dredged material. First, it does not alter the May 10, 1999, amendment to the definition of "discharge of dredged material," which explicitly excluded incidental fallback from the definition. In addition, today's rule provides for the consideration of project-specific evidence which shows that only incidental fallback results from the activity. Thus, we have taken the necessary steps to ensure that we do not regulate "incidental fallback" when it is the only material redeposited during certain removal activities. The Court's NAHB Motion Decision found our May 10, 1999, amendment consistent with the injunction in the NMA case, and today's rule does not change or alter the underlying provisions of that rule.

Nevertheless, several commenters have argued that the agencies are interpreting "incidental fallback" too narrowly and have not heeded language in the Court's NAHB Motion Decision that cautioned against applying a too narrow definition of incidental fallback that would be inconsistent with an objective and good faith reading of the *AMC* and *NMA* decisions. Today's rule, however, is entirely consistent with that order and the decisions in *AMC* and *NMA*. First, commenters are incorrect that we have construed the meaning of "incidental fallback" too narrowly because, in formulating the definition in today's regulation, we were guided by the descriptions of incidental fallback in the judicial opinions. The *NMA* decision indicates that incidental fallback "* * * returns dredged material virtually to the spot from which it came." 145 F. 3d at 1403. It also describes incidental fallback as occurring "when redeposit takes place in substantially the same spot as the initial removal." 145 F. 3d at 1401. Similarly, the District Court described incidental fallback as "the incidental soil movement from excavation, such as the soil that is disturbed when dirt is shoveled, or the back-spill that comes off a bucket and falls back into the same place from which it was removed." 951 F. Supp. at 270. We believe that adopting a definition that relies heavily on the judicial formulations of "incidental fallback" will ensure consistency with those opinions as well as help project proponents understand the agencies' view of "incidental fallback." We disagree strongly with commenters who suggested that we are trying to inappropriately parse the language of the *AMC* and *NMA* decisions, and believe that our definition of "incidental fallback" is based upon a good faith interpretation of those rulings. See section II C of today's preamble for additional discussion of this issue.

Nevertheless, as discussed in section III E of today's preamble, we did not adopt a definition of incidental fallback that would turn on whether the material was redeposited to "the same general area" from which it was removed. We believe this formulation could potentially be read to mean that incidental fallback would include any dredged material redeposited in the same overall site where excavation occurred, as opposed to the place of initial removal. We believe such a broad formulation would not adequately recognize court decisions that have found a regulable discharge where redeposits have occurred even though only a short distance from the removal point. *See, e.g., Deaton, Mango, etc.*

Moreover, contrary to one commenter's contentions, today's rule is not inconsistent with the approach taken by the agencies in the 1997 Tulloch Guidance ("*Corps of Engineers/ Environmental Protection Agency Guidance Regarding Regulation of Certain Activities in Light of American Mining Congress* v. *Corps of Engineers*," April 11, 1997) ("1997 Guidance"). The commenter pointed to language in the 1997 Guidance stating that if there is "movement of substantial amounts of dredged material from one location to another in waters of the United States (*i.e.*, the material does not merely fall back at the point of excavation), then the regulation of that activity is not affected by the Court's decision." Pointing to that language, the commenter went on to assert the 1997 Guidance meant that unless "substantial amounts" of dredged material were moved, then no discharge occurs, and concluded from this that the proposed rule was inconsistent with the 1997 Guidance. In response, we do not believe the 1997 Guidance can be properly read to support the commenter's conclusions. The language quoted by the commenter comes from a portion of the guidance under the section header "Types of Discharge Not Addressed by Court Decision." In addition, it simply provides guidance to field personnel that where an activity results in movement of substantial volumes of dredged material, regulation of the activity is unaffected by the court's decision. The 1997 Guidance thus does not mean we interpreted the *AMC* or *NMA* decisions to allow regulation only if relocation of substantial amounts of dredged material takes place. In fact, the 1997 Guidance provides at page 3 that: "The Court's decision only has implications for a particular subset of discharges of dredged material, i.e., those activities where the only discharges to waters of the U.S. are the *relatively small volume discharges* described by the Court as "incidental fallback * * *" (emphasis added). Nothing in today's rule is inconsistent with the 1997 Guidance.

The preamble to the proposed rule clearly recognized that there can be situations where due to the nature of the equipment used and its method of operation, a redeposit may consist of material limited to "incidental fallback." In addition, that preamble recognized (as do the regulations at 33 CFR 323.2(d)(2)(ii) and 40 CFR 232.2), for example, that the use of equipment to cut trees above the roots that does not disturb the root system would not involve a discharge. Moreover, as discussed in section II C of today's preamble, we have modified today's final rule to make it even more clear that project-specific information may be used to demonstrate that only "incidental fallback" will result. Despite the discussion in the proposed rule's preamble, some commenters contended that we were overreaching. We believe that the language changes reflected in today's rule as well as the discussion in today's preamble clarify that redeposits associated with the use of mechanized earth-moving equipment will only be regulated if more than incidental fallback is involved, while making clear our view that activities involving mechanized earth-moving equipment typically result in more than incidental fallback. Where the redeposits are limited to incidental fallback, they would not be regulated.

c. *Covers same activities as 1993 Tulloch Rule.* A number of commenters argued that the proposed rule was an improper attempt to circumvent the *NMA* decisions and reinstate the invalidated 1993 Tulloch Rule. They contended that the agencies relied on no new information in developing this rule and that large segments of the proposed rule appeared in, and were used to justify, the 1993 Rule. Moreover, as opposed to narrowing the definition of "discharge of dredged material" as instructed by the courts, several argued that the proposed rule simply swept in the same activities and created a vague and impossible standard for rebutting the presumption. Several asserted that the agencies made no attempt to create

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a "brightline" distinction between incidental fallback and regulable redeposits as encouraged by the courts and instead, simply shifted the burden to the regulated community. The end result, they argued, would be that the agencies would regulate activities that are not appropriately within the scope of the CWA, because, among other reasons, people lack the resources, wherewithal, or information to rebut the presumption.

The changes that we have made in the rule language further clarify the distinctions between our approach today and the 1993 Tulloch Rule. We believe that today's rule reflects important differences with the 1993 Tulloch Rule that make our action consistent with the *NMA* rulings. First, as discussed previously in this preamble, today's amendments along with those made on May 10, 1999, explicitly and repeatedly exclude incidental fallback from the definition of "discharge of dredged material." Today's rule also provides a descriptive definition of incidental fallback and explicitly indicates that project-specific evidence may be used to show that only incidental fallback will result from the activity. These provisions are a direct response to the *NMA* rulings and to the comments that we received. In contrast, the relevant sections of the 1993 Tulloch Rule included *any* redeposit, including redeposits consisting of only incidental fallback.

Similarly, contrary to the suggestion of one commenter, the rebuttable presumption would not have recast in different legal language the central hypothesis of the Tulloch Rule that every redeposit of dredged material was a discharge subject to regulation under section 404. The commenter referenced language from the 1993 Preamble stating that it is "virtually impossible to conduct mechanized landclearing, ditching, channelization or excavation in waters of the United States without causing incidental redeposition of dredged material (however small or temporary) in the process." 58 FR at 45017. In contrast, the position that we are taking today does not cast the jurisdictional net so broadly. Both the rebuttable presumption in the proposal and today's rule are more narrow in scope because we are not regulating incidental fallback. As discussed in the previous paragraph, the regulations defining the discharge of dredged material were amended on May 10, 1999, to make clear that incidental fallback is not encompassed within that definition and today's rule does not alter that exclusion.

Second, some commenters claimed that the rebuttable presumption that was in the proposed rule is the same as the *de minimis* exception that was added to the regulations as part of the 1993 Tulloch Rule and continues to be a part of the definition of discharge of dredged material today. 33 CFR 323.2(d)(3); 40 CFR 232.2. We believe that this comment misunderstands the relationship between today's rule and the *de minimis* exception contained in the 1993 Tulloch Rule. We have not reopened in this rulemaking the *de minimis* exception from the 1993 rule, since that provision is irrelevant to determining whether an activity results in a discharge of dredged material. As promulgated in the 1993 rule, the *de minimis* exception provides that section 404 authorization is not required for the incidental addition of dredged material associated with an activity that would not destroy or degrade a water of the U.S. Under the 1993 rule, mechanized landclearing, ditching, channelization, or other excavation activity that results in a redeposit into waters of the U.S. were presumed to destroy or degrade waters of the U.S., unless the project proponent demonstrated prior to proceeding with the activity that it would not cause such effects. 33 CFR 323.2(d)(3); 40 CFR 232.2. Thus, the *de minimis* exception in the existing regulations and its associated presumption address the issue of whether otherwise regulable discharges are excluded from section 404 authorization because of minimal effects on the environment, and does not, as some commenters suggested, serve as a means of asserting authority over activities outside our jurisdiction based on the effects of activities.

By contrast, today's rule addresses the issue of whether a regulable discharge of dredged material is even involved. Today's rule does not eliminate the requirement for a "discharge." Instead it reflects the agencies' view that regulable discharges generally are expected to occur when certain activities using mechanized earth-moving equipment are undertaken. The proposed rule described this view in terms of a presumption but allowed project proponents to demonstrate that their activities caused only incidental fallback, which is beyond section 404 jurisdiction. Today's rule does not use the words "presumption" or "presume" to avoid any misunderstanding that we are attempting to shift CWA burdens to the project proponent. If the activity involves only incidental fallback, it would not be regulated regardless of the level of associated environmental impact because the statutory prerequisite of a discharge has not occurred. Moreover, unlike the treatment of mechanized activities when attempting to qualify for the *de minimis* exception, neither the proposed nor final rules require that the project proponent affirmatively demonstrate to the agencies that no discharge will occur prior to proceeding with his activities. Thus, the *de minimis* exception and today's rule serve different purposes and operate differently within the context of the regulation and for that reason the *de minimis* exception was not reopened as part of this rulemaking.

In addition, one commenter charged that by adopting a rebuttable presumption similar to the one proposed in the 1992 proposal but that was dropped prior to final promulgation in 1993, the agencies make clear their intent to sweep into regulation specific activities rather than determine actual discharges. In response, we note that the 1992 proposal actually contained an irrebutable presumption that was more inclusive than what we promulgated in the 1993 Tulloch Rule and than either the proposed or final rules we are addressing today. In fact, contrary to the sentiment expressed in the comment, the allowance for project-specific evidence that the activity results in only incidental fallback reflects our effort to restrict regulation to only regulable discharges.

We do not believe that it is of any significance that there is overlap between the activities addressed by today's rule and the 1993 Tulloch Rule. The *NMA* court did not find that all activities potentially encompassed by that rule were beyond the scope of the CWA, but rather that incidental fallback was excluded. NAHB Motion Decision. Thus, it is no surprise that the two rules address some of the same activities.

d. *Improperly relies on an "effects" test.* Several commenters argued that the proposed rule improperly relies on the broad goals of the CWA and an "effects test" as the basis for establishing jurisdiction. They contended that this approach is inconsistent with the *NMA*-related decisions and with other cases addressing the basis for jurisdiction under the CWA. They stated further that the CWA was not intended to provide comprehensive protection for wetlands. We believe that the commenters misunderstood the purpose and effect of the proposal, as well as have misread the conclusions in the NAHB Motion Decision about an effects based test of jurisdiction.

First, the agencies agree that the CWA regulates "discharges" and today's rule

in no way establishes an effects-based test for asserting CWA jurisdiction. As was indicated in the proposal, the presence of a "discharge" of dredged or fill material into waters of the U.S. is a prerequisite to jurisdiction under section 404. The purpose of this rule is to provide further clarification of what constitutes a "discharge of dredged material." As indicated, we regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the U.S. as resulting in a discharge of dredged material unless there is project-specific information to the contrary. Thus, although significant adverse environmental effects can result from activities undertaken using mechanized earth-moving equipment, the jurisdictional basis is the presence of regulable discharges.

To the extent these comments are addressing the *de minimis* exception contained in the 1993 rule, the comments are outside the scope of this rulemaking because we have not reconsidered that provision here. We note that the continued operation of this existing regulatory provision is consistent with *AMC* and *NMA*. The NAHB Motion Decision affirmatively rejected the position that "the Court's injunction must be understood to bar application and enforcement of the effects-based test of jurisdiction * * * because the Court also rejected this component of the Tulloch Rule * * * [citation omitted.]" The Court stated :

> The Court rejected this test because the agencies were using it to assert jurisdiction over otherwise non-regulable activities; the Court expressly did not determine whether the effects-based test of jurisdiction would be valid if applied to activities that otherwise come within the scope of the Act. [citation omitted] Thus, where the effects-based test is not applied to otherwise non-regulable activities under the Act (such as incidental fallback), the Court's injunction does not bar its application.

NAHB Motion Decision, n. 8.

Likewise today's rule is not in conflict with the *Slinger* decision as asserted by one of the commenters. In *Slinger Drainage, Inc.*, EPA's Environmental Appeals Board affirmed EPA's general view that " the pivotal consideration for purposes of deciding whether an individual activity is or is not subject to the section 404 permitting requirement is whether a discharge of dredged material takes place." *In re: Slinger Drainage, Inc.*, CWA Appeal No. 98–10 (September 29, 1999)(slip opinion), at 19. Notably, the EPA Environmental Appeals Board also stated in that opinion that the requirement for a discharge "is not to say that the 'effects' of a particular activity are of no concern. In a broad sense effects are the driving force behind the entire regulatory scheme to protect wetlands." *Id.*

Finally, one commenter suggested that discussions in the proposed rule's preamble concerning the release of contaminants in the water column indicate that the agencies "base their finding of jurisdiction on analysis of the effects of the mechanized landclearing, ditching, or other activity." This is incorrect. Rather than being regulated based on the effect on water quality, as discussed in section III D of today's preamble, the transport of dredged material downstream or the release of previously bound-up or sequestered pollutants (which are in and part of the dredged material) may constitute a discharge, not by virtue of associated environmental impacts, but by virtue of being added to a new location in waters of the U.S. In evaluating whether suspension or downstream transport results in a regulable discharge or only incidental fallback, we would consider the nature and amount of such suspension and transport.

e. *Inconsistency with District Court "specified disposal site" rationale.* Several commenters contended that today's rule ignores the *AMC* court's analysis of "specified disposal sites." We do not see today's rule as inconsistent with this aspect of the court's decision. The court in *AMC* held that, even if the term "addition of a pollutant" were broad enough to cover incidental fallback, the language "specified disposal sites" in section 404(a) would have led the court to the same holding. Because today's rule does not regulate incidental fallback, it is entirely consistent with this aspect of the court's opinion. Moreover, the court's reasoning in *AMC* was that the 1993 rule effectively made all excavation sites into disposal sites, rendering the statutory language "at specified disposal sites" superfluous. Today's rule does not render the statutory language superfluous because we are only asserting jurisdiction over redeposits that occur outside the place of initial removal.

2. Proposal as Inconsistent With the CWA

Several other claims were made that today's rule is not consistent with the CWA. Those claims included several pronouncements that the CWA only regulates discharges and that the legislative history demonstrates that Congress did not intend the CWA to regulate minor discharges associated with dredging, mechanized landclearing, excavation, ditching, channelization, and other *de minimis* discharges. One commenter disagreed with the proposition that section 404(f)(2) supports the proposed rule because it reflects Congressional recognition that these activities result in discharges. This commenter cited an excerpt from the *NMA* court decision—that the court was "reluctant to draw any inference [from section 404(f)] other than that Congress emphatically did not want the law to impede these bucolic pursuits"—to support his assertion. Moreover, one commenter argued that the lack of a specific reference to excavation activities in the CWA is further evidence that small-volume, incidental deposits accompanying landclearing and excavation activities were not intended to be covered under section 404. Several commenters also contended that the CWA does not require a person to make a prima facie showing that activities are exempt from regulation under the Act and the agencies can not administratively impose this requirement.

As discussed in section III A d, we recognize that the statute and legislative history require a discharge for the requirements of the CWA to apply. The definition of discharge of dredged material contained in today's rule is, therefore, grounded on the statutory term "discharge of a pollutant" contained in section 502(12) of the Act and relevant court decisions that have construed the discharge requirement. We think, however, that some commenters' assertion that legislative intent mandates a broad construction of the term "incidental fallback" finds no support either in section 502(12) (defining "discharge of a pollutant" to include "*any* addition of *any* pollutant" (emphasis added)) or section 404(f). We do not agree that the 1972 and 1977 legislative histories generally indicate that Congress did not intend to regulate minor discharges resulting from certain activities, including excavation. To the contrary, while Congress was focused on preserving the Corps' autonomy with respect to navigational dredging, it is clearly over-reading the history to suggest that other types of removal activities implicitly were contemplated and rejected by the choice of words such as "discharge," "pollutant," "dredge spoil," or "disposal sites," as one commenter suggested.

Moreover, the treatment of incidental discharges in the 1977 Act helps illustrate Congress' view of these types of discharges. The 404(f) exemption was necessary because Congress recognized that, absent an exemption, regulation of discharges "incidental to" certain

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activities was encompassed within section 404 under certain circumstances. There is no support in the Act or legislative history for concluding that so-called "minor" discharges associated with excavation were intended by Congress to be categorically excluded from the Act. In fact, the very use of the word "incidental" in section 404(f)(2) suggests just the opposite. Incidental is defined as: "1. being likely to ensue as a chance or minor consequence; 2. occurring merely by chance or without intention or calculation" (Miriam-Webster's Collegiate Dictionary (10th Ed., 1998)); "1. occurring or likely to occur as an unpredictable or minor accompaniment; 2. of a minor, casual, or subordinate nature" (American Heritage Dictionary of the English Language; 4th Ed.); "happening or likely to happen in an unplanned or subordinate conjunction with something else" (Random House Dictionary of the English Language (2d Ed. 1987)). Thus, the use of the word "incidental" in section 404(f)(2) belies the notion that the Act mandates a broad interpretation of incidental fallback.

Senator Muskie, the sponsor of the 1977 CWA amendment, addressed the section 404(f) exemptions as follows:

> 404(f) provides that Federal permits will not be required for those narrowly defined activities that cause little or no adverse effects either individually or cumulatively. While it is understood that some of these activities may result in incidental filling and minor harm to aquatic resources, the exemptions do not apply to discharges that convert extensive areas of water into dry land or impede circulation or reduce the reach or size of the water body. 3 A Legislative History of the Clean Water Act of 1977, 95th Cong., 2d Sess., Ser. No. 95–14 (1978), at 474.

Thus, the Legislative History does not support the commenters' point.

In addition, we have clarified the rule in response to commenters who argued that the proposal was at odds with the CWA because the Act does not specifically require a discharger to make a prima facie case that its activities are exempt from the permit requirements. The revised language in today's rule clarifies that we are not requiring that a project proponent make a prima facie case as to the absence of jurisdiction. Today's rule sets forth the agencies' view that the use of mechanized earth-moving equipment in waters of the U.S. results in a discharge of dredged material unless there is evidence that only incidental fallback results, but expressly provides that the rule does not shift any burdens in administrative or judicial proceedings. This is fully consistent with the Act. See section III B of today's preamble for further discussion.

Some commenters have argued that because the regulatory definition of discharge of dredged material is broad, the presumption is unreasonable and cannot be refuted. As indicated in section II C of today's preamble, we have removed the presumption language and added a descriptive definition of incidental fallback, and also have clarified that the regulation does not shift any burden in any administrative or judicial proceeding under the CWA. We believe the definition mirrors the reach of the statute as interpreted by the courts and, therefore, is not unreasonable. As discussed in section III 1 b, we recognize that there will be situations when the project-specific information indicates that only incidental fallback results from the activity and thus it would not be regulated.

3. Proposal as Misreading Applicable Case Law

A number of commenters claimed that we have misread and are misapplying many of the cases we cited in support of today's action. Most of these comments addressed our analysis of the cases relating to what is a regulable discharge. We do not believe that we are unfairly reading the major cases in this area.

From these cases, we know that the following factors are relevant to determining regulable redeposits: quantity of material redeposited (*Avoyelles* and *Slinger* involved substantial quantities of redeposition); nature and type of relocation (redeposits adjacent to the removal area or backfilling are generally regulated, see *Deaton, Mango, M.C.C. of Florida* and *Slinger*); redeposit after some processing of material (*Rybachek* v. *EPA*, 904 F.2d 1276 (9th Cir. 1990)). As discussed in section II C of today's preamble, an assessment of such factors from the relevant cases will assist in determining whether a regulable redeposit takes place. We believe that in most situations, when applying the factors reflected in the cases, earth-moving activities undertaken using mechanized earth-moving equipment result in a discharge. Today's rule reflects that view while allowing evidence that only incidental fallback will result from the activity to preclude regulation.

Several commenters noted distinguishing facts that they believe undermine our reliance on some of the cases we cited. For example, several commenters noted that *Avoyelles* addresses the "discharge of fill material" not the "discharge of dredged material" and stated that our reliance on that case is misplaced. However, *Avoyelles* addresses the issue of what is an "*addition*," an analysis relevant for both the discharge of fill and the discharge of dredged material. Its conclusion that the redeposit of material constitutes a "discharge" thus is relevant to today's rule. Moreover, the court in *Deaton*, citing *Avoyelles* among other cases, noted that its understanding of the word "addition" as including redeposits was the same as nearly every other Circuit Court to consider the addition question. *Deaton* involved the "discharge of dredged material;" thus, we do not believe it is appropriate to reject *Avoyelles* because the court only expressly addressed how that activity involved a discharge of "fill."

Similar distinguishing facts or other purported problems were asserted with respect to other cases. For example, one commenter argued that we cited *Bay-Houston Towing Company* as if the court had ruled that "temporary stockpiling of peat in a wetland is a regulable discharge." In fact, the parenthetical in the preamble for *Bay-Houston* accurately reflects the court's determination that the activities at issue were subject to regulation ("Spreading the sidecasted bog material from the side of the ditch into the bog for future harvest * * * involves relocating the bog materials * * * for a period of time varying from 'a few hours' to 'a few days'" or more. * * * Thus, while there may be something a step further than 'incidental fallback' which would fall outside of the government's jurisdiction, Bay-Houston's harvesting activities are not it.") *Bay-Houston Towing Company*, No. 98–73252 (E.D. Mich. 2000)(slip opinion) at 8—9. We believe that the cases that we referenced in the proposed and final rule preambles support our action.

Finally, one commenter argued that our discussion of the effects of toxic releases from redeposited material does not justify our attempt to regulate activities that are beyond the scope of the CWA. As we noted in our discussion of the comments concerning the use of an effects based test to establish jurisdiction (see section III A 1 d of today's preamble), today's rule does not attempt to regulate activities beyond the scope of the CWA or base our jurisdiction on effects. We are only asserting jurisdiction over redeposits of dredged material that meet the statutory requirement of a "discharge."

4. Proposal as Complying With Applicable Law

Several other commenters asserted their view that the proposal was

consistent with the court's decision in *NMA*. They noted that the proposal reflected the concept expressed in *AMC* and *NMA* of "incidental fallback." They also noted that the proposal does not regulate incidental fallback, but rather other types of redeposits that exceed incidental fallback. These commenters pointed out that the *NMA* court explicitly declined to hold that the Corps may not legally regulate some forms of redeposit under section 404. For these reasons, the commenters stressed that the proposal fully complied with the *NMA* decision and nationwide injunction. As discussed in section II C of today's preamble, we agree that today's rule is consistent with *AMC* and *NMA* because, among other things, it retains the exclusion of incidental fallback from the definition of discharge of dredged material.

One commenter described the proposal as consistent with *NMA*, even though the proposal may regulate small or unintentional redeposits of dredged material. The commenter argued that *NMA* is misinterpreted when described as standing for the proposition that the word "incidental" in incidental fallback means that no regulable discharge results if only small amounts of material are moved, or material is moved simply as an unintentional consequence of other activity. The commenter stressed that the CWA prohibits the discharge of "any pollutant" not in accordance with a permit, not merely a specific quantity of pollutants. A focus on some concept of "significant" quantity of pollutants by weight, the commenter emphasized, makes no statutory or ecological sense because dredged spoil contains not only inert sediment but also small chemical constituents with potentially large environmental impacts. The commenter also noted that the CWA at no point suggests an added requirement that discharges be intentional.

We agree that neither *NMA* nor the CWA establishes a quantity threshold triggering the permit requirement, but instead regulate any addition of any pollutant which, in the case of dredged material, consists of the dirt, soil or rock that is dredged, including any biological or chemical constituents contained in the dirt, soil or rock. However, the amount of redeposit is a factor that we believe should be considered in determining if a redeposit constitutes more than incidental fallback. We note that under *AMC* and *NMA* incidental fallback involves small volume discharges returned to substantially the same place as the initial removal. We also agree that, under these decisions, incidental fallback does not extend to covering all material that may be incidentally redeposited in the course of excavation activities. Simply because a redeposit of dredged material may be unintended does not mean it is not a discharge, since the CWA requires a permit for *any* addition of a pollutant into waters of the U.S., regardless of the intent of discharger. The broad interpretation of *NMA* urged by other commenters would elevate intent to overarching status in discerning whether an addition has occurred, a result we do not believe appropriate or justified under the CWA scheme. This suggested interpretation would also blur any meaningful distinction between incidental fallback and regulable discharges because it would effectively remove the term "fallback" from EPA's regulation. In our view, to constitute "incidental fallback," a redeposit logically must be both "incidental" (*i.e.*, a minor, subordinate consequence of an activity) and "fallback" (*i.e.*, in substantially the same place as the initial removal). Neither *AMC* nor *NMA* compels us to expand the concept of "incidental fallback" to include all "incidental redeposits" without regard to the volume or location of the redeposit, and we decline to do so for the reasons stated above.

A number of commenters suggested that the agencies should find guidance not only from the *AMC* and *NMA* decisions, but also from other court decisions discussing the discharge of dredged material. In particular, the commenters argued that the "net addition" approach in *NMA* has been explicitly rejected in *Deaton* and implicitly rejected by many others. Two commenters quoted *Deaton* to stress that: "* * *[t]he idea that there could be an addition of a pollutant without an addition of material seems to us entirely unremarkable, at least when an activity transforms some material from a nonpollutant into a pollutant * * *" and that "[i]t is of no consequence that what is now dredged spoil was previously present on the same property in the less threatening form of dirt and vegetation in an undisturbed state." 209 F.3d at 335–36. Based on *Deaton*, several commenters believed there is ample support for a rule considering the redeposit of dredged material outside the place of initial removal as constituting an addition of dredged material. The commenters also noted that such an approach is consistent with the numerous other courts that have concluded that moving around dredged material within the same water body requires a permit. *See, e.g., U.S.* v. *Brace*, 41 F. 3d 117, 122 (3d Cir.), *cert. denied*, 515 U.S. 1158 (1994) (Clearing, churning, mulching, leveling, grading, and landclearing of the formerly wooded and vegetated site was a discharge of a dredged spoil that under the specific facts did not qualify for the 404(f)(1) farming exemption); *United States* v. *Huebner*, 752 F. 2d 1235 (7th Cir.), *cert. denied*, 474 U.S. 817 (1985) (Sidecasting and use of a bulldozer to spread the material over several acres constituted the discharge of dredged material that was not exempt under 404(f)); *Weiszmann* v. *U.S. Army Corps of Engineers*, 526 F. 2d 1302, 1306 (5th Cir. 1976)("Spill" of sediment during dredging of canal was a discharge of a pollutant; court rejected the argument that a spill is not a "discharge.").

We agree that *Deaton* and the other cases cited offer additional support. *Deaton* provides helpful post-*NMA* insights into what is an "addition" of a pollutant, and we note that the NAHB Motion Decision rejected the idea that there is a conflict between *Deaton* and *NMA*. NAHB Motion Decision at 16. We believe today's rule is consistent with *Deaton*, *AMC*, and *NMA*, and complies fully with the injunction affecting the 1993 Tulloch Rule.

Numerous commenters looked to the CWA as a basis for concluding the proposal was consistent with Congressional intent and *NMA*. One commenter observed that numerous courts, including the U.S. Supreme Court, have looked to the underlying policies of the CWA when interpreting authority to protect wetlands. The commenter noted that the goal of the CWA is to maintain the "chemical, physical, and biological integrity of the Nation's waters," and discussed the pollution and adverse effects to aquatic ecosystems caused by wetlands dredging and stream channelization. The commenter emphasized that it would frustrate the goal of the CWA to not regulate the incidental soil movements that occur during excavation. While we agree that regulation of discharges of dredged material into waters of the U.S. is a critical component of achieving CWA goals, consistent with *AMC* and *NMA*, CWA section 404 does not extend to incidental fallback, and today's rule has been drafted to ensure that we regulate only on the basis of the discharge of dredged material.

Some commenters suggested that today's rule also be guided by CWA section 404(f)(2) and its legislative history, which explicitly require the regulation of "incidental" discharges under certain circumstances even if they might otherwise be a result of a specially exempt category of activities. Most of these commenters concluded

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that section 404(f)(2) reflects an explicit Congressional intent to regulate minor and unintentional soil movements that occur during the process of constructing a drainage ditch in wetlands or otherwise are incidental to an activity that "impairs circulation and flow or reduces the reach" of waters of the U.S. One commenter concluded that this section of CWA does not provide support for today's rule.

One commenter asserted that section 404(f)(2) conveys important Congressional intent regarding how the term "discharge" should be interpreted, despite the fact that the section does not define the term "discharge." While agreeing with the District Court in *AMC* that the section does not use effects "to regulate activities that do not themselves constitute discharges" (951 F.Supp. 267, 275 n. 18), the commenter argued that section 404(f)(2) makes clear the proposition that: (1) At a minimum some category of "incidental" discharges are regulated by the CWA; (2) regulation under section 404(f)(2) does not depend on whether the "incidental" discharge itself has significant environmental effects but only on whether the activity, to which the discharge may be only "incidental," has certain environmental effects; and (3) regulated "incidental" discharges can occur during the excavation or dredging process, because the language of the section about "reducing the reach" and "impairing the flow" commonly occur through excavation of drainage ditches.

One commenter suggested that language of section 404(f)(1) similarly supported the idea that a permit should generally be required for activities that drained wetlands. For example, the commenter noted section 404(f)(1)(a) provides an exemption for "minor drainage" associated with farming and silvicultural activity. If discharges from such activities trigger the provisions of section 404(f)(2), the commenter asserted, Congress intended "minor drainage" to be regulated. The commenter argued that the plain language in section 404(f)(1) provides guidance for interpreting the term "discharge." Section 404(f)(1) states that "the discharge of dredged or fill material" resulting from these activities "is not prohibited by or otherwise subject to regulation." In other words, the commenter emphasized, the identified activities that may result in a discharge of dredged or fill material "are exempt from section 404 permit requirements" (quoting Corps and EPA implementing regulations, 33 CFR 323.2; 40 CFR 232.3(c)); otherwise, there would be no need for the 404(f)(1) exemptions.

As discussed in section III A 2 above, today's rule is based on the definition of "discharge of a pollutant" contained in section 502 of the Act, as construed by the caselaw, including the *AMC* and *NMA* opinions finding that incidental fallback is not a regulable discharge under the Act. We agree that section 404(f), and in particular the use of the term "incidental" in section 404(f)(2) provides evidence supporting our rejection of some commenters' assertions that the Act restricts us to only regulating substantial or significant redeposits of dredged material.

B. Overall Reasonableness of Presumption

Many commenters expressed views on the overall reasonableness of the presumption contained in the proposed rule. Commenters maintaining that the presumption is reasonable stated that it would not expand the regulatory authority of the agencies or be contrary to relevant court decisions, but instead would clarify how that existing authority would apply. Others noted that the presumption is reasonable because it is consistent with their experience or Corps experience in evaluating discharges of dredged material. Numerous commenters affirmed the validity of the examples of activities in the preamble of the proposed rule that are presumed to result in a discharge of dredged material, including those who asserted that the presumption would decrease regulatory uncertainty as a consequence. These commenters also stated their view that other specific activities (*e.g.*, grading, leveling, bulldozing) and redeposits of sediment away from the point of excavation during ditching and channelization were regulable discharges.

One commenter indicated that the very nature of how some equipment operates means that it will always result in a discharge with more than incidental fallback. Another asserted that dredging or excavation activities conducted in a wetland or stream will always result in a regulable discharge. A number of commenters provided citations from the scientific literature in support of the presumption for these activities. Several commenters maintained that the presumption is reasonable because in any instance a person conducting such activities would be given the opportunity to demonstrate that only incidental fallback would result.

Today's rule reflects a reasonable belief that mechanized earth-moving equipment when used in waters of the U.S. typically will cause regulated discharges because they are made to move large amounts of earth and will typically relocate the dredged material beyond the place of initial removal. We also recognize, however, that the activities addressed in today's rule will not always result in a discharge, and therefore, the final rule allows the necessary flexibility for considering project-specific information that only incidental fallback results.

Other commenters maintained that the presumption was not reasonable, arguing that it was at odds with controlling legal precedent. These commenters argued that to establish a rebuttable presumption, case law requires us to have a record demonstrating that it is more likely than not that the presumed fact exists. See e.g., *National Mining Association* v. *Babbitt*, 172 F.3d 906 (D.C. Cir. 1999). Some commenters asserted that the presumption was unreasonable because it did not clearly articulate the scope of what is not regulated (*i.e.*, what is incidental fallback). Some commenters also maintained that the presumption was not reasonable because it would require a permit for all of the types of activities addressed in the rule, and would thus regulate dredging itself rather than the discharges that result. Some asserted that because the presumption is not always true, it is not reasonable. Other commenters asserted that the recognition in the proposed rule's preamble that specialized and sophisticated techniques and machinery may limit redeposits to incidental fallback undercuts the proposed rule's presumption. One commenter likened the presumption in the proposed rule to the agencies presuming that all land was jurisdictional under section 404 of the CWA and then taking enforcement action based on that presumption without establishing that the agencies had jurisdiction. Another comment asserted that no technical analysis was offered to support the proposed rule's presumption.

As previously discussed in section II C of today's preamble, the final rule does not establish a rebuttable presumption. Therefore, commenters' arguments about not meeting the legal prerequisites for establishing a rebuttable presumption in the legal sense are not relevant to the final rule. Instead of a rebuttable presumption, the rule states our view that we will regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the U.S. as resulting in a discharge of dredged material unless project-specific evidence shows that the activity results in only incidental fallback. In addition, in response to comments that we received, we have included in the final rule a descriptive definition of "incidental fallback."

As today's rule expressly provides that it does not shift any burden in CWA judicial or administrative proceedings, we do not agree that the rule has the effect of simply presuming jurisdiction, as the burden to show that a regulable discharge occurs has not been altered. Further, because we do not use a rebuttable presumption in today's final rule, the legal standards under the caselaw for judging the adequacy of an agency's record to justify a rebuttable presumption are not relevant to this rule. We also do not agree that today's rule results in a permit being required in every circumstance in which the activities listed occur. Today's rule continues to expressly provide that incidental fallback is not a regulable discharge, and also provides for project-specific consideration of whether only incidental fallback results from the activities addressed by the rule. We believe that the modified regulatory language provides a measure of regulatory certainty as to the types of activities that are likely to result in a regulable discharge, while preserving necessary flexibility to address the specific circumstances of a given project.

We also believe that allowing for project-specific information that the activity is conducted in a manner that results in only incidental fallback is indicative of that flexibility, rather than undercutting the validity of our general view. With respect to consistency with legal precedent and the CWA, we have addressed such issues elsewhere in the preamble, primarily in sections II C and III A.

Today's regulation is based on the nature of earth-moving equipment (*i.e.*, machines that move the earth). Contrary to the assertion that no technical analysis was provided, the preamble to the proposed rule, as well as materials in the rule's record, do provide technical information supporting the reasonableness of the final rule. We also believe the rule is reasonable in that it helps ensure that activities resulting in discharges meant to be addressed by the CWA are in fact regulated. Moreover, the rule's explicit opportunity to consider project-specific evidence to the contrary, and express recognition that it does not shift any burden in any administrative or judicial proceeding under the CWA, ensures that activities outside our jurisdiction are not regulated.

One commenter contended that excavation activities result in environmental benefits, providing an example that the size of certain unnamed drainages underwent a net expansion as the result of excavation at mine sites. Another comment asserted that the presumption was not reasonable because during the interval between the court decision and the publication of the proposed rule, the Corps, according to the commenter, had implicitly or explicitly acknowledged circumstances where excavation activities could be undertaken without a discharge requiring a section 404 permit.

Whether or not one agrees that certain excavation activities result in a net expansion of waters or net benefit to the aquatic environment does not bear upon the issue of whether such activities produce regulable discharges. Many restoration activities and other environmentally beneficial efforts necessitate discharges into waters of the U.S., a number of which are provided authorization under Nationwide General Permits.

A number of commenters requested clarification of, or objected to, the rebuttal process due to vagueness. These commenters sought further specifics as to the type of information that could be used to rebut the presumption and the standard of proof. In addition, they expressed concern that it would be difficult or impractical to rebut the presumption contained in the proposed rule. These commenters were concerned that the proposal placed an unfair burden on the landowner by requiring the applicant to prove a standardless proposition or not rebut the presumption and risk enforcement. These commenters believed it would be difficult to present a valid case because the proposal did not establish a set of clearly defined criteria for rebutting the presumption of discharge; some said that the rule seemed to require that a party undertake the activity with its inherent enforcement risks in order to provide evidence to rebut the presumption; others argued that the description of a regulable discharge is so broad that the presumption can not be rebutted. Others expressed concern that any effort to rebut the presumption would be extremely time-consuming, confusing, technically challenging and cost prohibitive. Other commenters expressed the view that the rule unfairly placed the burden of determining jurisdiction on the regulated community, a burden that should be borne by the government instead.

As noted in the proposed rule preamble, the proposal expressed:

* * * our expectation that, absent a demonstration to the contrary, the activities addressed in the proposed rule typically will result in more than incidental fallback and thus result in regulable redeposits of dredged material. It would not, however, establish a new formal process or new record keeping requirements, and Section 404 permitting and application requirements would continue to apply only to regulable discharges and not to incidental fallback.

65 FR 50113.

The proposal would not have required project proponents or landowners to "prove a negative" or shift the burden of proof as to CWA jurisdiction from the government to the regulated community and the final rule clarifies our intent in this regard. As we have discussed in section II C of today's preamble, in light of comments received, we have revised the rule to make clear that it does not shift the burden of showing that a regulable discharge has occurred under the CWA, and also have included a descriptive definition of non-regulable incidental fallback in order to help provide a standard against which to judge regulable versus non-regulable redeposits. As a result, we do not believe the final rule somehow establishes or requires a time-consuming or expensive rebuttal process. Instead, it provides clarification to those who have unwittingly misread the *NMA* case to preclude regulation of all removal activities in waters of the United States. Issues related to the types of relevant information we will consider in determining if a regulable discharge has occurred are addressed in section II C of today's preamble.

Other commenters felt the proposed rule's presumption was unreasonable in light of the exclusion provided for "normal dredging operations." As in the original August 25, 1993, Tulloch Rule, several commenters suggested that all discharges of dredged material should be regulated, stating that it does not seem reasonable or consistent to exclude discharges incidental to "normal dredging operations" for navigation, while regulating excavation for non-navigation purposes.

In response we note that today's rule does not modify in any respect the provisions of the 1993 rule related to normal dredging operations, and we have not reopened any of these provisions in this rulemaking. The rationale for the normal dredging operation provisions was explained in the August 25, 1993 rulemaking (58 FR 45025–45026), and interested readers are referred to that discussion for further details.

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C. Reasonableness of rule as to specific activities

Commenters cited a number of circumstances or scenarios that may or may not result in a regulable discharge. As a general matter, there was not sufficient information provided in the comments to provide a case-specific response. The discussion below is not intended to be definitive, as an actual decision about whether a particular activity results in a discharge needs to be made on a case-by-case basis considering actual evidence of the particular activity in question. Literature citations and other information that such commenters provided have been added to the record for the rule.

We received several comments regarding mining practices. One stated that for mining-related activities, they were unable to name examples of any equipment used that was not included on the proposed rule's referenced list as falling within the rebuttable presumption. Therefore, according to the commenter, the presumption had the effect of precluding "per se" all mining related activities performed with mechanized equipment in jurisdictional areas in contravention of the *AMC* and *NMA* decisions. Another asserted that under the proposed definition, most placer mines, suction dredges, and exploration trenches would be required to obtain an individual section 404 permit. As discussed in section II C of today's preamble, the final rule does not establish a rebuttable presumption, and provides for consideration of project-specific information to determine if a discharge results. We thus do not believe that today's rule has the effect of "per se" precluding or regulating all activities conducted with mining equipment in waters of the U.S. For example, as noted in section III A 1 a of today's preamble, some suction dredging can be conducted in such a way as not to produce a regulable discharge.

Several commenters raised scenarios involving in-stream mining or other mechanized activities in dry, intermittent streambeds, particularly of the kind that may occur in arid regions of the country. One stated that excavation activities in arid regions would not result in the "parade of horribles" that the agencies presume result from excavation. One commenter put forward two specific scenarios of in-stream mining activities that he believed were not covered as regulated discharges. They were the use of a front-end loader to scoop out material from a dry, intermittent stream up against the stream bank or other face, and the use of a scraper to move material out of the dry stream. Some commenters contended that such activities are conducted with little or no sediment redeposition, stating they do not involve the uprooting of vegetation and are undertaken when the stream bed is completely dry after winter flow ends and before the threat of the first flow in the next winter. Other comments stated that it was necessary to recognize that the southwest is different from the east where "real wetlands" exist, contending that, in the west, wetlands for the most part are only wetlands because the government says they are. The commenters believed that one rule should not apply to all, and that the vast majority of the drainages located in the southwest are in arid climates, which in many instances involve nothing more than isolated ephemeral streams, or dry washes with very little if any aquatic resources and with flows that occur only in response to infrequent rains and effluent from stormwater discharge. Still other comments focused on flood control maintenance activities where they asserted the disturbances are minimal and include only minor water quality impacts such as deposit and removal of sediments to maintain flow conveyance. They stated their activities are typically performed in a dry riverbed or channel, where there are no aquatic resources, the material in the channel is primarily sand and gravel, and the potential for downstream impacts are minimal.

We acknowledge that the presence or absence of water in a jurisdictional stream or other jurisdictional area is a project-specific fact that would need to be considered in deciding whether an activity results in only incidental fallback or a regulable discharge. While we agree that the presence or absence of water is relevant to determining whether a discharge has occurred due to suspension and transport of material to a new location, regulable discharges can still occur in a dry streambed when mechanized equipment is used to push materials from one area of jurisdictional water to another. Discharges can also occur when material is deposited in such a way as to cause materials to slide back into the jurisdictional area.

Several commenters contended that by establishing a rebuttable presumption that mechanized landclearing produces more than incidental fallback, the proposed rule would have resulted in undue hardship by subjecting them to environmental review. They believe that the stated rationale for the agencies' proposed presumption with respect to mechanized landclearing fails to consider the clearly "incidental" nature of any soil movement associated with such activity. Another commenter maintained that landclearing activities, such as grubbing and raking with a small D–7 Caterpillar bulldozer, along with a K–G blade and a root rake, can be conducted so that the only soil displaced during a landclearing would be that which would "stick to and sometimes fall off the tracks of the bulldozer," or would be "scraped off the blade," or would be "pushed up by [a] stump or stuck to [a] stump or its root mass as it was knocked over and pulled from the ground." This commenter also maintained that the agencies were well aware of such landclearing techniques and should acknowledge that they do not produce regulable discharges.

In response, we first note that the final rule has eliminated the use of a rebuttable presumption. As stated elsewhere in today's preamble, the use of mechanized earth-moving equipment to conduct landclearing, because it typically involves movement of soils around a site, would typically involve more than incidental fallback. It is difficult to give generalized conclusions regarding specific subcategories of activities or practices, particularly where the description of the activities lacks detail. Whether a particular activity results in a discharge, or only incidental fallback, necessarily depends upon the particular circumstances of how that activity is conducted, and as a result, today's final rule allows for project-specific considerations. We also note that in the NAHB Motion Decision, the Court declined to decide, on a general level, that the displacing of soils, sediments, debris, or vegetation incidental to the use of root rakes and excavating root systems or knocking down or uplifting trees and stumps to be non-regulable under section 404. NAHB Motion Decision at 15. Whether or not these types of activities are conducted so as to avoid a regulable discharge depends upon project-specific considerations, which today's final rule provides for. See also section III A 1 of today's preamble for further discussion of certain activities, such as use of K–G blades.

Numerous commenters suggested that a backhoe was the classic example of how digging could be done with no more than incidental fallback. They believed that one-motion excavation, such as excavation with a conventional hydraulic-armed bucket (*e.g.*, trackhoe or backhoe), can be easily accomplished with only incidental fallback resulting. They contended that the small amount of material that falls from the bucket is, by definition, incidental to the operation of the bucket and the excavation and that no dredged material is introduced into the jurisdictional area, meaning a regulable discharge has not occurred. In summary, they believed that the proposed rule was too inclusive and should explicitly exclude certain types of excavation from the presumption of discharge.

The preamble to today's rule clearly recognizes that there are situations where, due to the nature of the equipment used and its method of operation, a redeposit may be limited to "incidental fallback." As emphasized repeatedly, today's rule would continue to exclude incidental fallback from regulation under section 404. We note, however, that backhoes by their nature (i.e., the size of the excavation machinery) are typically used to move more than small volumes of material in the course of excavation, and are thus likely to result in redeposits that exceed the definition of incidental fallback (*i.e.*, "*small volumes* of dredged material * * * [that] * * * falls back to *substantially the same place* as the initial removal.") However, the rule allows for project-specific evaluation of whether only incidental fallback occurs, and the definition of incidental fallback includes as an example "the back-spill that comes off a bucket when such small volume of soil or dirt falls into substantially the same place from which it was initially removed."

One commenter suggested that discing is not excavation, since there is no removal, but merely minor displacement. They believed that the proposed rulemaking suggests that disking results in more than incidental fallback, and they question how there can be any fallback of any nature where there is no excavation. Another commenter challenged the reasonableness of the presumption, because not all mechanized activities first "remove" material from waters of the U.S. and therefore such activities could not result in material being redeposited.

We acknowledge that there are mechanized activities that do not first excavate or remove material and therefore redepositional discharges do not occur (*e.g.*, the driving of piles in many circumstances). However, we also note that by pushing or redistributing soil, activities other than excavation can result in the addition of dredged material to a new location, and hence produce a regulable discharge.

Several commenters discussed the routine operation and maintenance of numerous existing flood control channels, levees and detention basins. They stated that existing facilities are vital to tax-paying citizens since they are critically needed to protect their health and safety. They also stated the intent of a flood control excavation project is to maintain hydraulic capacity and entirely remove accumulated sediment and debris from the facility, restoring it to its original lines and grades. They contended that the implementation of existing maintenance-related Best Management Practices addresses negative impacts of this work. Additionally they asserted that, under current regulation, no permit is required for excavation, the work can proceed in a timely manner, and costly submittals are not needed. They also contended that their "finished products" enhance, protect and maintain water quality. The commenters were concerned that all of their excavation projects under the proposed rule would be presumed to include an "addition" of pollutants.

One commenter, on behalf of a water authority, stated that they frequently engage in a number of activities subject to section 404 of the CWA, and which typically fall under the Nationwide permit program. Such activities include the construction of erosion control structures, channelization for temporary water diversions during construction of facilities, and building pipelines that infrequently occur in waters of the U.S. They stated that their efforts to enhance and restore wetlands often require mechanized landclearing to remove non-native, invasive vegetation. They asserted that, if implemented, the proposed revision would inappropriately deem these activities regulable discharges, when in fact they do not involve discharges beyond incidental fallback. Another commenter stated that they have restored several lakes, ponds, and sediment in streams with the one-step removal process under the Tulloch Rule. They utilize specialized low ground pressure equipment, to provide one step removal of accumulated sediments in a low impact manner to restore lakes, ponds, and streams. They also assert that they are very conscientious to prevent any fall back or otherwise discharges of materials into any waters of the U.S. and that they have very successfully restored many acres of U.S. waters, restoring aquatic habitat and navigability, and property values throughout their particular region of the U.S. They believed a distinction needs to be made between restoration activities to remove sediment from smothered aquatic habitats and draining jurisdictional areas to convert waters of the U.S. to upland uses.

In response, we note that some of the routine discharges from operation and maintenance of existing flood control channels, levees and detention basins are exempt from regulation under CWA section 404(f), and the exemption is not affected by this rule. Also, Corps Nationwide and Regional General Permits authorize some of the routine operation and maintenance work. We also note today's rule does not establish new requirements or procedures, and thus does not necessitate costly new submittals. Additionally, today's rule no longer establishes a rebuttable presumption, and project-specific information will be considered in determining whether an activity results in more than incidental fallback. If, as some of these commenters assert, their activities do not result in more than incidental fallback, then they would not be regulated under the CWA, nor are they currently regulated. We also note that because the determination of jurisdiction rests on the presence of a discharge of dredged material, which is not dependent upon either the effects of the activity or the intent of the person, the fact that an activity may or may not be beneficial, or is undertaken with the intent to remove material, does not form the basis for determining jurisdiction.

One commenter was concerned that the proposed rule's presumption would seriously impede the ability of water users to maintain their diversion structures, irrigation ditches, retaining ponds and reservoirs. In light of the fact that the term "waters of the U.S." determines the extent of the Corps jurisdiction under the CWA, they believed that the proposed rule would subject even the most routine maintenance of ditches, headgates and off-channel storage facilities to the permitting process and that resulting delays would hamper the efficient operation of water delivery systems, and jeopardize safety as well.

Today's final rule does not establish a rebuttable presumption, and as discussed in section II C and III A of today's preamble, would not result in the regulation of incidental fallback. We also note that because the determination of jurisdiction rests on the presence of a discharge of dredged material, which is not dependent upon the effects of the activity, the fact that an activity may or may not be beneficial does not form the basis for determining jurisdiction.

D. Regulation on Basis of Toxics/ Pollutant Releases

A number of commenters from the science profession provided extensive

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discussion regarding the discharge of pollutants. These scientists contended that mechanized excavation and drainage activities in wetlands, rivers and streams almost always cause the discharge of pollutants into waters of the U.S., and frequently result in severely harmful environmental effects. They noted that it is well-established in the peer-reviewed scientific literature that wetlands and many parts of river and stream beds act as natural sinks, collecting sediment, nutrients, heavy metals (*e.g.* lead, mercury, cadmium, zinc) toxic organic compounds (*e.g.*, polycyclic aromatic hydrocarbons-PAHs, polychlorinated biphenyls-PCBs) and other pollutants which enter wetlands through polluted runoff, direct discharges, and atmospheric deposition. Moreover, they provided citations which describe other characteristics of wetlands and water bottoms that also play an important role in storing precipitated metals and other pollutants. For instance, over time, fresh layers of sediment added to wetland and river and stream beds can gradually bury and sequester trace metals and toxics. Vegetation also helps soils immobilize toxins and heavy metals by attenuating flow of surface waters and stabilizing the substrate, allowing metal-contaminated suspended particles to settle into sediment.

Furthermore, these commenters cited scientific literature which illustrates that wetland soils and river and stream beds immobilize toxins and heavy metals and other pollutants. Briefly summarized, these indicate that anaerobic conditions occur when wetland, river, and stream soils are saturated by water for a sufficient length of time; microbial decomposition of organic matter in the sediment produces anaerobic conditions. The anaerobic soil environment, with the accompanying neutral pH levels and presence of organic matter in the sediment, triggers different chemical and microbial processes in the soils. These characteristic conditions of wetland, river, and stream soils result in the precipitation of trace and toxic metals as inorganic compounds, or complexed with large molecular-weight organic material—effectively immobilizing these compounds.

These commenters maintained, and provided citations illustrating, that when a wetland is ditched or drained, or a riverbed excavated, channelized or dredged, mechanized activities dislodge some of the sediments and resuspend them in the water column from both the bottom and the sides of the ditch or other waterbody. Water draining from ditched or excavated wetlands carries suspended sediments down ditches to receiving waters; similar resuspension and downstream movement occur when river and stream bottoms are channelized. They furthermore provided supporting literature from scientific journals documenting that when wetlands are ditched or drained or rivers and streams excavated, some pollutants move into the water column. As described, when wetlands soils are exposed to air, the anaerobic, neutral pH conditions that promoted toxins and heavy metals to precipitate-out can shift to aerobic conditions, and the soil chemistry is transformed by the oxidizing environment and possible shift in pH. The mobility of metals bound in sediment is generally determined by pH, oxidation-reduction conditions, and organic complexation—thus, precipitates may begin to dissolve and become available for transport when soils are exposed to air. Contaminated sediment resuspension does not usually result in a pH change in rivers; but there, as in wetlands, microbial action can release such pollutants as trace elements during the reoxidation of anoxic sediments that subsequently flow into drainage ditches and into receiving waters.

Finally, commenters from the science community pointed out that turbulence prolongs the suspension of sediment and contaminants in the water column, so moving water (*e.g.*, drainage ditches) retains suspended materials longer than standing water. In general, organic chemicals and toxic metals are more likely to be attached to smaller, lighter particles, which also are more likely to remain suspended in the water column. The commenters noted that smaller particles may also give up organic chemicals more efficiently than larger particles. Thus, they assert, exposing contaminated sediment to the water column causes some dissolution of pollutants, while the direct discharge of sediment into the water during dredging accelerates the release of contaminants.

The agencies thank these commenters for their detailed discussion of current scientific literature, which we have included in the administrative record. We agree that the evidence presented points to the harmful environmental effects that can be associated with redeposits of dredged material incidental to excavation activity within a particular water of the United States, even those redposits occurring in close proximity the point of initial removal. To the extent commenters believe that we should determine the scope of our jurisdiction based on such environmental effects, however, we decline to do so. As stated previously, today's rule does not adopt an effect-based test to determining whether a redeposit is regulated, but instead defines jurisdiction based on the definition of "discharge of a pollutant" in the Act and relevant caselaw. We have chosen to define our jurisdiction based not on the effects of the discharge, but on its physical characteristics—*i.e.*, whether the amount and location of the redeposit renders it incidental fallback or a regulated discharge. Nonetheless, the evidence reviewed in these comments points to serious environmental concerns that can be associated with redeposits other than incidental fallback (which are regulated under today's rule), and support the agencies' view that it would not be appropriate, as suggested by some commenters, to establish quantitative volume or other "significance" thresholds before asserting jurisdiction over such redeposits.

One technical commenter contended that the likelihood of toxicant release and mobility is many times greater for navigational dredging than it is for most other excavation activities, especially in wetlands. This commenter asserted that the primary reason for this is that the vast majority of excavation projects that would be subject to the proposed rule do not have toxic substances in toxic amounts present in the natural soils, but many navigational dredging projects in commercial ports do. The commenter stated that while it is true that some contaminants may be more mobile in an oxidized than reduced state, the conclusion that contaminants will be released from normal excavation project activities is without technical merit. The commenter further recommended that since the effects of navigational dredging were determined to be acceptable, the results of those same studies should be used to establish what is more than incidental fallback. As noted in today's preamble, the potential for release and distribution of pollutants contained in dredged material is a factor that would be considered in determining if a regulable discharge of dredged material beyond the place of initial removal results. We do not agree with the apparent suggestion that wetlands soils are necessarily in a pristine or natural state. As discussed in the proposed rule's preamble, wetlands can act as sinks for pollutants, and sequester contaminants. In addition, we note that the 404 program applies to waters of the U.S., which include not just wetlands, but rivers, lakes, harbors and the like as well. Finally, we do not agree that the environmental effects of harbor dredging should somehow be

used to establish what is more than incidental fallback. As previously noted in section III A 1 d of today's preamble and also discussed below, we do not believe that use of an effects-based test for jurisdiction is appropriate in light of the *AMC* and *NMA* decisions.

Other commenters strongly opposed the idea that the transport of dredged material downstream or the release of pollutants as a result of excavation activities should be treated as a discharge. Some of these commenters asserted that consideration of impacts on water quality resulted in the use of an "effects-based test" to establish jurisdiction, which they indicated was not allowable under the *NMA* decision. Others expressed the view that such an interpretation would result in regulation of incidental fallback and thus not be allowable.

These comments refer to the discussion in the proposed rule's preamble regarding the information that we would use to evaluate whether a regulable discharge has occurred. Among other things, that preamble stated:

> In evaluating [whether regulable discharges have occurred], the permitting authority will consider the nature of the equipment and its method of operation and whether redeposited material is suspended in the water column so as to release contaminants or increase turbidity, as well as whether downstream transportation and relocation of redeposited dredged material results.

65 Fed. Reg. at 50113.

The agencies continue to believe that when determining whether a discharge has occurred, it is relevant and appropriate to consider whether an activity results in the release and distribution of sequestered pollutants into the water column or in suspended material being carried away from the place of removal before settling out. In such cases, a pollutant is being added to a new location. This is not the use of an "effects-based test" to establish the existence of a discharge, but rather recognizes that when pollutants are released or relocated as a result of the use of earth-moving equipment, this can result in the "addition" of a "pollutant" from a "point source" to "waters of the U.S.," and thus constitute a regulable discharge. In *Deaton*, the Fourth Circuit recognized that one of the reasons sidecasting should be treated as a regulable discharge is that: "When a wetland is dredged, however, and the dredged spoil is redeposited in the water or wetland, pollutants that had been trapped may be suddenly released." *Deaton*, 209 F.3d at 336. The *NMA* court indicated that resuspension should not be used to regulate excavation and dredging activities that result only in incidental fallback. 145 F.3d at 1407. We would consider the nature and amount of any resuspension and transport in determining whether a regulable discharge occurred.

We also do not agree that allowing for consideration of the release of pollutants contained in the dredged material into the water column and the transport of suspended material downstream would necessarily result in the regulation of incidental fallback. These are relevant factors in determining if material has been moved to a new location, and consequently resulted in the addition of a pollutant to a new area. However, in evaluating these considerations, we would take into account the volume and location of redeposited material so as not to regulate incidental fallback.

A number of other commenters requested that the proposed rule be strengthened so as to require a permit for excavation and channelization activities which release even small amounts of pollutants (such as heavy metals or PCBs) into the water column or which would result in their transport down stream. Under today's rule, such pollutants (which constitute dredged material by virtue of having been dredged or excavated from waters of the U.S.) (see *e.g.*, 40 CFR 232.2 (defining dredged material as "material that is dredged or excavated from waters of the U.S.)) would be regulated if resuspended and transported to a location beyond the place of initial removal in such volume so as to constitute other than incidental fallback. We believe that is the appropriate test for evaluating any redeposit of dredged material, for reasons stated previously. As explained elsewhere in today's preamble, we expect that the use of mechanized earth-moving equipment in waters of the U.S. will generally result in a regulable discharge. However, we do not believe that it is appropriate to *per se* treat the redeposits described by these comments as a discharge of dredged material, as consideration needs to be given to the factors of each particular case in making a regulatory decision.

E. Need for Brightline Test

Many commenters expressed concern that the proposal did not provide a clear definition of what constitutes a regulable discharge or incidental fallback. Many of these commenters were concerned that without clear standards that the regulated community or the regulators can use in order to determine when an activity is subject to federal jurisdiction, the proposal would have resulted in a system that was arbitrary and uncertain and was too vague in light of the CWA's civil and criminal penalty scheme. Some of these commenters expressed the view that without clear standards the rule would be void for vagueness, not meet the due process standard of providing fair warning of what activities are regulated, or violate the Constitution's non-delegation doctrine as construed in *American Trucking Association* v. *Browner*, 175 F.3d 1027 (D.C. Cir. 1999). Commenters also expressed concern that this would result in uncertainty and the need for subjective case-by-case determinations. Many of those concerned with the lack of a definition requested the proposal be withdrawn and re-proposed to include such a provision; some of these also indicated that guidance on what constitutes a regulable discharge versus incidental fallback needs to take the form of a rule, and should not be attempted through informal guidance.

Our May 10, 1999, rulemaking amended the substantive aspects of the definition of "discharge of dredged material" to provide that we no longer would regulate "any" redeposit, and that "incidental fallback" was not subject to regulation. That continues to be the case under today's final rule. As noted in section II B of today's preamble, the May 10 rulemaking was considered by the *NMA* court in its September 13, 2000, opinion and found to be in compliance with the *AMC* and *NMA* opinions and associated injunction. NAHB Motion Decision at 10. Today's rule does not alter the substantive regulatory definition of what constitutes a discharge. Rather than create arbitrary or unclear standards as some commenters have claimed, today's rule provides additional clarification for both industry and the regulatory agencies as to what types of activities are likely to result in regulable discharges.

In addition, the preamble to the proposed rule did provide guidance as to the agencies' views on what constitutes a regulable redeposit versus incidental fallback. For example, that preamble explained that as the *NMA* court and other judicial decisions recognize, the redeposit of dredged material "some distance" from the point of removal (see *NMA*, 145 F.3d at 1407) can be a regulable discharge. Similarly, the preamble noted the language from the *NMA* opinion describing what constitutes incidental fallback: involving the return of ". . . dredged material virtually to the spot from which it came" (145 F.3d at 1403), as well as occurring "when redeposit takes

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place in substantially the same spot as the initial removal." 145 F.3d at 1401). Moreover, as explained in section II C of today's preamble, in response to comments on the need for a definition of incidental fallback, we have modified the final rule to include a descriptive definition consistent with relevant case law. Since the definition of incidental fallback reflects discussion in the *AMC* and *NMA* opinions of incidental fallback, and those cases were discussed in the preamble to the proposed rule, we do not believe that this revision to our proposal necessitates reproposal.

A number of commenters requested that the agencies adopt a "brightline test" to distinguish between incidental fallback on the one hand and regulable discharges on the other. Some of the commenters opposed to the proposed rule expressed the view that the proposal was contrary to the *NMA* decision and the preamble to the agencies' earlier May 10, 1999, rulemaking, in that it did not provide a sufficiently reasoned or clear attempt to draw a line between incidental fallback and regulable redeposits. We believe that the descriptive definition of incidental fallback in today's rule will provide greater certainty, but do not agree that the court in *NMA* mandated that we take any particular approach to defining our regulatory jurisdiction. *NMA* only stated that "a reasoned attempt by the agencies to draw such a line would merit considerable deference." 145 F.2d at 1405 (footnote omitted). As discussed previously, a descriptive definition of incidental fallback has been added to today's final rule. We do not believe that a more detailed definition is appropriate at this time.

Some comments suggested drawing a bright line on the basis of measurable criteria such as cubic yards of dredged material, total acres of land disturbed, gallons of water removed, tons of sediment disposed, or similar measures. Although consideration of factors such as the volume and amount of the material and nature and distance of relocation are relevant in determining whether incidental fallback or a regulable discharge occurs, these factors are inter-twined with one another, and do not lend themselves to a segregable hard and fast quantification of each specific factor (or combination of factors) so as to give rise to a hard and fast test. Moreover, we are not aware of, nor have commenters suggested, a sound technical or legal basis on which to establish brightline quantifiable limits on such factors. For example, we do not believe it is technically sound or feasible to simply establish universally applicable cut-off points for amount or distance.

Another commenter requested a brightline test be established by having the rule state a presumption *against* discharge for incidental soil movement associated with mechanized landclearing and excavation activities. More specifically, this commenter recommended that the rule provide that no discharge results from incidental soil movement associated with mechanized landclearing, ditching, channelization, draining, in-stream mining, or other mechanized excavation activity such as when (1) excavated soils and sediments fall from a bucket, blade or other implement back to the same general area from which it was removed; (2) surface soils, sediments, debris or vegetation are scraped, displaced or penetrated incidental to the use of machinery; (3) excavation machinery is dragged through soils or sediments; or (4) vegetative root systems are exposed, or trees and stumps are knocked down or uplifted, incidental to the use of machinery. The commenter's recommendation went on to provide that otherwise the Agency may demonstrate on a case by case basis that mechanized excavation activity in waters of the U.S. results in the discharge of dredged material.

We do not agree with this suggestion for a number of reasons. First, we believe a test of the "same general area from which it was removed" for determining whether incidental fallback has occurred could create the impression that material redeposited in virtually any part of the work area would not be a discharge, which we believe would be too broad of a test. As both *NMA* and *Deaton* recognize, for example, placement of dredged material in as close a proximity to the excavation point as the side of a ditch can result in a regulable redeposit. We thus believe a formulation based upon use of a "same general area test" to be too expansive to properly convey that short-distance relocations can result in regulable discharges. As discussed in section II C of today's preamble, we do believe a fair and objective reading of the *AMC* and *NMA* cases and the NAHB Motion Decision, as well as other relevant redeposit cases discussed in that section of the preamble, is that incidental fallback occurs when redeposit takes place in "substantially" the same place as the initial removal, and have so provided in today's final rule.

Moreover, the examples provided by the commenter (*e.g.*, dragging of equipment, scraping or displacement of soil or vegetation, uplifting of tree roots) often can result in the relocation and redeposit in waters of the U.S. of substantial volumes of material over considerable distances so as to constitute more than incidental fallback under the *AMC* and *NMA* opinions. The approach suggested by this commenter reflects perhaps a different conception of what constitutes incidental fallback than is contained in today's rule. If incidental fallback were to include any material incidentally redeposited in the course of mechanized activity, the establishment of a presumption of exclusion of the activities listed by the commenter might follow as reasonable. As discussed immediately above in this section, however, we believe that this formulation is not warranted and would be too broad. We believe that we have properly described incidental fallback in today's rule, and that it would not be reasonable to assume the activities listed by the commenter only cause incidental fallback. In fact, as today's rule clarifies, we regard such activities as typically resulting in more than incidental fallback, absent project-specific information to the contrary. However, there is substantial flexibility under today's rule to consider the types of activities listed by the commenter and determine on a case-by-case basis whether a specific project is subject to regulation.

Other commenters recommended that while the term "discharge" should not encompass the fallback of material precisely to the same spot during excavation activities, when the movement of the dredged material raises new environmental concerns (such as release of pollutants into the water column or more ready erosion of the material and movement downstream), this relocation should be treated as a discharge. These and other commenters also requested that the rule make clear that a permit is required for excavation and channelization activities which release even small amounts of pollutants (such as heavy metals or PCBs) into the water column or which would result in their transport downstream. For reasons stated previously, we do not agree that whether an activity results in new environmental concerns should be used as the basis for establishing jurisdiction. As discussed in both the proposed rule's and today's preamble, the nature and amount of transport and resettling of excavated material downstream from the area of removal, or release of pollutants previously bound up in sediment beyond the place of initial removal, are relevant factors to consider in determining if movement and relocation other than incidental fallback has occurred. Thus, these factors are relevant to determining whether a redeposit other than incidental fallback occurs, and are not used to assert jurisdiction on the basis of environmental effects.

Other comments urged that the rule identify certain activities as always requiring a permit or consisting of a regulable discharge. Examples mentioned in such comments included sidecasting, backfilling, and stockpiling; those supporting strengthening of the proposal also included bulldozing, grading, and leveling as always requiring a section 404 permit. As previously discussed in section II C of today's preamble and the preamble to the proposed rule, case law has found a number of activities (*e.g.*, sidecasting, backfilling of trenches) to be regulable discharges under section 404. We believe the preamble discussion on these points to be sufficiently clear and that inclusion of such specific examples in the regulation itself is unnecessary. To the extent grading and leveling involve redistribution of soils in waters of the U.S. around a site to create a level area, such activities would appear to typically involve not only a discharge of dredged material (through the pushing of dredged material from one location to another) but also possibly fill material (by filling low areas). *See Avoyelles* (movement of soils to depressed areas as discharge of fill material). In any event, case law on redeposit issues continues to evolve over time. Accordingly, we do not believe the listing of specific examples of discharges in the regulation itself to be appropriate.

F. Clarity of Proposal and Implementation Issues

1. Clarity

A number of commenters sought clarification with regard to section 404(f), as they were concerned or confused by the references to section 404(f) in the preamble to the proposed rule. Most of these commenters interpreted the preamble language to indicate that the rule would establish that certain silviculture or farming activities described in section 404(f) as being exempt from permit requirements would now be subject to regulation, particularly because these activities may involve the types of machinery and actions referenced in the proposal.

We regret that the references to section 404(f) in the preamble may have caused confusion regarding the relationship of section 404(f) to the rulemaking and emphasize that today's rule does not change the interpretation or use of the exemptions in any manner. Today's rule concerns the fundamental issue of what activities result in a discharge that is regulated under section 404. The section 404(f) exemptions describe those activities that, although resulting in a discharge, do not require a permit if they are conducted consistent with that provision. Activities covered by section 404(f), including silviculture, ranching, and agriculture, involving the use of equipment and methods such as those described in the rulemaking remain exempt, subject to the provisions of section 404(f), and are not altered by today's rule.

2. Comment Period

Two commenters requested an extension of the public comment period in order to better gauge the effects of the rule on their membership. One of these requested additional time to assess the potential impacts of the proposal on their industry and also requested a public hearing on the proposal. The other commenter expressed the view that the proposal was fundamentally different from previous iterations of the Tulloch Rule, and sought additional time in order to obtain more information on the physical settings and the use of many types of equipment by its membership. We believe that a 60-day comment period was adequate time to obtain widespread and effective public comment and that extending the public comment period or holding a public hearing is unnecessary. In general, it appears the public understood the proposal and was able to provide comments in a timely fashion. Of the approximately 9,650 comments that were received, only two sought an extension of the comment period, and only one of those requested a hearing. In addition, those two commenters did file specific and substantive comments within the 60-day comment period.

3. Implementation

A number of commenters raised issues associated with the implementation of the rule, including the ability of the agencies to effectively enforce, monitor, and budget for it, as well as the appropriate exercise of discretion on behalf of the agencies. Several commenters indicated that the agencies need to dedicate enough staff and other resources necessary to effectively enforce the rule. One commenter specifically recommended that the agencies request the necessary funding from Congress to allow effective implementation. Another commenter specifically mentioned the need for the agencies (or States or local governments) to monitor activities not requiring a permit, to determine if they were in fact not resulting in a discharge. One of these commenters supported review and documentation of completed projects determined a priori to not result in a discharge, to ensure that in fact no discharge resulted. One commenter who supported the objective of the proposed rule nonetheless recommended that we streamline the permitting process associated with activities that may involve incidental fallback. Another commenter specifically cited concern that the Corps would not be able to efficiently process permits and asserted that the processing of Nationwide General Permits is not as efficient as the agencies contend.

We concur with the commenters who stated that it was important for us to have adequate resources to effectively enforce, monitor, and otherwise implement the proposed rule. Consistent with agency priorities for aquatic resource protection and our overall missions, we do propose budgets to adequately accomplish our CWA statutory objectives. Effective enforcement and monitoring is an important part of the section 404 regulatory program. We will coordinate with State and local partners to ensure that today's rule, as well as wetlands regulations, in general, have effective compliance. Over the last two years, unreported Tulloch activities presented a challenge to us in obtaining information on the extent and nature of wetlands destruction that has occurred following the *NMA* decision. While many of these challenges remain, we believe that satisfactory monitoring, in cooperation with others, can be accomplished to adequately track the results of today's rule. We agree that pre-project information alone should not necessarily be the basis for concluding that an activity results only in incidental fallback and that other measures, such as field investigation or site visits, may be needed to assess whether an activity has actually resulted in any regulable discharges.

The agencies' goal is to work cooperatively with the public to ensure that their activities in the Nation's waters are fully consistent with the requirements of the Act and its implementing regulations, including today's rule. The Corps of Engineers is the principal contact for the public both in the context of responding to questions that arise prior to conducting any proposed activity in waters of the U.S., as well as monitoring permitted and unpermitted activities as they proceed in waters to verify compliance with permit conditions or, in the case of unpermitted activities, to ensure that no

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regulable discharge takes place. Consistent with its statutory responsibilities and relevant Memoranda of Agreement between EPA and the Corps, EPA also may serve as the lead agency in determining whether a regulable discharge has occurred.

It is a more effective use of agency resources and more efficient for project proponents to coordinate with the Corps before an activity in waters of the U.S. occurs to determine whether or not the project triggers the need for a CWA permit. We strongly recommend that anyone proposing projects which, for example, involve earth-moving activities using mechanized equipment such as bulldozers or backhoes contact the Corps well in advance of the project to determine whether or not a regulable discharge will occur. As appropriate, the Corps will also be involved in working with the public on a project-specific basis to monitor ongoing or completed projects which proceed without a section 404 permit through site visits, remote sensing, field investigations and so forth to verify that no regulable discharges have occurred.

With respect to streamlining the permit process for discharges that may involve incidental fallback, we note that neither the proposal nor today's rule establishes new procedural or informational requirements. In addition, we have provided additional discussion in today's preamble (see section II C) as well as a descriptive definition of incidental fallback in order to clarify the factors and information relevant to making the determination of incidental fallback versus regulable discharge. Given that case-specific evidence regarding whether an activity results only in incidental fallback will be considered, general authorizations based on a common set of circumstances would be inappropriate.

We have undertaken a number of successful efforts to ensure that activities regulated under the section 404 program are evaluated in an efficient manner, while ensuring environmental protection. In particular, with regard to the comment on the development and use of Nationwide General permits, such permits have provided an efficient process for allowing discharges with truly minimal impacts to move forward with little regulatory review, consistent with conditions that provide for aquatic resource protection. Despite successive annual increases in the use of general permits over the last ten years, processing times have remained low. Some 63,780 general permits required a priori action on the part of the Corps in Fiscal Year 2000 (as compared with approximately 4,313 individual permits), and these were evaluated in an average time of only 19 days.

A number of commenters addressed the issue of discretion by the agencies in implementing today's rule. The majority of these commenters advocated that discretion on the part of Corps Districts should be minimized. Several commenters stressed the need for consistent interpretation and application of the rule, citing the fact that several State and local jurisdictions have multiple Corps Districts. Other commenters noted that national guidance or consultation with the Headquarters offices of the agencies should be required, particularly if any local operating procedures for the rule are developed. One commenter recommended that Corps field staff document all communications with potential dischargers and submit such information to Corps and EPA Headquarters for periodic review. One commenter indicated that if any determination is a "close call" with regard to whether or not a discharge constitutes incidental fallback, it should be considered regulated in order to err on the side of protecting wetlands. One commenter asked for clarification that previous understandings with Corps Districts regarding certain "Tulloch" activities would remain in effect, specifically mentioning the preamble text in the proposed rule regarding the cutting of vegetation, as well as the use of vehicles and other "landclearing and excavation practices that have been deemed to fall within the exclusions . . . under the *Tulloch* Rule." Another commenter provided a specific example of guidance provided by a District that the commenter asserted ran counter to the agencies interpretation of the *NMA* decision: that entities "may engage in instream mining and dredging if the intent of the work is to create a discharge of dredged material that results only in incidental fallback."

We concur with those commenters that advocate consistent implementation of today's rule across Corps Districts, but also recognize that the case-specific nature of incidental fallback determinations necessitates some element of discretion. We have developed guidance on program implementation in light of the *AMC* and *NMA* decisions (issued on April 11, 1997, and updated on July 10, 1998), as well as provided further guidance in the May 10, 1999, rulemaking and today's rulemaking action. As additional issues are raised in the application of today's rule that lend themselves to additional guidance, we will provide such guidance. Moreover, to the extent that regional circumstances allow regional guidance to be provided on circumstances common to a particular part of the country, we will provide that as well. In the preparation of any regional guidance and in the consideration of "close calls," our headquarters will provide oversight and review to assist our field staff in reaching determinations that are consistent with governing law.

With respect to previous understandings with Corps Districts regarding the regulation of certain "Tulloch" activities, today's rule describes how potential discharges will be addressed. While the lack of specific details in many of the specific comments prevents us from making a determination here, we can clarify that the cutting of vegetation above the roots is not regulated as a discharge of dredged material under section 404. 33 CFR 323.2(d)(2)(ii) and 40 CFR 232.2. Likewise, driving vehicles such as cars, off-road vehicles, or farm tractors through a wetland in a manner in which such vehicle is designed to be used generally is not subject to regulation under CWA section 404. See our August 4, 1995, guidance entitled "Applicability of Clean Water Act Section 404 to Vehicle Use in Waters of the U.S." Landclearing and excavation practices are discussed above in section III C of today's preamble. With respect to the comment on guidance said to have been provided by a District that entities "may engage in instream mining and dredging if the intent of the work is to create a discharge of dredged material that results only in incidental fallback," the proper consideration is not the intent of the discharger, but whether, in fact, the activity results in only incidental fallback.

G. Need to Amend CWA

One commenter, while disagreeing with the *NMA* decision and its reasoning, indicated that besides rulemaking, the agencies also should seek action by Congress to amend the CWA so as to clarify agency authority to fulfill their duty under the CWA to protect the Nation's waters. Other commenters who were opposed to the proposed rulemaking expressed the view that it was necessary to obtain an amendment to the CWA before, or instead of, proceeding with rulemaking. Many of these commenters believed that the proposed rule exceeded the agencies' authority under the CWA (see discussion in section III A of today's preamble) and thus could not be undertaken without an amendment to the Act. In fact, one such commenter suggested that language in EPA

Administrator Carol Browner's Press Release announcing the August 16, 2000, proposal reflected a recognition that the agencies do not have the authority to undertake the action reflected in this rule because it called on "Congress to strengthen the Clean Water Act to fully protect and restore America's wetlands." Others felt that in light of the uncertainties and importance of the issue it was appropriate or even necessary to wait for Congressional action before proceeding. We do not agree. We believe today's rule is entirely consistent with the current CWA and relevant case law, and helps to clarify for the regulated community and the agencies what activities are likely to result in regulable discharges. In keeping with the *AMC* and *NMA* cases and the NAHB Motion Decision, today's rule does not provide for regulation of "incidental fallback," and a descriptive definition of that term has been provided in today's rule language. The language in the press release calling on Congress to strengthen the Act was a recognition that the statute, as interpreted in *AMC* and *NMA*, does not extend to regulating incidental fallback. Since today's rule does not regulate incidental fallback, but rather articulates an approach to determining whether redeposits of dredged material come within our existing statutory authority, today's rule is consistent with both the press release and the CWA as interpreted by the courts.

H. Other Issues

1. Loss Data

As noted in the proposed rule, available information indicated that more than 20,000 acres of wetlands were subject to ditching and more than 150 miles of stream channelized since the *NMA* decision. The activities causing such "Tulloch" losses typically take place without a CWA section 404 permit, and therefore are not systematically reported to either EPA or the Corps of Engineers. As a result, the numbers are believed to likely underestimate actual Tulloch losses. The proposed rule invited the public to submit further relevant information on Tulloch losses.

One commenter suggested that this invitation to submit data on Tulloch losses was an attempt to establish a *post hoc* rationalization for today's rule. We disagree. The CWA section 404 establishes a regulatory program for discharges of dredged material into waters of the U.S. The Act does not establish a threshold of impacts after which an activity will be regulated, nor as explained in sections III A 4 and III D of today's preamble, does today's rule use an effects-based test to establish jurisdiction. As a result, we do not need aggregate data showing extensive Tulloch losses or impacts to justify today's rulemaking. Such information is nonetheless helpful in answering inquiries from the public about the impacts of Tulloch activities, as well as in helping focus our limited resources on important environmental problems.

Many commenters emphasized that the uncertainty created by the *NMA* decision has led to a surge in wetlands drainage, resulting in deposits into wetlands of both unregulated "incidental fallback" and regulable redeposit of dredged material. Commenters expressed concern that project proponents may decide that a section 404 permit is not necessary and not contact the Corps for verification. One commenter described a philosophy of "if you don't ask, you don't have to worry about being told no." Several commenters suggested that Tulloch losses will continue to increase until the regulatory definition of "discharge of dredged material" is clarified and legislation closes the Tulloch "loophole." We appreciate these concerns and believe that by setting forth our expectation as to activities that are likely to result in regulable discharges, today's rule will help enhance protection of the Nation's aquatic resources.

Several commenters asserted that the proposal's estimates of Tulloch losses were conservative, and do not include impacts from numerous activities occurring throughout the U.S. For example, one commenter noted that its State data underestimated total wetland acres drained because estimates were based on less than 80% of identified sites on which unauthorized drainage had occurred. Other commenters emphasized that comprehensive data on Tulloch losses is difficult because developers are not contacting the Corps of Engineers or EPA about many of their projects. We agree that because Tulloch losses are not systematically reported, we have likely underestimated the magnitude of these losses.

Numerous commenters submitted information about wetlands and stream losses since the decision in *NMA*, and emphasized that impacts are national in scope. One commenter noted that Tulloch losses have been reported in some of the six ecoregions in the U.S. that have been targeted for special investment due to their biological diversity, and expressed concern that future losses in these key regions could have serious impacts on tourism, fishing, and other industries reliant on ecological resources. Many commenters highlighted Tulloch losses in their areas, or described aquatic resources that could be destroyed by future projects unregulated due to the "Tulloch loophole." These examples illustrate the nationwide implications of the NMA decision. Descriptions were received of losses in Arkansas, California, Connecticut, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, Nebraska, New York, North Carolina, Ohio, Oregon, Tennessee, Wisconsin, and Virginia, among others. Public comments providing these examples are included in the record for today's rule.

Many commenters discussed the environmental effects of Tulloch losses. Some commenters noted that extensive ditching and drainage of wetlands had resulted in siltation, sedimentation, and turbidity violations in designated shellfish waters, primary and secondary fishery nursery areas, and other sensitive coastal and estuarine waters. Commenters described potential adverse effects of instream mining on anadromous fish habitat in the Pacific Northwest and other regions. Several commenters expressed concern about the potential impacts on prairie potholes and other wetlands that provide important habitat for migratory waterfowl. Several commenters expressed concern about impacts on neighbors of unregulated wetlands drainage. Other adverse environmental effects from Tulloch losses described by commenters included: flooding of neighboring businesses, homes and farms; degradation of receiving waters; shellfish bed closures; degradation of drinking water supplies; loss of critical habitat; loss of aesthetics; loss of recreational activities such as bird watching; and increased toxics loadings from disturbed sediments.

Several commenters discussed the environmental impacts of the discharge of dredged material. One commenter quoted the court decision in *Deaton*, noting that the environmental impacts from the discharge of dredged material "[a]re no less harmful when the dredged spoil is redeposited in the same wetland from which it was excavated. The effects of hydrology and the environment are the same." The adverse environmental impacts of discharge described by commenters included such effects as: increased turbidity; reduced light penetration; mortality of aquatic plants and animals; depletion of dissolved oxygen; resuspension of contaminants; release of pollutants (heavy metals, nutrients, and other chemicals) from suspended material;

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biological uptake of pollutants; sedimentation and smothering of benthic organisms; algal population explosions; fish kills; nuisance odors; and a decline in biodiversity. As we noted in our discussion of the comments concerning the use of an effects based test to establish jurisdiction (see section III A 1 d of today's preamble), today's rule does not attempt to regulate activities beyond the scope of the CWA or base our jurisdiction on effects.

Some commenters characterized as unsubstantiated the preamble's estimates of wetland acres lost and stream miles channelized after the Tulloch Rule's invalidation. One commenter also suggested that data on Tulloch losses should be grouped by industry category. We agree that precise comprehensive data on Tulloch impacts is difficult to collect. The estimates discussed in the proposal reflect projects that have come to the attention of agencies' field offices, through field observations, individual reports, and/or newspapers and other information sources. We believe that the preamble estimates of Tulloch losses are conservative, because persons undertaking such activities often proceed under the assumption that no authorization from the Corps is required. The proposal's request for information on Tulloch losses is intended to help ensure available data is as complete as possible. We do not agree, however, that the collection and categorization of data by industry is necessary, because today's rule does not regulate by industry category but on the basis of discharges to waters of the U.S.

One commenter asserted that Tulloch losses have been more than offset by mitigation required for permitted losses, because the preamble to the proposal cites estimates of over 20,000 acres of unregulated wetlands loss after invalidation of the Tulloch Rule, plus an estimated 21,500 acres of wetlands lost through authorized activities in 1999, with 46,000 acres of compensatory mitigation obtained in 1999. However, only permitted losses resulted in obtaining compensatory mitigation. Compensatory mitigation ratios for permitted losses are typically higher than 1:1 to address a variety of factors considered during permit evaluation, such as the expected likelihood of success; the percentage of restoration, enhancement, and/or preservation intended; the temporal loss of functions and values before the mitigation is fully functioning; and other relevant considerations. Tulloch losses, on the other hand, involve activities which are not subject to environmental review or compensatory mitigation. Thus, the compensatory mitigation figures reported in the proposed rule's preamble were designed to offset permitted losses only, not Tulloch losses.

One commenter disagreed about implications of wetlands losses, expressing doubt about whether wetlands losses might result in a potential for increased flooding, and characterizing the link between the two as an unsupported assumption. We note, however, that an extensive body of scientific literature indicates that wetlands typically store water at least temporarily, keeping it from flowing further downhill and downstream, thereby helping reduce the frequency and severity of flooding. For example, the U.S. Geological Survey's National Water Summary on Wetlands Resources (1996) notes that "[i]n drainage basins with flat terrain that contains many depressions (for example, the prairie potholes and playa lake regions), lakes and wetlands store large volumes of snowmelt and (or) runoff. These wetlands have no natural outlets, and therefore this water is retained and does not contribute to local or regional flooding." Other studies, such as the 1994 report by the Interagency Floodplain Management Review Committee, similarly have found links between wetlands losses and flooding. Sharing the Challenge: Floodplain Management Into the 21st Century, at Vol. 1, pg. ix; Vol. V at pp 79–88.

2. Miscellaneous Issues

One commenter raised an issue with respect to whether or not snow plowed into headwater creeks would be regulated by today's rule. Although we recognize that other Federal or State requirements may govern such an activity, we do not regulate snow plowing into waters of the U.S. under section 404. Today's rule addresses discharges of dredged material, which snow is not. However, if during a snow removal operation, snowplows, front loaders, bulldozers, or similar equipment discharge gravel, sand, or other material into waters of the U.S. or move sediment or soil to new locations within a water of the U.S., then such activities would be regulated under section 404.

Some commenters raised concerns about the definition of "waters of the U.S.," expressing the view that the term is very broad and may be overly inclusive. Today's rule clarifies the definition of the term "discharge of dredged material" regulated under CWA section 404. It does not address the definition or scope of "waters of the U.S." We are contemplating initiating rulemaking to clarify the definition of "waters of the U.S." (see the Unified Regulatory Agenda, 65 FR 23574 (April 24, 2000)), and would encourage public comments on a proposed definition at that time. We also note issues related to the scope of "waters of the U.S." are currently pending before the Supreme Court in *Solid Waste Agency of Northern Cook County* v. *U.S. Army Corps of Engineers* (No. 99–1178) (*SWANCC*).

One commenter indicated support for the deletion of the "grandfather" provision that was a part of the previous definition of dredged material. We agree, and today's final rule deletes that provision as being out of date and no longer necessary.

A number of commenters raised issues that, while related to wetlands regulation, were not germane to the proposed rule. Examples include comments regarding delineation methodology or geographic jurisdiction of the section 404 program, fill material regulation or the agencies proposed rulemaking regarding the definition of fill material, and general statements about section 404 regulation. These comments have been made available to other relevant dockets or addressed, as appropriate, in the record for today's rule.

3. Economic Issues

Many commenters opposed to the rule expressed concern over its economic effects. Some of the commenters raising economic concerns believed that the proposal would have regulated "incidental fallback" or was a return to the Tulloch Rule invalidated by the court in *AMC* and *NMA*. Many of the comments raising economic issues questioned the discussion in the proposed rule's preamble that it did not alter or enlarge section 404 program jurisdiction or create information requirements. Other commenters expressed concern with the expense and difficulty of rebutting the presumption contained in the proposed rule, especially when, in their view, this was a standardless proposition. Another asserted their belief that the reference in the proposed rule preamble to "potentially" regulated entities was misleading, as all persons engaging in excavation activities listed in the rule would be regulated. Some of the commenters believed the proposal would have an annual economic effect of more than $100 million dollars, and that issuance of the proposal without a detailed economic analysis or consulting with affected entities violated the requirements of the

Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act or the Unfunded Mandates Reform Act (UMRA). Some of the commenters expressed concern that, coupled with the changes made in the Corps Nationwide Permit Program, the proposal would result in increased delays in obtaining authorizations; one commenter believed the proposal somehow superceded existing Nationwide Permits. Others questioned how the proposed rule could be deemed to have small economic effects when the preamble to the proposal noted upwards of 20,000 acres of wetlands were subject to ditching and more than 150 miles of streams channelized. Others questioned why, if the rule was not economically significant, it was deemed a "significant regulatory action" for purposes of Executive Order 12866. One commenter expressed concern over the absence of a grandfather provision.

We continue to believe that the economic impacts of the rule will be insignificant. While some of the commenters expressing concern with economic impacts believed they would have to consult in advance with the Corps or that all excavation activities would be subject to regulation, this is not the case. Nothing in today's rule alters the current regulatory provisions that exclude incidental fallback from regulation as a discharge, provisions which were found to comply with the *AMC* and *NMA* decisions by the court in its NAHB Motion Decision. Today's rule does not alter that *status quo*, and we thus do not agree with commenters whose economic concerns were premised on the proposal somehow enlarging program jurisdiction or reinstating the invalidated Tulloch Rule. See also section III A of today's preamble for further discussion.

Moreover, as noted in section II C of today's preamble, the final rule has been clarified in a number of respects to make clear it is not creating or imposing new process or information requirements and will not result in substantially increased workloads. First, it no longer uses a rebuttable presumption. Second, the final rule has been clarified to expressly provide that it does not alter any burden in any administrative or judicial proceeding under the CWA. Finally, we have provided a descriptive definition of incidental fallback which helps to clarify for both the regulated community and regulatory staff the type of redeposits which are not subject to regulation. In this respect, it may actually reduce costs for the potentially regulated entities conscientiously attempting to comply with the existing regulations. Moreover, as noted and discussed numerous times in today's preamble, the final rule continues to provide for project-specific considerations in determining if more than incidental fallback results. In this regard, the proposed rule's preamble reference to "potentially" regulated entities was intended to convey this case-by-case nature, and the final rule preamble thus continues to use that formulation. For all of these reasons, we continue to believe that today's rule does not have substantial economic effects, and does not trigger the requirements of the RFA as amended or UMRA.

Today's rule does not affect section 404 Nationwide permits for dredged material discharges. Rather, it clarifies the types of activities which we regard as being likely to result in regulable discharges. Where only incidental fallback results, a regulable discharge of dredged material does not occur, and there is no obligation to obtain coverage under either an individual or a Nationwide permit. Some of the commenters expressed concern over lengthy permit review times under Nationwide and individual permits; we do not believe that the facts warrant these concerns and have included the most recent available statistics on permit review time in the administrative record for informational purposes, although, as just noted, the rule does not alter existing requirements for permit coverage. With regard to commenters raising concerns over the economic effects of changes that have been made in the Nationwide permit program (see 65 FR 12818), although outside the scope of today's rule, we note that the Corps has prepared and is continuing to work on economic documentation related to that program.

We do not believe there is any inconsistency in the discussion of Tulloch losses in the proposed rule's preamble and the conclusion that the rule will not have significant economic effects. As evidenced by photos from field visits, some of those losses were accompanied by substantial relocation and movement of dredged material, and thus seem to reflect the mistaken belief that any excavation or drainage activity is exempt from regulation under CWA section 404, regardless of the presence of a discharge. Activities resulting in a discharge of dredged material already are subject to regulation under CWA section 404 and today's rule does not alter this jurisdictional prerequisite.

With regard to questions concerning consistency of our conclusion that the rule does not have significant economic impacts even though it was submitted for review under Executive Order 12866, we have clarified in today's preamble (see section IV B below) that this submittal is not made on the basis of economic effects, but rather on the portion of that Executive Order addressing, among other things, rules which involve legal or policy issues arising out of legal mandates or the President's priorities. In light of past litigation challenging the 1993 Tulloch Rule and the importance of effectively protecting our Nation's aquatic resources, the proposed and final rules were submitted for review under Executive Order 12866. Finally, with regard to the commenter expressing concern over the absence of a grandfather provision, we have not included one as today's rule still provides for consideration of project-specific information, and does not create new substantive or procedural requirements. We thus do not believe a grandfather provision is appropriate.

4. Tribal and Federalism Issues

Several commenters raised concerns that the proposed rule would have substantial direct effects on States, and so is subject to the "Federalism" Executive Order 13132 (64 FR 43255 (August 10, 1999)). One commenter additionally noted that the proposed rule imposes significant compliance costs on Tribal governments, and therefore must comply with the consultation requirements of Executive Order 13084. Some commenters were concerned specifically about the potential information burden of rebutting the presumption. We disagree that today's rule will have a substantial direct impact on States or impose significant compliance costs on Tribes. Today's rule does not change CWA section 404 program jurisdiction, nor affect a discharger's obligation to obtain a section 404 permit for discharges of dredged material into waters of the U.S. Section 404 always has regulated the "discharge of dredged material." Today's rule simply clarifies program expectations of what activities are likely to result in a regulable discharge. In addition, today's rule does not use the proposal's rebuttable presumption formulation, and has been clarified to expressly state it does not shift any burden in any administrative or judicial proceeding under the CWA.

Two commenters suggested that the CWA section 404 program itself was inconsistent with federalism principles, because it imposed on the traditional State area of regulating land use or is only weakly connected to a Federal responsibility. Such comments are

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beyond the scope of today's rulemaking. However, we do not agree that the section 404 program is inconsistent with federalism principles. Controlling the impacts of pollution and protecting natural resources has long been a matter of joint Federal and State concern, and the Federal government long has legislated in the field of environmental pollution control and resource protection. Section 404 does not constitute conventional land use planning or zoning, but instead is a form of environmental protection and pollution control that leaves the ultimate determination of land use to State and local authorities consistent with Federal pollution control requirements. In a case involving impacts of mining on Federal lands, the U.S. Supreme Court expressed the distinction this way: "Land use planning in essence chooses particular uses for the land; environmental regulation, at its core, does not mandate particular uses of the land but requires only that, however the land is used, damage to the environment is kept within prescribed limits." (*California Coastal Commission* v. *Granite Rock Co.*, 480 U.S. 572, 587 (1987)). Section 404 does not dictate the particular use for a parcel of property; it regulates the manner in which the proposed use can be accomplished by avoiding and/or mitigating the environmental impacts of a discharge of dredged or fill material into waters of the U.S.

One commenter argued that the proposed rule unlawfully expanded Constitutional limits to the Corps' ability to protect biological resources, by including protection of habitat with significant biological value but little or no commercial value. The commenter stated that such habitat does not involve interstate commerce, and as a result is beyond Federal powers and should be protected by State and local governments. This issue is not within the scope of today's rulemaking and raises questions about the definition of "waters of the U.S." which are currently pending before the U.S. Supreme Court in *SWANNC*. In addition, nothing in today's rule limits a State or local government's ability to protect habitat and other resources.

One commenter suggested that Federal regulation is not necessary because ample State and local authority exists to protect wetlands. Again, this issue is beyond the scope of today's rulemaking. We disagree about the lack of a need for a Federal presence in wetlands regulation. The Federal wetlands program both addresses interstate issues arising from wetlands protection, and helps support the States' own environmental objectives. For example, the section 404 program helps protect States from the effects that filling of wetlands in one State may have on water quality, flood control, and wildlife in another State. States with wetlands programs might coordinate closely with the Federal program, as a means of avoiding duplication and reducing any administrative burden. For example, States might choose to coordinate their environmental studies with Federal initiatives or to use Federal expertise in identification and mapping of wetlands. We also note that in the *SWANCC* case, eight states filed an *amicus* brief explaining the benefits of 404 regulation to the states and expressing their support for such regulation (CA, IA, ME, NJ, OK, OR, VT, and WA).

One commenter argued that no Federal reason has been demonstrated for regulating activities such as ditching and channelization, and the proposal should not be finalized until an economic analysis is completed that supports a valid Federal reason to "expand" the Corps' authority. Another commenter noted that the *NMA* decision has forced a number of States to incur significant financial costs by acting to stem further wetlands destruction, and that limited funding has prevented some States from stepping into the post-*NMA* loophole. We note that today's rule does not regulate on the basis of ditching and drainage activities, but instead on the presence of a discharge of dredged material into waters of the U.S., as called for under the CWA. Today's rule does not expand the scope of CWA section 404 program jurisdiction, nor establish a new program or new required processes affecting the regulated community. For these reasons, we do not agree that today's rule requires an economic analysis such as that called for by the commenter.

We note that many Federal environmental programs, including CWA section 404, were designed by Congress to be administered at the State or Tribal level whenever possible. The clear intent of this design is to use the strengths of the Federal and State and Tribal governments in a partnership to protect public health and the Nation's resources. EPA has issued regulations governing State and Tribal assumption of the section 404 program (40 CFR part 233). The relationship between EPA and the States and Tribes under assumption of the section 404 Program is intended to be a partnership. With assumption, States and Tribes assume primary responsibility for day-to-day program operations. EPA is to provide consistent environmental leadership at the national level, develop general program frameworks, establish standards as required by the CWA, provide technical support to States and Tribes in maintaining high quality programs, and ensure national compliance with environmental quality standards. Currently two States (New Jersey and Michigan) have assumed the section 404 program.

One Tribal commenter felt that the proposed rule impinges on Tribal sovereignty, in that it does not allow Tribal decisions to undertake ditching activities for flood control without Federal review. This commenter also contended that the agencies did not comply with Executive Order 13084 which would have required that the agencies consult with the Tribes on the proposed rule under certain circumstances. The commenter stated that the agencies' conclusion that the proposed rule will not significantly effect Indian communities nor impose significant compliance costs on Indian Tribal governments is erroneous. As mentioned above, today's rule does not change program jurisdiction. In addition, it does not create any new formal process. In fact, unlike the proposal, the final rule does not employ a rebuttable presumption, and also has been clarified to expressly provide that it does not shift any burden in any administrative or judicial proceeding under the CWA. We thus believe the rule does not create an impingement to Tribal sovereignty or significantly affect Tribal communities.

IV. Administrative Requirements

A. Paperwork Reduction Act

This action does not impose any new information collection burden or alter or establish new record keeping or reporting requirements. Thus, this action is not subject to the Paperwork Reduction Act.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" in light of the provisions of paragraph (4) above. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record.

C. Executive Order 13132 (Federalism).

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires us to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This rule does not have federalism implications. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not affect a discharger's (including State dischargers) obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the definition of "discharge of dredged material" contained in our existing regulations. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule.

D. Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, a small entity is defined as: (1) A small business based on SBA size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's rule on small entities, we certify that this action will not have a significant economic impact on a substantial number of small entities. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not change any discharger's obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the existing regulatory program. Moreover, we also do not anticipate that provision of project-specific information that a regulable discharge does not occur would result in significant costs.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not affect a discharger's obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the definition of "discharge of dredged material" contained in our existing regulations. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA. For the same reasons, we have determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

F. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (the NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs us to use voluntary consensus standards in our regulatory activities unless to do so would be

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inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs us to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards.

This rule does not involve technical standards. Therefore, we did not considering the use of any voluntary consensus standards.

G. Executive Order 13045

Executive Order 13045, entitled Protection of Children From Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Was initiated after April 21, 1997, or for which a notice of proposed rulemaking was published after April 21, 1998; (2) is determined to be "economically significant" as defined under Executive Order 12866, and (3) concerns an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children. If the regulatory action meets all three criteria, we must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives that we considered.

This final rule is not subject to Executive Order 13045 because it is not an economically significant regulatory action as defined by Executive Order 12866. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not affect a discharger's obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the definition of "discharge of dredged material" contained in our existing regulations. Furthermore, it does not concern an environmental health or safety risk that we have reason to believe may have a disproportionate effect on children.

H. Executive Order 13084

Under Executive Order 13084, we may not issue a regulation that is not required by statute, if it significantly or uniquely affects the communities of Indian Tribal governments and imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance cost incurred by the Tribal governments, or we consult with those governments. If we comply by consulting, Executive Order 13084 requires us to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of our prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires us to develop an effective process permitting elected officials and other representatives of Indian Tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian Tribal governments, nor does it impose significant compliance costs on them. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not affect a discharger's obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the definition of "discharge of dredged material" contained in our existing regulations. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

I. Environmental Documentation

As required by the National Environmental Policy Act (NEPA), the Corps prepares appropriate environmental documentation for its activities affecting the quality of the human environment. The Corps has made a determination that today's rule does not constitute a major Federal action significantly affecting the quality of the human environment, and thus does not require the preparation of an Environmental Impact Statement (EIS). One commenter expressed the view that an Environmental Impact Statement (EIS) was necessary for the rule. However, as we noted in the proposed rule's preamble, the Corps prepares appropriate NEPA documents, when required, covering specific permit situations. The implementation of today's rule would not authorize anyone (*e.g.*, any landowner or permit applicant) to perform any work involving regulated activities in waters of the U.S. without first seeking and obtaining an appropriate permit authorization from the Corps. As explained in sections II and III of today's preamble, the rule does not alter or enlarge section 404 program jurisdiction and therefore does not affect a discharger's obligation to obtain a section 404 permit for any discharge of dredged material into waters of the U.S. Rather, the rule identifies what types of activities are likely to give rise to an obligation to obtain such a permit under the definition of "discharge of dredged material" contained in our existing regulations. Accordingly, the Corps continues to believe an EIS is not warranted and has prepared an environmental assessment (EA) for the rule.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. We will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 16, 2001.

List of Subjects

33 CFR Part 323

Water pollution control, Waterways.

40 CFR Part 232

Environmental protection, Intergovernmental relations, Water pollution control.

Corps of Engineers

33 CFR Chapter II

Accordingly, as set forth in the preamble 33 CFR part 323 is amended as set forth below:

PART 323—[AMENDED]

1. The authority citation for part 323 continues to read as follows:

Authority: 33 U.S.C. 1344.

2. Amend section 323.2 as follows:

a. In paragraph (d)(1) introductory text, remove the words "paragraph (d)(2)" and add, in their place, the words "paragraph (d)(3)".

b. Redesignate paragraphs (d)(2) through (d)(5) as paragraphs (d)(3) through (d)(6), respectively.

c. Add new paragraph (d)(2).

d. In newly redesignated paragraph (d)(4), in the first sentence of paragraph (d)(4)(i) remove each time they appear the words "paragraphs (d)(4) and (d)(5)" and add, in their place, the words "paragraphs (d)(5) and (d)(6)", remove paragraph (d)(4)(iii), and redesignate paragraph (d)(4)(iv) as new paragraph (d)(4)(iii).

The addition reads as follows:

§ 323.2 Definitions.

* * * * *

(d) * * *

(2)(i) The Corps and EPA regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the United States as resulting in a discharge of dredged material unless project-specific evidence shows that the activity results in only incidental fallback. This paragraph (i) does not and is not intended to shift any burden in any administrative or judicial proceeding under the CWA.

(ii) *Incidental fallback* is the redeposit of small volumes of dredged material that is incidental to excavation activity in waters of the United States when such material falls back to substantially the same place as the initial removal. Examples of incidental fallback include soil that is disturbed when dirt is shoveled and the back-spill that comes off a bucket when such small volume of soil or dirt falls into substantially the same place from which it was initially removed.

* * * * *

Dated: January 8, 2001.

Joseph W. Westphal,

Assistant Secretary of the Army (Civil Works), Department of the Army.

Environmental Protection Agency

40 CFR Chapter I

Accordingly, as set forth in the preamble 40 CFR part 232 is amended as set forth below:

PART 232—[AMENDED]

1. The authority citation for part 232 continues to read as follows:

Authority: 33 U.S.C. 1344.

2. Amend section 232.2 as follows:

a. In paragraph (1) introductory text of the definition of "Discharge of dredged material", remove the words "paragraph (2)" and add, in their place, the words "paragraph (3)".

b. In the definition of "Discharge of dredged material", redesignate paragraphs (2) through (5) as paragraphs (3) through (6), respectively.

c. In the definition of "Discharge of dredged material", add new paragraph (2).

d. In the first sentence of newly redesignated paragraph (4)(i) remove each time they appear the words "paragraphs (4) and (5)" and add, in their place, the words "paragraphs (5) and (6)", remove paragraph (4)(iii), and redesignate paragraph (4)(iv) as new paragraph (4)(iii).

The addition reads as follows:

§ 232.2 Definitions.

* * * * *

Discharge of dredged material * * *

(2)(i) The Corps and EPA regard the use of mechanized earth-moving equipment to conduct landclearing, ditching, channelization, in-stream mining or other earth-moving activity in waters of the United States as resulting in a discharge of dredged material unless project-specific evidence shows that the activity results in only incidental fallback. This paragraph (i) does not and is not intended to shift any burden in any administrative or judicial proceeding under the CWA.

(ii) *Incidental fallback* is the redeposit of small volumes of dredged material that is incidental to excavation activity in waters of the United States when such material falls back to substantially the same place as the initial removal. Examples of incidental fallback include soil that is disturbed when dirt is shoveled and the back-spill that comes off a bucket when such small volume of soil or dirt falls into substantially the same place from which it was initially removed.

* * * * *

Dated: January 9, 2001.

Carol M. Browner,

Administrator, Environmental Protection Agency.

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Part XI

Department of Housing and Urban Development

24 CFR Part 1003
Revision to the Application Process for Community Development Block Grants for Indian Tribes and Alaska Native Villages; Final Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1003

[Docket No. FR–4612–F–02]

RIN 2577–AC22

Revision to the Application Process for Community Development Block Grants for Indian Tribes and Alaska Native Villages

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations for Community Development Block Grants for Indian Tribes and Alaska Native Villages (the "ICDBG" program). These amendments will permit the incorporation of the ICDBG grant application and selection procedures into HUD's SuperNOFA process. The SuperNOFA approach, in which the great majority of HUD's competitive funds are announced in one document, is designed to simplify the application process, bring consistency and uniformity to the application and selection process, and accelerate the availability of funding. In addition to the SuperNOFA-related amendments, this final rule amends the ICDBG program regulations to remove certain obsolete regulatory provisions and to clarify program requirements. This final rule follows publication of a November 2000 proposed rule and takes into consideration the public comments received on the proposed rule. After careful review of all of the public comments, HUD has decided to adopt the proposed regulatory amendments without change.

DATES: Effective Date: February 16, 2001.

FOR FURTHER INFORMATION CONTACT: Jacqueline Kruszek, Office of Grants Management, Office of Native American Programs, Department of Housing and Urban Development, Suite 3390, 1999 Broadway, Denver, CO 80202; telephone 1–800–561–5913 (this is a toll-free number). Hearing or speech-impaired persons may access this telephone number via TTY by calling the Federal Information Relay Service at 1–800–877–8339. Ms. Kruszek may also be contacted via e-mail at: Jacqueline_A._Kruszek@hud.gov.

SUPPLEMENTARY INFORMATION:

I. Background—The November 6, 2000, Proposed Rule

The Community Development Block Grants program for Indian Tribes and Alaska Native Villages (the "ICDBG" program) provides eligible grantees with direct grants for use in developing viable Indian and Alaskan Native communities, including decent housing, a suitable living environment, and economic opportunities, primarily for low- and moderate-income persons. On November 6, 2000 (65 FR 66592), HUD published a proposed rule to amend the ICDBG program regulations at 24 CFR part 1003. The principal reason for the proposed changes was to allow the integration of the ICDBG program application process into HUD's Super Notice of Funding Availability (SuperNOFA) approach. HUD, through letter dated July 12, 2000, provided Indian tribes and Alaska Native Villages with the opportunity to comment on the substance of the proposed regulatory changes during the development of the November 6, 2000 proposed rule. HUD received 7 comments on the proposed revisions, all in support of the regulatory changes and the incorporation of the ICDBG program requirements in the SuperNOFA process.

The SuperNOFA process, in which the great majority of HUD's competitive funds are announced in one document, is designed to simplify the application process, bring consistency and uniformity to the application and selection process, and accelerate the availability of funding. Unlike those HUD programs included in the SuperNOFA, the application process for funding under the ICDBG program has been implemented through separate stand-alone NOFAs. This was based, in part, on a determination that the considerations for grant award were substantially different for the ICDBG program when compared with those included in the SuperNOFA. Based upon closer review, HUD has determined that the SuperNOFA process, especially as it has evolved in the last two years, affords the degree of flexibility necessary to address important distinctions in funding considerations (such as project specific thresholds), while at the same time providing a framework within which application simplification procedures may be implemented. Certain regulatory changes, however, are required in order to permit the incorporation of the ICDBG program in the SuperNOFA process. Accordingly, HUD issued the November 6, 2000 proposed rule to revise the ICDBG program regulations application selection and rating procedures.

In addition to the SuperNOFA-related amendments, HUD took the opportunity provided by the November 6, 2000 proposed rule to make several streamlining and clarifying amendments to 24 CFR part 1003. These proposed amendments were non-substantive, but proposed to remove obsolete regulatory language and clarify existing program requirements. In addition, these proposed changes were designed to provide additional flexibility to address eligible activities under the ICDBG program.

The preamble to the November 6, 2000 proposed rule provides additional details regarding the proposed amendments to the ICDBG programs regulations at 24 CFR part 1003.

II. This Final Rule; Discussion of the Public Comments Received on the November 6, 2000, Proposed Rule

This final rule makes effective the policies and procedures contained in the November 6, 2000 proposed rule and takes into consideration the public comments received on the proposed rule. The public comment period on the proposed rule closed on December 6, 2000. By close of business on that date, HUD had received 9 public comments on the proposed regulatory amendments, all from Indian tribes. After careful review of all the public comments, HUD has decided to adopt the proposed regulatory amendments without change. This section of the preamble presents a summary of the significant issues raised by the public commenters, and HUD's responses to the comments.

A. Comments Regarding National Rating of ICDBG Applications

Comment: Final rule should provide that Area ONAPs will continue to rate ICDBG applications. The November 6, 2000, rule proposed to remove the requirement that applications be rated by each Area Office of Native American Programs (ONAP). The public commenters objected to this proposed change. The commenters wrote that each Area ONAP has the advantage of being intimately familiar with local tribes and local conditions that may affect ICDBG project costs (such as weather patterns, the availability of construction materials, and the local labor market). Several of the commenters also disagreed that a national rating panel would help to expedite the funding process, and wrote they were unaware of any funding delays necessitating the proposed change. For these reasons, the commenters believe that national ratings would be less accurate and fair than those performed by the Area ONAPs.

HUD response. HUD is sensitive to the concerns expressed by these public commenters, and assures them that a national review panel will not be used during the Fiscal Year (FY) 2001 ICDBG funding round. Applications for FY 2001 ICDBG funding will continue to be rated by the Area ONAPs. HUD continues to believe that the use of a national rating panel may assist in expediting the ICDBG funding approval process, and wishes to have the regulatory flexibility to consider such an option for future ICDBG funding rounds. The final rule provides HUD with this flexibility, but also continues to permit the rating of ICDBG applications by the Area ONAPs. HUD agrees with the commenters that there are several issues that need to be addressed before implementation of a national review panel. HUD will work with its tribal partners to address these issues of concern before establishing a national ICDBG review panel. HUD also wishes to note that, even if a national rating panel is established, ICDBG fund allocation and competition for these funds would continue to be made for and limited to each Area ONAP jurisdiction.

B. Comments Regarding Tribal Consultation/Comment Period

Comment: The reduced 30-day comment period was insufficient. Two commenters did not agree that the need to incorporate the ICDBG program in the FY 2001 SuperNOFA process justified reducing the customary 60-day public comment period for proposed rules to 30-days. One of the commenters wrote that delaying this incorporation would provide Indian tribes (and particularly small tribes) with the necessary time to become better acquainted with the SuperNOFA process.

HUD response. HUD agrees that public comment is essential to the success of the rulemaking process. In general, it is HUD's policy to provide the public with at least 60 days to submit comments on its proposed rules. However, HUD continues to believe that good cause existed to provide a reduced 30-day comment period for the November 6, 2000, proposed rule. The 30-day public comment period was necessary to ensure the inclusion of the ICDBG funding process in the FY 2001 SuperNOFA. Incorporation in the SuperNOFA will greatly benefit ICDBG program applicants. Among other benefits, the SuperNOFA's promotion of coordination and comprehensive planning will provide potential ICDBG grantees with greater flexibility in meeting local housing and community development needs, and will allow for the delivery of a wider, more integrated array of services. Provision of the customary 60-day public comment period had the potential to delay the rulemaking process and might have jeopardized the incorporation of the ICDBG program in the FY 2001 SuperNOFA process.

Further, HUD, through letter dated July 12, 2000, provided Indian tribes and Alaska Native Villages with the opportunity to comment on the substance of the proposed regulatory changes during the development of the proposed rule. HUD received 7 comments on the proposed revisions, all in support of the regulatory changes and the incorporation of the ICDBG program requirements in the SuperNOFA process. Accordingly, the reduced 30-day comment period did not unduly restrict the ability of ICDBG program participants to express their views on the proposed rule, since they had already been afforded an opportunity to comment on the regulatory changes.

Comment: HUD failed to consult with Indian Tribes prior to issuing the proposed rule. Several commenters objected to the perceived lack of tribal consultation in the development of the proposed rule. The commenters wrote that HUD was required to consult with Indian tribes before issuing these proposed amendments, in accordance with Executive Order 13084 regarding consultation and coordination with Indian tribes (published in the **Federal Register** on May 19, 1998 (63 FR 27655)). Two of the commenters however, acknowledged that the proposed incorporation of the ICDBG program in the SuperNOFA process "has been known and discussed among the tribes for a period of time."

HUD response. As noted above, HUD consulted with Indian tribes and Alaska Native Villages during the development of the proposed regulatory amendments. HUD received 7 comments on the proposed revisions, all in support of the regulatory changes and the incorporation of the ICDBG program requirements in the SuperNOFA process. HUD is committed to continue its consultation efforts with Indian tribes and Alaska Native Villages in the implementation of these regulatory changes to the ICDBG program. For example, HUD will work with its tribal partners to address issues of concern before implementing a national ICDBG review panel. HUD has also scheduled a series of meetings with Indian tribes during the week of January 8, 2000 to solicit additional input on the implementation of, and possible future changes to, these regulatory amendments to the ICDBG program. Further, and in accordance with the requirements of Executive Order 13084, HUD has also been working closely with Indian tribes in the development of its tribal consultation policy. The purpose of the consultation policy will be to enhance communication and coordination between HUD and federally recognized Indian tribes, and to outline guiding principles and procedures under which all HUD employees are to operate with regard to federally recognized Indian or Alaska Native tribes.

C. Other Comments

Comment: How will HUD determine the "reasonableness" of project costs? The November 6, 2000 rule proposed to revise 24 CFR 1003.100(b), which identifies the factors that an Area ONAP may take into account in approving a grant amount less than the requested amount. Specifically, HUD proposed to revise § 1003.100(b)(2) to clarify that the Area ONAP may consider the reasonableness of the project costs in making this determination. One commenter requested clarification on how HUD will determine whether proposed project costs are reasonable.

HUD response. The requirement that project costs be reasonable is not a new requirement, but is one of the threshold requirements for community appropriateness currently located at § 1003.301. As in previous years, information regarding how HUD will determine the reasonableness of project costs will be provided in the application kit for the FY 2001 ICDBG NOFA.

Comment: Clarification is needed regarding outstanding obligations threshold requirement. The November 6, 2000 rule proposed to continue to provide that an applicant that has an outstanding ICDBG obligation to HUD that is in arrears, or has not agreed to a repayment schedule, will be disqualified from the ICDBG competition (see proposed § 1003.301(a)). One commenter requested clarification of this provision. Specifically, the commenter asked whether this provision refers "only to an outstanding financial payment due to HUD." The commenter was concerned that this provision could be interpreted to include any prior grants that are simply behind schedule or past the desired two year time frame for completion. The commenter wrote that "[m]any obstacles in the construction industry are unpredictable, beyond the control of the grantee, and are the result of completely reasonable dynamics specific to the industry, with compelling justification."

HUD response. The regulatory language in question was not revised by the November 6, 2000, proposed rule.

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Rather, the quoted language is an existing requirement currently located at § 1000.301(a)(3)(iii). The language was repeated in the proposed rule solely for purposes of clarity and to place other proposed regulatory changes in context. This requirement has been consistently interpreted by HUD to refer only to outstanding financial debts or payments due to HUD as a result of ineligible costs or repayments.

Comment: Clarification is needed regarding the SuperNOFA rating factors. Current § 1003.303 (entitled "Project rating") establishes three separate rating categories: housing, community facilities, and economic development. Further, § 1003.303 establishes specific rating criteria for these categories (although some categories share similar criteria). The requirements for separate rating categories and related criteria based on the type of project are inconsistent with SuperNOFA requirements and procedures. Therefore, the November 6, 2000 rule proposed to amend § 1003.303 to provide for the use of the five uniform rating factors used in the SuperNOFA—Capacity, Need/Extent of the Problem, Soundness of Approach, Leveraging of Resources, and Comprehensiveness and Coordination. One of the commenters requested clarification on how HUD would measure need and the soundness of approach.

HUD response. Many of the criteria addressed by the SuperNOFA rating factors (such as need/extent of the problem, and soundness of approach) are currently addressed under the existing ICDBG rating factors, and will therefore be familiar to most ICDBG applicants. Additional details regarding the new rating factors will be provided in the ICDBG component of the SuperNOFA and the accompanying application kit.

III. Findings and Certifications

Environmental Impact

In accordance with 24 CFR 50.19(c)(2) of the Department's regulations, the amendments made by this final rule do not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Therefore, this final rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

Regulatory Flexibility Act

The Secretary has reviewed this final rule before publication, and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities. To the extent that the final rule has an impact on small Indian tribes and Alaskan Native Villages, it will be to reduce burden and expedite the ICDBG funding process. As described more fully in the preamble, the amendments made by this final rule will permit the incorporation of the ICDBG program application and selection procedures into HUD's highly successful SuperNOFA process. The inclusion of the ICDBG program in the SuperNOFA will simplify the ICDBG application process, conform the ICDBG application and selection procedures with those of other HUD competitive grant programs, and accelerate the availability of funding.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Consultation with Indian Tribal Governments

In accordance with Executive Order 13084, *Consultation and Coordination With Indian Tribal Governments*, issued on May 14, 1998, HUD has consulted with representatives of tribal governments concerning the subject of this rule. HUD, through letter dated July 12, 2000, provided Indian tribes and Alaska Native Villages the opportunity to comment on the substance of the proposed regulatory changes during the development of the November 6, 2000 proposed rule. HUD received 7 comments on the proposed revisions, all in support of the regulatory changes and the incorporation of the ICDBG program requirements in the SuperNOFA process. The comments received by HUD indicate that the regulatory changes are not controversial, and are supported by most Indian tribes and Alaska Native Villages. Additionally, the November 6, 2000, proposed rule provided Indian tribes with an additional opportunity to comment on the proposed regulatory changes. HUD has fully considered the public comments received on the proposed rule in the development of this final rule. HUD has also scheduled a series of meetings with Indian tribes during the week of January 8, 2000 to discuss implementation of, and possible future changes to, these regulatory amendments to the ICDBG program.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Catalog of Federal Domestic Assistance Numbers

The Catalog of Federal Domestic Assistance Number for the Community Development Block Grant Program for Indian Tribes and Alaska Native Villages is 14.862.

List of Subjects in 24 CFR Part 1003

Alaska, Community development block grants, Grant programs—housing and community development, Indians, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD amends 24 CFR part 1003 as follows:

PART 1003—COMMUNITY DEVELOPMENT BLOCK GRANTS FOR INDIAN TRIBES AND ALASKA NATIVE VILLAGES

1. The authority citation for 24 CFR part 1003 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 5301 *et seq.*

2. Revise 1003.100(b)(2) to read as follows:

§ 1003.100 General.

* * * * *

(b) * * *

(2) *Individual grant amounts.* An Area ONAP may approve a grant amount less than the amount requested. In doing so, the Area ONAP may take into account the size of the applicant, the level of demand, the scale of the activity proposed relative to need and

operational capacity, the number of persons to be served, the amount of funds required to achieve project objectives, the reasonableness of the project costs, and the administrative capacity of the applicant to complete the activities in a timely manner.

3. Revise § 1003.301 to read as follows:

§ 1003.301 Selection process.

(a) *Threshold requirement.* An applicant that has an outstanding ICDBG obligation to HUD that is in arrears, or one that has not agreed to a repayment schedule, will be disqualified from the competition.

(b) *Application rating.* NOFAs will define and establish weights for the selection criteria, will specify the maximum points available, and will describe how point awards will be made.

4. Revise § 1003.303 to read as follows:

§ 1003.303 Project rating.

Each project included in an application that meets the threshold requirements shall be competitively rated within each Area ONAP's jurisdiction under the five following rating factors. Additional details regarding the rating factors will be provided in the periodic NOFAs.

(a) *Capacity.* This factor will address the applicant's organizational resources necessary to successfully implement the proposed activities in a timely manner.

(b) *Need/Extent of the problem.* This factor will address the extent to which there is a need for the proposed project to address a documented problem among the intended beneficiaries.

(c) *Soundness of Approach.* This factor will address the quality and cost effectiveness of the proposed project, the commitment to sustain the proposed activities, and the degree to which the proposed project provides other benefits to community members.

(d) *Leveraging of resources.* This factor will address the level of tribal resources and resources from other entities that are used in conjunction with ICDBG funds to support the proposed project. HUD will evaluate the level of non-ICDBG resources based on the percentage of non-ICDBG resources provided relative to project costs.

(e) *Comprehensiveness and coordination.* This factor will address the extent to which the applicant's proposed activities are consistent with the strategic plans or policy goals of the community and further on-going priorities and activities of the community.

Dated: January 9, 2001.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 01–1206 Filed 1–16–01; 8:45 am]

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Social Security Administration
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National Foundation on the Arts and the Humanities
Corporation for National Community Service
Department of Transportation

Federal Financial Assistance Management Improvement Act of 1999; Notice

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DEPARTMENT OF AGRICULTURE

DEPARTMENT OF ENERGY

SMALL BUSINESS ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

SOCIAL SECURITY ADMINISTRATION

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FEDERAL EMERGENCY MANAGEMENT AGENCY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL SCIENCE FOUNDATION

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

DEPARTMENT OF TRANSPORTATION

Request for Comment; Interim/Draft Plan of Action To Implement Public Law 106–107, the Federal Financial Assistance Management Improvement Act of 1999

AGENCIES: Department of Agriculture, Department of Energy, Small Business Administration, National Aeronautics and Space Administration, Social Security Administration, Department of Commerce, Department of State, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Labor, Department of the Treasury, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of the Interior, Federal Emergency Management Agency, Department of Health and Human Services, National Science Foundation, National Endowment for the Arts—National Foundation on the Arts and the Humanities, National Endowment for the Humanities—ional Foundation on the Arts and the Humanities, Institute of Museum and Library Services—National Foundation on the Arts and the Humanities, Corporation for National and Community Service, Department of Transportation.

ACTION: Notice; request for public comments

SUMMARY: This notice is a request for comments, intended to help the Federal agencies satisfy the provisions of Public Law 106–107, the Federal Financial Assistance Management Improvement Act of 1999 (henceforth "the Act"), which requires each agency to develop and implement a plan that streamlines and simplifies the application, administrative, and reporting procedures for Federal financial assistance programs. The Act also requires the agencies to consult with representatives of non-Federal entities during the development and implementation of their plans.

This notice and interim/draft plan of action reflect the joint effort of the Federal grant-making agencies listed in Section X, below, to meet the requirements of the Act. The plan is being published for public comment in the **Federal Register** and on the Internet at the U.S. Chief Financial Officers Council's Grants Management Committee home page (http://www.financenet.gov/fed/cfo/grants/grants.htm), pursuant to Section 5 of the Act. One intent of the agencies is to use the information gathered through this notice to identify additional areas of the grant life cycle which lend themselves to common practices and implementation.

The Federal departments and agencies will refine this plan as the interagency, consultative effort identifies additional specific Federal Government actions needed to achieve the purposes of the Act. The initial plan will be submitted in May, 2001. As this plan evolves into more specific actions, the Federal agencies, after consultations with affected constituencies, will submit updated information to Congress in the annual implementation reports required by the Act.

Desired Focus of Comments

The participating agencies request your comments on the Federal grantmaking process and the objectives outlined in this plan, particularly on the following questions. To the maximum extent possible, please provide specific information in your responses. For example, the name of the Federal program or the number of a particular form. This information will assist the agencies in their efforts to reform these programs.

I. Application and Reporting Forms

A. Please identify application and reporting forms you believe could be improved or streamlined.

B. Please identify specific data elements on these forms that you believe could be eliminated or combined to reduce reporting burden while still providing the Federal agency enough information to manage the program.

C. What programs do you think could share common application and reporting forms that currently do not? Do not limit your response to programs within the same agency. For example, if there are programs administered by the Department of Agriculture and the Department of Health and Human Services that you believe should share common forms because they share a similar purpose, please identify them.

D. How do you obtain copies of the forms you need for your grant? Are they readily available over the Internet, or are they provided in materials you received from your awarding agency, such as a funding notice or handbook? What forms have been difficult to locate in updated formats?

II. Terms and Conditions

A. What terms and conditions are attached to your grants that you believe are not treated consistently from program to program, and across the various Federal agencies?

B. How would you suggest the agencies create more uniformity in these terms and conditions?

III. Payment Systems

A. What payment systems are you currently required to use to receive grant payments?

B. Which of these systems offer on-line services?

C. Does the use of multiple payment systems by Federal agencies cause a burden on your financial system?

IV. Audit Issues

A. What could the Federal agencies do to improve your understanding of the Single Audit process?

B. Have you used the Single Audit Clearinghouse to obtain information on subrecipient audits?

C. Do you believe that single audits provide appropriate audit coverage for your programs and the programs where you are a pass-through entity?

V. Electronic Processing

A. What electronic processing systems do you currently use for your Federal grants? Please note any systems you use due to Federal agency requirements, as well as any systems or technologies your organization uses for other activities.

B. What is the likelihood that your organization would utilize an on-line application or financial reporting system?

C. How can the agencies best prepare your organization for the future use of electronic processing option for your grants?

DATES: Comments in response to this notice must be received on or before March 19, 2001. Each Federal agency will submit an implementation plan to OMB and Congress before May 20, 2001 and report annually thereafter.

ADDRESSES: General comments on this notice, and those relating to more than one Federal agency, should be addressed to: Attn: PL 106–107 Comments, Department of Health and Human Services, 200 Independence Avenue, SW, Room 517–D, Washington, DC 20201. Comments may also be transmitted by E-mail (PL106107@os.dhhs.gov) or by fax, (202) 690–8772. Comments that are specific to a particular Federal agency or program should be directed to the agency's contact listed at the end of this notice.

FOR FURTHER INFORMATION CONTACT: For general questions regarding this notice, please contact Rodd Clay, Office of Grants Management, Department of Health and Human Services by E-mail (rclay@os.dhhs.gov) or phone at (202) 690–8723; for the hearing impaired only: TDD 202–690–6415. For agency-specific issues, please contact the agency's contact listed at the end of this notice. Additional information regarding the agencies' reform efforts may be found at the Chief Financial Officers (CFO) Council's Grants Management Committee home page (*http://www.financenet.gov/fed/cfo/grants/grants.htm*).

SUPPLEMENTARY INFORMATION:

I. Purpose

This interim/draft plan of action is being presented for public comment. It was developed jointly by the Federal grant-making agencies listed in Section X, below, to meet the requirements of the Financial Assistance Improvement Act of 1999 (Public Law 106–107, henceforth "the Act"). It sets out broad goals and objectives; describes an ongoing, coordinated interagency effort to implement the Act in consultation with non-Federal entities; and details accomplishments in some areas. The Federal agencies will refine this plan as the interagency, consultative effort identifies additional specific Federal Government actions needed to achieve the purposes of the Act. As this plan evolves into more specific actions, the Federal agencies, after consultations with affected constituencies, will submit updated information to Congress in the annual implementation reports required by the Act. This plan and the comments received will help the agencies to meet the requirements of the Act.

II. Background

Federal programs providing financial assistance comprise a large and diverse enterprise with widely varying purposes and recipient communities. The Catalog of Federal Domestic Assistance lists hundreds of programs in more than 25 Federal grant-making agencies with approximately $300 billion in annual expenditures. The programs stimulate or support a wide variety of public purposes in areas such as health, social services, law enforcement, agriculture, housing, community and regional development, education and training, and research.

III. Statutory Requirement

In enacting Public Law 106–107, Congress expressed concern that some requirements related to the award and administration of Federal financial assistance may be duplicative, burdensome, or conflicting, thus impeding the cost-effective delivery of services. Congress further found that State, local, and tribal governments and private, nonprofit organizations must deal with increasingly complex problems that require the delivery and coordination of many kinds of services and result in complex grant administration. To address these concerns, the Act requires each Federal agency to develop and implement a plan, with the direction, coordination and assistance of the Director of the Office of Management and Budget (OMB), in consultation with representatives of non-Federal entities, that:

- Streamlines and simplifies the application, administrative, and reporting procedures for Federal financial assistance programs administered by the agency;
- Demonstrates active participation in an interagency process to:
  - —Streamline and simplify administrative procedures and reporting requirements for non-Federal entities receiving Federal financial assistance;
  - —Improve interagency and intergovernmental coordination of information collection and sharing of data pertaining to Federal programs providing financial assistance; and
  - —Improve the timeliness, completeness, and quality of information received by Federal agencies from financial assistance recipients;
- Demonstrates appropriate agency use, or plans for use, of a common application and reporting system that includes:
  - —A common application or set of common applications, whereby a non-Federal entity can apply for Federal financial assistance from multiple Federal programs that serve similar purposes and are administered by different Federal agencies;
  - —A common system, including electronic processes, whereby a non-Federal entity can apply for, manage, and report on the use of financial assistance funding from multiple Federal programs that serve similar purposes and are administered by different Federal agencies; and
  - —Uniform administrative rules for Federal financial assistance programs across different Federal agencies;
- Designates a lead agency official for carrying out the responsibilities of the agency under the Act;
- Allows applicants the option to electronically apply for, and report on the use of, funds from programs of the agency that provides financial assistance;
- Ensures that recipients of financial assistance provide timely, complete, and high quality information in response to Federal reporting requirements; and
- Establishes, in cooperation with recipients of financial assistance, specific annual goals and objectives to further the purposes of the Act and measure annual performance as part of

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the agency's planning responsibilities under the Government Performance and Results Act of 1993 (Public Law 103–62).

IV. Goal

An appropriate interagency structure for accomplishing all aspects of this Act has been established, and the Federal agencies have agreed on a common goal: To maximize the effectiveness with which Federal financial assistance programs support the accomplishment of their purposes, consistent with good stewardship of public funds and accountability.

Several agencies have already undertaken efforts to identify common grant process flows and to streamline business practices. These agencies are continuing to work to identify and establish performance measures to effectively manage and track grantee use of funds. They have also been developing electronic systems for the entire grants life cycle which will support these efforts.

While there have been many studies, reports, and attempts at Federal financial assistance simplification in the past, a comprehensive, Government-wide review of this magnitude has not been undertaken since a standardization effort entitled, "Federal Assistance Review" was undertaken in 1969. That review, which took three years to complete, significantly reduced burdens on recipients and improved the uniformity among Federal agencies' assistance awards to governmental organizations. For example, it led to the issuance of OMB Circulars A–87 and A–102, which contain cost principles and uniform administrative requirements for awards to governmental organizations. It also resulted in a standard application: The Standard Form 424.

Similarly, the new interagency effort described in the next section of this plan is a multi-year effort. As it progresses, the Federal agencies will identify more specific goals, objectives and solutions, as the Act requires. Therefore, this plan is necessarily an interim/draft plan. It will evolve as the Federal agencies, in conjunction with their non-Federal partners, continue to identify problems to be addressed, devise ways to solve them, and specify the expected outcomes.

V. Process

A. Interagency Approach

Central to the development of the plan and its implementation is the active participation in an interagency process, with direction, coordination and assistance from OMB, in consultation with representatives of non-Federal entities. The Director of OMB charged the Grants Management Committee ("the Committee") of the Chief Financial Officers (CFO) Council to perform most of the work required in coordinating the interagency, consultative effort to meet the objectives of the Act. The Committee is chaired by the Deputy Chief Financial Officer of the Department of Health and Human Services (HHS), which is assisting OMB as the lead agency for implementation of the Act. All Federal grant-making agencies are participating through the Committee, and therefore, are developing this coordinated and consistent implementation plan with respect to the requirements of the Act. The Committee established four streamlining and simplification work groups to conduct the effort, chaired by representatives of various agencies. It also created a General Policy and Oversight Team to examine crosscutting issues and to oversee the progress of the work groups. Serving as co-chair of this oversight team along with HHS, OMB directs, coordinates and assists the process, and addresses individual agency and other related problems. The four streamlining and simplification work groups are the Pre-Award, Post-Award, Audit Oversight, and Electronic Processing work groups.

B. Public Consultations

One cornerstone of the interagency effort is consultation with representatives of non-Federal entities that apply for and receive Federal financial assistance. The consultation process began soon after enactment of Public Law 106–107, when several individual agencies posted information about the Act on their home pages. The agencies asked for comments and suggestions about the Federal processes for providing financial assistance. As they received input, they shared it with officials in other Federal agencies.

The Grants Management Committee reinforced and expanded those early efforts in two ways. First, it created a central Web site for information about the interagency process in general and the four work groups more specifically. The Web site allows the public to electronically submit comments and suggestions directly to the work group members who need it, which gets the input to them more rapidly and efficiently. Secondly, through its General Policy and Oversight Team and with assistance of the work group chairs, the committee conducted five public consultation meetings with the major recipient constituencies-States, local governments, tribal governments, universities and nonprofit organizations that conduct research, and other nonprofit organizations.

The consultation meetings provided the work groups with a variety of insights on issues that need to be addressed in the Act's implementation. These included specific examples, by agency and by program, of areas requiring attention and, in some cases, concrete suggestions for improvement. The public comments at the consultation meetings raised several significant issues of a crosscutting nature, such as those related to Native American tribal entities and to rural access and infrastructure (described in Section VI. A. of this plan). They also raised issues related to the different phases of the financial assistance process—pre-award, post-award, and audit—as well as with the technology that will support the process.

Non-Federal organizations, in general, are concerned with the announcement of funding opportunities, including the availability of information, its clarity (*e.g.*, clear statements of eligibility), and the time allowed for application preparation and submission. They also indicated a need for greater commonality in award requirements across agencies, including more consistent reporting requirements in terms of both content and timing. While there is widespread support in the non-Federal constituencies for making the process less paper intensive and using the electronic option, the participants in some of these sessions reminded the Federal agencies of the real limitations (*e.g.*, personnel, equipment, and access) they face and the need to ensure that training and technical assistance are available.

Further information about these consultation meetings, including summaries of public comments, is available on the Committee's home page (*http://www.financenet.gov/fed/cfo/grants/grants.htm*). The work groups and individual Federal agencies will continue to consult with recipients throughout the interagency streamlining and simplification effort.

C. Prior and Ongoing Efforts

A second cornerstone of the interagency process is to build on what has already been done or is already underway. There were numerous streamlining and simplification initiatives underway before the enactment of Public Law 106–107, although not of the magnitude called for by the Act. Some affected a particular set of activities, such as research, or a particular agency's programs. An example is the Federal Demonstration Partnership (FDP), an organization comprising 11 Federal awarding offices and 65 universities and nonprofit organizations, which already has made and is continuing to make more uniform these 11 Federal offices' applications, terms and conditions, and reporting requirements.

The Committee's work groups will build upon the results of groups like the FDP and prior or ongoing streamlining efforts of individual agencies and non-Federal entities. The work groups will use successful initiatives as models that may be expanded if they have broader applicability to more Federal agencies, to more Federal programs for other purposes, and to more of the many recipients of Federal grants and cooperative agreements.

In addition, the Committee has integrated several on-going Government-wide initiatives into its four new work groups, to increase the initiatives' priority and accelerate them. These include:

- The Interagency Committee on Debarment and Suspension which, with OMB's support, has been working to simplify and update the Government-wide common rule on debarment and suspension. The work of this committee has been integrated into the Pre-Award Work Group.
- The Committee's prior subcommittees that began the streamlining initiatives related to grantees' payments. One effort led to a policy decision, now being implemented, to consolidate numerous civilian agency payment systems into two systems (The Department of Defense will use the Defense Procurement Payment System). The efforts of the Committee's prior work have been incorporated into the Post-Award Work Group.
- The Interagency Electronic Grants Committee (IAEGC) that has established a standard transaction set for electronic submission of applications for grants and cooperative agreements, and is working toward a Government-wide system for applicant and recipient electronic business interactions with Federal awarding agencies. The IAEGC co-chairs are leading the Electronic Processing Work Group and electronic interagency grant coordination activities.
- The Single Audit Compliance Supplement Core group has been responsible for producing the annual update to the Compliance Supplement required by OMB Circular A–133. The group provides the information needed by auditors to guide them to the major compliance areas they should review in their single audit of Federal programs. The group ensures that compliance requirements are valid and up-to-date.

VI. Specific Projects

At the outset of the interagency, consultative process, the Committee identified specific projects for the General Policy and Oversight Team and the four work groups. As the effort progresses, the list of specific projects may be modified. The following paragraphs describe the projects being undertaken by each work group.

For most tasks, a goal is to have more uniform approaches across the many Federal agencies, at least when their programs have similar purposes. This involves three phases. The first phase is to establish what Federal agencies are doing today, as a baseline from which any improvements would be made. Data is being compiled from a number of sources, to help establish the scope of the undertakings and identify representative samples of Federal programs for detailed analysis. Input from applicants and recipients is being reviewed regarding the problems that they see with the way things are today.

The second phase of the effort is a critical assessment to determine which requirements and problems are candidates for elimination, streamlining or improvement. The groups must question the rationale for current requirements, particularly requirements that are not uniform across Federal agency programs with similar purposes and recipients.

The third and final phase is to assist OMB develop recommendations for the Committee and Congress.

A. General Policy and Oversight Team

The General Policy and Oversight Team is overseeing the progress of the work groups, and examining crosscutting issues and entitlement grant regulatory coverage. It is providing direction and assistance, and is coordinating interagency work groups' activities in their endeavors to improve the delivery of services to the public. A proposed budget has been developed based on an examination of resources available through the CFO Council to implement the Act.

One objective is to ensure that recipients provide timely, complete, and high quality information in response to Federal reporting requirements. Other objectives include streamlining and simplifying administrative requirements and procedures for Federal financial assistance programs; and improving the effectiveness and performance of programs by facilitating greater coordination among Federal agencies responsible for delivering services to the public, *e.g.*, to bring more coordination to the administrative process, particularly for similar programs.

In addition, this team will review and prioritize three areas of concern that arose during public consultation meetings with recipient communities. The team will consider these issues as tasks for possible expansion and/or assignment to one or more of the four work groups:

(1) Native American Tribal Entities

The objective of this task will be to study and address several issues unique to Native American tribal entities, such as developments under the Indian Self-Determination Act.

(2) Rural Access and Infrastructure

The objective of this task will be to examine problems related to access or infrastructure, as these problems affect the ability to participate in Federal financial assistance programs. For example, public comments highlighted that some rural and other participants encounter barriers due to communications infrastructure, including computers and high-speed transmission lines needed for optimal Internet access and electronic commerce with Federal agencies.

(3) Grantee Ombudsman

Due to the many issues raised by non-Federal grantees, the objective of this task would be to assess the extent to which requirements may be duplicative or unduly burdensome.

B. Pre-Award Work Group

The Pre-Award Work Group currently has three tasks: applications, terms and conditions, and debarment and suspension. The current plans for these projects are described in the following paragraphs.

To carry out the first two tasks, the work group created two subgroups based on recipient type. One subgroup will look at requirements for States, local and tribal governments, and nonprofit organizations participating in Federal programs for purposes other than research. The other subgroup will look at universities and nonprofit organizations that administer research awards. The work group's analysis of Federal funding data suggested that the two subcategories of nonprofit organizations are different sets of organizations. As the subgroups make progress on these two tasks, they may organize their work so as to recognize other types of recipients (*e.g.*, for-profit firms) and specific functions (*e.g.*, construction).

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(1) Applications

The objective of this task is to streamline and simplify application or proposal requirements and procedures for Federal financial assistance programs administered by the agencies.

The focus is on the types of information that Federal agencies require applicants or proposers to submit as a prerequisite to obtaining Federal funds, whether in paper form or electronically. The intent is to achieve greater consistency in the requirements of the many Federal agencies, particularly where programs have similar purposes. The goal of this group is to propose a standard set of data elements for application forms or electronic transaction sets, which will address more common formats.

(2) Terms and Conditions

The objective of this task is to streamline and simplify Federal agencies' grant terms and conditions, through which agencies communicate post-award requirements to recipients. This task includes eliminating unnecessary requirements and unjustified differences among the various awarding agencies (*e.g.*, in the language used and the placement of various provisions within the award document). This task also includes developing a model or standard set of terms and conditions, as well as standard assurances of compliance with applicable national requirements.

(3) Debarment and Suspension

This task involves completion of ongoing work of the existing Interagency Committee on Debarment and Suspension to simplify and update the Government-wide common rule on nonprocurement debarment and suspension, which also contains the Government-wide regulation implementing the Drug-Free Workplace Act of 1988. The Committee is drafting the rule in plain language format to make it easier to understand and use. The updated rule will be published as a Notice of Proposed Rulemaking in the **Federal Register**, with an opportunity for the public to comment.

C. Post-Award Work Group

The Post-Award Work Group has five tasks: reporting, agencies' payment systems, cost principles, grant financial system requirements, and pooled payments. These tasks will be addressed primarily in subgroups, and are described in the following paragraphs.

(1) Reporting

The objective of the first task is to review, streamline and simplify reporting requirements and procedures for Federal grant and cooperative agreement programs administered by the agencies.

This includes the development of more standard reports, particularly among programs that serve similar purposes and are administered by different Federal agencies. The current work group focus is on the types of information that Federal agencies require a recipient to submit for like programs, whether in paper form or electronic, and establishing necessary data elements for common forms/transaction sets. One goal is to consolidate forms, including specialized OMB-approved forms for major Federal programs, and ensure that instructions are clear.

Another goal is to improve the effectiveness and performance of programs by facilitating greater coordination among Federal agencies responsible for delivering services to the public, particularly for similar programs.

(2) Agencies' Payment Systems

On June 16, 1998, the CFO Council approved a plan to have non-Defense agencies select either the HHS Payment Management System (PMS) or the Automated Standard Applications for Payments (ASAP) operated by the Treasury's Financial Management Service and the Federal Reserve Bank of Richmond for use in making payments to their grantees. The Department of Defense will use the Defense Procurement Payment System. The work group will continue to monitor agency progress in implementing this plan.

(3) Cost Principles

One objective is to establish uniform administrative rules for programs that cross agency lines. The goal in this area is to improve the consistent use of language and terminology in describing the requirements that are similar in the OMB cost principles (Circulars A–21, A–87 and A–122). Currently there are differences in language, interpretation, and description for many items that basically have the same requirements. More consistent use of language and terminology among the circulars will improve the relationship between grantees, the Federal agencies, and external auditors. Adding new restrictions or eliminating current ones, is not an objective.

In addition, the work group will review widely varying agency implementations of Circular A–110 and differing interpretations of Circulars A–102 and A–110, and other crosscutting regulations, are also being reviewed. However, revision of these circulars and the regulations themselves is not a current focus of the work group.

(4) Grant Financial System Requirements

The work group will monitor agency progress in implementing the Grant Financial System Requirements, the first functional requirements document issued for grant financial systems of the Federal Government. It is one of a series of functional system requirements documents published by the Joint Financial Management Improvement Program (JFMIP) on Federal financial management systems requirements.

The Federal Financial Management Improvement Act of 1996 mandated that agencies implement and maintain systems that comply substantially with Federal financial management systems requirements, applicable Federal accounting standards, and the U.S. Government Standard General Ledger (SGL) at the transaction level. This act codified JFMIP financial systems requirements as a key benchmark that agency systems must meet, in order to be substantially in compliance with systems requirements provisions.

This document is intended to identify financial system requirements necessary to support grants programs. It is intended to assist system analysts, system accountants, and others who design, develop, implement, operate, and maintain financial management systems.

(5) Pooled Payments

On May 1, 2000, an advance notice of proposed revision to Circular A–110, that would require Federal awarding agencies to offer recipients the option to request cash advances on a "pooled" basis, was published in the **Federal Register** (65 FR 25396). Comments were sought on the merits of pooled payment systems and grant-by-grant payment systems. In that all comments have been received and analyzed, it is the intent of this group to clarify differing positions on the issue and specify when pooling is applicable.

D. Audit Oversight Work Group

The Audit Oversight Work Group's task is to streamline and simplify audit-related requirements and services. The plans for this project include examining the services provided by the Federal Audit Clearinghouse (FAC) to determine where improvements can be made to reduce the burden on auditors and auditees in complying with OMB Circular A–133, and improving those FAC services.

The work group will suggest changes to the FAC procedures to improve the FAC's dissemination of audit information to the public and Federal agencies, its assistance to Federal cognizant and oversight agencies in obtaining OMB Circular A–133 data and reporting packages, and the FAC's services provided to assist OMB's oversight and assessment of Federal award audit requirements. The work group will also study ways to improve the FAC's home page, the outputs of the FAC, and methods to identify and follow-up on delinquent audits.

Additional goals include improving single audit coverage of critical areas identified by program officials; analyzing the adequacy of methods to assess and measure single audit quality (*e.g.*, quality control reviews) to support Federal agency reliance on single audits; providing general information on the process, responsibilities, and role of the FAC; updating the Data Collection Form (Form SF–SAC); providing annual updates to the Compliance Supplement; and producing an overview of the single audit process to better inform recipients and funding officials of the purposes and benefits of the single audit process and the FAC.

E. Electronic Processing Work Group

The Electronic Processing Work Group is chaired by the two co-chairs of the Interagency Electronic Grants Committee. Its task is to enable effective use of electronic commerce throughout the Federal financial assistance community, including a common application, administrative and reporting system, and information collection and sharing. This work group will assist and provide electronic solutions to the other work groups in their endeavors. Plans are described in the following paragraphs.

(1) Common Application, Administrative and Reporting System

One goal is to allow applicants the option to electronically apply for, and report on the use of funds. This includes the development and use of a common application, administrative and reporting system for funding from multiple programs administered by different Federal agencies.

These electronic options will be accomplished through the establishment of a comprehensive, one-stop Federal Gateway for electronic grants processing: the Federal Commons. Given adequate funding, the Federal Commons will be developed and supported as the common face for E-Commerce over the entire grants life cycle, offering both general information exchange and secure electronic transaction processing. The Federal Commons would allow each grantee to choose how it conducts business with the Federal government, *i.e.*, translate whatever technology the grantee uses to a single standard; provide electronic search capability; and possibly be housed at HHS.

Several pilots are underway. If successful, they will be developed as modules of the Federal Commons. The first of these is based on the FedBizOpps.Gov site (maintained by the General Services Administration) for posting procurement opportunities. A contractor will develop a parallel, but separate, system based on the **Federal Register** that will be Web searchable. In addition to their work on Transaction Set 194 and current activity broadening, as necessary, for the non-research community, they are beginning to develop data standards for reporting.

Short term plans for the electronic option include supporting work groups, continuing to pilot test, using successful pilots to develop modules, rolling-out modules when ready, and deploying the Federal Commons across agencies. Longer term plans include developing data standards for reporting, enhancing Federal Commons modules using products/end results of work groups, expanding use of the Federal Commons across agencies, and eliminating unnecessary categorical barriers which impede true streamlining efforts.

(2) Grantee Information Collection and Sharing

The second goal is to improve interagency and intergovernmental coordination of information collection, and sharing of uniform data pertaining to financial assistance programs. It applies to grant recipients, not recipients of services, and it must be consistent with privacy and confidentiality constraints.

This coordination and sharing would be accomplished through the Federal Commons, with the development of a single information release form that allows "boiler-plate" information (including certifications and assurances) to be shared across Federal programs, so that participating grantees need not repeat the same information for each grant and Federal agency. Electronic processes would be available for interactive dialogue and updating. The form could be filed once, easily pulled up, referenced, and updated.

VII. Accomplishments

The following is a list of accomplishments that have been or are expected to be completed by May, 2001, or for which there will be a short-term plan for resolution.

- State, local government, tribal government, research, and other nonprofit entity consultation meetings conducted;
- The Joint Financial Management Improvement Program (JFMIP) standards for grants/financial systems issued. These are standards for financial transactions that are part of any grants management information system;
- Federal Commons concept: a single common portal for secure E-Grants Business. Five initial pilots have been successfully completed and are in the process of integration testing with three Federal agencies—the User Registration, Account Administration, Organizational Profile, Professional Profile, and Application Status Checking modules;
- Data standards developed for grant application, organizational and professional profiles, and grant award (promulgated by the National Institute for Standards and Technology);
- Data dictionary developed for all grants transactions as a result of in-depth reviews by interagency teams of the data elements used for grants administration;
- Focus/forum for E-grants;
- Federal commons electronic user administration completed (includes organization profile and professional profile capability);
- Debarment and suspension regulatory action;
- Entitlement grant regulatory coverage;
- Civilian agency conversion to HHS/Treasury payment systems;
- Pooled payment issues clarified in **Federal Register**;
- Audit clearinghouse form (SF–SAC revised); and
- Audit compliance supplement update issued

VIII. Time Frames/Conclusion

This effort will continue toward the establishment of further specific annual goals and objectives, and an interim plan will be submitted to Congress by May 20, 2001. However, this is a work in progress and completion is expected to take up to five years. Implementation of most aspects is expected by 2002, and the electronic option is expected to be functional by 2003.

We recognize the tremendous importance of Federal financial assistance programs and the services they provide, and are strongly committed to the accomplishment of the objectives of the Act. We are committed to making improvements in the areas described, and continuing to develop additional specific annual goals and objectives.

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Implementation can only be accomplished with full-time resources, so the CFO Council is working with OMB, the Chief Information Officers Council, and the Procurement Executives Council to secure the necessary funding for this multi-year effort.

IX. Potential Recommendations to Congress

Section 6 of the Act requires OMB to submit a report to Congress containing recommendations for changes in law to improve the effectiveness, performance, and coordination of Federal financial assistance programs. Therefore, a very important part of the interagency process described in Sections V and VI of this plan will be an assessment of the statutory impediments to accomplishing the streamlining and simplification that Public Law 106–107 intends. OMB will coordinate this assessment.

X. Individual Agency Commitments to the Interagency Process

The following agencies have jointly submitted the above-described plan for implementation of Public Law 106–107; are actively participating in the interagency process described in Sections V and VI of this plan; support the designation and use of the Federal Commons as the single portal for electronic business interactions with non-Federal entities related to grants award and administration; and will identify and address in their respective resource allocation processes the necessary agency resources, including both human and financial resources, to interconnect internal agency organizations and systems with the Federal Commons and otherwise implement this plan:

Department of Agriculture, Department of Energy, Small Business Administration, National Aeronautics and Space Administration, Social Security Administration, Department of Commerce, Department of State, Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Labor, Department of the Treasury, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of the Interior, Federal Emergency Management Agency, Department of Health and Human Services, National Science Foundation, National Endowment for the Arts—National Foundation on the Arts and the Humanities, National Endowment for the Humanities—National Foundation on the Arts and the Humanities, Institute of Museum and Library Services—National Foundation on the Arts and the Humanities, Corporation for National and Community Service, Department of Transportation.

XI. Lead Agency Officials

The following is a list of the participating agencies' designated lead agency official for carrying out the responsibilities of the agency under Section 5(a)(4) of the Act and, in some cases, additional contact information.

Department of Agriculture

Patricia Healy, Deputy Chief Financial Officer, 202–720–7407, phealy@cfo.usda.gov.

Department of Energy

Trudy Wood, Office of Procurement and Assistance Policy, Office of Procurement and Assistance Management, 202–586–5625, 202–586–0545 (Fax), trudy.wood@pr.doe.gov.

Small Business Administration

Sharon Gurley, Director, Office of Procurement and Grants Management, 202–205–6622, 202–205–6821 (Fax), sharon.gurley@sba.gov.

National Aeronautics and Space Administration

David Havrilla, Senior Systems Accountant, 202–358–2482, 202–359–2952 (Fax), dhavrill@nasa.gov.

Social Security Administration

Tom Staples, Deputy Chief Financial Officer, 410–965–3504, tom.staples@ssa.gov.

Department of Commerce

Elizabeth Dorfman, Acting Director, Office of the Executive Assistance Management, 202–482–3313, 202–482–3270 (Fax), Edorfman@doc.gov.

Department of State

Chris Flaggs, Director, Office of Financial Policy, Reporting and Analysis, 202–261–8625, 202–261–8622 (Fax), FlaggsCh@state.gov; and Lloyd W. Pratsch, Procurement Executive, Office of the Procurement Executive, 703–516–1680, 703–875–6155 (Fax), PratschLW@state.gov.

Agency for International Development

Kathleen O'Hara, Deputy Director, Office of Procurement, 202–712–4759, 202–216–3395 (Fax), KOHara@usaid.gov.

Department of Housing and Urban Development

Pamela Woodside, Director, Office of Systems Integration & Efficiency, Office of the Chief Information Officer, 202–708–0614 ext. 109, 202–708–3135 (Fax), pam_woodside@hud.gov; Barbara Dorf, Office of the Secretary, 202–708–0614 ext. 4637, barbara_dorf@hud.gov; Mailing Address: Regulations Division, Office of the General Counsel, Attn: Barbara Dorf, Room 10276, 451 7th Street, SW., Washington, DC 20410.

Department of Justice

Cynthia Schwimer, Comptroller, Office of Justice Programs, 202–307–3186, 202–514–9028 (Fax), cindy@ojp.usdoj.gov.

Department of Labor

Mark Wolkow, Systems Analyst, 202–693–6829, 202–693–6964 (Fax), wolkow-mark@dol.gov; and Phyllis McMeekin, Director, Departmental Procurement Policy, 202–219–9174, 202–219–9440 (Fax), mcmeekin-phyllis@dol.gov.

Department of the Treasury

Birdie McKay, Director, Program Compliance Division, Financial Management Service, 202–874–6925, 202–874–6965 (Fax), birdie.mckay@fms.treas.gov.

Sheryl Morrow, Director, Program Assistance Division, Financial Management Service, 202–874–6847, 202–874–6965 (Fax), sheryl.morrow@fms.treas.gov.

Department of Defense

Designated lead official: Director of Defense Research and Engineering.

Please send DOD-specific comments concerning this notice to: Mark Herbst, 703–696–0372, 703–696–0569 (Fax), herbstm@acq.osd.mil; and Ron Massengill, Financial Management Analyst, 703–602–0125, 703–602–0777 (Fax), massengr@osd.pentagon.mil.

Department of Education

Mark Carney, Deputy Chief Financial Officer, Office of the Chief Financial Officer, 202–401–3892, 202–401–2455 (Fax), mark_carney@ed.gov.

Department of Veterans Affairs

W. Todd Grams, Deputy CFO and Acting CFO, 202–273–5583, todd.grams@mail.va.gov.

Environmental Protection Agency

Bruce Feldman, Branch Chief, Grants Administration Division, 202–564–5308, 202–565–2469 (Fax), feldman.bruce@epa.gov.

William Kinser, Office of Grants and Debarment, Phone: 202–564–5378, Fax: 202–565–2470, kinser.william@epa.gov.

Department of the Interior

Ceceil Belong, Grants Policy Specialist, 202–208–3474, 202–208–6301 (Fax), ceceil_belong@ios.doi.gov; and Monica Taylor, 202–219–0213, 202–208–6940 (Fax), monica_taylor@ios.doi.gov.

Federal Emergency Management Agency

Richard Goodman, Director, Grants and Acquisition Division, 202–646–4181, 202–646–3846 (Fax), Richard.Goodman@fema.gov.

Department of Health and Human Services

George Strader, Deputy Chief Financial Officer; and Rodd Clay, Office of Grants Management, 202–690–8723, 202–690–6415 (TDD, for the hearing impaired), 202–690–8772 (Fax), rclay@os.dhhs.gov.

National Science Foundation

Jean Feldman, Head, Policy Office, Office of Budget, Finance and Award Management, 703–292–8243, 703–292–9141 (Fax), jfeldman@nsf.gov; and Rick Noll, Head, Institutional Ledger Section, Division of Financial Management, 703–292–4458, 703–292–9005 (Fax), rnoll@nsf.gov.

National Endowment for the Arts

Nicki Jacobs, Director, Grants and Contracts Office, 202–682–5546, 202–682–5610 (Fax), jacobsn@arts.endow.gov.

National Endowment for the Humanities

David Wallace, Director, Grants Office, 202–606–8494, 202–606–8633 (Fax), dwallace@neh.gov.

Institute of Museum and Library Services

Rebecca Danvers, Director of Research and Technology, 202–606–2478, rdanvers@imls.gov.

Corporation for National and Community Service

Jim Phipps, Office of Grants Management, 202–606–5000 ext. 271, 202–565–2850 (Fax), mjphipps@cns.gov.

Quinton Lynch, Grants/Financial Analyst, Office of Grants Management, 202–606–5000 ext. 160, 202–565–2850 (Fax), qlynch@cns.gov.

Department of Transportation

Robert G. Taylor, Office of the Senior Procurement Executive, 202–366–4289, 202–366–7510 (Fax), PL106107@ost.dot.gov; and Richard Meehleib, Office of Budget and Finance, Federal Highway Administration, 202–366–2869, 202–366–7510 (Fax), PL106107@ost.dot.gov.

Mailing address for comments: Office of the Senior Procurement Executive, Attn: Pub. L. 106–107–DOT, Room 7101, M–60, U. S. Department of Transportation, 400 7th St SW., Washington, DC 20590.

XII. Agency Adoptions

As stated in the common agency commitments in Section X, above, the following agencies are participating in this notice:

Department of Agriculture

For the Department of Agriculture.
Dated: December 1, 2000.

Patricia Healy,

Deputy Chief Financial Officer.

Department of Energy

For the Department of Energy.
Dated: November 16, 2000.

James J. Cavanagh,

Acting Director, Office of Procurement and Assistant Management.

Small Business Administration

For the Small Business Administration.
Dated: November 21, 2000.

Thomas Dumaresq,

Assistant Administrator for Administration.

National Aeronautics and Space Administration

For the National Aeronautics and Space Administration.
Dated: November 17, 2000.

David Havrilla,

Senior Systems Accountant.

Social Security Administration

For the Social Security Administration.
Dated: November 28, 2000.

Tom Staples,

Deputy Chief Financial Officer.

Department of Commerce

For the Department of Commerce.
Dated: November 20, 2000.

Raul Perea-Henze,

Deputy Assistant Secretary for Administration.

Department of State

For the Department of State.
Dated: November 22, 2000.

Chris Flaggs,

Office of Financial Policy, Reporting and Analysis.

Agency for International Development

For the Agency for International Development.
Dated: November 15, 2000.

Richard Nygard,

Deputy Assistant Administrator for Management.

Department of Housing and Urban Development

Initiatives Specific to the Department of Housing and Urban Development

The Department of Housing and Urban Development (HUD) has taken a number of steps to streamline management of its grant programs. Highlights of this are discussed below.

A. Creation of A Departmental Grants Management System (DGMS)

HUD is in the process of creating a department-wide Internet based system for managing its grants. The system covers the entire life cycle of a grant, including application submission, review and evaluation of a submission, award and monitoring, and finally close-out and audit. HUD currently has a number of different systems that are used for managing grants, none of which provide coverage through the entire grant life cycle, or provide a means of capturing data from the various systems to create one picture of grants across the department. The purpose of DGMS is to have information on HUD grants in one place, at one time. This will allow HUD to better monitor grantees for compliance with existing regulations and assist in assessing performance of grantees against agreed-upon performance measures. DGMS will also enable HUD to accurately report performance against the goals in the Annual Business Operating Plan and the strategic plan. DGMS will have current and active information for timely submission of HUD's Annual Progress Report to Congress. For grantees, DGMS can be a useful planning tool for the allocation and management of local financial resources and staff. DGMS will also allow grantees to have accurate knowledge of status of all their grants with HUD. The creation of DGMS has been a collaborative effort involving all arms of HUD that are directly or indirectly involved in providing information and assistance to grantees and potential applicants, or managing grants. Below are some results achieved through the DGMS development process:

- One process for accepting grant applications for all formula grants and one process for accepting competitive grant applications.
- A single unified way to commit, de-commit, obligate, and de-obligate funds to a selected applicant, issue grant

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awards, and issue grant amendments for all grant awards.

• Uniform elements for conducting risk assessments of grantees.

• Uniform monitoring module for assessing grantee performance over the life of the grant.

• Uniform method for grantees to identify the projects, activities they were undertaking as part of their grant programs. DGMS will include opportunity for grantees to include tasks but in consultation with grantees, it was determined to make tasks optional.

• Tracking of grant information as it was proposed in the application and as it was approved by HUD. DGMS will also track actual fund usage and accomplishments by activity.

• Tracking of draw downs and performance in completing projects and activities on time and within budget, plus or minus 10% of the approved program budget line items and have the ability to roll the activity items up into budget line items of salaries, fringe, travel, equipment, supplies, etc. for the entire grant. Grantees asked that DGMS use the accrual system to make it easier for accounting staff and auditors to track funds.

• Applicants/Grantees will enter information directly into DGMS to avoid errors or misunderstandings among grantees and HUD staff.

• Each program will have an administrator to set-up DGMS, including creation of parameters and checklists for applicants/grantees to use. This idea came from requests by grantees and public interest groups, as well as program staff.

• Interested parties wanting to get general grant program information or applications for assistance will be able to do so at HUD's home page (www.hud.gov).

• Program administrators will give access rights to staff and grantees, who will in turn give access rights to their staff and grantees.

• Tracking of funds down to an infinite levels of sub-recipients.

• A single process for close-out and audit of all HUD grants.

B. HUD's 2020 Management Reform Efforts

Over the past several years, HUD has been reforming its management and operational practices. As part of this effort, HUD examined the various processes used to manage its portfolio of grants, subsidies and contracts. Agency staff worked to streamline grant application processes, identified areas for streamlining and elimination of paperwork, and sought ways programs could better work together. Chief among examples of where HUD has successfully streamlined its processes is HUD's Consolidated Plan which combines four separate entitlement programs (CDBG, HOME, ESG, and HOPWA) into a single planning and application process that State and local governments can use to manage their HUD program dollars; the Continuum of Care Homeless Assistance Programs which consolidated the application and submission process for a variety of programs (Supportive Housing, Shelter Plus Care, Section 8 moderate Rehabilitation Single Room Occupancy); and the HOPE VI Revitalization program which includes demolition, revitalization, and Section 8 program funds into a single application. The Consolidated Plan won Harvard University's Innovations In Government Award in 1998; the Continuum of Care won this prestigious award in 1999; and HOPE VI in the year 2000.

The same effort that has gone into reforming HUD's programs is being used to reform HUD's management of its grant programs. Using a collaborative re-engineering process, HUD is currently working in Legal Joint Application Design sessions with the Office of General Counsel on streamlining application forms, developing common grant award documents, and standardized terms and conditions for formula and competitive grant awards.

C. Notice of Funding Availability (NOFA)

HUD now publishes all its competitive grant NOFAs at one time in a "SuperNOFA." Grant funding opportunities were previously announced at various times during the year, and often had varying policies and requirements for applications. With the SuperNOFA, HUD has established standardized policies and language for the following:

• Deadlines and acceptance of applications for competitive grants.

• Submission procedures for all applications.

• Basic criteria for rating and ranking applications—Capacity of the Applicant and Organizational Staff to Perform the Work; Need/Extent of the Problem; Soundness of Approach; Leveraging Resources; and Comprehensiveness and Coordination.

• Encouragement of applicants to participate in HUD policy initiatives.

• Eligibility based on program statutory and regulatory requirements.

• Threshold requirement for compliance with Fair Housing and Civil Rights Laws.

• Threshold requirements for compliance with the Americans With Disabilities Act of 1990, and if applicable, compliance with Section 3 of the Housing and Urban Development Act of 1968 for providing economic opportunities for Low and Very-Low Income Persons; and Affirmatively Furthering Fair Housing.

• Application of requirements under the Uniform Relocation Assistance and Real Property Acquisition Act of 1970, as amended, and the governmentwide rule in 49 CFR part 24.

• Use of Standard Forms in the application submission.

• Applicability of environmental requirements under 24 CFR part 50 and part 58.

• Applicability of OMB Circulars and provided information on how to obtain copies.

• Bonus Points in Rating Applications.

• Grant negotiations.

• Correction of Deficient Applications.

• Adjustments to Funding.

• Prohibitions on Lobbying.

• Requirements for documentation and public access under Section 102 of the HUD Reform Act of 1989 and the regulations codified in 24 CFR part 4, Subpart A in a uniform manner.

• Application forms that apply to all applications, in addition to program specific forms.

Dated: November 30, 2000.

Patricia L. Toppings,

Alternate Office of the Secretary of Defense Federal Register Liaison Officer.

Department of Education.

For the Department of Education.

Dated: November 20, 2000.

Thomas P. Skelly,

Acting Chief Financial Officer.

Department of Veterans Affairs

For the Department of Veterans Affairs.

W. Todd Grams,

Deputy Chief Financial Officer and Acting Chief Financial Officer.

Environmental Protection Agency

For the Environmental Protection Agency.

Dated: November 17, 2000.

Marty Monell,

Director, Grants Administration Division.

Department of the Interior

For the Department of the Interior.

Dated: November 14, 2000.

Debra E. Sonderman,

Director, Office of Acquisition and Property Management.

Federal Emergency Management Agency.

For the Federal Emergency Management Agency.

Dated: November 13, 2000.

Richard Goodman,

Director, Grants and Acquisition Division.

Department of Health and Human Services

For the Department of Health and Human Services.

Dated: November 22, 2000.

Terrence J. Tychan,

Deputy Assistant Secretary for Grants and Acquisition Management.

National Science Foundation

For the National Science Foundation.

Dated: November 17, 2000.

Lawrence Rudolph,

General Counsel.

National Foundation on the Arts and the Humanities

For the National Endowment for the Arts.

Dated: November 17, 2000.

Laurence Baden,

Deputy Chairman for Management and Budget.

For the National Endowment for the Humanities.

Dated: November 20, 2000.

John Roberts,

Deputy Chairman.

Institute of Museum and Library Services

For the Institute of Museum and Library Services.

Dated: December 6, 2000.

Rebecca Danvers,

Director of Research and Technology.

Corporation for National and Community Service

For the Corporation for National and Community Service.

Dated: November 16, 2000.

Anthony Musick,

Chief Financial Officer.

Department of Transportation

For the Department of Transportation.

David K. Kleinberg,

Deputy Chief Financial Officer.

[FR Doc. 01–1177 Filed 1–16–01; 8:45 am]

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Dated: November 17, 2000.

Stephen R. Colgate,

Assistant Attorney General for Administration.

Department of Labor

For the Department of Labor.

Dated: November 20, 2000.

Ken Bresnahan,

Chief Financial Officer.

Department of the Treasury

For the Department of the Treasury.

Dated: November 16, 2000.

Paul Gist,

Director of Asset Management Directorate.

Department of Defense

For the Department of Defense.

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Federal Register

Wednesday,
January 17, 2001

Part XIII

Department of Labor

Office of the Secretary

Civil Rights Center; Enforcement of Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons With Limited English Proficiency; Notice

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DEPARTMENT OF LABOR

Office of the Secretary

Civil Rights Center; Enforcement of Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of policy guidance with request for comment.

SUMMARY: The United States Department of Labor (DOL) is publishing policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons.

DATES: This guidance is effective immediately. Comments must be submitted on or before March 19, 2001. DOL will review all comments and will determine what modifications to the policy guidance, if any, are necessary.

ADDRESSES: Interested persons should submit written comments to Ms. Annabelle T. Lockhart, Director, Civil Rights Center, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–4123, Washington, DC 20210; Comments may also be submitted by e-mail at: lockhart-annabelle@dol.gov.

FOR FURTHER INFORMATION CONTACT: Annabelle Lockhart or Naomi Barry at the Civil Rights Center, U.S. Department of Labor, 200 Constitution Ave., NW., Room N–4123, Washington, DC 20210. Telephone 202–219–7026; TDD: 202–693–6516. Arrangements to receive the policy guidance in an alternative format may be made by contacting the named individuals.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.* and its implementing regulations provide that no person shall be subjected to discrimination on the basis of race, color, or national origin under any program or activity that receives federal financial assistance.

The purpose of this policy guidance is to clarify the responsibilities of recipients of federal financial assistance ("recipients") from the U.S. Department of Labor (DOL), and assist them in fulfilling their responsibilities to limited English proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964 and implementing regulations. The policy guidance reiterates DOL's longstanding position that in order to avoid discrimination against LEP persons on the grounds of national origin, recipients must take reasonable steps to ensure that such persons receive the language assistance necessary to afford them meaningful access to the programs, services, and information those recipients provide, free of charge. The text of the complete guidance document appears below.

Signed at Washington, D.C. this 11th of January 2001.

Alexis M. Herman,

Secretary of Labor.

Equal Opportunity Guidance Memorandum

January 3, 2001.

To: Recipients of Federal Financial Assistance from the United States Department of Labor

From: Annabelle T. Lockhart, Director, Civil Rights Center, Department of Labor

Subject: Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency

Purpose

Pursuant to Executive Order 13166, entitled "Improving Access to Services for Persons with Limited English Proficiency," issued by President Clinton on August 11, 2000, the U.S. Department of Labor's Civil Rights Center ("CRC") issues this memorandum, which addresses linguistic or language access, to offer guidance with respect to the responsibilities of recipients of federal financial assistance ("recipients") from the Department of Labor ("DOL") in serving persons of limited English proficiency ("LEP"), pursuant to the requirements of Title VI of the Civil Rights Act of 1964 ("Title VI") and section 188 of the Workforce Investment Act of 1998 ("section 188"). This policy guidance does not create new obligations but, rather, clarifies standards consistent with case law and well-established legal principles developed under Title VI. The CRC provides substantial technical assistance to recipients, and will continue to be available to provide such assistance to any recipient seeking to ensure that it operates an effective language assistance program.

Background

English is the predominant language of the United States. According to the 1990 Census (the most recent data available), English is spoken by 95 percent of U.S. residents. Of those U.S. residents who speak languages other than English at home, the 1990 Census reports that 57 percent above the age of four speak English "well to very well."

The United States is also, however, home to millions of national origin minority individuals who are "limited English proficient," including immigrants, some children of immigrants born in the United States, and other non-English speakers born in the United States, including some Native Americans. National statistics on the LEP population demonstrate that Spanish is the primary language for which assistance may be needed. Many recipients of DOL financial assistance have already implemented processes to improve services for Spanish speakers. However, other nationally significant language groups exist, including those that speak Chinese, French, Italian, German, Vietnamese, Laotian, and Khmer (Cambodian). Moreover, depending on the region of the country, countless other language groups may require assistance to access meaningful government assistance. Because of language differences and the inability to speak or understand English, LEP persons are often excluded from programs and activities, experience delays or denials of services, or receive assistance and services based on inaccurate or incomplete information. Such exclusions, delays or denials may constitute discrimination on the basis of national origin, in violation of Title VI and section 188.

In the course of its enforcement activities, CRC has found that persons who lack proficiency in English are unable to obtain basic knowledge on how to access various benefits and services for which they may be eligible, such as Unemployment Insurance, Job Corps, or other DOL funded employment programs and activities. For example, many intake interviewers and other front line employees who interact with LEP individuals are neither bilingual nor trained in how to properly serve LEP persons. As a result, LEP applicants are often either turned away, forced to wait for substantial periods of time, forced to find their own interpreter who is not often qualified to interpret, or forced to make repeated visits to the recipient's program offices until interpreters are available to provide assistance.

Some employment benefits, services, and job training providers have sought to bridge the language gap by encouraging language minority clients to provide their own interpreters as an alternative to the recipient's use of qualified bilingual employees or interpreters. Persons of limited English proficiency must sometimes rely on their minor children to interpret for them during visits to an employment services or job training facility. Alternatively, these clients may be required to call upon neighbors or even strangers they encounter at the recipients' program offices to act as interpreters or translators.

These practices have severe drawbacks and may violate Title VI and Section 188. In each case, the impediments to effective communication and adequate service are formidable. The LEP client's untrained "interpreter" is often unable to understand the concepts or official terminology s/he is being asked to interpret or translate. Even if the interpreter possesses the necessary language and comprehension skills, his or her mere presence may obstruct the flow of confidential information to the recipient. This is because the LEP client would naturally be reluctant to disclose or discuss intimate details of personal and family life in front of his or her child or a complete stranger who has no formal training or obligation to observe confidentiality.

When these types of circumstances are encountered, the level and quality of employment benefits, services, and job training available to persons of limited English proficiency stand in stark conflict to Title VI and section 188's promise of equal access to federally assisted programs and activities. Services denied, delayed or provided under adverse circumstances have serious consequences for a LEP person and may constitute discrimination on the basis of national origin in violation of Title VI and section 188. Accommodation of these language differences through the provision of effective language assistance will promote compliance with Title VI and section 188.

Although CRC's enforcement authority derives from Title VI and section 188, the duty of recipients to ensure that LEP persons can meaningfully access programs and services flows from a host of additional sources, including federal and state laws and regulations. In addition, the duty to provide appropriate language assistance to LEP individuals is not limited to the employment benefits, services, and job training context. Numerous federal laws require the provision of language assistance to LEP individuals seeking to access critical services and activities. For instance, the Voting Rights Act bans English-only elections in certain circumstances and outlines specific measures that must be taken to ensure that language minorities can participate in elections. *See* 42 U.S.C. 1973 b(f)(1). Similarly, the Food Stamp Act of 1977 requires states to provide translation and interpretation assistance to LEP persons under certain circumstances. *See* 42 U.S.C. 2020(e) (1) and (2). These and other provisions reflect the sound judgment that providers of critical services and benefits bear the responsibility for ensuring that LEP individuals can meaningfully access their programs and services.

This policy guidance is consistent with the Department of Justice ("DOJ") LEP Guidance, which addresses the application of Title VI's prohibition against national origin discrimination when information is provided in English to LEP persons.[1] It is also consistent with a government-wide Title VI regulation issued by DOJ in 1976, "Coordination of Enforcement of Nondiscrimination in Federally Assisted Programs," 28 CFR part 42, subpart F, that addresses the circumstances in which recipients must provide translation assistance to LEP persons.[2]

Legal Authority

Introduction

CRC has conducted investigations and reviews involving language differences that impede the access of LEP persons to employment benefits, services, and job training in programs and activities that are financially assisted by DOL. Where the failure to accommodate language differences discriminates on the basis of national origin, CRC has required recipients to provide appropriate language assistance to LEP persons. For instance, CRC has entered into voluntary compliance agreements that require recipients who operate employment benefits, services, and job training programs or activities to ensure that there are bilingual employees or language interpreters to meet the needs of LEP persons seeking services. CRC has also required these recipients to provide written materials and post notices in languages other than English. The legal authority for CRC's enforcement actions is Title VI and Section 188, the implementing regulations, and a consistent body of case law.

[1] The DOJ LEP Guidance was issued August 11, 2000. (65 FR 50123, August 16, 2000.)

[2] The DOJ coordination regulations at 28 CFR 42.405(d)(1) provide that "[w]here a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program needs service or information in a language other than English in order effectively to be informed of or to participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in appropriate languages to such persons. This requirement applies with regard to written materials of the type which is ordinarily distributed to the public."

Statute and Regulations

Section 601 of Title VI, 42 U.S.C. 2000d *et seq.* states: "No person in the United States shall on the grounds of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."

Department of Labor Regulations implementing Title VI, provide in part at 29 CFR 31.3 (b):

(1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on the grounds of race, color or national origin:

(i) Deny an individual any service, financial aid, or other benefit provided under the program;

(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program * * *;

(2) A recipient, in determining the types of services, financial aid or other benefits, or facilities that will be provided under any such program, or the class of individuals to whom, or the situations in which such services, financial aid or other benefits, or facilities will be provided * * * *may not directly, or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination, because of their race, color or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals of a particular race, color or national origin (emphasis added)* * *.

Section 188 of the Workforce Investment Act adopts the same prohibition against national origin discrimination that is found in Title VI: "No individual shall be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with any such program because of race, color, national origin, sex, religion, disability, political affiliation or belief, citizenship, or age."

Regulations implementing the nondiscrimination and equal opportunity provisions of section 188 of the Workforce Investment Act of 1998, speak specifically to national origin discrimination and language access at 29 CFR 37.35:

(a) A significant number or proportion of the population eligible to be served, or likely to be directly affected, by a WIA Title I-financially assisted program or activity may need services or information in a language other than English in order to be effectively informed about, or able to participate in, the program or activity. Where such a significant

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number or proportion exists, a recipient must take the following actions:

(1) Consider:

(i) The scope of the program or activity; and

(ii) The size and concentration of the population that needs services or information in a language other than English; and

(2) Based on those considerations, take reasonable steps to provide services and information in appropriate languages. This information must include the initial and continuing notice required under §§ 37.29 and 37.30, and all information that is communicated under § 37.34.

(b) In circumstances other than those describe in paragraph (a) of this section, a recipient should nonetheless make reasonable efforts to meet the particularized language needs of limited-English speaking individuals who seek services or information from the recipient.

Title VI and the Department of Labor regulations implementing Title VI published at 29 CFR part 31 apply to any program or activity receiving federal financial assistance from the Department of Labor. Some programs and activities receiving federal financial assistance from the Department of Labor are covered only under Title VI and the Department of Labor's Title VI regulations (*e.g.*, programs receiving assistance through the Mine Safety and Health Act and the Occupational Safety and Health Act).

Some programs and activities receiving Department of Labor financial assistance, i.e., those that receive financial assistance under Title I of WIA, are covered under both the DOL Title VI regulations and the section 188 implementing regulations. The regulation at 29 CFR 37.3 states that compliance with the regulations in 29 CFR part 37 will satisfy obligations of the recipient to comply with 29 CFR part 31.

The section 188 implementing regulations found in 29 CFR part 37 apply to any program or activity receiving financial assistance under Title I of WIA. In addition, the section 188 implementing regulations apply to programs and activities that are part of the One-Stop delivery system and that are operated by One-Stop partners listed in section 121(b) of WIA, to the extent that the programs and activities are being conducted as part of the One-Stop delivery system. Some One-Stop programs and activities receive federal financial assistance from other federal agencies (*e.g.*, Department of Education and Department of Housing and Urban Development). For purposes of the regulations in 29 CFR Part 37, however, "One-Stop partners," as defined in section 121(b) of WIA, are treated as "recipients," and are subject to the nondiscrimination requirements to the extent that they participate in the One-Stop delivery system. Some programs and activities that are part of the One-Stop delivery system and that receive financial assistance from a federal grantmaking agency other than the Department of Labor are covered under the Section 188 implementing regulations, but not under DOL's Title VI regulations. However, these programs and activities are subject to the Title VI regulations of a federal grantmaking agency other than the Department of Labor.

Although the regulatory language differs, the obligations of recipients to ensure accessibility by LEP persons to DOL financially assisted programs and activities are the same under Title VI and section 188. Accordingly, the CRC will apply the same standards in determining compliance with these obligations.

State and local laws may provide additional obligations to serve LEP individuals, but such laws cannot compel recipients of federal financial assistance to violate Title VI. For instance, given our constitutional structure, state or local "English-only" laws do not relieve an entity that receives federal funding from its responsibilities under federal anti-discrimination laws. Entities in states and localities with "English-only" laws are certainly not required to accept federal funding—but if they do, they have to comply with Title VI, including its prohibition against national origin discrimination by recipients of federal assistance. Failing to make federally assisted programs and activities accessible to individuals who are LEP will, in certain circumstances, violate Title VI.

Case Law

Extensive case law affirms the obligation of recipients of Federal financial assistance to ensure that LEP persons can meaningfully access Federally-assisted programs and activities.

The U.S. Supreme Court, in *Lau* v. *Nichols*, 414 U.S. 563 (1974), recognized that recipients of federal financial assistance have an affirmative responsibility, pursuant to Title VI, to provide LEP persons with meaningful opportunities to participate in public programs and activities. In *Lau* v. *Nichols*, the Supreme Court ruled that a public school system's failure to provide English language instruction to students of Chinese ancestry who did not speak English denied the students meaningful opportunities to participate in a public educational program in violation of Title VI. In providing the same services to the LEP students as it did for English proficient students—an education provided solely in English—the Supreme Court observed that "it seems obvious that the Chinese-speaking minority received fewer benefits than the English-speaking majority from respondent's school system which denies them a meaningful opportunity to participate in the educational program. * * *" Courts have applied the doctrine articulated in *Lau* both inside and outside the education context, including in cases involving driver's license tests and material relating to unemployment benefits.

As early as 1926, the Supreme Court recognized that language rules were often discriminatory. In *Yu Cong Eng et al.* v. *Trinidad, Collector of Internal Revenue*, 271 U.S. 500 (1926), the Supreme Court found that a Philippine Bookkeeping Act that prohibited the keeping of accounts in languages other than English, Spanish and Philippine dialects violated the Philippine Bill of Rights that Congress had patterned after the U.S. Constitution. The Court found that the Act deprived Chinese merchants, who were unable to read, write or understand the required languages, of liberty and property without due process.

In *Gutierrez* v. *Municipal Court of S.E. Judicial District*, 838 F.2d 1031,1039 (9th Cir. 1988), vacated as moot, 490 U.S. 1016 (1989), the court recognized that requiring the use of English only is often used to mask national origin discrimination. Citing McArthur, "Worried About Something Else," 60 Int'l J. Soc. Language, 87, 90–91 (1986), the court stated that because language and accents are identifying characteristics, rules that have a negative effect on bilingual persons, individuals with accents, or non-English speakers may be mere pretexts for intentional national origin discrimination.

Another case that noted the link between language and national origin discrimination is *Garcia* v. *Gloor*, 618 F.2d 264 (5th Cir. 1980) *cert. denied*, 449 U.S. 1113 (1981). The court found that on the facts before it a workplace English-only rule did not discriminate on the basis of national origin since the complaining employees were bilingual. However, the court stated that "to a person who speaks only one tongue or to a person who has difficulty using another language other than the one spoken in his home, language might well be an immutable characteristic like skin color, sex or place of birth." *Id.* At 269.

Again, in the employment context, the Court in *Pabon* v. *Levine*, 70 FRD 674 (S.D.N.Y. 1976), found that the plaintiffs, who challenged the state's failure to provide unemployment insurance information in languages other than English, properly raised a claim under Title VI.

Most recently, the Eleventh Circuit in *Sandoval* v. *Hagan*, 197 F. 3d 484 (11th Cir. 1999), *cert. granted sub. Nom., Alexander* v. *Sandoval*, 147 L. Ed. 2d 1051 (U.S. Sept. 26, 2000) (No. 99–1908) (accepting case to address whether or not there is a private right of action under Title VI), held that the State of Alabama's policy of administering a driver's license examination in English only was a facially neutral practice that had an adverse effect on the basis of national origin, in violation of Title VI. The court specifically noted the nexus between language policies and potential discrimination based on national origin. That is, in *Sandoval*, the vast majority of individuals who were adversely affected by Alabama's English-only driver's license examination policy were national origin minorities.

In the employment benefits, services, and job training context, a recipient's failure to provide appropriate language assistance to LEP individuals parallels many of the fact situations discussed in the cases above and, as in those cases, may have an adverse effect on the basis of national origin, in violation of Title VI.

The Title VI regulations prohibit both intentional discrimination and policies and practices that appear neutral but have a discriminatory effect. Thus, a recipient's policies or practices regarding the provision of benefits and services to LEP persons need not be intentional to be discriminatory, but may constitute a violation of Title VI and section 188 if they have an adverse effect on the ability of national origin minorities to meaningfully access programs and services. Accordingly, it is useful for recipients to examine their policies and practices to determine whether they adversely affect LEP persons. This policy guidance provides a legal framework to assist recipients in conducting such assessments.

Policy Guidance

Who Is Covered

All entities that receive federal financial assistance from the Department of Labor, either directly or indirectly, through a grant, contract or subcontract, are covered by this policy guidance. For purposes of section 188, covered entities include, but are not limited to: state-level agencies that administer, or are financed in whole or in part with, WIA Title I funds; State Employment Security Agencies; State and local Workforce Investment Boards; local Workforce Investment Areas ("LWIA") grant recipients; One-Stop operators; service providers, including eligible training providers; On-the-Job Training (OJT) employers; Job Corps contractors and center operators; Job Corps national training contractors; outreach and admissions agencies, including Job Corps contractors that perform these functions; and other national program recipients.[3] Entities may be receiving financial assistance through one or more of a number of DOL administered statutes, including, but not limited to, the Wagner-Peyser Act, the Workforce Investment Act, Welfare-to-Work, the Older Americans Act, the Social Security Act, the Mine Safety and Health Act, and the Occupational Safety and Health Act.

The term federal financial assistance to which Title VI applies includes, but is not limited to, grants and loans of federal funds, grants or donations of federal property, details of federal personnel, or any agreement, arrangement or other contract that has as one of its purposes the provision of assistance (see, 45 CFR 80.13(f); Appendix A to the Title VI regulations, and 29 CFR 37.4, for additional discussion of what constitutes federal financial assistance).

Title VI prohibits discrimination in any program or activity that receives federal financial assistance. What constitutes a program or activity covered by Title VI was clarified by Congress in 1988, when the Civil Rights Restoration Act of 1987 ("CRRA") was enacted. The CRRA provides that, in most cases, when a recipient receives federal financial assistance for a particular program or activity, all operations of the recipient are covered by Title VI, not just the part of the program or activity that uses the federal assistance. Thus, all parts of the recipient's operations would be covered by Title VI, even if the federal assistance is used only by one part. The definition of a WIA Title I-funded program or activity can be found at 29 CFR 37.4. Costs associated with providing meaningful access to LEP persons are considered allowable administrative costs.

[3] One-Stop participants that receive financial assistance from a federal grantmaking agency other than the Department of Labor are subject to the Title VI implementing regulations and guidance of that grantmaking agency.

Basic Requirements Under Title VI and Section 188

A recipient whose policies, practices or procedures exclude, limit, or have the effect of excluding or limiting, the participation of any LEP person in a federally assisted program or activity on the basis of national origin may be engaged in discrimination in violation of Title VI and Section 188. In order to ensure compliance with Title VI and section 188, recipients must take steps to ensure that LEP persons who are eligible have meaningful access during all hours of operation to the recipients' programs and services. The most important step in meeting this obligation is for recipients of federal financial assistance to provide the language assistance necessary to ensure such access, at no cost to the LEP person.

On August 11, 2000, the President issued Executive Order 13166 titled "Improving Access to Services by Persons With Limited English Proficiency ." 65 FR 50121 (August 16, 2000). On the same day, the Assistant Attorney General for Civil Rights issued a Policy Guidance Document titled "Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency" (hereinafter referred to as "DOJ LEP Guidance"), reprinted at 65 FR 50123 (August 16, 2000).

Executive Order 13166 requires Federal departments and agencies extending financial assistance to develop and make available guidance on how recipients should, consistent with the DOJ LEP Guidance and Title VI of the Civil Rights of 1964, as amended, assess and address the needs of otherwise eligible limited English proficient persons seeking access to federally assisted programs and activities. The DOJ LEP Guidance, in turn, provides general guidance on how recipients can ensure compliance with their Title VI obligation to "take reasonable steps to ensure 'meaningful' access to the information and services they provide." DOJ LEP Guidance, 65 FR at 50124. The DOJ LEP Guidance goes on to provide that [w]hat constitutes reasonable steps to ensure meaningful access will be contingent on a number of factors. Among the factors to be considered are the size of the recipient; the size of the eligible LEP population to serve; the nature of the program or service; the objectives of the program or service; the total resources available to the recipient; the frequency with which particular languages other than English are encountered; and, the

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frequency with which LEP persons come into contact with the program or service. Of these factors, the following four are considered the most pivotal to determining the nature of the language assistance provided by a recipient: the number or proportion of LEP individuals eligible to participate or likely to be directly or significantly affected by the program or activity; the frequency of contact a participant or beneficiary is required to have with the program or activity; the nature and importance of the program or activity to the participant or beneficiary; and, the resources available to the recipient in carrying out the program or activity. These factors constitute what herein after will be referred to as the elements of the "four-factor analysis." This Guidance for DOL is consistent with the compliance standards set out in the DOJ LEP Guidance.

The type of language assistance a recipient provides to ensure meaningful access will depend on a variety of factors, Programs and activities that serve a few or even one LEP person are still subject to the Title VI and section 188 obligation to take reasonable steps to provide meaningful opportunities for access. However, a factor in determining the reasonableness of a recipient's efforts is the number or proportion of people who will be excluded from the program or activity absent efforts to remove language barriers. The steps that are reasonable for a recipient who serves one LEP person a year will be different than those expected from a recipient who serves several LEP persons each day.

The importance of the recipient's program or activity to participants or beneficiaries will affect the determination of what is "reasonable." More affirmative steps must be taken in programs and activities where the denial of access may have serious implications, such as the receipt of Unemployment Insurance benefits. In assessing the effect of denying access, recipients must consider the importance of the benefit to individuals both immediately and in the long-term.

The resources available to a recipient of federal financial assistance may have an impact on the nature of the steps that recipients must take. For example, a small recipient with limited resources may not have to take the same steps as a larger recipient to provide LEP assistance in programs and activities that have a limited number of eligible LEP individuals, where contact is infrequent, and/or where the program or activity is not crucial to an individual's day-to-day existence. Claims of limited resources, especially from larger entities, will need to be well-substantiated.

Frequency of contacts between the program or activity and LEP individuals is another factor to be considered. For example, if a LEP individual must access a program or service on a daily basis, such as activities provided in a job training program, a recipient has greater duties than if program or activity contact is unpredictable or infrequent. LEP individuals must be able to access and participate in job training activities in a manner equally consistent and effective to that offered to non-LEP persons.

There is no "one size fits all" solution for Title VI and section 188 compliance with respect to LEP persons. CRC will make its assessment of the language assistance needed to ensure meaningful access on a case by case basis, and a recipient will have considerable flexibility in determining precisely how to fulfill this obligation. CRC will focus on the end result—whether the recipient has taken the necessary steps to ensure that LEP persons have meaningful access to programs and services.

The key to providing meaningful access for LEP persons, including LEP persons likely to be directly or significantly affected (*e.g.*, LEP parents of non-LEP students) is to ensure that the recipient and LEP person can communicate effectively. The steps taken by a recipient must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible, free-of-charge. The recipient must also ensure that the LEP person can effectively communicate the relevant circumstances of his or her situation to the service provider.

Effective language assistance programs usually contain the four elements described in the following section. In reviewing complaints and conducting compliance reviews, CRC will consider a program or activity to be in compliance when the recipient effectively incorporates and implements these four elements. The failure to incorporate or implement one or more of these elements does not necessarily mean noncompliance with Title VI and Section 188, and CRC will review the totality of the circumstances to determine whether LEP persons can meaningfully access the services and benefits of the recipient.

Ensuring Meaningful Access to LEP Persons

Introduction—The Four Keys to Title VI and Section 188 Compliance in the LEP Context

The key to ensuring meaningful access to services and benefits for LEP persons is to guarantee that the language assistance provided results in accurate and effective communication between the recipient and LEP applicant/client about the types of services and/or benefits available and about the applicant's or client's circumstances. Although DOL recipients have considerable flexibility in fulfilling this obligation, effective programs usually consist of the following four elements:

I. Assessment. The recipient conducts a thorough annual assessment of the language needs of the population to be served;

II. Development and Implementation of a Written Policy on Language Access. The recipient develops and implements a comprehensive written policy that will ensure meaningful communication. This plan is amended on an annual basis, as needed, depending on the local service population;

III. Training of Staff. The recipient takes steps to ensure that staff understands the policy and is capable of carrying it out; and

IV. Vigilant Monitoring. The recipient conducts regular oversight of the language assistance program to ensure that LEP persons can meaningfully access the program or activity.

The failure to implement one or more of these measures does not necessarily mean noncompliance with Title VI and section 188, and CRC will review the totality of the circumstances in each case. If implementation of one or more of these options would be so financially burdensome as to defeat the legitimate objectives of a recipient's program or activity, and if there are equally effective alternatives for ensuring that LEP persons have meaningful access to programs and services, CRC will not find the recipient in noncompliance. However, in reviewing recipients' compliance, the CRC will seek documentation and evidence that the recipient considered and, when appropriate, incorporated these elements into their language assistance programs.

I. Assessment

The first key to ensuring meaningful access is for the recipient to assess the language needs of the affected population. A recipient assesses language needs by:

• Identifying the languages other than English that are likely to be encountered in its program or activity and by estimating the number of LEP persons that are eligible for services and/or benefits and that are likely to be directly affected by its program or activity. This can be done by reviewing data from a combination of sources, including the census and state labor market information systems, client utilization data from client files, and statistics from school systems and community agencies and organizations. When a recipient believes that the provision of aid, services, benefits, or training to LEP persons has not been effective in the past, the primary source of data from which estimates of the eligible LEP population is made should not stem from client utilization data from client files;

• Determining the language needs of LEP clients, keeping in mind that some LEP individuals will not self-identify as LEP out of fear that their level of participation will be curtailed by their inability to communicate in the English language;

• Recording LEP status in clients' files to ensure that LEP individuals are consistently communicated with in the appropriate language as they navigate all stages of the recipient's program;

• Locating the points of contact of all stages of the program or activity where language assistance is likely to be needed;

• Reviewing delivery systems to determine whether any program system denies or limits participation by LEP individuals. For example, many states have implemented telephone certification systems for Unemployment Insurance programs. Telephone systems often only provide instructions in English, or in some cases, Spanish. Some states require UI applicants to request a waiver from participation in this system even if they are LEP. Programs offering computer-based technologies may encounter circumstances that similarly limit meaningful participation;

• Understanding circumstances in which, although the participant and/or beneficiary can communicate effectively in English, assistance may be needed when interacting with other pertinent individuals. For example, if a student under the age of eighteen needs his/her parents' signature to participate in a summer employment program, both written and oral language assistance may be necessary to provide information and obtain the necessary permission;

• Assessing the resources that will be needed to provide effective language assistance and the location and availability of these resources; and,

II. Development and Implementation of a Written Policy on Language Access

All recipients are required to ensure effective communication by developing and implementing a comprehensive written language assistance program that includes policies and procedures for identifying and assessing the language needs of its LEP applicants/clients and that provides for a range of interpreter assistance, notification to LEP persons in appropriate languages of the right to free language assistance, periodic training of staff, monitoring of the program, and translation of written materials in certain circumstances.[4] Certain recipients of DOL financial assistance are required, per 29 CFR 37.54, to establish and adhere to a Methods of Administration ("MOA"). Per the regulations, MOAs must be in writing, reviewed and updated every two years as required by Section 37.55, and, at a minimum, describe how the state programs and recipients have satisfied the requirements of regulations, including those found at Sections 37.35 and 37.42 (Section 37.35 can be found on pages 5–6 of this document).

Oral Language Interpretation

In designing an effective language assistance program, a recipient should develop procedures for obtaining and providing trained and competent interpreters and other interpretation services, in a timely manner, by taking some or all of the following steps:

• Hiring bilingual staff who are trained and competent in the skill of interpreting;

• Hiring staff interpreters who are trained and competent in the skill of interpreting;

• Contracting with an outside interpreter service for qualified interpreters;

• Arranging formally for the services of volunteers who are qualified interpreters;

• Arranging/contracting for the use of a telephone language interpreter service.

The following provides guidance to recipients in determining which language assistance options will be of sufficient quantity and quality to meet the needs of their LEP beneficiaries:

Bilingual Staff: Hiring bilingual staff for applicant and client contact positions facilitates participation by LEP persons. The ability of staff members to communicate directly with LEP clients, without third-party interpretation and translation assistance, maximizes agency resources and permits LEP clients to more fully engage in programs and services. However, where there are a variety of LEP language groups in a recipient's service area, this option may be insufficient to meet the needs of all LEP applicants and clients. Where this option is insufficient to meet the needs, the recipient must provide additional and timely language assistance. The qualifications of both current and future bilingual staff must be reviewed to ensure demonstrated proficiency in English and the second language, orientation and training on the skills and ethics of interpretation, and fundamental knowledge in both languages of any specialized terms or concepts.

Staff Interpreters: Paid staff interpreters are especially appropriate where there is a frequent and/or regular need for interpreting services. The qualifications of both current and future staff interpreters must be reviewed to ensure demonstrated proficiency in English and the second language, orientation and training on the skills and ethics of interpretation, and fundamental knowledge in both languages of any specialized terms or concepts. Staff interpreters must be readily available.

Contract Interpreters: The use of contract interpreters may be an option for recipients that have infrequent needs for interpreting services, have less common LEP language groups in their service areas, or need to supplement their in-house capabilities on an as-needed basis. Where non-staff interpreters are used, appropriate training must be provided. Training should include orientation and training on the skills and ethics of interpretation and fundamental knowledge in both languages of any specialized terms or concepts. Contract interpreters must also be readily available.

Community Volunteers: Use of community volunteers may provide recipients with a cost-effective method for providing interpreter services. However, experience has shown that to use community volunteers effectively, recipients must ensure that formal arrangements for interpreting services are made with community organizations so that these organizations are not

[4] Both the Americans with Disabilities Act and section 504 of the Rehabilitation Act of 1973 prohibit discrimination on the basis of disability and require entities to provide language assistance such as sign language interpreters for hearing impaired individuals or alternative formats such as braille, large print or tape for vision impaired individuals. In developing a comprehensive language assistance program, recipients should be mindful of their responsibilities under the ADA and section 504 to ensure access to programs and activities for persons with disabilities.

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subjected to *ad hoc* requests for assistance. In addition, recipients must ensure that these volunteers are qualified to interpret and understand their obligation to maintain client confidentiality. Where community volunteers are used, appropriate training must be provided. Training should include orientation and training on the skills and ethics of interpretation and fundamental knowledge in both languages of any specialized terms or concepts. Additional language assistance must be provided where competent volunteers are not readily available during all hours of service.

Telephone Interpreter Lines: A telephone interpreter service line may be a useful option as a supplemental system, or may be useful when a recipient encounters a language that it cannot otherwise accommodate. Such a service often offers interpreting assistance in many different languages and usually can provide the service in quick response to a request. However, recipients should be aware that such services may not always have readily available interpreters who are familiar with the terminology peculiar to the particular program or service. This method may also be inadequate if and when documents need to be reviewed. It is important that a recipient not offer this as the only language assistance option except where other language assistance options are unavailable.

Three recurring issues in the area of interpreter services involve (a) the use of friends, family, or minor children as interpreters; (b) the level of language ability; and, (c) the need to ensure that interpreters are qualified.

(a) *Use of Friends, Family, or Minor Children as Interpreters:* A recipient may expose itself to liability under Title VI and section 188 if it requires, suggests, or encourages a LEP person to use friends, family members, or minor children, as interpreters, as this could compromise the effectiveness of the service. Use of such persons could result in a breach of confidentiality or reluctance on the part of individuals to reveal personal information critical to their situations. In addition, family and friends usually are not competent to act as interpreters, since they are often insufficiently proficient in both languages, unskilled in interpretation, and unfamiliar with specialized terminology.

If after a recipient informs a LEP person of the right to free interpreter services, the person declines such services and requests the use of a family member or friend, the recipient may use the family member or friend, if the use of such a person would not compromise the effectiveness of services or violate the LEP person's confidentiality. The recipient should make efforts to document the offer and declination in the LEP person's file. Even if a LEP person elects to use a family member or friend, the recipient should suggest that a trained interpreter sit in on the encounter to ensure accurate interpretation.

(b) *Level of Language Ability:* As with English speakers, the ability of LEP individuals to read and comprehend written materials even in their native languages will vary. If persons are illiterate even in their native languages, oral interpretation of written materials may be necessary. As a general rule, interpreters should be aware of variances within a language, i.e. different words are used throughout the Spanish-speaking world to describe the same thing. Interpreters should be able to communicate with LEP individuals utilizing the appropriate colloquial speech.

(c) *Qualified Interpreters:* In order to provide effective services to LEP persons, a recipient must ensure that it uses persons who are qualified to provide interpreter services. Being qualified does not necessarily mean formal certification as an interpreter, though certification is helpful. On the other hand, being qualified requires more than self-identification as bilingual. The requirement to be qualified contemplates:

- Demonstrated proficiency in both English and the other language;
- Orientation and training that includes the skills and ethics of interpreting (e.g., issues of confidentiality);
- Fundamental knowledge in both languages of any specialized terms or concepts peculiar to the recipient's program or activity;
- Sensitivity to the LEP person's culture; and,
- A demonstrated ability to convey information in both languages, accurately.

A recipient must ensure that those persons it provides as interpreters are trained and qualified to act in this role.

Translation of Written Materials

An effective language assistance program ensures that written materials that are routinely provided in English to applicants, clients and the public are available in regularly encountered languages other than English. It is particularly important to ensure that vital documents, such as applications; consent forms; letters containing important information regarding participation in a program or activity; notices pertaining to the reduction, denial or termination of services or benefits and of the right to appeal such actions; notices that require a response from beneficiaries; information on the right to file complaints of discrimination; notices advising LEP persons of the availability of free language assistance; and, other outreach materials be translated into the languages other than English of each regularly encountered LEP group eligible to be served or likely to be directly or significantly affected by the recipient's program or activity.[5] Further, in some instances, translation of written materials is required as a reasonable step to ensure that LEP persons are effectively informed about, or able to participate in, a DOL financially assisted program or activity.

The CRC acknowledges the concern that translating documents may delay communication between the program or activity and the LEP client. It is expected that all vital documents, or all portions of documents that utilize "vital" language, be translated in preparation for assisting persons in language groups that are significantly represented in the service delivery area. Translation of non-vital language must occur on a timely basis so as not to delay the participation in and/or receipt of benefits to LEP clients.

As part of its overall language assistance program, a recipient should assess annually its local service population and develop and implement a plan to provide written materials in languages other than English where a significant number or percentage of the population eligible to be served or likely to be directly or significantly affected by the program or activity needs services or information in a language other than English to communicate effectively.

One way for a recipient to know with greater certainty that it will be found in compliance with its obligation to provide written translations in languages other than English is for the

[5] The requirements outlined in this guidance memorandum also apply to materials posted on web sites. However, the placement of materials on a web site need not change the recipients' original assessment regarding the number or proportion of LEP persons that comprise the intended audience for that document. The four-factor analysis applies to each individual "document" on a web site. Generally, entire web sites need not be translated; usually only the vital documents or vital information posted would require translation. If, in applying the four-factor analysis, the recipient determines that a particular document or piece of information should be translated, then, provided that the English version can be found on the web site, translations into appropriate languages other than English should also be posted. If documents are translated on a web site, the web site homepage should direct browsers to such information.

recipient to meet the guidelines outlined in paragraphs (A), (B) and (C) below.

Paragraphs (A) and (B) outline the circumstances that provide a "safe harbor" for recipients. A recipient that provides written translations under these circumstances will most likely be found in compliance with its obligation under Title VI and section 188 regarding written translations.[6] However, the failure to provide written translations under circumstances outlined in paragraphs (A), (B) and (C) will not necessarily mean noncompliance with Title VI and section 188.

In such circumstances, CRC will review the totality of the circumstances to determine the precise nature of a recipient's obligation to provide written materials in languages other than English. If written translation of a certain document or set of documents would be so financially burdensome as to defeat the legitimate objectives of its program or activity, and if there is an alternative means of ensuring that LEP persons have meaningful access to the information provided in the document (such as timely, effective oral interpretation of vital documents), CRC will not find the translation of written materials necessary for compliance with Title VI and section 188.

CRC will consider a recipient to be in compliance with the Title VI and section 188 obligation to provide written materials in languages other than English if:[7]

(A) The recipient provides translated written materials for each LEP language group that constitutes ten percent or 3,000, whichever is less, of the population of persons eligible to be served or likely to be directly or significantly affected by the recipient's program or activity;

(B) Regarding LEP language groups that constitute five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be directly or significantly affected by the recipient's program or activity, the recipient ensures that, at a minimum, vital documents are translated into the appropriate languages other than English of such LEP persons. Translation of other documents, if needed, can be provided orally; and,

(C) Notwithstanding paragraphs (A) and (B) above, a recipient with fewer than five percent or 1,000 persons in a language group eligible to be served or likely to be directly or significantly affected by the recipient's program or activity, need not translate written materials but rather may provide written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of written materials.

The term "persons eligible to be served or likely to be directly or significantly affected" relates to the issue of what is the recipient's service area for purposes of meeting the Title VI and section 188 obligation. There is no "one size fits all" definition of what constitutes "persons eligible to be served or likely to be directly or significantly affected."

Ordinarily, persons eligible to be served or likely to be directly or significantly affected by a recipient's program or activity are those persons who are in the geographic area that has been approved by a federal grant agency as the recipient's service area, and who are either eligible for the recipient's services or benefits, or otherwise might be directly or significantly affected by such a recipient's conduct. CRC may also determine the service area to be the geographic areas from which the recipient draws, or can be expected to draw, clients. This, for example, could occur in a local workforce investment area (LWIA) that manages more than a single One-Stop Center. Instead of being guided by a population survey for the LWIA, each One-Stop Center should assess its own local service population. States operating programs, such as the Unemployment Insurance program, should assess both statewide language groups that are represented significantly and require all local offices to conduct surveys of local service populations. Small entities, such as Vermont, Delaware, and the District of Columbia, that operate only a single One-Stop Center, should assess their overall populations and also be aware of "pockets" of LEP persons that may exist in certain areas (e.g., the Chinatown or Adams Morgan (largely Spanish-speaking) areas of Washington, D.C.).

As this guidance notes, Title VI and section 188 provide that no person may be denied meaningful access to a recipient's services and benefits, on the basis of national origin. To comply with Title VI and section 188, a recipient must ensure that LEP persons have meaningful access to and can understand information contained in program/activity-related written documents. Thus, for language groups that do not fall within paragraphs (A) and (B) above, a recipient can ensure such access by, at a minimum, providing notice, in writing, in the LEP person's primary language, of the right to receive free language assistance, including the right to competent oral interpretation of written materials, free of cost.

Recent technological advances have made it easier for recipients to store translated documents readily. At the same time, CRC recognizes that recipients in a number of areas, such as many large cities, regularly serve populations of people in which dozens and sometimes hundreds of different languages are spoken. It would be unduly burdensome to demand that recipients in these circumstances translate all written materials into all languages.

It is also important to ensure that the person translating the materials is well-qualified. In addition, it is important to note that in some circumstances verbatim translation of materials may not accurately or appropriately convey the substance of what is contained in the written materials. Moreover, written materials should be translated to serve the average reading level of the LEP community to be served. An effective way to address this potential problem is to reach out to community-based organizations to review translated materials to ensure that they are accurate and easily understood by LEP persons.

The "safe harbor" provisions apply to the translation of written documents only. They do not change the requirement to provide meaningful access to LEP individuals through competent oral interpreters.

Methods for Providing Notice to LEP Persons

A vital part of a well-functioning compliance program includes having effective methods for notifying LEP persons of their rights to receive or participate in the employment benefits, services, and job training programs to which they may be eligible. Outreach materials should notify LEP persons of their rights to language assistance and the availability of such assistance free of charge. These methods include but are not limited to:

- Advertising and outreach to communicate the rights of individuals to employment benefits, services, and job training programs to which they may be eligible, which could include public service announcements in appropriate languages on television or radio, newspaper advertisements, or

[6] The "safe harbor" provisions are not intended to establish numerical thresholds for when a recipient must translate documents. Because the numbers and percentages included in these provisions are based on the balancing of a number of factors, the Civil Rights Center will undertake additional assessment of the numerical thresholds, which may be revised as a result.

[7] The Civil Rights Center will undertake additional assessment of the numerical thresholds, which may be revised as a result.

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distributing materials to organizations that serve LEP persons;

• Use of language identification cards that allow LEP beneficiaries to identify their language needs to staff and for staff to identify the language needs of applicants and clients. To be effective, the cards (e.g., "I speak cards") must invite the LEP person to identify the language s/he speaks. This identification must be recorded in the LEP person's file;

• Posting and maintaining signs in regularly encountered languages in waiting rooms, reception areas and other initial points of entry. In order to be effective, these signs must inform LEP applicants/clients of their right to free language assistance services and invite them to identify themselves as persons needing such services;

• Translation of application forms and instructional, informational and other written materials into appropriate languages other than English by competent translators. Oral interpretation of documents for persons who speak languages not regularly encountered.

• Uniform procedures for timely and effective telephone communication between staff and LEP persons. This must include instructions for English-speaking employees to obtain assistance from interpreters or bilingual staff when receiving calls from or initiating calls to LEP persons.

III. Training of Staff

Another vital element in ensuring that its policies are followed is a recipient's dissemination of its policy to all employees likely to have contact with LEP persons and periodic training of these employees. Effective training ensures that employees are knowledgeable and aware of LEP policies and procedures; are trained to work effectively with in-person and telephone interpreters; and, understand the dynamics of interpretation between LEP clients, the recipient's staff and interpreters. It is important that this training be part of the orientation for new employees and that all employees in client contact positions be properly trained. Given the high turnover rate among some employees, recipients may find it useful to maintain a training registry that records the names and dates of employees' training. Over the years, CRC has observed that recipients often develop effective language assistance policies and procedures but that employees are unaware of the policies, or do not know how to, or otherwise fail to, provide available assistance. Effective training is one means of ensuring that there is not a gap between a recipient's written policies and procedures, and that the actual practices of employees who are in the front lines interacting with LEP persons are being followed.

IV. Monitoring

It is also crucial for a recipient to monitor its language assistance program at least biennially to assess the current LEP makeup of its service area, the current communication needs of LEP applicants and clients, whether existing assistance is meeting the needs of such persons, whether staff is knowledgeable about policies and procedures and how to implement them, and whether sources of and arrangements for assistance are still current and viable. One element of such an assessment is for a recipient to seek feedback from clients and advocates. Recipients should consider involving community groups in their monitoring processes, which can aid in assessing local demographics, as well as obtaining feedback on the effectiveness of policies and practices to serve LEP individuals. CRC believes that compliance with the Title VI and Section 188 language assistance obligation is most likely when a recipient continuously monitors its program, makes modifications where necessary, and periodically trains employees in implementation of the policies and procedures.

CRC's Assessment of Meaningful Access

The failure to take all of the steps outlined will not necessarily mean that a recipient has failed to provide meaningful access to LEP clients. As noted above, CRC will make assessments on a case by case basis and will consider several factors in assessing whether the steps taken by a recipient provide meaningful access. Those factors include the number or proportion of LEP individuals eligible to participate or likely to be directly or significantly affected by the program or activity; the frequency of contact a participant or beneficiary is required to have with the program or activity; the nature and importance of the program or activity to the participant or beneficiary; and, the resources available to the recipient in carrying out the program or activity.

Promising Practices

In meeting the needs of their LEP applicants and clients, some recipients have found unique ways of providing translation and interpretation services and reaching out to the LEP community. As part of its technical assistance, CRC has frequently assisted, and will continue to assist, recipients who are interested in learning about promising practices in the area of service to LEP populations. Examples of promising practices include the following:

Language Banks. In several parts of the country, both urban and rural, community organizations have created community language banks that train, hire and dispatch qualified interpreters, reducing the need to have on-staff interpreters for low demand languages. These language banks are frequently nonprofit and charge reasonable rates. This approach is particularly appropriate where there is a scarcity of language services, or where there is a large variety of language needs.

Language Support Office. An "Office for Language Assistance Services" could be created to test and certify all in-house and contract interpreters and to provide agency-wide support for translation of forms, client mailings, publications and other written materials into languages other than English.

Use of Technology. Some recipients use their internet and/or intranet capabilities to store translated documents online. These documents can be retrieved as needed. Translation software may also be useful.

Telephone Information Lines. Recipients have established telephone information lines in languages spoken by frequently encountered language groups to instruct callers, in the languages other than English, on how to leave a recorded message that will be answered by someone who speaks the caller's language.

Signage and Other Outreach. Recipients could provide information about services, benefits, eligibility requirements, and the availability of free language assistance, in appropriate languages by (a) posting signs and placards with this information in public places such as grocery stores, bus shelters and subway stations; (b) putting notices in newspapers and on radio and television stations that serve LEP groups; (c) placing flyers and signs in the offices of community-based organizations that serve large populations of LEP persons; and, (d) establishing information lines in appropriate languages.

Model Plan

The following is an example of a model language assistance program that is potentially useful for all recipients, but is particularly appropriate for recipients that serve a significant and diverse LEP population. This model plan incorporates a variety of options and methods for providing meaningful access to LEP beneficiaries:

• A formal written language assistance program, reviewed annually;

• Identification and biennial assessment of the languages that are likely to be encountered and estimating the number of LEP persons that are eligible for services and that are likely to be affected by its program or activity through a review of census, client utilization data and statistics from school systems, community agencies and organizations;

• Outreach to LEP communities, advertising program eligibility and the availability of free language assistance;

• Posting of signs in lobbies and in other waiting areas, in several languages, informing applicants and clients of their right to free interpreter services and inviting them to identify themselves as persons needing language assistance;

• Use of "I speak cards" by intake workers and other client contact personnel so that applicants/clients can identify their primary languages;

• Requiring intake workers to note the language of the LEP person in his/her record so that all subsequent interaction will be conducted in the appropriate language;

• Employment of a sufficient number of staff, bilingual in appropriate languages, in applicant and client contact positions. These persons must be qualified interpreters;

• Contracts with interpreting services that can provide qualified interpreters in a wide variety of languages, in a timely manner;

• Formal arrangements with community groups for qualified and timely interpreter services by community volunteers;

• An arrangement with a telephone language interpreter line;

• Translation of application forms, instructional, informational and other key documents into appropriate languages other than English. Oral interpretation of documents for persons who speak languages not regularly encountered;

• Procedures for effective telephone communication between staff and LEP persons, including instructions for English-speaking employees to obtain assistance from bilingual staff or interpreters when initiating or receiving calls from LEP persons;

• Notice to and training of all staff, particularly applicant and client contact staff, with respect to the recipient's Title VI and Section 188 obligation to provide language assistance to LEP persons, and on the language assistance policies and procedures to be followed in securing such assistance in a timely manner;

• Insertion of notices, in appropriate languages, about the right of LEP applicants and clients to free interpreters and other language assistance, in brochures, pamphlets, manuals, and other materials disseminated to the public and to staff;

• Notice to the public regarding the language assistance policies and procedures, plus notice to and consultation with community organizations that serve LEP persons regarding problems and solutions, including standards and procedures for using their members as volunteer interpreters;

• Adoption of a procedure for the resolution of complaints regarding the provision of language assistance, and for notifying and educating clients of the right to file a complaint of discrimination under Title VI and Section 188 with DOL; and,

• Appointment of a senior level employee to coordinate the language assistance program and ensure that there is regular monitoring of the program.

• Consideration of LEP needs when implementing new programs or activities, publishing new forms or notices, etc.

Compliance and Enforcement

The recommendations outlined above are not intended to be exhaustive. Recipients have considerable flexibility in determining how to meet their legal obligations in the LEP setting, and are not required to use all of the suggested methods and options listed. However, recipients must establish and implement policies and procedures to provide language assistance sufficient to fulfill their Title VI and section 188 responsibilities and that give LEP persons meaningful access to services.

CRC will enforce Title VI and section 188 as they apply to recipients' responsibilities to LEP persons through the procedures provided for in 29 CFR Parts 31 and 37. These procedures include complaint investigations, compliance reviews, efforts to secure voluntary compliance, and technical assistance.

CRC regulations state that CRC will investigate any complaint, report or other information that alleges or indicates possible noncompliance with Title VI and section 188. If the investigation results in a finding of compliance, CRC will inform the recipient in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, CRC will inform the recipient of the noncompliance in a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance. At this stage, the CRC will attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, CRC must secure compliance through (a) the termination of federal assistance after the recipient has been given an opportunity for an administrative hearing, (b) referral to DOJ for injunctive relief or other enforcement proceedings; or, (c) any other means authorized by law.

As the regulations set forth above indicate, CRC has a legal obligation to seek voluntary compliance in resolving cases and cannot seek the termination of funds until it has engaged in voluntary compliance efforts and has determined that compliance cannot be secured voluntarily. CRC will engage in voluntary compliance efforts, and will provide technical assistance to recipients at all stages of its investigation. During these efforts to secure voluntary compliance, CRC will propose reasonable timetables for achieving compliance and will consult with and assist recipients in exploring cost effective ways of coming into compliance, by increasing awareness of emerging technologies, and by sharing information on how other recipients have addressed the language needs of diverse populations.

In determining a recipient's compliance with Title VI and section 188, CRC's primary concern is to ensure that the recipient's policies and procedures overcome barriers resulting from language differences that would deny LEP persons meaningful opportunities to participate in and access programs, services and benefits. A recipient's appropriate use of the methods and options discussed in this policy guidance will be viewed by CRC as evidence of a recipient's willingness to comply with its Title VI and section 188 obligations.

Technical Assistance

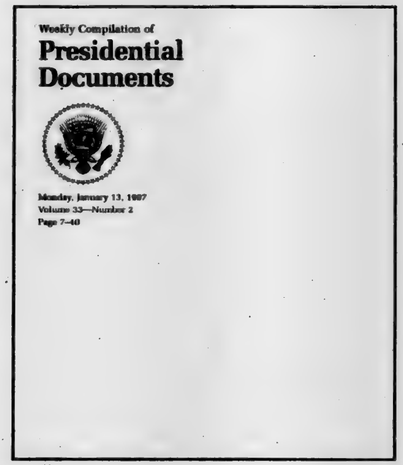
CRC will continue to provide substantial technical assistance to recipients, and will continue to be available to provide such assistance to any recipient seeking to ensure that it operates an effective language assistance program. In addition, during its investigative process, CRC is available to provide technical assistance to enable recipients to come into voluntary compliance.

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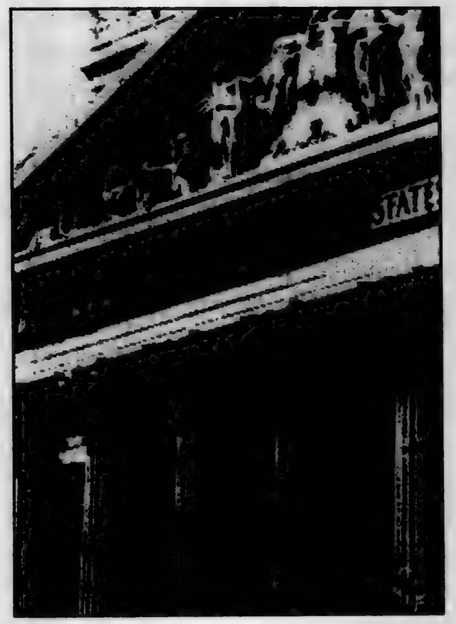
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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1436

RIN 0560–AG00

Farm Storage Facility Loan Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule finalizes an interim rule implementing the Commodity Credit Corporation's (CCC) Farm Storage Facility Loan Program (FSFLP). The program provides financing for producers to build or upgrade farm storage and handling facilities. On the basis of the comments and suggestions received, CCC is making several changes to the program provisions in the interim rule and is adding other provisions.

DATES: This rule is effective January 18, 2001.

ADDRESSES: Copies of the regulation are available from Price Support Division, Farm Service Agency, 1400 Independence Avenue, SW., STOP 0512, Washington., DC 20250–0512.

FOR FURTHER INFORMATION CONTACT: Chris Kyer, (202) 720–7935 or e-mail chris_kyer@wdc.fsa.usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule is issued in conformance with Executive Order 12866 and has been determined to be economically significant and has been reviewed by the Office of Management and Budget. The Cost/Benefit Assessment is summarized below.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this rule because the Farm Service Agency is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Chapter 8 of the Administrative Procedures Act)

The SBREFA generally requires that major rules be submitted to Congress for a 60-day review period before they may be made effective. This rule is considered major. However, section 808 of SBREFA (5 U.S.C. 808) provides that if good cause exists and public notice is impracticable, unnecessary, or contrary to the public purpose, a rule may be made effective immediately. CCC finds that because this rule affects the incomes of a large number of agricultural producers that it would be contrary to the public interest to delay this rule. Therefore, this rule is issued as final, effective immediately.

Environmental Evaluation

It has been determined by an environmental evaluation that this program, as a whole, will have no significant impact on the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement for the program is needed. However, because it is possible that individual projects may have limited impacts on the local environment, environmental evaluations for each project will be conducted to determine the need for environmental assessment and/or mitigation.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988. The provisions of this rule preempt State laws to the extent such laws are inconsistent with the provisions of this rule. Before any legal action may be brought regarding this rule, the administrative appeal provisions set forth at 7 CFR part 780 must be exhausted.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3014, subpart V, published at 48 FR 29115 (June 24, 1983).

The Unfunded Mandates Reform Act of 1995

This rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Paperwork Reduction Act of 1995

A notice with request for comments on the information collection was part of the interim rule. An emergency information collection package has been approved by OMB and assigned OMB control number 0560–204. No comments were received from the public during the 60-day comment period regarding the information collection. A regular information collection package will be submitted to OMB.

Executive Order 12612

It has been determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions, or on the distribution of power and responsibilities among the various levels of government.

Cost-Benefit Assessment Summary

U.S. grain storage capacity steadily declined from 1987 to 1997. Storage capacity has increased modestly since its low in 1997, but not sufficiently to keep pace with growing production. Despite persistent harvest-time storage capacity shortfalls and the advantages of on-farm storage for producers, low commodity prices and reduced farm income will limit the ability of producers to significantly expand their on-farm storage. The FSFLP will encourage the construction of grain storage capacity in deficit areas and help farmers adapt to identity-preserved storage and handling requirements for genetically enhanced production. The program will also assist dairy and livestock feeders who need new or additional silage or green-chop storage. For these producers, additional storage capacity increases their ability to manage feed inventories and control feed costs. One direct benefit to

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producers from the program will be reduced financing costs on facility construction. Interest savings for a grain farmer on the construction of a 15,000-bushel grain bin could total as much as $5,417 under the program when compared with financing through some commercial banks. Interest savings for a dairy or livestock feeder could be as much as $6,139 on a 2,000-ton bunker-type silage storage facility. Grain producers would also benefit from the potential for higher market returns on their crops because on-farm storage capacity creates pricing and hedging opportunities that can significantly increase marketing returns. The program is expected to expand on-farm grain storage by 746 million bushels and on-farm silage storage by 4.75 million tons over the next 5 years.

Background

The interim rule published in the **Federal Register** on May 11, 2000 (65 FR 30345) set out regulations to allow for loans to be made to assist producers in providing storage for certain agricultural commodities. The back ground provisions of that rule described, in addition, the statutory underpinnings of the program, those being provisions of the Commodity Credit Corporation Charter Act. One of those provisions is 15 U.S.C. 714c(b) (section 5(b) of that Act), which authorizes CCC to use its general powers to make available material and facilities required in connection with the production and marketing of agricultural commodities. Another is 15 U.S.C. 714b(h) (section 4(h) of the Act), which was incorrectly identified as section "4(f)" in the interim rule. The latter provides that the Corporation may make loans to grain producers needing storage facilities.

Comments regarding the provisions of the program were accepted until June 12, 2000. Comments were received from 272 entities or persons: 40 agricultural associations, six banks, one Commissioner of Agriculture, 19 FSA county committee members, 109 private agricultural companies or corporations representing storage structure manufacturers, distributors and construction contractors, one United States Senator, five grain storage elevator companies or cooperatives, 57 farmers, and 34 FSA State committee members or representatives.

Most of the comments addressed particular provisions in the interim rule. These are discussed below on a section-by-section basis, along with the changes that have been made to the interim rule. Changes to each section based on the experience of operating the program under the interim rule are also discussed on a section-by-section basis.

Background section of the interim rule

There were 63 comments regarding the background section of the interim rule. Within the background section of the interim rule it was stated that section 5(b) of the CCC Charter Act gives CCC broad authority to make available materials and facilities required in connection with the production and marketing of agricultural commodities. Thus, it was stated that CCC would explore making available facility loans for the storage of commodities harvested as other than grain such as silage, alternative types of storage arrangements such as "condominium storage", or storage facilities for other agricultural products.

There were 15 comments from elevators, agricultural associations, and cooperatives supporting a program to finance condominium-type storage arrangements. There were two respondents who did not favor such a program for on-farm type condominium storage because in their States, Ohio and Iowa, on-farm condominium storage would be subject to licensing requirements for public warehouses. Another respondent was against off-farm condominium storage because, in their opinion, on-farm storage works better for segregation of speciality crops.

Condominium-type grain storage is generally viewed as commercial off-farm storage offered by private companies or cooperatives where farmers can lease or purchase a set amount of shared storage space for a period of time. Farmers pay a set time purchase or lease fee for the storage and may subsequently pay an annual fee to cover the costs associated with the maintenance of the structure and grain maintenance and handling. In some cases, the condominium storage on a per-bushel basis may be less than the cost of constructing and owning on-farm grain storage structures. During years when the owner of the condominium storage may not use the entire quantity that is allocated to him, the storage owner may sublease or sell the space to another producer. This arrangement can result in giving condominium storage a value, which may be used by lenders as collateral to secure loans on condominium storage agreements. Condominium storage may allow the producer to market grain without further transportation or handling costs, and relief from the costs of owning and maintaining on-farm storage. Also a respondent pointed out that condominium storage loans if made to cooperatives could allow for a lessening of the administrative burden of operating the program by allowing the storage needs of multiple producers to be dealt with in one large loan rather than in many small loans.

The primary disadvantage of condominium storage expressed by some farmers is the waiting time to deliver their grain to the elevator when they should be in the field harvesting grain because the condition of the crop and ideal harvesting conditions are always time sensitive. On-farm storage provides that flexibility. Also, farmers indicate that once grain is delivered to the elevator, they may lose marketing flexibility because to sell grain that is in elevator storage they may be required to pay additional handling fees. Despite the comments received supporting a loan program for condominium storage, the respondents provided little information as to how FSA should operate such a program. Inasmuch as the primary focus of the program was on-farm storage and helping producers cope with their restricted storage capacity, condominium storage might not mitigate the storage problem and might ultimately only benefit commercial facilities who already have alternate financing at their disposal. Because a program including condominium storage would differ considerably from the on-farm storage program, at issue are program provisions such as the term of the loan; loan security requirements; who should be the borrower, (the elevator or individual farmers); eligible types of storage structures and handling equipment; applicant eligibility requirements; the maximum loan amount; environmental law compliance for large commercial storage structures; and loan servicing provisions such as loan assumptions, foreclosure procedures, loan deferments and extensions. CCC has not prepared a cost benefit assessment regarding off-farm condominium storage and must do so to consider implementing such a program. Also, it should be pointed out that farmers wishing to receive loans for shared, on-farm storage may do so under the present program as long as they otherwise meet all of the eligibility and security requirements. Accordingly, for these reasons, CCC will not implement loans for condominium type storage at this time.

There were nine comments regarding the timeliness of the program announcement. Generally, the announcement of the program on May 11 was regarded as being too late to allow producers to apply, obtain approval, and to finish construction in time to store crops that will be harvested for the 2000 crop year. To assist producers who took purchase actions based on the announcement of the program in the press on February 2, 2000, CCC provided that producers who made purchase decisions between February 2 and May 30, 2000, could apply and be approved for loans, if all other eligibility requirements were met. Furthermore, citing a critical need for storage in 19 States and recognizing the need to implement the program as soon as possible, CCC implemented the program under the interim rule effective on May 11, 2000. Additional relief in this regard would not be consistent with the nature of this program, which is designed to provide incentives rather than to make payments for past actions.

There were eight comments regarding the need for a program to finance the construction of storage for other agricultural products such as dry peas, lentils, peaches, cherries, pears, berries, vegetables, apples (including necessary cold storage equipment and cold storage supplies such as nitrogen), cotton seed, dry beans, straw, nuts, peanuts, rye, wood, wool, seed potatoes, grass seed, rice straw, livestock feed such as processed feed, cake, purchased feed, millet, and sugar. There were 16 comments supporting loans for structures to store dry hay. While CCC recognizes the support for such a program, CCC will not implement a program because of the lack of any USDA study indicating a critical need for a program to finance such storage for these commodities.

There were 130 comments regarding the provision to restrict the program to specified facility loan commodities harvested as whole grain as set out, and specified, in the interim rule. Under that rule, eligible facility loan commodities were limited to wheat, rice, soybeans, sunflower seed, canola, rapeseed, safflower, flaxseed, mustard seed, crambe, other oilseeds as determined and announced by CCC, corn, grain sorghum, oats, or barley harvested as whole grain. These commodities are the same commodities on which farmers can obtain CCC marketing assistance loans and loan deficiency payments. Generally, the respondents favored the financing of structures to store corn silage and other facility loan commodities that are commonly harvested as other than whole grain citing that dairy farmers are expanding their herds and need more upright silos for grains and forage to feed their animals, many farmers have been using temporary storage, and that it is more economical to store high moisture ground ear corn, high moisture shell corn, or corn silage to save on the cost of fuels for drying. Also, comments were received concerning the provisions in the interim rule that limited financing to certain kinds of facilities—certain cribs or bins designed for whole grain storage, certain upright silo-type structures designed for whole grain storage and flat-type storage structures for which the primary use is to store whole grain commodities. Some respondents favored extending financing also to other structures such as upright silos and bunker-type storage structures that are horizontal and generally constructed of concrete. Bunker-type silos are generally easier and cheaper to construct than upright silos because they are usually constructed from precast reinforced concrete panels and may have more recovery value than poured cement structures.

The interim rule specifically sought comments on extending the program beyond whole grain storage. Given CCC's broad authority, under the CCC Charter Act, to make available materials and facilities in the production and marketing of "agricultural commodities" and the overwhelming sense of the comments received, it has been determined that CCC will extend the program beyond facilities designed only for whole grain storage. Accordingly, eligible "facility loan commodities" (that is, the kind of commodities for which the building of a storage facility can be allowed under the rule) will be extended to also include corn, grain sorghum, wheat, oats or barley that is harvested for non-whole-grain use. Accordingly, the rule will also be amended to specifically provide for financing structures that are designed for that purpose. Other commodities will not at this time be folded into the program definition of "facility loan commodities" so as to expand the program further. Such an expansion would at a minimum involve a large-scale increase in the complexity of the program given that many commodities can have special needs such as refrigeration. Thus, the administrative difficulties of the program would increase dramatically. Moreover, and more importantly, the storage crisis mentioned in the interim rule was a crisis in the storage of grain (and certain related) crops and an expansion of the program beyond those would disperse the effect of the program unless there was to be a much greater commitment of funds to the program. At this time, there does not appear to be a justification for that kind of additional expenditure. On the other hand, the limited expansion, for silage, will allow farmers who grow the covered crops to have the flexibility of addressing their storage needs for all harvesting of their crop. This modest expansion should be workable, which, accordingly, closes the circle of storage needs for certain producers, does so without undue difficulty and should allow program expense to remain within reasonable bounds. Also, to the extent that silage facilities are available, such availability could remove the pressure that might otherwise exist in particular cases to make use of the storage available for whole grain harvesting of the same crop. In that sense, the expansion of eligibility will also tend to further the goals of the original interim rule. Further, this limitation of the program is also in accord with the special emphasis given in the Charter Act on grain crops as evidenced by Section 4(h) of that Act. Also for the sake of cohesiveness, the provisions in the rule dealing with eligible structures have also been amended to allow for bunker-silo type structures, in accord with the comments. Still further, certain clarifying changes have been made in the rules as regards pre-owned and manufactured structures.

There were six comments from banks regarding the need to implement a guaranteed farm storage facility loan program with an interest rate buy-down provision in addition to the direct loan program. Respondents cited the advantages of a guaranteed loan program such as easing the program administrative burden on already overburdened FSA employees, better use of taxpayer dollars, assisting more producers, and the level of good experience with banks that already participate in FSA's guaranteed loan program for FSA ownership and farm operating loans. While CCC recognizes the support for such a program, none of the respondents provided any information as to how CCC should operate such a program and an interest rate buy-down provision could prove to be very costly compared to the current program. Accordingly, CCC will not implement a guaranteed loan program at this time.

Section 1436.3 of the Interim Rule

There were no comments on this section, but the reference to a consent, disclaimer and subordination agreement was deleted and the definition of a severance agreement, and a subordination agreement were added to further clarify definitions. A definition of unsatisfactory credit history was added to provide guidance on eligibility determinations to approving county committees. The term "tribal venture" was added to the definition of a person to clarify that such ventures are eligible

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for the program. Finally, a definition of the calculation for computing the storage need requirement was added to provide further clarification.

Section 1436.4 of the Interim Rule

In order to clarify what actions applicants may take before a loan can be approved, section 1436.4(b) was amended by identifying the actual actions producers may take. Furthermore, the provision allowing producers who took actions between February 2, 2000 and May 30, 2000 to be considered for loans was removed because those producers should have been accommodated during the time the program was operated under the interim rule. That provision is, thus, no longer needed but its removal will not affect prior loans.

Section 1436.5 of the Interim Rule

There were five comments regarding the provision in section 1436.5(a)(5) that requires an eligible borrower to provide proof of crop insurance. Generally, the respondents, three farmers, one FSA State Executive Director, and the American Farm Bureau Federation, questioned the value of crop insurance in furthering an applicant's repayment ability when crop losses occur, the additional cost an applicant may incur just to obtain a farm storage facility loan and the subsequent costs to maintain the insurance during the term of the loan. CCC will not change the requirement except that, based on the comments, we will not require insurance on crops that are determined to be economically insignificant by CCC. A definition for a crop of economic significance was added to the definitions section 1436.3 and the provision was clarified in 1436.5(a)(5).

There was one comment regarding the requirement for applicant compliance with the Debt Collection Improvement Act of 1996. Because this is a statutory requirement, CCC cannot change the requirement. Section 1436.5(a)(2) was amended, however, to further clarify the provision dealing with compliance with the Debt Collection Improvement Act.

There were several comments regarding section 1436.5(a)(4), which requires that in order for an applicant to be eligible for a loan, the applicant must demonstrate a need for an increase in storage capacity. This does not allow farmers with adequate existing capacity to be eligible for a loan to add or replace handling and drying equipment or to upgrade existing storage space. Based on this comment, and because CCC encourages the proper handling and maintenance of stored commodities, section 1436.5(a)(4) and section 1436.6(b)(1) have been amended to allow loans for handling and drying equipment, and for loans to upgrade existing storage capacity without increasing storage capacity. We also amended section 1436.5(a)(1) to make reference to the definition of satisfactory credit history and to make reference to a current financial statement. Finally, section 1436.5(a)(10) was added to require that borrowers may not have been convicted under Federal or State law of certain controlled substance violations in order to conform to the rule according to 7 CFR Part 718.

Section 1436.6 of the Interim Rule

A comment from the Pennsylvania FSA State committee questioned the definition of commercial purpose. Commercial purpose is defined as the storage and handling of grain, whether paid or unpaid, for persons other than the applicant. According to the respondent and other State offices, this definition hinders family operations where family members store their commodities together. Recognizing this problem, CCC amended the definition of a commercial operation in section 1436.3 to exempt immediate family members from this requirement.

Two respondents questioned the requirement that the program only allows loans to be made on new storage structures. One stated that pre-owned equipment should be considered to be eligible if CCC's interest is protected. Another suggested that 1436.6(a)(2) be changed to "new oxygen limiting or used oxygen limiting storage built to original manufacturer's design specifications using original manufacturer's rebuild kits, and other upright silo type structures, designed for whole grain storage and having a useful life of at least 10 years." Based on this comment, as indicated, CCC amended section 1436.6 to allow for loans on remanufactured structures, built to original manufacturer's design specifications using original manufacturer's rebuild kits. Section 1436.6(b)(2) was amended to clarify that CCC may require safety equipment meeting OSHA standards. Section 1436.6(e) was added to provide that new storage and handling components of purchased pre-owned structures may be eligible for loan.

Section 1436.7 of the Interim Rule

There were several comments regarding the term of the loan, which is 7 years. It was suggested that the term be flexible at 7, 10, or 15 years depending on repayment ability. CCC will not change the term of the loan because at 7 years the term is longer than most commercial banks will offer and should be of sufficient length to allow the program goals to be met without jeopardizing repayment because of changed circumstances.

Section 1436.8 of the Interim Rule

There were 25 comments regarding this section, which provides for security for loans. Respondents generally cited a concern with the requirement in section 1436.8(b) that a lien on the real estate on which the farm storage facility is located will be required on all loans in the form of a real estate mortgage, deed of trust, or other security instrument approved by the CCC. Respondents were concerned that the requirement for what could be considered to be small loans was excessive and would create an unnecessary burden on loan applicants. CCC has responded to this concern by generally dropping the real estate lien requirement for loans with a principal amount less than $50,000. It was also recommended that all facility loans be cross collateralized when the facility is constructed on real estate where there is a direct FSA farm loan program mortgage in existence. Accordingly, section 1436.8(b) was amended to provide that a real estate lien will not be required for loans of $50,000 or less unless CCC determines through analysis of the applicant's financial condition that additional security in the form of a lien on real estate is necessary to protect CCC's interest in the collateral. Also, section 1436.8(b) has been clarified to provide that for loans exceeding $50,000, a junior lien position on the entire real estate parcel underlying the storage facility may be acceptable as long as CCC's security interest is sufficiently protected. Also section 1436.8(b) was amended to define when a loan is considered to be adequately secured and to specify that a title opinion or title insurance is required for loans exceeding $50,000. Section 1436.8(g) was amended to clarify fees that shall be paid by CCC or the applicant in connection with completing the loan transaction.

Section 1436.9 of the Interim Rule

There were 12 comments regarding this section, which explains how the amount of the loan is determined. Generally, the respondents cited a concern with the maximum amount of the loan, which is $100,000 per loan and the maximum aggregate outstanding loan balance, which is $100,000 per borrower. Respondents told FSA that $100,000 is not enough in many cases to finance the storage structures and handling equipment needed by some farmers to adequately store facility loan commodities. One respondent stated that, "Facilities and equipment can cost $500,000 or greater." An example of farm operations that may be adversely affected by this requirement are large family-run operations that have formed family partnerships. The family conducts business as a general partnership; however, generally, FSA recognizes for commodity programs that each member of the partnership can be a separate "person" for program payment purposes so long as certain conditions are met. For the purposes of the farm storage facility loan program under the interim rule, however, CCC limited the loan at $100,000 to the partnership since the loan limit was $100,000 per loan in all cases. As this limit may adversely impact some farmers contrary to normal principles that guide farm programs, section 1436.9 has been amended to change the maximum loan to $100,000 for each eligible borrower signing the loan note and security agreement and remove the limit of one loan per borrower per fiscal year. This will also allow more than one farmer to enter into a joint loan to share a storage structure with another and to receive a larger loan than one farmer acting alone. Section 1436.9 was also amended to remove the limit of one loan per borrower per fiscal year because the loan amount limit of $100,000 accomplishes the same thing as a limit on the number of loans a borrower may obtain.

Section 1436.10 of the Interim Rule

There were 13 comments regarding section 1436.10, which set out the down payment requirements for the program. The down payment amount is 25 percent of the total cost of the items eligible for loan. Respondents think that 25 percent is too high and that the requirement places undue burden on loan applicants to provide cash at a time when grain prices are low and cash flow problems exist. CCC recognizes this burden and has changed the requirement to 15 percent of the cost of the items eligible for loan. Also, CCC will allow fees such as attorney fees and archaeological study fees to be considered as an eligible net cost item (items that may be figured into the calculation of the total amount for which the loan may be made) and amended section 1436.9(b) to reflect the change. Finally, section 1436.10(b) was amended to clarify that farmers may obtain a loan for the down payment amount from another lending source.

Section 1436.11 of the Interim Rule

This section provides generally that the loan will be disbursed when all construction is complete, final cost data has been submitted, and the facility has been inspected and determined to be satisfactory by CCC. Four respondents addressed this portion of the rule and in one case the respondent suggested that the monies should be dispersed upon loan approval. Another suggested that the monies be dispersed upon delivery of the materials and a completion of the labor. Others suggested that the loan disbursements should always be jointly payable to both the borrower and the contractor or supplier, and that, in any event, CCC should always obtain a written release of liability from the contractor or supplier. The rule will continue allow the checks to be made payable to the borrower alone in certain cases as there does appear to be circumstance in which such payments could be made in that manner with sufficient security. However, the rule has been amended, in accord with the comments, to specify that in all cases a written release of liability from the contractors or suppliers involved will be required before loan funds are disbursed. These provisions should allow sufficient flexibility to handle all circumstances as might arise. Also, a provision was added to this section to specify that loan proceeds cannot be assigned. This will also reduce program complexity and allow for certainty in program administration.

Section 1436.12 of the Interim Rule

There were five comments regarding the interest rate for loans, which is the rate in effect on the date the loan is approved that is equivalent to Treasury securities of comparable maturity. Generally, respondents thought that the interest rate should be the lowest rate in effect at the time of application, approval, or disbursement. The rate allowed by the interim rule appears be to a fair rate, which will allow the accomplishment of the program goals and the terms of the rule, as provided for in the interim rule, will allow for certainty in the administration of loans. In the event that a applicant is dissatisfied with the rate, the applicant can withdraw from the program.

Section 1436.13 of the Interim Rule

There were five comments regarding section 1436.13, which provides provisions regarding repayment of the loan. Four comments focused on the term of the loan while one comment suggested discontinuance of the requirement to offset commodity loan or LDP proceeds towards facility loan installments before the installment is due or the borrower is delinquent. CCC will discontinue that requirement and amended section 1436.13(d) accordingly. Section 1436.13(c) was further amended to set out procedures that will be used in the event an installment is not paid.

Section 1436.15 of the Interim Rule

There was one comment regarding section 1436.15, which provides maintenance provisions for a program loan. The respondent suggested removing the requirement for an annual check by CCC of the loan collateral because FSA salary funds do not allow for "extreme" expenditures. CCC feels the requirement is reasonable and can be fulfilled with available resources.

Section 1436.16 of the Interim Rule

There were no comments regarding this section, but provisions have been added to this section for foreclosure, liquidation, and bankruptcy actions to help insure accomplishment of the goals of the program.

Section 1436.17 of the Interim Rule

There were two comments regarding the provision to require compliance with the National Environmental Policy Act. The provision requires that an environmental evaluation be conducted by CCC for each loan application. In most cases, this will require a farm visit to assess the impact of the proposed storage construction project on the environment and on historic and archaeological resources. Respondents generally indicated that the environmental assessment goes far beyond the intent and scope of a program designed to benefit farmers hard-pressed for storage capacity and in need of additional opportunities to enhance marketing returns. Respondents also pointed out that the requirement for compliance with local land use laws should be adequate for environmental compliance as well and that the interim rule states that the program as a whole will have no significant impact on the quality of the human environment. While CCC recognizes that the environmental review may delay loan approvals, this provision should help assure the maximum overall benefit from the expenditures to be made in this important program in conjunction with other programs, including conservation programs, operated by the participant.

Section 1436.18

Section 1436.18 was added to provide appeal provisions.

Additional editorial changes have also been made.

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List of Subjects in 7 CFR Part 1436

Administrative practice and procedure, Loan programs—agriculture, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, 7 CFR part 1436 is revised to read as follows:

PART 1436—FARM STORAGE FACILITY LOAN PROGRAM REGULATIONS

Sec.

1436.1 Applicability
1436.2 Administration
1436.3 Definitions
1436.4 Availability of loans
1436.5 Eligible borrowers
1436.6 Eligible storage or handling equipment
1436.7 Term of loan
1436.8 Security for loan
1436.9 Loan amount and loan application approvals
1436.10 Down payment
1436.11 Disbursements and assignments
1436.12 Interest and fees
1436.13 Loan installments, delinquency, and acceleration of maturity date
1436.14 Taxes
1436.15 Maintenance, liability, insurance, and inspections
1436.16 Foreclosure, liquidation, assumptions, sale or conveyance, bankruptcy
1436.17 Environmental compliance
1436.18 Appeals

Authority: 15 U.S.C. 714 *et seq.*

PART 1436—FARM STORAGE FACILITY LOAN PROGRAM REGULATIONS

§ 1436.1 Applicability.

The regulations of this part provide the terms and conditions under which CCC may provide low-cost financing for producers to build or upgrade on-farm storage and handling facilities. Because liens and security interests related to this activity may be governed by state law, CCC may adapt certain procedures relating to those issues that may vary between States.

§ 1436.2 Administration.

(a) The Farm Storage Facility Loan Program shall be administered under the general supervision of the Executive Vice President, CCC or designee and shall be carried out in the field by FSA State committees, FSA county committees and FSA employees.

(b) FSA State committees, FSA county committees and FSA employees, do not have the authority to modify or waive any of the provisions of the regulations of this part.

(c) The FSA State committee shall take any action required by these regulations that has not been taken by the county committee. The FSA State committee shall also:

(1) Correct, or require the FSA county committee to correct, any action taken by such FSA county committee that is not in accordance with the regulations of this part; and

(2) Require the FSA county committee to withhold taking any action that is not in accordance with the regulations of this part.

(d) No provision or delegation herein to a State or FSA county committee shall preclude the Executive Vice President, CCC, or a designee, or the Administrator, FSA, or a designee, from determining any question arising under the program or from reversing or modifying any determination made by the State or FSA county committee.

(e) The Deputy Administrator, Farm Programs, FSA, may authorize State and FSA county committees to waive or modify deadlines and other program requirements in cases where lateness or failure to meet such other requirements does not adversely affect the operation of the Farm Storage Facility Loan Program.

(f) A representative of CCC may execute Farm Storage Facility Loan Program applications and related documents only under the terms and conditions determined and announced by CCC. Any such document that is not executed in accordance with such terms and conditions, including any purported execution prior to the date authorized by CCC, shall be void.

(g) The Deputy Administrator may suspend this program at any time when it appears that there is no shortage of storage that needs to be addressed or where some other reason shall arise for which it appears that the program goals can be achieved more efficiently in a manner different from that provided for in this rule.

§ 1436.3 Definitions.

The following definitions shall be applicable to the program authorized by this part and will be used in all aspects of administering this program:

Aggregate outstanding balance means the sum of the outstanding balances of all loans disbursed under this part to each borrower signing the note and security agreement.

Assumption means the act or agreement by which one borrower takes over or assumes the debt of another borrower.

Collateral means the storage structure, drying equipment or handling equipment securing the loan.

Crop of economic significance means any insurable facility loan commodity that contributes 10 percent or more of the total expected value of all crops grown by the loan applicant except if the expected liability under the catastrophic level of crop insurance for a crop is equal to or less than the administrative fee for the crop, that crop shall not be economically significant.

Facility loan commodity means wheat, rice, soybeans, sunflower seed, canola, rapeseed, safflower, flaxseed, mustard seed, crambe, other oilseeds as determined and announced by CCC, corn, grain sorghum, oats, or barley harvested as whole grain except that corn, grain sorghum, oats, wheat, or barley shall be included whether harvested as whole grain or other than whole grain.

Financing statement means the appropriate document that gives legal notice of a security interest in personal property when properly filed or recorded.

Non-movable or non-salable collateral means either collateral the county committee determines cannot be sold and moved to a new location because of the type of construction involved or because the collateral has deteriorated to the point that it has no sale recovery value.

Person means any individual, group of individuals, partnership, corporation, estate, trust, association, cooperative, tribal venture, or other business enterprise, or other legal entity who is, or whose members are, a citizen or citizens of the United States, or a legal resident alien.

Satisfactory credit history means a history of repaying debts as they came due unless the failure to repay or tardiness in payment was due to circumstance beyond the applicant's control as determined by CCC upon proof submitted by the applicant.

Severance agreement means an agreement under which a party may consent to the security interest of another in property thereby allowing the severance of a fixture from the real estate.

Storage need requirement means the result of up to the average of the most recent 3 years available planted acreage from the applicant's share of the applicable farm operation for each facility loan commodity requiring storage at the proposed storage location multiplied by the applicable crop yield as determined reasonable by the county committee, multiplied by two, and less the available existing storage capacity. If there is no acreage data available, including prevented planted acres, or the data is not applicable relative to the storage need, a reasonable acreage projection may be made for newly acquired farms, changes in cropping operations, or for facility loan commodity crops being grown for the first time.

Subordination agreement means any agreement under which a party may subordinate a security interest in property to the interest of another party.

Uniform Commercial Code means the laws generally known by that name covering commercial transactions such as sales, negotiable instruments, and secured transactions.

§ 1436.4 Availability of loans.

(a) An application for a loan shall be submitted to the administrative county office that maintains the records of the farm or farms to which the application applies. With State office approval, loans may be made or serviced by a county office other than the administrative county office. Upon request, the applicant shall furnish information and documents as the State or county committee deems reasonably necessary to support the application. This may include financial statements, receipted bills, invoices, purchase orders, specifications, drawings, plats, or written authorization of access.

(b) Producers who authorize delivery, site preparation, or construction actions without an approved loan, do so at their own risk and without creating any liability on behalf of CCC.

§ 1436.5 Eligible borrowers.

(a) The term "eligible borrower" means any person who, as landowner, landlord, operator, producer, tenant, leaseholder, or sharecropper:

(1) Has a satisfactory credit history according to the definition in § 1436.3 and as recommended to the approving committee by a FSA employee with FSA loan approval authority;

(2) Demonstrates an ability to repay the debt arising under this program using a financial statement acceptable to CCC prepared within 90 days of the date of application, as recommended to the approving committee by a FSA employee with FSA loan approval authority;

(3) Has no disqualifying delinquent Federal debt under the Debt Collection Improvement Act of 1996;

(4) Is a producer of a facility loan commodity by CCC;

(5) Demonstrates a need for increased storage capacity as determined by CCC if the applicant is applying for a loan for a storage structure;

(6) Provides proof of crop insurance offered under the Federal Crop Insurance Program for insurable crops of economic significance on all farms operated by the borrower in the county where the storage facility is located;

(6) Is in compliance with USDA provisions for highly erodible land and wetlands conservation provisions according to 7 CFR part 12;

(7) Demonstrates compliance with any applicable local zoning, land use, and building codes for the applicable farm storage facility structures;

(8) Annually provides proof of flood insurance if CCC determines such insurance is necessary to protect the interests of CCC, and annually provides proof that the structures for which the loan is made has all peril structural insurance;

(9) Demonstrates compliance with the National Environmental Policy Act regulations at 40 CFR parts 1500–1508; and

(10) Has not been convicted under Federal or State law of a disqualifying controlled substance violation under 7 CFR part 718.

§ 1436.6 Eligible storage or handling equipment.

(a) Loans may be made only for the purchase and installation of eligible storage facilities and permanently affixed drying and handling equipment, for the remodeling of existing storage facilities, or for permanently affixed drying and handling equipment as provided in this section. Eligible storage and handling facilities shall include the following:

(1) New conventional-type cribs or bins designed and engineered for whole grain storage and having a useful life of at least 10 years;

(2) New oxygen-limiting storage structures or remanufactured oxygen-limiting storage structures built to the original manufacturer's design specifications using original manufacturer's rebuild kits, and other upright silo-type structures designed for whole grain storage or other than whole grain storage and having a useful life of at least 10 years; and

(3) New flat-type storage structures including a permanent concrete floor, designed for and primarily used to store facility loan commodities for the term of the loan and having a useful life of at least 10 years; and

(4) New structures that are bunker-type, horizontal, or open silo structures designed for whole grain storage or other than whole grain storage and having a useful life of at least 10 years.

(b) The calculation of the loan amount may include costs associated with building, improving, or renovating an eligible storage or handling facility, including:

(1) Permanently affixed grain handling equipment and grain drying equipment, including perforated floors determined by the approving committee to be needed and essential to the proper functioning of the grain storage system;

(2) Safety equipment as required by CCC and meeting OSHA requirements such as lighting, and inside and outside ladders;

(3) Equipment to improve, maintain, or monitor the quality of stored grain, such as cleaners, moisture testers, and heat detectors;

(4) Electrical equipment, including labor and materials for installation, such as lighting, motors, and wiring integral to the proper operation of the grain storage and handling equipment; and

(5) Concrete foundations, aprons, pits, and pads (including site preparation, labor and materials) essential to the proper operation of the grain storage and handling equipment.

(c) Storage and handling equipment with respect to which no loans for installation or related costs shall be disbursed under this part include:

(1) Portable grain drying equipment, portable handling equipment and portable augers;

(2) Structures of a temporary nature that require the weight or bulk of the stored commodity to maintain its shape (such as fences or bags);

(3) Used structures or handling equipment;

(4) Structures that are not suitable for storing the facility loan commodities for which a need is determined;

(5) Storage structures to be used for commercial purposes. Commercial purpose is defined as the storage and handling of grain, whether paid or unpaid, for persons other than the loan applicant, except for family members as defined in 7 CFR Part 718, and tenants or landlords sharing in the crop requiring storage. Any facility that is in working proximity to any commercial storage operation shall be considered to be part of a commercial storage operation; and

(6) Portable or permanent weigh scales.

(d) Loans may be approved for financing additions to or modifications of an existing storage facility with an expected useful life of at least 10 years if the county committee determines there is a need for the capacity of the structure, but not for the sole replacement of worn out items such as motors, fans, or wiring.

(e) Loans may be approved for new storage and handling components of a pre-owned structure provided the completed facility has a useful life of at least 10 years. The pre-owned structure must be purchased and moved to a new storage location. Eligible items for such a loan include costs such as new bin

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rings or roof panels needed to make a purchased pre-owned structure useable, new aeration systems, site preparation, construction off-farm paid labor cost, foundation material and off-farm paid labor. Ineligible items for such a loan include the cost of purchasing and moving the used structure.

§ 1436.7 Term of loan.

The maximum term of the loan shall be 7 years from the date of execution of a promissory note and security agreement. No extensions of the loan term will be granted. The loan balance and all attendant costs are due 7 years from the date of the execution of the promissory note and security agreement.

§ 1436.8 Security for loan.

(a) Except as agreed to by CCC, all loans shall be secured by a promissory note and security agreement covering the farm storage facility. The promissory note and security agreement shall grant CCC a security interest in the collateral and shall be perfected in the manner specified in the laws of the state where the collateral is located. CCC's security interest in the collateral shall constitute the sole security interest in such collateral except for prior liens on the underlying realty that by operation of law attach to the collateral if it is or will become a fixture. If any such prior lien on the realty will attach to the collateral, a severance agreement must be obtained in writing from each holder of such a lien, including all government or USDA agencies. No additional liens or encumbrances may be placed on the storage facility after the loan is approved unless CCC approves otherwise in writing.

(b) For loan amounts exceeding $50,000, or where the aggregate outstanding loan balance will exceed $50,000 or for loans where the approving committee determines as a result of financial analysis that additional security is required, a lien on the real estate parcel on which the farm storage facility is located will be required in the form of a real estate mortgage, deed of trust, or other security instrument approved by the United States Department of Agriculture's Office of General Counsel. CCC's interest in the real estate shall be superior to all other liens and is the first lien that secures the amount of the loan. A loan will be considered to be adequately secured when the real estate security for the loan is at least equal to the loan amount. If the real estate is covered by a prior lien, a lien waiver may be obtained by means of a subordination agreement approved for use in the State by USDA's Office of General Counsel. CCC will not require such an agreement from any agency of the Department of Agriculture. Loans may be secured by a junior lien on real estate when the loan is adequately secured and a severance agreement is obtained from prior lien holders.

(c) Title insurance or a title opinion is required for loans secured by real estate.

(d) Real estate liens may cover land separate from the collateral if a lien on the underlying real estate is not feasible and if:

(1) The borrower owns the separate acreage; and

(2) the acreage has sufficient value based on the fair market value of the acreage at the time of the application as determined by the county committee, to insure repayment of the loan.

(e) Notwithstanding the preceding subsections of this section, a borrower, in lieu of such liens as are otherwise required by those subsections, may provide a letter of credit, bond, or other form of security, as approved by CCC.

(f) If an existing structure is remodeled and an addition becomes an attached, integral part of the existing storage structure, CCC's security interest shall include the existing storage structure.

(g) The cost of loan closings by attorneys, title opinions, title insurance, title searches, filing and recording all real estate liens, fixture filings and later subordinations will be paid by the borrower. CCC shall pay such costs relating to credit reports, collateral lien searches, and filing and recording financing statements for the collateral.

§ 1436.9 Loan amount and loan application approvals.

(a) The cost on which the loan shall be based is the net cost of the eligible facility, accessories, and services to the applicant after discounts and rebates, not to exceed a maximum per-bushel cost established by the FSA State committee.

(b) The net cost for storage facilities and handling equipment may include the following: all real estate lien related fees paid by the borrower, including attorney fees, except for filing fees, environmental and historic review fees including archaeological study fees, the facility purchase price, sales tax, shipping, delivery charges, site preparation costs, installation cost, material and labor for concrete pads and foundations, material and labor for electrical wiring, electrical motors, off-farm paid labor, on farm site preparation and construction equipment costs not to exceed commercial rates approved by the county committee, and new on-farm material approved by the county committee. The net cost shall not include secondhand material or any other item that is determined by the approving authority to be ineligible for loan.

(c) The maximum principal amount of any farm storage facility loan shall be 85 percent of the net cost of the applicant's needed storage or handling equipment not to exceed $100,000 for each borrower signing the note and security agreement. Unless otherwise approved by CCC, borrowers shall be considered to be separate persons or borrowers for purposes of applying the preceding sentence only to the extent that they would normally be considered a separate person under the rules set out in 7 CFR part 1400.

(d) The aggregate outstanding balance of all facility loans for any one borrower signing the note and security agreement may not exceed $100,000.

(e) When a storage structure has a larger capacity than the applicant's needed capacity, as determined by CCC, the net cost eligible for a loan shall be prorated. Only costs associated with the applicant's needed storage capacity will be considered eligible for loan under this part.

(f) When a flat storage structure has space that is not used primarily for facility loan commodity storage, such as office space, the loan amount shall be adjusted for the ineligible space as determined by CCC.

(g) The FSA county committee may approve applications, if loan funds are available, up to the maximum approval amount unless the FSA State committee establishes a lower limit for county committee approval authority.

(h) Loan approvals will expire 4 months after the date of approval unless extended in writing for an additional 4 months by the FSA State Committee.

(i) CCC may at any time refuse to make new loans.

§ 1436.10 Down payment.

(a) A minimum down payment representing the difference between the net cost of the storage facility and the amount of the loan determined in accordance with § 1436.9 shall be made by the loan applicant to the supplier or contractor before the loan is disbursed.

(b) The down payment shall be in cash unless some other form of payment is approved by CCC. The down payment may be obtained by the borrower from another lending source.

(c) The down payment may not include any trade-in, discount, rebate, credit, deferred payment, post-dated check, or promissory note to the supplier or contractor.

§ 1436.11 Disbursement and assignments.

(a) Disbursement of the loan by CCC will be made after the farm storage facility has been delivered, erected, constructed, assembled, or installed and a CCC representative has inspected and approved such facility.

(b) Disbursement will be made only if the borrower furnishes satisfactory evidence of the total cost of the facility and payment of all debts on the facility in excess of the amount of the loan.

(c) Disbursement may be made jointly to the borrower and the contractor or supplier, except disbursement may be made to the borrower only if CCC determines the borrower has paid the contractor or supplier all amounts that are due and owing with respect to the facility and that all applicable liens, security interests, or other encumbrances have been released.

(d) A release of liability will be required from contractors and suppliers providing goods and services to the loan applicant.

(e) Loan proceeds cannot be assigned.

§ 1436.12 Interest and fees.

(a) Loans shall bear interest at the rate equivalent, as determined by CCC, to the rate of interest charged on Treasury securities of comparable maturity on the date the loan is approved.

(b) The interest rate for each loan will remain in effect for the term of the loan.

(c) The loan applicant shall pay a non-refundable application fee in such amount determined appropriate by CCC, which fee may not in any case be less then $45.

§ 1436.13 Loan installments, delinquency, and acceleration of maturity date.

(a) Equal installments of principal plus interest will be amortized over the loan term for purposes of setting a payment schedule. Installments are due and payable not later than the last day of each 12-month period of the loan, until the principal plus interest has been paid in full.

(b) Each installment may be paid in cash, money order, wire transfer, or by personal, certified, or cashier's check. Repayment shall be applied first to accrued interest and then to principal.

(c) The following actions will be taken when installments are not paid on the due date: A demand for payment shall be mailed to the debtor after the due date has passed. If the installment is not paid within 30 days of the due date or if a new due date acceptable to CCC has not been established based on a financial plan submitted by the debtor, the initial demand may be followed by two subsequent written demands at approximately 30-day intervals unless other action is needed to protect the interests of CCC. If the debtor files an appeal according to § 1436.18 of this part, collection action shall cease until the appeal process is complete, however, any payments due the debtor may be withheld and, depending on the outcome of the appeal, may later be offset and applied to reduce the indebtedness. In lieu of a foreclosure on the collateral in the case of a delinquency, CCC may permit a rescheduling of the debt or other measures consistent with the collection of other debts under the provisions of Part 1403. Alternately, CCC may implement such other collection procedures as it deems appropriate.

(d) A claim shall be established against a borrower for any amounts remaining due after liquidation of the loan.

(e) CCC may declare the entire indebtedness immediately due and payable if the borrower violates any of the terms and conditions of this part, fails to pay any installment on time, or breaches any of the terms and conditions of any of the instruments executed in connection with the loan, or if , during the life of the loan, the collateral is used in connection with or by any unauthorized commercial operation including, but not limited to, elevators, warehouses, dryers or processing plants.

(f) Any action authorized by the provisions of this section may be taken:

(1) Against a debtor's pro rata share of payments due any entity that the borrower participates in, either directly or indirectly, as determined by CCC.

(2) Against related persons or entities, irrespective of the debtors share, when CCC determines that the debtor has established an entity, or reorganized, transferred ownership of, or changed in some other manner, their operation, for the purpose of avoiding the payment of the debt.

(g) The loan may be paid in full or in part without penalty at any time before maturity.

(h) Upon payment of a loan, CCC shall release CCC's security interest in the collateral.

§ 1436.14 Taxes.

The borrower must pay, when due, all real and personal property taxes that may affect CCC's security interest in all collateral securing the note evidencing the loan. To protect its interests, CCC may pay any unpaid taxes with respect to the collateral securing a loan made in accordance with this part, and if CCC does so, the borrower shall reimburse CCC for such payment, and if unpaid by the borrower, such debt shall become due immediately.

§ 1436.15 Maintenance, liability, insurance, and inspections.

(a) The borrower must maintain the loan collateral in a condition suitable for the storage of one or more of the facility loan commodities. For purpose of this section the term "loan collateral" shall mean any property of any kind that was built or improved, or acquired using a loan made under this part.

(b) Until the loan has been repaid, the borrower shall be liable for all damages to or destruction of the loan collateral. CCC shall not assume any loss of the loan collateral.

(c) CCC may conduct annual collateral inspections to insure compliance with this part. The borrower must consent to such inspection as a term of the loan and failure to supply such access shall put the borrower into default.

(d) Structures must be insured against all perils in all cases and must also be insured against flooding if the structure is located in a flood plain, as determined by CCC. Proof of flood insurance, if required, and proof of all peril structural insurance, must be provided to CCC annually. CCC must be listed as a loss payee on all peril and flood insurance policies.

(e) CCC shall have rights of ingress and egress where the facility is located. Failure of the borrower to secure such access will render a borrower ineligible for the loan and, if a loan has already been made shall constitute a loan default for which the remaining balance of the loan shall become immediately due and payable.

§ 1436.16 Foreclosure, liquidation, assumptions, sale or conveyance, bankruptcy.

(a) The collateral or land securing a loan may be sold by CCC whenever CCC has declared the entire indebtedness immediately due and payable under this part as follows:

(1) If a demand for payment is not received by the due date acceptable to CCC, CCC may call the loan and initiate foreclosure proceedings by issuing a liquidation letter to the borrower.

(2) The debtor may voluntarily agree to allow removal of the collateral to facilitate sale by signing an agreement for sale. If the debtor objects to removal of collateral, the law of the state where the collateral exists will be used to foreclose on the property.

(3) For loans with movable collateral and no real estate lien, CCC may sell the collateral for the best price obtainable. Sales proceeds shall be distributed in the following order:

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(i) To CCC to satisfy the debtor's indebtedness including all costs associated with selling the collateral.

(ii) Payment to junior lien holders if approved by USDA's Office of the General Counsel and then to the borrower or other persons as determined appropriate by that office.

(4) For loans with nonmovable collateral, as determined by CCC, and no real estate lien, CCC may establish a claim according to 7 CFR part 1403.

(5) For loans secured with a real estate lien, CCC may obtain an appraisal of the property. Sales proceeds shall be distributed in the following order:

(i) To CCC to satisfy the debtor's indebtedness including all costs associated with selling the collateral and the appraisal.

(ii) To junior lien holders if approved by USDA's Office of the General Counsel; or

(iii) To the borrower or other persons as determined appropriate by that office.

(b) Assumption by another borrower of a farm storage facility loan is permitted subject to county committee approval and the subsequent borrower's ability to show a satisfactory credit history. An assumption of the loan may be approved when the collateral is sold by CCC to an otherwise eligible borrower, the current borrower will convey the collateral or property securing the loan to another eligible borrower, or the borrower is dead, incompetent, or missing and an eligible borrower wants to assume the loan.

(1) Requests for approval of assumptions shall be made to the county committee by the borrower, the borrower's successors, or representatives of the borrower. If approval is granted, the borrower's successors or representatives shall execute a new farm storage facility note and security agreement for the balance of the term of the loan.

(2) The principal amount of the loan shall include the unpaid amount of the loan, interest computed to the date of assumption, all past due installments, and any other charges that may be required.

(c) The borrower may voluntarily convey the collateral to CCC before repaying the loan. Before a borrower sells or conveys the facilities or other property securing a loan without repaying the loan in full, the borrower shall obtain approval for the sale or conveyance from the FSA county committee with the understanding that sale proceeds shall be paid to satisfy the borrowers indebtedness to CCC.

(d) Remedies provided for in this section shall, unless CCC determines otherwise, be subject to the administrative appeals provided for elsewhere in this part, including those that are found at § 1436.13.

§ 1436.17 Environmental compliance.

(a) Except as otherwise specified in this section, prior to approval of any farm storage facility loan, an environmental evaluation will be completed to determine if the proposed action will have any adverse impacts on the environment and cultural resources.

(b) If it is determined that a proposed action or group of proposed actions will not result in any adverse impact, the action will be considered as being categorically excluded for the purpose of compliance with the National Environmental Policy Act (NEPA), 40 CFR parts 1500–1508.

(c)(1) If adverse environmental impacts (either direct or indirect) are identified, an environmental assessment will be completed in accordance with the Council on Environmental Quality's Regulations for Implementing the Procedural Provisions of NEPA.

(2) The environmental assessment will be used to develop an action that results in no significant environmental impact on the human environment or cultural resources.

(3) No action will be approved that has been determined to have significant impacts on the human environment or cultural resources.

(d)(1) In order to minimize the exposure to environmental liabilities from the presence of contamination on real estate collateral, an evaluation will be made of the economic and environmental risks to the real estate collateral posed by the presence of hazardous substances and petroleum products.

(2) If the evaluation made under paragraph (d)(1) of this section reveals that the collateral is or may be contaminated, then the applicant will be notified and given an option of offering as collateral other real estate that is free from contamination or remediating the contamination on the original site offered as collateral.

§ 1436.18 Appeals.

The appeal, reconsideration, or review of all determinations made under this part, except for provisions for which there are no appeal rights because they are determined rules of general applicability, must be in accordance with parts 11 and 780 of this title.

Signed at Washington, DC, on January 10, 2001.

George Arredondo,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 01–1332 Filed 1–17–01; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF ENERGY

10 CFR Part 719

48 CFR Parts 931 and 970

RIN 1990–AA27

Contractor Legal Management Requirements; Department of Energy Acquisition Regulation

AGENCY: Department of Energy.

ACTION: Notice of final rulemaking.

SUMMARY: The Department of Energy (Department) is establishing new regulations covering contractor legal management requirements. Conforming amendments are also made to the Department of Energy Acquisition Regulation (DEAR). The new regulation covers legal costs to be reimbursed by the Department to its contractors at government owned or leased facilities with contracts exceeding $100,000,000. An Appendix to the regulation provides additional guidance to contractors.

EFFECTIVE DATE: This final rule is effective February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Laura Fullerton at (202) 586–3420 (Laura.Fullerton@hq.doe.gov) or Anne Broker at (202) 586–5060 (Anne.Broker@hq.doe.gov).

SUPPLEMENTARY INFORMATION:

I. Background.
II. Disposition of Comments.
III. Procedural Requirements.
A. Review Under Executive Order 12866.
B. Review Under Executive Order 12988.
C. Review Under the Regulatory Flexibility Act.
D. Review Under the Paperwork Reduction Act.
E. Review Under the National Environmental Policy Act.
F. Review Under Executive Order 13132.
G. Review Under the Unfunded Mandates Reform Act of 1995.
H. Review Under the Treasury and General Government Appropriations Act of 1999.
I. Congressional Notification.

I. Background

This final rulemaking creates a new part 719, in Chapter 10 of the Code of Federal Regulations, establishing regulations to monitor and control legal costs and to provide guidance to aid contractors and Department personnel in making determinations regarding the reasonableness of all outside legal costs, including the costs of litigation. This action finalizes the Notice of Proposed Rulemaking (NOPR) published October 25, 2000 (65 FR 63809). Today's rules cover all outside legal costs incurred by contractors with contracts exceeding $100,000,000 at facilities owned or leased by the Department. The policies also apply to legal counsel retained by the Department itself for litigation or other legal services where the legal costs over the life of the matter for which counsel has been retained are expected to exceed $100,000.

The regulation requires submission of a legal management plan by contractors where costs for legal services are to be reimbursed by the Department. Once approved by the Department, the legal management plan, as well as applicable regulations and contract provisions, forms the basis for approvals by the Department to reimburse litigation and other legal expenses. The cost principles and contract clauses in the Department's contracts generally make legal costs, including the cost of litigation, allowable if reasonable and incurred in accordance with the applicable cost principles and contract clauses.

The Department received some comments expressing concern about the potential waiver of attorney-client confidentiality privileges if contractors provide the type of information required under this rulemaking. The Department needs to receive information regarding contractor litigation in order to participate in strategy and to justify the reimbursement of the costs of litigation. Although it is true that attorney-client privilege can be waived by a disclosure of an otherwise confidential disclosure to a third party, there is an exception to this principle. The privilege is not waived when the nominal "third party" has a common interest with the client as to the subject matter of the communication. In the cases involving our contractors, the Department is contractually obligated, with few exceptions, to pay the contractors' litigation costs, as well as any judgment or settlements. In order to determine whether the costs are allowable and reasonable the Department needs to review the invoices, as well as budgets and staffing and resource plans. In addition, the Insurance—Litigation and claims clause provides that the Department can direct the defense of such litigation and provides for the collaboration between Department representatives and in-house or Department approved outside counsel. In order to provide guidance, the Department needs to be provided pleadings and other documents that deal with the strategy of the case.

In July 2000, the common interest privilege was upheld by the Supreme Court of Washington [1] in a case involving information provided to the Department by one of its contractors. The privilege was also recognized in a decision by the U.S. District Court for the District of New Mexico [2] which determined that a Litigation Plan is a privileged document and not subject to production.

An Appendix to the regulation provides additional "safe harbor" guidance for legal management practices. The guidance provided in the Appendix may be updated from time to time by the Department and those updates distributed to contractors, contracting officers and Department counsel.

Conforming technical amendments to the Department of Energy's Acquisition Regulation (DEAR), at 48 CFR Chapter 9, appear at the end of this notice of final rulemaking. Some changes have been made in the approach for these amendments.[3]

The proposal to add a clause to DEAR Part 952 and prescriptive language in Part 928 has been eliminated. Instead, prescriptive language has been added as Department coverage for the cost principle at 48 CFR 931.205–19, requiring the use of Insurance—Litigation and claims, 970.5228–1 (new citation) [970.5204–31 old citation], for contracts exceeding an amount of $100,000,000 involving work performed at a Department owned or leased site. Additionally, the language in the 48 CFR Part 970 clause, Insurance—Litigation and claims, 970.5228–1 (new citation) [970.5204–31 old citation], has been modified to permit use of that clause in non-M&O contracts now covered by 48 CFR 931.205–19. These changes involve only the elimination of references to DEAR Part 970 specific clauses and a substitution of generalized clause titles instead.

Department coverage for the Federal Acquisition Regulation (FAR) cost principle at FAR 31.205–33, Professional and consultant service costs, is added at DEAR 931.205–33(g) and DEAR 970.3102–05–33(g), to describe the applicability of 10 CFR Part 719 to M&O contracts, and to non-M&O contracts for an amount exceeding $100,000,000 involving work performed at facilities owned or leased by the Department, and for legal counsel retained directly by the Department for litigation or other legal matters.

Additionally, the language originally proposed to be inserted at subpart 970.71 has been revised and added to the contractor purchasing guidance contained at 970.5244–1 (new citation) [970.5204–22 old citation].

Contracting officers must apply these DEAR changes to solicitations issued on or after the effective date of this rule. Contracting officers may, at their discretion, include these DEAR changes in solicitations issued before the effective date of this rule, provided award of the resulting contract(s) occurs on or after the effective date.

Contracting officers must apply these DEAR changes: to contracts extended in accordance with the Department's extend/compete policies and procedures (48 CFR 917.6, 48 CFR 970.1702–1(a), and internal guidance); and to options exercised under competitively awarded management and operating contracts (48 CFR 970.1702–1(b)).

For management and operating contracts or other contracts already containing subparagraph (d)(4) of the Allowable costs clause, 970.5204–13, or 970.5204–14, or other reference to the Department's litigation management procedures and cost guidelines, these changes and the new 10 CFR part 719 are automatically applicable. These provisions address the allowability of reasonable legal costs incurred by contractors and include references to the Department's "approval of the contractors litigation management procedures (including cost guidelines)" and also include the caveat that "such procedures may be revised from time to time."

II. Disposition of Comments

General Comments

Comment: One commenter stated that the proposed rule duplicates existing litigation management and legal cost reporting requirements established by the Final Policy Statement, which addressed contractor litigation cost policies, terms of law firm engagement, and allowability of costs ("Policy Statement"), 65 FR 14763, (April 3, 1996) and therefore is unnecessary.

Response: One of the purposes of this rulemaking is to codify the legal

[1] *Brundridge, et al.* v. *Fluor Daniel, Inc., Fluor Daniel Hanford, Inc., Daniel Northwest, Inc.*, No. 69732–9, Ruling Denying Review, (Sup. Ct. Wash., 7/27/00).

[2] *Morrison Knudsen Corp.* v. *Ground Improvement Techniques, Inc., and Fireman's Fund Insurance Co.*, Order Denying Motion to Compel Discovery From the Department of Energy, Misc. No. 96–37 MV/LFG (D.N.M., 10/8/96).

[3] **Note:** The Department republished 48 CFR (DEAR) subpart 970 in a final rulemaking in the **Federal Register** on December 22, 2000 (65 FR 80994). This rulemaking action streamlined and reorganized DEAR subpart 970 and both the new and old citations for DEAR subpart 970 are provided for the convenience of the reader.

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management and cost policies described in the Policy Statement and related requirements from diverse sources and locations and to standardize those requirements. This regulation consolidates requirements from earlier contract reform initiatives and the Policy Statement and replaces those requirements. The commenter argues that the information collection in the proposed rule corresponds to the information collections in the Policy Statement and the Department agrees.

Comment: One commenter took issue with the Notice of Proposed Rulemaking's estimate of 15–30 hours to prepare a litigation management plan and stated that it expended estimated 150 hours reviewing, revising, and altering a litigation management plan and its office practices.

Response: The commenter did not explain how many of the 150 hours were used in the preparation of the legal management plan and how many were used reviewing its office practices. Also, the commenter did not state whether this time was expended for an initial legal management plan or for a plan and a series of revisions over a period of time. The NOPR's estimate of 15–30 hours for the initial preparation of a legal management plan was based on information provided by a contractor who had a litigation management plan in place. The Department expects that the time necessary to prepare and implement a legal management plan will vary from contractor to contractor, but does not expect that 150 hours for preperation of an initial plan will be the norm. Nevertheless, the Department notes that the time spent preparing the legal management plan is ordinarily an allowable cost that is paid for by the government.

Comment: The commenter noted that under its current practices with the Department that the retention agreement for, and then the billings and invoices for, any litigation must be submitted to the Department for prior approval. The commenter asked whether the $25,000 threshold pertaining to engagement letters would now replace their current practice.

Response: When the requirements contained in this regulation are incorporated into a contract, already existing guidance and requirements is canceled for that individual contract, unless specifically retained and made a part of the revised plan.

Comment: Two commenters stated that the goal of controlling legal costs should be addressed by agency guidance documents rather than in a mandatory regulation. The commenters argue that codifying the requirements in a regulation reduces the flexibility necessary for effective legal representation.

Response: The Department recognizes the concerns behind this view and has revised the regulation to provide more flexibility in the final rulemaking than provided in the NOPR. For example, in instances where the contractor does not know enough about the case at the time of filing an answer, the filing deadline for the staffing and resource plan is extended to 30 days after a determination that the costs of the matter are expected to exceed $100,000. Also, since there was concern that a contractor might be penalized for failing to determine whether a matter was significant for purposes of the staffing and resource plan, language has been added requiring the contractor to consult with Department counsel and an explanation that the primary purpose of the plan is informational. Finally, the requirement for advance approval of certain costs, in § 719.35, has been changed to permit submission of a justification after the incurrence of the cost.

Comment: Two commenters requested further explanation of the Department's reasons for including non-litigation matters in the rulemaking.

Response: It came to the Department's attention that there were instances where contractors incurred significant legal fees for matters not involving litigation. Given the Department's interest in assuring that appropriate cost controls are in place for all major legal representation and the interest Congress has in the expenditure of appropriated funds for legal fees, we decided it was prudent to include legal services for all matters expected to exceed $100,000.

Section 719.2 Definitions

Comment: One commenter suggested that the phrase "administrative expenses associated with the provision of legal services by retained counsel" could be ambiguous and proposed a revised definition for the term "legal costs" that excludes that phrase.

Response: The definition of "costs" contained at 48 CFR (FAR) 31.205–47, Costs related to legal and other proceedings, includes "administrative and clerical expenses" and the Department sees no reason to deviate from the FAR standard.

Section 719.3 What Contracts Are Covered by This Part?

Comment: One commenter observed that the Final Policy Statement applied to only management and operating contracts and requested an explanation for the Department's extension of the application of the regulation beyond the scope of the existing Policy Statement.

Response: The Final Policy Statement applied only to legal costs incurred by management and operating (M&O) contractors. Today's rule applies to all cost-reimbursement contracts in excess of $100,000,000 involving work performed at DOE facilities, including contracts that are not M&O contracts. The Department has experienced resistance against application of the Policy Statement in a number of non-M&O contracts that involve facility and site management responsibilities where the litigation management and cost policies need to be applied. The legal management plan has been expanded beyond DEAR part 970, which contains the M&O contract provisions, to make it clear that this requirement applies to some non-M&O type contracts.

Section 719.6(a) Are There Any Types of Legal Matters Not Included in the Coverage of This Part?

Comment: Seven commenters recommended against extending the coverage of the legal management requirements to matters handled by insurance carriers providing third party administrator (TPA) services or retrospective policies, as provided in § 719.6(a) of the NOPR. Some of the commenters noted that the purpose of using TPA services is to purchase the expertise and administrative capabilities of insurance companies and that part of the expertise package provided by the insurance carrier is the retention, oversight and direction of an outside law firm with specialized experience and contacts. They also noted that one of the benefits is reduced legal fees because of business volume and the ongoing relationship between the insurance carrier and law firm.

Response: The comments provided insight and experience and are persuasive. Proposed § 719.6 has been revised by deleting the references to matters handled by insurance carriers providing third party administrator and retrospective policy services and by inserting a new subparagraph (c) that excludes routine workers compensation matters.

Section 719.10 What Information Must Be Included in the Legal Management Plan?

Comment: One commenter stated an opinion that the information requirements in this section are too intrusive in the contractor's counsel selection process by dictating that the contractors abide by these criteria as a prerequisite for allowability of its legal counsel costs.

Response: The provisions of this section do not make any costs unallowable. The purpose of this section is to require the contractor to submit a legal management plan with its own individualized list of criteria. The regulation provides a list of criteria or factors that the contractor must consider prior to making its selection of retained legal counsel and that the Department must consider in determining if the costs are reasonable and allowable. No costs are made unallowable merely for failure to address all of the recommended criteria.

Section 719.14 Will the Department Notify the Contractor Concerning the Adequacy or Inadequacy of the Submitted Plan?

Comment: One commenter stated that it was unclear whether the term "deficiencies" as used in § 719.14(a) referred to failure to comply with a requirement in § 719.10 or an objection from the Department concerning the substance of the plan. The commenter noted also that the proposed regulation fails to specify a route for appeal or a remedy for a dispute concerning a deficiency.

Response: The term "deficiencies" in this section refers to the failure of the legal management plan to meet the mandatory requirements of § 719.10 and this clarification has been added to § 719.14(a). Section 719.14(b) has been revised to provide for a letter of appeal to the General Counsel disputing a deficiency determination.

Section 719.17 Are There Any Budgetary Requirements?

Comment: Four commenters expressed concern that prospective budgets would be entirely speculative and that requiring contractors to speculate on budget needs would set them up for criticism in the event the budgeted amount is exceeded. One of these commenters recommended clarifying that only "known or existing matters" are intended to be included in the prospective budget.

Response: The prospective budget requirement is intended to serve only as an information device for the Department and the contractor, so that both have a better understanding of the contractor's awareness of its legal staffing needs and the contractor's ability to estimate based on its experience. Clarifying language has been added in paragraph § 719.17(a) that the annual budget requirement covers only pending matters, and in § 719.17(c) to state that the purpose of the budget requirement is primarily informational and that the Department recognizes that there will be departures from the budget beyond the control of the contractor.

Comment: One commenter stated that the budget requirements of § 719.17(b) duplicate the staffing and resource plan requirements of § 719.16.

Response: No budgetary information is required in § 719.16. As defined in § 719.2, staffing and resource plan means a statement prepared by retained legal counsel describing plans for managing a significant matter. The budget described in § 719.17 is prepared by the contractor.

Section 719.20 When Must an Engagement Letter Be Used?

Comment: One commenter sought clarification whether the term "matters" meant particular, individual matters or all matters handled by an individual law firm.

Response: Section 719.20 has been modified by adding the phrase "for a particular matter" to make clear that as used in this section, the term "matter" refers to particular, individual matters handled by a law firm and not to a cumulative amount of matters handled by a particular firm.

Section 719.21 What Are the Required Elements of an Engagement Letter?

Comment: One commenter recommended a modification to allow both retained legal counsel and contractor counsel the flexibility to communicate material concerning the case in a manner that serves the Department's needs without creating risk of waiving any attorney-client confidentiality privilege.

Response: Section 719.21(b)(2) has been modified by adding language that an exemption for specific records may be obtained where contractors can demonstrate that a particular situation may provide grounds for a waiver. This change is intended to make clear that in instances when the contractor has demonstrated that production of specific documents may provide grounds for waiver of the attorney-client privilege, that material may be withheld.

Section 719.31 How Does the Department Determine Whether Fees Are Reasonable?

Comment: One commenter inquired whether the phrase "lowest reasonably achievable fees or rates" as used in 719.31(a) is intended to include consideration of the terms of engagement, § 719.21, and reimbursement guidance, subpart D, in the proposed rule.

Response: The phrase "lowest reasonably achievable fees or rates" is to be applied with due consideration for the individual circumstances of each situation, including the overall terms of engagement between the contractor and retained legal counsel, and the guidance found throughout part 719.

Comment: Another commenter asked how the Department will treat legal services obtained by a contractor which do not meet all the criteria in § 719.31 and whether the Department will pay at the rate it deems reasonable and allow the contractor to pay the difference if the contractor elects to use an attorney whose rates are determined to not be the lowest price available.

Response: The Department anticipates that there will be circumstances which do not meet all the criteria in this section. The Department will reimburse the amount that it determines to be allowable and reasonable. It is not the intent of this regulation to select legal representation for contractors, to limit the choice of legal representation available to the contractor, or prevent the contractor from engaging any particular attorney or firm. The purpose of this regulation is to outline the Department's approach to evaluating the reasonableness of costs associated with legal representation for purposes of determining legal cost reimbursement. Contractors may elect to deviate from the regulation but they run the substantial risk that the Department will determine costs that do not conform to the regulation to be unreasonable. Contractors are responsible alone for costs that are deemed unreasonable under part 719. This approach allows the contractor, for example, to pay the difference if the contractor wishes to retain the services of an attorney whose fees are higher than that deemed reasonable under part 719.

Section 719.35 What Categories of Costs Require Advance Approval?

Comment: Five commenters objected to requiring advance approval from Department counsel for attendance by more than one person at a deposition, court hearing, interview or meeting. One of these commenters also enquired whether this requirement is meant to include impromptu meetings or routine meetings between partners and associates. Two of these commenters also noted that quick turn around times often occur with litigation and recommended more flexibility in the system, such as a presumption of approval after a certain waiting time, exception process or pre-approval mechanism.

Response: These concerns have been addressed by adding language to § 719.35 to permit the contractor to

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submit a justification following the incurrence of the cost. The Department has not changed the language in § 719.35(d) covering attendance by more than one person at a deposition, court hearing, interview or meeting. If the contractor decides to have more than one person attend a meeting, justification for attendance of more than one person may be provided following the incurrence of that cost. This is the procedure the contractor should follow for impromptu and routine meetings.

Comment: Two commenters stated that the proposed requirement for advance approval for costs for items listed in this section creates cost allowability rules which are not consistent with current FAR cost allowability rules since the Federal Acquisition Regulation (FAR) does not contain specific advance approval requirements.

Response: This section of the final rule effectively puts contractors on advance notice that the contractors must demonstrate the reasonableness of certain listed costs. Contracting officers can require the contractor to demonstrate the reasonableness of a cost by questioning the cost. The Federal Acquisition Regulation already states, at 48 CFR (FAR) 31.201–3, that no presumption of reasonableness is attached to the incurrence of costs by a contractor. In accordance with 48 CFR (FAR) 31.201–3, the contracting officer shifts the burden of proof to the contractor when the reasonableness of the cost is questioned. Section 719.35 automatically invokes this process for the listed costs.

Section 719.37 Are There Any Special Procedures or Requirements Regarding Subcontractor Legal Costs?

Comment: One commenter viewed § 719.37(b) as subjecting subcontractors to the same set of requirements imposed on prime contractors while two commenters stated that this proposal is unworkable and unmanageable.

Response: The Department agrees that, as proposed, this section could be read in a manner that would make it somewhat unworkable and this section has been revised to require the contractor submit to Department counsel information copies of subcontractor invoices for legal services.

Section 719.39 What Happens When More Than One Contractor Is a Party to a Matter?

Comment: Two commenters stated that it is unreasonable to expect contractors and their retained legal counsel to waive ethical conflict issues which are created by the lead lawyer requirement.

Response: The Department has already provided for exceptions for situations where an ethical conflict arises, including an exception for situations where there are conflicts with the standards of professional conduct (§ 719.39(a)), and an opportunity for the contractor to demonstrate the reasonableness of its decision (§ 719.39(b)).

Comment: Another commenter recommended the section be modified to give Department counsel the authority to approve joint or lead counsel recommended by the parties and to designate directly only in those situations where recommended counsel is unacceptable or the contractors cannot agree on a choice.

Response: It is not the intent of the regulation to circumscribe the contractors' choice of counsel but to eliminate duplicative billings for identical legal services, particularly where the issues involved are similar for the contractors involved. The language in this section has been modified to permit contractors to propose their preference for the attorney or law firm to serve as lead counsel.

Comment: Two of the commenters interpreted this provision as making expressly unallowable legal costs incurred by a contractor who hires different counsel than the designated lead counsel.

Response: As stated earlier in this rulemaking, every situation will be reviewed on an individual basis. Reasonable costs will be reimbursed where the contractor can demonstrate the reasonableness of its decision to engage additional counsel based on contractor interests that diverge from those represented by lead counsel.

III. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, this final rule was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department has completed the required review and determined that, to the extent permitted by law, the regulations meet the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, requires that a federal agency prepare a regulatory flexibility analysis for any rule for which the agency is required to publish a general notice of proposed rulemaking. Such an analysis is not required, however, if the agency certifies that the rule would not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 605(b)).

The Department certifies that today's final rule creating a new part 10 CFR part 719 does not have a significant economic impact on a substantial number of small entities. This rule only restates and clarifies the Department's restrictions on the reimbursement of contractor legal costs. The rule affects only potential claims for reimbursement of costs. The rule does not directly regulate small entities.

D. Review Under the Paperwork Reduction Act

The final rule requires each covered contractor to submit a legal management plan that describes the contractor's practices for managing legal costs and matters for which it procures the services of retained legal counsel. This collection of information is required for the Department to determine whether to approve reimbursement of contractors' litigation and other legal expenses.

The Department submitted to the Office of Management and Budget (OMB) this collection of information for review and approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Office of Management and Budget has not yet approved the collection of information in this rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection has been reviewed and assigned a control number by OMB.

E. Review Under the National Environmental Policy Act

The Department has concluded that promulgation of this final rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by Department of Energy regulations (10 CFR part 1021, subpart D) implementing the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*). Specifically, this final rule is categorically excluded from NEPA review because the amendments to the DEAR would be strictly procedural (categorical exclusion A6). Therefore, this final rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

F. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 10, 1999) requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have "federalism implications." As defined in the Executive Order, policies that have federalism implications include regulations that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The Department has examined this final rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

G. Review Under the Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) generally requires a Federal agency to perform a detailed assessment of costs and benefits of any rule imposing a Federal Mandate with costs to State, local or tribal governments, or to the private sector, of $100 million or more. This rulemaking affects private sector entities, and the impact is less than $100 million.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub.L 105–277) requires federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Today's rule does not impact on the autonomy or integrity of the family institution. Accordingly, the Department has concluded that it is not necessary to prepare a Family Policymaking Statement.

I. Congressional Notification

As required by 5 U.S.C. 801, the Department will report to Congress promulgation of this final rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

10 CFR Part 719

Government contracts, Legal services, Reportintg and recordkeeping requirements.

48 CFR Parts 931 and 970

Government procurement.

Issued in Washington, DC on January 3, 2001.

T.J. Glauthier,

Deputy Secretary, Department of Energy.

For the reasons set out in the preamble, Chapter III of title10 and Chapter 9 of title 48 of the Code of Federal Regulations is amended as set forth below:

1. 10 CFR Part 719 is added to read as follows:

PART 719—CONTRACTOR LEGAL MANAGEMENT REQUIREMENTS

Subpart A—General Provisions

719.1 What is the purpose of this part?
719.2 What are the definitions of terms used in this part?
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719.5 What contracts are not covered by this part?
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Subpart B—Legal Management Plan

719.10 What information must be included in the legal management plan?
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719.30 Is there a standard for determining cost reasonableness?
719.31 How does the Department determine whether fees are reasonable?
719.32 For what costs is the contractor, or Department retained counsel, limited to reimbursement of actual costs only?
719.33 What categories of costs are unallowable?
719.34 What is the treatment for travel costs?
719.35 What categories of costs require advance approval?
719.36 Who at the Department must give advance approval?
719.37 Are there any special procedures or requirements regarding subcontractor legal costs?
719.38 Are costs covered by this part subject to audit?
719.39 What happens when more than one contractor is a party to the matter?

Subpart E—Department Counsel Requirements

719.40 What is the role of Department counsel as a contracting officer's representative?
719.41 What information must be forwarded to the General Counsel's Office concerning contractor submissions to Department counsel under this part?
719.42 What types of field actions must be coordinated with Headquarters?

Appendix to Part 719—Guidance for Legal Resource Management

Authority: 42 U.S.C. 2201, 5814, 5815 and 7101, *et seq.*; 50 U.S.C. 2401, *et seq.*

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Subpart A—General Provisions

§ 719.1 What is the purpose of this part?

This part is intended to facilitate control of Department and contractor legal costs, including litigation costs. The contractor is required to develop a procedure for retaining legal counsel, and to document the analysis used to decide when, where and who will be engaged as outside counsel and the terms of the engagement. Payment of law firm invoices and reimbursement of contractor legal costs under covered contracts is subject to compliance with this part.

§ 719.2 What are the definitions of terms used in this part?

For purposes of this part:

Alternative dispute resolution includes processes such as mediation, neutral evaluation, mini-trials and arbitration.

Contractor means any person or entity with whom the Department contracts for the acquisition of goods or services.

Covered contracts means those contracts described in § 719.3.

Department means the Department of Energy, including the National Nuclear Security Administration.

Department counsel means the individual in the field office, or Headquarter's office, designated as the contracting officer's representative and point of contact for a contractor or Department retained legal counsel, for purposes of this part only, for submission and approval of the legal management plan, advance approval of certain costs, and submission of a staffing and resource plan, as addressed in this part.

Legal costs include, but are not limited to, administrative expenses associated with the provision of legal services by retained legal counsel; the costs of legal services provided by retained legal counsel; the costs of the services of accountants, consultants, or others retained by the contractor or by retained legal counsel to assist retained legal counsel; and any similar costs incurred by or in connection with the services of retained legal counsel.

Legal management plan means a statement describing the contractor's practices for managing legal costs and matters for which it procures the services of retained legal counsel.

Retained legal counsel means members of the bar working in the private sector, either individually or in law firms, who are retained by a contractor or the Department to provide legal services.

Significant matters means legal matters, including litigation, involving significant issues as determined by Department counsel, and any legal matter where the amount of any legal costs, over the life of the matter, is expected to exceed $100,000.

Staffing and resource plan means a statement prepared by retained legal counsel describing plans for managing a significant matter.

§ 719.3 What contracts are covered by this part?

(a) This part covers cost reimbursement contracts:

(1) For an amount exceeding $100,000,000, and

(2) Involving work performed at the facilities owned or leased by the Department.

(b) This part covers contracts otherwise not covered by paragraph 3(a) of this section containing a specialized clause requiring compliance with this part.

(c) This part also covers Department contracts with retained legal counsel where the legal costs are expected to exceed $100,000.

§ 719.4 Are law firms that are retained by the Department covered by this part?

Retained legal counsel under fixed rate or other type of contract with the Department itself to provide legal services must comply with the following where the legal costs over the life of the matter for which counsel has been retained are expected to exceed $100,000:

(a) Requirements related to staffing and resource plans in subpart B of this part,

(b) Engagement letter requirements if legal work is contracted out, and

(c) Cost guidelines in subpart D of this part.

§ 719.5 What contracts are not covered by this part?

This part does not cover:

(a) Fixed price contracts;

(b) Cost reimbursement contracts for an amount less than $100,000,000; or

(c) Contracts for an amount exceeding $100,000,000 involving work not performed at a government owned or leased site.

§ 719.6 Are there any types of legal matters not included in the coverage of this part?

Matters not covered by this part include:

(a) Matters handled by counsel retained by an insurance carrier;

(b) Routine intellectual property law support services;

(c) Routine workers and unemployment compensation matters and labor arbitrations; and

(d) Routine matters handled by counsel retained through a GSA supply schedule.

§ 719.7 Is there a procedure for exceptions or deviations from this part?

(a) Requests for exceptions or deviations from this part by contractors must be made in writing to Department counsel and approved by the General Counsel. If an alternate procedure is proposed for compliance with an individual requirement in this part, that procedure must be included in the written request by the contractor.

(b) The General Counsel may authorize exceptions based on a recommendation of Department counsel. The General Counsel may also establish exceptions to this part based on current field office and contractor practices which satisfy the purpose of these requirements.

(c) Exceptions to this part which are also a deviation from the cost principles (see subpart D of this part) must be approved by the Procurement Executive. See 48 CFR (FAR) 31.101. Written requests from contractors for a deviation to a cost principle must be submitted to the contracting officer, with a copy provided to Department counsel.

Subpart B—Legal Management Plan

§ 719.10 What information must be included in the legal management plan?

The legal management plan must include the following items:

(a) A description of the legal matters that may necessitate handling by retained legal counsel.

(b) A discussion of the factors the contractor must consider in determining whether to handle a particular matter utilizing retained legal counsel.

(c) An outline of the factors the contractor must consider in selecting retained legal counsel, including:

(1) Competition;

(2) Past performance and proficiency shown by previously retained counsel;

(3) Particular expertise in a specific area of the law;

(4) Familiarity with the Department's activity at the particular site and the prevalent issues associated with facility history and current operations;

(5) Location of retained legal counsel relative to:

(i) The site involved in the matter,

(ii) Any forum in which the matter will be processed, and

(iii) Where a significant portion of the work will be performed;

(6) Experience as an advocate in alternative dispute resolution procedures such as mediation;

(7) Actual or potential conflicts of interest; and

(8) The means and rate of compensation (*e.g.*, hourly billing, fixed fee, blended fees, etc.).

(d) A description of:

(1) The system that the contractor will use to review each case to determine whether and when alternative dispute resolution is appropriate;

(2) The role of in house counsel in cost management;

(3) The contractor's process for review and approval of invoices from outside law firms or consultants;

(4) The contractor's strategy for interaction with, and supervision of, retained legal counsel;

(5) How appropriate interaction with the contracting officer and Department counsel will be ensured; and,

(6) The contractor's corporate approach to legal decision making.

§ 719.11 Who must submit a legal management plan?

Contractors identified under paragraphs (a) and (b) in § 719.3 must submit a legal management plan.

§ 719.12 When must the plan be submitted?

Contractors identified under paragraphs (a) and (b) in § 719.3 must submit a legal management plan within 60 days following the execution of a contract with the Department.

§ 719.13 Who at the Department must receive and review the plan?

The contractors identified under paragraphs (a) and (b) in § 719.3 must file a legal management plan with Department counsel.

§ 719.14 Will the Department notify the contractor concerning the adequacy or inadequacy of the submitted plan?

(a) The Department will notify the contractor within 30 days of the contractor's submission of the plan of any deficiencies relating to requirements in § 719.10.

(b) The contractor must either correct identified deficiencies within 30 days of notice of the deficiency or file a letter with the General Counsel disputing the determination of a deficiency.

§ 719.15 What are the requirements for a staffing and resource plan?

(a) For significant matters, the contractor must require retained legal counsel providing legal services to prepare a staffing and resource plan as provided in this section. The contractor must then forward the staffing and resource plan to Department counsel. Department retained counsel subject to this part must prepare a staffing and resource plan and forward it to Department counsel.

(b) A staffing and resource plan is a plan describing:

(1) Major phases likely to be involved in the handling of the matter;

(2) Timing and sequence of such phases;

(3) Projected cost for each phase of the representation; and

(4) Numbers and mix of resources, when applicable, that the retained legal counsel intends to devote to the representation.

(c) For significant matters in litigation, in addition to the generalized annual budget required by § 719.17 a staffing and resource plan must include a budget, broken down by phases, including at a minimum:

(1) Matter assessment, development and administration;

(2) Pretrial pleadings and motions;

(3) Discovery;

(4) Trial preparation and trial; and

(5) Appeal.

§ 719.16 When must the staffing and resource plan be submitted?

(a) For significant matters in litigation, the contractor or Department retained counsel must submit the staffing and resource within 30 days after the filing of an answer or a dispositive motion in lieu of an answer, or 30 days after a determination that the cost is expected to exceed $100,000.

(b) For significant legal services matters, the contractor or Department retained counsel must submit the staffing and resource plan within 30 days following execution of an engagement letter.

(c) Contractors and Department retained counsel must submit updates to staffing and resource plans annually or sooner if significant changes occur in the matter.

(d) When it is unclear whether a matter is significant, the contractor must consult with Department counsel on the question.

(e) The purpose of the staffing and resource plan is primarily informational, but Department counsel may state objections within 30 days of the submission of a staffing and resource plan. When an objection is stated, the contractor has 30 days to satisfy the objection or dispute the objection in a letter to the General Counsel.

§ 719.17 Are there any budgetary requirements?

(a) Contractors required to submit a legal management plan must also submit an annual legal budget covering then pending matters to Department counsel.

(b) The annual legal budget must include cost projections for known or existing matters for which reimbursable legal costs are expected to exceed $100,000, at a level of detail reflective of the types of billable activities and the stage of each such matter.

(c) For informational purposes for both the contractor and Department counsel, the contractor must report on its success on staying within budget at the conclusion of the period covered by each annual legal budget. The Department recognizes, however, that there will be departures from the annual budget beyond the control of the contractor.

Subpart C—Engagement Letters

§ 719.20 When must an engagement letter be used?

Contractors must submit an engagement letter to retained legal counsel expected to provide $25,000 or more in legal services for a particular matter and submit a copy of correspondence relating to § 719.21, including correspondence from retained legal counsel addressing any of the issues under § 719.21, to Department counsel.

§ 719.21 What are the required elements of an engagement letter?

(a) The engagement letter must require retained legal counsel to assist the contractor in complying with this part and any supplemental guidance distributed under this part.

(b) At a minimum, the engagement letter must include the following:

(1) A process for review and documented approval of all billing by a contractor representative, including the timing and scope of billing reviews.

(2) A statement that provision of records to the Government is not intended to constitute a waiver of any applicable legal privilege, protection, or immunity with respect to disclosure of these records to third parties. (An exemption for specific records may be obtained where contractors can demonstrate that a particular situation may provide grounds for a waiver.)

(3) A requirement that the contractor, the Department, and the General Accounting Office, have the right upon request, at reasonable times and locations, to inspect, copy, and audit all records documenting billable fees and costs.

(4) A statement that all records must be retained for a period of three (3) years after the final payment.

(c) The contractor must obtain the following information from retained counsel:

(1) Identification of all attorneys and staff who are assigned to the matter and

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the rate and basis of their compensation (i.e., hourly rates, fixed fees, contingency arrangement) and a process for obtaining approval of temporary adjustments in staffing levels or identified attorneys.

(2) An initial assessment of the matter, along with a commitment to provide updates as necessary.

(3) A description of billing procedures, including frequency of billing and billing statement format.

(d) The contractor must obtain retained counsel's agreement to the following:

(1) That in significant matters a staffing and resource plan for the conduct of the matter must be submitted by the retained legal counsel to the contractor in accordance with the requirements of §§ 719.15 and 719.16.

(2) That alternative dispute resolution must be considered at as early a stage as possible where litigation is involved.

(3) That retained counsel must comply with the cost guidelines in subpart D of this part.

(4) That retained counsel must provide a certification concerning the costs submitted for reimbursement that is consistent with the certification in the Attachment to Appendix A to this part.

(5) That professional conflicts of interest issues must be identified and addressed promptly.

(e) Additional requirements may be included in an engagement letter based on the needs of the contractor or the office requiring the Department retained counsel.

Subpart D—Reimbursement of Costs Subject to This Part

§ 719.30 Is there a standard for determining cost reasonableness?

The standard for cost reasonableness determinations, one of the criteria for an allowability determination, is contained in the Federal Acquisition Regulation (FAR), at 48 CFR 31.201–3.

§ 719.31 How does the Department determine whether fees are reasonable?

In determining whether fees or rates charged by retained legal counsel are reasonable, the Department may consider:

(a) Whether the lowest reasonably achievable fees or rates (including any currently available or negotiable discounts) were obtained from retained legal counsel;

(b) Whether lower rates from other firms providing comparable services were available;

(c) Whether alternative rate structures such as flat, contingent, and other innovative proposals, were considered;

(d) The complexity of the legal matter and the expertise of the law firm in this area; and

(e) The factors listed in § 719.10(c).

§ 719.32 For what costs is the contractor, or Department retained counsel, limited to reimbursement of actual costs only?

All costs determined to be allowable are reimbursable for actual costs only, with no overhead or surcharge adjustments.

§ 719.33 What categories of costs are unallowable?

(a) Specific categories of unallowable costs are contained in the cost principles at 48 CFR (FAR) part 31 and 48 CFR (DEAR) part 931 and 970.31. See also 41 U.S.C. 256(e).

(b) The Department does not consider for reimbursement any costs incurred for entertainment or alcoholic beverages. See 48 CFR (FAR) 31.205–14 and 31.205–51 and 41 U.S.C. 256(e).

(c) Costs that are customarily or already included in billed hourly rates are not separately reimbursable.

(d) Interest charges that a contractor incurs on any outstanding (unpaid) bills from retained legal counsel are not reimbursable.

§ 719.34 What is the treatment for travel costs?

Travel and related expenses must at a minimum comply with the restrictions set forth in 48 CFR (FAR) 31.205–46, or 48 CFR (DEAR) 970.3102–05–46, as appropriate, to be reimbursable.

§ 719.35 What categories of costs require advance approval?

Costs for the following require specific justification or advance written approval from Department counsel to be considered for reimbursement:

(a) Computers or general application software, or non-routine computerized databases specifically created for a particular matter;

(b) Charges for materials or non-attorney services exceeding $5,000;

(c) Secretarial and support services, word processing, or temporary support personnel;

(d) Attendance by more than one person at a deposition, court hearing, interview or meeting;

(e) Expert witnesses and consultants;

(f) Trade publications, books, treatises, background materials, and other similar documents;

(g) Professional or educational seminars and conferences;

(h) Preparation of bills or time spent responding to questions about bills from either the Department or the contractor;

(i) Food and beverages when the attorney or consultant is not on travel status and away from the home office; and

(j) Pro hac vice admissions.

§ 719.36 Who at the Department must give advance approval?

If advance approval is required under this part, the advance approval must be obtained from the Department counsel unless the Department counsel indicates that approval of a request may only be given by the contracting officer.

§ 719.37 Are there any special procedures or requirements regarding subcontractor legal costs?

(a) The contractor must have a monitoring system for subcontractor legal matters likely to reach $100,000 over the life of the matter. The purpose of this system is to enable the contractor to perform the same type of analysis and review of subcontractor legal management practices that the Department can perform of the contractor's legal management practices. The monitoring is intended to enable the contractor to keep the Department informed about significant subcontractor legal matters, including significant matters in litigation. The burden is on the prime contractor to be responsive to questions raised by the Department concerning significant subcontractor legal matters.

(b) Contractors must submit information copies of subcontractor invoices for legal services to Department counsel.

§ 719.38 Are costs covered by this part subject to audit?

All costs covered by this part are subject to audit by the Department, its designated representative or the General Accounting Office. See § 719.21.

§ 719.39 What happens when more than one contractor is a party to a matter?

(a) If more than one contractor is a party in a particular matter and the issues involved are similar for all the contractors, a single legal counsel designated by the General Counsel must either represent all of the contractors or serve as lead counsel, when the rights of the contractors and the government can be effectively represented by a single legal counsel, consistent with the standards for professional conduct applicable in the particular matter. Contractors may propose to the General Counsel their preference for the individual or law firm to perform as the lead counsel for a particular matter.

(b) If a contractor, having been afforded an opportunity to present its views concerning joint or lead representation, does not acquiesce in the designation of one retained legal

counsel to represent a number of contractors, or serve as lead counsel, then the legal costs of such contractor are not reimbursable by the Department, unless the contractor persuasively shows that it was reasonable for the contractor to incur such expenses.

Subpart E—Department Counsel Requirements

§ 719.40 What is the role of Department counsel as a contracting officer's representative?

(a) The individual selected as Department counsel for a contract subject to the requirements of this part must be approved by the contracting officer and the appropriate Chief Counsel, or General Counsel if at Headquarters. The Department counsel must receive written delegated authority from the contracting officer to serve as the contracting officer's representative for legal matters. The contractor must receive a copy of this delegation of authority.

(b) Actions by Department counsel may not exceed the responsibilities and limitations as delegated by the contracting officer. Delegated contracting officer representative authority may not be construed to include the authority to execute or to agree to any modification of the contract nor to attempt to resolve any contract dispute concerning a question of fact arising under the contract.

§ 719.41 What information must be forwarded to the General Counsel's Office concerning contractor submissions to Department counsel under this part?

Department counsel must submit through the General Counsel reporting system, the approved costs and status updates for all matters involving retained counsel, including but not limited to contractor litigation. The reports are to be received by the 15th day of the month following the end of each quarter of the fiscal year.

§ 719.42 What types of field actions must be coordinated with Headquarters?

(a) Requests from contractors for exception from this entire part must be coordinated with Headquarters.

(b) Requests from contractors for approval to initiate or defend litigation, or to appeal from adverse decisions, where legal issues of first impression, sensitive issues, issues of significance to the Department nationwide or issues of broad applicability to the Government that might adversely impact its operations are involved must be coordinated by Department counsel with the Deputy General Counsel for Litigation or his/her designee.

(c) Department field counsel must inform the General Counsel of any significant matter, as defined in this part, and must coordinate any action involving a significant matter with the General Counsel, or his/her designee, as directed by the General Counsel or his/her designee.

Appendix to Part 719—Guidance for Legal Resource Management

Management and Administration of Outside Legal Services
1.0 Initiation of Litigation
2.0 Defense of Litigation
2.1 Disapproval of Defensive Litigation
3.0 Notice to the Department of Significant Matters and Litigation
4.0 Alternative Dispute Resolution
5.0 Cost Allowability Issues
5.1 Underlying Cause for Incurrence of Costs
5.2 Fees and Other Charges
6.0 Role of Department Counsel as the Contracting Officer's Representative
7.0 Future Amendments to Guidance
Attachment—Contractor Litigation and Legal Costs, Model Bill Certification and Format

Management and Administration of Outside Legal Services

This guidance is intended to assist contractors and the Department's contracting officers and counsel in managing the costs of outside legal services. This guidance is also intended to assist retained legal counsel who provide services to the Department or to the Department's contractors.

1.0 Initiation of Litigation

(A) The Insurance—Litigation and Claims clause (48 CFR (DEAR) 970.5228–1) in the Department's facility management contracts provides that the contractor may not initiate litigation, including appeals from adverse decisions, without the prior authorization or approval of Department counsel acting in his/her capacity as the Department's contracting officer representative. The following are the minimum informational requirements for requests for authorization or approval under that clause:

(1) Identification of the proposed parties;

(2) The nature of the proposed action;

(3) Relief sought;

(4) Venue;

(5) Proposed representation and reason for selection;

(6) An analysis of the issues and the likelihood of success, and any time limitation associated with the requested approval;

(7) The estimated costs associated with the proposed action, including whether outside counsel has agreed to a contingent fee arrangement;

(8) Whether, for any reason, the contractor will assume any part of the costs of the action;

(9) A description of any attempts to resolve the issues that would be the subject of the litigation, such as through mediation or other means of alternative dispute resolution; and

(10) A discussion of why initiating litigation would prove beneficial to the contractor and to the Government.

(B) Department counsel should advise the contracting officer concerning each request and must provide assistance to the contracting officer in communicating the Department's decision to the contractor.

2.0 Defense of Litigation

(A) In accordance with the Insurance-Litigation and Claims clause, the contractor must immediately notify Department counsel, acting in his/her capacity as contracting officer representative, of the initiation of litigation against the contractor. Department counsel will advise the contractor as to:

(1) Whether the defense of the litigation will be either approved or disapproved or approval deferred and any conditions to which approval is subject;

(2) Whether the contractor must authorize the Government to defend the action;

(3) Whether the Government will take charge of the action; or

(4) Whether the Government must receive an assignment of the contractor's rights.

(B) When defensive litigation is approved at a later stage or at the conclusion of the matter, reimbursement can be made for only those expenses which would have been reimbursable as allowable costs if the Department had originally approved the defense of the litigation.

2.1 Disapproval of Defensive Litigation

If the Department disapproves in advance the costs of defense of the litigation, the contractor will be notified of the disapproval and that contract funds may not be used to fund the defense of the litigation. The contractor will also be informed if the Department changes its position. Contractor compliance with these policies and procedures does not itself obligate the Department to reimburse litigation costs or judgment costs when Departmental approval of the litigation cost has been denied or deferred.

3.0 Notice to the Department of Significant Matters and Litigation

The contractor's procedures under its Legal Management Plan should include provisions for earliest possible notification to the Department of the likely initiation of any "significant matters" involving class actions, radiation or toxic substance exposure, problems concerning the safeguarding of classified information, and any other matters involving issues which the contractor has reason to believe are of general importance to the Department or the government as a whole.

4.0 Alternative Dispute Resolution

Contractors are expected to evaluate all matters for appropriate alternative dispute resolution (ADR) at various stages of an issue in dispute, *e.g.*, before a case is filed, pre-discovery, after initial discovery and pre-trial. This evaluation should be done in coordination with the Department's ADR liaison if one has been established or appointed or the Department counsel if an ADR liaison has not been appointed. Contractors, contractor counsel, and Department counsel are also encouraged to consult with the Department's Director of the

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Office of Dispute Resolution. The Department anticipates that mediation will be the principal and most common method of alternative dispute resolution. In exceptional circumstances, arbitration may be appropriate. However, agreement to arbitrate should generally be consistent with the Administrative Dispute Resolution Act (incorporated in part at 5 U.S.C. 571, *et seq.*) and Department guidance issued under that Act. When a decision to arbitrate is made, a statement fixing the maximum award amount should be agreed to in advance by the participants.

5.0 Cost Allowability Issues

A determination of cost reasonableness may depend on a variety of considerations and circumstances. In accordance with 48 CFR (FAR) 31.201–3, no presumption of reasonableness is attached to the incurrence of costs by a contractor. 10 CFR part 719 and this Appendix provide contractors guidelines for incurring legal costs to which adherence should result in a determination of allowability if the cost is otherwise allowable under the contract.

5.1 Underlying Cause for Incurrence of Costs

(A) While 10 CFR part 719 provides procedures for incurring legal costs, the determination of the reason for the incurrence of the legal costs, *e.g.*, liability, fault or avoidability, is a separate determination. This latter determination may involve, for example, a possible finding of willful misconduct or lack of good faith by contractor management in the case of third party liability, or a finding of violation of a statute or regulation by the contractor in a governmental proceeding. The reason for the contractor incurring costs may be determinative of the allowability of the contractor's legal costs. For example, legal costs incurred by a contractor in defending actions brought by governmental agency may be covered by the Major Fraud Act, 41 U.S.C. 256(k), implemented as a cost principle at 48 CFR (FAR) 31.205–47. In such cases, the statute may restrict the Department's authority to reimburse legal costs incurred by the contractor regardless of the outcome of the action.

(B) In some cases, the final determination of allowability of legal costs cannot be made until a matter is fully resolved. This is particularly true in the case of legal defense costs covered by the restrictions in the Major Fraud Act and is also a common problem in cases covered by various whistleblower statutes and regulations. In certain circumstances, contract and cost principle language may permit conditional reimbursement of costs pending the outcome of the legal matter. Whether the Department makes conditional reimbursements or withholds any payment pending the outcome, legal costs ultimately reimbursed by the Department must satisfy the standards of cost reasonableness.

5.2 Fees and Other Charges

(A) Requests by retained legal counsel that are not in a direct contract with the Department for fee increases should be sent in writing to the contractor, who should review the request for reasonableness. If the contractor determines the request is reasonable, the contractor should seek approval for the request from Department counsel and the contracting officer before it authorizes any increase. Contractors should attempt to lock in rates for partners, associates and paralegals for at least a two-year period.

(B) Costs listed in 10 CFR 719.33(c) are usually incorporated into the rate or fee structure. Consultants or experts hired by retained legal counsel who do not include any overhead or similar charges, such as computer time, in their base rate, must have those charges approved in advance by Department counsel and the contracting officer. Time charged by law students should be scrutinized for its efficiency and have prior authorization.

(C) Travel time may be reimbursed at a full rate for the portion of time during which retained legal counsel actually performs work for which it was retained; any remaining travel time during normal working hours shall be reimbursed at 50 percent, except that in no event is travel time for time during which work was performed for other clients reimbursable. Also, for long distance travel that could be completed by various methods of transportation, *i.e.*, car, train, or plane, only the charge for the overall fastest travel time will be considered reasonable.

(D) For costs associated with the creation and use of computerized databases, contractors and retained legal counsel must ensure that the creation and use of computerized databases is necessary and cost-effective. Potential use of databases originally created by the Department or its contractors for other purposes, but that can be used to assist a contractor or retained legal counsel in connection with a particular matter, should be considered and be coordinated with Department counsel.

6.0 Role of Department Counsel as the Contracting Officer's Representative

(A) An attorney from the field office or from Headquarters will be appointed a contracting officer's representative by the cognizant contracting officer. A contracting officer may designate other Government personnel to act as authorized representatives for functions not involving a change in the scope, price, terms or conditions of the contract. This designation is made in writing and contains specific instructions regarding the extent to which the representatives may take action for the contracting officer, and prohibits the representative from signing contractual documents. The contracting officer is the only person authorized to approve changes in any of the requirements under the contract.

(B) Additional discussion of the authority and limitation of contracting officers can be found at 48 CFR (FAR) 1.602–1, and for contracting officer's representatives at 48 CFR (DEAR) 942.270–1. The clause, Technical Direction, 48 CFR (DEAR) 952.242–70, also discusses the responsibilities and limitations of a contracting officer's representative.

7.0 Future Amendments to Guidance

The Office of the General Counsel may by memorandum provide additional guidance to contractors. These memoranda will serve as guidance for "safe harbor" practices for contractors procuring outside legal services.

Attachment—Contractor Litigation and Legal Costs, Model Bill Certification and Format

1. Certification

Bills or invoices should contain a certification signed by a representative of the retained legal counsel to the effect that:

"Under penalty of law, [the representative] acknowledges the expectation that the bill will be paid by the contractor and that the contractor will be reimbursed by the Federal Government through the U.S. Department of Energy, and, based on personal knowledge and a good faith belief, certifies that the bill is truthful and accurate, and that the services and charges set forth herein comply with the terms of engagement and the policies set forth in the Department of Energy's regulation and guidance on contractor legal management requirements, and that the costs and charges set forth herein are necessary."

2. Model Bill Format

I.—FOR FEES

Date of service	Description of service	Name or initials of attorney	Approved rate	Time charged	Amount (rate × time)
(See Note 1 to this table).					

II.—FOR DISBURSEMENTS

Date	Description of disbursement	Amount
(See Note 2 to this table).		

Note 1—Description of Service: All fees must be itemized and described in sufficient detail and specificity to reflect the purpose and nature of the work performed (*e.g.*, subject matter researched or discussed; names of participants of calls/meetings; type of documents reviewed).

Note 2—Description of Disbursement: Description should be in sufficient detail to determine that the disbursement expense was in accordance with all applicable Department policies on reimbursement of contractor legal costs and the terms of engagement between the contractor and the retained legal counsel. The date the expense was incurred or disbursed should be listed rather than the date the expense was processed. The following should be itemized: copy charge (*i.e.*, number of pages times a maximum of 10 cents per page); fax charges (date, phone number and actual amount); overnight delivery (date and amount); electronic research (date and amount); extraordinary postage (*i.e.*, bulk or certified mail); court reporters; expert witness fees; filing fees; outside copying or binding charges; temporary help (assuming prior approval).

Note 3—Receipts: Receipts for all expenses equal to or above $75 must be attached.

2. The authority citation for Part 931 continues to read as follows:

Authority: 42 U.S.C. 7101, *et seq.*; 40 U.S.C. 486(c); 50 U.S.C. 2401, *et seq.*; 42 U.S.C. 2201.

PART 931—COST PRINCIPLES

3. Section 931.205–19 is added to read as follows:

931.205–19 Insurance and indemnification. (Department coverage-paragraph (h)).

(h) Cost reimbursement contracts involving work performed at facilities owned or leased by the Department for an amount exceeding $100,000,000 must insert the clause at 48 CFR 970.5228–1, Insurance-Litigation and claims.

4. Section 931.205–33 is added to read as follows:

931.205–33 Professional and consultant service costs. (Department coverage-paragraph (g)).

(g)(1) Reasonable litigation and other legal expenses are allowable when incurred in accordance with 10 CFR part 719, Contractor Legal Management Requirements, if not otherwise made unallowable by law or provisions of the contract.

(2)(A) Cost reimbursement contracts involving work performed at facilities owned or leased by the Department for an amount exceeding $100,000,000 are covered by this cost principle and 10 CFR part 719.

(B) This cost principle and 10 CFR part 719 are applicable to legal counsel retained by the Department itself for litigation and other legal services where the legal costs over the life of the matter for which counsel has been retained are expected to exceed $100,000.

(3) Contractors described in paragraph (g)(2)(A) of this section are required to submit a Legal Management Plan within 60 days of execution of a contract.

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

5. The authority citation for Part 970 continues to read as follows:

Authority: Atomic Energy Act of 1954 (42 U.S.C. 2201); Department of Energy Organization Act (42 U.S.C. 7101, *et seq.*); and National Nuclear Security Administration Act (50 U.S.C. 2401, *et seq.*)

6. Section 970.3102–05–33 is added to read as follows:

970.3102–05–33 Professional and consultant service costs. (Department coverage-paragraph (g)).

(g) Section 931.205–33 is applicable to management and operating contracts under this part.

7. Section 970.5228–1 is amended by:

a. revising clause paragraph (e)(2),

b. revising the introcutory text of clause paragraph (h),

c. revising clause paragraph (j)(4), and

d. removing clause paragraph (m).

The revisions read as follows:

970.5228–1 Insurance—litigation and claims.

* * * * *

(e) * * *

(2) For liabilities (and reasonable expenses incidental to such liabilities, including litigation costs) to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of cost or limitation of funds clause of this contract.

* * * * *

(h) In addition to the cost reimbursement limitations contained in the cost principles at FAR part 31, as supplemented in the DEAR, and notwithstanding any other provision of this contract, the contractor's liabilities to third persons, including employees but excluding costs incidental to workers' compensation actions (and any expenses incidental to such liabilities, including litigation costs, counsel fees, judgments and settlements), shall not be reimbursed if such liabilities were caused by contractor managerial personnel's * * *.

* * * * *

(j) * * *

(4) The term "contractor's managerial personnel" is defined in the Property clause in this contract.

* * * * *

8. Section 970.5244–1 is amended by revising the reference to "paragraphs (b) through (x)" in the last sentence of clause paragraph (a) to read "paragraphs (b) through (y)" and by adding clause paragraph (y) to read as follows:

970.5244–1 Contractor purchasing system.

* * * * *

(y) Legal Services. Contractor purchases of litigation and other legal services are subject to the requirements in 10 CFR part 719 and the requirements of this clause.

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DEPARTMENT OF ENERGY

10 CFR Parts 1040 and 1042

RIN: 1901–AA87

Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance

AGENCY: Department of Energy.

ACTION: Final rule.

SUMMARY: This final rule adds a new part to the Code of Federal Regulations to replace existing Department of Energy (DOE) regulations for the enforcement of Title IX of the Education Amendments of 1972, as amended ("Title IX"). Title IX prohibits recipients of Federal financial assistance from discriminating on the basis of sex in education programs or activities. The provisions of this final rule are the same as a common rule published by the Department of Justice on August 30, 2000, for Federal agencies that did not already have Title IX implementing regulations. DOE adopts the provisions of the common rule in order to promote consistent and adequate enforcement of Title IX.

EFFECTIVE DATE: February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Sharon Wyatt, Paralegal Specialist, Office of Civil Rights and Diversity, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20285. Telephone: (202) 586–2256.

SUPPLEMENTARY INFORMATION:

I. Background

On June 13, 1980, DOE published a final rule (10 CFR part 1040) to implement various nondiscrimination statutes, including Title IX of the Education Amendments of 1972. 45 FR 40514. DOE's Title IX regulations, which prohibit discrimination on the basis of sex in educational programs or activities operated by recipients of

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Federal financial assistance, are found principally in subpart C of 10 CFR part 1040.

On August 30, 2000, 20 Federal departments and agencies published a final common rule to provide for the enforcement of Title IX by participating Federal agencies that had not previously promulgated Title IX implementing regulations ("Title IX common rule"). 65 FR 52858. The Department of Justice coordinated development of the Title IX common rule, consistent with its responsibility under Executive Order 12250 to ensure the consistent and effective implementation of Title IX and other civil rights laws. DOE, as one of four Federal agencies that had already promulgated Title IX regulations, did not join in the common rulemaking.

Upon further consideration, and on the basis of the common notice of final rulemaking, DOE has decided to replace its existing regulations with the provisions of the common rule. DOE's current regulations have not been amended since 1980 and do not reflect intervening developments, including certain Supreme Court decisions, the Civil Rights Restoration Act of 1987 (Public Law 100–259), and various Executive orders. By adopting the common rule, DOE brings its regulations up-to-date and, by adopting the language and form of the Title IX common rule, should make it easier for recipients of DOE financial assistance to comply with Title IX requirements.

II. Overview of the Rule

Subpart A of this final rule sets forth definitions as well as provisions concerning remedial action and affirmative action, required assurances, adoption of grievance procedures, and notification of nondiscrimination policies. The effect of state and other laws and other requirements is also explained. Subpart B addresses the scope or coverage of Title IX, and Subpart C addresses nondiscrimination on the basis of sex in admission and recruitment practices with respect to students.

Subpart D addresses nondiscrimination on the basis of sex in education programs or activities. Specific areas covered in this subpart are housing, access to course offerings, access to schools operated by local education agencies, counseling, financial assistance, employment assistance to students, health and insurance benefits and services, consideration of marital and parental status, and athletics.

Subpart E covers the prohibitions of discrimination on the basis of sex in employment in educational programs or activities. Specific aspects of employment that are addressed include hiring and employment criteria, recruitment, compensation, job classification and structure, promotion and termination, fringe benefits, consideration of marital or parental status, leave practices, advertising, and preemployment inquiries as to parental and marital status. This subpart also includes a provision to exempt from Title IX coverage employment actions where sex is a bona fide occupational qualification.

Finally, Subpart F contains provisions that reference DOE's list of covered programs and incorporate DOE's procedures for implementation and enforcement of Title IX.

By adopting the provisions of the Title IX common rule in this rule, DOE is not imposing any new substantive requirements, beyond the requirements of Title IX, on recipients of DOE funding.

As shown in the following "cross-walk" table, some of the provisions of new part 1042 (numbered to correspond to the common rule) appear in different order than in the existing regulations in part 1042:

Part 1042	Part 1040 (current regulations)
Subpart A	
1042.100	1040.21
1042.105	1040.23
1042.110	1040.7
1042.115	1040.4
1042.120	1040.4(b)(1)
1042.125	1040.24
1042.130	1040.8
1042.135	1040.5
1042.140	1040.6
Subpart B	
1042.200	1040.22
1042.205	1040.25
1042.210	1040.26
1042.215	1040.27
1042.220	1040.28
1042.225	1040.29
1042.230	1040.30
1042.235	1040.27
Subpart C	
1042.300	1040.31
1042.305	1040.32
1042.310	1040.33
Subpart D	
1042.400	1040.34
1042.405	1040.35
1042.410	1040.36
1042.415	1040.37
1042.420	1040.38
1042.425	1040.39
1042.430	1040.40
1042.435	1040.41
1042.440	1040.42
1042.445	1040.43
1042.450	1040.44
1042.455	1040.45
Subpart E	
1042.500	1040.47
1042.505	1040.48
1042.510	1040.49
1042.515	1040.50
1042.520	1040.51
1042.525	1040.52
1042.530	1040.53
1042.535	1040.54
1042.540	1040.55
1042.545	1040.56
1042.550	1040.57
Subpart F	
1042.600	Appendix A
1042.605	1040.46

The only deviation in numbering between part 1042 and the Title IX common rule is in subpart F. Subpart F of the Title IX common rule is titled "Procedures" and contains § ____.600, "Notice of covered programs," that requires each participating agency to publish, within 60 days of the common rule's effective date, a notice of the programs covered by its Title IX regulations, and to periodically republish the notice listing the programs. In addition, most participating agencies have included in subpart F a § ____.605 that incorporates by reference the agencies' procedures for enforcing Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d, *et seq.*). DOE already has published a list of covered programs as appendix A to 10 CFR part 1040. Therefore, DOE includes in subpart F, titled "Other Provisions," a § 1042.600, "Covered programs," which simply references the list of covered programs in appendix A to part 1040. DOE has followed other agencies in including in subpart F a § 1042.605, "Enforcement procedures," that incorporates the procedures for enforcing Title VI in subparts G and H of part 1040.

This final rule includes various compliance deadlines included in the Title IX common rule, including deadlines for self-evaluation (§ 1042.110(c)) and initial notification of the recipient's nondiscrimination policy (§ 1042.140(a)(2)). Most DOE recipients already comply with these requirements, and DOE does not intend this rule to require any additional actions by them. DOE notes that the preamble to the final Title IX common rule explains that recipient educational institutions that have conducted a self-evaluation under Title IX need not, as a result of the Title IX common rule, conduct a new self-evaluation. 65 FR 52863.

III. Public Comment

This rule imposes no new substantive requirements on recipients of DOE financial assistance. These revisions to DOE's Title IX regulations only conform DOE's regulations to the Title IX common rule adopted by other Federal agencies and amend the text to reflect changes in the law that have occurred since DOE published its Title IX regulations in 1980. Thus, this final rule is not a significant rule involving equal employment opportunity that must be proposed for public comment under Executive Order 12067, section 1–305. Nor is an opportunity for public comment required by the rulemaking provisions of the Administrative Procedure Act, 5 U.S.C. 553.

Furthermore, the provisions of this final rule were proposed by the Department of Justice and public comment invited for a period of 60 days. See 64 FR 58567 (Oct. 29, 1999). DOJ received a total of 22 comments, five of which were submitted by other Federal agencies. The preamble to the final Title IX common rule contains a summary of the public comments and the participating agencies' responses to those comments. See 65 FR 52860–52864.

In light of the opportunity for public comment provided by the Department of Justice, and DOE's obligation under Executive Order 12250, section 1–402, to promulgate regulations "consistent with the requirements prescribed by the Attorney General," to the extent permitted by law, no purpose would be served by inviting public comment on these regulations.

IV. Procedural Requirements

A. Review Under Executive Order 12866

This final rule has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

B. Review Under Executive Order 12250

This final rule has been reviewed by the Attorney General in accordance with the provisions of Executive Order 12250, "Leadership and Coordination of Nondiscrimination Laws," (3 CFR, 1980 Comp., p. 298).

C. Review Under Executive Order 12067

These regulations were submitted for review by the Equal Employment Opportunity Commission pursuant to Executive Order 12067, "Providing for Coordination of Federal Equal Employment Opportunity Programs," (3 CFR, 1978 Comp., p. 206).

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4) generally requires a Federal agency to perform a detailed assessment of costs and benefits of any rule imposing a Federal mandate with costs to State, local, or tribal governments, or to the private sector, of $100 million or more. These Title IX regulations, which enforce a statutory prohibition on discrimination on the basis of sex, will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, nor will they significantly or uniquely affect small governments. No further action is required by the Unfunded Mandates Reform Act of 1995.

E. The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. DOE is not required by law to propose this financial assistance regulation for public comment. Accordingly, the Regulatory Flexibility Act requirements do not apply to this rulemaking, and no regulatory flexibility analysis has been prepared.

F. Paperwork Reduction Act of 1995

No new information or record keeping requirements are imposed by this rulemaking. Accordingly, no clearance by the Office of Management and Budget is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The information collections in this rule are covered by OMB Control No. 1910–0400.

G. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this final rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) Specifically, this rule is covered under the Categorical Exclusion in paragraph A5 to subpart D, 10 CFR part 1021, which covers rulemakings that interpret or amend an existing regulation without changing the environmental effect of the regulation. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

H. Executive Order 13132

These Title IX regulations will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. These Title IX regulations do not subject recipients of Federal funding to any new substantive obligations because all recipients of Federal funding that operate education programs or activities have been bound by Title IX's anti-discrimination provision since 1972. Therefore, in accordance with section 6 of Executive Order 13132, DOE has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. No further action is required.

I. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3 of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to eliminate drafting errors and ambiguity; write regulations to minimize litigation; provide a clear legal standard for affected conduct rather than a general standard; and promote simplification and burden reduction. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

J. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress promulgation of this final rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 10 CFR Parts 1040 and 1042

Administrative practice and procedure, Civil rights, Colleges and universities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal

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employment opportunity, Grant programs-education, Investigations, Marital status discrimination, Reporting and recordkeeping requirements, Schools, Sex discrimination, Student aid, Women.

Issued in Washington, D.C. on January 2, 2001.

T.J. Glauthier,

Deputy Secretary.

For the reasons stated in the preamble, DOE hereby amends chapter X of Title 10 of the Code of Federal Regulations as set forth below:

PART 1040—NONDISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS

1. The authority citation is revised to read as follows:

Authority: 20 U.S.C. 1681–1686; 29 U.S.C. 794; 42 U.S.C. 2000d to 2000d–4a, 3601–3631, 5891, 6101–6107, 6870, 7101 *et seq.*; and 50 U.S.C. 2401 *et seq.*

2. Section 1040.1 is amended by designating the current text as paragraph (a) and adding paragraphs (b) and (c) to read as follows:

§ 1040.1 Purpose.

* * * * *

(b) DOE regulations on enforcement of nondiscrimination on the basis of handicap in programs or activities conducted by DOE are in part 1041 of this chapter.

(c) DOE regulations on enforcement of nondiscrimination on the basis of sex, under Title IX of the Education Act Amendments of 1972, as amended, are in part 1042 of this chapter.

Subpart C—[Removed and Reserved]

3. Subpart C of 10 CFR part 1040 is removed and reserved.

4. Part 1042, is added to chapter X to read as follows:

PART 1042—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—Introduction

Sec.

1042.100 Purpose and effective date.
1042.105 Definitions.
1042.110 Remedial and affirmative action and self-evaluation.
1042.115 Assurance required.
1042.120 Transfers of property.
1042.125 Effect of other requirements.
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Subpart B—Coverage

1042.200 Application.
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1042.220 Admissions.
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1042.300 Admission.
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1042.400 Education programs or activities.
1042.405 Housing.
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1042.415 Access to course offerings.
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1042.425 Counseling and use of appraisal and counseling materials.
1042.430 Financial assistance.
1042.435 Employment assistance to students.
1042.440 Health and insurance benefits and services.
1042.445 Marital or parental status.
1042.450 Athletics.
1042.455 Textbooks and curricular material.

Subpart E—Discrimination on the Basis of Sex in Employment in Education Programs or Activities Prohibited

1042.500 Employment.
1042.505 Employment criteria.
1042.510 Recruitment.
1042.515 Compensation.
1042.520 Job classification and structure.
1042.525 Fringe benefits.
1042.530 Marital or parental status.
1042.535 Effect of state or local law or other requirements.
1042.540 Advertising.
1042.545 Pre-employment inquiries.
1042.550 Sex as a bona fide occupational qualification.

Subpart F—Other Provisions

1042.600 Covered programs.
1042.605 Enforcement procedures.

Authority: 20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688; 42 U.S.C. 7101 *et seq.*; and 50 U.S.C. 2401 *et seq.*

Subpart A—Introduction

§ 1042.100 Purpose and effective date.

The purpose of these Title IX regulations is to effectuate Title IX of the Education Amendments of 1972, as amended (except sections 904 and 906 of those Amendments) (20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688), which is designed to eliminate (with certain exceptions) discrimination on the basis of sex in any education program or activity receiving Federal financial assistance, whether or not such program or activity is offered or sponsored by an educational institution as defined in these Title IX regulations. The effective date of these Title IX regulations is February 20, 2001.

§ 1042.105 Definitions.

As used in these Title IX regulations, the term:

Administratively separate unit means a school, department, or college of an educational institution (other than a local educational agency) admission to which is independent of admission to any other component of such institution.

Admission means selection for part-time, full-time, special, associate, transfer, exchange, or any other enrollment, membership, or matriculation in or at an education program or activity operated by a recipient.

Applicant means one who submits an application, request, or plan required to be approved by an official of the Department of Energy, or by a recipient, as a condition to becoming a recipient of Federal financial assistance.

Designated agency official means the Director, Office of Civil Rights and Diversity or any official to whom the Director's functions under this part are relegated.

Educational institution means a local educational agency (LEA) as defined by 20 U.S.C. 8801(18), a preschool, a private elementary or secondary school, or an applicant or recipient that is an institution of graduate higher education, an institution of undergraduate higher education, an institution of professional education, or an institution of vocational education, as defined in this section.

Federal financial assistance means any of the following, when authorized or extended under a law administered by the Federal agency that awards such assistance:

(1) A grant or loan of Federal financial assistance, including funds made available for:

(i) The acquisition, construction, renovation, restoration, or repair of a building or facility or any portion thereof; and

(ii) Scholarships, loans, grants, wages, or other funds extended to any entity for payment to or on behalf of students admitted to that entity, or extended directly to such students for payment to that entity.

(2) A grant of Federal real or personal property or any interest therein, including surplus property, and the proceeds of the sale or transfer of such property, if the Federal share of the fair market value of the property is not, upon such sale or transfer, properly accounted for to the Federal Government.

(3) Provision of the services of Federal personnel.

(4) Sale or lease of Federal property or any interest therein at nominal consideration, or at consideration reduced for the purpose of assisting the recipient or in recognition of public interest to be served thereby, or permission to use Federal property or any interest therein without consideration.

(5) Any other contract, agreement, or arrangement that has as one of its purposes the provision of assistance to any education program or activity, except a contract of insurance or guaranty.

Institution of graduate higher education means an institution that:

(1) Offers academic study beyond the bachelor of arts or bachelor of science degree, whether or not leading to a certificate of any higher degree in the liberal arts and sciences;

(2) Awards any degree in a professional field beyond the first professional degree (regardless of whether the first professional degree in such field is awarded by an institution of undergraduate higher education or professional education); or

(3) Awards no degree and offers no further academic study, but operates ordinarily for the purpose of facilitating research by persons who have received the highest graduate degree in any field of study.

Institution of professional education means an institution (except any institution of undergraduate higher education) that offers a program of academic study that leads to a first professional degree in a field for which there is a national specialized accrediting agency recognized by the Secretary of Education.

Institution of undergraduate higher education means:

(1) An institution offering at least two but less than four years of college-level study beyond the high school level, leading to a diploma or an associate degree, or wholly or principally creditable toward a baccalaureate degree; or

(2) An institution offering academic study leading to a baccalaureate degree; or

(3) An agency or body that certifies credentials or offers degrees, but that may or may not offer academic study.

Institution of vocational education means a school or institution (except an institution of professional or graduate or undergraduate higher education) that has as its primary purpose preparation of students to pursue a technical, skilled, or semiskilled occupation or trade, or to pursue study in a technical field, whether or not the school or institution offers certificates, diplomas, or degrees and whether or not it offers full-time study.

Recipient means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof.

Student means a person who has gained admission.

Title IX means Title IX of the Education Amendments of 1972, Public Law 92–318, 86 Stat. 235, 373 (codified as amended at 20 U.S.C. 1681–1688) (except sections 904 and 906 thereof), as amended by section 3 of Public Law 93–568, 88 Stat. 1855, by section 412 of the Education Amendments of 1976, Public Law 94–482, 90 Stat. 2234, and by Section 3 of Public Law 100–259, 102 Stat. 28, 28–29 (20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688).

Title IX regulations means the provisions set forth in this 10 CFR Part 1042.

Transition plan means a plan subject to the approval of the Secretary of Education pursuant to section 901(a)(2) of the Education Amendments of 1972, 20 U.S.C. 1681(a)(2), under which an educational institution operates in making the transition from being an educational institution that admits only students of one sex to being one that admits students of both sexes without discrimination.

§ 1042.110 Remedial and affirmative action and self-evaluation.

(a) *Remedial action.* If the designated agency official finds that a recipient has discriminated against persons on the basis of sex in an education program or activity, such recipient shall take such remedial action as the designated agency official deems necessary to overcome the effects of such discrimination.

(b) *Affirmative action.* In the absence of a finding of discrimination on the basis of sex in an education program or activity, a recipient may take affirmative action consistent with law to overcome the effects of conditions that resulted in limited participation therein by persons of a particular sex. Nothing in these Title IX regulations shall be interpreted to alter any affirmative action obligations that a recipient may have under Executive Order 11246, 3 CFR, 1964–1965 Comp., p. 339; as amended by Executive Order 11375, 3 CFR, 1966–1970 Comp., p. 684; as amended by Executive Order 11478, 3 CFR, 1966–1970 Comp., p. 803; as amended by Executive Order 12086, 3 CFR, 1978 Comp., p. 230; as amended by Executive Order 12107, 3 CFR, 1978 Comp., p. 264.

(c) *Self-evaluation.* Each recipient education institution shall, within one year of February 20, 2001:

(1) Evaluate, in terms of the requirements of these Title IX regulations, its current policies and practices and the effects thereof concerning admission of students, treatment of students, and employment of both academic and non-academic personnel working in connection with the recipient's education program or activity;

(2) Modify any of these policies and practices that do not or may not meet the requirements of these Title IX regulations; and

(3) Take appropriate remedial steps to eliminate the effects of any discrimination that resulted or may have resulted from adherence to these policies and practices.

(d) *Availability of self-evaluation and related materials.* Recipients shall maintain on file for at least three years following completion of the evaluation required under paragraph (c) of this section, and shall provide to the designated agency official upon request, a description of any modifications made pursuant to paragraph (c)(2) of this section and of any remedial steps taken pursuant to paragraph (c)(3) of this section.

§ 1042.115 Assurance required.

(a) *General.* Either at the application stage or the award stage, the Department of Energy must ensure that applications for Federal financial assistance or awards of Federal financial assistance contain, be accompanied by, or be covered by a specifically identified assurance from the applicant or recipient, satisfactory to the designated agency official, that each education program or activity operated by the applicant or recipient and to which

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these Title IX regulations apply will be operated in compliance with these Title IX regulations. An assurance of compliance with these Title IX regulations shall not be satisfactory to the designated agency official if the applicant or recipient to whom such assurance applies fails to commit itself to take whatever remedial action is necessary in accordance with § 1042.110(a) to eliminate existing discrimination on the basis of sex or to eliminate the effects of past discrimination whether occurring prior to or subsequent to the submission to the designated agency official of such assurance.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended to provide real property or structures thereon, such assurance shall obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used to provide an education program or activity.

(2) In the case of Federal financial assistance extended to provide personal property, such assurance shall obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases such assurance shall obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Form.* (1) The assurances required by paragraph (a) of this section, which may be included as part of a document that addresses other assurances or obligations, shall include that the applicant or recipient will comply with all applicable Federal statutes relating to nondiscrimination. These include but are not limited to: Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681–1683, 1685–1688).

(2) The designated agency official will specify the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, subcontractors, transferees, or successors in interest.

§ 1042.120 Transfers of property.

If a recipient sells or otherwise transfers property financed in whole or in part with Federal financial assistance to a transferee that operates any education program or activity, and the Federal share of the fair market value of the property is not upon such sale or transfer properly accounted for to the Federal Government, both the transferor and the transferee shall be deemed to be recipients, subject to the provisions of §§ 1042.205 through 1042.235(a).

§ 1042.125 Effect of other requirements.

(a) *Effect of other Federal provisions.* The obligations imposed by these Title IX regulations are independent of, and do not alter, obligations not to discriminate on the basis of sex imposed by Executive Order 11246, 3 CFR, 1964–1965 Comp., p. 339; as amended by Executive Order 11375, 3 CFR, 1966–1970 Comp., p. 684; as amended by Executive Order 11478, 3 CFR, 1966–1970 Comp., p. 803; as amended by Executive Order 12087, 3 CFR, 1978 Comp., p. 230; as amended by Executive Order 12107, 3 CFR, 1978 Comp., p. 264; sections 704 and 855 of the Public Health Service Act (42 U.S.C. 295m, 298b–2); Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*); the Equal Pay Act of 1963 (29 U.S.C. 206); and any other Act of Congress or Federal regulation.

(b) *Effect of State or local law or other requirements.* The obligation to comply with these Title IX regulations is not obviated or alleviated by any State or local law or other requirement that would render any applicant or student ineligible, or limit the eligibility of any applicant or student, on the basis of sex, to practice any occupation or profession.

(c) *Effect of rules or regulations of private organizations.* The obligation to comply with these Title IX regulations is not obviated or alleviated by any rule or regulation of any organization, club, athletic or other league, or association that would render any applicant or student ineligible to participate or limit the eligibility or participation of any applicant or student, on the basis of sex, in any education program or activity operated by a recipient and that receives Federal financial assistance.

§ 1042.130 Effect of employment opportunities.

The obligation to comply with these Title IX regulations is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for members of one sex than for members of the other sex.

§ 1042.135 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each recipient shall designate at least one employee to coordinate its efforts to comply with and carryout its responsibilities under these Title IX regulations, including any investigation of any complaint communicated to such recipient alleging its noncompliance with these Title IX regulations or alleging any actions that would be prohibited by these Title IX regulations. The recipient shall notify all its students and employees of the name, office address, and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of recipient.* A recipient shall adopt and publish grievance procedures providing for prompt and equitable resolution of student and employee complaints alleging any action that would be prohibited by these Title IX regulations.

§ 1042.140 Dissemination of policy.

(a) *Notification of policy.* (1) Each recipient shall implement specific and continuing steps to notify applicants for admission and employment, students and parents of elementary and secondary school students, employees, sources of referral of applicants for admission and employment, and all unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of sex in the educational programs or activities that it operates, and that it is required by Title IX and these Title IX regulations not to discriminate in such a manner. Such notification shall contain such information, and be made in such manner, as the designated agency official finds necessary to apprise such persons of the protections against discrimination assured them by Title IX and these Title IX regulations, but shall state at least that the requirement not to discriminate in education programs or activities extends to employment therein, and to admission thereto unless §§ 1042.300 through 1042.310 do not apply to the recipient, and that inquiries concerning the application of Title IX and these Title IX regulations to such recipient may be referred to the employee designated pursuant to § 1042.135, or to the designated agency official.

(2) Each recipient shall make the initial notification required by paragraph (a)(1) of this section within 90 days of February 20, 2001 or of the date these Title IX regulations first apply to such recipient, whichever comes later, which notification shall include publication in:

(i) Newspapers and magazines operated by such recipient or by student, alumnae, or alumni groups for or in connection with such recipient; and

(ii) Memoranda or other written communications distributed to every student and employee of such recipient.

(b) *Publications.* (1) Each recipient shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalog, or application form that it makes available to any person of a type, described in paragraph (a) of this section, or which is otherwise used in connection with the recruitment of students or employees.

(2) A recipient shall not use or distribute a publication of the type described in paragraph (b)(1) of this section that suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by these Title IX regulations.

(c) *Distribution.* Each recipient shall distribute without discrimination on the basis of sex each publication described in paragraph (b)(1) of this section, and shall apprise each of its admission and employment recruitment representatives of the policy of nondiscrimination described in paragraph (a) of this section, and shall require such representatives to adhere to such policy.

Subpart B—Coverage

§ 1042.200 Application.

Except as provided in §§ 1042.205 through 1042.235(a), these Title IX regulations apply to every recipient and to each education program or activity operated by such recipient that receives Federal financial assistance.

§ 1042.205 Educational institutions and other entities controlled by religious organizations.

(a) *Exemption.* These Title IX regulations do not apply to any operation of an educational institution or other entity that is controlled by a religious organization to the extent that application of these Title IX regulations would not be consistent with the religious tenets of such organization.

(b) *Exemption claims.* An educational institution or other entity that wishes to claim the exemption set forth in paragraph (a) of this section shall do so by submitting in writing to the designated agency official a statement by the highest-ranking official of the institution, identifying the provisions of these Title IX regulations that conflict with a specific tenet of the religious organization.

§ 1042.210 Military and merchant marine educational institutions.

These Title IX regulations do not apply to an educational institution whose primary purpose is the training of individuals for a military service of the United States or for the merchant marine.

§ 1042.215 Membership practices of certain organizations.

(a) *Social fraternities and sororities.* These Title IX regulations do not apply to the membership practices of social fraternities and sororities that are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, 26 U.S.C. 501(a), the active membership of which consists primarily of students in attendance at institutions of higher education.

(b) *YMCA, YWCA, Girl Scouts, Boy Scouts, and Camp Fire Girls.* These Title IX regulations do not apply to the membership practices of the Young Men's Christian Association (YMCA), the Young Women's Christian Association (YWCA), the Girl Scouts, the Boy Scouts, and Camp Fire Girls.

(c) *Voluntary youth service organizations.* These Title IX regulations do not apply to the membership practices of a voluntary youth service organization that is exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, 26 U.S.C. 501(a), and the membership of which has been traditionally limited to members of one sex and principally to persons of less than nineteen years of age.

§ 1042.220 Admissions.

(a) Admissions to educational institutions prior to June 24, 1973, are not covered by these Title IX regulations.

(b) *Administratively separate units.* For the purposes only of this section, §§ 1042.225 and 1042.230, and §§ 1042.300 through 1042.310, each administratively separate unit shall be deemed to be an educational institution.

(c) *Application of §§ 1042.300 through 1042.310.* Except as provided in paragraphs (d) and (e) of this section, §§ 1042.300 through 1042.310 apply to each recipient. A recipient to which §§ 1042.300 through 1042.310 apply shall not discriminate on the basis of sex in admission or recruitment in violation of §§ 1042.300 through 1042.310.

(d) *Educational institutions.* Except as provided in paragraph (e) of this section as to recipients that are educational institutions, §§ 1042.300 through 1042.310 apply only to institutions of vocational education, professional education, graduate higher education, and public institutions of undergraduate higher education.

(e) *Public institutions of undergraduate higher education.* §§ 1042.300 through 1042.310 do not apply to any public institution of undergraduate higher education that traditionally and continually from its establishment has had a policy of admitting students of only one sex.

§ 1042.225 Educational institutions eligible to submit transition plans.

(a) *Application.* This section applies to each educational institution to which §§ 1042.300 through 1042.310 apply that:

(1) Admitted students of only one sex as regular students as of June 23, 1972; or

(2) Admitted students of only one sex as regular students as of June 23, 1965, but thereafter admitted, as regular students, students of the sex not admitted prior to June 23, 1965.

(b) *Provision for transition plans.* An educational institution to which this section applies shall not discriminate on the basis of sex in admission or recruitment in violation of §§ 1042.300 through 1042.310.

§ 1042.230 Transition plans.

(a) *Submission of plans.* An institution to which § 1042.225 applies and that is composed of more than one administratively separate unit may submit either a single transition plan applicable to all such units, or a separate transition plan applicable to each such unit.

(b) *Content of plans.* In order to be approved by the Secretary of Education, a transition plan shall:

(1) State the name, address, and Federal Interagency Committee on Education Code of the educational institution submitting such plan, the administratively separate units to which the plan is applicable, and the name, address, and telephone number of the person to whom questions concerning the plan may be addressed. The person who submits the plan shall be the chief administrator or president of the institution, or another individual legally authorized to bind the institution to all actions set forth in the plan.

(2) State whether the educational institution or administratively separate unit admits students of both sexes as regular students and, if so, when it began to do so.

(3) Identify and describe with respect to the educational institution or administratively separate unit any obstacles to admitting students without discrimination on the basis of sex.

(4) Describe in detail the steps necessary to eliminate as soon as practicable each obstacle so identified and indicate the schedule for taking these steps and the individual directly responsible for their implementation.

(5) Include estimates of the number of students, by sex, expected to apply for, be admitted to, and enter each class during the period covered by the plan.

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(c) *Nondiscrimination.* No policy or practice of a recipient to which § 1042.225 applies shall result in treatment of applicants to or students of such recipient in violation of §§ 1042.300 through 1042.310 unless such treatment is necessitated by an obstacle identified in paragraph (b)(3) of this section and a schedule for eliminating that obstacle has been provided as required by paragraph (b)(4) of this section.

(d) *Effects of past exclusion.* To overcome the effects of past exclusion of students on the basis of sex, each educational institution to which § 1042.225 applies shall include in its transition plan, and shall implement, specific steps designed to encourage individuals of the previously excluded sex to apply for admission to such institution. Such steps shall include instituting recruitment programs that emphasize the institution's commitment to enrolling students of the sex previously excluded.

§ 1042.235 Statutory amendments.

(a) This section, which applies to all provisions of these Title IX regulations, addresses statutory amendments to Title IX.

(b) These Title IX regulations shall not apply to or preclude:

(1) Any program or activity of the American Legion undertaken in connection with the organization or operation of any Boys State conference, Boys Nation conference, Girls State conference, or Girls Nation conference;

(2) Any program or activity of a secondary school or educational institution specifically for:

(i) The promotion of any Boys State conference, Boys Nation conference, Girls State conference, or Girls Nation conference; or

(ii) The selection of students to attend any such conference;

(3) Father-son or mother-daughter activities at an educational institution or in an education program or activity, but if such activities are provided for students of one sex, opportunities for reasonably comparable activities shall be provided to students of the other sex;

(4) Any scholarship or other financial assistance awarded by an institution of higher education to an individual because such individual has received such award in a single-sex pageant based upon a combination of factors related to the individual's personal appearance, poise, and talent. The pageant, however, must comply with other nondiscrimination provisions of Federal law.

(c) *Program or activity* or *program* means:

(1) All of the operations of any entity described in paragraphs (c)(1)(i) through (iv) of this section, any part of which is extended Federal financial assistance:

(i)(A) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(B) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(ii)(A) A college, university, or other post-secondary institution, or a public system of higher education; or

(B) A local educational agency (as defined in section 8801 of title 20), system of vocational education, or other school system;

(iii)(A) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(*1*) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(*2*) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(B) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(iv) Any other entity that is established by two or more of the entities described in paragraphs (c)(1)(i), (ii), or (iii) of this section.

(2)(i) *Program or activity* does not include any operation of an entity that is controlled by a religious organization if the application of 20 U.S.C. 1681 to such operation would not be consistent with the religious tenets of such organization.

(ii) For example, all of the operations of a college, university, or other post-secondary institution, including but not limited to traditional educational operations, faculty and student housing, campus shuttle bus service, campus restaurants, the bookstore, and other commercial activities are part of a "program or activity" subject to these Title IX regulations if the college, university, or other institution receives Federal financial assistance.

(d)(1) Nothing in these Title IX regulations shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Medical procedures, benefits, services, and the use of facilities, necessary to save the life of a pregnant woman or to address complications related to an abortion are not subject to this section.

(2) Nothing in this section shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion. Accordingly, subject to paragraph (d)(1) of this section, no person shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, employment, or other educational program or activity operated by a recipient that receives Federal financial assistance because such individual has sought or received, or is seeking, a legal abortion, or any benefit or service related to a legal abortion.

Subpart C—Discrimination on the Basis of Sex in Admission and Recruitment Prohibited

§ 1042.300 Admission.

(a) *General.* No person shall, on the basis of sex, be denied admission, or be subjected to discrimination in admission, by any recipient to which §§ 1042.300 through 1042.310 apply, except as provided in §§ 1042.225 and 1042.230.

(b) *Specific prohibitions.* (1) In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which §§ 1042.300 through 1042.310 apply shall not:

(i) Give preference to one person over another on the basis of sex, by ranking applicants separately on such basis, or otherwise;

(ii) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(iii) Otherwise treat one individual differently from another on the basis of sex.

(2) A recipient shall not administer or operate any test or other criterion for admission that has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown to predict validly success in the education program or activity in question and alternative tests or criteria that do not have such a disproportionately adverse effect are shown to be unavailable.

(c) *Prohibitions relating to marital or parental status.* In determining whether

a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which §§ 1042.300 through 1042.310 apply:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant that treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy, or recovery therefrom, or establish or follow any rule or practice that so discriminates or excludes;

(3) Subject to § 1042.235(d), shall treat disabilities related to pregnancy, childbirth, termination of pregnancy, or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is "Miss" or "Mrs." A recipient may make pre-admission inquiry as to the sex of an applicant for admission, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by these Title IX regulations.

§ 1042.305 Preference in admission.

A recipient to which §§ 1042.300 through 1042.310 apply shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity that admits as students only or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of §§ 1042.300 through 1042.310.

§ 1042.310 Recruitment.

(a) *Nondiscriminatory recruitment.* A recipient to which §§ 1042.300 through 1042.310 apply shall not discriminate on the basis of sex in the recruitment and admission of students. A recipient may be required to undertake additional recruitment efforts for one sex as remedial action pursuant to § 1042.110(a), and may choose to undertake such efforts as affirmative action pursuant to § 1042.110(b).

(b) *Recruitment at certain institutions.* A recipient to which §§ 1042.300 through 1042.310 apply shall not recruit primarily or exclusively at educational institutions, schools, or entities that admit as students only or predominantly members of one sex, if such actions have the effect of discriminating on the basis of sex in violation of §§ 1042.300 through 1042.310.

Subpart D—Discrimination on the Basis of Sex in Education Programs or Activities Prohibited

§ 1042.400 Education programs or activities.

(a) *General.* Except as provided elsewhere in these Title IX regulations, no person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other education program or activity operated by a recipient that receives Federal financial assistance. Sections 1042.400 through 1042.455 do not apply to actions of a recipient in connection with admission of its students to an education program or activity of a recipient to which §§ 1042.300 through 1042.310 do not apply, or an entity, not a recipient, to which §§ 1042.300 through 1042.310 would not apply if the entity were a recipient.

(b) *Specific prohibitions.* Except as provided in §§ 1042.400 through 1042.455, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-state fees and tuition;

(6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person that discriminates on the basis of sex in providing any aid, benefit, or service to students or employees;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

(c) *Assistance administered by a recipient educational institution to study at a foreign institution.* A recipient educational institution may administer or assist in the administration of scholarships, fellowships, or other awards established by foreign or domestic wills, trusts, or similar legal instruments, or by acts of foreign governments and restricted to members of one sex, that are designed to provide opportunities to study abroad, and that are awarded to students who are already matriculating at or who are graduates of the recipient institution; *Provided,* that a recipient educational institution that administers or assists in the administration of such scholarships, fellowships, or other awards that are restricted to members of one sex provides, or otherwise makes available, reasonable opportunities for similar studies for members of the other sex. Such opportunities may be derived from either domestic or foreign sources.

(d) *Aids, benefits or services not provided by recipient.* (1) This paragraph (d) applies to any recipient that requires participation by any applicant, student, or employee in any education program or activity not operated wholly by such recipient, or that facilitates, permits, or considers such participation as part of or equivalent to an education program or activity operated by such recipient, including participation in educational consortia and cooperative employment and student-teaching assignments.

(2) Such recipient:

(i) Shall develop and implement a procedure designed to assure itself that the operator or sponsor of such other education program or activity takes no action affecting any applicant, student, or employee of such recipient that these Title IX regulations would prohibit such recipient from taking; and

(ii) Shall not facilitate, require, permit, or consider such participation if such action occurs.

§ 1042.405 Housing.

(a) *Generally.* A recipient shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this section (including housing provided only to married students).

(b) *Housing provided by recipient.* (1) A recipient may provide separate housing on the basis of sex.

(2) Housing provided by a recipient to students of one sex, when compared to that provided to students of the other sex, shall be as a whole:

(i) Proportionate in quantity to the number of students of that sex applying for such housing; and

(ii) Comparable in quality and cost to the student.

(c) *Other housing.* (1) A recipient shall not, on the basis of sex, administer different policies or practices concerning occupancy by its students of

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housing other than that provided by such recipient.

(2)(i) A recipient which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take such reasonable action as may be necessary to assure itself that such housing as is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole:

(A) Proportionate in quantity; and

(B) Comparable in quality and cost to the student.

(ii) A recipient may render such assistance to any agency, organization, or person that provides all or part of such housing to students of only one sex.

§ 1042.410 Comparable facilities.

A recipient may provide separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex.

§ 1042.415 Access to course offerings.

(a) A recipient shall not provide any course or otherwise carry out any of its education program or activity separately on the basis of sex, or require or refuse participation therein by any of its students on such basis, including health, physical education, industrial, business, vocational, technical, home economics, music, and adult education courses.

(b)(1) With respect to classes and activities in physical education at the elementary school level, the recipient shall comply fully with this section as expeditiously as possible but in no event later than one year from February 20, 2001. With respect to physical education classes and activities at the secondary and post-secondary levels, the recipient shall comply fully with this section as expeditiously as possible but in no event later than three years from February 20, 2001.

(2) This section does not prohibit grouping of students in physical education classes and activities by ability as assessed by objective standards of individual performance developed and applied without regard to sex.

(3) This section does not prohibit separation of students by sex within physical education classes or activities during participation in wrestling, boxing, rugby, ice hockey, football, basketball, and other sports the purpose or major activity of which involves bodily contact.

(4) Where use of a single standard of measuring skill or progress in a physical education class has an adverse effect on members of one sex, the recipient shall use appropriate standards that do not have such effect.

(5) Portions of classes in elementary and secondary schools, or portions of education programs or activities, that deal exclusively with human sexuality may be conducted in separate sessions for boys and girls.

(6) Recipients may make requirements based on vocal range or quality that may result in a chorus or choruses of one or predominantly one sex.

§ 1042.420 Access to schools operated by LEAs.

A recipient that is a local educational agency shall not, on the basis of sex, exclude any person from admission to:

(a) Any institution of vocational education operated by such recipient; or

(b) Any other school or educational unit operated by such recipient, unless such recipient otherwise makes available to such person, pursuant to the same policies and criteria of admission, courses, services, and facilities comparable to each course, service, and facility offered in or through such schools.

§ 1042.425 Counseling and use of appraisal and counseling materials.

(a) *Counseling.* A recipient shall not discriminate against any person on the basis of sex in the counseling or guidance of students or applicants for admission.

(b) *Use of appraisal and counseling materials.* A recipient that uses testing or other materials for appraising or counseling students shall not use different materials for students on the basis of their sex or use materials that permit or require different treatment of students on such basis unless such different materials cover the same occupations and interest areas and the use of such different materials is shown to be essential to eliminate sex bias. Recipients shall develop and use internal procedures for ensuring that such materials do not discriminate on the basis of sex. Where the use of a counseling test or other instrument results in a substantially disproportionate number of members of one sex in any particular course of study or classification, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination in the instrument or its application.

(c) *Disproportion in classes.* Where a recipient finds that a particular class contains a substantially disproportionate number of individuals of one sex, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination on the basis of sex in counseling or appraisal materials or by counselors.

§ 1042.430 Financial assistance.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in providing financial assistance to any of its students, a recipient shall not:

(1) On the basis of sex, provide different amounts or types of such assistance, limit eligibility for such assistance that is of any particular type or source, apply different criteria, or otherwise discriminate;

(2) Through solicitation, listing, approval, provision of facilities, or other services, assist any foundation, trust, agency, organization, or person that provides assistance to any of such recipient's students in a manner that discriminates on the basis of sex; or

(3) Apply any rule or assist in application of any rule concerning eligibility for such assistance that treats persons of one sex differently from persons of the other sex with regard to marital or parental status.

(b) *Financial aid established by certain legal instruments.* (1) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government that require that awards be made to members of a particular sex specified therein; *Provided*, that the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(2) To ensure nondiscriminatory awards of assistance as required in paragraph (b)(1) of this section, recipients shall develop and use procedures under which:

(i) Students are selected for award of financial assistance on the basis of nondiscriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(ii) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to each student selected under paragraph (b)(2)(i) of this section; and

(iii) No student is denied the award for which he or she was selected under paragraph (b)(2)(i) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(c) *Athletic scholarships.* (1) To the extent that a recipient awards athletic scholarships or grants-in-aid, it must provide reasonable opportunities for such awards for members of each sex in proportion to the number of students of each sex participating in interscholastic or intercollegiate athletics.

(2) A recipient may provide separate athletic scholarships or grants-in-aid for members of each sex as part of separate athletic teams for members of each sex to the extent consistent with this paragraph (c) and § 1042.450.

§ 1042.435 Employment assistance to students.

(a) *Assistance by recipient in making available outside employment.* A recipient that assists any agency, organization, or person in making employment available to any of its students:

(1) Shall assure itself that such employment is made available without discrimination on the basis of sex; and

(2) Shall not render such services to any agency, organization, or person that discriminates on the basis of sex in its employment practices.

(b) *Employment of students by recipients.* A recipient that employs any of its students shall not do so in a manner that violates §§ 1042.500 through 1042.550.

§ 1042.440 Health and insurance benefits and services.

Subject to § 1042.235(d), in providing a medical, hospital, accident, or life insurance benefit, service, policy, or plan to any of its students, a recipient shall not discriminate on the basis of sex, or provide such benefit, service, policy, or plan in a manner that would violate §§ 1042.500 through 1042.550 if it were provided to employees of the recipient. This section shall not prohibit a recipient from providing any benefit or service that may be used by a different proportion of students of one sex than of the other, including family planning services. However, any recipient that provides full coverage health service shall provide gynecological care.

§ 1042.445 Marital or parental status.

(a) *Status generally.* A recipient shall not apply any rule concerning a student's actual or potential parental, family, or marital status that treats students differently on the basis of sex.

(b) *Pregnancy and related conditions.* (1) A recipient shall not discriminate against any student, or exclude any student from its education program or activity, including any class or extracurricular activity, on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom, unless the student requests voluntarily to participate in a separate portion of the program or activity of the recipient.

(2) A recipient may require such a student to obtain the certification of a physician that the student is physically and emotionally able to continue participation as long as such a certification is required of all students for other physical or emotional conditions requiring the attention of a physician.

(3) A recipient that operates a portion of its education program or activity separately for pregnant students, admittance to which is completely voluntary on the part of the student as provided in paragraph (b)(1) of this section, shall ensure that the separate portion is comparable to that offered to non-pregnant students.

(4) Subject to § 1042.235(d), a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan, or policy that such recipient administers, operates, offers, or participates in with respect to students admitted to the recipient's educational program or activity.

(5) In the case of a recipient that does not maintain a leave policy for its students, or in the case of a student who does not otherwise qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom as a justification for a leave of absence for as long a period of time as is deemed medically necessary by the student's physician, at the conclusion of which the student shall be reinstated to the status that she held when the leave began.

§ 1042.450 Athletics.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person, or otherwise be discriminated against in any interscholastic, intercollegiate, club, or intramural athletics offered by a recipient, and no recipient shall provide any such athletics separately on such basis.

(b) *Separate teams.* Notwithstanding the requirements of paragraph (a) of this section, a recipient may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport. However, where a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the other sex, and athletic opportunities for members of that sex have previously been limited, members of the excluded sex must be allowed to try out for the team offered unless the sport involved is a contact sport. For the purposes of these Title IX regulations, contact sports include boxing, wrestling, rugby, ice hockey, football, basketball, and other sports the purpose or major activity of which involves bodily contact.

(c) *Equal opportunity.* (1) A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural athletics shall provide equal athletic opportunity for members of both sexes. In determining whether equal opportunities are available, the designated agency official will consider, among other factors:

(i) Whether the selection of sports and levels of competition effectively accommodate the interests and abilities of members of both sexes;

(ii) The provision of equipment and supplies;

(iii) Scheduling of games and practice time;

(iv) Travel and per diem allowance;

(v) Opportunity to receive coaching and academic tutoring;

(vi) Assignment and compensation of coaches and tutors;

(vii) Provision of locker rooms, practice, and competitive facilities;

(viii) Provision of medical and training facilities and services;

(ix) Provision of housing and dining facilities and services;

(x) Publicity.

(2) For purposes of paragraph (c)(1) of this section, unequal aggregate expenditures for members of each sex or unequal expenditures for male and female teams if a recipient operates or sponsors separate teams will not constitute noncompliance with this section, but the designated agency official may consider the failure to provide necessary funds for teams for one sex in assessing equality of opportunity for members of each sex.

(d) *Adjustment period.* A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural athletics at the elementary school level shall comply fully with this section as expeditiously as possible but in no event later than one year from February 20, 2001. A recipient that operates or sponsors interscholastic, intercollegiate, club, or intramural

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athletics at the secondary or post-secondary school level shall comply fully with this section as expeditiously as possible but in no event later than three years from February 20, 2001.

§ 1042.455 Textbooks and curricular material.

Nothing in these Title IX regulations shall be interpreted as requiring or prohibiting or abridging in any way the use of particular textbooks or curricular materials.

Subpart E—Discrimination on the Basis of Sex in Employment in Education Programs or Activities Prohibited

§ 1042.500 Employment.

(a) *General.* (1) No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination in employment, or recruitment, consideration, or selection therefor, whether full-time or part-time, under any education program or activity operated by a recipient that receives Federal financial assistance.

(2) A recipient shall make all employment decisions in any education program or activity operated by such recipient in a nondiscriminatory manner and shall not limit, segregate, or classify applicants or employees in any way that could adversely affect any applicant's or employee's employment opportunities or status because of sex.

(3) A recipient shall not enter into any contractual or other relationship which directly or indirectly has the effect of subjecting employees or students to discrimination prohibited by §§ 1042.500 through 1042.550, including relationships with employment and referral agencies, with labor unions, and with organizations providing or administering fringe benefits to employees of the recipient.

(4) A recipient shall not grant preferences to applicants for employment on the basis of attendance at any educational institution or entity that admits as students only or predominantly members of one sex, if the giving of such preferences has the effect of discriminating on the basis of sex in violation of these Title IX regulations.

(b) *Application.* The provisions of §§ 1042.500 through 1042.550 apply to:

(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, application of nepotism policies, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications, and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, leave for pregnancy, childbirth, false pregnancy, termination of pregnancy, leave for persons of either sex to care for children or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including social or recreational programs; and

(10) Any other term, condition, or privilege of employment.

§ 1042.505 Employment criteria.

A recipient shall not administer or operate any test or other criterion for any employment opportunity that has a disproportionately adverse effect on persons on the basis of sex unless:

(a) Use of such test or other criterion is shown to predict validly successful performance in the position in question; and

(b) Alternative tests or criteria for such purpose, which do not have such disproportionately adverse effect, are shown to be unavailable.

§ 1042.510 Recruitment.

(a) *Nondiscriminatory recruitment and hiring.* A recipient shall not discriminate on the basis of sex in the recruitment and hiring of employees. Where a recipient has been found to be presently discriminating on the basis of sex in the recruitment or hiring of employees, or has been found to have so discriminated in the past, the recipient shall recruit members of the sex so discriminated against so as to overcome the effects of such past or present discrimination.

(b) *Recruitment patterns.* A recipient shall not recruit primarily or exclusively at entities that furnish as applicants only or predominantly members of one sex if such actions have the effect of discriminating on the basis of sex in violation of §§ 1042.500 through 1042.550.

§ 1042.515 Compensation.

A recipient shall not make or enforce any policy or practice that, on the basis of sex:

(a) Makes distinctions in rates of pay or other compensation;

(b) Results in the payment of wages to employees of one sex at a rate less than that paid to employees of the opposite sex for equal work on jobs the performance of which requires equal skill, effort, and responsibility, and that are performed under similar working conditions.

§ 1042.520 Job classification and structure.

A recipient shall not:

(a) Classify a job as being for males or for females;

(b) Maintain or establish separate lines of progression, seniority lists, career ladders, or tenure systems based on sex; or

(c) Maintain or establish separate lines of progression, seniority systems, career ladders, or tenure systems for similar jobs, position descriptions, or job requirements that classify persons on the basis of sex, unless sex is a bona fide occupational qualification for the positions in question as set forth in § 1042.550.

§ 1042.525 Fringe benefits.

(a) *"Fringe benefits" defined.* For purposes of these Title IX regulations, *fringe benefits* means: Any medical, hospital, accident, life insurance, or retirement benefit, service, policy or plan, any profit-sharing or bonus plan, leave, and any other benefit or service of employment not subject to the provision of § 1042.515.

(b) *Prohibitions.* A recipient shall not:

(1) Discriminate on the basis of sex with regard to making fringe benefits available to employees or make fringe benefits available to spouses, families, or dependents of employees differently upon the basis of the employee's sex;

(2) Administer, operate, offer, or participate in a fringe benefit plan that does not provide for equal periodic benefits for members of each sex and for equal contributions to the plan by such recipient for members of each sex; or

(3) Administer, operate, offer, or participate in a pension or retirement plan that establishes different optional or compulsory retirement ages based on sex or that otherwise discriminates in benefits on the basis of sex.

§ 1042.530 Marital or parental status.

(a) *General.* A recipient shall not apply any policy or take any employment action:

(1) Concerning the potential marital, parental, or family status of an employee or applicant for employment that treats persons differently on the basis of sex; or

(2) Which is based upon whether an employee or applicant for employment is the head of household or principal wage earner in such employee's or applicant's family unit.

(b) *Pregnancy.* A recipient shall not discriminate against or exclude from employment any employee or applicant for employment on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom.

(c) *Pregnancy as a temporary disability.* Subject to § 1042.235(d), a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, recovery therefrom, and any temporary disability resulting therefrom as any other temporary disability for all job-related purposes, including commencement, duration, and extensions of leave, payment of disability income, accrual of seniority and any other benefit or service, and reinstatement, and under any fringe benefit offered to employees by virtue of employment.

(d) *Pregnancy leave.* In the case of a recipient that does not maintain a leave policy for its employees, or in the case of an employee with insufficient leave or accrued employment time to qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom as a justification for a leave of absence without pay for a reasonable period of time, at the conclusion of which the employee shall be reinstated to the status that she held when the leave began or to a comparable position, without decrease in rate of compensation or loss of promotional opportunities, or any other right or privilege of employment.

§ 1042.535 Effect of state or local law or other requirements.

(a) *Prohibitory requirements.* The obligation to comply with §§ 1042.500 through 1042.550 is not obviated or alleviated by the existence of any State or local law or other requirement that imposes prohibitions or limits upon employment of members of one sex that are not imposed upon members of the other sex.

(b) *Benefits.* A recipient that provides any compensation, service, or benefit to members of one sex pursuant to a State or local law or other requirement shall provide the same compensation, service, or benefit to members of the other sex.

§ 1042.540 Advertising.

A recipient shall not in any advertising related to employment indicate preference, limitation, specification, or discrimination based on sex unless sex is a bona fide occupational qualification for the particular job in question.

§ 1042.545 Pre-employment inquiries.

(a) *Marital status.* A recipient shall not make pre-employment inquiry as to the marital status of an applicant for employment, including whether such applicant is "Miss" or "Mrs."

(b) *Sex.* A recipient may make pre-employment inquiry as to the sex of an applicant for employment, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by these Title IX regulations.

§ 1042.550 Sex as a bona fide occupational qualification.

A recipient may take action otherwise prohibited by §§ 1042.500 through 1042.550 provided it is shown that sex is a bona fide occupational qualification for that action, such that consideration of sex with regard to such action is essential to successful operation of the employment function concerned. A recipient shall not take action pursuant to this section that is based upon alleged comparative employment characteristics or stereotyped characterizations of one or the other sex, or upon preference based on sex of the recipient, employees, students, or other persons, but nothing contained in this section shall prevent a recipient from considering an employee's sex in relation to employment in a locker room or toilet facility used only by members of one sex.

Subpart F—Other Provisions

§ 1042.600 Covered programs.

The financial assistance programs to which this part applies are listed in Appendix A to 10 CFR part 1040.

§ 1042.605 Enforcement procedures.

The investigative, compliance, and enforcement procedural provisions of Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and applied to these Title IX regulations. These procedures may be found at 10 CFR part 1040, subparts G and H.

[FR Doc. 01–583 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 1044

[Docket No. SO–RM–00–3164]

RIN 1992–AA26

Office of Security and Emergency Operations; Security Requirements for Protected Disclosures Under Section 3164 of the National Defense Authorization Act for Fiscal Year 2000

AGENCY: Department of Energy.

ACTION: Interim final rule and opportunity for public comment.

SUMMARY: The Department of Energy (DOE) is publishing an interim final rule to prescribe the security procedures that a DOE employee or DOE contractor employee, including an employee or contractor employee of the National Nuclear Security Administration, who is engaged in defense activities must follow to make a protected disclosure of classified or other controlled information under the whistleblower protection provisions in section 3164 of the National Defense Authorization Act for Fiscal Year 2000. Anyone who follows these procedures when making a disclosure of classified or other controlled information may not be discharged, demoted, or otherwise discriminated against as a reprisal for making the disclosure.

EFFECTIVE DATE: The interim final rule is effective February 20, 2001. Interested persons may submit written comments on this interim rule by February 20, 2001. Comments received after this date will be considered to the extent practicable.

ADDRESSES: Written comments (3 copies) should be addressed to: U.S. Department of Energy, Docket No. SO–RM–00–3164, Attn: Richard Farman, Office of General Counsel, GC–74, 1000 Independence Ave., SW., Washington, DC 20585.

All comments received will be available for public inspection as part of the administrative record on file for this rulemaking in the Department of Energy Freedom of Information Office Reading Room, Room 1E–090, Forrestal Building, 1000 Independence Avenue, S.W, Washington, DC 10585, (202) 586–6020, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The docket material for this rulemaking will be filed under Docket No. SO–RM–00–3164.

FOR FURTHER INFORMATION CONTACT: Cathy Tullis, Office of Security and Emergency Operations (SO–211), U.S. Department of Energy, 19901

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Germantown Road, Germantown, MD 20874–1290, (301) 903–4805.

SUPPLEMENTARY INFORMATION:

I. Introduction

Today's notice adds a new Part 1044 to Title 10 of the Code of Federal Regulations to establish security requirements for the disclosure of classified and other controlled information under section 3164 of the National Defense Authorization Act for Fiscal Year 2000 (NDAA for FY 2000) (42 U.S.C. 7239). Section 3164 directs the Secretary of Energy to establish a program to ensure that DOE employees or DOE contractor employees engaged in defense activities may not be discharged, demoted, or otherwise discriminated against as a reprisal for making protected disclosures. The Secretary is required by section 3164(g) to prescribe regulations to ensure the security of any information disclosed under the program (42 U.S.C. 7239(g)). To qualify as a "protected disclosure' of classified or other controlled information, a covered employee must take appropriate steps to protect the security of the information in accordance with guidance provided by the DOE Inspector General, and reveal the information only to a person or entity specified in the statute (42 U.S.C. 7239(c)).

Section 3164(j) of the NDAA for FY 2000 provides that complaints of discriminatory acts taken in reprisal for making a protected disclosure may be submitted to the DOE Office of Hearings and Appeals for investigation (42 U.S.C. 7239(j)). Section 3164(k) directs the Secretary of Energy to take appropriate actions to abate acts of reprisal (42 U.S.C. 7239(k)).

II. Discussion of Rule Provisions

Part 1044 informs DOE and DOE contractor employees engaged in defense activities how to make a protected disclosure of classified and other controlled information. The definitions in section 1044.03 of "classified information" and "contractor" are drawn from 10 CFR Part 1045, "Nuclear Classification and Declassification." The same definitions apply to this rule because of the similar subject matter. DOE defines "defense activities" to cover the range of its defense activities carried out under the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*). The definition of "defense activities" in section 1044.03 is consistent with the definition of "Atomic Energy Defense Programs" in DOE's regulations concerning protection of unclassified controlled nuclear information (see 10 CFR 1017.3). All Departmental-related activities involving classified information and Unclassified Controlled Nuclear Information are considered to be "defense activities" covered by this rule.

The term "unclassified controlled nuclear information" is defined in section 1044.03, and used in conjunction with "classified information" throughout the rule to identify the types of information that are covered by the protected disclosure provisions of section 3164 of the NDAA for FY2000. For reasons that follow, DOE has concluded that unclassified controlled nuclear information under section 148 of the Atomic Energy Act (42 U.S.C. 2168) is the only type of information that falls within the meaning of "other information" in the phrase "classified or other information" used in section 3164(c)(3) to define "protected disclosures."

DOE's interpretation of "other information" in section 3164 is consistent with the apparent intent of Congress to cover the disclosure of controlled information. Under section 3164(g), DOE is required to prescribe regulations to ensure the security of any information disclosed under the statute. Other provisions impose an obligation on a whistleblower to take appropriate steps to protect the security of the information to be disclosed (section 3164(c)(1)), and restrict who may receive a disclosure of classified or other information (section 3164(d)). These provisions would not make sense if "other information" encompassed uncontrolled information. The legislative history also shows that Congress intended to address in section 3164 the disclosure of national security sensitive information. See Conference Report on the National Defense Authorization Act for Fiscal Year 2000, H.R. Conf. Rep. No. 106–301, at p. 920.

Section 1044.06 lists the persons and entities that may receive a protected disclosure (42 U.S.C. 7239(d)). Section 1044.07 provides that the Inspector General will assist the whistleblower by obtaining from the Office of Safeguards and Security a determination whether a particular person has the appropriate security access authorization to receive the classified or other controlled information.

Sections 1044.08 and 1044.09 provide that a person who wishes to make a protected disclosure must submit the information to the Inspector General, who in turn will obtain a determination from the Office of Nuclear and National Security Information on the security classification, if any, of the information. If the information is classified or controlled, section 1044.11 provides that the whistleblower must follow applicable security requirements concerning how to generate, mark, reproduce, store, destroy, and transmit classified and other controlled information. These security requirements derive from Executive Orders, DOE regulations, and current security directives issued by the Office of Safeguards and Security. The Inspector General will provide the whistleblower with guidance on how to comply with these requirements. The individual has a responsibility to obtain assistance and guidance before seeking to make a protected disclosure.

As required by the NDAA for FY 2000, DOE provides in section 1044.09 that the identity of a whistleblower under this program will be protected (42 U.S.C. 7239(f)(3)). Section 1044.12 describes the procedures provided in the statute (42 U.S.C. 7239(i)–(k)) for acting on complaints of alleged discrimination against employees as reprisal for making protected disclosures.

III. Public Comment

The interim final rule published today prescribes security procedures that DOE and DOE contractor employees must follow to make a protected disclosure of classified or other controlled information under section 3164(g) of the NDAA for FY 2000. As a rule of agency procedure, this rulemaking is exempt from the notice and comment requirements in the Administrative Procedure Act, 5 U.S.C. 553. DOE, nevertheless, is providing an opportunity for interested persons to submit written data and views on the interim rule. Interested persons should submit their comments to the address indicated in the ADDRESSES section of this notice. The outside of the envelope and the comments should be labeled as follows: "Protected Disclosure Rulemaking, Docket No. SO–RM–00–3164." If you believe that any information or data you submit may be exempt from public disclosure by law, you should submit one complete copy as well as one copy from which you have deleted the information you believe to be exempt from disclosure. The Department will determine if the information or data is exempt from disclosure.

All comments received will be available for public inspection as part of the administrative record on file for this rulemaking in the Department of Energy Freedom of Information Office Reading Room, Room 1E–090, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–6020, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

IV. Procedural Requirements

A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be "a significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule will not have a "significant economic impact on a substantial number of small entities." Today's interim final rule prescribes the security procedures that a DOE or DOE contractor employee engaged in defense activities must follow when making a protected disclosure of classified or other controlled information under section 3164 of the NDAA for FY 2000. DOE is not required by the Administrative Procedure Act (5 U.S.C. 553) or any other law to propose this rule for public comment. Accordingly, the Regulatory Flexibility Act requirements do not apply to this rulemaking, and no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Act

No additional information or record keeping requirements are imposed by this rulemaking. Accordingly, no OMB clearance is required under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

D. Review Under the National Environmental Policy Act

Today's rule describes the security requirements a DOE or DOE contractor employee engaged in defense activities must follow when making a protected disclosure of classified or other controlled information under section 3164 of the NDAA for FY 2000. Implementation of this rule will not affect whether such information might cause or otherwise be associated with an environmental impact. The Department has, therefore, determined that this rule is covered under the Categorical Exclusion found at paragraph A.6. of Appendix A to Subpart D, 10 CFR Part 1021, which applies to rulemakings that are strictly procedural. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," (61 FR 4729, February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this interim final rule meets the relevant standards of Executive Order 12988.

F. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 10, 1999) requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. DOE published its intergovernmental consultation policy and procedures on March 14, 2000 (65 FR 13735). "Policies that have federalism implications" is defined in the Executive Order to include regulations that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. DOE has examined this interim final rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each federal agency to prepare a written assessment of the effects of any federal mandate in a proposed or final agency rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. The Act also requires a federal agency to develop an effective process to permit timely input by elected officers of State, local, and tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity to timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. DOE's intergovernmental consultation process under the Unfunded Mandates Reform Act of 1995 is described in a statement of policy published by DOE on March 18, 1997 (62 FR 12820). The interim final rule published today does not contain any federal mandate, so these requirements do not apply.

H. Review Under Plain Language Initiative

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. We invite your comments on how to make this rule easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format make the rule easier to understand?
- What else could we do to make the rule easier to understand?

I. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress promulgation of the interim final rule prior to its effective date. The report will state that it has been determined that the rule is not a

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"major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 10 CFR Part 1044

Administrative practice and procedure, Classfied information, Energy, Government contracts, National security information, Security information, Whistleblowing

Issued in Washington, DC, on November 30, 2000.

T.J. Glauthier,

Deputy Secretary.

For the reasons set forth in the preamble, DOE hereby amends Chapter X of title 10 of the Code of Federal Regulations as set forth below:

1. New Part 1044 is added to read as follows:

PART 1044—SECURITY REQUIREMENTS FOR PROTECTED DISCLOSURES UNDER SECTION 3164 OF THE NATIONAL DEFENSE AUTHORIZATION ACT FOR FISCAL YEAR 2000

Sec.

1044.01 What is the purpose of this part?
1044.02 Who must follow the requirements contained in this part?
1044.03 What definitions apply to this part?
1044.04 What is a protected disclosure?
1044.05 What is the effect of a disclosure qualifying as a "protected disclosure"?
1044.06 Who may receive a protected disclosure?
1044.07 How can you find out if a particular person is authorized to receive a protected disclosure?
1044.08 Do you have to submit the documents for classification review before you give them to someone?
1044.09 What do you do if you plan to disclose classified or unclassified controlled nuclear information orally rather than by providing copies of documents?
1044.10 Will your identity be protected?
1044.11 How do you protect the documents and information that you want to disclose?
1044.12 What procedures can you invoke if you believe you have been discharged, demoted, or otherwise discriminated against as a reprisal for making a protected disclosure?

Authority: 42 U.S.C. 7101 et seq., 7239, and 50 U.S.C. 2401 *et seq.*

§ 1044.01 What is the purpose of this part?

This part prescribes the security requirements for making protected disclosures of classified or unclassified controlled nuclear information under the whistleblower protection provisions of section 3164 of the National Defense Authorization Act for Fiscal Year 2000.

§ 1044.02 Who must follow the requirements contained in this part?

The requirements apply to you if you are:

(a) An employee of DOE, including the National Nuclear Security Administration, or one of its contractors;

(b) Engaged in DOE defense activities; and

(c) Wish to make a protected disclosure as described in § 1044.04 of this part.

§ 1044.03 What definitions apply to this part?

The following definitions apply to this subpart:

Atomic Energy Act means the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.

Classified information means:

(1) Information classified as Restricted Data or Formerly Restricted Data under the Atomic Energy Act; or

(2) Information that has been determined pursuant to Executive Order 12958 or prior Executive Orders to require protection against unauthorized disclosure and is marked to indicate its classification status when in document form (also referred to as "National Security Information" in 10 CFR Part 1045 or "defense information" in the Atomic Energy Act).

Contractor means any industrial, educational, commercial or other entity, grantee or licensee at any tier, including an individual, that has executed an agreement with the Federal Government for the purpose of performing under a contract, license or other agreement.

Defense activities means activities of DOE engaged in support of:

(1) The production, testing, sampling, maintenance, repair, modification, assembly, disassembly, utilization, transportation, or retirement of nuclear weapons or components of nuclear weapons;

(2) The production, utilization, or transportation of nuclear material for military applications; or

(3) The safeguarding of activities, equipment, or facilities which support the production of nuclear weapons or nuclear material for nuclear weapons.

DOE means the Department of Energy, including the National Nuclear Security Administration.

Unclassified controlled nuclear information means unclassified government information prohibited from unauthorized dissemination under section 148 of the Atomic Energy Act and DOE implementing regulations in 10 CFR part 1017.

§ 1044.04 What is a protected disclosure?

A protected disclosure is:

(a) A disclosure of classified or unclassified controlled nuclear information that you reasonably believe provides direct and specific evidence of—

(1) A violation of law or Federal regulation;

(2) Gross mismanagement, a gross waste of funds, or an abuse of authority; or

(3) A false statement to Congress on pursuant to an issue of material fact; and

(b) Protected pursuant to the procedures in this part, including the security procedures referenced in § 1044.11; and

(c) Revealed only to a person or organization described in § 1044.06.

§ 1044.05 What is the effect of a disclosure qualifying as a "protected disclosure"?

If a DOE or DOE contractor employee follows the procedures of this part when making a disclosure of classified or unclassified controlled nuclear information, then the employer (DOE or DOE contractor as applicable) may not discharge, demote, or otherwise discriminate against the employee as a reprisal for making the disclosure.

§ 1044.06 Who may receive a protected disclosure?

The following persons or organizations may receive a protected disclosure:

(a) A member of a committee of Congress having primary responsibility for oversight of the department, agency, or element of the Government to which the disclosed information relates;

(b) An employee of Congress who is a staff member of such a committee and has an appropriate security access authorization for the information being disclosed;

(c) The Inspector General of the Department of Energy;

(d) The Federal Bureau of Investigation; or

(e) Any other element of the Government designated by the Secretary of Energy as authorized to receive the information being disclosed.

§ 1044.07 How can you find out if a particular person is authorized to receive a protected disclosure?

You must contact the Department of Energy Inspector General for help in determining whether a particular person is authorized to receive the classified or unclassified controlled nuclear information you wish to disclose. The Inspector General will contact the Office of Safeguards and Security as necessary to determine the security access authorization of the person to receive the protected disclosure.

§ 1044.08 Do you have to submit the documents for classification review before you give them to someone?

Yes, you must submit each document with a classification or control marking and any unmarked document generated in a classified or controlled subject area to the Inspector General. The Inspector General forwards each document to the Office of Nuclear and National Security Information for a determination as to whether the information in the document is properly classified, controlled, or may be released to the public.

§ 1044.09 What do you do if you plan to disclose classified or unclassified controlled nuclear information orally rather than by providing copies of documents?

You must describe in detail to the Inspector General what information you wish to disclose. The Inspector General may require that the information to be disclosed be put in writing in order to ensure the Inspector General obtains and provides accurate advice. The Inspector General will consult with the Office of Nuclear and National Security Information who will provide you with advice, through the Inspector General, as to whether the information is classified or controlled and any steps needed to protect the information.

§ 1044.10 Will your identity be protected?

Yes, both the Inspector General and the Office of Nuclear and National Security Information must protect, consistent with legal requirements, your identity and any information about your disclosure.

§ 1044.11 How do you protect the information that you want to disclose?

To protect classified information and unclassified controlled nuclear information you plan to disclose, you must:

(a) Only disclose the information to personnel who possess the appropriate clearance and need-to-know for the information disclosed as required in 10 CFR part 710, after verifying any special authorizations or accesses, such as Sensitive Compartmented Information, Special Access Program, and Weapon Data information;

(b) Use only equipment (such as computers or typewriters) that is approved for classified processing for the generation of classified documents;

(c) Mark documents as required by 10 CFR part 1045 (classified information), 10 CFR Part 1017 (unclassified controlled nuclear information), or as required by the Office of Nuclear and National Security Information.

(d) Use only approved copiers to reproduce documents;

(e) Store classified documents in facilities approved by the U.S. Government for the storage of classified material;

(f) Use only approved destruction devices to destroy classified documents;

(g) Use only appropriate secure means, such as secure facsimile or secure telephone, to provide classified information orally or electronically when transmitting or communicating that information (e.g. the applicable classified mailing address); and

(h) Follow any additional specific instructions from the Office of Safeguards and Security on how to protect the information.

§ 1044.12 What procedures can you invoke if you believe you have been discharged, demoted, or otherwise discriminated against as a reprisal for making a protected disclosure?

If you believe you have been discriminated against as a reprisal for making a protected disclosure, you may submit a complaint to the Director of the Office of Hearings and Appeals, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585–0107, or you may send your complaint to the Director, Office of Hearings and Appeals, by facsimile to FAX number (202) 426–1415. In your complaint, you should give your reasons for believing that you have been discriminated against as a reprisal for making a protected disclosure, and include any information you think is relevant to your complaint. The Office of Hearings and Appeals will conduct an investigation of your complaint unless the Director determines your complaint is frivolous. The Director will notify you in writing if your complaint is found to be frivolous. If an investigation is conducted, the Director will submit a report of the investigation to you, to the employer named in your complaint, and to the Secretary of Energy, or the Secretary's designee. The Secretary, or the Secretary's designee, will take appropriate action, pursuant to 42 U.S.C. 7239(k), to abate any discriminatory actions taken as reprisal for making a protected disclosure.

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 126

HUBZone Program

AGENCY: Small Business Administration.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations governing the HUBZone Empowerment Contracting Program (HUBZone program). In particular, this rule clarifies the application of the HUBZone program to state and local governments, revises the definition of the term "principal office," eliminates the program eligibility restrictions on allowable affiliations of HUBZone small business concerns, and eases the program eligibility requirements and procurement restrictions concerning qualified HUBZone small business concerns that operate as non-manufacturers.

DATES: This rule is effective on February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Michael McHale, Associate Administrator for the HUBZone Program, (202) 205–6731 or hubzone@sba.gov.

SUPPLEMENTARY INFORMATION: On October 3, 2000, the Small Business Administration (SBA) published in the **Federal Register**, 65 FR 58963, a proposed rule to amend its regulations governing the HUBZone program. The rule proposed to update the list of Federal agencies covered by the HUBZone program and clarify that the program does not apply to contracts awarded by state and local governments. In addition, the rule proposed to amend the definition of the term principal office to accommodate service and construction concerns, and to eliminate the program eligibility restrictions on allowable affiliations of HUBZone small business concerns (SBCs). Finally, the rule proposed to ease the program eligibility requirements and procurement restrictions concerning qualified HUBZone small business concerns that operate as non-manufacturers. The proposed regulatory amendments were intended to improve the efficiency and effectiveness of the program in light of SBA's experience since the effective date of the final regulations implementing the HUBZone Act of 1997, Title VI of the Small Business Reauthorization Act of 1997, Public Law 105–135.

Discussion of Comments on the Proposed Rule

SBA received 22 timely comments concerning the proposed amendments. The vast majority of the comments supported the proposed regulatory amendments and applauded SBA's efforts to improve and clarify the HUBZone regulations. In addition to expressing support for the amendments, a few commenters also recommended some modifications to two of the

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proposed amendments. As discussed below, SBA carefully considered the comments and recommendations in developing this final rule. SBA received a few comments addressing other sections of the HUBZone regulations. Because this final rule does not involve any of those sections, SBA does not discuss those comments here but will consider them for future amendments to the HUBZone regulations.

Four comments addressed SBA's proposal to revise § 126.101, to add three additional Federal agencies to the list of agencies covered by the HUBZone Act and to clarify that the program does not apply to state and local governments. Three of those comments supported those amendments. One of the four commenters, however, pointed out that Section 212 of Public Law 106–113, which extended the HUBZone program to the three Federal agencies that SBA proposed to add to the list, was effective for the fiscal year ending September 30, 2000. That commenter also noted that although the current § 126.101(b) makes clear that after September 30, 2000, the HUBZone program applies to all federal agencies that hire one or more contracting officers, it may be useful to retain the current list of covered agencies under § 126.101(a) because it spells out the program's applicability to HUBZone contracts awarded prior to September 30, 2000. SBA concurs with that recommendation and therefore has retained the original § 126.101(a) without change and has adopted in full a new paragraph (c) to § 126.101, as proposed on October 3, 2000.

The comments concerning the definition of "principle office," were all supportive of the proposed amendment of that definition in § 126.103. Under the proposed definition, "principle office" would continue to be defined as the location where the greatest number of the concern's employees perform their work, except that for concerns whose primary industry is service or construction, the determination of "principal office" would exclude the concern's employees who perform their work at separate job-site locations to fulfill specific contract obligations.

In the preamble to the proposed rule, SBA specifically requested public comments on the proposed employee exclusion provision for the construction and service industries. Responding commenters strongly supported that exclusion for firms engaged in the construction and service industries. They agreed that the current definition of "principal office" is appropriate for manufacturing concerns, because such firms tend to operate with fixed plant, equipment and personnel tied to one location, but that it did not make sense for service or construction industries. Accordingly, this final rule adopts the definition of "principal office" as proposed.

With one notable exception, commenters likewise endorsed the proposed amendment of § 126.204, to eliminate the current restriction on allowable affiliations of HUBZone SBCs to other qualified HUBZone SBCs, 8(a) Business Development program participants and women-owned small businesses. The one objecting commenter expressed concern that the proposed change would make it easier for large businesses to set up "store-front" affiliates to abuse the program. SBA disagrees. The proposed amendment to § 126.204 makes clear that the size of the HUBZone SBCs when combined with the size of all its affiliates must qualify as small under part 121 of title 13 of the Code of Federal Regulations. That requirement safeguards against possible abuse by large businesses in that regard.

Although supporting the proposed elimination of the existing restrictions on allowable affiliations, another commenter recommended that SBA relax the requirements of § 126.204 further by revising the directive for aggregating the size of the HUBZone SBC and its affiliates. That commenter suggested that SBA should only aggregate the "business activity resulting from" the affiliation. SBA declines to accept that recommendation. Given the broad definition of affiliation under § 121.103 of title 13 of the Code of Federal Regulations, it is not feasible to aggregate only the "business activity resulting from" the affiliation. Further, combining the size of a HUBZone concern with all its affiliates is consistent with governing size regulations under part 121, and does not impose undue burden on otherwise qualified HUBZone SBCs. SBA believes that a finding of affiliation should have the same consequences in each of SBA's programs. In other words, a finding of affiliation causes SBA to aggregate all of the receipts or employees of each of the affiliates. SBA does not look only at certain types of receipts of a firm's affiliates, but rather, combines all receipts of an affiliate from whatever source. SBA believes that that general rule is equally applicable to the HUBZone program. Consequently, the requirement for aggregating the size of a HUBZone SBC and all its affiliates is retained in this final rule.

Finally, SBA received several comments which were supportive of the proposed amendment to § 126.206 to eliminate the eligibility requirement that a non-manufacturer demonstrate that it can provide products manufactured by a qualified HUBZone SBC, and the proposed amendment to § 126.601(d) to allow qualified HUBZone SBCs that are non-manufacturers to supply the product of any business for HUBZone contracts at or below $25,000 in total value. Three of those commenters, however, requested that SBA adopt a higher maximum threshold of as high as $100,000 and $250,000. SBA does not believe that an increase in the proposed $25,000 threshold is justified at this time, since it would unfairly impact qualified HUBZone SBCs that are manufacturers. The $25,000 threshold also parallels the regulatory scheme of the Federal Acquisition Regulation, 48 CFR 19.502–2(c), which permits small businesses in small business set-asides where the anticipated cost of the procurement will not exceed $25,000, to provide the product or products of any domestic firm.

As suggested by one commenter, the final rule makes one clarification to the provisions regarding HUBZone non-manufacturers. In both § 126.206 and § 126.601(d), the final rule specifically references 13 CFR 121.406(b)(1)(i) and (ii), as the applicable definition of non-manufacturer. Other than that clarification, this final rule adopts without change the proposed amendments pertaining to HUBZone non-manufacturers.

Application of the Final Rule

As indicated above, this rule is effective thirty days from the date of publication. To ensure that applicants to and participants in the HUBZone program are subject to the same regulatory requirements, this final rule applies to all HUBZone applications submitted on or after the effective date of this rule, to all pending HUBZone applications, and to all currently certified HUBZone SBCs.

Compliance With Executive Orders 12866, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–602)

The Office of Management and Budget (OMB) reviewed this final rule as a "significant" regulatory action under Executive Order 12866.

For purposes of Executive Order 12988, SBA has drafted this rule, to the extent practicable, in accordance with the standards set forth in section 3 of that Order.

For purposes of Executive Order 13132, SBA has determined that this final rule has no federalism implications warranting the preparation of a Federalism Assessment.

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this rule does not impose new reporting or recordkeeping requirements.

SBA has determined that this final rule may have a significant beneficial economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (RFA), 5 U.S.C. § 601, *et seq.* This rule involves revising the definition of "principal office" and eliminating certain requirements governing the allowable affiliations of qualified HUBZone SBCs and SBCs that operate as non-manufacturers. The rule will affect a large percentage of the over 30,000 SBCs that SBA believes are now eligible or will become eligible for certification as qualified HUBZone SBCs over the life of the program.

Pursuant to the requirements of the RFA, SBA prepared an Initial Regulatory Flexibility Analysis (IRFA), fully discussing the economic impact of the amendments on small entities. SBA submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. No comments were submitted in response to the IRFA. Since this final rule implements the amendments without significant substantive change, this final rule does not change the nature of the economic impact of the amendments on small entities, nor alter the basis of SBA's IRFA. Accordingly, this Final Regulatory Flexibility Analysis incorporates by reference the entire IRFA. A copy of the Final Regulatory Flexibility Analysis and IRFA may be obtained by contacting the Chief Counsel for Advocacy of the Small Business Administration, (202) 205–6533.

The amendments that are the subject of this rule will affect primarily those SBCs that participate in Federal procurements, that have affiliates, or that are non-manufacturers. The amendments will make it easier for qualified SBCs to participate in the program because it provides a definition of "principal office" that accommodates the fluid nature of the construction and service industries and it allows qualified HUBZone SBCs to have any affiliates provided that they, together with their affiliates, do not exceed their applicable size standard under part 121 of title 13 of the Code of Federal Regulations. This final rule also will facilitate the certification of qualified HUBZone SBCs and open the door to more HUBZone contracts by eliminating the eligibility requirement that non-manufacturers must demonstrate that they can supply the goods of a qualified SBC as a prerequisite for program certification, and by exempting non-manufacturers from making that showing when submitting offers to supply goods for HUBZone contracts with a total value of $25,000 or less.

In addition, this final rule does not duplicate, overlap or conflict with relevant Federal regulations. SBA reviewed several alternatives to the amendments implemented by this rule and believes that the amendments are in the best interest of SBCs and the HUBZone Program.

(Catalog of Federal Domestic Assistance Programs, No. 59,009)

List of Subjects in 13 CFR Part 126

Administrative practice and procedure, Government procurement, Reporting and recordkeeping requirements, Small businesses.

Accordingly, for the reasons set forth above, SBA amends 13 CFR part 126, as follows:

PART 126—HUBZONE PROGRAM [AMENDED]

1. Revise the authority citation for 13 CFR part 126 to read as follows:

Authority: 15 U.S.C. 632(a); Pub. L. 105–135 sec. 601 *et seq.*, 111 Stat. 2592.

2. Amend § 126.101 by adding a new paragraph (c) to read as follows:

§ 126.101 Which government departments or agencies are affected directly by the HUBZone program?

* * * * *

(c) The HUBZone program does not apply to contracts awarded by state and local governments. However, state and local governments may use the List of qualified HUBZone SBCs to identify qualified HUBZone SBCs for similar programs authorized under state or local law.

3. Amend § 126.103 to revise the definition of "principal office" to read as follows:

§ 126.103 What definitions are important in the HUBZone program?

* * * * *

Principal office means the location where the greatest number of the concern's employees at any one location perform their work. However, for those concerns whose "primary industry" (see 13 CFR 121.107) is service or construction (see 13 CFR 121.201), the determination of principal office excludes the concern's employees who perform the majority of their work at job-site locations to fulfill specific contract obligations.

* * * * *

4. Revise § 126.204 to read as follows:

§ 126.204 May a qualified HUBZone SBC have affiliates?

A concern may have affiliates provided that the aggregate size of the concern and all its affiliates is small as defined in part 121 of this title.

5. Revise § 126.206 to read as follows:

§ 126.206 May non-manufacturers be certified as qualified HUBZone SBCs?

Non-manufacturers (referred to in the HUBZone Act of 1997 as "regular dealers") may be certified as qualified HUBZone SBCs if they meet all of the requirements set forth in § 126.200. For purposes of this part, a "non-manufacturer" is defined in § 121.406(b)(1)(i) and (ii) of this title.

6. Amend § 126.601 by revising paragraph (d) to read as follows:

§ 126.601 What additional requirements must a qualified HUBZone SBC meet to bid on a contract?

* * * * *

(d) A qualified HUBZone SBC which is a non-manufacturer may submit an offer on a HUBZone contract for supplies if it meets the requirements of the non-manufacturer rule set forth at § 121.406(b)(1)(i) and (ii) of this title, and if the small manufacturer providing the end item for the contract is also a qualified HUBZone SBC. However, for HUBZone contracts at or below $25,000 in total value, a qualified HUBZone SBC may supply the end item of any manufacturer, including a large business.

Dated: January 10, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1543 Filed 1–17–01; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–CE–57–AD; Amendment 39–12073; AD 2001–01–03]

RIN 2120–AA64

Airworthiness Directives; British Aerospace HP137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

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ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to all British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. This AD requires you to remove the nose landing gear steering actuator and install one that incorporates a modified piston rod. This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for the United Kingdom. The actions specified by this AD are intended to prevent failure of the nose landing gear steering actuator because of problems with the current design piston rod. Continued operation with the current design piston rod could result in loss of nose wheel steering and possible loss of control of the airplane during takeoff, landing, and taxi operations.

DATES: This AD becomes effective on February 24, 2001.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of February 24, 2001.

ADDRESSES: You may get the service information referenced in this AD from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 479888; facsimile: (01292) 479703. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–CE–57–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified FAA that an unsafe condition may exist on all British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. The CAA reports three occurrences of nose landing gear failure in the area of the undercut on the base of the eye and thread on the steering actuator. The CAA reports cracks in this area on 10 additional nose landing gear units.

Investigation of these occurrences reveals incorrect installation or insufficient lubrication at the steering actuator trunnions. This then causes bending loads in the steering actuator piston rod during operation.

What are the consequences if the condition is not corrected? Cracks in or failure of the steering actuator piston rod could result in loss of nose wheel steering and possible loss of control of the airplane during takeoff, landing, and taxi operations.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to all British Aerospace HP137 Mk1, Jetstream series 200, and Jetstream Models 3101 and 3201 airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on October 24, 2000 (65 FR 63551). The NPRM proposed to require you to remove the nose landing gear steering actuator and install one that incorporates a modified piston rod.

Was the public invited to comment? Interested persons were afforded an opportunity to participate in the making of this amendment. We have given due consideration to the comments received.

Comment Disposition

What is the Commenters' Concern? Several commenters express concern over the compliance time that FAA established. In particular, the comments are:

—200 hours time-in-service (TIS) is unrealistic for the installation because parts would not be available and many of the affected aircraft would be unjustly grounded; and

—since CAA and British Aerospace recommend 3,000 landings since May 5, 2000, FAA should adopt a similar compliance time.

What is FAA's Response to the Concern? After consulting with British Aerospace and CAA, we concur that 200 hours TIS would unjustly ground many of the affected aircraft. We are changing the compliance time of the installation in this final rule as follows:

"Within the next 3,000 landings after May 5, 2000 (the issue date of the applicable service information) or within the next 90 days after the effective date of this AD, whichever occurs later."

The FAA's Determination

What is FAA's Final Determination on this Issue? After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for the compliance time change and minor editorial corrections. We determined that this compliance time change and the minor corrections:

—Will not change the meaning of the AD; and

—Will not add any additional burden upon the public than was already proposed.

Cost Impact

How many airplanes does this AD impact? We estimate that this AD affects 264 airplanes in the U.S. registry.

What is the cost impact of this AD on owners/operators of the affected airplanes? We estimate the following costs to accomplish the modification:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. airplane operators
2 workhours × $60 per hour=$120	$1,520 per airplane	$1,640 per airplane	$432,960

Regulatory Impact

Does this AD impact various entities? The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by Reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–01–03 British Aerospace: Amendment 39–12073; Docket No. 2000–CE–57–AD.

(a) *What airplanes are affected by this AD?* This AD effects Models HP137 Mk1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes, all serial numbers, certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent failure of the nose landing gear steering actuator because of problems with the current design piston rod. Continued operation with the current design piston rod could result in loss of nose wheel steering and possible loss of control of the airplane during takeoff, landing, and taxi operations.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Action	Compliance time	Procedures
(1) Remove the nose landing gear steering actuator and install one that incorporates a modified piston rod.	Within the next 3,000 landings after May 5, 2000 (the issue date of the applicable service bulletin) or within the next 90 days after February 17, 2001 (the effective date of this AD), whichever occurs later, unless already accomplished. If the number of landings is unknown, you may use hours time-in-service (TIS) by multiplying the number of hours TIS by 0.75. In this carle, 3,000 landings would be equal to 4,000 hours TIS (4,000 hours TIS ×.75=3,000 landings).	In accordance with the procedures in APPH Ltd. Service Bulletin 32–73, dated April 2000, as referenced in British Aerospace Jetstream Manadatory Service Bulletin 32–JA000342, Issued: May 5, 2000.
(2) You may not install, on any affected airplane, a nose landing gear unit that does not incorporate a modified steering actuator piston rod, as required by paragraph (d)(1) of this AD.	As of February 17, 2001 (the effective date of this AD).	Not Applicable.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Mr. Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with APPH Ltd. Service Bulletin 32–73, dated April 2000, as referenced in British Aerospace Jetstream Mandatory Service Bulletin 32–JA000342, Issued: May 5, 2000. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland. You can look at copies at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on February 24, 2001.

Note 2: The subject of this AD is addressed in British AD 004–05–2000.

Issued in Kansas City, Missouri, on January 4, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–901 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–141–AD; Amendment 39–12078; AD 2001–01–08]

RIN 2120–AA64

Airworthiness Directives; BAE Systems (Operations) Limited (Jetstream) Model 4101 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all BAE Systems (Operations) Limited (Jetstream) Model 4101 airplanes, that requires inspection

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for cracking of the mounting brackets of the hydraulic hand pump at the frame attachment flanges, replacement of any cracked bracket with a new bracket, replacement of all bolts and nuts with new bolts and nuts, and installation of a particular "D" packer. The actions specified by this AD are intended to prevent failure of these brackets, which could result in inability to extend the landing gear in an emergency situation where the main hydraulic system is lost. This action is intended to address the identified unsafe condition.

DATES: Effective February 22, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 22, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all British Aerospace (Jetstream) Model 4101 airplanes was published in the **Federal Register** on October 30, 2000 (65 FR 64629). That action proposed to require inspection for cracking of the mounting brackets of the hydraulic hand pump at the frame attachment flanges, replacement of any cracked bracket with a new bracket, replacement of all bolts and nuts with new bolts and nuts, and installation of a particular "D" packer.

Manufacturer Name Change

The manufacturer name in the final rule has been changed from British Aerospace to BAE Systems (Operations) Limited to reflect the recent company name change.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule with the change described previously. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The FAA estimates that 59 airplanes of U.S. registry will be affected by this AD, that it will take approximately 4 work hours per airplane to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $14,160, or $240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–01–08 BAE Systems (Operations) Limited [Formerly British Aerospace Regional Aircraft]: Amendment 39–12078. Docket 2000–NM–141–AD.

Applicability: All Model Jetstream 4101 airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the mounting brackets of the hydraulic hand pump at the frame attachment flanges, which could result in inability to extend the landing gear in an emergency situation where the main hydraulic system is lost, accomplish the following:

Inspection and Installation

(a) Within 6 months after the effective date of this AD, perform a one-time dye penetrant inspection to detect cracking of the mounting brackets of the hydraulic hand pump at the frame attachment flanges, install "D" packers to the mounting brackets, and replace all bolts and nuts with new bolts and nuts, in accordance with the Accomplishment Instructions of Jetstream Service Bulletin J41–53–046, dated March 15, 2000. If any cracked bracket is found during the inspection, prior to further flight, replace it with a new bracket.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(d) The actions shall be done in accordance with Jetstream Service Bulletin J41–53–046, dated March 15, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in British airworthiness directive 003–03–2000.

Effective Date

(e) This amendment becomes effective on February 22, 2001.

Issued in Renton, Washington, on January 8, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1077 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–202–AD; Amendment 39–12076; AD 2001–01–06]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2 and A300 B4 (A300); Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600); and Model A310 Series Airplanes; Equipped With Dowty Ram Air Turbines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Industrie Model A300, A300–600, and A310 series airplanes; equipped with Dowty ram air turbines (RAT). That AD currently requires repetitive deployment tests of the RAT and checks of the adjustment of the locking rod. This amendment also requires modification of the RAT, which terminates the repetitive tests and checks. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to ensure the availability of the RAT in case of need.

DATES: Effective February 22, 2001.

The incorporation by reference of certain publications, as listed in the regulations, is approved by the Director of the Federal Register as of February 22, 2001.

The incorporation by reference of Airbus All Operator Telex 29–09, dated November 16, 1993, as listed in the regulations, was approved previously by the Director of the Federal Register as of March 2, 1994 (59 FR 7208, February 15, 1994).

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 94–04–05, amendment 39–8823 (59 FR 7208, February 15, 1994), which is applicable to certain Airbus Industrie Model A300, A300–600, and A310 series airplanes, was published as a supplemental notice of proposed rulemaking (NPRM) in the **Federal Register** on August 23, 2000 (65 FR 51254). The action proposed to continue to require repetitive deployment tests of the ram air turbine (RAT) and checks of the adjustment of the locking rod. The action also proposed to require modification of the RAT, which would terminate the repetitive tests and checks, and to expand the applicability of the existing AD.

Airplane Model Designation Change

Since the issuance of the supplemental NPRM, the FAA has determined that it is necessary to revise the manner in which it specifies the model designation for Airbus Model A300 and A300–600 series airplanes to reflect the designations that appear on the type certificate data sheet (TCDS). This final rule has been revised accordingly.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the supplemental NPRM or the FAA's determination of the cost to the public.

Conclusion

After careful review of the available data, the FAA has determined that air safety and the public interest require the adoption of the rule with the change previously described. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

There are approximately 126 airplanes of U.S. registry that will be affected by this AD.

The repetitive tests and checks that are required by AD 94–04–05, and retained in this AD, take approximately 2 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of this requirement on U.S. operators is

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estimated to be $15,120, or $120 per airplane, per test/check cycle.

The new modification that is required by this AD action will take approximately 6 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts will cost approximately $3,995 per airplane. Based on these figures, the cost impact of the new requirements of this AD on U.S. operators is estimated to be $548,730, or $4,355 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8823 (59 FR 7206, February 15, 1994), and by adding a new airworthiness directive (AD), amendment 39–12076, to read as follows:

2001–01–06 Airbus Industrie: Amendment 39–12076. Docket 99–NM–202–AD. Supersedes AD 94–04–05, Amendment 39–8823.

Applicability: Model A300 B2 and A300 B4 (A300); Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600); and Model A310 series airplanes; certificated in any category; equipped with Dowty ram air turbines (RAT) having the following part numbers:

RAT 16C 100 VG
RAT 16C 101 VG
RAT 16C 102 VG
RAT 16C 103 VG
RAT 16C 105 VG
RAT 16C 109 VG
RAT 16C 110 VG
768336
768338

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e)(1) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To ensure the availability of the RAT in case of need, accomplish the following:

Restatement of Requirements of AD 94–04–05:

Repetitive Tests and Checks

(a) Within 60 days after March 2, 1994 (the effective date of AD 94–04–05, amendment 39–8823), or 500 hours time-in-service after March 2, 1994, whichever occurs first, perform a deployment test of the RAT and check the adjustment of the locking rod, in accordance with Airbus All Operator Telex (AOT) 29–09, dated November 16, 1993. Repeat the deployment test and adjustment check thereafter at intervals not to exceed 10 months.

(1) If no discrepancy is found, prior to further flight, apply grease to the RAT leg at the entry and exit positions of the locking rod spring housing, in accordance with the AOT.

(2) If any discrepancy is found, prior to further flight, correct it and apply grease to the RAT leg at the entry and exit positions of the locking rod spring housing, in accordance with the AOT.

New Requirements of This AD:

New Service Bulletin Revisions

(b) As of the effective date of this new AD, Airbus Service Bulletin A300–29–0101 (for Model A300 series airplanes), A310–29–2039 (for Model A310 series airplanes), or A300–29–6030 (for Model A300–600 series airplanes); all Revision 02, all dated June 28, 2000; as applicable; must be used for accomplishment of the actions required by paragraph (a) of this AD.

Modification

(c) Within 24 months after the effective date of this AD, modify the RAT by installing a grease nipple and a scraper seal assembly, replacing the locking rod spring with a stronger spring, and re-identifying the RAT with a new part number; in accordance with Airbus Service Bulletin A300–29–0106 (for Model A300 series airplanes), A310–29–2078 (for Model A310 series airplanes), or A300–29–6039 (for Model A300–600 series airplanes); all Revision 03, all dated June 28, 2000; as applicable. Accomplishment of the modification constitutes terminating action for the repetitive tests and checks required by paragraph (a) of this AD.

Note 2: The service bulletins refer to Sundstrand Service Bulletin ERPS26T–29–1 for modification instructions and new part numbers.

Note 3: Accomplishment of the actions specified in Airbus Service Bulletin A300–29–0106, A310–29–2078, or A300–29–6039; Revision 01; all dated September 8, 1997; or Revision 02, all dated January 26, 1999; as applicable; prior to the effective date of this AD, is acceptable for compliance with paragraph (c) of this AD.

Spares

(d) As of the effective date of this AD, no person shall install a RAT having the following part numbers on any airplane:

RAT 16C 100 VG
RAT 16C 101 VG
RAT 16C 102 VG
RAT 16C 103 VG
RAT 16C 105 VG
RAT 16C 109 VG
RAT 16C 110 VG
768336
768338

Alternative Methods of Compliance

(e)(1) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

(2) Alternative methods of compliance, approved previously in accordance with AD 94–04–05, amendment 39–8823, are approved as alternative methods of compliance with paragraph (a) of this AD.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(g) The actions shall be done in accordance with Airbus All Operator Telex 29–09, dated November 16, 1993; Airbus Service Bulletin A300–29–0101, Revision 02, dated June 28, 2000; Airbus Service Bulletin A310–29–2039, Revision 02, dated June 28, 2000; Airbus Service Bulletin A300–29–6030, Revision 02, dated June 28, 2000; Airbus Service Bulletin A300–29–0106, Revision 03, dated June 28, 2000; Airbus Service Bulletin A310–29–2078, Revision 03, dated June 28, 2000; and Airbus Service Bulletin A300–29–6039, Revision 03, dated June 28, 2000; as applicable.

(1) The incorporation by reference of Airbus Service Bulletin A300–29–0101, Revision 02, dated June 28, 2000; Airbus Service Bulletin A310–29–2039, Revision 02, dated June 28, 2000; Airbus Service Bulletin A300–29–6030, Revision 02, dated June 28, 2000; Airbus Service Bulletin A300–29–0106, Revision 03, dated June 28, 2000; Airbus Service Bulletin A310–29–2078, Revision 03, dated June 28, 2000; and Airbus Service Bulletin A300–29–6039, Revision 03, dated June 28, 2000; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus All Operator Telex 29–09, dated November 16, 1993, was approved previously by the Director of the Federal Register as of March 2, 1994 (59 FR 7208, February 15, 1994).

(3) Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in French airworthiness directive 2000–259–315(B), dated June 28, 2000.

Effective Date

(h) This amendment becomes effective on February 22, 2001.

Issued in Renton, Washington, on January 8, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1076 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–325–AD; Amendment 39–12075; AD 2001–01–05]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Falcon 10 and Model Mystere-Falcon 50 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dassault Model Falcon 10 and Model Mystere-Falcon 50 series airplanes. For certain airplanes, this amendment requires modification of the aircraft wiring to illuminate the "T/O CONFIG" red warning light on the cockpit warning panel. For certain other airplanes, this amendment requires installation of a "NO TAKEOFF" red light on each pilot's instrument panel; modification of the associated aircraft wiring to activate the lights whenever the aircraft is not in the proper configuration for takeoff; and a revision to the Airplane Flight Manual (AFM) to check that the "NO TAKEOFF" lights are out prior to takeoff. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to prevent takeoff with the parking brake engaged, which could result in an extended takeoff roll or a rejected takeoff, and consequent runway overrun.

DATES: Effective February 22, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 22, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dassault Model Falcon 10 and Model Mystere-Falcon 50 series airplanes was published in the **Federal Register** on July 22, 1999 (64 FR 39448). For certain airplanes, that action proposed to require modification of the aircraft wiring to illuminate the "T/O CONFIG" red warning light on the cockpit warning panel. For certain other airplanes, that action proposed to require installation of a "NO TAKEOFF" red light on each pilot's instrument panel; modification of the associated aircraft wiring to activate the lights whenever the aircraft is not in the proper configuration for takeoff; and a revision to the Airplane Flight Manual (AFM) to check that the "NO TAKEOFF" lights are out prior to takeoff.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

Request for Credit for Previously Accomplished Work

One commenter, the manufacturer, requests that a statement be added to the proposed AD that would credit operators for the prior accomplishment of the original versions of the service bulletins. (The proposed AD specified that the modification be accomplished in accordance with Revision 1 of the corresponding service bulletins.)

The FAA concurs. Notes 2 and 4 have been added to the final rule to credit operators for the prior accomplishment of the modification in accordance with the original versions of the applicable service bulletins.

Request to Revise Cost Estimate

One commenter, the manufacturer, requests that the cost impact section of the proposed AD be revised to reflect certain information in its records: There are 144 U.S.-registered Model Falcon 10 series airplanes, of which 110 have already been modified; and 159 U.S.-registered Model Mystere-Falcon 50 series airplanes, of which 90 have already been modified. In addition, the commenter reports that the parts cost for Model Mystere-Falcon 50 series airplanes is $226.

The FAA acknowledges the revised information, and has revised the cost

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impact section of the final rule accordingly.

Request to Revise Applicability: AD Unnecessary for Falcon 50

One commenter, a pilot of Model Falcon 50 series airplanes, considers this AD to be unreasonable for those airplanes. The commenter cites a lack of incidents or accidents involving Model Falcon 50 series airplanes resulting from the parking brake being applied during takeoff. The commenter further suggests that the likelihood of such an event to occur is remote, based on the following considerations:

- The parking brake handle on the Model Falcon 50 series airplane is in the normal line of sight for the pilot.
- There are other cockpit indications available to advise the pilot if the parking brake is applied during takeoff.
- Except for one abnormal procedure, the available operational procedures (provided by the AFM, operating manual, and formal instruction) direct the use of the parking brake only full forward or full aft (full on) when the engine is operating.

The FAA infers that the commenter requests that Model Falcon 50 series airplanes be removed from the applicability of the proposed AD.

The FAA does not concur. The FAA disagrees with the commenter's claim that no incidents have occurred as a result of the identified unsafe condition. In fact, several incidents have been reported, despite the considerations identified by the commenter. In 1997 in Bursa, Turkey, the flightcrew of a Model Mystere-Falcon 50 series airplane rejected a takeoff, resulting in damage to the aircraft. The reported aircraft behavior was analyzed in a flight simulator, which indicated that the takeoff was attempted with the parking brake engaged at the first detent. In addition, the FAA has received reports of three similar occurrences on Model Falcon 10 series airplanes, resulting in four casualties and two injuries. In all three incidents, the crew attempted takeoff with the parking brake engaged at the first detent. Therefore, because of these incidents related to the unsafe condition, the FAA finds it necessary to require the actions for the identified airplanes as proposed. No change to the final rule is warranted in this regard.

Request to Revise Applicability: Potential To Cause Unsafe Operation

This same commenter suggests that the incorporation of Dassault Service Bulletin F50–240, as proposed by the notice of proposed rulemaking (NPRM), could cause unsafe operation of Model Mystere-Falcon 50 series airplanes. The commenter states:

> If the anti-skid system of the #1 brake system is malfunctioning or inoperative, then the use of the #2 brakes according to the MMEL [Master Minimum Equipment List] and Annex 4 of the AFM [Airplane Flight Manual] is permitted. Inadvertent minor touching of the brakes during take-off under such conditions with Service Bulletin F50–240 applied would cause the illumination of the 'T/O CONFIG' red warning light; if this were to occur near or above V1, it would cause an aborted takeoff. This is because all other meanings to the crew of the 'T/O CONFIG' red warning light are dangerous to flight.

The FAA infers that the commenter is again requesting that Model Mystere-Falcon 50 series airplanes be removed from the applicability of the proposed AD.

The FAA does not concur. Data from the manufacturer indicate the reliability of the anti-skid system to be very high. Thus, the risk of concurrent failure of the anti-skid system and operation of the #2 brakes, in accordance with Annex 4 of the AFM, is remote. In light of the incidents previously described, the FAA considers the required change to the airplane design a necessary improvement in airplane safety and not a design change that would result in unsafe operations. No change to the final rule is necessary in this regard.

Request for Alternative Solutions

This same commenter suggests that the FAA consider alternative solutions to indicate that the parking brake is applied to the intermediate position during takeoff. The commenter states that the proposed actions would conflict with procedures in Annex 4 (if permitted) of the AFM. The commenter suggests incorporating either a switch on the parking brake handle or a pressure switch in the parking brake system before it joins the #2 brake system. The commenter alternatively suggests prohibiting use of Annex 4.

The FAA acknowledges the commenter's suggestions but has determined that the actions as proposed will adequately address the unsafe condition. No change to the final rule is necessary.

Request To Revise MMEL

The manufacturer suggests incorporating the following sentence into the Maintenance and Operating procedures for the MMEL: "When dispatching with anti-skid failed, braking will illuminate the 'T/O config' Warning light when the aircraft is in take-off configuration." The commenter requests the change to alert the pilot of the pontential unsafe condition identified by the proposed AD.

The FAA does not concur. While there may be merit to the commenter's suggestions, this AD is not the appropriate context in which to evaluate those suggestions. Since the suggested changes would alter the actions currently required by this AD, additional rulemaking would be required. The FAA finds that to delay this action would be inappropriate in light of the identified unsafe condition. No change to the final rule is necessary in this regard.

Additional Change to Final Rule

The proposed AD inadvertently referred to Dassault Service Bulletin F10–280 as the appropriate source of service information for accomplishment of both the installation action of paragraph (b)(1) and the AFM revision of paragraph (b)(2). The service bulletin provides accomplishment instructions only for the installation required by paragraph (b)(1). The final rule has been revised accordingly.

Conclusion

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Cost Impact

The following table lists the estimated costs to operators to accomplish the requirements of this AD.

Model	Number of affected airplanes	Action	Work hours	Average labor rate (hour)	Parts cost	Per-airplane cost	Fleet cost
Falcon 10	34	Install light	50	$60	$2,280	$5,280	$179,520
		Revise AFM	1	60		60	2,040
Falcon 50	69	Modify wiring	8	60	226	706	48,714

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–01–05 Dassault Aviation: Amendment 39–12075. Docket 98–NM–325–AD.

Applicability: Model Falcon 10 series airplanes, serial numbers 1 through 152 inclusive, on which Dassault Modification M801 (reference Dassault Service Bulletin F10–280, Revision 1, dated February 10, 1999) has not been accomplished; and Model Mystere-Falcon 50 series airplanes, serial numbers 2 through 250 inclusive and 252, on which Dassault Modification M1850 (reference Dassault Service Bulletin F50–240, Revision 1, dated October 7, 1998) has not been accomplished; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent takeoff with the parking brake engaged, which could result in an extended takeoff roll or a rejected takeoff, and consequent runway overrun, accomplish the following:

Model Mystere-Falcon 50 Series Airplanes: Modification

(a) For Model Mystere-Falcon 50 series airplanes, within 9 months after the effective date of this AD, modify the aircraft wiring to add the "park brake handle not pushed forward" condition in the illumination conditions of the "T/O CONFIG" red warning light on the cockpit warning panel in accordance with Dassault Service Bulletin F50–240, Revision 1, dated October 7, 1998.

Note 2: Modification in accordance with Dassault Service Bulletin F50–240, dated April 5, 1995, is acceptable for compliance with the requirements of paragraph (a) of this AD.

Model Falcon 10 Series Airplanes: Modification and Airplane Flight Manual (AFM) Revision

(b) For Dassault Falcon 10 series airplanes, within 9 months after the effective date of this AD, accomplish the requirements of paragraphs (b)(1) and (b)(2) of this AD.

(1) Install a "NO TAKEOFF" red light on each pilot's instrument panel and modify the associated aircraft wiring to activate the lights whenever the aircraft is not in the proper configuration for takeoff, in accordance with Dassault Service Bulletin F10–280, Revision 1, dated February 10, 1999.

(2) Revise the Normal Procedures Section of the FAA-approved AFM to include the information specified in Falcon 10 AFM DTM722 Temporary Change No. 17, dated March 31, 1995, which introduces procedures for checking that the "NO TAKEOFF" lights are out prior to takeoff; and operate the airplane in accordance with those limitations and procedures.

Note 3: This may be accomplished by inserting a copy of Falcon 10 AFM DTM722 Temporary Change No. 17 in the AFM. When these temporary revisions have been incorporated into general revisions of the AFM, the general revisions may be inserted in the AFM, provided the information contained in the general revision is identical to that specified in Temporary Change No. 17.

Note 4: Modification in accordance with Dassault Service Bulletin F10–280, dated September 6, 1995, is acceptable for compliance with the requirements of paragraph (b)(1) of this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) Except as provided by paragraph (b)(2) of this AD: The actions shall be done in accordance with Dassault Service Bulletin F50–240, Revision 1, dated October 7, 1998; and Dassault Service Bulletin F10–280, Revision 1, dated February 10, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 6: The subject of this AD is addressed in French airworthiness directives 98–300–022(B), dated July 29, 1998, and 98–547–022(B), dated December 30, 1998.

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Effective Date

(f) This amendment becomes effective on February 22, 2001.

Issued in Renton, Washington, on January 8, 2001.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1075 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–SW–52–AD; Amendment 39–12074; AD 2001–01–04]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Model S–76A, S–76B, and S–76C Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–76A, S–76B, and S–76C helicopters. This AD requires initial and repetitive inspections of the main landing gear positioning rod assembly (rod assembly) and the side brace rod end (rod end) for corrosion. If any corrosion is found, this AD requires replacing any part that is corroded with an airworthy part before further flight. This amendment is prompted by a landing gear collapse caused by corrosion due to dissimilar metals in the landing gear rod end. The actions specified in this AD are intended to detect corrosion of the threaded joint in the rod assembly to prevent a collapse of the landing gear, and subsequent loss of control of the helicopter during landing.

DATES: Effective February 2, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 2, 2001.

Comments for inclusion in the Rules Docket must be received on or before March 19, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2000–SW–52–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.*

The service information referenced in this AD may be obtained from BF Goodrich Landing Gear Division, Attn.: Kenneth R. Madej, 8000 Marble Ave., Cleveland, OH 44105, telephone (216) 429–4461, fax (216) 429–4357. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Jeffrey Lee, Aviation Safety Engineer, Boston Aircraft Certification Office, 12 New England Executive Park, Burlington, MA 01803, telephone (781) 238–7161, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: This amendment adopts a new AD for Sikorsky Model S–76A, S–76B, and S–76C helicopters. This AD requires, within 14 days, inspecting the rod assembly, part number (P/N) 1945E–31A or 2071–31, and rod end, P/N 1945E235 or 2071–235, for corrosion. If the rod assembly and rod end were inspected and reassembled in accordance with BF Goodrich Component Maintenance Manual with Illustrated Parts List, 1945/2071 Series Main Landing Gear, No. 32–10–01, (formerly titled Cleveland Pneumatic Maintenance Manual 32–10–01), Revision 4, dated December 15, 1994, within the past 24 months, this AD requires an inspection within 90 days. If any corrosion is found, this AD requires replacing the unairworthy part with an airworthy part before further flight. This AD also requires, at intervals not to exceed 90 days, a repetitive inspection for corrosion on certain rod ends. For other rod ends, this AD requires a repetitive inspection for corrosion at intervals not to exceed 12 months or 1,500 hours time-in-service, whichever occurs first. This AD is prompted by a landing gear collapse on a helicopter that was in a hangar. Analysis showed that corrosion due to dissimilar metals in the rod end caused the rod end to fail with subsequent collapse of the landing gear. The actions specified in this AD are intended to detect corrosion of the threaded joint in the rod assembly and prevent a collapse of the landing gear and subsequent loss of control of the helicopter during landing.

The FAA has reviewed BF Goodrich Landing Gear Service Bulletin No. 76A–32–03, Revision 1, dated September 15, 2000, which describes procedures for inspecting and repairing or replacing the rod end and rod assembly.

Since an unsafe condition has been identified that is likely to exist or develop on other Sikorsky Model S–76A, S–76B, and S–76C helicopters of the same type design, this AD is being issued to detect corrosion of the threaded joint in the rod assembly and prevent a collapse of the landing gear. This AD requires inspecting the rod assembly and rod end for corrosion at specified intervals and replacing, before further flight, any component that has corrosion. The actions must be accomplished in accordance with the service bulletin described previously. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the structural integrity of the helicopter. Therefore, the actions previously mentioned are required within 14 days, and this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

The FAA estimates that 180 helicopters will be affected by this AD and that it will take approximately 4.5 work hours per helicopter to inspect the rod assembly and rod end and 1.5 work hours to remove and replace the rod assembly and rod end, if necessary. Required parts will cost approximately $14,600 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $2,692,800 ($14,960 per helicopter, assuming inspecting, removing, and replacing the rod assembly and rod end once).

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2000–SW–52–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2001–01–04 Sikorsky Aircraft Corporation: Amendment 39–12074. Docket No. 2000–SW–52–AD.

Applicability: Model S–76A, S–76B, and S–76C helicopters up to and including serial number 760513 with positioning rod assembly (rod assembly), part number (P/N) 1945E–31A or 2071–31, or side brace rod end (rod end), P/N 1945E–235 or 2071–235, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To detect corrosion of the threaded joint in the rod assembly and prevent a collapse of the landing gear and subsequent loss of control of the helicopter during landing, accomplish the following:

(a) Within 14 days, inspect the rod assembly and rod end for corrosion in accordance with Section 2., Accomplishment Instructions, in BF Goodrich Service Bulletin No. 76A–32–03, Revision 1, dated September 15, 2000 (SB), except that scrapping of corroded parts is not required. Replace any part that is corroded with an airworthy part before further flight.

(b) Within 90 days, if the rod assembly and rod end were inspected and reassembled in accordance with BF Goodrich Component Maintenance Manual with Illustrated Parts List, 1945/2071 Series Main Landing Gear, No. 32–10–01, (formerly titled Cleveland Pneumatic Maintenance Manual 32–10–01), Revision 4, dated December 15, 1994, within the past 24 months, inspect the rod assembly and rod end in accordance with Section 2. of the SB. Scrapping of corroded parts is not required. Replace any part that is corroded with an airworthy part before further flight.

(c) At intervals not to exceed 90 days, for rod ends that are not reassembled with Mastinox sealant or reassembled with Mastinox sealant but without cadmium plate restoration, inspect the rod assembly and rod end for corrosion in accordance with the Section 2. of the SB, except that scrapping of corroded parts is not required. Replace any part that is corroded with an airworthy part before further flight.

(d) At intervals not to exceed 12 months or 1,500 hours time-in-service, whichever occurs first, for rod ends assembled with Mastinox sealant and cadmium plate restoration or for rod ends reassembled with Mastinox but that did not previously require rework due to corrosion, inspect the rod assembly and rod end for corrosion in accordance with the Section 2. of the SB, except that scrapping of corroded parts is not required. Replace any part that is corroded with an airworthy part before further flight.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Boston ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Boston ACO.

(f) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(g) The inspections shall be done in accordance with Section 2., Accomplishment Instructions, in BF Goodrich Service Bulletin No. 76A–32–03, Revision 1, dated September 15, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from BF Goodrich Landing Gear Division, Attn.: Kenneth R. Madej, 8000 Marble Ave., Cleveland, OH 44105, telephone (216) 429–4461, fax (216) 429–4357. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on February 2, 2001.

Issued in Fort Worth, Texas, on January 5, 2001.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 01–1121 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–292–AD; Amendment 39–12079; AD 2001–01–09]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A330–301, –321, and –322 Series Airplanes; and Model A340–211, –212, –213, –311, –312, and –313 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to all Airbus Model A330–301, –321, and –322 series airplanes; and Model A340–211, –212, –213, –311, –312, and –313 series airplanes. The existing AD requires repetitive replacements of the yaw damper actuator installed on active position with a new or overhauled actuator. This action adds a requirement, for certain airplanes, to install upgraded flight control primary computers, which terminates the requirement for the repetitive actuator replacements for those airplanes. This action is necessary to prevent hydraulic leakage from the yaw damper actuator installed on active position, due to premature wear of the dynamic seals between the actuator piston and the piston bearing. Hydraulic leakage could lead to the complete loss of the green hydraulic circuit, which could result in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Effective February 2, 2001.

The incorporation by reference of certain publications, as listed in the regulations, is approved by the Director of the Federal Register as of February 2, 2001.

The incorporation by reference of certain other publications, as listed in the regulations, was approved previously by the Director of the Federal Register as of January 24, 2000 (64 FR 71004, December 20, 1999).

Comments for inclusion in the Rules Docket must be received on or before February 20, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–292–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-iarcomment@faa.gov*. Comments sent via fax or the Internet must contain "Docket No. 2000-NM–292-AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: On December 10, 1999, the FAA issued AD 99–26–12, amendment 39–11471 (64 FR 71004, December 20, 1999). That AD is applicable to all Airbus Model A330–301, –321, and –322 series airplanes; and Model A340–211, –212, –213, –311, –312, and –313 series airplanes. That AD requires repetitive replacements of the yaw damper actuator installed on active position with a new or overhauled actuator. That AD was prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The requirements of that AD are intended to prevent hydraulic leakage from the yaw damper actuator installed on active position due to premature wear of the dynamic seals between the actuator piston and the piston bearing. Hydraulic leakage could lead to complete loss of the green hydraulic circuit, which could result in reduced controllability of the airplane.

Actions Since Issuance of Previous Rule

As described in the proposed NPRM to AD 99–26–12, hydraulic fluid leakage from the yaw damper actuator has been attributed to premature wear of certain dynamic seals. Investigation revealed a link between the leakage and small inputs sent by the flight control primary computers (FCPC).

In the preamble to AD 99–26–12, the FAA specified that the actions required by that AD were considered "interim action" and that the manufacturer was developing a modification to positively address the unsafe condition. The FAA indicated that it may consider further rulemaking action once the modification was developed, approved, and available. The manufacturer now has developed such a modification for Model A330 series airplanes, and the FAA has determined that further rulemaking action is indeed necessary; this proposed AD follows from that determination.

A similar modification has been developed for Model A340 series airplanes. There currently are no such airplanes on the U.S. Register. The A340 modification will be included in the FAA Required Modification List for these airplanes. Actions identified on this list must be accomplished before the airplane may be imported into the United States.

Explanation of Relevant Service Information

Airbus has issued the following service bulletins for Model A330 series airplanes:

Service bulletin	Revision level	Date
A330–27–3068	Original ..	July 29, 1999.
A330–27–3071	Original ..	November 19, 1999.
A330–27–3055	02	March 24, 2000.

Service Bulletins A330–27–3068 and A330–27–3071 describe procedures for obtaining new software standards for the FCPCs by replacing or reprogramming the on-board replaceable modules, or by replacing the FCPCs with new, improved FCPCs. The actions specified by these service bulletins are intended to prevent premature wear and subsequent leakage of the active and damping yaw actuators.

Revision 02 of Service Bulletin A330–27–3055 was issued to, among other things, add a detailed visual inspection of the FCPC part numbers and revise certain repair procedures for replacing the yaw damper actuator. The actions otherwise are the same as those described in Revision 01 of the service bulletin, which was referred to in AD 99–26–12 as the appropriate source of service information for replacing the yaw damper actuator.

The DGAC classified the service bulletins as mandatory and issued French airworthiness directive 2000–076–115(B) R1, dated March 22, 2000, to ensure the continued airworthiness of

affected Model A330 series airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.19) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent hydraulic leakage from the yaw damper actuator installed on active position, which could lead to complete loss of the green hydraulic circuit and consequent reduced controllability of the airplane. This AD supersedes AD 99–26–12 to continue to require repetitive replacements of the yaw damper actuator installed on active position with a new or overhauled yaw damper actuator. This AD adds a requirement, for affected Model A330 series airplanes, to install upgraded FCPCs, which terminates the requirement for repetitive actuator replacements for those airplanes. The actions are required to be accomplished in accordance with the service bulletins described previously.

Cost Impact

None of the airplanes affected by this action are on the U.S. Register. All airplanes included in the applicability of this rule currently are operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers that this rule is necessary to ensure that the unsafe condition is addressed in the event that any of these subject airplanes are imported and placed on the U.S. Register in the future.

Should an affected airplane be imported and placed on the U.S. Register in the future, it would require approximately 2 work hours to accomplish the required actions, at an average labor rate of $60 per work hour. Required parts would cost approximately $390 per airplane. Based on these figures, the cost impact of this AD is estimated to be $510 per airplane.

Determination of Rule's Effective Date

Since this AD action does not affect any airplane that is currently on the U.S. register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, prior notice and public procedures hereon are unnecessary and the amendment may be made effective in less than 30 days after publication in the Federal Register.

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption ADDRESSES. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2000–NM–292–AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–11471 (64 FR 71004, December 20, 1999), and by adding a new airworthiness directive (AD), amendment 39–12079, to read as follows:

2001–01–09 Airbus Industrie: Amendment 39–12079. Docket 2000–NM–292–AD. Supersedes AD 99–26–12, Amendment 39–11471.

Applicability: The following airplanes, certificated in any category: Model A330–301, –321, and –322 series airplanes; excluding those on which Airbus Modification 46964 or 47221 has been installed; and Model A340–211, –212, –213, –311, –312, and –313 series airplanes.

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Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent hydraulic leakage from the yaw damper actuator, which could lead to complete loss of the green hydraulic circuit and consequent reduced controllability of the airplane, accomplish the following:

Restatement of Requirements of AD 99–26–12

Repetitive Replacement

(a) Prior to the accumulation of 6,500 total flight hours, or within 500 flight hours after January 24, 2000 (the effective date of AD 99–26–12, amendment 39–11471), whichever occurs later, replace the yaw damper actuator installed on active position with a new or overhauled yaw damper actuator in accordance with Airbus Service Bulletin A330–27–3055, Revision 01, dated July 1, 1998, or Revision 02, dated March 24, 2000 (for Model A330 series airplanes); or A340–27–4063, Revision 01, dated July 1, 1998 (for Model A340 series airplanes); as applicable. Thereafter, repeat the replacement at intervals not to exceed 6,500 flight hours. For Model A330 series airplanes, after the effective date of this AD, only Revision 02 of Service Bulletin A330–27–3055 may be used.

Note 2: Replacement of yaw dampers accomplished prior to January 24, 2000, in accordance with Airbus Service Bulletin A330–27–3055, dated August 25, 1997 (for Model A330 series airplanes), or Airbus Service Bulletin A340–27–4063, dated August 26, 1997 (for Model A340 series airplanes); as applicable; is an acceptable method of compliance for the initial replacement required by paragraph (a) of this AD.

New Requirements of This AD

Terminating Action

(b) For Model A330 series airplanes: Within 18 months after the effective date of this AD, install 3 upgraded flight control primary computers (FCPC), in accordance with Airbus Service Bulletin A330–27–3071, dated November 19, 1999, or A330–27–3068, dated July 29, 1999; as applicable. Accomplishment of the installation terminates the requirements of this AD for Model A330 series airplanes.

Spares

(c) As of the effective date of this AD, no person may install an FCPC, part number LA2K01500A40000 or LA2K1A100D20000, on any Model A330 series airplane.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of any approved alternative methods of compliance with this AD may be obtained from the International Branch, ANM–116.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(f) The actions shall be done in accordance with the following Airbus service bulletins, as applicable:

Service bulletin number	Revision level	Date
A330–27–3055	Revision 01	July 1, 1998
A330–27–3055	Revision 02	March 24, 2000
A340–27–4063	Revision 01	July 1, 1998
A330–27–3071	Original	November 19, 1999
A330–27–3068	Original	July 29, 1999

(1) The incorporation by reference of Airbus Service Bulletin A330–27–3055, Revision 02, dated March 24, 2000; Airbus Service Bulletin A330–27–3071, dated November 19, 1999; and Airbus Service Bulletin A330–27–3068, dated July 29, 1999; is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Airbus Service Bulletin A330–27–3055, Revision 01, dated July 1, 1998; and Airbus Service Bulletin A340–27–4063, Revision 01, dated July 1, 1998; was approved previously by the Director of the Federal Register as of January 24, 2000 (64 FR 71004, December 20, 1999).

(3) Copies of any of these service bulletins may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directives 1998–100–067(B) R2, dated May 19, 1999; 98–104–083(B), dated February 25, 1998; and 2000–076–115(B) R1, dated March 22, 2000.

Effective Date

(g) This amendment becomes effective on February 2, 2001.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1233 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–72–AD; Amendment 39–12077; AD 2001–01–07]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300 B2, A300 B4, A300 B4–600, A300 B4–600R, A300 F4–600R, and A310 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Airbus Model A300 B2, A300 B4, A300 B4–600, A300 B4–600R, A300 F4–600R, and A310 series airplanes, that requires modification of the escape slides. The actions specified by this AD are intended to prevent deflation of the escape slide after deployment, which could result in a delay during an emergency evacuation. This action is intended to address the identified unsafe condition.

DATES: Effective February 22, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 22, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Airbus Model A300 B2 and A300 B4 (A300); Model A300 B4–600, A300 B4–600R, and A300 F4–600R (A300–600); and Model A310 series airplanes was published in the **Federal Register** on October 31, 2000 (65 FR 64901). That action proposed to require modification of the escape slides.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 126 airplanes of U.S. registry will be affected by this AD, that it will take approximately 1 work hour per slide to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $124 to $185 per slide. Each Model A300 and A300–600 series airplane has 6 escape doors, and each Model A310 series airplane has 4 escape doors. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be between $736 and $1,470 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–01–07 Airbus Industrie: Amendment 39–12077. Docket 2000–NM–72–AD.

Applicability: The following airplanes, certificated in any category:

Model	Equipped with any BFGoodrich slide having part number	Excluding airplanes modified in accordance with
A300 B2 series A300 B4 series	7A1296–001 7A1296–002 7A1296–003 7A1296–004 7A1298–001 7A1298–002 7A1298–003 7A1298–004	Airbus Service Bulletin A300–25–0466, Revision 01, dated December 1, 1999; or BFGoodrich Service Bulletin 7A1296/7A1298–25–298, dated January 15, 1999.

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Model	Equipped with any BFGoodrich slide having part number	Excluding airplanes modified in accordance with
A300 B4–600 series	7A1296–001.	
A300 B4–600R series	7A1296–002.	
A300 F4–600R series	7A1296–003	Airbus Service Bulletin A300–25–6146, Revision 01, dated December 1, 1999; or BFGoodrich Service Bulletin7A1296/7A1298–25–298, dated January 15, 1999.
	7A1296–004	
	7A1298–001	
	7A1298–002	
	7A1298–003	
	7A1298–004	
A310 series	7A1298–001	Airbus Service Bulletin A310–25–2133, dated June 21, 1999; or BFGoodrich Service Bulletin 7A1296/7A1298–25–298, dated January 15, 1999.
	7A1298–002	
	7A1298–003	
	7A1298–004	

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent deflation of the escape slide after deployment, which could result in a delay during an emergency evacuation, accomplish the following:

Modification

(a) Within 34 months after the effective date of this AD, modify the escape slides in accordance with the applicable Airbus service bulletin listed in Table 1 of this AD, as follows:

TABLE 1.—SERVICE BULLETINS

Model	Service bulletin	Revision level	Date
A300	A300–25–0466	01	December 1, 1999.
A300–600	A300–25–6146	01	December 1, 1999.
A310	A310–25–2133	Original	June 21, 1999.

Note 2: The Airbus service bulletins refer to BFGoodrich Service Bulletin 7A1296/7A1298–25–298, dated January 15, 1999, as an additional source of service information for modifying the escape slides.

(b) As of the effective date of this AD, no person shall install, on any airplane, a BFGoodrich escape slide having a part number listed in Table 2 of this AD, unless that slide has been modified in accordance with this AD:

TABLE 2.—SLIDE PART NUMBERS

7A1296–001
7A1296–002
7A1296–003
7A1296–004
7A1298–001
7A1298–002
7A12 98–003
7A1298–004

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The modification shall be done in accordance with Airbus Service Bulletin A300–25–0466, Revision 01, dated December 1, 1999; Airbus Service Bulletin A300–25–6146, Revision 01, dated December 1, 1999; or Airbus Service Bulletin A310–25–2133, dated June 21, 1999; as applicable. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directive 2000–059–302(B), dated February 9, 2000.

Effective Date

(f) This amendment becomes effective on February 22, 2001.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1232 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR part 1

[TD 8941]

RIN 1545–AX87

Obligations of States and Political Subdivisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations that provide guidance to issuers of tax-exempt bonds for output facilities. This document also contains final regulations that provide guidance to certain nongovernmental persons that are engaged in the local furnishing of electric energy or gas using facilities financed with state or local government bonds. These regulations will affect issuers of tax-exempt bonds and nongovernmental persons engaged in the local furnishing of electric energy or gas after the effective date.

The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective January 19, 2001.

Applicability Date: For dates of applicability, see §§ 1.141–15T, 1.142(f)(4)–1(g), and 1.150–5(b).

FOR FURTHER INFORMATION CONTACT: Rose M. Weber (202) 622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information in this rule has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507 and assigned control number 1545–

The collection of information in this regulation is in § 1.142(f)(4)–1. This information is required to enable the IRS to identify persons engaged in the local furnishing of electric energy or gas that use facilities financed with exempt facility bonds under section 142(a)(8) and that expand their service area in a manner inconsistent with the requirements of sections 142(a)(8) and (f) who have made an election to ensure that those bonds will continue to be treated as exempt facility bonds. The data collected will be used by the IRS as the mechanism for identifying bonds that will remain tax-exempt notwithstanding a service area expansion that is inconsistent with the requirements of sections 142(a)(8) and (f). The collection of information is mandatory. The likely respondents are business institutions.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S:O Washington, DC 20224. Comments on the collection of information should be received by March 19, 2001. Comments are specifically requested concerning:

Whether the collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Estimated total annual reporting burden is 15 hours.

Estimated average annual burden hours per respondent is 1 hour.

Estimated number of respondents is 15.

Estimated annual frequency of responses is on occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document amends the Income Tax Regulations (26 CFR part 1) under section 141 by providing special rules for tax-exempt bonds issued for output facilities. This document also amends the Income Tax Regulations under section 142(f)(4) by providing rules to make the election provided in that section for nongovernmental persons engaged in local furnishing of electric energy or gas using facilities financed with tax-exempt bonds.

On January 22, 1998, temporary regulations (TD 8757) (the 1998 temporary regulations) were published in the **Federal Register** (63 FR 3256) to provide guidance under the Internal Revenue Code of 1986 regarding the application of the private activity bond tests under section 141(b)(1) and (2) to output contracts for output facilities; the application of the $15 million limit under section 141(b)(4) to output facility financings; the election provided in section 142(f)(4) for nongovernmental persons engaged in local furnishing of electric energy or gas using facilities financed with tax-exempt bonds; and the filing location for certain notices and elections. A notice of proposed rulemaking (REG–110965–97) cross-referencing the temporary regulations was published in the **Federal Register** on the same day (63 FR 3296). On April 28, 1998, the IRS held a public hearing on the proposed regulations. Written comments responding to the notice of proposed rulemaking were also received. After consideration of all the comments, the 1998 temporary regulations are revised by this Treasury decision. The new temporary regulations are referred to below as the "revised regulations." The revisions are discussed below.

Explanation of Provisions

A. Section 1.141–7T Special Rules for Output Facilities

1. Benefits and Burdens Test—Transmission Contracts

Under the 1998 temporary regulations, an agreement to provide firm or priority transmission services is generally treated as a take or take or pay contract. Commentators suggested that firm or priority transmission contracts should not automatically be treated as take or take or pay contracts. They recommended that the same standards that apply to determine whether generation contracts result in private business use, including the requirements contract provisions, should also apply to transmission contracts. The revised regulations adopt this recommendation by deleting the provision that generally treats all contracts for firm or priority transmission service as take or take or pay contracts.

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2. Retail Requirements Contracts

The 1998 temporary regulations provide that a retail requirements contract generally meets the benefits and burdens test to the extent it obligates the purchaser to make payments that are not contingent on the purchaser's output requirements. Commentators requested clarification regarding the application of this rule to reasonable contract damages and termination provisions. The revised regulations clarify that a retail requirements contract does not meet the benefits and burdens test by reason of (1) a provision that requires the purchaser to pay reasonable and customary damages (including liquidated damages) in the event of a default, or (2) a provision that permits the purchaser to pay a specified amount to terminate the contract while the purchaser has requirements, in each case if the amount of the payment is reasonably related to the purchaser's obligation to buy requirements that is discharged by the payment.

3. Output Contract Properly Characterized as a Lease

Under the 1998 temporary regulations, output contracts that provide the purchaser with specific rights to control the output of a facility or with other specific performance rights to the use of output of the facility are generally taken into account under the private business tests, even if the benefits and burdens test is not met. Commentators requested clarification of the scope of this rule.

The revised regulations amend the rule and clarify its application by specifying that an output contract that is properly characterized as a lease for federal income tax purposes is tested under §§ 1.141–3 and 1.141–4 to determine whether it is taken into account under the private business tests.

4. Special Rule for Facilities With Significant Unutilized Capacity

The 1998 temporary regulations provide that, if an issuer reasonably expects on the issue date that persons that are treated as private business users will purchase more than 30 percent of the actual output of the facility, the Commissioner may determine the number of units produced or to be produced by the facility in one year on a reasonable basis other than by reference to nameplate capacity, such as the average expected annual output of the facility. The revised regulations change the 30 percent threshold to 20 percent.

5. Special Rule for Facilities With a Limited Source of Supply

Under the 1998 temporary regulations, the available output of a facility that is constrained by a limited source of supply must be determined by reasonably taking those constraints into account. Commentators requested clarification of the meaning of limited source of supply. For example, they asked whether the term includes not only physical but also economic limitations.

The revised regulations clarify that a limited source of supply includes a physical limitation, such as the flow of water, but not an economic limitation, such as the cost of coal or gas.

6. Measurement of Private Business Use

The 1998 temporary regulations provide that, if an output contract results in private business use, the amount of such use generally is the capacity that must be reserved for the nongovernmental person under prudent reliability standards. Commentators stated that this provision is difficult to apply and may overstate the amount of private business use. They suggested that the amount of private business use should be the amount of output actually purchased under the contract.

The revised regulations provide that, if an output contract results in private business use, the amount of private business use generally is the amount of output purchased under the contract.

7. Exception for Small Purchases of Output

The 1998 temporary regulations provide that output contracts are not taken into account under the private business tests if the purchaser is not required to make a substantially certain payment in any year that is greater than 0.5 percent of the average annual debt service on an issue that finances the facility. Some commentators suggested that this provision should be amended to take into account average annual payments under a contract, rather than payments in any one year, and that the provision should apply based on all the outstanding bonds for the facility. Other commentators stated that the exception should be eliminated as inconsistent with a competitive electric industry.

The revised regulations provide that output contracts are not taken into account under the private business tests if the average annual payments under the contract that are substantially certain to be made do not exceed 0.5 percent of the average annual debt service on all outstanding tax-exempt bonds issued to finance the facility.

8. Exception for Short-Term Sales of Output

The 1998 temporary regulations provide that the exceptions for short-term use that apply to other types of arrangements under the general private activity bond rules in § 1.141–3 also apply to output contracts. Many commentators suggested that these exceptions may have limited practical application in the output context and recommended that they be expanded to permit contracts of a longer duration. These commentators stated that longer-term contracts are required in order to transfer substantial benefits of ownership and substantial burdens of debt service with respect to an output facility. Other commentators suggested that any sale of output by a municipal utility outside of its traditional service territory should result in private business use.

The revised regulations provide an exception under which an output contract with a nongovernmental person will not be taken into account under the private business tests if: (1) the term of the contract, including all renewal options, does not exceed one year; (2) the compensation under the contract is based on generally applicable and uniformly applied rates or represents a negotiated, fair market price; and (3) the facility is not financed for a principal purpose of serving that nongovernmental person.

9. Special Exception for Sales of Output Attributable to Excess Generating Capacity Resulting From Open Access

The 1998 temporary regulations contain an exception to private business use for certain output contracts if: (1) The contract term does not exceed three years; (2) the issuer does not utilize tax-exempt financing to increase the generating capacity of its system during the contract term; (3) the governmental owner offers non-discriminatory, open access transmission tariffs under certain rules of the Federal Energy Regulatory Commission (FERC) (or comparable provisions of state law pursuant to a plan approved by the FERC); (4) all of the output sold is attributable to excess capacity resulting from the offer of the open access tariffs; (5) the contract mitigates stranded costs attributable to the open access tariffs; and (6) any stranded costs recovered by the governmental owner are applied as promptly as is reasonably practical to redeem tax-exempt bonds in a manner consistent with § 1.141–12.

Comments were received regarding many of the above requirements. In particular, many commentators

suggested that the maximum contract term should be extended beyond three years. Some commentators recommended eliminating the prohibition on tax-exempt financing to increase capacity during the contract term. Others suggested that de minimis capacity increases should be permitted. Some commentators suggested that the requirement that a contract mitigate stranded costs should be eliminated because the purpose of that provision is accomplished by the requirement that all of the output sold be attributable to excess capacity from open access tariffs. Some commentators recommended deleting the reference to FERC approval of state open access plans because the FERC may not approve all such plans. Other commentators requested clarification regarding the amounts that an issuer must use to redeem bonds. Finally, some commentators recommended deleting the exception entirely.

The revised regulations retain the exception, with certain modifications. First, the revised exception permits tax-exempt financing during the contract term for property that does not increase the generating capacity of the issuer's system by more than three percent. Second, the amended exception deletes the reference to FERC approval of state open access plans. Third, the revised regulations remove the reference to stranded costs. Finally, the revised exception clarifies that the amounts that an issuer must use to redeem bonds consist of all payments that it receives under the contract, other than the portion of such payments that is properly allocable to the payment of ordinary and necessary expenses directly attributable to the operation and maintenance of the facility (as described in § 1.141–4(c)(2)(C)).

10. Special Exceptions for Transmission Facilities

The 1998 temporary regulations do not treat all use of transmission facilities pursuant to standard tariffs as general public use, but contain certain special exceptions to private business use of transmission facilities. Some commentators suggested that use of transmission facilities under standard tariffs should be treated as general public use, and therefore should never result in private business use. The revised regulations do not treat all use of transmission facilities pursuant to standard tariffs as general public use, but retain and modify the special exceptions, as discussed below.

The 1998 temporary regulations contain two special exceptions under which certain actions with respect to transmission facilities financed by an issue are not treated as deliberate actions under § 1.141–2(d). The first exception provides that the execution of a contract for the use of transmission facilities is not treated as a deliberate action if the contract is entered into in response to or in anticipation of a specific order by the FERC to wheel power under sections 211 and 212 of the Federal Power Act (16 U.S.C. 824j and 824k) (or a state regulatory authority under comparable provisions of state law pursuant to a plan approved by the FERC); the terms of the contract are bona fide and arm's-length; and the consideration paid is consistent with section 212(a) of the Federal Power Act.

Commentators suggested eliminating the requirement that orders of state regulatory authorities be undertaken pursuant to a FERC-approved state open access plan because FERC approval may not be required for all such plans. The revised regulations adopt this suggested change.

The second exception in the 1998 temporary regulations provides that an action is not treated as a deliberate action if it is taken to implement the offering of non-discriminatory, open access tariffs for the use of financed transmission facilities in a manner consistent with FERC rules, including the reciprocity conditions of FERC Order No. 888 (61 FR 21540, May 10, 1996). The exception also applies to orders and rules of state regulatory authorities pursuant to a plan approved by the FERC that are comparable to certain FERC orders and rules. The exception does not apply, however, to the sale, exchange, or other disposition of bond-financed transmission facilities to a nongovernmental person.

Commentators recommended that the exception be expanded to apply to open access tariffs that are offered under state law provisions that are comparable to FERC rules, regardless of whether those provisions are promulgated by a state regulatory authority or approved by the FERC. The revised regulations adopt this suggested change.

Commentators also requested clarification regarding the circumstances in which an independent system operator (ISO) may be treated as a private business user of transmission facilities. Some commentators suggested that the operation of transmission facilities by an ISO is a quasi-governmental function and thus should never constitute private business use. Some commentators requested clarification of whether the existing rules for management contracts under section 141 may be applied to arrangements for the operation of transmission facilities by an ISO.

The revised regulations do not provide that the operation of bond-financed transmission facilities by an ISO or other regional transmission organization (RTO) is disregarded under section 141. However, the existing rules for management contracts under section 141, including Revenue Procedure 97–13 (1997–1 C.B. 632), are applicable in determining whether an arrangement for the operation of transmission facilities by an ISO or other RTO results in private business use, including a determination of whether the arrangement is properly characterized as a lease for federal income tax purposes. Comments are requested on whether additional guidance is needed concerning the treatment under section 141 of arrangements for the operation of bond-financed transmission facilities by an ISO or other RTO.

The 1998 temporary regulations provide a special transition rule for bonds (other than advance refunding bonds) that refund bonds issued prior to July 9, 1996 (the effective date of FERC Order No. 888). Under this rule, an action taken or to be taken with respect to transmission facilities is not taken into account under the reasonable expectations test of § 1.141–2(d) if the action is described in one of the two special exceptions discussed above and the weighted average maturity of the refunding bonds does not exceed the remaining weighted average maturity of the prior bonds.

Commentators recommended that the July 9, 1996 date be changed to a date on or after February 23, 1998 (the effective date of the 1998 temporary regulations). The revised regulations change the cut-off date to February 23, 1998.

Under the 1998 temporary regulations, issuers may apply the special exceptions for transmission facilities to any bonds issued before the effective date of those regulations. However, issuers may not apply the exceptions to refunding bonds issued on or after the effective date, unless the refunding bonds are subject to the 1998 temporary regulations in their entirety. Commentators suggested that, in order to encourage open access, issuers should be permitted to apply the exceptions to refunding bonds that are not otherwise subject to the regulations. The revised regulations adopt this change.

11. Definition of Transmission Facilities

The 1998 temporary regulations define transmission facilities to include facilities that are necessary to provide

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ancillary services required to be offered as part of open access transmission tariffs under FERC rules. Commentators stated that the inclusion of ancillary services within the general definition of transmission facilities creates unwarranted complexity. They recommended that facilities used for ancillary services be treated as transmission facilities only for purposes of the special exceptions for transmission facilities in the regulations. The revised regulations adopt this approach.

B. Section 1.141–8T $15 Million Limitation for Output Facilities

Under the 1998 temporary regulations, property that replaces existing property is treated as part of the same project as the replaced property unless, among other things, the bonds that finance the replaced property have a weighted average maturity that is not greater than 120 percent of the reasonably expected economic life of the replaced property.

One commentator noted that it is not common to allocate bonds that finance output facilities to the specific assets that comprise those facilities, and thus it may be difficult to determine whether this 120 percent requirement is met. The revised regulations amend this rule so that it applies to the entire output facility of which the replaced property is a part, rather than the specific asset being replaced.

C. Need for Temporary Regulations and Request for Public Comments

Congress passed the Energy Policy Act of 1992 to encourage restructuring of the electric power industry. Since that time, the FERC and many states have adopted policies to open up access to transmission facilities. Treasury and the IRS are aware that these initiatives are causing rapid changes in the electric power industry.

The 1998 temporary regulations were published in order to provide immediate guidance under section 141 regarding the effect on the tax-exempt status of bonds of certain restructuring transactions necessary for utilities to participate in a restructured electric utility industry. Treasury and the IRS are aware, however, that restructuring efforts are evolving and uncertain, and that new types of arrangements may be developed to implement restructuring.

Accordingly, the revised regulations are published in both temporary and proposed form in order to continue to provide guidance on which issuers can rely in evaluating their participation in open access regimes, while providing the opportunity for public comment with respect to developments in the electric power industry that have occurred since the publication of the 1998 temporary regulations. The revised regulations are published in temporary form with the expectation that the Treasury and the IRS will reexamine them in light of new developments within the next three years.

Comments are invited on whether further guidance is needed to address the new types of contractual arrangements that are arising in the electric power industry. In particular, comments are invited on whether additional guidance is needed to address the proper treatment under section 141 of output contracts for the use of transmission and distribution facilities under open access, and output contracts for ancillary services that are necessary to maintain the reliability of a transmission grid. Comments are also requested on the impact of FERC Order No. 2000 (65 FR 810, January 6, 2000) on tax-exempt bonds issued by public power systems, including whether additional guidance is needed regarding the proper treatment under section 141 of arrangements for the operation of bond-financed transmission facilities by an ISO or other RTO that satisfies the requirements of Order 2000.

Effective Dates

Sections 1.141–7T and 1.141–8T are applicable to bonds sold on or after January 19, 2001. Section 1.142(f)(4)–1 applies to elections made on or after January 19, 2001. Section 1.150–5 applies to notices and elections filed on or after January 19, 2001.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations.

It is hereby certified that the collection of information in these regulations will not have a significant impact on a substantial number of small entities. This certification is based upon the fact that in the years 1987 through 1997 a total of only 80 different state or local government issuers of exempt facility bonds issued under section 142(f) for facilities for the local furnishing of electric energy or gas filed information returns with the IRS under section 149(e). Further, an election under section 142(f)(4) is in no event required to be filed with the Internal Revenue Service more than once. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Bruce M. Serchuk, and Rose M. Weber, Office of Chief Counsel (Tax-exempt and Government Entities), Internal Revenue Service, and Stephen J. Watson, Office of Tax Legislative Counsel, Department of the Treasury. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.141–0 is amended by revising the entire entries for §§ 1.141–7T, 1.141–8T and 1.141–15T to read as follows:

§ 1.141–0 Table of contents.

* * * * *

§ 1.141–7T Special Rules for Output Facilities (Temporary).

(a) Overview.
(b) Definitions.
(1) Available output.
(2) Measurement period.
(3) Sale at wholesale.
(4) Take contract and take or pay contract.
(5) Transmission facilities.
(6) Nonqualified amount.
(c) Output contracts.
(1) General rule.
(2) Benefits and burdens test.
(3) Take contract or take or pay contract.
(4) Requirements contracts.
(5) Output contract properly characterized as a lease.
(d) Measurement of private business use.
(e) Measurement of private security or payment.
(f) Exceptions for certain contracts.
(1) Small purchases of output.
(2) Swapping and pooling arrangements.
(3) Short-term output contracts.
(4) Special 3-year exception for sales of output attributable to excess generating capacity resulting from participation in open access.
(5) Special exceptions for transmission facilities.
(6) Certain conduit parties disregarded.
(g) Allocations of output facilities and systems.
(1) Facts and circumstances analysis.
(2) Illustrations.
(3) Transmission contracts.
(4) Allocation of payments.
(h) Examples.

§ 1.141–8T $15 Million Limitation for Output Facilities (Temporary).

(a) In general.
(1) General rule.
(2) Reduction in $15 million output limitation for outstanding issues.
(3) Benefits and burdens test applicable.
(b) Definition of project.
(1) General rule.
(2) Separate ownership.
(3) Generating property.
(4) Transmission.
(5) Subsequent improvements.
(6) Replacement property.
(c) Examples.

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§ 1.141–15T Effective Dates (Temporary).

(a) through (e) [Reserved].
(f) Effective dates for certain regulations relating to output facilities.
(1) General rule.
(2) Transition rule for requirement contracts.
(3) Elective application of 1998 temporary regulations.
(g) Refunding bonds.
(h) Permissive retroactive application.
(i) Permissive retroactive application of certain regulations pertaining to output contracts.

* * * * *

Par. 3. Section 1.141–7T is revised to read as follows:

§ 1.141–7T Special Rules for Output Facilities (Temporary).

(a) *Overview.* This section provides special rules to determine whether arrangements for the purchase of output from an output facility cause an issue of bonds to meet the private business tests. For this purpose, unless otherwise stated, water facilities are treated as output facilities. Sections 1.141–3 and 1.141–4 generally apply to determine whether other types of arrangements for use of an output facility cause an issue to meet the private business tests.

(b) *Definitions.* For purposes of this section and § 1.141–8T, the following definitions and rules apply:

(1) *Available output.* The available output of a facility financed by an issue is determined by multiplying the number of units produced or to be produced by the facility in one year by the number of years in the measurement period of that facility for that issue.

(i) *Generating facilities.* The number of units produced or to be produced by a generating facility in one year is determined by reference to its nameplate capacity or the equivalent (or where there is no nameplate capacity or the equivalent, its maximum capacity), which is not reduced for reserves, maintenance or other unutilized capacity.

(ii) *Transmission and other output facilities*—(A) *In general.* For transmission, cogeneration, and other output facilities, available output must be measured in a reasonable manner to reflect capacity.

(B) *Electric transmission facilities.* Measurement of the available output of all or a portion of electric transmission facilities may be determined in a manner consistent with the reporting rules and requirements for transmission networks promulgated by the Federal Energy Regulatory Commission (FERC). For example, for a transmission network, the use of aggregate load and load share ratios in a manner consistent with the requirements of the FERC may be reasonable. In addition, depending on the facts and circumstances, measurement of the available output of transmission facilities using thermal capacity or transfer capacity may be reasonable.

(iii) *Special rule for facilities with significant unutilized capacity.* If an issuer reasonably expects on the issue date that persons that are treated as private business users will purchase more than 20 percent of the actual output of the facility financed with the issue, the Commissioner may determine the number of units produced or to be produced by the facility in one year on a reasonable basis other than by reference to nameplate capacity, such as the average expected annual output of the facility. For example, the Commissioner may determine the available output of a financed peaking electric generating unit by reference to the reasonably expected annual output of that unit if the issuer reasonably expects, on the issue date of bonds that finance the unit, that an investor-owned utility will purchase more than 20 percent of the actual output of the facility during the measurement period under a take or pay contract, even if the amount of output purchased is less than 10 percent of the available output determined by reference to nameplate capacity. The reasonably expected annual output of the generating facility must be consistent with the capacity reported for prudent reliability purposes.

(iv) *Special rule for facilities with a limited source of supply.* If a limited source of supply constrains the output of an output facility, the number of units produced or to be produced by the facility must be determined by reasonably taking into account those constraints. For this purpose, a limited source of supply shall include a physical limitation (for example, flow of water), but not an economic limitation (for example, cost of coal or gas). For example, the available output of a hydroelectric unit must be determined by reference to the reasonably expected annual flow of water through the unit.

(2) *Measurement period.* The measurement period of an output facility financed by an issue is determined under § 1.141–3(g).

(3) *Sale at wholesale.* For purposes of this section, a sale at wholesale means a sale of output to any person for resale.

(4) *Take contract and take or pay contract.* A *take contract* is an output contract under which a purchaser agrees to pay for the output under the contract if the output facility is capable of providing the output. A *take or pay contract* is an output contract under which a purchaser agrees to pay for the output under the contract, whether or not the output facility is capable of providing the output.

(5) *Transmission facilities*—(i) *In general. Transmission facilities* are facilities for the transmission or distribution of output.

(ii) *Special rule for ancillary services.* For purposes of paragraph (f)(5), transmission facilities include facilities necessary to provide ancillary services required to be offered as part of open access transmission tariffs under rules promulgated by the FERC under sections 205 and 206 of the Federal Power Act (16 U.S.C. 824d and 824e). Thus, if a facility also serves another function (for example, a facility that provides for operating reserves for transmission and also provides generation) an allocable portion of the facility is treated as a transmission facility for purposes of paragraph (f)(5) of this section.

(6) *Nonqualified amount.* The nonqualified amount with respect to an issue is determined under section 141(b)(8).

(c) *Output contracts*—(1) *General rule.* The purchase by a nongovernmental person of available output of an output facility (output contract) financed with the proceeds of an issue is taken into account under the private business tests if the purchase has the effect of transferring substantial benefits of owning the facility and substantial burdens of paying the debt service on

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bonds used (directly or indirectly) to finance the facility (the benefits and burdens test). See paragraph (c)(5) of this section for the treatment of an output contract that is properly characterized as a lease for Federal income tax purposes. See paragraphs (d) and (e) of this section for rules regarding measuring the use of, and payments of debt service for, an output facility for determining whether the private business tests are met. See also § 1.141–8T for rules for when an issue that finances an output facility (other than a water facility) meets the private business tests because the nonqualified amount of the issue exceeds $15 million.

(2) *Benefits and burdens test*—(i) *Benefits of ownership.* An output contract transfers substantial benefits of owning a facility if the contract gives the purchaser (directly or indirectly) rights to capacity of the facility on a basis that is preferential to the rights of the general public.

(ii) *Burdens of paying debt service.* An output contract transfers substantial burdens of paying debt service on an issue to the extent that the issuer reasonably expects that it is substantially certain that payments will be made under the terms of the contract (disregarding default, insolvency, or other similar circumstances). For example, an output contract is treated as transferring burdens of paying debt service on an issue if payments must be made upon contract termination.

(iii) *Payments pursuant to pledged contract.* Payments made or to be made under the terms of an output contract that is pledged as security for an issue are taken into account under the private business tests even if the issuer reasonably expects that it is not substantially certain that payments will be made under the contract (disregarding default, insolvency, or other similar circumstances). For this purpose, an output contract is pledged as security only if the bond documents provide that the pledged contract cannot be substantially amended without the consent of bondholders or a trustee for the bondholders. This paragraph (c)(2)(iii) applies to pledges made on or after February 23, 1998, with respect to bonds that are subject to this section.

(3) *Take contract or take or pay contract.* The benefits and burdens test is met if a nongovernmental person agrees pursuant to a take contract or a take or pay contract to purchase available output of a facility.

(4) *Requirements contracts*—(i) *In general.* A requirements contract under which a nongovernmental person agrees to purchase all or part of its output requirements is taken into account under the private business tests only to the extent that, based on all the facts and circumstances, the contract meets the benefits and burdens test. See § 1.141–15T(f)(2) for special effective dates for the application of this paragraph (c)(4) to issues financing facilities subject to requirements contracts.

(ii) *Significant factors.* Significant factors that tend to establish that the benefits and burdens test is met under the rule set forth in paragraph (c)(4)(i) of this section include, but are not limited to—

(A) The purchaser's customer base has significant indicators of stability, such as large size, diverse composition, and a substantial residential component;

(B) The contract covers historical requirements of the purchaser, rather than only projected requirements that are in addition to historical requirements; and

(C) The purchaser agrees not to construct or acquire other power resources to meet the requirements covered by the contract.

(iii) *Special rule for retail requirements contracts.* In general, a requirements contract that is not a sale at wholesale (a *retail requirements contract*) does not meet the benefits and burdens test because the obligation to make payments on the contract is contingent on the output requirements of a single user. Such a requirements contract in general meets the benefits and burdens test, however, to the extent that it contains contractual terms that obligate the purchaser to make payments that are not contingent on the output requirements of the purchaser or that obligate the purchaser to have output requirements. For example, a requirements contract with an industrial purchaser meets the benefits and burdens test if the purchaser enters into additional contractual obligations with the issuer or another governmental unit not to cease operations. A retail requirements contract does not meet the benefits and burdens test by reason of a provision that requires the purchaser to pay reasonable and customary damages (including liquidated damages) in the event of a default, or a provision that permits the purchaser to pay a specified amount to terminate the contract while the purchaser has requirements, in each case if the amount of the payment is reasonably related to the purchaser's obligation to buy requirements that is discharged by the payment.

(5) *Output contract properly characterized as a lease.* Notwithstanding any other provision of this section, an output contract that is properly characterized as a lease for Federal income tax purposes shall be tested under the rules contained in §§ 1.141–3 and 1.141–4 to determine whether it is taken into account under the private business tests.

(d) *Measurement of private business use.* If an output contract results in private business use under this section, the amount of private business use generally is the amount of output purchased under the contract.

(e) *Measurement of private security or payment.* The measurement of payments made or to be made by nongovernmental persons under output contracts as a percent of the debt service of an issue is determined under the rules provided in § 1.141–4.

(f) *Exceptions for certain contracts*—(1) *Small purchases of output.* An output contract is not taken into account under the private business tests if the average annual payments under the contract that are substantially certain to be made under paragraph (c)(2)(ii) of this section do not exceed 0.5 percent of the average annual debt service on all outstanding tax-exempt bonds issued to finance the facility, determined as of the effective date of the contract.

(2) *Swapping and pooling arrangements.* An agreement that provides for swapping or pooling of output by one or more governmental persons and one or more nongovernmental persons does not result in private business use of the output facility owned by the governmental person to the extent that—

(i) The swapped output is reasonably expected to be approximately equal in value (determined over periods of one year or less); and

(ii) The purpose of the agreement is to enable each of the parties to satisfy different peak load demands, to accommodate temporary outages, to diversify supply, or to enhance reliability in accordance with prudent reliability standards.

(3) *Short-term output contracts.* An output contract with a nongovernmental person is not taken into account under the private business tests if—

(i) The term of the contract, including all renewal options, is not longer than 1 year;

(ii) The contract either is a negotiated, arm's-length arrangement that provides for compensation at fair market value, or is based on generally applicable and uniformly applied rates; and

(iii) The output facility is not financed for a principal purpose of providing that facility for use by that nongovernmental person.

(4) *Special 3-year exception for sales of output attributable to excess generating capacity resulting from participation in open access.* The purchase of output of an electric generating facility by a nongovernmental person is not treated as private business use if all of the following requirements are met:

(i) The term of the contract is not longer than 3 years, including all renewal options.

(ii) The issuer does not make expenditures to increase the generating capacity of its system during the term of the contract that are, or will be, financed with proceeds of tax-exempt bonds (other than expenditures for property that does not increase the generating capacity of the system by more than 3 percent).

(iii) The governmental owner offers non-discriminatory, open access transmission tariffs for use of its transmission system pursuant to rules promulgated by the FERC under sections 205 and 206 of the Federal Power Act (16 U.S.C. 824d and 824e) (or comparable provisions of state law).

(iv) All of the output sold under the contract is attributable to excess capacity resulting from the offer of the non-discriminatory, open access transmission tariffs referred to in paragraph (f)(5)(iii) of this section.

(v) All payments received by the governmental owner under the contract (other than the portion of such payments described in § 1.141–4(c)(2)(C)) are applied as promptly as is reasonably practical to redeem tax-exempt bonds that financed the output facility in a manner consistent with § 1.141–12.

(5) *Special exceptions for transmission facilities*—(i) *Mandated wheeling.* Entering into a contract for the use of transmission facilities financed by an issue is not treated as a deliberate action under § 1.141–2(d) if—

(A) The contract is entered into in response to (or in anticipation of) an order by the United States under sections 211 and 212 of the Federal Power Act (16 U.S.C. 824j and 824k) (or a state regulatory authority under comparable provisions of state law); and

(B) The terms of the contract are bona fide and arm's length, and the consideration paid is consistent with the provisions of section 212(a) of the Federal Power Act.

(ii) *Actions taken to implement non-discriminatory, open access.* An action is not treated as a deliberate action under § 1.141–2(d) if it is taken to implement the offering of non-discriminatory, open access tariffs for the use of transmission facilities financed by an issue in a manner consistent with rules promulgated by the FERC under sections 205 and 206 of the Federal Power Act (16 U.S.C. 824d and 824e) (or comparable provisions of state law). This paragraph (f)(5)(ii) does not apply, however, to the sale, exchange, or other disposition of transmission facilities to a nongovernmental person.

(iii) *Application of reasonable expectations test to certain current refunding bonds.* An action taken or to be taken with respect to transmission facilities refinanced by an issue is not taken into account under the reasonable expectations test of § 1.141–2(d) if—

(A) The action is described in paragraph (f)(5)(i) or (ii) of this section;

(B) The bonds of the issue are current refunding bonds that, directly or indirectly, refund bonds originally issued before February 23, 1998; and

(C) The weighted average maturity of the refunding bonds is not greater than the remaining weighted average maturity of those prior bonds.

(6) *Certain conduit parties disregarded.* A nongovernmental person acting solely as a conduit for the exchange of output among governmentally owned and operated utilities is disregarded in determining whether the private business tests are met with respect to financed facilities owned by a governmental person. Use of property by a power marketer in the trade or business of purchasing and reselling power, however, is taken into account under the private business tests.

(g) *Allocations of output facilities and systems*—(1) *Facts and circumstances analysis.* Whether output sold under an output contract is allocated to a particular facility (for example, a generating unit), to the entire system of the seller of that output (net of any uses of that system output allocated to a particular facility), or to a portion of a facility is based on all the facts and circumstances. Significant factors to be considered in determining the allocation of an output contract to financed property are the following:

(i) The extent to which it is physically possible to deliver output to or from a particular facility or system.

(ii) The terms of a contract relating to the delivery of output (such as delivery limitations and options or obligations to deliver power from additional sources).

(iii) Whether a contract is entered into as part of a common plan of financing for a facility.

(iv) The method of pricing output under the contract, such as the use of market rates rather than rates designed to pay debt service of tax-exempt bonds used to finance a particular facility.

(2) *Illustrations.* The following illustrate the factors set forth in paragraph (g)(1) of this section:

(i) *Physical possibility.* Output from a generating unit that is fed directly into a low voltage distribution system of the owner of that unit and that cannot physically leave that distribution system generally must be allocated to those receiving electricity through that distribution system. Output may be allocated without regard to physical limitations, however, if exchange or similar agreements provide output to a purchaser where, but for the exchange agreements, it would not be possible for the seller to provide output to that purchaser.

(ii) *Contract terms relating to performance.* A contract to provide a specified amount of electricity from a system, but only when at least that amount of electricity is being generated by a particular unit, is allocated to that unit. For example, a contract to buy 20 MW of system power with a right to take up to 40 percent of the actual output of a specific 50 MW facility whenever total system output is insufficient to meet all of the seller's obligations generally is allocated to the specific facility rather than to the system.

(iii) *Common plan of financing.* A contract entered into as part of a common plan of financing for a facility generally is allocated to the facility if debt service for the issue of bonds is reasonably expected to be paid, directly or indirectly, from payments substantially certain to be made under the contract (disregarding default, insolvency, or other similar circumstances).

(iv) *Pricing method.* Pricing based on the capital and generating costs of a particular turbine tends to indicate that output under the contract is properly allocated to that turbine.

(3) *Transmission contracts.* Whether use under an output contract for transmission is allocated to a particular facility or to a transmission network is based on all the facts and circumstances, in a manner similar to paragraphs (g)(1) and (2) of this section. In general, the method used to determine payments under a contract is a more significant contract term for this purpose than nominal contract path. In general, if reasonable and consistently applied, the determination of use of transmission facilities under an output contract may be based on a method used by third parties, such as reliability councils.

(4) *Allocation of payments.* Payments for output provided by an output facility financed with two or more sources of

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funding are generally allocated under the rules in § 1.141–4(c).

(h) *Examples.* The following examples illustrate the application of this section:

Example 1. Joint ownership. Z, an investor-owned electric utility, and City H agree to construct an electric generating facility of a size sufficient to take advantage of the economies of scale. H will issue $50 million of its 24-year bonds, and Z will use $100 million of its funds for construction of a facility they will jointly own as tenants in common. Each of the participants will share in the ownership, output, and operating expenses of the facility in proportion to its contribution to the cost of the facility, that is, one-third by H and two-thirds by Z. H's bonds will be secured by H's ownership interest in the facility and by revenues to be derived from its share of the annual output of the facility. H will need only 50 percent of its share of the annual output of the facility during the first 20 years of operations. It agrees to sell 10 percent of its share of the annual output to Z for a period of 20 years pursuant to a contract under which Z agrees to take that power if available. The facility will begin operation, and Z will begin to receive power, 4 years after the H bonds are issued. The measurement period for the property financed by the issue is 20 years. H also will sell the remaining 40 percent of its share of the annual output to numerous other private utilities under contracts of one year or less that satisfy the exception under paragraph (f)(3) of this section. No other contracts will be executed obligating any person to purchase any specified amount of the power for any specified period of time. No person (other than Z) will make payments substantially certain to be made (disregarding default, insolvency, or other similar circumstances) under paragraph (c)(2) of this section that will result in a transfer of substantial burdens of paying debt service on bonds used directly or indirectly to provide H's share of the facilities. The bonds are not private activity bonds, because H's one-third interest in the facility is not treated as used by the other owners of the facility. Although 10 percent of H's share of the annual output of the facility will be used in the trade or business of Z, a nongovernmental person, under this section, that portion constitutes not more than 10 percent of the available output of H's ownership interest in the facility.

Example 2. Requirements contract treated as take contract. (i) City J issues 20-year bonds to acquire an electric generating facility having a reasonably expected economic life substantially greater than 20 years and a nameplate capacity of 100 MW. The available output of the facility under paragraph (b)(1) of this section is approximately 17,520,000 MWh (100 MW × 24 hours × 365 days × 20 years). On the issue date, J enters into a contract with T, an investor-owned utility, to provide T with all of its power requirements for a period of 10 years, commencing on the issue date. J reasonably expects that T will actually purchase an average of 30 MW over the 10-year period. Based on all of the facts and circumstances, including the size, diversity, and composition of T's customer base, J reasonably expects that it is substantially certain (disregarding default, insolvency, or other similar circumstances) that T will actually purchase only an average of 26 MW over the 10-year period. The contract is a requirements contract that must be taken into account under the private business tests pursuant to paragraph (c)(4) of this section because it provides T with substantial benefits of ownership (rights to capacity) and obligates T with substantial burdens of making payments that the issuer reasonably expects are substantially certain.

(ii) Under paragraph (d) of this section, the amount of reasonably expected private business use under this contract is approximately 15 percent (30 MW × 24 hours × 365 days × 10 years, or 2,628,000 MWh) of the available output. Accordingly, the issue meets the private business use test. J reasonably expects that the amount to be paid for an average of 26 MW of power (less the operation and maintenance costs directly attributable to generating that 26 MW of power), will be more than 10 percent of debt service on the issue on a present-value basis. The payment for 26 MW of power is an amount that J reasonably expects is substantially certain to be made under paragraph (c)(2) of this section. Accordingly, the issue meets the private security or payment test because J reasonably expects that it is substantially certain that payment of more than 10 percent of the debt service will be indirectly derived from payments by T. The bonds are private activity bonds under paragraph (c) of this section. Further, if 15 percent of the sale proceeds of the issue is greater than $15 million and the issue meets the private security or payment test with respect to the $15 million output limitation, the bonds are also private activity bonds under section 141(b)(4). See § 1.141–7T.

Example 3. Allocation of existing contracts to new facilities. Power Authority K, a political subdivision created by the legislature in State × to own and operate certain power generating facilities, sells all of the power from its existing facilities to four private utility systems under contracts executed in 1999, under which the four systems are required to take or pay for specified portions of the total power output until the year 2029. Existing facilities supply all of the present needs of the four utility systems, but their future power requirements are expected to increase substantially beyond the capacity of K's current generating system. K issues 20-year bonds in 2004 to construct a large generating facility. As part of the financing plan for the bonds, a fifth private utility system contracts with K to take or pay for 15 percent of the available output of the new facility. The balance of the output of the new facility will be available for sale as required, but initially it is not anticipated that there will be any need for that power. The revenues from the contract with the fifth private utility system will be sufficient to pay less than 10 percent of the debt service on the bonds (determined on a present value basis). The balance, which will exceed 10 percent of the debt service on the bonds, will be paid from revenues derived from the contracts with the four systems initially from sale of power produced by the old facilities. The output contracts with all the private utilities are allocated to K's entire generating system. See paragraphs (g)(1) and (2) of this section. Thus, the bonds meet the private business use test because more than 10 percent of the proceeds will be used in the trade or business of a nongovernmental person. In addition, the bonds meet the private security or payment test because payment of more than 10 percent of the debt service, pursuant to underlying arrangements, will be derived from payments in respect of property used for a private business use.

Example 4. Allocation to displaced resource. Municipal utility MU, a political subdivision, purchases all of the electricity required to meet the needs of its customers (1,000 MW) from B, an investor-owned utility that operates its own electric generating facilities, under a 50-year take or pay contract. MU does not anticipate that it will require additional electric resources, and any new resources would produce electricity at a higher cost to MU than its cost under its contract with B. Nevertheless, B encourages MU to construct a new generating plant sufficient to meet MU's requirements. MU issues obligations to construct facilities that will produce 1,000 MW of electricity. MU, B, and I, another investor-owned utility, enter into an agreement under which MU assigns to I its rights under MU's take or pay contract with B. Under this arrangement, I will pay MU, and MU will continue to pay B, for the 1,000 MW. I's payments to MU will at least equal the amounts required to pay debt service on MU's bonds. In addition, under paragraph (g)(1)(iii) of this section, the contract among MU, B, and I is entered into as part of a common plan of financing of the MU facilities. Under all the facts and circumstances, MU's assignment to I of its rights under the original take or pay contract is allocable to MU's new facilities under paragraph (g) of this section. Because I is a nongovernmental person, MU's bonds are private activity bonds.

Example 5. Transmission facilities transferred to regional transmission organization. (i) In 2001, the public utilities commission of State C adopts a plan for restructuring its electric power industry. The plan fosters competition by providing both wholesale and retail customers with non-discriminatory access to transmission facilities within the State. The plan provides that investor-owned utilities will transfer operating control over all of their transmission assets to a regional transmission organization (RTO), which is a nongovernmental person that will operate those combined assets as a single, state-wide system. Municipally-owned utilities are eligible for, but are not required to participate in, the open access system implemented by the RTO. The functions of the RTO include control of transmission access and pricing, scheduling transmission, control area operations, and settlements and billing. The RTO's compensation under its operating agreement with transmission owners is based on a share of net profits from operating the facilities. The restructuring plan is approved by the FERC pursuant to sections 205 and 206 of the Federal Power Act.

(ii) In 1994, City D had issued bonds to finance improvements to its transmission system. In 2001, D transfers operating control of its transmission system to the RTO pursuant to the restructuring plan. At the same time, D chooses to apply the private activity bond regulations of §§ 1.141–1 through 1.141–15 to the 1994 bonds. The operation of the financed facilities by the RTO results in private business use under § 1.141–3. Under the special exception in paragraph (f)(5) of this section, however, the transfer of control is not treated as a deliberate action. Accordingly, the transfer of control does not cause the 1994 bonds to meet the private activity bond tests.

Example 6. Current refunding. The facts are the same as in Example 5 of this paragraph (h), and in addition D issues bonds in 2003 to currently refund the 1994 bonds. The weighted average maturity of the 2003 bonds is not greater than the remaining weighted average maturity of the 1994 bonds. D chooses to apply the private activity bond regulations of §§ 1.141–1 through 1.141–15 to the refunding bonds. In general, reasonable expectations must be separately tested on the date that refunding bonds are issued under § 1.141–2(d). Under the special exception in paragraph (f)(5) of this section, however, the transfer of the financed facilities to the RTO need not be taken into account in applying the reasonable expectations test to the refunding bonds.

Par. 4. Section 1.141–8T is revised to read as follows:

§ 1.141–8T $15 million limitation for output facilities (temporary).

(a) *In general*—(1) *General rule.* Section 141(b)(4) provides a special private activity bond limitation (the $15 million output limitation) for issues 5 percent or more of the proceeds of which are to be used to finance output facilities (other than a facility for the furnishing of water). Under this rule, an issue consists of private activity bonds under the private business tests of section 141(b)(1) and (2) if the nonqualified amount with respect to output facilities financed by the proceeds of the issue exceeds $15 million. The $15 million output limitation applies in addition to the private business tests of section 141(b)(1) and (2). Under section 141(b)(4) and paragraph (a)(2) of this section, the $15 million output limitation is reduced in certain cases. Specifically, an issue meets the test in section 141(b)(4) if both of the following tests are met:

(i) More than $15 million of the proceeds of the issue to be used with respect to an output facility are to be used for a private business use. Investment proceeds are disregarded for this purpose if they are not allocated disproportionately to the private business use portion of the issue.

(ii) The payment of the principal of, or the interest on, more than $15 million of the sales proceeds of the portion of the issue used with respect to an output facility is (under the terms of the issue or any underlying arrangement) directly or indirectly—

(A) Secured by any interest in an output facility used or to be used for a private business use (or payments in respect of such an output facility); or

(B) To be derived from payments (whether or not to the issuer) in respect of an output facility used or to be used for a private business use.

(2) *Reduction in $15 million output limitation for outstanding issues*—(i) *General rule.* In determining whether an issue 5 percent or more of the proceeds of which are to be used with respect to an output facility consists of private activity bonds under the $15 million output limitation, the $15 million limitation on private business use and private security or payments is applied by taking into account the aggregate nonqualified amounts of any outstanding bonds of other issues 5 percent or more of the proceeds of which are or will be used with respect to that output facility or any other output facility that is part of the same project.

(ii) *Bonds taken into account.* For purposes of this paragraph (a)(2), in applying the $15 million output limitation to an issue (the later issue), a tax-exempt bond of another issue (the earlier issue) is taken into account if—

(A) That bond is outstanding on the issue date of the later issue;

(B) That bond will not be redeemed within 90 days of the issue date of the later issue in connection with the refunding of that bond by the later issue; and

(C) 5 percent or more of the sale proceeds of the earlier issue financed an output facility that is part of the same project as the output facility that is financed by 5 percent or more of the sale proceeds of the later issue.

(3) *Benefits and burdens test applicable*—(i) *In general.* In applying the $15 million output limitation, the benefits and burdens test of § 1.141–7T applies, except that "$15 million" is substituted for "10 percent", or "5 percent" as appropriate.

(ii) *Earlier issues for the project.* If bonds of an earlier issue are outstanding and must be taken into account under paragraph (a)(2) of this section, the nonqualified amount for that earlier issue is multiplied by a fraction, the numerator of which is the adjusted issue price of the earlier issue as of the issue date of the later issue, and the denominator of which is the issue price of the earlier issue. Pre-issuance accrued interest as defined in § 1.148–1(b) is disregarded for this purpose.

(b) *Definition of project*—(1) *General rule.* For purposes of paragraph (a)(2) of this section, *project* has the meaning provided in this paragraph. Facilities that are functionally related and subordinate to a project are treated as part of that same project. Facilities having different purposes or serving different customer bases are not ordinarily part of the same project. For example, the following are generally not part of the same project—

(i) Generation and transmission facilities;

(ii) Separate facilities designed to serve wholesale customers and retail customers; and

(iii) A peaking unit and a baseload unit.

(2) *Separate ownership.* Except as otherwise provided in this paragraph (b)(2), facilities that are not owned by the same person are not part of the same project. If different governmental persons act in concert to finance a project, however (for example as participants in a joint powers authority), their interests are aggregated with respect to that project to determine whether the $15 million output limitation is met. In the case of undivided ownership interests in a single output facility, property that is not owned by different persons is treated as separate projects only if the separate interests are financed—

(i) With bonds of different issuers; and

(ii) Without a principal purpose of avoiding the limitation in this section.

(3) *Generating property*—(i) *Property on same site.* In the case of generation and related facilities, *project* means property located at the same site.

(ii) *Special rule for generating units.* Separate generating units are not part of the same project if one unit is reasonably expected, on the issue date of each issue that finances the units, to be placed in service more than 3 years before the other. Common facilities or property that will be functionally related to more than one generating unit must be allocated on a reasonable basis. If a generating unit already is constructed or is under construction (the first unit) and bonds are to be issued to finance an additional generating unit (the second unit), all costs for any common facilities paid or incurred before the earlier of the issue date of bonds to finance the second unit or the commencement of construction of the second unit are allocated to the first unit. At the time that bonds are issued to finance the second unit (or, if earlier, upon commencement of construction of

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that unit), any remaining costs of the common facilities may be allocated between the first and second units so that in the aggregate the allocation is reasonable.

(4) *Transmission.* In the case of transmission facilities, *project* means functionally related or contiguous property. Separate transmission facilities are not part of the same project if one facility is reasonably expected, on the issue date of each issue that finances the facilities, to be placed in service more than 2 years before the other.

(5) *Subsequent improvements*—(i) *In general.* An improvement to generating or transmission facilities that is not part of the original design of those facilities (the original project) is not part of the same project as the original project if the construction, reconstruction, or acquisition of that improvement commences more than 3 years after the original project was placed in service and the bonds issued to finance that improvement are issued more than 3 years after the original project was placed in service.

(ii) *Special rule for transmission facilities.* An improvement to transmission facilities that is not part of the original design of that property is not part of the same project as the original project if the issuer did not reasonably expect the need to make that improvement when it commenced construction of the original project and the construction, reconstruction, or acquisition of that improvement is mandated by the federal government or a state regulatory authority to accommodate requests for wheeling.

(6) *Replacement property.* For purposes of this section, property that replaces existing property of an output facility is treated as part of the same project as the replaced property unless—

(i) The need to replace the property was not reasonably expected on the issue date or the need to replace the property occurred more than 3 years before the issuer reasonably expected (determined on the issue date of the bonds financing the property) that it would need to replace the property; and

(ii) The bonds that finance (and refinance) the output facility have a weighted average maturity that is not greater than 120 percent of the reasonably expected economic life of the facility.

(c) *Example.* The application of the provisions of this section is illustrated by the following example:

Example. (i) Power Authority K, a political subdivision, intends to issue a single issue of tax-exempt bonds at par with a stated principal amount and sale proceeds of $500 million to finance the acquisition of an electric generating facility. No portion of the facility will be used for a private business use, except that L, an investor-owned utility, will purchase 10 percent of the output of the facility under a take contract and will pay 10 percent of the debt service on the bonds. The nonqualified amount with respect to the bonds is $50 million.

(ii) The maximum amount of tax-exempt bonds that may be issued for the acquisition of an interest in the facility in paragraph (i) of this *Example* is $465 million (that is, $450 million for the 90 percent of the facility that is governmentally owned and used plus a nonqualified amount of $15 million).

Par. 5. Section 1.141–15 is amended by revising paragraphs (c), (d) and (e) to read as follows:

§ 1.141–15 Effective dates.

* * * * *

(c) *Refunding bonds.* Sections 1.141–1 through 1.141–6(a), 1.141–9 through 1.141–14, 1.145–1 through 1.145–2, 1.150–1(a)(3) and the definition of bond documents contained in § 1.150–1(b) do not apply to any bonds issued on or after May 16, 1997, to refund a bond to which those sections do not apply unless—

(1) The refunding bonds are subject to section 1301 of the Tax Reform Act of 1986 (100 Stat. 2602); and

(2)(i) The weighted average maturity of the refunding bonds is longer than—

(A) The weighted average maturity of the refunded bonds; or

(B) In the case of a short-term obligation that the issuer reasonably expects to refund with a long-term financing (such as a bond anticipation note), 120 percent of the weighted average reasonably expected economic life of the facilities financed; or

(ii) A principal purpose for the issuance of the refunding bonds is to make one or more new conduit loans.

(d) *Permissive application of regulations.* Except as provided in paragraph (e) of this section, §§ 1.141–1 through 1.141–6(a), 1.141–9 through 1.141–14, 1.145–1 through 1.145–2, 1.150–1(a)(3) and the definition of bond documents contained in § 1.150–1(b) may be applied in whole, but not in part, to actions taken before February 23, 1998, with respect to—

(1) Bonds that are outstanding on May 16, 1997, and subject to section 141; or

(2) Refunding bonds issued on or after May 16, 1997 that are subject to section 141.

(e) *Permissive application of certain sections.* The following sections may each be applied to any bonds—

(1) Section 1.141–3(b)(4);

(2) Section 1.141–3(b)(6); and

(3) Section 1.141–12.

Par. 6. Section 1.141–15T is revised to read as follows:

§ 1.141–15T Effective dates (temporary).

(a) through (e) [Reserved]. For further guidance see § 1.141–15.

(f) *Effective dates for certain regulations relating to output facilities*—(1) *General rule.* Except as otherwise provided in this section, §§ 1.141–7T and 1.141–8T apply to bonds sold on or after January 19, 2001, that are subject to section 1301 of the Tax Reform Act of 1986 (100 Stat. 2602).

(2) *Transition rule for requirements contracts.* For bonds otherwise subject to §§ 1.141–7T and 1.141–8T, § 1.141–7T(c)(4) applies to output contracts entered into on or after February 23, 1998. An output contract is treated as entered into on or after that date if its term is extended, the parties to the contract change, or other material terms are amended on or after that date. For purposes of this paragraph (f)(2)—

(i) The extension of the term of a contract causes the contract to be treated as entered into on the first day of the additional term;

(ii) The exercise by a party of a legally enforceable right that was provided under a contract before February 23, 1998, on terms that were fixed and determinable before such date, is not treated as an amendment of the contract. For example, the exercise by a purchaser after February 23, 1998 of a renewal option that was provided under a contract before that date, on terms identical to the original contract, is not treated as an amendment of the contract; and

(iii) An amendment that reduces the term of a contract, or the amount of requirements covered by a contract, is not, in and of itself, material.

(3) *Elective application of 1998 temporary regulations.* For an issue sold on or after January 19, 2001, and before February 15, 2001, an issuer may apply the provisions of §§ 1.141–7T and 1.141–8T in effect prior to January 19, 2001 (26 CFR part 1, revised April 1, 2000) in whole, but not in part, in lieu of applying §§ 1.141–7T and 1.141–8T.

(g) *Refunding bonds in general.* Except as otherwise provided in paragraph (h) or (i) of this section, §§ 1.141–7T and 1.141–8T do not apply to any bonds sold on or after January 19, 2001, to refund a bond to which §§ 1.141–7T and 1.141–8T do not apply unless—

(1) The refunding bonds are subject to section 1301 of the Tax Reform Act of 1986 (100 Stat. 2602); and

(2)(i) The weighted average maturity of the refunding bonds is longer than—

(A) The weighted average maturity of the refunded bonds; or

(B) In the case of a short-term obligation that the issuer reasonably expects to refund with a long-term financing (such as a bond anticipation note), 120 percent of the weighted average reasonably expected economic life of the facilities financed; or

(ii) A principal purpose for the issuance of the refunding bonds is to make one or more new conduit loans.

(h) *Permissive retroactive application.* Except as provided in § 1.141–15(d) or (e) or paragraph (i) of this section, §§ 1.141–1 through 1.141–6, 1.141–7T through 1.141–8T, 1.141–9 through 1.141–14, 1.145–1 through 1.145–2, 1.150–1(a)(3) and the definition of bond documents contained in § 1.150–1(b) may be applied in whole, but not in part to—

(1) Outstanding bonds that are sold before January 19, 2001, and subject to section 141; or

(2) Refunding bonds sold on or after January 19, 2001, that are subject to section 141.

(i) *Permissive application of certain regulations pertaining to output contracts.* Section 1.141–7T(f)(4) and (5) may be applied to any bonds.

Par. 7. Section 1.142(f)(4)–1 is added to read as follows:

§ 1.142(f)(4)–1 Manner of making election to terminate tax-exempt bond financing.

(a) *Overview.* Section 142(f)(4) permits a person engaged in the local furnishing of electric energy or gas (a local furnisher) that uses facilities financed with exempt facility bonds under section 142(a)(8) and that expands its service area in a manner inconsistent with the requirements of sections 142(a)(8) and (f) to make an election to ensure that those bonds will continue to be treated as exempt facility bonds. The election must meet the requirements of paragraphs (b) and (c) of this section.

(b) *Time for making election*—(1) *In general.* An election under section 142(f)(4)(B) must be filed with the Internal Revenue Service on or before 90 days after the date of the service area expansion that causes bonds to cease to meet the requirements of sections 142(a)(8) and (f).

(2) *Date of service area expansion.* For the purposes of this section, the date of the service area expansion is the first date on which the local furnisher is authorized to collect revenue for the provision of service in the expanded area.

(c) *Manner of making election.* An election under section 142(f)(4)(B) must be captioned "ELECTION TO TERMINATE TAX-EXEMPT BOND FINANCING", must be signed under penalties of perjury by a person who has authority to sign on behalf of the local furnisher, and must contain the following information—

(1) The name of the local furnisher;

(2) The tax identification number of the local furnisher;

(3) The complete address of the local furnisher;

(4) The date of the service area expansion;

(5) Identification of each bond issue subject to the election, including the complete name of each issue, the tax identification number of each issuer, the report number of the information return filed under section 149(e) for each issue, the issue date of each issue, the CUSIP number (if any) of the bond with the latest maturity of each issue, the issue price of each issue, the adjusted issue price of each issue as of the date of the election, the earliest date on which the bonds of each issue may be redeemed, and the principal amount of bonds of each issue to be redeemed on the earliest redemption date;

(6) A statement that the local furnisher making the election agrees to the conditions stated in section 142(f)(4)(B); and

(7) A statement that each issuer of the bonds subject to the election has received written notice of the election.

(d) *Effect on section 150(b).* Except as provided in paragraph (e) of this section, if a local furnisher files an election within the period specified in paragraph (b) of this section, section 150(b) does not apply to bonds identified in the election during and after that period.

(e) *Effect of failure to meet agreements.* If a local furnisher fails to meet any of the conditions stated in an election pursuant to paragraph (c)(6) of this section, the election is invalid.

(f) *Corresponding provisions of the Internal Revenue Code of 1954.* Section 103(b)(4)(E) of the Internal Revenue Code of 1954 set forth corresponding requirements for the exclusion from gross income of the interest on bonds issued for facilities for the local furnishing of electric energy or gas. For the purposes of this section any reference to sections 142(a)(8) and (f) of the Internal Revenue Code of 1986 includes a reference to the corresponding portion of section 103(b)(4)(E) of the Internal Revenue Code of 1954.

(g) *Effective dates.* This section applies to elections made on or after January 19, 2001.

§ 1.142(f)(4)–1T [Removed]

Par. 8. Section 1.142(f)(4)–1T is removed.

Par. 9. Section 1.150–5 is added to read as follows:

§ 1.150–5 Filing notices and elections.

(a) *In general.* Notices and elections under the following sections must be filed with the Internal Revenue Service, 1111 Constitution Avenue, NW, Attention: T:GE:TEB:O, Washington, DC 20224 or such other place designated by publication of a notice in the Internal Revenue Bulletin—

(1) Section 1.141–12(d)(3);

(2) Section 1.142(f)(4)–1; and

(3) Section 1.142–2(c)(2).

(b) *Effective dates.* This section applies to notices and elections filed on or after January 19, 2001.

§ 1.150–5T [Removed]

Par. 10. Section 1.150–5T is removed.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 11. The authority for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 12. In § 602.101, paragraph (b) is amended by adding an entry in numerical order to the table to read as follows:

§ 602.101 OMB control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.142(f)(4)–1	1545–1730
* * * * *	

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: January 10, 2001.

Jonathan Talisman,

Assistant Secretary of the Treasury.

[FR Doc. 01–1412 filed 1–17–01; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 931

[NM–041–FOR]

New Mexico Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule, approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is

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approving a proposed amendment to the New Mexico regulatory program (hereinafter, the "New Mexico program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). New Mexico proposed to recodify the New Mexico Surface Coal Mining Regulations. The amendment revised the State program to improve operational efficiency and ensure that the New Mexico Surface Coal Mining Regulations were codified according to the New Mexico administrative rules.

EFFECTIVE DATE: January 18, 2001.

FOR FURTHER INFORMATION CONTACT: Willis L. Gainer, Telephone: (505) 248–5096, Internet address: WGAINER@SMRE.GOV.

SUPPLEMENTARY INFORMATION:

I. Background on the New Mexico Program

On December 31, 1980, the Secretary of the Interior conditionally approved the New Mexico program. General background information on the New Mexico program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the New Mexico program can be found in the December 31, 1980, **Federal Register** (45 FR 86459). Subsequent actions concerning New Mexico's program and program amendments can be found at 30 CFR 931.11, 931.15, 931.16, and 931.30.

II. Proposed Amendment

By letter dated September 22, 2000, New Mexico submitted a proposed amendment to its program (administrative record No. NM–840) pursuant to SMCRA (30 U.S.C. 1201 *et seq.*). New Mexico submitted the proposed amendment at its own initiative. New Mexico proposed to recodify the New Mexico Surface Coal Mining Regulations.

OSM announced receipt of the proposed amendment in the October 23, 2000, **Federal Register** (65 FR 63223), provided an opportunity for a public hearing or meeting on its substantive adequacy, and invited public comment on its adequacy (administrative record No. NM–842). Because no one requested a public hearing or meeting, none was held. The public comment period ended on November 22, 2000.

III. Director's Findings

As discussed below, the Director, in accordance with SMCRA and 30 CFR 732.15 and 732.17, finds that the proposed program amendment, submitted by New Mexico on September 22, 2000, is no less effective than the corresponding Federal regulations and no less stringent than SMCRA. Accordingly, the Director approves the proposed amendment.

Minor Revisions to New Mexico's Rules

New Mexico proposed recodification of previously-approved New Mexico Surface Coal Mining Regulations including revisions that are minor in nature, consisting of minor wording, editorial and punctuation changes. Specifically, New Mexico proposed to recodify its regulations from Title 19 (Natural Resources and Wildlife), Chapter 8, (Coal Mining), Part 2 (Coal Surface Mining) of the New Mexico Administrative Code (19 NMAC 8.2), Subparts 1 through 34 to Title 19 (Natural Resources and Wildlife), Chapter 8, (Coal Mining) of the New Mexico Administrative Code (19.8 NMAC), Parts 1 through 34. In addition to the renumbering and reformatting, New Mexico proposed to revise the history references after each section and added to the rule history at the end of each part. No substantive changes to the text of the regulations were proposed.

Because the proposed revisions to these previously-approved rules are minor in nature, the Director finds that these proposed New Mexico rules are no less effective than the Federal regulations at Title 30 (Mineral Resources), Chapter VII (Office of Surface Mining Reclamation and Enforcement, Department of the Interior), Parts 700 through 887. The Director approves the proposed recodification of New Mexico's rules.

IV. Summary and Disposition of Comments

Following are summaries of all substantive written comments on the proposed amendment that were received by OSM, and OSM's responses to them.

1. Public Comments

OSM invited public comments on the proposed amendment (administrative record Nos. NM–841 and NM–842), but none were received.

2. Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(i), OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the New Mexico program (administrative record No. NM–841). None were received.

3. Environmental Protection Agency (EPA) Concurrence and Comments

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to solicit the written concurrence of EPA with respect to those provisions of the proposed amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

None of the revisions that New Mexico proposed to make in its amendment pertain to air or water quality standards. Pursuant to 30 CFR 732.17(h)(11)(i), OSM solicited comments on the proposed amendment from EPA (administrative record No. NM–841). It did not respond to OSM's request.

4. State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Pursuant to 30 CFR 732.17(h)(4); OSM solicited comments on the proposed amendment from the SHPO and ACHP (administrative record No. NM–841). Neither SHPO nor ACHP responded to OSM's request.

V. Director's Decision

Based on the above finding, the Director approves New Mexico's proposed amendment as submitted on September 22, 2000.

The Federal regulations at 30 CFR part 931, codifying decisions concerning the New Mexico program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determination

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart federal regulation.

Executive Order 13132—Federalism

This rule does not have federalism implications. SMCRA delineates the rules of the federal and state governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that state laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and section 503(a)(7) requires that state programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: a. does not have an annual effect on the economy of $100 million; b. will not cause a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; and c. does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This determination is based upon the fact that the state submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates.

OSM has determined and certifies under the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on any local, State, or tribal governments or private entities.

List of Subjects in 30 CFR Part 931

Intergovernmental relations, Surface mining, Underground Mining.

Dated: January 3, 2001.

Brent T. Wahlquist,

Regional Director, Western Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 931—NEW MEXICO

1. The authority citation for part 931 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 931.15 is amended in the table by adding a new entry in chronological order by "Date of Final Publication" to read as follows:

§ 931.15 Approval of New Mexico regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
* * *	* * *	* * *
September 22, 2000	January 18, 2001	19.8 NMAC Parts 1 through 34 (recodification)

[FR Doc. 01–1474 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, and 485

[HCFA–3049–F]

RIN 0938–AK08

Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Anesthesia Services Condition of Participation (CoP) for hospitals, the Surgical Services Condition of Participation for Critical Access Hospitals (CAH), and the Ambulatory Surgical Center (ASC) Conditions of Coverage Surgical Services. This final rule changes the physician supervision requirement for certified registered nurse anesthetists furnishing anesthesia services in hospitals, CAHs, and ASCs. Under this final rule, State laws will determine which professionals are permitted to administer anesthetics and the level of supervision required, recognizing a State's traditional domain in establishing professional licensure and scope-of-practice laws. States and hospitals are free to establish additional standards for professional practice and oversight as they deem necessary.

The hospital anesthesia services CoP, CAH surgical services CoP, and the conforming change to the anesthesia Conditions of Coverage apply to all Medicare and Medicaid participating hospitals, CAHs, and ASCs.

EFFECTIVE DATE: These regulations are effective on March 19, 2001.

FOR FURTHER INFORMATION CONTACT:
Stephanie A. Dyson RN, BSN (410) 786–9226
Debbra M. Hattery RN, MS (410) 786–1855

SUPPLEMENTARY INFORMATION:

Copies

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I. Background

A. Legislation

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria for application for States establishing a Critical Access Hospital. Sections 1832(a)(2)(F)(i) and 1833(i) provide coverage requirements for ASCs. Section 1861(bb) of the Act, provides definitions for certified registered nurse anesthetists (CRNAs) and their services.

B. General

On December 19, 1997, we published the proposed rule, "Hospital Conditions of Participation, Provider Agreements and Supplier Approval," (62 FR 66726) in the **Federal Register**. This proposed rule generated over 60,000 public comments and approximately one-third of these comments addressed the proposed condition eliminating the Federal requirement for physician supervision of a licensed independent practitioner permitted by the State to administer anesthetics.

In 1997, when we proposed our changes to the current hospital conditions of participation (CoPs), we stated our desire to move toward standards that are patient-centered, evidence-based, and outcome oriented. We also stated that a fundamental principle was to facilitate flexibility in how a hospital meets our performance expectations, and eliminate structure and process requirements unless there is evidence that they are predictive of desired outcomes for patients. Where there is agreement on a structure or process requirement predictive of desired patient outcomes, we included that in our proposed rule. In fact, comments on the standard for physician supervision of CRNAs reflect a split between those who support flexibility in allowing States and hospitals to make decisions about anesthesia services and those who oppose the provision, supporting, instead, the structural requirement for physician supervision. We have already finalized the Organ Donation and Transplantation and Patients' Rights conditions, which were contained in the December 19, 1997 proposed hospital rule. We are now finalizing part of the anesthesia services standard describing anesthesia administration. We continue to work to finalize the other issues in the December 19, 1997 hospital conditions of participation proposed rule.

C. Need for Amended Anesthesia Services CoP

The existing hospital CoPs require hospitals, CAHs, and ASCs to provide quality care by adhering to our organizational and staffing requirements. The current hospital CoPs are not written in a way that promote or encourage a hospital, CAH, or ASC to assess the quality of care and improve patient outcomes. One of the clear messages we received from industry groups and professionals as we pursued this change in regulatory approach is that the old way of focusing on structure and process no longer represented current practice or the best available method to foster delivery of quality health care services.

Since publication of the December 19, 1997 proposed rule, we have continued to receive input from representatives of individual industry groups and have analyzed thousands of public comments from individual providers, beneficiaries, hospitals, and professional and provider organizations. We have given careful consideration to the scientific literature cited by commenters. We have found no compelling scientific evidence that an across-the-board Federal physician supervision requirement for CRNAs leads to better outcomes, or that there will be adverse outcomes by relying on State licensure laws instead.

We are also responding to considerable Congressional activity that has occurred since the 1997 publication of the proposed rule. Interest by Congress on both sides of the issue of physician supervision resulted in Appropriations Conference committee language in the Conference Report to the Balanced Budget Refinement Act (BBRA) of 1999 (H. Conf. Rep. No.106–479, at 873 (November 18, 1999)) urging the Secretary to determine whether there was sufficient information to move forward with a final rule. The literature we reviewed (see appendix) indicated that the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk.

There have been no studies published within the last 10 years demonstrating any need for Federal intervention in State professional practice laws governing CRNA practice. Currently, there is no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional. We believe there is no reason to change our proposed approach, which gives States and hospitals the flexibility to determine necessary oversight. We believe the change, based on the available information, appropriately reflects the important value of regulatory flexibility.

D. Recognizing State Laws and Professional Scope of Practice

Congress has specified which non-physician health professionals may receive separate payment for their professional services (such as CRNAs and nurse practitioners). In addition, Congress left the function of licensing these health professionals to the States. Medicare recognizes the scope of practice established by the States for these health professionals. Prior to this final rule, Medicare's hospital CoPs did not have Federal requirements for physicians to supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional, with the sole exception of the Federal requirement for physician supervision of CRNAs. We do not believe that there is evidence to support maintaining a special Federal requirement for physician supervision of CRNAs.

Eliminating the Federal requirement for physician supervision of CRNAs is not a judgment on our part that one health professional is better than another or that one type of care is superior. The change in regulatory approach reflected in this final rule was discussed in the preamble of the hospital CoPs proposed rule (62 FR 66740). This rule establishes a shared commitment to quality care among us, the States, and Medicare providers. Medicare providers are in the best position to assess the evidence and consider data relevant to their own situations (for example, physician access, hospital and patient characteristics and needs of rural areas) about the best way to deliver anesthesia care. Hospitals can always exercise stricter standards than required by State law. We will monitor the effects on the quality of anesthesia care furnished to Medicare beneficiaries resulting from the greater flexibility provided to States and hospitals under this rule.

II. Analysis of and Responses to Public Comments

We received approximately 20,000 comments on the issue of physician supervision of CRNA administration of anesthesia. Comments were largely split among CRNAs, representatives of rural areas, and supporters of State oversight who favor the proposal; and physicians who, in general, opposed the proposal and argued that anesthesia administration is the practice of medicine, requiring advanced medical education. A summary of the major issues and our responses follow:

State Law and Professional Scopes of Practice

Comment: The majority of comments focused on whether States' scope-of-practice laws are the proper level of regulatory oversight. Most physicians maintained that anesthesia is the practice of medicine which should only be practiced by a licensed physician, and opposed the provision permitting State licensed independent practitioners to administer anesthetics without physician supervision. These commenters argued that, because of disparities among the various States, laws are inconsistent and result in inequality of care across the country. As a result, they stated that Medicare beneficiaries would lose an important Federal guarantee for minimum standards of anesthesia care, and instead would be subjected to a variety of State laws. Conversely, other commenters argued that the Federal rule preempts State law, creating barriers to practice and limiting opportunity for nurse anesthetists licensed as independent practitioners. A physician supervision requirement, they asserted, diminishes the role of local jurisdictions and authorities that regulate and/or license other health professions and aspects of health service delivery. Commenters also stated that the current Federal requirement for physician supervision has been a disincentive for employers to hire CRNAs, decreasing flexibility and efficiency in anesthesia services, and limiting access in certain areas. One commenter wrote that it is the State that best understands its individual geographical, population, and financial needs and resources and how these resources can best be utilized to deliver safe, quality anesthesia services.

Response: We respect the authority of States to meet regional/local needs. Setting forth a final rule that allows States the ultimate determination regarding which licensed independent practitioners may administer anesthesia does not prohibit any State or hospital from requiring physician supervision. It will effectively provide greater discretion to State authorities that are experienced at regulating the licensing, education, training, and skills of the professionals practicing under their purview, without the burden associated with duplicative regulatory oversight. There is no evidence that States are less concerned with ensuring safety and quality than the Federal government, especially where the health of their citizens is at stake. We disagree that States are less capable or less committed to protecting patients and ensuring quality anesthesia services than the Federal government. The final rule removes the "across the board" Federal requirement for physician supervision in every case of anesthesia administration. At the same time, it broadens overall flexibility by permitting individuals and authorities closer to patient care delivery to make decisions about the best way to deliver health care services.

Comment: Some commenters were concerned that this change in regulatory approach would grant the right to practice medicine to individuals who were not properly prepared to do so. One commenter pointed out that we were giving unsupervised privileges to prescribe narcotics, paralytic agents, and cardiac drugs to people who have neither a medical license nor the training and credentialing that is associated with a medical license.

Response: States regulate professionals who may prescribe medicines as well as which medical procedures may be performed under a professional license through their professional practice laws. Our regulations do not determine prescribing authority or grant medical licenses, and this final rule does not change the traditional purview under which these professional scope-of-practice issues have occurred in the past. The final rule does not prohibit physicians from practicing medicine, nor does it allow nurse anesthetists to practice beyond the scope of their

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practice or authority granted them by States.

Comment: We received several comments from both physicians and nurse anesthetists in support of allowing physicians, hospitals, and surgical centers more responsibility for the care they furnished. Some commenters noted that the medical staffs within institutions should determine guidelines for supervision of all health care personnel contributing to the medical care of patients. Several commenters recognized the value of allowing hospital boards and medical staffs to set the standards of care. These commenters thought that relying on greater accountability from doctors and hospitals instead of Federal regulation would lead to better care for patients. Commenters noted that this rule would allow hospitals to set standards different from us, based on review and input from physicians and other health professionals. The American Hospital Association (AHA) also supported this rule change, stating "This new policy ensures that only personnel trained in administering anesthesia are allowed to do so. This requirement balances accountability with flexibility."

Response: We agree that providers have a shared responsibility, with us and the States, to assure quality standards of practice. We are pleased that the hospital industry recognizes the values of accountability and flexibility in Federal regulation. Allowing States to make determinations about health care professional standards of practice, and hospitals to make decisions regarding the delivery of care, assures that those closest to, and who know the most about, the health care delivery system are accountable for the outcomes of that care.

Comment: Several commenters stated that the administration of anesthesia has never been exclusively the practice of medicine. These commenters noted that anesthesia administration is within the scope of practice of nurses, physicians, dentists, podiatrists, and other professionals who have been properly educated and credentialed in the field of anesthesia. Since more surgical procedures are moving out of the hospital into clinic and office settings, an institution needs the flexibility to utilize the anesthesia professional of its choice which best matches the needs of the patient.

Response: Although this final rule governs anesthesia administration in hospital, CAH, and ASC settings only, we agree with the need for flexibility in other settings, especially as surgical techniques, methods for administering anesthesia and the availability of drugs is improved.

We believe that the range of patient types, surgical procedures, new technologies, and provider settings (for example, hospital outpatient departments, intensive care units, and teaching hospitals) makes an across-the-board Federal requirement overly burdensome. Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement is not applicable in every situation.

Comment: Several commenters objected to our arguments that eliminating CRNA supervision would, "allow greater flexibility to hospitals and practitioners" and would "give deference to State scope-of-practice laws". These commenters believe that our reasoning is weak, especially in the absence of documentation that either of these issues is a problem.

Response: We disagree with these commenters. As previously noted, we respect State control and oversight of health care professionals by deference to State licensing laws which regulate professional practice. There is no reason to consider physician supervision of CRNAs a special case requiring a national standard. Advances in anesthesia and surgical techniques, the availability and discovery of new drugs, and the varying medical presentations of patients make it less prudent to rely on a single national standard requiring physician supervision of CRNAs to be applied in every situation. Doing so risks losing the accountability of practitioners, both to make clinical decisions based on the needs of patients, and to utilize resources effectively. We believe States need flexibility from Federal oversight of those processes, such as professional licensing, for which they are ultimately accountable. In fact, it is at the State level where much direct input by health professionals into scope-of-practice and licensing laws takes place.

Comment: One commenter asked what rule would be operative in the absence of any State law.

Response: The final rule allows only a licensed practitioner permitted by the State to administer anesthetics to do so. Therefore, State health professional practice laws, such as those covering nurse and physician practice, as well as hospital licensing requirements, would be the basis for determining which health care professionals can administer anesthesia in any given State.

Safety and Quality of Care

Comment: Many of the commenters who wrote expressing concern over quality of anesthesia services referred to published research to support their point of view. For example, many commenters who support the proposed rule stated that evidence shows anesthesia administered by CRNAs to be as safe as that administered by anesthesiologists. In contrast, we also received comments from anesthesiologists who noted positive patient outcomes from anesthesia administration to be related to the presence of the anesthesiologist. The articles most frequently cited by commenters were three by Jeffrey Silber, M.D. and colleagues (1992, 1995, 1997), and another by J.P. Abenstein and M.A. Warner (1996). Many commenters claimed these studies concluded either an anesthesiologist alone, or a CRNA in "collaboration" with an anesthesiologist, had better patient outcomes than a CRNA alone. Many commenters contend, erroneously, the recommendations from the Abenstein & Warner article were adopted by the Minnesota legislature (although it is not clear to what recommendations the commenters were referring). Many other commenters urged us not to consider the change made by this rule until there is solid, scientifically defensible outcome data to establish that independent nurse anesthesia care is just as safe as anesthesiologist care.

Response: The conclusions of the commenters were not supported by findings from the studies they cited, nor do the studies conclude that States provide inadequate oversight and that a Federal standard is therefore necessary. We reviewed available literature and found the following major conclusions (see appendix).

- All literature surveyed agreed that the anesthesia-related death rate is extremely low, and the administration of anesthesia in the United States is safe relative to surgical risk. In fact, according to the 1999 Institute of Medicine Report *To Err Is Human*, "anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics administered in the early 1980s," a 40- to 60-fold improvement.
- There are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision. All of the studies we reviewed had significant limitations. Conclusions are limited by these studies' failure to control adequately for possible correlations among variables such as higher risk patients and hospital characteristics (for example, size and sophistication of medical technology) as they would affect deaths attributable to anesthesia.
- There is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of health professionals administering anesthesia. Nor has there been any evidence that States do a poor job in regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

In the Silber studies, the authors did not conclude that CRNAs may be providing poor care that might more likely lead to negative outcomes. The 1992 study did not address whether there is an association between patient outcomes and the type of professional who furnished anesthesia. The anesthesia variable used in the study was not specific to the patient, rather it was a variable at the hospital level (for example, percent of anesthesiologists who are board-certified). The anesthesia variable might be a proxy indicator of quality of the hospital: Thus, there would be lower mortality in the higher quality hospitals and if a complication occurred the patient would more likely be rescued.

Silber urges "that the limitations of the project be recognized." The limitations include: There were relatively few deaths, adverse outcomes and failures, and relatively few patients per hospital so the rates could only be compared for groups of hospitals, not specific facilities.

In a subsequent article to the one summarized above, Silber and colleagues (1995) found that "most of the predictable variation in outcome rates among hospitals appears to be predicted by differing patient characteristics rather than by differing hospital characteristics, that is, by who is treated rather than by the resources available for treatment." The authors found higher proportions of board-certified anesthesiologists to be associated with lower death and failure rates, but also with higher adverse occurrence rates. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another. Silber and his colleagues (1997) have also conducted methodological studies that compare the usefulness of three outcome measures, mortality, complication and failure-to-rescue rates. They concluded that for the general surgical procedures studied, the complication rate is poorly correlated with the death and failure rate. The authors suggest that great caution be taken when using complication rates and that they should not be used in isolation when assessing hospital quality of care. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. Nor did the study address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law.

Even on its own terms, the study has the following methodological shortcomings:

- The study used a non-experimental research design and only examined claims data, instead of reviewing medical records or observing actual care. Even though the researchers statistically controlled for 106 proxy indicators of care, without a stronger research design, they can only make a weak conclusion about an "association" between a variable and an outcome.
- The study did not control for the cause of death. Cases where a patient died from an anesthesia related cause, the surgery itself, an unrelated medical error, or an unknown medical condition are all considered, regardless of the cause of death. Not having data on deaths actually attributed to anesthesia is problematic since the mortality data used covers any death occurring within 30 days of a hospital admission. Events occurring 30 days from admission cannot be attributed to the anesthesia care alone. While the researchers argue that "delayed" death (that is, within 30 days of admission) is the appropriate measure of mortality for anesthesia care, the study does not produce causal evidence for such a theory. At a minimum, the researchers could have presented results for mortality measured for shorter periods of time such as within 72 hours of admission which may or may not have shown different outcomes for short-term and delayed deaths.
- Both the study and comparison groups included cases where physicians supervised CRNAs and personally furnished anesthesia. (The study group also included cases where anesthesiologists medically directed residents). The purpose of the study was to examine differences when an anesthesiologist versus a non-anesthesiologist physician is involved in the case. One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision.
- The study used data where anesthesia was furnished by unknown suppliers (incorrectly referred to in the article as "unknown providers") either personally providing care or supervising CRNAs. Because a supplier is not a physician there are likely to be data coding errors which could contaminate and bias the results.

Even if the methodological shortcomings were fixed, because the study did not address the issue in the final rule, it is inappropriate to impute results from this study to the issue in this final rule, the provision of care by CRNAs supervised and not supervised by physicians.

Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs. Such a policy is much more restrictive than current Medicare policy because it would prohibit non-anesthesiologist physicians to supervise CRNAs. This would make it difficult to perform surgeries in many small and rural hospitals because anesthesiologists generally do not practice in these hospitals.

Finally, even if we were to consider that the Silber article should guide our policy, we note, that due to the difference between relative risk and absolute risk, the reported size-effect is too small to cause us to change our

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decision. The Silber article reported an odds ratio for death of 1.08 corresponding to 2.5 excess deaths per 1000 cases (relative risk). However, due to the lack of medical record review in this study these excess deaths cannot be solely attributed to anesthesia care and thus is not the absolute risk. For example, if we accept the IOM review of the literature of 33.3–50 anesthesia related deaths per 10 million (*i.e.*, one per 200,000–300,000) then the absolute risk of excess deaths would be in the range of 2.7–4.0 per 10 million (.08 times range of 33.3–50). This size of absolute risk must be balanced against the risk of death due to lack of timely access to anesthesia services because of a federal imposition of a supervision requirement. At a minimum States are certainly capable of balancing the risks of lack of supervision versus the shortage of anesthesiologists given the supply of anesthesiologists in each of their respective States.

The Abenstein & Warner (1996) paper describes a number of aspects of anesthesia care and reviews studies in several areas. The paper notes that there has been a dramatic improvement in anesthetic deaths in the last 15 years: "Since 1979, five studies have documented a remarkably abrupt decrease in anesthetic-related death rates, morbidity, and risk of perioperative deaths." The paper concludes that: For many patients, it is now as safe to be anesthetized as to be a passenger in an automobile."

The paper notes that "identifying the cause for the improvement in anesthetic outcome is as problematic as determining the cause of perioperative death." The paper indicates that "huge numbers of surgical patients (that is, >1,000,000) must be enrolled in studies to provide the statistical power needed to determine whether there are associations between perioperative disability or death and various anesthetic techniques, technologies, and practice models." The paper notes that studies of this size are expensive. None of the studies reviewed meet this standard.

The paper reviewed two studies that compared mortality for anesthesia care furnished by anesthesiologists, and anesthesia care team and nurse anesthetist supervised by a physician. Neither meets the criteria for an adequate study identified in the paper. As the authors note, the first study did not provide statistical analysis of the data. The second study used data now 25 years old and found no statistically significant difference between the groups. Neither study examined the provision of anesthesia furnished independently by CRNAs, the issue of this rule.

The paper suggested a number of reasons for improved anesthesia care including "new and improved patient monitoring techniques." The paper also notes that the "decline in adverse outcomes occurred at the same time that the number of American trained physicians entering and graduating from anesthesiology residency programs more than doubled (1975–1985)." The paper suggests that "the increase in the number of physicians engaged in the practice of anesthesiology is primarily responsible for the dramatic improvement in perioperative outcomes." However, the paper also notes that during roughly the same period of time, 1970–1985, the number of active nurse anesthetists doubled.

On the basis of studies which are flawed methodologically, which do not prove causality, and which do not meet the authors' own criteria for rigorous study, the authors nevertheless conclude that "the presence of board-certified anesthesiologists has been associated with the decline in death and disability commonly attributed to adverse perioperative events." The authors' conclusion is not substantiated by their own review and analysis of the literature. Finally, the paper presents no information regarding the issue in the rule or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

As part of the decision to finalize the rule, we considered the feasibility of conducting a study comparing the mortality and adverse outcomes of Medicare patients for anesthesia care furnished by CRNAs with and without physician supervision. However, we concluded that it was not feasible to conduct such a retrospective study. Not only would the low overall anesthesia mortality make it difficult to develop a sufficient sample, but because of the current Medicare rule, there are no cases where CRNAs practice without supervision and thus there would be no data for the key comparison. We also considered the feasibility of conducting a study using data from non-Medicare patients. However, because Medicare's current hospital conditions of participation apply to all patients, here too there would be no data for the key comparison. Finally, we do not believe that it would be wise to conduct a prospective demonstration which would waive State law and prospectively randomly assign patients to study and control groups because it would remove patient choice of anesthesia professional.

Comment: Several commenters felt strongly that anesthesia should be considered a high-risk procedure where mistakes are measured in terms of death and injury. These commenters believe that millions of patients will be at a higher risk for injury without the supervision of board certified anesthesiologists. One commenter noted that without the requirement, no trained physician would be available to respond to any emergency during a case where a CRNA was practicing independently.

Response: If we were to require board certification for anesthesiologists as a hospital CoP it would be a stricter requirement than currently exists for the practice of any other medical specialty subject to our CoPs. Hospitals have been providing anesthesia care without a Federal requirement for board certified anesthesiologists since the inception of the Medicare program. This rule does not change the requirement that hospitals must have physicians available at all times and that all Medicare patients are under the care of a physician as defined in section 1861(r) of the Act. Therefore, the patient's medical and/or surgical care continues to be the responsibility of his or her assigned physician.

Comment: Several commenters wanted to know what had changed since a 1992 HCFA comment that, "In view of the lack of definitive clinical studies on this issue, and in consideration of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a nonphysician anesthetist unless under supervision by either an anesthesiologist or the operating practitioner."

Response: As discussed above, there are no definitive studies one way or the other which address this question. The studies we discussed in our 1992 final rule on fee schedules for CRNAs (57 FR 33878, July 31, 1992) have limitations, as does the literature since 1992. Moreover, there is no evidence that an across-the-board physician supervision requirement for CRNAs leads to better outcomes or that there will be adverse outcomes by relying on State licensure laws instead. What has changed since 1992 is our view that it is unnecessary to continue a special Federal preemption of State licensing laws regulating professional practice for CRNAs.

The 1999 IOM Report cites a drop in anesthesia mortality rates from two deaths per 10,000 anesthetics administered in the early 1980's to about one death per 200,000 to 300,000 anesthetics administered today. Chassin (1998) identifies several studies which note this improvement is a result of "a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines and other systematic approaches to reducing error." This is an impressive improvement and confirms the soundness of the approach taken in this final hospital CoP, which broadens the flexibility for States and providers, who are much closer to the realities of patient care, to make decisions about the best way to improve standards and implement best practices.

Comment: Several commenters stated that quality of care should be an important consideration in determining the need for physician supervision. Some commenters noted an association between improved anesthesia outcomes and increased numbers of anesthesiologists practicing. Many commenters noted that some CRNAs could function independently, but that others lack the judgement and knowledge to safely provide anesthesia without supervision. Further, commenters point out that CRNAs are more than capable of administering anesthesia on a healthy adult; however, when a patient's health is poor, an anesthesiologist should be involved in the care. Some nurse anesthetists report concern with their ability to deal with anesthetic complications without the availability of an anesthesiologist.

Response: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is because, as stated in the preamble of the proposed rule, we are committed to changing current regulations that focus largely on procedural requirements, such as the Federal regulation mandating physician supervision of CRNAs. These comments make clear there are a range of factors to be considered (for example, patient types, surgical procedures, technology, and provider settings). Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement applicable in every situation is not sensible.

Comment: One commenter noted that the practice of anesthesiology extends beyond the operating room to the Intensive Care Unit (ICU), pain management, and other medical consultation. The commenter believes that the removal of the medical supervision requirement risks removing the anesthesiologist from the practice of anesthesia.

Response: The change in the physician supervision requirement for CRNAs does not affect the anesthesiologist's ability to provide services outside the operating room.

Comment: A few commenters told us they believed it was the Federal government's responsibility to set safety standards for the nation and this rule evades that responsibility. One commenter agreed that CRNAs have a good safety record, but emphasized that they have been under the direct supervision of the anesthesiologist. He believed that eliminating the supervision requirement would cause these positive patient outcomes to occur less frequently. Other commenters agreed that physicians absolutely need to be involved for the practice of medicine to be safe, and this regulation change is in direct violation of this principle. Some commenters noted that the practice of safe anesthesia administration is largely due to better monitoring techniques, technology, improved drugs, and not to greater supervision by a physician. One commenter stated that in combination with improved drugs and techniques, CRNAs will bring greater access to anesthesia services in situations and areas where they are currently limited in their practice because of the physician supervision requirement, thus allowing such delivery of medical services that improve patient health and safety, and provide services to a greater number of people.

Response: We are acutely aware that ensuring patient safety and high quality patient outcomes are the principal considerations in regulating providers. There is no indication that physician supervision of a CRNA affects such outcomes. It is for this reason that we are moving away from a focus on physician supervision, where there is no evidence or data linking this structural requirement to patient outcomes. As previously noted, changing the supervision requirement does not obviate the requirement that every Medicare patient admitted to the hospital be under the care of a physician or doctor of osteopathy. This requirement remains an important component in the hospital CoPs. Even under the current regulation CRNAs are not required to be under the supervision of an anesthesiologist; the operating physician can meet the rule's supervision requirement. This rule does not prohibit anesthesiologist supervision or administration; it simply leaves the decision up to State law or hospital policy.

This rule recognizes the significant improvement in the safety of anesthesia administration made by improved technology and implementation of practice guidelines. As in other areas of health care, new drugs and pharmaceuticals have contributed to improved patient outcomes as well. This underscores the findings in our review of the literature that multiple variables, some interacting in combination with each other, contribute to anesthesia-related patient outcomes.

Comment: We received several comments from beneficiaries who had received anesthesia care from a CRNA and felt comfortable with the service that was provided. They describe their anesthesia experiences as compassionate and thorough, including quality service and attention from these professionals. Many felt their care was excellent. Another commenter noted nurse anesthetists take time to be compassionate and attentive to fears, approaching anesthesia care holistically.

We also received comments from beneficiaries who felt that their care was being compromised for economic reasons by not requiring a doctor to be in charge of their anesthesia. Many reported increased fears during a time when they are most vulnerable, without the guarantee that a doctor will be in charge of their anesthesia care. Many reported that, as senior citizens, they faced more complicated medical and surgical procedures than younger patients and therefore that hospitals should be required to have a doctor in charge of administering their anesthesia.

Response: Patient experiences can be influenced not only by the anesthetist, but the surgeon, the type of procedure, the emergency nature of the procedure, and other factors. We also believe that many Medicare beneficiaries have been receiving anesthesia from CRNAs without being specifically aware of the credentials of the administering professional. We agree that a patient's perception of the safety and concern demonstrated by medical personnel is important but there is no evidence linking safety or better patient outcomes to the Federal requirement for physician supervision.

The change made by this rule is not specific to the patient's status as a Medicare beneficiary but to the participation of the provider in the Medicare program. The increased flexibility gained by this rule will allow hospitals and doctors to make decisions, pursuant to State law, about what is best for patients, reinforcing the primacy of the doctor-patient relationship.

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Professional Education and Training

Comment: Several commenters noted the differences in training and education between a CRNA and an anesthesiologist. These differences were considered significant by anesthesiologists, who believe that anesthesia administration is the practice of medicine and should only be performed by physicians. Physician commenters pointed out that anesthesiologists receive in-depth training in physiology, pharmacology, diagnosis, treatment and independent management of patient care. In addition, because they are physicians and have received medical training, anesthesiologists assess a patient's medical condition, as well as plan and administer the anesthetic. One physician stated "nurse anesthetists are trained to assist anesthesiologists; they are not physicians and are not trained in medical diagnosis and therapy. The lack of medical background prevents the CRNA from being able to diagnose and treat the unexpected, and often serious, reactions that can accompany anesthesia in even the simplest of cases. CRNAs should be considered valued extenders of care but not as substitutes for the expertise of an anesthesiologist." Other commenters stated that nurses are trained to follow orders and medical protocols, and are not trained to diagnose and treat. Several anesthesiologists, who had been nurse anesthetists, wrote describing that not until they had medical school training did they understand the full impact of the differences between the education preparing them as nurse anesthetists versus their preparation to practice as anesthesiologists. One commenter stated he believed the regulation should be based on demonstrated formal education. Another physician commenter stated he believed CRNAs were well educated and trained and had good records of performance, but that this was due to their collaboration with doctors, and not their independent management of medical situations.

Some commenters stated, inaccurately, that the postgraduate training of nurse anesthetists is unique in that, after a minimum of a bachelors degree in nursing, the nurse anesthetist student is required to have at least two years of practical experience in a critical care setting before advanced formal education in anesthetic administration. They stated that this advanced training prepares the nurse anesthetist to provide the full range of anesthesia services, independently. Several commenters noted that nurse anesthetists must be board certified by successfully completing the National Certification Examination. Other commenters felt that the knowledge and expertise in nurse anesthesia care is equivalent to the preparation provided physicians. Some commenters reminded us that the Federal supervision requirement has been the only obstacle to independent practice, and that otherwise nurse anesthetists are licensed and trained to practice independently. One CRNA stated he did not agree with the contention that educational differences between CRNAs and anesthesiologists are sufficient reasons to place practice restrictions on CRNAs.

Response: Education and training requirements for CRNAs vary among the States. Decisions about appropriate and necessary education and training for health professionals are made by States and educational institutions in compliance with education accreditation standards. Professional schools, both medical and nursing, are accredited by educational organizations with specific standards for curriculum content. Evidence of graduation from an accredited school is part of a State's licensing and certification requirements, independent of Federal regulation. Anesthesia administration by nurse anesthetists has a long history in this country, including a level of independent practice in Department of Defense hospitals. We cannot agree that anesthesia administration is the practice of medicine and therefore can only be done after medical school training. Moreover, the rule does not allow any provider to practice outside the parameters of his or her professional license.

We also believe that this rule is consistent with both sides of this argument as reflected in the comments. The added flexibility and shared responsibility allows each health professional to practice within his/her licensed scope of practice without an across-the-board Federal requirement limiting any collaborative, team or independent practice.

Comment: Additional commenters claimed significant variation among program requirements in nurse anesthetist training. Some of these commenters cited an article from the June 1996 Journal of the American Association of Nurse Anesthetists, identifying that more than one-third (37 percent) of nurse anesthetists do not have bachelor's degrees, less than a quarter (22 percent) have a master's degree, and less than 1 percent have a Ph.D. In comparison, the writers note, all anesthesiologists have an undergraduate degree, 4 years of medical school and specialty training in anesthesiology.

Response: We recognize that education and training requirements vary among the States. As previously noted, States are well skilled at deciding requirements related to health care professional licensing. Our change in the hospital rule deferring to State oversight is not an endorsement of one health professional over another. It is not a rule that defines medical or nursing standards of practice or educational preparation. The rule merely allows the authority (that is, States) whose traditional role it is to make such determinations (for example, which health care professional is trained to provide which health care services) to do so in the case of anesthesia administration.

Comment: There was some concern expressed that eliminating the Federal requirement for supervision would result in decreased physician involvement in the training of CRNAs. One commenter speculated that this provision would reduce the incentive for a physician to specialize in anesthesiology and physician-administered anesthesia would soon vanish.

Response: We disagree that eliminating the Federal supervision requirement will necessarily lead to physicians making decisions about practice specialties, other than anesthesiology. This rule change is not a judgment about the value or contribution of one health professional or another. We believe that with greater staffing flexibility, opportunities for collaboration between physicians and nurse anesthetists will increase based on individual patient needs, hospital characteristics, and an increasing ability to implement best practice protocols..

Comment: A few commenters thought that eliminating supervision by the anesthesiologist will limit the choice of anesthesia modalities and deprive patients of an appropriate anesthesia plan. These commenters stated that CRNAs are not trained in various types of nerve blocks and/or the use of certain devices. These additional skills are necessary to care for critically ill patients.

Response: This change in regulatory approach does not permit any licensed independent health care provider to practice beyond his or her licensed scope of practice. While we acknowledge there will continue to be medical interventions or treatments that fall under the practice authority of a medical licensee, these determinations are not, and never have been, made by Federal regulation, but by States, with

input from, and consultation with, licensed health professionals. Typically these decisions on practice issues fall to provider credentialing, licensing or certification authorities. All areas of health care are constantly faced with implementing new technologies, procedures, drugs, biologicals, or devices. As these new techniques become available we believe it is the responsibility of States, hospitals, and professional organizations to implement standards for training and assuring practice competency. In addition, we have no evidence to indicate that eliminating the Federal supervision requirement for CRNAs will limit the choice of anesthetic modalities or deprive patients of appropriate anesthesia plans.

Comment: There were a few comments stating that the evolution of non-physician practitioners is expanding through the use of well-trained and very capable professionals. Advanced practice nurses represent part of the movement to broaden access, increase efficiency and maintain health care quality. One commenter applauded our efforts to eliminate restrictions preventing full utilization of these highly trained and qualified health professionals.

Others wrote in with concerns that this rule was opening the door to allowing other independent health professionals to engage in unsupervised practice in hospitals and through other providers regulated by us. Some of these commenters pointed to increasing activity at the State level to expand scope-of-practice laws for nonphysicians. Examples, such as psychologists seeking prescribing authority and complementary and alternative medicine practitioners lobbying to expand their professional practice rights, have been used to argue that lesser-trained professionals are attempting to practice medicine without the appropriate training or supervision. They point out that these are more examples of loosening regulatory safeguards over the practice of medicine and patient care.

Response: States have an excellent track record of protecting patient health through their own regulations. We respect State control and oversight of health professionals by deferring to State licensing laws to regulate professional practice. We have determined that there is no need for continuing Federal preemption of State laws by maintaining a requirement for physician supervision of CRNAs as a special case. There is no evidence that States are any less concerned with ensuring safety and quality than the Federal government, especially when it comes to the health and safety of their citizens. In fact, our evidence-based, outcome-oriented standards establish a shared commitment between us, the States, and Medicare providers to ensure safe, quality anesthesia administration. States have a good track record in determining best practices. In fact, it is at the State level where most direct input by health professionals into scope-of-practice licensing laws takes place.

Additionally, we believe that independently licensed health professionals have served a valuable role in expanding access to, and maintaining quality in, many health services. The change in the Federal requirement for physician supervision is not an endorsement of any health profession, model of care delivery, or promotion of a specific standard of care. It is a change in approach to regulatory oversight that recognizes the worth of State control in meeting regional/local needs.

Operating Surgeon Providing Physician Oversight

Previous regulation required physician supervision by either an anesthesiologist or the operating surgeon. We received many comments from surgeons asking about the surgeon's liability as well as questions about who would be considered in charge of the patient's care.

Comment: One surgeon noted that he is dependent on the anesthesiologist as a consultant to provide care and recommendations concerning his patient. Other surgeons did not want responsibility for the anesthesia care of their patients when they were not trained in anesthesia. One commenter stated "surgical residency programs have intensified training in surgical technical skills, and decreased emphasis on anesthesiology training, leaving such matters to the consultant in Anesthesiology. As a result, [the surgeon's] ability to supervise the CRNA has declined." This commenter asserted this should encourage us to require CRNA supervision by an anesthesiologist only. One anesthesiologist asked whether he would be responsible for anesthesia management done prior to his consultation.

Response: This final rule does not require supervision, direction, or oversight of any independently licensed practitioner administering anesthesia by the operating surgeon. The surgeon would still be able to involve an anesthesiologist as a consultant or in any other capacity. This rule does nothing to restrict that relationship. CRNAs, as well as anesthesiologists, are accountable for their own practices, the care they deliver, patient outcomes, as well as insurance liability coverage.

Comment: A few commenters stated there will be increasing pressure on surgeons, from hospitals, CAHs, and ASCs, to eliminate the anesthesiologist. Another commenter wrote that he believes if we allowed this change, it would not be long before private insurers would refuse to pay physicians no matter how sick the patient or complex the procedure.

Response: This rule governs participation requirements for hospitals, CAH, and ASCs participating in the Medicare program. It does not eliminate, restrict, or in any way limit the practice of any practitioner. In addition, an insurance company cannot establish health professional practice rules that are in conflict with State licensing laws.

Comment: We received several comments asserting the physician supervision requirement was responsible for surgeons choosing not to practice in some settings because they do not want the liability associated with the supervision responsibility. One commenter noted that one possible result of lifting the Federal supervision requirement is that more surgeons may be willing to practice in geographical areas they previously would have avoided partially because they did not want to be responsible for supervising the CRNA. Some believed the rule change will alleviate fears of surgeons who were concerned about taking on increased legal liability. Others noted that removing the supervision requirement afforded greater flexibility for surgeons and hospitals to choose their anesthesia providers without fear of increased liability.

Response: The rule makes no legal change in the scope of malpractice liability, traditionally a State issue. Our rule, permitting any State licensed health professional permitted by the State to administer anesthesia would not definitively affect any provider or professional the same way in all States. Because both scope-of-practice and malpractice liability differs from state to state, as a general matter, any professional who has contact with the patient could conceivably be held liable for personal injury, depending on the facts and circumstances of the case and on the State's laws. This issue is not the subject of this rulemaking.

Rural Issues

Comment: We had many comments on this provision relative to the practice of nurse anesthetists in rural areas. Even

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many physicians supported the changed supervision requirement in rural areas where access to anesthesiologists is limited. Some comments from surgeons practicing in small communities noted they have worked solely with CRNAs for all procedures, and they never felt they had a need for any additional supervision, regardless of the medical situation. They further point out that without nurse anesthetists willing to practice in medically underserved areas, no one would be available to administer anesthesia.

However, other physician commenters noted that under current regulation, even without a supervising anesthesiologist, the operating surgeon provides supervision to the nurse anesthetist. One commenter noted, "the administration of anesthetics by nurse anesthetists in rural communities of this country is a condition of necessity, not design, since these areas are generally underserved by physicians." The commenter disagrees with proposing a national standard based on these criteria.

Response: The intent of this rule is not to limit or prohibit any anesthesia care model. We are changing a thirty year old policy to more accurately reflect demands of current practice, variations in hospital, CAH or ASC, patient characteristics, resource management, technology, and ever-increasing medical knowledge. We concur with the experience of the commenters who state that nurse anesthetists have increased access to anesthesia care, and thereby, access to medical and surgical procedures that would likely be unavailable if not for a practitioner qualified to administer anesthesia. We disagree, however, that the new rule, by itself, will guarantee an adequate supply of CRNAs in rural settings. A patient population's medical or surgical needs; hospital, CAH, or ASC characteristics; State practice laws, etc. are all factors contributing to decisions of CRNAs about where to practice. These variables exist in rural as well as other geographic areas.

Comment: A few commenters believed we were erroneous in our assumption that allowing independent practice of CRNAs would increase access to needed medical procedures in rural areas. One commenter asserted we were wrong in our assumption that there is a problem of access to care in rural areas. CRNA commenters noted that CRNAs administer anesthesia unsupervised by an anesthesiologist in approximately 70 percent of rural hospitals within the United States, providing a full range of anesthetic services (for example, surgical, obstetrical, and trauma stabilization).

Response: Without CRNA availability in certain areas there would be limits on the types of surgical interventions or procedures that could be performed in those areas, because no anesthesia professionals other than CRNAs would be available.

Comment: Several people asked that we create a rural carve-out for CRNA independent practice. Some of these commenters agreed with keeping the requirement for operating physician supervision, while others supported full independent practice. Still others, even though in agreement with a rural carve-out, wanted us to create a requirement for supervision by an anesthesiologist wherever there were no shortages of this physician specialty. Additionally, these commenters wanted assurance that patient care outcomes would continue to be monitored so that all patients would be receiving the care they deserve.

Response: The purpose of the change in the requirement is not simply to respond to the needs of physician shortage areas. We gave full consideration to this option but decided that the importance of increased flexibility, decreased burden, and broadened implementation of best practice protocols were important for hospitals in all geographic settings. We believe there is no reason for an across-the-board Federal requirement that could potentially limit development of new practice models of anesthesia delivery, or interfere with progress in promoting practices that improve patient outcomes.

There are additional mechanisms in place to support monitoring of patient outcomes. There are other hospital standards and oversight activities that address how care is delivered and identify mechanisms hospitals must have in place to assure patients receive safe, quality care.

Comment: One commenter stated that by expanding CRNA independent practice outside of rural areas, increased competition would occur with anesthesiologists for jobs in better served areas and would result in CRNAs choosing not to locate in less desirable and under-served areas. This commenter supported a rural carve-out for fear that without such a carve-out, these underserved areas would again experience access problems. Another commenter mistakenly believed that requiring physician supervision would result in CRNAs working without payment, leading small community operating rooms to close.

Response: CRNAs are paid under the CRNA fee schedule. The CRNA may furnish the service under the "medical direction" of a physician, usually the anesthesiologist, or the CRNA may furnish the entire anesthesia service without medical direction, while still under the supervision of the operating surgeon. Payment rules for CRNAs, as well as for physician anesthesiologists, do not change as a result of this rule.

This issue of health professional shortage has always been present but there is no way to predict that this will be a definite outcome of the rule change. The Congress, the Department of Health and Human Services, and the States continue to address the issue of health professional shortages through a variety of mechanisms, including increasing educational grants and loans for those who choose to practice in designated critical shortage areas.

Pre- and Post-Anesthesia Evaluations

Comment: Several writers cited the importance of the pre-anesthesia evaluation as critical to prevention of complication during and after a procedure. Many of these commenters felt that only a physician with detailed knowledge of medicine has the ability to make a reasoned, informed judgment about the medical state of a patient. Other commenters noted that in addition to the pre-anesthetic evaluation, all peri-operative assessment and care requires physician oversight. One commenter pointed out that anesthesia complications might be a result of several factors, including inadequate pre-anesthetic preparation, severity of concurrent disease, inappropriate monitoring and lack of post-anesthetic follow-up care. Another commenter stated this process is more accurately described as "pre-procedure assessment", indicating the importance of thorough consideration of the patient's medical needs.

Response: We agree with commenters that a variety of factors and contributing variables influence surgical and anesthesia outcomes. Our literature review and analyses of comments confirms our conclusion that interactions among and between these variables are difficult to isolate in terms of their individual effects on outcomes. Education and training programs for CRNAs include pre- and post-anesthesia care. Pre- and post-anesthesia assessment and monitoring are scope-of-practice issues determined by each State as it considers education and training requirements for professional licensing.

We are sensitive to the debate between physician anesthesiologists and nurse anesthetists regarding what

constitutes the practice of medicine with regard to anesthesia administration. States have handled these issues through laws and health professional practice acts. Questions of who is properly trained to do a pre-anesthesia evaluation, care for a patient in recovery, order pain medication, or perform a procedure that results in conscious sedation of a patient, have all faced States when they adopted professional licensing laws. This rule change does not prohibit collaboration between medical professionals including surgeons, nurse anesthetists, and/or anesthesiologists in the total care and treatment of any patient in the hospital. As expanded scope-of-practice issues are debated at the State level, we expect continued involvement by medical and health professionals to ensure best practices and protocols are incorporated in final decisions about which professionals meet the required training and education to perform any particular service.

Collaboration and Anesthesia Team Approach

Comment: Several commenters explained that this rule would not significantly change the manner in which CRNAs currently work. One commenter noted that "anesthesia always has been and always will be given only as an adjunct to a surgical or diagnostic procedure. Collaboration must occur with the primary physician no matter if the anesthesia is provided by a physician anesthesiologist or a nurse anesthetist." Other commenters reaffirmed this by pointing out that collaboration is intrinsic to the practice of anesthesia administration, and therefore an explicit requirement of supervision is at best unnecessary. Others brought to our attention that State laws that require supervision vary in their definitions and in many cases define supervision as collaboration rather than direction.

Several anesthesiologists commented in support of the collaborative, team approach to anesthesia delivery. Commenters stressed the valuable and knowledgeable assets CRNAs are to the anesthesia team. These commenters expressed some concern that the rule will destroy the longstanding concept of the anesthesia care team, making it less likely hospitals will take advantage of the skills of the nurse anesthetist and the medical training of the anesthesiologist.

Response: As we have said, this rule makes no judgment in support of one model of care over another. In addition, the rule does not prohibit collaboration or teamwork during anesthesia administration. We believe the rule will promote best practices and encourage professional collaboration, in an effort to improve anesthesia care delivery and patient outcomes. We are pleased with the comments in recognition of the valuable contribution made by both professionals to the care of patients during anesthesia administration.

Comment: One commenter wrote that in most settings patient care is a team effort, and the current supervision requirement encourages polarization rather than collaboration. This commenter noted that when CRNAs have problems or questions about patient care they seek consultation with colleagues. Other commenters stated that the removal of the requirement provides surgeons, medical physicians, and others who perform diagnostic or surgical procedures freedom to collaborate or choose the anesthesia provider best suited to the procedure and the patient's needs. Additionally, many who supported the change in the rule believe that only a few CRNAs in certain circumstances would want to practice without supervision. They felt that both nurses and anesthesiologists preferred a team model of practice.

Two commenters stated that dentists, some physicians, and podiatrists work in settings where collaboration with an independent nurse anesthetist better suits the needs of the patient. They particularly noted the practice by nurse anesthetists of staying with patients for the entire duration of the procedure and through discharge from surgery as being helpful.

Similarly, we had several physicians state that the average healthy person can be safely managed by a CRNA. However, they contend a person with multiple medical problems or those undergoing complex or high-risk surgery should have a physician evaluation and medical direction during his or her care. The commenters believed that with this type of distinction in care, both parties would work together to deliver high quality anesthesia.

Response: One of the limits to requiring an overarching, across the board Federal requirement for supervision is the problem it creates for providers to tailor care to the needs of patients. These comments reaffirm what we have previously noted about the wide variability in patient presentations (for example, medical factors, type and nature of procedure, age, health, etc.) and how these variables influence clinical decisions about anesthesia administration. This rule change removes these unnecessary restrictions.

Cost to the Medicare Program

Comment: We received many comments on the financial motivations of various types of professionals for taking a position on one side of this issue or another. Many of the 20,000 comments accused one professional group or another of lacking concern for safety or adding additional burden to the health care delivery system for the sole purpose of financial gain or practice monopoly. We also received comments asserting that our motivation was to save money payable through the Medicare and Medicaid programs at the cost of quality anesthesia services. Those who support the change note that it removes a financial disincentive to use nurse anesthetists by no longer requiring payment to two professionals. They feel nurse anesthetist will be more efficient and expand a hospital's ability to provide services to more patients.

Many nurse anesthetists report having full responsibility for administering an anesthetic and caring for a patient while the anesthesiologist is somewhere else in the surgical area having no interaction with the patient. They note CRNAs are able to provide the same quality service at a lower cost, without the additional fee to an anesthesiologist for providing supervision. One commenter expressed support for the change as one that will greatly facilitate the use of cost-effective, outcome-based providers, noting "Unnecessarily mandated layers of supervision ultimately add cost to care, and yet have never documented any benefits." Many commenters wrote us with specific examples of how Medicare charges and costs would decrease as a result of the rule.

There was a common misunderstanding among many commenters that this change meant that Medicare patients would be forced to receive a lesser level of care because the rule changed the reimbursement for Medicare patients. One commenter asked, "Why would HCFA institute payment procedures that decrease the level of care provided to Medicare and Medicaid patients in the name of flexibility?" Another stated this rule proposes a double standard in that Medicare and Medicaid patients would not have the benefit of a physician's expertise to ensure their safety during critical peri-operative time.

Response: This rule does not change the payment policies for anesthesia services. Medicare payment rules remain the same. CFR section 415.110(a) requires that the anesthesiologist perform specific activities for each patient in order to be paid for providing

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"medical direction." It must be emphasized that the "medical direction" rules are rules for payment of the physician's service under the physician fee schedule. The physician fee schedule payment per service is related to the amount of physician work associated with the service. Thus, the medical direction requirement must establish some level of physician work that is reasonable in relation to the allowance recognized for the service. The "supervision" of the CRNA by a physician, usually the operating surgeon, is not a separately payable service for the surgeon. The payment for this service is considered a part of the global surgical fee paid to the surgeon.

Because this rule does not affect payment , the determination about supervision is not specific to a Medicare beneficiary. These rules apply to all patients receiving anesthesia services in Medicare participating hospitals, CAHs, and ASCs, thus Medicare patients would not receive a different level of care from non-Medicare patients and therefore, does not mean different care for Medicare or Medicaid patients. The rule is specific to the provision of anesthesia services in a Medicare participating hospital, CAH, or ASC, and applies to all patients.

Comment: Several commenters who opposed this provision warned that costs to the Medicare program will increase as a result of this rule. Many believed that, although there will be no immediate effect since payment remains the same, costs would increase in the long term because of resulting anesthetic complications and malpractice. Others told us they believe anesthesiologist consultations will increase because some of these services are included in the anesthesia administration fee but as consultants, anesthesiologists would have to charge separately for these services.

Response: Neither costs to the Medicare program nor payment to different professionals was part of the decision to change the hospital CoP for anesthesia services. The fears of long term negative outcomes, increasing medical complications and higher malpractice insurance premiums, related to professional type, are unwarranted, based on our review of the literature. This rule will not prohibit consultation, physician supervision, or anesthesiologist administration of anesthesia where State and/or hospital by-laws require it. Whether payment can be made for consultations will be determined by the usual physician coverage and payment rules.

General

Comment: We received many anecdotal comments from beneficiaries, describing both positive and negative experiences during anesthesia, such as, the importance of a caring, well-trained professional who gives the needed patient attention, and answers the patient's questions. Rarely did the comments identify the professional by credentials.

Response: These reports are important in that they confirm our commitment to patient-centered, outcome-oriented approaches to regulating Medicare participating providers.

Comment: Several certified anesthesiology assistants (AAs) expressed concerns about how the rule might affect their practice. Since the rule allows anesthesia to be administered only by a person licensed by the State to do so, they question whether this requirement would prohibit their practice. Some of the AAs recommended that we omit the term licensed and allow States to determine whether licensure is required at all to practice anesthesia.

Response: We do not agree with the comments that no State licensure should be required for anesthesia health professional practice. As noted, this rule defers to State scope-of-practice laws which identify health professionals that are allowed to administer anesthesia. Under this rule, AA s would be allowed to practice within their scope-of-practice specified by State law.

Comment: One commenter recommended that we require a CRNA to disclose that a nurse, not a doctor, would be providing anesthesia care and that if the patient desired to choose another provider his or her request would be honored. Other commenters stated that this rule is being promulgated without adequate input from patient advocate groups and without regard to how it might affect patient care. They believe that this rule serves special interests and that patient interests have not been adequately considered.

Response: The request for an anesthesia provider is usually made by the surgeon or physician in charge of the patient's care. We believe the flexibility allowed through this rule change will enable physicians to make the best and most suitable choice for their patient's characteristics, medical and anesthesia needs. Patients are always free to ask about the qualifications of any practitioner providing care, including doctors, nurses, therapists, surgeons, or anesthetists.

We received comments regarding this proposal from patient advocates and individual Medicare and Medicaid beneficiaries as well as providers on both sides of the issue. We agree that safety and quality patient outcomes should be the principal consideration in regulating providers. It is exactly this focus which has led to the regulatory change in supervision of CRNAs.

Comment: Several commenters pointed to other ways in which the Federal government supported nurse anesthetists, citing, as examples, Federal funds under Title VIII of the Public Health Service Act and Medicare Education Funds. One commenter wrote that nurse anesthetists received approximately $2.7 million dollars per year for student trainees, faculty fellowships, and new program startup money.

Response: As previously noted, this rule is not intended to endorse one health care professional over another. It is intended to recognize the value in flexibility for providers when making decisions about how to best manage resources to ensure access to quality health services.

Comment: We received a few comments from nurse anesthetists who believed that implementation of this rule would be easy in those parts of the country where CRNAs have practiced and are treated with respect. Some of these commenters identified difficulty in achieving professional courtesy and referrals from doctors who did not recognize their skills and abilities.

Response: To the extent that this rule provides opportunity for greater flexibility for providers and increased access to quality health care for patients, we hope that this will occur. It is not our goal in this rule to prescribe, or to limit, which health care professionals may collaborate, supervise or work independently. We do, however, hope to decrease barriers to access, increase efficiency, and encourage improved models of safe anesthesia delivery. We believe that is best accomplished by sharing the responsibility with States and providers.

III. Provisions of the Final Regulations

We are amending § 482.52(a)(4) of the current hospital CoPs and § 485.639(c)(1)(v) of the current critical access hospitals CoPs, to codify requirements for who may administer anesthesia under Subpart D—Standard: Anesthesia Services. This change is also reflected in a conforming amendment to the ASC Conditions of coverage at § 416.42(b)(2). This final regulation eliminates a Federal requirement for physician supervision and defers to States the determination of which licensed practitioners are allowed to administer anesthesia.

IV. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This rule is not considered to have a significant economic impact on hospitals and, therefore, is not considered a major rule. There are no requirements for hospitals to initiate new processes of care, reporting, or to increase the amount of time spent on providing or documenting patient care services. This final rule will provide hospitals with more flexibility in how they provide quality anesthesia services, and encourage implementation of the best practice protocols.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, all non-profit hospitals, and other hospitals with revenues of $5 million or less annually are considered to be small entities. Some critical access hospitals and some ASCs with revenues of $5 million or less annually are also considered to be small entities. Individuals and States are not included in the definition of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This rule places no additional cost requirements for implementation on the governments mentioned. It will allow CRNAs to practice without physician supervision where State law permits or to be supervised by a physician where such oversight is required by State law. This change is consistent with our policy of respecting State control and oversight of health care professions by deferring to State licensing laws to regulate professional practice. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule imposes no direct compliance costs on State or local governments.

B. Anticipated Effects

1. Medicare and Medicaid participating hospitals, CAHs, and Ambulatory Surgical Centers will defer to State licensing laws in determining which health professionals are permitted to administer anesthesia. In addition, these facilities are free to exercise stricter standards than required by State law.

2. First, it must be noted that this final rule does not change the Medicare payment policies for anesthesia services. There is an important payment distinction between the medical "direction" requirements and the physician "supervision" requirement. Payment made by Medicare on a fee schedule basis is not payment for "supervision" but rather payment for "direction" and the payment per service is related to the amount of physician work associated with the service.

Second, economic effects on individual health professionals as a result of this rule change will be influenced by other factors. Because the final rule defers to State licensing laws, the impact on either physician or CRNA income from billed services will be determined by each States' laws. State laws vary widely in both the definition and degree of physician supervision and oversight required of CRNAs. In addition, some State laws leave the determination up to individual hospital, CAH, or ASC medical staff by-laws, resulting in a financial impact that is different depending on where the physician or CRNA provides the services. In any of these situations the potential impact might include an increase or decrease in billed services by CRNAs practicing alone, in billed services by physicians practicing alone, in billed services by physicians providing medical direction in collaboration with CRNAs, as well as the possibility of no change in billed services by either provider. In some of these cases, where there is decreased physician billing, there may be increased savings to third party payers.

Finally, the flexibility resulting from the rule change could provide increased access to services in some areas, and broaden opportunity for providers to implement professional standards of practice that improve quality and promote more efficacious models of care delivery.

3. This rule increases flexibility in the provision of anesthesia services for Medicare and Medicaid hospitals, CAHs, and ASCs. It removes the burden of implementing a Federal requirement for physician supervision of CRNAs in all cases. The rule change will allow hospitals, CAHs, and ASCs the flexibility, within the authority of State licensing laws, to implement best-practice protocols in providing anesthesia services most associated with positive patient outcomes. Moreover, hospitals are free to exercise stricter practice standards. As discussed in the preamble of the December 19, 1997 proposed rule, this provision does not lend itself to a quantitative impact estimate, and we do not anticipate a substantial economic impact either in costs or savings.

C. Conclusion

We are changing the current across-the-board Federal requirement for physician supervision of CRNAs to allow State control and oversight through professional licensing laws. This change applies to all Medicare and Medicaid participating hospitals, CAHs, and ASCs. Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the

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practice of any licensed professional. The clinical evidence indicates anesthesia outcomes have improved substantially in recent years such that anesthesia is a relatively safe procedure. Both our literature review and comment analysis made clear that there is such a range of variables and influences to be considered (for example, patient types, surgical procedure, and/or availability of technology) that a single Federal requirement applicable in all situations is unnecessary and may actually interfere with factors that promote quality patient outcomes.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Federalism

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does significantly affect the rights, roles, and responsibilities of States. This final rule removes the Federal guideline that requires CRNAs to be supervised by a physician and allows the laws of the States to determine which practitioners are permitted to administer anesthetics and the level of supervision required.

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.42 is amended by revising paragraph (b) to read as follows:

§ 416.42 Condition for coverage—surgical services.

* * * * *

(b) *Standard: Administration of anesthesia.* Anesthesia must be administered by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

3. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

Subpart D—Optional Hospital Services

4. Section 482.52 is amended by revising paragraph (a) to read as follows:

§ 482.52 Condition of participation: anesthesia services.

* * * * *

(a) *Standard: Staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

5. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 (hh)).

Subpart F—Critical Access Hospitals (CAHs)

6. Section 485.639 is amended by revising paragraph (c) to read as follows:

§ 485.639 Condition of participation-surgical services.

* * * * *

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 5, 2001.

Robert A. Berenson,

Administrator, Health Care Financing Administration.

Approved: January 10, 2001.

Donna E. Shalala,

Secretary.

Note: This list of references will not appear in the Code of Federal Regulations.

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Proposed Rules

Federal Register
Vol. 66, No. 12
Thursday, January 18, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 312, and 601

[Docket No. 00N–0989]

Availability for Public Disclosure and Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics licensing regulations regarding confidentiality of information. The amendments would add provisions that would make available for public disclosure, and require submission for public disclosure of, certain data and information related to human gene therapy or xenotransplantation. The proposed regulation would apply specifically to the areas of human gene therapy and xenotransplantation because these areas of clinical research have the potential for unique public health risks and modification of the human genome. The proposed rule would provide for public disclosure of certain data and information related to an investigational new drug application (IND), to provide an opportunity for public education on, and discussion and consideration of, public health and safety issues. In addition, the proposed rule would require sponsors of clinical trials on human gene therapy or xenotransplantation to submit to FDA for public disclosure certain data and information that has been redacted to remove or obscure all information defined as confidential commercial or trade secret, or names and other personal identifiers of patients and certain other third parties.

DATES: Submit written comments on this proposed rule on or before April 18, 2001. Submit written comments on the information collection provisions by February 20, 2001.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to Wendy Taylor, FDA Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background Information

A. Current FDA Policies Regarding Disclosure of Information

FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs, including new biological drugs, in humans. Under part 312, the sponsor of a clinical study in humans must submit to FDA an IND which provides specific information regarding the investigational new drug and the clinical study. The IND must be authorized by FDA and approved by the local institutional review board (IRB) before the clinical study may begin. The provisions of this rulemaking do not alter the procedures specified in part 312 for submission of an IND. A manufacturer requesting approval to market a biological product in interstate commerce must submit a biologics license application (BLA) to FDA before the product may be introduced into interstate commerce (42 U.S.C. 262). Among other things, the BLA contains information and data resulting from the clinical studies performed under an IND (§ 601.2 (21 CFR 601.2(a))). All information and data concerning the product, including those submitted in applicable IND's and in the BLA, are held by FDA in a biological product file (see definition of "biological product file" in § 601.51(a) (21 CFR 601.51(a)) throughout the lifetime of the product.

The general requirements related to disclosure of information for all types of commodities regulated by FDA and for all types of documents are provided in part 20 (21 CFR part 20). Under these regulations, certain categories of information are exempt from mandatory disclosure. The categories of information relevant to human gene therapy and xenotransplantation clinical trials that have historically been exempt from public disclosure include trade secrets and commercial or financial information which is privileged or confidential (§ 20.61); personnel, medical, and similar files, the disclosure of which constitutes a clearly unwarranted invasion of personal privacy (§ 20.63); and at the discretion of FDA, interagency or intra-agency memoranda or letters, except for factual information which is reasonably segregable (§ 20.62).

Specific requirements for the availability for public disclosure of data and information in an IND, including those IND's relating to biological drug products, are included in § 312.130. FDA's policy for the confidentiality of data and information contained in an IND for a biological product and in a biological product file is provided in §§ 601.50 and 601.51 (21 CFR 601.50 and 601.51). Under §§ 601.50 and 601.51, and consistent with the other referenced disclosure regulations, FDA has not routinely publicly disclosed any data or information contained in an IND or a pending biological product file. FDA has not even acknowledged the existence of the IND or a pending biologics license application, unless its existence has previously been publicly acknowledged. Because the agency has no mechanism for reliably tracking what information concerning an unapproved, investigational product has been publicly acknowledged, the agency generally provides no information to the public concerning an investigational product, including information concerning any IND or pending BLA submissions, and refers the public to the sponsor of the IND or the pending biological license for further information. In some cases, FDA may publicly disclose selected portions of safety and effectiveness data, such as summary information for consideration at an open session of a Federal advisory committee meeting, or other public workshops or meetings (§ 601.51(d)(1)). Once a biological license has been approved, certain information, as specified in § 601.51(e), concerning the approved product and the clinical investigation of the product may be publicly disclosed.

B. Issues Related to Human Gene Therapy and Xenotransplantation

As a result of rapid advances in molecular biology, genomics, immunology, and transplant biology, new classes of biological therapeutics are being developed with the goal of providing future treatment options for genetic disease, cancer, and organ failure. Novel therapeutic approaches currently under consideration include the areas of human gene therapy and xenotransplantation. Human gene therapy and xenotransplantation are being proposed to treat genetic diseases such as cystic fibrosis, cardiovascular insufficiency, metabolic diseases such as diabetes, neurologic diseases such as Parkinson's and Huntington's disease, cancer, acquired immune deficiency syndrome (AIDS), and organ failure.

1. Definitions

Human gene therapy is defined as the administration of genetic material to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use. Cells may be modified ex vivo for subsequent administration to the subject or altered in vivo by gene therapy products given directly to the subject. Human gene therapy includes, but is not limited to, autologous or allogeneic bone marrow stem cells modified with a viral vector, intramuscular or intravascular injection of a therapeutic plasmid deoxyribonucleic acid (DNA) or a therapeutic viral vector, ribozyme technology, and use of sequence specific oligonucleotides to correct a genetic mutation. For the purposes of this regulation, gene therapy is not intended to include the administration of viral or cellular products (e.g., blood or unmodified bone marrow), or their derivatives, that do not contain genetic material that has been specifically engineered into the product for therapeutic purposes. While prophylactic vaccines, including plasmid DNA vaccines and genetically modified viral vector vaccines, and some replication competent viruses are excluded under this regulation from the gene therapy definition, they are similar in nature to gene therapy products. Issues relevant to gene therapy products, such as vector integration and biodistribution, also apply to prophylactic vaccines. Therefore, the agency requests comment on whether such products should be included under this rulemaking to allow information related to these products to be available for public disclosure.

The use of antisense oligonucleotides to block gene transcription is not intended to be included under gene therapy; however, as noted above, the use of sequence specific oligonucleotides to correct a genetic mutation would be included. The proposed mechanism of action of sequence specific oligonucleotides is to irreversibly change, insert, or delete a single base in the genome of a cell. This raises questions of whether base changes may result in mutations that may cause cancer, or express an immunogenic protein or have other adverse health affects. In addition, their use in vivo raises issues of activity in tissues other than the target and the risk of gonadal biodistribution leading to germ line changes.

Xenotransplantation refers to any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (1) Live cells, tissues, or organs from a nonhuman animal source; or (2) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. The live cells, tissues, or organs used in xenotransplantation are referred to as xenotransplantation products. Xenotransplantation products include those from transgenic or nontransgenic animals, as well as combination products that contain xenotransplantation products in combination with drugs or devices. These include, but are not limited to, porcine fetal neuronal cells, encapsulated porcine islet cells, encapsulated bovine adrenal chromaffin cells, baboon bone marrow, and external liver assist devices employing porcine liver, or porcine hepatocytes. Nonliving biological products or materials from animals, such as porcine heart valves and porcine insulin, are not classified as xenotransplantation products for the purposes of this rulemaking.

2. Public Health Issues

While human gene therapy offers great promise for improving the lives of patients with serious, life-threatening diseases and disorders, there are several risks inherent in its use as a medical intervention. These risks include the inadvertent infection of patients, and potentially their contacts, with replication competent virus present in gene therapy vector preparations. For example, infection with type C murine retroviruses, which could contaminate retroviral vector preparations, is known to cause a range of diseases in animals including spongiform encephalopathy, anemia, and neoplastic disease. In addition, these risks include the risk of infection with novel infectious agents generated by recombination in vivo, the consequences of which are unknown; the risk of insertional mutagenesis through disruption of the normal genetic sequence, resulting in altered gene expression; and the risk of inadvertent modification of the patient's germline and its effect on future offspring.

Although xenotransplantation provides a potential approach to address the shortage of human organs and for treatment of disease, the use of xenotransplantation products raises concerns about possible infection of the recipient and, subsequently, the public at large with both known and as-yet-unrecognized infectious agents. Experience with human allograft transplantation has demonstrated the potential for transmissibility of infections from donor to recipient through transplants (Refs. 1 to 3). The direct contact resulting from implantation of a xenotransplantation product into a recipient, with the associated disruption of anatomical barriers and the immunosuppression of the recipient, may facilitate interspecies transmission of xenogeneic infectious agents. The potential for subsequent transmission of a xenogeneic infectious agent from the recipient to the recipient's close contacts, and propagation through the general human population, is an additional risk and a recognized public health concern.

Insertional mutagenesis is a risk potentially associated with the infection of xenotransplant recipients and their close contacts and the general population with xenogeneic retroviruses. In addition to potential horizontal transmission of infectious agents from the recipient of a xenotransplantation product to the recipient's contacts, there is concern regarding vertical transmission of infectious agents from the recipient to progeny during gestation (e.g., transmission from mother to fetus of infectious agents across the placenta or during parturition). Vertical transmission of xenogeneic infectious agents could result in the development of infectious disease in progeny. In addition, vertical transmission of xenogeneic viruses can result in insertional mutagenesis with disruption of normal human development or integration into the germline resulting in transmission to future generations.

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Thus, human gene therapy and xenotransplantation investigative approaches individually pose: (1) Risks that extend beyond the individual (e.g., public health risks, including the potential for the transmission of infectious agents from the recipient to the public at large); and (2) risks of inadvertent modification of the germline (alterations of the genetic material of the progeny). Moreover, these approaches may also be used in combination (e.g., xenotransplantation products genetically modified before implantation), resulting in complex questions and issues for consideration and discussion prior to and during human clinical trials.

3. Public Education and Informed Consent Issues

Human gene therapy and xenotransplantation investigations call for additional mechanisms to provide the public access to clinical trial information relevant to the assessment of risks and benefits, and to informed consent. Special care is needed to ensure that individual subjects understand the experimental nature of the procedures and their known and unknown risks and burdens. Human gene therapy and xenotransplantation require the evaluation of risks to third parties such as health care workers, close contacts of the recipient, and the community. The informed consent process should address the need for long-term surveillance and post-mortem analysis and potential infectious disease risks to recipients and their contacts.

These investigative approaches raise new challenges for the local review bodies responsible for ensuring the safe and ethical conduct of this research. Local IRB's are responsible for reviewing biomedical and behavioral research involving human subjects, to protect the rights of human subjects (45 CFR part 46, Protection of Human Subjects, and 21 CFR part 56, Institutional Review Boards). Institutional Biosafety Committees (IBC's) are responsible for reviewing and overseeing basic and clinical research conducted at their institutions. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment (section IV–B–2 National Institutes of Health (NIH) Guideline for Research Involving Recombinant DNA Molecules). This proposed rule would provide a mechanism for public access to human gene therapy and xenotransplantation clinical trial information and for public education, informed discussion and participation that can form a foundation for safe and ethical research in these innovative areas.

The proposed rule would enhance the development of related Federal initiatives that provide for public access to clinical trial information through national data bases: There are also a number of Internet sites sponsored by associations, clinical centers or academic institutions, and nonprofit organizations that provide public access to similar types of clinical trial information. Examples include: Center Watch Clinical Trials Listing Service at http://www.centerwatch.com, a resource both for patients interested in participating in clinical trials and for research professionals; http://www.HealthAtoZ.com, a search engine for health and medical Internet resources; the Musella Foundation for brain tumor research and information, at http://www.virtualtrials.com; the National Alliance of Breast Cancer Organizations, at http://www.nabco.org, which, in an effort to increase awareness of clinical trials, lists brief descriptive summaries of clinical trials in the National Cancer Institute Physician Data Query (NCI PDQ) data base; the University of Michigan, at http://www.cancer.med.umich.edu, which lists clinical trials at the University of Michigan Cancer Center (UMCC) and supplies links to external clinical trials and resources; the former Surgeon General C. Everett Koop's Internet site, at http://www.drkoop.com, which allows the public to browse through a listing of therapeutic areas where volunteers are being sought for clinical trials; Biotechnology Industry Organization, a trade association, at http://www.bio.org, which lists press releases and industry news, and provides links to patient groups and professional medical societies; and http://www.investor.biospace.com, which has not only a biotechnology search engine that links to hundreds of companies, but also extensive information on the latest technologies and clinical trials, as a basis for investment. The proposed rule should facilitate the development of similar data bases, either publicly or privately sponsored, with information concerning the study of gene therapy and xenotransplantation. As provided under section 113 of the Food and Drug Modernization Act of 1997 (Public Law 105–115), NIH, through its National Library of Medicine, has created a national clinical trials data base at http://clinicaltrials.gov to provide patients, family members, and other members of the public with current information about clinical research studies.

4. Basis for Disclosure

Historically, public disclosure of information with regard to human gene therapy and xenotransplantation has assisted FDA in performing its duties and has benefitted the public. The categories of information that may be made publicly available by FDA as a result of this disclosure rule include information currently made public by other Federal agencies in connection with advisory committee meetings or other public workshops or meetings, and through general commercial disclosure.

The NIH Office of Biotechnology Activities (OBA; formerly the Office of Recombinant DNA Activities) administers the Recombinant DNA Advisory Committee (RAC). This committee was established in October 1975, in response to concerns about the potential public health risks and environmental hazards posed by recombinant DNA research, as well as the significant ethical, legal, and societal issues associated with this emerging technology. The RAC has met quarterly in open public session to discuss these issues and, since the first human gene transfer clinical trial was proposed in 1988, the committee has publicly reviewed selected human gene transfer clinical trial protocols. The minutes of RAC discussions of human gene transfer clinical trials and related issues are accessible to the public via the OBA website (http://www.nih.gov/od/oba/index.htm). RAC review and public discussions provide an important mechanism for receiving public input into Federal policy development and for making the public aware of potential toxicities and adverse events associated with gene transfer products. As one example, when a participant in a cystic fibrosis gene transfer clinical trial required intensive care treatment for an acute adverse event suffered shortly after administration of an adenoviral gene transfer product, the investigator was invited to discuss the occurrence with other experts in the field at the next public RAC meeting. This public discussion and analysis facilitated both dissemination of important information about this toxicity and enhanced understanding of its pathogenesis, thereby contributing to the safety of patients in other gene therapy trials.

NIH also collects information on gene transfer studies and makes it available to the public. Appendix M of the "NIH Guidelines for Research Involving Recombinant DNA Molecules" (Ref. 4) requires that investigators provide specific information for the purposes of protocol registration, RAC review, and potential public discussion, and that this information should not contain confidential commercial information or trade secrets, enabling all aspects of RAC review to be open to the public. The required information includes scientific and nontechnical abstracts, the informed consent document, statements on privacy and confidentiality, reports of serious adverse events, protocol amendments, and annual followup reports. Public disclosure of this information has facilitated progress and has contributed to improved patient safety in the field of human gene transfer by providing public access to clinical trial information, rapid dissemination of adverse event information, and summary information regarding outcomes of gene therapy clinical trials and adverse events.

All investigators receiving any NIH funds for basic and/or clinical research involving recombinant DNA molecules, and all investigators affiliated with institutions receiving any NIH funds for basic and/or clinical research involving recombinant DNA molecules, must comply with the NIH Guidelines. The NIH Guidelines also apply to collaborations between NIH-funded or affiliated researchers and privately funded investigators. In addition, commercial sponsors not affiliated with a NIH-funded institution have voluntarily submitted materials to OBA for RAC review. Therefore, the general practice in the field of human gene transfer has been to submit to NIH, OBA the information required under NIH Guidelines with the understanding that the information will be available for RAC review and potentially public discussion. This suggests that the information specified in Appendix M is not generally considered to be proprietary and that its disclosure does not impede commercial development.

The categories of information that would be disclosed as a result of this rulemaking include information that generally has been made public for xenotransplantation protocols. Sponsors of xenotransplantation IND's have publicly disclosed information regarding the scope of xenotransplantation clinical trials and the development of public health safeguards through: (1) Open public sessions of the Xenotransplantation Subcommittee of the Biologics Response Modifiers Advisory Committee (BRMAC) for the Center for Biologics Evaluation and Research (CBER), FDA (December 17, 1997, June 3 and 4, 1999, and January 13, 2000), and (2) Public Health Service (PHS) sponsored public workshops, including the workshop entitled "Developing U.S. Public Health Policy in Xenotransplantation," January 21 and 22, 1998, at which xenotransplantation clinical trials under FDA IND's were summarized by the sponsor or by a sponsor's designee. Transcripts of these meetings can be found on the CBER Internet site at http://www.fda.gov/cber. At these public meetings, FDA scientists and others presented data demonstrating that porcine endogenous retroviruses could be activated and could infect human cells in vitro, and the implications of these data for porcine xenotransplantation product development and regulation were discussed. Based on these discussions, the BRMAC concurred with FDA's decision to place all porcine xenotransplantation clinical trials on clinical hold. During these meetings, FDA publicly discussed testing requirements and results needed by manufacturers in order to address and remove the clinical hold, and allowed sponsors of porcine xenotransplantation IND's the opportunity to present testing strategies, assuring the industry of consistency in regulation. The public as well was assured that Federal oversight was being conducted in a responsible manner.

Information related to the categories of information FDA proposes to disclose is available through publicly accessible filings to the Securities and Exchange Commission (SEC). The Securities Act of 1933 requires that investors receive financial and other significant information concerning securities being offered for public sale. In an annual filing, a company must provide a comprehensive overview of its business. This includes a description of ongoing research programs including discussion of clinical study safety and efficacy results, disclosure of investigational sites and the investigators involved, plans for product development and commercialization, and financial information. This information may be found on the SEC Internet site at http://www.sec.gov/edgarhp.htm.

In addition, voluntary disclosure of information regarding clinical trials of unapproved products and therapies by individual sponsors over the Internet has become widespread. Company Internet sites often provide this information in the form of descriptive summaries of clinical trials, press releases, recruitment opportunities for patients, investment opportunities, and general awareness material.

Thus, information of the kind FDA proposes to disclose concerning clinical trials on human gene therapy and xenotransplantation is already widely disclosed. This disclosure has not impeded commercial development of these products. In addition, the agency considers public disclosure of data and for information from human gene therapy or xenotransplantation clinical trials essential for public education, and for informed discussion and consideration of the public health and safety risks associated with the use of these investigational therapies.

II. Overview of Proposed Rule

A. Scope

The scope of this proposed rule is limited to disclosure of information related to human gene therapy and xenotransplantation. Confidential commercial information, such as information regarding commercial licensing agreements or the identification of suppliers, trade secret manufacturing information, names and other personal identifiers of patients and, except as specifically provided in the regulations, names and personal identifiers of third parties, such as physicians, hospitals, etc., and, at FDA's discretion, interagency or intra-agency memoranda and letters would not be disclosed. FDA is proposing only to disclose certain information necessary to ensure a continued mechanism for public education and input, which FDA believes is essential to the evaluation of the public health impact of these new technologies. FDA believes that these categories of information have not been considered to be proprietary, since they have been made publicly available through various mechanisms and their disclosure has not impeded commercial development. The public expects the current level of information disclosure and public review to continue in the areas of human gene therapy and xenotransplantation where there is potential risk to the public health.

The categories of information related to an IND that would be disclosed under this regulation include: (1) Product and patient safety data and related information, including results from preclinical and clinical studies and tests that demonstrate the safety and/or feasibility of the proposed procedures; (2) the name and address of the sponsor; (3) the clinical indications to be studied; (4) the protocol for each planned study, to include a scientific abstract and a nontechnical abstract, a statement of the objectives, purpose, and rationale of the study, the name and address of each investigator, the name and address of the official contacts of each local review body as appropriate (IRB, IBC) and dated copies of approval by each group, the criteria for patient selection and

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exclusion, an estimate of the number of patients to be studied, a description of the treatment that will be administered to patients, and the clinical procedures, laboratory tests, or other measures to be taken to monitor the safety and effects of the drug in human subjects and to minimize risk; (5) written informed consent forms; (6) identification of the biological product(s) and a general description of the method of production, including a description of product features that may affect patient safety; (7) IND safety reports; (8) information submitted to FDA in the annual report; (9) the regulatory status of the investigation, the date of such action, and the reason for such action; and (10) other relevant data and information that the Director, CBER, determines are necessary for the appropriate consideration of the public health and scientific issues, including relevant ethical issues, raised by human gene therapy or xenotransplantation.

To facilitate public disclosure of this information, FDA proposes to require sponsors of human gene therapy and xenotransplantation clinical trials to submit to FDA the information defined above upon submission of: (1) The initial IND, (2) any amendment documenting changes or additions to the IND, at the time the amendment goes into effect, (3) IND safety reports, and (4) annual reports. FDA is not proposing to require the submission of any new information not previously submitted as part of the IND process. For example, FDA is not proposing that all variations and updates of informed consent forms be submitted to FDA for public disclosure; however, under the proposed rule, FDA would disclose any sample informed consent forms generally submitted with an initial IND submission.

The agency requests comment on whether this rulemaking should apply to information as defined above that is submitted in a BLA. Public disclosure of information in a BLA would provide a continuation of the availability of information for public disclosure up until the time of license approval. A disadvantage would be the amount of documentation that would be required to be submitted in order to support this initiative.

The proposed provisions of this rulemaking do not alter the procedures specified in part 312 for submission of an IND. However, with regard to clinical holds of an IND (§ 312.42), FDA would be able to place a human gene therapy or xenotransplantation investigation on clinical hold if the sponsor does not submit to the agency the redacted version of data and information for public disclosure, or if the redacted version submitted is incomplete or not properly redacted.

B. Legal Authority

The proposed regulation would make available for public disclosure specified safety and effectiveness information submitted in support of an IND [1] involving either a human gene therapy or xenotransplantation protocol. This information, discussed thoroughly in section II.C of this preamble, includes protocols, criteria for patient selection and exclusion, summary results of preclinical and clinical studies of the investigational article, a summary of the treatment that will be administered and the measures that will be taken to minimize risk to human subjects, safety reports, informed consent documentation, and information concerning the regulatory status of the product, such as whether it is on clinical hold and the reason for the hold. While such information relating to human gene therapy protocols has routinely been made available to the public through the NIH RAC process for the last 20 years, FDA regulations have consistently provided that similar information submitted to FDA as part of an IND is not publicly available. (See §§ 601.50 and 601.51.) This proposed rule is an attempt to harmonize these approaches for public review of important, new, but potentially hazardous and controversial, therapies. In this way, FDA will be able to more fully participate in existing and future venues for obtaining educated public input and discussion that could inform the agency's deliberations. The agency believes that there is great benefit in having human gene therapy and xenotransplantation products scrutinized, as they are being developed, by individuals with a wide variety of perspectives, including scientists from different disciplines, biomedical ethicists, patient advocacy organizations, and the general public, because of the unique blend of proposed benefit as well as potential risk to society that these products possess. Investigations of these types of products raise serious ethical and scientific issues, and, therefore, the decisionmaking process should be as transparent and fully informed as possible.

The proposed rule would formalize the existing practice of making certain specified types of safety and effectiveness information in IND's for human gene therapy and xenotransplantation publicly available. Such disclosure is necessary in order to protect the public health by informing the research community and the public of the nature and the hazards of the proposed research and by permitting comment on the merits of the proposed research.

The Freedom of Information Act (FOIA), 5 U.S.C. 552, generally provides that Federal agencies must disclose information in their files to the public on request. FOIA is designed to make federal agency records or information available to the public. The Supreme Court has stated that, "The basic purpose of [the] FOIA is to ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed." (See *NLRB* v. *Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978).)

The statute provides nine exemptions and three law enforcement exclusions that agencies may use to protect specific categories of information from disclosure (5 U.S.C. 552(b)). These exemptions are the only basis for withholding information requested by the public under the FOIA [2] and are discretionary, not mandatory. (See *Chrysler Corp.* v. *Brown*, 441 U.S. 281 (1979).) One of these exemptions is particularly relevant to this proposed rule and the disclosure of information in applications to investigate and market human gene therapy and xenotransplantation products.

Exemption 4 of the FOIA protects trade secrets and confidential commercial information from public disclosure. (See 5 U.S.C. 552(b)(4).) While trade secret information, narrowly defined as secret, commercially valuable information related to manufacturing methods or processes, is present in all IND's and biological product files, including those subject to this proposed rule, this proposal will not affect the confidentiality of such information, and therefore it will not be discussed. Confidential commercial information is defined under exemption 4 as "commercial or financial information obtained from a person and privileged or confidential." Each element of the definition must be satisfied for information to be confidential commercial information entitled to protection under exemption 4.

Historically, much of the data and information submitted in IND's and unapproved biological product files has been considered confidential commercial information. (See *Public Citizen Health Research Group* v. *FDA*, 704 F.2d 1280 (D.C. Cir. 1983); *R & D Laboratories, Inc.* v. *FDA* No. 00–CV–0165 (D.D.C. Sept. 7, 2000).) FDA's general information disclosure regulations define confidential commercial information, and provide that information submitted to FDA that falls within this definition is not disclosable. (See 21 CFR 20.61.) Further, the regulations that apply to the submission of IND's and biological product files define the contents of these applications as confidential commercial information generally exempt from disclosure and, indeed, even prohibit the agency from acknowledging the existence of an application (prior to approval) if it has not already been publicly disclosed. (See 21 CFR 312.130, 601.50, and 601.51.) The regulations provide different rules for disclosure after an approval letter has been sent, and when the application has been terminated, abandoned, or otherwise no longer has commercial value.

The agency is exercising its legal authority to promulgate new regulations that will make explicit and will formalize the circumstances and means by which certain safety and effectiveness information in these special types of applications will be made available for public disclosure. Such a change is especially warranted when, as here, the change is being made in large part to reflect the actual environment in which human gene therapy and xenotransplantation applications exist.

As has been discussed elsewhere in this preamble (in section I.B, Issues Related to Human Gene Therapy and Xenotransplantation), sponsors of IND's pertaining to human gene therapy have publicly disclosed the types of information covered by this proposed rule for many years as part of the process overseen by the RAC. Likewise, there has been widespread practice in the field of xenotransplantation to make publicly available a great deal of information concerning details of trials of xenotransplantation products during public advisory committee meetings and workshops sponsored by FDA and by the U.S. PHS. Information that is publicly disclosed by its owner cannot be confidential within the meaning of the FOIA and, as a result, can be made available for public disclosure by FDA. (See *CNA Fin.* v. *Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987).) The fact that these types of information cannot be considered confidential is the principal basis for issuing this proposed rule.

This proposed rule contains the public disclosure procedures the agency will apply to the safety and effectiveness information in human gene therapy and xenotransplantation applications that has historically been treated as confidential commercial information by the agency. These procedures will follow the consistent practice in the fields of human gene therapy and xenotransplantation of making such information available to the public. It is important to note that while certain safety and effectiveness data and information will be publicly available under this proposed rule, FDA does not intend to disclose the full reports of safety and effectiveness on the basis of which the product may be approved. FDA believes that, prior to approval of a biological product file, the full reports constitute confidential commercial information, as they traditionally have under the agency's regulations, and should not be released. (See 21 CFR 601.51(d).) However, under § 601.51(e), all safety and effectiveness data and information do become publicly available after a license is issued, and this practice will not be changed by this proposal.

In addition to the full reports, the agency also wishes to make clear that it will continue its current policy of not releasing confidential commercial information that is contained in a human gene therapy or xenotransplantation IND or unapproved biological product file. Examples of confidential commercial information that may exist in these applications would include information concerning licensing agreements and information identifying suppliers. This information ordinarily will remain confidential under exemption 4 unless it has already been publicly disclosed by the sponsor. Such business-related information is also not the type of information that FDA believes should be disclosed to further the public discussion and evaluation of human gene therapy and xenotransplantation trials. In addition, this proposed rule will not affect the rules governing the disclosure of personal medical and other similar information, the disclosure of which would cause an unwarranted invasion of personal privacy. (See 21 CFR 20.63.)

Based on the authorities discussed, the agency proposes to require sponsors of IND's related to human gene therapy and xenotransplantation to disclose certain specified safety and effectiveness data and information. This proposal will formalize and codify the existing practice in these fields under which these data and information have been publicly disclosed by their sponsors. Disclosure is especially necessary regarding these new, important, and also controversial technologies so that the research community and the public can be assured of the safety of conducting clinical trials of these products.

This proposal would require the sponsors of human gene therapy or xenotransplantation IND's to submit to FDA publicly available versions of information FDA requires in such IND's. The purpose of this requirement is to facilitate FDA's efforts to make important information concerning human gene therapy and xenotransplantation IND's available to the public in a timely and efficient manner. Sponsors would have to redact the information from IND submissions specified in proposed § 601.53. Sponsors would redact trade secrets, confidential commercial information, such as licensing agreements and suppliers, and names and other personal identifiers of patients and, except as specifically provided in the regulations, names and personal identifiers of third parties, such as physicians, hospitals, etc. (See §§ 20.61 and 20.63.) It would not be necessary for sponsors to redact the vast majority of the information in human gene therapy and xenotransplantation IND's since, as described in this proposal, such information would be publicly disclosable.

The proposed rule would also specify that FDA may place a human gene therapy or xenotransplantation investigation on clinical hold if the sponsor has not submitted to the agency a redacted and thus disclosable version of the required IND information that complies with the requirements of proposed § 601.53. A sponsor must properly purge its redacted version of trade secrets, confidential commercial information, and names and other personal identifiers and, except as specifically provided in the regulations, names and personal identifiers of third parties, such as physicians, hospitals,

[1] While human gene therapy and xenotransplantation protocols are generally regulated by CBER as biological products, it is possible that some of these products may be combination products consisting of biological components, drug components, and device components. The same rules of disclosure will apply to the drug or device components of combination products under the same theories discussed later in this section.

[2] It should be noted here that section 301(j) of the act prohibits the public disclosure of information, obtained under certain sections of the act, "concerning any method or process which as a trade secret is entitled to protection." (See 21 U.S.C. 331(j).) In addition, the so-called Federal Trade Secrets Act also contains certain restrictions on the public disclosure of trade secret and confidential commercial information. The Trade Secrets Act does provide for the disclosure of confidential commercial information where such disclosure is "authorized by law." (See 18 U.S.C. 1905.)

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etc. Section 505(i)(3) of the act authorizes FDA to prohibit a sponsor of an investigation from conducting that investigation if FDA determines that the drug involved represents an unreasonable risk to the safety of persons who are the subjects of the clinical investigation, or if there are other reasons that FDA has established by regulation for which the agency may issue a clinical hold. FDA recognizes that errors in redacting may occur and will provide sponsors with an opportunity to correct such errors. However, FDA will have the enforcement authority to place a human gene therapy and xenotransplantation investigation on clinical hold if resolution is not reached on any discrepancies found by FDA in the redacted versions, or if a redacted version is not submitted at all by the sponsor. As described in this proposal, it is important for proposed and ongoing human gene therapy and xenotransplantation investigations to be the subject of public education, discussion, and consideration in order for all relevant issues, including safety, to be explored.

As stated above, FDA has tentatively concluded that the information that would be disclosed as a result of this rulemaking is, in fact, already being made public through a variety of mechanisms, and therefore cannot be considered confidential. As such, it does not constitute confidential commercial (or trade secret) information within the meaning of FOIA Exemption 4.

However, FDA's issuance of this proposed rule is authorized even if the information to be disclosed could be considered confidential commercial information covered by Exemption 4 and within the scope of protection of the Trade Secrets Act (18 U.S.C. 1905). That statute prohibits the disclosure of confidential commercial or trade secret information, except as "authorized by law." Because agency regulations that specifically provide for the disclosure of such information can supply the requisite legal authorization for release of the information for purposes of the Trade Secrets Act, that statute would not present a bar to any of the disclosures contemplated by this proposed rule. (See, e.g., CNA Financial Corp., 830 F.2d 1132, 1138–1139 (D.C. Cir. 1987)).

The broad rulemaking authority conferred on FDA by Congress under the act (21 U.S.C. 201 *et seq.*) permits the agency to amend its regulations as contemplated by this proposed rule.

Section 505(i) of the act (21 U.S.C. 355(i)) gives FDA the authority to issue regulations imposing conditions on the investigation of new drugs. In addition to prescribing certain mandatory conditions, that section further provides that the agency may impose "other conditions" as necessary "relating to the protection of the public health." (21 U.S.C. 355(i)). This language was added to the act as part of the Drug Amendments of 1962 (Public Law 87–781) to make it "clear that the conditions prescribed in the [bill] are not the sole conditions that may be imposed for the protection of public health." H.R. Conf Rep. No. 2526, at 20 (1962), reprinted in 1962 U.S.C.C.A.N. 2927, 2929. Legislative history relating to these amendments also indicates that one purpose of the bill was to make "information on drugs * * * more readily available to physicians and the general public." (S. Rep. No. 1744, at 1 (1962), 1962 U.S.C.C.A.N. 2884). FDA's broad discretion in adopting regulations under this language has been upheld by the courts. (*United States* v. *Garfinkel*, 29 F.3d 451 (8th Cir. 1994)).

The proposed amendments to FDA's regulations are within FDA's statutory discretion in imposing conditions on products under development to promote the public health. The public health often is served not only by collection of research data and information, but also by disclosure of such information. (See e.g., *Dole* v. *United Steelworkers of America*, 494 U.S. 26, 28 (1990)).

The proposed rule would serve several significant public health goals. It would enhance the ability of patients with serious and life-threatening diseases and others seeking information about emerging therapies to obtain critically important information from FDA about the existence of clinical trials in which they might participate, about possible safety problems associated with the products they are taking, and about the regulatory status of applications pending before the agency.

As an aftermath of recent problems in clinical trials involving gene therapy products, FDA and NIH have launched two new initiatives to further strengthen the safeguards for individuals enrolled in clinical studies for gene therapy. One initiative, the Gene Therapy Clinical Trial Plan, would ensure: That sponsors meet their obligation to adequately monitor the clinical trials for which they are responsible; that there is appropriately independent oversight of such clinical trials; and that there is an increased level of government oversight, through increased inspection frequency and review of sponsors' monitoring plans and other clinical trial practices. Under the other initiative, FDA and NIH will, several times per year, convene Gene Transfer Safety Symposia to provide a critical forum with experts in gene transfer for the sharing and analysis of medical and scientific data from gene transfer research. FDA and NIH support will also be provided for professional organizations and academic centers to hold safety conferences focused on gene therapy. These safety symposia and educational outreach efforts are intended to guide the conduct of current clinical trials and enhance the design of future gene transfer trials to maximize public safety.

The ready availability of information concerning clinical trials involving gene therapy is essential to the success of these efforts. For example, such information would be discussed at the government's safety symposia, may be made available for other scientific discussions and to the general public, and would be used in evaluating current gene therapy practices, including sponsor monitoring and informed consent standards. Likewise, FDA intends to continue to sponsor and support government, professional, and academic conferences related to xenotransplantation. Thus, FDA believes that the disclosure of information contained in INDs related to gene therapy and xenotransplantation trials is essential to patient safety and appropriate informed consent.

In addition to section 505(i), section 701(a) of the act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the act. A regulation issued under section 701 of the act will be sustained as long as it is reasonably related to the purposes of the act. (*United States* v. *Nova Scotia Food Prod. Corp.*, 568 F.2d 240, 246 (2d Cir. 1977)). Section 903(b) of the act (21 U.S.C. 393(b)) explicitly states that the mission of FDA includes the promotion and protection of the public health. It has long been recognized by the courts, including the Supreme Court, that the primary purpose of the act is the protection of public health (*United States* v. *An Article of Drug, Bacto-Unidisk*, 394 U.S. 784, 798 (1969)). As a result, FDA's rulemaking authority under section 701(a) of the act has been broadly construed to uphold a wide variety of the agency's rulemaking activities intended to protect the public health. (See e.g., *National Ass'n of Pharmaceutical Mfrs.* v. *FDA*, 637 F.2d 877 (2d Cir. 1981)) (current good manufacturing practice regulations); *Pharmaceutical Mfrs. Ass'n* v. *FDA*, 484 F. Supp. 1179 (D. Del. 1980) (rule requiring disclosure of drug side effects to patients); *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976) (rule establishing common and usual names for certain nonstandard foods to provide consumers with relevant buying information), *aff'd*, 555 F.2d 1059 (D.C. Cir. 1977); *National Nutritional Foods Ass'n* v. *Weinberger*, 376 F. Supp. 142 (S.D.N.Y.) (rule requiring that certain vitamin preparations be restricted to prescription sale and be labeled accordingly), *aff'd*, 512 F.2d 688 (2d Cir. 1975)), *cert. denied*, 423 U.S. 827 (1975). FDA believes that its rulemaking authority under section 701(a) of the act supports the amendments proposed here because they advance public health goals concerning gene therapy and xenotransplantation studies.

FDA is also proposing to issue this new regulation under the authority of section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). Under section 361 of the PHS Act, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361 of the PHS Act authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Intrastate transactions may also be regulated under section 361 of the PHS Act.

This proposed regulation is part of a regulatory program that will further the goal of preventing the introduction, transmission, or spread of communicable disease. For this regulatory system to be effective in preventing the spread of disease, FDA must be able to regularly make publicly available information regarding these experimental procedures. By providing sponsors, clinical investigators, patients and their families, and the general public with access to the types of information proposed in this rule, FDA will be able to more rapidly identify and react appropriately to newly discovered or understood risks in order to prevent the spread of communicable disease.

Studies in the areas of gene therapy and xenotransplantation are conducted to explore the potential for considerable benefits. However, use of these procedures, particularly in the case of xenotransplantation, poses potential risks for the transmission of infectious disease. Infectious disease public health concerns focus not only on the transmission of known zoonoses, but also on the transmission of infectious agents as yet unrecognized. The disruption of natural anatomical barriers and immunosuppression of the recipient increase the likelihood of interspecies transmission of xenogeneic infectious agents. An infectious agent may pose risks if it can infect, cause disease in, and transmit among humans, or if its ability to infect, cause disease in, or transmit among humans remains inadequately defined. The public availability of information this proposed rule envisions will permit public attention to any emerging risks associated with these experimental techniques, early detection and definition of which will permit the agency and sponsors to take steps to prevent or minimize the introduction of communicable disease.

An additional concern is that these infectious agents could subsequently be transmitted from the patient to family members and other close contacts of the patients, to health care personnel, and to other members of the public. Because the potential risk of transmission of infectious disease extends beyond the patient receiving the treatment, it is vital that the public, as well as the patient, be informed and educated about potential infectious disease risks and methods for reducing those risks. Close contacts should understand the uncertainty regarding the risks of xenogeneic infections, behaviors known to transmit infectious agents from human to human (e.g., unprotected sex, breast feeding, intravenous drug use with shared needles, and other activities that involve potential exchange of blood or other body fluids) and methods to minimize the risk of transmission. Close contacts of recipients also need to know about the importance of reporting any significant unexplained illness through their health care provider to the research coordinator at the institutions where the xenotransplantation was performed. This broader concern for the spread of communicable disease is reflected in the proposed requirements providing for public disclosure. While informed consent procedures may try to address these educational needs, the public release and discussion of information that this proposed rule calls for is also necessary to ensure that all those potentially at risk have the information to manage these risks and so avoid or minimize the spread of communicable disease.

For all the above reasons, to promote and protect the public health, FDA is proposing to issue this proposed rule providing for public disclosure of certain information relating to gene therapy and xenotransplantation.

C. Discussion of the Proposed Rule

The proposed rule would create a new § 601.52 entitled "Availability for public disclosure of certain data and information related to human gene therapy or xenotransplantation" and § 601.53 entitled "Submission to FDA of certain data and information related to human gene therapy or xenotransplantation for public disclosure." In addition, conforming amendments are proposed to §§ 20.100, 312.42, 312.130, 601.50, and 601.51. The provisions of this rulemaking do not alter the procedures specified in part 312 for submission of an IND. The proposed regulations are discussed below.

1. Sections 601.50 and 601.51

Part 601 (21 CFR part 601) sets forth provisions that govern the licensing of biologic products by the FDA. Existing procedures and requirements regarding confidentiality of data and information contained in IND's for biological products or biologics license applications are described in §§ 601.50 and 601.51. The proposed rule would amend §§ 601.50 and 601.51 to include language that would reference the exceptions proposed in § 601.52 regarding the availability for public disclosure of certain data and information related to human gene therapy or xenotransplantation. Specifically, §§ 601.50(a) and 601.51(a) would be amended to add the words, "Except as provided in § 601.52."

In addition, FDA is proposing to amend the § 601.50 section heading and § 601.50(a) to replace the word "notice" with "application" to be consistent with other current regulations regarding investigational new drugs, i.e., part 312.

2. Proposed § 601.52

Proposed § 601.52 would set forth the requirements regarding the availability for public disclosure of certain data and information related to human gene therapy or xenotransplantation. These provisions would define the therapies and scope of the proposed regulation, and describe the types of data and information related to human gene therapy and xenotransplantation that may be disclosed by FDA.

a. *Definitions.* Proposed § 601.52(a) would include definitions of human gene therapy and xenotransplantation that are consistent with existing agency policy and guidance regarding these therapies. Proposed § 601.52(a)(1) would define "human gene therapy" to mean the administration of genetic material in order to modify or manipulate the expression of a gene

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product or to alter the biological properties of living cells for therapeutic use. FDA interprets this definition to include both the ex vivo and in vivo modification of cells. Proposed § 601.52(a)(2) would define "xenotransplantation" to mean any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: (a) Live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. This definition of xenotransplantation does not include the use of products that are nonliving, acellular products such as porcine heart valves, porcine insulin, or bovine serum albumin. The definition also does not include non-animal cells and tissues, such as bacteria and plant cells.

Because the terms "human gene therapy" and "xenotransplantation" are not currently used elsewhere in the regulations, FDA is proposing that, for the convenience of the user, the definitions be included in proposed § 601.52. If, in the future, additional regulations are issued using these terms, FDA intends to move these definitions to the section of the regulations which currently includes definitions of other terms applicable to biological products (21 CFR 600.3).

b. *Scope.* Proposed § 601.52(b) would describe the scope of the proposed regulation. Consistent with the use of the terms "human gene therapy" and "xenotransplantation," FDA intends that the proposed rule apply to the procedures, not specific products used in the therapies, although data and information regarding a product may be disclosed as proposed in § 601.52(c). FDA intends with this broadly-defined scope that the proposed regulation apply to any experimental use of human gene therapy and xenotransplantation, although the immediate impact of the proposed regulation would be on investigational products. For example, the proposed regulations would apply to any use of gene therapy or xenotransplantation in clinical studies in humans, including use of a licensed gene therapy or xenotransplantation product with an experimental drug or device being clinically studied for use in a gene therapy or xenotransplantation procedure.

FDA believes it is not necessary to disclose for purposes of public education and discussion all the information which may be included in an IND. Except as specifically provided in the proposed rule, FDA intends that information regarding human gene therapy or xenotransplantation investigations will continue to be held confidential, consistent with existing regulations in §§ 20.61, 20.62, 20.63, 20.100, 312.130, 601.50, and 601.51. Accordingly, proposed § 601.52(b) would specify that, except as specifically provided in proposed § 601.52, the availability for public disclosure of data and information related to human gene therapy or xenotransplantation shall remain in accordance with § 601.50 for IND's for a biological product.

c. *Information for public disclosure.* Proposed § 601.52(c) would specify the types of data and information related to human gene therapy or xenotransplantation that the FDA may make available for public disclosure. The types of information listed in proposed § 601.52(c) are already required for submission under existing regulations (parts 312 and 601) as part of an IND or BLA or as a supplement to a BLA.

Under proposed § 601.52(c)(1), FDA would make product and patient safety data and related information related to human gene therapy and xenotransplantation available for public disclosure. This proposed provision is similar to existing requirements in § 601.51(e)(1), which require that all safety and effectiveness data and information contained in a biological product file be made available for public disclosure immediately after a license has been issued. The proposed provisions in § 601.52, however, would extend this throughout the entire product development process for a product related to human gene therapy or xenotransplantation. The proposed rule further specifies in § 601.52(c)(1) that for the purposes of this proposed regulation, product and patient safety data and related information include results of preclinical and clinical studies and tests that demonstrate the safety and/or feasibility of the proposed procedures. In addition, FDA proposes in § 601.52(c)(1) to identify some of the types of product and patient safety data and related information that would be disclosed to the public that are particularly relevant or specific to human gene therapy and xenotransplantation. These types of product and patient safety data and related information are: (1) Analysis in animals, humans, or in vitro systems of gene transfer, expression, and persistence; (2) vector biodistribution; (3) evidence for immune response/anergy; (4) biological activity; (5) results of product safety testing including test results for known xenogeneic and human infectious agents and replication competent virus; (6) qualification of source herd, individual source animal, and source organ/tissue/cells for xenotransplantation in humans; and (7) information on monitoring or prevention of potential health risks to the recipient, close contacts, and health care workers. FDA does not intend this to be an exclusive list. In all cases, names and other personal identifiers of patients and, expect as specifically provided in the regulations, names and other personal identifiers of third parties, such as physicians or hospitals, would be removed. Furthermore, FDA does not intend product and patient safety data and related information under proposed § 601.52(c)(1) to include IND safety reports and annual reports, as provided for in §§ 312.32 and 312.33. Rather, specific requirements for the public disclosure of these types of reports are proposed below in § 601.52(c)(7) and (c)(8), respectively.

Under proposed § 601.52(c)(2) and (c)(3), FDA would make the name and address of the sponsor and the clinical indications to be studied available for public disclosure. The sponsor name and address and the indications to be studied are types of information that are consistent with information already required for submission to FDA in an IND under § 312.23(a)(1)(i) and (a)(3)(iv)(*b*), respectively.

Under proposed § 601.52(c)(4), FDA would make the protocol for each planned study available for public disclosure. A study protocol is required for submission in an IND under § 312.23(a)(6); proposed § 601.52(c)(4) would specify that certain elements of the protocol be available for public disclosure. Proposed § 601.52(c)(4)(i) through (c)(4)(vi) would describe the following specific elements of the protocol to be available for public disclosure: (1) A scientific abstract and a non-technical abstract; (2) a statement of the objectives, purpose, and rationale of the study (submitted in an IND under § 312.23(a)(6)(iii)(*a*)); (3) the name and address of each investigator (submitted in an IND under § 312.23(a)(6)(iii)(*b*)); (4) the name and address of the official contacts of each local review body as appropriate (IRB (submitted in an IND under § 312.23(a)(6)(iii)(*b*)), and IBC (NIH *Guidelines for Research Involving Recombinant DNA Molecules*, revised April 1998)) and dated copies of each committee's approval of the study; (5) the criteria for patient selection and exclusion and an estimate of the number of patients to be studied (submitted in an IND under § 312.23(a)(6)(iii)(*c*)); and (6) a description of the treatment that will be administered to patients and the clinical procedures, laboratory tests, or

other measures to be taken to monitor the safety and effects of the drug in human subjects and to minimize risk (similar to that submitted in an IND under § 312.23(a)(6)(iii)(*g*)). FDA intends that the term "investigator' in proposed § 601.52(c)(4)(iii) include "sponsor-investigators" (individuals who have the responsibility for both the development and clinical investigation of the product) as well as "investigators," both of which are defined in existing § 312.3(b). In proposed § 601.52(c)(4)(iv), FDA intends to make available for public disclosure the dated copies of the IRB's and IRC's approval of the proposed clinical study to identify when the IRB or IBC assumed responsibility for the continued review and approval of the IND.

Under proposed § 601.52(c)(5), FDA would make sample informed consent forms available for public disclosure. FDA proposes to provide public access to human gene therapy and xenotransplantation clinical trial information relevant to informed consent to promote public education, discussion, and consideration of the unique challenges that these novel therapies present to assuring adequate informed consent, as discussed previously in this proposed rule.

Under proposed § 601.52(c)(6), FDA would make the identification of the biological product(s) and a general description of the method of production, including a description of product features that may affect patient safety, available for public disclosure. This proposed provision contains types of information that are required for submission to FDA in an IND under § 312.23. FDA has modified the language taken from § 312.23 to reflect information needs related to human gene therapy and xenotransplantation and specifies that only a "general" description of the production method would be made available, excluding trade secret information. FDA does, however, propose to further specify in § 601.52(c)(6) that the identification and description would include the following types of information, as applicable: (1) The vector name and type; (2) gene insert; (3) regulatory elements and their source; (4) intended target cells; (5) source of cells, tissues, or organ(s); (6) method used to prepare the vector containing cells; (7) method used to procure and prepare cells, tissues, or organ(s) for xenotransplantation; (8) purity of cells; (9) adventitious agent testing; (10) description of the delivery system; (11) ancillary products used during production; (12) herd colony and individual source animal health maintenance and surveillance records; and (13) biological specimens to be archived from source animals. These types of information are consistent with information that is already submitted to and publicly disclosed by OBA for human gene therapy.

Under proposed § 601.52(c)(7), FDA would make IND safety reports, as provided in § 312.32, and other similar data and information available for public disclosure. Under § 312.32, sponsors of investigational drugs, including biological drugs, are required to submit to FDA certain adverse reaction reports concerning their product. Under § 601.51(e)(3), information concerning these adverse experience reports, excluding names and other identifiers of patients, health care facilities, and physicians, may be publicly disclosed after the licensure of the product. Under proposed § 601.52(c)(7), such adverse experience reports and other safety reports related to an investigational product could be publicly disclosed at any time throughout the lifetime of the product. The same limitations for disclosure included in § 601.51(e)(3) are included in proposed § 601.52(c) to protect the privacy of patients and health care workers.

Under § 601.52(c)(8), FDA would make information submitted in the annual report available for public disclosure. Sponsors must submit to FDA annual reports of the progress of the investigations as required under § 312.33. FDA proposes that the following types of information relevant to human gene therapy and xenotransplantation be included, as applicable, in the annual report submitted by the sponsor to FDA for public disclosure: (1) Evidence of gene transfer, gene expression in target cells, and biological activity; (2) assessment of immune response; (3) analysis of biodistribution; (4) significant preclinical and clinical toxicities; (5) evidence of infection by agents associated with the products; (6) adverse experiences; (7) number of subjects who died during participation in the investigation, with the cause of death for each subject and the status of autopsy requests; and (8) any available post mortem evidence of gene transfer, biodistribution, specifically including gonadal distribution. In all cases, names and other personal identifiers of patients and, except as specifically provided in the regulations, names and other personal identifiers of third parties, such as physicians or hospitals, would be removed.

Under proposed § 601.52(c)(9), FDA would make the regulatory status of the investigation, the date of a regulatory action, and the reason for an action available for public disclosure in order to identify to the public the current regulatory status of a clinical investigation. For example, FDA would disclose that an investigation is on clinical hold, or that an IND is inactive, withdrawn, or terminated. Additional information regarding the procedures and criteria for placing an investigation on clinical hold, withdrawal of an IND, inactive status for an IND, and IND termination may be found in §§ 312.42, 312.38, 312.45, and 312.44, respectively.

Under § 601.52(c)(10), FDA would make available for public disclosure other relevant data and information that the Director, CBER, determines are necessary for the appropriate consideration of the public health and scientific issues, including relevant ethical issues raised by human gene therapy or xenotransplantation. This proposed provision is included because the investigational nature of these therapies and the continuing evolution of the science surrounding these therapies renders FDA unable to anticipate all of the types of information related to human gene therapy and xenotransplantation that may warrant public education, discussion, and consideration. Examples of other relevant data that FDA may disclose could, under certain circumstances, include the details of a test used to determine eligibility for trial entry or autopsy or biopsy information. However, in general, FDA intends to release only the information specifically identified in this proposed rule, except in unique conditions or circumstances. Proposed § 601.52(c)(10) would provide that other relevant data and information may be approved for disclosure only by the Director of CBER.

3. Proposed § 601.53

Proposed § 601.53 would require sponsors of human gene therapy and xenotransplantation clinical trials to submit to FDA for public disclosure a redacted version of certain data and information. These provisions would specify when and what types of submissions to make to FDA in a redacted version for public disclosure, and the requirements for identifying and certifying these submissions.

Furthermore, proposed § 312.42(b)(6) provides that a sponsor's failure to submit to FDA the data and information specified in §§ 601.52 and 601.53 that has been properly redacted under § 601.53(a) is a basis for FDA placing the investigation on clinical hold. FDA recognizes that errors in redacting may occur and will provide sponsors with an

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opportunity to correct such errors. However, FDA will have the enforcement authority to place a human gene therapy and xenotransplantation investigation on clinical hold if resolution is not reached on any discrepancies found by FDA in the redacted versions, or if a redacted version is not submitted at all by the sponsor. It is important that FDA has the specific authority to place a human gene therapy or xenotransplantation investigation on clinical hold if the sponsor has not submitted required data and information to FDA in a form that FDA can make publicly available in a timely and efficient manner. As previously described in this proposal, due to the unique nature of human gene therapy and xenotransplantation, public participation in the consideration of proposed and ongoing clinical studies of such therapies is crucial. In order for such public education, discussion, and consideration to take place and be meaningful, FDA must be able to make all relevant and publicly disclosable data and information available to the public as soon as practicable. The agency has determined that having sponsors submit redacted versions that comply with proposed §§ 601.52 and 601.53 is the most efficient means to accomplish this.

Under proposed § 601.53(a), FDA would require the sponsor of an IND to submit to FDA for public disclosure a redacted version of the types of submissions identified in § 601.53(b)(1) through (b)(5). The sponsor would be required to include all applicable information identified as disclosable in § 601.52 and redact all information considered confidential as trade secret, names and other personal identifiers of patients and, except as specifically provided in the regulations, names and personal identifiers of third parties, such as physicians, hospitals, etc., and certain confidential commercial information, such as information regarding commercial licensing agreements or the identification of suppliers. Sponsors would be permitted to redact either by removing or obscuring the information exempt from disclosure.

Proposed § 601.53(b)(1) through (b)(5) would list the types of submissions that the sponsor would be required to submit to FDA in duplicate and as a redacted version for public disclosure. FDA believes this information should be available for public disclosure as soon as possible and therefore, would require under this paragraph that the redacted version be submitted to FDA concurrently with the original unabridged submission or at the specific time points noted.

Proposed § 601.53(b)(1) would require submission for public disclosure a redacted version of the information defined under § 601.52 to accompany the original unabridged IND submission.

Proposed § 601.53(b)(2) would require submission for public disclosure a redacted version of any amendment documenting changes or additions to the information defined under § 601.52 that occur either during the IND review process or after the IND goes into effect. FDA recognizes that some amendments may require negotiation with FDA and subsequent revision by the sponsor. As such, FDA would require that the redacted version of any amendment be submitted at the time the amendment goes into effect.

Proposed § 601.53(b)(3) would require submission for public disclosure of a redacted version of any IND safety report at the time of submission of the original report to FDA. Sponsors are required under § 312.32 to notify FDA in a written IND safety report of any serious and unexpected adverse experiences associated with the use of their drug no later than 15 days after the sponsor's initial receipt of the information. FDA believes that the timely availability of adverse experience information is essential for public education and informed discussion and consideration of the health and safety issues presented by the experiences.

Proposed § 601.53(b)(4) would require submission for public disclosure of a redacted version of the annual report, in accordance with § 312.33. Consistent with § 312.33, sponsors would be required to submit, within 60 days of the anniversary date that the IND went into effect, a redacted version of the annual report.

Under proposed § 601.53(b)(5), a sponsor would be required to submit for public disclosure a redacted version of other information upon specific request of the Director, CBER. For example, FDA may request that the sponsor submit information regarding a test used to determine eligibility for trial entry. This proposed provision is included because due to the investigational nature of these therapies and the continuing evolution of the science surrounding these therapies, FDA is not able to anticipate all of the types of information related to human gene therapy and xenotransplantation that may warrant public education, discussion, and consideration. However, in general, FDA does not intend to request information not identified in this proposed rule, except for unique conditions or circumstances.

Proposed § 601.53(c) would require that the sponsor submit the information identified in § 601.53(b) in duplicate, in a form readily separable from the nonredacted or original unabridged version or submission and clearly marked as suitable for public disclosure on each page of the submission. This proposed provision would enable FDA to identify and provide this information more rapidly to the public and would help assure that only appropriate information is disclosed to the public.

Proposed § 601.53(d) would require that any copyrighted material be included in a single appendix to the submission and listed in a bibliography in the redacted version. The proposal would specify that any copyrighted material whose copyright is not owned by the applicant shall not be included in any other section of the redacted version. FDA is including this provision to facilitate timely release of the redacted version on the Internet. In response to an FOIA request, copyrighted materials can be included in the response. However, with regard to posting on the Internet, copyrighted material must be redacted prior to electronic disclosure as this is not considered a "fair use" of copyrighted material. Therefore, FDA would not release the appendix containing copyrighted materials as part of the redacted version on the Internet, but may release the bibliography of materials included in the appendix.

Proposed § 601.53(e) would require that redacted versions be accompanied by the statement specified to ensure that the sponsor has redacted only the information identified in § 601.53(a) as exempt from disclosure (confidential commercial, trade secret, or personal information). In addition, under proposed § 601.53, the sponsor must include a declaration that the statement is true and correct, under penalty of perjury.

4. Conforming Amendments

The proposed rule would make conforming amendments to parts 20 and 312. Part 20 describes the procedures and policy regarding the availability and disclosure of information to the public. Section 20.100 lists the cross-references to other sections of title 21 CFR that contain requirements on the availability of specific categories of FDA records and how these records are handled upon a request for public disclosure. The proposed rule would amend § 20.100(c) by adding a paragraph (43) that would contain a cross-reference to the proposed § 601.52 regarding the availability for public disclosure of certain data and information submitted to FDA related to human gene therapy or xenotransplantation.

Part 312 describes the procedures and requirements that govern the use of investigational new drugs, including provisions for submission to and review by FDA of IND's. The provisions of this rulemaking do not alter the procedures specified in part 312 for submission of an IND. Section 312.42, among other things, lists the grounds for which FDA may impose a clinical hold of an investigation. Proposed § 312.42(b)(7) would amend § 312.42 by adding an additional basis for clinical hold for human gene therapy and xenotransplantation investigations. Under this proposal, FDA could place a human gene therapy or xenotransplantation investigation on clinical hold if the sponsor has not submitted to the agency a redacted version for public disclosure that complies with the requirements of § 601.53.

Section § 312.130 contains requirements regarding the availability for public disclosure of data and information in an IND. The proposed rule would amend § 312.130 by revising paragraph (b) to include a reference to proposed § 601.52, in addition to the existing references to §§ 601.50 and 601.51, when listing the provisions of this chapter that govern the availability for public disclosure of all data and information in an IND.

III. Implementation

Under the proposed rule, FDA would require that sponsors of human gene therapy and xenotransplantation clinical trials submit for public disclosure a redacted version of the information defined under § 601.52 as contained in the initial IND submission, amendments documenting changes or additions to the information defined under § 601.52 at the time the amendments go into effect, IND safety reports, and annual reports. The redacted version of these documents should be submitted to FDA in a form immediately releasable to the public, and clearly marked accordingly on each page of the submission as suitable for public disclosure. Acceptable approaches range from submitting a "marked up" version of the original that obscures the information which is not to be disclosed, to developing a separate document that abstracts the needed information for public disclosure from the original unabridged version submitted to FDA.

Specifically, FDA is proposing that the redacted version of the information specified in the proposed rule be submitted to FDA concurrently with the original unabridged IND submission or at the specific time points noted in the provisions. Sponsors of human gene therapy and xenotransplantation clinical trials would send an original and two copies of the original unabridged version of the IND submission (as required under existing § 312.23(d)) as well as one copy of the redacted version for public disclosure to FDA's CBER, where they would be received by the Document Control Center (DCC) to be logged, filed, and routed for appropriate documentation, review, and approval. DCC would route the submittals to the appropriate FDA reviewer, where, upon receipt, the redacted version for public disclosure would be reviewed for administrative completeness as well as to ensure that the submitting sponsor has appropriately redacted personal information regarding patients and third parties prior to release to the public. Once this review is complete, the redacted version for public disclosure would be sent to the Dockets Management Branch for public display where a docket number would be assigned. Each redacted version for public disclosure submitted to FDA would be tagged with the same docket number for that IND for reference. FDA is also proposing to make the redacted versions for public disclosure available to the public electronically on the Internet site according to the docket number.

In addition, to facilitate timely release by FDA of the redacted version, FDA is proposing to require that all copyrighted materials submitted in accordance with § 601.53 be placed in a single appendix and listed in a bibliography in the redacted version. Should an FOIA request be received for the data and information specified in § 601.52, FDA would be able to include a copy of any copyrighted materials in its response. However, FDA would not be able to publicly release any copyrighted material on the Internet as electronic posting of such information is not a "fair use" of that copyrighted material and must be redacted prior to electronic release. In this case, FDA instead would disclose the bibliography of copyrighted materials contained in the appendix.

FDA encourages, but would not require at this time, sponsors to submit the redacted version for public disclosure in electronic format. Pilot programs are currently underway regarding submission of electronic IND's and BLA's. (See 63 FR 29740 and 29741.) As such, FDA may, in the near future, implement electronic submission and disclosure of this information.

Sponsors of human gene therapy or xenotransplantation clinical trials who submit an initial IND or an amendment to an existing IND on or after the effective date of the final rule resulting from this rulemaking would be required to submit a redacted version for public disclosure in conformance with the rule.

Sponsors of xenotransplantation clinical trials who have submitted an IND to FDA prior to the effective date of the final rule resulting from this rulemaking would be required to submit for public disclosure a redacted version of the information defined under § 601.52, reflecting all amendments to date, by a date specified in the final rule.

Sponsors of human gene therapy clinical trials who have submitted IND's or amendments prior to the effective date of the final rule, need not submit redacted versions. For these IND's or amendments, FDA will rely on the existing OBA database as a source of the information that FDA will disclose.

For additional information regarding the proposed effective dates for the final rule see the end of this preamble.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts and Initial Regulatory Flexibility Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and under the Unfunded Mandates Reform Act (UMRA) (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. The UMRA requires that agencies prepare a written statement under section 202(a) of UMRA of

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anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year.

The agency believes that this final rule is consistent with the principles identified in Executive Order 12866. OMB has determined that the final rule is a significant regulatory action as defined by the Executive Order and so is subject to review. Because the rule does not impose mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule, will not approach $100 million for either the public or the private sector. As discussed below, because of the limited information that can be used to characterize the entities that may qualify as small businesses, the impact on small business establishments is uncertain. FDA has therefore prepared an Initial Regulatory Flexibility Analysis.

A. Background

In the discussion that follows, FDA will describe the purpose and requirements of the proposed rule, the estimated number of entities that will be affected, the estimated cost of compliance with the rule per IND, and a summary of estimated annual costs to industry.

The purpose of the proposed rule is to make available for public disclosure and to require submission in redacted version for public disclosure, certain data and information related to human gene therapy and xenotransplantation investigations. These areas of clinical investigation have the potential for unique public health risks and modification of the human genome. The public health and safety risks require that FDA be able to make timely disclosures of adverse outcomes, such as the development of novel infectious agents, unanticipated alterations of a recipient's germline, and severe toxicity resulting from the therapy, in order to prevent or contain further adverse occurrences.

These therapeutic research areas will effectively transform participating recipients into life-long research subjects. The length of commitment, coupled with the magnitude of potential risks to the recipients, their families and community, will present new challenges for risk assessment and the adequacy of informed consent. As noted earlier, these investigative approaches raise new challenges for Institutional Review Boards. The novelty and extent of the risk issues will call for expanded public access to clinical trial information relevant to assessment of risks and benefits, and public education and informed consent. These public information needs can only be addressed through disclosure of relevant information about the proposed and ongoing investigations.

The information to come under this disclosure regulation includes: (1) Product and patient safety data and related information including results of preclinical and clinical studies and tests that demonstrate the safety and/or feasibility of the proposed procedures; (2) the name and address of the sponsor; (3) the clinical indications to be studied; (4) the protocol for each planned study to include a scientific abstract and a nontechnical abstract, a statement of the objectives, purpose, and rationale of the study, the name and address of each investigator and subinvestigator, the name and address of the official contacts of each local review body as appropriate (IRB, IBC) and the dated copies of approval by each group, the criteria for patient selection and exclusion, an estimate of the number of patients to be studied, and a description of the treatment that will be administered to patients, and the clinical procedures, laboratory tests, or other measures to be taken to monitor the safety and effects of the drug in human subjects and to minimize risk; (5) the informed consent documentation; (6) the identification of the biological product(s) and a general description of the method of production, including a description of product features that may affect patient safety; (7) the IND safety reports; (8) the information submitted to FDA in the annual report; (9) the regulatory status of the investigation, the date of an action, and the reason for an action; (10) and other relevant data and information that the Director, CBER, determines are necessary for the appropriate consideration of the public health and scientific issues, including relevant ethical issues, raised by human gene therapy or xenotransplantation. After a license has been issued, all safety and effectiveness data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown (§ 601.51(e)(1)).

The sponsor of an IND involving human gene therapy or xenotransplantation will be required to submit this information in redacted version for public disclosure, removing all information that would be defined as trade secret, or personal information. The redacted submissions would be as follows:

1. Redacted version of information as defined under § 601.52 at the time of the initial IND submission.

2. Redacted version of any amendment documenting changes or additions to the information defined under § 601.52, at the time the amendment goes into effect.

3. Redacted version of IND safety reports at the time of submission of the initial report.

4. Redacted version of the annual progress report within 60 days of the anniversary date that the IND went into effect.

The redacted version would be submitted in a form that is readily identifiable and separable from the original unabridged submission to FDA.

The proposed rule will affect sponsors of human gene therapy or xenotransplantation clinical trials. The agency estimates that, at any one time, a total of 147 sponsors will be affected by the proposed rule. This includes 134 sponsors that have submitted IND's in the area of human gene therapy, and an additional 13 sponsors that have submitted IND's for clinical trials involving xenotransplantation. The number of new IND's per year in these two research areas has remained relatively constant at the level of approximately 45 IND submissions per year, for the past several years.

B. Cost Impact

Certain types of information have a substantial commercial value. This value may be particularly high for data pertaining to specific business plans, strategies, or lines of scientific research. The required disclosure of such information, however, imposes no economic impact where the relevant data are already available to competitors. As discussed earlier in this preamble, information that would be disclosed under this proposed rule is routinely examined and discussed by the RAC, in the case of gene therapy, and discussed at other public meetings addressing xenotransplantation issues, or through public filings with the SEC. Because the information proposed for disclosure has not been treated as confidential by industry, FDA finds that there is minimal incremental commercial value associated with the information that may be disclosed. The agency has, therefore, not attributed regulatory costs to its disclosure. The agency requests public comment on the validity of this view.

The proposed rule will require additional paperwork activities for affected firms. The primary impact on clinical trial sponsors will be the requirement for additional staff time to redact IND-related submissions, throughout the period in which the IND is active. Table 1 of this document provides a summary of the types of submissions that will be required for public disclosure and the estimated number of such submissions that FDA expects to receive each year across all active IND's in the areas of human gene therapy and xenotransplantation. The estimated time required per redacted submission is also shown in table 1. The numbers of submissions and redaction times are estimated by FDA staff involved in application review, based on their experience in recent years, and their familiarity with the content of the IND packages. The redaction is assumed to be performed by a relatively senior member of the scientific research staff at a sponsoring organization. The cost per hour of staff time is estimated to be approximately $38, based on the Bureau of Labor Statistics estimate of total hourly compensation for professional white-collar workers in the private goods-producing and service producing industries.[3] The redacted documents listed in table 1 reflect a series of submissions that would typically occur over several years. Based on FDA's estimate of the total volume of submissions of each type per year, the agency estimates that the total cost to the industry will be approximately $123,880 [$41,040+$5,130+$1,710+$76,000]. This yields an average annual cost of $843 per sponsor [$123,880/147].

TABLE 1.—ESTIMATES OF COST PER YEAR FOR INDUSTRY-WIDE REDACTION EFFORTS

Type of Redacted Submission	Total Industry Submissions per Year	Average Redaction Time/Submission	Estimated Industry Cost per Year
New IND[1]—initial and authorized version	45	24 hours	$41,040 [45 x 24 x $38]
IND amendments	270	0.5 hour	$5,130 [270 x 0.5 x $38]
IND safety reports	90	0.5 hour	$1,170 [90 x 0.5 x $38]
Annual reports	100	20 hours	$76,000 [100 x 20 x $38]
Total Annual Cost to Industry			$123,880
Average Annual Cost Per Sponsor (147 sponsors)			$843

[1] Investigational new drug application.

C. Benefits

Although human gene therapy offers the promise of more effective treatment, for diseases ranging from cystic fibrosis to human immunodeficiency virus (HIV), rapid progress and patient safety in research requires timely communication of new findings about the success or risks of candidate strategies. The key to success for any human gene therapy strategy is attaining a vector that can serve as a safe and efficient gene delivery vehicle (Ref. 5). In general, human gene therapy researchers work to maximize efficacy through the regulation of gene expression over long periods (Ref. 6). Simultaneous with this goal, researchers attempt to develop vectors and treatment strategies that will both minimize the patient's immune response (which counters the therapy) (Ref. 7) and minimize the toxicity of the gene therapy (Refs. 8 and 9). As different vectors are considered, it is critical that newly discovered risks be reported to alert other researchers considering similar vectors or developing therapies to treat similar conditions.

As described earlier, the importance of timely communication of risks is clearly demonstrated by the cystic fibrosis patient who developed an acute adverse event requiring intensive care after receiving an adenoviral vector. In this case, public discussion of the adverse event at the RAC meeting facilitated rapid dissemination of important information about this toxicity, thereby contributing to the safety of patients in other gene therapy trials.

For xenotransplantation, the disclosure of information is necessary for public education and more efficient product and recipient tracking. Communication of risks offers other benefits for recipients of xenotransplantation products, their families, and their communities. According to a recent World Health Organization report on xenotransplantation, "The practice of xenotransplantation carries with it an unquantifiable risk of xenozoonotic infection and disease. Measures are required to minimize risk and maximize safety in the potential use of this technology" (Ref. 10). The level of risk is particularly difficult to quantify since potential viruses may be unknown and "silent" in the donor species; that is, they may not be identified through the currently available battery of screening tests for known pathogens. In addition, the risk of infection in the recipient of a xenotransplantation product may be substantially increased as a result of the immunosuppressive drug therapy administered to prevent rejection of the transplanted xenotransplantation product.

New evidence supporting the possibility of this risk is reported in a recent study (Ref. 11) showing that pig pancreatic islets transplanted into severely immunodeficient mice produce porcine endogenous retroviruses (PERV) that can infect human cells that had been transplanted into the same mice receiving the porcine pancreatic cells. Although pigs are considered a promising alternative source of organs for xenotransplantation, this study found that the PERV were trancriptionally active and infectious cross-species in vivo after xenotransplantation of the pig tissues. These findings bolster earlier concerns about PERV infection from pig islet

[3] U.S. Dept of Labor, Bureau of Labor Statistics, Employer Costs for Employee Compensation, March 1997.

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xenotransplantation in immunosuppressed human patients.

Recent experience with zoonotic viruses has demonstrated the potential lethality of these viruses. An example is the 1998 to 1999 outbreak of a hendra-like virus in Malaysia and Singapore (Ref. 12). Documented cases occurred primarily among adults who had come in close contact with swine, which also showed signs of the illness. In some instances, illness in the pigs had occurred 1 to 2 weeks before illness in the humans. Illness in humans was characterized by 3 to 14 days of fever and headache followed by drowsiness and disorientation that often progressed to coma within 24 to 48 hours. During the period September 1998 to April 1999, 229 human cases were reported, 111 of which (48 percent) resulted in death. Although the first cases of human illness were reported in September 1998, the type and source of infection was initially unknown, so human exposures continued to occur, with the peak number of new cases occurring 6 months later, in March 1999. Once the type of virus was identified, through laboratory testing, and the source of infection (i.e., exposure to pigs) was serologically confirmed, public health measures were taken to prevent further outbreaks.

Ebola hemorrhagic fever is another disease that is transferable from animals to humans (Ref. 13) and consequently illustrates the importance of timely tracking of and public communication about zoonotic viruses. In the period from January to July 1995, a total of 316 persons became ill with hemorrhagic fever in Kikwit, Democratic Republic of the Congo (DRC) (Ref. 14). During the epidemic, a mortality rate of 60 to 80 percent was reported among hospital cases. After an incubation period of approximately 7 days, the early clinical features of the disease included fever, headache, sore throat, diarrhea and myalgias, followed by vomiting, worsening diarrhea, oliguria, shock and death after 7 to 14 days. In May of 1995, the month of peak onset of new cases, the DRC requested international assistance in investigating the cause of the outbreak. Laboratory testing by the Centers for Disease Control and Prevention (CDC) confirmed the presence of the Zaire subtype of Ebola hemorrhagic fever. Continued investigation and testing enabled the international team to identify modes of transmission and to specify the precautions necessary to prevent further spread of the virus. According to the CDC, prompt laboratory diagnosis is an essential component of the surveillance needed to maximize Ebola prevention and control measures (Ref. 15). In this instance, the lack of early detection and proper management of Ebola hemorrhagic fever patients resulted in numerous deaths among both health care personnel and patients (Rollin and Ksiazek, 1998). By hastening the disclosure of important risk information, the proposed rule would assist public health agencies and health care providers in more rapidly identifying and controlling any zoonotic viruses that might emerge following xenotransplantation.

As of April 1999, the United Network for Organ Sharing (UNOS) reported a total of 62,443 patients on the waiting list for an organ transplant. This number far exceeds the total of approximately 20,000 transplants performed each year (Ref. 16). In addition to bolstering the supply of viable organ transplants, patients may also benefit from cellular and tissue therapies involving a xenotransplantation product. Although the potential to fill unmet needs is great, the number of prospective xenotransplant recipients represents a sizeable population at potential risk of zoonotic infection. The proposed data disclosures would help to provide the information needed by the public to understand, manage, and minimize the risks associated with these advancing medical technologies.

D. Impact on Small Entities

The agency has only limited information to estimate the number of small entities conducting clinical investigations of human gene therapy or xenotransplantation. As indicated in the cost analysis, the overall number of business entities sponsoring clinical trials is estimated to be 147. Although a few companies are a part of larger firms, many others may have annual revenues of less than $5 million, which is the revenue level that identifies a small business, according to the Small Business Administration. The estimated cost impact of $843 per sponsor per year reflects the staff time that would need to be allocated to produce redacted versions of the specified documents for the purpose of public disclosure.

The proposed rule offers sponsors considerable flexibility in implementation by allowing for a range of approaches for preparing a redacted version. Under the proposed rule, acceptable approaches range from submitting a "marked up" version of the original that simply obscures the information not to be disclosed, to development of a separate document that abstracts the needed information for the public from the original unabridged version submitted to FDA. This flexibility will help to minimize the cost impact.

The agency does not anticipate that the estimated cost will significantly burden any of the sponsors. However, because of the limited information available for establishments sponsoring clinical trials in human gene therapy and xenotransplantation, and its importance in developing estimates of the small entity impact, the agency requests detailed comment on the number and type of businesses sponsoring clinical trials in human gene therapy or xenotransplantation, and the expected impact of the proposed requirements on these entities.

In developing the proposed rule, the agency considered but rejected two alternatives that might impose less burden on small businesses. The agency found, however, that these alternatives would be less effective in supporting the advancement of this research, because of unanswered concerns regarding patient safety and public health. One of the alternatives considered involved voluntary disclosure by clinical trial sponsors without a regulatory requirement. This alternative would reduce costs to industry only if establishments failed to voluntarily provide the needed information for disclosure. Moreover, while voluntary provision of this information would be no less burdensome for industry, it could prove inadequate in protecting public health, because the agency would have no means of assuring the quality and consistency of the content of the voluntarily disclosed information, or the timeliness of its reporting. The disclosure of timely, accurate, and complete information is critical to an appropriate agency response to adverse outcomes, including the emergence of novel and potentially life-threatening infectious agents, or the alteration of the germline in patients participating in the clinical study. Also, voluntary disclosure provides no means for the agency to ensure a balanced dissemination of information on identified risks and benefits. Such balance is central to an adequate public understanding of the technologies, and to an informed public discussion of the overall risk versus benefit to patients and communities.

A second alternative to the proposed rule would require disclosure, but would have FDA assume the sole responsibility for redaction of documents submitted by the sponsor. Although this alternative would reduce the direct cost impact for sponsors, the limited number of agency staff available to perform this task would introduce the risk of delay in producing the redacted version for public disclosure. This outcome could potentially result in delaying the research, or delaying the timely public availability of critical information.

VI. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Eastland, T., "Infectious disease transmission through cell, tissue and organ transplantation: reducing the risk through donor selection," *Cell Transplantation* vol 4. pp. 455–477, 1995.
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4. "Guidelines for Research Involving Recombinant DNA Molecules," Appendix M–Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Subjects (PTC), http://www4.od.nih.gov/oba/guidelines.html.
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9. Yang, E.Y., D. L. Cass, K. G. Sylvester, J. M. Wilson, and N. S. Adzick, "Fetal Gene Therapy: Efficacy, Toxicity, and Immunologic Effects of Early Gestation Recombinant Adenovirus," *Journal of Pediatric Surgery*, vol. 34, No. 2, pp. 235–241, February 1999.
10. *Report of WHO Consultation on Xenotransplantation*, World Health Organization, Emerging and other Communicable Diseases Surveillance and Control, Geneva, Switzerland, pp. 28–30, October 1997.
11. Van der Laan, L. J., C. Lockey, B. C. Griffeth, F. S. Frasier, C. A. Wilson, D. E. Onions, B. J. Hering, Z. Long, E. Otto, B. E. Torbett, D. R. Salomon, "Infection by Porcine Endogenous Retrovirus After Islet Xenotransplantation in SCID Mice," *Nature*, vol. 407 (6800), pp. 90–94, September 7, 2000.
12. U.S. Department of Health and Human Services, Centers for Disease Control, "Outbreak of Hendra-Like Virus—Malaysia and Singapore, 1998–1999," *Morbidity and Mortality Weekly Report*, vol. 48, No. 13, April 9, 1999.
13. Rollin, P. E. and T. G. Ksiazek, "Ebola Haemorrhagic Fever," *Transactions of the Royal Society of Tropical Medicine and Hygiene*, vol. 92, pp. 1–2, 1998.
14. Roels, T. H., A. S. Bloom, J. Buffington, G. L. Muhumgu, W. R. MacKenzie, A. S. Khan, R. Ndambi, D. L. Noah, H. R. Rolka, C. J. Peters, and T. G. Ksiazek, "Ebola Hemorrhagic Fever, Kikwit, Democratic Republic of the Congo, 1995: Risk Factors for Patients with a Reported Exposure," *The Journal of Infectious Diseases*, vol. 179 Supplement 1:S92–97, 1999.
15. Centers for Disease Control, "Update: Outbreak of Ebola Viral Hemorrhagic Fever—Zaire 1995," *Journal of the American Medical Association*, vol. 274, No. 5, August 1995.
16. *U.S. Facts About Transplantation*, UNOS, (c) 1998, http://www.unos.org/newsroom/critdata_main.htm.

VII. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have a practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Submission to FDA for Public Disclosure of Certain Data and Information Related to Human Gene Therapy or Xenotransplantation.

Description: FDA is proposing new regulations to require that sponsors of IND's involving human gene therapy or xenotransplantation submit information related to the IND in redacted version for public disclosure, removing all information that would be defined as trade secret or personal information whose disclosure would constitute a clearly unwarranted invasion of privacy, and certain confidential commercial information. Each submission for public disclosure would be accompanied by a statement, signed by a responsible person, that the information has been suitably redacted. FDA would then publicly disclose the redacted version to provide an opportunity for public education, discussion, and consideration of public health and safety issues, as well as consideration of societal and ethical issues.

FDA is also proposing to require that the sponsor submit any copyrighted material in a single appendix to each redacted version and any copyrighted material whose copyright is not owned by the sponsor not be included in any other section of the redacted version. The proposal would further require that the redacted version include a bibliography of the copyrighted material contained in the appendix. This provision would facilitate the timely public disclosure of the redacted version on the Internet, with the copyrighted information excluded. Making available copyrighted material on the Internet is not considered "fair use" of copyrighted material.

Description of Respondents: Sponsors of clinical investigations involving human gene therapy or xenotransplantation.

FDA has estimated the burden for each provision that describes a collection of information. The estimates are based on FDA's experience in reviewing IND submissions and in redacting documents related to an IND.

Under proposed § 601.53(b), approximately 147 sponsors of clinical investigations involving human gene therapy (134 sponsors) and xenotransplantation (13 sponsors) would be required to submit a redacted version of certain documents under the IND. For all 147 sponsors, these documents include the original IND (45 submissions/year), amendments to an IND (270 submissions/year), IND safety reports (90 submissions/year), and annual reports (100 submissions/year) for an estimated total of 505 submissions/year (45 + 270 + 90 + 100). FDA has estimated the time necessary to copy and redact each of the above types of submissions; i.e., IND submission, 24 hours/submission; amendments, .5 hour/per submission; IND safety reports, .5 hour/submission; and annual reports, 20 hours/submission. The total burden equals the sum of the burdens estimated for each type of submission (45x24 +

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270x.5 + 90x.5 + 100x20 equals 3,260 hours).

Under § 601.53(c) all submissions under § 601.53(b) must be readily separable from the original submission and clearly marked on each page as suitable for disclosure. Under § 601.53(d) of the proposed rule, sponsors of human gene theraphy and xenotransplantation clinical studies would be required to submit copyrighted material in a single appendix to each redacted submission and include in the redacted version a bibliography of these materials. The hours per response, therefore, are an average estimate of the total time for redaction of the document, separation of copyrighted material and preparation of a bibliography, marking of each page as suitable for public disclosure, and submission to FDA, as provided in § 601.53(b), (c), and (d). The information collection burdens associated with the submission of an IND as provided in part 312 are approved by OMB under OMB control number 0910–0014.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.53(b), (c), and (d)	147	3.4	505	6.5	3,282

[1] There are no capital costs and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), FDA has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons may submit comments on the information collection requirements of this proposal by February 20, 2001, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

VIII. Proposed Effective Dates

FDA proposes that any final rule that may issue based on this proposal become effective 90 days after the date of its publication in the **Federal Register**. On or after that date, sponsors of human gene therapy or xenotransplantation clinical trials would be required to submit a redacted version of the data and information specified in the final rule as part of a submission into an IND. Sponsors may voluntarily submit a redacted version immediately upon the date of issuance of the final rule. FDA is proposing, for sponsors of xenotransplantation clinical trials who have submitted an IND prior to the effective date of the final rule, that the sponsor submit for public disclosure a redacted version of the information held under the IND, to contain the information specified in proposed § 601.52. FDA invites comment on the length of time after issuance of the final rule that these sponsors should be provided to submit the redacted information.

IX. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by April 18, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit written comments on the information collection provisions by February 20, 2001. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 20, 312, and 601 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.100 is amended by adding paragraph (c)(43) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(43) Data and information submitted related to human gene therapy or xenotransplantation, in § 601.52 of this chapter.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

3. The authority citation for part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

4. Section 312.42 is amended by adding paragraph (b)(7) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(b) * * *

(7) *Clinical hold of any investigation, as defined in § 601.52 of this chapter, involving human gene therapy or xenotransplantation.* FDA may place a proposed or ongoing investigation, as defined in § 601.52 of this chapter, involving human gene therapy or xenotransplantation on clinical hold if it is determined that:

(i) Any of the conditions in paragraph (b)(1) or (b)(2) of this section apply; or

(ii) The sponsor has not submitted a redacted version of the data and information, as specified in § 601.52 of this chapter, for public disclosure that complies with the requirements of § 601.53 of this chapter.

* * * * *

5. Section 312.130 is amended by revising paragraph (b) to read as follows:

§ 312.130 Availability for public disclosure of data and information in an IND.

* * * * *

(b) The availability for public disclosure of all data and information in an investigational new drug application for a new drug or antibiotic drug will be handled in accordance with the provisions established in § 314.430 of this chapter for the confidentiality of data and information in applications submitted in part 314 of this chapter. The availability for public disclosure of all data and information in an investigational new drug application for a biological product will be governed by the provisions of §§ 601.50, 601.51, and 601.52 of this chapter.

* * * * *

PART 601—LICENSING

6. The authority citation for part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

7. Section 601.50 is amended by revising the section heading and paragraph (a) to read as follows:

§ 601.50 Confidentiality of data and information in an investigational new drug application for a biological product.

(a) Except as provided in § 601.52, the existence of an IND application for a biological product will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

* * * * *

8. Section 601.51 is amended by revising the section heading and paragraph (a) to read as follows:

§ 601.51 Confidentiality of data and information in a biologics license application.

(a) For purposes of this section the *biological product file* includes all data and information submitted with or incorporated by reference in any biologics license application, IND's incorporated in any such application, master files, and other related submissions. Except as provided in § 601.52, the availability for public disclosure of any record in the biological product file shall be handled in accordance with the provisions of this section.

* * * * *

9. Section 601.52 is added to subpart F to read as follows:

§ 601.52 Availability for public disclosure of certain data and information related to an IND concerning human gene therapy or xenotransplantation.

(a) *Definitions.* The following definitions of terms apply to this section:

(1) *Human gene therapy* means the administration of genetic material in order to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use. Cells may be modified ex vivo for subsequent administration or altered in vivo by gene therapy products given directly to the subject.

(2) *Xenotransplantation* means any procedure that involves the transplantation, implantation, or infusion into a human recipient of either: Live cells, tissues, or organs from a nonhuman animal source; or human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs.

(b) *Scope.* Except as otherwise provided in this section, the availability for public disclosure of data and information related to human gene therapy or xenotransplantation shall be in accordance with §§ 601.50 and 601.51.

(c) *Information for public disclosure.* FDA will make available for public disclosure the following types of data and information related to an IND concerning human gene therapy or xenotransplantation. Names and other personal identifiers of patients and, except as specifically provided in this section, names and personal identifiers of and third party, such as physicians or hospitals, will not be made available for public disclosure.

(1) Product and patient safety data and related information. For purposes of this section product and patient safety data and related information include results of preclinical and clinical studies and tests that demonstrate the safety and/or feasibility of the proposed procedures. This may include, but is not necessarily limited to, analysis in animals, humans, or in vitro systems of gene transfer, expression, and persistence; vector biodistribution; evidence for immune response/anergy; biological activity; and results of product safety testing including testing for known xenogeneic and human infectious agents and replication competent virus; and qualification of source herd, individual source animal, and source organ/tissue/cells for xenotransplantation in humans. Also included is information on monitoring or prevention of potential health risks to the recipient, close contacts, and health care workers, such as patient monitoring for replication competent retrovirus and viral shedding and measures taken to prevent transmission of infectious disease. The availability for public disclosure of data and information in an IND safety report or annual report, as provided under §§ 312.32 and 312.33 of this chapter, will be governed by the provisions of paragraphs (c)(7) and (c)(8) of this section.

(2) The name and address of the sponsor.

(3) The clinical indications to be studied.

(4) A protocol for each planned study, to include:

(i) A scientific abstract and a nontechnical abstract.

(ii) A statement of the objectives, purpose, and rationale of the study.

(iii) The name and address of each investigator.

(iv) The name and address of the official contacts of each local review body as appropriate (Institutional Review Board, Institutional Biosafety Committee) and the dated copies of each committee's approval of the study.

(v) The criteria for patient selection and exclusion and an estimate of the number of patients to be studied.

(vi) A description of the treatment that will be administered to patients and the clinical procedures, laboratory tests, or other measures to be taken to monitor the safety and effects of the drug in human subjects and to minimize risk.

(5) Written informed consent form(s) as provided in § 50.27 of this chapter.

(6) Identification of the biological product(s) and a general description of the method of production, including a description of product features that may affect patient safety. The information shall include, as applicable, the vector name and type; gene insert; regulatory elements and their source; intended target cells; source of cells, tissues, or organ(s); method used to prepare the vector containing cells; method used to procure and prepare cells, tissues, or organs for xenotransplantation; purity of cells; adventitious agent testing; description of the delivery system; ancillary products used during production; herd colony and individual source animal health maintenance and surveillance records; and biological specimens to be archived from source animals.

(7) IND safety reports, as provided in § 312.32 of this chapter, and other similar data and information.

(8) Information submitted in the annual report to include, as applicable, assessment of evidence of gene transfer, gene expression in target cells, biological activity, immune response, status of autopsy request and evidence of gene transfer and gonadal distribution upon autopsy, results from assessment for evidence of infection by agents associated with the product, adverse experiences, and a list of subjects who died during participation in the investigation, with the cause of death for each subject.

(9) The regulatory status of the IND, such as on hold, in effect, inactive, or

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withdrawn, the dates of these actions, and the reasons for these actions.

(10) Other relevant data and information that the Director, CBER, determines are necessary for the appropriate consideration of the public health and scientific issues, including relevant ethical issues, raised by human gene therapy or xenotransplantation.

10. Section 601.53 is added to subpart F to read as follows:

§ 601.53 Submission of certain data and information related to human gene therapy or xenotransplantation for public disclosure.

(a) A sponsor of an IND shall submit to FDA for public disclosure in a redacted version the submissions identified in paragraphs (b)(1) through (b)(5) of this section. Each submission shall include all applicable information identified as disclosable in § 601.52, but shall be redacted to remove or obscure all information considered confidential as a trade secret, certain confidential commercial information, such as information regarding commercial licensing agreements or the identification of suppliers, and names and other personal identifiers of patients and, except as specifically provided in this section, names and personal identifiers of any third party, such as physicians or hospitals, must be redacted.

(b) The following shall be submitted in a suitably redacted version and in duplicate at the time points noted:

(1) Information as defined under § 601.52 at the time of initial IND submission.

(2) Any amendment documenting changes or additions to the information as defined under § 601.52 at the time the amendment goes into effect.

(3) IND safety reports at the time of submission of the initial report to FDA.

(4) The annual report, within 60 days of the anniversary date that the IND went into effect, in accordance with § 312.33 of this chapter.

(5) Other information upon the specific request of the Director, CBER.

(c) The submissions identified in paragraph (b) of this section shall be submitted in a form readily separable from the original unabridged submission to FDA and clearly marked on each page of the redacted version as suitable for public disclosure.

(d) Any copies of copyrighted material shall be submitted in a single appendix to each redacted version. Copyrighted materials whose copyright is not owned by the applicant shall not be included in any other section of the redacted versions. A bibliography of copyrighted materials contained in the appendix shall be included as part of each redacted version.

(e) Any data or information submitted to FDA as a redacted version for public disclosure in accordance with paragraph (a) of this section shall be accompanied by the following statement signed by a responsible individual:

The information contained herein has been redacted for public disclosure. The only material removed from these records is: Confidential commercial or trade secret information exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552 (b)(4)) and the Food and Drug Administration's implementing regulations (21 CFR 20.61); names and other personal identifiers of patients and, except as specifically provided in the regulations, names and other personal identifiers of any third party.

I declare, under the penalty of perjury, that the foregoing is true and correct.

Dated: December 20, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 01–1048 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 192 and 592

[Docket No. 00N–1396]

RIN 0910–AC15

Premarket Notice Concerning Bioengineered Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA is taking this action to ensure that it has the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The proposed action will permit the agency to assess on an ongoing basis whether plant-derived bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written comments on the proposed rule by April 3, 2001. Submit written comments on the information collection provisions by February 20, 2001.

See section XIV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT:

Regarding human food issues: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

Regarding animal feed issues: William D. Price, Center for Veterinary Medicine (CVM) (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6652.

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I. Background

A. The 1992 Policy

In the **Federal Register** of May 29, 1992 (57 FR 22984), FDA published its "Statement of Policy: Foods Derived From New Plant Varieties" (the 1992 policy). The 1992 policy clarified the agency's interpretation of the application of the act with respect to human foods and animal feeds derived from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology. This proposal refers to foods derived from plant varieties that are developed using in vitro manipulations of DNA (generally referred to as rDNA technology) as "bioengineered foods."

The 1992 policy provided guidance to industry on scientific and regulatory issues related to plant-derived foods, including bioengineered foods. In developing the 1992 policy as it relates to bioengineered foods, FDA focused on modifications to foods that were likely to result in commercial products and did not attempt to predict future changes in foods that could result from technological advances. Instead, FDA intended to modify its policy as circumstances warranted (57 FR 22984 at 22985).

In announcing the 1992 policy, FDA invited interested persons to submit written comments. Comments received from the scientific community generally have supported the scientific guidance articulated in the 1992 policy, including the scientific guidance as it relates to bioengineered foods. In addition, the views expressed by the members of FDA's Food Advisory Committee (Ref. 1) and the joint meeting of FDA's Food Advisory Committee and Veterinary Medicine Advisory Committee (Ref. 2), generally supported the scientific guidance in the 1992 policy.

However, many consumers, a number of public interest groups, and some State officials have expressed concern about or opposed the regulatory guidance articulated in the 1992 policy, particularly regarding the ability of the regulated industry to make market entry decisions. Frequently, those comments suggested, as an important adjunct to the 1992 policy, that FDA require an administrative process, such as premarket notification, to ensure that the agency remains aware of new bioengineered foods entering commercial distribution.[1]

FDA is confident that the guidance articulated in the 1992 policy adequately addressed both the scientific and regulatory issues raised by the products that were approaching commercialization in 1992. FDA is aware, however, that rDNA technology continues to evolve and that it is not possible for the agency to anticipate all of the novel scientific and regulatory issues that may arise as the number and types of foods developed using this technology expands. As discussed more fully below, this proposed rule would modify the regulatory guidance laid out in the 1992 policy by requiring the submission to the agency of data and information regarding plant-derived bioengineered foods at least 120 days prior to the commercial distribution of such foods.

B. Consultations Under the 1992 Policy and the 1996 Procedures

In the 1992 policy, FDA explained that, under the act, developers of new foods have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the act (57 FR 22984 at 22985). In light of this responsibility, FDA has long regarded it to be a prudent practice for producers who use new technologies in the manufacture or development of foods and food ingredients to work cooperatively with FDA to ensure that the products of these new technologies are safe and comply with all applicable legal requirements (57 FR 22984 at 22991). Historically, the food industry generally has initiated consultation with FDA during the pioneer stages of a new technology, even if there is no legal obligation to do so. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information necessary to address any questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the agency in exercising their mutual responsibilities under the act.

In the 1992 policy, FDA noted that the agency expected this practice of consultation to continue with respect to bioengineered foods (57 FR 22984 at 22991). One early example of such a

[1] This document defines "commercial distribution" as the introduction, or delivery for introduction, into interstate commerce for sale or exchange for consumption in any form by humans or other animals.

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consultation involved FLAVR SAVR™ tomatoes.[2] In developing FLAVR SAV™ tomatoes, Calgene used rDNA technology to introduce an antisense polygalacturonase gene, which was derived from tomatoes, and the kanamycin resistance gene (the *kan*^{r} gene), which encodes the enzyme aminoglycoside-3′-phosphotransferase II (APH(3′)II). The enzyme APH(3′)II confers resistance to the clinically used antibiotics kanamycin and neomycin in the selection of new plant varieties developed using rDNA technology. The use of APH(3′)II raised several issues that had not previously been evaluated by the agency in the context of food safety. The initial consultation between the agency and Calgene about the intended use of APH(3′)II, which in this instance resulted in the filing and approval of a food additive petition (59 FR 26700, May 23, 1994), was an effective mechanism to fully explore and resolve these issues.

The resolution of these and other scientific issues entailed the use of nontraditional approaches to the evaluation of food safety. For example, traditional evaluation of the safety of a food additive frequently includes toxicological tests conducted in accordance with the principles outlined in the agency's "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (Redbook (Ref. 3)).[3] In addition to guidance on when certain tests may be appropriate, the Redbook includes specific recommendations on the protocols for conducting such tests.

In contrast, issues raised during the consultations on APH(3′)II and the FLAVR SAVR™ tomato required evaluation of data generated using procedures that had only rarely been used in the evaluation of food safety. For example, Calgene used "Southern blots" to determine which DNA sequences had been transferred to FLAVR SAVR™ tomatoes, "Northern blots" to demonstrate the intended technical effect in FLAVR SAVR™ tomatoes, and "Western blots" to determine the amount of APH(3′)II present in FLAVR SAVR™ tomatoes. The use of nontraditional strategies in the evaluation of food safety likely will become the norm as the use of rDNA technology expands, and further consultations between industry and the agency would foster the identification and design of reasonable test procedures to evaluate the composition and safety of whole foods.

Consultations are an appropriate forum for industry and the agency to address proactively issues that are relevant to bioengineered foods, and developers have actively consulted with FDA about their products since the issuance of the 1992 policy. In June 1996, FDA provided guidance to industry on procedures for these consultations (the 1996 procedures (Ref. 5)).[4] Under that process, a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food prior to marketing it. Depending on the experience the agency and the developer have with the kind of modification being considered, a developer may initiate such a consultation early or late in the development of the food. When the developer believes that it has accumulated adequate data or information to address any issues raised during the consultation, the developer begins the "final consultation" by submitting to FDA a summary of its scientific and regulatory assessment of the food. To date, the agency has completed its evaluation of data or other information from more than 45 such consultations (Ref. 6). FDA believes that, to date, all developers of bioengineered foods commercially marketed in the United States have consulted with the agency prior to marketing the food.

FDA continues to believe that the consultation process is appropriate for bioengineered foods. Accordingly, this proposed rulemaking includes FDA's recommendation that developers consult with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding a bioengineered food (see proposed § 192.10 and section VI of this document).

C. Public Meetings

In 1999, FDA announced that the agency would hold three public meetings, each in a different region of the United States (64 FR 57470, October 25, 1999). The purpose of those meetings was for the agency to share its current approach and experience over the past 5 years regarding bioengineered foods, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. In the notice announcing the public meetings (64 FR 57470), FDA requested comments on specific questions regarding bioengineered foods. As a result of those meetings and the request for comments, the agency subsequently received more than 35,000 written comments about its policy regarding bioengineered foods.

At those meetings, and in the comments, FDA heard three messages very clearly. First, there does not appear to be any new scientific information that raises questions about the safety of bioengineered foods currently being marketed. Second, some of the public is concerned about FDA's existing guidance and regulatory approach to overseeing the safety of these products. These concerns include whether FDA's guidance and regulatory approach will be adequate for future developments and whether firms will continue to inform FDA about new bioengineered foods under the present program. In addition, there was a concern that the current regulatory process lacks transparency (e.g., because FDA discloses each consultation about a bioengineered food only at the end of the process). Third, there are very strongly held but divergent views as to whether bioengineered foods should bear special labeling. However, there was general agreement that providing more information to consumers about bioengineered foods would be useful[5] (Ref. 8).

II. Legal Authority

FDA is responsible for ensuring that all foods[6] in the American food supply conform to the applicable provisions of the law. The act provides FDA with broad authority to regulate the safety and wholesomeness of food. In particular, the act prohibits the adulteration of food under section 402 of the act (21 U.S.C. 342) and the misbranding of food under section 403 of the act (21 U.S.C. 343). The act also requires that all food additives (as defined by section 201(s) of the act (21 U.S.C. 321(s))) be approved by FDA before they are marketed (sections 409 and 402 of the act (21 U.S.C. 348(a) and 342(a)(2)(C))). FDA is authorized to seek sanctions against foods that do not adhere to the act's standards, through seizure of foods that violate the act under section 304 of the act (21 U.S.C. 334); the agency is also authorized to seek an injunction against, or criminal prosecution of, those responsible for introducing such foods into commerce under sections 302 and 303 of the act (21 U.S.C. 332 and 333).

All plant breeding techniques have the potential to alter food source crops in ways relevant to the legal status of food derived from such crops. However, rDNA technology greatly facilitates, relative to traditional breeding techniques, both the introduction of specific new substances into foods and the directed modification of the composition of foods. This is in part because the technology expands the range of sources of new substances that can be introduced into plants, relative to those that can be introduced with traditional techniques, due principally to rDNA technology's ability to permit the transfer to a food crop of genetic material from virtually any organism. Similarly, at the present time, information related to the genomes of many organisms is rapidly expanding, with the result that newly identified genes are now available to breeders. In addition, rDNA technology increases the speed by which traits can be introduced into food crops, by allowing the introduction of specific, well-characterized genetic material and by reducing the need for backcrossing to remove undesirable traits. Given the efficiencies of rDNA techniques, the advances in these techniques, and the rapidly expanding information related to genomes, FDA expects that these techniques are likely to be utilized to an increasingly greater extent by plant breeders and that the products of this technology are likely in some cases to present more complex safety and regulatory issues than seen to date.

Alterations in food source plants accomplished using rDNA technology, with resulting changes in the foods derived from such plants, can present a range of regulatory issues (57 FR 22984 to 23005). For example, such alterations may present questions as to the food additive status of the substances introduced into the food as a result of the genetic transformation. As noted, bioengineering permits the introduction into food of substances from any source, and the number and types of genes available for use in rDNA technology are rapidly increasing. Thus, increasingly, substances may be introduced into food using rDNA techniques that cannot be introduced by traditional breeding. FDA noted in the 1992 policy that a nonpesticidal substance introduced into food by way of breeding is a food additive if the substance is not generally recognized as safe (GRAS) within the meaning of 21 U.S.C. 321(s). Because of the greater range of sources of substances that can be introduced into plants via rDNA technology, there is a greater likelihood that some of the new substances will be significantly different from substances that have a history of safe use in food or may otherwise not satisfy the GRAS standard in section 201(s) of the act(s). Thus, there is a greater potential for foods developed using rDNA technology to contain substances that are food additives.

The agency reiterates its view, as stated in the 1992 policy (57 FR 22990), that transferred genetic material can be presumed to be GRAS. Likewise, FDA is not altering its view, as set forth in the 1992 policy, that there is unlikely to be a safety question sufficient to question the presumed GRAS status of the proteins (typically enzymes) produced from the transferred genetic material, or of substances produced by the action of the introduced enzymes (such as carbohydrates, fats, and oils), when these proteins or other substances do not differ significantly from other substances commonly found in food and are already present at generally comparable or greater levels in currently consumed foods. However, FDA recognizes that because breeders utilizing rDNA technology can introduce genetic material from a much wider range of sources than previously possible, there is a greater likelihood that the modified food will contain substances that are significantly different from, or are present in food at a significantly higher level than, counterpart substances historically consumed in food. In such circumstances, the new substances may not be GRAS and may require regulation as food additives (57 FR 22990).

To date, FDA has not seen multiple examples of food additive substances introduced into food using rDNA technology. However, the agency recognizes that the potential for introducing such substances is real. There are, for example, certain plant-derived proteins that have a sweetening effect but whose biochemical function is not known.[7] In addition, they are found in plants that have not been used for food. Thus, in contrast to other proteins introduced into foods by genetic engineering, which have been presumed GRAS, there is little or no apparent basis for a GRAS presumption for such substances. Genes encoding the protein sweetener could be introduced into a fruit to enhance sweetness. In such circumstances, FDA should be made aware of the intended marketing of the modified food and have access to relevant information to evaluate whether the protein sweetener is a food additive within the act's definition under section 201(s) of the act. If the protein sweetener is a food additive, premarket approval of the substance would be required under section 409 of the act before the altered food could be lawfully marketed.

Another potential consequence of transferring genetic material from one source into another is the possibility of introducing a food allergen that would not be expected to be in a particular food, a change that would be relevant to the legal status of such food. This is because genes code for proteins, and virtually all allergens are proteins (although only a small subset of proteins are allergens). Thus, by increasing the range of potential proteins that can be introduced into food over that possible by traditional breeding, there is an increased potential for introducing an allergen into a food developed using rDNA technology. Also, rDNA technology can be used to express proteins at higher concentrations than they would otherwise be expressed; these higher concentrations may increase the potential for such proteins to be allergenic.

One implication of being able to transfer genes between unrelated plants using rDNA techniques is that it is possible to transfer genes from one food plant to another quite unrelated food plant, thereby allowing the potential transfer of an allergen from the first plant to the second. In such a case, food from the bioengineered plant could have an allergenic characteristic completely different from that of its conventional counterpart. Such a change would not be evident to the consumer. For example, a gene from a Brazil nut plant was introduced into a soy plant to improve the protein content of soy beans for use in animal feed. The seed was never commercialized, however, because when the company tested the

[2] This consultation was concluded in May 1994 (59 FR 26647 at 26700, May 23, 1994).

[3] In 1993, the Center for Food Safety and Applied Nutrition (CFSAN) released a revised Redbook for public comment (58 FR 16536, March 29, 1993). Following its evaluation of comments on each draft chapter of the Redbook, CFSAN is making revised chapters available on its Internet site (Ref. 4).

[4] In October 1997, FDA made administrative revisions to these procedures to reflect reorganizations within the Office of Premarket Approval, CFSAN, and the Center for Veterinary Medicine (CVM). In this document, FDA refers to these procedures as "the 1996 procedures" to reflect the year that the agency made them available.

[5] In May 2000, FDA announced that it intended to issue for public comment draft labeling guidance to aid manufacturers who wish to voluntarily label their products as made with or without the use of bioengineering or bioengineered ingredients (Ref. 7). The development of that draft guidance is outside the scope of this document.

[6] There are certain exceptions to this jurisdiction pertaining to meat, poultry, and egg products that are not relevant to this rulemaking.

[7] The proteins apparently do not make the plants more attractive to insects or animals, and thus would not likely function as natural sweeteners in plants in the wild.

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soy beans for allergenicity, they found that people allergic to Brazil nuts were also allergic to the bioengineered soy (Refs. 9 and 10). Given the potential consequences to sensitive consumers of eating soy products containing a Brazil nut allergen, such a food would likely be considered misbranded within the meaning of sections 201(n) and 403(a)(1) of the act, unless the presence of the new allergen were disclosed to consumers.

Further, in certain circumstances, labeling may not be adequate or practical to ensure that consumers are aware of the presence of unexpected allergens. FDA would likely consider such food containing an unexpected allergen to be adulterated within the meaning of section 402(a)(1) of the act because the unexpected allergen rendered the food possibly injurious to health. With alterations of this type, FDA should be made aware of the modification and have an opportunity to assess whether and how the food could legally be marketed. Specifically, FDA should have the opportunity to consider whether any labeling proposed by the developer would ensure that the engineered food is not misbranded within the meaning of sections 201(n) and 403(a)(1) of the act, and whether, even with labeling, the food would be adulterated because it may be injurious to health within the meaning of section 402(a)(1) of the act.

Compositional changes in foods created through breeding may also present regulatory status issues. Although traditional breeding techniques can be used to alter significantly the compositional characteristics of food, rDNA technology enhances that ability because rDNA technology enables breeders to make targeted changes in plant components such as proteins and other constituents. For example, rDNA techniques would facilitate a breeder's ability to modify a soy plant so that the composition of oil derived from the plant would more closely resemble that of a tropical oil than that of conventional soy oil. In these circumstances, the name "soy oil" would likely not be suitable for the oil derived from the altered soy plant because the composition of the new oil is significantly different from what is customarily understood to be "soy oil". Thus, a new common or usual name would likely be required for this new oil to ensure that the oil is not misbranded under section 403(i)(1) of the act. FDA should be made aware of compositional changes of this type so that the agency may consider whether a new common or usual name is required and, if so, what that new name should be.

Additionally, rDNA technology has recently begun to be used to introduce multiple genes to generate new metabolic pathways (Ref. 11). New metabolic pathways are intended to result in the synthesis of substances not normally present in the host plant. Such modifications may alter the composition of the food in a significant manner that may raise nutritional or safety issues or that would require use of a new common or usual name.

In addition to enabling breeders to introduce desired new characteristics into foods, all breeding methods used to develop new plant varieties have a potential for unintentionally introducing undesired new characteristics into foods (57 FR 22986). Broadly speaking, a breeding method's potential for introducing unintended changes to the characteristics of a food results either from bringing into a food plant extraneous genetic material encoding trait(s) additional to the desired trait(s), or from introducing mutations (such as deletions, amplifications, insertions, rearrangements, or DNA base-pair changes) into the plant's native genetic material that alter some characteristic(s) of the food.

The most commonly used breeding method is a "narrow cross," which is hybridization between varieties of the same species. Hybridization between related species or genera that cannot be cross-fertilized is a "wide cross." Wide crosses are useful for expanding the range of genetic source material that can be introduced into food crops, but are performed relatively infrequently because of technical and logistical difficulties. Both wide and narrow crosses will introduce into plants extraneous genetic material along with the genetic material encoding the desired traits. Breeders then attempt to remove any undesired traits through extensive backcrossing.

Plant breeders also use mutagenic techniques to modify plants. These techniques include random mutagenesis using a mutagenic agent and somaclonal variation. (Somaclonal variation refers to the process of growing a plant up from tissue culture and observing for phenotypic changes, which are often due to chromosomal rearrangements or other mutations.) Both techniques can introduce undesirable mutations along with possible desirable mutations. As with hybridization, breeders perform backcrosses to eliminate any undesirable traits. Cell fusion poses similar issues to those posed by wide crosses (because it generally is performed between cells of different species of plants) and posed by somaclonal variation (because it involves growing a plant up from tissue culture).

Recombinant DNA technology greatly reduces the likelihood of introducing extraneous genetic material, as compared with hybridization, because it enables breeders to introduce only the gene or genes of interest, with little or no extraneous deoxyribonucleic acid (DNA). However, it shares with mutagenesis techniques a potential for introducing unintended effects through mutations. In part, this is because rDNA technology involves growing plants from tissue culture, which can exhibit somaclonal variation, and, more significantly, because breeders using this technology generally cannot control the location in the plant genome at which genetic material will insert when introduced into a plant. Thus, with rDNA technology, the introduced genetic segment may insert into a genetically active chromosomal location. Such insertion may disrupt or inactivate an important gene or a regulatory sequence that affects the expression of one or several genes, thereby potentially affecting adversely the safety of the food or raising other regulatory issues. Such an occurrence is referred to as an insertional mutation.

FDA believes that in the future, plant breeders will increasingly use rDNA techniques to achieve more complicated compositional changes to food, sometimes introducing multiple genes residing on multiple vectors to generate new metabolic pathways. FDA expects that with the increased introduction of multiple genes, unintended effects may become more common. For example, rice modified to express pro-vitamin A was shown to exhibit increased concentrations of xanthophylls (Ref. 11), and rice modified to reduce the concentration of a specific protein was found to exhibit an increased concentration of prolamine (Ref. 12).

FDA believes that the use of rDNA techniques in plant breeding may lead to unintended changes in foods that raise adulteration or misbranding questions. These unintended changes may cause a food to be adulterated because the food may be rendered injurious to health within the meaning of section 402(a)(1) of the act, or, in the absence of a new common or usual name, cause the food to be misbranded under section 403(i)(1) of the act. Because of its role in ensuring the safety of the U.S. food supply, FDA needs to be aware of the modifications to food source plants from the application of rDNA technology and any unintended effects in food that result so that the agency can evaluate whether the foods

from such plants are adulterated or misbranded.

Because some rDNA-induced unintended changes are specific to a transformational event (e.g., those resulting from insertional mutagenesis), FDA believes that it needs to be provided with information about foods from all separate transformational events, even when the agency has been provided with information about foods from rDNA-modified plants with the same intended new trait and has had no questions about such foods. Similarly, the agency believes that it needs to be provided with information about foods from rDNA-modified plants whose intended change is the introduction of a pesticidal protein subject to oversight by the Environmental Protection Agency (EPA) rather than by FDA, because the transformational event that is used to introduce the pesticidal trait may also cause unintended changes to the food that would raise adulteration or misbranding questions subject to FDA jurisdiction.

In contrast, the agency does not believe that it needs to receive information about foods from plants derived through narrow crosses (including narrow crosses between different rDNA-modified lines). Narrow crosses, because they generally are performed between varieties that are themselves used in food or are very closely related to varieties used in food, are unlikely to introduce extraneous DNA that encodes traits that have not been in food before. In addition, plant lines used for narrow crosses generally have been subject to extensive backcrossing and field testing to ensure genetic stability (including lack of any active transposons that could cause insertional mutagenesis). Finally, because the plant lines are closely related to each other, crosses between them will involve homologous recombination and thus are unlikely to be subject to insertional mutagenesis. Therefore, narrow crosses are unlikely to result in unintended changes to foods that raise safety or other regulatory questions.

The agency recognizes that unintended changes associated with other non-rDNA breeding methods may pose regulatory questions similar to those posed by rDNA methods. For example, wide crosses, especially between a food plant variety and an undomesticated nonfood plant variety, have much greater potential than do narrow crosses for introducing unintended traits that may alter the safety of the food; undomesticated plants frequently produce toxins at levels unsafe for human consumption, and may also produce substances not found in food. The agency has not found it necessary to assess routinely the safety of foods derived from such breeding methods, because over the last 50 to 60 years that some of these techniques have been used in plant breeding, breeders have used well-established practices successfully to identify and eliminate, prior to commercial use, plants that exhibit unexpected adverse traits. The agency is not aware of a basis for additional FDA oversight of foods derived from plants modified by such techniques, given that there has not been such a need in the past and that there do not appear to be any significant changes in breeders' use of such techniques that would warrant new FDA oversight. Rather, because of the technical advantages of rDNA methods over these other techniques, FDA anticipates that, in the future, breeders will likely use non-rDNA methods less frequently to introduce new characteristics into food plants as they increasingly utilize rDNA techniques. Likewise, despite the similar potential for unintended effects, FDA believes that declining to propose a requirement that the agency be notified about the commercialization of food source plants transformed using techniques other than rDNA is consistent with its current conclusion that, unexpected effects aside, rDNA techniques have a greater potential, relative to conventional methods of breeding, to result in the development of foods that present legal status questions. The agency therefore is not proposing to include foods from crops modified by methods other than rDNA techniques within the scope of this proposed notification rule. The agency requests comment as to whether it should include foods from crops developed by wide crosses or other breeding methods in the scope of any final rule based upon this proposal.

FDA recognizes that whether there is a change in the legal status of a food resulting from a particular rDNA modification depends almost entirely on the nature of the modification, and that not every modification accomplished with rDNA techniques will alter the legal status of the food. In other words, many modifications will result in a food that does not contain an unapproved food additive, does not contain an unexpected allergen, and does not differ significantly in its composition compared with its traditional counterpart or otherwise require special labeling. For this reason, FDA is neither proposing to require premarket approval for all foods developed using rDNA technology nor is the agency proposing an across-the-board requirement that all such foods bear special labeling.

There is substantial basis to conclude, however, that there is greater potential for breeders, using rDNA technology, to develop and commercialize foods that are more likely to present legal status issues and thus require greater FDA scrutiny than those developed using traditional or other breeding techniques. It was in part for this reason that, in 1994, the agency initiated a consultation process. Since that time, developers have actively consulted with FDA regarding their new plant varieties; under this process, the agency has completed its evaluation of data and other information from some 45 consultations.

As noted, FDA believes that, to date, the developer of each rDNA variety commercially marketed in the United States has consulted with the agency prior to marketing food from the new variety. But these products represent only a small fraction of the potential products of rDNA technology.[8] Additionally, in general, the introduced traits have been agronomic in nature (i.e., directed at the characteristics of the plant and not at the characteristics of the food produced by the plant). However, this picture is rapidly changing. The current list, which is provided by the Animal and Plant Health Inspection Service (APHIS) in the U. S. Department of Agriculture (USDA), of field tests of plants being developed using rDNA technology shows that the plants under development have a broader variety of introduced traits (Ref. 13). Additionally, that list shows that many such traits are not simply agronomic, but are intended to modify the food itself, and thus would be more likely than in the past to raise regulatory issues falling under FDA's purview.[9] Finally, as noted previously, FDA believes that, given the efficiencies of rDNA techniques, the advances in these techniques, and the rapidly expanding information related to genomes, these techniques are likely

[8] For example, in the 45 consultations completed under the 1992 policy, only 11 different commodities are represented, including 12 consultations on corn, 7 on canola, 6 on tomatoes, 5 on cotton, and 4 on potatoes. Moreover, the 45 consultations do not represent 45 separate types of modifications; rather, these 45 consultations represent only 9 general types of modifications. These modifications were herbicide resistance, insect and virus resistance, delayed ripening or softening, male sterility or fertility restorer, high phosphorus availability, and modified oil.

[9] These include modifications for altered protein quality, increased carotenoid content, increased fruit solids, altered fiber quality, and increased fruit sweetness, among others.

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to be utilized by plant breeders to an increasingly greater extent.

The confluence of the increasingly broader use of rDNA techniques to develop foods for human and animal use and the globalization of the world's food supply also suggest that FDA needs to be aware of the various foods developed using rDNA technology. Currently, approximately 45 percent of the United States' plant-derived food is imported, and that percentage continues to increase. The agency expects that rDNA techniques may, over time, be used increasingly by plant breeders and developers in countries that export foods to this country. In such circumstances, the accuracy of FDA's knowledge about the presence in the U.S. food supply of foods developed using rDNA techniques is likely to decrease. In addition, the awareness of particular food allergies is not uniform throughout the world because the diets of some populations do not contain sufficiently large amounts of a food such that the allergic potential has been demonstrated; in these circumstances, it is particularly important that FDA be aware of imported foods modified using rDNA techniques that may unexpectedly contain a substance that is an allergen.

For all these reasons, FDA believes that the food products of rDNA technology are appropriately made subject to greater regulatory scrutiny by FDA in the form of enhanced agency awareness of all such foods intended for commercial distribution. This increased agency awareness will ensure that at this stage of this continuously evolving technology, all market entry decisions about new bioengineered foods, including those intended for import into the United States, are made consistently and in full compliance with the law. Similarly, in order for the agency to evaluate fully and consistently the possible regulatory consequences of the alterations made possible using rDNA technology, FDA must be made aware of the bioengineered foods entering commercial distribution.

Section 701(a) of the act (21 U.S.C. 371(a)) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to issue regulations for the efficient enforcement of the act; under section 903(d)(2) of the act (21 U.S.C. 393(d)(2), the Secretary is responsible for executing the act, including section 701(a), through the Commissioner of Food and Drugs. The authority under section 701(a) of the act to issue regulations under the act extends to both regulations that supplement a specific statutory mandate as well as regulations that are justified by the statutory scheme as a whole. (See *National Confectioner's Association* v. *Califano*, 569 F.2d 690, 693 (D.C. Cir. 1978), citing *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 163 (1967).) In assessing a regulation issued under section 701(a), it is important to consider both the statutory purpose as well as the practical aspects of the situation, including the possible enforcement problems that may be encountered by FDA. (See *National Confectioner's Association* v. *Califano*, 569 F.2d 690, 693 (D.C. Cir. 1978), citing *Toilet Goods Association* v. *Gardner*, 387 U.S. 158, 163 (1967).)

To ensure that FDA has the maximum amount of information about foods from bioengineered plants, the agency has tentatively concluded that, prior to initiation of commercial distribution in the United States of a bioengineered food, FDA must be notified of the intent to market such food, including foods intended for import into the United States. Notification will ensure that the agency is aware of all bioengineered foods entering commercial distribution that are subject to FDA's jurisdiction and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. This will permit the agency to assess on an ongoing basis whether foods developed using rDNA technology comply with the standards of the act. FDA believes that it is essential that all those developing and marketing bioengineered foods participate fully and completely in the proposed notification program. Therefore, the agency is proposing that the notification program that is described in this document be mandatory.

Accordingly, for the reasons set forth above concerning the special circumstances of bioengineered foods, to enforce the act efficiently, and in particular, to administer efficiently the act's various provisions that relate to food as such provisions apply to bioengineered food, including section 301 of the act (21 U.S.C. 331) and sections 402, 403, and 409 of the act, FDA is proposing regulations to require that the agency be notified at least 120 days prior to the initiation of commercial distribution in the United States of a bioengineered food. The elements of FDA's proposed program are discussed in detail below.

III. Scope

FDA is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA's proposal also includes a recommendation that prospective notifiers participate in a presubmission consultation program. The regulations regarding bioengineered foods that would be consumed by humans would be codified in new part 192. The regulations regarding bioengineered foods that would be consumed by animals would be codified in new part 592. The proposed regulations regarding bioengineered foods that would be consumed by animals parallel the proposed regulations regarding bioengineered foods that would be consumed by humans. For ease of discussion, in this proposed rule, FDA describes each of the regulations that would be codified in part 192, without describing the parallel regulations in part 592. Following this discussion, FDA describes areas of importance in the proposed animal feed regulations (section XI of this document).

IV. Definitions

FDA is proposing to codify five definitions that are associated with the proposed notification program (proposed § 192.1). These terms are bioengineered food, commercial distribution, notifier, premarket biotechnology notice (PBN or notice), and transformation event. FDA invites comments on these proposed definitions. FDA is particularly interested in comments on the proposed definitions of bioengineered food and transformation event. Specifically, FDA is requesting comment on whether these proposed definitions are consistent with the agency's intent (described in section V of this document) that the proposed notification program apply to a particular subset of plant-derived foods. Such comments may result in a modification to the proposed definitions.

Under the proposed definitions, a required PBN may be submitted by any person who is responsible for the development, distribution, importation, or sale of a bioengineered food. Based on the agency's experience, FDA expects that it ordinarily will be the seed developers and purveyors who notify the agency about a bioengineered food.

V. Requirement for Premarket Biotechnology Notice

FDA is proposing to require a submission to the agency of data and information regarding a plant-derived bioengineered food at least 120 days prior to the commercial distribution of the food (proposed § 192.5). The proposed regulation would include a bioengineered food derived from a new plant variety modified to contain a pesticidal substance, and would exclude a bioengineered food that meets three specified criteria. The rationale for this proposed notification requirement is discussed in section II of this document. FDA specifically requests comment on the scope of the proposed notification requirement and on the proposed conditions for exclusion from the notification requirement. Such comments may result in a modification to the proposed regulation.

A. Foods That Are Subject to the Requirement

FDA is proposing that the notification requirement apply to a bioengineered food derived from a new plant variety modified to contain a pesticidal substance (proposed § 192.2(a)). Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*), EPA has authority to regulate all pesticides, regardless of how they are made or their mode of action. Under the act, EPA has authority to regulate pesticide residues in foods and FDA has authority to regulate a nonpesticidal substance that may be introduced into a new variety and that is expected to become a component of food. Given this statutory framework, both FDA and EPA agree that any food safety questions beyond those associated with the pesticide, such as those raised by unexpected or unintended compositional changes, are under FDA's jurisdiction (57 FR 22984 at 23005). FDA's proposal to include in its notification program new plant varieties that contain a pesticidal substance will facilitate consultation between EPA and FDA on the scientific and regulatory issues that are not within the scope of EPA's authority under FIFRA and the act.

FDA is proposing to exclude from the notification requirement a bioengineered food that satisfies three conditions. The first condition is that the food derives from a plant line that represents a transformation event that has been addressed in a notice previously submitted to FDA (proposed § 192.5(a)(1)). Under § 192.5(a)(1), a separate notice would be required for distinct plant lines that are derived from separate transformed cells, even when those cells were transformed during a single transformation procedure. The second condition is that the use or application of the bioengineered food has been addressed in a notice previously submitted to FDA (proposed § 192.5(a)(2)). Under § 192.5(a)(2), a separate notice would be required, for example, if herbicide tolerance introduced into a variety of sweet corn that is used solely for human food is subsequently transferred, using traditional plant-breeding techniques, to a variety of field corn that would also be used in food intended for consumption by animals. The third condition is that a letter from FDA demonstrates that FDA has evaluated the use or application of the bioengineered food and has no questions about it (proposed § 192.5(a)(3)). Under § 192.5(a)(3), a notice would be required if, for example, a prior notice about another use of a bioengineered food is still pending or if the agency's response to a prior notice demonstrates that FDA did not consider the prior notice as providing a basis to conclude that the bioengineered food was in compliance with all applicable requirements of the act.

As mentioned, FDA believes that all developers of bioengineered foods that already are commercially marketed in the United States have consulted with the agency prior to marketing the food. FDA believes that any legal status questions that pertain to the applicable bioengineered foods have been identified and resolved through that consultation process. Therefore, the notification requirement would not extend to bioengineered food obtained from a plant line (or series of plant lines) that derives from a particular transformation event, as long as both the applicable transformation and the use or application of the bioengineered food has been addressed satisfactorily in a completed consultation under the voluntary program.

It is likely that some final consultations received under the 1996 procedures would still be pending on the date of a final rule based on this proposal. The proposed regulations include no specific provisions regarding a bioengineered food that is the subject of a pending final consultation under the 1996 procedures. FDA specifically requests comment on how FDA should administer such submissions. FDA also specifically requests comment on whether the process for administering a final consultation that is pending on the date of a final rule based on this proposal should be included in these regulations. Such comments may result in a modification to the proposed regulation.

FDA specifically requests comment on the scope of proposed notification requirement and on the proposed conditions for exclusion from the notification requirement. Such comments may result in a modification to the proposed regulation.

B. Origin of Data and Information

FDA is proposing that the data or information that a notifier submits to FDA regarding a bioengineered food must be generated from a plant line whose derivation can be traced to the transformation event that is the subject of the notice and that contains the genetic material introduced via the transformation event (proposed § 192.5(b)). As a practical matter, the proposed regulation will give flexibility to producers while providing the agency with relevant information concerning the nature of the bioengineered foods. FDA specifically requests comment on this proposed provision. Such comments may result in a modification to the proposed regulation.

C. Timing

FDA is proposing to require that a notifier submit a PBN at least 120 days before the bioengineered food is marketed (proposed § 192.5(c)). The proposed timeframe is consistent with contemporary expectations of the Congress for another notification program, the notification program for food contact substances (section 409(h) of the act).

FDA believes that it can, in most circumstances, complete its evaluation of a PBN within 120 days because, as discussed more fully below, FDA is recommending that prospective notifiers participate in a presubmission consultation program. The purpose of the presubmission consultation program is to enable a prospective notifier to identify and address relevant safety, nutritional, or other regulatory issues regarding the bioengineered food before submitting a PBN. Given this presubmission consultation program, FDA expects that a notifier will have sufficient information to prepare a notice that adequately addresses all issues and that scientific experts at the agency will be familiar with the issues raised by a particular bioengineered food when the agency receives the applicable PBN.[10]

VI. Recommendation for Presubmission Consultation

FDA is proposing to include in the regulation a recommendation that a prospective notifier consult with the agency, before submitting a PBN, to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food

[10] The consultation procedures do not identify a timeframe for FDA to complete its evaluation of a final consultation. As of April 2000, under that program the median time for FDA's response to a final consultation was approximately 155 days and the average time was approximately 175 days.

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(proposed § 192.10). The proposed recommendation describes procedures for requesting consultation and the public disclosure provisions that likely would apply to records that FDA maintains about the consultation. Under § 192.10(f), a notifier must state his view as to whether the fact that he is consulting with FDA, or any or all of the data or information that he submits to FDA, is exempt from disclosure under the Freedom of Information Act (FOIA) and must explain the basis for any such exemption claim. The recommendation to consult with FDA derives from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures. FDA discusses the details of this proposed recommendation immediately below.

Using rDNA technology, bioengineered plants such as corn are now being developed for non-food uses. Examples of such applications include the transfer of genes that encode pharmaceutical proteins, oral vaccines, and enzymes that would be used for non-food industrial applications. In some cases, such as most of the pharmaceutical proteins, the final product would be a highly purified component of the plant commodity. In other cases, such as some oral vaccines, the final product would be a minimally processed plant commodity. In some cases, there may be a potential for a bioengineered plant commodity that is not intended for use in food to enter the food supply inadvertently. FDA encourages developers of bioengineered plants that are not intended for use in food or feed, but that theoretically could enter the food or feed supply, to participate in the consultation program described in this proposed rule. This participation would ensure that developers have given careful consideration to the procedures needed to ensure that their products do not inappropriately get into the food supply, and are aware of the legal implications if their products do.

A. Presubmission Consultation Program

FDA is proposing to recommend that a prospective notifier participate in a presubmission consultation program (proposed § 192.10(a)). Under the program (proposed § 192.10(b)), a prospective notifier would write to FDA and ask to consult about a bioengineered food. FDA would establish an administrative file for each consultation and would meet with a prospective notifier upon request. Although FDA may provide written feedback during the consultation, that feedback would not release the prospective notifier from the proposed requirement to notify FDA about the bioengineered food at least 120 days before commercialization of the food. The proposed presubmission consultation program derives from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures.

B. Public Disclosure

FDA is proposing to provide information about the availability for public disclosure of: (1) The fact that a developer is consulting with FDA (proposed § 192.10(c)) and (2) the data or information in the file that FDA would establish for a presubmission consultation (proposed § 192.10(d)). The regulations would inform all parties of the fact that FDA must act in response to a request under FOIA for information on presubmission consultations, and must disclose, or protect from disclosure, the applicable record(s) in accordance with § 20.61 (21 CFR 20.61) (proposed § 192.10(c)(2) and (d)(1)).

In light of the significant public interest in bioengineered foods and in FDA's oversight of these foods, FDA believes that it is important for developers to be informed that FOIA may entitle the public to know that the developer has provided data or information to FDA about a bioengineered food and to receive a copy of those data or information. Likewise, FDA believes that it is equally important for the public to know that the fact that a developer is consulting with FDA may be exempt from disclosure under FOIA and that some or all of the data or information that are submitted to FDA during a presubmission consultation could be exempt from public disclosure.

Under FOIA, data or information that are submitted to the Federal Government are available for public disclosure unless those data or information fall within an established exemption of FOIA. The exemption that is most relevant to data or information provided to FDA during a presubmission consultation is "exemption 4," which applies to "trade secrets and commercial or financial information obtained from a person and privileged or confidential." (5 U.S.C. 552(b)(4)). FDA has issued regulations implementing exemption 4 of FOIA in § 20.61.

FDA believes that, in most cases, the fact that a developer is consulting with FDA would not constitute confidential commercial information. For example, most plants developed using rDNA technology are considered "regulated articles" under regulations of USDA's APHIS (7 CFR part 340), which regulates the introduction of certain "genetically engineered" plants. At some stage of research and development of a regulated article, a developer requests from APHIS a determination of the article's regulatory status, and, consistent with FOIA requirements, APHIS discloses that request. Thus, by virtue of the APHIS process, the fact that the developer is developing the plant and its food product would usually already be disclosed.

FDA also believes that, in most cases, most of the data or information provided to FDA during a presubmission consultation would not constitute a trade secret or confidential commercial information. For example, only a handful of the submissions that FDA has received under its current consultation program identified specific data or information that the developer claimed to be exempt under § 20.61. Nevertheless, there could be circumstances where a developer initiates a presubmission consultation about a product that has not previously been disclosed to the public and has grounds to claim that the fact of the consultation should not be available for public disclosure. In such circumstances, disclosing any data or information in the applicable submission would reveal the existence of the submission. Thus, as long as the existence of the consultation is exempt from disclosure, all data or information in the submission would necessarily be exempt from disclosure.

C. Standard Procedures

FDA is proposing that a prospective notifier ask FDA in writing for an opportunity to consult about a bioengineered food (proposed § 192.10(e)). A written request would provide clarity about the subject of the consultation.

FDA is proposing to require that a prospective notifier who initiates a consultation inform FDA whether, in his view, the fact of the consultation with FDA is confidential, and whether, in his view, any or all of the provided data or information is confidential (proposed § 192.10(f)(1)). FDA also is proposing to require that a prospective notifier who claims confidentiality for the existence or content of a presubmission consultation explain the basis for that claim (proposed § 192.10(f)(2)). FDA is proposing these requirements because of the significant public interest in bioengineered foods. These requirements would ensure that FDA is aware of the prospective notifier's position regarding the availability for public disclosure of the existence and content of the

consultation. In addition, FDA believes that these requirements would alert a prospective notifier to the fact that the data or information contained in a submission to FDA are available for disclosure unless the applicable criteria for exemption are satisfied.

FDA is proposing to recommend that a prospective notifier send FDA a synopsis about the requested consultation (proposed § 192.10(f)(3)). The recommended synopsis would include the prospective notifier's name and address, the name of the bioengineered food and the plant species from which it is derived, a distinctive designation(s) that the notifier uses to identify the applicable transformation events, a list of the identity(ies) and source(s) of introduced genetic material, a description of the purpose or intended technical effect of the transformation event (including expected significant changes in the composition or characteristic properties of food derived from the plant as a result of the transformation event, regardless of whether these changes result from the insertion of new genes or from a modification in the expression of endogenous genes), a description of the applications or uses of the bioengineered food, and a description of any applications or uses of the bioengineered food that are not suitable for the bioengineered food. FDA is proposing to recommend this synopsis because the agency believes that the information in the synopsis is both necessary and sufficient to characterize the bioengineered food in a manner that will enable the agency to engage in a meaningful dialogue with the prospective notifier. For example, information about the identity and intended technical effect of the transformation event would enable the agency to address the potential issue that the food would contain an unapproved food additive. A distinctive designation that the notifier uses to identify the applicable transformation event would enable the agency to efficiently locate other agency records regarding that transformation event. It would also facilitate discussions with APHIS and EPA, if sponsors use those same designations in information supplied to the other agencies. Information about the sources of the genetic material would enable the agency to identify issues associated with a known allergenic source. Information about expected significant changes in the composition of the food would enable the agency to discuss suggestions for an appropriate common or usual name for the bioengineered food. Information about the applications or uses of the food would enable the agency to identify applicable regulatory situations (e.g., whether the bioengineered food would likely be used in human food, animal feed, or both). Information about any applications or uses that the notifier believes would not be suitable for the bioengineered food would enable the agency to identify potential safety questions, if any, about such use of the bioengineered food.

FDA is proposing that a prospective notifier send a request for consultation regarding a bioengineered food to CFSAN (proposed § 192.10(g)). As necessary and appropriate, CFSAN would coordinate the consultation process with CVM. The proposed regulation is consistent with the approach in the 1996 procedures, which has worked well.

FDA is proposing that a prospective notifier should send an original and two paper copies of a written request for consultation and of any additional materials that are sent to FDA during the consultation process (proposed § 192.10(h)(1) and (h)(2)). FDA is proposing an original and two copies of these submissions for efficiency in providing information about the presubmission consultation to the agency's scientific reviewers.

Because it is likely the data or information in a presubmission consultation would be requested under FOIA by an outside party, FDA is proposing that a prospective notifier who claims that certain data or information provided to FDA during the presubmission consultation are exempt from disclosure should clearly identify, in each submission, the data or information at issue (proposed § 192.10(h)(3)(i)). When this is the case, FDA also is proposing that the prospective notifier should provide an additional paper copy of the submission that does not contain such data or information (i.e., a redacted paper copy under proposed § 192.10(h)(3)(ii)). Providing a redacted copy would communicate very clearly which data or information the prospective notifier considers to be exempt. These recommendations are consistent with a practice that is commonly used by firms who send FDA a food additive petition that contains information that the petitioner claims to be confidential, a practice that has worked well. In addition, the practice of providing a redacted copy also has been used in a few cases under the 1996 procedures.

FDA is proposing that the redacted paper copy be prepared in a manner that clearly identifies the location and relative size of deleted information. This proposed regulation is consistent with FDA's proposed regulations (64 FR 60143, November 4, 1999) regarding implementation of the Electronic Freedom of Information Act Amendments of 1996 (EFOIA (Public Law 104–231)). EFOIA includes, among other things, provisions requiring agencies to inform requesters about the amount of information not being released to them.

FDA is proposing to specify the materials that the agency would place in an administrative file that it establishes for a presubmission consultation (proposed § 192.10(i)(1)). These materials include any correspondence between the prospective notifier and FDA, any written materials that the prospective notifier provides during the consultation process, and a memorandum of each meeting or significant phone call between FDA and the prospective notifier during the consultation. This part of the regulation would inform both prospective notifiers and outside parties of the materials that ordinarily would be in the administrative file of the consultation and thus potentially be subject to disclosure under FOIA.

FDA's proposal includes its commitment to discuss issues associated with a bioengineered food with any prospective notifier who asks to do so (proposed § 192.10(i)(2)). FDA is proposing to include this commitment to both remind and encourage prospective notifiers that the purpose of the recommended program is for a prospective notifier to engage FDA in a discussion about the bioengineered food at an early stage of the food's development. However, the agency realizes that there may be circumstances where such a discussion would not be an efficient use of resources for either the prospective notifier or for FDA. For example, a prospective notifier may intend to notify FDA about bioengineered foods that derive from a series of plant lines that are the result of independent transformation events with the same genetic construct. After FDA has completed its evaluation of one of these bioengineered foods, the notifier likely would be aware of most or all of the applicable safety, nutritional, or other regulatory issues that could be associated with the food. Nevertheless, FDA would welcome the opportunity to be informed about the notifier's plans to submit additional notices because this information could help the agency to plan its workload.

The proposed regulation describes a flexible process for any discussion (e.g., by mentioning that the discussion could

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take place through a meeting or through a telephone conference). FDA is highlighting the opportunity to discuss the bioengineered food by a mechanism other than a face-to-face meeting to minimize the potential that a small business or academic research group would elect not to participate in the program due to the cost of travel. Given the agency's experience under the current consultation process, FDA is confident that a meaningful dialogue can often be accomplished without a face-to-face meeting.

VII. Premarket Biotechnology Notice: Administrative Information

FDA is proposing to codify certain administrative information that would apply to a PBN (proposed § 192.20). The proposed administrative information includes information about where to send a PBN, the number of copies to send, how to include information in a foreign language, how to refer to data or information that are already in FDA's files, how to obtain guidance on scientific issues, and the prerogative of a notifier to withdraw a PBN from FDA's consideration. Many of these administrative aspects of the proposed notification program are consistent with procedures already in place for the food additive petition program (§ 171.1 (21 CFR 171.1)). FDA discusses the details of these administrative aspects of the proposed notification program immediately below.

A. Submissions to CFSAN for Use in Human Food, Animal Feed, or Both

FDA is proposing that a notifier send a PBN regarding a bioengineered food to CFSAN (proposed § 192.20(a)). As necessary and appropriate, CFSAN would coordinate FDA's evaluation of the PBN with CVM. The proposed regulation is consistent with the approach that FDA recommended in the 1996 procedures, an approach that has worked well.

B. Paper Copies

FDA is proposing that a prospective notifier send to the agency an original paper version and one paper copy of a PBN (including any amendments) (proposed § 192.20(b)(1)). A notifier would have an option to submit one additional paper copy or, under proposed 192.20(c)(1), to submit an electronic copy that is formatted in a manner that makes it suitable for FDA to use while evaluating the PBN. The number of paper copies required by the regulation is consistent with the number of paper copies that FDA currently requires for other premarket submissions, such as a food additive petition. A requirement for multiple paper copies generally serves the purpose of providing a copy of the submission to multiple scientific reviewers. However, as discussed below, FDA also is recommending that a notifier submit an electronic copy of a PBN that is formatted in a manner that makes it suitable for FDA to use in evaluating a PBN. Because scientific reviewers could accomplish their review by accessing the electronic copy, under the proposed rule, a notifier who submits an electronic evaluation copy would submit one less paper copy. FDA would retain the original paper version at CFSAN, while the paper copy would be retained at CVM. Comments may result in a modification to the proposed requirement to submit a single paper copy.

Under the regulation, the paper copy would be the official version at FDA. This provision would clarify the status of an electronic copy that FDA also is proposing to require [11] (see proposed § 192.20(c)(1) and section VII.C of this document).

FDA is proposing that a notifier who claims that specific data or information in the PBN are confidential must prepare and submit one paper copy of the PBN that does not contain any of those data or information (proposed § 192.20(b)(2)). Consistent with the EFOIA proposed rule, the notifier would prepare this redacted paper copy in a manner that clearly identifies the location and relative size of deleted information. As discussed previously regarding a presubmission consultation (see section VI.C of this document), the redacted copy would be very useful as it would communicate very clearly which data or information the notifier considers to be exempt from disclosure.

C. Electronic Copies

FDA is proposing to include in the regulation a recommendation that a notifier submit an electronic copy (the evaluation copy) that is formatted in a manner that makes it suitable for FDA to use while evaluating the PBN (proposed § 192.20(c)(1)). Because technology is advancing at a rapid pace, the regulation would inform notifiers how to obtain information about the appropriate format of the electronic copy rather than specify that format. Under the regulation, a notifier would provide such an electronic copy of both the original PBN and of any amendments to the PBN. FDA is recommending the submission of an electronic evaluation copy to take advantage of the fact that contemporary technology makes it possible for notifiers to send, and FDA to evaluate, submissions of data or information in electronic form, and the availability of an electronic evaluation copy has the potential to improve the efficiency of FDA's review. To encourage manufacturers to submit an electronic evaluation copy, a notifier who submits such a copy would submit a total of two, rather than three, paper copies.

FDA also is proposing to require that a notifier submit an electronic copy (the disclosure copy) that is formatted in a manner that makes it suitable for FDA to use to make a PBN available to the public in an electronic reading room (proposed § 192.20(c)(2)). As would be the case with the electronic evaluation copy, the regulation would inform notifiers how to obtain information about the appropriate format of the electronic copy and a notifier would be required to provide such an electronic copy of both the original PBN and of any amendments to the PBN. Consistent with the EFOIA proposed rule, a notifier would delete data or other information claimed to be confidential from the electronic copy in a manner that clearly identifies the location and relative size of deleted information. FDA is proposing to require an electronic disclosure copy to facilitate the agency's compliance with EFOIA, which includes provisions regarding the availability of records in electronic form and the establishment of "electronic reading rooms." As discussed in the EFOIA proposed rule, section 4 of EFOIA (5 U.S.C. 552(a)(2)(D)) adds a new category of records that agencies must make available in their public reading rooms. This new category consists of copies of records that have been released to any person under FOIA and that, because of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records. In light of the significant public interest in bioengineered foods and in FDA's oversight of these foods, FDA has tentatively concluded that it is likely that each submitted PBN would be requested under FOIA multiple times.

The preparation of an electronic copy formatted in a manner that makes it suitable for FDA to use to make a PBN available to the public in an electronic reading room will require use of computer technology. Although the use of this technology is widespread, it is possible that a firm that develops a bioengineered food would not have access to the particular technology that will be needed. For this reason, under the proposed regulation a notifier may request a waiver from the requirement to submit an electronic disclosure copy. FDA would grant or deny the notifier's request on its merits.

FDA requests comments on its proposal to require an electronic disclosure copy of a PBN and to provide a notifier with an opportunity to request a waiver from this requirement. Such comments may result in a modification to the proposed requirement to submit such a copy.

D. English Language Translations, Incorporation by Reference, and Available Guidance Documents

FDA is proposing that a notifier who submits any material in a foreign language provide an English translation that is verified to be complete and accurate (proposed § 192.20(d)). This proposed regulation is necessary for the agency's efficient evaluation of a PBN and is consistent with other agency regulations regarding the submission of information in a foreign language (see e.g., § 171.1(a) and the agency's recent proposal for a premarket notification program for food contact substances (65 FR 43269, July 3, 2000)).

FDA is proposing that a notifier may incorporate by reference data or information that are already retained in FDA's files (proposed § 192.20(e)). The proposed regulation specifies that a notifier may simply incorporate by reference a file that the notifier previously submitted. If the notifier wishes to incorporate by reference a file that someone else previously submitted to FDA, the procedure to incorporate that file into the PBN depends on whether the file is publicly available (e.g., the file is in an electronic reading room or is otherwise available under FOIA). If the file is publicly available, a notifier may incorporate that file by referring FDA to it. If the file is not publicly available, a notifier may incorporate that file by referring FDA to it if the person who submitted the file authorizes the notifier to do so in a signed statement and the notifier includes that signed statement in the PBN. This proposed provision is similar to that described for incorporating previously submitted information into a food additive petition (§ 171.1(b)) and to that described in the agency's recent proposal for a premarket notification program for food-contact substances (65 FR 43269, July 13, 2000).

FDA is proposing to inform notifiers that they can obtain current guidance regarding specific technical issues by writing to FDA or by looking on FDA's site on the Internet (proposed § 192.20(f)). FDA is adding this provision to assist notifiers in addressing common technical issues, such as the estimation of dietary exposure to substances that are present in food. FDA expects that this provision will minimize the time spent, by the agency and the notifier, on routine technical issues.

E. Opportunity to Withdraw

FDA is proposing to codify a provision that a notifier may request, at any time during FDA's evaluation of a PBN, that FDA cease to evaluate that PBN (proposed § 192.30(g)). Under the regulation, the notifier could submit a future PBN about the same bioengineered food. FDA would retain the PBN in its files and would classify it as "withdrawn." A notifier could choose to withdraw a notice for several reasons. For example, it is possible that discussions between the notifier and FDA would result in a decision by the notifier to substantially revise the notice to provide data or information that address the applicable legal status questions in a more thorough manner than the submitted PBN.

The proposed regulation is consistent with the provisions of the food additive premarket review program (§ 171.7). Although a notifier does not need explicit authorization to withdraw a notice, a notifier may not be aware of this fact. Likewise, a notifier may not be aware that a notice that is "withdrawn" remains an agency record that could be requested under FOIA. Thus, the regulation would both clarify a prerogative accorded to a notifier and inform the notifier of consequences associated with that prerogative.

VIII. Premarket Biotechnology Notice: Required Parts

FDA is proposing that a PBN be separated into seven parts (proposed § 192.25). These would include a letter (proposed § 192.25(a)); a synopsis (proposed § 192.25(b)); administrative statements about the status of review of the bioengineered food by other Federal agencies or by foreign governments (proposed § 192.25(c)); data or information about the method of development (proposed § 192.25(d)); a discussion of any newly inserted genes that encode resistance to an antibiotic (proposed § 192.25(e)); data or information about substances introduced into, or modified in, the food (proposed § 192.25(f)); and data or information about the food (proposed § 192.25(g)). The proposed regulation fosters a case-by-case approach to addressing relevant scientific and regulatory issues rather than a single set of tests that likely would not be applicable in all circumstances. In general, the proposed requirements derive from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures. In proposing these requirements, FDA also has drawn on its experience in administering a proposed notification program for GRAS substances (62 FR 18938, April 17, 1997).[12]

The proposed regulation reflects FDA's current judgment based on contemporary scientific methods for development of bioengineered foods and the types of bioengineered foods that are now under development. Accordingly, the proposed regulation focuses on modifications to foods that are likely to result in commercial products and does not attempt to predict future changes in foods that may result from technological advances. In this field of rapid scientific development, if circumstances warrant, FDA would propose to revise any regulation that results from this proposal. FDA requests comment on technological advances in rDNA technology that are likely to result in commercial products and that would not be addressed by the proposed submission requirements. Such comments may result in a modification to the proposed submission requirements.

A. Part I: Letter

FDA is proposing to require that a responsible official of the notifier's organization, or the notifier's attorney or agent, date and sign a letter that informs FDA that the notifier is submitting a PBN under proposed § 192.25. In the letter, this official, attorney, or agent would state his position or title and attest to five statements.

1. Statements Regarding the Notifier's Responsibility and the Balanced Nature of the Notice

FDA is proposing to require that a notifier inform FDA that it is the

[11] Under 21 CFR 11.1(c), an electronic record that meets the requirements of 21 CFR part 11 may be used in lieu of a paper record, unless paper records are specifically required. However, CFSAN is not prepared, at this time, to accept an electronic record as the official record because CFSAN does not yet have specific guidance for the submission of records only in electronic form.

[12] FDA has not yet issued a final rule based on the GRAS proposal. However, in the GRAS proposal, FDA invited interested persons who determine that a use of a substance is GRAS to notify FDA of such GRAS determinations during the interim between the proposed and final rules (the interim period). During this interim period, FDA has received several dozen GRAS notices, which provided practical experience both with theoretical issues raised by that rulemaking and with practical issues associated with establishing an efficient program.

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notifier's view that the bioengineered food is as safe as comparable food and that the intended use of the bioengineered food is in compliance with all applicable requirements of the act (proposed § 192.25(a)(1)). Applicable requirements of the act would include, for example, the requirement under section 409(a) and 402(a)(2)(C) of the act for FDA review and approval of a food additive and the requirement under section 201(n) and 403 of the act that labeling for the food be appropriate. FDA also is proposing that a notifier state that to the best of the notifier's knowledge, the PBN is a representative and balanced submission that includes information, unfavorable as well as favorable, pertinent to the evaluation of the safety, nutritional, or other regulatory issues that may be associated with the bioengineered food (proposed § 192.25(a)(2)). FDA is proposing that the notifier attest to these statements because, under the act, developers of new foods have a responsibility to ensure that the foods they offer to consumers are safe and in compliance with all requirements of the act (57 FR 22984 at 22985).

FDA is proposing the standard "as safe as" because this is the standard that the agency currently uses to evaluate a notice that is submitted under the 1996 procedures. Because the proposed standard is a comparative standard ("as safe as"), it takes into account circumstances such as the existence of naturally occurring toxicants in many plants (e.g., solanine that occurs naturally in potatoes). As discussed below (see section VIII.G.1 and proposed § 192.25(g)(1)), FDA also is proposing that the notifier provide a justification for selecting a particular food or foods as the "comparable food" to which the notifier will compare the bioengineered food.

2. Statements Regarding the Availability of Data and Information for FDA's Review

FDA is proposing to require that a notifier agree to make relevant data or information that are not included in the PBN available to FDA upon request while FDA is evaluating the PBN or for cause (proposed § 192.25(a)(3)). FDA is proposing this requirement to ensure that the agency will have access to relevant data or other information if safety questions arise after the bioengineered food enters commercial distribution. This proposed requirement will also continue a practice that began under the 1996 procedures.

FDA also is proposing that a notifier agree to two procedures for making such data or information available to FDA (proposed § 192.25(a)(4)). The first procedure is to allow FDA to review and copy these data or information at a specified address during customary business hours. The second procedure is to send these data or information to FDA. FDA is proposing that a notifier agree to both of these two procedures to provide flexibility and efficiency to both the notifier and the agency.

3. Statement Regarding Public Disclosure

FDA is proposing that a notifier inform FDA as to whether the notifier claims that the existence of a PBN, or any or all of the data or information in the PBN, is exempt from disclosure under the FOIA and explain the basis for that claim (proposed § 192.25(a)(5)). FDA is proposing these requirements in light of the significant public interest in bioengineered foods. These requirements would ensure that FDA is aware of the notifier's position regarding the availability for public disclosure of the existence and content of a PBN. In addition, FDA believes that these requirements would alert a notifier that the data or information contained in a PBN are available for disclosure unless the applicable criteria for exemption are satisfied.

As discussed more fully below, this proposed rule assumes that the existence and content of a PBN is available for public disclosure unless the notifier establishes that the existence of the notice constitutes confidential commercial information or that specific data or information in the PBN constitute a trade secret or confidential commercial information. Thus, the proposed rule acknowledges that there could be circumstances in which the existence or content (or a portion of the content) of a PBN would be eligible for an exemption from public disclosure.

B. Part II: Synopsis

FDA is proposing that the first section of a PBN be a synopsis (proposed § 192.25(b)) that includes the same information that FDA is recommending for inclusion in a presubmission consultation (see proposed § 192.10(f)(3) and section VI.C of this document). The synopsis would be a concise document that describes the bioengineered food in a manner that is suitable for preparing a publicly accessible list of PBN's (see proposed § 192.40(c)(1)(i) and section X.A of this document).

C. Part III: Status at Other Federal Agencies and Foreign Governments

FDA is proposing that a notifier inform FDA of the status of any prior or ongoing evaluation of the bioengineered plant, or food derived from such a plant, by USDA/APHIS and EPA (proposed § 192.25(c)(1) and (c)(2)). The proposed regulation is consistent with the recommendations in a report issued in April 2000 by the National Research Council (the 2000 NRC Report) (Ref. 14). That report recommended, among other things, that FDA, EPA, and USDA/APHIS establish a process to ensure appropriate and timely exchange of information between agencies about bioengineered pest-protected plants. Under the regulation, FDA would be aware of any issues still pending at those agencies, that are relevant to FDA's evaluation of the bioengineered food in question. When necessary and appropriate, FDA would contact APHIS, EPA, or both agencies about their evaluation of the bioengineered plant.

In addition, as discussed previously in this notice, the purpose of this notification program is to provide FDA with the information necessary to determine whether there are legal status questions concerning a bioengineered food so as to permit FDA to carry out its enforcement responsibilities. This would include its responsibilities to enforce section 402(a)(2)(B) of the act, which addresses foods containing illegal pesticide residues.[13] If the EPA regulatory process regarding the bioengineered food is not yet complete and a tolerance or exemption from tolerance has not been established, the food would not be in full compliance with the law. Accordingly, in these circumstances, FDA would inform a notifier that the agency does not consider the notifier's PBN to satisfy the requirement for premarket notice (see proposed § 192.30(e) and section IX.C.5 of this document).

FDA also is proposing that a notifier inform FDA as to whether the bioengineered food is or has been the subject of review by any foreign government and, if so, describe the status of that review (proposed § 192.25(c)(3)). Foreign countries have instituted various regulatory requirements for bioengineered foods. Information about the status of a notifier's submission(s) to foreign

[13] Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides, including those introduced into food via bioengineering; under section 408 of the act (21 U.S.C. 346a), EPA sets a tolerance or grants an exemption from a tolerance for pesticide residues in food. FDA has the statutory responsibility to enforce these tolerances or exemptions; under section 402(a)(2)(B), a food is adulterated if it contains a pesticide residue that exceeds an established tolerance or for which there is no tolerance or exemption from the requirement for a tolerance.

countries could be pertinent to FDA's review. For example, some issues raised by a foreign country could be relevant to the legal status of the bioengineered food under the act.

D. Part IV: Method of Development

FDA is proposing that a PBN include data or information about the method of development (proposed § 192.25(d)). Specifically, FDA is proposing that the data or information that a notifier provides regarding the method of development include: (1) Characterization of the parent plant including scientific name, taxonomic classification, mode of reproduction, and pertinent history of development (proposed § 192.25(d)(1)); (2) construction of the vector used in the transformation of the parent plant, with a thorough characterization of the genetic material intended for introduction into the parent plant and a discussion of the transformation method, open reading frames, and regulatory sequences (proposed § 192.25(d)(2)); (3) characterization of the introduced genetic material, including the number of insertion sites, the number of gene copies inserted at each site, and information on DNA organization within the inserts; and information on potential reading frames that could express unintended proteins in the transformed plant (proposed § 192.25(d)(3)); and (4) data or information related to the inheritance and genetic stability of the introduced genetic material (proposed § 192.25(d)(4)). The proposed requirement derives from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures. FDA requests comment on technological advances in rDNA technology that are likely to result in commercial products and that would not be addressed by the proposed submission requirements. Such comments may result in a modification to the proposed submission requirements.

FDA also is proposing to require that a notifier include a discussion, as necessary, of other relevant data or information about the method of development (proposed § 192.25(d)(5)). This requirement would cover any issues about the method of development that are not explicitly addressed in proposed § 192.25(d)(1), (d)(2), (d)(3), and (d)(4). FDA expects that such issues would be identified during presubmission consultations on specific products.

E. Part V: Antibiotic Resistance

In September 1998, FDA issued for public comment a draft guidance document regarding the use of antibiotic resistance markers in bioengineered plants (the 1998 draft antibiotic resistance guidance (Ref. 15)).[14,15] Consistent with the thinking presented in that document, FDA is proposing to require that a PBN include a discussion about any newly inserted genes that encode resistance to an antibiotic (proposed § 192.25(e)). Because scientific methods to assess this issue are evolving, in the proposed regulation FDA is recommending that a notifier contact FDA about the agency's current thinking on this topic.

F. Part VI: Substances in the Food

FDA is proposing that a PBN include data or information about substances introduced into, or modified in, the food (proposed § 192.25(f)). These data or information would include data or information about the identity and function of these substances (proposed § 192.25(f)(1)), the level of these substances in the bioengineered food (proposed § 192.25(f)(2)), dietary exposure to these substances (proposed § 192.25(f)(3)), the potential that a protein introduced into the food will be an allergen (proposed § 192.25(f)(4)), and a discussion of other safety issues that may be associated with these substances (proposed § 192.25(f)(5)). In general, the proposed requirements derive from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures. FDA requests comment on these proposed submission requirements. Such comments may result in a modification to the proposed submission requirements.

1. Covered Substances

FDA is proposing that a notifier provide data or information about substances introduced into, or modified in, the food (proposed § 192.25(f)). Under the regulation, a "modified substance" would include a substance that is present in the bioengineered food at an increased level relative to comparable food. Because pesticidal substances are regulated by EPA, the proposed regulation regarding data and information about substances introduced into the plant excludes data and information about pesticidal substances.

As discussed previously (section II of this document), a nonpesticidal substance introduced into food by way of breeding is a food additive if the substance is not GRAS within the meaning of 21 U.S.C. 321(s). Thus, the legal status issues raised by bioengineered foods include the potential that the food would contain an unapproved food additive. In the 1992 policy, FDA expressed its view that there is unlikely to be a safety question sufficient to question the presumed GRAS status of the expression products of the transferred genetic material when the expression products do not differ significantly from other substances commonly found in food and are already present at generally comparable or greater levels in currently consumed foods (57 FR 22984 at 22990). In the 1992 policy, FDA identified proteins, carbohydrates, and fats and oils as substances commonly found in food because those were the substances that were being considered in products under development in 1992.[16] As discussed, rDNA technology has recently begun to be used to introduce multiple genes to generate new metabolic pathways (Ref. 11). As with proteins, carbohydrates, and fats and oils, it is FDA's view that the substances produced by the new pathways would be presumed to be GRAS if they do not differ significantly from other substances that are currently present at generally comparable or greater levels in food and, as such, are safely consumed.

2. Identity, Function, Level, and Dietary Exposure

FDA is proposing that a PBN include data or information about the identity and function of substances introduced into, or modified in, the food (proposed § 192.25(f)(1)) and the level in the bioengineered food of these substances (proposed § 192.25(f)(2)). The proposed regulation derives from the fact that the quantity and quality of scientific evidence required to establish that the use of a substance is safe vary

[14] In the 1992 policy, FDA discussed the role of genes that encode resistance to an antibiotic as part of the development of some bioengineered foods (57 FR 22984 at 22987). In the APH(3')II final rule, FDA approved the use of the enzyme expressed by one such gene, the kan' gene encoding resistance to kanamycin, in the development of new varieties of cotton, oilseed rape, and tomatoes. Between November 1996, and February 1997, FDA had several discussions with outside experts to determine whether circumstances exist under which FDA should recommend that a given antibiotic resistance gene not be used in crops intended for food use, and if so, to delineate the nature of those circumstances. Based on these discussions, FDA issued for public comment the 1998 draft antibiotic resistance guidance. FDA intends to issue final guidance in the near future.

[15] A report that describes the consultations that FDA relied on in developing this draft guidance is available (Ref. 16).

[16] As discussed in the 1992 policy, FDA has presumed that transferred nucleic acids would be GRAS (57 FR 22990). Under the proposed regulation, a notifier provides data or other information about transferred nucleic acids in Parts IV (method of development) and V (genes that encode resistance to an antibiotic).

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considerably depending upon the chemical, physical, and physiological properties of the substance and its estimated dietary exposure.

FDA is proposing that a notifier include either: (1) An estimate of dietary exposure to substances introduced into, or modified in, the food (proposed § 192.25(f)(3)(i)); or (2) a statement that explains the basis for the notifier's conclusion that an estimate of dietary exposure to these substances is not needed to support safety (proposed § 192.25(f)(3)(ii)). As discussed in the 1992 policy (57 FR 22984 at 22998), many substances that would be introduced into, or modified in, a bioengineered food would be present in the bioengineered food at a relatively low level. For example, since 1994, developers have completed more than 45 consultations about bioengineered foods, most of which contain newly introduced or modified enzymes (Ref. 6). In most cases, an estimate of dietary exposure to these enzymes was not critical to the safety assessment. However, this is not always the case, even for enzymes that would be present in food at a low level. For example, in the case of the enzyme APH(3′)II, FDA relied, in part, on the estimated dietary exposure to APH(′)II in concluding that active APH(3′)II in food would not interfere with the clinical efficacy of the orally administered antibiotic, kanamycin (59 FR 26700 at 26703). Thus, the particular circumstances will determine whether an actual estimate of dietary exposure to a substance that is introduced into a food plant is needed to support the notifier's view that the bioengineered food is as safe as comparable food.

3. Allergenicity

FDA is proposing that a notifier include a discussion of the available data or information that address the potential that a protein introduced into the food will be an allergen (proposed § 192.25(f)(4)). The proposed regulation is consistent with the 1996 procedures, which recommend that a notifier provide FDA with information regarding any known or suspected allergenicity and a discussion of the available information about the potential for the bioengineered food to induce an allergic response. Because scientific methods to assess this issue are evolving, in the proposed regulation FDA is recommending that a notifier contact FDA about the agency's current thinking on this topic.

FDA is developing guidance for evaluating the potential allergenicity of proteins introduced into bioengineered foods and intends to make that draft guidance available for public comment in the near future. The draft guidance will be based in part on recommendations made by scientific experts who attended a public scientific conference on food allergy and bioengineered foods that FDA, EPA, and USDA jointly hosted on April 18 and 19, 1994 (the 1994 allergenicity conference (Ref. 17)).[17]

4. Other Safety Issues

It is impracticable for FDA to either anticipate all classes of substances that could be introduced into food or provide specific guidance about each of those classes of substances. Therefore, FDA is proposing that a notifier provide a discussion of data or information relevant to other safety issues that may be associated with the substances introduced into, or modified in, the food (proposed § 192.25(f)(5)). This requirement would cover any issues that are not explicitly addressed in proposed § 192.25(f)(1), (f)(2), (f)(3), and (f)(4) regarding substances introduced into, or modified in, the food. Such issues could include, for example, the digestibility or toxicity of an introduced protein. FDA expects that such issues would be identified during presubmission consultations on specific foods.

G. Part VII: Data and Information About the Food

FDA is proposing that a notifier provide data or information about the bioengineered food (proposed § 192.25(g)). These data or information would include a justification for selecting a particular food(s) as "comparable food" (proposed § 192.25(g)(1)); a discussion of historic uses of the comparable food(s) (proposed § 192.25(g)(2)); data or information comparing the composition and characteristics of the bioengineered food to those of comparable food(s), with emphasis on significant nutrients, naturally occurring toxicants and antinutrients, and any intended changes to the composition of the food (proposed § 192.25(g)(3)); any other information relevant to the safety, nutritional, or other regulatory assessment of the bioengineered food (proposed § 192.25(g)(4)); and a narrative that explains the basis for the notifier's view that the bioengineered food is as safe as comparable food(s) and that the bioengineered food is otherwise in compliance with all applicable requirements of the act (proposed § 192.25(g)(5)). In general, the proposed requirements derive from the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures. FDA discusses the details of this proposed regulation immediately below. FDA requests comment on the proposed submission requirements regarding the food. Such comments may result in a modification to the proposed submission requirements.

1. Comparable Food

FDA is proposing that the notifier provide a justification for selecting a particular food or foods as the "comparable food" to which the notifier will compare the bioengineered food (proposed § 192.25(g)(1)). The proposed requirement is based on the 1992 policy and FDA's experience under the 1996 procedures.

Ordinarily, the comparable food would be the parental variety or commonly consumed varieties of the parent plant (57 FR 22984 at 22996 and Ref. 5)). However, when the intended effect of the transformation is to change the composition of the food, it may be appropriate to also compare the composition and characteristics of the bioengineered food to that of another commonly consumed food. For example, if an oilseed crop is modified to produce an oil that has a higher content of a particular fatty acid than commonly consumed varieties, it may be appropriate to also compare the composition and characteristics of the bioengineered food to that of a food that contains that fatty acid. FDA expects that any issues associated with the appropriate selection of comparable food(s) would be identified during presubmission consultations on specific products.

2. Historic Uses of the Comparable Food

FDA is proposing that the notifier provide a discussion of historic uses of the comparable food(s) to which the notifier will compare the bioengineered food (proposed § 192.25(g)(2)). Several notifiers who have consulted with FDA under the 1996 procedures have included such a discussion (e.g., as part of their description of the applications or uses of the bioengineered food). FDA has found that such a discussion is particularly helpful in identifying the potential uses of the bioengineered food, regardless of whether those uses are specifically targeted by the notifier.

3. Comparing the Composition and Characteristics of the Bioengineered Food to That of Comparable Food

Consistent with the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures, FDA is proposing that a notifier provide data or information comparing the composition and characteristics of the bioengineered food to those of comparable food(s), with emphasis on changes in the levels of significant nutrients and naturally occurring toxicants and antinutrients (proposed § 192.25(g)(3)(i) and (g)(3)(ii)). Such changes could raise legal status questions such as whether the name of the food adequately describes the food or whether the food is adulterated within the meaning of section 402(a)(1) of the act.

Consistent with the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures, FDA is proposing that a notifier provide data or information about any intended changes to the composition or characteristics of the food (proposed § 192.25(g)(3)). Such changes could raise legal status questions such as the appropriate common or usual name for the food. For example, FDA has been notified about a modification to a canola variety of rapeseed to produce an oil with a modified fatty acid composition. Because the name that is most often used to describe oil derived from the parent plant (i.e., canola oil) did not accurately reflect the characteristic properties of the bioengineered oil, the notifier suggested a new name for the oil.

Intended changes to the composition or characteristics of the food also could raise safety questions about the food. For example, it is possible that a developer could modify corn so that the corn becomes a significant dietary source of the nutrient folic acid. Folic acid is used to fortify many foods, including breakfast cereals, because of the relationship between consumption of folic acid and a reduced risk of neural tube defects (21 CFR 101.79). However, excess folic acid in the diet can mask the signs of vitamin B_{12} deficiency. Thus, an increased level of folic acid in a food such as corn, which is commonly used in breakfast cereals, could raise safety or other regulatory issues.

Under proposed § 192.25(g)(3), intended changes to the composition of food include modifications that are intended to reduce the level of a substance in food. For example, it is possible that a modification would be intended to decrease the level of a substance that is considered undesirable, such as the phytate that naturally occurs in soybeans. It also is possible that a modification would be intended to reduce the fat content of a food. As with intended increases in the level of substances already in food, changes that decrease the level of substances already in food could raise legal status questions such as the appropriate common or usual name for the food.

4. Other Relevant Information

Consistent with the 1992 policy, the 1996 procedures, and FDA's experience under the 1996 procedures, FDA is proposing that a notifier provide a discussion of any other information relevant to the safety, nutritional, or other regulatory assessment of the bioengineered food (proposed § 192.25(g)(4)). This requirement would cover any legal status issues about the food that are not explicitly addressed in proposed § 192.25(g)(1), (g)(2), and (g)(3). For example, under proposed § 192.25(g)(4), a notifier could discuss the basis for proposing a specific common or usual name for a bioengineered food, or any other proposed labeling that would accompany the bioengineered food. FDA expects that such issues would be identified during presubmission consultations on specific foods.

FDA requests comment on whether this rule should also include a requirement that a premarket notice for a bioengineered food include methods by which the food could be detected. In particular, the agency is interested in comments on the circumstances under which such methods should or should not be required, and the rationale for any such requirement (e.g., the modification to the crop makes the food acceptable for animal feed but unacceptable for human food). The agency is also interested in comments on whether any such required methods should be for raw agricultural commodities, representative finished foods likely to contain the modified food, or both; and whether any such required methods should contain sufficient information, such as primer sequences, to enable technically-proficient non-government laboratories to use them; and what other criteria, if any, there should be for required methods (e.g., cost). Such comments may result in a modification to the proposed submission requirements.

5. Narrative

FDA is proposing to require that a notifier provide a narrative that explains the basis for the notifier's view that the bioengineered food is as safe as comparable food and that the bioengineered food is otherwise in compliance with all applicable requirements of the act (proposed § 192.25(g)(5)). The narrative would provide an integrated discussion of the data and information submitted in a PBN. FDA is proposing this requirement because the notifier has the responsibility for determining that the intended use of the bioengineered food is as safe as comparable food and is otherwise lawful. Absent an integrated discussion of the underlying data and information, the basis for the notifier's conclusion about the legal status of the bioengineered food may not be apparent.

IX. Agency Administration of a Premarket Biotechnology Notice

A. Filing Decision

FDA is proposing to do an initial evaluation of the notice within 15 working days to see whether the notice appears to include all elements required under §§ 192.20 and 192.25 (proposed § 192.30(a)). FDA also is proposing to file a PBN that appears to include all required elements, and to contact a notifier to explain what is missing if the PBN does not appear to include all required elements. FDA is proposing this "filing decision" because the timeframe for the agency's response to the notifier (i.e., 120 days (see proposed § 192.5(c) and section V.C of this document) is relatively short. To enable the agency to complete its evaluation in this period, it is essential that the agency have a complete notice when the 120-day period begins.

The proposed timeframe for the filing decision (i.e., within 15 working days) is consistent with the timeframe for the filing decision for a food additive petition (§ 171.1(i)(1)). The proposed process that "FDA will inform the notifier" provides flexibility for the mechanism whereby FDA contacts a notifier. FDA expects to contact the notifier by telephone or possibly by electronic mail and expects that a notifier would provide the missing material promptly. However, should circumstances warrant (e.g., FDA is unable to reach a notifier by telephone, or the notifier does not provide the

[17] The goal of the 1994 allergenicity conference was to foster a scientific dialogue to assess information that was available at that time regarding the characteristic properties of food allergens and the methods that are available to assess allergenicity. The scientists who participated in this conference noted that serum from an individual who is sensitive to a known allergenic source can be used to assess the allergenic potential of proteins derived from that source. These scientists acknowledged that there are no direct methods to assess allergenicity of proteins from sources that are not known to produce food allergy. However, they suggested that the possibility that a new protein will cause an allergic reaction can, to some degree, be evaluated by comparing its similarity to characteristics of known food allergens. If a protein does not have characteristics of known food allergens, the potential that the protein would cause an allergic reaction is minimized. Because exceptions have been reported for the observed characteristics of allergens, and no one factor is fully predictive, the scientists recommended that an assessment of allergenicity be based on all available information.

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materials promptly), under the regulation, FDA could send a letter or telefax to the notifier explaining that the agency had received, but not filed, the PBN and the reasons therefor.

Under proposed § 192.30(a)(1), CFSAN will inform CVM about any PBN that it files. Regardless of whether the bioengineered food would be used in human food, food for animals, or both, this inter-Center communication will ensure that both Centers are aware of all bioengineered foods that are nearing commercialization.

B. Acknowledgment Letter

FDA is proposing to send, within 15 working days of filing a notice, a letter to the notifier (or, when applicable, the notifier's agent) informing the notifier of the date on which FDA filed the PBN (proposed § 192.30(b)). As a practical matter, such a letter would acknowledge receipt as well as inform the notifier of the date of filing.

C. Response Letter

FDA is proposing to respond to a notifier within 120 days of filing a notice (proposed § 192.30(c)). Because all submissions will be sent to CFSAN, CFSAN would issue the response to the notifier, regardless of whether the intended use of the bioengineered food is in human food, food for animals, or both. A response from CFSAN would make clear that CFSAN was aware of, and thus had been notified about, all bioengineered foods, regardless of their intended use.

As with any correspondence, the particular circumstances will determine the full text of the agency's letter. However, the agency believes that a letter would likely fall into one of four general categories (proposed § 192.30(d)(1), (d)(2), (d)(3), and (d)(4)). FDA discusses each of these four categories immediately below.

1. General Categories for FDA's Response

a. *Letter that extends FDA's evaluation.* FDA is proposing that the agency could inform a notifier that the agency is extending its evaluation of the premarket notice by 120 days (proposed § 192.30(d)(1)). Under the regulation, in this letter FDA would also inform the notifier that the agency expects that the bioengineered food will not be marketed during the extended evaluation period.

Ordinarily, FDA expects to send a final response to a notifier within 120 days, particularly if a prospective notifier discusses relevant scientific and regulatory issues with FDA, prior to submitting a PBN about a bioengineered food (see proposed § 192.10 and section VI of this document). However, there are several circumstances that could prevent the agency from completing its evaluation within that time period. For example, FDA may need to extend the review time if a notifier did not participate in the presubmission consultation program; the issues raised by a particular bioengineered food could be particularly novel and complex; parts of a submission could require clarification, amplification, or correction; or the submission could be poorly written or be of such poor scientific quality that it precludes timely evaluation by the agency.

As discussed previously, FDA is issuing this proposed rule to ensure that it has the appropriate amount of information about bioengineered foods and to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The goal of this rulemaking would not be achieved if a bioengineered food entered commercial distribution before FDA had completed its evaluation of the applicable notice.

b. *Letter that the notice does not provide a basis.* FDA is proposing that the agency have an option to inform a notifier that the premarket notice does not provide a basis for the notifier's view that the bioengineered food is as safe as comparable food or is otherwise lawful (proposed § 192.30(d)(2)). In so doing, FDA would inform the notifier of the reasons for this conclusion. Under the regulation, in this letter FDA would also inform the notifier that the agency expects that the bioengineered food will not be marketed.

FDA has had experience with another food program, the proposed notification program for GRAS substances, in which some submitted notices do not provide a basis for the notifier's view that the intended use of a substance is lawful (Ref. 18). The underlying reasons why the applicable notices have not provided a basis for a GRAS determination have been quite varied. Likewise, there could be various reasons why a premarket notice does not provide a basis for the notifier's view that the bioengineered food is as safe as comparable food or is otherwise lawful. For example, the notice may not provide a basis for the notifier's view that a substance introduced into the bioengineered food is not an unapproved food additive or that the bioengineered food would not be misbranded. As another example, the notice may not provide a basis to conclude that a bioengineered food that contains an unusually high level of a naturally occurring toxicant would not be adulterated. As a third example, if the poor quality of a notice makes it difficult for the agency to fully evaluate the notice, regardless of the time period available, FDA may inform the notifier of the inadequacies of the notice rather than extend its evaluation of the notice for another 120 days.

If a notice about a bioengineered food does not provide a basis to conclude that a bioengineered food is as safe as comparable food or is otherwise lawful, that food could be adulterated or misbranded and should not be marketed. If a notifier initiates commercial distribution of a bioengineered food after being informed that the applicable notice is not adequate, FDA will carefully and completely review the legal status of the applicable food and will use all available options to ensure that the food is fully in compliance with all provisions of the act. In particular, in such circumstances, the agency fully intends to bring to bear the complete range of its authorities and resources, including its authority under section 704 of the act (21 U.S.C. 374) to conduct inspections and investigations, collect samples, and perform analyses, as well as its authority under sections 705 and 903 of the act (21 U.S.C. 375 and 393) to engage in publicity and public education. When the agency concludes through the application of these resources that a food is adulterated, misbranded, or otherwise not in full compliance with the act, FDA will utilize the act's legal sanctions, as appropriate, including in rem seizure of violative foods and injunction proceedings against, or criminal prosecution of, those responsible for distributing such foods.

c. *Letter that FDA has no questions.* If, based on its evaluation of a notice, FDA has no questions regarding the notifier's view that the bioengineered food is as safe as comparable food and is otherwise lawful, FDA would inform a notifier of that fact (proposed § 192.30(d)(3)). Because the evaluation of food safety is a time-dependent judgment that is based on general scientific knowledge as well as specific data and information about the food, FDA would qualify its statement to clarify that the agency has no questions "at this time." This proposed response is similar to the letters that FDA has issued in response to submissions received under the 1996 procedures.

d. *Letter that a notifier has withdrawn the notice.* Under proposed § 192.20(g), if a notifier requests that FDA cease to evaluate a PBN, FDA would retain the PBN in its files and classify the PBN as "withdrawn." In such a circumstance, FDA would bring the notification process to closure by sending the notifier a letter acknowledging that the agency had received a withdrawal letter and had ceased to evaluate the PBN, effective on the date that FDA received the letter (proposed § 192.30(d)(4)). This proposed response is similar to responses issued by FDA under the proposed notification program for GRAS substances when the notifier requests that FDA cease to evaluate a GRAS notice (Ref. 18).

2. Status of the Bioengineered Food at EPA

If the bioengineered food contains a pesticidal substance, FDA is proposing that FDA's response letter will describe the status of the bioengineered food at EPA (proposed § 192.30(e)). If all applicable regulatory processes at EPA have come to closure (proposed § 192.30(e)(1)), FDA would say so and would respond as described above. As discussed above, if regulatory processes at EPA regarding the bioengineered food are still pending, FDA would inform the notifier that FDA does not consider the PBN to satisfy the requirement for premarket notice (proposed § 192.30(e)(2)).

X. Public Disclosure

FDA is proposing to inform notifiers about: (1) The public disclosure provisions that apply to the existence and content of a PBN; (2) procedures that a notifier should use to inform FDA of the notifier's view about whether the existence or content of a PBN is exempt from public disclosure; and (3) the criteria that FDA uses to evaluate the notifier's view (proposed § 192.40(a) through (d)). FDA also is proposing the procedures that FDA will use to disclose the agency's evaluation of, and response to, each PBN (proposed § 192.40(e)). This part of the regulation would ensure that both notifiers and the interested public have information about provisions that derive from the FOIA. FDA requests comment on these proposed provisions. Such comments may result in a modification to the proposed requirements.

A. Existence of the Notice

FDA is proposing that the existence of a filed PBN ordinarily is available for public disclosure on the date that FDA files it (proposed § 192.40(a)(1)). Under the regulation, a notifier who believes that the existence of a PBN is exempt from disclosure would be responsible for asserting that claim (proposed § 192.40(a)(2)). If a notifier claims that the existence of a PBN is confidential, FDA would evaluate that claim and would disclose the existence of the PBN, unless FDA determines that the criteria for exemption from disclosure in § 20.61 are satisfied (proposed § 192.40(a)(3)). If FDA determines that the existence of a PBN is confidential at the time that the agency files it, the existence of the PBN would become available for public disclosure, in accordance with § 20.61, when the criteria for exemption from disclosure are no longer satisfied (proposed § 192.40(a)(4)).

FDA has previously discussed the FOIA, and the exemption from public disclosure that the FOIA provides for trade secrets and confidential commercial information, with respect to data or information that a developer submits to FDA during a presubmission consultation (section VI.B of this document). Consistent with that discussion, FDA believes that, in most cases, the fact that a notifier had submitted a PBN would not constitute confidential commercial information. Nevertheless, there could be circumstances in which a notifier submits a PBN and has grounds to claim that the existence of the PBN should not be available for public disclosure.

FDA is proposing to make a list of filed PBN's easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying) (proposed § 192.40(b)). FDA expects that the list of PBN's would include most or all of the information in the synopsis of the PBN. Consistent with current procedures for updating an easily accessible inventory of notices received for another foods program (i.e., the GRAS notification program; see Ref. 18), FDA expects to update the list of filed PBN's on an approximately monthly basis. The proposed regulation to make this information easily accessible to the public is responsive to the input that FDA received at the public meetings that it convened in 1999, and to the comments that FDA received as a result of those meetings.

B. Content of the Notice

FDA is proposing that the data or information in a PBN ordinarily are available for public disclosure on the date that FDA files the PBN (proposed § 192.40(c)(1)). Under the regulation, a notifier who believes that some or all of the content of a PBN is exempt from disclosure would be responsible for asserting that claim (proposed § 192.40(c)(2)). If a notifier claims that some or all of the content of a PBN is confidential, FDA would evaluate that claim. FDA would disclose the content of the PBN, unless FDA determines that the criteria for exemption from disclosure in § 20.61 are satisfied (proposed § 192.40(c)(3)). If FDA determines that some or all of the content of a PBN is confidential at the time that the agency files it, the data or information in question would become available for public disclosure, in accordance with § 20.61, when the criteria for exemption from disclosure are no longer satisfied (proposed § 192.40(c)(4)).[18]

Consistent with the agency's discussion of its view regarding the disclosability of the data or information provided to FDA during a presubmission consultation (section VI.B of this document), FDA believes that, in most cases, most of the data or information in a PBN would not constitute a trade secret. For example, very few of the submissions that FDA has received under its current consultation program identify specific data or information that the developer claims to be exempt under § 20.61. However, when the existence of the PBN is exempt from disclosure, all data and information in the submission would necessarily be exempt from disclosure.

FDA anticipates that the PBN will be easily accessible to the public. Under EFOIA and FDA's proposed rule to implement EFOIA, frequently requested records, or records that are likely to be requested frequently, are placed in an "electronic reading room." As discussed above (see section VII.C of this document), FDA has tentatively concluded that it is likely that each submitted PBN would be requested under FOIA multiple times. Therefore, these records will be easily accessible to the public because they will be available electronically (proposed § 192.40(d)).

C. Disclosure of FDA's Evaluation of, Response to, a Notice

FDA is proposing to make two agency records associated with a PBN easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying) (proposed § 192.40(e)(1)). The applicable records include the text of the letter issued by the agency in response to each PBN, and the text of the agency's completed evaluation of each PBN.

[18] Section 20.61 describes both criteria for exemption from disclosure and procedures that apply in circumstances where FDA disagrees with the view of a person who submits data or information that some or all of those data or information satisfy the criteria for exemption from disclosure.

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The proposed regulation commits to make available the "text" of the agency's letter and the agency's memorandum, rather than a "copy" of these records, to enable FDA to satisfy the regulations by a mechanism other than providing a physical copy of these records (e.g., by providing an electronic copy on the Internet). Consistent with current procedures for updating an easily accessible inventory of notices received for another foods program (i.e., the GRAS notification program; see Ref. 18), FDA expects to add the text of applicable agency letters and memoranda to the easily accessible file on an approximately monthly basis. The proposed regulation to make this information easily accessible to the public is responsive to the input that FDA received at the public meetings that it convened in 1999, and to the comments that FDA received as a result of those meetings.

As discussed previously (proposed § 192.30(c)(1) and section IX.C.1 of this document), a notifier could receive a letter that informs the notifier that FDA is extending its evaluation of the premarket notice by 120 days. Under the proposed regulation to make the agency's response to a PBN easily accessible to the public, such an extension letter would be easily accessible to the public. When FDA issues a final letter regarding the applicable notice, it is likely that the agency would replace the extension letter with the final letter rather than making both letters easily accessible. The fact that the notifier had received an extension letter would still be readily apparent (e.g., because the date of the final response letter would be more than 120 days from the date of the extension letter). In addition, it is likely that FDA's final response letter would acknowledge the fact that the agency had sent a letter extending its evaluation.

XI. Proposed Regulations Regarding Bioengineered Foods That Would Be Used in Animal Feed

FDA is proposing to require the submission to the agency of data and information regarding bioengineered plant-derived foods that would be used in animal feed. FDA's proposal also includes a recommendation that prospective notifiers participate in a presubmission consultation program. In general, these proposed regulations regarding bioengineered foods intended to be fed to animals (proposed part 592) parallel the agency's proposed regulations for human food (proposed part 192). The following discussion addresses areas of importance in the proposed animal feed regulations (proposed part 592).

The number of different species encompassed by the term "animal," as used in the act, is extraordinarily broad. CVM has regulatory authority over the food consumed by all nonhuman species, ranging from those raised in aquaculture, such as lobster and fish, to pets, birds, and the traditional classes of farm animals like cattle, swine, and horses. These animals may consume parts of a bioengineered plant that are not eaten by people. For example, cattle and other herbivores eat the forage portion of the corn plant (stalk and leaves), which has no human food applications. In addition, animals may eat the byproducts or residues left over from the production of human foods. For example, soybean meal, which is a source of dietary protein widely used in animal diets, is a byproduct from the production of soybean oil, which is primarily used in human foods. As another example, broken rice, which is not desirable for human food, is a major pet food ingredient.

Undesirable substances can concentrate in the byproducts or residues left over from the production of human foods. For example, gossypol, a naturally occurring toxicant in cotton, concentrates in cottonseed meal, which is a byproduct obtained during the manufacture of cottonseed oil. The presence of gossypol limits the use of cottonseed meal in animal feed. As another example, some substances that can cause enlargement of the thyroid naturally occur in rapeseed plants and are concentrated in the meal (commonly called canola meal) that is a byproduct obtained during the manufacture of low erucic acid rapeseed oil (comonly called canola oil). These compounds must remain at a low level for the canola meal to be useful in animal feed.

In some cases, bioengineered foods could make up most of an animal's diet, which the animal could consume for its entire lifespan. For example, in a single year a high-producing dairy cow could eat as much as 6,000 pounds of a nutritional supplement containing added energy and protein. This supplement could contain up to 80 percent corn grain and 20 percent soybean meal. The same dairy cow could also consume as much as 4,380 pounds of fermented corn forage and ears (i.e., whole plant corn silage in that same year). Fattening beef cattle could eat a diet based on 10 percent whole plant corn silage, 80 percent corn grain, and 9 percent soybean meal. A typical swine diet contains 74 percent corn grain and 23 percent soybean meal, while broiler chicks might eat a ration that is 58 percent corn grain and 35 percent soybean meal. Because these foods may comprise such a large percentage of an animal's diet, an undesirable substance that is introduced into a bioengineered food, even at a low level, has the potential to adversely affect an animal that eats the food.

Because of these factors, notifiers in assembling a PBN to address bioengineered foods to be consumed by animals should pay particular attention to the intended use of the bioengineered food, including the species expected to consume it; the function and level of all introduced or modified substances; and any changes in the composition and characteristics of the food. FDA has concluded that the notices should contain adequate information about any potential safety issues for all substances introduced into, or modified in, the food. Concerns associated with any changes in the composition or characteristics of the bioengineered food should also be addressed. Notifiers should be aware that in some cases, animal diets are formulated using different nutritional parameters than those used by human nutritionists. For example, when a diet is formulated for cattle, nutritionists utilize parameters such as neutral detergent fiber and acid detergent fiber in evaluating the suitability of a potential ingredient. Notices for bioengineered plants intended to be fed to animals should incorporate these differences in how ingredients are evaluated for their nutritional content.

XII. Paperwork Reduction Act

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Premarket Notice Concerning Bioengineered Food

Description: Section 701 of the act sets forth authority to issue regulations for the efficient enforcement of the act. Section 201 of the act defines terms utilized within the act. Food is defined by section 201 of the act to mean: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." Thus, the act clearly incorporates animal feed and drink into its definition of food.

Section 403 of the act prohibits the misbranding of food. Section 402 of the act prohibits the adulteration of food. Section 409 of the act establishes a premarket approval requirement for "food additives." Section 201(s) of the act provides a two-step definition of "food additive." The first step broadly includes any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food, which under section 201(f) of the act includes animal food. The second step, however, excludes from the definition of food additive substances that are GRAS by qualified experts.

In this proposed rule, FDA is proposing to require the submission to the agency of data and information regarding plant-derived bioengineered foods. The proposed rule refers to foods derived from plant varieties that are developed using rDNA technology as "bioengineered foods." FDA is proposing that this submission be made at least 120 days prior to the commercial distribution of such foods. The notice would include data and information about the bioengineered food and a narrative that provides an integrated discussion of those data and information. The notifier would maintain a record of relevant data and information that are not included in the notice. FDA would make the existence of the notice, and the agency's evaluation of and response to the notice, easily accessible to the public. The content of the notice would be publicly available consistent with the FOIA and other federal disclosure statutes. FDA is also proposing to include in the regulation a recommendation that prospective notifiers consult with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding a bioengineered food.

Description of Respondents: Developers, manufacturers, distributors, or importers of food.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
192.10(e) through (g)	20	1	20	4	80
192.10(h)(1)	20	1	20	0.5	10
192.10(h)(2)	20	1	20	8	160
192.10(h)(3)(i)	2	1	2	2	4
192.10(h)(3)(ii)	2	1	2	5	10
192.20(b)(2)(i)	2	1	2	2	4
1192.20(b)(2)(ii)	2	1	2	5	10
192.20(c)(1)	20	1	20	8	160
192.20(c)(2)	20	1	20	8.4	168
192.20(d)	0.5	1	0.5	20	10
192.20(e)	0.5	1	0.5	2	1
192.20(g)	0.5	1	0.5	1	0.5
192.20(a) through (b)(1) and 192.25	20	1	20	190	3,800
Total					4,417.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
192.25(a)(2)	20	1	20	19	380
Total					380

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Under the proposed rule, a notifier sends a notice regarding a bioengineered food to CFSAN regardless of whether the intended use is in human food, food for animals, or both. Because FDA routinely issues separate regulations regarding human food and animal feed, the regulations associated with the notice are codified in two parts of title 21: part 192 and part 592. Both CFSAN and CVM have been consulting with developers of bioengineered foods, and have received submissions of data and information about such foods. Since 1994, FDA has received, on average, eight submissions about bioengineered foods that are ready for commercialization per year. However, given the efficiencies of rDNA techniques, the advances in these techniques, and the rapidly expanding information related to genomes, FDA expects that these techniques are likely to be utilized to an increasingly greater extent. Thus, for the purpose of this analysis FDA is estimating that the agency would receive 20 PBN's per year.

In this analysis, FDA is assuming that all notices about bioengineered foods will encompass both human food and food for animals. FDA is making this assumption because this was the case in approximately 70 percent of submissions that FDA has received since 1994. Because some 30 percent of notices may not encompass both human

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food and food for animals, FDA's assumption results in a conservative estimate of the reporting and recordkeeping burden.

Because FDA's analysis assumes that all notices will encompass both human food and food for animals, and because all notices are submitted to CFSAN, regardless of the intended use, FDA is estimating the recordkeeping and reporting burden only for the regulations issued in Part 192. FDA is making no separate estimate of the recordkeeping and reporting burden for the regulations issued in Part 592 because this burden is subsumed within the burden estimated for part 192.

A. Hourly Burden to Prepare a Report (Proposed §§ 192.20(a) through (b)(1) and § 192.25)

FDA contacted five firms that had made one or more submissions under FDA's existing procedures, which are summarized in a guidance first issued in 1996 (the 1996 procedures (Ref. 5)). FDA asked each of these firms for an estimate of the hourly burden to prepare a submission under the current process. Three of these firms subsequently provided the requested information. Based on this information, FDA is estimating that the average time to prepare a submission under the 1996 procedures is 150 hours.

The proposed rule would include some reporting requirements that are not described in the 1996 procedures. After considering the amount of time that firms need, on average, to prepare a submission under the 1996 procedures, and after considering the relative contribution of the additional parts, FDA is estimating that a firm would need 32 to 48 additional hours to prepare the additional sections. For the purpose of this analysis, FDA selected the average of these estimates (i.e., 40 additional hours).

FDA is estimating that the hourly burden to prepare a PBN is the sum of the hours that a firm currently spends, on average, to prepare a submission under the 1996 procedures and the additional hours that a firm would spend, on average, to prepare a submission that addresses requirements that are not described under the 1996 procedures. This sum is 150 hours plus 40 hours, or 190 hours.

B. Hourly Reporting Burden Associated With Confidential Information in a Report (Proposed § 192.20(b)(2)(i) and (b)(2)(ii)

FDA expects that most of the data or information in a PBN will be available for public disclosure. However, a few firms that made submissions under the 1996 procedures included information that they considered to be confidential. To ensure that FDA is aware of confidential information, under the proposed rule a notifier must identify any confidential information in the PBN. FDA is estimating that two PBN's per year would contain confidential information and that it would take a notifier 2 hours to identify this information. Under the proposed rule, a notifier who includes confidential information must prepare and submit an additional paper copy that has been edited to delete confidential information (i.e., a redacted copy). FDA is estimating that it would take a notifier 5 hours to prepare the redacted copy. FDA's estimates of the hourly reporting burden associated with confidential information are based on its familiarity with submissions received under the 1996 procedures, including the content and organization of those submissions. In most cases, the confidential information is present in limited locations within a given submission.

C. Hourly Reporting Burden Associated With Electronic Copies of the Report (Proposed §§ 192.20(c)(1) and (c)(2)

Under the proposed rule, a notifier ordinarily would submit an electronic copy that would be in a format that is suitable for FDA to use to make the PBN available in an electronic reading room (e.g., html format). FDA is estimating that it would take 8 hours to format the electronic disclosure copy. Because a notifier who includes confidential information must redact this copy, FDA is estimating that it would take an additional 4 hours to do the redacting and that this would occur in 2 of the 20 notices submitted per year. Thus, FDA is estimating that it would take a total of 8.4 hours, on average, to prepare the electronic disclosure copy. FDA's estimate of the hourly reporting burden associated with an electronic copy is based on its understanding of the attributes of commonly used software programs that likely would be used to prepare the electronic copy.

Under the proposed rule, a notifier may request a waiver from the proposed requirement to submit an electronic disclosure copy, e.g., because the notifier does not have access to the technology that is needed to prepare such a copy. Because a notifier who requests a waiver need only write an explanation of why he is requesting the waiver, FDA estimates that it would take 0.5 hours to request a waiver. Because most firms who have already consulted with FDA regarding bioengineered foods are large firms who likely would have access to the appropriate technology, FDA is assuming that a request for a waiver will be a rare event, and may not happen at all. Therefore, in this estimate of the hourly burden to prepare a notice, FDA is making the conservative assumption that all firms will submit an electronic disclosure copy, with an hourly burden of 8 hours, and that no firms will request a waiver, which would have a reduced burden of only 0.5 hours.

In addition, in the proposed rule FDA is recommending that a notifier submit an electronic copy that would be formatted in a manner that is suitable for FDA to use to evaluate the PBN (e.g., portable document format (PDF)). A notifier who submits an electronic evaluation copy would submit one less paper copy. FDA is estimating that it would take 8 hours to format the electronic evaluation copy.

D. Hourly Reporting Burden Associated With English Language Translations, Authorization to Incorporate Information by Reference, and Withdrawal (Proposed § 192.20(d), (e), and (g)

Under the proposed rule, a notifier who includes information in a foreign language must include an English translation that is verified to be accurate and complete. Based on its experience, FDA is estimating that it would take 20 hours to prepare such a translation and that this would happen very rarely (i.e., once every 2 years). However, FDA has limited experience with the hourly burden associated with English language translations and specifically requests comment on this estimate.

Under the proposed rule, a notifier who wishes to incorporate by reference a submission made by another party must include a signed statement from that party, authorizing the notifier to incorporate the information by reference, unless the referenced submission is publicly available (e.g., under the FOIA). FDA is estimating that it would take 2 hours to obtain the signed statement and that this would happen very rarely (i.e., once every 2 years). FDA's estimate is based on its experience with incorporation by reference in another food program (i.e., the food additives program).

Under the proposed rule, a notifier who wishes to withdraw a PBN from FDA's consideration must do so in writing. Because this can be done by a simple letter, FDA is estimating that it would take 1 hour. FDA also is estimating that this would happen very rarely (i.e., once every 2 years).

E. Hourly Reporting Burden Associated With a Voluntary Presubmission Consultation Program (Proposed § 192.10(e) through (g), (h)(2), (h)(3)(i), and (h)(3)(ii)

In the proposed rule, FDA is recommending that prospective notifiers participate in a presubmission consultation program. Accordingly, FDA has estimated the hourly burden to notifiers who choose to participate.

Under the proposed rule, a prospective notifier who requests consultation prepares a single submission to address potential uses of the bioengineered food in both human food and food intended for animals. The prospective notifier would send multiple paper copies of the submission to CFSAN, who would contact CVM when the bioengineered food would be consumed by animals. Based on its experience under the 1996 procedures, FDA is estimating that it would take 0.5 hours to prepare the multiple copies that would be submitted for each request for consultation.

Since 1994, FDA has received on average approximately seven requests per year for consultation about bioengineered foods that are under development (i.e., before the foods are ready for commercialization). However, given the efficiencies of rDNA techniques, the advances in these techniques, and the rapidly expanding information related to genomes, FDA expects that these techniques are likely to be utilized to an increasingly greater extent. For the purpose of this analysis FDA is estimating that the agency would receive 20 requests for consultation per year about bioengineered foods. Based on its experience under the 1996 procedures, FDA is estimating that it would take 4 hours to prepare written materials that accompany the original request for consultation and 8 hours to prepare one or several additional written submissions as the consultation proceeds.

To ensure that FDA is aware of confidential information, a notifier who submits confidential information must both identify the confidential information and prepare and submit an additional paper copy that does not contain such information. FDA is estimating that it would take 2 hours to identify such information in both the original and additional submissions and that it would take 5 hours to prepare redacted copies of these submissions. FDA also is estimating that approximately 2 of 20 requests for consultation would include confidential information. FDA's estimates are based on its familiarity with requests for consultation under the 1996 procedures, including the content and organization of written materials that accompanied those requests.

F. Hourly Recordkeeping Burden (Proposed § 192.25(a)(2))

Under the proposal, notifiers must retain the data and other information that provides the basis for their conclusions about the bioengineered food. FDA is assuming that notifiers would establish and maintain an administrative file that contains these data and information. Based on its experience with the content of submissions received under the 1996 procedures, FDA is estimating that the one-time process of establishing such a file would equal 10 percent of the hourly burden already estimated for preparing a PBN (i.e., 10 percent of 190 hours, or 19 hours).

In compliance with the PRA, the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons must submit written comments regarding information collection by February 20, 2001, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

XIII. Analysis of Economic Impacts

A. Cost-Benefit Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

B. Background

Bioengineered foods have the potential to offer multiple benefits such as: Improved yield, drought resistance, disease resistance, improved flavor, longer shelf life, increased nutrition, and reduced need for pesticides, among others. Consumers have expressed concern, however, about possible risks that can accompany bioengineered foods. From a public health perspective, the main concerns are allergenicity and toxicity. To ensure that bioengineered foods are as safe as their conventional counterparts, FDA instituted a consultation process with industry to review the development of new bioengineered foods (57 FR 22984 at 22991 and (Ref. 5)). Since then, food producers have completed some 45 consultations about bioengineered foods. To the best of our knowledge all bioengineered foods on the market have gone through FDA's process before they have been marketed.

Under the current process, a developer who intends to commercialize a bioengineered food meets with the agency prior to marketing to identify and resolve relevant safety, nutritional, or other regulatory issues regarding the bioengineered food. When the developer believes that it has accumulated adequate data or information to address and resolve any potential safety or other regulatory issues, the developer submits to FDA a summary of its assessment of these issues. Agency scientists evaluate that summary to determine whether any safety or other regulatory issues are resolved. This process ensures that developers of bioengineered foods are aware of and address safety and other issues prior to marketing.

However, because the consultation process is voluntary, food producers could choose not to notify FDA. Additionally, as food producers in countries that export foods to the United States begin to adopt bioengineered varieties, they may choose not to participate in the voluntary consultation process. Requiring premarket notification for bioengineered foods ensures that FDA will continue to have the opportunity to discuss safety and other regulatory issues with developers before new bioengineered foods go on the market, thereby putting an additional check in place for bioengineered foods.

1. Benefits

Although the current consultation process has been successful in that the agency believes that it has reviewed all of the bioengineered foods that have reached the market, a firm could bypass the current review process. In so doing, the firm may market a product that presents safety or other regulatory issues

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that would otherwise have been identified and resolved through consultation with the agency. For example, the food may contain an unexpected allergen or an unapproved food additive, or may be so significantly different from its conventional counterpart that special labeling would be required to enable consumers to identify the difference.

Bioengineering enables developers to expand greatly the range of sources of genes to introduce into foods. Genes code for proteins, and virtually all known food allergens are proteins. Therefore, by transferring a gene from one foodplant to another (and thereby essentially transferring a protein from one food to another) one may transfer the allergenic properties of the first food to the second. Because food allergies can result in serious harm, including anaphylactic shock and death, it is important to know the allergenic profile of food from a plant that is to be used as the source of a gene to be transferred to another foodplant.

It is also possible for a protein that has never been in food before to become an allergen once people become exposed to it in the diet. Therefore, it is also important to know whether a protein from a traditionally nonfood source has characteristics associated with allergenic proteins.

Similarly, because bioengineering enables developers to introduce genetic material from a wider range of sources than has traditionally been possible, there is a greater likelihood that a developer using bioengineering to modify a foodplant may introduce genetic material whose expression results in a substance that is significantly different from substances historically consumed in food. Such a substance may require premarket approval as a food additive because it may not be GRAS.

It is also possible with bioengineering that the newly introduced genetic material may be inserted into the chromosome of a foodplant in a location that causes the food derived from the plant to have higher levels of toxins than normal, or lower levels of a significant nutrient. In the former case, the food may not be safe to eat, or may require special preparation to reduce or eliminate the toxic substance. In the latter case, the food may require special labeling, so that consumers would know that they were not receiving the level of nutrients they would ordinarily expect from consuming a comparable food. It is important therefore for developers to evaluate bioengineered foods from new plant varieties to determine whether the composition of the food has been altered.

The additional provisions of the proposed rule, beyond what was requested by the 1996 procedures, aid in ensuring that relevant safety questions are addressed by the developer. The submission of a narrative of the developer's reasons for concluding that the bioengineered food is as safe as comparable food and its justification of the choice of comparable foods by the notifier will aid in ensuring that all potential safety issues have been considered. Discussion of unsuitable uses will provide FDA the opportunity to ensure that foods that would not be suitable for particular applications are not marketed for those applications. Submission of a redacted copy will aid the agency in protecting confidential information in the notice and in responding to FOIA requests. Submission of an electronic disclosure copy would facilitate the agency's making the PBN available in an electronic reading room.

2. Costs

For developers who would have gone through FDA's consultation process, the costs associated with the proposed required process would include only costs of the additional provisions of the proposed rule. The required process will be modeled on the experience and knowledge gained from the current consultation process, but there will be a number of new provisions that will have costs for notifiers. First, the rule would require a narrative explaining how the notifier concluded the bioengineered food is as safe as comparable food and that the food is in compliance with the act. Second, notifiers who inform FDA about a bioengineered food that contains a gene that encodes resistance to an antibiotic must specifically discuss the issues associated with the use of that gene. Although this provision was not in the 1992 policy or the 1996 procedures, in 1998 FDA released draft guidance for public comment. Since 1998, most notifiers who are in this situation have included this discussion in their submissions; in addition, many plant varieties are being developed without genes that encode resistance to an antibiotic. Therefore, FDA is considering that the requirement to discuss genes that encode resistance to an antibiotic be a cost of the proposed rule for only one submission per year (that is, FDA is estimating that only one relevant submission would have omitted this discussion without the rule). Third, notifiers must submit a written justification of their choice of foods that are comparable to the bioengineered food and the historic uses of these comparable foods. Fourth, if the bioengineered food is unsuitable for any applications or uses, notifiers must submit a description of these applications or uses. Because inappropriate uses are seldom an issue, FDA is considering that this issue would arise approximately once every 3 years. Fifth, if the submission includes confidential information, notifiers must submit redacted copies. Because very few submissions under the current process have included confidential information, FDA is considering that approximately one or two copies per year will contain confidential materials. Sixth, notifiers must ordinarily would submit an electronic copy suitable for making the PBN available in an electronic reading room, but could request a waiver if they have access to the technology that would be needed to prepare the copy.

FDA contacted five firms that had made one or more submissions under the 1996 procedures. FDA asked each of these firms for an estimate of the hourly cost associated with preparing a submission under the current process. Three of these firms subsequently provided the requested information. One firm estimated an average cost of $125 per hour; another firm estimated an average cost of $48 per hour; a third firm estimated an average cost of $60 per hour. Based on this information, FDA is estimating that the average cost to prepare a submission under the 1996 procedures is approximately $78 per hour.

The agency estimated the cost of a notice as the time needed multiplied by $78, the average cost associated with the person responsible for preparing a notice. Since 1994, FDA has received approximately eight submissions per year, but the agency expects this number of submissions to increase because of the increasing use of the technology. Because most firms who have consulted with FDA under the current process are large firms who likely would have access to the technology that would be needed to prepare an electronic disclosure copy, in this analysis FDA is estimating that no firms would request a waiver from the proposed requirement to submit such a copy. Therefore, total costs for these additional provisions are expected to be between $16,604 and $67,444 per year.

TABLE 3.

	Number of submissions per year	Time costs per submission (hours)	Cost per submission	Total annual cost
Narrative	8 to 20	8 to 16	$624 to $,1248	$4992 to $24960
Antibiotic resistance	1 to 2	8 to 16	$624 to $1248	$624 to $2496
Comparable foods	8 to 20	8 to 16	$624 to $1248	$4992 to $24960
Unsuitable uses	1/3	8 to 16	$624 to $1248	$208 to $416
Electronic disclosure copy	8 to 20	8.4	$655	$5242 to $13104
Redacted paper copy	1 to 2	7	$546	$546 to $1092

For developers who would not have chosen to notify FDA, the cost of the proposed rule would be higher. Regardless of whether they choose to consult with FDA, food producers are statutorily prohibited from marketing misbranded or adulterated foods. To ensure that the new food is not adulterated or misbranded, the developer must generate similar information to what would be required under the proposed notification requirement. Therefore, for these developers, the cost of the proposed notification requirement would be the submission of paperwork documenting the generation of the needed information, not the information itself. FDA's estimate of the time required to prepare a notice is discussed previously (section XII of this document). According to that analysis, the average submission would require 255.5 hours of preparation. Additionally, maintaining records of the notice would require 19 hours by the firm. At an average hourly cost of $78, the total cost of preparation and recordkeeping for a submission would be $21,411 (hourly cost x 274.5 hours).

As discussed above, FDA has requested comment on whether this rule should also include a requirement that a premarket notice for a bioengineered food include methods by which the food could be detected. As part of its analysis of impacts, FDA requests comments on the technical feasibility and if feasible, the costs of requiring such methods in a PBN. In particular, FDA requests comments on the feasibility and costs of requiring methods of detection in all circumstances and in a limited set of circumstances, such as foods whose use is restricted in some way. FDA also requests comments on the costs of supplying methods for detection of the bioengineered food in crops and in finished food products.

C. Regulatory Flexibility Act

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

Businesses in Agricultural Services are considered small if they have fewer than 500 employees, and in Commercial Physical and Biological Research (SIC 8731) if they have less than $5 million in annual receipts. Companies engaged in the development of bioengineered food may fit into either of these categories. Since 1994, more than 45 biotechnology submissions have been completely evaluated by FDA; these submissions were made by 11 distinct companies and 3 universities. Most of these companies are multinationals with hundreds of millions of dollars in annual sales and do not meet the criteria for a small entity. However, at least one of the companies that has notified FDA would meet the small entity definitions.

For firms that would not have notified FDA, the cost may be $21,411. FDA finds that this proposed rule would have a significant economic impact on a substantial number of small entities.

FDA considered a number of options to ease the burden on small businesses. Extra flexibility for small businesses meeting with FDA was considered. However, the proposed rule as written already includes flexibility for meeting with FDA, allowing phone meetings in lieu of meeting in person. Additional guidance was another option considered. However, the recommended presubmission consultation provides an opportunity for small businesses to get guidance from FDA about regulatory and safety concerns and how they can be dealt with by a small business. Thus, FDA has tentatively determined there is adequate flexibility written into the rule to accommodate the special needs of small businesses.

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA has tentatively determined that this proposed rule is not a significant action as defined in the Unfunded Mandates Reform Act and will not have an effect on the economy that exceeds $100 million adjusted for inflation in any one year. The correct inflation-adjusted statutory threshold is $107 million.

XIV. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 60 days after the date of publication of the final rule in the **Federal Register**.

XV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

XVI. Comments

Interested persons may submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written comments regarding this proposal by April 3, 2001. Submit written comments on the information collection provisions by February 20, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

XVII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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1. Transcript of the Meeting of FDA's Food Advisory Committee, Herndon, VA, April 6, 7, and 8, 1994.

2. Transcript of the Joint Meeting of FDA's Food Advisory Committee and Veterinary Medicine Advisory Committee, November 2 and 3, 1994.

3. Table of Contents, "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (Also known as "Redbook I"), FDA, Bureau of Foods (Now CFSAN), 1982. May be Purchased From: National Technical Information Services (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703–487–4650, NTIS Order Number PB83–170696.

4. Table of Contents, "Toxicological Principles for the Safety of Food Ingredients; Redbook 2000," available at http://vm.cfsan.fda.gov.

5. "Guidance on Consultation Procedures: Foods Derived From New Plant Varieties," available at http://vm.cfsan.fda.gov.

6. "Foods Derived From New Plant Varieties Derived Through Recombinant DNA Technology; Final Consultations Under FDA's 1992 Policy," available at http://vm.cfsan.fda.gov.

7. Press Release, U.S. Department of Health and Human Services, "FDA to Strengthen Pre-market Review of Bioengineered Foods," May 3, 2000, available at http://vm.cfsan.fda.gov.

8. Transcripts from Public Meetings Held on November 18, 1999, Chicago, IL, November 30, 1999, Washington, DC, and December 13, 1999, Oakland, CA; at http://www.fda.gov.

9. Nordlee, J. A. et al., "High Methionine Brazil Nut Protein Binds Human IgE," *Journal of Allergy and Clinical Immunology*, vol. 93, number 1, part 2, p. 209, 1994.

10. Nordlee, J. A. et al., "Identification of Brazil-Nut Allergen in Transgenic Soybeans," *New England Journal of Medicine*, vol. 334, pp.688–728, 1996.

11. Ye, X. et al., "Engineering the Provitamin A (Beta-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm," *Science* vol. 287: pp. 303–05, 2000.

12. Kubo, Tomoaki, "Potential of Foods From Which Unfavorable Component Have Been Removed," Topic 10, Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, Biotech 00/12, 29 May-2 June 2000, available at www.who.int/fsf/GMfood/consultation) May2000/biotech) 00) 12.pdf.

13. Agriculture Biotechnology: Permitting, Notification, and Deregulations, U.S. Department of Agriculture, Animal Plant Health and Inspection Service, available at http://www.aphis.usda.gov.

14. Genetically Modified Pest-Protected Plants: Science and Regulation. Committee on Genetically Modified Pest-Protected Plants, Board on Agriculture and Natural Resources, National Research Council, National Academy Press, Washington, DC 20055, available at http://www.nap.edu/.

15. "Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants," available at http://vm.cfsan.fda.gov.

16. "Report on Consultations Regarding Use of Antibiotic Resistance Marker Genes in Transgenic Plants," available at http://vm.cfsan.fda.gov.

17. Transcript of "Conference on Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops," Annapolis, MD, April 18 and 19, 1994, Document TR–1, summary available at http://vm.cfsan.fda.gov.

18. Inventory of GRAS Notices, available at http://vm.cfsan.fda.gov.

List of Subjects

21 CFR Part 192

Administrative practice and procedure, Food additives, Food labeling, Foods, Reporting and recordkeeping requirements.

21 CFR Part 592

Administrative practice and procedure, Animal feeds, Animal foods, Food additives, Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Title 21 CFR, Chapter I be amended as follows:

1. Add part 192 to read as follows:

PART 192—PREMARKET NOTICE CONCERNING BIOENGINEERED FOOD

Sec.

192.1 Definitions: What terms do I need to know?
192.5 Requirement for premarket biotechnology notice.
192.10 Recommendation for presubmission consultation.
192.20 Premarket biotechnology notice: Administrative information.
192.25 Premarket biotechnology notice—required parts: What must I include in a premarket biotechnology notice?
192.30 FDA evaluation and response: What will I get back from FDA and how long will it take?
192.40 Public disclosure.

Authority: 21 U.S.C. 331, 342, 343, 348, 371.

PART 192—PREMARKET NOTICE CONCERNING BIOENGINEERED FOOD

§ 192.1 Definitions: What terms do I need to know?

(a) A *bioengineered food* means food derived from a plant that is developed using a transformation event.

(b) *Commercial distribution* means introduction, or delivery for introduction, into interstate commerce for sale or exchange for consumption in any form by humans or other animals.

(c) A *notifier* is the person who submits a premarket biotechnology notice under this part. Any person who is responsible for the development, distribution, importation, or sale of a bioengineered food may be a notifier.

(d) A *premarket biotechnology notice* (PBN) is a submission to FDA regarding a bioengineered food that is intended to enter commercial distribution. Under this part, a PBN includes all data and information in the original submission and in any amendments to the original submission.

(e) *Transformation event* means the introduction into an organism of genetic material that has been manipulated in vitro. For the purpose of this part, "organism" refers to plants.

§ 192.5 Requirement for premarket biotechnology notice.

(a) *What foods must I notify FDA about?* You must notify FDA about any bioengineered food, including a bioengineered food derived from a new plant variety modified to contain a pesticidal substance, that will enter commercial distribution unless all of the following conditions are satisfied:

(1) The bioengineered food derives from a plant line that represents a transformation event that has been addressed in a PBN previously submitted to FDA;

(2) The use or application of the bioengineered food has been addressed in a notice previously submitted to FDA; and

(3) A letter from FDA demonstrates that FDA has evaluated the use or application of the bioengineered food and has no questions about it. This would include a letter issued between May 1, 1994, and the effective date of this rule.

(b) *Must the data or other information that I submit to support my PBN be generated from a particular plant line?* The data or other information that you submit to FDA regarding a bioengineered food must be generated from a plant line whose derivation can be traced to the transformation event that is the subject of the notice and that contains the genetic material introduced via the transformation event.

(c) *When do I submit my PBN?* You must submit your PBN at least 120 days before the bioengineered food is marketed.

§ 192.10 Recommendation for presubmission consultation.

(a) *Is there a program that provides an opportunity for me to consult with FDA about a bioengineered food before I submit a PBN?* FDA has established a presubmission consultation program to enable a prospective notifier to identify and discuss relevant safety, nutritional, or other issues regarding a bioengineered food before submitting a PBN about that food. FDA recommends that you participate in this program.

(b) *How does the presubmission consultation program work?* In this program, you inform FDA about the bioengineered food. FDA encourages you to discuss with us safety, nutritional, or other issues that may be associated with the bioengineered food. FDA will establish an administrative file for your consultation. Although FDA may provide written feedback during the consultation, that feedback would not release you from the requirement in § 192.5 to notify FDA about the bioengineered food as described in §§ 192.20 and 192.25.

(c) *Would the fact that I am consulting with FDA be confidential?* (1) In most cases, the fact that you are consulting with FDA would not be confidential.

(2) If you claim that the fact that you are consulting with FDA is confidential, FDA will evaluate your claim. If FDA is asked, under the Freedom of Information Act (FOIA), about whether you are consulting with us, FDA will disclose that fact unless we determine that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(d) *Would any of the data or other information in the administrative file of my consultation be disclosed to the public?* (1) If the fact that you are consulting with FDA is not confidential, then the data or other information in the administrative file of your presubmission consultation would be available for public disclosure in accordance with § 20.61 of this chapter.

(2) As long as the fact that you are consulting with FDA is confidential, then the data or other information in the administrative file of your presubmission consultation would not be available for public disclosure.

(e) *How do I get started?* To participate in the presubmission consultation program, write to FDA and tell us that you want to consult about a bioengineered food.

(f) *If I participate, what do I provide to FDA?* (1) You must state your view as to whether the fact that you are consulting with FDA, or any or all of the data or other information that you submit to FDA, is exempt from disclosure under the FOIA (i.e., is confidential).

(2) If you claim that the fact that you are consulting with FDA, or that any or all of the data or other information that you submit to FDA is confidential, you must explain the basis for your claim.

(3) We recommend that you send us the following synopsis about the requested consultation:

(i) Your name and address;

(ii) The name of the bioengineered food that is the subject of the presubmission consultation and the plant species from which it is derived;

(iii) The distinctive designation(s) that you use to identify the applicable transformation event(s);

(iv) A list of the identity(ies) and source(s) of introduced genetic material;

(v) A description of the purpose or intended technical effect of the transformation event. This includes expected significant changes in the composition or characteristic properties of food derived from the plant as a result of the transformation event, regardless of whether these changes result from the insertion of new genes or from a modification in the expression of endogenous genes;

(vi) A description of the intended applications or uses of the bioengineered food; and

(vii) A description of any applications or uses that are not suitable for the bioengineered food.

(g) *Where do I send my written request for consultation?* Send your written request for consultation about a bioengineered food to the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204. As necessary and appropriate, the Center for Food Safety and Applied Nutrition (CFSAN) will coordinate FDA's evaluation of your request with the Office of Surveillance and Compliance, Center for Veterinary Medicine (CVM).

(h) *What copies do I send?* (1) You should send an original and at least two paper copies of your written request for consultation.

(2) If you submit additional written information to FDA (i.e., after your original written request), you should send an original and at least two paper copies of each additional submission.

(3) If you claim that any specific data or other information that you provide to FDA during the consultation are confidential, you should:

(i) Clearly identify, in each submission, the data or other information that you claim are confidential;

(ii) Prepare and submit a "redacted" paper copy of the submission (i.e., a copy that does not contain any of those data or information).

(iii) Prepare this redacted paper copy in a manner that clearly identifies the location and relative size of deleted information.

(i) *What will FDA do with my written request for consultation?* (1) FDA will establish an administrative file for your consultation and will place the following materials in that file:

(i) Any correspondence between you and FDA;

(ii) Any written materials that you provide during the consultation process; and

(iii) A memorandum of each meeting or significant phone call that you have with FDA regarding the subject of your consultation.

(2) If you ask FDA to discuss the bioengineered food with you, we will do so (e.g., at a meeting at its offices or via a telephone conference).

§ 192.20 Premarket biotechnology notice: Administrative information.

(a) *Where do I send my PBN?* Send a PBN regarding a bioengineered food to the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. As necessary and appropriate, the Center for Food Safety and Applied Nutrition (CFSAN) will coordinate FDA's evaluation of your PBN with the Office of Surveillance and Compliance, Center for Veterinary Medicine (CVM).

(b) *What paper copies do I send?* (1) At a minimum, you must submit an original paper version and one paper copy of a PBN (including any amendments that you make to your PBN). The original paper version will be the official version at FDA. If, under paragraph (c)(1) of this section, you choose not to send an electronic evaluation copy of your PBN, then you must submit one additional paper copy, for a total of three paper copies.

(2) If you claim that specific data or other information in the PBN are confidential, you must:

(i) Clearly identify, in each submission, the data or information that you claim are confidential;

(ii) Prepare and submit a "redacted" paper copy of the PBN (i.e., a copy that does not contain any of those data or information); and

(iii) Prepare this redacted paper copy in a manner that clearly identifies the location and relative size of deleted information.

(c) *What electronic copies do I send?* (1) *Evaluation copy.* FDA recommends that you submit an electronic copy that is formatted in a manner that makes it suitable for FDA to use while evaluating your PBN. If you do so, you should submit such an electronic copy of your original PBN and of any amendments that you make to your PBN. To obtain current information about the technical format of this evaluation copy, contact the Office of Premarket Approval (OPA)

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at the address listed previously or look on OPA's home page on the Internet.

(2) *Disclosure copy.* (i) Unless waived under paragraph (c)(2)(ii) of this section, you must submit an electronic copy that is formatted in a manner that makes it suitable for FDA to use to make your PBN available to the public in an electronic reading room. This includes an electronic copy of your original PBN and of any amendments that you make to your PBN. If you claim that specific data or other information in the PBN are confidential, you must remove such data or information from the disclosure copy in a manner that clearly identifies the location and relative size of deleted information. To obtain current information about the technical format of this disclosure copy, write to OPA at the address listed previously or look on OPA's home page on the Internet.

(ii) You may request that FDA waive the requirement for an electronic disclosure copy, e.g., if you do not have access to the appropriate technology for formatting such a copy. FDA will grant or deny your request according to its merits.

(d) *May I submit any data or other information, such as a reprint of a published scientific article, in a foreign language?* If you submit any material in a foreign language, you must provide an English translation that is verified to be complete and accurate.

(e) *May I incorporate data or other information that are already retained in FDA's files by referring to them?* (1) If you previously submitted a file to FDA, you may incorporate that file by referring FDA to it.

(2) If someone else previously submitted a file to FDA, the procedure that you may use to incorporate that file into your PBN depends on whether the file is publicly available (e.g., the file is in an electronic reading room or is otherwise available under FOIA).

(i) If the file is publicly available, you may incorporate that file by referring FDA to it.

(ii) If the file is not publicly available, you may incorporate that file by referring FDA to it if the person who submitted the file authorizes you to do so in a signed statement and you include that signed statement in your PBN.

(f) *How can I get additional information that will help me to prepare a PBN?* You can obtain current guidance regarding specific technical issues by writing to OPA at the address listed previously or by looking on OPA's home page on the Internet.

(g) *May I withdraw a PBN from FDA consideration after I send it?* (1) At any time during FDA's evaluation of a PBN, you may request that FDA cease to evaluate it. Your request would not preclude you from submitting a future PBN about the same bioengineered food.

(2) If you request that FDA cease to evaluate your PBN, FDA will retain your PBN in its files and classify your PBN as "withdrawn."

§ 192.25 Premarket biotechnology notice—required parts: What must I include in a premarket biotechnology notice?

A PBN has seven parts. You must include all of the information described in each part, or explain why it does not apply to the bioengineered food.

(a) *Part I.* In your PBN, you must provide a letter that a responsible official of your organization, or your attorney or agent, dates and signs. In this letter, you inform FDA that you are submitting a PBN under § 192.25, state your position or title, and attest to the following:

(1) It is your view that:

(i) The bioengineered food is as safe as comparable food; and

(ii) The intended use of the bioengineered food is in compliance with all applicable requirements of the Federal Food, Drug, and Cosmetic Act (the act).

(2) You agree to make relevant data or other information that are not included in your PBN available to FDA upon request, either while FDA is evaluating your PBN or for cause.

(3) You agree to two procedures for making relevant data or other information that are not included in your PBN available to FDA by:

(i) Allowing FDA to review and copy these data or information at a specified address during customary business hours; or

(ii) Sending a copy of these data or information to FDA.

(4)(i) Your view as to whether the existence of your PBN, or any or all of the data or other information in your PBN, is exempt from disclosure under the FOIA (i.e., is confidential); and

(ii) If you claim that the existence of the PBN, or any or all of the data or other information in the PBN, is confidential, you must explain the basis for your claim.

(5) To the best of your knowledge, the PBN is a representative and balanced submission that includes information, unfavorable as well as favorable, pertinent to the evaluation of the safety, nutritional, or other regulatory issues that may be associated with the bioengineered food.

(b) *Part II.* In your PBN, you must provide the following synopsis:

(1) *Section 1.* Your name and address;

(2) *Section 2.* The name of the bioengineered food that is the subject of the PBN and the plant species from which it is derived;

(3) *Section 3.* The distinctive designation(s) that you use to identify the applicable transformation event(s);

(4) *Section 4.* A list of the identity(ies) and source(s) of introduced genetic material;

(5) *Section 5.* A description of the purpose or intended technical effect of the transformation event. This includes expected significant changes in the composition or characteristic properties of food derived from the plant as a result of the transformation event, regardless of whether these changes result from the insertion of new genes or from a modification in the expression of endogenous genes;

(6) *Section 6.* A description of the applications or uses of the bioengineered food; and

(7) *Section 7.* A description of any applications or uses that are not suitable for the bioengineered food.

(c) *Part III.* In your PBN, you must describe the status of the bioengineered food at other Federal agencies and foreign governments.

(1) *Status at the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS).* A statement as to whether the bioengineered food plant has been the subject of an initiated or completed authorization, or petition for nonregulated status by APHIS, under 7 CFR 340.

(2) *Status at the U.S. Environmental Protection Agency (EPA).* A statement as to whether any plant pesticide residue in the bioengineered food is or has been the subject of a consultation with, or review by, EPA and, if so, a description of the status of that consultation or review.

(3) *Status at foreign governments.* A statement as to whether the bioengineered food is or has been the subject of review by any foreign government and, if so, a description of the status of that consultation or review.

(d) *Part IV.* In your PBN, you must provide the following data or other information about the method of development of the food:

(1) *Section 1.* Characterization of the parent plant including scientific name, taxonomic classification, mode of reproduction, and pertinent history of development.

(2) *Section 2.* Construction of the vector used in the transformation of the parent plant. This includes a thorough characterization of the genetic material intended for introduction into the parent plant and a discussion of the transformation method, open reading frames, and regulatory sequences.

(3) *Section 3.* Characterization of the introduced genetic material, including the number of insertion sites, the number of gene copies inserted at each site, information on deoxyribonucleic acid (DNA) organization within the inserts, and information on potential reading frames that could express unintended proteins in the transformed plant.

(4) *Section 4.* Data or other information related to the inheritance and genetic stability of the introduced genetic material.

(5) *Section 5.* A discussion, as necessary, of other relevant data or other information about the method of development.

(e) *Part V.* In your PBN, you must discuss any newly inserted genes that encode resistance to an antibiotic. FDA recommends that you contact FDA about the agency's current thinking on this topic.

(f) *Part VI.* In your PBN, you must provide the following data or other information about substances (other than DNA, ribonucleic acid (RNA), or pesticidal substances) introduced into, or modified in, the food (including substances that you expect to be present in the bioengineered food at an increased level relative to comparable food):

(1) *Section 1.* Data or other information about the identity and function of substances introduced into, or modified in, the food;

(2) *Section 2.* Data or other information relating to the level in the bioengineered food of substances introduced into, or modified in, the food;

(3) *Section 3.* (i) An estimate of dietary exposure to substances introduced into, or modified in, the food; or

(ii) A statement that explains the basis for your conclusion that an estimate of dietary exposure to these substances is not needed to support your view that the bioengineered food is as safe as comparable food.

(4) *Section 4.* A discussion of the available data or other information that address the potential that a protein introduced into the food will be an allergen. FDA recommends that you contact FDA about the agency's current thinking on this topic.

(5) *Section 5.* A discussion of data or other information relevant to other safety issues that may be associated with the substances introduced into, or modified in, the food.

(g) *Part VII.* In your PBN, you must provide the following data or other information about the food:

(1) *Section 1.* Justification for selecting a particular food(s) as the comparable food to which you will compare the bioengineered food.

(2) *Section 2.* A discussion of historic uses of the comparable food(s) to which you will compare the bioengineered food.

(3) *Section 3.* Data or other information comparing the composition and characteristics of the bioengineered food to those of comparable food(s), with emphasis on:

(i) Levels of significant nutrients;

(ii) Levels of naturally occurring toxicants and antinutrients; and

(iii) Any intended changes to the composition of the food.

(4) *Section 4.* Any other information relevant to the safety, nutrition, or other assessment of the bioengineered food.

(5) *Section 5.* A narrative that explains the basis for your view that the bioengineered food is as safe as comparable food and that the bioengineered food is otherwise in compliance with all applicable requirements of the act.

§ 192.30 FDA evaluation and response: What will I get back from FDA and how long will it take?

(a) Within 15 working days of receipt, FDA will do an initial evaluation of your PBN to determine whether it appears to include all elements required under §§ 192.20 and 192.25.

(1) If your PBN appears to include all required elements, the Center for Food Safety and Applied Nutrition (CFSAN) will file it and will inform the Center for Veterinary Medicine (CVM) of the filing.

(2) If your PBN does not appear to include all required elements, FDA will inform you of that fact and explain what is missing.

(b) Within 15 working days of filing a notice, FDA will send you (or your agent) a letter that informs you of the date on which FDA filed the PBN.

(c) Within 120 days of filing a notice, FDA will send you (or your agent) a letter about its evaluation of your premarket notice.

(d) In general, FDA will respond as follows:

(1) FDA is extending its evaluation of your premarket notice by 120 days and expects that the bioengineered food will not be marketed during that evaluation; or

(2) FDA has completed its evaluation of your premarket notice. Based upon this evaluation, and as discussed in this letter, the premarket notice does not provide a basis for your view that the bioengineered food is as safe as comparable food or is otherwise in compliance with all applicable requirements of the act. Therefore, the agency expects that the bioengineered food will not be marketed; or

(3) FDA has completed its evaluation of your premarket notice. Based upon this evaluation, the agency has no questions, at this time, regarding your view that the bioengineered food is as safe as comparable food and is otherwise in compliance with all applicable requirements of the act; or

(4) FDA has received a letter in which you withdrew your PBN from its consideration without prejudice to a future filing. Given your letter, FDA ceased to evaluate your PBN on the date that we received your letter.

(e) If your PBN is about a bioengineered food that contains a plant pesticide, FDA will describe the status of the bioengineered food at EPA.

(1) If all applicable regulatory processes at EPA have come to closure, FDA will say so and will respond as described in paragraph (d) of this section.

(2) If regulatory processes at EPA regarding the bioengineered food are still pending, FDA will inform you that FDA does not consider your PBN to satisfy the requirement for premarket notice.

§ 192.40 Public disclosure.

(a) *When could anyone else find out that I sent a PBN to FDA?* (1) Ordinarily, the existence of your PBN is available for public disclosure on the date that FDA files it.

(2) If you believe that the existence of your PBN is confidential, it is your responsibility to say so. The way to do this is by making a claim for confidentiality in the letter that you send in Part I of your PBN (§ 192.25(a)(4)).

(3) If you claim that the existence of your PBN is confidential, FDA will evaluate your claim. FDA will disclose the existence of your PBN, unless FDA determines that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(4) If FDA determines that the existence of your PBN is confidential at the time that we file it, the existence of your PBN will become available for public disclosure, in accordance with § 20.61 of this chapter, when the criteria for exemption from disclosure in § 20.61 of this chapter are no longer satisfied.

(b) *How could anyone else find out that I sent a PBN to FDA?* (1) FDA will make a list of filed PBN's easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying).

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(2) In general, FDA will use the information submitted in Part II of each PBN (i.e., the information described in § 192.25(b) of this part) to prepare this list and will update this list on an approximately monthly basis.

(c) *Would the data or other information in my PBN (including an amendment to my PBN, or any data or information that I incorporate by reference) be available to the public?* (1) Ordinarily, the data or other information in your PBN are available for public disclosure, in accordance with § 20.61 of this chapter, as of the date that FDA files the PBN.

(2) If you believe that any or all of the data or other information in your PBN is confidential, it is your responsibility to say so. The way to do this is in the letter that you send in Part I of your PBN (§ 192.25(a)(4)). In addition, under § 192.20(b) and (c), it is your responsibility to provide copies of your PBN that do not contain any data or other information that you claim are confidential.

(3) If you claim that any or all of the data or other information in your PBN is confidential, FDA will evaluate your claim. FDA will disclose the data or information in your PBN unless FDA determines that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(4) If FDA determines that any or all of the data or other information in your PBN is confidential as of the date that we file it, those data or information would be available for public disclosure, in accordance with § 20.61 of this chapter, when the criteria for exemption from disclosure in § 20.61 of this chapter are no longer satisfied.

(5) As long as the existence of your PBN is confidential, then the data or other information in your PBN would not be available for public disclosure.

(d) *How could the public obtain disclosable data and information in my PBN?* Under the FOIA, the public could obtain the disclosable data or other information in your PBN or an amendment to your PBN, or that you incorporate by reference into your PBN, by looking for these data and information in FDA's electronic reading room or by asking FDA to send them a copy of these data and information.

(e) *Would the agency's evaluation of my PBN be available to the public?* FDA will make the following information easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying):

(1) The text of any letter issued by the agency under § 192.30(c).

(2) The text of the agency's completed evaluation of any notice submitted under this part.

2. Add part 592 to read as follows:

PART 592—PREMARKET NOTICE CONCERNING BIOENGINEERED FOOD

Sec.

592.1 Definitions: What terms do I need to know?
592.5 Requirement for premarket biotechnology notice.
592.10 Recommendation for presubmission consultation.
592.20 Premarket biotechnology notice: Administrative information.
592.25 Premarket biotechnology notice–required parts: What must I include in a premarket biotechnology notice?
592.30 FDA evaluation and response: What will I get back from FDA and how long will it take?
592.40 Public disclosure.

Authority: 21 U.S.C. 331, 341, 343, 348, 371.

§ 592.1 Definitions: What terms do I need to know?

(a) *A bioengineered food* means food derived from a plant that is developed using a transformation event.

(b) *Commercial distribution* means introduction, or delivery for introduction, into interstate commerce for sale or exchange for consumption in any form by humans or other animals.

(c) A *notifier* is the person who submits a premarket biotechnology notice under this part. Any person who is responsible for the development, distribution, importation, or sale of a bioengineered food may be a notifier.

(d) *A premarket biotechnology notice* (PBN) is a submission to FDA regarding a bioengineered food that is intended to enter commercial distribution. Under this part, a PBN includes all data and information in the original submission and in any amendments to the original submission.

(e) *Transformation event* means the introduction into an organism of genetic material that has been manipulated in vitro. For the purpose of this part, "organism" refers to plants.

§ 592.5 Requirement for premarket biotechnology notice.

(a) *What foods must I notify FDA about?* You must notify FDA about any bioengineered food, including a bioengineered food derived from a new plant variety modified to contain a pesticidal substance, that will enter commercial distribution unless all of the following conditions are satisfied:

(1) The bioengineered food derives from a plant line that represents a transformation event that has been addressed in a PBN previously submitted to FDA;

(2) The use or application of the bioengineered food has been addressed in a notice previously submitted to FDA; and

(3) A letter from FDA demonstrates that FDA has evaluated the use or application of the bioengineered food and has no questions about it. This would include a letter issued between May 1, 1994, and the effective date of this rule.

(b) *Must the data or other information that I submit to support my PBN be generated from a particular plant line?* The data or other information that you submit to FDA regarding a bioengineered food must be generated from a plant line whose derivation can be traced to the transformation event that is the subject of the notice and that contains the genetic material introduced via the transformation event.

(c) *When do I submit my PBN?* You must submit your PBN at least 120 days before the bioengineered food is marketed.

§ 592.10 Recommendation for presubmission consultation.

(a) *Is there a program that provides an opportunity for me to consult with FDA about a bioengineered food before I submit a PBN?* FDA has established a presubmission consultation program to enable a prospective notifier to identify and discuss relevant safety, nutritional, or other issues regarding a bioengineered food before submitting a PBN about that food. FDA recommends that you participate in this program.

(b) *How does the presubmission consultation program work?* In this program, you inform FDA about the bioengineered food. FDA encourages you to discuss with us safety, nutritional, or other issues that may be associated with the bioengineered food. FDA will establish an administrative file for your consultation. Although FDA may provide written feedback during the consultation, that feedback would not release you from the requirement in § 592.5 to notify FDA about the bioengineered food as described in §§ 592.20 and 592.25.

(c) *Would the fact that I am consulting with FDA be confidential?* (1) In most cases, the fact that you are consulting with FDA would not be confidential.

(2) If you claim that the fact that you are consulting with FDA is confidential, FDA will evaluate your claim. If FDA is asked, under the Freedom of Information Act (FOIA), about whether you are consulting with us, FDA will disclose that fact unless we determine that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(d) *Would any of the data or other information in the administrative file of my consultation be disclosed to the public?* (1) If the fact that you are consulting with FDA is not confidential, then the data or other information in the administrative file of your presubmission consultation would be available for public disclosure in accordance with § 20.61 of this chapter.

(2) As long as the fact that you are consulting with FDA is confidential, then the data or other information in the administrative file of your presubmission consultation would not be available for public disclosure.

(e) *How do I get started?* To participate in the presubmission consultation program, write to FDA and tell us that you want to consult about a bioengineered food.

(f) *If I participate, what do I provide to FDA?* (1) You must state your view as to whether the fact that you are consulting with FDA, or any or all of the data or other information that you submit to FDA, is exempt from disclosure under the FOIA (i.e., is confidential).

(2) If you claim that the fact that you are consulting with FDA, or that any or all of the data or other information that you submit to FDA, is confidential, you must explain the basis for your claim.

(3) We recommend that you send us the following synopsis about the requested consultation:

(i) Your name and address;

(ii) The name of the bioengineered food that is the subject of the presubmission consultation and the plant species from which it is derived;

(iii) The distinctive designation(s) that you use to identify the applicable transformation event(s);

(iv) A list of the identity(ies) and source(s) of introduced genetic material;

(v) A description of the purpose or intended technical effect of the transformation event. This includes expected significant changes in the composition or characteristic properties of food derived from the plant as a result of the transformation event, regardless of whether these changes result from the insertion of new genes or from a modification in the expression of endogenous genes;

(vi) A description of the intended applications or uses of the bioengineered food; and

(vii) A description of any applications or uses that are not suitable for the bioengineered food.

(g) *Where do I send my written request for consultation?* Send your written request for consultation about a bioengineered food to the Office of Premarket Approval (HFS-200), Center for Food Safety and Applied Nutrition, 200 C St. SW. Washington, DC 20204. As necessary and appropriate, the Center for Food Safety and Applied Nutrition (CFSAN) will coordinate FDA's evaluation of your request with the Office of Surveillance and Compliance, Center for Veterinary Medicine (CVM).

(h) *What copies do I send?* (1) You should send an original and at least two paper copies of your written request for consultation.

(2) If you submit additional written information to FDA (i.e., after your original written request), you should send an original and at least two paper copies of each additional submission.

(3) If you claim that any specific data or other information that you provide to FDA during the consultation are confidential, you should:

(i) Clearly identify, in each submission, the data or other information that you claim are confidential; and

(ii) Prepare and submit a "redacted" paper copy of the submission (i.e., a copy that does not contain any of those data or information).

(iii) Prepare this redacted paper copy in a manner that clearly identifies the location and relative size of deleted information.

(i) *What will FDA do with my written request for consultation?* (1) FDA will establish an administrative file for your consultation and will place the following materials in that file:

(i) Any correspondence between you and FDA;

(ii) Any written materials that you provide during the consultation process; and

(iii) A memorandum of each meeting or significant phone call that you have with FDA regarding the subject of your consultation.

(2) If you ask FDA to discuss the bioengineered food with you, we will do so (e.g., at a meeting at its offices or via a telephone conference).

§ 592.20 Premarket biotechnology notice: Administrative information.

(a) *Where do I send my PBN?* Send a PBN regarding a bioengineered food to the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. As necessary and appropriate, the Center for Food Safety and Applied Nutrition (CFSAN) will coordinate FDA's evaluation of your PBN with the Office of Surveillance and Compliance, Center for Veterinary Medicine (CVM).

(b) *What paper copies do I send?* (1) At a minimum, you must submit an original paper version and one paper copy of a PBN (including any amendments that you make to your PBN). The original paper version will be the official version at FDA. If, under paragraph (c)(1) of this section, you choose not to send an electronic evaluation copy of your PBN, then you must submit one additional paper copy, for a total of three paper copies.

(2) If you claim that specific data or other information in the PBN are confidential, you must:

(i) Clearly identify, in each submission, the data or information that you claim are confidential;

(ii) Prepare and submit a "redacted" paper copy of the PBN (i.e., a copy that does not contain any of those data or information); and

(iii) Prepare this redacted paper copy in a manner that clearly identifies the location and relative size of deleted information.

(c) *What electronic copies do I send?*

(1) *Evaluation copy.* FDA recommends that you submit an electronic copy that is formatted in a manner that makes it suitable for FDA to use while evaluating your PBN. If you do so, you should submit such an electronic copy of your original PBN and of any amendments that you make to your PBN. To obtain current information about the technical format of this evaluation copy, contact the Office of Premarket Approval (OPA) at the address listed previously or look on OPA's home page on the Internet.

(2) *Disclosure copy.*

(i) Unless waived under paragraph (2)(ii) of this section, you must submit an electronic copy that is formatted in a manner that makes it suitable for FDA to use to make your PBN available to the public in an electronic reading room. This includes an electronic copy of your original PBN and of any amendments that you make to your PBN. If you claim that specific data or other information in the PBN are confidential, you must remove such data or information from the disclosure copy in a manner that clearly identifies the location and relative size of deleted information. To obtain current information about the technical format of this disclosure copy, write to OPA at the address listed previously or look on OPA's home page on the Internet.

(ii) You may request that FDA waive the requirement for an electronic disclosure copy, e.g., if you do not have

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access to the appropriate technology for formatting such a copy. FDA will grant or deny your request according to its merits.

(d) *May I submit any data or other information, such as a reprint of a published scientific article, in a foreign language*? If you submit any material in a foreign language, you must provide an English translation that is verified to be complete and accurate.

(e) *May I incorporate data or other information that are already retained in FDA's files by referring to them*? (1) If you previously submitted a file to FDA, you may incorporate that file by referring FDA to it.

(2) If someone else previously submitted a file to FDA, the procedure that you may use to incorporate that file into your PBN depends on whether the file is publicly available (e.g., the file is in an electronic reading room or is otherwise available under FOIA).

(i) If the file is publicly available, you may incorporate that file by referring FDA to it.

(ii) If the file is not publicly available, you may incorporate that file by referring FDA to it if the person who submitted the file authorizes you to do so in a signed statement and you include that signed statement in your PBN.

(f) *How can I get additional information that will help me to prepare a PBN*? You can obtain current guidance regarding specific technical issues by writing to OSC at the address listed previously or by looking on CVM's home page on the Internet.

(g) *May I withdraw a PBN from FDA consideration after I send it*? (1) At any time during FDA's evaluation of a PBN, you may request that FDA cease to evaluate it. Your request would not preclude you from submitting a future PBN about the same bioengineered food.

(2) If you request that FDA cease to evaluate your PBN, FDA will retain your PBN in its files and classify your PBN as "withdrawn."

§ 592.25 Premarket biotechnology notice—required parts: What must I include in a premarket biotechnology notice?

A PBN has seven parts. You must include all of the information described in each part, or explain why it does not apply to the bioengineered food.

(a) *Part I.* In your PBN, you must provide a letter that a responsible official of your organization, or your attorney or agent, dates and signs. In this letter, you inform FDA that you are submitting a PBN under § 192.25 and attest to the following:

(1) It is your view that:

(i) The bioengineered food is as safe as comparable food; and

(ii) The intended use of the bioengineered food is in compliance with all applicable requirements of the the Federal Food, Drug, and Cosmetic Act (the act).

(2) You agree to make relevant data or other information that are not included in your PBN available to FDA upon request, either while FDA is evaluating your PBN or for cause.

(3) You agree to two procedures for making relevant data or other information that are not included in your PBN available to FDA by:

(i) Allowing FDA to review and copy these data or information at specified address during customary business hours; or

(ii) Sending a copy of these data or information to FDA.

(4)(i) Your view as to whether the existence of your PBN, or any or all of the data or other information in your PBN, is exempt from disclosure under the FOIA (i.e., is confidential); and

(ii) If you claim that the existence of the PBN, or any or all of the data or other information in the PBN, is confidential, you must explain the basis for your claim.

(5) To the best of your knowledge, the PBN is a representative and balanced submission that includes information, unfavorable as well as favorable, pertinent to the evaluation of the safety, nutritional, or other regulatory issues that may be associated with the bioengineered food.

(b) *Part II.* In your PBN, you must provide the following synopsis:

(1) *Section 1.* Your name and address;

(2) *Section 2.* The name of the bioengineered food that is the subject of the PBN and the plant species from which it is derived;

(3) *Section 3.* The distinctive designation(s) that you use to identify the applicable transformation event(s);

(4) *Section 4.* A list of the identity(ies) and source(s) of introduced genetic material;

(5) *Section 5.* A description of the purpose or intended technical effect of the transformation event. This includes expected significant changes in the composition or characteristic properties of food derived from the plant as a result of the transformation event, regardless of whether these changes result from the insertion of new genes or from a modification in the expression of endogenous genes;

(6) *Section 6.* A description of the applications or uses of the bioengineered food; and

(7) *Section 7.* A description of any applications or uses that are not suitable for the bioengineered food.

(c) *Part III.* In your PBN, you must describe the status of the bioengineered food at other Federal agencies and foreign governments.

(1) *Status at the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS).* A statement as to whether the bioengineered food plant has been the subject of an initiated or completed authorization, or petition for nonregulated status by APHIS, under 7 CFR part 340.

(2) *Status at the U.S. Environmental Protection Agency (EPA).* A statement as to whether any plant pesticide residue in the bioengineered food is or has been the subject of a consultation with, or review by, EPA and, if so, a description of the status of that consultation or review.

(3) *Status at foreign governments.* A statement as to whether the bioengineered food is or has been the subject of review by any foreign government and, if so, a description of the status of that consultation or review.

(d) *Part IV.* In your PBN, you must provide the following data or other information about the method of development of the food:

(1) *Section 1.* Characterization of the parent plant including scientific name, taxonomic classification, mode of reproduction, and pertinent history of development.

(2) *Section 2.* Construction of the vector used in the transformation of the parent plant. This includes a thorough characterization of the genetic material intended for introduction into the parent plant and a discussion of the transformation method, open reading frames, and regulatory sequences.

(3) *Section 3.* Characterization of the introduced genetic material, including the number of insertion sites, the number of gene copies inserted at each site, information on deoxyribonucleic acide (DNA) organization within the inserts, and information on potential reading frames that could express unintended proteins in the transformed plant.

(4) *Section 4.* Data or other information related to the inheritance and genetic stability of the introduced genetic material.

(5) *Section 5.* A discussion, as necessary, of other relevant data or other information about the method of development.

(e) *Part V.* In your PBN, you must discuss any newly inserted genes that encode resistance to an antibiotic. FDA recommends that you contact FDA about the agency's current thinking on this topic.

(f) *Part VI.* In your PBN, you must provide the following data or other information about substances (other than DNA, ribonucleic acid (RNA), or pesticidal substances) introduced into, or modified in, the food (including substances that you expect to be present in the bioengineered food at an increased level relative to comparable food):

(1) *Section 1.* Data or other information about the identity and function of substances introduced into, or modified in, the food;

(2) *Section 2.* Data or other information relating to the level in the bioengineered food of substances introduced into, or modified in, the food;

(3) *Section 3.* (i) An estimate of dietary exposure to substances introduced into, or modified in, the food; or

(ii) A statement that explains the basis for your conclusion that an estimate of dietary exposure to these substances is not needed to support your view that the bioengineered food is as safe as comparable food.

(4) *Section 4.* A discussion of the available data or other information that address the potential that a protein introduced into the food will be an allergen. FDA recommends that you contact FDA about the agency's current thinking on this topic.

(5) *Section 5.* A discussion of data or other information relevant to other safety issues that may be associated with the substances introduced into, or modified in, the food.

(g) *Part VII.* In your PBN, you must provide the following data or other information about the food:

(1) *Section 1.* Justification for selecting a particular food(s) as the comparable food to which you will compare the bioengineered food.

(2) *Section 2.* A discussion of historic uses of the comparable food(s) to which you will compare the bioengineered food.

(3) *Section 3.* Data or other information comparing the composition and characteristics of the bioengineered food to those of comparable food(s), with emphasis on:

(i) Levels of significant nutrients;

(ii) Levels of naturally occurring toxicants and antinutrients; and

(iii) Any intended changes to the composition of the food.

(4) *Section 4.* Any other information relevant to the safety, nutrition, or other assessment of the bioengineered food.

(5) *Section 5.* A narrative that explains the basis for your view that the bioengineered food is as safe as comparable food and that the bioengineered food is otherwise in compliance with all applicable requirements of the act.

§ 592.30 FDA evaluation and response: What will I get back from FDA and how long will it take?

(a) Within 15 working days of receipt, FDA will do an initial evaluation of your PBN to determine whether it appears to include all elements required under §§ 592.20 and 592.25.

(1) If your PBN appears to include all required elements, the Center for Food Safety and Applied Nutrition (CFSAN) will file it and will inform the Center for Veterinary Medicine (CVM) of the filing.

(2) If your PBN does not appear to include all required elements, FDA will inform you of that fact and explain what is missing.

(b) Within 15 working days of filing a notice, FDA will send you (or your agent) a letter that informs you of the date on which FDA filed the PBN.

(c) Within 120 days of filing a notice, FDA will send you (or your agent) a letter about its evaluation of your premarket notice.

(d) In general, FDA will respond as follows:

(1) FDA is extending its evaluation of your premarket notice by 120 days and expects that the bioengineered food will not be marketed during that evaluation; or

(2) FDA has completed its evaluation of your premarket notice. Based upon this evaluation, and as discussed in this letter, the premarket notice does not provide a basis for your view that the bioengineered food is as safe as comparable food or is otherwise in compliance with all applicable requirements of the act. Therefore, the agency expects that the bioengineered food will not be marketed; or

(3) FDA has completed its evaluation of your premarket notice. Based upon this evaluation, the agency has no questions, at this time, regarding your view that the bioengineered food is as safe as comparable food and is otherwise in compliance with all applicable requirements of the act; or

(4) FDA has received a letter in which you withdrew your PBN from its consideration without prejudice to a future filing. Given your letter, FDA ceased to evaluate your PBN on the date that we received your letter.

(e) If your PBN is about a bioengineered food that contains a plant pesticide, FDA will describe the status of the bioengineered food at EPA.

(1) If all applicable regulatory processes at EPA have come to closure, FDA will say so and will respond as described in paragraph (d) of this section.

(2) If regulatory processes at EPA regarding the bioengineered food are still pending, FDA will inform you that FDA does not consider your PBN to satisfy the requirement for premarket notice.

§ 592.40 Public disclosure.

(a) *When could anyone else find out that I sent a PBN to FDA*? (1) Ordinarily, the existence of your PBN is available for public disclosure on the date that FDA files it.

(2) If you believe that the existence of your PBN is confidential, it is your responsibility to say so. The way to do this is by making a claim for confidentiality in the letter that you send in Part I of your PBN (§ 592.25(a)(4)).

(3) If you claim that the existence of your PBN is confidential, FDA will evaluate your claim. FDA will disclose the existence of your PBN, unless FDA determines that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(4) If FDA determines that the existence of your PBN is confidential at the time that we file it, the existence of your PBN will become available for public disclosure, in accordance with § 20.61 of this chapter, when the criteria for exemption from disclosure in § 20.61 of this chapter are no longer satisfied.

(b) *How could anyone else find out that I sent a PBN to FDA*?

(1) FDA will make a list of filed PBN's easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying).

(2) In general, FDA will use the information submitted in Part II of each PBN (i.e., the information described in § 192.25(b) of this chapter) to prepare this list and will update this list on an approximately monthly basis.

(c) *Would the data or other information in my PBN (including an amendment to my PBN, or any data or information that I incorporate by reference) be available to the public*? (1) Ordinarily, the data or other information in your PBN are available for public disclosure, in accordance with § 20.61 of this chapter, as of the date that FDA files the PBN.

(2) If you believe that any or all of the data or other information in your PBN is confidential, it is your responsibility to say so. The way to do this is in the letter that you send in Part I of your PBN (§ 592.25(a)(4)). In addition, under § 592.20(b) and (c), it is your responsibility to provide copies of your PBN that do not contain any data or other information that you claim are confidential.

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(3) If you claim that any or all of the data or other information in your PBN is confidential, FDA will evaluate your claim. FDA will disclose the data or information in your PBN, unless FDA determines that your claim demonstrates that the criteria for exemption from disclosure in § 20.61 of this chapter are satisfied.

(4) If FDA determines that any or all of the data or other information in your PBN is confidential as of the date that we file it, those data or information would be available for public disclosure, in accordance with 20.61 of this chapter, when the criteria for exemption from disclosure in § 20.61 of this chapter are no longer satisfied.

(5) As long as the existence of your PBN is confidential, then the data or other information in your PBN would not be available for public disclosure.

(d) *How could the public obtain disclosable data and information in my PBN?* Under the FOIA, the public could obtain the disclosable data or other information in your PBN or an amendment to your PBN, or that you incorporate by reference into your PBN, by looking for these data and information in FDA's electronic reading room or by asking FDA to send them a copy of these data and information.

(e) *Would the agency's evaluation of my PBN be available to the public?*

FDA will make the following information easily accessible to the public (e.g., by placing the information on the Internet or in a paper or electronic file that is available at FDA for public review and copying):

(1) The text of any letter issued by the agency under § 192.30(c) of this chapter.

(2) The text of the agency's completed evaluation of any notice submitted under this part.

Dated: September 22, 2000.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 01–1046 Filed 1–17–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–107047–00]

RIN 1545–AY02

Hedging Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the character of hedging transactions. These proposed regulations reflect changes to the law made by the Ticket to Work and Work Incentives Improvement Act of 1999. The proposed regulations affect businesses entering into hedging transactions. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronically generated comments must be received by April 25, 2001. Requests to speak (with outlines of oral comments to be discussed) at the public hearing scheduled for May 16, 2001, at 10 a.m., must be submitted by April 25, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–107047–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–107047–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS internet site at *http://www.irs.gov/tax_regs/regslist.html*. The public hearing will be held in the IRS auditorium, 1111 Constitution Ave., NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Jo Lynn Ricks, (202) 622–3920; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, contact Lanita Vandyke, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control numbers 1545–1403 and 1545–1480.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains proposed amendments to 26 CFR part 1 under section 1221 of the Internal Revenue Code (Code). Prior to amendment in 1999, section 1221 generally defined a capital asset as property held by the taxpayer other than: (1) Stock in trade or other types of assets includible in inventory; (2) property used in a trade or business that is real property or property subject to depreciation; (3) certain copyrights (or similar property); (4) accounts or notes receivable acquired in the ordinary course of a trade or business; and (5) U.S. government publications.

In 1994, the IRS published in the **Federal Register** (59 FR 36360) final Treasury regulations under section 1221 providing for ordinary character treatment for most business hedges. The regulations generally apply to hedges that reduce risk with respect to ordinary property, ordinary obligations, and borrowings of the taxpayer and that meet certain identification requirements. (§ 1.1221–2). In 1996, the IRS published in the **Federal Register** (61 FR 517) final regulations on the character and timing of gain or loss from hedging transactions entered into by members of a consolidated group. The final regulations published in 1994 and 1996 are collectively referred to as the Treasury regulations in this preamble.

On December 17, 1999, section 1221 was amended by section 532 of the Ticket to Work and Work Incentives Improvement Act of 1999 (113 Stat. 1860) to provide ordinary gain or loss treatment for hedging transactions and consumable supplies. Section 1221(a)(7) provides ordinary treatment for hedging transactions that are clearly identified as such before the close of the day on which they were acquired, originated, or entered into.

The statute defines a hedging transaction generally to include a transaction entered into by the taxpayer in the normal course of business primarily to manage risk of interest rate, price changes, or currency fluctuations with respect to ordinary property, ordinary obligations, or borrowings of the taxpayer. § 1221(b)(2)(A)(i) and (ii). The statutory definition of hedging transaction also includes transactions to manage such other risks as the Secretary may prescribe in regulations. Section 1221(b)(2)(A)(iii). Further, the statute grants the Secretary the authority to provide regulations to address the treatment of nonidentified or improperly identified hedging transactions, and hedging transactions involving related parties (sections 1221(b)(2)(B) and (b)(3), respectively). The statutory hedging provisions are effective for transactions entered into on or after December 17, 1999.

Section 1221(a)(8) provides that supplies of a type regularly consumed by the taxpayer in the ordinary course of a taxpayer's trade or business are not capital assets. That provision is effective for supplies held or acquired on or after December 17, 1999.

The legislative history to the hedging provisions states that Congress intended that the approach taken in the Treasury regulations with respect to the character of hedging transactions generally should be codified as an appropriate interpretation of present law. S. Rep. No. 201, 106th Cong., 1st Sess. 24 (1999). These proposed regulations conform the Treasury regulations to these statutory provisions.

Explanation of Provisions

Paragraph (a) of the proposed regulations provides basic rules for the treatment of hedging transactions. The substance of these rules is the same as the rules under § 1.1221–2(a).

Accordingly, paragraph (a)(1) of the proposed regulations generally provides that property that is part of a hedging transaction, as defined in section 1221(b)(2)(A) and paragraph (b) of the proposed regulations, is not a capital asset. Paragraph (a)(2) of the proposed regulations provides a similar rule for short sales and options. Where a short sale or option is part of a hedging transaction, as defined, any gain or loss on the short sale or option is ordinary. Under paragraph (a)(3), if a transaction falls outside the regulations, gain or loss from the transaction is not made ordinary by the fact that property is a surrogate for a non-capital asset, that the transaction serves as insurance against a business risk, that the transaction serves a hedging function, or that the transaction serves a similar function or purpose. As under the Treasury regulations, Congress intended that the hedging rules be the exclusive means through which the gains and losses on hedging transactions are treated as ordinary. S. Rep. No. 201, 106th Cong., 1st Sess. 25 (1999).

The provisions of the proposed regulations generally apply to determine the character of gain or loss from transactions that also are subject to various international provisions of the Code. Paragraph (a)(4) of the proposed regulations, however, provides that section 988 transactions are excluded from these regulations because gain or loss on those transactions is ordinary under section 988(a)(1). Paragraph (a)(4) of the proposed regulations also provides that the definition of a hedging transaction under § 1.1221–2(b) of the proposed regulations does not apply for purposes of the hedging exceptions to the subpart F rules of section 954(c) and certain hedging rules in the interest allocation regulations under section 864(e).

Regulations under § 1.482–8 will address risk management activities in the context of a global dealing operation. Thus, except to the extent provided in §§ 1.475(g)–2, 1.482–8, and 1.863–3(h), these regulations do not apply in determining the allocation and source of income for a participant in a global dealing operation or whether a risk management function related to the activities of a regular dealer in securities has been conducted.

Proposed regulations under §§ 1.882–5 and 1.884–1 also refer to hedging under § 1.1221–2 for purposes of determining assets and liabilities of a foreign corporation for interest allocation and branch tax purposes. The IRS and Treasury are evaluating the appropriate requirements necessary to implement cross-border and worldwide hedging rules for these purposes and seek comments in this regard. Therefore, paragraph (a)(4) of the proposed regulations provides that the definition of hedging transaction in paragraph (b) of the proposed regulations is inapplicable in determining the hedging requirements under sections 882(c) and 884, except to the extent provided in regulations under those sections.

Paragraph (b) of the proposed regulations restates the definition of hedging transaction in section 1221(b)(2)(A). Under this rule, a hedging transaction is generally a transaction that a taxpayer enters into in the normal course of its business primarily to manage the risk of interest rate or price changes or currency fluctuations with respect to ordinary property, ordinary obligations, or borrowings of the taxpayer.

Paragraph (c) of the proposed regulations provides rules of application designed to ensure that the definition of hedging transaction is applied reasonably to include most common types of business hedges. Congress intended that the approach taken in the Treasury regulations with respect to the character of hedging transactions generally should be codified as an appropriate interpretation of present law. S. Rep. No. 201, 106th Cong., 1st Sess. 24 (1999). The Senate Finance Committee believed that the Treasury regulations interpret risk reduction flexibly to provide hedging transaction treatment for fixed to floating hedges, certain written call options, dynamic hedges, partial hedges, recycled hedges, and hedges of aggregate risk (see § 1.1221–2(c)). *Id.* at n.12. The Committee believed that (depending on the facts) the treatment of those transactions as hedging transactions is appropriate and that it is also appropriate to modernize the definition of hedging transaction by providing risk management as the standard. *Id.* These proposed regulations revise the Treasury regulations to reflect the risk management standard.

Paragraph (c)(1) of the proposed regulations deals with the meaning of risk management. It provides that, except as otherwise provided in paragraph (c), a transaction satisfies the risk management standard if it reduces risk. To enter into a hedging transaction, the taxpayer must have risk when all of its operations are considered—that is, there must be risk on a "macro" basis. Nonetheless, a hedge of a single asset or liability, or pool of assets or liabilities, will be respected as managing risk if the hedge reduces the risk attributable to the item or items being hedged and if the hedge is reasonably calculated to reduce the overall risk of the taxpayer's operations. In addition, if a taxpayer hedges a particular asset or liability, or a pool of assets or liabilities, and the hedge is undertaken as part of a program to reduce the overall risk of the taxpayer's operations, the taxpayer need not show that the hedge reduces its overall risk.

Paragraph (c)(1) of the proposed regulations also recognizes that fixed to floating hedges and certain types of written options may manage risk and may be hedging transactions in appropriate situations. For example, a covered call with respect to assets held or a written put option with respect to assets to be acquired may be a hedging transaction.

In addition, paragraph (c)(1) of the proposed regulations provides that a hedging transaction includes a transaction that reverses or counteracts a hedging transaction. This rule recognizes that some transactions are used to eliminate some or all of the risk reduction accomplished through another hedging transaction. Although the transactions are not risk reducing if viewed independently, they are considered to be part of the larger hedging transaction.

Paragraph (c)(1) of the proposed regulations further provides that a

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taxpayer may hedge any part or all of its risk for any part of the period during which it has risk. The proposed regulations also provide that the fact that a taxpayer frequently enters into and terminates hedging positions is not relevant to whether transactions are hedging transactions.

Except as otherwise provided in paragraph (c) of the proposed regulations, a transaction that is not entered into primarily to reduce risk is not a hedging transaction. For example, the so-called "store-on-the-board" transaction, in which a taxpayer disposes of its production output and enters into a long futures contract with respect to the same product, is not a hedging transaction. In this example, the long futures contact could be viewed as a surrogate for the storage of the commodity. The net proceeds from the sale of the production output and the gain or loss on the long futures contract simulates the price at which the production output would have sold if it had been physically stored and sold at a later time. However, because the production output to which the futures contract relates has been sold, there is no underlying position (with respect to ordinary property held or to be held) that exposes the taxpayer to price risk. Thus, the long position does not reduce risk. Moreover, gain or loss on the contract is not treated as ordinary on the grounds that it is a surrogate for inventory.

Paragraph (c)(2) of the proposed regulations provides that a hedging transaction may be entered into by using a position that was a hedge of one asset or liability to hedge another asset or liability.

Paragraph (c)(3) of the proposed regulations provides that the acquisition of certain assets, such as investments, may not be a hedging transaction. Even though acquisition of these assets may involve some risk reduction, they typically are not acquired primarily to manage risk. For example, a taxpayer's interest rate risk from a floating rate borrowing may be reduced by the purchase of debt instruments that bear a comparable floating rate. The proposed regulations provide that the acquisition of the debt instruments, however, is not made primarily to reduce risk and, therefore, is not a hedging transaction. Similarly, borrowings generally are not made primarily to manage risk. The IRS and Treasury request comments on the circumstances in which the acquisition of debt instruments or borrowings are made primarily to manage risk.

Paragraph (c)(4) defines the normal course requirement of paragraph (b) to include any transaction entered into in furtherance of a taxpayer's trade or business. Thus, for example, a liability hedge meets this requirement regardless of whether the liability is undertaken to fund current operations, an acquisition, or an expansion of a taxpayer's business. This definition does not apply to other uses of the term "normal course" in the Code or regulations.

Paragraph (c)(5) of the proposed regulations provides that a hedge of property or of an obligation is a hedging transaction only if a sale or exchange of the property, or performance or termination of the obligation, could not produce capital gain or loss. The special rule in the Treasury regulations for noninventory supplies (§ 1.1221–2(c)(5)(ii)), however, is not contained in these proposed regulations. Under the noninventory supply rule, if a taxpayer sells only a negligible amount of a noninventory supply, then, only for purposes of determining whether a hedge of the purchase of that noninventory supply is a hedging transaction, that noninventory supply is treated as ordinary property. This rule is not being proposed because section 1221(a)(8) generally provides ordinary gain or loss treatment for consumable supplies held or acquired on or after December 17, 1999.

Paragraph (c)(6) of the proposed regulations provides that the status of liability hedges as hedging transactions is determined without regard to the use that is made of the proceeds of a borrowing so long as the transaction is entered into in furtherance of the taxpayer's trade or business. The Service and Treasury believe that a liability hedge should not fail to qualify as a hedging transaction because the proceeds of the borrowing being hedged are used to purchase a capital asset.

Paragraph (c)(7) of the proposed regulations provides that, in the case of hedges of aggregate risk, all but a de minimis amount of the risk being hedged must be attributable to ordinary property, ordinary obligations, or borrowings.

Although the purpose of the rules in paragraph (c) is to ensure that the definition of hedging transaction will be interpreted reasonably to cover most common business hedges, not all hedges are intended to be covered. For example, the regulations do not apply where a taxpayer hedges a dividend stream, the overall profitability of a business unit, or other business risks that do not relate directly to interest rate or price changes or currency fluctuations with respect to ordinary property, ordinary obligations, or borrowings. Moreover, the regulations do not provide ordinary treatment for gain or loss from the disposition of stock where, for example, the stock is acquired to protect the goodwill or business reputation of the acquirer or to ensure the availability of goods.

Paragraph (c)(8) of the proposed regulations provides that a hedging transaction does not include a transaction entered into to manage risks other than interest rate or price changes, or currency fluctuations, unless a regulation, revenue ruling, or revenue procedure provides otherwise. Thus, until such guidance is published, a hedge of volume or revenue fluctuations is not a hedging transaction. One example of this type of hedge is a weather derivative used by an energy producer to hedge against the decrease in volume of sales from variations in weather patterns.

The IRS is considering whether to expand the definition of hedging transaction to include transactions that manage risks other than interest rate or price changes, or currency fluctuations with respect to ordinary property, ordinary obligations or borrowings of the taxpayer. The Service solicits comments on the types of risks that should be covered, including specific examples of derivative transactions that may be incorporated into future guidance.

The status of so-called "gap" hedges is not separately addressed in paragraph (c) of the proposed regulations. Insurance companies, for example, sometimes hedge the "gap" between their liabilities and the assets that fund them. Under the proposed regulations, a hedge of those assets does not qualify as a hedging transaction if the assets are capital assets. Whether a gap hedge qualifies as a liability hedge is a question of fact and depends on whether it is more closely associated with the liabilities than with the assets. For example, a contract to purchase assets is generally not a liability hedge even if the assets are being purchased to fund the liability. Other gap hedges may be appropriately treated as liability hedges and, therefore, may qualify as hedging transactions.

The rules in paragraphs (d), (e) and (f) of the proposed regulations, covering consolidated group hedging, identification and recordkeeping rules, and the effect of identification and non-identification, respectively, are generally unchanged from the corresponding rules in the Treasury regulations. This is because Congress generally intended to codify the approach to hedging transactions that was taken in the Treasury regulations. S. Rep. No. 201, 106th Cong., 1st Sess. 24 (1999).

Paragraph (d) of the proposed regulations provides rules applicable to hedging by members of a consolidated group. The proposed regulations retain the single-entity approach of the Treasury regulations. That is, they treat the risk of one member of the group as the risk of the other members, as if all the members were divisions of a single corporation. Thus, a member of a consolidated group that hedges the risk of another member by entering into a transaction with a third party may receive ordinary gain or loss treatment on that transaction if the transaction otherwise qualifies as a hedging transaction.

Under this single-entity approach, intercompany transactions are neither hedging transactions nor hedged items. Because they are treated as transactions between divisions of a single corporation, intercompany transactions do not manage the risk of that single corporation and, therefore, fail to qualify as hedging transactions.

The proposed regulations also retain the separate-entity election of the Treasury regulations, permitting a consolidated group to treat its members as separate entities when applying the hedging rules. The election is made by attaching a statement to the group's federal income tax return.

For a group that elects separate-entity treatment, an intercompany transaction is treated as a hedging transaction if and only if: (1) It would qualify as a hedging transaction if entered into with an unrelated party; and (2) it is entered into with a member that, under its method of accounting, marks its position in the intercompany transaction to market. If these requirements are satisfied, the member with respect to which it is an intercompany hedging transaction must account for its position in the transaction under § 1.446–4, and, if that member properly identifies the transaction as a hedging transaction, each member treats the gain or loss from its position in the transaction as ordinary.

The proposed regulations provide that, even when these two requirements are met, these regulations supplant only the character and timing rules of § 1.1502–13. Other aspects of the transaction, such as the source of the gain or loss, are unaffected by these regulations and thus may be governed by other portions of § 1.1502–13.

Pursuant to section 1221(a)(7), paragraph (e)(1) of the proposed regulations provides that hedging transactions must be identified before the close of the day on which they are entered into. Paragraph (e)(2) of the proposed regulations requires that the item, items, or aggregate risk being hedged be identified substantially contemporaneously with entering into the hedging transaction. The identification must be made no more than 35 days after entering into the hedging transaction.

Paragraph (e)(3) of the proposed regulations contains a series of special rules for identifying certain types of hedging transactions. In the case of inventory, the identification must specify the type or class of inventory to which the hedge relates. If particular inventory purchases or sales transactions are being hedged, the taxpayer must also identify the expected date and the amount to be acquired or sold. In the case of hedges of aggregate risk, the identification requirement is satisfied if a taxpayer's records contain a description of the hedging program and if there is a system for identifying transactions as entered into as part of that program. The intent underlying this rule is to provide verifiable information with respect to the item being hedged without requiring the taxpayer to identify individually the many items that give rise to the aggregate risk being hedged.

Paragraph (e)(4) of the proposed regulations provides rules with respect to how an identification is made. It must be clear that the identification is being made for tax purposes. In lieu of separately identifying each transaction, however, a taxpayer may establish a system in which identification is indicated by the type of transaction or the manner in which the transaction is consummated or recorded.

Paragraph (e)(5) of the proposed regulations deals with the required identification where the taxpayer is a member of a consolidated group, and paragraph (e)(6) of the proposed regulations provides that an identification for purposes of section 1256(e)(2) is also an identification for purposes of § 1.1221–2(e)(1).

Pursuant to section 1221(b)(2)(B), paragraph (f) of the proposed regulations deals with the effect of identification and non-identification. The rules in this paragraph are the same as the rules in paragraph (f) of the Treasury regulations.

The proposed regulations under section 1256 generally restate the rules of § 1.1256(e)–1 that coordinate the identification of hedges for purposes of section 1256(e). The citations to section 1256(e)(2)(C) in the Treasury regulations have been replaced with citations to section 1256(e)(2) in the proposed regulations.

Proposed Effective Date

The proposed regulations are proposed to be effective for transactions entered into on or after January 18, 2001. However, the IRS will not challenge any transaction entered into on or after December 17, 1999, and before January 18, 2001 that satisfies the provisions of these proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that the collection of information in these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that very few small businesses enter into hedging transactions due to their cost and complexity. Further, those small businesses that hedge enter into very few hedging transactions because hedging transactions are costly, complex, and require constant monitoring and a sophisticated understanding of the capital markets. Therefore, a Regulatory Flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any electronic or written comments (a signed original and eight (8) copies of written comments) that are submitted timely (in the manner described in ADDRESSES) to the IRS. The IRS and Treasury request comments on the clarity of the proposed rules and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 16, 2001, beginning at 10 a.m., in the IRS auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the 10th Street entrance, located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be

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admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see **FOR FURTHER INFORMATION CONTACT**.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written comments and an outline of topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by April 25, 2001. A period of 10 minutes will be allotted to each person making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Jo Lynn Ricks, Office of the Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by revising the entry for § 1.1221 to read as follows:

Authority: 26 U.S.C. 7805 * * * § 1.1221–2 also issued under 26 U.S.C. 1221(b)(2)(A)(iii), (b)(2)(B), and (b)(3). * * *

Par. 2. Section 1.1221–2 is revised to read as follows:

§ 1.1221–2 Hedging transactions.

(a) *Treatment of hedging transactions*—(1) *In general.* This section governs the treatment of hedging transactions under section 1221(a)(7). Except as provided in paragraph (f)(2) of this section, the term capital asset does not include property that is part of a hedging transaction (as defined in paragraph (b) of this section).

(2) *Short sales and options.* This section also governs the character of gain or loss from a short sale or option that is part of a hedging transaction. Except as provided in paragraph (f)(2) of this section, gain or loss on a short sale or option that is part of a hedging transaction (as defined in paragraph (b) of this section) is ordinary income or loss.

(3) *Exclusivity.* If a transaction is not a hedging transaction as defined in paragraph (b) of this section, gain or loss from the transaction is not made ordinary on the grounds that property involved in the transaction is a surrogate for a noncapital asset, that the transaction serves as insurance against a business risk, that the transaction serves a hedging function, or that the transaction serves a similar function or purpose.

(4) *Coordination with other sections*—(i) *Section 988.* This section does not apply to determine the character of gain or loss realized on a section 988 transaction as defined in section 988(c)(1) or realized with respect to any qualified fund as defined in section 988(c)(1)(E)(iii).

(ii) *Sections 864(e) and 954(c).* Except as otherwise provided in regulations issued pursuant to sections 864(e) and 954(c), the definition of hedging transaction in paragraph (b) of this section does not apply for purposes of sections 864(e) and 954(c).

(iii) *Global dealing operation.* Except as otherwise provided in §§ 1.475(g)–2, 1.482–8, and 1.863–3(h), the rules of application for purposes of the definition of a hedging transaction in paragraph (c) of this section do not apply in determining the allocation and source of income with respect to a participant in a global dealing operation or in determining whether a risk management function related to the activities of a regular dealer in securities has been conducted. See § 1.482–8(a) for the definitions of global dealing operation, regular dealer in securities, and participant.

(iv) *Sections 882(c) and 884.* Except as otherwise provided in regulations issued under sections 882(c) and 884, the definition of hedging transaction in paragraph (b) of this section does not apply for purposes of those sections.

(b) *Hedging transaction defined.* Section 1221(b)(2)(A) provides that a hedging transaction is any transaction that a taxpayer enters into in the normal course of the taxpayer's trade or business primarily—

(1) To manage risk of price changes or currency fluctuations with respect to ordinary property (as defined in paragraph (c)(5) of this section) that is held or to be held by the taxpayer;

(2) To manage risk of interest rate or price changes or currency fluctuations with respect to borrowings made or to be made, or ordinary obligations incurred or to be incurred, by the taxpayer; or

(3) To manage such other risks as the Secretary may prescribe in regulations (see paragraph (c)(8) of this section).

(c) *Rules of application.* The rules of this paragraph (c) apply for purposes of the definition of the term hedging transaction in section 1221(b)(2)(A) and paragraph (b) of this section. These rules must be interpreted reasonably and consistently with the purposes of this section. Where no specific rules of application control, the definition of hedging transaction must be interpreted reasonably and consistently with the purposes of section 1221(b)(2)(A) and this section.

(1) *Managing risk*—(i) *Transactions that manage risk.* Whether a transaction manages a taxpayer's risk is determined based on all of the facts and circumstances surrounding the taxpayer's business and the transaction. In general, a taxpayer's hedging strategies and policies as reflected in the taxpayer's minutes or other records are evidence of whether particular transactions were entered into primarily to manage the taxpayer's risk.

(ii) *Micro and macro hedges*—(A) *In general.* A taxpayer has risk of a particular type only if it is at risk when all of its operations are considered. Nonetheless, a hedge of a particular asset or liability generally will be respected as managing risk if it reduces the risk attributable to the asset or liability and if it is reasonably expected to reduce the overall risk of the taxpayer's operations. If a taxpayer hedges particular assets or liabilities, or groups of assets or liabilities, and the hedges are undertaken as part of a program that, as a whole, is reasonably expected to reduce the overall risk of the taxpayer's operations, the taxpayer generally does not have to demonstrate that each hedge that was entered into pursuant to the program reduces its overall risk.

(B) *Fixed-to-floating hedges.* Under the principles of paragraph (c)(1)(ii)(A) of this section, a transaction that economically converts an interest rate or price from a fixed rate or price to a floating rate or price may manage risk. For example, if a taxpayer's income varies with interest rates, the taxpayer may be at risk if it has a fixed rate liability. Similarly, a taxpayer with a fixed cost for its inventory may be at risk if the price at which the inventory can be sold varies with a particular factor. Thus, a transaction that converts an interest rate or price from fixed to floating may be a hedging transaction.

(iii) *Written options.* A written option may manage risk. For example, in appropriate circumstances, a written call option with respect to assets held by a taxpayer or a written put option with respect to assets to be acquired by a taxpayer may be a hedging transaction. See also paragraph (c)(1)(v) of this section.

(iv) *Extent of risk management.* A taxpayer may hedge all or any portion of its risk for all or any part of the period during which it is exposed to the risk.

(v) *Transactions that counteract hedging transactions.* If a transaction is entered into primarily to counteract all or any part of the risk reduction effected by one or more hedging transactions, the transaction is a hedging transaction. For example, if a written option is used to reduce or eliminate the risk reduction obtained from another position such as a purchased option, then it may be a hedging transaction.

(vi) *Number of transactions.* The fact that a taxpayer frequently enters into and terminates positions (even if done on a daily or more frequent basis) is not relevant to whether these transactions are hedging transactions. Thus, for example, a taxpayer hedging the risk associated with an asset or liability may frequently establish and terminate positions that hedge that risk, depending on the extent the taxpayer wishes to be hedged. Similarly, if a taxpayer maintains its level of risk exposure by entering into and terminating a large number of transactions in a single day, its transactions may nonetheless qualify as hedging transactions.

(vii) *Transactions that do not manage risk.* A transaction that is not entered into to reduce a taxpayer's risk does not manage risk. For example, assume that a taxpayer produces a commodity for sale, sells the commodity, and enters into a long futures or forward contract in that commodity in the hope that the price will increase. Because the long position does not reduce risk, and is not otherwise treated as a hedging transaction in this paragraph (c), the transaction is not a hedging transaction. Moreover, gain or loss on the contract is not made ordinary on the grounds that it is a surrogate for inventory. See paragraph (a)(3) of this section.

(2) *Entering into a hedging transaction.* A taxpayer may enter into a hedging transaction by using a position that was a hedge of one asset or liability as a hedge of another asset or liability (recycling).

(3) *No investments as hedging transactions.* If an asset (such as an investment) is not acquired primarily to manage risk, the purchase or sale of that asset is not a hedging transaction even if the terms of the asset limit or reduce the taxpayer's risk with respect to other assets or liabilities. For example, a taxpayer's interest rate risk from a floating rate borrowing may be reduced by the purchase of debt instruments that bear a comparable floating rate. The acquisition of the debt instruments, however, is not a hedging transaction because the transaction is not entered into primarily to reduce the taxpayer's risk. Similarly, borrowings generally are not made primarily to manage risk.

(4) *Normal course.* Solely for purposes of paragraph (b) of this section, if a transaction is entered into in furtherance of a taxpayer's trade or business, the transaction is entered into in the normal course of the taxpayer's trade or business. This rule applies even if the risk to be managed relates to the expansion of an existing business or the acquisition of a new trade or business.

(5) *Ordinary property and obligations.* Property is ordinary property to a taxpayer only if a sale or exchange of the property by the taxpayer could not produce capital gain or loss regardless of the taxpayer's holding period when the sale or exchange occurs. Thus, for example, property used in a trade or business within the meaning of section 1231(b) (determined without regard to the holding period specified in that section) is not ordinary property. An obligation is an ordinary obligation if performance or termination of the obligation by the taxpayer could not produce capital gain or loss. For purposes of the preceding sentence, termination has the same meaning as in section 1234A.

(6) *Borrowings.* Whether hedges of a taxpayer's debt issuances (borrowings) are hedging transactions is determined without regard to the use of the proceeds of the borrowing.

(7) *Hedging an aggregate risk.* The term hedging transaction includes a transaction that manages an aggregate risk of interest rate changes, price changes, and/or currency fluctuations only if all of the risk, or all but a de minimis amount of the risk, is with respect to ordinary property, ordinary obligations, or borrowings.

(8) *Hedges of other risks.* Except as otherwise determined in a regulation, revenue ruling, or revenue procedure, a hedging transaction does not include a transaction entered into to manage risks other than interest rate or price changes, or currency fluctuations.

(d) *Hedging by members of a consolidated group*—(1) *General rule: single-entity approach.* For purposes of this section, the risk of one member of a consolidated group is treated as the risk of the other members as if all of the members of the group were divisions of a single corporation. For example, if any member of a consolidated group hedges the risk of another member of the group by entering into a transaction with a third party, that transaction may potentially qualify as a hedging transaction. Conversely, intercompany transactions are not hedging transactions because, when considered as transactions between divisions of a single corporation, they do not manage the risk of that single corporation.

(2) *Separate-entity election.* In lieu of the single-entity approach specified in paragraph (d)(1) of this section, a consolidated group may elect separate-entity treatment of its hedging transactions. If a group makes this separate-entity election, the following rules apply.

(i) *Risk of one member not risk of other members.* Notwithstanding paragraph (d)(1) of this section, the risk of one member is not treated as the risk of other members.

(ii) *Intercompany transactions.* An intercompany transaction is a hedging transaction (an intercompany hedging transaction) with respect to a member of a consolidated group if and only if it meets the following requirements—

(A) The position of the member in the intercompany transaction would qualify as a hedging transaction with respect to the member (taking into account paragraph (d)(2)(i) of this section) if the member had entered into the transaction with an unrelated party; and

(B) The position of the other member (the marking member) in the transaction is marked to market under the marking member's method of accounting.

(iii) *Treatment of intercompany hedging transactions.* An intercompany hedging transaction (that is, a transaction that meets the requirements of paragraphs (d)(2)(ii)(A) and (B) of this section) is subject to the following rules—

(A) The character and timing rules of § 1.1502–13 do not apply to the income, deduction, gain, or loss from the intercompany hedging transaction; and

(B) Except as provided in paragraph (f)(3) of this section, the character of the marking member's gain or loss from the transaction is ordinary.

(iv) *Making and revoking the election.* Unless the Commissioner otherwise prescribes, the election described in this paragraph (d)(2) must be made in a separate statement saying "[Insert Name and Employer Identification Number of Common Parent] HEREBY ELECTS THE APPLICATION OF SECTION 1.1221–

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2(d)(2) (THE SEPARATE-ENTITY APPROACH)." The statement must also indicate the date as of which the election is to be effective. The election must be signed by the common parent and filed with the group's federal income tax return for the taxable year that includes the first date for which the election is to apply. The election applies to all transactions entered into on or after the date so indicated. The election may be revoked only with the consent of the Commissioner.

(3) *Definitions.* For definitions of consolidated group, divisions of a single corporation, group, intercompany transactions, and member, see section 1502 and the regulations thereunder.

(4) *Examples.* The following examples illustrate this paragraph (d):

General Facts. In these examples, *O* and *H* are members of the same consolidated group. *O*'s business operations give rise to interest rate risk "*A*," which *O* wishes to hedge. *O* enters into an intercompany transaction with *H* that transfers the risk to *H*. *O*'s position in the intercompany transaction is "*B*," and *H*'s position in the transaction is "*C*." *H* enters into position "*D*" with a third party to reduce the interest rate risk it has with respect to its position *C*. *D* would be a hedging transaction with respect to risk *A* if *O*'s risk *A* were *H*'s risk.

Example 1. Single-entity treatment—(i) *General rule.* Under paragraph (d)(1) of this section, *O*'s risk *A* is treated as *H*'s risk, and therefore *D* is a hedging transaction with respect to risk *A*. Thus, the character of *D* is determined under the rules of this section, and the income, deduction, gain, or loss from *D* must be accounted for under a method of accounting that satisfies § 1.446–4. The intercompany transaction *B–C* is not a hedging transaction and is taken into account under § 1.1502–13.

(ii) *Identification. D* must be identified as a hedging transaction under paragraph (e)(1) of this section, and *A* must be identified as the hedged item under paragraph (e)(2) of this section. Under paragraph (e)(5) of this section, the identification of *A* as the hedged item can be accomplished by identifying the positions in the intercompany transaction as hedges or hedged items, as appropriate. Thus, substantially contemporaneous with entering into *D*, *H* may identify *C* as the hedged item and *O* may identify *B* as a hedge and *A* as the hedged item.

Example 2. Separate-entity election; counterparty that does not mark to market. In addition to the *General Facts* stated above, assume that the group makes a separate-entity election under paragraph (d)(2) of this section. If *H* does not mark *C* to market under its method of accounting, then *B* is not a hedging transaction, and the *B–C* intercompany transaction is taken into account under the rules of section 1502. *D* is not a hedging transaction with respect to *A*, but *D* may be a hedging transaction with respect to *C* if *C* is ordinary property or an ordinary obligation and if the other requirements of paragraph (b) of this section are met. If *D* is not part of a hedging transaction, then *D* may be part of a straddle for purposes of section 1092.

Example 3. Separate-entity election; counterparty that marks to market. The facts are the same as in *Example 2* above, except that *H* marks *C* to market under its method of accounting. Also assume that *B* would be a hedging transaction with respect to risk *A* if *O* had entered into that transaction with an unrelated party. Thus, for *O*, the *B–C* transaction is an intercompany hedging transaction with respect to *O*'s risk *A*, the character and timing rules of § 1.1502–13 do not apply to the *B–C* transaction, and *H*'s income, deduction, gain, or loss from *C* is ordinary. However, other attributes of the items from the *B–C* transaction are determined under § 1.1502–13. *D* is a hedging transaction with respect to *C* if it meets the requirements of paragraph (b) of this section.

(e) *Identification and recordkeeping*—(1) *Same-day identification of hedging transactions.* Under section 1221(a)(7), a taxpayer that enters into a hedging transaction (including recycling an existing hedging transaction) must clearly identify it as a hedging transaction before the close of the day on which the taxpayer acquired, originated, or entered into the transaction (or recycled the existing hedging transaction).

(2) *Substantially contemporaneous identification of hedged item*—(i) *Content of the identification.* A taxpayer that enters into a hedging transaction must identify the item, items, or aggregate risk being hedged. Identification of an item being hedged generally involves identifying a transaction that creates risk, and the type of risk that the transaction creates. For example, if a taxpayer is hedging the price risk with respect to its June purchases of corn inventory, the transaction being hedged is the June purchase of corn and the risk is price movements in the market where the taxpayer buys its corn. For additional rules concerning the content of this identification, see paragraph (e)(3) of this section.

(ii) *Timing of the identification.* The identification required by this paragraph (e)(2) must be made substantially contemporaneously with entering into the hedging transaction. An identification is not substantially contemporaneous if it is made more than 35 days after entering into the hedging transaction.

(3) *Identification requirements for certain hedging transactions.* In the case of the hedging transactions described in this paragraph (e)(3), the identification under paragraph (e)(2) of this section must include the information specified.

(i) *Anticipatory asset hedges.* If the hedging transaction relates to the anticipated acquisition of assets by the taxpayer, the identification must include the expected date or dates of acquisition and the amounts expected to be acquired.

(ii) *Inventory hedges.* If the hedging transaction relates to the purchase or sale of inventory by the taxpayer, the identification is made by specifying the type or class of inventory to which the transaction relates. If the hedging transaction relates to specific purchases or sales, the identification must also include the expected dates of the purchases or sales and the amounts to be purchased or sold.

(iii) *Hedges of debt of the taxpayer*—(A) *Existing debt.* If the hedging transaction relates to accruals or payments under an issue of existing debt of the taxpayer, the identification must specify the issue and, if the hedge is for less than the full issue price or the full term of the debt, the amount of the issue price and the term covered by the hedge.

(B) *Debt to be issued.* If the hedging transaction relates to the expected issuance of debt by the taxpayer or to accruals or payments under debt that is expected to be issued by the taxpayer, the identification must specify the following information: the expected date of issuance of the debt; the expected maturity or maturities; the total expected issue price; and the expected interest provisions. If the hedge is for less than the entire expected issue price of the debt or the full expected term of the debt, the identification must also include the amount or the term being hedged. The identification may indicate a range of dates, terms, and amounts, rather than specific dates, terms, or amounts. For example, a taxpayer might identify a transaction as hedging the yield on an anticipated issuance of fixed rate debt during the second half of its fiscal year, with the anticipated amount of the debt between $75 million and $125 million, and an anticipated term of approximately 20 to 30 years.

(iv) *Hedges of aggregate risk*—(A) *Required identification.* If a transaction hedges aggregate risk as described in paragraph (c)(7) of this section, the identification under paragraph (e)(2) of this section must include a description of the risk being hedged and of the hedging program under which the hedging transaction was entered. This requirement may be met by placing in the taxpayer's records a description of the hedging program and by establishing a system under which individual transactions can be identified as being entered into pursuant to the program.

(B) *Description of hedging program.* A description of a hedging program must include an identification of the type of risk being hedged, a description of the type of items giving rise to the risk being aggregated, and sufficient additional information to demonstrate that the program is designed to reduce aggregate risk of the type identified. If the program contains controls on speculation (for example, position limits), the description of the hedging program must also explain how the controls are established, communicated, and implemented.

(4) *Manner of identification and records to be retained*—(i) *Inclusion of identification in tax records.* The identification required by this paragraph (e) must be made on, and retained as part of, the taxpayer's books and records.

(ii) *Presence of identification must be unambiguous.* The presence of an identification for purposes of this paragraph (e) must be unambiguous. The identification of a hedging transaction for financial accounting or regulatory purposes does not satisfy this requirement unless the taxpayer's books and records indicate that the identification is also being made for tax purposes. The taxpayer may indicate that individual hedging transactions, or a class or classes of hedging transactions, that are identified for financial accounting or regulatory purposes are also being identified as hedging transactions for purposes of this section.

(iii) *Manner of identification.* The taxpayer may separately and explicitly make each identification, or, so long as paragraph (e)(4)(ii) of this section is satisfied, the taxpayer may establish a system pursuant to which the identification is indicated by the type of transaction or by the manner in which the transaction is consummated or recorded. An identification under this system is made at the later of the time that the system is established or the time that the transaction satisfies the terms of the system by being entered, or by being consummated or recorded, in the designated fashion.

(iv) *Examples.* The following examples illustrate the principles of paragraph (e)(4)(iii) of this section and assume that the other requirements of paragraph (e) are satisfied.

(A) A taxpayer can make an identification by designating a hedging transaction for (or placing it in) an account that has been identified as containing only hedges of a specified item (or of specified items or specified aggregate risk).

(B) A taxpayer can make an identification by including and retaining in its books and records a statement that designates all future transactions in a specified derivative product as hedges of a specified item, items, or aggregate risk.

(C) A taxpayer can make an identification by designating a certain mark, a certain form, or a certain legend as meaning that a transaction is a hedge of a specified item (or of specified items or a specified aggregate risk). Identification can be made by placing the designated mark on a record of the transaction (for example, trading ticket, purchase order, or trade confirmation) or by using the designated form or a record that contains the designated legend.

(5) *Identification of hedges involving members of the same consolidated group*—(i) *General rule: single-entity approach.* A member of a consolidated group must satisfy the requirements of this paragraph (e) as if all of the members of the group were divisions of a single corporation. Thus, the member entering into the hedging transaction with a third party must identify the hedging transaction under paragraph (e)(1) of this section. Under paragraph (e)(2) of this section, that member must also identify the item, items, or aggregate risk that is being hedged, even if the item, items, or aggregate risk relates primarily or entirely to other members of the group. If the members of a group use intercompany transactions to transfer risk within the group, the requirements of paragraph (e)(2) of this section may be met by identifying the intercompany transactions, and the risks hedged by the intercompany transactions, as hedges or hedged items, as appropriate. Because identification of the intercompany transaction as a hedge serves solely to identify the hedged item, the identification is timely if made within the period required by paragraph (e)(2) of this section. For example, if a member transfers risk in an intercompany transaction, it may identify under the rules of this paragraph (e) both its position in that transaction and the item, items, or aggregate risk being hedged. The member that hedges the risk outside the group may identify under the rules of this paragraph (e) both its position with the third party and its position in the intercompany transaction. Paragraph (d)(4) *Example 1* of this section illustrates this identification.

(ii) *Rule for consolidated groups making the separate-entity election.* If a consolidated group makes the separate-entity election under paragraph (d)(2) of this section, each member of the group must satisfy the requirements of this paragraph (e) as though it were not a member of a consolidated group.

(6) *Consistency with section 1256(e)(2).* Any identification for purposes of section 1256(e)(2) is also an identification for purposes of paragraph (e)(1) of this section.

(f) *Effect of identification and non-identification*—(1) *Transactions identified*—(i) *In general.* If a taxpayer identifies a transaction as a hedging transaction for purposes of paragraph (e)(1) of this section, the identification is binding with respect to gain, whether or not all of the requirements of paragraph (e) are satisfied. Thus, gain from that transaction is ordinary income. If the transaction is not in fact a hedging transaction described in paragraph (b) of this section, however, paragraphs (a)(1) and (2) of this section do not apply and the character of loss is determined without reference to whether the transaction is a surrogate for a noncapital asset, serves as insurance against a business risk, serves a hedging function, or serves a similar function or purpose. Thus, the taxpayer's identification of the transaction as a hedging transaction does not itself make loss from the transaction ordinary.

(ii) *Inadvertent identification.* Notwithstanding paragraph (f)(1)(i) of this section, if the taxpayer identifies a transaction as a hedging transaction for purposes of paragraph (e) of this section, the character of the gain is determined as if the transaction had not been identified as a hedging transaction if—

(A) The transaction is not a hedging transaction (as defined in paragraph (b) of this section);

(B) The identification of the transaction as a hedging transaction was due to inadvertent error; and

(C) All of the taxpayer's transactions in all open years are being treated on either original or, if necessary, amended returns in a manner consistent with the principles of this section.

(2) *Transactions not identified*—(i) *In general.* Except as provided in paragraphs (f)(2)(ii) and (iii) of this section, the absence of an identification that satisfies the requirements of paragraph (e)(1) of this section is binding and establishes that a transaction is not a hedging transaction. Thus, subject to the exceptions, the rules of paragraphs (a)(1) and (2) of this section do not apply, and the character of gain or loss is determined without reference to whether the transaction is a surrogate for a noncapital asset, serves as insurance against a business risk, serves a hedging function, or serves a similar function or purpose.

(ii) *Inadvertent error.* If a taxpayer does not make an identification that satisfies the requirements of paragraph (e) of this section, the taxpayer may treat gain or loss from the transaction as ordinary income or loss under paragraph (a)(1) or (2) of this section if—

(A) The transaction is a hedging transaction (as defined in paragraph (b) of this section);

(B) The failure to identify the transaction was due to inadvertent error; and

(C) All of the taxpayer's hedging transactions in all open years are being treated on either original or, if necessary, amended returns as provided in paragraphs (a)(1) and (2) of this section.

(iii) *Anti-abuse rule.* If a taxpayer does not make an identification that satisfies all the requirements of paragraph (e) of this section but the taxpayer has no reasonable grounds for treating the transaction as other than a hedging transaction, then gain from the transaction is ordinary. The reasonableness of the taxpayer's failure to identify a transaction is determined by taking into consideration not only the requirements of paragraph (b) of this section but also the taxpayer's treatment of the transaction for financial accounting or other purposes and the taxpayer's identification of similar transactions as hedging transactions.

(3) *Transactions by members of a consolidated group*—(i) *Single-entity approach.* If a consolidated group is under the general rule of paragraph (d)(1) of this section (the single-entity approach), the rules of this paragraph (f) apply only to transactions that are not intercompany transactions.

(ii) *Separate-entity election.* If a consolidated group has made the election under paragraph (d)(2) of this section, then, in addition to the rules of paragraphs (f)(1) and (2) of this section, the following rules apply:

(A) If an intercompany transaction is identified as a hedging transaction but does not meet the requirements of paragraphs (d)(2)(ii)(A) and (B) of this section, then, notwithstanding any contrary provision in § 1.1502–13, each party to the transaction is subject to the rules of paragraph (f)(1) of this section with respect to the transaction as though it had incorrectly identified its position in the transaction as a hedging transaction.

(B) If a transaction meets the requirements of paragraphs (d)(2)(ii) (A) and (B) of this section but the transaction is not identified as a hedging transaction, each party to the transaction is subject to the rules of paragraph (f)(2) of this section. (Because the transaction is an intercompany hedging transaction, the character and timing rules of § 1.1502–13 do not apply. See paragraph (d)(2)(iii)(A) of this section.)

(g) *Effective date.* The rules of this section apply to transactions entered into on or after January 18, 2001.

Par. 2. Section 1.1256(e)–1 is revised to read as follows:

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§ 1.1256(e)–1 Identification of hedging transactions.

(a) *Identification and recordkeeping requirements.* Under section 1256(e)(2), a taxpayer that enters into a hedging transaction must identify the transaction as a hedging transaction before the close of the day on which the taxpayer enters into the transaction.

(b) *Requirements for identification.* The identification of a hedging transaction for purposes of section 1256(e)(2) must satisfy the requirements of § 1.1221–2(e)(1). Solely for purposes of section 1256(f)(1), however, an identification that does not satisfy all of the requirements of § 1.1221–2(e)(1) is nevertheless treated as an identification under section 1256(e)(2).

(c) *Consistency with § 1.1221–2.* Any identification for purposes of § 1.1221–2(e)(1) is also an identification for purposes of this section. If a taxpayer satisfies the requirements of § 1.1221–2(f)(1)(ii), the transaction is treated as if it were not identified as a hedging transaction for purposes of section 1256(e)(2).

(d) *Effective date.* This section applies to transactions entered into on or after January 18, 2001.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

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DEPARTMENT OF TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–105801–00]

RIN 1545–AX92

Capitalization of Interest and Carrying Charges Properly Allocable to Straddles

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that clarify the application of the straddle rules to a variety of financial instruments. The proposed regulations clarify what constitutes interest and carrying charges and when interest and carrying charges are properly allocable to personal property that is part of a straddle. The proposed regulations also clarify that a taxpayer's obligation under a debt instrument can be a position in personal property that is part of a straddle. The proposed regulations provide guidance to taxpayers that enter into straddle transactions. This document provides notice of a public hearing on these proposed regulations.

DATES: Written and electronic comments and requests to appear and outlines of topics to be discussed at the public hearing scheduled for May 22, 2001, at 10 a.m., must be submitted by May 1, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–105801–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–105801–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC.

Alternatively, taxpayers may submit comments electronically via the Internet by submitting comments directly to the IRS Internet site at http://www.irs.gov/tax_regs/regslist.html. The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Kenneth Christman (202) 622–3950; concerning submission and delivery of comments and the public hearing, Treena Garrett, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Sections 501 and 502 of the Economic Recovery Tax Act of 1981 (Pub. L. 97–34, 95 Stat. 172) added sections 1092 and 263(g), respectively, to the Internal Revenue Code to address certain deferral and conversion strategies involving economically offsetting positions in actively traded personal property. These economically offsetting positions are called straddles. Section 1092(c)(1).

In general, under section 1092, a taxpayer that realizes a loss on a position in actively traded personal property must defer the recognition of the loss to the extent the taxpayer has unrecognized gain on an economically offsetting position in the property. This deferral rule matches the recognition of loss with the recognition of the economically offsetting income. Section 263(g) addresses interest and carrying charges properly allocable to personal property that is part of a straddle. Under this section, these otherwise deductible expenses are not currently deductible. Instead, they must be capitalized into the basis of the property. By requiring capitalization, section 263(g) prevents: (1) A taxpayer from gaining a timing advantage by accruing deductions associated with carrying the straddle transaction before recognizing income from a position in personal property that is part of the straddle; and (2) the deductions from having a character different from that of the income.

These proposed regulations provide certain rules with respect to the application of section 263(g) and section 1092.

Explanation of Provisions

The proposed regulations consist of § 1.263(g)–1, which provides a general introduction, and §§ 1.263(g)–2, 1.263(g)–3, 1.263(g)–4, and 1.263(g)–5, described below. The proposed regulations also include a new paragraph 1.1092(d)–1(d).

The proposed regulations generally address four issues: (1) The definition of *personal property* as such term is used in section 263(g) (in § 1.263(g)–2); (2) the type of payments that are subject to the capitalization rules of section 263(g) (in § 1.263(g)–3); (3) the operation of the capitalization rules of section 263(g) (in § 1.263(g)–4); and (4) the circumstances under which an issuer's obligation under a debt instrument can be a position in actively traded personal property and, therefore, part of a straddle (in § 1.1092(d)–1(d)). These issues are discussed in more detail below.

Definition of the Term Personal Property for Purposes of Section 263(g)

Section 263(g)(1) requires capitalization of interest and carrying charges properly allocable to personal property that is part of a straddle (as defined in section 1092(c)). Section 1092(d)(1) defines personal property for purposes of section 1092, as personal property of a type that is actively traded. Commentators have suggested that because sections 263(g) and 1092 were enacted at the same time, the term *personal property* as used in section 263(g) should be given the same definition under section 1092(d)(1). This would limit the definition of personal property in section 263(g) to personal property of a type that is actively traded.

Despite this suggestion, the proposed regulations provide that personal property has its common law meaning in section 263(g) for two reasons. First, the definition in section 1092(d)(1) by its terms applies only for purposes of section 1092. Second, the broader, common law interpretation of personal property more closely accords with the purposes of section 263(g). Application of the limited definition in section 1092(d)(1) for purposes of section 263(g) could result in dissimilar tax treatment of economically similar transactions. For example, adoption of the narrower definition would cause section 263(g) to apply to a transaction in which a taxpayer borrows to purchase actively traded personal property that is a part of a straddle but not to a similar transaction in which the taxpayer borrows to purchase a derivative instrument that is not itself actively traded but is a position in actively traded property.

Consequently, proposed § 1.263(g)–2 defines personal property as a property right, whether or not actively traded, other than a right in real property. This definition includes both financial positions that provide substantial rights but do not impose substantial obligations on the holder (e.g., common stock or a purchased option) and executory contracts that impose both rights and obligations on the holder (e.g., notional principal contracts (NPC's) and forward transactions). However, the definition excludes straddles comprised only of financial positions that impose only obligations on the holder (e.g., the obligor's position in a debt instrument or a writer's position in an option).

Payments That Are Subject to the Capitalization Rules of Section 263(g)

Section 263(g)(1) provides for the capitalization of interest and carrying charges. For this purpose, *interest and carrying charges* are collectively defined in section 263(g)(2) as "interest incurred or continued to purchase or carry the personal property" and "all other amounts (including charges to insure, store, or transport) paid or incurred to carry the personal property," less certain types of income from the personal property.

The phrase "incurred or continued to purchase or carry" also appears in section 265(a)(2), which disallows interest expense on indebtedness incurred or continued to purchase or carry tax-exempt debt. Rev. Proc. 72–18 (1972–1 C.B. 740) sets out rules for determining when this standard is met for purposes of section 265(a)(2). Under that revenue procedure, indebtedness issued by a taxpayer that is not a dealer in tax-exempt obligations meets this standard if: (1) The proceeds of the indebtedness are directly traceable to the purchase of the tax-exempt obligations, (2) the tax-exempt obligations are used as collateral for the borrowing, or (3) the totality of the facts and circumstances supports a reasonable inference that the purpose of the borrowing was to purchase or carry tax-exempt obligations. In general, the facts-and-circumstances test is met if there is a "sufficiently direct relationship" between the borrowing and the investment in the tax-exempt obligations. Similarly, the proposed regulations provide that a sufficiently direct relationship between indebtedness or other financing and personal property that is part of a straddle exists if payments on the indebtedness or other financing are determined by reference to the value or change in value of the personal property. See § 1.263(g)–3(c).

Section 263(g) also applies to "all other amounts (including charges to insure, store or transport the personal property)" paid or incurred to carry personal property that is part of a straddle. As noted by one commentator, "taxpayers should not be permitted to deduct items incurred in connection with protecting or preserving the value of assets" that are part of a straddle. Therefore, the term, *to carry* in the context of section 263(g) includes the reduction of the risk of holding an asset. Because straddles necessarily involve positions that offset each other, the positions "carry" each other.

Accordingly, under § 1.263(g)–3(b) of the proposed regulations, interest and carrying charges subject to capitalization under section 263(g) include: (1) Otherwise deductible payments or accruals (including interest and original issue discount) on indebtedness or other financing issued or continued to purchase or carry personal property that is part of a straddle; (2) otherwise deductible fees or expenses paid or incurred in connection with the taxpayer's acquiring or holding personal property that is part of a straddle, including, but not limited to, fees or expenses incurred to purchase, insure, store, maintain, or transport the personal property; and (3) other otherwise deductible payments or accruals on financial instruments that are part of a straddle or that carry part of a straddle.

Section 263(g) requires capitalization of interest and carrying charges that exceed certain specified income inclusions (allowable offsets) listed in section 263(g)(2)(B). Section 1.263(g)–3(e) sets forth the allowable offsets, including amounts that are receipts or accruals on financial instruments that are part of a straddle or carry part of a straddle. The Treasury Department and the IRS solicit comments regarding whether other amounts should be treated as allowable offsets for purposes of section 263(g).

Operation of the Capitalization Rules of Section 263(g)

Generally, section 263(g) coordinates the character and timing of items of income and loss attributable to a taxpayer's position in a straddle by allocating interest and carrying charges to the capital account of a position in personal property that is part of the straddle. Proposed regulation § 1.263(g)–4 provides a set of allocation rules governing the "capitalization" of interest and carrying charges.

In many cases, certain allocation rules readily suggest themselves.

Congress was aware of "cash and carry" transactions in adopting section 263(g). See H.R. Rep. No. 201, 97th Cong. 1st Sess. 203–04 (1981). In a typical transaction, a taxpayer borrows to purchase personal property and sells the property forward. The debt instrument generates ordinary deductions (interest expense) that precede predictable (and approximately equal) capital gains on the sale of the personal property. Coordination of the amount and timing of income and loss in a cash and carry transaction is achieved under the proposed regulation by allocating the interest expense to the capital account of the personal property. This rule applies to all transactions in which a taxpayer has borrowed to purchase personal property that is part of a straddle.

If the proceeds of a borrowing are not used to purchase personal property, a second allocation rule allocates interest expense to personal property when the personal property collateralizes the borrowing. See Rev. Proc. 72–18, § 3.03 (disallowing interest deduction for debt secured by tax-exempt obligations); Rev. Rul. 78–348 (1978–2 C.B. 95) (applying yield restrictions to investments pledged by person benefitting from tax-exempt bond financing).

A third allocation rule of the proposed regulations allocates interest on indebtedness to personal property when payments on the indebtedness are determined by reference to the value, or change in value, of the personal property that is part of a straddle.

Fees and charges related to the maintenance of the personal property, such as charges to insure, store, or transport the personal property, are allocated to the capital account of that personal property. See S. Rep. No. 144, 97th Cong. 1st Sess. 154 (1981).

In other cases, the appropriate method for allocating capitalized interest and carrying charges is less obvious. This may be true of payments or accruals on a financial instrument, such as a NPC, described in proposed § 1.263(g)–3(d).

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For example, the proposed rules would apply to a taxpayer that holds stock and enters into an equity swap that is a short position with respect to the stock. In such a case, both the stock and the equity swap may be personal property that is part of a straddle, and payments on the equity swap could be capitalized with respect to the capital account of either the stock or the equity swap. However, it may not be clear how a capitalization rule would apply in conjunction with the rules under § 1.446–3 with respect to payments on NPCs. Accordingly, the proposed rules provide that, in cases to which a specific allocation rule is not applicable, interest and carrying charges will be allocated to personal property that is part of a straddle in the manner that is most appropriate under all the facts and circumstances. Proposed regulations § 1.263(g)–4(c) *Example 7* (relating to a straddle consisting of stock and an equity swap) illustrate one application of this facts and circumstances rule. The Treasury Department and the IRS invite comments and suggestions regarding both the proposed specific allocation rules and the general facts and circumstances allocation rule.

The regulations under section 263(g) are proposed to be effective for expenses paid, incurred, or accrued after the date the regulations are adopted as final for straddles established on or after January 17, 2001. See § 1.263(g)–5.

Obligation Under a Debt Instrument as a Position in Personal Property

If a taxpayer is the obligor under a debt instrument that provides for one or more payments linked to the value of actively traded personal property, the value of the taxpayer's obligation under the debt instrument changes as the value of the referenced property changes. For this reason, the taxpayer's position as obligor under the debt instrument functions as a position in the referenced property.

Some commentators have suggested that a debt instrument (other than one denominated in an actively traded foreign currency) cannot be a position of the obligor in personal property that is part of a straddle. Section 1092(d)(7) provides that an obligor's interest in a nonfunctional-currency-denominated debt instrument is treated under section 1092(d)(2) as a position in the nonfunctional currency. From this, the commentators infer that an obligor's interest in a debt instrument may never be treated as an interest in personal property other than a nonfunctional currency.

However, neither the legislative history nor the express language of section 1092(d)(7) indicates that Congress intended to exclude interests in personal property from the definition of *position* in section 1092(d)(2). A rule that a debt instrument can be a position in currency does not establish that a debt instrument is a position only in currency. This interpretation of section 1092(d)(7) has already been rejected by the IRS and Treasury in § 1.1275–4(b)(9)(vi), which provides that increased interest expense on a contingent payment debt instrument issued by a taxpayer may be a straddle loss subject to section 1092 deferral.

To clarify the definition of *position* under section 1092(d)(2), § 1.1092(d)–1(d) of the proposed regulations explicitly provides that an obligation under a debt instrument may be a position in personal property that is part of a straddle. This provision is proposed to be effective for straddles established on or after January 17, 2001. However, no inference is intended with respect to straddles established prior to Janaury 17, 2001. Thus, in appropriate cases, the IRS may take the position under section 1092(d)(2) that, even in the absence of a regulation, an obligation under a debt instrument was part of a straddle prior to the effective date of § 1.1092(d)–1(d) if the debt instrument functioned economically as an interest in actively traded personal property.

In 1995, the IRS published proposed regulation § 1.1092(d)–(2). See 60 F.R. 21482; FI–21–95, 1995–1 C.B. 935. The proposed regulations clarify the circumstances in which common stock may be personal property for the purposes of section 1092. Because proposed regulation §§ 1.1092(d)–2 and 1.1092(d)–1(d) address similar issues, the IRS proposes to finalize both regulations simultaneously. The Treasury Department and the IRS, therefore, invite additional comment on proposed § 1.1092(d)–(2).

In addition, in 1985, the Treasury Department and the IRS adopted Temporary Regulation § 1.1092(d)–5T(d), which defines the term *loss* for purposes of §§ 1.1092(b)–1T through 1.1092(b)–4T as a loss otherwise allowable under section 165(a). The Treasury Department and the IRS request comments on whether that definition should be expanded to include expenses such as interest and carrying charges or payments on notional principal contracts. If so, how should such a change be coordinated with the proposed regulations in this document?

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written or electronic comments (a signed original and eight (8) copies, if written) that are submitted timely (in the manner described in the **ADDRESSES** portion of this preamble) to the IRS. The IRS and Treasury request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 22, 2001, at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington DC. Due to building security procedures, visitors must enter at the 10th Street entrance located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identifications to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by May 1, 2001. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Kenneth Christman, Office of Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.263(g)–1 also issued under 26 U.S.C. 1092(b)(1).

Section 1.263(g)–2 also issued under 26 U.S.C. 1092(b)(1).

Section 1.263(g)–3 also issued under 26 U.S.C. 1092(b)(1).

Section 1.263(g)–4 also issued under 26 U.S.C. 1092(b)(1).

Section 1.263(g)–5 also issued under 26 U.S.C. 1092(b)(1). * * *

Section 1.1092(d)–1 also issued under 26 U.S.C. 1092(b)(1).

Par. 2. Sections 1.263(g)–1, 1.263(g)–2, 1.263(g)–3, 1.263(g)–4, and 1.263(g)–5 are added to read as follows:

§ 1.263(g)–1 Treatment of interest and carrying charges in the case of straddles; in general.

(a) Under section 263(g), no deduction is allowed for interest and carrying charges allocable to personal property that is part of a straddle (as defined in section 1092(c)). The purpose of section 263(g) is to coordinate the character and the timing of items of income and loss attributable to a taxpayer's positions that are part of a straddle. In order to prevent payments or accruals related to a straddle transaction from giving rise to recognition of deductions or losses before related income is recognized and to prevent the items of loss and income from having different character, no deduction is allowed for interest and carrying charges properly allocable to personal property that is part of a straddle. Rather, such amounts are chargeable to the capital account of the personal property to which the interest and carrying charges are properly allocable.

(b) Section 263(g) does not apply if none of the taxpayer's positions that are part of the straddle are personal property. Section 263(g) also does not apply to hedging transactions as defined in section 1256(e) (see section 263(g)(3)) or to securities to which the mark-to-market accounting method provided by section 475 applies (see section 475(d)(1)).

(c) Section 1.263(g)–2 provides a definition of personal property for purposes of section 263(g) and §§ 1.263(g)–1 through 1.263(g)–5. Section 1.263(g)–3 provides a definition of interest and carrying charges for purposes of section 263(g), section 1092, §§ 1.263(g)–1 through 1.263(g)–5, and § 1.1092(b)–4T. Section 1.263(g)–4 provides a set of allocation rules governing the capitalization of amounts to which section 263(g) applies.

§ 1.263(g)–2 Personal property to which interest and carrying charges may properly be allocable.

(a) *Definition of personal property.* For purposes of section 263(g) and of §§ 1.263(g)–1 through 1.263(g)–5, *personal property* means property, whether or not actively traded, that is not real property. For purposes of the preceding sentence, a position in personal property may itself be property. In general, however, a position in personal property is not property of a taxpayer unless the position confers or may confer substantial rights on the taxpayer.

(1) *Application to certain financial instruments.* Personal property includes a stockholder's ownership of common stock, a holder's ownership of a debt instrument, and either party's position in a forward contract or in a conventional swap agreement. Personal property does not include a position that imposes obligations but does not confer substantial rights on the taxpayer. Therefore, the obligor's position in a debt instrument generally is not personal property, even though the obligor may have typical rights of a debtor, such as the right to prepay the debt. However, the obligor on a debt instrument has a position in any personal property underlying the debt instrument. See § 1.1092(d)–1(d).

(2) *Options.* For the purposes of applying this section, a put option or call option imposes obligations but does not confer substantial rights on the grantor, whether or not the option is cash-settled.

(b) Example. The following example illustrates the rules stated in paragraph (a) of this section:

Example. (i) *Facts. A* purchases 100 ounces of gold at a cost of $x. *A* transfers the 100 ounces of gold to a trust that issues multiple classes of trust certificates and is treated as a partnership for tax purposes. In return, *A* receives two trust certificates that are not personal property of a type that is actively traded within the meaning of section 1092(d)(1). One certificate entitles *A* to a payment on termination of the trust at the end of four years equal to the value of the 100 ounces of gold up to a maximum value of $(*x* + *y*). The other certificate entitles *A* to a payment equal to the amount by which the value of 100 ounces of gold exceeds $(*x* + *y*) on termination of the trust. *A* sells the second certificate and keeps the first certificate.

(ii) *Analysis.* The trust certificate retained by *A* is property that is not real property. In addition, ownership of the trust certificate confers certain substantial rights on *A*. Therefore, although the trust certificate is not personal property of a type that is actively traded, *A*'s interest in the trust certificate is personal property for purposes of section 263(g).

§ 1.263(g)–3 Interest and carrying charges properly allocable to personal property that is part of a straddle.

(a) *In general.* For purposes of section 263(g), section 1092, §§ 1.263(g)–1 through 1.263(g)–5, and § 1.1092(b)–4T, *interest and carrying charges properly allocable to personal property that is part of a straddle* means the excess of interest and carrying charges (as defined in paragraph (b) of this section) over the allowable income offsets (as defined in paragraph (e) of this section).

(b) *Interest and carrying charges.* Interest and carrying charges are otherwise deductible amounts paid or accrued with respect to indebtedness or other financing incurred or continued to purchase or carry personal property that is part of a straddle and otherwise deductible amounts paid or incurred to carry personal property that is part of a straddle. As provided in section 263(g)(2), interest includes any amount paid or incurred in connection with personal property used in a short sale. Interest and carrying charges include—

(1) Otherwise deductible payments or accruals (including interest and original issue discount) on indebtedness or other financing issued or continued to purchase or carry personal property that is part of a straddle;

(2) Otherwise deductible fees or expenses paid or incurred in connection with acquiring or holding personal property that is part of a straddle including, but not limited to, fees or expenses incurred to purchase, insure, store, maintain or transport the personal property; and

(3) Other otherwise deductible payments or accruals on financial instruments that are part of a straddle or that carry part of a straddle.

(c) *Indebtedness or other financing incurred or continued to purchase or carry personal property that is part of a*

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straddle. For purposes of paragraph (b)(1) of this section, indebtedness or other financing that is incurred or continued to purchase or carry personal property that is part of a straddle includes—

(1) Indebtedness or other financing the proceeds of which are used directly or indirectly to purchase or carry personal property that is part of the straddle;

(2) Indebtedness or other financing that is secured directly or indirectly by personal property that is part of the straddle; and

(3) Indebtedness or other financing the payments on which are determined by reference to payments with respect to the personal property or the value of, or change in value of, the personal property.

(d) *Financial instruments that are part of a straddle or that carry part of a straddle.* For purposes of paragraph (b)(3), financial instruments that are part of a straddle or that carry part of a straddle include—

(1) A financial instrument that is part of the straddle;

(2) A financial instrument that is issued in connection with the creation or acquisition of a position in personal property if that position is part of the straddle;

(3) A financial instrument that is sold or marketed as part of an arrangement that involves a taxpayer's position in personal property that is part of the straddle and that is purported to result in either economic realization of all or part of the appreciation in an asset without simultaneous recognition of taxable income or a current tax deduction (for interest, carrying charges, payments on a notional principal contract, or otherwise) reflecting a payment or expense that is economically offset by an increase in value that is not concurrently recognized for tax purposes or has a different tax character (for example, an interest payment that is economically offset by an increase in value that may result in a capital gain in a later tax period); and

(4) Any other financial instrument if the totality of the facts and circumstances support a reasonable inference that the issuance, purchase, or continuation of the financial instrument by the taxpayer was intended to purchase or carry personal property that is part of the straddle.

(e) *Allowable income offsets.* The allowable income offsets are:

(1) The amount of interest (including original issue discount) includible in gross income for the taxable year with respect to such personal property;

(2) Any amount treated as ordinary income under section 1271(a)(3)(A), 1278, or 1281(a) with respect to such personal property for the taxable year;

(3) The excess of any dividends includible in gross income with respect to such property for the taxable year over the amount of any deductions allowable with respect to such dividends under section 243, 244, or 245;

(4) Any amount that is a payment with respect to a security loan (within the meaning of section 512(a)(5)) includible in income with respect to the personal property for the taxable year; and

(5) Any amount that is a receipt or accrual includible in income for the taxable year with respect to a financial instrument described in § 1.263(g)–3(d) to the extent the financial instrument is entered into to purchase or carry the personal property.

§ 1.263(g)–4 Rules for allocating amounts to personal property that is part of a straddle.

(a) *Allocation rules.* (1) Interest and carrying charges paid or accrued on indebtedness or other financing issued or continued to purchase or carry personal property that is part of a straddle are allocated, in the order listed—

(i) To personal property that is part of the straddle purchased, directly or indirectly, with the proceeds of the indebtedness or other financing;

(ii) To personal property that is part of the straddle and directly or indirectly secures the indebtedness or other financing; or

(iii) If all or a portion of such interest and carrying charges are determined by reference to the value or change in value of personal property, to such personal property.

(2) Fees and expenses described in § 1.263(g)–3(b)(2) are allocated to the personal property, the acquisition or holding of which resulted in the fees and expenses being paid or incurred.

(3) In all other cases, interest and carrying charges are allocated to personal property that is part of a straddle in the manner that under all the facts and circumstances is most appropriate.

(b) *Coordination with other provisions.* In the case of a short sale, section 263(g) applies after section 263(h). See sections 263(g)(4)(A) and (h)(6). In case of an obligation to which section 1277 (dealing with deferral of interest deduction allocable to accrued market discount) or 1282 (dealing with deferral of interest deduction allocable to certain accruals on short-term indebtedness) applies, section 263(g) applies after section 1277 and section 1282. See section 263(g)(4)(B). Capitalization under section 263(g) applies before loss deferral under section 1092.

(c) *Examples.* The following examples illustrate the rules stated in §§ 1.263(g)–2, 1.263(g)–3, and 1.263(g)–4.

Example 1. Cash and Carry Silver.

(i) *Facts.* On January 1, 2002, *A* borrows $*x* at 6% interest and uses the proceeds to purchase *y* ounces of silver from *B*. At approximately the same time, *A* enters into a forward contract with *C* to deliver *y* ounces of silver to *C* in one year.

(ii) *Analysis.* The *y* ounces of silver and the forward contract to deliver *y* ounces of silver in one year are offsetting positions with respect to the same personal property and therefore constitute a straddle. See sections 1092(c)(1), (c)(3)(A)(i). The proceeds of the debt instrument were used to purchase personal property that is part of the straddle. Consequently, *A*'s interest payments are interest and carrying charges properly allocable to personal property that is part of a straddle. See § 1.263(g)–3(b)(1) & (c)(1). Under § 1.263(g)–4(a)(1)(i), the interest payments must be charged to the capital account for the *y* ounces of silver purchased by *A* with the proceeds of the borrowing.

Example 2. Additional indebtedness issued to carry personal property.

(i) *Facts.* The facts are the same as for Example 1 except that during the year 2002, the market price of silver increases and *A* is required to post variation margin as security for its obligation to deliver *y* ounces of silver to *C*. *A* incurs additional indebtedness to obtain funds necessary to meet *A*'s variation margin requirement.

(ii) *Analysis.* The additional indebtedness is incurred to continue to carry *A*'s holding of *z* ounces of silver. Consequently, *A*'s interest payments on the additional indebtedness are interest and carrying charges properly allocable to personal property that is part of a straddle and must be charged to the capital account for the *y* ounces of silver.

Example 3. Contingent payment debt instrument.

(i) *Facts.* On January 1, 2002, *D* enters into a contract to deliver *x* barrels of fuel oil to *E* on July 1, 2004, at an aggregate price equal to $*y*. Soon afterward, *D* issues a contingent payment debt instrument to *F* with a principal amount of $*z* and a 2-year term that pays interest quarterly at a rate determined at the beginning of each quarter equal to the greater of zero and the London Interbank Offered Rate (LIBOR) adjusted by an index that varies inversely with changes in the price of fuel oil (so that the interest rate increases as the price of fuel oil decreases and vice versa). The change in the aggregate amount of interest paid on the $*z* of debt due to the functioning of the index approximates the concurrent aggregate change in value of *x* barrels of fuel oil and, thus, the value of *D*'s interest in the forward contract.

(ii) *Analysis.* The debt instrument and the forward contract are offsetting positions with respect to the same personal property and constitute a straddle. See section 1092(c)(1), (c)(3)(A)(i). When issued, the debt instrument is a position in personal property that is part of a straddle. See § 1.1092(d)–1(d). Consequently, *D*'s interest payments are interest and carrying charges properly allocable to personal property that is part of a straddle and must be allocated to the capital account for the forward contract for the delivery of *x* barrels of fuel oil to *E*. See §§ 1.263(g)–3(b)(1), (b)(3), (c)(3), and (d)(1) and -4(a)(1)(iii).

Example 4. Financial instrument issued to carry personal property that is part of a straddle. (i) *Facts.* The facts are the same as for Example 3 except that *D* also enters into a two-year interest rate swap under which *D* receives LIBOR times a notional principal amount equal to $*z* and pays 7% times $*z*.

(ii) *Analysis.* Because of the relationship between the two-year debt instrument issued by *D* and the interest rate swap, the interest rate swap is a financial instrument that carries personal property that is part of a straddle. See § 1.263(g)–3(d)(4). Net payments made by *D* under the interest rate swap are chargeable to the capital account for the forward contract for the delivery of *x* barrels of fuel oil to *E*. Similarly, net payments received by *D* under the interest rate swap are allowable offsets. See § 1.263(g)–3(e)(5).

Example 5. Contingent payment debt instrument with embedded short position.

(i) *Facts.* On January 1, 1998, G purchases 100,000 shares of the common stock of *XYZ* corporation (which is publicly traded). On January 1, 2002, the 100,000 shares of *XYZ* corporation common stock were worth $*x* per share. On that date, *G* issued a contingent payment debt instrument for $100,000*x*. The terms of the debt instrument provided that the holder would receive an annual payment of $2,000*x* on December 31 of each year up to and including the maturity date of December 31, 2007. On the maturity date, the holders would also receive a payment of $100,000*x* plus an additional amount, if the price of an *XYZ* share exceeded $1.2*x* on such date, equal to 100,000 times three-quarters of the amount of such excess per share. Thus, *G*'s aggregate payments on the debt instrument varied directly with the increase in value in the *XYZ* shares.

(ii) *Analysis.* The debt instrument is a position in *XYZ* stock. See § 1.1092(d)–1(d). The *XYZ* stock is personal property within the meaning of section 1092(d)(3)(B) because the debt instrument is a position with respect to substantially similar or related property (other than stock) within the meaning of section 1092(d)(3)(B)(i)(II). See § 1.1092(d)–2(c). The debt instrument and the *XYZ* shares are offsetting positions with respect to the same personal property and constitute a straddle. See sections 1092(c)(1), (c)(3)(A)(i). Consequently, *G*'s interest payments are interest and carrying charges properly allocable to personal property that is part of a straddle, see §§ 1.263(g)–3(b)(1), (b)(3), (c)(3), and (d)(1), and must be allocated to the capital account for the *XYZ* common stock, see § 1.263(g)–4(a)(1)(iii) and (a)(3).

Example 6. Straddle including partnership interest.

(i) *Facts.* H borrows money from I to purchase 100 ounces of gold at a cost of $*u*. *H* transfers the 100 ounces of gold and $*v* to a newly created trust that issues multiple classes of trust certificates and is treated as a partnership for tax purposes. In return, *H* receives two trust certificates. One certificate entitles the holder to a payment on termination of the trust at the end of four years equal to the value of the 100 ounces of gold up to a maximum value of $(*u* + *w*). The other certificate entitles the holder to a payment equal to the amount by which the value of 100 ounces of gold exceeds $(*u* + *w*) on termination of the trust. *H* sells the second certificate and keeps the first certificate. *H* also enters into a forward contract to sell 100 ounces of gold for $1.12*u* per ounce on a date two years after creation of the trust. The trust uses part of the $*v* and similar cash contributions from other investors to pay costs of storing the gold held by the trust and allocates *H*'s share of the expenses to *H*.

(ii) *Analysis.* The trust certificate retained by *H* and the forward contract entered into by *H* are personal property for the purposes of section 263(g). See § 1.263(g)–2(a). They are also offsetting positions and constitute a straddle. Section 1092(c)(1). The borrowing from *I* is an indebtedness incurred to purchase personal property that is part of a straddle. See §§ 1.263(g)–3(b)(1) and (c)(1). Similarly, the gold storage expenses are expenses incurred due to the taxpayer's holding personal property that is part of a straddle. See § 1.263(g)–3(b)(2). Therefore both the interest on the borrowing and the gold storage expenses must be allocated to the capital account for the partnership interest represented by the retained trust certificate. See § 1.263(g)–4(a)(1)(i) and (a)(2).

Example 7. Equity Swap.

(i) *Facts.* On January 1, 1998, *J* purchases 100,000 shares of the common stock of *XYZ* corporation (which is publicly traded). On December 31, 2001, the 100,000 shares of *XYZ* corporation common stock were worth $*x* per share. On that date, *J* entered into a NPC with *K*. The terms of the NPC provided that *K* would receive an annual payment on December 31 of each year equal to 100,000 times any appreciation in the value of a share of *XYZ* corporation stock above its price at the end of trading on December 31 of the preceding year and 100,000 times the dividends paid during the year on each share of *XYZ* corporation stock. In return, on December 31 of each year, *J* would receive an amount equal to LIBOR times the value of 100,000 XYZ shares at the end of trading on December 31 of the preceding year plus 100,000 times the amount of any decrease in the value of a share of *XYZ* corporation stock below its price at the end of trading on December 31 of the preceding year. Payments between *J* and *K* would be netted and continue up to and including the maturity date of the NPC on December 31, 2008. Thus, *J*'s aggregate payments on the NPC varied directly with the increase in value in the *XYZ* shares.

(ii) *Analysis.* The NPC is a position in *XYZ* stock. See § 1.1092(d)–2(c). The *XYZ* stock is personal property within the meaning of section 1092(d)(3)(B) because the NPC is a position with respect to substantially similar or related property (other than stock) within the meaning of section 1092(b)(3)(B)(i)(II). See § 1.1092(d)–2(a)(1)(ii). The NPC and the *XYZ* shares are offsetting positions with respect to the same personal property and constitute a straddle. See sections 1092(c)(1), (c)(3)(A)(i). Consequently, *J*'s payments are interest and carrying charges properly allocable to personal property that is part of a straddle. See §§ 1.263(g)–3(b)(3) and (d)(1). Therefore, they should be allocated to the personal property that is part of the straddle in the manner that is most appropriate under all the facts and circumstances. In this case, because these payments are incurred to carry the *XYZ* shares, they should be allocated to the capital account for the *XYZ* common stock. See § 1.263(g)–4(a)(3).

§ 1.263(g)–5 Effective dates.

Sections 1.263(g)–1, 1.263(g)–2, 1.263(g)–3, and 1.263(g)–4 apply to interest and carrying charges properly allocable to personal property that are paid, incurred, or accrued after the date these regulations are adopted as final regulations by publication in the **Federal Register** for a straddle established on or after January 17, 2001.

Par. 3. Section 1.1092(d)–1 is amended by revising paragraph (d) and adding paragraph (e), to read as follows:

§ 1.1092(d)–1 Definitions and special rules.

* * * * * *

(d) *Debt instrument linked to the value of personal property.* If a taxpayer is the obligor under a debt instrument one or more payments on which are linked to the value of personal property or a position with respect to personal property, then the taxpayer's obligation under the debt instrument is a position with respect to personal property and may be part of a straddle.

(e) *Effective dates.* Paragraph (b)(1)(vii) of this section applies to positions entered into on or after October 14, 1993. Paragraph (c) of this section applies to positions entered into on or after July 8, 1991. Paragraph (d) of this section is effective for straddles established on or after January 17, 2001.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–1240 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–115580–99]

RIN 1545–AX66

Equity Options With Flexible Terms; Qualified Covered Call Treatment

AGENCY: Internal Revenue Service (IRS), Treasury.

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ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations providing guidance on the application of the rules governing qualified covered calls. The new rules address concerns that were created by the introduction of new financial instruments several years after the enactment of the qualified covered call rules. The proposed regulations would provide guidance to taxpayers writing equity call options. This document also provides notice of public hearing on these proposed regulations.

DATES: Written and electronic comments and requests to appear and outlines of topics to be discussed at the public hearing scheduled for May 9, 2001, at 10 a.m., must be submitted by April 18, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–115560–99), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–115560–99), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option of the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.gov/tax_regs/regslist.html. The public hearing will be held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Pamela Law, (202) 622–3950; concerning submissions and the hearing, Guy Traynor, (202) 622–7180, (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

On June 25, 1998, the IRS published in the **Federal Register** proposed regulations (REG–104641–97, 63 FR 34616) addressing whether strike prices available for equity options with flexible terms affect the definition of a qualified covered call (QCC) under section 1092(c)(4) for equity options with standardized terms. No requests to speak at a public hearing were received, and no public hearing was held.

The proposed regulations provided that strike prices available for equity options with flexible terms do not affect the bench marks used to determine whether equity options with standardized terms are eligible for QCC treatment. That provision was adopted as § 1.1092(c)–1 of the final regulations (TD 8866), published in the **Federal Register** for January 25, 2000 (65 FR 3812).

The regulatory text of REG–104641–97 did not address whether an equity option with flexible terms is itself eligible for QCC treatment. The preamble to the proposed regulations, however, did request comments about whether equity options with flexible terms should be eligible for QCC treatment and, if eligible, what bench marks should apply. In light of the comments received, consideration was also given to the treatment of over-the-counter options and standardized options with terms of more than one year. After consideration of the written comments, this NPRM proposes regulations addressing the eligibility for QCC treatment of equity options with flexible terms, over-the-counter options and standardized options with terms longer than one year.

QCC Treatment

Section 1092(c) defines a straddle as offsetting positions with respect to personal property. Under section 1092(d)(3)(B)(i)(I), stock is personal property if the stock is part of a straddle that involves an option on that stock or substantially identical stock or securities. Under section 1092(c)(4), however, writing a QCC option and owning the optioned stock is not treated as a straddle under section 1092 if certain conditions are satisfied.

The legislative history of section 1092 indicates that QCCs were excepted from the loss deferral rule for straddles because "they are undertaken primarily to enhance the taxpayer's investment return on the stock and not to reduce the taxpayer's risk of loss on the stock." H.R. Rep. No. 432, 98th Cong., 2d Sess. at 1266–68 (1983). To qualify as a QCC, a covered call must, among other things, be exchange traded and not be deep in the money. An option is exchange traded if the option is traded on a national securities exchange that is registered with the Securities and Exchange Commission or on some other market that the Secretary determines has rules adequate to carry out the purposes of the QCC provisions. An option is deep in the money if the strike price of the option is lower than the lowest qualified bench mark for the stock at the time the option is written.

Section 1092(c)(4)(H) grants the Secretary of the Treasury the authority to prescribe regulations to carry out the purposes of the QCC exception, including regulations modifying the provisions of the exception as appropriate to take account of changes in the practices of options exchanges.

The introduction of exchange-traded equity options with flexible terms is one such change. Unlike equity options with standardized terms, equity options with flexible terms can have strike prices at other than fixed intervals and have other than standardized expiration dates. Options exchanges have also introduced standardized options with longer terms.

In response to the request for comments, two comments were received. One commentator argued that equity options with flexible terms should not be eligible for QCC treatment. This commentator noted that in 1984, when section 1092(c)(4) was enacted, only equity options with standardized terms were traded on the national exchanges and that it is likely that Congress did not intend to include customizable options within the definition of a QCC. This commentator also pointed out that equity options with flexible terms were developed to compete with over-the-counter (OTC) options, which are not eligible for QCC treatment. The commentator suggested that excluding equity options with flexible terms from QCC treatment would avoid a competitive imbalance from different tax treatment for competing products.

The second commentator stated that, as a matter of statutory analysis, equity options with flexible terms are already eligible for QCC treatment. This commentator argued that QCC treatment is appropriate if the taxpayer is using the option to increase the yield on its stock investment and not to reduce the risk of loss on its stock. In support of this point, the commentator noted that nothing in the applicable legislative history suggests that Congress intended to limit the QCC option exception to standardized options. Alternatively, this commentator argued that because equity options with flexible terms were designed to compete with OTC options, regulations should be promulgated allowing OTC options to qualify for QCC treatment on the same terms as exchange-traded equity options with flexible terms.

Explanation of Provisions

Equity Options With Flexible Terms and Qualifying OTC Options

After consideration of the comments received, the proposed regulations provide that equity options with flexible terms may be QCC options as long as they satisfy the general rules for QCC treatment described in section 1092(c)(4), are not for a term of longer than one year, and meet other specified requirements. In addition, an equity option with standardized terms must be outstanding for the underlying equity. For purposes of applying the general rules, the bench marks will be the same as those for an equity option with standardized terms on the same stock having the same applicable stock price.

The proposed regulations also provide that certain OTC options may be QCC options so that OTC options that are economically similar to equity options with flexible terms may enjoy the same tax benefits as equity options with flexible terms. Specifically, the proposed regulations provide that an OTC option is eligible for QCC treatment if it is entered into with a person registered with the Securities and Exchange Commission as a broker-dealer or alternative trading system and meets the same requirements for QCC treatment that apply to equity options with flexible terms.

QCC Status for Equity Options With Standardized Terms

In the process of considering the proper treatment for equity options with flexible terms, the IRS examined QCC status in general. At the time that Congress enacted section 1092(c)(4), options available on the national securities exchanges had a term of nine months or less. Congress did not include in the legislative history any guidance on the effect of the time value of money upon the strike price.

Subsequent to the enactment of section 1092(c)(4), the national securities exchanges began offering certain standardized options with expiration dates that are 12 or more months after the date entered into. The longer term of these options may reduce the taxpayer's risk of loss on its stock position because of the time period involved.

Increased risk reduction through the use of long term options applies equally to equity options with flexible terms, OTC options, and equity options with standardized terms. The proposed regulations therefore provide that a one-year term limit also applies to equity options with standardized terms. Comments are requested on this issue, including a discussion of time limitations in general, as well as the appropriateness of a one-year cutoff.

If QCC treatment should apply to longer-term options, it may be appropriate to change the deep-in-the-money standard to prevent the increase in risk reduction. A comment recommending a time limitation greater than one year or recommending that there be no time limitation should also provide detailed, comprehensive descriptions of possible solutions to the problem of increased risk reduction. Comments should also address the administrability of any proposed solutions.

Proposed Effective Date

These regulations would apply to options entered into on or after 30 days after the date that the Treasury decision adopting these rules as final regulations is published in the **Federal Register**.

Regulations concerning time limitations for equity options with standardized terms would be prospective in nature and would apply to transactions entered into on or after 90 days from the date of publication of the final regulation promulgating such rules.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based upon the fact that these regulations do not impose any recordkeeping or reporting requirements and therefore impose minimal compliance costs, if any, upon any small entities that may be affected. Because equity options with standardized terms will not be eligible for QCC treatment if such options have a duration of more than 1 year, some taxpayers may lose substantive tax benefits. This certification is further based upon the understanding that such taxpayers will not include a substantial number of small entities. Comments are specifically requested on the question of whether a substantial number of small entities (as opposed to large entities or individual investors) will suffer a significant economic impact under these regulations. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written or electronic comments (a signed original and eight (8) copies, if written) that are submitted timely (in the manner described in the **ADDRESSES** portion of this preamble) to the IRS. The IRS and Treasury request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for May 9, 2001, at 10 a.m., in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington DC. Due to building security procedures, visitors must enter at the 10th Street entrance located between Constitution and Pennsylvania Avenues, NW. In addition, all visitors must present photo identifications to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 15 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by April 18, 2001. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Pamela Law, Office of Associate Chief Counsel (Financial Institutions and Products). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * *

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Section 1.1092(c)–2 also issued under 26 U.S.C.1092(c)(4)(H).

Section 1.1092(c)–3 also issued under 26 U.S.C. 1092(c)(4)(H).* * *

Par. 2. Section 1.1092(c)–1 is amended as follows:

1. Paragraphs (b) and (d)(1)(ii) introductory text are revised.

2. Paragraphs (c) and (d)(3) are added.

3. Paragraph (e) is revised.

The revisions and addition read as follows:

§ 1.1092(c)–1 Equity options with flexible terms.

* * * * *

(b) *No effect on lowest qualified bench mark for standardized options.* The availability of strike prices for equity options with flexible terms does not affect the determination of the lowest qualified bench mark, as defined in section 1092(c)(4)(D), for an equity option with standardized terms.

(c) *Qualified covered call option status*—(1) *Requirements.* An equity option with flexible terms is a qualified covered call option only if—

(i) The option meets the requirements of section 1092(c)(4)(B) (taking into account paragraph (c)(2) of this section);

(ii) The only payments permitted with respect to the option are a single fixed premium paid not later than 5 business days after the day on which the option is granted, and a single fixed strike price stated as a dollar amount that is payable entirely at (or within 5 business days of) exercise;

(iii) The option is granted not more than 1 year before the day on which the option expires; and

(iv) An equity option with standardized terms is outstanding for the underlying equity.

(2) *Lowest qualified bench mark*—(i) *In general.* For purposes of determining whether an equity option with flexible terms is deep in the money within the meaning of section 1092(c)(4)(C), the lowest qualified bench mark under section 1092(c)(4)(D) is the same for an equity option with flexible terms as the lowest qualified bench mark for an equity option with standardized terms on the same stock having the same applicable stock price.

(ii) *Example.* The following example illustrates the rules set out in paragraph (c)(2)(i) of this section:

Example. Taxpayer owns stock in Corporation X. Taxpayer writes an equity call option with flexible terms on Corporation X stock through a national securities exchange. The applicable stock price for Corporation X stock is $73.75. Using the bench marks for an equity option with standardized terms with an applicable stock price of $73.75, the highest available bench mark less than the applicable stock price is $70, and the second highest bench mark is $65. Therefore, an equity call option with flexible terms on Corporation X with a term of 90 days or less will not be deep in the money if the strike price is not less than $70. If the term is greater than 90 days, an equity call option with flexible terms on Corporation X will not be deep in the money if the strike price is not less than $65.

(d) * * *

(1) * * *

(ii) That is traded on any national securities exchange which is registered with the Securities and Exchange Commission (other than those described in the SEC Releases set forth in paragraph (d)(1)(i) of this section) and is—

* * * * *

(3) *Equity option with standardized terms* means an equity option that is traded on a national securities exchange registered with the Securities and Exchange Commission and that is not an equity option with flexible terms.

(e) *Effective date*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, this section applies to equity options with flexible terms entered into on or after January 25, 2000.

(2) *Special effective date for paragraph (c).* Paragraph (c) of this section applies to equity options with flexible terms entered into on or after 30 days after the date that the Treasury decision adopting these regulations is published in the **Federal Register**.

Par. 3. Section 1.1092(c)–2 is added to read as follows:

§ 1.1092(c)–2 Equity options with standardized terms.

(a) *One-year limitation.* An equity option with standardized terms (as defined in § 1.1092(c)–1(d)(3)) is a qualified covered call only if—

(1) The option meets the requirements of section 1092(c)(4)(B); and

(2) The option is granted not more than 1 year before the day on which the option expires.

(b) *Effective date.* This section applies to equity options with standardized terms entered into on or after 90 days after the date that the Treasury decision adopting these regulations is published in the **Federal Register**.

Par. 4. Section 1.1092(c)–3 is added.

§ 1.1092(c)–3 Qualifying over-the-counter options.

(a) *In general.* Under section 1092(c)(4)(B)(i), an equity option is not a qualified covered call option unless it is traded on a national securities exchange which is registered with the Securities and Exchange Commission or other market which the Secretary determines has rules adequate to carry out the purposes of section 1092(c)(4). In accordance with section 1092(c)(4)(H), this requirement is modified as provided in paragraph (b) of this section.

(b) *Qualified covered call option status.* A qualifying over-the-counter option is a qualified covered call option if it meets the requirements of § 1.1092(c)–1(c) after substituting "qualifying over-the-counter option" for "equity option with flexible terms". For the purposes of this paragraph (b), a qualifying over the counter option is deemed to satisfy the requirements of section 1092(c)(4)(B)(i).

(c) *Qualifying over-the-counter option.* For the purposes of this section, *qualifying over-the-counter option* means an equity option that—

(1) Is not traded on a national securities exchange registered with the Securities and Exchange Commission; and

(2) Is entered into with a person registered with the Securities and Exchange Commission as—

(i) A broker-dealer under section 15 of the Securities Act of 1934 and the regulations thereunder; or

(ii) An alternative trading system under 17 CFR 242.300 *et seq.*

(d) *Effective date.* This section applies to qualifying over-the-counter options entered into on or after 30 days after the date that the Treasury decision adopting these regulations is published in the **Federal Register**.

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–1294 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–114998–99]

RIN 1545–AY71

Obligations of States and Political Subdivisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of notice of proposed rulemaking; notice of proposed rulemaking by cross-reference to temporary regulations; and notice of public hearing.

SUMMARY: This document withdraws portions of the notice of proposed rulemaking published in the **Federal Register** on January 22, 1998. In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations that provide guidance to state and local governments that issue bonds for output facilities. The text of those temporary regulations also serves as the text of these proposed regulations. This document provides a notice of public hearing on these proposed regulations.

DATES: Written comments must be received by July 18, 2001. Outlines of topics to be discussed at the public hearing scheduled for July 24, 2001, at 10 a.m. must be received by July 3, 2001.

ADDRESSES: Send submissions to: CC:M&SP:RU (REG–114998–99), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:M&SP:RU (REG–114998–99), courier's desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.gov/tax_regs/regslist.html. The public hearing will be held in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Rose M. Weber, (202) 622–3980; concerning submissions and the hearing, Treena Garrett, (202) 622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

Proposed regulations (REG–110965–97) §§ 1.141–7, 1.141–8 and 1.141–15(f) through (i), published on January 22, 1998 (63 FR 3296), addressed the application of the private activity bond tests of section 141(b) (1) and (2) to output contracts for output facilities and the application of the $15 million limitation under section 141(b)(4) to output facility financings. These proposed sections are withdrawn.

Sections 1.141–7T, 1.141–8T and 1.141–15T published in the Rules and Regulations portion of this issue of the **Federal Register** are issued to provide guidance on certain aspects of the private activity bond restrictions under section 141 of the Internal Revenue Code.

The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments that are submitted timely (preferably a signed original and eight copies) to the IRS. All comments will be available for public inspection and copying.

A public hearing has been scheduled for July 24, 2001, at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Because of access restrictions, visitors will not be admitted beyond the lobby more than 15 minutes before the hearing starts.

The rules of 26 CFR 601.601(a)(3) apply to the hearing.

Persons who wish to present oral comments at the hearing must submit written comments by July 18, 2001 and submit an outline of the topics to be discussed and the time to be devoted to each topic by July 3, 2001.

A period of 10 minutes will be allotted to each person for making comments.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal authors of these regulations are Bruce M. Serchuk, and Rose M. Weber, Office of Chief Counsel (Tax-exempt and Government Entities), Internal Revenue Service, and Stephen J. Watson, Office of Tax Legislative Counsel, Department of the Treasury. However, other personnel from the IRS and Treasury Department participated in their development.

Partial Withdrawal of Notice of Proposed Rulemaking

Under the authority of 26 U.S.C. 7805, §§ 1.141–7, 1.141–8 and 1.141–15(f) through (i) in the notice of proposed rulemaking that was published on January 22, 1998 (63 FR 3256) are withdrawn.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Sections 1.141–7 and 1.141–8 are added to read as follows:

§ 1.141–7 Special rules for output facilities.

[The text of this proposed section is the same as the text of § 1.141–7T published elsewhere in this issue of the **Federal Register**.]

§ 1.141–8 $15 million limitation for output facilities.

[The text of this proposed section is the same as the text of § 1.141–8T published elsewhere in this issue of the **Federal Register**.]

Par. 3. Section 1.141–15 is amended by adding paragraphs (f) through (i) to read as follows:

§ 1.141–15 Effective dates.

* * * * *

(f) through (i) [The text of proposed paragraphs (f) through (i) is the same as the text of § 1.141–15T(f) through (i) published elsewhere in this issue of the **Federal Register**.]

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

[FR Doc. 01–1413 Filed 1–17–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX–126–1–7477; FRL–6933–6]

Approval and Promulgation of Implementation Plans; Texas; the Dallas/Fort Worth Nonattainment Area; Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve the 1-hour ozone Attainment Demonstration State Implementation Plan (SIP), the Post 96 Rate-of-Progress (ROP) plan SIP, and the 15% ROP plan SIP for the Dallas/Fort Worth (DFW) serious ozone nonattainment area. The EPA is also proposing to extend the attainment date for the DFW area to November 15, 2007, from November 15, 1999, based on transport from the Houston/Galveston/Brazoria (HGA) ozone nonattainment area; approve the Motor Vehicle Emissions Budgets contained in the Attainment Demonstration SIP and the Post 1996 ROP plan SIP; approve the State's enforceable commitment to perform a mid-course review and submit a SIP revision to the EPA by May 2004; approve the State's enforceable commitment to revise the SIP Motor Vehicle Emissions Budgets using the MOBILE6 on-road emissions model; approve revisions to the 1990 base year inventory; and find that the DFW area meets the Reasonably Available Control Technology (RACT) requirements for major sources of volatile organic compounds (VOC) emissions. The EPA is also proposing to convert the conditional, interim approval of the DFW 15% plan (63 FR 62943) to a full approval because the requirements for full approval appear to have been met. This proposed action is based on the requirements of the Federal Clean Air Act (the Act) related to ozone demonstrations.

DATES: Written comments must be received on or before March 19, 2001.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD–L), at the EPA Region 6 Office listed below. Copies of documents relevant to this action, including the Technical Support Document (TSD) are available for public inspection during normal business hours at the following location.

Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Dallas, Texas 75202–2733.

Texas Natural Resource Conservation Commission, Office of Air Quality, 12124 Park Circle, Austin, Texas 78753.

Anyone wanting to examine these documents should make an appointment with the appropriate office at least two working days in advance.

FOR FURTHER INFORMATION CONTACT: Herbert R. Sherrow, Jr., Air Planning Section (6PD–L), 1445 Ross Avenue, Dallas, Texas 75202–2733. Telephone Number (214) 665–7237, e-Mail Address: sherrow.herb@epa.gov.

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SUPPLEMENTARY INFORMATION:

Throughout this document "we," "us," and "our" refers to EPA.

I. Attainment Demonstration and Attainment Date

A. Proposed Action

What Action Are we Taking?

We are proposing to approve the transport demonstration and attainment demonstration SIP developed for the DFW ozone nonattainment area because they meet the Clean Air Act. We believe that the State has adequately followed our 1998 Transport Guidance for demonstrating transport, and that the State's transport demonstration analyses indicate that there are impacts of ozone and ozone precursor transports from the upwind HGA area affecting the DFW area. In addition, we believe that the modeling, the provided weight-of-evidence analyses, and the analysis of transport of ozone and ozone precursor compounds from the HGA area, demonstrate that the control strategy chosen by the State will provide for attainment of the ozone standard. It is our technical position that the control strategy will provide for attainment of the ozone standard by November 15, 2007.

We are proposing to approve the DFW 1-hour ozone nonattainment area attainment demonstration SIP; the State's request for an extension of the attainment date to November 15, 2007, while retaining the area's current classification as serious; the Motor Vehicle Emissions Budgets; the State's enforceable commitment to conduct a mid-course review (including evaluation of all modeling, inventory data, and other tools and assumptions used to develop this attainment demonstration) and to submit a mid-course review SIP revision, with recommended mid-course corrective actions, to us by May 1, 2004; the Speed Limit Reductions in nine counties (including the DFW 4-county area; Dallas, Tarrant, Collin, and Denton Counties); a Voluntary Mobile Emissions Program in nine counties (including the DFW 4-county area); Transportation Control Measures in the DFW area; the 15% ROP Plan, the Post-1996 ROP Plan; revisions to the 1990 base year inventory; and the State's enforceable commitment to performing new mobile source modeling for the DFW area, using MOBILE6, our on-road mobile emissions factor computer model, within 24 months of the model's release; and, if transportation conformity analysis is to be performed between 12 months and 24 months after the MOBILE6 release, transportation conformity will not be determined until Texas submits a motor vehicle emissions budget which is developed using MOBILE6 and which we find adequate. We are also proposing to find that the DFW area meets all remaining outstanding VOC RACT requirements for major sources.

If the subsequent analyses conducted by the State as part of the mid-course review indicate additional reductions are needed for the DFW area to attain the ozone standard, we will require the State to implement additional controls as soon as possible which demonstrate attainment through photochemical grid modeling. We cannot finalize the proposed action upon the Attainment Demonstration SIP, the State's request for an extension of the attainment date, and the MVEB contained in the Attainment Demonstration SIP unless and until we have fully approved all of the control measures relied upon in the State's Attainment Demonstration SIP for the DFW area and the control measures required by the Act for a serious area such as the DFW area. See section F., *Action needed on Control Measures* for a complete list of the rulemaking actions which must be completed before we can finalize action on the DFW Attainment Demonstration SIP, the attainment date extension, and the Attainment Demonstration SIP's MVEB. Furthermore, we cannot finalize action on these three items unless and until the Governor submits the finally adopted enforceable commitment regarding MOBILE6. The State has begun its public comment process on an enforceable commitment and has committed to performing new mobile source modeling for the DFW area, using MOBILE6, within 24 months of the model's release. The public hearing is scheduled for January 4, 2001.

Was the Submittal Addressed in Public Hearings and Adopted by the State?

Four Public hearings were held in the DFW area on January 26 and 27, 2000. The State formally adopted the submittal on April 19, 2000. In addition, the State held six other public hearings in other cities on the submittal. The Governor of Texas submitted the Attainment Demonstration SIP, a request for extension of the attainment date for the DFW ozone nonattainment area, adopted rules, orders and initiatives, and the mid-course commitment on April 25, 2000. The State has gone forward with its public participation requirements on a commitment to performing new mobile source modeling for the DFW area, using MOBILE6. The public hearing on this commitment is scheduled for January 4, 2001. We anticipate that the Governor of Texas will submit this adopted enforceable commitment in the Spring of 2001. The Governor also submitted after public notice and hearing, the Post 1996 ROP Plan and revisions to the 1990 base year inventory on October 25, 1999.

B. Attainment Demonstration Contents

What Are the Contents of the Attainment Demonstration Submittal?

The April 25, 2000 submittal, concerning the ozone attainment demonstration and an extension of the attainment date for the DFW ozone nonattainment area, contains:

1. A photochemical modeling demonstration and additional weight-of-evidence analyses supporting the photochemical modeling demonstration,
2. An accompanying control strategy, comprised of:
   a. Regulations and initiatives in the DFW area (and their documentation);
   b. Regulations and initiatives in certain counties surrounding the DFW area (and their documentation); and
   c. Additional regional rules and orders (and their documentation), relied upon for demonstrating attainment in the DFW area.
3. A 2007 Motor Vehicle Emissions Budget (MVEB) for transportation conformity;
4. A demonstration of transport from the HGA area supporting an attainment date extension to 2007;
5. Emissions growth estimates, and a 2007 forecast emissions inventory; and,
6. A commitment to perform a mid-course review with submittal to us by May 1, 2004.

The attainment control strategy; *i.e.*, regulations, initiatives, and orders, are primarily designed to control Nitrogen Oxides (NO_X) emissions from various sources, since the modeling shows ozone reduction is more sensitive to NO_X controls.

For purposes of this action, we are reviewing the modeling, weight-of-evidence support, the transport analysis, the MVEB, forecasted emissions inventory, the mid-course enforceable commitment, and the Transportation Control Measures, the Speed limit reductions and the Voluntary Mobile Emissions Program local initiatives. We are also reviewing the enforceable commitment to perform new mobile source modeling for the DFW area, using MOBILE6, within 24 months of the model's release, including a provision stating that if transportation conformity analysis is to be performed between 12 months and 24 months after the MOBILE6 release, transportation conformity will not be determined until Texas submits a motor vehicle emissions budget which is developed using MOBILE6 and which we find adequate.

C. Photochemical Modeling

What Model Approach Was Used for the Analysis?

The state used the Comprehensive Air Quality Model with Extensions (CAMx) version 2.01 photochemical grid model to conduct both the SIP attainment demonstration modeling and the downwind transport modeling for the DFW ozone nonattainment area. The State demonstrated that CAMx performed better than UAM version IV, the regulatory model, in the HGA nonattainment area and petitioned us to approve its use in the DFW nonattainment area. We approved the use of CAMx for the DFW ozone nonattainment area based upon the model's better performance in the HGA nonattainment area. This was considered to be valid for the DFW area. The State's modeling activities were performed as outlined in a series of the modeling protocols, according to our "Guideline for Regulatory Application of the Urban Airshed Model" (July, 1991) (Guideline). The final modeling protocol developed by the State was submitted in August 1999. This protocol was reviewed and approved by us. The State used a relatively large modeling domain with nested grids to capture the influence of regional and long-range transport. The modeling domain covers the DFW ozone nonattainment area which is comprised of Dallas, Tarrant, Collin, and Denton Counties. The modeling domain also covers most counties in central and east Texas, including the ozone nonattainment counties of Harris, Jefferson, Orange, Chambers, Hardin, Liberty, Montgomery, Waller, Brazoria, Galveston, and Fort Bend counties. It also covers a number of other States; *e.g.*, Louisiana and Mississippi in the southeastern portion of the country.

How Were Exceedance Days Evaluated and What Days Were Modeled?

Our 1991 Guideline sets forth a recommended procedure for selecting ozone exceedance days appropriate for conducting a modeling demonstration. This procedure, in part, considers wind rose analyses based upon the four morning hours of 0700 to 1000 local standard time. These wind rose analyses are used to define the meteorological patterns for source-receptor relationships associated with high ozone events. The State used this method for defining meteorological patterns. The number of ozone exceedance days for the period, 1990–1996, associated with each meteorological pattern was identified. The most prominent meteorological pattern for ozone exceedance days (*i.e.*, 70%) was calm winds; *i.e.*, wind speeds < 3mph. The meteorological pattern with southerly winds was the second most prominent pattern with 25% of the ozone exceedance days.

A total of eleven ozone exceedance days were identified as candidates for modeling. From these, the State chose the candidate episodes in 1995 (calm winds) and 1996 (southerly winds), in part, since they are more applicable to the most currently available emissions inventory (the 1996 Periodic) and since more ambient data is generally available for these episodes.

The State selected June 21 and 22, 1995, which form a multi-day episode, as two of the three primary episode days to model from the calm meteorological regime. These two days also had 1-hour exceedances fairly close to the current ozone design value (*i.e.*, 139 ppb). For

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the third primary episode day, the State selected July 3, 1996. Although the meteorological pattern on July 3rd had neither calm nor southerly winds, since the two days prior exhibited southerly winds, the rationale for this selection is that July 3rd is associated with southerly winds. It also occurred during the period of enhanced aerometric monitoring. The high ozone episode days the State selected and modeled meet with the requisite three primary episode days and cover the two predominate types of meteorological patterns associated with high ozone in the DFW area. A more complete description of the episode selections and technical rationales can be found in the TSD.

How Was Potential Transport From the HGA Area Addressed?

The State demonstrated the potential transport of ozone and ozone precursors from the upwind HGA nonattainment area upon the DFW area for both the 1995 and the 1996 episodes. This demonstration was primarily based upon two modeling analyses. The first used the same set of air quality and meteorological inputs as used in the base case simulation, but with an emissions data set in which anthropogenic (man-made) emissions from the 8-county HGA area were eliminated. The second was an ozone source apportionment analysis. The CAMx model has an optional feature which tracks the sources of precursors that contribute to the ozone formed at a given location. This feature was used to assess the culpability of sources in the 8-county HGA nonattainment area to the DFW four-county nonattainment area. These analyses show that for July 3, 1996, 2–4 ppb of ozone in portions of the DFW area comes from HGA sources.

The State also submitted a back trajectory analysis of ozone exceedance days in the DFW area for the six year period, 1993 to 1998. During this period there were 160 exceedance days in the DFW area and approximately ten percent had trajectories going back to the HGA area.

Thus, emissions from the HGA area have the potential to influence DFW's ability to attain the 1-hour ozone standard. It is EPA's proposed technical position that for some ozone exceedance days, the DFW area is affected by transport from the HGA area. On other exceedance days, the DFW area is affected only by ozone precursor emissions generated within the DFW area itself.

Based on this transport demonstration, we propose to grant the State's request for an extension of the attainment date to November 15, 2007. A detailed discussion of the acceptability of the demonstration is in the section on *EPA's Analysis* in this notice. A discussion of the Transport Policy is in the BACKGROUND section of this notice.

D. Photochemical Modeling Results

What Were the Modeling Results for the Primary Episode Days and for the Future Attainment Date?

The model simulated ozone concentrations on selected primary episode days for the 1995 and 1996 episodes using emissions specific for those days, and emissions forecast to a 2007 future year. The resulting DFW area summary of the performance statistics and ozone peaks for 1995, 1996, and 2007 are shown in Table 1. The normalized bias and gross error performance statistics shown in Table 1 are well below our recommended maximum levels. This indicates that the model adequately replicated the spacial and temporal ozone formation that occurred on these ozone exceedance days. This provides an assurance that the model is useful in testing future control measures. These modeled ozone peaks reflect the results of the 2007 forecast emissions and control strategy for the 1995 and 1996 episode days.

TABLE 1—SUMMARY OF PERFORMANCE STATISTICS AND PEAK OBSERVED AND MODELED OZONE CONCENTRATIONS (PPB) IN THE DFW OZONE NONATTAINMENT AREA

Period	Episode days		
Primary Episode Day	6/21/95	6/22/95	7/3/96
Peak Observed	144	135	144
Peak Modeled Base Case	132.8	137.6	159.2
Peak Modeled 2007 Future Case	121.1	126.1	144.2
Peak Modeled 2007 Post-Control Case	110.3	113.1	131.5
Normalized Bias Greater Than 60 ppb	−10.1%	−8.8%	−3.4%
Normalized Gross Error Greater Than 60 ppb	12.2%	12.5%	15.0%

Do the Modeling Results Demonstrate Attainment of the Ozone Standard?

The *Guidance on Use of Modeled Results to Demonstrate Attainment of the Ozone NAAQS, (June, 1996)* recommends the use of either a statistical or deterministic approach to demonstrate attainment. Both of these approaches allow for the use of Weight-of-Evidence (WOE) to supplement the modeling results. The State elected to use the deterministic approach with WOE. As noted in Table 1, the 1-hour maximum predicted ozone concentration for the 2007 post-control modeling in the DFW area on the controlling day (July 3, 1996) (131.5 ppb) is above the standard; whereas, the other two episode days modeled are well below the standard.

The 2007 post-control modeling by itself does not conclusively demonstrate attainment of the standard; *(i.e.,* the deterministic test), but its results are so close to attainment to warrant the consideration of WOE analyses that support the demonstration of attainment. The State conducted several WOE analyses (see next section for further details) to provide additional confirmation that the demonstration shows that DFW will attain the standard by 2007 with the planned emission controls.

E. Weight-Of-Evidence

What WOE Analyses and Determinations Are Used To Support the Modeled Attainment Demonstration?

As presented in section D, our 1996 guidance document provides for the use of WOE to complement the control strategy modeling in demonstrating attainment. The key concept behind our June 1996 guidance is that determination of attainment, based on monitored ozone concentrations, allows for some exceedances of the 1-hour standard. Thus, even though the model may show some areas with peak concentrations slightly above the NAAQS, such modeled exceedances do not necessarily imply that monitored attainment will not be achieved.

Since the 2007 post-control modeling for the July 3, 1996, episode day is the only day exceeding the standard, most of the WOE analyses address this day. The State submitted the following WOE analyses:

1. *Notable higher peak modeled than monitored ozone concentrations:* The monitored peak in the DFW area on July 3, 1996, was 144 ppb versus a modeled peak of 159 ppb. Thus, there is some uncertainty regarding the modeled peak, even though the episode satisfied all of our criteria for model performance.

2. *Meteorology:* As previously indicated, the specific meteorology on July 3, 1996, was not of the types most associated with ozone exceedances in the DFW area. In addition, although the model performance for July 3, 1996, was acceptable, there was an indication that the meteorological features were not fully replicated for this day. There were scattered rain showers in the area which may have presented some meteorological effects which could not be modeled.

3. *Additional ozone reduction metrics:* The State presented additional metrics, aside from the modeled peak. The metrics presented are Area of exceedance, Area-hours of exceedance, and a measure of potential exposure. These metrics measure the geographic extent and temporal duration and duration of the ozone exceedance for various control strategies. The results show that the modeled control strategy produces a significant reduction in each of these additional metrics. This indicates that the selected control strategy should reduce the geographical and temporal aspects of the ozone exceedance, as well as the peak concentration.

4. *Estimated future design value:* The estimated future design value, as recommended in our draft guidance for assessing attainment of the 8-hour standard, is determined by proportioning the change in the modeled ozone results to a change in the design value.

To estimate the future design value, the State developed a ratio of the 2007 post-control modeling results to that of the original Base modeling results. Since episodes chosen for the DFW attainment demonstration occurred during 1995 and 1996, the State used monitoring data collected from 1995 to 1997 in the DFW area to establish the base design values. Then the ratio of the modeling results is multiplied by the 1995–1997 base design value to obtain an estimated future design value. Using this procedure the estimated future design value for July 3rd is 115.3 ppb, which is less than the standard. This result suggests that it is likely that the area will attain the standard by 2007.

5. *Design value trends:* The State analyzed historic monitored air quality data in the DFW area for the period of 1981 to 1999. The measure of air quality which determines the nonattainment classification is the design value. The design value is the highest of the fourth-highest daily peak ozone concentration over a three year period at any monitoring site in the area. There had been a general downtrend in the design value; however, it has remained constant in recent years. The constant trend has occurred despite dramatic increases in the level of construction and economic activity and substantial growth in the mobile fleet. Existing regulations appear to be adequate to keep the design value constant and new regulations included in the SIP should provide a significant decline in the design value.

6. *New technologies:* The State plans to continue reviewing and implementing new technologies as appropriate for the DFW area. The area will also benefit from our requirements for cleaner vehicles and fuels in the future.

In summary, the State's WOE analyses provide adequate support for the State's attainment demonstration. Maintaining air quality through recent periods is demonstrated and future progress in air quality improvement is shown to be likely. Our decision on the adequacy of the WOE is based on the composite of the analyses, and not on any single element. The WOE complements the modeled control strategy and indicates attainment should be reached by November 15, 2007.

The 1996 guidance recognizes a need to perform a mid-course review as a means for addressing uncertainty in the modeling results. Because of the uncertainty in long term projections, we believe that a viable attainment demonstration that relies on weight of evidence should contain provisions for periodic review of monitoring, emissions, and modeling data to assess the extent to which refinements to emission control measures are needed. The State submitted an enforceable commitment to perform such a mid-course review and to submit a SIP revision by May 2004.

F. Emission Control Strategy

What Emission Control Strategies Were Included in the Attainment Demonstration?

The DFW attainment demonstration SIP is directed at reductions of NO_X since the modeling shows reductions of NO_X will be most effective in bringing the area into attainment of the Standard.

The attainment demonstration SIP relies on a combination of Federal measures, State measures, CAA statutory requirements, local initiatives applied to different groups of counties in, and adjacent to, the DFW area, and projections of the level of control in the HGA area based on enforceable commitments in the November 1999 SIP for the HGA area. The attainment demonstration SIP also relies on Regional measures applied in east and central Texas. Please refer to the TSD for more details regarding these measures, initiatives, growth rates and emission reductions.

Federal Measures: The State included the following Federal Measures in the Future Year Base Case.

1. On-road mobile sources:
—Tier 2 vehicle emission standards and federal low sulfur gasoline in DFW and HGA.
—National Low Emitting Vehicles standards.
—Heavy-duty diesel standards.

We believe that the projected growth rates and emissions reductions from the sources subject to the above federal measures were calculated correctly by the State.

2. Off-road mobile sources:
—Lawn and garden equipment standards.
—Tier III heavy-duty diesel standards.
—Locomotive standards.
—Compression ignition standards for vehicles and equipment.
—Spark ignition standards for vehicles and equipment.
—Recreational marine standards.

We believe that the State correctly projected the growth rates and emissions reductions subject to these federal measures.

CAA Statutory Requirements: The State included the following CAA Statutory Requirements in the Future Year Base Case.

—Phase II reformulated gasoline (RFG) in the DFW four-county nonattainment area and HGA eight-county nonattainment area.
—Texas motorists' choice inspection and maintenance (I/M) program in Harris, Dallas and Tarrant Counties.

We believe that the State correctly projected the growth rates and

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emissions reductions from sources subject to these CAA Statutory Requirements.

State Measures: The State included the following State Measures as local (DFW) area controls in the Future Year Base Case.

—Electric generating and industrial point sources—four county area.
—An expanded vehicle Inspection/Maintenance program—nine county area.
—Low emission diesel fuel—nine county area.
—Heavy-duty diesel operating restrictions—four county area.
—Accelerated purchase of Tier 2/3 non-road compression ignition equipment—four county area.
—Airport ground support equipment electrification—airports of a certain size in the four county area.
—Gasoline heavy equipment engines—nine county area.
—Gas-fired water heaters, small boilers, and process heaters—State-wide.

We have already published actions on some of the above control measures in the **Federal Register** as discussed below. We believe that the State correctly projected the growth rates for and the emissions reductions from these affected sources.

Local Measures:

1. Speed limit reductions—nine county area.
2. Voluntary Mobile Emissions Program—nine county area.
3. Transportation Control Measures—four county area.

Our proposed action on these three local measures is discussed in more detail later in this section.

Regional Measures:

1. Agreed orders with Alcoa, Inc. (formerly Aluminum Company of America) for their Milam Facility, and the Eastman Chemical Company, Texas operations, for their facility near Longview, Texas.
2. Electric generating facilities and cement plants in central and eastern Texas.
3. Low Reid Vapor Pressure Gasoline in eastern and central Texas.
4. Stage I gasoline vapor recovery at gas stations in central and eastern Texas.

We have already published actions on the above control measures in the **Federal Register**, as discussed below.

Action Needed on Control Measures

We cannot finalize an action upon the Attainment Demonstration SIP, its MVEB, and the State's Request for an Extension of the Attainment Date until we have finalized action on the following:

1. The revised emission specifications in the DFW area for Electric Utility Boilers, Industrial, Commercial or Institutional Boilers and certain Process Heaters (30 TAC sections 117.104, 117.106, 117.108, 117.116, 117.206 as they relate to the DFW area, and the repeal of sections 117.109 and 117.601 as they relate to the DFW area): Proposed approval October 31, 2000. See 65 FR 64914.
2. Vehicle Inspection/Maintenance program (30 TAC 114.2, 114.50—114.53).
3. Low emission diesel fuel (30 TAC 114.6, 114.312–114.317, 114.319).
4. Non-Road Large Spark-Ignition (LSI) Engines (30 TAC 114.420, 114.421, 114.422, 114.427, and 114.429). Accelerated Purchase of Tier2/Tier3 Non-Road Compression-Ignition Equipment (30 TAC 114.410, 114.412, 114.416, 114.417, and 114.419). Non-Road Construction Equipment Restriction (30 TAC 114.432, 114.436, 114.437, and 114.439). Electrification of Airport Ground Support Equipment (GSE) (30 TAC 114.400, 114.402, 114.406, and 114.409.
5. The State-wide NO_X rules for Water Heaters, Small Boilers, and Process Heaters (30 TAC sections 117.460, 117.461, 117.463, 117.465, 117.467, 117.469): Direct final approval effective December 25, 2000. See 65 FR 64148.
6. The agreed orders with Alcoa, Inc. (formerly Aluminum Company of America) for their Milam Facility, and the Eastman Chemical Company, Texas operations, for their facility near Longview, Texas: Direct final approval effective December 25, 2000. See 65 FR 64148.
7. The NO_X rules for Electric Generating Facilities and cement plants in East and Central Texas (30 TAC sections 117.131, 117.133, 117.134, 117.135, 117.138, 117.141, 117.143, 117.145, 117.147, 117.149, 117.512, 117.260, 117.261, 117.265, 117.273, 117.279, 117.283, 117.524): Proposed approval October 31, 2000. See 65 FR 64914.
8. Lower Reid Vapor Pressure Gasoline in eastern and central Texas (30 TAC sections 114.1, 114.301, 114.304–114.307, and 114.309). Proposed approval November 20, 2000. See 65 FR 69720.
9. Stage I vapor recovery in eastern and central Texas (30 TAC sections 115.222–114.229): Proposed approval December 20, 2000. See 65 FR 79745.
10. VOC rules as RACT for batch processing (30 TAC sections 115.160–115.169) and wastewater (30 TAC sections 115.140–115.149): Proposed approval December 20, 2000. See 65 FR 79745.
11. The administrative revisions to the existing Texas NO_X SIP (30 TAC sections 117.101—117.121, 117.201–117.223, 117.510, 117.520, and 117.570): Proposed approval October 31, 2000. See 65 FR 64914.
12. Texas Clean Fleet Program (30 TAC 114.1, 114.3, 114.150, 114.151, 114.153–114.157, 114.201, 114.202, 114.152).
13. The 15% ROP Plan.
14. The Post 1996 ROP Plan.
15. The revisions to the 1990 base year inventory.
16. The speed limit reductions, the VMEP and the TCMs.
17. The finding that major sources of VOCs in the DFW area are meeting RACT.

It should be noted that several of these measures are the subject of ongoing litigation. Should the State lose, and as a result imperil any reductions needed for attainment, and there are no measures which make up the lost reductions, we may have to disapprove the attainment demonstration SIP.

What Are the Local Initiatives and Are They Approvable?

The State submitted three local initiatives: Speed limit reductions in the nine county area (Dallas, Tarrant, Collin, Denton, Ellis, Johnson, Parker, Rockwall, and Kaufman Counties), a Voluntary Mobile Emissions Program in the nine county area, and Transportation Control Measures in the four county area.

Speed Limit Reductions

The Texas Department of Transportation (TxDOT) revised regulations relating to speed limits to allow TNRCC to submit a request to change speed limits for environmental reasons when justified. Please see adopted rules, 25 TexReg 5686, June 9, 2000; and proposed rules, 25 TexReg 2018, March 10, 2000). TxDOT, using this authority, will lower all 70 mile per hour (mph) speed limits to 65 mph, and all 65 mph speed limits to 60 mph in the four county area. These slower speeds are anticipated to reduce the emissions of NO_X and improve air quality. We propose approval of the speed limit reductions control measure.

Voluntary Mobile Emissions Program (VMEP) Reductions

What Is EPA's VMEP?

Voluntary mobile source strategies that attempt to complement existing regulatory programs through voluntary, non-regulatory changes in local transportation activities or changes in in-use vehicle and engine composition

constitute the VMEP. The Clean Air Act allows SIP credit for new approaches to reducing mobile source emissions. This flexible approach is set forth in section 110. Economic incentive provisions are in sections 182 and 108 of the Act. Credits generated through VMEP can be counted toward attainment and maintenance of the NAAQS. Up to 3% of the total future year emissions reductions required to attain the appropriate NAAQS may be claimed under the VMEP policy.

What Qualifies for SIP Credit?

The basic framework for ensuring SIP credit for VMEPs is spelled out in guidance that came out under a memorandum from Richard D. Wilson, Acting Assistant Administrator for Air and Radiation, dated October 24, 1997, entitled "Guidance on Incorporating Voluntary Mobile Source Emission Reduction Programs in State Implementation Plans (SIPs)." Generally, to obtain credit for a VMEP, a State submits a SIP that:

(1) Identifies and describes a VMEP;

(2) Contains projections of emission reductions attributable to the program, along with any relevant technical support documentation;

(3) Commits to evaluation and reporting on program implementation and results; and

(4) Commits to the timely remedy of any credit shortfall should the VMEP not achieve the anticipated emission reductions.

More specifically, the guidance suggests the following key points be considered for approval of credits. The credits should be quantifiable, surplus, enforceable, permanent, and adequately supported.

In addition, VMEPs must be consistent with attainment of the standard and with the Rate of Progress requirements and not interfere with other Clean Air Act requirements.

What Did the State Submit?

The State submitted program descriptions that projected emission reductions attributable to each specific program as part of the DFW attainment demonstration submitted April 25, 2000. The State commits to evaluating each program to validate estimated credits. Table 2 lists the programs and projected credits. Programs submitted with no credit assigned are listed in Table 3.

TABLE 2.—VOLUNTARY MOBILE EMISSION REDUCTION PROGRAMS AND CREDITS CLAIMED

Program type	VOC benefits (tons per day)	NO_X benefits (tons per day)
Alternative Fuel Program	0.18	0.18
Employee Trip Reduction	0.29	0.53
Public Education Campaign/Ozone Season Fare Reduction	0.08	0.15
Tier II Locomotive Engines	0 to 0.6	0 to 3.0
Vehicle Retirement Program/Vehicle Maintenance*	0.56	0.77
Total Benefits (tpd)	1.11 to 1.71	1.63 to 4.63

* Emission benefits quantified for the Vehicle Retirement Program only. Emission benefits for Vehicle Maintenance are credited in the Vehicle Inspection and Maintenance Program.

TABLE 3.—VOLUNTARY EMISSION REDUCTION PROGRAMS WITH NO CREDIT ASSIGNED

Sustainable Development
Non-Road Ozone Season Reductions
Off-Road Heavy Duty Diesel Engine Retrofits

The State's goal is 5.0 tons per day of NO_X benefit from the VMEP program. This is within the 3% criteria in our guidance. The State has committed to evaluating and reporting on the program implementation and results and to timely remedy of any credit shortfall.

The State also committed to additional Transportation Control Measures that can be substituted for any shortfall in credit from the estimated credits for VMEP. These include Signal Improvements and Freeway Corridor Management.

Do the VMEPs Meet the Requirements for Approval?

A detailed analysis of all the VMEP measures can be found in the TSD for this document. For each creditable VMEP, the measure was found to be quantifiable. The reductions are surplus by not being substitutes for mandatory, required emission reductions. The measures will be enforced by the State. The reductions will continue at least for as long as the time period in which they are used by this SIP demonstration, so they are considered permanent. Each measure is adequately supported by personnel and program resources for implementation.

What Action is EPA Taking on the VMEP?

The DFW Attainment SIP VMEP meets the criteria for credit in the SIP. The State has shown that the credits are quantifiable, surplus, enforceable, permanent, adequately supported, and consistent with the SIP and the Act. We propose to approve the VMEP portion of the Texas SIP.

Transportation Control Measures (TCMs)

The State has included a variety of TCMs in the SIP as a control strategy for attainment of the ozone NAAQS. The specific TCMs have been described in detail in Appendix G of the SIP and will be incorporated by reference in the Code of Federal Regulations in the final approval action. Detailed information is necessary for those TCMs used as emissions reduction measures in the SIP to ensure that they are specific and enforceable as required by the Act and reflected in our policy. The TCMs' description in the SIP includes identification of each project, location, length of each project (if applicable), a brief project description, implementation date, and emissions reductions for both VOC and NO_X.

The TCMs identified through this process and included in the SIP are contained and funded in the metropolitan transportation plan (MTP) and transportation improvement program (TIP) to ensure funding for implementation. We propose approval of the transportation control measures.

What Are the Projected NO_X reductions From the Federal and State Control Measures and Local Initiatives?

Table 4 provides the projected NO_X reductions for the 2007 attainment year resulting from the Federal and State rules, and the local initiatives.

TABLE 4.—NO_X REDUCTION ESTIMATES
(tons per day)

	Reduction
Federal Measures	
On-road mobile	93.00
Off-road mobile	48.00
Total Federal Measures	141.00
State Measures	
Major point sources	129.00
Inspection/Maintenance	54.45

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TABLE 4.—NO_X REDUCTION ESTIMATES—Continued
(tons per day)

Low emission diesel fuel ...	3.48
HD diesel oper. restrictn (est) ...	2.50
Acc purchase Tier II/III spark ...	13.80
Airport GSE ...	9.54
Heavy equipment gas engines ...	1.80
Gas-fired water heaters, etc ...	0.50
Total State measures	215.07
Local Initiatives	
Speed limit reduction ...	5.42
VMEP (2.4 tpd—5.4 tpd) ...	5.00
TCMs ...	4.73
Total Local Initiatives	15.15
TOTAL NO_X REDUCTIONS ...	371.22

G. Motor Vehicle Emissions Budget

What Is a Motor Vehicle Emissions Budget (MVEB) and Why Is it Important?

The MVEB is the level of total allowable on-road emissions established by a control strategy implementation plan or maintenance plan. In this case, the MVEB establishes the maximum level of on-road emissions that can be produced in 2007, when considered with emissions from all other sources, which demonstrate attainment of the NAAQS. It is important because the MVEB is used to determine the conformity of transportation plans and programs to the SIP, as described by section 176(c)(2)(A) of the Act.

What Are the MVEBs Established by This Plan and Proposed for Approval by This Action?

The MVEBs established by this plan and that the EPA is proposing to approve are contained in Table 5.

TABLE 5.—2007 ATTAINMENT YEAR MOTOR VEHICLE EMISSIONS BUDGETS
(tons per day)

Pollutant	2007
VOC ...	107.60
NO_X ...	164.30

What Is the State's Commitment to Revise the Motor Vehicle Emissions Budgets With MOBILE6?

All States whose attainment demonstration includes the effects of the Tier 2/sulfur program have committed to revise and resubmit their motor vehicle emissions budgets after we release MOBILE6. The State has begun its public comment process on an enforceable commitment and has committed to performing new mobile source modeling for the DFW area, using MOBILE6, within 24 months of the model's release. The public hearing is scheduled for January 4, 2001. In addition, the enforceable commitment includes a provision stating that if a transportation conformity analysis is to be performed between 12 months and 24 months after the release of MOBILE6, transportation conformity will not be determined until the State submits an MVEB which is developed using MOBILE6 and which we find adequate. The North Central Texas Council of Governments and the Department of Transportation have been informed of the commitment.

After adoption by the Commissioners, the Governor of Texas must submit the enforceable commitment to us. If the State fails to meet its commitment to submit revised budgets using MOBILE6, we could make a finding of failure to implement the SIP, which would start a sanctions clock under section 179 of the Act.

What Is the Applicable Budget To Use for Conformity Analysis?

The proposed approval of the MVEB in Table 5 would be effective for conformity purposes only until revised motor vehicle emissions budgets are submitted and we have found them adequate. In other words, the budgets that are part of this attainment demonstration will apply for conformity purposes only until there are new, adequate budgets consistent with the State's commitments to revise the budgets. The revised budgets will apply for conformity purposes as soon as we find them adequate.

We are proposing to limit the duration of our approval in this manner because we are only proposing to approve the attainment demonstrations and their budgets because the States have committed to revise them after we release MOBILE6 and after the State conducts its mid-course review. Therefore, once we have confirmed that the revised budgets are adequate, they will be more appropriate than the budgets we are proposing to approve for conformity purposes now.

If the budgets we propose to approve raise issues about the sufficiency of the attainment demonstration, we will work with the State. If the revised budgets show that motor vehicle emissions are lower than the budgets we approve, a reassessment of the attainment demonstration's analysis will be necessary.

This action does not propose any change to the existing transportation conformity rule or to the way it is normally implemented with respect to other submitted and approved SIPs, which do not contain commitments to revise the budget.

H. EPA's Analysis

Did the State Adequately Document the Techniques and Data Used To Derive the Modeling Input Data and Modeling Results?

Yes, the submittal from the State thoroughly documented the techniques and data used to derive the modeling input data. The submittal adequately summarized the modeling outputs and the conclusions drawn from these model outputs. The submittal adequately documented the State's weight-of-evidence determinations and the bases for concluding that these determinations support the attainment demonstration.

Did the Modeling Procedures and Input Data Used Comply With the Environmental Protection Agency Guidelines and Clean Air Act Requirements?

Yes, the modeling procedures and input data (including the emissions inventory inputs and procedures) meet the requirements of the Act and are consistent with our July 1991 and June 1996 ozone modeling guidelines.

Does the Emission Control Strategy Meet the Requirements of the Clean Air Act?

Yes, the selected emission control strategy, based upon modeling and the WOE techniques, plus additional information regarding the effect of HGA upon DFW, demonstrates attainment of the 1-hour ozone standard in DFW.

Does the Weight-of-Evidence Support the Attainment Demonstration?

Yes, the submittal adequately documented the State's WOE determinations and the bases for concluding that these determinations adequately complement the attainment demonstration.

The WOE, when viewed in aggregate with the modeling, shows attainment of the standard and thus we are proposing approval.

Has the State Adopted the Selected Emission Control Strategy and Has the State Adopted the Emission Control Regulations Needed to Implement the Emission Control Strategies?

Yes, the State has adopted and submitted the emission control strategies and all associated emission control regulations, orders, and the TCMS, Speed Limit Reductions, and the VMEP initiatives.

Has the State Adopted all Local Measures Required by the Clean Air Act for the Area's Current Ozone Classification?

Yes, the State has adopted all VOC and NO_X emission control requirements required under the Clean Air Act (Act) for a serious ozone nonattainment area. Please see the TSD for a listing of requirements and the dates they were satisfied.

It is our position that the State of Texas has met the 1998 Transport Policy's criteria for adoption and submittal to EPA for approval of all measures required under the Act for an area classified as serious.

Has the State Implemented all Reasonably Available Control Measures?

Yes. Section 172(c)(1) of the Act requires SIPs to provide for the implementation of all reasonably available control measures (RACM) as expeditiously as practicable and for attainment of the standard. We have previously provided guidance interpreting the RACM requirements of 172(c)(1) in the General Preamble. See 57 FR 13498, 13560 (April 16, 1992). In the General Preamble, we indicated our interpretation of section 172(c)(1), under the 1990 amendments, as imposing a duty on States to consider all available control measures and to adopt and implement such measures as are reasonably available for implementation in the particular nonattainment area. We also retained our pre-1990 interpretation of the RACM provisions that where measures that might in fact be available for implementation in the nonattainment area could not be implemented on a schedule that would advance the date for attainment in the area, we would not consider it reasonable to require implementation of such measures. We indicated that States could reject certain RACM measures as not reasonably available for various reasons related to local conditions. A State could include area-specific reasons for rejecting a measure as RACM, such as the rejected measure would not advance the attainment date, or technological and economic feasibility in the area.

We also issued a recent memorandum reaffirming our position on this topic, "Guidance on the Reasonably Available Control Measures (RACM) Requirement and Attainment Demonstration Submissions for Ozone Nonattainment Areas." John S. Seitz, Director, Office of Air Quality Planning and Standards, dated November 30, 1999. A copy can be obtained from *www.epa.gov/ttn/oarpg/t1pgm.html*. In this memorandum, we state that in order to determine whether a state has adopted all RACM necessary for attainment and as expeditiously as practicable, the state will need to provide a justification as to why measures within the arena of potential reasonable measures have not been adopted. The justification would need to support that a measure was not reasonably available for that area and could be based on technological or economic grounds.

We reviewed additional potential available measures, as documented in the RACM analysis in the TSD (Appendix C) for this proposed rulemaking. Our analysis showed that the State is already controlling the significant major point sources and area sources to RACM levels and the SIP contains the transportation control measures reviewed nationally, as well as a motor vehicle Inspection and Maintenance program. Based on this analysis, we propose to conclude that any remaining evaluated measures are not reasonably available for the specific DFW area, because (a) some would require an intensive and costly effort for numerous small area sources or transportation control measures, and (b) since the DFW area relies in part on reductions from the upwind HGA area which are substantial, and the reductions projected to be achieved by the evaluated additional set of measures are relatively small, they would not produce emission reductions sufficient to advance the attainment date in the DFW area and, therefore, should not be considered RACM.

Although we encourage areas to implement available RACM measures as potentially cost effective methods to achieve emissions reductions in the short term, we do not believe that section 172(c)(1) requires implementation of potential RACM measures that either require costly implementation efforts or produce relatively small emissions reductions that will not be sufficient to allow the DFW area to achieve attainment in advance of full implementation of all other required measures.

Has the State Established an Acceptable MVEB?

The MVEB budget submitted by the State for the DFW area is adequate and is consistent with all pertinent SIP requirements, and the MVEB is proposed for approval.

Does the DFW Area Meet the RACT Requirements for Major Source VOC Emissions?

On March 7, 1995, as part of our action approving VOC requirements, we found that the State had implemented RACT on all major sources in the DFW area except those that were to be covered by post-enactment Control Technique Guidelines (CTG's) (44 FR 12438). Since that time many expected CTGs were issued as Alternative Control Technique documents—ACTs. Of the expected CTGs and ACT's, DFW had major sources in the following categories; batch processing, reactors and distillation, wood furniture and aerospace coating. We have approved measures for all of these categories as meeting RACT. (*See* the TSD for this action for dates.)

With regard to Aerospace coatings, we have approved Alternate RACT determinations for the major sources in the DFW area: Lockheed-Martin, Bell Helicopter Textron, and Raytheon Texas Instruments Systems, Inc. January 20, 1994 (*See* 59 FR 02532), May 30,1997 (*See* 62 FR 29297), and February 9, 1998 (*See* 63 FR 6491), respectively. With these Alternative RACT determinations, we concluded that RACT was in place for these Aerospace coating sources. On March 27, 1998, we published the National Emission Standards for Hazardous Air Pollutants (NESHAP) final rule and the Control Technique Guideline for Aerospace Manufacturing and Rework facilities. (*See* 63 FR 15006). The State submitted revisions to its coating rules on July 13, 2000 to ensure the control requirements for Aerospace companies remained consistent with the NESHAP rule. At the same time, the State requested that these replace the Alternative-RACT plans as a part of the Texas SIP. The revised 2000 aerospace rules provide provisions that are more consistent with the new MACT standards and we anticipate that we will propose approval of these provisions. In the mean time, we believe the previously approved alternative RACT plans continue to meet the RACT requirements for these three sources.

Also, with the reclassification of the DFW area to serious, the major source size was decreased to 50 tons per year. This necessitated that the State revise its rules for bakeries and adopt rules for the large offset lithographers category. We have approved the rule revisions for bakeries and the new rules for offset lithographers as meeting the RACT requirements. (*See* TSD for dates and cites).

Thus, it is our position that RACT is in place for all major sources of VOCs in the DFW area.

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Was the Demonstration of Transport From the HGA Area Acceptable To Support the Request for Extension of the Attainment Date?

The policy for the extension of an ozone attainment date is discussed in the **BACKGROUND** section of this notice. The State's compliance with these requirements is discussed here.

a. Identification of the area as a downwind area affected by ozone transport.

We have reviewed the photochemical modeling demonstrations, and are proposing to agree with the State that the July 3, 1996, episode adequately demonstrates transport of pollutants from the HGA area. We are proposing that this transported pollution affects DFW's ability to attain by the current attainment date. Thus, the DFW and HGA areas are inextricably linked. Without controls in the HGA area, the DFW area's ability to attain is jeopardized. We, therefore, propose to find that the State's demonstration of ozone transport meets the criteria in our attainment date extension policy.

b. Submittal of an approvable attainment demonstration.

EPA's review of the attainment demonstration SIP shows that it should be approved. The State has modeled and adopted an acceptable control strategy that demonstrates attainment. We are proposing to approve the attainment demonstration SIP, and to agree that it meets the criteria in the July 1998 transport policy and all other EPA guidance and the regulatory and statutory requirements.

c. Adoption of all applicable local measures required under the area's current ozone classification.

Texas has adopted all VOC and NO_X related emission control requirements required by the Act for a serious ozone nonattainment area. A listing of applicable CAA serious classification-related VOC and NO_X related regulations and their state-adopted dates for the DFW area, is provided in the TSD to this rulemaking.

It is our position that the State of Texas has met the 1998 Transport Policy's criteria for adoption and submittal of all measures required under the Act for an area classified as serious. We must finalize approval actions upon the remaining serious area requirements—the 15% ROP Plan, the Post-96 ROP Plan, the I/M SIP, and the Clean-fuel Vehicle SIP, before we can make a final finding that the DFW area is meeting all of its classification's statutory requirements, however.

d. Implementation of all adopted measures by the time upwind controls are expected.

All of the NO_X and VOC rules will be implemented as expeditiously as practicable, but no later than 2005, two years before the HGA attainment date of November 15, 2007.

We are proposing to find that this transport policy criteria has been met by the State. We are of the opinion that the phase-in compliance dates are as expeditious as practicable compared with the compliance dates of similar sources in serious ozone nonattainment areas of the country.

II. Post 1996 Rate of Progress Plan

A. Proposed Action

What Action Are We Taking?

We are proposing approval of the Post 1996 Rate of Progress (ROP) plan (9% plan), submitted by the Governor on October 25, 1999, which is designed to reduce ozone forming emissions from the baseline emissions by 9% in the DFW nonattainment area for the years 1997–1999. This plan meets the Reasonable Further Progress requirements of the Act (section 182(c)(2)). In addition, we are proposing to approve the MVEBs associated with the 9% plan. We are also proposing to approve the changes to the 1990 base year emissions inventory for the DFW area. The SIP was submitted October 25, 1999, and found complete January 6, 2000.

B. Calculation of Requirements

How Do we Calculate the Needed VOC Emissions Reductions?

Calculating the needed emission reductions is a multi-step process as described below.

Emissions Inventory: The 1990 Final Base Year Inventory is the starting point for calculating the reductions necessary to meet the requirements of the 1990 Act. The 1990 Final Base Year Inventory includes all area, point, non-road mobile, and on-road mobile source emissions in the four county DFW ozone nonattainment area. The 1990 base year inventory was originally approved November 8, 1994 (59 FR 55586). The State revised the VOC inventory on August 8, 1996. These changes were approved November 10, 1998 (63 FR 62943). The state revised the 1990 base year VOC inventory again with the October 25, 1999, SIP revision. The October 25, 1999, SIP revision also contained the State's first revisions to the 1990 base year NO_X emissions inventory. The changes resulted from data gathered for the 1993 and 1996 periodic inventories. Analysis of the changes in the periodic inventories was backcast to the 1990 inventory for consistency since the 1990 inventory remains the ROP beginning point. We have reviewed the inventory revisions and they have been developed in accordance with our guidance on emission inventory preparation. Thus, we are proposing approval of the October 25, 1999, revisions to the 1990 base year inventory. The revised 1990 base year inventory is summarized in Table 6. For more detail on how emissions inventories were estimated, see Appendix H in the TSD for this action.

TABLE 6.—1990 RATE-OF-PROGRESS BASE YEAR EMISSIONS INVENTORY
(tons per day)

Base year inventory		
Source type	VOC	NO_X
Point	63.98	71.76
Area	174.02	19.99
On-road Mobile	306.60	293.03
Non-road Mobile	105.19	166.05
Total	649.79	550.83

Adjusted Base Year Inventory: Section 182(b)(2)(C) explains that the baseline from which emission reductions are calculated should be determined as outlined in section 182(b)(1)(B) for 15% ROP plans. This requires that the baseline exclude emission reductions due to Federal Motor Vehicle Control Programs (FMVCP) promulgated by the Administrator by January 1, 1990, and emission reductions due to the regulation of Reid Vapor Pressure promulgated by the Administrator prior to the enactment of the Clean Air Act Amendments of 1990. These measures are not creditable to the Rate of Progress Plans.

Growth Estimates: States need to provide sufficient control measures in their ROP plans to offset any emissions growth. To do this the State must estimate the amount of growth that will occur. The State uses population and economic forecasts to estimate how emissions will change in the future. Generally, the State followed our standard guidelines in estimating the growth in emissions. For the projection of NO_X emissions from industrial sources, the State used data collected during the development of the 1996 periodic emissions inventory. With the 1996 periodic inventory, Texas surveyed industry to determine why emissions were changing, to determine if changes were actual changes in emissions to the atmosphere, or just changes in the emission estimation methodology. For example, many sources installed continuous emission monitors between 1990 and 1996, and actual measurements replaced engineering estimates. For more detail on how emissions growth was estimated, see Appendix H in the TSD for this action.

Calculation of Target Level: Table 7 shows how the emissions inventory, adjusted inventories and growth estimates are used to calculate the target levels of emissions and needed emission reductions.

TABLE 7.—CALCULATION OF REQUIRED VOC REDUCTIONS
(tons per day)

1990 Emission Inventory	649.79
1990 Adjusted Relative to 1996	547.54
1990 Adjusted Relative to 1999	535.78
RVP and Fleet Turnover	11.76
9% of 1990 Adjusted Relative to 1999	48.22
1996 Target level	465.52
1999 Target level	405.54
1999 Projection	575.28
Total Reductions required by 1999	169.74
Reductions required by 15%	139.98
Additional Reductions Required	29.76

How Are Those Emission Reductions Achieved?

Table 8 documents how the VOC emission reductions for this 9% plan are to be achieved. The following control measures are used: Aircraft Engines, Transportation Control Measures (TCMs), Windshield washer fluid, Utility Engines 1997—1999, Underground Storage Tank Remediation, vehicle Tier 1, vehicle Inspection/Maintenance, and RFG.

The State also revised its estimates of on-road motor vehicle emissions based on vehicle registration data updated to 1998. We are proposing to find them acceptable.

The State included a variety of TCMs in the SIP as a control strategy for attainment of the ozone NAAQS. The specific TCMs are described in detail in Appendix G of the SIP and will be incorporated by reference in Code of Federal Regulations in the final approval action. Please refer to the detailed discussion of TCM requirements under *Transportation Control Measures* in the Emission Control Strategy sub-section (sub-section I.E) of this action.

The TCMs identified through this process and included in the SIP are contained and funded in the metropolitan transportation plan (MTP) and transportation improvement program (TIP) to ensure funding for implementation.

Please refer to the TSD for details of our analysis of the control measures and our basis for proposing to find the projected emission reductions from these measures acceptable.

TABLE 8.—SUMMARY OF VOC EMISSION REDUCTIONS
(tons per day)

Required Reduction	29.76
Creditable Reductions	
Aircraft Engines	1.52
TCMs	3.74
Windshield washer fluid	0.29
1998 vehicle registration	3.57
Utility Engine 1997–1999	2.37
UST remediation	1.81
Tier 1, I/M, RFG	16.82
Total	30.12

Does the Plan Achieve the Goal of a 9% Reduction in VOCs From the Baseline for 1997 to 1999?

Yes. Since the required reductions are 29.76 tons per day and the creditable reductions are 30.12 tons per day, the plan has excess reductions of 0.36 tons per day and achieves the goal; therefore, we are proposing approval of the Post 1996 ROP Plan.

Did the State Submit Additional Reductions?

Yes. The State also submitted NO_X reductions. The State's basic NO_X RACT rules were approved September 1, 2000. See 65 FR 53172. We are accepting the State's NO_X reductions as creditable reductions.

TABLE 9.—SUMMARY OF NO_X EMISSION REDUCTIONS
(tons per day)

Required Reduction	0.00
Creditable Reductions	
NO_X RACT	10.45
RFG, I/M, FMVCP Tier I	56.25
Off-road heavy duty diesel	11.98
Total	78.68

C. Motor Vehicle Emissions Budget

What Are the MVEBs Established by This Plan and Approved by This Action?

The MVEBs established by this plan and that we are proposing to approve are contained in Table 10. The MVEBs have been found to meet the adequacy criteria and upon further review of the SIP for approvability continue to be consistent with ROP.

TABLE 10.—1999 9% ROP SIP MOTOR VEHICLE EMISSIONS BUDGETS
(tons per day)

Pollutant	1999
VOC	147.22
NO_X	284.14

III. 15% Rate of Progress Plan

Proposed Action

What Action Are We Taking?

We are proposing full approval of the 15% plan submitted on August 8, 1996, contingent upon us finalizing approval of the State's I/M program for the DFW area. The 15% plan was given conditional, interim approval on November 10, 1998, pending corrections to the DFW I/M program. It was given conditional, interim approval because it relied on emissions reductions from the I/M program that received conditional, interim approval. For further information on the I/M conditional, interim approval, see 62 FR 37138, published on July 11, 1997. We found that the State had met the conditions of the conditional approval. On April 23, 1999, we removed the conditions and granted Texas a final interim approval. See 64 FR 19910. The interim approval expired on February 11, 1999. Texas has submitted significant revisions to the I/M program for the DFW area. The revisions expand the program from the 2 core nonattainment counties to the 4 counties in the nonattainment area plus 5 additional counties. We are taking a separate action on these I/M revisions. Because the revisions appear to have eliminated the last impediment to full approval of the I/M program for the DFW area, we are proposing full approval of the DFW 15% plan. This proposed full approval of the DFW 15% plan will not be finalized until action on the I/M program is complete. If the I/M program is disapproved, a different action on the 15% plan will have to be taken. See 63 FR 62943 and the 15% plan TSD for additional information on the DFW 15% plan.

How Did the Inspection/Maintenance Program Submitted With the Attainment Demonstration Purport To Cure the Previous Deficiencies?

As stated previously, an interim conditional approval for the Motorist Choice Program was proposed on October 3, 1996 (61 FR 51651). An interim final conditional approval was published on July 11, 1997 (62 FR 37138). The conditions were removed from the interim approval on April 23, 1999 (64 FR 19910). The interim

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approval status of this program lapsed on February 11, 1999.

The State submitted an approvable 18-month demonstration on February 8, 1999, as required by the National Highway System Designation Act of 1995, Public Law 104–59, section 348(c)(1). The program was not fully approved at that time because one provision of the interim approval remained: that the State provide evidence that the remote sensing program was effective in identifying the shortfall in number of vehicles needed to make up for the lack of a tailpipe testing program in all the nonattainment counties. This evidence has yet to be submitted.

Modeling has since shown that NO_X reductions are essential to reaching attainment in the DFW area. As a result, the Texas Motorist Choice I/M program has been revised to include measurement for NO_X emissions and to provide additional NO_X emission reductions by expanding coverage of the program to all four counties within the DFW nonattainment area (Dallas, Tarrant, Collin and Denton) and selected attainment counties in the DFW consolidated metropolitan statistical area (Ellis, Johnson, Parker, Rockwall, and Kaufman). By revising the program to expand area coverage for NO_X SIP credits, the deficiency that prohibited full approval in DFW appears to be cured. All DFW nonattainment counties will be participating in the full program. As indicated above, we have not taken a final action on the I/M submittal. We will be seeking comment on the I/M program in a separate action.

IV. Background

A. The Relevant Clean Air Act Requirements

The Act requires us to establish National Ambient Air Quality Standards (NAAQS) for certain widespread pollutants that cause or contribute to air pollution that is reasonably anticipated to endanger public health or welfare (Clean Air Act sections 108 and 109). In 1979, we promulgated the 1-hour ground-level ozone standard of 0.12 parts per million (ppm) (120 parts per billion (ppb)). 44 FR 8202 (February 8, 1979).

Ground-level ozone is not emitted directly by sources. Rather, Volatile Organic Compounds (VOC) and Nitrogen Oxides (NO_X), emitted by a wide variety of sources, react in the presence of sunlight to form ground-level ozone. NO_X and VOC are referred to as precursors of ozone.

Ozone formation is accelerated or enhanced under certain meteorological conditions, such as high temperatures and low wind speeds. Higher ozone concentrations occur downwind of areas with relatively high VOC and NO_X concentrations or in areas subject to relatively high background ozone and ozone precursor concentrations (ozone and ozone precursors entering an area as the result of transport from upwind source areas).

VOC emissions are produced by a wide variety of sources, including stationary and mobile sources. Significant stationary sources of VOC include industrial solvent usage, various coating operations, industrial and utility combustion units, petroleum and oil storage and marketing operations, chemical manufacturing operations, personal solvent usage, etc. Significant mobile sources of VOC include on-road vehicle usage and off-road vehicle and engine usage, such as farm machinery, aircraft, locomotives, and motorized lawn care and garden implements.

NO_X emissions are produced primarily through combustion processes, including industrial and utility boiler use, process heaters and furnaces, and on-road and off-road mobile sources.

An area exceeds the 1-hour ozone standard each time an ambient air quality monitor records a 1-hour average ozone concentration above 124 ppb in any given day (only the highest 1-hour ozone concentration at the monitor during any 24 hour day is considered when determining the number of exceedance days at the monitor). An area violates the ozone standard if, over a consecutive 3-year period, more than 3 days of exceedances are expected to occur at any monitor in the area. 40 CFR Part 50, App. H.

The highest of the fourth-highest daily peak ozone concentrations over the 3 year period at any monitoring site in the area is called the ozone design value for the area. The Act, as amended in 1990, required EPA to designate as nonattainment any area that was violating the 1-hour ozone standard, generally based on air quality monitoring data from the 1987 through 1989 period. Clean Air Act section 107(d)(4); 56 FR 56694 (November 6, 1991). The Act further classified these areas, based on the areas' ozone design values, as marginal, moderate, serious, severe, or extreme.

The control requirements and date by which attainment is to be achieved vary with an area's classification. Marginal areas were subject to the fewest mandated control requirements and had the earliest attainment date, November 15, 1993. Severe and extreme areas are subject to more stringent planning requirements but are provided more time to attain the standard. Moderate areas were required to attain the 1-hour standard by November 15, 1996. Serious areas were required to attain by November 15, 1999, and severe areas are required to attain by November 15, 2005 or November 15, 2007, depending on the areas' ozone design values for 1987 through 1989. The DFW ozone nonattainment area was initially classified as "moderate" (56 FR 56694) with an attainment date of November 15, 1996. Since the area did not attain the standard by November 15, 1996, we reclassified the area to "serious" on March 20, 1998 (63 FR 8128). The statutory attainment date for a serious area is November 15, 1999. The DFW ozone nonattainment area contains Dallas, Tarrant, Collin, and Denton Counties (40 CFR 81.314 and 81.326).

The specific requirements of the Act for serious ozone nonattainment areas are found in part D, section 182(c) of the Act. Section 172 in part D provides the general requirements for nonattainment plans. Section 172(c)(6) and section 110 require SIPs to include enforceable emission limitations, and such other control measures, means or techniques as well as schedules and timetables for compliance, as may be necessary to provide for attainment by the applicable attainment date. Section 172(c)(1) requires the implementation of all reasonably available control measures as expeditiously as practicable and requires the SIP to provide for attainment of the NAAQS. Section 182(b)(1)(A) requires the SIP to provide for a 15% Rate of Progress Plan and also provide for specific annual reductions in emissions of VOC and NO_X "as necessary to attain" the ozone NAAQS by the applicable attainment date. Our "General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990" (57 FR 13498 dated April 16, 1992) provides the interpretive basis for EPA's rulemakings under the nonattainment plan provisions of the Act (General Preamble). Section 182(c)(2)(A) requires that a serious area use photochemical grid modeling or any other methods judged by us to be at least as effective, to demonstrate attainment of the ozone NAAQS by the applicable attainment date. In the General Preamble, we provide that this requirement for demonstrating attainment may be met by the use of EPA-approved modeling techniques.

Section 182(c)(2)(B) of the Act requires each serious and above ozone nonattainment area to submit a SIP revision by November 15, 1994, which describes, in part, how the area will achieve an actual volatile organic compound (VOC) (and NO_X if required) emission reduction from the baseline emissions of at least 3 percent of baseline emissions per year averaged over each consecutive 3-year period beginning 6 years after enactment (*i.e.*, November 15, 1996) until the area's attainment date. The plan providing for the reduction between November 1996 and November 1999 is referred to as the 9% Plan, the Post-1996 ROP Plan. As part of today's proposal, we are proposing action on the 15% ROP Plan, the 9% ROP Plan, and the attainment demonstration SIP revision submitted by the State of Texas for the DFW serious ozone nonattainment area.

B. Dates of State's SIP Submissions

As a result of the reclassification to serious, the State was required to submit both an attainment demonstration SIP with an attainment date of November 15, 1999; and a Rate of Progress SIP covering the years from November 15, 1996 to November 15, 1999. The State submitted those SIPs on March 19, 1999. The State had previously submitted the moderate area 15% ROP plan on August 8, 1996, before the area was reclassified to serious. The 15% plan was given conditional, interim approval.

Our review showed that the attainment demonstration SIP submitted in 1999 did not contain a control strategy or adopted measures to implement the strategy and the 1999 Post-1996 ROP SIP did not achieve the required 9% reduction in emissions for the time period. Therefore, we found both SIPs incomplete and started sanctions and Federal Implementation plan (FIP) clocks effective May 13, 1999.

A new Post-1996 ROP SIP was submitted October 25, 1999, and was found complete on December 16, 1999, since the new plan contained additional VOC reductions to meet the 9% requirement. The new attainment demonstration SIP was submitted April 25, 2000, and was found complete on June 23, 2000, because it contained a modeled control strategy and adopted regulations to implement the strategy. These two completeness findings stopped the sanctions clocks. The FIP clock continues to run unless and until we approve the 9% ROP Plan and the Attainment Demonstration SIP. Section 110(c)(1)(A) requires EPA to promulgate a FIP for the DFW nonattainment area by May 14, 2001 if we have not approved the SIPs by that time.

C. General Requirements for an Attainment Demonstration and its Motor Vehicle Emissions Budgets

In general, an attainment demonstration SIP includes a modeling analysis showing how an area will achieve the standard by its attainment date and the emission control measures necessary to achieve attainment. The attainment demonstration SIP must include MVEBs for transportation conformity purposes. Transportation conformity is a process required by Section 176(c) of the Act for ensuring that the effects of emissions from all on-road sources are consistent with attainment of the standard. Ozone attainment demonstrations must include the estimates of motor vehicle VOC and NO_X emissions that are consistent with attainment, which then act as a budget or ceiling for the purposes of determining whether transportation plans, programs, and projects conform to the attainment SIP.

D. Ozone Transport Policy and Attainment Date Extensions

The DFW area is classified as serious and, therefore, was required to attain the 1-hour ozone standard by November 15, 1999. The State of Texas, in submitting the April 2000 attainment demonstration SIP, requests an extension of the attainment date to November 15, 2007, based on our July 1998 transport policy.

In developing the attainment demonstration for DFW, the State makes the case that the 1998 Transport Policy is particularly relevant to DFW, which is downwind of the HGA area, and that the DFW area is affected by transport from HGA. If we approve of such a determination for DFW, the area would have until no later than November 15, 2007, the attainment date for HGA, to attain the 1-hour ozone standard.

In the DFW ozone attainment demonstration SIP reviewed here, the State also relies, in part, on regional and statewide NO_X emission reductions in Texas, including the upwind HGA area and eastern and central Texas. The SIP also relies on NO_X reductions from the NO_X SIP Call States where appropriate.

Attainment Demonstration SIPs were originally due November 1994. However, through a series of policy memoranda, we recognized that States had not submitted these attainment demonstrations and were constrained to do so until ozone transport had been further analyzed. One of the policy memoranda addressing the issue of ozone transport is the transport policy issued by us July 16, 1998, entitled "Extension of Attainment Dates for Downwind Transport Areas". That memorandum included our interpretation of the Act regarding the extension of attainment dates for ozone nonattainment areas that have been classified as moderate or serious for the 1-hour ozone standard and which are downwind of areas that have interfered with their ability to demonstrate attainment of the ozone standard by dates prescribed in the Act. That memorandum stated that we will consider extending the attainment date for an area or a State that:

(1) Has been identified as a downwind area affected by transport from either an upwind area in the same State with a later attainment date or an upwind area in another State that significantly contributes to downwind ozone nonattainment;

(2) Has submitted an approvable attainment demonstration with any necessary, adopted local measures and with an attainment date that shows it will attain the 1-hour standard no later than the date that the emission reductions are expected from upwind areas under the final NO_X SIP call and/or the statutory attainment date for upwind nonattainment areas, *i.e.*, assuming the boundary conditions reflecting those upwind emission reductions;

(3) Has adopted all applicable local measures required under the area's current ozone classification and any additional emission control measures demonstrated to be necessary to achieve attainment, assuming the emission reductions occur as required in the upwind areas; and

(4) Has provided that it will implement all adopted measures as expeditiously as practicable, but no later than the date by which the upwind reductions needed for attainment will be achieved.

Once an area receives an extension of its attainment date based on ozone/precursor transport impacts, the area would no longer be subject to reclassification to a higher ozone nonattainment classification based on its original attainment date. If the DFW area is granted an attainment date extension, it would no longer be subject to a reclassification to severe nonattainment for ozone and no longer subject to the additional emission control requirements that would result from the reclassification to severe nonattainment based on a failure to attain by its original attainment date.

Texas has requested an extension of the attainment date for the DFW nonattainment area in conjunction with the ozone attainment demonstration submittals. The ozone attainment

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demonstration SIP uses November 15, 2007 as the ozone attainment date. The chosen 2007 attainment date reflects the statutory attainment date for the HGA area, as the DFW area is downwind of the HGA area and is affected by transport from HGA.

V. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. This proposed action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this proposed rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The proposed rule does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This proposed rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Attainment, Hydrocarbons, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 4, 2001.

Gregg A. Cooke,

Regional Administrator, Region 6.

[FR Doc. 01–1346 Filed 1–17–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 123

[FRL–6933–3]

Water Pollution Control; Program Modification Application by South Dakota To Administer the Sludge Management (Biosolids) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; second notice of application and public comment period.

SUMMARY: The State of South Dakota has submitted an application to EPA to revise the existing South Dakota Pollutant Discharge Elimination System (SDPDES) program to include administration and enforcement of the sludge management (biosolids) program. According to the State's proposal dated March 23, 1998, this program would be administered by the South Dakota Department of Environment and Natural Resources (SDDENR).

The application was described in a **Federal Register** notice dated October 5, 2000 (65 FR 59385) and in notices published in the Rapid City Journal and the Sioux Falls Argus-Leader on October 20, 2000. Notices were mailed to persons known to be interested in such matters, including all persons on appropriate State and EPA mailing lists and all permit holders and applicants within the State. There were no comments received during the public comment period. The **Federal Register** notice provided for a 45–day comment period but did not state that a public hearing could be requested and would be considered by EPA. Therefore, EPA is extending the public comment period.

The application from South Dakota is complete and is available for inspection and copying. EPA has reviewed the State's request for delegation for completeness and adequacy and has found that the proposal meets Federal equivalency regulations.

DATES: Comments on this proposed rule received on or before March 5, 2001 will be considered before issuing a final rule. Comments postmarked after this date may not be considered.

ADDRESSES: You can view and copy South Dakota's application for modification from 8:00 a.m. until 5:00 p.m. Monday through Friday, excluding holidays, at the South Dakota Department of Environment and Natural Resources; Joe Foss Building, Pierre, South Dakota or at the EPA Regional Office at 999 18th Street, Denver, Colorado. Requests for copies should be addressed to Kelli Buscher, South Dakota Department of Environment and Natural Resources at the above address or at telephone number 605–773–3351. (There will be a $15 charge for copies.) Electronic comments are encouraged and should be submitted to brobst.bob@epa.gov or send written comments to Robert Brobst, U.S. EPA/8P–WP, 999 18th Street, Suite 300, Denver, Colorado 80202–2466.

FOR FURTHER INFORMATION CONTACT: Robert Brobst at the above address by phone at (303) 312–6129, or by e-mail at *brobst.bob@epa.gov*.

SUPPLEMENTARY INFORMATION: Section 405 of the Clean Water Act (CWA), 33 U.S.C. Section 1345, created the sludge management program, allowing EPA to issue permits for the disposal of sewage sludge under conditions required by the CWA. Section 405(c) of the CWA provides that a state may submit an application to EPA for administering its own program for issuing sewage sludge permits within its jurisdiction. EPA is required to approve each such submitted state program unless EPA determines that the program does not meet the requirements of Sections 304(i) and/or 402(b) of the CWA or the EPA regulations implementing those sections.

South Dakota's application for sludge management program approval contains a letter from the Governor requesting program approval, an Attorney General's Statement, copies of pertinent State statutes and regulations, amendments to the SDPDES Program Description, and amendments to the SDDENR/EPA Memorandum of Agreement (MOA) executed by the Regional Administrator, Region 8, EPA, and the Secretary, Department of Environment and Natural Resources.

The State of South Dakota has existing environmental self-evaluation laws and rules. These provide evidentiary privilege and limited immunity for certain disclosures made in an environmental self-evaluation. SDCL section 1–40–35 provides that no privilege or immunity exists for information required to be collected, developed, maintained, or reported to the department according to State law, rule, regulation, or permit.

South Dakota has incorporated Federal sludge management regulations by reference into its State rules. These rules require record keeping and reporting for certain technical monitoring and assessment, management practices, and certain certifications of compliance. Because these requirements and any requirement in sludge permits would be excluded from the self-evaluation privilege, EPA believes that South Dakota has the authority necessary to administer the sludge management program to assure protection of public health and the environment, and invites comment on this issue.

EPA discussed the SDDENR program application with the South Dakota Office of the U.S. Fish and Wildlife Service and received their concurrence dated June 29, 2000 stating that the proposed program authorization was unlikely to jeopardize the continued existence of any endangered species or threatened species, or result in the destruction or adverse modification of habitat of such species.

By Letter dated October 20, 1999, EPA discussed the program application with the South Dakota State Historic Preservation Officer and received concurrence by letter dated November 5, 1999. The State Historic Preservation Officer determined that no historic properties would be affected by the addition of the biosolids program.

What are biosolids? Biosolids are, in effect, a slow release nitrogen fertilizer with low concentrations of other plant nutrients. In addition to significant amounts of nitrogen, biosolids also contain phosphorus, potassium, and essential micronutrients such as zinc and iron. Many western soils are deficient in micronutrients. Biosolids are rich in organic matter that can improve soil quality by improving water holding capacity, soil structure and air and water transport. Proper use of biosolids can ultimately decrease topsoil erosion. When applied at agronomic rates (the rates at which plants require nitrogen during a defined growth period), biosolids provide an economic benefit in addition to their environmental benefits.

How do biosolids differ from sewage sludge? Most simply, biosolids is the new name for what had previously been referred to as sewage sludge. Biosolids are primarily treated organic solids at wastewater treatment plants—with the emphasis on the word treated—that are suitable for recycling as a soil amendment. Sewage sludge now refers to untreated primary and secondary organic solids. This differentiates biosolids that have received stabilization treatment at a municipal wastewater treatment plant from other types of existing sludge (such as oil and gas field wastes) that cannot be beneficially recycled as soil amendments.

What are the traditional practices in this region? Until 25 years ago, the traditional practice in this Region was to landfill or incinerate what was then called sewage sludge. During the past quarter century the practice changed to recycling biosolids as soil amendments. States in Region 8 recycle 85% of the biosolids generated in the six state Region.

What Are the Federal Requirements?

The EPA in 1993 set forth requirements for management of all biosolids generated during the process of treating municipal wastewater, commonly called the 503 rule. The 503 rule encourages the beneficial reuse of biosolids, and establishes strict standards under which wastewater residuals can be beneficially recycled as soil amendments. The EPA believes that biosolids are an important resource that can and should be safely recycled. The 503 rule is designed to protect public health and the environment. Most of the requirements were based on the results of extensive multimedia risk assessment and on more that 25 years of independent research. The 503 rule establishes standards for pathogen destruction and for levels of metals that can be present in biosolids. It also governs the agricultural practices, site restrictions, and crop harvesting restrictions and the stability of the materials by reducing the attraction of disease vectors (such as flies).

Indian Country

South Dakota is not authorized to carry out its Biosolids program in Indian Country, as defined in 18 U.S.C. 1151. This includes, but is not limited to: Lands within the exterior boundaries of the following Indian reservations located within the State of South Dakota:

A. Cheyenne River Indian Reservation,
B. Crow Creek Indian Reservation,
C. Flandreau Indian Reservation,
D. Lower Brule Indian Reservation,
E. Pine Ridge Indian Reservation,
F. Rosebud Indian Reservation,
G. Standing Rock Indian Reservation, and
H. Yankton Indian Reservation.

EPA held a public hearing on December 2, 1999, in Badlands National Park, South Dakota, and accepted public comments on the question of the location and the extent of Indian Country within the State of South Dakota. In a forthcoming **Federal Register** notice, EPA will respond to the comments that have been received and more specifically identify Indian Country areas in the State of South Dakota.

Public Notice Procedures

Copies of all submitted statements and documents shall become a part of the record submitted to EPA. All comments or objections presented in writing to EPA Region 8 and postmarked within 45 days of this notice will be considered by EPA before it takes final action on South Dakota's request for program modification approval. All written comments and questions regarding the sludge management program should be addressed to Robert Brobst at the above address. The public is also encouraged to notify anyone who may be interested in this matter. A public hearing may be requested. A public hearing will be held if response to this notice indicates significant public interest.

EPA's Decision

EPA will consider and respond to all significant comments received before taking final action on South Dakota's request for Sludge program approval. If no substantial comments are received,

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EPA will approve South Dakota's sludge management program. The decision will be based on the requirements of Sections 405, 402 and 304(i) of the CWA and EPA regulations promulgated thereunder.

If the South Dakota program modifications are approved, EPA will so notify the State and anyone who has submitted significant comments. Notice will be published in the **Federal Register** and, as of the date of program approval, EPA will suspend issuance of federal NPDES sludge management permits in South Dakota (except, as discussed above, for those dischargers in "Indian Country"). The State's program will operate in lieu of the EPA-administered program. However, EPA will retain the right, among other things, to object to SDNPDES permits proposed by South Dakota and to take enforcement actions for violations, as allowed by the CWA.

If EPA disapproves South Dakota's sludge management program, EPA will notify the State and anyone who submitted significant comments of the reasons for disapproval and of any revisions or modifications to the State program that are necessary to obtain approval.

Regulatory Flexibility Act

Based on General Counsel Opinion 78–7 (April 18, 1978), EPA has long considered a determination to approve or deny a State NPDES program submission to constitute an adjudication because an "approval," within the meaning of the Administrative Procedure Act (APA), constitutes a "licence," which, in turn, is the project of an "adjudication." For this reason, the statutes and Executive Orders that apply to rulemaking action are not applicable here. Among these are provisions of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.* Under the RFA, whenever a Federal agency proposes or promulgates a rule under section 553 of the APA, after being required by that section or any other law to publish a general notice of proposed rulemaking, the Agency must prepare a regulatory flexibility analysis for the rule, unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. If the Agency does not certify the rule, the regulatory flexibility analysis must describe an assess the impact of a rule on small entities affected by the rule.

Even if the NPDES program approval were a rule subject to the FRA, the Agency would certify that approval of the State proposed SDPDES program would not have a significant economic impact on a substantial number of small entities. EPA's action to approve an NPDES program merely recognizes that the necessary elements of an NPDES program have already been enacted as a matter of State law; it would, therefore, impose no additional obligation upon those subject to the State's program. Accordingly, the Regional Administrator would certify that this program, even if a rule, would not have significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires WPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or lease burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's decision includes no Federal mandates for State, local or tribal governments or the private sector. The Act excludes from the definition of a "Federal mandate" duties that arise from participation in a voluntary Federal program, except in certain cases where a "federal intergovernmental mandate" affects an annual federal entitlement program of $500 million or more which are not applicable here. South Dakota's request for approval of its budget management program is voluntary and imposes no Federal mandate within the meaning of the Act. Rather, by having its sludge management program approved, the State will gain the authority to implement the program within its jurisdiction, in lieu of EPA, thereby eliminating duplicative State and Federal requirements. If a State chooses not to seek authorization for administration of a sludge management program, regulation is left to EPA.

EPA's approval of state programs generally may reduce compliance costs for the private sector, since the State, by virtue of the approval, may now administer the program in lieu of EPA and exercise primary enforcement. Hence, owners and operators of sludge management facilities or businesses generally no longer face dual Federal and State compliance requirements, thereby reducing overall compliance costs. Thus, today's decision is not subject to the requirements of sections 202 and 205 of the UMRA.

The Agency recognizes that small governments may own and/or operate sludge management facilities that will become subject to the requirements of an approved State sludge management program. However, small governments that own and/or operate sludge management facilities are already subject to the requirements in 40 CFR parts 123 and 503 and are not subject to any additional significant or unique requirements by virtue of this program approval. Once EPA authorizes a State to administer its own sludge management program and any revisions to that program, these same small governments will be able to own and operate their sludge management facilities or businesses under the approved State program, in lieu of the Federal program. Therefore, EPA has determined that this document contains no regulatory requirements that might significantly or uniquely affect small governments.

Dated: January 4, 2001.

William P. Yellowtail,

Regional Administrator, Region 8.

[FR Doc. 01–1347 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

47 CFR Part 301

[Docket No. 001206341–0341–01]

RIN 0660–AA14

Mandatory Reimbursement Rules for Frequency Band or Geographic Relocation of Federal Spectrum-Dependent Systems

AGENCY: National Telecommunications and Information Administration, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Telecommunications and Information Administration (NTIA) proposes to amend its regulations to set forth the rules governing reimbursement to Federal entities by the private sector as a result of reallocation of frequency spectrum. This action is necessary to provide spectrum for future commercial wireless communications service and to compensate the Federal Government for the costs incurred in making that spectrum available.

DATES: Submit comments on or before March 19, 2001. Reply comments are due April 18, 2001.

ADDRESSES: The public is invited to submit written comments in paper or electronic form. Comments may be mailed to Milton Brown, Office of the Chief Counsel, National Telecommunications and Information Administration (NTIA), Room 4713, U.S. Department of Commerce, 1401 Constitution Avenue, N.W., Washington, DC 20230. Paper submissions should include a version on diskette in ASCII, Word Perfect (please specify version), or Microsoft Word (please specify version) format. Comments may be viewed on NTIA's website at http://www.ntia.doc.gov.

Comments submitted in electronic form may be sent to reimbursement@ntia.doc.gov. Electronic comments should be submitted in the formats specified above.

FOR FURTHER INFORMATION CONTACT: Milton Brown, NTIA, (202) 482–1816.

SUPPLEMENTARY INFORMATION:

Authority: 47 U.S.C. 921, *et seq.* (Supp. V. 1993); Strom Thurmond National Defense Authorization Act for FY 1999, Pub. L. No. 105–261, 112 Stat. 1920 (1998); 47 U.S.C. 923(g).

I. Introduction

1. NTIA is the executive branch agency principally responsible for developing and articulating domestic and international telecommunications policy. NTIA acts as the principal advisor to the President on telecommunications policies pertaining to the Nation's economic and technological advancement and to the regulation of the telecommunications industry. NTIA is also responsible for managing the Federal Government's use of the radio spectrum. The Federal Communications Commission (FCC), an independent agency of the Federal Government, manages electromagnetic spectrum used by the private sector, including state and local governments. With the proliferation of radio-based technologies, management and use of the radio spectrum has become increasingly complex. Federal agencies are extremely dependent on spectrum access to provide a wide variety of critical services to the American people. Congress has found that telecommunications and information are vital to the public welfare, national security, and competitiveness of the United States, and that technological advances in the telecommunications and information fields make it imperative that the United States maintain effective national and international policies and programs capable of taking advantage of these continued advancements.[1]

II. Background

2. On August 10, 1993, Title VI of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) was signed into law.[2] OBRA 93 authorized the FCC to use competitive bidding (auctions) for the reassignment and licensing of spectrum frequencies for certain commercial services. OBRA 93 also directed the Secretary of Commerce to transfer at least 200 megahertz (MHz) of spectrum below 5 gigahertz (GHz) from Federal agencies to the FCC for licensing to the private sector. Pursuant to OBRA 93, NTIA identified Federal bands for reallocation totaling 235 MHz from the Federal Government to non-Government use in its February 1995 Spectrum Reallocation Final Report.[3]

3. Title III of the Balanced Budget Act of 1997 (BBA 97) required the Secretary of Commerce to identify an additional 20 MHz below 3 GHz for reallocation to non-Federal users.[4] In response to this directive, NTIA issued a Spectrum Reallocation Report in February 1998 which identified the additional bands for reallocation.[5] BBA 97 directed the FCC to auction the 20 MHz by 2002 and the 1710–1755 band identified in the 1995 Spectrum Reallocation Final Report after January 1, 2001.[6]

4. In 1998, Congress passed the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 (the Act).[7] This legislation sought to encourage the transfer of electromagnetic spectrum from Federal government to private use by authorizing Federal entities to accept compensation payments when they relocate or modify their frequency use to accommodate non-Federal users of the spectrum.[8] Indeed the Act requires "any person on whose behalf a Federal entity incurs costs" pursuant to frequency spectrum relocation or modification "to compensate the Federal entity in advance" for the entity's modification or relocation expenses.[9] The Act also references various expenses associated with frequency relocation or modification that qualify for reimbursement including "the costs of any modification, replacement, or re-issuance of equipment, facilities, operating manuals, or regulations incurred by that entity."[10] Moreover, the Act requires the Federal entity to notify NTIA of the "marginal costs anticipated to be associated with such relocation or with the modifications necessary to accommodate prospective licensees."[11]

5. The Act directs NTIA and the FCC to "develop procedures for the implementation of [relocation] which * * * shall include a process for resolving any differences that arise between the Federal Government and commercial licensees regarding

[1] See National Telecommunications and Information Administration Organization Act, 47 U.S.C. 901 (b)(1)–(2).

[2] Pub. L. 103–66, 107 Stat. 31 (1993).

[3] See National Telecommunications and Information Administration, U.S. Department of Commerce, NTIA Special Publication 94–27, *Spectrum Reallocation Final Report* (Feb. 1995).

[4] Pub. L. 105–33, 111 Stat. 251 (1997).

[5] See National Telecommunications and Information Administration, U.S. Department of Commerce, NTIA Special Publication 98–36, Spectrum Reallocation Report (Feb. 1998).

[6] See note 4 *supra* at section 3002(b). Of the 20 MHz of spectrum, eight (8) MHz (i.e., 139–140.5 MHz, 141.5–143 MHz and 1385–1390 MHz bands) were subsequently reclaimed by the Federal Government in accordance with the National Defense Authorization Act for Fiscal Year 2000, See Pub. L. 106–65, 113 Stat. 512 (1999).

[7] Pub. L. 105–261, 112 Stat. 1920 (1998) (amending section 113(g) of the NTIA Organization Act (codified at 47 U.S.C. 923(g)).

[8] See 47 U.S.C. 923(g)(1)(A). "Federal entity" is defined as "any department, agency, or other instrumentality of the Federal Government that utilizes a Government station license obtained under section 305 of the 1934 Act (47 U.S.C. 305)." 47 U.S.C. 923(i).

[9] See 47 U.S.C. 923(g)(1)(B).

[10] See 47 U.S.C. 923(g)(1)(A).

[11] Id.

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estimates of relocation or modification costs."[12]

6. These proposed rules provide a procedure for Federal entities to receive reimbursement for the relocation or modification expenses that they incur as a result of the reallocation of radio spectrum mandated by OBRA 93, BBA 97, and future reallocations. As such, these proposed rules address reimbursement issues associated with the relocation or modification of frequency spectrum that have been reallocated. The proposed rules do not apply to issues involving the reallocation of frequency spectrum. These proposed rules provide a mechanism for the Federal entities to submit estimates of the costs to relocate. The proposed rules direct NTIA to solicit estimates of the costs of relocation from the affected Federal entities, and provide that information to the FCC at least 180 days prior to an auction.[13]

7. The proposed rules also provide procedures for the successful bidder to make payment to the Federal entity after an auction. Pursuant to direction from Congress, the proposed rules also include a process for resolving differences that arise between the Federal Government and the successful bidder regarding estimates of relocation or modification of costs. To the extent that a successful bidder disagrees with a Federal entity's estimated relocation costs, the proposed rules provide for a mandatory negotiation and/or third-party mediation period. If the parties do not agree to relocation costs within the mandatory negotiation period, the parties must enter into a non-binding arbitration program.

8. As required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603, NTIA has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in this document. The IRFA is set forth in the Regulatory Flexibility Analysis section of these proposed rules. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments filed in this Notice of Proposed Rulemaking (NPRM), but they must have a separate and distinct heading designating them as responses to the IRFA. NTIA shall send a copy of this NPRM, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 603(a).

III. Discussion

9. These proposed rules have been developed to ensure that the Federal Government is fully reimbursed for the expenses it incurs in retuning, modifying or relocating a system as a result of reallocation. To the extent that there are other ways to accomplish this goal, NTIA will entertain comments from interested parties.

Affected Bands

10. Pursuant to OBRA 93, NTIA identified 235 MHz of Federal Government spectrum for transfer to the private sector.[14] Similarly, NTIA identified another 20 MHz of spectrum for reallocation to the private sector as mandated by the BBA 97.[15] The table below shows the specific frequency bands reallocated from Federal Government use to the private sector as a result of the legislation and Federal Government action.

REALLOCATED FREQUENCY BANDS FROM THE FEDERAL GOVERNMENT TO THE PRIVATE SECTOR

Freq. band (MHz)	Legislation	Bandwidth (MHz)	Schedule
1390–1400	OBRA–93	10	January 1999
1427–1432	OBRA–93	5	January 1999
1670–1675	OBRA–93	5	January 1999
1710–1755	OBRA–93	45	January 2004[16]
2300–2310	OBRA–93	10	August 1995
2390–2400	OBRA–93	10	February 1995
2400–2402	OBRA–93	2	August 1995
2402–2417	OBRA–93	15	February 1995
2417–2450	OBRA–93	33	August 1995
3650–3700	OBRA–93	50	January 1999
4940–4990	OBRA–93[17]	50	January 1997
216–220	BBA–97	4	January 2002
1432–1435	BBA–97	3	January 1999
2385–2390	BBA–97	5	January 2005

11. On October 17, 1998, the President signed into law the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, which among other things, amended the NTIA Organization Act to require private sector entities to reimburse Federal users for relocations due to reallocation of spectrum assignments.[18] The Act also sets forth which spectrum would be the subject of the mandatory reimbursement rules: the 1710–1755 MHz band from the first reallocation report, the 20 MHz identified in the second reallocation report, and any future reallocations.[19] The affected frequency bands that currently qualify for reimbursement under the proposed rule include the following:

[12] See 47 U.S.C. 923(g)(1)(E).

[13] We note that the FCC will notify potential bidders prior to the auction of the estimated relocation costs submitted by the Federal entities for the affected bands.

[14] See note 3, supra. The Federal Government, however, later reclaimed fifty (50) MHz of this spectrum (*i.e.*, 4635–4685 MHz) and substituted 4940–4990 MHz in its place. See 47 U.S.C. 924(b), 926; see also Letter from Larry Irving, Assistant Secretary for Communications and Information, U.S. Department of Commerce, to William E. Kennard, Chairman, Federal Communications Commission (March 30, 1999) (notifying FCC of reclamation and substitutiuon of spectrum).

[15] See note 5, supra.

[16] The NTIA Spectrum Reallocation Final Report provided for early reallocation band (*i.e.*, 1999) for the top 25 major cities in the United States with the private sector reimbursing the Federal users. Subsequently, Title III of BBA 97 (entitled "Communications and Spectrum Allocation Provisions") provides for the reallocation of this band for competitive bidding commencing after January 1, 2001.

[17] See note 14, supra.

[18] See note 7, supra.

[19] See note 6, supra.

Bands That Qualify for Reimbursement

216–220 MHz
1432–1435 MHz
1710–1755 MHz
2385–2390 MHz

12. We seek comment on the affected bands identified above. Future bands that qualify for reimbursement will be identified via a public notice and request for comment.

Mandatory Relocation

13. DOBRA 93 and BBA 97 require NTIA to identify spectrum for reallocation to exclusive non-Government uses. Moreover, Section 3002 of BBA 97 amended the NTIA Organization Act to add a subsection to encourage Federal entities to relocate Government stations from the bands identified in any reallocation report through means of these reimbursement requirements or any other provision of law to "maximize[ ] the spectrum available for non-Federal use."[20] Nevertheless, in some cases, it may be technically possible for incumbent Federal entities to continue to share the reallocated spectrum with the new commercial licensees. We seek comment on whether these Federal entities should be required to relocate in those cases where sharing is technically possible. If not, we seek comment on the conditions whereby such Federal entities should be permitted to remain in the band and who would pay for any system modification that would enhance spectrum sharing. For example, because the spectrum will be reallocated to exclusive non-Government uses as required by DOBRA 93 or BBA 97, should such a Federal entity be permitted to remain in the band only on a non-interference basis after the appropriate regulatory approvals have been obtained?

14. We also solicit comment on whether a Federal entity should be entitled to reimbursement of relocation costs if it relocates to a landline communications system or commercial radio services.[21] We note that such an option may provide the most spectrum efficient and cost-effective alternative to a government-exclusive radio frequency system consistent with policy directive set forth in the NTIA Organization Act. For example, section 104 of the NTIA Organization Act provides that the Secretary of Commerce, in assigning frequencies for mobile radio services and other radio services "shall promote efficient and cost-effective use of the spectrum to the maximum extent feasible." 47 U.S.C. 903(d)(1). Moreover, the NTIA Organization Act provides that any Federal Government station identified for reallocation shall "to the maximum extent practicable * * * relocate its spectrum use to other frequencies that are reserved for Federal use or to consolidate its spectrum use with other Federal Government stations in a manner that maximizes the spectrum available for non-Federal use." Id. at section 923(h). There may also be other circumstances where no other frequency is available and a landline or other commercial service is a viable alternative available to the Federal entity that is required to relocate.

Availability of a Comparable Facility

15. The proposed rules do not require a Federal entity to relocate until a comparable facility is available to it for a reasonable time to make adjustments, determine compatibility, and ensure a seamless transition from an existing facility or frequency band(s) to the new or modified facility or frequency band(s). NTIA defines the term "comparable facility" to mean that the replacement facility restores the operational capabilities of the original facility to an equal or superior level. For example, in the 1710–1755 MHz band, the vast majority of Non-DoD Federal Government facilities are fixed point-to-point microwave networks, and may be replaced by fixed microwave facilities in other bands. On the other hand, DoD operates a number of systems, including highly mobile, non-communications systems. These military systems must operate within the limits of established doctrine.

16. NTIA will consider four basic factors to determine comparability of replacement communications facility, although there may be other factors to consider. These four basic factors are communications throughput, system reliability, operating costs, and operational capability. A replacement facility will be considered comparable if the new system's operational capability, communications throughput and reliability are equal to or greater than that of the system being replaced, taking into account the operating costs.

17. Communications throughput, for the purposes of this proceeding, means the amount of information transferred within the system for a given amount of time. For digital systems, communications throughput is measured in bits per second (bps), for analog systems the communications throughput is measured by the number of voice, video or data channels.

18. System reliability means the percentage of time information is accurately transferred within a system. The reliability of a system is a function of equipment failures (*e.g.*, transmitters, feed lines, antennas, receivers and battery back-up power) and the availability of the frequency channel given the propagation characteristics (*e.g.*, frequency, terrain, atmospheric condition, and noise) and equipment sensitivity. System reliability also includes the ability of a radio-communications station to perform a required function under stated conditions for a stated period of time. System reliability may involve three distinct concepts: Attaining a specified level of performance; the probability of achieving that level; and maintaining that level for a specified time. For digital systems this would be measured by the percent of time the bit error rate (BER) exceeds a desired value, and for analog transmissions this would be measured by the percentage of time that the receiver carrier-to-noise ratio exceeds the receiver threshold. It should be noted for many DoD systems, performance is defined by sophisticated system specifications as related to specific mission requirements. In measuring/assessing DoD systems, these specific system specifications must be used.

19. Operating costs are the costs to operate and maintain the Federal entity's replacement system. New licensees would compensate federal entities for any increased recurring costs associated with the replacement facilities (*e.g.*, additional rental payments and increased utility fees) for five years after relocation.

20. Operational capability is the measure of a system's ability to perform its validated functions within doctrinal requirements, including service, joint service, and allied interoperability requirements with related systems.

21. These four factors, however, may not be appropriate measures for all Federal Government stations required to relocate. For example, to measure comparability for radar systems it may be more accurate to compare the minimum required radar target cross section able to be detected at a given range with a specified probability of false alarm under mission-required conditions. Other measures of radar system comparability may include target resolution and the ability to meet performance specifications under adverse conditions such as weather and hostile jamming. Radar and other spectrum-dependent systems may require access to specific frequency bands to perform their missions in an

[20] See 47 U.S.C. 923(h).

[21] We note, however, that the statute provides reimbursement to Federal entities that relocate to "another frequency or frequencies." 47 U.S.C. 923(g).

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optimal manner. For example, long range surveillance functions relatively free of weather effects are optimized at low frequencies and weapon control at higher frequencies. The use of higher frequencies, however, may limit the useful range of some spectrum-dependent systems, such as radar or data links. Such limitations could affect mission performance.

22. NTIA seeks comments on this proposed definition and whether the factors described above are sufficient to determine comparability of facilities. If not, NTIA seeks comment on what other factors should be considered, and whether such factors should be tailored to specific Federal Government systems to be relocated.

Frequency Assignments Eligible for Reimbursement

23. The proposed rules outline the conditions, limitations and eligibility requirements for reimbursement of the costs associated with relocation as a result of reallocation.

24. *Equipment/system modification:* Sometimes radiocommunication systems in certain bands can be modified to tune outside of the reallocated band to the upper or lower portion of the incumbent band. Retuning is oftentimes less expensive to implement, assuming there is no congestion in the upper portion of the band as a result of the migration and assuming the transmitter-receiver frequency separation can be met. Retuning could save an agency a considerable amount of money because it does not require additional towers or stations, new feed lines or associated equipment. Thus, to the extent that a Federal entity that is required to relocate is able to modify its equipment, with the result that the retuned equipment provides operational capabilities comparable with its original system, NTIA proposes to limit reimbursement to the costs associated with re-tuning. We note, however, that modification/retuning may not be possible when taking into consideration the factor of "operational comparability" as noted above. We seek comment on this proposed limitation.

25. *Old Assignments versus new assignments:* NTIA identified the Federal bands for reallocation from the Federal Government to non-Government use in the February 1995 Spectrum Reallocation Final Report, as well as the February 1998 Spectrum Reallocation Report. On October 17, 1998, the President subsequently signed into law the National Defense Authorization Act for Fiscal Year 1999 that requires the private sector to reimburse Federal entities for the cost of relocation or modification of systems as a result of reallocation. Thus, for purposes of these proposed rules, we propose to characterize an old assignment to a Federal entity as one that was authorized before October 17, 1998, and a new assignment as one that was authorized after October 17, 1998. With respect to reimbursement under these rules, we propose that only old assignments within the affected bands (*i.e.*, 216–220 MHz, 143–1435 MHz, 1710–1755 MHz, 2385–2390 MHz) would be entitled to reimbursement. NTIA believes that the costs associated with any new assignment requested by Federal entities after the respective dates of reallocation reports in the affected bands should be borne by that Federal entity rather than a new commercial licensee to prevent unjust enrichment. We seek comment on this limitation.

26. *Exempted Federal power agencies:* Assignments made to Federal power agencies (FPAs) are statutorily exempt from the requirements to relocate under the reallocation reports.[22] Thus, the 1995 Spectrum Reallocation Final Report provides a list of frequency assignments in the 1710–1755 MHz band that support the FPAs and that are not required to relocate.[23] NTIA believes, however, that Section 923(g)(1)(A) of Title 47 of the U.S. Code can be read to permit an FPA to accept reimbursement for relocations undertaken on a voluntary basis. We seek comment on whether an FPA that wishes to relocate from a band of spectrum identified for reallocation can accept voluntary reimbursement from a commercial licensee. If so, should the parties be subject to these proposed rules or be left exclusively to voluntary negotiations?

27. *Other government stations:* Under the 1995 Spectrum Reallocation Final Report and the 1998 Spectrum Reallocation Report, NTIA also exempted other Federal Government assignments from the requirement to relocate from the bands identified for reallocation either indefinitely or for a longer terms of years.[24] We seek comment on whether these Federal entities can accept reimbursement for voluntarily relocating these stations to a commercial licensee, and if so, whether such negotiations should be subject to these proposed rules.

28. *Experimental Stations:* In general, the proposed rules do not permit reimbursement for relocated frequency assignments for experimental stations or experimental testing stations. An "experimental station" means a station utilizing radio waves in experiments with a view to the development of science or technique. An "experimental testing station" is used for the evaluation or testing of electronics, equipment or systems, including site selection and transmission path surveys. These stations are oftentimes temporary use stations and are operated on a non-interference basis. NTIA believes that most experimental stations not be entitled to reimbursement under the statute. Reimbursement, however, would still be required for frequency assignments to experimental stations for systems that are in the developmental stage that have been certified for spectrum support by NTIA for Stage 3 developmental testing.[25] Because systems at the Stage 3 are certified for testing of proposed operational hardware and potential equipment configurations, we believe that these systems are entitled to reimbursement. We seek comment on our treatment of experimental stations in the proposed rules.

Cost Sharing

29. NTIA proposes to adopt a cost-sharing plan where the potential requirement to reimburse a Federal entity for relocation costs could disproportionately fall upon one potential bidder or licensee or a small number of potential bidders or licensees. For example, there may be multiple bidders in a geographic area for small bandwidth that may result in division of a Federal entity's bandwidth. There is no mechanism in place to compensate the Federal entity for that portion of the spectrum that is not licensed or acquired by any particular auction winner. In these circumstances, one auction winner could be made to pay for the entire spectrum allocation held by the Federal entity, despite the fact that only a portion of the bandwidth is needed. On the other hand, auction bidders that need only a portion of the bandwidth may perceive the cost of relocating a Federal entity too expensive in the absence of a cost-sharing plan, and thus may forgo providing a particular service to a geographic area.[26] To ensure that no private entity bears the full cost burden of relocating a government entity and to ensure that a geographic area is not denied service because the costs of reimbursement are disproportionate, we seek comment on whether a cost sharing plan, among auction winners, should be implemented. We also seek comment on what measures might reasonably be implemented to assure that the federal entity is guaranteed full payment from multiple licensees. We also seek comment on whether a band manager or some other entity that licensees may establish would be appropriate to serve as a clearinghouse to administer the cost-sharing plan. Although we contemplate developing a cost-sharing plan and criteria for identifying a clearinghouse for each auction, NTIA proposes to determine on a case-by-case basis whether a cost-sharing plan is needed for each auction. We seek comment on whether this case-by-case approach is appropriate.

30. If the proposed cost-sharing plan is adopted, NTIA proposes and seeks comment on whether it should be administered by an industry-supported organization or the government. NTIA does not propose at this time to designate any particular organization as the representative of the industry that will benefit from the auction of government spectrum, nor does NTIA propose any particular form that such an organization might take. NTIA seeks comment on the criteria it should use in designating a clearinghouse, and on whether it should be an existing organization or a new entity created for this purpose. NTIA also seeks comment on how the clearinghouse would be funded. If a clearinghouse is established receipts from expenses already incurred would be submitted to the clearinghouse for accounting purposes. We propose to sunset the cost-sharing plan to five years after any auction of a government spectrum subject to reimbursement rules. We believe that it is important to set a date certain on which any clearinghouse will be dissolved, and adopt a cost-sharing plan with the fewest possible variables so that it will be easy to administer.

31. We also seek comment on how a negotiation framework can best be established so as to minimize the personnel and other budgetary costs to the Government. For example, should NTIA establish a negotiation framework that will permit relocation of each Government system on a system-wide basis? Under such a framework, a Federal agency could request that all auction winners with frequency assignments that require that the agency relocate its system, participate in a single negotiation process so that a system-wide relocation solution can be achieved. Each Federal entity would provide a single point of contact for such consolidated negotiations. NTIA believes that such a negotiation mechanism could benefit both affected agencies and the private sector by streamlining administrative processes and reducing negotiating costs for both parties.

Sunset of Reimbursement Rights

32. The Defense Authorization Act of 1999 mandated reimbursement to Federal agencies and did not limit the time period for reimbursement. Thus, these proposed rules do not provide a sunset provision with respect to the reimbursement rights of Federal entities. We seek comments on our proposal not to include a sunset provision in these rules. Specifically, we seek comment on whether the statute precludes a sunset date.

Costs to Relocate

33. The proposed rules identify the marginal relocation and modification costs that are reimbursable. NTIA proposes to define "marginal costs" as the costs that will be incurred by a Federal entity to achieve comparable capability of systems relocated to a new frequency assignment or band or otherwise modified. Specifically, marginal costs would include all engineering, equipment, software, site acquisition and construction costs, as well as any legitimate and prudent transaction expenses, including outside consultants, and reasonable additional costs incurred by the Federal entity that are attributable to relocation, including increased recurring costs associated with the replacement facilities. Marginal costs would include costs related to the need to achieve comparable capability when replacing, modifying or reissuing equipment in order to relocate when the systems that must be procured or developed have increased functionality due to technological growth, but would not include costs related to optional increased functionality that is independent of the need to achieve comparable capability. To the extent that a Federal entity needs to accelerate the introduction of systems and equipment to allow for relocation earlier than the Federal entity had planned, replacement costs of the accelerated systems and equipment shall be included in marginal costs. Marginal costs would also include the costs of any modification or replacement of equipment, software, facilities, operating manuals, training costs, or regulations that are attributable to relocation. Marginal costs would not include costs related to routine upgrades and operating costs and lifecycle replacements that would have occurred prior to the date of the required relocation. The costs identified as reimbursable in these proposed rules conform to those identified by Congress in 47 U.S.C. § 923(g)(1)(A) and 923 (g)(2)(A). We seek comment on this definition of marginal costs.

34. Consistent with the statute, the proposed rules would require reimbursement payments to be made in advance of relocation. The proposed rules would also require the successful bidder to guarantee to pay all marginal costs as a precondition of NTIA's withdrawal of the relevant Federal license. The proposed rules also would permit payments to be made in cash or in kind, as agreed to by the affected Federal entity. The proposed rules further require that cash payments be made in the account of the Federal entity in the Treasury of the United States, or in a separate account as authorized by law.

Notification of Marginal Costs

35. Under 47 U.S.C. 923(g)(1)(A), NTIA must provide information to the FCC so that the FCC can advise potential bidders of the marginal costs of relocation or modification. This statute also requires Federal entities that propose to relocate to notify NTIA of the marginal costs anticipated to be associated with such relocation or with modifications necessary to accommodate a prospective licensee. NTIA's proposed rules thus require Federal entities that propose to relocate, modify or retune systems to provide such marginal cost information to NTIA at least 240 days prior to an FCC

[22] See 47 U.S.C. § 923(c)(4)(C). The term Federal power agency refers to the Tennessee Valley Authority, the Bonneville Power Administration, the Western Area Power Administration, the Southwestern Power Administration, the Southeastern Power Administration, and the Alaska Power Administration.

[23] See Spectrum Reallocation Final Report, NTIA Special Publication 95–32, Appendix E, Tables 1and 2.

[24] See id. at Appendix E (Exempted Safety-of-Life Fixed Microwave Stations in the 1710–1755 MHz band); see also 1998 Spectrum Reallocation Report at 3–18 (Table 3–2), 3–36 (Table 3–4), 3–48 (Table 3–6), 4–1 (Table 4–1) (setting forth the sites exempt from relocation or with special relocation dates in the 216–220 MHz, 1432–1435 MHz, and 2385–2390 MHz bands).

[25] NTIA Manual of Regulations and Procedures for Federal Radio Frequency Management, Section 10.3.1 (September 1995). Stage 3 certification is required for testing proposed operational hardware and potential equipment configurations.

[26] There also may be circumstances where the national nature of federal systems is such that the requirement to reimburse a federal entity for relocation costs may disproportionately fall on a small number of successful bidders. Thus, a particular licensee's geographic area may cover a critical element of a much larger national system, such as a system where a small number of satellite uplink transmitter terminals, each located at a specific site, communicates to many satellites. In other situations, there are highly mobile systems (e.g., airborne telemetry or data link systems) that are not related to any specific geographic area.

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auction.[27] In turn, NTIA intends to provide this information to the FCC at least 180 days prior to such auction so that the FCC will have a sufficient amount of time to notify potential bidders.[28]

Negotiation and Mediation

36. Under the proposed rules, within 30 days after the license is granted, the auction winner would be required to contact the Federal entity that is required to relocate. Under the proposed rules, receipt of the notification by the Federal entity would trigger a 135-day negotiation and/or third-party mediation period between the Federal entity and the auction winner. During the mandatory negotiation period, parties are encouraged to resolve any differences with respect to relocation or modification costs or any other related issues. If, at the end of the 135-day period, the parties have not reached an agreement with respect to relocation, under the proposed rules, the parties may agree, by mutual consent, to extend the mandatory negotiation period. We believe that this mandatory negotiation period affords the parties an opportunity to freely, and without constraints, negotiate the terms relative to relocation. To the extent that the 135-day period is insufficient, we believe that the extension of time provision gives the party additional time that may be necessary to come to an agreement. This provision would also allow the parties to take advantage of a neutral third party to help facilitate the negotiation process without rendering a decision. We solicit comments on the proposed rule to require mandatory party-to-party negotiations and/or third-party mediation.

37. Under the proposed rules, the parties would be required to negotiate relocation or modification costs in good faith during the mandatory negotiation period. Good faith requires each party to provide information to the other that is reasonably necessary to facilitate the relocation process. Good faith means that (1) neither party may refuse to negotiate; and (2) each party must behave in a manner necessary to facilitate negotiation in a timely manner. We seek comments on these good faith obligations.

Non-Binding Arbitration

38. If the parties have not reached agreement and do not agree to extend the negotiation/mediation period, or if a previously extended negotiation/mediation period expires, the proposed rules would require the parties to enter into non-binding arbitration. The parties would have to agree on the arbitrator, and to prevent bias, the arbitrator would not be the same person as the mediator if mediation has been used by the parties and failed. Each party would pay its own costs for arbitration and share equally the cost of the arbitrator. The arbitrator's non-binding decision may be requested by NTIA as part of the record in a petition for relocation, as described below. The recommended decision may be a factor, among others, in NTIA's determination on a petition for relocation. We seek comments on the proposed requirement that parties enter into non-binding arbitration. We also seek comments on any alternative proposal for the resolution of disputes between the parties.

Petition for Relocation

39. Under 47 U.S.C. 923(g)(2), an auction winner seeking to relocate a Federal Government station must submit a petition for relocation to NTIA. Under the proposed rules, NTIA requires that a copy of the petition also be simultaneously provided to the FCC.[29] Moreover, under the proposed rule, NTIA's determination on the petition would be set forth in writing within six months after the petition has been filed and be provided to the auction winner and the Federal entity. The statute requires NTIA to limit or terminate the Federal entity's license within six months after receiving the petition if the following requirements are met:

(A) the person seeking relocation of the Federal Government station has guaranteed to pay all relocation or modification costs incurred by the Federal entity, including all engineering, equipment, site acquisition and construction, and regulatory fee costs;

(B) all activities necessary for implementing the relocation or modification have been completed, including construction of replacement facilities (if necessary and appropriate) and identifying and obtaining new frequencies for use by the relocated Federal Government station;

(C) any necessary replacement facilities, equipment modifications, or other changes have been implemented and tested to ensure that the Federal Government station is able to accomplish its purposes; and

(D) NTIA has determined that the proposed use of the spectrum frequency band to which the Federal entity will relocate is consistent with:

(i) Obligations undertaken by the United States in international agreements and United States national security and public safety interests; and

(ii) The technical characteristics of the band and other uses of the band.

If NTIA does not act within 6 months after the Petition for Relocation is filed, the Petition is deemed denied. NTIA's determination, or failure to act on a Petition within 6 months, would be final and conclusive upon the parties.

40. The proposed rules would permit an auction winner to file a petition for relocation anytime after an agreement has been reached on marginal costs. The proposed rules also permit an auction winner to file a petition for relocation if the parties fail to reach agreement and non-binding arbitration has occurred. In that case, the auction winner may file a petition for relocation with NTIA after a decision has been rendered by the arbitrator. Any recommended decision by the arbitrator may be requested by NTIA as part of the record in a petition for relocation determination. The recommended decision may be a factor, among others, in the NTIA determination on the petition for relocation. In making its determination, NTIA will consult with the affected Federal entity and, as appropriate, may also consult with the Office of Management and Budget and other executive branch agencies. We seek comment on these proposed rules as they relate to the Petition for Relocation.

41. In certain circumstances, it may be beneficial for the Federal entity to seek voluntary withdrawal of an assignment after the parties reach an agreement through negotiation, mediation, or non-binding arbitration. NTIA anticipates the vast majority of relocations to occur under agreements reached between the parties, thus permitting voluntary withdrawals of assignments would greatly streamline the administrative process of making the spectrum available to auction winners. NTIA seeks comment on permitting such voluntary requests for assignment withdrawal as an alternative to the petition for relocation in cases in which the parties have reached agreement.

Unclassified, Classified and Sensitive Assignments

42. *Unclassified government facilities.* With respect to unclassified government facilities, we propose to provide the following information to the FCC prior to an auction of the affected bands:

(1) List of Government facilities.

(2) Government agency operating each facility.

(3) Location of each facility.

(4) General type of operation and equipment (*e.g.*, fixed microwave, tactical mobile radio, etc.).

(5) Whether the facility can be retuned, modified, or must be relocated.

(6) Estimated marginal cost of retuning, modification, or relocation.

(7) Whether the facility overlaps to one or more license areas or spectrum blocks.

(8) Total estimated costs of relocation for all assignments.

43. *Classified government facilities.* These proposed rules would permit reimbursement to the Federal entity, even if an assignment is classified. As defined in the proposed rule and consistent with Executive Order 12958,[30] a "classified assignment" would be a frequency assignment and information related to a frequency assignment that has been determined pursuant to Executive Order 12958 or any predecessor order to require protection against unauthorized disclosure and that is marked as "confidential," "secret," or "top secret" to indicate its classified status when in documentary form. As directed by Executive Order 12958, Executive Order 12968[31] and related national security regulations, classified assignment can only be made available to individuals with the appropriate clearances and with a "need to know" (need for access) in order to perform or assist in performing a lawful and authorized government function.

44. Prior to an auction, Federal entities will provide a single, consolidated and unclassified figure to NTIA for the cost of relocating, retuning, or modifying all such classified systems. NTIA will provide this information to the FCC which in turn will provide the figure to bidders with the following conditions: To the extent it is consistent with national security considerations, the figure may be broken down by license service area and spectrum block to give those bidding on a geographic basis the best indication possible of the cost they may have to pay to relocate, retune or modify the systems at issue. Following the auction, the winner may apply for a facility clearance pursuant to the National Industrial Security Program Operating Manual and related individual security clearances. If those clearances and accesses are granted, classified information may be made available with regard to certain Government systems in accordance with the terms and conditions prescribed in the clearances and accesses provided, and subject to the overall rules and authorities found in Executive Order 12958, Executive Order 12968, and related federal laws, rules and regulations.

45. *Sensitive assignments.* As defined in the proposed rule, a "sensitive assignment" would be a frequency assignment and information related to a frequency assignment (e.g. operations or technical parameters) that are not releasable to the public under the Freedom of Information Act or relevant laws or regulations.[32] Prior to an auction, Federal entities will provide a single, consolidated and unclassified figure to NTIA for the cost of relocating, retuning, or modifying all such sensitive systems. NTIA will provide this information to the FCC which in turn will provide the figure to bidders with the following conditions: To the extent it is consistent with the sensitive nature of the assignment, the figure may be broken down by license service area and spectrum block to give those bidding on a geographic basis the best indication possible of the cost they may have to pay to relocate, retune or modify the systems at issue. Following the auction, we propose that the government agency release the sensitive information to the winning licensee pursuant to a non-disclosure agreement.

46. We seek comment on our proposed treatment of these assignments.

Other Information

Executive Order 12866

47. This proposed rule has been determined to be significant under section 3(f) of Executive Order 12866.

Executive Order 13312

48. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Regulatory Flexibility Act

49. As required by the Regulatory Flexibility Act (RFA)[33] NTIA has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the possible impact that this proposed rule, if adopted, would have on small entities. Written public comments are requested on the IRFA. Comment must be identified as responses to the IRFA and must be filed by the deadlines for comments on the NPRM.

Initial Regulatory Flexibility Analysis

50. As required by the Regulatory Flexibility Act (RFA), NTIA has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in this NPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on this NPRM.

A. Need for, and Objectives of, the Proposed Rules

51. The Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 authorized Federal entities to accept compensation payments when they relocate or modify their frequency use to accommodate non-Federal users of the spectrum.[34] In essence, the Act requires the private sector to reimburse Federal entities for the costs that are incurred as a result of the reallocation of radio spectrum mandated by Title VI of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93),[35] the Balanced Budget Act of 1997 (BBA 97) and future reallocations. The Act also directs NTIA and the Federal Communications Commission (FCC) to "develop procedures for the implementation of [relocation] which * * * shall include a process for resolving any differences that arise between the Federal Government and commercial licensees regarding estimates of relocation and modification costs."[36]

52. This initial regulatory flexibility analysis provides, to the extent possible, relevant information regarding reimbursement such as the Federal frequency assignments for reallocation and the estimated relocation costs that will ultimately be borne by the private sector. As stated above Congress directed NTIA and the FCC to develop procedures for the implementation of the reimbursement process. Pursuant to

[27] The marginal costs submitted on behalf of the Federal agencies as part of the notification process may be subject to review and approval by the Office of Management and Budget (OMB). OMB's review would assure the accuracy of the costs. See also Section 1064(d) of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999, Pub. L. No. 105–261, 112 Stat. 1920 (1998).

[28] For example, we anticipate that the first FCC auction for spectrum frequency subject to these rules will occur in December 2001. In that case, NTIA would provide cost information to the FCC no later than June 1, 2001. Therefore, the Federal entities would have to provide estimated cost information to NTIA by April 1, 2001.

[29] We note that the statute permits the Federal entity to reclaim its facilities if it demonstrates to the FCC that the new facilities are not comparable. See 47 U.S.C. 923(g)(3). Rules regarding the Federal entity's right to reclaim will be promulgated by the FCC. See also Reallocation of the 216–220 MHz, 1390–1395 MHz, 1427–1429 MHz, 1429–1432 MHz, 1432–1435 MHz, 1670–1675 MHz, and 2385–2390 MHz Government Transfer Bands, ET Docket No. 00–221, Notice of Proposed Rule Making, FCC 00–395, at ¶ 64 (November 20, 2000).

[30] Exec. Order No. 12958, 3 CFR 333 (1995).

[31] Exec. Order No. 12968, 3 C.F.R. 391 (1995).

[32] Many of these assignments involve federal public safety and law enforcement activities.

[33] See 5 U.S.C. 603.

[34] 47 U.S.C. 923(g)(1).

[35] Pub. L. 103–66, 107 Stat. 31 (1993).

[36] See 47 U.S.C. 923(g)(1)(E).

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this direction from Congress, NTIA prepared this NPRM. NTIA is not able to determine the type of entities that will be potential bidders for the particular spectrum frequencies at issue here, thus NTIA is unable to fully describe the effect that the proposed rules will have on small entities. However, significant economic impacts are unlikely because it is expected that bidders in an auction for the eligible spectrum, including small entities, will factor in the estimated relocation costs and adjust their bids accordingly.

B. Federal Frequency Assignments Subject to Reallocation

53. On August 10, 1993 OBRA 93 was signed into law. OBRA 93 authorized the FCC to use competitive bidding (auctions) for the reassignment and licensing of spectrum frequencies for certain commercial services. OBRA 93 also directed the Secretary of Commerce to transfer at least 200 megahertz (MHz) of spectrum below 5 gigahertz (GHz) from Federal agencies to the FCC for licensing to the private sector. Pursuant to OBRA 93, NTIA identified Federal bands for reallocation totaling 235 MHz from the Federal Government to non-Government use in its February 1995 Spectrum Reallocation Final Report.[37] Subsequently, BBA–97 required the Secretary of Commerce to identify an additional 20 MHz below 3 Ghz for reallocation to non-Federal users.[38] In response to this directive, NTIA issued a Spectrum Reallocation Report in February 1998 which identified the additional bands for reallocation.[39] The specific frequency bands that currently qualify for reimbursement pursuant to the proposed rules are: 216–220 MHz; 1432–1435 MHz; 1710–1755 MHz; and 2385–2390 MHz.

C. Estimated Relocation Costs

54. At this point, NTIA does not have the final estimated costs of relocation for all of the bands identified in the NPRM. In fact, the NPRM proposes dates for the Federal entities to provide that information to NTIA. The final spectrum reallocation reports prepared by NTIA in response to OBRA 93 and BBA 97 identified estimates of implementation costs to Federal agencies of approximately $1.5 billion based on data provided by major Federal agencies. Subsequent modifications to these estimates have been made based on a report to Congress from the Department of Defense (DoD), and changes to the reallocation plan as directed by the National Defense Authorization Act for FY 2000. Taking these factors into account, the current reimbursable long-term cost estimates to the Federal agencies of implementing the spectrum reallocations under OBRA 93 and BBA 97 is between $460–$810 million.

Although NTIA identifies spectrum to reallocate from the Federal government to the private sector, NTIA does not determine how the spectrum will be used by the private sector. The Federal Communications Commission, through its regulations identifies options for making use of bands transferred from Government to non-Government use pursuant to OBRA 93 and BBA 97. In fact, the FCC recently issued an NPRM on the allocation of 27 megahertz of spectrum from the 216–220 MHz, 1390–135 MHz, 1427–1429 MHz, 1429–1432 MHz, 1432–1435 MHz, 1670–1675 MHz, and 2385–2390 MHz bands.[40] In that NPRM, the FCC proposes general Fixed Service and Mobile Service allocation for these bands, and solicits comments on other possible allocations and potential service rules for the services to which the bands may be allocated. The FCC also solicits comments on its Initial Regulatory Flexibility Analysis of the NPRM which describes the number of small entities to which its proposed rules would apply.

In accordance with 5 U.S.C. 603, the following information is provided to conduct the necessary initial regulatory flexibility analysis:

D. Legal Basis

55. The objective of the proposed rule is to establish procedures to compensate the Federal Government for expenses it incurs in relocating to a new frequency as a result of a reallocation of spectrum. Congress determined that the Federal Government should be reimbursed by commercial licensees that are awarded spectrum previously held by the Federal Government. The legal basis for the proposed rule is the Defense Authorization Act for Fiscal Year 1999 which directs NTIA and the FCC to develop procedures to implement reimbursement, including a process for resolving differences that arise between the parties regarding estimates of relocation or modification costs.

E. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

56. It is difficult, if not impossible, to estimate the number of small entities, if any, to which the proposed rule would apply. The rule applies to winners of a competitive bidding (auction) that the FCC will hold at an undetermined date after January 2001. There is no way to predict, at this point in time, the type of entities that will be potential bidders for the spectrum that the FCC makes available. In fact, entities that are not even in existence at this time may be participating in a future auction for the particular spectrum frequency at issue. The FCC may impose eligibility requirements, however the auctions are usually open to any type of entity. Any estimate of the number of small entities to which this proposed rule will apply should be made after the FCC makes a determination of the type of service that the FCC allocates for these bands of spectrum. The proposed rules, however, require the FCC to provide the estimated cost of reimbursement to potential bidders. Thus, to the extent that a small entity is a potential bidder, it will be able to calculate its costs to bid on the particular spectrum frequency, taking into account the estimated cost to reimburse the Federal Government. As stated above the estimated costs of relocation at this time is between $460–$810 million. Because these costs are only estimates and bids may be adjusted to reflect these costs, it is difficult at this time to determine the impact that these costs will have on small entities. We solicit public comment on this IRFA as to the impact that the proposed rule will have on small entities as well as any alternative ways to alleviate such an impact.

F. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements

57. The proposed rules do not impose reporting, record keeping or other compliance requirements on the private sector, small entities or otherwise.

G. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

58. It does not appear that any other Federal rule duplicates, overlaps or conflicts with the proposed rule. The proposed rules are focused on reimbursement to Federal entities for relocation costs from specific spectrum frequencies. No other Federal rule requires the private sector to reimburse Federal entities for relocation costs of the specific radio spectrum frequencies identified in the proposed rules. The FCC, however, will promulgate service rules regarding these spectrum frequencies, however, we do not anticipate that the FCC's rules will duplicate, overlap or conflict with this proposed rule.

H. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

59. As stated above, the applicable statute requires NTIA to develop rules to implement the reimbursement process.[41] The NPRM, proposes and solicits comment on a number of alternatives which would minimize economic impact on small entities. For example, the proposed rules solicit comments on whether a Federal entity could retune or modify its equipment outside of the reallocated band to the upper or lower portion of the incumbent band. Re-tuning is usually less expensive to implement and can save an agency a considerable amount of money thus lessening the reimbursement obligation of the private sector. Another alternative in the proposed rule which could minimize the economic impact on small entities is the proposal to permit Federal entities to relocate to a landline communications system or a commercial radio service. Such an option may be a cost-effective alternative to the Federal entity relocating to another frequency. Again, this alternative may reduce reimbursement expenses that would be borne by the private sector and, perhaps, small entities. To the extent that there are other ways to accomplish the stated objectives of Congress, the proposed rule states that "[t]hese proposed rules have been developed to ensure that the Federal Government is fully reimbursed for the expenses it incurs in retuning, modifying or relocating a system as a result of reallocation. To the extent that there are other ways to accomplish this goal, NTIA will entertain comments from interested parties. Comments received addressing alternatives to the proposed rules will be discussed in a more thorough analysis in the Final Rule.

List of Subjects in 40 CFR Part 301

Administrative practice and procedure, Classified information, Communications, Communications equipment, Government procurement, Government property, Radio, Satellites, Telecommunications, Telephone.

[37] *See* National Telecommunications and Information Administration, U.S. Department of Commerce, NTIA Special Publication 94–27, *Spectrum Reallocation Final Report* (Feb. 1995).

[38] Pub. L. 105–33, 111 Stat. 251 (1997).

[39] Of the 20 MHz of spectrum, eight (8) MHz were subsequently reclaimed by the Federal Government in accordance with the National Defense Authorization Act for Fiscal Year 2000. *See* Pub. L. 106–65, 113 Stat. 512 (1999).

[40] Reallocation of the 216–220 MHz, 1390–1395 MHz, 1427–1429 MHz, 1429–1432 MHz, 1432–1435 MHz, 1670–1675 MHz, and 2385–2390 MHz Government Transfer Bands, ET Docket No. 00–221, Notice of Proposed Rule Making, FCC 00–395, at ¶ 64 (November 20, 2000).

[41] See 47 U.S.C. 923(g)(1)(E).

Proposed Rules

Accordingly, NTIA amends 47 CFR chapter III by adding part 301 to read as follows:

PART 301—MANDATORY REIMBURSEMENT FOR FREQUENCY BAND OR GEOGRAPHIC RELOCATION OF SPECTRUM-DEPENDENT SYSTEMS

Subpart A—General Information

Sec.
301.1 Purpose.
301.10 Applicability.
301.20 Definitions.

Subpart B—Procedure for Reimbursement for Relocations and Dispute Resolution.

301.100 Costs to relocate.
301.110 Notification of marginal costs.
301.120 Negotiations and mediation.
301.130 Nonbinding arbitration.
301.140 Petition for relocation.
301.150 Request for withdrawal.

Authority: 47 U.S.C. 921 *et seq.*; Pub. L. 105–261, 112 Stat. 1920.

Subpart A—General Information

§ 301.1 Purpose.

Pursuant to Public Law 105–261 (112 Stat. 1920), private sector entities are required to reimburse Federal users for relocation of Federal Government stations from one or more frequencies due to reallocation. Reimbursement costs are in addition to any costs paid by the successful bidder for the frequency spectrum at the FCC auction.

301.10 Applicability.

(a) *Affected bands.*

(1) These provisions apply to the following bands of frequencies located below 3 gigahertz:

(i) 216 to 220 MHz

(ii) 1432 to 1435 MHz

(iii) 1710 to 1755 MHz

(iv) 2385 to 2390 MHz

(2) NTIA may periodically identify additional bands that are subject to this part in a notice published in the **Federal Register**.

(b) *Availability of comparable facility.* The Federal entity will not relocate until a comparable facility, or modification to an existing facility, is available for enough time to determine comparability, make adjustments, and ensure a seamless handoff. The factors to be considered in determining comparability are communications throughput, system reliability, operating costs, and operational capability as defined in this part.

(c) *Frequency Assignments Eligible for Reimbursement.*

(1) *Equipment modification/retuning.* To the extent that a Federal entity that is required to relocate is able to modify/re-tune its equipment with the result that the modified equipment provides operational capabilities comparable with the original system, reimbursement will be limited to the marginal costs associated with modification/retuning.

(2) *Old assignments/new assignments.* Old assignments are those that were authorized prior to October 17, 1998 (i.e., 216–220 MHz, 143–1435 MHz, 1710–1755 MHz, 2385–2390 MHz). New assignments are those assignments in the affected bands that were authorized after October 17, 1998. New assignments in the affected bands are not eligible for reimbursement under these rules.

(3) *Exempted Federal power agencies.* Frequency assignments in the 1710–1755 MHz band that support the Federal power agencies that are exempt from reallocation requirements are not entitled to reimbursement under these rules.

(4) *Experimental stations.* Frequency assignments for experimental stations or experimental testing stations are not entitled to reimbursement under this part. Reimbursement shall apply to experimental stations that have been certified for spectrum support by NTIA for stage 3 developmental tests under section 10.3.1. of the *NTIA Manual of Federal Regulations and Procedures for Federal Radio Frequency Management.* This manual is available on NTIA's website at *http://www.ntia.doc.gov/osmhome/redbook/redbook.html.* The manual is also available from the U.S. Government Printing Office (S/N: 903–008–0025–3).

(5) *Certain other government stations.* Other exempted stations identified under the *1995 Spectrum Reallocation Final Report* and the *1998 Spectrum Reallocation Report* are not entitled to reimbursement under these rules. These reports are available at http://www.ntia.doc.gov.

(d) *Sunset of reimbursement rights.* There is no sunset of reimbursement rights for affected agencies.

§ 301.20 Definitions.

As used in this part:

(a) The term *allocation* means an entry in the national table of frequency allocations (47 CFR 2.105) of a given frequency band for the purpose of its use by one or more radiocommunication services, or the radio astronomy service under specified conditions.

(b) The term *assignment* means authorization given for a radio station to use a radio frequency or radio frequency channel under specified conditions.

(c) The term *auction* means the competitive bidding process that Congress authorized the Federal

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Communication Commission to use in title VI of the Omnibus Budget Reconciliation Act of 1993 and the Balanced Budget Act of 1997 for the reassignment and licensing of spectrum identified in § 301.10(a) of this subpart for certain commercial radio-based services.

(d) The term *classified assignment* means a frequency assignment and information related to a frequency assignment that has been determined pursuant to Executive Order 12958 or any predecessor order to require protection against unauthorized disclosure and that is marked as "confidential," "secret," or "top secret" to indicate its classified status when in documentary form.

(e) The term *Commission* or *FCC* means the Federal Communications Commission.

(f) The term *communications throughput* means the amount of information transferred within the system for a given amount of time. For digital systems, the communications throughput is measured in bits per second (bps) and for analog systems the communications throughput is measured by the number of voice, video or data channels.

(g) The term *comparable facility* means that the replacement facility restores the operational capabilities of the original facility to an equal or superior level taking into account at least four factors: communications throughput, system reliability, operating costs, and operational capability.

(h) The term *experimental station* means a station utilizing radio waves in experiments with a view to the development of science or technique.

(i) The term *experimental testing station* refers to an experimental station used for the evaluating or testing of electronics equipment or systems, including site selection and transmission path surveys, which have been developed for operational use.

(j) The term *Federal entity* means any department, agency or other instrumentality of the Federal Government that utilizes a Government station license obtained under section 305 of the Communications Act of 1934 (47 U.S.C. 305).

(k) The term *in-kind* means the value of non-cash contributions provided by non-Federal private parties. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefitting and specifically identifiable to the project or program.

(l) The term *marginal costs* means the costs that will be incurred by a Federal entity to achieve comparable capability of systems relocated to a new frequency assignment or band or otherwise modified.

(m) The term *mediation* means a flexible and voluntary dispute resolution procedure in which a specially trained mediator facilitates negotiations to reach a mutually agreeable resolution. The mediator may not dictate a settlement. The mediation process involves one or more sessions in which counsel, parties and the mediator participates, and may continue over the period of time specified in this part. The mediator can help the parties improve communication, clarify interests, and probe the strengths and weaknesses of positions. The mediator can also identify areas of agreement and help generate options that lead to a settlement.

(n) The term *NTIA* means the National Telecommunications and Information Administration.

(o) The term *operational costs* means the cost to operate and maintain the federal entity's replacement facility. New licensees would compensate federal entities for any increased recurring costs associated with the replacement facilities for five years after relocation. Such costs shall include, but not be limited to additional rental payments and increased utility fees.

(p) The term *operational capability* means the measure of a system's ability to perform its validated functions within doctrinal requirements, including service, joint service, and allied interoperability requirements with related systems.

(q) The term *relocation* refers to the process of moving a system that is displaced as a result of reallocation.

(r) The term *sensitive assignments* refer those assignments whose operations or technical parameters are not releasable to the public under the Freedom of Information Act.

(s) The term *system reliability* means the percentage of time information is accurately transmitted within a system. The reliability of a system is a function of equipment failures (e.g., transmitters, feed lines, antennas, receivers and battery back-up power), the availability of the frequency channel given the propagation characteristics (e.g., frequency, terrain, atmospheric condition and noise), and equipment sensitivity. System reliability also includes the ability of a radio-communications station to perform a required function under stated conditions for a stated period of time. System reliability may involve three concepts: attaining a specified level of performance; the probability of achieving that level; and maintaining that level for a specified time. For digital systems, system reliability shall be measured by the percentage of time the bit error rate (BER) exceeds a desired value, and for analog transmissions, this would be measured by the percentage of time that the received carrier-to-noise ratio exceeds the receiver threshold.

Subpart B—Procedure for Reimbursement for Relocations and Dispute Resolution

§ 301.100 Costs to relocate.

(a) *Relocation costs.* The auction winner is required to reimburse the Federal entity for all costs incurred as a result of modification, retuning and/or relocation.

(b) *Method of reimbursement.* Reimbursement payments shall be made in advance of relocation and may be in cash or in kind as agreed to by the affected Federal entity. Any such payment in cash shall be deposited in the account of such Federal entity in the Treasury of the United States or in a separate account as authorized by law. If actual costs are less than the payments made, the Federal entity shall refund the difference.

§ 301.110 Notification of marginal costs.

(a) NTIA shall provide the Federal entity's estimated marginal cost information to the FCC at least 180 days before to an auction. Marginal costs are the costs that will be incurred by a Federal entity to achieve comparable capability of systems relocated to a new frequency assignment or band or otherwise modified. Specifically, marginal costs would include all engineering, equipment, software, site acquisition and construction costs, as well as any legitimate and prudent transaction expenses, including outside consultants, and reasonable additional costs incurred by the Federal entity that are attributable to relocation, including increased recurring costs associated with the replacement facilities. Marginal costs would include costs related to the need to achieve comparable capability when replacing, modifying or reissuing equipment in order to relocate when the systems that must be procured or developed have increased functionality due to technological growth, but would not include costs related to optional increased functionality that is independent of the need to achieve comparable capability. To the extent that a Federal entity needs to accelerate the introduction of systems and equipment to allow for relocation earlier than the Federal entity had planned, replacement costs of the accelerated systems and equipment shall be included in marginal costs. Marginal costs would also include the costs of any modification or replacement of equipment, software, facilities, operating manuals, training costs, or regulations that are attributable to relocation. Marginal costs would not include costs related to routine upgrades and operating costs and lifecycle replacements that would have occurred prior to the date of the required relocation. Any Federal entity that proposes to relocate shall notify NTIA at least 240 days before the auction of the marginal costs anticipated to be associated with relocation or with modifications necessary to accommodate prospective licensees. The information provided to NTIA must also include the name and telephone number of a person within the Federal entity that can be contacted by the auction winner.

(b) Unclassified assignments. NTIA will provide the following information to the FCC prior to the auction with repect to unclassified government facilities:

(1) List of Government facilities.

(2) Government agency operating each facility.

(3) Location of each facility.

(4) General type of operation and equipment.

(5) Whether the facility can be retuned, modified, or must be relocated.

(6) Estimated marginal cost of retuning, modification, or relocation.

(7) Whether the facility overlaps to one or more license areas or spectrum blocks.

(8) Total estimated costs of relocation for all assignments.

(c) Classified assignments. Prior to an auction, Federal entities will provide a single, consolidated and unclassified figure to NTIA for the cost of relocating, retuning, or modifying all such classified systems. NTIA will provide this information to the FCC which in turn will provide the figure to bidders with the following conditions: To the extent it is consistent with national security considerations, the figure may be broken down by license service area and spectrum block to give those bidding on a geographic basis the best indication possible of the cost they may have to pay to relocate, retune or modify the systems at issue. Following the auction, the winner may apply for a facility clearance pursuant to the *National Industrial Security Program Operating Manual* and related individual security clearances. The manual is available throught the Defense Security Service at http://www.dss.mil/isec/nistom.htm or the Government Printing Office (ISBN 0-16-045560-X). If those clearances and accesses are granted, classified information may be made available with regard to certain Government systems in accordance with the terms and conditions prescribed in the clearances and accesses provided, and subject to the overall rules and authorities found in Executive Order 12958, Executive Order 12968, and related Federal laws, rules, and regulations.

(d) Sensitive assignments. Prior to an auction, Federal entities will provide a single, consolidated, and unclassified figure to NTIA for the cost of relocating, retuning, or modifying all such sensitive systems. NTIA will provide this information to the FCC which in turn will provide the figure to bidders with the following conditions: To the extent it is consistent with the sensitive nature of the assignment, the figure may be broken down by license service area and spectrum block to give those bidding on a geographic basis the best indication possible of the cost they may have to pay to relocate, retune, or modify the systems at issue. Following the auction, the government agency shall release the sensitive information to the winning licensee pursuant to a non-disclosure agreement.

§ 301.120 Negotiations and mediation.

(a) Within 30 days after the license is granted, the auction winner is required to contact the Federal entity that occupies the band that the FCC has awarded to the auction winner. Receipt of this notification by the Federal entity triggers the 135-day period for negotiation or mediation between the Federal entity and the auction winner. During this period, parties are encouraged to resolve any differences with respect to relocation or modification costs or any other related issues, either through party-to-party negotiations and/or a third party mediator. If, at the end of the 135-day period, the parties have not reached an agreement with respect to relocation, the parties may agree to extend the negotiation period.

(b) Good faith obligation. The parties are required to negotiate in good faith. Good faith means that:

(1) Neither party may refuse to negotiate; and

(2) Each party must behave in a manner necessary to facilitate the relocation process in a timely manner. Classified or sensitive information will be treated in accordance with § 301.110 of this subpart.

§ 301.130 Nonbinding arbitration.

If the parties have not reached agreement to extend the negotiation/mediation period, or if a previously extended negotiation/mediation period expires, the parties shall enter into nonbinding arbitration. The parties shall agree on an arbitrator, and the arbitrator may not be the same person as the mediator if mediation has been used by the parties and failed. The parties may design such rules for arbitration as deemed appropriate. The arbitrator's nonbinding decision may be requested by NTIA as part of the record in its determination on a petition for relocation under § 301.140. The decision may be a factor, among other things, in the NTIA determination on a petition for relocation.

301.140 Petition for relocation.

(a) In general. An auction winner seeking to relocate a Federal Government station must submit a petition for relocation to NTIA. A copy of the petition must also be simultaneously provided to the FCC. NTIA's determination shall be set forth in writing within 6 months after the petition for relocation has been filed, and be provided to the auction winner and the Federal entity. NTIA shall limit or terminate the Federal entity's operating license within 6 months after receiving the petition if the following requirements are met:

(1) The person seeking relocation of the Federal Government station has guaranteed to pay all modification and relocation costs incurred by the Federal entity, including all engineering, equipment, site acquisition and construction, and regulatory fees;

(2) All activities necessary for implementing the relocation or modification have been completed, including construction of replacement facilities (if necessary and appropriate) and identifying and obtaining new frequencies for use by the relocated Federal Government station (where such station is not relocating to spectrum reserved exclusively for Federal use);

(3) Any necessary replacement facilities, equipment modifications, or other changes have been implemented and tested to ensure that the Federal Government station is able to accomplish its purposes; and

(4)(i)NTIA has determined that the proposed use of the spectrum frequency band to which the Federal entity will relocate its operations is

(A) Consistent with obligations undertaken by the United States in international agreements and with United States national security and public safety interests; and

(B) Suitable for the technical characteristics of the band and consistent with other uses of the band.

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(ii) In exercising its authority, NTIA shall consult with the Secretary of Defense, the Secretary of State, or other appropriate officers of the Federal Government

(5) If these requirements are not met, NTIA shall notify the petitioner that the request is declined and why.

(6) If NTIA does not issue a determination under this section within 6 months of the filing of a petition for relocation, the petition for relocation is deemed to be denied.

(7) In making its determination under this section, NTIA shall consult with the affected Federal entity and, as appropriate, the Office of Management and Budget and other executive branch agencies.

(b) *Petition after agreement between the parties.* The auction winner may file a petition for relocation pursuant to § 301.140 of this subpart at anytime after the parties have reached agreement on relocation in negotiations or mediation as provided in § 301.120 of this subpart and submit the agreement as evidence of having met the requirements of the petition for relocation.

(c) *Petition after failure to reach an agreement.* If the parties fail to reach an agreement as provided in § 301.120 and non-binding arbitration has occurred pursuant to § 301.130, the auction winner may file a petition for relocation with NTIA after a decision has been rendered by the arbitrator. Any recommended decision by the arbitrator may be requested by NTIA as part of the record in a petition for relocation under § 301.140. The recommended decision may be a factor, among others, in the NTIA determination on the petition for relocation.

§ 301.150 Request for withdrawal.

If the parties reach an agreement in negotiations or mediation or agree with the decision of the arbitrator, the Federal entity may seek voluntary withdrawal of the assignments that are the subject of the relocation.

Dated: January 11, 2001.

Gregory L. Rohde,

Assistant Secretary for Communications and Information.

[FR Doc. 01–1306 Filed 1–17–01; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AG71

Endangered and Threatened Wildlife and Plants; Determinations of Whether Designation of Critical Habitat Is Prudent for 81 Plants and Proposed Designations for 76 Plants From the Islands of Kauai and Niihau, Hawaii

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period and public hearing.

SUMMARY: The U.S. Fish and Wildlife Service (Service) gives notice of a public hearing on the prudency determinations for 81 plants and the proposed critical habitat designations for 76 plants from the islands of Kauai and Niihau, Hawaii. In addition, the comment period which originally closed on January 8, 2001, will be reopened. The new comment period and hearing will allow all interested parties to submit oral or written comments on the proposal. We are seeking comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested parties concerning the proposed rule. Comments already submitted on the proposed rule need not be resubmitted as they will be fully considered in the final determination.

DATES: The comment period for this proposal now closes on February 19, 2001. Any comments received by the closing date will be considered in the final decision on this proposal. The public hearing will be held from 1:00 p.m. to 3:00 p.m. and 6:00 p.m. to 8:00 p.m. on Tuesday, February 6, 2001, on the island of Kauai, Hawaii. Prior to the public hearing, the Service will be available from 12:30 to 1:00 p.m. and from 5:30 to 6:00 p.m. to provide information and to answer questions.

ADDRESSES: The public hearing will be held at the Radisson Kauai Beach Resort, Pakalana Room, 4331 Kauai Beach Drive, Lihue, Kauai. Comments and materials concerning this proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, Pacific Islands Ecoregion Office, 300 Ala Moana Boulevard, Room 3–122, P.O. Box 50088, Honolulu, Hawaii 96850. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Paul Henson, at the above address, phone 808–541–3441, facsimile 808–541–3470.

SUPPLEMENTARY INFORMATION:

Background

On November 7, 2000, the Service published a notice of prudency determinations for 81 plants species and proposed designations of critical habitat for 76 plant species from the islands of Kauai and Niihau, Hawaii, pursuant to the Endangered Species Act of 1973, as amended (Act) in the **Federal Register** (65 FR 66808). The original comment period closed on January 8, 2001. The comment period now closes on February 19, 2001. Written comments should be submitted to the Service (see **ADDRESSES** section).

A total of 95 species historically found on Kauai and Niihau were listed as endangered or threatened species under the Act, between 1991 and 1996. Some of these species may also occur on other Hawaiian islands. At the time each plant was listed, we determined that designation of critical habitat was not prudent because designation would increase the degree of threat to the species and/or would not benefit the species.

Due to litigation, we reconsidered our previous prudency determinations for the 95 plants. From this review, we are proposing that critical habitat is prudent for 76 of these species because the potential benefits of designating critical habitat essential for the conservation of these species outweigh the risks of designation. We are proposing that the designation of critical habitat is not prudent for five species. The remaining 14 species historically found on Kauai and/or Niihau, no longer occur on these islands. However, these species do occur on other islands, so proposed prudency determinations will be made in future rules addressing plants on those islands.

This proposed rule also proposes designation of critical habitat for the 76 species. Twenty-three critical habitat units, covering a total of 24,539.23 hectares (60,636.42 acres), are proposed for designation on the islands of Kauai and Niihau.

Section 4(b)(5)(E) of the Act (16 U.S.C. 1531 *et seq.*), requires that a public hearing be held if it is requested within 45 days of the publication of a proposed rule. In response to a request from a government agency of the State of Hawaii, the Service will hold a public hearing on the date and at the address described in the **DATES** and **ADDRESSES** sections above.

Anyone wishing to make an oral statement for the record is encouraged

to provide a written copy of their statement and present it to the Service at the hearing. In the event there is a large attendance, the time allotted for oral statements may be limited. Oral and written statements receive equal consideration. There are no limits to the length of written comments presented at the hearing or mailed to the Service. Legal notices announcing the date, time, and location of the hearing will be published in newspapers concurrently with the **Federal Register** notice.

Comments from the public regarding the accuracy of this proposed rule are sought, especially regarding:

(1) The reasons why critical habitat for any of these species is prudent or not prudent;

(2) The reasons why any particular area should or should not be designated as critical habitat for any of these species;

(3) Specific information on the amount and distribution of habitat for any of these species;

(4) Land use practices and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(5) Any economic or other relevant impacts resulting from the proposed designations of critical habitat, including any impacts on small entities or families; and

(6) Economic and other potential values associated with designating critical habitat for the 76 plant species such as those derived from non-consumptive uses (*e.g.*, hiking, camping, birding, enhanced watershed protection, increased soil retention, "existence values", and reductions in administrative costs).

Reopening of the comment period will enable the Service to respond to the request for a public hearing on the proposed action. The comment period on this proposal now closes on February 19, 2001. Written comments should be submitted to the Service office listed in the **ADDRESSES** section.

Author

The primary authors of this notice Benton Pang and Christa Russell (see **ADDRESSES** section).

Authority: The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: January 3, 2001.

Rowan W. Gould,

Acting Regional Director, Region 1, Fish and Wildlife Service.

[FR Doc. 01–659 Filed 1–17–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AH05

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for Sidalcea oregana var. calva (Wenatchee Mountains checker-mallow)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for *Sidalcea oregana* var. *calva* (Wenatchee Mountains checker-mallow), pursuant to the Endangered Species Act of 1973, as amended (Act). An estimated maximum of 2,486 hectares (6,137 acres) lies within the boundary of the proposed critical habitat designation, located in Chelan County, Washington. If this proposal is made final, section 7 of the Act requires Federal agencies to insure that any action they fund, authorize, or carry out does not result in the destruction or adverse modification of critical habitat. Section 4 of the Act requires us to consider economic and other impacts of specifying any particular area as critical habitat. We solicit data and comments from the public on all aspects of this proposal, including data on the economic and other impacts of the designation. We may revise this proposal to incorporate or address new information received during the comment period.

DATES: We will accept comments until March 19, 2001. Public hearing requests must be received by March 5, 2001.

ADDRESSES: Comment Submission: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

You may submit written comments and information to Gerry Jackson, Manager, Western Washington Office, U.S. Fish and Wildlife Service, 510 Desmond Drive SE, Suite 102, Lacey, Washington, 98503–1263.

You may send comments by electronic mail (e-mail) to: checkermallow@fws.gov. See the Public Comments Solicited section below for file format and other information about electronic filing.

You may hand-deliver comments to our Western Washington Office at the address given above.

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for inspection, by appointment, during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: Ted Thomas, Ecologist, Endangered Species Branch, Western Washington Office (see **ADDRESSES** section) (telephone 360/753–4327; facsimile 360/534–9331).

SUPPLEMENTARY INFORMATION:

Background

Sidalcea oregana var. *calva*, the Wenatchee Mountains checker-mallow, is known to occur at six sites (populations). It is a plant found in mid-elevation wetlands and moist meadows in central Washington. The plant communities where the species is found are usually associated with meadows that have surface water or saturated soils during the spring and early summer. The species may also be found in open conifer forests dominated by *Pinus ponderosa* (ponderosa pine) and *Pseudotsuga menziesii* (Douglas-fir), and on the margins of shrub and hardwood thickets adjacent to seeps, springs, or small drainages. Soils are primarily composed of silt loams and clay loams with a high percentage content of organic material, and they are poorly drained.

A member of the mallow family (Malvaceae), *Sidalcea oregana* var. *calva* is an herbaceous perennial with a stout taproot that branches at the root-crown giving rise to several stems. Plants range in height from 20 to 150 centimeters (cm) (8 to 60 inches (in.)). Plants vary from glabrous (lacking hairs and glands) to pubescent (hairy) or stellate (with star-shaped hairs) below, and finely stellate above. Flower clusters with one to many stalked flowers are arranged singly along a common stem. The flowers have pink petals 1 to 2 cm (0.4 to 0.8 in.) long, and are borne on stalks ranging from 1 to 10 millimeters (mm) (0.04 to 0.4 in.) in length. The calyx (outer whorl of floral parts) ranges from uniformly finely stellate to bristly with a mixture of longer, simple to four-rayed, spreading hairs. These hairs are sometimes as long as 2.5 to 3 mm (0.1 to 0.12 in.) (Hitchcock and Cronquist 1961).

Flowering begins in the middle of June and peaks in the middle to end of July. Fruits are ripe in August. The species reproduces only from seed. Based on examination of seed capsules the production of seed appears to be high (Gamon 1987). The somewhat clumped distribution of mature *Sidalcea oregana* var. *calva* plants suggests that seed dispersal is restricted to the areas near to mature plants, unless the seeds

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are moved by animals or transported by water.

The physical and biological habitat features essential to the conservation of *Sidalcea oregana* var. *calva* include open meadows with surface water or saturated upper soil profiles in the spring and early summer; open conifer forests dominated by ponderosa pine and Douglas-fir; and the margins of shrub and hardwood thickets. All of these habitats have surface water or saturated soils well into the early summer. Elevations range from 488 to 1,000 meters (m) (1,600 to 3,300 feet (ft)). The species is generally found on flats or benches, but may also occur in small ravines and occasionally on gently sloping uplands.

Concentrations of *Sidalcea oregana* var. *calva* are found in the wetter portions of moist meadow habitat, in open forests in slight topographic depressions, on the perimeter of shrub and hardwood thickets dominated by quaking aspen (*Populus tremuloides*), and along permanent or intermittent streams in sparsely forested draws. Frequently associated plant species include quaking aspen, black hawthorn (*Crataegus douglasii*), common snowberry (*Symphoricarpos albus*), serviceberry (*Amelanchier alnifolia*), few-flowered peavine (*Lathyrus pauciflorus*), northern mule's-ear (*Wyethia amplexicaulis*), sticky purple geranium (*Geranium viscosissimum*), western bistort (*Polygonum bistortoides*), leafy aster (*Aster foliaceus*), Watson's willow-herb (*Epilobium watsonii*), false hellebore (*Veratrum californica*), and rudbeckia (*Rudbeckia occidentalis*) (Washington Department of Natural Resources (WDNR) 2000). One-half of the *Sidalcea oregana* var. *calva* populations are found in association with *Delphinium viridescens* (Wenatchee larkspur), a former Federal category 1 candidate plant species. The latter species was removed from candidate status on February 28, 1996 (61 FR 7610), because it was found to be more abundant or widespread than previously believed.

At the time the final rule for *Sidalcea oregana* var. *calva* was published (64 FR 71680), just five sites were known to exist. During mid-summer 1999, a sixth population was discovered on private property in Pendleton Canyon, an area that was burned and opened up by the Tyee Fire of 1994. This location is less than 8 kilometers (km) (5 miles (mi)) from the Camas Meadow population.

The wetland and moist meadow complex at Camas Meadows, an area managed as a Natural Area Preserve (NAP) by the WDNR, contains the largest population of *Sidalcea oregana* var. *calva* The Camas Meadow NAP includes approximately 539 hectares (ha) (1,333 acres (ac)) (WDNR 2000), and is located in the rural/wildland interface about 16 km (10 mi) south of Leavenworth, Washington. An estimated 3,300 *Sidalcea oregana* var. *calva* individuals occur there. Low density, rural residential home sites have been developed adjacent to the NAP. Also, the Camas Meadows Bible Camp has occupied the southern perimeter of the meadow since the late 1940s, and the U.S. Forest Service (Forest Service) administers properties surrounding the NAP.

Another population is located north of the Camas Meadow NAP, on land administered by WDNR, and has approximately 30 individual plants. At the time the final rule was published (64 FR 71680), this population occurred on private land. The private landowners have since traded this land to the State.

In addition to these two populations of *Sidalcea oregana* var. *calva*, two other populations of *Sidalcea oregana* var. *calva* are known to be present on private lands. One population, of about 200 individuals, is located at the Mountain Home Resort. The second population is located in Pendleton Canyon, and consists of about 60 plants. The last two known populations are located on Forest Service lands, containing less than 10 individual plants combined. The combined number of individual plants for all six populations is approximately 3,600.

The primary threats to *Sidalcea oregana* var. *calva* include habitat fragmentation and destruction due to alterations of hydrology, rural residential development and associated activities, conversion of native wetlands to orchards and other agricultural uses, competition from native and non-native plants, recreation, seed and plant collection, and fire suppression and associated activities. To a lesser extent, the species is threatened by livestock grazing, road construction, and timber harvesting and associated impacts including changes in surface runoff in the small watersheds in which the plant occurs.

Previous Federal Action

Federal action on *Sidalcea oregana* var. *calva* began when we published an updated Notice of Review for plants, published in the **Federal Register** on December 15, 1980 (45 FR 82480). This notice included *Sidalcea oregana* var. *calva* as a category 1 candidate species. Category 1 candidates were defined as those taxa for which we had sufficient information on the biological vulnerability and threats to support preparation of listing rules. The Notice of Review published on September 27, 1985 (50 FR 39526), included *Sidalcea oregana* var. *calva* as a category 2 candidate species. Category 2 candidates were defined as taxa for which available information indicated that a proposal to list as endangered or threatened was possibly appropriate, but for which persuasive data on biological vulnerability and threats were not sufficient to support a proposed rule.

Notices of review published on February 21, 1990 (55 FR 6184), and September 30, 1993 (58 FR 51144), identified the plant as a category 1 candidate species. Upon publication of the February 28, 1996, Notice of Review (61 FR 7596), we ceased using category designations and included *Sidalcea oregana* var. *calva* as a candidate species. Candidate species are those for which we have on file sufficient information on biological vulnerability and threats to support proposals to list the species as threatened or endangered.

On August 1, 1997, we published the proposed rule to list *Sidalcea oregana* var. *calva* as an endangered species (62 FR 41328). The final determination to list *Sidalcea oregana* var. *calva* as an endangered species was published in the **Federal Register** on December 22, 1999 (64 FR 71680). In the final rule, we found that designation of critical habitat for the species was prudent. Due to insufficient funding in our listing budget at the time, critical habitat designation was deferred in order to focus our limited resources on higher priority critical habitat, including court-ordered designations, and other listing actions (64 FR 71685), while still allowing us to put in place protections needed for the protection of *S. oregana* var. *calva* through the listing process.

Critical Habitat

Critical habitat is defined in section 3 of the Act as—(i) the specific areas within the geographic area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. "Conservation" means the use of all methods and procedures that are necessary to bring an endangered or a threatened species to the point at which listing under the Act is no longer necessary.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification of critical habitat with regard to actions carried out, funded, or authorized by a Federal agency. Section 7 also requires conferences on Federal actions that are likely to result in the destruction or adverse modification of critical habitat. In our regulations at 50 CFR 402.02, we define destruction or adverse modification as "* * * the direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical." Aside from the added protection that may be provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat. Because consultation under section 7 of the Act does not apply to activities on private or other non-Federal lands that do not involve a Federal nexus, critical habitat designation would not afford any additional protections under the Act against such activities.

In order to be included in a critical habitat designation, the habitat must first be "essential to the conservation of the species." Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (i.e., areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

Section 4 requires that we designate critical habitat at the time of listing and based on what we know at the time of the designation. When we designate critical habitat at the time of listing or under short court-ordered deadlines, we will often not have sufficient information to identify all areas of critical habitat. We are required, nevertheless, to make a decision and thus must base our designations on what, at the time of designation, we know to be critical habitat.

Within the geographic area occupied by the species, we will designate only areas currently known to be essential. Essential areas should already have the features and habitat characteristics that are necessary to sustain the species. We will not speculate about what areas might be found to be essential if better information became available, or what areas may become essential over time. If the information available at the time of designation does not show that an area provides essential life cycle needs of the species, then the area should not be included in the critical habitat designation. Within the geographic area occupied by the species, we will not designate areas that do not now have the primary constituent elements, as defined at 50 CFR 424.12(b), that provide essential life cycle needs of the species.

Our regulations state that, "The Secretary shall designate as critical habitat areas outside the geographic area presently occupied by the species only when a designation limited to its present range would be inadequate to ensure the conservation of the species." (50 CFR 424.12(e)). Accordingly, when the best available scientific and commercial data do not demonstrate that the conservation needs of the species require designation of critical habitat outside of occupied areas, we will not designate critical habitat in areas outside the geographic area occupied by the species.

The Service's Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (Vol. 59, p. 34271), provides criteria, establishes procedures, and provides guidance to ensure that decisions made by the Service represent the best scientific and commercial data available. It requires Service biologists, to the extent consistent with the Act and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by states and counties, scientific status surveys and studies, and biological assessments or other unpublished materials (i.e. gray literature).

Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, all should understand that critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under Section 7(a)(1) and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the Section 9 take prohibition, as determined on the basis of the best available information at the time of the action. We specifically anticipate that federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Methods

In determining areas that are essential to conserve *Sidalcea oregana* var. *calva*, we used the best scientific information available to us. This information included habitat suitability and site-specific species information, as well as discussions with Wenatchee National Forest and WDNR scientists about the management and conservation of this species. We have emphasized areas of current and historical *Sidalcea oregana* var. *calva* occurrences; maintenance of the genetic interchange necessary for the viability of a regional metapopulation; and maintenance of the integrity of the watershed hydrologic processes on which the wetlands and moist meadows that support the species depend. A metapopulation is a group of spatially separated populations that can occasionally exchange genes. The populations in a metapopulation are usually thought of as undergoing interdependent extinction and colonization, where individual populations may go extinct, but later recolonize from another population. Linking the known populations provides pathways for gene flow as well as opportunities for colonization by the species of areas where it may be extirpated. We believe that the maintenance of a viable regional metapopulation as well as the integrity of the hydrologic processes that control the wetland and moist meadow habitat are essential to the conservation of *Sidalcea oregana* var. *calva*.

We used data on known and historic locations and soil maps to identify areas important to the species. We mapped critical habitat based on orthoquads and aerial photos available from WDNR, and ground-checked these areas. We included areas with wetland vegetation communities dominated by native grasses and forbs and generally free of

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woody shrubs, hardwood trees, or conifers that would produce shade and/or compete with *Sidalcea oregana* var. *calva*. Seeps, springs and riparian corridors that have clay loam and silt loam soils were included because of their importance to maintaining the hydrologic processes that are essential to the conservation of the species. Inclusion of these areas also allows for the natural expansion of *Sidalcea oregana* var. *calva* populations that is essential for the conservation of the species.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat, we must consider those physical and biological features (primary constituent elements) that are essential to the conservation of the species. These include, but are not limited to, the following: space for individual and population growth, and for normal behavior; food, water, air, light, minerals or nutrients, or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distribution of a species.

The primary constituent elements of critical habitat for *Sidalcea oregana* var. *calva* are those that are essential for the primary biological needs of the species. The area we propose to designate as critical habitat provides the primary constituent elements for the species, which include: surface water or saturated upper soil profiles; a wetland plant community dominated by native grasses and forbs, and generally free of woody shrubs and conifers that would produce shade and competition for *Sidalcea oregana* var. *calva*; seeps and springs on fine textured soils (clay loams and silt loams), which contribute to the maintenance of hydrologic processes necessary to support meadows which remain moist into the early summer; and elevations of 488 m–1,000 m (1,600–3,300 ft).

Criteria Used To Identify Critical Habitat

In an effort to map areas that have the features essential to the conservation of the species, we used data on known *Sidalcea oregana* var. *calva* locations. We also considered the existing status of lands in designating areas as critical habitat. *Sidalcea oregana* var. *calva* is known to occur on Federal, State, and private lands. We are not aware of any Tribal lands essential to the conservation of *Sidalcea oregana* var. *calva*, or any in or near the proposed critical habitat designation. However, should we learn of any Tribal lands in the vicinity of the critical habitat designation subsequent to this proposal, we will coordinate with the Tribes before making a final determination as to whether any Tribal lands should be included as critical habitat for *Sidalcea oregana* var. *calva*.

In defining critical habitat boundaries, we made an effort to avoid developed areas, such as towns and other similar lands, that are unlikely to contribute to *Sidalcea oregana* var. *calva* conservation. However, limitations in our ability to map critical habitat for *Sidalcea oregana* var. *calva* did not allow us to exclude all developed areas, such as towns, or housing developments, or other lands unlikely to contain the primary constituent elements essential for conservation of *Sidalcea oregana* var. *calva*. Existing features and structures within the boundaries of the mapped unit, such as buildings, roads, aqueducts, railroads, airports, other paved areas, lawns, and other rural residential landscaped areas will not contain one or more of the primary constituent elements and are, therefore, not critical habitat. Federal actions limited to those areas would not trigger a section 7 consultation, unless they affect the species and/or primary constituent elements in adjacent critical habitat.

Proposed Critical Habitat

We are proposing critical habitat in one unit, comprised of 2,484 ha (6,135 ac). The approximate area, by land ownership, of this unit is shown in Table 1; lands proposed are under private, State, and Federal ownership. All of the proposed critical habitat for *Sidalcea oregana* var. *calva* is in Chelan County, Washington, and includes Camas Creek and the adjacent Pendleton Canyon sub-basin. The area proposed for critical habitat includes all of the lands that have the primary constituent elements below 1,000 m (3,300 ft) within the Camas Creek watershed and in the small tributary within Pendleton Canyon before its confluence with Peshastin Creek, and includes: (1) The entire area encompassed by the Camas Meadow Natural Area Preserve, which is administered by the WDNR; (2) two populations located on Forest Service land; (3) the small drainage north of the Camas Land, administered by the WDNR; and (4) the population on private property located in Pendleton Canyon.

Portions of the designated critical habitat are presumably unoccupied by *Sidalcea oregana* var. *calva* at present, although the entire area has not been recently surveyed. Soil maps indicate that the entire area provides suitable habitat for the species, and there may be additional, but currently unknown, populations present here. Because protection of the hydrological processes is necessary to ensure the viability of the wetland habitat of the species, we consider the entire area essential to the survival, eventual recovery, and delisting of *Sidalcea oregana* var. *calva*.

Wetlands and moist meadow habitat (native grassland and forb-dominated vegetation) suitable for *Sidalcea oregana* var. *calva* is generally surrounded by upland conditions, which are dominated by ponderosa pine and Douglas-fir forests. These upland conditions are less suitable as habitat for the species and are not essential to the conservation of the species. Moist meadow openings within sparse ponderosa pine and Douglas-fir forests, however, are suitable habitat and are included in this proposed critical habitat designation.

Pursuant to the definition of critical habitat in section 3 of the Act, any area so designated must also require "special managment considerations or protections." Some areas essential to the conservation of the species may not be designated critical habitat if they already have adequate special management. Adequate special management or protection is provided by a legally operative plan that addresses the maintenance and improvement of the essential elements and provides for the long-term conservation of the species. The Service considers a plan adequate when it meets all of the following three criteria: (1) The plan provides a conservation benefit to the species (*i.e.*, the plan must maintain or provide for an increase in the species' population or the enhancement or restoration of its habitat within the area covered by the plan); (2) the plan provides assurances that the management plan will be implemented (*i.e.*, those responsible for implementing the plan are capable of accomplishing the objectives, have an implementation schedule and/or have adequate funding to implement the management plan); and, (3) the plan provides assurances the conservation plan will be effective (*i.e.*, it identifies biological goals, has provisions for reporting progress, and is of a duration sufficient to implement the plan and achieve the plan's goals and objectives). If an area is covered by a plan that meets these criteria, it does not constitute critical habitat as defined by the Act.

The Camas Land NAP is managed by the WDNR, and a final Management Plan (Plan) for the area was approved in June, 2000. The NAP was established in 1989 to protect the large populations of *Sidalcea oregana* var. *calva* and *Delphinium viridescens* (Wenatchee larkspur) that occur at Camas Meadow. The general management policy described in the Plan applies to all NAPs managed by the WDNR. These include: (1) Protection of outstanding examples of rare or vanishing terrestrial or aquatic ecosystems, rare plant and animal species and unique geologic features; (2) the role of NAPs as a baseline to compare with similar ecosystems that are under the influence of human activities; and (3) areas that are important to preserving natural features of scientific or educational value. However, the Plan does not provide a specific management plan or prescription designed to conserve *Sidalcea oregana* var. *calva*, beyond permitting natural ecological and physical processes to continue (WDNR 2000). The Plan does call for management actions to enhance wet meadow habitat, which will benefit *Sidalcea oregana* var. *calva* by removing competing vegetation, including controlling noxious weeds; thinning ponderosa pine in the uplands; and improving and replacing culverts. However, these actions have not yet been implemented, and it is too early to assess their effectiveness.

Although the species is listed as endangered by the WDNR's Natural Heritage Program (1994), there is no State Endangered Species Act in the State of Washington. The WDNR designation provides no legal protection for *Sidalcea oregana* var. *calva*, and there are no State laws that specifically protect plants on State lands. Therefore, we believe that this management plan alone does not provide sufficient protection for *Sidalcea oregana* var. *calva*, and have included the Camas Land NAP within the proposed critical habitat designation.

Private residential properties on the periphery of the Camas Land NAP and the Camas Meadow Bible Camp located on the south side of the Camas Land, within the area designated as critical habitat, are not included in the designation. Private residential properties in the vicinity of the Camas Land NAP have been altered by the planting of lawns, installation of septic systems, and horse pastures. These properties are generally located in upland conditions that do not provide the primary constituent elements of critical habitat necessary for the long-term protection and conservation of *Sidalcea oregana* var. *calva*.

TABLE 1.—APPROXIMATE AREA OF PROPOSED CRITICAL HABITAT IN HECTARES (HA) AND ACRES (AC) [1] IN CHELAN COUNTY, WASHINGTON, BY LAND OWNERSHIP

[Area estimates reflect the proposed critical habitat unit boundaries; however, existing features and structures, such as buildings, roads, aqueducts, railroads, airports, other paved areas, lawns, and other rural residential landscaped areas not containing one or more of the primary constituent elements are not designated as critical habitat for *Sidalcea oregana* var. *calva*]

	Federal	Local/state	Private	Total
Areas Known to be Currently Occupied	0.5 ha (1 ac)	38 ha (94 ac)	0.5 ha (1 ac)	39 ha (96 ac)
Areas of Suitable Habitat of Unknown Occupancy	830 ha (2,050 ac)	540 ha (1,334 ac)	1,075 ha (2,655 ac)	2,445 ha (6,039 ac)
Total				2,484 ha (6,135 ac)

[1] Approximate acres have been converted to hectares (1 ha = 2.47 ac). Hectares and acres greater than 1 have been rounded to the nearest 5, except for totals which are sums of rows or columns.

We have determined that the habitat supporting the population found at the Mountain Home Resort (Resort) is not essential to the conservation of the species. This population is disjunct from the remaining populations, and located in an area entirely surrounded with private residences, private timberlands, and a road administered by Chelan County. The habitat on this property that contains *Sidalcea oregana* var. *calva*, and the former candidate species *Delphinium viridescens*, is confined to a small linear area associated with a drainage ditch adjacent to the Mountain Home road and is bordered on the north and south by gravel access roads leading to residences. It is likely that the habitat resulted from the construction of the road and the creation of the drainage ditch. The habitat is now dominated by non-native, sod-forming grasses and forbs mixed with native vegetation (Dottie Knecht, Forest Service, pers. comm. 2000). The class-B Washington State noxious weed, *Potentilla recta* (sulfur cinquefoil) (Washington Administrative Code 16–750–011) is frequently encountered in monitoring plots at this site, although at low cover (D. Knecht, pers. comm. 2000). Moving out of the occupied habitat and up the hill towards the Resort, the vegetation is also dominated by sod-forming pasture and lawn grasses, including *Agrostis alba* (creeping bentgrass), *Alopecuris pratensis* (meadow foxtail), *Phleum pratense* (timothy grass), and *Bromus inermis* (smooth brome). These species are not consistent with the primary constituent elements.

Through observation of the adjacent properties along the Mountain Home road, it is evident that, if the Resort were not present and the land had not been cleared to create a vista, the marginal habitat where the small population is found at this site would be forested with conifers mixed with hardwood trees and shrubs. Such habitat does not contain the vegetative requirements and open conditions of the primary constituent elements.

The population at the Resort is also disjunct from the other populations of the species, which are more than 16 km (10 mi) distant. Because of fragmentation and the patchy distribution of habitat between this population and other populations of the species, the persistence of this population cannot be assured. We believe that the most appropriate conservation strategy for *Sidalcea oregana* var. *calva* is one that focuses on the protection and expansion of the core habitat of the species rather than the protection of isolated populations of doubtful viability. Except through artificial means, there is no opportunity for gene exchange between this population and the other populations. Although no genetic testing has been conducted for this species, a small population, such as that found at the Resort, is likely to have reduced genetic diversity, which can result in decreased

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population viability due to inbreeding (Schemske *et al.* 1994).

Although the ability to predict random environmental events (stochastic events) is low, events such as forest fires (*e.g.*, the 1994 Rat Creek and Hatchery Creek Fires) and rain-on-snow flooding do occur. The effects of these stochastic events are most acute in small populations (Schemske *et al.* 1994). As a result of an increased importance of stochastic processes and changes in ecological interactions in declining populations, the probability of a population extirpation is expected to be negatively correlated with its size (Schemske *et al.* 1994).

The population found at Pendleton Canyon is on privately-owned land that has been included as critical habitat because it has the primary constituent elements required by *Sidalcea oregana* var. *calva*. It is located in a wildland setting with none of the modifications typically associated with a residence, unlike the private residences near Camas Meadow or the population of *Sidalcea oregana* var. *calva* at the Resort which lack the primary constituent elements and have been excluded from critical habitat designation.

The Recovery Team for *Sidalcea oregana* var. *calva* will be providing guidance on recovery planning for this species. The Recovery Team may provide additional guidance regarding the areas proposed for critical habitat designation. We will evaluate any of the Recovery Team's recommendations and re-examine our critical habitat designation, if necessary, to provide for the conservation of the species.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a) of the Act requires that Federal agencies, including the Service, must ensure that actions they fund, authorize, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for the survival and recovery of the species. Individuals, organizations, States, local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding.

Under section 7(a) of the Act, Federal agencies, including the Service, evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated or proposed. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) and regulations at 50 CFR 402.10 requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist the agency in eliminating conflicts that may be caused by the proposed action. The conservation recommendations in a conference report are advisory.

We may issue a formal conference report if requested by a Federal agency. Formal conference reports on proposed critical habitat contain a biological opinion that is prepared according to 50 CFR 402.14, as if critical habitat were designated. If such designation occurs, we may adopt the formal conference report as a biological opinion, if no significant new information or changes in the action alter the content of the opinion (see 50 CFR 402.10(d)).

When a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with us. Through this consultation, we would advise the agencies whether the permitted actions would likely jeopardize the continued existence of the species or destroy or adversely modify critical habitat.

When we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. Reasonable and prudent alternatives are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where critical habitat is subsequently designated and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation or conferencing with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

Activities on private or State lands requiring a permit from a Federal agency, such as a permit from the U.S. Army Corps of Engineers (Corps) under section 404 of the Clean Water Act, or a section 10(a)(1)(B) permit from the Service, or some other Federal action, including funding (*e.g.*, from the Federal Highway Administration or Federal Emergency Management Agency will also be subject to the section 7 consultation process. Federal actions not affecting listed species or critical habitat, and actions on non-Federal lands that are not federally funded, authorized, or permitted do not require section 7 consultation. Not all of the areas within the unit is capable of supporting Sidalcea oregana var. calva or its primary constituent elements, and such areas would not be subject to section 7 consultation. However, in the interests of having a clear boundary that is readily located on the ground, or because of mapping uncertainties, we have included some areas that may not be critical habitat as described below.

To properly portray the effects of critical habitat designation, we must first compare the section 7 requirements for actions that may affect critical habitat with the requirements for actions that may affect a listed species. Section 7 prohibits actions funded, authorized, or carried out by Federal agencies from jeopardizing the continued existence of a listed species or destroying or adversely modifying the listed species' critical habitat. Actions likely to "jeopardize the continued existence" of a species are those that would appreciably reduce the likelihood of the species' survival and recovery. Actions likely to "destroy or adversely modify" critical habitat are those that would appreciably reduce the value of critical habitat for the survival and recovery of the listed species.

Common to both definitions is an appreciable detrimental effect on both survival and recovery of a listed species. Given the similarity of these definitions, actions likely to destroy or adversely modify critical habitat would almost always result in jeopardy to the species concerned, particularly when the area of the proposed action is occupied by the species concerned. Designation of critical habitat in areas known to be occupied by *Sidalcea oregana* var. *calva*, and areas where the species is detected in surveys at the time of the action, is not likely to result in a significant regulatory burden above that already in place due to the presence of the listed species. For some previously reviewed actions, in instances where critical habitat is subsequently designated, and in those cases where activities occur on designated critical habitat where *Sidalcea oregana* var. *calva* is not found at the time of the action, an additional section 7 consultation with the Service not previously required may be necessary for actions funded, authorized, or carried out by Federal agencies.

Section 4(b)(8) of the Act requires us to briefly describe and evaluate in any proposed or final regulation that designates critical habitat those activities involving a Federal action that may adversely modify such habitat or that may be affected by such designation. When determining whether any of these activities may adversely modify critical habitat, we base our analysis on the effects of the action on the entire critical habitat area and not just on the portion where the activity will occur. Adverse effects on constituent elements or segments of critical habitat generally do not result in an adverse modification determination unless that loss, when added to the environmental baseline, is likely to appreciably diminish the capability of the critical habitat to satisfy essential requirements of the species. In other words, activities that may destroy or adversely modify critical habitat include those that alter the primary constituent elements (defined above) to an extent that the value of critical habitat for both the survival and recovery of the *Sidalcea oregana* var. *calva* is appreciably diminished.

Activities that, when carried out, funded, or authorized by a Federal agency, may affect critical habitat and require that a section 7 consultation be conducted include, but are not limited to:

(1) Damming, water diversion, channelization, excess groundwater pumping, repair and replacement of culverts, or other actions that appreciably reduce the hydrologic function and surface area of rivers, streams, seeps or springs;

(2) Timber harvesting and road construction that directly or indirectly effects the hydrology of sites harboring the species;

(3) Rural residential construction that include concrete pads for foundations and the installation of septic systems where a permit under section 404 of the Clean Water Act (33 U.S.C. 1344 *et seq.*) would be required from the Corps;

(4) Activities that alter watershed characteristics in ways that would appreciably reduce groundwater recharge or alter natural flooding regimes to alter natural, dynamic wetland communities. Such activities may include manipulation of vegetation such as timber harvesting, road construction, maintaining an unnatural fire regime either through fire suppression, or too frequent or poorly-timed prescribed fires, residential and commercial development, and grazing of livestock or horses that reduces fire frequency or otherwise degrades watershed values;

(5) Activities that appreciably degrade or destroy native wetland communities, such as livestock or horse grazing, land clearing, harvesting of trees or other forest products, introducing or encouraging the spread of non-native plant species; and

(6) Activities that appreciably alter stream channel morphology such as sand and gravel mining, road construction, channelization, impoundment, watershed disturbances, off-road vehicle use, heavy or poorly planned recreational uses, and possibly other uses.

Any of the above activities that appreciably diminish the value of critical habitat to the degree that they affect the survival and recovery of *Sidalcea oregana* var. *calva* may be considered an adverse modification or destruction of critical habitat. We note that such activities may also jeopardize the continued existence of the species.

If you have questions regarding whether specific activities will constitute destruction or adverse modification of critical habitat resulting from a Federal action, contact Gerry Jackson, Manager, Western Washington Office (see **ADDRESSES** section). Requests for copies of the regulations on listed wildlife, and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Branch of Endangered Species, 911 N.E. 11th Ave, Portland, Oregon 97232 (telephone 503/231–2063; facsimile 503/231–6243).

Available Conservation Measures

Activities by the landowners of the Mountain Home Resort have resulted in positive conservation measures for the species. The landowners have cooperated and supported the monitoring of this population by the Forest Service since 1994 when, during the Rat Creek and Hatchery Creek fires, approximately one-half of the area occupied by *Sidalcea oregana* var. *calva* and *Delphinium viridescens* was bulldozed and leveled to create a fire safety zone. After the fires, the landowners permitted the Forest Service and volunteers to restore and plant grass seed on their land to reduce erosion in the small drainage area where these two species occur. Within about 2 years, the hydrologic processes had returned to normal and *Delphinium viridescens* resprouted from rhizomes. *Sidalcea oregana* var. *calva* recolonized by seed from neighboring parent plants and the soil seed bank stored in soils not disturbed by bulldozers.

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of the exclusions outweigh the benefits of specifying the areas as critical habitat. We cannot exclude the areas from critical habitat when the exclusion will result in the extinction of the species. We will conduct an analysis of the economic impacts of designating these areas as critical habitat prior to making a final determination. When completed, we will announce the availability of this economic analysis with a notice in the **Federal Register**; if necessary, we will reopen the comment period at that time.

Public Comments Solicited

We intend that any final action resulting from this proposal be as accurate and as effective as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of designation will outweigh any benefits of exclusion;

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(2) Specific information on the amount and distribution of *Sidalcea oregana* var. *calva* and its habitat, and what habitat is essential to the conservation of the species and why;

(3) Land use practices and current or planned activities in the subject areas and their possible impacts on proposed critical habitat;

(4) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families; and

(5) Economic and other values associated with designating critical habitat for *Sidalcea oregana* var. *calva* such as those derived from nonconsumptive uses (*e.g.*, hiking, camping, birdwatching, enhanced watershed protection, improved air quality, increased soil retention, and "existence values.").

If you submit comments by e-mail, please submit them as an ASCII file and avoid the use of special characters and any form of encryption. Please also include "Attn: [*RIN number*]" and your name and return address in your e-mail message. If you do not receive a confirmation from the system that we have received your e-mail message, contact us directly by calling our Western Washington Office at telephone number 360/753–9440.

Our practice is to make comments available for public review during regular business hours, including names and home addresses of respondents. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish for us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of this review is to ensure listing decisions are based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the 60-day comment period on this proposed rule during preparation of a final rulemaking. Accordingly, the final decision may differ from this proposal.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations/notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical language or jargon that interferes with the clarity? (3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Is the description of the proposed rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? What else could we do to make the proposed rule easier to understand? Send any comments that concern how we could make this proposed rule easier to understand to the Gerry Jackson, Manager, Western Washington Office (see **ADDRESSES** section of this rule).

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, this document is a significant rule and was reviewed by the Office of Management and Budget (OMB). We are preparing a draft analysis of this proposed action, which will be available for public comment, to determine the economic consequences of designating the specific areas as critical habitat. The availability of the draft economic analysis will be announced in the **Federal Register** and in local newspapers so that it is available for public review and comments.

(a) This rule will not have an annual economic effect of $100 million or more or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. *Sidalcea oregana* var. *calva* was listed as an endangered species in 1999. In fiscal years 1999 through 2000, we conducted 1 formal section 7 consultation with a Federal agency to ensure that their actions would not jeopardize the continued existence of the species.

Under the Act, critical habitat may not be adversely modified by a Federal agency action; critical habitat does not impose any restrictions on non-Federal persons unless they are conducting activities funded or otherwise sponsored, authorized, or permitted by a Federal agency (see Table 2 below). Section 7 requires Federal agencies to ensure that they do not jeopardize the continued existence of the species. Based upon our experience with the species and its needs, we conclude that any Federal action or authorized action that could potentially cause an adverse modification of the proposed critical habitat would currently be considered as "jeopardy" under the Act in areas occupied by *Sidalcea oregana* var. *calva*. Accordingly, the designation of currently occupied areas as critical habitat does not have any incremental impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons that receive Federal authorization or funding. Designation of unoccupied areas as critical habitat may have impacts on what actions may or may not be conducted by Federal agencies or non-Federal persons who receive Federal authorization or funding. We will evaluate any impact through our economic analysis (under section 4 of the Act; see Economic Analysis section of this rule). Non-Federal persons that do not have a Federal "sponsorship" of their actions are not restricted by the designation of critical habitat (however, they continue to be bound by the provisions of the Act concerning "take" of the species).

TABLE 2. IMPACTS OF *Sidalcea Oregana* VAR. *Calva* LISTING AND CRITICAL HABITAT DESIGNATION

Categories of activities	Activities potentially affected by species listing only	Additional activities potentially affected by critical habitat designation [1]
Federal activities potentially affected [2].	Activities conducted by the Army Corps of Engineers, U.S. Forest Service, Environmental Protection Agency, Federal Highway Administration.	Activities by these Federal Agencies in any unoccupied critical habitat areas.
Private or other non-Federal activities potentially affected [3].	Activities that require a Federal action (permit, authorization, or funding) and may remove or destroy *Sidalcea oregana* var. *calva* habitat by mechanical, chemical, or other means (*e.g.*, grading, discing, ripping, and tilling, water diversion, impounding, groundwater pumping, irrigation, construction, road building, herbicide application, recreational use, etc.) or appreciably decrease habitat value or quality through indirect effects (*e.g.*, edge effects, invasion of exotic plants or animals, fragmentation of habitat).	Funding, authorization, or permitting such actions by Federal Agencies in any unoccupied critical habitat areas.

[1] This column represents activities potentially affected by the critical habitat designation in addition to those activities potentially affected by listing the species.
[2] Activities initiated by a Federal agency.
[3] Activities initiated by a private or other non-Federal entity that may need Federal authorization or funding.

(b) This rule will not create inconsistencies with other agencies' actions. As discussed above, Federal agencies have been required to ensure that their actions do not jeopardize the continued existence of *Sidalcea oregana* var. *calva* since the listing in 1999. The prohibition against adverse modification of critical habitat is not expected to impose any additional restrictions to those that currently exist in areas of occupied habitat. We will evaluate any impact of designating unoccupied habitat areas through our economic analysis. Because of the potential for impacts on other Federal agency activities, we will continue to review this proposed action for any inconsistencies with other Federal agency actions.

(c) This proposed rule, if made final, will not materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. Federal agencies are currently required to ensure that their activities do not jeopardize the continued existence of the species, and, as discussed above, we do not anticipate that the adverse modification prohibition (resulting from critical habitat designation) will have any incremental effects in areas of occupied habitat.

(d) This rule will not raise novel legal or policy issues. The proposed rule follows the requirements for determining critical habitat contained in the Act.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

In the economic analysis (required under section 4 of the Act), we will determine whether designation of critical habitat will have a significant effect on a substantial number of small entities. Many of these activities sponsored by Federal agencies within the proposed critical habitat areas are carried out by small entities (as defined by the Regulatory Flexibility Act) through contract, grant, permit, or other Federal authorization. As discussed under Regulatory Planning and Review above, this rule is not expected to result in any restrictions in addition to those currently in existence for areas of occupied critical habitat. We will also evaluate whether critical habitat designation of unoccupied areas will significantly affect a substantial number of small entities. As indicated on Table 1 (see Proposed Critical Habitat Designation section), we designated property owned by State and Federal governments, and private property.

Within these areas, the types of Federal actions or authorized activities that we have identified as potential concerns are:

(1) Activities such as damming, water diversion, channelization, excess groundwater pumping, repair and replacement of culverts, or other actions that appreciably reduce the hydrologic function and surface area of rivers, streams, seeps or springs;

(2) Activities such as timber harvesting and road construction that directly or indirectly effects the hydrology of sites harboring the species; and

(3) Activities such as rural residential construction that include concrete pads for foundations and the installation of septic systems where a permit under section 404 of the Clean Water Act (33 U.S.C. 1344 *et seq.*) would be required from the Corps.

(4) Activities that alter watershed characteristics in ways that would appreciably reduce groundwater recharge or alter natural flooding regimes to alter natural, dynamic wetland communities. Such activities may include manipulation of vegetation such as timber harvesting, road construction, maintaining an unnatural fire regime either through fire suppression, or too frequent or poorly-timed prescribed fires, residential and commercial development, and grazing of livestock or horses that reduces fire frequency or otherwise degrades watershed values;

(5) Activities that appreciably degrade or destroy native wetland communities, such as livestock or horse grazing, land clearing, harvesting of trees or other forest products, introducing or encouraging the spread of non-native plant species; and

(6) Activities that appreciably alter stream channel morphology such as sand and gravel mining, road construction, channelization, impoundment, watershed disturbances, off-road vehicle use, heavy or poorly planned recreational uses, and possibly other uses.

Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

In the economic analysis, we will determine whether designation of critical habitat will cause (a) any effect on the economy of $100 million or more, (b) any increases in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (c) any significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. As discussed above, we anticipate that the designation of critical habitat will not have any additional effects on these activities in areas of critical habitat occupied by the species.

Designation of unoccupied areas as critical habitat may have impacts on what actions may or may not be

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conducted, or how they will be conducted, by Federal agencies or non-Federal persons who receive Federal authorization or funding. We will evaluate any impact through our economic analysis.

Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) We believe this rule will not "significantly or uniquely" affect small governments. A Small Government Agency Plan is not required. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. However, as discussed above, these actions are currently subject to equivalent restrictions through the listing protections of the species, and no further restrictions are anticipated to result from critical habitat designation of occupied areas. In our economic analysis, we will evaluate whether designation of unoccupied areas has any significant effect on small governments.

(b) This rule will not produce a Federal mandate of $100 million or greater in any year; that is, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications. A takings implication assessment is not required. As discussed above, the designation of critical habitat affects only Federal agency actions. The rule will not increase or decrease the current restrictions on private property concerning take of *Sidalcea oregana* var. *calva*. Due to current public knowledge of the species' protection under the Act, the prohibition against take of the species both within and outside of the designated areas, and the fact that critical habitat provides no incremental restrictions in areas of occupied critical habitat, we do not anticipate that property values will be affected by the critical habitat designation. Additionally, critical habitat designation does not preclude development of habitat conservation plans and issuance of incidental take permits.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from and coordinated development of this critical habitat proposal with appropriate State resource agencies in Washington. The designation of critical habitat in areas currently occupied by Sidalcea oregana var. calva imposes no additional restrictions to those currently in place and, therefore, has little incremental impact on State and local governments and their activities. The designation may have some benefit to these governments in that the areas essential to the conservation of the species are more clearly defined, and the primary constituent elements of the habitat necessary to the survival of the species are specifically identified. While making this definition and identification does not alter where and what federally sponsored activities may occur, it may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We propose to designate critical habitat in accordance with the provisions of the Act and plan a public hearing on the proposed designation during the comment period. The rule uses standard property descriptions and identifies the primary constituent elements within the designated areas to assist the public in understanding the habitat needs of *Sidalcea oregana* var. *calva*.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

This rule does not contain any information collection requirements that requires Office of Management and Budget approval under the Paperwork Reduction Act.

National Environmental Policy Act

We determined that we do not need to prepare an Environmental Assessment and/or an Environmental Impact Statement as defined by the National Environmental Policy Act of 1969 in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and 512 DM 2, we understand that federally recognized Tribes must be related to on a Government-to-Government basis.

We are not aware of any Tribal lands essential for the conservation of *Sidalcea oregana*. var *calva*. therefore, we are not proposing to designate critical habitat for *Sidalcea oregana* var. *calva* on Tribal lands.

References Cited

Gamon, J. G. 1987. Report on the status of *Sidalcea oregana* (Nutt.) Gray var. *calva* C.L. Hitchcock. Unpublished report to the U.S. Fish and Wildlife Service, Olympia Washington. 41 pp.

Schemske, D.W., B.C. Husband, M.H. Ruckleshaus, C. Goodwillie, I.M. Parker, and J.G. Bishop. 1994. Evaluating approaches to the Conservation of Rare and Endangered Plants. Ecology, 75(3). Pp. 584–606.

Hitchcock, C.L., A. Cronquist, M. Ownbey, and J.W. Thompson. 1961. Part 3. Vascular plants of the Pacific Northwest. University of Washington Press, Seattle. 614 pp.

Washington Department of Natural Resources. 2000. Management plan for Camas Meadows Natural Area Preserve. Unpublished report. 52 pp + appendices.

Washington Natural Heritage Program. 1994. Endangered, threatened, and sensitive vascular plants of Washington, Department of Natural Resources, Olympia, Washington. 52 pp.

Author

The primary author of this proposed rule is Ted Thomas (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Rule Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.12(h) revise the entry for *Sidalcea oregana* var. *calva* under "FLOWERING PLANTS" to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
FLOWERING PLANTS							
*	*	*	*	*	*	*	
Sidalcea oregana var. *calva*.	Wenatchee Mountains checker-mallow.	U.S.A. (WA)	Malvaceae—(Mallow).	E	673	17.96(a)	N/A
*	*	*	*	*	*	*	

3. In § 17.96, as proposed to be amended at 65 FR 66865, November 7, 2000, amend paragraph (b) by adding an entry for *Sidalcea oregana* var. *calva* after the entry for *Kokia drynarioides* under the family Malvaceae to read as follows:

§ 17.96 Critical habitat-plants.

* * * * *

(b) * * *

Family Malvaceae: *Sidalcea oregana* var. *calva* (Wenatchee Mountains checker-mallow).

Washington, Chelan County. From USGS 7.5′ quadrangle maps Peshastin and Tip Top, Washington. T. 23 N., R 18 E., beginning at a point on Camas Creek in the NW¼ of NW¼ of section 35 at approximately 47°26′52″N latitude and 120°38′57″ W longitude proceeding downstream (northwesterly), expanding in all directions to include the entire wetland complex that comprises the Camas Meadow Natural Area Preserve, to a point approximately 0.4 km (0.25 mi) from the confluence of Pendleton Creek and Peshastin Creek, located at 47°31′06″ and 120°37′18″ W longitude. From this last point, the western boundary of the designated critical habitat parallels Peshastin Creek to a point at the southwest of the designated area located at 47°28′46″ N latitude and 120°38′57″ W longitude. The maximum elevation of the designated critical habitat is 1,000 m (3,300 ft) and the lowest elevation is 488 m (1,600 ft).

Within this area, critical habitat includes water courses and wetland habitat out to the beginning of upland habitat. Critical habitat does not include existing features and structures, such as buildings, roads, aqueducts, railroads, airports, other paved areas, lawns, and other rural residential landscaped areas not containing one or more of the primary constituent elements.

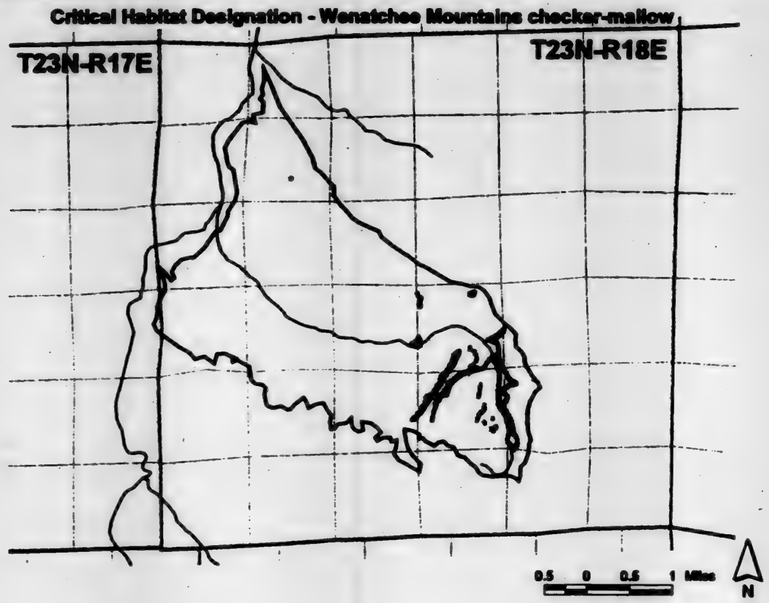
Known primary constituent elements of critical habitat for *Sidalcea oregana* var. *calva* include: surface water or saturated upper soil profiles; a wetland plant community dominated by native grasses and forbs, and generally free of woody shrubs and conifers that would produce shade and competition for *Sidalcea oregana* var. *calva*; seeps and springs on fine textured soils (clay loams and silt loams), which contribute to the maintenance of hydrologic processes necessary to support meadows which remain moist into the early summer; and elevations of 488 m-1,000 m (1,600–3,300 ft).

Note: Map follows:

* * * * *

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Dated: December 27, 2000.

Kenneth L. Smith,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–1333 Filed 1–17–01; 8:45 am]

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Notices

Federal Register
Vol. 66, No. 12
Thursday, January 18, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Intent to Prepare an Environmental Impact Statement for Southwestern Region, Arizona, Coconino County, Coconino National Forests

AGENCY: Forest Service, USDA.

SUMMARY: The Coconino National Forest is planning to prepare an environmental impact statement on a proposal to improve grassland and woodland conditions for wildlife and manage livestock grazing use on the Pickett Lake and Padre Canyon Grazing Allotments during the next 10 years.

DATES: Comments in response to this Notice of Intent concerning the scope of the analysis should be received in writing by on or before February 20, 2001.

ADDRESSES: Send written comments to USDA Forest Service, Coconino National Forest, Peaks Ranger Station, 5075 N Hwy 89, Flagstaff, AZ 86004. Electronic mail may be sent to mhannemann@fs.fed.us.

Responsible Official: The Forest Supervisor of the Coconino National Forest, Supervisor's Office 2323 Greenlaw Lane, Flagstaff, AZ 86004, will decide what actions are most appropriate for managing the Pickett and Padre Range Allotments.

FOR FURTHER INFORMATION CONTACT: Mike Hannemann, Interdisciplinary Team Leader, Peaks Ranger District, (520) 526–0866.

SUPPLEMENTARY INFORMATION: This proposal includes 14,774 acres of pinyon, juniper and ponderosa pine treatments. Ponderosa pine cuts would be on trees <6" in diameter at breast height (DBH). Slash crushing and seeding will be done in pinyon and juniper treatment areas where slash is heavy and dense trees have removed the grass seed source from the area. Approximately $258,810 will be spent on cutting the trees. Approximately $95,500 will be spent on slash crushing, harrowing and seeding. Approximately $126,500 would be spent on archaeological surveys on the tree cutting areas. The Forest Service will look for grants and partners to supplement normal Forest Service funds to complete the pinyon and juniper treatments, slash crushing, harrowing and seeding.

This proposal also has a Forest Service permit of up to 850 cattle from June 1 to September 30 on the 34,814 acres Pickett Lake Allotment and up to 125 cattle from August 1 to September 30 on the 20,993 acres Padre Canyon Allotment. This is a 10% reduction in cattle use on Pickett Lake Allotment and a 31% reduction in cattle use on the Padre Canyon Allotment. In addition, this proposal has a combined grazing system option of up to 913 cattle from June 1 to September 30 on both allotment areas, a 14% overall reduction in cattle use. In addition to maintaining current range structures, approximately $25,600 will be spent on one mile of barbwire fence, four miles of pipeline and five drinkers. The Forest Service will spend approximately $13,700 primarily for materials and the permittee will spend approximately $11,900 primarily for installation of the improvements.

Preliminary issues include the effect of grazing on the environment, especially watershed conditions and pronghorn antelope habitat.

The Proposed action was mailed to 104 individuals, organizations and cooperating resource agencies for review and comment on January 5, 2001. From comments received, the Team will develop statements to capture the substantive issues and developed alternatives other than the proposed action. If you would like a copy of the proposed action please contact our office. Your comments will be included in our environmental analysis.

It is anticipated that environmental analysis and preparation of the draft and final environmental impact statements will take about six months. The Draft Environmental Impact Statement can be expected April of 2001 and the Final EIS in summer. The comment period on the draft environmental impact statement extends 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. To be the most helpful, comments on the draft environmental impact statement should be as specific as possible and may address the adequacy of the statement or the merits of the alternatives discussed (see Council of Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3).

In addition, Federal court decisions have established that reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewers' position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC* 435 US 519, 553 (1978). Environmental objections that could have been raised at the draft state may be waived if not raised until after completion of the final environmental impact statement. *City of Angoon* v. *Hodel 9th Circuit*, 1986) and *Wisconsin Heritages, Inc* v. *Harris*, 490F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposal action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council of Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

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Dated: January 5, 2001.
Jim Golden,
Forest Supervisor.
[FR Doc. 01–1391 Filed 1–17–01; 8:45 am]
BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Intergovernmental Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Intergovernmental Advisory Committee (IAC) will meet on February 1, 2001, at the Hilton Hotel, 921 SW 6th Avenue, Portland, Oregon 97204–1296. The purpose of the meeting is to continue discussions on the implementation of the Northwest Forest Plan (NFP). The meeting will begin at 9:30 a.m. and continue until 3:30 p.m. Agenda items to be discussed include, but are not limited to: IAC Topics for advice, the Aquatic Riparian Effectiveness Monitoring Plan, and an update on the survey and Manage Record of Decision. The IAC meeting will be open to the public and is fully accessible for people with disabilities. Interpreters are available upon request in advance. Written comments may be submitted for the record at the meeting. Time will also be scheduled for oral public comments. Interested persons are encouraged to attend.

FOR FURTHER INFORMATION CONTACT: Questions regarding this meeting may be directed to Steve Odell, Executive Director, Regional Ecosystem Office, 333 SW, 1st Avenue, P.O. Box 3623, Portland, OR 97208 (Phone: 503–808–2166).

Dated: January 11, 2001.
Stephen J. Odell,
Designated Federal Official.
[FR Doc. 01–1467 Filed 1–17–01; 8:45 am]
BILLING CODE 3410–11–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; Michel V. Diago; Order Amending the Order Denying Permission To Apply for or Use Export Licenses

On, September 7, 1997, the acting director of the Office of Exporter Services entered an Order (the 1994 Order) against Michel V. Daigo denying his export privileges until February 25, 2003, based upon his February 25, 1993, conviction in the Untied States District Court for the Northern District of California of violating the Export Administration Act of 1979 as amended (50 U.S.C.A. app. 2401–2420 (1991, Supp. 1993, and Public Law 103–277, July 5, 1994)[1] the Act). The 1994 Order was issued under the authority of Section1 1(h) of the Act and Sections 766.25 and 750.8(a) of the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (1999)) (the Regulations). The 1994 Order was published in the **Federal Register** (50 FR 47299, September 15, 1994).

In the Matter of: MICHAEL V. DIAGO, 1183 Calle del Arroyo, Sonoma, California 95476.

On, October 18, 1994 Diago, through counsel, filed an appeal from the Order with the Under Secretary for Export Administration (Under Secretary), pursuant to Part 789 (currently Part 756) of the Regulations. On December 22, 2000, the Under Secretary issued his final decision on that appeal and granted partial relief from the terms of the 1994 Order by terminating the denial period as of December 31, 2000.

Accordingly, the 1994 Order is hereby amended to as follows:

Ordered

I. The date "February 25, 2003" in fourth paragraph and in the paragraphs labeled II and V of the 1994 Order is amended to read December 31, 2000.

II. A copy of this Order shall be delivered to Diago. This Order shall be published in the **Federal Register.**

Dated: January 2, 2001.
Eileen Albanese,
Director, Office of Exporter Services.
[FR Doc. 01–1392 Filed 1–17–01; 8:45 am]
BILLING CODE 3510–DT–M

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with section 351.213 (2000) of the Department of Commerce (the Department) regulations, that the Department conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

Opportunity to Request a Review:

Not later than the last day of January 2001, interested parties may request an administrative review of the following orders, findings, or suspended investigations, with anniversary dates in January for the following periods:

	Period
Antidumping duty proceedings	
Brazil: Brass Sheet and Strip, A–351–603	1/1/00–12/31/00
Brazil: Stainless Steel Wire Rod, A–351–819	1/1/00–12/31/00
Canda: Brass Sheet and Strip, A–122–601	1/1/00–12/31/00
France: Anhydrous Sodium Metasilicate (ASM), A–427–098	1/1/00–12/31/00
France: Stainless Steel Wire Rods, A–427–811	1/1/00–12/31/00
Taiwan: Stainless Steel Cooking Ware, A–583–603	1/1/00–12/31/00
The People's Republic of China: Potassium Permanganate, A–570–001	1/1/00–12/31/00
The Republic of Korea: Stainless Steel Cooking Ware, A–580–601	1/1/00–12/31/00

[1] The Act expired on August 20, 1994, Executive Order 12924 (3 CFR 1994 Comp. 917 (1995)), extended by Presidential Notices of August 15, 1995 (3 CFR, 1995 Comp. 501 (1996)), August 14, 1996 (3 CFR 1996 Comp. 298 (1997)), August 13, 1997 (3 CFR 1997 Comp. 306 (1998)), and August 13, 1998 (3 CFR, 1998 Comp. 294 (1999)), continued the Export Administration Regulations in effect under IEEPA. The Act was renewed and signed into law by the President on November 13, 2000.

	Period
Countervailing Duty Proceedings	
Brazil: Brass Sheet and Strip, C–351–604	1/1/00–12/31/00
Taiwan: Stainless Steel Cooking Ware, C–583–604	1/1/00–12/31/00
The Republic of Korea: Stainless Steel Cooking Ware, C–580–602	1/1/00–12/31/00
Suspension Agreements	
Japan: Sodium Azide, A–588–839	1/1/00–12/31/00

In accordance with section 351.213(b) of the regulations, an interested party as defined by section 771(9) of the Act, may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review, and the requesting party must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which were produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Six copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, Room 1870, U.S. Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, DC 20230. The Department also asks parties to serve a copy of their requests to the Office of Antidumping/Countervailing Enforcement, Attention: Sheila Forbes, in room 3065 of the main Commerce Building. Further, in accordance with section 351.303(f)(l)(i) of the regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of "Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation" for requests received by the last day of January 2001. If the Department does not receive, by the last day of January 2001, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute but is published as a service to the international trading community.

Dated: January 11, 2001.
Holly A. Kuga,
Acting Deputy Assistant Secretary, Group II for Import Administration.
[FR Doc. 01–1518 Filed 1–17–01; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of Coastal Zone Management Programs

AGENCY: Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), DOC.

ACTION: Notice of intent to evaluate.

SUMMARY: The NOAA Office of Ocean and Coastal Resource Management (OCRM) announces its intent to evaluate the performance of the Commonwealth of the Northern Mariana Islands Coastal Management Program, the California San Francisco Bay Conservation and Development Commission/State Coastal Conservancy Coastal Program, and the Puerto Rico Coastal Management Program.

These evaluations will be conducted pursuant to section 312 of the Coastal Zone Management Act of 1972 (CZMA), as amended and regulations at 15 CFR Part 923.

The CZMA requires continuing review of the performance of states with respect to coastal program implementation. Evaluation of Coastal Zone Management Programs require findings concerning the extent to which a state has met the national objectives, adhered to its coastal program document approved by the Secretary of Commerce, and adhered to the terms of financial assistance awards funded under the CZMA.

The evaluations will include a site visit, consideration of public comments, and consultations with interested Federal, State, and local agencies and members of the public. Public meetings will be held as part of the site visits.

Notice is hereby given of the dates of the site visits for the listed evaluations, and the dates, local times, and locations of the public meetings during the site visits.

The Commonwealth of the Northern Mariana Islands Coastal Management Program evaluation site visit will be from February 26–March 9, 2001. One public meeting will be held during the week. The public meeting will be held on Tuesday, March 6, 2001, at 5:30 p.m., at the Joeten Kiyu Library, Saipan.

The California San Francisco Bay Conservation and Development Commission/State Coastal Conservancy Coastal Program site visit will be from March 5–9, 2001. One public meeting will be held during the week. The public meeting will be held on Wednesday, March 7, 2001, from 4–6 p.m., in the McAteer-Petris Room, at the BCDC offices, 50 California Street, Suite 2600, San Francisco, California.

The Puerto Rico Coastal Management Program evaluation site visit will be from March 12–16, 2001. One public meeting will be held during the week. The public meeting will be held on Tuesday, March 13, 2001, at 6 p.m., at The Department of Natural and Environmental Resources Auditorium, Avenue Munoz Rivera, Stop 3½, San Juan, Puerto Rico.

Copies of States' most recent performance reports, as well as OCRM's notifications and supplemental request letters to the States, are available upon request from OCRM. Written comments from interested parties regarding these Programs are encouraged and will be accepted until 15 days after the public meeting. Please direct written comments to Margo E. Jackson, Deputy Director, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway, 10th Floor, Silver Spring, Maryland 20910. When the evaluations are completed, OCRM will place a notice in the **Federal Register**

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announcing the availability of the Final Evaluation Findings.

FOR FURTHER INFORMATION CONTACT: Margo E. Jackson, Deputy Director, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway, Silver Spring, Maryland 20910, (301) 713–3155, Extension 114.

(Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration)

Dated: January 10, 2001.

Capt. Ted I. Lillestolen,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 01–1525 Filed 1–17–01; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Air University Board of Visitors; Notice of Meeting

The Air University Board of Visitors will hold an open meeting on April 22–25, 2001, with the first business session beginning at 8:30 a.m. in the Air University Commander's Conference Room at Headquarters Air University, Maxwell Air Force Base, Alabama. (Five seats are available.)

The purpose of the meeting is to give the board an opportunity to review Air University educational programs and to present to the Commander, a report of their findings and recommendations concerning these programs.

For further information on this meeting, contact Dr. Dorothy Reed, Chief of Academic Affairs, Air University Headquarters, Maxwell Air Force Base, Alabama 36112–6335, (334) 953–5159.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 01–1393 Filed 1–17–01; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Air Force Institute of Technology (AFIT) Subcommittee of the Air University Board of Visitors; Notice of Meeting

The AFIT Subcommittee of the Air University Board of Visitors will hold an open meeting on March 25–27, 2001, with the first business session beginning at 8:30 a.m. in the Commandant's Conference Room, Building 125, Wright-Patterson Air Force Base, Ohio. (Five seats are available.)

The purpose of the meeting is to give the Board an opportunity to review Air Force Institute of Technology's educational programs and to present to the Commandant a report of their findings and recommendations concerning these programs.

For further information on this meeting, contact Ms. Beverly Houtz in the Directorate of Resources, Air Force Institute of Technology, (937) 255–5760.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 01–1394 Filed 1–17–01; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 20, 2001.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Acting Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren_Wittenberg@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.*, new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: January 11, 2001.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: Reinstatement.

Title: National Assessment of Adult Literacy.

Frequency: One time.

Affected Public: Businesses or other for-profit.

Reporting and Recordkeeping Hour Burden:

Responses: 956

Burden Hours: 703

Abstract: The 2002 National Adult Assessment of Literacy (NAAL) will assess the current status of the English language skills of adults in the United States, as well as how literacy proficiencies have changed since the 1992 National Adult Literacy Survey (NALS). The sample consists of adults 16 years of age and older who reside in private households at the time of the assessment.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her internet address Kathy_Axt@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service, (FIRS) at 1–800–877–8339.

[FR Doc. 01–1443 Filed 1–17–01; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF EDUCATION

[CFDA NO. 84.334]

Office of Postsecondary Education; Notice Inviting Applications for New Awards for Fiscal Year 2001—Gaining Early Awareness and Readiness for Undergraduate Programs—GEAR UP

Purpose of Program: The purpose of this program is to increase the number of low-income students who are prepared to enter and succeed in college. Through improved academic preparation and early awareness activities, eligible students are provided comprehensive mentoring, counseling, outreach and supportive services, including information to students and their parents about the benefits of postsecondary education and the availability of Federal financial assistance to attend college. Through the scholarship component, which is mandatory for State grants and recommended for Partnership grants, eligible students may receive scholarships for higher education.

Eligible Applicants: 1. For Partnership grants, eligible applicants include at least—

- One institution of higher education. This may be any degree-granting two-year or four-year college or university;
- One local educational agency (school district) on behalf of one or more schools with a 7th grade and the high school(s) that the students at these middle schools would normally attend. Generally, at least 50 percent of the students attending the participating school with a 7th grade must be eligible for free or reduced-price lunches. However, as an alternative, Partnerships may choose to work with one or more grade levels of students, beginning not later than the 7th grade, who reside in public housing; and
- Two additional organizations, such as businesses, professional associations, community-based organizations, State Agencies, elementary schools, philanthropic organizations, religious groups, and other public or private organizations.

2. For State grants, eligible applicants are State Agencies as designated by the State's Governor, one per State.

Applications Available: January 19, 2001.

Deadline for Transmittal of Applications: March 30, 2001.

Deadline for Intergovernmental Review: May 29, 2001.

Available Funds: Approximately $35,500,000 for Partnership grants and $23,000,000 for State grants. Federal funds shall provide not more than 50 percent of the total cost of any project funded by a grant under this program, except as provided for under 34 CFR 694.7. The non-Federal share of project costs may be in-cash or in-kind, fairly valued, including services, supplies or equipment.

Estimated Average Awards: No minimum, maximum or average award has been established for Partnership grants. The size of each Partnership grant will depend on the number of students served. However, there is a maximum annual Federal contribution of $800 per student for Partnership grants.

State grants have a $2.5 million maximum and no minimum award.

Estimated Number of Awards: Approximately 9–12 State grant awards and approximately 75–90 Partnership grant awards, depending on the size and configuration of each Partnership.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 86, 97, 98 and 99. (b) The regulations for this program in 34 CFR part 694.

Authorized Activities: Section 404D, 404E, 404F, and 404G of the Higher Education Act of 1965, as amended. [20 U.S.C. 1070a-24]

Selection Criteria: The Secretary uses the selection criteria in accordance with 34 CFR 75.209 and 75.210 to evaluate applications for Gaining Early Awareness and Readiness for Undergraduate Programs. The application package includes the selection criteria and the points assigned to the criteria.

Page Limits: The application narrative (Part 4 of the application) is limited to the equivalent of no more than 40 pages using the following standards:

- A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12-point or larger or no smaller than 10 pitch (characters per inch).

The page limit does not apply to Part 1, the cover sheet; Part 2, the Table of Contents; Part 3 the Abstract; or Part 5, the budget section, including the narrative budget justification; the assurances and certifications; or the resumes, the bibliography, or the letters of support. However, you must include all of the application narrative (Part 4) in the page limit. Reviewers will not read any pages of your application that exceed the page limit if you apply these standards or exceed the equivalent of the page limit.

Priorities

Competitive Priorities

Competitive Preference Priority 1

Under 34 CFR 75.105(c)(2)(i) and 34 CFR 694.15(b), the Secretary will give preference to Partnership projects that establish or maintain financial assistance programs that award scholarships to participating students, either in accordance with section 404E of the Higher Education Act of 1965, or in accordance with GEAR UP regulations 34 CFR 694.11. The Secretary will award up to five (5) points in addition to any points the applicant earns under the selection criteria, to applicants who meet this priority, depending on how well the application meets the priority.

Competitive Preference Priority 2

Under 34 CFR 75.105(c)(2)(ii) and 34 CFR 694.15(a), the Secretary gives competitive preference to an application for a Partnership or State grant that serves a substantial number or percentage of students who reside in or attend school in an Empowerment Zone, Supplemental Empowerment Zone, or Enterprise Community, under 34 CFR 75.105(2)(ii) and 34 CFR 694.15(a). This preference means that an applicant meeting this criterion would be placed above another application of comparable merit, and the preference will be used in the selection process as a tie-breaker.

For Applications Contact: Education Publications Center (EDPUBS), P.O. Box 1398, Jessup, Maryland 20794–1398. Telephone (toll free) 1–877–433–7827. Fax: (301) 470–1244. If you use a telecommunications device for the deaf (TDD) you may call toll free 1–877–576–7734. You may also contact EDPUBS at its web site: http://www.ed.gov/pubs/edpubs.html.

Or you may contact EDPUBS at its e-mail address: edpubs@inet.ed.gov.

If you request an application from EDPUBS, be sure to identify this competition as follows: CFDA number 84.334.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Education, Office of Postsecondary Education, Gaining Early Awareness and Readiness for Undergraduate Programs, 1990 K Street, NW., Room 6252, Washington, DC

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20006–8524, telephone 202–502–7676, fax (202) 502–7675, or e-mail gearup@ed.gov

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document or a copy of the GEAR UP application package in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) upon request to the contact number listed under **FOR FURTHER INFORMATION CONTACT.** However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register** in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/new.html

To use PDF you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have any questions about using PDF, call the U.S. Government Printing Office (GPO) at (202) 512–1530 or, toll free, at 1–888–293–6498.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the offical edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html.*

Program Authority: 20 U.S.C. 1070a–21—20 U.S.C. 1070a–28.

Dated: January 12, 2001.

A. Lee Fritschler,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 01–1529 Filed 1–17–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No.: 84.128G]

Migrant and Seasonal Farmworkers Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2001

Purpose of Program: To provide grants for vocational rehabilitation services to individuals with disabilities who are migrant or seasonal farmworkers, as determined in accordance with rules prescribed by the Secretary of Labor, and to the family members who are residing with those individuals (whether or not those family members are individuals with disabilities).

Eligible Applicants: A State designated agency; nonprofit agencies working in collaboration with a State agency; and a local agency working in collaboration with a State agency.

Applications Available: January 30, 2001.

Deadline for Transmittal of Applications: March 30, 2001.

Deadline for Intergovernmental Review: May 30, 2001.

Estimated Available Funds: $528,000.

Estimated Range of Awards: $150,000–$170,000.

Estimated Average Size of Awards: $165,000.

Estimated Number of Awards: 3.

Note: The Department is not bound by any estimates in this notice.

Reasonable Accommodations: We will consider, and may fund, requests for additional funding as an addendum to an application to reflect the costs of reasonable accommodations necessary to allow individuals with disabilities to be employed on the project as personnel on project activities.

Project Period: Up to 60 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, and 86.

Note: The regulations in 34 CFR part 79 apply to applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Priority: This competition focuses on projects designed to meet the priority in the notice of final competitive preference for this program, published in the **Federal Register** on November 22, 2000 (65 FR 70408). Under 34 CFR 75.105 (c)(2)(i) the Assistant Secretary adds a competitive preference to applications that are otherwise eligible for funding under this program.

The maximum score under the selection criteria for this program is 100 points; however, we will also use the following competitive preference so that up to an additional 10 points may be earned by an applicant for a total possible score of 110 points.

Up to 10 points may be earned based on the extent to which an application includes effective strategies for employing and advancing in employment qualified individuals with disabilities as project employees in projects awarded under this program. In determining the effectiveness of those strategies, we will consider the applicant's prior success, as described in the application, in employing and advancing in employment qualified individuals with disabilities.

Therefore, within this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this program (The selection criteria to be used for this competition will be provided in the application package for this competition). That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Application Procedures:

Note: Some of the procedures in these instructions for transmitting applications differ from those in the Education Department General Administrative Regulations (EDGAR) (34 CFR 75.102). Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments make procedural changes only and do not establish new substantive policy. Therefore, under 5 U.S.C. 553(b)(A), the Secretary has determined that proposed rulemaking is not required.

Pilot Project for Electronic Submission of Applications

The U.S. Department of Education is expanding its pilot project of electronic submission of applications to include certain formula grant programs, as well as additional discretionary grant competitions. The Migrant and Seasonal Farmworkers Program (CFDA 84.128G) is one of the programs included in the pilot project. If you are an applicant under the Migrant and Seasonal Farmworkers Program, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e-APPLICATION, formerly e-GAPS) portion of the Grant Administration and Payment System (GAPS). We request your participation in this pilot project. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in this e-APPLICATION pilot, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value or penalty because you submit a grant application in electronic or paper format.
- You can submit all documents electronically, including the Application for Federal Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Fax a signed copy of the Application for Federal Assistance (ED 424) after following these steps:

1. Print ED 424 from the e-APPLICATION system.
2. Make sure that the institution's Authorizing Representative signs this form.
3. Before faxing this form, submit your electronic application via the e-APPLICATION system. You will receive an automatic acknowledgement, which will include a PR/Award number (an identifying number unique to your application).
4. Place the PR/Award number in the upper right hand corner of ED 424.
5. Fax ED 424 to the Application Control Center within three working days of submitting your electronic application. We will indicate a fax number in e-APPLICATION at the time of your submission.

- We may request that you give us original signatures on all other forms at a later date. You may access the electronic grant application for the Migrant and Seasonal Farmworkers Program at: http://e-grants.ed.gov.

We have included additional information about the e-APPLICATION pilot project (see Parity Guidelines between Paper and Electronic Applications) in the application package.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, MD 20794–1398. Telephone (toll free): 1–877–433–7827. FAX: (301) 470–1244. If you use a telecommunications device for the deaf (TDD), you may call (toll free): 1–877–576–7734.

You may also contact ED Pubs via its Web site: http://www.ed.gov/pubs/edpubs.html.

Or you may contact ED Pubs at its e-mail address: edpubs@inet.ed.gov.

If you request an application from ED Pubs, be sure to identify this competition as follows: CFDA number 84.128G.

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the Grants and Contracts Services Team (GCST), U.S. Department of Education, 400 Maryland Avenue, SW., room 3317, Switzer Building, Washington, DC 20202–2550. Telephone: (202) 205–8351. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

FOR FURTHER INFORMATION CONTACT: Mary E. Chambers, U.S. Department of Education, 400 Maryland Avenue, SW., room 3322, Switzer Building, Washington, DC 20202–2647. Telephone (202) 205–8435. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain a copy of this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph.

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http://ocfo.ed.gov/fedreg.htm
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To use the PDF you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html

Program Authority: 29 U.S.C. 774.

Dated: January 12, 2001.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 01–1528 Filed 1–17–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Recognition of Accrediting Agencies, State Agencies for the Approval of Public Postsecondary Vocational Education, and State Agencies for the Approval of Nurse Education

AGENCY: National Advisory Committee on Institutional Quality and Integrity, Department of Education (The Advisory Committee).

What Is the Purpose of This Notice?

The purpose of this notice is to invite written comments on accrediting agencies whose applications to the Secretary for initial or renewed recognition will be reviewed at the Advisory Committee meeting to be held on May 23–25, 2001. The notice also invites written comments on agencies submitting interim reports that will be reviewed at the May meeting. Further, the notice invites written comments on one Federal agency seeking degree-granting authority.

Where Should I Submit My Comments?

Please submit your written comments by March 5, 2001 to Carol Griffiths, Chief, Accrediting Agency Evaluation, Accreditation and State Liaison. You may contact her at the U.S. Department of Education, 1990 K Street, NW, 7th Floor, Room 7105, Washington, DC 20006–8509, telephone: (202) 219–7011. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339.

What Is the Authority for the Advisory Committee?

The National Advisory Committee on Institutional Quality and Integrity is established under Section 114 of the Higher Education Act (HEA), as amended, 20 U.S.C. 1011c. One of the purposes of the Advisory Committee is to advise the Secretary of Education on the recognition of accrediting agencies and State approval agencies.

Will This Be My Only Opportunity To Submit Written Comments?

Yes, this notice announces the only opportunity you will have to submit written comments. However, a subsequent **Federal Register** notice will announce the meeting and invite individuals and/or groups to submit requests to make oral presentations before the Advisory Committee on the agencies that the Committee will review. That notice, however, does not offer a second opportunity to submit written comment.

What Happens to the Comments That I Submit?

We will review your comments, in response to this notice, as part of our evaluation of the agencies' compliance with the Secretary's Criteria for Recognition of Accrediting Agencies. The Criteria are regulations found in 34 CFR part 602 (for accrediting agencies) and in 34 CFR part 603 (for State approval agencies).

We will also respond to your comments, as appropriate, in the staff analyses we present to the Advisory Committee at its May 2001 meeting. Therefore, in order for us to give full consideration to your comments, it is important that we receive them by March 5, 2001. In all instances, your comments about agencies seeking initial

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or continued recognition must relate to the Criteria for the Recognition. In addition, your comments for any agency whose interim report is scheduled for review must relate to the issues raised and the Criteria for Recognition cited in the Secretary's letter that requested the interim report. You may obtain a copy of the Secretary's letter by calling (202) 219–7011.

What Happens to Comments Received After the Deadline?

We will treat any negative comments received after the deadline as complaints. If such comments, upon investigation, reveal that the accrediting agency is not acting in accordance with the Criteria for Recognition, we will take action either before or after the meeting, as appropriate. We will also notify the commentors of the disposition of those comments.

What Agencies Are on the Agenda for the Meeting?

The Secretary of Education recognizes accrediting agencies and State approval agencies for public postsecondary vocational education and nurse education if the Secretary determines that they meet the Criteria for Recognition. Recognition means that the Secretary considers the agency to be a reliable authority as to the quality of education offered by institutions or programs that are encompassed within the scope of recognition he grants to the agency. The following agencies will be reviewed during the May 2001 meeting of the Advisory Committee:

Nationally Recognized Accrediting Agencies

Petition for Initial Recognition

1. Teacher Education Accreditation Council (Requested scope of recognition: The accreditation of professional education programs in institutions offering baccalaureate and graduate degrees for the preparation of teachers and other professional personnel for elementary and secondary schools).

Petitions for Renewal of Recognition

1. Accrediting Council for Independent Colleges and Schools (Requested scope of recognition: The accreditation of private postsecondary institutions offering business and business-related programs and the accreditation and preaccreditation ("Recognized Candidate") of junior and senior colleges of business (including senior colleges with master's degree programs), as well as independent, freestanding institutions offering only graduate business and business-related programs at the master's degree level).

2. American College of Nurse-Midwives, Division of Accreditation (Current scope of recognition: The accreditation and preaccreditation ("Preaccreditation") of basic certificate and graduate nurse-midwifery education programs for registered nurses, as well as the accreditation and preaccreditation of pre-certification nurse-midwifery education programs) (Requested scope of recognition: The current scope of recognition plus the accreditation of midwifery education programs for non-nurses at the post-baccalaureate or higher academic level that lead to certificates or graduate degrees).

3. American Council on Pharmaceutical Education (Requested scope of recognition: The accreditation and preaccreditation ("Precandidate" and "Candidate") of professional degree programs in pharmacy leading to the degrees of Baccalaureate in Pharmacy and Doctor of Pharmacy).

4. Association for Clinical Pastoral Education, Inc., Accreditation Commission (Requested scope of recognition: The accreditation of clinical pastoral education (CPE) centers and CPE and supervisory CPE programs).

5. American Dental Association, Commission on Dental Accreditation (Requested scope of recognition: The accreditation of predoctoral dental education programs (programs leading to the D.D.S. or D.M.D. degree); dental auxiliary education programs (dental assisting, dental hygiene and dental laboratory technology); and advanced dental educational programs (general practices residency, advanced general dentistry, and the specialties of dental public health, endodontics, oral pathology, orthodontics, oral and maxillofacial surgery, pedodontics, periodontics, and prosthodontics)).

6. American Occupational Therapy Association, Accreditation Council for Occupational Therapy Education (Current scope of recognition: The accreditation of entry-level professional occupational therapy educational programs awarding baccalaureate degrees, post-baccalaureate certificates, professional master's degrees, and combined baccalaureate/master's degrees, and also for the accreditation of occupational therapy assistant programs leading to an associate degree or certificate) (Requested scope of recognition: The current scope of recognition plus the accreditation of entry-level doctoral degree professional occupational therapy educational programs and the accreditation of programs offered principally through distance education).

7. Council on Chiropractic Education, Commission on Accreditation (Requested scope of recognition: The accreditation of Doctor of Chiropractic programs and single-purpose institutions offering the Doctor of Chiropractic program).

8. Commission on Opticianry Accreditation (Requested scope of recognition: The accreditation of two-year programs for the ophthalmic dispenser and one-year programs for the ophthalmic laboratory technician).

9. Joint Review Committee on Education in Radiologic Technology (Requested scope of recognition: The accreditation of educational programs for radiographers and radiation therapists).

10. Joint Review Committee on Educational Programs in Nuclear Medicine Technology (Requested scope of recognition: The accreditation of higher education programs for the nuclear medicine technologist).

11. Southern Association of Colleges and Schools, Commission on Colleges (Requested scope of recognition: The accreditation and preaccreditation ("Candidate for Accreditation") of degree-granting institutions of higher education in Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Texas, and Virginia).

12. Western Association of Schools and Colleges, Accrediting Commission for Senior Colleges and Universities (Requested scope of recognition: The accreditation and preaccreditation ("Candidate for Accreditation") of senior colleges and universities in California, Hawaii, the United States territories of Guam and American Samoa, the Republic of Palau, the Federated States of Micronesia, the Commonwealth of the Northern Marianna Islands, and the Republic of the Marshall Islands).

Interim Reports (An interim report is a follow-up report on an accrediting agency's compliance with specific criteria for recognition that was requested by the Secretary when the Secretary granted renewed recognition to the agency.)

1. American Physical Therapy Association, Commission on Accreditation in Physical Therapy Education.

2. American Psychological Association, Committee on Accreditation.

3. Commission on Collegiate Nursing Education.

4. National Accrediting Commission of Cosmetology Arts and Sciences.

5. National Association of Nurse Practitioners in Women's Health, Council on Accreditation.

6. Transnational Association of Christian Colleges and Schools, Accreditation Commission.

State Agencies Recognized for the Approval of Public Postsecondary Vocational Education

Interim Report

1. Kansas Board of Regents.

Federal Agency Seeking Degree-Granting Authority

In accordance with the Federal policy governing the granting of academic degrees by Federal agencies (approved by a letter from the Director, Bureau of the Budget, to the Secretary, Health, Education, and Welfare, dated December 23, 1954), the Secretary is required to establish a review committee to advise the Secretary concerning any legislation that may be proposed that would authorize the granting of degrees by a Federal agency. The review committee forwards its recommendation concerning a Federal agency's proposed degree-granting authority to the Secretary, who then forwards the committee's recommendation and the Secretary's recommendation to the Office of Management and Budget for review and transmittal to the Congress. The Secretary uses the Advisory Committee as the review committee required for this purpose. Accordingly, the Advisory Committee will review the following institution at this meeting:

Proposed Master's Degree-Granting Authority

1. U.S. Marine Corps University, Quantico, VA (request to award a master's degree in Strategic Studies).

Where Can I Inspect Petitions and Third-Party Comments Before and After the Meeting?

Subject to the provisions of 5 U.S.C. 522, petitions, interim reports, and those third-party comments received in advance of the meeting, will, upon written request, be made available, on appointment, for inspection and copying at the U.S. Department of Education, 1990 K Street, NW., 7th Floor, Room 7105, Washington, DC 20006–8509, telephone (202) 219–7011 until May 4, 2001. They will be available again after the May 23–25 Advisory Committee meeting.

Authority: 5 U.S.C. Appendix 2.

Dated: January 11, 2001.

A. Lee Fritschler,

Assistant Secretary for Postsecondary Education.

[FR Doc. 01–1473 Filed 1–17–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Management of Certain Plutonium Residues and Scrub Alloy Stored at the Rocky Flats Environmental Technology Site

AGENCY: U.S. Department of Energy.

ACTION: Amended Record of Decision.

SUMMARY: The Department of Energy (DOE) has decided to revise its approach to managing approximately 315 kg of plutonium fluoride residues (containing approximately 142 kg of plutonium) that currently are stored at the Rocky Flats Environmental Technology Site (Rocky Flats Site). In an earlier Record of Decision (63 FR 66136, December 1, 1998), DOE decided that these plutonium fluoride residues would be shipped to the Savannah River Site (SRS) for processing and storage pending disposition. Due to the opening of the Waste Isolation Pilot Plant (WIPP) in New Mexico on March 26, 1999, and other circumstances, including delays in securing shipping container certification required prior to transporting the plutonium fluoride residues to SRS, DOE has now decided to prepare the plutonium fluoride residues appropriately and ship them to WIPP for disposal. This will help avoid delays in meeting the closure schedule for the Rocky Flats Site.

ADDRESSES: The potential environmental impacts of alternative approaches for management of these residues are analyzed in the Final Environmental Impact Statement on Management of Certain Plutonium Residues and Scrub Alloy Stored at the Rocky Flats Environmental Technology Site (hereinafter referred to as the Residues EIS) (DOE/EIS–0277F, August 1998) and were part of the basis for three prior Records of Decision issued for the plutonium-bearing residues at the Rocky Flats Site. Copies of the Residues EIS; the first and second Records of Decision (63 FR 66136, December 1, 1998, and 64 FR 8068, February 18, 1999, respectively); the first Amended Record of Decision (64 FR 47780, September 1, 1999); and this Amended Record of Decision and the Supplement Analysis (referenced herein) can be accessed from the DOE's NEPA Web site at *http://www.tis.eh.doe.gov/nepa*, under NEPA Analyses, or can be obtained by contacting the Center for Environmental Management Information, P.O. Box 23769, Washington, DC 20026–3769, telephone 1–800–736–3282 (in Washington, DC: 202–863–5084).

For further information concerning the management of plutonium residues and scrub alloy currently stored at the Rocky Flats Site, contact: Dr. W. Eric Huang, Program Manager, Rocky Flats Office (EM–33), Office of Site Closure, Environmental Management, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874, Telephone: 301–903–4630.

For further information concerning DOE's National Environmental Policy Act (NEPA) process, contact: Ms. Carol Borgstrom, Director, Office of NEPA Policy and Compliance (EH–42), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone (202) 586–4600, or leave a message at 1–800–472–2756.

SUPPLEMENTARY INFORMATION:

I. Background

In August 1998, DOE issued the Residues EIS that assessed the potential environmental impacts of processing certain plutonium residues and scrub alloy stored at the Rocky Flats Site near Golden, Colorado, in preparation for disposal or other disposition. These materials were produced in conjunction with nuclear weapons activities conducted by DOE during the Cold War and the materials are no longer needed. Currently, DOE is cleaning up and disposing of (where appropriate) such materials. The plutonium residues analyzed in the Residues EIS included approximately 315 kg of plutonium fluoride residues containing approximately 45 percent plutonium by weight (approximately 142 kg of plutonium). In the Residues EIS, the plutonium fluoride residues were included as part of a category called "wet residues," having an average of approximately 7 percent plutonium by weight. (Residues EIS Table 2–1.)

The Residues EIS analyzed three alternative technologies and a no-action alternative for processing plutonium fluoride residues stored at the Rocky Flats Site. The selected alternative for the plutonium fluoride residues in the first Record of Decision in 1998 was the preferred alternative in the Residues EIS, which is Purex processing and storage at SRS pending disposition (italicized below).

- *Alternative 1.* Dissolving the plutonium fluoride residues in acid and precipitating the plutonium with oxalic acid, at the Rocky Flats Site. The

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recovered plutonium would be packaged for storage at the Rocky Flats Site. (This is the no-action alternative.)

• *Alternative 2.* Blending down the plutonium fluoride residues at the Rocky Flats Site with an inert material so that each container would meet the safeguards termination limit for plutonium fluorides (0.2 percent plutonium by weight). The blended material would then be packaged into pipe overpack components and subsequently packaged into 55-gallon drums for transportation and disposal at the Waste Isolation Pilot Plant[1] (WIPP).

• *Alternative 3.* Two technologies for separation of plutonium from plutonium fluoride residues were analyzed.

—*Repackaging the plutonium fluoride residues at the Rocky Flats Site for transportation to SRS and separation of the plutonium there using the Purex process. The processed plutonium would be stored at SRS pending disposition as mixed oxide nuclear fuel or disposed of as vitrified high-level waste in a geologic repository.*

—Dissolving the plutonium fluoride residues in acid and precipitating the plutonium with oxalic acid at the Rocky Flats Site (this is the same as the no-action alternative). The recovered plutonium then would be dispositioned as mixed oxide nuclear fuel or disposed of as vitrified high-level waste in a geologic repository.

II. Original Decision

In addition to this amended Record of Decision, DOE has issued two Records of Decision and an earlier amended Record of Decision for the final Residues EIS. The first Record of Decision, issued on November 25, 1998 (63 FR 66136, December 1, 1998), addressed materials from each of the categories of Rocky Flats plutonium residues (*i.e.*, ash, salt, wet, and direct repackage) and scrub alloy. This first Record of Decision (Section VII.D.1) stated that DOE had decided to transport the plutonium fluoride residues to SRS and use the F-Canyon, where the Purex plutonium separation process is located, to separate plutonium (*i.e.*, one of the two sub-alternatives of Alternative 3 in the Residues EIS). The separated plutonium would then have been subject to disposition as mixed oxide fuel or disposed of as vitrified high-level waste pursuant to decisions that DOE made after completion of the Surplus Plutonium Disposition Environmental Impact Statement (DOE/EIS–0283, November 1999; Record of Decision, 65 FR 1608, January 11, 2000).

The first Record of Decision (Section VII.D.2) explained that the Purex plutonium separation process at SRS was selected for the plutonium fluoride residues because it posed less technical risk and would cost less than the establishment of a new acid dissolution/plutonium oxide recovery capability at the Rocky Flats Site (Alternative 1). The Record of Decision further explained that blend down[2] (to meet the safeguards termination limit) (Alternative 2) would result in a very large increase in the amount of transuranic waste requiring disposal, which would increase the cost of disposing of the material.

III. Events Since Issuance of the First Record of Decision

Since issuance of the first Record of Decision in 1998, DOE has been preparing to ship the plutonium fluoride residues to SRS for separation and has not undertaken any activity that would alter the chemical or physical conditions of these residues. Initially, DOE had planned to begin shipment of the plutonium fluoride residues to SRS by January 2000 and to complete these shipments by September 2000. Removal of these materials from the Rocky Flats Site by September 2000 would have supported near-term closure of the Protected Area[3] of the Site and, subsequently, closure of the entire Site by 2006.

Before shipping plutonium fluoride residues to SRS, however, DOE must certify the shipping container for plutonium fluoride residues, and additional testing required before certification would take at least 15 months to complete. Further delay in implementing the earlier decision (*i.e.*, plutonium separation using the Purex process at SRS) would in turn delay closure of the Protected Area and associated buildings, extend decommissioning schedules, and ultimately delay closure of the entire Rocky Flats Site. A delay in the closure of the Rocky Flats Site would be costly due to extended site security needs and site services, eliminating the cost advantages of implementing the earlier decision.

At the time the Residues EIS was being prepared, DOE believed that it was impractical to apply a variance to safeguards termination limits for plutonium fluoride residues due to the high plutonium concentration and the relative ease of recovering the plutonium from the residue matrix. Although the amount of the plutonium fluoride residues was small (315 kg), the amount of plutonium present in these residues (about 142 kg) subjected them at that time to a set of safeguards requirements to maintain control of the residues and to ensure that the plutonium in them was not stolen or diverted for illicit use (*e.g.*, to construct a nuclear weapon). Therefore, the Residues EIS only analyzed the impacts of blending and repackaging the plutonium fluorides to meet the safeguards termination limits for them (0.2 weight percent), and did not analyze an alternative to blend these particular residues down to less than 10 weight percent plutonium.

The Rocky Flats Site has since developed a blending matrix of inert material that would result in a blended material from which plutonium recovery is difficult. This development, in addition to the application of other conditions, has allowed the Rocky Flats Site to obtain a "variance" to the safeguards termination limits from DOE's Office of Defense Nuclear Nonproliferation. The other conditions applied include a modification of the packaging components of the pipe overpack container to make it more difficult to divert any plutonium and a re-evaluation of the recovery processing steps required to separate plutonium from the plutonium fluoride residues in their present condition. All these special conditions have made the application of a variance for the plutonium fluoride residues and their shipment to WIPP practical.

WIPP's opening in March 1999 and the issuance of WIPP's hazardous waste permit by the New Mexico Environment Department in November 1999 provided DOE with the option to dispose of a blended-down plutonium fluoride residues matrix at WIPP. Because the plutonium fluoride residues contain hazardous constituents, these residues would be subject to the requirements of WIPP's hazardous waste permit.

IV. Decision

After consideration of the potential environmental impacts identified in the Residues EIS, the new circumstances discussed above, and a Supplement Analysis (DOE/EIS–0277–SA–1), discussed below, DOE has decided to blend down the plutonium fluoride residues with inert material to less than 10 percent, apply a variance to the safeguards termination limits, and dispose of these residues at WIPP.

V. Basis for the Decision

The delay in obtaining the certification for the shipping container needed to transport the plutonium fluoride residues to SRS could prevent DOE from closing the Rocky Flats Site by 2006. DOE now has the ability to blend down this category of residues to less than 10 weight percent of plutonium and meet the variance requirements for safeguards termination limits. For the reasons described below in Section VI, DOE has concluded that blending the plutonium fluoride residues down to less than 10% plutonium by weight and shipping them to WIPP for disposal would have low impacts, well within those analyzed in the Residues EIS.

DOE's decision complies with Section 309 of the Fiscal Year 2001 Energy and Water Development Appropriations Act (Pub. L. 106–377), which specifies that: "None of the funds in this Act may be used to dispose of transuranic waste in WIPP which contains concentrations of plutonium in excess of 20 percent by weight for the aggregate of any material category on the date of enactment of this Act, or is generated after such date. For the purposes of this section, the material categories of transuranic waste at the Rocky Flats Environmental Technology Site include: (1) Ash residues, (2) salt residues, (3) wet residues, (4) direct repackage residues, and (5) scrub alloy as referenced in the 'Final Environmental Impact Statement on Management of Certain Plutonium Residues and Scrub Alloy Stored at the Rocky Flats Environmental Technology Site.'" (Plutonium fluoride residues are part of the "wet residues" category, which overall contains approximately 7 percent plutonium by weight.)

Furthermore, disposal of the plutonium fluoride residues at WIPP now provides the least technical risk and most cost-effective approach to the management of plutonium fluoride residues, and supports the Rocky Flats closure schedule of 2006. Therefore, there are no longer cost, waste management, or schedule advantages in shipping the plutonium fluoride residues to SRS for separation.

VI. Prior NEPA Analysis

DOE prepared a Supplement Analysis for the Final Environmental Impact Statement on Management of Certain Plutonium Residues and Scrub Alloy Stored at the Rocky Flats Environmental Technology Site (DOE/EIS–0277–SA–1). This Supplement Analysis was developed to determine whether the activities and impacts associated with blending down the plutonium fluoride residues to less than 10 percent plutonium by weight with a matrix of inert material, applying a safeguard termination limit variance, and disposing of the resulting blend at WIPP were encompassed within previous NEPA reviews or would present any significant new information or circumstances relevant to environmental concerns.

The results of this Supplement Analysis indicated that the activities and potential environmental impacts associated with the new action are encompassed within the activities and impacts analyzed under Alternative 2 (blend down) of the Residues EIS. In addition, the overall impacts for the new action will be very small for both the public and workers and within the levels of impacts considered in the Residues EIS. Worker exposure during the new blend down activities would be reduced to 8 person-rem from 365 person-rem estimated in the Residues EIS. The number of Latent Cancer Fatalities (LCF) for the total worker population would be smaller for the new action (0.003) than for Alternative 2 (0.142). The difference in LCF for the total worker population between Alternative 2 and the new action is a result of two factors. The first is a reduced duration of the blend down operation as blending down to less than 10 weight percent plutonium rather than 0.2 weight percent plutonium will result in a shorter period in which the material is handled. Secondly, enhanced worker shielding will reduce worker exposure during the blend-down activities. Additionally, the new action has fewer drums for transportation reducing the potential for traffic accidents during transportation of plutonium fluoride residues to WIPP. Accordingly, DOE determined that carrying out the new action would not constitute a substantial change in actions previously analyzed and would not constitute significant new circumstances or information relevant to environmental concerns and bearing on the previously analyzed action or its impacts. Therefore, DOE did not need to undertake additional NEPA analysis before issuing this amendment to the 1998 Record of Decision.

VII. Conclusion

This Amended Record of Decision is effective upon being made public, in accordance with DOE's NEPA implementation regulations (10 CFR 1021.315).

Issued in Washington, D.C., this 11th day of January 2001.

Carolyn L. Huntoon,

Assistant Secretary for Environmental Management.

[FR Doc. 01–1478 Filed 1–17–01; 8:45 am]

BILLING CODE 6450–01–P

[1] The Waste Isolation Pilot Plant, located near Carlsbad, New Mexico, is DOE's geologic repository for disposal of defense-related transuranic wastes. Transuranic waste contains alpha-emitting radionuclides with half-lives greater than 20 years in concentrations greater than 100 nanocuries per gram of waste at time of assay.

[2] Blend down is a process in which an inert material is mixed with a plutonium-bearing residue to reduce its plutonium concentration.

[3] The Protected Area is the area at the Rocky Flats Site that is encompassed by physical barriers, subject to access control, surrounding a material access area or area containing special nuclear material.

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Rocky Flats

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Rocky Flats. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register.**

DATES: Thursday, February 1, 2001, 6 p.m. to 9:30 p.m.

ADDRESSES: Arvada Center for the Arts and Humanities, 6901 Wadsworth Boulevard, Arvada, CO.

FOR FURTHER INFORMATION CONTACT: Ken Korkia, Board/Staff Coordinator, Rocky Flats Citizens Advisory Board, 9035 North Wadsworth Parkway, Suite 2250, Westminster, CO, 80021; telephone (303) 420–7855; fax (303) 420–7579.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

1. Quarterly update by the Environmental Protection Agency.
2. Presentation and discussion on recent worker contamination and safety violations at the site.
3. Draft recommendations on Radionuclide Soil Action Level review process.
4. Other Board business may be conducted as necessary.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Ken Korkia at the address or telephone number listed above. Requests must be received at least five days prior to the meeting and reasonable provisions will be made to include the presentation in the agenda. The Deputy

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Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Public Reading Room located at the Office of the Rocky Flats Citizens Advisory Board, 9035 North Wadsworth Parkway, Suite 2250, Westminister, CO 80021; telephone (303)420–7855. Hours of operations for the Public Reading Room are 9 a.m. to 4 p.m., Monday–Friday, except Federal holidays. Minutes will also be made available by writing or calling Deb Thompson at the address or telephone number listed above.

Issued at Washington, DC on January 12, 2001.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–1480 Filed 1–17–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Semi-Annual Chairs Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Semi-Annual Chairs Meeting. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Thursday, February 8, 2001, 6:45 a.m.–5:30 p.m.
Friday, February 9, 2001, 8 a.m.–5:30 p.m.
Saturday, February 10, 2001 8 a.m.–1:30 p.m.

ADDRESSES: St. Tropez All Suite Hotel, 455 East Harmon Avenue, Las Vegas, Nevada 89101, Phone: (702) 369–5400 or (800) 666–5400.

FOR FURTHER INFORMATION CONTACT: Martha Crosland, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–5793.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE and its regulators in the areas of future use, cleanup levels, waste disposition, and cleanup priorities.

Tentative Agenda

Thursday, February 8, 2001: EM SSAB Chairs Meeting (Day 1)

6:45 a.m.–5:30 p.m, Joint tour of the Nevada Test Site and Yucca Mountain
6:00 p.m.–7:00 p.m., Opening reception at the St. Tropez Hotel

Friday, February 9, 2001: EM SSAB Chairs Meeting (Day 2)

6:30–8:00 a.m., Continental Breakfast buffet in Truffles Lounge
8:00–8:20 a.m., Opening/Welcoming Remarks/Overview of Agenda (Martha Crosland, DOE/HQ; Carl Gertz, DOE/NV AMEM; etc.)
8:20–8:25 a.m., Introduction of Facilitators and Review of Ground Rules (Ted McAdam, *et.al.*)
8:25–9:30 a.m., Round Robin Ice Breaker. SSAB Chairs will introduce participants from their Boards and briefly list their Boards' Top Three Issues of Concern
9:30–9:40 a.m., Overview of Survey Results and Objectives of Topic-Specific Round Robins and Facilitated Discussions
9:40–10:30 a.m., Topic #1 Round Robin (five minutes for each SSAB). What is your Board's desired composition and how are new members recruited and selected? How effective is that process?
10:30–10:45 a.m., Morning break
10:45–11:25 a.m., Topic #1 Facilitated Discussion
11:25 a.m.–12:05 p.m., Topic #2 Round Robin (four minutes for each SSAB). How does your Board develop its annual work plan? How does your Board set its agenda?
12:05–12:40 p.m., Topic #2 Facilitated Discussion
12:40–1:45 p.m., Buffet lunch served in the hotel
1:45–2:25 p.m., Topic #3 Round Robin (four minutes for each SSAB). How are your Boards's committees structured? How do your Board's committees function? Do non-members participate in committee work?
2:25–3:00 p.m., Topic #3 Facilitated Discussion
3:00–3:15 p.m., Afternoon Break
3:15–3:55 p.m., Topic #4 Round Robin (four minutes for each SSAB). How does your Board develop its recommendations/advice? To whom are your recommendations addressed?
3:55–4:30 p.m., Topic #4 Facilitated Discussion
4:30–5:15 p.m., Review and Approval of Stewardship Core Value Statements
5:15–5:30 p.m., Public Comment
5:30–7:00 p.m., Free time
7:00 p.m. Dine Around Las Vegas. Groups depart for area restaurants—transportation to be provided

Saturday, February 10, 2001: EM SSAB Chairs Meeting (Day 3)

6:30–8:00 a.m., Continental Breakfast Buffet in Truffles Lounge
8:00–8:10 a.m., Welcome and Recap of Previous Day's Work (Martha Crosland or Ted McAdam)
8:10–8:50 a.m., Topic #5 Round Robin (five minutes for each SSAB). How does your Board conduct public outreach and how effective is that effort?
8:50–9:25 a.m., Topic #5 Facilitated Discussion
9:35–10:15 a.m., Topic #6 Round Robin (five minutes for each SSAB). How does your Board conduct self-evaluations, who else evaluates the Board's performance, and how effective is/are that/those process(es)?
10:15–10:55 a.m., Topic #6 Facilitated Discussion
10:55–11:10 a.m., Morning break
11:10a.m.–12:10 p.m., Facilitated Discussion of Issues of Concern to Each Site. Issues discussed will be based on those recorded during the Friday morning Ice Breaker Round Robin discussion.
12:10–12:30 p.m., Updates from DOE Headquarters
- Revised DOE Public Participation Policy Public Review & Comment
- Status Report Regarding Changes at DOE Under the New Administration (Betty Nolan)

12:30–12:45 p.m., Critique of the SSAB Chairs Meeting
12:45–1:00 p.m., Future SSAB Meetings and Workshops—Martha Crosland
1:00–1:15 p.m., Public comment
1:15–1:30 p.m., Closing remarks
1:30 p.m., Adjourn

(Agenda topics may change up to the day of the meetings: please contact Martha Crosland, Designated Federal Officer, (202) 586–5793 for the current agenda.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board facilitator either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Board Chair at their specific site, or Martha Crosland. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer, Martha Crosland, U.S. Department of Energy, is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: A written summary of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC, 20585 between 9 a.m. and 4 p.m., Monday–Friday, except Federal holidays. The meeting summary will also be available by writing the EM–SSAB Chair or Designated Deputy Federal Officer of every EM–SSAB that participated in the meeting.

Issued at Washington, DC on January 11, 2001.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–1481 Filed 1–17–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 00–53–NG, et al.]

Office of Fossil Energy; Chinook Pipeline Company (The Successor to Xeno, Inc.), et al.; Orders Granting and Transferring Authority To Import and Export Natural Gas

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during December 2000, it issued Orders granting and transferring authority to import and export natural gas. These Orders are summarized in the attached appendix and may be found on the FE website at http://www.fe.doe.gov, or on the electronic bulletin board at (202) 586–7853. They are also available for inspection and copying in the Office of Natural Gas & Petroleum Import & Export Activities, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, D.C., on January 9, 2001.

Clifford P. Tomaszewski,

Manager, Natural Gas Regulation, Office of Natural Gas & Petroleum, Import & Export Activities, Office of Fossil Energy.

Attachment.

APPENDIX.—ORDERS GRANTING AND TRANSFERRING IMPORT/EXPORT AUTHORIZATIONS

[DOE/FE Authority]

Order No.	Date Issued	Importer/Exporter FE Docket No.	Import volume	Export volume	Comments
1615–A	12/04/00	Chinook Pipeline Company (The Successor to Xeno, Inc.) 00–53–NG.			Transfer of blanket export authority.
992–A	12/08/00	Engage Energy Canada, L.P. (The Successor to Westcoast Gas Services Inc.) 94–74–NG.			Transfer of long-term import authority.
993–A	12/08/00	Engage Energy Canada, L.P. (The Successor to Westcoast Gas Services Inc.) 94–75–NG.			Transfer of long-term import authority.
994–A	12/08/00	Engage Energy Canada, L.P. (The Successor to Westcoast Gas Services Inc.) 94–76–NG.			Transfer of long-term import authority.
996–A	12/08/00	Engage Energy Canada, L.P. (The Successor to Westcoast Gas Services Inc.) 94–78–NG.			Transfer of long-term import authority.
1656	12/08/00	Pemex Gas Y Petroquimica Basica 00–93–NG.		(1)160 Bcf	Import and export a combined total to and from Canada and Mexico, beginning on January 1, 2001, and extending through December 31, 2002.
1657	12/08/00	Hunt Oil Company of Canada, Inc. 00–95–NG.	6 Bcf		Import from Canada beginning on December 1, 2000, and extending through November 30, 2002.
1658	12/15/00	Engage Energy Canada, L.P. 00–96–NG.	1,000 Bcf	1,000 Bcf	Import from Canada, including LNG and export to Canada, beginning on January 1, 2001, and extending through December 31, 2002.
1659	12/18/00	The Montana Power Company 00–94–NG.	20 Bcf		Import from Canada beginning on February 7, 2001, and extending through February 6, 2003.
1660	12/21/00	Coast Energy Group, A Division of Cornerstone Propane L.P. 00–99–NG.		40 Bcf	Import and export a combined total to and from Canada and Mexico, beginning on January 1, 2001, and extending through December 31, 2002.
1661	12/22/00	Sprague Energy Corp. 00–98–NG	50 Bcf		Import from Canada beginning on January 1, 2001, and extending through December 31, 2002.
1662	12/26/00	Wisconsin Gas Company 00–97–NG.	200 Bcf		Import from Canada beginning on January 1, 2001, and extending through December 31, 2002.

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APPENDIX.—ORDERS GRANTING AND TRANSFERRING IMPORT/EXPORT AUTHORIZATIONS—Continued
[DOE/FE Authority]

Order No.	Date Issued	Importer/Exporter FE Docket No.	Import volume	Export volume	Comments
1663	12/27/00	IDACORP Energy Solutions L.P. 00–100–NG.	730 Bcf		Import and export a combined total to and from Canada, beginning on December 20, 2000, and extending through December 19, 2002.

[FR Doc. 01–1479 Filed 1–17–01; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–208–000]

Amoco Production Company, et al.; Notice of Emergency Petition

DATE: January 11, 2001.

Take notice that on January 5, 2001, Amoco Production Company, BP Exploration & Oil Inc., Chevron U.S.A. Inc., ExxonMobil Gas Marketing Company, a division of Exxon Mobil Corporation, and Shell Offshore Inc. (Producers) tendered for filing an emergency petition requesting the Commission to issue an immediate temporary restraining order, prior to January 9, 2001, to prevent Southern Natural Gas Company from shutting in natural gas supply upstream of the Toca processing plants, located in Louisiana. In addition, the Producers request the Commission to schedule an emergency technical conference to explore all of the issues as soon as possible.

Producers states that copies of the filing have been served upon each person designated on the official service list compiled by the Secretary in this proceeding.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before January 16, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

David P. Boergers,
Secretary.
[FR Doc. 01–1424 Filed 1–17–01; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–46–002]

Carnegie Interstate Pipeline Company; Notice of Compliance Filing

January 11, 2001.

Take notice that on January 8, 2001, Carnegie Interstate Pipeline Company (CIPCO), tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheets, with an effective date of November 1, 2000:

Substitute first Revised Tariff Sheet No. 116

CIPCO states that this tendered sheet is filed in compliance with Order No. 587–L, issued in Docket No. RM96–1–014 by the Commission on June 30, 2000 and implements 18 CFR 284.(c)(ii), regarding the netting and trading of imbalances on CIPCO's system, and further responds to the Commission's directive in its Order of December 21, 2000, herein.

CIPCO states that a copy of the filing is being served on each of CIPCO's jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,
Secretary.
[FR Doc. 01–1422 Filed 1–17–01; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3661–001]

Central Hudson Gas & Electric; Notice of Filing

January 11, 2001.

Take notice that on December 11, 2000, Central Hudson Gas and Electric Corporation (Central Hudson), tendered for filing its FERC Rate Schedule No. 201 which sets forth the terms and charges for transmission facilities provided by the Company to Consolidated Edison company of New York, Inc., and Niagara Mohawk Power Corporation for the transmission of output from the Roseton Generating Station.

Rate Schedule FERC No. 201 is issued in compliance with the October 10, 2000 order issued in Docket No. ER00–3661–000, which required the Company to file rate schedule designations as required in Order No. 614. Accordingly, Rate Schedule FERC No. 201 supersede Rate Schedule FERC No. 42.

Central Hudson states that a copy of its filing was served on Con Edison, Niagara Mohawk and the State of New York Public Service Commission.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214), All such motions and protests should be filed on or before January 22, 2001. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,
Secretary.
[FR Doc. 01–1417 Filed 1–17–01; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–37–002]

Equitrans, L.P.; Notice of Compliance Filing

January 11, 2001.

Take notice that on January 8, 2001, Equitrans, L.P. (Equitrans), tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following revised tariff sheet, with an effective date of November 1, 2000:

Substitute Original Sheet No. 255

Equitrans states that this tendered sheet is filed in compliance with Order No. 587–L, issued in Docket No. RM96–1–014 by the Commission on June 30, 2000 and implements 18 CFR 284.(c)(ii), regarding the netting and trading of imbalances on Equitrans' system, and further responds to the Commission's directive in its Order of December 21, 2000, herein.

Equitrans states that a copy of the filing is being served on each of Equitrans' jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,
Secretary.
[FR Doc. 01–1423 Filed 1–17–01; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

January 11, 2001.

a. *Application Type:* Application to Amend License for the Big Creek Nos. 2A, 8 & Eastwood Power Station Project.

b. *Project No:* 67–089.

c. *Date Filed:* January 12, 2000, and supplemented on November 9, 2000.

d. *Applicant:* Southern California Edison Company (SCE).

e. *Name of Project:* Big Creek Nos. 2A, 8 & Eastwood Power Station Project.

f. *Location:* The project is located on the South Fork San Joaquin River and Big Creek in Fresno County, California. The project utilizes lands of the Sierra National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Stephen E. Pickett, Vice President and General Counsel, Southern California Edison Company, 2244 Walnut Grove Avenue, P.O. Box 800, Rosemead, CA 91770, (626) 302–4459.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Vedula Sarma at (202) 219–3273 or by e-mail at vedula.sarma@ferc.fed.us.

j. *Deadline for filing comments and/or motions:* February 16, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the project number (P–67–089) on any comments or motions filed.

k. *Description of Filing:* SCE proposes to remove 1.7 miles of transmission line from Big Creek #2A–Big Creek #8, and 5.6 miles of transmission line from Big Creek #8–Big Creek #3 from the project's license since they are part of the SCE's Transmission System Network. SCE also proposes to revise the project boundary by removing a telephone line, caretaker building, warehouse, microwave tower, and other miscellaneous project features because they are no longer used for project purposes. The proposed modifications would reduce the amount of federal lands used by the project by 158.4 acres.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on http://www.ferc.fed.us/online/rims.htm [call (202) 208–2222 for assistance]. A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the titles "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR

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"MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulation to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–1425 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–312–038]

Tennessee Gas Pipeline Company; Notice of a Change in Rates

January 11, 2001.

Take notice that on January 3, 2001, Tennessee Gas Pipeline Company (Tennessee), tendered for filing a notice of a change in rates for the October 18, 2000 Negotiated Rate Agreement between Tennessee and Dynegy Energy Marketing and Trade (Dynegy). The notice substitutes a fixed rate in place of a Margin calculation for certain volumes for TGP Service Package No. 35092. The fixed prices are effective from January 2, 2001 through January 31, 2001.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed on or before January 18, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

David P. Boergers,

Secretary.

[FR Doc. 01–1421 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EG01–96–000, et al.]

PSEG Nuclear LLC, et al.; Electric Rate and Corporate Regulation Filings

January 11, 2001.

Take notice that the following filings have been made with the Commission:

1. PSEG Nuclear LLC

[Docket No. EG01–96–000]

Take notice that on December 29, 2000, PSEG Nuclear LLC (PSEG Nuclear or Applicant), having its principal place of business at 80 Park Plaza, T–16, Newark, New Jersey, filed with the Federal Energy Regulatory Commission an application for redetermination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

PSEG Nuclear is a limited liability company organized under the laws of the State of Delaware. PSEG Nuclear will be engaged, directly or indirectly through an affiliate as defined in Section 2(a)(11)(B) of the Public Utility Holding Company Act of 1935, exclusively in owning, or both owning and operating eligible generating facilities, and engaging in sales of electric energy at wholesale.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

2. Duke Energy Audrain, LLC

[Docket No. EG01–97–000]

Take notice that on January 3, 2001, Duke Energy Audrain, LLC (Duke Audrain) filed an application with the Federal Energy Regulatory Commission (the Commission) for determination of exempt wholesale generator status pursuant to Section 32 of the Public Utility Holding Company Act of 1935, as amended, and Part 365 of the Commission's regulations.

Duke Audrain is a Delaware limited liability company that will be engaged directly and exclusively in the business of owning and operating all or part of one or more eligible facilities to be located in Audrain County, Missouri. The eligible facilities will consist of an approximately 640 MW natural gas-fired, simple cycle electric generation plant and related interconnection facilities. The output of the eligible facilities will be sold at wholesale.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

3. Guadalupe Power Partners, LP

[Docket No. EG01–98–000]

Take notice that on January 4, 2001, Guadalupe Power Partners, LP (GPP), filed with the Federal Energy Regulatory Commission an application for redetermination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

GPP is a Delaware limited partnership which will own and/or operate a natural gas-fired electric generating facility with an expected generating capacity of 1,000 MW to be located in Guadalupe County, Texas within the region governed by the Electric Reliability Council of Texas (ERCOT) and sell electricity at wholesale.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

4. Hamakua Energy Partners, L.P.

[Docket No. EG01–99–000]

Take notice that on January 8, 2001, Hamakua Energy Partners, L.P., a Hawaii limited partnership, with its principal office located at J. A. Jones Drive, Charlotte, North Carolina 28287, filed with the Federal Energy Regulatory Commission (Commission) information with respect to a change in facts relative to its status as an exempt wholesale generator and an Application for determination that it remains an exempt wholesale generator pursuant to Part 365 of the Commission's regulations and Section 32 of the Public Utility Holding Company Act of 1935, as amended. Applicant is a Hawaii limited partnership that will be engaged directly and exclusively in operating an approximately 63 MW net naphtha and distillate oil-fired power plant (the Facility) located in Honakaa, in the northern coastal region of the island of Hawaii, and selling energy at wholesale from the Facility.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

5. MEP Pleasant Hill Operating, LLC

[Docket No. EG01–100–000]

Take notice that on January 8, 2000, MEP Pleasant Hill Operating, LLC (MEPPH Operating), filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations and Section 32(a) of the Public Utility Holding Company Act of 1935. MEPPH Operating and CPN Pleasant Hill Operating, LLC (CPNPH Operating) will operate and sell power at wholesale from generation facilities under construction in Cass County, Missouri.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

6. North Carolina Power Holdings, LLC

[Docket No. EG01–101–000]

Take notice that on January 8, 2001, North Carolina Power Holdings, LLC (NCPH), a limited liability company with its principal place of business at 1400 Smith Street, Houston, Texas 77002, filed with the Federal Energy Regulatory Commission (Commission) an application for determination of exempt wholesale generator status pursuant to Part 365 of the Commission's regulations.

NCPH states that it will be engaged directly and exclusively in the business of owning two 35 MW generation facilities located in Elizabethtown and Lumberton, North Carolina. NCPH will sell its capacity exclusively at wholesale. A copy of the filing was served upon the Securities and Exchange Commission and the North Carolina Utilities Commission.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice. The Commission will limit its consideration of comments to those that concern the adequacy or accuracy of the application.

7. Ogden Martin Systems of Fairfax, Inc.

[Docket No. ES01–11–002]

Take notice that on January 5, 2001, Ogden Martin Systems of Fairfax, Inc. filed with the Commission an amendment to its application in the above-referenced proceeding, seeking to increase the amount of debt it may issue from $142 million to $160 million.

Comment date: January 23, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Duke Energy Audrain, LLC

[Docket No. ER01–884–000]

Take notice that on January 3, 2001, Duke Energy Audrain, LLC (Duke Audrain), tendered for filing pursuant to Section 205 of the Federal Power Act its proposed FERC Electric Tariff No. 1.

Duke Audrain seeks authority to sell energy and capacity, as well as ancillary services, at market-based rates, together with certain waivers and preapprovals. Duke Audrain also seeks authority to sell, assign, or transfer transmission rights that it may acquire in the course of its marketing activities.

Duke Audrain seeks an effective date sixty (60) days from the date of filing for its proposed rate schedules.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. American Electric Power Service Corporation

[Docket No. ER01–67–001]

Take notice that on January 8, 2001, American Electric Power Service Corporation tendered for filing, on behalf of the operating companies of the American Electric Power System (AEP), a proposed amendment to the Open Access Transmission Tariff accepted for filing by the Commission in Docket No. ER98–2786–000. The amendment is being submitted in response to a December 7, 2000 deficiency letter in this docket.

AEP requests waiver of notice to permit an effective date of December 1, 2000 for such amendments.

Copies of the filing have been served upon AEP's transmission customers and the stat utility regulatory commissions of Arkansas, Indiana, Kentucky, Louisiana, Michigan, Ohio, Oklahoma, Tennessee, Texas, Virginia and West Virginia.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. American Electric Power Service Corporation

[Docket No. ER01–257–001]

Take notice that on January 8, 2001, the American Electric Power Service Corporation (AEPSC), tendered for filing an Amendment to Filing in No. Docket ER01–257–000. In AEPSC's initial filing on October 25, 2000, AEPSC failed to provide designations for a Transaction Confirmation Agreement (Confirmation Agreement) which was submitted for filing by the AEP Companies in the above referenced docket. Pursuant to the Commissions' Order No. 614 in Docket No. RM99–12–000, AEPSC respectfully designates the Confirmation Agreement with the City of Vernon, California as Service Agreement No. 269 under the Wholesale Market Tariff of the AEP Operating Companies (Power Sales Tariff).

The Power Sales Tariff was accepted for filing effective October 10, 1997, and has been designated AEP Companies' FERC Electric Tariff Original Volume No. 5. AEPSC respectfully requests waiver of notice to permit this the Confirmation Agreement to be made effective as initially requested on or prior to October 1, 2000.

A copy of the filing was served upon the Parties and the State Utility Regulatory Commissions of Arkansas, Indiana, Kentucky, Louisiana, Michigan, Ohio, Oklahoma, Tennessee, Texas, Virginia and West Virginia.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Atlantic City Electric Company, Baltimore Gas & Electric Company, Delmarva Power & Light Company, Metropolitan Edison Company, PP&L Inc., PECO Energy Company, Potomac Electric Power Company, Public Service Electric and Gas Company, UGI Utilities, Inc.

[Docket No. ER01–897–000]

Take notice that on January 5, 2001, Potomac Electric Power Company (Pepco), tendered for filing a Notice of Assignment pursuant to which PPL Montour, LLC (PPLM) and Allegheny Energy Supply Conemaugh, LLC (AESC) will, as part of Pepco's transfer of its ownership interests in the Conemaugh Generating Station to PPLM and AESC, replace Pepco as a Generating Station Owner under the Conemaugh Generating Station Interconnection Agreement (Agreement) which is designated as follows: Atlantic City Electric Company Rate Schedule FERC No. 75; Baltimore Gas & Electric Company Rate Schedule FERC No. 58; Delmarva Power & Light Company Rate

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Schedule FERC No. 124; Metropolitan Edison Company Rate Schedule FERC No. 77; PP&L Inc. Rate Schedule FERC No. 168; PECO Energy Company Rate Schedule FERC No. 123; Potomac Electric Power Company Rate Schedule FERC No. 46; Public Service Electric and Gas Company Rate Schedule FERC No. 166; and, UGI Utilities, Inc. Rate Schedule FERC No. 9.

The Agreement will become effective at the time Pepco's ownership interest in the Conemaugh Generating Station is transferred to PPLM and AESC.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Arizona Public Service Company

[Docket No. ER01–898–000]

Take notice that on January 5, 2001, Arizona Public Service Company (APS), tendered for filing umbrella Service Agreements to provide Short-Term Firm and Non-Firm Point-to-Point Transmission Service to Morgan Stanley Capital Group, Inc., under APS' Open Access Transmission Tariff.

A copy of this filing has been served on Morgan Stanley Capital Group, Inc., and the Arizona Corporation Commission.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Louisville Gas and Electric Company, Kentucky Utilities Company

[Docket No. ER01–899–000]

Take notice that on January 5, 2001, Louisville Gas and Electric Company (LG&E) and Kentucky Utilities Company (KU), 220 West Main Street, Louisville, Kentucky 40202, tendered for filing with the Commission a notice that LG&E and KU were withdrawing from the Midwest Independent System Operator, Inc. (MISO), a motion requesting the Commission to authorize and approve such withdrawal effective upon the earliest date on which the Commission authorizes and approves the withdrawal from the MISO of either Commonwealth Edison Company or Illinois Power Company, and a motion requesting the Commission to authorize the recovery of LG&E's and KU's associated costs.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Pennsylvania Electric Company

[Docket No. ER01–900–000]

Take notice that on January 5, 2001, Potomac Electric Power Company (Pepco), tendered for filing a Notice of Assignment pursuant to which PPL Montour, LLC (PPLM) and Allegheny Energy Supply Conemaugh, LLC (AESC) will replace Pepco under the 115 kV Seward-Conemaugh Interconnection Facilities Agreement (Agreement), Penelec Rate Schedule No. 63, as part of Pepco's transfer of its ownership interests in the Conemaugh Generating Station to PPLM and AESC.

The Agreement will become effective at the time Pepco's ownership interest in the Conemaugh Generating Station is transferred to PPLM and AESC.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Pennsylvania Electric Company

[Docket No. ER01–901–000]

Take notice that on January 5, 2001, Potomac Electric Power Company (Pepco), tendered for filing a Notice of Assignment pursuant to which PPL Montour, LLC (PPLM) and Allegheny Energy Supply Conemaugh, LLC (AESC) will replace Pepco under the Conemaugh Generating Station Operating Agreement (Agreement), Penelec Rate Schedule No. 100, as part of Pepco's transfer of its ownership interests in the Conemaugh Generating Station to PPLM and AESC.

The Agreement will become effective at the time Pepco's ownership interest in the Conemaugh Generating Station is transferred to PPLM and AESC.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. California Power Exchange Corporation

[Docket No. ER01–902–000]

Take notice that on January 5, 2001, the California Power Exchange Corporation (CalPX), tendered for filing its proposed Tariff Amendment No. 22, consisting of a revised Sheet No. 59 and a new Sheet No. 59A to its Tariff. The purpose of Tariff Amendment No. 22 is to change the credit requirements pertaining to its current full requirements customers, namely Pacific Gas and Electric Company, Southern California Edison Company, and San Diego Gas Electric Company (IOUs). Tariff Amendment No. 22 modifies the credit rating requirements pertaining to the IOUs as a result of the Commission's December 15, 2000 order (93 FERC ¶ 61,294) and as a result of recent changes in institutional credit ratings for PG&E and Edison.

To permit the IOU's to continue trading in the CalPX Markets, CalPX requests waiver of the Commission's notice requirements to permit the tendered filing to become effective as of the date of this filing.

CalPX states that it has served this filing on its participants and on the California Public Utilities Commission and has also posted this filing on its website (*www.calpx.com*).

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Central Hudson Gas & Electric Corporation

[Docket No. ER01–903–000]

Take notice that on January 8, 2001, Central Hudson Gas and Electric Corporation (Central Hudson), tendered for filing its Rate Schedule FERC No. 202 which sets forth the terms and charges for substation service provided by the Company to Consolidated Edison Company of New York, Inc.

Rate Schedule FERC No. 202, which supersedes Rate Schedule FERC No. 43, also provides the development of actual costs for 1999 related to the provision of the aforementioned substation service.

Central Hudson indicates that the actual costs amounted to $274,659 for 1999 and will be the basis, excluding the New York State Gross Earnings Tax which was eliminated effective January 1, 2000, on which the estimated charges of $272,599 for 2000 will be billed.

Central Hudson states that a copy of its filing was served on Con Edison and the State of New York Public Service Commission.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. MEP Pleasant Hill Operating, LLC

[Docket No. ER01–905–000]

Take notice that on January 8, 2001, MEP Pleasant Hill Operating, LLC (MEPPH Operating), an indirect wholly owned subsidiary of UtiliCorp United Inc., tendered for filing a rate schedule to engage in sales at market-based rates and two service agreements thereunder. MEPPH Operating included in its filing a proposed code of conduct.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Xcel Energy Services

[Docket No. ER01–907–000]

Take notice that on January 8, 2001, Xcel Energy Services Inc. (XES), on behalf of Cheyenne Light, Fuel & Power (CLF&P), tendered for filing a letter approving its application for membership in the Western Systems Power Pool (WSPP).

CLF&P requests the Commission to allow its membership in the WSPP to become effective on January 9, 2001.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Allegheny Energy Service Corporation, on Behalf of Monongahela Power Company, The Potomac Edison Company, West Penn Power Company (Allegheny Power)

[Docket No. ER01–908–000]

Take notice that on January 8, 2001, Allegheny Energy Service Corporation on behalf of Monongahela Power Company, The Potomac Edison Company and West Penn Power Company (Allegheny Power), filed Service Agreement No. 334 to add Strategic Energy, L.L.C. to Allegheny Power's Open Access Transmission Service Tariff.

The proposed effective date under the agreement is January 5, 2001.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, and the West Virginia Public Service Commission.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. Consumers Energy Company

[Docket No. ER01–909–000]

Take notice that on January 8, 2001, Consumers Energy Company (Consumers), tendered for filing executed Firm and Non-Firm Point to Point Transmission Service Agreements with Nordic Electric, LLC (Customer) pursuant to the Joint Open Access Transmission Service Tariff filed on December 31, 1996 by Consumers and The Detroit Edison Company (Detroit Edison).

Both Agreements have effective dates of January 1, 2001.

Copies of the filed agreements were served upon the Michigan Public Service Commission, Detroit Edison, and the Customer.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. Consumers Energy Company

[Docket No. ER01–910–000]

Take notice that on January 8, 2001, Consumers Energy Company (Consumers), tendered for filing executed Firm and Non-Firm Point to Point Transmission Service Agreements with Commonwealth Edison Company and the City of Holland, Michigan Board of Public Works (Customers) pursuant to Consumers' Open Access Transmission Service Tariff filed on July 9, 1996 by Consumers.

All four Agreements have effective dates of January 1, 2001.

Copies of the filed agreements were served upon the Michigan Public Service Commission and the Customers.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. Niagara Mohawk Power Corporation

[Docket No. ER01–906–000]

Take notice that on January 8, 2001, Niagara Mohawk Power Corporation (Niagara Mohawk), tendered for filing an amendment to Niagara Mohawk's firm transmission service agreement with AES NY, L.L.C., FERC Rate Schedule No. 165, pursuant to Section 35.13 of the Code of Federal Regulations, 18 CFR 35.13.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

24. San Diego Gas & Electric Company, Complainant, v. Sellers of Energy and Ancillary Services Into Markets Operated by the California Independent System Operator and the California Power Exchange, Respondents

[Docket No. EL00–95–011]

Take notice that on January 8, 2001, Southern California Edison Company (Edison) tendered for filing pursuant to Ordering Paragraph (A) of the commission's December 15, 2000 Order Directing Remedies for California Wholesale Electric Markets (the Order), 93 FERC ¶ 61,294, its compliance filing.

Comment date: February 1, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1477 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–46–000, et al.]

Virginia Electric and Power Company, et al.; Electric Rate and Corporate Regulation Filings

January 10, 2001.

Take notice that the following filings have been made with the Commission:

1. Virginia Electric and Power Company

[Docket No. EC01–46–000]

Take notice that on January 8, 2001, Virginia Electric and Power Company (the Company) filed Exhibit G to supplement its Section 203 application in the above-captioned proceeding (the Application). In the Application, the Company committed to submit other federal and state applications in Exhibit G to the Commission when those applications are complete.

The Applicant states that copies of the filing have been served upon the utility commissions of the states of Virginia and North Carolina and the Company's wholesale requirements customers.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. San Joaquin Cogen Limited

[Docket No. ER01–896–000]

Take notice that on January 5, 2001, San Joaquin Cogen Limited (San Joaquin), an Exempt Wholesale Generator that owns and operates a natural gas-fired cogeneration facility in Lathrop, California tendered for filing a Power Purchase/Sale Transaction Confirmation (Agreement) in the above-captioned docket.

San Joaquin requests that the Agreement be permitted to become effective January 1, 2001.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. FirstEnergy Operating Companies

[Docket No. ER00–3771–003]

Take notice that on January 5, 2001, The Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company and The

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Toledo Edison Company (collectively, the FirstEnergy Operating Companies), tendered for filing a red-lined version of their FERC Electric Tariff, First Revised Volume No. 3, in which they are offering to make available ancillary services and interconnected operations services. The FirstEnergy Operating Companies state that this tariff identifies modifications to a tariff submitted in September 2000 that were required by the Order Accepting for Filing, as Modified, Proposed Tariff and Service Agreement which was issued in this proceeding on November 22, 2000.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Southern Company Services, Inc.

[Docket Nos. ER99–3531–002; ER99–4384–002]

Take notice that on January 5, 2001, Southern Company Services, Inc., as agent for Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (collectively Southern Companies), tendered for filing a refund report in compliance with the Commission's November 22, 2000, Letter Order in the above-referenced proceeding. The refund results from settlement rates associated with Southern Companies' generator balancing service tariff.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power & Light Company

[Docket No. ER01–874–000]

Take notice that on January 3, 2001, Florida Power & Light Company (FPL), tendered for filing Service Agreements between El Paso Merchant Energy, L.P.; DTE Energy Trading, Inc.; and Rainbow Energy Marketing Corporation for service pursuant to FPL's Market Based Rates Tariff

FPL requests that the Service Agreements be made effective on December 7, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Cinergy Services, Inc.

[Docket No. ER01–875–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Cinergy Services, Inc., (Customer).

This service agreement has a yearly firm transmission service with LGE Energy via the Gibson Unit Nos. 1–5 Generating Station.

Provider and Customer are requesting an effective date of January 1, 2001.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Cinergy Services, Inc.

[Docket No. ER01–876–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Cinergy Services, Inc., (Customer).

This service agreement has a yearly firm transmission service with LGE Energy via the Gibson Unit Nos. 1–5 Generating Station.

Provider and Customer are requesting an effective date of January 1, 2001.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Cinergy Services, Inc.

[Docket No. ER01–877–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Cinergy Services, Inc., (Customer).

This service agreement has a yearly firm transmission service with LGE Energy via the Gibson Unit Nos. 1–5 Generating Station.

Provider and Customer are requesting an effective date of January 1, 2001.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Cinergy Services, Inc.

[Docket No. ER01–878–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a Non-Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Cinergy and Engage Energy America Corp., (Customer).

Provider and Customer are requesting an effective date of December 11, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Cinergy Services, Inc.

[Docket No. ER01–879–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a Firm Point-To-Point Service Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Engage Energy America Corp., (Customer).

Provider and Customer are requesting an effective date of December 11, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. Cinergy Services, Inc.

[Docket No. ER01–880–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a service agreement and a Network Operating Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Strategic Energy, L.L.C., (Customer).

Provider and Customer are requesting an effective date of December 14, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Cinergy Services, Inc.

[Docket No. ER01–881–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a service agreement and a Network Operating Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and FirstEnergy Services Corp., (Customer).

Provider and Customer are requesting an effective date of December 14, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Cinergy Services, Inc.

[Docket No. ER01–882–000]

Take notice that on January 3, 2001, Cinergy Services, Inc. (Provider), tendered for filing a service agreement and a Network Operating Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Newenergy, Inc., (Customer).

Provider and Customer are requesting an effective date of December 14, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Cinergy Services, Inc.

[Docket No. ER01–883–000]

Take notice that on January 3, 2000, Cinergy Services, Inc. (Provider), tendered for filing a service agreement and a Network Operating Agreement under Cinergy's Open Access Transmission Service Tariff (OATT) entered into between Provider and Allegheny Energy Supply Company, LLC (Customer).

Provider and Customer are requesting an effective date of December 14, 2000.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. PJM Interconnection, L.L.C.

[Docket No. ER01–885–000]

Take notice that on January 3, 2001, PJM Interconnection, L.L.C. (PJM), tendered for filing an executed interim interconnection service agreement between PJM and PSEG Fossil L.L.C.

PJM requests a waiver of the Commission's 60-day notice requirement to permit the effective dates agreed to by the parties.

Copies of this filing were served upon PSEG Fossil L.L.C. and the state electric utility regulatory commissions within the PJM control area.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Southern Indiana Gas and Electric Company

[Docket No. ER01–886–000]

Take notice that on January 4, 2001, Southern Indiana Gas and Electric Company (SIGECO), on tendered for filing service agreements for firm and non-firm transmission service under Part II of its Transmission Services Tariff with Engage Energy America Corp. and for firm transmission service with Aquila Energy Marketing Corporation, respectively.

Copies of the filing were served upon each of the parties to each service agreements.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. New England Power Company

[Docket No. ER01–888–000]

Take notice that on January 3, 2001, New England Power Company (NEP), tendered for filing a service agreement between NEP and American Paper Mills of Vermont, Inc. (American) for Firm Local Generation Delivery Service under NEP's FERC Electric Tariff, Original Volume No. 9.

Copies of the filing have been served upon American and the Vermont Public Service Board.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Boston Edison Company

[Docket No. ER01–890–000]

Take notice that on January 4, 2001, Boston Edison Company, tendered for filing with the Commission an unexecuted Interconnection Agreement Between Sithe Mystic Development LLC and Boston Edison Company.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC

[Docket No. ER01–891–000]

Take notice that on January 4, 2000, Allegheny Energy Service Corporation on behalf of Allegheny Energy Supply Company, LLC (Allegheny Energy Supply), tendered for filing Service Agreement No. 107 to add one (1) new Customer to the Market Rate Tariff under which Allegheny Energy Supply offers generation services.

Allegheny Energy Supply proposes to make service available as of January 3, 2001 to Calpine Energy Services, L.P.

Copies of the filing have been provided to the Public Utilities Commission of Ohio, the Pennsylvania Public Utility Commission, the Maryland Public Service Commission, the Virginia State Corporation Commission, the West Virginia Public Service Commission, and all parties of record.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Entergy Services, Inc.

[Docket No. ER01–892–000]

Take notice that on January 4, 2001, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc., (collectively, the Entergy Operating Companies), tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement and a Short-Term Firm Point-To-Point Transmission Service Agreement both between Entergy Services, Inc., as agent for the Entergy Operating Companies, and Plum Point Energy Associates, LLC.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. Carolina Power & Light Company

[Docket No. ER01–893–000]

Take notice that on January 4, 2001, Carolina Power & Light Company (CP&L), tendered for filing an executed Service Agreement between CP&L and the following eligible buyer, Powerex Corp. Service to this eligible buyer will be in accordance with the terms and conditions of CP&L's Market-Based Rates Tariff, FERC Electric Tariff No. 4, for sales of capacity and energy at market-based rates.

CP&L requests an effective date of January 2, 2001 for this Service Agreement.

Copies of the filing were served upon the North Carolina Utilities Commission and the South Carolina Public Service Commission.

Comment date: January 25, 2001, in accordance with Standard Paragraph E at the end of this notice.

22. Entergy Services, Inc.

[Docket No. ER01–894–000]

Take notice that on January 5, 2001, Entergy Services, Inc. (Entergy), on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc. (collectively, the Entergy Operating Companies), tendered for filing a Second Revised Network Integration Transmission Service Agreement between Entergy, as agent for the Entergy Operating Companies, and East Texas Electric Cooperative, Inc., Sam Rayburn G&T Electric Cooperative, Inc., and Tex-La Electric Cooperative of Texas, Inc., (NITSA). Entergy states that this filing includes the Second Amendment to the NITSA and additionally reconciles alterations to the NITSA filed in Docket No. ER00–3610–000 and Docket Nos. EL99–6–001, ER99–231–001, ER99–232–001, and ER99–487–001 (consolidated).

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

23. The Dayton Power and Light Company

[Docket No. ER01–895–000]

Take notice that on January 5, 2001, The Dayton Power and Light Company (Dayton), tendered for filing a service agreement establishing Enron Power Marketing, Inc. as a customer under the terms of Dayton's FERC Electric Tariff, Original Volume No. 10.

Dayton requests an effective date of one day subsequent to this filing for the service agreements. Accordingly, Dayton requests waiver of the Commission's notice requirements.

Copies of this filing were served upon Enron Power Marketing, Inc. and the Public Utilities Commission of Ohio.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

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E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1416 Filed 1–17–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

January 11, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* New Major License.

b. *Project No.:* 2031–046.

c. *Date Filed:* August 30, 2000.

d. *Applicant:* Springville City.

e. *Name of Project:* Bartholomew Hydroelectric Project.

f. *Location:* Northeast of Springville City, within Bartholomew Canyon and on Hobble Creek, in Utah County, Utah. The project is partially situated on federal lands within the Unita National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Matthew Cassel at Psomas Consultants, 2825 East Cottonwood Parkway, #120, Salt Lake City, Utah 84121; (801) 270–5777.

i. *FERC Contact:* Jim Haimes, *james.haimes@ferc.fed.us;* (202) 219–2780.

j. *Deadline for Filing Motions to Intervene and Protest:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

The Commission's Rules of Practice and Procedure require all persons and entities filing requests to intervene in the subject proceeding to serve a copy of each document they file with the Commission on each person on the official service list for the subject project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application is not ready for environmental analysis at this time.

l. *Description of the Project:* The project, which does not include a dam or reservoir, operates using relatively small quantities of water removed from underground springs or small creeks located at high elevations and then transported via buried penstocks to three powerhouses and a powerhouse addition having a combined installed capacity of 2,000 kilowatts (kW). The project produces an average of approximately 4,653,000 kilowatt-hours of energy per year, primarily during the high runoff season each spring. Flows used to generate electricity either are diverted to the licensee's water distribution system for domestic and industrial consumption or are released into Hobble Creek.

The project also includes the following two transmission facilities: (1) A 5.9-mile-long line, which includes one 1-mile-long, underground segment and a 4.9-mile-long overhead segment, from Upper Bartholomew powerhouse to Hobble Creek powerhouse; and (2) a 6.9-mile-long, 12.47-kilovolt, underground cable from Lower Bartholomew powerhouse to Springville City's electric distribution system.

Although there are no developed recreational facilities within the boundaries of the subject project, Springville City owns and operates a 200-unit campground and an 18-hole golf course in the general vicinity of Hobble Creek powerhouse. In addition, the Rotary Club operates a park on City-owned property. This facility includes a ball field and a picnic area with approximately 20 tables/grills. Further, the Forest Service operates two small campgrounds along the right fork Hobble Creek.

m. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, Room 2A, located at 888 First Street, NE, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

o. All filings must: (1) bear in all capital letters the title "PROTEST" or "MOTION TO INTERVENE;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the subject application.

David P. Boergers,

Secretary.

[FR Doc. 01–1426 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Request for Extension of Time To Commence and Complete Project Construction and Soliciting Comments, Motions To Intervene, and Protests

January 11, 2001.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request for Extension of Time to Commence Project Construction.

b. *Project No.:* 3701–031.

c. *Date Filed:* December 27, 2000.

d. *Applicant:* Yakima-Tieton Irrigation District.

e. *Name of Project:* Tieton Dam Hydroelectric Project.

f. *Location:* The proposed project would be located at the Bureau of Reclamation's Tieton Dam and Reservoir on the Tieton River, in Yakima County, Washington. The Bureau's dam and reservoir and a portion of the project's proposed transmission line occupy U.S. Forest Service lands.

g. *Filed Pursuant to:* Public Law 104–244.

h. *Applicant Contact:* Richard Dieker, Secretary/Manager, Yakima-Tieton Irrigation District, Tieton Headquarters, 470 Camp 4 Road, Yakima, WA 98908, (509) 678–4101.

i. *FERC Contact:* Any questions on this notice should be addressed to Mr. Lynn R. Miles, at (202) 219–2671, or e-mail address: lynn.miles@ferc.fed.us

j. *Deadline for filing comments and or motions:* February 16, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, Mail Code: 888 First Street, NE., Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the project numbers (3701–031) on any comments or motions filed.

k. *Description of the Request:* The licensee has requested that the Commission grant its third and final extension of time request to commence project construction for an additional two-year period. The deadline to commence project construction for FERC Project No. 3701 would be extended to May 31, 2003. The deadline for completion of construction would be extended to May 31, 2005. The licensee's request is filed pursuant to sections 4.200(c) and 4.202(a) of the Commission's regulations..

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20425, or by calling (202) 208–1371.

This filing may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTESTS", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–1427 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

January 11, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11862–000.

c. *Date filed:* November 3, 2000.

d. *Applicant:* Crest Energy Company.

e. *Name of Project:* Eagle Mountain Project.

f. *Location:* In Riverside County, California. The project would utilize federal land managed by the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Arthur W. Lowe, Eagle Crest Energy Corporation, P.O. Box 2155, Palm Desert, CA 92261, (760) 779–0040.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. "Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www/ferc.fed.us/efi/doorbell.htm"

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed pumped storage project would consist of: (1) A proposed 1,150-foot-long, 77-foot-high upper reservoir dam; (2) a proposed 450-foot-long, 27-foot-high upper reservoir dam; (3) a proposed upper reservoir having a surface area of 210 acres, with a storage capacity of 23,600 acre-feet and a

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normal water surface elevation of 2,472 feet msl; (4) a proposed lower reservoir having a surface area of 150 acres, with storage capacity of 26,000 acre-feet and normal water surface elevation of 1,100 feet msl located within the East Pit of the inactive Eagle Mountain Mine; (5) two proposed intake and outlet structures; (6) a proposed 4,400-foot-long, 29-foot-diameter tunnel; (7) a proposed powerhouse containing three generating units having a total installed capacity of 1,000 MW; (8) a proposed 8,500-foot-long, 29-foot-diameter tailrace tunnel; (9) a proposed 83-mile-long, 500 kV transmission line; and (10) appurtenant facilities.

The project would have an annual generation of 6,000 GWh that would be sold to a local utility.

1. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposal project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (See 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, as the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–1429 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

January 11, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11865–000.

c. *Date filed:* November 20, 2000.

d. *Applicant:* Kabatica General Partners.

e. *Name of Project:* Lower Rocky Creek Project.

f. *Location:* On Rocky Creek, in Whatcom County, Washington. The project would utilize federal lands within Mt. Baker-Snoqualmie National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Dan Mahar, Kabatica General Partners, 2210 Huron Street, Bellingham, WA 98226, (360) 739–8128.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

"Comments and protests may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm"

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) An existing 60-foot-long, 60-foot-high Rocky Creek Diversion Dam with a negligible impoundment; (2) a proposed intake; (3) a proposed 300-foot-long, 4-foot-diameter steel penstock; (4) a proposed powerhouse containing a generating having an installed capacity of 1 MW; (5) a proposed tailrace; (6) a proposed 2-mile-long 34 kV underground transmission line; and (7) appurtenant facilities.

The project would have an annual generation of 25 MWh that would be sold to a local utility.

1. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permits application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–1430 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, and Comments

January 11, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 11866–000.

c. *Dated filed:* November 30, 2000.

d. *Applicant:* Davis Hydro.

e. *Name of Project:* Rock Creek Diversion Dam Project.

f. *Location:* On the North Fork Feather River, In Plumas County, California. The project would utilize no federal lands. This project is for additional capacity to the licensed Rock Creek and Cresta Dams Project, FERC No. 1962.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Richard Ely, d.b.a. Davis Hydro, 27264 Meadowbrook Drive, Davis, CA 95616, (530) 753–8864.

i. *FERC Contact:* Robert Bell, (202) 219–2806.

j. *Deadline for filing motions to intervene, protests and comments:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

The Commission's Rules of Practice and Procedure require all interveners

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filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may effect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Project:* The proposed project would consist of: (1) The existing 550-foot-long, 126-foot-high Rock Creek Diversion Dam; (2) the existing reservoir having a surface area of 80 acres and a storage capacity of 4,669 acre-feet and a normal water surface elevation of 2,216 feet msl; (3) a proposed intake; (4) a proposed powerhouse containing three generating units having a total installed capacity of 900 kW; (5) a proposed 1,300-foot-long 60 kV transmission line; and (9) appurtenant facilities.

The project would have an annual generation of 6 GWh that would be sold to a local utility.

1. A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A Washington, D.C. 20426, or by calling (202) 208–1371. The application may be viewed on http://www.ferc.fed.us/online/rims.htm (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 01–1431 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Motions To Intervene, Protests, Comments, Recommendations, and Terms and Conditions

January 11, 2001.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Conduit Exemption.

b. *Project No.:* 11867–000.

c. *Date Filed:* December 26, 2000.

d. *Applicant:* The Metropolitan Water District of Southern California.

e. *Name of Project:* Diamond Valley Lake Small Conduit Hydroelectric Project.

f. *Location:* In Riverside County, California. The project would be located in the Wadsworth Pumping Plant and would utilize water from Diamond Valley Lake. Diamond Valley Lake, an off-stream reservoir, stores water from the Colorado River Aqueduct that the Wadsworth Plant pumps into it from a forebay on the San Diego Canal. The California Aqueduct will be a source of water for the Lake by gravity flow, when construction of the Inland Feeder pipeline is complete. The project would not occupy federal or tribal lands.

g. *Filed Pursuant to:* Federal Power Act 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Joseph E. Tait, Assistant General Manager, The Metropolitan Water District of Southern California, P.O. Box 54153, Los Angeles, CA 90054–0153, (213) 217–6860.

i. *FERC Contact:* James Hunter, (202) 219–2839.

j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time—see the following paragraphs about filing responsive documents.

k. Deadline for filing motions to intervene, protests and comments: February 16, 2001.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the project number (P–11867–000) on any comments, protests, or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Project:* The project would consist of modifying the 12 existing pumps in the Wadsworth Plant to operate in a reverse turbine-generating mode. Energy currently dissipated in pressure control valves as water is released from the Lake into the Canal could then be captured. Each pump/generator would have an installed capacity of 3.3 megawatts (MW), for a total installed capacity of 39.6 MW. The average annual generation would be 30 gigawatt hours.

m. *Available Locations of Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 208–1371. This filing may be viewed on *http://www.ferc.fed.us/online/rims.htm* (call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the address shown in item h above.

Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in the public notice.

Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene is accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to Section 4.34(b) of the Regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 30 days from the issuance date of this notice. All reply comments must be filed with the Commission within 75 days from the date of this notice.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) bear in all capital lettters the title "PROTEST", "MOTION TO INTERVENE", "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATION," "COMMENTS," or "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

David P. Boegers,

Secretary.

[FR Doc. 01–1432 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11730–000]

Alverno Hydroelectric Project; Notice of Teleconference

January 11, 2001.

A teleconference will be convened by staff of the Office of Energy Projects on January 23, 2001, at 2:00 p.m. EST to discuss measures to protect fish and wildlife resources made by the U.S. Fish and Wildlife Service and Michigan Department of Natural Resources under section 10(j) of the Federal Power Act. On October 20, 2000, a notice of availability of draft environmental assessment (DEA) was issued for the Alverno Hydroelectric Project.

In letters dated November 8, 2000, to the U.S. Fish and Wildlife Service and the Michigan Department of natural Resources, the Commission's staff explained that the resource agency recommended measures to protect fish and wildlife resources were considered in the DEA, but did not recommend adopting all of them. We will discuss

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the resource agency recommendations that staff did not recommended for adoption.

Anyone wishing to participate by teleconference should call 1–888–928–9122. They will need to give the operator the passcode "COSTELLO" and the leader "JOHN COSTELLO".

If you have any questions about the teleconference, please call John Costello at (202) 219–2914 or e-mail at john.costello@ferc.fed.us.

David P. Boergers,

Secretary.

[FR Doc. 01–1428 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Third Interstate Natural Gas Facility-Planning Seminar

January 11, 2001.

The Office of Energy Projects will hold the third in a series of public meetings around the country for the purposes of exploring and enhancing strategies for constructive public participation in the earliest stages of natural gas facility planing. This seminar will be held in Tampa, Florida on Thursday, February 15, 2001. We are inviting interstate natural gas companies; Federal, state and local agencies; landowners and non-governmental organizations with an interest in developing new ways of doing business to join us in this effort. We will discuss the facility planning process, not the merits of any pending or planned pipeline projects.

The staff of the Commission's Office of Energy Projects will give a briefing on the results of our first two seminars in Albany, NY and Chicago, IL. We will discuss problems that were identified and potential solutions that were offered in the seminars.

Join us as we continue to explore new strategies being employed by the natural gas industry, agencies, and citizens to learn about each others' concerns and to engage the public and agencies in participatory project design. Interactive discussions will be held with panelists from various Federal and state agencies, representatives from natural gas companies, and private landowners or citizen representatives who have had relevant experiences. There will be substantial opportunity for the sharing of experiences and knowledge during both the panel discussions and in the interactive "brainstorming" session. So, bring your ideas with you and prepare to share them.

The objectives of the meeting are:

- Build upon the discussions from the first two seminars in Albany, NY and Chicago, IL.
- Explore steps taken to identify the parties directly involved with and affected by natural gas facility siting and/or permitting, so they can work together and resolve issues.
- Explore the best avenues for involving people and agencies toward fostering settlements through creative issue resolution.
- To encourage the submission of filings with no or few contested issues in order to reduce the Commission's processing time.
- Discuss the potential benefits of an interstate natural gas pipeline project.

Note: One of our panels this time will focus on the potential benefits of pipelines from each parties' perspective.

We are building on what was learned at our prior meetings and continuing to work toward developing a toolbox of the best available techniques for increasing public involvement and developing solutions to issues during the pre-filing planning process. This will help to plan projects with less opposition that can achieve faster action from the Commission with less controversy and fewer conditions.

The meeting in Tampa, Florida will be held at the Holiday Inn City Centre, located in Tampa, Florida. The meeting is scheduled to start at 9:30 a.m. and finish at 4 p.m. A preliminary agenda and directions to the Holiday Inn City Centre are enclosed. Also, see attachment 2 regarding the selection of locations of future meetings.

If you plan to attend, please email our team at: gasoutreach@ferc.fed.us by February 6, 2001. Or, you can respond via facsimile to Pennie Lewis-Partee at 202–208–0353. Please include in the response the names, addresses, and telephone numbers of all attendees from your organization. We will send an acknowledgment of your request.

To help us enhance our panel discussions, please consider issues and/or questions you would like to have addressed at the meetings and email them to us. If you have any questions, you may contact any of the staff listed below:

Richard Hoffmann, 202/208–0066
Lauren O'Donnell, 202/208–0325
Jeff Shenot, 202/219–2178
Howard Wheeler, 202/208–2299

J. Mark Robinson,

Director, Division of Environmental & Engineering Review, Office of Energy Projects.

Attachments (2).

Agenda

3rd Interstate Natural Gas Facility Planning Seminar, Federal Energy Regulatory Commission, Holiday Inn City Centre, Tampa, Florida

February 15, 2001—9:30 a.m. to 4 p.m.

9:30 a.m.—Introductions

Welcome: Mark Robinson, Director, Division of Environmental & Engineering Review, Office of Energy Projects, FERC, Rich Hoffmann, Office of Energy Projects (OEP), FERC

9:45—The Pipeline Planning/Approval Process—Lauren O'Donnell, OEP, What's the role of FERC?

10:00—Summary of Comments from the Albany and Chicago Meetings—Rich Hoffmann

10:30—Panel 1. Perspectives on Project Announcement, Route Planning, and How To Work Together—Howard Wheeler, OEP, Moderator.

[Discussion of factors re: announcement of the project, planning of the route, types of surveys needed; extent of disturbance, and who to tell. What are the needs of the various stakeholders?]

Representative from Duke Energy
John Ryan, League of Environmental Organizations, Ken Huntington, Florida Department of Environmental Protection

[10-minute discussion by each panelist with interactive Q&A session with panelists and audience for remainder of Panel]

12:00—Lunch

1:00—Panel 2. What are the Benefits (real and potential) of a natural gas project and right-of-way?—Lauren O'Donnell, Moderator

[Discussion of the various types of benefits of a pipeline project to the company, the individual, local area, region and/or state. How to identify them, how to advertize them.]

Pal Mulieri, County Commissioner, Pasco County, FL, John Shafer, Enron, Citizen/NGO Representative

[10 minute discussion by each panelist with interactive Q&A session with panelists and audience for remainder of Panel]

2:00—Discussion by Kearns & West, Inc., on Stakeholder Involvement.—Ann Gunning

2:15—Brainstorming Session * * *

OEP Staff will lend an all-participants discussion of issues regarding:

- How best to involve landowners and communities.
- How best to work with applicants and agencies;
- How to coordinate with multiple agencies/jurisdictions;
- How to get information on the need for a project; and
- How to describe workspace/right-of-way requirements.

3:55—Summary of the Day

Directions to: Holiday Inn City Centre [813–223–1351]

- Holiday Inn City Centre is located at 111 West Fortune Street, Tampa, FL 33602
- Take Interstate I–275 to exit #25—Ashley Street; Keep bearing right (Fortune St. will "Y" into Ashley St.—stay right); Holiday Inn is on the right side of the street.

Future Meetings?

Between now and September of 2001, we will conduct additional seminars at locations around the country. Locations for the meetings will be selected based on the history of past, present and especially future pipeline projects where interstate natural gas markets are developing or expanding.

Areas we are considering for meetings include:

Boston, Massachusetts/Portland, Maine Area.—March/April, 2001
Seattle/Puget Sound Washington—May/June, 2001 and/or
Reno, Nevada or Salt Lake City, Utah—July/August, 2001

If you care to voice your opinion about these or other areas, please follow the instructions for contacting us in the notice.

[FR Doc. 01–1420 Filed 1–17–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER00–3591–000, ER00–1969–001, ER01–94–000, and ER01–180–000]

New York Independent System Operator, Inc.; Supplemental Notice of Technical Conference

January 11, 2001.

The December 11, 2000, notice in this proceeding indicated that a technical conference will be held on January 22 and 23, 2001. That conference will be held in Hearing Rooms 5 and 6 (which will be combined to form one large room) at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. The conference will commence at 9:30 a.m. on January 22, 2001.

The agenda for the conference is set forth below. To facilitate efficient discussion, the various industry sectors should designate a spokesperson for their sector, although additional views may be stated as necessary. By 5:00 p.m. on January 18, 2001, participants should inform Stanley Wolf at 202–208–0891 or *stanley.wolf@ferc.fed.us* or Penny Murrell at 202–208–0531 or *penny.murrell@ferc.fed.us*, who the spokesperson for the industry sectors are, and for which sessions/topics listed below. If the industry sector cannot reach consensus on its selection of spokespersons, members of that sector may separately inform Mr. Wolf or Ms. Murrell of their selections. Staff may select some or all of these to participate in the discussions. Rather than repeat at length prior pleadings, spokespersons are requested to merely refer to such pleadings where appropriate.

David P. Boergers,

Secretary.

Technical Conference Schedule

Day 1: Morning Session 9:30–12:30

I. State of the Markets—Panel—3 hours

This panel will be comprised of a representative from each sector including, NYISO, Transmisison Owners, the Public Service Commission of New York State, Generators, Power Marketers, Endusers, and Public Power and Environment. The discussion will focus on the overall state of NYISO's markets; how things are going overall; whether the markets are generally working; what the major problems are in the markets; whether there are structural issues; whether there are any major problems with market rules and, if so, the solutions to the problems. This session will include a presentation by NYISO's Project Priority Team on the current status of its efforts to identify and assign priorities to the tasks facing the NYISO, focusing on preparations for the Summer 2001.

Lunch

Day 1: Afternoon Session 1:30–6:00

II. Energy Markets: What needs to be in place by Summer 2001? 3½ hours

This session will start with a presentation by NYISO on the changes that are proposed to be in place by Summer 2001. Discussions can include the details of the specific projects and whether the priorities proposed for theses projects are reasonable. The discussion may include the following topics:

NYISO "hybrid" fixed block generation pricing proposal
Out of merit commitment
Prorata curtailments
System security and adequacy during Summer 2001
Other reliability concerns
NO_x issues
Demand Response Mechanism
Billing issues
Data posting requirements
Communication and market information issues

III. Non-Spinning Reserves Markets—1 hour

This presentation will begin with a presentation by NYISO regarding the state of its NSR markets and the projects underway to make this a more competitive market. Discussions will follow concerning the short-term and long-term problems associated with these markets and the changes that are necessary to address these problems. Topics include:

Competitiveness of 10-minute non-spinning reserves markets
Physical self-supply of operating reserves
Use of western resources to meet operating reserves requirements
Locational pricing

Day 2: Morning Session 9:30–12:00

IV. Market Protection Measures—2½ hours

This session will include a presentation by NYISO regarding the use of its authority under its TEP. Discussions should follow regarding the extent of NYISO's price corrections and issuances of Extraordinary Corrective Actions (ECAs) under this authority and whether certain authority of the TEP should continue temporarily or if certain authority should be made a permanent part of the tariff. Participants may also discuss participant proposals concerning various market protection measures such as: circuit breaker, bid caps, in-city mitigation, and expanded rate correction authority

Lunch

Day 2: Afternoon Session 1:00–4:30

V. Energy Markets: Longer-term Fixes—2 hours

This session will start with a presentation by NYISO regarding the longer term changes necessary in its energy markets. Discussions can focus on the projects that will need to be in place in the longer term and whether the priorities established for these changes are reasonable. Topics include:

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Central East constraint
Generation
Seams Issues (RTOs)—Impact of NYISO practices and procedures on regional transactions
Balancing Market Evaluation (BME) performance and improvements
Virtual bidding, trading hubs and other proposals enhancing liquidity

VI. Next Steps—1½ hours

This session will be used to finalize a list of priorities for projects in the energy and NSR markets and to establish deadlines for their completion. This session will also be used to establish any further procedures required, including setting dates for initial and reply comments.

[FR Doc. 01–1418 Filed 1–17–01; 8:45 am]
BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6934–2]

Science Advisory Board; Notification of Public Advisory Committee Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92–463, notice is hereby given that the Science Advisory Board's (SAB's) Executive Committee will meet on the dates and times noted below. All times noted are Eastern Time. The meetings are open to the public, however, seating is limited and available on a first come basis.

1. Executive Committee—Teleconference Meeting—February 1, 2001

The U.S. EPA's Science Advisory Board (SAB) will conduct a public teleconference meeting on Thursday, February 1, 2001 between the hours of 1 and 3 p.m. Eastern Time. The meeting will be coordinated through a conference call connection in Room 6013 in the U.S. EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. The public is encouraged to attend the meeting in the conference room noted above. However, the public may also attend through a telephonic link, to the extent that lines are available. Additional instructions about how to participate in the conference call can be obtained by calling Ms. Diana Pozun no earlier than one week prior to the meeting (beginning on January 25) at (202) 564–4544, or via e-mail at *pozun.diana@epa.gov*.

Purpose of the Meeting: In this meeting, the Executive Committee plans to review reports from some of its Committees/Subcommittee, most likely including the following:

(a) Natural Attenuation Research Subcommittee of the Environmental Engineering Committee (EEC) "Review of EPA's Natural Attenuation Research Program" (see 65 FR 60189, dated October 10, 2000 for details).

(b) Radiation Advisory Committee (RAC): "An SAB Advisory: A Review of ORIA's Use and Adaptation of GENII Environmental Radiation Dosimetry System, GENII Version 2 (v.2)" (see 65 FR 18095, dated April 6, 2000 for details).

Availability of Review Materials: Drafts of the reports that will be reviewed at the meeting will be available to the public on the SAB website (http://www.epa.gov/sab) by close-of-business on January 16, 2001.

For Further Information: Any member of the public wishing further information concerning this meeting or wishing to submit brief oral comments must contact Dr. Donald Barnes, Designated Federal Officer, Science Advisory Board (1400A), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone (202) 564–4533; FAX (202) 501–0323; or via e-mail at *barnes.don@epa.gov*. Requests for oral comments must be in writing (e-mail preferred) and received by Dr. Barnes no later than noon Eastern Time on January 25, 2001.

2. Executive Committee—February 5–6, 2001

The U.S. EPA Science Advisory Board's (SAB's) Executive Committee will conduct a public meeting on Monday and Tuesday, February 5–6, 2001. The meeting will convene each day at 8:30 a.m. in Room 6013, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. The meeting will adjourn no later than 5 p.m. each day.

Purpose of the Meeting: At this meeting, the Executive Committee will receive updates from its committees and subcommittees concerning their recent and planned activities. As part of these updates, some committees will present draft reports for Executive Committee review and approval. We anticipate that the following report will be completed by the SAB Subcommittee involved and be ready for Executive Committee review at this meeting, however, to determine if this, or any other reports are under consideration at this meeting, please contact Ms. Diana Pozun at (202) 564–4544 or *pozun.diana@epa.gov*. Draft report(s) will appear on the Science Advisory Board website (*www.epa.gov/sab*) approximately two weeks prior to the meeting.

(a) Dioxin Reassessment Review Committee (DRRC) of the Science Advisory Board (SAB) "Review of EPA's Draft Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds" (see 65 FR 60190, dated October 10, 2000 for details).

As part of this two day meeting, the Executive Committee will also: (a) Meet with various Agency officials to discuss matters of mutual interest; (b) receive briefings from Agency staff on various topics; and (c) discuss future business of the Board including projects for FY2001.

Availability of Materials: The draft meeting agenda and drafts of any reports that will be reviewed at the meeting will be available to the public on the SAB website (http://www.epa.gov/sab) by close-of-business on January 22, 2001.

For Further Information: Any member of the public wishing further information concerning this meeting should contact Dr. Donald G. Barnes, Designated Federal Officer (DFO) for the Executive Committee at U.S. EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue NW., Washington, DC 20460; phone (202) 564–4533; fax (202) 501–0323; or via e-mail at <barnes.don@epa.gov>. Those wishing to submit brief oral comments should contact Dr. Barnes, *in writing*, no later than close of business January 29, 2001.

Providing Oral or Written Comments at SAB Meetings

It is the policy of the Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. *Oral Comments:* In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes. For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. *Written Comments:* Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to the appropriate DFO at the address/contact information noted above in the following formats: one hard copy with original signature, and one electronic copy via e-mail (acceptable file format: WordPerfect, Word, or Rich Text files (in IBM–PC/Windows 95/98 format). Those providing written comments and who attend the meeting are also asked to bring 25 copies of their comments for public distribution.

General Information: Additional information concerning the Science Advisory Board, its structure, function, and composition, may be found on the SAB website (*http://www.epa.gov/sab*) and in The FY2000 Annual Report of the Staff Director which is available from the SAB Publications Staff at (202) 564–4533 or via fax at (202) 501–0256. Committee rosters, draft Agendas and meeting calendars are also located on our website.

Meeting Access: Individuals requiring special accommodation at this meeting, including wheelchair access to the conference room, should contact Dr. Barnes at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: January 11, 2001.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 01–1520 Filed 1–17–01; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–66059; FRL–6762–9]

Notice of Receipt of Request for Cancellation of Registration of Bacillus thuringiensis (B.t.) subspecies tolworthi Cry9C and the Genetic Material Necessary for its Production in Corn

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of a request by Aventis CropScience USA LP the sole U.S. registrant, to cancel their registration of *Bacillus thuringiensis* (B.t.) subspecies tolworthi Cry9C and the genetic material necessary for its production in corn.

DATES: Unless the request is withdrawn, the Agency will approve these use deletions and the deletions will become effective on February 20, 2001.

FOR FURTHER INFORMATION CONTACT: By mail: Phil Hutton, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8260; e-mail address: hutton.phil@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Section 6(f)(1) of FIFRA, provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

II. Background

On May 12, 1998, EPA issued a registration to Plant Genetic Systems (America) Inc. for StarLink™ corn (original EPA Registration No. 70218–1). StarLink™ contains the active ingredient *Bacillus thuringiensis* subsp. tolworthi Cry9C protein and the genetic material necessary for its production in corn. EPA issued the registration, but restricted the use of the pesticide to field corn used for feed, industrial non-food uses, and seed increase because the Agency could not find that there was a reasonable certainty of no harm from its use in human food, based on a concern that the protein Cry9C could be allergenic. The Agency's assessment of Cry9C revealed that it has particular characteristics in common with known allergens: it is relatively heat stable and does not readily breakdown in simulated digestive fluids. This raises the possibility that it could be a human allergen. However, EPA determined that, notwithstanding its concern with respect to human ingestion of Cry9C, Cry9C was "safe" and when used as animal feed, would not present unreasonable risks to human health. Because the protein does not transfer to meat and poultry products, use in animal feed would not result in human dietary exposure to the protein/potential allergen.

On October 29, 1998, the StarLink™ corn registration was conveyed from Plant Genetic Systems (America) to AgrEvo USA. AgrEvo USA and Rhone Poulenc Ag Company subsequently formed Aventis CropScience USA LP (Aventis). As of February 22, 2000, the StarLink™ corn registration is now held by Aventis under registration number 264–669.

Test data from several sources demonstrate that StarLink™ corn was diverted into human food. Data from Aventis, Kraft Corporation, and the Food and Drug Administration confirmed the presence of Aventis' Cry9c DNA (the genetic material necessary for the production of Cry9C) in Taco Bell taco shells when tested using polymerase chain reaction (PCR) primers. The PCR primers used are unique to the Aventis *cry9c* gene.

III. Intent to Cancel Registration

This notice announces receipt by the Agency of an application from Aventis, to cancel the registration for StarLink™ corn (EPA Registration No. 264–669). The active ingredient in this product is *Bacillus thuringiensis* subsp. tolworthi Cry9C protein and the genetic material necessary for its production in corn.

The 30–day comment period will permit other interested members of the public to comment prior to the Agency's approval of the deletions. Users of this product who desire continued use should contact both the EPA contact person listed above, and the registrant at the following address: Dr. Sally Van Wert, Aventis CropScience, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709; telephone: (919) 549–2379, to discuss withdrawal of the application for cancellation before February 20, 2001. It should be noted however, that this cancellation is being proposed because Aventis has failed to ensure that StarLink™ corn will not be diverted to human food, it is incumbent on any proponent of further use to demonstrate either: (1) That further use will not be diverted to human food, or (2) that StarLink™ corn is safe for human consumption because it will not present an unreasonable allergenic risk.

IV. Existing Stocks Provision

For the purpose of this notice, existing stocks are defined as those stocks of Cry9C corn grain and corn seed (EPA Registration No. 264–669) that exist before the date on which the registration of this product is canceled. Under section 6(a)(1), the Administrator may permit the continued sale or use of existing stocks of a pesticide whose registration has been canceled, if she determines that such sale or use would be consistent with the purposes of FIFRA (7 U.S.C. 136d(a)(1)). Sales of corn grain produced by farmers growing

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StarLink™ corn or that corn in the required 660 foot buffer may only be sold or used for domestic animal feed or industrial non-food uses and cannot be sold for planting. No StarLink™ seed corn may be sold or distributed. Because of significant concerns regarding the potential for StarLink™ corn to enter the human food stream of commerce, the U.S. Department of Agriculture has undertaken an incentive program to ensure that all StarLink™ corn currently on the farm is either fed to livestock on the farm, or is directed only to domestic animal feed or industrial non-food uses.

This existing stocks disposition does not prohibit growers from using existing stocks of StarLink™ grain as animal feed. Nor will feeding animals StarLink™ corn render meat or milk derived from such animals adulterated. The existing tolerance exemption for the Cry9C protein and the genetic material necessary for its production, found at 40 CFR 180.1192, is not revoked by this Notice.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: January 8, 2001.

Susan B. Hazen,

Deputy Director, Office of Pesticide Programs.

[FR Doc. 01–1522 Filed 1–17–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6933–9]

Implementation Guidance for Radionuclides

AGENCY: Environmental Protection Agency.

ACTION: Notice, request for comments on the draft radionuclides implementation guidance.

SUMMARY: The United States Environmental Protection Agency (EPA) published the final National Primary Drinking Water Regulation for Radionuclides on December 7, 2000, in the **Federal Register** (65 FR 76708). The EPA has also prepared the Draft Implementation Guidance for the Radionuclides Rule. This Notice is announcing the availability of this draft document and asking for comments from stakeholders and the public. These comments will be considered in developing the Final Implementation Guidance document. The EPA encourages the full participation of all stakeholders and the public throughout this process.

The Draft Implementation Guidance for the Radionuclides Rule is a comprehensive reference to assist States in implementing the Rule. The draft guidance was developed based on the Final Rule, with input and review from EPA Headquarters and Regional staff, and comments from States and the public on a previous version of the document. Along with summaries of the Rule and implementation timelines, the document contains: A detailed explanation of the rule requirements; guidance for violation determinations, and significant non-compliance definitions; Safe Drinking Water Information (SDWIS) reporting requirements; guidance for State primacy revision applications, and special primacy requirements; and a series of "stand-alone" fact sheet guidance materials for States and Public Water Systems. The guidance document describes the new standards for uranium, as well as the revisions to the radionuclides monitoring framework.

The Appendices to the document provide further information and tools to assist States and EPA Regional Offices with primacy revisions and Rule implementation, including: Violation tables to assist with compliance determination; a sample Extension Agreement between EPA and the States to document how implementation responsibilities will be shared if States do not submit a primacy applications by the deadline; a primacy revision crosswalk; a "stand-alone" State reporting guidance; rule training materials; and beta and photon emitter conversion tables.

DATES: Comments must be submitted on or before March 30, 2001.

ADDRESSES: Address all comments concerning this Notice to Ed Thomas, Office of Ground Water and Drinking Water (MC–4606), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. See **SUPPLEMENTARY INFORMATION** section for information to request a copy of the draft guidance and electronic addresses.

FOR FURTHER INFORMATION CONTACT: For general information related to the Radionuclides Rule, contact: Ed Thomas, at (202) 260–0910 or e-mail to *thomas.edwin@epamail.epa.gov.*

SUPPLEMENTARY INFORMATION: Copies of the draft guidance may be obtained by contacting the Safe Drinking Water Hotline at 800–426–4791, or at EPA's Office of Ground Water and Drinking Water's (OGWDW) Web Site: *http://www.epa.gov/safewater/rads/implement.html,* or by contacting Ed Thomas of OGWDW at (202) 260–0910 or by e-mail at *thomas.edwin@epamail.epa.gov.*

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water, Environmental Protection Agency.

[FR Doc. 01–1521 Filed 1–17–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 9:00 a.m. on Friday, January 19, 2001, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Summary reports, status reports, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Final Amendments to Part 308—Rules of Practice and Procedure, to implement the requirements of the Program Fraud Civil Remedies Act.

Memorandum re: Information Sharing and Confidentiality Agreement Pursuant to Section 307 of Gramm-Leach-Bliley Act.

Discussion Agenda: Memorandum and Resolution Re: Proposed Amendments to Part 325—Capital Standards for Nonfinancial Equity Investments.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

The FDIC will provide attendees with auxiliary aids (*e.g.*, sign language interpretation) required for this meeting. Those attendees needing such assistance should call (202) 416–2089 (Voice); (202) 416–2007 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at (202) 898–6757.

Dated: January 12, 2001.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 01–1604 Filed 1–16–01; 10:58 pm]

BILLING CODE 6714–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Notice

AGENCY: Federal Election Commission

* * * * *

DATE & TIME: Tuesday, January 23, 2001 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. 437g.

Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE & TIME: Thursday, January 25, 2001 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Advisory Opinion 2000–40: Representative Jim McDermott, Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Acting Secretary of the Commission.

[FR Doc. 01–1638 Filed 1–16–01; 2:12 pm]

BILLING CODE 6715–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984. Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, NW., Room 940. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011642–004.

Title: East Coast United States/East Coast of South America Vessel Sharing Agreement.

Parties: A.P. Moller-Maersk Sealand, P&O Nedlloyd Limited, P&O Nedlloyd B.V., Oceanica AGW Com. E Rep. Ltda., Compania Sud Americana de Vapores, S.A., Companhia Libra de Navegacao S.A., Alianca Navegacao e Logistica Ltda., Hamburg-Sud.

Synopsis: The proposed amendment: deletes Euroatlantic Container Line and Braztrans Transportes Maritimos Limitada as parties to the agreement; adds Companhia Libra de Navegacao S.A. as a party to the agreement; revises slot allocations; and reflects the various trade names used by certain parties.

Dated: January 12, 2001.

By Order of the Federal Maritime Commission.

Bryant L. VanBrakle,

Secretary.

[FR Doc. 01–1514 Filed 1–17–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Reissuances

Notice is hereby given that the following Ocean Transportation Intermediary license has been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984, as amended by the Ocean Shipping Reform Act of 1998 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

License No.	Name/address	Date reissued
4619N	Amad Corporation d/b/a Amad Forwarding Corporation, 3550 N.W. 33rd Street, Miami, FL 33142	November 8, 2000.

Sandra L. Kusumoto,

Director, Bureau of Consumer Complaints and Licensing.

[FR Doc. 01–1513 Filed 1–17–01; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocations

The Federal Maritime Commission hereby gives notice that the following ocean transportation intermediary licenses have been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, effective on the corresponding dates shown below:

License Number: 7404N.

Name: Apollo Forwarders, Inc.

Address: 509 First Street, Rodeo, CA 94572.

Date Revoked: November 15, 2000.

Reason: Failed to maintain a valid bond.

License Number: 4061F.

Name: Caribwrap Inc. d/b/a Five Star Forwarding.

Address: 8140 N.W. 74th Avenue, Suite #18, Miami, FL 33166.

Date Revoked: November 15, 2000.

Reason: Failed to maintain a valid bond.

License Number: 4550F.

Name: Cynthia A. Keefe d/b/a 'Round The World Exports.

Address: 213 Lynnhaven Drive, North Syracuse, NY 13212.

Date Revoked: November 19, 2000.

Reason: Failed to maintain a valid bond.

License Number: 7394N.

Name: Gateways International, Inc. d/b/a Bekins Wide World.

Address: 2030 First Avenue, Suite 200, Seattle, WA 98121–2112.

Date Revoked: November 18, 2000.

Reason: Failed to maintain a valid bond.

License Number: 2062N and 2062F.

Name: N. Abbe International, Inc.

Address: 2 World Trade Center, Suite 2844, New York, NY 10048

Date Revoked: October 18, 2000 and November 22, 2000.

Reason: Failed to maintain valid bonds.

License Number: 798R.

Name: Mary Morris Reid d/b/a Reid & Company.

Address: 150 Marine Street, Lake Charles, LA 70601.

Date Revoked: December 4, 2000.

Reason: Failed to maintain a valid bond.

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License Number: 4292F.
Name: Satt International Forwarding Inc.
Address: 147–35 Farmers Blvd., Suite 202, Jamaica, NY 11434–5217.
Date Revoked: November 15, 2000.
Reason: Failed to maintain a valid bond.

License Number: 4351F.
Name: Shin Wha Park d/b/a Grand Bell Maritime, U.S.A.
Address: 623 E. Artesia Blvd., Carson, CA 90746.
Date Revoked: November 15, 2000.
Reason: Failed to maintain a valid bond.

License Number: 4574F.
Name: Zaky Transportation Services, Inc.
Address: 8600 N.W. 66th Street, Miami, FL 33166.
Date Revoked: November 18, 2000.
Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,
Director, Bureau of Consumer Complaints and Licensing.
[FR Doc. 01–1512 Filed 1–17–01; 8:45 am]
BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Board of Governors of the Federal Reserve System
SUMMARY:

Background

On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act, as per 5 CFR 1320.16, to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR 1320 appendix A.1. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the OMB 83–Is and supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Request for Comment on Information Collection Proposal

The following information collection, which is being handled under this delegated authority, has received initial Board approval and is hereby published for comment. At the end of the comment period, the proposed information collection, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

A. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

B. the accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

C. ways to enhance the quality, utility, and clarity of the information to be collected; and

D. ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before March 19, 2001.

ADDRESSES: Comments, which should refer to the OMB control number or agency form number, should be addressed to Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551, or mailed electronically to regs.comments@federalreserve.gov. Comments addressed to Ms. Johnson may be delivered to the Board's mail room between 8:45 a.m. and 5:15 p.m., and to the security control room outside of those hours. Both the mail room and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments received may be inspected in room M–P–500 between 9 a.m. and 5 p.m., except as provided in section 261.14 of the Board's Rules Regarding Availability of Information, 12 CFR 261.14(a).

A copy of the comments may also be submitted to the OMB desk officer for the Board: Alexander T. Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: A copy of the proposed form and instructions, the Paperwork Reduction Act Submission (OMB 83–I), supporting statement, and other documents that will be placed into OMB's public docket files once approved may be requested from the agency clearance officer, whose name appears below. Mary M. West, Federal Reserve Board Clearance Officer (202–452–3829), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact Diane Jenkins (202–452–3544), Board of Governors of the Federal Reserve System, Washington, DC 20551.

Proposal to Approve Under OMB Delegated Authority the Implementation of the Following Survey:

1. *Report Title:* Central Bank Survey of Foreign Exchange and Derivatives Market Activity.
Agency Form Number: FR 3036.
OMB Control Number: 7100–0285.
Frequency: one-time.
Reporters: Financial institutions that serve as intermediaries in the wholesale foreign exchange and derivatives market, dealers, and brokers.
Annual Reporting Hours: 9,458 hours.
Estimated Average Hours Per Response: Turnover survey: 50 hours; outstandings survey: 15 hours for FR 2436 reporters, 60 hours for non-FR 2436 reporters.
Number of Respondents: 161. Small businesses are not affected.
General Description of Report: This information collection is voluntary (12 U.S.C. 248(a), 353–359, and 461) and is given confidential treatment (5 U.S.C. 552(b)(4)).
Abstract: The survey is the latest in an ongoing series of surveys conducted by central banks every three years. The survey will be conducted in April and June of 2001 by the Federal Reserve Bank of New York. Data from the survey will provide information about the size and structure of the global markets for foreign exchange and financial derivatives transactions. The survey is part of a data collection effort conducted by over fifty other central banks and monetary authorities. The data will be useful to the Federal Reserve Board, other government agencies, and market participants for determining public policy relating to financial markets. Aggregate results from each central bank's survey will be provided to the Bank for International Settlements for the production of global market statistics.

Board of Governors of the Federal Reserve System, January 11, 2001.
Jennifer J. Johnson,
Secretary of the Board.
[FR Doc. 01–1437 Filed 1–17–01; 8:45 am]
BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 31, 2001.

A. Federal Reserve Bank of Atlanta (Cynthia C. Goodwin, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303–2713:

1. Nancy Barr Dixon, Eufaula, Alabama; Michael Charles Dixon, Sr., Eufaula, Alabama; Hope Cotton Dixon, Eufaula, Alabama; Michael Charles Dixon, Jr., Eufaula, Alabama; Claudia Dixon Balkcom, Atlanta, Georgia; Heather Barr Dixon, Eufaula, Alabama; Marian Christine Dixon, Birmingham, Alabama; Rebecca Janie Mac Dixon, Auburn, Alabama; Robert Mack Dixon, Eufaula, Alabama; Mary Elliott Dixon, Eufaula, Alabama; Mary Clayton Dixon, Eufaula, Alabama; Eric Ross Fenichel, Atlanta, Georgia; Janie Dixon King, Eufaula, Alabama; William Daniel King, Eufaula, Alabama; Robert Mack Dixon, Jr., Eufaula, Alabama; Preston Copeland Dixon, Birmingham, Alabama; James Franklin Dixon, III, Birmingham, Alabama; Rita Hallett Dixon, Birmingham, Alabama; Thomas Seay Lawson, Jr., Montgomery, Alabama; Sarah Clayton Lawson, Montgomery, Alabama; and Preston Copeland Clayton, Jr., Eufaula, Alabama; all to retain voting shares of Eufaula BancCorp, Inc., Eufaula, Alabama, and thereby indirectly retain voting shares of Southern Bank of Commerce, Eufaula, Alabama, and First American Bank of Walton County, Santa Rosa Beach, Florida.

Board of Governors of the Federal Reserve System, January 11, 2001.
Robert deV. Frierson,
Associate Secretary of the Board.
[FR Doc. 00–1434 Filed 1–17–01; 8:45 am]
BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 et seq.) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 9, 2001.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. First Bancorp, Troy, North Carolina; to merge with Century Bancorp, Inc., Thomasville, North Carolina, and thereby indirectly acquire voting shares of Home Savings, Inc., SSB, Thomasville, North Carolina.

B. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. American Bancorporation, Cedar Falls, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of The Newburg Corporation, Saint Ansgar, Iowa, and thereby indirectly acquire voting shares of Cedar Valley State Bank, Saint Ansgar, Iowa.

Board of Governors of the Federal Reserve System, January 11, 2001.
Robert deV. Frierson,
Associate Secretary of the Board.
[FR Doc. 00–1435 Filed 1–17–01; 8:45 am]
BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 31, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Northwest Suburban Bancorp, Inc., Mount Prospect, Illinois; to engage *de novo* in purchasing loan participations from its subsidiary banks, pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, January 11, 2001.
Robert deV. Frierson,
Associate Secretary of the Board.
[FR Doc. 00–1436 Filed 1–16–01; 8:45 am]
BILLING CODE 6210–01–S

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FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 1, 2001.

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. First Ainsworth Company, Ainsworth, Nebraska; to engage in extending credit and servicing loans pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, January 12, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–1523 Filed 1–17–01; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

Agency Holding the Meeting: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, January 22, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551

STATUS: Closed

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 12, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–1573 Filed 1–12–01; 4:17 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01017]

National Partnerships for Human Immunodeficiency Virus (HIV) Prevention With a Focus on Business and Labor, Youth-at-High Risk, and Migrant Workers; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for National Partnerships for Human Immunodeficiency Virus (HIV) Prevention. This program addresses the "Healthy People 2010" focus areas of HIV Educational and Community-Based Programs, and Sexually Transmitted Diseases. For a conference copy of "Healthy People 2010", visit the internet site:

http://www.health.gov/healthypeople.

The purpose of the program is to develop local, regional, State, and national leadership and support for HIV prevention programs and policies, and to provide technical assistance and service delivery in support of capacity building and skills development for Community-based organizations (CBOs), State and local health departments, and other organizations conducting HIV prevention activities at the local, regional, state, and national levels. This announcement is intended to help address gaps in leadership and technical assistance in the development and delivery of HIV prevention services.

For the purpose of this announcement the following definitions apply:

Leadership activities are defined as the development of communication and mobilization strategies including network development, partnership formation and coalition building, to raise and maintain community, as well as national awareness of HIV prevention needs and programs in specified populations. Leadership activities may also include developing and implementing strategies for needs assessments, policy analysis and service integration in collaboration with the private sector, federal partners, health departments, CBOs and Community planning groups (CPGs).

Technical assistance activities are defined as the provision of information and skills, consultation and training for individuals and organizations to improve the delivery and effectiveness of HIV prevention interventions. Service delivery activities may also be included under the technical assistance activity. Technical assistance funds available under this announcement must support assistance that improves the capacity of recipient agencies to design, develop, implement, and/or evaluate effective HIV prevention interventions for one or more of the three populations described below.

B. Eligible Applicants

To be eligible for funding under this announcement, applicants must be (1) a tax-exempt, non-profit national business or labor related, youth related, or migrant worker related organization; or (2) an academic institution working in a contractual relationship with a community-based partner; or (3) a federally recognized Indian tribal government, a non-federally recognized tribe or other organization that qualifies under the Indian Civil Rights Act, State Charter Tribes, Urban Indian Health Programs, Indian Health Boards, and/or Inter-Tribal Councils.

If you are applying to conduct activities internationally, you must demonstrate having at least two years of experience conducting leadership or technical assistance activities in an international setting.

Indian Tribal governments, non-federally recognized tribes and other organizations that qualify under the Indian Civil Rights Act, State Charter Tribes, Urban Indian Health Programs, Indian Health Boards, and Inter-Tribal Councils may apply under each category provided that these entities meet the eligibility criteria described under each category.

Proof of non-profit tax-exempt status must be provided with the application. CDC will not accept an application without proof of tax-exempt status. Non-profit tax-exempt status is determined by the Internal Revenue Service (IRS) Code, Section 501(c)(3). Tax-exempt status may be proved by providing a current copy of the 501(c)(3) non-profit tax-exempt of the current IRS Determination Letter.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an Federal funds constituting an award, grant, cooperative agreement, contract, loan, or any other form. Below is additional eligibility criteria for each category.

Category I—Business- or Labor-Related Organization Programs

A. A business- or labor-related organization is a professional or voluntary organization, that (1) has businesses, business leaders, or labor leaders as a focus or constituency; or (2) is a labor union; or (3) is a trade association. In addition, the organization (4) has a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories; and (5) has access to or relationships with national or regional corporate, business, union, or labor leaders and managers (*e.g.*, human resource managers). For example, a labor union with chapters in at least two States would meet the definition of a national business- or labor-related organization, whereas an individual State chapter of a national labor union would not.

B. Has a documented two year record of providing technical assistance or leadership activities focusing on HIV prevention with business and labor organizations and their employees or members.

Category II—Youth-Related Organization Programs

A. A youth-related organization is an organization that has youth, and/or service providers who work with youth, as a focus or constituency. The organization must have a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories. For example, an agency with a linked network of youth-serving providers with members residing in at least 2 States or Territories would meet the definition of a youth-related organization, whereas an individual chapter of a national organization would not.

B. Has a documented two year record of providing technical assistance, prevention services and/or leadership activities focusing on HIV prevention for Gay, Lesbian, Bisexual, Transgender and Questioning (GLBTQ) youth, homeless/run-away or street youth, and/or young women of color.

C. Has a young person, age 24 or younger from the target population, on the Board of Directors that oversees programmatic activities, or has an Advisory Committee to the Board of Directors that is made up of young people age 24 or younger from the target population.

Category III—Migrant Worker-Related Programs

A. A migrant worker-related organization is an organization that has migrant workers and/or the service providers who work with migrant workers, as a focus or constituency. The organization must have a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories. For example, an agency with a linked network of migrant worker-serving providers with members residing in at least two States or Territories would meet the definition of a migrant farmworker-related organization, whereas an individual chapter of a national organization would not.

B. Has a documented two year record of providing culturally tailored technical assistance or leadership activities focusing on HIV prevention for migrant workers.

C. Availability of Funds

Approximately $2.2 million is available in FY 2001 to fund approximately 9 awards. It is expected that the average award will be $225,000 ranging from $200,000 to $300,000. It is expected that the awards will begin on or about April 1, 2001, and will be made for a 12-month budget period within a project period of up to four years. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports, satisfactory site visits and the availability of funds.

Applicants may apply for funding in up to two categories, and within each category applicants may apply for one or both of the two activities, as defined in the section on "Recipient Activities". A separate application package and budget must be submitted for EACH category.

1. Category I—Business- or Labor-related Organization Programs up to three awards, including:
   - —Up to two that address Activity A (Leadership Activities); and
   - —Up to two that address Activity B (Technical Assistance Activities).
2. Category II—Youth-related Organization Programs up to three awards, including:
   - —Up to two that address Activity A (Leadership Activities), and
   - —Up to two that address Activity B (Technical Assistance Activities).
3. Category III—Migrant Farmworker-related Programs up to three awards, including:
   - —Up to two that address Activity A (Leadership Activities), and
   - —Up to two that address Activity B (Technical Assistance Activities).

Use of Funds

1. Funds available under this announcement must support activities that engage and develop their constituent communities for the purpose of increasing awareness, leadership, participation, and support for HIV prevention and/or increase the ability of organizations to design, develop, implement, and evaluate effective HIV prevention interventions.
2. These Federal funds may not supplant or duplicate existing funding for these activities.
3. The applicant must perform a substantial portion of the program activities and cannot serve merely as a fiduciary agent. Applications requesting funds to support only managerial and administrative functions will not be accepted.
4. No funds will be provided for direct patient care, including substance abuse treatment, medical treatment, or medications.
5. Before using funds awarded through this cooperative agreement to develop HIV prevention materials, recipients must check with the CDC National Prevention Information Network (NPIN) to determine if suitable materials are already available. Also, materials developed by recipients must be made available for dissemination through the CDC NPIN. Successful applicants will be contacted by NPIN for

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information on program resources for use in referrals and resource directories. Also, grantees should send three copies of all educational materials developed under this cooperative agreement to NPIN for inclusion in NPIN's databases.

Funding Preferences

Preference for funding in all categories will be given to:

1. Ensuring that leadership development and/or technical assistance is available to the designated target populations as a primary focus; and

2. Addressing gaps in current national/regional or local technical assistance services (gaps may be defined by geography; target population, race/ethnicity, risk behavior; or intervention type).

3. Ensuring that technical assistance activities will address a variety of intervention types (*e.g.*, small group intervention, counseling and testing, prevention case management) and strategies or programs that raise awareness about HIV.

4. Ensuring that technical assistance activities will address diverse target population groups.

Additional Funding Preference for Category I—Business and Labor:

Preference for funding will be given to ensuring that both business and labor organizations are funded in at least one of the two designated activities.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

1. Recipients in All Categories Must Conduct the Following Activities

a. Incorporate cultural competency and linguistic appropriateness into all technical assistance and skills building efforts, including those involving the development, production, dissemination, and marketing of health communication or prevention messages;

b. Use epidemiologic data, behavioral research, and program evaluation, to inform technical assistance and intervention development which meet the needs of the designated populations;

c. Coordinate program activities with relevant public sector partners, including national, regional, State, and local HIV prevention programs and Capacity Building Assistance (CBA) providers to prevent duplication of efforts. (Please see Attachment III for a list of the Division of HIV/AIDS Prevention Capacity-Building and Technical Assistance Providers. Also, see Section G. "Submission and Deadline" for online availability of complete program announcement, attachments, and forms);

d. Review and ensure consistency with applicable State and local comprehensive HIV prevention community plans when conducting program activities at the State and local levels;

e. Facilitate the dissemination of successful prevention interventions and program models through meetings, workshops, conferences, and communications with project officers;

f. Compile "lessons learned" from the project and share these with the CDC;

g. Monitor and conduct process evaluations on all major program activities and services supported with CDC HIV prevention funds under this cooperative agreement;

h. Submit CDC forms for initiating and completing technical assistance services. Forms will be provided by CDC.

2. Category I—Business- or Labor-Related Organization Programs—Recipient Activities

a. Activity A—Leadership Activities

(1) Develop and promote, at the national, State, and local levels, and when appropriate, at the international level, leadership in and support for HIV prevention policies and strategies, that promote private-public partnerships to enhance HIV/AIDS awareness and prevention;

(2) Influence and strengthen, at the national, State, and local levels, and when appropriate, international level, private sector engagement in shaping societal and community norms that dispel HIV/AIDS stigma, reduce discrimination against persons with HIV/AIDS, and facilitate HIV prevention by encouraging the adoption and maintenance of safer behaviors;

(3) Support the private sector development of policies and programs addressing HIV/AIDS and HIV prevention education in the workplace, at the national, State, regional, local, and when appropriate, international levels.

b. Activity B—Technical Assistance Activities

(1) Provide businesses and business- and labor-related organizations with technical assistance related to:

- Adopting and implementing appropriate CDC-recommended policies on HIV/AIDS in the workplace
- Educating managers and labor leaders about these policies
- Educating workers about HIV/AIDS in the workplace
- Educating workers and their families about HIV prevention, and
- Contributing to community efforts to control HIV transmission;

(2) Facilitate State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers in working with business, labor, and business-and labor-related organizations to strengthen and promote HIV prevention efforts in the community;

(3) Facilitate business, labor and business-and labor-related organizations in working with State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers to strengthen and promote HIV prevention efforts in the community.

These services are to be provided through the use of information transfer, skills building, technical consultation, technical services, and technology transfer. These services should be culturally appropriate and based in science.

(4) Implement a plan for developing and maintaining ongoing technical assistance and service delivery collaboration with CDC-funded CBOs, other CBOs, and State and local Health Departments.

(5) Implement a system that responds to technical assistance and service delivery requests. The system must include mechanisms for assessing and prioritizing requests; linking requests to other technical assistance and service resources and to services provided by other Technical Assistance providers.

(6) Identify and complement the technical assistance and service delivery efforts for the target population available locally. Cooperate with other national, regional, State, and local technical assistance and service providers to (a) avoid duplication of effort and (b) ensure that capacity-building assistance is allocated according to gaps in available services and the needs of organizations serving youth at high risk for acquiring and transmitting HIV and other STDs.

(7) Coordinate program activities with appropriate national, regional, State, and local governmental and non-governmental HIV prevention partners (*e.g.*, health departments, CBOs and CPGs). (Note: For this announcement, the term "coordinate" means exchanging information and altering activities for mutual benefit.)

(8) Incorporate cultural competency, age, linguistic and educational appropriateness into all capacity-building activities;

3. Category II—Youth-Related Organization Programs—Recipient Activities

a. Activity A—Leadership

(1) Develop and promote, at the national, State, and local levels, and when appropriate, at the international level, leadership support for HIV prevention policies, programs and services for HIV prevention for young women of color; homeless, run-away and/or street youth; and/or Gay, Lesbian, Bisexual, Transgender and Questioning (GLBTQ) youth;

(2) Influence and strengthen, at the national, State, and local levels, and when appropriate, at the international level, societal and community norms that dispel HIV/AIDS stigma, reduce discrimination against persons with HIV/AIDS, and facilitate HIV prevention by supporting the adoption and maintenance of safer behaviors in youth.

b. Activity B—Technical Assistance

1. Include CDC-funded CBOs, other CBOs, Health Department staff, State education agencies, and other potential consumers of the proposed services in planning and evaluating the proposed technical assistance and service delivery program.

2. Ensure the effective and efficient provision of technical assistance and/or delivery of effective services to address HIV prevention for the designated youth populations. (Examples include, but are not limited to, intervention replication or adaptation, use of behavioral and social sciences to increase intervention effectiveness, increasing the cultural competence and linguistic appropriateness of interventions, service integration, developing effective health communications messages, conducting population-based needs assessments, and evaluation planning and implementation.) Recipients should work closely with CDC to identify interventions for the designated youth populations that have a sound basis in science or proven program experience and are suitable for dissemination.

For a compilation of intervention types (*e.g.* small group interventions, counseling and testing, prevention case management) and other proven interventions please refer to the CDC Compendium of Effective Programs, titled, "Compendium of HIV Prevention Interventions with Evidence of Effectiveness" November 1999, CDC Prevention Research Synthesis to reach the designated population (*e.g.* young women of color, GLBTQ youth, runaway, homeless, or street youth). The "Compendium of HIV Prevention Interventions with Evidence of Effectiveness" may be found in Attachment II and on the CDC home page Internet address. (See Section G. "Submission and Deadline" for online availability of complete program announcement, attachments, and forms).

These services are to be provided through the use of information transfer, skills building, technical consultation, technical services, and technology transfer. These services should be culturally appropriate and based in science.

3. Implement a plan for developing and maintaining ongoing technical assistance and service delivery collaboration with CDC-funded CBOs, other CBOs, and State and local Health Departments.

4. Implement a system that responds to technical assistance and service delivery requests. The system must include mechanisms for assessing and prioritizing requests; linking requests to other technical assistance and service resources and to services provided by other Technical Assistance providers.

5. Identify and complement the technical assistance and service delivery efforts for the target population available locally. Cooperate with other national, regional, State, and local technical assistance and service providers including Capacity Building Assistance (CBA) providers, to (a) avoid duplication of effort and (b) ensure that capacity-building assistance is allocated according to gaps in available services and the needs of organizations serving youth at high risk for acquiring and transmitting HIV and other STDs.

6. Coordinate program activities with appropriate national, regional, State, and local governmental and non-governmental HIV prevention partners (*e.g.*, health departments, CBOs, CBA providers) and CPGs.

(Note: For this announcement, the term "coordinate" means exchanging information and altering activities for mutual benefit.)

7. Incorporate cultural competency, age, linguistic and educational appropriateness into all capacity-building activities;

8. Assist State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers in working with youth and youth serving organizations to strengthen and promote HIV prevention among youth in the community.

9. Assist youth serving organizations in working with State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers to strengthen and promote HIV prevention among youth in the community.

10. Participate in the CDC-coordinated Capacity-Building Assistance Network to enhance communication, coordination, and training.

4. Category III—Migrant Worker-Related Programs—Recipient Activities

a. Activity A—Leadership

1. Develop and promote, at the national, State, regional and local levels, and when appropriate, at the international level, leadership support for HIV prevention policies, programs and services for HIV prevention for migrant workers.

2. Influence and strengthen, at the national, State, and local levels, and when appropriate, at the international level, societal and community norms that dispel HIV/AIDS stigma, reduce discrimination against migrant workers with HIV/AIDS, and facilitate HIV prevention by supporting the adoption and maintenance of safer behaviors in migrant workers.

b. Activity B—Technical Assistance

1. Include CDC-funded CBOs, other CBOs, Health Department staff, State education agencies, and other potential consumers of the proposed services in planning and evaluating the proposed technical assistance and service delivery program.

2. Ensure the effective and efficient provision of technical assistance and/or delivery of effective services to address HIV prevention for migrant workers.

(Examples include, but are not limited to, intervention replication or adaptation, use of behavioral and social sciences to increase intervention effectiveness, increasing the cultural competence and linguistic appropriateness of interventions, service integration, developing effective health communications messages, conducting population-based needs assessments, and evaluation planning and implementation.) Recipients should work closely with CDC to identify interventions for the migrant worker population that have a sound basis in science or proven program experience and are suitable for dissemination.

These services are to be provided through the use of information transfer, skills building, technical consultation, technical services, and technology transfer. These services should be culturally and linguistically appropriate and based in science.

3. Implement a plan for developing and maintaining ongoing technical assistance and service delivery

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collaboration with CDC-funded CBOs, other CBOs, and State and local Health Departments.

4. Implement a system that responds to requests for technical assistance and service delivery. The system must include mechanisms for assessing and prioritizing requests; linking requests to other technical assistance and service resources and to services provided by other Technical Assistance providers.

5. Identify and complement the technical assistance and service delivery efforts for the target population available locally. Cooperate with other national, regional, State, and local technical assistance and service providers to (a) avoid duplication of effort, and (b) ensure that technical assistance is allocated according to gaps in available services and the needs of organizations serving migrant workers at risk for acquiring and transmitting HIV and other STDs.

6. Coordinate program activities with appropriate national, regional, State, and local governmental and non-governmental HIV prevention partners (e.g., health departments, CBOs, CBA providers), other technical assistance providers and CPGs. (Note: For this announcement, the term "coordinate" means exchanging information and altering activities for mutual benefit.)

7. Incorporate cultural and linguistic competency, and educational appropriateness into all technical assistance and prevention activities;

8. Assist State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers in working with migrant workers and/or organizations serving migrant workers to strengthen and promote HIV prevention among this community.

9. Assist migrant serving organizations in working with State and local HIV prevention community planning groups, health departments, CBOs, and other HIV prevention providers to strengthen and promote HIV prevention among youth in the community.

2. CDC Activities

a. Serve as the coordinator for technical assistance and service provision as part of CDC's overall capacity-building programs and network by ensuring coordination and collaboration with other capacity building and technical assistance providing grantees.

b. Provide consultation to recipients regarding planning, developing, implementing and evaluating technical assistance services. CDC will provide consultation and assistance and may also employ contractors; national, regional, and local organizations; and peer-to-peer assistance from CDC-funded partners.

c. Provide up-to-date scientific information on the risk factors for HIV infection, prevention measures, and program strategies for the prevention of HIV infection. Work closely with recipients to identify interventions that have a sound basis in science or proven program experience and are suitable for dissemination.

d. Facilitate and promote collaboration through the exchange of program information, coalition maintenance strategies, and technical assistance/capacity-building assistance among CBOs; State and local health departments; HIV prevention community planning Groups; national, regional, and local organizations; and other HIV prevention partners.

e. Support train-the-trainer opportunities that enhance capacity-building/technical assistance delivery systems.

f. Facilitate and collaborate in the dissemination of successful capacity-building/technical assistance strategies and successful innovations through meetings of grantees, workshops, and conferences.

g. Collaborate with recipients to standardize a system for tracking and reporting all technical assistance requests and delivery.

h. Coordinate an evaluation of the overall assistance program.

E. Application Content for All Applicants

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the evaluation criteria listed, so it is important to follow them in laying out your application. The narrative should be no more than 40 double-spaced pages (excluding the budget and attachments). Number each page, including appendices and attachments sequentially and provide a complete "Table of Contents" to the application and its attachments. Please begin each separate section of the application on a new page. The original and each copy of the application set must be submitted unstapled and unbound.

All material must be typewritten with a font of 10 pitch or 12 point on 8½" by 11" paper, with at least 1" margins, headings and footers; and printed on one side only. Materials which should be part of the basic plan will not be accepted if placed in the attachments. Attachments should be unbound and printed in black and white.

In developing the application, follow the format and instructions outlined below.

1. Proof of Eligibility

Include documents as specified below as proof of eligibility. Applicants must complete this section. Failure to provide the required documentation will result in your application being disqualified and returned to you without further review.

a. Indicate if your organization is a national, regional or local organization. Attach the specific charge from your organization's Articles of Incorporation, Bylaws, or a resolution from its executive board or governing body to operate nationally, regionally (in multiple states or territories), or internationally and proof of informal networks which allows your organization to work in multiple states and/or regions.

b. Indicate if your organization is (1) business or labor related, or a labor union/trade association, (2) youth related, (3) migrant worker related, (4) an academic institution working in a contractual relationship with a community-based partner or (5) a federally recognized Indian tribal government or a non-federally recognized tribe or other organization that qualifies under the Indian Civil Rights Act, State Charter Tribe, Urban Indian Health Program, Indian Health Board, or Inter-Tribal Council.

c. Does your organization have a currently valid 501(c)(3) non-profit tax-exempt status? Attach to this section a copy of the current, valid Internal Revenue Service (IRS) determination letter of your organization's 501(c)(3) non-profit tax-exempt status.

If you are applying as an academic institution: Include a "Memoranda of Understanding" which provides a detailed description and time-line of the activities to be conducted by the community-based partner with which you are contracting.

If you are applying to conduct international activities: Include documented evidence which demonstrates that you have at least two years of experience conducting leadership or technical assistance activities in an international setting.

If your organization conducts Business-or Labor-related programs:

(a) Submit documentation proving that your organization has businesses, business leaders, or labor leaders as a focus or constituency: or (1) is a labor union; or (2) is a trade association. In addition, the organization (3) has a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories; and (4) has access to national or regional corporate, business, union, or labor leaders and managers (e.g., human resource managers).

(b) Submit the following documents to demonstrate that your organization has a two year record of providing technical assistance, conducting leadership activities focusing on HIV prevention with business and labor organizations and their employees or members and/or delivering HIV prevention services: (1) Attach to this section a list of clients, including the organization name, location (i.e., city and State), dates of service, and type(s) of assistance provided, (2) Provide copies of memoranda of understanding, agreements, or contracts and/or consultants, (3) training agendas, (4) newspaper articles, (5) correspondence from recipients of assistance, (6) program brochures, (7) extracts from previous grants to support comparable activities.

If your organization conducts youth-related programs:

(a) Submit documentation demonstrating that your organization has a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories.

(b) Attach the following documents as evidence that your organization has a two year record of providing technical assistance, conducting leadership activities focusing on HIV prevention for youth and/or delivering HIV prevention services: (1) Attach to this section a list of clients, including the organization name, location (i.e., city and State), dates of service, and type(s) of assistance provided, (2) Provide copies of memoranda of understanding, agreements, or contracts/consultants, (3) training agendas, (4) newspaper articles, (5) correspondence from recipients of assistance, (6) program brochures, (7) extracts from previous grants to support comparable activities.

(c) Attach a complete list of the members of your board, governing body or advisory committee along with their positions on the board, age and gender as evidence that a person age 24 or younger participates on the Board that oversees programmatic activities, or that your organization has an Advisory Committee to the Board that is made up of young people age 24 or younger.

If your organization conducts Migrant Worker-related programs:

(a) Submit evidence of having a formal or informal network, chapters, affiliates, constituent organizations, or offices in at least two U.S. States or territories.

(b) Attach the following documents as evidence that your organization has a documented two year record of providing culturally tailored technical assistance, conducting leadership activities focusing on HIV prevention for migrant workers and/or delivering HIV prevention services: (1) Attach to this section a list of clients, including the organization name, location (i.e., city and State), dates of service, and type(s) of assistance provided, (2) Provide copies of memoranda of understanding, agreements, or contracts/consultants, (3) training agendas, (4) newspaper articles, (5) correspondence from recipients of assistance, (6) program brochures, (7) extracts from previous grants to support comparable activities.

2. Abstract (not to exceed two pages)

Summarize your proposed program activities. Include the following:

a. category and activity for which the application is being made;

b. brief summary of the need for the proposed activities and how the target audience perceives risk behaviors and preventive measures;

c. brief description of organizational history and capacity;

d. proposed first budget period objectives;

e. brief summary of proposed plan of operation;

f. brief description of planned collaborations with governmental and non-governmental organizations;

g. brief summary of plans for evaluating the activities of this project (only process evaluation is required); and

3. Organizational History and Capacity

4. Assessment of Need

5. Long-term Goals

6. Program Proposal

a. Objectives
b. Plan of Operation
c. Prioritize Program Activities
d. Coordination/Collaboration
e. Communications
f. Time Line

7. Scientific, Theoretical, or Conceptual Foundation for Proposed Activities

8. Plan for Process Evaluation

9. Project Management and Staffing

10. Budget Breakdown and Justification

For the personnel section, indicate the job title, annual salary/rate of pay, and percentage of time spent on this program.

For contracts contained within the application budget, identify the contractor, if known, describe the services to be performed, justify the use of a third party, and provide a breakdown of and justification for the estimated costs of the contracts, the kinds of organizations or parties to be selected, the period of performance, and the method of selection.

Note: If indirect costs are requested, you must provide a copy of your organization's current negotiated Federal indirect cost rate agreement.

11. Attachments

Provide the following as attachments:

a. Proof of nonprofit status;

b. An organizational chart and listing of existing and proposed staff, including volunteer staff;

c. Description of collaborating organizations or institutions, if appropriate and original, signed letters from the chief executive officers of each such organization or institution assuring their understanding of the intent of this program announcement, the proposed program, their role in the proposed program, and the responsibilities of recipients;

d. A description of any funding being received from CDC or other sources to conduct activities related to HIV and similar to those proposed which includes:

(1) A summary of funds and income received to conduct HIV/AIDS programs. This summary must include the name of the sponsoring organization/source of income, level of funding, a description of how the funds have been used, and the budget period. In addition, identify proposed personnel devoted to the project you are proposing and personnel supported by other funding sources and the activities they support.

(2) A summary of the objectives and activities of the funded programs described above.

(3) A description of how funds requested in this application will be used differently or in ways that will expand upon the funds already received, applied for, or being received; and

(4) An assurance that the funds being requested will not duplicate or supplant funds received from any other Federal or non-Federal source. CDC awarded funds can be used to expand or enhance services supported with other Federal or non-Federal funds.

e. Independent audit statements from a certified public accountant for the previous 2 years.

F. Evaluation Criteria

Each application will be evaluated individually against the following

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criteria by an independent review group appointed by CDC.

1. Organizational History and Capacity: (15 Total Points)

a. The extent to which the applicant describes their role as a national, regional, local or international entity and how they meet the eligibility criteria defined in this program announcement; describes their existing organizational structure, including constituent or affiliate organizations or networks, how that structure will support the proposed program activities, and how the proposed program will have the capacity to reach targeted communities or groups in multiple States or territories. (3 points)

b. The extent to which the applicant describes their past and current experience in developing and implementing similar programs in the appropriate category and activity; for leadership activities, describes capacity for and expertise in leadership development; for technical assistance activities, describes capacity and expertise in providing technical assistance; for HIV service deliver, describes capacity and expertise in delivering HIV prevention services. (3 points)

c. The extent to which the applicant describes their knowledge of HIV transmission and behavioral and social interventions for preventing HIV transmission, and experience in developing and implementing effective HIV prevention strategies and activities appropriate to the target audience; discusses their capacity and expertise in providing educational or prevention services to the target populations at risk for HIV. (3 points)

d. The degree to which the applicant describes their capacity to provide culturally competent and linguistically appropriate services that respond effectively to the cultural, gender, age, environmental, social and multilingual character of the target audiences, including any history of providing such services. (3 points)

e. The degree to which the applicant describes their experience and ability to (1) collaborate with other governmental and non-governmental organizations, including other national agencies or organizations, State and local health departments, CPGs, and State and local non-governmental organizations that provide HIV prevention services; and (2) coordinate program development with existing governmental and private prevention efforts. (2 points)

f. For any of the above areas in which the applicant does not have capacity or expertise, the degree to which the applicant describes measures to ensure that the proposed program obtains that capacity (*e.g.*, through a collaborating organization or a subcontractor). (1 point)

2. Assessment of Need (10 Total Points)

The extent to which the applicant clearly identifies the need that will be addressed by the proposed program; describes how the need for the proposed program was assessed; includes epidemiologic and other data used to identify the need, an inventory of resources currently available that address the identified need, and an analysis of the gap between the identified need and the resources currently available to address the need (*i.e.*, how will proposed activities or program address an important unmet HIV prevention need or risk-group?). State why the funds being applied for in this application are necessary to address the need.

3. Long-term Goals: (5 Total Points)

The extent to which the applicant describes the broad goals that the proposed program aims to achieve over the course of the project period; and describes how these goals relate to the prevention of HIV infection, either directly or indirectly.

4. Program Proposal (25 Total Points)

The extent to which the applicant describes the proposed program, including:

a. *Objectives:* Provides specific, realistic, time-phased and measurable objectives to be accomplished during the first budget period. Describes how these objectives relate to the program's long-term goals. Describes possible barriers to or facilitators for reaching these objectives. (5 points)

b. *Plan of Operation:* Describes in detail the methods (i.e., strategies and activities) used to achieve the proposed goals and objectives, and perform the required recipient activities. Identifies program staff responsible for conducting the proposed activities. Describes specifically how general and activity-specific requirements will be addressed. Describes their roles and responsibilities and those of each collaborating institution, organization, subcontractor or CBA provider in performing the proposed activities. (5 points)

c. *Prioritize Program Activities:* Describes how program activities will be prioritized to place emphasis on the target populations or communities that are disproportionately affected by HIV/AIDS. (4 points)

d. *Coordination/Collaboration:* Describes how they will work and coordinate with other national, regional, State, and local governmental and nongovernmental organizations, including CBA providers, the private sector, as well as other HIV prevention providers, to conduct the proposed activities. Describes how they will ensure consistency with applicable State and local comprehensive HIV prevention community plans when conducting program activities at the State and local levels. (4 points)

e. *Communications:* Describes how they will share successful approaches with other organizations and how "lessons learned" will be compiled and disseminated. (3 points)

f. *Time Line:* Provides a time line that indicates the approximate dates by which activities will be accomplished. (4 points)

5. Scientific, Theoretical, or Conceptual Foundation for Proposed Activities: (15 Total Points)

The extent to which the applicant provides a detailed description of the scientific, theoretical, or conceptual foundation on which the proposed activities are based and which support the potential effectiveness of these activities for addressing the stated need.

6. Plan of Evaluation: (15 Total Points)

The extent to which the applicant describe how activities to monitor progress to determine if the objectives are being achieved, and determine if the methods used to deliver the proposed activities are effective. Describes how data will be collected, analyzed, and used to improve the program.

7. Project Management and Staffing: (15 Total Points)

The extent to which the applicant describes how the proposed program will be managed and staffed, including the location of the program within the organization. Describe in detail each existing or proposed position by job title, function, general duties, and activities. Include the level of effort and allocation of time for each project activity by staff positions. If the identity of any key personnel who will fill a position is known, provide their curriculum vitae (not to exceed two pages per person) as an attachment. Note experience and training related to the proposed project.

8. Budget Breakdown and Justification: (Not Scored)

The extent to which the applicant provides a detailed budget for each proposed activity. Justifies all operating expenses in relation to the stated objectives and planned priority activities. Provides specific information about the program purpose of each budget item and itemizes calculations wherever appropriate. CDC may not approve or fund all proposed activities.

For the personnel section, indicates the job title, annual salary/rate of pay, and percentage of time spent on this program.

G. Submission and Deadline

Application: Submit the original and two copies of PHS 5161–1 (OMB Number 0937–0189) and Assurance of Compliance with the "Requirements of AIDS-related written materials, pictorials, audiovisuals, questionnaires, survey instruments, and educational sessions in Centers for Disease Control and Prevention (CDC) Assistance Programs".

Forms are available at the following Internet addresses: *www.cdc.gov/ * * *.* Forms or in the application kit.

The PHS 5161–1 form is available at *http://forms.psc.gov/forms/phs/ps5161–1.pdf*

The Assurance of Compliance Form is available at *http://www.cdc.gov/od/pgo/forms/hivpanel.htm*

On or before February 23, 2001 submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Postmarked on or before the deadline date and received in time for submission to the independent review group.

(Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Progress reports quarterly including technical assistance and service delivery requested and delivered;

2. financial status report, no more than 90 days after the end of the budget period; and

3. final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I in the application kit. (List all applicable requirements by number and title. The Grants Management Branch will include the applicable descriptions in the application kit.)

AR–4 HIV/AIDS Confidentiality Provisions
AR–5 HIV Program Review Panel Requirements
AR–7 Executive Order 12372 Review
AR–8 Public Health System Reporting Requirements
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements
AR–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(2) of the Public Health Service Act, [42 U.S.C. 247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.941.

J. Where to Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov* click on "Funding" then "Grants and Cooperative Agreements."

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888 472–6874).

You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Julia L. Valentine, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number: 770–488–2732, Email address: jxv1@cdc.gov.

For program technical assistance, contact: Karena Sapsis, Public Health Advisor, Training and Technical Support Systems Branch, Division of HIV/AIDS Prevention, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Rd., NE Mailstop E–40, Atlanta, GA 30333, Telephone: (404)639–5221 email: kes0@cdc.gov.

Dated: January 11, 2001.

Sandra R. Manning,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1468 Filed 1–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National Partnerships for HIV Prevention with a Focus on Business and Labor, Youth, and Migrant Workers

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National Partnerships for HIV Prevention with a Focus on Business and Labor, Youth, and Migrant Workers, Program Announcement #01017, meeting.

Times and Dates: 11 a.m.– p.m., March 4, 2001 (Open), 8:30 a.m.–4:30 p.m., March 5, 2001 (Closed), 8:30 a.m.–8:45 a.m., March 6, 2001 (Open), 8:45 a.m.–4:30 p.m., March 6, 2001 (Closed).

Place: National Center for HIV, STD, and TB Prevention, CDC, 8 Corporate Square Blvd., Conference Room 1A, B, and C, and 2A and 2C, Atlanta, Georgia 30329.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement #01017.

Contact Person for more Information: Elizabeth A. Wolfe, Prevention Support Office, National Center for HIV, STD, and TB Prevention, CDC, Corporate Square Office Park, 8 Corporate Square Boulevard, M/S E07, Atlanta, Georgia 30329, telephone 404/639–8025.

The Director, Management Analysis and Services office has been delegated the

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authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 11, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention CDC.

[FR Doc. 01–1469 Filed 1–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., February 13, 2001; 8:30 a.m.–12 p.m., February 14, 2001.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Discussed: Agenda items include issues pertaining to the Institute of Medicine Report "Ending Neglect", TB Drug Susceptibility Testing and TB in Low Incidence Areas.

Contact Person for More Information: Paulette Ford, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE, M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 11, 2001.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 01–1471 Filed 1–17–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Title IV–E Foster Care and Adoption Assistance Financial Report.

OMB No.: 0970–0205.

Description: This form is used by States and Puerto Rico to facilitate the reporting of expenditures for the Foster Care and Adoption Assistance programs. State agencies (including Puerto Rico) use this form to report data on a quarterly basis. The form provides specific data regarding financial disbursements, obligations and estimates. It provides States with a mechanism to request grant awards and certify the availability of State matching funds. Failure to collect this data would seriously compromise the Administration for Children and Families' ability to issue grant awards and monitor expenditures. This form is also used to prepare ACF budget submission to Congress.

Respondents: States and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
IV–E–1	52	4/YR	25	5200

Estimated Total Annual Burden Hours: 5200.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 11, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–1433 Filed 1–17–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1596]

Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA (we)) is announcing the availability of a draft guidance for industry entitled "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." FDA developed this draft guidance to assist manufacturers, who wish to voluntarily label their foods (human and animal) as being made with or without bioengineering or the use of bioengineered ingredients, to ensure that labeling is truthful and not misleading. FDA is taking this action in response to requests from food manufacturers and as part of the Clinton administration's initiatives to strengthen science-based regulation of bioengineered foods and consumer access to information.

DATES: Submit written comments concerning the draft guidance to ensure adequate consideration in the preparation of a revised guidance, if warranted, by March 19, 2001. However, you may submit written comments at any time. Submit written comments concerning the collection of information by March 19, 2001.

ADDRESSES: Submit written comments on the draft guidance and the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify the comments with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the draft guidance entitled "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering" to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. Alternatively, you may request a copy of the draft guidance by calling 202–205–4561, or you may fax your request to 202–205–4594. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Regarding human food issues: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

Regarding animal feed issues: William D. Price, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6652.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 29, 1992 (57 FR 22984), FDA published its "Statement of Policy: Foods Derived from New Plant Varieties" (the 1992 policy). The 1992 policy applies to foods (human and animal) developed from new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology, which is often referred to as "genetic engineering," "biotechnology," or "bioengineering." The 1992 policy provides guidance to industry on scientific and regulatory issues related to bioengineered foods and solicited written comments from interested persons. It includes guidance on questions to be answered by developers of foods from new plant varieties to ensure that the new products are safe and comply with applicable legal requirements.

In the 1992 policy, we also address the labeling of foods derived from new plant varieties, including plants developed by bioengineering. The 1992 policy does not establish special labeling requirements for bioengineered foods as a class of foods. The 1992 policy states that we have no basis for concluding that bioengeered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional plant breeding.

Although we do not require special labeling for bioengineered foods, as a class of foods, in the 1992 policy we advised that labeling requirements that apply to foods in general also apply to foods produced using biotechnology. Section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, under section 201(n) of the act (21 U.S.C. 321(n)), the labeling of food must reveal all facts that are material in light of representations made in the labeling or in light of consequences that may result from the use of the foods. Thus:

- If a bioengineered food is significantly different from its traditional counterpart, such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference.
- If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the labeling to describe the issue.
- If a bioengineered food has a significantly different nutritional property, its labeling must reflect the difference.
- If a new food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed in the labeling.

In the **Federal Register** of April 28, 1993 (58 FR 25837), we requested data and information (the 1993 information request) on certain labeling issues that had arisen from the labeling guidance in the 1992 policy. In 1999, we held three public meetings (64 FR 57470, October 25, 1999). The purpose of those meetings was for us to share our current approach and experience over the previous 5 years regarding bioengineered foods, to solicit views on whether our policies should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply. We received more than 50,000 written comments about our policy regarding safety and labeling of bioengineered foods. The theme related to labeling in those comments and the testimony at the meetings was that there are very strongly held but divergent views as to whether bioengineered foods should be required to bear special labeling. However, there was general agreement that providing more information to consumers about bioengineered foods would be useful. A number of comments supported the need for guidance from FDA regarding appropriate ways that industry could voluntarily provide information on a food label about bioengineering.

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We have reviewed information in the comments received in response to the 1992 policy and the 1993 information request as well as the comments from the meetings held in 1999. Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food. However, these comments did not provide data or other information regarding consequences to consumers from eating the foods or any other basis for us to find under section 201(n) of the act that such a disclosure was a material fact. Many of the comments expressed concern about possible long-term consequences from consuming bioengineered foods, but they did not contend that any of the bioengineered foods already on the market have adverse health effects. The comments were mainly expressions of concern about the unknown. We are still not aware of any data or other information that would form a basis for concluding that the fact that a food or its ingredients was produced using bioengineering is a material fact that must be disclosed under sections 403(a) and 201(n) of the act. We are, therefore, reaffirming our decision to not require special labeling of all bioengineered foods.

We are providing guidance to assist manufacturers who wish to label their foods voluntarily as being made with or without the use of bioengineered ingredients. While the use of bioengineering is not a material fact, many consumers are interested in the information, and some manufacturers may want to respond to this consumer desire. We developed this guidance using information from the comments and from focus groups, as well as other resources. The guidance is intended to help manufacturers ensure that their labeling is truthful and not misleading. In addition, because the act defines food as articles used for food or drink for man or other animals, this guidance applies to animal feeds as well as to human foods.

The guidance addresses the use of statements in the labeling of foods that are bioengineered or contain bioengineered ingredients. It is intended to provide guidance on how a manufacturer may make statements in the labeling about bioengineered foods and ingredients, without such statements being false or misleading.

The guidance also addresses the use of statements in the labeling that indicate that the food, or its ingredients, was not bioengineered. The agency is soliciting comments on the entire guidance document, but it is particularly interested in comments on how the draft guidance deals with statements like "GMO free," "GM free," "biotech free," and "no genetically engineered materials." For example, we are seeking comment on whether, and how, statements like "GM free" or "no genetically engineered material" can be made without being false or misleading. In the guidance document, FDA advises that the term "free" may be difficult to use without being false or misleading. If it implies "zero," it may be very difficult to substantiate. The adventitious presence of bioengineered material may make a "zero" claim inaccurate. Further, these terms would be misleading if they imply that the food is superior because the food is not bioengineered. We have concluded that the use, or absence of use, of bioengineering in the production of a food is not a fact that is material either with respect to consequences resulting from the use of the food or due to representations on the labeling.

We suggest in the guidance that terms like "GM free" and "biotech free" either not be used in bioengineering labeling statements or be in a context that makes clear that a zero level of bioengineered material is not implied. We recognize that the terms are popular among those manufacturers who have already made label statements that a food was not bioengineered. FDA requests comments on whether statements like "GM free," "biotech free," and "no genetically engineered materials" can be made without being false or misleading, and, if so, how. Does such a statement imply zero content of bioengineered material? If so, would a clarifying statement help the consumer to understand that there may be some low level of bioengineered material present? Should substantiation of no detectable bioengineered material be required in the absence of a clarifying statement? Does "biotech free" or another similar term imply that the labeled food is superior to foods that are not so labeled? If so, would a clarifying statement, for example, a statement that the absence of the use of bioengineering does not make the food superior to food not so labeled or to a bioengineered food or ingredient, clarify the term adequately? Would such a clarifying statement be needed in all instances or are there some uses of "GM free" and similar terms that would not imply that the labeled food is superior, and why? We specifically request comment on these as well as any other aspects of how to avoid false or misleading statements in the labeling about the absence of use of bioengineering in the production of a food or its ingredients.

This Level 1 draft guidance represents our current thinking on the voluntary labeling indicating whether foods have or have not been developed using bioengineering. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes, and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's good guidance practices (65 FR 56468, September 19, 2000).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering

Description: The 1992 policy stated that the method of development of a new plant variety, including plants developed using bioengineering, is not information that is material under section 201(n) of the act and, therefore, would not be required in the labeling of food. This conclusion is consistent with our historic interpretation of section 201(n) of the act, in that the method of plant breeding is not required to be disclosed in labeling. In the 1993 information request, we requested additional information on labeling issues that had risen from our 1992 policy. Subsequently, in 1999, we held three public meetings to get public input on our existing policy with regard to its premarket review of foods produced through biotechnology and the labeling of such products. In response to comments that we received on our 1992 policy, the 1993 information request, and the public meetings, we decided to develop guidance for voluntary labeling indicating whether foods have or have not been developed using bioengineering. This guidance will assist manufacturers in labeling foods that have or have not been developed using bioengineering so that the labeling statement is truthful, not misleading, and scientifically valid. The information that the manufacturers will collect is documentation of handling practices so that they can truthfully label their products to indicate, if they so choose, whether the food has or has not been developed using bioengineering.

In general, FDA anticipates that manufacturers that claim that a product is not developed using bioengineered material would substantiate the claim. If validated testing is not available to ensure the absence of bioengineered material for a specific food, we suggest that manufacturers document handling practices to substantiate a claim that a food was not developed using bioengineering, rather than using a "free" claim. Thus, to substantiate handling practices, the manufacturers would have to document the source of such foods. Examples of documentation that we anticipate will demonstrate handling practices and procedures about how the food was processed are recordkeeping, certifications or affidavits from farmers, processors, and others in the food production and distribution chain. We are neither suggesting that firms maintain a certain set list of documents nor are we suggesting that anything less or different would likely be considered unacceptable. Rather, we are leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was produced using traditional methods.

Description of Respondents: Manufacturers of foods that were and were not produced using bioengineering.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Operating and Maintenance Costs	Total Hours
893	21	18,753	1	$1,781,400	18,753

[1] There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Recordkeeper	Operating and Maintenance Costs	Total Hours
68	26	1,768	1	$53,040	1,768

[1] There are no capital costs associated with this collection of information.

FDA estimates that almost all of the organic producers and manufacturers who have issued statements that they will not use bioengineered ingredients will choose to label, and therefore, will incur the reporting burden. We determined the estimates for the annual reporting burden by using the approximately 18,753 products (16,985 organic products and 1,768 non-organic products) from producers who may not use bioengineered ingredients in their products. These manufacturers include producers who market to a niche of consumers who choose not to use products with bioengeered ingredients and manufacturers who have stated that they do not use bioengineered ingredients in their products. We estimated that the numbers of firms that will choose to label is 893 (825 firms for organic products and 68 for non-organic products). We estimated that the manufacturers of these products would choose to state on their label and in their labeling that those products were not developed using bioengineering. Such labeling would increase their paperwork burden. The estimates on the annual reporting burden (table 1 of this document) are based on agency knowledge of, and experience with, food labeling. The 18,753 product estimate may be too low if FDA has been unable to identify all producers that could use non-bioengineering labels or if FDA's labeling guidance encourages producers who have not issued bioengineering statements to now use such statements on the label. On the other hand, this may be an overestimate if some producers, who have been making statements indicating that they will try to use foods that were not developed using bioengineering, choose not to label their products.

We believe that the burden associated with the voluntary labeling of foods that have not been developed using bioengineering would be a one-time burden for the small number of firms that would decide, voluntarily, to add this additional information to the labels for their products, separate from any other label changes for their products. We estimate that at least 90 percent of firms would coordinate the addition of the statement on the label that their products were not developed using bioengineering with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be included almost entirely in the cost of other voluntary or required labeling changes. The incremental cost for these 803 firms (893 x 90 percent) would be approximately $50 per label for 16,878 labels, or $843,900 total. For the remaining 90 firms that would not coordinate changes with other labeling changes, we estimate that the cost would be approximately $500 per label for 1,875 labels, or $937,500 total. The estimated total operating and

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maintenance costs in table 1 of this document are, therefore, $1,781,400.

When determining the annual recordkeeping burden (table 2 of this document), we estimated that the number of firms that would maintain records to substantiate labeling that their products were not developed using bioengineering is the same as the number of respondents with the reporting burden minus the number of firms marketing organic products (i.e., 68). We did not include products that are labeled "organic" in the estimated annual recordkeeping burden because according to a proposal in the **Federal Register** of March 13, 2000 (65 FR 13512), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as "organic" would not be permitted to contain bioengineered materials. Therefore, the 16,985 organic products available today would be able to bear a voluntary labeling statement that the food was not developed using bioengineering. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using bioengineering for these products. Because most of the non-organic products whose producers have stated they will not use bioengineered ingredients are made by large firms for whom the verification process is not likely to impose a significant burden relative to the size of their operation, we assume that the paperwork processing time associated with testing or source verification for these products is approximately 1 hour for a total of 1,768 hours per year. Therefore, FDA estimated that the total recordkeeping burden would be 1,768 hours per year. Based on our experience, we have estimated that the overhead and maintenance cost are $30 per hour. The estimated total operating and maintenance cost in table 2 of this document are, therefore, $53,040 total.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by March 19, 2001, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, interested persons may submit written comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit to the Dockets Management Branch written comments concerning this collection of information by March 19, 2001. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance also is available on the Internet at http://www.cfsan.fda.gov/dms/.

Dated: November 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–1047 Filed 1–17–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

The estimated annual response burden is as follows:

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements for OPOs, hospitals, histocompatibility laboratories	30	1	30	40	1,200
121.6(c)—Submitting criteria for organ acceptance	900	1	900	0.1	90
121.6(c)—Sending criteria to OPOs	900	1	900	0.1	90
121.7(b)(4)—Reasons for Refusal	900	0.5	34,200	0.1	3,420
121.7(e)—Transplant to prevent organ wastage	900	0.5	420	0.1	42
121.9(b)—Designated Transplant Program Requirements	10	1	10	2	20

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Total	940	38.8	36,460	.1	4,862

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 10, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1390 Filed 1–17–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center For Research Resources; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources, Special Emphasis Panel, Research Centers in Minority Institutions.

Date: February 22, 2001.

Time: 6 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: C. William Angus, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892—7965, 301–435–0812.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1459 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(b) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel.

Date: January 10, 2001.

Time: 3 PM to 4:30 PM.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, Room 1AS–13, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Laura Moen, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13H, Bethesda, MD 20892, 301–594–3998.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: January 8, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1451 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personnel information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: February 20, 2001.

Time: 8:30 AM to 3:30 PM.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: John R. Lymangrover, PhD, Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301–594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1452 Filed 1–12–01; 8:45 am]

BILLING CODE 4140–01–M

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 00–20, Review of R01s.

Date: January 12, 2001.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anna Sandberg, PhD., Scientific Review Administrator, National Institute of Dental & Craniofacial Res., 45 Center Drive, Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (301) 594–3089.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 01–19, Review of P01.

Date: January 24, 2001.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Natcher Building, Rm. 4AN44F, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: H. George Hausch, PhD., Chief, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 00–16, Review of R13 Grants.

Date: January 31, 2001.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: H. George Hausch, PhD., Chief, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel 00–14, Review of R01 Grants.

Date: April 16, 2001.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Philip Washko, PhD., DmD, Scientific Review Administrator, 45 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594–2372.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1453 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders A.

Date: February 18–19, 2001.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Fort Lauderdale Beach, 909 Fort Lauderdale Beach Blvd., Fort Lauderdale, FL 33304.

Contact Person: Richard D. Crosland, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders B.

Date: February 22–23, 2001.

Time: 8:00 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: La Posada De Santa Fe Resort and Spa, 330 East Palace Avenue, Santa Fe, NM 87501.

Contact Person: Paul A. Sheehy, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders C.

Date: February 22–23, 2001.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: La Fonda on the Plaza, 100 East San Francisco Street, Santa Fe, NM 87501.

Contact Person: Alan L. Willard, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–9223.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1454 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: February 7, 2001.

Time: 8:30 am to 5 pm.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Rd, Bethesda, MD 20814.

Contact Person: Aftab A. Ansari, PHD, National Institutes of Health, NIAMS, Natcher Building, 45 Center Drive, Room 5AS25N, Bethesda, MD 20892, 301–594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1455 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: January 22, 2001.

Time: 2:00 pm to 2:30 pm.

Agenda: To review and evaluate grant applications.

Place: 45 Natcher Bldg., Rm 5As25u, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Tommy L. Broadwater, PhD, Chief, Grants Review Branch, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25U, Bethesda, MD 20892, 301–594–4952.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1456 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provision set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel.

Date: January 10, 2001.

Time: 10:30 am to 12:30 pm.

Agenda: To review and evaluate grant applications.

Place: 45 Natcher Bldg, Rm 5As25u, Bethesda, MD 20892.

Contact Person: Tommy L. Broadwater, PHD, Chief, Grants Review Branch, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25U, Bethesda, MD 20892, 301–594–4952.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1457 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health, Special Emphasis Panel.

Date: January 29, 20001.

Time: 1 p.m. to 2 p.m.

Agency: To review and evaluate grant applications.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Henry J. Haigler, PhD., Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Rm. 6150, MSC 9608, Bethesda, MD 20892–9608, 301/443–7216.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1460 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, "Novel Drug Delivery System for the Mouse".

Date: January 11, 2001.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Richard C. Harrison, Chief, Contract Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, 301–435–1437.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse, Special Emphasis Panel, "Chemical Libraries for Drug Development".

Date: January 18, 2001.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Eric Zatman, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, 301–435–1438.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, "Development of Science Education Materials or Programs".

Date: January 31, 2001.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 3158, MSC 9547, Bethesda, MD 20892–9547, 301–435–1439.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs, National Institutes of Health, HHS)

Dated: January 10, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1461 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–5(C2)B.

Date: January 24, 2001.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: 2 Democracy Plaza, Room 654, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Francisco O. Calvo, PhD., Acting Chief, Review Branch, DEA, NIDDK, Room 655, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8897.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–2(C2)B.

Date: February 15, 2001.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: 2 Democracy Plaza, 6707 Democracy Boulevard, Room 643, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Shan S. Wong, PhD., Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 643, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594–7797.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

Date: March 8–9, 2001.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Points by Sheraton Bethesda, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michele L. Barnard, PhD., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 657, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 594–8898.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 10, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1462 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Regents of the National Library of Medicine.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Regents of the National Library of Medicine.

Date: February 27–28, 2001.

Open: February 27, 2001, 9:00 am to 4:40 pm.

Agenda: Administrative Reports and Program Discussion.

Place: National Library of Medicine, Board Room, Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Closed: February 27, 2001, 4:40 pm to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, Board Room, Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Open: February 28, 2001, 9:15 am to 11:30 am.

Agenda: Administrative Reports and Program Discussion.

Place: National Library of Medicine, Board Room, Bldg 38, 2E–09, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Donald A.B. Lindberg, MD, Director, National Library of Medicine, National Institutes of Health, PHS, DHHS, Bldg 38, Room 2E17B, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1458 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Method for Preparing 17α-Acetoxy-11β-(4-,N-Dimethylaminophyl)-19-Norpregna-4, 9-Diene-3,20-Dione, Intermediates Useful in the Method, and Methods for the Preparation of Such Intermediates

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent Application Serial No. 08/413,755, filed March 30, 1995, issuing as U.S. Patent 5,929,262 entitled, "Method for Preparing 17α-Acetoxy-11β-(4-N,N-Dimethylaminophyl)-19-Norpregna-4, 9-Diene-3,20-Dione, Intermediates Useful in the Method, and Methods for the Preparation of such Intermediates" to HRA Pharma, a corporation of France, having a place of business in Paris, France. The patent rights in this invention have been assigned to the United States of America, as represented by the Department of Health and Human Services.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before April 18, 2001 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Dennis H. Penn, Pharm.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 496–7056, ext. 211; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: In an effort to develop an efficacious treatment for human reproductive disorders this invention describes methods for the synthesis of 17α-Acetoxy-11β-(4-N,N-Dimethylaminophyl)-19-Norpregna-4,9-Diene-3,20-Dione Intermediates Useful in the Method, and Methods for the Preparation of such Intermediates This compound may have utility in treating human reproductive disorders and hormone sensitive tumors.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 90 days from the date of this published Notice, NIH received written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the use of the invention for the synthesis 17α-Acetoxy-11β-(4-N,N-Dimethylaminophyl)-19-Norpregna-4, 9-Diene-3,20-Dione and intermediates useful in the method of synthesis and preparation of such intermediates.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 8, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–1465 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Orally Active Derivatives of 1,3,5(10)-Estratriene

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the invention embodied in: U.S. Patent Application Series No. 08/122,853, filed September 17, 1993, issuing as U.S. Patent 5,554,603 on September 10, 1996 entitled, "Orally Active Derivatives of 1,3,5(10)-Estratriene" to the R.W. Johnson Pharmaceutical Research Institute, a corporation of Delaware, having a place of business in Raritan, New Jersey. The patent rights in this invention have been assigned to the

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United States of America, as represented by the Department of Health and Human Services.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before March 19, 2001 will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Dennis H. Penn, Pharm.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 496–7056, ext. 211; Facsimile: (301) 402–0220.

SUPPLEMENTARY INFORMATION: In an effort to develop an efficacious treatment for human reproductive disorders this invention describes orally active derivatives of 1,3,5(10)-estratriene. This compound may have utility as a contraceptive and as an estrogen replacement for the treatment and prevention of postmenopausal conditions.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this published Notice, NIH received written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

The field of use may be limited to the use of the invention for the development of pharmaceutical compounds for use as a contraceptive and for treatment and prevention of postmenopausal conditions.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 8, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–1464 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Prophylactic and/or Therapeutic Vaccine Against Pseudomonas Aeruginosa, Chlamydia, Trachomatis and Mycoplasma Pneumonia

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of a limited field of use exclusive worldwide license to practice the inventions embodied in U.S. Serial Number 09/462,682, filed January 10, 2000 (claiming priority to U.S. Provisional Patent Application Serial No. 60/052,375, filed July 11, 1997), entitled "Pseudomonas exotoxin A-Like Chimeric Immunogens" and U.S. Serial Number 09/462,713 filed May 12, 2000 (claiming priority to U.S. Provisional Patent Application Serial No. 60/056,924, filed July 11, 1997), entitled "Pseudomonas Exotoxin A-like Chimera Immunogens for eliciting a secretory IgA-Mediated Immune Response" to Trinity BioSystems, L.L.C. of Los Altos Hills, California, U.S.A. The United States as represented by the Department of Health and Human Services is an assignee of these patent rights.

DATES: Only written comments and/or applications for a license which are received by NIH on or before March 19, 2001 will be considered.

ADDRESSES: Requests for a copy of these patent applications, inquiries, comments, and other materials relating to the contemplated license should be directed to: Carol A. Salata, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 496–7735 ext. 232; Facsimile: (301) 402–0220; E-mail: salatac@OD.NIH.GOV. A signed Confidential Disclosure Agreement (CDA) may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The patent applications describe the use of Pseudomonas exotoxin A-like chimeric immunogens in which a non-native epitope is inserted into a domain. These immunogens are useful to elicit humoral, cell-mediated and mucosal immune responses against the non-native epitope.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

It is anticipated that this license may be limited to the field of use as a prophylactic and/or therapeutic vaccine against Pseudomonas aeruginosa, Chlamydia trachomatis and Mycoplasma pneumoniae. Trinity BioSystems will use Pseudomonas exotoxin A to target and deliver pathogen peptide epitopes wherein said pathogen peptide epitopes are inserted into or replace a domain of Pseudomonas exotoxin A.

This propsective exclusive license may be granted unless within 60 days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 8, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 01–1463 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Office for Women's Services; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Advisory Committee for Women's Services of the Substance Abuse and Mental Health Services Administration (SAMHSA) on Friday January 26, 2001.

The meeting of the Advisory Committee for Women's Services will include a discussion of policy and program issues relating to women's substance abuse and mental health service needs; the SAMHSA fiscal year 2001 budget; specific Committee goals for the current year, planning discussions for SAMHSA's Third National Conference on Women,

consideration of the September 29, 2000 meeting minutes; and other policy issues.

A summary of the meeting and/or a roster of committee members may be obtained from: Nancy P. Brady, Executive Secretary, Advisory Committee for Women's Services, Office for Women's Services, SAMHSA, Parklawn Building, Room 13–99, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–5184.

Substantive information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Advisory Committee for Women's Services.

Meeting Date(s): Friday January 26, 2001.

Meeting Time: 2:30–5:00 p.m.

Place: 5600 Fishers Lane, Parklawn Building Room 16–105, Rockville, MD 20857.

Open: January 26, 2001.

Contact: Nancy P. Brady, Room 13–99, Parklawn Building, Telephone: (301) 443–8964.

Dated: January 8, 2001.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 01–1389 Filed 1–17–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4651N–01]

Proposed Information Collection, Comment Request, Economic Opportunities for Low- and Very Low-Income Persons

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice

SUMMARY: The proposed information collection requirement concerning the Section 3 program will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comment Due Date:* March 19, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Valerie T. Hayes, Department of Housing and Urban Development, 451 7th Street, SW., Room 5235, Washington, DC 20410. Telephone number (202) 708–3633.

FOR FURTHER INFORMATION CONTACT: Valerie T. Hayes, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone (202) 708–3633. (This is not a toll-free number). Hearing or speech-impaired individuals may access this number TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8399.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 34, as amended).

This Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Notice of Submission of Proposed Information Collection to OMB

Title of Proposal: Economic Opportunity for Low- and Very Low-Income Persons *Office:* Fair Housing and Equal Opportunity.

OMB Control Number: 2529–0043.

Description of the need for the information and proposed use: The information will be used by the Department to monitor program recipients' compliance with Section 3. HUD Headquarters will use the information to assess the results of the Department's efforts to meet the statutory objectives of Section 3. Also, the data collected will be used by recipients as a self-monitoring tool. If the information is not collected, HUD will be unable to prepare the mandatory reports to Congress or to assess the effectiveness of Section 3.

Agency form numbers, if applicable: Form HUD 60002 and HUD 958.

Members of affected public: State and local governments or their agencies, public and private non-profit organizations, or other public entities.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: On an annual basis approximately 58,594 respondents (HUD recipients) will submit one report to HUD. It is estimated that two hours per annual reporting period will be required of the recipients to prepare the Section 3 report for a total of 117,186 hours.

Status of the proposed information collection: Reinstatement of a currently approved collection to reflect the collection of information from HUD recipients.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 8, 2001.

John H. Waller,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 01–1402 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–38–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4655–N–01]

Proposed Information Collection: Comment Request—Recertification of Family Income, Composition and Statistical Report—Section 235(b) and Section 234(b), (l), and (j)

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 19, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Joseph McCloskey, Director, Office of Single Family Asset Management, Department of Housing and Urban Development, 451 7th Street SW.,

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Washington, DC 20410, telephone (202) 708–1672 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1955 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Recertification of Family Income and Composition.

OMB Control Number, if applicable: 2502–0082.

Description of the need for the information and propose use: Housing Programs, Housing Subsidy, Recertification of forms HUD–93101 and 93101A are submitted by homeowners to mortgagees to determine their continued eligibility for assistance and to determine the amount of assistance a homeowner is to receive. The forms are also used by mortgagees to report statistical and general program data to HUD.

Agency form numbers, if applicable: HUD–93101 and HUD–93101A.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The number of respondents is 77,265; the frequency of responses are on occasion, monthly, and annually; estimated time to prepare collection is 1.25 hours per response; and the total annual burden hours requested are 96,581.

Status of the proposed information collection: Reinstatement without change.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: January 12, 2001.

William C. Apgar,

Assistant Secretary for Housing—FHA.

[FR Doc. 01–1540 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–02]

Notice of Submission of Proposed Information Collection to OMB; Mortgagee's Application for Partial Settlement (Multifamily Mortgage)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 20, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. comments should refer to the proposal by name and/or OMB approval number (2502–0427) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice Also Lists the Following Information

Title of Proposal: Mortgagee's Application for Partial Settlement (Multifamily Mortgage).

OMB Approval Number: 2502–0427.

Form Numbers: HUD–2537.

Description of the Need for the Information and Its Proposed Use: When a FHA insured multifamily mortgage goes into default, the mortgagee may file a claim to receive insurance benefits. HUD Form 2537 provides required data to process a partial claim payment within 24 to 48 hours after assignment or conveyance of a multifamily mortgage.

Respondents: Business or other-for-profit, State, Local or Tribal Government.

Frequency of Submission: On occasion.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
215		1		3.98		54

Total Estimated Burden Hours: 54.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 9, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1399 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–03]

Submission of Proposed Information Collection to OMB—Application for FHA Insured Mortgage (Addendum to Uniform Residential Loan Application/ Mortgage Credit Analysis Worksheet)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 20, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0059) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Application for FHA Insured Mortgage (Addendum to Unoform Residential Loan Application/ Mortgage Credit Analysis Worksheet).

OMB Approval Number: 2502–0059.

Form Numbers: HUD–92900—A, HUD–92900–B, HUD–92900–WS, HUD–92900–PUR, HUD–92561, HUD–92544.

Description of the Need for the Information and Its Proposed Use: This application for an FHA insured mortgage, an addendum to Uniform Residential Loan Application (URLA) and related documents are needed to determine, the eligibility of the borrower and proposed mortgage transaction for FHA's insurance endorsement. This information is submitted by lenders seeking FHA's insurance endorsement.

Respondents: Application for benefits, Audit.

Frequency of Submission: On occasion.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
1,000,000		1		0.23		235,025

Total Estimated Burden Hours: 235,025.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 9, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1400 Filed 1–17–01; 8:45am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–04]

Submission of Proposed Information Collection to OMB—Lender Qualifications for Multifamily Accelerated Processing (Map)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comment Due Date:* February 20, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0541) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents

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submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also list the following information:

Title of Proposal: Lender Qualifications for Multifamily Accelerated Processing (MAP).

OMB Approval Number: 2502–0541.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use: To participate in MAP, lenders will be required to show that they have an experienced multifamily underwriter on staff, and that they have a satisfactory record on lending on multifamily housing properties. Qualified lenders can then take advantage of a mortgage application plan that will take substantially less processing.

Respondents: Business or other-for-profit.

Frequency of Submission: On occasion.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours of per response	=	Burden hours
130		1		10		1,300.

Total Estimated Burden Hours: 1,300.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 9, 2000.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1401 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–05]

Submission of Proposed Information Collection to OMB—Certificate of Need for Health Facility and Assurance of Enforcement of State Standards

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 20, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0210) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collection the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Certificate of Need for Health Facility and Assurance of Enforcement of State Standards.

OMB Approval Number: 2502–0210.

Form Numbers: HUD–2576–HF.

Description of the Need for the Information and its Proposed Use: Certificate of Need is used to comply with Sections 232 of the National Housing Act for Nursing Homes, and Intermediate Care Facilities, which requires the State to execute the HUD Form 2576–HF through and approved Lender in order to obtain an insured loan.

Respondents: Business or other- for-profit.

Frequency of Submission: On occasion.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
50		1		0.2		10

Total Estimated Burden Hours: 10.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 10, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1539 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–06]

Submission of Proposed Information Collection to OMB—Public and Indian Housing Drug Elimination Technical Assistance Program (DETAP) Consultant Services—Application Kit

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 20, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposak Comments should refer to the proposal by name and/or OMB approval number (2577–0133) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Public and Indian Housing Drug Elimination Technical Assistance Program (DETAP) Consultant Services-Application Kit.

OMB Approval Number: 2577–0133.

Form Numbers: HUD–52354.

Description of the Need for the Information and its Proposed Use: Eligible applicants will submit information under the SuperNOFA for the Drug Elimination Technical Assistance Program (DETAP). HUD will review and evaluate the information against ranking factors contained in the SuperNOFA for possible funding. Applicants will be notified of their selection/rejection.

Respondents: Not-for-profit institutions, State, Local or Tribal Government.

Frequency of Submission: Annually.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
1,500		1		20		30,000

Total Estimated Burden Hours: 30,000.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 11, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1541 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4638–N–02]

Notice of Certain Operating Cost Adjustment Factors

AGENCY: Office of the Secretary, HUD.

ACTION: Publication of Fiscal Year (FY) 2001 Operating Cost Adjustment Factors (OCAFs) for Section 8 rent adjustments at contract renewal under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA), as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPRHA) Projects assisted with Section 8 Housing Assistance Payments.

SUMMARY: This notice that establishes factors used in calculating rent adjustments under section 524 of the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA) as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, and under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 (LIHPRHA), was published on January 10, 2001, but the appendix to the notice was inadvertently not published. This notice is therefore republished with the appendix.

EFFECTIVE DATE: January 10, 2001.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410; telephone (202) 708–3000; (This is not a toll-free number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

This notice was originally published on January 10, 2001 (66 FR 1997), but

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the appendix to the notice was inadvertently not published. This notice is therefore republished with the appendix.

I. Operating Cost Adjustment Factors (OCAFs)

Section 514(e)(2) of the FY 1998 HUD Appropriations Act requires HUD to establish guidelines for rent adjustments based on an operating cost adjustment (OCAF) factor. The legislation requiring HUD to establish OCAFs for LIHPRHA projects and projects with contract renewals under section 524 of MAHRA is similar in wording and intent. HUD has therefore developed a single factor to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted.

Additionally, section 524 of the Act gives HUD broad discretion in setting OCAFs—referring simply to "operating cost factors established by the Secretary." The sole exception to this grant of authority is a specific requirement that application of an OCAF shall not result in a negative rent adjustment. OCAFs are to be applied uniformly to all projects utilizing OCAFs as the method by which rents are adjusted upon expiration of the term of the contract. OCAFs are applied to project contract rent less debt service.

An analysis of cost data for FHA-insured projects showed that their operating expenses could be grouped into nine categories: wages, employee benefits, property taxes, insurance, supplies and equipment, fuel oil, electricity, natural gas, and water and sewer. Based on an analysis of these data, HUD derived estimates of the percentage of routine operating costs that were attributable to each of these nine expense categories. Data for projects with unusually high or low expenses due to unusual circumstances were deleted from analysis.

States are the lowest level of geographical aggregation at which there are enough projects to permit statistical analysis. Additionally, no data were available for the Western Pacific Islands. Data for Hawaii was therefore used to generate OCAFs for these areas.

The best current measures of cost changes for the nine cost categories were selected. The only categories for which current data are available at the State level are for fuel oil, electricity, and natural gas. Current price change indices for the other six categories are only available at the national level. The Department had the choice of using dated State-level data or relatively current national data. It opted to use national data rather than data that would be two or more years older (*e.g.*, the most current local wage data are for 1996). The data sources for the nine cost indicators selected used were as follows:

Labor Costs—6/99 to 6/00 Bureau of Labor Statistics (BLS), "Employment Cost Index, Private Sector Wages and Salaries Component at the National Level."

Employment Benefit Costs—6/99–6/00 (BLS), "Employment Cost Index, Employee Benefits at the National Level."

Property Taxes—6/99–6/00 (BLS), "Consumer Price Index, All Items Index."

Goods, Supplies, Equipment—6/99–6/00 (BLS), "Producer Price Index, Finished Goods Less Food and Energy."

Insurance—6/99–6/00 (BLS), "Consumer Price Index, Tenant and Household Insurance."

Fuel Oil—Energy Information Agency, Petroleum Marketing Annual 1999, Table 18, "Prices of No.2 Distillate to Residences by PAD District and Selected States," (Petroleum Administration for Defense District (PADD) average changes were used for the States with too little fuel oil consumption to have values.)

Electricity—Energy Information Agency, Electric Power Annual Volume 1, 1999, Table 22 "Retail Sales of Electricity, Revenue and Average Revenue per Kilowatt-hour (and RSEs) by U.S. Electric Utilities to Ultimate Consumers by Census Division and State, 1998–1999—Residential."

Natural Gas—Energy Information Agency, Natural Gas Annual, 1999, Table 22, "Average Price of Natural Gas Delivered to Residential Consumers by State, 1995–1999 (Preliminary)."

Water and Sewer—6/99–6/00, (BLS), "Consumer Price Index—Detailed Report."

The sum of the nine cost components equals 100 percent of operating costs for purposes of OCAF calculations. To calculate the OCAFs, the selected inflation factors are multiplied by the relevant State-level operating cost percentages derived from the previously referenced analysis of FHA insured projects. For instance, if wages in Virginia comprised 50 percent of total operating cost expenses and wages increased by 4 percent from June 1999 to June 2000, the wage increase component of the Virginia OCAF for FY 2001 would be 2.0 percent (4% × 50%). This 2.0 percent would then be added to the increases for the other eight expense categories to calculate the FY 2000 OCAF for Virginia. These types of calculations were made for each State for each of the nine cost components, and are included as the Appendix to this Notice.

II. MAHRA OCAF Procedure

The Multifamily Assisted Housing Reform and Affordability Act of 1997, Title V of Public Law 105–65 (approved October 7, 1997), 42 U.S.C. 1437f (MAHRA) as amended by the Preserving Affordable Housing for Senior Citizens and Families into the 21st Century Act of 1999, created the Mark-to-Market Program to reduce the cost of Federal housing assistance, enhance HUD's administration of such assistance, and to ensure the continued affordability of units in certain multifamily housing projects. Section 524 of MAHRA authorizes renewal of Section 8 project-based assistance contracts for projects without Restructuring Plans under the Mark-to-Market Program, including renewals that are not eligible for Plans and those for which the owner does not request Plans. Renewals must be at rents not exceeding comparable market rents except for certain projects. For Section 8 Moderate Rehabilitation projects, other than single room occupancy projects (SROs) under the Stewart B. McKinney Homeless Assistance Act (McKinney Act, 42 U.S.C. 11301 *et seq.*), that are eligible for renewal under section 524(b)(3) of MAHRA, the renewal rents are required to be set at the lesser of: (1) The existing rents under the expiring contract, as adjusted by the OCAF; (2) fair market rents (less any amounts allowed for tenant-purchased utilities; or (3) comparable market rents for the market area.

III. Findings and Certifications

Environmental Impact

This notice sets forth rate determinations and related external administrative requirements and procedures that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

This notice does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of Executive Order 13132 (entitled "Federalism").

Catalog of Federal Domestic Assistance Number. The Catalog of Federal Domestic Assistance Number for this program is 14.187.

Dated: January 10, 2001.

Andrew Cuomo,

Secretary.

APPENDIX—FY 2001 OPERATING COST ADJUSTMENT FACTORS (OCAF) FOR RENT ADJUSTMENTS AT SECTION 8 CONTRACT RENEWAL

[In percent]

State	FY 2001 operating cost adjustment factor
ALABAMA	3.31
ALASKA	2.48
ARIZONA	3.45
ARKANSAS	3.19
CALIFORNIA	2.99
COLORADO	3.20
CONNECTICUT	2.88
DELAWARE	2.84
DISTRICT OF COLUMBIA	2.98
FLORIDA	3.09
GEORGIA	1.68
HAWAII	3.10
IDAHO	3.23
ILLINOIS	2.72
INDIANA	2.81
IOWA	2.79
KANSAS	2.88
KENTUCKY	2.89
LOUISIANA	3.08
MAINE	2.89
MARYLAND	3.19
MASSACHUSETTS	2.64
MICHIGAN	3.00
MINNESOTA	3.22
MISSISSIPPI	2.96
MISSOURI	2.97
MONTANA	3.54
NEBRASKA	3.08
NEVADA	3.21
NEW HAMPSHIRE	2.58
NEW JERSEY	3.31
NEW MEXICO	2.53
NEW YORK	2.79
NORTH CAROLINA	3.25
NORTH DAKOTA	2.90
OHIO	2.87
OKLAHOMA	3.03
OREGON	3.12
PENNSYLVANIA	1.94
RHODE ISLAND	2.35
SOUTH CAROLINA	3.24
SOUTH DAKOTA	3.25
TENNESSEE	3.12
TEXAS	2.79
UTAH	2.58
VERMONT	3.91
VIRGINIA	3.00
WASHINGTON	3.26
WEST VIRGINIA	3.11
WISCONSIN	3.24
WYOMING	3.07
PACIFIC ISLANDS	2.76
PUERTO RICO	3.21
VIRGIN ISLANDS	2.86
UNITED STATES AVERAGE	2.85

[FR Doc. 01–1396 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–33–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4556–N–04]

Mortgage Review Board: Administrative Actions—Clarification

AGENCY: Office of Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Public Notice, Mortgagee Review Board, Clarification of Administrative Action.

SUMMARY: In compliance with Section 202(c) of the National Housing Act, notice is given of the cause and description of administrative actions taken by HUD's Mortgage Review Board against HUD-approved mortgagees. This notice provides clarification regarding the description of and the cause for administrative action against a HUD-approved mortgagee.

FOR FURTHER INFORMATION CONTACT: D. Jackson Kinkaid, Secretary to the Mortgage Review Board, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3041 extension 3574 (this is not a toll-free number). Hearing or speech-impaired persons may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 202(c) of the National Housing Act (added by Section 142 of the Department of Housing and Urban Development Reform Act of 1989, Pub. L. 101–235, approved December 15, 1989), requires that HUD "publish a description of and the cause for administrative actions against a HUD-approved mortgage" by the Department's Mortgage Review Board. In compliance with the requirements of Section 202(c)(5), notice is hereby given of a clarification of a previously published description and cause for an administrative action against a HUD-approved mortgagee. The specific mortgagee that is the subject of this clarification is James B. Nutter & Company, Kansas City, Missouri, pursuant to an administrative action originally reported at 65 FR 53734 (#44) published on September 5, 2000. The clarification regarding the administrative action taken against this mortgagee is noted below:

1. James B. Nutter & Company, Kansas City, Missouri.

Action: Proposed settlement agreement of disputed matters that included a payment to the Department.

Cause: A review by HUD's Quality Assurance Division discovered alleged failures to comply with HUD/FHA Loss Mitigation and other HUD/FHA requirements.

Dated: January 10, 2001.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner, Chairman, Mortgagee Review Board.

[FR Doc. 01–1538 Filed 1–17–01; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Draft Environmental Assessment and Land Protection Plan for the Proposed Establishment of Green River National Wildlife Refuge, Henderson County, KY

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of availability of the Draft Environmental Assessment and Land Protection Plan for the proposed establishment of Green River National Wildlife Refuge.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service, Southeast Region, proposes to establish a new national wildlife refuge in the Scuffletown Bottoms area in Henderson County, Kentucky. The purpose of the proposed refuge is to protect, restore and manage a valuable complex of wetland habitats for the benefit of migrating and wintering waterfowl, non-game land birds, and other native fish and wildlife. A Draft Environmental Assessment and Land Protection Plan for the establishment of the proposed refuge has been prepared by Service biologists in coordination with the Kentucky Department of Fish and Wildlife Resources. The assessment considers the biological, environmental, and socioeconomic effects of establishing the refuge and evaluates three alternative actions and their potential impacts on the environment. Written comments or recommendations concerning the proposal are welcomed and should be sent to the address given below.

DATES: Land acquisition planning for the project is currently underway. The draft environmental assessment and land protection plan will be available to the public for review and comment on January 22, 2001. Written comments must be received no later than March 9, 2001, in order to be considered for the preparation of the final environmental assessment.

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ADDRESSES: If you wish to comment, you may submit your comments by any of several methods. You may mail your comments to Mr. Charles R. Danner, Team Leader, Planning and Support Team, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Atlanta, Georgia 30345. You may hand-deliver your comments to Mr. Danner at the same address. Or you may submit your comments by telephone at 1–800–419–9582. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. if you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations and businesses, available for public inspection in their entirety.

SUPPLEMENTARY INFORMATION: The proposal would establish a national wildlife refuge on up to 23,000 acres of wetlands and bottomland hardwoods along the confluence of the Green and Ohio Rivers in Henderson County, Kentucky. The Service is proposing to establish the refuge through a combination of fee title purchases from willing sellers and leases, conservation easements, or cooperative agreements from willing landowners.

The goals of the proposed refuge would be to provide (1) Habitat for migrating and wintering waterfowl, (2) habitat for non-game land birds, (3) habitats for a natural diversity of fish and wildlife, (4) nesting habitat for wood ducks and other locally nesting migratory waterfowl, (5) quality hunting and sportfishing opportunities, and (6) opportunities for environmental education, interpretation, and wildlife-oriented recreation.

Dated: January 5, 2001.

Sam D. Hamilton,

Regional Director.

[FR Doc. 01–1441 Filed 1–17–01; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–957–1430–BJ]

Idaho: Filing of Plats of Survey

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of the following described lands were officially filed in the Idaho State Office, Bureau of Land Management, Boise, Idaho, effective 9 a.m., on the dates specified:

The plat representing the entire survey record of the dependent resurvey of a portion of the subdivisional lines, T. 5 N., R. 1 E., Boise Meridian, Idaho, Group Number 1092, was accepted October 2, 2000. The plat was prepared to meet certain administrative needs of the Bureau of Land Management.

The plat representing the dependent resurvey of a portion of the east boundary and of the subdivisional lines, and the subdivision of section 36, T. 2 S., R. 36 E., Boise Meridian, Idaho, and the plat representing the dependent resurvey of portions of the east and north boundaries, and the subdivision of sections 13, 14, and 24, T. 3 S., R. 36 E., Boise Meridian, Idaho, Group Number 999, were accepted November 6, 2000. The plats were prepared to meet certain administrative needs of the Bureau of Indian Affairs, Fort Hall Agency.

FOR FURTHER INFORMATION CONTACT: Duane Olsen, Chief, Cadastral Survey, Idaho State Office, Bureau of Land Management, 1387 South Vinnell Way, Boise, Idaho 83709–1657, 208–373–3980.

Dated: January 3, 2001.

Harry K. Smith,

Acting Chief, Cadastral Surveyor for Idaho.

[FR Doc. 01–1395 Filed 1–17–01; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

Definition and Payback of Inadvertent Overruns for Delivery of Lower Colorado River Water; Notice of Public Comment Period

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public comment period.

SUMMARY: The Bureau of Reclamation (Reclamation) proposes a policy that will identify inadvertent overruns, will establish procedures that account for inadvertent overruns, and will define subsequent payback requirements to the Colorado River mainstream, and invites comments on its draft proposal.

DATES: Comments on this notice must be received at the address below on or before March 24, 2001.

ADDRESSES: If you wish to comment, you may mail comments to Deputy Area Manager, Boulder Canyon Operations Office, Lower Colorado Region, Bureau of Reclamation, BCOO–1010, P.O. Box 61470, Boulder City, Nevada 89006. You may also comment via the Internet at InadvertentOverrun@lc.usbr.gov. If you comment via the Internet, please submit comments as an ASCII file avoiding the use of special characters and any form of encryption. If you do not receive a confirmation via e-mail that we have received your Internet message, please contact us directly at (702) 293–8592.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

FOR FURTHER INFORMATION CONTACT: Mr. John Redlinger, (702) 293–8592.

SUPPLEMENTARY INFORMATION: In its June 3, 1963 opinion in the case of *Arizona* v. *California* (373 U.S. 546), the Supreme Court of the United States held that the Congress has directed the Secretary of the Interior (Secretary) to administer a network of useful projects constructed by the Federal Government on the lower Colorado River, and it has entrusted the Secretary with sufficient power to direct, manage, and coordinate their operation. The Court held that this power must be construed to permit the Secretary to allocate and distribute the waters of the mainstream of the Colorado River within the boundaries set down by the Boulder Canyon Project Act (45 Stat. 1057, 43 U.S.C. 617) (BCPA). The Secretary has entered into contracts for the delivery of Colorado River water with entities in Arizona, California, and Nevada in accordance with section 5 of the BCPA. The Secretary has the responsibility of operating Federal facilities on the Colorado River and delivering mainstream Colorado River water to users in Arizona, California, and Nevada that hold entitlements, including present perfected rights, to such water.

Article V of the Decree of the Supreme Court of the United States in *Arizona* v. *California* dated March 9, 1964 (376 U.S. 340) requires the Secretary to compile and maintain records of diversions of water from the mainstream, of return flow of such water to the mainstream as is available for consumptive use in the United States or in satisfaction of the Mexican Treaty obligation, and of consumptive use of such water. Reclamation reports this data each year in the Decree Accounting Record.

Pursuant to the Criteria for Coordinated Long-Range Operation of Colorado River Reservoirs developed as a result of the Colorado River Basin Project Act of September 30, 1968, the Secretary annually consults with representatives of the governors of the Colorado River Basin States, general public and others and issues an Annual Operating Plan (AOP) for the coordinated operation of the Colorado River reservoirs. Reclamation also requires each Colorado River water user in the Lower Basin to schedule water deliveries in advance for the following calendar year (calendar year is the annual basis for decree accounting of consumptive use in the lower Colorado basin) and to later report its actual water diversions and returns to the mainstream.

Pursuant to 43 CFR part 417, prior to the beginning of each calendar year, Reclamation consults with entities holding BCPA section 5 contracts (Contractor) for the delivery of water. Under these consultations, Reclamation makes recommendations relating to water conservation measures and operating practices in the diversion, delivery, distribution, and use of Colorado River water. Reclamation also makes a determination of the Contractor's estimated water requirements for the ensuing calendar year to the end that deliveries of Colorado River water to each Contractor will not exceed those reasonably required for beneficial use under the respective BCPA contract or other authorization for use of Colorado River water. Reclamation then monitors the actual water orders, receives reports of measured diversions and return flows from major Contractors and federal establishments, estimates unmeasured diversions and return flows, calculates consumptive use from preliminary diversions and measured and unmeasured return flows, and reports these records on an individual and aggregate monthly basis. Later, when final records are available, Reclamation prepares and publishes the final Decree Accounting Record on a calendar year basis.

For various reasons, a user may inadvertently consumptively use Colorado River water in an amount that exceeds the amount available under its entitlement (inadvertent overrun). Further, the final Decree Accounting Record may show that an entitlement holder inadvertently diverted water in excess of the quantity of the entitlement that may not have been evident from the preliminary records. Reclamation is therefore considering an administrative policy that defines inadvertent overruns, establishes procedures that account for the inadvertent overruns and defines the subsequent requirements for pay back to the Colorado River mainstream.

Any effects of the proposed administrative policy decision on the environment will be addressed pursuant to the National Environmental Policy Act.

Inadvertent Overruns

Reclamation is proposing for the Lower Colorado River Basin an inadvertent overrun policy that would include the following features:

a. Inadvertent overruns are those which the Secretary deems to be beyond the control of the water user; for example, overruns due to the discrepancy between preliminary and final stream flow and diversion records, or overruns due to an unanticipated but lawful use by a higher-priority water user.

b. An inadvertent overrun is Colorado River water diverted, pumped or received by an entitlement holder in excess of the water user's entitlement for that year. The inadvertent overrun policy provides a structure to pay back the amount of water diverted, pumped or received in excess of entitlement. The inadvertent overrun policy does not create any right or entitlement to this water, nor does it expand the underlying entitlement in any way. An entitlement holder has no right to order, divert, pump or receive an inadvertent overrun. If, however, water is diverted, pumped or received inadvertently in excess of entitlement, and the Contractor's State's apportionment of Colorado River water for that year is exceeded, the inadvertent overrun policy will govern the payback.

c. Payback will be required to commence in the calendar year that immediately follows the release date of a Decree Accounting Record that reports uses that are in excess of an individual's entitlement.

d. Payback must be made only from measures that are above and beyond the normal consumptive use of water (extraordinary conservation measures). Extraordinary conservation measures mean actions taken to conserve water that otherwise would not return to the mainstream of the Colorado River and be available for beneficial consumptive use in the United States or to satisfy the Mexican treaty obligation. Any entitlement holder with a payback obligation must submit to Reclamation, along with its water order, a plan which will show how it will intentionally forbear use of Colorado River water by extraordinary conservation and/or fallowing measures sufficient to meet its payback obligation, which are in addition to the measures found in its Reclamation approved conservation plan. Plans for payback could also include supplementing Colorado River system water supplies with non-system water supplies. Water banked off-stream or groundwater from areas not hydrologically connected to the Colorado River or its tributaries are examples of such supplemental supplies.

e. Maximum cumulative inadvertent overrun accounts will be specified for individual entitlement holders as 10 percent of an entitlement holder's normal year consumptive use entitlement. (Normal year means a year for which the Secretary has determined that sufficient mainstream Colorado River water is available for release to satisfy 7.5 maf of annual consumptive use in the States of California, Arizona and Nevada.)

f. The number of years within which an overrun, calculated from consumptive uses reported in final Decree Accounting Records, must be paid back, and the minimum payback required for each year shall be as follows:

1. In a year in which the Secretary makes a flood control release or a space building release, any accumulated amount in the overrun account will be forgiven.

2. If the Secretary has declared a 70 R surplus in the AOP, any payback obligation will be deferred at the entitlement holder's option.

3. When Lake Mead elevation is between the elevation for a 70R surplus declaration and elevation 1125 feet above mean sea level on January 1, the payback obligation must be paid back in full within 3 years, with a minimum payback that year of the greater of 20

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percent of the individual entitlement holder's maximum allowable cumulative overrun account amount or 33.3 percent of the total account balance.

4. When Lake Mead elevation is at or below elevation 1,125 feet above mean sea level on January 1, the total account balance will be paid back in full in that calender year.

5. For any year in which the Secretary declares a shortage under the Decree, the total account will be paid back in full that calender year, and further accumulation of inadvertent overruns will be suspended as long as shortage conditions prevail.

g. A separate inadvertent overrun account may be established in those limited cases in which a lower priority user is, or has agreed to be, responsible for consumptive uses by one or more un-quantified senior water entitlement or right holders having finite service area acreage. The separate inadvertent overrun account will be limited to a maximum cumulative amount of 10 percent of the senior right holders average consumptive use. Such inadvertent overrun accounts will be the assigned responsibility of the lower priority user. If, however, such senior entitlement or right holders' approved aggregate calendar year water orders are in excess of the specified amount above which the lower priority user will be responsible, such excess will not be deemed inadvertent and the lower priority user's water order for that year will be reduced accordingly by Reclamation.

h. Each month, Reclamation will monitor the actual water orders, receive reports of measured diversions and return flows from Contractors and federal establishments, estimate unmeasured diversions and return flows, and project individual and aggregate consumptive uses for the year. Should preliminary determinations indicate that monthly consumptive uses by individual users, or aggregate uses, when added to the approved schedule of uses for the remainder of that year, exceed contract entitlements but are not exceeding the maximum inadvertent overrun account amount, Reclamation will notify in writing the appropriate entities that the preliminary determinations are forecasting annual uses in excess of their entitlements.

i. During years in which an entitlement holder is forbearing use to meet its payback obligation, should preliminary determinations of monthly consumptive uses indicate that sufficient forbearance is not projected to occur, Reclamation will also notify the appropriate entitlement holders in writing that the preliminary determinations are forecasting that their annual payback obligations are not on target or being met. If this condition occurs for two consecutive years, in the second year Reclamation will advise the entitlement holder in writing by July 31, will consult with the entitlement holder on a modified release schedule and will limit releases to the entitlement holder for the remainder of the year such that by the end of the year the individual entitlement holder has met their payback obligation.

j. Should preliminary determinations indicate that monthly consumptive uses by individual users, or aggregate uses, when added to the approved schedule of uses for the remainder of that year, exceed the individual entitlement holder's maximum cumulative overrun account amount, Reclamation will advise the entitlement holder in writing by July 31, will consult with the entitlement holder on a modified release schedule and will limit releases to the entitlement holder for the remainder of the year such that by the end of the year the individual entitlement holder's maximum cumulative overrun account amount has not been exceeded.

k. Procedures will be established for accounting for inadvertent overruns on an annual basis and for supplementing the final Decree Accounting Record.

Reclamation invites comments on the features noted above and in particular on: what limits might be placed on any maximum cumulative overrun account; the duration of the payback period; and from what types of water would payback be allowed.

Public Meetings

Reclamation will hold public meetings to present information and solicit public input if there is a sufficient level of interest. Submit any request for a public meeting to Mr. John Redlinger (see **ADDRESSES**).

Dated: January 12, 2001.

Robert W. Johnson,

Regional Director, Lower Colorado Regional Office.

[FR Doc. 01–1531 Filed 1–17–01; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[INT–DES–01–02]

Pick-Sloan Missouri Basin Program, Angostura Unit, South Dakota

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability and public hearing on draft environmental impact statement (DEIS).

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Department of the Interior, Bureau of Reclamation, has prepared a DEIS on the proposed renewal of a long-term water service contract for irrigation water from the Federal Angostura Unit, Cheyenne River basin, South Dakota. The DEIS describes four alternatives, including no action, and evaluates their environmental consequences. No Preferred Alternative has been chosen at this time. One will be selected after the public review period. Public hearings have been scheduled to provide interested parties an opportunity to provide oral or written comments on the proposed renewal of a long-term water service contract.

DATES: A 90-day public review and comment period commences with the publication of this notice. Written comments on the DEIS should be submitted by April 27, 2001.

Written comments from interested parties unable to attend the hearings, those not wanting to make oral presentations, or those wishing to supplement their oral presentations at the public hearing should be transmitted to the Rapid City Field Office by April 27, 2001, for inclusion in the public record.

Public hearings have been scheduled for the following dates, times, and locations:

February 13, 2001, 7–9 PM, Rushmore Plaza Holiday Inn 505 N 5th St., Rapid City, South Dakota

February 14, 2001, 7–9 PM, Mueller Civic Center, 801 S. 6th St., Hot Springs, South Dakota

February 15, 2001, 1–5 PM, Oglala Lakota College, 3 Mile Creek, Piya Wiconi Rd., Kyle, South Dakota

February 21, 2000, 2–4 PM, Super 8 Motel, West Highway 212, Eagle Butte, South Dakota

February 22, 2001, 2–4 PM, Lower Brule Convention Center, Lower Brule Sioux Tribe, Lower Brule, South Dakota

Written comments on the DEIS should be submitted to the Rapid City Field Office Manager (Attention: Kenneth Parr), 515 9th Street, Room 101, Rapid City, SD 57701, or through email to kparr@gp.usbr.gov.

Our practice is to make comments, including names and home addresses of respondents, available for public review. Individual respondents may request that we withhold their home address from public disclosure, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold a respondent's identity from public disclosure, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public disclosure in their entirety.

You may request a Summary of the DEIS or the entire DEIS (with appendices in printed copy or on computer disk). Copies may be obtained from the above address, by telephone (605) 394–9757 ext. 3004, or through email at kparr@gp.usbr.gov. Copies are also available for public inspection and review on the internet at "www.dka.gp.usbr.gov" in the "Current Activities" section under "Angostura Unit".

See **SUPPLEMENTARY INFORMATION** section for additional addresses where the DEIS is available for public inspection and review.

FOR FURTHER INFORMATION CONTACT: Kenneth Parr, Rapid City Field Office, 515 9th Street, Room 101, Rapid City, SD 57701 telephone—(605) 394–9757 ext. 3004, or email kparr@gp.usbr.gov

SUPPLEMENTARY INFORMATION:

DEIS Public Inspection and Review Locations

Offices

- Bureau of Reclamation, Rapid City Field Office, 515 9th Street, Room 101, Rapid City, SD 57701—telephone (605) 394–9757 ext. 3004.
- Bureau of Reclamation, Dakotas Area Office, 304 East Broadway Ave., Bismarck, ND 58502—telephone (701) 250–4242.
- Bureau of Reclamation, Great Plains Regional Office, 316 North 26th Street, Billings, MT 59101—telephone (406) 247–7638.
- Bureau of Reclamation, Reclamation Service Center Library, Building 67, Room 167, Denver Federal Center, Sixth and Kipling, Denver, CO 80225—telephone (303) 445–2072.
- Bureau of Reclamation, Program Analysis Office, Room 7456, 1849 C Street NW, Washington, DC 20240—telephone (202) 208–4662.
- Angostura Irrigation District in South Dakota, Main Street, Oral, SD 57766.

Libraries

South Dakota State Library, Mercedes MacKay Building, 800 Governors Drive, Pierre, South Dakota 57501–2294.

Rapid City Public Library, 610 Quincy Street, Rapid City, SD 57701–3655.

Hot Springs Library, 1543 Baltimore Avenue, Hot Springs, South Dakota 57747.

Custer County Library, 447 Crook #4, Custer, South Dakota 57730.

Oglala Lakota College, 3 Mile Creek, Piya Wiconi Road, Kyle, South Dakota 57752.

Cheyenne River Community College, Main Street, Box 212, Eagle Butte, South Dakota 57625.

Lower Brule Tribal Library, Lower Brule Sioux Tribe, Lower Brule, South Dakota 57548.

Pine Ridge Library, Main St., Box 439, Pine Ridge, South Dakota 57770.

Hearing Process Information

Organizations and individuals wishing to present oral statements are strongly encouraged to contact Kenneth Parr, Bureau of Reclamation, Rapid City Field Office, at the address above, telephone (605) 394–9757 ext. 3004, or email at kparr@gp.usbr.gov, to announce their intention to participate in the public hearing. Requests to make presentations will also be accepted at the hearings. Written statements may also be submitted at the hearings.

Oral statements at the public hearings will be limited to 5 minutes. If time permits, the hearing officer may allow speakers to extend their oral statement after all persons wishing to comment have been heard. Whenever possible, speakers will be scheduled according to the time preference requested in their letter or telephone request. Scheduled speakers not present at the public hearing when called will lose their privilege in the scheduled order and will be recalled at the end of all the scheduled speakers. Those registering at the meetings may choose from the remaining time slots.

Please notify Reclamation at least 2 weeks in advance of the scheduled hearing if you require special needs in order to participate in the public hearing. Those having special needs should contact Kenneth Parr at (605) 394–9757 or through the Federal Relay System at (800) 877–8339 or via e-mail at kparr@gp.usbr.gov. Smoking will be prohibited in the hearing room and surrounding area.

Dated: January 3, 2001.

Gerald Kelso,

Assistant Regional Director.

[FR Doc. 01–1530 Filed 1–17–01; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation 332–425]

U.S.-Korea FTA: The Economic Impact of Establishing a Free Trade Agreement (FTA) Between the United States and the Republic of Korea

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation and scheduling of public hearing.

EFFECTIVE DATE: January 9, 2001.

SUMMARY: Following receipt of a request on December 18, 2000, from the Senate Committee on Finance (Committee), the Commission instituted investigation No. 332–425, U.S.-Korea FTA: The Economic Impact of Establishing a Free Trade Agreement (FTA) Between the United States and the Republic of Korea, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)). The Commission plans to submit its report by September 18, 2001.

As requested by the Committee, in its report the Commission will provide to the extent possible:

- An overview of the Korean economy
- An overview of the current economic relationship between the United States and the Republic of Korea, including a discussion of the important industry sectors in both countries
- An inventory and analysis of the main barriers (tariff and nontariff) to trade between the United States and the Republic of Korea
- To the extent data are available, the estimated effects of eliminating all quantifiable trade barriers (tariff and nontariff), with special attention to agricultural goods, on:
- The volume of trade in goods and services between the two countries
- Sectoral output and gross domestic product for each country
- Wages and employment across industry sectors for each country
- Final prices paid by consumers in each country
- A qualitative assessment of the effects of removing nonquantifiable trade barriers

FOR FURTHER INFORMATION CONTACT: Information may be obtained from Christine McDaniel, Project Leader (TEL: 202–708–5404; EMAIL: cmcdaniel@usitc.gov), Office of Economics, or Alan Fox, Deputy Project Leader (TEL: 202–205–3267; EMAIL: afox@usitc.gov), Office of Economics, U.S. International Trade Commission, Washington, DC, 20436. For information on the legal aspects, contact William

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Gearhart (TEL: 202–205–3091; EMAIL: wgearheart@ustic.gov), Office of the General Counsel. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202) 205–1810.

Background: In its letter to the Commission, the Committee stated that a number of the United States' trading partners have aggressively pursued free trade area negotiations that may segment markets to the commercial disadvantage of the United States. The Committee indicated that over the course of the next several months it expects to ask the Commission for a series of investigations under section 332 related to the economic impact of negotiating bilaterally or regionally with particular trading partners in the absence of a new round of multilateral talks.

Public Hearing: A public hearing in connection with the investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, beginning at 9:30 a.m. on May 17, 2001. All persons shall have the right to appear, by counsel or in person, to present information and to be heard. Requests to appear at the public hearing should be filed with the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436, no later than 5:15 p.m., April 27, 2001. Any prehearing briefs (original and 14 copies) should be filed no later than 5:15 p.m., May 4, 2001; the deadline for filing post-hearing briefs or statements is 5:15 p.m., May 25, 2001. In the event that, as of the close of business on April 27, 2001, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant may call the Secretary of the Commission (202–205–1806) after April 27, 2001, to determine whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements (original and 14 copies) concerning the matters to be addressed by the Commission in its report on this investigation. Commercial or financial information that a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each clearly marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). All written submissions, except for confidential business information, will be made available in the Office of the Secretary of the Commission for inspection by interested parties. To be assured of consideration by the Commission, written statements relating to the Commission's report should be submitted to the Commission at the earliest practical date and should be received no later than the close of business on May 25, 2001. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means.

Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov).

List of Subjects

Republic of Korea, Free Trade Agreement, Tariffs, and Imports.

Issued: January 10, 2001.
By order of the Commission.
Donna R. Koehnke,
Secretary.
[FR Doc. 01–1489 Filed 1–17–01; 8:45 am]
BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–919–920 (Preliminary)]

Certain Welded Large Diameter Line Pipe From Japan and Mexico

AGENCY: United States International Trade Commission.

ACTION: Institution of antidumping investigations and scheduling of preliminary phase investigations.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping investigations Nos. 731–TA–919–920 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) (the Act) to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Japan and Mexico of certain welded large diameter line pipe [1] that are alleged to be sold in the United States at less than fair value. Unless the Department of Commerce extends the time for initiation pursuant to section 732(c)(1)(B) of the Act (19 U.S.C. 1673a(c)(1)(B)), the Commission must reach a preliminary determination in antidumping investigations in 45 days, or in this case by February 26, 2001. The Commission's views are due at the Department of Commerce within five business days thereafter, or by March 5, 2001.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: January 10, 2001.

FOR FURTHER INFORMATION CONTACT: Diane J. Mazur (202–205–3184), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (http://www.usitc.gov).

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted in response to a petition filed on January 10, 2001, by Berg Steel Pipe Corp., Panama City, FL; American Steel Pipe Division of American Cast Iron Pipe Co., Birmingham, AL; and Stupp Corp., Baton Rouge, LA.

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on January 31, 2001, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Diane Mazur (202–205–3184) not later than January 29, 2001, to arrange for their appearance. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before February 5, 2001, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

Issued: January 10, 2001.
By order of the Commission.
Donna R. Koehnke,
Secretary.
[FR Doc. 01–1491 Filed 1–17–01; 8:45 am]
BILLING CODE 7020–02–P

[1] For purposes of these investigations certain welded large diameter line pipe are welded circular carbon and alloy products of a kind used in oil and gas pipelines with an outside diameter greater than 16 inches, regardless of stenciling. The products are provided for in subheadings 7305.11.10, 7305.11.50, 7305.12.10, 7305.12.50, 7305.19.10, and 7305.19.50 of the Harmonized Tariff Schedule of the United States.

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–438]

In the Matter of Certain Plastic Molding Machines With Control Systems Having Programmable Operator Interfaces Incorporating General Purpose Computers, and Components Thereof; Notice of a Commission Determination Not to Review an Initial Determination Terminating the Investigation on the Basis of a Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's ("ALJ's") initial determination ("ID") granting a joint motion to terminate the above-captioned investigation on the basis of a settlement agreement.

FOR FURTHER INFORMATION: Peter L. Sultan, Office of the General Counsel, U.S. International Trade Commission, telephone (202) 205–3094.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on October 13, 2000, based on a complaint filed by Milacron Inc. ("Milacron") alleging that respondents UBE Industries, Ltd. and UBE Machinery Inc. (collectively "UBE") violated section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, by importing, selling for importation, or selling within the United States after importation certain plastic molding machines with control systems having programmable operator interfaces incorporating general purpose computers, and components thereof, that infringe certain claims of Milacron's U.S. Letters Patent 5,062,052, as amended by Reexamination Certificate B1 5,062,052.

On November 6, 2000, Milacron and UBE entered into a settlement agreement, which included an agreement to file a joint motion to terminate the investigation. On November 13, 2000, Milacron and UBE filed the joint motion to terminate the investigation, which was supported by the Commission investigative attorney.

On December 20, 2000, the ALJ issued an ID (Order No. 2) granting the joint motion to terminate the investigation on the basis of the settlement agreement. None of the parties filed a petition to review the subject ID. The Commission subsequently determined not to review the subject ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and Commission rule 210.42, 19 CFR 210.42. Copies of the public version of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (http://www.usitc.gov).

Issued: January 10, 2001.
By order of the Commission.
Donna R. Koehnke,
Secretary.
[FR Doc. 01–1490 Filed 1–17–01; 8:45 am]
BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–01–003]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: January 22, 2001 at 2:00 p.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20426, Telephone: (202) 205–2000.

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STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none.
2. Minutes.
3. Ratification List.
4. Inv. Nos. 701–TA–409–412 and 731–TA–909–912 (Preliminary) (Low-Enriched Uranium from France, Germany, the Netherlands, and the United Kingdom)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on January 22, 2001; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on January 29, 2001.)
5. Outstanding action jackets:

(1) Document No. GC–00–100: Concerning Inv. No. 337–TA–432 (Certain Semiconductor Chips with Minimized Chip Package Size and Products Containing Same).

(2) Document No. INV–00–223: Approval of final report in Inv. No. TA–204–3 (Lamb Meat).

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: January 12, 2001.

By order of the Commission:

Donna R. Koehnke,

Secretary.

[FR Doc. 01–1695 Filed 1–16–01; 3:47 pm]

BILLING CODE 7020–02–P

JUDICIAL CONFERENCE OF THE UNITED STATES

Hearing of the Judicial Conference Advisory Committee on Rules of Civil Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Civil Procedure.

ACTION: Notice of open hearing.

SUMMARY: The Advisory Committee on Rules of Civil Procedure has proposed amendments to Rule C of the Supplemental Rules for Certain Admiralty and Maritime Claims. A public hearing on the amendments is scheduled to be held in Washington, DC on March 12, 2001.

The Judicial Conference Committee on Rules Practice and Procedure submits this rule for public comment. All comments and suggestions with respect to the amendments must be placed in the hands of the Secretary as soon as convenient and, in event, not later than April 2, 2001. Those wishing to testify should contact the Secretary at the address below in writing at least 21 days before the hearing. All written comments on the proposed rule amendments should be mailed to: Peter G. McCabe, Secretary, Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, Thurgood Marshall Federal Judiciary Building, Washington, DC 20544.

Comments on the proposed rule amendments may also be sent electronically via the Internet at *http://www.uscourts.gov/rules*. In accordance with established procedures all comments submitted on the proposed amendments are available to public inspection.

The text of the proposed rule amendments and the accompanying Committee Notes can be found at the United States Federal Courts' Home Page at *http://www.uscourts.gov/rules* on the Internet.

FOR FURTHER INFORMATION CONTACT: John K. Rabiej, Chief, Rules Committee Support Office, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: January 12, 2001.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 01–1476 Filed 1–17–01; 8:45 am]

BILLING CODE 2210–55–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

January 8, 2001.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy the ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact Karin Kurz ((202) 693–4127 or by E-mail to Kurz-Karin@dol.gov). To obtain documentation for ESA, MSHA, OHSA, and VETS contact Darrin King ((202) 693–4129 or by E-mail to King-Darrin@dol.gov).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Type of Review: New collection.

Agency: Employment and Training Administration.

Title: Workforce Investment Act (WIA) Employment and Training Administration (ETA) Financial Reporting Requirements for Indian and Native American (INA) Grantee Activities.

OMB Number: 1205–0New.

Affected Public: State, Local, or Tribal Government; business or other for-profit; not-for-profit institutions.

Frequency: Quarterly.

Number of Respondents: 150.

Estimated Time Per Respondent: 12 hours.

Total Burden Hours: 1,800.

Description: The collection of data for this report will provide accountability to the Department who is charged by law with the responsibility for ensuring that all WIA funds are expended in accordance with applicable laws and regulations while grantees are carrying out the purposes for which their grant was awarded. (Subtitle E, Sec. 185 and 29 CFR 668.600.)

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 01–1446 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act: Migrant and Seasonal Farmworker Youth Program Under WIA Section 127(b)(1)(A)(iii) and Section 167

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Proposed Data Collection.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation process to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This process helps to ensure that requested data can be provided in the desired format, reporting burdens are minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration (ETA), in consultation with the Migrant and Seasonal Farmworker Employment and Training Advisory Committee, is soliciting comments concerning the proposed institution of a "reporting and performance standards system for the Youth Title I-D Section 167 National Farmworker Jobs Programs of the Workforce Investment Act (WIA)". A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before March 19, 2001.

ADDRESSES: Alicia Fernandez-Mott, Chief, Division of Seasonal Farmworker Programs, Employment and Training Administration, U.S. Department of Labor, Room N–4641, 200 Constitution Avenue, NW, Washington, DC 20210. Telephone: (202) 693–3729 (VOICE) or (202) 693–3818 (FAX) (these are not toll-free numbers) or INTERNET: afernandez@doleta.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the information collection request are available for inspection in the Division of Seasonal Farmworker Programs at the above address, and will be mailed to persons who request copies in writing from Alicia Fernandez-Mott at the above address.

SUPPLEMENTARY INFORMATION:

I. Background

The Employment and Training Administration of the Department of Labor, in consultation with the Migrant and Seasonal Farmworker Employment and Training Advisory Committee, is requesting approval for a new reporting and performance standards system for Youth Title I–D Section 167 National Farmworker Jobs Programs of the Workforce Investment Act (WIA), youth grantees for three program years (July 1, 2000 to June 30, 2003). This is the first time since the Comprehensive Employment and Training Act (CETA), that funds have been appropriated for farmworker youth activities. The Department has developed the following recommended planning and reporting requirements.

II. Desired Focus of Comments

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's burden estimate for the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

III. Current Action

This proposed ICR will be used by approximately 10 Workforce Investment Act (WIA) section 167 (d) youth grantees as the primary reporting and performance measurement vehicle for enrolled youths, their characteristics, training and services provided, outcomes, including job placement and retention, and attainment of basic skills, as well as detailed financial data on program expenditures.

Type of Review: New.

Agency: Employment and Training Administration.

Title: Planning, reporting, and performance system for WIA title I–D, Section 167(d) National Farmworker Jobs Program youth grantees.

OMB Number: 1205–0NEW.

Catalog of Federal Domestic Assistance Number:

Record Keeping: Grantees shall retain supporting and other documents necessary for the compilation and submission of the subject reports for three years after submission of the final financial report for the grant in question [29 CFR 97.42 and/or 29 CFR 95.53].

Affected Public: State agencies; private, non-profit corporations.

Cite/Reference/Form/etc.: The collection instrument is the Youth, Title I–D, Section 167 National Farmworker Jobs Programs Planning, Reporting, and Performance System and related instructions. OMB-approved forms are provided for use in gathering information at the grantee field office level.

Total Respondents: 10.

Frequency: Annually for planning information; quarterly for both financial information and participation and characteristics information.

Total Annual Responses:

Planning—30 (one narrative, one Budget Information Summary, and one Program Planning Summary per grantee per year).

Participant Reporting—40 (one Program Status Summary per quarter, per grantee per year).

Participant Record Keeping (NFJP SPIR)—5,000 records.

There are four statutorily-required quarterly financial status reports per grantee per year, by year of appropriation. At this time, it is anticipated that the Standard Form (SF) 269 will be used to fulfill this requirement. Therefore, no separate collection/burden information for this standard form is being included here. For participation and characteristics information, there are four quarterly submissions per year, regardless of the year(s) of funding expended during the program year. There is only one format for the participation and characteristics report.

Average Time per Grantee Response:

Annual Plan—5 hours (narrative only).

Budget Information Summary (BIS)—15 hours; [ETA 8595].

Program Planning Summary (PPS)—15 hours; [ETA 8596].

Program Status Summary (PSS)—7 hours; [ETA 8598].

Record Keeping (SPIR)—3 hours (per participant record).

The individual time per response varies widely depending on the degree of automation attained by individual grantees. Grantees also vary according to

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the numbers of individuals served in each program year. If the grantee has a fully-developed and automated MIS, the response time is limited to one-time programming plus processing time for each response.

Estimated Total Annual Burden Hours:

Total Burden Hours—15,630 hours per year.

Planning narrative (NFJP)—10 responses times 5 hours per response equals 50 burden hours.

BIS (NFJP)—10 responses times 15 hours per response equals 150 burden hours.

PPS (NFJP)—10 responses times 15 hours per response equals 150 burden hours.

PSS (NFJP)—4 responses per grantee times 7 hours per response times 10 grantees equals 280 burden hours.

Record Keeping (NFJP SPIR)—5,000 files times 3 hours per file equals 15,000 hours.

Even though no burden estimate for the SF–269 is included here, it should be noted that expenditures must be reported on by year of appropriation, regardless of the year in which the funds were expended. Thus, if more that one year's appropriation is expended in a given quarter, two FSR's (or more) must be submitted for that period.

Total Burden Cost (capital/startup): $–0–.

Total Burden Cost (operating/maintaining):

Youth Title I–D National Farmworker Jobs Program—15,630 hours times $15.00 per hour equals $224,450.00.

Costs may vary widely among grantees, from nearly no additional cost to some higher figure, depending on the state of automation attained by each grantee and the wages paid to the staff actually completing the various forms. All costs associated with the submission of these forms are allowable grant expenses.

Comments submitted in response to this request will be summarized and/or included in the Office of Management and Budget request for approval of the information collection. All comments will become a matter of public record.

Signed at Washington, DC, this 11th day of January, 2001.

James C. DeLuca,

Acting Director, Office of National Programs.

[FR Doc. 01–1445 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Proposed Extension of Information Collection; Comment Request; ERISA Technical Release 91–1

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Pension and Welfare Benefits Administration is soliciting comments concerning the extension of the information collection request (ICR) incorporated in its Technical Release 91–1 related to the transfer of excess assets from a defined benefit plan to a retiree health benefits account. A copy of the ICR may be obtained by contacting the office listed in the addresses section of this notice.

DATES: Written comments must be submitted to the office shown in the addresses section below on or before March 19, 2001.

ADDRESSES: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 2000 Constitution Avenue, NW., Room N–5647, Washington, DC 20210. Telephone: (202) 219–4782; Fax: (202) 219–4745. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

ERISA section 101(e) sets forth certain notice requirements which must be satisfied before an employer may transfer excess assets from a defined benefit plan to a retiree health benefits account as otherwise permissible after satisfying the conditions set forth in section 420 of the Internal Revenue Code of 1986, as amended (Code). Section 101(e)(1) describes the plan administrator's obligation to provide advance written notification of such transfers to participants and beneficiaries. Section 101(e)(2)(A) describes the employer's obligation to provide advance written notification to the Secretaries of Labor and Treasury, the administrator, and each employee organization representing participants in the plan. The requirements relating to advance notification of transfers to retiree health benefit accounts were added to ERISA as part of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508). The ICR included in ERISA Technical Release 9–1 provides guidance on the type of information to be provided in the notices to both the participants and beneficiaries and the Secretaries.

II. Desired Focus of Comments

The Department is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

III. Current Action

This notice requests comments on the extension of the ICR included in ERISA Technical Release 91–1. The Department is not proposing or implementing changes to the existing ICR at this time.

Type of Review: Extension of a currently approved collection of information.

Agency: Pension and Welfare Benefits Administration, Department of Labor.

Titles: ERISA Technical Release 91–1.

OMB Number: 1210–0084.

Affected Public: Individuals or households; Business or other for-profit; Not-for-profit institutions.

Respondents: 66.

Frequency of Response: One time.

Responses: 231,000.

Estimated Total Burden Hours: 5,775.

Total Burden Cost (Operating and Maintenance): $90,000.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record.

Dated: January 11, 2001.

Gerald B. Lindrew,

Deputy Director, Office of Policy and Research, Pension and Welfare Benefits Administration.

[FR Doc. 01–1448 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Proposed Extension of Information Collection; Comment Request; Prohibited Transaction Exemption 92–6

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Pension and Welfare Benefits Administration is soliciting comments concerning the information collection request (ICR) incorporated in Prohibited Transaction Class Exemption 92–6 (PTCE 92–6), pertaining to the sale of individual life insurance or annuity contracts by a plan. A copy of the ICR may be obtained by contacting the office listed in the addresses section of this notice.

DATES: Written comments must be submitted to the office shown in the **ADDRESSES** section below on or before March 19, 2001.

ADDRESSES: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, NW., Room N–5647, Washington, DC 20210. Telephone: (202) 219–4782; Fax: (202) 219–4745. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

Prohibited Transaction Class Exemption 92–6 exempts from the prohibited transaction restrictions of the Employee Retirement Security Act of 1974 (ERISA) the sale of individual life insurance or annuity contracts by a plan to participants, relatives of participants, employers any of whose employees are covered by the plan, other employee benefit plans, owner-employees or shareholder-employees. In the absence of this exemption, certain aspects of these transactions might be prohibited by section 406 of ERISA.

Recordkeeping requirements incorporated within the class exemption are intended to protect the interests of plan participants and beneficiaries. The disclosure requirements protect plan participants by putting them on notice of the plan's intention to sell insurance or annuity contracts under which they are insured, and by giving the participants the right of first refusal to purchase such contracts.

II. Desired Focus of Comments

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

III. Current Action

This notice requests comments on the extension of the ICR included in PTCE 92–6. The Department is not proposing or implementing changes to the existing ICR at this time.

Type of Review: Extension of currently approved collection of information.

Agency: Pension and Welfare Benefits Administration.

Title: Prohibited Transaction Class Exemption 92–6.

OMB Number: 1210–0063.

Affected Public: Individuals or households; business or other for-profit; not-for-profit institutions

Respondents: 76,560.

Frequency of Response: On occasion.

Responses: 7,656.

Estimated Total Burden Hours: 1,276.

Estimated Burden Cost (Operating and Maintenance): $2,833.

Comments submitted in response to this notice will summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record.

Dated: January 11, 2001.

Gerald B. Lindrew,

Deputy Director, Office of Policy and Research, Pension and Welfare Benefits Administration.

[FR Doc. 01–1449 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–29–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

Proposed Extension of Information Collection; Comment Request; Regulation Regarding Participant Directed Individual Account Plans Under ERISA 404(c)

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

Currently, the Pension and Welfare Benefits Administration is soliciting comments concerning the extension of the information collection request (ICR) incorporated in a regulation pertaining to participant directed individual account plans under section 404(c) of the Employee Retirement Income Security Act of 1974 (ERISA). A copy of the ICR may be obtained by contacting the office listed in the addresses section of this notice.

DATES: Written comments must be submitted to the office shown in the

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ADDRESSES section below on or before March 19, 2001.

ADDRESSES: Gerald B. Lindrew, Office of Policy and Research, U.S. Department of Labor, Pension and Welfare Benefits Administration, 200 Constitution Avenue, NW, Room N–5647, Washington, D.C. 20210. Telephone: (202) 219–4782; Fax: (202) 219–4745. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

Section 404(c) of ERISA provides that if an individual account pension plan permits a participant or beneficiary to exercise control over assets in his account and the participant or beneficiary in fact exercises such control, that participant or beneficiary shall not be deemed to be a fiduciary by such exercise of control, and that no person otherwise a fiduciary shall be liable for any loss or breach that results from this exercise of control.

The opportunity to exercise control includes the opportunity to obtain sufficient information to make informed decisions with respect to investment alternatives. This regulation describes the type and extent of information required to be made available to participants and beneficiaries for this purpose. In the absence of such disclosures, participants might not be able to make informed decisions about investing their individual accounts, and persons who are otherwise fiduciaries with respect to these plans would not be afforded relief from the fiduciary responsibility provisions of Title I of ERISA with respect to these transactions.

II. Desired Focus of Comments

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

III. Current Action

This notice requests comments on the extension of the ICR included in the regulation pertaining to participant directed individual account plans under Section 404(c) of ERISA. The Department is not proposing or implementing changes to the existing ICR at this time.

Type of Review: Extension of a currently approved collection of information.

Agency: Pension and Welfare Benefits Administration, Department of Labor.

Title: Regulation Regarding Participant Directed Individual Account Plans (ERISA section 404(c) Plans).

OMB Number: 1210–0090.

Affected Public: Individuals or households; business or other for-profit institutions.

Respondents: 294,800.

Frequency of Response: On occasion.

Responses: 294,800.

Estimated Total Burden Hours: 52,900.

Total Burden Cost (Operating and Maintenance): $23.1 million.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of the information collection request; they will also become a matter of public record.

Dated: January 11, 2001.

Gerald B. Lindrew,

Deputy Director, Office of Policy and Research, Pension and Welfare Benefits Administration.

[FR Doc. 01–1450 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–29–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–006]

Notice of Prospective Patent License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of prospective patent license.

SUMMARY: NASA hereby gives notice that Nascent Technology Solutions, LLC, of Hampton, VA, has applied for an exclusive license to practice the invention disclosed in U.S. Patent No. 5,393,980 entitled "QUALITY MONITOR AND MONITORING TECHNIQUE EMPLOYING OPTICALLY STIMULATED ELECTRON EMISSION," which has been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. Written objections to the prospective grant of a license should be sent to Langley Research Center.

DATES: Responses to this notice must be received by March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Helen M. Galus, Patent Attorney, Langley Research Center, Mail Code 212, Hampton, VA 23681–2199; telephone (757) 864–3227.

Dated: January 9, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1472 Filed 1–17–01; 8:45 am]

BILLING CODE 7510–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Nuclear Regulatory Commission.

DATE: Weeks of January 15, 22, 29, February 5, 12, 19, 2001.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of January 15, 2001

Wednesday, January 17, 2001

9:25 a.m.—Affirmation Session (Public Meeting) (Tentative), a: Sequoyah Fuels Corporation (Gore, Oklahoma Site, Decommissioning) Docket No. 40–8027–MLA–4.

9:30 a.m.—Briefing on Status of Nuclear Reactor Safety (Public Meeting) (Contact: Mike Case, 301–415–1134).

This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*

Week of January 22, 2001—Tentative

There are no meetings scheduled for the Week of January 22, 2001.

Week of January 29, 2001—Tentative

Tuesday, January 30, 2001

9:30 a.m.—Briefing on Status of Nuclear Waste Safety (Public Meeting) (Contact: Claudia Seelig, 301–415–7243).

This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*

Wednesday, January 31, 2001

9:25 a.m.—Affirmation Session (Public Meeting) (If needed).

9:30 a.m.—Briefing on Status of OCIO Programs, Performance, and Plans (Public Meeting) (Contact: Donnie Grimsley, 301–415–8702).

This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*

Thursday, February 1, 2001

9:30 a.m.—Briefing on Status of OCFO Programs, Performance and Plans (Public Meeting) (Contact: Lars Solander, 301–415–6080).

This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*

Week of February 5, 2001—Tentative

Monday, February 5, 2001

1:55 p.m.—Affirmation Session (Public Meeting), (If needed).

Week of February 14, 2001—Tentative

Wednesday, February 14, 2001

9:25 a.m.—Affirmation Session (Public Meeting) (If needed).

Week of February 19, 2001—Tentative

Tuesday, February 20, 2001

9:25 a.m.—Affirmation Session (Public Meeting), (If needed).

9:30 a.m.—Briefing on Spent Fuel Pool Accident Risk at Decommissioning Plants and Rulemaking Initiatives (Public Meeting) (Contact: George Hubbard, 301–415–2870).

This meeting will be webcast live at the Web address—*www.nrc.gov/live.html*

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: David Louis Gamberoni (301) 415–1651.

Additional Information:

By a vote of 5–0 on January 9, and 10, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Affirmation of Private Fuels Storage, L.L.C. (Independent Spent Fuel Storage Installation); State of Utah's Partial Interlocutory Appeal of LBP–00–28" be held on January 10, and on less than one week's notice to the public.

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/SECY/smj/schedule.html

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to it, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to dkw@nrc.gov.

Dated: January 11, 2001.

David Louis Gamberoni,

Technical Coordinator, Office of the Secretary.

[FR Doc. 01–1592 Filed 1–16–01; 10:53 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27336; 70–9633]

Filings Under the Public Utility Holding Company Act of 1935, as Amended ("Act")

January 11, 2001.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 2, 2001, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After February 2, 2001, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Unitil Corporation, et al. (70–9633)

Unitil Corporation ("Unitil"), a registered holding company, and its subsidiary companies, Concord Electric Company, Exeter & Hampton Electric Company, Fitchburg Gas and Electric Light Company ("Fitchburg"), Unitil Power Corp., Unitil Realty Corp., Unitil Resources, Inc. and Unitil Services Corp. (collectively, "Subsidiaries" and, together with Unitil, "Applicants"), all located at 6 Liberty Lane West, Hampton, New Hampshire 03842–1720, have filed a post-effective amendment under sections 6(a), 7, 9(a), 10 and 12(b) of the Act and rules 43 and 45 under the Act, to a previously filed application-declaration.

By orders dated June 30, 1997, June 9, 2000, and December 15, 2000 (HCAR Nos. 26737, 27182, and 27307, respectively) ("Prior Orders"), the Commission authorized through June 30, 2003 ("Authorization Period"): (1) The Applicants to make unsecured short-term borrowings and to operate a system money pool ("Money Pool"); (2) Unitil to incur short-term borrowings from banks in an aggregate amount not to exceed $35 million ("Unitil Borrowing Authority"); and (3) Fitchburg to incur short-term borrowings from third parties and the other Applicants through the Money Pool in an aggregate amount not to exceed $20 million ("Fitchburg Borrowing Authority").

Applicants seek approval through the Authorization Period to increase: (1) the Unitil Borrowing Authority to $45 million and (2) the Fitchburg Borrowing Authority to $30 million. Applicants state that the requested increases in Unitil Borrowing Authority and Fitchburg Borrowing Authority will remain subject to the parameters as set forth in the Prior Orders.

Applicants state that the prices Unitil's subsidiaries, Unitil Power and Fitchburg, pay for wholesale electric and natural gas energy commodities have become unpredictably volatile. According to Applicants, the prices have risen sharply, putting a heavy strain on Unitil's working capital and significantly increasing its short-term borrowing requirements. Applicants state that the requested authorization is necessary to satisfy the cost of their wholesale energy obligations.

For the Commission by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1404 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–24824; File No. 812–12350]

Cova Series Trust, et al.

January 11, 2001.

AGENCY: Securities and Exchange Commission (the "Commission").

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ACTION: Notice of Application under Section 17(b) of the Investment Company Act of 1940 (the "1940 Act") for an exemption from Section 17(a) of the Act.

Summary of Application: Applicants request an order to permit certain series of Met Investors Series Trust ("MIT") to acquire all of the assets and liabilities of Cova Series Trust ("CST") and Securities First Trust ("SFT"). Because of certain affiliations, applicants may not rely on Rule 17a–8 under the Act.

Applicants: CST, SFT, MIT, Cova Financial Services Life Insurance Company ("Cova Financial Services Life"), Cova Financial Life Insurance Company ("Cova Financial Life", together with Cova Financial Services Life, "Cova Life"), Security First Life Insurance Company ("Security First Life") and Firstar Investment Research & Management Company, LLC ("FIRMCO").

Filing Dates: The application was filed on December 6, 2000.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing request should be received by the Commission by 5:30 p.m. on February 2, 2001, and should be accompanied by proof of service on Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Applicants: Cova Series Trust, Cova Financial Services Life Insurance Company and Cova Financial Life Insurance Company, One Tower Lane, Suite 3000, Oakbrook Terrace, Illinois, 60181; Security First Trust and Security First Life Insurance Company, 11365 W. Olympic Boulevard, Los Angeles, California 90064; Met Investors Series Trust, 610 Newport Centre Drive, Suite 1350, Newport Beach, California 92660; and Firstar Investment Research & Management Company, LLC, 777 E. Wisconsin Avenue, Suite 800, Oakbrook Terrace, Illinois 60181; Stacy H. Ostrowski, Esq., Sullivan & Worcester LLP, 1025 Connecticut Avenue, NW., Suite 1000, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Joyce M. Pickholz, Senior Counsel, or Keith E. Carpenter, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the Commission's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. (202) 942–8090).

Applicants' Representations

1. CST is a Massachusetts business trust registered under the 1940 Act as an open-end management investment company and is presently comprised of thirteen separate series, all of which are involved in the proposed transactions. Shares of each portfolio of CST are sold only to certain accounts of Cova Life and its affiliates to fund benefits under certain individual flexible premium and modified single premium variable life insurance policies and certain individual and group variable annuity contracts ("Variable Contracts") issued by Cova Life and its affiliates. As of the date of the application, Cova Life and its affiliates are the majority, and in most cases, the only shareholders of record of the Cova Portfolios.[1] CST, along with its series, are referred to herein collectively, as the "Cova Portfolios."

2. SFT is a Massachusetts business trust registered under the 1940 Act as an open-end management investment company and is presently comprised of four separate series. Shares of each series of SFT are sold only to certain accounts of Security First Life to fund benefits under certain Variable Contracts issued by Security First Life and to qualified pension and retirement plans. As of the date of this application, Security First Life's Separate Account A, its group employee 401(k) plan and its General Account are the only shareholders of record of the series of SFT. All four series are involved in the proposed transactions. SFT, along with its series, are referred to herein collectively, as the "Security First Portfolios" and collectively with the Cova Portfolios as the "Acquired Portfolios."

3. MIT is a newly created Delaware business trust registered under the 1940 Act as an open-end management investment company comprised of fourteen separate series which were established for purposes of the proposed transactions described herein. If shareholders approve the proposed transaction, MIT will be the surviving entity after the Cova and Security First Portfolios are merged into corresponding investment portfolios of MIT. A Registration Statement on Form N–1A was filed with the Commission for the newly created MIT and its series on October 23, 2000 and will become effective on the closing date of the proposed transactions. All of MIT's series are involved in the proposed transactions for which exemptive relief is being sought. MIT and its series are referred to herein collectively as the "Met Portfolios" and as the "Acquiring Portfolios."

4. Met Investors Advisory Corp. (formerly known as Security First Investment Management Corporation) ("Met Advisor") serves as investment adviser to SFT and will be the investment adviser to MIT but has delegated responsibility for the day-to-day management of the series to various unaffiliated sub-adviser. Met Advisory is a wholly-owned subsidiary of Security First Group, Inc. ("SFG"). SFG (which on or before February 5, 2001, will change its name to Met Investors Group, Inc.) is an indirect wholly-owned subsidiary of Metropolitan Life Insurance Company, a New York life insurance company ("MetLife"). Met Advisory is registered as an investment adviser under the Investment Advisers Act of 1940, as amended (the "Advisers Act").

5. Cova Investment Advisory Corporation ("Cova Advisory") serves as investment adviser to CST but has delegated responsibility for the day-to-day management of the series to certain unaffiliated investment sub-advisers.[2] Cova Advisory is an indirect wholly-owned subsidiary of MetLife. Cova Advisory is registered as an investment adviser under the Advisers Act.

6. Security First Life is a stock life insurance company founded in 1960 and organized under the laws of the State of Delaware. Security First Life is authorized to transact the business of life insurance, including annuities, and is currently licensed to do business in 49 states and the District of Columbia. Security First Life is a wholly-owned subsidiary of SFG.

7. Cova Financial Services Life is a stock life insurance company founded in 1981 and organized under the laws of the State of Missouri. Cova Financial Life, is a stock insurance company founded in 1972 and organized under the laws of the State of California. Cova Financial Services Life and Cova Financial Life are indirect wholly-owned subsidiaries of Met Life. Cova Life and its affiliates are authorized to transact the business of life insurance, including annuities, and among them are currently licensed to do business in 47 states and the District of Columbia.

8. FIRMCO currently serves as the investment sub-adviser to the Balanced, Equity Income and the Growth & Income Equity Portfolios of CST and will serve as investment adviser to the Firstar Balanced, Firstar Equity Income and the Firstar Growth & Income Equity Portfolios (collectively the "Firstar Portfolios") of the newly created MIT. FIRMCO is a subsidiary of Firstar Corporation. FIRMCO is registered as an investment adviser under the Advisers Act. FIRMCO currently owns of record 5% or more of each of the Balanced, Equity Income and Growth & Income Equity Portfolios of CST.

9. On November 1, 2000 and November 2, 2000, the Boards of Trustees of the Acquired Portfolios, including a majority of the Trustees who are not interested persons under Section 2(a)(19) of the 1940 Act (the "Disinterested Trustees"), authorized agreements and plans of reorganization (with respect to the Fund Reorganizations as defined below) (the "Plans") pursuant to which certain series of MIT will acquire all of the assets and stated liabilities of certain series of CST and SFT. Pursuant to the terms of the Plans, the Acquired Portfolios have agreed to sell all of their assets (subject to the assumption of certain stated liabilities) to certain corresponding Acquiring Portfolios in exchange for shares of the Acquiring Portfolios (the "Fund Reorganizations"). The exchange will take place at the respective net asset values calculated as of the close of business on the business day next preceding the date on which the Fund Reorganizations will occur. Shareholders of the Acquired Portfolios will exchange their shares for Class A shares of the Acquiring Portfolios. As a result of the Fund Reorganizations, each Acquired Portfolio shareholder will receive Acquiring Portfolio shares having an aggregate net asset value equal to the aggregate net asset value of the corresponding Acquired Portfolio's shares held by that shareholder. After the distribution of the Acquiring Portfolios' shares and the winding up of the Acquired Portfolios' business, the Acquired Portfolios will be liquidated.

10. No sales charge will be imposed in connection with Class A shares of the Acquiring Portfolios received by the Acquired Portfolios' shareholders. Accordingly, no sales charges will be incurred by shareholders of the Acquired Portfolios in connection with their acquisition of shares of the Acquiring Portfolios in the Fund Reorganizations. Upon consummation of the transactions described above, each Acquired Portfolio will distribute its full and fractional shares of the Acquiring Portfolio *pro rata* to its shareholders of record, determined as of the exchange date.

11. Prior to the Fund Reorganizations, the shareholders of the Acquired Portfolio and the Acquiring Portfolio will hold shares with similar characteristics. Shares of the Acquired Portfolios and Class A shares of the Acquiring Portfolios are sold without a front-end sales charge or a contingent deferred sales charge and are not subject to any Rule 12b–1 fees.

12. The investment objectives of each of the Acquired Portfolios is generally either identical to or similar to that of the corresponding Acquiring Portfolios. The investment strategies of each Acquired Portfolio and its corresponding acquiring Portfolio generally are also either identical or similar.

13. Each Plan may be terminated by the mutual agreement of the Boards of the Portfolios on behalf of the Acquiring Portfolio and the Acquired Portfolio, respectively.

14. The Boards of CST and SFT, on behalf of each of the Acquired Portfolios, including in each case a majority of Disinterested Trustee, approved the Fund Reorganization as in the best interests of shareholders and determined that the interests of existing shareholders will not be diluted as a result of the Fund Reorganizations. The Board of each Portfolio considered, among other things, (a) the terms and conditions of each Fund Reorganization; (b) whether the Fund Reorganization would result in the dilution of shareholders' interests; (c) the expense ratios, fees and expenses of the Acquiring Portfolios before the Fund Reorganization and the estimated expense ratios of the Acquiring Portfolios after the Reorganization; (d) comparability of the Acquiring and Acquiring Portfolios' investment restrictions; (e) the investment experience, expertise and resources of the investment advisers; (f) the service and distribution resources available to MIT and the anticipated increased array of investment alternatives available to shareholders of MIT; (g) the fact that the costs estimated to be incurred by the Portfolios as a result of the Fund Reorganizations will not be borne by the Portfolios but will be borne by MetLife or an affiliate; and (h) the expected federal income tax consequences of the Fund Reorganizations.

15. Each Fund Reorganization is subject to the approval of the Acquiring Portfolios shareholders. Special Meetings of the Shareholders of the Acquired Portfolios are scheduled to be held on or about January 26, 2000. Cova Life and its affiliates and Security First Life will vote all shares of the Acquired Portfolios in accordance with and in proportion to timely voting instructions received from Variable Contract owners participating in separate accounts requistered under the 1940 Act, the value of which are invested in shared of the Acquired Portfolio through such separate accounts at the record date. Shares of each Acquired Portfolio for which properly executed voting instructions are not received, including shares not attributable to Variable Contracts, will be voted in the same proportion as that of shares of such Acquired Portfolio for which instructions are received. Proxy materials have been mailed to the Variable Contract owners participating in registered separate accounts holding shares of the Acquired Portfolios. Proxies are not being solicited from 401(k) plan participants or any investment sub-advisers who hold shares of a Portfolio. The 401(k) plan fiduciary will vote its shares in proportion to the vote of Variable Contract owners.

16. Fund Reorganizations also are subject to the approval of the board of trustees of MIT (the "MIT Board"), on behalf of each of the Acquiring Portfolios, including in each case a majority of Disinterested Trustees. Prior to consummating the Fund Reorganization, the MIT Board will have reviewed the terms of the Fund Reorganizations and will have determined that the transactions are in the best interests of the Acquiring Portfolios. In approving the Plans, the Board will consider the relevant factors including, but not limited to those factors considered by the CST and SFT Boards.

17. MetLife or an affiliate will be responsible for the expenses incurred in connection with the Fund Reorganizations.

18. The Plans are subject to a number of conditions precedent, including requirements that (a) the Plans shall have been approved by the Boards on behalf of each of the Acquiring Portfolios and the Acquired Portfolio

[1] For ease of reference, the term "shareholder" is used hereinafter to refer to Variable Contract owners that are unit holders of any registered separate account that invests in a respective SFT Portfolio or Cova Portfolio (as defined herein).

[2] Shares of certain of the Cova Portfolios are held by their respective unaffiliated sub-advisers, including FIRMCO as discussed herein.

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and approved by the requisite votes of the holders of the outstanding shares of each of the Acquired Portfolios in accordance with the provisions of each Portfolio's Agreement and Declaration of Trust and By-laws; (b) the Acquired Portfolio and the Acquiring Portfolio have received opinions of counsel stating, among other things, that (i) each Fund Reorganization will constitute a "fund reorganization" under Section 368 of the Internal Revenue Code of 1986, as amended (the "Code"), (ii) the Acquiring Portfolio and the Acquired Portfolio is a "party to a fund reorganization" within the meaning of Section 368 of the Code, (iii) no gain or loss will be recognized by the Acquiring Portfolio upon the receipt of the assets of the Acquired Portfolio solely in exchange for the Acquiring Portfolio shares and the assumption by the Acquiring Portfolio of the identified liabilities of the Acquired Portfolio and (iv) no gain or loss will be recognized by the Acquired Portfolio upon the transfer of the Acquired Portfolio's assets to the Acquiring Portfolio in exchange for the Acquiring Portfolio shares and the assumption by the Acquiring Portfolio of the identified liabilities of the Acquired Portfolio or upon the distribution of the Acquiring Portfolio shares to Acquired Portfolio shareholders in exchange for their shares of the Acquired Portfolio; and (c) the Acquired Portfolio and the Acquiring Portfolio shall have received from the Commission an order exempting the Fund Reorganizations from the provisions of Section 17(a) of the 1940 Act.

Applicants' Legal Analysis

1. Section 17(a) of the 1940 Act provides, in pertinent part, that it is unlawful for any affiliated person of a registered investment company, or any affiliated person of such a person, "(1) knowingly to sell any security or other property to such registered company * * * [or] (2) knowingly to purchase from such registered company * * * any security or other property * * *" Section 2(a)(3) of the 1940 Act defines the term "affiliated person" of another person in include, in pertinent part, "(A) any person directly or indirectly owning, controlling, or holding with power to vote, 5 per centum or more of the outstanding voting securities of such other person; (B) any person 5 per centum or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such other person; (C) any person directly or indirectly controlling, controlled by, or under common control with, such other person * * *; and (E) if such other person in an investment company, any is an investment advises thereof * * *"

2. Applicants assert that Rule 17a–8 under the 1940 Act may not be available to exempt the proposed transactions described herein. The premise of Rule 17a–8 is that the investment companies involved in mergers or consolidations are under common control by virtue of having a common investment adviser, directors and/or officers and no other affiliation exists. In this case, certain of the Portfolios may be deemed to be affiliated persons or affiliated persons of each other because of the Insurance Companies and FIRMCO's share ownership of the Portfolios.

3. Section 17(b) of the 1940 Act provides that, notwithsfanding Section 17(a), any person may file with the Commission an application for an order exempting a proposed transaction from one or more provisions of that subsection and that the Commission shall grant such application and issue such order of exemption if evidence establishes that "(1) the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; (2) the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and reports filed under [the 1940 Act], and (3) the proposed transaction is consistent with the general purpose of [the 1940 Act] * * *."

4. Applicants submit that the terms of the Fund Reorganizations satisfy the standards set forth in section 17(b), in that the terms are fair and reasonable and do not involve overreaching on the part of any person concerned. Applicants note that the Boards of Trustees of CST and SFT, including the Disinterested Trustees, found that participation in the Fund Reorganization is in the best interests of each Portfolio based on the following factors: (a) The interests of shareholders will not be diluted; (b) the Portfolio's investment objectives and policies generally are substantially similar; (c) certain operational efficiencies may be achieved upon the combination of the Portfolios as a result of the economies of scale associated with a more diverse family of mutual funds; (d) no sales charges will be imposed in connection with the Fund Reorganizations; (e) the service and distribution resources available to MIT and the anticipated increased array of investment alternatives available to shareholders of MIT; (f) the transactions will be free from Federal income taxes; (g) the conditions and policies of Rule 17a–8 under the 1940 Act will be followed; (h) the transfer of securities in exchange for shares will be at relative net asset value; and (i) no overreaching by any person concerned with the transactions will occur.

Conclusion

For the reasons and upon the facts set forth above, Applicants state that the requested order meets the standards set forth in Section 17(b) and should, therefore, be granted.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1403 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–24823 (812–12276)]

PaineWebber PACE Select Advisors Trust and Mitchell Hutchins Asset Management, Inc.; Notice of Application

January 11, 2001.

AGENCY: Securities and Exchange Commission ("Commission")

ACTION: Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") to amend a prior order that granted an exemption from section 15(a) of the Act and rule 18f–2 under the Act.

Summary of Application: Applicants request an order amending a prior order ("Prior Order") that permits them to enter into and materially amend investment sub-advisory contracts without receiving shareholder approval.[1]

Applicants: PaineWebber PACE Select Advisors Trust (formerly, Managed Accounts Services Portfolio Trust) (the "Trust") and Mitchell Hutchins Asset Management Inc. ("Mitchell Hutchins").

Filing Date: The application was filed on November 30, 1999 and amended on January 5, 2001.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving

[1] *Managed Accounts Services Portfolio Trust and Mitchell Hutchins Asset Management, Inc.*, Investment Company Act Release Nos. 21590 (Dec. 15, 1995) (notice) and 21666 (Jan. 11, 1996) (order).

applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on February 5, 2001, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Commission, 450 Fifth Street, N.W., Washington, D.C. 20549–0609. Applicants: 1285 Avenue of the Americas, New York, New York 10019.

FOR FURTHER INFORMATION CONTACT: Sara P. Crovitz, Senior Counsel, at (202) 942–0667 or Nadya Roytblat, Assistant Director, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the Commission's Public Reference Branch, 450 Fifth Street, N.W., Washington, D.C. 20549–0101, (202) 942–8090.

Applicants' Representations

1. The Trust is an open-end management investment company currently composed of twelve investment portfolios ("Portfolios"). Mitchell Hutchins, a wholly owned subsidiary of PaineWebber, acts as investment manager and administrator to the Trust and is responsible, subject to oversight by the Board of Trustees of the Trust ("Board") for the selection of investment sub-advisers ("Sub-Advisers") and the ongoing review of the Sub-Advisers' performance.

2. On January 11, 1996, applicants received the Prior Order permitting the Trust and Mitchell Hutchins to enter into sub-advisory agreements ("Sub-Advisory Agreements") for the Portfolios without obtaining shareholder approval. Among other things, the Prior Order is subject to a condition that requires a notice, in the form of an information statement, be sent to shareholders following the hiring of a new Sub-Adviser or the implementation of a material change to a Sub-Advisory Agreement. Applicants seek to amend the Prior Order to preserve the requirement to provide notice to shareholders regarding the hiring of a new Sub-Adviser, but to eliminate the requirement to provide a notice in the form of an information statement of other material changes to a Sub-Advisory Agreement. Applicants state that supplements to the Trust's prospectus or statements of additional information serve as a more appropriate and less costly alternative to the latter requirement. Applicants also seek to amend the Prior Order to eliminate the requirement that shares of the Trust be offered exclusively to participants in the PaineWebber PACE Program (the "Pace Program") or other asset allocation services.

Applicants' Legal Analysis

1. Section 6(c) of the Act authorizes the Commission to exempt persons or transactions from any provisions of the Act to the extent that such exemptions are necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants submit that amending the Prior Order as requested would be consistent with the standards of section 6(c) of the Act.

Applicants' Conditions

Applicants agree that the order granting the requested relief will be subject to the following conditions:

1. Before a Portfolio may rely on the order, the operation of the Portfolio in the manner described in the application will be approved by a majority of the outstanding voting securities of the Portfolio, as defined in the Act, or in the case of a Portfolio whose public shareholders purchased shares on the basis of a prospectus containing the disclosure contemplated by condition 2 below, by the sole initial shareholder before offering shares of such Portfolio to the public.

2. The Trust will disclose in all prospectuses relating to any Portfolio the existence, substance and effect of any order granted pursuant to the application. In addition, each Portfolio relying on the requested order will hold itself out to the public as employing the management structure described in the application. The prospectus will prominently disclose that Mitchell Hutchins has the ultimate responsibility (subject to oversight by the Board) to oversee the Sub-Advisers and recommend their hiring, termination and replacement.

3. At all times, a majority of the trustees of the Trust will be persons each of whom is not an "interested person" of the Trust (as defined in section 2(a)(19) of the Act) (the "Independent Trustees"), and the nomination of new or additional Independent Trustees will be placed within the discretion of the then existing Independent Trustees.

4. Mitchell Hutchins will not enter into a Sub-Advisory Agreement with any Sub-Adviser that is an affiliated person (as defined in section 2(a)(3) of the Act) of the Trust, Mitchell Hutchins or the Portfolios, other than by reason of serving as a Sub-Adviser to one or more of the Portfolios (the "Affiliated Sub-Adviser") without such agreement, including the compensation to be paid thereunder, being approved by the shareholders of the applicable Portfolio.

5. When a Sub-Adviser change is proposed for a Portfolio with an Affiliated Sub-Adviser, the trustees of the Trust, including a majority of the Independent Trustees, will make a separate finding, reflected in the Board minutes, that the change is in the best interests of the Portfolio and its shareholders and does not involve a conflict of interest from which Mitchell Hutchins or the Affiliated sub-Adviser derives an inappropriate advantage.

6. Within 90 days of the hiring of any new SubAdviser, the Trust will furnish shareholders of the applicable Portfolio all information about a new Sub-Adviser that would be included in a proxy statement. Such information will include any change in such disclosure caused by the addition of a new Sub-Adviser. The Trust will meet this condition by providing shareholders with an information statement meeting the requirements of Regulation 14C and Schedule 14C and Item 22 of Schedule 14A under the Securities Exchange Act of 1934.

7. Mitchell Hutchins will provide general management and administrative services to the Trust, and, subject to review and approval by the Board, will: (a) Set the Portfolios' overall investment strategies; (b) evaluate, select and recommend Sub-Advisers to manage all or a part of the Portfolio's assets; (c) allocate and, when appropriate, reallocate the Portfolios' assets among Sub-Advisers; (d) monitor and evaluate the investment performance of Sub-Advisers; and (e) implement procedures reasonably designed to ensure that the Sub-Advisers comply with the relevant Portfolio's investment objectives, policies and restrictions.

8. No Trustee or officer of the Trust or director or office of Mitchell Hutchins will own directly or indirectly (other than through a polled investment vehicle that is not controlled by any such Trustee, director or officer) any interest in a Sub-Adviser except for: (a) Ownership of interest in Mitchell Hutchins or in any entity that controls, is controlled by, or is under common control with Mitchell Hutchins; or (b) ownership of less than 1% of the outstanding securities of any class of

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equity or debt of a publicly traded company that is either a Sub-Adviser or an entity that controls, is controlled by, or is under common control with a Sub-Adviser.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1405 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24825; 812–12352]

CityFed Financial Corp.; Notice of Application

January 11, 2001.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for an order under sections 6(c) and 6(e) of the Investment Company Act of 1940 ("Act") for exemption from all provisions of the Act, except sections 9, 17(a) (modified as discussed in the application), 17(d) (modified as discussed in the application), 17(e), 17(f), 36 through 45, and 47 through 51 of the Act and the rules thereunder.

SUMMARY OF APPLICATION: The requested order would exempt the applicant, CityFed Financial Corp. ("CityFed"), from certain provisions of the Act until the earlier of one year from the date the requested order is issued or such time as CityFed would no longer be required to register as an investment company under the Act. The order would extend an exemption granted until February 9, 2001.[1]

FILING DATES: The application was filed on December 4, 2000 and amended on January 10, 2001.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 5, 2001, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549–0609. CityFed, 4 Young's Way, P.O. Box 3126, Nantucket, MA 02584.

FOR FURTHER INFORMATION CONTACT: Bruce R. MacNeil, Senior Counsel, at (202) 942–0634, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. no. 202–942–8090).

Applicant's Representations

1. CityFed was a savings and loan holding company that conducted its savings and loan operations through its wholly-owned subsidiary, City Federal Savings Bank ("City Federal"). During the five-year period ending December 31, 1988, City Federal was the source of substantially all of CityFed's revenues and income. As a result of substantial losses in its mortgage banking and real estate operations, City Federal was unable to meet its regulatory capital requirements. Accordingly, on December 7, 1989, the Office of Thrift Supervision ("OTS") placed City Federal into receivership and appointed the Resolution Trust Corporation ("RTC") as City Federal's receiver. City Federal's deposits and substantially all of its assets and liabilities were acquired by a newly created federal mutual savings bank, City Savings, F.S.B. ("City Savings"). The OTS appointed the RTC as receiver of City Savings.

2. Once City Federal was placed into receivership, CityFed no longer conducted savings and loan operations through any subsidiary. Thus, since December 8, 1989, almost all of CityFed's assets consisted of cash that has been invested in (i) money market instruments with a maturity of one year or less, and (ii) money market mutual funds.

3. On June 2, 1994, the OTS issued a Notice of Charges ("OTS Action") against CityFed and certain current or former directors and, in some cases, officers of CityFed and City Federal ("Individual Respondents"). The OTS Action sought restitution from and a civil money penalty against both CityFed and the Individual Respondents. Also on June 2, 1994, the OTS issued a Temporary Order to Cease and Desist ("Temporary Order") against CityFed. The Temporary Order sought to freeze CityFed's assets by placing them in various respects under the controls of the OTS. On October 26, 1994, CityFed and the OTS entered into an escrow agreement with CoreStates Bank, N.A. (now First Union National Bank ("First Union")) ("Escrow Agreement") pursuant to which CityFed transferred substantially all of its assets to First Union for deposit into an escrow account. The Escrow Agreement provided CityFed with $15,000 per month for operating expenses and allowed CityFed to sell and purchase securities in the escrow account.

4. On May 19, 2000, CityFed finalized with the OTS and the Federal Deposit Insurance Corporation ("FDIC"), the statutory successor to the RTC, a settlement of the OTS Action ("Settlement"). Pursuant to the Settlement, the OTS dismissed with prejudice the OTS Action and the FDIC gave full and complete releases to CityFed and the Individual Respondents. In turn, CityFed and the Individual Respondents gave full and complete releases to the OTS and the FDIC. The OTS also dissolved the Temporary Order and authorized First Union to release to CityFed all of its assets remaining in the escrow account.

5. On December 7, 1992, the RTC filed suit against CityFed and two former officers of City Federal seeking damages of $12 million for failure to maintain the net worth of City Federal ("First RTC Action"). In light of the filing of the OTS Action on June 2, 1994, the RTC and CityFed agreed to dismiss without prejudice the RTC's claim against CityFed in the First RTC Action. Pursuant to the Settlement, the FDIC released CityFed from all claims in the First RTC Action.

6. The RTC also filed suit against several former directors and officers of City Federal alleging gross negligence and breach of fiduciary duty with respect tot certain loans ("Second RTC Action"). The RTC sought in excess of $200 million in damages. CityFed states that all of the defendants in the Second RTC Action have settled with the RTC or the FDIC. Pursuant to the Settlement, the FDIC assigned any rights it acquired in these settlements to CityFed. Under its bylaws, CityFed may be obligated to indemnify these former officers and directors and pay their legal expenses, including settlement amounts. On the advice of counsel to a special committee of CityFed's board of directors, comprised of directors who have not been named in the First or Second RTC Action, CityFed advanced reasonable

[1] CityFed Financial Corp., Investment Company Act Release Nos. 24252 (Jan. 13, 2000) (notice) and 24283 (Feb. 9, 2000) (order).

defense costs to the former directors and officers named in the Actions. CityFed is unable to determine with any accuracy the extent of its liability with respect to these indemnification claims, although the amount may be material.

7. On August 7, 1995, CityFed, acting in its own right and as shareholder of City Federal, filed a civil action in the United States Court of Federal Claims seeking damages for loss of "supervisory goodwill" on its books as a result of various acquisitions by City Federal of troubled depository institutions. Pursuant to the Settlement, CityFed assigned to the FDIC all of CityFed's interest in its supervisory goodwill action, ceased to be a party to the case, and has no right to share in the recovery in that case, should there be one.

8. CityFed is subject to a number of loss contingencies for which it is currently unable to assess reasonably the probability or range of loss. CityFed intends to resolve all claims against it at the minimum cost possible. While CityFed's board of directors has considered from time to time whether to engage in an operating business, CityFed states that it cannot resume an operating business at the present time because the amount required to resolve its currently outstanding claims cannot be reasonably estimated and could exceed CityFed's assets. Following the Settlement, CityFed may undergo reorganization, perhaps involving a bankruptcy proceeding. It is anticipated that CityFed's outstanding claims, including its indemnification claims, will be addressed prior to, or as part of, any reorganization.

9. CityFed states that at present there is no public market for its stock and that it is traded sporadically in the over-the-counter market. Since City Federal's receivership, the operating expenses of CityFed have consisted of the employees' salaries, office expenses, and accounting and legal expenses. CityFed currently has one full-time employee and one office. As of September 30, 2000, CityFed held cash and securities of approximately $6.4 million.

Applicant's Legal Analysis

1. Section 3(a)(1)(A) defines an investment company as any issuer "is or holds itself out as being engaged primarily * * * in the business of investing, reinvesting or trading in securities." Section 3(a)(1)(C) further defines an investment company as an issuer who is engaged in the business of investing in securities that have a value in excess of 40% of the issuer's total assets (excluding government securities and cash).

2. Section 6(c) of the Act provides that the SEC may exempt any person from any provision of the Act "if and to the extent that such exemption is necessary or appropriate in the public interest." Section 6(e) provides that in connection with any SEC order exempting an investment company from any provision of section 7, certain specified provisions of the Act shall be applicable to such company, and to other persons in their transactions and relations with such company, as through such company were registered under the Act, if the SEC deems it necessary or appropriate in the public interest or for the protection of investors.

3. CityFed acknowledges that it may be deemed to fall within one of the Act's definitions of an investment company. Accordingly, CityFed requests an exemption under sections 6(c) and 6(e) from all provisions of the Act, subject to certain exceptions described below. CityFed requests an exemption until the earlier of one year from the date of the requested order or such time as it would no longer be required to register as an investment company under the Act.

4. In determining whether to grant an exemption for a transient investment company, the SEC considers such factors as whether the failure of the company to become primarily engaged in a non-investment business or excepted business or liquidate within one year was due to factors beyond its control; whether the company's officers and employees during that period tried, in good faith, to effect the company's investment of its assets in a non-investment business or excepted business or to cause the liquidation of the company; and whether the company invested in securities solely to preserve the value of its assets. CityFed believes that it meets these criteria.

5. CityFed believes that its failure to become primarily engaged in a non-investment business by February 9, 2001, is due to factors beyond its control. CityFed asserts that the amount required to resolve its currently outstanding claims cannot be reasonably estimated and could exceed its assets. If CityFed is unable to resolve these claims successfully, it states that it may seek protection from the bankruptcy courts or liquidate. CityFed also asserts that it probably will not be in a position to determine what course of action to pursue until most, if not all, of its contingent liabilities are resolved. Additionally, CityFed states that its circumstances are unlikely to change over the requested one-year period in light of the number of claims currently pending against it. Since the filing of its initial application for exemptive relief under sections 6(c) and 6(e) on October 19, 1990, CityFed has invested in money market instruments and money market mutual funds solely to preserve the value of its assets.

6. During the term of the proposed exemption, CityFed states that it will comply with sections 9, 17(a) and (d) (subject to the modifications described in condition 4, below), 17(e), 17(f), 36 through 45, and 47 through 51 of the Act and the rules thereunder.

Applicant's Conditions

CityFed agrees that the requested order will be subject to the following conditions:

1. CityFed will not purchase or otherwise acquire any securities other than short-term U.S. government securities, certificates of deposit, commercial paper rated A–1/P–1, and shares of registered money market funds; except that CityFed may acquire equity securities of an issuer that is not an investment company as defined in section 3(a) of the 1940 Act or is relying on an exclusion from the definition of investment company under section 3(c) of the 1940 Act other than section 3(c)(1) or 3(c)(7), in connection with the acquisition of an operating business as evidenced by a resolution approved by CityFed's board of directors.

2. CityFed will not hold itself out as being engaged in the business of investing, reinvesting, owning, holding, or trading in securities.

3. CityFed's Form 10–KSB, Form 10–QSB and annual reports to shareholders will state that an exemptive order has been granted pursuant to sections 6(c) and 6(e) of the Act and that CityFed and other persons, in their transactions and relations with CityFed, are subject to sections 9, 17(a), 17(d), 17(e), 17(f), 36 through 45, and 47 through 51 of the Act, and the rules thereunder, as if CityFed were a registered investment company, except as permitted by the order requested hereby.

4. Notwithstanding sections 17(a) and 17(d) of the Act, an affiliated person (as defined in section 2(a)(3) of the Act) of CityFed may engage in a transaction that otherwise would be prohibited by these sections with CityFed:

a. If such proposed transaction is first approved by a bankruptcy court on the basis that (i) The terms thereof, including the consideration to be paid or received, are reasonable and fair to CityFed, and (ii) the participation of CityFed in the proposed transaction will not be on a basis less advantageous to CityFed than that of other participants; and

b. In connection with each such transaction, CityFed shall inform the

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bankruptcy court of (i) the identity of all of its affiliated persons who are parties to, or have a direct or indirect financial interest in, the transaction; (ii) the nature of the affiliation; and (iii) the financial interests of such persons in the transaction.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1484 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43827; File No. SR–CBOE–00–60]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. To Change Its Membership Application Posting Process and Clarify Its Membership Rules

January 9, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2000, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to change its membership application posting process and to make some clarifying revisions to its membership rules.

Below is the text of the proposed rule change. Proposed new language is italicized and proposed deletions are in brackets.

Chicago Board Options Exchange, Incorporated—Rules

* * * * *

Chapter III—Membership

* * * * *

Application Procedures and Approval or Disapproval

Rule 3.9.

(a)–(d) Unchanged.

(e) Within a reasonable time following receipt of an application for membership *from an applicant that has not been a member within 6 months prior to the date of receipt of the application by the Membership Department*[, an application to change membership capacity statutes set forth in Rule 3.2(b) or 3.3(b),] or an application to change Clearing Members, the name of the applicant and the application request shall be published in the Exchange Bulletin and posted on the Exchange Bulletin Board. The Membership Committee shall determine for each type of the foregoing applications the required time period that the above information must be posted on the Exchange Bulletin Board, provided that in no event shall any such required posting period be less than 10 days. Notwithstanding the foregoing, the required posting period for a member's application to change Clearing Members shall be waived if the Clearing Member(s) that will no longer be guaranteeing the member's Exchange transactions consent to such waiver in a form and manner prescribed by the Exchange. The Membership Committee may also determine to implement a posting period requirement for other types of applications submitted pursuant to paragraph (a) of this Rule. The Membership Committee may shorten or waive a required posting period for an applicant if the Membership Committee determines that doing so is warranted due to extenuating circumstances.

(f) The Membership Department shall investigate each applicant applying to be a member organization, each associated person required to be approved by the Membership Committee pursuant to Rule 3.6(b), and each applicant applying to be an individual member (with the exception of *any associated person applicant that is a current member*, any [individual] member applicant *that* [who] was *a* [an individual] member within 6 months prior to the date of receipt of that applicant's membership application by the Membership Department, *and any member or associated person applicant that was investigated by the Membership Department within 6 months prior to the date of receipt of that applicant's application by the Membership Department*). The Membership Department may [also] investigate *any applicant that is not required to be investigated pursuant to this paragraph (f) and* any other person or organization that submits an application pursuant to paragraph (a) of this Rule.

(g) Unchanged.

(h) The Membership Committee may approve an application submitted pursuant to paragraph (a) of this Rule only if any applicable posting period requirement pursuant to paragraph (e) of this Rule has been satisfied, any investigation pursuant to paragraph (f) of this Rule has been completed, and any applicable orientation and exam requirements pursuant to paragraph (g) of this Rule have been satisfied.

* * * Interpretations and Policies:

.01–.02 Unchanged.

* * * * *

Purchase of Membership

Rule 3.13.

(a)–(b) Unchanged.

(c) Payment. Not later than the second business day following the acceptance of a bid pursuant to paragraph (a) of this Rule or the matching of a bid and offer pursuant to paragraph (b) of this Rule, the purchaser shall deliver to the Membership Department a certified or cashier's check *in the amount of the purchase price* made payable to the Exchange [covering the purchase price of the membership] *or complete a wire transfer in the amount of the purchase price to an Exchange account designated the Exchange.*

Sale and Transfer of Membership

Rule 3.14.

(a)–(b) Unchanged.

(c) Transfer by Owner. The owner of a transferable membership may transfer the membership without adhering to the provisions contained in Rule 3.13(b) and paragraph (a) of this Rule so long as one of the following qualifying circumstances is applicable to and descriptive of the desired transfer and the transferee is approved to be an owner or lessor:

(i) The owner of a transferable membership (whether or not the membership is registered for a member organization) requests the transfer of the membership to the member's spouse, brother, sister, parent, child, grandparent, or grandchild;

(ii) The owner of a transferable membership requests the transfer of the membership to an organization which has succeeded, through statutory merger, exchange of stock, or acquisition of assets to the business of the transferor;

(iii) The owner of a transferable membership requests the transfer of the membership to an organization in which the transferor will maintain an interest at least equal in value to the current market price of the membership; or

(iv) The owner of a transferable membership requests the transfer of such membership to an individual or organization which is a partner or shareholder *with a 50% or greater interest in* [of] the transferor as part or all of a [liquidation] distribution of the transferor.

(d)(i)–(d)(vii) Unchanged.

(viii) The grant of an Authorization to Sell a membership shall include the grant of a security interest (*A*) in any proceeds from the sale of the membership that the grantee of the Authorization to Sell is entitled to receive pursuant to Rule 3.15(v)[,] and *(B) in the membership to the extent necessary to establish the priority of the preceding security interest in such proceeds. A* [a] properly executed Authorization to Sell form that has been filed with the Membership Department shall constitute a security agreement which grants the foregoing security interest to the grantee of the Authorization to Sell. The grantee of an Authorization to Sell may act to perfect the foregoing security interest under applicable law, which may include the filing of one or more UCC–1 Financing Statements. However, failure by a grantee of an Authorization to Sell to perfect the foregoing security interest under applicable law shall not affect the rights of the grantee under the Rules. In the event of a cancellation of an Authorization to Sell pursuant to paragraph (d)(iv) of this Rule, the grantee of the Authorization to Sell shall promptly file a Termination Statement with every filing authority where UCC–1 Financing Statement were filed with respect to the Authorization to Sell. The grantee of an Authorization to Sell shall promptly file with the Membership Department a file-stamped copy of any UCC filings made with respect to the Authorization to Sell.

* * * * *

Member Death Benefit

Rule 3.24

(a) Unchanged.

(b) The following individuals shall be eligible for the Member Death Benefit:

(i) any individual who is an active member at the time of his or her death; and

(ii) any individual who (i) was an active member within 90 days prior to the date of his or her death and (ii) was an active member during at least 274 out of 365 days preceding the date of his or her last termination from active member status.

(c) For the purposes of this Rule, the term "active member" shall mean any *individual member* [natural person] who is a nominee of a member organization, a Chicago Board of Trade exerciser, a lessee of an Exchange membership, or an owner of an Exchange membership that is not being leased to a lessee.

(d)–(e) Unchanged.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to change the Exchange's membership application posting process and to make some clarifying revisions to the Exchange's membership rules.

CBOE Rule 3.9(e) requires that a posting be included in the Exchange Bulletin and on the Exchange Bulletin Board with respect to any application for membership, any application from a current member to change membership capacity statuses, and any application to change Clearing Members (unless the posting is waived under certain specified circumstances in accordance with the provisions of the Rule). CBOE Rule 3.9(e) also provides that the posting period on the Exchange Bulletin Board be no less than ten days, and that the Exchange's Membership Committee shall determine the required posting period for each of these types of applications in conformity with this minimum time period. The posting period for each of these application categories is fourteen days. The posting is required to set forth the name of the applicant and the application request, and its purpose is to provide members with an opportunity to submit information concerning an applicant that may bear on the applicant's qualifications and fitness for membership under the Exchange's rules. Under CBOE Rule 3.9(h), an application may not be approved, among other things, until any applicable posting requirement has been satisfied.

There are two related factors that have caused the Exchange to propose changing its membership application posting process. First, the Exchange receives no submissions from members in response to the postings for the vast majority of applicants that are posted to the membership on the Exchange's Bulletin Board as part of the posting process. Second, the Exchange has a less extensive and shorter application process for current members that are applying to change membership capacity statutes and for member applicants that have been a member within the prior six months. In most cases, the Exchange is able to process these applications well before the expiration of the posting period. According, the vast majority of these applicants are required to wait for a period of time following the completion of the processing of their applications for their new membership capacities to become effective. This results in inefficiency in the conduct of business on the Exchange as well as inconvenience to these applicants.

As a result, the Exchange is proposing to change its membership application posting process in a manner that seeks to eliminate this inefficiency and inconvenience while at the same time preserving the ability of members to submit information concerning the qualifications and fitness for membership of applicants. Specifically, the Exchange is proposing to amend CBOE Rule 3.9(e) to eliminate the requirement that there be a posting period for current members that are applying to change membership capacity statuses and for member applicants that have been a member within the prior six months. Additionally, the Exchange intends to notify its membership via circular that the Membership Department will accept submissions concerning any current or former member at any time (in contrast to the current limited formal submission period during the posting period) and that these submissions will be retained in the member's membership file.[3] Subsequently, if a current or former member submits any membership

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The CBOE indicated that the circular will be detailed and widely disseminated. The circular will be attached to the back of the CBOE rule book and made readily available to the public. Telephone conversation between Arthur Reinstein, Associate General Counsel, CBOE, and Sapna C. Patel, Attorney, Division of Market Regulation, Commission (Jan. 5, 2001).

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application and there is a submission for that current or former member in the membership file at the time of submission of the application, the submission concerning that current or former member will be reviewed and considered in the same manner that occurs under the posting process.

The Exchange is proposing to retain the posting period requirement for new membership applicants (*i.e.*, those membership applicants that have never been a member or that have not been a member within the prior six months). The posting period generally does not result in a delay in processing these applications because they are subject to a more extensive and longer application process that takes in excess of fourteen days (during which there is adequate time to complete a fourteen day posting). In addition, the Exchange is proposing to retain the posting period for an application to change Clearing Members (which in the vast majority of cases is waived pursuant to the current provision of CBOE Rule 3.9(e), which provides for the waiver of this posting period if the Clearing Member(s) that will no longer be guaranteeing the member's Exchange transactions consents to such a waiver).

The Exchange is also proposing to make the following clarifying changes to its membership rules:

First, the Exchange is proposing to revise CBOE Rule 3.9(f) to clarify those categories of membership applicants for which the Exchange does not conduct a background investigation due to the fact that the applicant is a current member, the applicant was recently a member, or the Exchange recently conducted a background investigation concerning the applicant. Specifically, CBOE is proposing to revise Rule 3.9(f) to clarify that the Membership Department is not required under CBOE Rule 3.9(f) to investigate the following categories of applicants: (i) Any associated person applicant that is a current member, (ii) any member applicant that was a member within six months prior to the date of receipt of that applicant's membership application by the Membership Department, and (iii) any member or associated person applicant that was investigated by the Membership Department within six months prior to the date of receipt of that applicant's application by the Membership Department. In addition, CBOE is proposing to revise Rule 3.9(f) to clarify that the Membership Department retains the discretion to investigate any applicant that is not required to be investigated under CBOE Rule 3.9(f) if the Membership Department determines that a background investigation is warranted under the circumstances.

Second, CBOE is proposing to revise Rule 3.13(c) to clarify that the Exchange will accept payment for the purchase of a membership by a certified or cashier's check or via a wire transfer.

Third, the Exchange is proposing to clarify the provisions of CBOE Rule 3.14(c)(iv). CBOE Rule 3.14(c)(iv) sets forth one of the four circumstances pursuant to which a membership may be transferred without going through the normal auction process for the purchase and sale of Exchange memberships. Specifically, CBOE Rule 3.14(c)(iv) provides that the owner of a transferable membership may request the transfer of the membership to an individual or organization which is a partner or shareholder of the transferor as part or all of a distribution of the transferor. Under CBOE Rule 3.3.01, the transferee could also be a limited liability company member if the transferor were a limited liability company. CBOE is proposing to clarify Rule 3.14(c)(iv) in two respects. First, CBOE is proposing to revise Rule 3.14(c)(iv) to clarify that the transferee must have at least a fifty percent interest in the transferor. Without this provision, a person could avoid the normal membership auction process by becoming a nominal partner or shareholder in a member organization and then having the member organization transfer the membership to that partner or shareholder. Second, CBOE is proposing to revise Rule 3.14(c)(iv) to delete the word "liquidation" due to the fact that it results in confusion as to what constitutes a liquidation distribution and what constitutes a non-liquidation distribution (given that an entity can have partial liquidation in which it does not distribute all of its assets and continues in operation following the partial liquidation). Because the Exchange has interpreted Rule 3.14(c)(iv) to permit membership transfers in connection with partial liquidation distributions, and because the Exchange believes there is no meaningful distinction in this context between a partial liquidation distribution and a regular distribution, the Exchange is proposing to delete the word "liquidation" to make it easier for members to understand CBOE Rule 3.14(c)(iv).

Fourth, the Exchange is proposing to clarify the nature of the security interest received by the grantee of an Authorization to Sell under CBOE Rule 3.14(d)(viii). CBOE Rule 3.14(d) provides an owner of a transferable membership the ability to voluntarily grant to another member an Authorization to Sell the membership. The grantee of an Authorization to Sell is vested with all of the authority provided for under the Exchange's Constitution and Rules relating to the sale of the membership. The grantee of an Authorization to Sell also has the right on the sale of the membership to submit claims against the grantor pursuant to CBOE Rule 3.15(b), to be satisfied out of the proceeds of the sale of the membership, that are related to the grantor's Exchange business activities. CBOE Rule 3.14(d)(viii) provides that the grant of an Authorization to Sell a membership includes the grant of a security interest in any proceeds from the sale of the membership that the grantee of the Authorization to Sell is entitled to receive under CBOE Rule 3.15(b). The exchange is proposing to revise CBOE Rule 3.14(d)(viii) to clarify that the grant of an Authorization to Sell also includes the grant of a security interest in the membership itself to the extent necessary to establish the priority of the security interest in the membership sale proceeds the grantee is entitled to receive under CBOE Rule 3.15(b). The Exchange has interpreted CBOE Rule 3.14(d)(viii) to provide for such a security interest in the membership itself and believes that the grant of such a security interest is fairly and reasonably implied from the existing language of CBOE Rule 3.14(d)(viii). The Exchange is simply proposing to revise CBOE Rule 3.14(d)(viii) to make the language of CBOE Rule 3.14(d)(viii) more explicit in this regard.

Finally, the Exchange is proposing to revise CBOE Rule 3.24, the Exchange's Member Death Benefit Rule, to make clear that the term "active member" under that Rule only includes individual members and is not intended to include associated persons who are not individual members pursuant to the Exchange's Rules. Specifically, the definition of the term "active member" in CBOE Rule 3.24(c) would be revised to replace the words "natural person" in that definition with the words "individual member." The remainder of the definition of "active member" in CBOE Rule 3.24(c) would not be revised. Thus, as revised, the definition of "active member" contained in CBOE Rule 3.24(c) would state that the term "active member" shall mean any individual member who is a nominee of a member organization, a Chicago Board of Trade exerciser, a lessee of an Exchange membership, or an owner of an Exchange membership that is not being leased to a lessee. CBOE Rule 3.24(b) provides that the following individuals are eligible for the member Death Benefit: (i) Any individual who is an active member at the time of his or her death; and (ii) any individual who (a) was an active member within ninety days prior to the date of his or her death, and (b) was an active member during at least 274 out of the 365 days preceding the date of his or her termination from active member status.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act[4] in general, and in particular, with Section 6(b)(5) of the Act,[5] in that it is designed to remove impediments to and perfect the mechanism of a free and open market and to protect investors and the public interest. The proposed rule change seeks to revise the Exchange's membership application posting process in a manner that will reduce inefficiency in the conduct of business on the Exchange and inconvenience to membership applicants while preserving the ability of members to submit information concerning the qualifications and fitness for membership of membership applicants. The proposed rule change will also clarify certain provisions of the Exchange's membership rules making it easier for members to understand those rules.

B. Self-Regulatory Organization's Statement on Burden Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statement with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to File No. SR–CBOE–00–60 and should be submitted by February 8, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1407 Filed 1–17–01; 8:45 am]

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[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43829; File No. SR–CBOE–00–10]

Self-Regulatory Organizations; Order Granting Approval of Proposed Rule Change by the Chicago Board Options Exchange, Inc., and Notice of Filing and Order Granting Accelerated Approval of Amendment No. 1, to Permit the Chairman of the Appropriate Floor Procedure Committee to Decrease the Size of Orders Eligible for Entry into the Retail Automatic Execution System During Unusual Market Conditions

January 10, 2001.

I. Introduction

On March 28, 2000, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change that would grant the Chairman of an appropriate Floor Procedure Committee ("FPC"), or his designee, the authority to decrease the size of orders eligible for entry into the Exchange's Retail Automatic Execution System ("RAES") during unusual market conditions. On January 3, 2001, the Exchange filed Amendment No. 1 to the proposed rule change.[3]

The proposed rule change was published for comment in the **Federal Register** on June 8, 2004.[4] The Commission received no comments on the proposal. This order approves the proposal.

II. Description of Proposal

Currently, the appropriate FPC of the CBOE has the authority to determine the size of orders eligible for entry into RAES up to a maximum of seventy-five contracts.[5] In this proposal, the Exchange is seeking to amend Interpretation .05 to Rule 6.8, *RAES Operations*, to allow the Chairman of the appropriate FPC, or the Chairman's designee,[6] to exercise the authority of the FPC to decrease the size of orders eligible for entry into RAES for option classes during unusual market conditions.[7]

In its filing, the Exchange represented that it is sometimes necessary to temporarily reduce the eligible order size levels for RAES in situations where unusual market conditions exist. However, under the current Exchange rules,a decision to decrease the eligible

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Letter from Angelo Evangelou, Counsel, CBOE, to Jennifer Colihan, Attorney, Division of Market Regulation ("Division"), Commission, dated January 2, 2001. ("Amendment No. 1"). In Amendment No. 1, the Exchange clarified that the Chairman may designate his authority solely to: (1) another member of the FPC, or (2) or (2) two CBOE floor officials.

[4] *See* Securities Exchange Act Release No. 42862 (May 30, 2000), 65 FR 36481.

[5] *See* Exchange Rules 6.8(a)(i) and 6.8(e). The Commission recently approved a proposed rule change by the Exchange to increase the maximum size of RAES-eligible orders to seventy-five contracts. *See* Securities Exchange Act Release No. 43517 (November 3, 2000), 65 FR 69082 (November 15, 2000).

[6] *See* Amendment No. 1, *supra* note 3.

[7] The Exchange has represented that the minimum level to which the Chairman, or his designee, may decrease the size of orders eligible for entry into RAES pursuant to the proposed rule is ten contracts. Telephone conversation between Angelo Evangelou, Counsel, CBOE, and Jennifer Colihan, Attorney, Division, Commission, on September 8, 2000.

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order size must be made by the appropriate FPC. The Exchange represented that it is not practicable to provide notice to all the members of the appropriate FPC and convene a meeting during the day to make the decision to decrease eligible order size in the event of an unusual market situation.

Consequently, the Exchange seeks to delegate the authority provided in CBOE Rule 6.8(a)(i) to the Chairman of the appropriate FPC, or to the Chairman's designee, to decrease the eligible order size for RAES in unusual market conditions,[8] provided that the Chairman or his designee believes that the action is warranted and provided that the decision is made for no more than one trading day (as is currently the case for the Chairman increasing the order size eligibility for RAES).[9] To the extent that the conditions continue to exist on the following trading day, the Chairman or his designee must review the situation and make an independent decision to decrease the RAES eligible order size for that subsequent day. Further, any decisions made by the Chairman or his designee to decrease the RAES eligible order size for a particular option class for consecutive days will be reviewed by the FPC at its next regularly scheduled meeting. After reviewing these decisions, the FPC can provide guidance to the Chairman or his designee about the use of this authority if the FPC considers it appropriate.

III. Discussion

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, the requirements of section 6(b) of the Act[10] and the rules and regulations thereunder.[11] Section 6(b)(5) of the Act[12] states that the rules of an exchange must be designed to facilitate securities transactions and to remove impediments to and perfect the mechanism of a free and open market. The Commission believes that granting the Chairman of the appropriate FPC, or the Chairman's designee, the discretion to exercise the authority of the Committee to decrease the size of orders for entry into RAES is consistent with these statutory provisions.[13]

The Commission further believes that the requirement that the FPC review any decision made by the Chairman or his designee to decrease the size of orders eligible for entry into RAES for consecutive days will help ensure that the Chairman, or his designee, only uses the discretion in limited circumstances that require that such action be taken to ensure the market's integrity and adequate function. Finally, the Commission notes that because this proposed rule involves changing the parameters of the eligible RAES order size, any action taken pursuant to the proposed rule must be documented in accordance with CBOE Rule 6.8, Interpretation .08.[14]

IV. Amendment No. 1

In Amendment No. 1, the Exchange clarified that the Chairman may designate his authority to decrease the size of orders for entry into RAES during unusual market conditions only to: (1) Another member of the FPC, or (2) two CBOE floor officials.[15] The Commission believes that this limitation will help to ensure that only those persons with sufficient knowledge and judgment will be vested with the authority to make decisions that will affect the manner in which RAES is operated, and consequently the manner in which customer orders are executed. The Commission believes that is would be inappropriate for the Chairman of an FPC to delegate his authority to make decisions regarding how RAES is operated to an unlimited number of persons, with varying degrees of knowledge and aptitude for making such decisions.

The Commission, therefore, finds that Amendment No. 1 is consistent with section 6(b)(5) of the Act,[16] which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in relating, clearing, settling, processing information with respect to, and facilitating transactions in securities. The Commission also finds good cause to approve Amendment No. 1 to the proposed rule change prior to the thirtieth day after the date of publication of notice of filing of the amendment in the **Federal Register**. The Commission notes that Amendment No. 1 merely clarifies precisely who is eligible to be the "Chairman's designee" for purposes of the proposed interpretation. Accordingly, the Commission believes that there is good cause, consistent with section 6(b)(5) and 19(b) of the Act[17] to approve Amendment No. 1 on an accelerated basis.

V. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning Amendment No. 1, including whether Amendment No. 1 is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–CBOE–00–10 and should be submitted by February 8, 2001.

VI. Conclusion

For all of the aforementioned reasons, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.

It Is Therefore ordered, pursuant to section 19(b)(2) of the Act,[18] that the proposed rule change (SR–CBOE–00–10), as amended, is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[19]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1485 Filed 1–17–01; 8:45 am]

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[8] According to the Exchange, unusual market conditions may include drastic movement in the security underlying an option, or news pending about the issuer of the underlying security. Telephone conversation between Angelo Evangelou, Counsel, CBOE, and Jennifer Colihan, Attorney, Division, Commission, on September 8, 2000.

[9] Under CBOE Rule 6.8, Interpretation .05, the Chairman of the appropriate FPC currently is authorized to increase the order size eligibility for RAES if he believes that the action is in the interest of alleviating a potential backlog of unexecuted orders in situations where a particular class of option is experiencing a large influx of orders, and provided the decision is made for no more than one trading day. That rule, however, does not permit the Chairman to decrease the order size eligibility maximum.

[10] 15 U.S.C. 78f(b).

[11] In approving this rule change, the Commission has considered the proposal's impact on efficiency, competition, and capital formation, consistent with section 3(f) of the Act. 15 U.S.C. 78c(f).

[12] 15 U.S.C. 78f(b)(5).

[13] The Commission notes that approval of this rule change is not dispositive of whether all aspects of the revised interpretation comply with the terms and conditions of section IV.h.(i)(bb) of the Order Instituting Public Administrative Proceedings Pursuant to Section 19(h)(1) of the Securities Exchange Act of 1934, Making Finding and Imposing Remedial Sanctions (the "Order"). The parties to the Order, including the Exchange, are required to "specify the circumstances, if any, under which automated execution systems can be disengaged or operated in any manner other than the normal manner set forth in the exchange's rules and require the documentation of the reasons for each decision to disengage an automated execution system or operate it in any manner other than the normal manner." The Order further provides that parties to the Order must submit to the Commission staff draft proposed rule changes that comply with the requirements set forth above no later than six months from the date of the Order. *See* Securities Exchange Act Release No. 43268 (September 11, 2000).

[14] The Commission notes that Interpretation .08 to CBOE rule 6.8 requires the CBOE to document instances in which the Chairman or his designee decrease RAES order size eligibility levels pursuant to this proposal. *See* Securities Exchange Act Release No. 43196 (August 22, 2000), 65 FR 52800 (August 30, 2000) (noticing immediate effectiveness of SR–CBOE–00–38, which implemented Interpretation .08).

[15] *See* Amendment No. 1, *supra* note 3.

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(5) and 78s(b).

[18] 15 U.S.C. 78s(b)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 43824; File No. SR–EMCC–00–05]

Self-Regulatory Organizations; Emerging Markets Clearing Corporation; Order Approving a Proposed Rule Change Relating to Increasing the Minimum Clearing Fund Requirement for All EMCC Members to $3,000,000 and Establishing Two Tiers of Inter-Dealer Broker Membership Standards

January 9, 2001.

On July 14, 2000, the Emerging Markets Clearing Corporation ("EMCC") filed with the Securities and Exchange Commission ("Commission") and on August 16, 2000, and November 1, 2000, amended a proposed rule change (File No. SR–EMCC–00–05) pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] Notice of the proposal was published in the **Federal Register** on December 1, 2000.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The purpose of the rule change is to (i) increase the minimum clearing fund requirement for all EMCC members to $3,000,000 from the current required minimum of $1,000,000 and (ii) provide two tiers of IDB membership standards.[3]

With respect to the increased minimum clearing fund requirement, EMCC's risk advisory subgroup reviewed EMCC's two years of operations, including trade files and daily margin calculations. The subcommittee concluded that, generally, members' calculated clearing fund requirements did not go below $3,000,000. Moreover, raising the minimum requirement from $1,000,000 to $3,000,000 is consistent with the clearing fund requirements imposed on IDBs by other clearing corporations,[4] and it addresses the fact that IDB members have a potential clearing fund loss liability that could well exceed the current $1,000,000 clearing fund minimum. Accordingly, EMCC has determined that it would be more appropriate to have a greater amount of IDB funds on hand to cover the potential exposure than to have to request such a deposit if needed due to a loss. Therefore, EMCC has determined that it is appropriate to increase all members', including IDBs', minimum clearing fund requirement to $3,000,000.

The rule change also separates IDBs into two membership categories based on excess net capital or excess financial resources. Those IDBs with excess net capital, or excess financial resources for a broker or dealer regulated by the Securities and Futures Authority Limited, of between $10,000,000 and $20,000,000 will be margined using an "event factor" of 1.5 instead of the factor of 1.25 currently used in EMCC's base margining formula. This factor is representative of the volatilities experienced during the last three emerging market events.[5] Those IDBs with excess net capital or excess financial resources of more than $20,000,000 will be margined under the current event factor of 1.25.

EMCC believes that the two-tier membership standard will permit it to better collateralize the risk posed by IDBs with lower levels of capital. EMCC recognizes that the clearing fund is a key mitigant to market risk in the event of member insolvency and feels that margining those IDBs with less than $20,000,000 excess regulatory capital at an event factor of 1.5 should mitigate the risk of their lower capital levels.

The effective date for these approved changes will be thirty days following the date the Commission approves the filing for current members and will be immediately for any applicant who becomes a member after the rule change is approved.

II. Discussion

Section 17A(b)(3)(F) of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency for which it is responsible.[6] The Commission believes that the approval of EMCC's rule change is consistent with this Section. The Commission believes it is prudent for EMCC to have a greater amount of IDB funds on hand to cover the potential exposure than to have to request such a deposit if needed and to increase all members', including IDBs', minimum clearing fund requirements to $3,000,000. In addition, the Commission believes that the two-tier membership standard whereby EMCC will margin IDBs with less than $20,000,000 excess regulatory capital at an event factor of 1.5 will permit EMCC to better collateralize the risk posed by IDBs with lower levels of capital.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act and the rules and regulations thereunder.

It is Therefore Ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–EMCC–00–05) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[7]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1408 Filed 1–17–01; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 43618 (November 27, 2000), 65 FR 75327.

[3] EMCC's Rules define an IDB as "a broker-dealer that conducts securities trading which matches buyers and sellers who are banks or dealers, and who is designated as such by the Corporation."

[4] *See, e.g.*, Government Securities Clearing Corporation Rule 4, Section 2(c).

[5] October, 1997 (Asia), August, 1998 (Russia), and January, 1999 (Brazilian).

[6] 15 U.S.C. 78q–1(b)(3)(F) (1988).

[7] 17 CFR 200.30–3(a)(12).

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43830; File No. SR–ISE–00–19]

Self Regulatory Organizations; Notice of Filing of Proposed Rule Change by the International Securities Exchange LLC Adopting an Obvious Error Rule

January 10, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 20, 2000, the International Securities Exchange LLC ("ISE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organizations Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to adopt new ISE Rule 720, which gives the Exchange the authority to bust or adjust trades that result from clearly erroneous orders or quotations. Proposed new language is *italicized.*

* * * * *

Rule 720. Obvious Errors

The Exchange shall either bust a transaction or adjust the execution price of a transaction that results from an Obvious Error as provided in this Rule.

(a) Definition of obvious Error. For purposes of this Rule only, Obvious Error will be deemed to have occurred when:

(1) during regular market conditions (including rotations), the execution price of a transaction is higher or lower than the Theoretical Price for the series by an amount equal to at least two (2) times the maximum bid/ask spread allowed for the option, so long as such amount is 50 cents or more; or

(2) during fast market conditions (i.e., the Exchange has declared a fast market status for the option in question), the execution price of a transaction is higher or lower than the Theoretical Price for the series by an amount equal to at least three (3) times the maximum bid/ask spread allowed for the option, so long as such amount is 50 cents or more.

(b) Definition of Theoretical Price. For purposes of this Rule only, the Theoretical Price of an option is:

(1) if the series is traded on at least one other options exchange, the last bid or offer, just prior to the trade, found on the exchange that has the most liquidity in that option as provided in Supplementary Material .02 below; or

(2) if there are no quotes for comparison purposes,as determined by the Obvious Error Panel.

(c) Adjustments. Where the execution price of a transaction executed as the result of an Obvious Error is adjusted, the adjusted price will be:

(1) the Theoretical Price of the option in the case where the erroneous price is displayed in the market and subsequently executed by quotes or orders that did not exist in the System at the time of the erroneous price was entered; or

(2) the last bid or offer, just prior to the trade, found on the exchange that has the most liquidity in that option as provided in Supplementary Material .03 below in the case where an erroneous price executes against quotes or orders already existing in the System at the time the erroneous price was entered.

(d) Obvious Error Procedure. Designated personnel in the Exchange's market control center ("Market Control") shall administer the application of this Rule as follows.

(1) Notification. If a market maker on the Exchange believes that it participated in a transaction that was the result of an Obvious Error, it must notify Market Control within five (5) minutes of the execution. If an Electronic Access Member believes an order it executed on the Exchange was the result of an Obvious Error, it must notify Market Control within twenty (20) minutes of the execution. Except as provided below, no relief under this Rule will be provided unless notification is made within the prescribed time periods.

(2) Adjust or Bust. Market Control will determine whether there was an Obvious Error as defined above. If it is determined that an Obvious Error has occurred, Market Control shall take one of the following actions: (i) where each party to the transaction is a market maker on the Exchange, the execution price of the transaction will be adjusted unless both parties agree to bust the trade within ten (10 minutes of being notified by Market Control of the Obvious Error, or[3] (ii) where at least one party to the Obvious Error is not a market maker on the Exchange, the trade will be busted unless both parties agree to adjust the price of the transaction within thirty (30) minutes of being notified by Market Control of the Obvious Error.

(e) Obvious Error Panel.

(1) Composition. An Obvious Error Panel will be comprised of representatives from three (3) Members that are market makers on the Exchange, at least one (1) of which shall be a representative from a Member that is a Competitive Market Maker and not also a Primary market Maker.

(2) Request for Review. If a party affected by a determination made under this Rule so requests, the Obvious Error Panel will review decisions made by market Control under this Rule, including whether an Obvious Error occurred, whether the correct Theoretical Price was used, and whether an adjustment was made at the correct price. A party may also request that the Obvious Error Panel provide relief under this Rule in cases where the party failed to provide the notification required in paragraph (d)(1), but unusual circumstances must merit special consideration. The Obvious Error Panel shall review the facts and render a decision on the day of the transaction. All determinations by the Obvious Error Panel shall be final.

Supplementary Material to Rule 720

.01 For purposes of paragraph (a) of this Rule, the maximum bid/ask spread shall be the maximum bid/ask spread allowed under Rule 803(b), unless a wider spread has been allowed by the Exchange for the option because of unusual market conditions, such as high market volatility.

.02 The Theoretical Price will be determined under paragraph (b)(1) above as follows: (i) the bid price from the exchange providing the most volume will be used with respect to an erroneous bid price entered on the Exchange, and (ii) the offer price from the exchange providing the most volume will be used with respect to an erroneous offer price entered on the Exchange.

.03 The price to which a transaction is adjusted under paragraph (c)(2) above will be as follows: (i) the bid price from the exchange providing the most volume for the option will be used with respect to an erroneous offer price entered on the Exchange, and (ii) the offer price from the exchange providing the most volume for the option will be used with respect to an erroneous bid price entered on the Exchange. If there are no quotes for comparison purposes, the adjustment price will be determined by the Obvious Error Panel.

.04 When Market Control determines that an Obvious Error has occurred and action is warranted under paragraph (d)(2) above, the identity of the parties to the trade will be disclosed to each other in order to encourage conflict resolution.

.05 Each market maker firm shall designate at least one person that is knowledgeable about options market making on the ISE to be called upon by the Exchange to participate on an Obvious Error Panel. In no case shall an Obvious Error Panel include a person related to a party to the Obvious Error in question. To the extent reasonably possible, the Exchange shall call upon representatives of each market maker to participate on an Obvious Error Panel on an equally frequent basis.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt new ISE Rule 720 that would allow it to either adjust or bust a transaction in circumstances where a member or its customer has made an error and the price of the execution is "obviously" not correct.[4] In such situations, the Exchange does not believe it is consistent with just and equitable principles of trade to permit one market participant to receive a wind-fall at the expense of another market participant that made an obvious error. Conversely, the Exchange does not seek to permit market participants to reconsider poor trading decisions. The ISE believes that the proposed rule contains objective standards regarding when a transaction was clearly the result of an "obvious error," under what circumstances a trade will be adjusted or busted, and to what price a trade will be adjusted if adjustment is appropriate under the circumstances.

Under proposed ISE Rule 720, when a member believes that it has participated in a transaction that was the result of an obvious error, it must notify ISE Market Control within a specified time of the execution. The proposed rule requires Exchange market makers, who are continuously monitoring their transactions on the ISE, to notify ISE Market Control within five minutes of an execution. The proposed rule allows Electronic Access Members, which may handle customer orders on multiple exchanges simultaneously and which may need to contact customers for instruction, up to twenty minutes to notify ISE Market Control.

ISE Market Control will determine whether there was an obvious error according to the following objective criteria: (1) An obvious error will be deemed to have occurred during normal market conditions when the execution price of a transaction is higher or lower than the theoretical price[5] for the series by an amount equal to at least two times the maximum bid/ask spread allowed for the option, so long as such amount is 50 cents or more; and (2) an obvious error will be deemed to have occurred during fast market conditions when the execution price of a transaction is higher or lower than the theoretical price for the series by an amount equal to at least three times the maximum bid/ask spread allowed for the option, so long as such amount is 50 cents or more.[6] ISE Market Control is not given any discretion under proposed ISE Rule 720 to take actions with respect to transactions that do not come within the objective obvious error criteria. In situations where the theoretical price is not objectively determinable, a panel of member representatives will be convened to determine the theoretical price.

If it is determined that a transaction is the result of an obvious error, ISE Market Control will take one of the following actions: (1) Where each party to the transaction is an Exchange market maker,[7] the execution price of the transaction will be adjusted unless both parties agree to bust the trade; or (2) where at least one party to the obvious error is not a market maker on the Exchange, the trade will be busted unless both parties agree to adjust the price of the transaction. In the first instance, Exchange market makers, who commonly hedge transactions immediately, have indicated a preference for adjusting the price of a transaction rather than changing their positions. Thus, the default action will be to adjust the price of the execution according to the objective criteria discussed below. In the second instance, where customer limit orders may be involved, the Exchange does not believe it appropriate to adjust the price of a transaction without the consent of the market participants. Accordingly, the default will be to bust the trade unless both sides agree to adjust the price. The default action will be taken unless agreement is reached within ten minutes in the case where both parties are Exchange market makers, and within thirty minutes where at least one party is not an Exchange market maker.

Where an adjustment is made to a transaction price, the adjusted price will be determined by objective criteria. The adjusted price will be equal to the theoretical price of the option in the case where the erroneous price is displayed in the market and subsequently executed by quotes or orders that did not exist in the system at the time the price was entered. For example, if an option had a bid of $5 and offer of $5.20 on the options exchange with the most volume in that option and due to an erroneous quotation, the ISE displayed a bid of $7 that was executed against by an incoming sell order or market maker offer, the adjustment price would be $5, which is the fair price at which a market participant could have sold the option at the time of the transaction. The ISE would presume that, in this situation, the seller knew that the price was

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The ISE corrected a typographical error that appeared in the proposed rule language. Telephone conversation between Katherine Simmons, Vice President and Associate General Counsel, ISE, and Susie Cho, Attorney, Division of Market Regulation, Commission, January 10,2 001.

[4] While current ISE Rule 804(d)(2) gives the Exchange some flexibility with respect to customer orders when a market maker's quote is obviously an error, it only states that an obviously erroneous quote may not be "firm" for customer orders. ISE Rule 804 does not expressly give the Exchange authority to bust an executed transaction, nor does it contain any guidelines for determining when a quotation is obviously erroneous.

[5] The theoretical price of an option in the case of an erroneous bid (offer) is the last bid (offer), just prior to the trade, found on the exchange that has the most liquidity in that option other than the ISE. If there are no quotes for comparison purposes, the theoretical price will be determined by an obvious error panel.

[6] The reason for requiring a greater deviation from the theoretical price during fast market conditions is that when the price of an underlying is moving rapidly, it is not as "obvious" that an option price might be in error.

[7] A party to a transaction will be considered an Exchange market maker under proposed ISE Rule 720 if the resulting position is booked in an ISE market maker account. For example, under ISE Rule 803, a Competitive Market Maker ("CMM") on the ISE may execute up to 25 percent of its total volume in securities to which it is not appointed. An obvious error involving two CMMs will be adjusted under proposed ISE Rule 720 unless both agree to bust the trade.

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obviously erroneous as compared to the price being displayed by the primary options exchange for the option.

Where a participant enters a quotation or order in error that executes against standing interest on the Exchange, the contra side to the transaction had no notice of an erroneous price and took no action to execute at the erroneous price. In this instance, the adjustment price will be the bid (offer) price from the exchange providing the most volume in the case of an erroneous offer (bid) price entered on the Exchange. The ISE believes that this will result in a more favorable adjustment price for the participant with standing interest in the book than the participant that made the error. As a result, in the previous example, if the erroneous bid of $7 executed against an offer in the system at $6.50, the adjustment price would be $5.20 (the offer price) instead of 5 (the bid price). Again, the only time an adjustment will be made to the price of a transaction is in the case where both parties were ISE market makers or where both parties agree to the adjustment.

Finally, proposed ISE Rule 720 specifies that each market maker firm will designate at least one person that is knowledgeable about options market making on the ISE to be called upon by the Exchange to participate on an obvious error panel.[8] Proposed ISE Rule 720 provides that an obvious error panel will have the authority to: (1) Determine a theoretical price when there is no quote for an option on another options exchanges; and (2) upon request by a party to a potential obvious error, review whether the correct theoretical price was used and whether an adjustment was made at the correct price. A party to a potential obvious error may also request that the obvious error panel provide relief under the proposed rule in cases where the party failed to give notice within the required time periods, but there must be unusual circumstances to merit this special consideration. All determinations by an obvious error panel will be made on the same day as the transaction in question and shall be final.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(5)[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism for a free an open market and a national market system, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange did not solicit or receive written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–ISE–00–19 and should be submitted by February 8, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1409 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43831; File No. JR–NASA–00–72]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Relating to Nasdaq's Transaction Credit Pilot Program

January 10, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 13, 2000, the National Association of Securities Dealers, Inc. ("NASD" or "Association"), through its wholly owned subsidiary The Nasdaq Stock Market, Inc. ("NASD"), filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Nasdaq has designated this proposal as one establishing or changing a due, fee, or other charge imposed by the Association under Section 19(b)(3)(A)(ii) of the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to amend NASD Rule 7010, System Services, to extend Nasdaq's transaction credit pilot program for an additional three months for Tape A and B reports. The text of the proposed rule change is below. Proposed new language is in italics. Proposed deletions are in brackets.

7010. System Services

(a)–(b) No Change.

(c) * * *

(1) No Change.

(2) Exchange-Listed Securities Transaction Credit. For a pilot period, qualified NASD members that trade securities listed on the NYSE and Amex in over-the-counter transactions reported by the NASD to the Consolidated Tape Association may receive from the NASD transaction credits based on the number of trades so reported. To qualify for the credit with respect to Tape A reports, an NASD member must account for 500 or more average daily Tape A reports of over-the-counter transactions as reported to the Consolidated Tape during the concurrent calendar quarter. To qualify for the credit with respect to Tape B reports, an NASD member must account for 500 or more average daily Tape B reports of over-the-counter transactions as reported to the Consolidated Tape during the concurrent calendar quarter. If an NASD member is so qualified to earn credits based either on its Tape A activity, or its Tape B activity, or both, that member may earn credits from one or both pools maintained by the NASD, each pool representing 40% of the revenue paid by the Consolidated Tape Association to the NASD for each of Tape A and Tape B transactions. A qualified NASD member may earn credits from the pools according to the member's pro rata share of the NASD's over-the-counter trade reports in each of Tape A and Tape B for each calendar quarter starting with July 1, 2000 for Tape A reports (April 1, 2000 for Tape B reports) and ending with the calendar quarter starting on [October 1, 2000] *January 1, 2001.*

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II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq proposes to extend through March 31, 2001, its pilot program to provide a transaction credit[4] to NASD members that exceed certain levels of trading activity in exchange-listed securities. Nasdaq's InterMarket is a quotation, communication, and execution system that allows NASD members to trade stocks listed on the New York Stock Exchange ("NYSE") and the American Stock Exchange ("Amex"). The InterMarket competes with regional exchanges like the Chicago Stock Exchange ("CHX") and the Cincinnati Stock Exchange ("CSE") for retail order flow in stocks listed on the NYSE and the Amex. The NASD collects trade reports from broker-dealers trading these securities in the over-the-counter ("OCTC") market and provides the trade reports to the Consolidated Tape Association ("CTA") for inclusion in the Consolidated Tape. As a participant in the CTA Plan, the NASD is entitled to a portion of the revenue that the CTA generates by selling this market data information. NASD's share of the revenues is based on trades that it reports on behalf of these broker-dealers in NYSE-listed securities ("Tape A") and in Amex-listed securities ("Tape B").

The Transaction Credit Pilot Program began in 1999.[5] Under the Program, NASD shares a portion of these tape revenues by providing a transaction credit to NASD members who exceed certain levels of OTC trading activity in NYSE and Amex securities. The Program helps InterMarket market makers and investors lower costs associated with trading listed securities. The Program also is an important tool for Nasdaq to compete against other exchanges (particularly CSE and CHX) that offer similar programs[6] and thereby maintain market share in listed securities.

The Program works as follows: Nasdaq calculates two separate pools of revenue from which credits can be earned: one representing 40% of the gross revenues received by the NASD from the CTA for providing trade reports in NYSE-losted securities executed in the InterMarket for dissemination by CTA (Tape A), and the other representing 40% of the gross revenue received from the CTA for reporting Amex trades (Tape B).

Eligibility for transaction credits is based on concurrent quarterly trading activity. For example, an InterMarket participant that enters the market for Tape A or Tape B securities during a particular quarter and prints an average of 500 daily trades of Tape A securities during the time it is in the market, or that averages 500 Tape B prints during such quarter, would be eligible to receive transaction credits based on its trades during the third quarter. Only those NASD members who continue to average an appropriate daily execution level are eligible for transaction credits and thus able to receive a pro-rata portion of the appropriate pool.[7] These thresholds permit the NASD to recover appropriate administrative costs related to NASD members that do not exceed the threshold and to provide an incentive for NASD members to actively trade in these securities.

The current Program will expire on December 31, 2000. Because the Program has helped Nasdaq maintain market share in listed securities, Nasdaq proposes to extend the current Program through the first quarter of 2001. Nasdaq's transaction credit program is being proposed on a pilot basis only. There can be no guarantee that transaction credits will be available to qualifying NASD members beyond the term of the pilot.

2. Statutory Basis

Nasdaq believes the proposed rule change is consistent with section 15A(b)(6) of the Act[8] in the proposal is designed to promote just and equitable principles of trade and to remove impediments to and perfect the mechanism of a national market system and, in general, to protect investors and the public interest. Nasdaq also believes

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[8] In no case shall an obvious error panel include a person related to a party to the obvious error in question. To the extent reasonably possible, the Exchange shall call upon representatives of each market maker to participate on an obvious error panel on an equally frequent basis.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[1] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] The transaction credit can be applied to any and all charges imposed by the NASD or its non-self-regulatory organization affiliates. Any remaining balance may be paid directly to the member.

[5] *See* Securities Exchange Act Release No. 41174 (March 16, 1999), 64 FR 14034 (March 23, 1999) (SR–NASD–99–13). The Program was subsequently extended. *See* Securities Exchange Act Release Nos. 42095 (November 3, 1999), 64 FR 61680 (November 12, 1999) (SR–NASD–99–59); 42672 (April 12, 2000), 65 FR 21225 (April 20, 2000)(SR–NASD–00–10); and 42907 (June 7, 2000), 65 FR 37445 (June 14, 2000)(SR–NASD–00–32).

[6] *See* Securities Exchange Act Release No. 38237 (February 4, 1997), 62 FR 6502 (February 12, 1997) (SR–CHX–97–01) and 39395 (December 3, 1997), 62 FR 65113 (December 10, 1997)(SR–CSE–97–12).

[7] As explained in Nasdaq's original pilot filing, the qualification thresholds were selected based on Nasdaq's belief that such numbers represent clear examples of a member's commitment to operating in the InterMarket and competing for order flow. *See* Securities Exchange Act Release No. 41174 (March 16, 1999), 64 FR 14034 (March 23, 1999) (SR–NASD–99–13).

[8] 15 U.S.C. 78o–3(b)(6).

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the proposal is consistent with Section 15A(b)(5) of the Act[9] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility of system which the Association operates or controls.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[10] and subparagraph (f)(2) of Rule 19b–4 thereunder,[11] because it establishes or changes a due, fee, or other charge imposed by the Association. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to file number SR–NASD–00–72 and should be submitted by February 8, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1410 Filed 1–17–01; 8:45 am]

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[9] 15 U.S.C. 78o–3(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(ii).

[11] 17 CFR 240.19b–4(f)(2).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43822; File No. SR–PHLX–01–01]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Philadelphia Stock Exchange, Inc. Relating to the Dissemination of Options Quotations With Size

January 8, 2001.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 8, 2001, the Philadelphia Stock Exchange, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Phlx. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Phlx, pursuant to Rule 19b–4 of the Act, proposes to amend, on a temporary basis, Exchange Options Floor Procedure Advice ("OFPA") F–7, Bids and Offers, to state that the size of any bid or offer in a quotation disseminated by the Exchange shall be equal to the AUTO–X guarantee for the quoted option and shall be firm, except that the disseminated size of bids and offers of customer limit orders shall be ten (10) contracts and shall be firm, regardless of the actual size of such orders.

The complete text of the proposed rule change is available at the Office of the Secretary, Phlx and at the Commission.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Phlx included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Phlx has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to codify the Exchange's initial program for the dissemination of options quotations with size. It is anticipated that, on or about January 22, 2001, the Option Price Reporting Authority ("OPRA") will begin to support the dissemination of options quotations that include the size, or the number of contracts, represented in disseminated bids and offers on the Exchange.

On November 17, 2000, the Commission amended the Quote Rule[3] to require options exchanges and options market makers to publish firm quotes. The amended Quote Rule will require options exchanges to either: (1) Comply with the Quote Rule as it applies in the equity markets and collect from their members and make available to vendors the size associated with each quotation; or (2) establish by rule and periodically publish the quotation size for which their members' quotations are firm. The compliance date for the amendments to the Quote Rule is April 1, 2000.

While it is anticipated that OPRA will have the necessary systems capacity to accept and disseminate quotations with size by late January 2001, and that one or more options exchanges will be in a position to disseminate actual quotation size at that time, the Phlx will not have completed its application of the systems changes necessary to permit it to disseminate actual quotation size for a number of months.

Therefore, until the Exchange's systems disseminate actual quotation size on a quote-by-quote basis, the Phlx seeks herein to establish by rule and

[3] Exchange Act Rule 11Ac1–1; 17 CFR 240.11Ac1–1; *see* Securities Exchange Act Release No. 43591 (November 17, 2000), 65 FR 75439 (December 1, 2000) (File No. S7–17–00).

periodically publish, on its web site and through regulatory circulars to Exchange members and member organizations, the quotation size for which its members' quotations are firm as required by Rule 11Ac1–1(d)(1)(i) under the Act.[4]

In addition, the Exchange proposes to voluntarily disseminate to OPRA the applicable automatic execution size guarantee for each quoted option, except that with respect to customer limit orders the Phlx would disseminate a size of 10 contracts, regardless of the actual size of the customer order. In all cases, the Phlx would be firm for its disseminated quotation size (without regard to whether the given order would be eligible for automatic execution via the Exchange's automatic execution feature, AUTO–X).[5]

Until the Phlx has completed its application of the systems changes necessary to automatically update its quotation size on a continuous basis, the Phlx believes that the instant proposal represents a vast improvement over the current system, by increasing transparency and providing the market place with considerably more information upon which to base order routing decisions.

Finally, the Phlx expects to begin providing quotations with actual size on a floor-wide basis within one year. The Exchange will undertake to submit a further proposed rule change when the Exchange is able to disseminate actual size associated with its options quotes and customer limit orders.

The instant proposed rule change does not affect in any respect the Exchange's obligations concerning non-public customer orders.[6] Prior to the April 1, 2001 mandatory compliance date of the amended Quote Rule, the Exchange will establish firm quote requirements with respect to broker-dealers, as required by the amended Quote Rule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act[7] in general, and in particular, with Section 6(b)(5),[8] in that it is designed to perfect the mechanism of a free and open market and a national market system, protect investors and the public interest and promote just and equitable principles of trade by increasing transparency and providing the market place with considerably more information upon which to base order routing decisions.

Finally, after consultation with Commission staff, the Phlx believes that the proposed rule change described in this filing, including permitting SQF users to disseminate actual size when they are able to do so (as described in Footnote No. 5) is consistent with the amended Quote Rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Phlx does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days or such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Phlx consents, the Commission will:

(A) By order approve such proposed rule change, or,

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Phlx. All submissions should refer to file No. SR–Phlx–01–01 and should be submitted by February 8, 2001.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[9]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–1406 Filed 1–17–01; 8:45 am]

BILLING CODE 8010–01–M

[4] Exchange Act Rule 11Ac1–1(d)(1)(i), 17 CFR 240.11Ac1–1(d)(1)(i).

[5] In the event that certain Phlx specialist firms are able to develop and implement proprietary systems (called "Specialized Quote Feeds" or "SQFs") that are able to disseminate actual size prior to the Exchange's systems disseminating quotations with actual size on a floor-wide basis, the Phlx would undertake to file a further proposed rule change with the Commission requesting approval to disseminate actual size for those options classes assigned to such specialist firms.

[6] *See* Exchange Rule 1015(b) and Options Floor Procedure Advice A–11.

[7] 15 U.S.C. 78f.

[8] 15 U.S.C. 78f(b)(5).

DEPARTMENT OF STATE

[Public Notice 3549]

Culturally Significant Objects Imported for Exhibition; Determinations: "Gauguin's Nirvana: Portrait of Meyer de Haan"

AGENCY: United States Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, and Delegation of Authority No. 236 of October 19, 1999, as amended, I hereby determine that the objects to be included in the exhibition "Gauguin's Nirvana: Portrait of Meyer de Haan" imported from abroad for the temporary exhibition without profit within the United States, are of cultural significance. These objects are imported pursuant to loan agreements with the foreign lenders. I also determine that the exhibition or display of the exhibit objects at the Wadsworth Atheneum Museum of Art, Hartford, CT from on or about January 26, 2001, through on or about April 29, 2001, is in the national interest. Public Notice of these Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of exhibit objects, contact Jacqueline Caldwell, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202/619–6982). The address is U.S. Department of State, SA–

[9] 17 CFR 200.30–3(a)(12).

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44, 301 4th Street, SW., Room 700, Washington, DC 20547–0001.

Dated: January 10, 2001.

William B. Bader,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 01–1515 Filed 1–17–01; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 3550]

Culturally Significant Objects Imported for Exhibition; Determinations: "The Global Guggenheim: Selections From the Extended Collection"; Amendment

DEPARTMENT: United States Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 [79 Stat. 985, 22 U.S.C. 2459], the Foreign Affairs Reform and Restructuring Act of 1998 [112 Stat. 2681 *et seq.*], Delegation of Authority No. 234 of October 1, 1999 [64 FR 56014], and Delegation of Authority No. 236 of October 19, 1999 [64 FR 57920], as amended, I hereby determine that one additional object to be included in the exhibit, "The Global Guggenheim: Selections from the Extended Collection," imported from abroad for the temporary exhibition without profit within the United States, is of cultural significance. The object will be imported pursuant to a loan agreement with a foreign lender. I also determine that the temporary exhibition or display of the additional object at the Solomon R. Guggenheim Museum, New York, New York, from on or about February 6 to on or about April 22, 2001, is in the national interest. Public Notice of these determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of exhibit objects, contact Julianne C. Simpson, Attorney-Adviser, Office of the Legal Adviser, 202/619–6529, and the address is SA–44, Room 700, United States Department of State, 301 4th Street, S.W., Washington, DC 20547–0001.

Dated: January 12, 2001.

William B. Bader,

Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 01–1516 Filed 1–17–01; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice #3523]

Overseas Security Advisory Council (OSAC) Meeting Notice; Closed Meeting

The Department of State announces a meeting of the U.S. State Department—Overseas Security Advisory Council on February 13, 14, and 15, in San Diego, California. Pursuant to Section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552b(c)(1) and (4), it has been determined the meeting will be closed to the public. Matters relative to classified national security information as well as privileged commercial information will be discussed. The agenda will include updated committee reports, a world threat overview and a round table discussion that calls for the discussion of classified and corporate proprietary/security information as well as private sector physical and procedural security policies and protective programs at sensitive U.S. Government and private sector locations overseas.

For more information contact Marsha Thurman, Overseas Security Advisory Council, Department of State, Washington, D.C. 20522–1003, phone: 202–663–0533.

Dated: January 10, 2001.

Peter E. Bergin,

Director of the Diplomatic Security Service, Department of State.

[FR Doc. 01–1517 Filed 1–17–01; 8:45 am]

BILLING CODE 4710–08–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Industry Sector Advisory Committee on Small and Minority Business (ISAC–14)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of meeting.

SUMMARY: The Industry Sector Advisory Committee on small and Minority Business will hold a meeting on January 29, 2001, from 9:15 a.m. to 3 p.m. The meeting will be opened to the public from 9:15 a.m. to 3 p.m.

DATES: The meeting is scheduled for January 29, 2001, unless otherwise notified.

ADDRESSES: The meeting will be held at the Department of Commerce, Conference room 4830, located at 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Millie Sjoberg, (202) 482–4792, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230 (principal contact), or Dominic Bianchi, Office of the United States Trade Representative, 1724 F Street, NW., Washington, D.C. 20508, (202) 395–6120.

SUPPLEMENTARY INFORMATION: The following topics will be discussed:

- Discussion on 2001 APEC Small and Medium-sized enterprise (SME) Ministerial;
- Discussion on 2001 Summit of the Americas;
- Discussion on infrastructure security;
- Discussion on trade finance;
- Discussion on customs issues;
- Discussion on electronic commerce;
- Discussion on SME advocacy and outreach; and,
- Committee business.

Dominic Bianchi,

Acting Assistant United States Trade Representative for Intergovernmental Affairs and Public Liaison.

[FR Doc. 01–1532 Filed 1–17–01; 8:45 am]

BILLING CODE 3190–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Meeting of the Industry Sector Advisory Committee on Services (ISAC–13)

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of meeting

SUMMARY: The Industry Sector Advisory Committee on Services will hold a meeting on January 23, 2001, from 9 a.m. to 12 noon. The meeting will be opened to the public from 9 a.m. to 9:45 a.m., and closed to the public from 9:45 a.m. to 12 noon.

DATES: The meeting is scheduled for January 23, 2001, unless otherwise notified.

ADDRESSES: The meeting will be held at the Department of Commerce, Conference Room 6057, located at 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Karen Holderman, (202) 482–0345, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230 (principal contact), or Dominic Bianchi, Office of the United States Trade Representative, 1724 F Street, NW., Washington, DC 20508, (202) 395–6120.

SUPPLEMENTARY INFORMATION: During the opened portion of the meeting the Work Program of the General Agreement on Trade in Services (GATS), and the Proposed Free Trade Agreements between the united States and Singapore and the United States and Chile, will be discussed.

Dominic Bianchi,

Acting Assistant United States Trade Representative for Intergovernmental Affairs and Public Liaison.

[FR Doc. 01–1533 Filed 1–17–01; 8:45 am]

BILLING CODE 3190–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2001–8660]

Random Drug Testing Rate for Covered Crewmembers

AGENCY: Coast Guard, DOT.

ACTION: Notice of minimum random drug testing rate.

SUMMARY: The Coast Guard has set the calendar year 2001 minimum random drug testing rate at 50 percent of covered crewmembers. An evaluation of the 1999 Management Information System (MIS) data collection forms submitted by marine employers determined that random drug testing on covered crewmembers for the calendar year 1999 resulted in positive test results 1.7 percent of the time. Based on this percentage, we will maintain the minimum random drug testing rate at 50 percent of covered crewmembers for the calendar year 2001.

DATES: The minimum random drug testing rate is effective January 1, 2001 through December 31, 2001. You must submit your 2000 MIS reports no later than March 15, 2001.

ADDRESSES: You must mail your annual MIS report to Commandant (G–MOA), U.S. Coast Guard Headquarters, 2100 Second Street SW., Room 2403, Washington, DC 20593–0001.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Lieutenant Jennifer Ledbetter, Project Manager, Office of Investigations and Analysis (G–MOA), U.S. Coast Guard Headquarters, telephone 202–267–0684.

SUPPLEMENTARY INFORMATION: Under 46 CFR 16.230, the Coast Guard requires marine employers to establish random drug testing programs for covered crewmembers on inspected and uninspected vessels. All marine employers are required to collect and maintain a record of drug testing program data for each calender year, January 1 through December 31. You must submit this data to the Coast Guard in an annual MIS report (Form CG–5573 found in appendix B of 46 CFR 16). You may either submit your own MIS report or have a consortium or other employer representative submit the data in a consolidated MIS report. The chemical drug testing data is essential to analyze our current approach for deterring and detecting illegal drug abuse in the maritime industry.

Since 1999 MIS data indicates that the positive random testing rate is greater than one percent industry-wide (1.7 percent), the Coast Guard announces that the minimum random drug testing rate is set at 50 percent of covered employees for the period of January 1, 2001 through December 31, 2001 in accordance with 46 CFR 16.230(e).

You must submit your MIS report to the Coast Guard no later than March 15 of each calendar year. Each year we will publish a notice reporting the results of the previous calendar year's MIS data, and the minimum annual percentage rate for random drug testing for the next calendar year.

Dated: January 8, 2001.

R.C. North,

Rear Admiral, U.S. Coast Guard, Assistant Commandment for Marine Safety and Environmental Protection.

[FR Doc. 01–1545 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee and Executive Committee; Meetings

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the full Aviation Rulemaking Advisory Committee (ARAC) and Executive Committee of the Federal Aviation Administration's Aviation Rulemaking Advisory Committee. It has been nearly ten years since the last full committee meeting and the membership has expanded considerably since that time. The purpose of the meeting is to bring the full Committee together to discuss operational procedures, the future vision for ARAC, and committee accomplishments.

DATES: The full ARAC meeting will be held February 7, 2001, from 10 a.m.–12 Noon and the Executive Committee will begin at 1 p.m.

ADDRESSES: The meeting will be held at the Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Gerri Robinson, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–9678; fax (202) 267–5075; e-mail *Gerri.Robinson@faa.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the full Aviation Rulemaking Advisory Committee and the Aviation Rulemaking Advisory Committee Executive Committee to be held on February 7, 2001, at Hyatt Regency Crystal City. The agenda will include:

Full ARAC Committee Meeting, 10 a.m.–12 Noon:

- Welcome and introductions—Anthony Fazio, Executive Director, and Albert Prest, Chair.
- Remarks—Thomas E. McSweeney, Association Administrator for Regulation and Certification, Federal Aviation Administration.
- Federal Advisory Committee Act (FACA) requirements.
- Roles/Responsibilities.
- Public accessibility to ARAC information.
- Scheduled comments and statements to the committee.
- Adjournment.

Executive Committee Meeting, 1:00 p.m.

- Review and approval of previous meeting minutes.
- Status Report Fuel Tank Inerting working group.
- Status Report from Assistant Chairs.
- Remarks from other EXCOM members.
- Proposed meetings dates for CY 2001: May 9, August 8, and Nov. 7.

Attendance is open to the interested public but will be limited to the space available. Please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT** by January 31, 2001, if you plan to attend either of these meetings, plan to present a verbal statement, or you are in need of assistance or require a reasonable accommodation for this meeting. Requests to present a verbal statement should include a written summary of the remarks. Please focus your remarks and/or statements on the operations of ARAC, specific activities, projects or

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goals of the advisory committee, and benefits to the aviation public.

Individuals making verbal presentations or providing written statements at either meeting should bring at least 25 copies of the written material to the meeting. Copies of the materials may be provided to the audience at the discretion of the submitter.

The Committee will try to accommodate all speakers. Each speaker will be limited to no more than a 5-minute presentation. If available time does not permit this, speakers generally will be scheduled on a first-come-first-served basis. However, ARAC leadership reserves the right to exclude some speakers, if necessary, to present a balance of viewpoints and issues.

Issued in Washington, DC, on January 11, 2001.

Anthony F. Fazio,

Executive Director, Aviation Rulemaking Advisory Committee.

[FR Doc. 01–1506 Filed 1–12–01; 3:37 pm]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Cincinnati/Northern Kentucky International Airport, Covington, KY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Cincinnati/Northern Kentucky International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before February 20, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Memphis Airports District Office, 3385 Airways Boulevard, Suite 302, Memphis, Tennessee 38116–3841.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Robert F. Holscher, Director of Aviation of the Kenton County Airport Board at the following address: P.O. Box 752000, Cincinnati, Ohio 45275–2000.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Kenton County Airport Board under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry O. Bowers, Program Manager, Memphis Airports District Office, 3385 Airways Boulevard, Suite 302, Memphis, Tennessee 38116–3841, (901) 544–3495, Extension 21. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Cincinnati/Northern Kentucky International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On January 10, 2001, the FAA determined that the application to impose and use the revenue from a PFC submitted by Kenton County Airport Board was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 26, 2001.

The following is a brief overview of the application.

PFC Application No.: 01–06–C–00–CVG.

Level of the proposed PFC: $3.00.

Proposed charge effective date: July 1, 2001.

Proposed charge expiration date: March 1, 2002.

Total estimated net PFC revenue: $22,216,000.

Brief description of proposed project(s): Implement Noise Compatibility Program (NCP) Measures—1999 Part 150 Study Update, Construct Upgrade to Aircraft Rescue and Firefighting (ARFF) Facility, Close South Detention Basin, and Acquire FAR 107.14 Security Access System—reimbursement for original acquisition.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: (1) FAR Part 121 supplemental operators which operate at the Airport without an operating agreement with the Board and enplane less than 1,500 passengers per year and (2) Part 135 on-demand air taxis, both fixed wing and rotary.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Kenton County Airport Board.

Issued in Memphis, Tennessee on January 10, 2001.

LaVerne F. Reid,

Manager, Memphis Airports District Office, Southern Region.

[FR Doc. 01–1551 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Application To Use and To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Meadows Field Airport, Bakersfield, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to use and to impose and use the revenue from a PFC at Meadows Field Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before February 20, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Airports Division, 15000 Aviation Blvd., Room 3024, Lawndale, CA 90261. In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Raymond Bishop, Director of Airports of the county of Kern at the following address: 1401 Skyway Drive, Suite 200, Bakersfield, CA 93308. Air carriers and foreign air carriers may submit copies of written comments previously provided to the county of Kern under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. David Delshad, Airports Program Engineer, Standards Section, Airports Division, 15000 Aviation Blvd., Room 3024, Lawndale, CA 90261, Telephone: (310) 725–3627. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to use and to impose and use the revenue from a PFC at Meadows Field Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158). On December 15, 2000, the FAA determined that the application to use and to impose and use the revenue from a PFC submitted by the county of Kern was substantially complete within the requirements of § 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 17, 2001. The following is a brief overview of the application.

Project No. 1 (use project)

Level of proposed PFC: $3.00.

Charge effective date: January 1, 2000.

Proposed charge expiration date: May 1, 2002.

Total estimated PFC revenue: $317,000.

Brief description of proposed project: Land acquisition for Airport Expansion Project No. 2 (impose and use project).

Level of Proposed PFC: $4.50.

Proposed charge effective date: June 1, 2001.

Proposed charge expiration date: February 1, 2014.

Total estimated PFC revenue: $9,086,000.

Brief description of proposed project: Construct new passenger terminal Class or classes of air carriers which the public agency has requested not be required to collect PFCs: None.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.** In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Meadows Field Airport Administration Office.

Issued in Hawthorne, California, on December 22, 2000.

Ellsworth Chan,

Acting Manager, Airports Division Western-Pacific Region.

[FR Doc. 01–1552 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: King County, WA

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed road project in King County, Washington.

FOR FURTHER INFORMATION CONTACT: Elizabeth Healy, Transportation and Environmental Engineer, Federal Highway Administration, 711 South Capitol Way, Suite 501, Olympia, Washington 98501–1284, Telephone: (360) 534–9323 or Alan Andree, Senior Engineer, King County, Road Services Division, Department of Transportation, King Street Center M.S. KSC–TR–0231, 201 South Jackson Street, Seattle, WA 98104–3856, Telephone: (206) 296–8086.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Washington State Department of Transportation and King County Department of Transportation, will prepare an environmental impact statement (EIS) on a proposal to improve a portion of Northwest Novelty Hill Road in King County, Washington. The proposed improvement to the Northeast Novelty Hill Road would involve improvements to the road, and would include stormwater detention facilities, safety improvements and pedestrian, equestrian and bicycle facilities. The project is located between Avondale Road Northeast and the Redmond Ridge (formerly Northridge and Blakely Ridge) urban planned developments, including intersection improvements at 243rd Avenue Northeast, an approximately three mile long corridor.

Improvements to the road are considered necessary to reduce anticipated traffic congestion and improve safety by increasing vehicle capacity and providing improved pedestrian and bicycle facilities. Alternatives under consideration include (1) taking no action; (2) constructing a three-lane road; (3) constructing a five-lane road. Incorporated into and studied with the various build alternatives will be design variations of grade and alignment.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A series of public meetings will be held in King County between January 2001 and February 2002. In addition, a public hearing will be held. Public notice of actions related to the proposal which identify the date, time and place of the meetings and hearings, and note the length of review periods will be published when appropriate. The draft EIS will be available for public and agency review and comment prior to the public hearing. A formal scoping meeting is planned for Tuesday, January 23, 2001 and will be announced in the local news media and through a public mailing.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance program Number 20.205, Highway Planning and Construction. The regulations implementing Executive order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: January 9, 2001.

Elizabeth Healy,

Transportation and Environmental Engineer, Olympia, Washington.

[FR Doc. 01–1508 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: King County, WA

AGENCY: Federal Highway Administration, King County, Washington.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The FHWA is issuing this notice to advise the public that a joint NEPA/SEPA Environmental Impact Statement will be prepared for a proposed bicycle/pedestrian trail. The trail would be located primarily along a former rail corridor on the east side of Lake Sammamish between the Cities of Issaquah and Redmond in King County, Washington. The EIS will be prepared in conjunction with King County Department of Construction and Facilities Management.

FOR FURTHER INFORMATION CONTACT: Elizabeth Healy, Transportation and Environmental Engineer, Federal Highway Administration, 711 S. Capitol Way, Suite 501, Olympia, WA 98501, Telephone (360) 753–9480; or Ms. Robin Cole, Project Manager, King County Department of Construction and Facilities Management, 500 Fourth

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Avenue, Room 320, Seattle, WA 98104, Telephone (206) 296–4261.

SUPPLEMENTARY INFORMATION: The purpose of the proposed project is to design and construct a multi-use recreational trail and alternative transportation corridor primarily within the 10.8-mile former Burlington-Northern Santa Fe rail corridor, and to protect the federal railbanking status of the corridor, which was granted in September 1998. This East Lake Sammamish Trail would extend along the east side of Lake Sammamish from Redmond to Issaquah, linking King County's Marymoor Park and West Lake Sammamish Trail to Lake Sammamish State Park and other local and regional trails.

At this time, three alternatives are being considered: a No Action alternative, use of primarily the existing railbed with some off-railbed use, and use of the existing rail corridor with some off-corridor use. The range of alternatives may, however, be modified as a result of public involvement process.

Potential Environmental Issues

King County has conducted a community outreach and preliminary environmental evaluation process. As a result, the County and FWHA have identified the following areas of potentially significant environmental impacts associated with the proposed project: surface water, geology and soils, noise, land and shoreline use, vegetation, wildlife, fisheries, public services and utilities, transportation, safety, recreation, and aesthetics. Additional areas of potential impact may be identified during public involvement.

Public Involvement and Scoping Meetings

During spring and summer 2000, Neighborhood Vision Workshops and User Group Workshops were held by King County to gather information from neighbors of the trail and potential user groups including cyclists, runners, pedestrians, and equestrians.

King County held a public SEPA scoping meeting on November 15, 2000 to provide an opportunity for the public to help the project team identify issues for consideration and evaluation in the environmental review process. The meeting was held at the Inglewood Junior High School, 24120 NE 8th, Redmond, WA 98053.

A public scoping meeting will be held on February 20, 2001 to provide additional opportunity to ensure that proposed alternatives respond to previous input and are comprehensive. Notice of this meeting was also published in local newspapers, including the Seattle Times, the Eastside Journal, and the Issaquah Press. The February 20th scoping meeting will be held at: Skyline High School (Commons Area), 1122–228th Avenue SE, Sammamish, WA 98075, from 6:00 p.m. to 8:30 p.m.

To ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: January 9, 2001.

Elizabeth Healy,

Transportation and Environmental Engineer, Olympia, Washington.

[FR Doc. 01–1509 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Battle Ground, Yacolt & Chelatchie Prairie Railroad

[Docket Number FRA–2000–8501]

The Battle Ground, Yacolt & Chelatchie Prairie Railroad seeks a permanent waiver of compliance with the Safety Glazing Standards, 49 CFR part 223.1(c) which requires certified glazing in all locomotive windows, with the exception of locomotives used in yard service.

The Battle Ground, Yacolt & Chelatchie Prairie Railroad seeks relief for locomotive number 112 (AAR number designation pending), built in 1951 by American Locomotive Company (ALCO) for the Longview, Portland and Northern Railroad. This locomotive is currently equipped with Duolite A25, Duolite A5 110, Safety Sheeting AS2 Laminated M91 and Laminated Auto Safety Glazing. The operating railroad indicates that the locomotive will be utilized in passenger excursion service between Battle Ground, Washington (MP 14) and Chelatchie, Washington (MP 33).

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2000–8501 and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room Pl–401, Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at http://dms.dot.gov.

Issued in Washington, DC on January 10, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1559 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Waiver Petition Docket Number FRA–2000–8268]

Petition for Waivers of Compliance

In accordance with 49 CFR §§ 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received a request for a waiver of compliance with certain requirements of the Federal safety laws and regulations. The petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Burlington Northern Santa Fe Railway Company

Burlington Northern Santa Fe Railway (BNSF) seeks a permanent waiver of compliance from certain requirements of 49 CFR part 229 (Railroad Locomotive Safety Standards) for a select group of C–44–9W locomotives, road numbers BNSF 700–799, 960–1123, 4300–4999, and 5370–5499. Specifically, BNSF requests a waiver from 49 CFR 229.23(a), which requires that the interval between any two periodic inspections may not exceed 92 days. BNSF proposes to extend this interval to 122 days on this group of locomotives.

In support of this proposal BNSF states: "These locomotives contain the industry's latest technology in the areas of safety and reliability, are microprocessor controlled and equipped with New York Air Brake Corporation computer controlled brakes." They cite calender day inspections and other inspections that are done every 3 to 4 days which will help ensure safe operation. Since April 1, 1999, they have been performing periodic inspections every 61 days. They estimate that they have had a 0.87% defect rate after 61 days. In conclusion BNSF states: "Extending the periodic maintenance interval from 92 to 122 days will not adversely effect the safety or performance of C44–9W locomotives."

Interested parties are invited to participate in these proceedings by submitting written reviews, data, or comments. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request. FRA will schedule a public hearing in connection with these proceedings if the basis is found to be sufficient.

All communications concerning these proceedings should identify the appropriate docket number, (*e.g.*, Waiver Petition Docket Number FRA–2000–8268) and must be submitted to the DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 Seventh Street, SW., Washington, DC 20590. Communications received within 45 days from the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's web site at http://dms.dot.gov.

Issued in Washington, DC on January 11, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1555 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Carthage, Knightstown & Shirley Railroad Company

[Docket Number FRA–2000–8364]

The Carthage, Knightstown & Shirley Railroad Company (CKSI) seeks a permanent waiver of compliance for two locomotives from the requirements of the Safety Glazing Standards, 49 CFR part 223, which requires certified glazing in all locomotive windows, except those locomotives used in yard service. The railroad indicates that the locomotives number CKSI 468 and CKSI 215 are General Electric 45 ton center cab locomotives used passenger excursion service through mostly rural areas, 10 mile round trip in the Knightstown, Indiana area. The railroad operates May through October, on weekends, Friday, Saturday, and Sunday.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2000–8364) and must be submitted in triplicate to the Docket Clerk, DOT Central Docket Management Facility, Room Pl–401, Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at DOT Central Docket Management Facility, Room Pl–401 (Plaza Level), 400 Seventh Street SW., Washington, DC. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at http://dms.dot.gov.

Issued in Washington, DC on January 10, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1558 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Massena Terminal Railroad Company

[Docket Number FRA–2000–7949]

Massena Terminal Railroad Company (MSTR) seeks a permanent waiver of compliance with the Railroad Safety Appliance Standards, 49 CFR part 231.28(a) Running Boards, which references 231.1(c) Running Boards: (1) Number—One longitudinal running board; (2) Dimensions—Longitudinal running board shall be not less than 18 and preferably 20 inches in width; and (3) Location—Full length of car, center of roof.

MSTR is seeking relief for 75 Aluminum Covered Hopper Cars that were originally designed with 10 hatch covers, five down each side, and a running board positioned down the center of the car. Due to financial considerations MSTR has recently contracted with a facility, for the loading and unloading of these cars, that cannot accommodate this design. To facilitate the loading process MSTR has

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removed the running boards and positioned six (6) hatches down the center of the car. MSTR states that the loading facility employees access the roof via a permanent platform built to the same height as the car roof. They further claim that the cars are repaired at a site with a similar platform and to their knowledge no one else mounts the top of the car, therefore the running boards are unnecessary. They contend that the running boards would create a tripping hazard if applied down each side of the car roof as is currently the case with other covered hoppers with center mounted hatches. MSTR also sites cost and time constraints in relocating the running board as this would require removing two more hatch covers, welding aluminum plates over the hatches and remounting the running boards on the outside of the cars.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2000–7949) and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room Pl–401 (Plaza Level), 400 Seventh Street, SW., Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's Web site at http://dms.dot.gov.

Issued in Washington, DC on January 10, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1557 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Blacklands Railroad

[Docket Number FRA–2000–8366]

The Blacklands Railroad (BLR) of Sulphur Springs, Texas, has petitioned for a permanent waiver of compliance for one locomotive from the requirements of Safety Glazing Standards, 49 CFR part 223, which requires certified glazing. The BLR is located in Sulphur Springs, Texas. The BLR states that this locomotive is used in light switching service and operates over 65 miles of track, from Greenville, TX, through Commerce, Sulphur Springs, TX. It also states that it has an additional 10 miles of trackage rights over the Union Pacific Railroad for interchange in their Mt. Pleasant yard. The average track speed is 10–15 miles per hour with a maximum speed of 20 miles per hour.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number FRA–2000–8366) and must be submitted in triplicate to the Docket Clerk, DOT Central Docket Management Facility, Room P1–401, Washington, DC 20590–0001. Communications received within 45 days of the date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9:00 a.m.–5:00 p.m.) at DOT Central Docket Management Facility, Room P1–401 (Plaza Level), 400 Seventh Street SW., Washington, DC. All documents in the public docket are also available for inspection and copying on the internet at the facility's Web site at *http://dms.dot.gov.*

Issued in Washington, DC, on January 11, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1556 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2000–8267]

Petition for Waiver of Compliance

In accordance with part 211 of title 49 Code of Federal Regulations (CFR) notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Oil Creek & Titusville Lines

The Oil Creek & Titusville Lines (OCTL), seeks a waiver of compliance from certain provisions of the Safety Glazing Standards, 49 CFR 223, which requires certified glazing, for one locomotive. The OCTL is located in Titusville, Pennsylvania. The OCTL states they operate a short line freight operation and additionally an excursion railroad operation over 15.8 miles of track through rural countryside and one community on an average of two (2) round trips per week freight and three (3) round trips per week for passenger excursions.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.*, Waiver Petition Docket Number FRA–2000–8267) and must be submitted in triplicate to the Docket Clerk, DOT Central Docket Management Facility, Room P1–401, Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by FRA before final action been taken. Comments received after that date will be considered as far as practicable. All written communications concerning the proceedings are available for examination during regular business hours (9:00 a.m.–5:00 p.m.) at DOT Central Docket Management Facility, Room P10401 (Plaza Level), 400 Seventh Street, SW., Washington, DC.

All documents in the public docket are also available for inspection and copying on the internet at the docket facility's Web site at *http://dms.dot.gov.*

Issued in Washington, DC, on January 11, 2001.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 01–1554 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–00–7638; Notice 2]

Recommendations for Establishing Global Technical Regulations Under the United Nations/Economic Commission for Europe 1998 Global Agreement; Motor Vehicle Safety

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: NHTSA's recommendations to WP.29 for regulations to be considered under the 1998 Global Agreement.

SUMMARY: In July 2000, NHTSA published a notice seeking comments on its preliminary recommendations for the first motor vehicle safety technical regulations to be considered for establishment under the United Nations Economic Commission for Europe 1998 Global Agreement. NHTSA has reviewed and considered all public comments submitted in response to the notice and has prepared final recommendations to present to the World Forum for the Harmonization of Vehicle Regulations (WP.29) at the March 2001 meeting in Geneva. NHTSA will use the recommendations in deliberating with other Contracting Parties concerning the adoption of a program of work under the 1998 Global Agreement.

FOR FURTHER INFORMATION CONTACT: For technical and policy issues: Ms. Julie Abraham, Director, Office of International Policy and Harmonization, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590. Telephone: (202) 366–2114. Fax: (202) 366–2559.

For legal issues: Nancy Bell, Attorney Advisor, Office of the Chief Counsel, NCC–20, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590. Telephone: (202) 366–2992. Fax: (202) 366–3820.

SUPPLEMENTARY INFORMATION: You may read the materials placed in Docket No. NHTSA–00–7638 (*e.g.*, the comments submitted in response to the request for comments by other interested persons) by visiting the address: Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC, 20590. The hours of the Docket Management System (DMS) are indicated above in the same location. Alternatively, you may read the materials electronically on the Internet. To do so, take the following steps:

(1) Go to the Web page of the Department of Transportation DMS (http://dms.dot.gov/).

(2) On that page, click on "search" near the top of the page or scroll down to the words "Search the DMS Web" and click on them.

(3) On the next page (http://dms.dot.gov/search/), scroll down to "Docket Number" and type in the four-digit docket number (7638) shown in the title at the beginning of this notice. After typing the docket number, click on "search."

(4) On the next page ("Docket Summary Information"), which contains docket summary information for the materials in the docket you selected, scroll down to "search results" and click on the desired materials. You may download the materials.

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I. Background

The U.S. became a signatory to the United Nations/Economic Commission for Europe (UN/ECE) Agreement Concerning the Establishment of Global and Technical Regulations for Wheeled Vehicles, Equipment and Parts Which Can Be Fitted And/or Be Used On Wheeled Vehicles (the "1998 Global Agreement") in June 1998. The 1998 Global Agreement, which entered into force on August 25, 2000, provides for the establishment of global technical regulations regarding the safety, emissions, energy conservation and theft prevention of wheeled vehicles, equipment and parts.[1] The Agreement contains procedures for establishing global technical regulations by either harmonizing existing regulations or developing a new regulation.

On July 18, 2000, in anticipation of the entry into force of the 1998 Global Agreement, NHTSA published a notice to obtain public comments on a list of preliminary recommendations of standards or aspects of standards for consideration by Contracting Parties in prioritizing the development and establishment of global technical regulations under the 1998 Global Agreement. (65 Fed. Reg. 44565) In that notice, NHTSA placed its recommendations into two categories based on available information and analysis concerning the relative level of stringency and benefits of U.S. and foreign standards. The first category, the "Priority Recommendations," included some foreign standards or aspects of those standards that may represent best safety practices among existing national and regional regulations and that may lead to the improvement of vehicle safety in the U.S. NHTSA stated that, in allocating agency resources among the priority recommendation, it will give priority to the recommendations in this category. The second category, the "Other Recommendations," included U.S. standards or aspects of standards that may represent best current safety practices and that may lead to improvement of vehicle safety worldwide. NHTSA believes that the standards in this category should obtain international review and feedback and be considered in the establishment of global technical regulations under the 1998 Global Agreement.

In addition to the above mentioned categories, the notice also noted the suggestions that had been received by the United Nations' Economic Commission for Europe World Forum for Development of Global Technical Regulations (WP.29) from the governments of Japan and the Russian Federation and various industry and consumer groups. These suggestions are posted in the NHTSA docket (NHTSA–00–7638).

In response to NHTSA's request for suggestions for changes to its preliminary recommendations, the agency received comments from Advocates for Highway and Auto Safety, the Alliance of Automobile Manufacturers, Flat Glass Manufacturers Association of Japan, Honda, the International Organization of Motor Vehicle Manufacturers (OICA), the Rubber Manufacturers Association, and Toyota.

II. NHTSA's Final Recommendations to WP.29

A. Consideration of Comments

NHTSA has reviewed the comments submitted in response to the July 2000 notice. In addition, NHTSA has

[1] The covered equipment and parts inside, but are not limited to, exhaust systems, tires, engines, acoustic shields, anti-theft alarms, warning devices and child restraint systems.

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reviewed the suggestions that had been submitted by the governments of Japan and the Russian Federation and various industry and consumer groups to WP.29. These suggestions have been placed in the docket for the request for comments (NHTSA–00–7638).

The majority of those who commented on NHTSA's approach to priority setting indicated that they support NHTSA's approach in principle, but believe that modifications are needed. The reasons for these modifications included: (1) The need to continue work on standards for which resources already have been expended and considerable progress has been made; (2) the need to select regulations that are easier to harmonize from both the technical and the political points of view; (3) the need to include regulations that have been harmonized between Europe and Japan (under the 1958 Agreement); (4) cost-savings to industry and consumers; (5) the list of specific standards under each category is not comprehensive or includes subjects that ought to be removed because of the lack of a clear association with the category; and (6) harmonizing specific aspects of standards is not sufficient.

In response to the comments, NHTSA wishes to clarify its approach to priority setting. NHTSA's statutory mission, and thus the focus of its rulemaking activities, is improving vehicle safety. Accordingly, NHTSA must continue to focus its resources on those standards that improve motor vehicle safety in the U.S.

However, the agency also devotes considerable effort to refining and updating its standards to permit technological innovation, avoid imposing unnecessary regulatory burdens, and improve regulatory effectiveness. Accordingly, NHTSA recognizes the merit in including other standards in the work of WP.29. NHTSA agrees that consideration should be given to including some standards based on the fact that harmonization work is already underway and progress has been made on them. NHTSA itself has already spent considerable resources on some of these standards. With the expenditure of limited additional resources, NHTSA can work with other contracting parties toward their establishment as global technical regulations. NHTSA will also continue to collaborate with other contracting parties to the 1998 Global Agreement on standards of importance to those contracting parties. In addition, NHTSA agrees with including some standards on the basis that it may be easy to harmonize them. NHTSA believes that working on those standards will help the U.S. and other contracting parties gain experience with the process of the 1998 Global Agreement.

B. Recommended Priorities

NHTSA's recommended priorities are largely unchanged. However, NHTSA has decided to reorganize its recommendations according to the subject matter responsibilities of the WP.29 Working Parties of Experts to examine their potential impact on the workload for each of the Working Parties. Upon reviewing its preliminary recommendations and the specific standards that were recommended by other contracting parties, interest groups or commenters for each of the Working Parties of Experts, NHTSA found that the majority of the standards would be assigned to the Working Party on Passive Safety (GRSP). Therefore, in the interest of promoting a manageable workload, the agency has decided to defer some of its recommendations. In addition, based on the considerations discussed above, NHTSA added Motorcycle Brakes to its list of recommendations for the Working Party on Brakes and Running Gear (GRRF).

NHTSA's final recommendations to WP.29 are categorized below according to the Working Parties of Experts. These recommendations focus on standards that NHTSA believes could be productively worked on in the immediate future. NHTSA will continue to work on several long term projects that are currently underway in NHTSA and are also being coordinated in the International Harmonized Research Activities (IHRA). NHTSA will also reevaluate the list set out below on a regular basis to assess whether a revision is merited.

In announcing its final recommendations, NHTSA wants to reaffirm its commitment to achieving the goals of the National Traffic and Motor Vehicle Safety Act. Further, the agency cautions that its recommendations to WP.29 under the 1998 Global Agreement should not be confused with its more inclusive list of rulemaking activities under the Vehicle Safety Act.

NHTSA's final recommendations to be submitted to WP.29 at the March 2001 meeting.

1. *Working Party on Passive Safety*
   Head restraints
   Lower anchorages and tethers for child safety seats
   Door retention components
   Dummies (10 year old frontal dummy and 50th percentile side impact dummy)
   Frontal impact (full/offset) protection
2. Working Party on Brakes and Running Gears
   Tires
   Motorcycle brakes
3. *Working Party on Lighting and Light-Signaling*
   Signal lamp visibility
4. *Working Party on General Safety*
   Windshield wipers and washers
   Controls and displays
   Vehicle classification

III. Future Actions

At the March 2001 meeting in Geneva, NHTSA will use its final recommendations in deliberating with the other Contracting Parties to the 1998 Global Agreement about a program of work for the Working Parties of Experts. NHTSA will report to the public on the final outcome of the deliberations after that meeting.

Issued on January 12, 2001.

Rosalyn G. Millman,

Deputy Administrator.

[FR Doc. 01–1527 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–99–6324; Notice 2]

EMB Incorporated; Grant of Application for Temporary Exemption From Federal Motor Vehicle Safety Standards Nos. 108 and 120

This notice grants the application by EMB Incorporated ("EMB") of Sebastopol, California, for a 2-year exemption from portions of Federal Motor Vehicle Safety Standard Nos. 108 *Lamps, Reflective Devices and Associated Equipment*, and 120 *Tire Selection and Rims for Motor Vehicles Other Than Passenger Cars*. The company does business as Electric Motorbike, Inc., and has petitioned on behalf of its Lectra VR24 motorcycle. In the opinion of the company, a temporary exemption "would make the development or field evaluation of a low-emission motor vehicle easier and would not unreasonably lower the safety level of that vehicle" (49 U.S.C. 30113(b)(3)(B)(iii)).

Notice of receipt of the petition was published on July 17, 2000, and an opportunity afforded for comment (65 FR 44092).

The discussion that follows is based on information contained in EMB's application.

Why EMB needs a temporary exemption. The company is developing zero-emission (electric battery-powered) vehicles. Due to a lack of readily-available components for these vehicles needed to comply with Federal Motor Vehicle Safety Standards Nos. 108 and 120, as explained below, EMB must petition for an exemption from portions of them, until July 1, 2002, as explained below.

EMB's arguments why an exemption would facilitate the development and field evaluation of a low-emission motor vehicle and would not unreasonably degrade the safety of that vehicle. In order to make the company's products available for wider use, EMB believes that a test and development period is necessary to optimize product features and functions. During the development stage, it is likely that several design changes will be made "to optimize the product for acceptance by the wider public."

It is important to place a limited number of the product in service in order to gain insights into the features, functions and operating characteristics of the product.

In order to do so, the petitioner requested the following temporary exemptions:

1. Standard No. 108

EMB utilizes a 24-volt lighting system which presently creates an incompatibility with available lighting equipment, necessitating a temporary exemption from three requirements of Standard No. 108.

Table IV of Standard No. 108 requires motorcycle turn signal lamps to meet the applicable requirements of SAE Standard J588NOV8 *Turn Signal Lamps*. However, section 5.1.1.7 of Standard No. 108 provides that "a motorcycle turn signal lamp need meet only one-half of the minimum photometric values specified in Table 1 and Table 3" of SAE J588NOV84. EMB stated that "turn signals which operate at this voltage are difficult to locate." However, it has found a supplier in Spain "which offers European-compliant turn signals for 24-volt operation." The turn signal unit "meets European requirements 50R E9." EMB believes that the European standard is equivalent to that of section 5.1.1.7, *e.g.*, that an exemption would not unduly degrade the safety of the vehicle.

Table III of Standard No. 108 requires motorcycles to be equipped with turn signal lamps and a turn signal operating unit. Section 5.5.6 requires all vehicles equipped with a turn signal operating unit to have also an illuminated pilot indicator, which will inform the operator when one or more turn signal lamps fails to operate. However, no indication is required if a variable-load turn signal flasher has been installed on a motor vehicle type specified in section 5.5.6. A motorcycle is not one of the vehicle types specified, and the Lectra VR24 incorporates a variable load flasher. As noted above, the company uses a 24-volt DC power source for turn signal lamps. Outage indication is not presently available in 24 volt DC flasher units, therefore, the turn signal indicator on the dashboard will not indicate a failed lamp.

EMB argued that the open nature of the motorcycle makes it "easy for an operator to check for proper operation of all lights and signals * * *."

EMB also sought exemption from certain portions of Section 7.9 which specifies headlighting requirements for motorcycles. In pertinent part, EMB wishes to meet the photometric specifications of Figure 32. At the present time, motorcycle headlamps are not available in 24-volt versions, and the company has chosen "a military vehicle headlamp" manufactured by "Wagner Corporation." This headlamp "does meet requirements for passenger car headlighting systems." The upper beam of the headlamp meets all requirements for motorcycle headlamp upper beams, and complies with all lower beam test points as well, with the exception of Test Point 2D–3L, where there is a shortfall of 7 percent.

EMB argued that the shortfall does not unreasonably degrade safety because the Lectra VR24 is designed for a cruising speed of 30 mph and the headlamp does meet requirements for this equipment on motor driven cycles.

Finally, the lens of the headlamp will not be marked "motorcycle" as required by Section 7.9.5 for a headlamp of the type intended to be used.

During the exemption period, EMB plans to develop a lighting system that fully complies with Standard No. 108.

2. Standard No. 120

Section 5.2 *Rim marking* of Standard No. 120 requires, in pertinent part, that each rim be embossed or debossed with certain specified information. The wheel that EMB has selected was not embossed with the information at time of manufacture but has been subsequently stamped with indelible ink. All the information is present and in the required location. These wheels meet ISO 8644, ISO 8645, and TUV specifications. EMB will work with suppliers to ensure that future rims are properly marked.

EMB's arguments why an exemption would be consistent with the public interest and objectives of motor vehicle safety. EMB "is developing zero-emission vehicles which are consistent with the goals and desires of society for a cleaner and quieter environment, and reduced reliance on fossil fuels."

Even with the exemptions requested, EMB argued that the Lectra VR24 exhibits an overall level of safety equivalent to that prescribed by the Federal motor vehicle safety standards.

Agency Response and Decision

We received no public comments on the application.

EMB is eligible for a temporary exemption on the basis on which it has applied because it intends to produce a zero-emission vehicle. The manufacture of zero-emission vehicles is in the public interest, not only for California where EMB is located but also for the rest of the country as well.

In order to grant EMB's application, we must also make findings that an exemption would not unreasonably lower the safety of the Lectra VR24 motorcycle, and that an exemption would be consistent with the objectives of traffic safety.

Unlike other motorcycles, EMB has designed the Lectra VS24 with a 24-volt lighting system. The company does not know whether the turn signal system will comply with the optional performance allowed by Section 5.1.1.7, but has found that the unit will meet an applicable European requirement, which it believes is equivalent to the performance allowed by Section 5.1.1.7. *Does NHTSA, as opposed to the petitioner, believe that it is equivalent, and if so, on what objective basis do we form that belief? Pls look at Appendix B of 553. It addresses how the agency makes equivalency determinations. Pls note that it requires a degree of rigor in making such determinations.* It would seem, therefore, that the Lectra VS24 will have the equivalent of a complying turn signal system, and, if it does not, that it will be sufficiently close to the requirements of Standard No. 108 that the level of safety would not be "unreasonably" lower. *On what objective basis do we conclude that it will be sufficiently close?*

Standard No. 108 does not require that a turn signal pilot indicator be provided on vehicles other than motorcycles when the flasher is a variable-load type. The Lectra VS24 uses a variable load turn signal flasher, and no indicator has been provided. It argued that the open nature of the motorcycle makes it easy for an operator to check the proper operation of the signals. Variable load flashers are intended to accommodate vehicles larger than motorcycles that haul other vehicles on which turn signal systems

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are installed. Motorcycles were omitted from the exclusion, not for safety reasons, but because there was no reason to include them. We agree with EMB that an operator will have an actual visual indication if the Lectra VS24's system is not working. We find no safety impact under these circumstances.

The headlamp EMB has chosen is one for military vehicles. It fails to meet one photometric test point, with a shortfall of 7 percent. In addition, the lens is not marked "motorcycle." EMB argues that this does not unreasonably degrade safety because the Lectra VS24 is designed for a cruising speed of 30 mph and its headlamp will meet the requirement for headlamps on motor driven cycles.

We do not find this argument appropriate. The exceptions that Standard No. 108 makes for lighting equipment on motor driven cycles with a maximum speed of 30 mph are only for turn signals and stop lamps (see section 5.1.1.21 and section 5.1.1.22). While a shortfall of 7 per cent is a failure, it occurs at only one test point on the lower beam. Even if this is assumed to represent a lowering of the safety of the vehicle, the effect would be minimal and not "unreasonable." The presence of the word "motorcycle" on the headlamp lens is intended to advise prospective purchasers of replacement headlamps that the headlamp has not been designed for use on vehicles other than motorcycles. Since the petition has not been filed by the manufacturer of the headlamp and does not relate to the aftermarket, the noncompliance is of a technical nature only.

With respect to Standard No. 120, the required rim markings are present, but they have been stamped in indelible ink rather than being embossed or debossed. While the intent of the standard is to provide permanent marking for the rims, stamping in indelible ink ought to be an acceptable equivalent. *Does that mean we would grant an inconsequentiality request for rims marked with ink instead of embossed or debossed?* We note that future rims will be properly marked.

The exemptions from these requirements are minor, and hence, compatible with the safety mission of the agency.

On the basis of the foregoing, we find that a temporary exemption would make the development and field evaluation of a low-emission motor vehicle easier and would not unreasonably lower the safety level of that vehicle. We also find that a temporary exemption would be in the public interest and consistent with the objectives of motor vehicle safety. Accordingly, EMB Incorporated is granted NHTSA Temporary Exemption No. EX2000–4 from section 5.1.1.7 and section 7.9 of 49 CFR 571.108 Standard No. 108, *Lamps, Reflective Devices and Associated Equipment*, and from that portion of section 5.2 of 49 CFR 571.120 Standard No. 120, *Tire Selection and Rims for Motor Vehicles Other Than Passenger Cars* which requires marking "in lettering not less than 3 millimeters high, impressed to a depth or, at the option of the manufacturer, embossed to e height of not less than 0.125 millimeters." The exemption shall expire July 1, 2002.

Authority: 49 U.S.C. 30113; delegations of authority at 49 CFR 1.50 and 501.4.

Issued on: January 11, 2001.

Rosalyn G. Millman,

Deputy Administrator.

[FR Doc. 01–1526 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–59–U

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Docket No. RSPA–01–8587; Notice No. 01–01]

Hazardous Materials Safety Advisory: Unauthorized Marking of Compressed Gas Cylinders

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Safety Advisory Notice.

SUMMARY: This is to notify the public that RSPA is investigating the apparent unauthorized and improper marking of high-pressure compressed gas cylinders by FESS, Inc. d/b/a Fire Extinguisher Service and Sales, 3303 Superior Avenue, Cleveland, Ohio, during the period 1995 to the present. Those cylinders may pose a safety risk to the public. Under no circumstances should a cylinder described in this safety advisory be filled, refilled or used for any purpose other than scrap until it is reinspected and retested by a DOT-authorized retest facility.

RSPA requires that compressed gas cylinders undergo a visual reinspection and a hydrostatic retest on a periodic basis, in accordance with the Hazardous Materials Regulations (HMR), in order to verify that a cylinder has the structural integrity for continued use. If the required visual reinspection and hydrostatic retest are not performed properly, a cylinder with compromised structural integrity may fail (leak or burst) in continued service, when it should have been condemned. Serious personal injury, death, and property damage could result from rupture of a cylinder. Cylinders that have not been retested in accordance with the HMR may not be charged or filled with a hazardous material (compressed gas).

FOR FURTHER INFORMATION CONTACT: Guadalupe "Lupe" Castellanos, Hazardous Materials Enforcement Specialist, Central Region, Office of Hazardous Materials Enforcement, Research and Special Programs Administration, US Department of Transportation, 2350 East Devon Avenue, Des Plaines, Illinois 60018. Telephone: (847) 294–8580; Fax: (847) 294–8590.

SUPPLEMENTARY INFORMATION: Until March 19, 1998, FESS held a retester identification number (RIN) issued by RSPA, authorizing FESS to requalify DOT and ICC specification compressed gas cylinders for continued use in accordance with the requirements in 49 CFR 173.34(e) of the HMR for performing a periodic visual inspection and hydrostatic retest. In its most recent application for renewal of its RIN, FESS stated that it reinspected and retested approximately 800 DOT specification 3A, 3AA, and 3AL cylinders each year. When used as fire extinguishers, the retest period for these cylinders can be as long as 12 years. 49 CFR 173.34(e)(19)(ii).

During a recent inspection at FESS's facility in Cleveland, Ohio, RSPA determined that FESS had marked an undetermined number of cylinders after its RIN expired on March 19, 1998. RSPA also concluded that FESS had marked many cylinders, both before and after that date, which may not have been properly reinspected and retested. It appeared to RSPA's inspector that FESS was not able to assure that its hydrostatic retest equipment was accurate to the required degree, based on its failure to have documentation showing the test pressures and readings for its calibrated cylinder and based on the condition of its retest apparatus and calibrated cylinder at the time of the inspection. FESS acknowledged that it customarily marked cylinders before inspecting and testing them, and its test records were incomplete in a number of regards, including lack of entries for certain cylinders observed during RSPA's inspection; the dates on which cylinders were purportedly reinspected and retested; and the initial retest attempt when a cylinder was retested a second time due to equipment failure on the first retest attempt. In addition, FESS did not have the current version of the requirements for requalification of compressed gas cylinders in 49 CFR 173.34(e), and it did not hold pamphlets published by the Compressed Gas Association and incorporated by reference in the HMR that apply to its operations.

The current owner stated that he had assumed control of FESS during 1995. Because there has not been an inspection by an independent inspection agency since that date and FESS failed to renew its RIN when it expired, the matters discovered during RSPA's recent inspection raise questions as to the condition of any cylinder marked by FESS with a test date/year of "95" or later. These cylinders are marked with FESS's RIN number B404, bracketed by the month and year of the purported reinspection and retest date, in the following pattern:

B 4
Month Year
4 0

Any person holding a compressed gas cylinder that is marked as having been last inspected and retested by FESS since 1995 should not charge or fill the cylinder without first having it inspected and retested by a cylinder requalification facility holding a currently effective RIN. Any filled cylinder that is marked as having been last inspected and retested by FESS since 1995 should be properly and safely evacuated and purged (a cylinder filled with an atmospheric gas may be vented), and taken to a DOT-authorized cylinder retest facility for visual reinspection and hydrostatic retest to determine if it qualifies for continued use in accordance with the HMR. Under no circumstances should a cylinder described in this safety advisory be filled, refilled or used for any purpose other than scrap until it is reinspected and retested by a DOT-authorized retest facility.

Cylinder requalification facilities holding a currently effective RIN are listed on the internet web site of RSPA's Office of Hazardous Materials Safety, at *"http://hazmat.dot.gov/files/approvals/hydro/hydro_retesters.htm"*.

Persons finding or possessing cylinders described in this safety notice may contact Ms. Guadalupe Castellanos for additional information.

Issued in Washington, D.C. on January 11, 2001.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 01–1553 Filed 1–17–01; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8610 and Schedule A (Form 8610)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8610, Annual Low-Income Housing Credit Agencies Report, and Schedule A (Form 8610), Carryover Allocation of Low-Income Housing Credit.

DATES: Written comments should be received on or before March, 19, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Form 8610, Annual Low-Income Housing Credit Agencies Report, and Schedule A (Form 8610), Carryover Allocation of Low-Income Housing Credit.

OMB Number: 1545–0990.

Form Number: Form 8610 and Schedule A (Form 8610).

Abstract: State housing credit agencies (Agencies) are required by Code section 42(l)(3) to report annually the amount of low-income housing credits that they allocated to qualified buildings during the year. Agencies report the amount allocated to the building owners and to the IRS in Part I of Form 8609. Carryover allocations are reported to the Agencies in carryover allocation documents. The Agencies report the carryover allocations to the IRS on Schedule A (Form 8610). Form 8610 is a transmittal and reconciliation document for Forms 8609, Schedule A (Form 8610), binding agreements, and election statements.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: State, local or tribal governments.

Estimated Number of Respondents: 53.

Estimated Time Per Respondent: 112 hours, 28 minutes.

Estimated Total Annual Burden Hours: 5,961.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 8, 2001.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 01–1510 Filed 1–17–01; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Publication 1075

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

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SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Publication 1075, Tax Information Security Guidelines for Federal, State, and Local Agencies.

DATES: Written comments should be received on or before March 19, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the publication should be directed to Faye Bruce, (202) 622–6665, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Tax Information Security Guidelines for Federal, State, and Local Agencies.

OMB Number: 1545–0962.

Form Number: Publication 1075.

Abstract: Section 6103(p) of the Internal Revenue Code requires the Internal Revenue Service to provide periodic reports to Congress describing safeguard procedures utilized by agencies which receive information from the IRS to protect the confidentially of the information. This Code section also requires that these agencies furnish reports to the IRS describing their safeguards.

Current Actions: There are no changes being made to Publication 1075 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, and Federal, state, local, or tribal governments.

Estimated Number of Respondents: 5,100.

Estimated Time Per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 204,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 9, 2001.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 01–1511 Filed 1–17–01; 8:45 am]

BILLING CODE 4830–01–U

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

Federal Register

Thursday,
January 18, 2001

Part II

Department of Transportation

Federal Transit Administration

FTA Fiscal Year 2001 Apportionments, Allocations and Program Information; Notice

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FTA Fiscal Year 2001 Apportionments, Allocations and Program Information

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Department of Transportation (DOT) and Related Agencies Appropriations Act for Fiscal Year 2001 (FY 2001 DOT Appropriations Act) (Pub. L. 106–346) was signed into law by President Clinton on October 23, 2000, and provides FY 2001 appropriations for the Federal Transit Administration (FTA) transit assistance programs. Based upon this Act, and the Transportation Equity Act for the 21st Century (TEA–21), on November 3, 2000, FTA published, on its website, a list of apportionments and allocations for transit programs—excluding the FY 2001 Bus allocations for the Section 5309 Capital Investment Program. Publication of the "FTA Fiscal Year 2001 Apportionments, Allocations and Program Information Notice" in the **Federal Register** was delayed pending the completion of the appropriation process by Congress.

The FY 2001 Omnibus Consolidated Appropriations Act (Pub. L. 106–554), which was signed by the President on December 21, 2000, contains provisions that impact the level of funding made available to FTA in the FY 2001 DOT Appropriations Act and cause the FY 2001 apportionments and allocations previously published on the website to change. More specifically, the FY 2001 Omnibus Consolidated Appropriations Act contain the following provisions relative to FTA programs in this fiscal year: (1) Section 1403(a) Government-Wide Rescission, which rescinds an amount equal to .22 percent of the discretionary budget authority is to be applied to programs, projects, and activities; (2) Section 1108, which directs that funding for the Clean Fuels Formula Grant program under 49 U.S.C. 5309(m)(3)(C) does not apply to funds made available in the FY 2001 DOT Appropriations Act; and (3) Sections 1105, 1107, and 1123, which appropriate from the Mass Transit Account of the Highway Trust Fund, $1,000,000 for Southeast Light Rail Extension Project, in Dallas, TX, $3,000,000 for the Newark-Elizabeth rail link project in New Jersey, and $500,000 for Alabama A&M University buses and bus facilities, respectively.

This notice includes the apportionment of FY 2001 funds made available in the FY 2001 DOT Appropriations Act—as adjusted in accordance with the applicable provisions of the FY 2001 Omnibus Consolidated Appropriations Act—for the: Metropolitan Planning Program and State Planning and Research Program; Urbanized Area Formula Program; Nonurbanized Area Formula Program; Rural Transit Assistance Program; Elderly and Persons with Disabilities Program; and the Capital Investment Program for Fixed Guideway Modernization. This notice also contains the adjusted allocations for the New Starts and Bus categories under the Capital Investment Program and the Job Access and Reverse Commute Program. It contains general information about other programs established under TEA–21, including the Over-the-Road Bus Accessibility Program and the Clean Fuels Formula Program.

Information regarding TEA–21 funding authorization levels for use in developing Metropolitan Transportation Improvement Programs (TIPs) and Statewide Transportation Improvement Programs (STIPs) is included. For informational purposes, the notice contains the estimated apportionment of FY 2001 funds for the Federal Highway Administration (FHWA) Metropolitan Planning Program and the estimated apportionment of FY 2001 funds for the FHWA State Planning and Research Program.

Listings of prior year unobligated allocations for the section 5309 New Starts and Bus Programs are included, as in previous years. In addition, the FTA policy regarding pre-award authority to incur project costs and the Letter of No Prejudice Policy are provided. Other pertinent program information is also included.

FOR FURTHER INFORMATION CONTACT: The appropriate FTA Regional Administrator for grant-specific information and issues; Patricia Levine, Director, Office of Resource Management and State Programs, (202) 366–2053, for general information about the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, the Rural Transit Assistance Program, the Elderly and Persons with Disabilities Program, the Clean Fuels Formula Program, the Over-the-Road Bus Accessibility Program, or the Capital Investment Program; or Paul L. Verchinski, Chief, Statewide and Intermodal Planning Division, (202)366–1626, for general information concerning the Metropolitan Planning Program and the State Planning and Research Program; or Dr. Lewis P. Clopton, Director, Office of Research Management, (202)366–9157, for information about the Job Access and Reverse Commute Program.

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I. Background

Metropolitan Planning funds are apportioned by statutory formula to the Governors for allocation to Metropolitan Planning Organizations (MPOs) in urbanized areas or portions thereof to provide funds for their Unified Planning Work Programs. State Planning and Research funds are apportioned to states by statutory formula to provide funds for their State Planning and Research Programs. Urbanized Area Formula Program funds are apportioned by statutory formula to urbanized areas and to Governors to provide capital, operating and planning assistance in urbanized areas. Nonurbanized Area Formula Program funds are apportioned by statutory formula to Governors for capital, operating and administrative assistance in nonurbanized areas. Elderly and Persons with Disabilities Program funds are apportioned by statutory formula to Governors to provide capital assistance to organizations providing transportation service for the elderly and persons with disabilities. Fixed Guideway Modernization funds are apportioned by statutory formula to specified urbanized areas for capital improvements in rail and other fixed guideways. New Starts and Bus allocations identified in the FY 2001 DOT Appropriations Act or the Conference Report accompanying the FY 2001 DOT Appropriations Act are included in this notice. FTA will honor those allocations included in report language provided that the projects meet the statutory intent of the specific program.

II. Overview

A. Fiscal Year 2001 Appropriations

The FY 2001 DOT Appropriations Act made $6,271,000,000 available for FTA programs, which is the guaranteed funding level under TEA–21. After the .22 percent reduction for the government-wide rescission and addition of new funding (as directed in the FY 2001 Omnibus Consolidated Appropriations Act), and transfer of funds to the Office of the Inspector General (OIG) as directed in the FY 2001 DOT Appropriations Act, FTA's FY 2001 appropriation is $6,260,696,100. The revised/adjusted FY 2001 funding amounts for FTA programs are displayed in Table 1.

The following text provides a narrative explanation of the funding levels and other factors affecting the apportionments and allocations.

B. TEA–21 Authorized Program Levels

TEA–21 provides a combination of trust and general fund authorizations that total $7,274,000,000 for the FY 2001 FTA program. Of this amount, $6,271,000,000 was guaranteed under the discretionary spending cap and made available in the FY 2001 DOT Appropriations Act. Adjustments directed by the FY 2001 Omnibus Consolidated Appropriations Act reduce funding for FTA programs to $6,260,696,100 for FY 2001. See Table 11 for fiscal years 1998–2003 guaranteed funding levels by program and Table 11A for the total of guaranteed and non-guaranteed levels by program.

Information regarding estimates of the funding levels for 1999–2003 by state and urbanized area is available on the FTA website. The numbers are for planning purposes only as they will be revised in the future but may be used for programming Metropolitan Transportation Improvement Programs and Statewide Transportation Improvement Programs.

C. Project Management Oversight

Section 5327 of Title 49 U.S.C. allows the Secretary of Transportation to use not more than one-half percent of the funds made available under the Urbanized Area Formula Program and the Nonurbanized Area Formula Program, and three-quarters percent of funds made available under the Capital Investment Program to contract with any person to oversee the construction of any major project under these statutory programs to conduct safety, procurement, management and financial reviews and audits, and to provide technical assistance to correct deficiencies identified in compliance reviews and audits. Therefore, one-half percent of the funds appropriated for the Urbanized Area Formula Program and the Nonurbanized Area Formula Program for FY 2001, and three-quarters percent of Capital Investment Program funds were reserved for these purposes before funds were apportioned.

D. 2002 Winter Olympic Games

The FY 2001 DOT Appropriations Act made $60,000,000 available from the formula grants program for the 2002 Winter Olympic Games. After applying a .22 percent reduction, in accordance with the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, $59,868,000 is available for this activity. The funds shall be available for grants for the costs of planning, delivery and temporary use of transit vehicles for special transportation needs and

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construction of temporary transportation facilities for the XIX Winter Olympiad and the VIII Paralympiad for the Disabled, to be held in Salt Lake City, Utah.

III. Fiscal Year 2001 Focus Areas

A. Urbanized Area Formula Study

Section 3033 of TEA–21 requires the Secretary of Transportation to conduct a study of FTA's Urbanized Area Formula Program (49 U.S.C. 5307) and the needs of small urbanized areas with unusually high levels of transit service. On September 29, 2000, the Secretary of Transportation approved "The Urbanized Area Formula Program and the Needs for Small Intensive Cities", which reports the result of the study. The report concludes that sufficient issues exist suggesting that changes to the existing Urbanized Area Formula Grants Program should be considered as part of the FY 2004 and beyond reauthorization cycle. However, the formula apportionments should continue to reflect underlying transit needs. For further information contact Richard Steinmann, FTA Office of Policy Development, at (202) 366–4050.

B. National Transit Database Redesign

There have been major changes in federal reporting requirements affecting FTA. Most notable among these is prompt reporting of certain National Transit Database (NTD) data under the Government Performance and Results Act, and an increase in the level of detail. In addition, FTA must respond to congressional direction for new safety data reporting. These factors, along with other significant considerations and concerns, served as the impetus to redesign the NTD.

In the Spring of 2000, FTA conducted an outreach effort to the transit industry and then prepared a report to Congress entitled, "Review of the National Transit Database" (May 31, 2000), which evaluates the NTD reporting system. The report suggests a number of changes that will enhance the usefulness of the NTD while minimizing reporting burden. The report is available on the FTA website.

Presently, FTA is in the process of redesigning the data requirements of the NTD, which is expected to be completed by the Spring of 2001. System reprogramming and database testing will precede final implementation, which will take place during the Spring of 2002.

C. New Starts Roundtable

In FY 2000, FTA sponsored a series of New Starts Roundtable (NSR) meetings. The purpose of the NSR is to facilitate continued dialogue and information sharing between FTA and local sponsors of projects pursuing Capital Investment Program (section 5309) New Starts funding. This includes projects currently in FTA's New Starts pipeline or a study that may result in the selection of a major fixed guideway transit investment in the near future.

The NSR provides a forum for FTA and the New Starts community to jointly explore and address issues related to the New Starts planning, project development, and evaluation processes. The NSR Steering Committee, a partnership whose membership is comprised of the FTA Administrator, FTA staff and representatives from local transit agencies is responsible for outlining the strategy, developing topic areas and agendas and selecting sites and setting schedules for NSR meetings, in addition to implementing the NSR workplan activities.

The targeted participants for NSR meetings include planning directors or project/study managers who can share their views of the New Starts criteria and project development process. In FY 2000, two roundtable meetings were held: July 27th–28th, in Washington, DC; and August 2nd–3rd, in Las Vegas, NV. FTA is in the process of organizing NSR meetings for FY 2001. For additional information regarding this initiative, contact David Vozzolo or Tonya Holland, FTA Office of Planning Innovation and Analysis, at (202) 366–4033.

D. Intelligent Transportation Systems (ITS)

Section 5206(e) of TEA–21 requires that Intelligent Transportation Systems (ITS) projects using funds from the Highway Trust Fund (including the Mass Transit Account) conform to National ITS Architecture and Standards. Interim guidance on conformity with National ITS Performance Standards was issued October 2, 1998, jointly by FTA and FHWA. This document provides guidance for meeting this provision of TEA–21 and is available from FTA regional offices and on the FTA website. These standards and requirements apply to FY 2001 allocations included in this notice that contain ITS components. Using existing FTA oversight procedures, FTA has initiated a program to provide initial oversight and technical assistance with respect to National ITS Architecture Consistency requirements.

Questions regarding the applicability of these standards and requirements should be addressed to the FTA Regional Office or Ronald Boenau, FTA Office of Research, Demonstration and Innovation, at (202) 366–0195.

IV. Section 5303 Metropolitan Planning Program and Section 5313(b) State Planning and Research Program

A. Metropolitan Planning Program

Funding made available for the Metropolitan Planning Program in the FY 2001 DOT Appropriations Act was $52,113,600—the guaranteed funding level under TEA–21. This amount has been reduced to $51,998,950 after application of the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act.

The FY 2001 Metropolitan Planning Program apportionment to states for MPOs' use in urbanized areas totals $52,278,930. This amount includes $51,998,950 in FY 2001 funds, and $279,980 in prior year deobligated funds available for reapportionment under this program. A basic allocation of 80 percent of this amount ($41,423,144) is distributed to the states based on the state's urbanized area population as defined by the U.S. Census Bureau for subsequent state distribution to each urbanized area, or parts thereof, within each state. A supplemental allocation of the remaining 20 percent ($10,455,786) is also provided to the states based on an FTA administrative formula to address planning needs in the larger, more complex urbanized areas. Table 2 contains the final state apportionments for the combined basic and supplemental allocations. Each state, in cooperation with the MPOs, must develop an allocation formula for the combined apportionment, which distributes these funds to MPOs representing urbanized areas, or parts thereof, within the state. This formula, which must be approved by the FTA, must ensure to the maximum extent practicable that no MPO is allocated less than the amount it received by administrative formula under the Metropolitan Planning Program in FY 1991 (minimum MPO allocation). Each state formula must include a provision for the minimum MPO allocation. Where the state and MPOs desire to use a new formula not previously approved by FTA, it must be submitted to the appropriate FTA Regional Office for prior approval.

In FY 2001, the results of the 2000 Census will be made available and the Census Bureau will designate new urbanized areas. Since the statutory formula for distribution of the Metropolitan Planning Program utilizes the latest available decennial census, FTA anticipates use of the 2000 Census for FY 2002 funding apportionments. This will affect each state's apportionment. In addition, each state has an FTA approved in-state allocation formula to each urbanized area. States will be free to continue using their existing in-state formula distribution. When the Census Bureau issues its population data, FTA will request a state reaffirmation of these in-state formulas since most were last approved in FY 1992. A reaffirmation or new in-state formula should be submitted to the FTA Regional Office for approval prior to October 1, 2001 so that the funding distributions are effective in FY 2002.

Currently, guaranteed and authorized funding levels for each state over the life of TEA–21 (fiscal years 1999–2003) based on the 1990 Census, are posted at [http://www.fta.dot.gov/office/planning/gaf.htm]. By June 2001, FTA will post revised fiscal year 2002 and 2003 guaranteed and authorized funding levels based on the 2000 census for each state at this same website address. This information should be utilized by each state when reaffirming or revising in-state formulas.

B. State Planning and Research Program

Funding made available for the State Planning and Research Program in the FY 2001 DOT Appropriations Act was $10,886,400, the guaranteed funding level under TEA–21. This amount has been reduced to $10,862,450, after applying the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act.

The FY 2001 apportionment for the State Planning and Research Program (SPRP) totals $10,938,770. This amount includes $10,862,450 in FY 2001 funds, and $76,320 in prior year deobligated funds, which have become available for reapportionment under this program. Final state apportionments for this program are also contained in Table 2. These funds may be used for a variety of purposes such as planning, technical studies and assistance, demonstrations, management training, and cooperative research. In addition, a state may authorize a portion of these funds to be used to supplement metropolitan planning funds allocated by the state to its urbanized areas, as the state deems appropriate.

C. Data Used for Metropolitan Planning and State Planning and Research Apportionments

Population data from the 1990 Census is used in calculating these apportionments. The Metropolitan Planning funding provided to urbanized areas in each state by administrative formula in FY 1991 was used as a "hold harmless" base in calculating funding to each State.

D. FHWA Metropolitan Planning Program and State Planning and Research Program

For informational purposes, the estimated FY 2001 apportionments for the FHWA Metropolitan Planning Program (PL) and estimated apportionments for FY 2001 State Planning and Research Program (SPRP) are contained in Table 3. These estimates include expected SPRP funding increases from the Revenue Budget Aligned Authority authorized in TEA–21, Section 1105. The amounts are as originally provided by FHWA and may be adjusted by that agency to incorporate the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.

E. Local Match Waiver for Specified Planning Activities

Job Access Planning. Federal, state and local welfare reform initiatives may require the development of new and innovative public and other transportation services to ensure that former welfare recipients have adequate mobility for reaching employment opportunities. In recognition of the key role that transportation plays in ensuring the success of welfare-to-work initiatives, FTA and FHWA permit the waiver of the local match requirement for job access planning activities undertaken with Metropolitan Planning Program and State Planning and Research Program funds. FTA and FHWA will support requests for waivers when they are included in Metropolitan Unified Planning Work Programs and State Planning and Research Programs and meet all other appropriate requirements.

F. Planning Emphasis Areas for Fiscal Year 2001

The FTA and FHWA identify Planning Emphasis Areas (PEAs) annually to promote priority themes for consideration, as appropriate, in metropolitan and statewide transportation planning processes. Identification of PEAs calls attention to a national policy emphasis on the themes and priorities within FTA and FHWA for enhanced inventory of current practice, guidance and training in those areas. The FTA and FHWA are committed to providing opportunities to the planning community to exchange ideas and experiences on innovative practice in these topic areas throughout the year. Furthermore, this information will constitute an important component of guidance for implementing the planning and environmental provisions of TEA–21.

To that end, FTA and FHWA intend to periodically develop information that will be made available through publications, on the FTA and FHWA websites, and through other means. As opportunities become available, this information also will be promoted for inclusion on the agendas of regional and national conferences held during the year. To support these efforts, FTA and FHWA encourage planning organizations to expand their work activities on these topics through their planning work activities, as set forth in Unified Planning Work Programs (UPWPs) and State Planning and Research Programs. This will be the resource base and means by which innovative and effective practices can be identified and reported back to the planning community.

For FY 2001, five key planning themes have been identified as PEAs: (1) Mainstreaming safety in the transportation planning and decision-making process; (2) incorporation of environmental streamlining as a policy and planning analysis theme within planning processes; (3) transportation system management and operations; (4) demonstrated compliance with Title VI of the Civil Rights Act and accommodation of the principles of environmental justice; and (5) coordination of non-emergency transportation services.

(1) *Safety in Transportation.* TEA–21 emphasizes the safety of transportation systems as a national priority and calls for transportation plans and strategies that "increase the safety and security of transportation systems." The DOT Strategic Plan identifies safety as the highest priority and includes a goal to "promote the public health and safety by working toward the elimination of transportation-related deaths, injuries and property damage."

The DOT short-term objective is to integrate safety considerations into all stages of the transportation planning process, including identification of activities to be considered during the development of UPWPs and SPRPs. States and MPOs are encouraged to consider both long and short-term strategies for inclusion in their plans and transportation improvement programs (TIPs).

FTA and FHWA are working together to advance the state-of-practice in addressing safety in the metropolitan and statewide planning process. In May 2000, FTA and FHWA hosted a meeting along with the Transportation Research

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Board (TRB) of safety professionals and planners to address safety in the metropolitan planning process. From that meeting, a TRB report describing the issues and recommendations identified at the meeting will be produced, and is expected to be available on the TRB website in the Fall of 2000 at [*http://www.nas.edu/trb*]. Participants in the TRB meeting summarized the following strategies for addressing safety in planning processes:

- Establish a foundation for safety in planning;
- Improve access to safety data and encourage its use;
- Address safety in the consideration of alternative mode choice options;
- Explicitly address safety in federal and state regulatory policy; and
- Market and advocate safety through "champions" to user groups.

These suggested strategies are just a beginning. FTA and FHWA are also working to document good practice and develop guidance in the area of safety planning that will be a tool for both states and MPOs in addressing safety in their planning processes. Through good practice and guidance, MPOs can begin to identify methods to integrate safety within the planning process. These methods may include:

- Providing an umbrella for the coordination of transportation safety activities among various levels of government, the private sector and other specialized transportation safety groups;
- Enhancing the knowledge of local officials and the public on traffic safety; and
- Developing assessment tools for safety based upon existing problems and how proposed projects will decrease problems in a regional context.

(2) *Environmental Streamlining.* TEA–21 reflects the concerns of Congress and the transportation community that the planning and project development processes are requiring too much time before solutions to serious transportation problems are ready for implementation. TEA–21 mandated the elimination of the Major Investment Study as a stand-alone requirement and the streamlining of the process for complying with the National Environmental Policy Act (NEPA) and other environmental statutes and regulations. Developing and guiding projects through the planning and review processes faster, without compromising environmental safeguards, is a complex undertaking for which there is no easy solution.

FHWA and FTA have engaged the federal environmental and permitting agencies in a dialogue on ways to improve the planning and NEPA processes. This dialogue has produced a national Memorandum of Understanding (MOU) on environmental streamlining among the federal agencies, which formalizes their commitment to streamline the environmental review process for federally-funded highway and transit projects, while fulfilling their responsibilities to protect the environment. The MOU calls for early consideration of environmental and community issues during the planning process in consultation with federal and state environmental resource agencies. FHWA followed up on the national MOU by convening regional summits on environmental streamlining. These summits have resulted in a number of regional and statewide MOUs that address more specific linkage between planning and project development. These documents are generally available in the environmental streamlining "tool kit" that has been posted on the FHWA website at [http://www.fhwa.dot.gov/environment/strmlng.htm].

FTA and FHWA are establishing environmental streamlining as a PEA to encourage greater effort, innovative approaches, and a national dialogue on using the planning process to advance this objective. Examples of the kinds of innovative planning concepts that might serve to streamline the environmental process under the appropriate conditions include the introduction and use of new technologies such as Geographic Information Systems to study regional environmental issues in support of programmatic approvals, or closer coordination of transportation planning with other planning efforts such as land use planning, air quality planning, or watershed management and associated mitigation banking. Additional streamlining concepts are being explored in a number of states such as Florida, Oregon, and California through pilot projects or pilot programs specifically identified by the State DOTs, MPOs, and transit agencies for this purpose. An expert panel established through the National Cooperative Highway Research Program is monitoring, analyzing, and reporting on the status of the pilot streamlining effort around the country. The results will be added to the streamlining tool kit on the FHWA website mentioned above.

As part of this PEA, FHWA and FTA are seeking not only to demonstrate that earlier consideration of environmental issues during planning makes sense, but also actually to quantify, to the extent possible, the time savings and environmental benefits that result. To that end, a preliminary baseline assessment of processing times has been completed and a more detailed assessment is underway. As additional data becomes available, it too will be posted on the FHWA streamlining website.

(3) *Transportation System Management and Operations.* TEA–21 challenges the FHWA and FTA to move beyond traditional infrastructure-based approaches to improve the movement of people and goods. TEA–21 emphasizes a greater need to improve the way transportation systems are managed and operated. The challenge, in terms of transportation planning, is not only to make a good investment in infrastructure, but also to see that this investment is managed and operated to meet a broad range of customer needs. The FHWA and FTA are establishing management and operations as a PEA to encourage innovation, promote a national dialogue, and advance the state of the practice.

FTA and FHWA recognize that future transportation planning must look beyond the perception that management and operation strategies merely reduce congestion problems or move vehicles faster. The FHWA and FTA are convening a working group to develop recommendations to better integrate transportation operations and planning to address a broad array of transportation issues.

Information is available at website address [http://plan2op.fhwa.dot.gov] to guide and inform transportation planners on effective ways to consider management and operations investments, programs and actions in planning contexts. It provides a document library that may be searched for recent documents that deal with this subject and also presents a forum for the exchange of experiences.

(4) *Transportation Equity and Public Involvement.* Increasingly, concerns for compliance with provisions of Title VI of the Civil Rights Act have been raised by citizens and advocacy groups with regard to broad patterns of transportation investment and impact considered in metropolitan and statewide planning. While Title VI and environmental justice concerns have most often been raised during project development, it is important to recognize that the law applies equally to the processes and products of metropolitan and statewide planning. Public involvement is a major element of this process.

FTA and FHWA are working jointly to develop guidance to support metropolitan areas and states in their efforts to incorporate considerations of transportation equity in their local planning processes and substantiate Title VI compliance through demonstrated actions. Several releases of resource materials have taken place over the past year, including:

- "Title VI Environmental Justice Planning Technical Assistance Manual" with accompanying implementation training;
- brochure and fact sheet to facilitate a better understanding of Title VI/Environmental Justice considerations in transportation activities; and
- creation of an informational website which can be accessed at [http://*www.fhwa.dot.gov/environment/ej2.htm*].

Case studies and effective practice materials are being prepared for wide distribution, and a companion training and education package is being designed. These will be completed by the end of 2000.

States and Metropolitan Planning Organizations (MPOs) are advised to strengthen their planning processes in this area and to document their effort in two categories of work activity:

(a) Strengthen the focus of public involvement efforts, with special attempts to include the traditionally under-served and under-represented in the planning process; and

(b) assessing the distribution of benefits and adverse environmental impacts at both the plan and project levels.

Over the fiscal year, a range of possible procedural and analytical approaches for complying with provisions of Title VI and the Executive Order on Environmental Justice at the planning stage will be developed and disseminated through guidance and regulation. To support that effort, "innovative practice" case study development and training opportunities will be enhanced, based in part on the reported activities and experiences of metropolitan and statewide planning processes in this area.

(1) *Coordination of Non-Emergency Transportation Services.* Experience and research have shown that coordinating program resources for transportation services can lead to increased service availability and more cost-effective transportation services to persons with limited access and special needs. The DOT and the U.S. Department of Health and Human Services (HHS) recognize that there are over 70 federal programs in which some aspect of transportation services is an allowable use of funds. The Departments are jointly developing a coordination resource, the Transportation Coordination Toolkit, to assist states and communities in their efforts to improve access to transportation services for persons with special mobility needs.

The initial piece in the Transportation Coordination Toolkit is a guide to coordinating transportation planning for DOT and HHS. It addresses the information and actions necessary to coordinate the transportation resources of various programs of DOT and HHS. Additional pieces will include case studies, a compilation of federal-funding sources, and a program resource guide. Additional information on these can be found on the website for the Coordinating Council on Access and Mobility at [http://www.ccamweb.org].

G. Federal Planning Certification Reviews

The Intermodal Surface Transportation Efficiency Act (ISTEA) required FTA and FHWA to certify, at least every three years, that the planning processes conducted in the largest metropolitan areas were being carried out in compliance with applicable provisions of federal law. This provision applies specifically to localities termed "Transportation Management Areas" (TMA), which are urbanized areas with populations of 200,000 and above, or other urbanized areas that may be designated by the Secretary of Transportation. TEA–21 further required that, in conducting these certification reviews, provisions be made for public involvement appropriate to the metropolitan area under review.

To that end, an annual calendar of prospective dates and locations for certification reviews of TMAs anticipated in FY 2001 has been prepared and is posted on the FTA website at [http://www.fta.dot.gov/library/planning/cert2001.htm].

For further information regarding federal certifications of the planning process contact: for FTA, Charles Goodman, FTA Metropolitan Planning Division, (202) 366–1944, or Scott Biehl, FTA Office of Chief Counsel, (202) 366–4063; for FHWA, Sheldon Edner, FHWA Metropolitan Planning Division, (202) 366–4066, or Reid Alsop, FHWA Office of the Chief Counsel, (202) 366–1371.

H. Consolidated Planning Grants

In FY 1997, FTA and FHWA began offering states the option of participating in a pilot Consolidated Planning Grant (CPG) program. FTA and FHWA have now made CPG a permanent pilot. As part of the permanent pilot, additional state participants are sought so that FTA and FHWA can benefit from the widest possible range of participant input to improve and further streamline the process.

Since the first CPG grant was awarded in April 1997, almost $226 million has been obligated by the pilot states. Of this total, more than $180 million is from FHWA sources. Of the 11 pilot participants, three have used annual grants only; three have a mixture of grant time lengths, starting with annual and switching to multi-year grants or vice versa; and five have used only multi-year grants with the grant period ranging up to three years so far. Under the multi-year approach option, the CPG grant would remain open for a period of years to be determined by the state (and MPO, jointly, for Metropolitan Planning funds) with the approval of the federal government. New apportionments can be added by grant amendment, as funds become available. The annual approach treats the CPG much as FHWA funds are treated currently, that is, as basically annual apportionments with a yearly close-out of project activities and a deobligation and reobligation cycle. Those with the multi-year grants can close them at any time and begin the next year with either a new multi-year grant or an annual grant. The ease with which a state can opt for the single year or the multi-year approach to the CPG grant is just one example of the flexibility intended for the pilot.

Under the CPG, states can report metropolitan planning expenditures (to comply with the Single Audit Act) for both FTA and FHWA under the Catalogue of Federal Domestic Assistance number for FTA's Metropolitan Planning Program. Additionally, for states with an FHWA Metropolitan Planning (PL) fund matching ratio greater than 80 percent, the state (through FTA) can request a waiver of the 20 percent local share requirement in order that all FTA funds used for metropolitan planning in a CPG can be granted at the higher FHWA rate. For some states, this federal match rate can exceed 90 percent. Currently, two western states participating in the pilot are using the FHWA PL match rate.

Pre-award authority has been granted to FTA's planning programs for the life of TEA–21 (through FY 2003). This pre-award authority enables states to continue planning program activities from year to year with the assurance that eligible costs can later be converted to a regularly funded federal project without the need for prior approval or authorization from the granting agency. Beginning in FY 2000, the transfer procedures established to implement the transfer provision in TEA–21 (section 1103(i) "Transfer of Highway and Transit Funds") is applicable to

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FHWA funds used in CPG. For planning projects funded through CPG, the state DOT requests the transfer of funds in a letter to the FHWA Division Office. The FHWA-funded planning activities must be in accordance with the state's or MPO's Planning Work Program. The letter must be signed by the appropriate state official or their designee and must specify the state and the amount of funding to be transferred for the CPG by apportionment category (e.g. STP, CMAQ, Donor State Bonus, Funding Restoration, etc.) and by appropriation year. The letter should include only the funding for planning activities contained in the state's or MPO's Planning Work Program. If no FTA program, either Metropolitan Planning (49 U.S.C. 5303) or Statewide Planning and Research (49 U.S.C. 5313(b)), is indicated for transfers to CPG, funds will be credited to the Metropolitan Planning Program.

As part of the pilot, FTA will continue to work with participating states to increase the flexibility and further streamline the consolidated approach to planning grants. For further information on participating in the CPG Pilot, contact Candace Noonan, Intermodal and Statewide Planning Division, FTA, at (202) 366–1648 or Anthony Solury, Office of Planning and Environment, FHWA, at (202) 366–5003.

I. New Starts Approval To Enter Preliminary Engineering and Final Design

TEA–21 extends FTA's long-standing authority for approving the advancement of candidate New Starts projects into preliminary engineering (PE) by requiring that FTA also approve entrance into the final design (FD) stage of project development. Specifically, 49 U.S.C. 5309(e)(6) requires that the basis for PE/FD approval is FTA's evaluation of candidate project's New Starts criteria, leading to an overall project rating of "Highly Recommended," "Recommended," or "Not Recommended." FTA has established a set of decision rules for approving entrance into preliminary engineering and final design. After first meeting several basic planning, environmental, and project management requirements which demonstrate the "readiness" of the project to advance into the next stage of project development, candidate projects are subject to FTA evaluation against the New Starts project justification and local financial commitment criteria. Projects may advance to the next appropriate stage of project development (PE or FD) only if rated "Recommended" or "Highly Recommended," based on the criteria. Projects rated "Not Recommended" will not be approved to advance.

Section 5309(e)(8)(A) of Title 49 U.S.C. exempts projects which request a section 5309 New Starts share of less than $25 million from the requirements of section 5309(e). TEA–21 also provides statutory exemptions to certain specific projects. It is important to note that any exemption under section 5309(e)(8)(A) applies only to the New Starts criteria serving as the basis for FTA's approval to advance to preliminary engineering and final design for such projects. New Starts projects with less than $25 million in New Starts funding must still request entrance to the next stage of development, and must fulfill all appropriate planning, environmental, and project management requirements.

Aside from the formal evaluation and rating of (non-exempt) New Starts projects, the general process for approving entrance into PE and FD is largely consistent with FTA's prior procedures for approving entrance into preliminary engineering. FTA issued guidance for evaluating and approving local agency requests for advancing projects in the New Starts project development process in FY 2000. Another revision is planned for 2001.

V. Section 5307 Urbanized Area Formula Program

A. Total Urbanized Area Formula Apportionments

The amount made available to the Urbanized Area Formula Program in the FY 2001 DOT Appropriations Act was $2,942,578,081. After the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act and transfer of $1,000,000 to the OIG, $2,935,106,609 is available.

In addition to the $2,935,106,609 available in FY 2001 funds, the apportionment includes $4,735,805 in deobligated funds, which became available for reapportionment under the Urbanized Area Formula Program as provided by 49 U.S.C. 5336(i).

Table 4 displays the amount apportioned for the Urbanized Area Formula Program. After reserving ($13,682,722) for oversight, the amount of FY 2001 funds available for apportionment is $2,921,423,887. The funds to be reapportioned, described in the previous paragraph, are then added and increase the total amount apportioned for this program to $2,926,159,692.

An additional $4,639,280 is made available for the Alaska Railroad for improvements to its passenger operations, after the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act. After reserving ($24,196) for oversight, $4,815,084 is available for the Alaska Railroad.

Table 12 contains the FY 2001 apportionment formula for the Section 5307 Urbanized Area Formula Program.

B. Fiscal Year 2000 Apportionment Adjustments

An adjustment has been made to the apportionment for one urbanized area because of corrections to data that were used to compute the FY 2000 formula grant apportionment published in the **Federal Register** of October 28, 1999 (64 FR 58212). The difference between the corrected apportionment and the previously published apportionment has been resolved and the necessary adjustment has been made to the area's apportionment for FY 2001. The dollar amounts published in this notice contain the adjustment, and the affected urbanized area has been advised.

C. Data Used for Urbanized Area Formula Apportionments

Data from the 1999 NTD (49 U.S.C. 5335) Report Year submitted in late 1999 and early 2000 have been used to calculate the FY 2001 Urbanized Area Formula apportionments for urbanized areas 200,000 in population and over. The population and population density figures used in calculating the Urbanized Area Formula are from the 1990 Census.

D. Urbanized Area Formula Apportionments to Governors

The total Urbanized Area Formula apportionment to the Governor for use in areas under 200,000 in population for each state is shown in Table 4. This table also contains the total apportionment amount attributable to each of the urbanized areas within the state. The Governor may determine the allocation of funds among the urbanized areas under 200,000 in population with one exception. As further discussed below in Section H, funds attributed to an urbanized area under 200,000 in population, located within the planning boundaries of a transportation management area, must be obligated in that area.

E. Transit Enhancements

For urbanized areas with populations 200,000 and over, TEA–21 established a minimum annual expenditure requirement of one percent for transit projects and project elements that qualify as enhancements under the Urbanized Area Formula Program. Table 4 shows the amount set aside for enhancements in these areas. The term "transit enhancement" includes projects or project elements that are designed to enhance mass transportation service or use and are physically or functionally related to transit facilities.

(1) *Eligible Enhancements.* The following are transit projects and project elements that may be counted to meet the minimum enhancement expenditure requirement:

(a) historic preservation, rehabilitation, and operation of historic mass transportation buildings, structures, and facilities (including historic bus and railroad facilities);

(b) bus shelters;

(c) landscaping and other scenic beautification, including tables, benches, trash receptacles, and street lights;

(d) public art;

(e) pedestrian access and walkways;

(f) bicycle access, including bicycle storage facilities and installing equipment for transporting bicycles on mass transportation vehicles;

(g) transit connections to parks within the recipient's transit service area;

(h) signage; and

(i) enhanced access for persons with disabilities to mass transportation.

(2) *Requirements.* One percent of the Urbanized Area Formula Program apportionment in each urbanized area with a population of 200,000 and over must be made available only for transit enhancements. When there are several grantees in an urbanized area, it is not required that each grantee spend one percent of its Urbanized Area Formula Program funds on transit enhancements. Rather, one percent of the urbanized area's apportionment must be expended on projects and project elements that qualify as enhancements. If these funds are not obligated for transit enhancements within three years following the fiscal year in which the funds are apportioned, the funds will lapse and no longer be available to the urbanized area, and will be reapportioned under the Urbanized Area Formula Program.

It will be the responsibility of the MPO to determine how the one percent will be allotted to transit projects. The one percent minimum requirement does not preclude more than one percent being expended in an urbanized area for transit enhancements. Items that are only eligible as enhancements—in particular, operating costs for historic facilities—may be assisted only within the one percent fund level.

(3) *Project Budget.* The project budget for each grant application that includes enhancement funds must include a scope code for transit enhancements and specific budget activity line items for transit enhancements.

(4) *Bicycle Access.* TEA–21 provides that projects providing bicycle access to transit assisted with the FTA enhancement apportionment shall be eligible for a 95 percent Federal share.

(5) *Enhanced Access for Persons with Disabilities.* Enhancement projects or elements of projects designed to enhance access for persons with disabilities must go beyond the requirements contained in the Americans with Disabilities Act of 1990, 42 U.S.C. 12101 *et seq.*

(6) *Enhancement Report.* The recipient must submit a report to the appropriate FTA Regional Office listing the projects or elements of projects carried out with those funds during the previous fiscal year and the amount awarded. The report must be submitted with the Federal fiscal year's final quarterly progress report in the Transportation Electronic Awards and Management System (TEAM). The report should include the following elements: (a) Grantee name, (b) urbanized area name and number, (c) FTA project number, (d) transit enhancement category, (e) brief description of enhancement and progress towards project implementation, (f) activity line item code from the approved budget, and (g) amount awarded by FTA for the enhancement.

F. Fiscal Year 2001 Operating Assistance

FY 2001 funding for operating assistance is available only to urbanized areas with populations under 200,000. For these areas, there is no limitation on the amount of the state apportionment that may be used for operating assistance, and the Federal/local share ratio is 50/50.

TEA–21 provided two exceptions to the restriction on operating assistance in areas over 200,000 in population. These exceptions have been addressed and eligible areas identified.

G. Unobligated Funds for Operating Assistance

Unobligated funds for FY 1998, which were eligible for use as operating assistance, are still available for operating assistance. However, the operating assistance limitations remain on the unobligated FY 1998 funds. These funds continue to be available for obligation at the Federal/local share ratio of 50/50 through FY 2001. If the FY 1998 funds are not obligated before the end of FY 2001 they lapse to the area and are reapportioned. For unobligated FY 1998 funds for areas under 200,000, operating assistance as a capital project with an 80 percent federal match ratio (without limitation) will continue to be available through FY 2001.

H. Designated Transportation Management Areas

All urbanized areas over 200,000 in population have been designated as Transportation Management Areas (TMAs), in accordance with 49 U.S.C. 5305. These designations were formally made in a **Federal Register** Notice dated May 18, 1992 (57 FR 21160). Additional areas have been designated as TMAs upon the request of the Governor and the MPO designated for such area or the affected local officials. During FY 2000, no additions to existing TMAs were designated.

Guidance for setting the boundaries of TMAs is contained in the joint transportation planning regulations codified at 23 CFR part 450 and 49 CFR part 613. In some cases, the TMA boundaries, which have been established by the MPO for the designated TMA, also include one or more urbanized areas with less than 200,000 in population. Where this situation exists, the discretion of the Governor to allocate Urbanized Area Formula Program "Governor's Apportionment" funds for urbanized areas with less than 200,000 in population is restricted.

As required by 49 U.S.C. 5307(a)(2), a recipient(s) must be designated to dispense the Urbanized Area Formula funds attributable to TMAs. Those urbanized areas that do not already have a designated recipient must do so and notify the appropriate FTA Regional Office of the designation. This includes those urbanized areas with less than 200,000 in population that may receive TMA designation independently, or those with less than 200,000 in population that are currently included within the boundaries of a larger designated TMA. In either case, the Governor only has discretion to allocate Governor's Apportionment funds attributable to areas that are outside of designated TMA boundaries. To enable FTA and Governors to identify which urbanized areas under 200,000 in population are included within the boundaries of an existing TMA, so that they can be identified in future **Federal Register** notices, each MPO whose TMA planning boundaries include these smaller urbanized areas is requested to report such areas to FTA. This notification should be made in writing to the Associate Administrator for

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Program Management, Federal Transit Administration, 400 Seventh Street, SW, Washington, DC 20590, no later than July 1 of each fiscal year. To date, FTA has been notified of the following urbanized areas with population less than 200,000 that are included within the planning boundaries of designated TMAs:

Designated TMA	Small urbanized area included in TMA boundaries
Baltimore, Maryland.	Annapolis, Maryland.
Dallas-Fort Worth	Denton, Texas; Lewisville, Texas.
Houston, Texas ..	Galveston, Texas; Texas City, Texas.
Orlando, Florida	Kissimmee, Florida.
Melbourne-Palm Bay, Florida.	Titusville, Florida.
Philadelphia, Pennsylvania.	Pottstown, Pennsylvania.
Pittsburgh, Pennsylvania.	Monessen, Pennsylvania; Steubenville-Weirton, OH–WV–PA (PA portion).
Seattle, Washington.	Bremerton, Washington.
Washington, DC–MD–VA.	Frederick, Maryland (MD portion).

I. Urbanized Area Formula Funds Used for Highway Purposes

Urbanized Area Formula funds apportioned to a TMA can be transferred to FHWA and made available for highway projects if the following three conditions are met: (1) Such use must be approved by the MPO in writing after appropriate notice and opportunity for comment and appeal are provided to affected transit providers; (2) in the determination of the Secretary, such funds are not needed for investments required by the Americans with Disabilities Act of 1990 (ADA); and (3) the MPO determines that local transit needs are being addressed.

Urbanized Area Formula funds that are designated for highway projects will be transferred to and administered by FHWA. The MPO should notify FTA of its intent to program FTA funds for highway purposes.

J. National Transit Database Internet Reporting

The National Transit Database (NTD) is FTA's national database for statistics on the transit industry, including safety data. In recent years, about 600 FTA grantees have used diskettes to report on their operating, financial and safety statistics to FTA.

Urbanized Area Formula Program funds for areas 200,000 and over in population are apportioned, in part, using NTD statistics. In addition, NTD data is summarized and used to report to Congress on the performance of the transit industry and the associated costs. These data are also used to assess whether FTA Strategic Plan goals have been met.

In FY 2001, NTD data may be reported via a new Internet-based reporting system or by the traditional diskette. Over 300 NTD reporters have been trained on the new Internet system. Internet reporting should speed data collection and validation. The FTA encourages each agency to use the new Internet reporting system.

VI. Section 5311 Nonurbanized Area Formula Program and Section 5311(b) Rural Transit Assistance Program (RTAP)

A. Nonurbanized Area Formula Program

The amount made available for the Nonurbanized Area Formula Program in the FY 2001 DOT Appropriations Act was $205,461,168. After the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, $205,009,154 is available.

The FY 2001 Nonurbanized Area Formula apportionments to the states total $205,485,900 and are displayed in Table 5. Of the $205,009,154 available, ($1,025,046) was reserved for oversight. In addition to the FY 2001 funding, the funds available for apportionment included $1,501,792 in deobligated funds from fiscal years prior to FY 2001. The population figures used in calculating these apportionments are from the 1990 Census.

The Nonurbanized Formula Program provides capital, operating and administrative assistance for areas under 50,000 in population. Each state must spend no less than 15 percent of its FY 2001 Nonurbanized Area Formula apportionment for the development and support of intercity bus transportation, unless the Governor certifies to the Secretary that the intercity bus service needs of the state are being adequately met. FY 2001 Nonurbanized Area Formula grant applications must reflect this level of programming for intercity bus or include a certification from the Governor.

B. Rural Transit Assistance Program (RTAP)

Funding made available for the RTAP in the 2001 DOT Appropriations Act was $5,250,000—the guaranteed funding level under TEA–21. This amount has been reduced to $5,238,450, after applying the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act.

The FY 2001 RTAP allocations to the states total $5,404,340 and are also displayed in Table 5. This amount includes $5,238,450 in FY 2001 funds, and $165,890 in prior year deobligated funds, which are available for reapportionment.

The funds are allocated to the states to undertake research, training, technical assistance, and other support services to meet the needs of transit operators in nonurbanized areas. These funds are to be used in conjunction with the states' administration of the Nonurbanized Area Formula Program.

FTA requested and Congress made available an additional $750,000 in FY 2001 (in the FY 2001 DOT Appropriations Act) to support RTAP activities carried out at the national level. The national projects support the states in their use of the formula allocations for training and technical assistance. These funds are also subject to the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act and will be reduced accordingly.

VII. Section 5310 Elderly and Persons With Disabilities Program

Funds in the amount of $77,410,801 were made available for the Elderly and Persons with Disabilities Program in the FY 2001 DOT Appropriations Act. After the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, $77,240,497 is available.

A total of $77,560,406 is apportioned to the states for FY 2001 for the Elderly and Persons with Disabilities Program. In addition to the FY 2001 funding of $77,240,497, the FY 2001 apportionment includes $319,909 in prior year unobligated funds, which are available for reapportionment under the Elderly and Persons with Disabilities Program. Table 6 shows each state's apportionment.

The formula for apportioning these funds uses 1990 Census population data for persons aged 65 and over and for persons with disabilities.

The funds provide capital assistance for transportation for elderly persons and persons with disabilities. Eligible capital expenses may include, at the option of the recipient, the acquisition of transportation services by a contract, lease, or other arrangement.

While the assistance is intended primarily for private non-profit organizations, public bodies that coordinate services for the elderly and persons with disabilities, or any public body that certifies to the state that there are no non-profit organizations in the area that are readily available to carry out the service, may receive these funds.

These funds may be transferred by the Governor to supplement the Urbanized Area Formula or Nonurbanized Area Formula capital funds during the last 90 days of the fiscal year.

VIII. FHWA Surface Transportation Program and Congestion Mitigation and Air Quality Funds Used for Transit Purposes (Title 23, U.S.C.)

A. Transfer Process

TEA–21 made changes in how to apply the flexibility provisions of funds transferred from FHWA to FTA. Section 1103(i) of TEA–21, as amended, provides that when funds are transferred, obligation authority will be transferred to the receiving agency. Under ISTEA, obligation authority was not transferred.

Effective October 1, 1999, new procedures were implemented to accommodate this change for FY 2000 and subsequent years. The process for transfers to the FTA formula programs is described below. Information on the transfer of FHWA funds to FTA planning programs can be found in section IV.H., above.

Transfer from FHWA to FTA. FHWA funds designated for use in transit capital projects must result from the metropolitan and state planning and programming process, and must be included in an approved Statewide Transportation Improvement Program (STIP) before the funds can be transferred. The state DOT requests, by letter, the transfer of highway funds for a transit project to the FHWA Division Office. The letter should specify the project, amount to be transferred, apportionment year, state, federal aid apportionment category (*i.e.* Surface Transportation Program (STP), Congestion Mitigation and Air Quality (CMAQ), Interstate Substitute, or congressional earmark), and a description of the project as contained in the STIP.

The FHWA Division Office confirms that the apportionment amount is available for transfer and concurs in the transfer by letter to the state DOT and FTA. FHWA then transfers obligation authority and an equal amount of cash to FTA. All CMAQ or STP, or FHWA earmark funds will be transferred to one of the three FTA formula capital programs (i.e. Urbanized Area Formula (section 5307), Nonurbanized Area Formula (section 5311) or Elderly and Persons with Disabilities (section 5310).

The FTA grantee application for the project must specify for which Title 49 U.S.C., transit program funds will be used and the application should be prepared in accordance with the requirements and procedures governing that section. Upon review and approval of the grantee's application, FTA obligates funds for the project.

The transferred funds are treated as FTA formula funds, although they retain an identifying code for tracking purposes. The funds may be used for any purpose eligible under the FTA formula capital program to which they are transferred. CMAQ funds, however, have to be used for air quality purposes and some eligible projects are defined by the Clean Air Act. All FTA requirements are applicable to transferred funds. Transferred funds should be combined with regular FTA funds in a single annual grant application.

Transfers from FTA to FHWA. The Metropolitan Planning Organization (MPO) submits a request to the FTA Regional Office for a transfer of FTA section 5307 formula funds (apportioned to an urbanized area 200,000 and over in population) to FHWA based on approved use of the funds for highway purposes, as contained in the Governor's approved State Transportation Improvement Program. The MPO must certify that: (1) The funds are not needed for capital investments required by the Americans with Disabilities Act; (2) notice and opportunity for comment and appeal has been provided to affected transit providers; and (3) local funds used for non-Federal match are eligible to provide assistance for either highway or transit projects. The FTA Regional Administrator reviews and concurs in the request then forwards the approval to FTA Headquarters, where a reduction is made to the grantee's formula apportionment and FTA's National Operating Budget in TEAM (FTA's electronic grants management system), by the dollar amount being transferred to FHWA.

For information regarding these procedures, please contact Kristen D. Clarke, FTA Budget Division at (202) 366–1699 or Richard Meehleib, FHWA Finance Division at (202) 366–2869.

B. Matching Share for FHWA Transfers

The provisions of Title 23, U.S.C., regarding the non-federal share apply to Title 23 funds used for transit projects. Thus, FHWA funds transferred to FTA retain the same matching share that the funds would have if used for highway purposes and administered by the FHWA.

There are three instances in which a higher than 80 percent federal share would be permitted. First, in states with large areas of Indian and certain public domain lands, and national forests, parks and monuments, the local share for highway projects is determined by a sliding scale rate, calculated based on the percentage of public lands within that state. This sliding scale, which permits a greater federal share, but not to exceed 95 percent, is applicable to transfers used to fund transit projects in these public land states. FHWA develops the sliding scale matching ratios for the increased federal share.

Secondly, commuter carpooling and vanpooling projects and transit safety projects using FHWA transfers administered by FTA may retain the same 100 percent federal share that would be allowed for ride-sharing or safety projects administered by the FHWA.

The third instance includes the 100 percent federal safety projects; however, these are subject to a nationwide 10 percent program limitation.

IX. Section 5309 Capital Investment Program

A. Fixed Guideway Modernization

The formula for allocating the Fixed Guideway Modernization funds contains seven tiers. The allocation of funding under the first four tiers, through FY 2003, will be based on data used to apportion the funding in FY 1997. Funding under the last three tiers will be apportioned based on the latest available route miles and revenue vehicle miles on segments at least seven years old as reported to the National Transit Database.

Table 7 displays the FY 2001 Fixed Guideway Modernization apportionments. Fixed Guideway Modernization funds apportioned for this section must be used for capital projects to maintain, modernize, or improve fixed guideway systems.

All urbanized areas with fixed guideway systems that are at least seven years old are eligible to receive Fixed Guideway Modernization funds. A request for the start-up service dates for fixed guideways has been incorporated into the National Transit Database reporting system to ensure that all eligible fixed guideway data is included in the calculation of the apportionments. A threshold level of more than one mile of fixed guideway is required to receive Fixed Guideway Modernization funds. Therefore, urbanized areas reporting one mile or less of Fixed Guideway mileage under

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the National Transit Database are not included.

For FY 2001, $1,058,400,000 was made available for fixed guideway modernization in the FY 2001 DOT Appropriations Act, which was the guaranteed funding level in TEA–21. After applying the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, $1,056,071,520 is available.

An amount of ($7,920,536) was then deducted for oversight, leaving $1,048,150,984 available for apportionment to the eligible urbanized areas. In addition to the FY 2001 funding, $289,758 in deobligated funds from fiscal years prior to FY 2001 is added and increases the total amount apportioned to $1,048,440,742 under fixed guideway modernization. Table 13 contains information regarding the fixed guideway modernization apportionment formula.

B. New Starts

Amounts made available for New Starts in the FY 2001 DOT Appropriations Act was $1,058,400,000, which was fully allocated and represents the guaranteed funding level under TEA–21. After applying the .22 percent reduction for the government-wide rescission and adding appropriated funding of $1,000,000 for Southeast Light Rail Extension project, in Dallas, TX, and $3,000,000 for the Newark-Elizabeth rail link project in New Jersey, as directed by the FY 2001 Omnibus Consolidated Appropriations Act, $1,060,062,720 is available.

Of this amount ($7,942,987) was reserved for oversight activities, leaving $1,052,119,733 available for allocations to projects. Prior year unobligated funds specified by Congress to be reallocated in the amount of $26,994,048 are then added and increase the total amount allocated to $1,079,113,781. The reallocated funds were derived from unobligated and deobligated balances for the following projects: Burlington to Gloucester, New Jersey (Pub.L. 103–331), $1,488,750; Orlando, Florida Lynx rail project, $20,521,470; and Pittsburgh, Pennsylvania airport busway project (Pub.L. 105–66), $4,983,828. The final allocation for each New Starts project is shown in Table 8 of this notice.

Prior year unobligated allocations for New Starts in the amount of $459,373,575 remain available for obligation in FY 2001. This amount includes $448,966,118 in fiscal years 1999 and 2000 unobligated allocations, and $10,407,457 for fiscal years 1997 and 1998 unobligated allocations that were extended in the Conference Report. These unobligated amounts are displayed in Table 8A.

Capital Investment Program funds for New Starts projects identified as having been extended in the Conference Report accompanying the FY 2001 DOT Appropriations Act will lapse September 30, 2001. A list of the extended project amounts that remain unobligated as of September 30, 2000 is appended to Table 8A for ready reference.

The FY 2001 DOT Appropriations Act directs that a New Starts FY 1999 allocation for the Colorado North Front Range corridor feasibility study ($496,280) is to be made available for the "Colorado Eagle Airport to Avon light rail system feasibility study." Also, section 360 of the FY 2001 DOT Appropriations Act provides that a FY 1998 allocation for Jackson, Mississippi Intermodal Corridor is now available for obligation in this fiscal year for studies to evaluate and define transportation alternatives, including an intermodal facility at Jackson International Airport and for related preliminary engineering, final design or construction.

C. Bus

The FY 2001 DOT Appropriations Act provides $529,200,000, for the purchase of buses, bus-related equipment and paratransit vehicles, and for the construction of bus-related facilities. This amount represents the guaranteed funding level under TEA–21. After the .22 percent reduction for the government-wide rescission and adding newly appropriated funding of $500,000 for the Alabama A&M University buses and bus facilities project, as directed by the FY 2001 Omnibus Consolidated Appropriations Act, $528,534,660 is available.

TEA–21 established a $100,000,000 Clean Fuels Formula Program under Section 5308. The program is authorized to be funded with $50,000,000 from the Bus category of the Capital Investment Program, and $50,000,000 from the Formula Program. However, recent congressional appropriation actions have directed the formula portion of the Clean Fuels Program be transferred and available for the Bus category of the Capital Investment Program. In addition, these funds have been reduced by .22 percent, in accordance with the government-wide rescission. Thus, $578,424,660 of funds appropriated in FY 2001 is available for funding the Bus category of the Capital Investment Program. After deducting ($4,334,443) for oversight, the amount of FY 2001 funds available for allocation is $574,090,217.

The Conference Report accompanying the FY 2001 DOT Appropriations Act allocated most of the FY 2001 Bus funds to specified states or localities for bus and bus-related projects. FTA will honor those allocations to the extent that they comply with the statutory authorization for that program. However, allocations for two projects authorized to be funded under TEA–21 (the "Georgetown University fuel cell bus program" and the "Altoona bus testing facility") were not included in the Conference Report. Absent language overriding the authorization, these projects need to be funded with section 5309 Bus funds. To provide funding for these projects at the levels authorized under TEA–21, a minor deduction was applied to the other Bus allocations on a prorated basis. In addition, the suballocations for the Commonwealth of Virginia specified in the Conference Report exceeded the statewide allocation amount. Therefore, a prorated reduction was applied to each statewide suballocation to correct the difference so that the total for the suballocations equaled the statewide allocated amount. Table 9 displays the allocation of the FY 2001 Bus funds by state and project.

Prior year unobligated balances for Bus Program allocations in the amount of $443,354,553 remain available for obligation in FY 2001. This includes $436,416,460 in fiscal years 1999 and 2000 unobligated allocations, and $6,938,093 for fiscal years 1997 and 1998 unobligated allocations that were extended in the Conference Report. These unobligated amounts are displayed in Table 9A.

Capital Investment Program funds for Bus projects identified as having been extended in the Conference Report accompanying the FY 2001 DOT Appropriations Act will lapse September 30, 2001. A list of the extended project amounts that remain unobligated as of September 30, 2000 is appended to Table 9A for ready reference.

In addition, the Conference Report indicates that the following revisions to projects or the reprogramming of funds should be made under the bus category:

(1) Two FY 2000 bus allocations, Alabama, Gees Bend Ferry facilities, Wilcox County ($3,743,808) and Alabama, Jefferson State Community College/University of Montevallo pedestrian walkway ($198,503) are made available to the State of Alabama for buses and bus-related facilities;

(2) remaining balances of $800,000 from FY 1999 and FY 2000 allocations to Fayette County, PA are made available for an intermodal parking facility in Cambria County, PA;

(3) FY 2000 allocation for Michigan statewide buses is expanded to include "bus-related equipment and bus facilities;"

(4) up to $560,000 of funds allocated for the transportation depot and plaza project in Hot Springs, Arkansas in FY 2000, may be available for buses and bus facilities; and

(5) fiscal year 1999 and 2000 allocations for "Intermodal Facilities" for Washington County, and Westmoreland County, PA shall include "bus and bus facilities."

X. Job Access and Reverse Commute Program

The FY 2001 DOT Appropriations Act provides $100 million for the Job Access and Reverse Commute Program, which is the guaranteed funding level under TEA–21. After the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, this amount has been reduced to $99,780,000. Of this amount, $75,079,461 has been allocated to 67 states and localities specified in the FY 2001 Conference report. These allocations are listed in Table 10. FTA will honor those allocated projects that meet the statutory intent of the program.

This program, established under TEA–21, provides funding for the provision of transportation services designed to increase access to jobs and employment-related activities. Job Access projects are those that transport welfare recipients and low-income individuals in urban, suburban, or rural areas to and from jobs and activities related to their employment. Reverse Commute projects provide transportation services for the general public from urban, suburban, and rural areas to suburban employment opportunities. A total of up to $10,000,000 from the appropriation can be used for Reverse Commute Projects.

One of the goals of the Job Access and Reverse Commute program is to increase collaboration among transportation providers, human service agencies, employers, metropolitan planning organizations, states, and affected communities and individuals. All projects funded under this program must be derived from an area-wide Job Access and Reverse Commute Transportation Plan, developed through a regional approach which supports the implementation of a variety of transportation services designed to connect welfare recipients to jobs and related activities. A key element of the program is making the most efficient use of existing public, nonprofit and private transportation service providers.

In FY 2000, $49,570,000 was allocated to projects specified in the FY 2000 Conference report. FTA undertook a national solicitation of applications for the remaining funds under this program and conducted a competitive process to select applications. As a result, FTA selected 91 competitive proposals for a total of $25.69 million, including projects in 44 states and the District of Columbia.

XI. Over-the-Road Bus Accessibility Program

The amount made available for the Over-the-Road Bus Accessibility (OTRB) Program in the FY 2001 DOT Appropriations Act was $4,700,000, which is the guaranteed funding level under TEA–21. After applying the .22 percent reduction for the government-wide rescission required by the FY 2001 Omnibus Consolidated Appropriations Act, this amount has been reduced to $4,689,660. Of this amount, $2,993,400 is available to providers of intercity fixed-route service, and $1,696,260 is available to other providers of over-the-road bus services, including local fixed-route service, commuter service, and charter and tour service.

The OTRB program authorizes FTA to make grants to operators of over-the-road buses to help finance the incremental capital and training costs of complying with the DOT over-the-road bus accessibility final rule, published in a **Federal Register** Notice on September 24, 1998. Funds will be provided at 90 percent Federal share. FTA conducts a national solicitation of applications and grantees are selected on a competitive basis.

In FY 2000, a total of $2 million was available to intercity fixed-route providers and $1.7 million was available to all other providers. FTA selected 47 applicants from among the 57 applications submitted for funding incremental capital and training costs of complying with DOT's OTRB Accessibility requirements.

A separate **Federal Register** Notice providing program guidance and application procedures for FY 2001 will be issued.

XII. Clean Fuels Formula Program

TEA–21 established the Clean Fuels Formula Grant Program under section 5308 of Title 49 U.S.C., to assist non-attainment and maintenance areas in achieving or maintaining attainment status and to support markets for emerging clean fuel technologies. Under the program, public transit agencies in maintenance and non-attainment areas (as defined by the EPA) are to apply for formula funds to acquire clean fuel vehicles. The legislation specified the program to be funded with $50,000,000 from the bus category of the Capital Investment Program, and $50,000,000 from the Urbanized Area Formula Program in each fiscal year of TEA–21.

However, congressional appropriation actions in this fiscal year as well as in fiscal years 1999 and 2000, have provided no funds for this program.

XIII. Unit Values of Data for the Section 5307 Urbanized Area Formula Program, Section 5311 Nonurbanized Area Formula Program, and Section 5309 Capital Fixed Guideway Modernization

The dollar unit values of data derived from the computations of the Urbanized Area Formula Program, the Nonurbanized Area Formula Program, and the Capital Investment Program—Fixed Guideway Modernization apportionments are displayed in Table 14 of this notice. To determine how an apportionment amount was computed for an area, multiply its population, population density, and data from the NTD by the unit values.

XIV. Period of Availability of Funds

The funds apportioned under the Metropolitan Planning Program and the State Planning and Research Program, the Urbanized Area Formula Program, and the Fixed Guideway Modernization Program, in this notice, will remain available to be obligated by FTA to recipients for three fiscal years following FY 2001. Any of these apportioned funds unobligated at the close of business on September 30, 2004 will revert to FTA for reapportionment under these respective programs.

Funds apportioned to nonurbanized areas under the Nonurbanized Area Formula Program, including RTAP funds, will remain available for two fiscal years following FY 2001. Any such funds remaining unobligated at the close of business on September 30, 2003, will revert to FTA for reapportionment among the states under the Nonurbanized Area Formula Program. Funds allocated to states under the Elderly and Persons with Disabilities Program in this notice must be obligated by September 30, 2001. Any such funds remaining unobligated as of this date will revert to FTA for reapportionment among the states under the Elderly and Persons with Disabilities Program. The FY 2001 DOT Appropriations Act includes a provision requiring that FY 2001 New Starts and Bus funds not obligated for their original purpose as of September 30, 2003, shall be made available for other projects under 49 U.S.C. 5309.

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Capital Investment Program funds for New Starts and Bus projects identified as having been extended in the Conference Report accompanying the FY 2001 DOT Appropriations Act will lapse September 30, 2001.

XV. Automatic Pre-award Authority to Incur Project Costs

A. Policy

FTA provides blanket or automatic pre-award authority to cover certain program areas described below. This pre-award authority allows grantees to incur project costs prior to grant approval and retain their eligibility for subsequent reimbursement after grant approval. The grantee assumes all risk and is responsible for ensuring that all conditions, which are described below, are met to retain eligibility. This automatic pre-award spending authority permits a grantee to incur costs on an eligible transit capital or planning project without prejudice to possible future Federal participation in the cost of the project or projects. Prior to exercising pre-award authority, grantees must comply with the conditions and Federal requirements outlined in paragraphs B and C immediately below. Failure to do so will render an otherwise eligible project ineligible for FTA financial assistance. In addition, grantees are strongly encouraged to consult with the appropriate regional office if there could be any question regarding the eligibility of the project for future FTA funds or the applicability of the conditions and Federal requirements.

Authority to incur costs for FY 1998 Fixed Guideway Modernization, Metropolitan Planning, Urbanized Area Formula, Elderly and Persons with Disabilities, Nonurbanized Area Formula, STP or CMAQ flexible funds to be transferred from the FHWA and State Planning and Research Programs in advance of possible future Federal participation was provided in the December 5, 1997, **Federal Register** Notice. Pre-award authority was extended in the June 24, 1998 **Federal Register** Notice on TEA–21 to all formula funds and flexible funds that will be apportioned during the authorization period of TEA–21, 1998–2003.

Pre-award authority also applies to Capital Investment Bus allocations identified in this notice. Pre-award authority does not apply to Capital New Start funds, or to Capital Investment Bus projects not specified in this or previous notices, except as described in D. below. Pre-award authority also applies to preventive maintenance costs incurred within a local fiscal year ending during calendar year 1997, or thereafter, under the formula programs cited above.

For section 5309 Capital Investment Bus projects, the date that costs may be incurred is the date that the appropriation bill in which they are contained is enacted. For blanket pre-award authority in formula programs described above, the effective date is June 9, 1998.

B. Conditions

Similar to the FTA Letter of No Prejudice (LONP) authority, the conditions under which this authority may be utilized are specified below:

(1) The pre-award authority is not a legal or moral commitment that the project(s) will be approved for FTA assistance or that FTA will obligate Federal funds. Furthermore, it is not a legal or moral commitment that all items undertaken by the applicant will be eligible for inclusion in the project(s).

(2) All FTA statutory, procedural, and contractual requirements must be met.

(3) No action will be taken by the grantee that prejudices the legal and administrative findings that the Federal Transit Administrator must make in order to approve a project.

(4) Local funds expended by the grantee pursuant to and after the date of the pre-award authority will be eligible for credit toward local match or reimbursement if FTA later makes a grant for the project(s) or project amendment(s).

(5) The Federal amount of any future FTA assistance awarded to the grantee for the project will be determined on the basis of the overall scope of activities and the prevailing statutory provisions with respect to the Federal/local match ratio at the time the funds are obligated.

(6) For funds to which the pre-award authority applies, the authority expires with the lapsing of the fiscal year funds.

(7) The Financial Status Report, in TEAM, must indicate the use of pre-award authority.

C. Environmental, Planning, and Other Federal Requirements

FTA emphasizes that all of the Federal grant requirements must be met for the project to remain eligible for Federal funding. Some of these requirements must be met before pre-award costs are incurred, notably the requirements of the National Environmental Policy Act (NEPA), and the planning requirements. Compliance with NEPA and other environmental laws or executive orders (*e.g.*, protection of parklands, wetlands, historic properties) must be completed before state or local funds are spent on implementing activities such as final design, construction, and acquisition for a project that is expected to be subsequently funded with FTA funds. Depending on which class the project is included under in FTA environmental regulations (23 CFR 771), the grantee may not advance the project beyond planning and preliminary engineering before FTA has issued either a categorical exclusion (refer to 23 CFR 771.117(d)), a finding of no significant impact, or a final environmental impact statement. The conformity requirements of the Clean Air Act (40 CFR part 93) also must be fully met before the project may be advanced with non-Federal funds.

Similarly, the requirement that a project be included in a locally adopted metropolitan transportation improvement program and federally approved statewide transportation improvement program must be followed before the project may be advanced with non-Federal funds. For planning projects, the project must be included in a locally approved Planning Work Program that has been coordinated with the State. In addition, Federal procurement procedures, as well as the whole range of Federal requirements, must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this increased administrative flexibility requires a grantee to make certain that no Federal requirements are circumvented through the use of pre-award authority. If a grantee has questions or concerns regarding the environmental requirements, or any other Federal requirements that must be met before incurring costs, it should contact the appropriate regional office.

Before an applicant may incur costs either for activities expected to be funded by New Start funds, or for Bus Capital projects not listed in this notice or previous notices, it must first obtain a written LONP from FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA regional office.

D. Pre-Award Authority for New Starts Projects Approved for Preliminary Engineering and/or Final Design

New Starts Projects are required to follow a federally defined planning process. This process includes, among other things, FTA approval of entry of a project into preliminary engineering and approval to enter final design. The grantee request for entry into preliminary engineering and the request for entry into final design both document the project and how it meets the New Starts criteria in detail. With FTA approval to enter preliminary engineering, and subsequent approval to enter final design, FTA will automatically extend pre-award authority to that phase of project development. The pre-award authority to incur costs for final design is strictly limited to design work. No capital items or right of way acquisition is included in this blanket pre-award authority.

This provision was first implemented in FY 2000 and is intended to streamline and eliminate duplicative and unnecessary paperwork and reinforce the importance of these New Starts approval actions. New Starts construction or right-of-way acquisition as well as New Starts planning funded with section 5309 funds not covered by preliminary engineering or final design approval still need letters of no prejudice requested as described below.

XVI. Letter of No Prejudice Policy (Prior Approval of Pre-Award Authority)

A. Policy

Letter of No Prejudice (LONP) Policy authority allows an applicant to incur costs on a future project utilizing non-Federal resources with the understanding that the costs incurred subsequent to the issuance of the LONP may be reimbursable as eligible expenses or eligible for credit toward the local match should FTA approve the project at a later date. LONPs are applicable to projects not covered by automatic pre-award authority. The majority of LONPs will be for Section 5309 New Starts funds not covered under a full funding grant agreement or for Section 5309 Bus funds not yet appropriated by Congress. At the end of an authorization period, there may be LONPs for formula funds beyond the life of the current authorization.

Under most circumstances the LONP will cover the total project. Under certain circumstances the LONP may be issued for local match only. In such cases the local match would be to permit real estate to be used for match for the project at a later date.

B. Conditions

The following conditions apply to all LONPs.

(1) LONP pre-award authority is not a legal or moral commitment that the project(s) will be approved for FTA assistance or that FTA will obligate Federal funds. Furthermore, it is not a legal or moral commitment that all items undertaken by the applicant will be eligible for inclusion in the project(s).

(2) All FTA statutory, procedural, and contractual requirements must be met.

(3) No action will be taken by the grantee that prejudices the legal and administrative findings that the Federal Transit Administrator must make in order to approve a project.

(4) Local funds expended by the grantee pursuant to and after the date of the LONP will be eligible for credit toward local match or reimbursement if FTA later makes a grant for the project(s) or project amendment(s).

(5) The Federal amount of any future FTA assistance to the grantee for the project will be determined on the basis of the overall scope of activities and the prevailing statutory provisions with respect to the Federal/local match ratio at the time the funds are obligated.

(6) For funds to which this pre-award authority applies, the authority expires with the lapsing of the fiscal year funds.

C. Environmental, Planning, and Other Federal Requirements

As with automatic pre-award authority, FTA emphasizes that all of the Federal grant requirements must be met for the project to remain eligible for Federal funding. Some of these requirements must be met before pre-award costs are incurred, notably the requirements of the National Environmental Policy Act (NEPA), and the planning requirements. Compliance with NEPA and other environmental laws or executive orders (*e.g.*, protection of parklands, wetlands, historic properties) must be completed before state or local funds are spent on implementation activities such as final design, construction, or acquisition for a project expected to be subsequently funded with FTA funds. Depending on which class the project is included under in FTA's environmental regulations (23 CFR part 771), the grantee may not advance the project beyond planning and preliminary engineering before FTA has approved either a categorical exclusion (refer to 23 CFR part 771.117(d)), a finding of no significant impact, or a final environmental impact statement. The conformity requirements of the Clean Air Act (40 CFR part 93) also must be fully met before the project may be advanced with non-Federal funds.

Similarly, the requirement that a capital project be included in a locally adopted metropolitan transportation improvement program and federally approved statewide transportation improvement program must be followed before the project may be advanced with non-Federal funds. For planning projects, the project must be included in a locally approved Planning Work Program that has been coordinated with the State. In addition, Federal procurement procedures, as well as the whole range of Federal requirements, must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this pre-award authority requires a grantee to make certain that no Federal requirements are circumvented. If a grantee has questions or concerns regarding the environmental requirements, or any other Federal requirements that must be met before incurring costs, it should contact the appropriate regional office.

D. Request for LONP

Before an applicant may incur costs for a project not covered by automatic pre-award authority, it must first submit a written request for an LONP to the appropriate regional office. This written request must include a description of the project for which pre-award authority is desired and a justification for the request.

XVII. FTA Home Page on the Internet

FTA provides extended customer service by making available transit information on the FTA website, including this Apportionment Notice. Also posted on the website are FTA program Circulars: C9030.1C, Urbanized Area Formula Program: Grant Application Instructions, dated October 1, 1998; C9040.1E, Nonurbanized Area Formula Program Guidance and Grant Application Instructions, dated October 1, 1998; C9070.1E, The Elderly and Persons with Disabilities Program Guidance and Application Instructions, dated October 1, 1998; C9300.1A, Capital Program: Grant Application Instructions, dated October 1, 1998; 4220.1D, Third Party Contracting Requirements, dated April 15, 1996; C5010.1C, Grant Management Guidelines, dated October 1, 1998; and C8100.1B, Program Guidance and Application Instructions for Metropolitan Planning Program Grants, dated October 25, 1996. The FY 2001 Annual List of Certifications and Assurances is also posted on the FTA website. Other documents on the FTA website of particular interest to public transit providers and users include the 1998 Statistical Summaries of FTA Grant Assistance Programs, and the National Transit Database Profiles.

FTA circulars are listed at:[http://www.fta.dot.gov/library/admin/checklist/circulars.htm]. Other guidance

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of interest to Grantees can be found at: [http://www.fta.dot.gov/grantees/index.html].

Grantees should check the FTA website frequently to keep up to date on new postings.

XVIII. FTA Fiscal Year 2001 Annual List of Certifications and Assurances

The "Fiscal Year 2001 Annual List of Certifications and Assurances" is published in conjunction with this notice. It appears as a separate Part of the **Federal Register** on the same date whenever possible. The FY 2001 list contains several changes to the previous year's **Federal Register** publication. As in previous years, the grant applicant should certify electronically. Under certain circumstances the applicant may enter its PIN number in lieu of an electronic signature provided by its attorney, provided the applicant has on file the current affirmation of its attorney in writing dated this federal fiscal year. The applicant is advised to contact the appropriate FTA Regional Office for electronic procedure information.

The "Fiscal Year 2001 Annual List of Certifications and Assurances" is accessible on the Internet at [http://:www.fta.dot.gov/library/legal/ca.htm]. Any questions regarding this document may be addressed to the appropriate Regional Office.

XIX. Grant Application Procedures

All applications for FTA funds should be submitted to the appropriate FTA Regional Office. FTA utilizes an electronic grant application system known as TEAM and all applications should be filed electronically. FTA has provided exceptions to the requirement for electronic filing of applications for certain new, non-traditional grantees in the Job Access and Reverse Commute and Over-the-Road Bus Accessibility programs as well as to a few grantees that have not successfully connected to or accessed TEAM.

With FY 2001, FTA is establishing a 90-day goal for processing and approving all capital, planning and operating grants, including the section 5307 Urbanized Area Formula Program, section 5309 Fixed Guideway Modernization Program, the New Starts and Bus Programs, the section 5310 Elderly and Persons with Disabilities Program, the section 5311 Nonurbanized Area Formula Program, the Job Access and Reverse Commute Program, the Over-the-Road Bus Accessibility Program, section 5303 Metropolitan Planning Program, and section 5313(b) State Planning and Research Program. The 90-day processing time begins with the receipt of a complete application by the Regional Office. In order for an application to be considered complete, it must meet the following requirements: all projects must be contained in an approved STIP, all environmental findings must be made by FTA, there must be an adequate project description, local share must be secure, all required civil rights submissions must have been submitted, and certifications and assurances must be properly submitted. Once an application is complete, the FTA Regional Office will assign a project number and submit the application to the Department of Labor for a certification under section 5333(b). The FTA circulars referenced below contain more information regarding application contents and complete applications.

Formula and Capital Investment grant applications should be prepared in conformance with the following FTA Circulars: Program Guidance and Application Instructions for Metropolitan Planning Program Grants—C8100.1B, October 25, 1996; Urbanized Area Formula Program: Grant Application Instructions—C9030.1C, October 1, 1998; Nonurbanized Area Formula Program Guidance and Grant Application Instructions—C9040.1E, October 1, 1998; Section 5310 Elderly and Persons with Disabilities Program Guidance and Application Instructions C9070.1E, October 1, 1998; and Section 5309 Capital Program: Grant Application Instructions—C9300.1A, October 1, 1998. Guidance on preparation of applications for State Planning and Research funds may be obtained from each FTA Regional Office. Copies of circulars are available from FTA Regional Offices as well as the FTA website.

Applications for grants containing transferred FHWA funds (STP, CMAQ, and others) should be prepared in the same manner as for funds under the program to which they are being transferred. The application for flexible funds needs to specifically indicate the type and amount of flexible funds being transferred to FTA. The application should also describe which items are being funded with transferred funds, consistent with the Statewide Transportation Improvement Program (STIP).

Issued on: January 9, 2001.

Nuria I. Fernandez,

Acting Administrator.

BILLING CODE 4910-57-P

FEDERAL TRANSIT ADMINISTRATION

TABLE 1 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 APPROPRIATIONS FOR GRANT PROGRAMS

SOURCE OF FUNDS	ORIGINAL APPROPRIATION	REVISED APPROPRIATION	
TRANSIT PLANNING AND RESEARCH PROGRAMS			
Planning			
Section 5303 Metropolitan Planning Program	$62,113,680	$61,968,930	
Reapportioned Funds Added	279,990	279,990	
Total Apportioned	$62,393,680	$62,278,930	
Section 5313(b) State Planning and Research Program	$10,886,400	$10,862,480	
Reapportioned Funds Added	76,320	76,320	
Total Apportioned	$10,962,720	$10,938,770	
Research			
Section 5311(b)(2) Rural Transit Assistance Program (RTAP)	$5,280,000	$5,238,480	
Reapportioned Funds Added	165,880	165,880	
Total Apportioned	$5,415,880	$5,404,340	
FORMULA PROGRAMS	$3,348,000,000	$3,336,643,200	a/
Alaska Railroad (Section 5307)	4,849,980	4,839,280	
Less Oversight (one-half percent)	(24,280)	(24,196)	
Total Available	4,825,700	4,815,084	
Section 5309 Clean Fuels Formula Program	(60,000,000)	(49,999,000)	
Over-the-Road Bus Accessibility Program	4,700,000	4,689,696	
2002 Winter Olympic Games in Salt Lake City	$60,000,000	$49,988,000	
Section 5307 Urbanized Area Formula Program			
91.23% of Total Available for Sections 5307, 5311, and 5310	$2,943,573,081	$2,936,106,809	
Less Oversight (one-half percent)	(14,712,869)	(13,982,722)	
Reapportioned Funds Added	4,736,806	4,736,806	
Total Apportioned	$2,932,609,986	$2,926,189,892	
Section 5311 Nonurbanized Area Formula Program			
6.37% of Total Available for Sections 5307, 5311, and 5310	$205,461,166	$205,008,164	
Less Oversight (one-half percent)	(1,027,306)	(1,025,046)	
Reapportioned Funds Added	1,891,782	1,891,782	
Total Apportioned	$206,936,864	$205,486,900	
Section 5310 Elderly and Persons with Disabilities Formula Program			
2.4% of Total Available for Sections 5307, 5311, and 5310	$77,418,881	$77,248,457	
Reapportioned Funds Added	319,908	319,908	
Total Apportioned	$77,738,710	$77,568,408	
CAPITAL INVESTMENT PROGRAM	$2,898,000,000	$2,894,868,960	
Section 5309 Fixed Guideway Modernization	$1,068,469,000	$1,066,971,530	
Less Oversight (three-fourth percent)	(7,938,000)	(7,928,536)	
Reapportioned Funds Added	289,788	289,788	
Total Apportioned	$1,060,781,788	$1,058,446,742	
Section 5309 New Starts	$1,068,469,000	$1,066,968,720	
Less Oversight (three-fourth percent)	(7,938,000)	(7,942,987)	
Reallocated Funds Added	26,994,048	26,994,048	b/
Total Allocated	$1,077,486,048	$1,078,113,781	
Section 5309 Bus	$678,200,000	$678,434,960	c/
Less Oversight (three-fourth percent)	(4,244,000)	(4,234,443)	
Total Allocated	$674,056,000	$674,000,217	
JOB ACCESS AND REVERSE COMMUTE PROGRAM (Section 3037, TEA-21)	$100,000,000	$99,780,000	
TOTAL APPROPRIATION (Above Grant Programs)	$6,169,280,000	$6,149,191,900	

a/ Statutory percentages in formula programs are slightly adjusted due to a $1 million transfer to the OIG before the reduction was applied. The transfer to the OIG was required by the FY 2001 DOT Appropriations Act.

b/ Conference Report 106-940 reallocated funds from unobligated balances to other New Starts projects.

c/ Includes funds transferred from the Clean Fuels Formula Program.

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FEDERAL TRANSIT ADMINISTRATION

TABLE 2 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5303 METROPOLITAN PLANNING PROGRAM AND SECTION 5313(b) STATE PLANNING AND RESEARCH PROGRAM APPORTIONMENTS

STATE	REVISED SECTION 5303 APPORTIONMENT	REVISED SECTION 5313(b) APPORTIONMENT
Alabama	$467,908	$119,766
Alaska	200,116	64,694
Arizona	532,799	172,881
Arkansas	200,116	64,694
California	8,913,015	1,957,012
Colorado	686,203	184,775
Connecticut	611,144	159,844
Delaware	200,116	64,694
District of Columbia	201,827	64,694
Florida	2,809,720	662,471
Georgia	1,809,163	212,248
Hawaii	200,116	64,694
Idaho	200,116	64,694
Illinois	3,954,794	851,886
Indiana	741,698	175,299
Iowa	234,696	81,365
Kansas	271,290	86,302
Kentucky	324,845	83,112
Louisiana	861,380	145,824
Maine	200,116	64,694
Maryland	1,213,729	233,121
Massachusetts	1,466,370	307,906
Michigan	1,967,119	378,339
Minnesota	774,386	164,326
Mississippi	200,116	64,694
Missouri	866,194	181,131
Montana	200,116	64,694
Nebraska	200,116	64,694
Nevada	226,742	69,304
New Hampshire	200,116	64,694
New Jersey	2,891,730	431,523
New Mexico	200,116	64,694
New York	5,262,941	918,827
North Carolina	625,372	163,565
North Dakota	200,116	64,694
Ohio	1,901,618	433,309
Oklahoma	337,952	89,165
Oregon	378,662	92,433
Pennsylvania	2,336,661	469,143
Puerto Rico	666,666	138,335
Rhode Island	200,116	64,694
South Carolina	365,669	92,868
South Dakota	200,116	64,694
Tennessee	551,991	144,372
Texas	3,552,299	749,230
Utah	328,394	85,891
Vermont	200,116	64,694
Virginia	1,168,443	249,261
Washington	931,292	209,259
West Virginia	200,116	64,694
Wisconsin	662,627	169,431
Wyoming	200,116	64,694
TOTAL	$52,278,930	$10,938,770

FEDERAL HIGHWAY ADMINISTRATION

TABLE 3

FY 2001 ESTIMATED METROPOLITAN PLANNING PROGRAM (PL) AND ESTIMATED STATE PLANNING AND RESEARCH (SP&R) PROGRAM APPORTIONMENTS **

STATE	PL APPORTIONMENT	EST. TOTAL SP&R APPORTIONMENT	EST. SP&R PLANNING APPORTIONMENT a/
Alabama	$2,137,417	10,270,862	$7,702,922
Alaska	962,541	6,700,406	5,070,305
Arizona	3,085,368	9,980,102	7,401,827
Arkansas	962,541	7,335,479	5,501,609
California	29,883,006	50,286,824	37,715,118
Colorado	2,762,221	6,713,986	5,035,290
Connecticut	2,052,687	8,468,287	6,351,215
Delaware	962,541	2,542,102	1,906,577
District of Columbia	962,541	2,231,520	1,673,640
Florida	11,822,948	27,302,997	20,477,248
Georgia	3,787,798	19,640,764	14,730,573
Hawaii	962,541	2,901,287	2,175,965
Idaho	962,541	4,187,427	3,140,570
Illinois	9,848,369	18,549,432	13,912,074
Indiana	3,127,977	13,062,164	10,396,623
Iowa	1,095,043	6,775,895	5,081,896
Kansas	1,183,273	6,518,777	4,889,083
Kentucky	1,483,273	9,325,003	6,993,752
Louisiana	2,898,202	8,903,001	6,677,701
Maine	962,541	2,989,547	2,242,160
Maryland	4,189,443	8,816,395	6,612,296
Massachusetts	5,495,199	10,186,756	7,640,020
Michigan	6,782,123	18,153,944	13,615,458
Minnesota	2,784,223	8,180,431	6,135,323
Mississippi	962,541	6,620,582	4,965,437
Missouri	3,232,898	13,286,106	9,964,581
Montana	962,541	5,735,180	4,301,385
Nebraska	962,541	4,459,672	3,345,504
Nevada	1,068,384	4,168,312	3,126,234
New Hampshire	962,541	2,838,186	2,128,639
New Jersey	7,791,278	14,834,997	11,126,190
New Mexico	962,541	5,485,863	4,114,390
New York	16,398,084	27,991,938	20,993,954
North Carolina	2,919,998	15,508,585	11,631,514
North Dakota	962,541	3,782,193	2,836,645
Ohio	7,733,147	18,536,527	13,902,396
Oklahoma	1,573,288	8,482,966	6,362,149
Oregon	1,849,627	8,671,822	6,503,867
Pennsylvania	8,372,068	24,815,480	18,611,860
Rhode Island	962,541	3,431,998	2,573,998
South Carolina	1,667,387	9,617,917	7,213,438
South Dakota	962,541	4,008,528	3,006,396
Tennessee	2,576,572	11,664,961	8,748,721
Texas	13,210,694	43,111,291	32,333,442
Utah	1,532,871	4,388,588	3,290,691
Vermont	962,541	2,587,234	1,940,426
Virginia	4,448,858	14,369,987	10,777,490
Washington	3,734,436	9,906,991	7,429,368
West Virginia	962,541	4,601,921	3,451,441
Wisconsin	2,863,170	11,162,733	8,372,099
Wyoming	962,541	3,955,337	2,966,503
TOTAL	$192,508,331	$556,919,800	$417,689,850

a/ 75 percent of Est. (Estimated) Total SP&R Apportionment

** *Amounts may be adjusted by FHWA to incorporate the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.*

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FEDERAL TRANSIT ADMINISTRATION

TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED ONE PERCENT TRANSIT ENHANCEMENT	REVISED APPORTIONMENT
OVER 1,000,000 IN POPULATION	$21,444,964	$2,144,496,422
200,000-1,000,000 IN POPULATION	4,976,118	497,611,826
50,000-200,000 IN POPULATION	————	284,852,445
NATIONAL TOTAL	$26,421,072	$2,926,160,692

URBANIZED AREA/STATE	REVISED ONE PERCENT TRANSIT ENHANCEMENT	REVISED APPORTIONMENT
Amounts Apportioned to Urbanized Areas 1,000,000 and Over in Population:		
Atlanta, GA	$416,476	$41,647,668
Baltimore, MD	336,469	33,644,573
Boston, MA	940,117	94,011,695
Chicago, IL-Northwestern IN	1,049,736	104,973,616
Cincinnati, OH-KY	146,211	14,621,146
Cleveland, OH	391,731	39,173,121
Dallas-Fort Worth, TX	413,488	41,348,394
Denver, CO	279,186	27,912,637
Detroit, MI	367,316	36,731,584
Ft Lauderdale-Hollywood-Pompano Beach, FL	226,226	22,622,637
Houston, TX	472,016	47,201,480
Kansas City, MO-KS	103,691	10,368,126
Los Angeles, CA	1,066,286	106,628,491
Miami-Hialeah, FL	376,016	37,601,619
Milwaukee, WI	169,630	16,963,043
Minneapolis-St. Paul, MN	323,047	32,304,711
New Orleans, LA	169,130	16,913,709
New York, NY-Northeastern NJ	6,699,347	669,934,446
Norfolk-Virginia Beach-Newport News, VA	132,330	13,233,899
Philadelphia, PA-NJ	1,044,466	104,446,639
Phoenix, AZ	234,662	23,466,175
Pittsburgh, PA	297,842	29,784,232
Portland-Vancouver, OR-WA	266,967	26,696,749
Riverside-San Bernardino, CA	181,827	18,182,733
Sacramento, CA	130,761	13,076,121
San Antonio, TX	162,367	16,236,706
San Diego, CA	432,579	43,257,899
San Francisco-Oakland, CA	1,166,957	116,695,724
San Jose, CA	311,316	31,131,496
San Juan, PR	362,434	36,242,306
Seattle, WA	686,799	68,679,841
St. Louis, MO-IL	343,786	34,378,680
Tampa-St. Petersburg-Clearwater, FL	169,953	16,995,208
Washington, DC-MD-VA	986,994	98,699,436
TOTAL	$21,444,964	$2,144,496,422

FEDERAL TRANSIT ADMINISTRATION

TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED ONE PERCENT TRANSIT ENHANCEMENT	REVISED APPORTIONMENT
Amounts Apportioned to Urbanized Areas 200,000 to 1,000,000 in population		
Akron, OH	$62,109	$6,210,822
Albany-Schenectady-Troy, NY	84,165	8,416,462
Albuquerque, NM	51,840	5,184,006
Allentown-Bethlehem-Easton, PA-NJ	49,756	4,975,626
Anchorage, AK	26,634	2,663,406
Ann Arbor, MI	32,846	3,284,681
Augusta, GA-SC	18,996	1,899,636
Austin, TX	114,611	11,461,136
Bakersfield, CA	37,969	3,796,906
Baton Rouge, LA	38,894	3,889,377
Birmingham, AL	40,367	4,036,697
Bridgeport-Milford, CT	70,690	7,066,926
Buffalo-Niagara Falls, NY	118,366	11,836,490
Canton, OH	33,230	3,323,017
Charleston, SC	28,962	2,896,223
Charlotte, NC	72,367	7,236,726
Chattanooga, TN-GA	22,721	2,272,113
Colorado Springs, CO	37,514	3,751,430
Columbia, SC	26,974	2,697,421
Columbus, GA-AL	16,346	1,634,636
Columbus, OH	112,290	11,228,986
Corpus Christi, TX	36,216	3,621,636
Davenport-Rock Island-Moline, IA-IL	27,986	2,798,763
Dayton, OH	114,626	11,462,866
Daytona Beach, FL	29,348	2,934,763
Des Moines, IA	27,062	2,706,222
Durham, NC	36,186	3,618,619
El Paso, TX-NM	81,462	8,146,186
Fayetteville, NC	18,196	1,819,763
Flint, MI	61,783	6,178,284
Fort Myers-Cape Coral, FL	26,231	2,623,694
Fort Wayne, IN	20,193	2,019,274
Fresno, CA	84,662	8,466,206
Grand Rapids, MI	46,377	4,637,701
Greenville, SC	14,066	1,406,604
Harrisburg, PA	31,831	3,183,133
Hartford-Middletown, CT	92,837	9,283,678
Honolulu, HI	212,802	21,279,811
Indianapolis, IN	90,358	9,035,831
Jackson, MS	18,864	1,886,428
Jacksonville, FL	79,767	7,976,704
Knoxville, TN	25,842	2,584,176
Lansing-East Lansing, MI	33,994	3,399,402
Las Vegas, NV	162,194	16,219,380
Lawrence-Haverhill, MA-NH	33,571	3,357,076
Lexington-Fayette, KY	23,199	2,319,906

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TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED ONE PERCENT TRANSIT ENHANCEMENT	REVISED APPORTIONMENT
Amounts Apportioned to Urbanized Areas 200,000 to 1,000,000 in population (continued)		
Little Rock-North Little Rock, AR	28,633	2,863,344
Lorain-Elyria, OH	14,808	1,480,796
Louisville, KY-IN	108,839	10,883,888
Madison, WI	49,529	4,952,949
McAllen-Edinburg-Mission, TX	16,217	1,621,710
Melbourne-Palm Bay, FL	22,408	2,240,897
Memphis, TN-AR-MS	94,625	9,462,483
Mobile, AL	21,443	2,144,347
Modesto, CA	29,678	2,967,847
Montgomery, AL	12,397	1,239,686
Nashville, TN	49,999	4,999,999
New Haven-Meriden, CT	116,962	11,696,196
Ogden, UT	31,722	3,172,234
Oklahoma City, OK	89,325	8,932,919
Omaha, NE-IA	84,919	8,491,932
Orlando, FL	163,176	16,317,602
Oxnard-Ventura, CA	68,988	6,898,762
Pensacola, FL	20,663	2,066,300
Peoria, IL	21,688	2,167,999
Providence-Pawtucket, RI-MA	159,466	15,946,536
Provo-Orem, UT	30,691	3,069,698
Raleigh, NC	27,912	2,791,206
Reno, NV	32,743	3,274,198
Richmond, VA	63,783	6,378,276
Rochester, NY	71,787	7,178,769
Rockford, IL	18,987	1,898,739
Salt Lake City, UT	122,976	12,297,676
Sarasota-Bradenton, FL	40,139	4,013,928
Scranton-Wilkes-Barre, PA	32,272	3,227,198
Shreveport, LA	25,184	2,518,411
South Bend-Mishawaka, IN-MI	31,075	3,107,463
Spokane, WA	59,821	5,982,128
Springfield, MA-CT	69,009	6,900,940
Stockton, CA	50,401	5,040,120
Syracuse, NY	46,196	4,619,923
Tacoma, WA	115,488	11,548,831
Toledo, OH-MI	80,867	8,086,723
Trenton, NJ-PA	45,189	4,518,991
Tucson, AZ	81,167	8,116,666
Tulsa, OK	45,811	4,581,113
West Palm Beach-Boca Raton-Delray Bch, FL	168,178	16,817,806
Wichita, KS	31,331	3,133,147
Wilmington, DE-NJ-MD-PA	81,070	8,107,031
Worcester, MA-CT	43,917	4,391,682
Youngstown-Warren, OH	26,647	2,664,732
TOTAL	$4,976,118	$497,611,825

FEDERAL TRANSIT ADMINISTRATION

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TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
Amounts Apportioned to State Governors for Urbanized Areas 50,000 to 200,000 in Population	
ALABAMA:	$6,278,363
Anniston, AL	899,136
Auburn-Opelika, AL	455,479
Decatur, AL	453,380
Dothan, AL	391,571
Florence, AL	646,630
Gadsden, AL	462,148
Huntsville	1,539,880
Tuscaloosa, AL	944,799
ALASKA:	$0
ARIZONA:	$1,391,643
Flagstaff, AZ	543,541
Yuma, AZ-CA (AZ)	538,102
ARKANSAS:	$2,016,713
Fayetteville-Springdale, AR	686,577
Fort Smith, AR-OK (AR)	757,664
Pine Bluff, AR	512,667
Texarkana, TX-AR (AR)	160,475
CALIFORNIA:	$30,991,467
Antioch-Pittsburg, CA	1,746,987
Chico, CA	762,770
Davis, CA	925,985
Fairfield, CA	1,134,696
Hemet-San Jacinto, CA	536,264
Hesperia-Apple Valley-Victorville, CA	1,196,536
Indio-Coachella, CA	667,330
Lancaster-Palmdale, CA	2,013,382
Lodi, CA	786,196
Lompoc, CA	494,670
Merced, CA	666,663
Napa, CA	869,216
Palm Springs, CA	1,139,272
Redding, CA	647,700
Salinas, CA	1,704,696
San Luis Obispo, CA	667,236
Santa Barbara, CA	2,637,066
Santa Cruz, CA	1,263,699
Santa Maria, CA	1,248,624
Santa Rosa, CA	2,486,433
Seaside-Monterey, CA	1,616,491
Simi Valley, CA	1,630,539
Vacaville, CA	928,648
Visalia	1,066,946
Watsonville, CA	684,483
Yuba City, CA	932,621
Yuma, AZ-CA (CA)	3,320

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TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
COLORADO:	$6,692,086
Boulder, CO	1,306,866
Fort Collins, CO	1,064,939
Grand Junction, CO	699,636
Greeley, CO	643,788
Longmont, CO	798,991
Pueblo, CO	1,187,271
CONNECTICUT:	$21,397,236
Bristol, CT	897,166
Danbury, CT-NY (CT)	3,898,822
New Britain, CT	1,679,916
New London-Norwich, CT	1,351,539
Norwalk, CT	3,990,564
Stamford, CT-NY (CT)	4,883,037
Waterbury, CT	4,775,913
DELAWARE:	$428,434
Dover, DE	428,434
FLORIDA:	$13,087,889
Deltona, FL	436,168
Fort Pierce, F	1,042,434
Fort Walton Beach, FL	1,016,894
Gainesville, FL	1,296,625
Kissimmee, FL	693,183
Lakeland, FL	1,323,999
Naples, FL	871,312
Ocala, FL	895,391
Panama City, FL	878,376
Punta Gorda, FL	874,496
Spring Hill, FL	439,162
Stuart, FL	786,188
Tallahassee, FL	1,478,283
Titusville, FL	422,882
Vero Beach, FL	536,197
Winter Haven, FL	828,980
GEORGIA:	$5,739,288
Albany, GA	769,758
Athens, GA	889,486
Brunswick, GA	391,882
Macon, GA	1,272,131
Rome, GA	399,216
Savannah, GA	1,884,449
Warner Robins, GA	612,567
HAWAII:	$1,522,938
Kailua, HI	1,522,938

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TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
IDAHO:	$3,014,189
Boise City, ID	1,844,912
Idaho Falls, ID	691,186
Pocatello, ID	686,671
ILLINOIS:	$13,808,497
Alton, IL	746,140
Aurora, IL	2,088,719
Beloit, WI-IL (IL)	96,363
Bloomington-Normal, IL	1,282,833
Champaign-Urbana, IL	1,686,302
Crystal Lake, IL	691,856
Decatur, IL	964,896
Dubuque, IA-IL (IL)	22,342
Elgin, IL	1,997,421
Joliet, IL	1,743,916
Kankakee, IL	694,894
Round Lake Beach-McHenry, IL-WI (IL)	982,870
Springfield, IL	1,391,477
INDIANA:	$6,088,497
Anderson, IN	686,871
Bloomington, IN	971,299
Elkhart-Goshen, IN	973,448
Evansville, IN-KY (IN)	1,893,395
Kokomo, IN	686,499
Lafayette-West Lafayette, IN	1,393,873
Muncie, IN	867,823
Terre Haute, IN	737,188
IOWA:	$4,263,886
Cedar Rapids, IA	1,368,308
Dubuque, IA-IL (IA)	663,894
Iowa City, IA	734,534
Sioux City, IA-NE-SD (IA)	734,988
Waterloo-Cedar Falls, IA	840,418
KANSAS:	$2,128,416
Lawrence, KS	806,906
St. Joseph, MO-KS (KS)	6,663
Topeka, KS	1,316,776
KENTUCKY:	$1,677,530
Clarksville, TN-KY (KY)	204,886
Evansville, IN-KY (KY)	351,359
Huntington-Ashland, WV-KY-OH ((KY)	691,253
Owensboro, KY	730,252
LOUISIANA:	$4,998,188
Alexandria, LA	726,898
Houma, LA	699,884
Lafayette, LA	1,354,436
Lake Charles, LA	1,697,889
Monroe, LA	968,130
Slidell, LA	613,899

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(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
MAINE:	$2,162,246
Bangor, ME	444,306
Lewiston-Auburn, ME	816,278
Portland, ME	1,103,916
Portsmouth-Dover-Rochester, NH-ME (ME)	97,746
MARYLAND:	$2,404,623
Annapolis, MD	783,186
Cumberland, MD-WV (MD)	416,526
Frederick, MD	566,896
Hagerstown, MD-PA-WV (MD)	639,786
MASSACHUSETTS	$9,623,006
Brockton, MA	1,736,570
Fall River, MA-RI (MA)	1,696,646
Fitchburg-Leominster, MA	667,868
Hyannis, MA	490,866
Lowell, MA-NH (MA)	2,183,315
New Bedford, MA	1,866,952
Pittsfield, MA	444,490
Taunton, MA	444,819
MICHIGAN:	$9,128,663
Battle Creek, MI	675,720
Bay City, MI	758,340
Benton Harbor, MI	648,486
Holland, MI	615,840
Jackson, MI	767,823
Kalamazoo, MI	1,636,464
Muskegon, MI	906,186
Port Huron, MI	686,827
Saginaw, MI	1,476,176
MINNESOTA:	$2,866,866
Duluth, MN-WI (MN)	764,736
Fargo-Moorhead, ND-MN (MN)	467,466
Grand Forks, ND-MN (MN)	99,367
La Crosse, WI-MN (MN)	43,746
Rochester, MN	794,873
St. Cloud, MN	696,914
MISSISSIPPI:	$2,486,331
Biloxi-Gulfport, MS	1,539,369
Hattiesburg, MS	479,773
Pascagoula, MS ~	467,199
MISSOURI:	$3,436,196
Columbia, MO	676,419
Joplin, MO	475,834
Springfield, MO	1,696,746
St. Joseph, MO-KS (MO)	678,997

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(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
MONTANA:	$2,280,834
Billings, MT	676,622
Great Falls, MT	626,266
Missoula, MT	666,937
NEBRASKA:	$2,536,676
Lincoln, NE	2,426,891
Sioux City, IA-NE-SD (NE)	109,886
NEVADA:	$0
NEW HAMPSHIRE:	$3,079,194
Lowell, MA-NH (NH)	6,302
Manchester, NH	1,290,869
Nashua, NH	1,032,218
Portsmouth-Dover-Rochester, NH-ME (NH)	749,776
NEW JERSEY:	$2,332,990
Atlantic City, NJ	1,681,550
Vineland-Millville, NJ	651,440
NEW MEXICO:	$1,270,439
Las Cruces, NM	705,734
Santa Fe, NM	564,706
NEW YORK:	$7,048,802
Binghamton, NY	1,769,276
Danbury, CT-NY (NY)	23,991
Elmira, NY	726,521
Glens Falls, NY	499,617
Ithaca, NY	504,253
Newburgh, NY	664,788
Poughkeepsie, NY	1,378,466
Stamford, CT-NY (NY)	163
Utica-Rome, NY	1,484,726
NORTH CAROLINA:	$11,443,089
Asheville, NC	563,269
Burlington, NC	640,729
Gastonia, NC	936,190
Goldsboro, NC	467,230
Greensboro, NC	2,017,648
Greenville, NC	669,899
Hickory, NC	536,021
High Point, NC	962,244
Jacksonville, NC	571,082
Kannapolis, NC	628,849
Rocky Mount, NC	662,686
Wilmington, NC	822,212
Winston-Salem, NC	1,662,799

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(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
NORTH DAKOTA:	$2,223,367
Bismarck, ND	641,125
Fargo-Moorhead, ND-MN (ND)	927,232
Grand Forks, ND-MN (ND)	655,010
OHIO:	$6,113,239
Hamilton, OH	1,383,891
Huntington-Ashland, WV-KY-OH (OH)	321,767
Lima, OH	666,871
Mansfield, OH	666,710
Middletown, OH	668,709
Newark, OH	628,225
Parkersburg, WV-OH (OH)	78,391
Sharon, PA-OH (OH)	81,666
Springfield, OH	1,664,699
Steubenville-Weirton, OH-WV-PA (OH)	361,533
Wheeling, WV-OH (OH)	276,017
OKLAHOMA:	$661,491
Fort Smith, AR-OK (OK)	16,692
Lawton, OK	934,799
OREGON:	$4,662,691
Eugene-Springfield, OR	2,336,722
Longview, WA-OR (OR)	16,634
Medford, OR	721,048
Salem, OR	1,668,668
PENNSYLVANIA:	$12,971,664
Altoona, PA	666,137
Erie, PA	2,279,669
Hagerstown, MD-PA-WV (PA)	7,669
Johnstown, PA	917,167
Lancaster, PA	2,691,638
Monessen, PA	669,667
Pottstown, PA	632,291
Reading, PA	2,466,667
Sharon, PA-OH (PA)	372,638
State College, PA	776,623
Steubenville-Weirton, OH-WV-PA (PA)	2,788
Williamsport, PA	669,667
York, PA	1,619,677
PUERTO RICO:	$11,552,972
Aguadilla, PR	1,648,240
Arecibo, PR	870,891
Caguas, PR	2,666,264
Cayey, PR	768,466
Humacao, PR	666,437
Mayaguez, PR	1,419,264
Ponce, PR	3,139,462
Vega Baja-Manati, PR	1,428,669

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TABLE 4 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
RHODE ISLAND:	$782,799
Fall River, MA-RI (RI)	174,806
Newport, RI	667,806
SOUTH CAROLINA:	$3,236,163
Anderson, SC	434,431
Florence, SC	446,846
Myrtle Beach, SC	466,662
Rock Hill, SC	467,866
Spartanburg, SC	667,347
Sumter, SC	616,362
SOUTH DAKOTA:	$1,693,871
Rapid City, SD	616,666
Sioux City, IA-NE-SD (SD)	14,322
Sioux Falls, SD	1,078,749
TENNESSEE:	$2,462,276
Bristol, TN-Bristol, VA (TN)	232,616
Clarksville, TN-KY (TN)	666,766
Jackson, TN	436,161
Johnson City, TN	662,667
Kingsport, TN-VA (TN)	663,666
TEXAS:	$22,663,669
Abilene, TX	616,431
Amarillo, TX	1,612,464
Beaumont, TX	1,640,216
Brownsville, TX	1,611,621
Bryan-College Station, TX	1,612,744
Denton, TX	647,666
Galveston, TX	666,362
Harlingen, TX	743,669
Killeen, TX	1,421,266
Laredo, TX	1,766,632
Lewisville, TX	621,639
Longview, TX	621,346
Lubbock, TX	1,766,666
Midland, TX	776,332
Odessa, TX	666,126
Port Arthur, TX	636,366
San Angelo, TX	666,346
Sherman-Denison, TX	463,666
Temple, TX	466,176
Texarkana, TX-AR (TX)	366,711
Texas City, TX	662,761
Tyler, TX	766,462
Victoria, TX	632,726
Waco, TX	1,166,661
Wichita Falls, TX	626,667

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REVISED FY 2001 SECTION 5307 URBANIZED AREA FORMULA APPORTIONMENTS

URBANIZED AREA/STATE	REVISED APPORTIONMENT
UTAH:	$489,370
Logan, UT	489,370
VERMONT:	$806,089
Burlington, VT	806,089
VIRGINIA:	$8,399,876
Bristol, TN-Bristol, VA (VA)	166,181
Charlottesville, VA	799,369
Danville, VA	436,983
Fredericksburg, VA	612,836
Kingsport, TN-VA (VA)	31,186
Lynchburg, VA	731,830
Petersburg, VA	927,886
Roanoke, VA	1,775,196
WASHINGTON:	$5,066,386
Bellingham, WA	595,741
Bremerton, WA	1,184,063
Longview, WA-OR (WA)	804,083
Olympia, WA	897,899
Richland-Kennewick-Pasco, WA	936,677
Yakima, WA	967,942
WEST VIRGINIA	$3,896,087
Charleston, WV	1,563,389
Cumberland, MD-WV (WV)	18,657
Hagerstown, MD-PA-WV (WV)	4,722
Huntington-Ashland, WV-KY-OH (WV)	877,703
Parkersburg, WV-OH (WV)	864,475
Steubenville-Weirton, OH-WV-PA (WV)	342,862
Wheeling, WV-OH (WV)	614,319
WISCONSIN:	$10,638,317
Appleton-Neenah, WI	1,948,084
Beloit, WI-IL (WI)	417,571
Duluth, MN-WI (WI)	182,907
Eau Claire, WI	763,031
Green Bay, WI	1,479,997
Janesville, WI	861,548
Kenosha, WI	1,022,469
La Crosse, WI-MN (WI)	811,721
Oshkosh, WI	798,466
Racine, WI	1,579,204
Round Lake Beach-McHenry, IL-WI (WI)	882
Sheboygan, WI	967,446
Wausau, WI	486,792
WYOMING:	$1,113,729
Casper, WY	510,896
Cheyenne, WY	602,833
TOTAL	$284,062,446

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TABLE 5 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5311 NONURBANIZED AREA FORMULA APPORTIONMENTS, AND SECTION 5311(b) RURAL TRANSIT ASSISTANCE PROGRAM (RTAP) ALLOCATIONS

STATE	REVISED SECTION 5311 APPORTIONMENT	REVISED SECTION 5311(b) APPORTIONMENT
Alabama	$4,906,405	$113,962
Alaska	731,946	72,360
America Samoa	104,325	11,049
Arizona	2,148,770	86,430
Arkansas	3,924,065	104,135
California	9,577,395	160,516
Colorado	2,044,385	86,389
Connecticut	1,864,460	83,486
Delaware	462,840	69,614
Florida	6,156,763	126,402
Georgia	7,176,610	136,573
Guam	296,991	12,962
Hawaii	805,486	73,033
Idaho	1,625,002	81,206
Illinois	6,584,138	130,665
Indiana	6,360,128	128,430
Iowa	4,090,897	106,799
Kansas	3,256,179	97,484
Kentucky	5,371,940	118,578
Louisiana	4,442,983	109,310
Maine	2,143,913	86,362
Maryland	2,676,572	91,694
Massachusetts	2,968,472	93,606
Michigan	7,768,311	142,474
Minnesota	4,470,214	109,882
Mississippi	4,362,349	108,606
Missouri	5,206,649	116,927
Montana	1,316,379	78,128
Nebraska	1,996,250	84,809
Nevada	648,480	71,467
New Hampshire	1,717,006	82,124
New Jersey	2,464,955	89,484
New Mexico	1,929,966	84,249
New York	8,641,736	151,185
North Carolina	9,180,077	156,564
North Dakota	973,521	74,709
Northern Mariana	96,679	10,964
Ohio	9,345,956	158,200
Oklahoma	3,996,300	104,846
Oregon	3,172,303	96,638
Pennsylvania	10,426,612	168,975
Puerto Rico	3,115,471	96,071
Rhode Island	399,097	68,990
South Carolina	4,584,674	110,823
South Dakota	1,186,647	76,835
Tennessee	5,031,199	124,153
Texas	12,622,412	199,890
Utah	899,644	73,971
Vermont	1,060,985	76,581
Virgin Islands	227,061	12,265
Virginia	5,258,583	117,445
Washington	3,684,623	101,747
West Virginia	3,132,991	96,246
Wisconsin	5,413,442	116,999
Wyoming	767,131	72,561
TOTAL	$205,485,900	$5,404,340

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TABLE 6 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5310 ELDERLY AND PERSONS WITH DISABILITIES APPORTIONMENTS

STATE	REVISED APPORTIONMENT
Alabama	$1,341,753
Alaska	198,816
America Samoa	52,916
Arizona	1,108,931
Arkansas	832,236
California	7,346,882
Colorado	912,866
Connecticut	1,047,673
Delaware	306,599
District of Columbia	303,134
Florida	4,991,449
Georgia	1,746,626
Guam	134,396
Hawaii	393,486
Idaho	493,896
Illinois	3,194,583
Indiana	1,667,888
Iowa	1,003,498
Kansas	838,459
Kentucky	1,296,189
Louisiana	1,298,372
Maine	598,257
Maryland	1,296,662
Massachusetts	1,873,732
Michigan	2,736,678
Minnesota	1,314,996
Mississippi	996,187
Missouri	1,691,667
Montana	398,311
Nebraska	596,915
Nevada	431,897
New Hampshire	496,694
New Jersey	2,253,628
New Mexico	813,286
New York	5,243,663
North Carolina	1,996,974
North Dakota	316,931
Northern Marianas	52,572
Ohio	3,334,681
Oklahoma	1,196,684
Oregon	1,027,623
Pennsylvania	4,001,588
Puerto Rico	973,946
Rhode Island	469,473
South Carolina	1,099,122
South Dakota	337,161
Tennessee	1,567,436
Texas	4,133,396
Utah	477,138
Vermont	276,698
Virgin Islands	136,862
Virginia	1,662,119
Washington	1,479,903
West Virginia	776,536
Wisconsin	1,611,299
Wyoming	231,998
TOTAL	$77,599,406

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TABLE 7 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5309 FIXED GUIDEWAY MODERNIZATION APPORTIONMENTS

STATE	AREA	REVISED APPORTIONMENT
AZ	Phoenix	$1,436,247
CA	Los Angeles	28,832,813
CA	Oxnard-Ventura	883,945
CA	Riverside-San Bernardino	1,217,386
CA	Sacramento	2,666,661
CA	San Diego	8,836,470
CA	San Francisco	62,273,197
CA	San Jose	12,798,689
CO	Denver	1,466,770
CT	Hartford	1,297,716
CT	Southwestern Connecticut	36,386,919
DE	Wilmington	806,223
DC	Washington	62,668,996
FL	Ft. Lauderdale	2,681,710
FL	Jacksonville	100,466
FL	Miami	9,862,489
FL	Tampa	86,642
FL	West Palm Beach	2,376,886
GA	Atlanta	21,116,647
HI	Honolulu	926,871
IL	Chicago/Northwestern Indiana	126,962,048
IN	South Bend	886,679
LA	New Orleans	2,834,680
MD	Baltimore	7,986,866
MD	Baltimore Commuter Rail	16,986,661
MA	Boston	64,116,848
MA	Lawrence-Haverhill	1,491,297
MI	Detroit	337,140
MN	Minneapolis	3,666,969
MO	Kansas City	25,000
MO	St. Louis	3,439,466
NJ	Northeastern New Jersey	79,536,870
NJ	Trenton	1,283,900
NY	Buffalo	1,213,966
NY	New York	333,140,133
OH	Cleveland	12,361,276
OH	Dayton	4,387,228
OR	Portland	3,483,792
PA	Harrisburg	464,286
PA	Philadelphia/Southern New Jersey	88,363,302
PA	Pittsburgh	19,996,127
PR	San Juan	2,842,349
RI/MA	Providence	2,368,786
TN	Chattanooga	78,089
TN	Memphis	172,006
TX	Dallas	836,345
TX	Houston	6,136,712
VA	Norfolk	1,031,613
WA	Seattle	16,466,803
WA	Tacoma	767,077
WI	Madison	991,930
	TOTAL	$1,048,440,742

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TABLE 8 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5309 NEW STARTS ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	REVISED ALLOCATION
AK/HI	Alaska or Hawaii Ferry Projects	$10,362,680
AK	Eklutna to Wasilla, Alaska, Commuter Rail Project	14,998,647
AL	Birmingham, Alabama, Transit Corridor	4,963,216
AR	Little Rock, Arkansas, River Rail Project	2,971,930
AZ	Phoenix Metropolitan Area Transit Project	9,906,431
CA	Hollywood/Orange Branch Line Rail Extension Project	988,644
CA	Los Angeles Mid-City and East Side Corridors Projects	1,981,286
CA	Los Angeles North Hollywood Extension Project	49,532,168
CA	Los Angeles-San Diego LOSSAN Corridor Project	2,971,930
CA	Oceanside-Escondido, California, Light Rail Extension Project	9,906,431
CA	Orange County, California, Transitway Project	1,981,286
CA	Sacramento, California, South Corridor LRT Project	34,670,040
CA	San Bernardino, California, Metrolink Project	988,644
CA	San Diego Mission Valley East Light Rail Project	31,396,290
CA	San Francisco BART Extension to the Airport Project	79,251,454
CA	San Jose Tasman West Light Rail Project	12,136,379
CA	Stockton, California, Altamont Commuter Rail Project	5,943,859
CO	Colorado Roaring Fork Valley Project	988,644
CO	Denver Southeast Corridor Project	2,971,930
CO	Denver Southwest Corridor Project	29,619,993
CT	Stamford, Connecticut, Fixed Guideway Corridor	7,925,145
DE	Wilmington, Delaware, Downtown Transit Corridor Project	4,963,216
FL	Central Florida Commuter Rail Project	2,971,930
FL	Fort Lauderdale, Florida, Tri-County Commuter Rail Project	14,998,647
GA	Atlanta, Georgia, North Line Extension Project	24,766,899
HI	Honolulu, Hawaii, Bus Rapid Transit Project	2,478,899
IL	Chicago METRA Commuter Rail Projects	34,672,511
IL	Chicago Ravenswood and Douglas Branch Reconstruction Projects	14,998,647
IN	Indianapolis, Indiana Northeast-Downtown Corridor Project	2,971,930
IN	Northern Indiana South Shore Commuter Rail Project	1,981,286
KS	Johnson County, Kansas I-35 Commuter Rail Project	988,644
MA	Boston South Boston Piers Transitway Project	24,766,899
MA	Boston Urban Ring Project	988,644
MA	Lowell, Massachusetts-Nashua, New Hampshire Commuter Rail Project	1,981,286
MA	Massachusetts North Shore Corridor Project	988,644
MD	Baltimore Central LRT Double Track Project	2,971,930
MD	MARC expansion projects -- Penn-Camden Lines Connector and Midday Storage Facility	9,906,431
MD	Washington Metro Blue Line Extension - Addison Road (Largo) Project	7,429,824
ME	Calais, Maine, Branch Line Regional Transit Program	988,644
ME	Portland, Maine, Marine Highway Program	1,981,286
MI	Detroit, Michigan, Metropolitan Airport Light Rail Project	496,321
MN	Twin Cities Transitways Projects	4,963,216
MN	Twin Cities Transitways -- Hiawatha Corridor Project	49,532,168
MO	Kansas City, Missouri, Southtown Corridor Project	3,467,251
MO	St. Louis, Missouri MetroLink, Cross County Connector Project	988,644
MO	St. Louis - St. Clair MetroLink Extension Project	59,438,899
NC	Charlotte, North Carolina, North Corridor and South Corridor Transitway Projects	4,963,216
NC	Raleigh-Durham-Chapel Hill Triangle Transit Project	9,906,431
NJ	Newark-Elizabeth Rail Link Project	6,934,502
NJ	*Newark-Elizabeth Rail Link Project*	*2,978,949* a/

FEDERAL TRANSIT ADMINISTRATION

TABLE 8 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 SECTION 5309 NEW STARTS ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	REVISED ALLOCATION
NJ	New Jersey Hudson Bergen Project	110,867,821
NJ	Northwest New Jersey-Northeast Pennsylvania Passenger Rail Project	988,644
NJ	West Trenton, New Jersey, Rail Project	1,981,286
NM	Albuquerque/Greater Albuquerque Mass Transit Project	496,321
NM	Santa Fe-Eldorado, New Mexico, Rail Link Project	1,486,965
NV	Clark County, Nevada, RTC Fixed Guideway Project	1,486,965
NY	Long Island Railroad East Side Access Project	7,925,145
NY	Whitehall and St. George Ferry Terminal Projects	2,476,608
OH	Canton-Akron-Cleveland Commuter Rail Project	1,981,286
OH	Cleveland Euclid Corridor Improvement Project	3,962,572
OR	Portland- Interstate MAX LRT Extension Project	7,429,824
OR	Wilsonville to Washington County, Oregon, Commuter Rail Project	988,644
PA	Harrisburg-Lancaster Capital Area Transit Corridor 1 Commuter Rail Project	496,321
PA	Philadelphia-Reading SEPTA Schuylkill Valley Metro Project	9,906,431
PA	Philadelphia SEPTA Cross County Metro Project	1,981,286
PA	Pittsburgh North Shore- Central Business District Corridor Project	4,963,216
PA	Pittsburgh Stage II Light Rail Project	11,887,718
PR	San Juan Tren Urbano Project	74,298,238
RI	Rhode Island-Pawtucket and T.F. Green Commuter Rail and Maintenance Facility	496,321
TN	Memphis, Tennessee, Medical Center Rail Extension Project	5,943,859
TN	Nashville, Tennessee, Regional Commuter Rail Project	5,943,859
TX	Austin, Texas Capital Metro Light Rail Project	988,644
TX	Dallas North Central Light Rail Extension Project	69,346,021
TX	*Dallas Southeast Corridor Light Rail*	*997,800* a/
TX	Galveston, Texas, Rail Trolley Extension Project	988,644
TX	Houston Advanced Transit Project	2,476,608
TX	Houston Regional Bus Project	19,849,414
UT	Salt Lake City - University Light Rail Line Project	1,981,286
VA	Dulles Corridor Project	49,532,168
VA	Virginia Railway Express Commuter Rail Project	2,971,930
VT	Burlington-Bennington (ABRB), Vermont Commuter Rail Project	1,981,286
WA	Puget Sound RTA Sound Commuter Rail Project	4,963,216
WA	Seattle, Washington, Central Link LRT Project	49,532,168
WA	Spokane, Washington, South Valley Corridor Light Rail Project	3,962,572
WI	Kenosha-Racine-Milwaukee Rail Extension Project	3,962,572
	TOTAL ALLOCATION	$1,079,113,791

a/ Funding for project made available under the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554.

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FEDERAL TRANSIT ADMINISTRATION

TABLE 8A (REVISED) **

PRIOR YEAR UNOBLIGATED SECTION 5309 NEW START ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	FY 1999 UNOBLIGATED ALLOCATIONS	FY 2000 UNOBLIGATED ALLOCATIONS	TOTAL UNOBLIGATED ALLOCATION
AK/HI	Alaska or Hawaii Ferry Projects	$10,322,560	$10,293,210	$20,626,700
AK	Girdwood, Alaska Commuter Rail Project	0	9,810,787	9,810,787
AL	Birmingham- Transit Corridor	992,560	2,943,236	3,936,796
CA	Los Angeles-Mid-City and East Side Corridors Projects	420	0	420
CA	Los Angeles-San Diego LOSSAN Corridor Project	0	981,079	981,079
CA	Riverside County-San Jacinto Branch Line Project	496,280	0	496,280
CA	San Diego- Mid-Coast Corridor Project	1,986,160	4,908,304	6,894,464
CA	Stockton-Altamont Commuter Rail	0	981,079	981,079
CA	Orange County-Transitway Project	2,481,200	981,079	3,462,480
CO	Denver-North Front Range Corridor Feasibility Study	496,280	0	496,280
CO	Roaring Fork Valley Project	0	981,079	981,079
CT	Hartford-Light Rail Project	992,560	0	992,560
CT	Hartford- Old Saybrook Project	496,280	0	496,280
CT	Metro North Danbury to Norwalk	0	2,000,000	2,000,000
CT	New London-Waterfront Access Project	496,280	0	496,280
CT	Stamford-Fixed Guideway Connector	50	981,079	981,129
DE	Wilmington-Downtown Transit Connector	0	981,079	981,079
FL	Fort Lauderdale-Tri-County Commuter Rail Project	2,976,210	9,810,787	12,786,997
FL	Miami-Dade Transit East-West Corridor Project	2,977,000	1,471,618	4,448,278
FL	Miami Metro Dade - North 27th Avenue Corridor Project	7,460	0	7,460
FL	Pinellas County-Mobility Initiative Project	0	2,462,697	2,462,697
GA	Atlanta-South DeKalb Lindbergh Light Rail Project	992,560	981,079	1,973,639
GA	Savannah-Water Taxi	496,280	0	496,280
IA	Sioux City-Micro Rail Trolley System	248,140	0	248,140
IL	Chicago Metra Commuter Rail Exts. & Upgrades	8,066,320	24,528,968	32,482,288
IL	Chicago- Ravenswood Branch Line Project	0	3,433,776	3,433,776
IN	Indianapolis-Northeast Downtown Corridor Project	0	981,079	981,079
LA	New Orleans-Desire Streetcar Project	500,000	0	500,000
MA	Boston-North Shore Corridor	2	981,079	981,081
MA	Boston-North-South Rail Link	496,280	0	496,280
MA	Boston-South Boston Piers Transitway	53,590,976	52,875,236	106,466,210
MA	Boston-Urban Ring Project	3	981,079	981,082
MA/NH	Lowell, MA - Nashua, NH Commuter Rail Project	0	981,079	981,079
MD	Baltimore Central Downtown Transit Alternatives MIS	496,280	0	496,280
MD	Baltimore-Light Rail Double Track Project	0	4,908,129	4,908,129
MD	MARC Expansion Programs [Silver Spring Intermodal Center & Penn-Camden Rail Connection]	0	738,909	738,909
ME	Calais Branch Rail Line Regional Transit Program	0	3	3
MN	Minneapolis- Transitways Hiawatha Corridor Project	0	8,847,867	8,847,867
MN	Minneapolis-Transitways Projects	0	2,943,236	2,943,236
MO	Johnson County, KS, I-35 Commuter Rail Project	11,471	981,079	992,550
MO	St. Louis-MetroLink Cross County Corridor Project	0	2,462,697	2,462,697
NC	Charlotte-North-South Corridor Transitway Project	973,260	3,924,316	4,897,576
NC	Raleigh-Durham-Chapel Hill-Triangle Transit Project	9,926,525	7,848,630	17,774,155
NE	Omaha-Trolley System	992,560	0	992,560
NJ	Trans-Hudson Midtown Corridor Study	0	4,908,304	4,908,304
NJ	Urban Core- Newark Rail Link MOS-1 Project	0	11,772,946	11,772,946
NJ	West Trenton Rail Project	0	981,079	981,079

FEDERAL TRANSIT ADMINISTRATION

TABLE 8A (REVISED) **

PRIOR YEAR UNOBLIGATED SECTION 5309 NEW START ALLOCATIONS

STATE	PROJECT LOCATION AND DESCRIPTION	FY 1999 UNOBLIGATED ALLOCATIONS	FY 2000 UNOBLIGATED ALLOCATIONS	TOTAL UNOBLIGATED ALLOCATION
NM	Greater Albuquerque Mass Transit Project	2,964,795	6,867,861	9,832,316
NM	Santa Fe/El Dorado Rail Link	0	2,943,236	2,943,236
NY	New York-Second Avenue Subway	0	3,000,000	3,000,000
NY	New York-Whitehall Ferry Terminal Reconstruction Project	0	1,962,157	1,962,157
OH	Canton-Akron-Cleveland Commuter Rail Project	0	2,462,697	2,462,697
OH	Cleveland-Berea Red Line Extension	992,560	0	992,560
OH	Cleveland-Euclid Corridor Improvement Project	0	981,079	981,079
OH	Dayton-Light Rail Study	0	981,079	981,079
OR	Portland-Wilsonville to Washington County Connection to Westside	0	496,530	496,530
PA	Harrisburg-Capital Area Transit Corridor 1 Commuter Rail	992,560	496,530	1,489,090
PA	Philadelphia-Reading SEPTA Schuylkill Valley Metro Project	2,977,000	3,924,316	6,901,316
PA	Philadelphia-SEPTA Cross County Metro	762,560	981,079	1,743,639
PA	Pittsburgh-North Shore- Central Business District Corridor	992,560	9,810,787	10,803,337
PA	Pittsburgh-Stage II Light Rail Project	3,970,210	7,848,630	11,818,840
PR	Tren Urbano	0	31,394,510	31,394,510
TN	Knoxville- Memphis Commuter Rail Feasibility Study	992,530	0	992,530
TN	Memphis-Medical Center Rail Extension Project	2,183,610	2,462,697	4,636,312
TN	Nashville-Commuter Rail Project	992,560	981,079	1,981,639
TX	Galveston-Rail Trolley Extension Project	0	1,471,618	1,471,618
TX	Houston-Advanced Transit Program	0	2,943,236	2,943,236
UT	Salt Lake City-Olympic Transportation Infrastructure Investments	0	9,810,787	9,810,787
VA	Dulles Corridor Project	16,573,400	24,528,968	41,102,368
VA	Norfolk-Virginia Beach Corridor Project	0	981,079	981,079
VA	VRE-Woodbridge Station Improvements Project	0	2,168,373	2,168,373
VT	Burlington-Essex-Commuter Rail Project	1,986,160	0	1,986,160
WA	King County-Elliott Bay Water Taxi	248,140	0	248,140
WA	Seattle-Puget Sound RTA Sounder Com. Rail Proj.	0	4,908,304	4,908,304
WA	Spokane-South Valley Corridor Light Rail Project	992,560	1,962,167	2,954,727
WI	Kenosha-Racine-Milwaukee Commuter Rail Project	0	981,079	981,079
WV	Morgantown Fixed Guideway Modernization Project	3,970,210	0	3,970,210
	TOTAL UNOBLIGATED ALLOCATION	$140,666,190	$312,281,142	$448,966,110

Fiscal Year 1997 Allocations and 1998 Allocations Extended in Conference Report 106-490

CO	*Roaring Fork Valley rail project*	*$795,530*
MS	*Jackson, Mississippi intermodal corridor*	*2,990,300*
TX	*Galveston, Texas rail trolley system project*	*1,468,758*
VA	*Virginia Railway Express– Woodbridge station improvement project*	*2,279,069*
VT	*Burlington–Essex, Vermont commuter rail*	*2,883,828*
	Total Extended Allocations	*$10,407,457* a/

** *The table was revised to remove the Charleston, South Carolina Monobeam Corridor Project. Section 351 of the FY 2000 DOT Appropriations Act specifies that funds made available under this Act, and any prior year unobligated funds for this project shall be transferred and administered under the Transit Planning and Research account.*

a/ *Period of availability for funds extended in FY 2001 Appropriations Act is one additional year and they will lapse September 30, 2001. Projects extended in Conference Report 106-490 whose funds were obligated as of September 30, 2000 are not listed.*

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FEDERAL TRANSIT ADMINISTRATION

TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
AK	Alaska State Fair park and ride and passenger shuttle system	988,315
AK	Denali Depot intermodal facility	2,970,946
AK	Fairbanks Bus/Rail intermodal Facility	3,068,976
AK	Fairbanks parking garage and intermodal center	1,988,346
AK	Homer Alaska Maritime Wildlife Refuge intermodal and welcome center	841,788
AK	Port McKenzie intermodal facilities	7,427,361
AK	Ship Creek pedestrian and bus facilities and intermodal center/parking garage	4,961,574
AL	*Alabama A&M University buses and bus facilities*	494,500 a/
AL	Alabama State Docks intermodal passenger and freight facility	988,315
AL	Birmingham-Jefferson County Transit Authority buses and bus facilities	988,315
AL	Dothan–Wiregrass Transit Authority buses and bus facilities	742,736
AL	Huntsville Space and Rocket Center intermodal center	1,980,630
AL	Huntsville, intermodal facility	486,167
AL	Huntsville International Airport intermodal center	4,961,574
AL	Lanett, vans	247,579
AL	Mobile Waterfront Terminal	4,961,574
AL	Montgomery - Moulton Street intermodal Facility	2,970,946
AL	Montgomery, civil rights trail trolleys	247,579
AL	Shelby County, vans	198,063
AL	Statewide, bus and bus facilities	1,436,096
AL	Lamar County vans	49,516
AL	Tuscaloosa interdisciplinary science building parking and intermodal facility	9,407,991
AL	University of Alabama Birmingham fuel cell buses	1,980,630
AL	University of North Alabama, bus and bus facilities	1,980,630
AL	University of South Alabama, buses and bus facilities	2,475,787
AR	Central Arkansas Transit Authority, bus and bus facilities	1,044,782
AR	Hot Springs - national park intermodal parking facility	486,167
AR	Nevada County, vans and mini-vans	99,128
AR	Pine Bluff, buses	267,192
AR	River Market and College Station Livable Communities Program	1,980,346
AR	State of Arkansas, small rural and elderly and handicapped transit buses and bus facilities	2,970,946
AZ	Mesa bus maintenance facility - Regional Public Transportation Authority	1,980,630
AZ	Phoenix, bus and bus facilities	4,455,416
AZ	South Central Avenue transit center	1,980,630
AZ	Tucson intermodal transportation center at Union Pacific Depot	2,970,946
AZ	Tucson, bus and bus facilities	988,315
CA	AC Transit zero-emissions fuel cell bus deployment demonstration project	988,315
CA	Alameda Contra Costa Transit District, buses and bus facilities	486,167
CA	Anaheim, buses and bus facilities	247,579
CA	Brea, buses	148,547
CA	Calabasas, buses	486,167
CA	Contra Costa Transit Authority (County Connection), buses	486,167
CA	City of Livermore, park and ride facility	486,167
CA	Commerce, buses	988,315
CA	Compton, buses and bus-related equipment	247,579
CA	Culver City, buses	742,736
CA	Davis, buses	988,315
CA	El Dorado, buses	486,167
CA	El Segundo, Douglas Street gap closure and intermodal facility	2,079,891
CA	Folsom, transit stations	1,484,472
CA	FootHill Transit, buses and bus facilities	2,475,787
CA	Fresno, intermodal facilities	486,167
CA	Humboldt County, buses and bus facilities	486,167
CA	Los Angeles County Metropolitan Transportation Authority, buses	4,455,416
CA	Marin County, bus facilities	991,166
CA	Modesto, bus facility	247,579
CA	Monrovia, electric shuttles	574,363
CA	Monterey Salinas Transit Authority, buses and bus facilities	486,167

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
CA	Municipal Transit Operators Coalition, buses	1,980,630
CA	Oceanside, intermodal facility	1,980,630
CA	Placer County, buses and bus facilities	486,167
CA	Playa Vista, shuttle buses and bus-related equipment and facilities	2,970,946
CA	Redlands, trolley project	792,252
CA	Rialto, intermodal facility	544,573
CA	Riverside County, buses	486,167
CA	Sacramento, buses and bus facilities	988,315
CA	San Bernardino, intermodal facility	1,584,083
CA	San Bernardino, train station	594,189
CA	San Diego, East Village station improvement plan	988,315
CA	San Francisco, MUNI buses and bus facilities	1,980,630
CA	Santa Barbara County, mini-buses	237,676
CA	Santa Clara Valley Transportation Authority, buses	486,167
CA	Santa Clarita, maintenance facility	1,980,630
CA	Santa Cruz, buses and bus facilities	1,634,568
CA	Sonoma County, buses and bus facilities	988,315
CA	Sunline transit agency, buses	988,315
CA	Temecula, bus shelters	198,063
CA	Vista, bus center	297,094
CO	Statewide bus and bus facilities	9,903,148
CT	Bridgeport, intermodal center	4,961,574
CT	Hartford/New Britain busway	742,736
CT	New Haven, trolley cars and related equipment	988,315
CT	New London, parade project transit improvements	1,980,630
CT	Norwich bus terminal and pedestrian access	988,315
CT	Waterbury, bus garage	988,315
DC	Georgetown University fuel cell bus program	4,903,027
DE	Statewide bus and bus facilities	3,466,102
FL	Statewide bus and bus facilities (including Tallahassee)	16,346,948
GA	Atlanta, buses and bus facilities	1,980,630
GA	Chatham, buses and bus facilities	1,980,630
GA	Cobb County, buses	1,237,894
GA	Georgia Regional Transit Authority, buses and bus facilities	2,970,946
HI	Honolulu bus and bus facility improvements	5,941,892
IA	Ames maintenance facility	1,188,378
IA	Cedar Rapids intermodal facility	1,188,378
IA	Clinton facility expansion	486,167
IA	Des Moines park and ride	693,221
IA	Dubuque, buses and bus facilities	594,676
IA	Iowa City intermodal facility	1,188,378
IA	Mason City, bus facility	396,236
IA	Sioux City multimodal ground transportation center	1,980,630
IA	Sioux City Trolley system	693,221
IA	Statewide, bus and bus facilities	2,475,787
IA	Waterloo, buses and bus facilities	891,799
ID	Statewide, bus and bus facilities	3,466,102
IL	Harvey, intermodal facilities and related equipment	247,579
IL	Statewide, bus and bus facilities	5,941,892
IN	Evansville, buses and bus facilities	1,484,472
IN	Gary - Adam Benjamin intermodal center	792,252
IN	Greater Lafayette Public Corporation – Wabash Landing buses and bus facilities	1,484,472
IN	Indianapolis, buses and bus-related equipment	2,475,787
IN	South Bend, buses	2,970,946
IN	West Lafayette, buses and bus facilities	2,079,661

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TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
KS	Johnson County, buses	247,679
KS	Kansas City, buses	1,980,630
KS	Kansas City, JOBLINKS	247,679
KS	Kansas Department of Transportation, rural transit buses	2,970,946
KS	Lawrence bus and bus facilities	496,157
KS	Topeka, transit facility	804,190
KS	Wichita, buses and ITS related equipment	2,970,946
KS	Wyandotte County, buses	247,679
KY	Audubon Area Community Action	198,100
KY	Bluegrass Community Action, buses and bus-related equipment	198,401
KY	Central Community Action	99,032
KY	Community Action of Southern Kentucky	99,032
KY	Fulton County, vans and buses	138,644
KY	Hardin County, buses	297,094
KY	Kentucky Department of Transportation	243,221
KY	City of Frankfort- minibuses	97,148
KY	Community Action of Fayette/Lexington for cutaways and lifts	63,398
KY	Lexington Red Cross for minibuses	101,488
KY	Kentucky (southern and eastern) transit vehicles	2,970,946
KY	Lexington, LexTran, buses and bus facilities	3,466,102
KY	Louisville, bus and bus facilities	2,970,946
KY	Maysville, bus-related equipment	63,398
KY	Morehead, buses and bus-related equipment	38,822
KY	Murray/Calloway County, buses and bus related equipment	89,419
KY	Northern Kentucky Transit Agency, vans	41,583
KY	Paducah Transit Authority, bus and bus facilities	1,980,630
KY	Pennyrile, vans and related equipment	198,063
KY	Pikeville, transit facility	1,980,630
LA	Lafayette multi-modal facility	1,237,894
LA	Plaquemines Parish ferry	990,315
LA	St. Bernard Parish intermodal facilities	1,237,894
LA	Statewide bus and bus facilities	1,980
LA	Alexandria buses and vans	39,615
LA	Baton Rouge buses and bus equipment	49,519
LA	Jefferson Parish buses and bus related facilities	19,808
LA	Lafayette buses and bus related facilities	297,094
LA	Louisiana Department of Transportation and Development vans	133,692
LA	Monroe buses and bus related facilities	133,692
LA	New Orleans bus lease-maintenance	1,486,375
LA	Shreveport buses	282,143
LA	St. Tammany Parish park and ride	14,854
MA	Attleboro, intermodal facilities	990,315
MA	Berkshire, buses and bus facilities	990,315
MA	Beverly and Salem, intermodal station improvements	894,189
MA	Brockton, intermodal center	990,315
MA	Lowell, transit hub	1,237,894
MA	Merrimack Valley Regional Transit Authority, bus facility	496,157
MA	Montachusett, bus facilities, Leominster	247,679
MA	Montachusett, intermodal facility, Fitchburg	1,361,683
MA	Pioneer Valley, paratransit vehicles and equipment	990,315
MA	Springfield, intermodal facility	496,157
MA	Woburn, buses and bus facilities	247,679
ME	Bangor intermodal transportation center	1,486,472
ME	Statewide, bus, bus facilities and ferries	3,961,259
MD	Statewide bus and bus facilities	7,922,518
MI	Detroit, buses and bus facilities	2,970,946
MI	Flint, buses and bus facilities	496,157

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
MI	Lapeer, multi-modal transportation facility	49,516
MI	SMART community transit, buses and paratransit vehicles	4,066,648
MI	Statewide, buses and bus facilities	10,883,483
MI	Traverse City, transfer station	990,315
MN	Greater Minnesota buses and bus facilities	1,237,894
MN	Metro Transit, buses and bus facilities	13,366,289
MN	St. Cloud, buses and bus facilities	2,104,419
MO	Bi-State Development Agency, buses	2,970,946
MO	Dunklin, Mississippi, Scott, Ripley, Stoddard and Cape Girardeau counties, buses and bus facilities	990,315
MO	Excelsior Springs bus replacement	198,063
MO	Jefferson City van and equipment purchase	347,679
MO	Kansas City, buses and bus facilities	1,237,469
MO	OATS buses and vans	1,980,630
MO	Southeast Missouri Transportation Service bus and bus facilities	990,315
MO	Southwest Missouri State University, intermodal facility	990,315
MO	St. Joseph bus replacement	990,315
MO	State of Missouri bus and bus facilities	2,970,946
MS	Brookhaven multimodal transportation center	990,315
MS	Coast Transit Authority multimodal facility and shuttle service	2,970,946
MS	Harrison County, multimodal center	1,486,472
MS	Jackson, buses	990,315
MS	Picayune multimodal center	643,705
MS	State of Mississippi rural transit vehicles and regional transit centers	2,970,946
MT	Billings buses and intermodal facility	3,961,259
MT	Blackfoot Indian Reservation bus facility	496,157
MT	Great Falls Transit district buses and bus facilities	990,315
MT	Missoula Ravalli Transportation Management Association buses	742,736
NC	Statewide bus and bus facilities	8,417,675
ND	Statewide bus and bus facilities	2,475,787
NE	Missouri River pedestrian crossing - Omaha	3,961,259
NJ	Elizabeth Ferry Project	496,157
NJ	New Jersey Transit alternative fuel buses	3,961,259
NJ	Newark Arena bus improvements	3,961,259
NJ	Trenton, train/intermodal station	4,951,574
NM	Albuquerque automatic vehicle monitoring system (SOLAR)	1,980,630
NM	Albuquerque bus replacement	1,237,894
NM	Albuquerque, transit facility	4,951,574
NM	Angel Fire bus and bus Facilities	742,736
NM	Carlsbad, intermodal facilities	623,868
NM	Clovis, buses and bus facility	1,699,262
NM	Las Cruces, buses	496,157
NM	Santa Fe buses and bus facilities	1,980,630
NM	Valencia County, transportation station improvements	1,237,894
NV	Clark County bus passenger intermodal facility - Henderson	1,980,630
NV	Clark County, bus rapid transit	3,466,102
NV	Lake Tahoe CNG buses and fleet conversion	1,980,630
NV	Reno and Sparks, buses and bus facilities	990,315
NV	Washoe County buses and bus facilities	2,970,946
NY	Buffalo, buses	1,980,630
NY	Buffalo, intermodal facility	496,157
NY	Eastchester, Metro North facilities	247,679
NY	Greenport and Sag Harbor, ferries and vans	89,419
NY	Highbridge pedestrian walkway	99,032
NY	Jamaica, intermodal facilities	247,679

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TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
NY	Larchmont, intermodal facility	986,315
NY	Long Beach, bus maintenance facility	742,736
NY	Midtown West intermodal ferry terminal	8,932,284
NY	Nassau County, bus and bus facilities	1,891,098
NY	Nassau County, Medical Center and its community health centers	395,128
NY	New Rochelle, intermodal transportation center	986,315
NY	Oneida County, buses	986,315
NY	Rensselaer County, intermodal facility	493,157
NY	Rochester, buses and bus facilities	1,969,630
NY	Saratoga County, buses	643,788
NY	Suffolk County, senior and handicapped vans	493,157
NY	Sullivan County, buses, bus facilities, and related equipment	1,237,894
NY	Syracuse, buses	3,144,240
NY	Tompkins County, intermodal facility	918,948
NY	Westchester County, buses	986,315
NY	Westchester and Duchess counties, vans	196,863
OH	Cincinnati - Intermodal improvements	986,315
OH	Cincinnati Riverfront Transit Center	2,970,946
OH	Columbus Near East transit center	986,315
OH	Dayton - Second and Main Multimodal Transportation Center	918,948
OH	Statewide bus and bus facilities	13,864,490
OK	Metropolitan Tulsa Transit Authority pedestrian and streetscape improvements	2,478,787
OK	Oklahoma City bus transfer center	2,478,787
OK	Statewide bus and bus facilities	3,961,299
OR	Albany bus purchase - Linn-Benton transit system	196,863
OR	Basin Transit System buses	169,491
OR	Columbia County ADA buses	169,038
OR	Coos County buses	99,322
OR	Corvallis Transit System operations facility	257,482
OR	Hood River County bus and bus facility	237,576
OR	Lakeview buses	49,616
OR	Lane Transit District buses and bus facility	986,315
OR	Philomath buses	39,613
OR	Redmond, buses and vans	49,616
OR	Rogue Valley buses	986,782
OR	Salem Area Transit District buses	1,466,472
OR	Sandy buses	217,570
OR	South Clackamas Transportation District bus	89,138
OR	South Corridor Transit Center and park and ride facilities in Clackamas County	1,466,472
OR	Sunset Empire Transit District improvements to Clatsop County Intermodal Facility	792,262
OR	Tillamook County District transit facilities	166,491
OR	Union County bus	43,574
OR	Wasco County buses	96,070
PA	Allegheny County, buses	247,579
PA	Altoona bus testing facility	2,970,946
PA	Area Transit Authority, ITS related activities	1,782,567
PA	Beaver County, buses	986,315
PA	Berks County, buses and bus facilities	986,315
PA	Bethlehem intermodal facility	1,466,472
PA	Bradford County, buses and bus facilities	986,315
PA	Bucks County, intermodal facility improvements	1,237,894
PA	Cambria County Transit Authority, maintenance facilities	742,736
PA	Centre Area Transportation Authority, buses	1,894,893
PA	Fayette County, maintenance facilities	493,157
PA	Indiana, maintenance facilities	345,210
PA	Lancaster, buses	986,315
PA	Lycoming County, buses and bus facilities	1,969,630
PA	Mid County Transit Authority, buses	133,992
PA	Mid Mon Valley Transit Authority, buses	247,579

FEDERAL TRANSIT ADMINISTRATION

TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
PA	Monroe County, buses and bus facilities	986,315
PA	Philadelphia - Frankford Transportation Center	3,466,102
PA	Philadelphia, Callowhill bus garage	247,579
PA	Phoenixville, transit related improvements	1,237,894
PA	Somerset County, ITS related equipment	99,032
PA	Westmoreland County, buses and related equipment	237,576
PA	Wilkes-Barre intermodal transportation center	986,315
RI	Statewide, buses and bus facilities	3,961,299
SC	Statewide, buses and bus facilities	6,818,361
TN	Southern Coalition for Advanced Transportation, buses	1,969,630
TN	Statewide, buses and bus facilities	3,961,299
TX	Austin, buses	493,157
TX	Brazos Transit District, buses	493,157
TX	Corpus Christi, buses and bus facilities	986,315
TX	Dallas, buses	1,969,630
TX	El Paso, buses	986,315
TX	Fort Worth, intermodal transportation center	3,466,102
TX	Forth Worth, buses and bus facilities	2,970,946
TX	Galveston, buses and bus facilities	247,579
TX	Harris County, buses and bus facilities	1,969,630
TX	Houston Metro, Main Street Transit Corridor improvements	986,315
TX	Lubbock, buses and bus facilities	986,315
TX	Texas Rural Transit Vehicle Fleet Replacement Program	3,961,299
TX	Waco, maintenance facility	1,634,919
UT	Statewide Olympic bus and bus facilities	9,903,148
VA	Statewide bus and bus facilities	
VA	Charlottesville bus and bus facilities	978,945
VA	City of Richmond bus and bus facilities	1,969,080
VA	Danville bus replacement	86,727
VA	Fair Lakes League	486,023
VA	Fairfax County Transportation Association of Greater Springfield	486,023
VA	Falls Church Bus Rapid Transit terminus	978,945
VA	Farmville bus and bus facilities	97,804
VA	Hampton Roads bus and bus facilities	2,446,113
VA	Jamestown/Yorktown and Williamsburg CNG bus	1,467,067
VA	Loudoun Transit multi-modal facility	1,467,067
VA	Lynchburg bus and bus facility	1,467,067
VA	Prince William County fleet replacement	2,934,135
VA	Springfield station improvements	486,023
VT	Burlington multimodal transportation center	1,466,472
VT	Bellows Falls Multimodal	1,466,472
VT	Brattleboro multimodal center	2,478,787
VT	Central Vermont Transit Authority buses and bus facilities	1,466,472
VT	Chittenden County transportation authority, buses	986,315
VT	Vermont Statewide paratransit	1,466,472
WA	Clallam County, transportation center	493,157
WA	Clark County, intermodal facilities	986,315
WA	Ephrata, buses	435,738
WA	Everett, buses	1,466,472
WA	King County Metro Eastgate Park and Ride	2,970,946
WA	King County Metro transit bus and bus facilities	1,969,630
WA	Renton/Port Quendall transit project	493,157
WA	Richland, bus maintenance facility	986,315
WA	Snohomish County, buses and bus facilities	986,315
WA	Sound Transit, regional express buses	1,969,630
WA	Statewide combined small transit system request - bus and bus facilities	1,237,894

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FEDERAL TRANSIT ADMINISTRATION

TABLE 9

(Unless noted otherwise, project funding was made available under the 2001 DOT Appropriations Act. Adjustments made for the .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act.)

FY 2001 SECTION 5309 BUS ALLOCATIONS

STATE	PROJECT	ALLOCATION
WA	Thurston County, bus-related equipment	1,237,894
WI	Statewide bus and bus facilities	13,864,467
WV	Statewide buses and bus facilities	1,966,539
WY	Cheyenne transit and operation facility	911,899
	TOTAL ALLOCATION	$574,099,217

a/ Funding for project made available under the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554.

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
FY 1999 Unobligated Allocations		
AK	Anchorage	$4,267,750
AK	Fairbanks	1,985,000
AK	North Slope Borough	496,250
AK	Whittier	694,750
AL	Birmingham-Jefferson County	899,853
AL	Huntsville	992,500
AL	Pritchard	496,250
AL	Tuscaloosa	1,935,375
CA	Folsom	992,500
CA	Healdsburg	992,500
CA	Humboldt	992,500
CA	Lake Tahoe	496,250
CA	Los Angeles	2,481,250
CA	Morango Basin	645,125
CA	Riverside Transit Agency	992,500
CA	Sacramento	1,240,625
CA	San Diego	992,500
CA	San Fernando Valley	297,750
CA	San Joaquin (Stockton)	992,500
CA	Santa Rosa/Cotati	744,375
CA	Ukiah	496,250
CA	Windsor	744,375
CA	Woodland Hills	322,563
CA	Yolo County	1,191,000
CO	Colorado	100
CO	Denver	1,240,625
CT	Hartford	794,000
CT	Norwich	2,233,125
DC	Washington, D.C.	136,964
DC	Washington, D.C.	2,481,250
FL	Miami Beach	744,375
FL	Miami Beach	992,500
FL	Tampa	1,240,625
GA	Savannah/Chatham Area Transit	3,473,750
IA	Fort Dodge	878,363
IN	Gary	310,157
IN	South Bend	1,240,625
LA	Louisiana Statewide	
LA	Jefferson Parish	347,375
LA	State Infrastructure bank, transit account	347,375
LA	St. Tammany Parish	99,250
MA	Essex and Middlesex	208,000
MA	New Bedford/Fall River	248,125
MA	Pittsfield	4,565,500
MD	Maryland statewide	243,590
MN	Duluth Transit Authority	11,406
MN	Twin Cities Area Metro Transit	3,583,984
MO	St. Louis	1,240,625
MS	Harrison County	1,886,750
MS	High Street, Jackson	1,003,904

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FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
MS	Jackson	660,550
MT	Butte	660,150
NC	Statewide	4,400,800
ND	Statewide	339,158
NH	Statewide	632,177
NM	Albuquerque	3,721,875
NM	Northern New Mexico	1,986,000
NV	Washoe County	25,661
NY	Buffalo	2,977,800
NY	Buffalo	1,488,750
NY	Ithaca	1,240,625
NY	Mineola/Hicksville	1,240,625
NY	New York City	1,488,750
NY	Niagara Frontier Transportation Authority	496,250
NY	Rome	397,000
NY	Ulster County	992,500
NY	Utica	2,084,250
OR	Lane County	4,367,000
OR	Rogue Valley Transit District	992,500
OR	Salem Area Mass Transit System	992,500
OR	Wilsonville	397,000
PA	Chambersburg Transit Authority	297,750
PA	Chambersburg Transit Authority	992,500
PA	Fayette County	225,475
PA	Monroe County Transportation Authority	992,500
PA	Philadelphia	1,240,625
PA	Philadelphia	744,375
PA	Red Rose	992,500
PA	Robinson Towne Center	1,488,750
PA	Somerset County	173,688
PA	Towamencin Township	1,488,750
PA	Washington County	625,275
PA	Westmoreland County	198,500
PA	Wilkes-Barre	1,240,625
SC	Pee Dee	991,991
SD	South Dakota	794,000
SD	South Dakota	2,606,842
TX	Brazos Transit Authority	1,190,350
TX	Galveston	215,846
VA	Alexandria	992,500
VA	Alexandria	1,091,750
VA	Lynchburg	128,992
VA	Richmond	1,240,625
VA	Statewide	1,515,200
VA	Stringfellow Road/Interstate 66	992,500
VT	Brattleboro	2,481,250
VT	Burlington	992,500
WA	Anacortes	496,250
WA	Bremerton	992,500
WA	Mount Vernon	1,736,875
WA	Port Angeles center	992,500
WA	Seattle	1,240,625
WA	Vancouver Clark County (C-Tran)	992,500

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
WI	Wisconsin statewide	1,987,062
WI	Appleton, Green Bay, Shawano, Menominee Tribe and Oneida Tribe	2,059,438
WI	LaCrosse, Onalaska, Prairie Du Chien, Rice Lake, Viroqua and Ho Chuck Nation	992,500
WI	Ashland, Chippewa Falls, Eau Claire, Ladysmith, Marshfield, Rhinelander, Rusk County	297,750
	Subtotal FY 1999 Unobligated Allocations	*$125,023,252*
	FY 2000 Unobligated Allocations	
AK	Anchorage	$2,471,750
AK	Anchorage	4,414,928
AK	Fairbanks	1,962,190
AK	Juneau	1,471,643
AK	North Star Borough-Fairbanks	2,943,286
AK	Wasilla	991,096
AK	Whittier	1,133,166
AL	Birmingham-Jefferson County	1,226,369
AL	Dothan Wiregrass	494,926
AL	Wilcox County	98,110
AL	Huntsville	1,226,369
AL	Huntsville	3,433,833
AL	Jefferson	196,219
AL	Mobile	4,906,476
AL	Montgomery	3,433,833
AR	Arkansas Highway and Transit Department	1,962,190
AR	Arkansas State	462,876
AR	Fayetteville	490,547
AR	Hot Springs	991,096
AR	Hot Springs	649,413
AR	Little Rock	294,329
CA	Bell	196,219
CA	California Mountain Area Regional Transit Authority	78,487
CA	Commerce	353,194
CA	Contra Costa County Connection	245,274
CA	Cudahy	117,731
CA	Healdsburg	991,096
CA	I-5 Corridor	1,226,369
CA	Lodi	833,931
CA	Los Angeles County	92,736
CA	Los Angeles	2,207,464
CA	Maywood	117,731
CA	Monterey, Monterey-Salinas	613,185
CA	Redlands	784,876
CA	Sacramento	1,226,369
CA	San Bernardino Valley	991,096
CA	San Bernardino	2,943,286
CA	Santa Barbara	1,716,916
CA	Santa Clarita	1,967,894
CA	Santa Cruz	1,721,822
CA	Santa Maria Valley/Santa Barbara County	236,463

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FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
CA	Westminster	147,164
CA	Windsor	736,821
CA	Woodland Hills	613,185
CO	Colorado State	2,662,629
CO	Denver	1,226,369
CT	Norwich	2,207,464
DC	Washington, D.C.	123,716
DC	Washington, D.C.	2,462,738
FL	Jacksonville	981,096
FL	Miami Beach	736,821
FL	Tampa	490,547
GA	Chatham	3,433,833
GA	Georgia Regional Transportation Authority	1,962,190
GA	Georgia Statewide	2,696,012
HI	Hawaii	2,207,464
IA	Cedar	3,276,857
IA	Clinton	490,547
IA	Fort Dodge	968,299
IA	Iowa City	1,471,643
IA	Iowa Statewide	626,308
IA	Mason City	186,976
IL	East Moline	637,712
IL	Illinois Statewide	986,492
IN	Gary	306,593
IN	Indianapolis	4,906,476
IN	South Bend	1,226,369
KS	Girard	686,767
KS	Girard	470,926
KS	Kansas	1,471,643
KS	Topeka	686,667
KS	Wichita	2,462,738
KY	Lexington	981,096
LA	Baton Rouge	294,329
LA	Jefferson Parish	44,149
LA	Lafayette	147,164
LA	Monroe	284,518
LA	New Orleans	3,237,614
LA	St Tammany Parish	88,898
MA	Attleboro	490,547
MA	Greenfield Montague	490,547
MA	Merrimack Valley	468,882
MA	Montachusett	1,226,369
MA	Pittsfield	3,531,943
MA	Springfield	1,226,369
MA	Swampscott	63,772
MA	Westfield	490,547
MD	Maryland Statewide	11,282,883
MI	Detroit	3,868,080
MI	Michigan Statewide	22,074,625
MN	Duluth	981,096
MN	Duluth	490,547
MN	Duluth	490,547
MN	Greater Minnesota transit authorities	426,547

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
MN	Northstar Corridor	9,810,960
MN	Twin Cities	11,541,175
MO	Franklin County	96,219
MO	Jackson County	291,347
MO	Missouri Statewide	20,000
MO	OATS Transit	1,013,883
MO	Southeast Missouri	1,074,380
MO	Southwest Missouri	981,096
MO	St. Louis	1,226,369
MS	Harrison County	2,943,286
MS	Jackson	981,096
MS	North Delta planning and development district	1,177,314
NC	Greensboro	3,276,877
NC	Greensboro	1,471,643
NC	North Carolina Statewide	2,444,889
ND	North Dakota Statewide	404,899
NH	New Hampshire Statewide	2,943,286
NJ	New Jersey Transit	4,906,476
NJ	New Jersey Transit	1,716,916
NJ	Newark	1,618,907
NJ	Newark	1,226,369
NJ	South Amboy	1,226,369
NM	Las Cruces	736,821
NM	Northern New Mexico	2,696,012
NV	Lake Tahoe	686,767
NV	Washoe County	2,207,464
NY	Buffalo	1,962,190
NY	Dutchess County	160
NY	Ithaca	1,103,732
NY	Ithaca	1,226,369
NY	Long Island	1,226,369
NY	New York	981,096
NY	Putnam County	481,116
NY	Rensselaer	1,199,753
NY	Rochester	981,096
NY	Syracuse	2,943,286
NY	Utica	2,060,300
OH	Cleveland	613,185
OK	Oklahoma Statewide	638,728
OR	Lane County	4,316,819
OR	Lincoln County	248,274
OR	Portland	637,712
OR	Salem	490,547
OR	Sandy	98,110
OR	South Metro Area Rapid Transit (SMART)	196,219
OR	Sunset Empire Transit District	294,329
PA	Altoona	2,943,286
PA	Altoona	826,082
PA	Bethlehem	981,096
PA	Chester County	981,096
PA	Fayette County	1,246,991
PA	Lackawanna County	588,657
PA	Philadelphia	1,226,369

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FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
PA	Robinson	1,471,643
PA	Somerset County	171,691
PA	Towamencin Township	1,471,643
PA	Washington County	618,069
PA	Westmoreland County	196,219
PA	Wilkes-Barre	1,226,369
SC	Central Midlands COG	786,210
SC	Charleston	1,964,061
SC	Clemson	539,602
SC	Greenville	490,547
SC	Pee Dee	882,986
SC	Santee-Wateree	392,438
SC	South Carolina Statewide Virtual Transit Enterprise	1,198,936
SC	Spartanburg	588,657
SD	South Dakota Statewide	1,471,643
TN	Southern Coalition for Advanced Transportation (SCAT)	2,943,294
TX	Beaumont	961,096
TX	El Paso	961,096
TX	Galveston	961,096
TX	Texas Statewide	4,906,476
UT	Salt Lake City Olympics	2,035,818
UT	Salt Lake City Olympics	2,462,738
UT	Salt Lake City Olympics	490,547
VA	Alexandria	961,096
VA	Alexandria	961,096
VA	Dulles	1,962,190
VA	Fair Lakes League	196,219
VA	Richmond	1,226,369
VT	Burlington	2,648,967
VT	Essex Junction	490,547
VT	Killington-Sherburne	346,274
WA	Bremerton	736,821
WA	Grant County	490,547
WA	Grays Harbor County	1,226,369
WA	King Country	1,962,190
WA	King County	1,471,643
WA	King County	1,334,478
WA	Mount Vernon	1,316,916
WA	Pierce County	490,547
WA	Seattle	1,226,369
WA	Sequim	961,096
WA	Spokane	1,471,643
WA	Tacoma	346,274
WA	Vancouver Clark County	961,096
WA	Washington State DOT	1,962,190
WI	Wisconsin Statewide	13,990,996
WV	Parkersburg	4,414,928
WV	West Virginia Statewide	573,036
	Subtotal FY 2000 Unobligated Allocations	*$311,393,208*
	TOTAL UNOBLIGATED ALLOCATION	$436,416,460

FEDERAL TRANSIT ADMINISTRATION

TABLE 9A

PRIOR YEAR UNOBLIGATED SECTION 5309 BUS ALLOCATIONS

STATE	AREA	UNOBLIGATED ALLOCATION
Fiscal Years 1997 and 1998 Allocations Extended in Conference Report 106-490		
CA	*Lake Tahoe, intermodal transit center*	*$977,196*
CA	*Rialto, Metro Link depot*	*1,074,916*
CA	*San Joaquin, buses and bus facilities*	*1,954,393*
PA	*Wilkes Barre, mobility project*	*1,465,794*
VT	*Burlington, multimodal center*	*1,465,794*
	Total Extended Allocations	*$6,938,093* a/

a/ Period of availability for remaining unobligated funds extended one additional year and will lapse September 30, 2001. Projects extended in Conference Report 106-490 whose funds were obligated as of September 30, 2000 are not listed.

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FEDERAL TRANSIT ADMINISTRATION

TABLE 10 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 JOB ACCESS AND REVERSE COMMUTE PROGRAM ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	REVISED ALLOCATION
AK	Central Kenai Peninsula public transportation	$498,900
AK	Matanuska-Susitna borough, M.A.S.C.O.T, Alaska	99,968
AK	Sitka, Alaska transit expension program	398,120
AL	Easter Seals West Alabama work transition programs	948,130
AL	Mobile, Alabama	249,450
AL	State of Alabama	1,496,700
AL	Troy State University, Alabama – Rosa Parks Center	1,995,600
AR	State of Arkansas	3,991,200
AZ	Tucson, Arizona	997,800
CA	Alameda and Contra-Costa counties, California	$498,900
CA	Fresno, Tulare, Kings and Kern Counties, California	2,993,400
CA	Los Angeles, California	3,492,300
CA	Monterey, California	148,670
CA	Sacramento, California	997,800
CA	San Francisco, California	274,395
CA	Santa Clara County, California	498,900
CO	Archuleta County, Colorado	74,835
DC	District of Columbia	997,800
FL	Broward County, Florida	1,996,600
FL	Hillsborough County, Florida	998,800
GA	Chatham, Georgia	498,900
IA	Des Moines, Dubuque, Sioux City, Delaware and Jackson Counties, Iowa	1,996,400
IL	Chicago, Illinois	997,800
IL	DuPage County, Illinois	498,900
IL	Southern Illinois RIDES	148,670
IL	State of Illinois	997,800
IN	Indianapolis, Indiana	997,800
KS	Kansas City, Kansas	997,800
MA	Athol / Orange community transportation, Massachusetts	398,120
MA	Western Massachusetts	348,230
MD	State of Maryland	2,394,720
ME	State of Maine	498,900
ME	York County, Maine	998,020
MI	North Oakland County, Michigan	249,450
MO	Meramec Community Transit programs, Missouri	148,670
MO	OATS job access programs, Missouri	748,380
NH	State of New Hampshire	339,252
NM	Dona Ana County, New Mexico	248,450
NM	Las Cruces, New Mexico	298,428
NM	State of New Mexico	1,996,600
NV	Washoe County, Nevada	997,800
NY	Broome County Transit, New York	249,450
NY	Buffalo, New York	498,900
NY	Capital District Authority, New York	249,450
NY	Nassau County, New York	498,900
NY	Rochester, New York	298,340
NY	Suffolk County, New York	444,821

FEDERAL TRANSIT ADMINISTRATION

TABLE 10 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FY 2001 JOB ACCESS AND REVERSE COMMUTE PROGRAM ALLOCATIONS

STATE	PROJECT AND DESCRIPTION	REVISED ALLOCATION
NY	Sullivan County, New York	199,560
NY	Tompkins County, New York	299,340
NY	Ulster County, New York	199,560
OH	Central Ohio	748,350
OK	State of Oklahoma	4,490,100
OR	Portland, Oregon	1,836,962
PA	Greater Erie Community Action Committee, Pennsylvania	399,120
PA	Pittsburgh Port Authority of Allegheny County, Pennsylvania	1,996,600
PA	SEPTA, Philadelphia, Pennsylvania	2,993,400
RI	Rhode Island community food bank transportation	99,780
RI	Rhode Island Public Transit Authority	997,800
TN	State of Tennessee	1,996,600
TX	Corpus Christi RTA, Texas	548,790
VA	Commonwealth of Virginia	4,490,100
VA	Tysons Corner/Dulles Corridor, Virginia	498,900
VT	State of Vermont	1,496,700
WA	State of Washington	1,995,600
WI	State of Wisconsin	4,689,660
WV	State of West Virginia	1,496,700
---	Ways to Work family loan program, Southeastern U.S.	1,995,600
	TOTAL ALLOCATION	$75,079,461

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FEDERAL TRANSIT ADMINISTRATION

TABLE 11

TEA-21 AUTHORIZATION LEVELS (GUARANTEED FUNDING ONLY)

APPROPRIATION / PROGRAM	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	TOTAL
Urbanized Area Formula (Section 5307)	$2,296,852,727	$2,648,190,791	$2,772,890,281	$2,997,316,081	$3,220,601,506	$3,445,939,606	$17,283,790,992
Nonurbanized Area Formula (Section 5311)	134,077,934	177,923,858	193,612,968	209,283,168	224,873,743	240,607,843	1,180,379,114
Elderly and Persons with Disabilities (Section 5310)	62,219,389	67,035,601	72,946,801	78,850,801	84,724,801	90,652,801	456,430,194
Clean Fuels Formula Program (Section 5308)	0	50,000,000	50,000,000	50,000,000	50,000,000	50,000,000	250,000,000
Over the Road Bus Accessibility Program	0	2,000,000	3,700,000	4,700,000	6,950,000	6,950,000	24,300,000
Alaska Railroad (Section 5307)	4,849,950	4,849,950	4,849,950	4,849,950	4,849,950	4,849,950	29,099,700
Bus and Bus Related (Section 5309)	400,000,000	451,400,000	490,200,000	529,200,000	568,200,000	607,200,000	3,046,200,000
Fixed Guideway Modernization (Section 5309)	900,000,000	902,800,000	960,400,000	1,058,400,000	1,136,400,000	1,214,400,000	6,092,400,000
New Starts (Section 5309)	900,000,000	902,800,000	960,400,000	1,058,400,000	1,136,400,000	1,214,400,000	6,092,400,000
Job Access and Reverse Commute Program	0	50,000,000	75,000,000	100,000,000	125,000,000	150,000,000	500,000,000
Metropolitan Planning (Section 5303)	39,500,000	43,841,600	49,632,000	52,113,600	55,422,400	60,386,600	300,896,200
State Planning & Research (Section 5313(b))	8,250,000	9,158,400	10,368,000	10,886,400	11,577,600	12,614,400	62,854,800
National Planning & Research (Section 5314)	32,750,000	27,500,000	29,500,000	29,500,000	31,500,000	31,500,000	182,250,000
Rural Transit Assistance (Section 5311(b)(2))	4,500,000	5,250,000	5,250,000	5,250,000	5,250,000	5,250,000	30,750,000
Transit Cooperative Research (Section 5313(a))	4,000,000	8,250,000	8,250,000	8,250,000	8,250,000	8,250,000	45,250,000
National Transit Institute (Section 5315)	3,000,000	4,000,000	4,000,000	4,000,000	4,000,000	4,000,000	23,000,000
University Transportation Centers (Section 5317(b))	6,000,000	6,000,000	6,000,000	6,000,000	6,000,000	6,000,000	36,000,000
Administrative Expenses	45,738,000	54,000,000	60,000,000	64,000,000	67,000,000	73,000,000	363,738,000
FEDERAL TRANSIT ADMINISTRATION TOTAL:	$4,643,738,000	$5,315,000,000	$5,797,000,000	$6,271,000,000	$6,747,000,000	$7,226,000,000	$36,999,738,000

– Fiscal Years 1998-2003 funding for the Clean Fuels Program established under TEA-21 equals $100,000,000. $50,000,000 is shown under the Clean Fuels Program (Section 5308) and $50,000,000 is included under the Bus and Bus Related (Section 5309).

FEDERAL TRANSIT ADMINISTRATION

TABLE 11A

TEA-21 AUTHORIZATION LEVELS (GUARANTEED AND NONGUARANTEED FUNDING)

APPROPRIATION / PROGRAM	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	TOTAL
Urbanized Area Formula (Section 5307)	$2,296,852,727	$2,698,190,791	$2,922,890,281	$3,147,316,081	$3,370,601,506	$3,595,939,606	$18,033,790,992
Nonurbanized Area Formula (Section 5311)	134,077,934	177,923,858	193,612,968	209,283,168	224,873,743	240,607,843	1,180,379,114
Elderly and Persons with Disabilities (Section 5310)	62,219,389	67,035,601	72,946,801	78,850,801	84,724,801	90,652,801	456,430,194
Clean Fuels Formula Program (Section 5308)	0	150,000,000	150,000,000	150,000,000	150,000,000	150,000,000	750,000,000
Over the Road Bus Accessibility Program	0	2,000,000	3,700,000	4,700,000	6,950,000	6,950,000	24,300,000
Alaska Railroad (Section 5307)	4,849,950	4,849,950	4,849,950	4,849,950	4,849,950	4,849,950	29,099,700
Bus and Bus Related (Section 5309)	400,000,000	551,400,000	590,200,000	629,200,000	668,200,000	707,200,000	3,546,200,000
Fixed Guideway Modernization (Section 5309)	900,000,000	1,002,800,000	1,060,400,000	1,158,400,000	1,236,400,000	1,314,400,000	6,692,400,000
New Starts (Section 5309)	900,000,000	1,302,800,000	1,360,400,000	1,478,400,000	1,586,400,000	1,644,400,000	8,152,400,000
Job Access and Reverse Commute Program	0	150,000,000	150,000,000	150,000,000	150,000,000	150,000,000	750,000,000
Metropolitan Planning (Section 5303)	39,500,000	79,312,600	78,929,600	80,238,400	84,374,400	90,164,800	441,519,200
State Planning & Research (Section 5313(b))	8,250,000	14,668,000	16,670,400	16,761,600	17,625,600	18,836,200	92,230,800
National Planning & Research (Section 5314)	32,750,000	58,500,000	60,500,000	62,500,000	64,500,000	66,500,000	344,250,000
Rural Transit Assistance (Section 5311(b)(2))	4,500,000	5,250,000	5,250,000	5,250,000	5,250,000	5,250,000	30,750,000
Transit Cooperative Research (Section 5313(a))	4,000,000	8,250,000	8,250,000	8,250,000	8,250,000	8,250,000	45,250,000
National Transit Institute (Section 5315)	3,000,000	4,000,000	4,000,000	4,000,000	4,000,000	4,000,000	23,000,000
University Transportation Centers (Section 5317(b))	6,000,000	6,000,000	6,000,000	6,000,000	6,000,000	6,000,000	36,000,000
Administrative Expenses	45,738,000	67,000,000	74,000,000	80,000,000	84,000,000	91,000,000	441,738,000
TOTAL FUNDING ALL PROGRAMS:	$4,643,738,000	$6,341,000,000	$6,816,000,000	$7,274,000,000	$7,737,000,000	$8,194,000,000	$40,999,738,000

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FEDERAL TRANSIT ADMINISTRATION

TABLE 12

FY 2001 APPORTIONMENT FORMULA FOR FORMULA PROGRAM

Percent of Formula Funds Available

Section 5310: 2.4% States - allocated to states based on state's population of elderly and persons with disabilities

Section 5311: 6.37% Nonurbanized Areas - allocated to states based on state's nonurbanized area population

Section 5307: 91.23% Urbanized Areas (UZA)

UZA Population and Weighting Factors

50,000-199,000 in population: 9.32% of available Section 5307 funds
(Apportioned to Governors)
50% apportioned based on population
50% apportioned based on population x population density

200,000 and greater in population: 90.68% of available Section 5307 funds
(Apportioned to UZAs)
33.29% (Fixed Guideway Tier*)
95.61% (Non-incentive Portion of Tier)
— at least 0.75% to each UZA with commuter rail and pop. 750,000 or greater
50% - fixed guideway revenue vehicle miles
40% - fixed guideway route miles

4.39% ("Incentive" Portion of Tier)
-- at least 0.75% to each UZA with commuter rail and pop. 750,000 or greater
-- fixed guideway passenger miles x fixed guideway passenger miles/operating cost

66.71% ("Bus" Tier)
90.8% (Non-incentive Portion of Tier)
73.38% for UZAs with population 1,000,000 or greater
50% - bus revenue vehicle miles
25% - population
25% - population x population density
26.61% for UZAs pop. < 1,000,000
50% - bus revenue vehicle miles
25% - population
25% - population x density
9.2% ("Incentive" Portion of Tier)
-- bus passenger miles x bus passenger miles/operating cost

*Includes all fixed guideway modes, such as heavy rail, commuter rail, light rail, trolleybus, aerial tramway, inclined plane, cable car, automated guideway transit, ferryboats, exclusive busways, and HOV lanes.

FEDERAL TRANSIT ADMINISTRATION

TABLE 13

FY 1998 - 2003 SECTION 5309 FIXED GUIDEWAY MODERNIZATION PROGRAM APPORTIONMENT FORMULA

Tier 1 First $497,700,000 to the following areas:

Baltimore	$ 8,372,000
Boston	$ 38,948,000
Chicago/N.W. Indiana	$ 78,169,000
Cleveland	$ 9,800,500
New Orleans	$ 1,730,588
New York	$ 176,034,461
N. E. New Jersey	$ 60,604,653
Philadelphia/So. New Jersey	$ 58,924,764
Pittsburgh	$ 13,662,463
San Francisco	$ 33,969,571
SW Connecticut	$ 27,755,000

Tier 2 Next $70,000,000 as follows: Tier 2(A): 50 percent is allocated to areas identified in Tier 1; Tier 2(B): 50 percent is allocated to other urbanized areas with fixed guideway tiers in operation at least seven years. Funds are allocated by the Urbanized Area Formula Program fixed guideway tier formula factors that were used to apportion funds for the fixed guideway modernization program in FY 1997.

Tier 3 Next $5,700,000 as follows: Pittsburgh 61.76%; Cleveland 10.73%; New Orleans 5.79%; and 21.72% is allocated to all other areas in Tier 2(B) by the same fixed guideway tier formula factors used in fiscal year 1997.

Tier 4 Next $186,600,000 as follows: All eligible areas using the same year fixed guideway tier formula factors used in fiscal year 1997.

Tier 5 Next $70,000,000 as follows: 65% to the 11 areas identified in Tier 1, and 35% to all other areas using the most current Urbanized Area Formula Program fixed guideway tier formula factors. Any segment that is less than 7 years old in the year of the apportionment will be deleted from the database.

Tier 6 Next $50,000,000 as follows: 60% to the 11 areas identified in Tier 1, and 40% to all other areas using the most current Urbanized Area Formula Program fixed guideway tier formula factors. Any segment less than 7 years old in the year of the apportionment will be deleted from the database.

Tier 7 Remaining amounts as follows: 50% to the 11 areas identified in Tier 1, and 50% to all other areas using the most current Urbanized Area Formula Program fixed guideway formula factors. Any segment that is less than 7 years old in the year of the apportionment will be deleted from the database.

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FEDERAL TRANSIT ADMINISTRATION

TABLE 14 (REVISED)

(Revised to reflect .22 percent reduction required by the FY 2001 Omnibus Consolidated Appropriations Act, Pub. L. 106-554)

REVISED FISCAL YEAR 2001 FORMULA GRANT APPORTIONMENTS - UNIT VALUES OF DATA

			REVISED APPORTIONMENT UNIT VALUE
Section 5307 Urbanized Area Formula Program - Bus Tier			
Urbanized Areas Over 1,000,000:			
Population			$3.08784333
Population x Density			$0.00078464
Bus Revenue Vehicle Mile			$0.39000438
Urbanized Areas Under 1,000,000:			
Population			$2.79868288
Population x Density			$0.00123283
Bus Revenue Vehicle Mile			$0.47668619
Bus Incentive (PM denotes Passenger Mile):			
Bus PM x Bus PM ÷ Operating Cost			$0.00480633
Section 5307 Urbanized Area Formula Program - Fixed Guideway Tier			
Fixed Guideway Revenue Vehicle Mile			$0.54394821
Fixed Guideway Route Mile			$30,241
Commuter Rail Floor		$6,334,144	
Fixed Guideway Incentive:			
Fixed Guideway PM x Fixed Guideway PM ÷ Operating Cost			$0.00046770
Commuter Rail Incentive Floor		$290,837	
Section 5307 Urbanized Area Formula Program - Areas Under 200,000			
Population			$5.06223607
Population x Density			$0.00262469
Section 5311 Nonurbanized Area Formula Program			
Areas Under 50,000			
Population			$2.23046341

Section 5309 Capital Program - Fixed Guideway Modernization

	Tier 2	Tier 3	Tier 4	Tier 5	Tier 6	Tier 7
Legislatively Specified Areas:			*All Areas*			
Revenue Vehicle Mile	$0.03643443	—	$1.13683131	$0.63916107	$0.62517433	$0.97067462
Route Mile	$2,122.43	—	$7,832.52	$2,998.12	$1,991.51	$5,197.93
Other Urbanized Areas:						
Revenue Vehicle Mile	$0.16377360	$0.00579300		$0.12041122	$0.09629487	$0.41391295
Route Mile	$4,772.78	$166.83		$3,444.98	$2,512.15	$11,841.76

[FR Doc. 01–1082 Filed 1–17–01; 8:45 am]
BILLING CODE 4910–57–C

Federal Register

Thursday,
January 18, 2001

Part III

Department of Transportation

Federal Transit Administration

Assurances for Federal Transit Administration Grants and Cooperative Agreements; Notice

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 2001 Annual List of Certifications and Assurances for Federal Transit Administration Grants and Cooperative Agreements

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice.

SUMMARY: This Notice contains FTA's comprehensive compilation of the Federal Fiscal Year 2001 certifications and assurances to be used in connection with all Federal assistance programs FTA administers during Federal Fiscal Year 2001, as required by 49 U.S.C. 5323(n).

EFFECTIVE DATE: January 9, 2001.

FOR FURTHER INFORMATION CONTACT: FTA staff in the appropriate Regional Office listed below. For copies of other related documents, see the FTA Web Site at *http://www.fta.dot.gov* or contact the Office of Public Affairs, Federal Transit Administration (202) 366–4019.

Region 1: Boston

States served: Maine, New Hampshire, Vermont, Connecticut, Rhode Island, and Massachusetts, Telephone # 617–494–2055

Region 2: New York

States served: New York, New Jersey, and Virgin Islands, Telephone # 212–668–2170

Region 3: Philadelphia

States served: Pennsylvania, Delaware, Maryland, Virginia, West Virginia, and District of Columbia, Telephone # 215–656–7100

Region 4: Atlanta

States served: Kentucky, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Tennessee, and Puerto Rico, Telephone # 404–562–3500

Region 5: Chicago

States served: Minnesota, Wisconsin, Michigan, Illinois, Indiana, and Ohio, Telephone # 312–353–2789

Region 6: Dallas/Ft. Worth

States served: Arkansas, Louisiana, Oklahoma, Texas, and New Mexico, Telephone # 817–978–0550

Region 7: Kansas City

States served: Missouri, Iowa, Kansas, and Nebraska, Telephone # 816–523–0204

Region 8: Denver

States served: Colorado, Utah, Wyoming, Montana, North Dakota, South Dakota, Telephone # 303–844–3242

Region 9: San Francisco

States served: California, Hawaii, Guam, Arizona, Nevada, American Samoa, and the Northern Mariana Islands, Telephone # 415–744–3133

Region 10: Seattle

States served: Idaho, Oregon, Washington, and Alaska, Telephone # 206–220–7954

SUPPLEMENTARY INFORMATION: Before FTA may award a Federal grant or cooperative agreement, the Applicant must provide to FTA all certifications and assurances pertaining to itself or its project as required by Federal laws and regulations. The requisite certifications and assurances must be submitted to FTA irrespective of whether the project is financed under the authority of 49 U.S.C. chapter 53, or title 23, United States Code, or another Federal statute.

The Applicant's Annual Certifications and Assurances for Federal Fiscal Year 2001 covers all projects for which the Applicant seeks funding during that fiscal year. An Applicant's Annual Certifications and Assurances applicable to a specific grant or cooperative agreement generally remain in effect for the life of the grant or cooperative agreement to closeout, or the life of the project or project property when a useful life or standard industry life is in effect. If in a later year, however, the Applicant provides certifications and assurances that differ from the certifications and assurances previously made, the later certifications and assurances will apply to the grant, cooperative agreement, project, or project property, except as FTA otherwise permits.

Background

Since Federal Fiscal Year 1995, FTA has been consolidating the various certifications and assurances that may be required into one document. FTA intends to continue publishing this document annually in conjunction with its publication of the FTA annual apportionment Notice, which allocates funds made available by the latest U.S. Department of Transportation (U.S. DOT) annual appropriations act.

Federal Fiscal Year 2001 Changes: The following changes have been made:

(1) To accommodate FTA's Transportation Electronic Award and Management (TEAM) system numbering and alphabetical programming, Arabic numbers replace Roman numerals for designating categories.

(2) A reference to DOT regulations, "Protection of Human Subjects," 49 CFR part 11, is added to Certification 1. J(16) in connection with participation of individuals in research and development projects.

(3) In Certification 1.J(18), a reference to the latest OMB A–133 Compliance Supplement provisions for the Department of Transportation, dated March 2000 has been substituted for the previous compliance supplement.

(4) Subsection B of Certification 3 has been amended to emphasize that the "maximum extent feasible" requirement for private operator participation would be interpreted in accordance with FTA requirements and policies.

(5) A Clean Fuels Formula Program Certification has been added to Certification 12 in the event that funds are appropriated for that program.

(6) The Certifications and Assurances for the Elderly and Persons with disabilities program (Certification 13), the Nonurbanized Area Program (Certification 14), and the State Infrastructure Bank Program (Certification 15) have been streamlined to emphasize the state's responsibility to monitor its subrecipients' compliance with FTA requirements while providing the state more flexibility to extend those requirements in a manner other than requiring the submission of certifications in cases where certifications are not expressly required by Federal law or regulation.

(7) The Attorney is no longer responsible for notifying the Recipient of pending legislation or litigation that might affect the project after signing the Attorney's affirmation. Nevertheless, the Recipient continues to be responsible to FTA to provide that information as set forth in subsection 2.g of the Master Agreement.

Text of Federal Fiscal Year 2001 Certifications and Assurances

A detailed compilation of the provisions of the Certifications and Assurances and the Signature Page as set forth in Appendix A of this Notice, also appears in the Cert's & Assurances Tab Page of FTA's TEAM system. It is important that each Applicant be familiar with all fifteen (15) certification and assurance categories contained in this Notice as they may be a prerequisite for receiving FTA financial assistance. Provisions of this Notice supersede conflicting statements in any circular containing a previous version of the Annual Certifications and Assurances. The certifications and assurances contained in those circulars are merely examples, and are not acceptable or valid for Federal Fiscal Year 2001; do not rely on the statements within certifications and assurances appearing in circulars.

Significance of Certifications and Assurances

Selecting and submitting certifications and assurances to FTA, either through the TEAM system or submission of the Signature Page of Appendix A, signifies the Applicant's intent to comply with the requirements of those certifications and assurances to the extent they apply to a program for which the Applicant submits an application for assistance in Federal Fiscal Year 2001.

Requirement for Attorney's Signature

FTA requires a current (Federal Fiscal Year 2001) attorney's affirmation of the Applicant's legal authority to certify compliance with the funding obligations in this document. Irrespective of whether the Applicant chooses to make a single selection for all 15 categories or select individual options from the 15 categories, the attorney's signature from a previous year is not acceptable.

Deadline for Submission

All Applicants for FTA capital investment program or formula program assistance, and current grantees with an active project financed with FTA capital investment program or formula program assistance, are expected to provide Federal Fiscal Year 2001 Certifications and Assurances within 90 days from the date of this publication or with its first grant application in Fiscal Year 2001, whichever is first. Other Applicants are encouraged to submit their certifications and assurances as soon as possible.

Preference for Electronic Submission

FTA has expanded the use of the electronic programs for Applicants, first introduced in 1995. FTA expects Applicants registered in the TEAM system to submit their applications as well as certifications and assurances electronically through FTA's TEAM system. Only if an Applicant is unable to submit its certifications and assurances through the TEAM system should the Applicant use the Signature Page form in Appendix A of this Notice.

Procedures for Electronic Submission

The Cert's & Assurances Tab Page of the TEAM system contains fields for selecting the certifications and assurances to be submitted. Within that tab page are fields for the Applicant's authorized representative and its attorney to enter their personal identification numbers (PINs), and thus "sign" the certifications and assurances for electronic transmission to FTA. In certain circumstances, the Applicant may enter its PIN number in lieu of an electronic signature provided by its Attorney, provided the Applicant has on file the Affirmation of its Attorney in writing dated this Federal fiscal year as set forth in Appendix A of this Notice. Applicants may contact the appropriate Regional Office listed in this Notice or the TEAM Helpdesk for more information.

Procedures for Paper Submission

The following procedures apply to an Applicant that is unable to submit its certifications electronically. The Applicant must mark the certifications and assurances it is making on the Signature Page form in Appendix A of this Notice and submit it to FTA. The Applicant may signify compliance with all Categories by placing a single mark in the appropriate space at the top of the Signature Selection Page in Appendix A. In certain circumstances, the Applicant may certify in lieu of the signature of its Attorney, provided the Applicant has on file the Affirmation of its Attorney in writing dated this Federal fiscal year as set forth in Appendix A of this Notice. Applicants may contact the appropriate Regional Office listed in this Notice for more information.

References

The Transportation Equity Act for the 21st Century, Pub. L. 105–178, June 9, 1998, as amended by the TEA–21 Restoration Act 105–206, 112 Stat. 685, July 22, 1998, 49 U.S.C. chapter 53, Title 23, United States Code, U.S. DOT and FTA regulations at 49 CFR, and FTA Circulars.

Dated: January 9, 2001.

Nuria I. Fernandez,

Acting Administrator.

Appendix A

Federal Fiscal Year 2001 Certifications and Assurances for Federal Transit Administration Assistance Programs

In accordance with 49 U.S.C. 5323(n), the following certifications and assurances have been compiled for Federal Transit Administration (FTA) programs. FTA requests each Applicant to provide as many certifications and assurances as needed to cover all programs for which it will seek FTA assistance in Federal Fiscal Year 2001. FTA strongly encourages the Applicant to submit its certifications and assurances through FTA's Transportation Electronic Award and Management (TEAM) system.

The 15 Categories of certifications and assurances are listed by numbers 1 through 15 on the Cert's & Assurances tab page of the TEAM system and on the opposite side of the Signature Page at the end of this document. Categories 2 through 15 will apply to some, but not all, applicants. The designation of the 15 categories corresponds to the circumstances mandating submission of specific certifications, assurances, or agreements.

1. Certifications and Assurances Required of Each Applicant

Each Applicant for FTA assistance awarded must provide all certifications and assurances in this Category "1." FTA may not award any Federal assistance until the Applicant provides these certifications and assurances by selecting Category "1."

A. Authority of Applicant and Its Representative

The authorized representative of the Applicant and legal counsel attorney who sign these certifications, assurances, and agreements affirm that both the Applicant and its authorized representative have adequate authority under state and local law and the by-laws or internal rules of the Applicant organization to:

(1) Execute and file the application for Federal assistance on behalf of the Applicant;

(2) Execute and file the required certifications, assurances, and agreements on behalf of the Applicant binding the Applicant; and

(3) Execute grant agreements and cooperative agreements with FTA on behalf of the Applicant.

B. Standard Assurances

The Applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA grant or cooperative agreement. The Applicant agrees that it is under a continuing obligation to comply with the terms and conditions of the grant agreement or cooperative agreement issued for its project with FTA. The Applicant recognizes that Federal laws, regulations, policies, and administrative practices might be modified from time to time and affect the implementation of the project. The Applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise.

C. Debarment, Suspension, and Other Responsibility Matters for Primary Covered Transactions

As required by U.S. DOT regulations on Governmentwide Debarment and Suspension (Nonprocurement) at 49 CFR 29.510:

(1) The Applicant (Primary Participant) certifies, to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not, within a three (3) year period preceding this certification, been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal

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offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state, or local) transaction or contract under a public transaction, violation of Federal or state antitrust statutes, or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, state, or local) with commission of any of the offenses listed in subparagraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this certification had one or more public transactions (Federal, state, or local) terminated for cause or default.

(2) The Applicant also certifies that, if it later becomes aware of any information contradicting the statements of paragraph (1) above, it will promptly provide that information to FTA.

(3) If the Applicant (Primary Participant) is unable to certify to all statements in paragraphs (1) and (2) of this certification, it shall indicate so in its applications, or in the transmittal letter or message accompanying its annual certifications and assurances, and provide a written explanation to FTA.

D. Drug-Free Workplace Agreement

As required by U.S. DOT regulations, "Drug-Free Workplace Requirements (Grants)," 49 CFR part 29, Subpart F, as modified by 41 U.S.C. 702, the Applicant agrees that it will provide a drug-free workplace by:

(1) Publishing a statement notifying its employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in its workplace and specifying the actions that will be taken against its employees for violation of that prohibition;

(2) Establishing an ongoing drug-free awareness program to inform its employees about:

(a) The dangers of drug abuse in the workplace;

(b) Its policy of maintaining a drug-free workplace;

(c) Any available drug counseling, rehabilitation, and employee assistance programs; and

(d) The penalties that may be imposed upon its employees for drug abuse violations occurring in the workplace;

(3) Making it a requirement that each of its employees to be engaged in the performance of the grant or cooperative agreement be given a copy of the statement required by paragraph (1) of this certification;

(4) Notifying each of its employees in the statement required by paragraph (1) of this certification that, as a condition of employment financed with Federal assistance provided by the grant or cooperative agreement, the employee will be required to:

(a) Abide by the terms of the statement; and

(b) Notify the employer (Applicant) in writing of any conviction for a violation of a criminal drug statute occurring in the workplace no later than five (5) calendar days after that conviction;

(5) Notifying FTA in writing, within ten (10) calendar days after receiving notice required by paragraph (4)(b) above from an employee or otherwise receiving actual notice of that conviction. The Applicant, as employer of any convicted employee, must provide notice, including position title, to every project officer or other designee on whose project activity the convicted employee was working. Notice shall include the identification number(s) of each affected grant or cooperative agreement;

(6) Taking one of the following actions within thirty (30) calendar days of receiving notice under paragraph (4)(b) of this agreement with respect to any employee who is so convicted:

(a) Taking appropriate personnel action against that employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(b) Requiring that employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, state, or local health, law enforcement, or other appropriate agency; and

(7) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (1), (2), (3), (4), (5), and (6) of this agreement. The Applicant agrees to maintain a list identifying its headquarters location and each workplace it maintains in which project activities supported by FTA are conducted, and make that list readily accessible to FTA.

E. Intergovernmental Review Assurance

The Applicant assures that each application for Federal assistance it has submitted or will submit to FTA has been or will be submitted for intergovernmental review to the appropriate state and local agencies consistent with the requirements of the state or states affected. Specifically, the Applicant assures that it has fulfilled or will fulfill the obligations imposed on FTA by U.S. DOT regulations, "Intergovernmental Review of Department of Transportation Programs and Activities," 49 CFR part 17.

F. Nondiscrimination Assurance

As required by 49 U.S.C. 5332 (which prohibits discrimination on the basis of race, color, creed, national origin, sex, or age, and prohibits discrimination in employment or business opportunity), Title VI of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000d, and U.S. DOT regulations, "Nondiscrimination in Federally-Assisted Programs of the Department of Transportation—Effectuation of Title VI of the Civil Rights Act," 49 CFR part 21 at 21.7, the Applicant assures that it will comply with all requirements of 49 CFR part 21; FTA Circular 4702.1, "Title VI Program Guidelines for Federal Transit Administration Recipients", and other applicable directives, so that no person in the United States, on the basis of race, color, national origin, creed, sex, or age will be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination in any program or activity (particularly in the level and quality of transportation services and transportation-related benefits) for which the Applicant receives Federal assistance awarded by the U.S. DOT or FTA as follows:

(1) The Applicant assures that each project will be conducted, property acquisitions will be undertaken, and project facilities will be operated in accordance with all applicable requirements of 49 U.S.C. 5332 and 49 CFR part 21, and understands that this assurance extends to its entire facility and to facilities operated in connection with the project.

(2) The Applicant assures that it will take appropriate action to ensure that any transferee receiving property financed with Federal assistance derived from FTA will comply with the applicable requirements of 49 U.S.C. 5332 and 49 CFR part 21.

(3) The Applicant assures that it will promptly take the necessary actions to effectuate this assurance, including notifying the public that complaints of discrimination in the provision of transportation-related services or benefits may be filed with U.S. DOT or FTA. Upon request by U.S. DOT or FTA, the Applicant assures that it will submit the required information pertaining to its compliance with these requirements.

(4) The Applicant assures that it will make any changes in its 49 U.S.C. 5332 and Title VI implementing procedures as U.S. DOT or FTA may request.

(5) As required by 49 CFR 21.7(a)(2), the Applicant will include in each third party contract or subagreement provisions to invoke the requirements of 49 U.S.C. 5332 and 49 CFR part 21, and include provisions to invoke those requirements in deeds and instruments recording the transfer of real property, structures, improvements.

G. Disadvantaged Business Enterprise Assurance

In accordance with 49 CFR 26.13(a), the Recipient assures that it shall not discriminate on the basis of race, color, national origin, or sex in the implementation of the project and in the award and performance of any third party contract, or subagreement supported with Federal assistance derived from the U.S. DOT or in the administration of its DBE program or the requirements of 49 CFR part 26. The Recipient assures that it shall take all necessary and reasonable steps under 49 CFR part 26 to ensure nondiscrimination in the award and administration of all third party contracts and subagreements supported with Federal assistance derived from the U.S. DOT. The Recipient's DBE program, as required by 49 CFR part 26 and approved by the U.S. DOT, will be incorporated by reference and made part of the grant agreement or cooperative agreement for any Federal assistance awarded by FTA or U.S. DOT. Implementation of this DBE program is a legal obligation of the Recipient, and failure to carry out its terms shall be treated as a violation of the grant agreement or cooperative agreement. Upon notification by the Government to the Recipient of its failure to implement its approved DBE program, the U.S. DOT may impose sanctions as provided for under 49 CFR part 26 and may, in appropriate cases, refer the matter for enforcement under 18 U.S.C. 1001, and/or the Program Fraud Civil Remedies Act, 31 U.S.C. 3801 et seq.

H. Assurance of Nondiscrimination on the Basis of Disability

As required by U.S. DOT regulations, "Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance," at 49 CFR part 27, the Applicant assures that, as a condition to the approval or extension of any Federal assistance awarded by FTA to construct any facility, obtain any rolling stock or other equipment, undertake studies, conduct research, or to participate in or obtain any benefit from any program administered by FTA, no otherwise qualified person with a disability shall be, solely by reason of that disability, excluded from participation in, denied the benefits of, or otherwise subjected to discrimination in any program or activity receiving or benefiting from Federal assistance administered by the FTA or any entity within U.S. DOT. The Applicant assures that project implementation and operations so assisted will comply with all applicable requirements of U.S. DOT regulations implementing the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794, and the Americans with Disabilities Act of 1990, as amended, 42 U.S.C. 12101 et seq. at 49 CFR parts 27, 37, and 38, and any applicable regulations and directives issued by other Federal departments or agencies.

I. Procurement Compliance

The Applicant certifies that its procurements and procurement system will comply with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and FTA third party contracting regulations when promulgated, as well as other requirements FTA may issue. The Applicant certifies that it will include in its contracts financed in whole or in part with FTA assistance all clauses required by Federal laws, executive orders, or regulations, and will ensure that each subrecipient and each contractor will also include in its subagreements and contracts financed in whole or in part with FTA assistance all applicable clauses required by Federal laws, executive orders, or regulations.

J. Certifications Prescribed by the Office of Management and Budget (SF–424B and SF–424D)

As required by the Office of Management and Budget (OMB), the Applicant certifies that it:

(1) Has the legal authority to apply for Federal assistance and the institutional, managerial, and financial capability (including funds sufficient to pay the non-Federal share of project cost) to ensure proper planning, management, and completion of the project described in its application;

(2) Will give FTA, the Comptroller General of the United States and, if appropriate, the state, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives;

(3) Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest or personal gain;

(4) Will initiate and complete the work within the applicable project time periods following receipt of FTA approval;

(5) Will comply with all statutes relating to nondiscrimination including, but not limited to:

(a) Title VI of the Civil Rights Act, 42 U.S.C. 2000d, which prohibits discrimination on the basis of race, color, or national origin;

(b) Title IX of the Education Amendments of 1972, as amended, 20 U.S.C. 1681 through 1683, and 1685 through 1687, and U.S. DOT regulations, "Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance," 49 CFR part 25, which prohibit discrimination on the basis of sex;

(c) Section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794, which prohibits discrimination on the basis of handicaps;

(d) The Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 through 6107, which prohibit discrimination on the basis of age;

(e) The Drug Abuse Office and Treatment Act of 1972, Pub. L. 92–255, March 21, 1972, and amendments thereto, relating to nondiscrimination on the basis of drug abuse;

(f) The Comprehensive Alcohol Abuse and Alcoholism Prevention Act of 1970, Pub. L. 91–616, Dec. 31, 1970, and amendments thereto, relating to nondiscrimination on the basis of alcohol abuse or alcoholism;

(g) The Public Health Service Act of 1912, as amended, 42 U.S.C. 290dd–3 and 290ee–3, related to confidentiality of alcohol and drug abuse patient records;

(h) Title VIII of the Civil Rights Act, 42 U.S.C. 3601 et seq., relating to nondiscrimination in the sale, rental, or financing of housing;

(i) Any other nondiscrimination provisions in the specific statutes under which Federal assistance for the project may be provided including, but not limited to section 1101(b) of the Transportation Equity Act for the 21st Century, 23 U.S.C. 101 note, which provides for participation of disadvantaged business enterprises in FTA programs; and

(j) The requirements of any other nondiscrimination statute(s) that may apply to the project;

(6) Will comply, or has complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, (Uniform Relocation Act) 42 U.S.C. 4601 et seq., which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally-assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases. As required by U.S. DOT regulations, "Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs," at 49 CFR 24.4, and sections 210 and 305 of the Uniform Relocation Act, 42 U.S.C. 4630 and 4655, the Applicant assures that it has the requisite authority under applicable state and local law and will comply or has complied with the requirements of the Uniform Relocation Act, 42 U.S.C. 4601 et seq., and U.S. DOT regulations, "Uniform Relocation Assistance and Real Property Acquisition for Federal and Federally Assisted Programs," 49 CFR part 24 including, but not limited to the following:

(a) The Applicant will adequately inform each affected person of the benefits, policies, and procedures provided for in 49 CFR part 24;

(b) The Applicant will provide fair and reasonable relocation payments and assistance required by 42 U.S.C. 4622, 4623, and 4624; 49 CFR part 24; and any applicable FTA procedures, to or for families, individuals, partnerships, corporations or associations displaced as a result of any project financed with FTA assistance;

(c) The Applicant will provide relocation assistance programs offering the services described in 42 U.S.C. 4625 to such displaced families, individuals, partnerships, corporations, or associations in the manner provided in 49 CFR part 24 and FTA procedures;

(d) Within a reasonable time before displacement, the Applicant will make available comparable replacement dwellings to displaced families and individuals as required by 42 U.S.C. 4625(c)(3);

(e) The Applicant will carry out the relocation process in such a manner as to provide displaced persons with uniform and consistent services, and will make available replacement housing in the same range of choices with respect to such housing to all displaced persons regardless of race, color, religion, or national origin;

(f) In acquiring real property, the Applicant will be guided to the greatest extent practicable under state law, by the real property acquisition policies of 42 U.S.C. 4651 and 4652;

(g) The Applicant will pay or reimburse property owners for necessary expenses as specified in 42 U.S.C. 4653 and 4654, with the understanding that FTA will participate in the Applicant's eligible costs of providing payments for those expenses as required by 42 U.S.C. 4631;

(h) The Applicant will execute such amendments to third party contracts and subagreements financed with FTA assistance and execute, furnish, and be bound by such additional documents as FTA may determine necessary to effectuate or implement the assurances provided herein; and

(i) The Applicant agrees to make these assurances part of or incorporate them by reference into any third party contract or subagreement, or any amendments thereto, relating to any project financed by FTA involving relocation or land acquisition and provide in any affected document that these relocation and land acquisition provisions shall supersede any conflicting provisions;

(7) To the extent applicable, will comply with the Davis-Bacon Act, as amended, 40

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U.S.C. 276a through 276a(7), the Copeland Act, as amended, 18 U.S.C. 874 and 40 U.S.C. 276c, and the Contract Work Hours and Safety Standards Act, as amended, 40 U.S.C. 327 through 333, regarding labor standards for federally-assisted subagreements;

(8) To the extent applicable, will comply with flood insurance purchase requirements of section 102(a) of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012a(a), requiring recipients in a special flood hazard area to participate in the program and purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more;

(9) Will comply with the Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. 4801, which prohibits the use of lead-based paint in construction or rehabilitation of residence structures;

(10) Will not dispose of, modify the use of, or change the terms of the real property title, or other interest in the site and facilities on which a construction project supported with FTA assistance takes place without permission and instructions from the awarding agency;

(11) Will record the Federal interest in the title of real property in accordance with FTA directives and will include a covenant in the title of real property acquired in whole or in part with Federal assistance funds to assure nondiscrimination during the useful life of the project;

(12) Will comply with FTA requirements concerning the drafting, review, and approval of construction plans and specifications of any construction project supported with FTA assistance. As required by U.S. DOT regulations, "Seismic Safety," 49 CFR 41.117(d), before accepting delivery of any building financed with FTA assistance, it will obtain a certificate of compliance with 49 CFR part 41 seismic design and construction requirements;

(13) Will provide and maintain competent and adequate engineering supervision at the construction site of any project supported with FTA assistance to ensure that the complete work conforms with the approved plans and specifications and will furnish progress reports and such other information as may be required by FTA or the state;

(14) Will comply with environmental standards that may be prescribed to implement the following Federal laws and executive orders:

(a) Institution of environmental quality control measures under the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 et seq. and Executive Order No. 11514, as amended, 42 U.S.C. 4321 note;

(b) Notification of violating facilities pursuant to Executive Order No. 11738, 42 U.S.C. 7606 note;

(c) Protection of wetlands pursuant to Executive Order No. 11990, 42 U.S.C. 4321 note;

(d) Evaluation of flood hazards in floodplains in accordance with Executive Order 11988, 42 U.S.C. 4321 note;

(e) Assurance of project consistency with the approved state management program developed pursuant to the requirements of the Coastal Zone Management Act of 1972, as amended, 16 U.S.C. 1451 et seq.;

(f) Conformity of Federal actions to State (Clean Air) Implementation Plans under section 176(c) of the Clean Air Act of 1955, as amended, 42 U.S.C. 7401 et seq.;

(g) Protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, 42 U.S.C. 300h et seq.;

(h) Protection of endangered species under the Endangered Species Act of 1973, as amended, Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 et seq.; and

(i) Environmental protections for Federal transit programs, including, but not limited to protections for a park, recreation area, or wildlife or waterfowl refuge of national, state, or local significance or any land from a historic site of national, state, or local significance used in a transit project as required by 49 U.S.C. 303;

(j) Will comply with the Wild and Scenic Rivers Act of 1968, as amended, 16 U.S.C. 1271 et seq. relating to protecting components of the national wild and scenic rivers systems; and

(k) Will assist FTA in assuring compliance with section 106 of the National Historic Preservation Act of 1966, as amended, 16 U.S.C. 470f, Executive Order No. 11593 (identification and protection of historic properties), 16 U.S.C. 470 note, and the Archaeological and Historic Preservation Act of 1974, as amended, 16 U.S.C. 469a–1 et seq.;

(15) To the extent applicable, will comply with provisions of the Hatch Act, 5 U.S.C. 1501 through 1508, and 7324 through 7326, which limit the political activities of state and local agencies and their officers and employees whose principal employment activities are financed in whole or part with Federal funds including a Federal loan, grant, or cooperative agreement, but pursuant to 23 U.S.C. 142(g), does not apply to a nonsupervisory employee of a transit system (or of any other agency or entity performing related functions) receiving FTA assistance to whom the Hatch Act does not otherwise apply;

(16) Will comply with the National Research Act, Pub. L. 93–348, July 12, 1974, as amended, regarding the protection of human subjects involved in research, development, and related activities supported by Federal assistance and DOT regulations, "Protection of Human Subjects," 49 CFR part 11;

(17) Will comply with the Laboratory Animal Welfare Act of 1966, as amended, 7 U.S.C. 2131 et seq. pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by FTA assistance;

(18) Will have performed the financial and compliance audits required by the Single Audit Act Amendments of 1996, 31 U.S.C. 7501 et seq. and OMB Circular No. A–133, "Audits of States, Local Governments, and Non-Profit Organizations and Department of Transportation provisions of OMB A–133 Compliance Supplement, March 2000"

(19) Will comply with all applicable requirements of all other Federal laws, executive orders, regulations, and policies governing the project.

2. Lobbying Certification for an Application Exceeding $100,000

An Applicant that submits, or intends to submit this fiscal year, an application for Federal assistance exceeding $100,000 must provide the following certification. FTA may not award Federal assistance for an application exceeding $100,000 until the Applicant provides this certification by selecting Category "2."

A. As required by U.S. DOT regulations, "New Restrictions on Lobbying," at 49 CFR 20.110, the Applicant's authorized representative certifies to the best of his or her knowledge and belief that for each application for a Federal assistance exceeding $100,000:

(1) No Federal appropriated funds have been or will be paid, by or on behalf of the Applicant, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress pertaining to the award of any Federal assistance, or the extension, continuation, renewal, amendment, or modification of any Federal assistance agreement; and

(2) If any funds other than Federal appropriated funds have been or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any application to FTA for Federal assistance, the Applicant assures that it will complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," including the information required by the form's instructions, which may be amended to omit such information as permitted by 31 U.S.C. 1352.

B. The Applicant understands that this certification is a material representation of fact upon which reliance is placed and that submission of this certification is a prerequisite for providing Federal assistance for a transaction covered by 31 U.S.C. 1352. The Applicant also understands that any person who fails to file a required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

3. Certification Pertaining to the Effects of the Project on Private Mass Transportation Companies

An Applicant that is a state or local government seeking Federal assistance authorized by 49 U.S.C. chapter 53 to acquire the property of or an interest therein of a private mass transportation company or to operate mass transportation equipment or a facility in competition with or in addition to transportation service provided by an existing mass transportation company must provide the following certification. FTA may not award Federal assistance for that project until the Applicant provides this certification by selecting Category "3."

As required by 49 U.S.C. 5323(a)(1), the Applicant certifies that before it acquires property or an interest in property of a private mass transportation company or operates mass transportation equipment or a facility in competition with or in addition to transportation service provided by an existing mass transportation company it has or will have:

A. Found that the assistance is essential to carrying out a program of projects as determined by the plans and programs of the metropolitan planning organization;

B. Provided for the participation of private mass transportation companies to the maximum extent feasible consistent with applicable FTA requirements and policies;

C. Paid just compensation under state or local law to a private mass transportation company for its franchises or property acquired; and

D. Acknowledged that the assistance falls within the labor standards compliance requirements of 49 U.S.C. 5333(a) and 5333(b).

4. Public Hearing Certification for a Capital Project That Will Substantially Affect a Community or Its Transit Service

An Applicant seeking Federal assistance authorized by 49 U.S.C. chapter 53 for a capital project that will substantially affect a community or the community's mass transportation service must provide the following certification. FTA may not award Federal assistance for that project until the Applicant provides this certification by selecting Category "4."

As required by 49 U.S.C. 5323(b), the Applicant certifies that it has, or before submitting its application, will have:

A. Provided an adequate opportunity for a public hearing with adequate prior notice of the proposed project published in a newspaper of general circulation in the geographic area to be served;

B. Held that hearing and provided FTA a transcript or detailed report summarizing the issues and responses, unless no one with a significant economic, social, or environmental interest requests a hearing;

C. Considered the economic, social, and environmental effects of the project; and

D. Determined that the project is consistent with official plans for developing the urban area.

5. Certification Of Pre-Award and Post-Delivery Reviews Required for Acquisition of Rolling Stock

An Applicant seeking FTA assistance to acquire rolling stock must provide the following certification. FTA may not provide assistance to acquire rolling stock until the Applicant provides this certification by selecting Category "5."

As required by 49 U.S.C. 5323(m) and implementing FTA regulations at 49 CFR 663.7, the Applicant certifies that it will comply with the requirements of 49 CFR part 663 when procuring revenue service rolling stock. Among other things, the Applicant agrees to conduct or cause to be conducted the requisite pre-award and post-delivery reviews, and maintain on file the certifications required by 49 CFR part 663, subparts B, C, and D.

6. Bus Testing Certification Required for New Bus Acquisitions

An Applicant seeking FTA assistance to acquire new buses must provide the following certification. FTA may not provide assistance for the acquisition of new buses until the Applicant provides this certification by selecting Category "6."

As required by FTA regulations, "Bus Testing," at 49 CFR 665.7, the Applicant certifies that before expending any Federal assistance to acquire the first bus of any new bus model or any bus model with a new major change in configuration or components or authorizing final acceptance of that bus (as described in 49 CFR part 665):

A. The model of the bus will have been tested at a bus testing facility approved by FTA; and

B. It will have received a copy of the test report prepared on the bus model.

7. Charter Service Agreement

An Applicant seeking FTA assistance to acquire or operate transportation equipment or facilities using Federal assistance authorized by 49 U.S.C. chapter 53 or Title 23, U.S.C. (except 49 U.S.C. 5310) must enter into the following charter service agreement. FTA may not provide assistance for those projects until the Applicant enters into this agreement by selecting Category "7."

A. As required by 49 U.S.C. 5323(d) and FTA regulations, "Charter Service," at 49 CFR 604.7, the Applicant agrees that it and its recipients will:

(1) Provide charter service that uses equipment or facilities acquired with Federal assistance authorized for 49 U.S.C. 5307, 5309, or 5311 or Title 23 U.S.C., only to the extent that there are no private charter service operators willing and able to provide the charter service that it or its recipients desire to provide, unless one or more of the exceptions in 49 CFR 604.9 applies; and

(2) Comply with the provisions of 49 CFR part 604 before they provide any charter service using equipment or facilities acquired with Federal assistance authorized for the above statutes.

B. The Applicant understands that the requirements of 49 CFR part 604 will apply to any charter service provided, the definitions in 49 CFR part 604 apply to this agreement, and violation of this agreement may require corrective measures and the imposition of penalties, including debarment from the receipt of further Federal assistance for transportation.

8. School Transportation Agreement

An Applicant seeking FTA assistance to acquire or operate transportation facilities and equipment using Federal assistance authorized by 49 U.S.C. chapter 53 or Title 23, U.S.C. must agree as follows. FTA may not provide assistance for transportation facilities until the Applicant enters into this Agreement by selecting Category "8."

A. As required by 49 U.S.C. 5323(f) and FTA regulations, "School Bus Operations," at 49 CFR 605.14, the Applicant agrees that it and all its recipients will:

(1) Engage in school transportation operations in competition with private school transportation operators only to the extent permitted by 49 U.S.C. 5323(f), and implementing regulations; and

(2) Comply with the requirements of 49 CFR part 605 before providing any school transportation using equipment or facilities acquired with Federal assistance awarded by FTA and authorized by 49 U.S.C. chapter 53 or Title 23 U.S.C. for transportation projects.

B. The Applicant understands that the requirements of 49 CFR part 605 will apply to any school transportation it provides, the definitions of 49 CFR part 605 apply to this school transportation agreement, and a violation of this agreement may require corrective measures and the imposition of penalties, including debarment from the receipt of further Federal assistance for transportation.

9. Certification Required for the Direct Award of FTA Assistance to an Applicant for Its Demand Responsive Service

An Applicant seeking direct Federal assistance to support demand responsive service must provide the following certification. FTA may not award Federal assistance directly to an Applicant to support its demand responsive service until the Applicant provides this certification by selecting Category "9."

As required by U.S. DOT regulations, "Transportation Services for Individuals with Disabilities (ADA)," at 49 CFR 37.77, the Applicant certifies that its demand responsive service offered to persons with disabilities, including persons who use wheelchairs, is equivalent to the level and quality of service offered to persons without disabilities. When viewed in its entirety, the Applicant's service for persons with disabilities is provided in the most integrated setting feasible and is equivalent with respect to: (1) response time, (2) fares, (3) geographic service area, (4) hours and days of service, (5) restrictions on trip purpose, (6) availability of information and reservation capability, and (7) constraints on capacity or service availability.

10. Substance Abuse Certifications

If the Applicant is required by Federal regulations to provide the following substance abuse certifications, FTA may not provide Federal assistance to that Applicant until it provides these certifications by selecting Category "10."

A. Alcohol Testing Certification

As required FTA regulations, "Prevention of Alcohol Misuse in Transit Operations," at 49 CFR 654.83, the Applicant certifies that it has established and implemented an alcohol misuse prevention program in compliance with 49 CFR part 654, and if the Applicant has employees regulated by the U.S. Federal Railroad Administration (U.S. FRA), the Applicant also certifies that it has for those employees an alcohol misuse prevention program in compliance with U.S. FRA regulations, "Control of Alcohol and Drug Use," 49 CFR part 219.

B. Anti-Drug Program Certification

As required by FTA regulations "Prevention of Prohibited Drug Use in Transit Operations," at 49 CFR 653.83, the Applicant certifies that it has established and implemented an anti-drug program and conducted employee training in compliance with 49 CFR part 653, and if the Applicant also has employees regulated by the U.S.

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FRA, the Applicant also certifies that it has for those employees an anti-drug program in compliance with U.S. FRA regulations, "Control of Alcohol and Drug Use," 49 CFR part 219.

11. Certification Required for Interest or Other Financing Costs

The Applicant must provide the following certification in connection with requests for reimbursements of interest or other financing costs of capital projects. FTA may not provide assistance to support those costs until the Applicant provides this certification by selecting Category "11."

As required by 49 U.S.C. 5307(g), 49 U.S.C. 5309(g)(2)(B), 49 U.S.C. 5309(g)(3)(A), and 49 U.S.C. 5309(n), the Applicant certifies that it will not seek reimbursement for interest and other financing costs unless its records demonstrate it has used reasonable diligence in seeking the most favorable financing terms underlying those costs, to the extent FTA might require.

12. Certifications and Assurances for the Urbanized Area Formula Program, the Job Access and Reverse Commute Program, and the Clean Fuels Formula Program

Each Applicant to FTA for Urbanized Area Formula Program assistance authorized by 49 U.S.C. 5307, each Applicant for Job Access and Reverse Commute Program assistance authorized by section 3037 of the Transportation Equity Act for the 21st Century, 49 U.S.C. 5309 note, and each Applicant for the Clean Fuels Formula Program assistance authorized by 49 U.S.C. 5308 must provide the following certifications in connection with its application. FTA may not award Urbanized Area Formula Program assistance, the Job Access and Reverse Commute Program assistance, or the Clean Fuels Formula Program assistance to the Applicant until the Applicant provides these certifications and assurances by selecting Category "12" on the Cert's & Assurances tab page of the TEAM system or on the Signature Page at the end of this document. A state or other Applicant providing certifications and assurances on behalf of its prospective subrecipients is expected to obtain sufficient documentation from those subrecipients to assure the validity of its certifications and assurances.

In addition, each Applicant that has received Transit Enhancement funding authorized by 49 U.S.C. 5307(k)(1) must include within its quarterly report for the fourth quarter of the preceding Federal fiscal year a list of the projects carried out during the preceding Federal fiscal year with those Transit Enhancement funds. That list constitutes the report of transit projects carried out during the preceding fiscal year to be submitted as part of the Applicant's annual certifications and assurances, as required by 49 U.S.C. 5307(k)(3), and is thus incorporated by reference and made part of that Applicant's annual certifications and assurances. FTA may not award Urbanized Area Formula Program assistance to any Applicant that has received Transit Enhancement funding authorized by 49 U.S.C. 5307(k)(1), unless that Applicant's quarterly report for the fourth quarter of the preceding Federal fiscal year has been submitted to FTA and that report contains the requisite list.

A. Certifications Required by Statute

As required by 49 U.S.C. 5307(d)(1)(A) through (J), the Applicant certifies that:

(a) It has or will have the legal, financial, and technical capacity to carry out the proposed program of projects;

(b) It will adequately maintain the equipment and facilities;

(c) It will ensure that elderly or handicapped persons, or any person presenting a Medicare card issued to himself or herself pursuant to title II or title XVIII of the Social Security Act (42 U.S.C. 401 *et seq.* or 42 U.S.C. 1395 *et seq.*), will be charged for transportation during non-peak hours using or involving a facility or equipment of a project financed with Federal assistance authorized for 49 U.S.C. 5307 or for section 3037 of the Transportation Equity Act for the 21st Century (TEA–21), 49 U.S.C. 5309 note, not more than fifty (50) percent of the peak hour fare;

(d) In carrying out a procurement financed with Federal assistance authorized for the Urbanized Area Formula Program at 49 U.S.C. 5307 or section 3037 of TEA–21, 49 U.S.C. 5309 note, it will use competitive procurement (as defined or approved by the Secretary), it will not use a procurement using exclusionary or discriminatory specifications, and it will comply with applicable Buy America laws in carrying out a procurement;

(e) It has complied or will comply with the requirements of 49 U.S.C. 5307(c). Specifically, it has made available or before submitting its application it will make available: (1) to the public information on amounts available for the Urbanized Area Formula Program at 49 U.S.C. 5307 and, if applicable, the Job Access and Reverse Commute Grant Program, 49 U.S.C. 5309 note, and the program of projects it proposes to undertake with those funds; (2) in consultation with interested parties including private transportation providers, develop a proposed program of projects for activities to be financed; (3) publish a proposed program of projects in a way that affected citizens, private transportation providers, and local elected officials have the opportunity to examine the proposed program and submit comments on the proposed program and the performance of the Applicant; (4) provide an opportunity for a public hearing to obtain the views of citizens on the proposed program of projects; and (5) ensure that the proposed program of projects provides for the coordination of transportation services assisted under 49 U.S.C. 5336 with transportation services assisted by another Federal Government source; (6) consider comments and views received, especially those of private transportation providers, in preparing the final program of projects; and (7) make the final program of projects available to the public;

(f) It has or will have available and will provide the amount of funds required by 49 U.S.C. 5307(e) and applicable FTA policy specifying Federal and local shares of project costs;

(g) It will comply with: 49 U.S.C. 5301(a) (requirements for transportation systems that maximize mobility and minimize fuel consumption and air pollution); 49 U.S.C. 5301(d) (requirements for transportation of the elderly and persons with disabilities); 49 U.S.C. 5303 through 5306 (planning requirements); and 49 U.S.C. 5310(a) through (d) (programs for the elderly and persons with disabilities);

(h) It has a locally developed process to solicit and consider public comment before raising fares or implementing a major reduction of transportation; and

(i) As required by 49 U.S.C. 5307(d)(1)(J), unless it has determined that it is not necessary to expend one (1) percent of the amount of Federal assistance it receives for this fiscal year apportioned in accordance with 49 U.S.C. 5336 for transit security projects, it will expend at least one (1) percent of the amount of that assistance for transit security projects, including increased lighting in or adjacent to a transit system (including bus stops, subway stations, parking lots, and garages), increased camera surveillance of an area in or adjacent to that system, emergency telephone line or lines to contact law enforcement or security personnel in an area in or adjacent to that system, and any other project intended to increase the security and safety of an existing or planned transit system.

(2) As required by 49 U.S.C. 5307(k)(3), if it has received Transit Enhancement funds authorized by 49 U.S.C. 5307(k)(1), its quarterly report for the fourth quarter of the preceding Federal fiscal year includes a list of projects implemented in the preceding Federal fiscal year using Transit Enhancement funds, and that report is made part of its certifications and assurances.

B. Certification Required for Capital Leasing

As required by FTA regulations, "Capital Leases," at 49 CFR 639.15(b)(1) and 639.21, to the extent the Applicant uses Federal assistance authorized for 49 U.S.C. 5307 or section 3037 of TEA–21, 49 U.S.C. 5309 note, to acquire any capital asset by lease, the Applicant certifies that:

(1) It will not use Federal assistance authorized for 49 U.S.C. 5307 or section 3037 of TEA–21, 49 U.S.C. 5309 note, to finance the cost of leasing any capital asset until it performs calculations demonstrating that leasing the capital asset would be more cost-effective than purchasing or constructing a similar asset;

(2) It will complete these calculations before entering into the lease or before receiving a capital grant for the asset, whichever is later; and

(3) It will not enter into a capital lease for which FTA can only provide incremental funding unless it has the financial capacity to meet its future obligations under the lease in the event Federal assistance is not available for capital projects in subsequent years.

C. Certification Required for Sole Source Purchase of Associated Capital Maintenance Item

As required by 49 U.S.C. 5325(c), to the extent that the Applicant procures an associated capital maintenance item under the authority of 49 U.S.C. 5307(b)(1), the Applicant certifies that it will use competition to procure an associated capital maintenance item unless the manufacturer or supplier of that item is the only source for the item and the price of the item is no more than the price similar customers pay for the item, and maintain sufficient records pertaining to each such procurement on file easily retrievable for FTA inspection.

D. Clean Fuels Program Certification

As required by 49 U.S.C. 5308(c)(2), the Applicant certifies that, in connection with any application for assistance authorized for the Clean Fuels Formula Program, vehicles purchased with grant funds made available for 49 U.S.C. 5308 will be operated only with clean fuels.

13. Certifications and Assurances for the Elderly and Persons With Disabilities Program

An Applicant that intends to administer the Elderly and Persons with Disabilities Program on behalf of a state must provide the following certifications and assurances. In providing certifications and assurances on behalf of its prospective subrecipients, the Applicant is expected to obtain sufficient documentation from those subrecipients to assure the validity of its certifications and assurances. FTA may not award assistance for the Elderly and Persons with Disabilities Program until the Applicant provides these certifications and assurances by selecting Category "13."

The Applicant administering on behalf of the state the Elderly and Persons with Disabilities Program authorized by 49 U.S.C. 5310 certifies and assures that the following requirements and conditions will be fulfilled:

A. The state organization serving as the Applicant and each subrecipient has or will have the necessary legal, financial, and managerial capability to apply for, receive and disburse Federal assistance authorized for 49 U.S.C. 5310; and to implement and manage the project.

B. The state assures that each subrecipient either is recognized under state law as a private nonprofit organization with the legal capability to contract with the state to carry out the proposed project, or is a public body that has met the statutory requirements to receive Federal assistance authorized for 49 U.S.C. 5310.

C. The subrecipient's application for 49 U.S.C. 5310 assistance contains information from which the state concludes that the transit service provided or offered to be provided by existing public or private transit operators is unavailable, insufficient, or inappropriate to meet the special needs of the elderly and persons with disabilities.

D. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.

E. The subrecipient has, or will have by the time of delivery, sufficient funds to operate and maintain the vehicles and equipment purchased with Federal assistance awarded for this project.

F. The state assures that before issuing the state's formal approval of a project, its Elderly and Persons with Disabilities Formula Program is included in the Statewide Transportation Improvement Program as required by 23 U.S.C. 135; all projects in urbanized areas recommended for approval are included in the annual element of the metropolitan Transportation Improvement Program in which the subrecipient is located; and any public body that is a prospective subrecipient of capital assistance has provided an opportunity for a public hearing.

G. The state recognizes that the subrecipient, rather than the state itself, will be ultimately responsible for implementing many Federal requirements covered by the certifications the state has signed. Having taken appropriate measures to secure the necessary compliance by each subrecipient, the state assures, on behalf of each subrecipient, that each subrecipient has:

(1) Coordinated or will coordinate to the maximum extent feasible with other transportation providers and users, including social service agencies authorized to purchase transit service;

(2) Complied or will comply with all applicable civil rights requirements;

(3) Complied or will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprise in U.S. DOT programs;

(4) Complied or will comply with Federal requirements regarding transportation of elderly persons and persons with disabilities;

(5) Complied or will comply with the transit employee protective provisions of 49 U.S.C. 5333(b), by one of the following actions: (1) signing the Special Warranty for the Nonurbanized Area Formula Program, (2) agreeing to alternative comparable arrangements approved by the Department of Labor (DOL), or (3) obtaining a waiver from DOL; and the state has certified the subrecipient's compliance to DOL;

(6) Complied or will comply with 49 CFR part 604 in the provision of any charter service provided with equipment or facilities acquired with FTA assistance;

(7) Complied with or will comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations;

(8) Viewing its demand responsive service to the general public in its entirety, complied or will comply with the requirement to provide demand responsive service to persons with disabilities, including persons who use wheelchairs, meeting the standard of equivalent service set forth in 40 CFR 37.77(c), if it purchases non-accessible vehicles for use in demand responsive service for the general public;

(9) Established or will establish a procurement system and conducted or will conduct its procurements in compliance with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue;

(10) Complied or will comply with the requirement that its project provides for the participation of private mass transportation companies to the maximum extent feasible;

(11) Paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project;

(12) Complied or will comply with all applicable lobbying requirements for each application exceeding $100,000;

(13) Complied or will comply with all applicable nonprocurement suspension and debarment requirements;

(14) Complied or will comply with all applicable bus testing requirements for new bus models; and

(15) Complied or will comply with all applicable pre-award and post-delivery review requirements.

H. Unless otherwise noted, each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in the joint FHWA/FTA regulations, "Environmental Impact and Related Procedures," at 23 CFR 771.117(c). The state certifies that financial assistance will not be provided for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until FTA has made the required environmental finding. The state further certifies that no financial assistance will be provided for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until FTA makes the required conformity finding.

I. The state will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed.

J. The state recognizes the authority of FTA, U.S. DOT, and the Comptroller General of the United States to conduct audits and reviews to verify compliance with the foregoing requirements and stipulations, and assures that, upon request, the SIB and its subrecipients, as well as the states, will make the necessary records available to FTA, U.S. DOT and the Comptroller General of the United States. The state also acknowledges its obligation under 49 CFR 18.40(a) to monitor project activities carried out by its subrecipients to assure compliance with applicable Federal requirements.

14. Certifications and Assurances for the Nonurbanized Area Formula Program

An Applicant that intends to administer the Nonurbanized Area Formula Program on behalf of a state must provide the following certifications and assurances. In providing certifications and assurances on behalf of its prospective subrecipients, the Applicant is expected to obtain sufficient documentation from those subrecipients to assure the validity of its certifications and assurances. FTA may not award Nonurbanized Area Formula Program assistance to the Applicant until the Applicant provides these certifications and assurances by selecting Categories "1" through "11" and "14."

The Applicant administering on behalf of the state the Nonurbanized Area Formula Program authorized by 49 U.S.C. 5311 certifies and assures that the following requirements and conditions will be fulfilled:

A. The state organization serving as the Applicant and each subrecipient has or will

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have the necessary legal, financial, and managerial capability to apply for, receive and disburse Federal assistance authorized for 49 U.S.C. 5311; and to implement and manage the project.

B. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.

C. The state assures that before issuing the state's formal approval of the project, its Nonurbanized Area Formula Program is included in the Statewide Transportation Improvement Program as required by 23 U.S.C. 135; to the extent applicable, projects are included in a metropolitan Transportation Improvement Program.

D. The state has provided for a fair and equitable distribution of Federal assistance authorized for 49 U.S.C. 5311 within the state, including Indian reservations within the state.

E. The state recognizes that the subrecipient, rather than the state itself, will be ultimately responsible for implementing many Federal requirements covered by the certifications the state has signed. Having taken appropriate measures to secure the necessary compliance by each subrecipient, the state assures, on behalf of each subrecipient, that each subrecipient has:

(1) Coordinated or will coordinate to the maximum extent feasible with other transportation providers and users, including social service agencies authorized to purchase transit service;

(2) Complied or will comply with all applicable civil rights requirements;

(3) Complied or will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprise in U.S. DOT programs;

(4) Complied or will comply with Federal requirements regarding transportation of elderly persons and persons with disabilities;

(5) Complied or will comply with the transit employee protective provisions of 49 U.S.C. 5333(b), by one of the following actions: (1) Signing the Special Warranty for the Nonurbanized Area Formula Program, (2) agreeing to alternative comparable arrangements approved by the Department of Labor (DOL), or (3) obtaining a waiver from DOL; and the state has certified the subrecipient's compliance to DOL;

(6) Complied or will comply with 49 CFR part 604 in the provision of any charter service provided with equipment or facilities acquired with FTA assistance;

(7) Complied with or will comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations;

(8) Viewing its demand responsive service to the general public in its entirety, complied or will comply with the requirement to provide demand responsive service to persons with disabilities, including persons who use wheelchairs, meeting the standard of equivalent service set forth in 40 CFR 37.77(c), if it purchases non-accessible vehicles for use in demand responsive service for the general public;

(9) Established or will establish a procurement system and conducted or will conduct its procurements in compliance with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue;

(10) Complied or will comply with the requirement that its project provides for the participation of private enterprise to the maximum extent feasible;

(11) Paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project;

(12) Complied or will comply with all applicable lobbying requirements for each application exceeding $100,000;

(13) Complied or will comply with all applicable nonprocurement suspension and debarment requirements;

(14) Complied or will comply with all applicable bus testing requirements for new bus models;

(15) Complied or will comply with all applicable pre-award and post-delivery review requirements;

(16) Complied with or will comply with all assurances FTA requires for projects involving real property; and

(17) Complied with, or to the extent required by FTA will comply with, applicable anti-drug and alcohol program requirements.

F. Unless otherwise noted, each of the subrecipient's projects qualifies for a categorical exclusion and does not require further environmental approvals, as described in the joint FHWA/FTA regulations, "Environmental Impact and Related Procedures," at 23 CFR 771.117(c). The state certifies that financial assistance will not be provided for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until FTA has made the required environmental finding. The state further certifies that no financial assistance will be provided for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until FTA makes the required conformity finding.

G. The state will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed.

H. The state recognizes the authority of FTA, U.S. DOT, and the Comptroller General of the United States to conduct audits and reviews to verify compliance with the foregoing requirements and stipulations, and assures that, upon request, the SIB and its subrecipients, as well as the states, will make the necessary records available to FTA, U.S. DOT and the Comptroller General of the United States. The state also acknowledges its obligation under 49 CFR 18.40(a) to monitor project activities carried out by its subrecipients to assure compliance with applicable Federal requirements.

I. As required by 49 U.S.C. 5311(f), the state will expend not less than fifteen (15) percent of the Federal assistance authorized for 49 U.S.C. 5311(f) and apportioned during this fiscal year to carry out a program to develop and support intercity bus transportation, unless the chief executive officer of the state or his or her duly authorized designee certifies that the intercity bus service needs of the state are being adequately met.

15. Certifications and Assurances for the State Infrastructure Bank Program

An Applicant for a grant of Federal assistance for deposit in the State Infrastructure Bank (SIB) must provide the following certifications and assurances. In providing certifications and assurances on behalf of its prospective subrecipients, the Applicant is expected to obtain sufficient documentation from those subrecipients to assure the validity of its certifications and assurances. FTA may not award Nonurbanized Area Formula Program assistance for the State Infrastructure Bank program to the Applicant until the Applicant provides these certifications and assurances by selecting Categories "1" through "11" and "15."

The state serving as the Applicant for Federal assistance for the Transit Account of its state SIB program authorized by either section 350 of the National Highway System Designation Act of 1995, as amended, 23 U.S.C. 101 note, or the State Infrastructure Bank Pilot Program, 23 U.S.C. 181 note, certifies and assures that the following requirements and conditions will be fulfilled pertaining to any project financed with Federal assistance derived from the Transit Account of the SIB:

A. The state organization serving as the Applicant (state) agrees and assures the agreement of the SIB and each recipient of Federal assistance derived from the Transit Account of the SIB within the state (subrecipient) that each Project financed with Federal assistance derived from the Transit Account will be administered in accordance with the:

(1) Applicable provisions of section 350 of the National Highway System Designation Act of 1995, as amended, 23 U.S.C. 101 note, or of the State Infrastructure Bank Pilot Program, 23 U.S.C. 181 note, and any further amendments thereto;

(2) Provisions of FTA's NHS Guidelines, and any amendments thereto;

(3) Terms and conditions of Department of Labor Certification(s) of Transit Employee Protective Arrangements that are required by Federal law or regulations;

(4) Provisions of FHWA and FTA cooperative agreement with the state to establish the state's SIB program; and

(5) Provisions of the FTA grant agreement with the state that obligating Federal assistance for the SIB, except that any provision of the Federal Transit Administration Master Agreement incorporated by reference into that grant agreement will not apply if it conflicts with any provision of National Highway System Designation Act of 1995, as amended, 23 U.S.C. 101 note, or section 1511 of TEA–21, as amended, 23 U.S.C. 181 note, and FTA SIB Guidelines, the provisions of the cooperative agreement establishing the SIB program within the state, or the text within the FTA grant agreement.

B. The state agrees to comply with and assures the compliance of the SIB and each subrecipient of assistance under the SIB with all applicable requirements for the SIB program, as those requirements may be amended from time to time. Pursuant to the requirements of subsection 1511(h)(2) of TEA–21, 23 U.S.C. 181 note, applicants for assistance authorized by the state Infrastructure Bank Pilot Program agree that previous cooperative agreements entered into with states under section 350 of the National Highway System Designation Act of 1995, as amended, 23 U.S.C. 101 note, will be revised to comply with new requirements.

C. The state assures that the SIB will provide Federal assistance from its Transit Account only for transit capital projects eligible under section 350 of the National Highway System Designation Act of 1995, as amended, 23 U.S.C. 101 note or under section 1511 of TEA–21, 23 U.S.C. 181 note, and that those projects will fulfill all requirements imposed on comparable capital transit projects financed by FTA.

D. The state understands that the total amount of funds to be awarded for a grant agreement will not be immediately available for draw down. Consequently, the state assures that it will limit the amount of Federal assistance it draws down for deposit in the SIB to amounts that do not exceed the limitations specified in the underlying grant agreement or the approved project budget for that grant agreement.

E. The state assures that each subrecipient has or will have the necessary legal, financial, and managerial capability to apply for, receive, and disburse Federal assistance authorized by Federal statute for use in the SIB, and to implement, manage, operate, and maintain the project and project property for which such assistance will support.

F. The state assures that sufficient non-Federal funds have been or will be committed to provide the required local share.

G. The state recognizes that the SIB, rather than the state itself, will be ultimately responsible for implementing many Federal requirements covered by the certifications the state has signed. Having taken appropriate measures to secure the necessary compliance by the SIB, the state assures, on behalf of the SIB, that:

(1) The SIB has complied or will comply with all applicable civil rights requirements;

(2) The SIB has complied or will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprise in U.S. DOT programs;

(3) The SIB will provide Federal assistance only to a subrecipient that is either a public or private entity recognized under state law as having the legal capability to contract with the state to carry out its proposed project;

(4) Before the SIB enters into an agreement with a subrecipient under which Federal assistance will be disbursed to the subrecipient, the subrecipient's project is included in the Statewide Transportation Improvement Program; all projects in urbanized areas recommended for approval are included in the annual element of the metropolitan Transportation Improvement Program in which the subrecipient is located; a certification that an opportunity for a public hearing has been provided;

(5) The SIB will not provide Federal financial assistance for any project that does not qualify for a categorical exclusion described in 23 CFR 771.117(c) until the required Federal environmental finding has been made. Moreover, the SIB will provide no financial assistance for a project requiring a conformity finding in accordance with the Environmental Protection Agency's Clean Air Conformity regulations at 40 CFR parts 51 and 93, until the required Federal conformity finding has been made;

(6) Before the SIB provides Federal assistance for a transit project, each subrecipient will have complied with the applicable transit employee protective provisions of 49 U.S.C. 5333(b) as required for that subrecipient and its project; and

(7) The SIB will enter into a written agreement with each subrecipient stating the terms and conditions of assistance by which the project will be undertaken and completed, including specific provisions that any security or debt financing instrument the SIB may issue will contain an express statement that the security or instrument does not constitute a commitment, guarantee, or obligation of the United States.

H. The state recognizes that the subrecipient, rather than the state itself, will be ultimately responsible for implementing many Federal requirements covered by the certifications the state has signed. Having taken appropriate measures to secure the necessary compliance by the SIB and each subrecipient, the state assures, on behalf of each subrecipient, that each subrecipient has:

(1) Complied or will comply with all applicable civil rights requirements;

(2) Complied or will comply with applicable requirements of U.S. DOT regulations on participation of disadvantaged business enterprise in U.S. DOT programs;

(3) Complied or will comply with Federal requirements regarding transportation of elderly persons and persons with disabilities;

(4) Complied or will comply with the applicable transit employee protective provisions of 49 U.S.C. 5333(b) as required for that subrecipient and its project;

(5) Complied or will comply with 49 CFR part 604 in the provision of any charter service provided with equipment or facilities acquired with FTA assistance;

(6) Complied with or will comply with applicable provisions of 49 CFR part 605 pertaining to school transportation operations;

(7) Viewing its demand responsive service to the general public in its entirety, complied or will comply with the requirement to provide demand responsive service to persons with disabilities, including persons who use wheelchairs, meeting the standard of equivalent service set forth in 40 CFR 37.77(c), if it purchases non-accessible vehicles for use in demand responsive service for the general public;

(8) Established or will establish a procurement system and conducted or will conduct its procurements in compliance with all applicable requirements imposed by Federal laws, executive orders, or regulations and the requirements of FTA Circular 4220.1D, "Third Party Contracting Requirements," and other implementing requirements FTA may issue;

(9) Complied or will comply with the requirement that its project provides for the participation of private mass transportation companies to the maximum extent feasible;

(10) Paid or will pay just compensation under state or local law to each private mass transportation company for its franchise or property acquired under the project;

(11) Complied or will comply with all applicable lobbying requirements for each application exceeding $100,000;

(12) Complied or will comply with all nonprocurement suspension and debarment requirements;

(13) Complied with or will comply with all applicable bus testing requirements for new bus models;

(14) Complied with or will comply with all applicable pre-award and post-delivery review requirements;

(15) Complied with or will comply with all assurances FTA requires for projects involving real property; and

(16) Complied with, or to the extent required by FTA will comply with, applicable anti-drug and alcohol program requirements.

I. The state recognizes the authority of FTA, U.S. DOT, and the Comptroller General of the United States to conduct audits and reviews to verify compliance with the foregoing requirements and stipulations, and assures that, upon request, the SIB and its subrecipients, as well as the states, will make the necessary records available to FTA, U.S. DOT and the Comptroller General of the United States. The state also acknowledges its obligation under 49 CFR 18.40(a) to monitor project activities carried out by the SIB and its subrecipients to assure compliance with applicable Federal requirements.

Selection and Signature Pages Follow

Federal FY 2001 Certifications and Assurances for FTA Assistance

(Alternative to Electronic Filing)
Name of Applicant:_____

The Applicant Agrees To Comply With Applicable Requirements of Categories 1–15

____

(The Applicant may make this selection in lieu of individual selections below.)

OR

The Applicant Agrees To Comply With the Applicable Requirements of the Following Categories It Has Selected:

1. Certifications and Assurances Required of Each Applicant ____
2. Lobbying Certification ____
3. Certification Pertaining to Effects on Private Mass Transportation Companies ____
4. Public Hearing Certification for a Project with Substantial Impacts ____
5. Certification for the Purchase of Rolling Stock ____
6. Bus Testing Certification ____
7. Charter Service Agreement ____
8. School Transportation Agreement ____
9. Certification for Demand Responsive

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Service ___
10. Substance Abuse Certifications ___
11. Certification Required for Interest and Other Financing Costs ___
12. Certifications and Assurances for the Urbanized Area Formula Program, the Job Access and Reverse Commute Program, and the Clean Fuels Formula Program ___
13. Certifications and Assurances for the Elderly and Persons with Disabilities Program ___
14. Certifications and Assurances for the Nonurbanized Area Formula Program ___
15. Certifications and Assurances for the State Infrastructure Bank (SIB) Program ___

(Both sides of this Signature Page must be appropriately completed and signed where indicated.)

Federal Fiscal Year 2001 FTA Certifications and Assurances

(Required of all Applicants for FTA assistance and all FTA Grantees with an active capital or formula project)
Name of Applicant: _____
Name and Relationship of Authorized Representative: _____
BY SIGNING BELOW I, _____ (name), on behalf of the Applicant, declare that the Applicant has duly authorized me to make these certifications and assurances and bind the Applicant's compliance. Thus, the Applicant agrees to comply with all Federal statutes, regulations, executive orders, and administrative guidance required for each application it makes to the Federal Transit Administration (FTA) in Federal Fiscal Year 2001.
FTA intends that the certifications and assurances the Applicant selects on the other side of this document, as representative of the certifications and assurances in Appendix A, should apply, as required, to each project for which the Applicant seeks now, or may later, seek FTA assistance during Federal Fiscal Year 2001.
The Applicant affirms the truthfulness and accuracy of the certifications and assurances it has made in the statements submitted herein with this document and any other submission made to FTA, and acknowledges that the provisions of the Program Fraud Civil Remedies Act of 1986, 31 U.S.C. 3801 *et seq.*, as implemented by U.S. DOT regulations, "Program Fraud Civil Remedies," 49 CFR part 31 apply to any certification, assurance or submission made to FTA. The criminal fraud provisions of 18 U.S.C. 1001 apply to any certification, assurance, or submission made in connection with the Urbanized Area Formula Program, 49 U.S.C. 5307, and may apply to any other certification, assurance, or submission made in connection with any other program administered by FTA.
In signing this document, I declare under penalties of perjury that the foregoing certifications and assurances, and any other statements made by me on behalf of the Applicant are true and correct.
Signature _____
Name _____
Authorized Representative of Applicant
Date: _____

Affirmation of Applicant's Attorney
for _____ (Name of Applicant)
As the undersigned Attorney for the above named Applicant, I hereby affirm to the Applicant that it has authority under state and local law to make and comply with the certifications and assurances as indicated on the foregoing pages. I further affirm that, in my opinion, the certifications and assurances have been legally made and constitute legal and binding obligations on the Applicant.
I further affirm to the Applicant that, to the best of my knowledge, there is no legislation or litigation pending or imminent that might adversely affect the validity of these certifications and assurances, or of the performance of the project.
Signature _____
Name _____
Applicant's Attorney _____
Date: _____
Each Applicant for FTA financial assistance (except 49 U.S.C. 5312(b) assistance) and each FTA Grantee with an active capital or formula project must provide an Attorney's affirmation of the Applicant's legal capacity. The Applicant may enter its PIN in lieu of the electronic signature of its Attorney, provided the Applicant has on file this Affirmation of its Attorney in writing dated this Federal fiscal year.

[FR Doc. 01–1083 Filed 1–17–01; 8:45 am]
BILLING CODE 4910–57–P

Federal Register

Thursday,
January 18, 2001

Part IV

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317 and 381
Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products; Proposed Rule

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 98–005P]

RIN 0583–AC60

Nutrition Labeling of Ground or Chopped Meat and Poultry Products and Single-Ingredient Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. For these products, FSIS is proposing to make the guidelines currently in place for the voluntary nutrition labeling program mandatory. Thus, the Agency is proposing to require that nutrition information be provided for these products either on their label or at their point-of-purchase. During the most recent surveys of retail stores, the Agency did not find significant participation in its voluntary nutrition labeling program, which covers the major cuts of single-ingredient, raw products. Without nutrition information for these products, the Agency has tentatively concluded that the major cuts of single-ingredient, raw meat and poultry products would be misbranded under the Federal Meat Inspection Act and the Poultry Products Inspection Act.

FSIS is also proposing to amend its regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. Under existing regulations, multi-ingredient ground or chopped products, (*e.g.*, ground pork with seasonings), and heat processed ground or chopped products (*e.g.*, fully cooked or partially cooked patties) are required to be nutritionally labeled, unless they qualify for an exemption, but single-ingredient, raw ground or chopped products are not required to be so labeled. Without nutrition information for single-ingredient, raw ground or chopped products, the Agency has tentatively concluded that these products would be misbranded under the Federal Meat Inspection Act and the Poultry Products Inspection Act. The Agency has also tentatively determined that single-ingredient, raw ground or chopped meat and poultry products are different from other single-ingredient, raw meat and poultry products in several important respects. Thus, FSIS is proposing to make nutrition labeling requirements for all ground or chopped meat and poultry products consistent with those currently required for products in the mandatory nutrition labeling program (multi-ingredient and heat processed products).

FSIS is proposing to require nutrition labels on packages of single-ingredient, raw ground or chopped products, rather than at their point-of-purchase, largely because these products are similar to products in the mandatory nutrition labeling program (which requires nutrition information to be on the label of individual packages), in that certain parameters, such as their fat content, can be controlled precisely to obtain the desired product. Although FSIS believes that nutrition information on labels of individual packages of single-ingredient, raw products is useful, FSIS is proposing that nutrition information for the major cuts of single-ingredient, raw products may also be provided on point-of-purchase materials because FSIS believes that consumers have reasonable expectations as to the nutrient content of these products, the nutrient content of a specific major cut is relatively uniform across the market, and because these products are not formulated in the manner of ground or chopped products. For single-ingredient, raw products that are not major cuts and that are not ground or chopped, FSIS is not proposing to require nutrition information on their labels or at their point-of-purchase because FSIS has not yet assessed whether adequate nutrition information is being provided for these products and, therefore, has not determined whether it would be beneficial to require nutrition labeling for these products.

Finally, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the criteria to be labeled "low fat," a lean percentage claim may be included on the label or in labeling as long as a statement of the fat percentage also is displayed on the label or in labeling.

DATES: Comments must be received on or before April 18, 2001.

ADDRESSES: Submit one original and two copies of comments to FSIS Docket Clerk, Docket #98–005P, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW, Washington, DC 20250–3700. Reference material cited in the document and any comments received will be available for public inspection in the FSIS Docket Room from 8:30 a.m. to 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Post, Director, Labeling and Additives Policy Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0279.

SUPPLEMENTARY INFORMATION:

Background

The Current Mandatory and Voluntary Nutrition Labeling Programs

Mandatory nutrition labeling program. The Nutrition Labeling and Education Act (NLEA) of 1990 required nutrition labeling of most foods regulated by the Food and Drug Administration (FDA). FSIS published regulations establishing comparable nutrition labeling requirements for meat and poultry products. As explained in its proposed and final rules, FSIS determined that it had statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information, under section 1(n) of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601(n)(1)) and section 4(h)(1) of the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453(h)(1)) (56 FR 60305 and 58 FR 637). These statutory provisions state that a product is misbranded if it is false or misleading in any particular. FSIS published an advance notice of proposed rulemaking on nutrition labeling of meat and poultry products on April 2, 1991 (56 FR 13564), a proposed rule on November 27, 1991 (56 FR 60302), a final rule on January 6, 1993 (58 FR 632), and subsequently other amendments to the rule.

FSIS' regulations require nutrition labels on the packages of all multi-ingredient and heat processed meat and poultry products, unless an exemption applies. The required nutrition labeling provisions are referred to as "the mandatory nutrition labeling program." The regulations include exemptions from nutrition labeling requirements for food products produced by small businesses, products intended for further processing, products not offered for sale to consumers, products in small packages that are individually wrapped packages of less than ½ ounce net weight, custom slaughtered or prepared products, products intended for export, ready-to-eat products that are packaged

or portioned at a retail store or similar retail-type establishment, and multi-ingredient products processed at a retail store or similar retail-type establishment. The regulations also provide that nutrition labeling may be provided by alternate means for packages that have a total surface area available to bear labeling of less than 12 square inches; for these products, the regulations permit manufacturers to provide an address or telephone number on the package for consumers to write or call for nutrition information. Except for the nutrition labeling exemptions for custom slaughtered or prepared products and products intended for export, the exemptions from nutrition labeling requirements and the provision for alternate means of providing nutrition labeling on packages that have a limited surface area to bear labeling apply only when a product's labeling includes no nutrition claims or nutrition information. The regulations also state that restaurant menus generally do not constitute nutrition labeling or fall within the scope of the nutrition labeling regulations, and that foods represented or purported to be specifically for infants and children less than 4 years of age shall not include certain nutrient content declarations (see §§ 317.400 and 381.500).

The regulations specify the information that must be included on the labels of products in the mandatory nutrition labeling program. The required information includes the levels of total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, and certain vitamins and minerals in the product. In certain situations, information concerning some of these nutrients is not required. For example, the label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat per serving. The regulations also provide that information concerning stearic acid, polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, insoluble fiber, sugar alcohol, other carbohydrates, and calories from saturated fat may be included voluntarily. When claims related to these nutrients are made, or when certain related nutrients are declared, information concerning these nutrients is required.

The regulations require that the nutrient and food component quantities on the label of products in the mandatory nutrition labeling program be declared in relation to a serving. The regulations also require that the declaration of nutrient and food component content be on the basis of the product "as packaged"; in addition, the declaration of nutrient and food component content may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated. The regulations also prescribe format requirements for nutrient information, which include specified headings that must be used in the presentation of nutrition labeling information.

The regulations include provisions for Agency monitoring of compliance with the mandatory nutrition labeling requirements. FSIS conducts a continuous product sampling program to ensure compliance with nutrition labeling requirements (see §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8)).

Voluntary nutrition labeling program. In the preamble to the January 6, 1993, final rule, FSIS stated that it would not require nutrition labeling for single-ingredient, raw meat and poultry products because the nutrient values of these products are not modified through various stages of preparation, such as cooking and heat processing. Therefore, the Agency believed that consumers had reasonable expectations as to the nutritional qualities of these products (58 FR 637). In the preamble to the proposed rule, FSIS also stated that nutrition information for single-ingredient, raw products was available to consumers through other means such as the extension service, grocery stores, and trade associations (56 FR 60306). For these reasons, although the Agency adopted a mandatory nutrition labeling program for multi-ingredient products and heat processed products, it chose not to do so for single-ingredient, raw meat and poultry products, including single-ingredient, raw ground or chopped products. Instead, it established guidelines for voluntary nutrition labeling of these products (see §§ 317.345 and 381.445).

Under the voluntary nutrition labeling program, retailers and manufacturers are not required to provide nutrition information for single-ingredient, raw meat or poultry products. Instead, retailers and manufacturers voluntarily may provide nutrition information on the label of these products, or at their point-of-purchase by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. However, if a nutrition claim is made on these materials, all of the requirements of the mandatory nutrition labeling program apply.

If only nutrition information, and not a nutrition claim, is supplied on the point-of-purchase materials of single-ingredient, raw products, the requirements of the mandatory program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed basis"; the listing of percent of Daily Value for certain nutrients and the footnote explaining that the Daily Values are based on a 2,000 calorie diet and that daily values may differ depending on calorie needs (see §§ 317.309(d)(9) and 381.409 (d)(9)) may be omitted; and the point-of-purchase materials are not subject to any format requirements.

If, however, a retailer or manufacturer provides nutrition information on the label of single-ingredient, raw products, this information must be presented in the same format as that prescribed for mandatory nutrition labeling of various products. However, for these products, unlike products in the mandatory nutrition labeling program, the nutrition information may be declared on the basis of either "as consumed" or "as packaged." If the information is presented on the basis of "as consumed," the regulations provide that the methods used to cook the product must be specified and should be those which do not add nutrients from other ingredients (see §§ 317.345(d) and 381.445(d)). Also, unlike products in the mandatory program, the declaration of the number of servings per container need not be included on the nutrition label.

The regulations provide that the Agency will not conduct compliance sampling and testing of a product subject to the voluntary nutrition labeling program that contains nutrition labeling if the nutrition labeling is based upon the most current representative data base values contained in USDA's National Nutrient Data Bank or in its published form, the Agriculture Handbook No. 8 series, and if there are no nutrition claims made on the basis of the representative database values on the labeling of these products (§§ 317.309(h)(9), 317.345(e), 317.345(f), 381.409(h)(9), 381.445(e), and 381.445(f)).

The Agriculture Handbook No. 8 series is now out of print. The current released form of the USDA's National Nutrient Data Bank is the USDA Nutrient Database for Standard Reference. USDA's Nutrient Data Bank is the Agricultural Research Service's internal system that stores information and has features necessary to produce the released database. The USDA Nutrient Database for Standard Reference is developed and maintained by the Agricultural Research Service and can be found on the internet at the

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following address: http://www.nal.usda.gov/fnic/foodcomp.

The Agency may conduct sampling and testing for compliance with nutrition labeling requirements for single-ingredient, raw meat and poultry products if the nutrition information on their labeling is not based on the latest values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims made on the basis of the representative database values, on the labeling of these products.

Compliance with voluntary nutrition labeling guidelines. FSIS' regulations provide that the Agency monitor compliance with its voluntary nutrition labeling program guidelines by evaluating the participation of retailers in the voluntary program every two years, beginning in May 1995, to determine whether significant participation of at least 60 percent of all companies evaluated exists (§§ 317.343 and 381.443). FSIS stated that it would issue its first report of its survey findings on the voluntary program by May 1995, and that it would reevaluate every two years after 1995 whether significant participation existed in the voluntary nutrition labeling program (56 FR 60306).

FSIS regulations provide that a food retailer is participating at a significant level (1) if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products it sells; and (2) if the nutrition label on these products is consistent in content and format with the mandatory program, or if nutrition information is displayed at point-of-purchase in an appropriate manner. The regulations provide that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines. The regulations provide that the voluntary nutrition labeling program will remain in effect as long as there is significant participation in the voluntary program by retail stores (§§ 317.343 and 381.443).

FSIS contracted with an independent market research contracting firm to conduct the retail surveys in 1995, 1996, and 1999. For each of these surveys, the firm surveyed a nationally representative sample of approximately 2,000 retail stores to obtain the information necessary to assess compliance with the guidelines for voluntary nutrition labeling of single-ingredient, raw meat and poultry products.

The first survey to determine participation by retail stores in the voluntary nutrition labeling program was conducted in June 1995. At that time, the National Retail Tracking Index, Inc., found that 66.5 percent of the stores surveyed were providing nutrition information on 90 percent of the major cuts of single-ingredient, raw meat and poultry products. Therefore, this survey showed that significant participation in the voluntary nutrition labeling program existed. FSIS published a notice of availability of the survey results in the January 29, 1996 **Federal Register** (61 FR 2790). In this survey, stores were counted as participating in the voluntary nutrition labeling program if they used point-of-purchase materials developed by the Food Marketing Institute (FMI) prior to the 1993 final rule on nutrition labeling of meat and poultry products. These materials did not comply entirely with the voluntary nutrition labeling program provisions in the 1993 final rule. For example, the older materials did not include the required percent daily values for certain nutrients. Therefore, the results of this survey may overestimate participation in the voluntary nutrition labeling program.

The second survey was conducted in mid-December 1996. FSIS conducted it jointly with FDA. For this survey, the two agencies contracted with the firm that conducted the 1995 FSIS survey, now named Retail Diagnostics, Incorporated (RDI). At this time, RDI found that 57.7 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. The third survey was conducted in October 1999. At this time, RDI found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. Therefore, the two most recent surveys did not show significant participation in the voluntary nutrition labeling program, according to the voluntary nutrition labeling program regulations. Reports on the 1996 and 1999 surveys are available electronically on the FSIS web page at http://www.fsis.usda.gov.

Nutrient Content Claims

In addition to establishing the mandatory and voluntary nutrition labeling programs, the January 6, 1993, final rule provided definitions at §§ 317.362 and 381.462 for specific nutrient content claims, including the terms "lean" and "extra lean." The definitions of "lean" and "extra lean" provide that these terms may be used on the label or in labeling only if the product meets certain criteria (see §§ 317.362(e)(1) and (2) and 381.462(e)(1) and (2)). Meat products may be labeled "lean" if they contain less than 10 grams of fat, 4.5 grams or less of saturated fat, and less than 95 milligrams of cholesterol per 100 grams of product and per reference amount customarily consumed for individual foods. Meat products may be labeled "extra lean" if they contain less than 5 grams of fat, less than 2 grams of saturated fat, and less than 95 milligrams of cholesterol per 100 grams of product and per reference amount customarily consumed for individual foods. Ground beef and hamburger seldom meet the criteria that would allow producers to use the terms "lean" or "extra lean" on the label or in labeling of these products.

The existing nutrition labeling regulations also provide that the term "____ percent lean" is a synonym for the term "____ percent fat free," and that, in order for either term to be used on the label or in labeling of the product, the product must meet the criteria for "low fat" (§§ 317.362(b)(6) and 381.462(b)(6)). To meet the criteria for "low fat," a product must have a reference amount customarily consumed greater than 30 grams or greater than 2 tablespoons and must contain 3 grams of fat or less per reference amount customarily consumed for individual foods, or must have a reference amount customarily consumed of 30 grams or less or 2 tablespoons or less and must contain 3 grams or less of fat per reference amount customarily consumed and per 50 grams (§§ 317.362(b)(2) and 381.462(b)(2)). Most ground beef and hamburger do not qualify as "low fat." Therefore, existing regulations preclude the use of the term "____ percent lean" on these products.

On May 24, 1994 (59 FR 26916), FSIS published a proposed rule entitled "Nutrition Labeling of Ground Beef and Hamburger." In the preamble to the proposal, FSIS explained that the Agency had determined that, although the existing regulations precluded producers of ground beef and hamburger from using the terms "lean," "extra lean," and "____ percent lean," these products should be labeled to permit consumers to readily identify and differentiate between the varying lean to fat ratios in such products. The Agency also stated that allowing such labeling would assist consumers in selecting leaner versions of these products and would provide an incentive for manufacturers to market products lower in fat. Finally, FSIS recognized that many producers had been using lean percentages on the labeling of ground beef and hamburger products for a significant period of time (59 FR 26917).

Accordingly, FSIS proposed to amend its regulations to permit the use of percentage labeling for lean and fat on ground beef and hamburger products. Under this proposal, FSIS would have permitted a statement of the lean percentage on the labeling of ground beef and hamburger if it were contiguous to a statement of the fat percentage. The Agency would have allowed this labeling even when the ground beef or hamburger did not qualify as "low fat." The Agency proposed to allow the use of the statement of lean and fat percentages only if the product were accompanied by nutrition information presented on the label, or in point-of-purchase materials in close proximity to the product. FSIS stated that it would consider expanding the proposed percentage labeling to ground meat from other species and to ground poultry if information submitted during the comment period demonstrated the need and consumer acceptability of these terms for such products or that differential treatment of ground beef relative to other ground products would inappropriately restrict informed consumer choice (59 FR 26918).

The Agency received a total of 2,732 comments on this proposal. Fifty-five percent (1,504) of the commenters supported the proposal, 39 percent (1,063) opposed it, and 6 percent (165) addressed issues outside the scope of the proposed rule. Supporters of the proposal included trade associations representing food manufacturers and retailers, food manufacturers of both meat and poultry products, a large number of retailers, and State departments of agriculture. Supporters stated that percentage labeling provides useful information to consumers, that "lean labeling" aids consumers in selecting lower fat products, and that percentage labeling has been in use for more than 20 years. Opponents included consumer interest groups, health professionals and organizations, and consumers. They stated that the use of percent lean labeling is inherently misleading to consumers and will cause consumers to view ground beef as "lean" or "low fat."

Twenty-one of the 1,504 commenters who supported the provisions wanted them to also apply to other species or products. These commenters stated that allowing percentage labeling for lean and fat for other ground meat and poultry products, besides ground beef and hamburger, would allow consumers to compare the fat content of beef or poultry items and to make informed dietary choices.

On August 5, 1994, FSIS published a notice of extension of the date that it would enforce compliance with the nutrition labeling requirements for ground beef and hamburger (59 FR 39941). The Agency extended the compliance enforcement date for these products indefinitely, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger. The Agency has not published a final rule concerning percentage labeling of ground beef and hamburger. Therefore, producers and retailers continue to use the term "lean" in percentage labeling on the packages of ground beef and hamburger.

Other Nutrition Activities

In addition to developing this proposed nutrition labeling rule, USDA conducts numerous other activities related to nutrition. This proposed rule on nutrition labeling is an integral part of USDA's efforts to educate consumers concerning nutrition and diets. Since 1980 USDA and the Department of Health and Human Services (HHS) have jointly published the Dietary Guidelines for Americans every five years. The Dietary Guidelines provide advice concerning food choices that promote health and prevent disease. USDA and HHS released the Dietary Guidelines for Americans, 2000, at the National Nutrition Summit on May 30, 2000, which was jointly sponsored by USDA and HHS. The Dietary Guidelines for Americans, 2000, advises consumers to aim for a total fat intake of no more than 30 percent of calories (page 30). In addition, the Dietary Guidelines for Americans, 2000, includes a chart showing the recommended upper limits for grams of saturated fat and total fat per day for a range of total calories per day (page 30). The nutrition information that FSIS is proposing to require on labels of ground or chopped products and on either labels or point-of-purchase materials for the major cuts of single-ingredient, raw products would include the number of calories and the grams of total fat and saturated fat the product contains. The information FSIS is proposing to require would, therefore, assist consumers in following the advice in the Dietary Guidelines for Americans, 2000.

Proposed Changes

Nutrition labeling of the major cuts of single-ingredient, raw products. The Agency is proposing to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products, except for certain exemptions. For these products, FSIS is proposing to make the guidelines currently in place for the voluntary nutrition labeling program mandatory. Thus, for all of these products, other than raw ground beef and ground pork which are currently classified as major cuts, FSIS is proposing that nutrition information be provided on the label of these products or at their point-of-purchase. As discussed below, at this time, FSIS is not proposing to require nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped products.

In the preamble to the final rule on nutrition labeling of meat and poultry products, under the discussion of its voluntary nutrition labeling program which covered all single-ingredient, raw meat and poultry products, FSIS stated that it believed that it was important to provide nutrition information to consumers (58 FR 640). FSIS also stated that it believed that by allowing for the use of point-of-purchase materials for single-ingredient, raw meat and poultry products, retailers would be able to provide consumers with the necessary nutrition information (58 FR 640). FSIS continues to believe that nutrition information for these products is important and necessary.

In the two most recent surveys, FSIS found that significant participation in the voluntary nutrition labeling program does not exist. FSIS found that less than 60 percent of the stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products. In its proposed and final rules on nutrition labeling of meat and poultry products, FSIS stated that if it determined, during any evaluation of its voluntary guidelines, that significant participation did not exist, it would initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products (56 FR 60306, 58 FR 640).

Because the most recent surveys showed that significant participation in the voluntary nutrition labeling program does not exist, FSIS now believes that this proposed rule is necessary and that it would be beneficial to require the labeling of the major cuts of single-ingredient, raw meat and poultry products to bear nutrition information. FSIS believes that without nutrition information, consumers are not able to assess the nutrient content of the major cuts and thus cannot make educated

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choices about these products based on nutrition information. FSIS believes that the lack of this information on the labeling of the major cuts causes the labeling to be misleading. The FMIA and PPIA provide that product is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 601(n)(1) and 453(h)(1)). Therefore, without the nutrition information for the major cuts of single-ingredient, raw products that would be provided if significant participation in the voluntary program existed, the Agency has tentatively concluded that these products would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA. FSIS requests comments on whether consumers are currently able to assess the nutrient content of the major cuts and whether consumers are currently able to make educated choices about these products based on nutrition information.

If the guidelines currently in place for the voluntary nutrition labeling program are made mandatory, it would ensure that consumers are provided with necessary nutrition information concerning the major cuts. Therefore, the Agency is proposing to make mandatory for the major cuts of single-ingredient, raw meat and poultry products the current provisions for the voluntary nutrition labeling program for presentation of nutrition information on point-of-purchase materials.

FSIS intends to make point-of-purchase materials available over the Internet free of charge. The point-of-purchase materials reflecting the final nutrition labeling regulations that FMI developed show nutrition information in charts with columns covering multiple products. FSIS requests comments on whether the Agency should develop point-of-purchase materials that present nutrition information as a compilation of individual nutrition facts panels for each product or whether the nutrition information on the materials should be presented in charts with horizontal or vertical columns to cover multiple products.

Also, consistent with the existing provisions in the voluntary nutrition labeling program, the Agency is proposing to require that if nutrition information is provided on the label of individual packages of major cuts of single-ingredient, raw products, the current requirements of the mandatory nutrition labeling program will apply, but the nutrition information on the label may be declared either on the basis of "as consumed" or "as packaged."

FSIS is proposing to allow nutrition information on the label to be declared on the basis of "as consumed" without also requiring that the information on the label be declared on the basis of "as packaged" for the major cuts of single-ingredient, raw products because, as discussed below, most of these products will not need FSIS compliance scrutiny. Also as noted below, nutrition information for products under the existing mandatory nutrition labeling program must be provided on an "as packaged" basis for compliance purposes. Consistent with the existing voluntary nutrition labeling program, FSIS is proposing that the declaration of the number of servings per container need not be included on the nutrition label for the major cuts of single-ingredient, raw products. FSIS is not proposing to require that the number of servings per container be declared for the major cuts of single-ingredient, raw products because all of these products are random weight products, and the number of servings is not currently required on random weight products (see §§ 317.309(b)(10)(iii) and 381.409(b)(10)(iii)).

Although FSIS believes that nutrition information on labels of individual packages of single-ingredient, raw products is useful, FSIS is proposing that the nutrition information for the major cuts of single-ingredient, raw products may also be provided on point-of-purchase materials because, as stated in the 1993 rule, consumers have reasonable expectations as to the nutrient content of these products. Also, the nutrient content of a given major cut is relatively uniform across the market, and these products are not formulated in the manner of ground or chopped products. Therefore, FSIS believes it would be relatively easy to prepare point-of-purchase materials for the major cuts and relatively easy for consumers to find the nutrition information for a particular major cut on point-of-purchase materials. Although FSIS continues to believe that consumers have reasonable expectations as to the nutrient content of these products, FSIS also continues to believe that it is important to provide nutrition information to consumers, either through labels on packages or point-of-purchase materials. FSIS requests comment on whether consumers have reasonable expectations concerning the nutrient content of the major cuts of single-ingredient, raw products and on whether point-of-purchase materials are appropriate vehicles for conveying nutrition information for these products. FSIS specifically requests comment on whether it should require that nutrition labeling should be provided for these products on their label and, if so, on what basis it would require such labeling.

FSIS regulations provide that in evaluating whether there is significant participation in the voluntary nutrition labeling program, FSIS will consider only the major cuts of single-ingredient, raw meat and poultry products (§§ 317.343(a) and 381.443(a)). Consistent with the regulations, FSIS' voluntary nutrition labeling surveys only assessed whether nutrition labeling was provided for the major cuts of single-ingredient, raw meat and poultry products.

Examples of single-ingredient, raw products that are not major cuts (and that are not ground or chopped) include pork jowls, pigs feet, pork leg, pork shoulder picnic, and beef round rump. For single-ingredient, raw products that are not ground or chopped and are not major cuts, FSIS is not proposing that nutrition information must be provided. However, FSIS is proposing that if nutrition information is provided, it must be provided according to the existing guidelines for the current voluntary nutrition labeling program. Therefore, if nutrition information is provided for these products, it would be consistent with nutrition information for the major cuts of single-ingredient, raw products.

As the next step in the process of evaluating the need for nutrition labeling of meat and poultry products, FSIS will examine the current state of nutrition labeling for single-ingredient, raw products that are not ground or chopped and that are not major cuts. FSIS will assess whether adequate nutrition information is being provided for these products. Until this assessment is made, FSIS cannot determine whether it would be beneficial to require nutrition labeling for single-ingredient, raw products that are not ground or chopped and are not major cuts. Whether the labeling of these products should be required to bear nutrition information would depend on whether adequate nutrition information is being provided for them and, if it is not being provided, what the effect is of its not being available. If FSIS determines that adequate nutrition information is not being provided for these products, FSIS will consider whether to propose to require nutrition labeling for these products.

FSIS is proposing to revise the nutrition labeling regulations to clarify which provisions apply to nutrition labels on single-ingredient, raw products that are not ground or chopped, including the major cuts, and which provisions apply to point-of-purchase materials for these products. FSIS is proposing to revise the regulations so that the provisions for nutrition labels for these products are in §§ 317.309 and 381.409, and the provisions for point-of-purchase materials for these products are in §§ 317.345 and 381.445.

Nutrition labeling of ground or chopped products. The Agency is proposing to add new provisions at §§ 317.301 and 381.401, in the Federal meat and poultry product inspection regulations. In proposed § 317.301, FSIS is proposing to require that nutrition labels be provided for all ground or chopped (livestock species) and hamburger, with or without added seasonings, unless an exemption applies. In proposed § 381.401, FSIS is proposing to require that nutrition labels be provided for all ground or chopped (kind), with or without added seasonings, unless an exemption applies. Products that will have to bear nutrition labeling if this proposal is finalized include single-ingredient, raw hamburger, ground beef, ground beef patties, ground chicken, ground turkey, ground chicken patties, ground pork, and ground lamb. In this discussion, these products will be referred to as ground or chopped products. Ground or chopped products that are multi-ingredient products or heat processed products are already required to bear nutrition labeling, unless they qualify for an exemption. This proposed provision would extend the current mandatory nutrition labeling requirements to single-ingredient, raw ground or chopped products. The proposed provisions do not address sausages or other comminuted products. These products are typically multi-ingredient or heat processed products that are already required to bear nutrition information.

As discussed under the "Background" heading above, the existing regulations include exemptions from nutrition labeling requirements, such as an exemption for products produced by small businesses, custom slaughtered or prepared products, and certain products that are packaged, portioned or processed at retail. As discussed below under the "Exemptions" heading, most of these exemptions would apply to ground or chopped products that qualify for the exemptions. However, FSIS is proposing that the current exemptions from nutrition labeling for ready-to-eat products packaged or portioned at retail stores and similar retail-type establishments and for multi-ingredient products processed at retail stores and similar retail-type establishments not apply to ground or chopped meat and ground or chopped poultry products, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption. This issue is discussed further under the "Exemptions" heading below.

The terms "ground" and "chopped" are synonymous (see § 319.15). FSIS is proposing to use both terms because both are used in FSIS regulations and by industry. In the discussion below, any statements made regarding the nutrient values or the production of "ground" products would also apply to "chopped" products.

On June 3, 1997, the Center for Science in the Public Interest (CSPI) submitted a petition to FSIS stating that FSIS should require complete "Nutrition Facts" on ground beef labels that make nutrient content claims; should prohibit "% lean" claims on ground beef; should require ground beef to meet the same definitions of "lean" and "extra lean" that apply to other foods; and should require ground beef labels to replace "% lean" and "% fat" claims with the same "% less fat" claims used by other foods. CSPI also submitted information illustrating the variations in ground beef labels that include information on the lean or fat percentages of the product.

Consistent with CSPI's petition, the Agency has tentatively determined that nutrition information should be required on packages of all ground or chopped meat and poultry products, unless an exemption applies. FSIS is proposing to require this information even if there are no nutrient content claims on the label.

With regard to the statements in CSPI's petition concerning the use of "% lean," "lean," "extra lean," and "% less fat" claims on ground beef labeling, FSIS is not revising the regulations as the petitioner requested. As discussed below, FSIS is proposing to permit a statement of lean percentage on the label or in labeling of all ground or chopped meat and ground or chopped poultry products that do not meet the regulatory definition for "low fat" as long as a statement of the fat percentage is also provided, because consumers have become accustomed to this information, and because FSIS believes that this information provides a quick, simple, accurate means of comparing these products.

Unlike other single-ingredient, raw products, producers are able to formulate precisely the fat content of ground or chopped beef products. Therefore, in this respect, these products are similar to products in the existing mandatory program. The fat content of ground beef products can be formulated to range from under 6 percent to 30 percent. Below is a table that compares the nutrient values of three ground beef products that contain different levels of fat. All values are based on raw product.

Nutrient values per 100 g	Ground beef 17% fat	Ground beef 21% fat	Ground beef 27% fat
Calories	234	264	310.
Cholesterol	69 mg	75 mg	85 mg.
Fatty acids, saturated	6.8 g	8.3 g	10.8 g.

Source: USDA Nutrient Database for Standard Reference (1985 data)

FSIS believes that consumers cannot easily see the fat in ground or chopped beef. In ground or chopped beef products, the fat is uniformly distributed throughout the product and is not clearly distinguishable on the surface of the product. Therefore, consumers cannot estimate the level of fat in these products and cannot compare the levels of fat in these products to those in other products.

Fat is not the only factor that contributes to the nutrient variability of ground beef products. Producers sometimes use beef from advanced meat recovery (AMR) systems and low temperature rendering in ground or chopped beef products, which affect the nutrient variability of ground beef products. Product derived from low temperature rendering of beef tissue that is not fatty tissue, such as fat reduced beef or finely textured beef, is considered beef and can be used in ground or chopped beef or hamburger and other ground or chopped meat products. The regulations currently do not address the use of fat reduced beef or finely textured beef. FSIS may address the use of such products derived from low temperature rendering in a future rulemaking.

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An American Meat Institute (AMI) survey found that the use of product derived from AMR systems in ground beef was becoming more prevalent, although AMI did not obtain specific information concerning the volume of product from AMR systems (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 10). This survey also found that producers use product such as finely textured beef recovered via technology (a product derived from low temperature rendering) in ground beef products to achieve specific lean contents (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 11). It should be noted that beef from AMR systems is not used at retail, unless the retail establishment is grinding beef product produced at a Federal establishment. Ground beef produced at retail from a single cut of meat, such as ground chuck or ground round, would not typically include beef from AMR systems. However, ground beef produced at retail from trimmings produced at a Federal establishment could include beef from AMR systems.

Typically, meat from AMR systems does not comprise more than 10 percent of ground meat products, including ground beef (R.A. Field, "Bone Marrow Measurements for Mechanically Recovered Products from Machines that Press Bones," *Meat Science* 51 (1999): 206). Similarly, meat from low temperature rendering usually does not comprise more than 10 percent of ground products, including ground beef. However, because beef from AMR systems or low temperature rendering generally has higher levels of cholesterol, iron, and calcium than other beef, the use of these types of beef in ground beef products can affect the nutrient content of these products. The table below shows the percentage fat and the levels of iron and calcium per 100 grams of product for regular ground beef, for beef from AMR systems, and for product made from 90 percent regular ground beef and 10 percent beef from AMR systems. For regular ground beef and for beef from AMR systems, the table shows values from different studies (R.A. Field, "Bone Marrow Measurements for Mechanically Recovered Products from Machines that Press Bones," *Meat Science* 51 (1999): 206, 209). FSIS calculated the nutrient values for product comprised of 90 percent ground beef and 10 percent AMR product based on the values from the studies. FSIS calculated values for product made from 90 percent ground beef and 10 percent AMR product because, as stated above, typically meat from AMR systems does not comprise more than 10 percent of ground meat products. All values shown below are based on raw product.

Nutrient values per 100 grams	Regular ground beef (Anderson et al., 1986)	Beef from AMR (Hasiak and Marks, 1997)	Beef from AMR product (Leising, 1997)	Ground beef, 10% AMR product (Hasiak and Marks)	Ground beef, 10% AMR product (Leising)
Cholesterol	85 mg	115 mg	102 mg	88 mg	86.7 mg
Iron	1.7 mg	2.8 mg	5.6 mg	1.81 mg	2.09 mg
Calcium	8 mg	108 mg	115 mg	18.0 mg	18.7 mg

Even if producers do not use beef from AMR systems or beef derived from low temperature rendering, they are able to precisely control the amount of fat in the beef that is ground or chopped to create packages of ground or chopped beef. A study concerning testing for the fat content of ground beef found that, using two testing methods, ground beef formulated for a certain fat percentage varied by only 2 percentage points around the average fat percentage. Although this study found some problems concerning blending of ground beef and testing for the fat content in ground beef, its results show that the product can be and is precisely formulated and within the control of the producer (Robert Campbell, "Ground Beef Testing: Determining Fat Content and Distribution," *Meat and Poultry* (October, 1997): 67–69). Many ground beef producers have quality control programs to control the fat content of their product. These producers conduct regular sampling and testing for fat in ground beef products. Thus, producers are able to formulate these products to control the amount of fat in them more precisely than the fat can be controlled in other cuts. Other single-ingredient, raw products cannot be formulated in this manner or to this degree.

Although ground beef comprises the majority of ground meat products sold at retail, products such as ground lamb and ground pork are also available. Similar to ground beef products, these products may contain varying amounts of fat and varying nutrient content, which consumers cannot visually detect. In addition, ground pork may include product from AMR systems or from low temperature rendering, which may affect the nutrient content of these products. Therefore, FSIS is proposing to require nutrition labeling on these products and other ground or chopped meat products. As noted above, meat from AMR systems or low temperature rendering typically does not comprise more than 10 percent of ground meat products, including ground pork. Product from AMR systems or low temperature rendering is generally not used in ground or chopped lamb. Because products such as ground pork and ground lamb may contain varying amounts of fat and nutrient content, which consumers cannot visually detect, and because ground pork may include product from AMR systems or low temperature rendering, FSIS is proposing to require nutrition labeling on all ground or chopped meat products.

The fat-to-lean content of ground poultry products does not vary as greatly as that of ground beef products; however, the fat content of ground poultry can vary depending upon whether the product is ground light or dark meat, and whether the product includes poultry skin. As with the fat on ground meat products, consumers cannot readily detect the fat content of ground poultry products. The table below shows values for light and dark turkey meat, with skin and without skin. All values are based on raw product. The nutrient content of ground turkey would vary depending on which types of meat were used to produce the product.

Nutrient values per 100 grams	Turkey, dark meat and skin	Turkey, dark meat only	Turkey, light meat and skin	Turkey, light Meat only
Calories	172	130	165	116

Nutrient values per 100 grams	Turkey, dark meat and skin	Turkey, dark meat only	Turkey, light meat and skin	Turkey, light Meat only
Cholesterol	65 mg	62 mg	62 mg	58 mg
Fatty acids, saturated	2.99 g	1.64 g	2.19 g	.53 g

Source: USDA Nutrient Database for Standard Reference (1985 data)

Because the characteristics of ground or chopped poultry are similar to those of ground or chopped meat, FSIS is also proposing to require nutrition labeling on ground or chopped poultry products. The Agency is also proposing comparable requirements for ground or chopped meat and poultry products because it is committed to equitable treatment of meat and poultry products. FSIS has consistently taken the position that similar products should be regulated in a similar manner to facilitate consumers' ability to make comparisons among these products.

For the reasons discussed above, the Agency has tentatively concluded that ground or chopped meat and poultry products that do not bear nutrition information would be misbranded under section 1(n)(1) of the FMIA and section 4(h)(1) of the PPIA. As noted above, in the January 6, 1993 final rule, the Agency did not require nutrition labeling on packages of single-ingredient, raw meat and poultry products because FSIS believed that consumers had reasonable expectations as to the nutritional qualities of such products since they are not modified through various stages of preparation, such as cooking and heat processing (58 FR 637). FSIS now believes that the variation in the fat and nutrient content of different ground or chopped products, the formulated nature of these products, and the fact that the fat content of these products cannot be readily visually assessed makes it difficult for consumers to have a reasonable expectation as to the nutritional quality of these products. Further consideration of the issues raised in the petition from CSPI brought many of these issues to FSIS' attention. If this proposal is adopted, the existing mandatory nutrition labeling provisions in §§ 317.309 and 381.409 would apply to these products, unless they are subject to an exemption.

Although current labeling on ground beef products often includes information concerning the percentage of fat in the product, as noted in the CSPI petition, without complete nutrition labeling, consumers cannot easily determine the amount of fat per serving of ground beef. Also, without complete nutrition labeling, consumers cannot assess how much saturated fat, cholesterol, protein, or calories the product contains. Furthermore, consumers cannot easily compare fat percentages on the labeling of ground beef products with the information concerning grams of fat per serving or with the information concerning the percent daily values that is found on the labeling of products that are currently covered by the mandatory nutrition labeling program.

The Agency tentatively concludes that information concerning the nutritional qualities of ground or chopped meat and poultry products is particularly important because these products, especially ground beef, are widely consumed. Pertinent nutrition information is integral to consumer purchase decisions because use of this information may result in prevention of health problems and reduction of health risks for some consumers. Additional information about the nutrient values of ground or chopped meat and poultry products would enable consumers to make informed decisions about including these products in their diets and, therefore, will help consumers to construct healthy diets.

FSIS is proposing to require that nutrition information for ground or chopped meat and poultry products appear on the label of these products (unless an exemption applies), as is required for other products in the current mandatory nutrition labeling program, rather than on point-of-purchase materials. Ground or chopped products are similar to products in the mandatory nutrition labeling program, which requires nutrition information to be on the label of products, in that certain parameters, such as their fat content, can be controlled precisely to obtain the desired product. In addition, because there are numerous formulations of ground or chopped products, it would be difficult for producers or retailers to develop point-of-purchase materials that would address all the different formulations that exist for these products. Furthermore, it would be difficult for consumers to find the correct information for a specific ground or chopped product on point-of-purchase materials that include information concerning numerous formulations of these products. For these reasons, FSIS tentatively concludes that nutrition information should be required on the label of these products, consistent with the requirements in the existing mandatory nutrition labeling program. FSIS requests comments concerning whether nutrition information should be required on individual packages of ground or chopped product or whether the information should be allowed at their point-of-purchase.

In addition, consistent with requirements for products that fall under the existing mandatory nutrition labeling program, FSIS is proposing that the declaration of nutrient and food component content for ground or chopped products be required on an "as packaged" basis. The preamble to the final rule explained why products in the mandatory nutrition labeling program would be required to be labeled on an "as packaged" basis: "There are varieties of cooking methods that affect the nutrient values of food products differently. Therefore, there is no method to assure the accuracy or measure compliance of the nutrient values of food labeled on an 'as consumed' basis." (58 FR 648). These reasons for requiring nutrition information on an "as packaged" basis for products in the current mandatory nutrition labeling program also are the basis for requiring that ground or chopped products be required to be labeled on an "as packaged" basis. Whether or not the fat is drained off during the cooking of ground or chopped products would affect the nutrient values of ground or chopped products. As discussed below, ground or chopped products will be subject to FSIS compliance. Therefore, FSIS tentatively concludes that it is necessary to require that nutrition information be presented on an "as packaged" basis for ground or chopped products in order to assure the accuracy of nutrient values and to measure compliance of the nutrient values of these products. FSIS requests comment on whether it would be difficult for producers to comply with this requirement.

However, consistent with the provisions of the existing mandatory program, FSIS is proposing that nutrition information for ground or chopped products may be presented on an "as consumed" basis, in addition to the required "as packaged" basis, provided that preparation and cooking instructions are clearly stated. FSIS is proposing to allow nutrition

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information on as "as consumed" basis, in addition to the required "as packaged basis," because FSIS believes this is useful information for consumers.

FSIS requests comments on whether all Federal establishments and retail stores are able to control the fat and nutrient content of ground or chopped meat and poultry products. FSIS also requests comment on the practices of retail stores that grind or chop meat and poultry. FSIS is interested in whether retail stores that grind or chop product mix trimmings from one Federal establishment with trimmings from other Federal establishments. In addition, FSIS is interested in data on the extent to which product from AMR systems or product from low temperature rendering is used in ground or chopped products.

FSIS requests comments concerning whether consumers have reasonable expectations as to the nutritional quality of ground or chopped product, whether consumers know which ground or chopped products are lowest in fat, whether consumers understand that the fat content of ground or chopped product can affect other nutrients, whether consumers can see the fat in ground or chopped meat and poultry products, and whether consumers can make comparisons among ground or chopped products and other products.

Exemptions

Under §§ 317.400(a)(1) and 381.500(a)(1), food products produced by small businesses are exempted from mandatory nutrition labeling if the product labels bear no nutrition claims or nutrition information. The regulations provide that a small business is any single-plant facility or multi-plant company or firm that employs fewer than 500 people and, as of July 1996, that produces 100,000 pounds or less annually of the product that qualifies the establishment for the exemption from mandatory nutrition labeling. The Agency stated in the preamble to the January 6, 1993, final rule, that it would exempt small businesses from mandatory nutrition labeling requirements because these requirements would create undue economic hardship for small businesses and would create disincentives for these small businesses to develop more nutritious food products (58 FR 638).

For the reasons stated in the January 6, 1993 final rule, FSIS continues to believe that small businesses should be exempt from the mandatory nutrition labeling requirements proposed for ground or chopped meat and ground or chopped poultry products. Therefore, under this proposal, ground or chopped products produced by establishments that qualify for the small business exemption would be exempt from the proposed nutrition labeling requirements.

As discussed below, a significant amount of ground beef is processed at retail. Therefore, FSIS is proposing to revise the regulations to make clear that a single retail store or multi-retail store operation could qualify for the small business exemption. To qualify for this exemption, the retail facility must either be a single retail store that employs 500 or fewer people or a multi-retail store operation that employs 500 or fewer people. In addition, to qualify for the exemption, the retail establishment could produce no more than 100,000 pounds per year of the product that qualifies the establishment for an exemption. Consistent with existing regulations, the qualification of a multi-retail store operation for an exemption from nutrition labeling would be based upon its total annual production of the product for all of its stores that qualifies the operation for the exemption and the total number of employees for all of its stores (see 58 FR 638 for guidance on existing regulations).

As under current regulations, for the purposes of the small business exemption, a food product is a formulation, not including distinct flavors which do not significantly alter the nutritional profile of the product, sold in any size package in commerce. Therefore, ground or chopped products formulated to have different levels of fat would be considered different food products for purposes of the small business exemption. For example, if a multi-retail store operation employed 500 or fewer people in total and produced, in total among all of its stores, 70,000 pounds of ground beef that is 10 percent fat and 60,000 pounds of ground beef that is 20 percent fat annually, the multi-retail store operation would not be required to include nutrition information on the label of these specific products if the labels for these products bore no nutrition claims or nutrition information. However, for example, if a multi-retail store operation employed in total 500 or fewer employees and produced 130,000 pounds of 10 percent fat ground beef annually in total among all of its stores, it would not be exempt from nutrition labeling requirements on the basis of the "small business exemption." FSIS is interested in comments on whether the exemption proposed is appropriate for purposes of ground or chopped products produced at retail establishments.

FSIS does not believe that the reasons that necessitated the establishment of the small business exemption, as explained in the January 6, 1993 final rule, are applicable to the major cuts of single-ingredient, raw meat and poultry products produced by small businesses. For these products, FSIS is proposing that nutrition information may be provided on labels or alternatively at their point-of-purchase. FSIS intends to make point-of-purchase materials available over the Internet free of charge; therefore, the proposed nutrition labeling requirement for major cuts of single-ingredient, raw products should not impose an economic hardship for small businesses, including those that are retail stores. FSIS is proposing to revise §§ 317.400(a)(1) and 381.500(a)(1) to provide that the small business exemption would not apply to the major cuts of single-ingredient, raw products.

Under existing §§ 317.400(a)(7) and 381.500(a)(7), retail stores and similar retail-type establishments are exempted from nutrition labeling requirements for multi-ingredient products processed at retail establishments and ready-to-eat products packaged or portioned at retail establishments (which would include ready-to-eat and multi-ingredient ground or chopped products) if the products bear no nutrition claims or nutrition information. As stated in the preamble to the January 6, 1993 final rule, FSIS exempted retail establishments from mandatory nutrition labeling requirements for these products because the Agency determined that it would be impractical to enforce nutrition labeling requirements on these products prepared or served at retail, and because the Agency concluded, based on a review of National Food Consumption Survey (NFCS) data, that the average person's diet consisted of an insignificant proportion of ready-to-eat retail packaged products or retail processed products (58 FR 639).

Most ground poultry is processed and packaged outside retail establishments. However, most ground beef is ground and packaged at retail. An AMI report states that retail survey respondents reported that an average 18.5 percent of their ground beef sales was from product arriving in a finely ground state, ready to sell or ready for repackaging at retail. Retail stores or distribution centers ground or re-ground 81.3 percent of ground beef sold (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 7).

As noted above, in the preamble to the January 6, 1993, final rule, the Agency concluded that the average person's diet consists of an insignificant portion of ready-to-eat retail packaged products or retail processed products. Consumers who purchase ground beef likely consume a significant amount of ground beef processed at retail. Therefore, there may be a significant amount of ground beef products that are ready-to-eat retail packaged products or retail processed products.

As noted above, in the January 6, 1993 final rule, FSIS also exempted retail establishments from mandatory nutrition labeling partly because the Agency determined that it would be impractical to enforce nutrition labeling requirements on products prepared or served at retail. The Agency no longer believes enforcement of nutrition labeling requirements at retail stores to be impractical because FSIS is already conducting testing for *Escherichia coli* O157:H7 at retail.

Because a significant amount of ground beef is processed at retail, the Agency believes that there may be a significant amount of multi-ingredient ground beef retail processed products or ready-to-eat retail packaged products. FSIS also believes that enforcement of nutrition labeling at retail would not be impractical. Further, FSIS has tentatively concluded that ground or chopped products that do not include nutrition information would be misbranded for the reasons stated above. Therefore, the Agency is proposing that the current exemptions from nutrition labeling for ready-to-eat products packaged or portioned at retail stores and similar retail-type establishments and multi-ingredient products processed at retail stores and similar retail-type establishments not apply to ground or chopped meat and ground or chopped poultry products, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption. FSIS requests comments and data on the volume of ground or chopped products that are multi-ingredient retail processed products or ready-to-eat retail packaged products.

FSIS is also proposing to revise the current retail exemptions discussed above to make clear that if a retail establishment qualifies for the small business exemption discussed above, ground or chopped ready-to-eat products packaged or portioned at retail and ground or chopped multi-ingredient products processed at retail would be exempt from nutrition labeling requirements. Although most ground poultry is processed and packaged outside retail establishments, FSIS believes it is important to propose consistent requirements for all ground or chopped products. Therefore, for all ground or chopped products, including ground poultry, these exemptions would not apply, unless the retail store or similar retail-type establishment meets the requirements of the small business exemption.

The exemptions for ready-to-eat products packaged and portioned at retail stores and for multi-ingredient products processed at retail stores would not apply to the major cuts of single-ingredient, raw products because they are not ready-to-eat or multi-ingredient products.

As discussed above, in addition to the small business and retail exemptions, existing §§ 317.400 and 381.500 provide other exemptions from nutrition labeling requirements. These exemptions include products intended for further processing, products not for sale to consumers, products in small packages that are individually wrapped packages of less than ½ ounce net weight, custom slaughtered or prepared products, and products intended for export. To qualify for the first three exemptions, the product's label cannot bear nutrition information or a nutrition claim. In the preamble to the January 6, 1993, final rule, FSIS explained that it was providing an exemption for products intended for further processing and products not for sale to consumers because consumers do not see the nutrition information on products used for further processing or products that are not for sale to consumers. The Agency also explained that it would exempt individually wrapped packages of less than ½ ounce net weight, provided no nutrition claim or nutrition information was made on the label, because these products are an insignificant part of the diet. With regard to the custom exemption, the Agency explained that an exemption should apply because these custom services are performed solely for individuals. Finally, the Agency explained that products intended for export should be exempt because these products are labeled according to the requirements of the country where the product is to be exported (58 FR 639). The Agency has tentatively determined that the bases for these exemptions, as explained in the January 6, 1993 final rule, are valid as applied to nutrition labeling for ground or chopped products and for major cuts of single-ingredient, raw products. Therefore, under this proposal, any ground or chopped product or major cut of single-ingredient, raw product that qualifies for any of these exemptions will continue to be exempt even if the proposed nutrition labeling requirements are adopted.

Under current regulations, products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided the product's labeling includes no nutrition claims or nutrition information and provided that an address or telephone number that a consumer can use to obtain the required information is included on the label. FSIS allowed for nutrition information to be provided by alternative means for products of this size in order to incorporate sufficient flexibility in the regulations (58 FR 47625). For ground or chopped products, FSIS believes it is necessary to provide this flexibility for products in packages that have a total surface area available to bear labeling of less than 12 square inches, provided that the labels for these products bear no nutrition claims or nutrition information. However, because nutrition information for the major cuts of single-ingredient, raw meat and poultry products may be provided on point-of-purchase materials, FSIS is proposing that the provisions for providing nutrition labeling by alternate means for products in packages that have a total surface area available to bear labeling of less than 12 square inches would not apply to the major cuts of single-ingredient, raw meat and poultry products.

As stated in the existing regulations, restaurant menus generally do not constitute labeling or fall within the scope of these regulations. Likewise, restaurant menus that include ground or chopped products generally do not constitute nutrition labeling or fall within the scope of these regulations. Similarly, although a restaurant menu would most likely not include a major cut of single-ingredient, raw product, if it did, the menu would not fall within the scope of these regulations.

Finally, the current regulations provide that foods represented or purported to be specifically for infants and children less than 4 years of age must not include certain nutrient content declarations, because infants and children less than 4 years of age have different nutrition needs than adults and children older than 4 years of age. Under this proposal, any ground or chopped product or major cut of single-ingredient raw product represented or purported to be specifically for infants and children less than 4 years of age would be required to meet these same requirements.

FSIS requests comments on whether its proposed revisions to the nutrition labeling exemptions are appropriate and

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necessary for ground or chopped products and for the major cuts of single-ingredient, raw products.

Enforcement and Compliance

Ground or chopped products. FSIS conducts a continuous sampling program of products that fall under the mandatory nutrition labeling program. If the proposal to mandate nutrition labeling of ground or chopped meat and ground or chopped poultry products is adopted, the procedures set forth for product sampling and nutrient analysis in §§ 317.309(h)(1)–(8) and 381.409(h)(1)–(8) will be applicable to ground or chopped meat and to ground or chopped poultry products, respectively. Under this proposal, the Agency will sample and conduct nutrient analysis of ground or chopped products to verify compliance with nutrition labeling requirements, even if nutrition labeling on these products is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference and there are no claims on the labeling. Therefore, if these proposed provisions for ground or chopped meat and poultry products are adopted, the Agency will treat these products as it treats all other products for which regulations already require nutrition labels on their package.

FSIS is proposing that ground or chopped products be subject to compliance even if nutrition labeling on these products is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference because the fat content of different ground or chopped products can vary significantly, depending upon the level of fat in the product being ground and depending on whether product from advanced meat recovery systems is used. Additionally, at this time, there are a limited number of ground or chopped products in the database (*e.g.*, ground beef, 17% fat, 21% fat, and 27% fat).

Further, FSIS program employees cannot visually assess whether nutrition information on the label of ground or chopped products accurately reflects the labeled products' contents because, in most cases, it is not possible to visually assess the level of fat in a ground product. For example, FSIS program employees cannot visually determine whether product that is labeled 17 percent fat ground beef is actually 17 percent fat ground beef as opposed to 27 percent fat (or another percentage of fat) ground beef. Therefore, even if the retailer or other producer uses information from the USDA database to label these products, FSIS will need to conduct compliance sampling and nutrient analysis to ensure that the information on the label accurately reflects the nutrient content of the labeled products.

The Agency is also proposing to revise §§ 317.345(e) and 381.445(e) so that they refer to USDA's National Nutrient Data Bank and its released form, the USDA Nutrient Database for Standard Reference, and to remove current references to the Agriculture Handbook No. 8 series, because this handbook series is now out of print.

For the nutrition labeling of some ground or chopped meat or ground or chopped poultry, nutrient data may be immediately available through the USDA Nutrient Database for Standard Reference (*e.g.*, ground beef with 17 percent fat, ground beef with 21 percent fat, and ground beef with 27 percent fat). Private databases may be available to assess the nutrient content of other products. In addition, producers are able to provide the nutrition information for many products produced to meet purchase specifications. Because producers know the different cuts of meat that go into ground or chopped product, they have the information necessary to determine the nutrient content of the products. FSIS believes that if they need to conduct nutrient analysis, the analysis should not impose an excessive burden. FSIS will develop a list of published sources of information concerning the nutrient content of ground or chopped products, so that industry could obtain available literature from local libraries. This information would facilitate the development of nutrition labels for ground or chopped products. FSIS requests comments and supporting data on the costs that Federal and retail establishments would incur for conducting nutrient analysis of ground or chopped products.

For ground or chopped products that are nutritionally labeled at official establishments, FSIS program employees will collect samples for nutrient analysis at official establishments, consistent with the Agency's existing sampling program of products that fall under the mandatory nutrition labeling program. For ground or chopped products that are produced and nutritionally labeled at retail, it is likely that FSIS program employees will collect samples for nutrient analysis while they are conducting other program activities at retail stores. When collecting samples for nutrient analysis, FSIS will not typically collect samples of the same product from both Federal establishments and retail establishments, unless circumstances warrant sampling the same product at both locations. In general, if a product from a Federal establishment is further processed at retail, FSIS would only collect samples of that product at retail, where it would be packaged for sale to consumers. FSIS can distinguish between product packaged at retail versus product packaged at a Federal establishment.

Major cuts of single-ingredient, raw products. If nutrition labeling of the major cuts of single-ingredient, raw products (other than ground beef or ground pork) is based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, FSIS will not sample and conduct a nutrient analysis of these products. The Agency's sampling and testing policy for these products will be consistent with its policy under the current voluntary nutrition labeling program for these products.

For the major cuts of single-ingredient, raw products, FSIS personnel can visually identify the particular cut. If the nutrition information for these products is based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, and there are no nutrition claims on the labeling, it is not necessary for FSIS to verify the accuracy of this data because it is USDA data. If the nutrition information is based on USDA data, and there are no nutrition claims, FSIS program employees would only have to verify that the data presented accurately pertains to a particular major cut of single-ingredient, raw product. Therefore, FSIS does not need to conduct nutrient analysis for these products.

If the nutrition information on the label or at the point-of-purchase of major cuts of single-ingredient, raw products is based on databases other than the above referenced USDA ones or other data, or if there are nutrition claims on the labeling, these products would be subject to FSIS compliance analysis. Most nutrition information for the major cuts of single-ingredient, raw products is based on USDA data and, typically, no nutrition claims are made on the labeling of these products. Therefore, these products are and would generally continue to be exempt from the FSIS nutrition labeling compliance verification program.

It is likely that FSIS program employees will verify that nutrition information is provided for the major cuts of single-ingredient, raw products, either on their labels or at their point-of-purchase, at retail stores while they are conducting other program activities at retail. If nutrition information on the point-of-purchase materials or labels for these products is not based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims on the labeling, FSIS program employees may collect samples of the major cuts from retail stores for nutrient analysis. Similarly, if major cuts are nutritionally labeled at official establishments and the nutrition information on the label is not based on USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference, or if there are nutrition claims on the labeling, FSIS program employees may collect samples of these products from the official establishment for nutrient analysis.

Percentage Labeling

FSIS is withdrawing its proposed rule of May 24, 1994 (59 FR 26916), discussed above, which sought to amend the regulations by permitting percentage labeling for lean and fat on ground beef and hamburger, when the product did not meet the regulatory criteria established for "low fat," if the product had nutrition information on its labeling or in point-of-purchase materials that were in close proximity to the product. FSIS is withdrawing this proposal and proposing revised percentage labeling requirements in this rule. In this proposal, FSIS is expanding the categories of ground or chopped products that can have lean percentage labeling.

FSIS is proposing to permit a statement of lean percentage on the label or in labeling of ground or chopped meat and poultry products that do not meet the regulatory criteria for "low fat." The Agency is proposing to do so because many consumers have become accustomed to this labeling on ground beef products, and because FSIS believes this labeling provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. The proposed regulatory language requires that a statement of fat percentage be contiguous to, in lettering of the same color, size and type as, and on the same color background as, the statement of lean percentage. The Agency is proposing these requirements concerning size, type, and color to ensure that the statement of the fat percentage is as clear and readily observable as the statement of the lean percentage.

FSIS requests comments on whether percent fat/percent lean information provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. Also, FSIS is specifically requesting comments concerning whether its proposed percent fat/percent lean labeling provisions for ground or chopped meat and ground or chopped poultry products that do not meet the regulatory criteria for "low fat" would be misleading in any way. FDA's regulations do not provide for the nutrient content claim, "X percent lean." Similarly, FDA does not allow a statement of "percent fat/percent lean" on the products it regulates. FSIS requests comment on whether these discrepancies between FDA's and FSIS' regulations will cause confusion among consumers. Finally, FSIS is not requiring the statement of fat percentage to precede the statement of lean percentage but will allow the statements to appear in either order. FSIS requests comment on whether consumers are more likely to read and understand the statement of fat percentage when it precedes the statement of lean percentage than when it follows the statement of lean percentage.

Executive Order 12866—Preliminary Analysis

This action has been reviewed for compliance with Executive Order 12866. As this action is determined "significant" for purposes of Executive Order 12866, the Office of Management and Budget (OMB) has reviewed it.

Need for the Rule

During the 1996 nutrition labeling survey, RDI found 57.7 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. In the 1999 nutrition labeling survey, RDI found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. Therefore, the most recent surveys did not show significant participation in the voluntary nutrition labeling program as defined in the regulations. Without significant participation, the Agency has tentatively concluded that a lack of consistent and complete nutrition information for the major cuts of single-ingredient, raw products exists. FSIS has also tentatively concluded that producers' ability to control the formulation of single-ingredient, raw ground or chopped products results in variations across these products that may be difficult for consumers to detect. Without nutrition information, FSIS believes that these products would be misbranded under section 1(n) of the FMIA or section 4(h) of the PPIA and that further action is necessary in order to provide consumers with adequate nutrition information that is consistent with the provisions of the 1993 final nutrition labeling rule.

Baseline

In the analysis below, FSIS assumes that the level of voluntary labeling, absent any Federal action, would remain at the current level. The 1999 RDI nutrition labeling survey found that 54.8 percent of the stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines. As there has been little change in the level of compliance over the last several years (see discussion of previous surveys above), FSIS believes that it is appropriate to assume that this level of participation in the voluntary nutrition labeling program would not change unless the regulations are revised.

In the analysis below, FSIS also assumes that 80 percent of the retail establishments and processors have made investments in the equipment necessary to print, stamp, or affix nutrition labels on products. This assumption is based on the results of the 1999 RDI safe handling labeling compliance survey. This survey revealed that 96.7 percent of large chains, 90.5 percent of large independent retailers, and 84.1 percent of medium/small independents had already complied with the Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products final rule. FSIS used the 80 percent assumption in order to be conservative and not overestimate the percentage of processors and retailers that have already invested in the necessary equipment. Because the equipment needed to print, stamp, or affix nutrition labels is similar to the equipment used to print, stamp, or affix labels to meet the "safe handling" rule's requirements, FSIS assumes that 80 percent of establishments would not have to install new machines for stamping, printing, or affixing nutrition labels for ground or chopped products. FSIS is assuming that the same percentage of processors have invested in this equipment as retailers. Again, this is a conservative assumption. FSIS requests comments concerning whether the 80 percent

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estimate is appropriate for both processors and retailers.

To determine how many entities would be affected by this rulemaking, the Agency used a combination of FSIS developed databases and industry sources. Table 1 indicates that in 1999, 63 establishments produced ground poultry and 2,426 establishments produced ground meat. FSIS developed this data on establishments from its Enhanced Facilities Database (EFD). This source does not provide separate data for ground pork, lamb and beef. The number of establishments producing ground pork or lamb is, however, likely to be very small based on information from the AMI survey discussed below in the preliminary cost analysis. One plant that produced either meat or poultry and did not have employment size specification is excluded from Table 1.

TABLE 1.—SIZE DISTRIBUTION OF MEAT AND POULTRY HACCP PLANTS PRODUCING GROUND PRODUCTS

	Poultry	Meat	Total
Very Small	10	1,470	1,480
Small	23	843	866
Large	28	68	96
Missing Values	2	45	47
Total	63	2,426	2,489

Note: Very small=9 or less employees; small=10 to 499 employees; large=500 or more employees.

FSIS believes that a significant amount of ground beef is processed at retail. Table 2 shows the number of retail stores in 1999. Most of these stores grind beef. However, FSIS does not have specific data concerning the levels of ground beef ground at retail or on the size of retail stores that process ground beef. FSIS researched Census data for this information, but specific information related to retail establishments processing ground or chopped product was unavailable. Table 2 reports data from FMI. FSIS combined the first two categories of supermarkets with sales in excess of $2 million per year to compare their share with "other stores" with sales of less than $2 million per year. In 1999, there were 127,000 retail grocery stores.

TABLE 2.—NUMBER OF RETAIL GROCERY STORES, 1999

	1999 number	1999 % of total
Total	127,000	100
Supermarket Chains & Independent	31,500	25
Other Stores	37,200	29
Convenience Stores	57,500	45
Wholesale Clubs	800	0.6

Note: "Supermarkets" are defined to have sales of $2 million or more per year. "Other Stores" are defined to have sales of under $2 million.

Source: FMI Information Service, *Progressive Grocer, 67th Annual Report of the Grocery Industry*. April 2000, p.20.

With respect to consumers, FSIS assumes that without further action, they would have access to the current level of labeling information and continue with their current dietary habits. The 1999 RDI survey estimated that nutrition labeling, in accordance with the program guidelines, for the major cuts of single-ingredient, raw meat and poultry products was available to 62.8 percent of shoppers. This estimate was based on the sales volume of the stores surveyed. Consistent with the Agency's assumption about compliance among retail stores, FSIS assumes that this level of available nutrition information, in accordance with program guidelines, would not change without further regulatory action.

FSIS used data from USDA's Continuing Survey of Food Intake by Individuals (CSFII), and the associated Diet and Health Knowledge Survey (DHKS) to establish a baseline for fat, saturated fat, and cholesterol intake. The CSFII collects data on food intakes by individuals. Most recently, USDA conducted three separate one-year surveys for 1994–96. These surveys recorded two nonconsecutive days of food consumption, and collected information on what and how much individuals ate, and where the food was obtained. This information was used to develop estimates of nutrient intake for each individual respondent. The DHKS gathered data on consumers' knowledge of issues related to diet and heath, and contained several questions relating to the use of nutrition information labels and nutrition information for food products. Linking information from the two surveys allowed FSIS to correlate use of nutrition information from the DHKS with nutrient intake data from the CSFII. The Agency focused here on two key questions pertaining to nutrition information use on all food products and on meat and poultry in particular:

Q: *When you buy foods, do you use the nutrition panel that tells the amount of calories, protein, fat, and such [e.g., sodium, total carbohydrate] in the serving of a food: Often (always), sometimes, rarely, or never?* (Question 16–c, DKHS)

Q: *When you buy raw meat, poultry, or fish, do you look for nutrition information: Often (always), sometimes, rarely, or never? (Question 17–I, DHKS).*

Using data from the CSFII and the DHKS, FSIS estimated rates of nutrition information usage, based on these two questions. The results are presented in Table 3. Note that rates of label usage are uniformly higher for women than for men, and that rates of nutrition label usage are higher for food products as a whole than for raw meat, poultry and fish products.

TABLE 3.—CONSUMER USAGE OF NUTRITION INFORMATION

	Often		Sometimes		Rarely/never		Do not buy	
	Men	Women	Men	Women	Men	Women	Men	Women
Use Nutrition Facts Panel	26.7	41.7	25.6	32.6	47.7	25.6	n/a	N/A
Look for Nutrition Information on Raw Meat, Poultry, or Fish	16.9	22.1	18.2	18.0	62.7	57.9	2.2	2.0

Note: Percent of respondents, based on 3 year weighted averages, 1994–1996.

To establish a baseline of Intake of Fat, Saturated Fat, and Cholesterol, FSIS used the same data sources to estimate dietary intake of fat, saturated fat, and cholesterol, along with the percentage of calories from fat and saturated fat. The CSFII contains information on the intake of these food components, based on the food consumption reported by survey respondents.

Tables 4 and 5 present the estimated intake of fat, saturated fat, and cholesterol from the CSFII, broken down by types of nutrition information usage reported in the DHKS.

TABLE 4.—DIETARY INTAKE OF FAT, SATURATED FAT, BY USAGE OF NUTRITION FACTS PANEL

	Often	Sometimes	Rarely/never	Average
Men:				
Total Fat	83.13	92.52	98.14	92.51
Saturated Fat	26.93	31.43	33.67	31.12
Cholesterol	293.39	327.77	353.97	339.07
Women:				
Total Fat	55.95	62.78	63.98	60.16
Saturated Fat	18. 04	20.77	21.39	19.71
Cholesterol	196.60	216.84	230.03	210.53

Note: Fat intake in grams, cholesterol in milligrams.

TABLE 5.—DIETARY INTAKE OF FAT, SATURATED FAT, BY USAGE OF NUTRITION INFORMATION ON RAW MEAT, POULTRY, OR FISH

	Often	Sometimes	Rarely/never	Do not buy	Average
Men:					
Total Fat	81.64	92.49	96.09	74.48	92.51
Saturated Fat	27.20	31.09	32.44	24.02	31.12
Cholesterol	311.81	321.49	355.14	236.83	339.07
Women:					
Total Fat	53.90	61.70	62.18	57.23	60.16
Saturated Fat	17.39	20.60	20.41	17.27	19.71
Cholesterol	194.32	219.27	216.55	135.89	210.53

Note: Fat intake in grams, cholesterol in milligrams.

The estimated intake of fat and saturated fat can also be expressed as the percentage of calories from fat. This conversion is done with the following formula:

Percentage Calories from Fat = 900*fat/energy,

Where energy is total caloric intake (kilocalories), as measured by the CSFII. Tables 6 and 7 show the percentage of calories from fat (and total cholesterol) broken down by label and nutrition information usage:

TABLE 6.—PERCENTAGE OF CALORIES FROM FAT AND TOTAL CHOLESTEROL, BY USAGE OF NUTRITION FACTS PANEL

	Often	Sometimes	Rarely/never	Average
Men:				
Total Fat	31.54	33.63	35.27	33.44
Saturated Fat	10.19	11.38	12.00	11.19
Cholesterol	293.39	327.77	353.97	339.07
Women:				
Total Fat	31.14	33.40	34.49	32.49
Saturated Fat	10.00	11.38	11.59	10.64
Cholesterol	196.60	216.84	230.03	210.53

Note: Fat and Saturated Fat values are percentage of calories from fat source; cholesterol in milligrams.

TABLE 7.—PERCENTAGE OF CALORIES FROM FAT AND TOTAL CHOLESTEROL, BY USAGE OF NUTRITION INFORMATION ON RAW MEAT, POULTRY, OR FISH

	Often	Sometimes	Rarely/never	Do not buy	Average
Men:					
Total Fat	31.67	34.03	33.88	29.69	33.44
Saturated Fat	10.53	11.36	11.37	9.52	11.19
Cholesterol	311.81	321.49	355.14	236.83	339.07
Women:					
Total Fat	31.62	32.94	32.87	26.79	32.49
Saturated Fat	10.15	10.82	10.82	9.19	10.64
Cholesterol	194.32	219.27	216.55	135.89	210.53

Note: Fat and Saturated Fat values are percentage of calories from fat source; cholesterol in milligrams.

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Regulatory Options

FSIS considered several regulatory options: (1) Continuing with the existing voluntary program; (2) making the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products; (4) requiring nutrition information on labels of the major cuts of single-ingredient, raw meat and poultry products and on all ground or chopped products; and (5) requiring nutrition information on labels of all single-ingredient, raw meat and poultry products and all ground or chopped products.

Option 1: Continuing with the voluntary program. FSIS could continue with the existing voluntary program and attempt to increase participation by providing additional assistance to the nonparticipants. The 1999 nutrition labeling survey found a significant difference in participation rates according to outlet type. Chain stores showed a 65.5 percent participation rate, large independents showed a 46.5 percent participation rate, and medium and small independents showed a participation rate of 26.3 percent. Thus, FSIS could provide nutrition information or point-of-purchase materials to independent retail stores to encourage their participation in the voluntary nutrition labeling program.

Retail establishments would continue to provide, on a voluntary basis, nutrition labeling for all single-ingredient, raw meat and poultry products, including major cuts identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and cuts that are not identified as major cuts (including ground or chopped products not covered in §§ 317.344 and 381.444). This information could be provided at the point-of-purchase or on the label of the product.

Option 2: Make the voluntary program mandatory. FSIS could make the voluntary program mandatory by requiring nutrition information, either on labels or at the point-of-purchase, for all single-ingredient, raw meat and poultry products, including the major cuts of single-ingredient, raw products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and the nonmajor cuts of single-ingredient, raw meat and poultry products (including ground or chopped products not covered in §§ 317.344 and 381.444). Under this option, FSIS would assume that most retailers would display point-of-purchase information for these products rather than nutrition labels, because this is an inexpensive means of providing nutrition information for multiple products. This approach does not allow for any distinction between ground or chopped meat and poultry products and other cuts of meat. In addition, this approach does not distinguish between the major and nonmajor cuts.

Option 3: Require nutrition information on labels of all ground or chopped meat and poultry products and make the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products (other than ground beef and ground pork). FSIS could require nutrition information on the labels of all ground or chopped products and could require nutrition information, either on their labels or at their point-of-purchase, for the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 (other than ground beef and ground pork). Retail establishments and producers could continue to voluntarily provide nutrition information for nonmajor cuts of single-ingredient, raw meat and poultry products that are not ground or chopped. This approach allows for a distinction between ground or chopped meat and poultry and other cuts of meat and poultry. It also allows for a distinction between major and nonmajor cuts. Consistent with the regulations, the voluntary nutrition labeling surveys only assessed whether nutrition labeling was provided for the major cuts of single-ingredient, raw meat and poultry products. Until some assessment is made of whether adequate information is being provided for the nonmajor cuts of single-ingredient, raw products that are not ground or chopped, FSIS cannot determine whether it would be beneficial to require nutrition information for these products.

In their June 3, 1997, petition discussed above, CSPI stated that USDA should require complete "Nutrition Facts" on ground beef labels that make nutrient content claims. This option would require complete "Nutrition Facts" on all ground beef labels. Thus, CSPI's petition supports this aspect of this option. However, the CSPI petition also stated that point-of-purchase information is generally a poor substitute for labels and that the "Nutri-Facts" posters and brochures used by many stores have severe flaws. Thus, the CSPI petition does not support providing nutrition labeling at the point-of-purchase.

Option 4: Require nutrition information on labels of the major cuts of single-ingredient, raw meat and poultry products and on all ground or chopped products. FSIS could require nutrition information only on labels of the major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and on all other ground or chopped products not covered in §§ 317.344 and 381.444. As in Option 3, establishments could voluntarily provide nutrition information, either at the point-of-purchase or on the label, for the nonmajor cuts of single-ingredient, raw meat and poultry products that are not ground or chopped. This approach allows for a distinction between major cuts and nonmajor cuts that are not ground or chopped. Until some assessment is made of whether adequate information is being provided for the nonmajor cuts of single-ingredient, raw products that are not ground or chopped, FSIS cannot determine whether it would be beneficial to require nutrition information for these products.

Option 5: Require nutrition labels on all single-ingredient, raw meat and poultry products and on all ground or chopped products. FSIS could require nutrition information on labels of all single-ingredient, raw meat and poultry products, including both the major cuts of single-ingredient, raw products identified in §§ 317.344 and 381.444 (including ground beef and ground pork) and nonmajor cuts of single-ingredient, raw products, and on all ground or chopped products not covered in §§ 317.344 and 381.444. An April 4, 2000, press release on CSPI's web page, quotes the organization's executive director as stating, "Frozen and processed meats already have nutrition labels. That same information should be on fresh meat" (http://www.cspinet.org/new/nutr_labeling.html). Thus, CSPI supports this option.

FSIS requests comments on whether any of the options not chosen would be a viable alternative to the option chosen and on the possible costs and benefits of the options presented.

Quantification of Costs and Net Benefits of Regulatory Options

FSIS' preliminary analysis does not allow for a comparison of net benefits among the regulatory options. The Agency is unable, at this time, to distinguish between the benefits that accrue from moving from a voluntary program to a mandatory program and the benefits that would accrue from requiring nutrition labels on products versus nutrition information on point-of-purchase materials. Furthermore, although a comparison of costs of the regulatory options might be possible, FSIS has not quantified all costs. As a result, FSIS believes that it would be inappropriate to provide a comparison of net benefits of the regulatory options considered at this time.

Below, FSIS provides a preliminary analysis of the costs and benefits of the proposed rule. FSIS requests comments on this preliminary analysis and any data that would be useful in estimating the costs and benefits of the proposed rule.

The Proposed Rule

FSIS is proposing Option 3. FSIS is proposing to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies, and to make the voluntary nutrition labeling program mandatory for major cuts of single-ingredient, raw meat and poultry products identified in §§ 317.344 and 381.444, unless an exemption applies.

Without a mandatory labeling program for the major cuts of single-ingredient, raw products (that are not ground or chopped), FSIS believes that complete and consistent information on the nutritional attributes of these products will not be provided to every consumer. FSIS also believes that the producers' ability to control the fat and nutrient content of ground or chopped product and the consumers' inability to detect the nutritional variations in these products through observation makes it necessary to further require that labeling requirements for all ground or chopped meat and poultry products be consistent with those currently required for multi-ingredient and heat processed products. The Agency has tentatively concluded that ground or chopped products and the major cuts of single-ingredient, raw products would be misbranded without nutrition information under the FMIA and the PPIA (21 U.S.C. 601(n)(1) and 21 U.S.C. 453(h)(1)).

Many exemptions from the proposed nutrition labeling requirements would apply to ground or chopped products and to the major cuts of single-ingredient, raw products. The existing regulations provide that food products produced by small businesses are exempted from mandatory nutrition labeling if the product labels bear no nutrition claims or nutrition information. Under this rule, small businesses that qualify for the exemption would be exempt from the mandatory nutrition labeling requirements proposed for ground or chopped products. However, the small business exemption would not apply to the major cuts of single-ingredient, raw meat and poultry products. Also, the existing regulations provide that retail stores and similar retail-type establishments are exempted from nutrition labeling requirements for multi-ingredient products processed at retail and ready-to-eat products packaged or portioned at retail if the products bear no nutrition claims or nutrition information. In this rule, FSIS is proposing that these exemptions not apply to ground meat and poultry products, unless the retail store or similar retail-type establishment meets the requirements for the small business exemption. For a full discussion of the exemptions, see the "Exemptions" heading above. FSIS is requesting comments on whether these exemptions are appropriate and necessary for retail and Federal establishments. The preliminary cost and benefits analyses below do not take the exemptions into account because FSIS does not have sufficient data concerning the establishments that would qualify for the small business exemption or the volume of product that would be exempted from nutrition labeling requirements. Therefore, FSIS requests comments on how the exemptions would affect the costs and benefits of the proposed rule.

In addition to the proposed requirements discussed above, FSIS is proposing to amend the nutrition labeling regulations to provide that when a ground or chopped product does not meet the regulatory criteria to be labeled "low fat," a lean percentage claim may be included on the label or in labeling as long as a statement of the fat percentage also is displayed on the label or in labeling. Under existing regulations, in order for the phrase "___ percent lean" to be used on the label or in labeling of a product, the product must meet the regulatory criteria for "low fat." Most ground beef and hamburger products do not qualify as "low fat." Therefore, existing regulations preclude the use of the term "___ percent lean" on these products. FSIS extended the compliance enforcement date for nutrition labeling requirements for ground beef and hamburger indefinitely, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger (59 FR 39941); therefore, producers and retailers continue to use the term "lean" in percentage labeling on the packages of ground beef and hamburger. FSIS is proposing to allow this information on the label or in labeling for ground or chopped products because many consumers have become accustomed to this labeling on ground beef products, and because FSIS believes this labeling provides a quick, simple, accurate means of comparing all ground or chopped meat and poultry products. Under the preliminary cost analysis below, FSIS provided a preliminary cost estimate for developing new labels that include statements of the lean percentage and the fat percentage. FSIS intends to develop a more detailed analysis of this labeling provision in the final rule.

Preliminary Estimations of the Cost of the Proposed Rule

Making the voluntary program mandatory for the major cuts of single-ingredient, raw meat and poultry products. FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat and poultry products should not be significant. Retail establishments can choose between providing nutrition information through point-of-purchase materials or providing nutrition information on labels. Processors may also provide the information on labels or on point-of-purchase materials; however, FSIS would enforce these requirements at retail. Point-of-purchase materials are available for a nominal fee ($12.00 for members, $24.00 for nonmembers) through the Food Marketing Institute's web site (http://www.fmi.org). These materials meet the point-of-purchase requirements in this proposed rule. Also, FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site. Another factor that would mitigate the cost impact of this requirement is that, based on the nutrition labeling survey conducted in 1999, many stores are currently providing nutrition information for the major cuts of single-ingredient, raw products. As discussed above, the 1999 survey found that 54.8 percent of stores surveyed provided nutrition information for 90 percent of the major cuts of single-ingredient, raw meat and poultry products, in accordance with program guidelines.

FSIS estimates the one-time costs to retail establishments for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw meat and poultry products would be about $0.7 million. FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw meat and poultry products, because this is an inexpensive means of providing nutrition information for multiple

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products and because this rule will not require that manufacturers include nutrition labels on the major cuts of single-ingredient, raw meat and poultry products. FSIS estimates that obtaining point-of-purchase materials and making them available to consumers would take an average of 30 minutes. As shown in Table 2 above, there were 69,500 retail stores in 1999 (excluding convenience stores that do not normally sell meat products), and FSIS estimates salary and expenses costs for providing nutrition information to be $20 per hour (69,500 * 0.5 * $20 = 0.7 million). This estimate does not take into account the voluntary nutrition labeling survey results which show that many stores currently provide nutrition information for the major cuts of single-ingredient, raw products. Information concerning this cost is addressed in the Information Collection Request submitted to OMB and in the section on paperwork requirements below.

As discussed above, FSIS is proposing that many of the existing exemptions from nutrition labeling requirements would apply to the major cuts of single-ingredient, raw meat and poultry products. However, FSIS is proposing that the small business exemption from nutrition labeling requirements would not apply to the major cuts of single-ingredient, raw products. As explained above, FSIS does not believe that the reasons that necessitated the establishment of the small business exemption, as explained in the January 6, 1993, final rule, are applicable to the major cuts of single-ingredient products. Also, because nutrition information for the major cuts of single-ingredient, raw products may be provided on point-of-purchase materials, FSIS is proposing that the provisions for providing nutrition labeling by alternative means for products in packages that have a total surface area available to bear labeling of less than 12 square inches would not apply to the major cuts of single-ingredient, raw products.

Nutrition labeling of ground or chopped products. The costs of required labels would be incurred by ground meat or poultry processors supplying labeled products to retail stores for sale to consumers and by retail establishments who grind or chop meat and poultry products in their stores for sale to consumers. Costs would include the fixed costs of equipment, the operating costs of printing labels, including materials and labor, and the cost of nutrient analysis.

FSIS estimated the costs of nutrition labels based on the cost analysis conducted for the "Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products" proposed rule published November 4, 1993 (58 FR 58922); the costs estimates were not revised in the final rule in response to comments. The rationale for using the "safe handling" cost analysis is that the costs of the labels in these two proposals would be comparable for cost estimation purposes. FSIS is not using the regulatory impact analysis developed for the nutrition labeling regulations for cost estimation purposes because much less nutrient analysis will be required at this time than was required when the 1993 nutrition labeling regulations were published (January 6, 1993). There are currently much more data available for nutrition labeling than were available when the 1993 nutrition labeling regulations were published.

Safe Handling Cost Estimates

Fixed costs. The "safe handling" rule estimated the fixed costs of installing or retrofitting labeling equipment for stamping, printing, or affixing labels. The "safe handling" rule had estimated the fixed costs of labeling fresh meat and poultry products for processors to range from $50 to $100 million. These costs were based on an estimate that there were somewhere between 50,000 and 100,000 labels approved for use by processors that were affected and an estimated average label modification cost of $1,000 (58 FR 58925).

The fixed costs of compliance with the "safe handling" labeling rule for retail establishments were estimated to range from $144 to $216 million. These estimates assumed that larger retailers would modify their equipment to increase their label size to combine weight and price information with safe handling instructions if their existing equipment was incompatible. These estimates were based on the costs to the then (*i.e.*, 1992) existing 23,813 supermarkets (with annual sales exceeding $2.5 million/year). Based on conversations with equipment suppliers and two to three retailers, FSIS estimated that upgrading the automated scales/wrapping systems to accommodate a larger label would cost $6,000 to $9,000 per store. Assuming that all 24,000 (approx.) supermarkets upgraded their equipment, the cost would range from $144 ($6000 x 24,000) to $216 ($9000 x 24,000) million. FSIS estimated these costs for large retail chains, *i.e.*, supermarkets, because they constituted three-fourths of total grocery stores sales. For example, in 1992, of the total grocery stores sales of $360 billion (excluding sales taxes), supermarkets accounted for $274 billion, or 76 percent. FSIS also estimated these costs for large retail chains because FSIS assumed that small retailers would produce a second label using existing equipment to meet the "safe handling" rule requirements and, therefore, would incur mostly operating costs rather than fixed costs to meet the "safe handling" rule requirements.

Operating costs. The "safe handling" analysis assumed that all meat and poultry products already included some form of commercially prepared labels, and that the incremental cost of adding safe handling instructions to the label would increase the total per label cost by $0.0025 to $0.005. This estimate was also supported by the comment of one large retail chain. In their response to the an earlier interim rule that included a preliminary economic analysis (58 FR 43478), this commenter stated that including the safe handling label, as part of their price labels, would double the cost of their labels from $0.0025 to $0.005 per label. For firms that indicated that they would need separate labels for the safe handling statement (*e.g.*, the small retail stores), the most frequent comment in response to the preliminary analysis was that the labels for safe handling would cost $0.01 each. In the "safe handling" rule, FSIS assumed that large retail chains would incur the lower costs ($0.0025 to $0.005) per label by including the safe handling statement as part of their price label. For the smaller firms requiring separate labels for the safe handling statement, FSIS assumed that their costs would be $0.01 per package. The higher costs for small retailers can be explained by the absence of economies of scale available to these retailers.

As discussed above, in 1992, large retail chains had sales that accounted for 76 percent of total grocery store sales. In the "safe handling" rule, FSIS rounded this number and assumed that 80 percent of packages of meat and poultry products labeled and sold through retail would be sold through large retail chains. The "safe handling" rule estimated that there were 10 billion packages of meat and poultry product prepared and sold through retail. Therefore, the rule estimated that 8 billion packages would be prepared and sold by large retail chains and the remaining 2 billion packages would be prepared and sold by small retail firms. The safe handling rule estimated that the 10 billion retail packages would have recurring costs associated with the "safe handling" rule of $50 million per year. This estimate assumed that the 8 billion packages sold through large retail chains would have recurring costs of $0.00375 (midpoint of $.0025 and $0.005) and the 2 billion packages sold through small stores would have recurring costs of $0.01 per package.

In the "safe handling" rule, the additional labor costs for applying the 2 billion separate safe handling labels by use of label guns for small firms were estimated. Based on the number of staff years at 160 and an average salary of $20,000 per year, the "safe handling" rule estimated the labor costs at about $3.2 million per year.

The "safe handling" rule did not estimate operating costs of labeling for processors because they were expected to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to labels.

Adjustments to the Costs in the Safe Handling Rule

Estimating the volume of ground or chopped products. As explained above, the "safe handling" rule estimated the cost of labeling all fresh meat products. The number and volume of products that would require nutrition labels in this proposed rule are, however, much smaller relative to the number and volume of products in the "safe handling" rule, because the proposed rule would require nutrition labels on only ground or chopped meat and poultry products. FSIS adjusted the costs of the "safe handling" rule to reflect the costs related to the volume of ground or chopped product produced.

In 1996, total U.S. annual production of ground beef was 7 billion pounds (American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 5). The American Meat Institute (AMI) report cited has not been updated. However, according to AMI staff, total U.S. annual production of ground beef was 7.2 billion in 1998, an increase of less than 3 percent. For estimation purposes, FSIS believes the 1996 data are still valid. Based on discussion with AMI staff members, approximately 50 percent (or 3.5 billion) of this output is sold through retail stores (the rest goes through restaurants and institutions). As regards other ground or chopped products such as poultry, pork, and turkey, AMI estimates that for every 100 pounds of ground beef, 12.3 pounds of these competing meats are produced (The American Meat Institute Foundation, *Relative Ground Beef Contribution to the United States Beef Supply* (May 1996): 8). The estimate of 12.3 pounds is based on a survey sent by AMI to the top 50 retail chains and wholesalers. No attempt was made to expand the survey responses to a national level or develop estimates for the entire retail sector. In the absence of any information that would validate the survey responses for the entire retail sector, however, FSIS employed these estimates as approximate trends. However, FSIS invites comments and requests nationally representative data for the retailers for analysis of the final rule.

To arrive at the total volume of ground or chopped meat and poultry products sold in retail stores, FSIS first assumed that 50 percent of total production, or 3.5 billion pounds, represented ground or chopped beef sold in retail stores. Second, based on the AMI survey referred to above, FSIS assumed that ground or chopped poultry and other meats represented 12.3 percent of ground beef sales. Therefore, the total annual volume of ground or chopped meat and poultry sold through retail establishments amounted to 3.9 (3.5 ÷ .4) billion pounds [3.5 billion + (3.5 billion * 0.123 = .431 billion].

Fixed costs. As explained above, the "safe handling" rule had estimated the fixed costs of safe handling labeling for processors to range from $50 to $100 million. Also explained above, the fixed costs of compliance with the "safe handling" labeling rule for retail establishments were estimated to range from $144 to $216 million. The estimation of these fixed costs assumed that larger retail stores would modify equipment to increase their label size to combine weight and price information with safe handling instructions if their existing equipment was incompatible. In this rule, retail stores also might modify equipment to increase their label size to combine weight and price information with nutrition information.

To calculate the fixed costs of nutrition labeling of ground or chopped products, FSIS adjusted the fixed costs in the "safe handling" rule to account for existing equipment. FSIS believes that many establishments have already incurred fixed costs required for the "safe handling" rule. For example the 1999 safe handling survey revealed that 96.7 percent of large chains, 90.5 percent of large independents, and 84.1 percent of medium/small independents had already complied with the "safe handling" rule requirements. Therefore, as explained in the "Baseline" section above, FSIS made the conservative assumption that 80 percent of the estimated fixed costs were already incurred by retailers and processors and only 20 percent of the estimated fixed costs would be required for compliance with the proposed rule. Hence the estimated fixed costs of the proposed rule would range from $10 million to $20 million for processors and from $28.8 million to $43.2 million for retailers.

Although these costs were estimated based on 1992 prices, there has been virtually no change in their prices in the year 2000. For example, the index number for producer prices for blast furnaces and steel mills was 105.8 (1982 = 100) in 1992, and it was almost the same at 105.3 (1982 = 100) in July 2000. FSIS used this index number because these producers also manufacture equipment used for stamping and printing labels. Therefore, these costs are current and do not need any updating. These costs are shown in columns 1 and 2, Table 8.

Operating costs. As explained above, the safe handling analysis had assumed that all meat and poultry products already included some form of commercially prepared labels, and that the incremental cost of adding safe handling instructions to the labels would increase the total per label cost by $0.0025 to $0.005. The "safe handling" rule also estimated that the cost to firms that would need separate labels for the safe handling statement would be $0.01 per label. As in the "safe handling" rule, in this rule, FSIS is assuming that large retail chains would incur the lower costs ($0.0025 to $0.005) per label, because they would include nutrition information as part of their price labels. Similarly, consistent with the "safe handling" rule, for this rule, FSIS is assuming that smaller stores would apply a separate label with nutrition information.

As explained above, in the "safe handling" rule, FSIS assumed that large retail chains would account for 80 percent of all retail packages labeled at retail and that the smaller firms would account for 20 percent of all retail packages. FSIS believes that the estimate that 80 percent of retail-labeled packages are sold through large retail chains is likely to be valid in the year 2000 (without the need to round up) because of a number of mergers, acquisitions, and consolidations in this sector in the recent years. For example, Royal Ahold bought Giant Foods, Albertson's bought American Stores, SUPERVALUE bought Richfood, and Food Lion bought Hannaford (Sean Mehegan, "Merger Mania—Consolidation Changes the Face of the North American Supermarket Sector," *Meat & Poultry* (September 1999): 22–25). FSIS requests comments and data concerning whether the estimate that 80 of retail-labeled packages are sold through large retail chains is accurate.

For the proposed rule, FSIS is assuming that a package of ground or chopped meat or poultry would average

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two pounds. FSIS believes that most packages of ground or chopped product weigh at least a fraction over one pound; however, this product is also sold in bulk size packages that are significantly over one pound. Therefore, FSIS believes that two pounds is a reasonable estimate of the average weight of a package of ground or chopped product. If FSIS were to assume that the average size package were 1 pound, this assumption would double the estimated operating costs below. FSIS requests comments on whether two pounds is an accurate average weight estimate for packages of ground or chopped product.

Since the estimated annual volume of ground or chopped product sold through retail is about 4 billion pounds, there will be 2 billion packages (at two pounds each) requiring the labels. Because FSIS assumes that 80 percent of these packages would be accounted for by large firms, their corresponding shares of the packages would be 1.6 billion (80 percent of 2 billion) and small firms would account for the rest, *i.e.*, 0.4 billion packages (20 percent of 2 billion). Assuming a mid-point cost of $0.00375 for the range of safe handling label costs for large retail stores ($0.0025 to $0.005), the compliance cost for these stores would be $6 million (1.6 billion packages * $0.00375). The compliance cost for separate nutrition labels required by small firms would be about $4 million (0.4 billion packages times $0.01 per package). These costs were estimated in 1992, and there was an increase of 20 percent in related costs in July 2000. This increase is based on the producer price index numbers for plastics, foil, and coated paper bags, the materials on which labels would be printed (1992 = 142.9, July 2000 = 171.7). Therefore, these operating costs would increase by $2 million to $12 million in current prices.

As explained above, the "safe handling" rule estimated the labor costs of small firms applying separate safe handling labels by use of label guns at about $ 3.2 million per year, based on 2 billion labels, and 160 staff years at an average salary of $20,000 per year. According to data from the Bureau of Labor Statistics, the average hourly earnings in June of 1999 were $7.88 per hour. Assuming at least 2,000 work hours per year, the estimated annual earnings would be $15,760. FSIS adjusted the costs in the "safe handling" rule based on this earnings estimate. Therefore, FSIS revised the estimated "safe handling" labor costs to small firms to $3.0 million per year (160 staff years times $16,000 per staff totals $2,560,000 per year, which FSIS rounded to $3 million). Since these costs were for 2 billion packages for the safe handling rule, the prorated costs for 400 million packages for the proposed rule would be $0.6 million (400 million times $3 million divided by 2 billion). Therefore, estimated total operating or recurring costs associated with the proposed rule would be $12.6 (12 + 0.6). These costs are shown in Table 8, row 2, column 3.

The "safe handling" rule did not estimate operating costs of labeling for processors because they were expected to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to labels. Therefore, Table 8, row 1, column 3, reports their operating costs as "Not Applicable" (NA). The recurring costs of nutrition labeling for processors other than retail establishments are not estimated in this rule because, again, FSIS expects these processors to incur larger, upfront, one-time fixed costs, associated with making permanent modifications to their existing labels.

Paperwork burden costs. FSIS estimates that the one-time development and recordkeeping costs associated with nutrition labels for ground or chopped products for Federal establishments and retailers will total $8.8 million. As explained above, FSIS estimates the one-time costs to retail establishments for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw products will be about $0.7 million. The paperwork burden cost estimates for the required nutrition labels for ground or chopped products are based on the time required to develop 3 nutrition labels (120 minutes each), the time required for recordkeeping for the supporting data at Federal and retail establishments (5 minutes), and the time required for Federal establishments to submit label approval applications to FSIS (15 minutes). FSIS estimates that there are 2,489 Federal establishments affected by the rule and 69,500 retail establishments and estimates salary and expenses for these activities to be $20 per hour. Information concerning these costs is addressed in the Information Collection Request submitted to OMB and the Paperwork Requirements section below.

Table 8 shows that total operating compliance costs associated with nutrition labels for ground or chopped product are estimated at $12.6 million.

TABLE 8.—ESTIMATED COMPLIANCE COSTS FOR GROUND OR CHOPPED PRODUCTS ($ MILLION)

	Fixed costs		Operating costs	Paperwork burden costs
	Low	High		
Processors	10.0	20.0	NA	.3
Retailers	28.8	43.2	12.6	8.5
Total	38.8	63.2	12.6	8.8

Discounted value of compliance costs. The low and high estimates of fixed costs were added to the operating costs and paperwork burden costs estimated above. Therefore, FSIS obtained two series of costs, low and high, for a period of 20 years. The low estimate was $60.2 million per year ($38.8 million + 12.6 million + 8.8 million) and the high cost estimate was $84.6 million ($63.2 million + $12.6 million + $8.8 million). These series were discounted at 7 percent to compare them with discounted benefits, which are also discounted at 7 percent. It was assumed that the costs would be incurred in the middle of each year for the next 20 years. The results revealed that the present values of compliance costs for the next 20 years (from 2001 to 2020) ranged from $659.69 million to $927.05 million. Other than the paperwork costs discussed above, there should not be many costs associated with nutrition labels that would exceed the estimates in the "safe handling" rule. Nutrient content is dependent on fat levels, and there is a direct relationship between fat and other nutrients. Producers should be able to use available data or to extrapolate from existing data to develop the data for nutrition labels. In addition, FSIS will develop a list of published sources of information concerning the nutrient content of ground or chopped products, so that industry could obtain available literature from local libraries. This information would facilitate the development of nutrition labels for ground or chopped products. FSIS requests comments and data on any additional costs associated with nutrition labels that were not included in this preliminary cost analysis.

Although nutrition labels are not currently required on single-ingredient, raw ground or chopped products, such labels are often provided voluntarily on these products. According to information submitted by CSPI, a number of major supermarket chains, including Dominick's, Fred Meyer, Jewel, Kroger, Wegman's, Winn-Dixie, Albertson's, and some Lucky and Safeway stores, now include full "Nutrition Facts" labels on their ground beef (Bonnie Liebman, "Where's the Beef Labeling," *Nutrition Action Healthletter* (June 1999): 8–11). Because FSIS does not have complete information concerning the volume of ground or chopped packages that bear nutrition labels, FSIS is estimating the costs of labels for all packages of ground or chopped product in the cost estimates above.

Impact of estimated costs. The preceding estimates of fixed, operating and paperwork burden compliance costs for the proposed requirements concerning ground or chopped product at $60.2 to $84.6 million are not likely to be excessive relative to the volume of output of ground or chopped meat and poultry products sold at retail. For example, as noted above, the volume of these products is estimated at 3.9 billion pounds. Therefore, these costs would range from 1.5 to 2 pennies per pound ($60.2 million/3.9 billion pounds to $84.6 million/3.9 billion pounds). FSIS has not conducted a thorough analysis of how the costs to Federal and retail establishments would affect the price, supply, and demand of ground or chopped products. Similarly, FSIS has not thoroughly evaluated how any changes in consumer behavior that may occur as a result of this rule would affect the price, supply, and demand of ground or chopped products.

Percentage Labeling

The proposed percentage labeling for ground or chopped products would not result in significant costs because such labeling would be optional rather than mandatory. If retailers and other producers found this labeling to be costly, they would simply not exercise this option. Because FSIS extended the compliance enforcement date for use of the term "lean" for these products, pending publication of a final rule on percentage labeling for lean and fat on ground beef and hamburger, many of these products already bear these statements on their labels. If producers chose to develop new labels, the costs per label would be comparable to those for printing nutrition labels ($0.0025 to $0.05 per label if the information is included as part of their price label, and, $0.01 per label if they developed separate labels). FSIS requests comment on the costs and benefits of percent fat/percent lean labeling on ground or chopped products.

Benefits

The benefits of nutrition labeling depend on the extent to which consumers change their food consumption in favor of products that are more nutritious. As noted earlier, the absence of nutrition labeling to indicate nutrition contents of ground or chopped meat and poultry products and the major cuts of single-ingredient, raw products does not allow consumers to get adequate information for making their purchasing decisions. Provision of nutrition labels and point-of-purchase materials would disseminate nutrition information and enhance consumers' food purchasing decision-making process.

Consumption habits vary with knowledge of nutrition and health, preference for healthful diets, and socioeconomic status of different segments of the population. For example, consumers with preferences for healthful diets are likely to select products with lower fat and cholesterol levels to assist in the reduction of risk for coronary heart problems and cancerous diseases. Some consumers might perceive that a product is of higher quality or more nutritious if it has lower fat and cholesterol contents. Availability of nutrition labels on ground or chopped meat and poultry products and nutrition information for the major cuts of single-ingredient, raw products may help purchasing decision-making by these select groups of consumers.

Literature review of impact of labeling on diet quality. Nutrition labels on products such as cereals have existed for over two decades. Research studies on the effect of nutrition labeling on diet quality for these non-meat and poultry products indicate a positive relationship between these variables. Kreuter et al. (1997) analyzed survey data of 885 adult patients from four family medical clinics in Missouri (see the "References" section below for full citations of the literature referred to in this discussion). To participate, patients completed a self-administered survey while waiting to see their physicians. The results revealed that patients eating diets lower in fat were much more likely (51% versus 26%) than patients whose diets were higher in fat to report that nutrition labels influenced their food purchasing decisions.

Guthrie *et al.* (1995) linked USDA's 1989 Continuing Survey of Food Intakes by Individuals (one database) to Diet and Health Knowledge Survey (another database). They concluded that label use appeared to be associated with the consumption of diets that were higher in vitamin C and lower in cholesterol.

Neuhouser *et al.* (1999) analyzed data from a survey of 1,450 adult residents in Washington State. The survey assessed nutrition label use, fat-related diet habits, fruit and vegetable consumption, diet-related psychosocial factors, health behavior, and demographic characteristics. They concluded that label use was significantly associated with lower fat intake and, after controlling for all demographic, psychosocial, and behavioral variables, label use explained 6% of the variance in fat intake (their conclusion had a probability of 99.9%).

Mathios and Ippolito (1998) analyzed the effect of nutrition information in advertising and labels on consumption of food cereals with fiber content. They divided their study into two periods: First, the period, 1978–1984, when the FDA permitted printing of fiber content on cereal boxes but did not permit printing of any health claims, and the period 1985–87 when health claims were permitted. They concluded that in concert with an increase in fiber intake of cereals in their diets, the average intakes of fat, saturated fat, and cholesterol for both men and women declined during both the periods, albeit, the decline was greater during the second period relative to the first. They concluded that the increase in fiber and the decrease in fat and cholesterol consumption were associated with the consumption of labeled cereals.

Preliminary benefits analysis. FSIS consulted with ERS to develop the following empirical analysis of the benefits of nutrition labeling. The estimated benefits take the form of reductions in the incidence of coronary heart disease and three types of cancer which may accrue as consumers improve their diet quality through increased use of nutrition information generated by the regulation. FSIS used survey data on nutrient intake and label use to correlate intake of fat, saturated fat, and cholesterol to usage of existing nutrition information. The Agency estimated the value of the potential changes from intake of fat, saturated fat,

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and cholesterol that could occur as consumers respond to the newly available nutrition information. FSIS applied the model developed by Zarkin, et. al. which links changes in the serum cholesterol rate to changes in the percentage of total calories from polyunsaturated fat, saturated fat, and dietary cholesterol (Gary A. Zarkin, Nancy Dean, Josephine A. Mauskopf, and Richard Williams, "Potential Health Benefits of Nutrition Label Changes," *American Journal of Public Health* 83(5) (May 1993): 717–724; Gary A. Zarkin, Nancy Dean, Josephine A. Mauskopf, and Dierdre M. Neighbors, "Estimated Benefits of Nutrition Label Changes: Final Report, Volume 1," Center for Economics Research, Research Triangle Institute, Research Triangle Park, NC, 27709. April 1991). Changes in serum cholesterol are then used to estimate the health outcomes, which are reductions in the number of cases and mortality from three cancers (breast, colorectal, and prostate) and coronary heart disease. Finally, the Agency attached economic value to the public health changes by estimating the implied value of life associated with reductions in premature mortality.

To determine how much of a behavioral response and change in dietary intake may result from providing more nutrition information on meat and poultry products, FSIS makes the following assumption: The Agency assumes that when labels and other sources of nutrition information are provided for raw meat and poultry products that nutrition information usage rates will rise to match label usage rates for food products as a whole (see Table 3). Currently, some nutrition information is provided for some single-ingredient, raw meat and poultry products, but the information is not currently required. Mandatory nutrition labeling rules for the major cuts of single-ingredient, raw products and ground or chopped products would mean the nutrition information provided for these products would be comparable to that provided for other food products. FSIS therefore could reasonably assume that nutrition information usage rates for raw meat and poultry products would then become the same as the label usage rates for all foods taken together. For example, before mandatory nutrition information labeling, the data show that about 17 percent of men look for nutrition information on meat "Often" (Row 2 of table 3). In this analysis, then, FSIS assumed that after mandatory nutrition information labeling, 26.7 percent of men would use the nutrition fact panel or point-of-purchase materials for meat products, which is the label usage rate for all foods (Row 1 of table 3). Similarly, the Agency assumes that the percentage of women using nutrition information on meat products "Sometimes" would rise from 18 percent to 32.6 percent.

What does this mean for diet quality? Here, FSIS made another (admittedly strong) assumption: The Agency assumed that as nutrition information usage rates rise for consumers eating meat and poultry, dietary patterns will change in a manner consistent with current data. As shown above, there is strong statistical evidence that people who use nutrition information to guide their food consumption decisions have healthier diets. While other factors may be at work, and the role of information use in causing dietary changes is unclear, FSIS makes the assumption that the provision of additional nutrition information and making that information available to more consumers will lead to behavioral shifts and increased diet quality. Thus, FSIS assumes the effect of providing new information for meat and poultry products would make consumers who NEVER used nutrition information for meat and poultry products become aware of the diet implications of their choices in meat and poultry products. These consumers would then choose to consume the same mix of products as people who are currently aware of the nutritional quality of meat and poultry products. For example, men who currently do not look for nutrition information on meat in the absence of mandatory nutrition information labeling who would begin using this information "Sometimes" after labeling is in place would see a decrease in fat intake from 98 grams to 92.5 grams.

Under these assumptions, then, FSIS could see how requirements for mandatory nutrition information labeling on raw meat and poultry products could possibly affect diet quality. To reach the values shown in table 6, FSIS multiplied each cell in table 5 by the associated percentage of label use (nutrition facts panel use) from table 3. By doing this, FSIS increased the numbers of people in the "always" and "sometimes" cells, and decreased the number of people in the "rarely" and "never" cells, so that the distribution of label usage on meat and poultry products would reflect the distribution of label usage on all products. Aggregating across categories, FSIS got a new weighted average intake, which could be seen after the imposition of mandatory labeling requirements.

TABLE 9.—CHANGE IN INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory nutrition labeling of meat & poultry	After adjusting for increased label usage	Percentage decrease in intake
Men:			
Total Fat	92.51	91.31	1.30
Saturated Fat	31.12	30.69	1.37
Cholesterol	339.07	334.95	1.21
Women:			
Total Fat	60.16	58.57	2.65
Saturated Fat	19.71	19.21	2.55
Cholesterol	210.53	208.16	1.13

Note: Fat intake in grams, cholesterol in milligrams.

TABLE 10.—CHANGE IN PERCENTAGE OF CALORIES FROM FAT AND CHOLESTEROL INTAKE DUE TO INCREASED LABEL USAGE

	Intake prior to mandatory nutrition labeling of meat & poultry	After adjusting for increased label usage	Percentage decrease in calories from fat or intake
Men:			
Total Fat	33.44	33.33	0.11
Saturated Fat	11.19	11.14	0.04
Cholesterol	339.07	334.95	4.12
Women:			
Total Fat	32.49	32.37	0.11
Saturated Fat	10.64	10.54	0.10
Cholesterol	210.53	208.16	2.37

Note: Fat and saturated fat values are percent calories from fat. Cholesterol is mg.

Evaluation of health effects. Based on epidemiological research, FSIS related the reductions estimated in Table 10 to estimated decrease in incidence of major diseases associated with consumption of fat and cholesterol. The diseases considered in this analysis include three types of cancer—breast, prostate, and colon/rectal—and coronary heart disease. Epidemiological studies of the relationships between dietary fat and cholesterol intake and incidence of cancer and coronary heart disease indicate that saturated and polyunsaturated fat and cholesterol are converted into serum cholesterol. Serum cholesterol has an impact on the incidence rates of these diseases. FSIS used the following equation from Zarkin *et al.* (1993) to convert fat contents into the change in serum cholesterol (SC) rate, in milligram/deciliter (mg/dl):

(1) $SC\ (Mg/dl) = 2.16S - 1.65P + 0.097C$

Where SC is serum cholesterol, S is the change in percentage of total calories represented by saturated fat, P is the change in percentage of total calories represented by polyunsaturated fat, and C is the change in dietary cholesterol measured in mg/1000 calories.

FSIS substituted the estimated values of percentage changes in saturated fat and cholesterol intake from the last column of Table 10 into this equation. Since FSIS did not have separate data for polyunsaturated (P) fat, it was assumed that P would be one-third of total fats, as was also assumed by Zarkin *et al.* The estimates of serum cholesterol for male and female consumers are as follows:

TABLE 11.—REDUCTION IN SERUM CHOLESTEROL AND CHANGE IN MORTALITY

	% Change in calories from total fat	% Change in calories from sat. fat	Change in cholesterol intake	Change in serum cholesterol	% Reduction in mortality
Men	0.11	0.04	4.12	0.399	0.0240
Women	0.11	0.10	2.37	0.231	0.0139

FSIS used the calculated values of SC presented above to estimate incidence of breast, prostate, colon/rectal cancer, and coronary heart disease. Zarkin *et al.* (1993) concluded that an increase in serum cholesterol by 20 mg/dl was associated with a 1.2-percent increase in the incidence of each of these diseases. FSIS employed this rate to convert reductions in total fat, saturated fat, and cholesterol in Table 10 into SC. It is estimated that the reduction in mortality associated with changing dietary pattern from mandatory nutrition information labeling are 0.024 percent for men, and about 0.014 percent for women.

TABLE 12.—REDUCTION IN MORTALITY, ANNUAL NEW CASES OF MORTALITY, AND ESTIMATED LIVES SAVED

	Reduction in mortality (%)		Annual new cases of mortality		Lives saved		
	1	2	3	4	5	6	7
	Men	Women	Men	Women	Men	Women	Total
Breast Cancer	.....	0.0139	.....	41,200	0	6	6
Prostate Cancer	0.0240	.....	31,900	.....	8	0	8
Colorectal Cancer	0.0240	0.0139	28,000	28,000	7	4	11
Coronary Heart Disease	0.0240	0.0139	231,332	228,769	55	32	87

Table 12 presents data on the annual new cases of mortality associated with the three types of cancer and coronary heart disease for men and women in the United States in 1998. Data for the number of deaths came from the National Center for Health Statistics (coronary heart disease) and the American Cancer Society (cancer). Data on colorectal cancer were not available by gender; FSIS assumed the estimated 56,000 cases were distributed equally between men and women.

Estimating the benefits of preventing premature death. The benefits of the

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proposed nutrition information labeling rule would be the lives saved due to the estimated reductions in mortality rates associated with these diseases. However, placing reduction of the risk of premature death in an economic context is difficult and controversial (for an in-depth analysis of this issue, see Fred Kuchler and Elise Golan, "Assigning Value to Life: Comparing Methods for Valuing Health Risks," Agricultural Economic Report No. 784, U.S. Dept. Agric., Econ. Res. Service, Washington, DC, Nov. 1999). The problem is that there is no market for reducing diet-related fatal risks. If food were marketed by risk levels (say, probabilities of inducing cancer or heart disease) and consumers treated advertised risk levels like they do other objectively measurable product characteristics (e.g., weight or volume), there would be little difficulty in valuing food safety. Product prices could be statistically associated with risk levels, yielding the risk-dollar trade-off consumers make. That is, FSIS could measure, based on consumer purchases, the dollar value consumers attach to particular types of risk reduction.

There is no price that can be tabulated from commercial transactions that reflects the value of reducing diet-related fatal risks. Actions that individuals might take to reduce these risks do not leave a behavioral trail for analysts to follow. This information void makes it difficult to evaluate programs that might reduce diet-related risks. In particular, there is no obvious dollar value to assign to the major benefit of such programs, namely lives saved.

Ultimately, FSIS wanted to monetize the benefits of diet-related fatal health risk reduction. Other risks do leave a clear behavioral trail that analysts have followed, measuring the risk-dollar trade-off individuals make. The Agency's goal was to find a method of transferring market-based risk-dollar trade-off estimates to diet-related fatal cancer risks.

The most studied risk choices are those for on-the-job risks of accidental injury and death. Analysts have estimated the compensation required to induce workers to accept such risks. Many studies of labor market behavior have been carried out because the wide range of risk levels workers accept and the wide range of wages paid are amenable to statistical analysis. Available evidence suggests that workers' subjective assessments of risks they face are plausible (W.K. Viscusi, *Fatal Tradeoffs—Public & Private Responsibilities for Risk*. New York: Oxford University Press, 1992).

Viscusi (1992) summarized the empirical work estimating the value of risk of premature death. Several studies estimate the risk-dollar trade-off in the labor market by dividing the wage premium for risky jobs by the risk of a fatal job injury. Drawing on the compiled results of these studies, he stated: "Although the estimates of the risk-dollar tradeoff vary considerably depending on the population exposed to the risk, the nature of the risk, and similar factors, most of the reasonable estimates of the value of life are clustered in the $3 to $7 million range" (p. 73). Thus, compensating wages indicate that, on average, industrial workers value a statistical life at $5 million (December 1990 dollars), the midpoint of the range. ERS currently uses the $5 million per life estimate (adjusted upwards for inflation to 2000 dollars) to measure the benefits of preventing premature death from foodborne diseases caused by microbial pathogens (such as *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*.) (Crutchfield, Roberts, Buzby, and Frenzen, " Food Safety Efforts Accelerate in the 1990's," *Food Review*, 23 (3), September-December 2001, forthcoming). This estimate has been used by other government agencies to evaluate the benefits of regulations designed to reduce the risk of premature death. For example, The Food and Drug Administration (Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products Final Rule, 60 FR 65095) and the Consumer Product Safety Commission (Miller et al., "The Consumer Product Safety Commission's Revised Injury Cost Model," *Peer Review Draft Prepared for the U.S. Consumer Product Safety Commission*, July 1, 1997) currently use Viscusi's mid-point value of $5 million for each life saved. (Kuchler and Golan, "Assigning Value to Life: Comparing Methods for Valuing Health Risks," *Agricultural Economic Report No. 784*, U.S. Department of Agriculture, Economic Research Service, Washington, DC, November 1999, page 25). However, other agencies use lower life values in their analyses. FSIS requests comments on whether $5 million is an appropriate value of life estimate.

FSIS used the $5 million estimate as reflecting willingness to pay to avoid health risks. This is not the value an individual would pay to save his own life, but the aggregate value paid by many individuals to reduce a small risk of death each faces. To make this transfer, FSIS assumed that individuals make consistent risk choices, reducing health risks as much as their budgets allow. The Agency assumed individuals focus on the likelihood of health outcomes and how bad the outcomes might be, without regard to the different physical characteristics of hazards that give rise to health risks. The assumption critical for making the transfer from valuing job risks to valuing cancer risks is that individuals value years of life, and all years are equally valuable. All individuals are assumed to value a year of life equally.

FSIS adjusted for differences between years of life lost to cancer and heart disease fatalities and years of life lost to workplace fatalities. The value of statistical life estimate is based on a worker anticipating a fatal injury and losing an average life expectancy of 36.5 years (W.K. Viscusi, W.K. *Cigarette taxation and social consequences of smoking*. In James M. Poterba (ed.), *Tax Policy and the Economy*. Volume 9. Cambridge: MIT Press for the National Bureau of Economic Research, 1995). Potential life years lost to cancer and heart disease deaths were calculated by FSIS using data from National Centers for Health Statistics (National Center for Health Statistics, *National Vital Statistics Report* 48 (11) (July 24, 2000): 167). NCHS reports the number of years lost before age 75 per 100,000 population under the age of 75. These data were divided by the number of cancer and heart disease deaths for the population under 75 years of age to estimate the average number of life years lost up to age 75. The average number of life years lost were 14.9 for breast cancer, 3.9 for prostate cancer, 9.56 for colorectal cancer, and 10.2 for coronary heart disease. Thus, to calculate a value of life lost to cancer or heart disease, FSIS adjusted the $5 million estimate downward to reflect the fewer years of life lost to cancer or heart disease, compared to work-related deaths. This calculation is similar to that carried out by Viscusi for estimating the value of statistical lives lost to environmental tobacco smoke (Viscusi, 1995).

FSIS treated the last 36.5 years of life ($L_{36.5}$) as a capital asset with a current value of $5 million. If the risk market could be characterized as an efficient market, the asset price should be equal to the present value of the service flow the asset produces.

$$L_{36.5} = \$5 \text{ million} = \int_0^{36.5} Re^{-rt} dt$$

R is the (assumed) constant annual value of life and *r* is the time preference rate used to discount future benefits. Consider now the case of an individual facing an expected loss of 10.2 years of life from coronary heart disease. From this perspective, the value of the last 10.2 years of life for a victim of coronary heart disease is

$$L_{10.2} = e^{-26.3r}r^{-1}R(1 - e^{-10.2r}).$$

The equations for both $L_{36.5}$ and $L_{10.2}$ can be solved for R and equated, yielding

$$L_{10.2} = L_{36.5}\, e^{-26.3r}(1 - e^{-36.5r})^{-1}.$$

The value of cancer avoidance depends on an individual's rate at which future years of life are discounted. At an interest rate of 7 percent, the value is $636,755. At an interest rate of 3 percent, the value is $1,056,261.

This estimate is in December, 1990 dollars. Using the CPI–U to update this estimate from 1990 to 2000 dollars (CPI–U = 133.8 in December 1990, and 171.3 average for 2000), the value becomes $815,218 (7 percent discount rate) and $1,352,298 (3 percent) in 2000 dollars. Similar calculations were made for deaths associated with the other three diseases considered (which take into account the different number of life years lost for each disease). The results are reported in Tables 13 and 14. To arrive at an estimate of the benefits associated with reductions in mortality due to changes in fat and cholesterol intake, FSIS multiplied the dollar value assigned to each premature death prevented by the number of lives saved due to changes in diet quality. This estimate is reported for each disease as "Total benefits per year" in Tables 13 and 14. The total for all diseases is $86.6 million dollars at a 7 percent discount rate and $145.2 million at 3 percent.

It should be noted that the calculations used to estimate present value explicitly account for the time factor associated with delayed health impacts of dietary change. Decreases in intake of saturated fat, fat, and cholesterol will reduce the incidence of heart disease and cancer, but not immediately—the reductions in illness and death will begin to occur years into the future. However, the formulas used for calculating the present value of the benefits explicitly take this into account, for they reflect the value placed on lost years of life occurring in the future.

TABLE. 13—ESTIMATED LIVES SAVED AND ASSOCIATED ECONOMIC BENEFITS, USING A 7 PERCENT DISCOUNT RATE

	Breast cancer	Prostate cancer	Colorectal cancer	Coronary heart disease	All diseases
Deaths Per Year	41,200	31,900	28,028	228,231	329,359
Lives Saved Due to Dietary Changes from Labeling	6	8	11	87	111
Years of Life Lost Per Premature Death	14.9	3.9	9.6	10.2	N/A
Dollar Value of 1 Life Saved ($)	1,032,665	384,390	780,670	815,218	N/A
Total Benefits Per Year ($)	5,906,020	1,513,329	8,273,399	70,936,607	86,629,355
20 Year Present Value ($)	62,568,456	16,032,277	87,648,507	751,503,430	917,752,620

NOTE: Cancer deaths are for 2000, heart disease deaths are for 1998. Number of lives saved is rounded to the nearest integer. All benefits estimates are in year 2000 dollars.

TABLE. 14—ESTIMATED LIVES SAVED AND ASSOCIATED ECONOMIC BENEFITS, USING A 3 PERCENT DISCOUNT RATE

	Breast cancer	Prostate cancer	Colorectal cancer	Coronary heart disease	All diseases
Deaths Per Year (1998)	41,200	31,900	28,028	228,231	329,359
Lives Saved	6	8	11	87	111
Years of Life Lost Per Death	14.9	3.9	10.6	10.2	N/A
Dollar Value of 1 Life Saved ($)	1,844,723	570,731	1,395,308	1,352,298	N/A
Total Benefits Per Year ($)	10,550,343	2,246,945	14,787,213	117,670,918	145,255,419
20 Year Present Value ($)	156,962,464	33,428,870	219,996,395	1,750,646,120	2,161,033,850

NOTE: Cancer deaths are for 2000, heart disease deaths are for 1998. Number of lives saved is rounded to the nearest integer. All benefits are in year 2000 dollars.

It should be kept in mind that these estimates are based on annual data, and represent only one year's benefits. FSIS assumed that the reduction in mortality would continue each year. Using a twenty-year time horizon, FSIS estimated the present value (discounted at seven percent and three percent) of continuing reduction in premature deaths. This estimate was $918 million for all diseases at 7 percent, and $2.161 billion at 3 percent. FSIS requests comment on the benefits analysis above.

Summary of costs and benefits of the proposed nutrition labeling rule. As discussed above, FSIS' preliminary analysis does not allow for a comparison of the net benefits among the regulatory options considered.

For the proposed rule, the present values of benefits estimated in the two scenarios with 7 and 3 percent discount rates, respectively, range from $918 million to $2.161 billion. The present value (at a 7 percent discount rate for 20 years) of annualized fixed costs, operating and paperwork burden costs (including paperwork costs for providing nutrition information for the major cuts) for the lower bound estimate amounts to $659.69 million. In case the higher estimate of fixed costs is used, the fixed, the operating, and the paperwork burden costs amount to $927.05 million, at a 7 percent discount rate for 20 years.

Percentage labeling. This proposed rule would allow but would not require a statement of the fat and lean percentage in ground or chopped products. FSIS believes that this nutrition information helps consumers make better food choices and provides incentives to producers to continue producing nutritionally-improved products which contribute substantially to the health benefits associated with nutrition labeling. However, FSIS does not have the data necessary to quantify these benefits. FSIS requests comments concerning the benefits of percentage labeling on ground or chopped products.

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Regulatory Flexibility Act (RFA)—Preliminary Analysis

Based on the cost analysis above, FSIS has made an initial determination that this rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C 601). In the cost analysis above, FSIS estimated that the total costs for required nutrition labels on ground or chopped products would be between 1.5 and 2 pennies per pound. Also, as stated above, FSIS believes that the cost of providing nutrition labeling for the major cuts of single-ingredient, raw meat products should be negligible. FSIS estimates the total one-time costs to all retail establishments combined for obtaining point-of-purchase materials that include nutrition information for the major cuts of single-ingredient, raw products will be about $0.7 million.

The data in Table 1 in the "Baseline" section above suggest that about one-half of the poultry plants were large (28 out of 63) in 1999. The number of "small" and "very small" poultry plants was 23 and 10 respectively. In the absence of the availability of any data on production levels of these plants, FSIS assumes that the very small plants with less than ten employees are likely to produce less than 100,000 pounds per ground poultry product. This assumption is not unrealistic because poultry grinding is a labor-intensive process and less than ten employees are not likely to produce more than 100,000 pounds per ground product because these employees also process other products in these plants. Based on this assumption, 10 very small poultry establishments (or only 15% of all poultry establishments) are likely to be exempt from nutrition labeling requirements for ground or chopped products. However, these establishments would not be exempt if they are owned by a large corporation that owns several plants and employs 500 or more workers among all of its plants or produces more than 100,000 pounds of a particular ground product in total among all of its plants. FSIS did not have data linking these establishments to their corporate ownership.

The EFD indicates that most of the ground meat producing plants are very small. For example, of the 2,426 ground meat establishments, 1470 or 60% are very small. The number of small and large ground meat establishments are 843 and 68, respectively. Therefore, assuming that the very small establishments produce less than 100,000 pounds of a particular ground meat product, 60% of all these plants would be exempt from nutrition labeling requirements for ground or chopped products. In practice, the number of plants that would be exempt may be smaller than 60 percent because many of these plants may be owned by large, multi-plant corporations. However, FSIS does not have data on corporations that own these individual establishments.

As discussed above, FSIS believes that a significant amount of ground beef is processed at retail. Table 2 in the "Baseline" section above shows the number of retail stores in 1999. Most of these stores grind beef. However, FSIS does not have specific data concerning the levels of ground beef ground at retail or on the size of retail stores that process ground beef. FSIS researched Census data for this information, but specific information related to retail establishments processing ground or chopped product was unavailable. Therefore, FSIS does not currently have all the data necessary for a comprehensive analysis on the effects of this rule on small entities. In addition to the lack of data on retail stores producing ground or chopped product, FSIS does not have data on the specific types and quantities of ground products produced in individual plants to determine the number of single-plant facilities or multi-plant companies or firms that would be exempt from this regulation. Therefore, FSIS is requesting this information and inviting comments concerning potential effects. In particular, FSIS is interested in determining the number and kind of small entities that may incur benefits or costs from implementation of this proposed rule.

FSIS will make available a list of published sources of information so that industry can obtain literature from local libraries. This information will assist in the development of nutrition labels for ground or chopped products. This list of published sources of information should also help minimize the economic effect of this rule on small entities.

FSIS is cognizant of the possibility that while the exempted establishments would not have to incur labeling costs, they might not realize benefits of greater sales of the labeled products, in case they choose not to nutritionally label their products. This is because if demand for the labeled product increases relative to demand for non-labeled products, the exempt establishments would lose their market shares to the nonexempt establishments producing nutritionally labeled products. Therefore, to keep their market shares, these exempt establishments are likely to voluntarily include nutrition information on the product label. Such a strategy would minimize the adverse impact on these smaller establishments. It would, however, also increase their costs associated with labeling. Economic theory dictates that these establishments would compare the costs of nutrition labels with the benefits of retaining their market shares and would decide to label their products if the benefits of increasing the market shares exceed the label costs.

Nutrition labeling would be required, either on the product label or on point-of-purchase materials, for the major cuts of single-ingredient, raw product. Therefore, if manufacturers do not provide nutrition information on the label, retailers would be required to provide this information at the point-of-purchase or on product labels. However, as noted above, this requirement should not impose major costs or other burdens because many stores are currently providing nutrition information for these products, point-of-purchase materials are available for a nominal fee through FMI's web site ($12.00 for members, $24.00 for nonmembers), and FSIS intends to make point-of-purchase materials available, free of charge, on the FSIS web site.

The economic impact on retail stores is likely to be minimal because recently there has been considerable consolidation of these stores due to mergers and acquisitions resulting in an increased market share of large retailers relative to small ones. For example, recently Royal Ahold, the Dutch Conglomerate, bought out Giant Food. Earlier last year, Ahold also announced the pending purchase of Supermarket General-II Holdings Corporation, parent of the Pathmark chain. Similarly, SUPERVALUE acquired Richfood, Food Lion bought out Hannaford Brothers, and Scarborough, and Albertson's purchased American Stores. (Sean Mehegan, "Consolidation Changes the Face of the North American Supermarket Sector," *Meat & Poultry* (September 1999): 22–25). These mergers and acquisitions are likely to increase market shares of the large retailers at the cost of smaller ones.

Table 2 in the "Baseline" section above shows the number of retail grocery stores in 1999. The economic impact of the first-year costs of compliance on the processors and the retailers is determined by dividing the total first-year costs by the number of processors or retailers. Table 8 revealed the range of first-year costs to processors for labeling ground or chopped products at $10.3 million to 20.3 million. These costs include the fixed costs, operating costs, and the paperwork burden costs. Since the number of processors is 2,489 (see Table 1), the impact per processor would range from $4,138.21 ($10.3 million/2,489) to $8,155.89 ($20.3 million/2,489). Similarly, Table 8 also shows that the first-year costs to retailers for labeling ground or chopped products range from $ 49.90 million($28.8 + $12.6 million + $8.5 million) to $ 64.3 million ($43.2 million + $12.6 million +$8.5 million). In addition, as explained above, the total paperwork burden costs to retailers for providing point-of-purchase materials for the major cuts of single-ingredient, raw products is approximately $0.7 million. Thus, the total costs to retailers would range from $50.6 million to $65 million. Since the number of retail stores (see Table 2) in 1999 was 69,500 (excluding convenience stores that do not normally sell meat products), the impact per retail store would range from $728.06 ($50.6 million/69,500) to $935.25 ($65 million/69,500). Therefore, the impact of the first-year cost would be greater on the processors relative to retailers.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. However, States and local jurisdictions may exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States.

The proposed rule is not intended to have retroactive effect.

If this proposed rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in §§ 306.5 and 381.35 must be exhausted before there is any judicial challenge of the application of the proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under FMIA and PPIA.

Public Notification and Request for Data

FSIS requests information regarding the impact of this proposed rule on minorities, women, and persons with disabilities, including information on the number of minority-owned meat and poultry establishments, the makeup of establishment workforces, and the communities served by official establishments.

Public involvement in all segments of rulemaking and policy development are important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this proposed rule and are informed about the mechanism for providing their comments, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720–5704.

Paperwork Requirements

Title: Nutrition labeling of ground or chopped meat and poultry products and single-ingredient products.

Type of Collection: New.

Abstract: FSIS has reviewed the paperwork and record keeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, FSIS is requiring several information collection and recordkeeping activities. FSIS is proposing to require nutrition labeling on the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, unless an exemption applies. If the manufacturer provides nutrition information on the label of individual packages of the major cuts of single-ingredient, raw meat or poultry products, the retailer would not be required to provide the information at the point-of-purchase. However, if the manufacturer does not provide the nutrition information on the label of these products, the retailer would be required to provide the information at their point-of-purchase. In the estimate of burden below, FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw meat and poultry products, because this is an inexpensive means of providing nutrition information for multiple products and because this rule will not require that manufacturers include nutrition labels on the major cuts of single-ingredient, raw meat and poultry products. FSIS is also proposing to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies.

Estimate of burden: FSIS estimates that obtaining point-of-purchase materials and making them available for consumers would take an average of 30 minutes. FSIS believes that the nutrition information on most point-of-purchase materials will be based on the most current representative database values contained in USDA's National Nutrient Data Bank or the USDA Nutrient Database for Standard Reference. FSIS also believes it is unlikely that there will be any nutrition claims made on the point-of-purchase materials on the basis of the representative data base values. Therefore, these products will not be subject to FSIS compliance review, and there will be no recordkeeping requirements based on this information.

FSIS estimates that developing nutrition labels for ground or chopped products would take an average of 120 minutes. Labels developed at official establishments would be submitted to FSIS. FSIS estimates that each official establishment that produces ground or chopped product would submit three labels to FSIS for approval. FSIS estimates that it would take an average of 15 minutes to prepare and submit the form for prior approval. All ground or chopped product would be subject to FSIS compliance review; therefore, producers of ground or chopped product would be required to maintain records to support the validity of nutrient declarations contained on product labels. FSIS estimates the average time for recordkeeping would be 5 minutes.

Respondents: Meat and poultry establishments and retail stores.

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Estimated number of respondents: 71,989.

Estimated number of responses per respondent: 3.

Estimated total annual burden on respondents: 474,549.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th St., Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to Lee Puricelli, see address above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. Comments are requested by February 20, 2001. To be most effective, comments should be sent to OMB within 30 days of the publication date.

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List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat Inspection, Nutrition, Reporting and recordkeeping requirements.

9 CFR Part 381

Food labeling, Food packaging, Nutrition, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III, as follows:

PART 317—LABELING, MARKING DEVICES AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C 601–695; 7 CFR 2.18, 2.53.

2. Section 317.300 would be revised to read as follows:

§ 317.300 Nutrition labeling of meat and meat food products.

(a) Unless the product is exempted under § 317.400, nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw products that are not ground or chopped products described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials, except as exempted under § 317.400. For all other products for which nutrition labeling is required, including ground or chopped meat products described in § 317.301, nutrition labeling must be provided in accordance with the provisions of § 317.309, except as exempted under § 317.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and that are not major cuts of single-ingredient, raw meat products identified in § 317.344, either in accordance with the provisions of § 317.309 for nutrition labels, or in accordance with the provisions of § 317.345 for point-of-purchase materials.

3. A new § 317.301 would be added to read as follows:

§ 317.301 Required nutrition labeling of ground or chopped meat products.

(a) Nutrition labels must be provided for all ground or chopped products (livestock species) and hamburger with or without added seasonings (including, but not limited to, ground beef, ground beef patties, ground sirloin, ground pork, and ground lamb) that are intended for human consumption and offered for sale, in accordance with the provisions of § 317.309, except as exempted under § 317.400.

4. Section 317.309 would be amended as follows:

a. In paragraph (b)(3), the first sentence would be amended by adding "that are not ground or chopped meat products described in § 317.301" after the phrase "single-ingredient, raw products", and by removing "as set forth in § 317.345(a)(1)"; the second sentence would be revised by adding, "that are not ground or chopped meat products described in § 317.301" after the phrase "single-ingredient, raw products", and the following new sentence would be added after the first sentence:

* * * * *

(b) * * *

(3) * * * "For single-ingredient, raw products that are not ground or chopped meat products described in § 317.301, if data are based on the product "as consumed," the data must be presented in accordance with § 317.345(d). * * *

* * * * *

b. Paragraph (b)(10) would be amended by adding the following new sentence at the end of the paragraph:

* * * * *

(b) * * *

(10) * * * The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301, including those that have been previously frozen.

* * * * * *

c. Paragraph (b)(11) would be amended by adding the phrase "single-ingredient, raw products that are not ground or chopped meat products described in § 317.301 and" after "exception of".

d. Paragraph (d)(3)(ii) would be amended by removing the period and adding "or on single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301." at the end of the paragraph.

e. Paragraph (e)(3) would be amended by adding ", but may be on the basis of "as consumed" for single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301," after "as packaged".

f. Paragraph (h)(9) would be amended by removing the phrase "(including ground beef)" products", by adding, "that are not ground or chopped meat products described in § 317.301" after "products", by removing the phrase, "its published form, the Agriculture Handbook No. 8 series available from the Government Printing Office", and by adding, in its place, "its released form, the USDA Nutrient Database for Standard Reference", and by removing the period and adding the following at the end of the paragraph: " as provided in § 317.345(e) and (f)."

5. Section 317.343 would be removed.

6. Section 317.344 would be amended by removing the phrases "ground beef regular without added seasonings, ground beef about 17% fat," and "ground pork."

7. Section 317.345 would be amended as follows:

a. Paragraph (d) would be amended by removing "should" and adding, in its place, "for products covered in paragraphs (a)(1) and (a)(2) must".

b. Paragraph (e) would be amended by removing "its published form, the Agriculture Handbook No. 8 series" and by adding, in its place, "its released form, the USDA Nutrient Database for Standard Reference", and by removing "(including ground beef)".

c. Paragraph (f) would be amended by adding "provided" after "nutrition information is".

d. Paragraph (g) would be amended by removing the phrase "(including ground beef)".

e. The section heading and paragraphs (a) and (c) would be revised to read as follows:

§ 317.345 Nutrition labeling of single-ingredient, raw meat products that are not ground or chopped products described in § 317.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 317.400. If nutrition information is presented on the label, it must be provided in accordance with § 317.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw meat products that are not ground or chopped meat products described in § 317.301 and are not major cuts of single-ingredient, raw meat products identified in § 317.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 317.309.

(3) A retailer may provide nutrition information at the point-of-purchase, by various methods, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 317.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 317.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 317.309 (c)(8)) and footnote required by § 317.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 317.309(f).

* * * * *

8. Section 317.362 would be amended by adding a new paragraph (f) to read as follows:

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

* * * * *

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped meat products described in § 317.301 when the product does not meet the criteria for "low fat," defined in § 317.362(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background as the statement of the lean percentage.

* * * * *

9. Section 317.400 would be amended as follows:

a. Paragraph (a)(1), introductory text, would be amended by removing the comma and adding, at the end of the paragraph, ", except that this exemption does not apply to the major cuts of

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single-ingredient, raw products identified in § 317.344,".

b. Paragraph (a)(1)(ii) would be amended by adding ", including a single retail store," after the phrase "single-plant facility," and by adding, ", including a multi-retail store operation," after "company/firm".

c. Paragraph (a)(7)(i) would be amended by removing the semi-colon and by adding the following at the end of the paragraph: ", provided, however, that this exemption does not apply to ready-to-eat ground or chopped meat products described in § 317.301 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section;".

d. Paragraph (a)(7)(ii) would be amended by removing the period and by adding the following at the end of the paragraph: ", provided, however, that this exemption does not apply to multi-ingredient ground or chopped meat products described in § 317.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section."

e. Paragraph (d)(1) would be amended by removing the period at the end of the first sentence, and by adding the following to the end of the first sentence: ", except that this exemption does not apply to the major cuts of single-ingredient, raw meat products identified in § 317.344."

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

10. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

11. Section 381.400 would be revised to read as follows:

§ 381.400 Nutrition labeling of poultry products.

(a) Unless the product is exempted under § 381.500, nutrition labeling must be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw products that are not ground or chopped products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444. Nutrition labeling must be provided for the major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials, except as exempted under § 381.500. For all other products that require nutrition labeling, including ground or chopped poultry products described in § 381.401, nutrition labeling must be provided in accordance with the provisions of § 381.409, except as exempted under § 381.500.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and that are not major cuts of single-ingredient, raw poultry products identified in § 381.444, either in accordance with the provisions of § 381.409 for nutrition labels, or in accordance with the provisions of § 381.445 for point-of-purchase materials.

* * * * *

12. A new § 381.401 would be added to read as follows:

§ 381.401 Required nutrition labeling of ground or chopped poultry products.

Nutrition labels must be provided for all ground or chopped poultry (kind) with or without added seasonings (including, but not limited to, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of § 381.409, except as exempted under § 381.500.

* * * * *

13. Section 381.409 would be amended as follows:

a. In paragraph (b)(3), the first sentence would be amended by adding "that are not ground or chopped poultry products described in § 381.401" after the phrase "single-ingredient, raw products" and by removing "as set forth in § 381.445(a)(1)"; the second sentence would be amended by adding, "that are not ground or chopped poultry products described in § 381.401," after the phrase "single-ingredient, raw products"; and the following new sentence would be added after the first sentence:

* * * * *

(b) * * *

(3) * * * For single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401, if data are based on the product "as consumed," the data must be presented in accordance with § 381.445(d).* * *

b. Paragraph (b)(10) would be amended by adding the following new sentence at the end of the paragraph:

* * * * *

(b) * * *

(10) * * * The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401, including those that have been previously frozen.

* * * * *

c. Paragraph (b)(11) would be amended by adding the phrase "single-ingredient, raw products that are not ground or chopped poultry products described in § 381.401 and" after "exception of".

d. Paragraph (d)(3)(ii) would be amended by removing the period and adding "or on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401." at the end of the paragraph.

e. Paragraph (e)(3) would be amended by adding ", but may be on the basis of "as consumed" for single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401," after "as packaged".

f. Paragraph (h)(9) would be amended by adding, "that are not ground or chopped poultry products described in § 381.401" after "products", by removing the phrase, "its published form, the Agriculture Handbook No. 8 series", and by adding, in its place, "its released form, the USDA Nutrient Database for Standard Reference", and by removing the period and adding the following at the end of the paragraph: ", as provided in § 381.445(e) and (f)."

14. Section 381.443 would be removed.

15. Section 381.445 would be amended as follows:

a. Paragraph (d) would be amended by removing "should" and adding, in its place, "for products covered in paragraphs (a)(1) and (a)(2) of this section must".

b. Paragraph (e) would be amended by removing "its published form, the Agriculture Handbook No. 8 series" and by adding, in its place, "its released form, the USDA Nutrient Database for Standard Reference."

c. Paragraph (f) would be amended by adding "provided" after "nutrition information is".

d. The section heading and paragraph, (a) and (c) would be revised to read as follows:

§ 381.445 Nutrition labeling of single-ingredient, raw poultry products that are not ground or chopped products described in § 381.401.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 381.500. If nutrition information is presented on the label, it must be provided in accordance with the provisions of § 381.409. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw poultry products that are not ground or chopped poultry products described in § 381.401 and are not major cuts of single-ingredient, raw poultry products identified in § 381.444, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 381.409.

(3) A retailer may provide nutrition information at the point-of-purchase, by various methods, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 381.409 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 381.409 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 381.409(c)(8)) and footnote required by § 381.409(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

* * * * *

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 381.409(f).

* * * * *

16. Section 381.462 would be amended by adding a new paragraph (f) to read as follows:

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

* * * * *

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped poultry products described in § 381.401 when the product does not meet the criteria for "low fat," defined in § 381.462(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background as the statement of the lean percentage.

* * * * *

17. Section 381.500 would be amended as follows:

a. Paragraph (a)(1) would be amended by removing the comma and adding, at the end of the paragraph, ", except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444.

b. Paragraph (a)(1)(ii) would be amended by adding, ", including a single retail store," after the phrase "single-plant facility," and by adding ", including a multi-retail store operation" after "company/firm".

c. Paragraph (a)(7)(i) would be amended by removing the semi-colon and adding the following at the end of the paragraph: "provided, however, that this exemption does not apply to ready-to-eat ground or chopped poultry products described in § 381.401 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section," after "establishment".

d. Paragraph (a)(7)(ii) would be amended by removing the period and adding the following at the end of the paragraph: "provided, however, that this exemption does not apply to multi-ingredient ground or chopped poultry products described in § 381.401 that are processed at a retail establishment, unless the establishment qualifies for an exemption under paragraph (a)(1) of this section." after "establishment".

e. Paragraph (d)(1) would be amended by removing the period at the end of the sentence, and by adding the following to the end of the sentence: "except that this exemption does not apply to the major cuts of single-ingredient, raw poultry products identified in § 381.444."

Done in Washington, DC, on January 8, 2001.

Thomas J. Billy,

Administrator.

[FR Doc. 01–1119 Filed 1–17–01; 8:45 am]

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Note: The List of Public Laws for the 106th Congress, Second Session has been completed and will resume when bills are enacted into public law during the next session of Congress.

A cumulative List of Public Laws was published in Part II of the **Federal Register** on January 16, 2001.

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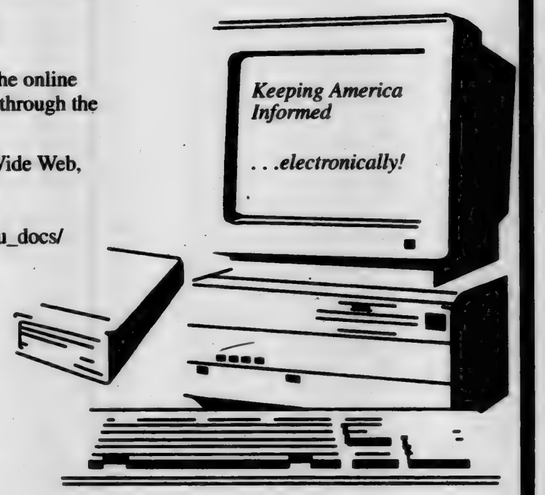
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Part V

Environmental Protection Agency

40 CFR Parts 69, 80, and 86
Control of Air Pollution From New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 69, 80, and 86

[AMS–FRL–6923–7]

RIN 2060–AI69

Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The pollution emitted by diesel engines contributes greatly to our nation's continuing air quality problems. Even with more stringent heavy-duty highway engine standards set to take effect in 2004, these engines will continue to emit large amounts of nitrogen oxides and particulate matter, both of which contribute to serious public health problems in the United States. These problems include premature mortality, aggravation of respiratory and cardiovascular disease, aggravation of existing asthma, acute respiratory symptoms, chronic bronchitis, and decreased lung function. Numerous studies also link diesel exhaust to increased incidence of lung cancer. We believe that diesel exhaust is likely to be carcinogenic to humans by inhalation and that this cancer hazard exists for occupational and environmental levels of exposure.

We are establishing a comprehensive national control program that will regulate the heavy-duty vehicle and its fuel as a single system. As part of this program, new emission standards will begin to take effect in model year 2007, and will apply to heavy-duty highway engines and vehicles. These standards are based on the use of high-efficiency catalytic exhaust emission control devices or comparably effective advanced technologies. Because these devices are damaged by sulfur, we are also reducing the level of sulfur in highway diesel fuel significantly by mid-2006. The program provides substantial flexibility for refiners, especially small refiners, and for manufacturers of engines and vehicles. These options will ensure that there is widespread availability and supply of the low sulfur diesel fuel from the very beginning of the program, and will provide engine manufacturers with the lead time needed to efficiently phase-in the exhaust emission control technology that will be used to achieve the emissions benefits of the new standards.

We estimate that heavy-duty trucks and buses today account for about one-third of nitrogen oxides emissions and one-quarter of particulate matter emissions from mobile sources. In some urban areas, the contribution is even greater. This program will reduce particulate matter and oxides of nitrogen emissions from heavy duty engines by 90 percent and 95 percent below current standard levels, respectively. In order to meet these more stringent standards for diesel engines, the program calls for a 97 percent reduction in the sulfur content of diesel fuel. As a result, diesel vehicles will achieve gasoline-like exhaust emission levels. We are also finalizing more stringent standards for heavy-duty gasoline vehicles, based in part on the use of the low sulfur gasoline that will be available when the standards go into effect.

The clean air impact of this program will be dramatic when fully implemented. By 2030, this program will reduce annual emissions of nitrogen oxides, nonmethane hydrocarbons, and particulate matter by a projected 2.6 million, 115,000 and 109,000 tons, respectively. We project that these reductions and the resulting significant environmental benefits of this program will come at an average cost increase of about $2,000 to $3,200 per new vehicle in the near term and about $1,200 to $1,900 per new vehicle in the long term, depending on the vehicle size. In comparison, new vehicle prices today can range well over $100,000 for larger heavy-duty vehicles. We estimate that when fully implemented the sulfur reduction requirement will increase the cost of producing and distributing diesel fuel by about five cents per gallon.

DATES: This rule will become effective March 19, 2001. The incorporation by reference of certain publications listed in this rule is approved by the Director of the Office of Federal Register as of March 19, 2001.

ADDRESSES: *Comments:* All comments and materials relevant to today's action have been placed in Public Docket No. A–99–06 at the following address: U.S. Environmental Protection Agency (EPA), Air Docket (6102), Room M–1500, 401 M Street, SW, Washington, DC 20460 (on the ground floor in Waterside Mall) from 8:00 a.m. to 5:30 p.m., Monday through Friday, except on government holidays. You can reach the Air Docket by telephone at (202) 260–7548 and by facsimile at (202) 260–4400. We may charge a reasonable fee for copying docket materials, as provided in 40 CFR part 2.

FOR FURTHER INFORMATION CONTACT: Margaret Borushko, U.S. EPA, National Vehicle and Fuel Emissions Laboratory, 2000 Traverwood, Ann Arbor MI 48105; Telephone (734) 214–4334, FAX (734) 214–4816, E-mail borushko.margaret@epa.gov

SUPPLEMENTARY INFORMATION:

Regulated Entities

This action will affect you if you produce or import new heavy-duty engines which are intended for use in highway vehicles such as trucks and buses, or produce or import such highway vehicles, or convert heavy-duty vehicles or heavy-duty engines used in highway vehicles to use alternative fuels, or produce or import light-duty highway diesel vehicles. It will also affect you if you produce, import, distribute, or sell highway diesel fuel, or sell nonroad diesel fuel.

The following table gives some examples of entities that may have to follow the regulations. But because these are only examples, you should carefully examine the regulations in 40 CFR parts 69, 80, and 86. If you have questions, call the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this preamble:

Category	NAICS Codes[a]	SIC Codes[b]	Examples of potentially regulated entities
Industry	336112	3711	Engine and Truck Manufacturers
	336120		
Industry	811112	7533	Commercial Importers of Vehicles and
	811198	7549	Vehicle Components
Industry	324110	2911	Petroleum Refiners
Industry	422710	5171	Diesel Fuel Marketers and Distributors
	422720	5172	
industry	484220	4212	Diesel Fuel Carriers

Category	NAICS Codes[a]	SIC Codes[b]	Examples of potentially regulated entities
	484230	4213	

[a] North American Industry Classifications System (NAICS).
[b] Standard Industrial Classification (SIC) system code.

Access to Rulemaking Documents Through the Internet

Today's final rule is available electronically on the day of publication from the Environmental Protection Agency Internet Web site listed below. Electronic copies of the preamble, regulatory language, Regulatory Impact Analysis, and other documents associated with today's final rule are available from the EPA Office of Transportation and Air Quality (formerly the Office of Mobile Sources) Web site listed below shortly after the rule is signed by the Administrator. This service is free of charge, except any cost that you incur for connecting to the Internet.

Environmental Protection Agency Web Site: *http://www.epa.gov/fedrgstr/* (Either select a desired date or use the Search feature.)

Office of Transportation and Air Quality (OTAQ) Web Site: *http://www.epa.gov/otaq/* (Look in "What's New" or under the "Heavy Trucks/ Busses" topic.)

Please note that due to differences between the software used to develop the document and the software into which document may be downloaded, changes in format, page length, etc. may occur.

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I. Overview

This rule covers the second of two phases in a comprehensive nationwide program for controlling emissions from heavy-duty engines (HDEs) and vehicles. It builds upon the phase 1 program we recently finalized (65 FR 59896, October 6, 2000). That action affirmed the 50 percent reduction in emissions of oxides of nitrogen (NO_X) from 2004 model year highway diesel engines, set in 1997 (62 FR 54693, October 21, 1997), and set new emission standards for heavy-duty gasoline-fueled engines and vehicles for 2005.

This second phase of the program looks beyond 2004, based on the use of high-efficiency exhaust emission control devices and the consideration of the vehicle and its fuel as a single system. In developing this rule, we took into consideration comments received in response to the advance notice of proposed rulemaking (64 FR 26142, May 13, 1999) and the notice of proposed rulemaking (NPRM) (65 FR 35430, June 2, 2000), including comments provided at five public hearings last June.

This program will result in particulate matter (PM) and NO_X emission levels that are 90 percent and 95 percent below the standard levels in effect today, respectively. In order to meet these more stringent standards for diesel engines, the rule mandates a 97 percent reduction in the sulfur content of diesel fuel. The heavy-duty engine standards will be effective starting in the 2007 model year and the low sulfur diesel fuel needed to facilitate the standards will be widely available in September 2006. As a result, diesel vehicles will achieve gasoline-like exhaust emission levels, in addition to their inherent advantages over gasoline vehicles with respect to fuel economy, lower greenhouse gas emissions, and lower evaporative hydrocarbon emissions. The rule also includes more stringent standards for heavy-duty gasoline vehicles. In addition to its impact on heavy-duty vehicle emissions, this rule will make clean diesel fuel available in time for implementation of the light-duty Tier 2 standards.

The standards will result in substantial benefits to public health and welfare and the environment through significant reductions in emissions of NO_X, PM, nonmethane hydrocarbons (NMHC), carbon monoxide (CO), sulfur oxides (SO_X), and air toxics. We project that by 2030, this phase 2 program will reduce annual emissions of NO_X, NMHC, and PM by 2.6 million, 115,000 and 109,000 tons, respectively. These emission reductions will prevent 8,300 premature deaths, over 9,500 hospitalizations, and 1.5 million work days lost. All told the benefits of this rule equal $70.3 billion. A sizeable part of the benefits in the early years of this program come from large reductions in the amount of direct and secondary PM caused by the existing fleet of heavy-duty vehicles. These reductions are due to the use of the higher quality diesel fuel in these vehicles.

A. What Requirements Are Being Set?

There are two basic parts to this program: (1) New exhaust emission standards for heavy-duty highway engines and vehicles, and (2) new quality standards for highway diesel fuel. The systems approach of combining the engine and fuel standards into a single program is critical to the success of our overall efforts to reduce emissions, because the emission standards will not be feasible without the fuel change. The feasibility of the emission standards is based on the use of high-efficiency exhaust emission control devices that would be damaged by sulfur in the fuel. This rule, by providing extremely low sulfur diesel fuel, will also enable cleaner diesel passenger vehicles and light-duty trucks. This is because the same pool of highway diesel fuel also services these light-duty diesel vehicles, and these vehicles can employ technologies similar to the high-efficiency heavy-duty exhaust emission control technologies that will be enabled by the fuel change. We believe these technologies are needed for diesel vehicles to comply with our Tier 2 emissions standards for light-duty highway vehicles (65 FR 6698, February 10, 2000).

We believe that this systems approach is a comprehensive way to enable effective new technologies for clean diesel, affecting all sizes of highway diesel engines, and may translate to future reductions from diesel engines used in nonroad applications too. The fuel change, in addition to enabling new technologies, will also produce emissions and maintenance benefits in the existing fleet of highway diesel vehicles. These benefits will include reduced sulfate PM and sulfur oxides emissions, reduced engine wear and less frequent oil changes, and longer-lasting exhaust gas recirculation (EGR) components on engines equipped with EGR. Heavy-duty gasoline vehicles will also be expected to have much lower emissions due to the transfer of recent technology developments for light-duty applications, and the recent action taken to reduce sulfur in gasoline as part of the Tier 2 rule.

The basic elements of the rule are outlined below. Detailed provisions and justifications for our rule are discussed in subsequent sections.

1. Heavy-Duty Emission Standards

We are finalizing a PM emissions standard for new heavy-duty engines of 0.01 grams per brake-horsepower-hour (g/bhp-hr), to take full effect for diesels in the 2007 model year.[1] We are also finalizing standards for NO_X and NMHC of 0.20 g/bhp-hr and 0.14 g/bhp-hr, respectively. These NO_X and NMHC standards will be phased in together between 2007 and 2010, for diesel engines. The phase-in will be on a percent-of-sales basis: 50 percent from 2007 to 2009 and 100 percent in 2010. This phase-in schedule differs somewhat from the proposed schedule for reasons explained in Section III. Gasoline engines will be subject to these standards based on a phase-in requiring 50 percent compliance in the 2008 model year and 100 percent compliance in the 2009 model year. This phase-in schedule also differs from that proposed for reasons explained in Section III. In addition, we are finalizing our proposal to include turbocharged diesels in the existing crankcase emissions prohibition, effective in 2007.

Standards for complete HDVs will be implemented on the same schedule as for gasoline engine standards. For certification of complete vehicles between 8500 and 10,000 pounds gross vehicle weight rating (GVWR), the standards are 0.2 grams per mile (g/mi) for NO_X, 0.02 g/mi for PM, 0.195 g/mi for NMHC, and 0.032 g/mi for formaldehyde.[2] For vehicles between

[1] Note that throughout this preamble we refer to diesel and gasoline vehicles and engines. We tend to use those terms given the preponderance of vehicles using diesel fuel or gasoline fuel in the U.S. heavy-duty highway market. However, when we refer to a diesel engine, we generally mean any engine using the diesel cycle. When we refer to a gasoline engine or vehicle, we generally mean any Otto-cycle vehicle or engine. Therefore, the emission standards discussed throughout this preamble apply equally to engines and vehicles fueled by alternative fuels, unless otherwise specified in the regulatory text accompanying today's rule.

[2] Vehicle weight ratings in this rule refer to GVWR (the curb weight of the vehicle plus its maximum recommended load of passengers and cargo) unless noted otherwise.

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10,000 and 14,000 pounds, the standards are 0.4 g/mi for NO_X, 0.02 g/mi for PM, 0.230 g/mi for NMHC, and 0.040 g/mi for formaldehyde. These standards levels are roughly comparable to the engine-based standards in these size ranges. Note that these standards will not apply to vehicles above 8500 pounds that we classify as medium-duty passenger vehicles as part of our Tier 2 program.

Finally, we are adopting new evaporative emissions standards for heavy-duty engines and vehicles, effective on the same schedule as the gasoline engine and vehicle exhaust emission standards. The new standards for 8500 to 14,000 pound vehicles are 1.4 and 1.75 grams per test for the 3-day diurnal and supplemental 2-day diurnal tests, respectively. Standards levels of 1.9 and 2.3 grams per test will apply for vehicles over 14,000 pounds. These standards represent more than a 50 percent reduction in the numerical standards as they exist today.

The program includes flexibility provisions to facilitate the transition to the new standards and to encourage the early introduction of clean technologies, and adjustments to various testing and compliance requirements to address differences between the new technologies and existing engine-based technologies. These provisions are described in Sections III and VI.

2. Fuel Quality Standards

This rule specifies that, beginning June 1, 2006, refiners must begin producing highway diesel fuel that meets a maximum sulfur standard of 15 parts per million (ppm). All 2007 and later model year diesel-fueled vehicles must be refueled with this new low sulfur diesel fuel. This sulfur standard is based on our assessment of the impact of sulfur on advanced exhaust emission control technologies, and a corresponding assessment of the feasibility of low sulfur fuel production and distribution.

Today's program includes a combination of flexibilities available to refiners to ensure a smooth transition to low sulfur highway diesel fuel. First, refiners can take advantage of a temporary compliance option, including an averaging, banking and trading component, beginning in June 2006 and lasting through 2009, with credit given for early compliance before June 2006. Under this temporary compliance option, up to 20 percent of highway diesel fuel may continue to be produced at the existing 500 ppm sulfur maximum standard. Highway diesel fuel marketed as complying with the 500 ppm sulfur standard must be segregated from 15 ppm fuel in the distribution system, and may only be used in pre-2007 model year heavy-duty vehicles. Second, we are providing additional hardship provisions for small refiners to minimize their economic burden in complying with the 15 ppm sulfur standard. Third, we are providing additional flexibility to refiners subject to the Geographic Phase-in Area (GPA) provisions of the Tier 2 gasoline sulfur program, which will allow them the option of staggering their gasoline and diesel investments. Finally, we are adopting a general hardship provision for which any refiner may apply on a case-by-case basis under certain conditions. These hardship provisions, coupled with the temporary compliance option, will provide a "safety valve" allowing up to 25 percent of highway diesel fuel produced to remain at 500 ppm for these transitional years to minimize any potential for highway diesel fuel supply problems.

In addition, today's program includes unique provisions for implementing the low sulfur diesel fuel program in the State of Alaska, given that it is exempt from the current 500 ppm standard. Certain U.S. territories are excluded from both the new engine standards and highway diesel fuel standards.

The compliance provisions for ensuring diesel fuel quality are essentially consistent with those that have been in effect since 1993 under the existing 500 ppm sulfur standard (55 FR 34120, August 21, 1990). Additional compliance provisions have been established primarily during the transition years of the program to verify refiners' compliance with the temporary compliance option to ensure the two grades of highway diesel fuel remain segregated, and to discourage misfueling of model year 2007 and later diesel vehicles.

B. Why is EPA Taking This Action?

1. Heavy-Duty Vehicles Contribute to Serious Air Pollution Problems

As discussed in detail in Section II, emissions from heavy-duty vehicles contribute greatly to a number of serious air pollution problems, and would have continued to do so into the future absent further controls to reduce these emissions. First, heavy-duty vehicles contribute to the health and welfare effects of ozone, PM, NO_X, SO_X, and volatile organic compounds (VOCs), including toxic compounds such as formaldehyde. These adverse effects include premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days), changes in lung function and increased respiratory symptoms, changes to lung tissues and structures, altered respiratory defense mechanisms, chronic bronchitis, and decreased lung function. Ozone also causes crop and forestry losses, and PM causes damage to materials and soiling of commonly used building materials and culturally important items such as statues and works of art. Second, NO_X, SO_X and PM contribute to substantial visibility impairment in many parts of the U.S. Third, NO_X emissions from heavy-duty trucks contribute to the acidification, nitrification and eutrophication of water bodies. Fourth, the Agency has concluded, and the Clean Air Scientific Advisory Committee has approved in public session, that diesel exhaust is likely to be carcinogenic to humans.

Millions of Americans live in areas with unhealthful air quality that currently endangers public health and welfare. Without emission reductions from the standards for heavy-duty vehicles, there is a significant risk that an appreciable number of 45 areas with 128 million people across the country will violate the 1-hour ozone national ambient air quality standard (NAAQS) during the period when these standards will take effect. Furthermore, our analysis shows that PM_{10} concentrations in 10 areas with a population of 28 million people face a significant risk of exceeding the PM_{10} NAAQS without significant additional controls between 2007 and 2030. Under the mandates and authorities in the Clean Air Act, Federal, state, and local governments are working to bring ozone and particulate levels into compliance with the 1-hour ozone and PM_{10} NAAQS through State Implementation Plan (SIP) attainment and maintenance plans, and to ensure that future air quality reaches and continues to achieve these health-based standards. The reductions in this rulemaking will play a critical part in these important efforts to attain and maintain the NAAQS. In addition, reductions from this action will also reduce public health and welfare effects associated with ozone and fine PM at concentrations that do not constitute a violation of the 1-hour ozone and PM_{10} NAAQS.

Emissions from heavy-duty vehicles account for substantial portions of the country's ambient PM and NO_X levels. (NO_X is a key precursor to ozone formation). By 2007, we estimate that heavy-duty vehicles will account for 28 percent of mobile source NO_X emissions and 20 percent of mobile source PM emissions. These proportions are even higher in some urban areas, such as in Sacramento, Atlanta, and Washington, DC, where HDVs contribute over 34 percent of the mobile source NO_X emissions, and in Santa Fe, Los Angeles, and Hartford, where heavy-duty vehicle PM emissions account for 38, 25 and 30 percent of the mobile source PM emissions inventory, respectively. Over time, the relative contribution of diesel engines to air quality problems will go even higher if diesel-equipped light-duty vehicles become more popular, as is expected by some automobile manufacturers. The PM and NO_X standards for heavy-duty vehicles in this rule will have a substantial impact on emissions. By 2030, NO_X emissions from heavy-duty vehicles under today's standards will be reduced by 2.6 million tons, and PM emissions will decline by about 109,000 tons, dramatically reducing this source of NO_X and PM emissions. Urban areas, which include many poorer neighborhoods, can be disproportionately impacted by HDV emissions, and these neighborhoods will thus receive a relatively larger portion of the benefits expected from new HDV emissions controls.

In addition to its contribution to PM inventories, diesel exhaust PM is of special concern because it has been implicated in an increased risk of lung cancer and respiratory disease. The EPA draft Health Assessment Document for Diesel Exhaust (Draft Assessment) was reviewed in public session by the Clean Air Scientific Advisory Committee (CASAC) on October 12–13, 2000.[3] The Agency has concluded, and the CASAC approved at this session, that diesel exhaust is likely to be carcinogenic to humans. State and local governments, in their efforts to protect the health of their citizens and comply with requirements of the Clean Air Act (CAA or "the Act"), have recognized the need to achieve major reductions in diesel PM emissions, and have been seeking Agency action in setting stringent new standards to bring this about.[4]

2. Technology-Based Solutions

Although the air quality problems caused by diesel exhaust are challenging, we believe they can be resolved through the application of high-efficiency emissions control technologies. As discussed in detail in Section III, the development of diesel emissions control technology has advanced in recent years so that very large emission reductions (in excess of 90 percent) are possible, especially through the use of catalytic emission control devices installed in the vehicle's exhaust system and integrated with the engine controls. These devices are often referred to as "exhaust emission control" or "aftertreatment" devices. Exhaust emission control devices, in the form of the well-known catalytic converter, have been used in gasoline-fueled automobiles for 25 years, but have had only limited application in diesel vehicles.

Based on the Clean Air Act requirements discussed in Section I.B.3, we are setting stringent new emission standards that will result in the use of these diesel exhaust emission control devices (see Section III). We are also finalizing changes to diesel fuel quality standards in order to enable these high-efficiency technologies (Section IV). Heavy-duty gasoline engines will also be able to reach the significantly lower emission levels envisioned in this rule by relying on the transfer of recent technology developments for light-duty applications, given the recent action taken to reduce sulfur in gasoline (65 FR 6698, February 10, 2000).

To meet the new standards, application of high-efficiency exhaust emission controls for both PM and NO_X will be needed. High-efficiency PM exhaust emission control technology has been available for several years, although engine manufacturers have generally not needed this technology in order to meet our PM emission standards. This technology has continued to improve over the years, especially with respect to durability and robust operation in use. It has also proven extremely effective in reducing exhaust hydrocarbon emissions. Thousands of such systems are now in use in fleet programs, especially in Europe. However, as discussed in detail in Section III, these systems are very sensitive to sulfur in the fuel. For the technology to be viable and capable of meeting the standards, we believe that it will require diesel fuel with sulfur content capped at the 15 ppm level.

Similarly, high-efficiency NO_X exhaust emission control technology will be needed if heavy-duty vehicles are to attain the new standards. We believe this technology, like the PM technology, is dependent on the 15 ppm maximum diesel fuel sulfur levels being adopted in this rule to be feasible and capable of achieving the standards. Similar high-efficiency NO_X exhaust emission control technology has been quite successful in gasoline direct injection engines that operate with an exhaust composition fairly similar to diesel exhaust. However, as discussed in Section III, application of this technology to diesels has some additional engineering challenges. In that section we discuss the current status of this technology. We also discuss the major development issues still to be addressed and the development steps that can be taken to address these issues. With the lead time available and the certainty of low-sulfur diesel fuel established by today's action, the evidence leaves us confident that the application of this technology to diesels will proceed at a reasonable rate of progress and will result in systems capable of achieving the standards.

The need to reduce the sulfur in diesel fuel is driven by the requirements of the exhaust emission control technology that we project will be needed to meet the standards. The challenge in accomplishing the sulfur reduction is driven by the feasibility of needed refinery modifications, and by the costs of making the modifications and running the equipment. Today, a number of refiners are acting to provide low sulfur diesel to some markets. In consideration of the impacts that sulfur has on the efficiency, reliability, and fuel economy impact of diesel engine exhaust emission control devices, we believe that controlling the sulfur content of highway diesel fuel to the 15 ppm level is necessary and feasible, and, in the context of this rule's overall program, cost effective.

3. Basis For Action Under the Clean Air Act

Section 202(a)(1) of the Act directs us to establish standards regulating the emission of any air pollutant from any class or classes of new motor vehicles or engines that, in the Administrator's judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare. Section 202(a)(3) requires that EPA set standards for heavy-duty trucks that reflect the greatest degree of emission reduction achievable through the application of technology which we determine will be available for the model year to which the standards apply. We are to give appropriate consideration to cost, energy, and safety factors associated with the application of such technology. We may revise such technology-based standards, taking costs into account, on the basis of information concerning the effects of air pollution from heavy-duty vehicles or engines and other sources of mobile source related

[3] EPA (2000) Review of EPA's Health Assessment Document for Diesel Exhaust (EPA 600/8–90/057E). Review by the Clean Air Scientific Advisory Committee (CASAC) December 2000. EPA–SAB–CASAC–01–003.

[4] For example, see letter dated July 13, 1999 from John Elston and Richard Baldwin on behalf of the State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials (docket A–99–06, item II–D–78).

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pollutants on the public health and welfare. Section 202(a)(3)(C) requires that promulgated standards apply for no less than three years and go into effect no less than 4 years after promulgation. This rule conforms with these statutory requirements.

We believe the evidence provided in Section III and the Regulatory Impact Analysis (RIA) indicates that the stringent emission standards finalized today are feasible and reflect the greatest degree of emission reduction achievable in the model years to which they apply. We have given appropriate consideration to costs in choosing these standards. Our review of the costs and cost-effectiveness of these standards indicate that they will be reasonable and comparable to the cost-effectiveness of other emission reduction strategies that have been required or could be required in the future. We have also reviewed and given appropriate consideration to the energy factors of this rule in terms of fuel efficiency and effects on diesel fuel supply, production, and distribution, as discussed below, as well as any safety factors associated with these standards.

The information regarding air quality and the contribution of heavy-duty engines to air pollution in Section II and the RIA provides strong evidence that emissions from such engines significantly and adversely impact public health or welfare. First, there is a significant risk that several areas will fail to attain or maintain compliance with the NAAQS for 1-hour ozone concentrations or PM_{10} concentrations during the period that these new vehicle and engine standards will be phased into the vehicle population, and that heavy-duty engines contribute to such concentrations, as well as to concentrations of other NAAQS-related pollutants. This risk will be significantly reduced by the standards adopted today; however, the evidence indicates that some risk remains even after the reductions achieved by these new controls on heavy-duty vehicles and diesel fuel. Second, EPA believes that diesel exhaust is likely to be carcinogenic to humans. The risk associated with exposure to diesel exhaust includes the particulate and gaseous components. Some of the toxic air pollutants associated with emissions from heavy-duty vehicles and engines include benzene, formaldehyde, acetaldehyde, dioxin, acrolein, and 1,3-butadiene. Third, emissions from heavy-duty engines contribute to regional haze and impaired visibility across the nation, as well as acid deposition, POM deposition, eutrophication and nitrification, all of which are serious environmental welfare problems.

Based on this evidence, EPA believes that, for purposes of section 202(a)(1), emissions of NO_X, VOCs, SO_x and PM from heavy-duty trucks can reasonably be anticipated to endanger the public health or welfare. In addition, this evidence indicates that it will not be appropriate to modify the technology-based standards pursuant to section 202(a)(3)(B). EPA believes that it is required under section 202(a)(3)(A) to set technology-based standards that meet the criteria of that provision, and is not required to make an affirmative determination under section 202(a)(1). Instead EPA is authorized to take air quality into consideration under section 202(a)(3)(B) in deciding whether to modify or not set standard under section 202(a)(3)(A). In this case, however, EPA believes the evidence fully supports a determination under section 202(a)(1) to set standards, and a determination not to modify such standards under section 202(a)(3)(B).

In addition, there is significant evidence that emissions from heavy-duty trucks contribute to levels of ozone such that large segments of the national population are expected to experience prolonged exposure over several hours at levels that present serious concern for the public health and welfare. The same is true for exposure to fine PM. These public health and welfare problems are expected to occur in many parts of the country, including areas that are in compliance with the 1-hour ozone and PM_{10} NAAQS (PM_{10} is particulate matter that is 10 microns or smaller). This evidence is an additional reason why the controls finalized today are justified and appropriate under the Act. While EPA sees this as additional support for this action, EPA also believes that the evidence of air pollution problems summarized above and described in greater detail elsewhere is an adequate justification for this rule independent of concern over prolonged exposure to ozone and fine PM levels.

Section 211(c) of the CAA allows us to regulate fuels where emission products of the fuel either: (1) Cause or contribute to air pollution that reasonably may be anticipated to endanger public health or welfare, or (2) will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it will be in general use were such a regulation to be promulgated. This rule meets each of these criteria. The discussion of the first test is substantially the same as the above discussion for the heavy-duty engine standards, because SO_x and sulfate PM emissions from heavy-duty diesel vehicles are due to sulfur in diesel fuel. The substantial adverse effect of high diesel sulfur levels on diesel control devices or systems expected to be used to meet the heavy-duty standards is discussed in depth in Section III.F and in the RIA. In addition, our authority under section 211(c) is discussed in more detail in Appendix A to the RIA.

C. Putting This Rule In Perspective

There are several helpful perspectives to establish in understanding the context for this rule: the growing popularity of diesel engines, past progress and new developments in diesel emissions control, Tier 2 light-duty emission standards and other related EPA initiatives (besides the above-discussed rulemaking for highway heavy-duty engine emission standards in 2004), and recent actions and plans to control diesel emissions by the States and in other countries.

1. Diesel Popularity

The diesel engine is increasingly becoming a vital workhorse in the United States, moving much of the nation's freight, and carrying out much of its farm, construction, and other labor. Diesel engine sales have grown significantly over the last decade, so that now about a million new diesel engines are put to work in the U.S. every year. Unfortunately, these diesel engines emit large quantities of harmful pollutants annually.

Furthermore, although diesel emissions in this country come mostly from heavy-duty trucks and nonroad equipment, an additional source may grow out of auto manufacturers' plans to greatly increase the sales of diesel-powered light-duty vehicles (LDVs) and especially of light-duty trucks (LDTs), a category that includes the fast-selling sport-utility vehicles, minivans, and pickup trucks. These plans reflect the continuation of an ongoing dieselization trend, a trend recently most evident in the growing popularity of diesel-powered light heavy-duty trucks (8500 to 19,500 pounds). Diesel market penetration is working its way from larger to smaller highway applications and to a broader array of nonroad equipment applications. Finally, especially in Europe where diesels have already gained a broad consumer acceptance, the diesel engine is increasingly viewed as an attractive technology option for reducing emissions of gases that contribute to global warming, because it has greater operating efficiency than a gasoline engine.

2. Past Progress and New Developments

Since the 1970's, highway diesel engine designers have employed numerous strategies to meet our emissions standards, beginning with smoke controls, and focusing in the 1990's on increasingly stringent NO_X, hydrocarbon, and PM standards. These strategies have generally focused on reducing engine-out emissions and not on exhaust emission controls, although relatively low-efficiency oxidation catalysts have been applied in some designs to reduce PM, with the recognition that their effectiveness is limited by sulfur in the fuel. On the fuel side, we set quality standards that provided emissions benefits by limiting the amount of sulfur and aromatics in highway diesel fuel beginning in 1993 (55 FR 34120, August 21, 1990). Our most recent round of standard setting for heavy-duty highway diesels occurred in 1997 (62 FR 54693, October 21, 1997), effective with the 2004 model year. These standards were recently reviewed in a final rulemaking (65 FR 59896, October 6, 2000). These actions will result in engines that emit only a fraction of the NO_X, hydrocarbons, and PM produced by engines manufactured just a decade ago. We consider this an important first phase of our current initiative to reconcile the diesel engine with the environment.

Nevertheless, certain characteristics inherent in the way diesel fuel combustion occurs have prevented achievement of emission levels comparable to those of today's gasoline-fueled vehicles. Although diesel engines provide advantages in terms of fuel economy, durability, and evaporative emissions, and have inherently low exhaust emissions of hydrocarbons and carbon monoxide, controlling NO_X emissions is a greater challenge for diesel engines than for gasoline engines, primarily because of the ineffectiveness of three-way catalysis in the oxygen-rich and relatively cool diesel exhaust environment. Similarly, PM emissions, which are inherently low for properly operating gasoline engines, are more difficult to control in diesel engines, because the diesel combustion process tends to form soot particles. The challenge is somewhat complicated by the fact that historical diesel NO_X control approaches tend to increase PM, and vice versa, but both are harmful pollutants that need to be controlled.

Considering the air quality impacts of diesel engines and the potential for growth of diesels in the lighter-duty portion of the market, it is imperative that progress in diesel emissions control continue. Significant progress has already been made in the design of exhaust emission control devices for diesel applications, driven in part by the challenge presented by the stringent Tier 2 standards for light-duty vehicles. As discussed in detail in Section III, new exhaust emission control technologies for NO_X, PM, and hydrocarbon reduction will allow a major advancement in diesel emissions control of a magnitude comparable to that ushered in by the automotive catalytic converter in the 1970's. However, changes in diesel fuel quality will be needed to enable these high-efficiency exhaust emission control devices.

3. Tier 2 Emissions Standards

Auto manufacturers' design plans for new light-duty diesel vehicle models will be greatly affected by our recent adoption of stringent new emission standards for light-duty highway vehicles (referred to as "Tier 2" standards) that will phase in between 2004 and 2009. These Tier 2 standards will require significant improvements in electronic engine controls and catalysts on gasoline vehicles. We anticipate that these advances will be transferred over to heavy-duty gasoline vehicles in meeting the standards finalized in this rule. The Tier 2 NO_X and PM standards, that apply equally to gasoline and diesel vehicles, will also require the use of high-efficiency emission control technologies on light-duty diesel vehicles. The low sulfur highway diesel fuel brought about by this rule will make it possible for designers to employ these high-efficiency exhaust emission control technologies in these light-duty applications. The timing of the fuel change provides for the use of these devices in time to satisfy Tier 2 phase-in requirements.

The Tier 2 program phases in interim and final standards over a number of years, providing manufacturers the option of delaying some of their production of final Tier 2 designs until later in the phase-in. For vehicles up to 6000 lbs GVWR (LDVs) and light light-duty trucks (LLDTs)), the interim standards begin in 2004 and phase out by 2007, as they are replaced by the final Tier 2 standards. For vehicles between 6000 and 8500 lbs (heavy light-duty trucks (HLDTs)), the interim standards begin in 2004 and phase out by 2009 as they are replaced by the final Tier 2 standards. A new category of vehicles between 8,500 and 10,000 lbs, medium-duty passenger vehicles (MDPVs), will follow the same phase-in schedule as HLDTs.

Our assessment in the Tier 2 final rule is that the interim standards are feasible for diesel vehicles without a need for fuel quality changes. Manufacturers can take advantage of the flexibilities provided in the Tier 2 program to delay the need for light-duty diesels to meet the final Tier 2 levels until late in the phase-in period (as late as 2007 for LDVs and LLDTs, and 2009 for HLDTs and MDPVs). However, low sulfur fuel is expected to be needed for diesel vehicles designed to meet the final NO_X and PM standards, because these vehicles are likely to employ light-duty versions of the sulfur-sensitive exhaust emission control technologies discussed in Section III. The gasoline quality changes and light-duty gasoline engine developments that will result from the Tier 2 rule will also help make it feasible for heavy-duty gasoline engines to meet the standards in this rule.

4. Mobile Source Air Toxics Rulemaking

Passenger cars, on-highway trucks, and nonroad equipment emit hundreds of different compounds and elements. Several of these are considered to be known, likely, or possible human carcinogens. These include diesel exhaust, plus several VOCs such as acetaldehyde, benzene, 1,3-butadiene, formaldehyde, and acrolein. Trace metals may also be present in heavy-duty diesel engine emissions, resulting from metals in fuels and lubricating oil, and from engine wear. Several of these metals have carcinogenic and mutagenic effects.

Important reductions in these and other mobile source air toxics have occurred under existing programs established under Clean Air Act Sections 202(a) (on-highway engine requirements), 211 (the fuel requirements), and 213 (nonroad engine requirements). Although these programs are primarily designed for control of criteria pollutants, especially ozone and PM_{10}, they also achieve important reductions in diesel PM and gaseous air toxics through VOC and hydrocarbon controls.

In addition to these programs, Section 202(l)(2) of the Act directs us to consider additional controls to reduce emissions of hazardous air pollutants from motor vehicles, their fuels, or both. Those standards are to reflect the greatest degree of emission reduction achievable through the application of technology which will be available, taking into account existing standards, costs, noise, energy, and safety factors. We published a proposed rule on mobile source air toxics on August 4,

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2000 (65 FR 48058). This MSAT final rule was signed on December 20, 2000. Interested parties should refer to the final rule if interested in the ultimate form of the regulation.

The mobile source air toxics (MSATs) rule consists of four parts. First, we identify a list of 21 MSATs that are known to be emitted from motor vehicles or their fuels and are considered by the Agency to pose potential adverse human health risks. Diesel exhaust is included on this MSAT list because, as discussed in Section II, human epidemiological studies have suggested that diesel exhaust is associated with increased risk of adverse respiratory effects and lung cancer. Second, the MSAT rule considers the contribution of mobile sources to the nation's air toxics inventory and evaluates the toxics benefits of existing mobile source emission control programs. The benefits of the program as proposed are included in this analysis. Third, the MSAT final rule considers whether additional controls are appropriate at this time, given technological feasibility, cost, and the other criteria specified in the Act. The final rule includes a toxics performance standard applicable to reformulated gasoline and anti-dumping standards that apply to conventional gasoline. With regard to additional vehicle-based controls, we proposed that it is not appropriate at this time to set more stringent standards than the technology forcing standards found in this rule and our recently adopted Tier 2 rulemaking. Finally, because of our concern about the potential future health impacts of exposure to the public of air toxics from the remaining emissions from mobile sources in the future, we continue our toxics-related research activities and to conduct a future rulemaking to evaluate whether, based on the additional data, additional mobile source air toxics controls should be adopted. This rulemaking would be completed no later than 2004.

EPA also intends to rely on today's rule to satisfy in part its obligations under section 202(l) of the Clean Air Act. In the mobile source air toxics NPRM, the Agency proposed a list of mobile source air toxics, including diesel exhaust, as well as a number of specific constituents of heavy-duty vehicle exhaust (gasoline and diesel).[5] The emissions standards established in today's action result in the greatest achievable reductions of diesel PM and heavy-duty vehicle NMHC. The Agency is scheduled to finalize the mobile source air toxics rulemaking on or before December 20, 2000.

5. Nonroad Engine Standards and Fuel

Although this rule covers only highway diesel engines and fuel, it is clear that potential requirements for nonroad diesel engines and fuel are related. It is expected that nonroad diesel fuel quality, currently unregulated, may need to be controlled in the future in order to reduce the large contribution of nonroad engines to NO_X and PM inventories. Refiners, fuel distributors, states, environmental organizations, and others have asked that we provide as much information as possible about the future specifications for both types of fuel as early as possible.

We do plan to give further consideration to additional control of nonroad engine emissions. As discussed below in Section VIII, an effective control program for these engines requires the resolution of several major issues relating to engine emission control technologies and how they are affected by fuel sulfur content. The many issues connected with any rulemaking for nonroad engines and fuel warrant serious attention, and we believe it is premature for us to take any action on this initiative in this rule. We plan to initiate action in the future to formulate proposals that would address both nonroad diesel fuel and engines.

6. State Initiatives

The California Air Resources Board (ARB) and local air quality management districts within California are also pursuing measures to better control diesel emissions. Key among these efforts is work resulting from the Board's designation of particulate emissions from diesel-fueled engines as a toxic air contaminant (TAC) on August 27, 1998. TACs are air pollutants that may cause or contribute to an increase in death or serious illness or may pose a present or future hazard to human health. The TAC designation was based on research studies showing that emissions from diesel-fueled engines may cause cancer in animals and humans, and that workers exposed to higher levels of emissions from diesel-fueled engines are more likely to develop lung cancer.

In September 2000 the ARB approved a Diesel Risk Reduction Plan developed by its staff following an extensive public process.[6] This plan includes several California measures related to highway diesel vehicles, including the major elements of the program we are establishing on a nationwide basis in this final rule. Because truck travel from other states has a large effect on California's air quality, the plan and the Board's resolution further encourages the EPA adopt this nationwide program, as well as other diesel-related emissions reduction programs.

The ARB has also adopted stringent new emission requirements for urban transit buses and is considering similar requirements for school buses.[7] This program is aimed at encouraging the use of clean alternative fuels and high-efficiency diesel emission control technologies. Their program includes requirements for zero-emissions buses, fleet average NO_X levels, and retrofits for PM control, as well as model year 2007 NO_X and PM standards levels of 0.2 and 0.01 g/bhp-hr, respectively (equal to the levels finalized in this rule). It also requires that all diesel fuel used by transit agencies after July 1, 2002 must meet a cap of 15 ppm sulfur. This is a much earlier schedule than that finalized in this rule, to support the ARB's proposed transit bus fleet program.

Other states, most notably Texas, have taken steps toward adopting programs for cleaner diesel fuel and cleaner diesel engines. On December 6, 2000, the Texas Natural Resource Conservation Commission adopted a program that, among other things, would require the capping of diesel fuel sulfur levels in many counties to 15 ppm by June 2006.[8] This proposal exemplifies the importance that states with air quality problems have attached to clean diesel fuel, and specifically to the 15 ppm maximum sulfur requirement in 2006 being set in this rule

7. Retrofit Programs

Many States facing air quality improvement challenges have expressed strong interest in programs that will reduce emissions from existing highway and nonroad diesel engines through the retrofitting of these engines with improved emission control devices. The urban transit bus program adopted by the California ARB includes such a retrofit requirement as one of its major components (see Section I.C.6). In March 2000 we announced our own Diesel Retrofit Initiative to support and encourage fleet operators, air quality planners, and retrofit manufacturers in creating effective retrofit programs. These programs are appealing because the slow turnover of the diesel fleet to the new low-emitting engines makes it difficult to achieve near-term air quality goals through new engine programs alone. Some of the exhaust emission control technologies discussed in this rule are especially appealing for use in retrofits because they can be fitted to an existing vehicle as add-on devices without major engine modifications, although some of the more sophisticated systems that require careful control of engine parameters may be more challenging.

Because of the uncertainty at this time in how and when such programs may be implemented, our analysis for today's rule does not calculate any benefits from them. Nevertheless, we believe that this program can enable the viability of these retrofit technologies. We expect that large emission benefits from the existing fleet could be realized as a result of the fuel changes we are finalizing here, combined with retrofit versions of the technologies that will be developed in response to the finalized engine standards. These benefits will be especially important in the early years of the program when new vehicles standards are just beginning to have an impact, and when States and local areas need to gain large reductions to attain air quality goals.

8. Actions In Other Countries

There is substantial activity taking place in many countries related to the regulation of diesel fuel and engines. The large light-duty vehicle market share enjoyed by diesels in many European countries has helped to stir innovation in dealing with diesel emissions problems. Advanced emissions control technologies are being evaluated there in the in-use fleet and experience gained from these trials is helping to inform the diesel emissions control discussion in the U.S. In addition, several European countries have low sulfur diesel fuel, with maximum sulfur levels varying from 10 to 50 ppm, and so experience gained from the use of these fuels, though not completely transferable to the U.S. situation, also provides valuable experience. European Union countries will limit sulfur in diesel fuel to 50 ppm by 2005, and even more aggressive plans are being discussed or implemented. The United Kingdom made a rapid conversion to 50 ppm maximum sulfur diesel fuel in 1999 by offering tax incentives. This change occurred with much smaller refinery investments than had been predicted, and some refinery production there is actually at levels well below the 50 ppm cap. Germany is moving forward with plans to introduce a 10 ppm sulfur cap for diesel fuel by 2003, also via tax incentives, and is attempting to get the 50 ppm specification that was adopted by the European Commission revised downward to the 10 ppm cap level. The Commission is reviewing the implications of moving to this level.

One European country has had extensive experience with the transition to low sulfur diesel fuel. In the early 1990's, Sweden decided to take advantage of the environmental benefits of 10 ppm sulfur/low aromatics fuel by introducing it with a reduction in the diesel fuel tax. The program has been quite successful, and in excess of 90 percent of the highway diesel fuel used there is of this 10 ppm maximum sulfur class.[9]

The government of Canada has expressed its intent to harmonize its fuel regulations with the U.S. fuels standards being adopted today.[10] This would simplify the operation of new-technology vehicles that cross the U.S.-Canada border. However, the success of the U.S. program does not depend on harmonized diesel fuel standards, and Section VI.H discusses how differences between the future fuel specifications in the U.S. and those in Canada and Mexico may be accommodated.

II. The Air Quality Need and Projected Benefits

A. Overview

Heavy-duty vehicle emissions contribute to air pollution with a wide range of adverse health and welfare impacts. Emissions of VOC, CO, NO_X, SO_x, and PM from HD vehicles contribute a substantial percentage of the precursors or direct components of ambient concentrations of ozone, PM, sulfur and nitrogen compounds, aldehydes, and substances known or considered likely to be carcinogens. Emissions of VOCs include some specific substances known or suspected to cause cancer. Of particular concern is human epidemiological evidence linking diesel exhaust to an increased risk of lung cancer, and the Agency is also concerned about the noncancer health effects of diesel exhaust We have finalized on December 20, 2000 a rule which lists diesel particulate matter and diesel exhaust organic gases as a mobile source air toxic under section 202(l) of the Clean Air Act, and the particulate matter standard finalized today reflects the greatest degree of emissions reductions achievable under section 202(l) for on-highway heavy-duty vehicle PM emissions. Heavy-duty vehicle emissions also cause adverse environmental effects including visibility reductions, acid rain, nitrification and eutrophication of water bodies.

Emissions from heavy-duty vehicles which are predominantly diesel-powered, account for substantial portions of the country's ambient PM and ground-level ozone levels. By 2007, we estimate that heavy-duty vehicles will account for 28 percent of mobile source NO_X emissions (including highway and non-road), and 20 percent of mobile source PM emissions. These proportions are even higher in some urban areas, such as Atlanta and Los Angeles. Urban areas, which include many poorer neighborhoods, can be disproportionately impacted by HDV emissions because of heavy traffic in and out of densely populated urban areas.

The Agency developed new emissions inventories and conducted new air quality modeling for this rule to determine the risk of exposure to unhealthy ambient concentrations of ozone and particulate matter in 2007, 2020 and 2030. This analysis, supplemented with local air quality modeling and other information on emissions and air quality trends, indicates that an appreciable number of the 45 areas with a total population of 128 million people face a significant risk of violating the 1-hour ozone standard between 2007 and 2030. Ten PM_{10} nonattainment areas with 28 million people face a significant risk of experiencing particulate matter levels that violate the PM_{10} standard during the same period.

Under the mandates and authorities in the Clean Air Act, federal, state, and local governments are working to bring ozone and particulate levels into compliance with the 1-hour ozone and PM_{10} NAAQS through SIP attainment plans. Areas that reach attainment without reductions from this rule are likely to need additional reductions to ensure that future air quality continues to achieve ozone and PM standards, and areas that seek redesignation to attainment may use the reductions from this rule in future maintenance plans.

The heavy-duty vehicle and engine emission standards, along with the diesel fuel sulfur standard finalized today, will have a dramatic impact in

[5] 65 FR 48058, August 4, 2000.

[6] State of California Air Resources Board Resolution 00–30, September 28, 2000.

[7] "Notice of Public Hearing To Consider the Adoption of a Public Transit Bus Fleet Rule and Emission Standards For New Urban Buses", California ARB, November 30, 1999, and ARB Resolution 00–2, dated February 24, 2000.

[8] Title 30, Texas Administrative Code, Chapter 114, Subchapter H, Division 2. Also see Texas Natural Resource Conservation Commission website www.tnrcc.state.tx.us.

[9] Memo from Thomas M. Baines to Docket A–99–06, October 29, 1999, Docket #A–99–06, Item II–G–12.

[10] "Process Begins to Develop Long term Agenda to Reduce Air Pollution from Vehicles and Fuels", Environment Canada press release, May 26, 2000.

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reducing the large contribution of HDVs to air pollution. These standards will result in substantial benefits to public health and welfare through significant annual reductions in emissions of NO_X, PM, NMHC, carbon monoxide, sulfur dioxide, and air toxics. For example, we project a 1.8 million ton reduction in NO_X emissions from HD vehicles in 2020, which will increase to 2.6 million tons in 2030 when the current HD vehicle fleet is completely replaced with newer HD vehicles that comply with these emission standards. When coupled with the emission reductions projected to result from the Phase 1 (model year 2004) HDV standards, the emission reductions from heavy-duty vehicles are projected to be as large as the substantial reductions the Agency expects from light-duty vehicles as a result of its recently promulgated Tier 2 rulemaking.

In sum, the Agency's air quality modeling and other evidence demonstrates that ambient concentrations of ozone, particulate matter, sulfur and nitrogen compounds, VOCs, air toxics, CO and diesel exhaust are anticipated to endanger public health, welfare and the environment in the time period between 2007 and 2030. Emission reductions expected from today's action are predicted to lessen future ambient concentrations of ozone and particulate matter and associated adverse public health and welfare effects.

B. Public Health and Welfare Concerns

1. Health and Welfare Concerns Raised During Public Hearings

The Agency received a significant number of comments on this section during the public hearings and in written comments from interested parties. Comments are addressed in this section as well as in the Response to Comment document that accompanies this action.

Throughout the five public hearings held around the country on the proposed heavy-duty engine and diesel fuel rule, the Agency received strong public support at each venue for increasing the stringency of heavy-duty truck and bus emission standards, and for further controls on sulfur in diesel fuel, in order to enable the necessary exhaust emission control. In addition to the 55,000 comments received from citizens in support of the Agency proposal to clean diesel fuel by mid-2006 and reduce emissions from diesel engines in 2007, we received 8,500 comments from citizens urging the Agency to act prior to 2007.

Public officials and representatives of environmental, public health, or community-based organizations testified regularly about the link between public health ailments, such as asthma and lung cancer, and air pollution caused by diesel exhaust and particulate matter. In different ways, many noted that the impact of diesel soot is compounded by the fact that it is discharged at street level where people live and breathe. A regular complaint was the close proximity of bus depots, transfer terminals, and heavily-trafficked roadways to homes and apartment buildings, and in particular, to hospitals, playgrounds and schools. A common theme revolved around the notion that since asthma is an incurable disease, it was of utmost importance to help reduce the severity and frequency of attacks by reducing environmental triggers such as ozone, particulate matter and diesel exhaust.

Major industries represented during these public hearings were the heavy-duty vehicle engine manufacturers, the oil industry, and the commercial truckers. While each had a different perspective, most supported the underlying intent of the proposal to improve public health and welfare, and some also supported the specific requirements as proposed. For those who objected to the proposal, the main thrust of their concerns related to the stringency and public health necessity of the new standards and the diesel fuel sulfur requirement. Largely in their written comments, these industries raised questions about the need for additional reductions in order to meet existing ozone and PM national ambient air quality standards and took exception with the Agency's characterization of diesel exhaust as a human carcinogen at environmental levels of exposure. Some industry commenters also challenged the Agency's reliance on public welfare and environmental effects such as visibility impairment and eutrophication of water bodies because the Agency had insufficiently quantified the benefits that would result from new standards on heavy-duty vehicles and diesel fuel.

The following subsections present the available information on the air pollution situation that is likely to exist without this rule for each ambient pollutant. We also present information on the improvement that is expected to result from this rule.

2. Ozone and Its Precursors

a. Health and Welfare Effects From Short-Term Exposures to Ozone

NO_X and VOC are precursors in the photochemical reaction which forms tropospheric ozone. A large body of evidence shows that ozone can cause harmful respiratory effects including chest pain, coughing, and shortness of breath, which affect people with compromised respiratory systems most severely. When inhaled, ozone can cause acute respiratory problems; aggravate asthma; cause significant temporary decreases in lung function of 15 to over 20 percent in some healthy adults; cause inflammation of lung tissue; produce changes in lung tissue and structure; may increase hospital admissions and emergency room visits; and impair the body's immune system defenses, making people more susceptible to respiratory illnesses. Children and outdoor workers are likely to be exposed to elevated ambient levels of ozone during exercise and, therefore, are at greater risk of experiencing adverse health effects. Beyond its human health effects, ozone has been shown to injure plants, which has the effect of reducing crop yields and reducing productivity in forest ecosystems.

There is strong and convincing evidence that exposure to ozone is associated with exacerbation of asthma-related symptoms. Increases in ozone concentrations in the air have been associated with increases in hospitalization for respiratory causes for individuals with asthma, worsening of symptoms, decrements in lung function and increased medication use. Studies have also indicated that exposure to particulate matter can be associated with altered lung function and increased respiratory symptoms, and asthmatic children are considered to be particularly sensitive to these effects. In addition, exposures to particulate matter or ozone have been shown to have a priming effect for responsiveness to allergens, with the pollutant exposure leading to heightened responses to allergens among allergic asthmatics. It is not believed, based on the current evidence, that exposure to outdoor pollutants such as ozone or particulate matter is a cause of asthma.

Asthma is one of the most common and costly diseases in the United States. According to the President's Task Force on Environmental Health Risks and Safety Risks to Children, America is in the midst of an asthma epidemic.[11]

[11] *Asthma and the Environment: A Strategy to Protect Children, President's Task Force on Environmental Health Risks and Safety Risks to Children*, January 28, 1999, Revised May, 2000.

Since 1980, the number of asthma sufferers in the United States has more than doubled from 6.7 million to 17.3 million in 1998.[12] Today, more than 5 percent of the US population has asthma. On average, 15 people died every day from asthma in 1995, and the death rate has nearly tripled since 1975. In 1998, the cost of asthma to the U.S. economy was estimated to be $11.3 billion, with hospitalizations accounting for the single largest portion of the cost.[13] A recent report by the Pew Environmental Health Commission at Johns Hopkins School of Public Health estimates that by 2010, 22 million Americans will suffer from asthma, or one in 14 Americans and one in every five families.[14] At present, asthma cannot be cured, only controlled.

To address this growing public health problem, the President's Task Force on Environmental Health Risks and Safety Risks to Children ranked asthma as its highest priority. The President's Task Force created and charged the Asthma Priority Area Workgroup, co-chaired by EPA and the Department of Health and Human Services, with reviewing current Federal efforts to address the issue, and to make recommendations. In May, 2000, the Task Force issued a strategy that focused on developing a greater understanding of the role environmental factors associated with the onset of asthma; and triggers of asthma. The report found that "children with asthma have long been recognized as particularly sensitive to outdoor air pollution," The report noted that "25 percent of children in America live in areas that regularly exceed EPA limits for ozone." The first guiding principle was to focus efforts to "eliminate the disproportionate impact of asthma in minority populations and those living in poverty." Testimony received during the Agency's five public hearings on this rule contained numerous references and detailed personal accounts as to the severe and sometimes fatal impact of asthma on the lives of American citizens.

[12] *Asthma Prevention Program of the National Center for Environmental Health*, Centers for Disease Control and Prevention, "At-A-Glance, 1999; Centers for Disease Control and Prevention, CDC, *Surveillance for Asthma—United States, 1960–1995*," MMWR 47 (No. SS-1) (April 1998).

[13] Asthma Statistics, National Institutes of Health, National, Heart, Lung, and Blood Institute, January, 1999.

[14] *Attack Asthma: Why America Needs A Public Health Defense System to Battle Environmental Threats*, Pew Environmental Health Commissions at the Johns Hopkins School of Public Health, June, 2000.

b. Current and Future Nonattainment Status With the 1-Hour Ozone NAAQS

Today, ground level ozone remains a pervasive pollution problem in the United States. As of July, 2000, 102 million people (1999 census) lived in 31 metropolitan areas designated nonattainment under the 1-hour ozone NAAQS.[15] This is a sharp decline from the 101 nonattainment areas originally identified under the Clean Air Act Amendments of 1990, but elevated ozone concentrations remain a serious public health concern throughout the nation.

Over the last decade, declines in ozone levels were found mostly in urban areas, where emissions are heavily influenced by controls on mobile sources and their fuels.[16] Twenty-three metropolitan areas have realized a decline in ozone levels since 1989, but at the same time, ozone levels in 11 metropolitan areas with 7 million people have increased.[17] Regionally, California and the Northeast have recorded significant reductions in peak ozone levels, while four other regions (the Mid-Atlantic, the Southeast, the Central and Pacific Northwest) have seen ozone levels increase.

The highest ambient concentrations are currently found in suburban areas, consistent with downwind transport of emissions from urban centers. Concentrations in rural areas have risen to the levels previously found only in cities. Over the last decade, ozone levels at 17 of our National Parks have increased, and in 1998, ozone levels in two parks were 30 to 40 percent higher than the ozone NAAQS.

i. Results of Photochemical Ozone Modeling and Analysis of Emissions Inventories

In conjunction with this rulemaking, the Agency performed ozone air quality modeling for nearly the entire Eastern U.S covering metropolitan areas from Texas to the Northeast.[18] This ozone air quality modeling was based upon the same modeling system as was used in the Tier 2 air quality analysis, with the addition of updated inventory estimates for 2007 and 2030.[19] This modeling supports the conclusion that there is a broad set of areas with predicted ozone concentrations in 2007 and 2030 at or above 0.125 ppm, in the baseline scenarios without additional emission reductions. EPA established the 1-hour standard at 0.12 parts per million (ppm) daily maximum 1-hour average concentration not to be exceeded more than once per year on average. Compliance with the 1-hour standard is judged on the basis of the most recent three years of ambient air quality monitoring data.

We have compared and supplemented our own ozone modeling with other modeling studies, submitted to us as state implementation plan (SIP) revisions, or brought to our attention through our consultations with states on SIP revisions that are in development. The ozone modeling in the SIP revisions has the advantage of using emission inventories that are more specific to the area being modeled, and of using meteorological conditions selected specifically for each area. Also, the SIP revisions included other evidence and analysis, such as analysis of air quality and emissions trends, observation-based models that make use of data on concentrations of ozone precursors, alternative rollback analyses, and information on the responsiveness of the air quality model. For some areas, we decided that the predictions of 1-hour ozone exceedances from our modeling were less reliable than conclusions that could be drawn from this additional evidence and analysis. For example, in some areas our episodes did not capture the meteorological conditions that have caused high ozone, while local modeling did so. Thus, these local analyses are considered to be more extensive than our own modeling for estimating whether there would be NAAQS nonattainment without further emission reductions, when interpreted by a weight of evidence method which meets our guidance for such modeling.

Photochemical ozone modeling conducted for this rulemaking was based in part on updated national emissions inventories for all sources. National emission trends for NO_X

[15] Memorandum to Air Docket, September 18, 2000. Information on ozone nonattainment areas and populations as of July 31, 2000 from US EPA website www.epa.gov/airs/nonattn.html, USA Air Quality Nonattainment Areas, Office of Air Quality Planning and Standards.

[16] National Emissions Trends database.

[17] National Air Quality and Emissions Trends Report, 1998, March, 2000, at 28.

[18] EPA also performed ozone air quality modeling for the western United States but, as described further in the air quality technical support document, model predictions were well below corresponding ambient concentrations. Because of poor model performance for this region of the country, the results of western ozone modeling were not relied on for this rule.

[19] Consistent with a commitment expressed in the proposal, the Agency released the emissions inventory inputs for, and a description of, ozone modeling into the public record (docket number A–99–06), and also onto a website developed expressly for this purpose, on a continuous basis as they were developed. Further discussion of this modeling, including evaluations of model performance relative to predicted future air quality, is provided in the air quality modeling Technical Support Document (TSD).

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predict a significant decline from 1996 to 2007, a leveling off of the downward trend between 2007 to 2020, and an increase in NO_X inventories from 2020 to 2030. By 2030, national NO_X levels are estimated to reach levels that are within ten percent of 2007 levels. Predictions of national VOC emissions indicate a reduction from 1996 to 2007, followed by an increase between 2007 and 2030 resulting in 2030 levels that are estimated to be 10 percent greater than VOC emissions levels in 2007. In metropolitan ozone nonattainment areas, such as Charleston, Chicago and Houston, NO_X or VOC emissions in 2030 are predicted to reach or exceed 2007 levels. These estimated national and metropolitan area emissions inventories of ozone precursors are consistent with the conclusions reached by analysis of ozone modeling conducted for this rule that additional reductions are needed in order to enable areas to reach and maintain attainment of the ozone standard between 2007 and 2030.

The Agency conducted ozone modeling based on inventories developed with and without reductions from this rulemaking for three future years: 2007, 2020 and 2030. The year 2007 was chosen because it is also the first year of implementation for the new standards adopted in today's action. It is also the year that nine major urban areas with a history of persistent and elevated ozone concentrations must demonstrate attainment, and is also relevant to the South Coast Air Basin of California (South Coast) with an attainment date of 2010. In addition, modeling was performed for 2030 when the full benefits of the rule are expected to be realized and for 2020 which represents an intermediate year between the start of the program and full turnover of the affected vehicle fleet. The year 2020 is also representative of the period when areas that have come into attainment may need additional reductions in order to maintain the standard.

Today's rule will provide a substantial reduction in emissions of ozone precursors, particularly NO_X. These emissions reductions will greatly lower ozone concentrations which will help federal and State efforts to bring about attainment of the current 1-hour ozone standard. As described in the Air Quality Modeling Technical Support Document for this rule, EPA performed regional scale ozone modeling for the Eastern U.S. to assess the impacts of the controls in this rule on predicted 1-hour ozone exceedances. The results of this modeling were examined for those 37 areas in the East for which EPA's modeling predicted exceedances in 2007, 2020 and/or 2030 and current 1-hour design values are above the standard or within 10 percent of the standard. The results for these areas combined indicate that there will be substantial reductions in the number of exceedances and the magnitude of high ozone concentrations in both 2020 and 2030 due to this rule. The modeling also indicates that without the rule, exceedances would otherwise increase by 37 percent between 2020 and 2030 as growth in emissions offsets the reductions from Tier 2 and other current control programs.

For all areas combined, the rule is forecast to provide a 33 percent reduction in exceedances in 2020 and a 38 percent reduction in 2030. The total amount of ozone above the standard is expected to decline by nearly 37 percent in 2020 and 44 percent in 2030. Also, daily maximum ozone exceedances are lowered by 5 ppb on average in 2020 and nearly 7 ppb in 2030. The modeling forecasts an overall net reduction of 39 percent in exceedances from 2007, which is close to the start of this program, to 2030 when controls will be fully in place. In addition, the results for each individual area indicates that all areas are expected to have fewer exceedances in 2030 with the HDV controls than without this rule.

During the public comment period on the proposed rule, EPA received several comments that expressed concern about potential increases in ozone that might result from this rule. As indicated above, the air quality modeling results indicate an overall reduction in ozone levels in 2007 and 2030 during the various episodes modeled. Examining individual areas, nearly the entire country is projected to benefit substantially from the reductions in this rule.[20] There is a metropolitan area that EPA modeled as having exceedances with the one-hour ozone standard under baseline conditions in 2007 through 2030, which the Agency's modeling for the HDV rule estimated could have less than a 3 percent increase in its peak ozone levels in 2020 and 2030 and small net increase (i.e., less than 1 ppb) in levels above the 1-hour standard in 2030. However, EPA's air quality modeling did not predict an increase in the number of exceedances in this CMSA/MSA in 2020 and a decrease in exceedances occurred in 2030. In another CMSA/MSA in another State, in 2030 there was less than a one percent increase in the summer peak level. Yet, this area had fewer exceedances and lower ozone above the 1-hour standard in both 2020 and 2030 under the rule. EPA expects that the States will have State Implementation Plans that will consider federal controls and complement them with State actions to provide attainment and will work with the States to ensure this occurs.

Considering all of EPA's air quality modeling results, it is clear that the significant ozone reductions from this rule outweigh the limited ozone increases that may occur in the future assuming no additional reductions from federal or local controls. Additional details on this are provided in the Response to Comments document and in EPA's Heavy Duty Rule Air Quality Modeling Technical Support Document. Furthermore, EPA's Regulatory Impact Analysis for this rule shows significant health and welfare benefits occurring from the ozone reductions that the rule provides (see details on the benefits in Section V.F.5 of the preamble and Chapter VII of the RIA).

ii. Areas At Risk of Exceeding the 1-Hour Ozone Standard in the Future

This section presents the Agency's conclusions about the risk of future nonattainment for 45 areas listed in Table II.B–1 based on photochemical ozone modeling conducted for this rule and other evidence such as local air quality modeling.[21] The areas listed in Table II.B–1 are separated into two broad groups: (1) Those areas with attainment dates in 2007 or 2010 that will benefit from reductions from this rule to attain and maintain the standard; and (2) those areas with attainment dates prior to 2007 that will benefit from reductions from this rule to maintain the standard after their attainment dates. Because ozone concentrations causing violations of the 1-hour ozone standard are well established to endanger public health and welfare, this indicates that it is appropriate for the Agency to set new standards for heavy-duty vehicles. The following discussion follows these groupings from top to bottom. A more detailed discussion is found in the Regulatory Impact Analysis (RIA).

Ten metropolitan areas contained within designated ozone nonattainment areas have statutorily-defined attainment dates of 2007 or 2010, or

[20] The air quality modeling was performed for the Eastern region of the United States, but EPA also expects the rule to benefit nonattainment areas throughout the entire nation, including California.

[21] In the proposal, we relied on photochemical ozone modeling performed for recently promulgated standards on light duty vehicles, or Tier 2. The results presented in this final rulemaking for heavy-duty vehicles and diesel fuel are largely consistent with the findings presented in the proposal, with small differences due to updated emissions inventories. As stated in the proposal, the ozone modeling methodologies used in the proposal and presented here in the final rule are identical.

have requested attainment date extensions to 2007. These 10 areas are listed at the top of Table II.B–1, and are New York City, Houston, Hartford, New London, Chicago, Milwaukee, Dallas, Beaumont-Port Arthur, Los Angeles, and Southeast Desert.

Each of these areas needs additional emission reductions in order to reach attainment by 2007, and to maintain the standards in the future. Some of these areas have emission reduction shortfalls that are identified in their attainment demonstrations (*i.e.*, South Coast Air Basin, New York and Houston), and reductions from this rule will assist State efforts to reach attainment.[22] Three other areas—Southeast Desert, Hartford, New London—are subject to ozone transport from upwind areas with identified shortfalls (South Coast and New York), and depend upon attainment from these upwind areas to reach attainment themselves. We have received attainment plans for two areas in Texas (Dallas and Beaumont-Port Arthur), and the Agency is likely to consider the reductions from this rule in its proposed approval of these attainment plans in **Federal Register** notices. Finally, there are two areas in the Midwest—Chicago and Milwaukee—that have incorporated reductions from this rule into their regional ozone modeling, and plan to rely on reductions from this rule to support their 2007 attainment demonstration.[23]

For all ten areas, even if all shortfalls were filled by the States, there is some risk that at least some of the areas will not attain the standards by their attainment dates of 2007, or 2010 for Los Angeles. In that event, the reductions associated with this program, which increase substantially after 2007, will help assure that any residual failures to attain are remedied. Finally, there is also some risk that the areas will be unable to maintain attainment after 2007. Considered collectively, there is a significant risk that some areas will not be in attainment throughout the period when the new standards will reduce heavy-duty vehicle emissions.

The rest of the areas have required attainment dates prior to 2007, or have no attainment date but are subject to a general obligation to have a SIP that provides for attainment and maintenance. These 34 areas, according to our modeling, are at risk of exceeding the ozone NAAQS between 2007 and 2030. These areas will be able to rely on reductions from this rule to continue to maintain the standard after attainment is reached, and will be able to take credit for this program in their maintenance plans when they seek redesignation to attainment of the ozone standard. If any of these areas reach attainment, and then fall back into nonattainment, or fail to reach attainment by 2007, reductions from this rule will assist these areas in achieving the ozone standard. If an area does not choose to seek redesignation, the continuing reductions from this rulemaking will help ensure maintenance (*i.e.*, prevent future exceedances) with the 1-hour standard after initial attainment is reached.

Areas with attainment dates prior to 2007 are presented in two groupings in the table at the end of this section: a group of 20 areas in the middle of Table II.B–1, and a group of 15 areas at the bottom of Table II.B–1. For the middle group of 20 areas, EPA and the States are pursuing the established statutory processes for attaining and maintaining the ozone standard, or have already redesignated these areas to attainment with a maintenance plan (*e.g.*, Cincinnati). EPA has re-instated the 1-hour ozone standard to some of these areas, restoring the applicability of these processes to them. The Agency believes that there is a significant risk that future air quality in a number of these areas will exceed the ozone standard at some time in the 2007 and later period. This belief is based on three factors: (1) Recent exceedances in 1997–1999, (2) predicted exceedances in 2007, 2020 or 2030 after accounting for existing mobile source requirements and other local or regional controls currently in place or required, and (3) our assessment of the magnitude of recent violations, the year-to-year variability of meteorological conditions conducive to ozone formation, transport from areas with later attainment dates, and other variables inherent in predicting future attainment such as the potential for some areas to experience unexpectedly high economic growth rates, growth in vehicle miles traveled, varying population growth from area to area, and differences in vehicle choice.

Only a subset of these 20 areas have yet adopted specific control measures that have allowed the Agency to fully approve an attainment plan. For some of these areas, we have proposed a finding, based on all the available evidence, that the area will attain by its applicable attainment date. We have approved a 10-year maintenance plan for Cincinnati, OH from 1999 to 2009. However, in many cases, these proposals depend on the State adopting additional emission reduction measures. The RIA provides more information on our recent proposals on attainment demonstrations and maintenance plans.[24] Until the SIPs for these areas are actually submitted, reviewed and approved by EPA, there is some risk that these areas will not adopt fully approvable SIPs.

Finally, there are 15 additional metropolitan areas for which the available ozone modeling and other evidence is less clear regarding the need for additional reductions (see Table II.B–1). Our ozone modeling predicted these areas to need further reductions to avoid exceedances in 2007, 2020 or 2030. The recent air quality monitoring data for these areas shows ozone levels with less than a 10 percent margin below the NAAQS. We believe there is a risk that future ozone levels will be above the NAAQS because of the year-to-year variability of meteorological conditions conducive to ozone formation, or because local emissions inventories may increase faster than national inventories.

iii. Conclusion

In sum, without these reductions, there is a significant risk that an appreciable number of the 45 areas, with a population of 128 million people in 1999, will violate the 1-hour ozone standard during the time period when these standards will apply to heavy-duty vehicles. The evidence summarized in this section, and presented in more detail in the air quality modeling TSD and the RIA, supports the Agency's belief that emissions of NO_X and VOC from heavy-duty vehicles in 2007 and later will contribute to a national ozone air pollution problem that warrants regulatory action under section 202(a)(3) of the Act.

[22] The South Coast's "additional measures" which rely on new technologies, are located in its 1994 SIP.

[23] Technical Support Document, Midwest Subregional Modeling: 1-Hour Attainment Demonstration for Lake Michigan Area and Emissions Inventory, Illinois Environmental Protection Agency, Indiana Department of Environmental Management, Michigan Department of Environmental Quality, Wisconsin Department of Natural Resources, September 27, 2000, at 14 and at 8.

[24] We have recently proposed favorable action, in some cases with a condition that more emission reductions be obtained, on attainment demonstrations in these areas with attainment dates prior to 2007: Philadelphia, Washington-Baltimore, Atlanta, and St. Louis.

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TABLE II.B–1 [a]

[Areas and 1999 Populations at Risk of Exceeding the Ozone Standard between 2007 and 2030]

MSA/CMSA/State	1999 Population (in millions)
Areas with 2007/2010 Attainment Dates (Established or Requested)	
Beaumont-Port Arthur, TX	0.4
Chicago-Gary-Kenosha, IL–IN–WI	8.9
Dallas-Fort Worth, TX	4.9
Hartford, CT	1.1
Houston-Galveston-Brazoria, TX	4.5
Los Angeles-Riverside-Orange County, CA	16.0
Milwaukee-Racine, WI	1.6
New London-Norwich, CT–RI	0.3
New York-Northern New Jersey-Long Island, NY–NJ–CT–PA	20.2
Southeast Desert, CA	0.5
10 areas	58.4
Areas with Pre-2007 Attainment Dates or No Specific Attainment Date, with a Recent History of Nonattainment.	
Atlanta, GA	3.9
Baton Rouge, LA	0.6
Birmingham, AL	0.9
Boston-Worcester-Lawrence, MA–HN–ME–CT	5.7
Charlotte-Gastonia-Rock Hill, NC–SC	1.4
Detroit-Ann Arbor-Flint, MI MSA	5.5
Huntington-Ashland, WV–KY–OH	0.3
Louisville, KY–IN	1.0
Macon, GA MSA	0.3
Memphis, TN–AR–MS	1.1
Nashville, TN	1.2
Philadelphia-Wilmington-Atlantic City, PA–NJ–DE–MD	6
Richmond-Petersburg, VA	1
Sacramento-Yolo, CA	1.7
San Diego, CA	2.8
San Francisco-Oakland-San Jose, CA	6.9
San Joaquin Valley, CA	3.2
St. Louis, MO–IL	2.6
Ventura County, CA	0.7
Washington, DC—Baltimore, DC, MD, VA MSA	7.4
20 Areas	54.2
Areas with Pre-2007 Attainment Dates and Recent Concentrations within 10 percent of an Exceedance.	
Barnstable-Yarmouth, MA	0.2
Benton Harbor, MI	0.2
Biloxi-Gulfport-Pascagoula, MS MSA	0.4
Charleston, WV MSA	0.3
Cincinnati-Hamilton, OH–KY–IN	2.0
Cleveland-Akron, OH CMSA	2.9
Grand Rapids-Muskegon-Holland, MI MSA	1.1
Houma, LA	0.2
Lake Charles, LA	0.2
New Orleans, LA MSA	1.3
Norfolk-Virginia Beach-Newport News, VA–NC MSA	1.6
Orlando, FL MSA	1.5
Pensacola, FL MSA	0.4
Providence-Fall River-Warwick, RI–MA	1.1
Tampa-St. Petersburg-Clearwater, FL MSA	2.3
15 areas	15.7
Total Areas: 45	Population: 128

[a] In order to determine the reliability of model predictions the Agency ran the ozone model for current ozone concentrations and compared those predictions with actual ozone levels recorded by ozone monitors. The results of the model's performance are presented in the RIA for this rule.

c. Public Health and Welfare Concerns from Prolonged and Repeated Exposures to Ozone

A large body of scientific literature regarding health and welfare effects of ozone has associated health effects with certain patterns of ozone exposures that do not necessarily include any hourly ozone concentration above the 0.12 parts per million (ppm) level of the 1-hour NAAQS. The science indicates that there are health effects attributable to prolonged and repeated exposures to lower ozone concentrations. Studies of 6 to 8 hour exposures showed health effects from prolonged and repeated exposures at moderate levels of exertion to ozone concentrations as low as 0.08 ppm. Prolonged and repeated ozone concentrations at these levels are common in areas throughout the country, and are found in areas that are exceeding, and areas that are not exceeding, the 1-hour ozone standard. For example, 153 million people, or 87 percent of the total population in counties evaluated (176 million), lived in areas with 2 or more days with concentrations of 0.09 ppm or higher in 1998, including areas currently violating the 1-hour NAAQS. In the 2007, before the application of emission reductions resulting from this rule, we estimated that 116 million, or 93 percent of the total population considered in the analysis, are predicted to live in areas with at least 2 days with model-adjusted 8-hour average concentrations of 0.08 ppm or higher. By 2030, the number of people (139 million) and the relative percentage (91 percent) of the total population considered in the analysis is projected to grow significantly without reductions from this rule. Since prolonged exposures at moderate levels of ozone are more widespread than exceedances of the 1-hour ozone standard, and given the continuing nature of the 1-hour ozone problem described above, adverse health effects from this type of ozone exposure can reasonably be anticipated to occur in the future in the absence of this rule. Adverse welfare effects can also be anticipated, primarily from damage to vegetation. See the RIA for further details.

Studies of acute health effects have shown transient pulmonary function responses, transient respiratory symptoms, effects on exercise performance, increased airway responsiveness, increased susceptibility to respiratory infection, increased hospital and emergency room visits, and transient pulmonary respiratory inflammation. Such acute health effects have been observed following prolonged exposures at moderate levels of exertion at concentrations of ozone well below the current standard of 0.12 ppm. The effects are more pronounced at concentrations above 0.09 ppm, affecting more subjects or having a greater effect on a given subject in terms of functional changes or symptoms. A more detailed discussion may be found in the RIA.

With regard to chronic health effects, the collective data have many ambiguities, but provide suggestive evidence of chronic effects in humans. There is a biologically plausible basis for considering the possibility that repeated inflammation associated with exposure to ozone over a lifetime, as can occur with prolonged exposure to moderate ozone levels below peak levels, may result in sufficient damage to respiratory tissue that individuals later in life may experience a reduced quality of life, although such relationships remain highly uncertain.

Ozone has many welfare effects, with damage to plants being of most concern. Plant damage affects crop yields, forestry production, and ornamentals. The adverse effect of ozone on forests and other natural vegetation can in turn cause damage to associated ecosystems, with additional resulting economic losses, as well as aesthetic impacts which may not be fully quantifiable in economic terms. Ozone concentrations of 0.10 ppm can be phytotoxic to a large number of plant species, and can produce acute injury and reduced crop yield and biomass production. Ozone concentrations at or below 0.10 ppm have the potential over a longer duration of creating chronic stress on vegetation that can result in reduced plant growth and yield, shifts in competitive advantages in mixed populations, decreased vigor, and injury from other environmental stresses.

Section 202(a) provides EPA with authority to promulgate standards applicable to motor vehicle emissions that "in the Administrator's judgment, cause or contribute to air pollution reasonably anticipated to endanger public health and welfare." The evidence in the RIA regarding the occurrence of adverse health effects due to prolonged and repeated exposure to ozone concentrations in the range discussed above, and regarding the populations that are expected to receive exposures at these levels, along with the welfare effects described above, supports a conclusion that emissions of NO_X and VOC from heavy-duty vehicles in 2007 and later will be contributing to a national air pollution problem that warrants regulatory action under section 202(a) of the Act.

3. Particulate Matter

a. Health and Welfare Effects

Particulate matter (PM) represents a broad class of chemically and physically diverse substances. It can be principally characterized as discrete particles that exist in the condensed (liquid or solid) phase spanning several orders of magnitude in size. All particles equal to and less than 10 microns are called PM_{10}. Fine particles can be generally defined as those particles with an aerodynamic diameter of 2.5 microns or less (also known as $PM_{2.5}$), and coarse fraction particles are those particles with an aerodynamic diameter greater than 2.5 microns, but equal to or less than a nominal 10 microns. The health and environmental effects of PM are strongly related to the size of the particles.

The emission sources, formation processes, chemical composition, atmospheric residence times, transport distances and other parameters of fine and coarse particles are distinct. Fine particles are directly emitted from combustion sources and are formed secondarily from gaseous precursors such as sulfur dioxide, nitrogen oxides, or organic compounds. Fine particles are generally composed of sulfate, nitrate, chloride and ammonium compounds; organic and elemental carbon; and metals. Combustion of coal, oil, diesel, gasoline, and wood, as well as high temperature process sources such as smelters and steel mills, produce emissions that contribute to fine particle formation. In contrast, coarse particles are typically mechanically generated by crushing or grinding and are often dominated by resuspended dusts and crustal material from paved or unpaved roads or from construction, farming, and mining activities. Fine particles can remain in the atmosphere for days to weeks and travel through the atmosphere hundreds to thousands of kilometers, while coarse particles deposit to the earth within minutes to hours and within tens of kilometers from the emission source.

Diesel particles are a component of both coarse and fine PM, but fall mostly in the fine and ultrafine size range.[25] Diesel PM contains small quantities of numerous mutagenic and carcinogenic compounds. While representing a very small portion (less than one percent) of the national emissions of metals, and a small portion of diesel particulate matter (one to five percent), we note that several toxic trace metals of potential

[25] Fine particulate matter includes particles with a diameter less than 2.5 micrometers. Ultrafine particulate matter include particles with a diameter less than 100 nanometers.

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toxicological significance are also emitted by diesel engines including chromium, manganese, mercury and nickel. In addition, small amounts of dioxins have been measured in diesel exhaust, some of which may partition into the particle phase, though the impact of these emissions on human health is not clear.

Particulate matter, like ozone, has been linked to a range of serious respiratory health problems. Scientific studies suggest a likely causal role of ambient particulate matter (which is attributable to a number of sources including diesel) in contributing to a series of health effects. The key health effects categories associated with ambient particulate matter include premature mortality, aggravation of respiratory and cardiovascular disease (as indicated by increased hospital admissions and emergency room visits, school absences, work loss days, and restricted activity days), aggravated asthma, acute respiratory symptoms, including aggravated coughing and difficult or painful breathing, chronic bronchitis, and decreased lung function that can be experienced as shortness of breath. Observable human noncancer health effects associated with exposure to diesel PM include some of the same health effects reported for ambient PM such as respiratory symptoms (cough, labored breathing, chest tightness, wheezing), and chronic respiratory disease (cough, phlegm, chronic bronchitis and suggestive evidence for decreases in pulmonary function). Symptoms of immunological effects such as wheezing and increased allergenicity are also seen. Studies in rodents, especially rats, show the potential for human inflammatory effects in the lung and consequential lung tissue damage from chronic diesel exhaust inhalation exposure. Both fine and coarse particles can accumulate in the respiratory system. Exposure to fine particles is most closely associated with such health effects as premature mortality or hospital admissions for cardiopulmonary disease. For additional information on health effects, see the RIA. PM also causes damage to materials and soiling of commonly used building materials and culturally important items such as statutes and works of art. It is a major cause of substantial visibility impairment in many parts of the U.S.

Heavy-duty vehicles contribute to particle formation through a number of pollutants. The contribution to PM fine varies by region of the country. Sulfate plays a major role in the composition of fine particulate across the country, but typically makes up over half the fine particles found in the Eastern United States. Organic carbon accounts for a large portion of fine particle mass, with a slightly higher fraction in the west. Diesel engines are the principal source of elemental carbon, which makes up about 5–6 percent of particle mass. Nationally, nitrate plays a relatively small role in the make up of fine particles, but ammonium nitrate plays a far larger role in southern California. Ammonium nitrate–formed secondarily from NO_X and ammonia emissions—is one of the most significant components of particulate matter pollution in California. During some of the worst episodes of elevated particle levels in the South Coast, ammonium nitrate can account for about 65–75 percent of the $PM_{2.5}$ mass. Reducing ammonium nitrate through controls on NO_X sources is a critical part of California's particulate matter strategy. Nationally, the standards finalized in this rule will significantly reduce HDV emissions of SO_X, NO_X, VOCs and elemental carbon, and thus contribute to reductions in ambient concentrations of PM_{10} and $PM_{2.5}$.

b. Attainment and Maintenance of the PM_{10} NAAQS

Under the CAA, we are to regulate HDV emissions if they contribute to air pollution that can reasonably be anticipated to endanger public health and welfare. We have already addressed the question of what concentration patterns of PM endanger public health, in setting the NAAQS for PM_{10} in 1987. The PM NAAQS were revised in 1997, largely by adding new standards for fine particles ($PM_{2.5}$) and modifying the form of the daily PM_{10} standard. On judicial review, the revised standards were remanded for further proceedings, and the revised PM_{10} standards were vacated. The Supreme Court is currently reviewing that decision. Oral arguments were held on November 7, 2000 and a decision by the Court is expected in 2001. Pending final resolution of the litigation, the 1987 PM_{10} standard is the applicable NAAQS for PM_{10}.

Commenters questioned the need for additional PM_{10} reductions in order to achieve attainment with the PM_{10} NAAQS, and questioned the Agency's statement that, unlike ozone, PM_{10} emissions are projected to increase in the future. Commenters are correct that significant progress has occurred over the last decade,[26] but the Agency's statement was based on projected PM_{10} inventory increases in the future between 1996 and 2030. During this period, inventory trends for current PM_{10} nonattainment areas, or those with concentrations within 10 percent of the standard, are predicted to increase significantly. For example, from 1996 to 2030, increases are predicted in Clark County (Las Vegas) of 41 percent, Harris County (Houston) of 37 percent, and Phoenix of 24 percent. A more detailed discussion is provided in the RIA.

i. Current PM_{10} Nonattainment

The most recent PM_{10} monitoring data indicates that 14 designated PM_{10} nonattainment areas with a projected population of 23 million violated the PM_{10} NAAQS in the period 1997–1999. Table II.B–3 lists the 14 areas, and also indicates the PM_{10} nonattainment classification and 1999 projected population for each PM_{10} nonattainment area. The projected population in 1999 was based on 1990 population figures which were then increased by the amount of population growth in the relevant county from 1990 to 1999.

TABLE II.B–3.—PM_{10} NONATTAINMENT AREAS VIOLATING THE PM_{10} NAAQS IN 1997–99

Area	Classification	1999 Population (projected, in millions)
Hayden/Miami, AZ	Moderate	0.004
Phoenix, AZ	Serious	2.977
Nogales, AZ	Moderate	0.025
San Joaquin Valley, CA	Serious	3.214
Imperial Valley, CA	Moderate	0.122

[26] Ambient concentrations of PM_{10} and PM_{10} emissions have declined over the last ten years by 25 percent and 19 percent, respectively. National Air Quality and Emissions Trends Report, 1998, US EPA, March, 2000.

TABLE II.B–3.—PM_{10} NONATTAINMENT AREAS VIOLATING THE PM_{10} NAAQS IN 1997–99—Continued

Area	Classification	1999 Population (projected, in millions)
Owens Valley, CA	Serious	0.018
Searles Valley, CA	Moderate	0.029
Coachella Valley, CA	Serious	0.239
South Coast Air Basin	Serious	14.352
Las Vegas, NV	Serious	1.200
Reno, NV	Moderate	0.320
Anthony, NM[b]	Moderate	0.003
El Paso, TX[a]	Moderate	0.611
Wallula, WA[b]	Moderate	0.052
Total Areas: 14		23.167

[a] EPA has determined that continuing PM_{10} nonattainment in El Paso, TX is attributable to international transport under section 179(B).
[b] The violation in this area has been determined to be attributable to natural events under section 188(f) of the Act.

In addition to the 14 PM_{10} nonattainment areas that are currently violating the PM_{10} NAAQS, there are 25 unclassifiable areas that have recently recorded ambient concentrations of PM_{10} above the PM_{10} NAAQS. EPA adopted a policy in 1996 that allows areas with PM_{10} exceedances that are attributable to natural events to retain their designation as unclassifiable if the State is taking all reasonable measures to safeguard public health regardless of the sources of PM_{10} emissions. Areas that remain unclassifiable areas are not required under the Clean Air Act to submit attainment plans, but we work with each of these areas to understand the nature of the PM_{10} problem and to determine what best can be done to reduce it. With respect to the monitored violations reported in 1997–99 in the 25 areas designated as unclassifiable, we have not yet excluded the possibility that factors such as a one-time monitoring upset or natural events, which ordinarily would not result in an area being designated as nonattainment for PM_{10}, may be responsible for the problem. Emission reductions from today's action will assist these currently unclassifiable areas to achieve ambient PM_{10} concentrations below the current PM_{10} NAAQS.

ii. Risk of Future Exceedances of the PM_{10} Standard

The new standards for heavy-duty vehicles will benefit public health and welfare through reductions in direct diesel particles and NO_X, VOCs, and SO_X which contribute to secondary formation of particulate matter. Because ambient particle concentrations causing violations of the PM_{10} standard are well established to endanger public health and welfare, this information supports the new standards for heavy-duty vehicles. The reductions from today's rule will assist States as they work with the Agency through implementation of local controls including development and adoption of additional controls as needed to move their areas into attainment by the applicable deadline, and maintain the standards thereafter.

The Agency's PM inventory analysis performed for this rulemaking predicts that without additional reductions 10 areas face a significant risk of failing to meet or to maintain the PM_{10} NAAQS even with federal, State and local controls currently in place.[27] Table II.B–4 presents information about these 10 areas and subdivides them into two groups. The first group of 6 areas are designated PM_{10} nonattainment areas which had recent monitored violations of the PM_{10} NAAQS in 1997–1999 and increasing inventories of PM_{10} from 2007 to 2030 (see Table II.B–3 for predicted increases in emissions). These areas have a population of 19 million. Included in the group are the nonattainment areas that are part of the Los Angeles, Phoenix and Las Vegas (Clark County) metropolitan areas, where traffic from heavy-duty vehicles is substantial. These six areas will benefit from the reductions in emissions that will occur from the new standards for heavy-duty vehicles, as will other areas impacted by heavy-duty vehicle emissions.

The second group of four counties listed in Table II.B–4 with a total of nine million people in 1999 also had predicted exceedances of the PM_{10} standard. While these four areas registered, in either 1997 or 1998, single-year annual average monitored PM_{10} levels of at least 90 percent of the PM_{10} NAAQS, these areas did not exceed the formal definition of the PM_{10} NAAQS over the three-year period ending in 1999. For each of these four areas (i.e., Cuyahoga, Harris, New York, and San Diego), inventories of total PM_{10} are predicted to increase between 1996, when these areas recorded values within 10 percent of the PM_{10} standard, and 2030 when this rule will take full effect. Additionally, EPA is in the process of taking final action on a request by the State of Ohio to redesignate Cuyahoga County as attainment. This action is based on locally developed information and is consistent with the requirements of the CAA which include, among other requirements a 10-year plan for maintenance of the PM_{10} standard.

For some of these areas, total PM_{10} inventories are predicted to decline or stay relatively constant from 1996 to 2007, and then increase after 2007. Based on inventory projections, the small margin of attainment which the four areas currently enjoy will likely erode between 1996 and 2030, and for some areas before 2007, if additional actions to reduce the growth of future emissions are not taken. We therefore consider these four areas to each individually have a significant risk of exceeding the PM_{10} standard between 2007 and 2030 without further emission reductions. The emission reductions from the new standards for heavy-duty vehicles will help these areas attain and maintain the PM_{10} NAAQS in conjunction with other processes that

[27] EPA has evaluated projected emissions for this analysis rather than future air quality because REMSAD, the model EPA has used for analyses related to this rule, was designed principally to estimate long-term average concentrations of fine particulate matter and its ability to predict short-term PM_{10} concentrations has not been satisfactorily demonstrated. In contrast with ozone, which is the product of complex photochemical reactions and therefore difficult to directly relate to precursor emissions, ambient PM_{10} concentrations are more heavily influenced by direct emissions of particulate matter and can therefore be correlated more meaningfully with emissions inventories.

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are currently moving these areas towards attainment.

TABLE II.B–4—AREAS WITH SIGNIFICANT RISK OF EXCEEDING THE PM_{10} NAAQS WITHOUT FURTHER EMISSION REDUCTIONS BETWEEN 2007 AND 2030

Area	Percent increases in PM_{10} emissions (1996–2030)	1999 Population (projected) (millions)
Areas currently exceeding the PM_{10} standard:		
Clark Co., NV (Las Vegas)	41	1.217
El Paso, TX[a]	14	0.611
Hayden/Miami, AZ	4	0.004
Los Angeles South Coast Air Basin, CA	14	14.352
Nogales, AZ	3	0.025
Phoenix, AZ	24	3.012
Subtotal for 6 Areas	.....	19.22
Areas within 10% of exceeding the PM_{10} standard:		
Cuyahoga Co., OH (Cleveland)	28	1.37
Harris, Co., TX (Houston)	37	3.26
New York Co., NY	14	1.55
San Diego Co., CA	13	2.83
Subtotal for 4 Areas	.....	9.01
10 Areas	.....	28.23

[a] EPA has determined that PM_{10} nonattainment in this area is attributable to international transport. While reductions in heavy-duty vehicle emissions cannot be expected to result in attainment, they will help reduce the degree of PM_{10} nonattainment.

EPA recognizes that the SIP process is ongoing and that nonattainment areas are in the process of implementing, or will be adopting and implementing, additional control measures to achieve the PM_{10} NAAQS in accordance with their attainment dates under the Clean Air Act. EPA believes, however, that as in the case of ozone, there are uncertainties inherent in any demonstration of attainment that is premised on forecasts of emission levels in future years. Even if these areas adopt and submit SIPs that EPA is able to approve as demonstrating attainment of the PM_{10} standard, and attain the standard by the appropriate attainment dates, the inventory analysis conducted for this rule and the history of PM_{10} levels in these areas indicates that there is still a significant risk that these areas will need the reductions from the heavy-duty vehicle standards adopted today to maintain the PM_{10} standards in the long term (ie, between 2007 and 2030). In addition, this list does not fully consider the possibility that there are other areas which are now meeting the PM_{10} NAAQS that have at least a significant probability of requiring further reductions to continue to maintain it.

c. Public Health and Welfare Concerns From Exposure to Fine PM

Many epidemiologic studies have shown statistically significant associations of ambient PM levels with a variety of human health endpoints in sensitive populations, including mortality, hospital admissions and emergency room visits, respiratory illness and symptoms measured in community surveys, and physiologic changes in mechanical pulmonary function. These effects have been observed in many areas with ambient PM levels at or below the current PM_{10} NAAQS. The epidemiologic science points to fine PM as being more strongly associated with some health effects, such as premature mortality, than coarse PM.

Associations of both short-term and long-term PM exposure with most of the above health endpoints have been consistently observed. The general internal consistency of the epidemiologic data base and available findings have led to increasing public health concern, due to the severity of several studied endpoints and the frequent demonstration of associations of health and physiologic effects with ambient PM levels at or below the current PM_{10} NAAQS. The weight of epidemiologic evidence suggests that ambient PM exposure has affected the public health of U.S. populations. Specifically, increased mortality associated with fine PM was observed in cities with longer-term average fine PM concentrations in the range of 16 to 21 $\mu g/m^3$.

Current 1999 $PM_{2.5}$ monitored values, which cover about a third of the nation's counties, indicate that at least 40 million people live in areas where long term ambient fine particulate matter levels are at or above 16 $\mu g/m^3$ (37 percent of the population in the areas with monitors), which is the low end of the range of long term average $PM_{2.5}$ concentrations in cities where statistically significant associations were found with serious health effects, including premature mortality (EPA, 1996).[28]

The Agency used the Regulatory Model System for Aerosols and Desposition (REMSAD) to model baseline and post-control ambient PM concentrations. For a description of the REMSAD model, the reader is referred to Chapter VII of the RIA.

Our REMSAD modeled predictions allow us to also estimate the affected population for the counties which do not currently have $PM_{2.5}$ monitors. According to our national modeled predictions, there were a total of 76 million people (1996 populations) living in areas with modeled annual average $PM_{2.5}$ concentrations at or above 16 $\mu g/m^3$ (29 percent of the population).[29]

The REMSAD model also allows us to estimate future $PM_{2.5}$ levels. However, the most appropriate method of making these projections relies on the model to predict changes between current and future states. Thus, we have estimated future conditions only for the areas with current $PM_{2.5}$ monitored data (which, as just noted, covers about a third of the nation's counties). For these counties, REMSAD predicts the current level of 37 percent of the population living in areas where fine PM levels are at or above 16 $\mu g/m^3$ to increase to 59 percent in 2030.

It is reasonable to anticipate that sensitive populations exposed to similar or higher levels, now and in the 2007 and later time frame, will also be at increased risk relative to the general population of premature mortality associated with exposures to fine PM. In addition, statistically significant relationships have also been observed in U.S. cities between PM levels and increased respiratory symptoms and decreased lung functions in children.

Since EPA's examination in the mid-1990s of the epidemiological and toxicological evidence of the health effects of PM, many new studies have been published that reevaluate or extend the initial research. The Agency is currently reviewing these new studies to stay abreast of the literature and adjust as necessary its assessment of PM's health effects. It is worth noting that within this new body of scientific literature, there are two new studies funded by the Health Effects Institute, a EPA-industry jointly funded group, that have generally confirmed the mid-1990s findings of the Agency about the association of fine particles and premature mortality and various other respiratory and cardiovascular effects. HEI's *National Morbidity, Mortality and Air Pollution Study* (NMMAPS), evaluated associations between air pollutants and mortality in 90 U.S. cities, and also evaluated associations between air pollutants and hospital admissions among the elderly in 14 U.S. cities.[30] In HEI's *Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality*, data were obtained from the original investigators for two previous studies.[31 32] The extensive analyses included replication and validation of the previous findings, as well as sensitivity analyses using alternative analytic techniques, including different methods of covariate adjustment, exposure characterization, and exposure-response modeling.[33]

Section 202(a) provides EPA with independent authority to promulgate standards applicable to motor vehicle emissions that "in the Administrator's judgment, cause or contribute to air pollution reasonably anticipated to endanger public health and welfare." The body of health evidence is supportive of our view that PM exposures are a serious public health concern. This concern exists for current exposures as well as exposures that can reasonably be anticipated to occur in the future. The risk is significant from an overall public health perspective because of the large number of individuals in sensitive populations that we expect to be exposed to ambient fine PM in the 2007 and later time frame, as well as the importance of the negative health effects. This information warrants a requirement to reduce emissions from heavy-duty vehicles, to address elevated levels of fine PM. This evidence supports EPA's conclusion that emissions from heavy-duty vehicles that lead to the formation of fine PM in 2007 and later will be contributing to a national air pollution problem that warrants action under section 202(a)(3).

d. Other Welfare Effects Associated with PM

The deposition of airborne particles reduces the aesthetic appeal of buildings, and promotes and accelerates the corrosion of metals, degrades paints, and deteriorates building materials such as concrete and limestone. This materials damage and soiling are related to the ambient levels of airborne particulates, which are emitted by heavy-duty vehicles. Although there was insufficient data to relate materials damage and soiling to specific concentrations, and thereby to allow the Agency to establish a secondary PM standard for these impacts, we believe that the welfare effects are real and that heavy-duty vehicle PM, NO_X, SO_X, and VOC contribute to materials damage and soiling.

e. Conclusions Regarding PM

There is a significant risk that, despite statutory requirements and EPA and State efforts towards attainment and maintenance, some areas of the U.S. will violate the PM_{10} NAAQS in 2007 and thereafter. Heavy-duty vehicles contribute substantially to PM_{10} levels, as shown in Section II.C below.

It is also reasonable to anticipate that concentrations of fine PM, as represented for example by $PM_{2.5}$ concentrations, will also endanger public health and welfare even if all areas attain and maintain the PM_{10} NAAQS. Heavy-duty vehicles contribute to this air pollution problem.

There are also important environmental impacts of PM_{10}, such as regional haze which impairs visibility. Furthermore, while the evidence on soiling and materials damage is limited and the magnitude of the impact of heavy-duty vehicles on these welfare effects is difficult to quantify, these welfare effects support our belief that this action is necessary and appropriate.

Finally, in addition to its contribution to PM inventories, diesel exhaust PM is of special concern because it has been implicated in an increased risk of lung cancer and respiratory disease in human studies, and an increased risk of noncancer health effects as well. The information provided in this section shows that there will be air pollution that warrants regulatory action under section 202(a)(3) of the Act.

4. Diesel Exhaust

Diesel emissions are of concern to the agency beyond their contribution to ambient PM. As discussed in detail in the draft RIA, there have been health studies specific to diesel exhaust emissions which indicate potential hazards to human health that appear to be specific to this emissions source. For chronic exposure, these hazards included respiratory system toxicity and carcinogenicity. Acute exposure also causes transient effects (a wide range of physiological symptoms stemming from irritation and inflammation mostly in the respiratory system) in humans though they are highly variable depending on individual human susceptibility. The chemical

[28] EPA (1996) Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information OAQPS Staff Paper. EPA–452/R–96–013.

[29] REMSAD modeling for $PM_{2.5}$ annual average concentrations. Total 1996 population in all REMSAD grid cells is 263 million.

[30] Samet JM, Zeger SL, Dominici F, Curriero F, Coursac I, Dockery DW, Schwartz J, Zanobetti A. 2000. The National Morbidity, Mortality and Air Pollution Study: Part II: Morbidity, Mortality and Air Pollution in the United States. Research Report No. 94, Part II. Health Effects Institute, Cambridge MA, June 2000.

[31] Dockery, D.W., Pope, C.A., III, Xu, X., Spengler, J.D., Ware, J.H., Fay, M.E., Ferris, B.G., Speizer, F.E. (1993) An association between air pollution and mortality in six U.S. cities. N. Engl. J. Med. 329:1753–1759.

[32] Pope, C. A., III, Thun, M. J., Namboodiri, M. M., Dockery, D. W., Evans, J. S., Speizer, F. E., Heath, C. W., Jr. (1995) Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am. J. Respir. Crit. Care Med. 151: 669–674.

[33] Krewski D, Burnett RT, Goldbert MS, Hoover K, Siemiatycki J, Jarrett M, Abrahamowicz M, White WH. (2000) Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. Special Report to the Health Effects Institute, Cambridge MA, July 2000.

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composition of diesel exhaust includes several hazardous air pollutants, or air toxics. In our Mobile Source Air Toxic Rulemaking under section 202(l) of the Act discussed above, EPA determined that diesel particulate matter and diesel exhaust organic gases be identified as a Mobile Source Air Toxic (MSAT). The purpose of the MSAT list is to provide a screening tool that identifies compounds emitted from motor vehicles or their fuels for which further evaluation of emissions controls is appropriate. As discussed in chapter 3 on engine technology, the particulate matter standard finalized today reflects the greatest degree of emissions reductions achievable under section 202(l) for on-highway heavy-duty vehicle PM emissions.

a. Potential Cancer Effects of Diesel Exhaust

The EPA has concluded that diesel exhaust is likely to be carcinogenic to humans by inhalation at occupational and environmental levels of exposure.[34] The draft Health Assessment Document for Diesel Exhaust (draft Assessment), was reviewed in public session by the Clean Air Scientific Advisory Committee (CASAC) on October 12–13, 2000.[35] The CASAC found that the Agency's conclusion that diesel exhaust is likely to be carcinogenic to humans is scientifically sound. CASAC concurred with the draft Assessment's findings with the proviso that EPA provide modifications and clarifications on certain topics. The Agency expects to produce the finalized Assessment in early 2001. Information presented here is consistant with that to be provided in the final Assessment.

In its review of the published literature, EPA found that about 30 individual epidemiologic studies show increased lung cancer risk associated with diesel emissions. In the draft Assessment EPA evaluated 22 studies that were most relevant for risk assessment, 16 of which reported significant increased lung cancer risks, ranging from 20 to 167 percent, associated with diesel exhaust exposure. Published analytical results of pooling many of the 30 studies showed that on average, the risks were increased by 33 to 47 percent. Questions remain about the influence of other factors (e.g., effect of smoking, other particulate sources), the quality of the individual epidemiologic studies, exposure levels, and consequently the precise magnitude of the increased risk of lung cancer. From a weight of evidence perspective, EPA concludes that the epidemiologic evidence, as well as supporting data from certain animal and mode of action studies, support the Agency's conclusion that exposure to diesel exhaust is likely to pose a human lung cancer hazard to occupationally exposed individuals as well as to the general public exposed to typically lower environmental levels of diesel exhaust.

Risk assessments in the peer-reviewed literature have attempted to assess the lifetime risk of lung cancer in workers occupationally exposed to diesel exhaust. These estimates suggest that lung cancer risk may range from 10^{-4} to 10^{-2}.[36 37 38] The Agency recognizes the significant uncertainties in these studies, and has not used these estimates to assess the possible cancer unit risk associated with ambient exposure to diesel exhaust.

While available evidence supports EPA's conclusion that diesel exhaust is likely to be a human lung carcinogen, and thus is likely to pose a cancer hazard to humans, EPA has concluded that the available data are not sufficient to develop a confident estimate of cancer unit risk. The absence of a cancer unit risk for diesel exhaust limits our ability to quantify, with confidence, the potential impact of the hazard (magnitude of risk) on exposed populations. In the draft Assessment, EPA acknowledged this limitation and provided a discussion of the possible environmental cancer risk consistent with the majority of the occupational epidemiological findings of increased lung cancer risk and the exposure differences between the occupational and environmental settings.[39] The Agency concluded in developing its perspective on risk that there is a reasonable potential that environmental lifetime cancer risks ("environmental risk range") from diesel exhaust may exceed 10^{-5} and could be as high as 10^{-3}.[40]

The environmental risk estimates included in the Agency's risk perspective are meant only to gauge the possible magnitude of risk to provide a means to understand the potential significance of the lung cancer hazard. The estimates are not to be construed as cancer unit risk estimates and are not suitable for use in analyses which would estimate possible lung cancer cases in exposed populations.

EPA recognizes that, as in all such risk assessments, there are uncertainties in this assessment of the environmental risk range including limitations in exposure data, uncertainty with respect to the most accurate characterization of the risk increases observed in the epidemiological studies, chemical changes in diesel exhaust over time, and extrapolation of the risk from occupational to ambient environmental exposures. As with any such risk assessment for a carcinogen, despite EPA's thorough examination of the available epidemiologic evidence and exposure information, at this time EPA can not rule out the possibility that the lower end of the risk range includes zero.[41] However, it is the Agency's best scientific judgement that the assumptions and other elements of this analysis are reasonable and appropriate for identifying the risk potential based on the scientific information currently available.

The Agency believes that the risk estimation techniques that were used in the draft Assessment to gauge the potential for and possible magnitude of risk are reasonable and the CASAC panel has concurred with the Assessment's discussion of the possible environmental risk range with an understanding that some clarifications and caveats would be added to the final version of the Assessment. Details of the technical approach used in estimating the possible range of environmental risks and uncertainties are provided in the RIA.

In the draft Assessment, the Agency also provided a discussion of the potential overlap and/or relatively small difference between some occupational settings where increased lung cancer risk is reported and ambient environmental exposures. The potential for small exposure differences underscores the concern that some degree of occupational risk may also be present in the environmental setting and that extrapolation of occupational risk to ambient environmental exposure levels should be more confidently judged to be appropriate. The relevant exposure information is presented in the RIA.

In the absence of having a unit cancer risk to assess environmental risk, EPA has considered the relevant epidemiological studies and principles for their assessment, the relative risk from occupational exposure as assessed by others, and relative exposure differences between occupational and ambient environmental levels of diesel exhaust exposure.

While uncertainty exists in estimating the possible magnitude of the environmental risk range, the likely hazard to humans together with the potential for significant environmental risks leads the Agency to believe that diesel exhaust emissions should be reduced in order to protect the public's health. We believe that this is a prudent measure in light of:

- The designation that diesel exhaust is likely to be carcinogenic to humans,
- The exposure of the entire population to various levels of diesel exhaust,
- The consistent observation of significantly increased lung cancer risk in workers exposed to diesel exhaust, and
- The potential overlap and/or relatively small difference between some occupational settings where increased lung cancer risk is reported and ambient exposures.

In the late 1980s, the International Agency for Research on Cancer (IARC) determined that diesel exhaust is "probably carcinogenic to humans" and the National Institute for Occupational Safety and Health classified diesel exhaust a "potential occupational carcinogen."[42 43] Based on IARC findings, the State of California identified diesel exhaust in 1990 as a chemical known to the State to cause cancer. In 1996, the International Programme on Chemical Safety of the World Health Organization listed diesel exhaust as a "probable" human carcinogen.[44] In 1998, the California Office of Environmental Health Hazard Assessment (OEHHA, California EPA) identified diesel PM as a toxic air contaminant due to the noncancer and cancer hazard and because of the potential magnitude of the cancer risk.[45] Most recently, the U.S. Department of Health and Human Services National Toxicology Program designated diesel exhaust particles as "reasonably anticipated to be a human carcinogen" in its Ninth Report on Carcinogens.[46] The concern for a carcinogenicity hazard resulting from diesel exhaust exposures is longstanding and widespread.

b. Noncancer Effects of Diesel Exhaust

The acute and chronic exposure-related noncancer effects of diesel exhaust emissions are also of concern to the Agency. Acute exposure to diesel exhaust can result in physiologic symptoms consistent with irritation and inflammation, and evidence of immunological effects including increased reaction to allergens and some symptoms associated with asthma. The acute effects data, however, lack sufficient detail to permit the calculation of protective levels for human exposure.

For chronic diesel exhaust exposure, EPA is completing the development of an inhalation reference concentration (RfC). The RfC is an estimate of the continuous human inhalation exposure (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. While the limited amount of human data are suggestive of respiratory distress, animal test data are quite definitive in providing a basis to anticipate a hazard to the human lung based on the irritant and inflammatory reactions in test animals. Thus, EPA believes that chronic diesel exhaust exposure, at sufficient exposure levels, increases the hazard and risk of an adverse health effect. Based on CASAC advice regarding the use of the animal data to derive the RfC, the Agency will provide in the final Assessment in 2001 an RfC based on diesel exhaust effects in test animals of approximately 5 $\mu g/m^3$.

In addition, it is also instructive to recognize that diesel exhaust particulate matter is part of ambient fine PM. A qualitative comparison of adverse effects of exposure to ambient fine PM and diesel exhaust particulate matter shows that the respiratory system is adversely affected in both cases, though a wider spectrum of adverse effects has been identified for ambient fine PM. Relative to the diesel PM database, there is a wealth of human data for fine PM noncancer effects. Since diesel exhaust PM is a component of ambient fine PM, the fine PM health effects data base can be informative. The final Assessment will discuss the fine PM health effects data and its relation to evaluating health effects associated with diesel exhaust.

5. Other Criteria Pollutants

The standards being finalized today will help reduce levels of three other pollutants for which NAAQS have been established: carbon monoxide (CO), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2). As of July, 2000, every area in the United States has been designated to be in attainment with the NO_2 NAAQS. There were 28 areas designated as nonattainment with the SO_2 standard, and 17 areas designated CO nonattainment areas.

A health threat of carbon monoxide at outdoor levels occurs for those who suffer from cardiovascular disease, such as angina petoris, where it can exacerbate the effects. Studies also show that outdoor levels can lower peak performance from individuals that are exercising and lower exercise tolerance of sensitive individuals. EPA believes that epidemiological evidence suggests that there is a risk of premature mortality and lowered birth weight from CO exposure.[47] The Carbon Monoxide Criteria Document was finalized in

[34] U.S. EPA (2000) Health Assessment Document for Diesel Exhaust: SAB Review Draft. EPA/600/8–90/057E Office of Research and Development, Washington, D.C. The document is available electronically at www.epa.gov/ncea/dieslexh.htm.

[35] EPA (2000) Review of EPA's Health Assessment Document for Diesel Exhaust (EPA 600/8–90/057E). Review by the Clean Air Scientific Advisory Committee (CASAC) December 2000. EPA–SAB–CASAC–01–003.

[36] California Environmental Protection Agency, Office of Health Hazard Assessment (CAL–EPA, OEHHA) (1998) Proposed Identification of Diesel Exhaust as a Toxic Air Contaminant. Appendix III Part B Health Risk Assessment for Diesel Exhaust. April 22, 1998.

[37] Harris, J.E. (1983) Diesel emissions and Lung Cancer. Risk Anal. 3:83–100.

[38] Stayner, L.S., Dankovic, D., Smith, R., Steenland, K. (1998) Predicted Lung Cancer Risk Among Miners Exposed to Diesel Exhaust Particles. Am. J. of Indus. Medicine 34:207–219.

[39] See Chapter 6.4 and 9.5.2 of the U.S. EPA (2000) Health Assessment Document for Diesel Emissions: SAB Review Draft. EPA/600/8–90/057E Office of Research and Development, Washington, D.C. The document is available electronically at www.epa.gov/ncea/dieselexh.htm.

[40] As used in this rule, environmental risk is defined as the risk (i.e. a mathematical probability) that lung cancer would be observed in the population after a lifetime exposure to diesel exhaust. Exposure levels may be occupational lifetime or environmental lifetime exposures. An environmental risk in the magnitude of 10^{-5} translates as the probability of lung cancer being evidenced in one person in a population of one hundred thousand having a lifetime exposure.

[41] EPA's scientific judgment (which CASAC has supported) is that diesel exhaust is likely to be carcinogenic to humans. Notably, similar scientific judgements about the carcinogenicity of diesel exhaust have been recently made by the National Toxicology Program of the Department of Health and Human Services, NIOSH, WHO, and OEHA of the State of California. In the risk perspective discussed above, EPA recognizes the possibility that the lower end of the environmental risk range includes zero. The risks could be zero because (1) some individuals within the population may have a high tolerance level to exposure from diesel exhaust and therefore are not susceptible to the cancer risks from environmental exposure and (2) although EPA has not seen evidence of this, there could be a threshold of exposure below which there is no cancer risk.

[42] National Institute for Occupational Safety and Health (NIOSH) (1988) Carcinogenic effects of exposure to diesel exhaust. NIOSH Current Intelligence Bulletin 50. DHHS, Publication No. 88–116. Centers for Disease Control, Atlanta, GA.

[43] International Agency for Research on Cancer (1989) Diesel and gasoline engine exhausts and some nitroarenes, Vol. 46. Monographs on the evaluation of carcinogenic risks to humans. World Heath Organization, International Agency for Research on Cancer, Lyon, France.

[44] World Health Organization (1996) Diesel fuel and exhaust emissions: International program on chemical safety. World Health Organization, Geneva, Switzerland.

[45] Office of Environmental Health Hazard Assessment (1998) Health risk assessment for diesel exhaust, April 1998. California Environmental Protection Agency, Sacramento, CA.

[46] U.S. Department of Health and Human Services (2000) Ninth report on carcinogens. National Toxicology Program, Research Triangle Park, NC. ehis.niehs.nih.gov/roc/toc9.html.

[47] U.S. Environmental Protection Agency. Air Quality Criteria for Carbon Monoxide, June 2000.

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August 2000 and made available to the public at that time.

6. Other Air Toxics

In addition to NO_X and particulates, heavy-duty vehicle emissions contain several other substances that are known or suspected human or animal carcinogens, or have serious noncancer health effects. These include benzene,1,3-butadiene, formaldehyde, acetaldehyde, acrolein, and dioxin. For some of these pollutants, heavy-duty engine emissions are believed to account for a significant proportion of total nation-wide emissions. Although these emissions will decrease in the short term, they are expected to increase between 2010 and 2020 without the emission limits, as the number of miles traveled by heavy-duty trucks increases. In the RIA, we present current and projected exposures to benzene, 1,3-butadiene, formaldehyde, and acetaldehyde from all on-highway motor vehicles.

By reducing hydrocarbon and other organic emissions, both in gas phase and bound to particles, the emission control program in today's action will also reduce the direct emissions of air toxics from HDVs. Today's action will reduce exposure to hydrocarbon and other organic emissions and therefore help reduce the impact of HDV emissions on cancer and noncancer health effects.

a. Benzene

Highway mobile sources account for 42 percent of nationwide emissions of benzene and HDVs account for 7 percent of all highway vehicle benzene emissions.[48] The EPA has recently reconfirmed that benzene is a known human carcinogen by all routes of exposure (including leukemia at high, prolonged air exposures), and is associated with additional health effects including genetic changes in humans and animals and increased proliferation of bone marrow cells in mice.[49] [50] [51] EPA believes that the data indicate a causal relationship between benzene exposure and acute lymphocytic leukemia and suggest a relationship between benzene exposure and chronic non-lymphocytic leukemia and chronic lymphocytic leukemia. Respiration is the major source of human exposure and at least half of this exposure is attributable to gasoline vapors and automotive emissions. A number of adverse noncancer health effects including blood, disorders, such as preleukemia and aplastic anemia, have also been associated with low-dose, long-term exposure to benzene.

b. 1,3-Butadiene

Highway mobile sources account for 42 percent of the annual emissions of 1,3-butadiene and HDVs account for 15 percent of the highway vehicle portion. Today's program will play an important role in reducing in the mobile contribution of 1,3-butadiene. Reproductive and/or developmental effects have been observed in mice and rats following inhalation exposure to 1,3-butadiene.[52] No information is available on developmental/reproductive effects in humans following exposure to 1,3-butadiene. In the EPA1998 draft Health Risk Assessment of 1,3-Butadiene, that was reviewed by the SAB, EPA proposed that 1,3-butadiene is a known human carcinogen based on human epidemiologic, laboratory animal data, and supporting data such as the genotoxicity of 1,3-butadiene metabolites.[53] The Environmental Health Committee of EPA's Scientific Advisory Board (SAB), reviewed the draft document in August 1998 and recommended that 1,3-butadiene be classified as a probable human carcinogen, stating that designation of 1,3-butadiene as a known human carcinogen should be based on observational studies in humans, without regard to mechanistic or other information.[54] In applying the 1996 proposed Guidelines for Carcinogen Risk Assessment, the Agency relies on both observational studies in humans as well as experimental evidence demonstrating causality and therefore the designation of 1,3-butadiene as a known human carcinogen remains applicable.[55] The Agency has revised the draft Health Risk Assessment of 1,3-Butadiene based on the SAB and public comments. The draft Health Risk Assessment of 1,3-Butadiene will undergo the Agency consensus review, during which time additional changes may be made prior to its public release and placement on the Integrated Risk Information System (IRIS).

c. Formaldehyde

Highway mobile sources contribute 24 percent of the national emissions of formaldehyde, and HDVs account for 36 percent of the highway portion. EPA has classified formaldehyde as a probable human carcinogen based on evidence in humans and in rats, mice, hamsters, and monkeys.[56] Epidemiological studies in occupationally exposed workers suggest that long-term inhalation of formaldehyde may be associated with tumors of the nasopharyngeal cavity (generally the area at the back of the mouth near the nose), nasal cavity, and sinus. Formaldehyde exposure also causes a range of noncancer health effects, including irritation of the eyes (tearing of the eyes and increased blinking) and mucous membranes. Sensitive individuals may experience these adverse effects at lower concentrations than the general population and in persons with bronchial asthma, the upper respiratory irritation caused by formaldehyde can precipitate an acute asthmatic attack. The agency is currently conducting a reassessment of risk from inhalation exposure to formaldehyde.

d. Acetaldehyde

Highway mobile sources contribute 29 percent of the national acetaldehyde emissions and HDVs are responsible for approximately 33 percent of these highway mobile source emissions. Acetaldehyde is classified as a probable human carcinogen and is considered moderately toxic by the inhalation, oral, and intravenous routes. The primary acute effect of exposure to acetaldehyde vapors is irritation of the eyes, skin, and respiratory tract. At high concentrations, irritation and pulmonary effects can occur, which could facilitate the uptake of other contaminants. The agency is currently conducting a reassessment of risk from inhalation exposure to acetaldehyde.

e. Acrolein

Highway mobile sources contribute 16 percent of the national acrolein emissions and HDVs are responsible for approximately 39 percent of these highway mobile source emissions. Acrolein is extremely toxic to humans when inhaled, with acute exposure resulting in upper respiratory tract irritation and congestion. The Agency has developed a reference concentration for inhalation (RfC) of acrolein of 0.02 micrograms/m^3.[57] Although no information is available on its carcinogenic effects in humans, based on laboratory animal data, EPA considers acrolein a possible human carcinogen.

f. Dioxins

Recent studies have confirmed that dioxins are formed by and emitted from heavy-duty diesel trucks and are estimated to account for 1.2 percent of total dioxin emissions in 1995. In the environment, the pathway of immediate concern is the food pathway (*e.g.*, human ingestion of certain foods, *e.g.* meat and dairy products contaminated by dioxin) which may be affected by deposition of dioxin from the atmosphere. EPA classified dioxins as probable human carcinogens in 1985. Recently EPA has proposed, and the Scientific Advisory Board has concurred, to classify one dioxin compound, 2,3,7,8-tetrachlorodibenzo-p-dioxin as a human carcinogen and the complex mixtures of dioxin-like compounds as likely to be carcinogenic to humans using the draft 1996 carcinogen risk assessment guidelines.[58] Using the 1986 cancer risk assessment guidelines, the hazard characterization for 2,3,7,8-tetrachlorodibenzo-p-dioxin is "known" human carcinogen and the hazard characterization for complex mixtures of dioxin-like compounds is "probable" human carcinogens. Acute and chronic noncancer effects have also been reported for dioxin.

7. Other Welfare and Environmental Effects

Some commenters challenged the Agency's use of adverse welfare and environmental effects associated with emissions from heavy-duty vehicles as a partial basis for this rulemaking. Other commenters went to great lengths to support the Agency's inclusion of these welfare and environmental effects. Additional information has been added since the proposal in order to update and clarify the available information on welfare and environmental impacts of heavy-duty vehicle emissions. The following section presents information on four categories of public welfare and environmental impacts related to heavy-duty vehicle emissions: acid deposition, eutrophication of water bodies, POM deposition, and impairment of visibility.

a. Acid Deposition

Acid deposition, or acid rain as it is commonly known, occurs when SO_2 and NO_X react in the atmosphere with water, oxygen, and oxidants to form various acidic compounds that later fall to earth in the form of precipitation or dry deposition of acidic particles.[59] It contributes to damage of trees at high elevations and in extreme cases may cause lakes and streams to become so acidic that they cannot support aquatic life. In addition, acid deposition accelerates the decay of building materials and paints, including irreplaceable buildings, statues, and sculptures that are part of our nation's cultural heritage. To reduce damage to automotive paint caused by acid rain and acidic dry deposition, some manufacturers use acid-resistant paints, at an average cost of $5 per vehicle—a total of $61 million per year if applied to all new cars and trucks sold in the U.S.

Acid deposition primarily affects bodies of water that rest atop soil with a limited ability to neutralize acidic compounds. The National Surface Water Survey (NSWS) investigated the effects of acidic deposition in over 1,000 lakes larger than 10 acres and in thousands of miles of streams. It found that acid deposition was the primary cause of acidity in 75 percent of the acidic lakes and about 50 percent of the acidic streams, and that the areas most sensitive to acid rain were the Adirondacks, the mid-Appalachian highlands, the upper Midwest and the high elevation West. The NSWS found that approximately 580 streams in the Mid-Atlantic Coastal Plain are acidic primarily due to acidic deposition. Hundreds of the lakes in the Adirondacks surveyed in the NSWS have acidity levels incompatible with the survival of sensitive fish species. Many of the over 1,350 acidic streams in the Mid-Atlantic Highlands (mid-Appalachia) region have already experienced trout losses due to increased stream acidity. Emissions from U.S. sources contribute to acidic deposition in eastern Canada, where the Canadian government has estimated that 14,000 lakes are acidic. Acid deposition also has been implicated in contributing to degradation of high-elevation spruce forests that populate the ridges of the Appalachian Mountains from Maine to Georgia. This area includes national parks such as the Shenandoah and Great Smoky Mountain National Parks.

A recent study of emissions trends and acidity of waterbodies in the Eastern United States by the General Accounting Office (GAO) found that sulfates declined in 92 percent of a representative sample of lakes from 1992 to 1999, and nitrate levels increased in 48 percent of the lakes sampled.[60] The decrease in sulfates is consistent with emissions trends, but the increase in nitrates is inconsistent with the stable levels of nitrogen emissions and deposition. The study suggests that the vegetation and land surrounding these lakes have lost some of their previous capacity to use nitrogen, thus allowing more of the nitrogen to flow into the lakes and increase their acidity. Recovery of acidified lakes is expected to take a number of years, even where soil and vegetation have not been "nitrogen saturated," as EPA called the phenomenon in a 1995 study.[61] This situation places a premium on reductions of SO_X and especially NO_X from all sources, including HDVs, in order to reduce the extent and severity of nitrogen saturation and acidification of lakes in the Adirondacks and throughout the United States.

The SO_X and NO_X reductions from today's action will help reduce acid rain and acid deposition, thereby helping to reduce acidity levels in lakes and streams throughout the country and help accelerate the recovery of acidified lakes and streams and the revival of ecosystems adversely affected by acid deposition. Reduced acid deposition levels will also help reduce stress on forests, thereby accelerating reforestation efforts and improving timber production. Deterioration of our

[48] U.S. EPA (2000) 1996 National Toxics Inventory. http://www.epa.gov/ttn/uatw/nata. Inventory values for 1,3 butadiene, formaldehyde, acetaldehyde, and acrolein discussed below also come from this source.

[49] International Agency for Research on Cancer, IARC monographs on the evaluation of carcinogenic risk of chemicals to humans, Volume 29, Some industrial chemicals and dyestuffs, International Agency for Research on Cancer, World Health Organization, Lyon, France, p. 345–389, 1982.

[50] Irons, R.D., W.S. Stillman, D.B. Colagiovanni, and V.A. Henry, Synergistic action of the benzene metabolite hydroquinone on myelopoietic stimulating activity of granulocyte/macrophage colony-stimulating factor in vitro, Proc. Natl. Acad. Sci. 89:3691–3695, 1992.

[51] Environmental Protection Agency, Carcinogenic Effects of Benzene: An Update, National Center for Environmental Assessment, Washington, DC. 1998.

[52] Environmental Protection Agency. Draft Health Risk Assessment of 1,3-Butadiene, National Center for Environmental Assessment, Office of Research and Development, U.S. EPA, EPA/600/P–98/001A, February 1998.

[53] An SAB Report: Review of the Health Risk Assessment of 1,3-Butadiene. EPA-SAB-EHC–98, August, 1998.

[54] Scientific Advisory Board. 1998. An SAB Report: Review of the Health Risk Assessment of 1,3-Butadiene. EPA-SAB-EHC–98, August, 1998.

[55] [55]: EPA 1996. Proposed guidelines for carcinogen risk assessment. **Federal Register** 61(79):17960–18011.

[56] Environmental Protection Agency, Assessment of Health Risks to Garment Workers and Certain Home Residents from Exposure to Formaldehyde, Office of Pesticides and Toxic Substances, April 1987.

[57] U.S. EPA (1993) Environmental Protection Agency, Integrated Risk Information System (IRIS), National Center for Environmental Assessment, Cincinnati, OH.

[58] U.S. EPA (2000) Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds. External Review Draft. EPA/600/P–00/001Ag.

[59] Much of the information in this subsection was excerpted from the EPA document, Human Health Benefits from Sulfate Reduction, written under Title IV of the 1990 Clean Air Act Amendments, U.S. EPA, Office of Air and Radiation, Acid Rain Division, Washington, DC 20460, November 1995.

[60] Acid Rain: Emissions Trends and Effects in the Eastern United States, US General Accounting Office, March, 2000 (GOA/RCED–00–47).

[61] Acid Deposition Standard Feasibility Study: Report to Congress, EPA 430R–95–001a, October, 1995.

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historic buildings and monuments, and of buildings, vehicles, and other structures exposed to acid rain and dry acid deposition also will be reduced, and the costs borne to prevent acid-related damage may also decline. While the reduction in sulfur and nitrogen acid deposition will be roughly proportional to the reduction in SO_X and NO_X emissions, respectively, the precise impact of today's action will differ across different areas.

b. Eutrophication and Nitrification

Eutrophication is the accelerated production of organic matter, particularly algae, in a water body. This increased growth can cause numerous adverse ecological effects and economic impacts, including nuisance algal blooms, dieback of underwater plants due to reduced light penetration, and toxic plankton blooms. Algal and plankton blooms can also reduce the level of dissolved oxygen, which can also adversely affect fish and shellfish populations.

In 1999, NOAA published the results of a five year national assessment of the severity and extent of estuarine eutrophication. An estuary is defined as the inland arm of the sea that meets the mouth of a river. The 138 estuaries characterized in the study represent more than 90 percent of total estuarine water surface area and the total number of US estuaries. The study found that estuaries with moderate to high eutrophication conditions represented 65 percent of the estuarine surface area. Eutrophication is of particular concern in coastal areas with poor or stratified circulation patterns, such as the Chesapeake Bay, Long Island Sound, or the Gulf of Mexico. In such areas, the "overproduced" algae tends to sink to the bottom and decay, using all or most of the available oxygen and thereby reducing or eliminating populations of bottom-feeder fish and shellfish, distorting the normal population balance between different aquatic organisms, and in extreme cases causing dramatic fish kills.

Severe and persistent eutrophication often directly impacts human activities. For example, losses in the nation's fishery resources may be directly caused by fish kills associated with low dissolved oxygen and toxic blooms. Declines in tourism occur when low dissolved oxygen causes noxious smells and floating mats of algal blooms create unfavorable aesthetic conditions. Risks to human health increase when the toxins from algal blooms accumulate in edible fish and shellfish, and when toxins become airborne, causing respiratory problems due to inhalation. According to the NOAA report, more than half of the nation's estuaries have moderate to high expressions of at least one of these symptoms—an indication that eutrophication is well developed in more than half of U.S. estuaries.

In recent decades, human activities have greatly accelerated nutrient inputs, such as nitrogen and phosphorous, causing excessive growth of algae and leading to degraded water quality and associated impairments of freshwater and estuarine resources for human uses.[62] Since 1970, eutrophic conditions worsened in 48 estuaries and improved in 14. In 26 systems, there was no trend in overall eutrophication conditions since 1970.[63] On the New England coast, for example, the number of red and brown tides and shellfish problems from nuisance and toxic plankton blooms have increased over the past two decades, a development thought to be linked to increased nitrogen loadings in coastal waters. Long-term monitoring in the United States, Europe, and other developed regions of the world shows a substantial rise of nitrogen levels in surface waters, which are highly correlated with human-generated inputs of nitrogen to their watersheds.

On a national basis, the most frequently recommended control strategies by experts surveyed by National Oceanic and Atmospheric Administration (NOAA) between 1992–1997 were agriculture, wastewater treatment, urban runoff, and atmospheric deposition.[64] In its Third Report to Congress on the Great Waters, EPA reported that atmospheric deposition contributes from 2 to 38 percent of the nitrogen load to certain coastal waters.[65] A review of peer reviewed literature in 1995 on the subject of air deposition suggests a typical contribution of 20 percent or higher.[66] Human-caused nitrogen loading to the Long Island Sound from the atmosphere was estimated at 14 percent by a collaboration of federal and state air and water agencies in 1997.[67] The National Exposure Research Laboratory, US EPA, estimated based on prior studies that 20 to 35 percent of the nitrogen loading to the Chesapeake Bay is attributable to atmospheric deposition.[68] The mobile source portion of atmospheric NO_X contribution to the Chesapeake Bay was modeled at about 30 percent of total air deposition.[69]

Deposition of nitrogen from heavy-duty vehicles contributes to elevated nitrogen levels in waterbodies. In the Chesapeake Bay region, modeling shows that mobile source deposition occurs in relatively close proximity to highways, such as the I–95 corridor which covers part of the Bay surface. The new standards for heavy-duty vehicles will reduce total NO_X emissions by 2.6 million tons in 2030. The NO_X reductions will reduce the airborne nitrogen deposition that contributes to eutrophication of watersheds, particularly in aquatic systems where atmospheric deposition of nitrogen represents a significant portion of total nitrogen loadings.

c. Polycyclic Organic Matter Deposition

EPA's Great Waters Program has identified 15 pollutants whose deposition to water bodies has contributed to the overall contamination loadings to the these Great Waters.[70] One of these 15 pollutants, a group known as polycyclic organic matter (POM), are compounds that are mainly adhered to the particles emitted by mobile sources and later fall to earth in the form of precipitation or dry deposition of particles. The mobile source contribution of the 7 most toxic POM is at least 62 tons/year and represents only those POM that adhere to mobile source particulate emissions.[71] The majority of these emissions are produced by diesel engines.

[62] Deposition of Air Pollutants to the Great Waters, Third Report to Congress, June, 2000.

[63] Deposition of Air Pollutants to the Great Waters, Third Report to Congress, June, 2000. Great Waters are defined as the Great Lakes, the Chesapeake Bay, Lake Champlain, and coastal waters. The first report to Congress was delivered in May, 1994; the second report to Congress in June, 1997.

[64] Bricker, Suzanne B., et al., National Estuarine Eutrophication Assessment, Effects of Nutrient Enrichment in the Nation's Estuaries, National Ocean Service, National Oceanic and Atmospheric Administration, September, 1999.

[65] Deposition of Air Pollutants to the Great Waters, Third Report to Congress, June, 2000.

[66] Valigura, Richard, et al., Airsheds and Watersheds II: A Shared Resources Workshop, Air Subcommittee of the Chesapeake Bay Program, March, 1997.

[67] The Impact of Atmospheric Nitrogen Deposition on Long Island Sound, The Long Island Sound Study, September, 1997.

[68] Dennis, Robin L., Using the Regional Acid Deposition Model to Determine the Nitrogen Deposition Airshed of the Chesapeake Bay Watershed, SETAC Technical Publications Series, 1997.

[69] Dennis, Robin L., Using the Regional Acid Deposition Model to Determine the Nitrogen Deposition Airshed of the Chesapeake Bay Watershed, SETAC Technical Publications Series, 1997.

[70] Deposition of Air Pollutants to the Great Waters—Third Report to Congress, June, 2000, Office of Air Quality Planning and Standards Deposition of Air Pollutants to the Great Waters—Second Report to Congress, Office of Air Quality Planning and Standards, June 1997, EPA–453/R–97–011.

[71] The 1996 National Toxics Inventory, Office of Air Quality Planning and Standards, October 1999.

POM is generally defined as a large class of chemicals consisting of organic compounds having multiple benzene rings and a boiling point greater than 100 degrees C. Polycyclic aromatic hydrocarbons are a chemical class that is a subset of POM. POM are naturally occurring substances that are byproducts of the incomplete combustion of fossil fuels and plant and animal biomass (e.g., forest fires). Also, they occur as byproducts from steel and coke productions and waste incineration. Evidence for potential human health effects associated with POM comes from studies in animals (fish, amphibians, rats) and in human cells culture assays. Reproductive, developmental, immunological, and endocrine (hormone) effects have been documented in these systems. Many of the compounds included in the class of compounds known as POM are classified by EPA as probable human carcinogens based on animal data.

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The particulate reductions from today's action will help reduce not only the particulate emissions from highway diesel engines but also the deposition of the POM adhering to the particles, thereby helping to reduce health effects of POM in lakes and streams, accelerate the recovery of affected lakes and streams, and revive the ecosystems adversely affected.

d. Visibility and Regional Haze

Visibility impairment, also called regional haze, is a complex problem caused by a variety of sources, both natural and anthropogenic (e.g., motor vehicles). Regional haze masks objects on the horizon and reduces the contrast of nearby objects. The formation, extent, and intensity of regional haze are functions of meteorological and chemical processes, which sometimes cause fine particle loadings to remain suspended in the atmosphere for several days and to be transported hundreds of kilometers from their sources (NRC, 1993).

Visibility has been defined as the degree to which the atmosphere is transparent to visible light (NRC, 1993). Visibility impairment is caused by the scattering and absorption of light by particles and gases in the atmosphere. Fine particles (0.1 to 2.5 microns in diameter) are more effective per unit mass concentration at impairing visibility than either larger or smaller particles (NAPAP, 1991). Most of the diesel particle mass emitted by diesel engines falls within this fine particle size range. Light absorption is often caused by elemental carbon, a product of incomplete combustion from activities such as burning diesel fuel or wood. These particles cause light to be scattered or absorbed, thereby reducing visibility.

Heavy-duty vehicles contribute a significant portion of the emissions of direct PM, NO_X, and SO_X that result in ambient PM that contributes to regional haze and impaired visibility. The Grand Canyon Visibility Transport Commission's report found that heavy-duty diesel vehicles contribute 41 percent of fine elemental carbon or soot, 20 percent of NO_X, 7 percent of fine organic carbon, and 6 percent of SO_X. The report also found that reducing total mobile source emissions is an essential part of any program to protect visibility in the Western U.S. The Commission identified mobile source pollutants of concern as VOC, NO_X, and elemental and organic carbon. The Western Governors Association, in later commenting on the Regional Haze Rule and on protecting the 16 Class I areas on the Colorado Plateau, stated that the federal government, and particularly EPA, must do its part in regulating emissions from mobile sources that contribute to regional haze in these areas. As described more fully later in this section, today's action will result in large reductions in these pollutants. These reductions are expected to provide an important step towards improving visibility across the nation. Emissions reductions being achieved to attain the 1-hour ozone and PM_{10} NAAQS will assist in visibility improvements. Moreover, the timing of the reductions from the standards fits very well with the goals of the regional haze program. We will work with the regional planning bodies to make sure they have the information to take account of the reductions from this final rule in their planning efforts.

The Clean Air Act contains provisions designed to protect national parks and wilderness areas from visibility impairment. In 1999, EPA promulgated a rule that will require States to develop plans to dramatically improve visibility in national parks. Although it is difficult to determine natural visibility levels, we believe that average visual range in many Class I areas in the United States is significantly less (about 50–66 percent of natural visual range in the West, about 20 percent of natural visual range in the East) than the visual range that will exist without anthropogenic air pollution. The final Regional Haze Rule establishes a 60-year time period for planning purposes, with several near term regulatory requirements, and is applicable to all 50 states. One of the obligations is for States to representative conduct visibility monitoring in mandatory Class I Federal areas and determine baseline conditions using data for year 2000 to 2004. Reductions of particles, NO_X, sulfur, and VOCs from this rulemaking will have a significant impact on moving all states towards achieving long-term visibility goals, as outlined in the 1999 Regional Haze Rule.

C. Contribution from Heavy-Duty Vehicles

Nationwide, heavy-duty vehicles are projected to contribute about 15 percent of the total NO_X inventory, and 28 percent of the mobile source inventory in 2007. Heavy-duty NO_X emissions also contribute to fine particulate concentrations in ambient air due to the transformation in the atmosphere to nitrates. The NO_X reductions resulting from today's standards will therefore have a considerable impact on the national NO_X inventory. All highway vehicles account for 34 percent and heavy-duty highway vehicles account for 20 percent of the mobile source portion of national PM_{10} emissions in 2007. The heavy-duty portion of the inventory is often greater in the cities, and the reductions in this rulemaking will have a relatively greater benefit in those areas.

1. NO_X Emissions

Heavy-duty vehicles are important contributors to the national inventories of NO_X emissions. Without NO_X reductions from this rule, HDVs are expected to contribute approximately 18 percent of annual NO_X emissions in 1996. The HDV contribution is predicted to fall to 15 percent in 2007 and 14 percent in 2020 due to reductions from the 2004 heavy-duty rulemaking, and then rise again to 16 percent of total NO_X inventory by 2030 (Table II.C–1). Annual NO_X reductions from this rule are expected to total 2.6 million tons in 2030.

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TABLE II.C–1—NO_X EMISSIONS FROM HDVS WITH AND WITHOUT REDUCTIONS FROM THIS RULE

Year	Without this rule (base case)		With this rule (control case)
	HDV annual NO_X tons	HDV annual NO_X tons as a percent of total NO_X	Reductions in annual HDV NO_X tons
1996	4,810,000	18	n/a
2007	3,040,000	15	58,000
2020	2,560,000	14	1,820,000
2030	2,960,000	16	2,570,000

The contribution of heavy-duty vehicles to NO_X inventories in many MSAs is significantly greater than that reflected in the national average. For example, HDV contributions to total annual NO_X is greater than the national average in the eight metropolitan statistical areas listed in Table II.C–2. Examples of major cities with a history of persistent ozone violations that are heavily impacted by NO_X emissions from HDVs include: Los Angeles, Washington, DC, San Diego, Hartford, Atlanta, Sacramento. As presented in the table below, HDV's contribute from 22 percent to 33 percent of the total NO_X inventories in these selected cities. NO_X emissions also contribute to the formation of fine particulate matter, especially in the West. In all areas, NO_X also contributes to environmental and welfare effects such as regional haze, and eutrophication and nitrification of water bodies.

TABLE II.C–2—HEAVY-DUTY VEHICLE PERCENT CONTRIBUTION TO NO_X INVENTORIES IN SELECTED URBAN AREAS IN 2007

MSA, CMSA / State	HDV NO_X as portion of total NO_X (%)	HDV NO_X as portion of mobile source NO_X (%)
National	*15*	*26*
Sacramento, CA	33	37
Hartford, CT	28	38
San Diego, CA	25	28
San Francisco, CA	24	29
Atlanta, GA	22	34
Los Angeles	22	26
Dallas	22	28
Washington-Baltimore, MSA	22	36

2. PM Emissions

Nationally, we estimate that primary emissions of PM_{10} to be about 33 million tons/year in 2007. Fugitive dust, other miscellaneous sources and crustal material (wind erosion) constitute approximately 90 percent of the 2007 PM_{10} inventory. However, there is evidence from ambient studies that emissions of these materials may be overestimated and/or that once emitted they have less of an influence on monitored PM concentration than this inventory share would suggest. Mobile sources account for 22 percent of the PM_{10} inventory (excluding the contribution of miscellaneous and natural sources) and highway heavy-duty engines, the subject of today's action, account for 20 percent of the mobile source portion of national PM_{10} emissions in 2007.

The contribution of heavy-duty vehicle emissions to total PM emissions in some metropolitan areas is substantially higher than the national average. This is not surprising, given the high density of these engines operating in these areas. For example, in Los Angeles, Atlanta, Hartford, San Diego, Santa Fe, Cincinnati, and Detroit, the estimated 2007 highway heavy-duty vehicle contribution to mobile source PM_{10} ranges from 25 to 38 percent, while the national percent contribution to mobile sources for 2007 is projected to be about 20 percent. As illustrated in Table II.C–3, heavy-duty vehicles operated in El Paso, Indianapolis, San Francisco, and Minneapolis also account for a higher portion of the mobile source PM inventory than the national average. These data are based on updated inventories developed for this rulemaking. Importantly, these estimates do not include the contribution from secondary PM, which is an important component of diesel PM.

TABLE II.C–3—2007 HEAVY-DUTY VEHICLE CONTRIBUTION TO URBAN MOBILE SOURCE PM INVENTORIES

MSA, State	HDV PM Contribution to mobile source PMG[a]
National (48 State)	*20*
Atlanta, GA MSA	25
Cincinnati-Hamilton, OH–KY–IN CMSA	26
Detroit-Ann Arbor-Flint, MI CMSA	25
El Paso, TX MSA	23
Hartford, CT MSA	30
Indianapolis, IN MSA	23
Los Angeles-Riverside-Orange County, CA CMSA	25
Minneapolis-St. Paul, MN–WI MSA	23
San Diego, CA MSA	27
San Francisco-Oakland-San Jose, CA CMSA	24
Santa Fe, NM MSA	38

[a] Direct exhaust emissions only; excludes secondary PM.

The city-specific emission inventory analysis and investigations of ambient $PM_{2.5}$ summarized in the RIA indicate that the contribution of diesel engines to PM inventories in several urban areas around the U.S. is much higher than indicated by the national PM emission inventories only. One possible explanation for this is the concentrated use of diesel engines in certain local or regional areas which is not well represented by the national, yearly average presented in national PM emission inventories. Another reason may be underestimation of the in-use diesel PM emission rates. Our current modeling incorporates deterioration only as would be experienced in properly maintained, untampered vehicles. We are currently in the process of reassessing the rate of in-use deterioration of diesel engines and vehicles which could significantly increase the contribution of HDVs to diesel PM.

3. Environmental Justice

Environmental justice is a priority for EPA. The Federal government stated its concern, in part, over this issue through issuing Executive Order 12898, Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations (February 11, 1994). This Order requires that federal agencies make achieving environmental justice part of their mission. Similarly, the EPA created an Office of Environmental Justice (originally the Office of Environmental Equity) in 1992, commissioned a task force to address environmental justice issues, oversees a Federal Advisory Committee addressing environmental justice issues (the National Environmental Justice Advisory Council), and has developed an implementation strategy as required under Executive Order 12898.

Application of environmental justice principles as outlined in the Executive Order advances the fair treatment of people of all races, income, and culture with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. Fair treatment implies that no person or group of people should shoulder a disproportionate share of any negative environmental impacts resulting from the execution of this country's domestic and foreign policy programs.

For the last several years, environmental organizations and community-based citizens groups have been working together to phase out diesel buses in urban areas. For example, the Natural Resources Defense Council initiated a "Dump Dirty Diesel" campaign in the 1990s to press for the phase out of diesel buses in New York City. Other environmental organizations operating in major cities such as Boston, Newark, and Los Angeles have joined this campaign. The Coalition for Clean Air worked with NRDC and other experts to perform exposure monitoring in communities located near distribution centers where diesel truck traffic is heavy. These two organizations concluded that facilities with heavy truck traffic are exposing local communities to diesel exhaust concentrations far above the average levels in outdoor air. The report states: "These affected communities, and the workers at these distribution facilities with heavy diesel truck traffic, are bearing a disproportionate burden of the health risks." [72] Other diesel "hot spots" identified by the groups are bus terminals, truck and bus maintenance facilities, retail distribution centers, and busy streets and highways.

While there is currently a limited understanding of the relationship of environmental exposures to the onset of asthma, the environmental triggers of asthma attacks for children with asthma have become increasingly well characterized.[73] Asthma's burden falls hardest on the poor, inner city residents, and children. Among children up to 4 years of age, asthma prevalence increased 160 percent since 1980.[74] African-American children have an annual rate of hospitalization three times that for white children, and are four times as likely to seek care at an emergency room.[75] In 1995, the death rate from asthma in African-American children, 11.5 per million, was over four times the rate in white American children, 2.6 per million.[76]

Local community groups and private citizens testified at public hearings held for this rule that the residents of their communities suffer greatly, and disproportionally, from air pollution in general, and emissions from heavy-duty vehicles in particular. For example, a testifier in New York pointed out that "since Northern Manhattan and the South Bronx experience asthma mortality and morbidity rates at three to five times greater than the citywide average, New York City's problem is Northern Manhattan's crisis." [77]

The new standards established in this rulemaking are expected to improve air quality across the country and will provide increased protection to the public against a wide range of health effects, including chronic bronchitis, respiratory illnesses, and aggravation of asthma symptoms. These air quality and public health benefits could be expected to mitigate some of the environmental justice concerns related to heavy-duty vehicles since the rule will provide relatively larger benefits to heavily impacted urban areas.

D. Anticipated Emissions Benefits

This subsection presents the emission benefits we anticipate from heavy-duty vehicles as a result of our new NO_X, PM, and NMHC emission standards for heavy-duty engines. The graphs and tables that follow illustrate the Agency's projection of future emissions from heavy-duty vehicles for each pollutant. The baseline case represents future emissions from heavy-duty vehicles at present standards (including the MY2004 standards). The controlled case quantifies the future emissions of heavy-duty vehicles once the new standards in this FRM are implemented.

We use the same baseline inventory as is used in the county-by-county, hour-by-hour air quality analyses associated with this rule. However, we made a slight modification to the controlled inventory to incorporate the changes between the proposed and final standards. Because the detailed air quality analyses took several months to perform, we had to use the proposed standards for the air quality analysis. Since beginning this analysis, we updated the control case emission inventories to reflect the final phase-in of the NO_X standard, slight changes to the timing of the HDGV standards, a temporary compliance option for introducing the low sulfur fuel requirements, and various hardship provisions for refiners in our emission inventory projections. The emission inventory calculations are presented in detail in the Regulatory Impact Analysis.

1. NO_X Reductions

The Agency expects substantial NO_X reductions on both a percentage and a tonnage basis from the new standards. The RIA provides additional projections between 2007 and 2030. As stated previously, HDVs contribute about 15 percent to the national NO_X inventory for all sources in 2007. Figure II.D–1 shows our national projections of total NO_X emissions with and without the engine controls finalized today. Table II.D–1 presents the total reductions.[78] This includes both exhaust and crankcase emissions.[79] The standards

[72] *Exhausted by Diesel: How America's Dependence on Diesel Engines Threatens Our Health*, Natural Resources Defense Council, Coalition for Clean Air, May 1998.

[73] *Asthma and the Environment: A Strategy to Protect Children, President's Task Force on Environmental Health Risks and Safety Risks to Children*, January 28, 1999, Revised May, 2000.

[74] Asthma Statistics, National Institutes of Health, National Heart, Lung and Blood Institute, January, 1999.

[75] *Asthma and the Environment: A Strategy to Protect Children, President's Task Force on Environmental Health Risks and Safety Risks to Children*, January 28, 1999, Revised May, 2000. The Task Force was formed in conjunction with Executive Order 13045 (April 21, 1997), is co-chaired by Department of Health and Human Services and EPA, and is charged with recommending strategies for protecting children's environmental health and safety. In April, 1998, the Task Force identified childhood asthma as one of its top four priorities for immediate attention.

[76] *Id.*

[77] Testimony by Peggy Shepard, Executive Director, West Harlem Environmental Action, June 19th, 2000.

[78] The baseline used for this calculation is the 2004 HDV standards (64 FR 58472). These reductions are in addition to the NO_X emissions reductions projected to result from the 2004 HDV standards.

[79] We include in the NO_X projections excess emissions, developed by the EPA's Office of Enforcement and Compliance, that were emitted by many model year 1998–98 diesel engines. This is described in more detail in Chapter 2 of the RIA.

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should result in close to a 90 percent reduction in NO_X from new engines.

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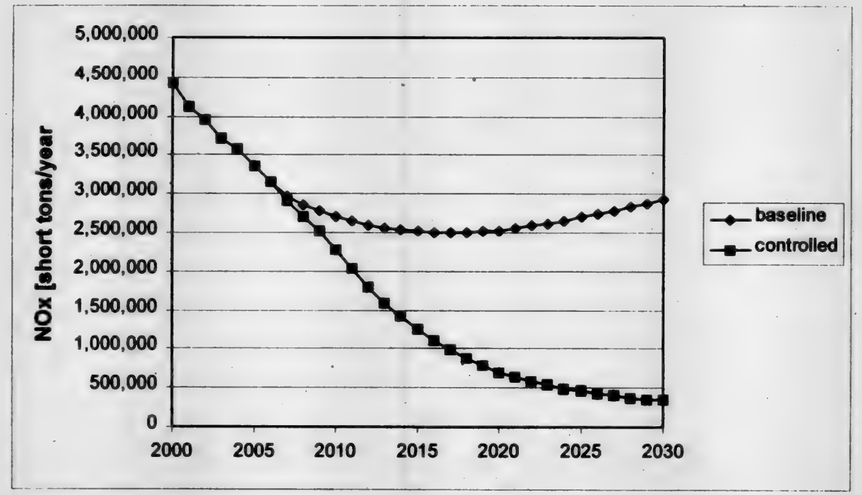


Figure II.D-1: Projected Nationwide Heavy-Duty Vehicle NOx Emissions

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TABLE II.D–1.—ESTIMATED REDUCTIONS IN NO_X

Calendar year	NO_X reduction [thousand short tons]
2007	58
2010	419
2015	1,260
2020	1,820
2030	2,570

2. PM Reductions

As stated previously, HDVs will contribute about 20 percent to the 2007 national PM_{10} inventory for mobile sources. The majority of the projected PM reductions are directly a result of the exhaust PM standard. However, a modest amount of PM reductions will come from reducing sulfur in the fuel. For the existing fleet of heavy-duty vehicles, a small fraction of the sulfur in diesel fuel is emitted directly into the atmosphere as direct sulfate, and a portion of the remaining fuel sulfur is transformed in the atmosphere into sulfate particles, referred to as indirect sulfate. Reducing sulfur in the fuel decreases the amount of direct sulfate PM emitted from heavy-duty diesel engines and the amount of heavy-duty diesel engine SOx emissions that are transformed into indirect sulfate PM in the atmosphere.[80] For engines meeting the new standards, we consider low sulfur fuel to be necessary to enable the PM control technology. In other words, we do not claim an additional benefit beyond the new exhaust standard for reductions in direct sulfate PM for new engines. However, once the low sulfur fuel requirements go into effect, many pre-2007 model year engines would also be using low sulfur fuel. Because these pre-2007 model year engines are certified with higher sulfur fuel, they will achieve reductions in PM beyond their certification levels.

Figure II.D–2 shows our national projections of total HDV PM (TPM) emissions with and without the new engine controls. This figure includes brake and tire wear, crankcase emissions and the direct sulfate PM (DSPM) benefits due to the use of low sulfur fuel by the existing fleet. These direct sulfate PM benefits from the existing fleet are also graphed separately. The new standards will result in about a 90 percent reduction in exhaust PM from new heavy-duty diesel engines. The low sulfur fuel should result in more than a 95 percent reduction in direct sulfate PM from pre-2007 heavy-duty diesel engines. Due to complexities of the conversion and removal processes of sulfur dioxide, we do not attempt to quantify the indirect sulfate reductions that would be derived from this rulemaking in the inventory analysis. Nevertheless, we recognize that these indirect sulfate PM reductions contribute significant additional benefits to public health and welfare, and we include this effect in our more detailed air quality analysis.

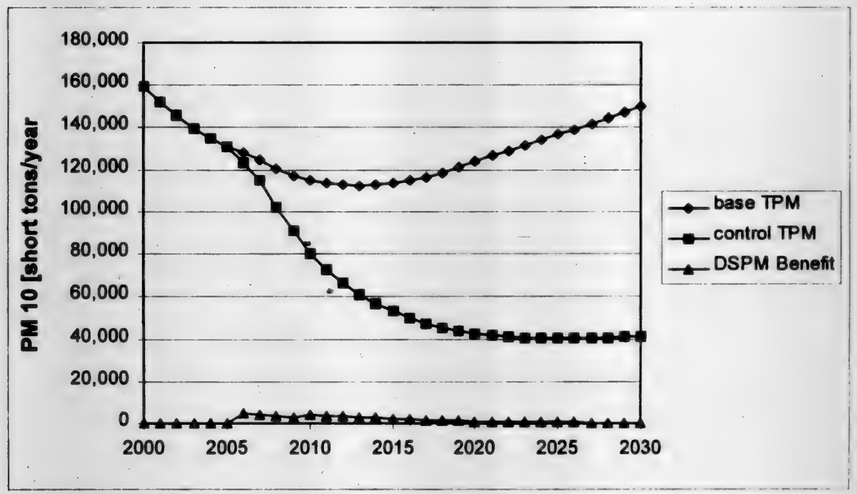


Figure II.D-2: Projected Nationwide Heavy-Duty Vehicle PM Emissions and Direct Sulfate Emission Reductions

[80] Sulfate forms a significant portion of total fine particulate matter in the Northeast Chemical speciation data in the Northeast collected in 1995 shows that the sulfate fraction of fine particulate matter ranges from 20 and 27 percent of the total fine particle mass. *Determination of Fine Particle and Concentrations and Chemical Composition in the Northeastern United States. 1995.* NESCAUM, prepared by Cass, et al., September 1999.

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TABLE II.D–2.—ESTIMATED REDUCTIONS IN PM

Calendar year	PM reduction [thousand short tons]
2007	11
2010	36
2015	61
2020	82
2030	109

3. NMHC Reductions

The standards described in Section III are designed to be feasible for both gasoline and diesel heavy-duty vehicles. Although the standards give manufacturers the same phase-in for NMHC as for NO_X, we model the NMHC reductions for diesel vehicles to be fully in place in 2007 due to the application of particulate control technology. We believe the use of aftertreatment for PM control will cause the NMHC levels to be below the standards as soon as the PM standard goes into effect in 2007.

HDVs account for about 3 percent of national VOC and 8 percent from mobile sources in 2007. Figure II.D–3 shows our national projections of total NMHC emissions with and without the new engine controls. This includes both exhaust emissions and evaporative emissions. Table II.D–3 presents the projected reductions of NMHC due to the new standards.

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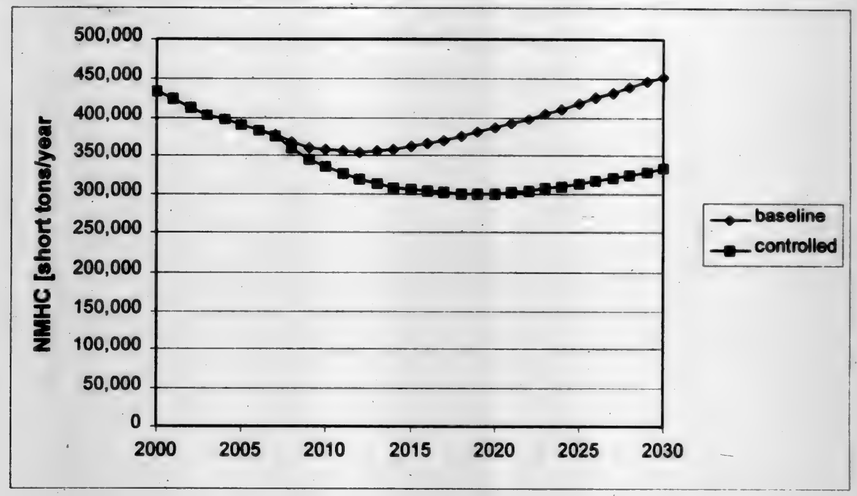


Figure II.D-3: Projected Nationwide Heavy-Duty Vehicle NMHC Emissions

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TABLE II.D–3.—ESTIMATED REDUCTIONS IN NMHC

Calendar year	NMHC reduction [thousand short tons]
2007	2
2010	21
2015	54
2020	83
2030	115

TABLE II.D–4.—ESTIMATED REDUCTIONS IN CO

Calendar year	CO reduction [thousand short tons]
2007	56
2010	317
2015	691
2020	982
2030	1,290

TABLE II.D–5.—ESTIMATED REDUCTIONS IN SO_X DUE TO LOW SULFUR FUEL

Calendar year	SO_X reduction [thousand short tons]
2007	79
2010	107
2015	117
2020	126
2030	142

4. Additional Emissions Benefits

This subsection looks at tons/year emission inventories of CO, SO_X, and air toxics from HDEs. Although we are not including stringent standards for these pollutants in this action, we believe the standards will result in reductions in CO, SO_X, and air toxics. Here, we present our anticipated benefits.

a. CO Reductions

In 2007, HDVs are projected to contribute to approximately 5 percent of national CO and 9 percent of CO from mobile sources. Although it does not include new CO emission standards, today's action would nevertheless be expected to result in a considerable reduction in CO emissions from heavy-duty vehicles. CO emissions from heavy-duty diesel vehicles, although already very low, would likely be reduced by an additional 90 percent due to the operation of emissions control systems that will be necessary to achieve today's new standards for hydrocarbons and particulate matter. CO emissions from heavy-duty gasoline vehicles would also likely decline as the NMHC emissions are decreased. Table II.D–4 presents the projected reductions in CO emissions from HDVs.

b. SO_X Reductions

HDVs are projected to emit approximately 0.5 percent of national SO_X and 8 percent of mobile source SO_X in 2007. We are requiring significant reductions in diesel fuel sulfur to enable certain emission control devices to function properly. We expect SO_X emissions to decline as a direct benefit of low sulfur diesel fuel. The majority of these benefits will be from heavy-duty highway diesel vehicles; however, some benefits will also come from highway fuel burned in other applications such as light-duty diesel vehicles and nonroad engines. As discussed in greater detail in the section on PM reductions, the amount of sulfate particles (direct and indirect) formed as a result of diesel exhaust emissions will decline for all HD diesel engines operated on low sulfur diesel fuel, including the current on-highway HD diesel fleet, and those non-road HD diesel engines that may operate on low sulfur diesel fuel in the future. Table II.D–5 presents our estimates of SO_X reductions resulting from the low sulfur fuel.

c. Air Toxics Reductions

This FRM establishes new non-methane hydrocarbon standards for all heavy-duty vehicles and a formaldehyde standard for complete heavy-duty vehicles. Hydrocarbons are a broad class of chemical compounds containing carbon and hydrogen. Many forms of hydrocarbons, such as formaldehyde, are directly hazardous and contribute to what are collectively called "air toxics." Air toxics are pollutants known to cause or suspected of causing cancer or other serious human health effects or ecosystem damage. The Agency has identified at least 20 compounds emitted from on-road gasoline vehicles that have toxicological potential, 19 of which are emitted by diesel vehicles, as well as an additional 20 compounds which have been listed as toxic air contaminants by California ARB.[81] [82] This action also will reduce emissions of diesel exhaust and diesel particulate matter (see Section II.B for a discussion of health effects).

Our assessment of heavy-duty vehicle (gasoline and diesel) air toxics focuses on the following compounds with cancer potency estimates that have significant emissions from heavy-duty vehicles: benzene, formaldehyde, acetaldehyde, and 1,3-butadiene. These compounds are an important, but limited, subset of the total number of air toxics that exist in exhaust and evaporative emissions from heavy-duty vehicles. The reductions in air toxics quantified in this section represent only a fraction of the total number and amount of air toxics reductions expected from the new hydrocarbon standards.

For this analysis, we estimate that air toxic emissions are a constant fraction of hydrocarbon exhaust emissions from future engines. Because air toxics are a subset of hydrocarbons, and new emission controls are not expected to preferentially control one type of air toxic over another, the selected air toxics chosen for this analysis are expected to decline by the same percentage amount as hydrocarbon exhaust emissions. We have not performed a separate analysis for the new formaldehyde standard since compliance with the hydrocarbon standard should result in compliance with the formaldehyde standard for all petroleum-fueled engines. The RIA provides more detail on this analysis. Table II.D–6 shows the estimated air toxics reductions associated with the reductions in hydrocarbons.

[81] National Air Quality and Emissions Trends Report, 1997, (EPA 1998), p. 74.

[82] California Environmental Protection Agency (1998) Report to the Air Resources Board on the Proposed Identification of Diesel Exhaust as a Toxic Air Contaminant. Appendix III, Part A: Exposure Assessment. April 1998.

TABLE II.D–6.—ESTIMATED REDUCTIONS IN AIR TOXICS (SHORT TONS)

Calendar year	Benzene	Formaldehyde	Acetaldehyde	1,3-Butadiene
2007	24	181	67	14
2010	358	1,670	608	135
2015	965	4,720	1,720	384
2020	1,340	7,080	2,600	567
2030	1,960	10,200	3,730	823

E. Clean Heavy-Duty Vehicles and Low-Sulfur Diesel Fuel are Critically Important for Improving Human Health and Welfare

Despite continuing progress in reducing emissions from heavy-duty engines, emissions from these engines continue to be a concern for human health and welfare. Ozone continues to be a significant public health problem, and affects not only people with impaired respiratory systems, such as asthmatics, but healthy children and adults as well. Ozone also causes damage to plants and has an adverse impact on agricultural yields. Particulate matter, like ozone, has been linked to a range of serious respiratory health problems, including premature mortality, aggravation of respiratory and cardiovascular disease, aggravated asthma, acute respiratory symptoms, and chronic bronchitis. Importantly, EPA has concluded that diesel exhaust is likely to be carcinogenic to humans by inhalation at occupational and environmental levels of exposure.

Today's action will reduce NO_X, VOC, CO, PM, and SO_X emissions from these heavy-duty vehicles substantially. These reductions will help reduce ozone levels nationwide and reduce the frequency and magnitude of predicted exceedances of the ozone standard. These reductions will also help reduce PM levels, both by reducing direct PM emissions and by reducing emissions that give rise to secondary PM. The NO_X and SO_X reductions will help reduce acidification problems, and the NO_X reductions will help reduce eutrophication problems. The PM and NO_X standard enacted today will help improve visibility. All of these reductions are expected to have a beneficial impact on human health and welfare by reducing exposure to ozone, PM, diesel exhaust and other air toxics and thus reducing the cancer and noncancer effects associated with exposure to these substances.

III. Heavy-Duty Engine and Vehicle Standards

In this section, we describe the vehicle and engine standards we are finalizing today to respond to the serious air quality needs discussed in Section II. Specifically, we discuss:

- The CAA and why we are finalizing new heavy-duty standards.
- The technology opportunity for heavy-duty vehicles and engines.
- Our new HDV and HDE standards, and our phase-in of those standards.
- Why we believe the stringent standards being finalized today are feasible in conjunction with the low sulfur gasoline required under the recent Tier 2 rule and the low sulfur diesel fuel being finalized today.
- The effects of diesel fuel sulfur on the ability to meet the new standards, and what happens if high sulfur diesel fuel is used.
- Plans for future review of the status of heavy-duty diesel NO_X emission control technology.

A. Why Are We Setting New Heavy-Duty Standards?

We are finalizing new heavy-duty vehicle and engine standards and related provisions under section 202(a)(3) of the CAA, which authorizes EPA to establish emission standards for new heavy-duty motor vehicles. (See 42 U.S.C. 7521(a)(3).) Section 202(a)(3)(A) requires that such standards "reflect the greatest degree of emission reduction achievable through the application of technology which the Administrator determines will be available for the model year to which such standards apply, giving appropriate consideration to cost, energy, and safety factors associated with the application of such technology." Section 202(a)(3)(B) allows EPA to take into account air quality information in revising such standards. Because heavy-duty engines contribute greatly to a number of serious air pollution problems, especially the health and welfare effects of ozone, PM, and air toxics, and because millions of Americans live in areas that exceed the national air quality standards for ozone or PM, we believe the air quality need for tighter heavy-duty standards is well founded. This, and our belief that a significant degree of emission reduction from heavy-duty vehicles and engines is achievable, giving appropriate consideration to cost, energy, and safety factors, through the application of new diesel emission control technology, further refinement of well established gasoline emission controls, and reductions of diesel fuel sulfur levels, leads us to believe that new emission standards are warranted.

B. Emission Control Technologies for Heavy-Duty Vehicles and Engines

For the past 30 or more years, emission control development for gasoline vehicles and engines has concentrated most aggressively on exhaust emission control devices. These devices currently provide as much as or more than 95 percent of the emission control on a gasoline vehicle. In contrast, the emission control development work for diesels has concentrated on improvements to the engine itself to limit the emissions leaving the combustion chamber.

However, during the past 15 years, more development effort has been put into diesel exhaust emission control devices, particularly in the area of PM control. Those developments, and recent developments in diesel NO_X control devices, make the widespread commercial use of diesel exhaust emission controls feasible. Through use of these devices, we believe emissions control similar to that attained by gasoline applications will be possible with diesel applications. However, without low sulfur diesel fuel, these technologies cannot be implemented on heavy-duty diesel applications. Low sulfur diesel fuel will at the same time

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also allow these technologies to be implemented on light-duty diesel applications.

As discussed at length in the preamble to our proposal, several exhaust emission control devices have been or are being developed to control harmful diesel exhaust pollutants. Of these, we believe that the catalyzed diesel particulate trap and the NO_X adsorber are the most likely candidates to be used to meet the very low diesel exhaust emission standards adopted today on the variety of applications in the heavy-duty diesel market. While other technologies exist that have the potential to provide significant emission reductions, such as selective catalytic reduction systems for NO_X control, and development of these technologies is being pursued to varying degrees, we believe that the catalyzed diesel particulate trap and the NO_X adsorber will be the only likely broadly applicable technology choice by the makers of engines and vehicles for the national fleet in this timeframe. However, as discussed in detail in the Final RIA, we strongly believe that none of these technologies can be brought to market on diesel engines and vehicles unless the kind of low sulfur diesel fuel adopted in this rule is available.

As for gasoline engines and vehicles, improvement continues to be made to gasoline emissions control technology. This includes improvement to catalyst designs in the form of improved washcoats and improved precious metal dispersion. Much effort has also been put into improved cold start strategies that allow for more rapid catalyst light-off. This can be done by retarding the spark timing to increase the temperature of the exhaust gases, and by using air-gap manifolds, exhaust pipes, and catalytic converter shells to decrease heat loss from the system.

These improvements to gasoline emission controls will be made in response to the California LEV–II standards and the federal Tier 2 standards.[83] These improvements should transfer well to the heavy-duty gasoline segment of the fleet. With such migration of light-duty technology to heavy-duty vehicles and engines, we believe that considerable improvements to heavy-duty gasoline emissions can be realized, thus allowing vehicles to meet the much more stringent standards adopted today.

The following discussion provides more detail on the technologies we believe are most capable of meeting very stringent heavy-duty emission standards. The goal of this discussion is to describe the emission reduction capability of these emission control technologies and their critical need for diesel fuel sulfur levels as low as those being finalized today. But first, we present the details of the new emission standards being finalized today.

C. What Engine and Vehicle Standards Are We Finalizing?

1. Heavy-Duty Engine Exhaust Emissions Standards

a. FTP Standards[84]

The emission standards finalized today for heavy-duty engines are summarized in Table III.C–1. For reasons explained below, the phase-in schedule for these standards differs from the proposed schedule. We are also finalizing an incentive provision to encourage the early introduction of engines meeting these new standards. This incentive provision is explained in section III.D. In addition, we have altered our Averaging, Banking, and Trading (ABT) provisions from what was proposed. The final ABT provisions are discussed in detail in section VI.

TABLE III.C–1.—FULL USEFUL LIFE HEAVY-DUTY ENGINE EXHAUST EMISSIONS STANDARDS AND PHASE-INS FOR INCOMPLETE VEHICLES

		Standard (g/bhp-hr)	Phase-In by Model Year[a]			
			2007	2008	2009	2010
Diesel	NO_X	0.20	50%	50%	50%	100%
	NMHC	0.14	50%	50%	50%	100%
	PM	0.01	100%	100%	100%	100%
Gasoline	NO_X	0.20	0%	50%	100%	100%
	NMHC	0.14	0%	50%	100%	100%
	PM	0.01	0%	50%	100%	100%

[a] Percentages represent percent of sales.

With respect to PM, this new standard represents a 90 percent reduction for most heavy-duty diesel engines from the current PM standard. The current PM standard for most heavy-duty engines, 0.10 g/bhp-hr, was implemented in the 1994 model year; the PM standard for urban buses implemented in that same year was 0.05 g/bhp-hr; these standards are not changing when other standards change in the 2004 model year timeframe. The new PM standard of 0.01 g/bhp-hr being finalized today is projected to require the addition of highly efficient PM traps to diesel engines, including those diesel engines used in urban buses; it is not expected to require the addition of any new hardware for gasoline engines.

With respect to NMHC and NO_X, these new standards represent significant reductions from the 2004 diesel engine standard which is either 2.4 g/bhp-hr NO_X+NMHC, or 2.5 g/bhp-hr NO_X+NMHC with a cap on NMHC of 0.5 g/bhp-hr. We generally expect that 2004 diesel engines will meet those standards with emission levels around 2.2 g/bhp-hr NO_X and 0.2 g/bhp-hr NMHC. Like the PM standard, the new NO_X standard is projected to require the addition of a highly efficient NO_X emission control system to diesel engines which, with help from the PM trap, will need to be optimized to control NMHC emissions. For gasoline

[83] See Chapter IV.A of the final Tier 2 Regulatory Impact Analysis, contained in Air Docket A–97–10, and McDonald, Joseph, and Jones, Lee, "Demonstration of Tier 2 Emission Levels for Heavy Light-Duty Trucks," SAE 2001–01–1957.

[84] The Phase 1 heavy-duty rule recently promulgated by EPA specified two supplemental sets of standards for heavy-duty diesel engines. (See 65 FR 59896, October 6, 2000.) Manufacturers of heavy-duty diesel engines must meet these supplemental standards, the Supplemental Emission Test (SET, formerly referred to as the Supplemental Steady-State (SSS) test) and the Not-to-Exceed (NTE) standards, beginning in model year 2007, in addition to meeting the preexisting standards, which must be met using the preexisting federal test procedure (FTP). For the purposes of this preamble, we refer to the standards met using the preexisting FTP as the FTP standards, though the SET and NTE test procedures have now been added to the regulations establishing the various federal test procedures for heavy-duty diesel engines.

engines, the 2005 model year standard recently finalized in the Phase 1 heavy-duty rule is 1.0 g/bhp-hr NO_X+NMHC. (See 65 FR 59896, October 6, 2000.) There is a direct trade off between NO_X and NMHC emissions with a gasoline engine, but we would generally expect NO_X levels over 0.5 g/bhp-hr and NMHC levels below that. Regardless of the NO_X and NMHC split, today's standards represent significant reductions for 2008 and later engines that will require substantial improvement in the effectiveness of heavy-duty gasoline emission control technology.

We proposed a new formaldehyde standard of 0.016 g/bhp-hr for both heavy-duty diesel and gasoline engines. However, we have decided not to finalize those standards. We proposed the formaldehyde (HCHO) standard because it is a hazardous air pollutant that is emitted by heavy-duty engines and other mobile sources. In the proposal, we stated our belief that formaldehyde emissions from gasoline and diesel engines are and will remain inherently low, but having the standard would ensure that excess emissions would not occur. Several commenters took issue with our proposed standard claiming that the benefits were nonexistent, that we should address toxic emissions in our toxics rulemaking, and that we had shown neither its technological feasibility nor its measurability. After further consideration we do believe that the proposed formaldehyde standard is not necessary because the NMHC standard we are promulgating today will almost certainly result in formaldehyde emissions well below our proposed formaldehyde standard. As a result, other comments on this issue such as those concerning technological feasibility and measurability are no longer relevant to this rule. We will continue to evaluate this issue to ensure that formaldehyde emissions do not become a problem in the future and may take action to consider standards if warranted.

We believe a phase-in of the diesel NO_X standard is appropriate. With a phase-in, manufacturers are able to introduce the new technology on a portion of their engines, thereby gaining valuable experience with the technology prior to implementing it on their entire fleet. Also, we are requiring that the NO_X, and NMHC standards be phased-in together for diesel engines. That is, engines will be expected to meet both of these new standards, not just one or the other. We are requiring this because the standard finalized in the Phase 1 heavy-duty rule is a combined NMHC+NO_X standard. With separate NO_X and NMHC phase-ins, say 50/50/50/100 for NO_X and 100 percent in 2007 for NMHC, the 2.5 gram engines being phased-out would have a 2.5 gram NO_X+NMHC standard and a new 0.14 gram NMHC standard with which to comply. While this could be done, we believe that it introduces unnecessary compliance complexity to the program.

In our NPRM, we requested comment on a range of possible phase-in schedules for NO_X including anything from our primary proposal of 25/50/75/100 percent phase-in to a possible requirement for 100 percent compliance in the 2007 model year. We have determined that a 50/50/50/100 percent phase-in schedule is the most appropriate schedule for several reasons.

Some commenters argued that we should require 100 percent compliance in the 2007 model year because of the 0.20 gram standard was both technologically feasible and critical given the nation's air quality needs. Other commenters were concerned that 100 percent compliance to the 0.20 gram NO_X standard in the first year of the program was ill advised as it would provide little opportunity for industry to "field test" new NO_X control technologies. These commenters also expressed concern over workload burdens on industry members needing to redesign all of their new engines and vehicles in one year. Some commenters were concerned that a 25/50/75/100 percent phase-in schedule would introduce competitiveness issues whereby those vehicles equipped with new NO_X control technology may be less attractive to some buyers than vehicles without the technology, making them difficult for manufacturers to sell.

We set standards and implementation schedules based on many factors including technological feasibility, cost, energy, and safety. Considering these factors, we believe that industry should be provided the flexibility of having a phase-in of the new NO_X standard. As discussed in section III.E below, we believe the 0.20 gram NO_X standard is feasible in the 2007 time frame. However, we believe a phase-in is appropriate for a couple of reasons. First, the phase-in will provide industry with the flexibility to roll out the NO_X control technology on only a portion of their fleet. This will allow them to focus their resources on that half of their fleet being brought into compliance in 2007. This ability to focus their efforts will increase both the efficiency and the effectiveness of those efforts. Second, a phase-in allows industry the ability to introduce the new technology on those engines it believes are best suited for a successful implementation which, in turn, provides a valuable opportunity to refine that technology on only a portion of their product line prior to the next push toward full implementation.

Another concern with respect to our proposed phase-in schedule was raised by several commenters and pertains to its interaction with the final implementation schedule for the new supplemental requirements (the Supplemental Emission Test, SET, and the Not-to-Exceed, NTE). These requirements, finalized in the Phase 1 heavy-duty final rule, will be implemented in the 2007 model year on all heavy-duty diesel engines. (See 65 FR 59896, October 6, 2000.) Under a 25/50/75/100 percent phase-in schedule of new diesel engine emission requirements, 25 percent of engines in the 2007 model year would meet 0.20 and 0.01 g/bhp-hr NO_X and PM, while 75 percent would meet 2.5 and 0.01 g/bhp-hr NO_X and PM. Further, all of those engines would be required, beginning in the 2007 model year, to meet the supplemental requirements based on the FTP emission standards to which they were certified. A 25/50/75/100 percent phase-in schedule would change the supplemental requirements for those 25 percent of engines in the 2008 model year that would have to change to meet the new 50 percent compliance requirement. This change would be required even though the supplemental requirements on those 25 percent of engines were first implemented only one model year earlier, in model year 2007. Commenters have questioned whether this is consistent with section 202(a)(3)(c) of the Clean Air Act, which requires that standards for heavy-duty vehicles and engines apply for no less than three model years without revision. Under this argument, the supplemental requirements implemented in the 2007 model year must be allowed three model years of stability, meaning that no changes can be required to those standards until the 2010 model year.

The final phase-in schedule, 50/50/50/100 percent, addresses any concerns about violating the stability requirement of the Act and addresses the technology and lead time benefits of a phase-in as discussed above.[85] While this phase-in does not provide certain commenters with their goal of 100 percent implementation of very low NO_X engines in 2007, we believe it is

[85] EPA need not determine, at this time, whether the 25/50/75/100 percent phase-in schedule violates section 202(a)(3)(c), as the 50/50/50/100 percent phase-in schedule clearly does not and is available to all manufacturers.

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appropriate for the technology, cost, and other reasons described above. This 50/50/50/100 percent phase-in schedule does provide a more rapid implementation of low NO_X engines and, more importantly, provides more air quality benefits in 2007 than would our proposed phase-in schedule. We are also finalizing provisions that would encourage manufacturers to introduce clean technology, both diesel and gasoline, earlier than required in return for greater flexibility during the later years of our phase-in. These optional early incentive provisions are analogous to those included in our light-duty Tier 2 rule and are discussed in more detail in section III.D. We have also revised our Averaging, Banking, and Trading program to increase flexibility as discussed further in section VI.

For gasoline engines, we proposed 100 percent compliance in the 2007 model year. However, since the proposal was published, we have set new standards for heavy-duty gasoline engines that take effect in the 2005 model year. Therefore, the three year stability requirement of the CAA requires that today's new standards not apply until the 2008 model year at the earliest. Further, while we had not proposed a phase-in for gasoline standards, based on comments received we believe that a phase-in should be provided. The phase-in will allow manufacturers to implement improved gasoline control technologies on their heavy-duty gasoline engines in the same timeframe as they implement those technologies on their Tier 2 medium-duty passenger vehicles (MDPV). This consistency with Tier 2 is discussed in more detail below in section III.C.2 on vehicle standards. Note that the gasoline engine phase-in schedule is the same as but separate from the gasoline vehicle phase-in schedule discussed below. As we have done for diesel engines, we have also revised our Averaging, Banking, and Trading program for gasoline engines to increase flexibility as discussed further in section VI.

For a discussion of why we believe these standards are technologically feasible in the time frame required, refer to section III.E below and for a more detailed discussion refer to the RIA contained in the docket. The averaging, banking, and trading (ABT) provisions associated with today's standards are discussed in Section VI of this preamble. The reader should refer to that section for more details.

b. Supplemental Provisions for HD Diesel Engines (SET & NTE)

In addition to the new FTP standards for HD diesel engines contained in today's final action, we are also finalizing the supplemental emission standards we proposed to apply to the new HDDEs, with a number of changes as discussed in this section. The supplemental provisions will help ensure that HD diesel engines achieve the expected in-use emission reductions over a wide range of vehicle operation and a wide range of ambient conditions, not only the test cycle and conditions represented by the traditional FTP. The Agency has historically relied upon the FTP and the prohibition of defeat devices to ensure that HDDE emission control technologies which operate during the laboratory test cycle continue to operate in-use. The supplemental provisions are a valuable addition to the FTP and the defeat device prohibition to ensure effective in-use emission control. The supplemental provisions for HD diesel engines consist of two principal requirements, the supplemental emission test and associated standards (SET),[86] and the not-to-exceed test and associated standards (NTE). The supplemental emission standards finalized today for heavy-duty diesel engines are summarized in Table III.C–2.

TABLE III.C–2.—FULL USEFUL LIFE HEAVY-DUTY DIESEL ENGINE SUPPLEMENTAL EXHAUST EMISSIONS STANDARDS

Supplemental test	Requirements for NO_X, NMHC, PM
Supplemental emission test.	1.0 × FTP standard (or FEL).
Not-to-exceed test	1.5 × FTP standard (or FEL).

The SET and NTE test procedures were recently adopted for 2007 on-highway HD diesel engines. (See 65 FR 59896, October 6, 2000.) In the recent HD Phase 1 rulemaking which promulgated the SET and NTE, the supplemental provisions were finalized in the context of the emission control technology expected to be used to meet the 2004 FTP standards, *i.e.*, injection timing strategies and cooled EGR. In this final action, we are finalizing a number of changes to the supplemental provisions to address specific technical issues raised by commenters and which result from the expected application of high efficiency exhaust emission control devices on HD diesel engines and vehicles to meet today's new standards. These changes are minor in nature and will not impact the emission reductions we expect from the Phase 2 standards. These changes are discussed in the following sections. Additional discussion regarding the supplemental provisions for HDDEs is contained in the RIA and the Response to Comments (RTC) for this final rule, as well as in Section III.E of this preamble ("Feasibility of the New Engine and Vehicle Standards").

i. Supplemental Emission Test

We are finalizing supplemental emission test provisions for HD diesel engines and vehicles certified to the new FTP standards contained in this final rule. The SET emission standard is equal to 1.0 times the FTP standard or FEL for HD diesel engines. Emission results from this test must meet the numerical standards for the FTP. The SET requirements are phased-in beginning with the 2007 model year, consistent with the phase-in of the new FTP standards. The supplemental emission test duty cycle consists of 13 modes of speed and torque, primarily covering the typical highway cruise operating range of heavy-duty diesel engines. The emission results from each of the modes are weighted by defined factors in the regulations, and the final weighted emission value for each pollutant must meet the SET standard. In addition, several of the 13 individual modes are in the NTE control zone, and must meet the applicable NTE requirements. The SET test is a laboratory test performed using an engine dynamometer under the same conditions which apply to the FTP, as specified in the regulations. (See 40 CFR 86.1360.)

The regulations for the SET in model year 2007 as they apply to the 2004 FTP emission standards contain additional steady-state test point emission limits. The Phase 1 supplemental requirements define a "Maximum Allowable Emission Limit" (MAEL) which the engines must comply with. The Phase 1 regulations allowed EPA to randomly select up to three steady-state test points prior to certification which the manufacturer would test to show compliance with the MAEL. These test points are referred to as "mystery points". In this final rule we have eliminated the MAEL for engines certified to the Phase 2 standards. The MAEL assures that an engine is calibrated to maintain emission control similar to the SET test under steady state conditions across the engine map, not just at the pre-defined 13 test points which comprise the SET test. For Phase 1 engines the MAEL was necessary to ensure this potential for gaming did not occur because the difference between the FTP standard and the NTE standard could be large, for example, 0.625 g/bhp-hr for NMHC + NO_X. However, for Phase 2 engines the NTE requirements are a mere 0.10 g/bhp-hr NO_X greater than the FTP standard. Considering this small increment, we have eliminated the MAEL for Phase 2 engines because it is redundant with the NTE. For the same reasons, we have eliminated the certification "mystery points" for engines complying with today's diesel engine standards.

ii. Not-to-Exceed

We are also finalizing revisions to the not-to-exceed emission standards for HD diesel engines certified to the Phase 2 FTP standards contained in this final rule. These NTE procedures apply under engine operating conditions within the range specified in the NTE test procedure that could reasonably be expected to be seen in normal vehicle operation and use. (See 40 CFR 86.1370.) The NTE procedure defines limited and specific engine operating regions (*i.e.*, speed and torque conditions) and ambient operating conditions (*i.e.*, altitude, temperature, and humidity conditions) which are subject to the NTE emission standards. Emission results from this test procedure must be less than or equal to 1.5 times the FTP standards (or FEL) for NO_X, NMHC, and PM. The new NTE requirements are phased-in starting with the 2007 model year, consistent with the new FTP standards.

The Not-To-Exceed (NTE) provisions were recently finalized for HDDEs certified to the 2004 FTP emission standards with implementation beginning in model year 2007. (See 65 FR 59896, October 6, 2000.) The NTE approach establishes an area (the "NTE control area") under the torque curve of an engine where emissions must not exceed a specified value for any of the regulated pollutants.[87] The NTE requirements would apply under engine operating conditions that could reasonably be expected to be seen in normal vehicle operation and use which occur during the conditions specified in the NTE test procedure. (See 40 CFR 86.1370.) This test procedure covers a specific range of engine operation and ambient operating conditions (*i.e.*, temperature, altitude, and humidity). The NTE control area, emissions standards, ambient conditions and test procedures for HDDEs are described in the regulations.

The NTE multiplier promulgated in the previous final rulemaking for HD diesel engines certified to the 2004 FTP standards is 1.25 × FTP standard (*e.g.*, 1.25 × 2.5g/bhp-hr NMHC+NO_X and 1.25 × 0.1 g/bhp-hr PM). We believe the NTE cap finalized today (1.5 × the Phase 2 FTP standards or FEL) allows sufficient headroom above the FTP standard to accommodate the technical challenges necessary to meet the NTE standard which must be met over a broader range of ambient conditions, a shorter time period, and a wider variety of operating conditions, than the FTP or the SET. While the 1.5 NTE multiplier we are finalizing is greater than what we proposed, in absolute terms the NTE requirement for Phase 2 engines is much smaller than for Phase 1 engines (*i.e.*, the magnitude of the cap in g/bhp-hr emissions), and the Phase 2 NTE cap will help ensure the emission reductions we expect from the Phase 2 standards will occur in-use. The NTE requirements have been modified from what we proposed based on our assessment of the emission performance of the exhaust emission control devices that will be used to meet the new FTP standards (*e.g.*, catalyzed particulate traps and NO_X adsorbers). Under the program finalized today, an NTE limit of 1.5 × the NO_X FEL would apply to 2007 and later model year engines certified with FELs less than 1.5 g/bhp-hr NO_X. As discussed throughout this notice, the stringent 2007 PM standard, 0.01 g/bhp-hr, can be met with the use of catalyzed particulate traps. Because of the very low particulate matter emissions which will be emitted by engines meeting the PM standard, this final rule also establishes a minimum PM NTE requirement for engines certified with FELs below 0.01 g/bhp-hr at 1.5 × the FTP standard, not the FEL. Based on our assessment of the expected exhaust emission control devices and their performance, the NTE standard of 1.5 × FTP standard is both technologically feasible and appropriate. A detailed discussion of the feasibility of the NTE requirements is contained in the RIA for this final rule.

Today's action allows the NTE deficiency provisions we recently finalized for 2007 HDDEs meeting the 2004 FTP standards to be used by HDDEs meeting the standards contained in today's final rule (See 40 CFR 86.007–11(a)(4)(iv) in the regulations, and 65 FR 59914 of the Phase 1 rule for a detailed discussion of the NTE deficiencies.). These deficiency provisions are similar to the deficiency provisions which currently apply to LD and HD on-board diagnostic systems. This will allow the Administrator to accept a HDDE as compliant with the NTE even though some specific requirements are not fully met. This provision will be available for manufacturers through 2013, though it will be more limited after 2009 as described below. In the Phase 1 rule, the Agency finalized deficiency provisions which were allowed through model year 2009. In this rule, it is appropriate to extend the availability of the NTE deficiency provisions beyond 2009. Given the nature of the phase-in requirements in this rule, manufacturers may be introducing new engine families certified to the Phase 2 NO_X and NMHC standards as late as model year 2010, and these families may need limited access to a NTE deficiency for a few years after their introduction. Therefore, we have extended the availability of deficiencies through model year 2013, but with one constraint. Given the considerable lead time available, we have limited the number of deficiencies to three per engine family for 2010 through 2013.

In addition, we have made a number of changes to the NTE requirements to address specific technical issues which arise from the application of high efficiency exhaust emission control devices to HDDEs. These provisions will only be summarized here. A detailed discussion is contained in the RIA and the RTC for this final rule. These changes include: engine start-up provisions; exhaust emission control device warm-up provisions; modifications of the NTE control zone; and adjustments to the NTE minimum emissions sample time.

Under this final rule, the NTE requirements will not apply during engine start-up conditions. EPA intended to include the provision excluding start-up provisions from the NTE requirements under the Phase 1 rulemaking, and it was discussed in the preamble for both the Phase 1 proposal and final rule. However, this provision was inadvertently left out of the regulations. We have corrected this in today's rule for both Phase 1 and Phase 2 engines. In addition, with the application of advanced exhaust emission control devices, an exhaust emission control device warm-up provision is a necessary criterion for the NTE. Specifically, until the exhaust gas temperature on the outlet side of the exhaust emission control device(s)

[86] In the Phase 1 rulemaking, the Supplemental Emission Test was referred to as the supplemental steady state test. As discussed in the Phase 1 rule, the supplemental steady state test is based on and is consistent with the European Commissions "EURO III ESC" test. (See 65 FR 59915.) In this final rule we have renamed the supplemental steady state test the Supplemental Emission Test (SET).

[87] Torque is a measure of rotational force. The torque curve for an engine is determined by an engine "mapping" procedure specified in the Code of Federal Regulations. The intent of the mapping procedure is to determine the maximum available torque at all engine speeds. The torque curve is merely a graphical representation of the maximum torque across all engine speeds.

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achieves 250 degrees Celsius, the engine is not subject to the NTE. Additional discussion of this provision is contained in the RIA.

We have made three changes to the NTE engine control zone. First, we have expanded the NTE engine control zone for engines certified to the new 0.01 g/bhp-hr PM standard. The NTE requirements as specified in the regulations for engines certified to the 2004 FTP standards provide specific "PM carve-outs" to the NTE control zone. These carve-outs define an area of the engine operating regime (speed and torque area) to which the NTE does not apply for PM emissions. (See 65 FR 59961.) The PM only carve-outs were specified because, under certain engine operating regions, the NTE requirements for PM could not be met with the technology projected to be used to meet the 2004 FTP standards. However, as discussed in the RIA, the advanced PM trap technology that will be used to meet the PM standard contained in today's final rule is very efficient at controlling PM emissions across the entire NTE control zone. Due to the high PM reduction capabilities of catalyzed PM traps, there is no need for the PM specific carve-outs. Therefore, we have eliminated the NTE PM carve-outs for Phase 2 engines. Second, we have added a provision which would allow a manufacturer to exclude defined regions of the NTE engine control zone from NTE compliance if the manufacturer could demonstrate that the engine, when installed in a specified vehicle(s), is not capable of operating in such regions. Finally, we have added a provision which would allow a manufacturer to petition the Agency to limit testing in a defined region of the NTE engine control zone during NTE testing. This optional provision would require the manufacturer to provide the Agency with in-use operation data which the manufacturer could use to define a single, continuous region of the NTE control zone. This single area of the control zone must be specified such that operation within the defined region accounts for 5 percent or less of the total in-use operation of the engine, based on the supplied data. Further, to protect against gaming by manufacturers, the defined region must generally be elliptical or rectangular in shape, and share a boundary with the NTE control zone. If approved by EPA, the regulations then disallow testing with sampling periods in which operation within the defined region constitutes more than 5.0 percent of the time-weighted operation within the sampling period.

We have also changed the minimum emissions sample time approach for NTE testing to address technical issues specific to the advanced exhaust emission control devices anticipated to be used to meet the NTE requirements. We proposed that the minimum emission sample time for the NTE was 30 seconds, which is what we recently finalized for engines certified to the Phase 1 standards. This short sample time was sufficient to ensure that momentary spikes in emissions (*e.g.*, such as could occur in a two or three second time frame) could not be isolated for determining compliance with the NTE (*e.g.*, an NTE test must be no shorter than a 30 second average). However, the use of highly efficient exhaust emission control devices complicates the minimum sample time requirements because of the potential for short-duration emission increases during regeneration events. We have adjusted the minimum sample time requirements to address this issue as follows (a detailed discussion of the need for this change is contained in the RIA). The regulations specify that the NTE sample time can be as short as 30 seconds provided no regeneration events occur within the sample period. However, if a regeneration event is included in the sample time, the sample time must include the period of time from the start of one regeneration event to the start of the next regeneration event, for each regeneration included in the sample. A regeneration event is determined by the engine manufacturer. This second provision regarding the minimum NTE sample time also cannot be shorter than 30 seconds. This sample time provision applies to any HDDE engine equipped with an exhaust emission control device which requires discreet regeneration events, regardless of the nature of the regeneration (*e.g.*, NO_X regeneration, desulfation).

c. Crankcase Emissions Control

Crankcase emissions are the pollutants that are emitted in the gases that are vented from an engine's crankcase. These gases are also referred to as "blowby gases" because they result from engine exhaust from the combustion chamber "blowing by" the piston rings into the crankcase. These gases are vented to prevent high pressures from occurring in the crankcase. Our emission standards have historically prohibited crankcase emissions from all highway engines except turbocharged heavy-duty diesel engines. The most common way to eliminate crankcase emissions has been to vent the blowby gases into the engine air intake system, so that the gases can be recombusted. We made the exception for turbocharged heavy-duty diesel engines in the past because of concerns about fouling that could occur by routing the diesel particulates (including engine oil) into the turbocharger and aftercooler. Our concerns are now alleviated by newly developed closed crankcase filtration systems, specifically designed for turbocharged heavy-duty diesel engines. These new systems (discussed more fully in Section III.E below and in Chapter III of the Final RIA) are already required for new on-highway diesel engines under the EURO III emission standards.

In today's action, we are eliminating the exception for turbocharged heavy-duty diesel engines starting in the 2007 model year. Manufacturers will be required to control crankcase emissions from these engines, preferably by routing them back to the engine intake or to the exhaust stream upstream of the exhaust emission control devices. However, in response to the manufacturers' comments, we are finalizing the crankcase control requirement to allow manufacturers to treat crankcase emissions from these engines the same as other exhaust emissions (*i.e.*, we provide a performance requirement and leave the design to the manufacturer). Under this allowance, manufacturers could potentially discharge some or all of the crankcase emissions to the atmosphere, but only if they were able to keep the combined total of the crankcase emissions and the other exhaust emissions below the applicable exhaust emission standards. They could do this by routing the crankcase gases into the exhaust stream downstream of the exhaust emission control devices, or by continuing the current practice of venting the gases to the engine compartment. But, they could take either of these approaches only if they make sure that the combined total of the crankcase emissions and the other exhaust emissions are below the applicable exhaust emission standards. Also, the manufacturer would have to ensure that the crankcase emissions were readily measurable during laboratory and in-use field testing.[88] Despite this allowance made at the request of commenters, given the low levels of today's final standards we believe that manufacturers will have to close the crankcases of all of their

[88] During laboratory testing, the crankcase emissions would need to be vented in a controlled manner so that they could be routed into the dilution tunnel to ensure their proper measurement and inclusion in the tested emission level.

engines by either routing the crankcase emissions into the engine intake or by routing them into the exhaust upstream of the exhaust emission control devices.

d. On-Board Diagnostics (OBD)

The Phase 1 heavy-duty final rule put into place OBD requirements for heavy-duty diesel and gasoline engines weighing 14,000 pounds or less. (See 65 FR 59896, October 6, 2000.) In that rule, the OBD thresholds for malfunction identification are based on multiples of the applicable FTP emission standards to which the engine is certified. Given the structure of the 2004 FTP emission standards (2005 FTP emission standards for gasoline engines), which are combined $NMHC+NO_X$ standards, the OBD thresholds are based on a multiple of the combined FTP standards. However, the structure of the 2007 FTP standards (2008 for gasoline engines) finalized today is not a combined $NMHC+NO_X$ standard, but is instead a separate NO_X and a separate NMHC standard.

Therefore, today's final rule is revising the existing section of the regulations to link OBD thresholds to whatever the appropriate standards are whether they are the combined FTP standards or the new separate FTP standards finalized today. This is consistent with the intent of our OBD requirements since inception—that the OBD thresholds be based on the FTP standards to which the vehicle or engine has been certified.

We are also revising the phase-in for the OBD requirements finalized in the Phase 1 rule. (See 65 FR 59896.) In that rule, OBD systems were required to phase-in on a schedule of 60/80/100 percent beginning in the 2005 model year. At least one commenter claimed that the OBD phase-in may require multiple changes to OBD systems in consecutive years, because OBD systems are tied to the FTP standards to which they are certified.[89] We have decided, for diesel engine OBD systems, to revise the 60/80/100 percent phase-in to 50/50/100 percent beginning in the 2005 model year. This revised phase-in not only alleviates the commenter's concerns, but also makes the OBD phase-in consistent with the implementation of new emission standards.

In addition, we have decided, for gasoline engine OBD systems, to revise the 60/80/100 percent phase-in to 60/80/80/100 percent beginning in the 2005 model year.[90] As with the new diesel OBD phase-in, this gasoline engine OBD phase-in alleviates the commenter's concerns, and it also makes the gasoline OBD phase-in more consistent with the implementation of new emission standards while maximizing the percentage of gasoline engines designed to meet the OBD requirements.

We also received comments suggesting that we commit to making any necessary changes to the OBD requirements based on the outcome of future rulemaking efforts by the California Air Resources Board (ARB). While we cannot make any such commitment, nor do we believe the commenter truly would want us to commit to making changes solely because ARB made changes, we do intend to continue our normal practice of working closely with ARB and harmonizing our OBD requirements where appropriate. Of course, any changes to our OBD requirements could only be done via rulemaking.[91]

2. Heavy-Duty Vehicle Exhaust Emissions Standards[92]

a. FTP Standards

The emission standards being finalized today for heavy-duty gasoline vehicles are summarized in Table III.C–3. We have already required that all complete heavy-duty gasoline vehicles, whether for transporting passengers or for work, be chassis certified. (See 65 FR 59896, October 6, 2000.) Current federal regulations do not require that complete diesel vehicles over 8,500 pounds be chassis certified; instead, our regulations have traditionally required certification of their engines. Today's final rule allows, as an option, chassis certification of complete heavy-duty diesel vehicles under 14,000 pounds. This option is discussed in more detail later in this section.

The Tier 2 final rule created a new vehicle category called "medium-duty passenger vehicles."[93] These vehicles, both gasoline and diesel, are required to meet requirements of the Tier 2 program, which carries with it a chassis certification requirement. As a result, diesel medium-duty passenger vehicles must certify using the chassis certification test procedure.[94] Today's heavy-duty vehicle based standards, or chassis standards, for 2008 and later model year heavy-duty gasoline vehicles would apply to the remaining complete gasoline vehicles under 14,000 pounds and those complete diesel vehicles under 14,000 pounds choosing the chassis certification option; these complete vehicles are typically used for commercial, non-passenger applications. The standards shown in Table III.C–3 are, we believe, comparable in stringency to the diesel and gasoline engine standards shown in Table III.C–1.

[89] EPA does not believe there would be any legal stability concern even if we had kept the OBD phase-in as finalized in the Phase 1 rule. However, EPA agrees with the commenter that the phase-in as finalized in the Phase 1 rule would have complicated compliance unnecessarily.

[90] For those manufacturers choosing compliance Options 1 or 2 as part of the Phase 1 program, the gasoline engine OBD phase-in will become 40/60/80/80/100 percent beginning in model year 2004. (See 65 FR 59896, October 6, 2000.)

[91] This comment also pertained to gasoline vehicle-based OBD systems. Our statements made here pertain to those requirements as well but are not repeated below in section III.2.c.

[92] As noted above, vehicle and engine standards apply to all vehicles and engines, even if they are alternative fueled vehicles and engines.

[93] Medium-duty passenger vehicles are defined as any complete vehicle between 8,500 and 10,000 pounds GVWR designed primarily for the transportation of persons. The definition specifically excludes any vehicle that (1) has a capacity of more than 12 persons total or, (2) is designed to accommodate more than 9 persons in seating rearward of the driver's seat or, (3) has a cargo box (*e.g.*, pick-up box or bed) of six feet or more in interior length. (See the Tier 2 final rulemaking, 65 FR 6698, February 10, 2000.)

[94] The Tier 2 final rule did make a limited allowance for engine certification of diesel MDPVS through the 2007 model year. The reader should refer to the Tier 2 final rule for details on that allowance. (See 65 FR 6750, February 10, 2000.)

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TABLE III.C–3.—FULL USEFUL LIFE HEAVY-DUTY VEHICLE EXHAUST EMISSIONS STANDARDS AND PHASE-INS FOR COMPLETE VEHICLES[a]

[Grams/mile]

Weight range (GVWR)		Standard (g/mi)	Phase-in by model year[b]	
			2008	2009
8,500 to 10,000 lbs	NO_X	0.2		
	NMHC	0.195		
	HCHO	0.032		
	PM	0.02		
10,001 to 14,000 lbs	NO_X	0.4	50%	100%
	NMHC	0.230		
	HCHO	0.040		
	PM	0.02		

[a] Does not include medium-duty passenger vehicles.
[b] Percentages represent percent of sales.

These NO_X standards represent a 78 percent reduction and a 60 percent reduction from the standards for 8,500–10,000 pound and 10,000–14,000 pound vehicles, respectively, finalized for the 2005 model year. The 2005 model year standards are equivalent to the California LEV–I NO_X standards of 0.9 g/mi and 1.0 g/mi, respectively. The NO_X standards shown in Table III.C–3 are consistent with the CARB LEV–II NO_X standards for low emission vehicles (LEVs) in each respective weight range. The NO_X standard is slightly higher for the 10,000 to 14,000 pound vehicles for several reasons: these vehicles are tested at a heavier payload; they generally have a larger frontal area which creates more drag on the engine and requires it to work harder; and their in-use duty cycle tends to be more severe. The increased weight results in using more fuel per mile than vehicles tested at lighter payloads; therefore, they tend to emit slightly more grams of pollutant per mile than lighter vehicles.[95]

The NMHC standards finalized today represent a 30 percent reduction from the 2005 standards for 8500–10,000 and 10,000–14,000 pound vehicles. The 2005 model year standards require such vehicles to meet NMHC standard levels of 0.28 g/mi and 0.33 g/mi, respectively (equal to the California LEV–I nonmethane organic gases (NMOG) standard levels). These new NMHC standards are consistent with the CARB LEV–II NMOG standards for LEVs in each respective weight class. The NMHC standard for 10,000–14,000 pound vehicles is higher than for 8,500–10,000 pound vehicles for the same reason as stated above for the higher NO_X standard for such vehicles.

The formaldehyde (HCHO) standards shown in Table III.C–3 are not the standards we proposed. The standards we are finalizing are equivalent to the California LEV–II LEV category standards. This approach is being taken to maintain consistency with the approach taken on NO_X and NMHC standards. Although we are not finalizing formaldehyde standards for engine certified systems, because all the exhaust emission standards for complete vehicles are consistent with the CARB LEV II standards, we believe it is appropriate to maintain the formaldehyde standard for gasoline vehicles. Formaldehyde is a hazardous air pollutant that is emitted by heavy-duty vehicles and other mobile sources, and we are finalizing these formaldehyde standards to prevent excessive formaldehyde emissions. These standards are especially important for any methanol-fueled vehicles because formaldehyde is chemically similar to methanol and is one of the primary byproducts of incomplete combustion of methanol. Formaldehyde is also emitted by vehicles using petroleum fuels (i.e., gasoline or diesel fuel), but to a lesser degree than is typically emitted by methanol-fueled vehicles. We expect that petroleum-fueled vehicles able to meet the NMHC standards should comply with the formaldehyde standards with large compliance margins. Based upon our analysis of the similar Tier 2 standards for passenger vehicles, we believe that formaldehyde emissions from petroleum-fueled vehicles when complying with the new PM, NMHC and NO_X standards should be as much as 90 percent below the standards.[96] Thus, to reduce testing costs, we are finalizing a provision that permits manufacturers of petroleum-fueled vehicles to demonstrate compliance with the formaldehyde standards based on engineering analysis. This provision requires manufacturers to make a demonstration in their certification application that vehicles having similar size and emission control technology have been shown to exhibit compliance with the applicable formaldehyde standard for their full useful life. This demonstration is expected to be similar to that required to demonstrate compliance with the Tier 2 formaldehyde standards.

The PM standard is 80 percent lower than the CARB LEV–II LEV category PM standard of 0.12 g/mi, which actually applies only to diesel vehicles. Note that the PM standard shown in Table III.C–3 represents not only a stringent PM level, but a new standard for federal HDVs where none existed before. Both the California LEV II program for heavy-duty diesel vehicles and the federal Tier 2 standards for over 8,500 pound gasoline and diesel vehicles designed for transporting passengers contain PM standards. The PM standard finalized today is consistent with the light-duty Tier 2 bins 7 and 8 level of 0.02 g/mi.

The timing for our final gasoline vehicle standards differs from what we had proposed. Our proposal had no phase-in, requiring 100 percent compliance in the 2007 model year. However, since the proposal was published, we have set new standards for heavy-duty gasoline complete vehicles that take effect in the 2005 model year. Therefore, the three year stability requirement of the CAA requires that today's new standards not apply until the 2008 model year at the earliest. Further, based on comments

[95] Engine standards, in contrast, are stated in terms of grams per unit of work rather than grams per mile. Therefore, engine emission standards need not increase with weight because heavier engines do not necessarily emit more per unit of work produced. In contrast, heavier vehicles, due to their greater mass, tend to emit more per mile due to the increased load placed on the engine which requires the engine to do more work to travel each mile.

[96] See the Tier 2 Response to Comments document contained in Air Docket A–97–10.

received, we believe that a phase-in should be provided. The phase-in will allow manufacturers to implement improved gasoline control technologies on their heavy-duty gasoline vehicles in the same timeframe as they implement those technologies on their Tier 2 medium-duty passenger vehicles (MDPV). The MDPVs generally use the same engines and emission control systems as do the heavy-duty versions of those vehicles. MDPVs must comply with our light-duty Tier 2 program at 50 percent beginning in the 2008 model year and then 100 percent in the 2009 model year. As a result of this MDPV phase-in, and the stability requirements of the CAA, and because we believe it provides the greatest emission control considering costs, we are finalizing a gasoline phase-in of 50/100 percent beginning in the 2008 model year. Commenters suggested a 40/80/100 percent phase-in beginning in the 2008 model year, but we believe that a 50/100 percent phase-in allows appropriate leadtime and synergy with the MDPV requirements of our Tier 2 program. It is worth clarifying that this phase-in excludes California complete heavy-duty vehicles, which are already required to be certified to the California emission standards. It also excludes vehicles sold in any state that has adopted California emission standards for complete heavy-duty vehicles. It would be inappropriate to allow manufacturers to "double-count" the vehicles by allowing them to count those vehicles both as part of their compliance with this phase-in and for compliance with California requirements. We would handle heavy-duty engines similarly if California were to adopt different emission standards than those being established by this rule.

We are also finalizing provisions that would encourage manufacturers to introduce clean technology earlier than required in return for greater flexibility during the later years of our phase-in. These optional early incentive provisions are analogous to those included in our light-duty Tier 2 rule and are discussed in more detail in section III.D.

As we have done for diesel and gasoline engines, we have revised our Averaging, Banking, and Trading program for gasoline vehicles and engines to increase flexibility as discussed further in section VI. The reader should refer to that section for more details. Note that the gasoline vehicle phase-in schedule is the same as but separate from the gasoline engine phase-in schedule discussed above. For a discussion of why we believe these standards are technologically feasible in the time frame required, refer to section III.E below, and for a more detailed discussion refer to the RIA contained in the docket.

We are also allowing complete heavy-duty diesel vehicles under 14,000 pounds to certify to the heavy-duty vehicle standards. The issue of chassis certification of diesels was raised as part of the Phase 1 rule. At that time, manufacturers expressed little interest in such a provision. Because the heavy-duty diesel industry is largely not a vertically-integrated industry, in that one company makes the engine and another makes the vehicle, chassis certification is not an immediately attractive or practical option for diesel engine manufacturers. Nonetheless, some manufacturers have begun to express interest in diesel chassis certification.[97] Also, the California Air Resources Board allows complete diesel vehicles to chassis certify. We like the idea of diesel chassis certification because it allows us to more easily evaluate such vehicles in-use. A chassis certified diesel could be acquired easily by EPA and tested in its vehicle configuration without the need to remove the engine for an engine test.

Therefore, while we fully expect that manufacturers will continue to certify the engines intended for complete diesel vehicles to the engine standards, we will allow the option to chassis certify such vehicles. Any chassis-certified complete diesel vehicles must meet the applicable Phase 2 emission standards for complete vehicles (i.e., this option is not available to diesels certified to the Phase 1 standards). In addition, while complete diesel vehicles would count against the phase-in requirements for diesel engines, they would not be allowed in the Averaging, Banking, and Trading program. Therefore, a chassis-certified diesel vehicle can neither use nor earn ABT credits, but counts as part of the 50 percent phase-in. Further, complete diesels choosing the chassis certification option would be required to comply with our federal OBD vehicle-based requirements for monitoring of exhaust emission control devices, even if choosing the option to demonstrate OBD compliance using the California OBD II requirements. Lastly, diesel vehicles choosing this option would be certified under subpart S which applies to chassis certified complete vehicles, but the evaporative emissions provisions of that subpart would not apply for diesel vehicles.

[97] See memorandum from Todd Sherwood to Air Docket A–99–06, dated December 6, 2000, Item #IV–E–47.

b. Supplemental Federal Test Procedure

We did not propose new supplemental FTP (SFTP) standards for heavy-duty vehicles. The SFTP standards control off-cycle emissions in a manner somewhat analogous to the NTE requirements for engines. We believe that the SFTP standards are an important part of our light-duty program just as we believe the NTE requirements will be an important part of our heavy-duty diesel engine program. Although we did not propose SFTP standards for heavy-duty vehicles, we stated an intention to do so via a separate rulemaking. We requested comment on such an approach, and on appropriate SFTP levels for heavy-duty vehicles along with supporting data.

We received unanimous support from industry commenters to address SFTP standards for heavy-duty vehicles in a separate rulemaking. In our Tier 2 final rule, we stated that we are currently contemplating a new SFTP rulemaking that would consider "Tier 2" SFTP standards for all Tier 2 vehicles, including MDPVs. California is also interested in developing more stringent SFTP standards within the context of their LEV II program and we are coordinating with California on these new SFTP standards. Given our concern over "off cycle" emissions, we believe it is appropriate that SFTP standards apply to all chassis certified vehicles, heavy-duty and light-duty. As part of the SFTP rule being contemplated, we expect to examine not only those issues stated in the Tier 2 rule (e.g., the SFTP test cycles and different SFTP standards for different vehicles sizes) but also the issue of heavy-duty SFTP standards.

c. On-Board Diagnostics (OBD)

The Phase 1 heavy-duty rule finalized OBD requirements for heavy-duty diesel engines, heavy-duty gasoline engines, and heavy-duty complete vehicles weighing 14,000 pounds or less. (See 65 FR 59896, October 6, 2000.) In that rulemaking, the final regulatory language stated the OBD catalyst thresholds for complete vehicles as multiples of a combined NMHC+NO_X emission standard. However, the emission standards for complete vehicles are not combined, as are the engine standards in that final rule. Therefore, the OBD catalyst thresholds for complete vehicles were not stated properly in the applicable sections of the regulations.

Today's final rule corrects that regulatory error by revising the appropriate regulatory language to link the OBD thresholds to a separate, rather than combined, set of FTP exhaust

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emission standards. This is consistent with the Phase 1 heavy-duty proposal which correctly linked the proposed OBD thresholds to the separate FTP exhaust emission standards. (See 64 FR 58472, October 29, 1999.) It is also consistent with the preamble to the Phase 1 final rule, which stated the catalyst monitor threshold correctly. This change makes the OBD thresholds for complete vehicle certifications consistent with the structure used since implementation of the federal OBD requirements. (See 58 FR 9468, February 19, 1993.)

Consistent with the changes already discussed in section III.C.1, we are also revising the phase-in for complete vehicle OBD requirements finalized in the Phase 1 rule. (See 65 FR 59896.) In that rule, OBD systems were required to phase-in on a schedule of 60/80/100 percent beginning in the 2005 model year. At least one commenter pointed out that the OBD phase-in may require multiple changes to OBD systems in consecutive years because OBD systems are tied to the FTP standards to which they are certified. We have decided, for gasoline vehicle OBD systems, to revise the 60/80/100 percent phase-in to 60/80/80/100 percent beginning in the 2005 model year.[98] This revised OBD phase-in alleviates the commenter's concerns, and it makes the gasoline OBD phase-in more consistent with the implementation of new emission standards while maximizing the percentage of gasoline vehicles designed to meet the OBD requirements.

3. Heavy-Duty Evaporative Emissions Standards

We are finalizing new evaporative emission standards for heavy-duty vehicles and engines. The new standards are shown in Table III.C–4. These standards will apply to heavy-duty gasoline-fueled vehicles and engines, and methanol-fueled heavy-duty vehicles and engines. Consistent with existing standards, the standard for the two day diurnal plus hot soak test sequence would not apply to liquid petroleum gas (LPG) fueled and natural gas fueled HDVs.

[98] For those manufacturers choosing compliance Options 1 or 2 as part of the Phase 1 program, the gasoline vehicle OBD phase-in will become 40/60/80/80/100 percent beginning in model year 2004. (See 65 FR 59896.)

TABLE III.C–4.—NEW HEAVY-DUTY EVAPORATIVE EMISSIONS STANDARDS[a]

[Grams per test]

Category	3 day diurnal + hot soak	Supplemental 2 day diurnal + hot soak[b]
8,500–14,000 lbs	1.4	1.75
>14,000 lbs	1.9	2.3

[a] To be implemented on the same schedule as the gasoline engine and vehicle exhaust emission standards shown in Tables III.C–1 and III.C–3. These new standards do not apply to medium-duty passenger vehicles, and do not apply to diesel fueled vehicles and engines.

[b] Does not apply to LPG or natural gas fueled HDVs.

These new standards represent more than a 50 percent reduction in the numerical standards as they exist today. The Phase 1 heavy-duty rule made no changes to the numerical value of the standard, but it did put into place new evaporative emission test procedures for heavy-duty complete gasoline vehicles.[99] (See 65 FR 59896, October 6, 2000.) For establishing evaporative emission levels from complete heavy-duty vehicles, the standards shown in Table III.C–4 presume the test procedures required in the Phase 1 heavy-duty rule.

The new standards for 8,500 to 14,000 pound vehicles are consistent with the Tier 2 standards for medium-duty passenger vehicles (MDPV). MDPVs are of consistent size and have essentially identical evaporative emission control systems as the remaining work-oriented HDVs in the 8,500 to 10,000 pound weight range. Therefore, the evaporative emission standards should be equivalent. We are requiring those same standards for the 10,000 to 14,000 pound HDVs because, historically, the evaporative emission standards have been consistent throughout the 8,500 to 14,000 pound weight range. We believe that the HDVs in the 10,000 to 14,000 pound range are essentially equivalent in evaporative emission control system design as the lighter HDVs; therefore, continuing this historical approach is appropriate.

We are finalizing slightly higher evaporative emission standards for the over 14,000 pound HDVs because of their slightly larger fuel tanks and for non-fuel emissions related to larger vehicle sizes. This is consistent with past evaporative emission standards. The levels chosen for the over 14,000 pound HDVs maintains the same ratio relative to the 8,500 to 14,000 pound HDVs as exists with current evaporative standards. To clarify, the current standards for the 3 day diurnal test are 3 and 4 grams/test for the 8,500 to 14,000 and the over 14,000 pound categories, respectively. The ratio of 3:4 is maintained for the new 2008 standards, 1.4:1.9.

The new standard levels are slightly higher than the California LEV-II standard levels. The California standard levels are 1.0 and 1.25 for the 3-day and the 2-day tests, respectively. However, federal vehicles are certified using the higher-volatility federal test fuel.[100] Arguably, the federal and California evaporative emission standards are equivalent in stringency despite the difference in standard levels. We believe that our standards are appropriate for federal heavy-duty vehicles.

We are requiring that the new evaporative emission standards be implemented on the same schedule as the gasoline engine and vehicle exhaust standards shown in Tables III.C–1 and III.C–3. This will allow manufacturers to plan any needed changes to new vehicles at the same time, although it is not necessary that the exhaust and evaporative standards be phased-in on the same vehicles and engines. Also, we are finalizing the revised durability provisions finalized in the Tier 2 rulemaking, which require durability demonstration using fuel containing at least 10 percent alcohol. Alcohol can break down the materials used in evaporative emission control systems. Therefore, a worst case durability demonstration would include a worst case alcohol level in the fuel (10 percent) because in some areas of the country there is widespread use of alcohol fuels.

D. Incentives for Early Introduction of Clean Engines and Vehicles

In our proposal, we requested comment on alternative phase-in approaches that could provide attractive implementation options to

[99] The test procedure changes codify a commonly approved waiver allowing heavy-duty gasoline vehicles to use the light-duty driving cycle for demonstrating evaporative emission compliance. The urban dynamometer driving schedule (UDDS) used for heavy-duty vehicles is somewhat shorter than that used for light-duty vehicles, both in terms of mileage covered and minutes driven. This results in considerably less time for canister purge under the heavy-duty procedure than under the light-duty procedure. We recognize this discrepancy and have routinely provided waivers under the enhanced evaporative program that allow the use of the light-duty procedures for heavy-duty certification testing. This is consistent with CARB's treatment of equivalent vehicles.

[100] The federal test fuel specification for fuel volatility, the Reid Vapor Pressure, is 8.7 to 9.2 psi. The California test fuel specification is 6.7 to 7.0 psi.

manufacturers without compromising air quality. We requested comment on a "declining standard" approach and a "cumulative phase-in" approach. We received only limited comment on those approaches with no commenters expressing particularly strong support for them. We did receive numerous comments suggesting that we provide some form of incentive for manufacturers to introduce clean technology engines earlier than required by the base program. We are finalizing the approach discussed here as an incentive for manufacturers to introduce clean diesel engines earlier than the 2007 model year (or the 2008 model year for gasoline engines and vehicles).

In our Tier 2 rule, we stated our belief that providing inducements to manufacturers to certify vehicles early to very low levels is appropriate. We believe that such inducements may help pave the way for greater and/or more cost effective emission reductions from future vehicles. We believe the program discussed here provides a strong incentive for manufacturers to maximize their development and introduction of the best available vehicle and engine emission control technology. This, in turn, provides a stepping stone to the broader introduction of this technology soon thereafter. Early production of cleaner vehicles enhances the early benefits of our program. If a manufacturer can be induced to certify to the new standards by the promise of reasonable extra credits, the benefits of that decision to the program may last for many years.

The incentive program finalized today is analogous to the provisions set forth in the final Tier 2 rule. We are finalizing provisions that permit manufacturers to take credit for diesel engines certified to this rule's final standards prior to the 2007 model year (prior to the 2008 model year for gasoline engines or vehicles) in exchange for making fewer diesel engines certified to these standards in or after the 2007 model year (2008 for gasoline engines or vehicles). In other words, a clean engine sold earlier than required displaces the requirement to sell a similar engine later. Note that the emission standards must be met to earn the early introduction credit. That is, emission credits earned under averaging, banking, and trading cannot be used to demonstrate compliance. Therefore, the early introduction engine credit is an alternative to the ABT program in that any early engines or vehicles can earn either the engine credit or the ABT emission credit, but not both. The purpose of the incentive is to encourage introduction of clean technology engines earlier than required in exchange for added flexibility during the phase-in years.

Any early engine credits earned for a diesel-fueled engine would, of course, be predicated on the assurance by the manufacturer that the engine would indeed be fueled with low sulfur diesel fuel in the marketplace. We expect this would occur through selling such engines into fleet applications, such as city buses, school buses, or any such well-managed centrally-fueled fleet. For this reason, we believe that any engines sold within this early incentive program would be sold primarily in urban areas where more centrally-fueled fleets exist. Because of the difficulty associated with low sulfur diesel fuel availability prior to mid-2006, we believe it is necessary and appropriate to provide a greater incentive for early introduction of clean diesel technology. Therefore, we will count one early diesel engine as 1.5 diesel engines later. This extra early credit for diesel engines means that fewer clean diesel engines than otherwise would be required may enter the market during the years 2007 and later. But, more importantly, it means that emission reductions would be realized earlier than under our base program. We believe that providing incentives for early emission reductions is a worthwhile goal for this program. Therefore, we are finalizing these provisions for manufacturers willing to make the early investment in cleaner engines. For gasoline engines and vehicles, the early engine credit will be a one-for-one credit because the gasoline needed by the engine or vehicle will be readily available.

We are providing this early introduction credit to diesel engines that meet all of today's final standards (0.20 g/bhp-hr NO_X, 0.14 g/bhp-hr NMHC, and 0.01 g/bhp-hr PM). We are also providing this early introduction credit to diesel engines that pull-ahead compliance with only the 0.01 g/bhp-hr PM standard. However, a PM-only early engine can offset only PM compliant engines during the phase-in years, not NO_X, NMHC, and PM compliant engines.

An important aspect of the early incentive provision is that it must be done on an engine or vehicle count basis. That is, a diesel engine meeting new standards early counts as 1.5 such diesel engines later and a gasoline engine or vehicle early counts as one gasoline engine or vehicle later. This contrasts with a provision done on an engine percentage basis which would count one percent of diesel engines early as 1.5 percent of diesel engines later. Basing the incentive on an engine count will alleviate any possible influence of fluctuations in engine and vehicle sales in different model years.

Another important aspect of this program is that it is limited to engines sold prior to the 2007 model year (2008 for gasoline). In other words, diesel engines sold in the 2007 through 2009 model years that exceed the required 50 percent phase-in will not be considered "early" introduction engines and will, therefore, receive no early introduction credit. The same is true for gasoline engines and vehicles sold in the 2008 model year. However, such engines and vehicles will still be able to generate ABT credits. Note that early gasoline vehicles can count for later gasoline vehicles, and early gasoline engines can count for later gasoline engines, but early gasoline vehicles cannot be traded for later gasoline engines and vice versa.

Table III.D–1 shows an example for a diesel engine manufacturer and how it might use this incentive provision on an assumed fleet of 100 engine sales growing at one percent per year beginning in the 2004 model year.

TABLE III.D–1.—EXAMPLE ENGINE INTRODUCTION UNDER OUR EARLY INCENTIVE PROGRAM

	2004	2005	2006	2007	2008	2009	2010
Total Sales	100	101	102	103	104	105	106
Clean Engines under Base program	0	0	0	52	52	53	106
Clean Engines under Incentive Program	4	4	4	46	46	47	106

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The four engines sold early in each of model years 2004 through 2006 generate a total credit of 18 engines (4×3×1.5=18). This allows the manufacturer to reduce its compliant engine count in each of model years 2007 through 2009 by six engines (18/3=6). This helps the manufacturer by reducing total costs through requiring fewer total engines at the low-emitting, clean engine level. But, more importantly, it introduces clean technology engines early and, by 2010 in this example, generates from four to six years of emission reductions that otherwise would not have occurred.

As further incentive to introduce clean engines and vehicles early, we are also finalizing a provision that would give manufacturers an early introduction credit equal to two engines during the phase-in years. This "Blue Sky" incentive would apply for diesel engines meeting one-half of today's final NO_X standard while also meeting the NMHC and PM standards. For gasoline engines, the same early introduction double engine credit would be available to engines sold prior to 2008 and meeting one-half the NO_X standard while also meeting the NMHC, PM, and evaporative emission standards. For gasoline vehicles, the double engine credit would be available to those vehicles certified early to the California SULEV levels and today's PM and evaporative emission standards.[101] Due to the extremely low emission levels to which these Blue Sky series engines and vehicles would need to certify, we believe that the double engine count credit is appropriate. Table III.D–2 shows the emission levels that would be required prior to the 2007 model year for diesel engines and the 2008 model year for gasoline vehicles and engines to earn any early introduction engine credits.

TABLE III.D–2.—EMISSION LEVELS AND CREDITS AVAILABLE FOR EARLY INTRODUCTION ENGINES

Category	Must meet[a]	Early engine credit[b]
Early Diesel PM-only[c]	Phase 2 PM & Phase 1 NO_X + NMHC	1.5-to-1
Early Diesel Engine[c]	All Phase 2 Standards	1.5-to-1
Early Gasoline Engine or Vehicle—Exhaust	Phase 2 Exhaust Standards	1-to-1
Early Gasoline Engine or Vehicle—Evap	Phase 2 Evaporative Standards	1-to-1
Blue Sky Series Diesel[c] or Gasoline Engine	0.10 g/bhp-hr NO_X & All other Phase 2 Standards[d]	2-to-1
Blue Sky Series Gasoline Vehicle	0.02 g/mi PM & California SULEV Level Standards[d]	2-to-1

[a] Phase 1 refers to standards required by 65 FR 59896, October 6, 2000; Phase 2 refers to today's final standards.
[b] Engine count credits must be earned prior to the phase-in years of 2007 for diesel and 2008 for gasoline.
[c] Early diesel engines must also meet the Phase 2 crankcase emissions requirements.
[d] For gasoline engines and vehicles, these must also meet the Phase 2 evaporative emission standards.

Alternative fueled vehicles and engines can also play a significant role in this incentive program. Any alternative fueled diesel-cycle engine certified to today's final standards prior to the 2007 model year can generate a 1.5 diesel-cycle engine count credit during the diesel phase-in years. Likewise, any alternative fueled Otto-cycle engine certified to today's final standards prior to the 2008 model year can generate one Otto-cycle engine count credit. Many commenters suggested that EPA should do more than was put forward in our proposal to encourage the introduction of alternative fuel technologies. To the extent that alternative fueled vehicles and engines are cleaner than diesels and gasolines, they may have an advantage within today's program. We believe that this program and its structure provides significant incentives for manufacturers to introduce alternative fueled vehicles and engines.

One final aspect of the incentive program is its interaction with our Tier 2 program. The Tier 2 final rule allows some MDPVs to be equipped with engine-certified diesel engines through the 2007 model year. Any such engines are required to comply with the diesel engine standards that apply during the given model year. Given that they are certified as heavy-duty diesel engines, any such engines that meet today's final diesel standards prior to the 2007 model year would be allowed within today's incentive program provided they in no way generate any emission or engine count credits within the Tier 2 program. Further, any MDPVs, whether gasoline or diesel, certified on a chassis dynamometer and being counted in any way as part of the Tier 2 program, cannot be used as part of today's incentive program because they are not considered heavy-duty vehicles.

E. Feasibility of the New Engine and Vehicle Standards

For more detail on the information and analyses supporting our assessment of the technological feasibility of today's standards, please refer to the Final RIA in the docket for this rule. The following discussion summarizes the more detailed discussion found in the Final RIA and in the Summary and Analysis of Comments document.

1. Feasibility of Stringent Standards for Heavy-Duty Diesel

The designers and manufacturers of diesel engines have made substantial progress over the last 20 years reducing NO_X emissions by 60 percent and PM emissions by almost 90 percent through better engine design. We believe that, in response to our Phase 1 heavy-duty rule, industry will have implemented all promising engine-based emission reduction technologies in order to meet the 2.5 g/bhp-hr NO_X+NMHC standard and the 0.1 g/bhp-hr PM standard. To get the substantial PM and NO_X reductions from diesel engines needed to solve the air quality problems identified in section II, we believe a new technology solution will be required. That solution is the application of high efficiency exhaust emission control technologies (catalysts) to diesel engines, analogous to the application of catalyst technologies to passenger cars in the 1970s. These high efficiency catalyst technologies, enabled by the use of diesel fuel with sulfur content at or below 15 ppm, can reduce NO_X and PM emissions by more than 90 percent. This dramatic reduction in emissions will enable diesel powered vehicles to reach emission levels well below today's gasoline emission levels. As detailed in the sections below, these technologies are rapidly being developed and will be available for application to diesel powered vehicles by, or even before, the 2007 model year provided the low sulfur diesel fuel required today is widely available.

[101] The California SULEV levels are, for 8,500 to 10,000 pound vehicles, 0.1 g/mi NO_X, 0.100 g/mi NMOG, 0.008 g/mi HCMO, and 0.06 g/mi PM; and for 10,000 to 14,000 pound vehicles, 0.2 g/mi NO_X, 0.117 g/mi NMOG, 0.010 g/mi HCHO, and 0.06 g/mi PM. With the exception of the PM standards, these emission levels are half or roughly half of this rule's final gasoline vehicle standards.

a. Meeting the PM Standard

Diesel PM consists of three primary constituents: Unburned carbon particles (soot), which make up the largest portion of the total PM; the soluble organic fraction (SOF), which consists of unburned hydrocarbons that have condensed into liquid droplets or have condensed onto unburned carbon particles; and sulfates, which result from oxidation of fuel and oil derived sulfur in the engine's exhaust. Several exhaust emission control devices have been developed to control harmful diesel PM constituents—the diesel oxidation catalyst (DOC), and the many forms of diesel particulate filters, sometimes called PM traps. DOCs have been shown to be durable in use, but they effectively control only the SOF portion of the total PM which, on a modern diesel engine constitutes only 10 to 30 percent of the total PM. Therefore, the DOC on its own would only offer a modest reduction in PM emissions, and would not be able to meet the PM standard set here.

Diesel particulate filters were first investigated some twenty years ago as a means to capture solid particles in diesel exhaust. A variety of approaches to this technology have been developed most of which provide excellent mechanical filtration of the solid particles that make up the bulk of diesel PM (60 to 80 percent). The collected PM, mostly carbon particles, must then be "burned off" of the filter before the filter becomes plugged. This burning off of collected PM (oxidation of the stored PM, releasing CO_2) is referred to as "regeneration," and can occur either:

- On a periodic basis by using base metal catalysts (including fuel-borne base metal catalysts) or an active regeneration system such as an electrical heater, a fuel burner, or a microwave heater; or,
- On a continuous basis by using precious metal catalysts.

Diesel particulate traps that regenerate on a periodic basis (referred to here as either uncatalyzed or base metal catalytic PM traps) demonstrated high PM trapping efficiencies many years ago, but the level of the applicable PM standard was such that it could be met through less costly "in-cylinder" control techniques. Un-catalyzed diesel particulate filters will not be able to meet the 0.01 g/bhp-hr PM standard finalized today as they are only moderately effective at controlling the SOF fraction of the particulate. In addition, they require active regeneration technology which must be engaged frequently making the systems expensive to operate (increasing fuel consumption) and less reliable.

We believe the kind of PM trap that would be able to meet the PM standard in a reliable, durable, cost effective manner, and the type of trap that will prove to be the industry's technology of choice, is one capable of regenerating on an essentially continuous basis. In addition these PM traps will be able to achieve very low PM emissions because:

- They are highly efficient at controlling the solid carbon portion of PM;
- Unlike uncatalyzed filters, they are highly efficient at oxidizing the SOF of diesel PM;
- They employ precious metals to produce conditions that reduce the temperature at which regeneration occurs, thereby allowing for passive regeneration under normal operating conditions typical of a diesel engine; [102]
- Because they regenerate continuously, they have lower average backpressure thereby reducing potential fuel economy impacts; and,
- Because of their passive regeneration characteristics, they need no extra burners or heaters like what would be required by an active regeneration system, thereby reducing potential failures and fuel economy impacts.

These catalyzed PM traps are able to provide in excess of 90 percent control of diesel PM when operated on diesel fuel with sulfur levels at or below 15 ppm. However, as discussed in detail in the RIA, the catalyzed PM trap cannot regenerate properly with current fuel sulfur levels, as such sulfur levels poison the catalytic function of the PM trap inhibiting the necessary NO to NO_2 reaction to the point of stopping trap regeneration.[103] Also, because SO_2 is so readily oxidized to SO_3, the 0.01 g/bhp-hr PM standard cannot be achieved with fuel sulfur levels above 15 ppm because of the resultant increase in sulfate PM emissions ("sulfate make").[104]

More than one exhaust emission control manufacturer is known to have or be developing these precious metal catalyzed, passively regenerating PM traps and to have them in broad field test programs in areas where low sulfur diesel fuel is currently available. In field trials since 1994, they have demonstrated highly efficient PM control and good durability with some units accumulating in excess of 360,000 miles of field use.[105] The experience gained in these field tests also helps to clarify the need for low sulfur diesel fuel. In Sweden, where below 10 ppm diesel fuel sulfur is readily available, more than 3,000 catalyzed diesel particulate filters have been introduced into retrofit applications without a single failure. These retrofit applications include intercity trains, airport buses, mail trucks, city buses and garbage trucks.[106] The field experience in areas where sulfur is capped at 50 ppm has been less definitive. In regions without extended periods of cold ambient conditions, such as the United Kingdom, field tests on 50 ppm sulfur cap fuel have been positive, matching the durability at 10 ppm, but would be unable to meet a 0.01 g/bhp-hr PM standard due to a substantial increase in sulfate PM. However, field tests on 50 ppm sulfur fuel in Finland where colder winter conditions are often encountered (similar to northern parts of the United States) have experienced a failure rate of 10 percent, due to trap plugging. This 10 percent failure rate has been attributed to insufficient trap regeneration due to fuel sulfur in combination with low ambient temperatures.[107] Other possible reasons for the high failure rate in Finland when contrasted with the Swedish experience appear to be unlikely. The Finnish and Swedish fleets were substantially similar, with both fleets consisting of transit buses powered by Volvo and Scania engines in the 10 to 11 liter range. Further, the buses were operated in city areas and none of the vehicles were operated in northern extremes such as north of the

[102] For PM trap regeneration without precious metals, exhaust metals, exhaust temperatures in excess of 650°C must be obtained. At such high temperatures, carbon will burn (oxidize to CO_2) provided sufficient oxygen is present. Although the largest heavy-duty diesels may achieve exhaust temperatures of 650°C under some operating conditions, smaller diesel engines, particularly light-duty and light heavy-duty diesel engines, will rarely achieve such high temperatures. For example, exhaust temperatures on the HDE Federal Test Procedure cycle typically range from 100°C to 450°C. Precious metal catalyzed traps use platinum to oxidize NO in the exhaust to No_2, which is capable of oxidizing carbon at temperatures as low as 250°C to 300°C.

[103] Cooper and Thoss, Johnson Matthey, SAE 890404.

[104] See the RIA for more detail on the relationship of fuel sulfur to sulfate make.

[105] Allansson, *et al.* SAE 2000–01–0480.

[106] Allansson, *et al.* SAE 2000–01–0480.

[107] Letter from Dr. Barry Cooper to Don Kopinski, US EPA, Air Docket A–99–06.

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Arctic Circle.[108] Given that the fleets in Sweden and Finland were substantially similar, and given that ambient conditions in Sweden are expected to be similar to those in Finland, we believe that the increased failure rates noted here are due to the higher fuel sulfur level in a 50 ppm cap fuel versus a 10 ppm cap fuel.[109] Testing on an even higher fuel sulfur level of 200 ppm was conducted in Denmark on a fleet of 9 vehicles. In less than six months all of the vehicles in the Danish fleet had failed due to trap plugging.[110] We believe that this real world testing clearly indicates that increasing diesel fuel sulfur levels limit trap regeneration, leading to plugging of the PM trap even at fuel sulfur levels as low as 50 ppm.

From these results, we can further conclude that lighter applications (such as large pick-up trucks and other light heavy-duty applications), having lower exhaust temperatures than heavier applications, may experience similar failure rates even in more temperate climates and would, therefore, need lower sulfur fuel even in the United Kingdom. These results are understood to be due to the effect of sulfur on the trap's ability to create sufficient NO_2 to carry out proper trap regeneration. Without the NO_2, the trap continues to trap the PM at high efficiency, but it is unable to oxidize, or regenerate, the trapped PM. The possible result is a plugged trap. This vulnerability of the catalyzed diesel particulate filter due to sulfur in the fuel and the consequences of trap plugging are discussed fully in section III.F and the RIA.

Several commenters raised concerns with our use of the extensive fleet experience in Europe, to draw conclusions about the necessary sulfur reductions required in order to ensure PM trap durability. Their concerns focused generally around the fact that these fleets were made up of retrofit applications, and that the nature of the fleet operation did not represent a controlled experiment (ideally all things would have been equal except for the fuel sulfur level). While we acknowledge these limitations in the data, we believe they still provide reasonable evidence of the need for low sulfur diesel fuel. The diversity of applications, climates, fuel properties, NO_X emission levels, and sulfur levels help to show the relative robustness of the technology. Further, we believe the PM trap manufacturer's analysis of the failure mode (*i.e.*, that cold ambient conditions coupled with diminished NO to NO_2 conversion due to sulfur led to the failures that were experienced) is the most likely explanation of the observed phenomena. Sulfur in diesel fuel is known to inhibit the oxidation of NO to NO_2 (as described in section III.F) leading to reduced ability to regenerate the PM filter, especially under low ambient conditions. For our detailed response to comments surrounding catalyzed diesel particulate filter durability refer to the RTC document.

Several progressive refineries have begun to produce diesel fuel with sulfur content less than 15 ppm for limited markets in the United States. The availability of this low sulfur diesel fuel makes it possible to introduce diesel particulate filters into these limited markets today. International Truck and Engine Corporation ("International") has announced its intent to commercialize its Green Diesel Engine Technology™ in 2001 coupled with less than 15 ppm sulfur fuel to achieve our proposed MY 2007 NMHC and PM emissions standards six years in advance of the requirement. International's ability to bring a catalyzed diesel particulate filter technology to commercialization in such a short period highlights the advanced state of this technology.[111]

Modern catalyzed PM traps have been shown to be very effective at reducing PM mass. In addition, recent data show that they are also very effective at reducing the overall number of emitted particles when operated on low sulfur fuel. Hawker, *et. al.*, found that a modern catalyzed PM trap reduced particle count by over 95 percent, including some of the smallest measurable particles (<50 nm), at most of the tested conditions. The lowest observed efficiency in reducing particle number was 86 percent. No generation of particles by the PM trap was observed under any tested conditions.[112] Kittelson, *et al.*, confirmed that ultrafine particles can be reduced by a factor of ten by oxidizing volatile organics, and by an additional factor of ten by reducing sulfur in the fuel. Catalyzed PM traps efficiently oxidize nearly all of the volatile organic PM precursors, and elimination of as much fuel sulfur as possible will substantially reduce the number of ultrafine PM emitted from diesel engines. The combination of catalyzed PM traps with low sulfur fuel is expected to result in very large reductions in both PM mass and the number of ultrafine particles.

The data currently available show that catalyzed particulate filters can provide significant reductions in PM. Catalyzed particulate filters, in conjunction with low sulfur fuel, have been shown to be more than 90 percent efficient over the FTP and at most SET modes.[113] Testing completed as part of the Diesel Emission Control Sulfur Effects (DECSE) program has demonstrated that a heavy duty diesel engine can achieve less than 0.01 g/bhp-hr PM emissions over the supplemental emission test when equipped with a catalyzed diesel particulate filter and operated on diesel fuel with sulfur content less than 15 ppm.[114] Further testing at NVFEL has demonstrated that FTP PM emissions can likewise be controlled below 0.01 g/bhp-hr provided less than 15 ppm sulfur diesel fuel is used with a catalyzed PM trap.[115] Based upon these test results, extensive field experience throughout the world and International Truck and Engine Corporation's commitment to produce vehicles with this technology in 2001, we conclude that the 0.01 g/bhp-hr FTP PM standard is feasible and that it represents the lowest emission level possible having given consideration to cost, energy and safety factors.

With regard to the NTE PM requirements, there is the potential for sulfate production during some operating modes covered by the NTE which would likely exceed the FTP PM standard. However, the NTE PM standard is equal to 1.5 × FTP standard. Even though the FTP standard of 0.01 g/bhp-hr PM is very low, the small additional head room provided by a NTE multiplier of 1.5 will be sufficient to enable PM trap equipped HDDEs to meet the NTE provisions, even when operated on 15 ppm sulfur fuel. This is supported by data generated as part of the DECSE test program, as well as data generated at our own laboratory, as discussed in greater detail in the RIA.[116] As discussed in the RIA, the expanded ambient condition requirements of the NTE test procedure will have little effect on the PM reduction capabilities of a PM trap. The SET PM requirements have also been demonstrated in our laboratory and are supported by the DECSE test program. A detailed discussion is contained in the RIA. Based on this information and assessment, we conclude that the PM supplemental requirements will be feasible in the 2007 time frame.

b. Meeting the NO_X Standard

NO_X emissions from gasoline-powered vehicles are controlled to extremely low levels through the use of the three-way catalyst technology first introduced in the 1970s. Today, an advancement upon this well-developed three-way catalyst technology, the NO_X adsorber, has shown that it too can make possible extremely low NO_X emissions from lean-burn engines such as diesel engines. The potential of the NO_X adsorber catalyst is limited only by its need for careful integration with the total vehicle system (as was done for three-way catalyst equipped passenger cars in the 1980s and 1990s) and by poisoning of the catalyst from sulfur in the fuel. Just as the Tier 2 rulemaking enables advanced three-way catalyst equipped vehicles to meet ultra low NO_X emission levels through the use of low sulfur gasoline, today's rulemaking will enable NO_X adsorbers through substantial reductions in diesel fuel sulfur levels. The NO_X adsorber has already been commercially introduced in a number of stationary and mobile source applications.

NO_X Adsorbers in Power Generation

NO_X adsorber catalysts were first introduced in the power generation market less than five years ago. Since then, NO_X adsorber systems in stationary source applications have enjoyed considerable success. In 1997, the South Coast Air Quality Management District of California determined that a NO_X adsorber system provided the "Best Available Control Technology" NO_X limit for gas turbine power systems.[117] Average NO_X control for these power generation facilities is in excess of 92 percent.[118] A NO_X adsorber catalyst applied to a natural gas fired powerplant has demonstrated better than 99 percent reliability for more than 21,000 hours of operation while controlling NO_X by more than 90 percent.[119]

NO_X Adsorbers in Lean-Burn Gasoline Vehicles

The NO_X adsorber's ability to control NO_X under oxygen rich (fuel lean) operating conditions has led the industry to begin applying NO_X adsorber technology to lean-burn engines in mobile source applications. NO_X adsorber catalysts have been developed and are now in production for lean-burn gasoline vehicles in Japan, including several vehicle models sold by Toyota Motor Corporation.[120] The 2000 model year saw the first U.S. application of this technology with the introduction of the Honda Insight, certified to the California LEV–I ULEV category standard. These lean burn gasoline applications are of particular interest because they are similar to diesel vehicle applications in terms of NO_X storage under lean exhaust conditions and the need for periodic NO_X regeneration under transient driving conditions. The substantial experience already gained and continuing to be gained from NO_X adsorber use in lean-burn gasoline vehicles provides a firm basis from which diesel NO_X adsorber development is proceeding.

NO_X Adsorbers in Light-Duty Diesel Vehicles

This rapid development pace of the NO_X adsorber technology is not limited to gasoline applications but includes markets where low sulfur diesel fuel is already available or has been mandated to coincide with future emission standards. In Japan, Toyota Motor Corporation has recently announced that it will begin introducing vehicles using its Diesel Particulate– NO_X Reduction (DPNR) system in 2003. This system uses a NO_X adsorber catalyst applied on the surface of a diesel particulate filter, providing greater than 80 percent reductions in both PM and NO_X. Toyota notes however, that DPNR requires fuel with low sulfur content in order to maintain high efficiency for a long duration.[121] In Europe, both Daimler Chrysler and Volkswagen, driven by a need to meet stringent Euro IV emission standards, have published results showing how they would apply the NO_X adsorber technology to their diesel-powered passenger cars. Volkswagen reports that it has already demonstrated NO_X emissions of 0.137 g/km (0.22 g/mi), a 71 percent reduction, on a diesel powered Passat passenger car equipped with a NO_X adsorber catalyst.[122]

US DOE Research Programs

The U.S. Department of Energy (DOE) has funded several test programs at national laboratories and in partnership with industry to investigate NO_X adsorber technology. At Oak Ridge National Laboratory, DOE researchers have shown that a NO_X adsorber and a laboratory regeneration system can reduce NO_X by more than 90 percent when used on a diesel powered Mercedes A-class passenger car. Following 600 miles of driving with 150 ppm sulfur fuel, the system performance degraded considerably.[123] While the system was not production ready, it does demonstrate that very high efficiencies are achievable with advanced emission control systems operating on low sulfur fuel.[124] With additional system development over the next several years we are confident that the remaining design challenges such as long-term durability will be solved.

EPA NVFEL Current Technology Evaluation Program

As part of an effort to evaluate the rapidly developing state of this technology, the Manufacturers of Emission Control Association (MECA) provided four different NO_X adsorber catalyst formulations to EPA for

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[108] Telephone conversation between Dr. Barry Cooper, Johnson Matthey, and Todd Sherwood, EPA, Air Docket A–99–06.

[109] The average temperatrue in Helsinki, Finland, for the month of January is 21°F. The average temperature in Stockholm, Sweden, for the month of January is 26°F. The average temperature at the University of Michigan in Ann Arbor, Michigan, for the month of January is 24°F. The temperature reported here are from *www.worldclimate.com* based upon the Global Historical Climatology Network (GHCN) produced jointly by the National Climatic Data Center and Carbon Dioxide Information Analysis Center at Oak Ridge National Laboratory (ORNL).

[110] Letter from Dr. Barry Cooper to Don Kopinski US EPA, Air Docket A–99–06.

[111] International Truck and Engine Corporation's comments on the proposed 2007-heavy duty vehicle standards, Air Docket A–99–06, page 2.

[112] Hawker, P., *et al.*, Effect of a Continuously Regenerating Diesel Particulate Filter on Non-Regulated Emissions and Particle Size Distribution, SAE 980189.

[113] Demonstration of Advanced Emission Control Technologies Enabling Diesel-Powered Heavy-Duty Engines to Achieve Low Emission Levels, Manufacturers of Emissions Controls Association, June 1999.

[114] Testing for the DECSE program was conducted on 3 ppm and 30 ppm diesel fuel. A straight-line fit to the results between 3 ppm and 30 ppm shows that a 15 ppm cap fuel would have emissions less than 0.01 g/bhp-hr. Diesel Emission Control Sulfur Effects (DECSE) Program, Phase I Interim Data Report No. 4: Diesel Particulate Filters—Final Report, January 2000.

[115] Memorandum from Charles Schenk, EPA, to Air Docket A–99–06, "Summary of EPA PM Efficiency Data," May 8, 2000.

[116] Diesel Emission Control Sulfur Effects (DECSE) Program—Phase II Interim Data Report No. 4, Diesel Particulate Filters—Final Report, January 2000, Table C1, www.ott.doe.gov/decse.

[117] Letter from Barry Wallerstein, Acting Executive Officer, SCAQMD, to Robert Danziger, Goal Line Environmental Technologies, dated December 8, 1997, www.glet.com.

[118] Reyes and Cutshaw, $SCONO_X$ Catalytic Absorption System, December 8, 1998, www.glet.com.

[119] Danziger, R. *et al.* 21,000 Hour Performance Report on SCONOX, 15 September 2000, Air Docket A–99–06.

[120] Toyota requires that their lean burn gasoline engines equipped with NO_X adsorbers are fueled on premium gasoline in Japan, which has an average sulfur content of 6 ppm. (See Item IV–E–31 in Air Docket A–99–06.)

[121] Revolutionary Diesel Aftertreatment System Simultaneously Reduces Diesel Particulate Matter and Nitrogen Oxides, Toyota Motor Corporation press release, July 25, 2000, contained in Air Docket A–99–06.

[122] Pott, E., *et al.*, "Potential of NO_X-Trap Catalyst Application for DI–Diesel Engines," Air Docket A–99–06.

[123] Diesel Vehicle Emission Control Sulfur Effects Project at Oak Ridge National Laboratory, Phase 1 Overview. Pete Devlin, DOE Office of Transportation Technologies, March 29, 2000, Air Docket A–99–06.

[124] Diesel Emission Control Sulfur Effects (DECSE) Program Phase II Summary Report: NO_X Adsorber Catalysts, October 2000, Air Docket A–99–06.

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evaluation. Testing of these catalysts at NVFEL revealed that all four formulations were capable of reducing NO_X emissions by more than 90 percent over the broad range of operation in the supplemental emission test (SET) procedure as summarized in Figure III–1. At operating conditions representative of "road-load" operation for a heavy duty on-highway truck, the catalysts showed NO_X reductions as high as 99 percent resulting in NO_X emissions well below 0.1 g/bhp-hr from an engine-out level of nearly 5 g/bhp-hr.[125] Testing on the FTP has shown similarly good results, with hot start FTP NO_X emissions reduced by more than 90 percent. These results demonstrate that significant NO_X reductions are possible over a broad range of operating conditions with current NO_X adsorber technology, as typified by the FTP and the SET.

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[125] For more information on testing conducted at NVFEL, refer to the in-depth discussion given in the RIA, and to the initial test report contained in Air Docket A–99–06, Item IV–A–29.

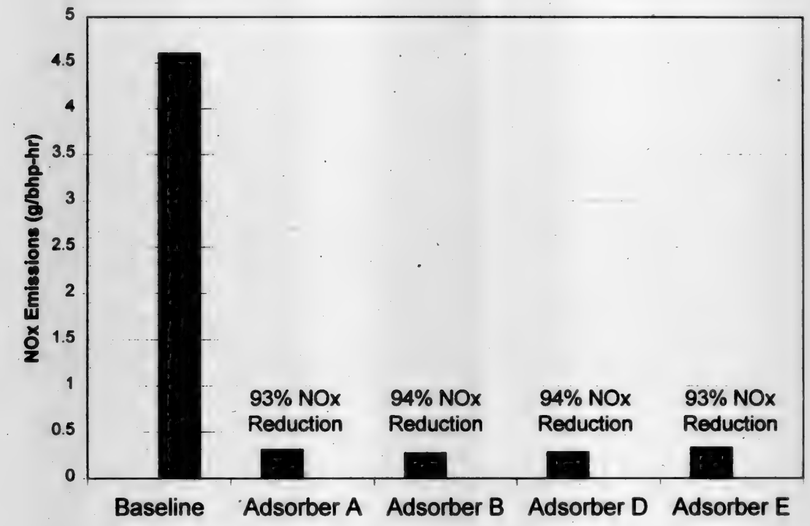


Figure III-1. NVFEL NOx Adsorber SET Composite Results

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This large body of evidence that NO_X adsorbers are highly effective, that they can be applied to diesel engines (as further described in the RIA), and that there is a clear and strong prospect for their further development, causes us to conclude that NO_X adsorbers will provide at least one feasible path to the NO_X standards we have set today. Further, we can conclude from this development experience that the 0.20 g/bhp-hr NO_X standard represents the lowest standard achievable by the year 2007, having given appropriate consideration to cost, energy, and safety as described elsewhere in sections III and V of this document and in the RIA.

Remaining Engineering Development

The considerable success in demonstrating NO_X adsorber technology in laboratory settings, as outlined above, clearly shows that the technology is currently capable of achieving the NO_X standard level. There are several engineering challenges that will be addressed in going from this level of demonstration to implementation of durable and effective emission control systems on production vehicles. One of these technical challenges involves changes to the way diesel engines will need to operate in order to take full advantage of the NO_X adsorber, representing a shift from current day engine operation. Working within the engine design and operating principles expected for 2004 model year engines, optimization of the total system (matching exhaust temperatures to the operating window of NO_X adsorbers and controlling exhaust air to fuel ratios), will be essential to getting the best performance from the NO_X adsorber. We have estimated in the RIA that diesel engine manufacturers collectively will need to invest $385 million in order to implement this change. In addition to the generic need to optimize operation to match the NO_X adsorber performance, industry will further need to address NO_X adsorber desulfation and its associated issues because some sulfur will still remain in the fuel and the engine's lubricating oil.

Clear engineering paths to address these problems can be described today, several years in advance of when they will need to be applied. The primary thing that must occur is to eliminate most of the sulfur from diesel fuel. The fuel sulfur standard set today in this rulemaking overcomes this obstacle. The second set of system engineering steps needed to accomplish both NO_X regeneration and desulfation are already being laid out in test programs conducted by DOE in the DECSE Phase II program and in our own test program at the National Vehicle and Fuel Emissions Laboratory. The DECSE Phase II program clearly demonstrates that, through changes in "in-cylinder" operation, diesel exhaust conditions can be generated that are optimized for NO_X storage (fuel lean operation), NO_X regeneration (fuel rich operation), or desulfation (hot, fuel rich operation). This in-cylinder approach, discussed more fully in the RIA, represents a likely technical solution for light heavy-duty vehicles which are expected to already have the necessary EGR and common rail fuel system technologies need for this approach by the 2004 model year. Testing at NVFEL shows yet another engineering path to optimizing the NO_X control system external to the combustion system. This approach segregates the exhaust into separate streams external to the engine and manipulates exhaust conditions by changing exhaust mass flow (through valves) and by adding supplemental fuel with an electronic fuel injector. This approach means that exhaust temperatures and air to fuel ratios can be controlled external to the engine allowing great flexibility to control and optimize NO_X regeneration and sulfur regeneration events. This approach may prove to be a good solution for heavy heavy-duty vehicles because of the freedom it allows for optimization of both the engine operation and the aftertreatment operation with fewer tradeoffs with regards to fuel consumption and engine durability. A complete description of this approach and its merits is given in the RIA.

Each of the engineering paths described here shows a means for compliance with the NO_X standard given further optimization and development and, given past experiences with the introduction of new technologies, other approaches are likely to be devised as well. Given industry's demonstrated ability to develop solutions to similar issues with gasoline three-way catalysts and gasoline-based NO_X adsorber technologies, we are confident that the NO_X emission control system can be designed for the long life required for heavy-duty diesel operation. We are not alone in this evaluation of NO_X adsorber development, as evidenced by the strong endorsement of the technology by many in the industry.[126] For example, one letter we have received stated, "We believe all NO_X Adsorber development issues have been identified and the technology is proceeding according to schedule. We have identified development paths leading toward production optimization and do not see insurmountable technical barriers. We are confident in our ability and experience in applying the science of surface chemistry and catalysis to achieve our objective." [127]

NTE NO_X Limits

The broad NO_X reduction capability of the NO_X adsorbers will also enable the NTE NO_X requirements to be met. As discussed previously, we have established an NTE NO_X standard of 1.5 × FTP standard, or 0.30 g/bhp-hr NO_X, which is 0.10 g/bhp-hr above the FTP standard. The NMHC+NO_X NTE standard for 2004 technology HDDEs is 1.25 × 2.5 g/bhp-hr NMHC + NO_X, or 3.125 g/bhp-hr, which is 0.625 g/bhp-hr above the 2004 FTP standard. As discussed in the RIA for this final rule, we would expect that the majority of the NTE standard for a 2004 technology engine would be comprised of NO_X emissions, perhaps as much as 3.0 g/bhp-hr (with the remainder, 0.125 g/bhp-hr, being HC). Based on available data, including data from our NVFEL test facility, we believe a NO_X adsorber system will be capable of a 90 percent or greater emission reduction across the entire NTE control zone, for the test conditions covered by the NTE test procedure, by model year 2007. A 90 percent reduction from the "base" NO_X NTE level of 3.0 g/bhp-hr would result in a tailpipe emission rate of 0.30 g/bhp-hr, which is 1.5 times the 2007 FTP NO_X standard. As discussed in the RIA, we have demonstrated NO_X reductions on the order of 90 percent or greater across the NTE control zone in our test program at NVFEL. A complete description of the NO_X adsorber testing completed at NVFEL is provided in the final RIA and in the docket associated with this rule. This testing was performed at standard laboratory conditions; however, we do not expect the expanded ambient conditions required for NTE compliance to have a significant impact on the performance of the exhaust emission control systems. Additional discussion of this issue is contained in the RTC and the RIA for this rule.

[126] Letter from Steven Suttle, Corning, Inc., to Margo Oge, EPA, dated October 23, 2000, Item IV–G–59; letter from Martin Lassen, Johnson Matthey, to Margo Oge, EPA, dated October 19, 2000, Item IV–G–55; letter from John Mooney, Engelhard Corporation, to Margo Oge, EPA, dated October 3, 2000, Item IV–G–38; MECA press release dated October 3, 2000, Item IV–G–53; and Department of Energy, dated September 6, 2000, Item IV–G–28; all contained in Docket A–99–06.

[127] Letter from John J. Mooney, Director, Technical Development and Business Groups, Engelhard Corporation, to Margo Oge, Director, OTAQ, EPA, dated October 3, 2000, Item IV–G–38, Docket A–99–06.

Sulfur Trap

The preceding discussion of NO_X adsorbers assumes that SO_X (SO_2 and SO_3) emissions will be "trapped" on the surface of the catalyst, effectively poisoning the device and requiring a "desulfation" (sulfur removal event) to recover catalyst efficiency. We believe that, at the 15 ppm cap fuel sulfur level, this strategy will allow effective NO_X control with moderately frequent desulfation and with a modest fuel consumption of one percent. We believe this fuel consumption impact will be more than offset by reduced reliance on current, more fuel inefficient NO_X control strategies (see discussion in Section III.G for estimates of overall fuel economy impacts). In the NPRM for this rulemaking, we sought comment on the potential of a separate SO_X trap catalyst to control sulfur poisoning of the NO_X adsorber catalyst. As detailed further in the final RIA and RTC documents, we believe that even if a separate SO_X trap system were used, fuel sulfur levels would have to be 15 ppm or lower in order for the NO_X adsorber technology to function properly over the life of a heavy-duty vehicle.

Urea SCR Technology

SCR Technology has been put forward by some as another means of meeting stringent NO_X standards. For reasons discussed below we do not believe that it provides an adequate basis for establishing the feasibility of today's emission standards. Selective Catalytic Reduction (SCR), like the NO_X adsorber technology, was first developed for stationary applications and is currently being refined for the transient operation found in mobile applications. With the SCR system, a urea solution is injected upstream of the catalyst which breaks down the urea into ammonia and carbon dioxide. The ammonia is used as a NO_X reductant across the SCR catalyst producing N_2 and water. Catalysts containing precious metals (platinum) can be used at the inlet and outlet of SCR systems designed for mobile applications to improve low temperature NO_X reduction performance and to oxidize any ammonia that may pass through the SCR, respectively. SCR systems using these oxidation catalysts and being developed for mobile applications are more often called "compact SCR" systems. Generally, reference to SCR throughout this preamble should be taken to mean compact SCR. The use of these platinum catalysts enables SCR systems to achieve NO_X reductions at lower temperatures (as required for diesel engine applications), but introduces sensitivity to sulfur in much the same way as for diesel particulate filter technologies. Sulfur in diesel fuel inhibits low temperature performance and results in high sulfate-make, leading directly to higher particulate emissions. For a further discussion of SCR system sensitivity to sulfur in diesel fuel, and of its need for low sulfur diesel fuel, refer to Section III.F.

Urea SCR catalysts, like NO_X adsorbers, need low sulfur diesel fuel to achieve high NO_X conversion efficiencies and to control sulfate PM emissions. If low sulfur fuel is required, SCR NO_X control may be possible in some applications by 2007. However we believe there are significant barriers to its general use for meeting the 2007 standards. SCR systems require vehicles to carry a supply of urea. The infrastructure for delivering urea at the diesel fuel pump would need to be in place for these devices to be feasible in the marketplace; and before development of the infrastructure could begin, the industry would have to decide upon a standardized method of delivery for the urea supply.

In addition to this, there would need to be adequate safeguards in place to ensure the urea is used throughout the life of the vehicle since, given the added cost of urea and the fact that urea depletion would not normally affect driveability, there would be an incentive not to refill the urea tank. This could lead to considerable uncertainties regarding the effectiveness of SCR, even if EPA were to promulgate the regulations that likely would be needed to require the regular replenishment of urea. Some commenters have suggested that this is the key issue with regard to urea SCR systems. One commenter further concludes that this issue could be addressed by designing engines with on-board diagnostic systems utilizing a NO_X sensor that would observe a loss of NO_X control. When observed, the engine would be designed to reduce power gradually until a 50 percent loss of power was realized. This power loss would serve to encourage the user to replenish the urea tank.[128] While such an approach may be possible, it raises concerns for public safety as poor engine performance could lead to inadequate power for safe merging onto highways and other related driving situations. We remain hesitant to base a national program on such technology when important issues such as driver training on the need to refill the urea tank and the consequences of failure to do so cannot be appropriately controlled. This approach would seem to suggest a need for EPA-mandated spot checks of individual vehicles to ensure compliance with the NO_X standard. How such a program would work and the burden that it might place on small business entities was not addressed in the comments. In testimony given at the public hearing held for this rulemaking in Los Angeles, the California Trucking Association raised concerns about the appropriateness of putting this regulatory burden on truckers when a simpler technology such as a diesel NO_X adsorber was available instead.[129] Without measures similar to these, we would expect that a substantial number of users would not remember to fill their urea tanks. Since failure to provide urea for a vehicle would lead to a total loss of NO_X control for that vehicle, we would need to model the loss of NO_X control to be expected from an SCR based program. Such a loss in NO_X control most likely would be appreciable and, in effect, the NO_X standard would not be met on a fleetwide basis.

We believe that these significant obstacles would prevent the widespread or general availability of SCR for use as a NO_X control strategy to meet the 0.20 g/bhp-hr NO_X standard. These problems may, however, be resolved in some niche applications; for example, certain well-managed centrally-fueled fleets. Because of the many obstacles to ensure in-use NO_X control with the SCR, we do not believe that feasibility of the 0.20 g/bhp-hr NO_X standard can be based upon SCR technology. For further discussion of urea SCR's need for low sulfur diesel fuel, refer to section III.F of this preamble.

Summary

Based on the discussion above, we believe that NO_X exhaust emission control technology, in combination with low sulfur diesel fuel of 15 ppm or lower, is capable of meeting the very stringent NO_X standards finalized today. The certainty provided by this rulemaking that low sulfur diesel fuel will be available in the future, and the emission standards finalized today that necessitate advanced NO_X controls, should lead to rapid development of these technologies. The NO_X adsorber technology has shown remarkable advancement in the last five years, both in stationary source applications and

[128] API Comments on the 2007 Heavy Duty Engine/Diesel Sulfur Proposed Rule, August 14, 2000, Air Docket A–99–06, IV–D–343.

[129] Testimony of Stephanie Williams—Director of Environmental Affairs, California Trucking Association to EPA public hearing June 27, 2000, Air Docket A–99–06, IV–F–190.

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lean-burn gasoline applications, and now for heavy-duty diesel engines. Given this rapid progress, the availability of low sulfur diesel fuel, the identification of engineering paths to resolving the technological issues, and the lead time provided by today's rulemaking, we believe that applying NO_X adsorbers to heavy-duty diesel engines will provide the emission reductions needed to comply with the 2007 HD NO_X standards. This can be done in a cost effective way, with little or no fuel economy impact, and no special concerns of safety.

c. Meeting the NMHC Standard

Historically control of non-methane hydrocarbon (NMHC) emissions on diesel engines has been relatively simple, when compared to gasoline engines, due to the net fuel lean (abundant oxygen) operation typical of diesel engines. In fact, due to this operating characteristic, diesel engine NMHC levels have often been significantly below the mandated levels. The introduction of catalytic NO_X control and the subsequent need to operate under alternately net lean and net rich conditions is likely to make NMHC control more difficult.

Meeting the NMHC standards under the lean operating conditions typical of the biggest portion of NO_X adsorber operation should not present any special challenges to diesel manufacturers. Since the devices discussed above—catalyzed particulate filters and NO_X adsorbers, contain platinum and other precious metals to oxidize NO to NO_2, they are also very efficient oxidizers of hydrocarbons. NMHC emission reductions of greater than 95 percent have been shown in these devices over the transient FTP and SET modes.[130] Given that typical engine-out NMHC is expected to be in the 0.20 g/bhp-hr range for engines meeting the 2004 standards, this level of NMHC reduction will mean that under lean conditions emission levels will be well below the standard.

However, the NO_X regeneration strategies for the NO_X adsorber technology may prove difficult to control precisely, leading to a possible increase in HC emissions under the rich operating conditions required for NO_X regeneration. Even with precise control of the regeneration cycle, HC slip may prove to be a difficult problem due to the need to regenerate the NO_X adsorber under net rich conditions (excess fuel) rather than the stoichiometric (fuel and air precisely balanced) operating conditions typical of a gasoline three-way catalyst. It seems likely therefore, that in order to meet the HC standards we have set, an additional clean up catalyst may be necessary. A diesel oxidation catalyst, like those applied historically for HC and partial PM control, can reduce HC reductions (including toxic HCs) by more than 80 percent.[131] This amount of additional control along with optimized NO_X regeneration strategies will ensure very low HC emissions. With such a downstream clean-up device to control HC slip during the periodic NO_X regeneration event, the HC standard we have set here can be met. For a complete description of how the clean up catalyst functions in conjunction with the NO_X adsorber technology, please refer to the complete system description given below in section III.E.1.e and to the final RIA.

Given industry's extensive experience with diesel oxidation catalysts, the long lead time provided by this rulemaking and the availability of less than 15 ppm sulfur diesel fuel, we conclude, having given consideration to cost, energy impacts and safety, that the NMHC standard is feasible.

d. Meeting the Crankcase Emissions Requirements

The most common way to eliminate crankcase emissions has been to vent the blow-by gases into the engine air intake system, so that the gases can be recombusted. Until today's rulemaking, we have required that crankcase emissions be controlled only on naturally aspirated diesel engines. We have made an exception for turbocharged heavy-duty diesel engines because of concerns in the past about fouling that could occur by routing the diesel particulates (including engine oil) into the turbocharger and aftercooler. However, this is an environmentally significant exception since most heavy-duty diesel trucks use turbocharged engines, and a single engine can emit over 100 pounds of NO_X, NMHC, and PM from the crankcase over its lifetime.

Given the available means to control crankcase emissions, we have eliminated this exception. We anticipate that the heavy-duty diesel engine manufacturers will be able to control crankcase emissions through the use of closed crankcase filtration systems or by routing unfiltered blow-by gases directly into the exhaust system upstream of the emission control equipment. However, the provision has been written such that if adequate control can be had without "closing" the crankcase then the crankcase can remain "open." Compliance would be ensured by adding the emission from the crankcase ventilation system to the emissions from the engine control system downstream of any emission control equipment.

We expect that in order to meet the stringent tailpipe emission standards set here, that manufacturers will have to utilize closed crankcase approaches as described here. Closed crankcase filtration systems work by separating oil and particulate matter from the blow-by gases through single or dual stage filtration approaches, routing the blow-by gases into the engine's intake manifold and returning the filtered oil to the oil sump. These systems are required for new heavy-duty diesel vehicles in Europe starting in 2000. Oil separation efficiencies in excess of 90 percent have been demonstrated with production ready prototypes of two stage filtration systems.[132] By eliminating 90 percent of the oil that would normally be vented to the atmosphere, the system works to reduce oil consumption and to eliminate concerns over fouling of the intake system when the gases are routed through the turbocharger. Mercedes-Benz currently utilizes this type of system on virtually all of its heavy-duty diesel engines sold in Europe. An alternative approach would be to route the blow-by gases into the exhaust system upstream of the catalyzed diesel particulate filter which would be expected to effectively trap and oxidize the engine oil and diesel PM. This approach may require the use of low sulfur engine oil to ensure that oil carried in the blow-by gases does not compromise the performance of the sulfur-sensitive emission control equipment.

e. The Complete System

We expect that the technologies described above would be integrated into a complete emission control system as described in the final RIA. The engine-out emissions will be balanced with the exhaust emission control package in such a way that the result is the most beneficial from a cost, fuel economy and emissions standpoint. The engine-out exhaust characteristics will also have a role in assisting the exhaust emission control devices used. The NO_X adsorber, for instance, will require periods of oxygen-depleted exhaust flow in order to accomplish NO_X regeneration and to allow for sulfur control using desulfation events. This may be most efficiently done by reducing the air-fuel ratio that the engine is operating under during the regeneration to reduce the oxygen content of the exhaust, or alternatively by partitioning the exhaust flow such that only a small portion of the exhaust flow is used for NO_X regeneration, thereby reducing the amount of oxygen needing to be depleted through fuel addition. Further, it is envisioned that the PM device will be integrated into the exhaust system upstream of the NO_X reduction device. This placement would allow the PM trap to take advantage of the engine-out NO_X as an oxidant for the particulate, while removing the particulate so that the NO_X exhaust emission control device will not have to deal with large PM deposits which may cause a deterioration in performance. Further it allows the NO_X adsorber to make use of the upstream PM filter as a pre-catalyst to oxidize some NO to NO_2 and to partially oxidize the reductant (diesel fuel or exhaust hydrocarbons) to a more desirable reductant form such as CO before entering the NO_X adsorber. Of course, there is also the possibility of integrating the PM and NO_X exhaust emission control devices into a single unit to replace a muffler and save space (Toyota's DNPR system being an example of this approach).[133] The final component in any of these system configurations is likely to be some form of clean up catalyst which can provide control of HC slip during NO_X regeneration as well as H_2S slip during SOx regeneration. Particulate free exhaust may also allow for new options in EGR system design to optimize its efficiency.

We expect that the emission reduction efficiency of the exhaust emission control system will vary across the NTE zone as a function of exhaust temperature and space velocity.[134] Consequently, to maintain the NTE emission cap, the engine-out emissions would have to be calibrated with exhaust emission control system performance characteristics in mind. This would be accomplished by lowering engine-out emissions where the exhaust emission control system was less efficient, for example by retarding fuel injection timing or increasing the EGR rate. Conversely, where the exhaust emission control system is very efficient at reducing emissions, the engine-out emissions could be tuned for higher emissions and better fuel economy. These trade-offs between engine-out emissions and exhaust emission control system performance characteristics are similar to those of gasoline engines with three-way catalysts in today's light-duty vehicles and can be overcome through similar system based engineering solutions. Managing and optimizing these trade-offs will be crucial to effective implementation of exhaust emission control devices on diesel applications.

2. Feasibility of Stringent Standards for Heavy-Duty Gasoline

Gasoline emission control technology has evolved rapidly in recent years. Emission standards applicable to 1990 model year vehicles required roughly 90 percent reductions in exhaust NMHC and CO emissions and a 75 percent reduction in NO_X emissions compared to uncontrolled emissions. Today, some vehicles' emissions are well below those necessary to meet the current federal heavy-duty gasoline standards, the 2004 heavy-duty gasoline standards, and the California Low-Emission Vehicle standards for medium-duty vehicles. The continuing emissions reductions have been brought about by ongoing improvements in engine air-fuel management hardware and software plus improvements in exhaust system and catalyst designs.

We believe that the types of changes being seen on current vehicles have not yet reached their technological limits and continuing improvement will allow them to meet today's standards. The RIA describes a range of specific emission control techniques that we believe could be used. There is no need to invent new technologies, although there will be a need to apply existing technology more effectively and more broadly. The focus of the effort will be in the application and optimization of these existing technologies.

In our light-duty Tier 2 rule, we have required that gasoline sulfur levels be reduced to a 30 ppm average, with an 80 ppm maximum. This sulfur level reduction is the primary enabler for the Tier 2 standards. Similarly, we believe that the gasoline sulfur reduction, along with refinements in existing gasoline emission control technology, will be sufficient to allow heavy-duty gasoline vehicles and engines to meet the emission standards sought by today's rule.

However, we recognize that the emission standards are stringent, and considerable effort will have to be undertaken. For example, we expect that every engine will have to be recalibrated to improve upon its cold start emission performance. Manufacturers will have to migrate their light-duty calibration approaches to their heavy-duty offerings to provide cold start performance in line with what they will have to achieve to meet the Tier 2 standards.

We also project that today's new heavy-duty gasoline standards would require the application of advanced engine and catalyst systems similar to those projected for their light-duty counterparts. Historically, manufacturers have introduced technology on light-duty gasoline applications and then applied those technologies to their heavy-duty gasoline applications. Today's standards will allow manufacturers to take this same approach. In other words, we expect that manufacturers will meet today's new standards through the application of technology developed to meet light-duty Tier 2 standards for 2004.

Improved calibration and systems management will be critical in optimizing the performance of the engine with the advanced catalyst system. Precise air/fuel control must be tailored for emissions performance and must be optimized for all types of driving. Calibration refinements may also be needed for EGR system optimization and to reduce cold start emissions through methods such as spark timing retard. We also project that electronic control modules with expanded capabilities will be needed on some vehicles and engines.

We also expect increased use of other technologies in conjunction with those described above. We expect some increased use of air injection to improve upon cold start emissions. We may also see air-gap manifolds, exhaust pipes, and catalytic converter shells as a means of improving upon catalyst light-off times thereby reducing cold start emissions. Other, non-catalyst related improvements to gasoline emission control technology include higher speed computer processors which enable more sophisticated engine control algorithms and improved fuel injectors providing better fuel atomization thereby improving fuel combustion.

Catalyst system durability is, and will always be, a serious concern. Historically, catalysts have deteriorated when exposed to very high temperatures. This has long been a concern especially for heavy-duty work

[130] "The Impact of Sulfur in Diesel Fuel on Catalyst Emission Control Technology," report by the Manufacturers of Emission Controls Association, March 15, 1999, pp. 9 & 11.

[131] Demonstration of Advanced Emission Control Technologies Enabling Diesel-Powered Heavy-Duty Engines to Achieve Low Emission Levels, Manufacturers of Emissions Controls Association, June 1999.

[132] Letter from Marty Barris, Donaldson Corporation, to Byron Bunker US EPA, March 2000. Air Docket A–99–06.

[133] Revolutionary Diesel Aftertreatment System Simultaneously Reduces Diesel Particulate Matter and Nitrogen Oxides, Toyota Motor Corporation press release, July 25, 2000, Air Docket A–99–06.

[134] The term, "space velocity," is a measure of the volume of exhaust gas that flows through a device.

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vehicles. However, catalyst manufacturers continue to make strides in the area of thermal stability and we expect that improvements in thermal stability will continue for the next generation of catalysts.

We believe that, by optimizing all of these technologies, manufacturers will be able to achieve today's standards. Advanced catalyst systems have already shown potential to reduce emissions to close to these levels. Some current California vehicles are certified to levels below 0.20 g/mi NO_X. California tested an advanced catalyst system on a vehicle loaded to a test weight comparable to a heavy-duty vehicle test weight and achieved NO_X and NMOG levels of 0.1 g/mi and 0.16 g/mi, respectively. The California vehicle with the advanced catalyst had not been optimized as a system to take full advantage of the catalyst's capabilities.

The compliance flexibility provisions can also be an important tool for manufacturers in implementing a new standard. The program allows manufacturers to transition to the more stringent standards by introducing emissions controls over a longer period of time, as opposed to a single model year. Manufacturers plan their product introductions well in advance. With the compliance flexibilities, manufacturers can better manage their product lines so that the new standards don't interrupt their product introduction plans. Also, the program allows manufacturers to focus on higher sales volume vehicles first and use credits for low sales volume vehicles.

3. Feasibility of the New Evaporative Emission Standards

The new evaporative emission standards appear to be feasible now. Many designs have been certified that already meet these standards. A review of 1998 model year certification data indicates that five of eight evaporative system families in the 8,500 to 14,000 pound range comply with the new 1.4 g/test standard, while all evaporative system families in the over 14,000 pound range comply with the new 1.9 g/test standard.

The new evaporative emission standards should not require the development of new materials but may, in some cases, require new application of existing materials. Low permeability materials and low loss connections and seals are already used to varying degrees on current vehicles, but that practice may become more widespread. Today's new standards would likely ensure their consistent use and discourage manufacturers from switching to cheaper materials or designs to take advantage of the large safety margins they have had under current standards.

There are two approaches to reducing evaporative emissions for a given fuel. One is to minimize the potential for permeation and leakage by reducing the number of hoses, fittings and connections. The second is to use less permeable hoses and lower loss fittings and connections. Manufacturers are already employing both approaches.

Most manufacturers are moving to "returnless" fuel injection systems. Through more precise fuel pumping and metering, these systems eliminate the return line in the fuel injection system. The return line carries unneeded fuel from the fuel injectors back to the fuel tank. Because the fuel injectors are in such close contact with the hot engine, the fuel returned from the injectors to the fuel tank has been heated. This returned fuel is a significant source of fuel tank heat and vapor generation. The elimination of the return line also reduces the total length of hose on the vehicle though which vapors can permeate, and it reduces the number of fittings and connections through which fuel can leak.

Low permeability hoses and seals, and low loss fittings are available and are already used on many vehicles. Fluoropolymer materials can be added as liners to hose and component materials to yield large reductions in permeability over such conventional materials as monowall nylon. In addition, fluoropolymer materials can greatly reduce the adverse impact of alcohols in gasoline on permeability of evaporative components, hoses and seals.

F. Need for Low Sulfur Diesel Fuel

The following discussion will build upon the brief sulfur sensitivity points made earlier in this section by providing a more in-depth discussion of sulfur's effect on the diesel exhaust emission control technologies. In order to evaluate the effect of sulfur on diesel exhaust control technologies, we used three key factors to categorize the impact of sulfur in fuel on emission control function. These factors were efficiency, reliability, and fuel economy. Taken together these three factors lead us to believe that diesel fuel sulfur levels of 15 ppm will be required in order to make feasible the heavy-duty vehicle emission standards. Brief summaries of these factors are provided below. A more in-depth review is given in the following subsections and in the final RIA.

The efficiency of emission control technologies to reduce harmful pollutants is directly affected by sulfur in diesel fuel. Initial and long term conversion efficiencies for NO_X, NMHC, CO and diesel PM emissions are significantly reduced by catalyst poisoning and catalyst inhibition due to sulfur. NO_X conversion efficiencies with the NO_X adsorber technology in particular are dramatically reduced in a very short time due to sulfur poisoning of the NO_X storage bed. In addition, total PM control efficiency is negatively impacted by the formation of sulfate PM. As explained in detail in the following sections, all of the advanced NO_X and PM technologies described here have the potential to make significant amounts of sulfate PM under operating conditions typical of heavy-duty vehicles. We believe that the formation of sulfate PM will be in excess of the total PM standard, unless diesel fuel sulfur levels are at or below 15 ppm. Based on the strong negative impact of sulfur on emission control efficiencies for all of the technologies evaluated, we believe that 15 ppm represents an upper threshold of acceptable diesel fuel sulfur levels.

Reliability refers to the expectation that emission control technologies must continue to function as required under all operating conditions for the life of the vehicle. As discussed in the following sections, sulfur in diesel fuel can prevent proper operation of both NO_X and PM control technologies. This can lead to permanent loss in emission control effectiveness and even catastrophic failure of the systems. Sulfur in diesel fuel impacts reliability by decreasing catalyst efficiency (poisoning of the catalyst), increasing diesel particulate filter loading, and negatively impacting system regeneration functions. Among the most serious reliability concerns with sulfur levels greater than 15 ppm are those associated with failure to properly regenerate. In the case of the NO_X adsorber, failure to regenerate will lead to rapid loss of NO_X emission control as a result of sulfur poisoning of the NO_X adsorber bed. In the case of the diesel particulate filter, sulfur in the fuel reduces the reliability of the regeneration function. If regeneration does not occur, catastrophic failure of the filter could occur. It is only by the availability of low sulfur diesel fuels that these technologies become feasible. The analysis given in the following section makes clear that diesel fuel sulfur levels will need to be under 15 ppm in order to ensure robust operation of the technologies under the variety of operating conditions anticipated to be experienced in the field.

Fuel economy impacts due to sulfur in diesel fuel affect both NO_X and PM control technologies. The NO_X adsorber sulfur regeneration cycle (desulfation cycle) can consume significant amounts of fuel unless fuel sulfur levels are very low. The larger the amount of sulfur in diesel fuel, the greater the adverse effect on fuel economy. As sulfur levels increase above 15 ppm, the adverse effect on fuel economy becomes more significant, increasing above one percent and doubling with each doubling of fuel sulfur level. Likewise, PM trap regeneration is inhibited by sulfur in diesel fuel. This leads to increased PM loading in the diesel particulate filter and increased work to pump exhaust across this restriction. With low sulfur diesel fuel, diesel particulate filter regeneration can be optimized to give a lower (on average) exhaust backpressure and thus better fuel economy. Thus, for both NO_X and PM technologies the lower the fuel sulfur level the lower the operating costs of the vehicle.

1. Catalyzed Diesel Particulate Filters and the Need for Low Sulfur Fuel

Diesel particulate filters (PM traps) function to control diesel PM through mechanical filtration of PM from the diesel exhaust stream and then oxidation of the stored PM (trap regeneration). Through oxidation in the catalyzed diesel particulate filter the stored carbonaceous PM is converted to CO_2 and released into the atmosphere. Failure to oxidize the stored PM leads to accumulation in the trap, eventually causing the trap to become so full that it severely restricts exhaust flow through the device, leading to trap or vehicle failure.

As discussed earlier in this section, uncatalyzed diesel particulate filters require exhaust temperatures in excess of 650° C in order for the collected PM to be oxidized by the oxygen available in diesel exhaust. That temperature threshold for oxidation of PM by exhaust oxygen can be decreased to 450° C through the use of base metal catalytic technologies. For a broad range of operating conditions typical of in use operation, diesel exhaust is significantly cooler than 400° C. If oxidation of the trapped PM could be assured to occur at exhaust temperatures lower than 300° C, then diesel particulate filters would be expected to be robust for most applications and operating regimes. Oxidation of PM (regeneration of the trap) at such low exhaust temperatures can occur by using oxidants which are more readily reduced than oxygen. One such oxidant is NO_2.

NO_2 can be produced in diesel exhaust through the oxidation of the nitrogen monoxide (NO), created in the engine combustion process, across a catalyst. The resulting NO_2-rich exhaust is highly oxidizing in nature and can oxidize trapped diesel PM at temperatures as cool as 250°C.[135] Some platinum group metals are known to be good catalysts to promote the oxidation of NO to NO_2. Therefore in order to ensure passive regeneration of the diesel particulate filters, significant amounts of platinum group metals (primarily platinum) are being used in the wash-coat formulations of advanced diesel particulate filters. The use of platinum to promote the oxidation of NO to NO_2 introduces several system vulnerabilities affecting both the durability and the effectiveness of the catalyzed diesel particulate filter when sulfur is present in diesel exhaust. The two primary mechanisms by which sulfur in diesel fuel limits the robustness and effectiveness of diesel particulate filters are inhibition of trap regeneration, through inhibition of the oxidation of NO to NO_2, and a dramatic loss in total PM control effectiveness due to the formation of sulfate PM. Unfortunately, these two mechanisms trade-off against one another in the design of diesel particulate filters. Changes to improve the reliability of regeneration by increasing catalyst loadings lead to increased sulfate emissions and, thus, loss of PM control effectiveness. Conversely, changes to improve PM control by reducing the use of platinum group metals and, therefore, limiting "sulfate make" leads to less reliable regeneration. We believe the only means of achieving good PM emission control and reliable operation is to reduce sulfur in diesel fuel, as shown in the following subsections.

a. Inhibition of Trap Regeneration Due to Sulfur

The passively regenerating diesel particulate filter technologies rely on the generation of a very strong oxidant, NO_2, to ensure that the carbon captured by the PM trap's filtering media is oxidized under the exhaust temperature range of normal operating conditions. This prevents plugging and failure of the PM trap. NO_2 is produced through the oxidation of NO in the exhaust across a platinum catalyst. This oxidation is inhibited by sulfur poisoning of the catalyst surface.[136] This inhibition limits the total amount of NO_2 available for oxidation of the trapped diesel PM, thereby raising the minimum exhaust temperature required to ensure trap regeneration. Without sufficient NO_2, the amount of PM trapped in the diesel particulate filter will continue to increase and can lead to excessive exhaust back pressure, low engine power, and even catastrophic failure of the diesel particulate filter itself.

The failure mechanisms experienced by diesel particulate filters due to low NO_2 availability vary significantly in severity and long term consequences. In the most fundamental sense, the failure is defined as an inability to oxidize the stored particulate at a rate fast enough to prevent net particulate accumulation over time. The excessive accumulation of PM over time blocks the passages through the filtering media, making it more restrictive to exhaust flow. In order to continue to force the exhaust through the now more restrictive filter, the exhaust pressure upstream of the filter must increase. This increase in exhaust pressure is commonly referred to as increasing "exhaust backpressure" on the engine.

The increase in exhaust backpressure represents increased work being done by the engine to force the exhaust gas through the increasingly restrictive particulate filter. Unless the filter is frequently cleansed of the trapped PM, this increased work can lead to reductions in engine performance and increases in fuel consumption. This loss in performance may be noted by the vehicle operator in terms of poor acceleration and generally poor driveability of the vehicle. In some cases, engine performance can be so restricted that the engine stalls, stranding the vehicle. This progressive deterioration of engine performance as more and more PM is accumulated in the filter media is often referred to as "trap plugging." Trap plugging also has the potential to cause engine damage. If the exhaust backpressure gets high enough to open the exhaust valves prematurely, the exhaust valves can then strike the piston causing catastrophic engine failure. Whether trap plugging occurs, and the speed at which it occurs, will be a function of many variables in addition to the fuel sulfur level; these variables include the vehicle application, its duty cycle, and ambient conditions. However, if the fuel sulfur level is sufficiently high to prevent trap regeneration in any real world conditions experienced, trap plugging can occur. This is not to imply that any time a vehicle is refueled once with high sulfur fuel trap plugging will occur. Rather, it is important to know that the use of fuel with sulfur levels higher than 15 ppm significantly

[135] Hawker, P. *et al.*, Experience with a New Particualte Trap Technology in Europe, SAE 970182.

[136] Hawker, P. *et al*, Experience with a New Particulate Trap Technology in Europe, SAE 970182.

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increases the chances of particulate filter failure.

Catastrophic failure of the filter can occur when excessive amounts of PM are trapped in the filter due to a lack of NO_2 for oxidation. This failure occurs when excessive amounts of trapped PM begin to oxidize at high temperatures (combustion-like temperatures of over 1000° C) leading to a "run-away" combustion of the PM. This can cause temperatures in the filter media to increase in excess of that which can be tolerated by the particulate filter itself. For the cordierite material commonly used as the trapping media for diesel particulate filters, the high thermal stresses caused by the high temperatures can cause the material to crack or melt. This can allow significant amounts of the diesel particulate to pass through the filter without being captured during the remainder of the vehicle's life. That is, the trap is destroyed and PM emission control is lost. Further the high temperatures generated during this event can destroy the downstream catalyst components, such as the NO_X adsorber, rendering them ineffective as well.

Full field test evaluations and retrofit applications of these catalytic trap technologies are occurring in parts of Europe where low sulfur diesel fuel is already available.[137] The experience gained in these field tests helps to clarify the need for low sulfur diesel fuel. In Sweden and some European city centers where below 10 ppm diesel fuel sulfur is readily available, more than 3,000 catalyzed diesel particulate filters have been introduced into retrofit applications without a single failure. Given the large number of vehicles participating in these test programs, the diversity of the vehicle applications which included intercity trains, airport buses, mail trucks, city buses and garbage trucks, and the extended time periods of operation (some vehicles have been operating with traps for more than 5 years and in excess of 300,000 miles[138]), there is a strong indication of the robustness of this technology on 10 ppm low sulfur diesel fuel. The field experience in areas where sulfur is capped at 50 ppm has been less definitive. In regions without extended periods of cold ambient conditions, such as the United Kingdom, field tests on 50 ppm cap low sulfur fuel have also been positive, matching the durability at 10 ppm, although sulfate PM emissions are much higher. However, field tests on 50 ppm fuel in Finland, where colder winter conditions are sometimes encountered (similar to many parts of the United States), showed a significant number of failures (~10 percent) due to trap plugging. This 10 percent failure rate has been attributed to insufficient trap regeneration due to fuel sulfur in combination with low ambient temperatures.[139] Other possible reasons for the high failure rate in Finland when contrasted with the Swedish experience appear to be unlikely. The Finnish and Swedish fleets were substantially similar, with both fleets consisting of transit buses powered by Volvo and Scania engines in the 10 to 11 liter range. Further, the buses were operated in city areas and none of the vehicles were operated in northern extremes such as north of the Arctic Circle.[140] Given that the fleets in Sweden and Finland were substantially similar, and given that ambient conditions in Sweden are expected to be similar to those in Finland, we believe that the increased failure rates noted here are due to the higher fuel sulfur level in a 50 ppm cap fuel versus a 10 ppm cap fuel.[141] Testing on an even higher fuel sulfur level of 200 ppm was conducted in Denmark on a fleet of 9 vehicles. In less than six months all of the vehicles in the Danish fleet had failed due to trap plugging.[142] The failure of some fraction of the traps to regenerate when operated on fuel with sulfur caps of 50 ppm and 200 ppm is believed to be primarily due to inhibition of the NO to NO_2 conversion as described here. Similarly the increasing frequency of failure with higher fuel sulfur levels is believed to be due to the further suppression of NO_2 formation when higher sulfur level diesel fuel is used.

As shown above, sulfur in diesel fuel inhibits NO oxidation leading to increased exhaust backpressure, reduced fuel economy, compromised reliability, and potentially engine damage. Therefore, we believe that, in order to ensure reliable and economical operation over a wide range of expected operating conditions, diesel fuel sulfur levels should be at or below 15 ppm. With these low sulfur levels we believe, as demonstrated by experience in Europe, that catalyzed diesel particulate filters will prove to be both durable and effective at controlling diesel particulate emissions. We did receive comments from the refining industry suggesting that PM filters could work on fuel sulfur levels as high as 50 ppm. The commenters pointed to some specific test programs where fuel with an approximate average sulfur level of 30 ppm was used as evidence of the robustness of the technology on higher sulfur fuels. While we do not deny that it is possible to operate some vehicles in limited applications over defined driving cycles on fuel as high as 30 ppm, we do not believe that this limited data should be the basis for a national program. The reality that some vehicles do fail on 50 ppm cap fuel, as demonstrated by the Finish fleet results mentioned above, shows that durability is not assured with the use of higher sulfur diesel fuel. We believe that the evidence, as a whole, shows that oxidation of NO to NO_2 will be poisoned due to these higher fuel sulfur levels with a resulting significant possibility of PM trap failures that is too great a concern for us to feel confident about a fuel sulfur level higher than 15 ppm.

b. Loss of PM Control Effectiveness

In addition to inhibiting the oxidation of NO to NO_2, the sulfur dioxide (SO_2) in the exhaust stream is itself oxidized to sulfur trioxide (SO_3) at very high conversion efficiencies by the precious metals in the catalyzed particulate filters. The SO_3 serves as a precursor to the formation of hydrated sulfuric acid ($H_2SO_4+H_2O$), or sulfate PM, as the exhaust leaves the vehicle tailpipe. Virtually all of the SO_3 is converted to sulfate under dilute exhaust conditions in the atmosphere as well in the dilution tunnel used in heavy-duty engine testing. Since virtually all sulfur present in diesel fuel is converted to SO_2, the precursor to SO_3, as part of the combustion process, the total sulfate PM is directly proportional to the amount of sulfur present in diesel fuel. Therefore, even though diesel particulate filters are very effective at trapping the carbon and the SOF portions of the total PM, the overall PM reduction efficiency of catalyzed diesel particulate filters drops off rapidly with increasing sulfur levels due to the formation of sulfate PM downstream of the trap.

[137] Through tax incentives 50 ppm cap sulfur fuel is widely available in the United Kingdom and 10 ppm sulfur is available in Sweden and in certain European city centers.

[138] Allansson, et al. SAE 2000-01-0480

[139] Letter from Dr. Barry Cooper, Johnson Matthey, to don Kopinski, US EPA, Air Docket A-99-06.

[140] Telephone conversation between Dr. Barry Cooper, Johnson Matthey, and Todd Sherwood, EPA, Air Docket A-99-06.

[141] The average temperature in Helsinki, Finland, for the month of January is 21° F. The average temperature in Stockholm, Sweden, for the month of juanuary is 21° F. The average temperature at the University of Michigan in Ann Arbor, Michigan, for the month of January is 24° F. The temperatures reported here are from www.worldclimate.com based upon the Global Historical Climatology Network (GHCN) produced jointly by the National Climatic Data Center and Carbon Dioxide Information Analysis Center at Oak Ridge National Laboratory (ORNL).

[142] Letter from Dr. Barry Cooper to Don Kopinski US EPA, Air Docket A-99-06.

SO_2 oxidation is promoted across a catalyst in a manner very similar to the oxidation of NO, except it is converted at higher rates, with peak conversion rates in excess of 50 percent. The SO_2 oxidation rate for a platinum based oxidation catalyst typical of the type which might be used in conjunction with, or as a washcoat on, a catalyzed diesel particulate filter can vary significantly with exhaust temperature. At the low temperatures typical of some urban driving and the heavy-duty federal test procedure (HD-FTP), the oxidation rate is relatively low, perhaps no higher than ten percent. However at the higher temperatures that might be more typical of highway driving conditions and the Supplemental Emission Test (also called the EURO III or 13 mode test), the oxidation rate may increase to 50 percent or more. These high levels of sulfate make across the catalyst are in contrast to the very low SO_2 oxidation rate typical of diesel exhaust (typically less than 2 percent). This variation in expected diesel exhaust temperatures means that there will be a corresponding range of sulfate production expected across a catalyzed diesel particulate filter.

The US Department of Energy in cooperation with industry conducted a study entitled DECSE to provide insight into the relationship between advanced emission control technologies and diesel fuel sulfur levels. Interim report number four of this program gives the total particulate matter emissions from a heavy-duty diesel engine operated with a diesel particulate filter on several different fuel sulfur levels. A straight line fit through this data is presented in Table III.F-1 below showing the expected total direct PM emissions from a heavy-duty diesel engine on the supplemental emission test cycle.[143] The data can be used to estimate the PM emissions from heavy-duty diesel engines operated on fuels with average fuel sulfur levels in this range.

TABLE III.F-1.—ESTIMATED PM EMISSIONS FROM A HEAVY-DUTY DIESEL ENGINE AT THE INDICATED FUEL SULFUR LEVELS

Fuel sulfur [ppmm]	Supplemental emission test performance	
	Tailpipe PM[b] [g/bhp-hr]	PM increase relative to 3 to 3 ppm sulfur
3	0.003	
7[a]	0.006	100%
15[a]	0.009	200%
30	0.017	470%
150	0.071	2300%

[a] The PM emissions at these sulfur levels are based on a straight-line fit to the DECSE data; PM emissions at other sulfur levels are actual DECSE data. (Diesel Emission Control Sulfur Effects (DECSE) Program—Phase II Interim Data Report No. 4, Diesel Particulate Filters-Final Report, January 2000. Table C1.) Although DECSE tested diesel particulate filters at these fuel sulfur levels, they do not conclude that the technology is feasible at all levels, but they do note that testing at 150 ppm is a moot point as the emission levels exceed the engine's baseline emission level.

[b] Total exhaust PM (soot, SOF, sulfate).

Table III.F-1 makes it clear that there are significant PM emission reductions possible with the application of catalyzed diesel particulate filters and low sulfur diesel fuel. At the observed sulfate PM conversion rates, the DECSE program results show that the 0.01 g/bhp-hr total PM standard is feasible for diesel particulate filter equipped engines operated on fuel with a sulfur level at or below 15 ppm. The results also show that diesel particulate filter control effectiveness is rapidly degraded at higher diesel fuel sulfur levels due to the high sulfate PM make observed with this technology. It is clear that PM reduction efficiencies are limited by sulfur in diesel fuel and that, in order to realize the PM emissions benefits sought in this rule, diesel fuel sulfur levels must be at or below 15 ppm. The data further indicates that were the fuel sulfur level set at a 30 ppm average, as some commenters suggested, the PM emissions from the controlled vehicles would be nearly three times the emissions from a vehicle operating on fuel with a 7 ppm average.

c. Increased Maintenance Cost for Diesel Particulate Filters Due to Sulfur

In addition to the direct performance and durability concerns caused by sulfur in diesel fuel, it is also known that sulfur can lead to increased maintenance costs, shortened maintenance intervals, and poorer fuel economy for particulate filters. Diesel particulate filters are highly effective at capturing the inorganic ash produced from metallic additives in engine oil. This ash is accumulated in the filter and is not removed through oxidation, unlike the trapped carbonaceous PM. Periodically the ash must be removed by mechanical cleaning of the filter with compressed air or water. This maintenance step is anticipated to occur on intervals of well over one hundred thousand miles. However, sulfur in diesel fuel increases this ash accumulation rate through the formation of metallic sulfates in the filter, which increases both the size and mass of the trapped ash. By increasing the ash accumulation rate, the sulfur shortens the time interval between the required maintenance of the filter and negatively impacts fuel economy.

2. Diesel NO_X Catalysts and the Need for Low Sulfur Fuel

All of the NO_X exhaust emission control technologies discussed previously in Section III are expected to utilize platinum to oxidize NO to NO_2 to improve the NO_X reduction efficiency of the catalysts at low temperatures or as in the case of the NO_X adsorber, as an essential part of the process of NO_X storage. This reliance on NO_2 as an integral part of the reduction process means that the NO_X exhaust emission control technologies, like the PM exhaust emission control technologies, will have problems with sulfur in diesel fuel. In addition, NO_X adsorbers have the added problem that the adsorption function itself is poisoned by the presence of sulfur. The resulting need to remove the stored sulfur (desulfate) leads to a need for extended high temperature operation which can deteriorate the NO_X adsorber. These limitations due to sulfur in the fuel affect the overall performance and feasibility of the technologies.

a. Sulfur Poisoning (Sulfate Storage) on NO_X Adsorbers

The NO_X adsorber technology relies on the ability of the catalyst to store NO_X as a nitrate (MNO_3) on the surface of the catalyst, or adsorber (storage) bed, during lean operation. Because of the similarities in chemical properties of SO_X and NO_X, the SO_2 present in the exhaust is also stored by the catalyst surface as a sulfate (MSO_4). The sulfate compound that is formed is significantly more stable than the nitrate compound and is not released and reduced during the NO_X release and reduction step (NO_X regeneration step). Since the NO_X adsorber is essentially 100 percent effective at capturing SO_2 in the adsorber bed, the sulfur build up on the adsorber bed occurs rapidly. As a result, sulfate compounds quickly occupy all of the NO_X storage sites on the catalyst

[143] Note that direct emisisons are those pollutants emitted directly from the engine or from the tailpipe depending on the context in which the term is used, and indirect emissions are those pollutants formed in the atmosphere through chemical reactions between direct emissions and other atmospheric constituents.

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thereby rendering the catalyst ineffective for NO_X storage and subsequent NO_X reduction (poisoning the catalyst).

The stored sulfur compounds can be removed by exposing the catalyst to hot (over 650°C) and rich (air-fuel ratio below the stoichiometric ratio of 14.5 to 1) conditions for a brief period.[144] Under these conditions, the stored sulfate is released and reduced in the catalyst.[145] While research to date on this procedure has been very favorable with regards to sulfur removal from the catalyst, it has revealed a related vulnerability of the NO_X adsorber catalyst. Under the high temperatures used for desulfation, the metals that make up the storage bed can change in physical structure. This leads to lower precious metal dispersion, or "metal sintering," (a less even distribution of the catalyst sites) reducing the effectiveness of the catalyst.[146] This degradation of catalyst efficiency due to high temperatures is often referred to as thermal degradation. Thermal degradation is known to be a cumulative effect. That is, with each excursion to high temperature operation, some additional degradation of the catalyst occurs.

One of the best ways to limit thermal degradation is by limiting the accumulated number of desulfation events over the life of the vehicle. Since the period of time between desulfation events is expected to be determined by the amount of sulfur accumulated on the catalyst (the higher the sulfur accumulation rate, the shorter the period between desulfation events) the desulfation frequency is expected to be proportional to the fuel sulfur level. In other words for each doubling in the average fuel sulfur level, the frequency and accumulated number of desulfation events are expected to double. We believe, therefore, that the diesel fuel sulfur level must be set as low as possible in order to limit the frequency and duration of desulfation events. Without control of fuel sulfur levels below 15 ppm, we can no longer conclude with any confidence that sulfur poisoning can be controlled without unrecoverable thermal degradation. Some commenters have suggested that the NO_X adsorber technology could meet the NO_X standard using diesel fuel with a 30 ppm average sulfur level. This would imply that the NO_X adsorber could tolerate as much as a four fold increase in desulfation frequency (when compared to an expected seven to 10 ppm average) without any increase in thermal degradation. This conclusion is inconsistent with our understanding of the technology that, with each desulfation event, some thermal degradation occurs. Therefore, we believe that diesel fuel sulfur levels must be at or below 15 ppm in order to limit the number and frequency of desulfation events. Limiting the number and frequency of desulfation events will limit thermal degradation and, thus, enable the NO_X adsorber technology to meet the NO_X standard.

Sulfur in diesel fuel for NO_X adsorber equipped engines will also have an adverse effect on fuel economy. The desulfation event requires controlled operation under hot and net fuel rich exhaust conditions. These conditions, which are not part of a normal diesel engine operating cycle, can be created through the addition of excess fuel to the exhaust. This addition of excess fuel causes an increase in fuel consumption. We have developed a spreadsheet model that estimates the frequency of desulfation cycles from published data and then estimates the fuel economy impact from this event.[147] Table III–F.2 shows the estimated fuel economy impact for desulfation of a NO_X adsorber at different fuel sulfur levels assuming a desired 90 percent NO_X conversion efficiency. The estimates in the table are based on assumed average fuel sulfur levels associated with different sulfur level caps. Note that, although we can estimate the fuel consumption penalty of operation on diesel fuel sulfur levels higher than 15 ppm, this analysis does not consider the higher degree of thermal degradation due to the more frequent desulfation events which are required for operation on these higher sulfur levels.

TABLE III.F–2.—ESTIMATED FUEL ECONOMY IMPACT FROM DESULFATION OF A 90% EFFICIENT NO_X ADSORBER

Fuel sulfur cap (ppm)	Average fuel sulfur (ppm)	Fuel economy penalty (in percent)
500	350	27
50	30	2

[144] Dou, Danan and Bailey, Owen, "Investigation of NO_X Adsorber Catalyst Deactivation," SAE 982594.

[145] Guyon M. et al, "Impact of Sulfur on NO_X Trap Catalyst Activity—Study of the Regeneration Conditions", SAE 982607.

[146] though it was favrosible to decompose sulfate at 800°C, performance of the NSR (NO_X Storage Reduction catalyst, *i.e.* NO_X Adsorber) catalyst decreased due to sintering of precious metal.—Asanuma, T. *et al*, "Influence of Sulfur Concentration in Gasoline on NO_X Storage—Reduction Catalyst", SAE 1999–01–3501.

[147] Memo from Byron Bunker, to docket A–99–06, "Estimating Fuel Economy Impacts of NO_X Adsorber De-Sulfurization."

TABLE III.F–2.—ESTIMATED FUEL ECONOMY IMPACT FROM DESULFATION OF A 90% EFFICIENT NO_X ADSORBER—Continued

Fuel sulfur cap (ppm)	Average fuel sulfur (ppm)	Fuel economy penalty (in percent)
25	15	1
15	7	<1
5	2	<<<1

The table highlights that the fuel economy penalty associated with sulfur in diesel fuel is noticeable even at average sulfur levels as low as 15 ppm and increases rapidly with higher sulfur levels. It also shows that the use of a NO_X adsorber with a 15 ppm sulfur cap fuel would be expected to result in a fuel economy impact due to the need for desulfation of the catalyst of less than one percent, absent other changes in engine design. However, as discussed in Section G below, we anticipate that other engine modifications could be made to offset this fuel economy impact. For example, a NO_X control device in the exhaust system could allow use of fuel saving engine strategies, such as advanced fuel injection timing, that could be used to offset the increased fuel consumption associated with the NO_X adsorber. The result is that low sulfur fuel enables the NO_X adsorber which, in turn, enables fuel saving engine modifications. The total emission control system fuel economy impact, which we estimate to be zero under a 15 ppm cap program, is discussed below in Section III.G.

Future improvements in the NO_X adsorber technology are expected and needed if the technology is to provide the environmental benefits we have projected today. Some of these improvements are likely to include improvements in the means and ease of removing stored sulfur from the catalyst bed. However because the stored sulfate species are inherently more stable than the stored nitrate compounds (from stored NO_X emissions), we expect that a separate release and reduction cycle (desulfation cycle) will always be needed in order to remove the stored sulfur. Therefore, we believe that fuel with a sulfur level at or below 15 ppm sulfur will be necessary in order to control thermal degradation of the NO_X adsorber catalyst and to limit the fuel economy impact of sulfur in diesel fuel.

b. Sulfate Particulate Production and Sulfur Impacts on Effectiveness of NO_X Control Technologies

The NO_X adsorber technology relies on a platinum based oxidation function in order to ensure high NO_X control efficiencies. As discussed more fully in section III.F.1, platinum based oxidation catalysts form sulfate PM from sulfur in the exhaust gases significantly increasing PM emissions when sulfur is present in the exhaust stream. The NO_X adsorber technology relies on the oxidation function to convert NO to NO_2 over the catalyst bed. For the NO_X adsorber this is a fundamental step prior to the storage of NO_2 in the catalyst bed as a nitrate. Without this oxidation function the catalyst will only trap that small portion of NO_X emissions from a diesel engine which is NO_2. This would reduce the NO_X adsorber effectiveness for NO_X reduction from in excess of 90 percent to something well below 20 percent. The NO_X adsorber relies on platinum to provide this oxidation function due to the need for high NO oxidation rates under the relatively cool exhaust temperatures typical of diesel engines. Because of this fundamental need for a catalytic oxidation function, the NO_X adsorber inherently forms sulfate PM when sulfur is present in diesel fuel, since sulfur in fuel invariably leads to sulfur in the exhaust stream.

The Compact-SCR technology, like the NO_X adsorber technology, uses an oxidation catalyst to promote the oxidation of NO to NO_2 at the low temperatures typical of much of diesel engine operation. As discussed above, there are substantial questions regarding the ability of SCR systems to be implemented successfully to meet the requirements finalized today. By converting a portion of the NO_X emissions to NO_2 upstream of the ammonia SCR reduction catalyst, the overall NO_X reductions are improved significantly at low temperatures. Without this oxidation function, low temperature SCR NO_X effectiveness is dramatically reduced making compliance with the NO_X standard impossible. As discussed previously in Section III, platinum group metals are known to be good catalysts to promote NO oxidation, even at low temperatures.[148] Therefore, future Compact-SCR systems would need to rely on a platinum oxidation catalyst in order to provide the required NO_X emission control. This use of an oxidation catalyst in order to enable good NO_X control means that Compact SCR systems will produce significant amounts of sulfate PM when operated on anything but the lowest fuel sulfur levels due to the oxidation of SO_2 to sulfate PM promoted by the oxidation catalyst.

Without the oxidation catalyst promoted conversion of NO to NO_2, neither of these NO_X control technologies can meet the NO_X standard set here. Therefore each of these technologies will require low sulfur diesel fuel to control the sulfate PM emissions inherent in the use of oxidation catalysts. The NO_X adsorber technology may be able to limit its impact on sulfate PM emissions by releasing stored sulfur as SO_2 under rich operating conditions. The Compact-SCR technology, on the other hand, has no means to limit sulfate emissions other than through lower catalytic function or lowering sulfur in diesel fuel. The degree to which the NO_X emission control technologies increase the production of sulfate PM through oxidation of SO_2 to SO_3 varies somewhat from technology to technology, but it is expected to be similar in magnitude and environmental impact to that for the PM control technologies discussed previously in section III.F.1, since both the NO_X and the PM control catalysts rely on precious metals to achieve the required NO to NO_2 oxidation reaction.

Thus, we believe that diesel fuel sulfur levels will need to be at or below 15 ppm in order to apply any of these NO_X control technologies. Without this low sulfur fuel, the NO_X control technologies are expected to create PM emissions well in excess of the PM standard regardless of the engine-out PM levels. Again, as noted with the PM control technologies, test results to date on catalysts with high oxidation potential indicate that were the fuel sulfur level set with a 30 ppm average, as some commenters suggested, the PM emissions from the controlled vehicles would increase nearly three fold over the level expected from fuel with a 7 ppm average, the average fuel sulfur level we would expect from a 15 ppm cap fuel (see Table III.F.1).

3. What About Sulfur in Engine Lubricating Oils?

Current engine lubricating oils have sulfur contents which can range from 2,500 ppm to as high as 8,000 ppm by weight. Since engine oil is consumed by heavy-duty diesel engines in normal operation, it is important that we account for the contribution of oil derived sulfur in our analysis of the need for low sulfur diesel fuel. One way to give a straightforward comparison of this effect is to express the sulfur consumed by the engine as an equivalent fuel sulfur level. This approach requires that we assume specific fuel and oil consumption rates for the engine. Using this approach, estimates ranging from two to seven ppm diesel fuel sulfur equivalence have been made for the sulfur contribution from engine oil.[149] [150] If values at the upper end of this range accurately reflect the contribution of sulfur from engine oil to the exhaust this would be a concern as it would represent 50 percent of the total sulfur in the exhaust under a 15 ppm diesel fuel sulfur cap (with an average sulfur level assumed to be approximately seven ppm). However, we believe that this simplified analysis, while valuable in demonstrating the need to investigate this issue further, overstates the likely sulfur contribution from engine oil by a significant amount due to its inclusion of engine oil lost through the open crankcase system in the estimate of oil consumption to the exhaust.

Current heavy-duty diesel engines operate with open crankcase ventilation systems which "consume" oil by carrying oil from the engine crankcase into the environment. This consumed oil is correctly included in the total oil consumption estimates, but should not be included in estimates of oil entering the exhaust system for this analysis, since as currently applied this oil is not introduced into the exhaust. At present we estimate that the majority of lube oil consumed by an engine meeting the 0.1 g/bhp-hr PM standard is lost through crankcase ventilation, rather than through the exhaust. Based on assumed engine oil to PM conversion rates and historic soluble organic fraction breakdowns we have estimated the contribution of sulfur from engine oil to be less than two ppm fuel equivalency. With our action to close the crankcase, coupled with the use of closed crankcase ventilation systems that separate in excess of 90 percent of the oil from the blow-by gases, we believe that this very low contribution of lube oil to sulfur in the exhaust can be maintained. For a further discussion of our estimates of the sulfur contribution from engine oil refer to the final RIA in the docket.

G. Fuel Economy Impact of High Efficiency Control Technologies

The high efficiency emission control technologies expected to be applied in order to meet the NO_X and PM standards involve wholly new system components integrated into engine designs and calibrations, and as such

[148] Platinum group metals include platinum, palladium, rhodium, and other precious metals.

[149] Whitacre, Shawn. "Catalyst Compatible" Diesel Engine Oils, DECSE Phase II, Presentation at DOE/NREL Workshop "Exploring Low Emission Diesel Engine Oils." January 31, 2000.

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may be expected to change the fuel consumption characteristics of the overall engine design. After reviewing the likely technology options available to the engine manufacturers, we believe that the integration of the engine and exhaust emission control systems into a single synergistic emission control system will lead to heavy-duty vehicles which can meet demanding emission control targets without increasing fuel consumption beyond today's levels.

1. Diesel Particulate Filters and Fuel Economy

Diesel particulate filters are anticipated to provide a step-wise decrease in diesel particulate (PM) emissions by trapping and oxidizing the diesel PM. The trapping of the very fine diesel PM is accomplished by forcing the exhaust through a porous filtering media with extremely small openings and long path lengths.[151] This approach results in filtering efficiencies for diesel PM greater than 90 percent but requires additional pumping work to force the exhaust through these small openings. The additional pumping work is anticipated to increase fuel consumption by approximately one percent.[152] However, we believe this fuel economy impact can be regained through optimization of the engine—PM trap—NO_X adsorber system, as discussed below.

2. NO_X Control Technologies and Fuel Economy

NO_X adsorbers are expected to be the primary NO_X control technology introduced in order to provide the reduction in NO_X emissions envisioned in this rulemaking. NO_X adsorbers work by storing NO_X emissions under fuel lean operating conditions (normal diesel engine operating conditions) and then by releasing and reducing the stored NO_X emissions over a brief period of fuel rich engine operation. This brief periodic NO_X release and reduction step is directly analogous to the catalytic reduction of NO_X over a gasoline three-way catalyst. In order for this catalyst function to occur the engine exhaust constituents and conditions must be similar to normal gasoline exhaust constituents. That is, the exhaust must be fuel rich (devoid of excess oxygen) and hot (over 250°C). Although it is anticipated that diesel engines can be made to operate in this way, it is assumed that fuel economy while operating under these conditions will be worse than normal. We have estimated that the fuel economy impact of the NO_X release and reduction cycle would, all other things being equal, increase fuel consumption by approximately one percent. Again, we believe this fuel economy impact can be regained through optimization of the engine—PM trap—NO_X adsorber system, as discussed below.

In addition to the NO_X release and regeneration event, another step in NO_X adsorber operation may affect fuel economy. As discussed earlier, NO_X adsorbers are poisoned by sulfur in the fuel even at the low sulfur levels mandated here. As discussed in the RIA, we anticipate that the sulfur poisoning of the NO_X adsorber can be reversed through a periodic "desulfation" event. The desulfation of the NO_X adsorber is accomplished in a similar manner to the NO_X release and regeneration cycle described above. However it is anticipated that the desulfation event will require extended operation of the diesel engine at rich conditions.[153] This rich operation will, like the NO_X regeneration event, require an increase in the fuel consumption rate and will cause an associated decrease in fuel economy. With a 15 ppm fuel sulfur cap, we are projecting that fuel consumption for desulfation would increase by one percent or less, which we believe can be regained through optimization of the engine-PM trap-NO_X adsorber system as discussed below.

While NO_X adsorbers require non-power producing consumption of diesel fuel in order to function properly and, therefore, have an impact on fuel economy, they are not unique among NO_X control technologies in this way. In fact NO_X adsorbers are likely to have a very favorable NO_X to fuel economy trade-off when compared to other NO_X control technologies like cooled EGR and injection timing retard that have historically been used to control NO_X emissions. Today, most diesel engines rely on injection timing control (retarding injection timing) in order to meet the 4.0 g/bhp-hr NO_X emission standard. For 2004 model year compliance, we expect that engine manufacturers will use a combination of cooled EGR and injection timing control to meet the 2.0 g/bhp-hr NO_X standard. Because of the more favorable fuel economy trade-off for NO_X control with EGR when compared to timing control, we have forecast that less reliance on timing control will be needed in 2004. Therefore, fuel economy will not be changed even at this lower NO_X level.

NO_X adsorbers have a significantly more favorable NO_X to fuel economy trade-off when compared to cooled EGR or timing retard alone, or even when compared to cooled EGR and timing retard together.[154] Current NO_X adsorber data show greater than 90 percent reduction in NO_X emissions over the SET, while only increasing fuel consumption by a very reasonable two percent. Further the data show that, for significant portions of the engine's typical operating range, NO_X control in excess of 98 percent is possible even with engine-out emissions as high as 5 g/bhp-hr.[155] Therefore, we expect manufacturers to take full advantage of the NO_X control capabilities of the NO_X adsorber and project that they will decrease reliance on technologies with a less favorable emissions to fuel economy trade-off, especially injection timing retard, when operating at conditions where the NO_X adsorber performance is significantly greater than 90 percent. We would therefore predict that the fuel economy impact currently associated with NO_X control from timing retard would be decreased by at least three percent. In other words, through the application of advanced NO_X emission control technologies, which are enabled by the use of low sulfur diesel fuel, we expect the NO_X - trade-off with fuel economy to continue to improve significantly when compared to today's technologies. This will result in both much lower NO_X emissions, and potentially overall improvements in fuel economy. Improvements could easily offset the fuel consumption of the NO_X adsorber itself and, in addition, the one percent fuel economy loss projected to result from the application of PM filters. Consequently, we are projecting no fuel economy penalty to result from this rule.

3. Emission Control Systems for 2007 and Net Fuel Economy Impacts

We anticipate that, in order to meet the stringent NO_X and PM emission standards set today, the engine manufacturers will integrate engine-based emission control technologies and post-combustion emission control technologies into a single systems-based approach that will fundamentally shift historic trade-offs between emissions control and fuel economy. As outlined in the preceding two sections, individual components in this system will introduce new constraints and opportunities for improvements in fuel efficient control of emissions. Having considered the many opportunities to fundamentally improve these relationships, we believe that it is unlikely that fuel economy will be lower than today's levels and, in fact, may improve through the application of these new technologies and this new systems approach. Therefore, for our analysis of economic impacts in Section V, no penalty or benefit for changes to fuel economy are considered.

H. Review of the Status of Heavy-Duty Diesel NO_X Emission Control Technology

In the NPRM, we provided a detailed technical evaluation of test data and other information that concluded that the proposed program would be technologically feasible for all heavy-duty engines. During the public comment period, we received many comments as well as additional information about the likely status and capability of emission control technology development in the 2007 time frame. To this information we have added our own updated evaluation of test data as well as technical information developed by ourselves and others.

Based on this information, and as discussed in Sections III.E and III.F above, we now have an even higher degree of confidence that manufacturers will be able to meet the new heavy-duty standards. Manufacturers of heavy-duty gasoline engines will apply essentially the same technology that is being developed for light-duty trucks under the Tier 2 program and should not have major problems doing so, especially given the significant available lead time. Regarding diesels, although the technological challenges are somewhat greater than for gasoline engines, we believe that manufacturers will achieve the engine standards adopted today for 2007 and later years, in conjunction with the low sulfur diesel fuel we are also requiring.

As we discussed earlier, there are two primary technologies that diesel engine manufacturers expect to use to meet the standards adopted in today's rule, and they are at different stages of commercial development. Catalyzed diesel PM trap technologies are in widespread fleet testing today, we have shown that there are no serious impediments to the widespread application of this technology to heavy-duty diesel engines that can meet our new standards by 2007, if not earlier. Diesel NO_X adsorber technology, the emission control technology we believe will be used for heavy-duty diesel engines to meet the very low NO_X emission standards adopted today, is less developed relative to PM control technology. Still, as we discussed earlier, we have identified a clear technological pathway to compliance with the NO_X standards using NO_X adsorber technology. While we do not anticipate major obstacles in commercializing these systems by 2007, it is important that the various parties in the industry continue to make good progress in their development of NO_X adsorber technology for heavy-duty diesel engines.

As a mechanism for monitoring and evaluating this technological progress, we believe it will be important to publicly reassess the status of heavy-duty diesel NO_X adsorber systems on an ongoing basis. To accomplish this, we will conduct regular biennial reviews of the status of heavy-duty NO_X adsorber technology. For each review, we will collect and analyze information from engine manufacturers, NO_X adsorber manufacturers, our own testing, and other sources. At the end of each review cycle, we will release (and post on the Web) a report discussing the status of the technology and any implications for the heavy-duty engine emission control program. We will release the first report by December 31, 2002 and subsequent reports at the end of each second year through December 31, 2008. This biennial process is similar to that used by the State of California to monitor and evaluate their emission control programs.

IV. Our Program for Controlling Highway Diesel Sulfur

With today's action, we are requiring substantial reductions in highway diesel fuel sulfur levels nationwide, because sulfur significantly inhibits the ability of the diesel emission control devices to function which are necessary to meet the emission standards finalized today. With the highway diesel fuel sulfur standard we are finalizing today, we have concluded that there will be technology available to achieve the reductions required by the stringent emission standards we are implementing for model year 2007 and later heavy-duty engines.

In developing the provisions of the fuel program being adopted today, we identified several goals that we want the program to achieve. First, we must ensure that there will be an adequate supply of highway diesel fuel for all vehicles. Second, we must ensure that low sulfur diesel fuel will be readily available nationwide for the 2007 and later model year heavy-duty vehicles that need it. Finally, we want to ensure a smooth transition to low sulfur fuel.

In the NPRM, we proposed that refiners be required to start producing all of their highway diesel fuel at the 15 ppm sulfur level beginning in 2006. We also requested comment on a range of options for transitioning to the low sulfur diesel fuel over time. With regard to the programmatic goals noted above, the proposed approach, which would have required all highway diesel fuel to meet the 15 ppm sulfur standard in 2006, guaranteed availability of the low sulfur diesel fuel throughout the nation. However, many commenters stated concerns that the proposed program would not ensure adequate overall supplies of highway diesel fuel, especially if some refiners chose not to continue producing highway diesel fuel to avoid the changes needed to meet the low sulfur levels.

The final diesel fuel program we are adopting today includes flexibilities for the refining industry as a whole, as well as additional flexibilities for refiners experiencing hardship circumstances. First, the program gives refiners a temporary compliance option for low sulfur diesel fuel beginning in mid-2006. The final program also includes additional flexibilities for refineries located in certain western states (the Geographic Phase-In Area (GPA)[156]), provisions for qualifying small refiners, and a general hardship provision for which any refiner may apply under certain conditions. These flexibilities ensure that the vast majority of refiners nationwide can fully comply at the earliest possible date while avoiding an excessive burden on a subset of refiners. The following section details each of the requirements of the highway diesel fuel program for refiners and importers, summarizes the analyses we have performed on the impacts of the temporary compliance option being adopted today, and describes additional information we have received that supports the changes made to the proposed program. Section VII provides additional information about the

[150] This estimate assumes that a heavy-duty diesel engine consumes 1 quart of engine oil in 2,000 miles of operation, consumes fuel at a rate of 1 gallon per 6 miles of operation and that engine oil sulfur levels range from 2,000 to 8,000 ppm.

[151] Typically, the filtering media is a porous ceramic monolith or a metallic fiber mesh.

[152] Engine, Fuel, and Emissions Engineering, Incorporated, "Economic Analysis of Diesel Aftertreatment System Changes Made Possible by Reduction of Diesel Fuel Sulfur Content," December 14, 1999, Air Docket A–99–06.

[154] Zelenka, P. *et al*, Cooled EGR—A Key Technology for Future Efficient HD Diesels, SAE 980190, Society of Automotive Engineers 1998. Figure 2 from this paper gives a graphical representation of how new technologies (including exhaust emission control technologies) can shift the trade-off between NO_X emissions and fuel economy.

[155] "2007 Diesel Emission Test Program, Initial Test Report," December 11, 2000, Air Docket A–99–06, Item IV–A–29.

[156] As defined in the Tier 2 final rulemaking (see 65 FR 6698, February 10, 2000), the GPA encompasses the states of Alaska, Colorado, Idaho, Montana, New Mexico, North Dakota, Utah and Wyoming. Note that minor changes to this area are currently under consideration. Any such changes subsequent to today's rule are intended to be carried over into today's rule as well.

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compliance and enforcement provisions that will accompany these requirements.

We believe the highway diesel fuel program we are adopting today meets all of the programmatic goals noted above. We believe that the final program will ensure that the overall supply of highway diesel fuel will be sufficient for all vehicles. To the extent there may have been supply concerns with a complete fuel turnover to low sulfur diesel in 2006 as some commenters have suggested, the flexibilities for refiners contained in the final program will serve as a "safety valve" by allowing up to 25 percent of the highway diesel fuel to remain at the current 500 ppm sulfur standard and providing additional time, if needed, for some refiners to fully convert over to low sulfur fuel. The combination of flexibilities provided to refiners in today's final rule should eliminate any concerns about the potential for supply shortfalls of highway diesel fuel. The final diesel fuel program is carefully structured so that we are confident there will be widespread availability of low sulfur fuel across the nation for 2007 and later model heavy-duty vehicles. In this way, the important health benefits of this program to people throughout the country can be achieved expeditiously, at a reasonable cost, while minimizing the burden on the affected industries.

This section also summarizes our technical feasibility analysis of the low sulfur highway diesel fuel program, and the impact of the program on other fuel properties and specialty fuels. Finally, the following section describes how state programs will be affected by today's action including a provision that allows the State of Alaska the option of developing an alternative transition plan for implementing low sulfur fuel.

A. Highway Diesel Sulfur Standards for Refiners and Importers

The requirements of the highway diesel fuel sulfur control program will become effective in time to be available with the introduction of the first heavy-duty engines meeting the model year 2007 and later engine standards we are adopting today. The following paragraphs describe the requirements, standards, and deadlines that apply to refiners and importers of highway diesel fuel and the options available to all refiners.

1. *Standards and Deadlines That Refiners and Importers Must Meet*

As described earlier in Section III.H. above, the new standards being adopted today for heavy-duty engines will begin with the 2007 model year. With today's action, we are adopting specific dates when fuel intended to be marketed as low sulfur diesel fuel must be produced at the refinery, distributed at the terminal level, and marketed at the retail level. Refiners and importers are required to produce highway diesel fuel meeting the 15 ppm sulfur standard beginning June 1, 2006.[157] At the terminal level, highway diesel fuel sold as low sulfur fuel is required to meet the 15 ppm sulfur standard beginning July 15, 2006. For retail stations and wholesale purchaser-consumers, highway diesel fuel sold as low sulfur fuel must meet the 15 ppm sulfur standard by September 1, 2006.

In the NPRM, we proposed a set of compliance dates slightly earlier than the dates contained in today's final rule. Under the proposal, refiners, terminals and retailers would have had to begin producing low sulfur diesel fuel by April 1, 2006, May 1, 2006 and June 1, 2006, respectively. Several commenters pointed out that the April introduction date for refiners occurred at the same time refiners would be changing over from winter to summer gasoline to comply with Reid Vapor Pressure (RVP) requirements. They recommended that the introduction of low sulfur diesel fuel be delayed for a couple of months to provide refiners and the distribution system the opportunity to focus on the two conversions separately and ensure that each occurs as designed. Commenters also suggested that we extend the time period between the refinery and downstream deadlines to better allow for the time it may take the distribution system to make a complete transition to the 15 ppm sulfur level.

In response to these concerns, today's action provides a few additional months for introduction of the low sulfur diesel fuel compared to the NPRM and provides an additional month between the refinery and retail compliance dates, to provide a smoother transition through the distribution system. We believe the additional time provides appropriate relief for the refiners, while still assuring that low sulfur diesel fuel will be available at the retail level no later than September 1, 2006. This schedule will allow manufacturers to introduce 2007 and later model year diesel engines and vehicles as early as September 1, 2006. While a slight delay from the dates of the proposal, the Agency does not believe this delay will place any undue burden on the engine manufacturers. Historically, new heavy-duty vehicle models were introduced on or around January 1 (of the same calendar year as the model year). Only recently, manufacturers have begun introducing some model lines earlier, particularly light heavy-duty vehicles.

In the NPRM, we proposed that all highway diesel fuel be required to comply with the 15 ppm sulfur standard starting in 2006. Today's program includes a combination of flexibilities available to refiners to ensure a smooth transition to low sulfur highway diesel fuel. Refiners can take advantage of a temporary compliance option, including an averaging, banking and trading component, beginning in June 2006 and lasting through 2009, with credit given for early compliance before June 2006. Under this option, up to 20 percent of highway diesel fuel may continue to be produced at the existing 500 ppm sulfur maximum standard, though it must be segregated from 15 ppm fuel in the distribution system, and may only be used in pre-2007 model year heavy-duty vehicles. We are providing additional hardship provisions for small refiners to minimize their economic burden in complying with the 15 ppm sulfur standard and giving additional flexibility to refiners subject to the Geographic Phase-in Area (GPA) provisions of the Tier 2 gasoline sulfur program, which will allow them the option of staggering their gasoline and diesel investments. Finally, we are adopting a general hardship provision for which any refiner may apply on a case-by-case basis under certain conditions. These hardship provisions, coupled with the temporary compliance option, will provide a "safety valve" allowing up to 25 percent of highway diesel fuel produced to remain at 500 ppm for these transitional years to effectively address the concerns over highway diesel fuel supply.

It should be noted that the requirements of the fuel program described below apply to refiners and importers only.[158] We are not adopting any retailer availability requirements

[157] Highway diesel fuel (referred to as motor vehicle diesel fuel in the regulatory language to be consistent with language in existing laws and regulations) includes any diesel fuel or any distillate product that is used, intended for use, or made available for use as a fuel in highway diesel vehicles or engines that are subject to the standards finalized today. However, kerosene or other distillates such as JP–8 are only considered to be highway diesel fuel and thus subject to our program at the point in the production or distribution system that they are either designated as such, or otherwise used, intended for use, or made available for use in highway diesel vehicles. Thus, if refiners do not designate these other distillates as highway diesel fuel, they are not subject to the 15 ppm sulfur standard.

[158] As described above, distributors and retailers marketing low sulfur diesel fuel have deadlines for compliance with the sulfur standards, as well as other requirements such as pump labeling. Section VII of today's action provides further details on the downstream requirements for distributors and retailers.

with these provisions. In other words, we are not requiring that diesel retailers sell the 15 ppm fuel. Rather, retailers may sell 15 ppm sulfur diesel fuel, 500 ppm sulfur diesel fuel, or both. We believe the program being adopted today for refiners and importers will ensure that adequate supplies of low sulfur diesel fuel are available throughout the nation. The voluntary compliance and hardship provisions have been designed with a required level of production that we believe will ensure that 15 ppm fuel is distributed widely through pipelines and at terminals throughout the country without the need for a retailer availability requirement. Our analysis supporting the design of these provisions can be found in Chapter IV of the RIA for today's action.

2. *Temporary Compliance Option for Refiners and Importers*

We believe there are several advantages to allowing some flexibility in the early years of the program such that not all of the highway diesel fuel pool must be converted to low sulfur diesel fuel at one time. First, some commenters expressed concerns over adequate supplies of highway diesel fuel if the entire pool converted to low sulfur diesel fuel in 2006, because they believe some refiners might produce less total highway diesel fuel volume or choose to leave the highway diesel fuel market altogether. Allowing the temporary compliance option lowers this concern because a portion of the highway diesel pool can remain at the current 500 ppm sulfur standard, if necessary, providing additional time for the market to adjust. This portion of the highway diesel pool that refiners choose to delay will likely be the portion that is more costly for them to desulfurize and, thus, most likely to raise concerns with respect to shortfalls. Second, a temporary compliance option can benefit refiners by reducing the fuel production costs in the early years of the program, because refiners are able to spread out their capital investments. The option also benefits refiners by spreading out the industry-wide demand for engineering and construction resources over several years, and also by allowing more time between the gasoline sulfur and diesel sulfur compliance dates. Third, refiners that are able to delay investment could attain lower costs for such equipment as technology improvements are realized during that time and as refiners see how well the desulfurization technologies achieve the 15 ppm sulfur standard.

The primary emissions benefits of low sulfur highway diesel fuel are the emissions reductions that will occur over time as new vehicles designed to meet the emission standards adopted today are introduced into the vehicle fleet. Consequently, in the NPRM we requested comment on several options that would allow refiners and importers to phase in the production of low sulfur highway diesel fuel. With today's action, we are adopting a temporary compliance option for refiners and importers that will allow them to produce less than 100 percent of their highway diesel fuel at the 15 ppm sulfur level. Refiners and importers may choose to participate in the compliance option on a refinery-by-refinery basis. A refiner must demonstrate compliance with the compliance option on an annual basis. Refiners with special financial hardships have additional flexibility provisions, which are described further in Section IV.C.

We believe today's temporary compliance option in combination with the hardship provisions discussed in Section IV.C. has the potential to provide flexibility to more than half of all U.S. refineries by allowing up to 25 percent[159] of the highway diesel fuel volume in the country to continue to be produced at the current sulfur level of 500 ppm. We estimate that refiners will be able to save as much as $1.7 billion over the duration of the optional compliance program compared to the proposed requirement that all highway diesel fuel comply with 15 ppm sulfur in 2006. Much, but not all, of this potential savings will be offset by increased costs in the distribution system. We project that in total a small overall savings should result from refiners taking advantage of the temporary compliance option.

Under the temporary compliance option finalized today, a refinery may produce up to 20 percent of its total highway diesel fuel at the existing highway diesel fuel sulfur standard of 500 ppm, determined on an annual basis. The remaining 80 percent of the highway diesel fuel produced at that refinery during the year must meet a sulfur standard of 15 ppm.[160] As part of this temporary compliance option, a PADD-based averaging, banking, and trading (ABT) program will be available. Figure IV–1 presents the five PADDs into which the United States is divided.[161] For example, a refinery could produce more than 80 percent of its highway diesel fuel as low sulfur diesel fuel and generate credits based on the volume of highway diesel fuel produced at 15 ppm that exceeded the 80 percent requirement. Within that same PADD (within the limits noted below for California, Alaska, Hawaii, and any state with an EPA-approved waiver from the federal program), these credits may be averaged with another refinery owned by that refiner, banked for use in future years, or sold to another refinery.

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[159] Up to 5 percent of which is small refiner production.

[160] We are aware that today there are refiners that produce one grade of diesel fuel for both highway and off-highway purposes, where dye is added by parties downstream if it is to be sold as off-highway diesel fuel. To the extent possible, we do not want to interfere with this practice. Consequently, for purposes of determining compliance with these optional requirements, a refiner producing all 15 ppm fuel may include the entire volume it produces in the calculation. Furthermore, a refiner producing all 500 ppm fuel must count any diesel fuel produced with a sulfur content of 500 ppm or less unless it has been dyed by the refiner to be used as nonroad diesel fuel. A refiner would only include kerosene in its volume calculation if the kerosene is less than 500 ppm sulfur content and the kerosene is blended at the refinery into non-dyed fuel with a sulfur content of less than 500 ppm.

[161] The Department of Energy divides the United States into five Petroleum Administrative Districts for Defense, or PADDs. The states encompassed by each of the five PADDs are defined in the Code of Federal Regulations at Title 40, § 80.41.

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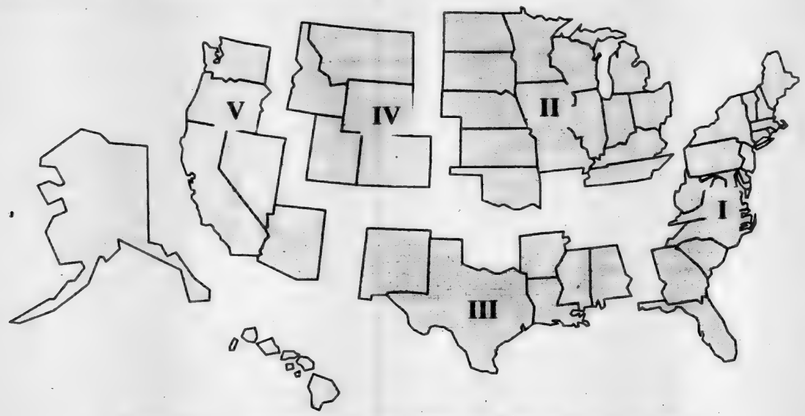


Figure IV-1. Petroleum Administrative Districts for Defense (PADDs)

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Also, a refinery may produce less than 80 percent of its highway diesel fuel at the 15 ppm sulfur level, as long as it obtains enough credits from another refinery within the PADD to offset the volume of 500 ppm sulfur fuel produced that exceeded the 20 percent of highway diesel fuel allowed to be produced at the 500 ppm sulfur level. As noted above, any credit trading will be limited to those refineries within the same PADD (within the limits noted below for California, Alaska, Hawaii, and any state with an EPA-approved waiver from the federal program). This restriction is necessary to limit the possibility that any area of the country is dominated by refineries complying via purchases of credits and, thus, producing a small volume of low sulfur diesel fuel, which could lead to concerns that the low sulfur diesel fuel would not be sufficiently available throughout the country.

Based on an extensive analysis which incorporates the hardship provisions and GPA refiner provisions discussed in Section IV.B. and C., we have chosen a level of 80 percent to have confidence that there will be widespread availability of 15 ppm fuel throughout the United States. Given the requirements of today's program, we believe that all pipelines are likely to carry the 15 ppm fuel. Pipelines that may be able to carry only one grade of highway diesel fuel are likely to carry 15 ppm as the majority diesel fuel in the market.[162] Those that are able to carry more than one grade of highway diesel fuel will facilitate the distribution of the remaining 500 ppm fuel. In addition, to ensure widespread availability of low sulfur diesel fuel throughout the nation, we have found it necessary to set the 15 ppm production threshold high enough so that there is a sufficient geographic scattering of refineries producing low sulfur diesel fuel around the country. At a lower threshold, there could be isolated regions of the country where 15 ppm fuel would not be available in sufficient quantities.

We have analyzed the refinery/pipeline distribution system in the United States in the context of the small refiner hardship and other provisions of the rule and believe a 80 percent temporary compliance option level for 15 ppm is necessary to achieve widespread availability and avoid shortages in specific areas. At levels below an 80 percent level, we would have concerns over whether 15 ppm sulfur diesel fuel would be the primary highway diesel fuel distributed through pipelines and whether the low sulfur diesel fuel would be available to all areas of the country in sufficient quantities. The reader is directed to Chapter IV of the RIA for today's action for our complete analysis supporting the development of the temporary compliance option.

[162] Today, many pipelines carry only one grade of distillate (e.g., only 500 ppm sulfur high diesel fuel) rather than both 500 ppm sulfur highway fuel and off-highway fuel which has even higher levels of sulfur (e.g., on the order of 3,000 ppm).

While we have set the minimum requirement under the compliance option at 80 percent, we believe most refineries will focus on production of one grade or the other. We expect that certain refineries will find it more economically advantageous to install the necessary equipment to produce all of their highway diesel fuel at the 15 ppm sulfur level and generate credits. Conversely, other refineries may find it advantageous to continue producing all of their highway diesel fuel at the 500 ppm sulfur fuel through the period of the compliance option, by obtaining credits to demonstrate compliance. This will provide additional time for those refiners that have not converted to low sulfur fuel. This will allow refiners to spread out their capital investments and provide more time to arrange for engineering and construction resources. In addition, the refiners that are able to delay investment could attain lower costs for such equipment as technology improvements are realized during that time and as refiners see how well the range of desulfurization technologies works to achieve the 15 ppm sulfur standard.

Foreign refiners may choose to participate in the temporary compliance option. For purposes of determining compliance with the low sulfur diesel requirements, foreign refiners must demonstrate compliance based on the amount of highway diesel fuel they import into the United States. Therefore, a given foreign refiner must demonstrate that at least 80 percent of the highway diesel fuel it imported into each PADD

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Figure IV-1. Petroleum Administrative Districts for Defense (PADDs)

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Also, a refinery may produce less than 80 percent of its highway diesel fuel at the 15 ppm sulfur level, as long as it obtains enough credits from another refinery within the PADD to offset the volume of 500 ppm sulfur fuel produced that exceeded the 20 percent of highway diesel fuel allowed to be produced at the 500 ppm sulfur level. As noted above, any credit trading will be limited to those refineries within the same PADD (within the limits noted below for California, Alaska, Hawaii, and any state with an EPA-approved waiver from the federal program). This restriction is necessary to limit the possibility that any area of the country is dominated by refineries complying via purchases of credits and, thus, producing a small volume of low sulfur diesel fuel, which could lead to concerns that the low sulfur diesel fuel would not be sufficiently available throughout the country.

Based on an extensive analysis which incorporates the hardship provisions and GPA refiner provisions discussed in Section IV.B. and C., we have chosen a level of 80 percent to have confidence that there will be widespread availability of 15 ppm fuel throughout the United States. Given the requirements of today's program, we believe that all pipelines are likely to carry the 15 ppm fuel. Pipelines that may be able to carry only one grade of highway diesel fuel are likely to carry 15 ppm as the majority diesel fuel in the market.[162] Those that are able to carry more than one grade of highway diesel fuel will facilitate the distribution of the remaining 500 ppm fuel. In addition, to ensure widespread availability of low sulfur diesel fuel throughout the nation, we have found it necessary to set the 15 ppm production threshold high enough so that there is a sufficient geographic scattering of refineries producing low sulfur diesel fuel around the country. At a lower threshold, there could be isolated regions of the country where 15 ppm fuel would not be available in sufficient quantities.

We have analyzed the refinery/pipeline distribution system in the United States in the context of the small refiner hardship and other provisions of the rule and believe a 80 percent temporary compliance option level for 15 ppm is necessary to achieve widespread availability and avoid shortages in specific areas. At levels below an 80 percent level, we would have concerns over whether 15 ppm sulfur diesel fuel would be the primary highway diesel fuel distributed through pipelines and whether the low sulfur diesel fuel would be available to all areas of the country in sufficient quantities. The reader is directed to Chapter IV of the RIA for today's action for our complete analysis supporting the development of the temporary compliance option.

[162] Today, many pipelines carry only one grade of distillate (*e.g.*, only 500 ppm sulfur high diesel fuel) rather than both 500 ppm sulfur highway fuel and off-highway fuel which has even higher levels of sulfur (*e.g.*, on the order of 3,000 ppm).

While we have set the minimum requirement under the compliance option at 80 percent, we believe most refineries will focus on production of one grade or the other. We expect that certain refineries will find it more economically advantageous to install the necessary equipment to produce all of their highway diesel fuel at the 15 ppm sulfur level and generate credits. Conversely, other refineries may find it advantageous to continue producing all of their highway diesel fuel at the 500 ppm sulfur fuel through the period of the compliance option, by obtaining credits to demonstrate compliance. This will provide additional time for those refiners that have not converted to low sulfur fuel. This will allow refiners to spread out their capital investments and provide more time to arrange for engineering and construction resources. In addition, the refiners that are able to delay investment could attain lower costs for such equipment as technology improvements are realized during that time and as refiners see how well the range of desulfurization technologies works to achieve the 15 ppm sulfur standard.

Foreign refiners may choose to participate in the temporary compliance option. For purposes of determining compliance with the low sulfur diesel requirements, foreign refiners must demonstrate compliance based on the amount of highway diesel fuel they import into the United States. Therefore, a given foreign refiner must demonstrate that at least 80 percent of the highway diesel fuel it imported into each PADD meets a 15 ppm sulfur level, or show that it has enough credits from other refiners in the PADD into which it imported the fuel to cover the volume of fuel below the 80 percent requirement. Foreign refineries may also generate credits if they exceed the 80 percent requirement in a given PADD, and may sell those credits within the same PADD. A foreign refiner may also choose to not participate in the temporary compliance option and, as described below, let the fuel importer be the party which demonstrates compliance.

Importers of highway diesel fuel (i.e., companies that import fuel but are not solely refiners) may also participate in the temporary compliance option. Importers must demonstrate that at least 80 percent of the highway diesel fuel imported into each PADD (within the limits noted below for California, Alaska, Hawaii, and any state with an EPA-approved waiver from the federal program) meets a 15 ppm sulfur level, or show that they have enough credits from other refiners in the PADD into which the fuel is imported to cover the volume of fuel below the 80 percent requirement. Importers may also generate credits if they exceed the 80 percent requirement in a given PADD. Importers that import highway diesel fuel from foreign refiners that are participating in the temporary compliance option must exclude the volume of fuel purchased from those refiners in their compliance calculations or credit generation calculations.

Because we expect most refineries to choose to produce fuel either all at the 15 ppm sulfur level or all at the 500 ppm sulfur level, credits will be generated by some refiners and desired by others. Thus, the ABT program will play an important part in achieving overall compliance. The details of the ABT program are described below.

a. Generating Credits

Beginning on June 1, 2006 and continuing through December 31, 2009, refineries and importers may generate credits based on the volume of low sulfur diesel fuel produced above the required percentage (i.e., 80 percent). One credit will be generated for every gallon of highway diesel fuel produced at 15 ppm sulfur that exceeds the 80 percent requirement. Credits will be calculated on a calendar-year basis. For example, if a refinery produces 10 million gallons of highway diesel fuel in 2007, it must produce 80 percent of its highway diesel volume (8 million gallons) as low sulfur during 2007. If the refinery actually produces 100 percent of its highway diesel fuel as low sulfur during 2007, it can generate credits based on the volume of the "extra" 20 percent of low sulfur fuel it produced above the required minimal percentage—that is, two million gallons of credits. Because the requirements for low sulfur fuel begin in the middle of 2006, a refinery will generate credits in 2006 based on the volume of low sulfur fuel produced beginning June 1, 2006 that exceeds 80 percent of the highway diesel fuel produced at its facility between June 1, 2006 and December 31, 2006. Once credits are generated by a refinery, they may be used by the refinery for averaging purposes with other refineries owned by the same refiner, traded to another refinery, or banked for use in future calendar year averaging or trading. Credits may only be used in the PADD in which they are generated, with the further limitations on credit generation and use in PADD V noted below for California, Alaska, and Hawaii.

Refineries may no longer generate credits after December 31, 2009. Beginning January 1, 2010, every refinery must either comply with the low sulfur diesel fuel requirements by (1) producing 100 percent of its highway diesel fuel at the 15 ppm sulfur level or (2) by using credits through May 31, 2010 to demonstrate compliance with the 100 percent requirement, provided that banked credits are available to the refinery (described in more detail below). Starting June 1, 2010, all refineries must produce 100 percent of their highway diesel fuel as low sulfur fuel (without the use of credits).

Finally, early credits, or credits from low sulfur fuel produced at a refinery prior to June 1, 2006, may be generated, but only under limited circumstances. Unlike in the Tier 2 program, where significant emission benefits accrued with the early introduction of low sulfur gasoline, very little emission benefit (only a small reduction in sulfate PM emissions from the in-use fleet) will result from the early introduction of 15 ppm diesel fuel. Consequently, the main purpose in allowing early credits under the diesel program is to smooth program implementation beginning June 1, 2006, by allowing a pool of credits to be available upon program startup. By allowing the generation of early credits, both purchasers and sellers of credits can have confidence in the legitimacy of the credits traded, which, in turn, allows for the purchaser to have increased confidence in their ability to rely on the ABT program for compliance. Consequently, beginning June 1, 2005 we will allow refineries to generate credits for any volume of highway diesel fuel produced which meets the 15 ppm cap. Any refiner that chooses to do so may bank these credits for later use during the compliance option years, or may trade them to other refineries within the same PADD for use during the compliance option years. The one restriction placed on the generation of these credits is that refiners will have to demonstrate that the 15 ppm fuel produced early is segregated in the distribution system and not commingled with current 500 ppm sulfur fuel. Only that volume that the refiner verifies was actually sold as 15 ppm fuel at retail or into centrally-fueled fleets will be eligible for early credits.

Providing refiners with an incentive to produce diesel fuel complying with the 15 ppm cap earlier than required will not only instill confidence in the ABT program under the temporary compliance option, but will also provide both refiners and the distribution system the opportunity to gain valuable experience prior to the start of the program with producing and distributing fuel meeting the 15 ppm cap. We believe that allowing early credit generation for one year prior to the start of the program will provide the opportunity for the generation of sufficient early credits to provide refiners with the program implementation flexibility they will need. If we allowed early credits to be generated in this manner for a longer time period, we are concerned that the significant amounts of early credits that could be generated could compromise availability of 15 ppm fuel at the startup of the program. Use of these credits after June 1, 2006 could affect the availability of low sulfur highway diesel fuel across the country when the 2007 model year heavy-duty engines are introduced in the market, because the amount of 500 ppm fuel could significantly exceed the 20 percent threshold allowed under our temporary compliance option.

The only situation in which we will allow for the generation of credits prior to June 1, 2005 is if a refiner demonstrates that the fuel will be used in vehicles certified to meet the 2007 particulate matter standard being adopted today for heavy-duty engines (0.01 g/bhp-hr) or in vehicles with retrofit technologies that achieve emission levels equivalent to the 2007 NO_X or PM standard verified as part of a retrofit program administered by EPA or a state. (Refer to section I.C.7 for more discussion on retrofit programs.) Under this situation, we will have confidence that emission benefits are in fact accruing early, along with the fuel sulfur credits. The early credit provision of this fuel program will complement the provisions that encourage the

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introduction of cleaner vehicles earlier than the 2007 model year, as discussed in Section III.D.

b. Using Credits

If a refinery does not meet the 80 percent minimum requirement for low sulfur highway diesel fuel with actual production at that refinery, the refinery will be able to use credits to demonstrate compliance with the 80 percent requirement. The use of credits is limited to credits generated by refineries within the same PADD (within the limits noted below for California, Alaska, Hawaii, and any state with an EPA-approved waiver from the federal program). Under the temporary compliance option, for every gallon of 500 ppm sulfur fuel produced by a refinery that exceeds the maximum allowed limit of 20 percent, the refinery must obtain one credit from another refinery within the same PADD or use banked credits (that were generated within the same PADD).

Although credits will not officially exist until the end of the calendar year (based on the generating refinery's actual low sulfur fuel production for that calendar year), refineries may contract with each other for credit sales prior to the end of the year, based on anticipated production. The actual trading of credits will not take place until the end of the year. All credit transfer transactions will have to be concluded by the last day of February after the close of the annual compliance period and each refinery must submit documentation (as described in Section VII.E.) demonstrating compliance with the appropriate volume of low sulfur highway diesel fuel. For example, a refinery that wishes to purchase credits from another refinery to comply with the 2007 required percentage of low sulfur fuel can do so based on the generating refinery's projections of low sulfur fuel production. By the end of February 2008, both the credit-purchasing refinery and the credit-selling refinery must reconcile the validity of the credits, and demonstrate compliance with the 80 percent requirement. As noted earlier, at the beginning of the program, the initial compliance period will begin on June 1, 2006 and end on December 31, 2006. For this initial period, refineries must submit documentation, by February 28, 2007, demonstrating compliance with the appropriate levels of low sulfur highway diesel fuel for the period between June 1, 2006 and December 31, 2006.

Because there could be situations where a refinery planning to use credits to comply with the minimum percentage of fuel required comes up short at the end of the year, we are adopting provisions that allow a limited amount of carryover, or "credit deficits." A refinery that does not meet the required percentage of low sulfur fuel production in a given year will be allowed to carry forward a credit deficit for one year, as long as the deficit does not exceed five percent of its annual highway diesel fuel production. However, the refinery will have to make up the credit deficit and come into compliance with the required low sulfur production percentage in the next calendar year, or the refinery will be in violation of the program requirements. This provision is intended to give some relief to refineries faced with an unexpected shutdown or that otherwise are unable to obtain sufficient credits to meet the required percentage of low sulfur fuel production.

With regard to credit trading, any person can act as a broker in facilitating credit transactions, whether or not such person is a refiner and/or importer, so long as the title to the credits are transferred directly from the refinery generating the credits to the refinery purchasing the credits. Whether credits are transferred directly from the generating refinery to the purchasing refinery, or through a broker, the refinery purchasing the credits should have sufficient information to fully assess the likelihood that credits are valid. Any credits that are traded to another refinery may, in turn, be traded to another refinery; however, the credits cannot be traded more than twice. We believe this provision is necessary because repeated transfers of credits would significantly reduce our ability to verify the validity of credits.

c. How Long Will Credits Last?

The goal of the ABT provisions is to provide additional flexibility to refiners in the early years of the low sulfur diesel fuel program. After the first few years of the program, there will be a significantly greater proportion of after-treatment-equipped vehicles in the fleet. It will be important to ensure a full transition to the new low sulfur fuel to prevent misfueling of those vehicles and preserve the environmental benefits of the program. Therefore, the ability of refineries to generate credits will end on December 31, 2009. Refineries will be allowed to use any available banked credits, including early credits, for fuel produced through May 31, 2010. Any remaining credits not used for the compliance period until May 31, 2010 will expire. Beginning June 1, 2010, all refineries must produce 100 percent of their highway diesel fuel at the 15 ppm sulfur level without the use of credits, and the ABT program will end.

d. Additional Limitations on Credit Trading for Some States

At this time we are adopting a low sulfur highway diesel fuel program that will apply throughout the United States, with trading of credits limited to those refineries located within the same PADD. Although we are adopting a diesel fuel program that currently will apply nationwide, it is possible that the State of California, or some other state, may adopt in the future a different highway diesel fuel program than that adopted today.[163] To assure that adequate supplies of low sulfur diesel fuel will be available throughout all regions of the country, we are adopting provisions that do not allow refineries located in states with a state-approved 15 ppm highway diesel sulfur program to participate in the credit program. In other words, credit trading is limited only to those refineries complying with the federal program. For example, without such provisions, if California were to adopt its own state program requiring the production of 15 ppm diesel fuel, we are concerned that it might be possible for California refineries to generate enough credits such that areas outside of California in PADD V are dominated by the production of 500 ppm sulfur diesel fuel, with little or no 15 ppm fuel available. This would be problematic for the model year 2007 and later heavy-duty engines designed to be operated on low sulfur fuel. The reader is directed to Chapter IV of the RIA for today's action for our complete analysis supporting the development of the temporary compliance option.

As discussed in Section IV.F. of this preamble, the State of Alaska, which is a part of PADD V, will have the opportunity to develop, and submit to us for approval, an alternative transition plan for implementing the low sulfur highway diesel fuel program. Such a plan will allow Alaska to develop a transition program tailored to its isolated market. If, for some reason, Alaska does not submit an alternative plan, or we do not approve the plan submitted by Alaska, then the federal program described in today's action will apply. In the event we do not approve an alternative plan for Alaska, based on our analysis of the likely response of refineries in Alaska to the temporary compliance option and because its fuel distribution system is essentially isolated from the rest of PADD V, we are

[163] See Section IV.F. for a discussion of preemption of state diesel sulfur requirements.

concerned that all of the fuel offered for sale in Alaska could be 500 ppm sulfur fuel if refineries in Alaska were allowed to purchase credits from other PADD V refineries. For this reason, under today's program, refineries in Alaska will be allowed to generate credits as described earlier. However, they may only sell credits to, or purchase credits from, other refineries in or importers of fuel to Alaska. We believe this will provide assurance that low sulfur highway diesel fuel will be sufficiently available in Alaska and will also reduce the chance that credits from Alaska will result in significantly less low sulfur diesel fuel in PADD V areas outside of Alaska. Again, these default provisions of the national program will only be effective in the event that we do not approve an alternate transition plan for Alaska.

Hawaii is in a similar situation to Alaska with regard to fuel distribution. Hawaii, which is part of PADD V, is an isolated market and we have similar concerns with regard to whether low sulfur diesel fuel would be available in Hawaii if the two refineries currently operating were able to purchase credits from other PADD V refineries and produce all 500 ppm sulfur fuel. For this reason, under today's program, the refineries in Hawaii will be allowed to generate credits as described earlier. However, they may only sell credits to, or purchase credits from, other refineries in or importers of fuel to Hawaii. We believe this will ensure that low sulfur highway diesel fuel will be available in Hawaii.

3. What Information Must Refiners/Importers Submit to Us?

To ensure a smooth transition to the program and to evaluate compliance once the program has begun, we are requiring refiners and importers to submit a variety of information to us. Section VII.E of this document and the regulatory language for today's action provide detailed description of the information that must be submitted and the dates when such submittals are due.[164]

First, refiners and importers that currently or in 2006 expect to produce or supply highway diesel fuel are required to register with us by December 31, 2001. This will inform us on the universe of refiners that we expect to participate in the highway diesel market once the program begins.

Second, to help facilitate the market for credit trading under the temporary compliance option, any refiner or importer planning to produce or import highway diesel in 2006, is required to submit to us an annual pre-compliance report. Refiners and importers are required to submit these annual pre-compliance reports from 2003 through 2005. These reports must contain estimates of the volumes of 15 ppm sulfur fuel and 500 ppm sulfur fuel that will be produced at each refinery, and, for those refineries planning to participate in the trading program, a projection of how many credits will be generated or must be used by each refinery. These pre-compliance reports must also contain information outlining each refinery's timeline for compliance and provide information regarding engineering plans (e.g., design and construction), the status of obtaining any necessary permits, and capital commitments for making the necessary modifications to produce low sulfur highway diesel fuel. Based on the information submitted by refiners and importers, we plan to issue an annual report that summarizes, in a way that protects the confidentiality of individual refiners and importers, the information contained in the pre-compliance reports. Our annual report will provide information, summarized and aggregated on a PADD basis, describing the volumes of 15 ppm and 500 ppm highway diesel planned to be produced, and estimates of the number of credits that refineries expect to generate or use. We believe this information will be important to refiners as they make plans for complying with the temporary compliance option. For example, this information will be useful in giving refiners a better indication of the potential market for credits and availability of credits in their PADD. To prevent the release of confidential information, our annual report will not contain any information on individual refinery compliance plans.

Third, refiners and importers are required to submit annual compliance reports that demonstrate compliance with the requirements of this final rule. The first annual compliance report is due by the end of February 2007 (for the period of June 1, 2006 through December 31, 2006) and is required annually through February 2011. The reports must show, on a refinery basis, the volumes of 15 ppm and 500 ppm sulfur highway diesel fuel produced at each refinery during the compliance period, the number of credits used (or generated) at each refinery to demonstrate compliance with the 80 percent requirement for low sulfur diesel fuel, and the sources of the credits used. The information submitted in the annual compliance reports must be segregated by PADD.

[164] As described in Sections IV.B., IV.C. and VII.E., small refiners and GPA refiners have special supplementary reporting requirements relating to the optional program they are participating in.

4. Impacts of the Highway Diesel Fuel Program

Based on analyses we have performed, as described in more detail below, we believe the temporary compliance provisions contained in today's final rule will assure adequate supplies of highway diesel fuel, will provide flexibility for refiners, and should result in lower costs for both refiners and consumers. In addition, we believe the temporary compliance provisions as adopted today will ensure sufficient availability of low sulfur highway diesel fuel to new vehicle owners who need it without the need for a retailer availability requirement, and should not lead to significant levels of misfueling and the associated loss of emission benefits. We have analyzed each of these issues in developing the final fuel program. A summary of our analyses and the conclusions we have drawn are discussed below. A detailed description of these analyses are contained in the RIA for today's action. In addition, a complete list of the comments related to a possible phase-in program and our response to those comments is included in the Response to Comments document for this final rule.

a. Ensures Adequate Supplies of Highway Diesel Fuel

We received several comments on the NPRM fuel program that suggested there would be a shortfall in the amount of highway diesel supply if all of the highway diesel fuel were required to meet a 15 ppm sulfur limit beginning in 2006. As described later in Section V.C., in response to these comments we analyzed the capability of the entire diesel fuel refining industry in the U.S. to adjust to the low sulfur fuel requirements. Based on this analysis, we believe that supplies of highway diesel fuel will be sufficient even if all highway diesel fuel were required to comply with the 15 ppm standard in 2006. The temporary compliance option included in today's rule is intended as a "safety valve" that, along with the hardship provisions discussed in Section IV.C.,will further help to ensure adequate supplies of highway diesel fuel beginning in 2006.

In performing the analysis of diesel fuel supply, we examined all diesel fuel refiners (including those that currently make only off-highway diesel fuel but not highway diesel fuel) to assess the likelihood of their investing in the production of 15 ppm highway diesel

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fuel. Using a refinery cost model, we made projections of the likely response by refineries to today's low sulfur requirements by estimating the cost for each refinery to produce low sulfur diesel fuel. The results of our analysis show that the overall supply of highway diesel fuel will continue to be adequate to meet market demands as refiners are required to start producing low sulfur highway diesel fuel. Most refineries that currently produce highway diesel fuel will produce about the same volume of low sulfur diesel fuel once the program takes effect. However, several refineries could economically expand their current highway diesel fuel production by shifting some of their off-highway production today, and a few others currently producing only off-highway diesel fuel could economically shift to some highway diesel production. Consequently, our analysis indicates that there is ample capability in the refining industry to continue to economically supply sufficient quantities of highway diesel fuel when today's program goes into effect. For a fuller discussion of this analysis, see Section V of this preamble and Chapter IV of the RIA.

If any potential for highway diesel fuel shortfalls exists by requiring all fuel to meet 15 ppm sulfur in 2006, as CRA's analysis suggests, we believe that allowing some continued supply of 500 ppm, as we are doing under the temporary compliance option and hardship provisions contained in today's action, addresses this concern. Since the final rule allows some transition period before the entire highway diesel pool is required to meet the 15 ppm sulfur standard, some refiners will not need to change their current operations and will be able to continue producing 500 ppm fuel during these years. Those refiners that delay production of low sulfur diesel fuel until the later years of the program will tend to be the refiners with the highest cost to comply and, thus, refiners that would otherwise have the greatest tendency not to invest and thereby impact supply. Refiners that begin producing low sulfur diesel fuel in the later years of the program will also be able to take advantage of ongoing improvements in desulfurization technology. Together, these factors will help avoid or reduce any potential losses in highway diesel fuel production when the program requires full compliance with low sulfur diesel fuel.

b. Ensures Widespread Availability of Low Sulfur Diesel Fuel

A major concern we noted in the NPRM regarding a fuel phase-in program was ensuring the widespread availability of low sulfur diesel fuel. Without an assurance of widespread availability, there would be concerns whether the 2007 and later model year heavy-duty vehicles that were designed to operate on low sulfur fuel would be able to purchase it in all parts of the country. If such vehicles were fueled with 500 ppm diesel fuel, the emission control systems could be irreversibly damaged and any benefit of the new emission standards could be eliminated (see Section III.F. above). Therefore, in setting the requirements for the temporary compliance option, we have analyzed the likelihood that fuel will be widely available so that 2007 and later model year heavy-duty vehicles will be able to find low sulfur fuel in all local markets across the country. To achieve this goal, we believe there need to be assurances that refineries producing 15 ppm fuel are sufficiently scattered throughout each of the PADDs and that most pipelines will carry 15 ppm fuel (either as the only highway diesel fuel or in addition to 500 ppm highway fuel).

In determining what fraction of highway diesel fuel would need to be low sulfur under the temporary compliance option provision, taking into account the potential impact of the hardship provisions, we used a refinery cost model to estimate the costs of producing 15 ppm fuel for all refineries. We then assumed that the refineries with the lowest costs would convert to 15 ppm fuel and assumed the other refineries would purchase credits and continue producing 500 ppm fuel through the compliance option period. We then overlaid the information on which refineries were estimated to be producing 15 ppm fuel with the highway diesel fuel distribution system in the United States. We examined different levels for the temporary compliance option beginning as low as 20 percent and ranging as high as 90 percent. The results of the analysis show that at temporary compliance option levels for 15 ppm below 80 percent, there are local regions of the country where we believe there would likely be shortages of low sulfur diesel fuel. The areas where we believe there would be shortages are either (1) served by pipelines that we believe would not carry 15 ppm fuel, because the refineries serving those pipelines are projected to produce primarily 500 ppm; or (2) dominated by refineries we believe would continue producing 500 ppm fuel under the temporary compliance option and are not currently capable of receiving significant supplies of a second grade of diesel fuel through other reasonable means. At the 80 percent level, we believe that all pipelines will carry low sulfur diesel fuel, since there are a sufficient number of refineries scattered across the country producing low sulfur diesel fuel and at sufficient volumes for pipelines to choose to carry it. We also believe that the program ensures that low sulfur diesel fuel will be sufficiently available to retail outlets at a reasonable cost either at a local terminal or by trucking the fuel a limited distance.

As noted earlier, we are not adopting any retailer availability requirements with today's fuel program. Given the amount of low sulfur diesel fuel required under today's temporary compliance option, we believe the distribution system will make low sulfur diesel fuel widely available without any requirements on retail outlets to supply low sulfur diesel fuel.

c. Provides Lower Costs to Refineries

One benefit of the temporary compliance option being adopted today is that a significant number of refiners will have the ability to delay the date when they convert their highway diesel fuel production to 15 ppm, allowing the refining industry to stretch out its engineering and construction resources. Given the flexibilities being adopted today, we believe that many large refineries, and other refineries for which diesel desulfurization is least expensive, will make the commitment to convert their entire highway diesel pool to 15 ppm sulfur in 2006 and sell credits to other refineries that will continue to produce all of their fuel at the 500 ppm sulfur level. Using a refinery cost model to estimate how refineries will respond to the temporary compliance option requirements, we believe that more than half of the refineries will delay capital investment by buying credits and continue producing 500 ppm sulfur diesel fuel under the temporary compliance option and small refiner hardship provisions. We estimate that refiners will be able to save as much as $1.7 billion over the transition period compared to a requirement that all highway diesel fuel comply with 15 ppm sulfur in 2006. As noted earlier, much of this potential savings will be offset by increased costs in the distribution system. Nevertheless, we project that in total, an overall savings of approximately $0.65 billion could result.

d. Misfueling Concerns Should Be Minimized

By allowing a 500 ppm and 15 ppm sulfur highway diesel fuels to be in the market at the same time, there is the possibility that model year 2007 and later heavy-duty vehicles will be misfueled with 500 ppm sulfur fuel, either accidentally or intentionally. As discussed above, if such vehicles are fueled with 500 ppm diesel fuel, the emission control systems could be irreversibly damaged and any benefit of the new emission standards could be eliminated. To minimize the possibility of misfueling, we are adopting labeling requirements that apply to both retail stations and vehicle manufacturers. Under these provisions, labels will be applied at the diesel fuel pumps at retail stations and at the fuel tank inlet on the vehicle. The labels must indicate that only 15 ppm sulfur highway diesel fuel may be used in 2007 and later model year heavy-duty vehicles. The labeling requirements for fuel pumps and vehicles are described in detail in Sections VII.C. and VI.G., respectively.

Given the program being adopted today, we believe that intentional misfueling will not be a serious problem. The main incentive vehicle owners may have for using 500 ppm sulfur fuel would likely be cost savings. In general, producing 500 ppm sulfur should be cheaper than producing 15 ppm fuel. However, given the requirements adopted today, we believe there should not be a large cost differential between the 15 ppm sulfur fuel and the 500 ppm sulfur fuel at retail outlets. Under the credit trading program, to produce 500 ppm fuel, most refiners will have to purchase credits from other refiners producing 15 ppm fuel, increasing the cost of the 500 ppm fuel, while decreasing the cost of the 15 ppm fuel. At the refinery gate, the cost of both fuels should be approximately the same. In addition, given the amount of 15 ppm fuel required under the temporary compliance option, 15 ppm fuel will be distributed through essentially the entire pipeline system. The distribution of 500 ppm fuel, on the other hand, will be more limited, due to its much lower volume. We expect that the 500 ppm fuel will be distributed by truck in the areas nearby refineries producing this fuel and through a few major pipelines to a limited number of major fuel consuming areas. Overall, the better economies of scale of transporting 15 ppm fuel should compensate for any additional handling cost due to the need to more carefully avoid contamination with higher sulfur fuels. For these reasons, we expect the price to consumers of 500 ppm sulfur fuel to be generally close to that of 15 ppm sulfur fuel and, therefore, there should not be a significant economic incentive to misfuel with 500 ppm sulfur fuel. Finally, because vehicle owners will likely void the manufacturer's warranty if they misfuel with 500 ppm sulfur fuel, they will have an additional incentive not to misfuel. Owners of heavy-duty vehicles make significant investments in these vehicles and will not want to take the chance of voiding their warranty for a relatively small savings in fuel cost.

In addition to our concern about intentional misfueling, we also have some concerns about accidental misfueling during the optional compliance program years. This concern is lessened to some extent because of the limited amount of 500 ppm sulfur fuel that will be available, the short duration of the optional compliance program, the knowledgeable owners and operators of trucks and most importantly, the labels that will be required on both the vehicle and the fuel pumps. Thus, we do not expect either type of misfueling to be a significant problem.

e. Summary

In summary, today's program has been structured to ensure a smooth transition to low sulfur highway diesel fuel. We believe this will allow the refining industry the ability to spread out capital investments and provide more time for the market to transition to the low sulfur diesel fuel. This, in turn, will help to mitigate any potential for concerns about highway diesel fuel supply shortfalls. We also believe the provisions included in the program will continue to provide assurance that adequate supplies of low sulfur highway diesel fuel will be available throughout the nation for the 2007 and later model year heavy-duty vehicles that will require the fuel to comply with the emission standards. Moreover, because the flexibilities included in the program should reduce the economic impact on refiners, we will also expect there to be a reduction in the costs to highway diesel fuel users.

B. What Provisions Apply in the Geographic Phase-in Area?

1. What Is the Geographic Phase-in Area and How Was it Established?

In the low sulfur gasoline rule, we established the GPA provision which provides temporarily less stringent standards for gasoline sold in certain parts of the West and Alaska (40 CFR 80.215). A map of the area is shown in Figure IV–2, below.[165] As described in the preamble to the low sulfur gasoline final rule, we used two criteria to develop and evaluate the GPA approach: (1) Relative environmental need and (2) the ability of U.S. refiners and the distribution system to provide compliant gasoline.

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[165] Alaska, Colorado, Idaho, Montana, New Mexico, North Dakota, Utah, and Wyoming. Note that minor changes to this area are currently under consideration. Any such changes subsequent to today's rule are intended to be carried over into today's rule as well.

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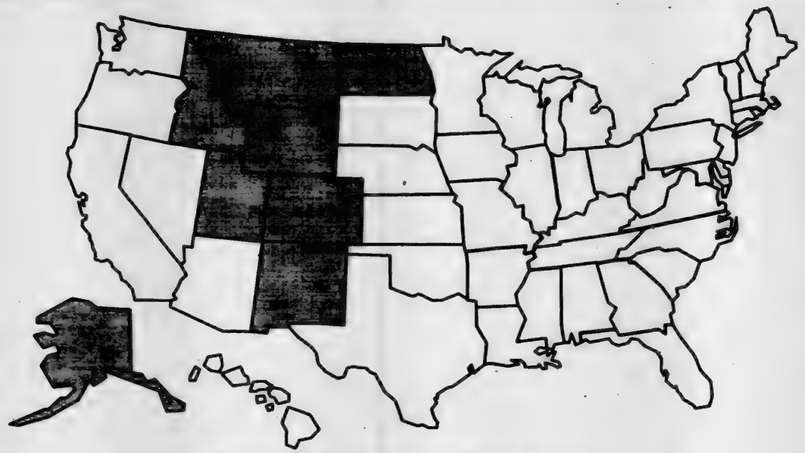


Figure IV-2. Geographic Phase-in Area

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In part, we defined the GPA based on the relative difficulty of producing or obtaining complying low sulfur gasoline (see preamble to the low sulfur gasoline rule at 65 FR 6698, February 10, 2000). The refining industry in the GPA is dominated by small capacity, geographically-isolated refineries located within that area. As a general rule, refineries in this area will (because of their crude oil capacity, corporate size, and location) have the most difficult time of all refineries nationwide in competing for the engineering and construction resources needed to modify their refineries to comply with the low sulfur gasoline standards.

Furthermore, an assessment of gasoline production and use data and information on the products pipeline system shows that states and counties in the GPA are solely or predominantly dependent on gasoline produced by these refineries and have limited or no access to gasoline from other parts of the country. Specifically, Department of Energy data for 1998 indicate that over 80 percent of the gasoline sold in this area is produced by the relatively small refineries located within the region. Much of this gasoline is produced by small volume refineries that are not owned by small businesses, and are therefore not afforded the flexibility of the small refiner provisions described in Section IV.C. Providing low sulfur gasoline to these states and counties is expected to be more difficult and costly in the near term.

The temporary gasoline provisions for the GPA apply for three years, 2004 through 2006. Since the low sulfur gasoline standards for the rest of the country require compliance in January 2006 with a 30 ppm refinery average standard and an 80 ppm gallon cap, the geographic phase-in provides an additional year for refiners to reach those standards. This extra year and the somewhat less stringent standards during the gasoline phase-in will provide the refining industry the opportunity for a more orderly transition to the 30/80 ppm gasoline sulfur standards by January 2007.

The gasoline GPA provision covers all gasoline produced (or imported) for use in the GPA[165], whether refined within the area or distributed within the area via pipeline, barge, truck, or rail. Foreign refiners are involved in this program through importers, which are the regulated entities.

2. *Highway Diesel Provisions for GPA Refiners*

In response to our proposal, we received many comments from the refining industry and others regarding the timing of our proposed highway diesel fuel sulfur program. Commenters argued that the proposed schedule for diesel sulfur compliance, beginning in mid-2006, would be a problem since it directly coincides with the December 2006 gasoline sulfur compliance date for the GPA. Some said that the timing of the diesel program could effectively negate the benefit to refiners of the GPA program since desulfurization investments would need to take place during essentially the same time period. This could thus increase the difficulty of refiners in this region to raise capital and to engage engineering and construction resources. Some also said that an extension of the GPA gasoline program would allow more rational planning without unduly reducing the air quality benefits of the program.

We agree with many of the commenters in this regard—refineries supplying the GPA tend to be disproportionately challenged compared to other refiners with respect to capital formation, the availability of engineering and construction resources, and the isolated nature of many of the markets. Moreover, the introduction of low sulfur highway diesel fuel in June 2006 indeed overlaps with the conclusion of the interim low sulfur gasoline standards for GPA refiners.

In consideration of these comments, we believe that it is appropriate to grant additional flexibility to refiners that supply gasoline to the GPA while also meeting the low sulfur diesel standards. Additional flexibility for GPA refiners will allow them to spread out their capital investments for producing low sulfur gasoline and highway diesel fuel. In light of the above, we are modifying

[165] As stated in the Tier 2/Gasoline Sulfur final rule (See § 80.215(a)(2)), we plan to expand the GPA to include counties and tribal lands in states adjacent to the eight core GPA states.

the GPA gasoline program while still achieving significant environmental benefits. We expect this provision will have little long-term impact on the environmental benefits of the Tier 2/ Gasoline Sulfur program, while providing for considerable near-term implementation flexibility and improved feasibility of the highway diesel fuel program.

Refiners that produce both gasoline and highway diesel fuel and are subject to the GPA gasoline sulfur program may choose to stagger their desulfurization investments for the two fuels. Refiners that comply with the low sulfur diesel fuel standard by June 1, 2006 for all of their highway diesel fuel production may receive a two-year extension of their interim GPA gasoline standards for 2006, that is through December 31, 2008. In addition to allowing refiners the opportunity to spread out their desulfurization investments, we believe this provision will encourage the production of 15 ppm diesel fuel by some refiners producing fuel for the GPA, which will further help to ensure the new fuel is widely available for new vehicles throughout the area. Although the GPA gasoline program applies to both refiners and importers, the extension of the GPA gasoline program under today's program applies only to refiners. This reflects the fact that only refiners have to make capital investments to comply with the diesel sulfur standard.

To receive the two-year extension of the GPA standards, a U.S. refinery must by June 1, 2006 produce 100 percent of its highway diesel fuel at 15 ppm sulfur (including refineries that supply only a fraction of their gasoline production to the GPA). In addition, the refinery must maintain a production volume of 15 ppm highway diesel fuel that is at least 85 percent of the baseline highway diesel volume that was produced at that refinery on average during calendar years 1998 and 1999. We believe that it is very important that the extension of a GPA refinery's interim gasoline sulfur standard be linked to a substantial environmental benefit from the production of 15 ppm diesel fuel in 2006. We have established a minimum volume requirement to prevent the extension of the GPA gasoline program from applying in situations where a refinery changes its refinery product slate to produce very little highway diesel fuel—even though this production is at 15 ppm sulfur. We believe the 85 percent level is sufficient to reflect a substantial investment in desulfurization technology. At the same time the 85 percent level should allow for any reasonable variation in production of highway diesel fuel that would be expected to occur in typical situations between now and 2006, particularly given the continued growth of the highway diesel market.

Similarly, a foreign refinery that meets the same conditions as a domestic GPA refiner may also sell gasoline into the GPA that meets a less stringent sulfur standard during 2007 and 2008.[167] That is, a foreign refinery that by June 1, 2006 sells 100 percent of the highway diesel fuel it imports into the U.S. as 15 ppm fuel (and that maintains the 85 percent of baseline volume requirement) may sell somewhat higher-sulfur gasoline into the GPA in 2007 and 2008. The actual gasoline sulfur standard during this period, as with domestic refiners, would be based on the foreign refinery's gasoline sulfur baseline.

If a situation arises where a GPA refinery did not produce highway diesel fuel in 1998 or 1999 but later begins to produce 15 ppm diesel fuel, use of the GPA gasoline phase-in extension will require case-by-case EPA approval. In its application for such approval, a refinery must show us that the loss of emission reductions will not be significant and must propose an appropriate minimum production volume. In evaluating such a proposed minimum volume, we may consider, among other factors, the typical ratio between highway diesel and gasoline production for other refineries in the industry. Again, the reason for the two-year extension of the gasoline interim program is to allow the GPA refinery to spread out its capital investments while increasing the quantity of 15 ppm fuel being produced. We expect that GPA refineries using this option will make a substantive capital investment in diesel desulfurization and have thus set this minimum 15 ppm diesel production volume limit.

Since refiners participating in this program are required to produce 100 percent of their highway diesel at 15 ppm, those that choose this option cannot participate in the highway diesel temporary compliance option, and, therefore, are not permitted to generate credits on the low sulfur diesel fuel that they produce. If, after June 1, 2006, a foreign refinery is not producing 100 percent of its highway diesel fuel imported into the U.S. at 15 ppm sulfur in the required volume, it forfeits the two-year extension or any remaining portion of the extension of its interim gasoline program.

3. *How Do Refiners Apply for an Extension of the GPA Gasoline Program?*

Any refinery that seeks an extension of its GPA gasoline standards must apply to us as a part of its registration, due by December 31, 2001. In this application, the refinery must indicate its intention to produce 100 percent of its highway diesel fuel at 15 ppm (and at a volume at least 85 percent of the highway diesel fuel volume it produced on average during calendar years 1998 and 1999) by June 1, 2006.

4. *Required Reporting for GPA Refiners*

As described in Section VII.E below, refiners that plan to use the extension of the GPA gasoline standard must report their plans and progress several times over the course of the program. In addition to their initial registration and application discussed above, a refinery must submit pre-compliance reports in 2003, 2004, and 2005, describing its progress toward the capacity to produce 100 percent of its highway diesel fuel at 15 ppm sulfur (at a volume at least 85 percent of its baseline volume). Then, by July 1, 2006, such a refinery must confirm to us that by June 1, 2006 it was producing 100 percent of its highway diesel fuel at 15 ppm, at the appropriate volume.[168] After the diesel sulfur program is underway in 2006, the refinery must provide us with annual compliance reports by the end of February of 2007, 2008, and 2009 (i.e., until after the end of the extended interim gasoline sulfur program for GPA refiners on December 31, 2008).

C. Hardship Provisions for Qualifying Refiners

This section describes various provisions for certain qualifying refiners, both domestic and foreign, that may face hardship circumstances.

1. *Hardship Provisions for Qualifying Small Refiners*

In developing our diesel sulfur program, we evaluated the need and the ability of refiners to meet the 15 ppm standard as expeditiously as possible. This analysis is described in detail in Chapter IV of the RIA. As a part of this analysis, we found that while the majority of refiners would be able to meet the needed air quality goals in the

[167] Prior to 2007, foreign refiners can participate in the GPA program through importers. Under today's provisions for 2007 and 2008, importers are not eligible and foreign refiners can participate directly as refiners.

[168] If the refiner was not producing 15 ppm fuel for all its highway diesel production at that refinery by June 1, 2006, the July 1, 2006 letter must confirm that the refiner is forfeiting the "automatic" two-year extension of that refinery's interim gasoline program.

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2006 time frame, there would be some refiners that would face particularly challenging circumstances which would cause them to have more difficulty, in comparison to the industry as a whole, in meeting the standards.

We believe it is feasible and necessary for the vast majority of the program to be implemented reasonably quickly to achieve the air quality benefits as soon as possible. To do otherwise would be to base the time frame of the entire program on the lowest common denominator. Thus, we have provided special flexibility provisions for a subset of refiners that qualify as "small refiners," which represent about five percent of the overall highway diesel volume. As described in more detail below, and in the Regulatory Impact Analysis (Chapter VIII of the RIA), we concluded that refineries owned by small businesses face unique hardship circumstances, compared to larger companies.

a. Qualifying Small Refiners

The primary reason for special small refiner provisions is that small businesses generally lack the resources available to large companies which enable the large companies (including those large companies that own small volume refineries) to raise capital for investing in desulfurization equipment. The small businesses are also likely to have more difficulty in securing loans, competing for engineering resources, and completing construction of the needed desulfurization equipment in time to meet the standards adopted today which begin in 2006. In addition, the implementation of the low sulfur diesel program will occur in the same general time frame as the implementation of the low sulfur gasoline program, since most of those small refiners that are covered by the interim standards under the Tier 2/Gasoline Sulfur program (40 CFR Part 80, Subpart H) are also covered by today's diesel fuel sulfur program.

The emissions benefits of the low sulfur diesel program are needed as soon as possible—to allow the implementation of new emission reduction requirements on heavy-duty engines and vehicles and, thus, to reduce ozone, particulate matter, and other harmful air pollutants. Since our analysis showed that small businesses in particular face hardship circumstances, we are adopting temporary provisions that will provide refineries owned by small businesses additional time to meet the ultimate 15 ppm sulfur cap or balance investments of this program with those related to the Tier 2/Gasoline Sulfur program. This approach allows us to achieve the earliest implementation date for advanced technology diesel vehicles (i.e., the 2007 model year) and the needed emission reductions they will bring.

We believe that the temporary flexibilities described below are an effective way to begin the broad implementation of the standards as expeditiously as is feasible and thereby achieve significant air quality benefits in an expeditious manner. This section describes the special provisions we are offering small businesses to mitigate the impacts of our program on them and generally explains the analysis we undertook of those impacts. Please refer to the Response to Comments document for a detailed discussion of comments we received on these provisions, and to the RIA for a more detailed discussion of our analysis of small refiner circumstances.

As explained in the discussion of our compliance with the Regulatory Flexibility Act in Section X.B. and in the Regulatory Flexibility Analysis in Chapter VIII of the RIA, we considered the impacts of our proposed regulations on small businesses. We have historically, as a matter of practice, considered the potential impacts of our regulations on small businesses. We believe that the temporary flexibilities we are adopting for small refiners contributed to our development of a framework to achieve significant environmental benefits from lower sulfur diesel in the most expeditious manner that is reasonably practicable.

A large part of the analysis of small business impacts conducted for this rulemaking was performed in conjunction with a Small Business Advocacy Review (SBAR) Panel we convened, pursuant to the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). In the SBREFA amendments, Congress stated that "uniform Federal regulatory requirements have in numerous instances imposed unnecessary and disproportionately burdensome demands including legal, accounting, and consulting costs upon small businesses . . . with limited resources[,]" and directed agencies to consider the impacts of certain actions on small entities. The final report of the Panel is available in the docket. Through the SBREFA process, the Panel provided information and recommendations regarding:

- The significant economic impact of the proposed rule on small entities;
- Any significant alternatives to the proposed rule which would ensure that the objectives of the proposal were accomplished while minimizing the economic impact of the proposed rule on small entities;
- The projected reporting, recordkeeping, and other compliance requirements of the proposed rule; and,
- Other relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition to our participation in the SBREFA process, we conducted our own outreach, fact-finding, and analysis of the potential impacts of our regulations on small businesses. Some of the small refiners with whom we and the Panel met indicated their belief that their businesses may close due to the substantial costs, capital and other impacts of meeting the 15 ppm diesel fuel standard without either additional time or flexibility with respect to gasoline sulfur compliance. Based on these discussions and analyses, the Panel and we agree that small refiners would likely experience a significant and disproportionate financial hardship in reaching the objectives of our diesel fuel sulfur program. However, the Panel also noted that the burden imposed upon the small refiners by our sulfur requirements varied from refiner to refiner and could not be alleviated with a single provision. We agree with the Panel and are offering qualifying small refiners three options to choose from in moving toward compliance with the low sulfur diesel fuel requirements.

For today's action, we have structured a selection of temporary flexibilities for qualifying small refiners, both domestic and foreign, based on the factors described below. Generally, we structured these provisions to address small refiner hardship while expeditiously achieving air quality benefits and ensuring that the low sulfur diesel fuel coincides with the introduction of 2007 model year diesel vehicles.

First, the compliance deadlines in the program, combined with flexibility for small refiners, will quickly achieve the air quality benefits of the program, while helping to ensure that small refiners will have adequate time to raise capital for new or revamped equipment. Most small refiners have limited additional sources of income beyond refinery earnings for financing the equipment necessary to produce low sulfur diesel. Because these small refiners typically do not have the financial backing that larger and generally more integrated companies have, they can benefit from additional time to secure capital financing from their lenders.

Second, we believe that allowing time for refinery sulfur-reduction technologies to be proven out by larger refiners before small refiners have to put them in place will reduce the risks incurred by small refiners that utilize these technologies to meet the standards. The added time will likely allow for lower costs of these improvements in desulfurization technology (e.g., better catalyst technology or lower-pressure hydrotreater technology). Because of the poorer economies of scale and the higher relative capital and operating costs faced by small refiners, more time for technology development and commercialization will limit the economic consequences for small refiners. Small refiners are disadvantaged by the economies of scale that exist for the larger refining companies-capital costs and per-barrel fixed operating costs are generally higher for small refiners.

Third, providing small refiners more time to comply will increase the availability of engineering and construction resources. Since most large and small refiners must install additional processing equipment to meet the sulfur requirements, there will be a tremendous amount of competition for technology services, engineering manpower, and construction management and labor. Our analysis shows that there are limits to the price elasticity of these resources. In addition, vendors will be more likely to contract their services with the major companies first, as their projects will offer larger profits for the vendors.

Finally, because the gasoline and diesel sulfur requirements will occur in approximately the same time frame, small refiners that produce both fuels will have a greater difficulty than most other refiners in securing the necessary financing. Hence, any effort that increases small refiners' ability to stagger investments for low sulfur gasoline and diesel will facilitate compliance with the two programs.

Providing these options to assist small refiners experiencing hardship circumstances enables us to go forward with the 15 ppm sulfur standard beginning in 2006. Without this flexibility, the benefits of the 15 ppm standard would possibly not be achieved as quickly. By providing temporary relief to those refiners that need additional time, we are able to adopt a program that expeditiously reduces diesel sulfur levels in feasible manner for the industry as a whole. In addition, we believe the volume of diesel that will be affected by this hardship provision is marginal. We estimate that small refiners contribute approximately five percent of all domestic diesel fuel production.

b. How Do We Define Small Refiners?

The following definition of small refiner is based closely on our small refiner definition in the Tier 2/Gasoline Sulfur rule. We define a refiner that meets both of the following criteria as a "small refiner" for purposes of this rule:

- No more than 1,500 employees corporate-wide, based on the average number of employees for all pay periods from January 1, 1999 to January 1, 2000.
- A corporate crude oil capacity less than or equal to 155,000 barrels per calendar day (bpcd) for 1999.

In determining the total number of employees and crude oil capacity, a refiner must include the number of employees and crude oil capacity of any subsidiary companies, any parent company and subsidiaries of the parent company, and any joint venture partners. We define a subsidiary of a company to mean any subsidiary in which the company has a 50 percent or greater ownership interest. This definition of small refiner is the same definition used under the recently promulgated Tier 2/Gasoline Sulfur program (40 CFR 80.225), except that we have included additional regulatory language to clarify our interpretation of the term "subsidiary" and we have updated the time period used to determine the employee number and crude oil capacity criteria to reflect data for the most recent calendar years. This approach is consistent with the Small Business Administration's regulations, which specify that, where the number of employees is used as a size standard, the size determination is to be based on the average number of employees for all pay periods during the preceding 12 months (13 CFR 121.106).

The gasoline sulfur standards and the diesel sulfur standards will impact small refiners in approximately the same time frame. For this reason, we will consider any refiner that we approve as meeting the small refiner definition under the gasoline sulfur program (40 CFR 80.235) to be a small refiner under the highway diesel sulfur rule as well without further demonstration.

In addition, a company that after January 1, 2000 either acquires or reactivates a refinery that was shutdown or non-operational between January 1, 1999 and January 1, 2000 may also apply for small refiner status. Such an application needs to be submitted to us no later than June 1, 2003. In this case, we will judge eligibility under the employment and crude oil capacity criteria based on the most recent 12 consecutive months unless data provided by the refiner indicates that another period of time is more appropriate. Companies with refineries built after January 1, 2000 are not eligible for the small refiner hardship provisions.

If a refiner with approved small refiner status later exceeds the 1,500 employee threshold or the corporate crude oil capacity of 155,000 bpcd without merger or acquisition, it may keep its small refiner status. This is to avoid stifling normal company growth and is subject to our finding that the company did not apply for and receive the small refiner status in bad faith. On the other hand, if a refiner with approved small refiner status later exceeds the small refiner criteria through merger or acquisition, its refineries must forfeit their small refiner status and begin complying with the national standards by January 1 of the next calendar year. For example, if a small refiner with two refineries purchases a third refinery in 2007 and that purchase causes the refiner to exceed the employee or corporate crude oil capacity thresholds for small refiner status, then that refiner must forgo its small refiner status and begin complying with the national standards by January 1, 2008 at all its refineries.

c. What Options Are Available for Small Refiners?

All refiners producing highway diesel fuel are able to take advantage of the temporary compliance option discussed in Section IV.A. Diesel producers that also market gasoline in the GPA may receive additional flexibility under today's rule (Section IV.B.). As an alternative, refiners that seek and are granted small refiner status may choose from the following three options under the diesel sulfur program. These three options have evolved from concepts on which we requested and received comment in the proposal. In most cases, we believe that small refiners will find these options preferable to either the broader diesel fuel temporary compliance option or the GPA provision discussed above.

500 ppm Option. A small refiner may continue to produce and sell diesel fuel meeting the current 500 ppm sulfur standard for four additional years, until May 31, 2010, provided that it reasonably ensures the existence of sufficient volumes of 15 ppm fuel in the marketing area(s) that it serves.

Small Refiner Credit Option. A small refiner that chooses to produce 15 ppm fuel prior to June 1, 2010 may generate and sell credits under the broader

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temporary compliance option. Since a small refiner has no requirement to produce 15 ppm fuel under this option, any fuel it produces at or below 15 ppm sulfur will qualify for generating credits.

Diesel/Gasoline Compliance Date Option. For small refiners that are also subject to the Tier 2/Gasoline sulfur program (40 CFR Part 80, Subpart H), the refiner may choose to extend by three years the duration of its applicable interim gasoline standards, provided that it also produces all its highway diesel fuel at 15 ppm sulfur beginning June 1, 2006.

All refiners producing diesel fuel are required to provide us with basic data on their progress toward compliance in 2003–2005 under the pre-compliance reporting requirements described above in Section IV.A. As a part of their pre-compliance reports, small refiners must provide a limited amount of additional information specific to the option they choose. We discuss each option, and the special pre-compliance reporting requirements for each option, in the next paragraphs and in Section VII.E below.

i. 500 ppm Option

The 500 ppm option is available for any refiner that qualifies as a small refiner. Under this option, small refiners may continue selling highway diesel fuel with sulfur levels meeting the current 500 ppm standard for four additional years, provided that they supply information showing that sufficient alternate sources of 15 ppm diesel fuel in their market area will exist for fueling new heavy-duty highway vehicles. Under this option, small refiners may supply current 500 ppm highway diesel fuel to any markets for use only in vehicles with older (pre-2007) technology until May 31, 2010. In other words, small refiners that choose this option may delay production of highway diesel fuel meeting the 15 ppm standard for four years.

This 500 ppm option for small refiners is similar to the option provided to all refiners under the temporary compliance option described in Section IV.A above in that it allows a refiner to continue producing and selling the current 500 ppm fuel for a period of time. However, this option differs from the broader compliance option in that small refiners may produce and sell 100 percent of their highway fuel at 500 ppm without needing to buy credits. In contrast, under the broader temporary compliance option, refiners must buy credits to produce any volume of 500 ppm fuel over 20 percent of their total highway diesel production.

At the retail level, retailers will not be subject to any availability requirements and thus may sell 500 ppm fuel, 15 ppm highway fuel, or both (as is the case under the broader diesel temporary compliance option described in Section IV.A). All parties in the diesel fuel distribution system will have to maintain the segregation of 15 ppm fuel and 500 ppm fuel and only 15 ppm fuel may be sold for use in model year 2007 and later heavy-duty diesel vehicles.

As a part of their pre-compliance reporting due June 1, 2003 (see Section IV.A. above), any small refiners taking advantage of this 500 ppm option must show that sufficient sources of 15 ppm fuel will likely exist in the area served by the small refiner in the absence of production of 15 ppm fuel by that refiner.[169] A small refiner could approach this showing in different ways. For example, depending on the circumstances, the refiner might point to the presence of other refiners in the area that are expected to produce 15 ppm fuel, or to the refiner's proximity to a major pipeline that will be carrying 15 ppm fuel. Similarly, the refiner might show that its market share in the area's highway diesel market will be too small to significantly affect the volume of 15 ppm fuel regardless of the small refiner's actions.

Another approach could be to indicate practical steps that the refiner itself is prepared to take to help ensure that 15 ppm diesel fuel will be available. One commenter suggested a plan to add a separate tank and expand its fuel loading rack for handling 15 ppm diesel fuel that would be supplied by a different refiner—thus making low sulfur fuel available, at least at the wholesale level, at its refinery gate even though it produced no 15 ppm fuel.

Because of the wide distribution of 15 ppm fuel that we believe will occur under the industry-wide optional compliance program discussed in Section IV.A. above, we expect that few if any small refiners wishing to use the 500 ppm option will find it difficult to make the showing that 15 ppm fuel will exist in the area. If we do not take action on this showing within four months of receiving a refiner's 2003 pre-compliance report (i.e., by October 1, 2003 at the latest), the refiner's showing will be considered approved.

[169] If circumstances arise that cause the availability of 15 ppm fuel in the refiner's market area to decline, the refiner must provide a supplemental showing in its pre-compliance reports due in June 1, 2004 and/or June 1, 2005. As with the 2003 report, we will either approve or disapprove these additional showings within four months or, if we take no action, the showing will be deemed approved.

Finally, we are providing this option so that small refiners may use the temporary flexibility provided by the 500 ppm option as a pathway toward compliance with the 15 ppm standard and not as an opportunity for those refiners to greatly expand their production of fuel meeting the 500 ppm sulfur standard. To help ensure that any significant expansion of refining capacity that a small refiner undertakes in the future will be accompanied by an expansion of desulfurization capacity, we are limiting the volume of 500 ppm sulfur fuel that a small refiner may produce under this option to a baseline level. Specifically, small refiners selecting this 500 ppm option must limit the volume they produce of highway diesel fuel meeting the 500 ppm sulfur standard to the lesser of the following values: (1) 105 percent of the average highway diesel volume it produced from crude oil in calendar years 1998 and 1999 or (2) the average highway diesel volume it produced from crude oil in calendar years 2004 and 2005. Any volume of 500 ppm highway diesel fuel (averaged over the previous 12 consecutive months) that exceeds this limitation after 2006 must comply with the diesel sulfur standards that apply to other refiners under the broader program (i.e., the standards described in Section IV.A. above, including the 80% requirement of the temporary compliance option).

ii. Small Refiner Credit Option

We believe that the relative difficulty for small refiners to comply with today's program warrants compliance flexibility for these refiners. At the same time, we want to encourage all refiners to produce low sulfur diesel fuel as early and in as many geographic areas as possible. As an incentive for small refiners to invest in desulfurization capacity, those that choose to produce 15 ppm fuel earlier than required under the 500 ppm option may generate credits for each gallon of diesel fuel produced that meets the 15 ppm standard. This includes the ability to generate credits prior to the start of the program on June 1, 2006 under the provisions described in Section IV.A.1.a. They could then sell these credits to other refiners for use in the broader optional diesel fuel compliance program described above in Section IV.A, helping to offset some low sulfur diesel fuel production costs.

Under this option, credits may be generated based on the volume of any diesel fuel that meets the 15 ppm standard. Refiners may then sell their remaining highway diesel fuel under the 500 ppm option above.

Pre-compliance reporting for small refiners choosing this Small Refiner Credit option is identical to that for the 500 ppm option (that is, if the small refiner is also producing 500 ppm highway diesel fuel), with the additional requirement that the refiner also report on any credits it expects to generate and sell. If the quantity of 15 ppm fuel that the refiner is preparing to produce is significant, this factor may be useful in making the necessary showing that 15 ppm fuel will be available in the refiner's market area.

iii. Diesel/Gasoline Compliance Date Option

The Tier 2/Gasoline Sulfur program included a special provision that applies for refiners that qualify as small refiners (40 CFR Part 80, Subpart H). Under that program, each small refiner is assigned an interim gasoline sulfur standard for each of its refineries. This interim standard for each refinery is established based on the baseline sulfur level of that refinery. The standards are designed to require each small refiner to either make a partial reduction in their gasoline sulfur levels or, if they already produce low sulfur fuel, to maintain their current levels. The interim program lasts for four years, 2004 through 2007, and the refiner can apply for an extension of up to three years. After the interim program expires, small refiners must produce the same low sulfur gasoline as other refiners.

Today's diesel sulfur program takes effect in the same time frame as the small refiner interim program for low sulfur gasoline. To avoid the need for simultaneous investments in both gasoline and diesel fuel desulfurization, several small refiners subject to both programs raised the concept of allowing those investments to be staggered in time. Because of the relative difficulty small refiners will face in financing desulfurization projects, especially for both diesel and gasoline desulfurization in the same time frame, we agree that this concept has merit and have adopted it for this rule. Under this concept, small refiners may extend the duration of their gasoline sulfur interim standards and, thus, potentially postpone some or all of their gasoline desulfurization investments while they work to achieve the low sulfur diesel standard "on time" in 2006. To the extent that small refiners choose this Diesel/Gasoline Compliance Date option, this provision will benefit the overall diesel program by increasing the availability of 15 ppm diesel fuel in the small refiners' market areas.

Specifically, this option provides that a small refiner can receive a three-year extension of a refinery's interim gasoline standard, until January 1, 2011, if it meets two criteria: (1) It produces both gasoline and diesel fuel at a refinery and chooses to comply with the 15 ppm diesel fuel sulfur standard by June 1, 2006 for all its highway diesel production at that same refinery, and (2) it produces a minimum volume of 15 ppm fuel at that refinery that is at least 85 percent of the average volume of highway diesel fuel that it produced at that refinery during calendar years 1998 and 1999. We believe that it is very important that the extension of a small refiner's interim low sulfur gasoline standard be linked to a substantial environmental benefit from the production of low sulfur diesel fuel in 2006. We have established a minimum volume requirement to prevent the Diesel/Gasoline Compliance Date option from applying in situations where a refiner changes its refinery product slate to produce very little highway diesel fuel—even though this production is at a 15 ppm sulfur level—and yet receives an extension of its interim gasoline sulfur standard.[170] We believe the 85 percent level is sufficient to reflect a substantial investment in desulfurization technology. At the same time the 85 percent level should allow for any reasonable variation in production of highway diesel fuel that would be expected to occur in typical situations between now and 2006, particularly given the continued growth of the highway diesel market. Again, the three-year extension of the gasoline interim program is to allow small refiners to stretch out their capital investments while increasing the quantity of 15 ppm fuel being produced. We expect that small refiners using this option will make a substantive capital investment in diesel desulfurization and have thus set this minimum 15 ppm diesel volume limit.

We believe that the additional three-year extension of the interim gasoline sulfur standards provided today is warranted without any further action by small refiners, provided that they assume the financial burden of full low sulfur diesel compliance in 2006 (i.e., instead of choosing the flexibility of the broader temporary compliance program). The diesel and gasoline desulfurization investments for those refiners can thus be staggered in time. We believe a three-year extension is appropriate due to the substantial investment in highway diesel fuel that these small refiners will be undertaking.

By July 1, 2006, small refiners that plan to use the Diesel/Gasoline Compliance Date option for one or more refineries must send a letter to us confirming that by June 1, 2006 they were producing 100 percent of their highway diesel fuel in compliance with the 15 ppm sulfur standard at their refinery(ies). These refiners must make similar confirmations each year through 2011 in their annual compliance reports (due by the end of February of each year)—until after the end of the extended interim low sulfur gasoline program for small refiners on December 31, 2010.

If a given small refiner was not producing 15 ppm fuel for all its highway diesel production at that refinery by June 1, 2006, the July 1, 2006 letter must confirm that the refiner is forfeiting the "automatic" three-year extension of that refinery's interim gasoline program (although the refiner may still apply for a case-by-case extension through the Tier 2/Gasoline Sulfur program under 40 CFR 80.260). In this case, we will consider a request that the refiner be allowed to use either the 500 ppm option or the Small Refiner Credit option, or both, provided that information addressing the conditions of these options as described above are included in the July 1, 2006 letter. If the refiner does not request the use of the 500 ppm option or the Small Refiner Credit option, the letter must confirm that the refiner is complying with the diesel sulfur requirements applicable to refiners that are not small refiners.

The Tier 2/Gasoline Sulfur program includes a general hardship provision for which refiners may apply. (Today's program also includes a similar provision). Depending on the nature of its hardship, a small refiner that applies for this general hardship provision under the gasoline program may be granted a "tailor-made" interim gasoline sulfur program different from the "default" program established in the rule. If such a small refiner were then to be covered by today's diesel fuel requirements and chose this Diesel/Gasoline Compliance Date option, we will allow it an extension of its special interim program for gasoline (as established under the general hardship provision) for three years beyond the scheduled end date (although no later than December 31, 2010) so long as it

[170] If a situation arises where a small refiner did not produce highway diesel fuel in 1998 or 1999 but later begins to produce 15 ppm diesel fuel, use of the Diesel/Gasoline Compliance Date option will require case-by-case EPA approval. In its application for such approval, a refiner must show us that the net loss of emission reductions will not be significant and must propose an appropriate minimum production volume. In evaluating such a proposed minimum volume, we may consider, among other factors, the typical ratio between highway diesel and gasoline production for small-to-medium sized refineries in the industry.

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met the 15 ppm diesel fuel standard and production volume requirements in 2006.

As with the other two options, refiners expecting to use the Diesel/Gasoline Compliance Date option and thus to produce their highway diesel fuel exclusively at 15 ppm fuel will have to report certain information beginning in 2003. As a part of their pre-compliance reporting due June 1, 2003 (see Section IV.A. above), any small refiners taking advantage of this option must provide information showing that diesel desulfurization plans are on track. The information supplied under this requirement must include, but will not be limited to, the following: (1) Status of applying for and receiving any necessary air pollution control permits, (2) financing that is in place or being sought, and (3) the status of engineering or construction contracts. As a part of the pre-compliance reporting due in 2004 and 2005, the refiner must provide more complete information as it becomes available to update its earlier report (e.g., the status of beginning or completing construction of desulfurization equipment).

iv. Relationship of the Options to Each Other

By definition, since a small refiner must produce 100 percent of its highway diesel as 15 ppm under the Diesel/Gasoline Compliance Date option, that option is not compatible with either the 500 ppm option or the Small Refiner Credit option. Thus a refiner choosing the Diesel/Gasoline Compliance Date option may not choose either of the other two options. However, the 500 ppm option and the Small Refiner Credit option are compatible with each other, and so a refiner may choose either or both of these options.

d. How Do Small Refiners Apply for Small Refiner Status?

Refiners that are not small refiners under the gasoline sulfur program but that are seeking small refiner status under the diesel sulfur program must apply to us as a part of their registration for the general diesel sulfur program, due no later than December 31, 2001. The application must include the following information: [171]

- The name and address of each location at which any employee of the company, including any parent companies or subsidiaries,[172] worked during the 12 months preceding January 1, 2000;
- The average number of employees at each location, based on the number of employees for each of the company's pay periods for the 12 months preceding January 1, 2000;
- The type of business activities carried out at each location; and
- The total crude oil refining capacity of its corporation. We define total capacity as the sum of all individual refinery capacities for multiple-refinery companies, including any and all subsidiaries, as reported to the Energy Information Administration (EIA) for 1999, or in the case of a foreign refiner, a comparable reputable source, such as professional publication or trade journal.[173] Refiners do not need to include crude oil capacity used in 1999 through a lease agreement with another refiner in which it has no ownership interest.

The crude oil capacity information reported to the EIA or comparable reputable source is presumed to be correct. However, in cases where a company disputes this information, we will allow 60 days after the company submits its application for small refiner status for that company to petition us with detailed data it believes shows that the EIA or other source's data was in error. We will consider this data in making a final determination about the refiner's crude oil capacity.

We will consider any refiner that was granted small refiner status under the Tier 2/Gasoline Sulfur program to also qualify as a small refiner under today's program, provided that it also produced highway diesel fuel in 1999. Such a refiner only needs to indicate as a part of its registration for this program that it is covered by the gasoline sulfur small refiner program and that it expects to be eligible for any small refiner optioins available in today's diesel program.

2. *Farmer Cooperative Refiners Will Benefit From the Flexible Provisions Available to Other Refiners*

Some refineries in the U.S. are owned by farmer cooperatives. In the NPRM, we asked for comment on whether it would be appropriate to extend hardship relief to farmer cooperatives, similar to the flexibility options for small refiners. Representatives of farmer cooperative refiners have commented to us that as refiners they face unique challenges under a diesel fuel sulfur program. As described in more detail below and in the Response to Comments document, we have carefully considered the situation of farmer cooperative refiners. We have concluded that while there are clearly differences in how farmer cooperative refiners are organized and are financed compared to other refiners, we are not able to make a determination that farmer cooperative refiners, as a class, face unique economic hardship. As discussed further below, we believe that the combination of flexibilities built into today's diesel program will be valuable to farmer cooperative refiners. To the extent any of the farmer cooperative refiners face economic hardship in complying with the diesel sulfur program, this determination can best be made on a case-by-case basis for each farmer cooperative refiner, as discussed further below.

As is the case for all refiners, we believe that farmer cooperative refiners will be able to benefit significantly from the several flexibility provisions discussed elsewhere in Section IV of this preamble. As we mentioned above, the farmer cooperative refiner with the smallest refinery appears to meet the criteria for status as a "small refiner," and thus will likely be eligible for the special provisions discussed earlier (Section IV.C.1. above). The second smallest refinery owned by a farmer cooperative is located and markets all or most of its gasoline within the geographic GPA and, as such, is eligible for GPA low sulfur gasoline extension described in Section IV.B. above (if it meets the production and volume requirements for 15 ppm fuel). Alternatively, this refinery could participate in the temporary compliance option for diesel fuel described in Section IV.A. above.

The two other farmer cooperative refiners (as well as any other refiner) may participate in the temporary compliance option for diesel fuel and the averaging, banking, and trading provisions described above (Section IV.A.), potentially allowing them to postpone diesel desulfurization investments. If needed, any of the farmer cooperative refiners may also apply for case-by-case hardship relief (Section IV.C.3. below). Through such a case-by-case review, we will be in a better position to make a determination of whether a particular farmer cooperative refiner faced an economic hardship situation, as we would then have available to us specific financial information about each cooperative owner. If we determine that a cooperative refiner faced an economic hardship situation, we could then tailor any temporary hardship provisions to best suit the needs of that refiner. Given this combination of options and "safety valves" built into the diesel sulfur program, and the factors discussed below, we do not believe it is necessary to provide special provisions specifically for farmer cooperative refiners as a class.

Farmer cooperatives that own refineries, like all farmer cooperatives, are organized as a means for individual farmers (or local cooperatives owned by individual farmers) to collectively gain benefits in important aspects of their farming businesses—in this case, the production and distribution of the fuel needed for their operation. It should also be noted that the diesel fuel produced by farmer cooperative refiners is sold not only to farmers, but also to the wholesale petroleum market, for sale at service stations, truck stops, or fleets. Individual farmers and others become members of local cooperatives that provide a range of products and services to their members. These local cooperatives in turn often form the membership of larger, regional cooperatives, including those that own three of the four farmer cooperative refineries in the U.S.

Refiners that are also cooperative businesses are significantly different from other refiners in several respects. The key aspect is that several avenues for accessing capital used by many other refiners (in this case, the capital needed to carry out diesel fuel desulfurization projects in their refineries) are not available to, or are not practical for, cooperative refiners. In particular, farmer cooperatives, unlike publicly-held corporations, are generally not permitted to raise equity capital in the securities markets (that is, by selling stock). At the same time, the equity financing provided by the membership, usually a modest amount assessed from each member as a condition of membership, provides a return for the members only to the extent that the members purchase the products or services of the cooperative. Conventional investors that do not regularly patronize the cooperative have little incentive to provide investment from the outside, since their investment will not appreciate in value.

For farmer cooperatives, money for capital projects is generally raised internally as equity from members and as loans from banks or other financial institutions. In this sense, farmer cooperative refiners are similar to privately-held refining companies, which are also unable to raise capital by selling public stock. In the case of farmer cooperatives, equity capital is raised either by assessment of the members or, more often, by retaining a portion of the cooperative's earnings that would otherwise be distributed to the members (on the basis of how much business they have done with the cooperative). The amount of equity available to the cooperative, as well as the earning prospects of the cooperative, usually determine whether financial institutions will lend additional capital, how much money will be lent, and what terms the cooperative will have to agree to. For example, when a cooperative's equity is low and/or the farm economy is stressed (and thus the prospects for strong earnings performance by the cooperative are diminished) cooperatives can have difficulty competing among other potential borrowers for loans for large capital projects.

While the unique structural and financial characteristics of farmer cooperative refiners can present special challenges to these refiners, their status as cooperatives can also provide advantages not shared by other refiners. The same federal and state laws and regulations that place limitations on the financial avenues available to cooperatives also tend to include special provisions only available to cooperatives. These include special treatment for cooperatives under securities laws, antitrust laws, contractual marketing laws, and restrictive corporate entity laws, some or all of which may come into play in efforts to capitalize refinery desulfurization projects.

Also, the relatively large regionally-based cooperatives that own refineries have a variety of other business interests as well. This broader business base, which involves not only the refining and distribution of fuels but also a variety of other agricultural supply, processing, and related operations, may often provide an advantage to these larger cooperative refiners as compared to competing refiners that have little or no business beyond refining and fuel marketing. Finally, the three larger farmer cooperative refiners have developed several economic relationships among one another—including joint refinery ownership, a joint refinery operating agreement, and a joint fuel distribution and marketing organization—that together create greater options for financing than are available to many other refiners.

Based on the compliance option provisions in this action we do not believe that farmer cooperative refiners as a class face a disproportionate economic burden in complying with the diesel sulfur program. However, certain cooperative refiners may face additional economic obstacles, therefore the potential need exists for some financial assistance to farmer cooperative refiners from U.S. government programs. During interagency review, concerns were discussed relating to the uniqueness of the structure of farmer cooperative refineries and the key issue of accessing capital was identified. The U.S. Department of Agriculture (USDA) has indicated an interest and willingness to review its existing authorities for the potential mechanisms to provide financial assistance to refiner cooperatives who do invest in desulfurization programs. Congress and USDA have long recognized the unique circumstances of farmers and rural communities by establishing programs to provide assistance. This assistance would be primarily in the form of guaranteed loans, which could provide a significant source of funding for cooperative refiners to make capital investment in desulfurization. However, USDA's loan program is subject to limitations, including a $25 million annual cap on individual loans, so the cooperative refiners may have to acquire additional financing. EPA understands that USDA supports efforts, where appropriate, to provide assistance to farmer-owned cooperatives from other sources.

In conclusion, after reviewing this information, we have not been able to clearly distinguish a unique economic burden that today's program will place on farmer cooperative refiners, as a class, apart from other refiners, especially other refiners of similar size and/or those that are privately-held companies. However, as described above, several of the flexible provisions we have incorporated into the overall diesel sulfur program will be valuable to farmer cooperative refiners.

3. *General Hardship Provisions*

a. Temporary Waivers from Low Sulfur Diesel Requirements in Extreme Unforseen Circumstances

In this final rule, we are adopting a provision which, at our discretion, will permit domestic or foreign refiners to seek a temporary waiver from the highway diesel sulfur standards under certain rare circumstances. This waiver provision is similar to provisions in the reformulated gasoline (RFG) and low sulfur gasoline regulations. It is intended to provide refiners short-term relief in unanticipated circumstances—such as a refinery fire or a natural disaster—that cannot be reasonably foreseen now or in the near future.

[171] See the Section VII.E below and regulatory language associated with this rule for detailed requirements for registration and application for small refiner status.

[172] "Subsidiary" here covers entities of which the parent company has 50 percent or greater ownership.

[173] We will evaluate each foreign refiner's documentation of crude oil capacity on an individual basis.

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Under this provision, a refiner may seek permission to distribute highway diesel fuel that does not meet the applicable low sulfur standards for a brief time period. An approved waiver of this type could, for example, allow a refiner that has reached its maximum allowable production volume of 500 ppm sulfur fuel under the temporary compliance option to temporarily and modestly exceed that volume, so long as the other conditions described below were met. Such a request will be based on the refiner's inability to produce complying highway diesel fuel because of extreme and unusual circumstances outside the refiner's control that could not have been avoided through the exercise of due diligence. The request will also need to show that other avenues for mitigating the problem, such as purchase of credits toward compliance under the temporary compliance option, had been pursued and yet were insufficient.

As with other types of relief established in this rule, this type of temporary waiver will have to be designed to prevent fuel exceeding the 15 ppm standard from being used in 2007 and later vehicles. As with the small refiner hardship provisions described above, any such waiver must show that other sources of 15 ppm fuel exist in the refiner's market area to help reduce the risk that owners of 2007 and later diesel vehicles will have difficulty finding the 15 ppm fuel they need during the period of the waiver.

The conditions for obtaining a low sulfur diesel waiver are similar to those in the RFG and low sulfur gasoline regulations. These conditions are necessary and appropriate to ensure that any waivers that are granted are limited in scope, and that refiners do not gain economic benefits from a waiver. Therefore, refiners seeking a waiver must show that the waiver is in the public interest, that the refiner was not able to avoid the nonconformity, that it will make up the air quality detriment associated with the waiver, that it will make up any economic benefit from the waiver, and that it will meet the applicable diesel sulfur standards as expeditiously as possible.

b. Temporary Waivers Based on Extreme Hardship Circumstances

In addition to the provision for short-term relief in extreme unforseen circumstances, we are adopting a provision for relief based on extreme hardship circumstances. In developing our diesel sulfur program, we considered whether any refiners would face particular difficulty in complying with the standards in the lead time provided. As described earlier in this section, we concluded that refineries owned by small businesses will experience more difficulty in complying with the standards on time because they have less ability to raise the capital necessary for refinery investments, face proportionately higher costs because of poorer economies of scale, and are less able to successfully compete for limited engineering and construction resources. However, it is possible that other refiners that are not small refiners will also face particular difficulty in complying with the sulfur standards on time. Therefore, we are including in this final rule a provision which allows us, at our discretion, to grant temporary waivers from the diesel sulfur standards based on a showing of extreme hardship circumstances.

The extreme hardship provision allows any domestic or foreign refiner to request a waiver from the sulfur standards based on a showing of unusual circumstances that result in extreme hardship and significantly affect a refiner's ability to comply with the low sulfur diesel standards by June 1, 2006. An approved extreme hardship waiver may provide refiners with provisions similar to those for small refiners, or as with the waiver for extreme unforseen circumstances, may provide a greater allowance for producing 500 ppm (for sale only for use in pre-2007 vehicles) during the period the temporary compliance option is in effect. As with other relief provisions established in this rule, any waiver under this provision must be designed to prevent fuel exceeding the 15 ppm standard from being used in 2007 and later vehicles.

By providing short-term relief to those refiners that need additional time because they face hardship circumstances, we can adopt an overall program that reduces diesel fuel sulfur beginning in 2006 for the majority of the industry. However, we do not intend for this waiver provision to encourage refiners to delay planning and investments they would otherwise make. We do not expect to grant temporary waivers that apply to more than approximately one percent of the national highway diesel fuel pool in any given year.

The regulatory language for today's action includes a complete list of the information that must be included in a refiner's application for an extreme hardship waiver. If a refiner fails to provide all the information, as specified in the regulations, as part of its hardship application, we can deem the application void. The following are some examples of the types of information that must be contained in an application:

—The crude oil refining capacity and diesel fuel sulfur level at each of the refiner's refineries.

—Details on how the refiner plans to modify its current operation to achieve future diesel fuel sulfur levels.

—The anticipated timing for the overall project the refiner is proposing and key milestones to ultimately produce 100 percent of highway diesel fuel at the 15 ppm sulfur standard.

—The refiner's capital requirements for the proposed project

—Plans for financing the project and financial statements

—List of the areas where the refiner's diesel fuel will be sold.

We will consider several factors in our evaluation of the hardship waiver applications. Such factors will include whether a refinery's configuration is unique or atypical; the proportion of diesel fuel production relative to other refinery products; whether the refiner, its parent company, and its subsidiaries are faced with severe economic limitations (for example, a demonstrated inability to raise necessary capital or an unfavorable bond rating); steps the refiner has taken to attempt to comply with the standards, including efforts to obtain credits towards compliance. In addition, we will consider the total crude oil capacity of the refinery and its parent or subsidiary corporations, if any, in assessing the degree of hardship and the refiner's role in the diesel market. Finally, we will consider where the diesel fuel will be sold in evaluating the environmental impacts of granting a waiver.

This extreme hardship provision is intended to address unusual circumstances that should be apparent now or will emerge in the near future. Thus, refiners seeking additional time under this provision must apply for relief by June 1, 2002. Applicants for a hardship waiver must also submit a plan demonstrating how they will achieve the standards as quickly as possible. In submitting the plan, applicants must include a timetable for obtaining the necessary capital, contracting for engineering and construction resources, obtaining any necessary permits, and beginning and completing construction.

We will review and act on applications and, if a waiver is granted, will specify a time period, not to extend beyond May 31, 2010, for the waiver.

D. Technological Feasibility of the Low Sulfur Diesel Fuel Program

This section summarizes our assessment of the feasibility of refining and distributing diesel fuel with a sulfur content of no more than 15 ppm. Based on this evaluation, we believe it is technologically feasible for refiners to meet the 15 ppm sulfur standard in the lead time provided. We are summarizing our analysis here and we refer the reader to the RIA for more details.

1. *What Technology Will Refiners Use?*

Conventional diesel desulfurization technologies have been available and in use for many years. Conventional hydrotreating technology involves combining hydrogen with the distillate (material falling into the boiling range of diesel fuel) at moderate pressures and temperatures and flowing the mixture through a fixed bed of catalyst.

We project that all refiners will be technically capable of meeting the 15 ppm sulfur cap with extensions of the same conventional hydrotreating which they are using to meet the current highway diesel fuel standard of 500 ppm sulfur. This extension will likely mean adding a second stage of conventional hydrotreating. Converting an existing one-stage hydrotreater into a two-stage hydrotreater will involve adding an additional reactor as well as other, more minor units to support the new desulfurization unit. These units could include hydrogen plants, sulfur recovery plants, amine plants and sour water scrubbing facilities. All of these units are already operating in refineries, but may have to be expanded or enlarged. We also project that all refiners will utilize recently developed, high activity catalysts, which increase the amount of sulfur that can be removed relative to the catalysts which were available when the current desulfurization units were designed and built.

While still utilizing this conventional hydrotreating technology, we expect that some refiners (roughly 20 percent of current production volume) will decide to invest in a completely new two-stage hydrotreater rather than revamp their current unit. This could occur because the current hydrotreater is too old or designed to operate at too low a pressure, or because the refiner desires to expand production of highway diesel fuel.

The sufficiency of conventional hydrotreating to meet a 15 ppm sulfur cap with current diesel fuel blendstocks is based primarily on information provided by several refining technology vendors.[174] The vendors all projected that two-stage hydrotreating would be sufficient to meet a 15 ppm sulfur cap. However, their projections of hydrogen consumption and requisite reactor volume varied widely. Our projections for hydrogen consumption and reactor volume are near the lower end of the range and are essentially the same projections as were made in support of the proposed rule.

Many refiners commented that we had underestimated the cost of meeting the 15 ppm sulfur cap. They argued that higher pressure, thick walled reactors of greater volume would be needed and that hydrogen consumption would be much higher than we projected. With one exception, neither the refiners, nor the technology vendors provided any underlying catalyst performance data with which we could use to arbitrate between the varying projections. One vendor did submit catalyst performance data from a commercial unit processing a diesel fuel like that produced in the U.S. Such commercial data is very limited, as refiners are generally not currently producing diesel fuel at sulfur levels below 10 ppm with this technology from diesel fuel feedstocks typical of U.S. refiners. Some refiners are currently producing diesel fuel at sulfur levels below either 10 or 50 ppm. However, their diesel fuel blendstocks differ substantially in quality from those available in the U.S., so their experience cannot be extrapolated easily to producing sub-15 ppm sulfur diesel fuel in the U.S.

Based on our review of the limited catalyst performance data in the published literature and the one set of confidential data submitted, we believe that the projections of the more optimistic vendors are the most accurate for the 2006 timeframe. For example, the confidential commercial data indicated that five ppm sulfur levels could be achieved with two-stage hydrotreating a moderate hydrogen pressures despite the presence of a significant amount of light cycle oil (LCO). The key factor was the inclusion of a hydrogenation catalyst in the second stage, which saturated many of the poly-nuclear, aromatic rings in the diesel fuel, allowing the removal of sulfur from the most sterically hindered compounds. In addition, refiners that are able to defer production of 15 ppm diesel fuel through the purchase of credits will have the added benefit of being able to observe the operation of those hydrotreating units starting up in 2006. This should allow these refiners to be able to select from the best technologies which are employed in the first phase of the program.

In addition, alternative technologies are presently being developed which could produce additional savings for refiners that are able to delay production of 15 ppm fuel until 2010. Phillips 66 Company, for example, just announced that they are developing a version of their S-Zorb technology for diesel fuel desulfurization. This technology has been selected by at least one major refiner (Marathon-Ashland) to meet the Tier 2/low sulfur gasoline requirements. In conjunction with a DOE research program, Phillips is designing and constructing a commercially sized S-Zorb diesel fuel unit at their Borger refinery. This unit is currently scheduled for start-up in 2004. We believe that this technology could reduce the cost of meeting the 15 ppm cap by roughly 25 percent.

2. Have These Technologies Been Commercially Demonstrated?

As mentioned above, conventional diesel desulfurization technologies have been available and in use for many years. U.S. refiners have roughly seven years of experience with this technology in producing highway diesel fuel with less than 500 ppm sulfur. Refiners in California also have the same length of experience with meeting the California 500 ppm cap on sulfur and an additional aromatics standard.[175] To meet both sulfur and aromatics standards, refineries in California are producing highway and nonroad diesel fuel with an average sulfur level of 150 ppm.

Some refiners in Europe are producing a very low-sulfur, low aromatics diesel fuel for use in the cities in Sweden (Class I Swedish Diesel) using two-stage hydrotreating. This "Swedish city diesel" is averaging under 10 ppm sulfur and under 10 volume percent aromatics. While clearly demonstrating the feasibility of consistently producing diesel fuel with less than 10 ppm sulfur from selected feedstocks, there are a few differences between the Swedish fuel and typical U.S. diesel fuel. First, the tight aromatics specification applicable to Swedish City diesel fuel usually requires the use of ring-opening or dearomatization catalysts in the second stage of the two-stage hydrotreating unit. Second, Swedish Class I diesel fuel also must meet a tight density specification. Third, it is not clear

[174] Technology vendors were invited to submit projections of technology and cost to two studies of the cost of diesel fuel desulfurization by Mathpro, Inc. One study was performed for EMA, and the other for the National Petroleum Council.

[175] California allows refiners to use an engine test to certify an alternative fuel mixture which meets or exceeds the NO_x reducing performance of a 10 volume percent maximum aromatics and a 500 ppm maximum sulfur diesel fuel.

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whether any refiner is producing a large fraction of their distillate production to this specification. Thus, the European experience demonstrates the efficacy of the two-stage process and its ability to produce very low sulfur diesel fuel. However, doing so without saturating most of the aromatics present and with heavier feedstock has only been demonstrated in pilot plants and not commercially. Even this pilot plant data has not been available for us to evaluate directly, due to vendors' competitiveness concerns.

Europe has adopted a 50 ppm cap sulfur standard for all diesel fuel which takes effect in 2005. Some countries, including England, have implemented tax incentives for refiners to produce this fuel sooner. The majority of diesel fuel in England already meets the 50 ppm specification. Refiners have reported no troubles with this technology. This diesel fuel is being produced in one-stage hydrotreaters. However, as mentioned above, European diesel fuel contains less heavier compounds than diesel fuel in the U.S., so the use of one-stage conventional hydrotreating to meet very low sulfur levels is applicable, but not sufficient to demonstrate feasibility in the U.S. Germany has also established a tax incentive, but for diesel fuel containing 10 ppm or less sulfur. One European technology vendor indicated that they have already licensed two desulfurization units to German refiners planning to produce diesel fuel to obtain this tax credit. Europe also is considering a 10 ppm sulfur cap to take effect later in the decade. However, no refiner is currently producing number two diesel fuel to this specification.

Phillips Petroleum is currently in the process of designing and constructing a commercial sized S-Zorb unit to produce sub-15 ppm diesel fuel at their Borger, Texas refinery. This plant is scheduled to begin commercial operation in 2004. This may not be in time to give refiners sufficient confidence in this novel process to rely on it to meet the 2006 deadline. However, this process, with its attendant hydrogen, cost, and global emission savings should be available for those refiners that are able to defer investment under the temporary compliance option and hardship provisions of today's rule. While we are confident that this and other technology will be available to meet the requirements of today's rule, EPA will work with the Department of Energy, refiners and technology providers to continue to monitor and analyze the progress in further developing and implementing this new diesel desulfurization technology. This will allow us to improve our understanding of how this new technology can be employed to enhance the implementation of this program.

3. Feasibility of Distributing Low Sulfur Highway Diesel Fuel

We believe that with relatively minor changes and associated costs, the existing distribution system will be capable of adequately managing sulfur contamination during the transportation of 15 ppm highway diesel fuel from the refinery through to the end-user. Further, we believe that the existing system is capable of handling two grades of highway diesel fuel (500 ppm and 15 ppm sulfur cap) in a limited fashion during the transition period of the sulfur program at acceptable cost with the addition of storage tanks at a fraction of distributor facilities.

The following minor changes in distribution practices will be needed as a result of today's rule during the transition years of the fuel program when various hardship and optional compliance provisions are in effect and thereafter:

—To adequately separate shipments of highway diesel fuel from shipments of higher sulfur products, pipeline operators will need to increase the amount of highway diesel fuel that they downgrade to a lower value product.

—Instead of cutting the mixture of jet fuel and highway diesel fuel that results during pipeline shipments of these products into the highway diesel pool, pipeline operators will need to segregate this mixture and sell it into the nonroad diesel pool. This change will necessitate the addition at some terminals of small tanks to handle the mixture of jet fuel and highway diesel fuel.

—Terminal operators will need to perform additional quality control testing to ensure compliance with the 15 ppm sulfur cap.

We also recognize that tank truck operators will need to more carefully and consistently observe current industry practices to limit contamination during the transport of 15 ppm sulfur highway diesel fuel. However, because these practices already exist and need only to be better enforced by distributors, we continue to believe that this can be accomplished at insignificant cost. We believe that there will not be a significant increase in the volume of highway diesel fuel discovered to exceed the sulfur standard downstream of the refinery as a result of today's rule. Distributors will quickly optimize the distribution system using the means described above to avoid creating additional volumes of out of specification product.

To accommodate two grades of highway diesel fuel during the transition period, additional storage tanks will need to be added at some refineries, terminals, bulk plants, and truck stops. There are significant costs associated with the addition of tanks which are fully accounted for during the transition period (see Section V). Commenters on the NPRM stated that in addition to the substantial economic burden that adding additional storage tanks would represent for some distributors, limitations in available space and permitting restrictions could preclude some distributors from installing additional tanks. This transition is also an added concern for those users of specialty fuels (i.e., military fuels, etc.) who currently compete for the limited storage tanks because these fuels must be segregated. We believe that the burden of adding new storage tanks to the system is made manageable by the fact that not all distributors will need to handle 500 ppm as well as 15 ppm sulfur highway diesel fuel during this time period. Marketplace forces will determine which facilities assume the additional burden of handling both grades of highway diesel fuel. Those facilities for which the addition of a storage tank would represent an unacceptable burden would opt not to serve the 500 ppm sulfur highway diesel market during the transition years.

We received several comments on the proposed rule that substantial uncertainties exist regarding the ability of the distribution system to adapt to the added hardship of limiting sulfur contamination of highway diesel fuel meeting a 15 ppm sulfur cap. These commenters noted that under today's rule other products in the distribution system would have a sulfur content of over 300 times the 15 ppm highway diesel fuel sulfur cap, and that unavoidable mixing of small quantities of these high sulfur products into highway diesel fuel could easily cause the 15 ppm sulfur cap to be exceeded. To illustrate the magnitude of the challenge, these commenters noted that currently the maximum sulfur content of any product that shares the distribution system with highway diesel fuel is no more than 10 times the current 500 ppm sulfur cap for highway diesel fuel.[176] Some commenters stated that the only way to adequately limit sulfur contamination in the distribution of diesel fuel with a 15 ppm sulfur cap may be to create a completely segregated system (at an unacceptably high cost). These commenters stated that unavoidable contamination could cause many batches of highway diesel fuel to be noncompliant with the 15 ppm cap resulting in shortages and high costs. Some commenters stated that additional evaluation is needed to determine the capability of the distribution system to limit contamination to the very low levels necessitated by today's rule.

While we acknowledge that today's rule will pose a substantial new challenge to the distribution system, we believe that the additional measures outlined in this section will substantially address issues associated with adequately limiting sulfur contamination during the distribution of 15 ppm sulfur highway diesel fuel.[177] Its true that not all of the potential minute sources of sulfur contamination in the distribution sources have been identified and that the cumulative magnitude from these sources is uncertain. However, we believe that the contamination from such sources, while made more significant by the implementation of the 15 ppm sulfur cap, is not of a sufficient magnitude to jeopardize the feasibility of distributing low sulfur highway diesel fuel. We will work with the Department of Energy, refiners and others involved in diesel fuel distribution to analyze, compile data, and conduct additional research, where appropriate, to not only more fully understand all sources of contamination and deliverability in the distribution of diesel fuel below the 15ppm cap, but also their impact on the deliverability of other fuels, including specialty military fuels. This information will be used, in conjunction with information being developed on the operation of emission control devices (which are affected by exposure to sulfur), to monitor progress on the successful implementation of this final rule which depends on an integrated vehicle/fuel systems approach. Please refer to Section V.D. on the costs of today's rule to the distribution system, and to the Regulatory Impact Analysis and Response to Comments documents for additional discussion regarding the feasibility of distributing highway diesel fuel with a 15 ppm sulfur cap.

[176] Nonroad diesel fuel has a sulfur cap of 5,000 ppm versus a 500 ppm for current highway diesel fuel.

[177] See the Response to Comments document for this rule.

E. What Are the Potential Impacts of the Low Sulfur Diesel Program on Lubricity and Other Fuel Properties?

1. What Is Lubricity and Why Might It Be a Concern?

Engine manufacturers depend on diesel fuel lubricity properties to lubricate and protect moving parts within fuel pumps and injection systems for reliable performance. Unit injector systems and in-line pumps, commonly used in heavy-duty engines, are actuated by cams lubricated with crankcase oil, and have minimal sensitivity to fuel lubricity. However, rotary and distributor type pumps, commonly used in light and medium-duty diesel engines, are completely fuel lubricated, resulting in high sensitivity to fuel lubricity.

In the United States, there is no government or industry standard for diesel fuel lubricity. Thus, specifications for lubricity are determined by the market. Since the beginning of the 500 ppm sulfur highway diesel program in 1993, fuel system producers, engine and vehicle manufacturers, and the military have been working with the American Society for Testing and Materials (ASTM) to develop protocols and standards for diesel fuel lubricity in its D–975 specifications for diesel fuel. Although the ASTM has not yet adopted specific protocols and standards, we understand that refiners have been treating diesel fuel with lubricity additives on a batch to batch basis, when poor lubricity fuel is expected. In addition, the military has found that traditional corrosion inhibitor additives that it uses in its fuels have been highly effective in reducing fuel system component wear. Some commenters expressed concern about the impacts of a 15 ppm standard on fuel lubricity.

Experience has shown that it is very rare for a naturally high-sulfur fuel to have poor lubricity, although, most studies show relatively poor overall correlation between sulfur content and lubricity. Considerable research remains to be performed for a better understanding of the fuel components most responsible for lubricity. Consequently, we are uncertain about the potential impacts of the 15 ppm sulfur standard on fuel lubricity. There is evidence that the typical process used to remove sulfur from diesel fuel—hydrotreating—can impact lubricity depending on the severity of the treatment process and characteristics of the crude. Because refiners will likely rely on hydrotreating to achieve the proposed sulfur limit, there may be reductions in the concentration of those components of diesel fuel which contribute to adequate lubricity. As a result, the lubricity of some batches of fuel may be reduced compared to today's levels, resulting in an increased need for the use of lubricity additives in highway diesel fuel. In response to the proposal, all comments submitted regarding lubricity either stated or implied that the proposed sulfur standard of 15 ppm would likely cause the refined fuel to have lubricity characteristics that would be inadequate to protect fuel injection equipment, and that mitigation measures such as lubricity additives would be necessary. However, the commenters suggested varied approaches for addressing lubricity. For example, some suggested that we need to establish a lubricity requirement by regulation, but others suggested that the current voluntary (market) system would be adequate. The Department of Defense recommended that we encourage the industry (ASTM) to adopt lubricity protocols and standards before the implementation date of the low sulfur fuel established by today's action. Other suggested approaches included incorporation of biodiesel as a solution to the lubricity issue, and the need to further examine the issues.

Blending small amounts of lubricity-enhancing additives increases the lubricity of poor-lubricity fuels to acceptable levels. These additives are available in today's market, are effective, and are in widespread use around the world. For example, in the U.S., we understand that refiners are treating diesel fuel with lubricity additives on a batch to batch basis, when poor lubricity fuel is expected. Other examples include Sweden, Canada, and the U.S. military. Since 1991, the use of lubricity additives in Sweden's 10 ppm sulfur Class I fuel and 50 ppm sulfur Class II fuel has resulted in acceptable equipment durability.[178] Since 1997, Canada has required that its 500 ppm sulfur diesel fuel not meeting a minimum lubricity be treated with lubricity additives. The U.S. military has found that the traditional corrosion inhibitor additives that it uses in its fuels have been highly effective in reducing fuel system component wear.

2. Today's Action on Lubricity: A Voluntary Approach

We have decided to not establish a lubricity standard in today's action, but have included a 0.2 cents per gallon cost in our calculations for the economic

[178] See letter from MTC to Michael P. Walsh, dated October 16, 2000. In public docket, document IV–G–42.

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impact to account for the potential increased use of lubricity additives (see section V.D.2). We believe the best approach is to allow the industry and the market to address the lubricity issue in the most economical manner, while avoiding an additional regulatory scheme. A voluntary approach should provide adequate customer protection from engine failures due to low lubricity, while providing the maximum flexibility for the industry. This approach will be a continuation of current industry practices for diesel fuel produced to meet the current federal and California 500 ppm sulfur diesel fuel specifications, and benefits from the considerable experience gained since 1993. It will also include any new specifications and test procedures that we expect will be adopted by the American Society for Testing and Materials (ASTM) regarding lubricity of highway diesel fuel quality.

We do not believe that an EPA regulation for lubricity is appropriate for several reasons. First, the expertise and mechanism for a lubricity standard already exist in the industry. According to the comments, the industry has been working on a lubricity specification for ASTM D–975, and low cost remedies for poor lubricity have already been proven and are already being used around the world. Although some commenters expressed concerns that the ASTM process might move too slowly to establish a lubricity specification by 2006, we fully expect the refining industry, engine manufacturers and end users to work together to resolve any issues as part of their normal process in dealing with customer and supplier fuel quality issues. Today's action will increase the urgency of those working to establish an ASTM D–975 lubricity specification, and we believe they will do so in time for the production and distribution of the low sulfur highway diesel fuel. We will do our part to encourage the ASTM process be brought to a successful conclusion.

Second, we have no firm basis to justify a lubricity specification in today's action. One such basis might be adequate demonstration that a lubricity level below or above a certain specification would either cause emissions to increase, or hinder the operation of emission control equipment. However, we have no evidence that lubricity impacts emissions, or emission control equipment. This issue is primarily a concern about equipment performance. Equipment performance is more appropriately addressed by the industry rather than government regulation by this Agency.

Third, even if we had a statutory basis to justify a lubricity standard, we are concerned that establishing an EPA lubricity regulation would provoke the same disagreements that the industry is now engaged in its efforts to establish an ASTM D–975 specification. We are in no better position to judge those issues than the industry experts who are already involved. Further, once a specification is put into the regulations and the industry subsequently determines that the specification should be changed, based on new information or circumstances, the burden would be on us to amend the mandated specification by rulemaking. This is a significant burden to put on the Agency for an engine performance issue that can and should be resolved by the industry without government intervention.

Subsequent to the close of the comment period another issue related to lubricity concerns was raised to the Agency. These concerns related to potential incompatibilities in old vehicles of the new engine oils the industry hopes to develop for use in the new 2007 and later model year vehicles. Much of the ash in today's motor oil results from the need to control acidification of the engine oil (maintain total base number, or TBN control), which is in large part a function of the sulfur content of the fuel and the sulfuric acid that it forms. Without the ability to control acidification of the engine oil, engine wear increases significantly. The ash in the oil, however, will tend to shorten the maintenance intervals for particulate filters to remove built up ash on new 2007 and later model year vehicles. At the same time, engines operated on low sulfur fuel have much less need for TBN control and the high ash levels that result. Consequently, manufacturers are investigating with the lubricant industry the potential of lower ash oils for use in engines operated on low sulfur diesel fuel and equipped with particulate traps. If the new oil developed is not "backwards compatible" to sufficiently control acidification and wear in the pre-existing fleet of vehicles on the road that may still be operated on high sulfur diesel fuel for the first few years of the program, then two grades of motor oil would have to be on the market simultaneously. This has caused some stakeholders to raise vehicle performance and durability concerns that might result from using the new oil in the old vehicles—namely "mis-oiling."

Since the engine and lubricant industries still have a number of years to develop these new oil formulations, it is still premature to determine whether or not the new oils will be backwards compatible and whether mis-oiling would raise any serious concerns. While this would not appear to be an air quality concern and as such something the Agency generally leaves up to the industry to resolve, we will nevertheless offer to work with the industry and industry associations on this issue over the coming years." EPA anticipates that engine manufacturers would likely provide engine labels to distinguish low ash oil from high ash oil because misoiling could result in engine damage.

3. What Are Today's Actions on Fuel Properties Other Than Sulfur?

We are not taking action today on any fuel properties other than sulfur. We have examined the impact of fuel properties other than sulfur, such as aromatics, on the materials used in engines and fuel supply systems. We do not believe there will be impacts on materials from such other fuel properties.

While there were some problems with leaks from fuel pump O-ring seals made of a certain material (Nitrile) after the introduction of 500 ppm sulfur diesel fuel in the United States in 1993, these issues have since been addressed by equipment manufacturers who switched to materials that are compatible with low aromatic fuels. The leakage from the Nitrile seals was determined to be due to low aromatics levels in some 500 ppm sulfur fuel, not the low sulfur levels. In the process of lowering the sulfur content of some fuel, some of the aromatics had also been removed. Normally, the aromatics in the fuel penetrate the Nitrile material and cause it to swell, thereby providing a seal with the throttle shaft. When low-aromatics fuel is used after conventional fuel has been used, the aromatics already in the swelled O-ring will leach out into the low-aromatics fuel. Subsequently, the Nitrile O-ring will shrink and pull away, thus causing leaks, or the stress on the O-ring during the leaching process will cause it to crack and leak. Not all 500 ppm sulfur fuels caused this problem, because the amount and type of aromatics varied. Fuel pumps using a different material (Viton) for the seals did not experience leakage. We believe that no additional problems will occur with a change of fuel from 500 to 15 ppm sulfur.

F. How Are State Programs Affected by the Low Sulfur Diesel Program?

1. State Preemption

Section 211(c)(4)(A) of the CAA prohibits states (and political subdivisions of states) from prescribing or attempting to enforce controls or prohibitions respecting any fuel characteristic or component if EPA has prescribed a control or prohibition applicable to such fuel characteristic or component under section 211(c)(1). This preemption applies to all states except California, as explained in section 211(c)(4)(B). For states other than California, the Act provides two mechanisms for avoiding preemption. First, section 211(c)(4)(A)(ii) creates an exception to preemption for state prohibitions or controls that are identical [179] to the prohibition or control adopted by EPA. Second, states may seek EPA approval of SIP revisions containing fuel control measures, as described in section 211(c)(4)(C). We may approve such SIP revisions, and thereby "waive" preemption, only if it finds the state control or prohibition "is necessary to achieve the national primary or secondary ambient air quality standard which the plan implements."

When we adopted the current highway diesel fuel sulfur standard of 500 ppm pursuant to our authority under section 211(c)(1) of the CAA in 1990, States were preempted from also doing so under the provisions of section 211(c)(4)(A). The 15 ppm highway diesel fuel sulfur standard promulgated today modifies the existing standard and, as a result, do not initiate any new preemption of state authority. Today's action continues the explicit preemption under section 211(c)(4)(A) of state actions to prescribe or enforce highway diesel fuel sulfur controls. States other than California with highway diesel fuel sulfur control programs not already approved into their SIPs are preempted under Section 211(c)(4)(A) and will therefore need to obtain a waiver from us under the provisions described in section 211(c)(4)(C) for all state fuel sulfur control measures, unless the state control or prohibition is identical to ours.

Aside from the explicit preemption in Section 211(c)(4)(A), a court could also consider whether a state sulfur control is implicitly preempted under the Supremacy Clause of the U.S. Constitution. Courts have determined that a state law is preempted by federal law where the state requirement actually conflicts with federal law by preventing compliance with both federal and state requirements, or by standing as an obstacle to accomplishment of Congressional objectives. A court could thus consider whether a given state sulfur control is preempted, notwithstanding waiver of preemption under 211(c)(4)(C), if it places such significant cost and investment burdens on refiners that refiners cannot meet both state and federal requirements in time, or if the state control would otherwise meet the criteria for conflict preemption.

[179] In evaluating whether a state fuel prohibition or control is "identical" to a prohibition or control adopted by us, we might consider but is not limited to the following factors in comparing the measures: (1) The level of an emission reduction or pollution control standard for any particular batch of diesel fuel; (2) the use of "per gallon" or "averaged" amounts in setting that level; (3) the lead time allowed to the affected industry for compliance; (4) the test method(s) and sampling requirements used in determining compliance; and (5) reporting and recordkeeping requirements.

2. What Provisions Apply in Alaska?

There are important nationwide environmental and public health benefits that will be achieved with cleaner diesel engines and fuel, particularly from reduced particulate emissions, nitrogen oxides, and air toxics (as further discussed in section II). Therefore, it is also important to implement this program in Alaska. Any 2007 and later model year diesel vehicles in Alaska, or driven to Alaska, must be fueled with low sulfur highway diesel, or risk potential damage to the aftertreatment technologies or even the engines themselves. Although the engine standards established today are not based upon different technology and cost implications for Alaska as compared to the rest of the country, the low sulfur fuel program has different implications.

Unlike the rest of the nation, Alaska is currently exempt from the 500 ppm sulfur standard for highway diesel fuel and dye requirements. Since the beginning of the 500 ppm highway diesel fuel program, we have granted Alaska exemptions from meeting the sulfur standard and dye requirements, because of its unique geographical, meteorological, air quality, and economic factors. (These unique factors are discussed generally in this section, and in more detail in the RIA.) Because of these unique factors, we are establishing in today's action an alternative option for implementing the low sulfur fuel program in Alaska.

We are providing the State of Alaska an opportunity to develop an alternative low sulfur transition plan. We intend to facilitate the development of this plan by working in close cooperation with the state and key stakeholders. This plan must ensure that sufficient supplies of low sulfur diesel fuel are available in Alaska to meet the demand of any new 2007 and later model year diesel vehicles. Given that Alaska's demand for highway diesel fuel is very low and only a small number of new diesel vehicles are introduced in Alaska each year, it may be possible to develop an alternative implementation plan for Alaska in the early years of the program that provides low sulfur diesel only in sufficient quantities to meet the demand from the small number of new diesel vehicles. This would give Alaska refiners more flexibility during the transition period because they would not have to desulfurize the entire highway diesel volume. Our goal in offering this additional flexibility is to transition Alaska into the low sulfur fuel program in a manner that minimizes costs, while still ensuring that the new vehicles receive the low sulfur fuel they need. We expect that the transition plan will begin to be implemented at the same time as the national program, but the state will have an opportunity to determine what volumes of low sulfur fuel must be supplied, and in what timeframes, in different areas of the state.

At a minimum, this transition plan must: (1) Ensure an adequate supply (either through production or imports) of 15 ppm fuel to meet the demand of any 2007 or later model year vehicles, (2) ensure sufficient retail availability of low sulfur fuel for new vehicles in Alaska, (3) address the growth of supply and availability over time as more new vehicles enter the fleet, (4) include measures to ensure segregation of the 15 ppm fuel and avoid contamination and misfueling, and (5) ensure enforceability. We anticipate that, to develop a workable transition plan, the state will likely work in close cooperation with refiners and other key stakeholders, including retailers, distributors, truckers, engine manufacturers, environmental groups, and other interested groups. For example, the state will likely rely on input from the trucking industry in determining the expected low sulfur fuel volume needed in Alaska, based on the anticipated number of new vehicles, and how this volume is expected to grow during the first few years of the program. Similarly, the state will likely rely on the Alaska refiners' input regarding plans for supplying (either through production or imports) low sulfur fuel to meet the expected demand. Further, the state will likely rely on input and cooperation from retailers and distributors to determine at which locations the low sulfur fuel should be made available. Retailers offering low sulfur fuel will have to take measures to prevent misfueling, such as pump labeling, which must include

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provisions that are at least as stringent as those required of retailers nationally by the regulations and as described in section VII. Similarly, all parties in the distribution system must ensure the low sulfur fuel remains segregated and must take measures to prevent sulfur contamination, in a manner that is at least as stringent as that required nationally by the regulations and as described in section VII.

If the state anticipates that the primary demand for low sulfur fuel will be along the highway system (e.g., to address truck traffic from the lower-48 states) in the early years of the program, then the initial stages of the transition plan could be focused in these areas. We believe it would be appropriate for the state to consider an extended transition schedule for implementing the low sulfur program in rural Alaska, as part of the state's overall plan, based on when they anticipate the introduction of a significant number of 2007 and later model year vehicles in the remote areas.

Under this approach, the state will be given the opportunity to develop such a transition plan, as an alternative to the national program, and submit it to us for approval. We intend to help facilitate the development of the plan, by working closely with the state and the relevant stakeholders so they will have an opportunity to address our concerns in their submittal. It is our intent that any flexibility that is available to small refiners nationwide (as described in Section IV) will also be available to small refiners in Alaska under an approved alternative transition plan. To ensure that refineries and other affected parties will have certainty regarding their regulatory requirements with adequate lead time, Alaska must submit this plan by April 1, 2002 (approximately one year after the effective date of today's rule). If Alaska submits such a plan to us within one year, and if it provides a reasonable alternative as described above, we will conduct a rulemaking with notice for public comment and then publish a final rule promulgating the new regulatory scheme for Alaska. Our intent is to issue such a final rule within one year of Alaska's submittal of the plan. However, if the state chooses not to submit an alternative plan, or if the plan it submits does not provide a reasonable alternative for Alaska as described above, then refiners and other regulated parties in Alaska will be subject to the national program, including the implementation schedule established in today's action, without further regulatory action.

a. Today's Action Regarding the 500 ppm Standard in Alaska

We are extending the existing temporary exemption from the current diesel fuel sulfur standard of 500 ppm for the areas of Alaska served by the Federal Aid Highway System (FAHS) to the effective date for the new standard (*i.e.*, June 1, 2006 at the refinery level; July 15, 2006 at the terminal level; and September 1, 2006 at all downstream locations). While Alaska submitted a petition for a permanent exemption from the 500 ppm standard for these areas, we are not taking further action on that petition. Our goal is to take action on that petition in a way that minimizes costs through Alaska's transition to the new low sulfur program. The cost of compliance could be reduced if Alaska refiners were given the flexibility to meet the low sulfur standard in one step, rather than two steps (*i.e.*, once for the current 500 ppm sulfur standard in 2004 when the temporary exemption expires, and again for the new 15 ppm standard in 2006).

As already discussed, we are allowing Alaska to develop an alternative transition plan for implementing the low sulfur diesel fuel program. During such a transition period, it is possible that both low sulfur diesel fuel (for 2007 and later model year vehicles) and higher sulfur (for older vehicles) highway fuels might be available in Alaska. To avoid the two-step sulfur program described above during an alternative transition period, we will consider additional extensions to the temporary exemption of the 500 ppm standard beyond 2006 (*e.g.*, for that portion of the highway diesel pool that is available for the pre-2007 vehicles) during Alaska's transition period. We will make a decision on any additional temporary extensions, if appropriate, in the context of the separate rulemaking taking action on the alternative transition plan submitted by Alaska.

As in previous actions to grant Alaska sulfur exemptions, we will not base any vehicle or engine recall on emissions exceedences caused by the use of high-sulfur (>500 ppm) fuel in Alaska during the period of the temporary sulfur exemption. Our in-use testing goals are to establish whether representative engines, when properly maintained and used, will meet emission standards for their useful lives. These goals are consistent with the requirements for recall outlined in Section 207(c)(1) of the CAA. Further, manufacturers may have a reasonable basis for denying emission related warranties where damage or failures are caused by the use of high sulfur fuel in Alaska.

The Engine Manufacturers Association commented that the level of protection provided to engine manufacturers under the current exemption for Alaska and the proposal, as described above, falls short of what is reasonable and necessary. It asserted that the use of high sulfur diesel fuel by an engine should raise a "rebuttable presumption" that the fuel has caused the engine failure, and that EPA should have the burden of rebutting that presumption. It also asserted that the emissions warranty is a regulatory requirement under Section 207, that only EPA has the authority to exclude claims based on the use of high sulfur diesel fuel. We understand and concur with the manufacturers' concerns about in-use testing of engines operated in an area exempt from fuel sulfur requirements. Consequently, we affirm that, for recall purposes, we will not seek to conduct or cause the in-use testing of engines we know have been exposed to high sulfur fuels. We will likely screen any engines used in our testing program to see if they have been operated in the exempt area. We believe we can readily obtain sufficient samples of engines without testing engines from exempt areas. Also, in any recall that we order, manufacturers have the option of requesting a public hearing. The use of engines that have seen high sulfur fuel will increase the likelihood of a recall hearing. We expect manufacturers to scrutinize any test engines for sulfur usage that were used to justify an ordered recall. In reviewing the warranty concerns of the Engine Manufacturers Association, we have determined that our position regarding warranties, as previously stated and described above, is consistent with section 207(a) and (b) of the CAA and does not require any new or amended regulatory language to implement.

Today's action also grants Alaska's request for a permanent exemption from the dye requirement of 40 CFR 80.29 and 40 CFR 80.446 for the entire state. The costs of complying with the low sulfur (both the current 500 ppm sulfur and new 15 ppm sulfur) diesel fuel requirements could be reduced significantly if Alaska were not required to dye the non-highway fuel. Dye contamination of other fuels, particularly jet fuel, is a serious potential problem. This is a serious issue in Alaska since the same transport and storage tanks used for jet fuel (which is more than half of Alaska's distillate market) are generally also used for other diesel products, including off-highway diesel products which are required to be dyed under the current

national program. This issue is discussed further in the RIA (Chapter VIII).

b. Why Are We Treating Alaska Uniquely?

Section 211(i)(4) of the Clean Air Act (CAA) provides that the states of Alaska and Hawaii may seek an exemption from the diesel fuel sulfur standard (500 ppm as specified in section 211(i)) in the same manner as provided in section 325 of the CAA. The requested exemption could be granted if EPA determines that compliance with such requirement is not feasible or is unreasonable due to unique geographical, meteorological, or economic factors of the territory, or other local factors as EPA considers significant.

On February 12, 1993, Alaska submitted a petition under section 325 of the CAA to exempt highway vehicle diesel fuel in Alaska from paragraphs (1) and (2) of section 211(i) of the CAA, except for the minimum cetane index requirement.[180] The petition requested that we temporarily exempt highway vehicle diesel fuel in communities served by the FAHS from meeting the sulfur content (500 ppm) specified in section 211(i) of the CAA and the dye requirement for non-highway diesel fuel of 40 CFR 80.29, until October 1, 1996. The petition also requested a permanent exemption from those requirements for areas of Alaska not reachable by the FAHS'the remote areas. On March 22, 1994, (59 FR 13610), we granted the petition based on geographical, meteorological, air quality, and economic factors unique to Alaska.

On December 12, 1995, Alaska submitted a petition for a permanent exemption for all areas of the state served by the FAHS, that is, those areas covered only by the temporary exemption. On August 19, 1996, we extended the temporary exemption until October 1, 1998 (61 FR 42812), to give us time to consider comments to that petition that were subsequently submitted by stakeholders. On April 28, 1998 (63 FR 23241) we proposed to grant the petition for permanent exemption. Substantial public comments and substantive new information were submitted in response to the proposal. To give us time to consider those comments and new information, we extended the temporary exemption for another nine months until July 1, 1999 (September 16, 1998, 63 FR 49459). During this time period, we started work on a nationwide rule to consider more stringent diesel fuel requirements, particularly for the sulfur content (today's action). To coordinate the decision on Alaska's request for a permanent exemption with the new nationwide rule on diesel fuel quality, we extended the temporary exemption until January 1, 2004 (June 25, 1999, 64 FR 34126).

As discussed in the previous section, in today's action we are extending the temporary exemption from the 500 ppm diesel fuel sulfur standard to the effective date for the new nationwide 15 ppm diesel fuel sulfur standard in 2006. While it is important to implement in Alaska the cleaner diesel engines and fuel of today's action, our goal is to take action on the petition in a way that minimizes costs through Alaska's transition to the new low sulfur program. The cost of compliance could be reduced if Alaska refiners were given the flexibility to meet the low sulfur standard in one step (i.e., going straight from uncontrolled levels to the 15 ppm sulfur standard), rather than in two steps. We considered the prior public comments we received as a result of our previous notices and actions regarding exemptions from the 500 ppm sulfur standard for highway diesel fuel in Alaska (see RIA).

Unlike in the rest of the country, diesel fuel consumption for highway use in Alaska represents only five percent of the State's total distillate fuel consumption. Aviation and marine applications, power generation and heating consume most of the distillate, while Alaska's highway diesel vehicle fleet is relatively small, particularly outside the FAHS. The state estimates that there are less than 9000 diesel vehicles in the entire state, with less than 600 of these vehicles in all of rural Alaska. The state also indicates that new model vehicles are introduced into the Alaska market at a slower rate than elsewhere, thus Alaska does not need to transition its highway fuel to low sulfur as quickly as the rest of the nation.

Most of the fuel consumed in Alaska is produced by refineries located in Alaska. This is primarily because of the more severe cloud point specification needed for the extremely low temperatures experienced in much of Alaska during the winter and the high cost to import fuel that is produced elsewhere. There are four commercial refineries in Alaska. Only one of these refineries currently has any desulfurization capacity, which is relatively small. Consequently, because these refineries will have to reduce sulfur from uncontrolled levels to meet the new 15 ppm standard established by today's action, these refineries could incur substantially higher costs than those in the rest of the nation. Given the very small highway diesel demand, however, it is doubtful that more than one or two Alaska refineries will choose to produce low sulfur highway fuel, and these refiners could even decide to import it from refineries outside of Alaska.

Further, Alaska's fuel distribution system faces many unique challenges. Unlike the rest of the country, because of its current exemption from the 500 ppm sulfur standard and dye requirements, Alaska does not currently segregate highway diesel fuel from that used for off-road, marine, heating oil, and other distillate uses. Therefore, the distribution system costs for segregating a low sulfur grade of diesel for highway uses will be significant. The existing fuel storage facilities limit the number of fuel types that can be stored. In addition to significant obstacles to expanding tankage in Alaska, the cost of constructing separate storage facilities, and providing separate tanks for transporting low sulfur diesel fuel (e.g., by barge or truck), could be significant. Most of Alaska's communities rely on barge deliveries, and ice formation on the navigable waters during the winter months restricts fuel delivery to these areas. Construction costs are 30 percent higher in Alaska than in the lower-48 states, due to higher costs for freight deliveries, materials, electrical, mechanical, and labor. There is also a shorter period of time during which construction can occur, because of seasonal extremes in temperature and the amount of daily sunlight.

The severe impacts to Alaska's fuel distribution system of implementing a low sulfur requirement for highway diesel fuel would likely occur whether we require the current 500 ppm standard or the new 15 ppm standard. The impacts to Alaska's refineries and fuel importers are greater at 15 ppm than at 500 ppm. It is likely that the refiners and fuel importers would have a significant incremental impact if we required Alaska to implement the 500 ppm diesel fuel sulfur standard in 2004 when the current exemption expires, and the 15 ppm diesel fuel sulfur standard in 2006 when the new national requirement becomes effective, rather than only once for the 15 ppm diesel fuel sulfur standard in 2006.

[180] Copies of information regarding Alaska's petition for exemption, subsequent requests by Alaska, public comments received, and actions by EPA area available in public docket A–96–26.

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3. What Provisions Apply in American Samoa, Guam, and the Commonwealth of Northern Mariana Islands?

a. Today's Action Regarding the Highway Diesel Fuel Standard in the Territories

As we proposed, today's action excludes American Samoa, Guam and the Commonwealth of Northern Mariana Islands from the new diesel fuel sulfur requirement of 15 ppm and the 2007 heavy-duty diesel vehicle and engine emissions standards, and other requirements associated with those emission standards. The territories will continue to have access to 2006 heavy-duty diesel vehicle and engine technologies, at least as long as manufacturers choose to market those technologies. We will not, however, allow the emissions control technology in the territories to backslide from those available in 2006. If, in the future, manufacturers choose to market only heavy-duty diesel vehicles and engines with 2007 and later emission control technologies, we believe the market will determine when and if the territories will make the investment needed to obtain and distribute the low sulfur diesel fuel necessary to support these technologies.

This exclusion from emission standards does not apply to the new heavy-duty gasoline engine and vehicle emission standards, because low sulfur gasoline that complies with our regulations will be available, and so concerns about damage to engines and emissions control systems will not exist. This exclusion from emission standards also does not apply to light-duty diesel vehicles and trucks because gasoline vehicles and trucks meeting the emission standards and capable of fulfilling the same functions will be available. We believe that the market will determine when and if having access to new light-duty diesel technologies in the territories, in place of or in addition to gasoline technologies, is important enough to obtain and distribute the low sulfur diesel fuel needed to support those technologies.

As we also proposed, we are requiring all heavy-duty diesel motor vehicles and engines for these territories to be certified and labeled to the applicable requirements (either to the 2006 model year standards and associated requirements under the exclusion, or to the standards and associated requirements applicable for the model year of production under the nationwide requirements) and warranted, as otherwise required under the Clean Air Act and EPA regulations. Special recall and warranty considerations due to the use of excluded high sulfur fuel are the same as those for Alaska during its exemption and transition periods (see the discussion in previous section). To protect against this exclusion being used to circumvent the emission requirements applicable to the rest of the United States (*i.e.*, continental United States, Alaska, Hawaii, Puerto Rico and the U.S. Virgin Islands) after 2006 by routing exempted (pre-2007 technology) vehicles and engines through one of these territories, we are restricting the importation of vehicles and engines from these territories into the rest of the United States. After the 2006 model year, diesel vehicles and engines certified under this exclusion to meet the 2006 model year emission standards for sale in American Samoa, Guam and the Commonwealth of the Northern Mariana Islands will not be permitted entry into the rest of the United States.

b. Why Are We Treating These Territories Uniquely?

Unlike the rest of the nation (except Alaska), these territories are currently exempt from the 500 ppm sulfur standard for highway diesel fuel. Section 325 of the CAA provides that upon request of Guam, American Samoa, the Virgin Islands, or the Commonwealth of the Northern Mariana Islands, we may exempt any person or source, or class of persons or sources, in that territory from any requirement of the CAA, with some specific exceptions. The requested exemption could be granted if we determine that compliance with such requirement is not feasible or is unreasonable due to unique geographical, meteorological, or economic factors of the territory, or other local factors as we consider significant.

Prior to the effective date of the current highway diesel sulfur standard of 500 ppm, the territories of American Samoa, Guam and the Commonwealth of Northern Mariana Islands petitioned us for an exemption under section 325 of the CAA from the sulfur requirement under section 211(i) of the CAA and associated regulations at 40 CFR 80.29. The petitions were based on geographical, meteorological, air quality, and economic factors unique to those territories. We subsequently granted the petitions.[181]

These U.S. territories are islands with limited transportation networks. Combined, these three territories have only approximately 1300 registered diesel vehicles. Diesel fuel consumption in these vehicles represents just a tiny fraction of the total diesel fuel volume consumed on these islands; the bulk of diesel fuel is burned in marine, nonroad, and stationary applications. Consequently highway diesel vehicles are believed to have a negligible impact on the air quality in these territories, which, with minor exceptions, is very good.

All three of these territories lack internal petroleum supplies and refining capabilities and rely on long distance imports. Given their remote location from Hawaii and the U.S. mainland, most petroleum products are imported from East rim nations, particularly Singapore. Although Australia, the Philippines, and certain other Asian countries have or will soon require low sulfur diesel fuel, their sulfur limit is 500 ppm, not the new 15 ppm sulfur limit established by today's action for the United States. Compliance with low sulfur (15 ppm) requirements for highway fuel would require construction of separate storage and handling facilities for small quantities of a unique grade of diesel fuel for highway purposes, or use of low sulfur (15 ppm) diesel fuel for all purposes to avoid segregation. Either of these alternatives would require importation of the low sulfur fuel from Hawaii or the U.S. mainland, and would significantly add to the already high cost of diesel fuel in these territories, which rely heavily on United States support for their economies.

G. Refinery Air Permitting

Prior to making diesel desulfurization changes, some refineries may be required to obtain a preconstruction permit, under the New Source Review (NSR) program, from the applicable state/local air pollution control agency.[182] We believe that today's program provides sufficient lead time for refiners to obtain any necessary NSR permits well in advance of the compliance date. Further, refiners will be able to stagger their construction of desulfurization projects, since many

[181] See 57 FR 32010, July 20, 1992 for American Samoa; 57 FR 32010, July 30, 1992 for Guam; and 59 FR 26129, May 19, 1994 for CNMI.

[182] Hydrotreating diesel fuel involves the use of process heaters, which have the potential to emit pollutants associated with combustion, such as NO_X, PM, CO and SO^2. In addition, reconfiguring refinery processes to add desulfurization equipment could increase fugitive VOC emissions. The emissions increases associated with diesel desulfurization will vary widely from refinery to refinery, depending on many source-specific factors, such as crude oil supply, refinery configuration, type of desulfurization technology, amount of diesel fuel produced, and type of fuel used to fire the process heaters.

refineries could take advantage of the temporary compliance option for low sulfur diesel fuel from 2006–2009, as described in Section IV.A. Although some refiners commented that obtaining air permits would be a factor in their ability to comply in the 2006 time frame, state/local agencies commented that they will make the issuance of permits a top priority, because they strongly support achieving the environmental objectives of the low sulfur highway diesel program. State/local agencies further commented that they are committed to working with all affected parties to expedite the processing and issuance of any necessary permits.

For the Tier 2/gasoline sulfur control program promulgated in December 1999, refiners had expressed concerns that permit delays might impede their ability to meet compliance dates. Although we believed that the Tier 2 program provided sufficient lead time for refiners to obtain permits, we committed to undertake several actions to minimize the possibility of any delays for refineries obtaining major NSR permits for gasoline desulfurization projects. These actions include providing federal guidance on emission control technologies[183] and the appropriate use of motor vehicle emission reductions (resulting from the use of low sulfur gasoline), where available, as emission offsets, as well as forming EPA permit teams to assist states in quickly resolving issues, where needed. These three items are discussed in more detail in the Tier 2 final rule (see 65 FR 6773, Feb. 10, 2000).

Given that today's diesel sulfur program provides more than five years of lead time, as well as an additional transitional period, we believe refiners will have ample time to obtain any necessary preconstruction permits. Nevertheless, we believe it is reasonable to continue our efforts under the Tier 2 program, as described above, to help states in facilitating the issuance of permits under the highway diesel sulfur program. For example, the guidance on BACT and LAER control technology that is currently under development for the gasoline sulfur program should have application for diesel desulfurization projects as well. We will plan to reevaluate this guidance to the extent that it may need to be revised or updated for application to highway diesel desulfurization projects. Similarly, we believe the concept of EPA permit teams for gasoline sulfur projects could readily be extended to permits related to diesel projects as well. These teams will track the overall progress of permit issuance and will be available to assist state/local permitting authorities, refineries and the public upon request to resolve site-specific permitting questions. Further, in Tier 2, we announced our plan to issue guidance to help states determine whether and to what extent they may wish to use vehicle emissions reductions as offsets for refineries implementing gasoline desulfurization projects. We are currently in the process of evaluating public comments received on the draft guidance relating to the use of Tier 2 reductions as refinery offsets. Whatever resolution we determine is appropriate for this guidance in the Tier 2 context, we plan to apply a similar approach for diesel desulfurization projects as well. Finally, to facilitate the processing of permits, we encourage refineries to begin discussions with permitting agencies and to submit permit applications as early as possible.

[183] Best Available Control Technology (BACT) and Lowest Achievable Emission Rate (LAER) technology.

V. Economic Impact

This Section discusses the projected economic impact and cost effectiveness of the emission standards and low-sulfur fuel requirement. Full details of our cost and cost effectiveness analyses can be found in the RIA.

A. Cost for Diesel Vehicles to Meet Emissions Standards

1. Summary of New System and Operating Costs

The technologies described in Section III represent significant technological advancements for controlling emissions, but also make clear that much effort remains to develop and optimize these new technologies for maximum emission-control effectiveness with minimum negative impacts on engine performance, durability, and fuel consumption. On the other hand, it has become clear that manufacturers have a great potential to advance beyond the current state of understanding by identifying aspects of the key technologies that contribute most to hardware or operational costs or other drawbacks and pursuing improvements, simplifications, or alternatives to limit those burdens. To reflect this investment in long-term cost savings potential, the cost analysis includes an estimated $385 million in R&D outlays for heavy-duty engine designs and $220 million in R&D for catalysts systems giving a total R&D outlay for improved emission control of more than $600 million. The cost and technical feasibility analyses accordingly reflect substantial improvements on the current state of technology due to these future developments.

Estimated costs are broken into additional hardware costs and life-cycle operating costs. The incremental hardware costs for new engines are comprised of variable costs (for hardware and assembly time) and fixed costs (for R&D, retooling, and certification). Total operating costs include the estimated incremental cost for low-sulfur diesel fuel, any expected increases in maintenance cost or fuel consumption costs along with any decreases in operating cost expected due to low-sulfur fuel. Cost estimates based on these projected technology packages represent an expected incremental cost of engines in the 2007 model year. Costs in subsequent years will be reduced by several factors, as described below. Separate projected costs were derived for engines used in three service classes of heavy-duty diesel engines. All costs are presented in 1999 dollars.

The costs of these new technologies for meeting the 2007 model year standards are itemized in the RIA and summarized in Table V.A–1. For light heavy-duty vehicles, the cost of an engine is estimated to increase by $1,990 in the early years of the program reducing to $1,170 in later years and operating costs over a full life-cycle to increase by approximately $500 in the near term. For medium heavy-duty vehicles the cost of a new engine is estimated to increase by $2,560 initially decreasing to $1,410 in later years with life-cycle operating costs increasing by approximately $900 in the near term. Similarly, for heavy heavy-duty engines, the vehicle cost in the first year is expected to increase by $3,230 decreasing to $1,870 in later years. Estimated additional life-cycle operating costs for heavy heavy-duty engines in the near term are approximately $3,800. The higher incremental increase in operating costs for the heavy heavy-duty vehicles is due to the larger number of miles driven over their lifetime (714,000 miles on average) and their correspondingly high lifetime fuel usage. Emission reductions are also proportional to VMT and so are significantly higher for heavy heavy-duty vehicles.

We also believe there are factors that will cause cost impacts to decrease over time, making it appropriate to distinguish between near-term and long term costs. Research in the costs of manufacturing has consistently shown that as manufacturers gain experience in production, they are able to apply innovations to simplify machining and

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assembly operations, use lower cost materials, and reduce the number or complexity of component parts.[184] Our analysis, as described in more detail in the RIA, incorporates the effects of this learning curve by projecting that the variable costs of producing the low-emitting engines decreases by 20 percent starting with the third year of production (2009 model year) and by reducing variable costs again by 20 percent starting with the fifth year of production. Additionally, since fixed costs are assumed to be recovered over a five-year period, these costs are not included in the analysis after the first five model years. Finally, manufacturers are expected to apply ongoing research to make emission controls more effective and to have lower operating cost over time. However, because of the uncertainty involved in forecasting the results of this research, we have conservatively not accounted for it in this analysis. Table V.A–1 lists the projected costs for each category of vehicle in the near-and long-term. For the purposes of this analysis, "near-term" costs are those calculated for the 2007 model year and "long term" costs are those calculated for 2012 and later model years.

TABLE V.A–1.—PROJECTED INCREMENTAL SYSTEM COST AND LIFE CYCLE OPERATING COST FOR HEAVY-DUTY DIESEL VEHICLES

[net present values in the year of sale, 1999 dollars]

Vehicle class	Model year	Hardware cost	Life-cycle operating cost [a b]
Light	near term	1,990	509
Heavy-duty	long term	1,170	537
Medium	near term	2,560	943
Heavy-duty	long term	1,410	996
Heavy	near term	3,230	3,785
Heavy-duty	long term	1,870	3,979

[a] Incremental life-cycle operating costs include the incremental costs to refine and distribute low sulfur diesel fuel, the service cost of closed crankcase filtration systems, the maintenance cost for PM filters and the lower maintenance costs realized through the use of low sulfur diesel fuel (see discussion in Section V.C).

[b] These costs are for new vehicles only and do not reflect any costs or savings for the existing fleet.

2. New System Costs for NO_X and PM Emission Control

Several new technologies are projected for complying with the 2007 model year emission standards. We are projecting that NO_X adsorbers and catalyzed diesel particulate filters will be the most likely technologies applied by the industry in order to meet the emissions standards. The fact that manufacturers will have several years before implementation of the new standards ensures that the technologies used to comply with the standards will develop significantly before reaching production. This ongoing development could lead to reduced costs in three ways. First, we expect research will lead to enhanced effectiveness for individual technologies, allowing manufacturers to use simpler packages of emission control technologies than we would predict given the current state of development. Similarly, we anticipate that the continuing effort to improve the emission control technologies will include innovations that allow lower-cost production. Finally, we believe that manufacturers will focus research efforts on any drawbacks, such as fuel economy impacts or maintenance costs, in an effort to minimize or overcome any potential negative effects.

We anticipate that in order to meet the standards, industry will introduce a combination of primary technology upgrades for the 2007 model year. Achieving very low NO_X emissions will require continued development of NO_X emission control technologies and improvements in engine management to take advantage of the exhaust emission control system capabilities. The manufacturers are expected to take a systems approach to the problem of optimizing the engine and exhaust emission control system to realize the best overall performance possible. Since most research to date with exhaust emission control technologies has focused on retrofit programs, there remains room for significant improvements by taking such a systems approach. The NO_X adsorber technology in particular is expected to benefit from re-optimization of the engine management system to better match the NO_X adsorbers performance characteristics. The majority of the $600 million dollars we have estimated for research is expected to be spent on developing this synergy between the engine and NO_X exhaust emission control systems. PM control technologies are expected to be less sensitive to engine operating conditions as they have already shown good robustness in retrofit applications with low-sulfur diesel fuel.

The NO_X adsorber system that we are anticipating will be applied in 2007 consists of a catalyst which combines traditional gasoline three-way conversion technology with a newly developed NO_X storage function, a reductant metering system and a means to control exhaust air fuel (A/F) ratio. The NO_X adsorber catalyst itself is a relatively new device, but is benefitting in its development from over 20 years of gasoline three-way catalyst development. In order for it to function properly, a systems approach that includes a reductant metering system and control of exhaust A/F ratio is also necessary. Many of the new air handling and electronic system technologies developed in order to meet the 2004 heavy-duty engine standards can be applied to accomplish the NO_X adsorber control functions as well. Some additional hardware for exhaust NO_X or O_2 sensing, for exhaust partitioning and for fuel metering will likely be required. The RIA also calculates an increase in warranty costs for this additional hardware. In total the new NO_X control technologies required in order to meet the 2007 emission standards are estimated to increase light heavy-duty engine costs by $1,000, medium heavy-duty engine costs by $1,310 and heavy heavy-duty engine costs by $1,650 in the year 2007. In the year 2012 and beyond the incremental costs are expected to decrease to $590 for a light heavy-duty engine, $690 for a medium heavy-duty engine and to $930 for a heavy heavy-duty engine.

Catalyzed diesel particulate filters are experiencing widespread retrofit use in much of Europe as low-sulfur diesel fuel becomes readily available. These technologies are proving to be robust in their non-optimized retrofit applications requiring no modification to engine or vehicle control functions. We therefore anticipate that catalyzed diesel particulate filters can be integrated with new diesel engines with only a minimal amount of engine development. We do not anticipate that additional hardware beyond the diesel particulate filter itself and an exhaust pressure sensor for OBD will be required in order to meet the PM standard. However, in order to ensure trap durability under all possible operating conditions, some engine manufacturers may choose to provide backup regeneration technologies for their PM filter based systems. As detailed further in the RIA and the RTC documents, we do not anticipate that these redundant systems will add to variable costs. We estimate in 2007 that diesel particulate filter systems will add $730 to the cost of a light heavy-duty vehicle, $950 to the cost of a medium heavy-duty vehicle and $1,190 to the cost of a heavy heavy-duty vehicle. By 2012 these costs are expected to decrease to $425, $530, and $690 respectively. These cost estimates are comparable to estimates made by the Manufacturers of Emission Controls Association for these technologies.[185]

The hydrocarbon (HC) exhaust standards set in this rulemaking will be challenging for both diesel and gasoline engine technologies. For diesel engines utilizing the NO_X adsorber based technology solution to control NO_X emissions, HC control due to imprecise NO_X regeneration control may be difficult. One way to ensure HC compliance will be to apply a separate diesel oxidation catalyst which can control HC emissions to the limits set here. These diesel oxidation catalysts are expected to add an additional cost to the system of $206 for light heavy-duty vehicles, $261 for medium heavy-duty vehicles, and $338 for heavy heavy-duty vehicles.

We have eliminated the exemption that allowed turbo-charged heavy-duty diesel engines to vent crankcase gases directly to the environment, so called open crankcase systems, and have projected that manufacturers will rely on engineered closed crankcase ventilation systems which filter oil from the blow-by gases. We estimate that the initial cost of these systems in 2007 will be $37, $42, and $49 for light, medium and heavy heavy-duty diesel engines respectively. Additionally we expect a portion of the oil filtration system to be a service replacement oil filter which will be replaced on a 30,000 mile service interval with a service cost of $10, $12, and $15 for light, medium, and heavy heavy-duty diesel engines respectively. These cost are summarized with the other cost for emission controls in Table V.A–1 and are included in the aggregate cost reported in Section V.D.

3. Operating Costs Associated With NO_X and PM Control

The RIA assumes that a variety of new technologies will be introduced to enable heavy-duty vehicles to meet the new emissions standards. Primary among these are advanced emission control technologies and low-sulfur diesel fuel. The many benefits of low-sulfur diesel fuel are described in Section III, and the incremental cost for low-sulfur fuel is described in Section V.C. The new emission control technologies are themselves not expected to introduce additional operating costs in the form of increased fuel consumption. Operating costs are estimated in the RIA over the life of the vehicle and are expressed as a net present value (NPV) in 1999 dollars for comparison purposes.

Total operating cost estimates include both the expected increases in maintenance and fuel costs (both the incremental cost for low-sulfur fuel and any fuel consumption penalty) due to the emission control systems application and the predicted decreases in maintenance cost due to the use of low-sulfur fuel. Our analysis projects some increase in operating costs due to the incremental cost of low-sulfur diesel fuel but no net increase in fuel consumption with the application of the new emission control technologies (see discussion in Section III.G). The net increase in operating costs are summarized in Table V.A–1. While we are using these incremental operating cost estimates for our cost effectiveness calculations, it is almost certain that the manufacturers will improve existing technologies or introduce new technologies in order to offset at least some of the increased operating costs.

We estimate that the low-sulfur diesel fuel required in order to enable these technologies will have an incremental cost of approximately $0.045/gallon in the near term increasing to $0.050/gallon in the long term as discussed in Section V.C. The low-sulfur diesel fuel may also provide additional benefits by reducing the engine maintenance costs associated with corrosion due to sulfur in the current diesel fuel. These benefits, which are discussed further in Section V.C.5 and in the RIA, include extended oil change intervals due to the slower acidification rate of the engine oil with low-sulfur diesel fuel. Service intervals for the EGR system are also expected to increase due to lower-sulfur induced corrosion than will occur with today's higher-sulfur fuel. This lengthening of service intervals provides a significant savings to the end user. As described in more detail in the RIA we anticipate that low-sulfur diesel fuel will provide additional cost savings to the consumer of $153 for light heavy-duty vehicles, $249 for medium heavy-duty vehicles and $610 dollars for heavy heavy-duty vehicles.

The operating costs for replacement filters in the closed crankcase filtration systems expressed as a net present value in the year of sale are estimated to be $31 for light heavy-duty vehicles, $59 for medium heavy-duty vehicles and $218 for heavy heavy-duty vehicles for vehicles sold in 2007.

PM filter based technologies capture all forms of particulate in the exhaust including inorganic solid particles which can come from the engine oil or wear products of the engine. These inorganic particles (often call ash) must be periodically cleaned from the particulate filter. We have estimated the additional maintenance cost to clean the PM filter expressed as a net present value in the year of sale of $55 for light heavy-duty vehicles, $56 for medium heavy-duty vehicles and $208 dollars for heavy heavy-duty vehicles, as detailed in the RIA.

Factoring the cost savings due to low sulfur diesel fuel into the additional cost for low-sulfur diesel fuel and the service cost of the closed crankcase ventilation system and the PM filter system yields an increase in vehicle operating costs expressed as a net present value in the year of sale of $509 for a light heavy-duty vehicle, $943 for a medium heavy-duty vehicle and $3,785 for a heavy heavy-duty vehicle. These life cycle operating costs are also summarized in Table V.A–1. The net increase in operating cost can also be expressed as an average annual operating cost for each class of heavy-duty vehicle by dividing the total undiscounted operating costs by the average vehicle life assumed to be 9 years for light heavy-duty vehicles, and

[184] See Chapter V of the final Tier 2 Regulatory Impact Analysis, contained in Air Docket A–97–10.

[185] Letter from Bruce Bertelsen, Manufacturers of Emission Controls Association (MECA) to William Charmley, US EPA, December 17, 1998. The letter documents a MECA member survey of expected diesel particulate filter costs. Air Docket A–98–32 Item II–D–09.

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11 years for medium and heavy heavy-duty engines. Expressed as an approximate annual per vehicle cost, the additional operating cost is estimated as $80 for a light heavy-duty vehicle, $130 for a medium heavy-duty vehicle, and $510 for a heavy heavy-duty vehicle.

B. Cost for Gasoline Vehicles to Meet the New Emissions Standards

1. Summary of New System Costs

To perform a cost analysis for the final gasoline standards, we first determined a package of likely technologies that manufacturers could use to meet the standards and then determined the costs of those technologies. In making our estimates, we have relied on our own technology assessment which included publicly available information such as that developed by California, confidential information supplied by individual manufacturers, and the results of our own in-house testing.

In general, we expect that heavy-duty gasoline vehicles would (like Tier 2 light duty vehicles) be able to meet these standards through refinements of current emissions control components and systems rather than through the widespread use of new technology. More specifically, we anticipate a combination of technology upgrades such as the following:

- Improvements to the catalyst system design, structure, and formulation, plus an increase in average catalyst size and loading.
- Air and fuel system modifications including changes such as improved oxygen sensors, and calibration changes including improved precision fuel control and individual cylinder fuel control.
- Exhaust system modifications, possibly including air gapped components, insulation, leak free exhaust systems, and thin wall exhaust pipes.
- Increased use of fully electronic exhaust gas recirculation (EGR).
- Increased use of secondary air injection.
- Use of ignition spark retard on engine start-up to improve upon cold start emission control.
- Use of low permeability materials and minor improvements to designs, such as the use of low-loss connectors, in evaporative emission control systems.

We expect that the technologies needed to meet the heavy-duty gasoline standards will be very similar to those required to meet the Tier 2 standards for vehicles over 8,500 pounds GVWR. Few heavy-duty gasoline vehicles currently rely on technologies such as close coupled catalysts and secondary air injection, but we expect they would to meet the new standards.

For each group we developed estimates of both variable costs (for hardware and assembly time) and fixed costs (for R&D, retooling, and certification). Cost estimates based on the current projected costs for our estimated technology packages represent an expected incremental cost of vehicles in the near-term. For the longer term, we have identified factors that would cause cost impacts to decrease over time. First, since fixed costs are assumed to be recovered over a five-year period, these costs disappear from the analysis after the fifth model year of production. Second, the analysis incorporates the expectation that manufacturers and suppliers would apply ongoing research and manufacturing innovation to making emission controls more effective and less costly over time. Research in the costs of manufacturing has consistently shown that as manufacturers gain experience in production and use, they are able to apply innovations to simplify machining and assembly operations, use lower cost materials, and reduce the number or complexity of component parts.[186] These reductions in production costs are typically associated with every doubling of production volume. Our analysis incorporates the effects of this "learning curve" by projecting that a portion of the variable costs of producing the new vehicles decreases by 20 percent starting with the third year of production. We applied the learning curve reduction only once since, with existing technologies, there would be less opportunity for lowering production costs than would be the case with the adoption of new technology. We did not apply the learning curve reduction to precious metal costs, nor did we apply it for the evaporative standards.

We have prepared our cost estimates for meeting the new heavy-duty gasoline standards using a baseline of current technologies for heavy-duty gasoline vehicles and engines. Finally, we have incorporated what we believe to be a conservatively high level of R&D spending at $2,500,000 per engine family where no California counterpart exists. We have included this large R&D effort because calibration and system optimization is likely to be a critical part of the effort to meet the standards. However, we believe that the R&D costs may be generous because the projection probably underestimates the carryover of knowledge from the development required to meet the light-duty Tier 2 and CARB LEV–II standards.

Table V.B–1 provides our estimates of the per vehicle cost for heavy-duty gasoline vehicles and engines. The near-term cost estimates in Table V.B–1 are for the first years that vehicles meeting the standards are sold, prior to cost reductions due to lower productions costs and the retirement of fixed costs. The long-term projections take these cost reductions into account.

TABLE V.B–1.—PROJECTED INCREMENTAL SYSTEM COST AND LIFE CYCLE OPERATING COST FOR HEAVY-DUTY GASOLINE VEHICLES

[Net Present Values in the year of sale, 1999 dollars]

Vehicle class	Model year	Incremental system cost	Life-cycle operating cost
Heavy-Duty Gasoline	near term	$198	$0
	long term	167	0

[186] See Chapter V of the final Tier 2 Regulatory Impact Analysis, contained in Air Docket A–97–10.

2. Operating Costs Associated With Meeting the Heavy-Duty Gasoline Standard

Low sulfur gasoline is a fundamental enabling technology which will allow heavy-duty gasoline vehicles to meet the very low emission standards being finalized today. The low sulfur gasoline required under the Tier 2 proposal will enable advanced exhaust emission control for heavy-duty vehicles as well. Today's final rule puts no additional requirements on gasoline sulfur levels and as such should not increase gasoline fuel costs. Additionally, the new technologies being employed in order to meet the new standards are not expected to increase fuel consumption for heavy-duty gasoline vehicles. In fact, there may be some small improvement in fuel economy from the application of improved fuel and air control systems on these engines. Therefore, in the absence of changes to gasoline specifications and with no decrease in fuel economy, we do not expect any increase in vehicle operating costs.

C. Cost of Fuel Change

We estimate that the overall net cost associated with producing and distributing 15 ppm diesel fuel, when those costs are allocated to all gallons of highway diesel fuel, will be approximately 5.0 cents per gallon in the long term, or an annual cost of roughly $2.2 billion per year once the program is fully effective starting June 1, 2010. During the initial years under temporary compliance option, the overall net cost is projected to be 4.5 cents per gallon, or an annual cost of roughly $1.7 billion per year.

This cost consists of a number of components associated with refining and distributing the new fuel. The majority of the cost is related to refining. From 2006–2010, refining costs are estimated to be approximately 3.3 cents per gallon of highway diesel fuel (4.1 cents per gallon for that portion produced to the 15 ppm standard), increasing to 4.3 cents per gallon once the program is fully in place. In annual terms, the 2006–2010 refining costs are expected to be about $1.4 billion per year, increasing to about $1.8 billion in 2011. These figures include the cost of producing slightly more volume of diesel fuel because: (1) Desulfurization decreases the energy density of the fuel and (2) slightly more highway diesel fuel is expected to be downgraded to nonroad diesel fuel in the distribution system.

A small cost of 0.2 cents per gallon is associated with an anticipated increase in the use of additives to maintain fuel lubricity. Also, distribution costs are projected to increase by 1.0 cents per gallon during the initial years under the temporary compliance option, including the cost of distributing slightly greater volumes of fuel. Together, these two cost components only amount to about $0.5 billion per year beginning in 2006. These costs drop to only about $0.3 billion in 2011.

As discussed in Sections V.A. and V.C.5, operation with 15 ppm sulfur diesel fuel is expected to reduce average vehicle maintenance costs by approximately 1 cent on a per gallon basis. Beginning in 2011, this reduction in maintenance costs will total roughly $400 million per year. All of these cost estimates are discussed in more detail below and in the RIA.

1. Refinery Costs

As explained in Section IV, EPA believes that refiners will meet the 15 ppm sulfur standard through an extension of the same hydrotreating technology which is used today to meet the current 500 ppm sulfur standard. Meeting the new standard will generally require refiners to install additional hydrotreating equipment. Most refiners are expected to add another hydrotreating reactor and other related equipment to their existing desulfurization unit. However, we project that some refiners, roughly 20 percent, will conclude that it is not economical to add onto their existing unit and will instead build an entirely new hydrotreater.

Consistent with our analysis for the NPRM, we estimate that a refinery's diesel fuel will have to average 7 ppm in order to consistently meet the 15 ppm standard. For the NPRM, we estimated the cost of producing highway diesel fuel with a 7 ppm average sulfur level for the average U.S. refinery. We received a number of comments on the NPRM which indicated that the cost for various refiners would differ dramatically, as would the cost of treating the various blendstocks which comprise highway diesel fuel. In response, we extended our refining cost model to be specific to each refinery in the U.S., based on a refinery's production volume and estimated composition of its highway diesel fuel. Using this model, we estimated each refinery's cost of producing 7 ppm sulfur highway diesel fuel and then aggregated these results to estimate a national average cost.

This analysis considers the fact that some diesel fuel blendstocks are more difficult to desulfurize than others. As indicated in some comments on the NPRM, this could lead refiners to shift their blendstocks between highway diesel fuel and other distillate products in order to minimize costs. For example, our analysis found that the incremental cost of desulfurizing current highway diesel fuel can be more expensive for some refiners than the cost to other refiners of desulfurizing nonroad diesel fuel to meet the 15 ppm standard, despite the fact that the current sulfur level of nonroad diesel fuel is roughly 2500–3000 ppm.

We evaluated costs under two scenarios: (1) all current producers of highway diesel fuel continued to do so, and (2) some refiners increase production of highway diesel fuel and some refiners facing higher desulfurization costs leave the highway diesel fuel market. Our cost projections presented below are based on the first scenario. This is conservative, because in this scenario, some refineries currently produce relatively low volumes of highway diesel fuel and would face relatively high costs per gallon to desulfurize this same volume of fuel.

We project that the average refining cost to meet the 15 ppm cap standard will be 4.3 cents per gallon, including capital costs amortized at 7 percent per year before taxes, once the standard is fully in place in June, 2010. Refining costs will be lower, 4.1 cents per gallon of 15 ppm fuel (or 3.3 cents per gallon of all highway diesel fuel), during optional compliance provisions (2006–2010), because we expect that those refiners facing the lowest cost of meeting the standard in each PADD will invest to produce the new fuel. We project that refiners will invest $3.8 billion in new equipment in order for about 80 percent of highway diesel fuel to meet the 15 ppm standard in 2006. An additional $1.4 billion will be invested for the rest of the highway diesel fuel market to meet the new standard in 2010, for a total capital cost of $5.2 billion. The average refinery is projected to spend about $43 million in capital costs, and $7 million per year in operating costs.

Table V.C–1 shows the range of average costs per refinery by PADD. Despite the varying size of refineries and differences in their available distillate blendstocks, the variations in the average cost between PADDs in either 2006 or 2010 are small, with the exception of PADD 4. PADD 4 average costs are 30–40 percent higher than the costs in the other PADDs.

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TABLE V.C–1.—AVERAGE REFINING COSTS BY PADD (CENTS PER GALLON OF 15 PPM FUEL)

	2006	2010
PADD 1	4.4	4.7
PADD 2	4.3	4.5
PADD 3	3.8	3.9
PADD 4	5.1	5.3
PADD 5	4.2	4.5
U.S. Average	4.1	4.3

A number of other estimates of the cost of the 15 ppm sulfur standard were submitted as part of the comments. Mathpro used a notional refinery model to estimate the national average costs of the proposed standard for EMA. Charles River Associates (CRA), along with Baker and O'Brien, used the Prism refinery model to estimate the cost for each refinery in the U.S. for API. Finally, EnSys used the Oak Ridge National Laboratory PADD 3 refinery model to estimate costs for DOE. Table V.C–2 summarizes these estimates after adjusting the projected costs to represent a 7 percent rate of return on investment before taxes (except for the CRA cost, which could not be adjusted).

TABLE V.C–2.—COMPARISON OF NATIONAL AVERAGE REFINING COST ESTIMATES

[7 percent rate of return on investment before taxes]

	Average cost (cents per gallon of 15 ppm fuel)	Capital cost ($ billion)
EPA (Full program)	4.4	5.3
Methpro for EMA*	4.2–6.1	3.4–6.1
CRA for API (10% after tax rate of return)	6.2	—
EnSys for DOE (conservative technology)*†	5.1–6.0	3.9–6.5
EnSys for DOE (optimistic technology)*†	4.2–4.4	2.7–4.5

*Lower end of range assumes 100 percent revamped equipment; upper end assumes all new equipment.
†Costs are only for the Gulf Coast refining region, which have slightly lower per-gallon costs than the entire U.S., and about half the capital costs.

The costs estimated by Mathpro are the most similar to those estimated by EPA. This is primarily because the desulfurization technology projected to be used were similar in the two studies.

CRA projected the use of similar technology, but estimated that 40 percent of refiners would build new desulfurization units, versus our estimate of 20 percent. CRA also assumed that technology vendors are inherently optimistic in their projections and increased their projected costs by roughly 20 percent. CRA also projected that nonroad diesel fuel sulfur levels would be capped at 500 ppm. How this affected the projected cost of producing 15 ppm fuel is not clear. CRA assumed that this 500 ppm fuel would be produced by blending 8 ppm sulfur highway diesel fuel and 3000 ppm heating oil. Much of this production was assumed to occur due to mixing in the distribution system. An unknown amount of 500 ppm fuel was produced at refineries. Desulfurization costs are not linear, as shown by CRA's own study. Thus, any blending of 15 ppm sulfur highway diesel fuel with non-desulfurized heating oil at refineries was much more costly than simply hydrotreating nonroad diesel fuel to 500 ppm. It also required refiners to hydrotreat the most difficult blendstocks at a much higher cost. Because of these significant differences in both methodology and assumptions, it is not surprising that CRA's costs would be higher than those estimated by Mathpro or ourselves.

EnSys's cost estimates require some explanation due to the number of scenarios they analyzed. EnSys did not estimate how many refiners would build new desulfurization units and how many would modify their current hydrotreaters, but simply presented costs if refiners took one approach or the other. Thus, the lower limits of the ranges shown in Table V.C–2 assume refiners modify their current hydrotreaters, while the upper limits assume that refiners would build new units. EnSys also projected costs for two separate sets of technologies. One set was considered conservative and relied on technologies that are already in commercial use. The other was considered to be optimistic and was similar to that projected to be used by EPA, Mathpro and CRA. EnSys' costs using the conservative technology are higher than our estimates. This is due to the fact that this technology involves greater capital investment and greater consumption of hydrogen. These greater costs are due to the fact that this technology is not just designed to reduce sulfur, but to reduce aromatic content, increase cetane levels and perform some cracking. EnSys' costs using the optimistic technology are much more similar to those of EPA and Mathpro, considering that EnSys' range of costs reflects both revamped and new desulfurization units and that EPA's costs are dominated (80 percent) by revamped units.

Some of the variation in the costs projected by the various studies involves uncertainty in exactly what degree of hydrotreating will be necessary to meet the 15 ppm sulfur standard day in and day out with a variety of distillate feedstocks. As discussed in Section IV above, there is currently no commercial experience in the U.S. and only a limited amount of information in the public literature on the costs associated with reducing the sulfur level in diesel fuel to very low levels on an ongoing operational basis. Thus, any cost projections involve a significant amount of uncertainty.

2. Highway Diesel Fuel Supply

While API and many refiners did not question the feasibility of the 15 ppm standard, they did indicate that the cost would be higher than that projected by EPA. API believes that those refiners facing higher than average costs may decide to leave the highway diesel fuel market. They argue this is especially a possibility if they are faced with a sulfur standard below a 30 ppm average (or 50 ppm cap), which they believe will require very large investments for high pressure hydrotreating to maintain current highway diesel production volumes. API also believes that many refiners may reduce their production of highway diesel fuel, by switching the feedstocks (i.e., LCO) which are most difficult to desulfurize to other markets, thus avoiding the higher investments associated with high pressure hydrotreating. If some refiners reduce highway diesel fuel production, that could present an opportunity for other refiners, who choose to make the investment, of higher prices for the new 15 ppm sulfur product.

This view is embodied by a study by Charles River Associates (CRA) and Baker and O'Brien which was commissioned by API. CRA polled refiners concerning their plans under a 15 ppm sulfur cap. Using the results of this survey, as well as other information, CRA projected refiners' costs of meeting the 15 ppm standard, as well as their likely production volumes. CRA concluded that U.S. refiners would likely reduce their highway diesel fuel production by an average of 12 percent, creating significant shortages and price spikes.

CRA's conclusions appear to have been strongly affected by their assumptions, as well as the refiner survey they conducted. For example, CRA assumed that the new sulfur standard would cause 10 percent more highway diesel fuel to be "lost" in the distribution system compared to today (i.e., downgraded to off-highway diesel fuel). We believe based on the analysis outlined in the RIA that 2.2 percent is a more accurate estimate, resulting in 9 percent more 15 ppm fuel being available than CRA estimated. This difference alone accounts for 75 percent of the potential national supply shortfall projected by CRA.

CRA also concluded, with little explanation, that 20 refineries producing highway diesel fuel today would not produce highway diesel fuel under the 15 ppm standard and that many more would reduce production. Given the lack of information provided in the study, it was not possible to evaluate CRA's criteria in selecting these 20 refineries, nor was it possible to determine how much of the shortfall was attributable to this conclusion. While CRA evaluated whether refiners currently producing highway diesel fuel would be likely to leave the market, they did not assess whether any refineries currently not producing highway diesel fuel might enter the market. EPA did conduct such an assessment. We found 2 refineries that produce essentially no highway diesel fuel today which could meet the new standard for less than 5 cents per gallon. Production from these refineries would increase highway diesel fuel production by 9 percent. We also found based on our assessment that 4 other refineries could produce highway diesel fuel from their off-highway diesel blendstocks for less than 5 cents per gallon. Production from these 6 refineries would increase highway diesel fuel production by 7 percent. Together with a more reasonable estimate of downgrades in the distribution system, this would more than compensate for any potential lost production, even as estimated by CRA.

CRA also implicitly assumed that the material it projected could be removed from the highway diesel market could be sold at a reasonable price. However, CRA did not analyze the impact of this additional supply on the prices which could be obtained in these markets, or even if these alternative markets could physically absorb all of this material. Much of this material is not diesel fuel, but poor quality blendstock. It is not clear that such material could be blended into non-highway diesel fuel and CRA did not analyze this likely problem. Our analyses, supported by a study by Muse, Stancil and Co., indicate that any substantial quantities of highway diesel fuel diverted to other markets will depress prices in those markets substantially.[187] Hydrotreating diesel fuel to meet the 15 ppm standard avoids these depressed prices, reducing the net cost of meeting the new standard. Since CRA only considered the cost to desulfurize highway diesel fuel, and ignored the added cost of dumping this fuel into markets with depressed prices, CRA's conclusions must be considered to be seriously flawed in this regard.

Furthermore, CRA ignored the fact that roughly 15 percent of today's highway diesel fuel is consumed in engines and furnaces not requiring this fuel. Any shortage of highway diesel fuel would lead many of these non-essential users to switch to nonroad diesel fuel or heating oil. Only limitations in the fuel distribution system would cause these users to continue to burn highway diesel fuel.

These problems with CRA's analysis, plus the lack of detail available concerning the specifics of the study, lead us to reject the study's conclusions that there will be significant supply shortfalls under a 15 ppm sulfur standard.

Finally, if any potential for highway diesel fuel shortfalls exists by requiring all fuel to meet 15 ppm sulfur in 2006, as CRA's analysis suggests, we believe that allowing some continued supply of 500 ppm, as we are doing under the temporary compliance option and hardship provisions contained in today's action, addresses this concern. Since the final rule allows some transition period before the entire highway diesel pool is required to meet the 15 ppm sulfur standard, some refiners will not need to change their current operations and will be able to continue producing 500 ppm fuel during these years. Those refiners that delay production of low sulfur diesel fuel until the later years of the program will tend to be the refiners with the highest cost to comply and, thus, refiners that would otherwise have the greatest tendency not to invest and thereby impact supply. Refiners that begin producing low sulfur diesel fuel in the later years of the program will also be able to take advantage of ongoing improvements in desulfurization technology. Together, these factors will help avoid or reduce any potential losses in highway diesel fuel production when the program requires full compliance with low sulfur diesel fuel.

As mentioned above, EPA agrees that some refiners will face higher desulfurization costs than others. This is generally the case with any fuel quality regulation, since the crude oils processed by, as well as the configurations and product slates of individual refineries vary dramatically. As mentioned above and summarized in the RIA, we used our refining cost model to assess the likelihood that refiners would leave the highway diesel fuel market or reduce their production of highway diesel fuel. We also assessed the likelihood of other refiners entering this market. We found that a number of refiners appear to be in a position to expand their highway diesel fuel production capacity very economically relative to other refiners facing higher desulfurization costs. We also found that up to 2 refineries not now producing highway diesel fuel could easily enter the highway diesel fuel market at very competitive costs.

Some refiners may have an alternative market for their diesel fuel. In the extreme, a refiner would likely prefer to only shift his light cycle oil to other distillate products, like nonroad diesel fuel and No. 2 heating oil, retaining his other blendstocks in the higher value highway diesel fuel market. However, in many cases, a refiner cannot shift light cycle oil directly to a distillate product, because the resulting non-highway fuel would no longer meet applicable specifications, such as sulfur or cetane. In most cases, we expect that the refiner must shift highway diesel fuel to alternative markets in order to be able to obtain a reasonable price.

As mentioned above, Muse, Stancil, & Co. analyzed the ability of refiners to

[187] "Alternate Markets for Highway Diesel Fuel Components," Muse, Stancil & Co., for Southwest Research Institute, for U.S. EPA, September, 2000.

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divert highway diesel fuel or its blendstocks to other distillate markets. Muse, Stancil found that this ability varied significantly by PADD. In PADDs II and IV, it would be difficult for refiners to move any appreciable quantity of highway diesel fuel to other markets. For example, compared to the value of highway diesel fuel today, the achievable value for the diverted material would decrease by 14 to 20 cents per gallon if refiners tried to move more than 5 percent of their highway diesel fuel to other markets. The loss in value was highest in these two PADDs, because growth in nonroad diesel fuel consumption is small or negative, the ability to reduce the consumption of highway diesel fuel by users other than highway vehicles was limited, and exports are only available through the Gulf or West Coasts with a large transportation cost of getting the material there.

In PADDs III and V, the loss of value was lower, at 4.5–5 cents per gallon and was the lowest in PADD I, 2 cents per gallon. This was primarily because of the ability to export high sulfur diesel fuel overseas. Generally, these losses in value apply if diesel fuel was being diverted to other distillate markets. If light cycle oil was being diverted, the value would drop an additional 3–3.5 cents per gallon.

At lower levels of diversion (e.g., 5 percent or less), the loss in value was much less, ranging from 1.6–5 cents per gallon across the five PADDs. However, the primary reason for this was the reduced use of highway diesel fuel by users other than highway vehicles, who do not require this fuel. Muse believed that such conversions were limited, but real and could represent roughly a third of the current use of highway diesel fuel in other than highway vehicles. If this occurs, then demand for highway diesel fuel drops at the same time. Thus, in this case, the total refining costs associated with the new sulfur standard will decline because the total amount of fuel; needing to be desulfurized will decrease.

The only area where refiners could easily divert substantial amounts of highway diesel fuel is PADD I. PADD I refiners currently produce a relatively low amount of highway diesel fuel and substantial amounts of high sulfur diesel fuel/heating oil are imported. Thus, refiners in PADD I facing relatively high costs of meeting the 15 ppm standard could shift some or all of their highway diesel fuel to other markets, reducing imports and not substantially affecting prices in this market.

In the end, refiners will make their decisions regarding investment based on their projections of demand of 15 and 500 ppm diesel fuel, the prices of these fuels and the prices available in alternative markets. At this time, we do not project that the specifics involved in this case (technology, cost, alternative markets) are significantly different from those which have existed in the past. The last time EPA regulated diesel fuel, the refining industry actually overbuilt desulfurization capacity for the current 500 ppm standard, as evidenced by the significant use in the nonroad market of diesel fuel produced to the current highway diesel sulfur standard of 500 ppm and the relatively low price of highway diesel fuel relative to nonroad diesel fuel. Some of this overproduction may have been due to limitations in the distribution system to distribute both highway and nonroad grades of diesel fuel. However, the refinery system as a whole was able to supply both highway diesel vehicles, plus the use of highway diesel fuel by other users. This was accomplished despite the fact that a number of small refiners did decide to switch from the highway diesel fuel market to the nonroad diesel fuel market, presumably for economic reasons.

3. Cost of Lubricity Additives

As discussed in Section IV, the refinery processes needed to achieve the sulfur standard have some potential to degrade the natural lubricity characteristics of the fuel. Consequently, an increase in the use of lubricity additives for diesel fuel may be anticipated over the amounts used today. As described in more detail in the Regulatory Impact Analysis in the Public Docket, we include in our fuel cost estimate an average cost of 0.2 cents per gallon for lubricity additives over the entire pool of low sulfur highway diesel fuel (the same cost estimate as used in the proposal). This estimate is comparable to an estimate made by Mathpro in a study sponsored by the Engine Manufacturers Association, and is consistent with the cost estimate submitted by Cummins in its comments.

Prior to the proposal, we contacted various producers of lubricity additives to get their estimates of what costs might be incurred for this increase in the use of lubricity additives. The cost estimates varied from 0.1 to 0.5 cents per gallon. The cost is likely to be a strong function of not only the additive type, but also the assumed treatment rate and the volume of fuel that needs to be treated, both of which will be, to some extent, a function of the sulfur cap. We requested comment on our cost estimate, including whether there may be unique costs for the military to maintain the lubricity of their distillate fuels. We requested that comments addressing this issue include a detailed discussion of the volumes of fuel affected, current lubricity additive use, and the additional measures that might be needed (and associated costs) to maintain the appropriate level of fuel lubricity. In response to the proposal, we received few comments on the cost of lubricity additives, and none on the volumes of fuel affected, current lubricity additive use, or additional measures that might be needed to maintain the appropriate level of lubricity. In considering the comments, we have found no basis in today's action to use a different average cost estimate to treat low sulfur diesel for lubricity than that which was used in the proposal (0.2 cents per gallon). See more discussion in the Response to Comments Document in the Public Docket.

4. Distribution Costs

We estimate that as a result of today's rule, distribution costs will increase by 0.5 cents per gallon of highway diesel fuel supplied when the sulfur requirements are fully implemented beginning in the year 2010. During the initial years (2006 through May 31, 2010) we estimate that the increase in distribution costs will be 0.4 cents per gallon of highway diesel fuel supplied, with an additional 0.7 cents per gallon equivalent related to capital costs for additional storage tanks to handle two grades of highway diesel fuel.[188]

In the proposal, we estimated that distribution costs would increase by 0.2 cents per gallon if the proposed requirement that the entire highway diesel fuel pool meet a 15 ppm sulfur cap beginning in 2006 be adopted. This cost was comprised of roughly 0.1 cents per gallon due to an increase in pipeline interface and testing costs, and 0.1 cents per gallon for distributing the additional volume of highway diesel fuel needed due to an anticipated decrease in fuel energy density as a side effect of reducing the sulfur content to the proposed 15 ppm cap. The case evaluated in the NPRM is most similar to that for the fully implemented sulfur program in this final rule.

We took advantage of additional information contained in the comments to the NPRM in formulating a more comprehensive estimate of the

[188] This cost is expressed in terms of the total volume of highway diesel fuel supplied, including the fuel which meets the 15 ppm sulfur cap and that which meets the 500 ppm sulfur cap.

distribution costs under today's rule. In some cases this involved adjusting an estimate for a parameter that factored into our calculation of costs in the NPRM. One important example is that we increased our estimate of the additional volume of highway diesel shipped by pipeline that would need to be downgraded to a lower-value product. This product downgrade is necessitated by mixing that takes place between products that abut each other while in the pipeline. The mixture is referred to as interface when it can be blended into another product and transmix when it must be returned to the refinery for reprocessing. In other cases, our reevaluation of distribution costs included the consideration of parameters that did not factor into the estimation of distribution costs in the proposed rule. For example, commenters to the NPRM brought to our attention that there would be additional costs associated with needed changes in the handling practices for interface volumes which result from shipments of jet fuel and highway diesel fuel that abut each other in the pipeline.

There are a number of common factors in the estimation of distribution costs during the initial period and after the sulfur requirements are fully implemented, such as the increase in interface volumes for pipeline shipments of highway diesel fuel. However, there are other factors that are unique to the estimation of costs during the initial years as well. For example, with two grades of highway diesel fuel in the distribution system at the same time there are costs associated with the need for additional storage tanks at some petroleum terminals and refineries. Our estimation of distribution costs under these two periods is discussed separately in the following sections. Where there is a commonality, the issue is discussed under the section on distribution costs for the fully implemented program.

a. Distribution Costs Under the Fully Implemented Program

Based on the considerations discussed below, we estimate that the increase in distribution costs under the fully implemented sulfur program will be 0.5 cents per gallon of highway diesel fuel supplied.

The cost of distributing the additional volume of highway diesel fuel needed to compensate for the lower energy density of highway diesel fuel that meets a 15 ppm sulfur cap is estimated at 0.17 cents per gallon of highway diesel fuel supplied. As in the NPRM, the cost of producing this additional volume was included in the calculation of refinery costs (see Section V.C.1.). In the NPRM, we estimated that the cost of distributing highway diesel fuel was equal to the difference in price at the refinery rack and the retail price. For today's final rule, we based our estimate of distribution cost on a PADD by PADD evaluation of the difference in the price of highway diesel fuel at the refiner rack versus the retail price. The price differential for each PADD was weighted by the additional volume of fuel we anticipate will need to be produced in each PADD to arrive at an estimate of distributing the additional volume needed for the nation as a whole. We believe this approach provides a more accurate estimate of costs.

Based on additional information provided in the comments on the changes in pipeline interface practices that would result from today's rule, we adjusted our estimate of the increased volume of highway diesel fuel that would be downgraded to a lower-value product from 1.5 percent to 2.2 percent of highway diesel fuel supplied (see the RIA to this rule). As in the NPRM, the cost of producing this additional volume was included in the calculation of refinery costs (see Section V.C.1.). The cost of downgrading the increased volume of highway diesel fuel to a lower-value product is based on the difference in the cost of 15 ppm sulfur diesel fuel and the product to which the interface is downgraded. Under the fully imlemented program, this downgrade would be made into the nonroad diesel pool. The cost of this increased volume of downgrade is estimated at approximately 0.14 cents per gallon of highway diesel supplied.

We identified that there would also be an increase in the economic impact for the existing volume of interface currently associated with pipeline shipments of highway diesel fuel. This is because the cost of downgrading the existing interface volume would be determined by the difference between the cost of 15 ppm sulfur fuel and nonroad diesel fuel rather than the difference in cost between current 500 ppm diesel fuel and nonroad diesel fuel as it is today. We estimate that the increase in the cost of downgrading the existing highway diesel interface would be 0.09 cents per gallon of highway diesel fuel supplied.

We anticipate that there may be minor costs in addition to those discussed above associated with optimizing the distribution system to adequately limit sulfur contamination. These costs could result from various minor changes to distribution practices and or hardware discovered to be needed by industry while preparing to comply with today's rule. While it is not possible to specifically identify the nature of these changes, they could include the occasional replacement of a leaking valve or improvements in communication practices to facilitate batch changes in the pipeline system. There may also be some cost associated with the process that we anticipate the distribution industry will undertake to evaluate its readiness to comply with the requirements in today's rule. Such costs might result from testing to determine the level of contamination introduced through the use of various distribution hardware or practices. It is not possible to specifically identify the costs that might be associated with this optimization process. However, given the limited nature of the changes that might be needed and that the need for such changes would not be widespread, we believe that the associated costs would not pose a substantial burden. We estimate that the miscellaneous costs associated with optimizing the distribution system to limit sulfur contamination would be 0.025 cents per gallon of highway diesel fuel supplied (on average) during the period from when the sulfur program is fully implemented (2010) through the year 2020. These costs were amortized at a rate of 7% over the period of 2006 through 2020. The per gallon cost is somewhat higher during the initial years.

Commenters to the proposed rule stated that it is current practice for all of the interface generated when highway diesel fuel abuts jet fuel in the pipeline to be cut into highway diesel fuel. They pointed out that this practice would no longer be possible when all highway diesel fuel is required to meet a 15 ppm sulfur cap because of the relatively high sulfur content of jet fuel (as high as 3000 ppm).[189] They stated that the mixture of highway diesel fuel meeting a 15 ppm sulfur cap and jet fuel would need to be returned from the terminal to the refinery for reprocessing, at high cost (*i.e.* would need to be treated as transmix). While we agree that handling procedures for this mixture will need to change, we believe that it will not be necessary to treat it as transmix. We believe that there will be opportunity for the mixture to be sold from the terminal into the nonroad diesel pool. This will increase the cost associated with downgrading this mixture.

[189] During the initial years of the sulfur program, the current practice used to handle the interface between shipments of jet fuel and highway diesel fuel can be used for that portion of the highway diesel fuel that continues to meet a 500 ppm sulfur cap.

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Expressed in terms of the volume of highway diesel fuel supplied, we estimate this cost at 0.07 cents per gallon. Additional storage tanks will be needed to handle the mixture at those terminals that currently do not handle nonroad diesel fuel. The cost of these tanks has been fully accounted for in the calculation of costs during the initial years of the program.

The additional quality control testing at the terminal level needed to ensure compliance with the 15 ppm sulfur cap would be the same during the initial years as after the requirements are fully implemented. We estimate that the cost of this additional testing would be as we projected in the proposal, 0.002 cent per gallon of highway diesel supplied (see the RIA to this rule).

We believe that there will not be a significant increase in the volume of highway diesel fuel discovered to exceed the sulfur standard downstream of the refinery as a result of today's rule. We believe this will be the case both during the initial years and after the sulfur requirements are fully implemented. We anticipate that distributors will quickly optimize their practices to avoid sulfur contamination. We also anticipate that distributors will gain some experience in reducing sulfur contamination in the distribution system through complying with the recently finalized Tier 2 low sulfur gasoline requirements (65 FR 6698, February 10, 2000). While outside the scope of this final rule, it is worth pointing out that potential difficulties in distributing 15 ppm diesel fuel would be lessened if the sulfur content of nonroad diesel fuel is reduced by a future rulemaking (as discussed in Section 8). We anticipate that the batches of highway diesel fuel that are discovered to exceed the 15 ppm sulfur cap will be coped with as follows:

—When possible, by blending highway diesel fuel that is below the 15 ppm cap with the out-of-specification batch to bring the resulting mixture into compliance. This practice will be more difficult than it is currently because the amount of fuel needed to blend the out-of-specification batch into compliance may increase. However, we expect it to continue to be the method of choice for handling out-of-specification highway diesel whenever possible.

—By downgrading the batch either to nonroad diesel fuel or to 500 ppm highway diesel during the initial years.

—By reprocessing the batch to meet the 15 ppm cap, but only in those infrequent instances where the previous options do not exist.

We do not believe that the cost of handling out-of specification highway diesel batches will increase significantly as a result of today's action.

Tank truck, tank wagon, and barge operators may need to more carefully and consistently observe current industry practices to limit contamination in some situations. However, these situations are more the exception than the rule and are of a limited nature. Consequently, we believe that this can be accomplished at an insignificant cost. Additional considerations exist for distributors during the initial years as discussed in the following section.

Please refer to the Response to Comments Document for an evaluation of the comments received on the increase in fuel distribution costs associated with today's rule, and to the RIA for a detailed discussion of the way in which we derived the our cost estimates.

b. Distribution Costs During the Initial Years

The factors that cause distribution costs to differ during the initial years include:

—Having a lesser volume of 15 ppm diesel fuel in the system reduces the costs associated with distributing 15 ppm fuel.

—Having an additional grade of highway diesel fuel in the system (500 ppm) creates additional pipeline interface volumes, and additional product downgrade costs.

—The need for additional equipment to handle an additional grade leads to additional costs that must be accounted for during the initial years.

—Having 500 ppm highway diesel fuel in the system allows some opportunity for the pipeline interface volumes associated with the shipment of 15 ppm fuel and jet fuel to be downgraded to 500 ppm diesel fuel rather than nonroad diesel fuel. This will reduce the cost associated with downgrading the subject interface volumes.

In calculating the distribution costs for the initial years of the program, we estimated that 60 percent of the 15 ppm highway diesel fuel shipped by pipeline will be carried in pipelines that choose not to carry 500 ppm diesel fuel. We estimated that the remaining 40 percent of 15 ppm highway diesel fuel shipped by pipeline would be carried in pipelines that carry 500 ppm as well as nonroad diesel fuel. For the sake of simplicity and to allow a comparison with distribution costs when the program is fully implemented, the distribution costs during the initial years as discussed below are expressed in terms of the total volume of highway diesel fuel supplied. This includes 500 ppm as well as 15 ppm highway diesel fuel.

For the reasons outlined above, the following costs, which are also present under the fully implemented sulfur program, were adjusted to reflect the unique conditions during the initial years. During the initial years, the cost of distributing the additional volume of highway diesel fuel needed to compensate for lower energy density of 15 ppm sulfur fuel is estimated at 0.14 cents per gallon of highway diesel fuel supplied. The cost of the increased volume of highway diesel fuel that must be downgraded to a lower-value product is estimated at 0.1 cents per gallon of highway diesel supplied. We estimate that during the initial years of the program the increase in the cost of downgrading the existing highway diesel interface would be 0.08 cents per gallon of highway diesel fuel supplied. During the initial years, the cost of downgrading the interface between pipeline shipments of jet fuel and highway diesel fuel is estimated to increase by 0.03 cents per gallon of highway diesel fuel supplied. The cost of the additional tanks required at terminals to handle this interface is estimated at 0.009 cents per gallon of highway diesel fuel supplied. This tank cost was amortized over the period of the four-year transition period. We estimate that the miscellaneous costs associated with optimizing the distribution system to limit sulfur contamination would be 0.027 cents per gallon of highway diesel fuel supplied (on average) during the initial period (2006—2010).

As noted in the previous section, the additional quality control testing at the terminal level needed to ensure compliance with the 15 ppm sulfur cap would be the same during the initial years and after the requirements are fully implemented. We estimate that the cost of this additional testing would be as we projected in the proposal, 0.002 cent per gallon of highway diesel supplied.

The cost during the initial years of downgrading the additional interface volumes associated with having two grades of highway diesel fuel in part of the pipeline system is estimated at 0.004 cents per gallon of highway diesel full supplied

The most substantial costs associated with the provisions during the initial years of the program are due to the need to handle an additional grade of highway diesel fuel in the distribution system. Under the final program, the production of 500 ppm sulfur fuel will be much less than that of 15 ppm fuel. At the same time, most of the diesel vehicle fleet can burn 500 ppm fuel during the initial period. Because of its greater volume and the need to distribute it everywhere in the country, we expect that essentially all pipelines and terminals will handle 15 ppm fuel. In contrast, distribution of 500 ppm fuel will concentrate on those areas nearest the refineries producing that fuel, plus a few major pipelines serving major refining areas.

Regarding distribution to the final user, we expect that nearly all truck stops in areas where 500 ppm fuel is available will invest in piping and tankage to handle a second fuel. Because of the significant expense involved in adding a second tank, in these areas, we expect service stations will only carry one fuel or the other, as market demands dictate. Likewise, we expect that centrally fueled fleets and card locks will only handle 15 ppm fuel. Under this scenario, sales of 500 ppm fuel are limited to only those vehicles which refuel at truck stops and service stations. This is somewhat conservative since some centrally fueled fleets may have the flexibility to inexpensively handle two fuels. Likewise, some card locks in a given area may be able to carry 15 ppm fuel and others 500 ppm fuel and still serve their clients at little extra cost. Still, given the above assumptions, we project that the 500 ppm fuel will have to be distributed to areas representing about 50 percent of the national diesel fuel demand. Also, as the fleet turns over to 2007 and later vehicles during the initial years, the amount of 500 ppm fuel produced will gradually decrease from just over 20 percent in 2007 to about 16 percent in 2010.

The tankage cost at refineries, terminals, pipelines and bulk plants handling both fuels is estimated to be $0.81 billion. The cost for truck stops to handle two fuels is roughly $0.24 billion, for a total cost of $1.05 billion. Amortized over all of the highway diesel fuel supplied during the initial four-years (15 ppm and 500 ppm) at 7 percent per annum, the cost per gallon is 0.7 cents.

5. Benefits of Low-Sulfur Diesel Fuel for the Existing Diesel Fleet

We estimate that the low-sulfur diesel fuel will provide additional benefits to the existing heavy-duty vehicle fleet as soon as the fuel is introduced. We believe these benefits will offer significant cost savings to the vehicle owner without the need for purchasing any new technologies. The RIA has catalogued a variety of benefits from the low-sulfur diesel fuel. These benefits are summarized in Table V.C–3.

TABLE V.C–3.—COMPONENTS POTENTIALLY AFFECTED BY LOWER SULFUR LEVELS IN DIESEL FUEL

Affected components	Effect of lower sulfur	Potential impact on engine system
Piston Rings	Reduce corrosion wear	Extended engine life and less frequent rebuilds.
Cylinder Liners	Reduce corrosion wear	Extended engine life and less frequent rebuilds.
Oil Quality	Reduce deposits and less need for alkaline additives.	Reduce wear on piston ring and cylinder liner and less frequent oil changes.
Exhaust System (tailpipe)	Reduces corrosion wear	Less frequent part replacement.
EGR	Reduces corrosion wear	Less frequent part replacement.

The actual value of these benefits over the life of the vehicle will depend upon the length of time that the vehicle operates on low-sulfur diesel fuel and the degree to which vehicle operators change engine maintenance patterns to take advantage of these benefits. For a vehicle near the end of its life in 2007 the benefits will be quite small. However for vehicles produced in the years immediately preceding the introduction of low-sulfur fuel the savings will be substantial. The RIA estimates that a heavy heavy-duty vehicle introduced into the fleet in 2006 will realize savings of $610 over its life. This savings could alternatively be expressed in terms of fuel costs as approximately 1 cent per gallon as discussed in the RIA. These savings will occur without additional new cost to the vehicle owner beyond the incremental cost of the low-sulfur diesel fuel, although these savings will require changes to existing maintenance schedules. Such changes seem likely given the magnitude of the savings and the nature of the regulated industry.

D. Aggregate Costs

Using current data for the size and characteristics of the heavy-duty vehicle fleet and making projections for the future, the diesel per-engine, gasoline per-vehicle, and per-gallon fuel costs described above can be used to estimate the total cost to the nation for the emission standards in any year. Figure V.D–1 portrays the results of these projections.[190] All capital costs have been amortized.

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[190] Figure V.E–1 is based on the amortized engine, vehicle and fuel costs as described in the RIA. Actual capital investments, particularly important for fuels, would occur prior to and during the initial years of the program.

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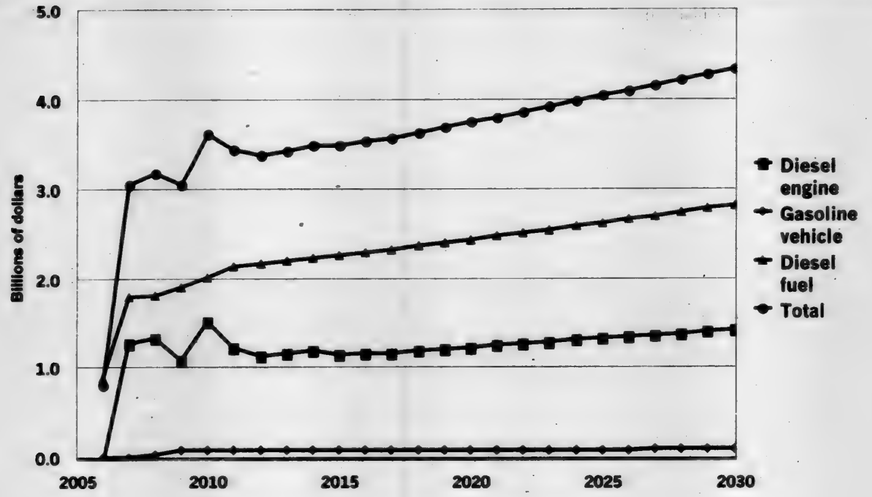


Figure V.D-1 Total Annualized Costs

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As can be seen from the figure, the annual costs start out at less than 1.0 billion dollars in year 2006 and increase during the initial years to about $3.6 billion in 2010. Thereafter, total annualized costs are projected to continue increasing due to the effects of projected growth in engine sales and fuel consumption. The RIA provides further detail regarding these cost projections.

Future consumption of 15 ppm diesel fuel may be influenced by a potential influx of diesel-powered cars and light trucks into the light-duty fleet. At the present time, virtually all cars and light trucks being sold are gasoline fueled. However, the possibility exists that diesels will become more prevalent in the car and light-duty truck fleet, since automotive companies have announced their desire to increase their sales of diesel cars and light trucks. For the Tier 2 rulemaking, the Agency performed a sensitivity analysis using A.D.Little's "most likely" increased growth scenario of diesel penetration into the light-duty vehicle fleet which culminated in a 9 percent and 24 percent penetration of diesel vehicles in the LDV and LDT markets, respectively, in 2015 (see Tier 2 RIA, Table III.A.–13). Were this scenario to play out, the increased number of diesel-powered cars and light-duty trucks would increase the societal costs (those costs, in total, paid by consumers) for the higher priced diesel fuel because more diesel fuel would be consumed. However, were more diesel vehicles to penetrate the light-duty fleet, less gasoline would be consumed than was estimated in our Tier 2 cost analysis. Also, diesel vehicles tend to get higher fuel economy. As a result, the effect of increased dieselization of the light-duty fleet will likely have little or no impact on the aggregate costs estimated for the standards being finalized in today's action.

E. Cost Effectiveness

One tool that can be used to assess the value of new standards for heavy-duty vehicles and engines is cost effectiveness, in which the costs incurred to reach the standards are compared to the mass of emission reductions. This analysis results in the calculation of a $/ton value, the purpose of which is to show that the reductions from the engine and fuel controls being finalized today are cost effective, in comparison to alternative means of control. This analysis involves a comparison of our program not only to past measures, but also to other potential future measures that could be implemented. Both EPA and States have already adopted numerous control measures, and remaining measures tend to be more expensive than those previously employed. As we and States tend to employ the most cost effective available measures first, more expensive ones must be adopted to achieve further emission reductions.

Comments we received in response to our Notice of Proposed Rulemaking on the subject of our cost effectiveness analysis are addressed in the Response to Comments Document.

1. What Is the Cost Effectiveness of This Program?

We have calculated the cost-effectiveness of our diesel engine/gasoline vehicle/diesel sulfur standards based on two different approaches. The first considers the net present value of all costs incurred and emission reductions generated over the life of a single vehicle meeting our standards. This per-vehicle approach focuses on the cost-effectiveness of the program from the point of view of the vehicles and engines which will be used to meet the new requirements. However, the per-vehicle approach does not capture all of the costs or emission reductions from our diesel engine/gasoline vehicle/diesel sulfur program since it does not account for the use of 15 ppm diesel fuel in current diesel engines. Therefore, we have also calculated a 30-year net present value cost-effectiveness using the net present value of costs and emission reductions for all in-use vehicles over a 30-year time frame. The baseline or point of comparison for this evaluation is the previous set of engine, vehicle, and diesel sulfur standards (in other words, the applicable 2006 model year standards).

As described earlier in the discussion of the cost of this program, the cost of complying with the new standards will decline over time as manufacturing costs are reduced and amortized capital investments are recovered. To show the effect of declining cost in the per-vehicle cost-effectiveness analysis, we have developed both near term and long term cost-effectiveness values. More specifically, these correspond to vehicles sold in years one and six of the vehicle and fuel programs. Chapter VI of the RIA contains a full description of this analysis, and you should look in that document for more details of the results summarized here.

The 30-year net present value approach to calculating the cost-effectiveness of our program involves the net present value of all nationwide emission reductions and costs for a 30 year period beginning with the start of the diesel fuel sulfur program and introduction of model year 2007 vehicles and engines in year 2006. This 30-year timeframe captures both the early period of the program when very few vehicles that meet our standards will be in the fleet, and the later period when essentially all vehicles in the fleet will meet the new standards. We have calculated the 30-year net present value cost-effectiveness using the net present value of the nationwide emission reductions and costs for each calender year. These emission reductions and costs are given for every calendar year in the RIA, in addition to details of the methodology we used to calculated the 30-year net present value cost-effectiveness.

Our per-vehicle and 30-year net present value cost-effectiveness values are given in Tables V.E–1 and V.E–2. Table V.E–1 summarizes the per-vehicle, net present value cost-effectiveness results for our diesel engine/gasoline vehicle/diesel sulfur standards using sales weighted averages of the costs (both near term and long term) and emission reductions of the various vehicle and engine classes affected. Table V.E–2 provides the same information from the program 30-year net present value perspective. It is based on the net present value of the 30 year stream of vehicle and fuel costs and NMHC+ NO_X and PM emission reductions, resulting in the 30-year net present value cost-effectiveness. Diesel fuel costs applicable to diesel engines have been divided equally between the adsorber and trap, since 15 ppm diesel fuel is intended to enable all technologies to meet our standards. In addition, since the trap produces reductions in PM and also operates as an enabling device for the NO_X adsorber, we have divided the total trap costs equally between compliance with the PM standard and compliance with the NO_X and NMHC standards.

Tables V.E–1 and V.E–2 also display cost-effectiveness values based on two approaches to account for the reductions in SO_2 emissions associated with the reduction in diesel fuel sulfur. While these reductions are not central to the program and are therefore not displayed with their own cost-effectiveness, they do represent real emission reductions due to our program. The first set of cost-effectiveness numbers in the tables simply ignores these reductions and bases the cost-effectiveness on only the NO_X, NMHC, and PM emission reductions from our program. The second set accounts for these ancillary reductions by crediting some of the cost of the program to SO_2. The amount of cost allocated to SO_2 is based on the cost-effectiveness of SO_2

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emission reductions that could be obtained from alternative, potential future EPA programs. The SO_2 credit was applied only to the PM calculation, since SO_2 reductions are primarily a means to reduce ambient PM concentrations.

TABLE V.E–1.—PER-ENGINE[a] COST EFFECTIVENESS OF THE STANDARDS FOR 2007 AND LATER MY VEHICLES

Pollutants	Discounted lifetime cost effectiveness per ton	Discounted lifetime cost effectiveness per ton with SO_2 credit[b]
Near-term costs:		
NO_X+NMHC	$2,125	$2,125
PM	14,237	7,599
Long-term costs:		
NO_X+NMHC	1,621	1,621
PM	11,340	4,701

[a] As described above, per-engine cost effectiveness does not include any costs or benefits from the existing, pre-control, fleet of vehicles that would use the 15 ppm diesel fuel.
[b] $446 credited to SO_2 (at $4800/ton) for PM cost effectiveness.

TABLE V.E–2.—30-YEAR NET PRESENT VALUE[a] COST EFFECTIVENESS OF THE STANDARDS

	30-year n.p.v. cost effectiveness per ton	30-year n.p.v. cost effectiveness per ton with SO_2 credit[b]
NO_X+NMHC	$2,149	$2,149
PM	13,607	4,195

[a] This cost effectiveness methodology reflects the total fuel costs incurred in the early years of the program when the fleet is transitioning from pre-control to post-control diesel vehicles. In 2007 <10% of highway diesel fuel is anticipated to be consumed by 2007 MY vehicles. By 2012 this increases to >50% for 2007 and later MY vehicles.
[b] $7.1 billion credited to SO_2 (at $4800/ton).

2. Comparison With Other Means of Reducing Emissions

In comparison with other mobile source control programs, we believe that our program represents a cost effective strategy for generating substantial NO_X, NMHC, and PM reductions. This can be seen by comparing the cost effectiveness of today's program with a number of mobile source standards that EPA has adopted in the past. Table V.E–3 summarizes the cost effectiveness of several past EPA actions for NO_X+NMHC. Table V.E–4 summarizes the cost effectiveness of several past EPA actions for PM.

TABLE V.E–3.—COST EFFECTIVENESS OF PREVIOUS MOBILE SOURCE PROGRAMS FOR NO_X+NMHC

Program	$/ton
Tier 2 vehicle/gasoline sulfur	1,340–2,260
2004 Highway HD diesel	212–414
Off-highway diesel engine	425–675
Tier 1 vehicle	2,054–2,792
NLEV	1,930
Marine SI engines	1,171–1,846
On-board diagnostics	2,313
Marine CI engines	24–176

Note: Costs adjusted to 1999 dollars.

TABLE V.E–4.—COST EFFECTIVENESS OF PREVIOUS MOBILE SOURCE PROGRAMS FOR PM

Program	$/ton
Marine CI engines	5222–3881
1996 urban bus	12,264–19,622
Urban bus retrofit/rebuild	30,251
1994 highway HD diesel	20,900–24,467

Note: Costs adjusted to 1999 dollars.

We can see from these tables that the cost effectiveness of our diesel engine/gasoline vehicle/diesel sulfur standards falls within the range of these other programs for both NO_X+NMHC and PM. Our program overlaps the range of the recently promulgated standards for Tier 2 light-duty vehicles and gasoline sulfur shown in Table V.E–3. Our program also overlaps the cost-effectiveness of past programs for PM. It is true that some previous programs have been more cost efficient than the program we are finalizing today. However, it should be expected that the next generation of standards will be more expensive than the last, since the least costly means for reducing emissions is generally pursued first.

In evaluating the cost effectiveness of our diesel engine/gasoline vehicle/diesel sulfur program, we also considered whether the new standards are cost effective in comparison with possible stationary source controls. In the context of the Agency's rulemaking which would have revised the ozone and PM NAAQS,[191] the Agency compiled a list of additional known technologies that could be considered in devising new emission reductions strategies.[192] Through this broad review, over 50 technologies were identified that could reduce NO_X, VOC, or PM. The cost effectiveness of these technologies averaged approximately $5,000/ton for VOC, $13,000/ton for NO_X, and $40,000/ton for PM. Although a $10,000/ton limit was actually used in the air quality analysis presented in the NAAQS revisions rule, these values clearly indicate that, not only are future emission control strategies likely to be more expensive (less cost effective) than past strategies, but the cost effectiveness of our program falls well below the average of those choices, and is near the lower end of the range of potential future strategies.

In summary, we believe that the weight of the evidence from alternative means of providing substantial NO_X + NMHC and PM emission reductions indicates that our diesel engine/gasoline vehicle/diesel sulfur program is cost effective relative to other means of achieving air quality improvements. We believe this is true from the perspective of other mobile source control programs and from the perspective of other stationary source technologies that might be considered.

F. Does the Value of the Benefits Outweigh the Cost of the Standards?

While EPA uses relative cost-effectiveness as the principal economic policy criterion for these standards, further insight regarding the merits of the standards can be provided by benefit-cost analysis. The purpose of this section is to summarize the methods we used and results we obtained in conducting an analysis of the economic benefits of the HD Engine/Diesel Fuel program, and to compare these economic benefits with the estimated costs of the rule. In summary, the results of our analysis indicate that the economic benefits of the HD Engine/Diesel Fuel standards will exceed the costs of meeting the standards. The annual estimated benefits we were able to quantify were $70.4 billion (1999$).

1. What Was Our Overall Approach to the Benefit-Cost Analysis?

The basic question we sought to answer in the benefit-cost analysis was, "What are the net yearly economic benefits to society of the reduction in mobile source emissions likely to be

[191] This rulemaking was remanded to EPA by the D.C. Circuit Court on May 14, 1999. However, the analyses completed in support of that rulemaking are still relevent, since they were designed to investigate the cost effectiveness of a wide variety of potential future emission control strategies. An appeal is currently pending before the U.S. Supreme Court.

[192] Regulatory Impact Analyses for the Particulate Matter and Ozone National Ambient Air Quality Standards and Proposed Regional Haze Rule," Appendix B, "Summary of control measures in the PM, regional haze, and ozone partial attainment analyses," Innovative Strategies and Economics Group, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC, July 17, 1997.

achieved by the final HD Engine/Diesel Fuel program?" In designing an analysis to address this question, we selected a future year for analysis (2030) that is representative of full-implementation of the program (i.e., when the US heavy-duty truck fleet is composed of virtually only compliant heavy-duty vehicles). We also adopted an analytical structure and sequence similar to that used in the "section 812 studies" to estimate the total benefits and costs of the full Clean Air Act.[193] Moreover, we used many of the same models and assumptions used in the section 812 studies as well as other Regulatory Impact Analyses (RIAs) prepared by the Office of Air and Radiation. One difference from previous RIAs, however, is that for particulate matter air quality modeling we used the Regulatory Modeling System for Aerosols and Deposition (REMSAD) model. This model was used in the most recent section 812 study to model air quality in the West. By adopting the major design elements, models, and assumptions developed for the section 812 studies and other RIAs, we have largely relied on methods which have already received extensive review by the independent Science Advisory Board (SAB), by the public, and by other federal agencies.

2. What Are the Significant Limitations of the Benefit-Cost Analysis?

Every benefit-cost analysis examining the potential effects of a change in environmental protection requirements is limited to some extent by data gaps, limitations in model capabilities (such as geographic coverage), and uncertainties in the underlying scientific and economic studies used to configure the benefit and cost models. Deficiencies in the scientific literature often result in the inability to estimate changes in health and environmental effects, such as potential increases in premature mortality associated with increased exposure to carbon monoxide. Deficiencies in the economics literature often result in the inability to assign economic values even to those health and environmental outcomes which can be quantified. While these general uncertainties in the underlying scientific and economics literatures are discussed in detail in the RIA and its supporting documents and references, the key uncertainties which have a bearing on the results of the benefit-cost analysis of today's action are the following:

- The exclusion of potentially significant benefit categories (e.g., health and ecological benefits of reduction in hazardous air pollutants emissions);
- Errors in measurement and projection for variables such as population growth;
- Uncertainties in the estimation of future year emissions inventories and air quality;
- Uncertainties associated with the extrapolation of air quality monitoring data to some unmonitored areas required to better capture the effects of the standards on the affected population;
- Variability in the estimated relationships of health and welfare effects to changes in pollutant concentrations; and
- Uncertainties associated with the effect of potential future actions to limit emissions.

Despite these uncertainties, we believe the benefit-cost analysis provides a reasonable indication of the expected economic benefits of the HD Engine/Diesel Fuel program in 2030 under a set of assumptions. For the final HD Engine/Diesel Fuel benefit analysis, we adopt an approach similar to the Tier 2/Gasoline Sulfur RIA and the section 812 study. We first present an estimate for a primary set of benefit endpoints followed by a presentation of alternative calculations of key health and welfare endpoints to characterize uncertainty in this primary set.

One key area of uncertainty is the value of a statistical life (VSL) for risk reductions in mortality. The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. There is general agreement that the value to an individual of a reduction in mortality risk tends to vary based on several factors, including the age of the individual, the type of risk, the level of control the individual has over the risk, the individual's attitude toward risk, and the health status of the individual. Age in particular may be an important difference between populations affected by air pollution mortality risks and populations affected by workplace risks. Premature mortality risks from air pollution tend to affect the very old more than the working age population. As such, any adjustments to VSL for age differences may have a large impact on total benefits. However, EPA prefers not to draw distinctions in the monetary value assigned to the lives saved even if they differ in age, health status, socioeconomic status, gender or other characteristic of the adult population.

In the recent Tier 2/Gasoline Sulfur benefits analysis, we employed a value of statistical life years (VSLY) approach developed for the Section 812 studies in exploring the impact of age on VSL. However, since these earlier analyses were completed, the SAB Environmental Economics Advisory Committee (EEAC) issued a new advisory report which identifies significant additional limitations in this method. Specifically, the SAB EEAC notes that "inferring the value of a statistical life year, however, requires assumptions about the discount rate and about the time path of expected utility of consumption" (EPA–SAB–EEAC–00–013). They also note that "the theoretically appropriate method is to calculate [willingness to pay (WTP)] for individuals whose ages correspond to those of the affected population, and that it is preferable to base these calculations on empirical estimates of WTP by age."

SAB advised that the EPA "continue to use a wage-risk-based VSL as its primary estimate, including appropriate sensitivity analyses to reflect the uncertainty of these estimates," and that "the only risk characteristic for which adjustments to the VSL can be made is the timing of the risk" (EPA–SAB–EEAC–00–013). In developing our primary estimate of the benefits of premature mortality reductions, we have appropriately discounted over the lag period between exposure and premature mortality. However, an empirical basis that meets the SAB's standards of reliability for adjusting the current $6 million VSL for many of these factors does not yet exist. A discussion of these factors is contained in the RIA and supporting documents. EPA recognizes the need for additional research by the scientific community to develop additional empirical support for adjustments to VSL for the factors mentioned above.

In accordance with the SAB advice, we use the VSL in our primary estimate and present alternative calculations of adjustment for age and other factors. Specifically, several studies conducted by Jones-Lee, et al. (1985, 1989, 1993) found a significant effect of age on the value of mortality risk reductions expressed by citizens in the United Kingdom. The results are supported by a recent analysis which asked samples of Canadian residents their values for reductions in mortality risk (Krupnick *et al.*, 2000). As alternative calculations, we apply the ratios based on the Jones-

[193] The section 812 studies include: (1) US EPA, Report to Congress: The Benefits and Costs of the Clean Air Act, 1970 to 1990, October 1997 (also known as the "Section 812 Retrospective Report"); and (2) the first in the ongoing series of prospective studies estimating the total costs and benefits of the Clean Air Act (see EPA report number: EPA–410–R–99–001, November 1999).

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Lee, *et al.* (1989, 1993) studies to the estimated premature mortalities within the appropriate age groups to provide alternative age-adjusted estimates of the value of avoided premature mortalities.

In the same way, the presentation of the other alternative calculations for certain endpoints seeks to demonstrate how much the overall benefit estimate might vary based on the value EPA has given to a parameter (which has uncertainty associated with it) underlying the estimates for human health and environmental effect incidence and the economic valuation of those effects. These alternative calculations represent conditions that might occur; however, EPA has selected the best values supported by current scientific literature for use in the primary estimate. The alternate calculations include the following:

- Estimating PM-related premature mortality benefits based on different concentration-response (C–R) function estimates;
- Value of avoided premature mortality incidences based on VSLY;
- Consideration of reversals in chronic bronchitis treated as lowest severity cases;
- Estimate of ozone-related chronic asthma;[194]
- Value of visibility changes in all Federal Class I areas;
- Value of visibility changes in US residential areas;
- Value of reduced household soiling damage;
- Alternative sensitivities of crops to ozone exposure from National Crop Loss Assessment Network estimates; and
- Avoided costs of reducing nitrogen loadings in three case study eastern estuaries and nine other eastern estuaries.

Unfortunately, it is not possible to combine all of the assumptions used in the alternate calculations to arrive at different total benefit estimates because, it is highly unlikely that the selected combination of alternative values would all occur simultaneously. Therefore, it is better to consider each alternative calculation individually to assess the sensitivity of total benefits to individual assumptions. For instance, estimating PM-related premature mortality benefits based on different concentration-response functions may be an important uncertainty. Specifically, the Harvard Six Cities study by Dockery *et al.* (1993) of the relationship between PM concentration and premature mortality is a plausible alternative to the American Cancer Society (ACS)/Krewski *et al.* (2000) study used for the primary estimate of benefits. The SAB has noted that "the study had better monitoring with less measurement error than did most other studies" (EPA–SAB–COUNCIL–ADV–99–012, 1999). However, the Dockery *et al.* study had a more limited geographic scope (and a smaller study population) than the ACS/Krewski *et al.* study and the ACS/Krewski *et al.* study appears more likely to mitigate a key source of potential confounding. The Dockery *et al.* study did cover a broader age category (25 and older compared to 30 and older in the ACS study) and followed the cohort for a longer period (15 years compared to 8 years in the ACS study). For these reasons, the Dockery *et al.* study is considered to be a plausible alternative estimate of the avoided premature mortality incidences associated with this final rule. The alternative estimate for mortality can be substituted for the valuation component in our primary estimate of mortality benefits to observe how the net benefits of the program may be influenced by this assumption.

In addition to the estimate for the primary set of endpoints and alternative calculations of benefits, our RIA also presents an appendix with supplemental benefit estimates and sensitivity analyses of other key parameters in the benefits analysis that have greater uncertainty surrounding them due to limitations in the scientific literature. The following sensitivity analyses include alternative income elasticities of willingness to pay;[195] alternative discount rates;[196] alternative PM exposure lags preceding mortality; threshold analysis for PM mortality;[197] and other analyses.

Even with our efforts to fully disclose the uncertainty in our estimate, this uncertainty presentation method does not provide a definitive or complete picture of the true range of monetized benefits estimates. The set of alternative calculations is only representative of those benefits that we were able to quantify and monetize.

3. How Has the Benefit-Cost Analysis Changed From Proposal?

No quantitative benefits analysis was conducted for the proposal, although we outlined the methodology to be used for the final rule analysis. We summarized and responded to public comment regarding the methods in the Summary and Analysis of Comment document. Moreover, we have improved the methods that were presented at proposal. For the benefits assessment for the final rule, EPA updated the C–R functions for health endpoints (*e.g.*, Krewski *et al.*, 2000), updated the emissions inventory, and presented air quality information regarding urban and residential visibility. For the air quality inputs to the benefits analysis, we used the REMSAD model which offers improved chemistry, resolution, and other capabilities over the Source-Receptor Matrix discussed in the proposal. The model's performance, including uncertainties, are discussed elsewhere in the RIA and technical support documents. In addition, we also updated our presentations of monetary benefits of the reduced premature mortality based on advice from the SAB.[198] All of the changes made since the proposal serve to improve the analysis.

4. What Are the Benefits in the Years Leading up to 2030?

The HD Engine/Diesel Fuel program has various cost and emission related components, as described earlier in this section. These components would begin at various times and in some cases would phase in over time. This means that during the early years of the program there would not be a consistent match between cost and benefits. This is especially true for the vehicle control portions of the program, where the full vehicle cost would be incurred at the time of vehicle purchase, while the fuel cost along with the emission reductions and benefits resulting from all these costs would occur throughout the lifetime of the vehicle. Because of this inconsistency and our desire to more appropriately match the costs and emission reductions of our program, our analysis uses a future year when the fleet is nearly fully turned over (2030).

In the years before 2030, the benefits from the HD Engine/Diesel Fuel program will be less than those estimated here, because the compliant heavy-duty fleet will not be fully phased in. Annualized costs, on the other hand, reach nearly their full value within a few years of program initiation (once all phase-ins are completed). This can be seen by comparing the anticipated emission reductions described earlier in section II.D with the aggregate costs of section V.E. Thus, a benefit-cost ratio computed for the earlier years of the program would be expected to be lower than a ratio based on our 2030 analysis. On the other hand, since the estimated benefits are more than ten times the costs in 2030, the emission reduction and cost trends suggest that it is likely that annual benefits would exceed costs from a time early in the life of the program.[199]

Furthermore, to the extent that a lower ratio of benefits to costs early in the program is the result of the mismatch of costs and benefits in time, a simple analysis of an individual year would be misleading. A more appropriate means of capturing the impacts of timing differences in benefits and costs would be to produce a net present value comparison of the costs and benefits over some period of years (an approach analogous to the aggregate cost effectiveness presented in section V.F). Unfortunately, while this is relatively straight-forward for the costs, it is currently not feasible to do a multi-year analysis of the benefits as this would require a significant amount of air quality modeling to capture each year.

5. What Were the Results of the Benefit-Cost Analysis?

The benefit-cost analysis for the HD Engine/Diesel Fuel program reflects a single year "snapshot" of the yearly benefits and costs expected to be realized once the standards have been fully implemented and non-compliant vehicles have all been retired. As discussed in section V.F–4, the benefit-cost ratio would be expected to be lower than the results calculated here in the early years of the program.

Table V.F–1 presents EPA's primary estimate of the benefits of the rule, both the estimated reductions in incidences and the estimated economic value of those incidence reductions. In interpreting the results, it is important to keep in mind the limited set of effects we are able to monetize. Specifically, the table lists the avoided incidences of individual health and environmental effects, the pollutant associated with each of these endpoints, and the estimated economic value of those avoided incidences. For several environmental effects such as visibility, the concept of incidences or cases does not apply as it does for health effects; thus, for these categories economic values are applied directly to air quality conditions. As the table indicates, we estimate that the HD Engine/Diesel Fuel program will produce about 5,500 fewer cases of chronic bronchitis, and we also see significant improvements in minor restricted activity days (with an estimated 9,838,500 fewer cases). Our estimate also incorporates significant reductions in impacts on children's health, showing reductions of 17,600 cases of acute bronchitis, 192,900 fewer cases of lower respiratory symptoms, and 193,400 fewer cases of upper respiratory symptoms in asthmatic children each year. In addition, today's rule is estimated to reduce 361,400 incidents of asthma attacks each year in asthmatics of all ages from reduced exposure to ozone and particles. Asthma is the most prevalent chronic disease among children and currently affects over seven percent of children under 18 years of age.

Total monetized benefits, however, are driven primarily by the estimated 8,300 fewer premature fatalities each year, which account for almost 89 percent of total benefits. We assume for this analysis that some of the incidences of premature mortality related to PM exposures occur in a distributed fashion over the five years following exposure. To take this into account in the valuation of reductions in premature mortality, we apply an annual three percent discount rate to the value of premature mortality occurring in years after our analysis year.

TABLE V.F–1.—EPA PRIMARY ESTIMATE OF THE ANNUAL QUANTIFIED AND MONETIZED BENEFITS ASSOCIATED WITH IMPROVED AIR QUALITY RESULTING FROM THE HD ENGINE/DIESEL FUEL RULE IN 2030 [A]

Endpoint	Pollutant	Avoided incidence [A C] (cases/year)	Monetary benefits [A D] (millions 1999$)
Premature mortality [B] (adults, ages 30 and over)	PM [B]	8,300	$62,580
Chronic bronchitis	PM	5,500	$2,430
Hospital Admissions from Respiratory Causes	Ozone and PM	4,100	$60
Hospital Admissions from Cardiovascular Causes	Ozone and PM	3,000	$50
Emergency Room Visits for Asthma	Ozone and PM	2,400	<$5
Acute bronchitis (children, ages 8–12)	PM	17,600	<$5
Upper respiratory symptoms (asthmatic children, ages 9–11)	PM	193,400	$10
Lower respiratory symptoms (children, ages 7–14)	PM	192,900	<$5
Asthma attacks (asthmatics, all ages) [E]	Ozone and PM	361,400	B_8
Work loss days (adults, ages 18–65)	PM	1,539,400	$160
Minor restricted activity days (adults, ages 18–65) (adjusted to exclude asthma attacks).	Ozone and PM	9,838,500	$530
Other health effects [E]	Ozone, PM, CO, NMHC	$U_1+U_2+U_3+U_4$	$B_1+B_2+B_3+B_4$
Decreased worker productivity	Ozone		$140
Recreational visibility (86 Class I Areas)	PM		$3,260
Residential visibility	PM		B_5
Household soiling damage	PM		B_6
Materials damage	PM		B_7
Nitrogen Deposition to Estuaries	Nitrogen		B_9
Premature mortality [B] (adults, ages 30 and over)	PM [B]	8,300	$62,580

[194] McDonnell, W.F., D.E. Abbey, N.Nishino, M.D. Lebowitz. Long-term Ambient Ozone Concentration and the Incidence of Asthma in Nonsmoking Adults: The Ahsmog Study. Environmental Research. A:80, 110–121. 1999.

[195] Income elasticity of WTP characterizes the relationship between changes in real income and changes in the WTP for a particular commodity. Income elasticity of WTP is measured as the percentage change in WTP for a one percent change in real income. For example, an income elasticity of 0.5 implies that a 10 percent increase in real income would lead to a 5 percent increase in WTP.

[196] The choice of a discount rate, and its associated conceptual basis, is a topic of ongoing discussion within the federal government. EPA adopted a 3 percent discount rate for its primary analysis in this case to reflect reliance on a "social rate of time preference" discounting concept. We have also calculated benefits and costs using a 7 percent rate consistent with an "opportunity cost of capital" concept to reflect the time value of resources directed to meet regulatory requirements. In this case, the benefit and cost estimates were not significantly affected by the choice of discount rate. Further discussion of this topic appears in EPA's Guidelines for Preparing Economic Analyses (in press).

[197] The SAB has advised EPA that there is no current scientific basis for selecting a threshold for PM-related health effects considered in this analysis (EPA–SAB–Council–ADV–99–012, 1999).

[198] Full documentation of the SAB advice can be found at their website (*www.epa.gov/sab*) or in the docket under the following reference: EPA–SAB–EEAC–00–013, July 27, 2000. An SAB Report on EPA's White Paper Valuing the Benefits of Fatal Cancer Risk Reduction.

[199] While emission reduction trends give a general indication of the likely trends in the benefits, there are sufficient non-linearities and interactions among pollutants in the atmospheric chemistry used in our modeling that it is not possible to attempt a quantitative estimate of the benefits simply from changes in the inventories in years that were not fully modeled.

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TABLE V.F–1.—EPA PRIMARY ESTIMATE OF THE ANNUAL QUANTIFIED AND MONETIZED BENEFITS ASSOCIATED WITH IMPROVED AIR QUALITY RESULTING FROM THE HD ENGINE/DIESEL FUEL RULE IN 2030 [A]—Continued

Endpoint	Pollutant	Avoided incidence [A] [C] (cases/year)	Monetary benefits [A] [D] (millions 1999$)
Chronic bronchitis	PM	5,500	$2,430
Hospital Admissions from Respiratory Causes	Ozone and PM	4,100	$80
Hospital Admissions from Cardiovascular Causes	Ozone and PM	3,000	$50
Emergency Room Visits for Asthma	Ozone and PM	2,400	<$5
Acute bronchitis (children, ages 8–12)	PM	17,600	<$5
Upper respiratory symptoms (asthmatic children, ages 9–11)	PM	193,400	$10
Lower respiratory symptoms (children, ages 7–14)	PM	192,900	<$5
Asthma attacks (asthmatics, all ages) [E]	Ozone and PM	361,400	B_8
Work loss days (adults, ages 18–65)	PM	1,539,400	$160
Minor restricted activity days (adults, ages 18–65) (adjusted to exclude asthma attacks)	Ozone and PM	9,838,500	$530
Other health effects [E]	Ozone and PM	$U_1+U_2+U_3+U_4$	$B_1+B_2+B_3+B_4$
	CO, NMHC		
Decreased worker productivity	Ozone		$140
Agricultural crop damage (6 crops)	Ozone		$1,120
Commercial forest damage, (6 species in Eastern US)	Ozone		B_9
Commercial forest damage, other	Ozone		B_{10}
Other welfare effects [E]	Ozone, PM		$B_{11}+B_{12}+B_{13}+B_{14}$
	CO, NMHC		
Monetized Total [F]			$70,360+B

Notes:
[A] Ozone-related benefits are only calculated for the Eastern US due to unavailability of reliable modeled ozone concentrations in the Western US, thus underestimating national ozone-related benefits. See RIA and technical support documents for details.
[B] Premature mortality, associated with ozone is not separately included in this analysis. It is assumed that the ACS/Krewski, *et al.* (2000) C–R function for premature mortality captures both PM mortality benefits and any mortality benefits associated with other air pollutants. Also note that the valuation assumes the 5 year distributed lag structure described earlier and a 3 percent discount rate over that lag period.
[C] Incidences are rounded to the nearest 100.
[D] Dollar values are rounded to the nearest 10 million. Monetary benefits account for growth in real GDP per capita between 1990 and 2030.
[E] The Ui are the incidences and the Bi are the values for the unquantified category i. For some categories such as asthma attacks, we were able to quantify the reduction in incidence, but we present the monetization as an alternative calculation. A detailed listing of unquantified PM, ozone, CO, and NMHC related health and welfare effects is provided in Table V.F–2. NMHC shown here are also hazardous air pollutants listed in the Clean Air Act.
[F] B is equal to the sum of all unmonetized categories, *i.e.* Ba+B1+B2+...+Bn.

This table also indicates with a "B" those additional health and environmental benefits which could not be expressed in quantitative incidence and/or economic value terms. A full listing of the benefit categories that could not be quantified or monetized in our estimate are provided in Table V.F–2. For instance, visibility is expected to improve in all areas of the country, with the largest improvements occurring in heavily populated residential areas (*e.g.*, half of the urban areas show an improvement of 0.5 deciviews or more). However, due to limitations on sources to value these effects, we include a "B" in the primary estimate table for this category. Likewise, the HD Engine/Diesel Fuel rule will also provide progress for some estuaries to meet their goals for reducing nitrogen deposition (*e.g.*, nitrogen loadings for the Albemarle/Pamlico Sound are reduced by 24 percent of their reductions goal), however, this endpoint is also displayed with a "B" in the table. A full appreciation of the overall economic consequences of the HD Engine/Diesel Fuel standards requires consideration of all benefits and costs expected to result from the new standards, not just those benefits and costs which could be expressed here in dollar terms.

In summary, EPA's primary estimate of the benefits of the HD Engine/Diesel Fuel rule is $70.4 billion in 2030. This estimate accounts for growth in real gross domestic product (GDP) per capita between 1990 and 2030.

TABLE V.F–2.—ADDITIONAL, NON-MONETIZED BENEFITS OF THE HD ENGINE/DIESEL FUEL STANDARDS

Pollutant	Unquantified effects
Ozone Health	Premature mortality; [A] Increased airway responsiveness to stimuli; Inflammation in the lung; Chronic respiratory damage; Premature aging of the lungs; Acute inflammation and respiratory cell damage; Increased susceptibility to respiratory infection; and Non-asthma respiratory emergency room visits.
Ozone Welfare	Decreased yields for commercial forests; Decreased yields for fruits and vegetables; Decreased yields for non-commercial crops; Damage to urban ornamental plants; Impacts on recreational demand from damaged forest aesthetics; and Damage to ecosystem functions.
PM Health	Infant mortality; Low birth weight; Changes in pulmonary function; Chronic respiratory diseases other than chronic bronchitis; and Morphological changes.
PM Welfare	Visibility in non-class I areas; Soiling and materials damage; and Damage to ecosystem functions.
Nitrogen and Sulfate Deposition Welfare.	Impacts of acidic sulfate and nitrate deposition on commercial forests; Impacts of acidic deposition to commercial freshwater fishing; Impacts of acidic deposition to recreation in terrestrial ecosystems; Reduced existence values for currently healthy ecosystems; Impacts of nitrogen deposition on commercial fishing, agriculture, and forests; Impacts of nitrogen deposition on recreation in estuarine ecosystems; and Damage to ecosystem functions.

TABLE V.F–2.—ADDITIONAL, NON-MONETIZED BENEFITS OF THE HD ENGINE/DIESEL FUEL STANDARDS—Continued

Pollutant	Unquantified effects
CO Health	Premature mortality; [A] Behavioral effects; Hospital admissions—respiratory, cardiovascular, and other; Other cardiovascular effects; Developmental effects; Decreased time to onset of angina; and Non-asthma respiratory ER visits.
NMHC Health	Cancer (benzene, 1,3-butadiene, formaldehyde, acetaldehyde); [B] Anemia (benzene); Disruption of production of blood components (benzene); Reduction in the number of blood platelets (benzene); Excessive bone marrow formation (benzene); Depression of lymphocyte counts (benzene); Reproductive and developmental effects (1,3-butadiene); Irritation of eyes and mucus membranes (formaldehyde); Respiratory irritation (formaldehyde); Asthma attacks in asthmatics (formaldehyde); Asthma-like symptoms in non-asthmatics (formaldehyde); Irritation of the eyes, skin, and respiratory tract (acetaldehyde); and Upper respiratory tract irritation and congestion (acrolein).
NMHC Welfare	Direct toxic effects to animals; Bioaccumulation in the food chain; and Damage to ecosystem function.

[A] Premature mortality associated with ozone and carbon monoxide is not separately included in this analysis. In this analysis, we assume that the ACS/Krewski, *et al.* C–R function for premature mortality captures both PM mortality benefits and any mortality benefits associated with other air pollutants.
[B] Non-methane hydrocarbons related to this rule are also hazardous air pollutants listed in the Clean Air Act.

In addition, in analyzing the present rule, we recognized that the benefits estimates were subject to a number of uncertainties with other parameters. In Table V.F–3 we present key alternatives to assumptions regarding individual elements of the benefits analysis and their effect on the primary estimate of benefits. This table also displays some assumptions that can be made to value some of the categories that are indicated with a "B" in the primary estimate. For example, this table can be used to answer questions like, "What would total benefits be if we were to use the ACS/Krewski, *et al.* regionally adjusted $PM_{2.5}$ C–R function to estimate avoided premature mortality?" This table is not meant to be comprehensive but to identify the impact of key issues identified by EPA or in public comment as affecting the total benefits estimation.

TABLE V.F—3. KEY ALTERNATIVE BENEFITS CALCULATIONS FOR THE HD ENGINE/DIESEL FUEL RULE IN 2030[A]

Description of alternative		Avoided incidences	Impact on primary benefits estimate adjusted for growth in real income (million 1999$)
Alternative Concentration-Response Functions for PM-related Premature Mortality			
1. Krewski/ACS Study Regional Adjustment Model [B]		9,400	+$7,370 (+10.5%)
2. Pope/ACS Study [C]		9,900	+12,780 (+18.2%)
3. Krewski/Harvard Six-city Study [D]		24,200	+$118,500 (+168.4%)
Alternative Methods for Valuing Reductions in Incidences of PM-related Premature Mortality			
Value of avoided premature mortality incidences based on age-specific VSL	Jones-Lee (1989) [E]	8,300	−$28,510 (−40.5%)
	Jones-Lee (1993) [F]	8,300	−$6,820 (−10.0%)

[A] Section VII–F of the RIA provides complete information about the estimates in this table.
[B] This C–R function is included as a reasonable specification to explore the impact of adjustments for broad regional correlations, which have been identified as important factors in correctly specifying the PM mortality C–R function.
[C] The Pope et al. C–R function was used to estimate reductions in premature mortality for the Tier 2/Gasoline Sulfur benefits analysis. It is included here to provide a comparable estimate for the HD Engine/Diesel Fuel rule.
[D] The Krewski et al. "Harvard Six-cities Study" estimate is included because the Harvard Six-cities Study featured improved exposure estimates, a slightly broader study population (adults aged 25 and older), and a follow-up period nearly twice as long as that of Pope, et al. and as such provides a reasonable alternative to the primary estimate.
[E] Jones-Lee (1989) provides an estimate of age-adjusted VSL based on a finding that older people place a much lower value on mortality risk reductions than middle-age or younger people.
[F] Jones-Lee (1993) provides an estimate of age-adjusted VSL based on a finding that older people value mortality risk reductions only somewhat less than middle-aged or younger people.

The estimated annualized 2030 cost for businesses to implement the final HD Engine/Diesel Fuel program from Table V.D–1 of the RIA is $4.3 billion (1999$). When considered in a broader social cost context of the cost to society of the resources used, which is the right metric for cost-benefit analysis, the annualized cost is $4.2 billion. The monetized benefits are approximately $70.4 billion and EPA believes there is considerable value to the public of the benefits it could not monetize. The net benefit that can be monetized is $66.2 billion. Therefore, implementation of the HD Engine/Diesel Fuel program is expected to provide society with a net gain in social welfare based on economic efficiency criteria. Tables V.F–4 summarizes the costs, benefits, and net benefits.

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TABLE V.F–4.—2030 ANNUAL MONETIZED COSTS, BENEFITS, AND NET BENEFITS FOR THE FINAL HD ENGINE/DIESEL FUEL RULE[a]

	Billions of 1999$
Annual compliance costs	$4.2
Monetized PM-related benefits[b]	$69.0 + B_{PM}
Monetized Ozone-related benefits[b, c]	$1.4 + B_{Ozone}
NMHC-related benefits	not monetized (B_{NMHC})
CO-related benefits	not monetized (B_{CO})
Total annual benefits	$70.4 + B_{PM} + B_{Ozone} + B_{NMHC} + B_{CO}
Monetized net benefits[d]	$66.2 + B

[a] For this section, all costs and benefits are rounded to the nearest 100 million. Thus, figures presented in this chapter may not exactly equal benefit and cost numbers presented in earlier sections of the chapter.

[b] Not all possible benefits or disbenefits are quantified and monetized in this analysis. Potential benefit categories that have not been quantified and monetized are listed in Table VII–1. Unmonetized PM- and ozone-related benefits are indicated by B_{PM} and B_{Ozone}, respectively.

[c] Ozone-related benefits are only calculated for the Eastern U.S. due to unavailability of reliable modeled ozone concentrations in the Western U.S. This results in an underestimate of national ozone-related benefits. See US EPA (2000a) for a detailed discussion of the UAM–V ozone model and model performance issues.

[d] B is equal to the sum of all unmonetized benefits, including those associated with PM, ozone, CO, and NMHC.

VI. Requirements for Engine and Vehicle Manufacturers

A. Compliance with Standards and Enforcement

We are making some changes to the compliance-related requirements that will apply to vehicles and engines certified to the new standards. These changes are described below. Changes related to the supplemental emission requirements are discussed in Section III.C, along with the discussion of revised standards for those requirements. In general, however, existing compliance provisions will continue to apply to the vehicles and engines subject to today's standards.

1. Allowable Maintenance

Our existing regulations contain provisions (40 CFR § 86.004–25) that would affect scheduled maintenance of NO_X adsorbers, PM traps, and other devices that may be used to comply with the new standards. These provisions limit the amount of maintenance to emission-related components that the manufacturer is allowed to conduct during durability testing (or specify in the maintenance instructions that it gives to operators). We believe that the continuation of these requirements is appropriate because we expect that, with very low fuel sulfur levels, these technologies will be very durable in use and will last the full useful life with little or no scheduled maintenance other than cleaning. However, we are modifying these provisions slightly. The existing regulations would have allowed a manufacturer to specify something as drastic as replacement of the adsorber catalyst bed or the trap filter after as little as 100,000–150,000 miles if there was a "reasonable likelihood" that the maintenance would get done. To ensure that no manufacturer underdesigns their adsorbers or traps (compared to the level of durability that is achievable), we are requiring that these technologies be designed to last for the full useful life of the engine. More specifically, the final regulations state that scheduled replacement of the PM filter element, NO_X adsorber, or other catalyst module bed is not allowed during the useful life, unless the manufacturer can show that the replacement will in fact occur and pays for the replacement. Otherwise, only cleaning and adjustment will be allowed as scheduled maintenance. It is important to note that this restriction only applies to the manufacturer's specified maintenance. Owners and operators are, of course, allowed to perform additional maintenance.

2. Emission Data Waivers

Today's action includes PM standards for all heavy-duty engines. However, because gasoline engines have inherently low PM emissions, it will be appropriate in some cases to waive the requirement to measure PM emissions for certification. Therefore, the final regulations give us the flexibility to allow manufacturers to certify gasoline engines and vehicles without measuring PM emissions, provided they can demonstrate compliance in some other way such as with previous data, analyses, or other information. The flexibility is the same as that allowed for PM emissions from light-duty gasoline vehicles and for CO emissions from heavy-duty diesel engines. We are also allowing the same type of analysis to be used with respect to formaldehyde emissions from all petroleum-fueled heavy-duty vehicles.

3. Crankcase Emissions

Section III describes a new requirement for manufacturers to control crankcase emissions from turbocharged diesel engines. Historically, control of crankcase emissions has meant sealing the crankcase and routing the crankcase gases into the air intake system so they can be combusted. However, some manufacturers have expressed a reasonable concern that this would be unnecessarily restrictive, and suggested that we should allow for alternative controls. Therefore, we are making some revisions from the proposed regulations. First, we are clarifying that this closed crankcase provision does not require that crankcase gases be routed into the engine intake. We will also allow manufacturers to route crankcase gases into the exhaust system, including upstream of the exhaust emission controls. Furthermore, we are also changing the regulations to allow manufacturers to instead measure crankcase emissions and add them to the measured exhaust emissions (or to measure them together). Manufacturers choosing to use this allowance rather than to seal the crankcase will need to modify their exhaust deterioration factors or to develop separate deterioration factors to account for increases in crankcase emissions as the engine ages. Manufacturers would also be responsible for ensuring that crankcase emissions would be readily measurable in use.

4. Non-Conformance Penalties

We are not establishing non-conformance penalties (NCPs) for the new standards at this time. NCPs are monetary penalties that manufacturers can pay instead of complying with an emission standard. In order for us to establish NCPs for a specific standard, we would have to find that: (1) Substantial work will be required to meet the standard for which the NCP is offered; and (2) there is likely to be a "technological laggard" (*i.e.*, a manufacturer that cannot meet the standard because of technological (not economic) difficulties and, without NCPs, might be forced from the marketplace). According to the CAA (Section 206(g)), such NCPs "shall remove any competitive disadvantage to manufacturers whose engines or vehicles achieve the required degree of emission reduction." We also must determine compliance costs so that appropriate penalties can be established. While we have established NCPs in past rulemakings, their use has been rare since the implementation of our averaging, banking and trading program.

We requested comment on the need for NCPs in this rulemaking. However, after reviewing the comments, we cannot conclude that NCPs will be needed. While we believe that substantial work will be required to meet the 2007 standards, we currently have no information indicating that a technological laggard is likely to exist. Recognizing that it may have been difficult for manufacturers to comment on these criteria at this early stage of development, when implementation of these standards is still more than six years away, it may be appropriate to reconsider NCPs in a future action.

5. Idle CO Standards

We are also eliminating the idle CO emission standards for heavy-duty vehicles and engines below 14,000 pounds beginning in the 2004 model year, provided they are certified to the OBD requirements of our Phase 1 rule. (See 65 FR 59896, October 6, 2000.) The certified OBD systems on those vehicles will likely serve as the basis for future inspection and maintenance tests in areas testing vehicles in that weight class. Certification data show that heavy-duty engines and vehicles are certifying with idle CO levels well below the standard. We believe that the existing standard is not the forcing function for these low idle CO levels, but instead it is the electronic computer-controlled engines of today. In effect, we believe that the idle CO standard places an unnecessary testing burden on manufacturers whose vehicles are certified to the OBD requirements. We also eliminated the idle CO standard for light-duty trucks in our Tier 2 rule. (See 65 FR 6698, February 10, 2000.) Note that we are considering a future rule that would implement OBD on engines over 14,000 pounds. We would consider eliminating the idle CO requirement for those engines in the event that OBD requirements are put into place.

B. Compliance With Phase-in Schedules

In Section III we described the phase-in options for diesel engine manufacturers. These options are based on percentages of a manufacturer's production. We recognize, however, that manufacturers need to plan for compliance well in advance of the start of production, and that actual production volumes for any one model year may differ from their projections. This is a bigger concern for the diesel engines than for gasoline engines because of the three-year phase-in of the new diesel NO_X standards. On the other hand, we believe that it would be inappropriate to base compliance solely on a manufacturer's projections. That could encourage manufacturers to overestimate their production of the low-emission engines, and could result in significantly lower emission benefits during the phase-in. Given these conflicting factors, we are finalizing a compromise approach. We will initially only require diesel manufacturers to project compliance with the phase-in based on their projected production volumes, provided that they made up any deficits (in terms of percent of production) the following year. Thus, a manufacturer that projected 50 percent of its production in 2007 would be low-NO_X (*i.e.*, meet the 0.20 g/bhp-hr NO_X standard), but that was only able to actually produce 45 percent of its production as low-NO_X, could achieve compliance by producing at least 55 percent of its production as low-NO_X in 2008. However, since production volumes differ from year to year, deficits would be calculated and made up based on numbers of engines or vehicles, rather than percent of production. This is similar to the approach that we used in phasing-in the Tier 2 emission standards.

Since we expect that a manufacturer making a good-faith projection of sales would not be very far off of the actual production volumes, we are limiting the size of the deficit that could be excused. In all cases, the manufacturer will be required to produce at least 25 percent of its production as low-NO_X engines in model years 2007, 2008, and 2009. Another important restriction is that manufacturers will not be allowed to have a deficit in the third year of the phase-in (2009). This restriction is being finalized to ensure that manufacturers are able to make up the deficit. Since they could not produce more than 100 percent low-NO_X engines in 2010, it would not be possible to make up a deficit from 2009.

C. Averaging, Banking, and Trading

We are continuing the basic structure of the existing ABT program for heavy-duty engines. This program allows manufacturers to certify their engine families at various specified emissions levels above or below the standard, as long as they comply with the applicable standards when averaged across their various engine families. More specifically, manufacturers are allowed to certify their engine families with various family emission limits (FELs), provided that in each model year the average of the FELs does not exceed the standard when weighted by the numbers of engines produced in each family for that model year. To do this, they generate certification emission credits by producing engine families that are certified below the applicable standard. These credits can then be used to offset the production of engine families that are certified to have emissions in excess of the applicable standards. Manufacturers are also allowed to bank these credits for later use or trade them to other manufacturers. We are adopting some restrictions to ensure that the environmental benefits of the program are not jeopardized as described in the Response to Comments document. These restrictions are described below along with other changes made in response to comments. We are continuing this ABT program because we believe that it will provide the manufacturers significant compliance flexibility. This compliance flexibility could be a significant factor in the manufacturers' ability to comply with the standards in 2007 and will help to allow implementation of the new, more stringent standards as soon as permissible under the CAA.

We proposed two separate averaging sets during the diesel phase-in period. In one set, engines would be certified to the 2.4 g/bhp-hr NO_X+NMHC standard (which applies for model years 2004–2006), and would be subject to the restrictions and allowances established for those model years. In the other set, engines would be certified to the 0.20 g/bhp-hr NO_X standard, and would be subject to the restrictions and allowances in the proposed program.

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While we proposed to not allow averaging between these two sets, based on the comments we received, the final regulations allow manufacturers to transfer credits across these averaging sets, with some restrictions. Manufacturers could use credits generated during the phase-out of engines subject to the 2.4 g/bhp-hr NO_X+NMHC standard to comply with the 0.20 g/bhp-hr NO_X standard, but these credits will be subject to a 20 percent discount. (Each gram of NO_X+NMHC credits from the phase-out engines would be worth 0.8 grams of NO_X credits in the new ABT program.) This discount reflects the fact that the change from our proposed ABT program provides manufacturers with substantial flexibility in meeting the final standards and also accounts for the NMHC component of the credit. In the first year of the phase-in, this flexibility will allow manufacturers to reduce fleetwide emissions more than would have been possible with the proposed program. Manufacturers will be able to reduce emissions for a substantial percentage of their production, reflecting the use of low-NO_X technologies, without being required to produce a full 50 percent of their production with NO_X emissions near or below 0.20 g/bhp-hr in the initial year of the phase-in. This generation and use of credits will give manufacturers a greater opportunity to gain experience with the low-NO_X technologies before they are required to meet the final standards across their full production. As part of the averaging program during the phase-in period (model years 2007–2009), we will allow diesel engine credits to be averaged across service class using a modified form of the ABT program. These credit exchanges would occur in the same manner as other credit exchanges, except that the credits generated from one service class would need to be calculated using the useful life and horsepower values of the engine family using credits. This would make the credit exchanges equivalent to the vehicle count phase-in provisions. This allowance is restricted to averaging. Banked or traded credits cannot be used across service class.

We are also adopting a restriction on the use of banked NO_X+NMHC credits generated from diesel engines certified to the 2.4 g/bhp-hr NO_X+NMHC standard. While we proposed to prohibit any such use, the final regulations will allow manufacturers to use banked credits to show compliance with the 0.20 g/bhp-hr standard, but the credits will be discounted by 20 percent when they are used for this purpose.[200] This is consistent with the cross-averaging set discount described above. In addition, we are setting an upper bound on the number of engines for which a manufacturer could use such banked credits during any one model year. The upper limit is ten percent of the manufacturer's annual U.S.-directed production of heavy-duty highway diesel engines, and would apply only for engines certified to FELs higher than 0.50 g/bhp-hr. We believe that this limit is necessary to prevent manufacturers from delaying the introduction of the low-NO_X technologies by using a large number of banked credits. This kind of delay would be contrary to the goals of the phase-in, which in large part is intended for manufacturers to gain some initial experience with the low-NO_X technologies for a limited portion of their production. Although it does not appear likely (based on manufacturer expectations) that such credits will exist in large numbers, this limit appears prudent to ensure that such a problem does not occur.

We are making similar changes to the ABT programs for heavy-duty gasoline engines and vehicles. We will allow exchange of credits from the chassis-certified vehicles to engines (and vice versa) on a credit for credit face-value basis, subject to a 20 percent discount.[201] The discount is necessary to account for the uncertainty in converting between g/mi standards and g/bhp-hr standards. We will also allow NO_X+NMHC credits from gasoline engines certified to the combined standards (including banked credits) to be used in the new NO_X-only ABT program, also subject to the 20 percent discount, for reasons discussed above and in the Response to Comments document. This discount would not apply for banked or averaged gasoline vehicle credits used within the vehicle ABT program, since the existing program is already a NO_X-only program. In connection to this option, we believe that it would be appropriate to allow gasoline engine manufacturers to voluntarily participate in an NMHC ABT program, instead of forcing them to convert their NO_X+NMHC credits into NO_X credits when the new standards take effect. While we believe that manufacturers will generally prefer to use these credits as NO_X credits, NMHC credits may be of some value to manufacturers since gasoline engine emission controls often have a NO_X-NMHC emission tradeoff much like the NO_X-PM tradeoff for diesel engines. Therefore, we are extending the ABT programs for gasoline engines and vehicles to include NMHC, beginning with the 2007 model year. These NO_X and NMHC ABT programs parallel the NO_X and PM ABT programs for diesels. In the NMHC ABT programs, the NMHC credits would be subject to the same allowances, restrictions, and discounts as the NO_X credits. In addition, we are adopting a provision to allow vehicle manufacturers to bank NMHC credits before 2008 for complete vehicles that are certified to the 2008 standards early. (Engine manufacturers are already allowed to bank NO_X+NMHC credits for model year 2004 and later engines.)

It is worth noting three other aspects of this new banking program. First we recognize that NO_X+NMHC credits are not the same as NO_X-only credits. However, both NMHC reductions and NO_X reductions have environmental value, although they are not necessarily equivalent. Thus, given the 20 percent discount that would be applied to the NO_X+NMHC credits if they are transferred into the new NO_X ABT program, we believe that it is appropriate to allow those credits to be used in the new NO_X program. This is especially true for diesels, which are expected to have low NMHC levels for model years 2004–2006 (probably about one-tenth of the expected NO_X levels). Second, the final program does not include the proposed provisions for banking undiscounted credits by meeting all of the new diesel standards early, because we believe that the early compliance option described in Section III would accomplish essentially the same flexibility. Finally, we are not finalizing any new discounts or restrictions for banked PM credits. Considering the simple 100 percent phase-in of the PM standards in 2007, we believe that such restrictions are not necessary to achieve the goals of this program for PM, especially given the 0.02 g/bhp-hr PM FEL cap, which is described below.

The existing ABT program includes limits on how high the emissions from credit-using engines can be. These limits are referred to as FEL caps. No engine family may be certified above these caps using credits. These limits provide the manufacturers compliance flexibility while protecting against the introduction of unnecessarily high-emitting engines. In the past, we have generally set the FEL caps at the emission levels allowed by the previous standard, unless there was some specific reason to do otherwise. However, we proposed much lower FEL caps, because the proposed standard levels were so much lower than the previous levels and because we wanted to ensure that manufacturers did not continue to produce old-technology high-emitting engines under the new program. In today's FRM, for model year 2007 and later diesel engines, we are adopting a more flexible cap for NO_X emissions during the first three years of the program than was proposed, but are adopting the proposed FEL cap for PM emissions. We believe that this approach for NO_X is more consistent with the rest of the ABT program (as is described above) than applying the proposed FEL cap during this interim period. Specifically, model year 2007 through 2009 diesel engines subject to the 0.20 g/bhp-hr standard will not be allowed to have NO_X emissions higher than 2.0 g/bhp-hr, or PM emissions higher than 0.02 g/bhp-hr. The NO_X level represents a conservative estimate of the emission level that is expected under the combined NO_X+NMHC standards that will apply beginning in model year 2004. The proposed NO_X FEL cap of 0.50 g/bhp-hr would not apply until model year 2010. We believe that the higher FEL cap is appropriate during the transition to the much lower standards, to allow some meaningful use of averaging. However, since the 2.0 g/bhp-hr cap is ten times the level of the new standard, it would not be appropriate as a long-term cap.

The PM cap is also lower than the previous standard of 0.10 g/bhp-hr. As noted above, this is being done in connection with the absence of the kind of restrictions on the use of PM credits that are being set for NO_X credits. The NO_X credits restrictions are designed to better coordinate the NO_X ABT program with the NO_X standard phase-in; and the PM standard is not phased-in. Without those types of restrictions, we believe that it is appropriate to adopt the proposed lower FEL cap to prevent the possibility of PM credits being used to delay the implementation of the program and its benefits.

The FEL caps for gasoline vehicles and engines are being set at the previous standards, and the approximate NO_X and NMHC levels inherent in the NO_X+NMHC standards that will apply for model year 2004–2007 engines. Since engine manufacturers will have the option of certifying their engines to a 1.5 g/bhp-hr NO_X+NMHC standard for model years 2004–2007 (instead of the 2005 standard of 1.0 g/bhp-hr), those manufacturers choosing that option, will also be allowed higher FEL caps for model years 2008–2010. All of these FEL caps are shown in Table VI.D–1 and are discussed in more detail in the Response to Comments document. These new FEL caps do not apply for the phase-out engines and vehicles.

TABLE VI.D–1.—NEW FEL CAPS FOR AVERAGING BANKING AND TRADING

	NO_X FEL cap	PM/NMHC FEL cap
HDDE	0.50 g/bhp-hr[a]	0.02 g/bhp-hr PM.
HDGE	0.50 g/bhp-hr[b]	0.30 g/bhp-hr[b] NMHC.
Complete HDGV less than or equal to 10,000 pounds GVWR	0.9 gpm	0.28 gpm NMHC.
Complete HDGV over 10,000 pounds GVWR	1.0 gpm	0.33 gpm NMHC.

[a] The NO_X FEL cap is 2.0 for model years 2007–2009 diesel engines.
[b] The NO_X and NMHC FEL caps are 0.80 and 0.40 g/bhp-hr, respectively, for model years 2008–2010 gasoline engines for manufacturers choosing to certify to the 1.5 g/bhp-hr NO_X+NMHC level in 2004.

D. FTP Changes to Accommodate Regeneration of Exhaust Emission Controls

It is expected that some of the exhaust emission control devices used to meet today's standards will have discrete regeneration events that could affect emission characteristics. For example, NO_X adsorbers incorporate discrete regenerations. The NO_X adsorber stores NO_X under normal conditions until the NO_X storage capacity is nearly full, at which point the regeneration event is triggered to purge the stored NO_X and reduce it across a catalyst. We expect that these regeneration events would be controlled by the engine computer, and would thus be generally predictable. Even passively regenerating catalytic PM trap designs can have discrete regeneration events that can be predictable.

Discrete regeneration events can be important because it is possible for exhaust emissions to increase during the regeneration process. The regeneration of a NO_X adsorber for instance, could result in increased particulates, NMHC and NO_X due to the rich exhaust gas required to purge and reduce the NO_X. We expect that in most cases, the regeneration events will be sufficiently frequent to be included in the measured emissions. Our feasibility analysis projects very frequent regeneration of the NO_X adsorbers, and continuously regenerating PM traps. Nevertheless, this issue becomes a regulatory concern because it is also conceivable that these emission storage devices could be designed in such a way that a regeneration event would not necessarily occur over the course of a single heavy-duty FTP cycle, and thus be unmeasured by the current test procedure. In addition, desulfation of NO_X adsorbers is clearly not likely to occur frequently enough to reliably be caught in the FTP. Since these regeneration events could produce increased emissions during the regeneration process, it will be important to make sure that regeneration is captured or accounted for as part of the certification testing.

In order to ensure control of emissions during regeneration (including desulfation), we will require manufacturers to determine and use a mathematical adjustment of measured emissions to account for increased emissions during infrequent regeneration events that do not occur during the testing. Conversely, we will also require manufacturers to provide us with a consistent reverse adjustment factor for tests in which the regeneration does occur. For example, if a system requires a desulfation after every 20 FTP transient cycles, and PM emissions increase by 0.01 g/bhp-hr during an FTP transient cycle with a desulfation, we

[200] It should be noted that the existing regulations already contain provisions that would discount diesel NO_X+NMHC credits in some cases when they are banked or traded. The reason for this discount is an interest in encouraging engine designs that are significantly cleaner than the 2.4 g/bhp-hr standard while that standard is in effect. There are also similar provisions for gasoline engines and vehicles. While the new regulations do not change these existing provisions, they do account for the previous discount by capping the total discount at 20 percent.

[201] See preceding footnote.

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will require measured emissions to be adjusted upward by 0.0005 g/bhp-hr (0.01 g/bhp-hr divided by 20 cycles) for all tests in which that regeneration does not occur. The equivalent reverse adjustment (downward) for tests in which the regeneration does occur would be 0.0095 g/bhp-hr (0.01 g/bhp-hr multiplied by 19/20). The reason that the adjustment downward would be so much larger than the adjustment upward is that it is correcting for a significant emission increase over a single emission test, while the adjustment downward would be correcting for that same emission increase over the other 19 tests. No adjustment will be made for events that are so frequent that they always occur during FTP testing. In designs for which these activities are not commanded at regular intervals, such as those based on changes in backpressure or NO_X levels, the manufacturer would be required to determine an average frequency of the regeneration (during repeat FTP transient tests). In all cases, manufacturers would need to provide information to allow testers to know when an infrequent regeneration has occurred during the test, such as by identifying the controller command signal for this event. If this information is not available, manufacturers would be required to meet the standards during all tests, without regard to whether a regeneration occurs.

E. Improvements to the Test Procedures

In response to manufacturer comments, we are finalizing changes to the test procedures to improve the precision of emission measurements. The changes fully address the manufacturers concerns about the potential effect of measurement precision on the feasibility of the standards. It is important to note that these changes are not intended to make measurements higher or lower, but only to improve the repeatability of the measurements. Based on our experience with these modified test procedures, and our discussions with manufacturers about their experiences, we are confident that these changes will not affect the stringency of the standards. These changes are summarized briefly here. A more complete description can be found in a memorandum to the docket.[202]

Most of the changes being finalized are in three general areas. Many of the changes are to the PM sampling procedure. These include changes to the type of PM filters that are used, and improvements in how PM filters are weighed before and after emission measurements, including requirements for more precise microbalances. Another area includes changes to the dilution air specifications to allow for lower dilution ratios. The final area of change is the NO_X calibration procedure. The new calibration procedures will result in more precise continuous measurement of very low concentrations of NO_X.

Other changes are being made to the regulations to allow for other measurement options. In some cases, manufacturers will be allowed to use their current procedures, even though EPA will adopt the changes for our own testing. The reason for this is that some of these changes may not be convenient or cost-effective in the short term, and manufacturers may be willing to live with some slightly higher measurement variability in order to lower testing costs. We believe that manufacturers should be able to individually optimize their test facilities in this manner. However, it is important for manufacturers to understand that we will conduct our confirmatory testing in the accurate and precise manner specified in these regulations.

We are including a new regulatory provision that specifies the steps that someone needs to go through to demonstrate that their own alternate measurement procedure is as good as or better than the procedure specified by our regulations. This provision is found in 40 CFR § 86.1306–07. It is also worth noting that, although we requested comment on changes to the NO_X humidity correction factors used for FTP testing, we did not receive any such comments. Thus we will continue to use the existing NO_X humidity correction factors for FTP testing.

F. Certification Fuel

It is well established that measured emissions are affected by the properties of the fuel used during the test. For this reason, we have historically specified allowable ranges for test fuel properties such as cetane and sulfur content. These specifications are intended to represent most typical fuels that are commercially available in use. Because today's action is lowering the upper limit for sulfur content in the field, we are also establishing a new range of allowable sulfur content for testing that is 7 to 15 ppm (by weight). We believe that this range best represents the fuel that diesel vehicles will potentially see in use. Beginning in the 2007 model year, these specifications will apply to emission testing conducted for Certification and Selective Enforcement Audits, as well as any other laboratory engine testing for compliance purposes. Because the same in-use fuel is used for light- and heavy-duty highway diesel vehicles, we are also changing the specifications for light-duty diesel vehicle testing.

It is important to note that while these specifications include the maximum sulfur level allowed for in-use fuel, we believe that it is generally appropriate to test using the most typical fuels. We expect that refineries will typically produce diesel fuel with about 7 ppm sulfur, and that the fuel could have slightly higher sulfur levels after distribution. Thus, we expect that we would use fuel having a sulfur content between 7 and 10 ppm sulfur for our emission testing. Should we determine that the typical in-use fuel has significantly more sulfur than this, we would adjust this target upward.

We are including a regulatory change to the heavy-duty gasoline test fuel specifications to make them the same as the recently established Tier 2 fuel specifications for light-duty vehicles. We are also extending to heavy-duty engines and vehicles the Tier 2 allowance for manufacturers to use California test gasoline for certification. As is the case with Tier 2, this allowance does not affect our authority to conduct our own testing using federal fuel. Also consistent with our approach under Tier 2, we will consider requests, prior to manufacturer or EPA in-use testing, to permit preconditioning procedures designed solely to remove the effects of high sulfur gasoline on vehicles produced through the 2007 model year.

We are also allowing as an option the use of the new diesel test fuel beginning in the 2004 model year for vehicles employing sulfur-sensitive technology that are certifying to the Tier 2 standards. This allowance to use the new fuel in model years 2004–2006 will only be available for vehicles for which the manufacturer recommends to the owner that the vehicle be operated on fuel with 15 ppm sulfur or less, where available. Any testing that we perform on these vehicles would also use fuel meeting this lower sulfur specification. This optional certification fuel provision is targeted at encouraging the introduction of low-emission light-duty diesel technologies under the new Tier 2 standards that will be taking effect at that time. The provision accounts for the fact that these vehicles will use the lower sulfur fuel during most, perhaps all, of their operating life, given the clear manufacturer recommendation for use of low-sulfur fuel in these vehicles, combined with prospects for early availability of this fuel under the

[202] Memorandum from Matthew Spears to Docket A–99–06, dated December 6, 2000.

incentive provisions discussed in Section IV, and the assured availability of this fuel by mid-2006. Furthermore, we will allow manufacturers choosing to exercise this option in certifying vehicles for sale in both California and the other 49 states to use a fuel that, on a specification by specification basis, meets the requirements of either the federal or the California fuel specifications. This option is appropriate for light-duty vehicles and trucks since they would otherwise face a very complicated transition period, in which they would need to retest and potentially recalibrate vehicles for as many as four different test fuels during a three-year period.

G. Misfueling Concerns for Light- and Heavy-Duty Diesel Vehicles

As explained in Section III, the emissions standards contained in these regulations will make it necessary for manufacturers to employ exhaust emission control devices that require low-sulfur fuel to ensure proper operation. This action therefore restricts the sulfur content of highway diesel fuel sold in the U.S. There are, however, some situations in which vehicles requiring low-sulfur fuel may be accidentally or purposely misfueled with higher-sulfur fuel. Vehicles operated within the continental U.S. may cross into Canada and Mexico, countries that may not adopt the same low sulfur requirements on the same schedule. High-sulfur nonroad fuel may illegally be used by some operators to fuel highway vehicles. Any of these misfueling events could seriously degrade the emission performance of sulfur-sensitive exhaust emission control devices, or perhaps destroy their functionality altogether.

There are, however, some factors that help to mitigate concerns about misfueling. Most operators are very conscious of the need to ensure proper fueling and maintenance of their vehicles. The fear of large repair and downtime costs may often outweigh the temptation to save money through misfueling. The likelihood of misfueling in Canada and Mexico is lessened by current cross-border shipment practices and prospects for eventual harmonization of standards. Canada has recently expressed its intent to harmonize its fuel regulations with U.S. fuels standards.[203] This would offer vehicle owners the option of refueling with low-sulfur fuel there. Even if Canada were to lag behind the U.S. in mandating low-sulfur fuels, these fuels would likely become available along major through routes to serve the needs of U.S. commercial traffic that have the need to purchase it. In addition, there is less potential for U.S. commercial vehicles needing low-sulfur fuel to refuel in Canada because Canadian fuel is currently more costly than U.S. fuel. As a result, most vehicle owners will prefer to purchase fuel in the U.S., prior to entering Canada, whenever possible. This is facilitated by large tractor-trailer trucks that can have long driving ranges—up to 2,000 miles per tankful or so—and the fact that most of the Canadian population lives within 100 miles of the United States/Canada border.

In Mexico, the entrance of trucks beyond the border commercial zone has been prohibited since before the conclusion of the North American Free Trade Agreement in 1994. This prohibition applies in the U.S. as well, as entrance of trucks into the U.S. beyond the border commerce zone is also not allowed. Since these prohibitions are contrary to the intent of the Free Trade Agreement, a timetable was established to eliminate them.[204] However, these prohibitions remain in force at this time.

The NAFTA negotiations included creation of a "corridor" where commercial truck travel occurs, and where Mexico is obligated to provide "low-sulfur" fuel. At the time of the NAFTA negotiations, "low-sulfur" fuel was considered 500 ppm, which was the level needed to address the needs of engines meeting the 1994 emission standards. The travel prohibition currently in place may be lifted at some point. At that time, the issue of assuring, for U.S. vehicles, the availability of fuel with a sulfur level needed by the new technology may need to be addressed.

Even considering these mitigating factors, we believe it is reasonable to adopt additional measures with very minor costs to manufacturers, fuel distributors, and consumers. First, we are requiring that highway diesel fuel pumps and co-located nonroad diesel fuel pumps be prominently labeled, as described in Section VII.

We are also adopting a requirement that heavy-duty vehicle manufacturers notify each purchaser of a model year 2007 or later diesel-fueled vehicle that the vehicle must be fueled only with the low-sulfur diesel fuel meeting the regulations being adopted in this FRM. We believe this requirement is necessary to alert vehicle owners to avoid higher sulfur fuel in the U.S. and to seek out low-sulfur fuel when operating in areas such as Canada and Mexico where it may not be widely available. We are also requiring that model year 2007 and later heavy-duty diesel vehicles must be equipped by the manufacturer with labels on the dashboard and near the refueling inlet that say: "Use Low Sulfur Diesel Fuel Only" or "Low Sulfur Diesel Fuel Only". For non-integrated manufacturers, the engine manufacturer will be required to provide such a label to the vehicle manufacturer, which the vehicle manufacturer will be required to install. Optionally, if a vehicle manufacturer chooses to install its own label, the engine manufacturer will not be required to provide the label.

We believe that these measures will help vehicle owners find and use the correct fuel and will be sufficient to address misfueling concerns. Thus, more costly provisions, such as vehicles fuel inlet restrictors, will not be necessary.

We are also requiring that the labeling and purchaser notification requirements described above for heavy-duty vehicles also be applied to the light-duty diesel vehicles certified to the final Tier 2 standards using certification test fuel with 15 ppm or less sulfur. These vehicles are expected to also need the low-sulfur fuel and be equally susceptible to misfueling damage.

H. In-Use Compliance Levels During the Transition Years to New Technologies

The Phase 2 standards will be challenging for diesel and gasoline engine manufacturers to achieve, and will require manufacturers to develop new technologies for their engines. Not only will manufacturers be responsible for ensuring that these technologies will allow engines to meet the standards at the time of certification, they will also have to ensure that these technologies continue to be highly effective in a wide range of in-use environments so that their engines would comply in-use when tested by EPA. However, in the early years of a program that introduces new technology, there are risks of in-use compliance problems that may not appear in the certification process or during developmental testing. Thus, we believe that it is appropriate to adjust the compliance levels for assessing in-use compliance for low emission engines (i.e., diesel engines equipped with the new exhaust emission control devices expected for Phase 2 diesel engines, and gasoline engines

[203] "Process Begins to Develop Long Term Agenda to Reduce Air Pollution from Vehicles and Fuels", Environment Canada press release, May 26, 2000.

[204] See NAFTA, Volume II, Annex I, Reservations for Existing Measures and Liberalization Commitments, Pages I–M–69 and 70, and Pages I–U–19 and 20.

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employing Tier 2/Phase 2 level technology). This will provide assurance to the manufacturers that they will not face recall if they exceed standards by a small amount during this transition to clean technologies. This approach is very similar to that taken in the Tier 2 final rule, which involves a similar introduction of new technologies (65 FR 6796, February 10, 2000).

Table VI.H–1 shows the in-use adjustments that we will apply to diesel and gasoline engines. These adjustments will be added to the appropriate FELs (or for engines certified to the standards without the use of credits, to the standards themselves) in determining the in-use compliance level for a given in-use mileage. For example, a light HD diesel engine with a useful life of 110,000 miles and a NO_X FEL of 0.20 g/bhp-hr would have an in-use compliance level of 0.30 g/bhp-hr (0.20 + 0.10) throughout its useful life. A heavy HD diesel engine, having a useful life of 435,000 miles and a NO_X FEL of 0.20 g/bhp would have an in-use compliance level of 0.30 g/bhp-hr through 110,000 miles, 0.35 g/bhp-hr from there through 185,000 miles, and 0.40 g/bhp-hr through the remainder of its useful life. The adjustment levels were chosen to be roughly equivalent to the temporary in-use standard adjustments adopted for low-emitting vehicles in the Tier 2 program, accounting for the higher mileage requirements reflected in the useful lives of the larger heavy-duty engines. Note too in the table footnotes the limiting of these adjustments to engine certified to levels below certain threshold levels. This is similar to the approach taken in the Tier 2 rule which applied the in-use standards only to vehicles in certain low-emitting bins.

TABLE VI.H–1.—ADD-ON LEVELS USED IN DETERMINING IN-USE STANDARDS FOR DIESEL & GASOLINE ENGINES

Engine mileage (miles)	Diesel[a] and gasoline[b] NO_X Add-on level to FEL (g/bhp-hr)	Diesel PM Add-on level to FEL (g/bhp-hr)	Gasoline[c] NMHC Add-on level to FEL (g/bhp-hr)
<110,000	0.10	0.01	0.10
110,000 to 185,000	0.15	0.01	[d] N/A
185,000 to 435,000	0.20	0.01	[d] N/A

[a] Applicable to those diesel engines with FELs at or below 1.3 g/bhp-hr NO_X through 2011.
[b] Applicable to those gasoline engines with NO_X FELs at or below 0.5 g/bhp-hr through 2011.
[c] Applicable to those gasoline engines with NMHC FELs at or below 0.3 g/bhp-hr through 2011.
[d] Note that the useful life for gasoline engines is 110,000 miles, so these add-on levels have significance only to that mileage for gasoline engines.

Similar examples apply for diesel engine PM, with the exception that the PM in-use add-on level is a constant 0.01 regardless of mileage. Likewise for gasoline NMHC where the add-on level is a constant 0.10 g/bhp-hr through the 110,000 mile useful life.

These same in-use add-on levels will be applied to the certification SET and NTE levels after applying the SET and NTE multipliers for the purpose of determining the corresponding in-use standards. In other words, for heavy HD diesel engine with a NO_X FEL of 0.20 g/bhp-hr, the in-use SET standard would be 0.30, 0.35, and 0.40 g/bhp-hr in each respective mileage range (remember that the SET multiplier is 1.0 × the FTP standard or FEL). The in-use NTE standard, with a multiplier of 1.5 × the FTP standard or FEL, would be 0.40, 0.45, and 0.50 g/bhp-hr in each of the respective mileage ranges (0.20 × 1.5 = 0.30; + 0.1 = 0.40; + 0.15 = 0.45; + 0.20 = 0.50).

Note that these in-use add-on levels apply only to engines certified through the 2011 model year and having FELs below the specified levels. These levels are very low and represent levels we believe will require significant effort by manufacturers to reach. The in-use add-ons are available through 2011 because some diesel engine models may not incorporate the emission control technology until 2010 as a result of the final phase-in schedule. Engine models incorporating these technologies for the first time in 2010 may account for as many as 50 percent of all diesel engines sold in that year. We believe these engine models should be provided the in-use adjustment for at least the first two years of their market introduction. In the case of gasoline engines, the phase-in ends in the 2009 model year. However, we have decided to allow the in-use adjustments through model year 2011, consistent with the diesel provision.

For HD complete gasoline vehicles, and any complete diesel vehicles choosing the chassis certification option, we will have a flat in-use adjustment of 0.1 g/mile NO_X, 0.100 g/mile NMHC (gasoline vehicles only), and 0.01 PM for all weight classes. These in-use adjustments will apply only to those vehicles certified with FELs at or below the applicable Phase 2 standards. Further, they will apply for vehicles certified through 2010 so that those vehicle models newly certified to the Phase 2 standards in 2009 are given two years of certification experience prior to elimination of the in-use adjustments. Table VI.H–2 shows the adjustments that will apply to HD chassis certified vehicles.

TABLE VI.H–2.—IN-USE ADJUSTMENTS FOR CHASSIS CERTIFIED VEHICLES

Weight range (GVWR)	Durability period (miles)	NO_X[a] (g/mi)	NMHC[a] (g/mi)	PM (g/mi)
8,500 to 10,000 lbs.	120,000	0.1	0.100	0.01
10,000 to 14,000 lbs.	120,000	0.1	0.100	0.01

[a] Applicable to those vehicles with NO_X and/or NMHC FELs at or below the appropriate Phase 2 standards through 2010.

During the certification demonstration, manufacturers will still be required to demonstrate compliance with the unadjusted Phase 2 certification standards using deteriorated emission rates. Therefore, the manufacturer will not be able to use these in-use standards as the design targets for the engine or vehicle. They will need to project that most engines would meet the standards in-use without adjustment. The in-use adjustments will merely provide some assurance that they would not be forced to recall engines or vehicles because of some small miscalculation of the expected deterioration rates. Furthermore, given that a new diesel fuel will be in place and it will be sold alongside higher sulfur diesel fuel being marketed to the existing fleet, there is a small likelihood of accidental misfueling during the phase-in years as users become familiar with the importance of using the lower sulfur fuel. As discussed in detail in sections III.E and III.F, sulfur has adverse impacts on exhaust emission control devices.

VII. Highway Diesel Fuel Program: Compliance, Enforcement and Downstream Provisions

For the highway diesel fuel sulfur program that we are adopting today to be successful in achieving its large emission reduction goals, it is vital for all parties that are affected by the program to thoroughly understand what is expected of them to comply, what compliance options may apply to them, and how their compliance will be assessed and enforced. If you believe that you are or may be subject to the program, the most important information is found in the regulatory language following this preamble. There, readers will find the detailed legal requirements of the program for each party and how we will assess and enforce compliance with the program requirements.

A key purpose of this preamble is to supplement the regulatory language by providing a context for and an explanation of the requirements of the program. Section IV above discusses in some detail most of the requirements under the highway diesel fuel sulfur program adopted today. In addition, this section (Section VII) builds on the Section IV discussions by addressing specific compliance and enforcement provisions we have adopted in today's rule to ensure that highway diesel fuel standards are met at all points in the distribution system—from the refiner or importer that introduces the fuel into the distribution system, through all the parties that may distribute the fuel, to the retailers and other parties that provide the fuel to its ultimate user. This section also explains certain requirements of the program in more detail.

After touching on a few general aspects of the highway diesel fuel program, this section discusses the compliance and enforcement provisions that apply to refiners and importers and those that apply to the downstream parties that handle diesel fuel. This section also discusses diesel fuel sampling and testing for sulfur, reporting and recordkeeping requirements, limited exemptions from the program, and how liability for any noncompliance would be handled.

A. General Provisions

1. Definition of Diesel Fuel Covered by This Program

In this preamble, we refer to the fuel covered by the program adopted today as "highway diesel fuel." For technical and legal consistency with the Clean Air Act and existing fuels regulations, the regulatory language associated with today's rule uses the term "motor vehicle diesel fuel" in order to assure consistency with the language in existing laws and regulations. "Nonroad diesel fuel" refers to diesel fuel intended for use in nonroad vehicles or equipment, and is not covered by the highway diesel fuel sulfur requirements of the program. However, any fuel that is available for highway vehicles and engines, whether or not it is also available for nonroad vehicles and engines or for other purposes, is treated as highway diesel fuel under today's program.

2. Relationship to Highway Diesel Standards

As discussed in Section IV above, today's final rule reduces the sulfur cap standard for highway diesel fuel from 500 ppm to 15 ppm nationally[205] effective in 2006. (Implementation dates are discussed further in Section VII.C.2. below.) The existing standards for cetane and aromatics will remain in effect and are not being changed by today's action (40 CFR § 80.29(a)). The highway diesel fuel sulfur, cetane, and aromatics standards will be enforced through sampling and testing at all points in the distribution system, combined with inspection of fuel delivery records and other commercial documents. The general compliance requirements of this rule are very similar to those in the current diesel fuel rule, except that the sulfur standard is substantially more stringent (see 40 CFR 80.29 and 80.30). Prior to the implementation dates for today's rule, all the requirements and prohibitions of the current diesel fuel rule will remain in effect, with limited modifications concerning sulfur sampling methods.

B. What Are the Requirements for Refiners and Importers?

1. General Requirements

As discussed earlier in this preamble, the sulfur sensitivity of emission controls that will be used on model year 2007 and later motor vehicles requires that the sulfur content of highway diesel fuel dispensed into 2007 and later heavy-duty vehicles not exceed 15 ppm. To ensure that highway diesel fuel meets this standard as it leaves the refinery or import facility, today's final rule adopts the proposed approach that if the sulfur content of highway diesel fuel at a refinery or import facility exceeds 15 ppm by any amount, the fuel is in violation of the sulfur standard. The determination of compliance with the sulfur standard for highway diesel fuel at the refinery level is not subject to a test tolerance.[206]

Consistent with the proposal, today's final rule does not require that refiners or importers engage in mandatory sampling and testing of every batch of highway diesel fuel they produce or import.[207] This is because the highway diesel fuel sulfur standard is a national cap standard and compliance can be monitored at any point in the distribution system by taking samples of fuel for testing. However, under the presumptive liability scheme, any refiner producing noncomplying product would face liability for fuel in violation of the standard, regardless where the violation is discovered. (See Sections VII.G. and VII.H. for a discussion of liability and penalties.) Consequently, we expect that refiners and importers will voluntarily test every batch of highway diesel fuel produced or imported for their own purposes, including the need to demonstrate compliance with pipeline specifications.

Today's program requires all refiners that on January 1, 2000 produced—or by June 1, 2006 expect to produce—highway diesel fuel for U.S. sale to

[205] Except as noted elsewhere in the preamble and final rule, today's rule applies to all states, including the State of California. See Section IV.F for unique implementation provisions for Alaska and exemptions for diesel fuel in certain U.S. territories.

[206] However, test variability is taken into account in determination of compliance for diesel fuel at locations downstream of the refinery or import facility. See Section VII.C.1.

[207] However, any refiner producing highway diesel fuel complying with the 500 ppm standard for use in pre-model year 2007 motor vehicles, under any of the several refiner flexibility options, would have to maintain records designating each batch as complying with the 15 ppm standard or the 500 ppm standard.

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register with EPA. Similarly, all importers that on January 1, 2000 imported—or by June 1, 2006 expect to import—highway diesel fuel into the U.S. also need to register with EPA. This registration process will provide an essentially complete and up-to-date picture of the universe of highway diesel suppliers that exist at the beginning of this program. Refiners and importer must register by December 31, 2001. See Section VII.E. below for more details about registration requirements.

2. Refiner and Importer Temporary Compliance Option Provisions and the Credit Trading Program

As described in Section IV.A.2 above, today's final rule adopts a program that allows refiners and importers to transition in the production and importation of 15 ppm sulfur content diesel fuel. The temporary compliance option is available to all refiners and importers and includes a credit averaging, banking, and trading program. This temporary compliance option allows a refiner or importer to designate and sell a certain percentage of its highway diesel fuel as fuel subject to a 500 ppm sulfur standard, for use in pre-2007 model year heavy-duty vehicles.

Section IV.A.2 above describes most of the compliance requirements associated with the temporary compliance option. The paragraphs below supplement the earlier information.

a. Early Credits Program

As discussed in Section IV.A.2.a, today's regulation allows refiners and importers to generate early credits (prior to June 1, 2006) under limited circumstances. Most of the compliance requirements associated with the early credits program are described in that section. The following paragraphs add certain supplemental information.

The early credits program has two sets of provisions: (1) credits generated after May 31, 2005 but before June 1, 2006, and (2) credits generated after June 1, 2001 but before May 31, 2005. For a refiner or importer to generate early credits after May 31, 2005, it must demonstrate that the 15 ppm fuel produced early was segregated in the distribution system and not commingled with current 500 ppm sulfur fuel. Only that volume the refiner could verify was actually sold as 15 ppm fuel at retail or to centrally-fueled fleets would be eligible for early credits. Prior to generating credits, the refiner or importer must submit a notification to EPA and demonstrate how it will ensure segregation of the fuel from other highway diesel fuel and that the fuel will be sold as 15 ppm fuel (*e.g.*, through voluntary pump labeling and/or through information provided in PTDs).

The program also specifies that early credits can be generated prior to June 1, 2005. In this case, however, the refiner or importer must demonstrate that the 15 ppm fuel will be used in vehicles certified to meet the 2007 particulate matter standard being adopted today for heavy-duty engines (0.01 g/bhp-hr) or in vehicles with retrofit technologies that achieve emission levels equivalent to the 2007 NO_X or PM standard verified as part of a retrofit program administered by EPA or a state. (See Section VIII for further discussion of the credit program for heavy-duty engines.) To meet this condition, the refiner or importer must notify EPA, and in its notification it must demonstrate that any early credits that it claims are only for the volume of 15 ppm fuel that is dispensed into vehicles meeting the emission standards as described above (*e.g.*, into designated fleet vehicles).

All early credits generated, banked, transferred, obtained or used must be identified as early credits in records and in reports. The refiner's annual pre-compliance reports must provide the volume of early credit fuel produced, credits generated, credits transferred, and continued demonstration that the early credit fuel is sold appropriately (*i.e.*, as 15 ppm fuel after May 31, 2005, or into vehicles meeting the 2007 standards up to May 31, 2005).

b. Credit Use in a Credit Deficit Situation

Today's rule allows a refiner or importer to have a credit deficit in any given year (as long as the deficit does not exceed five percent of its annual highway diesel fuel production) so long as the refinery or importer makes up for that credit deficit the next year. In other words, the year following the deficit the refiner or importer must have enough credits (or actual production volume of 15 ppm fuel) to cover the previous year's deficit and to cover the current year's compliance. A refinery or importer (by PADD) must use credits to cover its own compliance before it can transfer credits to another refinery or importer, and although a refinery is allowed to be in deficit for a given year, it cannot lawfully transfer credits in the deficit year.

c. Resolving Issues of Invalid Credits

We recognize that there is potential for credits to be generated by one party and subsequently purchased and used in good faith by another party, yet the credits are later found to have been calculated or created improperly, or otherwise found to be invalid. As with the RFG rule and the Tier 2/Gasoline Sulfur rule, invalid credits purchased in good faith cannot be legally used. To allow such use would not be consistent with the environmental goals of the regulation. Further, both the seller and purchaser of invalid credits would have to adjust their credit calculations to reflect the proper credits and either party (or both) could be deemed in violation if the adjusted calculations demonstrated noncompliance.

Nevertheless, our strong preference is to hold the credit seller liable for the violation, rather than the credit purchaser. As a general matter we would expect to enforce a shortfall in credit compliance calculations against the credit seller, and we would expect to enforce a compliance shortfall (caused by the good faith purchase of invalid credits) against a good faith purchaser only in cases where we are unable to recover sufficient valid credits from the seller to cover the shortfall. Moreover, in settlement of such cases we would strongly encourage the seller to purchase credits to cover the good faith purchaser's credit shortfall. EPA will consider the covering of a credit deficit through the purchase of valid credits a very important factor in mitigation of any case against a good faith purchaser, whether the purchase of valid credits is made by the seller or by the purchaser.

d. Compliance Provisions

Today's rule includes compliance provisions under the temporary compliance option to allow the determination of the volumes of each of the two grades of highway diesel fuel produced or imported by each participating refinery or importer. For parties participating in the credit program, the rule includes provisions to ensure compliance with the credit generation, banking and trading provisions. The requirements include the designation of each batch of highway diesel fuel as meeting either the 500 ppm sulfur standard or the 15 ppm highway diesel sulfur standard; maintenance of records concerning the volumes of each grade of highway diesel fuel produced (and for foreign refiners and importers, volumes by PADD of import); and maintenance of records concerning the generation, use, transfer and purchase of credits, if applicable (by PADD in the case of foreign refiners and importers). Beginning in 2007, annual compliance reports demonstrating compliance with the applicable provisions are required. These recordkeeping and reporting requirements are discussed more fully in Section VII.E below.

The rule also includes enforcement and compliance provisions to assure that highway diesel fuel subject to the 15 ppm sulfur standard is not caused to exceed the standard by being contaminated with highway diesel fuel subject to the 500 ppm sulfur standard (or other high sulfur products such as nonroad diesel fuel), and to assure that 500 ppm diesel fuel is not introduced into model year 2007 and later motor vehicles. Participating refiners and importers are required to provide identifying information on product transfer documents for highway diesel fuel subject to the 500 ppm standard to help prevent contamination of 15 ppm product. (As discussed more fully below, transfers of 15 ppm highway diesel fuel must also be accompanied by product transfer documents identifying such fuel.)

e. Additional Provisions for Importers of Diesel Fuel and for Foreign Refiners Subject to the Temporary Compliance Option and Hardship Provisions

Since today's final rule includes several compliance options that can be used by diesel fuel importers and foreign refiners, we are also including specific compliance and enforcement provisions to ensure compliance for imported highway diesel fuel. These special foreign refiner provisions are similar to those under the conventional gasoline regulations and the gasoline sulfur regulations (see 40 CFR 80.94 and 80.410).

Under today's rule, standards for highway diesel fuel produced by foreign refineries must be met by the importer, unless the foreign refiner has been approved to produce highway diesel fuel under the temporary compliance option or hardship provisions of today's rule. If the foreign refiner is so approved, the volume requirements are to be met by the foreign refinery and the foreign refinery would be the entity generating, using, banking or trading credits for the highway diesel fuel produced and imported into the U.S.

Any foreign refiner that applies for and obtains approval to produce highway diesel fuel subject to the temporary compliance option or hardship provisions will be subject to the same requirements as domestic refiners operating under the same provisions. Additionally, foreign refiners are subject to provisions similar to the provisions at 40 CFR 80.94 and 80.410, which include:

—Segregating highway diesel fuel produced at the foreign refinery until it reaches the U.S. and separately tracking volumes imported into each PADD;
—Controls on product designation;
—Load port and port of entry testing;
—Attest requirements; and
—Requirements regarding bonds and sovereign immunity.

These provisions aid the Agency in tracking highway diesel fuel from the foreign refinery to its point of import into this country. We believe these provisions are necessary and sufficient to ensure that foreign refiners' compliance can be monitored and that the requirements of today's rule can be enforced against foreign refiners. (For more discussion of the rationale for these enforcement provisions, see preamble to the final RFG/CG foreign refineries rule (see 62 FR 45533 (August 28, 1997) and the gasoline sulfur rule, 40 CFR 80.410).)

3. Refiner Hardship Provisions

a. General Refiner Hardship Provisions

Section IV.C. above describes two types of hardship provisions for which any refiner may petition. We will consider such petitions in cases of extreme unforseen circumstances and of extreme hardship circumstances. Petitions for extreme unforseen circumstances may be submitted at any time; petitions for extreme hardship circumstances must be submitted to EPA by June 1, 2002. If any relief granted includes allowing the refiner to produce 500 ppm highway diesel fuel (or additional 500 ppm highway diesel fuel beyond that allowed under the temporary compliance option) for use in pre-2007 heavy-duty vehicles and engines, we would apply enforcement provisions at least as stringent as those that apply for the temporary compliance option.

Any application for hardship relief later found to be based on false or inaccurate information will be void ab initio.

b. Small Refiner Hardship Provisions

Section IV.C.1 above describes three small refiner relief provisions. Section IV.C.1.b defines "small refiner," Section IV.C.1.c describes the special provisions that approved small refiners are eligible for, and Section IV.C.1.d describes how a refiner applies for status as a small refiner. Section VII.E below describes the additional information that small refiners need to include in their application for small refiner status, in their pre-compliance reports, and in their annual compliance reports (these requirements vary depending on which small refiner provision they choose). Any application for small refiner status will be void ab initio if approval is based on false or inaccurate information.

For an approved small refiner to use the Diesel/Gasoline Compliance Date Option (described in Section IV.C. above) at one or more refineries, it must fulfill two main conditions: (1) 100 percent of the highway diesel volume it produces during each annual compliance period starting June 1, 2006 must meet the 15 ppm standard, and (2) the actual volume of highway diesel fuel it produces during each annual compliance period through 2010 must be at least 85 percent of its 1998–1999 baseline highway diesel fuel volume (i.e., through the end date of the extended small refiner interim gasoline program). If a refiner at some point did not fulfill one or both of these conditions, it would forfeit the entire three year extension (or any remaining portion of the extension) of its Tier 2/Gasoline Sulfur small refiner standards and would thus need to comply with the 30/80 ppm sulfur standards by January 1, 2008. During the period when the national gasoline sulfur standard would otherwise be in effect for a small refiner (2008–2010), if the refiner fails to meet the two conditions above, it would be subject to the 30/80 gasoline sulfur standard for that year and future years.

However, a small refiner may elect to petition EPA to permanently opt out of this Diesel/Gasoline Compliance Date Option and opt into another small refiner option or into the temporary compliance option, so long as it does so for the full year that the change in program options takes place. Once it makes that election, it must thereafter meet the 30/80 gasoline sulfur standard.

c. Relief for Refiners Supplying Gasoline to the Tier 2 Geographic Phase-In Area (GPA)

As discussed in Section IV.B, refiners or importers supplying gasoline to the Geographic Phase-In Area (GPA) established in the Tier 2/Gasoline Sulfur program may apply for an additional two years to meet interim Tier 2 GPA gasoline sulfur standards (through December 31, 2008). Similar to the criteria for small refiners under the Diesel/Gasoline Compliance Date Option above, a refiner wishing to receive this extension of the Tier 2 GPA standards must meet two main conditions: (1) 100 percent of the highway diesel volume it produces during each annual compliance period starting June 1, 2006 must meet the 15 ppm standard, and (2) the actual volume of highway diesel fuel it produces during each annual compliance period through 2008 must be at least 85 percent

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of its 1998–1999 baseline highway diesel fuel volume (i.e., through the end date of the extended GPA gasoline program). Refiners may not participate both in this option and the temporary compliance option.

To be eligible for this option, a refiner must apply to EPA in writing by December 31, 2001, at the same time that it registers as a highway diesel fuel producer with EPA. As with applications by refiners for "small refiner" status, a refiner's application must submit its average annual highway diesel volume baseline for 1998 and 1999 for each of its refineries it expects to be covered by the GPA provisions under today's program.

If a refiner did not fulfill one or both of the conditions above, it would forfeit the entire two-year extension of the GPA standards, or any remaining extension, and would thus need to comply with the 30/80 ppm sulfur standards by January 1 of the following year.

However, a refiner may elect to petition EPA to permanently opt out of this GPA program and opt into the temporary compliance option, so long as it does so for the full year that the change in program options takes place. Once it makes that election, it must thereafter meet the 30/80 gasoline sulfur standard.

C. What Requirements Apply Downstream of the Refinery or Import Facility?

1. Downstream Enforcement of the Standards

In the NPRM, we proposed an industry-wide 15 ppm cap on sulfur content for highway diesel fuel. In the proposal we stated our belief that refiners would likely have to produce diesel fuel meeting a 7–8 ppm average sulfur content in order to ensure compliance downstream. We received comments to the NPRM indicating that enforcing the 15 ppm sulfur cap at all levels of the distribution system downstream of the refinery or import facility would effectively require refiners to produce diesel fuel having a maximum sulfur content of 7 ppm due to variability in sulfur content test results that may occur between laboratories when testing the same sample of diesel fuel for sulfur content. Commenters stated that at test reproducibility level of +/−4 ppm,[208] refiners would have no assurance of downstream compliance with the 15 ppm cap if they produced any fuel with a sulfur content greater than 7 ppm. Consequently, commenters suggested either that we adopt a less stringent downstream sulfur standard, based on test variability, as was done in the Tier 2/Gasoline Sulfur rule (40 CFR 80.210), or that we state a downstream test tolerance, based on test variability.

After considering the comments, we agree that it is appropriate to recognize test variability in determination of compliance with the sulfur standard downstream of the refinery or import facility. However, we anticipate that the reproducibility of sulfur test methods is likely to improve to two ppm or even less by the time the rule goes into effect. Thus, today's rule provides that for all 15 ppm sulfur highway diesel fuel at locations downstream of the refinery or import facility, sulfur test results can be adjusted by subtracting 2 ppm to account for the expected reproducibility of sulfur test methods. The sole purpose of this downstream compliance provision is to address test variability concerns. With this change, we anticipate that refiners will be able to produce diesel fuel at an average level of approximately 7–8 ppm, as was intended by the proposal, without fear of causing a downstream violation due solely to test variability. As test methods improve in the future, we may reevaluate whether two ppm is the appropriate allowance for purposes of this compliance provision.

This change is not expected to undermine the environmental goals of the regulation since it should not result in diesel fuel exceeding the 15 ppm sulfur standard at any point in the distribution system. All highway diesel fuel subject to the 15 ppm standard is still required to meet the 15 ppm standard at the refinery gate, without allowance for test variability.[209] The purpose of taking testing variability into account in compliance determinations for fuel sampled downstream of the refinery or import facility is merely to ensure that fuel actually meeting the 15 ppm cap is not rejected by pipelines or otherwise treated as noncompliant due to concerns about testing variability. It is not expected to result in any increase in the actual sulfur content of highway diesel fuel above 15 ppm at any point in the distribution system.

2. Other Provisions

a. Implementation Dates

As discussed in Section IV.A, today's rule staggers the implementation dates for highway diesel fuel for use in 2007 and later vehicles to comply with the 15 ppm sulfur standard, based on a facility's position in the distribution system. Refiners and importers must meet the 15 ppm sulfur standard by June 1, 2006. Fuel in the distribution system downstream of the refinery or import facility, including fuel at truck loading terminals,but not including fuel at retail outlets or wholesale purchaser-consumers, must be in compliance by July 15, 2006. Highway diesel fuel at retailers' and wholesale purchaser-consumers' storage tanks must be in compliance by September 1, 2006, and pump labeling requirements (see Section VII.C.2.c below) also must be in place by that date. We believe the dates finalized in today's rule will allow sufficient time for downstream parties to transition tanks from 500 ppm sulfur levels to 15 ppm sulfur levels.

The date by which all highway diesel fuel produced by refiners must meet the 15 ppm sulfur standard is June 1, 2010.[210] The final compliance date for all highway diesel fuel in the distribution system to meet the 15 ppm standard, other than at retail outlets and wholesale purchaser-consumer facilities, is October 1, 2010. The final compliance date for all highway diesel fuel at retail and wholesale purchaser-consumer facilities to meet the 15 ppm sulfur standard is December 1, 2010.

b. Product Segregation and Contamination

Under today's diesel sulfur program, it is imperative that distribution systems segregate highway diesel fuel from high sulfur distillate products such as home heating oil and nonroad diesel fuel. The sulfur content of those products is frequently as high as 3,000 ppm. We are also concerned about potential misfueling at retail outlets and wholesale purchaser-consumer facilities, even if segregation of the different grades of diesel fuel has been maintained in the distribution system. Thus, certain downstream compliance and enforcement provisions of the rule are aimed at both preventing contamination of highway diesel fuels with fuels containing higher levels of sulfur, and preventing misfueling of motor vehicles with high sulfur fuels.

Similarly, it is imperative that all parties in the distribution system avoid contamination of 15 ppm highway diesel fuel with 500 ppm highway diesel fuel. Thus, the final rule has adopted a requirement for product

[208] The NPRM preamble suggested a possible reproducibility level of 4 ppm.

[209] Once motor vehicle diesel fuel is moved from the tank in which it was blended at the refinery (and which the refiner's designation of the fuel as meeting the 15 ppm standard was based), the two ppm adjustment applies.

[210] Under the temporary compliance option, for the period from January 1, 2010 through May 31, 2010, refiners can produce 500 ppm fuel only through the use of credits.

transfer documents accompanying deliveries of motor vehicle diesel fuel diesel fuel to identify the sulfur standard it meets and its allowed use. All parties in the distribution system face liability if highway diesel fuel is contaminated such that it fails to meet the applicable standard.

We are also adopting provisions designed to discourage the downgrading of 15 ppm diesel to 500 ppm diesel in the distribution system during the initial years of the program when the optional compliance provision is in effect. Our concern is that if 15 ppm diesel is routinely downgraded and sold as 500 ppm fuel, this practice could lead to availability problems (*i.e.*, risk of 15 ppm not being widely available across the country). We fully recognize that some amount of 15 ppm downgrading will be necessary where the 15 ppm fuel becomes contaminated in the distribution system (*e.g.*, pipeline interfaces). In fact, one advantage of the temporary compliance option is that if 15 ppm fuel becomes contaminated, it can still be sold as highway fuel (downgraded to 500 ppm fuel), rather than downgrading it to off-highway fuel. However, we also recognize that there is the potential for parties in the distribution system to intentionally mix 15 ppm product with 500 ppm fuel, and still sell the product as 500 ppm fuel. While we don't expect this practice to be widespread, it could occur, especially where there is only a small price differential between the two fuels.

Therefore, we are restricting the volume of 15 ppm fuel that can be downgraded to 500 ppm highway diesel fuel at each point in the distribution system (downstream of the refinery gate) to not more than 20 percent on an annual basis. Each party in the distribution system subject to this provision will be required to meet this requirement separately, based on the amount of 15 ppm fuel it receives and transfers/sells to the next party (or end user, in the case of retailers and wholesale purchaser-consumers) on an annual basis. We believe that this limit will be more than sufficient to allow for some downgrading for any contamination that may occur, while still being restrictive enough to discourage downgrading and commingling of 15 ppm fuel with 500 ppm fuel. These provisions will be in effect through May 31, 2010.

We recognize that, in some parts of the country, highway-grade diesel fuel is commonly sold into off-highway markets, due to limitations in the distribution system for carrying one grade of diesel. We do not want to preclude this practice in the future; thus, we are not preventing 15 ppm diesel from being downgraded to off-highway fuel. The downgrading restriction applies only to 15 ppm downgraded to 500 ppm highway diesel fuel. We do not anticipate increased instances of downgrading to off-highway diesel fuel relative to today, given the increase in the price differential between highway diesel and off-highway diesel fuel that will likely result from this program. Therefore, we do not believe it is necessary to impose a regulatory restriction on downgrading of 15 ppm highway diesel to off-highway diesel.

All parties in the distribution system downstream of the refinery gate are subject to this provision, except for those retailers that offer for sale and wholesale purchaser-consumers that use 15 ppm fuel (either as the only grade of diesel or in addition to 500 ppm diesel). In other words, the only retailers and wholesale purchaser-consumers that are subject to this requirement are those that offer for sale or use only 500 ppm diesel (but not 15 ppm diesel).

Since all parties in the distribution system are required by other provisions in this final rule to maintain product transfer documents, which will indicate whether the diesel fuel meets the 15 ppm or 500 ppm standard as well as the volume of such fuel, we are not requiring new recordkeeping requirements beyond these to demonstrate compliance with these provisions. The parties will merely have to ensure that at the end of each year during the period the temporary compliance option is in effect that they comply with the 20 percent requirement based on the incoming and outgoing PTD records described in Section VII.E.5 below.

c. Diesel Fuel Pump Labeling

As discussed in Section IV.A.2 above and in the Chapter IV of the RIA, we believe that clear information about the proper fuel to use and the consequences of misfueling will minimize the potential for misfueling of new-technology vehicles. Under our final fuel program approximately 75% of the fuel in each PADD will meet the 15 ppm standard during the first few years. We believe that this will ensure that the fuel will be widely available in every part of the United States. Moreover, within four years all highway diesel fuel will meet this standard. Under these circumstances we believe the potential for misfueling will be limited. Nevertheless, we did receive considerable comment expressing concerns over the potential for misfueling.

In addition to the required labels on diesel fuel pumps described below, we believe that the use of unique nozzles, color-coded scuffguards, or dyes to distinguish the grades of diesel fuel may be useful in preventing accidental misfueling. While we are not finalizing any requirements today, we will plan to work with the vehicle manufacturers and representatives of the fuel industry and other interested stakeholders over the next several years to develop workable solutions that are consistent with current industry practices and other regulatory requirements.

For any multiple-fuel program like the temporary compliance option adopted today, clearly labeling diesel fuel pumps is vital for end users to distinguish between the two grades of fuel. We received comments on the NPRM that concurred with our assessment in the proposal that pump labels, in conjunction with vehicle labels, would also have the effect of helping to help prevent misfueling of motor vehicles with high sulfur diesel fuel. Section VI.G. above describes the labels that manufactures will place on vehicle and information that will be provided to vehicle owners. Today's rule also adopts pump labeling requirements for retailers and wholesale purchaser-consumers similar to those we proposed, but with modifications to account for the availability of diesel fuel subject to the 500 ppm sulfur standard for use in pre-2007 motor vehicles. The text of the labels appears below; the specific requirements for label size and appearance are found in the regulatory language for this rule.

For pumps dispensing 15 ppm diesel fuel, the label will read as follows:

LOW-SULFUR DIESEL FUEL

Recommended for use in all diesel highway vehicles.

Required for model year 2007 and later highway vehicles.

For pumps dispensing 500 ppm diesel fuel the label will reads as follows:

HIGH-SULFUR DIESEL FUEL—WARNING

May damage model year 2007 and later highway vehicles.

Federal Law *prohibits* use in these vehicles.

Finally, for pumps dispensing nonroad diesel fuel that are located at the same retail outlet as highway diesel fuel pumps, the label will read as follows:

NONROAD DIESEL FUEL—WARNING

May damage highway vehicles.

Federal Law *prohibits* use in any highway vehicle.

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3. Use of Used Motor Oil in New Diesel Vehicles

We understand that used motor oil is sometimes disposed of by blending it with diesel fuel for use as fuel in diesel vehicles. Such practices range from blending used motor oil directly into the vehicle fuel tank, to blending it into the fuel storage tanks, to blending small amounts of motor oil from the vehicle crank case into the fuel system as the vehicle is being operated. To the extent such practices could cause vehicles to exceed their emissions standards, the person blending the oil, or causing or permitting such blending, could be considered to be rendering emission controls inoperative in violation of Section 203 of the CAA and potentially liable for a civil penalty (Section 203(a)(3) of the Act, 42 U.S.C. 7522(a)(3)).

Since current formulations of motor oil contain very high levels of sulfur, the addition of used oil to highway diesel fuel could substantially impair the sulfur-sensitive emissions control equipment expected to be used by engine manufacturers to meet the emissions standards in today's rule. Depending on how the oil is blended, it could increase the sulfur content of the fuel burned in the vehicle by as much as 200 ppm. As a result, we believe blending used oil into highway diesel fuel could render inoperative the emission control technology on the vehicle and potentially cause driveability problems.

Therefore, today's rule prohibits any person from introducing or causing or allowing the introduction of used motor oil, or diesel fuel containing used motor oil, into the fuel delivery systems of vehicles manufactured in model year 2007 and later. The only exception to this is where the engine is explicitly certified to the emission standard with oil added and the oil is added in a manner consistent with the certification. Please refer to the Response to Comments document for a discussion of concerns raised by commenters on this issue.

4. Use of Kerosene in Diesel Fuel

As we discussed in the NPRM, kerosene is commonly added to highway diesel fuel to reduce fuel viscosity in cold weather. Today's rule will not limit this practice. Consistent with the proposal, under today's rule, kerosene that is used, intended for use, or made available for use as or for blending with 15 ppm sulfur highway diesel fuel is itself required to be classified as "motor vehicle diesel fuel" and meet the 15 ppm standard, as well as the standards for aromatics and cetane (see Section 80.2(y) of the regulatory language following this preamble). This classification for highway fuel use may be made by the fuel's refiner or may be made by a downstream party at the point when that party chooses to use the kerosene in its possession for highway fuel use.

To help ensure that only distillates that comply with the 15 ppm highway diesel fuel standard are blended into 15 ppm highway diesel fuel, today's rule has adopted the proposed requirement that kerosene meeting the 15 ppm standard and distributed by the transferring party for use in motor vehicles, must be accompanied by PTDs accurately stating that the product meets the 15 ppm sulfur standard (See Section VII.E.5. below).

As a general matter, any party who blends kerosene, or any blendstock, into motor vehicle diesel fuel, or who produces motor vehicle diesel fuel by mixing blendstocks, is a refiner and would be subject the requirements and prohibitions applicable to refiners under the rule. However, under today's rule, in deference to the longstanding and widespread practice of blending kerosene into diesel fuel at downstream locations, downstream parties who only blend kerosene into motor vehicle diesel fuel will not be subject to the requirements applicable to refiners, provided that they do not alter the fuel in any other way. Further, downstream parties choosing to blend kerosene into 15 ppm highway diesel fuel will be entitled to the 2 ppm adjustment factor for both the kerosene and the diesel fuel into which it is blended at downstream locations, provided that the kerosene had been transferred to the party with a PTD indicating compliance with that standard. Sulfur test results from downstream locations of parties who do not have such a PTD for their kerosene will not be subject to this adjustment factor, either for the kerosene itself, or for the highway diesel fuel into which it is blended.

In order to ensure the continued compliance of 15 ppm fuel with the 15 ppm standard, downstream parties choosing to blend kerosene into 15 ppm highway diesel fuel are required by the final rule to either have a PTD for that kerosene indicating compliance with the 15 ppm standard, or to have test results for the kerosene establishing such compliance.

Any party who causes the sulfur level of 15 ppm highway diesel fuel to exceed 15 ppm by blending kerosene into highway diesel fuel, or by using high sulfur kerosene as highway diesel fuel, would be subject to liability for violating the sulfur standard. Similarly, parties who cause the sulfur level of 500 ppm highway diesel fuel to exceed that standard by blending kerosene into the fuel, would also be subject to liability.

The rule does not require refiners or importers of kerosene to produce or import kerosene meeting the 15 ppm sulfur standard. However, we believe that refiners will produce low sulfur kerosene in the same refinery processes that they use to produce low sulfur highway diesel fuel, and that the market will drive supply of low sulfur kerosene for those areas where, and during those seasons when, the product is needed for blending with highway diesel fuel. Comments to the NPRM regarding this provision generally supported this approach.

5. Use of Diesel Fuel Additives

Diesel fuel additives include corrosion inhibitors, cold-operability improvers, and static dissipaters. Use of such additives is distinguished from the use of kerosene by the low concentrations at which they are used and their relatively more complex chemistry.[211] We proposed that diesel fuel additives used in highway diesel fuel meet the same cap on sulfur content required for the fuel itself. Additive manufacturers commented[212] that there was no need to impose a 15 ppm sulfur cap on such additives in order to effectively limit the sulfur content of finished diesel fuel. They asserted that imposing such a cap would result in unjustified costs and disruptions to the producers and users of diesel additives. Additive manufacturers also stated that for certain additives, such as static dissipaters needed to prevent explosion hazards at terminal facilities, there are currently no effective alternatives that comply with a 15 ppm cap on sulfur content.

Additive manufacturers suggested an approach whereby shipments of additives that have a sulfur content above 15 ppm would be accompanied by a product transfer document (PTD) that includes information on additive sulfur content, maximum recommended treatment rate, and the potential impact on the sulfur content of the fuel when the additive is used at the maximum recommended treatment rate. Under such an approach, they suggested that the use of diesel additives should be permitted to result in an increase in the sulfur content of the finished fuel of less than 0.5 ppm, such that fuel would effectively be required to meet a sulfur cap of 15.5 ppm.

In response to these comments, we are allowing the use of diesel fuel additives with a sulfur content greater than 15 ppm. However, we believe that this can be accomplished without allowing the 15 ppm cap on fuel sulfur content to be exceeded. The 15 ppm cap is based on our understanding of the level that is necessary to ensure the durability and proper operation of the emissions control hardware that will be used to comply with the emissions standards in today's rule. We believe that it is most appropriate for the market to determine how best to accommodate increases in the fuel sulfur content from the refinery gate to the end user, while maintaining the 15 ppm cap, and whether such increases result from contamination in the distribution system or diesel additive use. By providing this flexibility, we anticipate that market forces will encourage an optimal balance between the competing demands of manufacturing fuel lower than the 15 ppm sulfur cap, limiting contamination in the distribution system, and limiting the additive contribution to fuel sulfur content.

Our review of data submitted by additive and fuel manufacturers to comply with EPA's Fuel and Fuel Additive Registration requirements (40 CFR Part 79) indicates that additives to meet every purpose (including static dissipation) are currently in common use which meet a 15 ppm cap on sulfur content (see Chapter IV.D. of the RIA for more information on additives). Since such low-sulfur additives are currently in use side-by-side with high-sulfur additives, it is reasonable to conclude that there is not a significant difference in their cost. Even if not yet available for certain purposes, we believe that it is reasonable to assume that low-sulfur additives will become available before this rule is implemented in 2006. The ability of industry to provide low-sulfur additives is supported by the fact that diesel fuel meeting a 10 ppm cap on sulfur content has been marketed in Sweden for some time, and ARCO Petroleum recently began marketing fuel meeting a 15 ppm sulfur cap in California.

The unusually high sulfur content of a few additives may discourage their use in diesel fuel that meets a 15 ppm sulfur cap. However, it will generally continue to be possible for additive manufacturers to market additives that contain greater than 15 ppm sulfur for use in highway diesel fuel. Such additives can also continue to be used in nonroad diesel fuel. Additive manufacturers that market such additives and blenders that use them in highway diesel fuel will have additional requirements to ensure that the 15 ppm sulfur cap on highway diesel fuel is not exceeded. Although today's rule may encourage the gradual retirement of additives that do not meet a 15 ppm sulfur cap for use in highway diesel fuel, we do not anticipate that this will result in disruption to additive users and producers or a significant increase in cost. Additive manufactures commonly reformulate their additives on a periodic basis as a result of competitive pressures. We anticipate that any reformulation that might need to occur to meet a 15 ppm sulfur cap will be substantially accommodated within this normal cycle.

Today's rule limits the continued use in highway diesel fuel of diesel fuel additives that exceed 15 ppm sulfur to additives that are used at concentrations of less than one volume percent. We believe that this limitation is appropriate and will not cause any undue burden because the diesel fuel additives for which this flexibility was included are always used today at concentrations well below one volume percent. Further, one volume percent is the threshold above which the blender of an additive becomes subject to all the requirements applicable to a refiner (40 CFR 79.2(d)(1).

The specific requirements in today's rule regarding the use of diesel fuel additives are as follows:

—Additives that have a sulfur content at or below 15 ppm must be accompanied by a PTD that states: "The sulfur content of this additive does not exceed 15 ppm."

—Additives that exceed 15 ppm sulfur may continue to be used in highway diesel fuel provided that they are used at a concentration of less than one volume percent and their transfer is accompanied by a PTD that lists the following:

(1) The additive's maximum sulfur concentration

(2) The maximum recommended concentration for use of the additive in diesel fuel, and

(3) The contribution to the sulfur level of the fuel that would result if the additive is used at the maximum recommended concentration.

Blenders of additives that exceed 15 ppm in sulfur content will be held liable if their actions cause the sulfur content of the finished fuel to exceed 15 ppm. In some cases, blenders may not find it feasible to conduct testing, or otherwise obtain information on the sulfur content of the fuel either before or after additive blending, without incurring substantial cost. We anticipate that blenders will manage the risk associated with the use of additives above 15 ppm in sulfur content under such circumstances with actions such as the following:

—Selecting an additive with minimal sulfur content above 15 ppm that is used at a low concentration, and

—Working with their upstream suppliers to provide fuel of sufficiently low sulfur content to accommodate the small increase in sulfur content which results from the use of the additive.

This is similar to the way distributors will manage contamination from their distribution hardware (tank trucks, etc.). Distributors will not necessarily test for fuel sulfur content after each opportunity for contamination, but rather will rely on mechanisms set up to minimize the contamination, and to obtain fuel sufficiently below the standard to accommodate the increase in sulfur content from the contamination.

The recordkeeping, reporting, and PTD provisions associated with these requirements are discussed in Section VII.E below. The liability provisions are discussed in Section VII.G below.

D. What Are the Testing and Sampling Methods and Requirements?

1. Diesel Fuel Testing Requirements and Test Methods

As part of the diesel fuel sulfur program adopted today, EPA is designating the test method that we will use in determining compliance for samples collected at all points in the distribution system. This designated method is called "Test Method for Total Sulfur in Liquid Aromatic Hydrocarbons and Their Derivatives by Oxidative Combustion and Electrochemical Detection," or ASTM D 6428–99.

In the notice of proposed rulemaking, we proposed to designate ASTM D 2622–98 with minor modifications as the designated test method for quantifying the sulfur content of diesel fuel. This designated test method would be the one that EPA would utilize in its own laboratory in order to determine whether a given sample taken at any point in the distribution system is in compliance with the appropriate diesel sulfur standard or not. We proposed to apply this designated test method not

[211] Diesel fuel additives are used at concentrations commonly expressed in parts per million. Diesel fuel additives can include specially-formulated polymers and other complex chemical components. Kerosene is used at much higher concentrations, expressed in volume percent. Unlike diesel fuel additives, kerosene is a narrow distillation fraction of the range of hydrocarbons normally contained in diesel fuel. See Section VII.C.4 above regarding the requirements associated with the addition of kerosene to diesel fuel.

[212] See comments of the American Chemistry Council, Docket Item IV–D–163 in Docket A–99–06 associated with this rule.

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just to this final rule, which will be effective in 2006, but also to the existing diesel sulfur requirements, which are currently in effect. The modifications were designed to ensure appropriate precision at low sulfur levels below 15 ppm. Specifically, the modifications consisted of substitution of a measurement blank that more closely resembles the boiling point range and density of diesel fuel and a change to the calibration line to ensure that it goes through zero.[213]

We received several comments related to the proposed test method. Some parties suggested further modifications to ASTM D 2622–98 and others recommended that we select ASTM D 5453–00 entitled, "Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Motor Fuels and Oils by Ultraviolet Fluorescence" as the designated test method in the regulation. We have considered the comments carefully and agree that it is desirable to choose an accepted ASTM method as our designated test method. However, we do not believe that ASTM D 5453 is capable of measuring all sulfur containing compounds. Specifically, we do not believe that it will measure sulfonates, which are found in certain diesel additives typically added at terminals. Because of the stringent 15 ppm sulfur standard adopted today, the sulfonate compounds in these additives may become significant contributors to the overall sulfur level of the fuel.

Under this final rule, there is no requirement for every-batch testing for refiners or importers. However, because the diesel sulfur standard will be enforced at all points in the fuel distribution system, we believe that refiners and importers will engage in such testing, because satisfactory test results may be used to form the basis for an affirmative defense in the event of a violation. Downstream fuel suppliers such as truck loading terminals that blend additives to highway diesel fuel may not find it practical to engage in testing every time they blend additives into diesel fuel. As described in the previous section, manufacturers of fuel additives will be required to provide appropriate information about how to blend the additive properly (the treatment rate) and will be required to retain samples of additive batches for the prescribed time period in order to demonstrate compliance with this regulation, as discussed in the previous section.

[213] For a detailed description of the proposed modifications to ASTM D 2622–98, see 65 FR 35530–35531 (June 2, 2000).

We believe that there is more than one test method that may be used to determine the sulfur content of diesel fuel at low levels and believe that it is appropriate to allow alternative analytical test methods as long as they are correlated to the designated test method to be used by EPA. The ASTM methods that are allowed as alternative test methods under this rule are ASTM D 3120–96, "Standard Test Method for Trace Quantities of Sulfur in Light Liquid Petroleum Hydrocarbons by Oxidative Microcoulometry." and ASTM D 4045–99, "Standard Test Method for Sulfur in Petroleum Products by Hydrogenolysis and Rateometric Colorimetry." Furthermore, we will allow the use of the modified form of ASTM D 2622, which was proposed to be the designated test method, as an alternative test method. As stated above, results from the use of all alternative analytical test methods must be correlated to the designated test method.

We believe that choosing an appropriate ASTM method as our designated test method for enforcement testing purposes and allowing the use of these alternative test methods furthers the purposes of the "National Technology Transfer and Advancement Act of 1995" (NTTAA), section 12(d) of Public Law 104–113, and Office of Management and Budget (OMB) Circular A–119. Both of these documents are designed to encourage the adoption of standards developed by "voluntary consensus bodies" and to reduce reliance on government-unique standards where such consensus standards would suffice. In the future, we plan to adopt a performance based test method approach that would address the use of these alternative methods, including "in-house" test methods developed by individual refiners and importers. We also intend to continue working with the industry and ASTM in the future to develop and improve sulfur test methods, and will consider modifications to today's rule as developments warrant.

We also received comments indicating that there would not be any field test equipment for 15 ppm diesel fuel available by 2006. With regard to field testing, we believe that the technology that will enable the development of appropriate equipment or modifications to existing equipment exists or will be developed in response to the requirements of this rule.

In the NPRM, we discussed a comment received in response to the ANPRM that ASTM D 2622–98 may not be suitable for determining the sulfur content of biodiesel fuel, or mixtures of biodiesel and conventional diesel fuel. In response to the NPRM, we received comment indicating that significant modifications would be required to ASTM D 2622–98 in order to adapt it for use with biodiesel and biodiesel blends. We believe the selected method, ASTM D 6428–99, is appropriate for use with biodiesel and biodiesel blends. However, depending on the product, any of the test methods allowed by this rule may require some adaptation by the operator.

The test method for determination of sulfur in motor oil is ASTM D 4297–96, entitled, "Standard Test Methods for Elemental Analysis of Lubricant and Additive Components—Barium, Calcium, Phosphorus, Sulfur, and Zinc by Wavelength-Dispersive Fluorescence Spectroscopy." This method uses the same apparatus as ASTM D 2622–98, but includes specific methodology to compensate for interferences caused by additives present in motor oil. Consistent with the goals of the NTTAA and OMB Circular A–119, and in order to provide greater flexibility for regulated parties, we recognize that ASTM D 5453–00 may be selected by regulated parties as an appropriate alternative analytical test method for the purpose of measuring sulfur in motor oil.

2. Diesel Fuel Sampling Methods

The final rule adopts the proposed sampling methods. There were no negative comments regarding these technical changes. The requirement to use these methods is effective June 1, 2001. These same methods were adopted for use in the Tier 2/Gasoline Sulfur rule.31[214] These sampling methods are ASTM D 4057–95 (manual sampling) and D 4177–95 (automatic sampling from pipelines/in-line blending). We are requiring the use of these ASTM methods instead of the methods currently provided in 40 CFR part 80, Appendix G, for determining compliance under both the new 15 ppm sulfur standard, and the 500 ppm standard currently in place. That is because these methods have been updated by ASTM, and the updates have provided clarification and have eliminated certain requirements that are not necessary for sampling petroleum products such as diesel fuel.

[214] 65 FR 6833–34 (Feb. 10, 2000). These methods are also proposed for use under the RFG and CG rules. See 62 FR 37337 *et seq.* (July 11, 1997).

E. What Are the Recordkeeping, Reporting and Product Transfer Document Requirements?

1. Registration of Refiners and Importers

a. All Refiners and Importers

By December 31, 2001, refiners and importers that may produce or supply highway diesel fuel by 2006 must register with EPA. Specifically, refiners and importers that are either currently producing or supplying highway diesel fuel, or that expect to do so by June 1, 2006, must register. The registration must include the following information:

—Corporate name and address of the refiner or importer and any parent companies and a contact person
—Name and address of all refineries or import facilities (including, for importers, the port of entry and PADD)
—A contact person.
—Location of records
—Business activity (refiner or importer)
—Capacity of each refinery in barrels of crude oil per calendar day

b. Prospective Small Refiners

In addition to the basic registration requirements above, a refiner seeking status as a small refiner needs to apply for this status as a part of their registration and provide the average number of employees for all pay periods from January 1, 1999 to January 1, 2000, for the company, all parent companies, and all subsidiaries or joint ventures. The application also must include which small refiner option the refiner expects to use at each of its refineries.

c. Refiners Seeking an Extension of the GPA Gasoline Sulfur Standards

In addition to the basic registration requirements above, a refiner or importer seeking an extension of the special GPA gasoline sulfur standards (see Section IV.B above) must apply for such an extension in their registration.

2. Pre-Compliance Reports

a. All Refiners

As discussed in Section IV above, by June 1, 2003, all refiners and importers must report to EPA on their progress toward compliance with the highway diesel fuel sulfur standards adopted today. Subsequently, these pre-compliance reports are also due on June 1 of 2004 and 2005. EPA will maintain the confidentiality of information submitted in pre-compliance reports. We will present generalized data from the reports on a PADD basis in annual reports following the receipt of each year's pre-compliance reports. These reports are for information purposes only and, while refiners must truthfully report on their projected plans in order for this provision to have any value, we will not hold refiners liable if their actual actions deviate from these reports. We fully expect that refiners' plans may change, which is why we are requiring these reports to be updated annually through 2005.

In their pre-compliance reports, refiners and importers need to include the following information:

—Any changes in their basic corporate or facility information since registration.
—Estimates of the volumes (in gallons) of 15 ppm fuel and, if applicable, 500 ppm fuel to be produced from crude oil in each refinery, as well as the volumes of each grade of highway diesel fuel produced from other sources.
—For entities expecting to participate in the credit program, estimates of numbers of credits to be earned and/or used.
—Information regarding engineering plans (e.g., design and construction), the status of obtaining any necessary permits, and capital commitments for making the necessary modifications to produce low sulfur highway diesel fuel, and actual construction progress. The pre-compliance reports due in 2004 an 2005 must provide an update of the progress in each of these areas.

b. Small Refiners

In addition to the information required for all refiners above, small refiners must provide additional information in their pre-compliance reports. The information required varies according to which small refiner option the refiner plans to use, as discussed in Section IV.C above. The following paragraphs summarize the supplementary information required for each small refiner option.

500 ppm Option

The pre-compliance report for a refiner planning use the 500 ppm Option must make a showing that sufficient sources of 15 ppm fuel will likely exist in the area. If after 2003 the sources of 15 ppm fuel decrease, the pre-compliance reports for 2004 and/or 2005 must identify this change and must include a supplementary showing that the sources of 15 ppm fuel are still sufficient.

Small Refiner Credit Option

Pre-compliance reporting for small refiners choosing this Small Refiner Credit option is identical to that for the 500 ppm option (that is, if the small refiner is also producing 500 ppm highway diesel fuel), with the additional requirement that the refiner also report on any credits it expects to generate and sell.

Diesel/Gasoline Compliance Date Option

Pre-compliance reports from any small refiners expecting to use the Diesel/Gasoline Compliance Date Option must provide information showing that diesel desulfurization plans are on track. In addition to the information about the expansion of desulfurization capacity required above for all refiners, the pre-compliance reports for small refiners expecting to use this option need to reasonably show that the refiner will be in a position by June 1, 2006 to produce of 100 percent of the refiners highway diesel fuel at 15 ppm sulfur at a volume at least 85 percent of its baseline highway diesel volume.

c. GPA Refiners

As with small refiners expecting to use the Diesel/Gasoline Compliance Option above, pre-compliance report from any refiners or importers expecting to use the extension of the GPA gasoline sulfur standards must provide information showing that diesel desulfurization plans are on track. In addition to the information about the expansion of desulfurization capacity required above for all refiners, the pre-compliance reports for prospective GPA refiners need to reasonably show that the refiner will be in a position by June 1, 2006 to produce of 100 percent of the refiners highway diesel fuel at 15 ppm sulfur at a volume at least 85 percent of its baseline highway diesel volume.

3. Annual Compliance Reports

a. All Refiners

After the highway diesel sulfur requirements begin June 1, 2006, refiners and importers will be required to submit annual compliance reports that demonstrate compliance with the requirements of this final rule. The first annual compliance report will be due by the end of February 2007 (for the period of June 1, 2006 through December 31, 2006) and would be required annually through February 2011. A refiner's annual compliance reports must include the following information, for each refinery:

—The volumes of 15 ppm and 500 ppm sulfur highway diesel fuel produced from crude oil during the compliance period, as well as the volumes of each grade of highway diesel fuel produced from other sources.

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—The number of credits, if any, used to demonstrate compliance with the 80 percent requirement for 15 ppm sulfur fuel, and their source(s).
—The number of credits, if any generated.

b. Small Refiners

As with pre-compliance reports, small refiners must supply additional information related to the small refiner option they are using in their annual compliance reports.

500 ppm Option and Small Refiner Credit Option

In their annual compliance reports, small refiners choosing the 500 ppm Option or the Small Refiner Credit Option need to show that the volume they produce of highway diesel fuel meeting the 500 ppm sulfur standard meets the lesser of the following values: (1) 105 percent of the average highway diesel volume it produced in calendar years 1998 and 1999 or (2) the average highway diesel volume it produced from crude oil in calendar years 2004 and 2005.

Diesel/Gasoline Compliance Date Option

A small refiner using this option needs to confirm in each annual compliance report that it continues to produce 100 percent of its highway diesel fuel at 15 ppm sulfur and that its highway diesel volume continues to be at least 85 percent of its baseline volume.

4. Initial Confirmation of 15 ppm Fuel Production

Small refiners using the Diesel/Gasoline Compliance Date Option and refiners using the extension of the GPA gasoline sulfur standard must confirm to EPA by July 1, 2006 that they began on June 1, 2006 producing 100 percent of their highway diesel fuel at 15 ppm sulfur.

5. Product Transfer Documents (PTDs)

a. Diesel Fuel

We are adopting the proposed requirements that refiners and importers provide information on commercial PTDs that identifies diesel fuel distributed for use in motor vehicles and that states the fuel complies with the 15 ppm sulfur standard. Since today's rule adopts provisions for production and sale of diesel fuel having a sulfur content of 500 ppm for use in pre-2007 model year vehicles, the rule also adopts provisions requiring PTDs to identify such fuel and state that its use in motor vehicles is limited to pre-2007 motor vehicles.[215] We believe this additional information on commercial PTDs is necessary because of the importance of preventing commingling of highway diesel fuel with high sulfur distillate products, avoiding contamination of 15 ppm highway diesel fuel with 500 ppm highway diesel fuel, and preventing misfueling of model year 2007 and later vehicles with any fuel having a sulfur content greater than 15 ppm. In addition, we are requiring that each PTD include the volume of fuel delivered (for each grade, 15 ppm and 500 ppm), that is necessary to demonstrate compliance with the fuel downgrading restrictions discussed in Section VII.C.2.b above.

Except for transfers to truck carriers, retailers and wholesale purchaser-consumers, product codes may be used to convey the information. More explicit language on PTDs to these parties is necessary since employees of such parties are less likely to be aware of the meaning of product codes. PTDs are not required for transfers of product into motor vehicles at retail outlets or wholesale purchaser-consumer facilities.

To assure that downstream parties can determine whether kerosene, or other distillates, distributed for use for blending into highway diesel fuel to reduce viscosity in cold weather meets the 15 ppm sulfur standard, today's rule adopts the proposed requirement for PTD identification of distillates distributed for such use as meeting the 15 ppm standard.

Today's rule adopts the proposal to retain the current diesel rule's PTD requirement regarding the identification of dyed, tax-exempt highway diesel fuel. This provision is useful for wholesale purchaser-consumers that need to know that the diesel fuel they purchase is appropriate for tax exempt motor vehicle use despite the presence of red dye.[216]

b. Additives

The NPRM proposed that PTDs for additives for use in highway diesel fuel would be required to state that the additive complies with the 15 ppm sulfur standard. Today's rule has been modified to allow the sale of additives, for use by fuel terminals or other parties in the diesel fuel distribution system, that have a sulfur content greater than 15 ppm under specified conditions. As a result, under today's rule the PTD provisions for such additives are modified as follows:

For additives that have a sulfur content not exceeding 15 ppm, the PTD must state: "The sulfur content of this additive does not exceed 15 ppm."

For additives that may have a sulfur content exceeding 15 ppm, the additive manufacturer's PTD, and PTDs accompanying all subsequent transfers, must provide: a warning that the additive's sulfur content exceeds 15 ppm; the maximum sulfur content of the additive; the appropriate amount of additive to blend to highway diesel fuel, stated as gallon of additive per gallon of diesel fuel; and the increase in sulfur concentration of the fuel the additive will cause when used at the specified concentration.

The proposed provisions for consumer additives for use in diesel motor vehicles are slightly modified in the final rule due to concerns that additives designed for nonroad engines could accidentally be introduced into motor vehicle engines if they have no label stating appropriate use. Under today's rule consumer additives for use in any diesel engines must be accompanied by information that states that the additive either: complies with the sulfur content requirements for diesel motor vehicles; or that it has a sulfur content exceeding 15 ppm and is not for use in model year 2007 or later motor vehicles. This information is necessary for consumers to determine if an additive is appropriate for diesel motor vehicle use.

6. Recordkeeping Requirements

Refiners that produce (or importers that import) both 500 ppm highway diesel fuel and 15 ppm highway diesel fuel under the temporary compliance option or any hardship program, or that produce only 15 ppm sulfur content diesel fuel and that wish to generate credits (including early credits), must maintain records for each batch of highway diesel fuel produced, of the batch designations and the batch volumes. The refiner must maintain records regarding credit generation, use, transfer, purchase, or termination.

In general, refiners and importers participating in the temporary compliance option or any hardship program must keep records of the following information, as applicable for each refinery (and in the case of foreign refiners, separately by refinery and by PADD of import), or for importers, for each PADD:

—The total volume of highway diesel fuel produced or imported;

[215] Such fuel can also be used in nonroad vehicles, whose fuel is currently unregulated.

[216] The federal tax code requires the use of red dye in both off-highway distillate fuels and in highway diesel fuel sold for tax exempt use.

—The total volume of highway diesel fuel produced or imported meeting the 500 ppm; sulfur standard;
—The total volume of highway diesel fuel produced or imported meeting the 15 ppm sulfur standard;
—For small refiners or GPA refiners using the gasoline sulfur program extensions, a statement of the baseline volume and whether the volume of 15 ppm produced or imported fuel is at least equal to 85 percent of the baseline volume;
—The percentage of highway diesel fuel produced or imported meeting the 15 ppm sulfur standard before inclusion of credits;
—The volume of 15 ppm highway diesel fuel represented by credits;
—The percentage of 15 ppm highway diesel fuel produced or imported that is represented by credits;
—The number of credits in the refinery's or importer's possession at the beginning of the compliance period, separately by early credits and all other credits;
—The number of credits generated during the compliance period;
—The number of credits used, separately by early credits and all other credits;
—If any credits were obtained from or transferred to other parties, for each other party, its name, its EPA refiner or importer registration number, and the number of credits obtained from or transferred to the other party, provided separately for early credits and all other credits;
—The percentage of compliance with the 15 ppm motor vehicle diesel 80 percent volume requirement by use of credits (provided separately for early credits and all other credits);
—The number of credits that will carry over to the next averaging period, provided separately for early credits and all other credits;
—Records regarding test results, including mandatory quality assurance tests; and
—Contracts or other commercial documents that establish each transfer of credits.

Refiners approved for temporary hardship relief due to extreme unforseen circumstances or extreme financial hardship must include certain information in their application for relief. The required information, and the factors we will consider in determining what relief, if any, is appropriate, are discussed in Section IV.B.3. Such refiners will also have reasonable recordkeeping and reporting requirements, which will be fashioned on a case-by-case basis depending on the nature of any temporary waiver approved.

7. Record Retention

Today's rule adopts the NPRM proposal that the retention period for all records required to be kept by the rule is 5 years. This is the same period of time required in other fuels rules, and it coincides with the applicable statute of limitations. We believe that for other reasons, most parties in the distribution system would maintain some or all of these records for this length of time even without the requirement.

This retention period applies to PTDs, records of any test results performed by any regulated party for quality assurance purposes or otherwise, along with supporting documentation such as date of sampling and testing, batch number, tank number, and volume of product. Business records regarding actions taken in response to any violations discovered are also required to be maintained for 5 years.

All records required to be maintained by refiners participating in the temporary compliance option or hardship options (or by importers of diesel fuel produced by a foreign refiner approved for the temporary compliance option or a hardship option), including small refiner and farmer cooperative and GPA options, are also covered by the retention requirement.

F. Are There Any Exemptions From the Highway Diesel Fuel Requirements?

1. Research and Development

Today's rule exempts from the sulfur standards diesel fuel used for research, development and testing purposes (R & D), as was proposed in the NPRM. We recognize that there may be legitimate research programs that require the use of highway diesel fuel with higher sulfur levels than allowed under today's proposed rule. As a result, today's rule contains provisions for obtaining an exemption from the prohibitions for persons distributing, transporting, storing, selling, or dispensing highway diesel fuel that exceeds the standards, where such diesel fuel is necessary to conduct a research, development, or testing program.

Under the rule, parties seeking an R&D exemption are required to submit to EPA an application for exemption that describes the purpose and scope of the program and the reasons that the use of the higher-sulfur diesel fuel is necessary. Upon presentation of the required information, an exemption may be granted at the discretion of the Administrator, with the condition that EPA may withdraw the exemption *ab initio* in the event the Agency determines the exemption is not justified. Fuel subject to this exemption is exempt from the other provisions of today's rule, provided certain requirements are met. These requirements include the segregation of the exempt fuel from non-exempt highway diesel fuel, identification of the exempt fuel on product transfer documents, pump labeling, and where appropriate, the replacement, repair, or removal from service of emission systems damaged by the use of the high sulfur fuel.

2. Racing Vehicles

Today's rule adopts the NPRM proposal to provide no exemption from the sulfur content standard and other requirements of today's rule for diesel fuel used in racing vehicles. In the NPRM, we requested comment on whether such an exemption is needed and we received no comments supporting the need for such exemption. As we stated in the NPRM, we see no advantage for racing vehicles to use fuel having higher sulfur levels (or lower cetane or higher aromatic levels) than are required by today's rule, and we are concerned about the potential for misfueling of motor vehicles that could result from having a high sulfur (*e.g.*, 3,000 ppm) automotive fuel available in the marketplace. Consequently, the rule does not provide an exemption from the highway diesel fuel requirements for vehicles used in racing.

3. Military Fuel

Based on EPA's existing definition of diesel fuel, we previously concluded that JP–8 military fuel is not subject to EPA's existing requirements for diesel fuel. Today's rule revises the definition of diesel fuel so that JP–5 and JP–8 military fuel that is used or intended for use in highway diesel motor vehicles will be subject to all of the requirements applicable to diesel fuel under today's rule.[217] However, today's rule also exempts JP–5 and JP–8 fuels from EPA's diesel fuel requirements if it is used in tactical military vehicles that have a national security exemption or if it is used in tactical military vehicles that are not covered by a national security exemption but for national security reasons, such as the need to be ready for immediate deployment overseas, need to be fueled on the same fuel as motor

[217] Any JP–5, JP–8, or other distillate product that is not designated by the refiner or importer as motor vehicle diesel fuel, and that does not otherwise meet the definition of motor vehicle diesel fuel, would not be included by the refiner or importer in any computation of motor vehicle diesel fuel volume for baseline or other purposes.

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vehicles with a national security exemption. Use of JP–5 and JP–8 fuel not meeting the highway diesel fuel standards in a motor vehicle other than the tactical military vehicles described above is prohibited under today's rule.

Due to national security considerations, EPA's existing regulations allow the military to request and receive national security exemptions (NSE) for their motor vehicles from emissions regulations if the operational requirements for such vehicles warrant such an exemption. These provisions have worked successfully in the past to enable us to meet both our national air quality and security goals simultaneously. Today's rule does not change these provisions.

In discussions with the Department of Defense (DOD), DOD stated that certain tactical military vehicles must be ready to be shipped overseas quickly in response to an emergency and must be ready to be fueled on whatever fuel is available under tactical conditions (typically JP–8). To avoid problems experienced in the past when switching between fuel types in tactical vehicles, JP–8 has been selected as the common tactical fuel for use by the military in the U.S. and overseas. Thus, the use of the high sulfur fuel, which is normally supplied overseas under tactical situations, is expected to continue after the implementation of this rule. However, use of the high sulfur fuel in these engines equipped with the aftertreatment technology, necessary to meet the emissions requirements of today's rule could result in engine failure, driveability problems, and permanently destroy the emission control system.

Therefore, it appears that requiring tactical military vehicles that may be used outside of the U.S. to comply with the emissions requirements in today's rule is not compatible with the operational requirements for such vehicles. In their comments on the proposed rule, DOD stated that it would be appropriate for EPA to cover the tactical military vehicles that would otherwise be subject to the emissions regulations in today's rule under a national security exemption. We recognize the national security concerns raised by DOD, and will address this issue using the Agency procedures established for this purpose.[218] These guidelines are contained in EPA's "Guidelines for National Security Exemptions of Motor Vehicles and Motor Vehicle Engines—Guidelines for Tactical Vehicles/Engines."

We also recognize that there are tactical military vehicles manufactured before the requirements of today's rule become effective that for national security purposes need to continue to be operated on JP–5 or JP–8 fuel while in the U.S. to facilitate their readiness to be fueled on whatever fuel is available overseas. Consistent with an exemption for certain military vehicles, EPA is also exempting diesel fuel from the sulfur standard in this rule, where the fuel is used in vehicles exempted from the emissions standards in this rule (pursuant to 40 CFR 85.1708) or in tactical motor vehicles that are not covered by a national security exemption but for national security reasons need to be fueled on the same fuel as motor vehicles with a national security exemption. To more clearly identify the tactical motor vehicles to be covered by the diesel fuel exemption the Department of Defense will submit a notification to EPA describing the rationale and supporting data for the request and a description of the covered tactical motor vehicles. The one-time notification should be sent to EPA by December 15, 2003 in order to provide sufficient time for EPA to review the information as well as lead time to the Department of Defense for logistics planning purposes. EPA will then respond to DOD identifying all vehicles that are covered by the fuel exemption. Based on data provided by the Department of Defense to date, EPA believes that providing an exemption for JP–5 and JP–8 fuel used in tactical motor vehicles does not have any significant environmental impact.

G. Liability and Penalty Provisions for Noncompliance

1. General

The liability and penalty provisions of the diesel sulfur rule are similar to the liability and penalty provisions found in the gasoline sulfur rule, RFG rule and other EPA fuels regulations.[219] Regulated parties are subject to prohibitions which are typical in EPA fuels regulations, such as selling or distributing fuel that does not comply with the standard, and causing others to commit prohibited acts. Liability also arises under the diesel rule for prohibited acts specific to the diesel sulfur control program, such as introducing diesel fuel not meeting the 15 ppm sulfur standard into diesel motor vehicles of model year 2007 and later. In addition, parties will be liable for a failure to meet certain requirements, such as the recordkeeping, reporting, or PTD requirements, or causing others to fail to meet such requirements.

Under today's rule, the party in the diesel fuel's distribution system that controls the facility where the violation occurred, and other parties in that fuel's distribution system (such as the refiner, reseller, and distributor), are presumed to be liable for the violation.[220] As in the Tier 2 gasoline sulfur rule ("Tier 2 sulfur rule"), today's diesel sulfur rule explicitly prohibits causing another person to commit a prohibited act or causing non-conforming diesel fuel to be in the distribution system. Non-conforming means: (1) Diesel fuel with sulfur content above 15 ppm incorrectly designated as appropriate for model year 2007 and above motor vehicles or (2) diesel fuel with sulfur content above 500 ppm incorrectly designated as appropriate for any model year motor vehicle. Parties outside the diesel fuel distribution system, such as diesel additive manufacturers and distributors, would also be subject to liability for those diesel rule violations which could have been caused by their conduct.

Affirmative defenses are provided for each party deemed presumptively liable for a violation, and all presumptions of liability are rebuttable. In general, in order to rebut the presumption of liability, parties are required to establish that: (1) The party did not cause the violation; (2) PTD(s) exist which establish that the fuel or diesel additive was in compliance while under the party's control; and (3) the party conducted a quality assurance sampling and testing program. Diesel fuel refiners, diesel fuel additive manufacturers, and blenders of high sulfur additives into diesel fuel, would also be required to provide test results establishing the conformity of the product prior to leaving that party's control.[221] Branded refiners have additional affirmative defense elements to establish. The defenses under the diesel sulfur rule are similar to those available to parties for violations of the RFG, volatility, and the Tier 2 sulfur regulations. Today's final rule also clarifies that parent corporations are liable for violations of subsidiaries, in a manner consistent with the Tier 2 sulfur rule. Finally, the final diesel sulfur rule mirrors the Tier 2 sulfur rule by clarifying that each partner to a joint venture will be jointly and severally liable for the violations at the joint venture facility or by the joint venture operation.

As is the case with the other EPA fuels regulations, today's final diesel sulfur rule applies the provisions of section 211(d)(1) of the Clean Air Act (Act) for the collection of penalties. These penalty provisions subject any person that violates any requirement or prohibition of the diesel sulfur rule to a civil penalty of up to $27,500 for every day of each such violation and the amount of economic benefit or savings resulting from the violation. A violation of a diesel sulfur cap standard constitutes a separate day of violation for each day the diesel fuel giving rise to the violation remains in the fuel's distribution system. Under the regulation, the length of time the diesel fuel in question remains in the distribution system is deemed to be twenty-five days unless there is evidence that the fuel remained in its distribution system a lesser or greater amount of time—the same time presumption that is incorporated in the RFG and Tier 2 sulfur rules. The penalty provisions are similar to the penalty provisions for violations of the RFG and the Tier 2 sulfur regulations.

EPA has included in today's rule two prohibitions for "causing" violations: (1) Causing another to commit a violation; and (2) causing non-complying diesel fuel to be in the distribution system. These causation prohibitions are like similar prohibitions included in the Tier 2 gasoline sulfur regulations, and, as discussed in the preamble to that rule, EPA believes they are consistent with EPA's implementation of prior motor vehicle fuel regulations. See the liability discussion in the preamble to the Tier 2 final rule, at 65 FR 6812 et seq.

The prohibition against causing another to commit a violation would apply where one party's violation is caused by the actions of another party. For example, EPA may conduct an inspection of a terminal and discover that the terminal is offering for sale highway diesel fuel designated as complying with the 15 ppm sulfur standard, while it, in fact, had an actual sulfur content greater than the standard.[222] In this scenario, parties in the fuel's distribution system, as well as parties in the distribution system of any diesel additive that had been blended into the fuel, would be presumed liable for causing the terminal to be in violation. Each party, of course, would have the right to present an affirmative defense to rebut this presumption.

The prohibition against causing non-complying diesel fuel to be in the distribution system would apply, for example, if a refiner transfers non-complying diesel fuel to a pipeline. This prohibition could encompass situations where evidence shows high sulfur diesel fuel was transferred from an upstream party in the distribution system, but EPA may not have test results to establish that parties downstream also committed violations with this fuel.

The Agency intends to enforce the liability scheme of the diesel sulfur rule in the same manner that we have enforced the similar liability schemes in our prior fuels regulations. As in other fuels programs, we will attempt to identify the party most responsible for causing the violation in determining that party that should primarily be liable for penalties for the violation.

2. What Is the Liability That Additive Manufacturers and Distributors, and Parties That Blend Additives Into Diesel Fuel, Are Subject To?

a. General

In the NPRM, the Agency did not propose that additive manufacturers or distributors would be presumed liable for any violations of the diesel regulation. Only parties that were in the diesel fuel distribution system were to be presumed liable for diesel fuel violations. Parties in the additive distribution system would only be subject to liability for fuels violations where the Agency established that they caused others (such as fuel distributors or retailers) to be in violation. This approach was followed because the NPRM prohibited the downstream blending into highway diesel fuel of any additive whose sulfur content exceeded the 15 ppm standard. This limitation reduced the potential that the additive could be the cause of sulfur non-compliance in fuel within the diesel distribution system.

Various additive manufacturers provided comments regarding the need for certain diesel fuel additives that may exceed the 15 ppm sulfur standard. Today's final rule, therefore, permits the blending of diesel additives with sulfur content in excess of 15 ppm into 15 ppm highway diesel fuel under limited circumstances, in response to those comments. As more fully discussed in section VII(C)(5) of this preamble, today's rule permits downstream parties to blend into 15 ppm highway diesel fuel additives having a sulfur content exceeding 15 ppm, provided that: (1) The blending of the additive does not cause the diesel fuel's sulfur content to exceed the 15 ppm sulfur standard; (2) the additive is added in an amount no greater than one volume percent of the blended product; and (3) the downstream party obtained from its additive supplier a product transfer document ("PTD") with the additive's sulfur content and the recommended treatment rate, and that it complied with such treatment rate, as appropriate.

Since the final rule permits the limited use in highway diesel fuel of additives with high sulfur content, the Agency believes it is now more likely that a diesel fuel sulfur violation could be caused by the use of high sulfur additives. This could result from the additive manufacturer's misrepresentation or inaccurate statement of the additive's sulfur content or recommended treat rate on the additive's PTD, or an additive distributor's contamination of low sulfur additives with high sulfur additives during transportation. The increased probability that parties in the additive distribution system could cause a violation of the sulfur standard warrants the imposition by the Agency of increased liability for such parties under the final rule. As one example of this, the final rule explicitly makes parties in the additive distribution system liable for the sale of nonconforming diesel fuel additives, even if such additives have not yet been blended into diesel fuel. In addition, the

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[218] These guidelines are contained in EPA's "Guidelines for National Security Exemptions of Motor Vehicles and Motor Vehicle Engines—Guidelines for Tactical Vehicles/Engines"

[219] See section 80.5 (penalties for fuels violations); section 80.23 (liability for lead violations); section 80.28 (liability for volatility violations); section 80.30 (liability for diesel violations); section 80.79 (liability for violation of RFG prohibited acts); section 80.80 (penalties for RFG/CG violations); section 80.395 (liability for gasoline sulfur violations); section 80.405 (penalties for gasoline sulfur regulations).

[220] An additional type of liability, vicarious liability, is also imposed on branded refiners under these fuels programs.

[221] The requirement of conforming test results was not included in the NPRM as an affirmative defense element for the fuel refiner. However, under both the NPRM and today's final rule, refiners need to establish that they didn't cause the violation. As a practical matter, refiners generally establish their lack of causation using such test results. The Agency believes that it is nonetheless important to require these test results as an affirmative defense element for refiners because under today's final rule, refiners are given the ability to produce high sulfur highway diesel fuel as well as low sulfur product. This makes the possibility of refiner causation of violations much more likely, and the production of conforming test results—the one most convincing piece of evidence which would establish the refiner's lack of causation—much more essential. Further, conducting such testing should not be a significant burden for refiners to comply with. Refiners typically already test their batches to assure component quality for commercial reasons, and refiners are usually the party in the distribution system with the most resources—both financial and analytical—to conduct quality testing. In any case, refiners may choose not to conduct this testing, since it is merely an affirmative defense element, and the tests would only become relevant once a violation is discovered.

[222] The violation would occur if EPA's test result showed a sulfur content of greater than 17 ppm, which takes into account the two ppm adjustment factor for testing reproducibility for downstream parties.

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final rule imposes presumptive liability on parties in the additive distribution system if diesel fuel into which the additive has been blended is determined to have a sulfur level in excess of its permitted concentration. This presumptive liability differs depending on whether the blended additive was designated as meeting the 15 ppm sulfur standard (a "15 ppm additive") or designated as a greater than 15 ppm sulfur additive (a "high sulfur additive"), as discussed below.

b. Liability When the Additive Is Designated as Complying With the 15 ppm Sulfur Standard

With the sole exception of diesel additives blended into highway diesel fuel at a concentration no greater than one percent by volume of the blended fuel, any additive blended into diesel fuel downstream of the refinery must have a sulfur content no greater than 15 ppm, and must be accompanied by PTD(s) accurately identifying them as complying with the 15 ppm sulfur standard.

All parties in the fuel and additive distribution systems are subject to presumptive liability if the blended fuel exceeds the sulfur standard (with the two ppm downstream adjustment applied when EPA tests the fuel subject to the 15 ppm sulfur standard). Low sulfur additives present a less significant threat to diesel fuel sulfur compliance than would occur with the use of additives designated as possibly exceeding 15 ppm sulfur. Thus, parties in the additive distribution system of the low sulfur additive will be permitted to rebut the presumption of liability by showing the following: (1) Additive distributors will only be required to produce PTDs asserting that the additive complies with the 15 ppm sulfur standard (2) additive manufacturers will also be required to produce PTDs complying in an accurate manner with the regulatory requirements, as well as producing test results (or retained samples on which tests could be run) establishing the additive's compliance with the 15 ppm sulfur standard prior to leaving the manufacturer's control. Once their presumptive liability would be refuted by producing such documentation in a convincing manner, these additive system parties would only be held responsible for the diesel fuel non-conformity in situations in which EPA can establish that the party actually caused the violation.

Under today's final rule, parties in the diesel fuel distribution system will have the typical presumptive liability defenses as proposed. For parties blending an additive into their diesel fuel, the requirement of producing PTDs showing that the product complied with the regulatory standards will necessarily include PTDs for the additive that was used, affirming the additive's compliance as well as the fuel's.

c. Liability When the Additive Is Designated as Having a Possible Sulfur Content Greater Than 15 ppm

Under today's rule, if an additive manufacturer produces an additive for use in 15 ppm highway diesel fuel at a concentration no greater than one volume percent of the blended fuel, then the additive is permitted to have a maximum sulfur content above 15 ppm. However, if highway diesel fuel containing that additive is found by EPA to have high sulfur content, then all the parties in both the additive's and the fuel's distribution chain will be presumed liable for causing the diesel fuel violation. Since this type of high sulfur additive presents a much greater probability of causing diesel fuel non-compliance, parties in the additive's distribution system will have to satisfy an additional element to establish an affirmative defense. In addition to the elements of an affirmative defense described above, parties in the distribution system for such a high sulfur additive must also establish that they did not cause the violation, an element of an affirmative defense that is typically required in EPA fuel programs to rebut presumptive liability.

Parties in the diesel fuel's distribution system will essentially have to establish the same affirmative elements as proposed, with one addition. Blenders of high sulfur additives into 15 ppm sulfur diesel fuel, by the act of blending such an additive into that fuel, subject themselves to the need for establishing a more rigorous quality control program than would exist without the addition of such a high sulfur addition. The Agency believes that parties blending high sulfur additives into their 15 ppm sulfur diesel fuel should be required to produce test results establishing that the blended fuel was in compliance with the 15 ppm sulfur standards after being blended with the high sulfur additive. This additional defense element is required as an added safeguard to ensure diesel fuel compliance, since the blender has voluntarily chosen to use an additive which increases the risk of diesel fuel non-compliance.

H. How Will Compliance With the Sulfur Standards Be Determined?

In the NPRM, EPA proposed that compliance with the diesel sulfur standards would be determined based on the sulfur level of the diesel fuel, as measured using the regulatory testing methodology. We further proposed that any evidence from any source or location could be used to establish the diesel fuel sulfur level, provided that such evidence is relevant to whether the level would have been in compliance if the regulatory sampling and testing methodology had been correctly performed. In today's action, consistent with the approach taken under the Tier 2 sulfur rule, EPA is adopting the proposed regulatory provisions.

The final regulations provide that the primary determinant of compliance with the standards will be the specified regulatory test method.[223] Additionally, other information may be used under the rule, including test results using non-designated test methods, if the evidence is relevant to determining whether the sulfur level would meet applicable standards had compliance been determined using the specified test methodology. Moreover, since evidence other than regulatory test results must be relevant to compliance using the regulation test method, EPA believes that the rule enables parties to rely with confidence on the proper use of the regulatory method.

For example, the Agency might not have sulfur results derived from the regulatory test method for diesel fuel sold by a terminal, yet the terminal's own test results, based on testing using methods other than those specified and approved in the regulations, could reliably show an exceedence of the sulfur standard. Under today's rule, evidence from the non-regulatory test method could be used to establish the diesel fuel's sulfur level that would have resulted if the regulatory test method had been conducted. This type of evidence is available for use by either the EPA or the regulated party, and could be used to show either compliance or noncompliance. Similarly, absent the existence of sulfur test results using the regulation method, commercial documents asserting the sulfur level of diesel fuel or additive could be used as some evidence of that sulfur level if the product would have been tested using the regulatory method.[224]

[223] Under today's final rule, several specified alternative test methods are also permitted, provided they have been properly correlated with the regulatory method.

[224] The ability to use such evidence is in addition to the presumption established under the final rule, that when a mandated product transfer document asserts that diesel fuel complies with the 500 ppm sulfur standard, the fuel accompanied by that transfer document will be presumed to comply with the 500 standard and not to comply with the 15 ppm standard, unless the party can establish otherwise.

[225] See the final rule, 63 FR 56968, October 23, 1998 for more about the history of these regulations.

The Agency believes that the same statutory authority for EPA to adopt the Tier 2 sulfur rule's evidentiary provisions (Clean Air Act section 211(c)), provides appropriate authority for our adoption of the evidentiary provisions of today's diesel rule. For a fuller explanation of this statutory authority, see Section VI(I) of the Tier 2 final rule preamble, 65 FR 6815, February 10, 2000.

VIII. Standards and Fuel For Nonroad Diesel Engines

Although this program covers only highway diesel engines and highway diesel fuel, our potential plans for nonroad diesel engines, and especially the sulfur content of nonroad diesel, fuel are clearly related. For example, depending on whether and how nonroad diesel fuel is regulated, factors including the costs, leadtime, environmental impacts, and impacts on competitive relationships in the marketplace associated with this program could be affected. We would need to address these factors in any future regulatory action on nonroad diesel fuel.

Because of these factors, various stakeholders inquired during the public comment period about the potential requirements that could apply to nonroad diesel fuel. Several states, environmental organizations, and other commenters urged us to take action on nonroad because of the nonroad contribution to air quality problems. The remainder of this section summarizes the background behind this issue and our current thinking about the future regulation of nonroad diesel engines and fuel.

After establishing an initial set of emission standards for nonroad diesel engines in 1994, we proposed in 1997, and finalized in 1998, a comprehensive program of emission standards for most diesel engines designed for nonroad use.[225] This program established NMHC + NO_X and PM standards that are phasing in over the 1999–2006 time frame, with engines of different horsepower ranges coming into the program in different years. At the same time, we set long-term ("Tier 3") NMHC + NO_X standards, but not PM standards, for medium and high horsepower engines, to begin in 2006. This rule also included a plan to reassess the Tier 3 NMHC + NO_X standards and to establish a PM test cycle and associated standards in the 2001 time frame. In addition, the 1998 rule anticipated an EPA reassessment of the NMHC + NO_X standards for the smaller engines (less than 50 horsepower), which are to be phased in beginning in 2004 (referred to as nonroad "Tier 2" standards).

We did not include regulations on nonroad diesel fuel in the first diesel fuel sulfur control program which was established in 1993 for highway diesel fuel. We estimate that the average sulfur content for nonroad diesel fuel is currently around 3000 ppm,[226] as compared to the cap for highway diesel fuel of 500 ppm.[227]

We believe that any specific new requirements for nonroad diesel fuel would need to be carefully considered in the context of a proposal for further nonroad diesel engine emission standards. For the nonroad program, we expect to use the same systems-based approach as we used for the Tier 2/ Gasoline Sulfur program and today's highway diesel fuel and heavy-duty engine standards program. This is because of the close interrelationship between fuels and engines—the best emission control solutions may not come through either fuel changes or engine improvements alone, but perhaps through an appropriate balance between the two. This is especially significant given that engine manufacturers and diesel fuel refiners would need to address potential challenges such as capital cost, leadtime, and engineering and construction resources, of simultaneously meeting the highway standards under this program with the nonroad standards that may be implemented. Thus we need to address issues in both the fuel and engine arenas together.

The many issues connected with any rulemaking for nonroad engines and fuel warrant serious attention, and we believe it would be premature today for us to attempt to raise potential resolutions to them. We plan to initiate action in the future to formulate thoughtful proposals covering both nonroad diesel fuel and engines.

IX. Public Participation

A wide variety of interested parties participated in the rulemaking process that culminates with this final rule. The formal comment period and five public hearings associated with the NPRM provided additional opportunities for public input. EPA also met with a variety of stakeholders, including environmental and public health organizations, oil company representatives, auto company representatives, emission control equipment manufacturers, and states at various points in the process.

We prepared a detailed Response to Comments document that describes the comments received on the NPRM and presents our response to each of these comments. The Response to Comments document is available in the docket for this rule and on the Office of Transportation and Air Quality internet home page. Comments and our responses are also included throughout this preamble for several key issues.

X. Administrative Requirements

A. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency is required to determine whether this regulatory action will be "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The order defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or,
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, EPA has determined that this rule is a "significant regulatory action" because the engine standards, diesel fuel sulfur standards, and other regulatory provisions will have an annual effect on the economy in excess of $100 million. Accordingly, we have prepared a Final Regulatory Impact Analysis (RIA) which is available in the docket for this rulemaking and at the internet address listed under **ADDRESSES** above. This action was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12866. Written comments from OMB on today's action

[226] National Institute for Petroleum and Energy Research (NIPER) report. Diesel Fuel Oils, 1996.

[227] Information from recent national fuel surveys by NIPER and the Alliance of Automobile Manufacturers.

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and responses from EPA to OMB comments are in the public docket for this rulemaking.

B. Regulatory Flexibility Analysis

EPA has decided to prepare a Final Regulatory Flexibility Analysis in connection with this final rule. For purposes of assessing the impact of today's rule on small entities, small entities are defined as described under section X.B.3 below.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities in accordance with section 609(b) of the RFA (see 65 FR 35541, June 2, 2000). A detailed discussion of the Panel's advice and recommendations is found in the Panel Report contained in the docket for this rulemaking. A summary of the Panel's recommendations is presented at 65 FR 35541.

We have also prepared a final regulatory flexibility analysis (FRFA) for today's final rule. The FRFA addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket and is summarized below.[228] The key elements of the FRFA include:

—The need for, and objectives of, the rule;
—The significant issues raised by public comments on the Initial RFA, a summary of the Agency's assessment of those issues, and a statement of any changes made to the proposed rule as a result of those comments;
—The types and number of small entities to which the rule will apply;
—The reporting, recordkeeping, and other compliance requirements of the rule, including the classes of small entities that will be affected and the type of professional skills necessary to prepare the report or record;
—The steps taken to minimize the significant impact on small entities consistent with the stated objectives of the applicable statute, including a statement of the factual, policy and legal reasons why the Agency selected the alternatives we did, and why other significant alternatives to the rule which affect the impact on small entities were rejected.

We summarize the key elements of the FRFA below. A fuller discussion of each of these elements can be found in the FRFA (Chapter VIII of the RIA).

1. Need for and Objectives of the Rule

Section I of this preamble provides a summary of the need for and objectives of this rule. As discussed in detail in Section II of this preamble, emissions from heavy-duty vehicles contribute greatly to a number of serious air pollution problems, and would have continued to do so into the future absent further controls to reduce these emissions. Although the air quality problems caused by diesel heavy-duty vehicles are challenging, we believe they can be resolved through the application of high-efficiency emissions control technologies. Based on the Clean Air Act requirements discussed in Section I.B.3, we are setting stringent new emission standards that will result in the use of these diesel exhaust emission control devices (see Section III). We are also finalizing changes to diesel fuel sulfur standards in order to enable these high-efficiency technologies (Section IV). In consideration of the impacts that sulfur has on the efficiency, reliability, and fuel economy impact of diesel engine exhaust emission control devices, we believe that controlling the sulfur content of highway diesel fuel to the 15 ppm level is necessary, feasible and cost effective. The standards will result in substantial benefits to public health and welfare and the environment through significant reductions in emissions of nitrogen oxides, particulate matter, nonmethane hydrocarbons, carbon monoxide, sulfur oxides, and air toxics.

2. Summary of Significant Public Comments on the IRFA

EPA received many comments from small refiners and others pertaining to the options for hardship relief described in the NPRM. In general, many small refiners commented on the financial difficulty their refinery would face in complying with the proposed diesel sulfur program, and encouraged EPA to provide hardship relief. Many small refiners acknowledged that there was not one single hardship relief option to best suit the needs of all small refiners, and thus supported a menu of options. Section IV.C of the preamble discusses the three hardship relief options available to small refiners under today's program. These three options are based on concepts which were considered by the SBAR Panel and on which we requested and received comment in the proposal. A summary of the comments pertaining to regulatory alternatives for small refiners, and our response to them, is contained in the Response to Comments document contained in the docket.

3. Types and Number of Small Entities

Today's program, which establishes new emission standards for heavy-duty engines and new standards for the sulfur content of highway diesel fuel, will directly affect manufacturers of heavy-duty engines and petroleum refiners that produce highway diesel fuel, respectively. In addition, but to a lesser extent, the program will directly affect diesel distributors and marketers.

We have not identified any manufacturers of heavy-duty engines that meet SBA's definition of a small business. However, we have identified several petroleum refiners that produce highway diesel fuel and meet the SBA's definitions for a small business for the industry category. According to the SBA's definition of a small business for a petroleum refining company (Standard Industrial Classification (SIC) 2911), which we have used for purposes of assessing the impact of today's rule on small entities, a company must have 1500 or fewer employees to qualify as an SBA small business. Of the approximately 158 refineries in the U.S. today, we estimate that approximately 24 refiners (owning 27 refineries) would meet the SBA definition and produce highway diesel fuel. We estimate that these 24 refiners produce approximately five percent of highway diesel fuel nationwide.

EPA also has identified several thousand businesses in the diesel distribution and marketing industry that meet SBA's definitions of small business. More information about these industries is contained in the Final RFA. The low sulfur diesel fuel rule contains certain downstream compliance and enforcement provisions, for all parties in the diesel fuel distribution system downstream of the refinery gate, to prevent (1) contamination of highway diesel fuels with fuels containing higher levels of sulfur and (2) misfueling of motor vehicles with high sulfur fuels.

Under this rule, distributors and retailers may choose to handle 500 ppm diesel fuel, 15 ppm diesel fuel, or both (as permitted under the temporary compliance option and small refiner hardship provisions described in the preamble). However, distributors and marketers will have to segregate low sulfur diesel fuel from other distillates just as they do today with 500 ppm diesel fuel. Retailers and wholesale purchaser-consumers will be responsible for ensuring that only low sulfur diesel fuel is sold for use in model year 2007 and later heavy-duty vehicles. Under the temporary compliance option for refiners and small refiner hardship provisions (described in Section IV), where two grades of highway diesel fuel are allowed for the initial years of the program, some distributors and marketers may voluntarily decide (presumably based on economics) to add tankage or make additional modifications to accommodate two grades of highway diesel fuel. We have taken such costs into account in our diesel fuel cost analysis (described in more detail in Chapter V of the RIA).

The low sulfur diesel fuel rule also includes a product downgrading restriction that is designed to discourage the intentional downgrading of 15 ppm diesel fuel to 500 ppm diesel fuel in the distribution system during the initial years of the program when the optional compliance provision is in effect. This provision and its impacts on affected entities is discussed more in Section VII of this preamble and in the FRFA. This provision does not require any new recordkeeping or reporting requirements beyond those required of the rest of the program.

4. Reporting, Recordkeeping and Other Compliance Requirements

As with all refiners complying with the highway diesel fuel program, small refiners will be subject to registration, pre-compliance reporting, annual compliance reporting, and product transfer document requirements. In addition, the low sulfur diesel fuel program contains several hardship options to assist small refiners in producing low sulfur diesel fuel. Under these options, small refiners may be subject to additional reporting and recordkeeping requirements to help ensure compliance with the options and the integrity of the low sulfur diesel fuel as it moves from the refinery gate to the retail outlet. For example, all refiners producing diesel fuel are required to provide us with basic data on their progress toward compliance in 2003–2005 under the pre-compliance reporting requirements described in Section IV.A. As a part of their pre-compliance reports, small refiners must provide a limited amount of additional information specific to the option they choose. However, we believe the benefits of these hardship options will far outweigh any burdens imposed by their associated recordkeeping and reporting requirements.

The low sulfur diesel fuel program does not impose any new reporting requirements for small diesel marketers or distributors. However, this program does impose new record keeping requirements for such parties, specifically product transfer documents that track transfers of diesel fuel. Such transfer records are currently maintained by most parties for business and/or tax reasons. In addition, the record keeping requirements for downstream parties are fairly consistent with those in place today under other EPA fuel programs, including the current highway diesel fuel program. Therefore, we expect that the new record keeping requirements for downstream parties will not impose a significant burden.

These recordkeeping, reporting and compliance requirements are discussed in more detail in Sections IV and VII of this preamble and in the FRFA.

5. Regulatory Alternatives To Minimize Impact on Small Entities

The Small Business Advocacy Review Panel was convened by EPA on November 12, 1999. The Panel consisted of representatives of the Small Business Administration (SBA), the Office of Management and Budget (OMB) and EPA. During the development of the proposal to this rule, EPA and the Panel were in contact with representatives from the small businesses that will be subject to the provisions in today's rule. In addition to verbal comments from industry noted by the Panel at meetings and teleconferences, written comments were received from each of the affected industry segments or their representatives. The Panel report contains a summary of these comments and the Panel's recommendations on options that could mitigate the adverse impacts on small businesses.

The Panel considered a range of options and regulatory alternatives for providing small businesses with flexibility in complying with new sulfur standards for highway diesel fuel. As part of the process, the Panel requested and received comment on several ideas for flexibility that were suggested by small entity representatives (SERs) and Panel members. The Panel's recommendations are discussed in detail in the Panel Report, contained in the docket. In the NPRM, EPA sought public comment on several ideas that stemmed from the Panel's recommendations, as well as on the Panel's recommendations. Taking into consideration the comments received on these ideas, as well as additional business and technical information gathered about potentially affected small entities, we are finalizing certain of those options today, as discussed in detail in Section IV above.

In addition to our participation in the SBREFA process, we conducted our own outreach, fact-finding, and analysis of the potential impacts of our regulations on small businesses. Some of the small refiners with whom we and the Panel met indicated their belief that their businesses may close due to the substantial costs, capital and other impacts of meeting the 15 ppm diesel fuel standard without either additional time or flexibility with respect to gasoline sulfur compliance. Based on these discussions and analyses, the Panel and we agree that small refiners would likely experience a significant and disproportionate financial hardship in reaching the objectives of our diesel fuel sulfur program. However, the Panel also noted that the burden imposed upon the small refiners by our sulfur requirements varied from refiner to refiner and could not be alleviated with a single provision. We agree with the Panel and are offering qualifying small refiners three options to choose from in moving toward compliance with the low sulfur diesel fuel requirements.

For today's action, we have structured a selection of temporary flexibilities for qualifying small refiners, both domestic and foreign, based on the factors described below. Generally, we structured these provisions to address small refiner hardship while expeditiously achieving air quality benefits and ensuring that the low sulfur diesel fuel coincides with the introduction of 2007 model year diesel vehicles. First, the compliance deadlines in the program, combined with flexibility for small refiners, will quickly achieve the air quality benefits of the program, while helping to ensure that small refiners will have adequate time to raise capital for new or revamped equipment. Second, we believe that allowing time for refinery sulfur-reduction technologies to be proven out by larger refiners before small refiners have to put them in place will likely allow for lower costs of these improvements in desulfurization technology (*e.g.*, better catalyst technology or lower-pressure hydrotreater technology). Third, providing small refiners more time to comply will increase the availability of engineering and construction resources. Since most large and small refiners must install additional processing equipment to meet the sulfur requirements, there will be a tremendous amount of competition for technology services, engineering manpower, and construction management and labor. Finally, because the gasoline and diesel sulfur requirements will occur in approximately the same time frame, small refiners that produce both fuels

[228] The Final RFA is contained in Chapter VIII of the RIA.

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will have a greater difficulty than most other refiners in securing the necessary financing. Hence, any effort that increases small refiners' ability to stagger investments for low sulfur gasoline and diesel will facilitate compliance with the two programs. These factors are discussed further in Section IV.C.

Providing these options to assist small refiners experiencing hardship circumstances enables us to go forward with the 15 ppm sulfur standard beginning in 2006. Without this flexibility, the benefits of the 15 ppm standard would possibly not be achieved as quickly. By providing temporary relief to those refiners that need additional time, we are able to adopt a program that expeditiously reduces diesel sulfur levels in feasible manner for the industry as a whole. In addition, we believe the volume of diesel that will be affected by this hardship provision is marginal. We estimate that small refiners contribute approximately five percent of all domestic highway diesel fuel production.

The Final RFA evaluates the financial impacts of today's program on small entities. EPA believes that the regulatory alternatives finalized in this rule will provide substantial relief to qualifying small businesses from the potential adverse economic impacts of complying with today's rule. The three hardship options available to small refiners under today's rule are summarized below, and are discussed in more detail in Section IV.C and the FRFA.

500 ppm Option. A small refiner may continue to produce and sell diesel fuel meeting the current 500 ppm sulfur standard for four additional years, until May 31, 2010, provided that it reasonably ensures the existence of sufficient volumes of 15 ppm fuel in the marketing area(s) that it serves.

Small Refiner Credit Option. A small refiner that chooses to produce 15 ppm fuel prior to June 1, 2010 may generate and sell credits under the broader temporary compliance option. Since a small refiner has no requirement to produce 15 ppm fuel under this option, any fuel it produces at or below 15 ppm sulfur will qualify for generating credits.

Diesel/Gasoline Compliance Date Option. For small refiners that are also subject to the Tier 2/Gasoline sulfur program (40 CFR Part 80), the refiner may choose to extend by three years the duration of its applicable interim gasoline standards, provided that it also produces all its highway diesel fuel at 15 ppm sulfur beginning June 1, 2006.

One alternative for which we sought public comment, but are not finalizing today, is an option of allowing small refiners to produce highway diesel fuel meeting a less stringent sulfur standard (*e.g.*, 50 ppm). Some small refiners, and other refiners, commented that the costs of meeting a 50 ppm sulfur cap would be significantly less than those to meet a 15 ppm cap. However, we are not adopting less stringent sulfur standards for small refiners today, because the new diesel exhaust emissions control devices require diesel fuel with a sulfur content capped at 15 ppm in order to be viable and capable to meeting the 2007 emission standards. The need for 15 ppm sulfur diesel fuel is discussed in detail in Section III. Additional discussion of this issue can be found in the Response to Comments document. Additional information on the factual, policy, and legal reasons for the selection of alternatives considered for small refiners, and on any rejected alternatives, can be found in the FRFA, as well as in appropriate sections of the Preamble, RIA, and RTC.

As required by Section 212 of SBREFA, EPA also is preparing a small entity compliance guide to help small entities comply with this rule. Once available, small businesses will be able to obtain a copy through our web site at http://www.epa.gov/otaq.

C. Paperwork Reduction Act

This action establishes a standard for low sulfur diesel fuel that will become effective in 2006 and that involves the collection of information under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for our regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

For 500 ppm diesel fuel standards currently in effect, the existing ICR is "Regulations of Fuel and Fuel Additives; Fuel Quality Regulations for Highway Diesel Sold in 1993 and Later Calendar Years; Recordkeeping Requirements," OMB Control Number 2060–0308, EPA ICR Number 1718.12 (expires July 31, 2001). Copies of this ICR may be obtained from Delores Evans, Office of Policy, Regulatory Information Division, U.S. Environmental Protection Agency (Mail Code 2137), 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please mark requests, "Attention: Desk Officer for EPA" and include the ICR in any correspondence.

The Paperwork Reduction Act stipulates that ICR documents estimate the burden of activities that will be required of regulated parties within a three year time period. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The information collection requirements (ICR) for this rule as it relates to low sulfur (15 ppm) diesel fuel will undergo any required public notice and comment and be submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* prior to any required information collection.

D. Intergovernmental Relations

1. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and the private sector. Under Section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "federal mandates" that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more for any single year. Before promulgating a rule, for which a written statement is needed, Section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of Section 205 do not apply when they are inconsistent with applicable law. Moreover, Section 205 allows EPA to adopt an alternative that is not the least costly, most cost effective, or least burdensome alternative if EPA provides an explanation in the final rule of why such an alternative was adopted.

Before we establish any regulatory requirement that may significantly or uniquely affect small governments, including tribal governments, we must develop a small government plan pursuant to Section 203 of the UMRA. Such a plan must provide for notifying potentially affected small governments, and enabling officials of affected small governments to have meaningful and timely input in the development of our regulations with significant federal intergovernmental mandates. The plan must also provide for informing, educating, and advising small governments on compliance with the regulatory requirements.

This rule contains no federal mandates for state, local, or tribal governments as defined by the provisions of Title II of the UMRA. The rule imposes no enforceable duties on any of these governmental entities. Nothing in this rule will significantly or uniquely affect small governments.

EPA has determined that this rule contains federal mandates that may result in expenditures of more than $100 million to the private sector in any single year. EPA considered and evaluated a wide range of regulatory alternatives before arriving at the program finalized today. EPA believes that today's final rule represents the least costly, most cost effective approach to achieve the air quality goals of the rule. The cost-benefit analysis required by the UMRA is discussed in Section V above and in the RIA. See the "Administrative Designation and Regulatory Analysis" Section (XI.A.) in today's preamble for further information regarding these analyses.

2. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian Tribal governments. The engine emissions, diesel fuel, and other related requirements for private businesses in today's rule will have national applicability, and thus will not uniquely affect the communities of Indian Tribal Governments. Further, no circumstances specific to such communities exist that will cause an impact on these communities beyond those discussed in the other sections of this rule. Thus, EPA's conclusions regarding the impacts from the implementation of today's rule discussed in the other sections of this preamble are equally applicable to the communities of Indian Tribal governments. Accordingly, the requirements of Section 3(b) of Executive Order 13084 do not apply to this rule.

E. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Section 12(d) of Public Law 104–113, directs EPA to use voluntary consensus standards in its regulatory activities unless it would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rule references technical standards adopted by the Agency through previous rulemakings. No new technical standards are established in today's rule. The standards referenced in today's rule involve the measurement of diesel fuel parameters and engine emissions. The measurement standards for diesel fuel parameters referenced in today's rule are all voluntary consensus standards. The engine emissions measurement standards referenced in today's rule are government-unique standards that were developed by the Agency through previous rulemakings. These standards have served the Agency's emissions control goals well since their implementation and have been well accepted by industry. EPA is not aware of any voluntary consensus standards for the measurement of engine emissions. Therefore, the Agency is using the existing EPA-developed standards found in 40 CFR Part 86 for the measurement of engine emissions.

F. Executive Order 13045: Children's Health Protection

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, Section 5–501 of the Order directs the Agency to evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is subject to the Executive Order because it is an economically significant regulatory action as defined by Executive Order 12866 and it concerns in part an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children.

This rulemaking will achieve significant reductions of various emissions from heavy-duty engines, including NO_x, PM, VOCs and air toxics. These pollutants raise concerns regarding environmental health or safety risks that EPA has reason to believe may have a disproportionate effect on children, such as impacts from ozone, PM and certain toxic air pollutants. See Section II and the RIA for a further discussion of these issues.

The effects of ozone and PM on children's health were addressed in detail in EPA's rulemaking to establish the NAAQS for these pollutants, and EPA is not revisiting those issues here. The emission reductions from the strategies in this rulemaking will further reduce air toxics and the related adverse impacts on children's health. In a separate rulemaking under Section 202(l) of the Act, EPA addresses the emissions of hazardous air pollutants from motor vehicles and fuels, and the appropriate level of control of HAPs from these sources. It is important to note that the air toxics reductions that the Agency expects to achieve based on

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today's action are an integral part of the Agency's comprehensive strategy to address air toxics from motor vehicles under section 202(l).

In this rule, EPA has evaluated several regulatory strategies for reductions in emissions from heavy-duty engines. (See Section III of this rule as well as the RIA.) For the reasons described there, EPA believes that the strategies are preferable under the CAA to other potentially effective and reasonably feasible alternatives considered by the Agency, for purposes of reducing emissions from these sources as a way of helping areas achieve and maintain the NAAQS for ozone and PM. Moreover, EPA believes that it has selected for this rule the most stringent and effective control reasonably feasible at this time, in light of the technology and cost requirements of the Act.

G. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under Section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the regulation.

Section 4 of the Executive Order contains additional requirements for rules that preempt State or local law, even if those rules do not have federalism implications (i.e., the rules will not have substantial direct effects on the States, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government). Those requirements include providing all affected State and local officials notice and an opportunity for appropriate participation in the development of the regulation. If the preemption is not based on express or implied statutory authority, EPA also must consult, to the extent practicable, with appropriate State and local officials regarding the conflict between State law and Federally protected interests within the agency's area of regulatory responsibility.

This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Section 211(d)(4)(A) of the CAA prohibits states from prescribing or attempting to enforce controls or prohibitions respecting any fuel characteristic or component if EPA has prescribed a control or prohibition applicable to such fuel characteristic or component under Section 211(c)(1) of the Act. This rule merely modifies existing EPA diesel fuel and heavy-duty vehicle standards and therefore will merely continue an existing preemption of State and local law as discussed in Section VI. Thus, Executive Order 13132 does not apply to this rule.

Although Section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with representatives of various State and local governments in developing this rule. In particular EPA consulted with the State of Alaska in the design of the program as it applies to them, as discussed in Section IV. EPA also talked to representatives from the State of California as well as representatives from STAPPA/ALAPCO, which represents state and local air pollution officials.

H. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is a "major rule" as defined by 5 U.S.C. 804(2).

XI. Statutory Provisions and Legal Authority

Statutory authority for the engine controls finalized in this document can be found in Sections 202, 203, 206, 207, 208, and 301 of the CAA, as amended, 42 U.S.C. 7521, 7522, 7525, 7541, 7542, and 7601.

Statutory authority for the fuel controls finalized in this notice comes from Section 211(c) and 211(i) of the CAA, which allows EPA to regulate fuels that either contribute to air pollution which endangers public health or welfare or which impair emission control equipment which is in general use or has been in general use. Additional support for the procedural and enforcement-related aspects of the fuel's controls in today's rule, including the record keeping requirements, comes from Sections 114(a) and 301(a) of the CAA.

List of Subjects

40 CFR Part 69

Environmental protection, Air pollution control.

40 CFR Part 80

Environmental protection, Fuel additives, Gasoline, Imports, Incorporation by reference, Labeling, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

40 CFR Part 86

Environmental protection, Administrative practice and procedure, Confidential business information, Incorporation by reference, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: December 21, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, we amend parts 69, 80 and 86 of title 40 of the Code of Federal Regulations to read as follows:

PART 69—SPECIAL EXEMPTIONS FROM THE REQUIREMENTS OF THE CLEAN AIR ACT

1. The authority citation for part 69 is revised to read as follows:

Authority: 42 U.S.C. 7545(c), (g) and (i), and 7625–1.

Subpart E—Alaska

2. Section 69.51 of subpart E is revised to read as follows:

§ 69.51 Motor vehicle diesel fuel.

(a) Diesel fuel that is designated for use only in Alaska and is used only in Alaska, is exempt from the sulfur standard of 40 CFR 80.29(a)(1) and the dye provisions of 40 CFR 80.29(a)(3) and 40 CFR 80.29(b) until the implementation dates of 40 CFR 80.500, provided that:

(1) The fuel is segregated from non-exempt diesel fuel from the point of such designation; and

(2) On each occasion that any person transfers custody or title to the fuel, except when it is dispensed at a retail outlet or wholesale purchaser-consumer facility, the transferor must provide to the transferee a product transfer document stating:

This diesel fuel is for use only in Alaska. It is exempt from the federal low sulfur standards applicable to highway diesel fuel and red dye requirements applicable to non-highway diesel fuel only if it is used in Alaska.

(b) Beginning on the implementation dates in 40 CFR 80.500, diesel fuel that is designated for use in Alaska or is used in Alaska, is subject to the applicable provisions of 40 CFR Part 80, Subpart I, except as provided under paragraph (c) of this section. The Governor of Alaska may submit for EPA approval, by April 1, 2002, a plan for implementing the sulfur standard in Alaska as an alternative to the temporary compliance option provided under §§ 80.530–80.532. If EPA approves an alternative plan, the provisions as approved by EPA under that plan shall apply to the diesel fuel subject to this paragraph (b).

(c) If such diesel fuel is designated as fuel that does not comply with the standards and requirements for motor vehicle diesel fuel under 40 CFR Part 80, Subpart I, it is exempt from the dye presumption of 40 CFR 80.520(b)(2) provided that:

(1) The fuel is segregated from all motor vehicle diesel fuel.

(2) On each occasion that any person transfers custody or title to the fuel, except when it is dispensed at a retail outlet or wholesale purchaser-consumer facility, the transferor must provide to the transferee a product transfer document complying with the requirements of 40 CFR 80.590(a) through (d) and (g), and stating:

This diesel fuel is for use only in Alaska and is not for use in highway vehicles. It is exempt from the red dye requirement applicable to non-highway diesel fuel only if it is used in Alaska.

(3) Any pump dispensing the fuel must comply with the labeling requirements in 40 CFR 80.570(c).

PART 80—REGULATION OF FUELS AND FUEL ADDITIVES

3. The authority citation for part 80 is revised to read as follows:

Authority: 42 U.S.C. 7414, 7545, and 7601(a).

4. Section 80.2 is amended by revising paragraphs (x) and (y) and adding paragraphs (bb), (nn), and (xx) to read as follows:

§ 80.2 Definitions.

* * * * *

(x) *Diesel fuel* means any fuel sold in any state or Territory of the United States and suitable for use in diesel motor vehicles, diesel motor vehicle engines or diesel nonroad engines, and which is commonly or commercially known or sold as diesel fuel.

(y) *Motor vehicle diesel fuel* means any diesel fuel, or any distillate product, that is used, intended for use, or made available for use, as a fuel in diesel motor vehicles or diesel motor vehicle engines.

* * * * *

(bb) *Sulfur percentage* is the percentage of sulfur in diesel fuel by weight, as determined using the applicable sampling and testing methodologies set forth in § 80.580.

* * * * *

(nn) *Batch of motor vehicle diesel fuel* means a quantity of diesel fuel which is homogeneous with regard to those properties that are specified for motor vehicle diesel fuel under subpart I of this part.

* * * * *

(xx) *Motor vehicle diesel fuel additive* means any substance not composed solely of carbon and/or hydrogen, or of diesel blendstocks, that is added, intended for adding, used, or offered for use in motor vehicle diesel fuel subsequent to the production of diesel fuel by processing crude oil from refinery processing units, or in diesel motor vehicle fuel systems.

* * * * *

5. Section 80.29 is amended by revising paragraphs (a) and (b), to read as follows:

§ 80.29 Controls and prohibitions on diesel fuel quality.

(a) *Prohibited activities.* Beginning October 1, 1993 and continuing until the implementation dates for subpart I of part 80 as specified in § 80.500, except as provided in 40 CFR 69.51, no person, including but not limited to, refiners, importers, distributors, resellers, carriers, retailers or wholesale purchaser-consumers, shall manufacture, introduce into commerce, sell, offer for sale, supply, store, dispense, offer for supply or transport any diesel fuel for use in motor vehicles, unless the diesel fuel:

(1) Has a sulfur percentage, by weight, no greater than 0.05 percent;

(2)(i) Has a cetane index of at least 40; or

(ii) Has a maximum aromatic content of 35 volume percent; and

(3) Is free of visible evidence of the dye solvent red 164; unless it is used in a manner that is tax-exempt as defined under section 4082 of the Internal Revenue Code (26 U.S.C. 4082).

(b) *Determination of compliance.* (1) Any diesel fuel which does not show visible evidence of being dyed with dye solvent red 164 (which has a characteristic red color in diesel fuel) shall be considered to be available for use in diesel motor vehicles and motor vehicle engines, and shall be subject to the prohibitions of paragraph (a) of this section.

(2) Compliance with the sulfur, cetane, and aromatics standards in paragraph (a) of this section shall be determined based on the level of the applicable component or parameter, using the sampling methodologies specified in § 80.330(b), as applicable, and the appropriate testing methodologies specified in § 80.580(a) for sulfur, § 80.2(w) for cetane index, and § 80.2(z) for aromatic content. Any evidence or information, including the exclusive use of such evidence or information, may be used to establish the level of the applicable component or parameter in the diesel fuel, if the evidence or information is relevant to whether that level would have been in compliance with the standard if the appropriate sampling and testing methodology had been correctly performed. Such evidence may be obtained from any source or location and may include, but is not limited to, test results using methods other than the compliance methods in this paragraph (b), business records, and commercial documents.

(3) Determination of compliance with the requirements of this section other than the standards described in paragraph (a) of this section, and determination of liability for any violation of this section, may be based on information obtained from any source or location. Such information may include, but is not limited to, business records and commercial documents.

* * * * *

6. Section 80.30 is amended by revising paragraphs (g)(2)(ii) and (g)(4)(i), and adding paragraph (h), to read as follows:

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§ 80.30 Liability for violations of diesel fuel controls and prohibitions.

* * * * *

(g) *Defenses.* * * *

* * * * *

(2) * * *

(ii) Test results, performed in accordance with the applicable sampling and testing methodologies set forth in §§ 80.2(w), 80.2(z), 80.2(bb), and 80.580, which evidence that the diesel fuel determined to be in violation was in compliance with the diesel fuel standards of § 80.29(a) when it was delivered to the next party in the distribution system;

* * * * *

(4) * * *

(i) Test results, performed in accordance with the applicable sampling and testing methodologies set forth in §§ 80.2(w), 80.2(z), 80.2(bb), and 80.580, which evidence that the diesel fuel determined to be in violation was in compliance with the diesel fuel standards of § 80.29(a) when it was delivered to the next party in the distribution system;

* * * * *

(h) *Detection of violations.* In paragraphs (a) through (f) of this section, the term "is detected at" means that the violation existed at the facility in question, and the existence of the violation at that facility may be established through evidence obtained or created at that facility, at any other location, and by any party.

7. Section 80.215 is amended by revising paragraph (b) to read as follows:

§ 80.215 What is the scope of the geographic phase-in program?

* * * * *

(b) *Duration of the program.* (1) The geographic phase-in program applies to the 2004, 2005, and 2006 annual averaging periods, except as provided in paragraph (b)(2) of this section.

(2) Subject to the provisions of § 80.540, the geographic phase-in program shall also apply to the 2007 and 2008 annual averaging period for refiners approved for GPA standards in 2007 and 2008 under § 80.540.

* * * * *

8. Section 80.220 is amended by adding paragraph (c) to read as follows:

§ 80.220 What are the downstream standards for GPA gasoline?

* * * * *

(c) Notwithstanding paragraph (a) of this section, the sulfur content standard of 326 ppm at any downstream location may be extended as provided under § 80.540(m).

9. Section 80.240 is amended by adding paragraph (e), to read as follows:

§ 80.240 What are the small refiner gasoline sulfur standards?

* * * * *

(e) Notwithstanding paragraph (a) of this section, the temporary sulfur standards for small refiners may be extended as provided under § 80.553.

10. Subpart I is added to part 80 to read as follows:

Subpart I—Motor Vehicle Diesel Fuel

General Information

Sec.

80.500 What are the implementation dates for the diesel fuel sulfur control program?
80.501 What diesel fuel is subject to the provisions of this subpart?
80.502–80.519 [Reserved]

Motor Vehicle Diesel Fuel Standards and Requirements

80.520 What are the standards and dye requirements for motor vehicle diesel fuel?
80.521 What are the standards and identification requirements for motor vehicle diesel fuel additives?
80.522 May used motor oil be dispensed into diesel motor vehicles?
80.523 What diesel fuel designation requirements apply to refiners and importers?
80.524 What sulfur content standard applies to motor vehicle diesel fuel downstream of the refinery or importer?
80.525 What requirements apply to kerosene blenders?
80.526 [Reserved]
80.527 Under what conditions may motor vehicle diesel fuel subject to the 15 ppm sulfur standard be downgraded as motor vehicle diesel fuel subject to the 500 ppm sulfur standard?
80.528—80.529 [Reserved]

Temporary Compliance Option

80.530 Under what conditions can 500 ppm motor vehicle diesel fuel be produced or imported?
80.531 How are motor vehicle diesel fuel credits generated?
80.532 How are credits used and transferred?
80.533–80.539 [Reserved]

Geographic Phase-In Provisions

80.540 How may a refiner be approved to produce gasoline under the GPA gasoline sulfur standards in 2007 and 2008?
80.541–80.549 [Reserved]

Small Refiner Hardship Provisions

80.550 What is the definition of a small refiner under this subpart?
80.551 How does a refiner obtain approval as a small refiner under this subpart?
80.552 What compliance options are available to small refiners?
80.553 Under what conditions may the small refiner gasoline sulfur standards be extended for a small refiner of motor vehicle diesel fuel?
80.554–80.559 [Reserved]

Other Hardship Provisions

80.560 How can a refiner seek temporary relief from the requirements of this subpart in case of extreme hardship circumstances?
80.561 How can a refiner or importer seek temporary relief from the requirements of this subpart in case of extreme unforseen circumstances?
80.562–80.569 [Reserved]

Labeling Requirements

80.570 What labeling requirements apply to retailers and wholesale purchaser-consumers of motor vehicle diesel fuel?
80.571–80.579 [Reserved]

Sampling and Testing

80.580 What are the sampling and testing methods for sulfur?
80.581–80.589 [Reserved]

Recordkeeping and Reporting Requirements

80.590 What are the product transfer document requirements for motor vehicle diesel fuel?
80.591 What are the product transfer document requirements for additives to be used in motor vehicle diesel fuel?
80.592 What records must be kept?
80.593 What are the reporting and registration requirements for refiners and importers of motor vehicle diesel fuel subject to temporary refiner relief standards?
80.594 What are the pre-compliance reporting requirements?
80.595 How does a refiner apply for a motor vehicle diesel fuel volume baseline?
80.596 How is a refinery motor vehicle diesel fuel volume baseline calculated?
80.597 What are the registration requirements?
80.598–80.599 [Reserved]

Exemptions

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Subpart I—Motor Vehicle Diesel Fuel

General Information

§ 80.500 What are the implementation dates for the diesel fuel sulfur control program?

The implementation dates for standards for motor vehicle diesel fuel and diesel fuel additives, and for other provisions of this subpart, are as follows:

(a) *Implementation date for standards applicable to production or importation of motor vehicle diesel fuel, and to motor vehicle diesel fuel additives.* Except as provided in paragraph (d) of this section, beginning June 1, 2006:

(1) The standards and requirements under § 80.520(a) and (b) shall apply to any motor vehicle diesel fuel produced or imported by any refiner or importer; and

(2) The standards and requirements under § 80.521 shall apply to any motor vehicle diesel fuel additive.

(b) *Implementation date for standards applicable to motor vehicle diesel fuel downstream of the refinery or importer.* Except as provided in paragraphs (c) and (d) of this section, beginning July 15, 2006, the standards and requirements under § 80.520(a) and (b) shall apply to any motor vehicle diesel fuel at any downstream location.

(c) *Implementation date for standards applicable to motor vehicle diesel fuel at retail outlets and wholesale purchaser-consumer facilities.* Except as provided in paragraph (d) of this section, beginning September 1, 2006, the standards and requirements under § 80.520(a) and (b) shall apply to any motor vehicle diesel fuel at any retail outlet or wholesale purchaser-consumer facility.

(d) *Implementation date for motor vehicle diesel fuel subject to the 500 ppm sulfur content standard in § 80.520(c).* (1) Beginning June 1, 2006, the sulfur content standard of § 80.520(c) shall apply to motor vehicle diesel fuel, but only where authorized under, and subject to, an applicable provision of this Subpart.

(2) Beginning June 1, 2010, the sulfur content standard of § 80.520(c) shall no longer apply to any motor vehicle diesel fuel produced or imported by any refiner or importer.

(3) Beginning October 1, 2010, the sulfur content standard of § 80.520(c) shall no longer apply to any motor vehicle diesel fuel at any downstream location other than a retail or wholesale purchaser-consumer facility.

(4) Beginning December 1, 2010, the sulfur content standard of § 80.520(c) shall no longer apply to any motor vehicle diesel fuel.

(e) *Other provisions.* All other provisions of this subpart apply beginning June 1, 2006, unless another date is specified.

(f) For purposes of this subpart, the term "downstream location" shall mean any point in the diesel fuel distribution system downstream from refineries and import facilities, including diesel fuel at facilities of distributors, carriers, retailers, kerosene blenders, and wholesale purchaser-consumers.

§ 80.501 What diesel fuel is subject to the provisions of this subpart?

(a) *Included fuel and additives.* The provisions of this subpart apply to motor vehicle diesel fuel as defined in § 80.2(y), motor vehicle diesel fuel additives as defined in § 80.2(xx), and motor oil that is used as or intended for use as fuel in diesel motor vehicles or is blended with diesel fuel for use in diesel motor vehicles at any downstream location, as provided in § 80.500(f).

(b) *Excluded fuel.* The provisions of this subpart do not apply to motor vehicle diesel fuel that is designated for export outside the United States, and identified for export by a transfer document as required under § 80.590.

§§ 80.502–80.519 [Reserved]

Motor Vehicle Diesel Fuel Standards and Requirements

§ 80.520 What are the standards and dye requirements for motor vehicle diesel fuel?

(a) *Standards.* All motor vehicle diesel fuel is subject to the following per-gallon standards:

(1) *Sulfur content.* 15 parts per million (ppm) maximum, except as provided in paragraph (c) of this section;

(2) *Cetane index and aromatic content.* (i) A minimum cetane index of 40; or

(ii) A maximum aromatic content of 35 volume percent.

(b) *Dye requirements.* (1) All motor vehicle diesel fuel shall be free of visible evidence of dye solvent red 164 (which has a characteristic red color in diesel fuel), except for motor vehicle diesel fuel that is used in a manner that is tax exempt under section 4082 of the Internal Revenue Code.

(2) Any diesel fuel that does not show visible evidence of dye solvent red 164 shall be considered to be motor vehicle diesel fuel and subject to all the requirements of this subpart for motor vehicle diesel fuel, except for diesel fuel designated or classified for use only in:

(i) The State of Alaska as provided under 40 CFR 69.51; or

(ii) Jet aircraft, a research and development testing program exempted under 80.600, or motor vehicles covered by an exemption under § 80.602.

(c) Pursuant and subject to the provisions of §§ 80.530–80.532, 80.552(a), 80.560–80.561, and 80.620, only motor vehicle diesel fuel produced or imported in full compliance with the requirements of those provisions is subject to the following per-gallon standard for sulfur content: 500 ppm maximum.

(d) Kerosene and any other distillate product, that meets the definition of motor vehicle diesel fuel, is subject to the standards and requirements under this section.

§ 80.521 What are the standards and identification requirements for motor vehicle diesel fuel additives?

(a) Except as provided in paragraph (b) of this section, any motor vehicle diesel fuel additive that is added, intended for adding, used, or offered for use in motor vehicle diesel fuel subject to the 15 ppm sulfur content standard, at any downstream location must:

(1) Have a sulfur content not exceeding 15 ppm; and

(2) Be accompanied a product transfer document pursuant to § 80.591 indicating that the additive complies with the 15 ppm standard for motor vehicle diesel fuel, except for those diesel fuel additives which are only sold in containers for use by the ultimate consumer of motor vehicle diesel fuel and which are subject to the requirements of § 80.591(d).

(b) Any motor vehicle diesel fuel additive that is added, intended for adding, used, or offered for use in motor vehicle diesel fuel subject to the 15 ppm sulfur content standard may have a sulfur content exceeding 15 ppm provided that:

(1) The additive is added or used in the motor vehicle diesel fuel in a quantity less than 1% by volume of the resultant additive/diesel fuel mixture;

(2) The product transfer document pursuant to § 80.591 indicates that the additive may exceed the 15 ppm sulfur standard, that improper use of the additive may result in non-complying fuel, and that the additive complies

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with the sulfur information requirements of § 80.591(b)(3); and

(3) The additive is not used or intended for use by an ultimate consumer in diesel motor vehicles.

§ 80.522 May used motor oil be dispensed into diesel motor vehicles?

No person may introduce used motor oil, or used motor oil blended with diesel fuel, into the fuel system of model year 2007 or later diesel motor vehicles, unless both of the following requirements have been met:

(a) The vehicle or engine manufacturer has received a Certificate of Conformity under 40 CFR Part 86 and the certification of the vehicle or engine configuration is explicitly based on emissions data with the addition of motor oil; and

(b) The oil is added in a manner and rate consistent with the conditions of the Certificate of Conformity.

§ 80.523 What diesel fuel designation requirements apply to refiners and importers?

Any refiner or importer shall accurately and clearly designate all fuel it produces or imports for use in diesel motor vehicles as either motor vehicle diesel fuel meeting the 15 ppm sulfur standard under § 80.520(a)(1) or as motor vehicle diesel fuel meeting the 500 ppm sulfur standard under § 80.520(c).

§ 80.524 What sulfur content standard applies to motor vehicle diesel fuel downstream of the refinery or importer?

(a) Except as provided in paragraph (b) of this section or otherwise in the provisions of this Subpart I, the 15 ppm sulfur content standard of § 80.520(a) shall apply to all motor vehicle diesel fuel at any downstream location.

(b) Prior to the October 1, 2010 and December 1, 2010 dates specified in § 80.500(d)(3) and (4), the 500 ppm sulfur content standard of § 80.520(c) shall apply to motor vehicle diesel fuel at any downstream location, provided the following conditions are met:

(1) The product transfer documents comply with the requirements of § 80.590, including indicating that the fuel complies with the 500 ppm sulfur standard for motor vehicle diesel fuel and is for use only in model year 2006 and older diesel motor vehicles, or the fuel is downgraded pursuant to the provision of § 80.527 to motor vehicle diesel fuel subject to the 500 ppm sulfur standard;

(2) The motor vehicle diesel fuel is not represented or intended for sale or use as subject to the 15 ppm sulfur content standard, and is not dispensed, or intended to be dispensed, into model year 2007 and later motor vehicles by a retailer or wholesale purchaser-consumer; and

(3) For retailers or wholesale purchaser-consumers, the pump labeling requirements of § 80.570(a) are satisfied.

§ 80.525 What requirements apply to kerosene blenders?

(a) For purposes of this subpart, a kerosene blender means any refiner who produces motor vehicle diesel fuel by adding kerosene to motor vehicle diesel fuel downstream of the refinery that produced the motor vehicle diesel fuel or of the import facility where the motor vehicle diesel fuel was imported, without altering the quality or quantity of the motor vehicle diesel fuel in any other manner.

(b) Kerosene blenders are not subject to the requirements of this subpart applicable to refiners of motor vehicle diesel fuel, but are subject to the requirements and prohibitions applicable to downstream parties.

(c) For purposes of compliance with § 80.524(b)(1), the product transfer documents must indicate that the fuel to which kerosene is added complies with the 500 ppm sulfur standard for motor vehicle diesel fuel and is for use only in model year 2006 and older diesel motor vehicles, or the fuel is properly downgraded pursuant to the provisions of § 80.527 to motor vehicle diesel fuel subject to the 500 ppm sulfur standard.

(d) Kerosene that a kerosene blender adds or intends to add to motor vehicle diesel fuel subject to the 15 ppm sulfur content standard must meet the 15 ppm sulfur content standard, and the following requirements:

(1) The product transfer document received by the kerosene blender indicates that the kerosene is motor vehicle diesel fuel that complies with the 15 ppm sulfur content standard; or

(2) The kerosene blender has test results indicating the kerosene complies with the 15 ppm sulfur standard.

§ 80.526 [Reserved]

§ 80.527 Under what conditions may motor vehicle diesel fuel subject to the 15 ppm sulfur standard be downgraded as motor vehicle diesel fuel subject to the 500 ppm sulfur standard?

(a) *Definition.* As used in this section, *downgrade* means changing the classification of motor vehicle diesel fuel subject to the 15 ppm sulfur standard under § 80.520(a)(1) to motor vehicle diesel fuel subject to the 500 ppm sulfur standard under § 80.520(c). A *downgrade* occurs when the change in classification takes place. Changing the classification of motor vehicle diesel fuel subject to the 15 ppm sulfur standard under § 80.520(a)(1) to any fuel that is not motor vehicle diesel fuel is not a *downgrade* for purposes of this section and is not limited by the provisions of this section.

(b) *Who may downgrade.* Any person in the motor vehicle diesel fuel distribution system who has custody or title to motor vehicle diesel fuel may downgrade it.

(c) *Downgrading limitation.* (1) Except as provided in paragraphs (d) and (e) of this section, a person described in paragraph (c)(4) of this section may not downgrade a total of more than 20% of the motor vehicle diesel fuel (by volume) that is subject to the 15 ppm sulfur standard of § 80.520(a)(1) while such person has title to or custody of such fuel. In addition, a refiner or importer may only downgrade (subject to the 20% limit) motor vehicle diesel fuel designated under § 80.523 as subject to 15 ppm sulfur standard under § 80.520(a)(1) after it has been so designated and after it has been moved from the refinery's, or import facility's, storage tank or other vessel where the diesel fuel batch was designated as subject to the sulfur standard of § 80.520(a) under § 80.523.

(2) The limitation of paragraph (c)(1) of this section applies separately to each person who has custody or title of the fuel when it is downgraded.

(3) Compliance with the limitation of paragraph (c)(1) of this section shall be on an annual, calendar year basis (except in 2006 compliance shall be for the period June 1, 2006 through December 31, 2006, and in 2010 compliance shall be for the period January 1 through May 31).

(4) The limitation of this section applies to persons who sell, offer for sale, dispense, supply, store or transport diesel fuel. The limitation does not apply to persons who are transferred custody or title to motor vehicle diesel fuel when it is dispensed into motor vehicles at retail outlets.

(d) *Diesel fuel in violation of the 15 ppm standard.* Where motor vehicle diesel fuel subject to the sulfur standard of § 80.520(a)(1) is found to be in violation of any standard under § 80.520(a) and is consequently downgraded, the person, or persons, having custody and title to the fuel at the time it is found to be in violation must include the volume of such fuel toward its 20% volume limitation under paragraph (c)(1) of this section, unless the person, or persons, demonstrates that it did not cause the violation.

(e) *Special provisions for retail outlets and wholesale purchaser-consumer facilities.* Notwithstanding the provisions of paragraph (c)(1) of this section, retailers and wholesale purchaser-consumers shall comply with the downgrading limitation as follows:

(1) Retailers and wholesale purchaser-consumers who sell, offer for sale, or dispense motor vehicle diesel fuel that is subject to the 15 ppm sulfur standard under § 80.520(a)(1) are exempt from the volume limitations of paragraph (c)(1) of this section.

(2) A retailer or wholesale purchaser-consumer who does not sell, offer for sale, or dispense motor vehicle diesel fuel subject to the 15 ppm sulfur standard under § 80.520(a)(1) may not downgrade a volume of motor vehicle diesel fuel classified as subject to the 15 ppm sulfur standard greater than 20% of the total volume of motor vehicle diesel fuel that it sells, offers for sale, or dispenses annually.

(f) *Product transfer documents.* If the custody or title to any motor vehicle diesel fuel that is downgraded under this section is transferred, the product transfer documents under § 80.590 for such fuel must reflect the change in classification to motor vehicle diesel fuel subject to the 500 ppm sulfur standard.

(g) *Recordkeeping requirement.* Any person subject to the provisions of this section, as described in paragraph (c)(4) of this section, who downgrades any motor vehicle diesel fuel previously classified as subject to the 15 ppm sulfur standard under § 80.520(a)(1) during any calendar year, must make and maintain records sufficient to show compliance with the requirements and limitations of this section.

(h) *Termination of downgrading limitations.* The provisions of this section shall not apply after May 31, 2010.

§§ 80.528–80.529 [Reserved.]

Temporary Compliance Option

§ 80.530 Under what conditions can 500 ppm motor vehicle diesel fuel be produced or imported?

(a) Beginning June 1, 2006, a refiner or importer may produce or import motor vehicle diesel fuel subject to the 500 ppm sulfur content standard of § 80.520(c) if all of the following requirements are met:

(1) Each batch of motor vehicle diesel fuel subject to the 500 ppm sulfur content standard must be designated by the refiner or importer as subject to such standard, pursuant to § 80.523.

(2) The refiner or importer must meet the requirements for product transfer documents in § 80.590 for each batch subject to the 500 ppm sulfur content standard.

(3)(i) The volume V_{500} of diesel fuel that is produced or imported during a compliance period, as provided in paragraph (a)(5) of this section, may not exceed the following volume limit:

(A) For compliance periods prior to 2010, 20% of the volume V_t of diesel fuel that is produced or imported during a compliance period plus an additional volume of motor vehicle diesel fuel represented by credits properly generated and used pursuant to the requirements of §§ 80.531 and 80.532.

(B) For the compliance period of January 1, 2010 through May 31, 2010, the volume of motor vehicle diesel fuel represented by credits properly generated and used pursuant to the requirements of §§ 80.531 and 80.532.

(ii) The terms V_{500} and V_t have the meaning specified in § 80.531(a)(2).

(4) Compliance with the volume limit in paragraph (a)(3) of this section must be determined separately for each refinery. For an importer, such compliance must be determined separately for each Credit Trading Area (as defined in § 80.531) into which motor vehicle diesel fuel is imported. If a party is both a refiner and an importer, such compliance shall be determined separately for the refining and importation activities.

(5) Compliance with the volume limit in paragraph (a)(3) of this section shall be determined on a calendar year basis, where the calendar year period is from January 1st through December 31st. For the year 2006, compliance shall be determined for the period June 1, 2006 through December 31, 2006. For the year 2010, compliance shall be determined for the period of January 1, 2010 through May 31, 2010.

(6) Any motor vehicle diesel fuel produced or imported above the volume limit in paragraph (a)(3) of this section shall be subject to the 15 ppm sulfur content standard. However, for any compliance period prior to and including 2009, a refiner or importer may exceed the volume limit in paragraph (a)(3) of this section by no more than 5 percent of the volume V_t of diesel fuel produced or imported during the compliance period, provided that for the immediately following calendar year:

(i) The refiner or importer complies with the volume limit in paragraph (a)(3) of this section; and

(ii) The refiner or importer produces or imports a volume of motor vehicle diesel fuel subject to the 15 ppm sulfur standard, or obtains credits properly generated and used pursuant to the requirements of §§ 80.531 and 80.532 that represent a volume of motor vehicle diesel fuel, equal to the volume of the exceedence for the prior compliance period.

(b) After May 31, 2010, no refiner or importer may produce or import motor vehicle diesel fuel subject to the 500 ppm sulfur content standard pursuant to this section.

§ 80.531 How are motor vehicle diesel fuel credits generated?

(a) *Generation of credits from June 1, 2006 through December 31, 2009.* (1) A refiner or importer may generate credits during the period June 1, 2006 through December 31, 2009, for motor vehicle diesel fuel produced or imported that is designated as subject to the 15 ppm sulfur content standard under § 80.520(a)(1). Credits may be generated only if the volume of motor vehicle diesel fuel designated under § 80.523 as subject to the 15 ppm sulfur standard of § 80.520(a) exceeds 80% of the total volume of diesel fuel produced or imported as described in paragraph (a)(2) of this section.

(2) The number of credits generated shall be calculated for each compliance period (as specified in § 80.530(a)(5)) as follows:

$$C = V_{15} - (0.80 \times V_t)$$

Where:

C = the positive number of credits generated, in gallons.

V_{15} = the total volume in gallons of motor vehicle diesel fuel produced or imported that is designated under § 80.523 as subject to the standards of § 80.520(a) during the compliance period.

V_{500} = the total volume in gallons of motor vehicle diesel fuel produced or imported that is designated under § 80.523 as subject to the 500 ppm sulfur standard under § 80.520(c) plus the total volume of any other diesel fuel (not including V_{15}, or diesel fuel that is dyed in accordance with § 80.520(b) at the refinery or import facility where the diesel fuel is produced or imported) represented as having a sulfur content not exceeding 500 ppm.

$V_t = V_{15} + V_{500}$.

(3) Credits shall be generated and designated as follows:

(i) Credits shall be generated separately for each refinery of a refiner.

(ii) Credits shall be generated separately for each credit trading area (CTA), as defined in paragraph (a)(5) of this section, into which motor vehicle diesel fuel is imported by an importer.

(iii) Credits shall be designated separately by year of generation and by CTA of generation. In the case of a refiner, credits shall also be designated by refinery, and in the case of an importer, credits shall also be designated by port of import.

(iv) Credits may not be generated by both a foreign refiner and by an importer for the same motor vehicle diesel fuel.

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(4) Credits shall be generated by a foreign refiner as provided in § 80.620(c) and this section.

(5) For purposes of this subpart, the CTAs are:

(i) PADDs 1, 2, 3 and 4, as described in § 80.41(r), except as provided in paragraph (a)(5)(iv) of this section. The CTAs shall be designated as CTA 1, 2, 3, and 4, respectively, and correspond to PADD 1, 2, 3, and 4, respectively;

(ii) CTA 5 shall correspond to PADD 5, as described in § 80.41(r), except as provided in paragraphs (a)(5)(iii) and (iv) of this section;

(iii) The states of Hawaii and Alaska shall each be treated as a separate CTA and not a part of CTA 5. Alaska shall be CTA 6. Hawaii shall be CTA 7;

(iv) If any state (through a waiver of federal preemption under Section 211(c)(4) of the Clean Air Act, 42 U.S.C. 7545(c)(4)) implements a law or regulation that requires a greater volume of motor vehicle diesel fuel to meet a sulfur standard of less than or equal to 15 ppm than the volume that is required under this subpart, no motor vehicle diesel fuel produced in that state or imported directly into that state may generate credits under this subpart, effective on the implementation date of the sulfur program under the state statute or regulation that implements the more stringent state requirements.

(6) No credits may be generated under this paragraph (a) after December 31, 2009.

(7) No refinery may generate credits under both this paragraph (a) and under paragraph (e) of this section.

(b) *Generation of early credits from June 1, 2001 through May 31, 2005.* (1) Beginning June 1, 2001, a refiner or importer may generate one credit for each gallon of motor vehicle diesel fuel meeting the sulfur content standard in § 80.520(a)(1) that is used in vehicles with engines that are certified to meet the model year 2007 heavy duty engine PM standard under 40 CFR 86.007–11, or vehicles with retrofit technologies that achieve emission levels equivalent to the 2007 NO_X or PM emission standard verified as part of a retrofit program administered by EPA or a state. Such refiners and importers must comply with the requirements of paragraphs (b) and (d) of this section.

(2)(i) Any refiner or importer planning to generate credits under this paragraph must provide notice of intent to generate early credits at least 120 calendar days prior to the date it begins generating credits under this paragraph by submitting such notice to Attn: Early Diesel Credits Notice, at the address in § 80.595.

(ii) The notice shall include a detailed plan that demonstrates that the motor vehicle diesel fuel meeting the 15 ppm sulfur standard of § 80.520(a)(1) for which credits are generated under this paragraph will be used in vehicles with engines that are certified to meet the model year 2007 heavy duty engine PM standard under 40 CFR 86.007–11 or in vehicles with retrofit technologies that achieve emission levels equivalent to the 2007 NO_X or PM emission standard verified as part of a retrofit program administered by EPA or a state. The notice must include the refiner's or importer's detailed plan for ensuring that all motor vehicle diesel fuel that generates early credits under this paragraph will be segregated from all other motor vehicle diesel fuel not meeting the sulfur standard under § 80.520(a)(1), from the refinery or import facility to its ultimate use in motor vehicles.

(3) No credits may be generated under this paragraph (b) after May 31, 2005.

(4) A refiner or importer may generate credits under this paragraph and also generate credits under paragraph (a) of this section, and a small refiner, as defined under § 80.550, may generate credits under this paragraph (b) and paragraph (e) of this section.

(c) *Generation of early credits from June 1, 2005 through May 31, 2006.* (1) Beginning June 1, 2005, a refiner or importer may generate one credit for each gallon of motor vehicle diesel fuel that is dispensed at retail outlets or at wholesale-purchaser consumer facilities exclusively as motor vehicle diesel fuel meeting the 15 ppm sulfur standard in § 80.520(a)(1). Such refiners and importers must comply with the requirements of this paragraph (c) and paragraph (d) of this section.

(2)(i) Any refiner or importer planning to generate credits under this paragraph must provide notice of intent to generate early credits at least 120 calendar days prior to the date it begins generating credits under this paragraph (c).

(ii) The notice shall include a detailed plan that demonstrates that the motor vehicle diesel fuel meeting the sulfur standard under § 80.520(a)(1) will be dispensed exclusively at retail outlets or at wholesale-purchaser consumer facilities as 15 ppm sulfur content motor vehicle diesel fuel. The plan must demonstrate that the refiner or importer will assure that all motor vehicle diesel fuel that generates early credits under this paragraph (c) will be segregated from all other motor vehicle diesel fuel from the refinery or import facility to its ultimate use in motor vehicles.

(3) No credits may be generated under this paragraph after May 31, 2006.

(4) A refiner or importer may generate credits under this paragraph (c) and also generate credits under paragraph (a) of this section, and a small refiner, as defined under § 80.550, may generate credits under this paragraph (c) and paragraph (e) of this section.

(d) *Additional requirements for early credits.* Early credits generated under paragraphs (b) and (c) of this section are subject to the following additional requirements:

(1) The designation requirements of § 80.523, and all recordkeeping and annual reporting requirements of §§ 80.592, 80.593 and 80.594.

(2) Credits generated under paragraphs (b) and (c) of this section shall be generated separately by CTA as defined in paragraph (a)(5) of this section and must be designated by CTA of generation, and by the refiner and refinery, or by importer and port of import, as applicable.

(3) Credits may not be generated for the same fuel by both a foreign refiner and an importer.

(4) The plan under paragraph (b)(2)(ii) or (c)(2)(ii) of this section must include provisions to include information on product transfer documents and on pump stands dispensing the fuel identifying the fuel as 15 ppm sulfur content motor vehicle diesel fuel. The plan must also identify the specific retail outlets or wholesale purchaser-consumer facilities that the fuel will be provided to. The Administrator may require a refiner or importer to submit additional information, as needed.

(5) In addition to the reporting requirements under paragraph (d)(1) of this section, the refiner or importer must submit a report to the Administrator no later than the last day of February for the prior calendar year period (or for the period June 1, 2001 through December 31, 2001, the period June 1, 2005 through December 31, 2005, or the period January 1, 2006 through May 31, 2006, as applicable) demonstrating that all the motor vehicle diesel fuel produced or imported for which credits were generated met the applicable requirements of paragraph (b), (c), or (d)(4) of this section. If the Administrator finds that such credits did not in fact meet the requirements of paragraphs (b)(1) and (c)(1) of this section, as applicable, or if the Administrator determines that there is insufficient information to determine the validity of such credits, the Administrator may deny the credits submitted in whole or in part.

(e) *Credits generated by small refiners.* (1) Notwithstanding the provisions of paragraph (a) of this section, a small refiner that is approved by the EPA as a small refiner under § 80.551(g) may generate credits under § 80.552(b). Such a small refiner may generate one credit for each gallon of motor vehicle diesel fuel produced that is designated under § 80.523 as subject to the 15 ppm sulfur standard under § 80.520(a)(1).

(2)(i) Credits may be generated under this paragraph (e) and § 80.552(b) only during the compliance periods beginning June 1, 2006 and ending on May 31, 2010. Credits shall be designated separately by refinery, separately by CTA of generation, and separately by annual compliance period. The annual compliance period for 2006 shall be June 1, 2006 through December 31, 2006. The annual compliance period for 2010 shall be January 1, 2010 through May 31, 2010.

(ii) The small refiner must meet the requirements of paragraphs (d)(1), (d)(2) and (d)(3) of this section, and the recordkeeping and reporting requirements of §§ 80.592, 80.593 and 80.594.

(iii) In addition, a foreign refiner that is approved by the Administrator to generate credits under § 80.552(b) shall comply with the requirements of § 80.620.

§ 80.532 How are credits used and transferred?

(a) *Credit use.* Credits generated under § 80.531 may be used to meet the volume limit of § 80.530(a)(3) provided that:

(1) The credits were generated and reported according to the requirements of this subpart; and

(2) The requirements of paragraphs (b), (c), (d), and (e) of this section are met.

(b) Credits generated under § 80.531 may be used by a refinery or by an importer to comply with section 80.530 by applying one credit for every gallon of motor vehicle diesel fuel needed to meet compliance with the volume limit of § 80.530(a)(3).

(c) Credits generated may be banked for use or transfer in a later compliance period or may be transferred to another refinery or importer for use as provided in paragraph (d) of this section.

(d) *Credit transfers.* (1) Credits obtained from another refinery or from another importer, including early credits and small refiner credits as described in § 80.531 (b), (c) (d), and (e), may be used to satisfy the volume limit of § 80.530(a)(3) if all the following conditions are met:

(i) The credits were generated in the same CTA as the CTA in which credits are used to achieve compliance;

(ii) The credits are used in compliance with the time period limitations for credit use in this subpart;

(iii) Any credit transfer takes place no later than the last day of February following the compliance period when the credits are used;

(iv) No credit may be transferred more than twice, as follows: The first transfer by the refiner or importer who generated the credit may only be made to a refiner or importer who intends to use the credit; if the transferee cannot use the credit, it may make a second and final transfer only to a refiner or importer who intends to use the credit. In no case may a credit be transferred more than twice before being used or terminated;

(v) The credit transferor must apply any credits necessary to meet the transferor's annual compliance requirements before transferring credits to any other refinery or importer;

(vi) No credits may be transferred that would result in the transferor having a negative credit balance; and

(vii) Each transferor must supply to the transferee records indicating the year the credits were generated, the identity of the refiner (and refinery) or importer who generated the credits, the CTA of credit generation, and the identity of the transferring party, if it is not the same party who generated the credits.

(2) In the case of credits that have been calculated or created improperly, or are otherwise determined to be invalid, the following provisions apply:

(i) Invalid credits cannot be used to achieve compliance with the transferee's volume requirements regardless of the transferee's good faith belief that the credits were valid.

(ii) The refiner or importer who used the credits, and any transferor of the credits, must adjust their credit records, reports and compliance calculations as necessary to reflect the proper credits.

(iii) Any properly created credits existing in the transferor's credit balance after correcting the credit balance, and after the transferor applies credits as needed to meet the compliance requirements at the end of the compliance period, must first be applied to correct the invalid transfers before the transferor trades or banks the credits.

(e) *Limitations on credit use.* (1) Credits may not be used to achieve compliance with any requirements of this subpart other than the volume limit of § 80.530(a)(3), unless specifically approved by the Administrator pursuant to a hardship relief petition under § 80.560 or § 80.561.

(2) A refiner or importer possessing credits must use all credits in its possession prior to applying the credit deficit provisions of § 80.530(a)(6).

(3) No credits may be used to meet compliance with this subpart subsequent to the compliance period ending May 31, 2010.

§§ 80.533–80.539 [Reserved]

Geographic Phase-In Provisions

§ 80.540 How may a refiner be approved to produce gasoline under the GPA gasoline sulfur standards in 2007 and 2008?

(a) A refiner that has been approved by EPA under § 80.217 for the geographic phase-in area (GPA) gasoline sulfur content standards under § 80.216 may apply to EPA for approval to produce gasoline subject to the GPA standards in 2007 and 2008. Such application shall be submitted to EPA, at the address provided in § 80.595(b), by December 31, 2001. A foreign refiner must apply under the provisions of paragraph (n) of this section.

(b) The refiner must submit an application in accordance with the provisions of §§ 80.595 and 80.596. The application must also include information, as provided in § 80.594(c), demonstrating that starting no later than June 1, 2006, all motor vehicle diesel fuel produced by the refinery for United States use will comply with the 15 ppm sulfur content standard under § 80.520(a)(1), and that the volume of motor vehicle diesel fuel produced will comply with the volume requirements of paragraph (e) of this section.

(c) The Administrator may approve a refiner's application to produce gasoline subject to the GPA gasoline sulfur content standards in 2007 and 2008 if the provisions of paragraph (b) of this section are satisfied. In approving an application, the Administrator shall establish a motor vehicle diesel fuel volume baseline under §§ 80.595 and 80.596.

(d) Starting June 1, 2006, and continuing through December 31, 2008, all motor vehicle diesel fuel produced by a refiner that has been approved under paragraph (c) of this section to produce gasoline subject to the GPA gasoline sulfur content standards in 2007 and 2008, must be accurately designated under § 80.523 as meeting the 15 ppm sulfur content standard of § 80.520(a)(1).

(e) The total volume of motor vehicle diesel fuel produced for use in the United States and designated as meeting the 15 ppm sulfur content standard under paragraph (d) of this section must meet or exceed 85% of the baseline volume established under paragraph (c) of this section, except that for the year

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2006, the total volume must meet or exceed 50% of the baseline volume.

(f) Compliance with the volume requirements in paragraph (e) of this section shall be determined on a calendar year basis, except that for the year 2006 compliance shall be determined for the period June 1, 2006 through December 31, 2006.

(g) If a refiner fails to comply with the requirements of paragraph (d) of this section, or if the approval of the application, including the baseline, was based on false or inaccurate information, the approval to produce gasoline subject to the GPA gasoline sulfur content standards under this section during the years 2007 and 2008 shall be void ab initio, and gasoline produced for use in the GPA must meet the gasoline sulfur content standards of subpart H of this Part as if there had been no approval to produce gasoline subject to the GPA gasoline sulfur content standards in 2007 and 2008.

(h) If for any compliance period a refiner fails to meet the volume requirements in paragraph (e) of this section, the approval to produce gasoline subject to the GPA gasoline sulfur content standards shall be void for that compliance period and for all succeeding compliance periods, and gasoline produced for use in the GPA must meet the gasoline sulfur standards under subpart H of this subpart as if there had been no approval to produce gasoline subject to the GPA gasoline sulfur content standards under this section in 2007 and 2008.

(i) A refiner that is approved for production of gasoline subject to the GPA gasoline sulfur standards under this section in 2007 and 2008 must meet all applicable recordkeeping and reporting requirements of §§ 80.592, 80.593, and 80.594, and shall meet all the recordkeeping and reporting requirements under §§ 80.219, 80.365 and 80.370.

(j) A refiner approved to produce gasoline subject to the GPA gasoline sulfur standards under this section in 2007 and 2008 may not generate or use credits under § 80.531(a) or (e), or § 80.532 unless the approval is vacated as provided in paragraph (k) of this section.

(k) A refiner may petition the Administrator to vacate approval to produce gasoline subject to the GPA gasoline sulfur content standards in 2007 and 2008. EPA may grant such a petition, effective January 1 of the compliance period following EPA's receipt of such petition (or effective June 1, in 2006, if applicable). Upon such effective date and thereafter, gasoline produced for use in the GPA must meet the gasoline sulfur content standards under subpart H of this Part as if there had been no approval to produce gasoline subject to the GPA gasoline sulfur content standards under this section in 2007 and 2008. Upon such effective date, the refiner shall not be subject to the requirements of this section.

(l) The provisions of this section shall apply separately for each refinery of a refiner.

(m) If any refinery is approved for production of gasoline subject to GPA gasoline sulfur content standards under this section in 2007 and 2008, the GPA downstream gasoline sulfur standard under § 80.220(a)(2) shall apply as follows:

(1) During the period of February 1, 2005 through January 31, 2009, the sulfur content of GPA gasoline at any downstream location other than at a retail outlet or wholesale purchaser-consumer facility shall not exceed 326 ppm.

(2) During the period of March 1, 2005 through February 28, 2009, the sulfur content of GPA gasoline at any downstream location shall not exceed 326 ppm.

(n) A foreign refiner may apply to the Administrator to produce gasoline that is subject to the gasoline sulfur standards for GPA gasoline under § 80.216 for the compliance years 2007 and 2008. Such application must be submitted to the EPA, at the address in § 80.595(b), by December 31, 2001.

(1) The Administrator may approve such interim GPA gasoline sulfur standards for the foreign refiner provided that the foreign refiner applies for a gasoline sulfur baseline under paragraph (n)(2) of this section and complies with:

(i) The requirements of paragraphs (b) through (l) of this section;

(ii) The requirements for the import of motor vehicle diesel fuel under § 80.620; and

(iii) All applicable gasoline requirements for refiners under subpart H of this Part, including the foreign refiner requirements under § 80.410, the attest requirements of § 80.415, the recordkeeping and reporting requirements of §§ 80.365 and 80.370, the designation and product transfer document requirements of § 80.219, the sampling and testing requirements of § 80.330, and the sample retention requirements of § 80.335.

(2) The refiner must submit an application for a gasoline sulfur baseline under the provisions of §§ 80.216(a), 80.295, and 80.410(b).

(3) After review of the foreign refiner's individual refinery gasoline sulfur baseline, its individual refinery motor vehicle diesel fuel baseline, and other information submitted with the application, the Administrator may approve such baselines and the application for GPA gasoline sulfur standards for 2007 and 2008.

(o) An importer is not eligible for approval to import gasoline subject to the GPA standards in 2007 or 2008 under this section.

§§ 80.541—80.549 [Reserved]

Small Refiner Hardship Provisions

§ 80.550 What is the definition of a small refiner under this subpart?

(a) A small refiner is defined as any person, as defined by 42 U.S.C. 7602(e), who:

(1) Produces diesel fuel at a refinery by processing crude oil through refinery processing units;

(2) Employed an average of no more than 1,500 people, based on the average number of employees for all pay periods from January 1, 1999, to January 1, 2000; and

(3) Had an average crude capacity less than or equal to 155,000 barrels per calendar day (bpcd) for 1999.

(b) For the purpose of determining the number of employees and crude capacity under paragraph (a) of this section, the refiner shall include the employees and crude capacity of any subsidiary companies, any parent company and subsidiaries of the parent company in which the parent has 50% or greater ownership, and any joint venture partners.

(c) The definition under paragraph (a) of this section applies to domestic and foreign refiners. For any refiner owned by a governmental entity, the number of employees as specified in paragraph (a) of this section shall include all employees and total crude capacity of the government of which the governmental entity is a part.

(d) Notwithstanding the provisions of paragraph (a) of this section, a refiner that acquires a refinery after January 1, 2000, or reactivates a refinery that was shutdown or was non-operational between January 1, 1999, and January 1, 2000, may apply for small refiner status in accordance with the provisions of § 80.551(c)(1)(ii).

(e) *Ineligible parties.* The following are ineligible for the small refiner provisions:

(1) Refiners or refineries built or started up after January 1, 2000;

(2) Persons who exceed the employee or crude oil capacity criteria under this section on January 1, 2000, but who meet these criteria after that date, regardless of whether the reduction in employees or crude oil capacity is due to operational changes at the refinery or a company sale or reorganization;

(3) Importers; and

(4) Refiners who produce motor vehicle diesel fuel other than by processing crude oil through refinery processing units.

(f)(1) Refiners who qualify as small refiners under this section and who subsequently employ more than 1500 people as a result of merger with or acquisition of another entity, are disqualified as small refiners. If this occurs, the refiner shall notify EPA in writing no later than 20 days following this disqualifying event.

(2) Any refiner whose status changes under this paragraph shall comply with the sulfur standard of § 80.520(a)(1) beginning January 1 of the calendar year following the disqualifying event in paragraph (f)(1) of this section.

(g) Notwithstanding the criteria in paragraph (a) of this section, any small refiner that has been approved by EPA as a small refiner under § 80.235 and meets the criteria of paragraph (a)(1) of this section, will be considered a small refiner under this section as well, for as long as they are a small refiner under § 80.225. The provisions of paragraph (f) of this section apply to any such refiner.

§ 80.551 How does a refiner obtain approval as a small refiner under this subpart?

(a)(1) Applications for small refiner status must be submitted to EPA by December 31, 2001 as part of the refiner's registration under § 80.597.

(2) In the case of a refiner who acquires a refinery after January 1, 2000, or reactivates a refinery that was shutdown between January 1, 1999, and January 1, 2000, the application for small refiner status must be submitted to EPA by June 1, 2003.

(b) Applications for small refiner status must be sent via certified mail with return receipt or express mail with return receipt to: U.S. EPA–Attn: Diesel Small Refiner Status (6406J), 1200 Pennsylvania Avenue, NW (6406J), Washington, DC 20460 (certified mail/return receipt) or Attn: Diesel Small Refiner Status, Transportation and Regional Programs Division,501 3rd Street, NW (6406J), Washington, DC 20001 (express mail/return receipt).

(c) The small refiner status application must contain the following information for the company seeking small refiner status, plus any subsidiary companies, any parent company and subsidiaries of the parent company in which the parent has 50% or greater ownership, and any joint venture partners:

(1)(i) A listing of the name and address of each location where any employee worked during the 12 months preceding January 1, 2000; the average number of employees at each location based upon the number of employees for each pay period for the 12 months preceding January 1, 2000; and the type of business activities carried out at each location; or

(ii) In the case of a refiner who acquires a refinery after January 1, 2000, or reactivates a refinery that was shutdown between January 1, 1999, and January 1, 2000, a listing of the name and address of each location where any employee of the refiner worked since the refiner acquired or reactivated the refinery; the average number of employees at any such acquired or reactivated refinery during each calendar year since the refiner acquired or reactivated the refinery; and the type of business activities carried out at each location.

(2) The total corporate crude capacity of each refinery as reported to the Energy Information Administration (EIA) of the U.S. Department of Energy (DOE) for the most recent 12 months of operation. The information submitted to EIA is presumed to be correct. In cases where a company disagrees with this information, the company may petition EPA with appropriate data to correct the record when the company submits its application for small refiner status. EPA may accept such alternate data at its discretion.

(3) An indication of whether the refiner, for each refinery, is applying for:

(i) The ability to produce motor vehicle diesel fuel subject to the 500 ppm sulfur content standard under § 80.520(c) or generate credits under § 80.531, pursuant to the provisions of § 80.552(a) or (b); or

(ii) An extension of the duration of its small refiner gasoline sulfur standard under § 80.553, pursuant to the provisions of § 80.552(c).

(4) A letter signed by the president, chief operating or chief executive officer of the company, or his/her designee, stating that the information contained in the application is true to the best of his/her knowledge.

(5) Name, address, phone number, facsimile number and e-mail address (if available) of a corporate contact person.

(d) For joint ventures, the total number of employees includes the combined employee count of all corporate entities in the venture.

(e) For government-owned refiners, the total employee count includes all government employees.

(f) Approval of small refiner status for refiners who apply under § 80.550(d) will be based on all information submitted under paragraph (c) of this section, except as provided in § 80.550(d).

(g) EPA will notify a refiner of approval or disapproval of small refiner status by letter. If disapproved, the refiner must comply with the sulfur standard in § 80.520, except as otherwise provided in this subpart.

(h) If EPA finds that a refiner provided false or inaccurate information on its application for small refiner status, upon notice from EPA the refiner's small refiner status will be void ab initio.

(i) Upon notification to EPA, an approved small refiner may withdraw its status as a small refiner. Effective on January 1 of the year following such notification, the small refiner will become subject to the sulfur standard of § 80.520 unless one of the hardship provisions of this subpart apply.

§ 80.552 What compliance options are available to small refiners?

(a) A refiner that has been approved by EPA as a small refiner under § 80.551(g) may produce motor vehicle diesel fuel subject to the 500 ppm sulfur content standard pursuant to the provisions of § 80.530, except that the volume limits of § 80.530(a)(3) shall only apply to that volume V^{500} of diesel fuel that is produced or imported during a calendar year that exceeds 105% of the baseline volume established under § 80.595. The calendar year period shall be from January 1st through December 31st. For the period June 1, 2006 through December 31, 2006, the volume limits shall only apply to that volume VV^{500} that exceeds 60% of the baseline volume.

(b) A refiner that has been approved by EPA as a small refiner under § 80.551(g) may generate motor vehicle diesel fuel credits pursuant to the provisions of § 80.531, except that for purposes of § 80.531(a) the term Credit shall equal VV^{15}, without further adjustment.

(c) A refiner that has been approved by EPA as a small refiner under § 80.551(g) may apply for an extension of the duration of its small refiner gasoline sulfur standards pursuant to § 80.553.

(d) A refiner that produces motor vehicle diesel fuel under the provisions of paragraph (a) of this section or generates credits under the provisions of paragraph (b) of this section may not receive an extension of its small refiner gasoline sulfur standard under the provisions of paragraph (c) of this section. A refiner that receives an extension of its small refiner gasoline

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sulfur standard under the provisions of paragraph (c) of this section may not produce motor vehicle diesel fuel under the provisions of paragraph (a) of this section and may not generate credits under the provisions of paragraph (b) of this section.

(e) The provisions of this section shall apply separately for each refinery owned or operated by a small refiner.

§ 80.553 Under what conditions may the small refiner gasoline sulfur standards be extended for a small refiner of motor vehicle diesel fuel?

(a) A refiner that has been approved by EPA for small refiner gasoline sulfur standards under § 80.240 may apply, under § 80.551, for an extension of the duration of its small refiner gasoline sulfur standards through the calendar year 2010 annual averaging period.

(b) As part of its application, the refiner must submit an application for a motor vehicle diesel fuel baseline in accordance with the provisions of §§ 80.595 and 80.596. The application must also include information, as provided in § 80.594, demonstrating that starting no later than June 1, 2006, all motor vehicle diesel fuel produced by the refiner will comply with the 15 ppm sulfur content standard under § 80.520(a)(1), and that the volume of motor vehicle diesel fuel produced will comply with the volume requirements of paragraph (e) of this section.

(c) The Administrator may approve an application for extension of the small refiner gasoline sulfur standards if the provisions of paragraph (b) of this section and §§ 80.595 and 80.596 are satisfied. In approving an application for extension, the Administrator shall establish a motor vehicle diesel fuel volume baseline under §§ 80.595 and 80.596.

(d) Beginning June 1, 2006, and continuing through December 31, 2010, all motor vehicle diesel fuel produced by a refiner that has received an extension of its small refiner gasoline sulfur standards under this section must be accurately designated under § 80.523 as meeting the 15 ppm sulfur content standard under § 80.520(a)(1).

(e) The total volume of motor vehicle diesel fuel produced for use in the United States and designated as meeting the 15 ppm sulfur content standard under paragraph (d) of this section must meet or exceed 85% of the baseline volume established under paragraph (c) of this section, except that for the year 2006, the total volume must meet or exceed 50% of the baseline volume.

(f) Compliance with the volume requirements in paragraph (e) of this section shall be determined on a calendar year basis, except that for the year 2006 compliance shall be determined for the period June 1, 2006 through December 31, 2006.

(g) If a refiner fails to comply with the requirements of paragraph (d) of this section, or if approval of the application, including the baseline, was based on false or inaccurate information, the extension of the applicable small refiner gasoline sulfur standards under this section shall be void ab initio, and all gasoline produced by the refinery must meet the gasoline sulfur standards under subpart H of this Part as if there had been no extension of the small refiner gasoline sulfur standards.

(h) If for any compliance period a refiner fails to meet the volume requirements in paragraph (e) of this section, the extension of the small refiner gasoline sulfur standards shall be void for that compliance period and for all succeeding compliance periods and all gasoline produced by the refinery must meet the gasoline sulfur standards under subpart H of this part as if there had been no extension of the small refiner gasoline sulfur standards under this section for such compliance periods.

(i) A refiner that is approved for an extension of the interim small refiner gasoline sulfur standards under this section must meet all applicable recordkeeping and reporting requirements of §§ 80.592, 80.593, and 80.594, and shall meet all the recordkeeping and reporting requirements under §§ 80.210, 80.365 and 80.370. Any foreign refiner shall meet all additional requirements under §§ 80.620 and 80.410.

(j) A refiner approved for the small refiner gasoline sulfur standards extension under this section may not generate or use credits under § 80.531(a) or (e), or § 80.532.

(k) A refiner may petition the Administrator to vacate an extension of the small refiner gasoline sulfur content standards. EPA may grant such a petition, effective January 1 of the compliance period following receipt of such petition (or effective June 1, 2006, if applicable). Upon such effective date, all gasoline produced by the refiner must meet the gasoline sulfur content standards under subpart H of this Part as if there had been no extension of the small refiner gasoline sulfur content standards under this section. Upon such effective date, the refiner shall not be subject to the requirements of this section.

(l) The provisions of this section shall apply separately for each refinery of a refiner.

§§ 80.554–80.559 [Reserved]

Other Hardship Provisions

§ 80.560 How can a refiner seek temporary relief from the requirements of this subpart in case of extreme hardship circumstances?

(a) EPA may, at its discretion, grant a refiner, for one or more of its refineries, temporary relief from some or all of the provisions of this subpart. Such relief shall be no less stringent than the small refiner compliance options specified in § 80.552. EPA may grant such relief provided that the refiner demonstrates that:

(1) Unusual circumstances exist that impose extreme hardship and significantly affect the refiner's ability to comply by the applicable date; and

(2) It has made best efforts to comply with the requirements of this subpart.

(b) Applications must be submitted to EPA by June 1 2002 to the following address: Applications for small refiner status must be sent via certified mail with return receipt or express mail with return receipt to: U.S. EPA-Attn: Diesel Hardship (6406J), 1200 Pennsylvania Avenue, NW (6406J), Washington, DC 20460 (certified mail/return receipt) or Attn: Diesel Hardship, Transportation and Regional Programs Division, 501 3rd Street, NW (6406J), Washington, DC 20001 (express mail/return receipt). EPA reserves the right to deny applications for appropriate reasons, including unacceptable environmental impact. Approval to distribute motor vehicle diesel fuel not subject to the 15 ppm sulfur standard may be granted for such time period as EPA determines is appropriate, but shall not extend beyond May 31, 2010.

(c) Applications must include a plan demonstrating how the refiner will comply with the requirements of this subpart as expeditiously as possible. The plan shall include a showing that contracts are or will be in place for engineering and construction of desulfurization equipment a plan for applying for and obtaining any permits necessary for construction or operation, projected timeline for beginning and completing construction, and for beginning actual operation of such equipment, and a description of plans to obtain necessary capital, and a detailed estimate of when the requirements of this subpart will be met.

(d) Applicants must provide, at a minimum, the following information:

(1) Detailed description of efforts to obtain capital for refinery investments and efforts made to obtain credits for compliance under § 80.531;

(2) Bond rating of entity that owns the refinery (in the case of joint ventures, include the bond rating of the joint venture entity and the bond ratings of all partners; in the case of corporations, include the bond ratings of any parent or subsidiary corporations); and

(3) Estimated capital investment needed to comply with the requirements of this subpart by the applicable date.

(e) In addition to the application requirements of paragraph (b) of this section, a refiner's application for temporary relief under this paragraph must also include a compliance plan. Such compliance plan shall demonstrate how the refiner will engage in a quality assurance testing program to ensure that its motor vehicle diesel fuel subject solely to the sulfur standards under § 80.520(c) has not caused motor vehicle diesel fuel subject to the 15 ppm standard § 80.520(a)(1) to fail to comply with that standard. The quality assurance program must at least include periodic sampling and testing at the party's own facilities and at downstream facilities in the refiner's or importer's diesel fuel distribution system, to determine compliance with the applicable sulfur standards for both categories of motor vehicle diesel fuel; examination at the party's own facilities and at applicable downstream facilities, of product transfer documents to confirm appropriate transfers and deliveries of both products; and inspection of retailer and wholesale purchaser-consumer pump stands for the presence of the labels and warning signs required under this section. Any violations that are discovered shall be reported to EPA within 48 hours of discovery.

(f) Applications under this section must be accompanied by:

(1) A letter signed by the president, chief operating or chief executive officer of the company, or his/her designee, stating that the information contained in the application is true to the best of his/her knowledge.

(2) The name, address, phone number, facsimile number and e-mail address of a corporate contact person.

(g) Applicants must also provide any other relevant information requested by EPA.

(h) Refiners who are granted a hardship relief standard for any refinery, and importers of fuel subject to temporary refiner relief standards, may not distribute the diesel fuel subject to the sulfur standard under § 80.520(c) for use in model year 2007 and later vehicles and must comply with all applicable provisions of this subpart, including the provisions of this subpart.

(i) EPA may impose any reasonable conditions on waivers under this section, including limitations on the refinery's volume of motor vehicle diesel fuel subject to a temporary refiner relief standards.

(j) The provisions of this section are available only to refineries that produce diesel fuel from crude.

(k) The individual refinery sulfur standard and the compliance plan will be approved or disapproved by the Administrator, and approval will be effective when the refiner (or importer, as applicable, in the case of compliance plans) receives an approval letter from EPA. If disapproved, the refiner or importer must comply with the motor vehicle diesel fuel standard under § 80.520(a)(1) by the appropriate compliance date specified in § 80.500.

(l) If EPA finds that a refiner provided false or inaccurate information on its application for small refiner status, upon notice from EPA the refiner's small refiner status will be void ab initio.

§ 80.561 How can a refiner or importer seek temporary relief from the requirements of this subpart in case of extreme unforseen circumstances?

In appropriate extreme, unusual, and unforseen circumstances (e.g., natural disaster or refinery fire) which are clearly outside the control of the refiner or importer and which could not have been avoided by the exercise of prudence, diligence and due care, EPA may permit a refiner or importer, for a brief period, to distribute motor vehicle diesel fuel which does not meet the requirements of this subpart if:

(a) It is in the public interest to do so (e.g., distribution of the nonconforming diesel fuel is necessary to meet projected shortfalls which cannot otherwise be compensated for);

(b) The refiner or importer exercised prudent planning and was not able to avoid the violation and has taken all reasonable steps to minimize the extent of the nonconformity;

(c) The refiner or importer can show how the requirements for motor vehicle diesel fuel will be expeditiously achieved;

(d) The refiner or importer agrees to make up any air quality detriment associated with the nonconforming motor vehicle diesel fuel, where practicable;

(e) The refiner or importer pays to the U.S. Treasury an amount equal to the economic benefit of the nonconformity minus the amount expended pursuant to paragraph (d) of this section, in making up the air quality detriment; and

(f) In the case of motor vehicle diesel fuel distributed under this section that does not meet the 15 ppm sulfur standard under § 80.520(a)(1), such diesel fuel shall not be distributed for use in model year 2007 or later motor vehicles, and must meet all the requirements and prohibitions of this subpart applicable to diesel fuel meeting the sulfur standard under § 80.520(c), or to diesel fuel that is not motor vehicle diesel fuel, as applicable.

§§ 80.562–80.569 [Reserved]

Labeling Requirements

§ 80.570 What labeling requirements apply to retailers and wholesale purchaser-consumers of motor vehicle diesel fuel?

(a) Any retailer or wholesale purchaser-consumer who sells, dispenses, or offers for sale or dispensing, motor vehicle diesel fuel subject to the 500 ppm sulfur standard of § 80.520(c), must prominently and conspicuously display in the immediate area of each pump stand from which motor vehicle fuel subject to the 500 ppm standard is offered for sale or dispensing, the following legible label, in block letters of no less than 36-point bold type, printed in a color contrasting with the background:

HIGH-SULFUR DIESEL FUEL—WARNING

May damage model year 2007 and later highway vehicles.

Federal Law *prohibits* use in these vehicles.

(b) Any retailer or wholesale purchaser-consumer who sells, dispenses, or offers for sale or dispensing, motor vehicle diesel fuel subject to the 15 ppm sulfur standard of § 80.520(a)(1), must affix the following conspicuous and legible label, in block letters of no less than 36-point bold type, and printed in a color contrasting with the background, to each pump stand:

LOW-SULFUR DIESEL FUEL

Recommended for use in all diesel vehicles.

Required for model year 2007 and later vehicles.

(c) Any retailer or wholesale purchaser-consumer who sells, dispenses, or offers for sale or dispensing, diesel fuel for nonroad equipment that does not meet the standards for motor vehicle diesel fuel, must affix the following conspicuous and legible label, in block letters of no less than 36-point bold type, and printed in a color contrasting with the background, to each pump stand:

NONROAD DIESEL FUEL—WARNING

May damage or destroy highway engines and their emission controls.

Federal Law *prohibits* use in any highway vehicle.

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(d) The labels required by paragraphs (a) through (c) of this section must be placed on the vertical surface of each pump housing and on each side with gallonage and price meters. The labels shall be on the upper two-thirds of the pump, in a location where they are clearly readable by the public.

§§ 80.571–80.579 [Reserved]

Sampling and Testing

§ 80.580 What are the sampling and testing methods for sulfur?

(a) *Diesel fuel and diesel fuel additives.* For purposes of §§ 80.520 and 80.521, the sulfur content of diesel and diesel fuel additives is to be determined in accordance with this section.

(1) *Sampling method.* The applicable sampling methodology provided in § 80.330(b).

(2) *Test method for sulfur.* (i) For diesel fuel and diesel fuel additives subject to the 15 ppm sulfur standard of § 80.520(a)(1), the American Society for Testing and Materials (ASTM) standard method D 6428–99, entitled "Test Method for Total Sulfur in Liquid Aromatic Hydrocarbons and Their Derivatives by Oxidative Combustion and Electrochemical Detection."

(ii) For diesel fuel and diesel fuel additives subject to the 500 ppm sulfur standard of 80.520(c), ASTM standard method D 2622–98, "Standard Test Method for Sulfur in Petroleum Products by X-Ray Spectrometry."

(3) *Alternative test methods for sulfur.* (i) For diesel fuel and diesel fuel additives subject to the 15 ppm standard of § 80.520(a)(1), sulfur content may be determined using ASTM D 5453–99, entitled "Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Motor Fuels and Oils by Ultraviolet Fluorescence," or ASTM D 3120–96, entitled "Standard Test Method for Trace Quantities of Sulfur in Light Liquid Petroleum Hydrocarbons by Oxidative Microcoulometry," provided that the refiner or importer test result is correlated with the appropriate method specified in paragraph (a)(2) of this section.

(ii) For diesel fuel and diesel fuel additives subject to the 500 ppm standard of § 80.520(c), sulfur content may be determined using ASTM D 5453–99, "Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Motor Fuels and Oils by Ultraviolet Fluorescence," or ASTM D 6428–00, entitled "Test Method for Total Sulfur in Liquid Aromatic Hydrocarbons and Their Derivatives by Oxidative Combustion and Electrochemical Detection," provided that the refiner or importer test result is correlated with the appropriate method specified in paragraph (a)(2) of this section.

(4) *Adjustment Factor for downstream test results.* An adjustment factor of negative 2 ppm shall be applied to the test results, to account for test variability, but only for testing of motor vehicle diesel fuel identified as subject to the 15 ppm sulfur standard of § 80.520(a)(1), at a downstream location as defined in § 80.500(f).

(b) *Incorporation by reference.* ASTM Standard Methods D 2622–98, "Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry," D 3120–96, "Standard Test Method for Trace Quantities of Sulfur in Light Liquid Petroleum Hydrocarbons by Oxidative Microcoulometry," D 6428–99, "Test Method for Total Sulfur in Liquid Aromatic Hydrocarbons and Their Derivatives by Oxidative Combustion and Electrochemical Detection," and D 5453–00, "Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Motor Fuels and Oils by Ultraviolet Fluorescence," are incorporated by reference. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428–2959. Copies may be inspected at the Air Docket Section (LE–131), Room M–1500, U.S. Environmental Protection Agency, Docket No. A–99–06, 401 M Street, SW, Washington, DC 20460, or at the Office of the Federal Register, 800 North Capitol Street, NW, Suite 700, Washington, DC.

§§ 80.581–80.589 [Reserved]

Recordkeeping and Reporting Requirements

§ 80.590 What are the product transfer document requirements for motor vehicle diesel fuel?

On each occasion that any person transfers custody or title to motor vehicle diesel fuel, including distillates used or intended to be used as motor vehicle diesel fuel, except when such fuel is dispensed into motor vehicles at a retail outlet or wholesale purchaser-facility, the transferor must provide to the transferee documents identifying the fuel as motor vehicle diesel fuel, and which include the following information:

(a) The name and address of the transferor and transferee.

(b) The volume of motor vehicle diesel fuel which is being transferred.

(c) The location of the motor vehicle diesel fuel at the time of the transfer.

(d) The date of the transfer.

(e) Except as provided in 40 CFR 69.51, an accurate statement, as applicable, that:

(1) "This fuel complies with the 15 ppm low sulfur standard for motor vehicle diesel fuel.";

(2) "This fuel complies with the 500 ppm high sulfur standard for motor vehicle diesel fuel and is for use only in MY 2006 and older diesel motor vehicles.";

(3) "This is high sulfur motor vehicle diesel fuel for use only in Guam, American Samoa, or the Northern Mariana Islands.";

(4) "This diesel fuel is for export use only.";

(5) "This diesel fuel is for research, development, or testing purposes only.";

(6) "This diesel fuel is for use in diesel vehicles having an EPA-approved national security exemption only.".

(f) For motor vehicle diesel fuel that contains visible evidence of the dye solvent red 164, and is intended to be used in a manner that is tax-exempt as defined under section 4082 of the Internal Revenue Code, the following statement:

This fuel is motor vehicle diesel fuel for tax-exempt use only, in accordance with Section 4082 of the Internal Revenue Code.

(g) Except for transfers to truck carriers, retailers or wholesale purchaser-consumers, product codes may be used to convey the information required under this section if such codes are clearly understood by each transferee. Codes used to convey the statement in paragraph (e)(1) of this section must contain the number "15", and codes used to convey the statement in paragraph (e)(2) of this section must contain the number "500".

(h) Beginning June 1, 2001 and ending May 31, 2005, any transfer subject to this section, which is also subject to the early credit provisions of § 80.531(b), must comply with all applicable requirements of this section except those in paragraph (e) of this section.

(i) Beginning June 1, 2005 and ending May 31, 2006, any transfer subject to this section, which is also subject to the early credit requirements of § 80.531(c), must comply with all applicable requirements of this section.

§ 80.591 What are the product transfer document requirements for additives to be used in diesel fuel?

(a) Except as provided in paragraphs (b) and (d) of this section, on each occasion that any person transfers custody or title to a motor vehicle diesel fuel additive to a party in the additive distribution system or in the motor vehicle diesel fuel distribution system for use downstream of the diesel fuel refiner, the transferor must provide to the transferee documents which identify the additive, and:

(1) Identify the name and address of the transferor and transferee; the date of transfer; the location at which the transfer took place; the volume of additive transferred; and

(2) Indicates compliance with the 15 ppm sulfur standard by inclusion of the following statement:

The sulfur content of this diesel fuel additive does not exceed 15 ppm.

(b) On each occasion that any person transfers custody or title to a motor vehicle diesel fuel additive subject to the requirements of § 80.521(b), to a party in the additive distribution system or in the motor vehicle diesel fuel distribution system for use in diesel fuel downstream of the diesel fuel refiner, the transferor must provide to the transferee documents which identify the additive, and:

(1) Identify the name and address of the transferor and transferee; the date of transfer; the location at which the transfer took place; the volume of additive transferred.

(2) Indicate the high sulfur potential of the additive by inclusion of the following statement:

This motor vehicle diesel fuel additive may exceed the federal 15 ppm sulfur standard. Improper use of this additive may result in non-complying diesel fuel.

(3) Includes the following information:

(i) The additive's maximum sulfur concentration;

(ii) The maximum recommended concentration in volume percent for use of the additive in diesel fuel; and

(iii) The contribution to the sulfur level of the fuel, in ppm, that would result if the additive is used at the maximum recommended concentration.

(c) Except for transfers of motor vehicle diesel fuel additives to truck carriers, retailers or wholesale purchaser-consumers, product codes may be used to convey the information required under paragraphs (a) and (b) of this section, if such codes are clearly understood by each transferee. Codes used to convey the statement in paragraph (a)(2) of this section must contain the number "15" and codes used to convey the statement in paragraph (b)(2) of this section may not contain such number.

(d) For those motor vehicle diesel fuel additives which are sold in containers for use by the ultimate consumer of diesel fuel, each transferor must have displayed on the additive container, in a legible and conspicuous manner, either of the following statements, as applicable:

(1) "This diesel fuel additive complies with the federal low sulfur content requirements for use in diesel motor vehicles."; or

(2) For those additives sold in containers for use by the ultimate consumer, with a sulfur content in excess of 15 ppm: "This diesel fuel additive does not comply with federal low sulfur content requirements for use in model year 2007 and newer diesel motor vehicles.".

§ 80.592 What records must be kept?

(a) *Records that must be kept by parties in the motor vehicle diesel fuel and motor vehicle diesel fuel additive distribution systems.* Beginning June 1, 2006, or for a refiner the first compliance period in which the refiner is generating early credits under § 80.531(b) or (c), whichever is earlier, any person who produces, imports, sells, offers for sale, dispenses, distributes, supplies, offers for supply, stores, or transports motor vehicle diesel fuel subject to the provisions of this subpart, must keep the following records:

(1) The applicable product transfer documents required under §§ 80.590 and 80.591;

(2) For any sampling and testing for sulfur content, cetane index or aromatics content of motor vehicle diesel fuel or motor vehicle diesel fuel additives, conducted as part of a quality assurance program or otherwise:

(i) The location, date, time and storage tank or truck identification for each sample collected;

(ii) The name and title of the person who collected the sample and the person who performed the testing; and

(iii) The results of the tests for sulfur content (including where applicable the test results with and without application of the adjustment factor under § 80.580(a)(4)) or other standard content, and the volume of product in the storage tank or container from which the sample was taken;

(3) The actions the party has taken, if any, to stop the sale or distribution of any motor vehicle diesel fuel found not to be in compliance with the sulfur standards specified in this subpart, and the actions the party has taken, if any, to identify the cause of any noncompliance and prevent future instances of noncompliance.

(b) *Additional records to be kept by refiners and importers of motor vehicle diesel fuel subject to temporary refiner relief standards, small refiner standards, and early credit provisions.* Beginning June 1, 2006, or for a refiner the first compliance period in which the refiner is generating early credits under § 80.531(b) or (c), whichever is earlier, any refiner producing motor vehicle diesel fuel subject to the sulfur standard under § 80.520(a)(1), for each of its refineries, and any importer importing such motor vehicle diesel fuel, shall keep records that include the following information for each batch of motor vehicle diesel fuel produced or imported:

(1) The batch volume.

(2) The batch number, assigned under the batch numbering procedures under § 80.65(d)(3).

(3) The date of production or import.

(4) A record designating the batch as meeting the 500 ppm sulfur standard or the 15 ppm sulfur standard.

(5) For foreign refiners, the designations and other records required to be kept under § 80.620.

(6) In the case of importers, the designations and other records required under § 80.620(o).

(7) Information regarding credits, kept separately for each calendar year compliance period, kept separately for each refinery and in the case of importers, kept separately for imports into each CTA, as follows:

(i) The number of credits in the refiner's or importer's possession at the beginning of the calendar year;

(ii) The number of credits generated;

(iii) The number of credits used;

(iv) If any were obtained from or transferred to other parties, for each such other party, its name, its EPA refiner or importer registration number consistent with § 80.593(d), in the case of credits generated by an importer the port and CTA of import of the diesel fuel that generated the credits, and the number obtained from, or transferred to, the other party;

(v) The number in the refiner's or importer's possession that will carry over into the subsequent calendar year compliance period; and

(vi) Commercial documents that establish each transfer of credits from the transferor to the transferee.

(8) The calculations used to determine compliance with the volume requirements of this subpart.

(9) The calculations used to determine the number of credits generated.

(10) A copy of reports submitted to EPA under § 80.593.

(c) *Additional records importers must keep.* Any importer shall keep records

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that identify and verify the source of each batch of certified diesel fuel program foreign refiner (DFR)-Diesel and non-certified DFR-Diesel imported and demonstrate compliance with the requirements under § 80.620.

(d) *Length of time records must be kept.* The records required in this section shall be kept for five years from the date they were created, except that records relating to credit transfers shall be kept by the transferor for 5 years from the date the credits were transferred, and shall be kept by the transferee for 5 years from the date the credits were transferred, used or terminated, whichever is later.

(e) *Make records available to EPA.* On request by EPA the records required in paragraphs (a), (b) and (c) of this section must be made available to the Administrator or the Administrator's authorized representative. For records that are electronically generated or maintained the equipment and software necessary to read the records shall be made available, or if requested by EPA, electronic records shall be converted to paper documents which shall be provided to the Administrator's authorized representative.

§ 80.593 What are the reporting and registration requirements for refiners and importers of motor vehicle diesel fuel subject to temporary refiner relief standards?

Beginning with 2006, or the first compliance period during which credits are generated under § 80.531(b) or (c), whichever is earlier, any refiner or importer who produces or importes motor vehicle diesel fuel subject to the 500 ppm sulfur standard under § 80.520(c), or any refiner or importer who generates, uses, obtains or transfers credits under §§ 80.530 through 80.532, and continuing for each year thereafter, must submit to EPA annual reports that contain the information required in this section, and such other information as EPA may require:

(a) *Refiners and importers.* Refiners and importers must report the following information separately for each refinery or CTA, in the case of importers, subject to a phase-in sulfur standard, small refiner standard or temporary refiner relief sulfur standard, or who generates, uses or transfers credits under §§ 80.530 through 80.532:

(1) The refiner's name and the EPA refinery registration number.

(2) For all motor vehicle diesel fuel produced for use in the United States during the compliance period:

(i) The total volume of motor vehicle diesel fuel produced;

(ii) The volume, in gallons, that complied with a sulfur content standard of 500 ppm; and

(iii) The volume, in gallons, that complied with the 15 ppm sulfur content standard.

(3) The percentage of the volume motor vehicle diesel fuel produced during the calendar year that met the 15 ppm sulfur standard and the percentage that met the 500 ppm sulfur standard prior to the application of any volume credits.

(4) The percentage of volume of motor vehicle diesel fuel produced meeting the 15 ppm sulfur standard after the inclusion of any credits.

(5) Information regarding credits, separately for each refinery and for credits or debits related to imported motor diesel fuel, separately by importer and separately by CTA of import as follows:

(i) The CTA of the refiner's refinery or the importer's or the foreign refiner's CTA and port of importation;

(ii) The number of credits at the beginning of the compliance period;

(iii) The number of credits generated;

(iv) The number of credits used;

(v) If any credits were obtained from or transferred to other refineries or import ports, for each other refinery or importer, its name, address (or Port) and CTA, EPA refinery or importer registration number, and the number of credits obtained from or transferred to the other refinery or importer (by import CTA);

(vi) The number of credits, if any, that will carry over to the subsequent compliance period; and

(vii) The number of credits in deficit that must be made up for the following year;

(6) The reporting requirements under § 80.620, if applicable.

(7) For each batch of motor vehicle diesel fuel produced or imported during the compliance period:

(i) The batch number assigned using the batch numbering conventions under § 80.65(d)(3) and the appropriate designation under § 80.523;

(ii) The date the batch was produced; and

(iii) The volume of the batch, in gallons.

(8) When submitting reports under this paragraph (a), any importer shall exclude certified DFR-Diesel.

(b) *Additional reporting requirements for importers.* Importers of motor vehicle diesel fuel subject to the 500 ppm sulfur standard must report the following information:

(1) The importer's name and EPA registration number.

(2) For each foreign refinery from which motor vehicle diesel fuel is imported that is subject to a sulfur standard under § 80.520(c), the importer must report, for each batch of diesel fuel imported, the information required to be reported under § 80.620(o).

(c) *Report submission.* Any annual report required by this section shall be:

(1) Signed and certified as meeting all the applicable requirements of this subpart by the owner or a responsible corporate officer of the refiner or importer; and

(2) Submitted to EPA no later than the last day of February for the prior calendar year period.

§ 80.594 What are the pre-compliance reporting requirements?

(a) Beginning on June 1, 2003, and on June 1, 2004 and June 1, 2005, all refiners and importers planning to produce or import motor vehicle diesel fuel subject to the provisions of this subpart, shall submit the following information to EPA:

(1) Any changes to the information submitted for the company registration;

(2) Any changes to the information submitted for any refinery or import facility registration;

(3) An estimate of the annual production or importation, in gallons, after June 1, 2006, for each refinery and import facility, of 15 ppm motor vehicle diesel fuel produced from crude oil and, if applicable, 500 ppm motor vehicle diesel fuel produced from crude oil, and the volumes of each grade of motor vehicle diesel fuel produced from other sources;

(4) If expecting to participate in the temporary compliance options provisions and the credit trading program, estimates of the number of credits to be generated and/or used each year the program is applicable;

(5) Information regarding engineering plans (e.g., design and construction), the status of obtaining any necessary permits, and capital commitments for making the necessary modifications to produce low sulfur motor vehicle fuel, and actual construction progress. The pre-compliance reports due 2004 and 2005 must provide an update of the progress in each of these areas.

(b) Beginning on June 1, 2003, all approved small refiners shall submit the following additional information to EPA, as applicable:

(1) In the case of a refinery with an approved application under § 80.552(a):

(i) A showing that sufficient sources of 15 ppm motor vehicle diesel fuel will likely be available in its marketing area after June 1, 2006 and through 2010;

(ii) If after 2003 the sources of 15 ppm motor vehicle diesel fuel decrease, the pre-compliance reports for 2004 and/or 2005 must identify this change and must include a supplementary showing that the sources of 15 ppm motor vehicle diesel fuel are still sufficient.

(2) In case of a refinery with an approved application under § 80.552(c), a demonstration that by June 1, 2006 its motor vehicle diesel fuel will be at 15 ppm sulfur at a volume at least 85% of its baseline motor vehicle diesel fuel volume.

(c) For each refiner and importer approved under § 80.540, a demonstration that by June 1, 2006 all of its motor vehicle diesel fuel will be at 15 ppm sulfur at a volume of at least 85% of its baseline motor vehicle diesel fuel volume.

(d) By July 1, 2006, each refiner and importer of motor vehicle diesel fuel shall submit a report to EPA stating that the production or importation of 15 ppm sulfur motor vehicle diesel fuel commenced by June 1, 2006.

§ 80.595 How does a refiner apply for a motor vehicle diesel fuel volume baseline?

(a) Any small refiner applying for extension of the duration of its small refiner gasoline sulfur standards of § 80.240, under §§ 80.552(c) and 80.553, or any refiner applying for an extension of the duration of the GPA standards under § 80.540 must apply for a motor vehicle diesel fuel volume baseline by December 31, 2001. A separate volume baseline must be sought for each refinery for which application of the provisions of § 80.553 or § 80.540 is sought.

(b) The volume baseline must be sent via certified mail with return receipt or express mail with return receipt to: U.S. EPA-Attn: Diesel Baseline (6406J), 1200 Pennsylvania Avenue, NW (6406J), Washington, DC 20460 (certified mail/return receipt) or Attn: Diesel Baseline, Transportation and Regional Programs Division, 501 3rd Street, NW (6406J), Washington, DC 20001 (express mail/return receipt).

(c) The motor vehicle diesel fuel volume baseline application must include the following information:

(1) A listing of the names and addresses of all refineries owned by the refiner for which the refiner is applying for a motor vehicle diesel fuel volume baseline.

(2) The average annual volume (in gallons) of motor vehicle diesel fuel produced for U.S. use in 1998 and 1999, for each refinery for which the refiner is applying for such baseline, calculated in accordance with § 80.596. The refiner shall follow the procedures, applicable to volume baselines and using motor vehicle diesel fuel instead of gasoline, specified in §§ 80.91 through 80.93 to establish the volume of motor vehicle diesel fuel that was produced for U.S. use in 1998 and 1999 for purposes of establishing a volume baseline under this section.

(3) A letter signed by the president, chief operating, or chief executive officer of the company, or his/her delegate, stating that the information contained in the volume baseline determination is true to the best of his/her knowledge.

(4) Name, address, phone number, facsimile number, and e-mail address (if availabale) of a corporate contact person.

(5) The following information for each batch of motor vehicle diesel fuel produced for U.S. use in 1998 and 1999:

(i) Batch number assigned to the batch under procedures such as those in § 80.65(d) or § 80.101(i), or, if unavailable, such other identifying information as is available; and

(ii) Volume of the batch, in gallons.

(6) For a refinery that was not in operation during part or all of the period 1998 and 1999, the information required under this paragraph (c) for the motor vehicle diesel fuel produced for U.S. use during the most recent calendar year that the refinery was in operation after the refinery was reactivated.

(d) Within 120 days of receipt of an application under this section, EPA will notify the refiner of an approval of the refinery's baseline, or of any deficiencies in the application.

(e) If at any time the baseline submitted in accordance with the requirements of this section is determined to be incorrect, EPA will notify the refiner of the corrected baseline. The corrected baseline shall apply to all applicable compliance calculations under this subpart.

(f)(1) If insufficient information is available for the Administrator to establish a baseline under the provisions of paragraph (c) of this section and § 80.596(a), the refiner shall submit additional information sufficient for the Administrator to establish a baseline.

(2) To satisfy the requirements of paragraph (f)(1) of this section, the Administrator may require, and consider, any information pertinent to establish a baseline, including:

(i) Motor vehicle diesel fuel production volumes for other years;

(ii) Crude capacity of the refinery;

(iii) The ratio, or the typical ratio, for other similarly sized or configured refineries, between motor vehicle diesel fuel production and gasoline production.

§ 80.596 How is a refinery motor vehicle diesel fuel volume baseline calculated?

(a) For purposes of this subpart, a refinery's motor vehicle diesel fuel volume baseline is calculated using the following equation:

$$V_{Base} = \frac{\sum_{i=1}^{n}(V_i)}{m/12}$$

Where:

V_{Base} = Volume baseline value.

V_i = Volume of motor vehicle diesel fuel batch i.

n = Total number of batches of motor vehicle diesel fuel produced for U.S. use during January 1, 1998 through December 31, 1999 (or the total number of batches of motor vehicle diesel fuel produced during the most recent calendar year the refinery was in operation after being reactivated pursuant to § 80.595(c)(6)); or, for a foreign refinery, the total number of batches of motor vehicle diesel fuel produced and imported into the U.S. during January 1, 1998 through December 31, 1999 (or the total number of batches of motor vehicle diesel fuel produced and imported into the U.S. during the most recent calendar year the refinery was in operation after being reactivated pursuant to § 80.595(c)(6)).

i = Individual batch of motor vehicle diesel fuel produced during January 1, 1998 through December 31, 1999 (or individual batch of motor vehicle diesel fuel produced during the most recent calendar year the refinery was in operation after being reactivated pursuant to § 80.595(c)(6)); or, for a foreign refinery, individual batch of motor vehicle diesel fuel produced and imported into the U.S. during January 1, 1998 through December 31, 1999 (or individual batch of motor vehicle diesel fuel produced and imported into the U.S. during the most recent calendar year the refinery was in operation after being reactivated pursuant to § 80.595(c)(6)).

m = Number of months in the baseline period (24 except in the case of a startup or reactivation).

(b) If insufficient information is available for the Administrator to establish a baseline under paragraph (a) of this section, the baseline may be determined under the provisions of § 80.595(f).

§ 80.597 What are the registration requirements?

Refiners having any refinery that is subject to a sulfur standard under § 80.520(c), and importers importing such diesel fuel, must provide EPA the information under § 80.76 no later than December 31, 2001, if such information has not been provided under the provisions of this part. In addition, for each import facility, the same identifying information as required for each refinery under § 80.76(c) must be provided.

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§§ 80.596–80.599 [Reserved]

Exemptions

§ 80.600 What are the requirements for obtaining an exemption for motor vehicle diesel fuel used for research, development or testing purposes?

(a) *Written request for R&D exemption.* Any person may receive an exemption from the provisions of this subpart for motor vehicle diesel fuel used for research, development, or testing ("R&D") purposes by submitting the information listed in paragraph (c) of this section to:

(1) Director (6406J), Transportation and Regional Programs Division, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460 (postal mail); or

(2) Director (6406J), Transportation and Regional Programs Division, U.S. Environmental Protection Agency, 501 3rd Street, NW., Washington, DC 20001 (express mail/courier); and

(3) Director (2242A), Air Enforcement Division, U.S. Environmental Protection Agency, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.

(b) *Criteria for an R&D exemption.* For an R&D exemption to be granted, the person requesting an exemption must:

(1) Demonstrate a purpose that constitutes an appropriate basis for exemption;

(2) Demonstrate that an exemption is necessary;

(3) Design an R&D program to be reasonable in scope; and

(4) Exercise a degree of control consistent with the purpose of the program and EPA's monitoring requirements.

(c) *Information required to be submitted.* To demonstrate each of the elements in paragraphs (b)(1) through (4) of this section, the person requesting an exemption must include the following information in the written request required under paragraph (a) of this section:

(1) A concise statement of the purpose of the program demonstrating that the program has an appropriate R&D purpose.

(2) An explanation of why the stated purpose of the program cannot be achieved in a practicable manner without performing one or more of the prohibited acts under this subpart.

(3) To demonstrate the reasonableness of the scope of the program:

(i) An estimate of the program's duration in time and, if appropriate, mileage;

(ii) An estimate of the maximum number of vehicles or engines involved in the program;

(iii) The manner in which the information on vehicles and engines used in the program will be recorded and made available to the Administrator upon request; and

(iv) The quantity of diesel fuel which does not comply with the requirements of §§ 80.520 through 80.525.

(4) With regard to control, a demonstration that the program affords EPA a monitoring capability, including:

(i) The site(s) of the program (including facility name, street address, city, county, state, and zip code);

(ii) The manner in which information on vehicles and engines used in the program will be recorded and made available to the Administrator upon request;

(iii) The manner in which information on the diesel fuel used in the program (including quantity, fuel properties, name, address, telephone number and contact person of the supplier, and the date received from the supplier), will be recorded and made available to the Administrator upon request;

(iv) The manner in which the party will ensure that the R&D fuel will be segregated from motor vehicle diesel fuel and fuel pumps will be labeled to ensure proper use of the R&D diesel fuel;

(v) The name, address, telephone number and title of the person(s) in the organization requesting an exemption from whom further information on the application may be obtained; and

(vi) The name, address, telephone number and title of the person(s) in the organization requesting an exemption who is responsible for recording and making available the information specified in this paragraph (c), and the location where such information will be maintained.

(d) *Additional requirements.* (1) The product transfer documents associated with R&D motor vehicle diesel fuel must comply with requirements of § 80.590(b)(5).

(2) The R&D diesel fuel must be designated by the refiner or supplier, as applicable, as R&D diesel fuel.

(3) The R&D diesel fuel must be kept segregated from non-exempt motor vehicle diesel fuel at all points in the distribution system.

(4) The R&D diesel fuel must not be sold, distributed, offered for sale or distribution, dispensed, supplied, offered for supply, transported to or from, or stored by a diesel fuel retail outlet, or by a wholesale purchaser-consumer facility, unless the wholesale purchaser-consumer facility is associated with the R&D program that uses the diesel fuel.

(5) At the completion of the program, any emission control systems or elements of design which are damaged or rendered inoperative shall be replaced on vehicles remaining in service, or the responsible person will be liable for a violation of the Clean Air Act Section 203(a)(3) unless sufficient evidence is supplied that the emission controls or elements of design were not damaged.

(e) *Mechanism for granting of an exemption.* A request for an R&D exemption will be deemed approved by the earlier of sixty (60) days from the date on which EPA receives the request for exemption, (provided that EPA has not notified the applicant of potential disapproval by that time), or the date on which the applicant receives a written approval letter from EPA.

(1) The volume of diesel fuel subject to the approval shall not exceed the estimated amount in paragraph (c)(3)(iv) of this section, unless EPA grants a greater amount in writing.

(2) Any exemption granted under this section will expire at the completion of the test program or three years from the date of approval, whichever occurs first, and may only be extended upon re-application consistent will all requirements of this section.

(3) The passage of sixty (60) days will not signify the acceptance by EPA of the validity of the information in the request for an exemption. EPA may elect at any time to review the information contained in the request, and where appropriate may notify the responsible person of disapproval of the exemption.

(4) In granting an exemption the Administrator may include terms and conditions, including replacement of emission control devices or elements of design, that the Administrator determines are necessary for monitoring the exemption and for assuring that the purposes of this subpart are met.

(5) Any violation of a term or condition of the exemption, or of any requirement of this section, will cause the exemption to be void ab initio.

(6) If any information required under paragraph (c) of this section should change after approval of the exemption, the responsible person must notify EPA in writing immediately. Failure to do so may result in disapproval of the exemption or may make it void ab initio, and may make the party liable for a violation of this subpart.

(f) *Effects of exemption.* Motor vehicle diesel fuel that is subject to an R&D exemption under this section is exempt from other provisions of this subpart provided that the fuel is used in a manner that complies with the purpose of the program under paragraph (c) of this section and the requirements of this section.

(g) *Notification of Completion.* The party shall notify EPA in writing within thirty (30) days of completion of the R&D program.

§ 80.601 What requirements apply to motor vehicle diesel fuel for use in the Territories?

The sulfur standards of § 80.520(a)(1) and (c) do not apply to diesel fuel that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in the Territories of Guam, American Samoa or the Commonwealth of the Northern Mariana Islands provided that such diesel fuel is:

(a) Designated by the refiner or importer as high sulfur diesel fuel only for use in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands;

(b) Used only in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands;

(c) Accompanied by documentation that complies with the product transfer document requirements of § 80.590(e)(3); and

(d) Segregated from non-exempt motor vehicle diesel fuel at all points in the distribution system from the point the diesel fuel is designated as exempt fuel only for use in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands, while the exempt fuel is in the United States but outside these Territories.

§ 80.602 What exemption applies to diesel fuel used in vehicles having a national security exemption from motor vehicle emissions standards?

The motor vehicle diesel fuel standards of § 80.520(a)(1), (a)(2), and (c) do not apply to diesel fuel that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in:

(a) Vehicles for which EPA has granted a national security exemption under 40 CFR 85.1708 from motor vehicle emissions standards under 40 CFR Part 86; or

(b) Tactical military motor vehicles that are not subject to a national security exemption from motor vehicle emissions standards but for national security purposes (for purposes of readiness for deployment oversees) need to be fueled on the same fuel as motor vehicles for which EPA has granted a national security exemption, provided that such fuel is:

(1) Used only in vehicles identified in paragraph (a) of this section or this paragraph (b);

(2) Accompanied by product transfer documents as required under § 80.590;

(3) Segregated from non-exempt motor vehicle diesel fuel at all points in the distribution system; and

(4) Dispensed from a fuel pump stand, fueling truck or tank that is labeled under the provisions of § 80.570(c). Any such fuel pump stand, fueling truck or tank may also be labeled with the appropriate designation of the fuel, such as "JP–8".

§§ 80.603–80.609 [Reserved]

Violation Provisions

§ 80.610 What acts are prohibited under the diesel fuel sulfur program?

No person shall:

(a) *Standard or dye violation.* Produce, import, sell, offer for sale, dispense, supply, offer for supply, store or transport motor vehicle diesel fuel that does not comply with the applicable standards and dye requirements under § 80.520.

(b) *Additive violation.* (1) Produce, import, sell, offer for sale, dispense, supply, offer for supply, store or transport any motor vehicle diesel fuel additive for use at a downstream location that does not comply with the requirements under § 80.521(a) or (b), as applicable.

(2) Blend or permit the blending into motor vehicle diesel fuel at a downstream location, or use, or permit the use, as motor vehicle diesel fuel, of any additive which does not comply with the requirements of § 80.521(a) or (b), as applicable.

(c) *Used motor oil violation.* Introduce into the fuel system of model year 2007 or later diesel motor vehicles, or permit the introduction into the fuel system of such vehicles of used motor oil, or used motor oil blended with diesel fuel, which does not comply with the requirements of § 80.522.

(d) *Improper fuel usage violation.* (1) Introduce, or permit the introduction of, diesel fuel into model year 2007 or later diesel motor vehicles, and beginning December 1, 2010 into any diesel motor vehicle, which does not comply with the standards and dye requirements of § 80.520(a) and (b).

(2) Produce, import, sell, offer for sale, dispense, offer for supply, store, or transport for use in model year 2007 or later diesel motor vehicles, or introduce or permit the introduction into such motor vehicles, motor vehicle diesel fuel that is identified as other than diesel fuel complying with the 15 ppm sulfur standard; and beginning December 1, 2010, diesel fuel for use in or introduced into any diesel motor vehicle.

(e) *Cause another party to violate.* Cause another person to commit an act in violation of paragraphs (a) through (d) of this section.

(f) *Cause violating fuel or additive to be in the distribution system.* Cause motor vehicle diesel fuel to be in the motor vehicle diesel fuel distribution system which does not comply with the applicable standard and dye requirements of § 80.520(a) and (b), or cause any motor vehicle diesel fuel additive to be in the motor vehicle diesel fuel additive distribution system which does not comply with the applicable sulfur, cetane, and/or aromatics standards of § 80.521.

§ 80.611 What evidence may be used to determine compliance with the prohibitions and requirements of this subpart and liability for violations of this subpart?

(a) *Compliance with sulfur, cetane, and aromatics standards.* Compliance with the standards in §§ 80.520, 80.521, and 80.522 shall be determined based on the level of the applicable component or parameter, using the sampling methodologies specified in § 80.330(b), as applicable, and the appropriate testing methodologies specified in § 80.580(a)(2) for sulfur, or one of the alternative methodologies for sulfur as approved under § 80.580(a)(3); § 80.2(w) for cetane index; and § 80.2(z) for aromatic content. Any evidence or information, including the exclusive use of such evidence or information, may be used to establish the level of the applicable component or parameter in the diesel fuel or additive, or motor oil to be used in diesel fuel, if the evidence or information is relevant to whether that level would have been in compliance with the standard if the regulatory sampling and testing methodology had been correctly performed. Such evidence may be obtained from any source or location and may include, but is not limited to, test results using methods other than the compliance methods in this paragraph (a), business records, and commercial documents.

(b) *Compliance with other requirements.* Determination of compliance with the requirements of this subpart other than the standards described in paragraph (a) of this section and in §§ 80.520, 80.521, and 80.522, and determination of liability for any violation of this subpart, may be based on information obtained from any source or location. Such information may include, but is not limited to, business records and commercial documents.

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§ 80.612 Who is liable for violations of this subpart?

(a) *Persons liable for violations of prohibited acts.*—(1) *Standard, dye, additives, motor oil, and introduction violations.* (i) Any refiner, importer, distributor, reseller, carrier, retailer, or wholesale purchaser-consumer who owned, leased, operated, controlled or supervised a facility where a violation of § 80.610(a) through (d) occurred, or any other person who violates § 80.610(a) through (d), is deemed liable for the applicable violation.

(ii) Any person who causes another person to violate § 80.610(a) through (d) is liable for a violation of § 80.610(e).

(iii) Any refiner, importer, distributor, reseller, carrier, retailer, or wholesale purchaser-consumer who produced, imported, sold, offered for sale, dispensed, supplied, offered to supply, stored, transported, or caused the transportation or storage of, motor vehicle diesel fuel that violates § 80.610(a), is deemed in violation of § 80.610(e).

(iv) Any person who produced, imported, sold, offered for sale, dispensed, supplied, offered to supply, stored, transported, or caused the transportation or storage of a motor vehicle diesel fuel additive which is used in motor vehicle diesel fuel that is found to violate § 80.610(a), is deemed in violation of § 80.610(e).

(2) *Cause violating motor vehicle diesel fuel or additive to be in the distribution system.* Any refiner, importer, distributor, reseller, carrier, retailer, or wholesale purchaser-consumer or any other person who owned, leased, operated, controlled or supervised a facility from which motor vehicle diesel fuel or additive was released into the motor vehicle diesel fuel or additive distribution system which does not comply with the applicable standards or dye requirements of § 80.520 or § 80.521, is deemed in violation of § 80.610(f).

(3) *Branded refiner/importer liability.* Any refiner or importer whose corporate, trade, or brand name, or whose marketing subsidiary's corporate, trade, or brand name appeared at a facility where a violation of § 80.610(a) occurred, is deemed in violation of § 80.610(a).

(4) *Carrier causation.* In order for a motor vehicle diesel fuel or motor vehicle diesel fuel additive carrier to be liable under paragraph (a)(1)(ii), (iii) or (iv) of this section, as applicable, EPA must demonstrate, by reasonably specific showing by direct or circumstantial evidence, that the carrier caused the violation.

(5) *Parent corporation.* Any parent corporation is liable for any violations of this subpart that are committed by any subsidiary.

(6) *Joint venture.* Each partner to a joint venture is jointly and severally liable for any violation of this subpart that occurs at the joint venture facility or is committed by the joint venture operation.

(b) *Persons liable for failure to comply with other provisions ofthis subpart.* Any person who:

(1) Fails to comply with the requirements of a provision of this subpart not addressed in paragraph (a) of this section is liable for a violation of that provision; or

(2) Causes another person to fail to comply with the requirements of a provision of this subpart not addressed in paragraph (a) of this section, is liable for causing a violation of that provision.

§ 80.613 What defenses apply to persons deemed liable for a violation of a prohibited act?

(a) *Presumptive liability defenses.* (1) Any person deemed liable for a violation of a prohibition under § 80.612(a)(1)(i) or (iii), (a)(2), or (a)(3), will not be deemed in violation if the person demonstrates:

(i) The violation was not caused by the person or the person's employee or agent;

(ii) Product transfer documents account for fuel or additive found to be in violation and indicate that the violating product was in compliance with the applicable requirements when it was under the party's control;

(iii) The person conducted a quality assurance sampling and testing program, as described in paragraph (d) of this section, except for those parties subject to the provisions of paragraph (a)(1)(iv) or (v) of this section. A carrier may rely on the quality assurance program carried out by another party, including the party who owns the diesel fuel in question, provided that the quality assurance program is carried out properly. Retailers, wholesale purchaser-consumers, and ultimate consumers of diesel fuel are not required to conduct quality assurance programs;

(iv) For refiners and importers of motor vehicle diesel fuel subject to the 15 ppm standard under § 80.520(a)(1), test results which:

(A) Were conducted according to the test methodology required under § 80.580 (a)(2) or an approved alternative test method under § 80.580(a)(3); and

(B) Establish that, when it left the party's control, the sulfur content of motor vehicle diesel fuel subject to the 15 ppm standard did not exceed 15 ppm; and

(v) For any person who, at a downstream location, blends a diesel fuel additive subject to the requirements of § 80.521(b) into motor vehicle diesel fuel subject to the sulfur standard under § 80.520(a)(1), except a blender who blends additives into fuel trucks at a truck loading rack subject to the provisions of (d)(1) of this section, test results which are conducted subsequent to the blending of the additive into the fuel, and which comply with the requirements of paragraphs (a)(4)(iv)(A) and (B) of this section.

(2) Any party deemed liable for a violation under § 80.612(a)(1)(iv), in regard to a diesel fuel additive subject to the requirements of § 80.521(a), will not be deemed in violation if the person demonstrates that:

(i) Product transfer document(s) account for the additive in the fuel found to be in violation, which comply with the requirements under § 80.591(a), and indicate that the additive was in compliance with the applicable requirements while it was under the party's control; and

(ii) For the additive's manufacturer or importer, test results which accurately establish that, when it left the party's control, the additive in the diesel fuel determined to be in violation did not have a sulfur content in excess of 15 ppm.

(A) Analysis of the additive sulfur content pursuant to this paragraph (a)(2) may be conducted at the time the batch was manufactured or imported, or on a sample of that batch which the manufacturer or importer retains for such purpose for a minimum of two years from the date the batch was manufactured or imported.

(B) After two years from the date the additive batch was manufactured or imported, the additive manufacturer or importer is no longer required to retain samples for the purpose of complying with the testing requirements of this paragraph (a)(2) of this section.

(C) The analysis of the sulfur content of the additive must be conducted pursuant to the requirements of § 80.580(a).

(3) Any person who is deemed liable for a violation under § 80.612 (a)(1)(iv) with regard to a diesel fuel additive subject to the requirements of § 80.521(b), will not be deemed in violation if the person demonstrates that:

(i) The violation was not caused by the party or the party's employee or agent;

(ii) Product transfer document(s) which comply with the additive information requirements under § 80.591 (b), account for the additive in the fuel found to be in violation, and indicate that the additive was in compliance with the applicable requirements while it was under the party's control; and

(iii) For the additive's manufacturer or importer, test results which accurately establish that, when it left the party's control, the additive in the diesel fuel determined to be in violation was in conformity with the information on the additive product transfer document pursuant to the requirements of § 80.591(b). The testing procedures applicable under paragraph (a)(2) of this section, also apply under this paragraph (a)(3).

(b) *Branded refiner defenses.* In the case of a violation found at a facility operating under the corporate, trade or brand name of a refiner or importer, or a refiner's or importer's marketing subsidiary, the refiner or importer must show, in addition to the defense elements required under paragraph (a)(1) of this section, that the violation was caused by:

(1) An act in violation of law (other than the Clean Air Act or this Part 80), or an act of sabotage or vandalism;

(2) The action of any refiner, importer, retailer, distributor, reseller, oxygenate blender, carrier, retailer or wholesale purchaser-consumer in violation of a contractual agreement between the branded refiner or importer and the person designed to prevent such action, and despite periodic sampling and testing by the branded refiner or importer to ensure compliance with such contractual obligation; or

(3) The action of any carrier or other distributor not subject to a contract with the refiner or importer, but engaged for transportation of diesel fuel, despite specifications or inspections of procedures and equipment which are reasonably calculated to prevent such action.

(c) *Causation demonstration.* Under paragraph (a)(1) of this section for any person to show that a violation was not caused by that person, or under paragraph (b) of this section to show that a violation was caused by any of the specified actions, the person must demonstrate by reasonably specific showing, by direct or circumstantial evidence, that the violation was caused or must have been caused by another person and that the person asserting the defense did not contribute to that other person's causation.

(d) *Quality assurance and testing program.* To demonstrate an acceptable quality assurance program under paragraph (a)(1)(iii) of this section, a person must present evidence of the following:

(1) A periodic sampling and testing program to ensure the motor vehicle diesel fuel or additive the person sold, dispensed, supplied, stored, or transported, meets the applicable standards.

(2) For those parties who, at a downstream location, blend diesel fuel additives subject to the requirements of § 80.521(b) into fuel trucks at a truck loading rack, the periodic sampling and testing program required under this paragraph (d) must ensure, by taking into account the greater risk of noncompliance created through use of a high sulfur additive, that the diesel fuel into which the additive was blended meets the applicable standards subsequent to the blending.

(3) On each occasion when motor vehicle diesel fuel or additive is found not in compliance with the applicable standard:

(i) The person immediately ceases selling, offering for sale, dispensing, supplying, offering for supply, storing or transporting the non-complying product; and

(ii) The person promptly remedies the violation and the factors that caused the violation (for example, by removing the non-complying product from the distribution system until the applicable standard is achieved and taking steps to prevent future violations of a similar nature from occurring).

(4) For any carrier who transports motor vehicle diesel fuel or additive in a tank truck, the quality assurance program required under this paragraph (d) need not include its own periodic sampling and testing of the motor vehicle diesel fuel or additive in the tank truck, but in lieu of such tank truck sampling and testing, the carrier shall demonstrate evidence of an oversight program for monitoring compliance with the requirements of this subpart relating to the transport or storage of such product by tank truck, such as appropriate guidance to drivers regarding compliance with the applicable sulfur standard and product transfer document requirements, and the periodic review of records received in the ordinary course of business concerning motor vehicle diesel fuel or additive quality and delivery.

§ 80.614 What penalties apply under this subpart?

(a) Any person liable for a violation under § 80.612 is subject to civil penalties as specified in section 205 of the Clean Air Act for every day of each such violation and the amount of economic benefit or savings resulting from each violation.

(b)(1) Any person liable under § 80.612(a)(1) for a violation of an applicable standard or requirement under § 80.520, or of causing another party to violate such standard or requirement, is subject to a separate day of violation for each and every day the non-complying motor vehicle diesel fuel remains any place in the distribution system.

(2) Any person liable under § 80.612(a)(2) for causing motor vehicle diesel fuel to be in the distribution system which does not comply with an applicable standard or requirement of § 80.520, is subject to a separate day of violation for each and every day that the non-complying motor vehicle diesel fuel remains any place in the motor vehicle diesel fuel distribution system.

(3) Any person liable under § 80.612(a)(1) for blending into motor vehicle diesel fuel an additive violating the applicable sulfur standard pursuant to the requirements of § 80.521(a) or (b), as appropriate, or of causing another party to so blend or add such an additive, is subject to a separate day of violation for each and every day the motor vehicle diesel fuel into which the noncomplying additive was blended, remains any place in the fuel distribution system.

(4) For purposes of this paragraph (b), the length of time the motor vehicle diesel fuel in question remained in the motor vehicle diesel fuel distribution system is deemed to be twenty-five days, unless a person subject to liability or EPA demonstrates by reasonably specific showings, by direct or circumstantial evidence, that the non-complying motor vehicle diesel fuel remained in the distribution system for fewer than or more than twenty-five days.

(c) Any person liable under § 80.612(b) for failure to meet, or causing a failure to meet, a provision of this subpart is liable for a separate day of violation for each and every day such provision remains unfulfilled.

§§ 80.615–80.619 [Reserved]

Provisions for Foreign Refiners and Importers for Motor Vehicle Diesel Fuel Subject to a Temporary Compliance Option or Hardship Provision

§ 80.620 What are the additional requirements for motor vehicle diesel fuel produced by foreign refineries subject to a temporary refiner compliance option or hardship provisions?

(a) *Definitions.* (1) A foreign refinery is a refinery that is located outside the

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United States, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands (collectively referred to in this section as "the United States").

(2) A foreign refiner is a person who meets the definition of refiner under § 80.2(i) for a foreign refinery.

(3) A diesel fuel program foreign refiner ("DFR") is a foreign refiner that has been approved by EPA for participation in any motor vehicle diesel fuel credits program, motor vehicle diesel fuel temporary compliance option, hardship or GPA provisions of §§ 80.530 through 80.532, § 80.540, § 80.552, § 80.553, § 80.560 or § 80.561 (collectively referred to as "diesel foreign refiner program").

(4) "DFR-Diesel" means motor vehicle diesel fuel produced at a DFR refinery that is imported into the United States.

(5) "Non-DFR-Diesel" means motor vehicle diesel fuel that is produced at a foreign refinery that has not been approved as a DFR foreign refiner, motor vehicle diesel fuel produced at a DFR foreign refinery that is not imported into the United States, and motor vehicle diesel fuel produced at a DFR foreign refinery during a period when the foreign refiner has opted to not participate in the DFR-Diesel diesel foreign refiner program under paragraph (c)(3) of this section.

(6) "Certified DFR-Diesel" means DFR-Diesel the foreign refiner intends to include in the foreign refinery's compliance calculations under §§ 80.530 through 80.532, § 80.540, § 80.552, § 80.553, § 80.560 or § 80.561 and does include in these compliance calculations when reported to EPA.

(7) "Non-Certified DFR-Diesel" means DFR-Diesel fuel that a DFR foreign refiner imports to the United States that is not Certified DFR-Diesel.

(b) *Baseline.* For any foreign refiner to obtain approval under the diesel foreign refiner program of this subpart for any refinery, it must apply for approval under the applicable provisions of this subpart. To obtain approval the refiner is required, as applicable, to demonstrate a volume baseline for calendar years 1998 and 1999 for motor vehicle diesel fuel produced for use in the United States under §§ 80.595 and 80.596.

(1) The refiner shall follow the procedures, applicable to volume baselines and using motor vehicle diesel fuel instead of gasoline, in §§ 80.91 through 80.93 to establish the volume of motor vehicle diesel fuel that was produced at the refinery and imported into the United States during 1998 and 1999 for purposes of establishing a baseline under §§ 80.595 and 80.596.

(2) In making determinations for foreign refinery baselines EPA will consider all information supplied by a foreign refiner, and in addition may rely on any and all appropriate assumptions necessary to make such determinations.

(3) Where a foreign refiner submits a petition that is incomplete or inadequate to establish an accurate baseline, and the refiner fails to correct this deficiency after a request for more information, EPA will not assign an individual refinery motor vehicle diesel fuel volume baseline.

(c) *General requirements for DFR foreign refiners.* A foreign refiner of a refinery that is approved under the diesel foreign refiner program of this subpart must designate each batch of motor vehicle diesel fuel produced at the foreign refinery that is exported to the United States as either Certified DFR-Diesel or as Non-Certified DFR-Diesel, except as provided in paragraph (c)(3) of this section. It must further designate all Certified DFR-Diesel as complying with either the 15 ppm sulfur standard under § 80.520(a)(1) or the 500 ppm sulfur standard under § 80.520(c).

(1) In the case of Certified DFR-Diesel, the foreign refiner must meet all requirements that apply to refiners under this subpart, except that:

(i) For purposes of complying with the compliance option requirements of § 80.530, motor vehicle diesel fuel produced by a foreign refinery must comply separately for each Credit Trading Area of import, as defined in § 80.531(a)(5).

(ii) For purposes of complying with the compliance option requirements of § 80.530, credits obtained from any other refinery or from any importer must have been generated in the same Credit Trading Area as the Credit Trading Area of import of the fuel for which credits are needed to achieve compliance.

(iii) For purposes of generating credits under this subpart, credits shall be generated separately by Credit Trading Area of import and shall be designated by Credit Trading Area of importation and by port of importation.

(2) In the case of Non-Certified DFR-Diesel, the foreign refiner shall meet all the following requirements:

(i) The designation requirements in this section.

(ii) The reporting requirements in this section and § 80.593.

(iii) The product transfer document requirements in this section.

(iv) The prohibitions in this section and § 80.610.

(3)(i) Any foreign refiner that has been approved to produce motor vehicle diesel fuel subject to the diesel foreign refiner program for a foreign refinery under this subpart may elect to classify no diesel fuel imported into the United States as DFR-Diesel provided the foreign refiner notifies EPA of the election no later than November 1 of the prior calendar year.

(ii) An election under paragraph (c)(3)(i) of this section shall be for an entire calendar year and apply to all motor vehicle diesel fuel that is produced by the foreign refinery that is imported into the United States, and shall remain in effect for each succeeding year unless and until the foreign refiner notifies EPA of the termination of the election. The change in election shall take effect at the beginning of the next calendar year.

(d) *Designation, product transfer documents, and foreign refiner certification.* (1) Any foreign refiner of a foreign refinery that has been approved by EPA to produce motor vehicle diesel fuel subject to the diesel foreign refiner program must designate each batch of DFR-Diesel as such at the time the diesel fuel is produced, unless the refiner has elected to classify no diesel fuel exported to the United States as DFR-Diesel under paragraph (c)(3) of this section.

(2) On each occasion when any person transfers custody or title to any DFR-Diesel prior to its being imported into the United States, it must include the following information as part of the product transfer document information in this section:

(i) Identification of the diesel fuel as Certified DFR-Diesel or as Non-Certified DFR-Diesel, and if it is Certified DFR-Diesel, further designation as meeting the 500 ppm sulfur standard under § 80.520(c) or the 15 ppm sulfur standard under § 80.520(a)(1) pursuant to § 80.523; and

(ii) The name and EPA refinery registration number (under § 80.593) of the refinery where the DFR-Diesel was produced.

(3) On each occasion when DFR-Diesel is loaded onto a vessel or other transportation mode for transport to the United States, the foreign refiner shall prepare a certification for each batch of the DFR-Diesel that meets the following requirements.

(i) The certification shall include the report of the independent third party under paragraph (f) of this section, and the following additional information:

(A) The name and EPA registration number of the refinery that produced the DFR-Diesel;

(B) The identification of the diesel fuel as Certified DFR-Diesel or Non-Certified DFR-Diesel;

(C) The volume of DFR-Diesel being transported, in gallons;

(D) In the case of Certified DFR-Diesel:

(*1*) The sulfur content as determined under paragraph (f) of this section, and the designation of the fuel as complying with the 15 ppm sulfur content standard for motor vehicle diesel fuel under § 80.520(a)(1) or the 500 ppm sulfur content standard for motor vehicle diesel fuel under § 80.520(c); and

(*2*) A declaration that the DFR-Diesel is being included in the applicable compliance calculations required by the EPA under this subpart.

(ii) The certification shall be made part of the product transfer documents for the DFR-Diesel.

(e) *Transfers of DFR-Diesel to non-United States markets.* The foreign refiner is responsible to ensure that all diesel fuel classified as DFR-Diesel is imported into the United States. A foreign refiner may remove the DFR-Diesel classification, and the diesel fuel need not be imported into the United States, but only if:

(1)(i) The foreign refiner excludes:

(A) The volume of diesel from the refinery's compliance report under § 80.593; and

(B) In the case of Certified DFR-Diesel, the volume of the diesel fuel from the compliance report under § 80.593.

(ii) The exclusions under paragraph (e)(1)(i) of this section shall be on the basis of the designations under § 80.523 and volumes determined under paragraph (f) of this section.

(2) The foreign refiner obtains sufficient evidence in the form of documentation that the diesel fuel was not imported into the United States.

(f) *Load port independent sampling, testing and refinery identification.* (1) On each occasion that DFR-Diesel is loaded onto a vessel for transport to the United States a foreign refiner shall have an independent third party:

(i) Inspect the vessel prior to loading and determine the volume of any tank bottoms;

(ii) Determine the volume of DFR-Diesel loaded onto the vessel (exclusive of any tank bottoms before loading);

(iii) Obtain the EPA-assigned registration number of the foreign refinery;

(iv) Determine the name and country of registration of the vessel used to transport the DFR-Diesel to the United States; and

(v) Determine the date and time the vessel departs the port serving the foreign refinery.

(2) On each occasion that Certified DFR-Diesel is loaded onto a vessel for transport to the United States a foreign refiner shall have an independent third party:

(i) Collect a representative sample of the Certified DFR-Diesel from each vessel compartment subsequent to loading on the vessel and prior to departure of the vessel from the port serving the foreign refinery;

(ii) Determine the sulfur content value for each compartment using the methodology specified in § 80.580 by:

(A) The third party analyzing each sample; or

(B) The third party observing the foreign refiner analyze the sample;

(iii) Review original documents that reflect movement and storage of the certified DFR-Diesel from the refinery to the load port, and from this review determine:

(A) The refinery at which the DFR-Diesel was produced; and

(B) That the DFR-Diesel remained segregated from:

(*1*) Non-DFR-Diesel and Non-Certified DFR-Diesel; and

(*2*) Other Certified DFR-Diesel produced at a different refinery.

(3) The independent third party shall submit a report:

(i) To the foreign refiner containing the information required under paragraphs (f)(1) and (f)(2) of this section, to accompany the product transfer documents for the vessel; and

(ii) To the Administrator containing the information required under paragraphs (f)(1) and (f)(2) of this section, within thirty days following the date of the independent third party's inspection. This report shall include a description of the method used to determine the identity of the refinery at which the diesel fuel was produced, assurance that the diesel fuel remained segregated as specified in paragraph (n)(1) of this section, and a description of the diesel fuel's movement and storage between production at the source refinery and vessel loading.

(4) The independent third party must:

(i) Be approved in advance by EPA, based on a demonstration of ability to perform the procedures required in this paragraph (f);

(ii) Be independent under the criteria specified in § 80.65(e)(2)(iii); and

(iii) Sign a commitment that contains the provisions specified in paragraph (i) of this section with regard to activities, facilities and documents relevant to compliance with the requirements of this paragraph (f).

(g) *Comparison of load port and port of entry testing.* (1) Load port and port of entry testing requirements, as follows:

(i) Any foreign refiner and any United States importer of Certified DFR-Diesel shall compare the results from the load port testing under paragraph (f) of this section, with the port of entry testing as reported under paragraph (o) of this section, for the volume of diesel and the sulfur value; except that

(ii) Where a vessel transporting Certified DFR-Diesel off loads this diesel fuel at more than one United States port of entry, and the conditions of paragraph (g)(2)(i) of this section are met at the first United States port of entry, the requirements of paragraph (g)(2) of this section do not apply at subsequent ports of entry if the United States importer obtains a certification from the vessel owner that meets the requirements of paragraph(s) of this section, that the vessel has not loaded any diesel fuel or blendstock between the first United States port of entry and the subsequent port of entry.

(2)(i) The requirements of this paragraph (g)(2) apply if:

(A) The temperature-corrected volumes determined at the port of entry and at the load port differ by more than one percent; or

(B) The sulfur value determined at the port of entry is higher than the sulfur value determined at the load port, and the amount of this difference is greater than the reproducibility amount specified for the port of entry test result by the American Society of Testing and Materials (ASTM).

(ii) The United States importer and the foreign refiner shall treat the diesel fuel as Non-Certified DFR-Diesel, and the foreign refiner shall exclude the diesel fuel volume from its motor vehicle diesel fuel volumes calculations and sulfur standard designations under § 80.523.

(h) *Attest requirements.* Refiners, for each calendar year, must arrange to have an attest engagement performed of the underlying documentation that forms the basis of any report required under this subpart. The attest engagement must comply with the procedures and requirements that apply to refiners under §§ 80.125 through 80.130 and must be submitted to the Administrator of EPA by May 30 of each year for the prior calendar year. The following additional procedures shall be carried out for any foreign refiner of DFR-Diesel:

(1) The inventory reconciliation analysis under § 80.128(b) and the tender analysis under § 80.128(c) shall include Non-DFR-Diesel.

(2) Obtain separate listings of all tenders of Certified DFR-Diesel and of Non-Certified DFR-Diesel, and obtain separate listings of Certified DFR-Diesel

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based on whether it is 15 ppm sulfur content motor vehicle diesel fuel or 500 ppm sulfur content motor vehicle diesel fuel. Agree the total volume of tenders from the listings to the diesel fuel inventory reconciliation analysis in § 80.128(b), and to the volumes determined by the third party under paragraph (f)(1) of this section.

(3) For each tender under paragraph (h)(2) of this section, where the diesel fuel is loaded onto a marine vessel, report as a finding the name and country of registration of each vessel, and the volumes of DFR-Diesel loaded onto each vessel.

(4) Select a sample from the list of vessels identified in paragraph (h)(3) of this section used to transport Certified DFR-Diesel, in accordance with the guidelines in § 80.127, and for each vessel selected perform the following:

(i) Obtain the report of the independent third party, under paragraph (f) of this section, and of the United States importer under paragraph (o) of this section.

(A) Agree the information in these reports with regard to vessel identification, diesel fuel volumes and sulfur content test results.

(B) Identify, and report as a finding, each occasion the load port and port of entry sulfur content and volume results differ by more than the amounts allowed in paragraph (g) of this section, and determine whether the foreign refiner adjusted its refinery calculations as required in paragraph (g) of this section.

(ii) Obtain the documents used by the independent third party to determine transportation and storage of the Certified DFR-Diesel from the refinery to the load port, under paragraph (f) of this section. Obtain tank activity records for any storage tank where the Certified DFR-Diesel is stored, and pipeline activity records for any pipeline used to transport the Certified DFR-Diesel, prior to being loaded onto the vessel. Use these records to determine whether the Certified DFR-Diesel was produced at the refinery that is the subject of the attest engagement, and whether the Certified DFR-Diesel was mixed with any Non-Certified DFR-Diesel, Non-DFR-Diesel, or any Certified DFR-Diesel produced at a different refinery.

(5) Select a sample from the list of vessels identified in paragraph (h)(3) of this section used to transport certified and Non-Certified DFR-Diesel, in accordance with the guidelines in § 80.127, and for each vessel selected perform the following:

(i) Obtain a commercial document of general circulation that lists vessel arrivals and departures, and that includes the port and date of departure of the vessel, and the port of entry and date of arrival of the vessel.

(ii) Agree the vessel's departure and arrival locations and dates from the independent third party and United States importer reports to the information contained in the commercial document.

(6) Obtain separate listings of all tenders of Non-DFR-Diesel, and perform the following:

(i) Agree the total volume and sulfur content of tenders from the listings to the diesel fuel inventory reconciliation analysis in § 80.128(b).

(ii) Obtain a separate listing of the tenders under this paragraph (h)(6) where the diesel fuel is loaded onto a marine vessel. Select a sample from this listing in accordance with the guidelines in § 80.127, and obtain a commercial document of general circulation that lists vessel arrivals and departures, and that includes the port and date of departure and the ports and dates where the diesel fuel was off loaded for the selected vessels. Determine and report as a finding the country where the diesel fuel was off loaded for each vessel selected.

(7) In order to complete the requirements of this paragraph (h) an auditor shall:

(i) Be independent of the foreign refiner;

(ii) Be licensed as a Certified Public Accountant in the United States and a citizen of the United States, or be approved in advance by EPA based on a demonstration of ability to perform the procedures required in §§ 80.125 through 80.130 and this paragraph (h); and

(iii) Sign a commitment that contains the provisions specified in paragraph (i) of this section with regard to activities and documents relevant to compliance with the requirements of §§ 80.125 through 80.130 and this paragraph (h).

(i) *Foreign refiner commitments.* Any foreign refiner shall commit to and comply with the provisions contained in this paragraph (i) as a condition to being approved for a temporary refiner diesel fuel program option.

(1) Any United States Environmental Protection Agency inspector or auditor must be given full, complete and immediate access to conduct inspections and audits of the foreign refinery.

(i) Inspections and audits may be either announced in advance by EPA, or unannounced.

(ii) Access will be provided to any location where:

(A) Diesel fuel is produced;

(B) Documents related to refinery operations are kept;

(C) Diesel fuel or blendstock samples are tested or stored; and

(D) DFR-Diesel is stored or transported between the foreign refinery and the United States, including storage tanks, vessels and pipelines.

(iii) Inspections and audits may be by EPA employees or contractors to EPA.

(iv) Any documents requested that are related to matters covered by inspections and audits must be provided to an EPA inspector or auditor on request.

(v) Inspections and audits by EPA may include review and copying of any documents related to:

(A) Refinery baseline establishment, if applicable, including the volume and sulfur content; transfers of title or custody of any diesel fuel or blendstocks whether DFR-Diesel or Non-DFR-Diesel, produced at the foreign refinery during the period January 1, 1998 through the date of the refinery baseline petition or through the date of the inspection or audit if a baseline petition has not been approved, and any work papers related to refinery baseline establishment;

(B) The volume and sulfur content of DFR-Diesel;

(C) The proper classification of diesel fuel as being DFR-Diesel or as not being DFR-Diesel, or as Certified DFR-Diesel or as Non-Certified DFR-Diesel, or as meeting the 15 ppm sulfur standard under § 80.520(a)(1) or the 500 ppm sulfur standard under § 80.520(c);

(D) Transfers of title or custody to DFR-Diesel;

(E) Sampling and testing of DFR-Diesel;

(F) Work performed and reports prepared by independent third parties and by independent auditors under the requirements of this section, including work papers; and

(G) Reports prepared for submission to EPA, and any work papers related to such reports.

(vi) Inspections and audits by EPA may include taking samples of diesel fuel, diesel fuel additives or blendstock, and interviewing employees.

(vii) Any employee of the foreign refiner must be made available for interview by the EPA inspector or auditor, on request, within a reasonable time period.

(viii) English language translations of any documents must be provided to an EPA inspector or auditor, on request, within 10 working days.

(ix) English language interpreters must be provided to accompany EPA inspectors and auditors, on request.

(2) An agent for service of process located in the District of Columbia shall be named, and service on this agent constitutes service on the foreign refiner or any employee of the foreign refiner for any action by EPA or otherwise by the United States related to the requirements of this subpart.

(3) The forum for any civil or criminal enforcement action related to the provisions of this section for violations of the Clean Air Act or regulations promulgated thereunder shall be governed by the Clean Air Act, including the EPA administrative forum where allowed under the Clean Air Act.

(4) United States substantive and procedural laws shall apply to any civil or criminal enforcement action against the foreign refiner or any employee of the foreign refiner related to the provisions of this section.

(5) Submitting a petition for participation in the diesel foreign refiner program or producing and exporting diesel fuel under any such program, and all other actions to comply with the requirements of this subpart relating to participation in any diesel foreign refiner program, or to establish an individual refinery motor vehicle diesel fuel volume baseline (if applicable) constitute actions or activities that satisfy the provisions of 28 U.S.C. section 1605(a)(2), but solely with respect to actions instituted against the foreign refiner, its agents and employees in any court or other tribunal in the United States for conduct that violates the requirements applicable to the foreign refiner under this subpart, including conduct that violates Title 18 U.S.C. section 1001 and Clean Air Act section 113(c)(2).

(6) The foreign refiner, or its agents or employees, will not seek to detain or to impose civil or criminal remedies against EPA inspectors or auditors, whether EPA employees or EPA contractors, for actions performed within the scope of EPA employment related to the provisions of this section.

(7) The commitment required by this paragraph (i) shall be signed by the owner or president of the foreign refiner business.

(8) In any case where DFR-Diesel produced at a foreign refinery is stored or transported by another company between the refinery and the vessel that transports the DFR-Diesel to the United States, the foreign refiner shall obtain from each such other company a commitment that meets the requirements specified in paragraphs (i)(1) through (7) of this section, and these commitments shall be included in the foreign refiner's petition to participate in any diesel foreign refiner program .

(j) *Sovereign immunity.* By submitting a petition for participation in any diesel foreign refiner program under this subpart (and baseline, if applicable) under this section, or by producing and exporting diesel fuel to the United States under any such program, the foreign refiner, and its agents and employees, without exception, become subject to the full operation of the administrative and judicial enforcement powers and provisions of the United States without limitation based on sovereign immunity, with respect to actions instituted against the foreign refiner, its agents and employees in any court or other tribunal in the United States for conduct that violates the requirements applicable to the foreign refiner under this subpart including conduct that violates Title 18 U.S.C. section 1001 and Clean Air Act section 113(c)(2).

(k) *Bond posting.* Any foreign refiner shall meet the requirements of this paragraph (k) as a condition to approval for any diesel foreign refiner program under this subpart.

(1) The foreign refiner shall post a bond of the amount calculated using the following equation: Bond = G × $0.01

Where:
Bond = amount of the bond in U.S. dollars.
G = the volume baseline for motor vehicle diesel fuel produced at the foreign refinery and exported to the United States, in gallons.

(2) Bonds shall be posted by:

(i) Paying the amount of the bond to the Treasurer of the United States;

(ii) Obtaining a bond in the proper amount from a third party surety agent that is payable to satisfy United States administrative or judicial judgments against the foreign refiner, provided EPA agrees in advance as to the third party and the nature of the surety agreement; or

(iii) An alternative commitment that results in assets of an appropriate liquidity and value being readily available to the United States, provided EPA agrees in advance as to the alternative commitment.

(3) Bonds posted under this paragraph (k) shall:

(i) Be used to satisfy any judicial judgment that results from an administrative or judicial enforcement action for conduct in violation of this subpart, including where such conduct violates Title 18 U.S.C. 1001 and Clean Air Act section 113(c)(2);

(ii) Be provided by a corporate surety that is listed in the United States Department of Treasury Circular 570 "Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds" (available from the Department of Treasury website at *http://www.fms.treas.gov* or from the Government Printing Office, phone (202) 512–1800); and

(iii) Include a commitment that the bond will remain in effect for at least five (5) years following the end of latest annual reporting period that the foreign refiner produces motor vehicle diesel fuel pursuant to the requirements of this subpart.

(4) On any occasion a foreign refiner bond is used to satisfy any judgment, the foreign refiner shall increase the bond to cover the amount used within 90 days of the date the bond is used.

(5) If the bond amount for a foreign refiner increases, the foreign refiner shall increase the bond to cover the shortfall within 90 days of the date the bond amount changes. If the bond amount decreases, the foreign refiner may reduce the amount of the bond beginning 90 days after the date the bond amount changes.

(l) [Reserved]

(m) *English language reports.* Any report or other document submitted to EPA by a foreign refiner shall be in English language, or shall include an English language translation.

(n) *Prohibitions.* (1) No person may combine Certified DFR-Diesel with any Non-Certified DFR-Diesel or Non-DFR-Diesel, and no person may combine Certified DFR-Diesel with any Certified DFR-Diesel produced at a different refinery, until the importer has met all the requirements of paragraph (o) of this section, except as provided in paragraph (e) of this section.

(2) No foreign refiner or other person may cause another person to commit an action prohibited in paragraph (n)(1) of this section, or that otherwise violates the requirements of this section.

(o) *United States importer requirements.* Any United States importer shall meet the following requirements:

(1) Each batch of imported motor vehicle diesel fuel shall be classified by the importer as being DFR-Diesel or as Non-DFR-Diesel, and each batch classified as DFR-Diesel shall be further classified as Certified DFR-Diesel or as Non-certified DFR-Diesel, and each batch of Certified DFR-Diesel shall be further classified as complying with the 500 ppm motor vehicle diesel fuel sulfur standard under § 80.520(c) or the 15 ppm motor vehicle diesel fuel sulfur standard under § 80.520(a)(1).

(2) Motor vehicle diesel fuel shall be classified as Certified DFR-Diesel or as Non-Certified DFR-Diesel according to the designation by the foreign refiner if this designation is supported by product

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transfer documents prepared by the foreign refiner as required in paragraph (d) of this section, unless the diesel fuel is classified as Non-Certified DFR-Diesel under paragraph (g) of this section. Additionally, the importer shall comply with all requirements of this subpart applicable to domestic refiners subject to any diesel foreign refiner program under this subpart.

(3) For each diesel fuel batch classified as DFR-Diesel, any United States importer shall perform the following procedures:

(i) In the case of both Certified and Non-Certified DFR-Diesel, have an independent third party:

(A) Determine the volume of diesel fuel in the vessel;

(B) Use the foreign refiner's DFR-Diesel certification to determine the name and EPA-assigned registration number of the foreign refinery that produced the DFR-Diesel;

(C) Determine the name and country of registration of the vessel used to transport the DFR-Diesel to the United States; and

(D) Determine the date and time the vessel arrives at the United States port of entry.

(ii) In the case of Certified DFR-Diesel, have an independent third party:

(A) Collect a representative sample from each vessel compartment subsequent to the vessel's arrival at the United States port of entry and prior to off loading any diesel fuel from the vessel;

(B) Obtain the compartment samples; and

(C) Determine the sulfur value of each compartment sample using the methodologies specified in § 80.580, by:

(*1*) The third party analyzing the sample; or

(*2*) The third party observing the importer analyze the sample.

(4) Any importer shall submit reports within thirty days following the date any vessel transporting DFR-Diesel arrives at the United States port of entry:

(i) To the Administrator containing the information determined under paragraph (o)(3) of this section; and

(ii) To the foreign refiner containing the information determined under paragraph (o)(3)(ii) of this section, and including identification of the port and Credit Trading Area at which the product was offloaded.

(5) Any United States importer shall meet the requirements specified in § 80.520, for any imported motor vehicle diesel fuel that is not classified as Certified DFR-Diesel under paragraph (o)(2) of this section.

(p) *Truck Imports of Certified DFR-Diesel produced at a Foreign Refinery.*

(1) Any refiner whose Certified DFR-Diesel is transported into the United States by truck may petition EPA to use alternative procedures to meet the following requirements:

(i) Certification under paragraph (d)(5) of this section;

(ii) Load port and port of entry sampling and testing under paragraphs (f) and (g) of this section;

(iii) Attest under paragraph (h) of this section; and

(iv) Importer testing under paragraph (o)(3) of this section.

(2) These alternative procedures must ensure Certified DFR-Diesel remains segregated from Non-Certified DFR-Diesel and from Non-DFR-Diesel until it is imported into the United States. The petition will be evaluated based on whether it adequately addresses the following:

(i) Provisions for monitoring pipeline shipments, if applicable, from the refinery, that ensure segregation of Certified DFR-Diesel from that refinery from all other diesel fuel;

(ii) Contracts with any terminals and/or pipelines that receive and/or transport Certified DFR-Diesel, that prohibit the commingling of Certified DFR-Diesel with any of the following:

(A) Other Certified DFR-Diesel from other refineries.

(B) All Non-Certified DFR-Diesel.

(C) All Non-DFR-Diesel;

(iii) Procedures for obtaining and reviewing truck loading records and United States import documents for Certified DFR-Diesel to ensure that such diesel fuel is only loaded into trucks making deliveries to the United States;

(iv) Attest procedures to be conducted annually by an independent third party that review loading records and import documents based on volume reconciliation, or other criteria, to confirm that all Certified DFR-Diesel remains segregated throughout the distribution system and is only loaded into trucks for import into the United States.

(3) The petition required by this section must be submitted to EPA along with the application for temporary refiner relief individual refinery highway diesel sulfur standard under this subpart I and this section.

(q) *Withdrawal or suspension of a foreign refinery's temporary refinery flexibility program approval.* EPA may withdraw or suspend a diesel refiner temporary compliance option diesel fuel sulfur program approval for a foreign refinery where:

(1) A foreign refiner fails to meet any requirement of this section;

(2) A foreign government fails to allow EPA inspections as provided in paragraph (i)(1) of this section;

(3) A foreign refiner asserts a claim of, or a right to claim, sovereign immunity in an action to enforce the requirements in this subpart; or

(4) A foreign refiner fails to pay a civil or criminal penalty that is not satisfied using the foreign refiner bond specified in paragraph (k) of this section.

(r) *Early use of a foreign refiner baseline.* (1) A foreign refiner may begin using an individual refinery baseline before EPA has approved the baseline, provided that:

(i) A baseline petition has been submitted as required in paragraph (b) of this section;

(ii) EPA has made a provisional finding that the baseline petition is complete;

(iii) The foreign refiner has made the commitments required in paragraph (i) of this section;

(iv) The persons who will meet the independent third party and independent attest requirements for the foreign refinery have made the commitments required in paragraphs (f)(3)(iii) and (h)(7)(iii) of this section; and

(v) The foreign refiner has met the bond requirements of paragraph (k) of this section.

(2) In any case where a foreign refiner uses an individual refinery baseline before final approval under paragraph (r)(1) of this section, and the foreign refinery baseline values that ultimately are approved by EPA are more stringent than the early baseline values used by the foreign refiner, the foreign refiner shall recalculate its compliance, ab initio, using the baseline values approved by the EPA, and the foreign refiner shall be liable for any resulting violation of the motor vehicle highway diesel fuel requirements.

(s) *Additional requirements for petitions, reports and certificates.* Any petition for approval to produce motor vehicle diesel fuel subject to the diesel foreign refiner program, any alternative procedures under paragraph (p) of this section, any report or other submission required by paragraph (c), (f)(2), or (i) of this section, and any certification under paragraph (d)(3) of this section shall be:

(1) Submitted in accordance with procedures specified by the Administrator, including use of any forms that may be specified by the Administrator.

(2) Be signed by the president or owner of the foreign refiner company, or by that person's immediate designee, and shall contain the following declaration:

I hereby certify: (1) that I have actual authority to sign on behalf of and to bind [insert name of foreign refiner] with regard to all statements contained herein; (2) that I am aware that the information contained herein is being certified, or submitted to the United States Environmental Protection Agency, under the requirements of 40 CFR Part 80, subpart I, and that the information is material for determining compliance under these regulations; and (3) that I have read and understand the information being certified or submitted, and this information is true, complete and correct to the best of my knowledge and belief after I have taken reasonable and appropriate steps to verify the accuracy thereof.

I affirm that I have read and understand the provisions of 40 CFR Part 80, subpart I, including 40 CFR 80.620 apply to [insert name of foreign refiner]. Pursuant to Clean Air Act section 113(c) and Title 18, United States Code, section 1001, the penalty for furnishing false, incomplete or misleading information in this certification or submission is a fine of up to $10,000 U.S., and/or imprisonment for up to five years.

PART 86—CONTROL OF EMISSIONS FROM NEW AND IN-USE HIGHWAY VEHICLES AND ENGINES

11. The authority citation for part 86 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

12. Section 86.1 is amended by revising paragraph (b)(1) to read as follows:

§ 86.1 Reference materials.

* * * * *

(b) * * *

(1) *ASTM material.* The following table sets forth material from the American Society for Testing and Materials that has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than this section, in which the matter is referenced. Copies of these materials may be obtained from American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

Document number and name	40 CFR part 86 reference
ASTM E29–67 (Reapproved 1980), Standard Recommended Practice for Indicating Which Places of Figures Are To Be Considered Significant in Specified Limiting Values.	86.1105–87.
ASTM E29–90, Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications.	86.609–84; 86.609–96; 86.609–97; 86.609–98; 86.1009–84; 86.1009–96; 86.1442; 86.1708–99; 86.1709–99; 86.1710–99; 86.1728–99.
ASTM D5186–91, Standard Test Method for Determination of Aromatic Content of Diesel Fuels by Supercritical Fluid Chromatography.	86.113–07; 86.1313–91; 86.1313–94; 86.1313–98; 1313–2007.
ASTM D2163–91, Standard Test Method for Analysis of Liquefied Petroleum (LP) Gases and Propane Concentrates by Gas Chromatography.	86.113–94; 86.1213–94; 86.1313–94.
ASTM D1945–91, Standard Test Method for Analysis of Natural Gas By Gas Chromatography	86.113–94; 86.513–94; 86.1213–94; 86.1313–94.
ASTM E29–93a, Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications.	86.098–15; 86.004–15; 86.007–11; 86.007–15; 86.1803–01; 86.1823–01; 86.1824–01; 86.1825–01; 86.1837–01.
ASTM D2986–95a, (Reapproved 1999) Standard Practice for Evaluation of Air Assay Media by the Monodisperse DOP (Dioctyl Phthalate) Smoke Test.	86.1310–2007.
ASTM F1471–93, Standard Test Method for Air Cleaning Performance of a High-Efficiency Particulate Air-Filter System.	86.1310–2007.

* * * * *

13. Section 86.004–2 is amended by adding in alphabetical order a definition of "U.S.-directed production" to read as follows:

§ 86.004–2 Definitions.

* * * * *

U.S.-directed production means the engines and/or vehicles (as applicable) produced by a manufacturer for which the manufacturer has reasonable assurance that sale was or will be made to ultimate purchasers in the United States, excluding engines and/or vehicles that are certified to state emission standards different than the emission standards in this part.

* * * * *

14. Section 86.004–28 is amended by adding paragraph (i) to read as follows:

§ 86.004–28 Compliance with emission standards.

* * * * *

(i) Emission results from heavy-duty engines equipped with exhaust aftertreatment may need to be adjusted to account for regeneration events. This provision only applies for engines equipped with emission controls that are regenerated on an infrequent basis. For the purpose of this paragraph (i), the term "regeneration" means an event during which emissions levels change while the aftertreatment performance is being restored by design. Examples of regenerations are increasing exhaust gas temperature to remove sulfur from an adsorber or increasing exhaust gas temperature to oxidize PM in a trap. For the purpose of this paragraph (i), the term "infrequent" means having an expected frequency of less than once per transient test cycle. Calculation and use of adjustment factors are described in paragraphs (i)(1) through (i)(5) of this section.

(1) *Development of adjustment factors.* Manufacturers must develop separate pairs of adjustment factors (an upward adjustment factor and a downward adjustment factor) for each pollutant based on measured emission data and observed regeneration frequency. Adjustment factors may be carried-over to subsequent model years or carried-across to other engine families only where the Administrator determines that such carry-over or carry-across is consistent with good engineering judgment. Adjustment factors should generally apply to an entire engine family, but manufacturers may develop separate adjustment factors for different engine configurations within an engine family. All adjustment factors for regeneration are additive.

(2) *Calculation of adjustment factors.* The adjustment factors are calculated from the following parameters: the measured emissions from a test in which the regeneration occurs (EF_H), the measured emissions from a test in which the regeneration does not occur (EF_L), and the frequency of the regeneration event in terms of fraction of tests during which the regeneration occurs (F). The average emission rate (EF_A) is calculated as:

$$EF_A = (F)(EF_H) + (1 - F)(EF_L)$$

(i) The upward adjustment factor (UAF) is calculated as: $UAF = EF_A - EF_L$.

(ii) The downward adjustment factor (DAF) is calculated as: $DAF = EF_A - EF_H$.

(3) *Use of adjustment factors.* Upward adjustment factors are added to

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measured emission rates for all tests in which the regeneration does not occur. Downward adjustment factors are added to measured emission rates for all tests in which the regeneration occurs. The occurrence of the regeneration must be identified in a manner that is readily apparent during all testing. Where no regeneration is identified, the upward adjustment factor shall be applied.

(4) *Sample calculation.* If EF_L is 0.10 g/bhp-hr, EF_H is 0.50 g/bhp-hr, and F is 0.1 (*i.e.*, the regeneration occurs once for each ten tests), then:

$EF_A = (0.1)(0.5 \text{ g/bhp-hr}) + (1.0 - 0.1)(0.1 \text{ g/bhp-hr}) = 0.14 \text{ g/bhp-hr}$

$UAF = 0.14 \text{ g/bhp-hr} - 0.10 \text{ g/bhp-hr} = 0.04 \text{ g/bhp-hr}$

$DAF = 0.14 \text{ g/bhp-hr} - 0.50 \text{ g/bhp-hr} = -0.36 \text{ g/bhp-hr}$

(5) *Options.* (i) A manufacturer may elect to omit adjustment factors for one or more of its engine families (or configurations) because the effect of the regeneration is small, or because it is not practical to identify when regenerations occur. In these cases, no upward or downward adjustment factor shall be added, and the manufacturer is liable for compliance with the emission standards for all tests, without regard to whether a regeneration occurs.

(ii) Upon request by the manufacturer, the Administrator may account for regeneration events differently than is provided in this paragraph (i). However, this option only applies for events that occur extremely infrequently, and which cannot be practically addressed using the adjustment factors described in this paragraph (i).

15. Section 86.004–40 is amended by revising the introductory text to read as follows:

§ 86.004–40 Heavy-duty engine rebuilding practices.

The provisions of this section are applicable to heavy-duty engines subject to model year 2004 or later standards and are applicable to the process of engine rebuilding (or rebuilding a portion of an engine or engine system). The process of engine rebuilding generally includes disassembly, replacement of multiple parts due to wear, and reassembly, and also may include the removal of the engine from the vehicle and other acts associated with rebuilding an engine. Any deviation from the provisions contained in this section is a prohibited act under section 203(a)(3) of the Clean Air Act (42 U.S.C. 7522(a)(3)).

* * * * *

16. Section 86.005–10 is amended by revising paragraph (a)(1)(ii)(C) to read as follows:

§ 86.005–10 Emission standards for 2005 and later model year Otto-cycle heavy-duty engines and vehicles.

* * * * *

(a) * * *

(1) * * *

(ii) * * *

(C) *Idle carbon monoxide.* For all Otto-cycle HDEs utilizing aftertreatment technology, and not certified to the onboard diagnostics requirements of § 86.005–17: 0.50 percent of exhaust gas flow at curb idle.

* * * * *

17. Section 86.005–17 is amended by revising paragraphs (b) introductory text, (b)(1), (b)(2), (b)(3), (b)(4), (b)(5), and (k) to read as follows:

§ 86.005–17 On-board diagnostics.

* * * * *

(b) *Malfunction descriptions.* The OBD system must detect and identify malfunctions in all monitored emission-related engine systems or components according to the following malfunction definitions as measured and calculated in accordance with test procedures set forth in subpart N of this part (engine-based test procedures) excluding the test procedure referred to as the "Supplemental emission test; test cycle and procedures" contained in § 86.1360, and excluding the test procedure referred to as the "Not-To-Exceed Test Procedure" contained in § 86.1370, and excluding the test procedure referred to as the "Load Response Test" contained in § 86.1380.

(1) *Catalysts and particulate traps.* (i) *Otto-cycle.* Catalyst deterioration or malfunction before it results in an increase in NMHC (or NO_X+NMHC, as applicable) emissions 1.5 times the NMHC (or NO_X+NMHC, as applicable) standard or FEL, as compared to the NMHC (or NO_X+NMHC, as applicable) emission level measured using a representative 4000 mile catalyst system.

(ii) *Diesel.* (A) If equipped, catalyst deterioration or malfunction before it results in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NO_X (or NO_X+NMHC, as applicable) or PM. This requirement applies only to reduction catalysts; monitoring of oxidation catalysts is not required. This monitoring need not be done if the manufacturer can demonstrate that deterioration or malfunction of the system will not result in exceedance of the threshold.

(B) If equipped with a particulate trap, catastrophic failure of the device must be detected. Any particulate trap whose complete failure results in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NMHC (or NO_X+NMHC, as applicable) or PM must be monitored for such catastrophic failure. This monitoring need not be done if the manufacturer can demonstrate that a catastrophic failure of the system will not result in exceedance of the threshold.

(2) *Engine Misfire.* (i) *Otto-cycle.* Engine misfire resulting in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NMHC, NO_X (or NO_X+NMHC, as applicable) or CO; and any misfire capable of damaging the catalytic converter.

(ii) *Diesel.* Lack of cylinder combustion must be detected.

(3) Oxygen sensors. If equipped, oxygen sensor deterioration or malfunction resulting in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NMHC, NO_X (or NO_X+NMHC, as applicable) or CO.

(4) *Evaporative leaks.* If equipped, any vapor leak in the evaporative and/or refueling system (excluding the tubing and connections between the purge valve and the intake manifold) greater than or equal in magnitude to a leak caused by a 0.040 inch diameter orifice; an absence of evaporative purge air flow from the complete evaporative emission control system. Where fuel tank capacity is greater than 25 gallons, the Administrator may, following a request from the manufacturer, revise the size of the orifice to the smallest orifice feasible, based on test data, if the most reliable monitoring method available cannot reliably detect a system leak equal to a 0.040 inch diameter orifice.

(5) *Other emission control systems.* Any deterioration or malfunction occurring in an engine system or component directly intended to control emissions, including but not necessarily limited to, the exhaust gas recirculation (EGR) system, if equipped, the secondary air system, if equipped, and the fuel control system, singularly resulting in exhaust emissions exceeding 1.5 times the applicable emission standard or FEL for NMHC, NO_X (or NO_X+NMHC, as applicable), CO or diesel PM. For engines equipped with a secondary air system, a functional check, as described in paragraph (b)(6) of this section, may satisfy the requirements of this paragraph (b)(5) provided the manufacturer can demonstrate that deterioration of the flow distribution system is unlikely. This demonstration is subject to Administrator approval and, if the demonstration and associated functional check are approved, the diagnostic system must indicate a malfunction when some degree of secondary airflow is not detectable in the exhaust system during the check. For engines equipped with positive crankcase ventilation (PCV), monitoring of the PCV system is not necessary provided the manufacturer can demonstrate to the Administrator's satisfaction that the PCV system is unlikely to fail.

* * * * *

(k) *Phase-in for heavy-duty engines.* Manufacturers of heavy-duty engines must comply with the OBD requirements in this section according to the following phase-in schedule, based on the percentage of projected engine sales within each category. The 2004 model year requirements in the following phase-in schedule are applicable only to heavy-duty Otto-cycle engines where the manufacturer has selected Otto-cycle Option 1 or Option 2 for alternative 2004 compliance according to § 86.005–01(c)(1) or (2). The 2005 through 2007 requirements in the following phase-in schedule apply to all heavy-duty engines intended for use in a heavy-duty vehicle weighing 14,000 pounds GVWR or less. Manufacturers may exempt 2005 model year diesel heavy-duty engines from the requirements of this section if the 2005 model year commences before July 31, 2004 from the requirements of this section. Manufacturers may exempt 2005 model year Otto-cycle heavy-duty engines and vehicles from the requirements of this section if the manufacturer has selected Otto-cycle Option 3 and if the 2005 model year commences before July 31, 2004. For the purposes of calculating compliance with the phase-in provisions of this paragraph (k), heavy-duty engines may be combined with heavy-duty vehicles subject to the phase-in requirements of paragraph § 86.1806–05(l). The OBD Compliance phase-in table follows:

OBD COMPLIANCE PHASE-IN FOR HEAVY-DUTY ENGINES INTENDED FOR USE IN A HEAVY-DUTY VEHICLE WEIGHING 14,000 POUNDS GVWR OR LESS

Model year	Otto-cycle phase-in based on projected sales	Diesel Phase-in based on projected sales
2004 MY	Applicable only to Otto-cycle engines complying with Options 1 or 2; 40% compliance; alternative fuel waivers available.	
2005 MY	60% compliance; alternative fuel waivers available	50% compliance; alternative fuel waivers available.
2006 MY	80% compliance; alternative fuel waivers available	50% compliance; alternative fuel waivers available.
2007 MY	80% compliance; alternative fuel waivers available	100% compliance.
2008+ MY	100% compliance	100% compliance.

18. Section 86.007–11 is amended by revising the introductory text, paragraphs (a) through (a)(2), (a)(3), (a)(4)(i), (b)(3) through (d), and adding paragraphs (a)(4)(iv)(C), (a)(4)(v), (e), (f), (g) and (h) to read as follows:

§ 86.007–11 Emission standards and supplemental requirements for 2007 and later model year diesel heavy-duty engines and vehicles.

This section applies to new 2007 and later model year diesel HDEs. Section 86.007–11 includes text that specifies requirements that differ from § 86.004–11. Where a paragraph in § 86.004–11 is identical and applicable to § 86.007–11, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.004–11.".

(a)(1) Exhaust emissions from new 2007 and later model year diesel HDEs shall not exceed the following:

(i) *Oxides of Nitrogen (NO_X).* (A) 0.20 grams per brake horsepower-hour (0.075 grams per megajoule).

(B) A manufacturer may elect to include any or all of its diesel HDE families in any or all of the NO_X and NO_X plus NMHC emissions ABT programs for HDEs, within the restrictions described in § 86.007–15 or § 86.004–15. If the manufacturer elects to include engine families in any of these programs, the NO_X FELs may not exceed the following FEL caps: 2.00 grams per brake horsepower-hour (0.75 grams per megajoule) for model years before 2010; 0.50 grams per brake horsepower-hour (0.19 grams per megajoule) for model years 2010 and later. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading programs.

(ii)(A) *Non-Methane Hydrocarbons (NMHC) for engines fueled with either diesel fuel, natural gas, or liquefied petroleum gas.* 0.14 grams per brake horsepower-hour (0.052 grams per megajoule).

(B) *Non-Methane Hydrocarbon Equivalent (NMHCE) for engines fueled with methanol.* 0.14 grams per brake horsepower-hour (0.052 grams per megajoule).

(iii) *Carbon monoxide.* (A) 15.5 grams per brake horsepower-hour (5.77 grams per megajoule).

(B) 0.50 percent of exhaust gas flow at curb idle (methanol-, natural gas-, and liquefied petroleum gas-fueled diesel HDEs only). This does not apply for vehicles certified to the requirements of § 86.005–17

(iv) *Particulate.* (A) 0.01 grams per brake horsepower-hour (0.0037 grams per megajoule).

(B) A manufacturer may elect to include any or all of its diesel HDE families in any or all of the particulate ABT programs for HDEs, within the restrictions described in § 86.007–15 or other applicable sections. If the manufacturer elects to include engine families in any of these programs, the particulate FEL may not exceed 0.02 grams per brake horsepower-hour (0.0075 grams per megajoule).

(2) The standards set forth in paragraph (a)(1) of this section refer to the exhaust emitted over the operating schedule set forth in paragraph (f)(2) of appendix I to this part, and measured and calculated in accordance with the procedures set forth in subpart N or P of this part, except as noted in § 86.007–23(c)(2).

(3) *SET* (i) The weighted average exhaust emissions, as determined under § 86.1360–2007(e)(5) pertaining to the supplemental emission test cycle, for each regulated pollutant shall not exceed 1.0 times the applicable emission standards or FELs specified in paragraph (a)(1) of this section.

(ii) For engines not having a NO_X FEL less than1.5 g/bhp-hr, gaseous exhaust emissions shall not exceed the steady-state interpolated values determined by the Maximum Allowable Emission Limits (for the corresponding speed and load), as determined under § 86.1360–2007(f), when the engine is operated in the steady-state control area defined under § 86.1360–2007(d).

(4) *NTE* (i)(A) The brake-specific exhaust NMHC or NO_X emissions in g/bhp-hr, as determined under § 86.1370–2007 pertaining to the not-to-exceed test procedures, shall not exceed 1.5 times the applicable NMHC or NO_X emission standards or FELs specified in paragraph (a)(1) of this section, during engine and vehicle operation specified

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in paragraph (a)(4)(ii) of this section except as noted in paragraph (a)(4)(iii) of this section.

(B) For engines not having a NO_X FEL less than1.50 g/bhp-hr, the brake-specific NO_X and NMHC exhaust emissions in g/bhp-hr, as determined under § 86.1370–2007 pertaining to the not-to-exceed test procedures, shall not exceed 1.25 times the applicable emission standards or FELs specified in paragraph (a)(1) of this section (or of § 86.004–11, as allowed by paragraph (g) of this section), during engine and vehicle operation specified in paragraph (a)(4)(ii) of this section except as noted in paragraph (a)(4)(iii) of this section.

(C) The brake-specific exhaust PM emissions in g/bhp-hr, as determined under § 86.1370–2007 pertaining to the not-to-exceed test procedures, shall not exceed 1.5 times the applicable PM emission standards or FEL (for FELs above the standard only) specified in paragraph (a)(1) of this section, during engine and vehicle operation specified in paragraph (a)(4)(ii) of this section except as noted in paragraph (a)(4)(iii) of this section.

(D) The brake-specific exhaust CO emissions in g/bhp-hr, as determined under § 86.1370–2007 pertaining to the not-to-exceed test procedures, shall not exceed 1.25 times the applicable CO emission standards or FEL specified in paragraph (a)(1) of this section, during engine and vehicle operation specified in paragraph (a)(4)(ii) of this section except as noted in paragraph (a)(4)(iii) of this section.

* * * * *

(iv) * * *

(C) For model years 2010 through 2013, the Administrator may allow up to three deficiencies per engine family. The provisions of paragraphs (a)(4)(iv)(A) and (B) of this section apply for deficiencies allowed by this paragraph (a)(4)(iv)(C). In determining whether to allow the additional deficiencies, the Administrator may consider any relevant factors, including the factors identified in paragraph (a)(4)(iv)(A) of this section. If additional deficiencies are approved, the Administrator may set any additional conditions that he/she determines to be appropriate.

(v) The emission limits specified in paragraphs (a)(3) and (a)(4) of this section shall be rounded to the same number of significant figures as the applicable standards in paragraph (a)(1) of this section using ASTM E29–93a (Incorporated by reference at § 86.1).

* * * * *

(b)(3) and (b)(4) [Reserved]. For guidance see § 86.004–11.

(c) No crankcase emissions shall be discharged directly into the ambient atmosphere from any new 2007 or later model year diesel HDE, with the following exception: HDEs equipped with turbochargers, pumps, blowers, or superchargers for air induction may discharge crankcase emissions to the ambient atmosphere if the emissions are added to the exhaust emissions (either physically or mathematically) during all emission testing. Manufacturers taking advantage of this exception must manufacture the engines so that all crankcase emission can be routed into a dilution tunnel (or other sampling system approved in advance by the Administrator), and must account for deterioration in crankcase emissions when determining exhaust deterioration factors. For the purpose of this paragraph (c), crankcase emissions that are routed to the exhaust upstream of exhaust aftertreatment during all operation are not considered to be "discharged directly into the ambient atmosphere."

(d) Every manufacturer of new motor vehicle engines subject to the standards prescribed in this section shall, prior to taking any of the actions specified in section 203(a)(1) of the Act, test or cause to be tested motor vehicle engines in accordance with applicable procedures in subpart I or N of this part to ascertain that such test engines meet the requirements of paragraphs (a), (b), (c), and (d) of this section.

(e) [Reserved]. For guidance see § 86.004–11.

(f) (1) Model year 2007 and later diesel-fueled heavy-duty engines and vehicles for sale in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands shall be subject to the same standards and requirements as apply to 2006 model year diesel heavy-duty engines and vehicles, but only if the vehicle or engine bears a permanently affixed label stating:

THIS ENGINE (or VEHICLE, as applicable) CONFORMS TO US EPA EMISSION STANDARDS APPLICABLE TO MODEL YEAR 2006. THIS ENGINE (or VEHICLE, as applicable) DOES NOT CONFORM TO US EPA EMISSION REQUIREMENTS IN EFFECT AT TIME OF PRODUCTION AND MAY NOT BE IMPORTED INTO THE UNITED STATES OR ANY TERRITORY OF THE UNITED STATES EXCEPT GUAM, AMERICAN SAMOA, OR THE COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS.

(2) The importation or sale of such a vehicle or engine for use at any location U.S. other than Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands shall be considered a violation of section 203(a)(1) of the Clean Air Act. In addition, vehicles or vehicle engines subject to this exemption may not subsequently be imported or sold into any state or territory of the United States other than Guam, American Samoa, or Commonwealth of the Northern Mariana Islands.

(g) Phase-in options. (1) For model years 2007, 2008, and 2009, manufacturers may certify some of their engine families to the combined NO_X plus NMHC standard applicable to model year 2006 engines under § 86.004–11, in lieu of the separate NO_X and NMHC standards specified in paragraph (a)(1) of this section. These engines must comply with all other requirements applicable to model year 2007 engines. The combined number of engines in the engine families certified to the 2006 combined NO_X plus NMHC standard may not exceed 50 percent of the manufacturer's U.S.-directed production of heavy-duty diesel motor vehicle engines for model year 2007, 2008, or 2009, except as explicitly allowed by this paragraph (g).

(2)(i) Manufacturers certifying engines to all of the applicable standards listed in paragraph (a) and (c) of this section (without using credits) prior to model year 2007 may reduce the number of engines that are required to meet the standards listed in paragraph (a) of this section in model year 2007, 2008 and/or 2009, taking into account the phase-in option provided in paragraph (g)(1) of this section. For every two engines that are certified early, the manufacturer may reduce the number of engines that are required by paragraph (g)(1) of this section to meet standards listed in paragraph (a)(1) of this section by three engines. For example, if a manufacturer produces 100 heavy-duty diesel engines in 2006 that meet all of the applicable standards listed in paragraph (a) of this section, and it produced 10,000 heavy-duty diesel engines in 2007, then only 4,850 ((10,000)(0.50) − (100)(1.5)) of the engines would need to comply with the standards listed in paragraph (a) of this section.

(ii) Manufacturers certifying engines to the PM standards listed in paragraph (a), and to all of the applicable standards in paragraph (c) of this section (without using credits) prior to model year 2007 may reduce the number of engines that are required to meet the PM standard listed in paragraph (a) of this section in model year 2007, 2008 and/or 2009. For every two engines that are certified to the PM standard early, the manufacturer may reduce the number of engines that are otherwise required to meet the PM standard listed in paragraph (a)(1) of this section by three engines.

(3) Manufacturers may initially base compliance with the phase-in requirements of paragraph (g)(1) or (g)(2) of this section on projected U.S.-directed production estimates. This is allowed for model year 2007 and/or 2008. However, if a manufacturer's actual U.S. directed production volume of engines that comply with the model year 2007 NO_X and NMHC standards is less than the required amount, the shortfall (in terms of number of engines) must be made up prior to 2010. For example, if a manufacturer plans in good faith to produce 50 percent of its projected 10,000 2007 engines (i.e., 5,000 engines) in compliance with the 2007 NO_X and NMHC standard, but is only able to produce 4,500 such engines of an actual 10,000 2007 engines, the manufacturer would need to produce an extra 500 engines in 2008 or 2009 in compliance with the 2007 NO_X and NMHC standard. The deficit allowed by this paragraph (g)(3) may not exceed 25 percent of the U.S. directed production volume.

(4) Manufacturers certifying engines to a voluntary NO_X standard of 0.10 g/bhp-hr (without using credits) in addition to all of the other applicable standards listed in paragraphs (a) and (c) of this section prior to model year 2007 may reduce the number of engines that are required to meet the standards listed in paragraph (a)(1) of this section in model year 2007, 2008 and/or 2009, taking into account the phase-in option provided in paragraph (g)(1) of this section. For every engine that is certified early under this provision, the manufacturer may reduce the number of engines that are required by paragraph (g)(1) of this section to meet the standards listed in paragraph (a)(1) of this section by two engines.

(5) For engines certified under paragraph (g)(1) of this section to the NO_X+NMHC standard in § 86.004–11, the standards or FELs to which they are certified shall be used for the purposes of paragraphs (a)(3) and (a)(4) of this section.

(h)(1) For model years prior to 2012, for purposes of determining compliance after title or custody has transferred to the ultimate purchaser, for engines having a NO_X FEL no higher than 1.30 g/bhp-hr, the applicable compliance limit shall be determined by adding the applicable adjustment from paragraph (h)(2) of this section to the otherwise applicable standard or FEL for NO_X.

(2)(i) For engines with 110,000 or fewer miles, the adjustment is 0.10 g/bhp-hr.

(ii) For engines with 110,001 to 185,000 miles, the adjustment is 0.15 g/bhp-hr.

(iii) For engines with 185,001 or more miles, the adjustment is 0.20 g/bhp-hr.

(3) For model years prior to 2012, for purposes of determining compliance after title or custody has transferred to the ultimate purchaser, the applicable compliance limit shall be determined by adding 0.01 g/bhp-hr to the otherwise applicable standard or FEL for PM.

19. A new § 86.007–is added to Subpart A to read as follows:

§ 86.007–15 NO_X and particulate averaging, trading, and banking for heavy-duty engines.

Section 86.007–15 includes text that specifies requirements that differ from § 86.004–15. Where a paragraph in § 86.004–15 is identical and applicable to § 86.007–15, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.004–15."

(a) through (l) [Reserved]. For guidance see § 86.004–15.

(m) The following provisions apply for model year 2007 and later engines (including engines certified during years 2007–2009 under the phase-in provisions of § 86.007–11(g)(1), § 86.005–10(a), or § 86.008–10(f)(1)). These provisions apply instead of the provisions of paragraphs § 86.004–15 (a) through (k) to the extent that they are in conflict.

(1) Manufacturers of Otto-cycle engines may participate in an NMHC averaging, banking and trading program to show compliance with the standards specified in § 86.008–10. The generation and use of NMHC credits are subject to the same provisions in paragraphs § 86.004–15 (a) through (k) that apply for NO_X plus NMHC credits, except as otherwise specified in this section.

(2) Credits are calculated as NO_X or NMHC credits for engines certified to separate NO_X and NMHC standards. NO_X plus NMHC credits (including banked credits and credits that are generated during years 2007–2009 under the phase-in provisions of § 86.007–11(g)(1), § 86.005–10(a), or § 86.008–10(f)(1)) may be used to show compliance with 2007 or later NO_X standards (NO_X or NMHC standards for Otto-cycle engines), subject to an 0.8 discount factor (e.g., 100 grams of NO_X plus NMHC credits is equivalent to 80 grams of NO_X credits).

(3) NO_X or NMHC (or NO_X plus NMHC) credits may be exchanged between heavy-duty Otto-cycle engine families certified to the engine standards of this subpart and heavy-duty Otto-cycle engine families certified to the chassis standards of subpart S of this part, subject to an 0.8 discount factor (e.g., 100 grams of NO_X (or NO_X plus NMHC) credits generated from engines would be equivalent to 80 grams of NO_X credits if they are used in the vehicle program of subpart S, and vice versa).

(4) Credits that were previously discounted when they were banked according to paragraph (c) of § 86.004–15, are subject to an additional discount factor of 0.888 instead of the 0.8 discount factor otherwise required by paragraph (m)(2) or (m)(3) of this section. This results in a total discount factor of 0.8 (0.9 × 0.888 = 0.8).

(5) For diesel engine families, the combined number of engines certified to FELs higher than 0.50 g/bhp-hr using banked NO_X (and/or NO_X plus NMHC) credits in any given model year may not exceed 10 percent of the manufacturer's U.S.-directed production of engines in all heavy-duty diesel engine families for that model year.

(6) The FEL must be expressed to the same number of decimal places as the standard (generally, one-hundredth of a gram per brake horsepower-hour). For engines certified to standards expressed only one-tenth of a gram per brake horsepower-hour, if the FEL is below 1.0, then add a zero to the standard in the second decimal place and express the FEL to nearest one-hundredth of a gram per brake horsepower-hour.

(7) Credits are to be rounded to the nearest one-hundredth of a Megagram using ASTM E29–93a (Incorporated by reference at § 86.1).

(8) Credits generated for 2007 and later model year diesel engine families, or generated for 2008 and later model year Otto-cycle engine families are not discounted (except as specified in paragraph (m)(2) or (m)(3) of this section), and do not expire.

(9) For the purpose of using or generating credits during a phase-in of new standards, a manufacturer may elect to split an engine family into two subfamilies (e.g., one which uses credits and one which generates credits). The manufacturer must indicate in the application for certification that the engine family is to be split, and may assign the numbers and configurations of engines within the respective subfamilies at any time prior to the submission of the end-of-year report required by § 86.001–23.

(i) Manufacturers certifying a split diesel engine family to both the Phase 1 and Phase 2 standards with equally sized subfamilies may exclude the engines within that split family from end-of-year NO_X (or NO_X+NMHC) ABT calculations, provided that neither

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subfamily generates credits for use by other engine families, or uses banked credits, or uses averaging credits from other engine families. All of the engines in that split family must be excluded from the phase-in calculations of § 86.007–11(g)(1) (both from the number of engines complying with the standards being phased-in and from the total number of U.S.-directed production engines.)

(ii) Manufacturers certifying a split Otto-cycle engine family to both the Phase 1 and Phase 2 standards with equally sized subfamilies may exclude the engines within that split family from end-of-year NO_X (or NO_X+NMHC) ABT calculations, provided that neither subfamily generates credits for use by other engine families, or uses banked credits, or uses averaging credits from other engine families. All of the engines in that split family must be excluded from the phase-in calculations of § 86.008–10(f)(1) (both from the number of engines complying with the standards being phased-in and from the total number of U.S.-directed production engines.)

(iii) Manufacturers certifying a split engine family may label all of the engines within that family with a single NO_X or NO_X+NMHC FEL. The FEL on the label will apply for all SEA or other compliance testing.

(iv) Notwithstanding the provisions of paragraph (m)(9)(iii) of this section, for split families, the NO_X FEL shall be used to determine applicability of the provisions of § 86.007–11(a)(3)(ii), (a)(4)(i)(B), and (h)(1), and § 86.008–10(g).

(10) For model years 2007 through 2009, to be consistent with the phase-in provisions of § 86.007–11(g)(1), credits generated from engines in one diesel engine service class (e.g., light-heavy duty diesel engines) may be used for averaging by engines in a different diesel engine service class, provided the credits are calculated for both engine families using the conversion factor and useful life of the engine family using the credits, and the engine family using the credits is certified to the standards listed in § 86.007–11(a)(1). Banked or traded credits may not be used by any engine family in a different service class than the service class of the engine family generating the credits.

20. A new § 86.007–23 is added to Subpart A to read as follows:

§ 86.007–23 Required data.

Section 86.007–23 includes text that specifies requirements that differ from § 86.095–23, § 86.098–23, or § 86.001–23. Where a paragraph in § 86.095–23, § 86.098–23, or § 86.001–23 is identical and applicable to § 86.007–23, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.095–23.", "[Reserved]. For guidance see § 86.098–23.", or "[Reserved]. For guidance see § 86.001–23.".

(a) through (b)(1) [Reserved]. For guidance see § 86.098–23.

(b)(2) [Reserved]. For guidance see § 86.001–23.

(b)(3) and (b)(4) [Reserved]. For guidance see § 86.098–23.

(c) *Emission data.*—(1) *Certification vehicles.* The manufacturer shall submit emission data (including, methane, methanol, formaldehyde, and hydrocarbon equivalent, as applicable) on such vehicles tested in accordance with applicable test procedures and in such numbers as specified. These data shall include zero-mile data, if generated, and emission data generated for certification as required under § 86.000–26(a)(3). In lieu of providing emission data the Administrator may, on request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with certain applicable emission standards of this part. Standards eligible for such manufacturer requests are those for idle CO emissions, smoke emissions, or particulate emissions from methanol-fueled or gaseous-fueled diesel-cycle certification vehicles, those for particulate emissions from Otto-cycle certification vehicles or gaseous-fueled vehicles, and those for formaldehyde emissions from petroleum-fueled vehicles. Also eligible for such requests are standards for total hydrocarbon emissions from model year 1994 and later certification vehicles. By separate request, including appropriate supporting test data, the manufacturer may request that the Administrator also waive the requirement to measure particulate or formaldehyde emissions when conducting Selective Enforcement Audit testing of Otto-cycle vehicles.

(2) *Certification engines.* The manufacturer shall submit emission data on such engines tested in accordance with applicable emission test procedures of this subpart and in such numbers as specified. These data shall include zero-hour data, if generated, and emission data generated for certification as required under § 86.000–26(c)(4). In lieu of providing emission data on idle CO emissions or particulate emissions from methanol-fueled or gaseous-fueled diesel-cycle certification engines, on particulate emissions from Otto-cycle engines, or on CO emissions from diesel-cycle certification engines, the Administrator may, on request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with the applicable emission standards of this part. In lieu of providing emission data on smoke emissions from methanol-fueled or petroleum-fueled diesel certification engines, the Administrator may, on the request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with the applicable emissions standards of this part. In lieu of providing emissions data on smoke emissions from diesel-cycle engines when conducting Selective Enforcement Audit testing under subpart K of this part, the Administrator may, on separate request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with the applicable smoke emissions standards of this part .

(d) through (e)(1) [Reserved]. For guidance see § 86.098–23.

(e)(2) and (e)(3) [Reserved]. For guidance see § 86.001–23.

(f) through (g) [Reserved]. For guidance see § 86.095–23.

(h) through (k) [Reserved]. For guidance see § 86.098–23.

(l) [Reserved]. For guidance see § 86.095–23.

(m) [Reserved]. For guidance see § 86.098–23.

21. A new § 86.007–25 is added to Subpart A to read as follows:

§ 86.007–25 Maintenance.

Section 86.007–25 includes text that specifies requirements that differ from § 86.094–25, § 86.098–25, or § 86.004–25. Where a paragraph in § 86.094–25, § 86.098–25, or § 86.004–25 is identical and applicable to § 86.007–25, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–25.", "[Reserved]. For guidance see § 86.098–25.", or "[Reserved]. For guidance see § 86.004–25.".

(a) through (a)(2) [Reserved]. For guidance see § 86.004–25.

(b) introductory text through (b)(3)(ii) [Reserved]. For guidance see § 86.094–25.

(b)(3)(iii) through (b)(3)(v)(H) [Reserved]. For guidance see § 86.004–25.

(b)(3)(vi)(A) through (b)(3)(vi)(D) [Reserved]. For guidance see § 86.094–25.

(b)(3)(vi)(E) through (b)(3)(vi)(J) [Reserved]. For guidance see § 86.098–25.

(b)(4) introductory text through (b)(4)(iii)(C) [Reserved]. For guidance see § 86.004–25.

(b)(4)(iii)(D) Particulate trap or trap oxidizer systems including related components (adjustment and cleaning only for filter element, replacement of the filter element is not allowed during the useful life).

(b)(4)(iii)(E) [Reserved]. For guidance see § 86.004–25.

(F) Catalytic converter (adjustment and cleaning only for catalyst beds, replacement of the bed is not allowed during the useful life).

(b)(4)(iii)(G) through (b)(6) [Reserved]. For guidance see § 86.004–25.

(b)(7) through (h) [Reserved]. For guidance see § 86.094–25.

(i) Notwithstanding the provisions of § 86.004–25(b)(4)(iii) introductory text through (b)(4)(iii)(C), paragraph (b)(4)(iii)(D) of this section, § 86.004–25(b)(4)(iii)(E), paragraph (b)(4)(iii)(F) of this section, § 86.004–25(b)(4)(iii)(G), and § 86.004–25(b)(6), manufacturers of heavy-duty engines may schedule replacement or repair of particulate trap (or trap oxidizer) systems or catalytic converters (including NO_X adsorbers), provided:

(1) The manufacturer demonstrates to the Administrator's satisfaction that the repair or replacement will be performed according to the schedule; and

(2) The manufacturer pays for the repair or replacement.

22. A new § 86.007–35 is added to Subpart A to read as follows:

§ 86.007–35 Labeling.

Section 86.007–35 includes text that specifies requirements that differ from § 86.095–35. Where a paragraph in § 86.095–35 is identical and applicable to § 86.007–35, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.095–35.".

(a) Introductory text through (a)(1)(iii)(L) [Reserved]. For guidance see § 86.095–35.

(a)(1)(iii)(M) [Reserved.]

(a)(1)(iii)(N)(*1*) For vehicles exempted from compliance with certain revised performance warranty procedures, as specified in § 86.096–21(j), a statement indicating the specific performance warranty test(s) of 40 CFR part 85, subpart W, not to be performed.

(*2*) For vehicles exempted from compliance with all revised performance warranty procedures, as specified in § 86.096–21(k), a statement indicating:

(*i*) That none of the performance warranty tests of 40 CFR part 85, subpart W, is to be performed; and

(*ii*) The name of the Administrator-approved alternative test procedure to be performed.

(2) Light-duty truck and heavy-duty vehicles optionally certified in accordance with the light-duty truck provisions.

(i) A legible, permanent label shall be affixed in a readily visible position in the engine compartment.

(ii) The label shall be affixed by the vehicle manufacturer who has been issued the certificate of conformity for such vehicle, in such a manner that it cannot be removed without destroying or defacing the label. The label shall not be affixed to any equipment which is easily detached from such vehicle.

(iii) The label shall contain the following information lettered in the English language in block letters and numerals, which shall be of a color that contrasts with the background of the label:

(A) The label heading: Important Vehicle Information;

(B) Full corporate name and trademark of the manufacturer;

(C) Engine displacement (in cubic inches or liters), engine family identification, and evaporative/refueling family;

(a)(2)(iii)(D) through (a)(2)(iii)(E) [Reserved]. For guidance see § 86.095–35.

(a)(2)(iii)(F) [Reserved]

(a)(2)(iii)(G) through (a)(2)(iii)(K) [Reserved]. For guidance see § 86.095–35.

(a)(2)(iii)(L) [Reserved]

(a)(2)(iii)(M) through (a)(2)(iii)(N) [Reserved]. For guidance see § 86.095–35.

(a)(2)(iii)(O)(*1*) For vehicles exempted from compliance with certain revised performance warranty procedures, as specified in § 86.096–21(j), a statement indicating the specific performance warranty test(s) of 40 CFR part 85, subpart W, not to be performed.

(*2*) For vehicles exempted from compliance with all revised performance warranty procedures, as specified in § 86.096–21(k), a statement indicating:

(*i*) That none of the performance warranty tests of 40 CFR part 85, subpart W, is to be performed, and

(*ii*) The name of the Administrator-approved alternative test procedure to be performed.

(a)(3) heading through (b) [Reserved]. For guidance see § 86.095–35.

(c) Model year 2007 and later diesel-fueled vehicles must include permanent readily visible labels on the dashboard (or instrument panel) and near all fuel inlets that state "Use Low-Sulfur Diesel Fuel Only" or "Low-Sulfur Diesel Fuel Only".

(d) through (i) [Reserved]. For guidance see § 86.095–35.

23. A new § 86.007–38 is added to Subpart A to read as follows:

§ 86.007–38 Maintenance instructions.

Section 86.007–38 includes text that specifies requirements that differ from those specified in § 86.094–38 or § 86.004–38. Where a paragraph in § 86.094–38 or § 86.004–38 is identical and applicable to § 86.007–38, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–38.", or "[Reserved]. For guidance see § 86.004–38.".

(a) through (f) [Reserved]. For guidance see § 86.004–38.

(g) [Reserved]. For guidance see § 86.094–38.

(h) [Reserved]. For guidance see § 86.004–38.

(i) For each new diesel-fueled engine subject to the standards prescribed in § 86.007–11, as applicable, the manufacturer shall furnish or cause to be furnished to the ultimate purchaser a statement that "This engine must be operated only with low sulfur diesel fuel (that is, diesel fuel meeting EPA specifications for highway diesel fuel, including a 15 ppm sulfur cap)."

24. A new § 86.008–10 is added to subpart A to read as follows:

§ 86.008–10 Emission standards for 2008 and later model year Otto-cycle heavy-duty engines and vehicles.

Section 86.008–10 includes text that specifies requirements that differ from § 86.099–10. Where a paragraph in § 86.099–10 is identical and applicable to § 86.008–10, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.099–10.".

(a)(1) Exhaust emissions from new 2008 and later model year Otto-cycle HDEs shall not exceed:

(i)(A) *Oxides of Nitrogen (NO_X).* 0.20 grams per brake horsepower-hour (0.075 grams per megajoule).

(B) A manufacturer may elect to include any or all of its Otto-cycle HDE families in any or all of the NO_X and NO_X plus NMHC emissions ABT programs for HDEs, within the restrictions described in § 86.008–15 or § 86.004–15. If the manufacturer elects to include engine families in any of these programs, the NO_X FEL may not exceed 0.50 grams per brake horsepower-hour (0.26 grams per

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megajoule). This ceiling value applies whether credits for the family are derived from averaging, banking, or trading programs. The NO_X FEL cap is 0.80 for model years before 2011 for manufacturers choosing to certify to the 1.5 g/bhp-hr NO_X+NMHC standard in 2003 or 2004, in accordance with § 86.005–10(f).

(ii)(A) *Non-methane Hydrocarbons (NMHC) for engines fueled with either gasoline, natural gas, or liquefied petroleum gas.* 0.14 grams per brake horsepower-hour (0.052grams per megajoule).

(B) *Non-methane Hydrocarbon Equivalent (NMHCE) for engines fueled with methanol.* 0.14 grams per brake horsepower-hour (0.052grams per megajoule).

(C) A manufacturer may elect to include any or all of its Otto-cycle HDE families in any or all of the NMHC emissions ABT programs for HDEs, within the restrictions described in § 86.008–15 or § 86.004–15. If the manufacturer elects to include engine families in any of these programs, the NMHC FEL may not exceed 0.30 grams per brake horsepower-hour. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading programs. The NMHC FEL cap is 0.40 for model years before 2011 for manufacturers choosing to certify to the 1.5 g/bhp-hr NO_X+NMHC in 2004, as allowed in § 86.005–10.

(iii)(A) *Carbon monoxide.* 14.4 grams per brake horsepower-hour (5.36 grams per megajoule).

(B) *Idle Carbon Monoxide.* For all Otto-cycle HDEs utilizing aftertreatment technology, and not certified to the onboard diagnostics requirements of § 86.005–17: 0.50 percent of exhaust gas flow at curb idle.

(iv) *Particulate.* 0.01grams per brake horsepower-hour (0.0037grams per megajoule).

(2) The standards set forth in paragraph (a)(1) of this section refer to the exhaust emitted over the operating schedule set forth in paragraph (f)(1) of appendix I to this part, and measured and calculated in accordance with the procedures set forth in subpart N or P of this part.

(3) [Reserved]

(4) [Reserved]

(b) Evaporative emissions from heavy-duty vehicles shall not exceed the following standards. The standards apply equally to certification and in-use vehicles. The spitback standard also applies to newly assembled vehicles. For certification vehicles only, manufacturers may conduct testing to quantify a level of nonfuel background emissions for an individual test vehicle. Such a demonstration must include a description of the source(s) of emissions and an estimated decay rate. The demonstrated level of nonfuel background emissions may be subtracted from emission test results from certification vehicles if approved in advance by the Administrator.

(1) Hydrocarbons (for vehicles equipped with gasoline-fueled, natural gas-fueled or liquefied petroleum gas-fueled engines).

(i) For vehicles with a Gross Vehicle Weight Rating of up to 14,000 lbs:

(A)(*1*) For the full three-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 1.4 grams per test.

(*2*) For the supplemental two-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements (gasoline-fueled vehicles only): 1.75 grams per test.

(B) Running loss test (gasoline-fueled vehicles only): 0.05 grams per mile.

(C) Fuel dispensing spitback test (gasoline-fueled vehicles only): 1.0 grams per test.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs:

(A)(*1*) For the full three-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 1.9 grams per test.

(*2*) For the supplemental two-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements (gasoline-fueled vehicles only): 2.3 grams per test.

(B) Running loss test (gasoline-fueled vehicles only): 0.05 grams per mile.

(2) Total Hydrocarbon Equivalent (for vehicles equipped with methanol-fueled engines).

(i) For vehicles with a Gross Vehicle Weight Rating of up to 14,000 lbs:

(A)(*1*) For the full three-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 1.4 grams carbon per test.

(*2*) For the supplemental two-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 1.75 grams carbon per test.

(B) Running loss test: 0.05 grams carbon per mile.

(C) Fuel dispensing spitback test: 1.0 grams carbon per test.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 14,000 lbs:

(A)(*1*) For the full three-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 1.9 grams carbon per test.

(*2*) For the supplemental two-diurnal test sequence described in § 86.1230–96, diurnal plus hot soak measurements: 2.3 grams carbon per test.

(B) Running loss test: 0.05 grams carbon per mile.

(3)(i) For vehicles with a Gross Vehicle Weight Rating of up to 26,000 lbs, the standards set forth in paragraphs (b)(1) and (b)(2) of this section refer to a composite sample of evaporative emissions collected under the conditions and measured in accordance with the procedures set forth in subpart M of this part.

(ii) For vehicles with a Gross Vehicle Weight Rating of greater than 26,000 lbs., the standards set forth in paragraphs (b)(1)(ii) and (b)(2)(ii) of this section refer to the manufacturer's engineering design evaluation using good engineering practice (a statement of which is required in § 86.098–23(b)(4)(ii)).

(4) All fuel vapor generated in a gasoline- or methanol-fueled heavy-duty vehicle during in-use operations shall be routed exclusively to the evaporative control system (e.g., either canister or engine purge). The only exception to this requirement shall be for emergencies.

(c) No crankcase emissions shall be discharged into the ambient atmosphere from any new 2008 or later model year Otto-cycle HDE.

(d) Every manufacturer of new motor vehicle engines subject to the standards prescribed in this section shall, prior to taking any of the actions specified in section 203(a)(1) of the Act, test or cause to be tested motor vehicle engines in accordance with applicable procedures in subpart N or P of this part to ascertain that such test engines meet the requirements of this section.

(e) [Reserved]. For guidance see § 86.099–10.

(f) Phase-in options. (1)(i) For model year 2008, manufacturers may certify some of their engine families to the exhaust standards applicable to model year 2007 engines under § 86.005–10, in lieu of the exhaust standards specified in this section. These engines must comply with all other requirements applicable to model year 2008 engines, except as allowed by paragraph (f)(1)(ii) of this section. The combined number of engines in the engine families certified to the 2007 combined NO_X plus NMHC standard may not exceed 50 percent of the manufacturer's U.S.-directed production of heavy-duty Otto-cycle motor vehicle engines for model year 2008, except as explicitly allowed by paragraph (f)(2) of this section.

(ii) For model year 2008, manufacturers may certify some of their engine families to the evaporative standards applicable to model year 2007 engines under § 86.005–10, in lieu of the standards specified in this section. These engines must comply with all other requirements applicable to model year 2008 engines, except as allowed by paragraph (f)(1)(i) of this section. The combined number of engines in the engine families certified to the 2007 standards may not exceed 50 percent of the manufacturer's U.S.-directed production of heavy-duty Otto-cycle motor vehicle engines for model year 2008.

(2)(i) Manufacturers certifying engines to all of the applicable exhaust standards listed in paragraph (a) of this section prior to model year 2008 (without using credits) may reduce the number of engines that are required to meet the NO_X and NMHC exhaust standards listed in paragraph (a) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (f)(1) of this section. For every engine that is certified early, the manufacturer may reduce the number of engines that are required by paragraph (f)(1) of this section to meet the NO_X and NMHC standards listed in paragraph (a) of this section by one engine. For example, if a manufacturer produces 100 heavy-duty Otto-cycle engines in 2007 that meet all of the applicable standards listed in paragraph (a) of this section, and it produced 10,000 heavy-duty Otto-cycle engines in 2009, then only 9,900 of the engines would need to comply with the NO_X and NMHC standards listed in paragraph (a) of this section.

(ii) Manufacturers certifying engines to all of the applicable evaporative standards listed in paragraph (b) of this section prior to model year 2008 may reduce the number of engines that are required to meet the evaporative standards listed in paragraph (a) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (f)(1) of this section. For every engine that is certified early, the manufacturer may reduce the number of engines that are required by paragraph (f)(1) of this section to meet evaporative standards listed in paragraph (b) of this section by one engine.

(3) Manufacturers certifying engines to a voluntary NO_X standard of 0.10 g/bhp-hr (without using credits) in addition to all of the applicable standards listed in paragraphs (a) and (b) of this section prior to model year 2008 may reduce the number of engines that are required to meet the NO_X and NMHC standards listed in paragraph (a) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (f)(1) of this section. For such every engine that is certified early, the manufacturer may reduce the number of engines that are required by paragraph (f)(1) of this section to meet the NO_X and NMHC standards listed in paragraph (a) of this section by two engines.

(g) For model years prior to 2012, for purposes of determining compliance after title or custody has transferred to the ultimate purchaser, for engines having a NO_X FEL no higher than 0.50 g/bhp-hr, the applicable compliance limits for NO_X and NMHC shall be determined by adding 0.10 g/bhp-hr to the otherwise applicable standards or FELs for NO_X and NMHC.

25. A new § 86.113–07 is added to subpart B to read as follows:

§ 86.113–07 Fuel specifications.

Section 86.113–07 includes text that specifies requirements that differ from § 86.113–94 or § 86.113–04. Where a paragraph in § 86.113–94 or § 86.113–04 is identical and applicable to § 86.113–07, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.113–94." or "[Reserved]. For guidance see § 86.113–04.".

(a) [Reserved]. For guidance see § 86.113–04.

(b)(1) [Reserved]. For guidance see § 86.113–94.

(b)(2) Petroleum fuel for diesel vehicles meeting the following specifications, or substantially equivalent specifications approved by the Administrator, must be used in exhaust emissions testing. The grade of petroleum diesel fuel recommended by the engine manufacturer, commercially designated as "Type 2–D" grade diesel, must be used:

Item		ASTM test method No.	Type 2–D
(i) Cetane Number		D613	40–50
(ii) Cetane Index		D976	40–50
(iii) Distillation range:			
(A) IBP	°F	D86	340–400
	(°C)		(171.1–204.4)
(B) 10 pct. point	°F	D86	400–460
	(°C)		(204.4–237.8)
(C) 50 pct. point	°F	D86	470–540
	(°C)		(243.3–282.2)
(D) 90 pct. point	°F	D86	560–630
	(°C)		(293.3–332.2)
(E) EP	°F	D86	610–690
	(°C)		(321.1–365.6)
(iv) Gravity	°API	D287	32–37
(v) Total sulfur	ppm	D2622	7–15
(vi) Hydrocarbon composition:			
(A) Aromatics, minimum (Remainder shall be paraffins, naphthenes, and olefins)	pct.	D5186	27
(vii) Flashpoint, min.	°F	D93	130
	(°C)		(54.4)
(viii) Viscosity	centistokes	D445	2.0–3.2

(3) Petroleum fuel for diesel vehicles meeting the following specifications, or substantially equivalent specifications approved by the Administrator, shall be used in service accumulation. The grade of petroleum diesel fuel recommended by the engine manufacturer, commercially designated as "Type 2-D" grade diesel fuel, shall be used: (b)(4) through (g) [Reserved]. For guidance see § 86.113–94.

Item		ASTM test method No.	Type 2–D
(i) Cetane Number		D613	38–58

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Item		ASTM test method No.	Type 2–D
(ii) Cetane Index		D976	min. 40
(iii) Distillation range:			
90 pct. point	°F	D86	540–630
(iv) Gravity	°API	D287	30–39
(v) Total sulfur	ppm	D2622	7–15
(vi) Flashpoint, min.	°F	D93	130
	(°C)		(54.4)
(vii) Viscosity	centistokes	D445	1.5–4.5

(h)(1) For model year 2004 through 2006 Tier 2 diesel-fueled vehicles that incorporate sulfur-sensitive technologies, the manufacturer may test the vehicle using a test fuel meeting the specifications listed in paragraphs (b)(2) and (b)(3) of this section, provided the manufacturer clearly recommends to the ultimate purchaser in the owner's manual that the vehicle should use fuel with no higher than 15 ppm sulfur.

(2) For model year 2004 through 2006 Tier 2 diesel-fueled vehicles that incorporate sulfur-sensitive technologies and that are certified for 50-state sale (*i.e.*, certified to California and EPA standards), the manufacturer may test the vehicle using a test fuel whose qualities, on a specification by specification basis, meet the requirements of either the specifications listed in paragraph (b)(2) of this section or the California test fuel specifications, provided the manufacturer clearly recommends to the ultimate purchaser in the owner's manual that the vehicle should use fuel with no higher than 15 ppm sulfur.

(3) Where a manufacturer uses a test fuel under paragraph (h)(1) or (h)(2) of this section, EPA shall use the same fuel for its compliance testing.

26. A new § 86.1213–04 is added to Subpart M to read as follows:

§ 86.1213–04 Fuel specifications.

The test fuels listed in § 86.1313–04 shall be used for evaporative emission testing.

27. A new § 86.1306–07 is added to subpart N to read as follows:

§ 86.1306–07 Equipment required and specifications; overview.

Section 86.1306–07 includes text that specifies requirements that differ from § 86.1306–96. Where a paragraph in § 86.1306–96 is identical and applicable to § 86.1306–07, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1306–96.".

(a) and (b) [Reserved]. For guidance see § 86.1306–96.

(c)(1) Upon request, the Administrator may allow a manufacturer to use some of the test equipment allowed for model year 2006 and earlier engines instead of the test equipment required for model year 2007 and later engines, provided that good engineering judgment indicates that it would not adversely affect determination of compliance with the applicable emission standards of this part.

(2) A manufacturer may use the test equipment required for model year 2007 and later engines for earlier model year engines, provided that good engineering judgment indicates that it would not adversely affect determination of compliance with the applicable emission standards of this part.

(d) Approval of alternate test system. (1) If on the basis of the information described in paragraph (d)(5) of this section, the Administrator determines that an alternate test system would consistently and reliably produce emission test results that are at least equivalent to the results produced using the test systems described in this subpart, he/she shall approve the alternate system for optional use instead of the test systems described in this subpart.

(2) Any person may submit an application for approval of an alternate test system.

(3) In approving an alternate test system, the Administrator may approve it for general use, or may approve it conditionally.

(4) The Administrator may revoke the approval on the basis of new information that indicates that the alternate test system is not equivalent. However, revocation of approval must allow manufacturers sufficient lead-time to change the test system to an approved system. In determining the amount of lead-time that is required, the Administrator will consider relevant factors such as:

(i) The ease with which the test system can be converted to an approved system.

(ii) The degree to which the alternate system affects the measured emission rates.

(iii) Any relevant conditions included in the approval.

(5) The application for approval must include:

(i) *An explanation of the theoretical basis of the alternate system.* This technical description should explain why the detection principle of the alternate system would provide equivalent results to the detection principle of the prescribed system for the full range of emission properties being measured. This description may include equations, figures, and references. For example, a NO_X measurement application should theoretically relate the alternate detection principle to the chemiluminescent detection principle of detecting nitric oxide for a typical range of NO to NO_2 ratios. A PM measurement application should explain the principle(s) by which the alternate system quantifies PM mass independent of PM composition, and how it is impacted by semi-volatile and volatile species= phase distributions. For any proportioning or integrating system, the application should compare the alternate system's theoretical response to the prescribed system's response.

(ii) *A technical description of the alternate system.* This section shall detail all of the hardware and software included in the alternate system. Dimensioned drawings, flow-charts, schematics, and component specifications shall be included. Any data manipulation (*i.e.* calculations) that the system performs shall be presented in this section.

(iii) *A description of the procedures used to operate the system including the level of training that an operator must have to achieve acceptable results.* This section of the application shall describe all of the installation, calibration, operation, and maintenance procedures in a step-by-step format. Note that empirical calibration with respect to another prescribed or approved measurement system is not acceptable. Calibration should be performed with NIST traceable standards, or equivalent national standards. Diagrams, schematics, and other graphics may be used to enhance the description.

(iv) *A comparison of results from the alternate system and from the prescribed system (or other system approved by the Administrator).* The two systems must be calibrated independently to NIST traceable standards or equivalent national standards for this comparison. While other statistical analyses may be acceptable, it is recommended that the comparison be based on a minimum of 7 collocated and simultaneous tests. This comparison shall be performed over the "hot-start" portion of the FTP test cycle. If the comparison is paired, it must demonstrate that the alternate system passes a two-sided, paired t-test described in this paragraph. If the test is unpaired, it must demonstrate that the alternate system passes a two-sided, unpaired t-test described in this paragraph. Other statistical criteria may be set by the Administrator. The average of these tests for the reference system must return results less than or equal to the applicable emissions standard. The t-test is performed as follows, where "n" equals the number of tests:

(A) Calculate the average of the alternate system results; this is A_{avg}.

(B) Calculate the average of the results of the system to which the alternate system was referenced; this is R_{avg}.

(C) For an unpaired comparison, calculate the "n−1" standard deviation for the alternate and reference averages; these are A_{sd} and R_{sd} respectively. A_{sd} must be less than or equal to R_{sd}. If A_{sd} is greater than R_{sd}, the Administrator will not approve the application.

(D) For an unpaired comparison, calculate the t-value:

$t_{unpaired} = (A_{avg} - R_{avg})/((A_{sd}^2 + R_{sd}^2)/n)^{1/2}$

(E) For a paired comparison, calculate the "n−1" standard deviation (squared) of the differences, d_i, between the paired results, where "i" represents the ith test of n number of tests:

$S_D^2 = (Sd_i^2 - ((Sd_i)^2/n))/(n-1)$

(F)(*1*) For a paired comparison, calculate the t-value:

$t_{paired} = (A_{avg} - R_{avg})/(S_D^2/n)^{1/2}$

(*2*) The absolute value of t must be less than the critical t value, t_{crit} at a 90% confidence interval for "n−1" degrees of freedom. The following table lists 90% confidence interval t_{crit} values for n−1 degrees of freedom:

90% Confidence interval critical t values vs. n−1 degrees of freedom for a two-sided, paired t−test

n − 1	t_{crit}
6	1.94
7	1.89
8	1.86
9	1.83
10	1.81
11	1.80
12	1.78
13	1.77
14	1.76
15	1.75
16	1.75
17	1.74
18	1.73
19	1.73
20	1.72

28. Section 86.1309–90 is amended by revising the section heading and paragraph (a)(1) to read as follows:

§ 86.1309–90 Exhaust gas sampling system; Otto-cycle and non-petroleum-fueled engines.

(a)(1) *General.* The exhaust gas sampling system described in this paragraph is designed to measure the true mass of gaseous emissions in the exhaust of either gasoline-fueled, natural gas-fueled, liquefied petroleum gas-fueled or methanol-fueled engines. In the CVS concept of measuring mass emissions, two conditions must be satisfied; the total volume of the mixture of exhaust and dilution air must be measured, and a continuously proportioned volume of sample must be collected for analysis. Mass emissions are determined from the sample concentration and total flow over the test period.

* * * * *

29. A new section 86.1310–07 is added to Subpart N to read as follows:

§ 86.1310–2007 Exhaust gas sampling and analytical system for gaseous emissions from heavy-duty diesel-fueled engines and particulate emissions from all engines.

(a) *General.* The exhaust gas sampling system described in this paragraph is designed to measure the true mass of both gaseous and particulate emissions in the exhaust of heavy-duty diesel engines, and particulate emissions in the exhaust of all heavy-duty engines. (Gaseous emissions from non-petroleum-fueled diesel engines are measured using the system described in § 86.1309.) This system utilizes the CVS concept (described in § 86.1309) of measuring the combined mass emissions of THC, NO_X, CH_4 (if applicable) CO, CO_2 and particulate matter. For all emission measurement systems described in this section, multiple or redundant systems may be used during a single test. Statistical averages of data from multiple systems may be used to calculate test results, consistent with good engineering judgment. Weighted averages are allowed, where appropriate Statistical outliers may be discarded, but all results must be reported. If the Administrator determines that the statistical analysis is not consistent with good engineering judgment, he/she may determine compliance from the arithmetic mean of the results. A continuously integrated system may be used for THC, NO_X, CO and CO_2 measurement. The use of proportional bag sampling for sample integration is allowed for THC, NO_X, CO, and CO_2 measurement, but requirements specific to bag sampling from diesel exhaust must be met for the THC and NO_X emissions measurements. CH_4 measurement for calculation of NMHC (if applicable) is measured using GC–FID analysis of a proportional bag sample. The mass of gaseous emissions is determined from the sample concentration and total flow over the test period. The mass of particulate emissions is determined from a proportional mass sample collected on a filter and from the sample flow and total flow over the test period. As an option, the measurement of total fuel mass consumed over a cycle may be substituted for the exhaust measurement of CO_2. General requirements are as follows:

(1) This sampling system requires the use of a CVS The CVS system may use a PDP or a CFV. PDP systems must use a heat exchanger. CFV systems may use either a heat exchanger or electronic flow compensation. When electronic flow compensation is used, the CFV may be replaced by a subsonic venturi (SSV) as long as the CVS concept as defined in § 86.1309 is maintained (i.e., a constant volumetric flow-rate through the CVS is maintained for the duration of the test). Figure N07–1 is a schematic drawing of the CVS system.

(2) The THC analytical system for diesel engines requires a heated flame ionization detector (HFID) and heated sample system (191 ± 11 °C) using either:

(i) Continuously integrated measurement of diluted THC meeting the minimum requirements and technical specifications contained in paragraph (b)(3) of this section. Unless compensation for varying mass flow is made, a constant mass flow system must be used to ensure a proportional sample; or

(ii) Heated (191 ± 11 °C) proportional bag sampling systems for hydrocarbon measurement will be allowed if the bag sampling system meets the performance specifications for outgassing and permeability as defined in paragraph (b)(2) of this section.

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(3) CH_4 measurement, if applicable, shall be conducted using a proportional bag sampling system with subsequent analysis using a gas chromatograph and FID. The CH_4 measurement shall be done in accordance with SAE Recommended Practice J1151, "Methane Measurement Using Gas Chromatography" (1994 SAE Handbook, Volume 1: Materials, Fuels, Emissions, and Noise, Section 13, Page 13.170), which is incorporated by reference pursuant to § 86.1(b)(2). As an alternative, the manufacturer may choose one of the options set forth in § 86.004–28(c)(8).

(4) [Reserved]

(5) [Reserved]

(6) The CO and CO_2 analytical system requires:

(i) Bag sampling (§ 86.1309) and analytical (§ 86.1311) capabilities, as shown in Figure N07–1; or

(ii) Continuously integrated measurement of diluted CO and CO_2 meeting the minimum requirements and technical specifications contained in paragraph (b)(5) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a proportional sample; and

(7) The NO_X analytical system requires:

(i) Continuously integrated measurement of diluted NO_X meeting the minimum requirements and technical specifications contained in paragraph (b)(5) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a proportional sample.

(ii) Bag sampling (§ 86.1309) and analytical (§ 86.1311) capabilities, as shown in Figure N07–1 (or Figure 07–2) will be allowed provided that sample gas temperature is maintained above the sample's aqueous dewpoint at all times during collection and analysis.

(8) The mass of particulate in the exhaust is determined via filtration. The particulate sampling system requires dilution of the exhaust to a temperature of 47 °C ± 5 °C, measured upstream of a single high-efficiency sample filter (as close to the filter as practical).

(9) Since various configurations can produce equivalent results, exact conformance with these drawings is not required. Additional components such as instruments, valves, solenoids, pumps, and switches may be used to provide additional information and coordinate the functions of the components of the system. Other components, such as snubbers, which are not needed to maintain accuracy on some systems, may be excluded if their exclusion is based upon good engineering judgment.

(10) Other sampling and/or analytical systems may be used if shown to yield equivalent results and if approved in advance by the Administrator (see § 86.1306–07).

(b) *Component description.* The components necessary for exhaust sampling shall meet the following requirements:

(1) *Exhaust dilution system.* The CVS shall conform to all of the requirements listed for the exhaust gas CVS systems in § 86.1309(b), (c), and (d). With respect to PM measurement, the intent of this measurement procedure is to perform the sample cooling primarily via dilution and mixing with air rather than via heat transfer to the surfaces of the sampling system. In addition the CVS must conform to the following requirements:

(i) The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream at the temperatures required for the measurement of particulate and hydrocarbon emission noted below and at, or above, the temperatures where aqueous condensation in the exhaust gases could occur. This is achieved by the following method. The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream in the primary dilution tunnel at a temperature of 191 °C or less at the sampling zone and as required to prevent condensation at any point in the dilution tunnel. Gaseous emission samples may be taken directly from this sampling point. An exhaust sample must then be taken at this point to be diluted a second time for use in determining particulate emissions. The secondary dilution system must provide sufficient secondary dilution air to maintain the double-diluted exhaust stream at a temperature of 47 C ± 5 C, measured at a point located between the filter face and 16 cm upstream of the filter face.

(ii) For the CVS , either a heat exchanger (*i.e.* CFV–CVS) or electronic flow compensation (*i.e.* EFC–CFV–CVS), which also includes the particulate sample flows is required Refer to Figure N07–1.

(iii) When a heat exchanger is used, the gas mixture temperature, measured at a point immediately ahead of the critical flow venturi, shall be within ±11 °C of the average operating temperature observed during the test with the simultaneous requirement that aqueous condensation does not occur. The temperature measuring system (sensors and readout) shall have an accuracy and precision of ±1.9 °C. For systems utilizing a flow compensator to maintain proportional sampling, the requirement for maintaining constant temperature is not necessary.

(iv) The primary dilution air and secondary dilution air:

(A) Shall have a primary and secondary dilution air temperature equal to or greater than 15 °C.

(B) Primary dilution air shall be filtered at the dilution air inlet. The manufacturer of the primary dilution air filter shall state that the filter design has successfully achieved a minimum particle removal efficiency of 98% (less than 0.02 penetration) as determined using ASTM test method F 1471–93 (incorporated by reference at section 86.1). Secondary dilution air shall be filtered at the dilution air inlet using a high-efficiency particulate air filter (HEPA). The HEPA filter manufacturer shall state the HEPA filter design has successfully achieved a minimum particle removal efficiency of 99.97% (less than 0.0003 penetration) as determined using ASTM test method F 1471–93. It is recommended that the primary dilution air be filtered using a HEPA filter. EPA intends to utilize HEPA filters to condition primary dilution air in its test facilities. It is acceptable to use of a booster blower upstream or downstream of a HEPA filter in the primary dilution tunnel (and upstream of the introduction of engine exhaust into the CVS) to compensate for the additional pressure loss associated with the filter. The design of any booster blower located downstream of the filter should minimize the introduction of additional particulate matter into the CVS.

(C) Primary dilution air may be sampled to determine background particulate levels, which can then be subtracted from the values measured in the diluted exhaust stream. In the case of primary dilution air, the background particulate filter sample shall be taken immediately downstream of the dilution air filter and upstream of the engine exhaust flow (Figure N07–1). The provisions of paragraphs (b)(7) of this section, and of § 86.1312–2007 also apply to the measurement of background particulate matter, except that the filter temperature must be maintained below 52 °C.

(2) *Heated proportional bag sampling systems.* If a heated (191 ± 11 °C) proportional bag sampling system is used for THC measurement, sample bags must demonstrate minimal outgassing and permeability by passing the following performance test:

(i) Performance test for sample bag HC outgassing and CO_2 permeability. Bring the bag system to its operational temperature. Fill the heated sample bag with a nominal mixture of 1% CO_2 in N_2. Perform an initial measurement of CO_2 and THC from the sample bag, and repeat the measurement after one hour. Acceptable performance criteria are <2% decrease of the initial CO_2 reading and <1 ppmC THC.

(ii) [Reserved]

(3) *Continuous HC measurement system.* (i) The continuous HC sample system (as shown in Figure N07–1) uses an "overflow" zero and span system. In this type of system, excess zero or span gas spills out of the probe when zero and span checks of the analyzer are made. The "overflow" system may also be used to calibrate the HC analyzer per § 86.1321(b), although this is not required.

(ii) No other analyzers may draw a sample from the continuous HC sample probe, line or system, unless a common sample pump is used for all analyzers and the sample line system design reflects good engineering practice.

(iii) The overflow gas flow rates into the sample line shall be at least 105% of the sample system flow rate.

(iv) The overflow gases shall enter the heated sample line as close as practicable to the outside surface of the CVS duct or dilution tunnel.

(v) The continuous HC sampling system shall consist of a probe (which must raise the sample to the specified temperature) and, where used, a sample transfer system (which must maintain the specified temperature). The continuous hydrocarbon sampling system (exclusive of the probe) shall:

(A) Maintain a wall temperature of 191°C ± 11°C as measured at every separately controlled heated component (*i.e.*, filters, heated line sections), using permanent thermocouples located at each of the separate components.

(B) Have a wall temperature of 191°C ± 11°C over its entire length. The temperature of the system shall be demonstrated by profiling the thermal characteristics of the system at initial installation and after any major maintenance performed on the system. The temperature profile of the HC sampling system shall be demonstrated by inserting thermocouple wires (typically Teflon™ coated for ease of insertion) into the sampling system assembled in-situ where possible, using good engineering judgment. The wire should be inserted up to the HFID inlet. Stabilize the sampling system heaters at normal operating temperatures. Withdraw the wires in increments of 5 cm to 10 cm (2 inches to 4 inches) including all fittings. Record the stabilized temperature at each position. The system temperature will be monitored during testing at the locations and temperature described in § 86.1310–90(b)(3)(v)(A).

Note: It is understood that profiling of the sample line can be done under flowing conditions also as required with the probe. This test may be cumbersome if test facilities utilize long transfer lines and many fittings; therefore it is recommended that transfer lines be kept as short as possible and the use of fittings should be kept minimal.

(C) Maintain a gas temperature of 191°C ±11°C immediately before the heated filter and HFID. These gas temperatures will be determined by a temperature sensor located immediately upstream of each component.

(vi) The continuous hydrocarbon sampling probe shall:

(A) Be defined as the first 25.4 cm (10 in) to 76.2 cm (30 in) of the continuous hydrocarbon sampling system;

(B) Have a 0.483 cm (0.19 in) minimum inside diameter;

(C) Be installed in the primary dilution tunnel at a point where the dilution air and exhaust are well mixed (*i.e.*, approximately 10 tunnel diameters downstream of the point where the exhaust enters the dilution tunnel);

(D) Be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influence of any wakes or eddies; and

(E) Increase the gas stream temperature to 191°C ± 11°C by the exit of the probe. The ability of the probe to accomplish this shall be demonstrated at typical sample flow rates using the insertion thermocouple technique at initial installation and after any major maintenance. Compliance with the temperature specification shall be demonstrated by monitoring during each test the temperature of either the gas stream or the wall of the sample probe at its terminus.

(vii) The response time of the continuous measurement system shall be no greater than:

(A) 1.5 seconds from an instantaneous step change at the port entrance to the analyzer to within 90 percent of the step change;

(B) 10 seconds from an instantaneous step change at the entrance to the sample probe or overflow span gas port to within 90 percent of the step change. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets if necessary; and

(C) For the purpose of verification of response times, the step change shall be at least 60 percent of full-scale chart deflection.

(4) *Primary-dilution tunnel.* (i) The primary dilution tunnel shall be:

(A) Small enough in diameter to cause turbulent flow (Reynolds Number greater than 4000) and of sufficient length to cause complete mixing of the exhaust and dilution air. Good engineering judgment shall dictate the use of mixing plates and mixing orifices to ensure a well-mixed sample. To verify mixing, EPA recommends flowing a tracer gas (*i.e.* propane or CO_2) from the raw exhaust inlet of the dilution tunnel and measuring its concentration at several points along the axial plane at the sample probe. Tracer gas concentrations should remain nearly constant (*i.e.* within 2%) between all of these points.

(B) At least 8 inches (20 cm) in diameter.

(C) Constructed of electrically conductive material which does not react with the exhaust components.

(D) Electrically grounded.

(E) EPA recommends that the tunnel should have minimal thermal capacitance such that the temperature of the walls tracks with the temperature of the diluted exhaust.

(ii) The temperature of the diluted exhaust stream inside of the primary dilution tunnel shall be sufficient to prevent water condensation.

(iii) The engine exhaust shall be directed downstream at the point where it is introduced into the primary dilution tunnel.

(5) *Continuously integrated NO_X, CO, and CO2 measurement systems.* (i) The sample probe shall:

(A) Be in the same plane as the continuous HC probe, but shall be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influences of any wakes or eddies; and

(B) Heated and insulated over the entire length, to prevent water condensation, to a minimum temperature of 131°F (55° C). Sample gas temperature immediately before the first filter in the system shall be at least 131° F (55° C).

(ii) The continuous NO_X, CO, or CO2 sampling and analysis system shall conform to the specifications of subpart D of this part, with the following exceptions:

(A) The system components required to be heated by subpart D need only be heated to prevent water condensation, the minimum component temperature shall be 131° F (55° C);

(B) The system response defined in § 86.329–79 shall be no greater than 10 seconds. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets, if necessary;

(C) Alternative NO_X measurement techniques outlined in § 86.346–79 are

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not permitted for NO_X measurement in this subpart;

(D) All analytical gases shall conform to the specifications of § 86.1314;

(E) Any range on a linear analyzer below 100 ppm shall have and use a calibration curve conforming to § 86. 1323–07; and

(F) The measurement accuracy requirements are specified in § 86. 1338–07 .

(iii) The signal output of analyzers with non-linear calibration curves shall be converted to concentration values by the calibration curve(s) specified in subpart D of this part (§ 86.330–79) before flow correction (if used) and subsequent integration takes place.

(6) *Particulate sampling system.* This method collects a proportional sample from the primary tunnel, and then transfers this sample to a secondary dilution tunnel where the sample is further diluted. The double-diluted sample is then passed through the collection filter. Proportionality (i.e., mass flow ratio) between the primary tunnel flow rate and the sample flow rate must be maintained within ±5%, excluding the first 10 seconds of the test at start-up. The requirements for this system are:

(i) The particulate sample transfer tube shall be configured and installed so that:

(A) The inlet faces upstream in the primary dilution tunnel at a point where the primary dilution air and exhaust are well mixed.

(B) The particulate sample exits on the centerline of the secondary tunnel.

(ii) The entire particulate sample transfer tube shall be:

(A) Sufficiently distant (radially) from other sampling probes (in the primary dilution tunnel) so as to be free from the influence of any wakes or eddies produced by the other probes.

(B) 0.85 cm minimum inside diameter.

(C) No longer than 36 in (91 cm) from inlet plane to exit plane.

(D) Designed to minimize the diffusional and thermophoretic deposition of particulate matter during transfer (i.e., sample residence time in the transfer tube should be as short as possible, temperature gradients between the flow stream and the transfer tube wall should be minimized). Double-wall, thin-wall, air-gap insulated, or a controlled heated construction for the transfer tube is recommended.

(E) Constructed such that the surfaces exposed to the sample shall be an electrically conductive material, which does not react with the exhaust components, and this surface shall be electrically grounded so as to minimize electrostatic particulate matter deposition.

(iii) The secondary dilution air shall be at a temperature equal to or greater than 15° C.

(iv) The secondary-dilution tunnel shall be constructed such that the surfaces exposed to the sample shall be an electrically conductive material, which does not react with the exhaust components, and this surface shall be electrically grounded so as to minimize electrostatic particulate deposition.

(v) Additional dilution air must be provided so as to maintain a sample temperature of 47° C ± 5° C upstream of the sample filter. Temperature shall be measured with a thermocouple with a 3/16″ shank, having thermocouple wires with a gage diameter 24 AWG or smaller, a bare-wire butt-welded junction; or other suitable temperature measurement with an equivalent or faster time constant and an accuracy and precision of ± 1.9° C.

(vi) The filter holder assembly shall be located within 12.0 in (30.5 cm) of the exit of the secondary dilution tunnel.

(vii) The face velocity through the sample filter shall not exceed 100 cm/s (face velocity is defined as the standard volumetric sample flow rate (i.e., scm3/sec) divided by the sample filter stain area (i.e., cm2)).

(7) *Particulate sampling.* (i) *Filter specifications.* (A) Polytetrafluoroethylene (PTFE or Teflon™) coated borosilicate glass fiber high-efficiency filters or polytetrafluoroethylene (PTFE or Teflon™) high-efficiency membrane filters with an integral support ring of polymethylpentene (PMP) or equivalent inert material are required. Filters shall have a minimum clean filter efficiency of 99% as measured by the ASTM D2986–95a DOP test (incorporated by reference at § 86.1).

(B) Particulate filters must have a diameter of 46.50 ± 0.6 mm (38 mm minimum stain diameter).

(C) The dilute exhaust is simultaneously sampled by a single high-efficiency filter during the cold-start test and by a second high efficiency filter during the hot-start test.

(D) It is recommended that the filter loading should be maximized consistent with temperature requirements.

(ii) *Filter holder assembly.* The filter holder assembly shall comply with the specifications set forth for ambient PM measurement in 40 CFR Part 50, Appendix L 7.3.5, figures L–25 and L–26, with the following exceptions:

(A) The material shall be 302, 303, or 304 stainless steel instead of anodized aluminum.

(B) The 2.84 cm diameter entrance to the filter holder may be adapted, using sound engineering judgment and leak-free construction, to an inside diameter no smaller than 0.85 cm, maintaining the 12.5° angle from the inlet of the top filter holder to the area near the sealing surface of the top of the filter cartridge assembly. Figure N07–2 shows acceptable variation from the design in 40 CFR Part 50, Appendix L. Similar variations using sound engineering design are also acceptable provided that they provide even flow distribution across the filter media and a similar leak-free seal with the filter cartridge assembly.

(C) If additional or multiple filter cartridges are stored in a particulate sampler as part of an automatic sequential sampling capability, all such filter cartridges, unless they are installed in the sample flow (with or without flow established) shall be covered or sealed to prevent communication of semi-volatile matter from filter to filter; contamination of the filters before and after sampling; or loss of volatile or semi-volatile particulate matter after sampling.

(iii) *Filter cartridge assembly.* The filter cartridge assembly shall comply with the specifications set forth for ambient PM measurement in 40 CFR Part 50, Appendix L 7.3.5, figures L–27, L–28, and L–29, with the following exceptions:

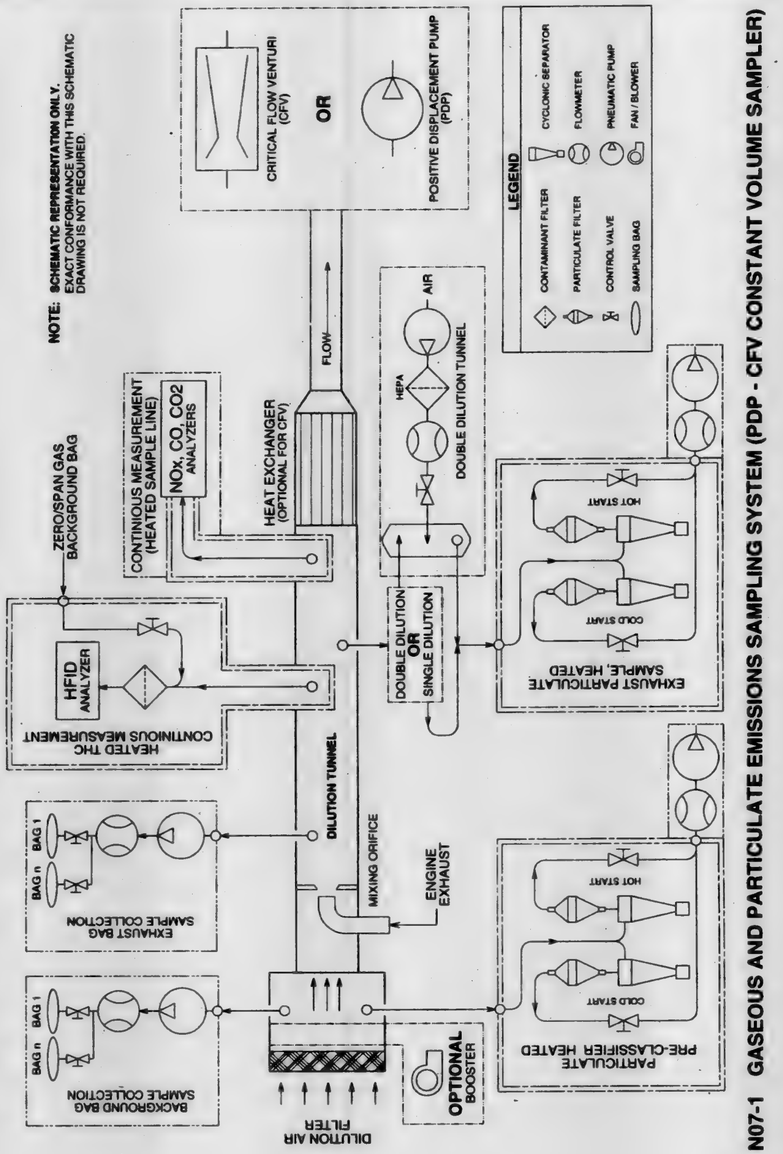
(A) In addition to the specified Delrin™ material, 302, 303, or 304 stainless steel, polycarbonate or acrylonitrile/butadiene/styrene (ABS) resin, or a combination of these materials may also be used.

(B) A bevel introduced on the inside diameter of the entrance to the filter cartridge, as used by some commercially available automated sequential particulate filter cartridge changers, is also acceptable (see Figure N07–3).

(iv) *Particle preclassifier.* A particle preclassifier shall be installed immediately upstream of the filter holder assembly (N07–1). The purpose of the preclassifier is to remove coarse, mechanically generated particles (e.g., rust from the engine exhaust system or carbon sheared from the sampling system walls) from the sample flow stream while allowing combustion-generated particles to pass through to the filter. The preclassifier may be either an inertial impactor or a cyclonic separator. The preclassifier manufacturer 50% cutpoint particle diameter shall be between 2.5 μm and 10 μm at the volumetric flow rate selected for sampling of particulate matter emissions. Sharpness of cut is not specifically defined, but the preclassifier geometry shall allow at least 99% of the mass concentration of 1 μm particles to pass through the exit of the preclassifier to the filter at the volumetric flow rate selected for sampling particulate matter emissions. Periodic servicing of the preclassifier will be necessary to prevent a buildup of mechanically separated particles. The particle preclassifier may be made integral with the top of the filter holder assembly. The preclassifier may also be made integral with a mixing-tee for introduction of secondary dilution air, thus replacing the secondary dilution tunnel; provided that the preclassifier provides sufficient mixing.

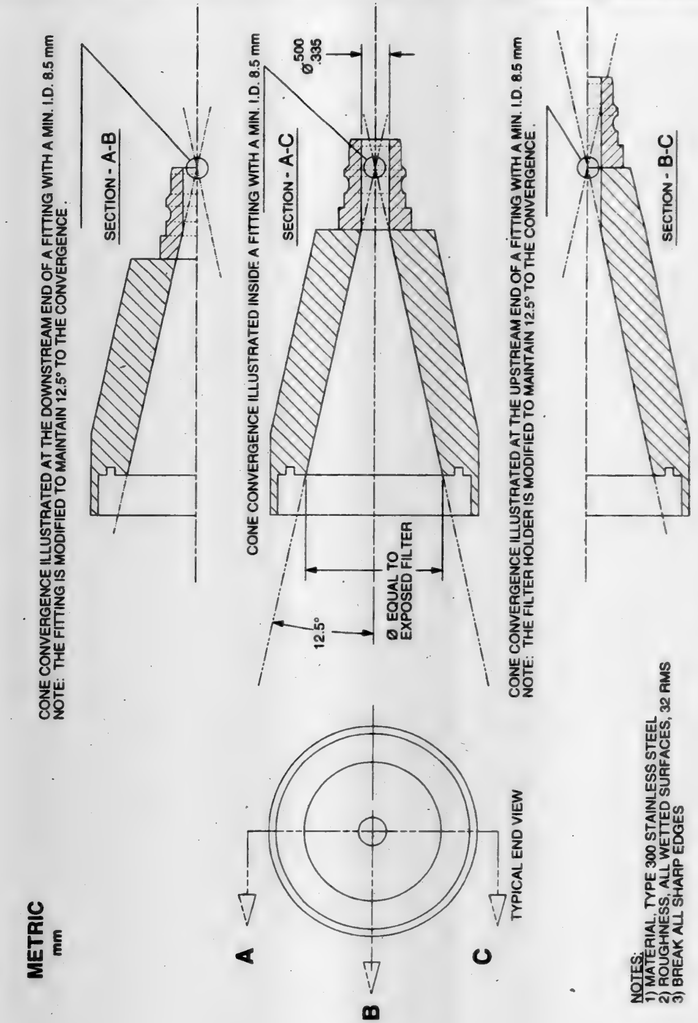
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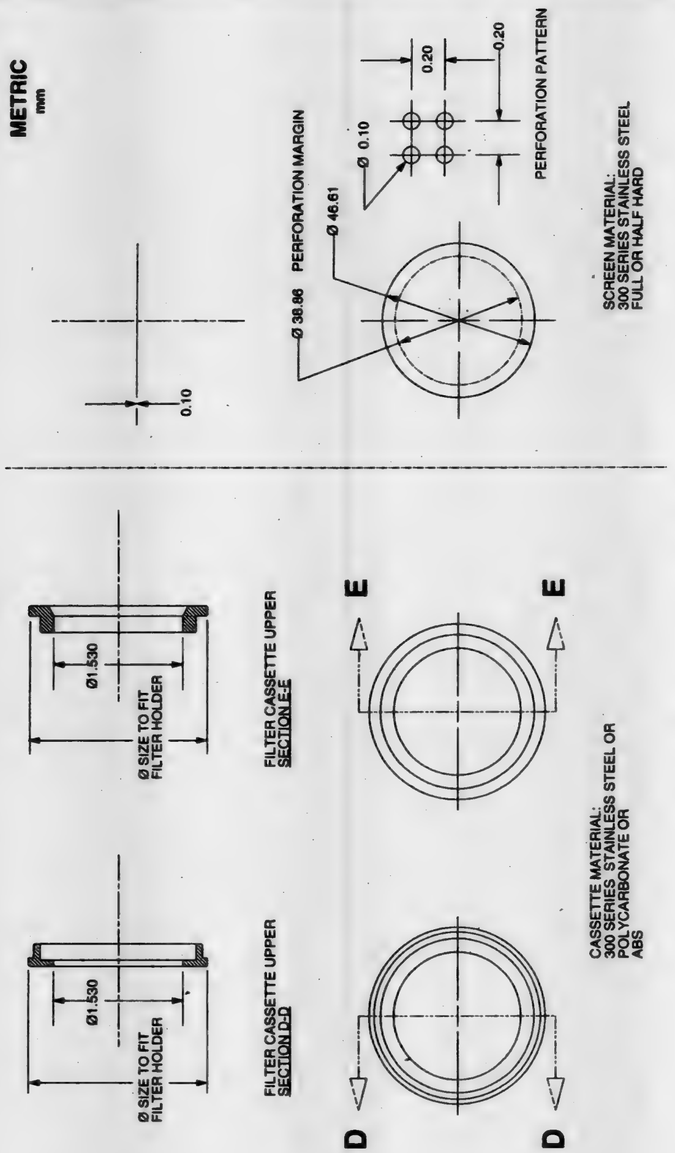
Figures to § 86.1310-2007

N07-1 GASEOUS AND PARTICULATE EMISSIONS SAMPLING SYSTEM (PDP - CFV CONSTANT VOLUME SAMPLER)



N07-2 FILTER HOLDER GEOMETRY

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30. A new section 86.1312–2007 is added to Subpart N to read as follows:

§ 86.1312–2007 Filter stabilization and microbalance workstation environmental conditions, microbalance specifications, and particulate matter filter handling and weighing procedures.

(a) *Ambient conditions for filter stabilization and weighing.*—(1) *Temperature and humidity.* (i) The filter stabilization environment shall be maintained at 22 °C ± 3 °C and a dewpoint of 9.5 °C ± 1 °C. Dewpoint shall be measured with an instrument that exhibits an accuracy of at least ±0.25 °C NIST traceable as stated by the instrument manufacturer. Temperature shall be measured with an instrument that exhibits an accuracy of at least ±0.2°C or better.

(ii) The immediate microbalance workstation environment shall be maintained at 22 °C ± 1 °C and a dewpoint of 9.5 °C ± 1 °C. If the microbalance workstation environment freely circulates with the filter stabilization environment, and this entire environment meets 22 °C ± 1 °C and a dewpoint of 9.5 °C ± 1 °C , then there is no requirement to measure temperature and dewpoint at the microbalance separate from the filter stabilization location. Otherwise, temperature at the microbalance workstation shall be measured with an instrument that exhibits an accuracy of at least ±0.2°C or better, and dewpoint shall be measured with an instrument that exhibits an accuracy of at least ±0.25 °C NIST traceable as stated by the instrument manufacturer.

(2) *Cleanliness.* (i) The microbalance and filter stabilization environments shall be free of ambient contaminants (such as dust or other aerosols) that could settle on the particulate filters. It is recommended that these environments be built to conform with the Class 1000 specification (or cleaner) as determined by Federal Standard 209D or 209E for clean room classification (Available from the Institute of Environmental Standards and Technology website at *www.iest.org* or phone (847) 255–1561). An alternative recommendation would be to equilibrate and/or weigh the filters within a separate, smaller, particle-free, temperature and humidity-controlled chamber (*i.e.*, "glove box").

(ii) Reference filters shall be used to monitor for gross particle contamination. It is required that at least two unused reference filters remain in the filter stabilization environment at all times in partially covered glass petri dishes, as in paragraph (c) (1) of this section. These reference filters shall be placed in the filter stabilization environment. The reference filters shall be weighed within 2 hours of, but preferably at the same time as, the sample filters. The reference filters shall be changed at least once a month, but never while any sample filters are between their tare weight (pre-sampling) and gross weight (post-sampling) measurements. The reference filters shall be the same size and material as the sample filters.

(3) *Quality control of ambient conditions.* (i) If, before the start of a weighing session, the temperature or dewpoint of the filter stabilization environment are not within specifications, then filters must remain in the environment for at least 30 minutes after conditions are corrected. If the filter stabilization environment changes during a weighing session such that the specifications are no longer met, the weighing session shall be suspended until the environment has returned to within specifications for at least 30 minutes. Once the environment has returned to within specifications for at least 30 minutes, the reference filters shall be reweighed and the criteria in paragraph (a)(3)(ii) of this section shall apply. Note that temperature and dewpoint shall be sampled once per second, and an unweighted 5-minute moving average of this data shall be calculated once per second. This moving average shall be used to determine the environment temperature and dewpoint for the purpose of determining whether or not the environment is within specifications.

(ii) If the average change in weight of the reference filters is more than 10 micrograms (after correcting for buoyancy as described in paragraph (c)(3) of this section), then all filters in the process of stabilization shall be discarded and all data collected with respect to the discarded filters shall be considered void. Note that more than 2 reference filters may be used to achieve a more robust average of the change in weight of the reference filters.

(b) *Microbalance specifications.* The microbalance used to determine the weights of all filters shall have a precision (standard deviation) of at least ±0.25 micrograms or better for repeated weighing of a calibration weight, a precision of at least ±2.5 micrograms or better for repeated weighing of a clean filter, and a readability equal to or less than 0.1 micrograms. It is recommended that the microbalance be installed on a vibration isolation platform to isolate the microbalance's load cell from external vibration. It is also recommended that the microbalance should be shielded from convective airflow by means of an electrically grounded static dissipative draft shield. Microbalance manufacturer specifications for all preventive maintenance, periodic certification, calibration, and re-zeroing shall be followed. All certification and calibration procedures shall be NIST traceable, or traceable to an equivalent national standard.

(c) *Particulate matter filter handling and weighing.* Care should be taken to prevent contamination of the sample filters and to prevent a buildup of static charge on the filters that could interfere with filter weighing. Static neutralizers, such as Po-210 sources, shall be used to neutralize charge on a filter prior to each weighing. A static neutralizer should be replaced at the interval recommended by its manufacturer, or when it is no longer able to reduce static charge on a filter to less than ±2 VDC as measured with an electrostatic monitor at the microbalance workstation. The person weighing filters shall be grounded with respect to the microbalance to prevent imparting a static charge on the filters. This can be accomplished safely by using a grounding strap such as the wrist straps that are commonly used in the microelectronics industry, or by connecting a similar grounding strap to the tweezers. To prevent electrical shock, a 1-megohm resistor should be installed in series between the person weighing filters and ground.

(1) Within the filter stabilization environment, a pair of clean and electrically conductive tweezers shall be used to place a filter in the lower half of a filter cassette and the cassette shall be placed in a partially open glass petri dish. The petri dish lid should extend over the filter to prevent gross contamination, but it should be left slightly open on one edge to permit stabilization with the environment for at least 30 minutes.

(2) After at least 30 minutes of stabilization, each filter shall be weighed using the specified microbalance. The process of weighing a filter may be repeated and a statistical mean weight of a single filter may be calculated. Sound engineering judgment shall dictate the use of statistics to discard outliers and the weighting of averages. For a clean filter its single weight or statistical mean weight shall be considered the uncorrected tare weight of the filter.

(3) All filter weights shall be corrected for filter buoyancy in air. For the uncorrected tare weight of a filter, this calculated value is the corrected tare weight of the filter, and it must be recorded (see § 86.1344(e)(18)).

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Barometric pressure of the microbalance environment shall be measured with an instrument that exhibits ±0.01% full-scale accuracy and 0.01% per-year full scale stability, and the full-scale value used for such a specification shall not exceed 200 kPa.

(i) Buoyancy correction calculation. (A) Calculate vapor pressure of liquid water using the dewpoint temperature in the Magnus formula:

$P_w = 0.6113 \times 10^{\wedge}((7.5 \times T_{dp})/(237.3 + T_{dp}))$

Where:

P_w=vapor pressure of liquid water, kPa.
T_{dp}=dewpoint temperature, °C.

(B) Calculate air density using the ideal gas relationship and molecular weights of standard air and water:

$A=(3.484\times P-1.317\times P_w)/(T+273.15)$

Where:

A=air density, kg/m³.
P=barometric pressure, kPa.
P_w=vapor pressure of liquid water, kPa.
T=temperature, °C.

(C) Buoyancy correction:

$M=R\times(1-(A/\rho_w))/(1-(A/\rho_s))$.

Where:

M=corrected mass in units of the balance display.
R=uncorrected filter weight in units of the balance display.
A=calculated air density, kg/m³.
ρ_w=density of calibration weight used to calibrate the balance, kg/m³.
ρ_s=density of filter material used to sample PM emissions, kg/m³.

(ii) For determining ρ_s note that PTFE (Teflon™) and borosilicate glass both have densities in the range of 2,200 to 2,400 kg/m³. Therefore, for PTFE-coated borosilicate glass fiber filters, an acceptable ρ_s is 2,300 kg/m³. Note also that polymethylpentene has a density of 850 kg/m³. Because Teflon PTFE membrane filters have an integral polymethylpentene support ring that accounts for 95% of the filter mass, an acceptable ρ_s for these filters is 920 kg/m³. Other ρ_s values for other filters may be obtained similarly. Information about "ρ_s should be available from the calibration weight manufacturer.

(iii) This paragraph (c)(3)(iii) shows an example of the buoyancy correction. This example assumes the following inputs: Barometric pressure (P)=101.325 kPa, temperature (T)=22.0 °C, dewpoint temperature (T_{dp})=9.5 °C, balance display (R)=100.0000 mg, calibration weight density (ρ_w)=8,000 kg/m³, and filter material density (ρ_s)=2,300 kg/m³. Then:

(A) The water vapor pressure (P_w) is calculated as:

$P_w = 0.6113 \times 10\ ((7.5 \times 9.5)/(237.3 + 9.5)) = 1.186$ kPa.

(B) The air density (A) is calculated as:

$A = (3.484 \times 101.325 - 1.317 \times 1.186)/(22.0 + 273.15) = 1.191$ kg/m³.

(C) The corrected mass (M) is calculated as:

$M=100.0000 \times (1 - (1.191/8000))/(1 - (1.191/2300)) = 100.0369$ mg.

(4) The uncorrected weight, corrected weight, barometric pressure, temperature and humidity, of the filter shall be recorded. Afterward the filter shall be returned to the lower half of the filter cassette, and the upper half of the cassette shall be set in place. The cassette-with filter-shall then be stored in a covered glass petri dish or a sealed (*i.e.*, ends plugged) filter holder assembly, either of which shall remain in the filter stabilization environment until needed for testing. It is recommended that the filter be transported between the filter stabilization environment and the location of the emissions test within a sealed filter holder assembly.

(5) After the emissions test, the filter cassette shall be removed from the filter holder assembly. If this removal is performed in the filter stabilization environment, the upper half of the cassette shall be removed using a properly designed separator tool, the lower half of the cassette-with filter-shall be placed in a partially covered petri dish, and allowed to stabilize for at least 30 minutes. Otherwise, the cassette and filter shall be placed in a closed petri dish until it can be returned to the filter stabilization environment. Once the closed petri dish is returned to the filter stabilization environment, the petri dish shall be opened, the upper half of the cassette shall be removed using a properly designed separator tool, the lower half of the cassette-with filter-shall be placed in a partially covered petri dish, and allowed to stabilize for at least one hour.

(6) After at least 30 minutes, but no more than 60 hours of stabilization, each filter may be weighed using the specified microbalance. The process of weighing a filter may be repeated and a statistical mean may be calculated. Sound engineering judgment shall dictate the use of statistics to discard outliers and the weighting of averages. For a used filter, its single weight or statistical mean weight shall be identified as the uncorrected gross weight of the filter. The uncorrected gross weight shall be corrected for filter buoyancy using the procedure in (c)(3) of this section. The uncorrected gross filter weight, corrected gross filter weight, barometric pressure, temperature, and dewpoint shall be recorded.

(7) The net particulate matter weight (Pf) of each filter shall be equal to the corrected gross filter weight minus the corrected tare filter weight.

(8) Should the particulate matter on the filters contact the petri dish, tweezers, microbalance or any other surface, the data with respect to that filter is void.

31. A new § 86.1313–2004 is added to subpart N to read as follows:

§ 86.1313–2004 Fuel specifications.

Section 86.1313–04 includes text that specifies requirements that differ from § 86.1313–94 and § 86.1313–98. Where a paragraph in § 86.1313–94 or § 86.1313–98 is identical and applicable to § 86.1313–04, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1313–94." or "[Reserved]. For guidance see § 86.1313–98.".

(a) *Gasoline fuel.* (1) Gasoline having the following specifications will be used by the Administrator in exhaust and evaporative emission testing of petroleum-fueled Otto-cycle engines, except that the Administrator will not use gasoline having a sulfur specification higher than 0.0045 weight percent. Gasoline having the following specification or substantially equivalent specifications approved by the Administrator, must be used by the manufacturer in exhaust and evaporative testing except that octane specifications do not apply:

Item	ASTM test method No.	Value
(i) Octane, Research, Min.	D2699	93
(ii) Sensitivity, Min.		7.5
(iii) Lead (organic), maximum: g/U.S. gal. (g/liter)	D3237	0.050 (0.013)
(iv) Distillation Range:	D86	
(A) IBP[1]: °F (°C)		75–95 (23.9–35)
(B) 10 pct. point: °F (°C)		120–135 (48.9–57.2)
(C) 50 pct. point: °F (°C)		200–230 (93.3–110)
(D) 90 pct. point: °F (°C)		300–325 (148.9–162.8)
(E) EP, max: °F (°C)		415 (212.8)
(v) Sulfur, weight pct.	D1266	0.0015–0.008
(vi) Phosphorous, max. g/U.S. gal (g/liter)	D3231	0.005 (0.0013)
(vii) RVP[2,3]	D3231	8.7–9.2 (60.0–63.4)
(viii) Hydrocarbon composition:	D1319	
(A) Olefins, max. pct.		10
(B) Aromatics, max, pct.		35
(C) Saturates		Remainder

[1] For testing at altitudes above 1,219 m (4000 feet), the specified range is 75–105 deg. F (23.9–40.6 deg. C).
[2] For testing which is unrelated to evaporative emission control, the specified range is 8.0–9.2 psi (55.2–63.4 kPa).
[3] For testing at altitudes above 1,219 m (4000 feet), the specified range is 7.6–8.0 psi (52–55 kPa).

(2) For engines certified for sale in the 50 United States, "California Phase 2" gasoline having the specifications listed in the table in this section may be used in exhaust emission testing as an option to the specifications in paragraph (a)(1) of this section. If a manufacturer elects to utilize this option, the manufacturer must conduct exhaust emission testing with gasoline having the specifications listed in the table in this paragraph (a)(2). However, the Administrator may use or require the use of test fuel meeting the specifications in paragraph (a)(1) of this section for certification confirmatory testing, selective enforcement auditing and in-use testing. All fuel property test methods for this fuel are contained in Chapter 4 of the California Regulatory Requirements Applicable to the National Low Emission Vehicle Program (October, 1996). These requirements are incorporated by reference (see § 86.1). The table follows:

Fuel property	Limit
(i) Octane, (R+M)/2 (min)	91
(ii) Sensitivity (min)	7.5
(iii) Lead, g/gal (max) (No lead added)	0–0.01
(iv) Distillation Range, °F:	
(A) 10 pct. point,	130–150
(B) 50 pct. point,	200–210
(C) 90 pct. point,	290–300
(D) EP, maximum	390
(v) Residue, vol % (max)	2.0
(vi) Sulfur, ppm by wt.	15–40, except that Administrator may use and approve for use, lower ranges where such ranges are consistent with current California requirements.
(vii) Phosphorous, g/gal (max)	0.005
(viii) RVP, psi	6.7–7.0
(ix) Olefins, vol %	4.0–6.0
(x) Total Aromatic Hydrocarbons (vol %)	22–25
(xi) Benzene, vol %	0.8–1.0
(xii) Multi-Substituted Alkyl Aromatic Hydrocarbons, vol %	12–14
(xiii) MTBE, vol %	10.8–11.2
(xiv) Additives	See Chapter 4 of the California Regulatory Requirements Applicable to the National Low Emission Vehicle Program (October, 1996). These procedures are incorporated by reference (see § 86.1).
(xv) Copper Corrosion	No. 1
(xvi) Gum, Washed, mg/100 ml (max)	3.0
(xvii) Oxidation Stability, minutes (min)	1000
(xviii) Specific Gravity	No limit; report to purchaser required
(xix) Heat of Combustion	No limit; report to purchaser required
(xx) Carbon, wt %	No limit; report to purchaser required
(xxi) Hydrogen, wt %	No limit; report to purchaser required

(3)(i) Unless otherwise approved by the Administrator, unleaded gasoline representative of commercial gasoline that will be generally available through retail outlets must be used in service accumulation. Unless otherwise approved by the Administrator, this gasoline must have a minimum sulfur content of 15 ppm. Unless otherwise approved by the Administrator, fuel used for evaporative emission durability demonstration must contain ethanol as required by § 86.1824–01(a)(2)(iii). Leaded gasoline must not be used in service accumulation.

(ii) Unless otherwise approved by the Administrator, the octane rating of the gasoline used must be no higher than 1.0 Retail octane number above the lowest octane rating that meets the fuel grade the manufacturer will recommend to the ultimate purchaser for the relevant production vehicles. If the manufacturer recommends a Retail octane number rather than a fuel grade, then the octane rating of the service accumulation gasoline can be no higher than 1.0 Retail octane number above the recommended Retail octane number. The service accumulation gasoline must

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also have a minimum sensitivity of 7.5 octane numbers, where sensitivity is defined as the Research octane number minus the Motor octane number.

(iii) The Reid Vapor Pressure of the gasoline used must be characteristic of the motor fuel used during the season in which the service accumulation takes place.

(4) The specification range of the gasoline to be used under paragraph (a) of this section must be reported in accordance with § 86.094–21(b)(3).

(b) heading and (b)(1) [Reserved]. For guidance see § 86.1313–94.

(b)(2) [Reserved]. For guidance see § 86.1313–98.

(b)(3) through (g) [Reserved]. For guidance see § 86.1313–94.

32. A new § 86.1313–2007 is added to Subpart N to read as follows:

§ 86.1313–2007 Fuel specifications.

Section 86.1313–2007 includes text that specifies requirements that differ from § 86.1313–94 and § 86.1313–2004. Where a paragraph in § 86.1313–94 or § 86.1313–2004 is identical and applicable to § 86.1313–2007, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1313–94." or "[Reserved]. For guidance see § 86.1313–04.".

(a) [Reserved]. For guidance see § 86.1313–2004.

(b) heading and (b)(1) [Reserved]. For guidance see § 86.1313–94.

(b)(2) Petroleum fuel for diesel engines meeting the specifications in Table N07–2, or substantially equivalent specifications approved by the Administrator, shall be used in exhaust emissions testing. The grade of petroleum fuel used shall be commercially designated as "Type 2-D" grade diesel fuel except that fuel commercially designated as "Type 1-D" grade diesel fuel may be substituted provided that the manufacturer has submitted evidence to the Administrator demonstrating to the Administrator's satisfaction that this fuel will be the predominant in-use fuel. Such evidence could include such things as copies of signed contracts from customers indicating the intent to purchase and use "Type 1-D" grade diesel fuel as the primary fuel for use in the engines or other evidence acceptable to the Administrator. (Note: Vehicles certified under § 86.007–11(f) must be tested using the test fuel specified in § 86.1313–2004, unless otherwise allowed by the Administrator.) Table N07–2 follows:

TABLE N07–2

Item		ASTM test method No.	Type 1–D	Type 2–D
(i) Cetane Number		D613	40–54	40–50
(ii) Cetane Index		D976	40–54	40–50
(iii) Distillation range:				
(A) IBP	°F	D86	330–390	340–400
	(°C)		(165.6–198.9)	(171.1–204.4)
(B) 10 pct. point	°F	D86	370–430	400–460
	(°C)		(187.8–221.1)	(204.4–237.8)
(C) 50 pct. point	°F	D86	410–480	470–540
	(°C)		(210.0–248.9)	(243.3–282.2)
(D) 90 pct. point	°F	D86	460–520	560–630
	(°C)		(237.8–271–1)	(293.3–332.2)
(E) EP	°F	D86	500–560	610–690
	(°C)		(260.0–293.3)	(321.1–365.6)
(iv) Gravity	°API	D287	40–44	32–37
(v) Total sulfur	ppm	D2622	7–15	7–15
(vi) Hydrocarbon composition:.				
(A) Aromatics, minimum (Remainder shall be paraffins, naphthenes, and olefins).	pct.	D5186	8	27
(vii) Flashpoint, min	°F	D93	120	130
	(°C)		(48.9)	(54.4)
(viii) Viscosity	centistokes	D445	1.6–2.0	2.0–3.2

(3) Petroleum Diesel fuel for diesel engines meeting the specifications in table N07–3, or substantially equivalent specifications approved by the Administrator, shall be used in service accumulation. The grade of petroleum diesel fuel used shall be commercially designated as Type 2–D" grade diesel fuel except that fuel commercially designated as "Type 1–D" grade Diesel fuel may be substituted provided that the manufacturer has submitted evidence to the Administrator demonstrating to the Administrator's satisfaction that this fuel will be the predominant in-use fuel. Such evidence could include such things as copies of signed contracts from customers indicating the intent to purchase and use "Type 1–D" grade diesel fuel as the primary fuel for use in the engines or other evidence acceptable to the Administrator. Table N07–03 follows:

TABLE N07–3

Item		ASTM test method No.	Type 1–D	Type 2–D
(i) Cetane Number		D613	40–56	38–58
(ii) Cetane Index		D976	min. 40	min. 40
(iii) Distillation range:				
90 pct. point	°F	D86	440–530	540–630
	(°C)		(226.7–276–7)	(293.3–332.2)
(iv) Gravity	°API	D287	39–45	30–39
(v) Total sulfur	ppm	D2622	7–15	7–15

TABLE N07–3—Continued

Item		ASTM test method No.	Type 1–D	Type 2–D
(vi) Flashpoint, min	°F	D93	130	130
	(°C)		(54.4)	(54.4)
(vii) Viscosity	centistokes	D445	1.2–2.2	1.5–4.5

(b)(4) through (g) [Reserved]. For guiDance see § 86.1313–94.

33. Section 86.1319–90 is amended by redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e) to read as follows:

§ 86.1319–90 CVS calibration.

* * * * *

(e) *SSV calibration.* (1) The calibration of the SSV located in the tunnel shall be conducted in a similar manner as the CFV or PDP calibration. Gas flow within the SSV is a function of inlet pressure, P_1, the inlet temperature, T_1, and the pressure drop between the throat and the inlet, DP. Note that the following procedure is consistent with SAE J244. The calibration procedure described in paragraph (e)(3) of this section establishes the values of the coefficients at measured values of pressure, temperature and airflow.

(i) The flow rate for a subsonic venturi is calculated as a volumetric flow rate (Q_s) or a mass flow rate (Q_m) as follows:

or

$$Q_s = \frac{Q_m}{\rho_s} = \frac{K_q}{\rho_s}\left(\frac{C_d * Y * d^2}{\sqrt{1-\beta^4}}\right)\sqrt{\rho_i * \Delta P}$$

$$Q_m = K_q * C_d * Y * d^2\left(\frac{\rho_i * \Delta P}{1-\beta^4}\right)^{1/2}$$

$$Y = \left[r^{\frac{2}{k}}\left(\frac{k}{k-1}\right)\left(\frac{1-r^{\left(\frac{k-1}{k}\right)}}{1-r}\right)\left(\frac{1-\beta^4}{1-\beta^4 * r^{\frac{2}{k}}}\right)\right]^{\frac{1}{2}}$$

Where:

K_q = 0.0021074 (SI units).
Q_s = Air Volume Flow, SCFM (m^3/min).
Q_m = Air Mass Flow, lbm/min (kg/min).
ρ_s = Density at Standard Conditions, lbm/ft^3 (kg/m^3) as specified in paragraph (e)(1)(v) of this section.
ρ_s = Density at inlet conditions, lbm/ft^3 (kg/m^3), as specified in paragraph (e)(1)(iii) of this section.
C_d = Coefficient of Discharge = Actual Air Flow/Theoretical Air Flow.
Y = Expansion factor, as specified in paragraph (e)(1)(ii) of this section.
d = Throat diameter, inch (mm).
β = Ratio of venturi throat diameter to approach pipe diameter.
ΔP = Pressure drop between inlet and throat, in. H_2O (kPa).

(ii) The expansion factor (Y) is calculated as follows:

$$r = 1 - \frac{\Delta P}{P_{abs}}$$

$$\beta = \frac{d}{D}$$

d = Throat diam., in (mm)

D = Inlet Pipe diam., in (mm)

k = Ratio of Specific Heat (1.40 for Air)

(iii) The inlet density (ρ_1) is calculated as follows:

$$\rho_1 = \frac{P_{abs}}{R_{mix} * T_{abs}}$$

Where:
$P_{abs} = P_1 + P_B$
$T_{abs} = T_1 + 2731$
$R_{mix} = R_u / MW_{mix}$
R_u = 8.3144 kJ/kg-mole-K

MW_{mix} = the molecular weight of the mix, as calculated in paragraph (e)(1)(iv) of this section.

(iv) The molecular weight of the mix, is calculated as follows:

$$MW_{mix} = \frac{MW_{AIR} * (P_{abs} - P_V) + MW_{H_2O} * P_v}{P_{abs}}$$

Where:
P_V = Vapor pressure, in Hg (kPa)
MW_{AIR} = 28.964 kg/kg-mole

MW_{H_2O} = 18.015 kg/kg-mole

(v) The density at standard conditions of 101.33 kPa and 20 °C is calculated as follows:

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$$\rho_s = \frac{101.33}{\frac{8.3144}{28.964} * 293.15} = 1.2041 \text{ kg/m}^3$$

(2) The venturi manufacturer's recommended procedure shall be followed for calibrating electronic portions of the SSV.

(3) Measurements necessary for flow calibration of the SSV are as follows:

CALIBRATION DATA MEASUREMENT

Parameter	Sym	Units	Tolerance
(i) Barometric pressure (corrected to 32° F)	P_B	in. Hg (kPa)	± .01in. Hg (± .034kPa)
(ii) Air temperature, into calibration venturi	ETI	° F (° C)	±5 °F (.28° C)
(iii) Pressure drop between the inlet and throat of calibration venturi (corrected to 68° F).	EDP	in. H_2O (kPa)	± .05 in. H_2O (±.012kPa)
(iv) Air Flow	Q_S	Std ft³/min (m^3/min).	± 5% of NIST "true" value
(v) SSV inlet depression	P_I	in. H_2O (kPa)	± .23 in. H_2O (±.057kPa)
(vi) Pressure drop between the inlet and throat of SSV	DP	in. H_2O (kPa)	±.05 in. H_2O (±.012kPa)
(vii) Water vapor pressure of inlet air	P_V	in. Hg (kPa)	±.10 in. Hg (± .34kPa)
(vii) Temperature at SSV inlet	T_I	°F (°C)	±4.0 °F (2.2° C)

(4) Set up equipment similar to CFV or PDP calibration except the variable flow restrictor valve can be deleted or set in the open position, and the pressure drop reading device must be added. The calibration test must be conducted with the test subsonic venturi in place in its permanent position. Any subsequent changes in upstream or downstream configuration could cause a shift in calibration. Leaks between the calibration metering device and the SSV must be eliminated.

(5) Adjust the variable flow blower or restrictor valve to its maximum in-use flow rate. Allow the system to stabilize and record data from all instruments. Be sure to avoid choke condition.

(6) Vary the flow through a minimum of eight steps covering the intended in-use operating range of the SSV.

(7) Data analyses. If the calibration venturi is used at the tunnel inlet (free standing), then assume a value of β=0. If the SSV installed in the CVS tunnel, use the actual inside tunnel diameter and the throat diameter to compute β.

(i) Assume an initial value for Cd = 0.98 to calculate Q_m for the calculation of Reynolds number, Re_v:

$$Re = \frac{6.667E4 * Q_m}{\pi * d * \mu}$$

Where: μ = viscosity of air, centipoise

$$\mu = K_\mu * \frac{T_k^{1.5}}{(T_K + 110.4)}$$

$K\mu$=1.458E–3

T_K=(T_I°C+273.16)

(ii) From the initial calibration of the venturi, establish an equation of Cd as a function of Re. The following functional forms should be reviewed, but a power series, least-squares fit polynomial equation may result in the best fit. Many factors involved in the installation of SSV and the operating range of the Reynolds number can affect the functional relationship of the Cd with Re. Calculate Cd based on this initial equation of Re. Compute a final Q_m based on this calculated Cd for both the calibration nozzle and the inline SSV.

(8)(i) Compute the percent difference in air flow between the calibration venturi and the inline SSV. If the difference in percent of point is greater than 1%, compute a new Cd and Re for the in-tunnel venturi as follows:

Cd_{new}=Actual Air Flow/Theoretical Air Flow=Qm_{act} /Qm_{theo}

$$Re_{new} = \frac{0.8 Qm_{cal}}{\pi * d * \mu}$$

(ii) Qm_{act} is flow measured by the calibration venturi and Qm_{theo} is the theoretical calculated flow based on the in-tunnel SSV conditions with Cd set equal to 1. Re_{new} is based on the calibrated venturi flow, but the in-tunnel SSV properties. Recalculate a new curve fit of Cd_{new} for the inline venturi as a function of Re_{new} following the guidelines in paragraph (e)(7) of this section. Agreement of the fit should be within 1.0% of point. Install the new Cd curve fit in the test cell flow computing device and conduct the propane injection, flow verification test.

* * * * *

34. A new section 86.1323–2007 is added to Subpart N to read as follows:

§ 86.1323–2007 Oxides of nitrogen analyzer calibration.

This section describes the initial and periodic calibration of the chemiluminescent oxides of nitrogen analyzer.

(a) Prior to introduction into service and at least monthly thereafter, the chemiluminescent oxides of nitrogen analyzer must be checked for NO2 to NO converter efficiency. The Administrator may approve less frequent checks of the converter efficiency. Figure N84–9 is a reference for paragraphs (a) (1) through (11) of this section.

(1) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance.

(2) Zero the oxides of nitrogen analyzer with zero-grade nitrogen.

(3) Connect the outlet of the NO_X generator to the sample inlet of the oxides of nitrogen analyzer, which has been set to the most common operating range.

(4) Introduce into the NO_X generator-analyzer system an NO-in-nitrogen (N2) mixture with an NO concentration equal to approximately 80 percent of the most common operating range. The NO2 content of the gas mixture shall be less than 5 percent of the NO concentration.

(5) With the oxides of nitrogen analyzer in the NO mode, record the concentration of NO indicated by the analyzer.

(6) Turn on the NO_X generator O2 supply and adjust the O2 flow rate so that the NO indicated by the analyzer is about 10 percent less than indicated in paragraph (a)(5) of this section. Record the concentration of NO in this NO + O2 mixture.

(7) Switch the NO_X generator to the generation mode and adjust the generation rate so that the NO measured by the analyzer is 20 percent of that measured in paragraph (a)(5) of this section. There must be at least 10 percent unreacted NO at this point. Record the concentration of residual NO.

(8) Switch the oxides of nitrogen analyzer to the NO_X mode and measure total NO_X. Record this value.

(9) Switch off the NO_X generator but maintain gas flow through the system. The oxides of nitrogen analyzer will indicate the NO_X in the NO + O2 mixture. Record this value.

(10) Turn off the NO_X generator O2 supply. The analyzer will now indicate the NO_X in the orignal NO-in-N2 mixture. This value should be no more than 5 percent above the value indicated in paragraph (a)(4) of this section.

(11) Calculate the efficiency of the NO_X converter by substituting the concentrations obtained into the following equation:

$$\text{Percent} - \text{efficiency} = \left(1 + \frac{a-b}{c-d}\right) \times 100$$

Where:

a = concentration obtained in paragraph (a)(8) of this section,

b = concentration obtained in paragraph (a)(9) of this section,

c = concentration obtained in paragraph (a)(6) of this section,

d = concentration obtained in paragraph (a)(7) of this section.

(12) If converter efficiency is not greater than 90 percent, repair the analyzer. The repaired analyzer must achieve a converter efficiency greater than 90 percent before the analyzer may be used.

(b) *Accuracy.* The accuracy at the minimum limit of the NO_X analyzer is defined in § 86.1338–2007. In general the analyzer's minimum limit shall be the lowest concentration within a given range, in which it has an accuracy of ±2 percent of point.

(c) *Initial and periodic calibration.* Prior to its introduction into service and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be calibrated on all normally used instrument ranges. Use the same flow rate as when analyzing samples. Proceed as follows:

(1) Adjust analyzer to optimize performance.

(2) Zero the oxides of nitrogen analyzer with zero-grade nitrogen (N2).

(3) (i) Calibrate all operating ranges with a minimum of 9 NO-in-N2 calibration gases (*e.g.*, 10, 20, 30, 40, 50, 60, 70, 80, and 90 percent of that range) and one zero-grade N2 gas. Sound engineering judgment shall dictate appropriate spacing and weighting of the calibration points.

(ii) For each range calibrated, if all deviations from a least-squares best-fit straight line are within ±2 percent of the value at each non-zero data point and within ±0.3 percent of full scale on the zero data point, then concentration values may be calculated using the linear calibration equation for that range. If the specified deviations are exceeded for ranges that have a minimum limit of 1 ppm or greater, then the best-fit non-linear equation that represents the data within these deviations may be used to determine concentration values. For ranges that have a minimum limit less than 1 ppm, only a linear or second order non-linear equation that represents the data within these deviations, may be used to determine concentration values.

(d) *Chemiluminescent NO_X analyzer interference check (i.e., quench check).* Prior to its introduction into service and at least once per year thereafter, the quench check described in this section shall be performed on CLD NO_X analyzers. CO2 and water vapor interfere with the response of a CLD by collisional quenching. The combined quench effect at their highest expected concentrations shall not exceed 2 percent.

(1) *CO_2 quench check procedure:* (i) For the procedure described in this paragraph, variations are acceptable provided that they produce equivalent $\%CO2_{quench}$ results. Connect a pressure-regulated CO_2 span gas to one of the inlets of a three-way valve. Its CO2 concentration should be approximately twice the maximum CO_2 concentration expected during testing. The valve must be leak-free, and its wetted parts must be made of a stainless steel or other inert material. Connect a pressure-regulated zero-grade N_2 gas to the other inlet of the three-way valve. Connect the single outlet of the valve to the balance-gas port of a properly operating gas divider. Connect a pressure-regulated NO span gas, which has approximately twice the typical NO concentration expected during testing, to the span-port of the gas divider. Configure the gas divider such that nearly equal amounts of the span gas and balance gas are blended with each other. Viscosity corrections shall be applied appropriately to ensure correct mass flow determinations.

(ii) With the CO_2 flowing to the balance port and the NO flowing to the span port, measure a stable CO_2 concentration from the gas divider's outlet with a properly calibrated NDIR analyzer. Record this concentration in percent (%); this is "$\%CO_2$". This value will be used in the water vapor quench check calculations that are detailed in the following section. After the $\%CO_2$ measurement, measure the NO concentration at the gas divider outlet with the CLD analyzer in the NO mode. Record this concentration in ppm; this is "NO_{CO2}". Then switch the three-way valve such that 100 percent N_2 flows to the balance port inlet. Monitor the CO_2 concentration of the gas divider's outlet until its concentration stabilizes at zero. Then measure the stable NO concentration from the gas divider's outlet. Record this value in ppm; this is "NO_{N2}". Calculate $\%CO_{2quench}$ as follows:

$$\%CO_{2quench} = (1.00 - (NO_{CO2}/NO_{N2})) \times 100$$

(2) Water vapor quench check procedure:

(i) For all dry CLD analyzers it must be demonstrated that for the highest expected water vapor concentration (*i.e.*, "$\%H_2O_{exp}$" as calculated later in this section), the water removal technique maintains CLD humidity at less than or equal to 5 $g_{water}/kg_{dry\ air}$ (or about 0.008 percent H_2O), which is 100% RH at 3.9 °C and 101.3 kPa. This humidity specification is also equivalent to about 25% RH at 25 °C and 101.3 kPa. This may be demonstrated by measuring the temperature at the outlet of a thermal dehumidifier, or by measuring humidity at a point just upstream of the CLD. Humidity of the CLD exhaust might also be measured as long as the only flow into the CLD is the flow out of the dehumidifier.

(ii) For all "wet" CLD analyzers the following water vapor quench check procedure shall be followed. Measure an NO span gas, which has 90% to 100% of the typical NO expected during testing, using the CLD in the NO mode. Record this concentration in ppm; this is "NO_{dry}". Then bubble the same NO span gas through distilled water in a sealed vessel at 25 °C ±10 °C. This temperature specification imposed to ensure that the H_2O_{vol} calculation (refer to (iii) of this section) returns an accurate result. To prevent subsequent condensation, this temperature must also be less than any temperature that the wetted sample will experience between the sealed vessel's outlet and the CLD. Record the vessel's water temperature in °C; this is "T_{sat}". Record the vessel's absolute pressure in kPa; this is "P_{sat}". Measure the wetted span gas with the CLD, and record this value in ppm; this is "NO_{wet}".

(iii) Calculations for water quench must consider dilution of the NO span gas with water vapor and scaling of the water vapor concentration to that expected during testing.

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(A) Calculate the volume fraction of water vapor in the wetted span gas, as $H_2O_{vol} = (\exp(3.69 - (81.28/T_{sat})) + 1.61)/P_{sat}$. This calculation approximates some of the thermodynamic properties of water based on the "1995 Formulation for the Thermodynamic Properties of Ordinary Water Substance for General and Scientific Use", issued by The International Association for the Properties of Water and Steam (IAPWS). However, this approximation should only be used as prescribed in this section because it is an exponential fit that is accurate for data at 25 °C ±10 °C. Then, assuming a diesel fuel atomic hydrogen to carbon ratio of 1.8, and an intake and dilution air humidity of 75 grains (10.71 $g_{water}/kg_{dry\ air}$ or 54.13 percent RH at 25 °C and 101.3 kPa),

(B) Calculate the maximum percent water vapor expected during testing; as $\%H_2O_{exp} = (0.90 \times \%CO_2) + 1.69$. $\%CO_2$ is the value measured during the $\%CO_2$ quench check.

(C) Calculate the expected wet concentration of NO in ppm; as $NO_{exp} = NO_{dry} \times (1.00 - H_2O_{vol})$

(iv) Calculate the percent water vapor quench as:

$\%H_2O_{quench} = ((NO_{exp} - NO_{wet})/NO_{exp}) \times (\%H_2O_{exp}/H_2O_{vol})$

(3) Add the $\%CO_{2quench}$ and the $\%H_2O_{quench}$ values. Their sum may not exceed the limit set in paragraph (d). If their sum is greater than this limit, then the CLD instrument may not be used to perform testing unless it is repaired. The analyzer must be shown to pass this quench check after the repair before it may be used for testing.

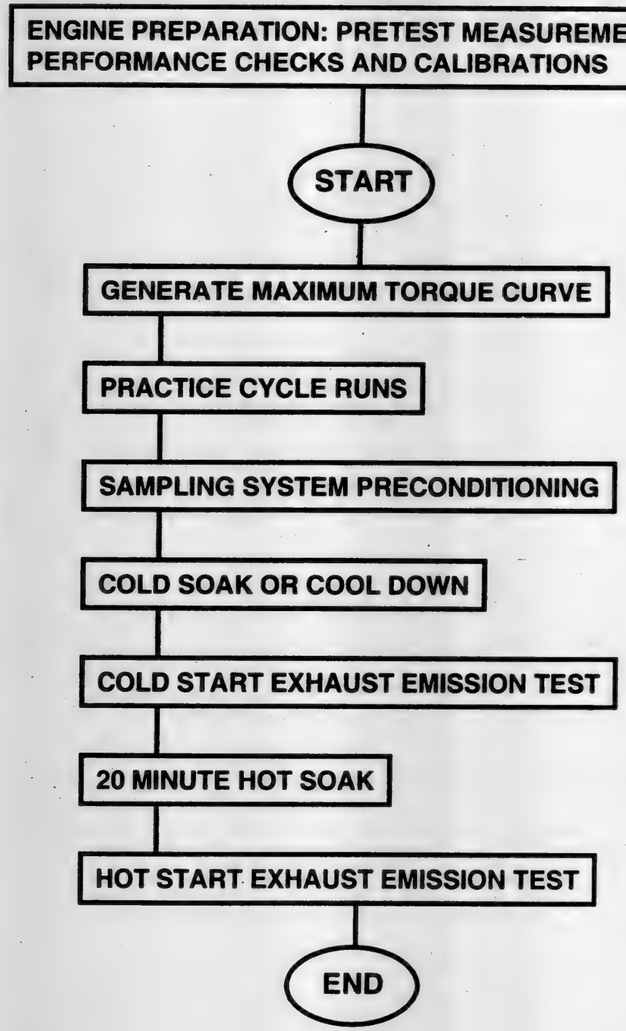
35. Section 86.1330–90 is amended by revising paragraph (a) to read as follows:

§ 86.1330–90 Test sequence; general requirements.

(a) The test sequence shown in Figure N90–10 shows the major steps of the test procedure, as follows:

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Figure N90-10 Test Sequence



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36. Section 86.1334–84 is amended by revising paragraph (a)(1) and (a)(2) to read as follows:

§ 86.1334–84 Pre-test engine and dynamometer preparation.

(a) * * * (1) Before the cold soak or cool down:

(i) Final calibration of the dynamometer and throttle control systems may be performed. These calibrations may consist of steady-state operations and/or actual practice cycle runs, and must be completed before sampling system preconditioning (if applicable).

(ii) Conduct sampling system preconditioning for diesel engines (optional for model years prior to 2007) by operating the engine at a condition of rated-speed, 100 percent torque for a minimum of 20 minutes while simultaneously operating the CVS and secondary dilution system and taking particulate matter emissions samples from the secondary dilution tunnel . Particulate sample filters need not be stabilized or weighed, and may be discarded. Filter media may be changed during conditioning as long as the total sampled time through the filters and sampling system exceeds 20 minutes. Flow rates shall be set at the approximate flow rates selected for transient testing. Torque shall be reduced from 100 percent torque while maintaining the rated speed condition as necessary to prevent exceeding the maximum sample zone temperature specifications of § 86.1310–2007.

(2) Following sampling system preconditioning cycle, the engine shall be cooled per § 86.1335–90.

* * * * *

37. A new section 86.1337–2007 is added to subpart N to read as follows:

§ 86.1337–2007 Engine dynamometer test run.

(a) The following steps shall be taken for each test:

(1) Prepare for the cold-start test.

(i) For gasoline- and methanol-fueled engines only, evaporative emission canisters shall be prepared for use in this testing in accordance with the procedures specified in § 86.1232–96 (h) or (j). The size of the canisters used for testing shall correspond with the largest canister capacity expected in the range of vehicle applications for each engine. (The Administrator may, at his/her discretion, use a smaller canister capacity.) Attach the evaporative emission canister(s) to the engine, using the canister purge plumbing and controls employed in vehicle applications of the engine being tested. Plug the canister port that is normally connected to the fuel tank.

(ii) Prepare the engine, dynamometer, and sampling system.

(iii) Change filters, etc., and leak check as necessary.

(2) Connect evacuated sample collection bags to the dilute exhaust and dilution air sample collection systems if bag sampling is used.

(3) For methanol-fueled vehicles, install fresh methanol and formaldehyde impingers (or cartridges) in the exhaust and dilution air sample systems for methanol and formaldehyde. A single dilution air sample covering the total test period may be utilized for methanol and formaldehyde background. (Background measurements of methanol and formaldehyde may be omitted and concentrations assumed to be zero for calculations in § 86.1344.)

(4) Attach the CVS to the engine exhaust system any time prior to starting the CVS.

(5) Start the CVS (if not already on), the sample pumps (except for the particulate sample pump(s), if applicable), the engine cooling fan(s), and the data collection system. The heat exchanger of the constant volume sampler (if used), and the heated components of any continuous sampling system(s) (if applicable) shall be preheated to their designated operating temperatures before the test begins. (See § 86.1340(e) for continuous sampling procedures.)

(6) Adjust the sample flow rates to the desired flow rates and set the CVS gas flow measuring devices to zero. CFV–CVS sample flow rate is fixed by the venturi design.

(7) For engines tested for particulate emissions, carefully install a clean, loaded particulate sample filter cartridge into the filter holder assembly. It is recommended that this be done within the filter stabilization environment, with both ends of the filter holder assembly plugged during transport to the emissions test facility. Install the assembled filter holder into the sample flow line.

(8) Follow the manufacturer's instructions for cold starting. Simultaneously start the engine and begin exhaust and dilution air sampling. For petroleum-fueled diesel engines (and natural gas-fueled, liquified petroleum gas-fueled or methanol-fueled diesels, if used) Turn on the hydrocarbon and NO_X (and CO and CO_2, if continuous) analyzer system integrators (if used), and turn on the particulate sample pumps and indicate the start of the test on the data collection medium.

(9) Allow the engine to idle freely with no-load for 24±1 seconds. This idle period for automatic transmission engines may be interpreted as an idle speed in neutral or park. All other idle conditions shall be interpreted as an idle speed in gear. It is permissible to lug the engine down to curb idle speed during the last 8 seconds of the free idle period for the purpose of engaging dynamometer control loops.

(10) Begin the transient engine cycles such that the first non-idle record of the cycle occurs at 25±1 seconds. The free idle time is included in the 25±1 seconds.

(i) During particulate sampling it must be demonstrated that the ratio of main tunnel flow to particulate sample flow does not change by more than ±5.0 percent of its set point value (except for the first 10 seconds of sampling). For double dilution operation, sample flow is the net difference between the flow rate through the sample filters and the secondary dilution air flow rate.

(ii) Record flow. If the set flow rate cannot be maintained because of high particulate loading on the filter, the test shall be terminated. The test shall be rerun using a lower sample flow rate or greater dilution.

(11) Begin the transient engine cycles such that the first non-idle record of the cycle occurs at 25±1 seconds. The free idle time is included in the 25±1 seconds.

(12) On the last record of the cycle, cease sampling. Immediately turn the engine off and start a hot-soak timer. Also turn off the particulate sample pumps, the gas flow measuring device(s) and any continuous analyzer system integrator and indicate the end of the test on the data collection medium. Sampling systems should continue to sample after the end of the test cycle until system response times have elapsed.

(13) Immediately after the engine is turned off, turn off the engine cooling fan(s) if used. As soon as possible, transfer the "cold start cycle" exhaust and dilution air bag samples to the analytical system and process the samples according to § 86.1340. A stabilized reading of the exhaust sample on all analyzers shall be obtained within 20 minutes of the end of the sample collection phase of the test. Analysis of the methanol and formaldehyde samples shall be obtained within 24 hours of the end of the sample collection period. For particulate measurements, carefully remove the filter holder from the sample flow apparatus

(14) Allow the engine to soak for 20±1 minutes.

(15) Prepare the engine and dynamometer for the hot start test.

(16) Connect evacuated sample collection bags to the dilute exhaust and dilution air sample collection systems.

(17) Install fresh methanol and formaldehyde impingers (or capsules) in the exhaust and dilution air sample systems for methanol and formaldehyde.

(18) Start the sample pumps (except the particulate sample pump(s), if applicable), the engine cooling fan(s) and the data collection system. The heat exchanger of the constant volume sampler (if used) and the heated components of any continuous sampling system(s) (if applicable) shall be preheated to their designated operating temperatures before the test begins. See § 86.1340(e) for continuous sampling procedures.

(19) Adjust the sample flow rates to the desired flow rate and set the CVS gas flow measuring devices to zero.

(20) For diesel engines tested for particulate, carefully install a clean, loaded particulate sample filter cartridge in the filter holder assembly and install the filter holder assembly in the sample flow line.

(21) Follow the manufacturer's choke and throttle instruction for hot starting. Simultaneously start the engine and begin exhaust and dilution air sampling. For diesel engines, turn on the hydrocarbon and NO_X (and CO and CO2, if continuous) analyzer system integrator (if used), indicate the start of the test on the data collection medium, and turn on the particulate sample pump(s).

(22) [Reserved]

(23) Allow the engine to idle freely with no-load for 24±1 seconds. The provisions and interpretations of paragraph (a)(9) of this section apply.

(24) Begin the transient-engine cycle such that the first non-idle record of the cycle occurs at 25±1 seconds. The free idle is included in the 25±1 seconds.

(25) On the last record of the cycle, allow sampling system response times to elapse and cease sampling. Turn off the particulate sample pump(s) (if appropriate), the gas flow measuring device(s) and any continuous analyzer system integrator and indicate the end of the test on the data collection medium.

(26) As soon as possible, transfer the "hot start cycle" exhaust and dilution air bag samples to the analytical system and process the samples according to § 86.1340. A stabilized reading of the exhaust sample on all analyzers shall be obtained within 20 minutes of the end of the sample collection phase of the test. Analyze the methanol and formaldehyde samples within 24 hours. (If it is not possible to perform analysis within 24 hours, the samples should be stored in a cold (approximately 0 deg.C) dark environment until analysis can be performed). For particulate measurements, carefully remove the filter holder assembly. It is recommended that the filter cartridge be transferred to and from the filter stabilization environment within the filter holder assembly with both ends plugged, and that the cartridge be removed from the filter holder assembly within the stabilization environment. Transfer the particulate filter to the stabilization environment for post-test stabilization. Filters may be stabilized in the petri dishes while still within the filter cartridges, or the cartridge tops may be removed for stabilization, or the filters may be entirely removed from the filter cartridges and stabilized in the petri dishes alone. Removal of the filters from the filter cartridges shall only take place within the stabilization environment.

(27) The CVS and the engine may be turned off, if desired.

(b) The procedure in paragraph (a) of this section is designed for one sample bag for the cold start portion and one for the hot start portion.

(c) If a dynamometer test run is determined to be void, corrective action may be taken. The engine may then be allowed to cool (naturally or forced) and the dynamometer test rerun.

38. A new section 86.1338–2007 is added to Subpart N to read as follows:

§ 86.1338–2007 Emission measurement accuracy.

(a) *Minimum limit.* (1) The minimum limit of an analyzer must be equal to or less than one-half of the average diluted concentration for an engine emitting the maximum amount of the applicable pollutant allowed by the applicable standard. For example, if with a given dilution and sampling system, an engine emitting NO_X at the level of the standard (*e.g.*, 0.20 g/bhp-hr NO_X) would result in an average NO_X concentration of 1.0 ppm in the diluted sample, then the minimum limit for the NO_X analyzer must be less than or equal to 0.5 ppm.

(2) For the purpose of this section, "minimum limit" means the lowest of the following levels:

(i) The lowest NO_X concentration in the calibration curve for which an accuracy of ±2 percent of point has been demonstrated as specified in paragraph (a)(3) of this section; or

(ii) Any NO_X concentration for which the test facility has demonstrated sufficient accuracy to the Administrator's satisfaction prior to the start of testing, such that it will allow a meaningful determination of compliance with respect to the applicable standard.

(3) For determination of the analyzer's minimum limit, a NO_X concentration that is less than or equal to one-half of the average NO_X concentration determined in paragraph (a)(1) of this section shall be measured by the oxides of nitrogen analyzer following the analyzer's monthly periodic calibration. This measurement must be made to ensure the accuracy of the calibration curve to within ±2 percent of point accuracy of the appropriate least-squares fit, at less than or equal to one half of the average expected diluted NO_X concentration determined in paragraph (a)(1) of this section.

(b) *Measurement accuracy—Bag sampling.* Analyzers used for bag analysis must be operated such that the measured concentration falls between 15 and 100 percent of full scale, with the following exception: concentrations below 15 percent of full scale may be used if the minimum limit of the analyzer within the range meets the requirement of paragraph (a) of this section.

(c) *Measurement accuracy—Continuous measurement.* (1) Analyzers used for continuous analysis must be operated such that the measured concentration falls between 15 and 100 percent of full scale, with the following exceptions:

(i) Concentrations below 15 percent of full scale may be used if the minimum limit of the analyzer within the range meets the requirement of paragraph (a) of this section.

(ii) Analyzer response over 100% of full scale may be used if it can be shown that readings in this range are accurate.

(2) If the analyzer response exceeds the level allowed by paragraph (c)(1)(ii) of this section, the test must be repeated using a higher range and both results must be reported. The Administrator may waive this requirement.

(d) If a gas divider is used, the gas divider shall conform to the accuracy requirements specified in § 86.1314–84(g), and shall be used according to the procedures contained in paragraphs (a) and (b) of this section.

39. Section 86.1339–90 is amended by adding paragraph (h) to read as follows:

§ 86.1339–90 Particulate filter handling and weighing.

* * * * *

(h) This section does not apply for tests conducted according to the provisions of § 86.1312–2007.

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40. Section 86.1360–2007 is amended by revising the section heading, adding introductory text, and revising paragraphs (b), (e)(2), (e)(3), and (e)(6)(ii), to read as follows:

§ 86.1360–2007 Supplemental emission test; test cycle and procedures.

The test procedures of this subpart N apply for supplemental emission testing, except as specified otherwise in this section.

* * * * *

(b) *Test cycle.* (1)(i) The following 13-mode cycle must be followed in dynamometer operation on the test engine:

Mode number	Engine speed	Percent load	Weighting factor	Mode length (minutes)
1	Idle		0.15	4
2	A	100	0.08	2
3	B	50	0.10	2
4	B	75	0.10	2
5	A	50	0.05	2
6	A	75	0.05	2
7	A	25	0.05	2
8	B	100	0.09	2
9	B	25	0.10	2
10	C	100	0.08	2
11	C	25	0.05	2
12	C	75	0.05	2
13	C	50	0.05	2

(ii) Upon Administrator approval, the manufacturer may use mode lengths other than those listed in paragraph (b)(1)(i) of this section.

(2) In addition to the 13 test points identified in paragraph (b)(1) of this section, for engines not certified to a NO_X standard or FEL less than1.5 g/bhp-hr, EPA may select, and require the manufacturer to conduct the test using, up to 3 additional test points within the control area (as defined in paragraph (d) of this section). EPA will notify the manufacturer of these supplemental test points in writing in a timely manner before the test. Emissions sampling for the additional test modes must include all regulated gaseous pollutants. Particulate matter does not need to be measured.

* * * * *

(e) * * *

(2) *Test sequence.* The test must be performed in the order of the mode numbers in paragraph (b)(1) of this section. Where applicable, the EPA-selected test points identified under paragraph (b)(2) of this section must be performed immediately upon completion of mode 13. The engine must be operated for the prescribed time in each mode, completing engine speed and load changes in the first 20 seconds of each mode. The specified speed must be held to within ±50 rpm and the specified torque must be held to within plus or minus two percent of the maximum torque at the test speed.

(3) *Particulate sampling.* One filter shall be used for sampling PM over the 13-mode test procedure. The modal weighting factors specified in paragraph (b)(1) of this section shall be taken into account by taking a sample proportional to the exhaust mass flow during each individual mode of the cycle. This can be achieved by adjusting sample flow rate, sampling time, and/or dilution ratio, accordingly, so that the criterion for the effective weighting factors is met. The sampling time per mode must be at least 4 seconds per 0.01 weighting factor. Sampling must be conducted as late as possible within each mode. Particulate sampling shall be completed no earlier than 5 seconds before the end of each mode.

* * * * *

(6) * * *

(ii) For PM measurements, a single filter must be used to measure PM over the 13 modes. The brake-specific PM emission level for the test must be calculated as described for a transient hot start test in § 86.1343. Only the power measured during the sampling period shall be used in the calculation.

* * * * *

41. Section 86.1370–2007 is amended by revising paragraphs (a), (b)(6) and (d), removing and reserving paragraph (b)(5), and adding paragraphs (b)(7) and (g) to read as follows:

§ 86.1370–2007 Not-To-Exceed test procedures.

(a) *General.* The purpose of this test procedure is to measure in-use emissions of heavy-duty diesel engines while operating within a broad range of speed and load points (the Not-To-Exceed Control Area) and under conditions which can reasonably be expected to be encountered in normal vehicle operation and use. Emission results from this test procedure are to be compared to the Not-To-Exceed Limits specified in § 86.007–11 (a)(4), or to later Not-To-Exceed limits. The Not-To-Exceed Limits do not apply for engine starting conditions.

(b) * * *

(5) [Reserved]

(6)(i) For petroleum-fueled diesel cycle engines, the manufacturer may identify particular engine-vehicle combinations and may petition the Administrator at certification to exclude operating points from the Not-to-Exceed Control Area defined in § 86.1370(b)(1) through (5) if the manufacturer can demonstrate that the engine is not capable of operating at such points when used in the specified engine-vehicle combination(s).

(ii) For diesel cycle engines that are not petroleum-fueled, the manufacturer may petition the Administrator at certification to exclude operating points from the Not-to-Exceed Control Area defined in § 86.1370(b)(1) through (5) if the manufacturer can demonstrate that the engine is not expected to operate at such points in normal vehicle operation and use.

(7) Manufacturers may petition the Administrator to limit NTE testing in a single defined region of speeds and loads. Such a defined region must generally be of elliptical or rectangular shape, and must share some portion of its boundary with the outside limits of the NTE zone. Under this provision testing would not be allowed with sampling periods in which operation within that region constitutes more than 5.0 percent of the time-weighted operation within the sampling period. Approval of this limit by the Administrator is contingent on the manufacturer satisfactorily demonstrating that operation at the speeds and loads within that region accounts for less than 5.0 percent of all in-use operation (weighted by vehicle-miles-traveled or other EPA-approved weightings) for the in-use engines of that configuration (or sufficiently similar engines). At a minimum, this demonstration must include operational data from representative in-use vehicles.

* * * * *

(d) *Not-to-exceed control area limits.* (1) When operated within the Not-To-Exceed Control Area defined in paragraph (b) of this section, diesel engine emissions shall not exceed the applicable Not-To-Exceed Limits specified in § 86.007–11(a)(4) when averaged over any period of time greater than or equal to 30 seconds, except where a longer averaging period is required by paragraph (d)(2) of this section.

(2) For engines equipped with emission controls that include discrete regeneration events, if a regeneration event occurs during the NTE test, then the averaging period must be at least as long as the time between the events multiplied by the number of full regeneration events within the sampling period. The requirement in this paragraph (d)(2) only applies for engines that send an electronic signal indicating the start of the regeneration event.

* * * * *

(g) *NO_X and NMHC aftertreatment warm-up.* For engines equipped with one or more aftertreatment devices that reduce NO_X or NMHC emissions, the NTE NO_X and NMHC emission limits do not apply when the exhaust gas temperature is measured within 12 inches of the outlet of the aftertreatment device and is less the 250°C. For multi-bed systems, it is the temperature at the outlet of the device with the maximum flow rate that determines whether the NTE limits apply.

42. § 86.1803–01 is amended by adding a definition of "U.S. heavy-duty vehicle sales" in alphabetical order to read as follows:

§ 86.1803–01 Definitions.

* * * * *

U.S. heavy-duty vehicle sales means sales of heavy-duty vehicles subject to the standards of this subpart, where the sale takes place in any state of the United States except for California (or a state that has adopted California motor vehicle standards for that model year pursuant to section 177 of the Clean Air Act).

* * * * *

43. § 86.1806–05 is amended by revising paragraphs (b) introductory text, (b)(1), and (l) to read as follows:

§ 86.1806–05 On-board diagnostics.

* * * * *

(b) *Malfunction descriptions.* The OBD system must detect and identify malfunctions in all monitored emission-related powertrain systems or components according to the following malfunction definitions as measured and calculated in accordance with test procedures set forth in subpart B of this part (chassis-based test procedures), excluding those test procedures defined as "Supplemental" test procedures in § 86.004–2 and codified in §§ 86.158, 86.159, and 86.160.

(1) *Catalysts and particulate traps.* (i) *Otto-cycle.* Catalyst deterioration or malfunction before it results in an increase in NMHC emissions 1.5 times the NMHC standard or FEL, as compared to the NMHC emission level measured using a representative 4000 mile catalyst system.

(ii) *Diesel.* (A) If equipped, catalyst deterioration or malfunction before it results in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NO_X or PM. This requirement applies only to reduction catalysts; monitoring of oxidation catalysts is not required. This monitoring need not be done if the manufacturer can demonstrate that deterioration or malfunction of the system will not result in exceedance of the threshold.

(B) If equipped with a particulate trap, catastrophic failure of the device must be detected. Any particulate trap whose complete failure results in exhaust emissions exceeding 1.5 times the applicable standard or FEL for NO_X or PM must be monitored for such catastrophic failure. This monitoring need not be done if the manufacturer can demonstrate that a catastrophic failure of the system will not result in exceedance of the threshold.

* * * * *

(l) *Phase-in for complete heavy-duty vehicles.* Complete heavy-duty vehicles weighing 14,000 pounds GVWR or less that are not Otto-cycle MDPVs must meet the OBD requirements of this section according to the following phase-in schedule, based on the percentage of projected vehicle sales. The 2004 model year requirements in the following phase-in schedule are applicable only to heavy-duty Otto-cycle vehicles where the manufacturer has selected Otto-cycle Option 1 or 2 for alternative 2003 or 2004 compliance according to § 86.004–01(c)(1) or (2). The 2005 through 2007 requirements in the following phase-in schedule apply to all heavy-duty vehicles weighing 14,000 pounds GVWR or less, excluding MDPVs. If the manufacturer has selected Otto-cycle Option 3 it may exempt 2005 model year complete heavy-duty engines and vehicles whose model year commences before July 31, 2004 from the requirements of this section. For the purposes of calculating compliance with the phase-in provisions of this paragraph (l), heavy-duty vehicles subject to the phase-in requirements of this section may be combined with heavy-duty vehicles subject to the phase-in requirements of paragraph § 86.005–17 (k). The phase-in schedule follows:

OBD Compliance Phase-in for Complete Heavy-Duty Vehicles Weighing 14,000 Pounds GVWR or Less

Model year	Phase-in based on projected sales
2004 MY	Applicable only to Otto-cycle engines complying with Options 1 or 2; 40% compliance; alternative fuel waivers available.
2005 MY	60% compliance; alternative fuel waivers available.
2006 MY	80% compliance; alternative fuel waivers available.
2007 MY	80% compliance; alternative fuel waivers available.
2008+ MY	100% compliance.

44. A new § 86.1807–07 is added to subpart S to read as follows:

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§ 86.1807–07 Vehicle labeling.

Section 86.1807–07 includes text that specifies requirements that differ from those specified in § 86.1807–01. Where a paragraph in § 86.1807–01 is identical and applicable to § 86.1807–07, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1807–01.".

(a) through (g) [Reserved]. For guidance see § 86.1807–01.

(h) Model year 2007 and later diesel-fueled Tier 2 vehicles (certified using a test fuel with 15 ppm sulfur or less), must include permanent readily visible labels on the dashboard (or instrument panel) and near all fuel inlets that state "Use Low-sulfur Diesel Fuel Only" or "Low-sulfur Diesel Fuel Only".

45. A new § 86.1808–07 is added to subpart S to read as follows:

§ 86.1808–07 Maintenance instructions.

Section 86.1808–07 includes text that specifies requirements that differ from those specified in § 86.1808–01. Where a paragraph in § 86.1808–01 is identical and applicable to § 86.1808–07, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1808–01.".

(a) through (f) [Reserved]. For guidance see § 86.1808–01.

(g) For each new diesel-fueled Tier 2 vehicle (certified using a test fuel with 15 ppm sulfur or less), the manufacturer shall furnish or cause to be furnished to the purchaser a statement that "This vehicle must be operated only with low sulfur diesel fuel (that is., diesel fuel meeting EPA specifications for highway diesel fuel, including a 15 ppm sulfur cap).".

46. Section 86.1810–01 is amended by revising the introductory text to read as follows:

§ 86.1810–01 General standards; increase in emissions; unsafe conditions; waivers.

This section applies to model year 2001 and later light-duty vehicles and light-duty trucks fueled by gasoline, diesel, methanol, natural gas and liquefied petroleum gas fuels. This section also applies to MDPVs and complete heavy-duty vehicles certified according to the provisions of this subpart. Multi-fueled vehicles (including dual-fueled and flexible-fueled vehicles) shall comply with all requirements established for each consumed fuel (or blend of fuels in the case of flexible fueled vehicles). The standards of this subpart apply to both certification and in-use vehicles unless otherwise indicated. For Tier 2 and interim non-Tier 2 vehicles, this section also applies to hybrid electric vehicles and zero emission vehicles. Unless otherwise specified, requirements and provisions of this subpart applicable to methanol fueled vehicles are also applicable to Tier 2 and interim non-Tier 2 ethanol fueled vehicles.

* * * * *

47. Section 86.1816–05 is amended by revising paragraph (g) to read as follows:

§ 86.1816–05 Emission standards for complete heavy-duty vehicles.

* * * * *

(g) *Idle exhaust emission standards, complete heavy-duty vehicles.* Exhaust emissions of carbon monoxide from 2005 and later model year gasoline, methanol, natural gas-and liquefied petroleum gas-fueled complete heavy-duty vehicles shall not exceed 0.50 percent of exhaust gas flow at curb idle for a useful life of 11 years or 120,000 miles, whichever occurs first. This does not apply for vehicles certified to the requirements of § 86.1806–05

* * * * *

48. A new § 86.1816–08 is added to subpart S, to read as follows:

§ 86.1816–08 Emission standards for complete heavy-duty vehicles.

Section 86.1816–08 includes text that specifies requirements that differ from those specified in § 86.1816–05. Where a paragraph in § 86.1816–05 is identical and applicable to § 86.1816–08, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1816–05.". This section applies to 2008 and later model year complete heavy-duty vehicles (excluding MDPVs) fueled by gasoline, methanol, natural gas and liquefied petroleum gas fuels except as noted. Multi-fueled vehicles shall comply with all requirements established for each consumed fuel. For methanol fueled vehicles, references in this section to hydrocarbons or total hydrocarbons shall mean total hydrocarbon equivalents and references to non-methane hydrocarbons shall mean non-methane hydrocarbon equivalents.

(a) *Exhaust emission standards.* (1) Exhaust emissions from 2008 and later model year complete heavy-duty vehicles at and above 8,500 pounds Gross Vehicle Weight Rating but equal to or less than 10,000 Gross Vehicle Weight Rating pounds shall not exceed the following standards at full useful life:

(i) [Reserved]

(ii) *Non-methane hydrocarbons.* (A) 0.195 grams per mile; this requirement may be satisfied by measurement of non-methane organic gas or total hydrocarbons, at the manufacturer's option. For alcohol-fueled vehicles, this standard is 0.195 grams per mile NMHCE.

(B) A manufacturer may elect to include any or all of its test groups in the NMHC emissions ABT programs for heavy-duty vehicles, within the restrictions described in § 86.1817–05. or § 86.1817–08. If the manufacturer elects to include test groups in any of these programs, the NMHC FEL may not exceed 0.28 grams per mile. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading.

(iii) *Carbon monoxide.* 7.3 grams per mile.

(iv) *Oxides of nitrogen.* (A)0.2 grams per mile.

(B) A manufacturer may elect to include any or all of its test groups in the NO_X emissions ABT programs for heavy-duty vehicles, within the restrictions described in § 86.1817–05 or § 86.1817–08. If the manufacturer elects to include test groups in any of these programs, the NO_X FEL may not exceed 0.9 grams per mile. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading.

(v) *Particulate.* 0.02 grams per mile.

(vi) *Formaldehyde.* 0.032 grams per mile.

(2) Exhaust emissions from 2008 and later model year complete heavy-duty vehicles above 10,000 pounds Gross Vehicle Weight Rating but less than 14,000 pounds Gross Vehicle Weight Rating shall not exceed the following standards at full useful life:

(i) [Reserved]

(ii) *Non-methane hydrocarbons.* (A) 0.230 grams per mile; this requirement may be satisfied by measurement of non-methane organic gas or total hydrocarbons, at the manufacturer's option. For alcohol-fueled vehicles, this standard is 0.230 grams per mile NMHCE.

(B) A manufacturer may elect to include any or all of its test groups in the NMHC emissions ABT programs for heavy-duty vehicles, within the restrictions described in § 86.1817–05. or § 86.1817–08. If the manufacturer elects to include test groups in any of these programs, the NMHC FEL may not exceed 0.33 grams per mile. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading.

(iii) *Carbon monoxide.* 8.1 grams per mile.

(iv) *Oxides of nitrogen.* (A)0.4 grams per mile.

(B) A manufacturer may elect to include any or all of its test groups in the NO_X emissions ABT programs for heavy-duty vehicles, within the restrictions described in § 86.1817–05. or § 86.1817–08. If the manufacturer elects to include test groups in any of these programs, the NO_X FEL may not exceed 1.0 grams per mile. This ceiling value applies whether credits for the family are derived from averaging, banking, or trading.

(v) *Particulate.* 0.02 grams per mile.

(vi) *Formaldehyde.* 0.040 grams per mile.

(b) [Reserved]

(c) [Reserved]

(d) *Evaporative emissions.* Evaporative hydrocarbon emissions from gasoline-fueled, natural gas-fueled, liquefied petroleum gas-fueled, and methanol-fueled complete heavy-duty vehicles shall not exceed the following standards. The standards apply equally to certification and in-use vehicles. The spitback standard also applies to newly assembled vehicles.

(1) For the full three-diurnal test sequence, diurnal plus hot soak measurements: 1.4 grams per test.

(2) Gasoline and methanol fuel only. For the supplemental two-diurnal test sequence, diurnal plus hot soak measurements: 1.75 grams per test.

(3) Gasoline and methanol fuel only. Running loss test: 0.05 grams per mile.

(4) Gasoline and methanol fuel only. Fuel dispensing spitback test: 1.0 grams per test.

(e) through (h) [Reserved]. For guidance see § 86.1816–05.

(i) *Phase-in options.* (1)(i) For model year 2008, manufacturers may certify some of their test groups to the standards applicable to model year 2008 vehicles under § 86.1816–05, in lieu of the exhaust standards specified in this section. These vehicles must comply with all other requirements applicable to model year 2007 vehicles. The combined number of vehicles in the test groups certified to the 2008 standards may not exceed 50 percent of the manufacturer's U.S. heavy-duty vehicle sales of complete heavy-duty Otto-cycle motor vehicles for model year 2008, except as explicitly allowed by paragraph (i)(2) of this section.

(ii) For model year 2008, manufacturers may certify some of their test groups to the evaporative standards applicable to model year 2007 engines under § 86.1816–05, in lieu of the evaporative standards specified in this section. These vehicles must comply with all other requirements applicable to model year 2008 vehicles, except as allowed by paragraph (i)(1)(i) of this section. The combined number of vehicles in the test groups certified to the 2007 standards may not exceed 50 percent of the manufacturer's U.S. heavy-duty vehicle sales of complete heavy-duty Otto-cycle motor vehicles for model year 2008.

(2)(i) Manufacturers certifying vehicles to all of the applicable standards listed in paragraph (a) of this section prior to model year 2008 (without using credits) may reduce the number of vehicles that are required to meet the standards listed in paragraph (a) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (i)(1) of this section. For every vehicle that is certified early, the manufacturer may reduce the number of vehicles that are required by paragraph (i)(1) of this section to meet the standards listed in paragraph (a) of this section by one vehicle. For example, if a manufacturer produces 100 heavy-duty Otto-cycle vehicles in 2007 that meet all of the applicable the standards listed in paragraph (a) of this section, and it produced 10,000 heavy-duty Otto-cycle vehicles in 2009, then only 9,900 of the vehicles would need to comply with the standards listed in paragraph (a) of this section.

(ii) Manufacturers certifying vehicles to all of the applicable evaporative standards listed in paragraph (d) of this section prior to model year 2008 may reduce the number of vehicles that are required to meet the standards listed in paragraph (d) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (i)(1) of this section. For every vehicle that is certified early, the manufacturer may reduce the number of vehicles that are required by paragraph (i)(1) of this section to meet the evaporative standards listed in paragraph (d) of this section by one vehicle.

(3) Manufacturers certifying vehicles to all of the applicable standards listed in paragraph (i)(3)(i) or (ii) of this section (without using credits) and the evaporative standards listed in paragraph (d) of this section prior to model year 2008 may reduce the number of vehicles that are required to meet the standards listed in paragraph (a) of this section in model year 2008 and/or 2009, taking into account the phase-in option provided in paragraph (i)(1)(i) of this section. For every such vehicle that is certified early with sufficiently low emissions, the manufacturer may reduce the number of vehicles that are required by paragraph (i)(1)(i) of this section to meet the standards listed in paragraph (a) of this section by two vehicles. The applicable standards are:

(i) For complete heavy-duty vehicles at and above 8,500 pounds Gross Vehicle Weight Rating but equal to or less than 10,000 Gross Vehicle Weight Rating: 0.100 g/mile NMHC, 0.10 g/mile NO_X, 3.2 g/mile CO, 0.008 g/mile formaldehyde, and 0.02 g/mile PM.

(ii) For complete heavy-duty vehicles at or above 10,000 pounds Gross Vehicle Weight Rating but equal to or less than 14,000 Gross Vehicle Weight Rating: 0.117 g/mile NMHC, 0.20 g/mile NO_X, 3.7 g/mile CO, 0.010 g/mile formaldehyde, and 0.02 g/mile PM.

(j) (1) For model years prior to 2012, for purposes of determining compliance after title or custody has transferred to the ultimate purchaser, for vehicles meeting the applicable emission standards of this section, the applicable compliance limits shall be determined by adding the applicable adjustment from paragraph (j)(2) of this section to the otherwise applicable standard or FEL.

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(2) The in-use adjustments are:
(i) 0.1 g/bhp-hr for NO_X.
(ii) 0.100 g/bhp-hr NMHC.
(iii) 0.01 g/bhp-hr for PM.

49. A new § 86.1817–08 is added to Subpart S to read as follows:

§ 86.1817–08 Complete heavy-duty vehicle averaging, trading, and banking program.

Section 86.1817–08 includes text that specifies requirements that differ from § 86.1817–05. Where a paragraph in § 86.1817–05 is identical and applicable to § 86.1817–08, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1817–05."

(a) through (o) [Reserved]. For guidance see § 86.1817–05.

(p) The following provisions apply for model year 2008 and later engines. These provisions apply instead of the provisions of paragraphs § 86.1817–05 (a) through (o) to the extent that they are in conflict.

(1) Manufacturers of Otto-cycle vehicles may participate in an NMHC averaging, banking and trading program to show compliance with the standards specified in § 86.1806–08. The generation and use of NMHC credits are subject to the same provisions in paragraphs § 86.1817–05 (a) through (o) that apply for NO_X credits, except as otherwise specified in this section.

(2) NO_X or NMHC (or NO_X plus NMHC) credits may be exchanged between heavy-duty Otto-cycle test groups certified to the engine standards of subpart A of this part and heavy-duty Otto-cycle test groups certified to the chassis standards of this subpart, subject to an 0.8 discount factor (e.g., 100 grams of NO_X credits generated from vehicles would be equivalent to 80 grams of NO_X credits if they are used in the engine program of subpart A of this part, and vice versa). Credits that were previously discounted when they were banked according to § 86.1817–05(c), are subject to an additional discount factor of 0.888 instead of the 0.8 discount factor otherwise required by this paragraph (p)(2). This results in a total discount of 0.8 ($0.9 \times 0.888 = 0.8$).

(3) Credits are to be rounded to the nearest one-hundredth of a Megagram.

(4) To calculate credits relative to the NO_X standards listed in § 86.1816–08 (a)(1)(iv)(A) or (a)(2)(iv)(A) (0.2 or 0.4 grams per mile, respectively) express the standard and FEL to the nearest one-hundredth of a gram per mile prior to calculating the credits. Thus, either 0.20 or 0.40 should be used as the value for "Std".

(5) Credits generated for 2008 and later model year test groups are not discounted (except as specified in § 86.1817–05(c) and paragraph (p)(2) of this section), and do not expire.

(6) For the purpose of using or generating credits during a phase-in of new standards, a manufacturer may elect to split an test group into two subgroups: one which uses credits and one which generates credits. The manufacturer must indicate in the application for certification that the test group is to be split, and may assign the numbers and configurations of vehicles within the respective subfamilies at any time prior to the submission of the end-of-year report described in § 86.1817–05 (i)(3). Manufacturers certifying a split test group may label all of the vehicles within that test group with the same FELs: either with a NO_X FEL and an NMHC FEL, or with a single NO_X+NMHC FEL. The FEL(s) on the label will apply for all SEA or other compliance testing.

(7) Vehicles meeting all of the applicable standards of § 86.1816–08 prior to model year 2008 may generate NMHC credits for use by 2008 or later test groups. Credits are calculated according to § 86.1817–05(c), except that the applicable FEL cap listed in § 86.1816–08(a)(1)(ii)(B) or (2)(ii)(B) applies instead of "Std" (the applicable standard).

50. A new § 86.1824–07 is added to subpart S, to read as follows:

§ 86.1824–07 Durability demonstration procedures for evaporative emissions.

§ 86.1824–07 includes text that specifies requirements that differ from those specified in § 86.1824–01. Where a paragraph in § 86.1824–01 is identical and applicable to § 86.1824–07, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1824–01.". This section applies to gasoline-, methanol-, natural gas- and liquefied petroleum gas-fueled LDV/Ts, MDPVs, and HDVs.

(a) through (f) [Reserved]. For guidance see § 86.1824–01.

51. § 86.1829–01 is amended by revising paragraph (b)(1)(iii)(B) and adding paragraph (b)(1)(iii)(F) to read as follows:

§ 86.1829–01 Durability and emission testing requirements; waivers.

* * * * *

(b) * * *
(1) * * *
(iii)* * *

(B) In lieu of testing an Otto-cycle light-duty vehicle, light-duty truck, or heavy-duty vehicle for particulate emissions for certification, a manufacturer may provide a statement in its application for certification that such vehicles comply with the applicable standards. Such a statement must be based on previous emission tests, development tests, or other appropriate information.

* * * * *

(F) In lieu of testing a petroleum-fueled heavy-duty vehicle for formaldehyde emissions for certification, a manufacturer may provide a statement in its application for certification that such vehicles comply with the applicable standards. Such a statement must be based on previous emission tests, development tests, or other appropriate information.

* * * * *

52. A new § 86.1863–07 is added to subpart S, to read as follows:

§ 86.1863–07 Optional chassis certification for diesel vehicles.

(a) A manufacturer may optionally certify heavy-duty diesel vehicles under 14,000 pounds GVWR to the standards specified in § 86.1816–08. Such vehicles must meet all requirements of Subpart S that are applicable to Otto-cycle vehicles, except for evaporative, refueling, and OBD requirements.

(b) Diesel vehicles optionally certified under this section are subject to the OBD requirements of § 86.005–17.

(c) Diesel vehicles optionally certified under this section may be tested using the test fuels, sampling systems, or analytical systems specified for diesel engines in Subpart N of this part.

(d) Diesel vehicles optionally certified under this section may not be included in any averaging, banking, or trading program.

(e) The provisions of § 86.004–40 apply to the engines in vehicles certified under this section.

(f) Diesel vehicles may be certified under this section to the standards applicable to model year 2008 prior to model year 2008.

(g) Diesel vehicles optionally certified under this section in model years 2007, 2008, or 2009 shall be included in phase-in calculations specified in § 86.007–11(g).

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Occupational Safety and Health Administration

29 CFR Part 1926

Safety Standards for Steel Erection; Final Rule

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket No. S–775]

RIN No. 1218–AA65

Safety Standards for Steel Erection

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: By this notice the Occupational Safety and Health Administration (OSHA) revises the construction industry safety standards which regulate steel erection. The final rule enhances protections provided to workers engaged in steel erection and updates the general provisions that address steel erection. The final rule sets performance-oriented criteria, where possible, to protect employees from steel erection related hazards such as working under loads; hoisting, landing and placing decking; column stability; double connections; hoisting, landing and placing steel joists; and falls to lower levels. To effectuate this, the final rule contains requirements for hoisting and rigging, structural steel assembly, beam and column connections, joist erection, systems-engineered metal building erection, fall protection and training.

DATES: *Effective dates.* This standard will become effective on July 18, 2001.

ADDRESSES: In accordance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor of Labor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 to receive petitions for review of the final rule.

FOR FURTHER INFORMATION CONTACT: Ms. Bonnie Friedman, Director, Office of Public Affairs, Room N–3647, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210; telephone: (202) 693–1999. For additional copies of this **Federal Register** notice contact: OSHA, Office of Publications, U.S. Department of Labor, Room N–3101, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1888. Electronic copies of this **Federal Register** notice, as well as news releases, fact sheets, and other relevant documents, can be obtained from OSHA's web page on the Internet at http://www.OSHA.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Congress amended the Contract Work Hours and Safety Standards Act (CWHSA) (40 U.S.C. 327 *et seq.*) in 1969 by adding a new Section 107 (40 U.S.C. 333) to provide employees in the construction industry with a safer work environment and to reduce the frequency and severity of construction accidents and injuries. The amendment, commonly known as the Construction Safety Act (CSA) [Pub. L. 91–54; August 9, 1969], significantly strengthened employee protection by providing for occupational safety and health standards for employees of the building trades and construction industry in Federal and Federally-financed or Federally-assisted construction projects. Accordingly, the Secretary of Labor issued Safety and Health Regulations for Construction in 29 CFR part 1518 (36 FR 7340, April 17, 1971) pursuant to Section 107 of the Contract Work Hours and Safety Standards Act.

The Occupational Safety and Health Act (the Act) (84 Stat. 1590; 29 U.S.C. 651 *et seq.*), was enacted by Congress in 1970 and authorized the Secretary of Labor to adopt established Federal standards issued under other statutes, including the CSA, as occupational safety and health standards. Accordingly, the Secretary of Labor adopted the construction standards which had been issued under the CSA, in accordance with Section 6(a) of the Act (36 FR 10466, May 29, 1971). The Safety and Health Regulations for Construction were redesignated as part 1926 of 29 CFR later in 1971 (36 FR 25232, December 30, 1971). Subpart R of part 1926, entitled "Steel Erection," incorporating §§ 1926.750 through 1926.752, was adopted as an OSHA standard during this process. The requirements in the existing standard cover flooring, steel assembly, bolting, plumbing-up and related operations. In 1974 a revision in the temporary flooring requirement was made pursuant to a rulemaking conducted under section 6(b) of the Act (39 FR 24361).

Since that time, OSHA has received several requests for clarification of various provisions. The Agency began drafting a proposed rule to revise several provisions of its steel erection standard in 1984 and on several occasions discussed its intention with its Advisory Committee on Construction Safety and Health (ACCSH). The discussions with ACCSH led to the development of several draft notices requesting information or proposing changes to the rule. None of these draft notices was published, nor was public comment sought, except through the proceedings of the Advisory Committee.

In 1986, the Agency issued a Notice of Proposed Rulemaking for subpart M (Fall Protection) and announced that it intended the proposed rule to apply to all walking/working surfaces found in construction, alteration, repair (including painting and decorating), and demolition work, except for five specific areas. Although none of the specific areas pertained to steel erection, the Agency noted that "Additional requirements to have fall protection for connectors and for workers on derrick and erection floors during steel erection would remain in subpart R—Steel Erection."

This statement led to confusion. Many of the commenters to the subpart M rulemaking noted that they were not sure whether subpart M or subpart R would govern their activities. In one case, two sets of comments were provided, one to be used if subpart M applied and the other if subpart R applied. In the face of this uncertainty, the Agency decided that it would regulate the fall hazards associated with steel erection in its planned revision of subpart R.

OSHA announced its intention to regulate the hazards associated with steel erection, and in particular the fall hazards associated with steel erection, in a notice published in the **Federal Register** on January 26, 1988 (53 FR 2048). In that notice OSHA stated the following:

> The rulemaking record developed to date indicates that the Agency needs more information in order to develop a revised standard covering fall protection for employees engaged in steel erection activities. The comments received to date have convinced the Agency to develop a separate proposed rule which will provide comprehensive coverage for fall protection in steel erection. OSHA intends, therefore, that the consolidation and revision of fall protection provisions in subpart M do not apply to steel erection and that the current fall protection requirements of Part 1926 continue to cover steel erection until the steel erection rulemaking is completed. Accordingly, in order to maintain coverage under existing fall protection standards pending completion of the separate steel erection fall protection rulemaking, OSHA plans to redesignate existing §§ 1926.104, 1926.105, 1926.107(b), 1926.107(c), 1926.107(f), 1926.500 (with Appendix A), 1926.501, and 1926.502 into subpart R when the Agency issues the final rule for the subpart M rulemaking.

Since that time, the Agency drafted several documents which it presented to

ACCSH for comment. The Agency was also petitioned by affected parties to institute negotiated rulemaking. The first request for negotiated rulemaking was submitted to the Agency in 1990. At that time, it appeared the Agency would soon publish a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** and, therefore, the request was denied. However, affected parties once again made their concerns known, and the Agency delayed publication of the NPRM while it made a further, more comprehensive study of the concerns raised.

OSHA retained an independent consultant to review the fall protection issues raised by the draft revisions to subpart R, to render an independent opinion on how to resolve the issues, and to recommend a course of action. In 1991, the consultant recommended that OSHA address the issue of fall protection as well as other potential revisions to subpart R by using the negotiated rulemaking process.

Based on this recommendation and continued requests for negotiated rulemaking by affected stakeholders, on December 29, 1992, OSHA published a **Federal Register** notice of intent to establish a negotiated rulemaking committee (57 FR 61860). The notice requested nominations for membership on the Committee and comments on the appropriateness of using negotiated rulemaking to develop a steel erection proposed rule. In addition, the notice described the negotiated rulemaking process and identified some key issues for negotiation.

In response to the notice of intent, OSHA received more than 225 submissions, including more than 60 nominations for membership on the Committee and several sets of comments. After an evaluation of the submissions, it was apparent that an overwhelming majority of commenters supported this action, and OSHA decided to go forward with the negotiated rulemaking process. The Agency selected the members of the Committee from among the nominations.

On May 11, 1994, OSHA announced that it had established the Steel Erection Negotiated Rulemaking Advisory Committee (SENRAC) (59 FR 24389) in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. I), the Negotiated Rulemaking Act of 1990 (NRA) (5 U.S.C. 561 *et seq.*) and section 7(b) of the Occupational Safety and Health Act (OSH Act) (29 U.S.C. 656(b)) to make a recommendation to OSHA on the contents of a Notice of Proposed Rulemaking. Appointees to the Committee included representatives from labor, industry, public interests and government agencies. OSHA was a member of the committee, representing the Agency's interests.

The members of the Committee who participated in the 18 months of negotiations to develop the recommendation to OSHA are: Richard Adams—Army Corps of Engineers, replaced by Donald Pittinger and later replaced by Sam Testerman; William W. Brown—Ben Hur Construction Company; Bart Chadwick—Regional Administrator, Region VIII, Occupational Safety and Health Administration (since retired); James E. Cole—International Association of Bridge, Structural & Ornamental Ironworkers; Stephen D. Cooper—International Association of Bridge, Structural & Ornamental Ironworkers; Phillip H. Cordova—El Paso Crane & Rigging, Inc.; Perry A. Day—International Brotherhood of Boilermakers, Iron Ship Builders, Blacksmiths, Forgers & Helpers, later replaced by David Haggerty; James R. Hinson—J. Hinson Network, Inc.; Jim Lapping—Building and Construction Trades Department (AFL–CIO), replaced by Brad Sant, replaced by Sandy Tillett and later replaced by Phyllis Israel; John R. Molovich—United Steelworkers of America; Carol Murkland—Gilbane Building Company; John J. Murphy—Williams Enterprises of Georgia, Inc., replaced by Fred Codding—NAMOA; Steven L. Rank—Holton & Associates, Ltd.; Ray Rooth—CAL/OSHA; Alan Simmons—International Association of Bridge, Structural & Ornamental Ironworkers; William J. Smith—International Union of Operating Engineers; Ronald Stanevich—National Institute for Occupational Safety and Health (NIOSH) later replaced by Tim Pizatella, Division of Safety Research; C. Rockwell Turner—L.P.R. Construction Co.; and Eric Waterman—National Erectors Association.

SENRAC was chaired by Philip J. Harter, Esq., a nationally recognized expert in negotiated rulemaking and a trained facilitator.

SENRAC began negotiations in mid-June, 1994, and met 11 times as a full Committee. Committee workgroups developed detailed reports and recommendations which were presented at full committee meetings. At each meeting, the Committee debated the workgroups' reports, heard submissions from interested parties, and negotiated to find common ground on regulatory issues. In December 1995, the Committee developed a proposed revision of subpart R. OSHA then developed a preamble and Preliminary Economic Analysis based on the recommended regulatory text. The Agency presented this document to SENRAC for their review and approval. After Committee approval, on July 24, 1997, SENRAC presented OSHA with a consensus proposed standard at a signing ceremony held at the Department of Labor in Washington, DC.

On August 13, 1998, OSHA issued a notice of proposed rulemaking (NPRM) for subpart R—Steel Erection (63 FR 43452). The proposal set a time period, ending November 12, 1998, during which interested parties could submit written comments. In addition, the proposal provided a notice of a public hearing to begin on December 1, 1998. OSHA received 367 submissions, including testimony and documentary evidence, in response to the Notice of Proposed Rulemaking (NPRM). In addition, OSHA received 55 submissions, including requests to testify at the public hearing, in response to the notice of hearing contained in the NPRM.

The informal public hearing was held on December 1–11, 1998, with Administrative Law Judge John Vittone presiding. Judge Thomas Burke and Judge Richard Stansel-Gamm also presided at times during the nine days of hearings. At the close of the hearing, Judge Stansel-Gamm established a post-hearing comment period. The first part of the post hearing comment period, ending March 11, 1999, allowed participants to submit additional data and information. Participants were then permitted to submit briefs, arguments and summations until April 12, 1999. OSHA received 27 post-hearing submissions.

After analyzing the rulemaking record, the Agency developed draft final regulatory text. In accordance with the SENRAC's groundrules, OSHA convened a public meeting of SENRAC on December 16, 1999 (64 FR 66595) to consult with the Committee on the Agency's draft final rule. The purpose of the consultation meeting was to obtain comments and feedback from the Committee on OSHA's proposed revisions, prior to the issuance of a final standard. Among the topics discussed at the meeting were erection bridging, scope, fall protection, slippery surfaces, and joist holes. The discussions at the meeting aided OSHA in finalizing the draft steel erection standard.

On June 12, 2000, Judge Vittone certified the rulemaking record, including the hearing transcript and all written submissions to the docket, which closed the record for this proceeding.

A wide range of employers, businesses, labor unions, trade

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associations, state governments, and other interested parties contributed to the development of this record. Many of these parties also participated in the negotiated rulemaking process. OSHA appreciates these efforts to help develop a rulemaking record that provides a sound basis for the promulgation of a final rule for subpart R—Steel Erection.

OSHA believes that the final subpart R will substantially reduce the significant risk of death and serious injury that has continued to confront workers engaged in steel erection. In addition, the clarified and revised language of the final rule and consolidation of relevant provisions will help employers and employees to understand the requirements of the steel erection standard. The final rule provides additional protection and closes gaps in the current rule's coverage of steel erection hazards. These improvements have been achieved through the SENRAC negotiations, and the record developed during the proposed rule comment period, public hearing and post-hearing comment period.

In this final rule, OSHA provides notice to all affected employers and employees of these revisions to subpart R, which the Agency believes are necessary to protect employees. OSHA believes the clarified language of the final rule will help employers to protect their employees more effectively through a standard that is easier to understand and comply with.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* ("the Act"), is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards, 655(b) (authorizing promulgation of standards pursuant to notice and comment), 654(b) (requiring employers to comply with OSHA standards)).

A safety or health standard is a standard "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment" (29 U.S.C. 652(8)).

A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk, and is economically feasible, technologically feasible, and cost effective, and is consistent with prior Agency action or is a justified departure, is supported by substantial evidence, and is better able to effectuate the Act's purposes than any national consensus standard it supersedes.

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. *American Textile Mfrs. Institute* v. *OSHA*, 452 U.S. 490, 513 (1981) ("*ATMI*"); *AISI* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991) ("AISI").

A standard is economically feasible if industry can absorb or pass on the costs of compliance without threatening its long-term profitability or competitive structure. See *ATMI*, 452 U.S. at 530 n. 55; *AISI*, 939 F.2d at 980. A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. *ATMI*, 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994) ("*LOTO III*").

Section 6(b)(7) authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. 655(b)(7).

All standards must be highly protective. See 58 FR at 16614–16615; *LOTO III*, 37 F.3d at 669. Finally, whenever practical, standards shall "be expressed in terms of objective criteria and of the performance desired." *Id.*

As discussed in various places in this preamble, OSHA has determined that hazards associated with steel erection activities pose significant risks to employees and that the provisions of the final rule are reasonable and necessary to protect affected employees from those risks. The Agency estimates that full compliance with the existing and revised steel erection standard will reduce the risk of identified hazards (preventing 30 fatalities and 1,142 injuries annually). This constitutes a substantial reduction of significant risk of material harm for the exposed population of approximately 56,840 steel erection employees.

OSHA has determined that there are no technological obstacles to compliance with the final rule. As discussed in Section IV, Summary and Explanation of the Final Rule, the rulemaking record indicates that many of the requirements contained in the final rule are already in general use throughout the industry.

OSHA also concludes that compliance is economically feasible because, as documented in the Final Economic Analysis, all regulated sectors can readily absorb or pass on compliance costs and the standard's costs, benefits, and compliance requirements are consistent with those of other safety standards.

The record indicates clearly that steel erection employees face significant risks and that compliance with the final steel erection standard is reasonably necessary to protect affected employees from that risk. OSHA has considered and responded to all substantive comments regarding the proposed steel erection standard on their merits in Section IV, Summary and Explanation of the Final Rule. In particular, OSHA evaluated all suggested changes to the proposed rule in terms of their impact on worker safety, their feasibility, their cost effectiveness, and their congruity with the OSH Act.

III. Hazards Involved

Accidents during steel erection continue to cause injuries and fatalities at construction sites. Based on a review of compliance problems and public comments over the past several years, OSHA has determined that the current standard, which has been in place with little change for 30 years, needs a complete revision to provide greater protection and eliminate ambiguity and confusion. OSHA believes that reorganizing the standard's requirements into a more logical sequence will help employers to understand better how to protect their employees from the hazards associated with steel erection and will thus reduce the incidence of injuries and fatalities in this workforce.

OSHA tracks workplace fatalities through its Integrated Management Information System (IMIS) which captures a large percentage of the fatalities in the steel erection industry. However, detailed information on the conditions that give rise to steel erection accidents is less readily available. The best available data on steel erection hazards and accidents are derived from NIOSH and industry studies and from the Bureau of Labor Statistics (BLS).

During SENRAC negotiations, OSHA staff and a Committee statistical workgroup analyzed accident information derived from OSHA's IMIS system (Exs. 9–14A and 9–42). This data provided the best source of accident descriptions. However, it was frequently difficult to determine several critical elements, such as the precise activity being undertaken at the time of the accident; whether the victim was a trained ironworker; or the type of structure under construction or repair.

The following examples from OSHA's IMIS reports of accident investigations illustrate the types of accidents that occur in steel erection:

1. March 14, 1997: One fatality. Bundles of decking were being placed on bar joists that spanned approximately 40 feet. In the area where the decking was being landed, the joists had not been welded at both ends and "x" bracing had not been installed between the joists. Three bundles of decking had been landed near the ends of the joists. When two employees attempted to land a fourth bundle farther out on the unattached and unbraced joists, the joists moved and fell to the concrete slab below fatally injuring one employee. OSHA believes that compliance with the joist requirements of § 1926.757(e)(4) and (e)(5) of the final rule could have prevented this accident. Paragraph (e)(4) requires that no bundle of decking may be placed on steel joists until all bridging has been installed and anchored and all joist bearing ends are attached. In addition, paragraph (e)(5) requires that the edge of construction loads be placed within one foot of the bearing surface of the joist end.

2. October 1, 1997: One fatality. A worker was on a 24 foot steel I-beam attempting to connect to a 21 foot high steel column. The worker was on a ladder placed on the concrete slab. The column displaced from the foundation bolts during the connecting process, knocking the worker from the ladder and fatally injuring him. OSHA believes that compliance with the column anchorage requirements of § 1926.755(a) of the final rule could have prevented this accident by requiring that all columns be anchored by a minimum of four anchor rods (anchor bolts) and if applicable, paragraph (b) of that section requires that any repair, replacement or field modification of anchor rod (anchor bolt) be approved by the structural engineer of record.

3. October 1, 1997: One fatality. An employee was working at the 20 foot level re-positioning steel bar joists when three of the joists twisted and fell to the concrete slab below fatally injuring the employee. OSHA believes that compliance with the requirements of § 1926.757(b)(3), and possibly § 1926.757(a)(8), of the final rule could have prevented this accident. Paragraph (b)(3) requires that unless joists have been panelized, they shall be attached to the support structure, at least at one end, immediately upon placement in the final erection position and before additional joists are placed. In addition, if the joists are in bays of 40 feet or more, final rule paragraph (a)(8) requires that these joists be bolted to the structure to prevent such unintentional displacement of long limber joists.

4. January 27, 1998: One fatality. An employee fell 23 feet 6 inches while walking on a steel rafter. The employee finished bolting-up a steel purlin to the rafter and was in the process of walking back to get another purlin when he fell. OSHA believes that compliance with the fall protection requirements of the final rule could have prevented this accident. § 1926.760(a)(1) of the final rule requires that, with some exceptions, each employee engaged in steel erection be protected from falls when working on a surface more than 15 feet above a lower level. This includes workers engaged in bolt-up activities.

5. August 12, 1999: One fatality. A worker inadvertently picked up a marked, unsecured wooden cover over a 3′ × 3′ skylight hole. The worker accidently stepped into the hole and fell to the ground below. OSHA believes that compliance with the requirements of § 1926.754(e)(3) for covering roof and floor openings could have prevented this accident.

For its assessment of baseline risk in steel erection, OSHA used 1994–98 fatality data from the U.S. Bureau of Labor Statistics' (BLS) Census of Fatal Occupational Injuries. Based on analysis of the BLS data, OSHA estimates that structural metal workers experience an average of 35 fatalities per year. OSHA determined that, of the 35 fatalities, approximately 30 deaths per year are caused by factors that are addressed by the final standard (see the final economic analysis, Chapter III, summarized below in Section V). Furthermore, OSHA analysis of the results from the BLS Annual Survey of Occupational Injuries and Illnesses for the years 1994 to 1998 identifies an average of 2,279 lost-workday injuries per year whose circumstances would be addressed by provisions in the final standard. With an estimated workforce of 56,840 iron workers in construction ([BLS, Occupational Employment Statistics Survey, 1998]; see the final economic analysis), OSHA concludes that these baseline fatality and injury levels are high and clearly pose a significant risk to these workers that justifies Agency action.

In order to provide a more useful database for future rulemaking, OSHA has developed and implemented an enhanced coding system to be used by OSHA compliance officers when recording construction fatality investigations for entry into the Agency's IMIS. This system was implemented nationally on January 1, 1997. The data OSHA is now recording when making fatality investigations will provide a greater source of detailed information indicating how and where construction fatalities occur.

Three years after this final rule is implemented, OSHA will use the improved fatality data to evaluate the rule's effectiveness. Based upon this evaluation, a determination will be made as to whether modifications to the standard are necessary.

OSHA believes that this final rule will enhance employee protections by adding new requirements to close gaps in current coverage, strengthening many of the existing requirements, and promoting compliance by clarifying and consolidating current requirements. For further discussion of accident rates and significant risk, see Section V, Summary of the Final Economic Analysis.

Based on the available information referenced in OSHA's economic analysis and other record evidence, OSHA finds that structural metal workers are faced with a significant risk of serious injury or death that can be reduced substantially by the revisions contained in this final rule. The Agency estimates that each year approximately 56,840 workers in the United States suffer 2,279 serious (*i.e.*, lost-workday) steel erection injuries. In addition, an estimated 35 steel erection workers die every year as a result of hazardous workplace conditions that are preventable. OSHA estimates that, of the 35 annual steel erection fatalities, 8 fatalities will be averted by full compliance with the existing standard and that an additional 22 fatalities will be averted by compliance with the final standard. Additionally, of the 2,279 lost-workday steel erection injuries occurring annually, OSHA estimates that 1,142 injuries will be averted by full compliance with the existing and final standards (303 injuries will be averted by full compliance with the existing standard and 838 injuries will be averted by full compliance with the final standard; figures do not add to the total due to rounding). Therefore, OSHA finds it both necessary and appropriate to proceed with final rulemaking for steel erection activities.

IV. Summary and Explanation of the Final Rule

The following discussion explains how the final rule corresponds to or differs from the proposed steel erection standard and the existing standard, how SENRAC's negotiations and the comments and testimony presented on each provision influenced the drafting of the final rule and why we believe the provisions will protect steel erection

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workers. Except where otherwise indicated, proposed provisions which did not elicit comment have been promulgated as proposed, for reasons stated in the preamble to the proposed rule which is incorporated by reference (63 FR 43457).

In addition to revisions to subpart R, Steel Erection, this rulemaking makes necessary revisions to Subpart M of this Part, Fall Protection, for purposes of consistency. Current § 1926.500(a)(2)(iii) states: "Requirements relating to fall protection for employees performing steel erection work are provided in § 1926.105 and in subpart R of this part". This final rule revises the language of § 1926.500(a)(2)(iii) to read: "Fall protection requirements for employees performing steel erection work (except for towers and tanks) are provided in subpart R of this part". This revision clarifies that steel erection is covered exclusively by subpart R. In addition, since tanks and towers are excluded from the scope of subpart R, this final rule adds paragraph § 1926.500(a)(2)(iv) to subpart M to clarify that fall protection requirements for tanks and communication and broadcast towers are covered by § 1926.105. This new provision states: "Requirements relating to fall protection for employees engaged in the erection of tanks and communication and broadcast towers are provided in § 1926.105". The final revision to subpart M is to revise § 1926.500(a)(3)(iv). Section 1926.500(a)(3)(iv) currently states that the fall protection systems and criteria contained in § 1926.502 do not apply to steel erection. Since the final steel erection standard refers to § 1926.502 for the criteria for its fall protection systems, it is necessary to revise this paragraph to exclude only tanks and communication and broadcast towers from § 1926.502. The criteria for tanks and communication and broadcast towers will continue to be covered by § 1926.104. Section 1926.500(a)(3)(iv) is revised read as follows: "Section 1926.502 does not apply to the erection of tanks and communication and broadcast towers. (Note: Section 1926.104 sets the criteria for body belts, lanyards and lifelines used for fall protection during tank and communication and broadcast tower erection. Paragraphs (b), (c) and (f) of § 1926.107 provide definitions for the pertinent terms.)

Section 1926.750 Scope

Paragraphs (a) through (c) of § 1926.750 describe the scope of subpart R. In the proposed rule, the scope section was in two paragraphs, with the first designated "Scope" and the second designated "Application." To avoid confusion, these sub-titles have been eliminated, and the entire section designated "scope."

Paragraph (a) provides that subpart R applies to employers engaged in steel erection activities involved in the construction, alteration and/or repair of any type of building or structure—single and multi-story buildings, bridges, and other structures—where steel erection occurs. The paragraph makes clear that differences in coverage under the previous standards between single and multi-story (or tiered) buildings, as well as buildings and other types of steel structures, are no longer relevant. All the provisions of revised subpart R now apply irrespective of such distinctions. Paragraph (a) also includes a "Note," which sets out numerous examples of structures where steel erection may occur (this is not an exclusive list). This list was also in the proposed rule.

As indicated in the proposal, SENRAC discussed at length the differences between construction and maintenance since the construction industry performs millions of workerhours per year of "industrial maintenance" work. 29 CFR 1910.12(b) defines "construction work" as follows:

> Construction work means work for construction, alteration, and/or repair, including painting and decorating.

OSHA has interpreted this definition to include alteration, repair, renovation, rehabilitation and remodeling of existing facilities or structures.

The distinction between construction and maintenance is based on the nature of the work being performed rather than on the job title of the worker performing it. SENRAC acknowledged that the scope of proposed subpart R was governed by the definition of construction work contained in § 1910.12(b) which applies to all of part 1926.

The final rule defines steel erection (in § 1926.751) as "the construction, alteration or repair of steel buildings, bridges and other structures, including the installation of metal decking and all planking used during the process of erection." In the proposed rule, steel erection was defined as "the erection of" these structures. That unintentionally conflicted with proposed paragraph (a), which stated that steel erection activities also included "alteration and repair," activities which include work on structures that have already been erected. The definition of steel erection in the final rule was changed to correct this error.

One commenter stated that the phrase "alteration and/or repair" is unclear in that some of these activities may be considered construction work, while others may be considered maintenance. The commenter suggests that OSHA define these terms (Ex. 13–183).

All OSHA construction standards apply to "alteration and/or repair." These terms play a significant role in determining the scope of all of these standards. With respect to subpart R, there was little discussion during the SENRAC negotiations of how to define these terms. The Agency has decided that it would be inappropriate to define them separately under these circumstances. Therefore, definitions for them have not been added in the final rule. OSHA's general interpretation of these terms will apply to the steel erection standard in the same way as for other construction standards.

The requirements of subpart R apply to employers engaged in steel erection unless otherwise specified. Subpart R does not apply to electrical transmission towers, communication and broadcast towers, or tanks.

Paragraph (b)(1) sets out a list of specific steel erection activities covered under subpart R. These steel erection activities include hoisting, laying out, placing, connecting, welding, burning, guying, bracing, bolting, plumbing and rigging structural steel, steel joists and metal buildings; installing metal deck and siding systems, miscellaneous metals, ornamental iron and similar materials; and moving point-to-point while performing these activities.

In the proposed rule, the erection of curtain walls and window walls, as well as "laying out," "placing," "burning," "guying," "bracing" and "plumbing" structural steel, steel joists and metal buildings were inadvertently omitted from this paragraph; this has been corrected in the final rule. Otherwise the paragraph is the same as proposed.

A definition of "structural steel" has also been added to help clarify this section. It means a steel member, or a member made of a substitute material (such as fiberglass, aluminum, composites, etc.). Structural steel includes, but is not limited to, steel joists, joist girders, purlins, columns, beams, trusses, splices, seats, metal decking, girts, and all bridging, and cold formed metal framing which is integrated with the structural steel framing of a building. At the hearing, SENRAC members (Ex. 205X; p. 258) explained that in some instances buildings are now constructed with members that are configured like structural steel members, but are made of a substitute material (for example, solid web beams made of fiberglass). Since the erection process, the configuration of the structural framework and the members are the same as in a structure made of structural steel, these are included in the definition.

Cold formed metal framing is included in the definition of "structural steel" only when it is integrated with the structural steel framing of a building. An example of where it is *not* integrated with structural steel framing is in residential construction where such framing is referred to as "metal studs" and is installed by carpenters.

Paragraph (b)(2) lists a number of activities that are covered by subpart R when they occur during and are a part of the steel erection activities described in paragraph (b)(1). OSHA has changed the first sentence to explicitly state that coverage depends on whether an activity occurs *during* and is a part of steel erection. For example, there are standing seam metal roofing systems that incorporate a layer of insulation under the metal roof. In the installation process, a row of insulation is installed, which is then covered by a row of metal roofing. Once that row of roofing is attached, the process is repeated, row by row, until the roof is completed. The installation of the row of insulation is a part of the installation of the metal roofing (which is steel erection), and so the installation is covered by subpart R.

A note to paragraph (b) of the proposed rule listed activities "which could be considered covered by this subpart when they occur during the process of steel erection activities * * *" Some commenters stated that the list as proposed was confusing and subject to misinterpretation, since it was difficult to determine when the activities would be covered by subpart R. One stated that the examples are much too broad and confusing, subject to misinterpretation, and that a literal interpretation would include the installation of handrails, gaskets, sealants, doors and windows within a building as steel erection whether or not it was actually a part of steel erection activities (Ex. 201X; p. 54). Others stated that the text of the scope paragraph was adequate and the note should be eliminated in order to avoid misinterpretation (Ex. 13–163); that the note is confusing because of its length, location and the implication that all listed activities, performed on listed structures, constitute steel erection; and that the note should be relocated to a non-mandatory appendix (Ex. 13–183). One commenter (Ex. 13–37) noted that many of the listed activities are equally likely to occur on structures with other types of structural frames (such as concrete, masonry or wood) which are covered by other subparts in 29 CFR 1926. Examples of activities that can be found on all buildings, regardless of frame type, are "installing metal decks, siding systems, miscellaneous metals, ornamental iron and similar materials." In this commenter's view, the notes should be deleted, since it will be difficult for employers to have a clear understanding of which subpart directly applies to the different structural frames (Ex. 13–31). This commenter also expressed concerns with the overly broad scope of the proposed standard as described in § 1926.750 and the effect this would have on achieving a clear understanding of, and compliance with, the technical provisions of the standard. That commenter stated that it is not clear how subpart R and the other requirements in Part 1926 would apply to employers doing very similar work, based on the building's structure and whether steel erection is being done.

The changes to the first sentence of the list in the final rule are intended to address these concerns and give a clearer indication of when the listed activities are covered.

Several commenters asserted that the list of activities include some which were outside the scope of proposed § 1926.750(a). For example, paragraph (a) specifically excludes tanks, yet water containment structures, bins, and hoppers are listed as examples of structures where steel erection may occur. These commenters indicated that those examples should be omitted and that OSHA should include the following definition of tank: "A container made out of material including metal, fiberglass, wood or concrete that can be any shape including: cylindrical, rectangular, conical, spherical, spheroidal or elliptical, and may be used, constructed, altered and/or repaired to process, hold, store or treat any substance in various states including under a vacuum, at atmospheric pressure or pressurized" (Exs. 13–296, 13–207, 13–207D, 13–310, 13–317, and 13–316).

The Agency has added a definition of tank, but one that is simpler than the one suggested above. The definition of tank in the final rule is, "a container for holding gases, liquids, or solids." Although tanks are excluded, as the Agency explained in the preamble to the proposed rule, subpart R does cover the steel structure that supports a tank (63 FR 43458). Also, water containment structures other than tanks, bins and hoppers do not meet the definition of tank, so these examples are included in the associated list of examples as proposed by SENRAC.

Others wanted to expand the list. One commenter (Ex. 205X; p. 233) stated that "structural precast" should be included in the list of examples because steel erectors erect many segments of a structure, including columns, beams, as well as architectural materials mounted on steel frames. Another commenter (Ex. 205X; pp. 239–265) stated that "structural precast" should be included because the associated hazards during erection and hoisting, etc. of structural shapes made out of something other than steel are identical to those associated with steel.

A commenter (Ex. 13–129) requested that "architectural precast concrete" be removed from the list. His reasons included: (1) activities associated with architectural precast concrete are regulated under subpart M; and (2) an erector would not consider the erection of a precast concrete panel as steel erection—the process is simpler, safer, and faster than steel erection.

When OSHA established SENRAC, it stated that the scope of subpart R to be addressed by the Committee was limited to steel erection and did not include the erection of precast concrete (59 FR 25848). Furthermore, in an October 18, 1994 letter to the General President of the United Brotherhood of Carpenters and Joiners of America, OSHA reiterated the decision that subpart R would not cover precast concrete.

The final rule does not cover the erection of precast concrete. The final list of conditionally covered activities does not include erection of precast concrete. In the proposed rule, the "Note" that listed activities that could be covered by subpart R included "architectural precast concrete". Because OSHA clearly stated to the public that precast erection would not be covered by subpart R, we have removed "architectural precast concrete" from the listed activities in § 1926.750(b)(2) of the final rule. In addition, because precast concrete is sometimes mounted on steel frames, "stone and other architectural materials mounted on steel frames" has been changed to "stone and other non-precast concrete architectural materials mounted on steel frames."

Paragraph (c) provides that the duties of controlling contractors under this rule include, but are not limited to, the duties specified in § 1926.752(a) (approval to begin steel erection), § 1926.752(c) (site layout), § 1926.755(b)(2) (notification of repair, replacement or modification of anchor bolts), § 1926.759(b) (protection from

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falling objects) and § 1926.760(a)(2)(i) (perimeter safety cables).

The reference to the controlling employer provisions and the notation that this is not an exclusive list of responsibilities were added to the final rule to be consistent with OSHA's multi-employer policy. In the proposal, in setting out particular duties of controlling employers, it was not OSHA's intent to eliminate their responsibilities under the multi-employer doctrine. Therefore, the final rule specifically states that the controlling contractors' duties are not limited to those specified in the rule.

Numerous commenters, most of which were general contractors, objected to imposing any obligations on controlling contractors who were not performing the steel erection work themselves. In their view, requiring employers to take actions to protect the employees of other employers is inappropriate and not permitted under the OSH Act. For example, Massman Construction Company (Ex. 13–16); Robinson Quality Constructors (Ex. 13–36); Hayner Hoyt Corporation (Ex. 13–223); St. Louis Bridge Company (Ex. 13–244); J. F. O'Healy Construction Corporation (Ex. 13–358), and other commenters wrote:

> We also adamantly oppose the process of SENRAC taking upon themselves to expand the scope of the OSHA Act of 1970 by introducing a definition of controlling contractor that expands the scope of OSHA. If controlling contractor language as presently written is permitted in Subpart R, it is our belief that the precedent set by such an action will lead to this same controlling contractor language being introduced into future revisions to other OSHA standards such as scaffolding, stairways and ladders, fall protection, and excavation.

Another series of comments OSHA received also opposed the controlling contractor provisions. The comments written by RK Building Systems (Ex. 13–168); Fleischer-Seeger Construction Corporation (Ex. 13–169); Massman Construction Co. (Ex. 170A); WM. R. Montgomery and Associates, Inc. (Ex. 13–170C); Robinson Quality Constructors (Ex. 13–170D); J.F. O'Healy Construction Corporation (Ex. 13–327); and many other commenters stated:

> We are adamantly opposed to the introduction of controlling contractor in the proposed standard revisions. If the proposed standard becomes law, the general contractor or construction manager will become responsible for many of the activities of the steel erector subcontractors. This will be in spite of the fact that the general contractor or construction manager subcontracts with the steel erector because that particular subcontractor has expertise in performing steel erection work. The subcontractor should be allowed to perform its work without OSHA mandated intervention between the general contractor or construction manager and the subcontractor.

OSHA recognizes that steel erection subcontractors are hired for their expertise in performing steel erection work. In that respect, steel erection subcontractors are similar to other subcontractors, all of whom are hired because they are experts in their specialties. But while each subcontractor has special expertise, it is typically the general contractor or construction manager who controls the overall project and coordinates the work of the subcontractors. The general contractor's or construction manager's control over the project gives it the ability to see that safety and health hazards created by subcontractors are corrected. Accordingly, when the general contractor or construction manager has reason to know of violative conditions created by a subcontractor, has the authority to prevent or correct that condition by reason of its supervisory authority over the worksite, and fails to take appropriate action to prevent or correct the violation, the general contractor or construction manager is liable for the violation as a controlling employer. See OSHA Directive No. CPL 2–00.124 (Dec. 10, 1999). OSHA stresses that the general contractor or construction manager is not strictly liable for subcontractor violations but is only responsible if it fails to take reasonable and feasible steps to discover and correct unsafe or unhealthful working conditions on the work site. *Id.*

OSHA's policy of holding controlling employers liable for violations they can prevent or correct by reason of their supervisory capacity has been upheld by a number of courts and the Review Commission. See, for example, *Universal Construction Company*, Inc. v. *OSHRC*, 182 F.3d 726 (10th Cir., 1999); *R.P. Carbone Constr. Co.* v. *Occupational Safety and Health Review Comm'n*, 166 F.3d 815 (6th Cir., 1998); *Grossman Steel & Aluminum Corp.*, 4 BNA OSHC 1185 (Rev. Commission, 1975); *Marshall* v. *Knutson Construction Co.*, 566 F. 2d 596 (8th Cir., 1977); *Centex-Rooney Construction Co.*, 16 BNA OSHC 2127 (Rev. Commission 1994).

OSHA has, by regulation, placed specific obligations on controlling employers for the protection of other employers' employees in a number of standards. See, for example, § 1910.1200(e)(2), Hazard Communication; § 1910.146, Permit-Required Confined Spaces; and § 1926.1101(d), Asbestos. Therefore, the assertion that the Agency does not have the authority to place such obligations on controlling contractors in subpart R is unpersuasive.

SENRAC found that many controlling contractors have already accepted responsibility for the five specific duties now codified in the final rule. This was corroborated in testimony by several general contractors/construction managers at the rulemaking hearing. (See, for example, Ex. 201X, pp. 35–38; Ex. 201X, p. 63; Ex. 201X, pp. 93–95 and 105–107; Ex. 201X, pp.150–151; and Ex. 201X, p.211.) Specifically, the following is Mr. Jenkins' response (Ex. 201X, pp. 35–38) when questioned during testimony at the public hearing:

> QUESTION: In fact, most of the [controlling contractor] requirements that have been mentioned through cross examination you seem to be doing already.
>
> MR. JENKINS: That's correct, because we try to run safe job sites. (Id.)

Furthermore, controlling contractors were represented on SENRAC by William Brown representing the Associated General Contractors of America (AGC), Rockwell Turner representing the Associated Builders and Contractors (ABC), and Carol Murkland representing Gilbane Building Company. They endorsed the proposed rule, which contained these same provisions. Accordingly, it is both necessary and appropriate to place these obligations on controlling contractors.

Section 1926.751 Definitions

The final rule definition section lists and defines major terms used in the standard. Approximately twenty of the proposed definitions, all developed by SENRAC with input from the Steel Joist Institute (SJI), the Steel Deck Institute (SDI) and others, received no comments nor were they discussed in testimony at the hearing. Accordingly, these definitions are promulgated as proposed and are not discussed in the final rule.

In the proposal, OSHA defined the terms "clipped connection", "cold formed joist", and "composite joists". Because these terms are not used in the final rule, OSHA has removed the definitions for these terms. The term "clipped connection" is considered an "equivalent connection device" under § 1926.756(c)(1) and has been moved to Appendix H.

The remaining proposed definitions did receive considerable attention during this rulemaking. Accordingly, the following discussion addresses these definitions in more detail.

"Column." This term is defined in the final rule to mean a load-carrying vertical member that is part of the primary skeletal framing system. Columns do not include "posts" such as wind posts, and posts supporting stair landings, wall framing, mezzanines and other substructures (see definition of "post"). As discussed later in this preamble (see discussion of final § 1926.755), the Agency determined that a definition for column is needed to clarify which members are subject to the requirements of the column anchorage provisions in § 1926.755.

"Competent person." This term is already defined in § 1926.32(f), which applies to all construction work. A "competent person" is a person who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them. Because the term appears so frequently in this standard, OSHA is repeating this definition in subpart R. One commenter (Ex, 13–153) suggested adding "typically, but not necessarily, the competent person on a steel erection project will be the person responsible for the steel erection." OSHA does not believe the recommended language clarifies the definition. Also, the term is used in all construction applications and the Agency does not feel it is appropriate to change the definition for steel erection.

"Connector" means an employee who, working with hoisting equipment, is placing and connecting structural members and/or components. This definition is unchanged from the proposal. Several commenters (Exs. 13–365, 13–334; 13–193A; 13–173; and 13–215) stated that this definition does not clearly indicate what activities are performed by a connector. They specifically argued that the definition does not indicate whether spreading and securing of bar joists would be considered connecting. One witness testified (Ex. 201X; p. 81) that the proposed definition was so broad that it would include almost any operation performed by ironworkers. OSHA disagrees with these commenters. SENRAC intended to make this definition as narrow as possible, and the Agency believes that the final definition carries out this intention. The definition is very specific; connecting is distinguished from other steel erection activities by the elements in the definition. For example, spreading and securing bar joists by hand would not be considered connecting, since that work is not done "with hoisting equipment." Therefore, an employee is a "connector" only when working with "hoisting equipment". This includes placing components as they are received from hoisting equipment, and then connecting those components while hoisting equipment is overhead.

"Constructibility." This term is defined to mean the ability to erect structural steel members in accordance with subpart R without having to alter the over-all structural design. As discussed in the preamble of final rule § 1926.755, the Agency has determined that a definition for constructability is needed for clarification. In the proposal, several provisions contained exceptions where "design and constructibility do not allow" compliance. However, the term "design and constructibility" was not defined. The term was included in the proposal to allow exemptions from specific requirements where the overall design of the structure prevents compliance with such requirements. In other words, in order to comply with the requirements, the overall design of the structure would have to be altered. Since "constructibility" includes "design" constraints, the Agency has replaced "structural design and constructability" with "constructibility." This term is used in several places in the final rule, specifically § 1926.754(e)(2)(i), § 1926.756(e)(1) and (e)(2), and § 1926.757(a)(8)(ii).

"Controlled Decking Zone (CDZ)." This term is defined to mean an area in which certain work (for example, initial installation and placement of metal deck) may take place without the use of guardrail systems, personal fall arrest systems, restraint systems or safety net systems provided that alternative procedures (for example, controlled access combined with worker training, specified work practices and use of control lines or equivalent) are implemented. Controlled decking zones are discussed in final rule § 1926.760(c).

"Controlling contractor." OSHA defines this term to mean a prime contractor, general contractor, construction manager, owner acting as the general contractor, or any other legal entity that has overall responsibility for the construction of the project—its planning, quality, and completion.

One witness (Ex. 201X; p. 8–39) suggested that a company would be considered a controlling contractor under this definition if it controls the schedule at the worksite, dictates when other contractors will do their work, makes it a practice to inform other contractors on the site of safety problems and requires the other contractors to take corrective action. He further argued that, while these are not all of the relevant factors, they are typical of the types of authority that controlling contractors have.

Some commenters stated that the definition of a controlling contractor was vague and could be interpreted to include a "private or public owner, the project architect, general contractor or other contractors on a multiple prime contractor project[s]." The provision defines the term with respect to the extent of control of the worksite. A controlling contractor is an entity that has general supervisory authority over the worksite such that it can correct safety and health violations itself or have others correct them. So, an owner, project architect or any other entity that has this authority would be considered a controlling contractor.

The proposed phrase "by contract with other parties" has been omitted in the final rule because an employer may have the "overall responsibility for the project, its planning, quality and completion" without it provided for by contract.

"Critical lift" means a lift that (1) exceeds 75% of the rated capacity of the crane or derrick, or (2) requires the use of more than one crane or derrick. A commenter (Ex. 13–210) stated that critical lifts are not unique to steel erection and should be addressed in OSHA's crane standard, 29 CFR 1926.550. While OSHA agrees that these types of lifts occur in industries other than steel erection, there currently are no special requirements in OSHA's crane standard that specifically address these types of lifts. Since cranes are the primary equipment used in steel erection to lift/hoist steel members, the Agency feels it is important to address critical lifts in the steel erection standard. As stated in the proposal, this definition was developed by a SENRAC workgroup.

"Decking hole." This term is defined to mean a gap or void more than 2 inches (5.1 cm) in its least dimension and less than 12 inches (30.5 cm) in its greatest dimension in a floor, roof or other walking/working surface whereas "opening" means a gap or a void large enough to present a fall hazard. Pre-engineered holes in cellular decking are not included in the definition of "decking hole".

SENRAC believed that it was important to distinguish between holes that are too small to fall through (but are a tripping and falling object hazard), and holes which are large enough to fall through. This allowed the proposed rule to have safety requirements tailored to whether the hole presents a tripping/falling object hazard or a fall hazard. It therefore used the terms "decking hole" for small holes and "opening" for large holes.

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Two commenters stated that the definitions of hole and opening should be consistent with the definitions in the general fall protection standard for construction, 29 CFR subpart M, § 1926.500(b) (Ex. 13–210 and 13–222). They pointed out that the definition of "opening" in the proposal is different from the definition for that term in § 1925.500(b). Another commenter (Ex. 13–1) noted that the proposal's definitions of holes and openings are consistent with the definitions in ANSI A1264.1–1995, although the ANSI standard does not apply to construction.

The definition of "decking hole" in subpart R, which has both a minimum and maximum measurement—2 inches in its least dimension and 12 inches in its greatest dimension—refers to small holes. In contrast, the definition of "hole" in subpart M (§ 1926.500(b)) includes large as well as small holes; it has only a minimum measurement—2 inches or more in its least dimension. Additionally, in subpart R, the term "opening" refers to holes large enough to be a fall hazard. In subpart M, the term "opening" refers to gaps or voids large enough to be a fall hazard, but only in walls (or partitions).

The definition of "decking hole" and "opening" in the proposal were developed by SENRAC specifically for the steel erection industry for this purpose. While the terms are inconsistent with comparable terms in subpart M, the Committee found that the proposal's definitions reflect the steel erection industry's use of these terms. While consistency between standards is desirable, the subpart M terms would not meet the needs of this standard. Therefore, the Agency has retained the subpart R terms from the proposal.

"Derrick floor." This term is defined to mean the elevated floor of a building or structure that has been designated to receive hoisted pieces of steel prior to their final placement. A commenter (Ex. 13–308) suggested changing the term to "staging floor" since it is not clear if the references in § 1926.754(e)(5)(i) and (e)(5)(ii) are intended to refer to floors used to support crane derricks or staged materials. SENRAC has noted that the term "derrick floor" is a term commonly used in the steel erection industry to refer to the floor on which the erection process for the floors above is taking place. The derrick floor may or may not have a derrick on it but it is considered the erection floor and serves as a staging area for construction loads that are necessary to perform the work at the levels above. Since the term is a generally understood term within the industry, the Agency feels that the term "staging area" is too limiting and may lead to confusion over the intended use of the floor. The Agency concurs with SENRAC's recommended term and is promulgating the final definition as proposed.

"Double connection seat" means a structural attachment that, during the installation of a double connection, supports the first member while the second member is connected. This definition replaces the proposed definition of "seat". The definition was modified to be consistent with the revisions made to final § 1926.756(c). "Seat" was changed to "double connection seat" to clarify that these devices are used in double connections.

"Erection Bridging" means the bolted diagonal bridging that is required to be installed prior to releasing the hoisting cables from the steel. One commenter stated that the term should be replaced with "bridging" (Ex. 13–308). He asserts that "erection bridging" incorrectly implies that the bridging is temporary and required for erection proposes only, similar to erection bracing, erection bolts, etc. However, the Agency disagrees. Erection bridging refers to bridging that must be installed during the erection process, and becomes a permanent part of the structure. This term was recommended by SJI, and accepted, as a term that is commonly understood by the industry. Therefore, the term is unchanged in the final rule.

"Fall restraint system." The final rule defines a fall restraint system as a fall protection system that prevents the user from falling any distance. The system is comprised of either a body belt or body harness along with an anchorage, connectors and other equipment necessary for the system to prevent the worker from falling any distance. The other components typically include a lanyard, and may also include a lifeline and other devices. When used while working on a horizontal surface, the system prevents the worker from stepping past the edge of the walking/working surface (in contrast, a fall arrest system limits the distance of a fall).

In the proposed rule, the Agency used the term "fall restraint (positioning device)." In the final rule, OSHA has deleted the parenthetical reference to a positioning device, modified the definition, and added a separate definition for the term "positioning device." The term used in the proposal was defined as a system used to prevent an employee from falling more than two feet, consisting of an anchorage, connectors, a body belt or full body harness and a lanyard, lifeline or suitable combination of these, and permitting self-rescue. The reasons for changing the term and its definition are discussed in the discussion of final rule § 1926.760.

"Final interior perimeter." This is a new term in the final rule and means the perimeter of a large permanent open space within a building such as an atrium or courtyard. This does not include openings for stairways, elevator shafts, etc. The term, used in § 1926.760(a)(2), describes those areas that are considered a final perimeter of the structure but are not exterior perimeters.

"Hoisting equipment." This term is defined to mean commercially manufactured lifting equipment designed to lift and position a load of known weight to a location at some known elevation and horizontal distance from the equipment's center of rotation. "Hoisting equipment" includes but is not limited to cranes, derricks, tower cranes, barge-mounted derricks or cranes, gin poles and gantry hoist systems. The definition for hoisting equipment includes all commercially manufactured equipment that is used in steel erection to lift loads to a specified location. The intent was to ensure that this term is not strictly limited to cranes. The definition was also crafted to prevent a steel erector from claiming as "connectors" employees who are not true connectors (such as detailers) by providing them with a "come-a-long" to meet the definition of connector. A "come-a-long" is *not* included in the definition of hoisting equipment. A "come-a-long" is a mechanical device, usually consisting of a chain or cable attached at each end, that is used to facilitate movement of materials through manual force and leverage. It has been excluded from the definition of "hoisting equipment" because it is manually powered. A commenter (13–308) suggested deleting "an erection" from the proposed definition since it is not necessary in the context of the definition. OSHA agrees with the commenter that the phrase is not necessary. In addition, this commenter suggested that "come-a-longs" should be considered hoisting equipment when they are used for overhead loads. The Agency does not agree with the commenter on this point. A "come-a-long" is used to adjust the position of a member, not to "hoist" it from one level to another. Hoisting equipment has purposely been defined to only include the traditional equipment used for hoisting steel members into place. A "come-a-long" does not fit into this definition. OSHA has also made editorial changes to the definition to make it clearer.

"Opening." This term is defined to mean a gap or void 12 inches (30.5 cm) or more in its least dimension in a floor, roof or other walking/working surface. For the purposes of this subpart, skylights and smoke domes that do not meet the strength requirements of § 1926.754(e)(3) are regarded as openings (see the discussion on "decking hole" for a more detailed explanation).

"Personal fall arrest system." The final rule defines a personal fall arrest system (PFAS) as a system used to arrest an employee in a fall from a working level. It consists of an anchorage, connectors and body harness, and may also include a lanyard, deceleration device, lifeline or suitable combinations of these. The final rule's definition deletes the proposed reference in the proposal to body belts, since these are no longer permitted to be used in fall arrest systems.

"Positioning device system." As discussed above under the definition of "fall restraint system," the final rule distinguishes the terms fall restraint system and positioning device system. Consequently, a separate definition for positioning device system has been added. It defines this term as a body belt or body harness rigged to allow an employee to be supported on an elevated, vertical surface, such as a wall or column, and work with both hands free while leaning.

This definition omits the reference in the proposal's definition of "fall restraint (positioning device)" to the ability to self-rescue. That capability is assured by the fact that the final rule, in paragraph § 1926.760(d)(1), requires positioning device systems to comply with the requirements of § 1926.502. Section 1926.502(e) requires positioning device systems to limit the worker's fall to no more than two feet, which allows workers using these devices to rescue themselves in the event of an arrested fall. When using "fall restraint" and "positioning device systems," employers do not need to provide employees with self rescue devices. The reason such devices are not required is that "fall restraint" and "positioning device systems" must be designed to prevent employees from being exposed to fall hazards.

"Post." This term is defined to mean a structural member with a longitudinal axis that is essentially vertical, that: (1) Weighs 300 pounds or less and is axially loaded (a load presses down on the top end), or (2) is not axially loaded, but is laterally restrained by the above member. Posts typically support stair landings, wall framing, mezzanines and other substructures. As discussed in the summary and explanation of final rule § 1926.755, the Agency feels that a definition for post is needed to clarify the application of § 1926.755. (See also the definition of "Column" in § 1926.751.)

"Project structural engineer of record." This term is defined in the final rule to mean the registerpd, licensed professional responsible for the design of structural steel framing and whose seal appears on the structural contract documents. One commenter (Ex. 13–356) suggested expanding the definition by adding "and other structural systems" after structural steel framing. The necessity for such an addition has not been demonstrated; the definition is promulgated unchanged.

"Qualified person." This term is also defined in § 1926.32(m), which applies to all construction work covered by part 1926. A "qualified person" means one who, by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated the ability to solve or resolve problems relating to the subject matter, the work, or the project. As with the definition of "competent person", because of the frequent use of the term in this standard, and as a matter of convenience for users, the definition is repeated in subpart R even though the definition already exists in § 1926.32. One commenter (Ex. 13–153) suggested changing the definition to be more specific to steel erection. However, the record does not show a significant need to have a different definition.

"Steel Erection." This term means the construction, alteration or repair of steel buildings, bridges and other structures, including the installation of metal decking and all planking used during the process of erection. This is a revision of the definition in the proposal, which defined steel erection as "the erection of steel buildings, bridges and other structures, including the installation of steel flooring and roofing members and all planking and decking used during the process of erection." One commenter indicated that steel erection is understood to include alteration and/or repair activities, but that the definition in the proposal was limited to the erection of entire structures (Ex. 13–183).

The definition in the proposal unintentionally conflicted with the proposed § 1926.750(a), which stated that steel erection activities also included "alteration and repair," activities which include work on structures that have already been erected. The definition of steel erection in the final rule has been changed to correct this error.

"Steel joist." This term is defined to mean an open web, secondary load-carrying member of 144 feet (43.9 m) or less, designed by the manufacturer, used for the support of floors and roofs. This term does not include structural steel trusses or cold-formed joists. A commenter (Ex. 13–153) suggested adding "designed by the manufacturer" to this definition to make it consistent with that of steel joist girder and differentiate it from a steel truss which is designed by the structural engineer of record. OSHA agrees with this suggestion and has changed the definition in the final rule accordingly.

"Structural steel" means a steel member, or a member made of a substitute material (such as, but not limited to, fiberglass, aluminum or composite members). These members include, but are not limited to: steel joists, joist girders, purlins, columns, beams, trusses, splices, seats, metal decking, girts, and all bridging, and cold formed metal framing which is integrated with the structural steel framing of a building. This definition was added because it is an important term that is used in the scope section of this standard. Also, at the hearing and the December 16, 1999 SENRAC consultation meeting, SENRAC members explained (Ex. 205X, pp. 230–233, 248–249, and 257–271; Ex. 206X, p. 70; and Ex. 208X, pp. 144–145) that in some instances buildings are now constructed with members that are configured like structural steel members, but are made of a substitute material (for example, solid web beams made of fiberglass). Since the erection process, configuration of the structural framework and the members are the same as in a structure made of structural steel, these are included in the definition as well.

"Systems-engineered metal building." This term replaces the term "pre-engineered metal buildings" that was used in the proposed rule. The final rule definition of systems-engineered metal building is essentially the same as the proposed definition of pre-engineered metal building. It means a field-assembled building system consisting of framing, roof and wall coverings. Typically, many of these components are cold-formed shapes. These individual parts are fabricated in one or more manufacturing facilities and shipped to the job site for assembly into the final structure. The engineering design of the system is normally the responsibility of the systems-engineered metal building manufacturer. The definition was developed by a SENRAC

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workgroup. Although no comments were received on the definition, the term itself was changed for reasons explained in the discussion of § 1926.758.

"Tank" is a new definition. It means a container for holding gases, liquids or solids. Although, as explained in the discussion of § 1926.750(a), subpart R does not cover tanks, it covers the erection of steel structures supporting tanks.

Section 1926.752 Site Layout, Site-Specific Erection Plan and Construction Sequence

This section of the final rule sets forth OSHA's requirements for proper communication between the controlling contractor and the steel erector prior to the beginning of the steel erection operation and proper pre-planning by the steel erector to minimize overhead exposure during hoisting operations. Appendix A, which is referred to in this section, also provides guidelines for employers who elect to develop a site-specific erection plan. OSHA's current standard does not contain provisions similar to those being adopted in this section.

SENRAC recognized that under current practices in the industry, erection decisions are often made in the field when the steel arrives. SENRAC believes that pre-planning and coordination are currently not occurring to the extent they should be (63 FR 43461).

Paragraph (a) Approval To Begin Steel Erection and (b) Commencement of Steel Erection

Paragraph (a) requires that the controlling contractor ensure that written notifications be provided to the steel erector that (1) The concrete in the footings, piers, and walls and the mortar in the masonry piers and walls have cured to a level that will provide the proper strength to support any forces imposed on the concrete during steel erection; and (2) that any repairs, replacements, and modifications made to anchor bolts meet the requirements of § 1926.755(b). The criteria for adequate strength for concrete footings depend on the results of required American Society for Testing and Materials (ASTM) standard test methods. (Note: requirements for the controlling contractor to notify the steel erector of any repair, replacement or modification to anchor bolts are found in § 1926.755(b))

SENRAC found that many accidents involving collapse could have been averted had adequate pre-erection communication and planning occurred (63 FR 43461). This section of the rule is designed to ensure proper communication and pre-planning between contractors pouring concrete footings, contractors making repairs to repairing anchor bolts, the controlling contractor, and the steel erector. This communication must take place prior to the beginning of steel erection. The written notification can be transmitted electronically.

Some commenters (Exs. 13–4, 13–7, 13–26, 13–63A and 13–193A) stated that a controlling contractor would not know if concrete had cured to the point that steel erection could begin. They go on to state that steel erectors know more about how much concrete needs to cure, and that they should be the ones to determine if the proper information has been provided so that steel erection can start.

OSHA agrees that both the controlling contractor and steel erector usually would not know if concrete has cured unless the ASTM standard test method has been performed. This requirement is similar to the OSHA requirement for concrete construction found in § 1926.703(e)(ii), which requires that formwork not be removed from cast-in-place concrete "* * * until the concrete has been properly tested with an appropriate ASTM standard test method designed to indicate the concrete compressive strength, and the test results indicate that the concrete has gained sufficient strength to support its weight and superimposed loads." Since the footings, piers and walls intended to be covered by this proposed section will be supporting the steel structure being erected, OSHA, as well as the Committee, wishes to ensure that this information is provided to the steel erector before the steel is placed on the concrete.

In the proposed rule, the controlling contractor would have had to provide the ASTM test results to the steel erector. The final rule has been changed to reflect that the controlling contractor must ensure that the test results are provided to the steel erector. This rephrasing will allow the controlling contractor to have a contractor familiar with the ASTM test methods perform the test and provide the results to the steel erector.

Commenters also stated (Exs. 13–164, 13–264, 13–334 and 13–359) that the steel erection contractor, not the controlling contractor, was the best person to evaluate site conditions and approve the commencement of steel erection. The final rule, however, does not contain a broad-based requirement that the controlling contractor evaluate whether the site is in proper condition to begin steel erection. Rather, it sets out two specific aspects of the site that the controlling contractor must evaluate before approving the commencement of steel erection. The controlling contractor is in a better position to gather the required information than the steel erector, since much of this information must be obtained from persons over whom the steel erector has no control, such as the laboratory testing the concrete samples or the concrete contractor repairing the damaged anchor bolts. OSHA has also added a new provision, § 1926.752(b), to ensure that a steel erector does not begin erecting steel before receiving the information required in § 1926.752(a).

A commenter (Ex. 13–149) suggested that the word "must" in the proposed § 1926.752(a) be replaced with the word "shall." Although these words have the same meaning, the word "shall" is used throughout this standard, and the change was made in the interest of consistency.

Paragraph (c) Site Layout

Paragraph (c)(1) and (c)(2) of the final rule requires that the access roads and a drained and graded area be provided and maintained by the controlling contractor. These conditions enable the steel erector to move around the site and perform necessary operations in a safe manner. The provision does not apply to roads outside of the construction site.

Some commenters (Exs. 13–26, 13–63A, 13–193A, 13–215 and 13–241) pointed out that safe access roads are already required in § 1926.20 (General Safety and Health Provision); § 1926.550 (Cranes and Derricks); and § 1926.602(a)(3)(i) (Material Handling Equipment standards). However, these standards do not protect employees from the hazards addressed in § 1926.752(b). For example, these standards do not address adequate access roads into and through the site. As noted earlier, OSHA has attempted to bring together the provisions that are unique to steel erection work in subpart R.

Testifying as to the need for this provision in the steel erection industry, Steve Rank, a member of SENRAC who represented the insurance interest, stated the following:

> I am talking about the site conditions. Normally, you don't talk about fatalities when you talk about site conditions, but the statistics that OSHA never got were those disabling injuries where ironworkers' feet were crushed or legs were crushed because of trying to off-load their material on job sites. Structural steel iron has to be unloaded, sorted, and stood up before you can get it in the air. We as an industry not only want to focus on the fatalities, but also those disabling injuries that have plagued our industry. (208X; p.34)

The final rule adds an exception for roads outside the construction site in response to a commenter (Ex. 13–214) who objected to the proposed provision because there are worksites that have city or county owned access roads. When such conditions exist, the controlling contractor does not have any authority to correct problems with the road, or to assign lay down areas for steel erectors to prepare their work. OSHA agrees with the commenters that there are circumstances where the controlling employer would not have such control, such as where a city or county owns the access roads. For this reason, OSHA has added language to the final rule to provide an exception where the controlling contractor does not have control over the road.

Paragraph (c)(2) requires that the controlling contractor provide and maintain a firm, properly graded, drained area, readily accessible to the work and with adequate space for the safe storage of materials and the safe operation of the erector's equipment. As stated in the proposed rule, SENRAC found that the controlling contractor is in the best position to minimize the hazards associated with improper site layout and conditions. The provisions in paragraphs (c)(1) and (c)(2) were derived from the AISC code of standard practice for steel buildings and bridges (Ex. 9–36).

Some commenters (Exs. 13–279, 13–210, 13–311, 13–193 and 13–164) indicated that the term "adequate" in the requirement in (c)(1) should be defined to delineate what would be acceptable for roads. After considering this suggestion, OSHA has concluded that no definition could be created that would encompass all possible site conditions. For this reason, OSHA has left the word adequate in the final rule, and it will be the responsibility of the controlling contractor to determine that a road is properly graded to support equipment without the danger of rollover and properly drained so that equipment can be safely maneuvered.

One commenter (Ex. 13–155) objected to the provision on the grounds that the steel erector, rather than the controlling contractor, is best able to determine access and work area needs for the work. At the hearing, a witness (Ex. 208X; p. 78–79) testified that the steel erector does not have any ability to say where the access roads and storage areas will be placed, or who can work in those areas. He went on to state that these decisions are usually made by the controlling contractor. Another witness (Ex. 202X; p. 42) testified that when he needs the access road or storage area smoothed out, he contacts the general contractor, or controlling contractor.

The record shows that it is the controlling contractor that is in the best position to ensure that the necessary changes are made (see, for example, Ex. 201X; pp. 93–95). Further, in these situations, the controlling contractor is able to make necessary changes. It will either have the personnel and equipment, or can assign the task to another contractor, to maintain site conditions. For these reasons, OSHA has not made any changes to the provision regarding the responsibility to maintain adequate site conditions.

Paragraph (d) Pre-planning of Overhead Hoisting Operations

Paragraph 1926.752(d) requires that all hoisting operations in steel erection be pre-planned to ensure that they comply with the requirements of § 1926.753(d), the paragraph regulating "working under loads."

The purpose of final rule paragraph (d) (paragraph (c) of the proposed rule), is to address the hazards associated with overhead loads. Specifically, these hazards include failure of the lifting device, which would create a crushing hazard, and items falling from the load, which creates a struck-by and crushing hazard, among others. Given the nature of the loads used in steel erection, either of these events could result in serious injury or death.

After reviewing comments made on this paragraph (Exs. 13–170C, 13–210, 13–218, 13–263, and 13–334) OSHA recognized that the title of the proposed paragraph—"Overhead protection" was confusing in that it suggested that this paragraph dealt with the actual process of making lifts. In response to the comments, OSHA has changed the proposed title of paragraph (d) from "overhead protection" to "pre-planning of overhead hoisting operations" to reflect that § 1926.752(d) addresses requirements for the pre-planning of lifts and not the requirements for the actual hoisting and rigging of materials.

Commenters stated (Exs. 13–4, 13–7, 13–26, 13–63A, 13–180, 13–193, 13–215, and 13–334) that there are times when materials being lifted would be required to have a swing area that would cover areas where workers are present. In their view, this requirement would cause the controlling contractor to clear the whole site. This is not what the Committee intended nor is it what the provision requires. In addition, a similar requirement already exists in OSHA's crane and derrick standard. § 1926.550(a)(19) requires that "all employees shall be kept clear of loads about to be lifted and of suspended loads." The intent of final rule 1926.752(d) is to require employers to pre-plan lifts to facilitate compliance with the overhead load requirements. Through pre-planning, employers can adjust schedules and assignments to avoid worker exposure to overhead loads. For a more detailed discussion see preamble for § 1926.753(d)—working under loads.

Paragraph (e) Site-specific Erection Plan

Paragraph § 1926.752(e) sets out criteria for site-specific erection plans. The plans must be developed by a qualified person and be available at the worksite. The standard does not require such plans for all steel erection worksites; three specific provisions of this rule allow them as alternatives to specific provisions of the standard: One, is when an employer wishes to provide "equivalent protection", rather than deactivating or making safety latches on hoisting hooks inoperable (§ 1926.753(c)(5)). The second is when an employer provides an alternative erection method for setting certain steel joists detailed in § 1926.757(a)(4). The third is when an employer places decking bundles on steel joists and, under certain circumstances, must document in an erection plan that the structure can support the load (§ 1926.757(e)(4)(i)). This paragraph is unchanged from the proposal. OSHA has provided Appendix A as a guideline for establishing the components of a site-specific erection plan, as recommended by SENRAC. In the proposed rule, OSHA explained why it was not requiring the employer to establish a site-specific erection plan for every site (63 FR 43462). During initial discussions, SENRAC considered a requirement for every steel erection employer to develop a site-specific erection plan in writing for every project but decided that such a requirement would be unnecessarily paperwork-intensive, especially for small businesses. A site-specific erection plan will be easier to complete once the erector has developed a model plan. Some site-specific conditions that might lead an employer to rely on an alternative rather than the requirements specified in paragraphs § 1926.753(c)(5), § 1926.757(a)(4), and § 1926.757(e)(4)(i), and examples of possible alternative methods, are addressed in the discussion of these paragraphs later in this preamble.

Section 1926.753 Hoisting and Rigging

Rigging and hoisting of steel members and materials are essential activities in

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the steel erection process. This section sets safety requirements to address the hazards associated with these activities. In this final rule, new paragraphs (a) and (b) were added to clarify the application of the general crane requirements to subpart R. As indicated in the proposed introductory language, the new provisions recommended by SENRAC were designed to supplement rather than displace the requirements in § 1926.550.

Paragraph (a) of the final rule provides that all provisions of § 1926.550, the general construction requirements for cranes and derricks, apply to hoisting and rigging operations in steel erection except for § 1926.550(g)(2), the general requirements for crane or derrick suspended personnel platforms. Provisions for the use of suspended platforms in steel erection are in paragraph (c)(4) of this section.

Paragraph (b) provides that, in addition to the § 1926.550 provisions, the requirements in paragraphs (c) through (e) of this section apply as well. Final rule paragraphs (a) and (b) were added because hoisting safety is critical in steel erection operations and the § 1926.550 provisions are, in many respects, outdated.

Paragraph (c) General

Paragraph (c) contains the requirements for pre-shift inspections of cranes and rigging used in steel erection. This paragraph is redesignated from the proposal where it was paragraph (a).

Paragraph (c)(1) requires that a competent person must perform a pre-shift visual inspection of the cranes to be used for steel erection. The inspection must meet the requirements of § 1926.550 along with the supplemental requirements listed in paragraph (c) of this section. The SENRAC committee recognized that OSHA's crane standard incorporates ANSI B30.5–1968, Safety Code for Crawler, Locomotive, and Truck Cranes (Ex. 9–114), which does not reflect the most current safety requirements for modern cranes and the heavier loads they are now able to hoist. As a result, the updated crane requirements in ANSI B30.5–1994, Mobile and Locomotive Cranes standard (Ex. 9–113), are used as the principal basis for the supplemental provisions added in paragraph (c) of this section. SENRAC believed the additional inspection criteria were needed to ensure that safe equipment and procedures would be used to perform the specialized and potentially hazardous types of hoisting operations in steel erection. These include the use of cranes to hoist employees on personnel platforms (§ 1926.753(c)(4)); to suspend loads over certain employees (§ 1926.753(d)); and to perform multiple lifts (§ 1926.753(e)). In addition, SENRAC believed that a more frequent inspection is needed for cranes being used for steel erection. According to SENRAC, an inspection prior to each shift is needed to provide an added measure of protection for the specialized and potentially hazardous hoisting operations (63 FR 43462).

Section § 1926.550 requires pre-shift inspections by a competent person but does not spell out the detailed inspection requirements contained in the new § 1926.753. SENRAC determined and OSHA agrees that subpart R must address all issues relating to safety during steel erection. Hoisting operations are integral to steel erection and defects in hoisting equipment can harm steel erection workers in many ways. Therefore, it is necessary to include these requirements in this standard.

The complete visual inspection must be performed before each shift by a competent person. This person might be the operator or oiler of the hoisting equipment being used or, on a large project, the master mechanic who checks each crane. The pre-shift visual inspection must also include "observation for deficiencies during operation" and is anticipated to take between 10 and 20 minutes (63 FR 43462). At a minimum, the inspection must include the items listed in paragraphs (c)(1)(i)(A) through (L); namely, inspection of (A) all control mechanisms for maladjustment; (B) control and drive mechanisms for excessive wear of components and contamination by lubricants, water or other foreign matter; (C) safety devices, including, but not limited to, boom angle indicators, boom stops, boom kick-out devices, anti-two block devices, and load moment indicators where required; (D) air, hydraulic, and other pressure lines for deterioration or leakage, particularly those which flex in normal operation; (E) hooks and latches for deformation, chemical damage, cracks, or wear; (F) wire rope reeving for compliance with hoisting equipment manufacturer's specifications; (G) electrical apparatus for malfunctioning, signs of excessive deterioration, dirt, or moisture accumulation; (H) hydraulic system for proper fluid level; (I) tires for proper inflation and condition; (J) ground conditions around the hoisting equipment for proper support, including ground settling under and around outriggers, ground water accumulation or other similar conditions; (K) the hoisting equipment for level position and; (L) the hoisting equipment for level position after each move and setup during the shift.

Paragraph (c)(1)(ii) requires that if the inspection identifies a deficiency, the competent person must immediately determine whether the deficiency constitutes a hazard. The paragraph as proposed did not specify who was to make this determination. Because this type of determination requires the skills of a competent person and since the inspection is conducted by a competent person, the paragraph in the final rule explicitly states that a competent person must make the determination as to whether the deficiency constitutes a hazard. There were no comments about this paragraph.

Paragraph (c)(1)(iii) of the final rule requires that if a deficiency is determined to constitute a hazard, the hoisting equipment shall be removed from service until the deficiency is corrected. There were no objections to this paragraph.

The proposed rule contained a provision (proposed rule paragraph (a)(1)(iv)) that would have required a certification record of the pre-shift inspection of the hoisting equipment to indicate that the inspection has been completed. This certification would have included the date the hoisting equipment items were inspected, the signature of the inspector, and a serial number or other identifier for the hoisting equipment inspected. It is the Agency's policy to minimize paperwork burdens on employers. In light of the fact that the pre-shift inspection required in § 1926.550(a)(5) does not require a written certification, OSHA has omitted this requirement from the final rule.

Paragraph (c)(1)(iv) makes the operator responsible for operations under his/her direct control and gives the operator the authority to refuse any load that he/she deems unsafe. The Inpernational Union of Operating Engineers (Ex. 208X; p.55) believed it was necessary to clarify the operator's responsibilities during hoisting operations. OSHA agrees that the operator must have the authority to shut down unsafe operations of the crane. This requirement is the same as the parallel requirement in the ANSI B30.5–1968 standard for operating practices that are currently incorporated into 1926.550.

The most current ANSI standard, B30.5–1994, gives the authority to the supervisor. OSHA has adopted the approach in the previous ANSI standard because the crane operator is in a better position to make these assessments than the supervisor. This view was explained in a letter from a professional engineering firm to the secretary of the B30 committee (Ex. 9–133):

> Control of a heavy-lifting operation solely under the direction of a supervisor or any other person who may be less qualified than he, is not prudent. The crane operator has instrumentation in the crane to base his action upon, and should be the ultimate person to make decisions about the capacity and safety of both the machine and lifting operations.

Unlike a qualified crane operator, who has the training and experience to make informed decisions about handling a crane load, a supervisor may not have the qualifications and experience necessary for safe crane operation.

Paragraph (c)(2) requires a qualified rigger to inspect the rigging prior to each shift. Two commenters (Exs. 13–148 and 13–222) stated that there is a need for a definition of "qualified rigger" to clarify what specific qualifications are required for that status. One commenter (Ex. 13–149) indicated that the proposal is unclear as to who is responsible for ensuring that a rigger is qualified. This commenter also asserted that this provision would encourage unsafe acts by untrained people who want to cut time and costs. Another commenter (Ex. 202X; p.7) also noted that the qualifications of a rigger were not defined. According to this commenter, this is a significant issue because a lot of responsibility is placed on the qualified rigger in the standard.

OSHA is not adding a definition for a "qualified rigger." As discussed below, the Agency believes sufficient guidance exists on assessing whether a rigger is "qualified" under this standard.

A qualified rigger is defined as a "qualified person" who is performing the inspection of the rigging equipment. Based on the definition of a "qualified person", a qualified rigger must have demonstrated successfully the ability to solve or resolve rigging problems. Since there are no degree or certification programs for "riggers", they must have extensive experience to support this demonstration. The final rule requires the rigger to follow the requirements in § 1926.251, Rigging Equipment for Material Handling, which requires significant knowledge in the areas it specifies. It should be noted that a SENRAC member (Ex. 208X; p.69) testified that he is a member of an industry committee that will issue an industry standard defining the qualifications of a qualified rigger. OSHA believes that the industry will develop criteria in the near future.

Paragraph (c)(3) prohibits the use of the headache ball, hook or load to transport personnel except as provided in paragraph (c)(4) of this section. These practices are widely recognized as unsafe because of the risk of falling off the ball, hook or load (or, in a case where the load falls, falling with the load). No comments were received on this paragraph.

Paragraph (c)(4) states that employers engaged in steel erection work do not have to comply with the requirements of § 1926.550(g)(2)—Crane or Derrick Suspended Personnel Platforms if they hoist employees on a personnel platform. § 1926.550(g)(2) requires an employer to demonstrate that the use of conventional methods to access the work station "would be more hazardous or is not possible because of structural design or workday conditions" if the employer wants to hoist employees on a personnel platform. Final rule paragraph (c)(4) is slightly re-worded from the proposed rule for clarity. The preamble to the proposed rule explained why SENRAC believed that hoisting employees using personnel platforms is safer than climbing, why elevators cannot be used, and why hazards will be reduced by using these platforms (63 FR 43464). The work station during the steel erection process moves rapidly as pieces of structural steel are connected to each other and elevators and stairways usually cannot be installed until much of the structure has been completed. Exposure to fall hazards and the other hazards associated with erection and dismantling of scaffolds for extremely short term activities are eliminated by the use of a personnel platform.

Some commenters objected to the provision as proposed because they believe that it is feasible for steel erectors to use conventional methods of gaining access to the work station. AGC of Metropolitan Washington DC (Ex. 13–334) did not believe a blanket exemption from the personnel platform requirements for those who do steel erection work was a good idea. It was also noted by the a Department of Energy (Ex. 13–31) that relaxing the hoisting regulations for steel erection would create a double standard, since all other trades would not have the same exemption even though they often work side by side. DOE suggested that the paragraph be deleted.

The SENRAC committee believed that many steel erection activities, particularly those that are repetitive and of short duration, such as bolting-up, can be performed more safely, with greatly reduced exposure to fall hazards, when done from a personnel platform. This is largely due to the fact that the ironworker's workstations are high up, far apart, and change fairly rapidly. Use of the personnel platform would eliminate the numerous climbs up and down scaffolds, long ladders, etc. that would otherwise be required. OSHA has not relaxed the other requirements of the hoisting standard and only allows the use of personnel platforms as long as they comply with the crane standard. These requirements include performing the lift in a slow, cautious and controlled manner; holding pre-lift meetings; conducting trial lifts; requiring a safety factor of ten; and the use of engineering controls, such as anti-two blocking protection and controlled lowering capability. The rulemaking record does not indicate that the workstations of the other trades change as rapidly and span the same large distances as those of the ironworkers.

The term "notwithstanding" was removed from the proposed standard and the paragraph re-written for clarification of its intent.

Paragraph (c)(5) prohibits safety latches on hooks from being deactivated or made inoperable except when a qualified rigger has determined that the hoisting and placing of purlins and single joists can be performed more safely by doing so, or when equivalent protection is provided in a site specific erection plan.

SENRAC found that there are some activities in steel erection in which it is safer to hoist lighter members with a deactivated safety latch. One example is when deactivating the latch eliminates the need for a worker to climb up or onto an unstable structural member, such as a single bar joist, to unhook the member. The first part of paragraph (c)(5) requires all latched hooks to be latched in the absence of a determination by the qualified rigger that using the latch is unsafe. The second part of paragraph (c)(5) states that if the latch is deactivated without such a determination by a qualified rigger, the employer must have some form of equivalent protection in its site-specific erection plan.

Paragraph (d) Working Under Loads

Paragraph (d) (proposed rule paragraph (c)) requires routes for suspended loads to be pre-planned and prohibits employees from working under a hoisted load except for workers engaged in initial connection activities or employees who are necessary for unhooking the load. It also lists three specific requirements that must be met when these exceptions apply. The materials shall be rigged by a qualified

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rigger so that unintentional displacement is prevented. Also, hooks with self closing safety latches (or their equivalent) must be used to prevent components from slipping out of the hook. The requirements in paragraph (d) were patterned after the California Code of Regulations (Ex. 9–24D1), which regulates and limits exposure to overhead loads to occasional, unavoidable instances.

In the proposal preamble, OSHA noted that although overhead passes normally can be avoided, they cannot be entirely eliminated due to the complexity of modern construction, which requires that many activities take place concurrently. On many building sites, existing buildings, structures, streets, overhead lines and similar factors make it necessary to move loads over the same work areas throughout the course of the project. On some large projects, such as the construction of power plants, many hoisting operations take place simultaneously. In such situations, cranes must be located throughout the site to provide access to every part of the project. Scheduling the work to avoid moving loads over occupied work areas is not always feasible. Although paragraph (d) allows loads to be moved overhead, it requires the employer to limit such exposure.

The final rule allows workers doing initial connection work and those required to hook or unhook loads to work under the load because overhead exposure is generally unavoidable during these activities and while hooking and unhooking loads. This is similar to other OSHA rules that allow employees to work under loads in specific work situations where it has been sufficiently demonstrated that it is infeasible to accomplish the work otherwise. For example, § 1926.704(e) of the Concrete and Masonry standard provides, "no employee shall be permitted under precast concrete members being lifted or tilted into position except those employees required for the erection of those members." Section 1926.705(k)(1) of that standard allows some employees to work under suspended loads as well:

> No employees, except those essential to the jacking operation, shall be permitted in the building/structure while any jacking operation is taking place unless the building/structure has been reinforced sufficiently to ensure its integrity during erection.

An argument can be made in opposition to this paragraph that it appears to be in conflict with § 1926.550(a) of the crane standard, which explicitly prohibits employees from being exposed to suspended loads in section 1926.550(a)(19). However, the record has no data to indicate that the new rule will result in an increase in exposure to an overhead load, and OSHA is relying upon the expertise of SENRAC that the new rule will indeed lower that exposure.

As explained above, OSHA already has two exceptions to § 1926.550(a)(19) in place, which allow employees to work under loads. The final rule provides as much protection as is feasible by limiting the steel erection exception to two groups of employees who are occasionally exposed to a suspended load and specifying steps that must be followed when they are exposed to overhead loads.

In the original proposal, SENRAC recommended that OSHA eliminate the requirement to have tag lines on loads because they believed the swinging lines presented a hazard to the connectors by being in the way. They contended that these lines could knock a connector off balance if left swinging freely. OSHA agreed but the final rule continues to allow for the use of tag lines where need be to control a load.

Paragraph (e) Multiple Lift Rigging Procedure

The procedure, known as "Christmas Treeing," "multiple lifting," or "tandem loading," is not explicitly addressed in OSHA's current steel erection standard. A specific procedure for multiple lift rigging was prescribed in the proposed rule and such a procedure is included in the final rule. SENRAC believes this procedure, when executed as prescribed in this paragraph, is a safe and effective method for decreasing the number of total crane swings and employee exposure on the steel while connecting. In the past, OSHA has not looked favorably upon "Christmas Treeing" because, when performed incorrectly, it can present significant hazards to workers. SENRAC committee members and other interested parties demonstrated that there is a safe way of performing christmas treeing. Multiple lifting can be done safely in steel erection work if it is executed in compliance with the method prescribed in the proposed standard (Ex. 208X; p. 51). Based on the record of this rulemaking, OSHA defers to the expertise of SENRAC on this particular practice.

Paragraph (e) of the final rule applies when a steel erector chooses to lift multiple pieces of steel at one time as an alternative to hoisting individual structural members. It limits the use of this procedure to the lifting of beams and similar structural members and requires specific equipment and work practices to be used. SENRAC (Ex. 208X; p. 51) believes that Christmas treeing is already an industry practice and that the requirements of this standard will make it safer to execute.

Some commenters (Exs. 13–60 and 13–182) assert that this is not an accepted practice throughout the industry and do not agree that this is a safe practice, even with the proposal's requirements. The record does not substantiate the view that it is an unsafe practice when the specified procedures are followed. As mentioned above, the record lacks statistics on the injury and fatality rate associated with Christmas treeing. One reason for the lack of reliable statistics pertaining to Christmas treeing activities is that it is often difficult to identify the exact cause of an accident during this activity. For example, the fact that a person fell or was struck by an object during Christmas treeing activities does not mean that it was caused by Christmas treeing itself.

The record contains evidence that there are several advantages to performing multiple lifts, especially (as demonstrated by SENRAC members) when performed using the procedures specified by this paragraph (Ex 208X; p. 44) (63 FR 43465). For example, multiple lifting can be safer than individual lifting when connecting floor beams. Floor beams are relatively light and in most cases will not safely support a bundle of steel placed upon them. The normal erection procedure requires them to be stacked on the ground and delivered to the bay one by one. The multiple lifting technique allows multiple beams to be brought to a bay in one swing of the crane. They are uniform in weight and size, which makes a multiple load a lot easier to balance and handle. Multiple lifting significantly decreases the number of times that employees who are not involved in the connection process are exposed to overhead loads. It also reduces the time a connector has to spend out on the iron because the whole process is quicker.

Bill Brown of Ben Hur Construction testified that "Christmas treeing and your stringing iron, we find to be in our operation to be a very safe, effective, and economical way of erecting generally repetitive members in building construction." (Ex. 205X; p. 8)

After discussing how MLRPs can reduce the number of lifts by 80%, Mr. Brown discussed the impact of this factor on his crane operators:

> Well, the operators claim that once you get them set up in the right way to do this, it's a lot easier on them.

> Like I said because if they are in a boom-up swing in swing mode, that's when steel erection seems to be the most fatiguing and the most intense work for the operators, except for putting a piece in the guy's hands who's going to make the connection.
>
> Our operators say that by doing this and having repetition of less cycles, it's a lot more less—or it's less stressful and fatiguing * * * (Ex. 205X; p. 35)

In addition, Mr. Philip Torchio of Williams Enterprises testified that "Multiple lift rigging procedure will improve ironworker safety as well as reducing exposure of other job site crafts through increased training, inspections, improved equipment design and selection coupled with reduced lift cycles and reduced total worker exposure time" (Ex. 208X; p. 44). Mr. Torchio went on to state that "* * * utilizing multiple lift procedure reduces total worker exposure time, increases worker training and mental focus. It increases equipment reliability both for crane and rigging. It requires safer crane operation and reduces total job duration. All these items contribute to increased worker safety" (Ex. 208X; pp. 45–46).

OSHA has acknowledged the potential advantages of multiple lifting in interpretation letters such as the one dated September 9, 1993, from the Director of the Office of Construction and Engineering to the Regional Administrator of OSHA Region I which read:

> Christmas treeing could indeed be productive and efficient on projects when erecting floor or roof filler beams, all of the same length and weight with similar details at each end of the beams. In large industrial projects where the location of the crane is much farther away from the bay under erection, Christmas treeing could also prove to be efficient. Further, the practice reduces the total number of swings the crane makes in each project, thus reducing the risk of exposing the workers located in the vicinity of the crane or in the path of travel of the load (Ex. 9–13G; p. 2).

The different parts of paragraph (e) address six aspects of the MLRP process: lifting criteria (paragraph (e)(1)); design, capacity of equipment (paragraph (e)(2)), load limits (paragraph (e)(3)); rigging assembly (paragraph (e)(4)); setting the members (paragraph (e)(5)); and use of controlled load lowering (paragraph (e)(6)).

The first lifting criterion in paragraph (e)(1)(i) requires that a multiple lift rigging assembly (defined in the definition section) be used. By definition, the assembly must have been manufactured by a wire rope rigging supplier. Since this is a specialized type of lift, the rigging assembly must have been designed specifically for the particular use in a multiple lift and meet each aspect of the definition.

Paragraph (e)(1)(ii) of this section states that a multiple lift may not involve hoisting more than five members during the lift. Limiting the number of members hoisted is essential to safety. SENRAC determined that five members is the maximum number that can be hoisted safely. This limit takes into account the need to control both the load and the empty rigging. It also accounts for the fact that a typical bay, which consists of up to five members, can be filled with a single lift. Too many members in a lift may create a string that is too awkward to control or allow too much empty rigging to dangle loose, creating a hazard to employees.

Paragraph (e)(1)(iii) allows only beams and similar structural members (like solid web beams and certain open web steel joists) to be lifted during a multiple lift. Other items, such as bundles of decking, meet the definition of structural members but do not lend themselves to the MLRP. A typical multiple lift member would be a wide flange beam section between 10 and 30 feet long, typically weighing less than 1,800 pounds.

Paragraph (e)(1)(iv) requires that employees engaged in a multiple lift operation must be trained in these procedures in accordance with 1926.761 (c)(1), which contains specific training requirements for employees engaged in multiple lifts. Due to the specialized nature of multiple lifts and the knowledge necessary to perform them safely, this training requirement is necessary to ensure that employees are properly trained in all aspects of multiple lift procedures.

Paragraph (e)(1)(v) prohibits the use of a crane in a multiple lift if the crane manufacturer recommends that the crane not be used for that purpose. This new provision is included for clarification purposes. Crane manufacturers often recommend that employers do not execute multiple lifting with their cranes. It has been argued that there are too many variables associated with attempting Christmas treeing and any miscalculations of those component variables (such as the weights and center of gravity of the beams, crane capacity, the stability of the load under lift conditions, and inconsistent rigging techniques) could contribute to an accident. A commenter (Ex. 13–182) noted that if crane manufacturers prohibit the practice, paragraph (e), as proposed, would allow the erector to violate 1926.550(a) of the crane standard, which requires the employer to comply with the manufacturer's specifications and limitations applicable to the operation of any and all cranes and derricks.

OSHA remains consistent in requiring employers to follow the manufacturer's recommendations and specifications for its product. If the manufacturer of a crane prohibits the use of its crane in multiple lifts and an employer uses that crane to perform a multiple lift, that employer is in violation of both § 1926.550(a) and § 1926.760(e)(1)(v) which states:

> No crane is permitted to be used for a multiple lift where such use is contrary to the manufacturer's instructions.

Paragraph (e)(2) requires that employers that perform multiple lifts use multiple lift rigging assembly components assembled and designed for a specified capacity. The employer must ensure that each multiple lift rigging assembly is designed and assembled with a maximum capacity for both the total assembly and for each individual attachment point. This capacity, which must be certified by the manufacturer or qualified rigger, must be based on the manufacturer's specifications and must have a 5 to 1 safety factor for all components. The rigging must be certified by the qualified rigger who assembles it or the manufacturer who provides the entire assembly to ensure that the assembly can support the whole load, and that each hook is capable of supporting the individual members. The appropriate rigging assembly to be used is the lightest one that will support the load. Typically, one assembly is manufactured and certified for the heaviest anticipated multiple lift on the job, and this rigging is then used for all the MLRPs.

To ensure that a MLRP does not overload the hoisting equipment, the Committee recommended prohibiting the total load of the MLRP from exceeding either the rated capacity of the hoisting equipment as specified in the hoisting equipment load charts, or the rated capacity of the rigging as specified in the rigging rating chart. Several crane manufacturers have recognized that MLRP is becoming an industry practice and have accepted the use of their cranes for this purpose, provided that the crane is utilized in a manner consistent with the safe practices defined in the operator's manual and crane capacity chart (Ex. 9–30). Paragraph (e)(3) reflects these provisions.

Another commenter (Ex. 13–60) felt that multiple lifting is unsafe because forces such as rigging torques and the wind tend to make the beams helicopter, increasing the chances of the steel coming out of the choker hitch.

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The commenter also felt that the only justification for taking such risks is to benefit production.

SENRAC (Ex. 208X; p. 44), however, found that these conditions can be either eliminated through engineering or controlled with proper training of the employees engaged in the lift.

Several members of SENRAC stated in full committee that the use of an MLRP reduces total employee exposure to suspended load hazards as well as to the hazards associated with crane-supported loads traveling horizontally. An MLRP is treated as an engineered lift and therefore receives the full attention of the entire raising gang. The lifts are made in a more controlled fashion due to the special rigging and physical size of the assembled load. In addition, cranes used for multiple lifts must have controlled load lowering devices.

A Committee workgroup was formed (Ex. 208X; pp. 42–60) to develop the MLRP section of the proposed regulatory text. This workgroup noted several additional benefits of MLRPs. For example, the increased weight of the load hoisted using an MLRP results in reduced swing, boom, and hoist speeds, which increases the amount of control the operator has over the lift. The workgroup also stated that crane operators report that the swing operation has the greatest potential for operator error and loss of load control, and therefore reducing the number of swings enhances safety. The workgroup believed that the reduced number and speed of swing operations associated with MLRPs would increase safety, and that lift precision would also be increased because MLRPs require that controlled load lowering devices be used on cranes making such lifts. According to the workgroup (63 FR 43466), when the operator is working in the blind (where the connectors cannot be seen), reducing the number of swing cycles is particularly important because it minimizes the opportunity for a communication error, which could cause an accident. Furthermore, the workgroup stated that the total suspended load time and the frequency of loads passing overhead are reduced for all non-erection personnel on the job when an MLRP is being performed. This was considered particularly important, because these workers normally are occupied with other tasks and often do not pay attention to suspended loads that may be passing overhead. This group of employees includes those working under canopies and partially completed floor systems who cannot see hoisted material passing overhead but could be injured if a load were dropped.

In addition, when single pieces of steel are hoisted, the emphasis is often on speed. The load is often hoisted, swung and boomed at maximum crane speed in an effort to maximize production. Under these circumstances, the Committee felt that single piece hoisting increases the potential for problems in the hoist sequence and in the final placement of each member and additionally contributes to operator fatigue.

According to the workgroup (63 FR 43466), a major safety benefit of multiple lifting is that the manipulation of the members at the point of connection limits the movement of the hoist hook, in most cases, to an area less than 10 feet in diameter and additionally requires that such movement be done at a slow speed and with maximum control. The hazard that connectors consider the most serious, that of a high speed incoming beam, is thus minimized using the MLRP process.

Paragraph (e)(4) requires that the multiple lift rigging assembly be rigged with the members attached at their center of gravity and be kept reasonably level, be rigged from the top down, and have a distance of at least 7 feet (2.1 m) between the members. In practice, these procedures mean that the choker attached to the last structural member of the group to be connected is the one attached on the rigging assembly closest to the headache ball. The next-to-last member to be connected is attached to the next lower hook on the rigging assembly, and so on. As each member is attached, it is lifted approximately two feet off the ground to verify the location of the center of gravity and to allow the choker to be checked for proper connection. Adjustments to choker location are made during this trial lift procedure. The choker length is then selected to ensure that the vertical distance between the bottom flange of the higher beam and the top flange of the next lower beam is never less than 7 feet. Thus, when the connector has made the initial end connections of the lower beam and moves to the center of each beam to remove the choker, there will be sufficient clearance to prevent the connector from contacting the upper suspended beam. Furthermore, although the OSHA letter referred to earlier (Ex. 9–13G) suggested that the beam spacing could be eight or nine feet, the Committee determined, and OSHA agrees, that seven feet is more appropriate since, in addition to the necessary clearance just mentioned, a typical connector could easily reach up and grab the member at seven feet but might have some trouble doing so if the spacing were greater.

Paragraph (e)(5) requires that the members be set from the bottom up. This is the only practical way that the members can be set, and OSHA is including this requirement for clarity and completeness.

Paragraph (e)(6) requires controlled load lowering (through the use of a controlled load lowering device) to be used whenever the load is over the connectors. This means that the cranes in a multiple lift must use controlled load lowering when lowering loads into position for the connectors to set the members. The record shows that control load lowering is essential to prevent accidents that could result from the crane operator's foot slipping off the brake, brake failure, or from the load slipping through the brake. It assures that the operator has maximum control over the load. Compliance with his requirement would have prevented the July 20, 1990, fatality in Austin, Texas, referred to in Ex. 9–13G (p. 4).

A commenter (Ex. 13–340) advocated limiting MLRP required training to those involved in the MLRP and specifying levels of training that these individuals must achieve. The commenter apparently believes the word "all" in section 1926.753(e)(iv) means all steel erection employees on the site. The standard states:

> All employees engaged in the multiple lift have been trained in these procedures in accordance with section 1926.761(c)(1).

The standard requires that only the employees engaged in the multiple lift have to be trained in the requirements of this paragraph in accordance with § 1926.761(c)(1), not all employees affected by the lift as the comment seems to indicate.

Section 1926.754 Structural steel assembly

This section sets forth the requirements for the assembly of structural steel. Paragraph (a) requires that the structural stability be maintained at all times during the erection process. This is a general requirement for any type of steel structure, including single story, multi-story and other structures. Since structural stability is essential to the successful erection of steel structures, this section is intended to prevent collapse due to lack of stability, a major cause of fatalities in this industry. The Agency received no comments on paragraph (a) and it is unchanged from the proposed rule. Additional requirements that specifically apply to multi-story structures are provided in paragraph (b) of this section.

Paragraph (b)(1) requires that permanent floors be installed as the erection of structural members progresses and that there be not more than eight stories between the erection floor and the upper-most permanent floor, except where the structural integrity is maintained as a result of the design. This paragraph is identical to both the proposed rule and the existing § 1926.750(a)(1) in OSHA's previous steel erection standard.

Paragraph (b)(2) prohibits having more than four floors or 48 feet (14.6 m), whichever is less, of unfinished bolting or welding above the foundation or uppermost permanently secured floor, except where the structural integrity is maintained as a result of the design. This paragraph is the same as proposed and essentially the same as existing § 1926.750(a)(2), except for the addition pertaining to situations where structural integrity is maintained as a result of the design. The Committee recommended an exception similar to that in paragraph (b)(1) to allow for flexibility in design, and this recommendation is reflected in the final rule.

Paragraph (b)(3) requires that a fully planked or decked floor or nets be maintained within 2 stories or 30 feet (9.1 m), whichever is less, directly under any erection work being performed. This is essentially the same provision as existing § 1926.750(b)(2)(i), except for the option of installing nets in addition to the planked or decked floor options. This provision serves many purposes: limits falls of employees to 30 feet, provides falling object protection, and can be used as a staging area for emergency rescue. Paragraph (b) thus retains many of the requirements of OSHA's existing steel erection rule. No comments were received and paragraph (b) is promulgated as proposed.

Paragraph (c) of the final rule sets forth requirements that address slipping/tripping hazards encountered when working on steel structures. SENRAC pointed out that the tripping hazards posed by shear connectors (a type of attachment) on working surfaces need to be addressed in the revision of subpart R. Shear connectors are commonly found in bridges and in other types of steel structures. As explained in the preamble to the proposed rule, the Committee found that when attachments, like shear connectors, are shop-welded to the top flange of beams, the resulting projections can create a significant tripping hazard. Field installation of these attachments can significantly reduce exposure to this hazard. It is much safer to walk on a beam that is not studded with these shear connectors or otherwise covered with a temporary working surface. It also found that this would increase the productivity of employees who walk on the top flange of the structural steel because they can walk less hesitantly. Shear connectors are addressed in paragraph (c)(1) of the final rule.

Paragraph (c)(1)(i) prohibits the attachment of shear connectors (such as headed steel studs, steel bars or steel lugs), reinforcing bars, deformed anchors or threaded studs to the top flanges of beams, joists or beam attachments so that they project vertically from or horizontally across the top flange of the member until after the decking, or other walking/working surface, has been installed. Additionally, paragraph (c)(1)(ii) requires that when shear connectors are used in the construction of composite floor, roofs and bridge decks, the laying out and installation of the shear connectors shall be done after the decking has been installed, using the deck as a working platform. This paragraph also prohibits the installation of shear connectors from within a controlled decking zone (CDZ), as specified in § 1926.760(c)(8).

Many comments were received in response to the proposed paragraph (c)(1). Those opposed to the proposal shared several concerns: technical problems with field welding caused by outdoor atmospheric conditions, increased exposure to fall hazards, back injuries from field-installation of the connectors, an increased risk of falling objects, and additional costs with field installation. A wide variety of components are commonly welded in the field (such as the K, LH and DLH series steel joists addressed in § 1926.757(b), discussed below). Most of the steel beams/girders available on the market can be field welded. Preheating of steel flanges is generally not required for either shop or field installation. In addition, some commenters indicated that there are companies that already routinely field-weld shear connectors (Exs. 202X; p. 29, 44, 87; 205X; p. 359). While one commenter described extra steps that are needed for field-welding (Ex. 201X; p. 45), another commenter found that productivity was higher for field-installation (Ex. 208X; p. 166). The record does not show that atmospheric conditions or other technical obstacles pose any greater difficulties for welding shear connectors in the field than for welding other components, or that welding them in the field presents significant technical obstacles.

The claim that field-installation of shear connectors will increase the likelihood of falls (Exs. 13–176; 13–180; 13–210) is based on the assumption that workers installing shear connectors will have greater exposure to fall hazards. The provisions of this standard, however, will protect these workers. For example, § 1926.754(c)(i) prohibits the installation of the connectors until the metal decking (or other walking/working surface) has been installed. Once the decking has been installed, under § 1926.760(a)(2), perimeter safety cables must be installed. Therefore, those installing the shear connectors will have a safe walking/working surface to work from, and will be protected from the exterior fall hazard by the perimeter safety cable. Furthermore, SENRAC, as well as several commenters (Exs. 202X; p. 29, 44, 87; 203X; p. 185; 205X; pp. 166, 359), were of the view that field installation is safer then factory installation. The concern about an increased risk of back injuries has not been substantiated. In addition, the provision is designed to address the greater problem of fatal falls, which can occur if a worker trips on a shear connector.

While field-installation of shear connectors will increase the number of objects and tools aloft, and thus increase the potential for falling objects, the requirements in § 1926.759 are designed to protect against that type of risk in this and other contexts.

There were also objections raised on the grounds that compliance with paragraph (c)(1) may not always be possible in bridge construction (Exs. 13–113; 13–170G; 13–210). Specifically, a commenter stated that, in bridge construction, "installation of shear connectors from a deck may not always be possible." It appears that these commenters are asserting that, in bridge construction, there may be instances where compliance with some or all of the provisions is not feasible. Because the extent and types of circumstances where this would be the case are not well defined, the Agency believes that it would be inappropriate to provide an exception for bridge work. Nor does the record clearly indicate that paragraph (c)(1) would not be feasible for bridge construction. An employer may raise these problems as an affirmative defense in individual situations.

In sum, the record shows that the use of shop installed shear connectors poses a significant safety hazard, and that the use of field-installed connectors is a feasible means of reducing that hazard. Shop-welded shear connectors result in projections on top flanges of beams/

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girders that create a tripping hazard to the workers engaged in steel erection. The record supports the contention that it is safer to install the shear connectors after the decking has been installed, so that the deck can be used more safely as a working platform. Using the deck as a work platform, combined with the presence of perimeter safety cables, effectively eliminates the fall hazards associated with field installation of shear connectors. The record does not show that there are significant technical or other obstacles to field-installation. Accordingly, the provision is promulgated as proposed with only minor wording changes.

Final rule paragraph (c)(2) "slip resistance of metal decking" is reserved. OSHA is reserving paragraph (c)(2) to allow additional time to study the slippery surface aspects of metal decking and identify appropriate rules to reduce the risk factor from those conditions. A coalition of steel-producing and steel-related organizations (the Steel Coalition) continues to gather data and prepare recommendations to a SENRAC workgroup on slippery surfaces with respect to paragraph (c)(2). The Steel Coalition intends to identify the principal factors contributing to slip and fall injuries resulting from slippery metal decking, and devise feasible and effective approaches to reduce those risks (Ex. 9–151). Once SENRAC reviews this information and makes recommendations, the Agency will determine what actions will be taken in this area.

Paragraph (c)(3) will reduce the risk of steel erection workers slipping on coated steel members installed three years after the effective date of this standard. At that time, it will prohibit employees from walking on the top surface of any structural steel member that has been coated with paint or similar material, unless the coating has achieved a minimum average slip-resistance of 0.50 when wet on an English XL tribometer, or the equivalent measurement on another device. This paragraph does not require that the particular coated member be tested. Rather, it requires the test to be done on a sample of the paint formulation produced by the paint manufacturer. The testing laboratory must use an acceptable ASTM method and an English XL tribometer or equivalent tester must be used on a wetted surface and the laboratory must be capable of employing this method. The test results must be available at the site and to the steel erector. Appendix B lists two appropriate ASTM standard test methods that may be used to comply with the paragraph. If other ASTM methods are approved, they too are allowed under this provision.

The final paragraph differs from the proposal in two significant respects. Proposed paragraph (c)(3) would have prohibited employees from walking on the top surface of any structural steel member with a finish coat that decreased the coefficient of friction (CoF) from that of the uncoated steel. The final text sets a specific slip-resistance for the coated surface, when tested wet. In addition, proposed paragraph (c)(3) stated that the paragraph applied to coated steel installed at the effective date of the standard, rather than, as in the final, three years later.

The Hazard

Based on SENRAC's discussions, and the rulemaking record, OSHA finds that working on steel surfaces coated with paint or other protective coatings presents slip and fall hazards to employees and that this standard must reduce this hazard using feasible means. SENRAC described the hazards as the use of paint or coatings on steel for structures exposed to highly corrosive materials (such as those used in mills and chemical plants) or exposed to varying weather conditions (such as stadiums). In the proposal, OSHA set out SENRAC's concerns as follows:

> The Committee found that a major cause of falls in the steel erection industry is the presence of slippery walking, working and climbing surfaces in steel erection operations when fall protection is not used. The problem initially arises from the application of protective coatings on structural steel used, for example in the construction of mills, chemical plants and other structures exposed to highly corrosive materials as well as in the construction of stadiums or other structures exposed to varying weather conditions. It is usually impractical to leave the steel uncoated and then to paint the entire structure in the field after erection. Unfortunately, steel coated with paints or protective coatings can be extremely slippery. When there is moisture, snow, or ice on coated steel, the hazard is increased * * * (63 FR 43467).

As discussed below regarding § 1926.760, accident data in this record demonstrate that falls from elevations of 30 feet or less resulted in many ironworker injuries and fatalities. In addition, the Agency recognizes that slips on the same level also lead to many injuries. We believe that provisions to reduce the slip potential of surfaces walked on by steel erection workers are clearly needed. OSHA and SENRAC examined the factors involved in slippery surfaces and determined that the most effective and feasible approach is to increase slip resistance and allow employees to walk on only those coated surfaces which meet a threshold for acceptable slip resistance. Much of the discussion in this rulemaking involves issues regarding which slip-resistant threshold to set; whether it is feasible to measure it; and whether compliance with such a provision is technically and economially feasible.

Commenters affirmed the existence of a serious hazard from coated surfaces; many asserted that slick or slippery paint is very dangerous (Exs. 13–49, 13–66, 13–95, 13–345, 13–348, and 13–355B). Most of these commenters (Ex.13–66 and a group of 124 ironworkers in Ex. 13–355B) added that slippery paint is the worst condition they run into on structural steel, and they asked that the paint be made safe. Other ironworkers (Ex. 13–355B) asserted that epoxy paint was hazardous to erectors. All together, 230 of these ironworkers commented in support of a provision to make painted steel less slippery. A comment from a structural steel fabricator (Ex. 13–228) stated that they agreed that "painted [steel], moist or wet, is slipperier."

In contrast to the comments asserting that coated surfaces present a slipping hazard, a comment from an engineer for a state government agency (Ex. 13–359) stated that slippery surfaces were attributable to a variety of causes, such as weather conditions, which can reduce traction on coated or uncoated surfaces (Ex. 13–359). He added that there was no basis for the requirements that addressed a CoF in subpart R "since there are no accepted methods for determining friction at the job site and tests would not be relevant to site conditions." In addition, the American Iron and Steel Institute Steel Coalition submitted a consultant's report asserting that it is not really necessary to know a CoF in evaluating pedestrian traction, and that it is important to rate the traction under various relevant conditions (Ex. 13–307A, pp. 24–25).

In response to the first concern that slippery surfaces are attributable to a variety of causes, OSHA points out that requiring less slippery coatings in no way suggests that employers should ignore other unsafe conditions. The general construction standard for training § 1926.21 requires employers to "instruct each employee in the recognition and avoidance of unsafe conditions * * *" This includes slipping hazards due to factors such as moisture from weather conditions and unsafe footwear. OSHA agrees however, with its expert witnesses, William English, David Underwood and Keith Vidal, who stated in their report, that

"contaminants" (including rain water, condensation and ice) and shoe bottom construction are important factors, but are not as easily controlled as surface coatings (Ex. 17, p. 2). Also, the rule will require wet testing, thus accounting for most weather-related slip hazards.

In response to the second concern that it is not really necessary to know a CoF in evaluating traction, the final rule text does not set a required CoF—the 0.50 measurement is a slip resistance measurement for the walking surface. While related to CoF (a ratio of forces), the 0.50 referred to in the final rule is a measurement on a tester that is designed to mimic (to some extent) the dynamic forces involved in walking on a surface. While different types of shoe material (and different amounts of wear) affect the amount of traction experienced by the worker, the record shows that it is not feasible to establish a requirement that would account for all the factors that relate to the CoF. Nor would it be feasible to measure slip resistance at the site under the numerous and ever-changing "relevant conditions." The English reports and testimony of English, Underwood and Vidal (as discussed below) shows that setting a requirement for the walking surface (when wet) will improve traction.

A commenter suggested that OSHA focus on ironworkers' footwear rather than specifying a slip resistance for the paint (Ex. 13–307A, pp. 2–5). The Agency finds that this type of approach would not work as a substitute for addressing the slip resistance of the paint because ironworkers' footwear typically become contaminated with mud, gravel, and other substances that would alter the slip resistance characteristics of the sole material (Exs. 203X, p. 213 and 204X, p. 292).

Other commenters recommended that only uncoated surfaces be allowed to be erected (Exs. 13–41, 13–138 through 13–142, 13–234, and 13–341). The record does not demonstrate that uncoated steel is necessary for employee safety since surface coatings can provide equivalent or greater protection against falls. Also, SJI identified several significant problems with requiring the steel to be uncoated when erected. Among these would be increased costs associated with painting the steel in the field after it was erected, which it estimated would amount to $450 to $800 million, and a slowing of the construction process by two to four weeks (Ex. 204X; p.17).

Use of the Term "Finish Coat"

The final rule specifies the acceptable slip resistance of structural steel "coated with paint or similar material," whereas the proposal limited the provision to steel which had been "finish-coated". This change clarifies that the provision applies to the surface of the coated structural steel when the steel is erected. OSHA believes that the rulemaking record demonstrates that the hazard posed by slippery coated steel is present irrespective of whether the coat is part of a multi-coat system. In addition, we note that both the English I study (Ex. 9–64) commissioned by SENRAC and the English II study (Ex. 17) commissioned by OSHA, which tested slippery coated surfaces, evaluated coatings that were not necessarily "finish" coats. According to Paul Guevin, an OSHA expert witness, the English II study looked at three types of slip-resistant primers: Alkyd paints without additives; zinc-rich primers, and alkyds or other resin-based primers with polyolefin (Ex. 18, p. 2). The modification to "coating" also responds to concerns that it would be difficult to determine which paints are "finish" coats. Thus, the reworded provision now clearly applies to steel members coated with standard shop primers where the shop primer is the uppermost coat when the steel is erected.

A number of commenters asked OSHA to clarify and/or define the term "finish coat" (Exs. 13–182, 13–209, 13–228, 13–363, and 13–367). One of these commenters (Ex. 13–182) opined that finish-coated means painting after erection, which they indicated was done in many situations. A fabricator (Ex. 13–228) commented that a finish coat is the final coat of a multi-coat paint system, whether it was applied in the shop or the field is immaterial. Another commenter (Ex. 13–367, p. 16) noted that "it is frequently not possible to determine if an applied coating is a single coat or a multi-coat system". The American Institute of Steel Construction (AISC) speculated (Ex. 13–209, pp. 31–32) that SENRAC's use of "finish-coat" was an attempt to address certain epoxies and polyurethanes, which are typically the second and third coats found in multi-coat paint systems, but that "[t]he scope of the proposed rule could be twisted to apply to all paints, not merely that small segment of the market that may present a problem." OSHA disagrees with this characterization of the provision's intended application. By deleting the term "finish coat," OSHA clarifies that the provision applies to coated steel on which employees must walk, regardless of whether the coating will remain the last coat of paint after the steel erection is over, and regardless of the chemical composition of the coating.

Benchmark Slip-Resistance Criterion

The final standard requires that coated steel must score at a minimum average slip resistance of 0.50 as measured on an English XL tribometer or equivalent reading on another tester. Proposed § 1926.754(c)(3) would have required that the structural steel surface be no more slippery than bare, uncoated steel. OSHA stated in the proposal that SENRAC, after reviewing various industry presentations, "concluded that it could not determine a minimum value for slip-resistance or CoF, given all the variables to be considered, nor could it agree on an acceptable testing method" (63 FR 43468).

After reviewing the entire record, OSHA has determined that it is necessary to set a specific slip-resistance value for coated steel. No other regulatory approach to reducing the risk of slipping is as appropriate. The record supports using the English XL value of 0.50 (or the equivalent) as the cutoff for acceptable coated steel surfaces on which employees may walk. The record demonstrates that acceptable testing methods will be available when the provision goes into effect.

The English II report noted that a level of 0.50 was reasonably safe and has been recognized for many years:

> The non-controversial 0.50 threshold of safety that has been recognized in the safety engineering literature and case law for 50 years would provide a vast enhancement of footwear traction that would produce a significant improvement in the safety of ironworkers working at high elevations. (Ex. 17, p.12)

In post-hearing comments (Ex. 64), Mr. Guevin explained that when the Federal Trade Commission published a proposed rule for floor polishes in 1953 it determined a minimum of 0.50 when measured on a James machine to be a safe value (Ex. 64, pp.3–4). In his testimony at the hearing (Ex. 200X; p.120), Dr. Underwood added that he understood that 0.50 came from rounding up a CoF of 0.35 to give a small margin of safety for walking slowly in a normal way. He indicated that the CoF of 0.35 came from determining a ratio of an average hip height of 3 feet (0.91m) and a common distance of 2 feet (0.61m) per step taken in a normal stride.

The English II study indicates that the recommendation of 0.50 on the English XL scale was based on the previously established benchmark of 0.50 CoF (Ex. 17, p.12). We find that the information and testimony from the rulemaking record show that 0.50 on the English XL

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scale is an appropriate minimum value to designate slip-resistant surfaces when measured under wet conditions using the ASTM methods referenced in Appendix B to this subpart.

As noted above, OSHA is changing the proposed benchmark for acceptable slip-resistance, from bare steel, to a specific slip resistance value for the coated steel. Thus, there is no need for employers, paint companies or fabricators to measure the slip resistance of bare steel for purposes of complying with this standard. Some participants objected to using the slip-resistance of bare steel as the benchmark. OSHA believes that the revised provision addresses these concerns. A comment from a builder's association (Ex. 13–121) stated that "it is next to impossible to provide CoF equal to original steel after coating it." The Steel Coalition wrote that the proposal's reference to a test for a comparative coefficient of friction in § 1926.754(c)(3) would not be practical or meaningful, and that coatings with a high slip-resistance score would be considered unacceptable when compared to original steel with a higher score (Ex. 13–307, pp. 35–36). The American Institute of Steel Construction (AISC) (Ex. 13–209, p. 36) stated that "[t]he benchmark of bare steel is ambiguous." AISC explained that using bare, uncoated steel as a benchmark was problematic because it was impossible to find a single uniform steel surface with which to make comparisons—"there is no such thing as a uniform piece of bare steel" (*Ibid*, p. 30). The AISC also objected on the grounds that each piece of steel would have to be tested, before and after it was coated (*Ibid*, p. 30).

The Society for Protective Coatings (SSPC) (Ex. 13–367, p 16) stated that "* * * data from the English study [English I study] shows that a pristine millscale steel surface received one of the poorest ratings by ironworkers and by the English machine. Therefore, it is extremely risky to make an assumption about slip resistance based on whether the steel is coated or uncoated."

During the hearing, Mr. English testified that he did not support the benchmark of original or bare steel:

> First of all, * * * pristine bare steel is pretty rare. Secondly, * * * the baseline would be variable. Thirdly, we find that pristine bare steel, it's slippery * * * And as a practical matter, it rarely occurs as a problem at erection sites (Ex. 200X; pp.115, 128–129).

Some comments supported using bare steel as the benchmark of acceptable slip-resistance. Journeymen ironworkers (54 individuals, Ex.13–207C) signed statements saying that they backed limiting coatings to the equivalent of bare steel. However they did not provide information concerning the feasibility or adequacy of relying on "bare steel'.

In sum, the record supports OSHA's decision that bare steel is not an appropriate benchmark. We agree with the commenters who stated that there is considerable variability in bare steel surfaces due to both manufacturing specifications and extent of oxidation, that variability would also pose substantial problems in implementing the requirement, and that some bare steel is unacceptably slippery.

Test Methods

The final rule requires that beginning three years after the effective date of the rest of the standard, employees may not walk on coated steel unless the coating has been tested and found to meet the threshold 0.50 using an appropriate ASTM test method. Appendix B specifies two methods now approved by ASTM. The record shows that these methods are sufficiently accurate and yield sufficiently reproducible results for use in testing coatings to determine their compliance with the specified 0.50 measurement.

Evidence in the record shows that testing using the VIT (English XL) according to ASTM F1679–96 will provide reproducible and accurate results of the slip-resistance of coated steel: the authors of the English II study stated that the VIT has achieved satisfactory precision and bias according to ASTM E691–92 Standard Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method. The report of their testing showed that highly consistent results were produced from repeating the VIT tests, and that there was substantial correlation between the ironworker rankings with VIT rankings.

Also, the final rule's designation of approved ASTM testing methods as appropriate to determine compliance with a performance criterion is consistent with other OSHA standards. For example, in OSHA's standard for nationally recognized testing laboratories, an "ASTM test standard used for evaluation of products or materials" falls under the term "appropriate test standard" (as set out in the introductory text to paragraph (c) of that section, § 1910.7).

Various participants, however, claimed that the two ASTM testing methods lack precision and bias statements, which in their view render those standards "meaningless" (see *e.g.* Dr. Kyed's testimony Ex. 204X; p. 262 and Ex. 13–367; pp. 3–4). However, various witnesses (including one who offered the position above) stated that precision and bias statements often lagged behind a new approval by ASTM of a test method. "Test methods can be temporarily issued without these statements, but they must eventually comply with this requirement. Generally, it's a 5-year period." (Ex. 204X; p.262). Dr. Mary McKnight from the National Institute for Standards and Technology (NIST), testifying with a panel from the Society for Protective Coating (SSPC) [formerly the Steel Structures Painting Council], agreed that "* * within 5 years, there will be a group of laboratories that become proficient in running the test method and who will participate in a round-robin study. At the end of this process, ASTM includes a number describing statistical significance of different responses, with a 95-percent repeatability limit and/or confidence level" (Ex. 205X; pp. 56–68). In post-hearing comments (Ex. 71, p. 4), Mr. English stated that the ASTM F1679 precision and bias study has been approved by letter ballot, and at a recent meeting of the F13.10 Traction subcommittee, two-thirds of those present voted to find all negatives non-persuasive.

OSHA concludes that the rulemaking record demonstrates that the methods identified in Appendix B are sufficiently reliable in evaluating the slip-resistance of coated steel. The record also shows that this reliability is likely to be confirmed by the ASTM precision and bias statement process within the 5-year period this provision will be delayed.

In post-hearing comments, the major industry groups who objected to OSHA's designating ASTM methods stated that "several of their organizations actively participate in research and development efforts involving the validation and adoption of a testing machine and test methodology appropriate to coated structural steel" and recommended that OSHA delay the effective date for 3 years to allow further expert evaluation (Exs. 63, p. 7 and 75, p. 4). These groups also wanted this additional time to determine if implementation of the provision was feasible.

Although the ASTM methods are the best available, OSHA acknowledges that the ASTM methods lack a protocol for representative samples of steel and their preparation. The Agency anticipates that either these parallel issues will be addressed by ASTM within the time frame before paragraph (c)(3) becomes final (5 years after the effective date of the final rule) or alternative steps can be taken to ensure accounting for these parameters.

Availability of Paints to Meet the Slip-resistance Benchmark

The final standard delays the effective date of the slip-resistant coating provision for 5 years from the date the rest of the standard becomes effective. This is a change from the proposal, which would not have delayed the effective date. OSHA finds that although some slip-resistant coatings suitable for use in the steel erection industry are now available, widespread distribution and use of suitable coatings will take additional time. We have chosen a 5-year delay in agreement with the post-hearing requests of the major organizations commenting on this issue. These organizations submitted their comments as the Unified Steel Construction Consensus Group (USCCG) (Ex. 63), a group that consists of eight large organizations as signatories. The USCCG explained that their membership represents design, engineering, fabrication, manufacturing, and field installation components of the steel construction industry. (The following organizations were listed as signatories: The Steel Joist Institute; Steel Erectors Association of America; National Council of Structural Engineers Associations; National Institute of Steel Detailing; Council of American Structural Engineers; American Institute of Steel Construction; Metal Building Manufacturers Association; and the Society for Protective Coatings). They stated that the rulemaking record was uncertain about the extent adequate coatings were now available, and that developing, testing and distributing appropriate slip-resistant coatings for the industry would take time. Also, during the rulemaking, many paint formulators and steel fabricators stated that they do not now use the specific paints tested in the English II study. (For example, see Ronner at Ex. 204X, pp. 15 and 108–109; and Appleman at Ex. 205X, pp. 139 and 157–158.) In addition, some formulators and fabricators and their representatives stated that there is a lack of information about whether the paints/coatings in use can meet the standard's slip-resistant threshold. (For example, see Ex. 13–367, pp. 7 and 17; Ex. 13–307, pp. 38–39; Ex. 13–209, pp. 36–37; and Ex. 206X, pp. 34–35.)

OSHA finds that there is some uncertainty as to the extent to which there are adequately slip-resistant coatings currently available that would meet the industry's needs. In view of the fact that there are many such coatings presently on the market (see Ex. 17, pp. 3 and 10–11; Ex. 18, pp. 1–2; Ex. 200X, pp. 54, 62–63, 70, 137–139, and 168–169; Ex. 204X, pp.193–194; Ex. 205X, pp. 139 and 157–158) and the technology for developing additional coatings is in place (see Ex. 205X, pp. 51, 93–94, 99–102, 139, 151–152, 157–158, 167–168 and 217–219; Ex. 63, pp. 3 and 7; and Ex. 64, pp. 2–3), it is reasonable to expect that the 5-year delay will provide enough time for the industry to develop coatings that comply with the final rule.

OSHA agrees that the record evidence on the availability of slip resistant paint which meets the standard is conflicting. The witnesses who conducted the English I study commissioned by SENRAC (Ex. 9–64), and the English II study commissioned by OSHA (Ex. 17), testified that one reason for conducting these studies was to determine whether slip-resistant paint was widely available for use by the steel erection industry. They contended that slip resistant paints are available. They surveyed fabricators first, to identify coatings actually in use for steel erection, tested these coatings in their studies, and found that most of them passed the tests for slip-resistance (Ex.18, pp. 1–2). In post-hearing comments (Ex. 71, p. 4), Mr. English stated that "paints now being applied on something over 80 percent of the fabricated steel products in the U.S. can be easily made to comply with the proposed specification with no complications to application methodology, coatability, corrosion or UV resistance or any of the "problems" raised by * * * those opposed to this standard." He added that the paints that do not already comply could be brought into compliance with "the simple addition of the plastic powder * * *" Another witness (Ex. 205X; pp. 220–221) acknowledged that zinc-rich primers that are currently being used "extensively" had good slip-resistant qualities. However, he also stated that they are not generally used by the industry (*Ibid;* pp. 139 and 157–158).

Various other rulemaking participants told OSHA that the coatings used in the English studies represented only a small percentage of coatings used in steel erection. According to a telephone survey of 180 fabricators conducted by Mr. Ronner for the Steel Joist Institute (SJI) (Ex. 28), only 14 (7 percent) used the paints tested in the English II study (Ex. 204X; p. 15), and that although slip-resistant coatings are now used for various military applications such as helicopter flight decks and aircraft carriers, they are not generally used by the steel erection industry (Ex. 205X, pp. 139 and 157–158). The SSPC commented that slip-resistance has not been a design factor for coatings used on structural steel and that slip-resistant paints have not generally been tested for durability (Ex. 13–367, p. 7). A representative of the SJI (Ex. 204X, p. 13) testified that the zinc-rich primers, paint with polyolefin beads and some alkyd-based primers used in the English II study are for spray applications only, are not recommended for dip operations. He added that steel joists typically are coated by dipping them in dip tanks (Ex. 204X; p. 13), and that the industry could not spray on paints due to state and Federal environmental restrictions. These commenters assert that there is no basis for assuming that the same slip resistance would be achieved if the paints were dipped, and that there are technical problems with applying some of the slip resistant paints by dipping (See for example Mr. Ronner's testimony, Ex. 204X; p.13, and Mr. Appleman's testimony at Ex.205X; p. 93). Both Mr. Guevin and Mr. English acknowledged that they do not know if the same slip results reported in the English II study for the paints with beads would be obtained if that paint had been applied by dipping (Ex. 200X; pp. 62–63).

Promising approaches to providing slip-resistant coatings for the steel erection industry were identified during the rulemaking. As explained in the English II study (Ex. 17, p. 11) and as Mr. Guevin (Ex. 200X, p. 56) stated by ICI Devoe in Western Canada developed a slip-resistant 3-coat system, using "DevBeads," an additive of polyolefin beads. However, various participants questioned whether grit particles such as polyolefin beads could be added to paints and primers in steel erection. For example, George Widas (OSHA expert witness who peer reviewed the English II study) questioned whether such coatings would retain their corrosion protection (Ex. 204X; p. 240); Mr. Sunderman of KTA Tator, Inc., questioned whether polyolefins would be degraded by ultraviolet light (Ex. 206X, p. 34–35). Mr. Sunderman also challenged the notion that specific properties of paint can be modified "randomly" without affecting the balance of properties, and without extensive testing and evaluation (Id, p. 35–36).

Several participants stated such that slip resistant coatings could be developed for use in steel erection , but that time would be needed to do this. Robert Kogler, a research engineer, explained that testing corrosion control materials takes several years, and they still rely very heavily on long-term exposure data, but are coming up with accelerated testing that gives us

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reasonable data (Ex. 205X; p. 74, to same effect, see testimony of Dr. Appleman Ex. 205X; p. 51).

On a related issue OSHA finds that obtaining documentation or certification that coated steel meets this requirement also is feasible. However, paint manufacturers told OSHA in their post-hearing comments that they will work with interested parties to formulate, test and evaluate coatings to meet the standard's criteria (See Exs. 63, p. 7 and 75, p. 4 and 205X, p. 218). Mr. Guevin testified that based on his experience with contacting paint manufacturers to obtain slip-resistant coating for the English II study, and his knowledge of typical paint technical bulletins issued by manufacturers setting out specifications, tests conducted, and results, companies would readily certify if their coatings meet OSHA slip-index requirements in accordance with the recognized ASTM Method (Ex. 200X; p. 168). Thus, OSHA does not agree with a project manager for a steel fabricator (Ex. 13–300) who commented that the requirement was "not viable" because paint manufacturers will not provide documentation out of concerns for liability.

In sum, OSHA finds that although there are slip resistant coatings in use for structural steel in limited specialized applications, most of them have not been adequately tested to determine whether they comply with the standard and meet the performance needs of other kinds of structures. The coatings industry has committed to develop, test and distribute coatings that comply with this standard in a reasonable time frame. OSHA believes that the hazard of slipping on coated steel is significant; that the paint and fabrication industries feasibly can produce and use coated steel that complies with this provision within the time frame stated in the regulatory text; and in any event, there are now coatings on the market that meet the standard that can be used to some extent even before the widespread production of new slip-resistant coatings. The need for this provision is amply supported in the record. We believe that by issuing a delay of the effective date of this provision the needs of the industries affected by this provision will be met and the long-term safety concerns of the workers who must walk on these surfaces will also be met.

Paragraph (d) Plumbing-up

Paragraph (d)(1) requires that, when deemed necessary by a competent person, plumbing-up equipment shall be installed in conjunction with the steel erection process to ensure the stability of the structure. The proposed rule contained the requirement that "connections of the equipment used in plumbing-up shall be properly secured." In the preamble to the proposed rule, OSHA requested public comments on whether the final rule should contain an additional requirement that "plumbing-up equipment shall be installed in conjunction with the steel erection process to ensure the stability of the structure." This request for public comment was based on concerns that SENRAC members raised regarding whether or not the plumbing-up provisions are specific enough to ensure structural stability at all times during the erection process.

The Agency adopts the provision as stated in the final rule, based upon consultations with SENRAC members. To avoid the implication that plumbing-up equipment is always installed during steel erection, OSHA had added the phrase "when deemed necessary by a competent person" to the beginning of paragraph (d)(1). Consistent with this change, OSHA introduces final rule paragraph (d)(2) with the phrase "when used".

The Structural Engineers Association of Illinois (Ex. 13–308) requested that the following requirement be added: "Plumbing-up equipment shall be in place and properly installed before the structure is loaded with construction material such as loads of joists, bundles of decking or bundles of bridging." The commenter stated that loading the structure before it is plumbed can change the true lines of beams and columns, altering the final alignment of the members. The Agency agrees that this clarifies the intent of the requirement to ensure that connections of the equipment used in plumbing-up shall be properly secured, and has modified the provisions by adding paragraph (d)(2) as proposed by the commenter and several SENRAC members (63 FR 43484).

Paragraph (d)(3) (proposed paragraph (d)(2)) requires the approval of a competent person before plumbing-up equipment is removed. This paragraph is slightly different from OSHA's current standard, which provided that, "Plumbing-up guys shall be removed only under the supervision of a competent person." In the final rule, which is identical to the proposed rule, "guys" has been changed to "equipment." This is necessary because "guys" implies guy lines only, while plumbing equipment also includes stabilizer bars and solid web members. Additionally, the term "under the supervision" has been changed to "with the approval" of a competent person for greater regulatory clarity. In addition, with respect to open web steel joists, the stabilizer plate requirement of § 1926.757(a)(1)(i) will greatly facilitate the plumbing-up of structures.

There were no comments received regarding paragraph (d). The Agency adopts the changes as proposed.

Paragraph (e) Metal Decking

This paragraph of the final standard addresses specific requirements to protect employees during the installation of metal decking. As stated in the preamble to the proposed rule, the requirements in § 1926.754(e) address many of the hazards which cause decking accidents.

One commenter (Ex. 13–312) asserted that it is difficult to apply rules designed for steel frame erection and floor decks in high rise buildings to metal roofing, and suggested that OSHA address metal roofing in a separate section. However, there is insufficient information in the record for this Agency to develop a separate provision.

In the proposal, the terms "decking" and "floor decking" were used. In order to clarify that § 1926.754(e)(1) through (e)(5) applies to all activities associated with the use of metal decking used as a support element in a floor or roof system, the terms decking and floor decking have been changed to metal decking. Metal decking as defined in § 1926.751 means a commercially manufactured, structural grade, cold rolled metal panel formed into a series of parallel ribs; for this subpart, this includes metal floor and roof decks, standing seam metal roofs, other metal roof systems and other products such as bar gratings, checker plate, expanded metal panels, and similar products. After installation and proper fastening, these decking materials serve a combination of functions including, but not limited to: a structural element designed in combination with the rest of the structure to resist, distribute and transfer loads, stiffen the structure and provide a diaphragm action; a walking/working surface; a form for concrete slabs; a support for roofing systems; and a finished floor or roof.

The National Riggers and Erectors commented (Ex. 13–314) that, as a group of steel erectors and installers of metal decking, they agree with the proposed requirements to protect employees during decking activities because decking installation is one of the most hazardous operations for an ironworker and orientation, training, and good laws are key to ensuring employee safety.

The Bridge, Structural, Ornamental and Reinforcing Ironworkers submitted a written comment (Ex. 13–198) in support of the decking requirements and expressed their opinion that over time, accident statistics will support the proposed changes.

Paragraph (e)(1) of the final rule addresses some of the common hazards associated with hoisting, landing and placing of deck bundles. Many of the requirements of this paragraph are adapted from the *Steel Deck Institute Manual of Construction With Steel Deck* (Ex. 9–34A).

Paragraph (e)(1)(i) of the final rule requires employers to ensure that the packaging and strapping on the deck bundle are specifically designed for hoisting purposes. Bundle straps usually are applied at the factory and are intended to keep the bundle together until it is placed for erection and the sheets are ready to be spread. Decking is bundled differently; some manufacturers design the strapping to be used as a lifting device. However, hoisting a bundle by straps that are not designed for lifting is extremely dangerous. The bundle straps can break apart or loosen, creating a falling object hazard or, if a structural member is hit by the bundle or its contents, it could cause the structure to collapse (63 FR 43468). OSHA believes that compliance with this requirement will prevent these hazards. There were no comments received regarding this requirement.

Paragraph (e)(1)(ii) requires employers to secure loose items such as dunnage, flashing, or other materials placed on the top of deck bundles before a bundle is hoisted. Sometimes, to expedite unloading and hoisting, items such as dunnage or flashing are placed on the decking bundle to save time. Dunnage, for example, will be sent up with the bundle to help support it on the structure and to protect the decking which has already been installed. Id. This requirement will not allow hoisting loose items or "piggy backing" unless the items are secured to prevent them from falling off the bundle in the event that it catches on the structure and tilts. There were no comments regarding this requirement.

Paragraph (e)(1)(iii) requires employers to land bundles of decking on joists in accordance with § 1926.757(e)(4), which sets out the six conditions that must be met by employers before a bundle of decking is placed on steel joists where all bridging has not been installed and anchored. First, a qualified person must determine, and document in the site-specific erection plan, that the structure or portion of the structure is capable of supporting the load. The bundle of decking must be placed on a minimum of three steel joists and the joists supporting the bundle must be attached at both ends. At least one row of bridging must be installed and anchored and the edge of the bundle must be placed within one foot of the bearing surface of the joist end. The total weight of the bundle of decking may not exceed 4,000 pounds. SDI commented that a portion of the preamble to the final rule misrepresented the position of SDI in the sentence, "The Steel Deck Institute (SDI) has indicated that, in the future, manufacturers will deliver decking in bundles that will accommodate this load limit" (Ex. 203X; p. 99–101). Also, SDI suggested adding the following requirement: "When an erection plan requires any maximum weight, this information must be provided to the deck manufacturer along with any other bundling instructions, i.e. provide approval labels or special marking instructions' (Ex. 13–356). SDI also stated that this must be done with sufficient lead time to allow production coordination between the erector and the manufacturer.

OSHA believes it is unrealistic to require buyers to give sufficient lead time to manufacturers. The 4,000 pound weight limit for decking bundles applies only if the employer has determined that all six conditions can be met prior to landing a bundle of decking on steel joists where all bridging has not been installed and anchored. At this time, the employer may negotiate with the manufacturer to restrict a specific bundle weight to 4,000 pounds, or the employer may also opt to install and anchor all bridging in order to continue with the erection process without delay.

Paragraph (e)(1)(iv) requires employers to land bundles on framing members in such a manner that the decking can be unbanded without losing the support of the structure. If the blocking were to move while the bundle is being unbanded, the bundle would need to have enough support to prevent it from tilting and falling.

One commenter requested adding, "When cutting bundle straps or breaking down crates, care must be taken to prevent straps or dunnage from falling on personnel or equipment" (Ex. 13–356). OSHA agrees that unbanding decking bundles poses hazards from falling objects and § 1926.759(b) addresses this issue. That section prohibits work below on-going steel erection activities unless overhead protection is provided.

OSHA considers hazards associated with cutting banding straps to be widely recognized throughout construction and general industries. In addition to falling straps and dunnage, cutting banding straps poses serious hazards to eyes as well as cuts, abrasions, as well as bruises, strains or other injuries while attempting to hold or secure the contents of the bundle. Training in the establishment, access, proper installation techniques and work practices required by § 1926.754(e) would be covered by § 1926.21(b)(2), OSHA's general training requirements for construction work. In addition, special training programs in § 1926.761(c) (which supplements § 1926.21) specifically address employees who work in a controlled decking zone. All recognized hazards, including those associated with cutting banding straps, would be part of the work practices training to ensure that employees recognize unsafe conditions in the work environment and know the measures to control or eliminate hazards.

Paragraph (e)(1)(v) requires employers to secure decking against displacement after the end of the shift or when environmental or job site conditions warrant. Decking may become dislodged from the structure or bundle because of conditions such as high winds. Wind can also move a sheet of loose decking and create a hazard where an employee inadvertently steps onto a sheet of loose piece of decking, believing it to be secured.

Paragraph (e)(2) Roof and Floor Holes and Openings.

This paragraph sets requirements for installing metal decking to minimize the risks of falling through holes and openings in decking.

There are differences between the use of the terms "holes" and "openings" in subpart M and subpart R. Subpart M uses the term "hole" to describe all holes and openings in floors, roofs and other walking surfaces and uses the term "opening" to apply only to holes and openings in walls. However, SENRAC used these terms differently in the proposed steel erection standard, incorporating the terms as they are commonly used by steel erection employers and employees (see the definition of "decking hole" for a more detailed discussion). For instance, in steel erection, the term "hole" means a small gap or void that presents a tripping hazard or a falling object hazard, while "opening" means a gap or void that is large enough for an employee to fall through.

OSHA made changes in the proposed regulatory text to clarify that § 1926.754(e)(2) applies to the installation of all metal decking supporting either a floor or roof system. The terms "decking" and "floor

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decking" have been changed to read "metal decking".

Paragraph (e)(2)(i) requires employers to ensure that all framed metal deck openings have structural members turned down to allow continuous deck installation, except in cases where structural design constraints and constructibility do not allow this. Requiring framed deck openings to be turned down allows continuous decking to be performed without having to cut the deck around the opening. This procedure would apply to smaller openings rather than larger openings, such as elevator or mechanical shaft openings. Whereas smaller openings may be cut at a later time, it may not be appropriate to delay larger openings.

A group of fifty-four ironworkers commented and specifically agreed with the requirement that framed deck openings be turned down in order to allow continuous decking (Ex. 13–207C).

Paragraph (e)(2)(ii) requires roof and floor openings to be decked over. Where large size, configuration or other structural design does not allow for covering of the roof and floor holes and openings, they must be protected in accordance with § 1926.760(a)(1).

The committee intended the proposed standard to require continuous decking except in certain cases where continuous decking is not feasible due to structural design. For example, large openings such as elevator shafts and stairways, are typically too large to cover, and would usually be protected with a guardrail. The standard has been reworded to clearly reflect this intention.

Paragraph (e)(2)(iii) requires employers to delay cutting decking holes and openings until immediately before they are permanently filled with the equipment or structure needed or intended to fulfill their specific use. That equipment or structure must either meet the strength requirements of paragraph (e)(3) of this section, or be immediately covered. This has been revised from the proposed rule for clarity and in response to a commenter who requested a clear and concise definition of "essential to the construction process" in order to eliminate the many possible interpretations (Ex. 13–222).

Two commenters indicated that paragraphs (e)(2)(ii) and (iii) can be interpreted to require continuous decking over all holes which are cut out later and that this requirement would be a cost issue as well as a safety issue because covering large openings with decking may require temporary supports to sustain anticipated working loads on the deck (Exs. 201X; p.76 and 201X; p.11). We note, however, as discussed above, that paragraph (e)(2)(ii) specifically states that large openings do not have to be decked over if the employer protects employees using guardrails or other fall protection pursuant to § 1926.760 (a)(1).

Fifty-nine comments were received which expressed agreement with the proposed decking requirements (Exs. 13–207C; 13–345; 208X, pp.136–139; 203X, p.108–161; 13–198; and 13–347). One commenter indicated that his company does not allow any hole to be cut in any raised level unless the person using the hole is there, ready to cover or protect it (Ex.13–198). Fifty-four commenters agreed with delaying the cutting of deck holes and the requirement to immediately cover or protect the deck openings (Ex. 13–207C). Another 195 letters were received in support of "covering and marking of deck holes and openings (Ex. 13–355B). One commenter added that there is no good reason to not deck over and clearly mark roofing holes (Ex. 13–355B). A commenter suggested that barricades be used to protect floor openings (Ex. 13–355B). One commenter stated that "Covering and marking holes in the deck with strong material and painting with high visibility paint will prevent a lot of injuries." (Ex. 13–355B). Another commenter strongly urged that all holes and openings on the work floor be covered with plank, screens or nets and that all sheets of decking around columns should be cut into their proper place, and welded down (Ex. 13–355B).

Delaying the cutting of holes in decking was established to prevent the employee and objects from falling through the holes and eliminate tripping hazards that may be presented by covers over holes that would not be used for some time. The holes are typically smaller than those addressed in paragraph (e)(2)(i) of this section. OSHA has revised the standard to clarify these points and address the issues raised in the comments.

Paragraph (e)(3) Covering roof and floor openings.

Final rule paragraph (e)(3) addresses proper coverings required by § 1926.754(e)(2)(iii), which will protect employees from falling into or through openings in roofs and floors. These provisions have been moved in the final from proposed § 1926.760(d).

Paragraph (e)(3)(i) requires that covers be strong enough to withstand the weight of employees, equipment and materials by requiring that covers support twice that combined weight.

Proposed provision § 1926.760(d)(1) stated that covers must support the greater of (1) 30 pounds per square foot (psf) for roofs and 50 psf for floors, or (2) twice the combined weight of the employees, equipment and materials that may be on the cover. The final rule, § 1926.754(e)(3)(i), deletes the specific strength requirement of 30 psf for roofs and 50 psf for floors. These figures were based on strength requirements specified in the Steel Deck Institute's Manual of Construction with Steel Deck (Ex. 9–34A).

Mr. Philip Hodge from HABCO Inc. (Ex. 13–153), stated that some buildings designed for snow loads may not meet the 30 psf requirement and that the temporary cover, in some instances, may be stronger than the remainder of the roof if this section remained. In subpart M, in § 1926.502 (i), the Agency instituted a requirement that covers support twice the combined weight of employees, equipment and materials, rather than specifying a particular minimum psf. We believe that the subpart M approach is also appropriate here. Because the proposed provision would require unnecessarily strong covers for roof and floor openings, the provision has been modified to accord with subpart M.

Paragraphs (e)(3)(ii) and (e)(3)(iii) are unchanged from the proposal, except for being re-numbered. Paragraph (e)(3)(ii) requires that all covers be secured when installed so as to prevent accidental displacement by the wind, equipment or employees. This provision eliminates a fall hazard. Paragraph (e)(3)(iii) requires that all covers be painted with high visibility paint or be marked with the word "HOLE" or "COVER" to warn of the hazard and to prevent an employee from inadvertently removing the cover. These provisions are consistent with the requirements in subpart M.

Paragraph (e)(3)(iv) addresses the hazards associated with smoke domes and skylight fixtures. Installed smoke domes and skylight fixtures are not to be considered covers for the purposes of this section unless the strength requirement of paragraph (e)(3)(i) is met. If these structures are not capable of supporting the load, they may give way, causing a fall. Unless they have adequate strength, these structures cannot be relied upon to protect employees from falls. Employees commonly lean or sit on skylights or smoke domes and these structures need to be capable of supporting the load without failure.

Paragraph(e)(4) Decking gaps around columns.

Final § 1926.754(e)(4) (proposed paragraph § 1926.754(e)(3)) requires that wire mesh, exterior plywood, or equivalent be installed around columns where planks or metal decking do not fit tightly thus leaving a gap. The materials used must be of sufficient strength to provide fall protection for personnel and prevent objects from falling through.

Proposed paragraph (e)(3) used the term "space." Three commenters explained that the proposed standard did not identify what a space is and how big a space must be (Exs. 201X, p.76; 13–173 and 13–31). One of the three commenters added that the standard should require that the material used to cover these gaps must be strong enough to prevent people and objects from falling through (Ex. 201X; p.76).

OSHA agrees that the term "space" is not defined and that this could lead to misinterpretations. The proposed regulatory text did not discuss the strength of the materials to be used, the only reference to the strength is in the preamble to the proposed standard which explains that gauge metal, typically cut out to the profile of the column, is commonly used for this purpose and would be considered an equivalent material.

OSHA has revised the standard to clarify the issues addressed in the comments by changing the title to "Decking gaps around columns" and adding strength and fit requirements to the final rule.

Paragraph (e)(5) Installation of metal decking.

Paragraph (e)(5) of the final rule (proposed paragraph (e)(4)) requires metal decking to be laid tightly and immediately secured upon adjustment to prevent accidental movement or displacement, except as provided in § 1926.760(c). Section 1926.760(c) provides for a "Controlled Decking Zone" (CDZ) which allows up to 3,000 square feet of decking to be unsecured until adjustment when safety attachment is then required (see discussion on "safety deck attachment" in § 1926.760(c)).

There were three comments received in support of the requirement to secure decking immediately after it is laid and aligned (Exs. 13–198; 13–356 and 202X, pp. 129–130). A representative of the Bridge, Structural, Ornamental and Reinforcing Ironworkers (Ex. 13–198) commented that bays of unfastened sheets are unnecessary. SDI (Ex. 13–356) agreed that all decking, whether single or multi-span, should be fastened immediately after alignment and should not be used as a working platform until properly attached. A witness (Ex. 202X, pp. 129–130) testified that stepping on, or leaving a deck sheet unsecured should be prohibited because of the following: (1) Decking can separate due to ice, snow, water, oils, or combinations of these that cause side laps to uncouple easily, (2) loose decking has an aerodynamic effect and in some winds it can fly, resulting in injuries and property damage, and (3) there are situations where the supports are not level resulting in a sag in the decking that increases the chance that two sheets could unmarry.

OSHA agrees with the requirement that all metal decking must be laid tightly and secured, once it has been aligned and adjusted, to prevent accidental movement or displacement. This may be accomplished by installing final deck attachments or safety deck attachments such as tack-welding the panel, or with a mechanical attachment, such as self-drilling screws or pneumatic fasteners. In order to be consistent with the rest of Subpart R, we have revised the final rule by changing the terms "decking," "metal deck," "deck," and "floor decking" to "metal decking." This was done to clarify that § 1926.754(e)(5) applies to all metal decking used as a support element for either a floor or roof system. Also, the proposed requirement in the CDZ provision (proposed § 1926.760(c)(5)) that during initial placement, metal decking panels must be placed to ensure full support by structural members, has been moved to final rule paragraph § 1926.754(e)(5)(ii). This was determined to be more of an erection procedure than fall protection. Paragraph (e) of § 1926.754 (Structural steel assembly) now encompasses all of the procedures for the installation of all metal decking, whether in a CDZ or not.

Paragraph (e)(6) Derrick Floors.

Paragraph (e)(6) of the final rule (proposed paragraph (e)(5)), addresses the use of derrick floors during erection. Paragraph (e)(6)(i) requires that a derrick floor be fully decked and/or planked and the steel member connections be completed to ensure that the floor will support the intended load.

Paragraph (e)(6)(ii) requires that temporary loads on a derrick floor be distributed over the underlying support members in order to prevent spot overloading. These provisions contain essentially the same requirements as those in existing § 1926.750(b). There were no comments received regarding these provisions and they remain, in final, unchanged from the proposed rule.

Section 1926.755 Column Anchorage

This section addresses the hazards associated with column stability and, specifically, the proper use of anchor rods (anchor bolts) to ensure column stability. Section 1926.755 of the final rule specifies the criteria for column anchorage. Inadequate anchor rod (anchor bolt) installation has been identified both by SENRAC and by witnesses at the public hearing as a contributing factor to structural collapses. One participant, a connector by trade, addressed a SENRAC meeting and asserted that collapses due to poor footings and anchor bolts are currently the primary cause of connector accidents (Ex. 6–3, p. 4). This section sets out requirements for ensuring that columns are adequately stabilized during their erection to withstand construction loads.

Paragraph (a) General requirements for erection stability

The final rule differs from the proposal in several areas. First, the title of the section has been changed from "Anchor bolts" to "Column anchorage". Two commenters suggested changing the section title, the Safety Advisory Committee of the Structural, Ornamental, Rigging and Reinforcing Steel Industry (SAC) (Ex. 55) and the Unified Steel Consensus Group (USCCG) (Ex. 63). The SAC Committee suggested "Erection Stability" while the USCCG recommended changing the title to "Column Anchorage". Since the section contains several means of achieving column stability in addition to the anchor bolt requirements, the Agency believes "column anchorage" better describes the subject of the section.

Paragraph (a)(1) of the final rule requires that all columns be anchored by a minimum of 4 anchor rods/bolts. In addition, paragraph (a)(2) requires that each column anchor rod/bolt assembly, including the column-to-base plate weld and the column foundation, be designed to resist a minimum eccentric gravity load of 300 pounds (136.2 kg) located 18 inches (.46m) from the extreme outer face of the column in each direction at the top of the column shaft. These provisions are similar to those in proposed paragraph (a)(1) with minor changes that clarify the type and location of the eccentric load. The proposed paragraph (a)(1) has been split into two paragraphs in the final rule because there are two distinct requirements.

Several commenters objected on the grounds that this section imposes design requirements for the structure. In their

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view, it is inappropriate for OSHA to set such requirements. In particular, Korte Construction Company (Ex. 13–170F) asserted that while having four anchor bolts is a good practice, the general contractor/construction manager cannot guarantee that the engineers and designers will design the building to OSHA's specifications. Additionally, they indicated that the engineers and designers specify by contract that the means and methods of construction are the contractor's responsibility. Another commenter, Summit Construction Group (Ex. 13–200) questioned whether engineers and designers will follow the regulations in the design of the structure since the engineers and designers are not identified as being required to follow Subpart R. Engineers and designers design structures for compliance only with building codes and other related industry standards to assure public safety after completion of the structure. KEUKA Construction Corporation (Ex. 13–154) opposes the idea that OSHA can, by regulation, determine how many column anchor bolts are necessary regardless of what the design architect or engineer may require. They also state that it is inappropriate for OSHA to "micro-manage" steel erection.

OSHA, however, strongly believes that it is as appropriate for the Agency to require that avoidable safety hazards be engineered out for the protection of those erecting the building as it is for local jurisdictions to set design criteria for the safety of the building's occupants. The report of the SENRAC statistical workgroup (Ex. 9–42 and 9–49) shows that connector fatalities are 17% of the total fatalities involving falls from heights. In addition, during SENRAC meetings, ironworker connectors identified insufficient anchor bolts as the primary cause of connector accidents (Ex. 6–3, p. 4). The record establishes that there is a hazard of columns collapsing due to anchor rod/bolt problems and this requirement is necessary to reduce the fatalities and injuries caused by inadequate anchor bolt assemblies.

An overwhelming majority of commenters agreed that 4 anchor rods/bolts should be required. According to testimony from Robert Murman of E–M–E, Inc. (Ex. 202X; pp. 83–85), "* * * a four-bolt system is a lot safer, it's a lot easier to plumb." Mr. Murman went on to describe the differences between using two anchor bolts and using four, stating that:

> * * * a four-bolt system, you've got four corners holding it down. Two bolts, you've got only half of it and the other side is rocking. A lot of times you're using shims, you're shim packing, trying to get these things to plumb. The more shims you put under there, the less stability you're going to have and the greater chance of pulling the anchor bolt out or breaking an anchor bolt, shearing them off, or it could snap. If it's not placed properly, then you have to chemically or epoxy it in, and you have a chance of pulling the after-bolt out, which is only like a pencil. An anchor bolt, traditionally, is on a 90 [a 90° angle], or it's built so that it's in the concrete and holding under the footing. So when you're plumbing a column that's on a shim pack, sometimes you're loosening the nut.

Upon questioning, Mr. Murman further stated:

> When the column is going in, 90 percent of the time we set a column without a person—they'd have the guy on the ground with the impact wrench and he's going to tighten up. It's set with the crane and they cut him loose and let the choker slide down the column, and 95 percent of the time he's not up on that column, unless you have a problem with the choker not coming down, or he has to get the ladder to get up on top of your beam to connect the column and the beam together. That's when you have your greater exposure.

In describing the loads imposed on the column during erection, Mr. Murman added, "a 200 or 250 pound person up on that ladder is really putting some stress on that [the column]. As long as you've got two anchor bolts, you've got the potential there of having it going into the hole." Also, Mr. Mike Cushing, testifying as part of the Ironworker panel (Ex. 205X; p. 337), when questioned whether he thought four anchor bolts on every column will make a safer situation than we have today, stated:

> I don't think I've ever seen a column go over that had four anchor bolts in it that didn't have an installation problem with the bolts * * * [h]owever, two anchor-bolt columns, I can think of about a dozen that I've seen go over. And they don't go the way the two bolts are. They go to the left or the right of the bolts, you wouldn't have that situation [with the proposed language]."

In addressing paragraph (a)(1) of the proposed rule, several commenters suggested that the standard allow for exceptions to the 4 anchor rod/bolt for posts and small columns and where four anchor rods/bolts are otherwise not feasible or necessary. The American Institute of Steel Construction (AISC) (Ex. 13–209) commented that "[t]he provision for four anchor bolts is appropriate for large columns, but not necessarily needed for smaller posts used for stair platforms, architectural features, wall framing, mechanical support platforms, mezzanines and similar structures." In addition, Mr. Jim Larson (Ex. 203X; pp.16–17) testified:

> * * * [t]he requirements for four anchor bolts in all major columns is endorsed by [Steel Erectors Association of America] SEAA for additional stability according to the ironworker when they are exposed to the initial phase of erecting steel. There may be specific limited applications in which four anchor rods (anchor bolts) are not feasible on minor columns and/or secondary posts."

Following up, Mr. Eddie Williams (Ex. 203X; pp. 24–25) stated that a small column sitting on an eight inch wall could have two anchor bolts and be stronger than four if there is not enough concrete to get coverage on the four anchor bolts. LeMessurier Consultants (Ex. 13–127) commented that "* * * there are cases where a 4-anchor rod pattern is neither practical nor feasible, such as a column base bearing on a narrow wall, at the edge of a pit, or at some corners. For such cases, the standard should allow the structural design engineer the design flexibility of using 2 or 3 anchor rods to safely resist the 300 pound load applied at the 18-inch prescribed eccentricity." Another commenter (Ex. 13–151) shared the same view that "* * * there are certain foundation considerations which prohibit an effective 4 anchor rod pattern. Typical of these are column bases on narrow walls, near the edges of pits, and at corners." Another commenter (Ex. 13–153) commented that the requirement as proposed "* * * would reduce the use of steel columns embedded in masonry walls. This would encourage the construction of free-standing CMU [concrete masonry unit] walls supporting steel roofs, which is generally recognized as not as safe a construction method as a complete steel framed structure with CMU in-fill." The National Council of Structural Engineers Associations (Ex. 13–308) stated "[i]n some cases, 4 anchor bolts may not provide any more stability for the column than 2 anchor bolts. The proposed rule needs to differentiate between main load bearing columns and posts." In addition, Basic Metal Products, Inc. (Ex. 13–245) commented that the four anchor bolt minimum is proper for main columns, but should not be required for miscellaneous "post columns" such as those supporting stairs, wind posts, etc.

Similarly, The Council of American Structural Engineers (Ex. 13–320) recommended that OSHA either clarify its intent as to the scope of this provision, or define "column" to exclude small posts, roof mounted machinery platforms and other supports which are not subject to being climbed by an ironworker during installation. The American Institute of Steel Construction (Ex. 13–209) suggested

distinguishing between columns, which clearly require the safety of four or more anchor bolts and posts, which would not.

The proposed four anchor bolt requirement appeared to cover all columns, without exception. Neither SENRAC nor OSHA intended this requirement to apply to all vertical members. Some vertical members (also called posts), are typically smaller, do not support the main structure, and are not climbed by a connector. For these reasons, such vertical members do not require the anchorage described in this paragraph. These structural members are either attached at both ends or are hung from above (such as wind posts). In contrast, a column attached at its base functions as a freestanding cantilever during some period of time in the construction process and is climbed by the connector.

The Agency agrees with the commenters that some flexibility should be provided for in the standard for these situations. The final rule, therefore, defines "column" to exclude posts. The Agency feels that this definition adequately addresses the feasibility concerns expressed in the record. The definitions, in the final rule, of column and post read as follows:

> Column means a load-carrying vertical member that is part of the primary skeletal framing system. Columns do not include posts.
>
> Post means a structural member with a longitudinal axis that is essentially vertical, that: (1) is axially loaded (a load presses down on the top end) and weighs 300 pounds or less, or (2) is not axially loaded, but is laterally restrained by the above member. Posts typically support stair landings, wall framing, mezzanines and other substructures.

Therefore, in the final rule, the "Column Anchorage" section only applies to columns and does not apply to posts. The record does not support the need to add additional exceptions. OSHA believes that the changes in the definitions are sufficient to address the concerns expressed by the commenters.

Proposed paragraph (a)(1) also stated that, "each column anchor bolt assembly, including the welding of the column to the base plate, shall be designed to resist a 300 pound (136.2 kg) eccentric load located 18 inches (0.46 m) from the column face in each direction at the top of the column shaft." One commenter (Ex. 13–127) suggested that "[t]he standard must clarify how the 18 inch eccentricity is measured along the weak axis of a typical H-shaped column. For these, the 18 inches probably should be measured from the edges of the column flanges." Another commenter (Ex. 13–151) suggested that when calculating the moment to be applied at the column base in the weak axis direction, OSHA needs to define whether "face" of a column means face of the column web or edges of the column flanges. For clarity, final paragraph (a)(2) specifies that the eccentricity is measured from the extreme outer face of the column at the top of the column shaft.

In addition, the final rule revises the term "eccentric load" to read "eccentric gravity load" to clarify the design criteria for columns. This issue was addressed by a commenter (Ex. 13–207) who felt "horizontal load" would better describe all of the forces imposed on the column including pulling and prying by the ironworker along with any wind factor. Mr. Doug Rutledge (Ex. 207X; pp. 116–118) testified that describing the load as a horizontal load more closely characterizes the nature of the forces. After evaluating all the characteristics of the forces applied to the column during erection, the Agency determined that "eccentric gravity" is a better term to describe those forces. In addition, "and the column foundation" has been added to clarify that the anchor bolt assembly must be designed such that the foundation (as well as the column-to-base plate weld) can resist the forces applied.

Another change is the introduction of the term "anchor rod" wherever the term "anchor bolts" was used in the proposal. Two commenters stated that the term "anchor rod" is the industry term that is commonly used and would be consistent with the current AISC design specifications. LeMessurier Consultants (Ex. 13–127) suggested changing the term "anchor bolts" to "anchor rods" in the standard. They stated that the AISC and the Steel Industry now refer to the anchors at column bases as anchor rods. The Structural Steel Fabricators of New England, Inc. (Ex. 13–228) commented that since not all anchorages of steel column base plates to foundations fall under the definition of "bolts", the industry has changed the terminology to "anchor rods". They recommended the new term "anchor rods" be substituted through the standard.

The term "anchor bolt (anchor rod)" has been inserted in the final rule wherever the term anchor bolt was used in the proposed rule. Since the term has just recently been changed in the industry, the Agency has elected to keep both terms in the standard for purposes of clarity.

Paragraph (a)(3) of the final rule requires that columns be set on level finished floors, pre-grouted leveling plates, leveling nuts, or shim packs which are adequate to transfer the construction loads. This provision is identical to proposed § 1926.755(a)(2). No comments were received on this paragraph.

Final rule paragraph (a)(4) requires that all columns be evaluated by a competent person to determine whether guying or bracing is needed and, if needed, be installed. This is changed from proposed paragraph (a)(3) which limited the required evaluations to "unstable columns." Several commenters noted that the proposed provision was too vague because of its reliance on the term "unstable columns." Others criticized it on the grounds that all columns should be guyed or braced. At the hearing, upon questioning, Mr. Jim Larson (Ex. 203X; p. 41) stated "[i]n and of itself, * * *, the anchor bolt, four anchor bolts or two anchor bolts, I do not believe were intended to be the only method of stability". Gibble, Norden, Champion (Ex. 13–70) commented that "[a]ll columns must be stabilized by guy cables and to imply that a column can be safely stabilized by anchor rods will lull erectors into ignoring proper guying, resulting in an unsafe condition."

Since the condition of a column is not known until it is evaluated, all columns need to be evaluated in order to determine whether any of them are unstable and need to be guyed or braced. Therefore, the final rule paragraph (a)(4) (proposed paragraph (a)(3)) requires that all columns be evaluated by a competent person and be guyed or braced where necessary. The Agency feels that anchor bolts alone cannot be assumed to be capable of achieving the necessary stability, and that all columns need to be evaluated and guyed or braced to resist the normal effects of wind on the partially completed structure. In support of this, Mr. Doug Rutledge (Ex. 207X; pp. 63–64) testified:

> [p]rovision should be made for allowing design innovation and improvement while still meeting the necessary performance criteria. Furthermore, I believe the standard must recognize the impossibility in some instances and the economic impracticability in other instances of achieving column stability in all instances. Such columns, I believe, should be identified by the designer of the structures, thereby signaling the erector or responsible individual that these columns require special attention. They require temporary bracing. They require guying. They require some means other than the ordinary standard of simply erecting the column and assuming the column will be self-stable.

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In summary, paragraphs (a)(1) through (a)(4) requires that all columns must be secured with 4 anchor rods (anchor bolts) and evaluated by a competent person to determine whether guying or bracing is needed. In addition, posts will be excluded from the 4 anchor rod/bolt requirement by definition.

Paragraph (b) Repair, Replacement or Field Modification of Anchor Rods (Anchor Bolts)

This paragraph addresses the situation where the steel erector encounters an anchor bolt that has been repaired, replaced or modified. The steel erector often cannot visually tell when an anchor bolt has been repaired and thus will not be aware of the repair unless notified that a repair has been made. If an anchor bolt has been improperly repaired, replaced or modified, it could lead to a collapse. The intent of this paragraph is to ensure that the erector has the opportunity to make sure that any work on anchor bolts has been adequately performed.

The title of this paragraph has been changed by adding "of anchor rods (anchor bolts)" to clarify that this section deals with the repair, replacement and field modification of anchor rods/bolts.

Paragraph (b)(1) of the final rule prohibits the repair, replacement or field modification of anchor rods (anchor bolts) without the approval of the project structural engineer of record. Commenters supported this requirement, and it is unchanged from the provision in the proposal. Emile Troup of The National Council of Structural Engineers Association (Exs. 13–308 and 52) commented that most structural engineers would agree that repairs or necessary modifications to structural steel components should be designed or reviewed by the Structural Engineer of Record (SER). However, he also stated, that the safety or stability of the structure during construction, is the direct responsibility of the steel erector and its' ironworkers, and should not be transferred to the SER as a result of repairs or modifications. The Structural Steel Fabricators of New England (Ex. 13–228) commented that they "* * * agree with the standard in requiring the project structural engineer of record to approve repair, modification or replacement of anchor rods." The Structural Engineers Association of Illinois (Ex. 13–294) agreed that modification, repair or alteration of any component should require approval from the project structural engineer of record. They went on to state that the rule "* * * should clarify that the project structural engineer of record is not responsible to ensure that the conditions requiring modification, repair or alteration are identified * * *"

Paragraph (b)(2) of the proposed rule would have required that the Structural Engineer of Record (SER) determine whether guying or bracing is necessary if an anchor bolt was repaired, replaced or modified. This provision has not been included in the final rule. Commenters asserted that it was not within the SER's expertise to determine when guying or bracing is necessary for repaired, replaced or modified anchor rods (anchor bolts). One commenter (Ex. 13–294) stated that "[t]he project structural engineer of record is not familiar enough with erection procedures, and is not trained to assess the stability of any column or post for interim construction loads that may or may not require temporary bracing." Furthermore, "[a] competent person should make this determination based on the notification required by paragraph (b)(3) [of the proposal]."

OSHA is persuaded by this comment. Under § 1926.755(a)(4), all columns need to be evaluated by a competent person to determine whether guys or braces are necessary, including those instances where anchor rods have been repaired or replaced. The repair or replacement of anchor rods/bolts needs to be approved by the SER, but the SER should not be the one to determine whether guying or bracing of the column and frame is necessary.

Paragraph (b)(2) of the final rule (proposed paragraph (b)(3)) requires that prior to the erection of a column, the controlling contractor must provide written notification to the steel erector if there has been any repair, replacement, or modification of the anchor bolts for that column. This requirement, working in conjunction with § 1926.752(a)(2), completes a crucial communication loop. The steel erector generally does not have contact with the project structural engineer of record. The steel erector cannot rely on the controlling contractor at present to convey the approval of the project structural engineer of record for repair, replacement or modification of anchor bolts because it is not required.

OSHA received comments that fell into three categories: (1) Controlling contractors should notify the steel erector of modifications and repairs to anchor bolts (Ex. 208X, p. 77); (2) contractors that make the repairs or modification should contact the steel erector (Exs. 13–173, 13–210, 13–215, 13–222, 13–334); and (3) the steel erector should find out if repairs or modifications have been made (Exs. 201X, P. 77; 13–13–173; 13–210; 13–215; 13–222; 13–334).

OSHA agrees with the commenters who supported requiring controlling contractors to notify the steel erector of modifications and repairs; that is what the final rule requires. On the second point, OSHA notes that a problem with relying solely on the contractor or individual that makes the repair to notify the steel erector is that the steel erector may not be on site at the time of the repair. Therefore, the controlling contractor is in the best position to obtain and relay this type of information.

With regard to the comments stating that the steel erection contractors should be responsible for finding out if repairs or modifications have been made, OSHA believes that if a steel erector notices that modifications have been made, the steel erector will contact the controlling contractor as a result of this provision. The purpose of this provision is to address the fact that it is often difficult, if not impossible, for the steel erector to tell if a repair or modification has been made. This provision is designed to ensure that the erector is made aware of such changes.

Section 1926.756 Beams and Columns

Section 1926.756 sets forth requirements for connections of beams and columns to minimize the hazard of structural collapse during the early stages of the steel erection process. Recognizing that inappropriate or inadequate connections of beams and columns is hazardous and can lead to collapses and worker fatalities, OSHA, in this section, establishes performance and specification requirements to address these hazards.

Paragraph (a) General

Paragraph (a) requires that during the final placing of solid web structural members, the load must not be released from the hoisting line until the members are secured with at least two bolts per connection, of the same size and strength as shown in the construction documents. The members must be drawn up snug tight or secured by an equivalent connection as specified by the project structural engineer of record. While reflecting § 1926.751(a) of OSHA's current steel erection standard, the proposal added the alternative provision, "or the equivalent as specified by the project structural engineer of record". This phrase was added to allow for alternative types of connections approved by the SER, such as welding or, in the case of heavier members, the use of more than two bolts.

In addition, the final rule allows only bolts of the same strength and size as shown in the erection drawings to be used in securing the member until the final connections can be made. This will prevent collapses caused by the use of lesser strength/size bolts.

This paragraph, as set out in the proposal, did not contain the reference to cantilevered members. While no commenters directly opposed the paragraph as proposed, one commenter (Ex. 206X; p. 55) asked OSHA to address cantilevered connections. OSHA agrees that cantilevered connections need to be addressed as they may require more than two bolts due to the different load angles placed upon them while executing a double connection. Therefore, a new paragraph (a)(2) has been added requiring a competent person to determine if more than two bolts are necessary to ensure the stability of cantilevered members, and that additional bolts be installed if necessary.

Paragraph (b) Diagonal Bracing

Paragraph (b) requires that solid web structural members used as diagonal bracing be secured by at least one bolt per connection drawn snug tight or secured by an equivalent connection as specified by the project structural engineer of record. In many cases, solid web structural members, such as channels or beams, are used as diagonal bracing or wind bracing. When used for this purpose, a one-bolt connection is sufficient. These members play a different role in erection stability than members used for other purposes since these members are designed to provide stability for the final completed structure and are not used as walking/working surfaces. Compliance with this provision will provide safe connections for these members. No comments were received addressing this paragraph and the final rule is issued as proposed.

Paragraph (c) Double Connections

A double connection is a type of attachment in which the ends of two steel members join to opposite sides of a central (carrying) member—such as a beam, girder or column web—using the same bolts. The erection process is as follows: the first member is bolted to a beam, girder or column web. Later, a second member is added to the opposite side of the existing connection. This second member is attached using the same bolts (going through the same holes) that are being used to attach the first member. To attach the second member, the nuts on the first beam's bolts have to be removed and the bolts backed most of the way out; the ends of the bolts have to be flush with the surface of the central member so that the second member can be lined up with the existing holes. Only fractions of an inch of the ends of the bolts are now preventing the first beam from falling. Once the holes in the connection plate of the second member are lined up with the first beam's bolts, the bolts are pushed back through all the holes and the nuts are put back on the bolts and tightened to secure the three pieces of steel together.

This maneuver is extremely dangerous. The process often takes place with a worker sitting on the first beam. If the first beam collapses, the worker falls. The risk of collapse is high because of the tenuous grip of the loosened bolts and the possibility that the connector's spud wrench, which is used to align the second (incoming) member, may slip. If at any time the carrying member (the central member to which the first and second members are being attached) reacts to residual stresses developed through welding and/or misaligned connections at lower elevations, the carrying member can move suddenly, causing the bolts or the spud wrench to become dislodged. The second (incoming) member can also cause problems if it bumps up against the fitting or wrench end. Additionally, crane operators, wind, structural movements and the connector straining to make a tough connection impose stresses that can lead to disengagement of the connection.

The current steel erection standard does not address this hazard. SENRAC believed that double connections are essential in some steel erection designs (63 FR 43471). SENRAC's analysis of NIOSH and BLS fatality statistics (Exs. 9–14, 9–39, and 9–42) indicated that structural collapses constitute a significant cause of steel erection deaths. SENRAC also concluded that failed double connections are a major cause of structural collapses. One commenter (Ex. 207X; p. 111) believed that the "engineering community" could accommodate a standard that prohibited employee exposure to double connections with a few exceptions. While the record indicates that designers can engineer structures with minimal use of double connections, it does not appear to be necessary to prohibit double connections since there are means available to perform double connections safely.

Testimony on behalf of SEAA (Ex. 203X; p. 77) that attachments such as seats are already being used in the field to eliminate the double connection hazard strongly supports the view that this is a feasible means of making these connections safe. OSHA believes that the severity of the consequences of a failed double connection warrant these provisions.

The Ironworkers International Union (Ex. 208X; p. 120) commented that the hazard associated with double connections is not a design problem that should be prohibited but is a safety issue and should be addressed in the standard like other things, such as stairs, that employees use on a regular basis. Huber, Hunt, and Nichols (Ex. 201X; p. 216) emphasized the frequent exposure of connectors to the hazards of double connections and that it has become something that the individual employee has to deal with in everyday connecting They assert that when a double connection is not properly executed, the resulting failure can lead to the immediate collapse of the entire structure, endangering the connector and every other worker on or around the structure.

A commenter (Ex. 207X; pp. 57–165) suggested that double connections be identified on the erection drawings so that erector recognizes where there will be difficult connections in advance and can assure that the appropriate devices are present to eliminate the hazard. OSHA believes that double connections are already commonly indicated on erection drawings.

Paragraph (c)(1) requires that when making a double connection, the first member must remain connected to a supporting member by at least one connection bolt at all times unless a connection seat (see definition) or equivalent connection device is supplied with the members to secure the first member and prevent the column from being displaced. This requirements is the same as proposed. At a minimum, one bolt must remain wrench tight in order to keep the first member from separating from the supporting member when the nuts are removed from the bolts that are to be shared with the second member. Appendix H is added to the final rule to provide examples of equivalent connection devices. They include "clipped end" and "staggered bolt" connections.

Steel Erectors Safety Association of Colorado (SESAC) (Ex. 13–207) suggested that the provision cover all double connections, including the installation of floor beams in the web of a beam not over a column. OSHA is deferring to SENRAC expertise that it is not necessary for this provision to address floor beam (filler beam) connection hazards. SENRAC noted that the connector does not have to sit on the floor beam when making floor beam

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type of double connections—the connector can sit on the header beam to which the other members are being attached. Also, the structure is much more stable by the time floor beams are ready to be installed.

Several commenters, such as FABCO (Ex. 13–21), described ways of minimizing the double connection hazard by maintaining the one bolt connection throughout the connection process. OSHA agrees that there are methods of engineering a connection point that maintain the one bolt connection requirement of paragraph (c)(1). The staggered bolt method and clipped end connection method are two ways of maintaining the one bolt connection at all times, and do not require the use of any of the alternative methods listed under paragraph (c)(1). These two methods are described in Appendix H.

A commenter (Ex. 13–207) suggested that we include a graphic to show the clipped connection as an example of how to comply with the "one bolt in place rule". Diagrams are included in Appendix H to show an illustration of a clipped end and a staggered bolt connection. Methods like clipped end and staggered bolt connections were discussed during the hearing and in comments but were not directly addressed in the proposed standard. The record shows that these are relatively simple and safe methods of engineering out the hazards presented by double connections.

The National Council of Structural Engineers (Ex. 13–308) suggested that we change "wrench-tight" to "snug-tight" because, they argue, the latter is a known and defined term in the steel erection industry. However, wrench-tight is a term that is consistent with 1926.751(a) of the current steel erection standard. Wrench-tight is also the term recommended by SENRAC , and OSHA defers to SENRAC on this issue

The proposed standard stated that at least one bolt with its wrench-tight nut had to remain connected to the first member unless an attached seat or similar connection device "is present." That phrase has been changed to "is supplied with the member" to make it clear that the member must come with the device in order for the erector to be permitted to erect it.

The Steel Erectors Association of America (SEAA) (203X; p. 18) strongly supports the requirement to have seats for double connections because of the historical evidence that collapses occur from the failure of inadequately secured bolts and connection work done on semi-stable structures. The Safety Advisory Committee of the Structural, Ornamental, Rigging, and Reinforcing Steel Industry (205X; p. 328) also thought this was a simple solution to a very big problem.

The record does not include any persuasive evidence to oppose the use of a connection seat to increase the level of safety in making a double connection. However the majority of the debate was in reference to the provision in the proposal that stated: in a double connection, there must be either "a shop-attached or field-bolted seat or similar connection device present * * *". The testimony of SENRAC members and AISC panels indicated that there is disagreement as to whether the seats need to be shop-attached, or if a field-attachment should be permitted if there is no shop attached seat.

Some commenters, however, interpreted the proposed standard to allow only shop-attached or field-bolted seats. Under these options, the fabricator would have to either attach the seats itself in the shop or provide holes in the members for the erectors to bolt the supplied seats on in the field.

For example, the American Institute of Steel Construction (AISC) (Ex. 13–209) believed that the proposed paragraph required the attachments to be bolted to the beam and prohibited other field attachment methods like welding or clamping. They would like other methods of adding a seat to be available such as, clamping, welding, and similar positive attachment methods. Also, the Metal Building Manufacturers Association (MBMA) (Ex. 207X; p. 244) indicated that a determination by erectors in the field would be the most efficient method of complying with the standard.

On the other hand, SEAA (Ex. 203X; p. 75) believes the seats should be attached in the controlled environment of a fabrication shop. SEAA testified that while they use extra holes and clips in most of their jobs, a shop-attached clip would be greatly preferable. The SENRAC panel addressing anchor bolts, double connections, and specificity on plumbing-up (Ex. 208X; p. 108) testified that even though the placement of extra holes where double connections occur has been a standard engineering practice in 1964, the hazards that occur during double connections have not been eliminated. The panel (Ex. 208X; p. 206) also had no confidence in "seat clamps" and engineering clamps due to the unpredictable loads on the beams. The language "supplied with the member" has been substituted for "is present" to better reflect SENRAC's and OSHA's intent that the member arrive at the site along with the unattached seat placed on the member in close proximity to where the double connection is to be made on the member. If the seat does not accompany the member to the site, then there is no guarantee that the erector will know that it needs to field attach the seat before making the double connection. Many commenters, including the SENRAC panel and SEAA, were concerned that both the clamps and the unattached seats would end up stored in trailers or in places other than where double connections are being made. Another commenter (Ex. 203X; p. 76) was confident that if the fabricators needed to attach the seats to the beams, the chances that they would be in place during the erection process would be much greater than if the responsibility were left up to erection supervisors.

Some erectors argued in favor of a requirement to shop-attach the seats because they would have too many seat installation methods to deal with on different jobs, they contend that it will be confusing and inefficient for them to try to figure out how to install the seats in each case. Erectors also thought that it would be easier and less time consuming for them to erect steel safely if the fabricators were to install the seats in the shop.

Those who opposed the shop-attached seats, such as the Metal Building Manufacturers Association (MBMA) (Ex. 207X; p. 244) and Basic Metal Products (Ex. 13–245), stated that there are many other devices that are available to erectors to use for the many difficult connections that they have to face. The phrase in the proposed standard, "or similar connection devices," meant that methods other than "field-bolted or shop-attached seat" are permitted. While bolting the attachment to the member is the preferred alternative method, it was not the intent of the proposed standard to prohibit other, equally effective methods. OSHA agrees that equivalent devices supplied with the member are acceptable and provides illustrations of such devices in Appendix H.

The final rule incorporates several clarifications. First, in paragraph (c)(1), the proposed phrase "similar connection device" has been changed to "equivalent connection device" to clarify that devices other than a shop attached or field bolted seat are permitted, as long as they provide equivalent protection. OSHA did not intend that the alternative "device" had to physically resemble a "seat" as implied by the term "similar". "Equivalent connection device" requires that the function of the device must mirror that of a seat and be equally effective.

Secondly, the term "field-bolted" has been changed to "field-attached" to clarify that other attachment methods, such as welding, is permitted.

Haven Steel (Ex. 206X; p. 22) asserted that OSHA does not have jurisdiction to mandate product specifications and designs over which the parties affected by the rule had little or no input. They argued that the standard should put more emphasis on the actions of the steel erector and its employees. Commenters opposing the provision were not necessarily opposed to using an attachment to secure double connection members but were opposed to requiring the manufacturers and designers to shop-install the attachments for the erectors.

Some commenters (Exs. 13–320, 13–21, and 207X; pp. 57–65) argued against both drilling holes in the members for attachments and welding the attachments because of the possibility that some structural integrity of the beams may be lost. The argument against drilling holes for attachments is the same as the one against drilling holes in columns for attaching perimeter cables in § 1926.756(f)(3) of the proposed standard. When holes are drilled in members, they argued, it may require the use of heavier, more expensive, members where they would not otherwise be needed. FABCO (Ex. 13–21) testified that putting holes in the flanges could weaken the flanges unless heavier, more expensive members were used. The Council of American Structural Engineers (Ex.13–320) added that damage may occur due to welding attachments to the columns without proper preheat and that adding holes to members that were not designed to accommodate them could degrade the structural integrity of the member. However, there is no indication in the record that the industry could not engineer in holes or weld on attachments for safety devices for the erection process, just as it routinely accommodates public safety requirements and specifications. Since double connections are a part of the design of the structure, those designing the members would know if they needed to pre-engineer additional holes for a seat or to specify a welded attachment.

OSHA acknowledges that as with other aspects of structural design, incorrect procedures and calculations when drilling holes or welding attachments could reduce the structural integrity of lightweight beams. However, the hazards of double connections made without the safeguards in this standard are great and are acknowledged by most industry experts. Alternatives to installing seats are not to use double connections at all, or to maintain the connection of one bolt with its nut "wrench tight". Certainly, in a worst-case scenario, concerns about "structural integrity of beams" can be quelled merely by using heavier members, as noted above. OSHA concurs with SENRAC on its conclusion that requirements in paragraph (c) are necessary to reduce the well acknowledged hazards of performing double connections, and that they provide considerable flexibility for compliance.

Paragraph (c) of the proposal allowed the use of a seat if the one bolt connection requirement could not be met. A commenter (Ex. 206X; p. 62) feared that erectors would use seats to temporarily connect beams until they could maneuver other members in place, therefore increasing the probability of a collapse. Temporarily connecting the bolts for the seats may invite the erector to not install the final connection bolts until large portions of the structure are ready to be plumbed up and bolted.

Paragraph (c)(2) in the final rule does not permit such a practice. It requires the erector to secure a seat (designed to support the load) to both the supporting and first members while the double connection is being made. The function of the seat is to provide support to the members until the double connection can be safely connected. Connecting the first member to the supporting member with the seat is a crucial step in making these double connections safely, since one of the dangers is that either the supporting member or the first member will be bumped or will pull away during the double connection process. The connection seat is only intended to facilitate that particular double connection.

Paragraph (c)(2) also explicitly requires that seats or equivalent devices must be designed to support the load during the double connection process. If these devices are to be used, they have to be capable of supporting the weight of the members involved; and that weight may vary significantly from job to job. The erector may not know what the magnitude of the loads are in time to have devices engineered and fabricated for the job. It is more efficient to incorporate this engineering determination into the design of the members and connections.

Some commenters, such as (Ex. 206X, p. 173), believed that it should be solely the erector's responsibility to devise a method in which to keep its employees safe by securing the steel frame of the structure. They also argued that § 1926.754(a) requires structural stability to be maintained at all times. They also point to section 7 of the AISC Code of Standard Practice as support for their position.

Under the AISC Code of Standard Practice indicates that the industry currently recognizes that it is the responsibility of the erector to stabilize the working platform of its employees. However, this does not mean that the best way to ensure that the double connection is made safely is to rely solely on the erector to make whatever arrangements it thinks are necessary. The testimony of the SENRAC members established (Ex. 208X, p. 205) that it would be unrealistic to expect most erectors to have in-house personnel who could make the technical engineering assessments necessary to determine whether a particular device would be capable of supporting the loads during a double connection. In their view, requiring that the device be supplied with the member will provide greater assurance that the device is capable of supporting the loads. The erector does not have the ability to ascertain if a column could accept additional holes or welding, nor the ability to control the column's design.

AISC (Ex. 13–209, attachments 4&5) suggested that OSHA add the phrase "where constructibility allows" because there are some instances, which they identified, where they believe seats or attachments will not work. Similarly, Unified Steel Consensus Group (Ex. 13–63) suggest the following addition: "Where structural design and constructibility does not allow for a shop attached connection device, it shall be noted on the erection drawing and the erector shall adequately brace and support the structural member to prevent movement before nuts are removed from the double connection and the double connection is completed."

The record shows that an exception that would permit double connections to be made without the specified safety precautions is neither necessary nor appropriate. The final rule permits an "equivalent" connection device to be supplied with the member.

Paragraph (d) Column Splices

Paragraph (d) requires that each column splice be designed to resist a minimum eccentric gravity load of 300 pounds (136.2 kg) located 18 inches (.46 m) from the extreme outer face of the column in each direction at the top of the column shaft. This paragraph has been revised to be consistent with final rule § 1926.755(a)(2) (anchor rods/bolts) and to further clarify the type and

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location of the eccentric gravity load. This requirement, along with the requirements in § 1926.755(a)(1) and (a)(2) for anchor rods/bolts, will help to stabilize columns that employees have to climb during the erection process. By specifying requirements for certain key building elements, such as anchor bolts, column splices, and double connections, the standard will prevent structural collapses. This section specifies a minimum force that a column splice must withstand without failure before an employee is allowed to climb it. There were very few objections to these provisions.

The Council of American Structural Engineers (Ex. 13–320), AISC (Ex. 13–209), and Basic Metal Products (Ex. 13–245) had concerns about OSHA prescribing design specifications. They believe that the standard should not specify means, methods, or location with respect to column splices—that such requirements may compromise the structural design or seriously affect architectural finishes.

OSHA believes that it is as appropriate to require building components to meet the safety needs of those constructing a building as it is to require a completed structure to meet the safety needs of its occupants. A well established principle of occupational safety and health is that eliminating or reducing a hazard by modifying the design of whatever is posing the hazard is the preferable method of controlling a recognized hazard. OSHA anticipates that by ensuring that column splices are designed to withstand a 300 pound eccentric gravity load, the hazard of collapse due to the instability of the column should be virtually eliminated. This minimizes the number of columns that an erector will need to stabilize before employees climb them. A SENRAC workgroup, with engineering assistance, determined that 300 pounds was an appropriate load. In addition, the 300 pound eccentric gravity load is the same design criteria that is required for column anchorages in § 1926.755(a)(2).

The record does not indicate that this requirement presents significant obstacles to designers with respect to their choice of exterior finishes. Nor does it show that it would be difficult to accommodate the requirements in the structural design.

Paragraph (e) Perimeter Columns

Paragraph (e)(1) of the final rule prohibits the erection of perimeter columns unless the column extends a minimum of 48 inches (1.2m) above the finished floor to permit installation of perimeter safety cables prior to the erection of the next tier, except where constructibility does not allow. Final rule paragraph 1926.760(a)(2) requires that the perimeter safety cables be installed at the final interior and exterior perimeters of the structure's finished floors of multi-story structures as soon as the decking has been installed. When the safety cables must be attached to the perimeter columns, the columns must be at least 48 inches above the finished floor in order for the perimeter cable system to comply with the requirements of Subpart M. Paragraph § 1926.760(d) requires that perimeter safety cable systems conform to the criteria for guardrail systems in § 1926.502.

Some commenters (Exs. 13–320; 13–245; 13–209, p. 19) argued, as with section 1926.756(d), that OSHA has no jurisdiction to put design restrictions on the engineering community. Although they contended that would limit their flexibility in structural design and in the materials they use, they did not specify how their design capability would be impaired. American Bridge Co. (Ex. 206X; p.55–56) suggested that it was more appropriate to place an obligation on the contractor and erector to ensure that "the cable [is] 42 to 45 inches above the working surface and sufficiently anchored to withstand a horizontal force of X amount of pounds at a point 45 inches above the working surface."

OSHA is convinced that the industry can accommodate this requirement. As noted, no commenter submitted details on the extent of design impairment or examples of the projected negative effect of this requirement. It is appropriate for OSHA to require the engineering of safety elements into the design of perimeter columns if they provide support for a fall protection system. Paragraph 1926.760(a)(2) requires perimeter cables to be installed on multi-story buildings as soon as the decking is completed. OSHA agrees with SENRAC's conclusion that the presence of holes or attachments on the columns facilitates the erection of the cables therefore minimizing the installers' exposure to a perimeter fall. OSHA also agrees that columns are an appropriate and often-used support for the perimeter safety cable.

Paragraph (e)(2) requires that the perimeter columns have holes or other devices in or attached to them at 42–45 inches above the finished floor and the midpoint between the finished floor and the top hole to permit the installation of perimeter cables, except where constructibility does not allow. This allows the erector to install the cables promptly when the columns have been erected.

A commenter (Ex. 206X; pp.67–68) believed that by specifying the method of erecting perimeter cables, the industry is denied the opportunity to negotiate language in its contracts. The general contractor has no reason to include any language to protect the fabricator because it knows the OSHA regulation requires the fabricator to make the holes or attachments available to be utilized by the erectors. The fabricator has no control over the system's installation, condition, maintenance, or use and subjects the fabricator to lawsuits regarding any accident involving the perimeter safety cable systems.

Fabricators and engineers also argued that the proposal impermissibly regulates employers beyond the steel erection industry by requiring fabricators to install holes or attachment points. Some fabricators testified that this section would limit their flexibility in engineering a structure. Grewe Jenkins Design & Construction Company (Ex. 201X; p.17) stated that by requiring a shop to attach bolts or holes, it would be limiting the methods and means by which an employer may protect its employees from perimeter falls. They also argued this requirement may necessitate regulations for the design of the different types of attachments that fabricators and engineers may use. The American Institute of Steel Construction (Ex. 13–209) objected to OSHA prescribing how to manufacture its product.

A commenter representing AISC (Ex. 206X; p. 59) testified that fabricators do not control the erection sequence and schedule of placement of structural steel elements which is set forth on contract documents. Neither do they dictate, he argues, how steel erectors will utilize the holes and attachments that they are required to provide. In his view, the fabricator assumes liability because it would be difficult to defend litigation regarding system failure: (a) If they cannot be assured that it will be erected and maintained properly, and (b) if they have no prior knowledge of where and how the members with the holes or attachments are going to be installed during the erection sequence. AISC believed that this provision would make fabricators liable for any failure of the perimeter cable system, including the incorrect field installation of attachments. They assert that this would be unfair since they have no control over how the cables are installed or maintained. Hagerman Construction Corporation (Ex. 13–224) commented that additional staff would be needed and the cost of liability insurance would skyrocket. These combined factors, they argue, could help to drive up the price of the steel members.

OSHA requires that holes or attachments for erecting perimeter cables are on or in the perimeter columns before the steel can be erected because it believes that it is appropriate to engineer safety components into a structure just as public safety specifications are adhered to in the drafting stage of a structure.

The proposed provision, paragraph (e)(3), stated that holes or devices "shall be provided by the fabricator/supplier and shall be in or attached to perimeter columns * * *". OSHA has revised this provision to make clear that, in addition to requiring that the columns have holes or devices, the erector may not erect perimeter columns, unless the columns comply with paragraph (e)(2). In final paragraph (e)(2), the erector is prohibited from erecting the perimeter columns in the absence of the holes or attachments.

SENRAC and OSHA agree that getting the perimeter safety cables erected properly and promptly will help to reduce the number of falls to the exterior of the building. This provision not only affects steel erectors but other trades that follow them in the construction sequence of the building. Incorporation of the perimeter system into the design of the structure enables all trades to be protected against perimeter falls most quickly and effectively.

Some commenters were not convinced that providing the erectors with attachments will help to aid in the erection of perimeter cables. Southern Iron Works (Ex. 206X; p.107) asserted that they have often provided steel erectors clips that the erectors did not use. Since the proposed standard did not expressly require the erector to use the holes or attachments supplied by the fabricator, they argued that the fabricator may needlessly incur this expense.

While the standard does not require the erectors (or any other trade) to use the holes or attachments, it does require the installation of perimeter cables (see § 1926.760). OSHA assumes that the installer of the perimeter cables will use the holes or attachments because that will be easier then the option of installing stanchions to support the cable.

An erector representing the Steel Erectors Association of America (SEAA) (Ex. 203X; pp.73–74) testified that it is common for holes/attachments to be included in contract requirements through negotiation. He stated that he had holes drilled in columns on 90% of his jobs, and that fabricators have been providing them for 5 years for projects in his area. A general contractor (Ex. 203X; p.168–169) decided that it made more sense to use holes/attachments, since using the columns does away with the need for installing stanchion posts. SEAA stated that if holes/attachments were required by regulation, steel fabricators would comply with little or no economic damage to the industry because all steel erection projects would have to follow the same rules. Erectors and fabricators are presently negotiating these sort of safety measures into their contracts.

The steel erection industry already meets a variety of architectural and public safety needs, and designs and manufactures structural components so precisely as to locate holes and calculate loads for every nut and bolt. OSHA is confident that this industry can also arrange to have these holes/attachments in perimeter columns. These holes and/or attachments will make the construction of the structure safer for the employees that have to use it as a work platform. Commenters in opposition to requiring holes and/or attachments gave no explanation in the record as to why this requirement would make it more difficult to design or produce columns.

The claim that holes/attachments would affect architectural finishes was similarly unsubstantiated. Even if there were some instances where that would be a problem, the final standard includes an exception where constructibility does not allow them to be installed.

FABCO (Ex. 13–21) stated that putting holes in the flanges could "cripple" the strength of the flanges unless heavier, more expensive members were used. They suggest that perimeter cables be supported by an engineered, temporary clamping device of the erector's design or, at the erector's option, by making additional holes or using shop-installed column attachments.

OSHA acknowledges that a hole in the flanges of a column could compromise the structural design of the structure, especially if the column is part of a "moment resisting" frame. "Crippling" may occur when the web is subjected to high compressive stresses from concentrated loads and/or reactions. Failure by fracture could also occur under some circumstances. However, the claim that the holes/attachments may compromise the structural design assumes that the holes would be installed only after the column was already designed, without regard to the need to accommodate the holes. However, it is clear that from an engineering standpoint, the effect of holes (or attachments) on the strength of columns needs to be factored into the structural design. The evidence that was introduced to show why that could not be done was not convincing. While in some instances larger columns might be necessary to accommodate holes, information on the number of those instances was not submitted to the record. It should be noted that holes are not required if constructability does not allow, and that the provision allows the installation of attachments instead of holes.

AISC (Ex. 13–209) stated that attachments could get damaged or cause stacking problems in stockyards. FABCO (Ex. 3–21) indicated that they could get knocked off while being delivered. While these comments indicate that more care would have to be taken, these are not particularly difficult problems to overcome. Some steel components already have angles and other protruding attachments.

Perimeter cable holes can be engineered into the original design of the columns as any other hole would be. At times, perimeter columns must be strengthened to compensate for drilling a hole in a structural member, adding cost to the process. However, OSHA believes that those instances will be minimal in comparison to the number of columns that currently are able to accommodate perimeter cable holes.

E–M–E Steel Erection Company (Ex. 202X; p.31) testified that they currently weld nuts to columns while others use washers in the field. They think that having holes put in the columns will cost a few dollars more but that they are worth the extra cost. In addition, the costs must be considered in the context of the lives that can be saved by both the fall protection afforded by the perimeter cables and by the speed in which they may be erected, which will greatly reduce employees' exposure to fall hazards while installing the cables.

The physical criteria that the perimeter cables must meet are found in § 1926.760(d)(3). That section references § 1926.502, and Appendix G repeats that section to assist employers and employees.

Section 1926.757 Open Web Steel Joists

Some of the most serious risks facing the ironworker are encountered during the erection of open web steel joists, particularly landing loads on unbridged joists and improperly placing loads on joists. Based on an analysis of ironworker fatalities from January 1984 to December 1990 OSHA determined that of the approximately 40 fatalities caused by collapse, more than half were

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related to the erection of steel joists (Ex. 9–14A). Although the existing OSHA steel erection standard addresses joist hazards in a limited manner, this final rule section significantly increases protection from the most hazardous activities during joist erection. The Agency believes that the combination of specification and performance requirements in this section will provide more comprehensive protection to workers engaged in these activities.

Paragraph (a) General.

Paragraph (a) of the final rule provides general requirements for the erection of steel joists. To make the requirements of paragraphs (a)(1) through (a)(5) of the proposed rule more understandable, OSHA has reorganized them in the final rule. The requirements that relate to stabilization of the joist attached at a column are contained in paragraph (a)(1). Those joists that do not, for design reasons, attach at the columns are addressed in a new paragraph (a)(2). Paragraphs (a)(3) and (a)(4) address conditions that apply to joists that attach either at or near the columns.

Paragraph (a)(1) requires that where steel joists are utilized, and columns are not framed in at least two directions with solid web structural steel members, a steel joist (commonly referred to as the "OSHA joist," see explanation below in the discussion of paragraph (a)(1)) must be field-bolted at the column except as provided in paragraph (a)(2) of this section which addresses these joists installed near the column. This paragraph is nearly identical to the existing steel erection standard provision, § 1926.751(c)(1). The final rule paragraph (a)(1) differs from the proposed paragraph (a)(1) in that it does not contain the phrase "or near" when describing the location of the joist in relation to the column. The SJI (Ex. 13–208) suggested deleting this language in paragraph (a)(1) and treating joists installed near the column separately because of feasibility considerations. The purpose of the stabilizer plate, required by paragraph (a)(1)(i) of this section, is to provide stabilization and prevent rotation of the extended bottom chord of the joist required by paragraph (a)(1). The Agency agrees with SJI that when the joist is not located directly at the column, it is not possible to stabilize the bottom chord using a stabilizer plate on the column, and some other means of stabilizing the bottom chord must be provided. Therefore, paragraph (a)(2) has been added to the final rule to address the situation where a steel joist attaches near, but not at, the column. SJI also suggested deleting the language, "to provide lateral stability to the column during erection," which describes the purpose of bolting the joist. SJI argues that joists are not designed to do this but simply to support a uniform load. Nonetheless, this language comes from the existing standard and SENRAC believed it to be an accurate description of an additional function of this joist, whether designed for this purpose or not. Accordingly, the final rule retains this language requiring lateral stability during erection.

Final rule paragraphs (a)(1)(i) through (a)(1)(iii) refer to special requirements for joists connected at the column. Paragraph (a)(1)(i) is virtually identical to paragraph (a)(4) of the proposed rule. It requires a minimum 6-inch by 6-inch vertical stabilizer plate to extend at least 3 inches (76 mm) below the bottom chord of the steel joist. The plate is required to have a $^{13}/_{16}$ inch (21 mm) hole placed in it to provide an attachment point for guying or plumbing cables. The SJI (Ex. 13–208) suggested language to better describe the stabilizer plate. They noted that for the stabilizer plate to function as intended, the plate would need to have a minimum length and width of 6 inches and be oriented vertically so that the bottom chord of the joist will straddle the plate. Bottom chords of joists are essentially two angle irons placed back to back with steel webbing welded in between into triangles. The space created between the angle irons by the webbing is large enough so that the bottom chord, when extended to the column, can straddle the stabilizer plate, thus preventing the OSHA joist from rotating. OSHA agrees that these changes would improve the requirement. Paragraph (a)(1)(ii) works in conjunction with paragraph (a)(1)(i) and requires that the bottom chords of steel joists at columns be stabilized to prevent rotation. This provision largely carries forward the language of proposed paragraph (a)(5). The SJI (Ex. 13–208) commented in support of this provision stating that it "* * * clarifies and reiterates the need to prevent horizontal axis rotation of joists and joist girders during erection."

The foregoing provisions will result in a more stable primary structure upon which to erect the remaining steel joists in each bay. Since the sequence of guying is essential to safety, a stabilizer plate provides a ready attachment point for more efficient guying, thus helping to prevent collapse as the steel is set in place.

Final rule paragraph (a)(2) attempts to clarify the proposed rule by addressing the situation where the joist required by paragraph (a)(1) of this section does not attach at the column but, rather, near the column. Two commenters (Ex. 13–208 and 13–153) suggested that the standard address this situation. It was noted by a commenter (Ex. 13–153) that this can occur at expansion joints, unequal bay spacing and non-rectangular buildings. The Agency agrees with the commenters and recognizes that the proposed rule paragraphs (a)(1) and (a)(5) could not apply unless the joist or joist girder were attached at the column. Since the joist or joist girder cannot always be attached at the columns (due to design constraints), this paragraph provides a means to ensure that the joist nearest the column, (that serves the same purpose as a joist at the column) is as stable as a joist that is attached at the column.

The Agency believes that the clarification referred to above is necessary due to the feasibility and sequencing complications that arise when OSHA joists are not attached at the column. For example, attaching a stabilizer plate to a column is much simpler than providing the same plate on a narrow solid web beam or a steel joist girder. In addition, since the sequencing of erection of the structure is frequently not known beforehand, the erector needs to stabilize the bottom chord of the OSHA joist on both sides of the column. This is necessary because erection could begin at either end of the column line as dictated by conditions at the site at the time of erection.

Accordingly, final rule paragraph (a)(2) requires that where constructibility does not allow the steel joist to be installed at the column, an alternate means of stabilizing joists must be installed on both sides near the column. Such alternate means must provide stability equivalent to OSHA joists attached at the column; be designed by a qualified person; be shop installed; and be included in the erection drawings. OSHA believes that, even though OSHA joists are attached to the column the overwhelming majority of the time, workers need to receive the same protection from collapse when the OSHA joist is attached near the column. Thus, the alternate means of stabilization must be considered and planned in the early stages of design and material preparation.

An additional protection that was intended by SENRAC but not specifically referred to in the proposal had to do with the release of hoisting cables for OSHA joists. The Committee addressed timing of the release of hoisting cables for all joists other than OSHA joists in § 1926.757(d). Seeing the need for clarification, SJI recommended

language addressing the release of hoisting cables from the OSHA joist (Ex. 13–208). Accordingly, both final paragraphs (a)(1) and (a)(2) of this section require that hoisting cables not be released until the seat at each end of the steel joist is attached and the joist is stabilized. For OSHA joists that are field-bolted at the column, paragraph (a)(1)(iii) prohibits hoisting cables from being released until the seat at each end of the joist is bolted and both ends of the bottom chord of the joist are restrained by the stabilizer plate. In addition, for OSHA joists installed near the column, paragraph (a)(2)(ii) prohibits hoisting cables from being released until the seat at each end of the joist is field-bolted and the joist is stabilized.

Paragraph (a)(3) (proposed paragraph (a)(2)) requires that a steel joist (OSHA joist) at or near the column that spans 60 feet or less be designed with sufficient lateral stiffness that the joist does not need erection bridging to maintain its stability when an employee goes out onto it to release the hoisting cable. Since the joist at the column is the OSHA joist and is either the first joist in place or the joist that boxes the bay, there is no other joist in place nearby for the erector to attach erection bridging. Therefore, without this provision, compliance with the final rule's bridging requirements would be infeasible for an OSHA joist. Consequently, the OSHA joist itself must possess sufficient lateral stiffness to allow the erection process to progress safely. One comment (Ex. 13–208) was received in support of the requirement. The commenter felt that the need to design and manufacture heavier joists for placement at columns is reasonable to insure the safe placement of these critical OSHA joists.

Paragraph (a)(4) of the final rule (proposed paragraph (a)(3)) addresses a longer steel joist at the same position. This provision requires that steel joists located at or near the column that span more than 60 feet must be set in tandem, i.e., two steel joists must be attached together, usually with all bridging installed (both bolted diagonal erection and horizontal bridging). These larger OSHA joists are commonly used in open structures such as warehouses, gymnasiums and arenas. This provision also allows the use of alternate means of erection of such long span steel joists, provided that the alternative is designed by a qualified person to ensure equivalent stability and is included in a site-specific erection plan. This paragraph is effectively the same as proposed paragraph (a)(3) except that "or near" was added as explained above. According to SJI (Ex. 13–208), joists tied together with standard bridging will not possess sufficient stability to serve as a working platform in all cases. However, both the proposed rule and the final rule require that the erector install all bridging (not just erection bridging) when these long joists are set in tandem as OSHA joists.

Compliance with these provisions should help to satisfy the stability requirements of paragraph (a)(5) of this section (proposed paragraph (a)(6)). Paragraph (a)(5) prohibits the placement of steel joists or steel joist girders on any support structure unless it has been stabilized. This is essentially the same as proposed paragraph (a)(6) but it has been revised to include steel joist girders along with steel joists. This language change was recommended by SJI (Ex. 13–208). They also commented in support of the requirement by stating that this paragraph to stabilize joist support structures is one of the best elements of the steel erection standard and will substantially enhance worker safety in steel erection. OSHA agrees that the provision needs to include steel joist girders for consistency since they are also connected to the support structure.

Another commenter (Ex. 13–210) indicated that the term "stabilized" is open to interpretation and should be defined. OSHA disagrees and feels that the requirements in paragraphs (a)(1) through (a)(4) of this section together with provisions in several other sections of the standard adequately set out the stability requirements for the structure without the need to define "stabilized".

Paragraph (a)(6) (proposed paragraph (a)(7)) of the final rule addresses the hazard that arises when a single steel joist or a bundle of joists are placed on the structure and then left unattended and unattached. An example of this might involve lighter steel joists, under 40 feet in length, that would not require erection bridging under this section. A common practice in erecting these lighter joists, which can be set in place by hand, is to have a crane set the columns, steel joist girders, or solid web primary members and bolted joists at the columns as required by paragraph (a)(1) of this section, thus boxing the bays. The crane would then place a bundle of filler joists at an end or, more likely, at the center of the bay for installation by hand, and then move on to the next bay. Because cranes are among the more costly pieces of equipment on a steel erection job, minimizing crane time at the site is cost effective. This provision requires that, when steel joists are landed on structures, they be secured to prevent unintentional displacement, *i.e.*, the bundles must remain intact prior to installation until the time comes for them to be set. This paragraph also prevents those ironworkers who are shaking out the filler joists from getting too far ahead of those workers welding the joists, a practice that leaves many joists placed but unattached. Paragraph (b)(3) of this section, discussed below, requires that at least one end of each steel joist be attached immediately upon placement in its final erection position and before additional joists are placed. Another example of a situation addressed by this paragraph is if the exact dimensions of a piece of mechanical equipment to be installed in the decking are not known. A common practice, when this occurs, is to leave a joist unattached until the dimension is known. This paragraph requires such a joist to be secured (probably to the support structure or an attached joist) pending its final attachment. One comment was received by SJI (Ex. 13–208). SJI supported this provision stating that it "* * * will greatly reduce accidental displacement caused by striking the bundles while placing other construction materials." This paragraph is substantively unchanged from the proposed rule.

Paragraph (a)(7) of the final rule (proposed paragraph (a)(11)) addresses the potential for failure that can occur when a steel joist or joist girder is modified from its original manufactured state. As reflected in the proposed rule, the Agency believes modifications to joists can have disastrous consequences if performed by jobsite personnel without taking into account the design characteristics of the joist or joist girder. This provision prohibits modification without the prior approval of the project structural engineer of record. The only change to this provision from the proposed rule is the inclusion of steel joist girders for consistency since neither joists or joist girders should be modified without SER approval. This language change was recommended by SJI (Ex. 13–208).

Final rule paragraph (a)(8)(i) requires that, except for steel joists that have been pre-assembled into panels (panelized), connections of individual steel joists to steel structures in bays of 40 feet (12.2 m) or more shall not be made unless they have been fabricated to allow for field bolting during erection. This means that both the joists and the supporting member must be fabricated with holes to allow the joists to be bolted to the supporting structure; otherwise they are prohibited from being erected. Final rule paragraph (a)(8)(ii) requires that, unless

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constructibility does not allow, these connections must be made by field bolting.

These paragraphs replace paragraph (a)(8) of the proposed rule, and have been modified to require that the holes in the joists be used for the connection of the joists and to allow for welding of the joists in situations where constructibility will not permit the joists to be bolted. As reflected in the proposed rule, the Agency has found that many long steel joists that are placed in bays of 40 feet or more have a greater tendency to twist or rotate, which creates hazards for the workers installing them. This finding was based on several examples of hazardous situations that steel erectors encounter when working with these long joists. The record shows that certain joists that are thin and flexible can be difficult to install because of their "sweep" (tendency to bend). Bolting these types of joists first allows straightening of the joist, correcting its camber and eliminating torque. Additionally, after bolting, final welding can be more easily accomplished. Bolting is safer whenever unattached joists could be displaced by wind or construction activity, by the movement of employees, by trailing welding leads, by accidental impact against the supporting structure by a crane or other equipment, or by harmonic motion, or vibration. Further, joists can roll and pop welds due to the movement of a worker on the joist or the stresses caused by removing the sweep, which could cause a collapse. Finally, there are unique hazards associated with welding. These include impairment of the vision and balance of an employee working at elevation while wearing a welding hood.

Many comments were received in response to proposed paragraph (a)(8). These comments fell into three major groups. In the first group of comments, the commenters claimed that holes for bolting joists were not needed because: (1) Welding joist ends [instead of bolting] is not dangerous; (2) there are no data supporting a need for the requirement; and (3) the holes will have to be drilled, but bolting was optional, many of the holes would not be used by the erector. Consequently, they claimed, millions of unused holes would be needlessly drilled. They contended that welding is really a safety concern, in this situation OSHA should require that the holes be used.

Addressing the first and second issue of this group, several commenters stated that welding joist ends is not dangerous and there are no statistics to support the need for the requirement. They contended that the assumption that welding joist ends is more hazardous than bolting is not supported by industry data. Specifically, some commenters referred to a Steel Joist Institute (SJI) study of 100 accidents involving steel joists over a 14 year period which showed that none were a result of welding joist ends. Some commenters also referred to OSHA IMIS data reviewed by both OSHA staff and a SENRAC workgroup (Exs. 9–14A and 9–42) showing no fatalities related to joist end welding over the seven and eleven year periods, respectively. Two commenters (Ex. 13–9 and 13–18) stated that, based on their experience, they had never heard of or witnessed an accident related to welding of joists. The Steel Joist Institute (Ex. 66), referring to the SENRAC meetings, comment period and public hearing, stated "[n]o data was produced which suggests that bolting is inherently safer than the welding of joist ends to their supporting members."

OSHA's accident data do not cast any light on whether welding of joist ends is a hazard. These data in many cases do not provide enough detail as to the role of welding in the reported accidents involving joists.

Addressing the third issue of this group, numerous commenters asserted that the proposed rule would require millions of holes to be drilled or punched, most of these holes would not be used since the proposal did not require that these members be bolted. These concerns become moot since the final rule does require that the members be bolted unless constructibility does not allow. Eleven commenters specifically stated that, since the requirement would be optional, erectors would most likely choose not to use the holes. One commenter in particular (Ex. 13–158) stated that "[i]t is apparent that this provision would cause joist manufacturers and steel fabricators to punch or drill millions of unnecessary holes every year." Several other commenters (Exs. 13–21, 13–25, 13–97, 13–186 and 13–279) also suggested that millions of holes will be drilled or punched and will not be used. One commenter (Ex. 13–290) stated "* * * these connections would not be used especially since they are optional." Another commenter (Ex. 13–144) responded "[t]he only significant effect of this new requirement is increasing the cost of fabrication of steel girders." and "* * * it only requires manufacturers to provide the holes in the girders. The proposed rule does not require the steel erectors to actually use the holes." A commenter (Ex. 13–309) stated they believe that "* * * this rule will add cost to fabrication of joists and that the bolted connections will not be used by steel erectors in the field." Metro Fabricators, Inc. (Ex. 13–62) responded "[d]ue to the additional cost involved in bolting each joint, our erectors (subcontracted) have indicated that they would elect not to use the bolted procedure." As indicated above, the final rule requires that the holes be used and the connections be made by field bolting unless constructibility does not allow.

In the second major group of comments, commenters claimed that bolting is more dangerous than welding because: (1) Erectors will install erection bolts and then replace them with high strength bolts. To do that the surface will have to be prepped in accordance with AISC. Or, if the designers require a final weld, the erector will have to come back to weld, doubling the connection time and increasing fall exposure. If high strength bolts are required for a final connection, the erector must handle extra tools, bolts, nuts, washers, etc. and prep the surface; (2) Unused holes will weaken the members. If an erector elects not to use the holes, the designer may require that the holes be filled since unfilled holes may be a deficiency; (3) The holes will have to be slotted, which does not provide the rigidity of a weld; and (4) Welding is easier than installing a bolt from the top and a nut from the bottom.

Addressing the first issue in this group, many commenters (41) raised a concern about the structural integrity of the bolted connection because the holes would have to be slotted or oversized. In particular, they argued that bolts used to meet the proposed paragraph would be erection bolts, which would have to be replaced with high strength bolts. This, they asserted, would require that the surface also be prepped in accordance with AISC requirements. One commenter (Ex. 13–357) claimed that if the designers require a final weld, the worker would have to come back to weld the connection, also doubling the connection time and increasing fall exposure. These re-connections would be necessary to provide lateral stability to the top flange of the supporting member. Another commenter (Ex. 13–342) stated:

> * * * the erection connection will not be the final connection. A final connection by welding or replacement of the erection bolts with high strength bolts will have to be provided. The bolted connection would require proper cleaning and preparation of the connecting surfaces, use of plate washers, and torqueing of the bolts.

Moreover, erectors would not install final high strength bolts during this erection phase due to the time to prep and install the bolts to AISC

specifications. A final bolted connection during this phase would be extremely expensive since the crane would be on site during the whole process. As indicated below, erectors want to get the joists up as quickly as possible to reduce the crane time on the job.

The Professional Engineers Group, Inc. (Ex. 13–110) responded that the "[b]est case scenario is the erector uses erection bolts and then goes back to make a final connection, either bolted or welded. This places the erector's personnel in a position twice that can lead to an accident rather than once." A steel erector (Ex. 13–118) commented "[t]he use of erection bolts is only a temporary attachment; a worker will still have to return to each location to "complete" the connection, resulting in an increased exposure." Further, this commenter stated "* * * the net result of this proposed rule change will be increased costs, reduced market share, and increased worker exposure." A steel fabricator (Ex. 13–283) responded that their joist suppliers had advised them that "* * * a bolted connection will very often not be acceptable for a final connection since more load may be present than can be transferred without additional welding."

Four commenters (Exs. 13–6, 13–57, 13–89 and 13–277) suggested that if high strength bolts would be required for a final connection, the worker would have to handle extra tools, bolts, nuts, washers, etc. and as mentioned above, the surface would be required to be prepped prior to installing the bolts. These added activities would create additional hazards to the steel erector. One commenter, a General Contractor (Ex. 13–6), responded that the proposed paragraph (a)(8) would: increase the number of falling/dropped objects creating an overhead hazard; increase the possibility of pinching, crushing or cutting fingers, and; increase injuries due to the significant amount of time needed for the alignment process. These commenters claimed that the bolts will only serve as a temporary connection and that a rigid final connection will be required by either replacing the erection bolts with high strength bolts or welding the joist ends.

All of these concerns are addressed by the revision to paragraph (a)(8) in the final rule, which requires the use of bolts in the initial connection but is silent on the final connection. The bolted connection covered by paragraph (a)(8) serves as an initial erection connection, making the structure stable more quickly for the worker. In addition, the erection bolts would not need to be replaced by high strength bolts where the final connection is made by welding. If the employer elects to have the final rigid connection to be a bolted connection, the surface preparation would then be necessary. However, whether bolted or welded, the final rigid connection will be made from a deck or otherwise more stable structure. Thus, the employees performing the final connection will have lower exposure to collapse and falls.

The Agency believes that the total time involved by the worker in making a complete connection as required by this provision is actually less than making an initial and final welded connection. As discussed in more detail below, the erection bolt takes about 15 seconds to install. The welder will not be exposed to the hazards of welding on or at an unstable connection or sites because the joists will be stable at the point they are connected to the primary structure with these bolts. As Mr. Cushing testified, (Ex. 208X; p. 399) when performing the final weld, "[Y]ou would weld in production mode. You wouldn't be welding and tying up the crane." Since much of the testimony against this provision was economic in nature, OSHA recognizes that freeing the crane up sooner would result in a cost savings.

The contention that the worker would have to do the connection twice—once to initially install an erection bolt and again to replace it with a permanent, high-strength bolt (or weld the joint)—is based on two assumptions: first, that the initial bolts would be erection bolts, and second, that the need for slotted holes to make the initial connection may require a final rigid connection to replace the erection connection, thus requiring workers to visit the connection twice. As explained below, this provision does not create the need for an additional visit to the connection since this is already necessary when initial welded connections are used.

OSHA notes, however, that the Steel Joist Institute Technical Digest No. 9 currently recommends that "Immediately after each subsequent joist is set in its proper position, one side of the joist bearing seat on each end of the joist should be tack welded." The Technical Digest further recommends that "After all of the bridging is installed, the final welds are made on the bearing seats of the joists." Thus, the SJI recommendations already require two visits to the joist end attachments.

Under current practices, where welding is used for the attachment of joists, the worker welds one end of the joist, installs bridging which helps to straighten out the joist, and then welds the other end. Normally, both sides of one end or alternate sides of both ends are attached to the primary member with a weld smaller than the final weld required in § 1926.757(b). This smaller weld is commonly referred to as a "tack weld". This allows the worker greater flexibility in pulling the sweep out of the joist while installing the erection bridging. Nevertheless, even when using welding to attach joists, a second visit to the initial attachment point must be made to make the final weld.

Some commenters (Ex. 13–6, 13–89, 13–97 and 13–191) stated that welding is easier and safer than bolting and that welding is currently the recommended method of attachment by the Steel Joist Institute. The Agency expects that this will continue to be the standard practice for joists in bays less than 40 feet, and the final rule does not require field bolting for these shorter joists. However, due to the inherent instability of joists over 40 feet and other considerations discussed above, final paragraph (a)(8) provides a safer environment to erect the longer joists. As discussed earlier, even if the joists are attached with erection bolts initially, the erector may make the final attachment by welding—but the connection work will then be performed from a more stable structure.

Addressing the second issue of this group, many commenters (see for example Ex. 13–97 and 13–228) were unsure whether the designers will require unused holes to be filled. This will not be a concern since in most cases the final rule requires that the holes be used unless constructibility does not allow. Commenters generally felt that the holes will either have to be filled or larger members used to account for the holes. If the holes require filling, the commenters suggest, there would be a significant burden on the erector. It is unclear how many erectors would choose to bolt joists if given the option. According to the Steel Erectors Association of America (SEAA) survey of their members (Ex. 29), most SEAA members would elect not to bolt. In that survey, however, 11 members did state that they felt this is a safe practice. Paragraph (a)(8) of the final rule requires that holes be provided for field bolting, and that for the initial connection of these joists be performed by field bolting, with a very limited exception. The Agency agrees that it would be inappropriate to require the holes be provided and not require that they be used.

As mentioned above, many commenters stated, if it were an option, that erectors would elect not to use the optional holes as proposed for connection of the joists. This led to commenters concerns as to whether the

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unused bolting holes would weaken the structural member and whether the erector would need to fill them. Four commenters responded directly to this issue (Exs. 13–97, 13–153, 13–228, and 13–261). SteelFab (Exs. 13–97 and 13–261) stated "[o]wners and even designers may not know whether these open holes are a structural deficiency." On the other hand, a commenter (Ex. 13–228) feels strongly that "* * * the architect will most certainly require erectors to plug the unfilled holes, again resulting in increased exposure of the erectors." In addition, HABCO (Ex. 13–153) suggested "[t]here is a huge design penalty for open holes in a girder top chord versus holes containing bolts." and "[t]his, in turn, will require the erector to either drag an air hose to each end of each joist, or a torque wrench." This commenter went on to state that the girder size would have to be increased if there are holes in the member that might not get filled, leading to an associated cost increase of approximately 25%. "Therefore, if the designer is required to design holes into the girder top chords, and if the fabricator is required to furnish holes, the erector *must* be required to fill them with properly sized and torqued bolts." As already discussed, these concerns of unfilled holes are all addressed by bolting requirements in the final rule, requiring the holes to be used.

In addressing the third issue of this group, many commenters (Exs. 13–43 through 13–48, 13–54, 13–55, 13–56, 13–71, 13–77, 13–152, 13–217, 13–256, 13–265, 13–266, 13–355) responded that the holes required by proposed paragraph (a)(8) would need to be slotted (or oversized) and that slotted holes would not provide the necessary rigidity that a weld does. EMC Structural Engineers (Exs. 13–43 through 13–48) noted that to allow for field tolerances as a result of the proposed provision "* * * all bolt holes will not be simple round holes but instead will be slotted holes which will allow the sweep to remain in the joist." Another commenter (Ex. 13–217) stated that the requirement would require installing bolts and then having to weld the joist "to freeze the connection" as a result of using a slotted hole on the joist. In addition this commenter stated that using "* * * proper amount of bridging as the joists are being set, and using an established safety procedure, we can set the joist safely without bolting each joist as they are set." Another commenter (13–335) responded that they:

> * * * have spoken with several joist manufacturers and they have indicated that in order to meet this proposed provision, they will have to pre-punch all joists with [slotted] holes. The slotted holes would be required for field adjustments/construction tolerances. This would create a significant problem from our (the Structural-Engineer-of-Record's) standpoint. With slotted holes placed in the joists for bolting, we would have to design the beams as laterally unsupported.

These commenters indicated that holes must be slotted to allow for field adjustments. They contended that since the joists are long and tend to curve somewhat, some room is needed to pull the joist into place; exact sized holes would not, in most cases, be workable, the holes would have to be slotted. This, in turn, would not allow the initial connection to serve as the final rigid connection, and most likely a final weld would be necessary. OSHA recognizes the validity of some of these concerns. The final provision contemplates that the initial bolted connections will, in fact, be temporary connections and that the joists will be stabilized with a final weld or high strength bolt connection for the rigid connection. The required initial bolting is intended to increase employee safety during the initial placement and connection of the joists.

The fourth issue of this group was addressed by two commenters (Exs. 13–97 and 13–165) claiming that welding is easier than bolting. They suggested that welding is a faster and safer anchoring application for joists, and that it is easier to weld from the top than install a bolt from the top and a nut from the bottom. In contrast, Phil Cordova, SENRAC member and owner of a steel erection company, described the time it takes to weld versus bolting the joist (Ex. 208X; p. 199). When asked how long it takes to tack a joist initially, Mr. Cordova stated:

> You have many considerations that take place there. You need to get the endow of a joist. You need to find the proper location. You need to get a man up there who is in a secure position to work without vision of the ground by working under a welding hood to tack this. A tack could take quite a significant amount of time. Meaning, by the time they get set up in position, it could be five to ten minutes on each tack.

Further, Mr. Cordova described the time it would take to put in an erection bolt and tighten it by stating:

> That would just be a few seconds. Quite significantly, under a minute. We are talking, by the time you thread the bolt down through the hole and put the nut on it, an ironworker could put each nut and bolt on there on the magnitude of about 10 to 15 seconds—I would think.

In the final analysis, the issue is, whether an initial joist attachment with erection bolts provides greater stability and exposes the employee to less risk of falls or collapse than an initial joist attachment with tack welds. OSHA believes that it does. OSHA believes the bolting requirements of this paragraph will reduce both fall and collapse hazards.

The third major group of comments on this paragraph addressed costs, fabrication burden, and feasibility issues.

Some commenters felt that the bolting provision was unnecessary since the other requirements in § 1926.757 adequately addressed the activities and procedures that cause the accidents in joist erection. According to the commenters, joist collapses are most often associated with inadequate bridging and placing a construction load on unstable, un-bridged joists. One commenter (Ex. 13–40) stated:

> * * * all joists are bolted adjacent to the column in each bay [currently required by § 1926.751(c)(1) and proposed as § 1926.757(a)(1)]. This, along with the recent requirement for joists of 40 feet and longer to have bolted bridging in place before slackening the hoisting lines [proposed § 1926.757(d)(1)], and not permitting the application of any loads to the joist until the bridging is installed [proposed § 1926.757(e)(2)], provide a safe erection procedure. I am not aware of any instances where, when these procedures were followed, there has been an accident that additional bolting of the ends of the joists would have prevented. All of the accidents are a result of direct violations of these requirements.

Another commenter, the USCCG (Ex. 63), suggested that:

> [a]ny possible safety concerns addressed by this paragraph are better addressed by the other joist provisions dealing with installation and anchorage of bridging, keeping the hoisting cable in place until one end is attached, stabilization of the structure prior to installing joists, among other provisions * * * The causes of joist collapse are addressed by the other provisions of [proposed § 1926.757].

The Steel Joist Institute (Ex. 66) agreed that other provisions in proposed § 1926.757 addressed joist erection hazards and stated:

> [t]he holes for bolting are not required to prevent unintentional displacement as the proposed rule contains a multitude of other provisions that address this concern. Specifically, paragraphs (a)(2), (a)(6), (a)(7), (b)(3) and (c)(1)[referring to paragraphs of proposed § 1926.757] * * *

The Agency agrees that the proposed requirements for landing and placing joists, structure stabilization prior to joist erection, and attachment requirements contained in paragraphs (b)(3) and (c)(1) address many of the hazards identified as causing many accidents in joist erection. However, the hazard addressed by paragraph (a)(8) is uniquely associated with long, limber joists and is not adequately addressed in these other provisions of the standard.

Several concerns were raised by commenters about the feasibility of bolting. Specifically, the preamble of the proposed rule stated that prior to sizing a structural member for supporting mechanical equipment, the structural engineer of record or design engineer must know the exact operating weight and physical footprint of the equipment that will be imposed onto the structure. This type of information is critical in the sizing of the foundations and the primary and secondary structural members (63 FR 43473). Their concern was that if the size of the equipment is not known prior to fabrication of the steel members, joists may need to be moved to accommodate the equipment during erection. In that situation, the bolt holes would be in the wrong place and another means of attachment would have to be used. Seven commenters responded to the issue of location and size of mechanical equipment. Two commenters (Ex. 13–294 and 13–308) stated "[t]he structural engineer does not need the exact size, weight or location of equipment to properly size the members. Approximate weights and dimensions are sufficient for design." Another commenter (Ex. 13–184) responded that:

> * * * The supporting member of [the] joist can be drawn & fabricated without knowing the exact location of [the] bar joist since the joist is field welded to the supporting member. Delays in fabrication and shipping of these supporting members will become commonplace. Coordination will become a nightmare.

In a post hearing comment (Ex. 52), the National Council of Structural Engineers Associations (NCSEA), commented that "[l]ocation of services and equipment are often not finalized until erection of the steel frame is well underway, or perhaps even complete." Another commenter (Ex. 13–64) responded that "[t]he welded detail allows for joist spacing to be revised to suit mechanical coordination up until installation. In today's fast track projects, this flexibility is demanded." The SJI, in a post hearing comment (Ex. 66) added that:

> [t]he most pernicious cost-factor will be the interruption of scheduled work in the fabricator shop to await the final positioning of heating, air conditioning and other mechanical equipment. [further] * * * the design, fabrication and manufacture of structural steel and steel joists is on a just-in-time basis. To hold everything in abeyance until the mechanical equipment is decided upon, purchased and available will frustrate the whole construction sequence and drive up the carrying costs of steel construction.

In addition, commenters raised several general feasibility concerns about the hole requirement in paragraph (a)(8). They stated that it would be difficult to line the holes up (Ex. 13–233), the reality of construction would not allow the procedure to be effective (Ex. 13–278), and since that the joist manufacturer and steel fabricator are most often separate businesses, the coordination of precise hole locations would not be easy (Ex. 13–226). The American Institute of Steel Construction (AISC) (Ex. 13–209) addressed the coordination concern by stating:

> [t]o allow for bolting on every job, the fabricator and the joist manufacturer must know the exact joist spacing to prepare shop drawings of the individual members for approval and fabrication. This presents a severe logistical problem since contractors commonly purchase steel well in advance of the building's mechanical system * * * [s]afe, existing practice allows the fabricator to order joists and mill steel (long lead-time items) prior to finalization of all other elements of the project design. The proposed requirement would not allow for field adjustment of the joists if exact hole location is required. In addition, if the final location of the joists is not known during the fabrication, how will the fabricator know where to put the holes and if the location changes, as it often does, there is no means to move the holes? In addition, field adjustability is not possible with bolted hole connections causing problems for mechanical equipment of which the location may not be known prior to fabrication.

OSHA agrees that there is a need to allow for situations where field adjustment is needed. Paragraph (a)(8)(ii) of the final rule allows for immediate welding of the joist and also for movement of the joist where constructibility does not allow for bolting. In these instances, where a joist would need to be moved to allow for the placement of mechanical equipment or if the joist location had to change after fabrication and prior to erection, a weld would be permitted to secure the joist if it is necessary for the joist to be positioned such that the holes cannot be used. In addition, as stated in the preamble to the proposed rule, the Agency hopes this will create better pre-job communication between the fabricator and erector. Furthermore, OSHA notes that all solid-web member construction requires precise hole alignment. Therefore, the Agency feels that if solid web structural steel can be fabricated with precise hole alignment for multi-story sky scrapers, sports stadiums and other large structures, then the same can be done for open web steel joist structures.

Another concern was that the proposed provision would unnecessarily increase the hazards to fabrication workers to put the holes in the members. Vulcraft (Ex. 13–289) stated:

> * * * the cost to people ordering these products will increase due to the additional, unnecessary fabrication requirements, this will increase the safety and health risk of the fabrication workers and this risk is much greater than the non-risk of welding the ends of joists in the field."

Another commenter (Ex. 13–25) stated "[f]abricators will drill millions of holes for no reason; [there is] no justification for exposing shop fabricators to additional hazards." Several commenters (Exs. 13–41, 13–234, 13–290, 13–165, 13–14, 13–144, 13–22, 13–42, 13–309, 13–226, 13–51 and 13–209) further suggested that the requirement would place additional burdens on the fabricator, primarily a cost burden. The American Institute of Steel Construction (AISC) (Ex. 13–209) stated that the requirement "* * * imposes tremendous economic, manufacturing, scheduling, detailing and other burdens on both the structural steel fabricator and the steel joist manufacturer to install bolt holes to accommodate an erection method that will be merely optional." Another commenter (Ex. 13–42) stated "* * * the passing of this final rule would, in some cases[,] probably double the cost of detailing beams that would support bolted connections for joists 40 feet or [over]."

Another concern of the fabrication industry involved small fabricators and their inability to compete with the larger fabricators to drill or punch holes in the members. One commenter (Ex. 13–22), referring to the proposed provision, stated "[t]his would put an unnecessary, and unfair burden on small fabricators who do not have computerized drilling and/or punching lines by greatly increasing the cost of labor." Another commenter (Ex. 13–12) again referring to proposed paragraph (a)(8), stated that if the rule were adopted, he would be forced to close his business. Because he has a small shop and all holes are drilled by hand, he said that he would not be able to compete with larger shops that have automated equipment.

The Agency believes that paragraph (a)(8) will increase safety for those workers installing larger joists. The record does not demonstrate that the provision will increase exposure to hazards in the fabrication industry. In addition, since the final rule requires that the holes be used for erection of the

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joists, the fabricator will not be needlessly drilling the holes.

Finally, many commenters suggested that the proposed requirement would increase the cost of joist erection without increasing employee safety. Without any identified increase in safety, many commenters felt that the increase in costs to the steel joist industry and the structural steel fabrication industry is unjustified. One commenter (Ex. 13–252) noted "* * * adding 10 to 15 percent for additional labor and materials will only serve to push these jobs out of the reach of many small businesses." Additionally, SJI in a post hearing comment (Ex. 66) presented an economic analysis of the impact of this proposal on the steel joist industry that showed a first year cost of $68,000,000 for this provision. They also noted that structural steel fabricators anticipate an increase in cost of $126 per ton if the proposed regulation is implemented. That amounts to an increase cost for fabricated structural steel of $184.8 million, above the costs to the joist industry. Another commenter (Ex. 13–342) responded "the cost of steel projects will increase significantly with little, if any, advantage in job site safety. Cost increases will result because of the joist girder top chord or beam top flange will have to be increased in size and holes will have to be punched in every joist seat. Erection cost increases will also result in making the final connection."

One commenter (Ex. 13–57) responded that their company has never had a worker injured during the process of welding joist ends to structural steel beams, and that the proposed change to paragraph (a)(8) would neither improve safety nor stability, might require increased beam sizes and might create a tripping hazard. Another commenter (Ex. 13–89) stated that the proposed paragraph would not provide any safety benefit and could increase accidents due to the efforts to bolt the ends of non-rigid joists which would require a difficult balancing act to perform. Other commenters expressed concern that proposed paragraph (a)(8) could be detrimental to the steel joist industry. Specifically, the added costs for engineering, coordination, fabrication and erection will make this type of construction non-competitive.

As indicated above, paragraph (a)(8) only applies to long and limber joists (40 feet or more in length) to ensure that at the critical time of initial connection, the employee is not exposed to a hazard as a result of the joist not being adequately secured upon its placement. The Agency believes that the costs (addressed in the economic analysis) of this provision will be accompanied by an significant increase in safety. In addition, as was discussed earlier, there may be a cost savings in erection time by performing the bolted connection. SENRAC member Alan Simmons of the Ironworkers International Union, and an ironworker with much field experience, stated at the hearing (Ex. 208X, p. 189), "It takes considerably less time to bolt than to weld a joist in my opinion." In addition, Mike Cushing, an ironworker for 29 years, described in testimony (Ex. 208X; p. 377) how bolting is easier, faster and safer than welding. "With welding, there is no right spot, you have to pull a tape, get drums out and determine the exact location of the joist to weld it. With holes, you just stick the bolt in the hole just like any other piece of iron." He goes on to state that "* * * welding is not a very long process, but laying it [the connection point of the joists] out, it probably will take longer than to do the actual welding." Also, Steve Rank (Ex. 208X; p. 204), a SENRAC member and an ironworker with much field experience, stated that these long joists pose a displacement hazard as well as a hazard to the ironworkers that are stepping onto and dragging welding weight over them. He states that alignment is a serious issue, and that such long joists can pop the welds and lead to accidents during erection.

In summary, most of the concerns expressed about the proposed requirements for the holes for bolting long steel joists are eliminated by final § 1926.757(a)(8) which does not just require that holes be provided for field bolting: it also requires that initial connections be field bolted instead of welded. In addition, many of the remaining concerns are eliminated by the constructibility exceptions.

In the proposed rule, OSHA justified the need for the holes in the joists for the following reasons: (1) The provision is necessary because certain joists that are thin and flexible can be difficult to install because of their sweep. Bolting these types of joists first allows straightening of the joist, thus returning its camber and eliminating torque. Additionally, after bolting, welding can be more easily accomplished. (2) Long steel joists that are placed in bays of 40 feet or more have a greater tendency to twist or rotate, which creates hazards for the workers installing them. (3) Bolting is safer whenever unattached joists could be displaced by wind or construction activity, by the movement of employees, by trailing welding leads, by accidental impact against the supporting structure by a crane or other equipment, or by harmonic motion or vibration. (4) The vision and balance of an employee working at elevation can be impaired while wearing a welding hood, which may make bolting a safer approach in this situation. (5) Joists can roll and pop welds due to the movement of an worker on the joist or the stresses caused by removing the sweep; if the weld breaks, the joist fails and may cause a structural collapse.

The Agency believes that a bolted erection connection in joists in bays of 40 feet or more will reduce the risk of an employee fall or collapse that can result when a long, unstable steel joist breaks loose from its attachment. Slotted holes for bolting will provide easier plumbing-up and alignment before the final rigid attachment is completed. Sweep can be taken out and the bridging installed without fear that the seat will break off. When asked for his sense of the cost savings to a steel erector, Mr. Cordova, who has used bolted connections in steel joists, stated (Ex. 208X; p. 211):

> I think it is a significant saving in that they can protect their workers by minimizing the exposure of the worker out there on the structure that's unstable. If you have a bolted slotted connection, you can stabilize the structure.

Bolted connections help protect employees from falling. Barry Cole of Miller Safety (Ex. 208X; p. 252) stated: "Whenever we can give a guy a better grip, a better handling, or a better way mechanically with some certainty and some instantaneous versus long, drawn out, [sic] then you're better off." Mr. Cole went on to describe bolted connections as a type of fall protection "[b]ecause they reduce exposure to a loss of balance * * *" In the Summary of the Final Economic and Regulatory Flexibility Analysis (Section V), below, OSHA addresses the issue of cost impact to steel joist fabricators.

SENRAC determined, and OSHA concurs, that bolting of longer joists for their initial connection will provide additional stability during this unstable erection period.

Paragraph (a)(9) of the final rule (proposed paragraph (a)(10)) prohibits the use of steel joists and steel joist girders as anchorage points for a fall arrest system unless written direction allowing such use is obtained from a qualified person. Although performance criteria and manufacturer's specifications are not currently available regarding the adequacy of steel joists and steel joist girders as anchorages for fall protection systems, this provision recognizes that some joists and girders may be strong enough to meet the load

requirements for anchorages in § 1926.760. One commenter (Ex. 13–210) suggested that the structural engineer of record should be the one to provide the approval. OSHA believes the SER may not have the knowledge of steel joist erection necessary to approve tie-off to joists. The qualified person, however, as defined is the appropriate entity to make the determination.

Paragraph (a)(10) of the final rule (proposed paragraph (a)(9)) addresses the hazard posed by bridging joists without establishing an adequate terminus point for the bridging. Bridging is not effective until a terminus point is created. "Bridging," an operation integral to steel joist construction, refers to the steel elements that are attached between the joists (from joist to joist) to provide stability. "Erection bridging" is defined as "* * * the bolted diagonal bridging that is required to be installed prior to releasing the hoisting cables from the steel joists." "Horizontal bridging," usually angle iron, is attached between steel joists, to the top and bottom chords of each joist, by welding. There are several provisions in this section that require bridging to be anchored. This means, by definition, that the steel joist bridging must be connected to a bridging terminus point. The term, "bridging terminus point," is defined as follows:

> Bridging terminus point means a wall, beam, tandem joists (with all bridging installed and a horizontal truss in the plane of the top chord) or other element at an end or intermediate point(s) of a line of bridging that provides an anchor point for the steel joist bridging.

Final rule paragraph (a)(10) simply requires that a terminus point be established prior to installing the bridging in order for the bridging to be anchored. OSHA is aware that steel erection is a progressive process that requires one piece to be erected before the subsequent piece can be attached to it. This provision requires pre-planning to determine the particular location of the terminus point for the attachment of bridging. To assist in developing or determining terminus points, OSHA is providing illustrative drawings of examples of bridging terminus points in non-mandatory Appendix C. In addition, paragraph (c)(5) of this section, discussed below, deals with the situation in an erection sequence where the permanent bridging terminus points are not yet in existence at the time the joists and bridging are erected. This provision remains the same as the proposed rule and no comments were received on this paragraph.

Paragraph (b) Attachment of Steel Joists and Joist Girders

There are three types of joists identified by SJI as being used in the steel erection industry. The K-Series open web steel joists, having joist depths from 8 inches through 30 inches, are primarily used to provide structural support for floors and roofs of buildings. Although light in weight, they possess a high strength to weight ratio (Ex. 9–141). The LH-Series steel joists span up to and including 96 feet. These joists are used for the direct support of floor or roof slabs or decks between walls, beams, and main structural members, and their depths range from 18 inches to 48 inches. The "Deep Longspan," or DLH-Series joists can run up to 144 feet and have depths from 52 inches through 72 inches. The attachment of all three series of joists is addressed in paragraph (b) of this section. The hazard addressed in this paragraph is the adequacy of the attachment of joists that could affect the stability of the joist and thus the safety of the employee erecting the joist. Paragraphs (b)(1) and (b)(2) specify the minimum attachment specifications for the lighter and the heavier joists, respectively. At a minimum, the K-Series must be attached with either two 1/8″ (3 mm) fillet welds 1 inch (25 mm) long, or with two 1/2″ (13 mm) bolts. In addition, the provision provides alternative performance language "or the equivalent" to allow for attachment by any another means that provides at least equivalent connection strength. Similarly, at a minimum, the LH-Series and DLH-Series must be attached with either two 1/4″ (6 mm) fillet welds 2 inches (51 mm) long, or with two 3/4″ (19 mm) bolts. Again, OSHA is providing performance language, "or the equivalent," for the reasons discussed above. Paragraphs (b)(1) and (b)(2) were adopted from SJI specifications. One commenter (Ex. 13–208 commented on these paragraphs in support stating that these provisions have "* * * been adopted from the Steel Joist Institute Specifications and emphasize the need for positive attachment of joists to [their] supporting elements." Final paragraphs (b)(1) and (b)(2) remain unchanged from the proposed rule.

Paragraph (b)(3) of the final rule addresses the hazards associated with the following improper erection sequence: landing joists on the support structure; spreading them out unattached to their final position; and then attaching them. This procedure creates the potential for worker injury because joists handled in this manner may fall or the structure may collapse. To eliminate these hazards, this paragraph requires, with one exception discussed in paragraph (b)(4) below, that each steel joist be attached, at least at one end on both sides of the seat, immediately upon placement in its final erection position, before any additional joists are placed. The language, "both sides of the seat", is added in the final rule to clarify what OSHA means by attachment. One comment was received on this provision (Ex. 13–208). It supported the requirement, stating that "[t]his is a good provision that establishes the need to secure joists as they are placed thus preventing inadvertent displacement."

Paragraph (b)(4) is an exception to the paragraph (b)(3) "attachment upon final placement" requirement. It addresses the situation where steel joists have been pre-assembled into panels prior to placement on the support structure. One commenter (Ex. 13–308) stated that in applying the proposed provision, one might confuse the corners of the panels with the steel joists creating the panels. The Agency agrees that the proposed language could cause confusion, and that we need to clarify that it is the corners of the panel that must be attached to the structure. Final rule paragraph (b)(4) has been re-worded to require that panels that have been pre-assembled from steel joists with bridging must be attached to the structure at each corner before the hoisting cables are released.

Pre-assembly of panels usually involves the installation of diagonal and horizontal bridging to form a platform at ground level, which eliminates fall hazards associated with attaching bridging at elevated work stations. Placing joists on the support structure in this manner eliminates the single joist instability concerns. Furthermore, because of the inherent stability of these pre-assembled panels, this paragraph requires only that the four corners of the panel be attached to the support structure before releasing the hoisting cables. The attachment can be either bolted or welded.

An additional benefit of panelizing joists is that, following installation on the primary support structure, in all likelihood, the panel will immediately provide anchorage points for fall protection systems.

Additionally, the pre-assembly allows for alternative joist erection methods such as a hybrid form of steel erection involving steel/wood-panelized roof structures, where wooden decking (dimensional wood and plywood) is attached to a single steel joist and the resulting panels are set on the support structure (Exs. 9–94, 9–95). Again, by placing joists on the support structure in

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this manner, the instability concerns and other hazards associated with attaching single joists are avoided. The same commenter (Ex. 13–208) supported this provision by stating "[t]his is a strong provision that extends the requirement for attachment even in instances when the erector chooses to panelize joists for erection."

Paragraph (c) Erection of steel joists. Paragraph (c)(1) of the final rule requires that for joists that require bridging as provided in Tables A and B, at least one end of each steel joist must be attached on both sides of the seat to the support structure before the hoisting cables can be released. This paragraph is nearly identical to the proposed paragraph (c)(1) except that it was clarified by adding "on both sides of the seat" so that it is understood that two attachments are required at the one end of the joist. Thus, an end attachment is considered to be attachment of both sides of the joist seat. This change is consistent with the change in paragraph (b)(3) above. For further clarification, to address an oversight in the proposed standard and to conform with SJI specifications, this provision has been limited to the joists that require bridging as identified in Table A or B. This clarification will allow smaller lighter joists (that do not require bridging and can be landed in bundles) to be placed on the structure and spread out by hand. Once the joists have been placed in their final position, however, they must be attached in accordance with paragraph (b)(3) of this section.

The Agency also determined that paragraph (c) did not properly address the erection of heavy joists over 60 feet. Therefore, final rule paragraph (c)(2) has been added to address the special erection needs of these long heavy joists to conform with SJI specifications. This paragraph will require that the seat on both ends of the joist be attached permanently and the bridging requirements of paragraph (d) met before hoisting cables can be released. The SJI (Ex. 13–208) commented that it is necessary to require that the joists be secured at least at one end prior to allowing workers on the joists.

Paragraph (c)(3) of the final rule (proposed paragraph (c)(2)) addresses steel joists that do not require erection bridging as required by Tables A and B. This paragraph has been revised to eliminate the reference to joists that span 40 feet or less. This was done to be consistent with paragraph (d) of this section as discussed below.

In the last 25 years, many new and different open web steel joists have been manufactured. In developing Tables A and B, SJI demonstrated that there are dozens of joists that span less than 40 feet that require erection bridging to maintain stability during erection. SJI also demonstrated that there are joists over 40 feet that do not need such bridging. The Agency has accepted these findings and is following SJI recommendations with respect to which joists need erection bridging. SJI (Ex. 13–208) commented in support of the provision allowing only one worker on the joists that do not need bridging "* * * prior to the joist being secured and the bridging being installed and anchored."

Based on the recognition of the inherent danger of employees working on unstable joists, paragraph (c)(4) of the final rule (proposed paragraph (c)(3)) requires that no employee be allowed on steel joists, where the span is equal to or greater than the span shown in Table A or B, unless the requirements of paragraph (d) of this section are met. This paragraph has also been modified in the final rule as a result of the changes to paragraph (d). Since the 40 foot minimum length has been eliminated, this paragraph now prohibits workers from going out on any joist that is equal to or longer than the span specified for that joist in Table A or B unless the bridging provisions of paragraph (d) of this section are met. The SJI (Ex. 13–208) commented in support of this requirement.

Paragraph (c)(5) of the final rule (proposed paragraph (c)(4)) addresses the situation where the erection sequence calls for joists to be erected before the permanent bridging terminus points have been established. This situation commonly occurs in a single story structure that has masonry or architectural precast walls installed after the steel is partially or fully erected. Complying with paragraph (c)(5) will involve pre-planning and the addition of temporary bridging terminus points to provide stability and prevent structure collapse in this situation. Examples of bridging terminus points can be found in Appendix C. SJI (Ex. 13–208) commented in support of this provision by stating "[t]his provision recognizes situations when it is simply not possible to terminate or anchor bridging utilizing standard procedures. In those situations it is imperative that provisions be made to provide the necessary stability."

Paragraph (d) Erection Bridging

Paragraph (d) of the final rule provides that, where the span of the steel joist is equal to or greater than the span shown in Tables A and B, a row of bolted diagonal erection bridging must be installed near the midspan of the joist, the bolted diagonal erection bridging must be installed and anchored before the hoisting cables can be released, and no more than one employee is allowed on the joist until all other bridging (diagonal and horizontal bridging) is installed and anchored.

Final rule paragraph (d) has been revised from the proposed rule by eliminating the requirement that all joists in bays of 40 through 60 feet (in addition to those equal to or greater to the spans in Table A and B) have bridging. Under the final rule, the requirements of paragraph (d)(1) apply only to the joists identified in the Tables as needing bridging.

Under the current standard, joists less than 40 feet long do not require bridging, but all joists 40 feet and over do. The proposed rule was somewhat different. Like the current standard, bridging would have been required when erecting any joist 40 feet or longer. Unlike the current standard, however, bridging would also have been required when erecting those joists less than 40 feet long that are identified in Tables A or B as requiring that procedure.

Tables A and B rate the stability (when unbraced) of a wide range of joists—including joists 40 feet and over. According to the Tables, a number of steel joists over 40 foot are stable without bridging. Nonetheless, the proposed rule would have required bridging for all joists over 40 feet in length.

Tables A and B were developed for the proposed rule and were based on the SJI tables. The SJI tables were developed in 1994 and designed to rate the capacity of joists with respect to a uniform dead load (an unmoving weight resting on the joist) and live loading (for example, a person walking on a completed roof). SJI developed the tables to determine which joists could support, without bridging, a static 300 pound load placed on the top cord at the mid-span of the joist.

SJI retained a consultant to develop and check their tables for a single point loading in the center of the joists. The consultant first developed a theoretical equation to evaluate the joists, and rated the joists. The joists were then field tested for a stationary point loading. The testing corroborated the theoretical ratings. SJI provided this information to SENRAC and the information was used in the development of Tables A and B in the proposal. The Tables relate the attachment and bridging requirements to the actual performance of particular joists.

SENRAC decided to use the portion of the tables that identified the need for

bridging of joists less than 40 feet in the proposed rule. The proposal required bridging for all joists over 40 feet, although the SJI tables indicated that certain joists with spans from 40 to 60 feet do not require erection bridging. SENRAC based its decision on the following: (1) OSHA's current steel erection standard requires all joists over 40 feet to be braced, and (2) the SJI tables are not reliable because the loads imposed during the SJI tests were static loads; the loads imposed by an employee are dynamic.

There were a number of commenters that objected to the failure of the proposal to use the Steel Joist Institute (SJI) Tables in their entirety. The Steel Erectors Association of America (SEAA) (Ex. 13–203) stated that it could not understand why only half of SJI's stabilization tables was used. In its view, if the testing is valid the testing should be accepted in its entirety or not used at all.

Another commenter, Mr. Eddie Williams (Ex. 203X; p. 171), testified that 40 feet is not necessarily an appropriate threshold for the requirement—there may be joists that are 30 feet that need a row of x-bridging in the center while others are stable well over 40 feet without bridging. Speaking as an erector, he believes that it is acceptable to rely on the SJI tables above 40 feet. Mr. Cary Andrews (Ex. 204X; p. 133) and Mr. Studebaker (Ex. 204X; p. 33) in similar statements said that 40 feet should not be a threshold. They stated that the requirement for bolted x-bridging should be based on the stability of the particular joist.

SJI (Ex. 13–208) stated that it strongly objects to the imposition of the 40 foot rule for erection bridging. It reports that extensive SJI research has proven that many joists over 40 feet exhibit a sufficient degree of stiffness to allow for safe erection without erection bridging. SJI submitted the tables based on their research. In SJI's view, the choice of a 40-foot span as the point at which erection bridging must be used is arbitrary.

A commenter, (Ex. 201X; p. 79 and Ex. 13–334), questioned the Agency's authority to regulate the design of structures. They believe that this is a matter that should not be regulated. Another commenter, Mr. Emile Troup, from the National Council of Structural Association (Ex. 13–308), said that: (1) joists listed in Tables A and B are susceptible to instability without external support; and (2) proposed rule paragraphs 1926.757(c) and (d) are cumbersome. Mr. Troup believes that the paragraphs should be simplified to make it easier for structural engineers, joist manufacturers and erectors to understand the requirements. Mr. Studebaker, (Ex. 204X; p. 141) challenged the reliability of the SENRAC tables. The results reflected in the tables are based on static load testing. He argues that this is improper since the loads actually imposed during erection are dynamic loads, such as when an ironworker leans to install bridging. Ironworkers move across the joist and move back off of it and try to balance and stabilize themselves. In his view, the 300 pounds is a safe limit but it could be increased sightly.

In support of the proposal, Mr. Lott (Ex. 204X; p. 100) said that the lack of bridging could cause buckling failure. As the ironworker moves toward the center, the compressive force in the top chord is increased. If there is a failure, the member will fail in compression. Mr. Williams (Ex. 204X; p. 95) supported requiring bridging in joists over 40 feet.

As discussed earlier, OSHA believes that it is as necessary and appropriate at times to require building components to meet the safety needs of those constructing a building as it is to require a completed structure to meet the safety needs of its occupants. A well established principle of occupational safety and health is that eliminating or reducing a hazard by modifying the design of whatever is posing the hazard is preferable to relying exclusively on controlling a hazard through personal protective equipment.

An open web joist is light and has a high degree of strength along one axis—its height. In other words, once in place, it can resist loads placed along its top edge. However, the joist is extremely weak along the secondary axis—for a truss in place, this means that it has little capacity to resist a force pressing against the (wide) side of the truss. In its 1994 presentation before SENRAC, SJI addressed the research on stability that it used to develop its tables was addressed. The research showed that many joists over 40 feet exhibit sufficient stiffness for safe erection without erection bridging.

In response to the concern that the dead loading tests were insufficient, the Agency's engineers evaluated the tests and methodology used to develop the tables. The Agency's engineers estimate that for a 200 pound worker with 50 pounds of equipment, an additional 50 pounds of live loading will provide a safety factor of 1.2. In their opinion a test with a larger static loading is not needed and this is an appropriate safety factor for this type of situation. Consequently, the Agency believes that the SJI tables that were originally submitted by SJI are reasonable. SJI's research demonstrated that the joists over 40 feet identified in the Table as not needing erection bridging during erection are sufficiently stable. In addition, the record lacks evidence showing that the tables are unreliable. In sum, the record does not show a basis for cutting off the SJI Tables at 40 feet. OSHA has therefore incorporated the SJI tables in their entirety in the final rule and modified the proposal's provisions accordingly.

Paragraph (d)(1)(i) of the final rule requires that bolted diagonal erection bridging be installed near the midspan of the joist. In the proposed rule, the provision stated simply that this row of erection bridging had to be bolted diagonal bridging, but there was no requirement to install the bridging. This provision was clarified in the final rule by requiring that the bolted diagonal erection bridging be installed near the midpoint of the joist.

Paragraph (d)(1)(ii) prohibits releasing the hoisting cables until the bolted diagonal erection bridging is installed and anchored. As proposed, the provision did not require the bridging to be anchored. One commenter (Ex.13–208) suggested that the wording "and anchored" be added because bridging does not perform its function unless it is anchored. He pointed out that paragraph (a)(9) of this section requires that a bridging terminus point be established before bridging is installed (it refers to Appendix C, which provides examples of bridging terminus points). That suggests that, in the proposal, the intent was for the bridging to be anchored.

OSHA agrees that, to be effective, the bridging must be anchored, and has added this anchoring requirement to clarify that in order to comply with this paragraph and paragraph (a)(9) of this section, the bridging must be anchored.

Paragraph (d)(1)(iii) prohibits more than one employee from being on the joist until all the bridging is installed. This provision will require that all bridging that is required for the joist (both bolted diagonal and horizontal bridging) be installed before additional employees are allowed on the joist. No comments were received on this provision, and it is promulgated without change.

Paragraph (d)(2) addresses the bridging requirements for steel joists over 60 feet through 100 feet. Paragraph (d)(2)(i) has been added to the final rule. It requires that all rows of bridging for these spans be bolted diagonal bridging. This provision was added in response to a comment from SJI (Ex. 13–208) in which they stated that for these longer

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joists, bolted diagonal bridging provides necessary stability for the joist. The Agency's addition of this requirement reflects the current best practice in the industry.

Paragraph (d)(2)(ii) of the final rule requires that two rows of bolted diagonal erection bridging be installed at the third points of the joists that span 60 through 100 feet in length. An explicit requirement that the bridging be installed has been added, as explained above with respect to paragraph (d)(1)(i).

Paragraph (d)(2)(iii) of the final rule (proposed paragraph (d)(2)(ii)) prohibits the hoisting cables from being released until these two rows of erection bridging are installed and anchored. The phrase "and anchored" was added for the reasons discussed with respect to paragraph (d)(1)(ii) above.

Paragraph (d)(2)(iv) of the final rule (proposed paragraph (d)(2)(iii)) requires that no more than two employees be allowed on a span until all other bridging is installed and anchored. The phrase "and anchored" has been added for the reasons discussed with respect to paragraph (d)(1)(ii) above. This paragraph provides that all the bolted diagonal bridging that is required for the joist must be installed and anchored (to a bridging terminus point) before more than two employees are allowed on the joist.

Paragraph (d)(3) applies to steel joists where the span is between 100 feet through 144 feet. Paragraph (d)(3)(i) requires bolted diagonal bridging for all rows of bridging. The Agency received no comments on this provision and it is unchanged in the final rule. Paragraph (d)(3)(ii) prohibits the hoisting cables to be released until all bridging is installed and anchored. There were no specific comments on the proposed provision. However, as explained above, the words "and anchored" have been added for consistency.

Paragraph (d)(3)(iii) restricts access to no more than two employees until all bridging is installed and anchored. There were no specific comments on this provision. However, the words "and anchored" have been added as explained above.

Paragraph (d)(4) applies to steel members spanning over 144 feet and requires that erection of these members be in accordance with § 1926.756. The Agency received no comment on this provision and it is unchanged in the final rule.

Paragraph (d)(5) requires the installation of bridging before the release of hoisting cables on any steel joist specified in paragraphs (c)(2), (d)(1), (d)(2) and (d)(3). There were no specific comments on this provision. However, as explained above, the words "and anchored" have been added. The final rule paragraph requires that where any steel joist in paragraphs (c)(2) and (d)(1), (d)(2) and (d)(3) of this section is a bottom chord bearing joist, a row of bolted diagonal bridging shall be provided near the support(s). This bridging shall be installed and anchored before the hoisting cable(s) is released.

Paragraph (d)(6) specifies that when bolted diagonal erection bridging is required by this section, the erection drawings must indicate the bridging and the erection drawings shall be the exclusive indicator of the proper bridging placement. This is to eliminate any confusion that might arise where bridging placement is specified through other means; reliance is to be placed only on the erection drawings for this information. In addition, shop-installed bridging clips or functional equivalents must be provided where bridging bolts to the steel joists. Paragraph (d)(6) also requires that when a common bolt and nut attach two pieces of bridging to a steel joist, the nut that secures the first piece of bridging may not be removed from the bolt for the attachment of the second piece. In addition, when bolted diagonal erection bridging is required, bridging attachments may not protrude above the top chord of the steel joist. No comments on paragraph (d)(6) were received and it is promulgated as proposed.

Paragraph (e) Landing and Placing Loads

The work practice provisions found in § 1926.754(e) regarding the hoisting, landing and placing of deck bundles, in general, have already been discussed above. This paragraph (e) of § 1926.757 also addresses the hazards of landing and placing loads on steel joists. As discussed earlier, the proposed term "decking;" has been changed to "metal decking" in the final rule. This definition clarifies that paragraphs (e)(1) through (e)(5) apply to all activities associated with metal decking that is used as a support element for either a floor or roof system.

Paragraph (e)(1) applies to any employer who places a load on steel joists during steel erection. This paragraph requires that the load is adequately distributed so that the carrying capacity of any steel joist is not exceeded. After this general requirement is met, the employer must meet the specific conditions set forth in the remainder of § 1926.757(e).

The Agency received no comment on this provision, and therefore, promulgates this requirement as proposed.

Paragraph (e)(2) prohibits placement of any construction loads on steel joists until all bridging is installed and anchored and all joist bearing ends are attached in accordance with § 1926.757(b). As defined in the final rule, a construction load means any load other than the weight of the employee(s), the joists and the bridging bundle. Although bundles of decking constitute a construction load under this definition, under certain conditions decking can be placed safely on the steel joists before all the bridging is installed and anchored. These conditions form the basis for the exceptions in paragraph (e)(4) of this section.

The Agency received no comment on this provision, and therefore, promulgates this requirement as proposed.

Paragraph (e)(3) provides requirements for safe and stable placement of bridging bundles on steel joists. A bridging bundle is not considered a "construction load." The weight of the bridging bundle is limited to 1,000 pounds because bridging will be placed on the joists before they have been fully stabilized. To ensure safe placement, this paragraph requires that the bundle of joist bridging be placed over a minimum of 3 steel joists that are secured at one end. Also, to ensure stability of the load, this provision requires that the edge of the bridging bundle be positioned within 1 foot of the secured end (some clearance is necessary for material handling purposes and to provide employee access to the steel joist's attachment point).

The Agency received no comments on this provision, and therefore, promulgates this requirement as proposed.

Paragraph (e)(4) sets forth special conditions which must be met before an employer is permitted to place a bundle of decking on steel joists that do not yet have all bridging installed. This paragraph applies only to bundles of decking and not to other construction loads. All six conditions must be met before the exception to the provisions of § 1926.757(e)(2) applies.

Paragraph (e)(4)(i) requires employers to determine, based on information from a qualified person, that the structure or portion of the structure is capable of safely supporting the load of decking. This determination must be documented in a site-specific erection plan which is made available at the construction site.

Paragraph (e)(4)(ii) requires that the bundle of metal decking be placed over a minimum of three joists to distribute the load.

Paragraph (e)(4)(iii) requires that the three steel joists supporting the bundle of metal decking have both ends attached to the support structure. The attachments must meet the requirements prescribed in § 1926.757(b).

Paragraph (e)(4)(iv) requires at least one row of bridging be attached and anchored to the three joists specified in § 1926.757(e)(4)(iii). The qualified person determines the type of bridging, erection bridging or horizontal bridging, needed to satisfy this requirement.

Paragraph (e)(4)(v) limits the weight of the bundle of metal decking to 4,000 pounds (1816 kg).

Paragraph (e)(4)(vi) requires that the edge of the bundle of metal decking be placed within a foot (0.30 m) of the bearing surface of the joist.

In the proposed rule, this paragraph stated that, "The edge of the bundle of decking is placed within 1 foot (.30m) of the bearing surface of the joist end." One commenter (Ex. 13–208) requested that it be revised to reference § 1926.757(e)(5) since both requirements are the same. The Agency agrees that the requirements are identical and has revised the provision accordingly for consistency.

Paragraph (e)(5) specifies the location for safe placement of all construction loads, not just metal decking, by requiring that the edge of the construction load be positioned within 1 foot of the secured end of the steel joists in order to enhance the stability of the load (some clearance is necessary for material handling purposes and for access to the steel joist's attachment point to the support structure).

Section 1926.758 Systems-engineered metal buildings

During SENRAC's deliberations on the prerequisites for anchor bolts, beams, columns and open web steel joists, the Committee discussed many anomalies that appeared to be associated with systems-engineered metal buildings. The Committee was advised by the Metal Building Manufacturers Association (MBMA) that over 50 percent of industrial buildings in steel erection are systems-engineered. This type of building frequently has lighter, cold formed members such as girts, eave struts and purlins (see definitions). Larger members in this type of construction are called rigid frames, a term not used in conventional steel erection. There are a large number of small specialized steel erectors who exclusively perform systems-engineered metal building erection. In light of these considerations and in an effort to facilitate compliance with this subpart, SENRAC developed a separate section for systems-engineered metal buildings. OSHA proposed a separate section and continues this approach in the final rule.

This section sets forth requirements to erect systems-engineered metal buildings safely. Systems-engineered metal buildings are defined in the definition section of this proposal. Systems-engineered metal buildings include structures ranging from small sheds to larger structures such as warehouses, gymnasiums, churches, airplane hangers and arenas.

Systems-engineered metal buildings use different types of steel members and a different erection process than typical steel erection. Many contractors erect systems-engineered metal buildings exclusively. An overwhelming majority of these erectors are small employers (63 FR 43477). The erection of systems-engineered metal structures presents certain unique hazards that are not addressed specifically by OSHA's existing steel erection standard. Although some of the hazards are similar to general steel erection, other hazards, such as those associated with anchor bolts, construction loads and double connections, are different.

Most of the requirements in this section are similar to those in other sections of this document. Where a conflict arises between a provision in the systems-engineered metal building section and that of another section of subpart R, to the extent that the work being performed is systems-engineered metal building work, the more specific systems-engineered metal building section would apply. This section, however, must not be interpreted to mean that (apart from sections 1926.755 and 1926.757), the other provisions of subpart R do not apply to systems-engineered metal buildings where appropriate.

In the proposed rule, the title of this section was "Pre-engineered metal buildings." During the public hearing, a representative of the Metal Building Manufacturers Association (MBMA) (Ex. 207X; pp. 246–247), advised SENRAC that the title of this section used an out-of-date term, and suggested that it be replaced with a more current term such as "metal-building systems." MBMA's position was based on its view that "buildings are predominately custom engineered for each application and are no longer selected from a catalog of standard designs." The Agency believes that MBMA's suggestion is valid. However, MBMA's suggested term "metal-building systems" could be too broadly interpreted and mistakenly applied to all buildings made entirely of metal instead of only to those which are engineered and supplied as a complete, integrated product. Therefore, OSHA believes that "systems-engineered metal buildings" better reflects that intent and has changed the title accordingly.

Paragraph (a) states that all of the requirements contained in subpart R apply to systems-engineered metal buildings except for §§ 1926.755 (Column Anchorage) and 1926.757 (Open Web Steel Joists). This paragraph has been revised from the proposed rule to clarify that § 1926.758 contains all anchor bolt and joist requirements that are specific to systems-engineered metal buildings.

Paragraph (b) requires all structural columns be anchored by at least four anchor bolts. One commenter expressed concern with this requirement and observed that different anchorage designs, including some with fewer bolts, could meet the safety intent of this paragraph (Ex. 13–153). It is conceivable that under certain conditions, other designs for anchorages could provide the stability needed for safe construction. However, it would be very difficult for those responsible for erecting the structures to know if, from and engineering standpoint, these other approaches would provide sufficient stability. OSHA has decided to defer to the expertise of the Committee, which found that a four-bolt system would be more effective and simpler to institute.

Another commenter supported the Agency's efforts to ensure column stability while questioning the Agency's authority to compel structural design specifications that will require engineering expertise (Ex.13–210). As noted earlier in the discussion of Column Anchorage (§ 1926 755) and Double Connections (§ 1926.756(c)), the Agency believes it is appropriate to prohibit the erection of structural members that lack key safety features.

Additionally, one commenter asked if this requirement would apply to all columns or just to those with structural significance (Ex. 13–173). As discussed in the Column Anchorage section, the Agency has added definitions for columns and posts. The intent of adding these definitions was to distinguish between columns that need to have four bolts and those that do not. Those definitions apply to this section as well. Only columns that fit the definition are required to have four anchor rods/bolts.

The requirement in paragraph (c) is unique to the erection of systems-engineered metal buildings because rigid frames are found only in this type of structure. This paragraph requires that rigid frames have 50 percent of

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their bolts or the number of bolts specified by the manufacturer (whichever is greater) installed and tightened on both sides of the web adjacent to each flange before the hoisting equipment is released. Like final § 1926.756(a), this provision requires an adequate number of bolts to ensure stability before the hoist line is released. Rigid frames are fully continuous frames that provide the main structural support for a systems-engineered metal building. They provide the support that is typically provided by columns and beams in conventional steel erection. Due to design and load requirements, connections in rigid frames occupy a greater area and require more than two bolts upon initial connection. The remaining bolts are used to attach other members to the structure and provide stability against wind loading. To allow these connections to be bolted only with two bolts would not be adequate in many cases to prevent a collapse hazard. No comments were received on this paragraph and it is promulgated as proposed.

Paragraph (d) also pertains to stability and prohibits construction loads from being placed on any structural steel framework unless such framework has been safely bolted, welded or otherwise adequately secured. Without proper bolting or welding to provide stability, a construction load could cause a collapse of the structure. No commenter were received on paragraph (d) and it remains unchanged in the final rule.

For clarity, the regulatory text of proposed paragraphs (e)(1) and (e)(2) has been incorporated into a single paragraph (e) in the final rule. However, the paragraph is promulgated with the proposed requirements intact.

Paragraph (e) pertains to double connections in systems-engineered metal buildings. When girts or eave struts share common connection holes, a double connection hazard exists. As with § 1926.756(c), a seat or similar connection will prevent one member from becoming displaced during the double connection activity. In girt and eave strut to frame connections where girts or eave struts share common connection holes, paragraph (e) requires that at least one bolt with its wrench-tight nut remain in place for the connection of the first member unless a field-attached seat or similar connection device is present to secure the first member so that the girt or eave strut is always secured against displacement. In addition, paragraph (e) maintains that the seat or similar connection device must be provided by the manufacturer of the girt or eave strut so that it is designed properly for the intended use. Because this form of double connection is unique to systems-engineered metal building construction and might not be considered a double connection under a literal reading of § 1926.756(c), this provision specifically addresses girt and eave strut to frame connections.

Changes to proposed paragraph (e)(2) were suggested by two commenters (Ex. 13–153), one who recommended that "the seat or similar connection that would normally be welded to the frame, * * * should be provided by the frame manufacturer * * *". The other commenter (Exs. 43 and 207X) suggested that paragraph (e) be revised to reflect current steel erection methods in which the responsibility of installing temporary girt or eave supports is assigned to the erector. This suggestion also included a request to delete paragraph (e)(2).

Systems-engineered metal buildings are designed as an integrated product—each element is designed for the completed unit. In fact, MBMA (Ex. 207X) pointed out (in the context of what the title should be for the section) that almost all metal buildings are now "custom engineered." Consequently, the designers of the building are particularly well situated to know where the double connections will be, the loads on the seats during assembly, and how to design the seats. In contrast, the erector does not normally have this type of design expertise and is not well situated to assess the type of seat or other connection device necessary for each particular double connection.

Paragraph (f) provides that both ends of all steel joists or cold formed joists shall be fully bolted and/or welded to the support structure before releasing the hoisting cables, allowing an employee on the joists, or allowing any construction loads on the joists. A commenter suggested that this paragraph be deleted because joists are addressed more thoroughly in § 1926.757 (Ex. 13–153). Two building trades representatives submitted similar comments expressing concern that paragraph (f)(1) was inconsistent with § 1926.756(a) and that the requirement for joist ends to be fully bolted or welded is excessive. (Exs. 13–210 and 13–222). SENRAC found that systems-engineered metal buildings are erected differently than other steel structures. These different construction methods were discussed in the preamble for the proposed rule (63 FR 43477). Systems-engineered metal buildings rely on these connections for stability and strength. These construction methods are essential to guard against collapse of systems-engineered metal buildings. Therefore, the Agency is deferring to SENRAC's expertise with respect to this difference and promulgates this paragraph unchanged.

Paragraph (g) prohibits the use of purlins and girts as anchorage points for a fall arrest system unless written approval to do so is obtained from a qualified person. Generally, purlins and girts are lightweight members designed to support the final structure. They may not have been designed to resist the force of a fall arrest system. If, however, a qualified person determines that the purlin or girt is of sufficient strength to support a fall arrest system, it may be used for that purpose. The qualified person would be required to provide written documentation of this determination. This requirement is identical to the one for steel joists in proposed § 1926.757(a)(9).

Paragraph (h) provides that purlins may only be used as a walking/working surface when installing safety systems, after all permanent bridging has been installed and fall protection is provided. Purlins are "Z" or "C" shaped lightweight members, generally less than ⅛" thick, 2–4" wide on the top and up to 40 feet long. They are not designed to be walked on and, because of their shape, are likely to roll over when used as a walking/working surface if not properly braced. One commenter (Ex. 43) suggested that the use of cold-formed joists as walking/working surfaces should be prohibited along with purlins in paragraph (h). OSHA has not included cold-formed joists in this paragraph because they provide greater stability than do purlins which are not designed to be used as walking/working surfaces without the addition of specific safety precautions.

Paragraph (i) addresses the placement of construction loads on systems-engineered metal buildings to prevent collapse due to improper loading of the structure. This paragraph requires that construction loads be placed within a zone that is not more than 8 feet (2.5 m) from the centerline of the primary support member. Unlike conventional decking, systems-engineered metal building decking bundles are lighter, and the sheets in the bundle are staggered. This staggering means that the bundles must be set so that the end of one bundle overlaps another bundle since the lengths of the sheets vary. The zone needs to be big enough to allow for the lapping while still having the support of the structure. An 8 foot (2.5 m) zone allows enough room to meet these objectives. No comments were received and the final remains as proposed.

Section 1926.759 Falling object protection

This section sets forth the requirements for providing employees with protection from falling objects. A real, everyday hazard posed to steel erection employees is loose items that have been placed aloft that can fall and strike employees working below.

Paragraph (a) requires that all materials, equipment, and tools that are not in use while aloft be secured against accidental displacement. The Agency received no comments on this section of the standard, and the provision is unchanged in the final rule.

The intent of paragraph (b) is that, when it is necessary to have work performed below on-going steel erection activities (other than hoisting), effective overhead protection must be provided to those workers to prevent injuries from falling objects. If this protection is not provided, work by other trades is not to be permitted below steel erection work. One way controlling contractors can reduce the hazards associated with falling objects is by scheduling work in such a way that employees are not exposed.

In the proposed rule, this section was titled, "overhead protection." Most of the comments OSHA received on this section confused this provision with the requirements for protecting workers from falling objects associated with hoisting operations, which is addressed by § 1926.753(d). OSHA has changed the title of this paragraph to "Protection from falling objects other than materials being hoisted" so employers will not confuse the two provisions.

As proposed, § 1926.759(b) stated that, "The controlling contractor shall ensure that no other construction processes take place below steel erection unless adequate overhead protection for the employees below is provided." Two commenters (Exs. 13–318 and 201X; p. 120) stated that the controlling contractor may not always be able to ensure that nobody is working under a steel erector. In other words, these commenters believe that the use of the word "ensure" would make the controlling contractor strictly liable—would have to guarantee—that no one worked below the steel erection activities. The use of the word "ensure" in this standard does not make the controlling contractor liable if it institutes reasonable measures to comply with the requirement. All defenses normally available to employers are equally available where a requirement is phrased using the term "ensure."

For a different reason, however, the Agency has rephrased the provision to read that the controlling contractor will "bar" other construction processes below steel erection. This change was made to more directly state that the employer must institute measures to keep employees out of the area below the steel erection activities.

Section 1926.760 Fall Protection

Paragraph (a) General Requirements

Paragraph (a) sets the fall protection threshold height for steel erection activities. Final paragraph (a)(1) requires that, with two exceptions, each employee covered by this rule who is on a walking/working surface with an unprotected side or edge more than 15 feet (4.6m) above a lower level must be protected by conventional fall protection (systems/devices that either physically prevent a worker from falling or arrest a worker's fall). One exception allows connectors to not use their personal fall protection to avoid hazards while working at heights between 15 and 30 feet. The other exception allows workers engaged in decking in a controlled decking zone to work without conventional fall protection at heights between 15 and 30 feet.

This is essentially the same as the proposed rule and SENRAC's recommendation. OSHA added a provision setting out the types of protection allowed. Protection must be provided by the use of guardrail systems, safety net systems, personal fall arrest systems, positioning devices systems or fall restraint systems. The Agency also re-worded the exception for connectors to clarify that they are permitted to not use their fall protection system where, in their sole discretion, they determine that is necessary to avoid a hazard.

Prior to enactment of this final rule, the fall protection requirements for steel erection were in three separate provisions. Depending on the structure and the type of fall exposure, one of the following applied: §§ 1926.750(b)(1)(ii), 1926.750(b)(2)(i) (both are in subpart R), or § 1926.105(a) (subpart E, Personal Protective and Life Saving Equipment). These provisions were the subject of considerable litigation, the product of which was the following: (1) In single story structures, § 1926.105(a) applied, which required fall protection at and above 25 feet for both fall hazards to the interior and exterior of the structure; (2) in multi-tiered buildings, § 1926.750 applied to fall hazards to the interior of the building. Several courts held that, under that standard, fall protection was required at and above 30 feet; (3) in multi-tiered buildings, § 1926.105(a) applied to fall hazards to the exterior of the building, which required fall protection at and above 25 feet. With the exception of § 1926.754(b)(3), the final rule eliminates distinctions between interior and exterior fall hazards and tiered versus untiered buildings for the fall protection trigger heights.

The fall protection rules for steel erection differ from the general fall protection rules in subpart M, which set six feet as the trigger height for fall protection. OSHA agrees with SENRAC that steel erection activities are different from most other construction activities. The different trigger height reflects these differences. OSHA also agrees with SENRAC that the former fall protection rules relating to steel erection are insufficiently protective and need to be strengthened.

In examining the issue of the threshold height for requiring conventional fall protection, SENRAC considered 29 CFR 1926 subpart M, the general fall protection standard for construction. In general, the subpart M trigger height for fall protection is six feet. SENRAC evaluated whether the trigger height in steel erection should be different than that in subpart M and concluded that it needed to be higher.

Steel erection differs from general construction in three major respects—the narrowness of the working surface, its location above, rather than below, the rest of the structure, and a minimum distance of approximately 15 feet to the next lower level. We explained the steel erection process in the proposal as follows (63 FR 43478–79):

> Initially, vertical members, referred to as columns, are anchored to the foundation. The columns are then connected with solid web beams or steel joists and joist girders to form an open bay. In a multi-story building, the columns are usually two stories high. These structural members are set by connectors in conjunction with a hoisting device (typically a crane). When the two-story columns are set in place, the connector installs the header beams at the first level, which forms the first bay. Each floor is typically 12.5 to 15 feet in height. After an exterior bay is formed ("boxing the bay"), the filler beams or joists are placed in the bay. The connector then ascends the column to the next level, where the exterior members are connected to form a bay, and so on. The floor or roof decking process basically consists of hoisting and landing of deck bundles and the placement and securing of the metal decking panels.

In short, a new, very narrow working surface is constantly being created as skeletal steel is erected at various heights. For many steel erectors, especially connectors, the work starts at the top level of the structure.

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The special circumstances of steel erection can make conventional fall protection very difficult to deploy below 15 feet. For many steel erectors, especially connectors, the work starts at the top level of the structure. This means that anchor points above foot level are often limited or unavailable. Because of the nature of the structure, the available fall arrest distance is usually about 15 feet.

Thus, we noted in the proposal that fall equipment manufacturers appeared before the Committee and discussed the relationship between the fall distance when fall arrest systems are used and the trigger height for requiring fall protection (63 FR 43479). The location of anchor points, in conjunction with a number of other factors, will affect the fall arrest distance—the distance a worker will fall before the fall arrest system stops the fall. The fall arrest distance is the sum of the distance the worker falls before the fall arrest system begins to stop the fall, plus the additional distance that it takes for the system to slow and then finally stop the fall completely. Other factors that affect the fall arrest distance include the type of fall protection system used, the type of components and how the system is configured and anchored. The degree of mobility needed for the worker, location of available anchor points, and the need to limit the arresting forces on the worker's body also affect the choice of system and its installation.

Personal fall arrest systems commonly used by workers in full body harnesses often have one of the following: (1) Shock absorbing lanyard; (2) self-retracting lifeline; (3) rope grab with vertical lifeline; or (4) shock absorbing lanyard with rope grab and vertical lifeline. Fall arrest distances can vary with different types and lengths of lanyards. The distances can also vary in systems that permit the user to adjust the amount of slack.

The three common types of anchorage systems include: (1) Horizontally mobile and vertically rigid (such as a trolley connected to a flange of a structural beam); (2) horizontally fixed and vertically rigid (such as an eyebolt, choker or clamp connected to a structural beam, column or truss); and (3) horizontally mobile and vertically flexible (such as a horizontal lifeline suspended between two structural columns or between stanchions, which are attached to a structural beam and designed to support the lifeline). Eight feasible combinations of personal fall arrest systems and anchorage connectors were discussed (63 FR 43479). The total fall distance can differ significantly depending on how the system is configured. A system using an anchorage connector, harness and shock absorbing lanyard will have a total fall distance between 3 and 23 feet, while the total fall distance for a system using an anchorage connector, harness and self-retracting lifeline will measure between 4 and 10.5 feet. (Exs. 6–10 and 9–77-Tables 6 and 7). In 1995, one fall protection manufacturer indicated to SENRAC that the lowest point of the ironworker's body should be at least 12.5 feet above the nearest obstacle in the potential fall path when using a properly rigged, rigidly anchored, personal fall arrest system of the shock absorbing lanyard type or self-retracting lifeline type. In view of the types of equipment available, potential locations of anchor points, and typical distance between work surfaces and the next lower level, the Committee determined that 15 feet was an appropriate threshold for requiring fall protection, subject to the two exceptions mentioned above.

OSHA received comments supporting a requirement for fall protection beginning at 15 feet (Exs. 13–354; 13–151; and 13–207C). The National Erectors Association (Ex. 208X, p. 115) supported a 15-foot rule and testified against the "one size fits all" trend (relative to having a 6-foot rule). Robert Banks of the Safety Advisory Committee of Structural Steel (Ex. 205X, p. 294) felt that, when finalized, the proposed rule would generate widespread use of personal fall arrest equipment. Innovative Safety, (Ex. 207X, pp. 15–16) testified that 15 feet was realistic and that various fall arrest systems could be used at that height. One commenter (Ex. 13–246) advocated a 10-foot rule.

However, OSHA also received comments and testimony in support of a 6-foot fall protection rule. Several commenters advocated consistency between Subpart R and M (Exs.13–159; 13–148; 13–121; 13–260; and 13–215). Some general contractors stated they support a 6-foot fall protection rule for steel erectors (Exs. 207X, p. 211; 207X, pp.134–135, p.172; 207X, pp. 182–186; 207X, p. 172; 13–366; 13–352; 13–306; 13–346; 13–340; 13–338; 13–240; 13–229; 13–214; 13–192; 13–167; and 13–159). Five of these companies testified to the successful implementation of their 6-foot programs for steel erection for all steel erection operations, including connecting and decking. For example, a representative from Kellogg Brown & Root testified (Ex. 207X, pp. 133–134) that their company has had a 6-foot policy for eight years. When the structure cannot accommodate fall protection or fall prevention systems, their company uses aerial lifts and/or scissors lifts. W.S. Bellows Construction Corp. implemented a 6-foot fall protection policy in 1994 (Ex. 207X, pp. 136–141) when subpart M took effect. Bellows testified that their policy has increased productivity, decreased insurance costs, and saved lives. An official from CENTEX Construction Co., a general contractor, declared (Ex. 207X, pp.182–186) that his company, because of positive experiences on earlier projects, implemented a policy to hire only subcontractors using 6-foot programs. Turner Construction Company's spokesman testified (Ex. 207X, p. 211) that their company would prefer a 6-foot rule, but could operate with a 15-foot threshold.

Four commenters referenced the fatality statistics and were concerned that OSHA included the SENRAC fall protection provisions in the proposed rule. These commenters contended that technology was available to protect steel erection workers at 6 feet (Nigel Ellis Ex. 23; Beacon Skanska Const. Co. Ex.–13–285; Clark Construction. Co. Ex. 202X, p. 9–10; and Joseph Fitzgerald Ex. 13–31). However, one of these commenters, Mr. Nigel Ellis, acknowledged that preplanning might not preclude all the anchorage point problems, and where employers prove that it is infeasible to provide overhead anchorage points, the rule should contain provisions that would permit free fall distances greater than 6 feet. For example, if workers are in situations where the only anchor point is at foot level, there would be difficulties when using personal fall protection at 6 feet. In general, in order to use a personal fall arrest system at 6 feet, the system would have to either be anchored above the worker's head or set up to restrain the worker from stepping past an open side or hole. For many steel erection activities, he noted this may be difficult to achieve at 6 feet.

During the rulemaking process, SENRAC and OSHA analyzed accident information derived from OSHA's IMIS system. There were two studies on steel erection fatalities—a seven-year OSHA study and a subsequent eleven-year OSHA/SENRAC study (which included the previous study's data; Exs. 9–14A; 9–42 and 49). An earlier OSHA five-year study of construction fatalities in general showed that 8% of the fatal falls occurred between 6 and 10 feet and that 25% occurred between 11 and 20 feet. However, of that 25%, the Agency does not know how many ironworker fatalities occurred between 11 and 15 feet. With this significant gap in the data, we cannot determine whether a high proportion of the falls between 11 and 20 feet occurred below 15 feet. We note that much of the steel erection work involving single story structures, such as warehouses, is done at or above 15 feet.

After analyzing the entire record, the Agency has determined that the use of conventional fall protection at 15 feet and above is necessary and feasible in most cases. While some general contractors and large industrial steel erectors may be providing fall protection below 15 feet, the data are unclear with respect to how much of a need there may be for requiring fall protection in steel erection at those lower heights. Also, many situations in steel erection do not permit connecting fall protection below 15 feet. In addition, steel erection work that is done between 6 and 15 feet is often performed from ladders, scaffolds, or personnel work platforms (63 FR 43479). Therefore, OSHA has decided not to require conventional fall protection in steel erection below 15 feet.

Paragraph (a)(2) covers requirements for perimeter safety cables. It is modified from the proposal and moved from proposed § 1926.756(f)(1). It specifies that perimeter safety cables shall be installed at the final interior and exterior perimeters of multi-story structures as soon as the decking has been installed. These cables must be installed regardless of other fall protection systems in use. They must meet the criteria for guardrail systems in subpart M (1926.502(b)).

The final requirements differ from those proposed by specifying when the cables must be installed: "as soon as the decking has been installed." Although the proposal's preamble stated SENRAC's and OSHA's intention that "these cables * * * be installed as soon as the deck has been installed * * *" (63 FR 43471), the proposed regulatory text carried over the broader language of the current requirement that cables be installed "during structural steel assembly." To carry out SENRAC's intention, as well as to improve clarity, we have specified when the cables must be installed, so that they can protect the detail crews which follow the decking crews (Id.).

The final rule also changes the minimum thickness requirement of the cable to ¼" to conform to the guardrail specifications required in subpart M (§ 1926.502(b)). We had proposed the cable be at least ½," which was the previous requirement of subpart R. We agree with the commenters that the subpart M requirements for guardrails are appropriate for the perimeter safety cables in steel erection.

The Associated General Contractors of Wisconsin and D.C. (Exs. 13–334 and 13–210) suggested that the name "perimeter cable" be changed to "perimeter cable guardrails" to be consistent with Subpart M. Because the term "perimeter safety cable" is so commonly used in the steel erection industry, the Agency has decided not to adopt this suggestion.

A few participants (Exs. 206X, p. 55; 13–63; and 13–209) stated that the meaning of perimeter is undefined because the perimeter may change as work progresses. However, in the vast majority of buildings the perimeter columns define the final perimeter where the edges will not be expanded. LeMessurier Consultants (Ex. 13–127) suggested that the proposed words "periphery" and "perimeter" lead the reader to believe that only the outermost edges of the structure have to be guarded and that the final interior perimeters (such as for atriums) are similar to final exterior perimeters in that these edges will not be expanded. We agree, and the final text makes clear that the final "interior" as well as the final "exterior" must be protected by the use of safety cables. However, we are not including an appendix with diagrams, as suggested, because of the wide variety of perimeter configurations.

One commenter (Ex. 206X, p. 55) testified that the steel erectors had the ingenuity to erect the perimeter safety cables and should be responsible for complying with the standard. Others commented that it should be the controlling contractor's responsibility to comply with the standard or to make sure, by contract, that competent people do the work and that it is a common practice for erectors to be tasked, by contract, with installing perimeter safety cables along with their other work.

The majority of the general contractors testified (see for example, Exs. 13–63, 13–116, 13–161 and 13–203) that they were opposed to making the controlling contractor responsible for the erection of equipment required in the steel erection standard. They feel the erectors are the most experienced at erecting perimeter safety cables and should have that responsibility.

The perimeter cable provision in the proposal did not specify either the steel erector or the controlling contractor as responsible for installing the perimeter cables. Section 1926.750(a) states, in part, that "the requirements of this subpart apply to employers engaged in steel erection unless otherwise specified." Since the perimeter cable provision does not specify any particular entity as responsible for installing the cables, all employers engaged in steel erection with respect to the project are responsible for compliance with this provision, including the controlling contractor. The extent of the controlling contractor's responsibility for complying with this provision would be determined in accordance with the Agency's multi-employer policy; that policy applies to all controlling employers, irrespective of the type of construction.

Paragraph (a)(3) requires that connectors and employees working in controlled decking zones be protected from fall hazards as provided in paragraphs (b) and (c) of this section, respectively. The final rule retains (with some modifications) the proposed exceptions to the general requirement that fall protection be provided at heights above 15 feet. According to paragraphs (b) and (c), employers of connectors are partly excepted from the general rule and employers of leading edge decking workers are excepted from some of the general fall protection requirements if they comply with specified alternative procedures in these paragraphs. These provisions were the subject of much division of opinion both during SENRAC's deliberations and during the post-proposal phase of this rulemaking procedure. We discuss these provisions immediately below.

Paragraph (b) provides a special rule for employers of connectors. Paragraphs (b)(1) and (b)(2) are unchanged from the proposal. Paragraph (b)(1) requires each connector be protected from fall hazards of more than two stories or 30 feet (9.1 m) above a lower level, whichever is less. Protection at this height is currently required by OSHA's existing steel erection standard for all employees engaged in steel erection. Paragraph (b)(2) requires each connector to complete connector training in accordance with § 1926.761. Such training must be specific to connecting and cover the recognition of hazards, and the establishment, access, safe connecting techniques and work practices required by § 1926.756(c) and § 1926.760(b).

Final paragraph (b)(3) provides that connectors must be provided, at heights over 15 and up to 30 feet above a lower level, with a personal fall arrest system, positioning device system or fall restraint system and wear the equipment necessary to be tied off, or be provided with other means of protection from fall hazards in accordance with paragraph (a)(1) (or, for protection against perimeter falls, (a)(2)) of this section.

This provision reflects SENRAC's findings that at times connectors need to remain unencumbered. The revised

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final provision also makes clear that this exception applies only where the employer has provided the connector with a complete personal fall protection system. This includes a personal fall arrest system as defined in § 1926.751 with secure anchorages for tying off. Employers may, of course, protect connectors working between 15 feet and 30 feet with another allowable fall protection system, in which case this limited exception does not apply.

The Committee's minutes (Ex. 6–1 through 6–11) show that the proposed "connector exception" was a compromise position. It was adopted by the Committee after listening to testimony of connector panels, fall protection equipment representatives, general contractor representatives, and steel erector representatives, all presenting differing views on whether connectors need different fall protection requirements than other non-connecting ironworkers. The Committee was informed that California's rule allowed the connector to be untied between 15 and 30 feet and the rule appears to be operating successfully (June 27–29, 1995-Committee Minutes). SENRAC told OSHA that it intended to define "connector" narrowly because the primary purpose of the definition was to specifically define which ironworkers are covered by the "connection exemption."

We proposed this exemption to reflect SENRAC's consensus agreement. As shown above, SENRAC recognized that the issue of fall protection for connectors was highly controversial. The minutes of the Committee show that some of its members agreed on the provision only when they were assured that within 3 years from the rule's effective date, the Agency would evaluate the available accident data and assess whether the rule was sufficiently protective.

The proposal set out reasons why SENRAC believed that this exception was necessary: "The Committee believes that under certain conditions, the connector is at greater risk if he/she is tied off. For example, in the event of structural collapse, a tied-off connector could be forced to ride the structure to the ground." (63 FR 43480).

The major concern of proponents of the exception both during SENRAC's meetings and during the rulemaking comment period and hearing, was that connectors needed freedom of movement and requiring them to tie-off would hinder this. The concern, as stated previously, was that in the event of structural collapse, a connector would be forced to "ride the structure to the ground" if tied off, whereas he/she could jump free of the collapsing structure if he/she were not tied off. The ability to move without restraint in order to get away from incoming loads is also stated as a reason for connectors not to tie off.

The following discussion of the record combines information in the minutes of the committee with as information and comment submitted directly into the post-proposal record.

Fall protection was discussed during every SENRAC meeting. From the start, some committee participants stated that connectors need to remain unencumbered, both to do their job and to avoid dangerous conditions they commonly face. In the July, 1994 meeting where the full committee met with the fall protection workgroup, this point was made. Participants noted that connectors and some other steel erection workers are highly trained and experienced. It was stated that it would be a "greater hazard" to tie off such highly experienced people. (The term "greater hazard" has a precise legal meaning; it is an affirmative defense which requires employers to demonstrate various elements in order to be relieved of a citation. However, throughout SENRAC's discussions and the subsequent rulemaking, the term was used informally.) In its deliberations, SENRAC considered whether there are any jobs that requires a person to not be protected from fall protection because it is technically and economically infeasible. In the August, 1994 SENRAC meeting, a group of connectors from the Ironworkers Local #7 discussed "their experiences and views on the relative merits of mandatory fall protection for connectors and other workers." They uniformly stated that they needed to remain unencumbered when they were working with hoisting equipment and some members recounted personal experiences where they were able to escape collapses and incoming steel only because they were not tied off. By the November 27–December 1, 1995 meeting, SENRAC agreed on a consensus view incorporating the limited exception for connectors, as proposed. A few participants insisted that OSHA review fall statistics within 3 years after the final rule becomes effective, to check on whether the exception is adequately protective of connectors.

Issue #12 in the proposal asked the public to comment on whether there should be specific criteria indicating when connectors should tie-off. We also asked if it was feasible or posed a greater hazard for connectors to tie-off and if it should be the employer's responsibility to determine where and when fall protection should be required. Several ironworkers testified during the December 1998 hearings about their personal experiences and belief that it is important to be able to move freely and, at times, to jump off a collapsing steel member.

Several commenters (Exs. 13–68; 13–345; 13–349; 13–331; and 13–114) stated connectors needed freedom of movement up to 30 feet. One commenter (Ex. 13–114) said the concern is not with falling, but being able to get away from the steel during a collapse. A member of the Ironworkers' Panel No. 1 testified (Ex. 205X, pp. 312–313) that even though the connector appears to be "running around like he's crazy, he's not. He has a place to go, and he knows where he is going at all times."

A number of other commenters objected to allowing connectors to choose whether to use fall protection, but none of these individuals indicated that they had experience connecting (Exs. 13–31; 13–60; 13–210; 13–222; and 13–334). The point was made, however, that, "in the case of structural collapse, the connector will "ride the structure to the ground" whether or not he/she is tied off" (Ex. 13–31). The companies described above that advocated requiring fall protection at 6 feet require the connectors on their projects to be tied-off at all times. Furthermore, some commenters supporting the connector exception acknowledge that incoming steel can injure or kill connectors when they are not tied-off; Peterson Beckner Industries, Inc., (Ex.13–354) related the case of two employees who were hit by incoming loads: the one who was tied off was hit and suffered a broken arm. The one who was not tied off was knocked off of a beam at the exterior of a building and was killed.

The record also contains two studies on steel erection fatalities—a seven-year study and a subsequent eleven-year study (which included the previous study's data) (Exs. 9–14A; 9–42 and 49). The eleven-year study categorized fatalities in a number of ways, including by "activity" and by "cause." Of the various causes listed, collapse was the third highest at 15.8% of the fatalities (the highest category was falls from slipping at 24%; second was "unknown" at 17%). By activity, connecting was second highest at 17% (the most dangerous activity was decking, at 23%).

The concern about collapses is the most cited reason for allowing connectors to not use fall protection equipment. SENRAC recommended and OSHA proposed new provisions that address the causes of collapses such as inadequately cured concrete column foundations and inadequate or improperly repaired anchor bolts. The final rule addresses these by requiring concrete to be properly cured, a sufficient number of anchor bolts to support the columns and that anchor bolts are properly repaired (§ 1926.752(a); § 1926.755(a); and § 1926.755(b)). This should reduce the risk of collapse to connectors.

With respect to uncontrolled incoming steel exposing connectors to struck-by hazards, the final rule contains criteria for hoisting and rigging of steel members to minimize the likelihood of a suspended load shifting, falling and striking employees. Paragraph (a) of 1926.753 requires a competent person to perform a pre-shift visual inspection of the crane, and for qualified riggers to inspect all rigging prior to each shift. Section 1926.753(b) addresses working under the load. This paragraph requires employers to minimize employee exposures to the extent possible; however, it may be necessary for certain employees, such as connectors and those hooking and unhooking loads, to briefly work directly below a suspended load. To minimize this hazard, qualified riggers are required to rig the load to prevent displacement and to use a self-closing safety latch (or equivalent). These precautions are designed to minimize the chance of components disengaging from the hook and causing the load to fall, which should also reduce the risk to connectors.

After reviewing the comments and testimony submitted to the rulemaking record after the proposal was published, OSHA has determined that the post-proposal rulemaking record is similar to the comment and testimony submitted to the Committee during its meetings and in various workgroup meetings. In addition, the consensus agreement of the Committee, which included representatives of all interests affected by this rule, reflects an agreement that employee safety would be promoted by the adoption of the proposed standard, including the connector exception. Comment and testimony submitted by connectors and various representatives of ironworker employees overwhelmingly supported the proposed provision allowing connectors to not tie-off when working below 30 feet. For all these reasons, the Agency has decided to defer to the determinations of the Committee and allow connectors to not be tied-off in order to avoid hazards. The definition of "connector" reflects SENRAC's intention to define that term narrowly. And as requested by some members of SENRAC, OSHA will examine the compliance experience of this provision within 3 years to determine if connectors are adequately protected from falls applying these provisions.

In sum, since the Committee considered the full range of evidence on this issue in its deliberations, the Agency is deferring to its expertise and assessment of that evidence. The Committee's expertise, in combination with the information relied upon by the Committee, has provided OSHA with much of the supporting evidence for this standard. While other approaches for protecting connectors against falls may be possible, based on the Agency's concurrence with the negotiated proposal, the information in the record, including material used and generated by SENRAC during the negotiating process, OSHA has relied on the Committee's expertise and decided in this instance in favor of the approach recommended by SENRAC.

Paragraph (c) Controlled Decking Zone (CDZ).

The final standard's provisions for controlled decking zones (CDZ) are mostly unchanged from the proposal. The CDZ is an alternative to fall protection for leading edge decking workers between 15 and 30 feet above a lower level. If an employer establishes a CDZ that conforms to paragraph (c), employees authorized to be in that zone who are trained pursuant to § 1926.761, do not have to be provided with or use a fall protection system. OSHA proposed the provision based on SENRAC's consensus view that this alternative approach to fall protection would substantially reduce the number of accidents involving falls during decking.

Paragraph (c)(1) requires that each employee doing leading edge work in a CDZ must be protected from fall hazards of more than two stories or 30 feet, whichever is less. CDZs are inappropriate for decking operations at and above these heights. For example, single story, high bay warehouse structures and pre-engineered metal buildings often require decking operations more than 30 feet above lower levels. The exception would not apply in these situations.

An important aspect of a CDZ is controlled access. OSHA fatality date (Ex. 9–14 and 9–49), indicate that some employees who suffered fatal falls from areas that were being decked were not engaged in leading edge work. Paragraph (c)(2) limits access to the CDZ exclusively to those employees who are actually engaged in and trained in the hazards involved in leading edge work.

Final paragraph (c)(3) addresses the physical limits of a CDZ, and requires that the boundaries be designated and clearly marked. The CDZ shall not be more than 90 feet (27.4 m) wide and 90 feet (27.4 m) deep from any leading edge, and control lines, or the equivalent (for example, the perimeter wall), shall be used to restrict access to the area.

The proposal asked for public comment on whether a definition of "control lines" was necessary, or whether non-mandatory appendix D, which describes acceptable criteria for control lines, provided an adequate description. It also asked whether appendix D should be incorporated into the fall protection provisions.

Several commenters (Exs. 13–113, 13–170G, 13–344, 13–173, 13–210 and 13–215) requested that Subpart R's control line criteria conform to the criteria found in subpart M—§ 1926.502(g)(3). In the final rule, OSHA has made the provision more consistent with subpart M where possible. A new paragraph was added to subpart R's appendix D regarding flagging or marking of the control line with highly visible material. The only remaining difference in the control line requirements is the allowable distance from the leading edge. A control line for a controlled decking zone is to be erected not more than 90 feet (27.4 m) from the leading edge, while the maximum distance permitted in Subpart M is 25 feet. The longer maximum distance in Subpart R is needed because of the size of the bays that are decked.

A commenter (Ex. 13–86), a contractor who performs traditional and pre-engineered steel erection, asked OSHA to conform the requirements for "control lines" in subpart R with the requirements for "warning lines" in subpart M since, in its view, the two systems serve basically the same purpose. OSHA disagrees with the commenter. We believe the systems perform different functions and therefore need different criteria to address those differences.

The controlled decking zone section requires that the boundaries of the zone be designated and clearly marked and that the access be limited exclusively to those employees engaged in leading edge work. One means of fulfilling this obligation is to erect control lines. While other methods might also be used, control lines are commonly used to restrict access to the unprotected area by creating a highly visible boundary. Their high visibility readily defines the area in which employees will work

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without conventional fall protection, and visually warns employees that access is limited to authorized personnel. Warning line systems, however, are erected close to the edge of a roof (as close as 6 feet). They delineate the area where mechanical equipment may be used on roofs, and warn employees when they are approaching a fall hazard. The criteria for warning lines contemplated that there would be unintended contact with the line (such as an employee backing into it), and that such contact will attract the employee's attention, enabling the employee to stop in time to avoid falling off the roof. As referenced in the preamble to subpart M (59 FR 40712), the basis for the warning line system originated from the 1980 rule for Guarding of Low-Pitched-Roof-Perimeters During the Performance of Built-Up Roofing Work (45 FR 75618–631). The 1980 preamble specifically stated that warning lines function by providing a direct physical contact with the employees. This direct physical contact with the line dictates that the criteria for warning lines be substantially stronger and more rigid then a system whose primary function is to limit access by a visual warning.

Paragraph (c)(4) states that each employee working in a CDZ must complete the CDZ training, as specified in this subpart. Employees are required to be trained to recognize the hazards associated with working in a controlled decking zone, and trained in the establishment, access, safe installation techniques and work practices required by certain sections of this subpart, such as § 1926.754(e)—Decking and § 1926.760(c)—Controlled Decking Zone.

Paragraph (c)(5) requires that during initial placement, deck panels shall be placed to ensure full support by structural members. This provision addresses the specific hazard that results when full support is absent when placing metal decking. For example, in steel joist construction, metal deck sheets are typically 20 feet or longer and may span more than 4 joists (typically spaced 5 feet apart). A hazard is created if the deck is placed so that only three joists are supporting the sheet and the deck ends are unsupported. A worker not using fall protection and stepping onto the unsupported end of a deck sheet so placed is exposed to a potentially fatal fall hazard.

Paragraph (c)(6) states that unsecured decking in a CDZ shall not exceed 3000 square feet (914.4 m^2). This section is intended to limit the area of unsecured decking in which employees work. Because metal decking sheets are typically not uniformly sized and can create alignment problems, it is common practice to install a series of unsecured sheets on the structural member prior to fastening. The Committee believed that 3000 s.f. would be necessary for the metal decking to be placed and then properly aligned prior to tack welding.

The final rule, in § 1926.760(c)(6), prohibits more than 3000 feet of unsecured decking in the CDZ. This provision is unchanged from the proposal. OSHA explained this provision in the preamble to the proposal as follows: "The proposal would limit the area of unsecured deck to 3000 square feet (914.4 m^2) to restrict the exposure to employees engaged in the placement of these deck sheets. Given the dimensions of typical bay (a typical bay is approximately 9000 s.f.), 3000 square feet was determined to be an appropriate limit that would allow for the decking to be placed and alignment to be performed prior to tack welding. This limit would thus greatly reduce the hazards associated with large areas of decking being left unattached and unattended." (63 FR 43481). The Steel Decking Institute's representative, Robert Paul, recommended that the provision be changed to require immediate securing of the decking in a CDZ. "The SDI cannot endorse the concept of a CDZ with deck being unfastened and petitions that it be changed. Our position is and [has] always been that decking can be fastened immediately and should not be walked on until after it is fastened." (Ex. 203X; p. 98). Phil Cordova, a SENRAC member, acknowledged that immediate securing was probably feasible in some cases: "* * * I think that you're probably correct on some decks probably need to be attached immediately." (Ex. 203X; p. 104). By contrast, SDI acknowledged in testimony that there were instances where you could not immediately attach the decking: In response to Mr. Cordova's question: "How would you align these decks if they're attached and they vary in size?", Mr. Paul stated: "Most decks, those with a nestable side lap, certainly have an adjustability that they can be laid to a varying level of coverage. Even decks that have a button punchable side lap within the standard button punchable type side up, there is some leeway to it. Some decks cannot. Some decks do need to be incremented that have no adjustability in the button punchable side lap. And really the only way to put those down is to increment them." (Ex. 203X; p. 105). Mr. Cordova elaborated on the kind of decking which cannot be immediately secured. It is "type B" decking, a corrugated type of decking used generally as a "roof deck, not as a floor deck" that "we generally see in warehouse applications". (Ex. 203X; p. 142–143). Mr. Cordova agreed that this type of decking is used in multi-story structures as well (*Id*).

Since this issue was so closely considered by the Committee during its deliberations, the Agency has decided to defer to its judgment and promulgate the provision essentially unchanged. Although the final rule does not require it, OSHA encourages employers to use alternative kinds of decking which are easier to attach initially, wherever such decking is appropriate and available.

Paragraph (c)(7) states that safety deck attachments shall be performed in the CDZ from the leading edge back to the control line and shall have at least two attachments per panel. This provision was intended to address the hazard in leading edge work that arises when an employee turns his/her back to the leading edge while attaching deck sheets. This provision will help prevent employees from inadvertently stepping off the leading edge. Safety deck attachments are usually accomplished with tack welds but can also be achieved with a mechanical attachment, such as self-drilling screws, or pneumatic fasteners.

Paragraph (c)(8) prohibits final deck attachments and the installation of shear connectors from being done in the CDZ. Activities such as these are not leading edge work, and employees performing this type of work can be readily protected from falls by the use of conventional fall protection.

Phil Cordova, testifying for the Decking Panel of SENRAC, stated: "this controlled decking zone that [SENRAC has] created will save lives. It will make the job a lot safer. This is our recommendation * * *" (Ex. 208X; p. 143). Fred Codding, another member of SENRAC, testified that the CDZ provision "was one of the most important decisions made during the course of SENRAC" (Ex. 208X; p. 211). Mr. Codding noted that the decision to recommend the CDZ "influenced other segments of the proposed standard, which deal with decking such as loads, covering holes and other things. They were all part of a real * * * compromise * * *" (*Id*).

Some of the comments to the record questioned the sufficiency of the CDZ alternative to prevent falls in light of the statistical information in the record showing that a high percentage of steel erection fatalities result from decking accidents. SENRAC believed that many

of the accidents attributed as falls during decking will be prevented by the restricted access of the CDZ, and by requirements for decking construction in paragraph § 1926.754. SENRAC's position was stated by Mr. Codding at the rulemaking hearing:

> [M]any of these accidents were merely not people just walking off or falling off the leading edge of decking, but * * * (were due to) the lack of knowledge on how to install floor or roof decking; * * * people were walking through the area that had no business in the area (and) were falling and slipping through the sheets; that they had no idea the sheets were loose and could become displaced; that there was improper bearing on the sheets on the structural beam supporting them; that bundles of the decking were landed on unsecured members.

(*Id* at 67).

As pointed out by the testimony of Mr. Robert Samela, president of a metal deck erecting company operating as deck erectors since 1972, "this reduction in fatalities ignores the positive effects of additional training * * *" (Ex. 208X; p. 138–139).

The question of whether to require conventional fall protection for decking operations was vigorously debated during the SENRAC deliberations. SENRAC reached its position after various contractors, equipment manufacturers and decking workers appeared before the Committee and discussed both the feasibility of conventional fall protection and whether to rely instead on CDZs to protect workers from falls.

When OSHA proposed the standard, we asked the public for information about the feasibility and hazard potential of providing fall protection to deckers (63 FR 43485). Comments were submitted which indicated that some general contractors had successfully employed fall protection systems for decking workers (Ex. 207X; pp. 172–173, 207X; pp. 235–239, 202X; pp. 153–154, 207X; pp. 292–293 and 13–73). However, the evidence and objections to the provision submitted after the proposal were similar to the evidence and objections considered by the Committee during its deliberations. Virtually all the employees who testified or submitted opinions into the record on their experience on the decking issue supported the Committee's recommended provisions for the CDZ alternative to fall protection.

On this record, the Agency defers to the Committee and leaves the provision unchanged in the final rule. Other approaches for protecting decking employees against falls may be possible. However, based on the Agency's concurrence with the negotiated proposal and its reliance on the Committee's expertise, we have decided to promulgate SENRAC's CDZ alternative as proposed.

The CDZ alternative has built-in restrictions and will allow only a small number of workers to work without fall protection. Although the accident data presented to the record shows that decking accidents rank first in fatalities in steel erection, further analysis shows that some of the "decking" fatalities involved workers doing other jobs (for example, roofers falling onto unsecured decking; see also Ex. 9–14 and 9–49). The CDZ alternative applies only to workers performing leading edge work and initially attaching the decking. These are the only workers who are allowed to enter a CDZ. We agree with Mr. Bill Shuzman's statement (Ex. 208X; p. 130) that: "The controlled decking zone deals with a very small percentage of the number of people who are considered deckers. These are the people who do leading edge deck work." Further, the CDZ alternative provisions to fall protection apply only while leading edge work is being performed. "Leading edge" in this standard has the same meaning as in subpart M, OSHA's general construction fall protection standard. That standard, § 1926.500 (b), states that "leading edge means the edge of a * * * walking/working surface (such as the deck) which changes location as additional * * * decking [is] placed * * *". For decking in steel erection, the core "leading edge" tasks are lifting decking panels from the bundles placed on the secured decking next to the leading edge, and placing and aligning the panels prior to tack welding. As soon as the decking for the leading edge is finished (placed for fastening), that area no longer qualifies for use of a CDZ, and any employees in the area must be otherwise protected from falls.

The provisions making up this exception clearly limit the exception's application. We emphasize that the CDZ is not a general exception to fall protection requirements for all employees who install decking, or who work in the area while decking is being installed. Paragraph § 1926.760(c) states that a CDZ alternative to fall protection is allowed only for decking employees when metal decking is being initially installed and while that decking material forms the leading edge of a work area.

A core requirement of the CDZ alternative is § 1926.761(c)(3), which specifies that only employees trained in accordance with the standard's CDZ training provisions are allowed in the CDZ. That provision requires that each employee be provided training in "the nature of the hazards associated with work within a controlled decking zone; and the establishment, access, proper installation techniques and work practices required by § 1926.760(c) and § 1926.754(e). This special CDZ training supplements the required fall hazard training in § 1926.761(a). OSHA believes that the implementation of these new training provisions will improve the safety of all employees who work in areas where decking is being installed. The record contains evidence that some employers are already providing this training. At the hearing Mr. Michael White of the Training Department of the International Association of Bridge, Structural Ornamental and Reinforcing Ironworkers stated that his organization, "in response to the new training provisions" has already started to develop specialized training curriculum for CDZ workers and other activities required to be trained under SENRAC's recommended standard. According to the statement read by Mr. White, these training programs "will be taught at approximately 160 training centers as an integral part of the apprenticeship training and journeyman training conducted at these centers. In addition, this new training curricula will also be used at the annual Ironworkers Instructors Training Program, * * * held * * * for a period of two weeks to train persons who are certified instructors in local and state ironworker training programs through the United States * * * " (Ex. 208X; pp. 62–63). Mr. Codding (Ex. 208X; p. 65), an employer representative, also testified that he introduced SENRAC's training recommendations on CDZ work and other areas at the annual instructor training referenced by Mr. White. "There were some 500 participants that I reviewed those (the decking requirements and several of the connecting requirements) with." Mr. Codding continued: "I really want to point out that we as employer contractor representatives have also taken steps to coordinate this training curriculum, which is being developed."

Paragraph (d) Criteria for Fall Protection Equipment

A new paragraph (d) was added to the final rule to clearly state that the protective systems mentioned in paragraph (a)(1) must conform to the criteria found in subpart M. Several commenters felt that proposed paragraph (a)(2) was too confusing. Some confusion resulted from the proposed rule's requirement that restraint systems meet the requirements

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of § 1926.502. The confusion stems from the fact that § 1926.502 does not mention restraint systems.

Final paragraph (d)(1) requires guardrail systems, safety net systems, personal fall arrest systems, positioning device systems and their components to conform to the criteria in § 1926.502. Section 1926.502 does contain requirements for components of personal fall arrest systems, many of which are also used in restraint systems.

Final paragraph (d)(2) clarifies that the components used in a restraint system in steel erection work must meet the requirements in § 1926.502 for those components. Proposed paragraph (a)(2) indicated that the terms "fall restraint system" and "positioning device system" were interchangeable. Two fall protection consultants, Mr. Dan Paine and Mr. Nigel Ellis, testified that the terms should be distinguished. Mr. Paine describes a restraint system as a means to restrain someone from falling by not allowing them to get to the leading edge (Ex. 207X, pp. 12–13). Mr. Ellis says (Ex. 202X, pp. 128–129) that OSHA should decide whether fall restraint is a means of restricting a person's motion towards an edge or is the same as a work positioning device. He further stated that these systems are poorly understood by the construction industry, manufacturers and by various OSHA offices due to the similarity of their components. Other commenters (Exhibits 13–3, 13–192 and 13–221) expressed concern over allowing workers to fall while wearing a body belt, apparently in reference to the fact that body belts are permitted to be used in positioning devices and restraint systems. They urged consistency between subparts R and M.

The Agency has recognized that restraint systems and positioning devices refer to different types of protective devices. Under subpart M, a positioning device (1) allows an employee to be supported on an elevated, vertical work surface, such as formwork or rebar assemblies; (2) permits the worker to work with both hands free while leaning backwards, and (3) limits a fall to up to two feet. Restraint systems are not mentioned in subpart M. However, the Agency has defined restraint systems in letters of interpretation as systems that prevent workers from being exposed to any fall. Restraint systems may be used on either a horizontal or vertical work surface.

In brief, a positioning device enables an employee to work in a position that allows the employee to fall, but only up to two feet. A fall restraint system prevents the employee from reaching an open side or edge, thus preventing the employee from falling.

Because the Agency has correctly distinguished these devices in the past, the final rule has been changed to be consistent with these distinctions. Both systems must use components that comply with § 1926.502. We are reprinting the criteria from § 1926.502 in Appendix G to assist employers and employees.

Final rule paragraph (d)(3) requires that perimeter safety cables must comply with the relevant criteria for guardrail systems in § 1926.502. E–M–E, Inc. (Ex. 202X; p. 65) testified that other trades often use the cables to climb or tie off to. Perimeter safety cables must not be used as an anchorage point for personal fall arrest systems unless they were engineered to serve that purpose.

The proposed rule included perimeter safety cables as one of the specified methods of fall protection and specified that the cables consist of ½-inch wire rope or equivalent. Final paragraph (d)(1) requires that if perimeter safety cables are used, they must consist of ¼ inch wire rope or its equivalent. OSHA retained the requirement for the cables to be made of wire due to the higher probability that these cables may be struck by loads or exposed to the heat of welding on steel structures.

Many commenters asked to change the ½ inch diameter requirement for perimeter cables to ¼ inch. Arguments were made that some companies have already purchased ¼ inch cable and a switch to ½ inch would be costly. We presume that those companies have invested in ¼ inch cable to comply with Subpart M, which requires ¼ inch cables for fall protection systems, for their non-steel erection work. Vulcraft (Ex. 13–4) and Fred Weber, Inc. (Ex. 13–218) had concerns that if the ¼ inch cable requirement were switched, those that have invested in ⅜ inch would have to switch to ¼ inch.

The final rule in paragraph § 1926.760(d)(3) explicitly states that perimeter safety cables shall meet the criteria for guardrail systems in § 1926.502(b) (subpart M). This was not clear in the proposed regulatory text as pointed out by some rulemaking participants. Mr. Bob Emmerich, AGC of Wisconsin, testified (Ex. 201X, p. 78, pp. 88–90, pp. 107–108) that his organization agreed with the proposal, but felt the requirement should be consistent with subpart M. He stated that confusion could be avoided if the criteria for perimeter safety cables in subpart R mirrored that in subpart M's guardrail provision. Others also advocated consistency with subpart M (Exs.13–173; 13–210 and 13–215).

Under Subpart M, § 1926.502 (b)(9), top and midrail cables must be at least ¼ inch ("to prevent cuts and lacerations"), but they may be thicker. So, employers operating under Subpart M now, with large stocks of ¼ inch cable, will not have to purchase ½ inch cable if they begin working on steel erection jobs.

A safety consultant (Ex. 13–151) suggested that instead of specifying a minimum diameter, we specify the strength, grade, lay and cores of the cable, as well as the spacing between the supports. We point out that, apart from the ¼ inch diameter requirement, subpart M specifies strength and deflection performance requirements in lieu of specifications.

Paragraph (e) addresses the need to ensure that fall protection equipment is maintained even after steel erectors have completed their work. Usually, perimeter safety cables are initially installed and maintained by the steel erector, but the cables remain on site after steel erection work is completed. With this provision, the fall protection equipment will only be left in place if the controlling contractor (or its authorized representative) has taken responsibility for ensuring that it will be properly maintained. Without this provision, the fall protection could fall into disrepair and become ineffective. This requirement is fairly similar to the AISC Code of Standard Practice (Ex. 9–36, p. 15) which states:

> When safety protection provided by the erector is left remaining in an area to be used by other trades after steel erection activity is completed, the owner shall be responsible for accepting and maintaining this protection, assuring that it is adequate for the protection of all other affected trades, assuring that it complies with all applicable safety regulations when being used by other trades, indemnifying the erector from any damages incurred as a result of the safety protection's use by other trades, removing the safety equipment when no longer required and returning it to the erector in the same condition as it was received.

Commenters in support of the provision stated that steel erectors were concerned that if they left their fall protection in place after finishing their work, nobody would maintain the fall protection, and they would be held liable. OSHA agrees with the commenters that this could give employers of other trades a false sense of security, and could cause employees to be injured.

Other commenters asserted that controlling contractors should not be required to provide fall protection to the employees of other employers. First, this provision does not require the controlling contractor to accept responsibility for the fall protection equipment. The controlling contractor has the option of refusing to accept responsibility. If it refuses to accept responsibility, then the fall protection equipment must be removed. Second, the controlling contractor already has obligations with respect to the safety of employees of other employers under the Agency's multi-employer policy. A controlling contractor may refuse to accept responsibility for the equipment and require the other trades to erect and maintain their own fall protection equipment. Such a decision would be consistent with both that policy and this provision. As a practical matter, it was SENRAC's view that the controlling contractor is in the best position to make the decision about whether to accept responsibility for the equipment, since it has authority over the site and can best coordinate the other trades and deal with the ramifications of this type of decision. The record does not show that view to be unreasonable.

Section 1926.761 Training

The OSHA steel erection standard has many new requirements involving more widespread use of personal fall protection equipment and special procedures for making multiple lifts, for decking activities in controlled decking zones and for connecting. SENRAC and OSHA recognized the need for a separate training section to address these and other requirements. The requirements in § 1926.761 supplement OSHA's general training and education requirements for construction contained in § 1926.21.

Since the employer can choose the provider, method and frequency of training that are appropriate for the employees being trained, the employer has flexibility in developing and implementing a training program. The program must meet the requirements of this section, and each employee must be provided the training prior to exposure to the hazard. The employer can choose the provider, method and frequency of training that are appropriate for the employees being trained. The provider may be an outside, professional training organization or other qualified entity, or the employer may develop and conduct the training in-house.

A commenter (Ex. 13–246) pointed out that the training provisions do not require that the employer verify that the employees understand what they have been taught. Another commenter (Ex. 13–216) recommended that OSHA's goal should be to mandate that ironworkers are trained and certified as competent by their employer.

The requirement to provide training is met only when the training is effective in providing the knowledge stipulated in these provisions. An effective training program necessarily involves some means of determining whether the instruction is understood by the employee. This can be done in a variety of ways, such as formal oral or written tests, observation, or through discussion. The previous commenter added that retraining is not addressed but needs to be included with a requirement for annual refresher training with verification (Ex. 13–246). Another commenter (Ex. 13–354) asserted that there is no mention of prior training received from previous employers. He argued that if an ironworker has been trained by his previous employers to possess a certain skill or skills (for example, a connector), it seems costly and unnecessary to require the ironworker to be re-trained prior to going to work for another employer.

While retraining/refresher training is not specifically addressed, the employer is responsible for making sure that it has programs necessary to comply with the training requirements in § 1926.21(b)(2): "The employer shall instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his work environment to control or eliminate any hazards or other exposure to illness or injury." Steel erection involves progressive sequences of erection, so that the work environment on any one day may involve entirely different or unique new hazards than the day before and that new employees may enter the erection process when it is already underway. In order to apply § 1926.21 during steel erection activities, an employer would have to assess the type of training needed on a continuing basis as the environment and changes in personnel occur. It is the employer's responsibility to determine if an employee needs retraining in order to strengthen skills required to safely perform the assigned job duties, and whenever the work environment changes to include newly recognized or encountered hazards. This is a key element in the employer's accident prevention program.

Where an employer hires a worker, such as a connector, who is already trained and skilled, OSHA anticipates that the employee's high level of knowledge will be readily apparent and easily ascertained by informal discussion and observation.

A commenter (Ex. 13–216) suggested that the complexity of the steel erection standard will require extensive training to ensure that ironworkers are aware of the new way of performing their work. The Safety Advisory Committee of the Structural, Ornamental, Rigging and Reinforcing Steel Industry (SAC) (Ex. 208X; p. 68) commented that they support the training requirements as proposed.

OSHA agrees that additional training will be required to ensure that the employees are aware of and understand the regulations applicable to their work environment. However, the Agency believes that the new requirements in this rule are needed to make steel erection safer, and the additional training requirements will play a major role in achieving that increased safety.

Paragraph (a) requires that all training required by this section be provided by a qualified person. As discussed earlier, a "qualified person," is defined in § 1926.751 as one who, by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated the ability to solve or resolve problems relating to the subject matter, the work, or the project.

Paragraphs (b)(1) through (b)(5) require employers to provide a training program for all employees exposed to fall hazards. The program must include training and instruction in recognition and identification of fall hazards in the work area [(b)(1)]; the use and operation of guardrail systems, personal fall arrest systems, fall restraint systems, safety net systems, controlled decking zones and other protection to be used [(b)(2)] ; the correct procedures for erecting, maintaining, disassembling, and inspecting the fall protection systems to be used [(b)(3)]; the procedures to be followed to prevent falls to lower levels and through or into holes and openings in walking/working surfaces and walls [(b)(4)]; and the fall protection requirements of § 1926.760 [(b)(5)].

In the proposal, paragraph (b)(2) stated that training had to be given with respect to perimeter safety cables as well as guardrails. The reference to perimeter safety cables in the training section has been deleted in the final rule because, under the final rule, perimeter safety cables are considered guardrails (under § 1926.760 (b)(3), they must meet the requirements for guardrails in § 1926.502). There were no comments received regarding these provisions, and no other changes were made in the final rule.

Paragraph (c) requires specialized training for employees engaged in multiple lift rigging procedures, connecting activities and work in controlled decking zones, due to the

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hazardous nature of these activities. There were no comments received regarding the provisions in § 1926.761(c)(1), (c)(2) and (c)(3), and they are promulgated without change.

Paragraphs (c)(1)(i) and (c)(1)(ii) require additional training for employees performing multiple lift rigging in accordance with the provisions in § 1926.753(e). The special training includes, at a minimum, the nature of the hazards associated with multiple lifts; and the proper procedures and equipment to perform multiple lifts.

Paragraphs (c)(2)(i) and (c)(2)(ii) require employers to ensure that each connector has been provided training in the hazards associated with connecting, and in the establishment, access, proper connecting techniques and work practices required by § 1926.760(b) (fall protection) and § 1926.756(c) (double connections).

Paragraphs (c)(3)(i) and (c)(3)(ii) require employers to provide additional training for controlled decking zone employees. The training must cover the hazards associated with work within a controlled decking zone, and the establishment, access, proper installation techniques and work practices required by § 1926.760(b) (fall protection) and § 1926.754(e) (decking operations).

Appendices to Subpart R

The following appendices neither create additional obligations nor eliminate obligations otherwise contained in the standard. They are intended to provide useful, explanatory material and information to employers and employees who wish to use it as an aid to understanding and complying with the standard.

Appendix A to Subpart R—Guidelines for Establishing the Components of a Site-Specific Erection Plan (Non-Mandatory). As explained in the discussion for the section governing site-specific erection plans (§ 1926.752), this appendix was developed by SENRAC as a non-mandatory set of guidelines to assist employers in complying with the requirements of final paragraph § 1926.752(e). If an employer follows these guidelines to prepare a site-specific erection plan, it will be deemed as complying with the requirements of paragraph § 1926.752(e). No comments were received on this Appendix and it remains unchanged from the proposed rule except for adding "anchor rod" in (c)(3)(iii) to be consistent with the changes made to § 1926.755 of the final rule.

Appendix B to Subpart R—Acceptable Test Methods for Testing Slip-Resistance of Walking/Working Surfaces (Non-Mandatory). Appendix B is provided to serve as a non-mandatory guide to assist employers in complying with the requirements of final rule paragraph § 1926.754(c)(3). The two nationally recognized test methods referred to in appendix B, ASTM F1677–96 (Standard Test Method for Using a Portable Inclineable Articulated Strut Slip Tester) and ASTM F1679–96 (Standard Test Method for Using a Variable Incidence Tribometer), provides the protocol for testing coatings for skeletal structural steel surfaces to obtain the documentation or certification required by § 1926.754(c)(3). No comments were received on this Appendix and it remains unchanged from the proposed rule except for correcting the cite to ASTM F1677–96 which was incorrectly identified as ASTM F1678–96 in the proposed rule.

Appendix C to Subpart R—Illustrations of Bridging Terminus Points (Non-Mandatory). This appendix is a non-mandatory guide to assist employers in understanding the requirements of section §§ 1926.757(a)(10) and 1926.757(c)(5). The illustrations show several (but not all) common bridging terminus points. This Appendix remains unchanged from the proposed rule except that a reference was added to § 1926.757(a)(10) which was overlooked in the proposed rule and correcting an inaccurate reference to § 1926.757(c)(3) in the proposed rule. This appendix is provided to employers as a non-mandatory guide to assist in complying with the requirements of sections 1926.757(a)(10) and 1926.757(c)(5).

The Agency received two written comments addressing this appendix. One commenter (Ex. 13–308) stated that: (1) The anchors indicated in many of the figures should be labeled as "appropriate anchors" rather than "lag with shield or embedded anchor;" (2) lag shield anchors are not always appropriate; and (3) the notation "looped around top chord" should be changed to "wrapped around top chord." The other commenter (Ex. 13–151) identified a number of deficiencies in the illustrations.

The Agency's engineers reviewed the comments on the illustrations and believe the illustrations are accurate illustrations of some common bridging terminus points. The titles of the illustrations are terms that are commonly understood in the industry. These illustrations were not meant to cover all construction site situations. Therefore, the agency has not changed the illustrations or the titles. The proposed text in Appendix C is adopted as a nonmandatory reference.

Appendix D to Subpart R—Illustration of the Use of Control Lines to Demarcate Controlled Decking Zones (CDZs) (Non-Mandatory). Appendix D is provided to serve as a non-mandatory guide to assist employers in complying with the requirements of final rule paragraph § 1926.760(c)(3). If the employer follows these guidelines to establish a control line to demarcate a CDZ, OSHA will accept the control line as meeting the requirements of paragraph § 1926.760(c)(3). This appendix neither creates additional obligations nor eliminates obligations otherwise contained in the standard. It is intended to provide useful explanatory material and information to employers and employees who wish to use it as an aid to understanding and complying with the standard. No comments were received on this appendix and it remains unchanged from the proposed rule.

Appendix E to Subpart R—Training: (Non-Mandatory). Appendix E is provided to serve as a non-mandatory guide to assist employers in complying with the requirements of final paragraph § 1926.761. Even before the existence of OSHA, the Ironworkers International Union provided apprenticeship training in steel erection to its members. This training has been approved by the U.S. Department of Labor's Bureau of Apprenticeship Training for over forty years. As soon as this program is updated to reflect the requirements of this new subpart R, training under this program will be deemed as complying with the training requirements of § 1926.761. As stated in Article XI of the current approved National Apprenticeship and Training Standards for Ironworkers:

> The [Ironworkers Joint Apprenticeship] Committee shall seek the cooperation of all employers to instruct the apprentices in safe and healthful work practices and shall insure that the apprentices are trained in facilities and other environments that are in compliance with either the occupational safety and health standards promulgated by the Secretary of Labor under [the OSH Act] or state [plan] standards* * * (Ex. 9–139; p. 8).

Training approved by the U.S. Department of Labor's Bureau of Apprenticeship Training is not the only training that OSHA will accept under this standard. Employers may choose to provide their own training, provided that it fulfills the requirements of § 1926.761.

As proposed, Appendix E stated: "The training requirements of § 1926.761 will be deemed to have been met if employees have completed a training course on steel erection, including instruction in the provisions of this standard, that has been approved by the U.S. Department of Labor's Bureau of Apprenticeship."

One commenter (Ex. 13–222) indicated that there are many other avenues for training that are not approved by the U.S. Department of Labor's Bureau of Apprenticeship Training, such as trade associations, training organizations, consultants and in-house training programs; yet the appendix does not include any sources other than those approved by the U.S. Department of Labor's Bureau of Apprenticeship Training.

Another commenter (Ex. 13–210) expressed a similar concern, stating that the Appendix implies that the only training that is acceptable is training done through an apprenticeship program approved by the U.S. Department of Labor's Bureau of Apprenticeship Training. The commenter recommended that trade associations, training organizations, consultants and in-house training programs be included in Appendix E as acceptable/recognized training entities; if not, then Appendix E should be omitted. Another commenter (Ex. 201X; p. 82) recommended that OSHA either state in Appendix E that "employers may choose to provide their own training, provided that it fulfills the requirements of § 1926.761," or omit appendix E.

OSHA has decided to retain appendix E as proposed. We emphasize that appendix E does not require that training be approved by the U.S. Department of Labor's Bureau of Apprenticeship Training. Training provided by others is sufficient if it meets the requirements of § 1926.761. The Appendix simply identifies certain training—training approved by the U.S. Department of Labor's Bureau of Apprenticeship Training—that OSHA deems acceptable to meet the requirements of § 1926.761. It is appropriate for OSHA to acknowledge a training program that is administered through another office within the Department of Labor.

Training approved by the U.S. Department of Labor's Bureau of Apprenticeship Training may be used as a guide for developing and assessing other training programs. The proposed text in Appendix E is adopted as proposed.

Appendix F to Subpart R—Perimeter Columns (Non-Mandatory). Since perimeter safety cables are the method prescribed by § 1926.756(e) for guarding of perimeters, final rule appendix F provides guidance for installing them. As proposed, the first part of appendix F stated that, "in multi-story structures, the project structural engineer of record (SER) may facilitate the ease of erecting perimeter safety cables, where structural design allows, by placing column splices sufficiently high so as to accommodate perimeter safety cables located at 42–45 inches above the finished floor. The SER may also consider allowing holes to be placed in the column web, when the column is oriented with the web perpendicular to the structural perimeter, at 42–45 inches above the finished floor and at the midpoint between the finished floor and the top cable * * *".

The National Council of Structural Engineers (Ex. 13–308) suggested that the reference to the SER be removed and replaced by a reference to a "competent person." Commenters, including a staff member from Minnesota DOT-Office of Bridges and Structures (Ex. 13–359), stated that the erector is the most competent party when it comes to erecting perimeter cables. In their view it has been a responsibility written into their contracts in the past and the responsibility should remain with them. It was also argued in testimony (201X; p. 49) that if SERs were to follow the guidelines in appendix F, they would be taking on the responsibility of ensuring that the components of a perimeter cable system comply with the requirements of subpart R, which would raise liability issues.

Apart from these concerns, the Agency has determined that this first part of the appendix could be confusing. The appendix may give the impression that having columns extend a minimum of 48 inches above the finished floor to permit installation of perimeter safety cables prior to the erection of the next tier is suggested but not required. That is not the case—it is required by § 1926.756(e)(1). The standard also requires perimeter columns to be supplied with holes or other devices in or attached to perimeter columns at 42–45 inches above the finished floor and the midpoint between the finished floor and the top cable to permit installation of perimeter safety cables (except where constructibility does not allow). Therefore, this first part of the appendix has been omitted in the final rule.

The rest of the proposed appendix does not refer to the SER. It is being retained because it contains design suggestions that would facilitate compliance with the requirements of § 1926.756(e). The appendix recommends that column splices be placed at every other or fourth levels, as design allows.

Appendix G to Subpart R—Fall Protection Systems Criteria and Practices from § 1926.502 (Non-Mandatory). Appendix G is provided to assist employers in complying with the requirements of § 1926.760(d). Appendix G restates paragraphs (b) through (e) of § 1926.502, which provide the criteria for guardrail systems, safety net systems, personal fall arrest systems and positioning device systems. These criteria are referenced by § 1926.760(d), and are included here for the convenience of employers and employees.

Appendix H to Subpart R—Double Connections (Non-Mandatory). Appendix H illustrates two methods (clipped end connection and staggered connection) that an employer may use to comply with the requirement in § 1926.756(c)(1) by maintaining at least a one bolt connection with its wrench tight nut while making a double connection. These two methods are not the only ways to comply with the standard.

These illustrations were added in response to a commenter's suggestion that OSHA add an illustration to show an example of a clipped end connection (Ex. 13–207). Clipped end and staggered connections are sound, engineered methods for maintaining a one bolt connection throughout the double connection process. OSHA is adding an illustration of a staggered connection as well, which is also an effective means of maintaining the one bolt connection.

V. Summary of the Final Economic and Regulatory Flexibility Analysis

Introduction

This final standard is a significant regulatory action under Executive Order (EO) 12866 and a major rule under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act. Accordingly, OSHA has developed a final economic analysis (FEA)(Ex. 83) of the costs, benefits, and regulatory and non-regulatory alternatives of the rule, as required by the EO. The FEA revises OSHA's preliminary economic analysis (Ex. 11) and is based upon a thorough review of the rulemaking record. This section of OSHA's notice of final rulemaking summarizes the Agency's economic analysis of the final steel erection standard.

The Regulatory Flexibility Act of 1980, as amended in 1996, requires OSHA to determine whether the Agency's regulatory actions will have a

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significant impact on a substantial number of small entities. Making such a determination for this final standard required OSHA to perform a screening analysis to identify any such impacts. OSHA's screening analysis indicated that the rule might, under two worst-case scenarios, have significant impacts on a substantial number of small entities. Accordingly, OSHA has prepared a Final Regulatory Flexibility Analysis, summarized below, to accompany the final steel erection rule.

OSHA's final economic analysis and final regulatory flexibility analysis include a description of the industries potentially affected by the standard; a summary of the major changes between OSHA's existing steel erection standard (subpart R of Part 1926) and the final rule; an evaluation of the risks addressed; an assessment of the benefits attributable to the final standard; a determination of the technological feasibility of the new requirements; an estimate of the costs employers will incur to comply with the standard; a determination of the economic feasibility of compliance with the standard; and an analysis of the potential worst-case economic and other impacts associated with this rule, including those on small businesses. Below are summaries of each of the major sections of OSHA's final economic analysis.

Affected Industries

This final steel erection standard affects industries and establishments within the construction industry. Table 1 presents the industry groups in construction that will be directly affected by the final standard. Construction employers who are subject to the rule because they have employees engaged in steel erection activities are concentrated within SIC 1791, Structural Steel Erection, an industry with 4,675 establishments and 55,965 employees in 1998, as reported by Dun & Bradstreet [D&B, 1998]. Within this industry, 3,898 establishments, or 83 percent of the total number of establishments, employed nineteen or fewer employees in 1998, while 3,238 establishments (69 percent) employed nine or fewer employees. SIC 1791, however, also includes employers and workers who perform construction activities other than steel erection, notably pre-cast concrete erection. Further, contractors primarily engaged in other activities sometimes have employees engaged in steel erection. Thus, any comprehensive profile of the steel erection industry must, in addition to examining affected industry groups, focus on the type of work and the trade of the workers engaged in this form of construction.

TABLE 1.—INDUSTRY GROUPS IN CONSTRUCTION POTENTIALLY AFFECTED BY THE FINAL STEEL ERECTION STANDARD

SIC	Industry group	Iron workers [a]	Establishments with 1–9 employees		Establishments with 1–19 employees		Establishments with 1–99 employees		Establishments with 100 + employees		All Establishments [b]	
			Number of establishments	Total employment	Number of establishments	Total employment	Number of establishments	Total employment	Number of establishments	Total employment	Number of establishments	Total industry employment
15	Building Construction—General Contractors and Operative Builders	19,310	273,905	765,249	291,906	989,256	302,859	1,362,573	925	169,293	305,474	1,531,866
152	General Building Contractors—Residential Buildings	2,310	216,235	561,751	226,036	702,822	230,404	843,782	222	38,239	231,632	882,021
153	General Building Contractors—Operative Builders	50	17,995	48,256	19,123	62,040	19,879	86,737	52	9,422	20,049	96,159
154	General Building Contractors—Nonresidential Buildings	16,950	39,675	135,242	46,745	224,394	52,576	432,054	651	121,632	53,793	553,686
1541	Industrial Buildings and Warehouses		8,198	23,208	8,755	30,164	9,140	44,564	54	9,543	9,290	54,107
1542	Nonresidential Buildings, other than In SIC 1541		31,477	112,034	37,990	194,230	43,436	387,490	597	112,089	44,503	499,579
16	Heavy Construction other than Building Construction	4,600	34,243	114,530	40,506	194,080	47,406	454,086	1,130	246,814	51,039	700,900
161	Highway and Street Construction, except Elevated Highways	540	13,055	43,972	15,320	72,574	17,173,932	173,347	478	100,804	18,735	274,151
162	Heavy Construction, except Highway and Street Construction	4,060	21,186	70,558	25,186	121,486	29,474	280,739	652	146,010	32,304	426,749
1622	Bridge, Tunnel, and Elevated Highway Construction		582	2,295	817	5,263	1,191	19,627	78	14,597	1,464	34,224
1623	Water, Sewer, Pipeline, and Communications and Power Line Construction		6,730	26,237	8,961	54,908	11,488	148,642	304	53,651	13,575	202,293
1629	Heavy Construction, Not Elsewhere Classified		13,876	42,026	15,408	61,315	16,795	112,470	272	77,762	17,285	190,232
17	Construction—Special Trade Contractors	32,930	553,399	1,619,537	602,349	2,240,163	636,193	3,407,594	2,560	458,521	641,897	3,866,115
171	Plumbing, Heating and Air-Conditioning	640	115,500	345,897	126,268	483,637	133,483	735,986	563	100,757	134,655	836,743
174	Masonry, Stonework, Tile Setting, and Plastering	580	45,405	133,866	50,217	194,823	54,367	339,551	372	60,803	54,991	400,354
175	Carpentry and Floor Work	1,100	48,720	128,525	51,184	157,737	52,595	204,788	114	19,147	52,896	223,935
176	Roofing, Siding, and Sheet Metal Work	3,900	39,893	118,921	43,650	166,437	46,331	258,269	124	17,592	46,681	275,861
177	Concrete Work	250	23,575	78,296	26,764	118,177	28,801	185,887	118	18,536	29,094	204,423
179	Miscellaneous Special Trade Contractors	26,440	109,187	317,915	118,213	431,565	124,083	628,259	397	81,002	125,195	709,261
1791	Structural Steel Erection		3,238	11,259	3,898	19,712	4,544	42,215	73	13,750	4,675	55,965
	Construction Totals	56,840	861,547	2,499,316	934,761	3,423,479	986,458	5,224,253	4,615	874,628	998,410	6,098,881

[a] U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics Survey, 1998.
[b] For some industry groups, Dun &ampl Bradstreet identified a small percentage of establishments and sales that could not be classified by establishment size. OSHA included these data in the industry totals in this table.
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, based on Dun & Bradstreet, National Profile of Businesses software, Dun &ampl Bradstreet Information Services, 1998.

The workers directly benefitting from the final standard are identified in occupational surveys as structural metal workers; in the industry, they are known as iron workers. According to the Bureau of Labor Statistics' Occupational Employment Statistics Survey [BLS, 1998], there were 56,840 structural metal workers in construction in 1998, the majority of whom are found in SIC 179, Miscellaneous Special Trade Contractors (26,440 structural metal workers), and SIC 154, Contractors—Nonresidential Buildings (16,950 structural metal workers) (Table 1). For this final economic analysis, OSHA used the BLS employment total for structural metal workers to estimate the number of iron workers potentially affected by the final rule in its benefits assessment and cost analysis.

Final Changes to OSHA's Steel Erection Standard

This final steel erection standard modifies and strengthens the steel erection standard it replaces in a number of areas. For example, the final standard includes a scope section that identifies the types of construction projects and activities subject to the rule. Structures excluded from coverage under the scope of the standard are steel electrical transmission towers, steel communication and broadcast towers, steel water towers, steel light towers, steel tanks, and reinforced and pre-cast concrete structures. The final rule also includes a new section addressing site layout, site-specific erection plans, and construction sequence. Other revisions to the existing standard include:

- Explicit requirements for hoisting and rigging and the protection of workers and the public from the hazards of overhead loads;
- Additional and strengthened requirements for the structural steel assembly of beams, columns, joists, decking, and systems-engineered metal buildings, including provisions for the protection of employees from tripping hazards and slippery surfaces on walking/working surfaces;
- Modified and clarified requirements for fall protection for connectors, decking assemblers, and other iron workers during the erection of structural steel; and
- New requirements for training in fall hazards, multiple lift rigging, connecting, and controlled decking zones.

For the final economic analysis, OSHA identified those requirements of the final rule that would create substantial impacts or generate substantial benefits for members of the regulated community, including workers. For many provisions of the rule, current industry practice in many establishments is adequate to meet these requirements. OSHA estimates that current industry practice meets the final regulatory requirements for 50 percent to 98 percent of affected projects with regard to providing fall arrest systems (*i.e.*, 50 percent—98 percent of affected workers currently are supplied with this equipment, with the percentage increasing with the height of the building), and that current industry practice in the use of personnel nets is such that 20 percent of affected projects meet the final regulatory requirements; 75 percent of workers receive safety training that would meet the final regulatory requirements; nearly 100 percent of all construction uses 2-rod (bolt) column anchorage (but only 10 percent use 4-rod anchorage); and 50 percent to 98 percent of projects, depending on building height, already meet the final regulatory requirements for guardrail systems. OSHA anticipates that the final standard's requirements pertaining to overhead loads, trips and slips, falls, falling objects, collapses, and worker training will both generate substantial benefits for affected employers and impose costs on them.

Evaluation of Risk and Potential Benefits

For this final economic analysis, OSHA developed a profile of the risks facing iron workers who are performing steel erection operations. OSHA's risk profile for steel erection is based on data from the Bureau of Labor Statistics' National Census of Fatal Occupational Injuries, data from the Bureau's Survey of Occupational Injuries and Illnesses, and an analysis by a SENRAC workgroup of OSHA fatality/catastrophe inspection data obtained from the Agency's Integrated Management Information System.

OSHA anticipates that the final standard will significantly reduce the number of accidents and fatalities currently reported in the steel erection industry, particularly those accidents caused by falls from elevated levels and by objects such as dislodged structural members and building materials striking workers. OSHA believes that the more protective requirements for fall protection, structural stability, and training in the final standard will help to save lives and prevent injuries in the iron worker workforce. For accidents involving events or exposures potentially addressed by the final standard, OSHA estimates that approximately 35 fatalities and 2,279 lost-workday injuries currently occur annually among structural metal workers (see Table 2, below); this is the current industry risk baseline used in this analysis. OSHA projects that full compliance with the final standard would prevent 30 of these fatalities and 1,142 of these lost-workday injuries. Eight of these fatalities and 303 serious injuries could be prevented if employers were currently in compliance with OSHA's existing steel erection standard. The final standard will thus prevent an additional 22 fatalities and 838 injuries that would not be prevented even by full compliance with the existing standard. Further, OSHA believes that issuance of this new final steel erection standard will enhance compliance even with provisions that were included in the existing standard because the final revision allows for more flexibility in compliance, is easier to understand, and is effectively targeted toward steel erection hazards.

TABLE 2.—SUMMARY OF ESTIMATED NUMBER OF DEATHS AVERTED AND INJURIES AVOIDED BY FULL COMPLIANCE WITH THE FINAL STEEL ERECTION STANDARD

	Number of fatalities and lost-workday injuries currently occurring among iron workers (a)	Number of fatalities and lost-workday injuries preventable by compliance with the existing standard	Additional number of fatalities and lost-workday injuries preventable by compliance with the final standard	Total number of fatalities and lost-workday injuries preventable by compliance with the existing and final standards	Number of fatalities and lost-workday injuries judged not to be preventable by either standard based on analysis of accident and fatality data
Fatalities	35	8	22	30	5
Lost-Workday Injuries	2,279	303	838	1,142	1,137

Note: Figures in the rows may not sum to totals due to rounding.
(a) Includes fatalities and injuries judged to be potentially preventable by the final standard.
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

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In addition to saving lives and improving overall safety in the steel erection industry, OSHA believes that the final standard, once fully implemented by erection contractors, will yield substantial cost savings to parties within and connected with the industry and ultimately to society as a whole. These monetized benefits take the form of reductions in employer, employee, and insurer accident-related costs in several areas: the value of lost output associated with temporary total disabilities and permanent partial disabilities; reductions in accident-related medical costs; reductions in administrative expenses incurred by workers' compensation insurance providers (including employers who self-insure); and indirect costs related to productivity losses to other workers, work stoppages, and the conduct of accident investigations and reports. Applying data from the construction and insurance industries on the direct costs of accidents and data from the literature on the indirect costs of accidents and other tort- and administrative-related costs to OSHA's estimate of avoided injuries (see Chapter III in the final economic analysis), the Agency has monetized the value of the cost savings employers and society will accrue by avoiding these injuries. The monetized benefits therefore underestimate the true benefits that will be realized by the standard. They also do not, in accordance with Agency policy, attempt to place a monetary value on the lives the final rule will save. These benefits estimates are thus gross underestimates of the true benefits that will be realized by the standard. OSHA estimates that annual cost savings of $10.4 million would result from full compliance with the current rule and an additional $29.1 million would be saved as a result of full compliance with the final rule (Table 3).

TABLE 3.—SUMMARY OF ANNUAL INCREMENTAL MONETIZED BENEFITS OF PREVENTABLE LOST-WORKDAY INJURIES ATTRIBUTABLE TO THE FINAL STEEL ERECTION STANDARD

Lost Output Associated with Temporary Disabilities	$4,397,104
Lost Output Associated with Permanent Disabilities	14,586,035
Medical Costs	4,009,699
Insurance Costs (Administrative)	2,437,064
Indirect Costs	3,686,840
Costs Associated with Liability Claims Avoided	N/Q
Total Cost Savings	29,116,743

N/Q—Not Quantified
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

In addition to these monetized benefits, cost savings to employers attributable to a decline in the number of third-party liability suits can be expected. Although quantification of these tort-related legal defense costs and dollar awards is difficult because of the lack of data, OSHA believes that these employer costs are substantial and would be reduced significantly through compliance with the final standard.

Technological Feasibility and Compliance Costs

Consistent with the legal framework established by the OSH Act and court decisions, OSHA has assessed the technological feasibility of the final steel erection standard. The final rule clarifies and strengthens the Agency's existing standard, provides more stringent and specific requirements in some areas, and includes requirements for some steel erection hazards newly addressed by the Agency. Many of the final revisions are consistent with current construction means and methods used by leading firms within the steel erection industry. The success of these firms in this competitive industry demonstrates that the requirements of the final standard can be met with existing equipment and production methods. Moreover, the final standard is based on a consensus draft recommended to the Agency by a negotiated rulemaking committee consisting of divergent industry interests—including small employers—who would be affected by any changes to subpart R. Among these changes, addressing ironworker activity on walking and working surfaces is an innovative approach to safety that requires that coatings of structural members meet a standard for slip-resistance. Evidence from SENRAC meetings and elsewhere in the record point to the feasibility of this standard (see the discussion on this provision in Section IV, Summary and Explanation of the Rule). In this and other areas in the steel erection draft, the committee reached consensus on the language, thereby implicitly acknowledging the feasibility of the final revisions to the standard. Therefore, OSHA has determined that the final steel erection standard is technologically feasible.

OSHA developed estimates of the costs of compliance for construction employers subject to the final standard; OSHA's analysis is based on the preliminary economic analysis and additional data gathering and analysis. OSHA estimated annualized compliance costs for two compliance scenarios: (1) Costs to achieve compliance with OSHA's existing steel erection standard, and (2) costs to achieve compliance with the final standard. OSHA's cost estimates take into account the extent of current industry compliance, i.e., the extent to which employers are already in compliance with the requirements of OSHA's existing standard and with the requirements of the final steel erection standard. Accounting for these costs, i.e., subtracting them from the costs attributed to the final standard, is important because only those costs employers would actually incur to come into compliance with the final standard are properly attributed to that standard.

Table 4 presents OSHA's annualized compliance cost estimates, by provision or safety control, for establishments in the industries subject to the final standard.

TABLE 4.—ANNUALIZED COMPLIANCE COSTS OF THE FINAL STEEL ERECTION STANDARD BY INDUSTRY GROUP AND CONTROL[a]
[1998 dollars]

SIC	Industry group and size	Controls									Total
		Fall arrest systems	Personnel nets	Guardrails	Anchor rods (bolts)	Joist erection	Slip-resistant surfaces	Concrete curing tests	Training	Recordkeeping	
152	General Building Contractors–Residential Buildings:										
	Establishments with 1–9 Employees	330,947	(119,016)	67,329	252,129	445,054	679,763	94,408	23,177	32,540	1,806,330
	Establishments with 1–99 Employees	188,427	(67,783)	38,334	143,551	253,395	387,028	53,752	13,196	18,527	1,028,447

TABLE 4.—ANNUALIZED COMPLIANCE COSTS OF THE FINAL STEEL ERECTION STANDARD BY INDUSTRY GROUP AND CONTROL[a]—Continued
[1998 dollars]

SIC	Industry group and size	Controls									Total
		Fall arrest systems	Personnel nets	Guardrails	Anchor rods (bolts)	Joist erection	Slip-resistant surface	Concrete curing tests	Training	Recordkeeping	
	Establishments with 100+ Employees	395,842	(142,282)	80,491	301,417	532,056	812,647	112,863	27,708	38,901	2,159,442
	All Establishments	584,069	(210,045)	118,825	444,968	785,450	1,199,675	166,615	40,904	57,428	3,187,869
154	General Building Contractors–Nonresidential Buildings:										
	Establishments with 1–9 Employees	850,282	(305,781)	23,575	647,780	1,143,451	1,746,476	242,556	59,547	83,603	4,491,489
	Establishments with 1–99 Employees	2,870,887	(1,032,437)	79,598	2,187,159	3,860,739	5,896,787	816,984	201,055	282,276	15,165,028
	Establishments with 100+ Employees	1,414,816	(508,800)	39,227	1,077,885	1,902,829	2,908,024	403,596	99,083	139,110	7,473,551
	All Establishments	4,285,702	(1,541,237)	118,825	3,265,024	5,763,368	8,802,811	1,222,562	300,137	421,386	22,638,579
161	Highway and Street Construction, except Elevated Highways:										
	Establishments with 1–9 Employees	38,461	(13,831)	7,825	29,301	51,722	78,999	10,972	2,694	3,782	209,922
	Establishments with 1–99 Employees	99,173	(35,305)	19,973	74,792	132,022	201,647	28,005	6,875	9,653	536,835
	Establishments with 100+ Employees	38,363	(13,796)	7,805	29,226	51,590	78,797	10,944	2,687	3,772	209,386
	All Establishments	136,536	(49,101)	27,777	104,018	183,612	280,444	38,949	9,562	13,425	745,221
162	Heavy Construction, except Highway and Street Construction:										
	Establishments with 1–9 Employees	163,753	(58,889)	33,314	124,754	220,213	336,348	46,713	11,468	16,101	893,775
	Establishments with 1–99 Employees	515,174	(221,231	125,153	468,685	827,280	1,263,565	175,488	53,082	80,486	3,357,883
	Establishments with 100+ Employees	411,371	(147,939)	83,691	313,400	553,208	844,955	117,350	28,809	40,448	2,245,293
	All Establishments	1,026,546	(369,189)	208,844	782,065	1,380,486	2,108,520	282,838	71,891	100,934	5,602,956
171	Plumbing, Heating and Air-Conditioning:										
	Establishments with 1–9 Employees	50,397	(18,124)	10,253	38,394	67,773	103,515	14,376	3,529	4,955	275,069
	Establishments with 1–99 Employees	134,411	(48,337)	27,345	102,400	180,755	276,081	38,343	9,413	13,216	733,627
	Establishments with 100+ Employees	27,409	(9,857)	5,576	20,881	36,859	56,297	7,819	1,919	2,695	149,598
	All Establishments	161,820	(58,194)	32,921	123,281	217,614	332,378	46,162	11,333	15,911	883,225
174	Masonry, Stonework, Tile Setting, and Plastering:										
	Establishments with 1–9 Employees	43,891	(15,712)	8,889	33,286	58,756	89,742	12,464	3,060	4,296	238,470
	Establishments with 1–99 Employees	124,913	(44,922)	25,413	95,164	167,982	256,571	35,633	8,748	12,282	681,784
	Establishments with 100+ Employees	21,736	(7,817)	4,422	16,560	29,231	44,646	6,201	1,522	2,137	118,636
	All Establishments	148,649	(52,738)	29,835	111,724	197,213	301,217	41,834	10,270	14,419	800,422
175	Carpentry and Floor Work:										
	Establishments with 1–9 Employees	133,084	(47,853)	27,071	101,374	178,943	273,313	37,959	9,319	13,063	726,272
	Establishments with 1–99 Employees	245,389	(88,247)	49,923	186,947	329,997	504,028	70,001	17,185	24,128	1,339,349
	Establishments with 100+ Employees	32,736	(11,774)	6,661	24,942	44,027	67,246	9,339	2,293	3,219	178,693
	All Establishments	278,128	(100,021)	56,583	211,899	374,024	571,274	79,340	19,478	27,347	1,518,042
176	Roofing, Siding and Sheet Metal Work:										
	Establishments with 1–9 Employees	355,846	(127,899)	72,354	270,946	478,269	730,496	101,453	24,907	34,986	1,941,141
	Establishments with 1–99 Employees	899,629	(323,527)	183,024	685,375	1,209,812	1,847,834	256,633	63,003	88,455	4,910,237
	Establishments with 100+ Employees	86,461	(31,094)	17,590	65,870	116,273	177,591	24,664	6,055	8,501	471,913
	All Establishments	986,091	(354,621)	200,614	751,244	1,326,085	2,025,426	281,297	69,058	96,956	5,382,150
1791	Structural Steel Erection:										
	Establishments with 1–9 Employees	1,193,984	(429,384)	242,908	909,626	1,605,657	2,452,437	340,602	83,617	117,397	6,516,844
	Establishments with 1–99 Employees	5,312,751	(1,910,587)	1,080,844	4,047,472	7,144,533	10,912,364	1,515,543	372,064	522,369	28,997,353
	Establishments with 100+ Employees	1,372,439	(493,580)	279,214	1,045,580	1,845,642	2,818,983	391,509	96,115	134,943	7,490,864
	All Establishments	6,685,190	(2,404,147)	1,360,057	5,093,052	8,990,175	13,731,347	1,907,052	468,179	657,312	36,488,217
	All Significantly Affected Industry Groups:										
	Establishments with 1–9 Employees	3,160,225	(1,136,489)	493,517	2,407,589	4,249,838	6,491,087	901,502	221,318	310,725	17,099,312
	Establishments with 1–99 Employees	10,489,755	(3,772,356)	1,629,606	7,991,526	14,106,514	21,545,904	2,992,382	734,621	1,031,391	56,749,324
	Establishments with 100+ Employees	3,800,976	(1,366,918)	524,676	2,695,740	5,111,514	7,807,187	1,084,286	266,191	373,728	20,497,378
	All Establishments	14,290,731	(5,139,274)	2,154,281	10,687,266	19,218,028	29,353,091	4,076,668	1,000,812	1,405,117	77,246,701
	Other Affected Industry Groups[b]	80,910	(29,097)	789,533	61,641	108,807	166,189	23,081	5,666	7,955	1,194,685
	Total	14,371,641	(5,168,371)	2,923,815	10,948,907	19,326,835	29,519,280	4,099,729	1,006,478	1,413,072	78,441,386

Note: Figures in the table may not sum to totals due to rounding.
[a] Total compliance costs were distributed among industry groups according to the percentage of iron workers employed in that group (see Table 1). Within SIC groups, costs were distributed by share of revenue for firms in the size class.
[b] Other industries potentially affected by the final steel erection standard employ a small percentage of iron workers. These industry groups are: SIC 153, General Building Contractors—Operative Builders; and SIC 177, Concrete Work. Because firms in these industries are seldom involved directly in structural steel erection, OSHA has grouped them separately.
Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

OSHA projects that full compliance with the final standard will, after deducting costs incurred to achieve compliance with the existing standard, result in net (or incremental) annualized costs of $78.4 million for affected establishments. Among incremental annualized costs, expenditures for slip-resistant coatings of skeletal structural steel are expected to total $29.5 million, or 38 percent of total costs; expenditures for the safe design and erection of steel joists required by the final standard account for $19.3 million, or 25 percent of total costs; fall arrest systems account for $14.4 million, or 18 percent of total costs; and expenditures for anchor bolts necessary for structural stability account for $11.0 million, or 14 percent of total costs. Other control costs associated with compliance with the final steel erection standard are those for guardrails ($2.9 million); recordkeeping associated with administrative controls (1.4 million); and training ($1.0 million). In addition, OSHA anticipates that the expanded use of fall arrest systems in bridge erection will eventually lead to a dramatic reduction in the use of personnel safety nets on those projects, resulting in estimated cost savings of $5.2 million.

Potential Economic Impacts

OSHA analyzed the potential impacts of these compliance costs on prices, profits, construction output and other economic indices in the steel erection industry. In particular, OSHA examined potential economic impacts on establishments in SIC 1791, Structural Steel Erection, where the majority of the 57,000 structural metal workers are employed. This analysis shows that the final standard is economically feasible for these firms.

OSHA examined the potential economic impacts of the final standard by making two assumptions used by

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economists to bound the range of possible impacts: the worst-case assumption of no-cost pass-through, *i.e.*, that employers will be unable to pass any of the costs of compliance forward to their customers, and the worst-case assumption of full-cost pass-through, *i.e.*, that employers will be able to pass all of the costs of compliance forward to their customers. As summarized in Table 5, below, OSHA estimates that, if affected firms in SIC 1791 were forced to absorb these compliance costs entirely from profits (a highly unlikely scenario), profits would be reduced by an average of 6.5 percent. If, at the other extreme, affected firms were able to pass all of these compliance costs forward to general contractors and project owners, OSHA projects that the price (revenue) increase required to pay for these costs would be less than 1 percent (0.40 percent). A price increase of 0.40 percent would have little, if any, effect on the choice between steel erection and other forms of building.

In addition to examining the economic effects of the final standard on firms in SIC 1791, OSHA estimated the impacts of the final standard on two other construction industry divisions involving steel erection: (1) The entire construction sector; and (2) construction activity where structural steel constitutes the physical core of the project, termed "steel-frame construction" by OSHA.

For the dollar value of business for the entire construction sector, OSHA totaled 1996 sales data for SICs 15, 16, and 17 provided in a Dun & Bradstreet national business database [D&B, 1996a]. OSHA derived pre-tax income (Column 2 in Table 5) for the construction sector by, first, calculating industry profit using Dun & Bradstreet data on post-tax return on sales (post-tax profits) and, second, applying a formula that converts post-tax income to pre-tax income based on tax rates in the U.S. corporate tax code. OSHA found that, for the construction sector as a whole, price impacts under full cost pass-through would be 0.01 percent, and profit impacts assuming no cost pass-through would be 0.2 percent. Thus in the context of the construction sector as a whole, the final standard would have little impact.

TABLE 5.—POTENTIAL ECONOMIC IMPACTS OF THE FINAL STEEL ERECTION STANDARD ON SELECTED SECTORS WITHIN THE CONSTRUCTION INDUSTRY

[Under Worst-Case Conditions, 1996 Revenue and Profit Data]

	Dollar value of business (a) ($millions)	Pre-tax income (b)($millions)	Compliance costs as a percent of revenue (c)	Compliance costs as a percent of profit (c)
SIC 1791, Structural Steel Erection	9,285.7	562.4	0.39	6.49
Construction Sector as a Whole	768,155.9	43,839	0.01	0.18
Steel-Frame Construction (d)	119,979.2	6,847.2	0.07	1.15

(a) Based on data from Dun & Bradstreet, National Profile of Businesses, 1996.
(b) Based on data from Dun & Bradstreet, National Profile of Businesses, 1996; Dun & Bradstreet, Industry Norms and Key Business Ratios, 1996; and OSHA profit calculations.
(c) Revenue and profit impacts were calculated by dividing annual compliance costs for each of the four construction sectors shown in the table by, respectively, the dollar value of business and pre-tax income. Compliance costs assigned to these sectors are based on total costs of $78.4 million and were applied as follows: construction sector as a whole—$78.4 million; steel-frame construction—$78.4 million; and SIC 1791, Structural Steel Erection—$36.5 million.
(d) Steel-Frame Construction is defined by OSHA as the body of construction projects where steel framing constitutes the physical core of the structure. The dollar value of business and pre-tax income for Steel-Frame Construction were computed by applying the percentage of the value of the steel market share (15.6 percent), excluding that for tanks and towers, of all construction starts to the dollar value of business and pre-tax income for the entire construction sector. Data on the steel market share for 1995 are based on memoranda to OSHA from Construction Resources Analysis, College of Business Administration, University of Tennessee, Knoxville [Exs. 9–143 and 9–144].

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

OSHA calculated the value of steel-frame construction using data provided by the Construction Resources Analysis office of the University of Tennessee, College of Business Administration on the value of the steel market share of the entire construction industry. In this calculation, OSHA applied the percentage of the value of the steel market share (15.6 percent), excluding that for tanks and towers, of all construction starts to the dollar value of business and pre-tax income for the entire construction sector, thereby eliminating all non-steel construction (as defined in the final standard) from the earnings total. Price increases for steel frame construction as a whole are of particular interest because they represent the price increases to the ultimate customers of steel erection services, the purchasers of buildings, bridges, etc. Under the worst-case price increase scenarios, the price of such projects would increase by 0.1 percent. It is exceedingly unlikely that a customer would fail to go ahead with a project as a result of a price increase of this magnitude.

OSHA believes that, prior to the generation of the cost savings projected to accrue from implementation of the standard, most steel erectors will handle the increase in direct costs by increasing their prices somewhat and absorbing the remainder from profits. Within steel erection markets, the particular blend of impacts experienced by a given firm will depend on the degree of competition with concrete erection and other alternative types of construction in the firm's local market area. Although these minimal economic impacts would be felt by most affected employers after implementation of the standard, OSHA anticipates—based on testimony by members of SENRAC and other industry representatives whose current fall protection programs and other safety measures mirror those required by the final standard [Exs. 6–3, 6–8, and 6–10]—that offsetting cost savings will at least partially reverse any negative economic impacts.

Regulatory Flexibility Screening Analysis

The Regulatory Flexibility Act of 1980 (RFA), as amended in 1996 (5 U.S.C. 601 *et seq.*), requires regulatory agencies to determine whether regulatory actions will have a significant impact on a substantial number of small entities. Pursuant to the RFA, OSHA has assessed the potential small-business impact of the final steel erection standard under two worst-case scenarios. On the basis of a regulatory flexibility screening assessment and the underlying data, summarized below, OSHA has determined that the final standard will have a significant impact on a substantial number of small entities. Thus, OSHA has conducted a full Final Regulatory Flexibility Analysis, as required. OSHA's Final Regulatory Flexibility Analysis follows the screening analysis presented in this section.

The Small Business Administration defines small entities, or "concerns," in terms of the number of employees or the annual receipts of establishments in affected sectors. For employers in SIC 17, small concerns are defined by SBA as those with $7.0 million or less in annual receipts. OSHA has estimated that in SIC 1791, Structural Steel Erection, based on 1998 data from Dun & Bradstreet (D&B) and using D&B's estimate of the dollar value of business to represent annual receipts, the class of establishments with 99 or fewer employees comes closest to the class of firms qualifying as small concerns under the SBA definition. Not all firms in this class would have annual receipts of less than $7.0 million; however, OSHA has conservatively chosen to overestimate the number of small firms rather than try to extrapolate the number of small firms from the limited data available. Establishments with 99 or fewer employees represent 98.4 percent of the 4,675 establishments and employ 75.4 percent of the 55,965 workers in SIC 1791, according to Dun & Bradstreet's national market profile [D&B, 1998].

In this regulatory flexibility screening analysis, OSHA assessed the impacts of compliance costs within the industry group with the largest concentration of affected employers and employees, SIC 1791, Structural Steel Erection. According to data from the Bureau of Labor Statistics, of the approximately 57,000 iron workers in construction, roughly 26,000 are employed in SIC 179, Miscellaneous Special Trade Contractors. OSHA believes that the great majority of these workers are found in SIC 1791, Structural Steel Erection, because the other industries in SIC 179 (glass and glazing, excavation work, wrecking and demolition, installation and erection of building equipment (such as installing elevators, revolving doors and industrial machinery and specialty trade contractors not elsewhere classified) are unlikely to employ significant numbers of iron workers. This contention is supported by the fact that available data on iron worker deaths (see Table III–2 in the final economic analysis) show that SIC 1791 accounted for roughly 90 percent of iron worker deaths in SIC 179 in 1994–98. Total employment for all trades in SIC 1791 is 55,965 workers, according to Dun & Bradstreet [D&B, 1998]. BLS and D&B data indicate that iron workers constitute roughly 47 percent of the labor force in SIC 1791, the largest concentration of iron workers in any four-digit group where iron workers are employed. In addition, only firms in SIC 1791 earn the majority of their revenues from steel erection. (According to the definitions used in the SIC system, this means that firms that do steel erection but are classified in other sectors earn only a minority of their total revenues from their steel erection business.)

Compared with all other industry groups in the construction industry, firms in SIC 1791 have the greatest number of iron workers per firm and the highest percentage of iron workers relative to total employment. Since the costs of compliance are approximately proportional to the number of iron workers in a given firm, establishments in SIC 1791 will experience the greatest economic impact.

In this analysis of impacts, OSHA estimated the costs of compliance for SIC 1791 by applying the percentage of iron workers in that industry group, presented in Table 1, to the total costs estimated for all affected industry groups in construction. According to the 1998 BLS employment survey [BLS, 1998], SIC 179, Miscellaneous Special Trade Contractors, employs approximately 47 percent of the 56,840 iron workers in the entire construction sector. Assuming that most, if not all of the iron workers in SIC 179 are employed in SIC 1791, OSHA estimates that 47 percent of the iron workers in construction are employed in SIC 1791. OSHA estimates that, in general, compliance costs under the final standard are proportional to employment. Thus, compliance costs in SIC 1791 can be approximated by applying to total costs the percentage of iron workers (47 percent) in SIC 1791. Therefore, OSHA estimates that if net annual costs for all of construction will be $78.4 million, then net annual costs in SIC 1791 will be 47 percent (46.5 percent before rounding) of total costs, or $36.5 million.

To assess the possible economic impacts of the final standard on small firms in SIC 1791, OSHA distributed compliance costs within size classes according to an estimate of the percent of revenue (gross sales) earned by establishments within those size classes. Applying Dun & Bradstreet revenue figures, OSHA has determined that costs represent less than one percent (0.40 percent after rounding) of revenues for firms with 99 or fewer employees, so that under the extreme case of full-cost pass-through to consumers, prices would rise by no more than one percent (see Table 6, below). Similarly, for the very smallest firms, those with fewer than ten employees, price impacts are projected to be low: 0.40 percent after rounding.

TABLE 6.—POTENTIAL ECONOMIC IMPACTS OF THE FINAL STEEL ERECTION STANDARD ON SMALL FIRMS IN THE STEEL ERECTION INDUSTRY UNDER WORST-CASE CONDITIONS

[1996 Revenue and Profit Data]

	Annual compliance costs (a) ($millions)	Compliance cost per establishment [a]	Dollar value of business [b] ($millions)	Revenue per establishment [b]	Pre-tax income [c] ($millions)	Pre-tax income per establishment [c]	Compliance costs as a percent of revenue	compliance costs as a percent of profit
SIC 1791,Structural Steel Erection	36.5	8,175.7	9,285.7	2,080,606.0	562.4	126,024.2	0.39	6.49
SIC 1791, 1–99 Employees	25.0	5,758.8	6,369.2	1,465,541.8	395.8	91,074.8	0.39	6.32
SIC 1791, 1–9 Employees	8.9	2,866.7	2,260.8	729,530.4	95.8	30,898.0	0.39	9.28

[a] Based on Table 4 and data on number of establishments from Dun & Bradstreet, National Profile of Businesses, 1996. Compliance costs for size groups were derived by applying the percentage of revenue in the size groups to total costs for all of SIC 1791.
[b] Based on data from Dun & Bradstreet, National Profile Businesses, 1996.
[c] Based on data from Dun & Bradstreet, National Profile of Businesses, 1996; Dun & Bradstreet, Industry Norms and Key Business Ratios, 1995–96; and OSHA profit calculations.

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

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Under the alternate scenario of full-cost profit absorption (an extremely unlikely scenario) among steel erection contractors with 99 or fewer employees, profit impacts would be 6.3 percent; for firms with one to nine employees, profit impacts would be 9.3 percent. Thus, costs as a percentage of profits and revenues for SIC 1791 are lower when a small entity is defined to include all firms within the SBA size standards (less than $7 million in revenue) than for small entities employing fewer than 10 workers. The difference in these projected profit impacts for the two smaller size categories of firms reflects a difference in the 1995–96 profit rates for the two groups [D&B, 1996b] applied by OSHA in this impacts analysis: (1) an average 3.6 percent rate of net-profit-after-tax-to-net-sales for establishments with fewer than ten employees (roughly defined as those with assets of less than $250,000) and (2) an average 4.9 percent post-tax profit/sales ratio for establishments with one to ninety-nine employees (roughly defined as those with assets of $250,000 to $1 million) (see Chapter VI in the final economic analysis for further explanation).

OSHA believes that most small erectors will, along with the rest of the industry, receive economic benefits from compliance with the final rule that will serve to significantly offset any direct cost impacts. As noted above, employer representatives on the committee and at the public hearing commented on numerous occasions that the safety program implicit within the final standard is compatible with maintaining a profitable business operation, and that such a program would, in fact, improve profitability and competitiveness [Exs. 6–3; 6–8; 6–10; 202X, pp. 99, 119; 206X, pp. 274–275]. Therefore, OSHA anticipates that most small entities will experience minimal economic impacts as a result of implementation of the final standard. However, since compliance costs under the worst-case scenario exceed 5 percent of profits in some of the industries affected, OSHA's internal guidelines with respect to the Regulatory Flexibility Act require the Agency to conduct a full Final Regulatory Flexibility Analysis.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires that a Final Regulatory Flexibility Analysis contain the following elements:

(1) A succinct statement of the need for and objectives of the rule;

(2) A summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the Agency's assessment of such issues, and a statement of any changes made to the rule as a result of such comments;

(3) A description and an estimate of the number of small businesses to which the rule will apply or an explanation of why no such estimate is available; and

(4) A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of the report or record.

In addition, a Regulatory Flexibility Analysis must contain a description of the steps the Agency has taken to minimize any significant economic impacts on small entities consistent with the stated objectives of applicable statues, including a statement of the factual, policy and legal reasons for selecting the alternative adopted in the final rule, and the reasons for rejecting each of the other significant alternatives [SBA, 2000].

Reasons for the Final Rule

According to OSHA's analysis of accident data for an eleven-year period (1984–1994), 319 fatalities involved hazardous conditions that are addressed by OSHA's current and revised steel erection standard (for details, see Chapter III, Risk Assessment and Benefits, and Appendix B of the preliminary economic analysis). Based on a review of BLS injury census data for the period 1994–98, OSHA estimates that an average of 35 fatalities and 2,279 lost-workday injuries annually involve circumstances that would be addressed by provisions in the final OSHA steel erection standard. For an industry with an estimated work-force of only 56,840 workers, these fatality and injury levels clearly demonstrate that the risk confronting these workers is significant. Therefore, OSHA has developed final regulatory text that is designed to address this risk.

Objectives of the Final Rule

The objective of this final standard is to reduce the risk of occupational exposure to a variety of hazards on steel erection construction worksites, such as those involving falls, slips, trips, being struck by or crushed by objects or loads, and structural collapses. These occupational hazards will be reduced by this final rule through the use of engineering controls, work practice controls, inspections of worksite conditions, training, communication, and recordkeeping. Implementation of these measures has been shown to minimize or eliminate occupational exposure to these hazards during the erection of steel structures and thus to reduce the risk of injury or death among workers.

Significant Issues Raised in the Initial Regulatory Flexibility Analysis

Among the issues raised in the notice of proposed rulemaking and in the initial regulatory flexibility analysis, the most significant concerned the impact of the proposed standard on small fabricators of structural steel members, including shops that fabricate open web steel joists and that complete the final detailing and coating of other structural steel members. These firms would be affected by provisions in the final rule that require joists, columns, and girders to arrive at the site meeting certain design specifications. For example, joists erected in bays of 40 feet or greater must be designed for bolting in the final connection of joists to the permanent structure. Therefore, all joist fabricators who produce joists that meet this criterion must drill or punch holes in appropriate locations on the joists to allow for bolting at the site.

In the pre-proposal period and during the hearing, the Steel Joist Institute argued that some small firms may lack the equipment to prepare joists as required by the standard, and that as a result such firms could be severely impacted (*see*, for example, Ex. 204X, pp. 60–63). However, buildings requiring joists of over 40 feet in length represent only a portion of the total market. In the Preliminary Economic Analysis, OSHA suggested that, to the extent that there are small firms lacking suitable equipment, such firms could still produce fabricated steel for a variety of steel erection projects and for portions of other projects. As a result, in that analysis, OSHA did not anticipate a significant impact, if any, on those firms that lack the proper equipment to prepare joists of greater than 40 feet for bolting.

In the Initial Regulatory Flexibility Analysis, OSHA solicited comment on two issues: (1) Whether there are small firms lacking suitable equipment to prepare joists in the manner prescribed by the rule; and (2) the percentage of the steel framing market that requires the use of joists of greater than 40 feet in length. In response, the Steel Joist Institute (SJI) presented cost data to demonstrate that the proposed requirement for bolt holes would severely impact the joist manufacturing industry. SJI stated that production costs for the industry as a whole could rise by as much as 11 percent after the rule is promulgated and joist fabricators are required to drill and punch holes in the joists (Ex. 204X, p. 62). The American Institute of Steel Construction echoed these concerns about the economic impacts of the proposed joist requirements (Ex. 13–209).

As a result of these concerns, OSHA examined the impact of the final standard on the fabricated structural metal industry (SIC 3441), which produces iron and steel for structural purposes such as the construction of bridges and buildings, even though these employers are not affected employers under the OSH Act. This sector would need to bore holes in joists greater than 40 feet in length so they can be bolted rather than welded (§ 1926.757). In addition, this sector would need to supply seats or equivalent connection devices for double connections (§ 1926.756); supply holes or other devices attached to perimeter columns to permit installation of perimeter safety cables (§ 1926.756); provide a vertical stabilizer plate on each column for steel joists (§ 1926.757); and ensure, through approved test methods, that paint coatings on top surfaces of structural steel members achieve a minimum average slip resistance (§ 1926.754).

OSHA's impact analysis assumes that this sector would bear all of the costs associated with these provisions of the final standard concerning open web joists, slip resistance of skeletal structural steel, column connections for perimeter safety cables and double connections. In fact, however, because of contractual arrangements among fabricators, steel erectors and building owners, most of the costs borne by the fabricators affected by this provision would be transmitted through steel erectors to building owners and would appear in the bid price of the project or would be incurred as onsite costs.

For purposes of this analysis, OSHA has defined small firms in the fabricated structural metal industry using the SBA definition of small firms: firms with fewer than 500 employees. Department of Commerce data show that there were 2,891 small firms in this sector in 1997. (Small firms represented 99.7 percent of all firms). Department of Commerce data also show that these small firms had total revenues of over $13.3 billion, over 80 percent of all industry revenues. Dun and Bradstreet data show that in fiscal year 1995, the median profits for firms in this sector were a healthy 3.5 percent of sales. Small firms were assumed to bear costs in proportion to their revenues. OSHA has not estimated costs to small fabricators for the design, engineering, testing, and manufacture of the special devices and coatings that will be supplied to steel erectors to enable them to achieve compliance with the final standard. However, OSHA anticipates that even if all of the costs of these provisions of the standard are borne by the fabricated structural metal industry, these costs will represent only a small percentage (0.37 percent) of revenues and 10.5 percent of profits for small firms in this sector (if all compliance costs were absorbed from profits, a highly unlikely scenario). Thus, OSHA finds that the costs of the standard will not cause a significant impact on small firms in this sector.

On the other hand, other speakers at the hearing who have field experience on this issue testified that the bolted joist provision could lead to cost savings by reducing the exposure time of workers who would otherwise be welding the connection (Ex. 208X, pp. 211, 252). After weighing this offsetting evidence, the Agency has concluded that in the fabricated structural metal industry, any additional production costs—and associated increases in prices for materials used by steel erectors—are likely to be offset, at least to some extent, by cost savings and benefits (fatalities and injuries avoided) in the industry—structural steel erection—directly affected by the rule. Therefore, OSHA believes that the provision is justified. In this preamble to the final rule, OSHA makes similar arguments for the other provisions in the standard, discussed above, that impact parties that are indirectly affected by the standard. In sum, OSHA finds that these provisions of the final rule are essential for the comprehensive safety program envisioned by this final steel erection standard.

In another example of a provision in the final rule where smaller entities connected to the steel erection industry would be affected by design criteria, § 1926.754 of the final standard specifies that coatings of structural steel members must achieve a minimum average slip resistance—with documentation or certification that the standard has been reached, based on an appropriate test method—before workers are permitted to walk the top surface of the steel member. Thus, all fabricators who coat steel members before shipping to the site would need to certify that the steel members meet the slip resistance standard. It is also possible that there may be impacts on small paints and coatings manufacturers. OSHA anticipates that the most likely scenario is that costs of friction resistant coatings will be passed forward to fabricators, and, in turn, to steel erection firms.

OSHA has examined the technological and economic implications of these and other issues raised in the rulemaking that affect smaller entities and has addressed any concerns about inequitable regulatory impacts on those entities in this preamble to the final standard and in the final economic analysis. In sum, based on comment in the record, OSHA finds that, although some smaller firms may experience impacts as a result of the design specifications in the final rule, these cost impacts can generally be passed forward to intermediate and final customers in the market—that is, the steel erectors, general contractors, owners and tenants of the building project—in such a way as to minimize impacts on the market share of smaller fabrication shops. Furthermore, OSHA believes that technological developments and market innovations will help to smooth the transition to the new market environment created by the final rule. For additional discussion of these technological and economic issues and their small-firm implications, see IV. Summary and Explanation of the Final Rule in this preamble and Chapter IV, Technological Feasibility, in the final economic analysis.

Description of the Number of Small Entities

For this rulemaking, OSHA has identified the population at risk of injury in the construction workforce and the industry groups where steel erection is conducted, but cannot with certainty estimate the number of small entities to which the final rule will apply because some firms even in SIC 1791 often perform work unrelated to steel erection and some firms in other SICs occasionally do steel erection work. There were no comments in the record that directly addressed this question. In SIC 1791, Structural Steel Erection, where the majority of iron workers are employed, there are roughly 4,544 establishments defined as small by the SBA, *i.e.*, these entities earn less than $7 million in annual revenue. If all establishments in SIC 1791 were affected by the final standard, then small entities would comprise 97 percent of all affected entities, using the SBA size standard. There are 3,898 very small establishments, i.e., those employing fewer than 20 employees in SIC 1791; these very small establishments comprise 83 percent of all establishments in the industry.

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Description of the Reporting, Recordkeeping and Other Compliance Requirements of the Final Rule

The final rule would require, in the following provisions, that employers establish and maintain records for the use of engineering controls, work practices, inspections, and training:

- Site layout, site-specific erection plan, and construction sequence;
- Hoisting and rigging;
- Structural steel assembly;
- Open-web steel joists; and
- training.

Most steel erection employers would be affected by the reporting and recordkeeping requirements in these sections. In estimating the cost of establishing and maintaining the records for each of these control areas, OSHA used the wage rate of the applicable professional personnel. To give two examples: (1) For the cost of certifying that lift rigging meets manufacturer's specifications, OSHA applied the wage rate for an ironworker supervisor; and (2) for the costs of documenting alternative methods for joist erection, OSHA applied the wage rates of a project manager and a structural engineer. All recordkeeping requirements included in the final rule could be performed by existing staff in any of the covered industries. A detailed description of the recordkeeping requirements appears in Chapter II, Industry Profile, and in Chapter V, Costs of Compliance, of this final economic analysis.

Relevant Federal Rules

In this final rule, OSHA is revising the current safety standard for steel erection that has been in place with little change for nearly 30 years. OSHA believes that this thorough and comprehensive revision to existing subpart R will provide greater protection and eliminate ambiguity and confusion, thereby improving safety in this important segment of the construction industry. There are no other federal workplace rules or guidelines that overlap with the OSHA steel erection standard.

Significant Alternatives Considered

Through its deliberations, the Negotiated Rulemaking Committee considered alternatives to many of the provisions of the final standard. Several of these, and the Committee's choices with respect to them, are discussed below. For example, the final standard features, wherever possible, performance language that permits maximum flexibility for achieving safety outcomes. In the area of site-specific plans, the final rule provides an opportunity to those employers who select alternative means and methods for complying with certain sections of the standard, and to incorporate these alternatives into a site-specific erection plan. OSHA considered small contractors when it elected not to propose a universal requirement for a site-specific erection plan for all steel erection sites. Instead, the final standard provides guidelines for establishing a site-specific erection plan in a non-mandatory appendix to assist employers who choose to develop such a plan, as recommended by SENRAC.

Other areas of the final standard that involve the consideration of alternatives and are responsive to small contractors include rules for the safe use of cranes and other lifting equipment and the proper assembly of metal buildings other than those constructed of heavy structural steel. In light of the number of small steel erectors potentially affected by the hoisting and rigging section of the final standard, OSHA has attempted to minimize the burden of the pre-shift visual crane inspections by having the inspection checklist apply only to the most essential safety elements, as recommended by SENRAC. Additionally, since there are a large number of small builders who erect pre-engineered metal structures exclusively, OSHA determined that a separate section in the final standard dedicated to this type of steel erection would ease compliance for small erectors.

The Regulatory Flexibility Act emphasizes the importance of performance-based standards for small businesses. For example, in § 1926.760, Fall Protection, employers are required to protect certain employees exposed to fall distances of 15 feet or greater. Paragraph (a)(1) of § 1926.760 lists the types of general safety systems—*i.e.*, guardrail systems, safety net systems, personal fall arrest systems, positioning device systems or fall restraint systems—that must be used by employers to provide fall protection to their employees. However, the standard does not mandate particular engineering solutions by structure type, site location, crew size, or other criteria. Employers are free to select any one system or combination of systems that is most compatible with company practice and employee protection so long as the performance measure—fall protection at 15 feet—is achieved.

As another example of OSHA's concern for the potential impacts on small businesses, the final standard minimizes recordkeeping burden where training, notifications, and other forms of communication are required, as recommended by SENRAC. Regarding training provisions, general instruction in fall hazards is mandated for all employees exposed to that risk, but the scope of additional special training is limited to three particularly hazardous activities: multiple lift rigging, connecting, and decking. Employers are to ensure that the training is provided but do not have to document or certify the program. Other requirements where communication will be necessary, including those involving field curing of concrete footings and modification of anchor bolts, were written in such a way as to limit the notifications to cover only the most essential information. Supplementary explanatory materials, presented in appendices to the standard, are intended to assist employers in complying with the rule and otherwise providing a safer workplace.

Another approach recommended by the Regulatory Flexibility Act is compliance date phase-ins for small businesses. Throughout their deliberations, the negotiated rulemaking advisory committee recognized the importance of effective outreach to the steel erection community prior to and following promulgation of the standard. In fact, as stated by a committee member prior to the issuance of the proposed standard, many employers in the industry are aware of, and have already begun to align their safety programs with, the standard (Ex. 9–156). With the exception of the requirement addressing slip resistance of skeletal structural steel (the date for mandatory compliance with this provision is five years after the effective date of the standard), the standard as a whole becomes effective within 180 days. OSHA believes that any compliance extensions for affected employers, including small employers, would only marginally ease the economic burden, given the progress in occupational safety already underway throughout industry and the non-capital-intensive nature of the rule, and would delay unnecessarily the protection of workers who would otherwise benefit from compliance with the rule.

In sum, throughout the process of negotiated rulemaking and during the period leading to this notice of final rulemaking for OSHA's steel erection standard, alternatives that would benefit small employers were considered and addressed on a routine basis. After considering a number of alternatives and adopting those that were consistent with the mandate imposed by the OSH Act, OSHA has developed a final rule that would minimize the burden on small employers, while maintaining the level of worker protection mandated by the OSH Act.

Non-Regulatory Alternatives

The primary objective of this final standard on structural steel erection is to minimize the number of construction worker injuries and fatalities. To develop this standard, OSHA employed negotiated rulemaking using an advisory committee composed of representatives from the construction industry (both labor and management and both small and larger firms), the insurance industry, the engineering field, and Federal and State government regulatory and research agencies. OSHA itself was also a member of the committee.

OSHA also examined throughout this rulemaking a number of non-regulatory approaches to enhancing workplace safety, including the operation of the classical free market, the tort liability insurance system and the workers' compensation insurance system. OSHA has concluded that these social and economic alternatives to a Federal workplace standard fail to adequately protect workers from the hazards associated with structural steel erection in the construction industry. The private market offers economic signals that could have the potential to direct workers toward desirable combinations of risk and reward. However, market imperfections and social and economic institutions—such as limitations to mobility, accumulated benefits, and social welfare programs—prevent workplaces from achieving the most optimal safety outcomes, creating inefficient, inadequately compensated risks for workers. Tort liability laws and workers' compensation provide some protection, but fall far short of fully compensating injured employees for the loss of wages, the medical costs, and the legal and other costs resulting from workplace accidents. Furthermore, these approaches are inherently reactive, rather than proactive, and largely fail to introduce progressive safety programs at all levels of industry. Therefore, OSHA finds that this final revision to the steel erection standard provides the necessary remedy.

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VI. Environmental Assessment

The final rule has been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (CEQ) (40 CFR part 1500), and DOL NEPA Procedures (29 CFR part 11). The provisions of the standard focus on the reduction and avoidance of accidents occurring during structural steel erection. Consequently, no major negative impact is foreseen on air, water or soil quality, plant or animal life, the use of land or other aspects of the environment.

VII. Federalism

Executive Order 13132, "Federalism," (64 FR 43255; Aug. 10, 1999), sets forth fundamental Federalism principles, Federalism policymaking criteria, and provisions for consultation by Federal agencies with State or local governments when policies are being formulated which potentially affect them. The Order generally requires that agencies, to the extent possible, refrain from limiting State policy options; consult with States prior to taking actions that would restrict State policy options; and take such action only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 also provides that agencies shall not promulgate regulations which have significant Federalism implications and impose substantial direct compliance costs on State or local governments, unless the agency consults with State and local officials early in the process of developing the proposed regulation and provides a summary Federalism impact statement in the preamble of the final rule. Finally, the Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so, and provides that any such preemption is to be limited to be limited to the extent possible.

Executive Order 13132 required agencies to have in place by January 31, 2000 an intergovernmental consultation process for proposed regulations with Federalism implications; the Steel Erection standard was published for public comment prior to that date, on August 13, 1998, and accordingly was not subject to the new consultation procedure.

Among the Federalism policy criteria addressed by Executive Order 13132 is the principle that national action limiting the policymaking discretion of the States shall be taken only when "national activity is appropriate in light of the presence of a problem of national significance." Since many steel erection-related injuries and fatalities are reported every year in every State and since the hazards of steel erection work are present in workplaces in every State of the Union, steel erection hazards are clearly a national problem. The final standard on steel erection is written so that employees in every State will be protected by the standard. To the extent that there are any State or regional peculiarities, States with occupational safety and health plans approved under section 18 of the OSH Act can develop their own comparable State standards to deal with any special problems.

In short, there is a clear national problem related to occupational safety and health for employees exposed to MSD hazards in the workplace. Any steel erection standard developed by States that have elected to participate under section 18 of the OSH Act would not be preempted by this final rule if the State standard is determined by Federal OSHA to be "at least as effective" as the Federal standard.

Another policy criterion expressed in the Executive Order is that "regulatory preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the

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regulations are promulgated." The preemptive effects of the final steel erection standard upon the States are determined by the OSH Act itself: as an occupational safety and health standard issued under section 6(b) of the Act, the standard preempts any State or local law which regulates the issue of workplace steel erection protection. *Gade* v. *Nat'l Solid Waste Management Ass'n*, 505 U.S.C. 88 (1992). However, neither the OSH Act nor this standard completely displace State responsibilities which relate to steel erection injuries and fatalities in the workplace; pursuant to section 4(b)(4) of the OSH Act, State laws and programs which address the rights of employers or employees with respect to injuries or illnesses arising out of employment, including State worker compensation programs, are not subject to preemption under the OSH Act. Moreover, under section 18(b) of the Act, any State which wishes to assume responsibility for adopting and enforcing safety or health standards on issues addressed by OSHA standards may do so by submitting and obtaining Federal OSHA approval of a State plan under 18(b) of the Act; among other things, the State plan must include standards which are "at least as effective as" those of Federal OSHA. Accordingly, OSHA finds that the final steel erection standard is consistent with the policies set forth in Executive Order 13132 relating to preemption of State laws.

Section 6(b) of the Executive Order provides that agencies shall not issue regulations which impose "substantial direct compliance costs" on State or local governments without consulting with State and local officials early in the process of developing the proposed regulation, and without including in the preamble to the final rule a Federalism impact statement. The OSH Act specifically exempts workplaces maintained by States or their political subdivisions from coverage under Federal safety and health standards issued by OSHA, and accordingly nothing in the steel erection standard requires any compliance expenditure by State or local governments. However, 18(c)(6) of the Act requires any State which administers an OSHA-approved State plan to apply the same State occupational safety or health standards applied to private-sector employers to workplaces maintained by State and local government. Slightly under one-half the States and Territories have chosen to implement State plans and enforce "at least as effective" State health and safety standards to public sector workplaces. Thus, State and local employers in States which have elected to administer approved State plans will likely incur roughly comparable compliance costs, and will likely attain comparable benefits in the form of reduced injuries and compensation costs, as employers directly subject to the Federal steel erection standard. These costs of complying with State safety regulations are not "direct" costs which trigger the application of 6(b) of the Executive Order. Moreover, compliance costs to protect public workers under an approved State plan do not constitute an unfunded Federal mandate under the Unfunded Mandates Relief Act, which does not apply to Federal programs where State participation is voluntary, see 2 U.S.C. 658(5) and 1502.

In summary, the final steel erection standard imposes no substantial direct impact on State or local governments; it indirectly affects State or local employers only in States which have chosen to administer Federally-approved State plans. The final standard contains no special preemption provisions, and preempts State steel erection requirements only to the extent provided by Congress in the OSH Act for any section 6 standard. So therefore the rule does not have Federalism implications as defined in the Executive Order.

The Assistant Secretary certifies that OSHA has complied with applicable requirements of E.O. 13132 in preparing the final steel erection standard. State comments were invited on the proposed rule, and were fully considered in the development of this final rule.

VIII. Unfunded Mandates

For the purposes of the Unfunded Mandates Reform Act of 1995, as well as Executive Order 12875, this rule does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments, or increased expenditures by the private sector of more than $100 million in any year.

IX. OMB Review Under the Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995, agencies are required to seek OMB approval for all collections of information. As a part of the approval process, agencies are required to solicit comment from affected parties with regard to the collection of information, including the financial and time burdens estimated by the agencies for the collection of information.

This final rule contains collections of information as defined in OMB's regulations at 60 FR 44978 (August 29, 1995) in § 1926.752(a)(1), § 1926.752(a)(2), § 1926.753(c)(5), § 1926.753(e)(2), § 1926.754(c)(3), § 1926.757(a)(4), § 1926.757(a)(7), § 1926.757(a)(9) § 1926.757(e)(4)(i), § 1926.758(g), and § 1926.761. OSHA's rationale for the need to collect information is set forth in the discussion of each of these provisions in Section IV of this preamble.

OSHA solicited comment from the public on all aspects of these collections of information, but the Agency received no comments. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OSHA requested Office of Management and Budget (OMB) approval of the collections of information described above. OMB has granted approval of the information requirements under OMB Control Number 1218–0237. The approval expires on October 31, 2001.

X. State Plan Standards

The 25 States and territories with their own OSHA approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of this final standard. These 25 states and territories are: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for state and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a state standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these states.

XI. List of Subjects

List of Subjects in 29 CFR Part 1926

Structural steel erection, Construction industry, Construction safety, Occupational Safety and Health Administration, Occupational safety and health.

XII. Authority

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333), Secretary of Labor's Order No. 6–96 (62 FR 111), and 29 CFR part 1911, the Agency amends part 1926 of Title 29 of the Code of Federal Regulations as set forth below.

Signed at Washington, D.C., this 8th day of January, 2001.

Charles N. Jeffress,

Assistant Secretary of Labor.

PART 1926—[AMENDED]

Subpart M—Fall Protection

1. The authority citation for subpart M of Part 1926 is revised to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); Sec. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Orders Nos. 1–90 (55 FR 9033), 6–96 (62 FR 111); and 3–2000 (65 FR 50017), as applicable, and 29 CFR Part 1911.

2. Paragraphs (a)(2) (v) and (vi) of § 1926.500 are redesignated as paragraphs (a)(2) (vi) and (vii), respectively. In addition, paragraphs (a)(2) (iii) and (v) and (a)(3)(iv) are revised to read as follows:

§ 1926.500 Scope, application, and definitions applicable to this subpart.

(a) * * *

(2) * * *

(iii) Fall protection requirements for employees performing steel erection work (except for towers and tanks) are provided in subpart R of this part.

* * * * *

(v) Requirements relating to fall protection for employees engaged in the erection of tanks and communication and broadcast towers are provided in § 1926.105.

* * * * *

(3) * * *

* * * * *

(iv) Section 1926.502 does not apply to the erection of tanks and communication and broadcast towers. (Note: Section 1926.104 sets the criteria for body belts, lanyards and lifelines used for fall protection during tank and communication and broadcast tower erection. Paragraphs (b),(c) and (f) of § 1926.107 provide definitions for the pertinent terms.)

* * * * *

Subpart R—[Amended]

3. The authority citation for subpart R of part 1926 is revised to read as follows:

Authority: Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); Sec. 4, 6, and 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 3–2000 (65 FR 50017), and 29 CFR part 1911.

4. Subpart R of part 1926 is revised to read as follows:

Subpart R—Steel Erection

Sec.

1926.750 Scope.
1926.751 Definitions.
1926.752 Site layout, site-specific erection plan and construction sequence.
1926.753 Hoisting and rigging.
1926.754 Structural steel assembly.
1926.755 Column anchorage.
1926.756 Beams and columns.
1926.757 Open web steel joists.
1926.758 Systems-engineered metal buildings.
1926.759 Falling object protection.
1926.760 Fall protection.
1926.761 Training.
Appendix A to Subpart R—Guidelines for establishing the components of a site-specific erection plan: Non-Mandatory Guidelines for Complying with § 1926.752(e)
Appendix B to Subpart R—Acceptable test methods for testing slip-resistance of walking/working surfaces: Non-Mandatory Guidelines for Complying with § 1926.754(c)(3)
Appendix C to Subpart R—Illustrations of bridging terminus points: Non-Mandatory Guidelines for Complying with § 1926.757(a)(10) and § 1926.757(c)(5)
Appendix D to Subpart R—Illustration of the use of control lines to demarcate controlled decking zones (CDZs): Non-Mandatory Guidelines for Complying with § 1926.760(c)(3)
Appendix E to Subpart R—Training: Non-Mandatory Guidelines for Complying with § 1926.761
Appendix F to Subpart R— Perimeter columns: Non-Mandatory Guidelines for Complying with § 1926.756(e) to Protect the Unprotected Side or Edge of a Walking/Working Surface
Appendix G to Subpart R—Fall protection systems criteria and practices from § 1926.502: Non-Mandatory Guidelines for Complying with Complying with § 1926.760(d)
Appendix H to Subpart R—Double connections: Illustration of a clipped end connection and a staggered connection: Non-Mandatory Guidelines for Complying with Complying with § 1926.756(c)(1)

Subpart R—Steel Erection

§ 1926.750 Scope.

(a) This subpart sets forth requirements to protect employees from the hazards associated with steel erection activities involved in the construction, alteration, and/or repair of single and multi-story buildings, bridges, and other structures where steel erection occurs. The requirements of this subpart apply to employers engaged in steel erection unless otherwise specified. This subpart does not cover electrical transmission towers, communication and broadcast towers, or tanks.

Note to paragraph (a): Examples of structures where steel erection may occur include but are not limited to the following: Single and multi-story buildings; systems-engineered metal buildings; lift slab/tilt-up structures; energy exploration structures; energy production, transfer and storage structures and facilities; auditoriums; malls; amphitheaters; stadiums; power plants; mills; chemical process structures; bridges; trestles; overpasses; underpasses; viaducts; aqueducts; aerospace facilities and structures; radar and communication structures; light towers; signage; billboards; scoreboards; conveyor systems; conveyor supports and related framing; stairways; stair towers; fire escapes; draft curtains; fire containment structures; monorails; aerialways; catwalks; curtain walls; window walls; store fronts; elevator fronts; entrances; skylights; metal roofs; industrial structures; hi-bay structures; rail, marine and other transportation structures; sound barriers; water process and water containment structures; air and cable supported structures; space frames; geodesic domes; canopies; racks and rack support structures and frames; platforms; walkways; balconies; atriums; penthouses; car dumpers; stackers/reclaimers; cranes and craneways; bins; hoppers; ovens; furnaces; stacks; amusement park structures and rides; and artistic and monumental structures.

(b)(1) Steel erection activities include hoisting, laying out, placing, connecting, welding, burning, guying, bracing, bolting, plumbing and rigging structural steel, steel joists and metal buildings; installing metal decking, curtain walls, window walls, siding systems, miscellaneous metals, ornamental iron and similar materials; and moving point-to-point while performing these activities.

(2) The following activities are covered by this subpart when they occur during and are a part of steel erection activities: rigging, hoisting, laying out, placing, connecting, guying, bracing, dismantling, burning, welding, bolting, grinding, sealing, caulking, and all related activities for construction, alteration and/or repair of materials and assemblies such as structural steel; ferrous metals and alloys; non-ferrous metals and alloys; glass; plastics and synthetic composite materials; structural metal framing and related bracing and assemblies; anchoring devices; structural cabling; cable stays; permanent and temporary bents and towers; falsework for temporary supports of permanent steel members; stone and other non-precast concrete architectural materials mounted on steel frames; safety systems for steel erection; steel and metal joists; metal decking and raceway systems and accessories; metal

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roofing and accessories; metal siding; bridge flooring; cold formed steel framing; elevator beams; grillage; shelf racks; multi-purpose supports; crane rails and accessories; miscellaneous, architectural and ornamental metals and metal work; ladders; railings; handrails; fences and gates; gratings; trench covers; floor plates; castings; sheet metal fabrications; metal panels and panel wall systems; louvers; column covers; enclosures and pockets; stairs; perforated metals; ornamental iron work, expansion control including bridge expansion joint assemblies; slide bearings; hydraulic structures; fascias; soffit panels; penthouse enclosures; skylights; joint fillers; gaskets; sealants and seals; doors; windows; hardware; detention/security equipment and doors, windows and hardware; conveying systems; building specialties; building equipment; machinery and plant equipment, furnishings and special construction.

(c) The duties of controlling contractors under this subpart include, but are not limited to, the duties specified in §§ 1926.752 (a) and (c), 1926.755(b)(2), 1926.759(b), and 1926.760(e).

§ 1926.751 Definitions.

Anchored bridging means that the steel joist bridging is connected to a bridging terminus point.

Bolted diagonal bridging means diagonal bridging that is bolted to a steel joist or joists.

Bridging clip means a device that is attached to the steel joist to allow the bolting of the bridging to the steel joist.

Bridging terminus point means a wall, a beam, tandem joists (with all bridging installed and a horizontal truss in the plane of the top chord) or other element at an end or intermediate point(s) of a line of bridging that provides an anchor point for the steel joist bridging.

Choker means a wire rope or synthetic fiber rigging assembly that is used to attach a load to a hoisting device.

Cold forming means the process of using press brakes, rolls, or other methods to shape steel into desired cross sections at room temperature.

Column means a load-carrying vertical member that is part of the primary skeletal framing system. Columns do not include posts.

Competent person (also defined in § 1926.32) means one who is capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.

Connector means an employee who, working with hoisting equipment, is placing and connecting structural members and/or components.

Constructibility means the ability to erect structural steel members in accordance with subpart R without having to alter the over-all structural design.

Construction load (for joist erection) means any load other than the weight of the employee(s), the joists and the bridging bundle.

Controlled Decking Zone (CDZ) means an area in which certain work (for example, initial installation and placement of metal decking) may take place without the use of guardrail systems, personal fall arrest systems, fall restraint systems, or safety net systems and where access to the zone is controlled.

Controlled load lowering means lowering a load by means of a mechanical hoist drum device that allows a hoisted load to be lowered with maximum control using the gear train or hydraulic components of the hoist mechanism. Controlled load lowering requires the use of the hoist drive motor, rather than the load hoist brake, to lower the load.

Controlling contractor means a prime contractor, general contractor, construction manager or any other legal entity which has the overall responsibility for the construction of the project—its planning, quality and completion.

Critical lift means a lift that (1) exceeds 75 percent of the rated capacity of the crane or derrick, or (2) requires the use of more than one crane or derrick.

Decking hole means a gap or void more than 2 inches (5.1 cm) in its least dimension and less than 12 inches (30.5 cm) in its greatest dimension in a floor, roof or other walking/working surface. Pre-engineered holes in cellular decking (for wires, cables, etc.) are not included in this definition.

Derrick floor means an elevated floor of a building or structure that has been designated to receive hoisted pieces of steel prior to final placement.

Double connection means an attachment method where the connection point is intended for two pieces of steel which share common bolts on either side of a central piece.

Double connection seat means a structural attachment that, during the installation of a double connection, supports the first member while the second member is connected.

Erection bridging means the bolted diagonal bridging that is required to be installed prior to releasing the hoisting cables from the steel joists.

Fall restraint system means a fall protection system that prevents the user from falling any distance. The system is comprised of either a body belt or body harness, along with an anchorage, connectors and other necessary equipment. The other components typically include a lanyard, and may also include a lifeline and other devices.

Final interior perimeter means the perimeter of a large permanent open space within a building such as an atrium or courtyard. This does not include openings for stairways, elevator shafts, etc.

Girt (in systems-engineered metal buildings) means a "Z" or "C" shaped member formed from sheet steel spanning between primary framing and supporting wall material.

Headache ball means a weighted hook that is used to attach loads to the hoist load line of the crane.

Hoisting equipment means commercially manufactured lifting equipment designed to lift and position a load of known weight to a location at some known elevation and horizontal distance from the equipment's center of rotation. "Hoisting equipment" includes but is not limited to cranes, derricks, tower cranes, barge-mounted derricks or cranes, gin poles and gantry hoist systems. A "come-a-long" (a mechanical device, usually consisting of a chain or cable attached at each end, that is used to facilitate movement of materials through leverage) is not considered "hoisting equipment."

Leading edge means the unprotected side and edge of a floor, roof, or formwork for a floor or other walking/working surface (such as deck) which changes location as additional floor, roof, decking or formwork sections are placed, formed or constructed.

Metal decking means a commercially manufactured, structural grade, cold rolled metal panel formed into a series of parallel ribs; for this subpart, this includes metal floor and roof decks, standing seam metal roofs, other metal roof systems and other products such as bar gratings, checker plate, expanded metal panels, and similar products. After installation and proper fastening, these decking materials serve a combination of functions including, but not limited to: a structural element designed in combination with the structure to resist, distribute and transfer loads, stiffen the structure and provide a diaphragm action; a walking/working surface; a form for concrete slabs; a support for roofing systems; and a finished floor or roof.

Multiple lift rigging means a rigging assembly manufactured by wire rope rigging suppliers that facilitates the attachment of up to five independent loads to the hoist rigging of a crane.

Opening means a gap or void 12 inches (30.5 cm) or more in its least dimension in a floor, roof or other walking/working surface. For the purposes of this subpart, skylights and smoke domes that do not meet the strength requirements of § 1926.754(e)(3) shall be regarded as openings.

Permanent floor means a structurally completed floor at any level or elevation (including slab on grade).

Personal fall arrest system means a system used to arrest an employee in a fall from a working level. A personal fall arrest system consists of an anchorage, connectors, a body harness and may include a lanyard, deceleration device, lifeline, or suitable combination of these. The use of a body belt for fall arrest is prohibited.

Positioning device system means a body belt or body harness rigged to allow an employee to be supported on an elevated, vertical surface, such as a wall or column and work with both hands free while leaning.

Post means a structural member with a longitudinal axis that is essentially vertical, that: (1) weighs 300 pounds or less and is axially loaded (a load presses down on the top end), or (2) is not axially loaded, but is laterally restrained by the above member. Posts typically support stair landings, wall framing, mezzanines and other substructures.

Project structural engineer of record means the registered, licensed professional responsible for the design of structural steel framing and whose seal appears on the structural contract documents.

Purlin (in systems-engineered metal buildings) means a "Z" or "C" shaped member formed from sheet steel spanning between primary framing and supporting roof material.

Qualified person (also defined in § 1926.32) means one who, by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated the ability to solve or resolve problems relating to the subject matter, the work, or the project.

Safety deck attachment means an initial attachment that is used to secure an initially placed sheet of decking to keep proper alignment and bearing with structural support members.

Shear connector means headed steel studs, steel bars, steel lugs, and similar devices which are attached to a structural member for the purpose of achieving composite action with concrete.

Steel erection means the construction, alteration or repair of steel buildings, bridges and other structures, including the installation of metal decking and all planking used during the process of erection.

Steel joist means an open web, secondary load-carrying member of 144 feet (43.9 m) or less, designed by the manufacturer, used for the support of floors and roofs. This does not include structural steel trusses or cold-formed joists.

Steel joist girder means an open web, primary load-carrying member, designed by the manufacturer, used for the support of floors and roofs. This does not include structural steel trusses.

Steel truss means an open web member designed of structural steel components by the project structural engineer of record. For the purposes of this subpart, a steel truss is considered equivalent to a solid web structural member.

Structural steel means a steel member, or a member made of a substitute material (such as, but not limited to, fiberglass, aluminum or composite members). These members include, but are not limited to, steel joists, joist girders, purlins, columns, beams, trusses, splices, seats, metal decking, girts, and all bridging, and cold formed metal framing which is integrated with the structural steel framing of a building.

Systems-engineered metal building means a metal, field-assembled building system consisting of framing, roof and wall coverings. Typically, many of these components are cold-formed shapes. These individual parts are fabricated in one or more manufacturing facilities and shipped to the job site for assembly into the final structure. The engineering design of the system is normally the responsibility of the systems-engineered metal building manufacturer.

Tank means a container for holding gases, liquids or solids.

Unprotected sides and edges means any side or edge (except at entrances to points of access) of a walking/working surface, for example a, floor, roof, ramp or runway, where there is no wall or guardrail system at least 39 inches (1.0 m) high.

§ 1926.752 Site layout, site-specific erection plan and construction sequence.

(a) *Approval to begin steel erection.* Before authorizing the commencement of steel erection, the controlling contractor shall ensure that the steel erector is provided with the following written notifications:

(1) The concrete in the footings, piers and walls and the mortar in the masonry piers and walls has attained, on the basis of an appropriate ASTM standard test method of field-cured samples, either 75 percent of the intended minimum compressive design strength or sufficient strength to support the loads imposed during steel erection.

(2) Any repairs, replacements and modifications to the anchor bolts were conducted in accordance with § 1926.755(b).

(b) *Commencement of steel erection.* A steel erection contractor shall not erect steel unless it has received written notification that the concrete in the footings, piers and walls or the mortar in the masonry piers and walls has attained, on the basis of an appropriate ASTM standard test method of field-cured samples, either 75 percent of the intended minimum compressive design strength or sufficient strength to support the loads imposed during steel erection.

(c) *Site layout.* The controlling contractor shall ensure that the following is provided and maintained:

(1) Adequate access roads into and through the site for the safe delivery and movement of derricks, cranes, trucks, other necessary equipment, and the material to be erected and means and methods for pedestrian and vehicular control. Exception: this requirement does not apply to roads outside of the construction site.

(2) A firm, properly graded, drained area, readily accessible to the work with adequate space for the safe storage of materials and the safe operation of the erector's equipment.

(d) *Pre-planning of overhead hoisting operations.* All hoisting operations in steel erection shall be pre-planned to ensure that the requirements of § 1926.753(d) are met.

(e) *Site-specific erection plan.* Where employers elect, due to conditions specific to the site, to develop alternate means and methods that provide employee protection in accordance with § 1926.753(c)(5), § 1926.757(a)(4) or § 1926.757(e)(4), a site-specific erection plan shall be developed by a qualified person and be available at the work site. Guidelines for establishing a site-specific erection plan are contained in Appendix A to this subpart.

§ 1926.753 Hoisting and rigging.

(a) All the provisions of § 1926.550 apply to hoisting and rigging with the exception of § 1926.550(g)(2).

(b) In addition, paragraphs (c) through (e) of this section apply regarding the

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hazards associated with hoisting and rigging.

(c) *General.* (1) Pre-shift visual inspection of cranes.

(i) Cranes being used in steel erection activities shall be visually inspected prior to each shift by a competent person; the inspection shall include observation for deficiencies during operation. At a minimum this inspection shall include the following:

(A) All control mechanisms for maladjustments;

(B) Control and drive mechanism for excessive wear of components and contamination by lubricants, water or other foreign matter;

(C) Safety devices, including but not limited to boom angle indicators, boom stops, boom kick out devices, anti-two block devices, and load moment indicators where required;

(D) Air, hydraulic, and other pressurized lines for deterioration or leakage, particularly those which flex in normal operation;

(E) Hooks and latches for deformation, chemical damage, cracks, or wear;

(F) Wire rope reeving for compliance with hoisting equipment manufacturer's specifications;

(G) Electrical apparatus for malfunctioning, signs of excessive deterioration, dirt, or moisture accumulation;

(H) Hydraulic system for proper fluid level;

(I) Tires for proper inflation and condition;

(J) Ground conditions around the hoisting equipment for proper support, including ground settling under and around outriggers, ground water accumulation, or similar conditions;

(K) The hoisting equipment for level position; and

(L) The hoisting equipment for level position after each move and setup.

(ii) If any deficiency is identified, an immediate determination shall be made by the competent person as to whether the deficiency constitutes a hazard.

(iii) If the deficiency is determined to constitute a hazard, the hoisting equipment shall be removed from service until the deficiency has been corrected.

(iv) The operator shall be responsible for those operations under the operator's direct control. Whenever there is any doubt as to safety, the operator shall have the authority to stop and refuse to handle loads until safety has been assured.

(2) A qualified rigger (a rigger who is also a qualified person) shall inspect the rigging prior to each shift in accordance with § 1926.251.

(3) The headache ball, hook or load shall not be used to transport personnel except as provided in paragraph (c)(4) of this section.

(4) Cranes or derricks may be used to hoist employees on a personnel platform when work under this subpart is being conducted, provided that all provisions of § 1926.550 (except for § 1926.550(g)(2)) are met.

(5) Safety latches on hooks shall not be deactivated or made inoperable except:

(i) When a qualified rigger has determined that the hoisting and placing of purlins and single joists can be performed more safely by doing so; or

(ii) When equivalent protection is provided in a site-specific erection plan.

(d) *Working under loads.*

(1) Routes for suspended loads shall be pre-planned to ensure that no employee is required to work directly below a suspended load except for:

(i) Employees engaged in the initial connection of the steel; or

(ii) Employees necessary for the hooking or unhooking of the load.

(2) When working under suspended loads, the following criteria shall be met:

(i) Materials being hoisted shall be rigged to prevent unintentional displacement;

(ii) Hooks with self-closing safety latches or their equivalent shall be used to prevent components from slipping out of the hook; and

(iii) All loads shall be rigged by a qualified rigger

(e) *Multiple lift rigging procedure.*

(1) A multiple lift shall only be performed if the following criteria are met:

(i) A multiple lift rigging assembly is used;

(ii) A maximum of five members are hoisted per lift;

(iii) Only beams and similar structural members are lifted; and

(iv) All employees engaged in the multiple lift have been trained in these procedures in accordance with § 1926.761(c)(1).

(v) No crane is permitted to be used for a multiple lift where such use is contrary to the manufacturer's specifications and limitations.

(2) Components of the multiple lift rigging assembly shall be specifically designed and assembled with a maximum capacity for total assembly and for each individual attachment point. This capacity, certified by the manufacturer or a qualified rigger, shall be based on the manufacturer's specifications with a 5 to 1 safety factor for all components.

(3) The total load shall not exceed:

(i) The rated capacity of the hoisting equipment specified in the hoisting equipment load charts;

(ii) The rigging capacity specified in the rigging rating chart.

(4) The multiple lift rigging assembly shall be rigged with members:

(i) Attached at their center of gravity and maintained reasonably level;

(ii) Rigged from top down; and

(iii) Rigged at least 7 feet (2.1 m) apart.

(5) The members on the multiple lift rigging assembly shall be set from the bottom up.

(6) Controlled load lowering shall be used whenever the load is over the connectors.

§ 1926.754 Structural steel assembly.

(a) Structural stability shall be maintained at all times during the erection process.

(b) The following additional requirements shall apply for multi-story structures:

(1) The permanent floors shall be installed as the erection of structural members progresses, and there shall be not more than eight stories between the erection floor and the upper-most permanent floor, except where the structural integrity is maintained as a result of the design.

(2) At no time shall there be more than four floors or 48 feet (14.6 m), whichever is less, of unfinished bolting or welding above the foundation or uppermost permanently secured floor, except where the structural integrity is maintained as a result of the design.

(3) A fully planked or decked floor or nets shall be maintained within two stories or 30 feet (9.1 m), whichever is less, directly under any erection work being performed.

(c) *Walking/working surfaces.*

(1) *Shear connectors and other similar devices.*

(i) *Tripping hazards.* Shear connectors (such as headed steel studs, steel bars or steel lugs), reinforcing bars, deformed anchors or threaded studs shall not be attached to the top flanges of beams, joists or beam attachments so that they project vertically from or horizontally across the top flange of the member until after the metal decking, or other walking/working surface, has been installed.

(ii) *Installation of shear connectors on composite floors, roofs and bridge decks.* When shear connectors are used in construction of composite floors, roofs and bridge decks, employees shall lay out and install the shear connectors after the metal decking has been installed, using the metal decking as a working platform. Shear connectors shall not be installed from within a controlled decking zone (CDZ), as specified in § 1926.760(c)(8).

(2) *Slip resistance of metal decking.* [Reserved]

(3) *Slip resistance of skeletal structural steel.* Workers shall not be permitted to walk the top surface of any structural steel member installed after July 18, 2006 that has been coated with paint or similar material unless documentation or certification that the coating has achieved a minimum average slip resistance of .50 when measured with an English XL tribometer or equivalent tester on a wetted surface at a testing laboratory is provided. Such documentation or certification shall be based on the appropriate ASTM standard test method conducted by a laboratory capable of performing the test. The results shall be available at the site and to the steel erector. (Appendix B to this subpart references appropriate ASTM standard test methods that may be used to comply with this paragraph (c)(3)).

(d) *Plumbing-up.*

(1) When deemed necessary by a competent person, plumbing-up equipment shall be installed in conjunction with the steel erection process to ensure the stability of the structure.

(2) When used, plumbing-up equipment shall be in place and properly installed before the structure is loaded with construction material such as loads of joists, bundles of decking or bundles of bridging.

(3) Plumbing-up equipment shall be removed only with the approval of a competent person.

(e) *Metal decking.*—(1) *Hoisting, landing and placing of metal decking bundles.*

(i) Bundle packaging and strapping shall not be used for hoisting unless specifically designed for that purpose.

(ii) If loose items such as dunnage, flashing, or other materials are placed on the top of metal decking bundles to be hoisted, such items shall be secured to the bundles.

(iii) Bundles of metal decking on joists shall be landed in accordance with § 1926.757(e)(4).

(iv) Metal decking bundles shall be landed on framing members so that enough support is provided to allow the bundles to be unbanded without dislodging the bundles from the supports.

(v) At the end of the shift or when environmental or jobsite conditions require, metal decking shall be secured against displacement.

(2) *Roof and floor holes and openings.* Metal decking at roof and floor holes and openings shall be installed as follows:

(i) Framed metal deck openings shall have structural members turned down to allow continuous deck installation except where not allowed by structural design constraints or constructibility.

(ii) Roof and floor holes and openings shall be decked over. Where large size, configuration or other structural design does not allow openings to be decked over (such as elevator shafts, stair wells, etc.) employees shall be protected in accordance with § 1926.760(a)(1).

(iii) Metal decking holes and openings shall not be cut until immediately prior to being permanently filled with the equipment or structure needed or intended to fulfill its specific use and which meets the strength requirements of paragraph (e)(3) of this section, or shall be immediately covered.

(3) *Covering roof and floor openings.*

(i) Covers for roof and floor openings shall be capable of supporting, without failure, twice the weight of the employees, equipment and materials that may be imposed on the cover at any one time.

(ii) All covers shall be secured when installed to prevent accidental displacement by the wind, equipment or employees.

(iii) All covers shall be painted with high-visibility paint or shall be marked with the word "HOLE" or "COVER" to provide warning of the hazard.

(iv) Smoke dome or skylight fixtures that have been installed, are not considered covers for the purpose of this section unless they meet the strength requirements of paragraph (e)(3)(i) of this section.

(4) *Decking gaps around columns.* Wire mesh, exterior plywood, or equivalent, shall be installed around columns where planks or metal decking do not fit tightly. The materials used must be of sufficient strength to provide fall protection for personnel and prevent objects from falling through.

(5) *Installation of metal decking.* (i) Except as provided in § 1926.760(c), metal decking shall be laid tightly and immediately secured upon placement to prevent accidental movement or displacement.

(ii) During initial placement, metal decking panels shall be placed to ensure full support by structural members.

(6) Derrick floors. (i) A derrick floor shall be fully decked and/or planked and the steel member connections completed to support the intended floor loading.

(ii) Temporary loads placed on a derrick floor shall be distributed over the underlying support members so as to prevent local overloading of the deck material.

§ 1926.755 Column anchorage.

(a) *General requirements for erection stability.* (1) All columns shall be anchored by a minimum of 4 anchor rods (anchor bolts).

(2) Each column anchor rod (anchor bolt) assembly, including the column-to-base plate weld and the column foundation, shall be designed to resist a minimum eccentric gravity load of 300 pounds (136.2 kg) located 18 inches (.46m) from the extreme outer face of the column in each direction at the top of the column shaft.

(3) Columns shall be set on level finished floors, pre-grouted leveling plates, leveling nuts, or shim packs which are adequate to transfer the construction loads.

(4) All columns shall be evaluated by a competent person to determine whether guying or bracing is needed; if guying or bracing is needed, it shall be installed.

(b) *Repair, replacement or field modification of anchor rods (anchor bolts).*

(1) Anchor rods (anchor bolts) shall not be repaired, replaced or field-modified without the approval of the project structural engineer of record.

(2) Prior to the erection of a column, the controlling contractor shall provide written notification to the steel erector if there has been any repair, replacement or modification of the anchor rods (anchor bolts) of that column.

§ 1926.756 Beams and columns.

(a) *General.* (1) During the final placing of solid web structural members, the load shall not be released from the hoisting line until the members are secured with at least two bolts per connection, of the same size and strength as shown in the erection drawings, drawn up wrench-tight or the equivalent as specified by the project structural engineer of record, except as specified in paragraph (b) of this section.

(2) A competent person shall determine if more than two bolts are necessary to ensure the stability of cantilevered members; if additional bolts are needed, they shall be installed.

(b) *Diagonal bracing.* Solid web structural members used as diagonal bracing shall be secured by at least one bolt per connection drawn up wrench-tight or the equivalent as specified by the project structural engineer of record.

(c) (1) *Double connections at columns and/or at beam webs over a column.* When two structural members on

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opposite sides of a column web, or a beam web over a column, are connected sharing common connection holes, at least one bolt with its wrench-tight nut shall remain connected to the first member unless a shop-attached or field-attached seat or equivalent connection device is supplied with the member to secure the first member and prevent the column from being displaced (See Appendix H to this subpart for examples of equivalent connection devices).

(2) If a seat or equivalent device is used, the seat (or device) shall be designed to support the load during the double connection process. It shall be adequately bolted or welded to both a supporting member and the first member before the nuts on the shared bolts are removed to make the double connection.

(d) *Column splices.* Each column splice shall be designed to resist a minimum eccentric gravity load of 300 pounds (136.2 kg) located 18 inches (.46 m) from the extreme outer face of the column in each direction at the top of the column shaft.

(e) *Perimeter columns.* Perimeter columns shall not be erected unless:

(1) The perimeter columns extend a minimum of 48 inches (1.2 m) above the finished floor to permit installation of perimeter safety cables prior to erection of the next tier, except where constructibility does not allow (see Appendix F to this subpart);

(2) The perimeter columns have holes or other devices in or attached to perimeter columns at 42–45 inches (107–114 cm) above the finished floor and the midpoint between the finished floor and the top cable to permit installation of perimeter safety cables required by § 1926.760(a)(2), except where constructibility does not allow. (See Appendix F to this subpart).

§ 1926.757 Open web steel joists.

(a) *General.* (1) Except as provided in paragraph (a)(2) of this section, where steel joists are used and columns are not framed in at least two directions with solid web structural steel members, a steel joist shall be field-bolted at the column to provide lateral stability to the column during erection. For the installation of this joist:

(i) A vertical stabilizer plate shall be provided on each column for steel joists. The plate shall be a minimum of 6 inch by 6 inch (152 mm by 152 mm) and shall extend at least 3 inches (76 mm) below the bottom chord of the joist with a 13/16 inch (21 mm) hole to provide an attachment point for guying or plumbing cables.

(ii) The bottom chords of steel joists at columns shall be stabilized to prevent rotation during erection.

(iii) Hoisting cables shall not be released until the seat at each end of the steel joist is field-bolted, and each end of the bottom chord is restrained by the column stabilizer plate.

(2) Where constructibility does not allow a steel joist to be installed at the column:

(i) an alternate means of stabilizing joists shall be installed on both sides near the column and shall:

(A) provide stability equivalent to paragraph (a)(1) of this section;

(B) be designed by a qualified person;

(C) be shop installed; and

(D) be included in the erection drawings.

(ii) hoisting cables shall not be released until the seat at each end of the steel joist is field-bolted and the joist is stabilized.

(3) Where steel joists at or near columns span 60 feet (18.3 m) or less, the joist shall be designed with sufficient strength to allow one employee to release the hoisting cable without the need for erection bridging.

(4) Where steel joists at or near columns span more than 60 feet (18.3 m), the joists shall be set in tandem with all bridging installed unless an alternative method of erection, which provides equivalent stability to the steel joist, is designed by a qualified person and is included in the site-specific erection plan.

(5) A steel joist or steel joist girder shall not be placed on any support structure unless such structure is stabilized.

(6) When steel joist(s) are landed on a structure, they shall be secured to prevent unintentional displacement prior to installation.

(7) No modification that affects the strength of a steel joist or steel joist girder shall be made without the approval of the project structural engineer of record.

(8) *Field-bolted joists.* (i) Except for steel joists that have been pre-assembled into panels, connections of individual steel joists to steel structures in bays of 40 feet (12.2 m) or more shall be fabricated to allow for field bolting during erection.

(ii) These connections shall be field-bolted unless constructibility does not allow.

(9) Steel joists and steel joist girders shall not be used as anchorage points for a fall arrest system unless written approval to do so is obtained from a qualified person.

(10) A bridging terminus point shall be established before bridging is installed. (See Appendix C to this subpart.)

(b) *Attachment of steel joists and steel joist girders.* (1) Each end of "K" series steel joists shall be attached to the support structure with a minimum of two 1/8-inch (3 mm) fillet welds 1 inch (25 mm) long or with two 1/2-inch (13 mm) bolts, or the equivalent.

(2) Each end of "LH" and "DLH" series steel joists and steel joist girders shall be attached to the support structure with a minimum of two 1/4-inch (6 mm) fillet welds 2 inches (51 mm) long, or with two 3/4-inch (19 mm) bolts, or the equivalent.

(3) Except as provided in paragraph (b)(4) of this section, each steel joist shall be attached to the support structure, at least at one end on both sides of the seat, immediately upon placement in the final erection position and before additional joists are placed.

(4) Panels that have been pre-assembled from steel joists with bridging shall be attached to the structure at each corner before the hoisting cables are released.

(c) *Erection of steel joists.* (1) Both sides of the seat of one end of each steel joist that requires bridging under Tables A and B shall be attached to the support structure before hoisting cables are released.

(2) For joists over 60 feet, both ends of the joist shall be attached as specified in paragraph (b) of this section and the provisions of paragraph (d) of this section met before the hoisting cables are released.

(3) On steel joists that do not require erection bridging under Tables A and B, only one employee shall be allowed on the joist until all bridging is installed and anchored.

TABLE A.—ERECTION BRIDGING FOR SHORT SPAN JOISTS

Joist	Span
8L1	NM
10K1	NM
12K1	23–0
12K3	NM
12K5	NM
14K1	27–0
14K3	NM
14K4	NM
14K6	NM
16K2	29–0
16K3	30–0
16K4	32–0
16K5	32–0
16K6	NM
16K7	NM
16K9	NM
18K3	31–0
18K4	32–0
18K5	33–0
18K6	35–0

TABLE A.—ERECTION BRIDGING FOR SHORT SPAN JOISTS—Continued

Joist	Span
18K7	NM
18K9	NM
18K10	NM
20K3	32–0
20K4	34–0
20K5	34–0
20K6	36–0
20K7	39–0
20K9	39–0
20K10	NM
22K4	34–0
22K5	35–0
22K6	36–0
22K7	40–0
22K9	40–0
22K10	40–0
22K11	40–0
24K4	36–0
24K5	38–0
24K6	39–0
24K7	43–0
24K8	43–0
24K9	44–0
24K10	NM
24K12	NM
26K5	38–0
26K6	39–0
26K7	43–0
26K8	44–0
26K9	45–0
26K10	49–0
26K12	NM
28K6	40–0
28K7	43–0
28K8	44–0
28K9	45–0
28K10	49–0
28K12	53–0
30K7	44–0
30K8	45–0
30K9	45–0
30K10	50–0
30K11	52–0
30K12	54–0
10KCS1	NM
10KCS2	NM
10KCS3	NM
12KCS1	NM
12KCS2	NM
12KCS3	NM
14KCS1	NM
14KCS2	NM
14KCS3	NM
16KCS2	NM
16KCS3	NM
16KCS4	NM
16KCS5	NM
18KCS2	35–0
18KCS3	NM
18KCS4	NM
18KCS5	NM
20KCS2	36–0
20KCS3	39–0
20KCS4	NM
20KCS5	NM
22KCS2	36–0
22KCS3	40–0
22KCS4	NM
22KCS5	NM
24KCS2	39–0
24KCS3	44–0

TABLE A.—ERECTION BRIDGING FOR SHORT SPAN JOISTS—Continued

Joist	Span
24KCS4	NM
24KCS5	NM
26KCS2	39–0
26KCS3	44–0
26KCS4	NM
26KCS5	NM
28KCS2	40–0
28KCS3	45–0
28KCS4	53–0
28KCS5	53–0
30KC53	45–0
30KCS4	54–0
30KCS5	54–0

NM=diagonal bolted bridging not mandatory for joists under 40 feet.

TABLE B.—ERECTION BRIDGING FOR LONG SPAN JOISTS

Joist	Span
18LH02	33–0.
18LH03	NM.
18LH04	NM.
18LH05	NM.
18LH06	NM.
18LH07	NM.
18LH08	NM.
18LH09	NM.
20LH02	33–0.
20LH03	38–0.
20LH04	NM.
20LH05	NM.
20LH06	NM.
20LH07	NM.
20LH08	NM.
20LH09	NM.
20LH10	NM.
24LH03	35–0.
24LH04	39–0.
24LH05	40–0.
24LH06	45–0.
24LH07	NM.
24LH08	NM.
24LH09	NM.
24LH10	NM.
24LH11	NM.
28LH05	42–0.
28LH06	42–0.
28LH07	NM.
28LH08	NM.
28LH09	NM.
28LH10	NM.
28LH11	NM.
28LH12	NM.
28LH13	NM.
32LH06	47–0 through 60–0.
32LH07	47–0 through 60–0.
32LH08	55–0 through 60–0.
32LH09	NM through 60–0.
32LH10	NM through 60–0.
32LH11	NM through 60–0.
32LH12	NM through 60–0.
32LH13	NM through 60–0.
32LH14	NM through 60–0.
32LH15	NM through 60–0.
36LH07	47–0 through 60–0.
36LH08	47–0 through 60–0.
36LH09	57–0 through 60–0.
36LH10	NM through 60–0.

TABLE B.—ERECTION BRIDGING FOR LONG SPAN JOISTS—Continued

Joist	Span
36LH11	NM through 60–0.
36LH12	NM through 60–0.
36LH13	NM through 60–0.
36LH14	NM through 60–0.
36LH15	NM through 60–0.

NM = diagonal bolted bridging not mandatory for joists under 40 feet.

(4) Employees shall not be allowed on steel joists where the span of the steel joist is equal to or greater than the span shown in Tables A and B except in accordance with § 1926.757(d).

(5) When permanent bridging terminus points cannot be used during erection, additional temporary bridging terminus points are required to provide stability. (See appendix C of this subpart.)

(d) *Erection bridging.* (1) Where the span of the steel joist is equal to or greater than the span shown in Tables A and B, the following shall apply:

(i) A row of bolted diagonal erection bridging shall be installed near the midspan of the steel joist;

(ii) Hoisting cables shall not be released until this bolted diagonal erection bridging is installed and anchored; and

(iii) No more than one employee shall be allowed on these spans until all other bridging is installed and anchored.

(2) Where the span of the steel joist is over 60 feet (18.3 m) through 100 feet (30.5 m), the following shall apply:

(i) All rows of bridging shall be bolted diagonal bridging;

(ii) Two rows of bolted diagonal erection bridging shall be installed near the third points of the steel joist;

(iii) Hoisting cables shall not be released until this bolted diagonal erection bridging is installed and anchored; and

(iv) No more than two employees shall be allowed on these spans until all other bridging is installed and anchored.

(3) Where the span of the steel joist is over 100 feet (30.5 m) through 144 feet (43.9 m), the following shall apply:

(i) All rows of bridging shall be bolted diagonal bridging;

(ii) Hoisting cables shall not be released until all bridging is installed and anchored; and

(iii) No more than two employees shall be allowed on these spans until all bridging is installed and anchored.

(4) For steel members spanning over 144 feet (43.9 m), the erection methods used shall be in accordance with § 1926.756.

(5) Where any steel joist specified in paragraphs (c)(2) and (d)(1), (d)(2), and

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(d)(3) of this section is a bottom chord bearing joist, a row of bolted diagonal bridging shall be provided near the support(s). This bridging shall be installed and anchored before the hoisting cable(s) is released.

(6) When bolted diagonal erection bridging is required by this section, the following shall apply:

(i) The bridging shall be indicated on the erection drawing;

(ii) The erection drawing shall be the exclusive indicator of the proper placement of this bridging;

(iii) Shop-installed bridging clips, or functional equivalents, shall be used where the bridging bolts to the steel joists;

(iv) When two pieces of bridging are attached to the steel joist by a common bolt, the nut that secures the first piece of bridging shall not be removed from the bolt for the attachment of the second; and

(v) Bridging attachments shall not protrude above the top chord of the steel joist.

(e) *Landing and placing loads.* (1) During the construction period, the employer placing a load on steel joists shall ensure that the load is distributed so as not to exceed the carrying capacity of any steel joist.

(2) Except for paragraph (e)(4) of this section, no construction loads are allowed on the steel joists until all bridging is installed and anchored and all joist-bearing ends are attached.

(3) The weight of a bundle of joist bridging shall not exceed a total of 1,000 pounds (454 kg). A bundle of joist bridging shall be placed on a minimum of three steel joists that are secured at one end. The edge of the bridging bundle shall be positioned within 1 foot (.30 m) of the secured end.

(4) No bundle of decking may be placed on steel joists until all bridging has been installed and anchored and all joist bearing ends attached, unless all of the following conditions are met:

(i) The employer has first determined from a qualified person and documented in a site-specific erection plan that the structure or portion of the structure is capable of supporting the load;

(ii) The bundle of decking is placed on a minimum of three steel joists;

(iii) The joists supporting the bundle of decking are attached at both ends;

(iv) At least one row of bridging is installed and anchored;

(v) The total weight of the bundle of decking does not exceed 4,000 pounds (1816 kg); and

(vi) Placement of the bundle of decking shall be in accordance with paragraph (e)(5) of this section.

(5) The edge of the construction load shall be placed within 1 foot (.30 m) of the bearing surface of the joist end.

§ 1926.758 Systems-engineered metal buildings.

(a) All of the requirements of this subpart apply to the erection of systems-engineered metal buildings except §§ 1926.755 (column anchorage) and 1926.757 (open web steel joists).

(b) Each structural column shall be anchored by a minimum of four anchor rods (anchor bolts).

(c) Rigid frames shall have 50 percent of their bolts or the number of bolts specified by the manufacturer (whichever is greater) installed and tightened on both sides of the web adjacent to each flange before the hoisting equipment is released.

(d) Construction loads shall not be placed on any structural steel framework unless such framework is safely bolted, welded or otherwise adequately secured.

(e) In girt and eave strut-to-frame connections, when girts or eave struts share common connection holes, at least one bolt with its wrench-tight nut shall remain connected to the first member unless a manufacturer-supplied, field-attached seat or similar connection device is present to secure the first member so that the girt or eave strut is always secured against displacement.

(f) Both ends of all steel joists or cold-formed joists shall be fully bolted and/or welded to the support structure before:

(1) Releasing the hoisting cables;

(2) Allowing an employee on the joists; or

(3) Allowing any construction loads on the joists.

(g) Purlins and girts shall not be used as an anchorage point for a fall arrest system unless written approval is obtained from a qualified person.

(h) Purlins may only be used as a walking/working surface when installing safety systems, after all permanent bridging has been installed and fall protection is provided.

(i) Construction loads may be placed only within a zone that is within 8 feet (2.5 m) of the center-line of the primary support member.

§ 1926.759 Falling object protection.

(a) *Securing loose items aloft.* All materials, equipment, and tools, which are not in use while aloft, shall be secured against accidental displacement.

(b) *Protection from falling objects other than materials being hoisted.* The controlling contractor shall bar other construction processes below steel erection unless overhead protection for the employees below is provided.

§ 1926.760 Fall protection.

(a) *General requirements.* (1) Except as provided by paragraph (a)(3) of this section, each employee engaged in a steel erection activity who is on a walking/working surface with an unprotected side or edge more than 15 feet (4.6 m) above a lower level shall be protected from fall hazards by guardrail systems, safety net systems, personal fall arrest systems, positioning device systems or fall restraint systems.

(2) *Perimeter safety cables.* On multi-story structures, perimeter safety cables shall be installed at the final interior and exterior perimeters of the floors as soon as the metal decking has been installed.

(3) Connectors and employees working in controlled decking zones shall be protected from fall hazards as provided in paragraphs (b) and (c) of this section, respectively.

(b) *Connectors.* Each connector shall:

(1) Be protected in accordance with paragraph (a)(1) of this section from fall hazards of more than two stories or 30 feet (9.1 m) above a lower level, whichever is less;

(2) Have completed connector training in accordance with § 1926.761; and

(3) Be provided, at heights over 15 and up to 30 feet above a lower level, with a personal fall arrest system, positioning device system or fall restraint system and wear the equipment necessary to be able to be tied off; or be provided with other means of protection from fall hazards in accordance with paragraph (a)(1) of this section.

(c) *Controlled Decking Zone (CDZ).* A controlled decking zone may be established in that area of the structure over 15 and up to 30 feet above a lower level where metal decking is initially being installed and forms the leading edge of a work area. In each CDZ, the following shall apply:

(1) Each employee working at the leading edge in a CDZ shall be protected from fall hazards of more than two stories or 30 feet (9.1 m), whichever is less.

(2) Access to a CDZ shall be limited to only those employees engaged in leading edge work.

(3) The boundaries of a CDZ shall be designated and clearly marked. The CDZ shall not be more than 90 feet (27.4 m) wide and 90 (27.4 m) feet deep from any leading edge. The CDZ shall be marked by the use of control lines or the equivalent. Examples of acceptable procedures for demarcating CDZ's can be found in Appendix D to this subpart.

(4) Each employee working in a CDZ shall have completed CDZ training in accordance with § 1926.761.

(5) Unsecured decking in a CDZ shall not exceed 3,000 square feet (914.4 m^2).

(6) Safety deck attachments shall be performed in the CDZ from the leading edge back to the control line and shall have at least two attachments for each metal decking panel.

(7) Final deck attachments and installation of shear connectors shall not be performed in the CDZ.

(d) *Criteria for fall protection equipment.* (1) Guardrail systems, safety net systems, personal fall arrest systems, positioning device systems and their components shall conform to the criteria in § 1926.502 (see Appendix G to this subpart).

(2) Fall arrest system components shall be used in fall restraint systems and shall conform to the criteria in § 1926.502 (see Appendix G). Either body belts or body harnesses shall be used in fall restraint systems.

(3) Perimeter safety cables shall meet the criteria for guardrail systems in § 1926.502 (see Appendix G).

(e) *Custody of fall protection.* Fall protection provided by the steel erector shall remain in the area where steel erection activity has been completed, to be used by other trades, only if the controlling contractor or its authorized representative:

(1) Has directed the steel erector to leave the fall protection in place; and

(2) Has inspected and accepted control and responsibility of the fall protection prior to authorizing persons other than steel erectors to work in the area.

§ 1926.761 Training.

The following provisions supplement the requirements of § 1926.21 regarding the hazards addressed in this subpart.

(a) *Training personnel.* Training required by this section shall be provided by a qualified person(s).

(b) *Fall hazard training.* The employer shall provide a training program for all employees exposed to fall hazards. The program shall include training and instruction in the following areas:

(1) The recognition and identification of fall hazards in the work area;

(2) The use and operation of guardrail systems (including perimeter safety cable systems), personal fall arrest systems, positioning device systems, fall restraint systems, safety net systems, and other protection to be used;

(3) The correct procedures for erecting, maintaining, disassembling, and inspecting the fall protection systems to be used;

(4) The procedures to be followed to prevent falls to lower levels and through or into holes and openings in walking/working surfaces and walls; and

(5) The fall protection requirements of this subpart.

(c) *Special training programs.* In addition to the training required in paragraphs (a) and (b) of this section, the employer shall provide special training to employees engaged in the following activities.

(1) *Multiple lift rigging procedure.* The employer shall ensure that each employee who performs multiple lift rigging has been provided training in the following areas:

(i) The nature of the hazards associated with multiple lifts; and

(ii) The proper procedures and equipment to perform multiple lifts required by § 1926.753(e).

(2) *Connector procedures.* The employer shall ensure that each connector has been provided training in the following areas:

(i) The nature of the hazards associated with connecting; and

(ii) The establishment, access, proper connecting techniques and work practices required by § 1926.756(c) and § 1926.760(b).

(3) *Controlled Decking Zone Procedures.* Where CDZs are being used, the employer shall assure that each employee has been provided training in the following areas:

(i) The nature of the hazards associated with work within a controlled decking zone; and

(ii) The establishment, access, proper installation techniques and work practices required by § 1926.760(c) and § 1926.754(e).

Appendix A to Subpart R—Guidelines for Establishing the Components of a Site-specific Erection Plan: Non-mandatory Guidelines for Complying with § 1926.752(e).

(a) *General.* This appendix serves as a guideline to assist employers who elect to develop a site-specific erection plan in accordance with § 1926.752(e) with alternate means and methods to provide employee protection in accordance with § 1926.752(e), § 1926.753(c)(5), § 1926.757(a)(4) and § 1926.757(e)(4).

(b) *Development of a site-specific erection plan.* Pre-construction conference(s) and site inspection(s) are held between the erector and the controlling contractor, and others such as the project engineer and fabricator before the start of steel erection. The purpose of such conference(s) is to develop and review the site-specific erection plan that will meet the requirements of this section.

(c) *Components of a site-specific erection plan.* In developing a site-specific erection plan, a steel erector considers the following elements:

(1) The sequence of erection activity, developed in coordination with the controlling contractor, that includes the following:

(i) Material deliveries;

(ii) Material staging and storage; and

(iii) Coordination with other trades and construction activities.

(2) A description of the crane and derrick selection and placement procedures, including the following:

(i) Site preparation;

(ii) Path for overhead loads; and

(iii) Critical lifts, including rigging supplies and equipment.

(3) A description of steel erection activities and procedures, including the following:

(i) Stability considerations requiring temporary bracing and guying;

(ii) Erection bridging terminus point;

(iii) Anchor rod (anchor bolt) notifications regarding repair, replacement and modifications;

(iv) Columns and beams (including joists and purlins);

(v) Connections;

(vi) Decking; and

(vii) Ornamental and miscellaneous iron.

(4) A description of the fall protection procedures that will be used to comply with § 1926.760.

(5) A description of the procedures that will be used to comply with § 1926.759.

(6) A description of the special procedures required for hazardous non-routine tasks.

(7) A certification for each employee who has received training for performing steel erection operations as required by § 1926.761.

(8) A list of the qualified and competent persons.

(9) A description of the procedures that will be utilized in the event of rescue or emergency response.

(d) *Other plan information.* The plan:

(1) Includes the identification of the site and project; and

(2) Is signed and dated by the qualified person(s) responsible for its preparation and modification.

Appendix B to Subpart R—Acceptable Test Methods for Testing Slip-Resistance of Walking/Working Surfaces (§ 1926.754(c)(3)). Non-Mandatory Guidelines for Complying With § 1926.754(c)(3).

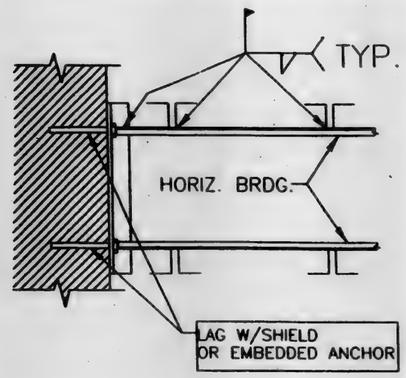
The following references provide acceptable test methods for complying with the requirements of § 1926.754(c)(3).

- Standard Test Method for Using a Portable Inclineable Articulated Strut Slip Tester (PIAST)(ASTM F1677–96)
- Standard Test Method for Using a Variable Incidence Tribometer (VIT)(ASTM F1679–96)

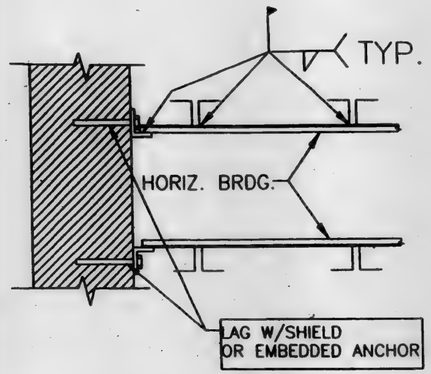
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Appendix C to Subpart R – Illustrations of Bridging Terminus Points: Non-mandatory

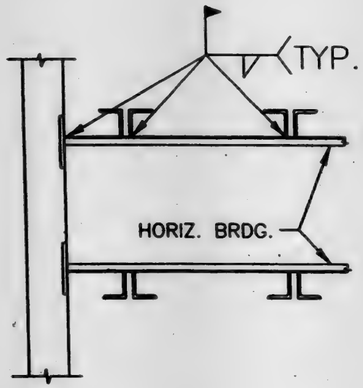
Guidelines for Complying with §§1926.757(a)(10) and 1926.757(c)(5).



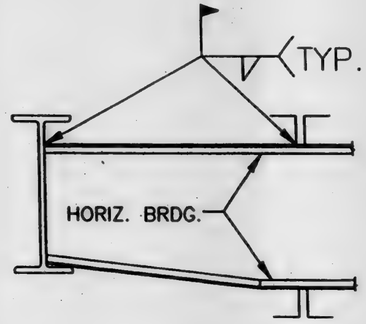
HORIZONTAL BRIDGING TERMINUS AT WALL



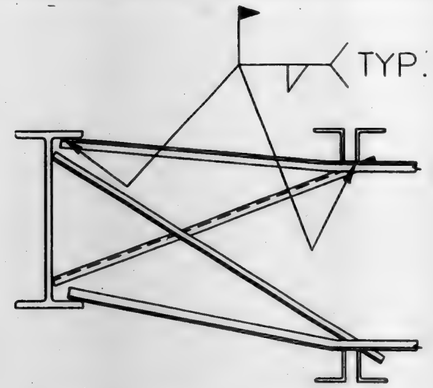
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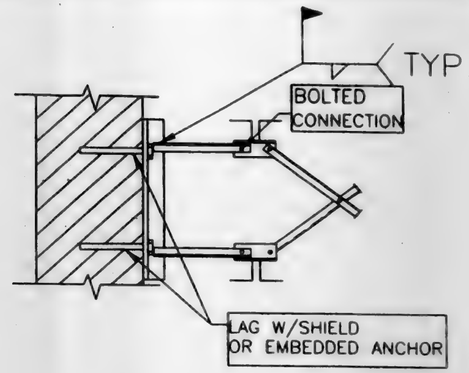
HORIZONTAL BRIDGING TERMINUS AT PANEL WALL



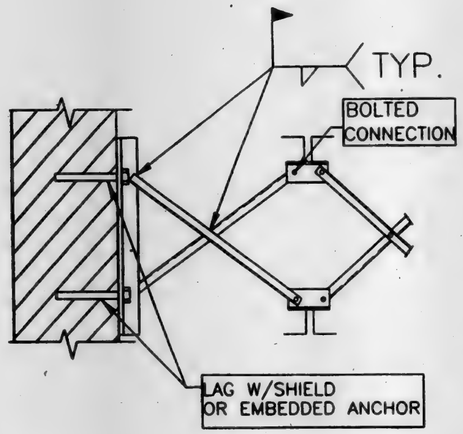
HORIZONTAL BRIDGING TERMINUS AT STRUCTURAL SHAPE



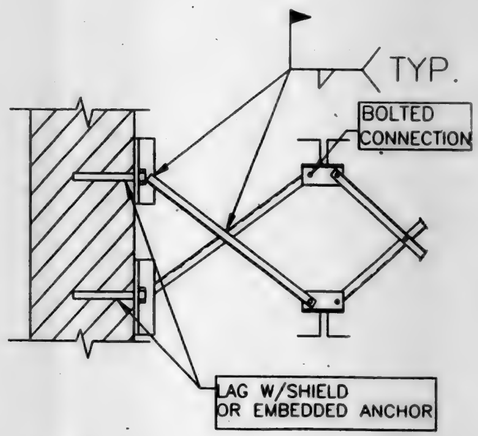
HORIZONTAL BRIDGING TERMINUS AT STRUCTURAL SHAPE WITH OPTIONAL "X-BRIDGING"



BOLTED DIAGONAL BRIDGING TERMINUS AT WALL



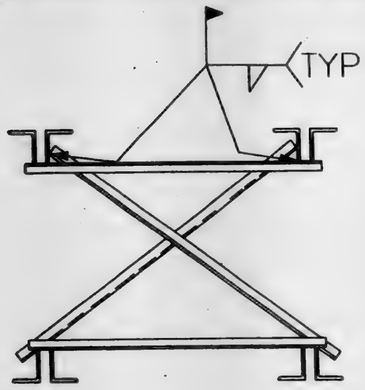
BOLTED DIAGONAL BRIDGING TERMINUS AT WALL



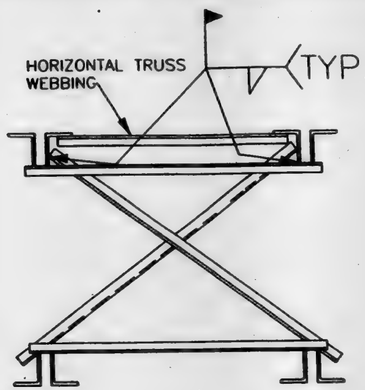
BOLTED DIAGONAL BRIDGING TERMINUS AT WALL

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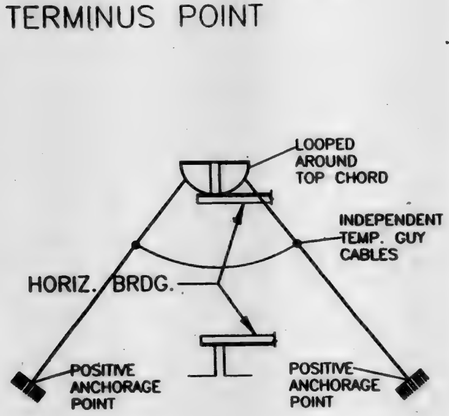
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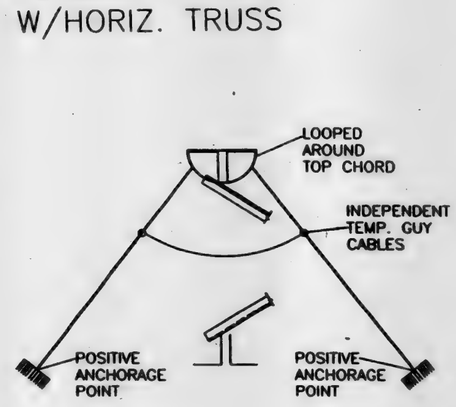
JOISTS PAIR BRIDGING TERMINUS POINT



JOISTS PAIR BRIDGING TERMINUS POINT W/HORIZ. TRUSS



HORIZONTAL BRIDGING TERMINUS POINT SECURED BY TEMP. GUY CABLES



DIAGONAL BRIDGING TERMINUS POINT SECURED BY TEMP. GUY CABLES

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Appendix D to Subpart R—Illustration of the Use of Control Lines to Demarcate Controlled Decking Zones (CDZs): Non-mandatory Guidelines for Complying with § 1926.760(c)(3)

(1) When used to control access to areas where leading edge and initial securement of metal deck and other operations connected with leading edge work are taking place, the controlled decking zone (CDZ) is defined by a control line or by any other means that restricts access.

(i) A control line for a CDZ is erected not less than 6 feet (1.8 m) nor more than 90 feet (27.4 m) from the leading edge.

(ii) Control lines extend along the entire length of the unprotected or leading edge and are approximately parallel to the unprotected or leading edge.

(iii) Control lines are connected on each side to a guardrail system, wall, stanchion or other suitable anchorage.

(2) Control lines consist of ropes, wires, tapes, or equivalent materials, and supporting stanchions as follows:

(i) Each line is rigged and supported in such a way that its lowest point (including sag) is not less than 39 inches (1.0 m) from the walking/working surface and its highest point is not more than 45 inches (1.3 m) from the walking/working surface.

(ii) Each line has a minimum breaking strength of 200 pounds (90.8 kg).

Appendix E to Subpart R—Training: Non-mandatory Guidelines for Complying with § 1926.761

The training requirements of § 1926.761 will be deemed to have been met if employees have completed a training course on steel erection, including instruction in the provisions of this standard, that has been approved by the U.S. Department of Labor Bureau of Apprenticeship.

Appendix F to Subpart R—Perimeter Columns: Non-Mandatory Guidelines for Complying with § 1926.756(e) To Protect the Unprotected Side or Edge of a Walking/Working Surface

In multi-story structures, when holes in the column web are used for perimeter safety cables, the column splice must be placed sufficiently high so as not to interfere with any attachments to the column necessary for the column splice. Column splices are recommended to be placed at every other or fourth levels as design allows. Column splices at third levels are detrimental to the erection process and should be avoided if possible.

Appendix G to Subpart R—§ 1926.502 (b)–(e) Fall Protection Systems Criteria and Practices

(b) "Guardrail systems." Guardrail systems and their use shall comply with the following provisions:

(1) Top edge height of top rails, or equivalent guardrail system members, shall be 42 inches (1.1 m) plus or minus 3 inches (8 cm) above the walking/working level. When conditions warrant, the height of the top edge may exceed the 45-inch height, provided the guardrail system meets all other criteria of this paragraph (§ 1926.502(b)).

Note: When employees are using stilts, the top edge height of the top rail, or equivalent member, shall be increased an amount equal to the height of the stilts.

(2) Midrails, screens, mesh, intermediate vertical members, or equivalent intermediate structural members shall be installed between the top edge of the guardrail system and the walking/working surface when there is no wall or parapet wall at least 21 inches (53 cm) high.

(i) Midrails, when used, shall be installed at a height midway between the top edge of the guardrail system and the walking/working level.

(ii) Screens and mesh, when used, shall extend from the top rail to the walking/working level and along the entire opening between top rail supports.

(iii) Intermediate members (such as balusters), when used between posts, shall be not more than 19 inches (48 cm) apart.

(iv) Other structural members (such as additional midrails and architectural panels) shall be installed such that there are no openings in the guardrail system that are more than 19 inches (.5 m) wide.

(3) Guardrail systems shall be capable of withstanding, without failure, a force of at least 200 pounds (890 N) applied within 2 inches (5.1 cm) of the top edge, in any outward or downward direction, at any point along the top edge.

(4) When the 200 pound (890 N) test load specified in paragraph (b)(3) of this section (§ 1926.502) is applied in a downward direction, the top edge of the guardrail shall not deflect to a height less than 39 inches (1.0 m) above the walking/working level. Guardrail system components selected and constructed in accordance with the appendix B to subpart M of this part will be deemed to meet this requirement.

(5) Midrails, screens, mesh, intermediate vertical members, solid panels, and equivalent structural members shall be capable of withstanding, without failure, a force of at least 150 pounds (666 N) applied in any downward or outward direction at any point along the midrail or other member.

(6) Guardrail systems shall be so surfaced as to prevent injury to an employee from punctures or lacerations, and to prevent snagging of clothing.

(7) The ends of all top rails and midrails shall not overhang the terminal posts, except where such overhang does not constitute a projection hazard.

(8) Steel banding and plastic banding shall not be used as top rails or midrails.

(9) Top rails and midrails shall be at least one-quarter inch (0.6 cm) nominal diameter or thickness to prevent cuts and lacerations. If wire rope is used for top rails, it shall be flagged at not more than 6-foot intervals with high-visibility material.

(10) When guardrail systems are used at hoisting areas, a chain, gate or removable guardrail section shall be placed across the access opening between guardrail sections when hoisting operations are not taking place.

(11) When guardrail systems are used at holes, they shall be erected on all unprotected sides or edges of the hole.

(12) When guardrail systems are used around holes used for the passage of materials, the hole shall have not more than two sides provided with removable guardrail sections to allow the passage of materials. When the hole is not in use, it shall be closed over with a cover, or a guardrail system shall be provided along all unprotected sides or edges.

(13) When guardrail systems are used around holes which are used as points of access (such as ladderways), they shall be provided with a gate, or be so offset that a person cannot walk directly into the hole.

(14) Guardrail systems used on ramps and runways shall be erected along each unprotected side or edge.

(15) Manila, plastic or synthetic rope being used for top rails or midrails shall be inspected as frequently as necessary to ensure that it continues to meet the strength requirements of paragraph (b)(3) of this section (§ 1926.502).

(c) *Safety net systems.* Safety net systems and their use shall comply with the following provisions:

(1) Safety nets shall be installed as close as practicable under the walking/working surface on which employees are working, but in no case more than 30 feet (9.1 m) below such level. When nets are used on bridges, the potential fall area from the walking/working surface to the net shall be unobstructed.

(2) Safety nets shall extend outward from the outermost projection of the work surface as follows:

Vertical distance from working level to horizontal plane of net	Minimum required horizontal distance of outer edge of net from the edge of the working surface
Up to 5 feet	8 feet
More than 5 feet up to 10 feet	10 feet
More than 10 feet	13 feet

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(3) Safety nets shall be installed with sufficient clearance under them to prevent contact with the surface or structures below when subjected to an impact force equal to the drop test specified in paragraph (4) of this section [§ 1926.502].

(4) Safety nets and their installations shall be capable of absorbing an impact force equal to that produced by the drop test specified in paragraph (c)(4)(i) of this section [§ 1926.502].

(i) Except as provided in paragraph (c)(4)(ii) of this section (§ 1926.502), safety nets and safety net installations shall be drop-tested at the jobsite after initial installation and before being used as a fall protection system, whenever relocated, after major repair, and at 6-month intervals if left in one place. The drop-test shall consist of a 400 pound (180 kg) bag of sand 30+ or −2 inches (76+ or −5 cm) in diameter dropped into the net from the highest walking/working surface at which employees are exposed to fall hazards, but not from less than 42 inches (1.1 m) above that level.

(ii) When the employer can demonstrate that it is unreasonable to perform the drop-test required by paragraph (c)(4)(i) of this section (§ 1926.502), the employer (or a designated competent person) shall certify that the net and net installation is in compliance with the provisions of paragraphs (c)(3) and (c)(4)(i) of this section (§ 1926.502) by preparing a certification record prior to the net being used as a fall protection system. The certification record must include an identification of the net and net installation for which the certification record is being prepared; the date that it was determined that the identified net and net installation were in compliance with paragraph (c)(3) of this section (§ 1926.502) and the signature of the person making the determination and certification. The most recent certification record for each net and net installation shall be available at the jobsite for inspection.

(5) Defective nets shall not be used. Safety nets shall be inspected at least once a week for wear, damage, and other deterioration. Defective components shall be removed from service. Safety nets shall also be inspected after any occurrence which could affect the integrity of the safety net system.

(6) Materials, scrap pieces, equipment, and tools which have fallen into the safety net shall be removed as soon as possible from the net and at least before the next work shift.

(7) The maximum size of each safety net mesh opening shall not exceed 36 square inches (230 cm) nor be longer than 6 inches (15 cm) on any side, and the opening, measured center-to-center of mesh ropes or webbing, shall not be longer than 6 inches (15 cm). All mesh crossings shall be secured to prevent enlargement of the mesh opening.

(8) Each safety net (or section of it) shall have a border rope for webbing with a minimum breaking strength of 5,000 pounds (22.2 kN).

(9) Connections between safety net panels shall be as strong as integral net components and shall be spaced not more than 6 inches (15 cm) apart.

(d) "Personal fall arrest systems." Personal fall arrest systems and their use shall comply with the provisions set forth below. Effective January 1, 1998, body belts are not acceptable as part of a personal fall arrest system.

Note: The use of a body belt in a positioning device system is acceptable and is regulated under paragraph (e) of this section (§ 1926.502).

(1) Connectors shall be drop forged, pressed or formed steel, or made of equivalent materials.

(2) Connectors shall have a corrosion-resistant finish, and all surfaces and edges shall be smooth to prevent damage to interfacing parts of the system.

(3) Dee-rings and snaphooks shall have a minimum tensile strength of 5,000 pounds (22.2 kN).

(4) Dee-rings and snaphooks shall be proof-tested to a minimum tensile load of 3,600 pounds (16 kN) without cracking, breaking, or taking permanent deformation.

(5) Snaphooks shall be sized to be compatible with the member to which they are connected to prevent unintentional disengagement of the snaphook by depression of the snaphook keeper by the connected member, or shall be a locking type snaphook designed and used to prevent disengagement of the snaphook by the contact of the snaphook keeper by the connected member. Effective January 1, 1998, only locking type snaphooks shall be used.

(6) Unless the snaphook is a locking type and designed for the following connections, snaphooks shall not be engaged:

(i) directly to webbing, rope or wire rope;

(ii) to each other;

(iii) to a dee-ring to which another snaphook or other connector is attached;

(iv) to a horizontal lifeline; or

(v) to any object which is incompatibly shaped or dimensioned in relation to the snaphook such that unintentional disengagement could occur by the connected object being able to depress the snaphook keeper and release itself.

(7) On suspended scaffolds or similar work platforms with horizontal lifelines which may become vertical lifelines, the devices used to connect to a horizontal lifeline shall be capable of locking in both directions on the lifeline.

(8) Horizontal lifelines shall be designed, installed, and used, under the supervision of a qualified person, as part of a complete personal fall arrest system, which maintains a safety factor of at least two.

(9) Lanyards and vertical lifelines shall have a minimum breaking strength of 5,000 pounds (22.2 kN).

(10)(i) Except as provided in paragraph (d)(10)(ii) of this section [§ 1926.502], when vertical lifelines are used, each employee shall be attached to a separate lifeline.

(ii) During the construction of elevator shafts, two employees may be attached to the same lifeline in the hoistway, provided both employees are working atop a false car that is equipped with guardrails; the strength of the lifeline is 10,000 pounds [5,000 pounds per employee attached] (44.4 kN); and all other criteria specified in this paragraph for lifelines have been met.

(11) Lifelines shall be protected against being cut or abraded.

(12) Self-retracting lifelines and lanyards which automatically limit free fall distance to 2 feet (0.61 m) or less shall be capable of sustaining a minimum tensile load of 3,000 pounds (13.3 kN) applied to the device with the lifeline or lanyard in the fully extended position.

(13) Self-retracting lifelines and lanyards which do not limit free fall distance to 2 feet (0.61 m) or less, ripstitch lanyards, and tearing and deforming lanyards shall be capable of sustaining a minimum tensile load of 5,000 pounds (22.2 kN) applied to the device with the lifeline or lanyard in the fully extended position.

(14) Ropes and straps (webbing) used in lanyards, lifelines, and strength components of body belts and body harnesses shall be made from synthetic fibers.

(15) Anchorages used for attachment of personal fall arrest equipment shall be independent of any anchorage being used to support or suspend platforms and capable of supporting at least 5,000 pounds (22.2 kN) per employee attached, or shall be designed, installed, and used as follows:

(i) as part of a complete personal fall arrest system which maintains a safety factor of at least two; and

(ii) under the supervision of a qualified person.

(16) Personal fall arrest systems, when stopping a fall, shall:

(i) limit maximum arresting force on an employee to 900 pounds (4 kN) when used with a body belt;

(ii) limit maximum arresting force on an employee to 1,800 pounds (8 kN) when used with a body harness;

(iii) be rigged such that an employee can neither free fall more than 6 feet (1.8 m), nor contact any lower level;

(iv) bring an employee to a complete stop and limit maximum deceleration distance an employee travels to 3.5 feet (1.07 m); and,

(v) have sufficient strength to withstand twice the potential impact energy of an employee free falling a distance of 6 feet (1.8 m), or the free fall distance permitted by the system, whichever is less.

Note: If the personal fall arrest system meets the criteria and protocols contained in Appendix C to subpart M, and if the system is being used by an employee having a combined person and tool weight of less than 310 pounds (140 kg), the system will be considered to be in compliance with the provisions of paragraph (d)(16) of this section [§ 1926.502]. If the system is used by an employee having a combined tool and body weight of 310 pounds (140 kg) or more, then the employer must appropriately modify the criteria and protocols of the Appendix to provide proper protection for such heavier weights, or the system will not be deemed to be in compliance with the requirements of paragraph (d)(16) of this section (§ 1926.502).

(17) The attachment point of the body belt shall be located in the center of the wearer's back. The attachment point of the body harness shall be located in the center of the wearer's back near shoulder level, or above the wearer's head.

(18) Body belts, harnesses, and components shall be used only for employee protection (as part of a personal fall arrest system or positioning device system) and not to hoist materials.

(19) Personal fall arrest systems and components subjected to impact loading shall be immediately removed from service and shall not be used again for employee protection until inspected and determined by a competent person to be undamaged and suitable for reuse.

(20) The employer shall provide for prompt rescue of employees in the event of a fall or shall assure that employees are able to rescue themselves.

(21) Personal fall arrest systems shall be inspected prior to each use for wear, damage and other deterioration, and defective components shall be removed from service.

(22) Body belts shall be at least one and five-eighths (1⅝) inches (4.1 cm) wide.

(23) Personal fall arrest systems shall not be attached to guardrail systems, nor shall they be attached to hoists except as specified in other subparts of this Part.

(24) When a personal fall arrest system is used at hoist areas, it shall be rigged to allow the movement of the employee only as far as the edge of the walking/working surface.

(e) *Positioning device systems.* Positioning device systems and their use shall conform to the following provisions:

(1) Positioning devices shall be rigged such that an employee cannot free fall more than 2 feet (.9 m).

(2) Positioning devices shall be secured to an anchorage capable of supporting at least twice the potential impact load of an employee's fall or 3,000 pounds (13.3 kN), whichever is greater.

(3) Connectors shall be drop forged, pressed or formed steel, or made of equivalent materials.

(4) Connectors shall have a corrosion-resistant finish, and all surfaces and edges shall be smooth to prevent damage to interfacing parts of this system.

(5) Connecting assemblies shall have a minimum tensile strength of 5,000 pounds (22.2 kN)

(6) Dee-rings and snaphooks shall be proof-tested to a minimum tensile load of 3,600 pounds (16 kN) without cracking, breaking, or taking permanent deformation.

(7) Snaphooks shall be sized to be compatible with the member to which they are connected to prevent unintentional disengagement of the snaphook by depression of the snaphook keeper by the connected member, or shall be a locking type snaphook designed and used to prevent disengagement of the snaphook by the contact of the snaphook keeper by the connected member. As of January 1, 1998, only locking type snaphooks shall be used.

(8) Unless the snaphook is a locking type and designed for the following connections, snaphooks shall not be engaged:

(i) directly to webbing, rope or wire rope;

(ii) to each other;

(iii) to a dee-ring to which another snaphook or other connector is attached;

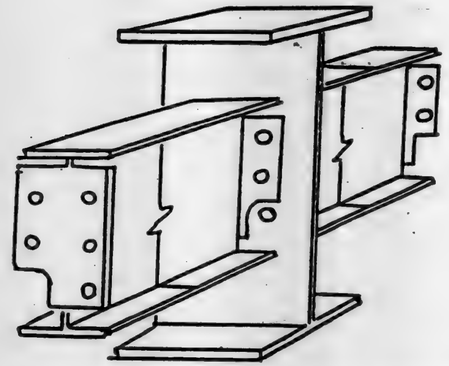
(iv) to a horizontal lifeline; or to depress the snaphook keeper and release itself.

(v) to any object which is incompatibly shaped or dimensioned in relation to the snaphook such that unintentional disengagement could occur by the connected object being able to depress the snaphook keeper and release itself.

(9) Positioning device systems shall be inspected prior to each use for wear, damage, and other deterioration, and defective components shall be removed from service.

(10) Body belts, harnesses, and components shall be used only for employee protection (as part of a personal fall arrest system or positioning device system) and not to hoist materials.

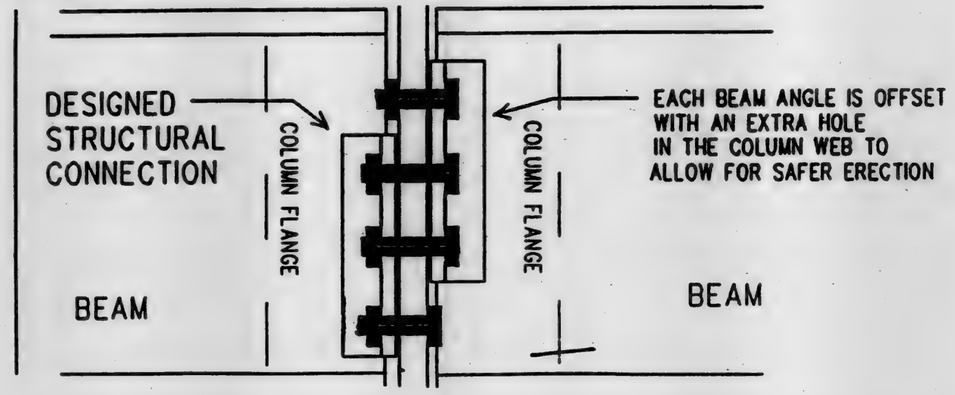
Appendix H to Subpart R— Double Connections: Illustration of a Clipped End Connection and a Staggered Connection: Non-Mandatory Guidelines for Complying with §1926.756(c)(1).



Clipped end connections are connection material on the end of a structural member which has a notch at the bottom and/or top to allow the bolt(s) of the first member placed on the opposite side of the central member to remain in place. The notch(es)

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fits around the nut or bolt head of the opposing member to allow the second member to be bolted up without removing the bolt(s) holding the first member.



Staggered connections are connection material on a structural member in which all of the bolt holes in the common member web are not shared by the two incoming members in the final connection. The extra hole in the column web allows the erector to maintain at least a one bolt connection at all times while making the double connection.

[FR Doc. 01–979 Filed 1–17–01; 8:45 am]
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Federal Register

Thursday,
January 18, 2001

Part VII

Department of the Interior

Fish and Wildlife Service

50 CFR Part 86

Boating Infrastructure Grant Program; Final Rule

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 86

RIN 1018–AF38

Boating Infrastructure Grant Program

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: This regulation provides for the uniform administration of the national Boating Infrastructure Grant Program and survey authorized by Section 7404 of the Sportfishing and Boating Safety Act of 1998. Through this program, the U.S. Fish and Wildlife Service will provide funds to States to install or upgrade tie-up facilities for transient recreational boats 26 feet or more in length.

DATES: This rule is effective on February 20, 2001.

ADDRESSES: The administrative record for this rule, including copies of comments received, is available for viewing Monday through Friday, 8 am to 4 pm, in the Division of Federal Aid, 4401 North Fairfax Drive, Room 140, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Steve Farrell, Project Officer, U.S. Fish and Wildlife Service, Division of Federal Aid, 4401 North Fairfax Drive, Suite 140, Arlington, Virginia 22203; telephone (703) 358–2156; fax (703) 358–1705; email <steve_farrell@fws.gov>.

SUPPLEMENTARY INFORMATION:

Background

Economic Status of Boating in the United States

Historically, coastal and inland waterways were the first highways along our shores and into the interior of the continent. Americans used boats almost exclusively for transportation of people and goods. Today we use more than 12 million recreational boats to cruise and fish. Recreational boating is now a significant economic activity in many areas of the country and in many respects exceeds that of waterborne commerce. Given the present demographic forces, we expect this rule to have a positive economic impact by adding facilities to accommodate larger cruising boats.

Purpose of the Boating Infrastructure Grant Program

Recreational boats 26 feet or more in length, called "nontrailerable" boats, represent about 4 percent, or more than 600,000, of the recreational boats in the United States. Although we have approximately 12,000 marinas in the United States, Congress recognized that insufficient tie-up facilities exist for transient, nontrailerable boats for reasonable and convenient access from our navigable waters. These boaters are unable to enjoy many recreational, cultural, historic, scenic, and natural resources of the United States. We also have an insufficient quantity of marinas or commercial tie-up facilities along extended stretches of our coastlines and rivers that benefit transient, nontrailerable boats. In many parts of the country, the number of places to tie-up, moor, or anchor a cruising boat, especially during a storm, is limited. Basic features, such as tie-ups, fuel, utilities, and restrooms, are often nonexistent. As a result, Congress passed the Sport Fishing and Boating Safety Act of 1998 (16 U.S.C. 777g). Under the Act, the U.S. Fish and Wildlife Service conducts the Boating Infrastructure Grant (BIG) Program. The BIG Program will provide $32 million to States and Territories over 4 years to construct, renovate, or maintain tie-up facilities for recreational boats 26 feet or more in length.

This program will:

(a) Create dockage for transient recreational boats 26 feet or more in length for recreational opportunities and safe harbors;

(b) Provide navigational aids for boaters to use these facilities;

(c) Enhance access to recreational, historic, cultural, natural, and scenic resources;

(d) Strengthen local ties to the boating community and its economic benefits;

(e) Promote public/private partnerships and entrepreneurial opportunities;

(f) Provide continuity of public access to the shore; and

(g) Promote awareness of transient boating opportunities.

The Act also directs us to:

(a) Develop a national framework or methodology to conduct a boat access needs assessment or survey to determine the adequacy of facilities for recreational boats of all sizes;

(b) Encourage States to complete the boat access needs survey; and

(c) Complete a comprehensive national assessment of boat access needs and facilities (the assessment will be a compilation of information from the States' surveys into a national report of boat access needs).

Analysis of Public Comments and Changes Made to the Proposed Rule

On January 20, 2000, the U.S. Fish and Wildlife Service (Service) published a proposed rule in the **Federal Register** (65 FR 3331) and requested comments on the proposed rule and information collection for the national BIG Program. The Service received 13 written responses by the close of the comment period on March 20, 2000. The responses came from nongovernmental organizations, a private individual, and Federal and State employees and agencies.

We received a total of 170 comments from the 13 written responses covering the following areas: survey (74), criteria for selection (11), State plans (8), clarifications (3), suspected typographical errors (3), and comments of a general nature (71). We may not reflect these actual numbers in the list below due to combining similar comments or questions. We have addressed all of the comments in this section of the preamble and made any necessary changes to the proposed rule. As a result, some sections of the proposed rule were combined or eliminated. Comments pertaining to the proposed information collection are addressed under Substantive Comments, Issues 1 through 9.

The following is clarification or analysis and reporting of any substantial changes to the rule that the Service made in response to these comments. The Service also corrected other minor errors in the proposed rule, as described below.

Minor Changes

In § 86.12(n), in response to a comment asking us to define "transient," we are adding the following definition, "Passing through or by a place, staying 10 days or less."

In § 86.13(d), we changed "seasonal" to "transient" to avoid confusing wording.

In § 86.13(f), in response to a suggestion, we added "docks" after the word "floating" to clarify.

In § 86.13, in response to suggestions, we added at paragraphs (o), (p), and (q), "dockside" to clarify where utilities are placed.

In § 86.13, in response to a suggestion, we added "(r) Debris deflection booms."

In § 86.13, in response to suggestions, we added "(s) Marine fueling stations."

In § 86.20(a)(1), in response to a suggestion, we added a second sentence as follows: "You must design new construction and renovations to last at least 20 years."

In § 86.20(e)(1), in response to a suggestion, we deleted from

subparagraph (vii) to end, as the activities listed in the proposed rule are not appropriate preconstruction activities.

In § 86.20, in response to a suggestion, we added a new item, "(f) Produce information and education materials such as charts, cruising guides, and brochures."

In § 86.21(d), in response to a suggestion, we changed the sentence to read: "Construct or renovate principal structures not expected to last at least 20 years."

In § 86.44(b), in response to a suggestion, we replaced "* * * we will" with "* * * The State must * * *"

In § 86.54(f)(1)(i) in the proposed rule (now § 86.53(d)(1)(i)), in response to several comments, we changed the section to clarify that no State Tier One proposal may exceed $100,000 in any given fiscal year.

Substantive Changes

Issue 1. Questions and comments on the survey included issues of respondent burden (how long to complete a section), unclear questions, issues of confidentiality, site-specific questions, and the value of answers to specific questions in determining national need.

Response: In response to all of the comments received on the technical aspects of the proposed survey, we completed significant revisions to the survey instrument. We considered all comments and redesigned the survey, improved guidance and questions, and decreased the time burden for completion. The revised survey began its approval process when it was published in the **Federal Register** (65 FR 63606) on October 24, 2000 for a 60-day public comment period. The survey will be ready for use during the FY 2001 grant cycle, and the Service will notify eligible applicants upon receiving OMB approval.

Issue 2. How can States pay for the survey?

Response: States can pay the costs for conducting the survey using Federal Aid in Sport Fish Restoration program funds, and credit expenditures toward the 15% minimum used for motor boat access (16 U.S.C. 777g (g)(4)).

Issue 3. Is the survey required?

Response: The Service does not require States to conduct surveys to receive funding under the national BIG program. However, the Service must produce a comprehensive national assessment of recreational boat access needs and facilities. The States, by conducting and forwarding their survey results to the Service, are ensuring that their needs are known (16 U.S.C. 777g (g)(2)). States may use existing, recent survey results, approved by the appropriate Service Regional Office, to determine boating infrastructure needs (§ 86.113).

Issue 4. States completing a survey should receive ranking points.

Response: No "points" are assigned in the criteria for completing a survey; the only available points are outlined in § 86.60. States must use the survey results to develop a State plan for boating infrastructure. The plan (any plan certified by the Service Regional Office) is then eligible for 15 ranking points.

Issue 5. Can States add questions to the survey?

Response: States cannot add any questions to the survey. If OMB approves the final survey as written, we will reimburse States only for administering it as approved.

Issue 6. Typographical errors occur in the survey tables.

Response: We fixed typographical errors in both tables describing the type of participant in survey parts.

Issue 7. States should submit survey results electronically.

Response: The Service wants the results transmitted to the Service Regional Offices in a common electronic format, such as Microsoft Word, Word Perfect, Excel or Quattro Pro. We added a requirement regarding electronic transmission of results to § 86.111.

Issue 8. Clarify "boat service providers" as the term relates to public access.

Response: We changed § 86.102(b)(2)(i) and (ii) to include a phrase that specifies boat service providers "who allow public access."

Issue 9. What are the survey response rate requirements?

Response: We changed § 86.115 to read "plus or minus 10 percent." We also replaced the language that suggests a 70 percent response rate with language that says the State is responsible for selecting a statistically valid sample size.

Issue 10. In § 86.60, the points do not add up to 100, or no points are allowed for completing surveys.

Response: This section needed several minor editorial changes to make it clear and concise. Among these, we changed the point total to 105. The issue regarding awarding points for completing surveys is addressed in Issue 4.

Issue 11. According to § 86.54, why are proposals that are awarded less than 60 points when held to the criteria in § 86.60 automatically moved to Tier Two?

Response: We removed this "60 point" break when we revised the Tier One/Two break.

Issue 12. By awarding 15 points for a State plan, the Service is making State plans mandatory, penalizing all nonplan proposals.

Response: State plans are desirable under the Act (16 U.S.C. 777g (g)). They help set priorities and describe how a State will fulfill recreational boaters' needs. We can also use plans to help set national priorities in the comprehensive national assessment of recreational boat access needs and facilities described in the Act. The plan nonetheless is optional. The Act states, "A State may develop a plan for," and in the proposed rule, § 86.131 states "Plans are voluntary." However, the Service will award 15 criteria points to any acceptable plan, already existing and current, or a newly developed plan based on the OMB-approved survey or other recent approved survey results. The reason for the 15 criteria points is that projects coming from an accepted plan will establish priorities based on a formal needs assessment.

Issue 13. Add a statement to identify priorities in the State plan in § 86.60(b)(1).

Response: We added to § 86.60(b)(1), after the word "following" "priorities identified in" your State's program plan. We also agreed with the second thought presented in this comment and changed "construct and renovate" to "construct, renovate, and maintain."

Issue 14. Change the point values assigned to certain criteria.

Response: We are not making a change to the final rule as a result of this comment. We believe that we did a thorough job of stakeholder involvement when we assigned these point values.

Issue 15. A possible conflict exists in § 86.60(b)(4) about match funds.

Response: We have changed § 86.60(b)(4) to read "Include private, local, or other State funds in addition to the non-Federal match described in § 86.42."

Issue 16. Because of typographical errors in § 86.60(b)(4)(i), the percentage range was left out.

Response: In § 86.60(b)(4), we changed paragraph (i) to read "Twenty-six percent to thirty-five percent—5 points," paragraph (ii) to remove the word "above" at the end, and paragraph (iii) to insert the word "and" so it reads "Fifty percent and above—15 points."

Issue 17. Add the word "proposed" before "tie-up" to the second sentence in § 86.60(b)(5), and delete the word "access" from the same sentence.

Response: We do not believe this suggestion adds to the clarity of the

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sentence. We are making no changes to the proposed rule as a result of this comment.

Issue 18. In § 86.60(b)(6), change the wording of the sentence to restrict the sites to those near population centers and raise the value of the points assigned.

Response: We believe this change would unnecessarily restrict State proposals. We believe the sentence is clear and the points are appropriate. The sentence remains unchanged.

Issue 19. In § 86.60(b)(7), substitute "enhanced opportunities" for "access."

Response: We are not changing this paragraph as a result of this comment because we believe the sentence is clear as written.

Issue 20. In § 86.60(b)(8), add "adjacent" before the word "community," and add "as the result of construction, renovation, or increased use," at the end of the first sentence.

Response: We believe this change would unnecessarily restrict the program criteria. The proposed sentence stands unchanged.

Issue 21. Allow Tier One dollars to finance State plans because not to do so creates an unfunded Federal mandate.

Response: The Act states that "* * * a State may develop and submit to the Secretary a plan for* * *," not "must" (16 U.S.C. 777g–1 (c)). A mandate does not exist. However, States may do planning under other Sport Fish Restoration Act grant programs for purposes eligible under those programs and apply the resulting plan to the BIG Program.

Issue 22. Will the Service accept existing plans?

Response: The Service will accept any plan certified by the appropriate Service Regional Office that ensures that public boat access is and will be adequate to meet the needs of recreational boaters on your State's waters (§ 86.134).

Issue 23. What are the products of the National Assessment?

Response: The products of the Comprehensive National Assessment are listed in § 86.124.

Issue 24. Complying with the National Environmental Policy Act and the Endangered Species Act could cause up to 2 years of delay.

Response: All grantees must agree to and certify compliance with all applicable Federal laws. We use a certified "Assurances" statement. We are making no changes to the proposed rule as a result of this comment.

Issue 25. Can States use consultant fees, design, permitting, and construction administration costs as match for Tier One projects?

Response: Allowable matching and cost-sharing regulations are in 43 CFR 12.64; specific questions should be directed to the appropriate Service Regional Office.

Issue 26. Reduce match to where local governments or small marinas can compete for funds.

Response: In accordance with the Act, only States are eligible for funding under this grant program.

Issue 27. Are pre-award costs allowable?

Response: Only as described under § 86.20.

Issue 28. Who assumes the administrative burden after the program expires in 3 years?

Response: We discuss maintenance of approved projects in 50 CFR 80.17.

Issue 29. How much money can we charge the public to tie-up?

Response: The going rate in the locality determines the amount for the facility. We are making no change to the proposed rule as a result of this comment.

Issue 30. For projects in Tier Two that exceed available funding in Tier Two, what is the methodology for awarding funds other than what States request?

Response: There is none. We cannot exceed established spending levels. If a State requires funds from two or more different programs to obtain full funding, the State is responsible for securing the funds.

Issue 31. In § 86.20(a)(3), substitute "deep enough" for "6 feet of depth at the lowest tide * * *."

Response: We researched these depths before making this specification, and we are not making the recommended change.

Issue 32. In § 86.20(a)(5)(iii), delete the reference to "this program," so that the sentence reads: "You may use funds from the Clean Vessel Act Program."

Response: We encourage the construction of pumpout stations with either set of funds. We are making no changes to the proposed rule as a result of this comment.

Issue 33. In § 86.20(e)(1), add "contract documents."

Response: No contract should be prepared and awarded until after we sign a grant; therefore, contract documents are not allowed as a pre-agreement cost. We are making no changes to the proposed rule as a result of this comment.

Issue 34. In § 86.21(e) and (g), add note on one-time dredging to (e) and add dinghy docks to (g).

Response: We address one-time dredging in § 86.20, and dinghy docks are not for transient vessels more than 26 feet in length. We are making no changes to the proposed rule as a result of this comment.

Issue 35. In § 86.21, make the State plan eligible for funding under BIG.

Response: State plans are eligible activities under the Sport Fish Restoration Act (16 U.S.C. 777).

Issue 36. In accordance with § 86.30, must I allow the public to use grant-funded facilities?

Response: Yes, § 86.30 specifies that reasonable access must be allowed and explains what that means.

Issue 37. In regard to § 86.54, one responder commented that the criterion referenced in § 86.60 was developed for competitive Tier Two projects and was not meant for Tier One projects. Tier One project funding was developed for States meeting the requirements in §§ 86.13 and 86.20.

Response: We agree and will change § 86.54(f)(1)(ii) (now § 86.53(d)(1)(ii) in the final rule) to read "* * * using the eligibility requirements in §§ 86.14 and 86.20." (Section 86.13 from the proposed rule has become § 86.14 in the final rule.)

Issue 38. In regard to § 86.55(f), why are two sets of $100,000 proposals required? Why not require one $200,000 proposal?

Response: Tier One proposals in the first grant cycle will be funded by 2 different fiscal years. To provide additional clarity, we replaced the second sentence in § 86.55(f) (now § 86.54(f)) with wording similar to the following, "We will fund one proposal for each fiscal year provided that each proposal meets the eligibility requirements in §§ 86.13 (now 86.14) and 86.20."

Issue 39. Sections 86.20 and 86.21 conflict in useful life of some outputs.

Response: We do not agree. Principal structures expected to last 20 years or more are different from navigational aids which may have a shorter lifespan. Only principal structures must be designed to last at least 20 years, therefore a conflict does not exist.

Issue 40. In regard to § 86.56, after the Service awards funds for a project, if it is found not to meet compliance requirements, where will these funds go?

Response: If a State cannot bring the project into compliance according to § 86.56 (now § 86.55), the funds may revert as required by the Act (16 U.S.C. 777c).

Issue 41. Regarding § 86.60(b), a respondent recommended considering construction in remote areas in the scoring priority and adding a statement to the Regulatory Flexibility Act section to give criteria points for remote sites.

Response: Section 86.60(b)(6) and (7) considers remote areas as they relate to significant links to prominent destinations, way-points, and national, regional, and local significant areas. Therefore, we do not see the need to alter the present guidance.

Issue 42. In § 86.60(b)(8), how will we assess "significant positive economic impact?"

Response: States should assess the economic impact of projects using a cost/benefit analysis as described in the example in § 86.60(b)(8). States should address this issue, along with all the other criteria, in the grant proposal.

Issue 43. In § 86.82(b), replace the word "slippage" with "deviation."

Response: "Slippage" is the term used in 43 CFR 12.80(b)(2)(ii), which provides reporting requirements for assistance programs. We are making no changes to the proposed rule as a result of this comment.

Issue 44. In § 86.80, remove the requirement for quarterly reports.

Response: We are removing the requirement for quarterly reporting for Tier One projects only, according to 43 CFR 12.80, Monitoring and Reporting Program Performance.

Issue 45. In § 86.91, make States give credit to the Sport Fish Restoration Program for BIG grants.

Response: Credit to the Sport Fish Restoration Program remains optional. We have nothing on which to base making this issue mandatory. We are changing "may" in the last sentence to "* * * are encouraged to * * *".

Issue 46. Could priority for services at tie-up facilities be given to transient boats over 26 feet in length? If so, how would States enforce the priority?

Response: No. While we intend the program to benefit transient, nontrailerable boats, States must give equal public access to all boaters. Consequently, enforcement is unnecessary.

Issue 47. The Service Director should convene a nongovernmental advisory committee to provide expertise on "recreational boating facilities needs."

Response: Under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App.1), requirements for creating an advisory committee would significantly delay the distribution of the first cycle grant funds. However, opportunities may exist for the nongovernmental community to participate in the grant selection process, and the Service will investigate such opportunities.

Issue 48. Are maintenance and operation costs in remote areas eligible under § 86.20(4)?

Response: We cover maintenance under § 86.20(a); we specifically exclude operation and janitorial costs under § 86.21.

Issue 49. Provide sufficient time to rank and award proposals.

Response: We changed the application period for the first grant cycle to allow applicants 90 days to submit grant proposals to the appropriate Service Regional Office. This change occurs in § 86.50.

Regulatory Planning and Review (E.O. 12866)

In accordance with the criteria in Executive Order 12866, this rule is a significant regulatory action according to the following:

(a) This rule will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. Program funds total $8 million per year for 4 years, for a total of $32 million. Program funds for surveys total $1,050,000. States must match these amounts with 25 percent or $2 million per year. State match totals $8 million over 4 years. The program will not negatively affect an economic sector, productivity, jobs, and other units of government. The program will have a positive effect on these factors.

(b) This rule will not create inconsistencies with other agencies' actions. We will require the necessary Federal, State, and local reviews and permits before allowing construction of all facilities approved under the program. These reviews will ensure that this rule will not create inconsistencies with other agencies' actions.

(c) This rule will materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. This rule establishes a new grant program using existing funds that are otherwise available to State natural resource agencies under the Sport Fish Restoration Act (16 U.S.C. 777–777m). Recipients will voluntarily accept all stipulations prior to the Service awarding funds for facility construction. The program only obligates the recipient to maintain the facility. User fees are not mandatory and the program allows only enough charges to maintain the facility established by the grant.

(d) This rule will not raise novel legal or policy issues. This program will award funds to States to install facilities for transient nontrailerable boats. We will review all actions for compliance with the National Environmental Policy Act. This grant program is similar to past Federal Aid grant programs for construction of facilities.

Regulatory Flexibility Act

The Department certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Eight million dollars will be available annually for a 4-year period. The effects of these regulations occur to agencies in the States, Puerto Rico, Guam, the Virgin Islands, American Samoa, the District of Columbia, and the Northern Mariana Islands. These are not small entities under the Regulatory Flexibility Act. Some small entities, mainly marina operators, may receive grant funds. The program will place facilities where none exist now, in remote areas where no competition exists, and in populated areas where marinas have not previously installed them. Employment, investment, productivity, and innovation should all increase because the program will construct facilities to attract transient boaters. The result will be a net transfer of expenditures in the area. U.S.-based enterprises' ability to compete with foreign-based enterprises should not be affected by this rule.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This regulation is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act, as discussed in the Regulatory Planning and Review and Regulatory Flexibility Act sections above.

Unfunded Mandates Reform Act

This regulation does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. This regulation does not have a significant or unique effect on State, local, tribal governments, or the private sector. The rule establishes a grant program that States may participate in voluntarily. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not necessary.

Takings (E.O. 12630)

In compliance with Executive Order 12630, this regulation does not have significant takings implications. The rule provides standardized procedures for administering a Federal discretionary grant program.

Federalism Assessment (E.O. 13132)

In compliance with Executive Order 13132, this regulation does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. Through this regulation,

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eligible States will receive grants for construction, renovation, maintenance of boating facilities, and public information and education programs. Therefore, the rule is consistent with Executive Order 13132.

Civil Justice Reform (E.O. 12988)

In compliance with Executive Order 12988, the Office of the Solicitor has determined that this regulation does not unduly burden the judicial system and meets the requirements of §§ 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

The information collection requirements contained in this regulation are only those necessary to fulfill applicable grant application requirements of 43 CFR Part 12; see 43 CFR 12.4 for information concerning OMB approval of those requirements. We have submitted the collections of information contained in this rule to the Office of Management and Budget for approval as required under 44 U.S.C. 3501 *et seq.* The Service will not collect this information until OMB has granted us approval. Additionally, no person may be required to respond to a collection of information unless it displays a currently valid OMB number.

The information collection requirement related to the surveys has a current OMB Approval Number 1018–0106 under the provisions of 44 U.S.C. 3501 *et seq.* In response to the comments received on the technical aspects of the proposed survey, we revised the survey improving the guidance, questions, and a lower time burden for completion.

What Intergovernmental Review Procedures Must I as a State follow?

Executive Order 12372, "Intergovernmental Review of Federal Programs," and 43 CFR Part 9, "Intergovernmental Review of Department of the Interior Programs and Activities," applies to the national BIG Program. Under the Order, you may design your own processes to review and comment on proposed Federal assistance under covered programs.

What Is My Responsibility as a State if I Participate in the Executive Order Process Having Single Points of Contact?

You should alert your Single Points of Contact (SPOC) to the prospective applications and receive any necessary instructions to provide material the SPOC requires. You must submit all required materials, if any, to the SPOC and show the date of this submittal (or the date of contact if the SPOC does not require submittal) on the narrative. If you are from a State that chooses to exempt the grants, you need take no action regarding E.O. 12372.

Author

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Regulation Promulgation

Accordingly, the Service hereby establishes part 86, subchapter F of Chapter I, Title 50 Code of Federal Regulations, as set forth below:

List of Subjects in 50 CFR Part 86

Administrative practice and procedure, Boats and boating, Grant programs—recreation, Natural resources, Recreation and recreation areas, Reporting and record keeping requirements.

For the reasons set out in the preamble, we amend Subchapter F of Chapter I, Title 50 of the Code of Federal Regulations, by adding a new part 86 to read as follows.

PART 86—BOATING INFRASTRUCTURE GRANT (BIG) PROGRAM

Subpart A—General Information About the Grant Program

Sec.

86.10 What does this regulation do?
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Authority: 16 U.S.C. 777g, 777g–1.

Subpart A—General Information About the Grant Program

§ 86.10 What does this regulation do?

In this part, the terms "I," "you," "my," and "your" refer to the State agency seeking participation in the national Boating Infrastructure Grant (BIG) Program. "We" and "us" refers to the Fish and Wildlife Service. This part establishes your requirements under the Sportfishing and Boating Safety Act of 1998 to:

(a) Participate in the national BIG Program,

(b) Complete your boat access survey, and

(c) Develop State plans to install tie-up facilities for transient nontrailerable recreational vessels.

§ 86.11 What does the national BIG Program do?

This program provides funds for States to construct, renovate, and maintain tie-up facilities with features for transient boaters in vessels 26 feet or more in length, and to produce and distribute information and educational materials about the program.

§ 86.12 Definitions of terms used in part 86.

For the purposes of this part, the following terms are defined:

Construct means engaging in activities that produce new capital improvements and increase the value or usefulness of existing property. These activities include building new tie-up facilities or replacing or expanding existing tie-up facilities.

Grant means financial assistance the Federal Government awards to an eligible applicant.

Grant agreement means a contractual agreement used to obligate Federal Aid funds for carrying out work covered by an approved grant proposal.

Maintain means engaging in activities that allow the facility to continue to function, such as repairing docks. These activities exclude routine janitorial activities.

Navigable waters means waters connected to or part of the jurisdictional waters of the United States that transient nontrailerable recreational vessels currently use or can use.

Nontrailerable recreational vessels mean motorized boats 26 feet or more in length manufactured for and operated primarily for pleasure, including vessels leased, rented, or chartered to another person for his or her pleasure.

Project means a specific plan or design.

Proposal means a description of one or more projects for which a State requests grant funds.

Recreational waters means navigable waters that vessels use for recreational purposes.

Renovate means to rehabilitate or repair a tie-up facility to restore it to its original intended purpose, or to expand its purpose to allow transient nontrailerable recreational vessels.

States means individual States within the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

Survey instrument means a tool developed by the Service and approved by OMB to assess the need for boating facilities.

Tie-up facilities mean facilities that transient nontrailerable recreational vessels occupy temporarily, not to exceed 10 consecutive days; for example, temporary shelter from a storm; a way station en route to a destination; a mooring feature for fishing; or a dock to visit a recreational, historic, cultural, natural, or scenic site.

Transient means passing through or by a place, staying 10 days or less.

Water-body means the lake, section of river, or specific area of the coast, such as a harbor or cove, where tie-up facilities or boat access sites are located.

§ 86.13 What is boating infrastructure?

Boating infrastructure refers to features that provide stopover places for transient nontrailerable recreational vessels to tie up. These features include, but are not limited to:

(a) Mooring buoys (permanently anchored floats designed to tie up nontrailerable recreational vessels);

(b) Day-docks (tie-up facilities that do not allow overnight use);

(c) Navigational aids (*e.g.*, channel markers, buoys, and directional information);

(d) Transient slips (slips that boaters with nontrailerable recreational vessels occupy for no more than 10 consecutive days);

(e) Safe harbors (facilities protected from waves, wind, tides, ice, currents, etc., that provide a temporary safe anchorage point or harbor of refuge during storms);

(f) Floating docks and fixed piers;

(g) Floating and fixed breakwaters;

(h) Dinghy docks (floating or fixed platforms that boaters with nontrailerable recreational vessels use for a temporary tie-up of their small boats to reach the shore);

(i) Restrooms;

(j) Retaining walls;

(k) Bulkheads;

(l) Dockside utilities;

(m) Pumpout stations;

(n) Recycling and trash receptacles;

(o) Dockside electric service;

(p) Dockside water supplies;

(q) Dockside pay telephones;

(r) Debris deflection booms; and

(s) Marine fueling stations.

§ 86.14 Who may apply for these grants?

You, with authority from your State Government. You must identify one key contact only and submit proposals through this person.

§ 86.15 How does the grant process work?

To ensure that grants address the highest national priorities identified in the Act, we make funds available on a competitive basis. You must submit your proposals by the appropriate date as specified in § 86.50. You must address certain questions and criteria (listed in § 86.52) to be eligible and competitive. We will conduct a panel review of all proposals, and the Service Director will make the final grant awards. You may begin work on your project only after you receive a fully executed grant agreement.

§ 86.16 What are the information collection requirements?

This part contains both routine information collection and survey requirements, as follows:

(a) The routine information collection requirements for grants applications and associated record keeping contained in this part are only those necessary to fulfill applicable requirements of 43 CFR part 12. These requirements include record keeping and reporting requirements. See 43 CFR 12.4 for information concerning OMB approval of those requirements.

(b) The revised information collection requirements related to the surveys will be submitted to OMB for approval as changed. They will not be imposed until

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we receive OMB approval under the provisions of 44 U.S.C. 3501 *et seq.* The surveys are voluntary and are for States to determine the adequacy, number, location, and quality of facilities that provide public access for all sizes of recreational boats. The public's burden estimate for the survey is as follows:

Type of information	Number of respondents*	Average time required per response (minutes)	Annual burden hours
Boat owners: Part A	11,200	12	2,240
Boat owners: Part B	28,000	12	5,600
Boat Service Providers: Part C	8,400	20	2,800
Boat Service Providers: Part D	4,000	20	1,333

*These numbers are not additive since some boaters will fill out both Parts A and B, and most of the providers will fill out both Parts C and D.

(c) Send comments regarding this collection of information to the Service Information Collection Clearance Officer, MS—222 ARLSQ, Fish and Wildlife Service, Washington, DC 20240, and the Office of Management and Budget, Department of Interior, Desk Officer, 1849 C Street, NW., Washington, DC 20503. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, to ensure maximum consideration, you must send your comments to OMB by the above referenced date.

Subpart B—Funding State Grant Proposals

§ 86.20 What activities are eligible for funding?

Your project is eligible for funding if you propose to:

(a) Construct, renovate, and maintain either publicly or privately owned boating infrastructure tie-up facilities. To be eligible you must:

(1) Build these tie-up facilities on navigable waters, available to the public. You must design new construction and renovations to last at least 20 years;

(2) Design these tie-up facilities for temporary use for transient nontrailerable recreational vessels;

(3) Build these tie-up facilities in water deep enough for nontrailerable recreational vessels to navigate (a minimum of 6 feet of depth at the lowest tide or other measure of lowest fluctuation);

(4) Provide security, safety, and service for these boats; and,

(5) Install a pumpout station, if you construct a facility for overnight stays:

(i) If there is already a pumpout within a reasonable distance (generally within 2 miles) of the facility, you may not need one;

(ii) For facilities intended as day stops, we encourage you to install a pumpout; and,

(iii) You may use funds from the BIG program, or the Clean Vessel Act pumpout grant program also administered by us, to pay for a pumpout station.

(b) Do one-time dredging only, to give transient vessels safe channel depths between the tie-up facility and maintained channels or open water.

(c) Install navigational aids, limited to giving transient vessels safe passage between the tie-up facility and maintained channels or open water.

(d) Apply funds to grant administration.

(e) Fund preliminary costs:

(1) Preliminary costs may include any of the following activities completed before signing a grant agreement:

(i) Conducting appraisals;

(ii) Administering environmental reviews and permitting;

(iii) Conducting technical feasibility studies, for example, studies about environmental, economic, and construction engineering concerns;

(iv) Carrying out site surveys and engaging in site planning;

(v) Preparing cost estimates; and

(vi) Preparing working drawings, construction plans, and specifications.

(2) We will fund preliminary costs only if we approve the project.

(3) If the project is approved, the appropriate Service Regional Director must still approve preliminary costs.

(f) Produce information and education materials such as charts, cruising guides, and brochures.

§ 86.21 What activities are ineligible for funding?

Your project is ineligible for funding if you propose to:

(a) Complete a project that does not provide public benefits, for instance, a project that is not open to the public for use;

(b) Involve law enforcement activities;

(c) Significantly degrade or destroy valuable natural resources or alter the cultural or historic nature of the area;

(d) Construct or renovate principal structures not expected to last at least 20 years;

(e) Do maintenance dredging;

(f) Fund operations or routine, custodial, and janitorial maintenance of the facility;

(g) Construct, renovate, or maintain boating infrastructure tie-up facilities for nontrailerable vessels, for example the following:

(1) Tie-up slips available for occupancy for more than 10 consecutive days by a single party;

(2) Dryland storage;

(3) Haul-out features; and

(4) Boating features for trailerable or "car-top" boats (boats less than 26 feet in length), such as launch ramps and carry-down walkways.

(h) Develop a State program plan to construct, renovate, and maintain boating infrastructure tie-up facilities; and

(i) Conduct surveys to determine boating access needs.

(1) You may conduct the survey with funds allocated to motorboat access to recreational waters under subsection (b)(1) of section 8 of the Federal Aid in Sport Fish Restoration Act of 1950, as amended (16 U.S.C. 777).

(2) You may combine surveys under one contractor where feasible if you can realize a cost or other savings.

Subpart C—Public Use of the Facility

§ 86.30 Must I allow the public to use the grant-funded facilities?

(a) You must allow reasonable access to all recreational vessels for the useful life of the tie-up facilities. Accessible to the public means located where the public can reasonably reach the facility and where all boats typical to that facility can easily use it, charging equitable fees, and being open for reasonable periods. You must allow public access to the shore and basic features such as fuel and restrooms in facilities that have them. You must specify precise details of the public access in the contract with the facility manager. We do not require public access to the remainder of a park or marina where the facility is found. Nor do we require any restrictions in that park or marina.

(b) You must comply with Americans with Disabilities Act requirements when you construct or renovate all tie-up facilities under this grant.

§ 86.31 How much money may I charge the public to use tie-up facilities?

You may charge the public only a reasonable fee, based on the prevailing rate in the area. You must determine a fee that does not pose an unreasonable, competitive amount, based on other publicly and privately owned tie-up facilities in the area. You must approve any proposed changes in fee structure by a sub-grantee.

Subpart D—Funding Availability

§ 86.40 How much money is available for grants?

There is $32 million available for grants under the BIG program ($8 million per year for fiscal years 2000–2003).

§ 86.41 How long will the money be available?

Under the Act, funding for the BIG program is provided for FY 2000–2003. Each year's funds remain available for obligation for a total of three fiscal years (e.g. FY 2000 funds will remain available through FY 2002) (16 U.S.C. 777c(b)(3)(B)).

§ 86.42 What are the match requirements?

The Act authorizes the Secretary of the Interior (through the Director of the U.S. Fish and Wildlife Service (Service)) to award grants to States to pay up to 75 percent of the cost to construct, renovate, or maintain tie-up facilities for transient nontrailerable recreational vessels. You or a partner must pay the remaining project cost—at least a 25 percent match is required. Title 43 CFR 12.64 applies to cost sharing or matching requirements for Federal grants.

§ 86.43 May someone else supply the match?

Third-party contribution, including property and in-kind services, is allowable, but must be necessary and reasonable to accomplish grant objectives. In-kind contributions must also represent the current market value of noncash contributions that the third party furnishes as part of the grant.

§ 86.44 What are my allowable costs?

(a) The State may spend grant funds to pay only costs that are necessary and reasonable to accomplish the approved grant objectives. Grant costs must meet the applicable Federal cost principles in 43 CFR 12.62. You may purchase informational and program signs as allowable costs.

(b) If you include purposes other than those eligible under the Act, you must prorate the costs equitably according to Federal cost principles in 43 CFR 12.62 and 50 CFR 80.15.

§ 86.45 When will I receive the funds?

Once you sign the grant agreement, we will make the funds available.

Subpart E—How States Apply for Grants

§ 86.50 When must I apply?

(a) We will accept proposals between February 20, 2001, and May 18, 2001, for the first grant cycle; between July 1, 2001, and September 30, 2001, for the second grant cycle; and between July 1, 2002, and September 30, 2002, for the third grant cycle. This program starts fiscal year 2000 and ends fiscal year 2003. We will have $16 million to award the first grant cycle, and $8 million each cycle after that.

(b) The annual schedule follows:

Action	FY 2000–2001	FY 2002	FY 2003
We announce the beginning of the grant cycle.	February 20, 2001	July 1, 2001	July 1, 2002.
You submit your grant proposal by	May 18, 2001	September 30, 2001	September 30, 2002.
Regions submit the proposals to Washington by.	June 18, 2001	October 31, 2001	October 31, 2002.
We rank the proposals by	July 17, 2001	November 30, 2001	November 30, 2002.
The Director approves proposals by.	August 16, 2001	December 31, 2001	December 31, 2002.
Regions finalize their grant agreements by.	October 15, 2001	February 28, 2002	February 28, 2003.

§ 86.51 To whom must I apply?

You must submit your proposals to the appropriate regional office of the U.S. Fish and Wildlife Service. See the chart below for the address you will need.

Region	State	Address	Telephone
1	California, Hawaii, Idaho, Nevada, Oregon, Washington, American Samoa, Commonwealth of the Northern Mariana Islands, and Guam.	Division of Federal Aid, U.S. Fish & Wildlife Service, Eastside Federal Complex, 911 NE 11th Avenue, Portland, OR 97232–4181.	503–231–6128, Fax: 503–231–6996
2	Arizona, New Mexico, Oklahoma, and Texas.	Division of Federal Aid, U.S. Fish & Wildlife Service, P.O. Box 1306, 625 Silver, SW, Suite 325, Albuquerque, NM 87102.	505–248–7450, Fax: 505–248–7471
3	Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	Division of Federal Aid, U.S. Fish & Wildlife Service, Bishop Henry Whipple Federal Building, 1 Federal Drive, Fort Snelling, MN 55111–4056.	612–713–5130, Fax: 612–713–5290
4	Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and the Virgin Islands.	Division of Federal Aid, U.S. Fish & Wildlife Service, 1875 Century Boulevard, Suite 324, Atlanta, Georgia 30345.	404–679–4159, Fax: 404–679–4160

Region	State	Address	Telephone
5	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia.	Division of Federal Aid, U.S. Fish & Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035–9589.	413–253–8200, Fax: 413–253–8487
6	Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.	Division of Federal Aid, U.S. Fish & Wildlife Service, Denver Federal Center, P.O. Box 25486, Lake Plaza North Building, 134 Union Boulevard, 4th Floor, Denver, Colorado 80225.	303–236–7392, Fax: 303–236–8192
7	Alaska	Division of Federal Aid, U.S. Fish & Wildlife Service, 1011 East Tudor Road, Anchorage, Alaska 99503.	907–786–3435, Fax: 907–786–3575

§ 86.52 What information must I include in my grant proposals?

You must submit the following standard forms and narrative for all projects (Tier One and Tier Two) (see § 86.53):

(a) Standard Form 424 series as prescribed by the Office of Management and Budget. The SF 424 series consists of the Applications for Federal Assistance (SF 424), Budget Information—Non-Construction Programs (SF 424A), Assurances—Non-Construction Programs (SF 424B), Budget Information—Construction Programs (SF 424C), and Assurances—Construction Programs (SF 424D). Submit forms appropriate for either construction or nonconstruction projects. Forms are available from your appropriate Service Regional Office.

(b) Information requested under OMB Circular A–102 (Application Booklet for Federal Aid Grants—pending approval under the Paperwork Reduction Act).

§ 86.53 What are funding tiers?

(a) This grant program will consist of two tiers of funding.

(i) You may apply for one or both tiers.

(ii) The two tiers will allow all States some certainty of base level funding.

(b) Tier One funding will ensure broad geographical distribution to meet the needs of transient nontrailerable recreational vessels.

(c) Tier Two funding will allow States with large projects to compete with other States with large projects based on individual project merits.

(d) We describe the two tiers as follows:

(1) *Tier One Projects.*

(i) You may submit a proposal with an unlimited number of projects within this tier. However, your total request cannot exceed $100,000 of Federal funds for any given fiscal year.

(ii) Tier One projects must meet the eligibility requirements in §§ 86.14 and 86.20.

(2) *Tier Two Projects.*

(i) While we expect available funds for Tier Two proposals to be between $3 million and $4 million per grant cycle, we have no dollar limit for Tier Two proposals. You may submit any number of projects, which we will score and rank separately according to the criteria in § 86.60.

(ii) Each project will compete nationally against every other project in Tier Two.

(iii) Tier Two projects must also meet the eligibility requirements in §§ 86.14 and 86.20.

§ 86.54 How must I submit proposals?

(a) You may apply for either Tier One funding or Tier Two funding or both.

(b) You may submit more than one project proposal within Tier One and Tier Two.

(c) You may submit one proposal that includes Tier One and Tier Two projects.

(d) If your proposal includes Tier One and Tier Two projects, you must describe Tier One projects separately from Tier Two projects.

(e) You must describe each project in Tier Two separately, so that the Service can rank and score each project in Tier Two separately.

(f) For the first grant cycle, which includes fiscal years 2000 and 2001, a State may submit one Tier One proposal not to exceed $100,000 per fiscal year. States should submit proposals between February 20, 2001, and May 18, 2001. We will fund one Tier One proposal per State for each fiscal year provided that each proposal meets the eligibility requirements in §§ 86.14 and 86.20. Fiscal year 2000 funds are available only for Tier One proposals. Tier One proposals need not meet the criteria in § 86.60. We will fund Tier Two proposals received between February 20, 2001, and May 18, 2001, that meet the criteria in §§ 86.14, 86.20, and 86.60 with fiscal year 2001 funds and the remainder of fiscal year 2000 funds.

(g) For the remaining grant cycles, you may submit only one proposal of Tier One projects per fiscal year.

(h) When we approve projects, the appropriate Service Regional Office will determine how many grant agreements are necessary.

§ 86.55 What are my compliance requirements with Federal laws, regulations, and policies?

(a) To receive Federal funds, you must agree to and certify compliance with all applicable Federal laws, regulations, and policies. You must submit an Assurance Statement, as described in 43 CFR part 12.51(c), that describes how you comply with Federal grant requirements; and

(b) You may have to provide additional documentation to comply with environmental and other laws, as defined in Fish and Wildlife Service Manual 523 FW 1 (available on the internet at http://www.fws.gov/directives/523fw1.html). The Service Regional Office Grant Administrator may request preliminary evidence at the grant proposal stage that the proposed project will meet these compliance requirements. Consult with the appropriate Service Regional Office for specific applicability.

Subpart F—How the Service Selects Projects To Receive Grants

§ 86.60 What are the criteria used to select projects for grants?

(a) We will rank all Tier Two proposals according to the criteria in paragraph (b) of this section and the attached chart, which sets forth points we will ascribe for various factors.

(b) We will consider proposals that:

(1) Plan to construct, renovate, and maintain tie-up facilities for transient nontrailerable recreational vessels following priorities identified in your State's program plan (see Subpart M for State program plan information) that the Secretary of the Interior has approved under section 7404(c) of the Sportfishing and Boating Safety Act.	15 points.
(2) Provide for public/private and public/public partnership efforts to develop, renovate, and maintain tie-up facilities. These partners must be other than the Service and lead State agency:	
(i) One partner	5 points.
(ii) Two partners	10 points.
(iii) Three or more partners	15 points.
(3) Use innovative techniques to increase the availability of tie-up facilities for transient nontrailerable recreational vessels (includes education/information).	0–15 points.
(4) Include private, local, or other State funds in addition to the non-Federal match, described in § 86.42:	
(i) Twenty-six percent to thirty-five percent	5 points.
(ii) Between thirty-six and forty-nine percent	10 points.
(iii) Fifty percent and above	15 points.
(5) Are cost efficient. Proposals are cost efficient when the tie-up facility or access site's features add a high value compared with the funds from the proposal, for example, where you construct a small feature such as a transient mooring dock within an existing harbor that adds high value and opportunity to existing features (restrooms, utilities, *etc.*). A proposal that requires installing all of the above features would add less value for the cost.	0–10 points.
(6) Provide a significant link to prominent destination way points such as those near metropolitan population centers, cultural or natural areas, or that provide safe harbors from storms.	10 points.
(7) Provide access to recreational, historic, cultural, natural, or scenic opportunities of national, regional, or local significance. Projects that provide access to opportunities of national, regional, or local significance receive 5 points for each, for a maximum of 15 points	
(8) Provide significant positive economic impacts to a community. For example, a project that costs $100,000 and attracts a number of boaters who altogether spend $1 million a year in the community.	1–5 points.
(9) Include multi-State efforts that result in coordinating location of tie-up facilities	5 points.
(10) Total possible points	105 points.

Criteria	Points
(1) Construct Tie-up Facilities	15
(2) Provide Partnership Efforts	5–15
(3) Use Innovative Techniques	0–15
(4) Include Other Funding Sources	5–15
(5) Are Cost Efficient	0–10
(6) Provide Way Point Linkage	10
(7) Provide Access To Opportunities	5–15
(8) Provide Significant Economic Impacts	1–5
(9) Include Multi-State Efforts	5
(10) Total Possible Points	105

§ 86.61 What process does the Service use to select projects for grants?

The Service's Division of Federal Aid convenes a panel of professional staff to review, rank, and recommend funding to the Service Director. This panel will include representatives from the Service's Washington, DC, and Regional Offices. The Director may convene an advisory panel of nongovernmental organizations to advise and make recommendations to the Federal panel. The Service Director will select projects for grants by August 16, 2001, August 10, 2001, and August 10, 2002, for the three grant cycles.

§ 86.62 What must I do after my project has been selected?

After we approve your award, we will notify you to work with the appropriate Service Regional Office to fulfill the grant documentation requirements and finalize the grant agreement.

§ 86.63 May I appeal if my project is not selected?

If you have a difference of opinion over the eligibility of proposed activities or differences arising over the conduct of work, you may appeal to the Director. Final determination rests with the Secretary of the Interior (50 CFR 80.7).

Subpart G—How States Manage Grants

§ 86.70 What are my requirements to acquire, install, operate, and maintain real and personal property?

(a) You will find applicable regulations for this subject in 43 CFR 12.71 and 12.72. If you have questions about applicability, contact the appropriate Service Regional Office.

(b) You must ensure that the design and installation of tie-up facilities provide for substantial structures that will have a significant longevity, at least 20 years.

(c) You must ensure that you operate, maintain, and use the tie-up facilities and features for the stated grant purpose. You must obtain prior written approval from the appropriate Service Regional Director before you can convert these tie-up facilities to other uses.

§ 86.71 How will I be reimbursed?

For details on how we will pay you, refer to 43 CFR 12.61.

§ 86.72 Do any other Federal requirements apply to this program?

For administrative requirements not covered under these specific guidelines, check 43 CFR 12, which generally applies to all Federal grant programs.

§ 86.73 What if I do not spend all the money?

Funds not obligated or expended after 3 fiscal years from the date of the award revert to the Secretary of Transportation for use in State recreational boating safety programs. (16 U.S.C. 777c(b)(3)(B), 16 U.S.C. 777c(b)(4))

§ 86.74 What if I need more money?

Funds for grants are available only on a competitive basis. Therefore, if you need more money, you must compete in the next grant cycle.

Subpart H—Reporting Requirements for the States

§ 86.80 What are my reporting requirements for this grant program?

(a) For all projects, you must submit to the appropriate Service Regional Office an annual report and a final performance report and otherwise comply with 43 CFR 12.80.

(b) For Tier Two projects, you must submit quarterly reports according to 43 CFR 12.80.

§ 86.81 When are the reports due?

Reports are due as follows:

(a) Annual reports are due 90 days after the grant year ends;

(b) The final performance report is due 90 days after the expiration or termination of grant support;

(c) Tier Two quarterly reports are due January 31, April 30, July 31, and October 31 unless specified otherwise in the grant agreement; and

(d) The State must report certified percentage of completion data and other significant developments in accordance

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with the grant agreement or 43 CFR 12.80.

§ 86.82 What must be in the reports?

The reports must include the following:

(a) You must identify the actual accomplishments compared to the objectives established for the period;

(b) You must identify the reasons for any slippage if established objectives were not met; and

(c) You must identify any additional pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

Subpart I—State Use of Signs and Sport Fish Restoration Symbols

§ 86.90 What are my responsibilities for information signs?

You should install appropriate information signs at boating infrastructure tie-up facilities. You should ensure that this information is clearly visible, directing boaters to the facility. Information should show fees, restrictions, hours of operation, a contact name, and telephone number to report an inoperable facility.

§ 86.91 What are my program crediting responsibilities?

You should give public credit to the Federal Aid in Sport Fish Restoration (SFR) program as the source of funding for the BIG Program. You should recognize this program by using the SFR logo. You are encouraged to use the crediting logo identified in § 80.26 of this chapter to identify national BIG Program projects.

§ 86.92 Who can use the SFR logo?

The States may use the SFR logo and should encourage others to display it. Other people or organizations may use the logo for purposes related to the national BIG Program as authorized in § 80.26 of this chapter.

§ 86.93 Where should I use the SFR logo?

You should display the logo on tie-up facilities that you construct, acquire, develop, or maintain under these grants. You should also use the logo on printed material or other visual representations that relate to project accomplishments or education/information. Refer to § 85.47 of this chapter for logo colors.

§ 86.94 What crediting language should I use?

Suggested examples of language to use when crediting the national BIG Program follow:

(a) Example 1: The Federal Aid in Sport Fish Restoration Program funded this facility thanks to your purchase of fishing equipment and motorboat fuels.

(b) Example 2: The Federal Aid in Sport Fish Restoration Program is funding this construction thanks to your purchase of fishing equipment and motorboat fuels. And,

(c) Example 3: The Federal Aid in Sport Fish Restoration Program funded this (pamphlet) thanks to your purchase of fishing equipment and motorboat fuels.

Subpart J—Service Completion of the National Framework

§ 86.100 What is the National Framework?

The National Framework is the survey, required by the Act, you must use to determine boating access needs in your State. Through a State survey, you must conduct a boating access needs assessment or data collection to determine the adequacy, number, location, and quality of tie-up facilities and boat access sites providing access to recreational waters for all sizes of recreational boats.

§ 86.101 What is the Service schedule to adopt the National Framework?

The Secretary of the Interior adopted the National Framework on September 28, 2000 via a notice in the **Federal Register** (Volume 65, Number 189, Page 58284).

§ 86.102 How did the Service design the National Framework?

The Framework divides the survey into two components: boater survey, and boat access provider survey.

(a) The purpose of the boater survey component is to identify boat user preferences and concerns for existing and needed access available to the public.

(1) The nontrailerable boat data set will fulfill informational needs for you to develop your State program plans as called for in the Act.

(2) The boater survey will survey registered boat owners in your State for two types of boats:

(i) Part A—for nontrailerable recreational vessels.

(ii) Part B—for trailerable and "car-top" boats (less than 26 feet long).

(b) The purpose of the boat access provider component is to identify boat access providers' ideas about current and needed facility and site locations and perceptions of boat user preferences and concerns regarding access. We developed these questions to guide interviews of boat access facility and site managers.

(1) The nontrailerable boat data set will fulfill the informational needs for you to develop your State plans as called for in the Act.

(2) The boat access provider survey will survey facility providers in your State for two types of boats:

(i) Part C—a survey to all providers in your State who allow public access, including State agency and non-State entities (Federal and local government entities, corporate and private/commercial providers), and operate tie-up facilities for nontrailerable recreational vessels.

(ii) Part D—a survey to all providers in your State who allow public access and operate boat access sites for boats less than 26 feet long.

Subpart K—How States Will Complete Access Needs Surveys

§ 86.110 What does the State survey do?

The State survey determines the status of boating access facilities for all recreational boats in your State and your future boater access needs.

§ 86.111 Must I do a survey?

The Act does not require surveys. They are voluntary. However, if you do a survey, you must complete it following the National Framework to receive funds. You must transmit the results to the Service Regional Offices in a common electronic format, such as Microsoft Word, Word Perfect, Excel or Quattro Pro.

§ 86.112 What are the advantages of doing a survey?

Surveys provide the information necessary to fully understand the needs of boaters in your State. Surveys allow you to develop a meaningful plan to provide better access to boaters. Use surveys to complete the plan.

§ 86.113 What if I have recently completed a boat access survey?

If the recent survey substantially answers the provisions in § 86.118, the appropriate Service Regional Office will determine if it is sufficient to meet the needs of the program. If the Regional Office determines that the survey is not sufficient, you must complete that portion(s) or an entire new survey to receive credit for completing a recent survey.

§ 86.114 Do I need to conduct a survey if I already have a plan for installing tie-up facilities?

You need not conduct the survey if the appropriate Secretary of the Interior certifies that you have developed and are carrying out a State program plan, as described in Subpart M of this chapter, that ensures that public boat access exists and is adequate to meet the needs of recreational boaters on your waters.

§ 86.115 How should I administer the survey?

Use a consultant or university specializing in administration of such surveys. Use sample sizes large enough to achieve statistical accuracy so the estimate is within plus or minus 10 percent of the true number.

(a) You may use a telephone, mail, or other type of survey for a sample population of boaters within the State. Costs for telephone and mail surveys are roughly similar. However, response rates for mail surveys are generally lower.

(b) For boat access providers, we prefer that you survey all State agency and non-State providers, but you may survey a sample population.

(c) You may develop your own methodology to collect data, which may include telephone, mail, fax, or other inventory means. We do not expect you to use automated, electronic, mechanical, or similar means of information collection.

(d) Data collected are unique to each respondent. Data collection should use standard survey method criteria to gather information from each respondent.

§ 86.116 May I change the questions in the survey?

You must not change the questions because we need information that is comparable nationwide. We have developed a survey instrument for completing the surveys. We are seeking approval from OMB on the survey questions and the OMB approval does not extend to additional questions.

§ 86.117 Reserved for survey approval schedule.

§ 86.118 What does this survey instrument include?

(a) We divided this survey into four parts. Part A being for transient nontrailerable boat owners. Part B is for trailerable or "car-top" boat owners. Part C is for State agency and non-State providers of facilities for nontrailerable recreational vessels in the State. Part D is for State and non-State providers of access sites for trailerable or "car-top" boats.

(b) Follow these instructions to complete Part A—BOAT OWNER SURVEY FOR TIE-UP FACILITIES FOR NONTRAILERABLE RECREATIONAL VESSELS:

(1) If the boater owns a nontrailerable recreational vessel, ask the boater to fill out Part A;

(2) If the boater owns more than one boat 26 feet or more in length, ask the boater to provide information for the boat he or she uses most often;

(3) If the boater owns at least one boat more than and at least one boat less than 26 feet in length, ask the boater to fill out both Parts A and B; and,

(4) You should use a sample size large enough to achieve statistical accuracy so the estimate is within 10 percent of the true number.

(c) Follow these instructions to complete Part B—BOAT OWNER SURVEY FOR TRAILERABLE OR "CAR-TOP" BOAT ACCESS SITES:

(1) If the boater owns a boat less than 26 feet long, ask the boater to fill out Part B;

(2) If the boater owns more than one boat less than 26 feet long, ask the boater to provide information for the boat he or she uses most;

(3) If the boater owns at least one boat more than and at least one boat less than 26 feet in length, ask the boater to complete both Parts A and B; and,

(4) You should use a sample size large enough to achieve statistical accuracy so the estimate is within 10 percent of the true number.

(d) Parts C and D are surveys for providers of tie-up facilities and boat access sites. Part C is for State agency and non-State providers of facilities for nontrailerable recreational vessels in the State. Part D is for State and non-State providers of boat access sites for boats less than 26 feet in length.

(e) Follow these instructions to complete Part C—STATE AGENCY AND NON-STATE PROVIDER SURVEY FOR TIE-UP FACILITIES:

(1) Ask State agency and non-State providers of tie-up facilities for nontrailerable recreational vessels to fill out Part C.

(2) If more than one State agency manages these facilities, send this survey to all of those agencies.

(3) If the State agency or non-State provider awards grants to others who provide facilities, ask these grantees to respond for these facilities instead of the State agency or non-State provider.

(4) If a State agency or non-State provider operates facilities and sites for both nontrailerable and trailerable boats, ask the provider to fill out both Parts C and D.

(5) Ask State agency and non-State providers to identify all tie-up facilities.

(6) For all questions, if you need additional space, make copies of the appropriate page.

(f) Follow these instructions to complete Part D—STATE AGENCY AND NON-STATE PROVIDER SURVEY FOR TRAILERABLE BOAT ACCESS SITES:

(1) Ask State agency and non-State providers of access sites for boats less than 26 feet long to fill out Part D.

(2) Non-State providers include the Federal Government, local government, corporations, private owners, and others.

(3) If more than one State agency manages these sites, send this survey to all of them.

(4) If the State agency or non-State provider awards grants to others who provide sites, ask these grantees to respond for these sites instead of the State agency or non-State provider.

(5) If a State agency or non-State provider operates facilities and sites for both nontrailerable and trailerable boats, ask the provider to fill out both Parts C and D.

(6) We prefer that the State agency or non-State provider identify all boat access sites and water-bodies, but if he or she has many sites and water-bodies, the provider may group the information together rather than identify each site individually.

(7) For all questions, if you need additional space, make copies of the appropriate page.

Subpart L—Completing the Comprehensive National Assessment

§ 86.120 What is the Comprehensive National Assessment?

The Comprehensive National Assessment is a national report integrating the results of State boat access needs and facility surveys.

§ 86.121 What does the Comprehensive National Assessment do?

The Comprehensive National Assessment determines nationwide the adequacy, number, location, and quality of public tie-up facilities and boat access sites for all sizes of recreational boats.

§ 86.122 Who completes the Comprehensive National Assessment?

The Service completes the Assessment. We will develop standards in consultation with the States.

§ 86.123 Comprehensive National Assessment schedule.

Using the results from the State surveys, the Service will compile the results and produce the Comprehensive National Assessment by September 30, 2003.

§ 86.124 What are the Comprehensive National Assessment products?

The Comprehensive National Assessment products are:

(a) A single report, including the following information:

(1) A national summary of all the information gathered in the State surveys.

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(2) A table of States showing the results of the information gathered.

(3) One-page individual State summaries of the information.

(4) Appendices that include the survey questions, and names, addresses, and telephone numbers of State contacts.

(5) An introduction, background, methodology, results, and findings.

(6) Information on the following:

(i) Boater trends, such as what types of boats they own, where they boat, and how often they boat.

(ii) Boater needs, such as where facilities and sites are now found, where boaters need new facilities and boat access sites, and what changes of features boaters need at these facilities and sites. And

(iii) Condition of facilities.

(b) Summary report abstracting important information from the final national report. And

(c) A key findings fact sheet suitable for widespread distribution.

Subpart M—How States Will Complete the State Program Plans

§ 86.130 What does the State program plan do?

The State program plan identifies the construction, renovation, and maintenance of tie-up facilities needed to meet nontrailerable recreational vessel user needs in the State.

§ 86.131 Must I do a plan?

The Act does not require plans. Plans are voluntary. However, if you do a plan, you must complete it following these regulations.

§ 86.132 What are the advantages to doing a plan?

Plans provide the information necessary to fully understand the needs of boaters operating nontrailerable recreational vessels in your State. The plan will make you more competitive when you submit grants under this program. We will give you 15 points for having an approved plan.

§ 86.133 What are the plan standards?

You must base State program plans on a recent, completed survey following the National Framework.

§ 86.134 What if I am already carrying out a plan?

You need not develop a program plan if we certify that you have developed and are carrying out a plan that ensures public boat access is and will be adequate to meet the needs of recreational boaters on your waters.

§ 86.135 Reserved for plan approval schedule.

§ 86.136 What must be in the plan?

The plan must:

(a) Identify current boat use and patterns of use.

(b) Identify current tie-up facilities and features open to the public and their condition.

(c) Identify boat access user needs and preferences and their desired locations. Include repair, replacement, and expansion needs and new tie-up facilities and features needed.

(d) Identify factors that inhibit boating in specific areas, such as lack of facilities, or conditions attached that inhibit full use of facilities. Identify strategies to overcome these problems.

(e) Include information about the longevity of current tie-up facilities.

§ 86.137 What variables should I consider?

You should consider the following variables:

(a) Location of population centers,

(b) Boat-based recreation demand,

(c) Cost of development,

(d) Local support and commitment to maintenance,

(e) Water-body size,

(f) Nature of the fishery and other resources,

(g) Geographic distribution of existing tie-up facilities,

(h) How to balance the need for new tie-up facilities with the cost to maintain and improve existing facilities.

Dated: December 8, 2000.

Kenneth L. Smith,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 01–951 Filed 1–17–01; 8:45 am]

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Part VIII

Department of Health and Human Services

Administration for Children and Families

45 CFR Part 1310

Head Start Program; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1310

RIN 0970–AB24

Head Start Program

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), DHHS.

ACTION: Final rule.

SUMMARY: This final rule implements the statutory provision for establishing requirements for the safety features and the safe operation of vehicles used by Head Start agencies to transport children participating in Head Start programs.

DATES: 45 CFR 1310.11 and 1310.15(c) are effective January 20, 2004. 45 CFR 1310.12(a) and 1310.22(a) are effective January 18, 2006. 45 CFR 1310.2(c) and 1310.12(b) are effective February 20, 2001. The other provisions of this part are effective January 18, 2002.

FOR FURTHER INFORMATION CONTACT: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, DC 20013; (202) 205–8572.

SUPPLEMENTARY INFORMATION:

I. Program Purpose
II. Background and Purpose of Rule
III. Summary of Major Provisions of the Rule
IV. Rulemaking History
V. Section-by-Section Discussion of Comments
VI. Impact Analysis
VII. List of Subjects in 45 CFR Part 1310
Final Rule

SUPPLEMENTARY INFORMATION

I. Program Purpose

Head Start is authorized under the Head Start Act (the Act), Title VI, Subtitle A, Chapter 8 of the Public Law 97–35, the Omnibus Reconciliation Act of 1981 (42 U.S.C. 9801 *et seq.*). It is a national program providing comprehensive child development services primarily to low-income children, predominantly age three to the age of compulsory school attendance, and their families. To help enrolled children achieve their full potential, Head Start programs provide comprehensive health, nutritional, educational, social and other services.

Additionally, section 645A, of the Head Start Act provides authority to fund programs for families with infants and toddlers. Programs receiving funds under the authority of this section are referred to as Early Head Start programs. Programs are required to provide for the direct participation of the parents of enrolled children in the development, conduct, and direction of local programs. Parents also receive training and education to foster their understanding of and involvement in the development of their children.

While Head Start is intended to serve primarily children whose families have incomes at or below the poverty line, or who receive public assistance, Head Start regulations permit up to 10 percent of the children in local programs to be from families who do not meet these low-income criteria. The Act also requires that a minimum of 10 percent of the enrollment opportunities in each program be made available to children with disabilities. Such children are expected to participate in the full range of Head Start services and activities with their non-disabled peers and to receive needed special educational and related services.

The Head Start Improvement Act of 1992 contained a provision that requires the Head Start Bureau to develop regulations for the safe transportation of Head Start children. In addition, the Final Report of the Advisory Committee on Head Start Quality and Expansion included in its recommendations the development of "* * * regulations to assure that safe and effective transportation services are available." Finally, In July 1999 the National Transportation Safety Board (NTSB) sent a letter to the Department of Health Human Services reporting findings from the investigation of four accidents in which children being transported in non-conforming vans were killed. One of the fatalities was a Head Start child. The NTSB issued clear recommendations to Head Start based on its findings. The NTSB's letter stated that "when States allow children to be transported in vehicles not meeting Federal school bus construction standards, NHTSA's intent of protecting school children is undermined * * *. The Safety Board is firmly convinced that the best way to maximize pupil transportation safety is to require the use of school buses or buses built to equivalent occupant crash protection standards." The NTSB commented that the release of the Head Start Transportation "* * * rulemaking should be expedited to prevent future injuries and fatalities to children enrolled in Head Start programs". The specific recommendations included that "Head Start children be transported in vehicles built to Federal school bus structural standards or the equivalent" and that guidelines provided by the National Highway Traffic Safety Administration's Guideline for the Safe Transportation of Preschool Age Children in School Buses be mandated in the rule. The guidelines are related to child passenger restraint systems. The development of "Performance Standards" for Head Start transportation supports the goal of ensuring that children and families receive high quality Head Start services.

II. Background and Purpose of the Rule

The authority for this final rule is found in sections 640(i) and 644(a) and (c) and 645A(b)(9) of the Head Start Act (42 U.S.C. 9801 *et seq.*). Section 640(i) directs the Secretary to issue regulations establishing requirements for the safety features and the safe operation of vehicles used to transport children participating in Head Start programs. Section 645A(b)(9) requires that Early Head Start agencies comply with requirements established by the Secretary concerning design and operation of such programs. Sections 644(a) and (c) require the issuance of regulations setting standards for organization, management, and administration of Head Start programs.

Since the inception of the program, most Head Start agencies have routinely provided transportation for some Head Start children to and from the classroom when needed, although there has never been a requirement to do so. To date, information on transportation provided to Head Start programs has been limited to a series of Information Memoranda which provide guidance to programs on issues around transportation safety, but which do not require any action on the part of Head Start agencies. The following is a summary of that information:

ACYF–IM–82–01, "Bus Safety," issued on January 19, 1982. This Information Memorandum addresses the applicability of The National Highway Traffic Safety Administration's (NHTSA) Federal Motor Vehicle Safety Standards (45 CFR Part 571) to school buses with a seating capacity of eleven (11) or more. The Administration for Children, Youth and Families suggested that all buses purchased or leased to transport Head Start children meet the NHTSA standards.

ACYF–IM–83–06, "Transportation Safety," issued March 24, 1983. This Information Memorandum provided notification to Head Start programs of a Highway Accident Report prepared by the National Transportation Safety Board (NTSB) on an accident involving a Head Start vehicle. As a result of their investigation, the NTSB recommended that ACYF advise all Head Start programs of the circumstances of the accident in hopes that the report would draw attention to the importance of transportation safety. The Information Memorandum also notified programs of the NTSB's recommendation that ACYF adopt, and emphasize the need for adherence to, the policies and guidelines provided by the National Highway Traffic Safety Administration's (NHTSA) Pupil Transportation Safety Standards, Highway Safety Program Standard Number 17 (now Guideline 17). A copy of Standard 17 was included and programs were "urged" to use the Standard to assess the adequacy of their transportation systems.

ACYF–IM–93–10. "Transportation," issued on March 18, 1993. This Information Memorandum replaced ACYF–IM–82–01 and ACYF–IM–83–06, since both the Federal Motor Vehicle Safety Standards (FMVSS) and NHTSA's Pupil Transportation Safety Standards had been revised. The Information Memorandum provided Head Start programs with a copy of the new Guideline 17 and again encouraged programs to purchase only vehicles that meet the FMVSS for school buses. The Information Memorandum also provided Head Start programs with new information regarding the Federal Highway Administration's (FHWA) Commercial Motor Vehicle Safety Act and the Commercial Driver's License (CDL) program.

As these issuances have been advisory and not legally binding, there have been differing degrees of implementation. Not all Head Start agencies offer transportation services and, among the agencies that do provide transportation, there are varying degrees of quality and safety.

Because of the impact on the overall quality of services provided to children and families and to assure them access to services, we strongly believe that transportation services in Head Start must meet safety and quality regulations. Many low income families who enroll children in Head Start have limited, if any, access to regular transportation. They often do not own, or cannot afford to operate, a vehicle. They frequently are geographically isolated from, or unable to afford, public transportation. Some communities do not provide any public transportation. Head Start transportation services may be required to ensure the enrollment and attendance of the highest need children.

When Head Start children are transported to and from the program, it is important that the time spent in transit be safe and support Head Start learning experiences. In a typical rural Head Start program some children are transported over long distances and spend a significant part of their day en route to and from the classroom. Therefore, the time children spend on the vehicle should be treated with the same level of importance as the time the children spend in the classroom and in other program activities.

We know from experience and documentation that significant variation exists among States in terms of whether or not drivers and vehicles that transport Head Start children are included under the purview of State school bus requirements.

In developing this rule, the Head Start Bureau commissioned a survey of the States to determine whether and the extent to which, the requirements in the State's pupil transportation safety plan applied to Head Start programs. Of the 48 States that responded to the survey, 14 of them stated that their Head Start programs are covered by the State regulations governing pupil transportation, 23 States responded that their Head Start programs are not covered, 10 States gave a conditional response and one (1) State did not know. The survey also indicated significant variation among the States in the amount of training required for school bus drivers. Of the 45 States that responded to this question, 39 have some mandated training requirements for school bus drivers, three States reported that driver training was handled at the local level, and three States reported no mandated training requirements for school bus drivers. More significantly, only 13 States reported mandated driver training for Head Start bus drivers.

This variation, both in the way Head Start programs are viewed by the States as well as differing requirements among the States, limits reliance on the States as the sole source of transportation safety standards for Head Start programs.

Variation among the States in regulation of Head Start transportation services and oversight, was one of the primary determinants of our decision to develop minimum standards for all Head Start programs, regardless of the State or jurisdiction in which they operate.

We have substantially revised the proposed rule by providing that within five years of the date of publication of these regulations, Head Start agencies must use for activities defined as "transportation services", either a school bus or an "Allowable Alternate Vehicle." These two classes of vehicles are defined in the regulations under section 1310.3. The term "Allowable Alternate Vehicle" is used to describe a vehicle which complies with the FMVSS applicable to school buses related to crash survivability and mirrors, but does not meet the other FMVSS which apply to crash prevention, such as the requirements for flashing school bus lights and stop arms, or the provisions in Guideline 17 relating to the color of the vehicle and the use of lights and stop arms. All other parts of the regulation, with the exception of Section 1310.11 and Section 1310.15(a) which are effective three years from the date of publication and Sections 1310.2(c) and 1310.12(b) which are effective 30 days from the date of publication, are effective one year from the date of publication.

The provisions that are effective in one year are important to child passenger safety and pose less burden to grantees than the vehicle, safety restraint, and monitor provisions. The Notice of Proposed Rulemaking included a three year phase-in period for all of the provisions with the exception of driver training. The NPRM invited comments about the feasibility of the three year period. The implementation periods that were selected for each provision resulted from review of the comments and analysis of current Head Start requirements. To improve transportation safety as quickly as possible where it was reasonable the implementation period was changed to one year.

The additional category of vehicle was added to address two significant issues raised during the NPRM comment period. The first issue related to the fact that some States prohibit Head Start and other community based programs from using school buses. The second issue related to concerns raised by Community Transportation Agencies (CTAs) about their ability to continue serving Head Start programs if all Head Start agencies providing transportation services were required to use only school buses. Some CTAs operate vehicles which serve both Head Start grantees and other community organizations, and believe that using only school buses to provide transportation for Head Start programs would interfere with their ability to use the same vehicles to meet the needs of other segments of the community. Other groups, such as senior citizens, might object to the use of school buses to meet their needs, and it would be prohibitively expensive for the CTAs to have separate vehicles to meet the needs of Head Start programs and those of

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other groups. Reconciling the opposing issues related to vehicle structural safety took several years of painstaking work. Significant progress was accomplished through the contributions of the Joint Department of Health and Human Services and Department of Transportation Coordinating Council on Human Services Transportation (now known as the Coordinating Council on Access and Mobility). The development of the allowable alternate vehicle evolved through information exchange, inclusion of multiple perspectives, and willingness to compromise in order to improve the safety of children.

We believe that recognizing an additional class of vehicle without the exterior crash avoidance features is appropriate since those features are not necessary to serving Head Start children. Under Section 1310.20(b)(6), children who must cross the street or highway to board or after exiting the vehicle because curbside drop-off or pick-up is impossible, must be escorted across the street by a bus monitor or other adult. The crash avoidance features are therefore unnecessary to ensure the safety of children being transported to and from Head Start programs.

Formerly, NHTSA interpreted the statutes it is charged with enforcing to prohibit vendors from selling vehicles for use in transporting children enrolled in Head Start programs that do not meet the standards adopted pursuant to those statutes for school buses. The basis for this position was its interpretation of the term "school" in the definition of "schoolbus" appearing in 49 U.S.C. 30125(a)(1) to include Head Start programs.

At the suggestion of the Head Start Bureau, NHTSA reconsidered its interpretation in light of the new wording added to the Head Start Act by the Coats Human Service Reauthorization Act of 1998, Section 102, Pub. L. 105–285, 112 Stat. 2702, 2703. The statute amended Section 636 of the Head Start Act (42 U.S.C. 9831) to provide that "[i]t is the purpose of this subchapter to promote *school readiness* by enhancing the social and cognitive development of low-income children through the provision, to low-income children and their families, of health, educational, nutritional, social, and other services that are determined, based on family needs assessments to be necessary." (Emphasis added.) In view of the rewording of the statute, NHTSA agreed that it was no longer appropriate to consider the Head Start program to be a school program.

The change in NHTSA's position made it possible for the Head Start program to authorize use of a separate category of vehicle, the "Allowable Alternate Vehicle", to transport children enrolled in Head Start programs. The Allowable Alternate Vehicle symbolizes the cooperative approach adopted by the Departments of Transportation and Health and Human Services, over the course of nearly a decade, to solve the complicated problems related to improving the safety of Head Start transportation services.

Vehicles meeting the specifications of Allowable Alternate Vehicles are currently in use in some States that prohibit Head Start programs from using school buses. These vehicles also may be used in States where Head Start is not included under pupil transportation regulations and a program chooses a vehicle with the structural features, but not the appearance, of a school bus. The Head Start Bureau anticipates that manufactures will be able to meet the increased demand for alternate vehicles because school bus manufacturers currently produce such vehicles.

In the development of the rule, we have, with only minor variations, adopted a number of the relevant provisions of Guideline 17 and have referenced several of the Federal Motor Vehicle Safety Standards applicable to school buses. This final rule was developed through ongoing consultation with the National Highway Traffic Safety Administration on the application of the FMVSS and Guideline 17 to Head Start programs.

It should be noted that we do not want to place Head Start agencies in conflict with State requirements. On the contrary, it is our intention to continue to work with the States beyond the implementation of the rule to enhance the relationship between Head Start programs and the State agencies responsible for pupil transportation safety. Toward that end, we consulted with the National Association of State Directors of Pupil Transportation throughout the development of this rule.

Where Guideline 17 lacked specificity or was silent on some aspect that is important for transporting Head Start children, we relied on other resources, such as the National Standards for School Bus Operations, in determining regulatory criteria. For example, the regulation includes requirements for the content of driver training and rules for trip routing. The Transportation Research Board's (TRB) Special Report 222 provided valuable information regarding the use of seat belts on school buses, the need for strict rules for trip routing, and the need to train children in safe riding practices both on and off the bus.

The TRB's examination of the use of seat belts on school buses in Special Report 222, along with NHTSA's recommendation in Guideline 17 that passengers in vehicles with a gross vehicle weight rating of less than 10,000 pounds (which is the class of vehicle most frequently used by Head Start programs) use occupant restraints, raises an issue of special significance to the safe transportation of Head Start children. The use of standard Type I (lap) and Type II (lap and shoulder) seat belts is inappropriate for children who weigh 50 pounds or less, because of the potential for injury from the seat belt itself. Children weighing 50 pounds or less should be seated in child restraint systems designed in accordance with FMVSS No. 213, "Child Restraint Systems." Since almost all Head Start children fall into this lower weight category, we have included such a requirement in the rule. Our decision to include this requirement is based on consultation with organizations such as the American Academy of Pediatrics, the Children's National Medical Center in Washington, DC and the Riley Hospital for Children, Automotive Safety for Children Program in Indianapolis, Indiana. The regulation provides that within three years of its publication, all vehicles must be equipped for use of child restraint systems. In some instances, this may require replacement of existing vehicles. While the regulation allows up to five years to use school buses or allowable alternate vehicles, the full five years will not be available if vehicles are being used that cannot accommodate, or be safely retrofitted to accommodate child restraint systems. We recognize the financial effect that a three year versus a five year implementation period may have for some grantees. We urge grantees to evaluate existing vehicles for capacity to accommodate child restraint systems and plan accordingly. The use of child restraint systems for children weighing 50 pounds or less is critical to their safety.

We have excluded the transportation provided under the Head Start and Early Head Start home-based program option from the requirement for use of school buses or allowable alternate vehicles, and the requirements on driver qualifications and bus monitors. In the home-based option, it may only be necessary to transport parents and children to twice monthly group socializations and other program activities. Usually, the transportation is provided in a vehicle other than a school bus driven by the home visitor, although many programs already use

school buses to transport children enrolled in home-based programs. We anticipate that programs already using school buses will continue the practice. Programs will also need to comply with other requirements of the regulations when transporting children enrolled in home-based programs. We also expect that as more grantees acquire school buses and allowable alternate vehicles for use in transporting children enrolled in other program options, they will make available to children enrolled under the home-based option the same transportation services provided to children enrolled under other program options. We are, however, reluctant at this time to apply the same requirements under the home-based option as other options because local circumstances may at times make it impossible to comply fully with the requirements of the regulations. There may be situations, for example, in rural communities with widely dispersed populations when it will not be possible for a grantee to coordinate its use of vehicles to provide the necessary services using school buses or allowable alternate vehicles to meet the needs of children enrolled in the home-based option as well as those enrolled under the other options that it operates.

It should be noted that the requirements in the regulation which are generally applicable to Head Start, Early Head Start and delegate agencies, such as the requirements for safety education in 45 CFR 1310.21, the requirement for release of a child to a parent, legal guardian, or other individual identified in writing by the parents in 45 CFR 1310.10(g) and the use of appropriate child restraint systems in 45 CFR 1310.11, apply to services under the home-based option.

We recognize that implementing this regulation will require programs to learn its provisions and determine their application in reference to existing State regulations. There are a variety of resources available to support agencies. The Head Start Act requires that an allotment of Head Start and Early Head Start funding be dedicated to training and technical assistance for staff and parents. This is accomplished through a variety of avenues, many of which will be instrumental in supporting grantees as they adopt the provisions of the transportation regulation. The training and technical assistance network consists of local, regional, and national resources. Each region has a Quality Improvement Center (QIC) which supplies the Head Start and Early Head Start programs in its region with a variety of training opportunities that are responsive to program needs and emerging issues. Several of the QIC staff have become experts in transportation issues based on the current needs of grantees they serve. The Head Start Publications Management Center provides the vehicle for distributing information material to all of the Head Start and Early Head Start Grantees and delegate agencies. Materials offered by the Publications Center include the "Transportation Tool Kit" which was developed to provide Head Start programs with resources and information related to transportation services. There are also various training opportunities available through each State's Department of Transportation and several national organizations, including the International Center for Injury Prevention and the Community Transit Assistance Program, have volunteered to participate in providing training to Head Start programs. The National Highway Traffic Safety Program offers extensive training resources and has already been involved in providing materials to Head Start programs. The NHTSA document entitled "Guideline for the Safe Transportation of Pre-school Age Children in School Buses" was distributed to all grantee and delegate agencies in 1999.

III. Summary of the Major Provisions of the Rule

A summary of the major provisions of the final rule follows. The rule:

- Establishes requirements for transportation services for all Head Start, Early Head Start and delegate agencies that transport children to and from program activities;
- Requires that, beginning five years from the publication of the regulation, vehicles used to provide transportation services to Head Start, Early Head Start, and delegate agency program activities be either "school buses" or "allowable alternate vehicles" as those terms are defined in the regulation;
- Requires that children receiving Head Start, Early Head Start and delegate agency transportation services be seated in height and weight-appropriate child restraint systems when the vehicle is equipped for use of such devices.
- Describes the minimum qualifications for operators of vehicles that are used to provide transportation services to children enrolled in Head Start, Early Head Start and delegate agency program activities;
- Describes the training requirements for operators of vehicles that are used to provide transportation service to children enrolled in Head Start, Early Head Start and delegate agencies;
- Describes the vehicle and pedestrian safety training requirements for parents and children;
- Describes the requirements for transportation of children with disabilities; and
- Defines the role of Head Start, Early Head Start and delegate agencies in local efforts to plan and implement coordinated transportation systems in order to achieve greater overall cost effectiveness in providing safe transportation.

The contents of this rule include aspects of the following Department of Transportation guidelines and standards:

- Highway Safety Program Guideline No. 17, "Pupil Transportation Safety," referred to in this text as Guideline 17, published in the **Federal Register** (56 FR 19270, April 26, 1991) and (57 FR 56991, December 2, 1992);
- 49 CFR part 571—Federal Motor Vehicle Safety Standards;
- 49 CFR part 383—Commercial Driver's License Standards: Requirements and Penalties; 49 CFR part 391—Qualifications of Drivers;
- 1990 National Standards for School Buses and School Bus Operations, National Safety Council; and
- Special Report 222, "Improving School Bus Safety," Transportation Research Board, National Research Council, 1989.

We also reviewed the National Highway Traffic Safety Administration's "1999 Guideline for the Safe Transportation of Pre-school Age Children in School Buses." This document confirms that, based on conclusive crash testing research results, preschool age children are most safely transported on school buses when seated using weight-appropriate child safety restraint systems.

IV. Rulemaking History

On June 15, 1995, the Department published a Notice of Proposed Rule Making (NPRM) in the **Federal Register** (60 FR 31612), proposing regulations establishing requirements for the safety features and the safe operation of vehicles used by Head Start agencies to transport enrolled children, safety education, and transportation coordination. Copies of the proposed rule were mailed to all Head Start grantee and delegate agencies. Interested individuals were given 60 days in which to comment on the proposed rule. During the 60-day comment period the Department received more than 800 comments from more than 300 respondents. The respondents included Head Start grantees and public and private agencies and individuals

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interested in Head Start transportation services.

V. Section-by-Section Discussion of Comments

The comments were analyzed and categorized according to regulatory section and again by nature of comment. Only those sections for which comments were made or to which changes were made are discussed below. The discussion of the sections follows the order of the NPRM table of contents and a notation is made wherever the section designations have been changed or deleted from the final rule.

Subpart A—General

Section 1310.1—Purpose

There were no significant comments submitted in response to this section. Language was added to the final rule to clarify that training in pedestrian safety is an included element of the regulation. Language was also added to the effect that agencies must make reasonable efforts to coordinate resources in order to control costs and improve the quality and availability of transportation services.

Section 1310.2—Applicability

Section 1310.2(a) (re-designated as Section 1310.2(c) in the final rule)

This section described the rule's applicability to all Head Start grantees, Early Head Start grantees and delegate agencies.

Comments. Paragraph (a) in the proposed rule specified the rule's applicability to all Head Start grantees and delegate agencies that provide transportation to children. Several respondents objected on the grounds that a school bus would not be able to safely navigate the challenging terrain encompassed within their program area.

Response. We recognize that there are rare circumstances when programs may use non-traditional forms of transportation (*e.g.*, boats for some island programs) to bring children to and from the program. Waiver authority has been added to the final rule under Section 1310.2(c) so that, on a case-by-case basis, the Department of Health and Human Services official may permit exclusion from one or more requirements of the final rule based on "good cause". Good cause will exist only if adherence to a requirement of the Part itself causes a safety hazard in the circumstances faced by the Head Start, Early Head Start or delegate agency. The waiver provision will take effect 30 days after publication of the regulation.

We have excluded home-based program transportation from the vehicle, drive qualification, and bus monitor provisions of the regulation. Home-based Head Start programs may provide transportation to small groups of children and their parents twice per month. Many home-based programs currently use school buses for such transportation and home-based programs are strongly encouraged to use school buses or allowable alternate vehicles whenever possible. When the State in which a Head Start or Early Start program operates sets a higher standard than this regulation, agencies shall comply with the State regulation.

The rule is applicable to all Head Start and Early Head Start grantees and delegate agencies regardless of whether they offer transportation services or not. Some provisions are not applicable if an agency does not provide any transportation services, either directly of through another organization. This includes sub-parts related to vehicles, drivers and trip routing. Other sections are applicable regardless of whether the program provides transportation services or not. Sections which provide requirements for all grantees and delegate agencies include, Section 1310.10(a), (b) and (g), Section 1310.21(a), (c)(2), and (e) and Section 1310.22(c).

Section 1310.3 Definitions

This section supplied definitions for the relevant terms used in the regulation. There were no comments submitted in response to this section of the proposed rule. We have deleted several definitions for terms that were either deleted from the regulation or are self-explanatory and added clarifying language to several others. The term "Transportation" is redefined under "Transportation Services" in the final rule. We added definitions for the terms "Agency", "Agency Providing Transportation Services", "Delegate Agency", "Early Head Start Agency", "Early Head Start Program", "Head Start Agency", "Head Start Program" and "seat belt cuter" to clarify the use of these terms in the regulation. We also added a definition of the "Allowable Alternate Vehicle" because it is a term used in the final rule. We added a definition for "school bus" as the term is used throughout the regulation. Deleted definitions were: "coordinated transportation", "crossing control arm", "stop signal arm", "driver", "winter packs", "driver qualifications", "Guideline 17", "transportation supervisor", "training", "school bus loading zone", and "vehicle". The remaining terms are listed alphabetically in the final rule.

Subpart B—Transportation Requirements

Section 1310.10 General

Section 1310.10(a) (re-designated in the final rule as Section 1310.10(c))

This section required that programs providing transportation to Head Start children comply with the applicable requirements of this Part.

Comments. The majority of letters were supportive and indicated that adoption of the NPRM would yield safer and higher quality transportation services for children in Head Start. Some other respondents expressed concern that the requirement jeopardizes some transportation services provided for Head Start children by public school districts, regional transit authorities and contractors. Many writers expressed support for the increased safety the regulation affords, but are concerned about the cost of compliance. For example, respondents wrote that the increased costs associated with bus monitors, driver certification and training, child safety restraints, using vehicles that meet the identified safety standards, and providing communication equipment would be prohibitive without additional grant funds. Several also objected that the three-year phase in period was unrealistic with respect to replacement of existing vehicles. Some respondents recommended that waivers be allowable for all or most of the rule's requirements.

Response. The requirements of the regulation are essential in assuring the safe transportation of preschool age children. However, waivers under section 1310.2(c) of the final rule shall be granted on a case-by-case basis where adherence to a specific provision would cause a safety hazard in the circumstances faced by the Head Start, Early Head Start, or delegate agency. Requests for waivers should be made to the responsible official of the Department of Health and Human Services.

In response to comments that three years is not a reasonable period for replacement of existing vehicles in order to comply with the regulations, the effective date of sections 1310.12(a) and 1310.22(a), which now provide that children enrolled in Head Start agencies be transported in either school buses or allowable alternate vehicles, will be five years from the date of publication of this part in the **Federal Register**. This change will provide additional time for

necessary financial planning and upgrading and replacing vehicles.

The requirement which appeared in the NPRM at section 1310.11(i) that children are seated in child safety restraint systems is addressed in the final regulation sections 1310.11 and 13.10.15(a) and (d). Those provisions require that beginning on the date three years from publication in the **Federal Register**, each vehicle used to transport children enrolled in Head Start must be equipped for use of height and weight appropriate child restraint systems which conform to the performance requirements (49 CFR 571.213) for use by children weighing fifty pounds or less who will be transported in the vehicle. This requirement can be met either by retrofitting vehicles already in service or by acquiring new vehicles. For an additional explanation of the reasons for the change in the requirements regarding child safety restraint systems, see the discussion of section 1310.11 in this preamble.

Section 1310.10(b)

Paragraph (b) required that Head Start programs assess and document annually decisions about providing transportation to some, all, or none of the enrolled children.

Comments. Several respondents interpreted the requirement to mean programs are required to transport all children. Others feared they would not be allowed to enroll children they could not transport. Respondents objected to the requirement on the basis that additional transportation requirements are too expensive and they would need to reduce their enrollment to meet the transportation requirements.

Response. The requirement's intent is that programs provide transportation services to the degree possible when the lack of such services would preclude an eligible child from participating in Head Start. It requires programs to consider the most efficient and appropriate service provision. The language in the final rule was clarified to make sure that Head Start agencies assist as many children as possible to obtain transportation, either by providing it directly or through some other means, but are not required to transport every child in the program. We deleted the requirement for specified documentation of Head Start agencies' efforts under this section as unnecessarily burdensome.

Section 1310.10(c) (re-designated as Section 1310.10(a) in the final rule)

The section required Head Start agencies that do not provide transportation to some or all of the enrolled children to provide reasonable assistance to help families arrange transportation for their children to and from the program.

Comments. One respondent expressed concern that an implied liability would exist for a Head Start agency that recommended or arranged child transportation services.

Response. We agree that child safety is a primary concern and that programs must be cautious in assisting families in making alternative transportation arrangements. The regulation requires Head Start agencies to assist as many children as possible who need transportation to attend the program to get that transportation. Parents and guardians are responsible for the safety of children in their care when they bring those children to or from Head Start program activities. When the grantee or delegate agency cannot provide transportation services, possible alternative arrangements may be suggested to parents. This is consistent with Head Start Performance Standard 1304.41(a)(2) which requires grantees and delegates agencies to support collaborations that promote the access of children and families to resources that are responsive to their needs.

Section 1310.10(d) (deleted from the final rule)

Paragraph (d) required each Head Start program providing transportation services to have designated full or part-time transportation supervisor to ensure compliance with the requirements of this Part.

Comments. Some respondents objected that if the transportation services are provided contractually or via a school district, a Head Start employed transportation supervisor is not necessary. The objection most frequently cited was that an additional staff position could not be accommodated through existing grant funds.

Response. The requirement for a designated transportation supervisor reflected recognition of the critical nature of safe transportation services and the time and expertise required to ensure safety. Upon consideration of the comments and given the variety of Head Start staffing patterns, we determined that a separate dedicated staff position may not always be necessary to ensure safe and effective transportation services. The language in the final rule specifies transportation regulation oversight and compliance with he applicable requirements of this part in section 1310.10(c). Head Start agencies providing transportation through another organization or individual must monitor the compliance of the transportation provider with the requirements of this part.

Section 1310.10(e) (re-designated as Section 1310.15(c) in the final rule)

Paragraph (e) required vehicles providing Head Start transportation be staffed with at least one bus monitor in addition to the driver.

Comments. The objections to this paragraph related mainly to the cost of employing bus monitors or the belief that monitors are not necessary for small groups of children. Some respondents indicated that finding volunteer monitors is too difficult. Several writers objected to requiring bus monitors to wear seatbelts as they felt this would negatively impact the monitor's ability to assist children during the ride. Several writers recommended additional monitors for larger groups of children.

Response. The final rule maintains the requirement of at least one bus monitor on vehicles transporting Head Start children. Preschool children require adult supervision and assistance to safely board and exit the vehicle, fasten safety restraints, and to evacuate the vehicle in the event of emergencies. The driver's attentions must be primarily focused on safe operation of the vehicle. The final regulations provide in section 1310.15(d) that, except for bus monitors while they are assisting children, all occupants of the vehicle must be seated and wearing seat belts while the vehicle is in motion. As necessary based on passenger needs, programs may elect to assign more than one monitor to a vehicle. Although the term "bus monitor" is being used in the regulations, the requirement in 45 CFR 1310.15(c) applies to all vehicles, except for those used to transport children served under the home-based option, used to provide transportation services after the effective date of the provision.

Section 1310.10(f)

Paragraph (f) required that all accidents involving Head Start vehicles, with or without children on board, must be reported in accordance with State regulations for reporting school bus accidents. There were no specific comments to this section. The language in the final rule was changed to reference "applicable State requirements" to improve clarity.

Section 1310.10(g) (re-designated as Section 1310.10(d)(1) in the final rule)

Paragraph (g) required that vehicles transportation Head Start children be equipped with a communication system for use in the event of emergencies. The

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NPRM referenced a citizen band radio as an example of a communication system.

Comment. Many writers understood the NPRM to require citizen band radios on vehicles that transport Head Start children and objected on several grounds. Notably, some State police departments have advised against this device fearing it could inform potential criminals of the location of a stranded bus load of children and staff. Most respondents were supportive of equipping vehicles that transport Head Start children with communication capacity.

Response. The final rule continues to require a communication system on vehicles, but defers to grantees to select the most appropriate equipment.

Section 1310.10(h) (deleted from the final rule)

Paragraph (h) required the use of special equipment (*e.g.*, winter packs and air conditioning) as necessary for vehicles transporting Head Start children in extreme climatic conditions.

Comments. Some writers requested a definition "extreme climatic conditions." Others stated that the approporiate outfitting of buses should be a local decision.

Response. It was not our intent that this section be prescriptive. We agreed with the respondents who stated that the appropriate outfitting of vehicles should be a local decision and have deleted the special equipment for climate extremes from the final rule.

Section 1310.10(i) (re-designated as Section 1310.10(g), in the final rule)

Paragraph (i) specified that children must be released only to authorized individuals.

Comments. There were few comments in response to this section of the proposed regulation. Two writers recommended clarifying the section to stipulate that child release procedures be required even if the Head Start program is not directly providing the transportation services. One respondent was concerned that a parent with a disability might be unable get outside to put their child on the vehicle and meet the child at the end of the day.

Response. The language in the final rule contains clarification to reinforce that all providers of Head Start, Early Head Start and delegate agency services, including transportation services, must abide by the child release regulation. The provision allows for a child's parent or legal guardian to designate, in writing, other individuals authorized to pick up the child.

Section 1310.11—Vehicles (re-designated as Sections 1310.12–1310.15 in the final rule)

Section 1310.11(a) (re-designated as Section 1310.12(a) in the final rule)

Paragraph (a) specified that vehicles used to transport Head Start children must comply with the recommendations regarding "school buses" as provided in Guideline 17 and prohibited the use of vans in transporting Head Start children.

Comments. This NPRM section elicited the largest number of comments. A number of respondents strongly objected to the prohibition against using vans. While a few writers advocated the use of buses over vans for safety advantages, most stated that programs would not be able to afford to replace vans with school buses and that buses are an inefficient method to transport individual or small groups of children. There were also comments that in some regions of the country, roads are unpaved and require four wheel drive vehicles. Many individuals cited very geographically large service areas as an impediment to reasonably efficient school bus use. One writer cited a State rule permitting the use of qualified vans and drivers if the number of children is fewer than ten and the route would be excessively long if a regular school bus was used.

Response. Substantial effort was devoted to creating a solution that would both improve the safety of vehicles providing Head Start transportation services, not contradict existing State regulations, and be reasonable for use by various transportation providers. The solution provides for the use of either a vehicle that qualifies as a "school bus" or an "Allowable Alternate Vehicle" which is not a school bus but does meet the structural, or crash protection, standards of a school bus. This decision to require that Head Start transportation service providers only use vehicles with the interior safety features required for school buses reflects the research demonstrating that school buses are safer than other vehicles.

The National Highway Traffic Safety Administration confirms that based on research, "school buses have been and remain the safest form of highway transportation" *(School Bus Safety: Safe Passage for America's Children* (1998), p. 5). NHTSA based its conclusion in part on data documenting that the school bus occupant fatality rate of 0.2 fatalities per 100 million vehicle miles traveled (VMT) is much lower than the rates for passenger cars (1.5 per 100 million VMT) or light trucks and vans (1.3 per hundred million VMT). NHTSA established the Federal Motor Vehicle Safety Standards (FMVSS) to make school buses stronger and to provide improved occupant protection (p. 7).

Further evidence of serious safety hazards posed by the use of vans is provided by the National Transportation Safety Board's Highway Special Investigation report titled "Pupil Transportation In Vehicles Not Meeting Federal School Bus Standards" (June 1999). The report's findings are based on the investigation of child fatalities in four accidents where children were being transported in vehicles that did not meet the crash protection standards of school buses. One of the accidents involved children being transported to a Head Start program. The report includes detailed analysis of the crashworthiness of the nonconforming vehicles and provides a table describing the crash protection attributes of different vehicle types. Fifteen-passenger vans do not possess the joint strength or roof rollover protection provided by school buses. Federal school bus standards require that body panel joints be strong enough to resist separation during a crash that can cause sharp cutting edges and openings through which children can be ejected. The Safety Board included a comparison of two accidents, one involving a school bus and one involving a fifteen-passenger van. Although the bus was struck by a much larger, heavier truck it suffered far less intrusion damage than the fifteen-passenger van. The Board found that if the children involved in the van accident had been on a bus, they would have had more "survivable space." The report concludes that "given their better crashworthiness and occupant protection, had school buses or buses providing equivalent occupant crash protection been used in the four accidents * * * the vehicles probably would have suffered less damage and the passengers may have suffered fewer and less severe injuries."

Based on its report, the National Transportation Safety Board issued a letter to the Department of Health and Human Services (July, 1999) recommending the expedition of the rule requiring that Head Start Children be transported in vehicles built to Federal school bus structural standards or the equivalent and that the guidelines from the National Highway Safety Administration's Guideline for the safe Transportation of Preschool Age Children in School Buses regarding child passenger restraint systems be incorporated in the regulation. Both of the Safety Board's recommendations are reflected in the final rule.

Because all children attending Head Start must be accompanied by an adult if they cross a street or highway to board or exit a vehicle, the final regulation permits the use of an "Allowable Alternate Vehicle" which would not be identified as a "school bus," be painted yellow or equipped with flashing lights and a stop arm. The final regulation provides for waiver of one or more of its specific requirements when adherence to a requirement of this part would itself create a safety hazard in the circumstances faced by the Head Start, Early Head Start, or delegate agency, such as when use of a school bus or allowable alternate vehicle is ruled out because of terrain in the area served by the grantee or some other safety factor. In response to the concern about navigating unpaved roads, it should be noted that four wheel drive school buses are currently available.

Section 1310.11(b) (re-designated as Section 1310.12(a) in the final rule)

Section 1310.11(b)(1)(deleted from the final rule)

Paragraph (b)(1) stated that vehicles used for Head Start transportation must comply with all of the Federal Motor Vehicle Safety Standards (FMVSS) for school buses.

Comments. Some respondents objected that Head Start should not be required to use vehicles meeting the FMVSS if Head Start is not included in the State's pupil transportation regulations. Many people asked for additional clarification regarding the definition of allowable exceptions. For example, are medical visits considered incidental and do they require a vehicle complying with the FMVSS for school buses? Cost was again a major topic and several writers suggested a gradual implementation period to reasonably replace existing vehicles with school buses. One writer was concerned that school buses do not include the proper safety restraint systems for young children. Again, several respondents said that school buses cannot navigate rural roadways, which may be unpaved, or very narrow. One comment noted that some States prohibit transit authorities from using school buses and the rule would effectively prevent those agencies from providing Head Start transportation services.

Response. Under section 1310.12(a) the final rule requires that when school buses, as defined in the rule, are used for the planned transportation of Head Start children, they must comply with the FMVSS for school buses, including both crash prevention and crash survivability standards.

In response to the concern that school buses may not be the most practical vehicle to provide transportation in certain circumstances, an alternative acceptable vehicle has been defined in the rule for the purpose of Head Start transportation. The alternative vehicle, called the "allowable alternate vehicle," is defined in these regulations as one which must meet the FMVSS applicable to school buses for crash survivability and mirrors (49 CFR part 571), but is not required by these regulations to meet the standards related to visibility and traffic control. The latter are collectively called crash prevention standards and they include the color of the vehicle, flashing school bus lights, and a stop arm. Crash prevention standards are related to the appearance of vehicles. They include FMVSS 49 CFR 571.108 and 571.131. Requiring the allowable alternate vehicle to meet the crash survivability standards, but not the crash prevention standards, permits greater flexibility in vehicle appearance while maintaining the structural safety features afforded by school buses.

Because Head Start children must be accompanied by an audit when they must cross the street before boarding or after exiting the vehicle, the crash avoidance features are not required for allowable alternate vehicles.

Incidental transportation, which is the unplanned, necessary, transportation of a single child or small group of children for some exceptional purpose, is not required to meet the requirements of the rule relating to transportation services. The distinction between planned and unplanned transportation is designed to allow transportation of children to occur as necessary in unanticipated or exceptional situations. Programs should make every effort to use school buses or allowable alternate vehicles whenever possible. Section 1310.11(b)(1) was deleted in the final rule as it duplicated provisions already specified.

Section 1310.11(b)(2) (re-designated as Section 1310.10(d)(2) and (3) in the final rule)

Proposed paragraph (b)(2) described the requirement that vehicles that transport Head Start children be properly equipped with a fire extinguisher and a first aid kit with location signs for both visibly posted.

Comment. One comment was submitted suggesting most standard first aid kits do not contain adequate supplies for conditions such as shock or severe bleeding.

Response. The final rule maintains the requirement that vehicles transporting Head Start children must be equipped with a fire extinguisher and first aid kit. Seat belt cutters were added to the required safety devices in response to concerns that child safety restraints might slow evacuation of children in an emergency. Grantees are reminded to follow applicable State agency guidelines concerning contents of first aid kit.

Section 1310.11(b)(3) (re-designated under Section 1310.12(a) in the final rule)

Paragraph (b)(3) required that vehicles used to transport Head Start children be equipped with mirrors complying with 49 CFR 571.111.

Comments. There were not comments in response to this section of the proposed regulation.

Response. The specific provision regarding mirrors was deleted as its content is included within the definitions for school buses and allowable alternate vehicles.

Section 1310.11(b)(4) (deleted from the final rule)

Paragraph (b)(4) required that bus steps be equipped with a lower step panel at the primary access point to permit children to step on and off the bus unassisted.

Comments. Several respondents objected to the lower step panel on the grounds that it is too prescriptive and may be unsafe on certain terrain. Further, it was noted that Head Start children vary in size and physical ability and are expected to always have adult assistance when boarding or exiting a Head Start vehicle.

Response. The requirement was deleted from the final rule because we agree with comments that it was more prescriptive than necessary.

Section 1310.11(b)(5) (re-designated as Section 1310.12(a) and (b)(2) in the final rule)

Proposed paragraph (b)(5) stated that vehicles providing Head Start transportation services must be equipped with reverse beepers.

Comments. Writers regarded the reverse beepers as unnecessary because the proposed rule prohibited backing up.

Response. The rule specifies that "vehicles must not be required to back up * * * [on their routes] except when necessary for reasons of safety or because of physical barriers." This requirement reflects that it is not safe for school bus routes to be mapped so that backing up is necessary. A bus, however, may need to back up for reasons of safety or physical barrier. In either instance the reverse beepers notify pedestrians of the driver's

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intention and could prevent accidents and injury. Therefore, the provision was retained.

Section 1310.11(b)(6) (provision addressed in Section 1310.22 in the final rule)

Paragraph (b)(6) specified that vehicles that transport Head Start children must be equipped to accommodate children's special needs (e.g., wheelchair lifts).

Comments. Many respondents interpreted the section to mean that every Head Start vehicle must be equipped to meet the potential needs of children with disabilities and were concerned about unnecessary effort and prohibitive expense. Several respondents asked for clarification regarding the definition of "special equipment" and the portion of an agency's fleet that should be so equipped.

Response. The language in the final rule, section 1310.22(b), specifies that Head Start agencies must meet the requirements of the Americans with Disabilities Act, section 504 of the Rehabilitation Act of 1973, and the Head Start Performance Standards for Children with Disabilities. It is not necessary, or advisable, that every vehicle transporting Head Start children be equipped with a wheelchair lift. We emphasize that Head Start programs must be prepared to meet the special transportation needs of children with disabilities who enroll in the program. Agencies must consider the needs of children with disabilities when arranging for transportation services using school buses or allowable alternate vehicles. Whenever possible, children with disabilities must be transported along with their peers who do not have disabilities.

Section 1310.11(c) (deleted from the final rule)

Paragraph (c) specified that, to the extent allowable within State requirements, vehicles that transport Head Start children must comply with the following recommendations for identification and equipment of a school bus contained in Guideline 17: (1) Be identified with the words "School Bus" printed in letters not less than eight inches high, located between the warning signal lamps as high as possible without impairing visibility of the lettering from both front and rear, and have no other lettering on the front or rear of the vehicle except as required by Federal Motor Vehicle Safety Standards (FMVSS), 49 CFR part 571; (2) be painted National School Bus Glossy Yellow, in accordance with the specification of National Institute of Standards and Technology (NIST) Federal Standard No. 595a, Color 13432, except that the hood should be either that color or lusterless black, matching Nist Federal Standard No. 595a, Color 37038; (3) have bumpers of glossy back, matching NIST Federal Standard 595a, Color 17038, unless, for increased visibility, they are covered with a reflective material; (4) be equipped with a stop signal arm as specified in FMVSS No. 131 (49 CFR 571.131) and a crossing control arm; and (5) be equipped with a system of signal lamps that conforms to the performance requirements of FMVSS No. 108 (49 CFR 571.108).

Comments. No significant comments were received in response to paragraphs (c)(1)–(2). There were, however, a few respondents objecting to the bumper color requirement on the grounds it would require expensive retrofitting of existing vehicles. There were also respondents who objected to paragraphs (c)(4) and (5) which required that vehicles comply with the FMVSS for stop signal arms, crossing control arms, and signal lamps. Several respondents indicated that crossing control arms are unnecessary because Head Start children should only enter or exit buses curbside. There were objections to increased costs for all safety features.

Response. The safety features that would have been required by the proposed Section 1310.11(c)(1)–(5) were deleted from the final regulations because they are not necessary in view of the requirement that children using Head Start vehicles be accompanied by a bus monitor or other adult when they must cross the street before boarding or after exiting the vehicle. The final rule identified the required features for allowable alternate vehicles and school buses under its definitions, Section 1310.3.

Section 1310.11(d) (re-designated as Section 1310.14 in the final rule)

Section 1310.11(d)(1) (re-designated as Section 1310.14 in the final rule)

Paragraph (d)(1) required Head Start agencies to assure that vehicle specifications are correctly provided and that the intended use is identified in bid announcements.

Comments. Respondents requested that bus specifications and purchase procedures be provided by the Head Start Bureau.

Response. Requirements for vehicles to be used in Head Start transportation services are defined in the final rule either explicitly or through reference to other requirements, such as provisions of the FMVSS. Grantees can comply with the requirement to ensure that bid solicitations include correct vehicle specifications by citing or restating the relevant requirements of these regulations, as well as any applicable State requirements. Since the relevant Federal specifications are set forth in the regulations, no changes were made to the final rule.

Section 1310.11(d)(2) (re-designated as Section 1310.14 in the final rule)

Section 1310.11(e) (re-designated as Sections 1310.12(a) and (b) in the final rule)

Paragraph 1310.11(e) specified that existing vehicles not compliant with the FMVSS and the minimum capacity requirement must be replaced within a three-year period. It also reminded readers that, in accordance with 42 U.S.C. 9839(g)(2)(c), Head Start funds may be used for capital expenditures to purchase buses.

Comments. Many respondents objected to the three-year phase in period as far shorter than the useful life of some vehicles. Several individuals suggested periods between five and ten years as more accomplishable and reasonable.

Response. Head Start agencies that are transporting children enrolled in their programs in vehicles which do not meet the requirements under Section 1310.12 should consider replacing those vehicles with compliant vehicles as soon as possible. The allowable limit for vehicle replacement has been extended to five years in order to accommodate the useful life of vehicles that are relatively new at the time the rule is published. Also, the wording of the final regulation has been changed to require that each agency providing transportation services must transport children enrolled in its programs in school buses or allowable alternate vehicles that are equipped for use of height and weight appropriate child restraint systems, and that have reverse beepers. It should be noted that existing vehicles which cannot be equipped to safely accommodate child restraint systems must be replaced within three years of publication of the final rule. We recognize that in a minority of cases this could necessitate vehicle replacement before the full five year period expires or the vehicle's useful like is completely exhausted. This constitutes a reasonable compromise because it will affect relatively few vehicles, three years is an adequate amount of planning time, and restraint systems are essential to child passenger safety. The implementation of child restraint systems should occur as quickly as is reasonably possible.

Paragraph (b) was added to the final rule to clarify that, beginning thirty days after publication of the rule, vehicles purchased with Head Start funds for use transporting children must meet the requirements of paragraph (a).

The language reminding readers that Head Start funds may be used for capital expenditures including buses was deleted as it appears elsewhere (as referenced above) and it is not directly a part of this regulation.

Section 1310.11(f) and (h) (combined and re-designated as Section 1310.15(a) in the final rule)

Paragraph (f) proposed that all passengers on a Head Start vehicle be seated while it is in motion. Paragraph (h) proposed that bus drivers, monitors and other passengers must wear seat belts when the vehicle is in motion.

Comments. Two respondents stated that bus monitors may need to attend to children while the bus is moving and therefore might not be able to remain seated.

Response. While the vehicle is in motion, all children and adults must be wearing appropriate safety restraints. In the event of an emergency while the bus is moving, the monitor may need to unfasten his or her seatbelt and move to assist a child. The language in the final rule was changed slightly to require that, other than a monitor assisting a child, all passengers must remain seated and use appropriate safety restraints while the vehicle is in motion.

Section 1310.11(g) (re-designated as Section 1310.10(e) in the final rule)

Paragraph (g) stated that the use of auxiliary seating was prohibited.

Comments. Several respondents objected to the prohibition against auxiliary seating in wheelchair lift equipped vehicles or adjacent to an emergency door.

Response: The NPRM did to intend to prohibit correctly installed auxiliary seating. The final rule clarifies that all seats must be permanent and pass inspection.

Section 1310.11(i) (re-designated as Section 1310.15(a) in the final rule)

The NPRM indicated that children weighing less than 50 pounds should be seated using child safety restraint seats.

Comments. There were few responses to this item. One respondent objected to the cost and space implications of child safety seats, saying that installing the seats would reduce seating capacity by a third. Another respondent suggested that transportation staff training in the correct use of transportation safety seat use be required in the final rule. A final respondent expressed concern that use of child restraint systems would delay the evacuation of children in an emergency.

Response. Because the National Highway Traffic Safety Administration Guideline for the Safe Transportation of Preschool Children in School Buses concludes that children weighing 50 pounds or less are most safely transported on school buses when they are seated in age- and weight-appropriate restraint systems, this requirement was retained with explicit reference to the 50-pound requirement (National Highway Traffic Safety Administration, 1999). It is expected that programs will make sure transportation staff receive instruction in the correct use of the child restraint system. There are more child restraint systems and more vehicle configurations than were available when the NPRM was published in 1995. The three year implementation period for child safety seats and the five year period for vehicle implementation was designed to provide planning time for grantees with regard to issues such as seat spacing. The final rule requires vehicles transporting Head Start children to be equipped with seat belt cutters which could be used to speed the evacuation of children in an emergency.

Section 1310.11(j) (re-designated as Section 1310.15(b) in the final rule)

Section 1310.11(k) (re-designated as Section 1310.13 in the final rule)

Section 1310.11(k)(1) (re-designated as Section 1310.13(a) in the final rule)

This standard proposed a thorough safety inspection of each vehicle at least annually through a State licensed or operated inspection system.

Comments. One response objected that the requirement is too prescriptive, another suggested it should specifically identify inspection components, a third voiced concern that the rule would conflict with State regulations and a final respondent stated unconditional support.

Response. Regular vehicle inspections are an integral element of safe transportation services. As provided in section 1310.2(a) of the final rule, this provision will apply except when there is an applicable State or local requirement that sets a higher standard.

Section 1310.11(k)(2) (re-designated as Section 1310.13(b) in the final rule)

Section 1310.11(k)(3) (re-designated as Section 1310.13(c) in the final rule)

Section 1310.12—Driver Qualifications (re-designated as Section 1310.16 in the final rule)

Section 1310.12(a) (re-designated as Section 1310.16(a) in the final rule)

Section 1310.12(a)(1) (deleted from the final rule)

Paragraph (a)(1) addressed Head Start transportation service driver qualifications. The proposed requirement was that drivers be at least 21 years of age.

Comments. Several people wrote that they currently use drivers who are eighteen or nineteen years and older as is allowable in their States. Others strongly supported that drivers be at least 21 years old.

Response. The minimum age requirement was removed from the final rule. The final regulation requires that all drivers of vehicles providing Head Start transportation possess Commercial Drivers Licenses and meet physical and other requirements.

Section 1310.12(a)(2) (re-designated as Section 1310.16(a)(1) in the final rule)

Paragraph (a)(2) listed the requirement that drivers providing Head Start transportation possess a Commercial Driver's License (CDL).

Comments. The majority of objections were to the cost implications of having current drivers obtain and meet the ongoing requirements for the CDL. Several respondents were also concerned that the wages paid to Head Start drivers are not competitive with public school bus drivers or commercial truck drivers. One writer objected that the CDL requirement is "just a way to ensure that all Head Start drivers are drug and alcohol tested." A few respondents were concerned about the implications of the CDL requirement for the Home-based program option.

Response. The Commercial Driver's License requirements establish a driver's qualifications to operate the appropriate class of passenger vehicle. The CDL is viewed as the best assurance that drivers will meet essential minimum standards. The final rule retains the CDL requirement in States where such licenses are granted. All operators of commercial motor vehicles are required to have CDLs. Commercial motor vehicles include vehicles designed to carry 16 or more passengers, including the driver. Many States have extended the inclusion to all vehicles used to provide pupil transportation. To

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obtain a CDL, vehicle operators must pass written and driving tests in accordance with Federal Standards for the vehicle the person intends to operate. The knowledge test includes such topics as proper procedures for loading and unloading passengers, proper response to emergencies, proper response at railroad crossings and proper braking procedures. The skills test requires applicants to demonstrate basic vehicle control, safe driving, and air brake skills. The topics addressed by the CDL tests are deemed essential for operators of vehicles transporting children. The cost of transportation services may increase as current transportation providers employ drivers with CDLs to meet the requirements of this part. However, many providers already employ CDL drivers as is required by their State. Grantees and delegate agencies will need to assess current practice and make training and budget plans accordingly.

Home-based programs are encouraged to use drivers with CDL's to provide child transportation services, however, home-based programs are excluded from the vehicle type, driver qualification and bus monitor provisions of this regulation. Incidental transportation is not included under the provisions of this Part.

Section 1310.12(a)(3) (re-designated as Section 1310.16(a)(2) in the final rule)

Paragraph (a)(3) proposed that drivers meet physical, mental, moral, and other requirements established by Federal and State regulations, including rules regarding drug and alcohol use.

Comments. The majority of respondents emphasized the importance of drug and alcohol testing. Some objected to the term "moral requirements" as too subjective.

Response. We agreed with writers that the word "moral" is subject to variable interpretation and it was deleted from the final rule.

Section 1310.12(b) (re-designated as Section 1310.16(b) in the final rule)

Paragraph (b) proposed that each Head Start agency establish its own applicant screening procedure and system for informing applicants of required background checks. Criteria for the rejection of applicants not meeting the requirements would also be established.

Comments. There were two respondents who indicated that their current background check procedures are adequate. Several comments supported the importance of background checks as part of applicant screening.

Response. Driver background checks are an important element of safe transportation services. Some agencies will find that they already meet the requirements of the rule and others will need to establish or improve their systems. This section remains unchanged in the final rule.

Section 1310.12(c) (re-designated as Section 1310.16(b)(1) in the final rule)

Section 1310.12(c)(1) (re-designated under Section 1310.16(b) in the final rule)

Paragraph (c)(1) proposed that applicant screening procedures include an application that provides employment history, educational background, and personal references. There were no significant comments to this section. However, paragraph (c)(1) was removed and the introductory language in (c) edited to include a reference to 45 CFR 1304.52(b)(1), which contains requirements for staff recruitment and selection.

Section 1310.12(c)(2) (re-designated under Section 1310.16(b) in the final rule)

This paragraph required an interview and screening procedure to help establish that an applicant is "of good moral character" and does not abuse drugs or alcohol.

Comments. Writers objected to the phrase "good moral character" as subjective and ambiguous.

Response. We agree that the term "good moral character" is difficult to define and it was deleted from the final rule. The required physical, interviews and background checks will help identify any candidate who fails to meet established employment criteria. In the interest of accuracy and inclusiveness, the term "State Department of Motor Vehicles" was changed to the final rule to "appropriate State agency."

Section 1310.12(c)(4) (re-designated as Section 1310.16(b)(3) in the final rule.)

This section proposed that drivers have physical examinations.

Comments. Writers were generally supportive of physical examinations for bus drivers.

Response. This provision has been rewritten to require that after a conditional offer of employment and before the applicant begins work as a driver, a medical examination must be performed by a licensed doctor of medicine or osteopathy to establish that the individual possesses the physical ability to perform any job-related functions with any necessary accommodations. The wording of the provision was changed to make the provision consistent with the requirements of the Americans with Disabilities Act.

Section 1310.13—Driver Training (re-designated as Section 1310.17 in the final rule)

Section 1310.13(a) (re-designated as Section 1310.17(a) in the final rule)

Paragraph (a) in the NPRM required that driver training plans include both pre-service and annual in-service training programs.

Comments. There were not comments specifically applicable to paragraph (a). Comments on other sections reflected a need to clarify the requirements in this section.

Response. The provision was re-worded in the final rule to clarify that drivers must receive training prior to operating a vehicle and annually thereafter. The words "pre-service" and "in-service" were replaced to reflect the growing number of twelve month programs.

Section 1310.13(b)(1) (re-designated as Section 1310.17(b) in the final rule).

The section proposed that drivers transporting Head Start children receive a minimum of 40 hours of skills training prior to providing transportation and outlined specific skill areas.

Comments. This area attracted multiple comments objecting to the 40 hour pre-service requirement on the grounds it is excessive and unreasonable. Others stated that the pre-service training regulation is substantially more than their State requires for public school drivers. Another respondent raised the practical difficulty of providing 40 hours of pre-service training to a driver hired during the program year, rather than at the beginning.

Response. We agree with the respondents who wrote the 40 hours of pre-service training may, in some cases, be more than necessary. Per respondent recommendation, the language in the final rule has been changed to require training topics, rather than hours. Each program will decide on the number of hours necessary to effectively cover the required material. The required content of training remains unchanged and programs are expected to design training plans that will include the required skill areas.

Section 1310.13(b)(1)(i)–(vii) (re-designated as Section 1310.17(b)(1)–(7) in the final rule)

Section 1310.13(b)(2)(i)–(iii) (re-designated as Section 1310.17(b)(2) and (c) in the final rule)

Paragraphs (b)(2)(i)–(iii) specified pre-service training in addition to the previously listed skills training.

Comments. Respondents again objected to the time requirement for pre-service training.

Response. The final rule has been modified to allow the non-skills based training to occur in accordance with the agency's driver training plan. This allows programs to design and deliver training that is effective and efficient in meeting individual program needs.

Section 1310.13(c)(2) (re-designated under Section 1310.17 in the final rule)

Section 1310.13(c)(1) and (2) (deleted from the final rule)

These items proposed eight hours of in-service training annually to maintain and enhance driver skills.

Comments. Respondents were evenly split on whether eight hours would constitute too much or too little in-service driver training.

Response. The final rule specifies content requirements for in-service training and leaves decisions concerning the number of hours of training to individual Head Start agencies. Sections 1310.13(c)(1) and (2) were deleted from the final rule.

Section 1310.13(d) (re-designated as Section 1310.17(e) in the final rule)

Section 1310.13(e) (re-designated as Section 1310.17(f) in the final rule)

Section 1310.13(f) (Re-designated as Section 1310.17(a) in the final rule)

Paragraph (f) stated that drivers of vehicles that transport Head Start children employed on the effective date of this regulation must meet the pre-service training as new drivers within three months of that date.

Comments. There were several comments suggesting that three months is insufficient to provide the required training for existing drivers.

Response. There are two changes in the final rule that address the above concerns and provide time requirement relief. The first is that the rule identifies training topic requirements, but leaves decisions about the amount of training time necessary to the grantee. The second is that the time to train currently employed drivers has been extended from three months from the provisions' effective date to one year and 90 days from that date. This change will allow agencies to use their regularly scheduled staff training to provide the required driver training. Programs are expected to provide the required training to drivers as quickly as possible.

Section 1310.13(g) (re-designated as Section 1310.17(f)(1) in the final rule)

Paragraph (g) specified that Head Start drivers must be evaluated annually by the transportation supervisor and that the evaluation must include an on-board observation of driving performance.

Comments. Respondents requested that the wording be changed from "transportation supervisor" to "supervisor" to allow local flexibility in performing this function.

Response. While the supervisory functions outlined for transportation services in the NPRM remain, the requirement for a "transportation supervisor" has been deleted. We anticipate that most programs directly providing transportation services will employ a full- or part-time person to supervise transportation services. Some programs may elect to assign the supervisory responsibilities to an existing position. Agencies that use another organization or an individual for transportation services will monitor a contract or agreement that requires the contractor to perform driver supervision.

Section 1310.13(h) (re-designated as Section 1310.17(f)(2) in the final rule)

Paragraph (h) proposed that programs should provide the same pre- and in-service training to bus monitors that they provide for drivers.

Comments. Many respondents objected to this requirement on the basis that bus monitors are often volunteers who would not be amenable or available for this training. Some respondents also indicated that it is not necessary that bus monitor training be as rigorous as driver training.

Response. The final rule was changed to state that programs must specifically provide bus monitors with training in the areas of: child boarding and exiting procedures, use of child restraint systems, responding to emergencies, emergency evacuation procedures, use of special equipment, required paperwork, child pick up and release procedures and pre- and post-trip vehicle checks (*e.g.*, ensure that there are no safety hazards and that no child is left on the bus). The burden of the requirement has been eased by eliminating the requirement that monitors receive exactly the same training as drivers. The provisions identifies types of training that monitors must receive to ensure that safety-related topics are included.

Section 1310.20—Trip Routing

Section 1310.20(b)(1)

This paragraph proposed limiting the transit time for a child to or from Head Start to no more than one-hour unless there is express written approval from the Regional Office.

Comments. Several writers stated that the one-hour limit is unrealistic or even impossible in rural areas.

Response. We acknowledge that limiting bus routes to one-hour is problematic in some areas. We wish to stress that children should spend the shortest amount of time possible on the Head Start vehicle given the routing safety parameters outlined in Section 1310.20(a) and the geography of the service area. The language in the final rule has been modified to allow greater flexibility.

Section 1310.20(b)(2)

The NPRM proposed that vehicles transporting Head Start children may not be loaded beyond capacity at any time.

Comments. A few respondents proposed that, because preschool children are "small," three could be seated per bench even though this exceeds the vehicle's posted capacity.

Response. All children receiving Head Start transportation must be seated with a size-appropriate safety restraint in a manufacturer designated seat. The final rule retains the stipulation that at no time may vehicle capacity be exceeded. The wording of the provision has been changed by eliminating the first sentence of the proposed rule to clarify the requirement.

Section 1310.20(b)(3)

The proposed rule stated that vehicles should not be required to back up or perform "U" turns during routes.

Comments. Some respondents objected on the grounds that there may be situations (*e.g.*, roads with no outlet) when a three-point or "U" turn is required. It as noted that prohibiting "U" turns could result in more need for children to cross the street. Finally, a contradiction between the preamble's prohibition of "U" turns and this section's use of the term "should not" was identified.

Response. The final rule emphasizes that vehicles must not be required to back up on their routes or make "U" turns, except when necessary for reasons of safety or because of physical barriers. Every effort to avoid these maneuvers must be made through route planning. Extreme caution must be used

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in negotiating "U" turns, backing up, or three point turns.

Section 1310.20(b)(4)–(6)

These paragraphs proposed that Head Start vehicle stops should: be located to minimize traffic disruptions and allow the driver a good field of view in front of and behind the vehicle; and minimize the need for children to cross the street to board or leave the vehicle. In addition, the section proposed that if children must cross the street or highway after boarding or exiting the vehicle, they must be escorted across the street by the driver, bus monitor, or another adult, and that under no circumstances may a school bus stop be located in a way that children must cross the street or highway unless the vehicle is equipped to stop traffic as described in the proposed section 1310,.11(c)(1)–(5).

Comments. Respondents strongly objected to a driver leaving the vehicle to accompany a child across the street. It was also noted that some States prohibit flashing red lights in urban areas.

Response. We agree that under no circumstance should a driver leave the vehicle to escort a child across the street and have changed the final rule to so state. The requirement for equipping school buses with flashing red lights and other exterior features proposed in section 1310.11(c)(1)–(5) has been withdrawn from the final regulation. The bus monitor or another adult must accompany every child boarding or exiting the bus. The word "should" which appeared in the NPRM was changed to "must" to clarify that this is a requirement and not a recommendation.

Section 1310.20(b)(7)

The section proposed establishment of specific procedures in the event alternate routes are required by hazardous weather or other situations.

Comments. Respondents requested clarification of the NPRM phrase "or other situations which may arise that could affect the safety of the children en route."

Response. The final rule, while recognizing that every contingency cannot be anticipated, has listed several events that could lead to the need to find a different route. The intent is to assure that there are specific procedures in place in the event unplanned re-routing is required by any situation. Possible hazards, in addition to weather conditions such as ice or water build up, include water or natural gas line breaks, emergency road repair, natural disaster damage caused by earthquake, tornado, or flood, a motor vehicle accident, a building fire, or a crime scene.

Section 1310.21—Safety Education

Section 1310.21(a)

This requirement proposed that Head Start programs should provide pedestrian safety training to caregivers and children who do not receive Head Start transportation.

Comments. All respondents supported this section. It was noted that programs will need to use careful practices to emphasize that preschool age children should not be crossing the street alone. Also, there was a suggestion that the phrase "as developmentally appropriate" be included in the section.

Response. We have re-worded the final rule slightly to emphasize that preschool children must not cross the street alone. We have also specified that pedestrian safety teaching must be appropriate for each child's development. Finally, we removed specific content requirements so grantees may design training to meet individual community needs and conditions.

Section 1310.21(b)(1)–(5)

Paragraph (b) identified the safety instruction that Head Start programs would be required to provide to children transported to and from the program.

Comments. Comments were submitted suggesting the safety education be included in the daily lesson plan and that nationally produced videos be supplied for programs to use for safety instruction.

Response. The final rule remains unchanged except that the term "bus" is changed to "vehicle" to clarify applicability to various transportation possibilities. The rule defines the content safety teaching must include, but leaves the method to the local program.

Section 1310.21(c) (re-designated Section 1310.21(c)(1) in the final rule)

Section 1310.21(e) (re-designated as Section 1310.21(c)(2) in the final rule)

Paragraph (e) proposed that child and caregiver safety training should occur within the first five days of the program year.

Comments. There were many objections that the five-day time limit is unreasonable and, in some cases, impossible.

Response. As suggested by respondents, the final rule was modified to allow that safety instruction must occur within the first thirty days of the program year.

Section 1310.21(f) (re-designated as Section 1310.21(d) in the final rule)

This section proposed that a minimum of two bus evacuation drills per year in addition to the one required under section 1310.21 (b)(5) be required.

Comments. The comments ranged from recommending monthly evacuation drills to suggesting that the drills themselves could pose a safety risk and are unnecessary.

Response. The requirement is consistent with the pupil transportation regulations in many States and, therefore, remains unchanged in the final rule.

Section 1310.21(g) (re-designated as Section 1310.21(e) in the final rule)

Paragraph (g) proposed that teachers should develop daily activities to remind children of the safety procedures.

Comments. Some respondents questioned the need for daily lessons.

Response. The final rule requires staff to make safety reminders an integral, developmental and individualized part of program experiences rather than a discrete, daily, directly instructed lessons. The word "should" was replaced by "must" because passenger and pedestrian safety awareness are essential elements of safe transportation service. Based on data indicating that most school bus related fatalities occur when a child is in the loading zone, NHTSA states that "educating children on how to be safe pedestrians is fundamental to school bus safety" (*School Bus Safety: Safe Passage for America's Children*, p.7)

Section 1310.22—Children With Disabilities

This section of the NPRM specified that transportation services to children with disabilities enrolled in Head Start comply with the Head Start performance Standards on Service for Children with Disabilities.

Comments. There were no significant comments to this section of the regulation. Other sections provoked concerns that the proposed rule would require all vehicles used for Head Start transportation be wheelchair accessible.

Response. Head Start and Early Head Start programs are currently obligated to meet the requirements of the Americans with Disabilities Act, Head Start Performance Standards on Services for Children with Disabilities and Section 504 of the Rehabilitation Act of 1973. Under these regulations they must accommodate the special needs of children with disabilities. Paragraph (a) of this section in the final rule was amended to clarify that Head Start transportation services must be accessible and that children with disabilities should be transported on vehicles that meet the requirements for school buses or allowable alternate vehicles. Transportation provided under the home-based option is excepted from this provision unless the agency uses school buses or allowable alternate vehicles to transport other children enrolled in the home-based option. This exception has been created because it may not always be possible to ensure that when the agency does not regularly use school buses or allowable alternate vehicles to transport children receiving home-based services that an accessible school bus or allowable alternate vehicle will be available from another source when needed. The rule also specifies that, whenever possible, children with disabilities should be transported on the same vehicles used to transport other children in the program.

Section 1310.23—Coordinated Transportation

Section 1310.23 (a)(1) (re-designated under Section 1310.23(a) and 1310.23(b)(1) in the final rule)

Paragraphs (a) and (a)(1) proposed that Head Start grantees coordinate transportation resources with other human service agencies whenever possible to maximize access and efficiency. Agencies would be required to provide an analysis of the cost of providing transportation directly versus contracting for the service.

Comments. Many respondents cited examples of difficulties obtaining transportation services from other providers. In particular, it was noted that while public schools might like to transport Head Start children, they rarely have space available on their buses. Finally, respondents noted that the vehicles used by other human service agencies would likely not meet Head Start vehicle requirements.

Response. The NPRM was prefaced with the phrase "whenever possible and to the extent feasible." It is understood that the opportunities for coordinated transportation services will vary across communities. The final rule was changed to clarify transportation coordination activities in which Head Start transportation providers will participate whenever possible. The phrase "coordinate transportation services as follows" was deleted from the final rule as it is unnecessary.

Section 1310.23(a)(3) (re-designated as § 1310.23(b)(3) in the final rule)

The NPRM stated that where no coordinated transportation system exists in a community, the Head Start grantee should make every effort to provide the impetus for the formation of a transportation coordinating council.

Comments. Respondents suggested that the language needs to more strongly emphasize recognition that, with the exception of the local education agency (LEA), Head Start may be the only transportation service provider operating in some communities.

Response. The phrases "make every effort" and "where feasible" in the NPRM were intended to reflect responsiveness to individual community needs. The requirement in the final rule specifies that when there is no coordinated transportation system, Head Start agencies will identify any other agencies providing transportation and support the establishment of a local transportation coordinating council where reasonable.

Section 1310.23(a)(4) (deleted from the final rule)

This item specified that records be maintained to document compliance with the coordination requirements.

Comments. Respondents objected to keeping additional records.

Response. We agree with the respondents that this paragraph posed an unnecessary burden and have deleted it from the final rule. However, programs are expected to support the continuity and efficiency of community transportation whenever possible.

VI. Impact Analysis

Executive Order 12866

Executive Order 12866 requires that regulations be drafted to ensure that they are consistent with the priorities and principles set forth in this Executive Order. The Department has determined that this rule is consistent with these priorities and principles. This final rule implements the statutory authority to promulgate regulations for the safe transportation of Head Start children.

Congress made no additional appropriation to fund this new authority, however, and so any money spent toward the purchase of vehicles, additional personnel, training or other purposes related to this regulation is money that would have been spent otherwise by the program or other programs from the same appropriation amount. We believe that we have focused these rules in ways that encourage maximum cost-effectiveness in transportation spending decisions.

Executive Order 13132

Executive Order 13132 on Federalism applies to policies that have federalism implications, defined as "regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This rule does not have federalism impacts as defined in the Executive Order.

The Head Start Bureau surveyed the States to determine the applicability of State pupil transportation regulations to the Head Start program and learn about each States pupil transportation system. The Bureau also consulted extensively with Head Start programs and the Department of Transportation in the development of the regulation.

Family Well-Being Impact

As required by Section 654 of the Treasury and General Government Appropriation Act of 1999, we have assessed the impact of this final rule on family well-being. This rule will improve the safety of preschool children being transported to and from Head Start programs and promote pedestrian and passenger safety training to adults and children.

Regulatory Flexibility Act of 1980

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses. For each rule with a "significant economic impact on a substantial number of small entities" an analysis must be prepared describing the rule's impact on small entities. Small entities are defined by the Act to include small businesses, small non-profit organizations and small governmental entities. These regulations would affect small entities. However, it should be noted that many Head Start agencies already provide transportation services in accordance with State and local requirements. Furthermore, the increased costs associated with implementing this regulation's provisions are small and well within grantees' capacity to manage. The total estimate of $18.9 million, less than one-third of one-percent of Head Start's annual budget, is comprised of three requirements. These are: $4.8 million to employ additional bus monitors for those relatively few programs currently operating vehicles without monitors;

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$10 million to recruit and retain qualified bus drivers with Commercial Driver's Licenses for programs currently using drivers without the credential; and $4.1 million to purchase child safety restraint systems. ACF acknowledges that compliant vehicles can, in some cases, be more costly than non-compliant vehicles. However, these additional costs are generally offset by the fact that compliant vehicles may last longer, accommodate more children, and incur lower insurance costs than non-compliant vehicles.

Currently, approximately 75 percent of all programs offer transportation services to some or all of their enrolled children and about 53 percent of all Head Start enrolled children receive transportation services. It is not anticipated that the implementation of the rule will cause any significant change in the numbers of children being transported.

We believe that meeting the requirements of this regulation is feasible and will not impose excessive burden because we are providing a five-year phase-in period for compliance with vehicle requirements, a three-year compliance period for child safety restraint systems, and a twelve-month compliance period for other provisions of the rule. The five-year implementation period was adopted in response to comments elicited by the NPRM indicating that the useful life of a vehicle may be longer than the three years proposed in the NPRM. Therefore, the potential financial burden posed by the regulation will be significantly offset by avoiding the premature replacement of vehicles. The five-year period is further supported by the fact that 20–30 percent of the vehicles operated by Head Start are replaced each year. The rule offers ample margins to absorb the useful life of most existing vehicles. The financial burden on Head Start agencies that acquire vehicles meeting the standards in these regulations is further eased by a provision in the Head Start Act which authorizes the Secretary to allow Head Start grantees to use grant funds to pay the cost of amortizing the principal and the interest on loans to finance the purchase of vehicles (42 U.S.C. 9839(g)(2)(C)). Finally, grantees have been instructed for several years to purchase only conforming vehicles with Federal funds, so the majority of vehicles in the existing fleet are school buses or qualify as allowable alternate vehicles. For the reasons outlined above, no additional costs are anticipated related to vehicle replacement.

The potential burden imposed by the transportation regulation's requirement for bus monitors is lessened by the fact that Head Start agencies that directly operate transportation services already employ more than 7,500 bus monitors. Many other organizations providing transportation services to children enrolled in Head Start also currently, either voluntarily or in response to State or local regulation, staff vehicles providing transportation to Head Start and Early Head Start agencies with bus monitors in addition to the driver. This part of the regulation has a three-year implementation period to ease the impact by providing planning time for transportation providers not currently employing or using volunteer bus monitors. In addition, many bus monitors fulfill dual roles, such as kitchen aide or teacher aide and bus monitor. This may be financially advantageous to both the employee and the employer and represents a mechanism to further reduce the impact of the provisions.

The regulation specifies that agencies must offer transportation assistance to families when transportation services are not provided through the Head Start program. This requirement is consistent with section 1304.41(a)(2) which directs grantee and delegate agencies to "promote the access of children and families to community services that are responsive to their needs * * *" Because such assistance is an integral element of the ongoing work of grantees and delegate agencies, the provision poses no additional burden.

The decision to require two-way communication capacity on vehicles was carefully weighed in consideration of both its contributions to improved safety and increased cost. Many vehicles that transport children are now supplied with two-way communication devices. While the requirement represents an expense for some operators, the flexibility regarding type of equipment and the steadily decreasing cost for communication equipment suggest a minimal financial burden.

Head Start and Early Head Start grantees and delegate agencies that currently rely on drivers who do not possess Commercial Drivers Licenses (CDLs) may find an increased cost associated with recruiting and retaining drivers with that license or retaining transportation services from another organization that supplies drivers with CDLs. However, in 1993, the Administration for Children and Families issued an Information Memorandum (ACYF–IM–9310) advising Head Start grantees and delegate agencies of the requirement that any vehicle designed to carry 16 or more passengers must be operated by a driver with a CDL. Many drivers providing Head Start transportation services currently possess CDLs and there is not an anticipated increase in the overall number of drivers, therefore; the burden of the provision is diminished.

Substantial attention was dedicated to assessing alternative methods for improving transportation safety through channels other than the provisions of this regulation. Extensive research, the strongly worded recommendations of the National Transportation Safety Board and Head Start's 35-year history providing transportation services to very young children guided development of each of the regulation's provisions.

For example, some respondents suggested that the adult-to-child ratio while children are being transported should be the same as the one required in Head Start classrooms. That would result in, depending on the children's ages, between one adult for every nine children and one adult for every four children. Another commenter indicated that bus monitors are not necessary at all as the driver can handle vehicle operation and child safety needs without assistance. The decision to require a minimum of one bus monitor per vehicle ensures that children's safety needs will be met, the driver can focus primarily on operating the vehicle, and that the burden is reasonable. One monitor is considered adequate during transportation, but not in the classroom, because children are not mobile while riding the vehicle and the space is contained. The NPRM provisions required the exclusive use of vehicles meeting the Federal standards for a school bus in providing Head Start transportation services. The provision was modified in the final rule to permit the use of an allowable alternate vehicle. The alternate vehicle provides a higher degree of flexibility for transportation providers and is responsive to many of the comments elicited by the NPRM.

We believe that as Head Start agencies become more familiar with these requirements, any additional burden will be rendered less significant through the improved transportation safety for Head Start children. For these reasons, the Secretary certifies that these rules will not have a significant impact on substantial numbers of small entities.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act (Pub. L. 104–4) requires agencies to prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an expenditure of $100,000,000 or more in any one year. Resources presently allocated by Head Start programs for transportation services are substantial and may be supplemented as necessary to meet additional requirements posed by the rule over the course of the implementation period.

Congressional Review

This rule is not a major rule as defined in 5 U.S.C., Chapter 8.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980, Public Law 96–511, all Departments are required to submit to the Office of Management and Budget (OMB) for review and approval any reporting or record-keeping requirement inherent in a proposed or final rule. This final rule contains no new information collection requirements.

List of Subjects in 45 CFR Part 1310

Head Start, Reporting and recordkeeping requirements, Transportation.

(Catalog of Federal domestic Assistance Program Number 93.600, Project Head Start)

Dated: September 6, 2000.

Olivia A. Golden,

Assistant Secretary for Children and Families.

Approved: October 11, 2000.

Donna E. Shalala,

Secretary.

For the reasons set forth in the Preamble, 45 CFR Chapter XIII is amended by adding Part 1310 as follows:

PART 1310—HEAD START TRANSPORTATION

Subpart A—General

Sec.
1310.1 Purpose.
1310.2 Applicability.
1310.3 Definitions.

Subpart B—Transportation Requirements

1310.10 General.
1310.11 Child Restraint Systems.
1310.12 Required use of School Buses or Allowable Alternate Vehicles.
1310.13 Maintenance of vehicles.
1310.14 Inspection of new vehicles at time of delivery.
1310.15 Operation of vehicles.
1310.16 Driver qualifications.
1310.17 Driver and bus monitor training.

Subpart C—Special Requirements

1310.20 Trip routing.
1310.21 Safety education.
1310.22 Children with disabilities.
1310.23 Coordinated transportation.

Authority: 42 U.S.C. 9801 *et seq.*

Subpart A—General

§ 1310.1 Purpose.

Under the authority of sections 640(i) and 645A(b)(9) of the Head Start Act (42 U.S.C. 9801 *et seq.*), this part prescribes regulations on safety features and the safe operation of vehicles used to transport children participating in Head Start and Early Head Start programs. Under the authority of sections 644(a) and (c) and 645A(b)(9) of the Head Start Act, this part also requires Head Start, Early Head Start, and delegate agencies to provide training in pedestrian safety and to make reasonable efforts to coordinate transportation resources to control costs and to improve the quality and the availability of transportation services.

§ 1310.2 Applicability.

(a) This rule applies to all Head Start and Early Head Start agencies, and their delegate agencies (hereafter, agency or agencies), including those that provide transportation services, with the exceptions provided in this section, regardless of whether such transportation is provided directly on agency owned or leased vehicles or through arrangement with a private or public transportation provider. Transportation services to children served under the home-based Option for Head Start and Early Head Start services are excluded from the requirements of 45 CFR 1310.12, 1310.15(c), and 1310.16. Except when there is an applicable State or local requirement that sets a higher standard on a matter covered by this part, agencies must comply with requirements of this part.

(b) Sections 1310.12(a) and 1310.22(a) of this part are effective January 18, 2006. Sections 1310.11 and 1310.15(c) of this part are effective January 20, 2004. Paragraph (c) of this section and § 1310.12(b) of this part are effective February 20, 2001. All other provisions of this part are effective January 18, 2002.

(c) Effective February 20, 2001 an agency may request a waiver of specific requirements of this part, except for the requirements of this paragraph. Requests for waivers must be made in writing to the responsible Health and Human Services (HHS) official, as part of an agency's annual application for financial assistance or amendment thereto, based on good cause. "Good cause" for a waiver will exist when adherence to a requirement of this part would itself create a safety hazard in the circumstances faced by the agency. Under no circumstance will the cost of complying with one or more of the specific requirements of this part constitute good cause. The responsible HHS official is not authorized to waive any requirements of the Federal Motor Vehicle Safety Standards (FMVSS) made applicable to any class of vehicle under 49 CFR part 571. The responsible HHS official shall have the right to require such documentation as the official deems necessary in support of a request for a waiver. Approvals of waiver requests must be in writing, be signed by the responsible HHS official, and be based on good cause.

§ 1310.3 Definitions.

Agency as used in this regulation means a Head Start or Early Head Start or delegate agency unless otherwise designated.

Agency Providing Transportation Services means an agency providing transportation services, either directly or through another arrangement with a private or public transportation provider, to children enrolled in its Head Start or Early Head Start program.

Allowable Alternate Vehicle means a vehicle designed for carrying eleven or more people, including the driver, that meets all the Federal Motor Vehicle Safety Standards applicable to school buses, except 49 CFR 571.108 and 571.131.

Bus monitor means a person with specific responsibilities for assisting the driver in ensuring the safety of the children while they ride, board, or exit the vehicle and for assisting the driver during emergencies.

Child Restraint System means any device designed to restrain, seat, or position children who weigh 50 pounds or less which meets the requirements of Federal Motor Vehicle Safety Standard No. 213, Child Restraint Systems, 49 CFR 571.213.

Commercial Driver's License (CDL) means a license issued by a State or other jurisdiction, in accordance with the standards contained in 49 CFR part 383, to an individual which authorizes the individual to operate a class of commercial motor vehicles.

Delegate Agency means a local public or private not-profit or for-profit agency to which a Head Start or Early Head Start agency has delegated all or part of its responsibility for operation of a Head Start program.

Early Head Start Agency means a public or private non-profit or for-profit agency or delegate agency designated to operate an Early Head Start program

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pursuant to Section 645A of the Head Start Act.

Early Head Start Program means a program of services provided by an Early Head Start Agency funded under the Head Start Act.

Federal Motor Vehicle Safety Standards (FMVSS) means the National Highway and Traffic Safety Administration's standards for motor vehicles and motor vehicle equipment (49 CFR part 571) established under section 30111 of Title 49, United States Code.

Fixed route means the established routes to be traveled on a regular basis by vehicles that transport children to and from Head Start or Early Head Start program activities, and which include specifically designated stops where children board or exit the vehicle.

Head Start Agency, means a local public or private non-profit or for-profit agency designated to operate a Head Start program pursuant to Section 641 of the Head Start Act.

Head Start Program means a program of services provided by a Head Start agency or delegate agency and funded under the Head Start Act.

National Driver Register means the National Highway Traffic Safety Administration's automated system for assisting State driver license officials in obtaining information regarding the driving records of individuals who have been denied licenses for cause; had their licenses denied for cause, had their licenses canceled, revoked, or suspended for cause, or have been convicted of certain serious driving offenses.

National Standards for School Buses and School Bus Operations means the recommendations resulting from the Eleventh National Conference on School Transportation, May 1990, published by the National Safety Council, Chicago, Illinois.

Reverse beeper means a device which automatically sounds an intermittent alarm whenever the vehicle is engaged in reverse.

School Bus means a motor vehicle designed for carrying 11 or more persons (including the driver) and which complies with the Federal Motor Vehicle Safety Standards applicable to school buses.

Seat Belt Cutter means a special device that may be used in an emergency to rapidly cut through the seat belts used on vehicles in conjunction with child restraint systems.

State means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments.

Transportation Services means the planned transporting of children to and from sites where an agency provides services funded under the Head Start Act. Transportation services can involve the pick-up and discharge of children at regularly scheduled times and pre-arranged sites, including trips between children's homes and program settings. The term includes services provided directly by the Head Start and Early Head Start grantee or delegate agency and services which such agencies arrange to be provided by another organization or an individual. Incidental trips, such as transporting a sick child home before the end of the day, or such as might be required to transport small groups of children to and from necessary services, are not included under the term.

Trip routing means the determination of the fixed routes to be traveled on a regular basis for the purpose of transporting children to and from the Head Start or Early Head Start program or activities.

Subpart B—Transportation Requirements

§ 1310.10 General.

(a) Each agency must assist as many families as possible who need transportation in order for their children to attend the program in obtaining that transportation.

(b) When an agency has decided not to provide transportation services, either for all or a portion of the children, it must provide reasonable assistance to the families of such children to arrange transportation to and from its activities. The specific types of assistance being offered must be made clear to all prospective families in the program's recruitment announcements.

(c) Each agency providing transportation services is responsible for compliance with the applicable requirements of this Part. When an agency provides transportation through another organization or an individual, the agency must ensure the compliance of the transportation provider with the requirements of this part.

(d) Each agency providing transportation services, must ensure that each vehicle used in providing such services is equipped with:

(1) a communication system to call for assistance in case of an emergency:

(2) safety equipment for use in an emergency, including a charged fire extinguisher that is properly mounted near the driver's seat and a sign indicating its location;

(3) a first aid kit and a sign indicating the location of such equipment; and

(4) a seat belt cutter for use in an emergency evacuation and a sign indicating its location.

(e) Each agency providing transportation services must ensure that any auxiliary seating, such as temporary or folding jump seats, used in vehicles of any type providing such services are built into the vehicle by the manufacturer as part of its standard design, are maintained in proper working order, and are inspected as part of the annual inspection required under § 1310.13(a) of this subpart.

(f) Each agency providing transportation services must ensure that all accidents involving vehicles that transport children receiving such services are reported in accordance with applicable State requirements.

(g) Each agency must ensure that children are only released to a parent or legal guardian, or other individual identified in writing by the parent or legal guardian. This regulation applies when children are not transported and are picked up from the classroom, as well as when they are dropped off by a vehicle Agencies must maintain lists of the persons, including alternates in case of emergency, and up-to-date child rosters must be maintained at all times to ensure that no child is left behind, either at the classroom or on the vehicle at the end of the route.

§ 1310.11 Child Restraint Systems.

Effective January 20, 2004, each agency providing transportation services must ensure that each vehicle used to transport children receiving such services is equipped for use of height- and weight-appropriate child safety restraint systems.

§ 1310.12 Required use of School Buses or Allowable Alternate Vehicles.

(a) Effective January 18, 2006, each agency providing transportation services must ensure that children enrolled in its program are transported in school buses or allowable alternate vehicles that are equipped for use of height- and weight-appropriate child restraint systems, and that have reverse beepers. As provided in 45 CFR 1310.2(a), this paragraph does not apply to transportation services to children served under the home-based option for Head Start and Early Head Start.

(b) Effective February 20, 2001, each Head Start and Early Head Start agency receiving permission from the responsible HHS official to purchase a vehicle with grant funds for use in providing transportation services to children in its program or a delegate agency's program must ensure that the funds are used to purchase a vehicle that is either a school bus or an allowable alternate vehicle and is equipped

(1) for use of height- and weight-appropriate child restraint systems; and

(2) with a reverse beeper.

(c) As provided in 45 CFR 1310.2(a), paragraph (b) of this section does not apply to vehicles purchased for use in transporting children served under the home-based option for Head Start and Early Head Start.

§ 1310.13 Maintenance of vehicles.

Each agency providing transportation services must ensure that vehicles used to provide such services are maintained in safe operating condition at all times. The organization operating the vehicle must establish and implement procedures for:

(a) a thorough safety inspection of each vehicle on at least an annual basis through an inspection program licensed or operated by the State;

(b) systematic preventive maintenance on such vehicles; and

(c) daily pre-trip inspection of the vehicles by the driver.

§ 1310.14 Inspection of new vehicles at the time of delivery.

Each agency providing transportation services must ensure that bid announcements for school buses and allowable alternate vehicles for use in transporting children in its program include the correct specifications and a clear statement of the vehicle's intended use. Such agencies must ensure that there is a prescribed procedure for examining such vehicles at the time of delivery to ensure that they are equipped in accordance with the bid specifications and that the manufacturer's certification of compliance with the applicable FMVSS is included with the vehicle.

§ 1310.15 Operation of vehicles.

Each agency providing transportation services, either directly or through an arrangement with another organization or an individual, to children enrolled in its program must ensure that:

(a) On a vehicle equipped for use of such devices, any child weighing 50 pounds or less is seated in a child restraint system appropriate to the height and weight of the child while the vehicle is in motion.

(b) Baggage and other items transported in the passenger compartment are properly stored and secured and the aisles remain clear and the doors and emergency exits remain unobstructed at all times.

(c) Effective January 20, 2004, there is at least one bus monitor on board at all times, with additional bus monitors provided as necessary, such as when needed to accommodate the needs of children with disabilities. As provided in 45 CFR 1310.2(a), this paragraph does not apply to transportation services to children served under the home-based option for Head Start and Early Head Start.

(d) Except for bus monitors who are assisting children, all vehicle occupants must be seated and wearing height- and weight- appropriate safety restraints while the vehicle is in motion.

§ 1310.16 Driver qualifications.

(a) Each agency providing transportation services must ensure that persons who drive vehicles used to provide such services, at a minimum:

(1) in States where such licenses are granted, have a valid Commercial Driver's License (CDL) for vehicles in the same class as the vehicle the driver will operating; and

(2) meet any physical, mental, and other requirements established under applicable law or regulations as necessary to perform job-related functions with any necessary reasonable accommodations.

(b) Each agency providing transportation services must ensure that there is an applicant review process for use in hiring drivers, that applicants for driver positions must be advised of the specific background checks required at the time application is made, and that there are criteria for the rejection of unacceptable applicants. The applicant review procedure must include, at minimum:

(1) all elements specified in 45 CFR 1304.52(b), with additional disclosure by the applicant of all moving traffic violations, regardless of penalty;

(2) a check of the applicant's driving record through the appropriate State agency, including a check of the applicant's record through the National Driver Register, if available in the State; and

(3) after a conditional offer of employment to the applicant and before the applicant begins work as a driver, a medical examination, performed by a licensed doctor of medicine or osteopathy, establishing that the individual possesses the physical ability to perform any job-related functions with any necessary accommodations.

(c) As provided in 45 CFR 1310.2(a), this section does not apply to transportation services to children served under the home-based option for Head Start and Early Head Start.

§ 1310.17 Driver and bus monitor training.

(a) Each agency providing transportation services must ensure that persons employed to drive vehicles used in providing such services will have received the training required under paragraphs (b) and (c) of this section no later than 90 days after the effective date of this section as established by § 1310.2 of this part. The agency must ensure that drivers who are hired to drive vehicles used in providing transportation services after the close of the 90 day period must receive the training required under paragraphs (b) and (c) prior to transporting any child enrolled in the agency's program. The agency must further ensure that at least annually after receiving the training required under paragraphs (b) and (c), all drivers who drive vehicles used to provide such services receive the training required under paragraph (d) of this section.

(b) Drivers must receive a combination of classroom instruction and behind-the-wheel instruction sufficient to enable each driver to:

(1) operate the vehicle in a safe and efficient manner;

(2) safely run a fixed route, including loading and unloading children, stopping at railroad crossings and performing other specialized driving maneuvers;

(3) administer basic first aid in case of injury;

(4) handle emergency situations, including vehicle evacuation procedures;

(5) operate any special equipment, such as wheelchair lifts, assistance devices or special occupant restraints;

(6) conduct routine maintenance and safety checks of the vehicle; and

(7) maintain accurate records as necessary.

(c) Drivers must also receive instruction on the topics listed in 45 CFR 1304.52(k)(1), (2) and (3)(i) and the provisions of the Head Start Program Performance Standards for Children with Disabilities (45 CFR 1308) relating to transportation services for children with disabilities.

(d) Drivers must receive refresher training courses including the topics listed in paragraphs (b) and (c) of this section and any additional necessary training to meet the requirements applicable in the State where the agency operates.

(e) Each agency providing transportation services must ensure that drivers who transport children receiving

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the services qualify under the applicable driver training requirements in its State.

(f) Each agency providing transportation services must ensure that:

(1) the annual evaluation of each driver of a vehicle used to provide such services includes an on-board observation of road performance; and

(2) before bus monitors assigned to vehicles used to provide such services begin their duties, they are trained on child boarding and exiting procedure, use of child restraint systems, any required paperwork, responses to emergencies, emergency evacuation procedures, use of special equipment, child pick-up and release procedures and pre- and post-trip vehicle check.

Subpart C—Special Requirements

§ 1310.20 Trip routing.

(a) Each agency providing transportation services must ensure that in planning fixed routes the safety of the children being transported is the primary consideration.

(b) The agency must also ensure that the following basic principles of trip routing are adhered to:

(1) The time a child is in transit to and from the Head Start or Early Head Start program must not exceed one hour unless there is no shorter route available or any alternative shorter route is either unsafe or impractical.

(2) Vehicles must not be loaded beyond the maximum passenger capacity at any time.

(3) Vehicles must not be required to back up or make "U" turns, except when necessary for reasons of safety or because of physical barriers.

(4) Stops must be located to minimize traffic disruptions and to afford the driver a good field of view in front of and behind the vehicle.

(5) When possible, stops must be located to eliminate the need for children to cross the street or highway to board or leave the vehicle.

(6) If children must cross the street before boarding or after leaving the vehicle because curbside drop off or pick up is impossible, they must be escorted across the street by the bus monitor or another adult.

(7) Specific procedures must be established for use of alternate routes in the case of hazardous conditions that could affect the safety of the children who are being transported, such as ice or water build up, natural gas line breaks, or emergency road closing. In selecting among alternatives, transportation providers must choose routes that comply as much as possible with the requirements of this section.

§ 1310.21 Safety education.

(a) Each agency must provide training for parents and children in pedestrian safety. The training provided to children must be developmentally appropriate and an integral part of program experiences. The need for an adult to accompany a preschool child while crossing the street must be emphasized in the training provided to parents and children. The required transportation and pedestrian safety education of children and parents, except for the bus evacuation drills required by paragraph (d) of this section, must be provided within the first thirty days of the program year.

(b) Each agency providing transportation services, directly or through another organization or an individual, must ensure that children who receive such services are taught:

(1) safe riding practices;

(2) safety procedures for boarding and leaving the vehicle;

(3) safety procedures in crossing the street to and from the vehicle at stops;

(4) recognition of the danger zones around the vehicle; and

(5) emergency evacuation procedures, including participating in an emergency evacuation drill conducted on the vehicle the child will be riding.

(c) Each agency providing transportation services must provide training for parents that:

(1) emphasizes the importance of escorting their children to the vehicle stop and the importance of reinforcing the training provided to children regarding vehicle safety; and

(2) complements the training provided to their children so that safety practices can be reinforced both in Head Start and at home by the parent.

(d) Each agency providing transportation services must ensure that at least two bus evacuation drills in addition to the one required under paragraph (b)(5) of this section are conducted during the program year.

(e) Each agency providing transportation services must develop activities to remind children of the safety procedures. These activities must be developmentally appropriate, individualized and be an integral part of the Head Start or Early Head Start program activities.

§ 1310.22 Children with disabilities.

(a) Effective January 18, 2006 each agency must ensure that there are school buses or allowable alternate vehicles adapted or designed for transportation of children with disabilities available as necessary to transport such children enrolled in the program. This requirement does not apply to the transportation of children receiving home-based services unless school buses or allowable alternate vehicles are used to transport the other children served under the home-based option by the grantee. Whenever possible, children with disabilities must be transported in the same vehicles used to transport other children enrolled in the Head Start or Early Head Start program.

(b) Each Head Start, Early Head Start and delegate agency must ensure compliance with the Americans with Disabilities Act (42 U.S.C. 12101 *et seq.*), the HHS regulations at 45 CFR part 84, implementing Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), and the Head Start Program Performance Standards on Services for Children with Disabilities (45 CFR part 1308) as they apply to transportation services.

(c) Each agency must specify any special transportation requirements for a child with a disability when preparing the child's Individual Education Plan (IEP) or Individual Family Service Plan (IFSP), and ensure that in all cases special transportation requirements in a child's IEP or IFSP are followed, including:

(1) special pick-up and drop-off requirements;

(2) special seating requirements;

(3) special equipment needs;

(4) any special assistance that may be required; and

(5) any special training for bus drivers and monitors.

§ 1310.23 Coordinated transportation.

(a) Each agency providing transportation services must make reasonable efforts to coordinate transportation resources with other human services agencies in its community in order to control costs and to improve the quality and the availability of transportation services.

(b) At a minimum, the agency must:

(1) identify the true costs of providing transportation in order to knowledgeably compare the costs of providing transportation directly versus contracting for the service;

(2) explore the option of participating in any coordinated public or private transportation systems existing in the community; and

(3) where no coordinated public or private non-profit transportation system exists in the community, make every effort to identify other human services agencies also providing transportation services and, where reasonable, to participate in the establishment of a

local transportation coordinating council.

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Part IX

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries; Final Rule

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H370A]

RIN 1218–AB85.

Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries; Final Rule

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor

ACTION: Final Rule; Request for Comment on the Information Collection (Paperwork) Requirements

SUMMARY: The Occupational Safety and Health Administration is revising the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

DATES: Effective Date: The effective date is April 18, 2001. Written comments: Written comments on the Information Collection Requirements must be submitted on or before March 19, 2001.

ADDRESSES: Copies of materials in the docket may be obtained from the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693–2350. Referenced documents are included in Docket H370A and are identified by the exhibit number indicated.

Submit written comments on the Information Collection Requirements to the Docket Office, Docket No. ICR–0180 (2001), OSHA, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693–1648.

In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of the standard.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Director, OSHA Office of Public Affairs, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693–1999.

SUPPLEMENTARY INFORMATION:

I. Events Leading to the Amended Final Rule

Blood and other potentially infectious materials have long been recognized as a potential threat to the health of employees who are exposed to these materials by percutaneous contact (penetration of the skin). Injuries from contaminated needles and other sharps have been associated with an increased risk of disease from more than 20 infectious agents (Exs. 3–172GG, 3–274C). The primary agents of concern in current occupational settings are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV).

To reduce the health risk to workers whose duties involve exposure to blood or other potentially infectious materials, OSHA promulgated the Bloodborne Pathogens (BBP) standard (29 CFR 1910.1030) on December 6, 1991 (56 FR 64004). The provisions of the standard were based on the Agency's determination that a combination of engineering and work practice controls, personal protective equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission.

Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials continue to be of concern due to the high frequency of their occurrence and the severity of the health effects associated with exposure. The Centers for Disease Control and Prevention has estimated that healthcare workers in hospital settings sustain 384,325 percutaneous injuries involving contaminated sharps annually (Ex. 5–4). When non-hospital healthcare workers are included, the best estimate of the number of percutaneous injuries involving contaminated sharps is 590,164 per year (Ex. 3–172V). When these injuries involve exposure to infectious agents, the affected workers are at risk of contracting disease. Workers may also suffer from adverse side effects of drugs used for post-exposure prophylaxis and from psychological stress due to the threat of infection following an exposure incident.

Since publication of the BBP standard, a wide variety of medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. These "safer medical devices" replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. In a September 9, 1998, Request for Information (RFI), OSHA solicited information on occupational exposure to bloodborne pathogens due to percutaneous injury (63 FR 48250). Based in part on the responses to the RFI, the Agency has pursued an approach to minimize the risk of occupational exposure to bloodborne pathogens that involves three components. First, the Agency proposed that the revised Recordkeeping standard (29 CFR 1904) include a requirement that all percutaneous injuries from contaminated needles and other sharps be recorded on OSHA logs (61 FR 4030). Second, OSHA issued a revised compliance directive for the BBP standard on November 5, 1999, to reflect advances made in medical technology and treatment. The directive guides OSHA's compliance officers in enforcing the standard and ensures that consistent inspection procedures are followed. Third, the Agency placed amendment of the bloodborne pathogens standard on its regulatory agenda to more effectively address sharps injuries.

Congress was prompted to take action in response to growing concern over bloodborne pathogen exposures from sharps injuries and in response to recent technological developments that increase employee protection. On November 6, 2000, the Needlestick Safety and Prevention Act was signed into law. The Act directs OSHA to revise the BBP standard in accordance with specific language included in the Act.

II. Statutory Authority

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act, Pub. L. 106–430. The Act requires OSHA to revise the BBP standard within six months of the Act's enactment. To facilitate expeditious completion of this directive, Congress explicitly exempted OSHA from procedural requirements generally attending rulemaking under OSH Act 6(b) and from the procedural requirements of the Administrative Procedure Act (5 U.S.C. 500 *et seq.*).

III. Summary and Explanation

The revisions to OSHA's BBP standard required under the Needlestick Safety and Prevention Act can be broadly categorized into four areas: modification of definitions relating to engineering controls; revision and updating of the Exposure Control Plan; solicitation of employee input; and recordkeeping.

The revised standard adds two additional terms to the definition section found in paragraph (b) and alters the definition of one other term. It adds "Sharps with Engineered Sharps Injury Protections" and defines this term as "a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident." This term encompasses a broad array of devices that make injury involving a contaminated sharp less likely, and includes, but is not limited to, syringes with a sliding sheath that shields the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; and intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering.

The revised standard also adds the term "Needleless Systems," which is defined as "a device that does not use needles for: (A) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (B) the administration of medication or fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps." "Needleless Systems" provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle.

The definition of "Engineering Controls" has been modified to include as examples "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems." This change clarifies that safer medical devices are considered to be engineering controls under the standard. The term "Engineering Controls" includes all control measures that isolate or remove a hazard from the workplace, encompassing not only sharps with engineered sharps injury protections and needleless systems but also other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Examples include blunt suture needles and plastic or mylar-wrapped glass capillary tubes, as well as controls that are not medical devices, such as sharps disposal containers and biosafety cabinets.

The expanded definitions reflect the intent of Congress to have OSHA amend the BBP standard to clarify

> * * * the direction already provided by OSHA in its Compliance Directive; namely, that employers who have employees with occupational exposure to bloodborne pathogens must consider and, where appropriate, use effective engineering controls, including safer medical devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments * * * (Ex. 5–3).

Thus, the revised definitions do not reflect any new requirements being placed on employers with regard to protecting workers from sharps injuries, but are meant only to clarify the original standard, and to reflect the development of new safer medical devices since that time.

Paragraph (c)(1)(iv) of the standard is revised to add new requirements to the annual review and update of the Exposure Control Plan. The review and update of the plan is now required to "(A) reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Thus, the additional provisions require that employers, in their written Exposure Control Plans, account for innovations in procedure and technological developments that reduce the risk of exposure incidents. This would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption; the method or methods used to evaluate devices and the results of evaluations; and justification for selection decisions. This information must be updated at least annually.

The revised Exposure Control Plan requirements make clear that employers must implement the safer medical devices that are appropriate, commercially available, and effective. No one medical device is appropriate in all circumstances of use. For purposes of this standard, an "appropriate" safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated. Although new devices are being continually introduced, OSHA recognizes that a safer device may not be available for every situation. If a safer device is not available in the marketplace, the employer is not required to develop any such device. Furthermore, the revised requirements are limited to the safer medical devices that are considered to be "effective." For purposes of this standard, an "effective" safer medical device is a device that, based on reasonable judgment, will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used.

Paragraph (c)(1)(v) of the revised standard now requires that "An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." This change represents a new requirement, which is performance-oriented. No specific procedures for obtaining employee input are prescribed. This provides the employer with flexibility to solicit employee input in any manner appropriate to the circumstances of the workplace. A dental office employing two hygienists, for example, may choose to conduct periodic conversations to discuss identification, evaluation, and selection of controls. A large hospital, on the other hand, would likely find that an effective process for soliciting employee input requires the implementation of more formal procedures. The solicitation of input required by the standard requires employers to take reasonable steps to obtain employee input in the identification, evaluation, and selection of controls. Methods for soliciting employee input may include

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involvement in informal problem-solving groups; participation in safety audits, worksite inspections, or exposure incident investigations; participation in analysis of exposure incident data or in job or process hazard analysis; participation in the evaluation of devices through pilot testing; and involvement in a safety and health committee properly constituted and operated in conformance with the National Labor Relations Act.

Employee input can serve to assist the employer in overcoming obstacles to the successful implementation of control measures. A number of respondents to the RFI indicated that they encountered some resistance when new devices required staff members to adopt new techniques, or when staff members perceived that use of the device might have an adverse effect on the patient (*e.g.*, Exs. 3–50, 3–79, 3–99, 3–133). As a way of addressing this resistance, staff involvement in the selection process can play an important role in the acceptance and proper use of safer medical devices (*e.g.*, Exs. 3–18, 3–42, 3–56, 3–88, 3–324, 3–355). According to their experience, the participation of frontline workers can help to overcome the following barriers:

- Safer medical devices often require adjustments in technique, and a number of respondents noted that staff members are often reluctant to revise practices to which they have become accustomed.
- Equipment compatibility problems. With the broad array of devices being used in healthcare settings, it is critical to ensure that devices will work together when necessary.
- The need for continued evaluation of devices and the allotment of sufficient time for adequate device evaluation. After initial use by employees, some facilities found it necessary to replace the device originally selected with a more suitable device.

The Community Health Network (CHN) of San Francisco provides an example of a safety and health committee with responsibility for sharps injury prevention (Ex. 5–5). Representatives of both labor and management serve on the committee, and are provided with access to non-confidential information regarding bloodborne pathogen exposure incidents at CHN facilities. The committee is responsible for establishing criteria for safer devices; overseeing device evaluation by representative groups of device users; and selecting preferred devices for purchase. The committee is also responsible for developing safer alternatives to work practices that are associated with exposure incidents.

The concept of involving a team in sharps injury prevention programs is supported by the American Hospital Association (AHA) in guidelines to assist hospitals and health systems in developing such programs (Ex. 5–1). According to AHA, a successful program revolves around communication, education, training, and collaboration. Among the specific steps recommended are assembling a multidisciplinary team that includes representation of frontline workers and departments using devices; selecting targeted devices for evaluation; pilot-testing of devices; and collecting data after a device is adopted to evaluate its impact.

The standard requires that employers seek input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps. Employees involved in administering treatment or performing any procedure in the presence of an individual receiving care are considered to be involved in direct patient care. For example, an employee who uses a needled syringe to collect blood from patients in a nursing home, or an employee who administers flu vaccinations in a factory employee health unit, would both be considered to be involved in direct patient care and engaged in activities that put them at risk of direct exposure due to needlestick injuries. Employers may also choose to include other employees in the request for input, such as lab technicians, housekeeping staff, maintenance workers, and management-level personnel who may be at risk of injury involving contaminated sharps. An employer who is otherwise required to establish an Exposure Control Plan under the standard, but does not have any non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps, is not required to solicit employee input with respect to this provision.

The revised standard does not require employers to request input from all potentially exposed employees involved in direct patient care; however, the employees involved by the employer should represent the range of exposure situations encountered in the workplace. Input from employees covered by a collective-bargaining agreement may also be requested through their authorized bargaining agent.

The revised standard requires that solicitation of input from employees be documented in the Exposure Control Plan. Employers can meet this obligation by identifying the employees who were involved and describing the process by which input was requested. Employers should also describe the input obtained with regard to identification, evaluation, and selection of controls. Evidence that employee input has been sought can include, for example, meeting minutes, copies of documents used to request employee participation, or records of responses received from employees such as reports evaluating the effectiveness of a safer medical device in trial applications.

The requirement for solicitation of input from employees has been designated as paragraph (c)(1)(v) in the revised standard. The requirement that the Exposure Control Plan be made available to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health upon request, previously designated as paragraph (c)(1)(v), has been moved and is now paragraph (c)(1)(vi) in the revised standard.

The recordkeeping requirements of the standard at paragraph (h) have been amended by adding paragraph (h)(5) to require that employers maintain a sharps injury log to serve as a tool for identifying high risk areas and evaluating devices. Paragraph (h)(5)(i) now states, "The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum: (A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The sharps injury log must be maintained for the period required by 29 CFR 1904. The requirement to establish and maintain the log only applies to employers who are otherwise required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 (OSHA's Recordkeeping rule).

The sharps injury log must include the specified minimum information regarding the device involved (if known), the location of the incident, and the description of the events that resulted in the injury. The level of detail presented should be sufficient to allow ready identification of the device, location, and circumstances surrounding an exposure incident (*e.g.*, the procedure being performed, the body part affected, objects or substances involved and how they were involved) so that the intended evaluation of risk and device effectiveness can be accomplished.

Information in the sharps injury log must be recorded and maintained in a manner that protects the privacy of the injured employee. If data from the log are made available to other parties, any information that directly identifies an employee (e.g., name, address, social security number, payroll number) or information that could reasonably be used to identify indirectly a specific employee (*e.g.*, exact age, date of initial employment) must be withheld.

The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (*e.g.*, paper or electronic), and may include information in addition to that required by the standard, so long as the privacy of injured workers is protected. The Agency recognizes that many employers already compile reports of percutaneous exposure incidents in a variety of ways. Existing mechanisms for collecting these reports will be considered sufficient to meet the requirements of the standard for maintaining a sharps injury log, provided that the information gathered meets the minimum requirements specified in the standard, and the confidentiality of the injured employee is protected.

Under newly published revisions to OSHA's Recordkeeping rule (29 CFR 1904), employers are required to record sharps injuries involving contaminated objects on the OSHA 300 Log of Work-Related Injuries and Illnesses and the OSHA 301 Injury and Illness Incident Report (the new forms replace the current 200 and 101 forms). When the revisions become effective, employers may elect to use the OSHA 300 and 301 forms to meet the sharps injury log requirements, provided two conditions are met. First, the employer must enter the type and brand of the device on either the 300 or 301 form. Second, the employer must maintain the records in a way that segregates sharps injuries from other types of work-related injuries and illnesses, or allows sharps injuries to be easily separated. For example, if OSHA 300 and 301 records are maintained on a computer, the employer must ensure that the computer is able to produce a record of sharps injuries that does not include other types of work-related injuries and illnesses (*i.e.*, through using a program that allows for sorting of entries by injury type). If records are kept on paper forms, the employer would need to use a separate page of the 300 Log for sharps injuries.

The revisions to the Recordkeeping rule will not become effective until January 1, 2002, at the earliest, and until then many sharps injuries involving contaminated objects will not be recordable on the OSHA log. Therefore, employers must keep a separate sharps log from the effective date of this rule until the revised Recordkeeping rule becomes effective.

These revisions to the BBP standard become effective April 18, 2001. Exposure Control Plans that are reviewed and updated on or after this effective date must reflect the requirements of the revised standard. Percutaneous exposure incidents that occur on or after this effective date must be recorded on the sharps injury log.

OSHA's BBP standard, including the amendments herein promulgated, is applicable to general industry and shipyard employment (as referenced in 29 CFR 1915.1030).

IV. Economic Analysis

Incremental Costs of the Mandated Revisions to the Standard

OSHA has determined that the total cost of this action is $33,814,991 per year, and thus, that it is not an economically significant regulatory action within the meaning of Executive Order 12866. However, the rule is defined as a significant rule under the Executive Order, and has been reviewed by the Office of Management and Budget. This amendment to the final standard does not involve any new engineering requirements to protect workers from sharps injuries, but it does include two new recordkeeping requirements: First, the amended standard requires employers to "establish and maintain a sharps injury log for the recording of percutaneous injuries * * *" However, for recordable needlestick incidents, OSHA already requires employers to collect much of the information needed for developing such a log under other rules, the Recording and Reporting Occupational Injuries and Illnesses regulation (29 CFR 1904) in particular. Moreover, OSHA has recently published revisions to 29 CFR 1904 that would cover the remaining, previously nonrecordable needlestick injuries. Second, the current action requires any employer "who is required to establish an Exposure Control Plan" to "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." The methodology OSHA has used for computing costs for each requirement of the amended standard is presented in the next two sections.

Cost of Establishing and Maintaining a Sharps Injury Log

The rule requires employers to maintain a log for all needlestick and sharps injuries. At a minimum, the sharps injury log must contain: "(A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The costs attributable to the log correspond directly to the number of needlestick and sharps injuries. The International Health Care Worker Safety Center (IHCWSC) provides the best available estimate of the number of needlestick injuries (Ex. 3–172V). IHCWSC has computed that 590,164 needlestick and sharps injuries occur annually.

Needlestick and sharps injury cases will require an effort pertaining to collection of data on the type and brand of device, the department or work area where the incident occurred, and an explanation of how the incident occurred. Because the amount of information required to be collected is limited, OSHA estimates that it will require an average of five minutes per case (0.08 hours) to collect the data and enter it onto the separate log. Assuming that the task of collecting information related to the incident and entry onto the log will be conducted by an individual with the skill level of a Personnel Training and Labor Relations Specialist, an hourly wage of $26.32 is used to compute cost. (The hourly wage for Personnel Training and Labor Relations Specialist as reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is $19.03; benefits are computed at 38.3 percent of the hourly wage.) Thus, the incremental annual cost of the separate sharps injury log is:

(590,164 cases) × (0.08 hours/case) × ($26.32/hour) = $1,294,352.

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In summary, OSHA estimates that the total annual cost of maintaining a sharps injury log will be $1,294,352. This estimate is likely to overstate true costs for at least three reasons. First, for already recordable incidents, the data needed to maintain a separate sharps injury log are already collected and entered into a log format for other purposes, namely for the requirements set forth by 29 CFR Part 1904. It is unlikely that the data will need to be "re-entered." Instead, businesses are likely to develop procedures for automating the process or for organizing log information, thereby significantly reducing the incremental costs associated with this incremental action. For nonrecordable cases, the data collection required by the Needlestick Safety and Prevention Act and this revision to the BBP standard will be required under 29 CFR Part 1904 (once revisions to Part 1904 become effective), so that the incremental costs associated with the separate sharps injury log are short-term in nature. Finally, and perhaps most importantly, the above cost estimate significantly overstates costs because it includes costs for all establishments in SIC 80. Under revisions to 29 CFR Part 1904, SICs 801, 802, 803, 804, 807, and 809 are exempted from recordkeeping requirements under Part 1904 and will thus not be required by this amendment to the BBP standard to keep a needlestick and sharps injury log. This is potentially significant because SICs 801, 802, 803, 804, 807, and 809 constitute 31 percent of employment for SIC 80, though not necessarily 31 percent of sharps injuries.

Cost of Solicitation of Employee Input

The cost associated with solicitation of employee input is comprised of three components: (1) The initial solicitation, conducted by a manager; (2) the employee response; and (3) documentation of the solicitation in the Exposure Control Plan.

The cost of the initial solicitation is likely to vary with establishment size, number of incidents, and employee interest. The establishments that will be affected are those that are: (1) Required to develop an Exposure Control Plan, and (2) have employees who are involved in direct patient care and who are potentially exposed to needlestick injuries. The overwhelming majority of such establishments are in SIC 80, Health Services. County Business Patterns reports that in 1997 (1997 data are used as the most recent year for which data are available using the SIC reporting system), there were 502,724 establishments in SIC 80. OSHA estimates that the initial solicitation or call for employee input will require an average of 15 minutes (0.25 hours) of managerial time. The wage rate of a Medicine and Health Care Manager is $33.22 per hour, including fringe benefits. (The hourly wage for a Medicine and Health Care Manager reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is $24.02; benefits are computed at 38.3 percent of the hourly wage.) The estimated cost of the initial solicitation is:

(502,724 establishments) × (0.25 hours/establishment) × ($33.22/hour) = $4,175,080.

The cost associated with the employee response varies with the number of employees and the response rate to the initial solicitation. According to County Business Patterns, there were 11,348,141 individuals employed in SIC 80 in 1997. OSHA estimates that it will require 15 minutes (0.25 hours) of employee time to respond to the solicitation and that approximately 33 percent of employees will respond. Using a wage rate of $25.90 (which is the total hourly compensation in 1998 for professional specialty and technical employees in Health Services reported in the Bureau of Labor Statistics publication Employer Costs for Employee Compensation, 1986–1988), the estimated costs associated with employee response are:

(11,348,141 employees) × (33% response rate) × (0.25 hours/employee) × ($25.90/hour) = $24,248,140.

Note that it is implicitly assumed that input is solicited from *all* employees. This assumption will result in an overstatement of costs because the standard requires that input be solicited only from the fraction of employees who are involved in direct patient care and who are potentially exposed to needlestick injuries.

Finally, the revised standard requires that the employer document the solicitation in the Exposure Control Plan. Because the affected employers are already required to establish a Plan, the incremental effort associated with this documentation will be small. OSHA estimates that it will require only 15 minutes (0.25 hours) of managerial time. Thus, the total annual cost of documenting the solicitation in the Exposure Control Plan is estimated to be:

(502,724 establishments) × (0.25 hours/establishment) × ($33.22/hour) = $4,175,080.

In summary, OSHA has estimated the total cost of the solicitation to be $32,598,300 ($4,175,080 + $24,248,140 + $4,175,080). This estimate is likely to overstate the cost because employers have several avenues for achieving this requirement of the standard, many of which will reduce costs. For example, employers are not required to solicit input from all employees and could meet the requirement by, for example, consulting a properly constituted safety committee consisting of a subset of employees. In fact, recent state legislation has mandated sharps safety committees in a number of states. In these situations, the only incremental cost associated with the solicitation mandated by this amendment to the BBP standard will be documentation of the solicitation in the Exposure Control Plan.

Total Cost and Cost Per Establishment

According to the above analysis, the maximum total annual cost of this action is $33,892,653, consisting of $1,294,352 associated with maintaining a sharps injury log and $32,598,300 associated with soliciting and documenting employee input into the Exposure Control Plan. This amounts to $67 per establishment, per year, which will not cause significant economic impact on either large or small affected establishments.

V. Unfunded Mandates

OSHA has determined that, for the purposes of section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), this rule does not include any federal mandate that may result in increased expenditures by state, local, or tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million. Moreover, the Agency has determined that for purposes of section 203 of the Act, this rule does not significantly or uniquely affect these entities.

Background

The Unfunded Mandates Reform Act was enacted in 1995. While much of the Act is designed to assist the Congress in determining whether its actions will impose costly new mandates on state, local, and tribal governments, the Act also includes requirements to assist federal agencies to make this same determination with respect to regulatory actions.

Analysis

As discussed in Section IV, Economic Analysis, this rule will have incremental costs of $34 million per year, all of which are associated with maintaining the sharps injury log and soliciting and documenting employee information. These total costs represent an average cost of $67 per year per affected establishment. OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation, or particular state, local or tribal governments, or urban or rural communities.

VI. Environmental Impacts

The National Environmental Policy Act requires that "major Federal actions significantly affecting the quality of the human environment" be accompanied by a statement addressing the environmental impact of the proposed action. (42 U.S.C. 4332(C)) Department of Labor regulations establish a criteria for determining when an environmental impact statement is required in a rulemaking proceeding:

> Preparation of an environmental impact statement will always be required for proposals for promulgation, modification or revocation of health standards which will significantly affect air, water or soil quality, plant or animal life, the use of land or other aspects of the human environment.
>
> 29 CFR 11.10 (a)(3)

OSHA has concluded that no significant environmental impacts would result from this rulemaking. This final standard expands the universe of engineering controls permissible for reducing occupational exposure to bloodborne pathogens. It also widens the scope of Exposure Control Plan review, requires maintenance of a sharps injury log, and mandates the solicitation of input from employees on the identification, evaluation, and selection of effective engineering and work practice controls. The Agency has not identified any impacts of these requirements on the environment.

VII. Federalism

This standard has been reviewed in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, Aug. 10, 1999). The order requires that agencies, to the extent possible, refrain from limiting state policy options; consult with states prior to taking actions that would restrict state policy options; and take such action only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 also provides that agencies shall not promulgate regulations that have significant Federalism implications and impose substantial direct compliance costs on state or local governments, unless the agency consults with state and local officials early in the process of developing the proposed regulation and provides a summary Federalism impact statement in the preamble of the final rule. Finally, the Order provides for preemption of state law only if there is a clear Congressional intent for the agency to do so, and provides that any such preemption is to be limited to the extent possible.

Under Section 6(b) of the Executive Order, an agency is exempt from state consultation requirements if it is promulgating a regulation that is required by statute. The amendments to OSHA's BBP standard codified in this rule were explicitly written by Congress and enacted as Public Law 106–430. Moreover, Congress clearly intended the revised BBP standard to have the same legal effect as other standards issued under 6(b) of the Occupational Safety and Health Act of 1970. Nonetheless, OSHA has consulted extensively with those 25 States and territories that operate OSHA-approved State plans with regard to OSHA policy on safe needle devices and the requirements of the subject legislation.

Section 18 of the OSH Act expresses Congress' intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption only if it submits, and receives Federal approval for, a State plan for the development and enforcement of standards. OSHA-approved State plans operate under authority of State law and must adopt occupational safety and health standards which, among other things, must be at least as effective in providing safe and healthful employment and places of employment as Federal standards.

In *Gade* v. *National Solid Wastes Management Assoc.*, the U.S. Supreme Court reaffirmed the view that Section 18 of the OSH Act effectively preempts states without approved plans from adopting or enforcing any laws that directly, substantially, and specifically regulate occupational safety and health. 505 U.S. 88, 107 (1992). However, needlestick laws in states without an OSHA-approved State plan would not be affected to the extent to which they regulate the occupational safety and health conditions of state or local government employees (see Section 3(5) of the OSH Act).

VIII. State Plan States

The 23 states and 2 territories that operate their own federally approved occupational safety and health plans must adopt a comparable amended standard within six months of the publication date of a final Federal OSHA standard. The States and territories with this obligation include: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as state and territorial standards are amended, Federal OSHA will provide interim enforcement assistance, as appropriate.

IX. Paperwork Reduction Act

This final rule contains new collection of information (paperwork) requirements in revisions to the Bloodborne Pathogen Standard (1910.1030 and 1915.1030) made as a result of the Needlestick Safety and Prevention Act (Pub. L. 106–430). These new paperwork requirements are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA 95), 44 U.S.C. 3501 *et seq.*, and its regulation at 5 CFR Part 1320. OSHA solicits public comments concerning its estimate of the burden hours and costs for the revised paperwork requirements. The Agency will summarize the comments received and include a summary of them in its request to OMB to approve the information collection requirements; they will also become a matter of public record. OSHA seeks this information as part of its continuing effort to reduce

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paperwork and respondent burden. The information helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The Needlestick Safety and Prevention Act requires employers who have exposure control plans in accordance with § 1910.1030 (c)(1)(iv), "to review and update such plans to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens." The exposure control plan must also "document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Employers required to have exposure control plans must also "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan."

The Needlestick Safety and Prevention Act also requires employers, who currently maintain a log of occupational injuries and illnesses under 29 CFR 1904, to "establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps." The information in the sharps injury log must be recorded and maintained so that the confidentiality of the injured worker is protected. The log must contain at least the following information: "(A) the type and brand of device involved in the incident; (B) the department or work area where the exposure incident occurred; and (C) an explanation of how the incident occurred."

Respondents are not required to comply with collection of information (paperwork) requirements unless a currently valid OMB control number is displayed (§ 1320.5 (b)(2)(i)). OSHA will publish the OMB control number as soon as it receives approval on its ICR for the revised collections. A copy of the Agency's revised ICR for the BBP standard is available for inspection and copying as part of Docket ICR1218–0180(2000) in the OSHA Docket Office, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210, or you may request a mailed copy by telephoning Todd Owen at (202) 693–2444.

Comments on the ICR should be submitted to the Docket Office, Docket Number ICR–0180 (2001), OSHA, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693–2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693–1648.

The Department and OMB are particularly interested in comments that

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Title: Bloodborne Pathogens standard (29 CFR 1910.1030).

OMB Number: 1218–0180 (Revision).

Frequency: Employers must: annually review their exposure control plans; initially establish and maintain a sharps injury log; as necessary, make injury recordings in the log; and solicit input from non-managerial employees.

Affected Public: The respondents are those employers that must maintain an exposure control plan, and employers who are required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904.

Total Respondents: 502,724 establishments.

Average time per response: Three to five minutes for employers to record needlestick incidents; fifteen minutes for employers to solicit non-managerial employees on effective engineering and work practice controls; fifteen minutes for employers to modify their existing exposure control plans.

Estimated Burden Hours: 49,180 hours for employers to log needlestick incidents; 125,681 hours for employers to solicit non-managerial employees; and 125,681 hours for employers to update existing exposure control plans.

Estimated Cost (Operation and Maintenance): 0.

X. Authority and Signature

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657) and the Needlestick Safety and Prevention Act (Pub. L. 106–430, 114 Stat. 1901, November 6, 2000); and Secretary of Labor's Order No. 3–2000 (65 FR 50017), 29 CFR part 1910 is amended as set forth below.

List of Subjects in 29 CFR Part 1910

Blood, Blood diseases, Health, Healthcare, Hepatitis B virus, Hepatitis C virus, Hospitals, Human immunodeficiency virus, Needlestick, Occupational safety and health, Sharps injury.

Signed at Washington, DC, this 10th day of January 2001.

Charles N. Jeffress,

Assistant Secretary of Labor for Occupational Safety and Health.

XI. Amended Final Rule and Appendix

The Occupational Safety and Health Administration is amending part 1910 of title 29 of the Code of Federal Regulations as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for 29 CFR part 1910, subpart Z, is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), 1–90 (55 FR 9033), 6–96 (62 FR 111), or 3–2000 (65 FR 50017), as applicable; and 29 CFR part 1911.

All of subpart Z issued under Sec. 6(b) of the Occupational Safety and Health Act, except those substances that have exposure limits listed in Tables Z–1, Z–2, and Z–3 of 29 CFR 1910.1000. The latter were issued under Sec. 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z–1, Z–2 and Z–3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z–1, Z–2, and Z–3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

Sections 1910.1018, 1910.1029 and 1910.1200 are also issued under 29 U.S.C. 653.

Section 1910.1030 is also issued under Pub. L. 106–430, 114 Stat. 1901.

* * * * *

2. Section 1910.1030 is amended as follows:

A. In § 1910.1030, paragraph (b), the definition for "Engineering Controls" is revised and definitions are added in alphabetical order to read as set forth below:

B. Paragraph (c)(1)(iv) is revised to read as set forth below:

C. Paragraph (c)(1)(v) is redesignated paragraph (c)(1)(vi), and a new paragraph (c)(1)(v) is added to read as set forth below:

D. A new paragraph (h)(5) is added to read as set forth below:

§ 1910.1030 Bloodborne pathogens.

* * * * *

(b) * * *

Engineering controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

* * * * *

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

(2) The administration of medication or fluids; or

(3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

* * * * *

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

* * * * *

(c) * * *

(1) * * *

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

(B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

* * * * *

(h) * * *

(5) *Sharps injury log.* (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(A) The type and brand of device involved in the incident,

(B) The department or work area where the exposure incident occurred, and

(C) An explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

* * * * *

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Part X

Department of Labor

Office of the Secretary

29 CFR Part 4

Service Contract Act; Labor Standards for Federal Service Contracts; Final Rule

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DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 4

RIN 1215–AB26

Service Contract Act; Labor Standards for Federal Service Contracts

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule an amendment to the regulations exempting certain contracts for commercial services meeting specific criteria from coverage under the McNamara-O'Hara Service Contract Act (SCA). The proposed regulation was issued based on a request by the Administrator for Federal Procurement Policy, Office of Federal Procurement Policy (OFPP), in a May 12, 1999, letter to the Secretary of Labor, representing that the requested exemptions were both necessary and proper in the public interest, and in accord with the remedial purpose of the SCA to protect prevailing labor standards. Amendments/modifications were made to the OFPP-requested exemptions based on the written comments submitted in response to the proposed rule.

EFFECTIVE DATE: March 19, 2001.

FOR FURTHER INFORMATION CONTACT: William W. Gross, Director, Office of Wage Determinations, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3028, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–0062. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act

This rule contains no reporting or recordkeeping requirements subject to the Paperwork Reduction Act of 1980 (Pub. L. 96–511). The existing information collection requirements contained in Regulations, 29 CFR part 4 were previously approved by the Office of Management and Budget under OMB control number 1215–0150.

II. Background

On October 1, 1995, the Federal Acquisition Regulations were amended to implement provisions of the Federal Acquisition Streamlining Act (FASA). One provision of the final regulation, 48 CFR 12.504(a)(10), provided that the requirements of the McNamara-O'Hara Service Contract Act (SCA) are not applicable to subcontracts at any tier for the acquisition of commercial items or services. This provision of the final rule had not been included in the proposed regulation. When the Department of Labor became aware of the regulation, the Administrator of the Wage and Hour Division wrote to the Administrator for Federal Procurement Policy, OFPP, questioning the appropriateness of the FAR regulation. The Department of Labor stated its view that questions of coverage and exemptions under the SCA were properly within the purview of the Secretary of Labor pursuant to section 4 of SCA. After a review of the issue by the FAR Council the Administrator for Federal Procurement Policy wrote to the Secretary of Labor and requested that the Department propose an exemption for a more limited group of commercial service contracts (both prime contracts and subcontracts). The Administrator stated that the FAR Council had concluded that a blanket exemption of all subcontracts for commercial items may not adequately serve the Administration's policy of supporting exemptions of the SCA only where they do not undermine the purposes for which the SCA was enacted. In addition, the FAR Council recognized the Department's authority to exempt contracts as well as subcontracts on all types of contracts. Therefore the FAR Council agreed that any exemption from the coverage of SCA for subcontracts for the acquisition of commercial items or components should be accomplished under the Secretary of Labor's authority in the SCA, and stated that it would withdraw the FAR provision.

The FAR Council indicated that the adoption of their recommendations would further the commitment of the Administration to be more commercial-like, encourage broader participation in government procurement by companies doing business in the commercial sector, and reinforce their commitment to reduce government-unique terms and conditions from their contracts. Furthermore, the FAR Council represented that the limited exemptions that it proposed could be accomplished without compromising the remedial purpose of the SCA to protect prevailing labor standards.

On July 26, 2000, the Department of Labor published an NPRM, proposing the limited exemption from the SCA recommended by the FAR Council. On the same date, the FAR Council published a final rule in the **Federal Register** removing SCA from the list of laws inapplicable to subcontracts for commercial items, previously at FAR at 48 CFR 12.504(a)(10). The FAR final rule became effective August 25, 2000. As a result, a small group of commercial subcontracts that were previously exempted under the FAR rule and that also meet the requirements of DOL's proposed rule could change from exempt to nonexempt and back to exempt if the DOL proposal becomes final as it was proposed. Therefore, to prevent the disruption that could be caused by such changes, including the possible disruption of services if the current subcontractor did not agree to continue the subcontract services under the requirements of SCA, the Department also published a final rule in the same **Federal Register**, temporarily exempting from the SCA those commercial subcontracts which met the criteria of the proposed rule. The rule was to remain in effect for one year, or until final action was taken on the NPRM, whichever occurred first. With the publication of this final rule, the final rule for commercial subcontracts is superceded and is withdrawn.

The NPRM addressed two separate but somewhat related issues. First, the NPRM proposed to modify the current exemption for the maintenance and repair of Automated Data Processing (ADP) equipment, 29 CFR 4.123(e)(1), to reflect terminology changes in law that have occurred since the exemption was originally established; broaden the exemption to cover information technology as currently defined; apply the exemption to installation services; and apply the exemption to subcontracts as well as prime contracts. Second, a new exemption was proposed, similar to the current ADP exemption, to exempt both prime contractors and subcontractors for a specified subset of commercial services that meet certain criteria.

III. Summary/Analysis of the Comments

A total of eleven comments were received. Three comments from contractor associations are generally supportive of but recommend certain changes to the proposed exemption. Eight comments—one from a contractor association and seven from union organizations—are generally opposed to all or specific portions of the proposed exemption. Since most of the comments focus on the proposed services or the proposed criteria for exemption, this summary also is organized on the basis of individual services and criteria.

Before addressing the individual services, however, several commenters raise an overarching issue regarding the statutory and regulatory requirements for exemption under the Service Contract Act. The American Federation of Labor—Congress of Industrial Organizations (AFL–CIO), the Laborers' International Union of North America (LIUNA), and the Building and Construction Trades Department, AFL–CIO (Building Trades), note that section 4(b) of SCA limits the Secretary of Labor the authority to grant exemptions from SCA to those situations where the exemption is "necessary and proper in the public interest or to avoid the serious impairment of government business, and is in accord with the remedial purpose of this Act to protect prevailing labor standards." The AFL–CIO and LIUNA further note that 29 CFR 4.123, the Department's regulation implementing section 4(b) of SCA, provides that "a request for exemption from the Act's provisions will be granted upon a strong affirmative showing" that the statutory requirements for exemption are met. They argue that the reasons proffered are inadequate as a matter of law. The AFL–CIO further states that the FAR Council offers no factual support for its requested exemption, and that "the Department cannot defer to the FAR Council's unsupported 'representations' as to whether the exemptions satisfy the 'public interest' and serious impairment' standards."

The Department agrees that exemptions from the SCA may only be granted upon a strong affirmative showing that the statutory requirements for exemption are met. This does not mean, however, that the Department cannot or should not give great weight to the representations of the FAR Council. The FAR Council's experience with and knowledge of the Federal procurement process is clear, and we believe it is appropriate to give the FAR Council's representations due consideration. Absent evidence or arguments to the contrary, a representation by the FAR Council may constitute a "strong affirmative showing" that the requirements for exemption are met. Therefore, on the one hand, we did not summarily reject the FAR Council's request, and on the other hand, the FAR Council's representations have not been accepted without question. They have been evaluated in light of the comments received.

The AFL–CIO also argues that there is no basis for the proposal to expand the FAR exemption for subcontracts to both prime contracts and subcontracts. The Department disagrees with this comment. The Department notes that SCA coverage and exemptions are commonly applicable to both prime contracts and subcontracts, and the Department sees no basis for limiting the exemption for certain commercial services to subcontracts, provided the required showing is met.

A. Expansion of the current ADP exemption

Based upon the recommendation of the FAR Council, the Department proposed that the current ADP maintenance exemption be updated to reflect the current statutory definition of "information technology" and be consistent with other regulations. Further, the proposal added installation services to the current regulatory exemption where those services are not subject to the Davis-Bacon Act. The FAR Council noted that service contracts often involve installation of information technology (IT) equipment, for example installing and maintaining a local area network, or installing and maintaining new telephones or a telephone system. The same employees are performing installation as are performing maintenance and repair services. Thus, the FAR Council argued that the same conditions supporting the exemption for the maintenance services also support an exemption for installation services. Finally, the FAR Council recommended that the exemption be made applicable to subcontracts as well as prime contracts.

The Council of Defense and Space Industry Associations (CODSIA) and the Contract Services Association (CSA) support the expansion of the current ADP exemption to a broader IT definition. CODSIA states that it is "pleased that the Department of Labor has virtually exempted all IT prime and subcontracts from the Service Contract Act." CSA states that the "new 'ADP' exemption has been significantly enlarged to a new definition of IT." Both CODSIA and CSA state that the proposed rule recognizes that "the IT marketplace provides a vibrant and effective guarantor of fair wage practices for virtually all IT workers."

The AFL–CIO, LIUNA and the Building Trades all oppose changing the current ADP exemption to adopt a new information technology definition. The unions also oppose the addition of installation services. The AFL–CIO states that the "growth of data networks does not change the fundamental distinction between the manipulation of data by computers—which is automated data processing—and the transmission of data over telecommunications networks—which is a telecommunications service." The AFL–CIO further states that installing and maintaining new telephone lines or a telephone system is not automated data processing. The AFL–CIO states that the proposal "inappropriately extends the ADP exemption to service work that involves the 'switching, interchange, transmission, or reception of data or information.'"

It goes on to note:

"Installation and maintenance of telephone lines (where unregulated) has historically been covered by the SCA. The service work has not changed substantially even when installation and maintenance involves data rather than voice networks. The service work involved in the installation and maintenance of a local area data network is comparable to the service work involved in the installation and maintenance of a voice PBX or Centrex system, work which is currently covered by the SCA."

The FAR Council's request to change the current ADP definition was made primarily to reflect the current statutory definition of information technology and be consistent with other regulations. The FAR Council did not indicate that the definition needed to be expanded because it was having difficulty procuring telecommunications services. With respect to the addition of installation services, the FAR Council indicated only that the same employees are performing installation services as are performing maintenance and repair services. Thus, the FAR Council concluded that the same conditions supporting the exemption for maintenance services also support an exemption for installation services.

Based upon this description, the Department did not view the change in definition to "information technology" and the addition of installation services to be a significant expansion to the ADP exemption. Rather, the Department considered these changes to be mostly language changes to reflect other statutory terminology changes. The comments—both for and against the proposed change—clearly indicate that the proposed change is a significant expansion of the current exemption. In this light, we have concluded that the present record does not constitute a "strong affirmative showing" that the proposed exemption meets the requirements for exemption in section 4(b) of the Act. Therefore, the current ADP definition will be retained and installation services will not be added to the scope of exempt ADP maintenance services.

With respect to applying the ADP exemption to subcontracts, the Department specifically asked "whether there is any reason that the exemption at the prime contract level should not be applied equally to subcontracts that meet the criteria." As mentioned above, SCA coverage and exemptions ordinarily apply to both prime and

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subcontracts, where the criteria are met. There were no substantive comments against the application of the ADP exemption to both prime and subcontracts. That aspect of the proposed change will be retained. However, the certification requirement is modified to make it clear that a certification by a prime contractor that it meets the criteria also constitutes a certification that if it subcontracts the services, the subcontractor in turn will meet the criteria.

CODSIA and CSA also express concern that the NPRM apparently eliminated "scientific equipment and medical apparatus equipment" from the exemption. To the contrary, the Department did not propose to eliminate such equipment. Rather, the NPRM simply did not reprint those portions of the regulation that were not affected by the proposal. The final regulation reprints the exemption in its entirety, with the clarification that in order to be exempt, a contract or subcontract must be principally for the services in question.

B. New exemptions for Commercial Services

The NPRM was intended to address certain situations where an employee's work on a government contract represents a small portion of his or her time and the balance of the time is spent on commercial work. In such cases, the FAR Council represented that the Government loses the full benefits of competition for its service contracts because some contractors decline to compete for Government work due to specific government requirements. To remedy this situation, the FAR Council recommended an exemption framework that it believed would protect prevailing labor standards and avoid the undercutting of such standards by contractors. The proposed exemption would apply only to a specified list of commercial services for which the FAR Council has found a particular need for an SCA exemption. In addition, in order that the exemption comport with the statutory requirement that it be in accord with the remedial purposes of the Act to protect prevailing labor standards, the proposed regulation provided a number of criteria which must be satisfied.

In selecting the services to which it believed the new exemption should apply, the FAR Council focused on services which the Government is having difficulty acquiring or for which the Government is getting limited competition, or where the Government is unable to acquire the quality of services needed because commercial sources are reluctant to do business with the Government, thereby causing impairment to Government business. The FAR Council stated that it avoided selecting services where the Government may be in a position to motivate the payment of less than prevailing wages by contractors striving to win Government contracts. The factual basis for the FAR Council's view that the proposed exemption for each of the specified services is necessary and proper in the public interest or to avoid the serious impairment of Government business was set forth in the NPRM.

1. Proposed Exempt Services

a. Automated data processing and telecommunication services. Unlike the current exemption for ADP equipment, which applies to maintenance and service of ADP hardware, the new proposed exemption for ADP and telecommunications services would have exempted a broad range of software-type services within the information technology industry. The FAR Council explained that in this information age, the Federal Government is contracting for more and more information technology (IT) services. This is driven by the need to maximize the use of technology to improve the efficiency and effectiveness of agency performance. However, increasingly the Government is less of a player in the IT marketplace in terms of market share (less than 3%). IT providers have an abundance of work in an industry with a tight labor market. The FAR Council stated that IT providers are often reluctant or unwilling to deal with Government unique requirements such as the Service Contract Act when they have an abundance of work available and are experiencing difficulty keeping pace with their commercial work. The FAR Council further represented that unless the Federal Government can more closely align the Government's contracting practices and requirements with commercial practice, it will not be able to generate enough interest to permit the Federal Government to take full advantage of the opportunities to use information technology and to obtain the requisite quality of services needed to satisfy critical agency mission needs.

Many of the comments group this new proposed exemption for software services with the ADP maintenance services and the comments clearly address both proposed exemptions. For example, CODSIA and CSA are "pleased that the Department of Labor has virtually exempted all IT prime and subcontracts." Other than this broad reference to IT, CODSIA and CSA do not separately comment on the individual services on the proposed list. With respect to the new list of services, both CODSIA and CSA primarily express concern that this list is too limited.

Similarly, most of the union commenters comment together on both the new ADP/telecommunications exemption and the expansion of the current ADP exemption. In commenting on the proposed new exemption for ADP and telecommunication services, the AFL–CIO states that "one of the predominant purposes and effect of the proposed rule is to eliminate coverage in one of the largest growth sectors of the Nation's economy, the ADP, IT and telecommunications industry." The AFL–CIO and the Building Trades contend that the services within the scope of this proposed new exemption "are performed by many employees enjoying the protection of prevailing wage standards under the SCA. There is no guarantee that these service employees will not experience a reduction in wages and benefits or lose their jobs as a result of application of the exemption in the proposed rule."

These union commenters also challenge the FAR Council's justification for the proposed exemption. In addition to the comments on telecommunications, summarized above, the AFL–CIO states that the Communications Workers of America (CWA) (one of its member unions) represent employees performing "network integration" services for several large companies, and that these firms would be at a disadvantage in bidding for government contracts under the proposed exemption. They also state that the International Brotherhood of Teamsters (IBT) perform "a multitude of very technical work with regard to data collection and distribution for the Department of Defense" in Alaska. LIUNA states that the FAR Council stated that the Government "is contracting for more and more information (IT) services * * * [but n]owhere has the FAR Council stated that it cannot obtain these services or that there are actual instances where this has occurred." The union commenters also state that the proposed ADP exemption is contrary to Congressional intent, as expressed in the 1976 amendments to the SCA, to comprehensively cover white collar service workers.

Based upon the comments, it is clear that all parties—those in favor of the proposal as well as those opposed—view the combined expansion of the current ADP exemption and the addition of ADP and telecommunication

services to the proposed additional list of exempt services as an intent to exempt virtually the entire ADP, IT and telecommunications industry. While the Department still believes that the additional criteria would limit the proposed exemption to a smaller set of contracts than those apparently envisioned by the commenters, the Department also recognizes that the scope of the new ADP and telecommunications exemption is broadly defined. Compared with the other exemptions proposed, the proposed ADP exemption is not as tightly focused on an area where the Government has been having trouble obtaining bidders. In light of the comments and representations challenging the need for a broad-based ADP and telecommunications exemption, the Department has concluded that the record does not adequately demonstrate that the statutory requirements for exemption have been met for this broad classification of ADP and telecommunication services. If at some future time the FAR Council or an individual agency can demonstrate that the statutory requirements for exemption are met for a more specific type of ADP or telecommunications service, then the Department will consider such a request based upon the facts applicable to that specific type of procurement or specific service.

b. Automotive or other vehicle maintenance services. Federal agencies that maintain a fleet of automobiles have a need for services such as normal maintenance (*e.g.*, changing oil and filters, rotating tires, etc.), mechanical repairs, paint and body work, glass replacement, and other repairs needed to maintain the automobile or other vehicle. Unless the agency has a dedicated Government facility for such work, it is contracted out to commercial firms. The FAR Council stated that the General Services Administration (GSA), which is responsible for providing Interagency Fleet Management Services, has been unsuccessful in contracting for these services because of the unwillingness of commercial sources to deal with Government unique requirements such as the Service Contract Act for the small amount of Government work involved. As a result, GSA and other agencies often acquire these services on an as needed basis using micro-purchase procedures and the Government Purchase Card. The FAR Council stated that unless GSA and other agencies can more closely align the Government's contracting practices and requirements with commercial practice, it will not be able to generate enough interest or business to permit the Federal Government to take advantage of the quality improvements and lower prices that will likely result from establishing contractual relationships with commercial service centers. While the individual transactions are small (typically under $2,500), the aggregate volume and dollar value of transactions across the nation is substantial. The Federal Government would benefit from the lower prices it can negotiate for parts and supplies used to service vehicles if it were able to contract for services rather than treat each transaction individually. Additionally, the Federal Government could expect to receive better service because it will be viewed as a "corporate" customer who gives its business to a particular contractor(s) in a certain location. The FAR Council stated that an exemption is necessary to permit the Government to enhance the quality of service while reducing its cost through leveraging the Federal Government's collective buying power.

The FAR Council provided the following specific example: The Department of Interior's Office of Aircraft Services in Boise, ID, contracts for maintenance of about 100 of its own aircraft and also provides contract support for other agencies such as the U.S. Forest Service. The Office of Aircraft Services reports that it has about a dozen contracts at various locations around the country. These are commercial services procured from commercial sources where the maintenance of Government aircraft is performed alongside regular non-government aircraft. Contractors' work is predominantly non-government. Some commercial contractors have refused to do work for the Government because of concerns with the SCA requirements. The result has been limited competition for such contracts.

Only a few comments were received regarding this service, and none of those comments provide any detailed information. The AFL–CIO states that contractors supplying "automotive and other vehicle maintenance services to the government often subcontract these services, and members of IBT perform this work for both prime contractors and subcontractors and enjoy SCA protection. An exemption for this work risks a loss of that protection, particularly under fixed price contracts where there may be an incentive to cut employment costs." This comment, however, does not address the limiting effect that the application of the required criteria will have on the application of the exemption to these services. As noted in the proposal, the exemption would not apply to contracts for the operation of a Government motor pool or similar facility. Further, the exemption would not apply where the volume of the government work is such that the contractor could perform the work with a workforce dedicated to the government contract. As noted in the FAR Council's request, GSA and other government agencies often acquire these services on an as needed basis using micro-purchase procedures and the Government Purchase Card. Thus, in many cases the services that would be covered by this exemption are not now subject to the prevailing wage requirements of SCA, and in these cases the exemption would not result in loss of SCA protection for employees currently working on SCA covered contracts. Furthermore, under the criteria discussed below, the exemption would not be available unless price is equal to or less important than the combination of other non-price or cost factors in selecting the contractor. Therefore, the Department has concluded that the statutory requirements for exemption are met for this narrow vehicle maintenance service category.

c. Financial services. Increasingly, the Government is contracting for and using the services of financial institutions that provide credit, debit, or purchase cards. These cards are used by Federal employees while traveling or to make small purchases for commercial items to meet the day-to-day needs of their organizations. The providers of these services use the financial networks of firms like VISA, MASTERCARD, and American Express to provide the services. The FAR Council stated that while the Federal Government's use of these services is significant, it represents a small fraction of the transactions that flow through the financial infrastructure. Transactions flowing through the networks are processed in the same fashion and by the same workforce regardless of the ultimate user of the cards. As a result, the FAR Council stated that it is very difficult to get competition for these services when the Federal Government imposes unique requirements on the contractors. It stated that contractors will not change their way of doing business to accommodate a customer that represents a small portion of their business; it is impossible for them to segregate what is done for the Federal Government from commercial activity.

None of the comments specifically opposes this category of services. Therefore, based upon the FAR Council's recommendation, this

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exemption for financial services meeting the specified criteria is adopted.

d. Lodging at hotels/motels. Agencies of the Federal Government often contract with hotels/motels for meeting rooms for conferences of limited duration (*e.g.*, one to five days). These contracts may be for conferences where attendance is limited to Government employees or may involve attendance by other organizations and/or the public. These contracts may also involve furnishing lodging and meals to those participating in the conference. In other cases, agencies establish contractual arrangements with hotels/motels to obtain special rates for lodging when the agency has a large number of employees that frequently travel to a particular location. The hotel/motel agrees to special reduced rates in exchange for being designated a preferred provider for the agency travelers to that city/location. In both of these cases, the FAR Council stated that hotels/motels are unwilling to agree to contract with the Government when it would mean they would have to pay different rates to employees as a result of a Service Contract Act wage determination or would have to keep special/different payroll or other records. Typically these contracts are for relatively small dollar amounts (less than $25,000). The FAR Council stated that this severely limits the Governments ability to contract for these services when needed.

Several union commenters oppose the inclusion of this service category. The Hotel Employees and Restaurant Employees International Union (HERE) state that this exemption "clearly disadvantages hotels/motels which are unionized or paying prevailing wages as compared to the status quo existing under the SCA." HERE states that if "certain hotels/motels are unwilling to contract with the Government, the Government can simply contract with unionized hotels/motels, which * * * will have no problem fulfilling the requirements of the SCA without paying different rates to employees just for Government events." HERE's comments also focus on the prevailing fringe benefit requirements of SCA, and it notes that maintaining the level of benefits is particularly important in a low-wage industry such as the hotel/motel industry. HERE also states that there is no justification for eliminating the protections of section 4(c), which it considers an "integral aspect of the SCA's attempt to protect prevailing wages and fringe benefits." The AFL–CIO makes very similar comments regarding this service category, and points out that the FAR Council does not assert that it has been unable to contract for its required services, but just that "certain hotels/motels" have refused to enter into contracts.

The Department has considered these comments within the context of the types of lodging services outlined in the proposal. With respect to conferences, the Government does not always contract for these services in the same manner. In some cases, the Government may simply have the hotel/motel hold a block of rooms for conference participants. The rooms are then reserved and paid for by the participants. In these situations the Government may also reserve and pay for meeting rooms. In other cases, especially if the conference participants are all from the same agency and the number of participants is known, the agency may award a contract not only for meeting rooms but also for lodging. In the first situation, the contract is typically less than $2500 and SCA prevailing wage requirements would not be applicable; however, in the latter situation SCA would apply. Under the proposal, both types of contracts would be treated the same and neither would be covered by SCA where the regulatory criteria are met.

The Department is sympathetic to the issues raised by the union commenters, especially their comments relative to fringe benefits. However, as the above examples demonstrate, even if this proposal were not adopted, SCA still would not apply to a large number of Government meetings and conferences at private hotels/motels. Furthermore, while the comments regarding the availability of union hotels/motels willing to accept the application of SCA might be true in large cities with a substantial number of union establishments, that scenario might not always be the case for meetings in smaller metropolitan or nonmetropolitan areas. While government meetings and conferences may be frequent in cities such as Washington, DC, they would not be frequent in small metropolitan areas. As HERE acknowledges, hotels/motels are not likely to change their pay practices simply to attract Government conferences or meetings.

With respect to other types of lodging contracts, these are ordinarily long-term contracts where the Government has a continuing need for a block of rooms, *e.g.*, lodging for military recruits or government employees attending training at an agency training center, and the agency enters into a contract with a hotel/motel for number of rooms over a longer period of time. The application of SCA to this type of contract is more direct, and determining compliance with SCA is simpler. Unlike conferences or meetings that are one-time contracts, these lodging contracts fulfill a continuing lodging need. Furthermore, contrary to the comments of HERE, section 4(c) provisions would apply to options, and to renewals for services currently subject to section 4(c).

Based upon the foregoing, the Department has determined that it will revise the proposed exemption for lodging services and apply the exemption only to contracts for meetings or conferences. Contracts for a block of rooms on a continuing basis would be outside the scope of the exemption. As already noted, the application of SCA to contracts with hotels/motels for conferences currently varies depending upon the form of the contract. Further, it is the Department's view that the application or non-application of SCA to these contracts does not impact the remedial purpose of the Act to protect prevailing labor standards. On the other hand, contracts for a block of rooms on a continuing basis are different. Regardless of their form, these contracts should all be subject to SCA at the present time, and the record does not provide adequate support for extending the exemption to this type of lodging contract.

e. Maintenance services for all types of specialized building or facility equipment. Agencies that operate and maintain Government owned and/or operated buildings often contract for operation and maintenance of the building or facility and the prime contractor will then typically subcontract for services related to specialized equipment. In other cases, the Government will contract directly for the maintenance and servicing of such equipment. In either case, the FAR Council reported that it is very difficult to acquire the quality of service needed from contractors who are not authorized representatives of the manufacturer and therefore do not have access to parts needed for repairs and training that is essentially only available from the original equipment manufacturer. While there may be other contractors who indicate they have the capability to provide the service, the FAR Council states that experience often shows that the quality of service obtained from such sources is not satisfactory. The FAR Council stated that the Government, as a result of the reluctance of some of the best contractors to accept Government unique requirements such as those related to the Service Contract Act, is deprived of the opportunity to improve the quality of service for the

maintenance and servicing of critical building equipment and systems.

The Mechanical Contractors Association of America (MCAA), AFL–CIO, LIUNA, International Union of Elevator Constructors (IUEC), United Association of Journeymen and Apprentices of the Plumbing and Pipe Fitting Industry of the United States and Canada (UA), International Union of Operating Engineers (IUOE), and Building Trades all strongly oppose the proposed exemption for this category. Although the comments all provide slightly different individual perspectives, the thrust of these comments is similar: (1) qualified contractors and employees can and do perform these services with the application of SCA; and (2) this exemption would have a negative impact upon workers currently covered by SCA.

Several commenters challenge the FAR Council statement that the exemption is needed because "some of the best contractors" are reluctant to accept government unique requirements such as SCA. MCAA—a mechanical construction industry trade association with about 2,000 member firms—states that its member firms compete for federal agency building systems contracts that are the subject of the NPRM. It also asserts that alternate procurement and contracting planning would be a better way to address any problems with lack of offerors or diminished contracting leverage. MCAA states that "[c]ompetent firms will compete for federal contract opportunities when those contracts are fairly awarded and administered and are performed with high business and labor standards applied to all contractors." The AFL–CIO, and others contend that the "best" contractors do not have a problem paying prevailing wages, and this exemption would "attract lower quality contractors that pay lower wages, hire less skilled and less productive employees and perform less well." Several commenters note that the proposed exemption would encourage agencies to replace on-site stationary engineers employed by SCA covered contractors with employees assigned to a number of buildings on a service route. To the extent that a legitimate problem exists, the commenters contend that it is not caused by the application of SCA and the FAR Council should seek other solutions. The IUOE stated that it has 120,000 members who are stationary engineers employed in the field of operations and maintenance of mechanical, electrical, electronic and plumbing systems, including computer-operated HVAC systems and/or automated building control systems, fire life safety systems, elevators, and escalators. The IUOE expressed its concern that the proposed rule would have the potential to replace more highly skilled stationary engineers in Government facilities with entry level workers. They also state that there are very few HVAC applications where "a manufacturer or original equipment supplier can validate that only their mechanics or technicians can properly service the equipment in question. If that were true, the commercial facilities that exist in the United States would not be able to function without constant interaction and a mandatory lifetime service agreement from the manufacturer." The IUEC notes that the proposed exemption does not "make any sense" in the context of the elevator industry. The IUEC states that "in the elevator industry, the lead, national manufacturing companies * * * are all signatory to collective bargaining agreements with the IUEC under which they are obligated to pay contractual rates that are tantamount to prevailing wages. Thus, if there is in fact reluctance on the part of these manufacturers to bid on federal maintenance, it is not because they do not want to pay prevailing wages, because they are doing that already."

Based upon the comments, the record does not support the conclusion that the statutory requirements for exemption are met, and this category of service will be deleted from the final rule. It is evident that this work is currently performed under SCA contracts. Furthermore, as discussed below, if the Government needs to contract only with the original manufacturer or supplier, that exemption remains available.

f. Installation, maintenance, calibration or repair services for all types of equipment where services are obtained from the equipment manufacturer or supplier of the equipment. Agencies acquire a wide range of equipment and often have a need to acquire services to install, maintain, calibrate, service or repair the equipment from the manufacturer or original supplier in order to avoid compromising a warranty or because proprietary information needed to perform the work is only available from the manufacturer, an authorized representative of the manufacturer or the supplier of the equipment. Typically, these contracts involve sophisticated equipment that requires access to proprietary information or requires employees involved in performing the work to have extensive training that is often only available through the manufacturer or equipment supplier. In such cases, the Government's need to contract with a particular source or a limited number of sources must be properly justified and approved, if applicable, under the statutory competition requirements outlined in 48 CFR part 6 of the Federal Acquisition Regulation. Examples of the types of equipment include automated building control systems, HVAC equipment, building security systems, and elevators or escalators. The FAR Council reported that in many of these cases, the Government has limited leverage to negotiate with the contractor to accept Government unique requirements such as those related to the Service Contract Act and has had great difficulty obtaining services from commercial sources who are unwilling to accommodate such requirements.

The commenters that oppose the exemption for specialized building or facility equipment also oppose the exemption for other equipment services obtained from the manufacturer of supplier of the equipment. Many of their comments apply equally to both service categories. For example, IUEC notes that the major elevator manufacturers are already paying prevailing wages pursuant to their collective bargaining agreements. Therefore, any reluctance to contract with the Government on the part of these companies should not be caused by a concern with the SCA.

The Department believes, however, that there is an important difference between the proposed exemptions. While the services for specialized building or facility equipment could be performed by the manufacturer or supplier of the equipment, the services relative to this category must be performed by the manufacturer or supplier. Further, this exemption was not intended to provide an exemption for the manufacturer or supplier when they are competing with other service providers, but to limit the exemption to situations where the manufacturer or supplier is the only source for the services. In a sole source situation, as set forth in the FAR at 48 CFR 6302–1, other contractors are not disadvantaged because there are not other contractors available to perform the services. Therefore the Department believes that the statutory requirements for exemption are met for this narrow sole source exemption. The Department notes that the sole source aspect of this exemption was discussed in the preamble, but was not set forth in the regulatory language. The regulatory language of the final rule has been clarified to specify that the exemption

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shall only apply when the contract is awarded on a sole source basis.

g. Transportation of persons by air, motor vehicle, rail, or marine on regularly scheduled routes or via standard commercial services (not including charter services) The General Services Administration (GSA) enters into contracts with airlines called "City Pairs" so that Federal employees traveling on Government business can get discount air fares.

Under these contracts, Federal employees typically obtain tickets through travel management contracts awarded by GSA or other agencies and the Federal employee travels on regularly scheduled routes of commercial airlines but receive tickets at a substantial discount. While the Federal Government's use of these services is significant, it represents a small fraction of the transactions that flow through the airlines. Tickets that are issued to Federal travelers flow through the same networks and are processed in the same fashion as other travelers. As a result, the FAR Council reported that it is very difficult to get competition for these services if the Federal Government imposes unique requirements like those in the Service Contract Act on the contractors. The airlines will not change their way of doing business to accommodate a customer that represents a small portion of their business. It is impossible for them to segregate what is done for the Federal Government from commercial activity. The Federal Government also enters into similar contracts for the carriage of passengers by other modes of transportation.

The AFL–CIO and LIUNA both oppose this exemption. The AFL–CIO states that "[m]any IBT members work in the industries covered by this proposed exemption. The FAR Council's rationale for this exemption is unpersuasive and it could have a serious detrimental impact on service workers." LIUNA comments that the "FAR Council nowhere states that it cannot obtain these services or that any contractor has refused to bid in these categories of services."

The proposed exemption mirrors an exemption for the carriage of mail that was granted prior to the 1972 amendments to SCA. The exemption was necessary because mail is not considered to be freight and the transportation of mail did not fall within the scope of the transportation exemption in section 7(3) of SCA. Because the exemption for the carriage of mail was granted prior to the 1972 amendments, it was not accompanied by a finding that the exemption was in accord with the remedial purpose of the Act to protect prevailing labor standards. Nevertheless, the Department is not aware of any instance where the exemption for the transportation of mail has adversely impacted prevailing labor standards.

The exemption for the transportation of persons is necessary at this time because of deregulation in the transportation industry. When the "City Pairs" contracts were first awarded, these contracts fell within the scope of the transportation exemption in section 7(3). With deregulation, it is not clear that "City Pair" fares still constitute published tariffs. Since SCA has not been applied to these contracts previously, the Department has concluded that the exemption would not have a detrimental impact on service workers. In addition, the Department has concluded that the application of SCA to these contracts would seriously impair government business and would likely cause the contracts to be discontinued. Therefore, the statutory requirements for exemption are met for these transportation services. The Department wishes to emphasize that this exemption is narrow, extending only to common carriers providing the services in question to the general public, as well as the Government. It does not extend to charter services, where the Government contracts with a carrier to provide the service just to the Government, such as shuttle buses between Government buildings. The wording of the proposal has been clarified in the final rule.

h. Real estate services. Federal agencies involved in acquiring and disposing of real property often contract for real estate services, including lease acquisition, real property appraisal, broker, space planning, lease re-negotiation, tax abatement, and real property disposal services. The primary classes of workers that are involved in performing the work are appraisers, leasing specialists, brokers, space planners, interior designers, fire safety engineers, and project managers. In many cases, the employees are required by contracts with the Government to be licensed. In many cases, the Department of Labor has not established wage determinations that apply to these classes of workers. The individual requirements are typically relatively low dollar value (under $25,000) and require that services be performed in a variety of different geographic locations. Knowledge of the local real estate market is required to perform the services effectively. Therefore, individual employees, particularly in rural areas, spend only a small fraction of their time working on Government contracts.

While the Federal Government's use of these services is significant, it represents a small fraction of the transactions that flow through the industry/commercial sources. As a result, the FAR Council reported that it is very difficult to get competition for these services where the Federal Government imposes unique requirements like those in the Service Contract Act on the contractors. The contractors will not change their way of doing business to accommodate a customer that represents a small portion of their business. The FAR Council stated that as the Government continues to downsize, it must rely more and more on commercial sources for these services and it is critical that the Federal Government has access to well-qualified sources of supply for these types of services.

LIUNA opposed this exemption simply by commenting that the "FAR Council nowhere states that it cannot obtain these services or that any contractor has refused to bid in these categories of services." No other comments were directed specifically at this service category. While LIUNA is correct that the FAR Council did not state that contractors had "refused to bid," the FAR Council did report that it is very difficult to get competition for these services. The Department does not believe that LIUNA's comment, unsupported by factual statements as to how the work is currently done or as to how the Government could obtain the services, is of sufficient weight to counter the FAR Council's representations. Therefore the exemption for real estate services is retained in the final rule.

i. Relocation services. Employee relocation services are available for Federal employees or military personnel and their families being transferred to new duty stations anywhere within the continental United States and Puerto Rico. These contracts offer a multitude of flexible services to customize a solution that best meets the employee's needs. The contracts save time and money and reduce stress by offering Federal employees and military these services: Home marketing assistance, home sales services, destination area services, management reporting services, mortgage counseling, property management services, and other related services. The individual requirements are typically relatively low dollar value (under $25,000) and require that services be performed in a variety of different geographic locations.

Knowledge of the local real estate market is required to perform the services effectively. Therefore, individual employees, particularly in rural areas, spend a fraction of their time working on Government contracts.

While the Federal Government's use of these services is significant, the FAR Council stated that it represents a small fraction of the transactions that flow through the industry/commercial sources. As a result, it is very difficult to get competition for these services if the Federal Government imposes unique requirements like those in the Service Contract Act on the contractors. The contractors will not change their way of doing business to accommodate a customer that represents a small portion of their business. The FAR Council stated that it is in the Government's interest to maximize the availability of these services to its personnel; accordingly it is detrimental to the Government's interests when it is unable to attract commercial sources as providers of these services.

LIUNA opposed this exemption with the same comments that it made relative to real estate services. In this case also, although the FAR Council did not state that contractors had "refused to bid," the FAR Council did report that it is very difficult to get competition for these services. LIUNA's comment is not sufficient to change the Department's preliminary conclusion in the NPRM that the statutory criteria for exemption have been met.

The American Moving and Storage Association (AMSA) supported the proposed exemption and stated that the term "relocation services" should be clarified to specifically include moving and storage services. AMSA states that its members have "usually performed their services pursuant to FAR-exempt rate tenders rather than contracts. Formerly, the rates contained in tenders were predicated upon published tariff rates that were also filed with the Interstate Commerce Commission. Today, the rates and charges offered for Federal Government service are contained in published tariffs that must be available for inspection * * * but are not filed with a Federal regulatory agency although the tariffs are filed with contracting Government Agencies." AMSA notes that the Department of Defense has recently replaced rate tenders with contracts subject to SCA for several test relocation programs. AMSA analyzes moving and storage services to demonstrate how these services meet all of the proposed exemption criteria.

The application of the SCA section 7(3) exemption for transportation services is not the subject to this rulemaking. That exemption is explained in § 4.118 and the Department has not proposed any change to that section. As indicated in that section, the section 7(3) exemption has only had application to services performed under rate tenders. Even before deregulation, DOD agencies had numerous contracts for moving and storage services that have always been subject to SCA. Since deregulation, it is the Department's experience that even those previously exempt tender services are now performed pursuant to contracts subject to SCA, rather than by tender agreement, as evidenced by the DOD test relocation contracts noted in the AMSA comments.

When the Department proposed the exemption for relocation services, it never considered moving and storage services within the scope of the proposed exemption. None of the services listed in the preamble to the proposed rule—home marketing assistance, home sales services, destination area services, management reporting services, mortgage counseling, or property management services—is similar to moving and storage services. If the Department intended moving and storage to be included within the scope of this exemption, it certainly would have listed moving and storage services and not have included this dominant aspect of the relocation within the catch-all phrase "other related services."

Based upon the comments and the recommendation of the FAR Council, the Department has concluded that the statutory requirements for exemption are met for the relocation services described in the proposal. The final rule will be clarified, however, to indicate clearly that moving and storage services are not within the scope of this exemption.

j. Other Services. The preamble to the proposal specifically solicited comments regarding the listed services and asked whether other services should be added to that list. The Department indicated that if sufficient justification were received for any additional service, it would issue a new proposal to add the new service. As noted in the discussion of relocation services AMSA submitted comments recommending that the definition of relocation services be clarified to specifically indicate that moving and storage services would fall within the scope of that exemption. As discussed above, the Department never intended moving and storage services to be a part of relocation services and has not adopted that recommendation. The Department believes that the AMSA comment is more appropriately considered as a recommendation for the addition of a new service to the list. In that regard, while AMSA has submitted comments to show how moving and storage services typically meet the proposed criteria, it has not demonstrated that such an exemption is "necessary and proper in the public interest or to avoid the serious impairment of government business, and is in accord with the remedial purpose of [the] Act to protect prevailing labor standards." Accordingly, the Department is not issuing a new proposal at this time to add moving and storage services to the list of exempt services.

CODSIA and CSA both comment that the criteria should be applied to all commercial services and should not be limited to those services listed in the proposal. CODSIA and CSA specifically identify trash pickup, pest control, and childcare as services for which an exemption would be appropriate. As with AMSA's comments regarding moving and storage services, however, CODSIA and CSA have not provided a more specific justification to demonstrate that their recommended expansion of the list of services (to either all commercial services or the three specified additional services) meets the statutory requirements for exemption, and the Department is not issuing a new proposal at this time to add these services to the list.

Finally, a clarifying revision has been made to the introductory language to the list of exempt services to make it clear that the contract must be principally for the listed service in order to be exempt.

2. Proposed Criteria

As explained above, the listed services would only be exempt if specified criteria were satisfied. The recommended criteria were intended to limit the exemption to those procurements where the services being procured are such that it would be more efficient and practical for an offeror to perform the services with a workforce that is not primarily assigned to the performance of government work. Thus, contracts for base support services where the work is performed by an on-site dedicated workforce would not meet the exemption criteria. Similarly, contracts where the services have been performed by a dedicated group of federal employees (A–76 procurements) would be unlikely to meet the exemption criterion that the workers perform only a small part of their time on the contract; however, the NPRM explained that it is possible that some

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subcontracts for a portion of those services might meet the criteria for exemption.

The criteria were designed to ensure that the remedial purpose of the Act to protect prevailing labor standards is preserved. This would be accomplished in two ways. First, the proposed exemption would apply only when the contract award is not determined primarily upon the factor of cost. Therefore, the contractor providing the best service at a somewhat higher cost would not be at a competitive disadvantage. Second, the criteria would limit the application of the exemption to circumstances where the nature of the procurement dictates that the most efficient and practical performance of the workload can be accomplished with a workforce that is not dedicated to working primarily on the Government contract. Thus, the competitive pressures upon employee wages that might exist if the services were performed by a workforce dedicated to the Government contract would not come into play on the contracts within the scope of the recommended exemption. Furthermore, even if a contractor might be inclined use a dedicated workforce or to reduce wages to secure the Government contract, the criteria would forbid that practice.

Several comments were received regarding the proposed criteria for exemption. These comments will be organized and analyzed based upon each individual criterion.

(1) *The services are commercial services.* The NPRM explained that a basic underlying purpose of the proposed exemption was to permit a prospective contractor to utilize its commercial compensation practices for both Government and private commercial work. If the prospective contractor does not currently perform the solicited services, then conforming to the SCA requirements would not cause the contractor to alter its commercial compensation practices.

The AFL-CIO commented that this criterion is easily met, covering virtually all commercial contractors that do not exclusively rely upon government contracts. CODSIA commented, "if the contracting officer is using FAR part 12, then presumption should exist that the service being solicited will be COMMERCIAL." CSA made comments similar to CODSIA's.

This criterion was not intended to be limiting to any considerable extent. This criterion is intended only to distinguish services that are unique or specially adapted for the government contract from those that are not provided in the commercial marketplace. The Department agrees that services of the type described in paragraph (f) of the definition of "commercial item" at FAR 2.101 would meet the requirements of this criterion; however, other aspects of the definition of "commercial item" in FAR 2.101 are not fully consistent with all aspects of this proposed exemption. Also, the definition in FAR 2.101 may change in the future. Therefore, the Department has not included any reference to FAR parts 2, 10, or 12 in the commercial service criterion, and the final rule retains the language in the proposal for this criterion.

(2) The prime or subcontract will be awarded on a sole source basis or primarily upon factors other than cost. One of the basic purposes of the Service Contract Act is to counteract the negative impact that competition based on price alone may have upon wages. If a contract is awarded on a sole source basis, there is no competition and price is clearly not the basis for awarding the contract. For the majority of other contracts that are competitively awarded, this criterion would attempt to largely remove wages from consideration by making quality of service and other non-cost factors equal to or more important than the bottom-line price. If one assumes that the best employees (contractors) are paid (pay) higher wages, then this criterion would allow these employees (contractors) to compete on the basis of the employees' increased productivity and higher quality service. These employees/contractors should not be disadvantaged even though the employee wages and possibly the resulting contract price are somewhat higher than the lowest offer.

The AFL–CIO comments that "[e]ven in best value contracting, price will always play a critical and often decisive role. . . . If the Government truly wished to obtain the best quality services at the best cost, the better approach is for agencies to fully maintain SCA rates, and then use best value contracting to hire the most qualified contractors that offer the best price."

This criterion is not intended to imply that all best value contracts should be exempt from SCA. In fact, the opposite is true and most best value service contracts will remain subject to SCA. This criterion is intended to operate in conjunction with all of the other criteria, and help to ensure that prevailing wage and benefit rates are not adversely affected by the application of this exemption. This criterion is retained without change in the final rule.

(3) The services are furnished at catalogue or market prices. This criterion was designed to ensure that the contractor will provide the services to the Government on the same basis that the contractor services commercial accounts. Combined with the other criteria, this requirement should ensure that contractors do not decrease employee compensation as a part of the competitive contracting process.

The AFL–CIO commented that this criterion differs from § 4.123(e)(1)(ii)(B) because it contemplates that market price information could also be established by surveying firms in a particular industry or market. This additional sentence in the criterion applicable to the new services was not intended to imply that the market price would or could be determined in a manner different from the determination of market price under § 4.123(e)(1)(ii)(B). To avoid any confusion, however, this additional sentence will be deleted from the criterion in the final rule, and this criterion will be consistent with the language currently used in § 4.123(e)(1)(ii)(B).

(4) The service employees performing the exempt services will spend only a small portion of their time (a monthly average of less than 20%) servicing the government contract. The NPRM explained that if the employees spend only a small portion of their available work hours on the Government contract, the contractor would not likely be willing to alter its compensation practices simply to obtain the Government contract. (Note: Criterion 5 would also specifically preclude any such change in compensation practices.) Furthermore, the criteria for exemption would not be satisfied by rotating the workforce and having different employees work on the contract each day of the week. In the Department's experience it would be extraordinary for a contractor to staff a contract in this manner. Therefore in such a case, although each individual employee would spend less than 20% of his/her work hours on the Government contract, a contracting officer or prime contractor (in the case of a subcontract) could not certify—as required by Criterion 6—that all or nearly all offerors would staff the contract with service employees who spend only a small portion of their time on the project.

This criterion generated considerable comment on both sides of the issue. CODSIA and CSA both strongly oppose any type of hours restriction whatsoever. CODSIA notes that several of the proposed criteria have their foundation in the current ADP exemption, but it states that "the Department has effectively eviscerated

the previous foundation by adding a new qualification that requires a potential commercial subcontractor to perform the work without being able to dedicate the company's workforce in excess of more that 20% of the service worker's annualized hours to the government contract." CODSIA further states that "no commercial company would execute a government subcontract with the understanding (and obligation) that its service workers cannot be dedicated to the subcontract until completion . . . [t]herefore, no prudent company will seek to meet this qualification and the SCA will apply." CODSIA concludes that "SCA wages should not be superimposed upon the commercial market place due to an artificial, ill-founded criterion," and "the workforce requirement should be eliminated."

CSA makes many of the same comments as CODSIA but focuses those comments on the application of the criterion to subcontracts. CSA also states "no commercial service subcontractor will contract under an obligation that clearly impairs the efficient performance of its work." CSA concludes that "the 20% limitation should be eliminated for commercial service subcontractors."

On the other side of the issue, several union commenters take the position that the 20% criterion should be more limiting. The AFL–CIO comments that under the proposed rule a service contract worker could spend virtually all of his or her time performing work that has been covered by SCA, but receive no SCA protection. "[I]f a contractor had numerous service contracts with one or more government agencies, and no employee spent more that 19.9 percent of his or her time on any one contract, the contractor could be exempt from the SCA even if one or more of its employees spent 99 percent of his or her time on five separate contracts, taken together." The AFL–CIO states that this criterion "would encourage bid splitting by government agencies and contractors to avoid SCA coverage." Therefore, it recommends that § 4.123(e)(2)(ii)(D) require that "contractors treat the total time spent on government contracts or subcontracts cumulatively in calculating employee time allocated to government contract work." Also, "[t]o further ensure that contractors perform a significant amount of government contract work remain subject to the SCA," AFL–CIO recommends that "the Department should also place a cap on the total amount of time a contractor can devote to government contracts and still be eligible for the exemption." AFL–CIO suggests five percent as a reasonable level. Finally, the AFL–CIO states that "[w]ithout recordkeeping requirements, the contractor itself may not know if any employee works a monthly average of more than 20 percent of available hours on an annualized basis on a government contract or subcontract." "To address the exemptions' failure to include recordkeeping requirements," the AFL–CIO suggests that "the regulation define a 'small portion' of a worker's time as 'no more than 20 percent in any one month.'"

The Department believes that these comments overlook the primary purpose of this criterion. The criterion is not designed to dictate how the contractor manages its workforce, but rather to describe the nature of the services being procured. The proposed criteria are designed to complement each other and to work as a whole. Therefore, each individual criterion must be evaluated within the context of the whole. In evaluating this criterion, therefore, it is important to remember that a subsequent criterion requires that the contracting officer (or the prime contractor in the case of a subcontract) determine in advance that all or nearly all of the prospective contractors will meet the criteria. Therefore, the 20 percent criterion should primarily serve as a guide for the contracting officer in evaluating the services to be procured. A hypothetical example might illustrate this point better. An agency is contracting for routine maintenance on a fleet of automobiles. The fleet is large enough that the agency expects to have at least five cars in the shop at all times. In this example, a contractor could clearly perform the government work with a dedicated workforce. Because it is therefore highly unlikely that all or nearly all the bidders would perform the contract in a way that would meet this criterion, the contracting officer would make the determination that the exemption would not apply to this procurement. The fact that a large repair shop could divide the work and ensure that none of its mechanics spends more than 20 percent of his or her time (on an annualized monthly basis) servicing the government vehicles would not alter the determination that SCA applies to this contract. An example of an exempt vehicle maintenance contract would be one where the government's fleet is relatively small or dispersed so that it is not likely that more than one or two vehicles per month will be serviced by one facility. In this case, the mechanics for all or nearly all of the offerors would clearly spend less than 20 percent of their time servicing the government vehicles. The contractor's certification that its employees will not spend more than 20 percent of their time servicing the government vehicles is largely a confirmation that the contracting officer's evaluation of the nature of the contract work was correct.

Because the contracting officer should have already determined that all or nearly all offerors would meet this criterion, no contractor should be required to restructure its workforce to comply with the 20 percent limitation. Furthermore, the limitation requires employees to spend no more than 20 percent of their hours on the contract on an annualized basis, thereby permitting longer hours where required by the interim exigencies of the contract or to accommodate short-term workforce fluctuations. Therefore, the underlying basis for the CODSIA and CSA recommendation to delete this criterion should not exist. If a contractor could perform the services with a dedicated workforce, then the contracting officer should not consider the exemption to be applicable.

Further, with respect to the AFL–CIO's recommendation that the 20 percent limitation be based upon all government work and not just the contract in question, this is a question for which the contracting office would not have direct knowledge, and is something that would change from one contractor to the next. If the AFL–CIO's recommendation were adopted, one company might be exempt because it only had one government contract whereas another would be subject to SCA because it had numerous contracts. This would convert the determination on application of the exemption from one based upon the overall requirements of the contract to a determination based upon the individual contractor's workforce utilization. The Department does not intend this exemption to permit the situation where an exempt contractor would compete against a nonexempt contractor, and we have not adopted the AFL–CIO recommendation. Similarly, we have not adopted the AFL–CIO recommendation to limit the overall amount of Government work that an exempt contractor would be allowed to perform.

Finally, the Department has not adopted the AFL–CIO's recommendation to apply the 20 percent limitation on a month-by-month basis rather than an annualized monthly average. As already explained, this criterion was established primarily to describe the nature of the exempt services. In the automotive maintenance example described previously, the

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Department does not believe that the exemption should be denied simply because in one month the agency's entire fleet of twenty vehicles needs servicing and for the remainder of the year no more than one car per month is in the shop. While the contracting officer should have informed knowledge about the amount of work anticipated over a normal year period, the contracting officer may not always be able to predict when repairs will be needed. The application of the exemption should not be impacted by unexpected fluctuations in service needs as long as the overall nature of the contract is not changed. Accordingly, the Department has not changed this annualized monthly average concept.

The criterion is adopted with a minor wording change to make it clear that the 20% limitation applies on an employee-by-employee basis, rather than an average of all of the employees working on the contract.

(5) The contractor utilizes the same compensation plan for both contract and commercial work. This criterion would ensure that the employees servicing the government contract will be compensated exactly as they would be if they were servicing a commercial account. Thus, the prevailing labor standards for private work would not be impacted in any way by the award of the Government contract. Furthermore, because contract award is not determined primarily on the basis of cost (Criterion 2), the contractor paying the lowest wages would not have a competitive advantage over other employers who pay average or above average wages. These contractors would compete for the Government work on the same basis that they compete for private work—quality of service and overall value.

The AFL–CIO and LIUNA commented that the Department improperly substituted the term "equivalent commercial wage" for the statutory term "prevailing." The AFL–CIO recommended that this criterion be changed to require that the contractor's compensation plan be not less than the SCA wages and benefits. If this recommendation were adopted, the exemption would serve no purpose. If the contractor is already paying SCA rates then it should not matter whether SCA is applied to the contract. This comment, however, also goes to the issue of whether the exemption is "in accord with the remedial purpose of the Act to protect prevailing labor standards." The Department believes that the criteria as a whole achieve this goal. If the employer does not change its pay practices to obtain the Government contract, prevailing wages should not be affected. Furthermore, an employer would be unlikely to change its pay practices in any event where no worker spends more than 20% of his or her time on the Government contract. In addition, the criteria limit the application of the exemption to situations where employee wages are not a primary factor in deciding which company is awarded the contract. Thus, the Government contract should not serve to either increase or decrease prevailing labor standards. This recommendation, therefore, is not adopted, and the criterion is retained in the final rule as proposed.

(6) The contracting officer determines in advance that all or nearly all of the offerors will meet the requirements of the criteria. This requirement was designed to ensure that all contractors compete on an equal basis, and that a contractor subject to SCA would not be forced to compete against a contractor that would be exempt from SCA. Furthermore, as noted in the discussion of Criterion 4, this requirement—which takes into consideration not only the practices of likely offerors but also the nature of the contract requirements—is a necessary safeguard to prevent individual offerors from juggling staffing patterns simply in an effort to avoid SCA coverage. This criterion also would serve to protect those employees (either contractor or Federal employees) who might currently be engaged in performing the solicited services on a full-time basis.

The AFL–CIO noted that this criterion is designed to ensure that all contractors compete on an equal basis. The AFL–CIO questions whether the criterion accomplishes this goal since it only requires that all or "nearly all" of the offerors meet the requirements of the other criteria. The AFL–CIO suggests that this standard be changed to require that all offerors meet the requirements.

The Department's intention is that a contracting officer would not make this determination unless he or she has a high degree of confidence that all offerors will meet the requirements. It is unlikely that any contracting officer would feel able to determine absolutely that every offeror will qualify for the exemption. The "or nearly all" language therefore would permit the extraordinary situation where one bidder might not qualify as exempt. Returning to the automotive maintenance example described previously, an employer with a single employee and a relatively small number of commercial customers could bid on the contract to maintain on average a few vehicles a month. With that small volume of government work, the workforce for "nearly all" prospective contractors would spend less than 20 percent of their time working on the contract. The single employee working for a company with relatively few commercial accounts, however, might spend more than 20 percent of his or her time performing work on the contract. While this company's offer might be rejected for other reasons (*e.g.*, the contract might require a capacity to service more than one vehicle at a time—a capacity that the two-person shop might not possess), the fact that one non-exempt contractor might bid on the contract should not negate the application of the exemption to everyone else. The Department believes that retaining some amount of flexibility in this regard is appropriate, and the criterion is retained.

The Department would like to emphasize that "nearly all" does not mean most or a majority. The words "nearly all" are intended to recognize the possibility of exceptional circumstances where an individual offeror might not meet all of the criteria. If this offeror receives the contract, of course, the contract would be subject to SCA prevailing wage requirements. On the other hand, the Department realizes that there may be circumstances where, once bids are received, the contracting officer determines that he or she was incorrect in the determination that all or nearly all bidders would meet the exemption requirements. The regulation has therefore been revised to provide that in such circumstances SCA will apply to the procurement.

(7) The exempted contractor or subcontractor certifies to the provisions of criteria (1) and (3) through (5). This criterion would provide a mechanism for addressing and correcting situations where the exemption may have been misapplied. If the Department of Labor, in its enforcement, determines that the contract is not in fact exempt, it would require that SCA stipulations be included in the contract. In the case of a subcontract, the prime contractor, who in almost all cases would have SCA stipulations already included in its contract, would be ultimately responsible for compliance with the requirements of the Act. The Department could therefore require that the SCA requirements be effective as of the date of contract award. The Department noted in the NPRM that an exempt contractor or subcontractor would not be required to keep any particular records to meet its burden of showing that the criteria are satisfied.

CODSIA and CSA both comment that this was an unauthorized certification requirement. They note that section 4301 of the Clinger-Cohen Act of 1996 (Pub. L. 104–106) prohibits the imposition of contractor and subcontractor certification requirements in the Federal Acquisition Regulations unless the certification is required by statute or justified in writing and approved by the FAR Council and the Administrator of the Office of Federal Procurement Policy (OFPP). While CODSIA and CSA correctly identify the procedural requirements for approval of these certifications, the Department does not consider this to be a substantive deficiency since the FAR Council and the Administrator of OFPP recommended the certifications. The Department notes that no contracting officer can be expected to know whether individual contractors in fact satisfy the exemption. Therefore the Department considers certification essential to ensure that the criteria for the exemption have been met. The FAR Council has now made the required justification, and it has been approved by the Administrator of OFPP. Therefore the certification requirement is retained, and modified to make it clear that a certification by a prime contractor that it meets the criteria also constitutes a certification that if it subcontracts the services, the subcontractor in turn will meet the criteria.

CSA also "recommends that the Department adopt the same policy that accompanies the Buy America Act (BAA) certification. Under the BAA policy, the contracting officer is permitted to accept the contractor's self-certification." In considering this comment the Department notes that the contracting officer or the prime contractor has already reviewed the requirements of the proposed contract/subcontract and has determined that all or nearly all of the offerors will meet the criteria. Therefore, the contracting officer or prime contractor should have no reason to question the contractor/subcontractor's certification. Accordingly, the Department has concluded that it is not necessary for the contracting officer or prime contractor to review the contractor/subcontractor's certification and this requirement has been deleted from the final rule. The fact that the requirement for review has been eliminated, however, does not mean that the contracting officer or prime contractor may not review the certification if they choose to do so, such as where they possess information which causes them to question the validity of the certification. Further, if it is determined that the certification is not correct, then the contracting officer or the prime contractor should not proceed with award of an exempt contract or subcontract. Because the contracting officer will no longer be required to review the certification in advance, the Department has also amended the regulation to delete the language applying SCA as of the date of the Department's determination. As provided in § 4.5(c)(2) of the regulations, the Department may require retroactive application of the SCA where it determines it is appropriate under the circumstances.

The AFL–CIO, while not opposing the criterion, commented that in the absence of a formal monitoring system, it is unlikely that any misapplication of the exemption would ever be identified. The Department shares the AFL–CIO's concern that this exemption not be misapplied. Certainly, the Department expects that contracting agencies and prime contractors would exercise their responsibilities to ensure that such misapplication is minimized. At the same time, the Department recognizes that mistakes may be made; however, the Department does not believe that the mere possibility of a mistake should preclude adopting an exemption that is otherwise justified. The Department will monitor allegations of abuse to determine whether future changes in this exemption are warranted.

3. Other Issues

Several commenters raised additional issues that were not specifically related or limited to a single aspect of the proposed exemptions. Those issues are addressed separately in this section.

Several union commenters, including the AFL–CIO and LIUNA, recommended that the exclusion for contracts subject to the provisions of section 4(c) of SCA be expanded to include "resolicitations and other successor contracts for substantially the same services." They also recommended that this limitation be added to contracts under the current ADP exemption. The Department agrees that the regulation should be revised to make it clear that the exemption does not apply to any contract which is subject to section 4(c), as well as all options exercised and extensions of the contract. The Department does not believe, however, that there is sufficient justification to extend this limitation to all future resolicitations for substantially the same services, where the predecessor contract was not subject to section 4(c). In addition, the Department does not believe sufficient justification has been presented to add this requirement to the existing ADP exemption. This exemption has been in existence for nearly twenty years and the Department is not aware of any problems arising from the absence of this requirement.

Several union commenters recommended that the Department promulgate a new procedure under which the contracting agency is required to demonstrate in advance of issuing the solicitation that the section 4(d) requirements are satisfied for a proposed exemption of a particular contract or subcontract. This recommendation is consistent with other union comments that the contracting officers and prime contractors should not be delegated the responsibility to decide whether a contractor is exempt from SCA coverage. The purpose of the proposed exemptions, however, is to carefully describe a class of contracts where exemption from SCA is appropriate. Every day contracting officers decide whether SCA should be applied to a particular contract, and the decisions required to be made in this case are no different. The Department does not believe that case-by-case determination is necessary where, as in the instant situation, the record supports an exemption for a particular class of contracts.

4. Conclusion

For the reasons discussed above, the Department has concluded that the exemptions as set forth in this rule are necessary and proper in the public interest or to avoid serious impairment of Government business, and are in according with the remedial purpose of the Service Contract Act to protect prevailing labor standards. The list of services is narrowly tailored to include only commercial services which the Government has had difficulty in acquiring or where the Government is getting limited competition because of unique requirements imposed by the Government. The additional criteria, when viewed as a whole, are designed to ensure that the contractor will not be motivated to change its wage practices and pay less than the prevailing wage in order to obtain the Government contract, and that the Government in turn will not be motivated to award contracts to offerors who pay less than prevailing wages.

IV. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, Public Law 96–354 (94 Stat. 1164; 5 U.S.C. 601 *et seq.*), Federal Agencies are required to prepare and make available for public comment and initial regulatory flexibility analysis that describes the anticipated impact of

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proposed rules on small entities. The Department received no comments regarding the Regulatory Flexibility Analysis prepared for this rule.

(1) The Need for and Objectives of the Rule

This rule was made at the request of the Administrator for Federal Procurement Policy, OFPP, in her letter of May 12, 1999. The Administrator, on behalf of the FAR Council, stated that the exemption "will further the commitment of the Administration to be more commercial-like, encourage broader participation in government procurement by companies doing business in the commercial sector, and reinforce our commitment to reduce government-unique terms and conditions from our contracts. We believe that all of this can be accomplished without compromising the purpose of the SCA to protect prevailing labor standards." The FAR Council developed a short list of services to which it believed an exemption should apply in the best interest of the Government and to avoid impairment to Government business.

Pursuant to section (4)(b) of SCA, the Secretary of Labor may grant reasonable exemptions to the provisions of the Act, but only in special circumstances where the "exemption is necessary and proper in the public interest or to avoid the serious impairment of government business, and is in accord with the remedial purpose of this Act to protect prevailing labor standards."

After a review of the comments and the representations of the FAR Council, the Department of Labor determined that the exemption, as revised based upon the public comments, will be both "necessary and proper in the public interest" and will also be "in accord with the remedial purpose of th[e] Act to protect prevailing labor standards."

(2) Summary of Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis

The Department received a number of comments regarding the proposed exemptions. Those comments are discussed in detail in the preamble to this rule. The Department did not receive separate comments concerning its initial regulatory flexibility analysis.

(3) Number of Small Entities Covered Under the Rule

The definition of "small business" varies considerably depending upon the policy issues and circumstances under review, the industry being studied, and the measures used. The Small Business Administration's Office of Advocacy generally uses employment data as a basis for size comparisons, with firms having fewer than 100 employees or fewer than 500 employees defined as small. The types of services covered by the proposed exemptions span a variety of industries. Based upon analyses done by the U.S. Small Business Administration, Office of Advocacy, some of the industries affected by the proposed exemptions are characterized as "large-business-dominated industries" (*e.g.*, air transportation and business credit institutions) and others are characterized as "small-business-dominated industries" (*e.g.*, automotive repair and real estate).[1] Thus, at least some of the services covered by the exemption would be performed primarily by small businesses. In fact, with the exception of those contracts for financial services involving the issuance and servicing of cards, the contracts for the transportation of persons, and contracts with equipment manufacturers, it would appear that a majority of the contracts affected by the proposed exemption likely would be performed by small businesses.

It is also difficult to determine with precision the value of Federal contracts that would be affected by the exemption. Federal Procurement Data System (FPDS) compiles and reports information on approximately 500,000 annual transactions exceeding $25,000; however, as discussed above, many of the contracts covered by the exemption (*e.g.*, food and lodging contracts for conferences) are currently or would likely be less that $25,000. Also, the criteria that must be met for the specified services to be within the scope of the exemption will limit the application of the exemptions to a relatively small subset of contracts within a specific SIC code. Thus, FPDS data does not provide an accurate estimate of the contracts potentially covered by the exemption. Nevertheless, in view of the limiting criteria for the listed services, the total value of the exempt contracts should be relatively small, and it is believed that the SCA would no longer apply to only a relatively small number of contracts that currently contain SCA wage determination provisions.

(4) Reporting, Recordkeeping and Other Compliance Requirements of the Rule

The exemption does not impose any new reporting or recordkeeping requirements. Although offerors are required to certify that the criteria for exemption are met, offerors are not required to maintain records to support the certification. The certification, which can be submitted as part of the bid package, is an important element to satisfy the statutory requirement that exemptions be "in accordance with the remedial purpose of the Act to protect prevailing labor standards." Contractors and subcontractors to whom the exemption applies will not be required to comply with the wage and reporting requirements of the SCA.

(5) Description of the Steps Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Objectives of the Service Contract Act

The exemption does not contain any new reporting, recordkeeping, or other compliance requirements applicable to small business. Rather, the exemption would relieve small businesses and other contractors from the requirements of the SCA on certain contracts where the contractor certifies that the requirements of the exemption have been met. Furthermore, any contractor performing on a contract within the scope of the exemption may elect to perform the contract under the requirements of SCA rather than make the necessary certifications. Because application of the exemption will have been determined in advance by the contracting officer, the Department anticipates that questions regarding proper application of the exemption will be rare. Contractors will not be required to maintain any records to support the exemption, although they may be required to furnish payroll and other existing records to the Department in the event of an investigation.

V. Executive Order 12866 and 13132; Section 202 of the Unfunded Mandates Reform Act of 1995; Small Business Regulatory Enforcement Fairness Act

This rule is being treated as a "significant regulatory action" within the meaning of Executive Order 12866 because of the significant impact of this rule on other agencies. Therefore, the Office of Management and Budget has reviewed the rule. However, the Department concurs with the view of the Federal Acquisition Regulatory Council that this rule is not "economically significant" as defined in section 3(f)(1) of E.O. 12866, and therefore it does not require a full economic impact analysis under section 6(a)(3)(C) of the Order. Under the new exemption, contracts would not be exempt unless price is equal to or less important than the combination of other non-price or cost factors in selecting the contractor. Therefore it is not anticipated that the changed rule will have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

The Department has similarly concluded that this rule is not a "major rule" requiring approval by the Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). It will not likely result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For purposes of the Unfunded Mandates Reform Act of 1995, this rule does not include any federal mandate that may result in excess of $100 million in expenditures by state, local and tribal governments in the aggregate, or by the private sector. Furthermore, the requirements of the Unfunded Mandates Reform Act, 2 U.S.C. 1532, do not apply here because the rule does not include a "Federal mandate." The term "Federal mandate" is defined to include either a "Federal intergovernmental mandate" or a "Federal private sector mandate." 2 U.S.C. 658(6). Except in limited circumstances not applicable here, those terms do not include an enforceable duty which is "a duty arising from participation in a voluntary program." 2 U.S.C. 658(7)(A). A decision by a contractor to bid on Federal service contracts is purely voluntary in nature, and the contractor's duty to meet Service Contract Act requirements arises "from participation in a voluntary Federal program."

The Department has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

VI. Document Preparation

This document was prepared under the direction and control of Thomas M. Markey, Deputy Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 4

Administrative practice and procedures, Employee benefit plans, Government contracts, Investigations, Labor, Law enforcement, Minimum wages, Penalties, Recordkeeping requirements, Reporting requirements, wages.

Accordingly, for the reasons set out in the preamble, 29 CFR part 4 is amended as set forth below:

PART 4—LABOR STANDARDS FOR FEDERAL SERVICE CONTRACTS

1. The authority citation for part 4 is revised to read as follows:

Authority: 41 U.S.C. 351 *et seq.*; 41 U.S.C. 38 and 39; 5 U.S.C. 301.

2. Section 4.123(e) is revised to read as follows:

§ 4.123 Administrative limitations, variances, tolerances, and exemptions.

* * * * *

(e) The following types of contracts have been exempted from all the provisions of the Service Contract Act of 1965, pursuant to section 4(b) of the Act, which exemptions the Secretary of Labor found are necessary and proper in the public interest or to avoid serious impairment of the conduct of Government business, and are in accord with the remedial purpose of the Act to protect prevailing labor standards:

(1)(i) Prime contracts or subcontracts principally for the maintenance, calibration, and/or repair of:

(A) Automated data processing equipment and office information/word processing systems;

(B) Scientific equipment and medical apparatus or equipment where the application of microelectronic circuitry or other technology of at least similar sophistication is an essential element (for example, Federal Supply Classification (FSC) Group 65, Class 6515, "Medical Diagnostic Equipment"; Class 6525, "X-Ray Equipment"; FSC Group 66, Class 6630, "Chemical Analysis Instruments"; Class 6665, "Geographical and Astronomical Instruments", are largely composed of the types of equipment exempted under this paragraph);

(C) Office/business machines not otherwise exempt pursuant to paragraph (e)(1)(i)(A) of this section, where such services are performed by the manufacturer or supplier of the equipment.

(ii) The exemptions set forth in this paragraph (e)(1) shall apply only under the following circumstances:

(A) The items of equipment are commercial items which are used regularly for other than Government purposes, and are sold or traded by the contractor (or subcontractor in the case of an exempt subcontract) in substantial quantities to the general public in the course of normal business operations;

(B) The prime contract or subcontract services are furnished at prices which are, or are based on, established catalog or market prices for the maintenance, calibration, and/or repair of such commercial items. An "established catalog price" is a price included in a catalog, price list, schedule, or other form that is regularly maintained by the manufacturer or the contractor, is either published or otherwise available for inspection by customers, and states prices at which sales currently, or were last, made to a significant number of buyers constituting the general public. An "established market price" is a current price, established in the usual course of trade between buyers and sellers free to bargain, which can be substantiated from sources independent of the manufacturer or contractor; and

(C) The contractor utilizes the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract as the contractor uses for these employees and equivalent employees servicing the same equipment of commercial customers;

(D) The contractor certifies to the provisions in this paragraph (e)(1)(ii). Certification by the prime contractor as to its compliance with respect to the prime contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services. The certification shall be included in the prime contract or subcontract.

(iii)(A) Determinations of the applicability of this exemption to prime contracts shall be made in the first instance by the contracting officer on or before contract award. In making a judgment that the exemption applies, the contracting officer shall consider all factors and make an affirmative determination that all of the conditions in paragraph (e)(1) of this section have been met.

(B) Determinations of the applicability of this exemption to subcontracts shall be made by the prime contractor on or before subcontract award. In making a judgment that the exemption applies, the prime contractor shall consider all factors and make an affirmative determination that all of the conditions in paragraph (e)(1) have been met.

(iv)(A) If the Administrator determines after award of the prime

[1] The State of Small Business: A Report of the President, 1996 (1997).

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contract that any of the requirements in paragraph (e)(1) for exemption has not been met, the exemption will be deemed inapplicable, and the contract shall become subject to the Service Contract Act, effective as of the date of the Administrator's determination. In such case, the corrective procedures in § 4.5(c)(2) shall be followed.

(B) The prime contractor is responsible for compliance with the requirements of the Service Contract Act by its subcontractors, including compliance with all of the requirements of this exemption (see § 4.114(b)). If the Administrator determines that any of the requirements in paragraph (e)(1) for exemption has not been met with respect to a subcontract, the exemption will be deemed inapplicable, and the prime contractor may be responsible for compliance with the Act effective as of the date of contract award.

(2)(i) Prime contracts or subcontracts principally for the following services where the services under the contract or subcontract meet all of the criteria set forth in paragraph (e)(2)(ii) of this section and are not excluded by paragraph (e)(2)(iii):

(A) Automobile or other vehicle (*e.g.*, aircraft) maintenance services (other than contracts to operate a Government motor pool or similar facility);

(B) Financial services involving the issuance and servicing of cards (including credit cards, debit cards, purchase cards, smart cards, and similar card services);

(C) Contracts with hotels/motels for conferences, including lodging and/or meals which are part of the contract for the conference (which shall not include ongoing contracts for lodging on an as needed or continuing basis);

(D) Maintenance, calibration, repair and/or installation (where the installation is not subject to the Davis-Bacon Act, as provided in § 4.116(c)(2)) services for all types of equipment where the services are obtained from the manufacturer or supplier of the equipment under a contract awarded on a sole source basis;

(E) Transportation by common carrier of persons by air, motor vehicle, rail, or marine vessel on regularly scheduled routes or via standard commercial services (not including charter services);

(F) Real estate services, including real property appraisal services, related to housing federal agencies or disposing of real property owned by the Federal Government; and

(G) Relocation services, including services of real estate brokers and appraisers, to assist federal employees or military personnel in buying and selling homes (which shall not include actual moving or storage of household goods and related services).

(ii) The exemption set forth in this paragraph (e)(2) shall apply to the services listed in paragraph (e)(2)(i) only when all of the following criteria are met:

(A) The services under the prime contract or subcontract are commercial—*i.e.*, they are offered and sold regularly to non-Governmental customers, and are provided by the contractor (or subcontractor in the case of an exempt subcontract) to the general public in substantial quantities in the course of normal business operations.

(B) The prime contract or subcontract will be awarded on a sole source basis or the contractor or subcontractor will be selected for award on the basis of other factors in addition to price. In such cases, price must be equal to or less important than the combination of other non-price or cost factors in selecting the contractor.

(C) The prime contract or subcontract services are furnished at prices which are, or are based on, established catalog or market prices. An established price is a price included in a catalog, price list, schedule, or other form that is regularly maintained by the contractor or subcontractor, is either published or otherwise available for inspection by customers, and states prices at which sales are currently, or were last, made to a significant number of buyers constituting the general public. An established market price is a current price, established in the usual course of trade between buyers and sellers free to bargain, which can be substantiated from sources independent of the manufacturer or contractor.

(D) Each service employee who will perform services under the Government contract or subcontract will spend only a small portion of his or her time (a monthly average of less than 20 percent of the available hours on an annualized basis, or less than 20 percent of available hours during the contract period if the contract period is less than a month) servicing the government contract or subcontract.

(E) The contractor utilizes the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract or subcontract as the contractor uses for these employees and for equivalent employees servicing commercial customers.

(F) The contracting officer (or prime contractor with respect to a subcontract) determines in advance, based on the nature of the contract requirements and knowledge of the practices of likely offerors, that all or nearly all offerors will meet the requirements in paragraph (e)(2)(ii) of this section. Where the services are currently being performed under contract, the contracting officer or prime contractor shall consider the practices of the existing contractor in making a determination regarding the requirements in paragraph (e)(2)(ii). If upon receipt of offers, the contracting officer finds that he or she did not correctly determine that all or nearly all offerors would meet the requirements, the Service Contract Act shall apply to the procurement, even if the successful offeror has certified in accordance with paragraph (e)(2)(ii)(G) of this section.

(G) The contractor certifies in the prime contract or subcontract, as applicable, to the provisions in paragraph (e)(2)(ii)(A) and (C) through (E) of this section. Certification by the prime contractor as to its compliance with respect to the prime contract also constitutes its certification as to compliance by its subcontractor if it subcontracts out the exempt services. If the contracting officer or prime contractor has reason to doubt the validity of the certification, SCA stipulations shall be included in the prime contract or subcontract.

(iii)(A) If the Administrator determines after award of the prime contract that any of the requirements in paragraph (e)(2) for exemption has not been met, the exemption will be deemed inapplicable, and the contract shall become subject to the Service Contract Act. In such case, the corrective procedures in § 4.5(c)(2) shall be followed.

(B) The prime contractor is responsible for compliance with the requirements of the Service Contract Act by its subcontractors, including compliance with all of the requirements of this exemption (see § 4.114(b)). If the Department of Labor determines that any of the requirements in paragraph (e)(2) for exemption has not been met with respect to a subcontract, the exemption will be deemed inapplicable, and the prime contractor may be responsible for compliance with the Act, as of the date of contract award.

(iv) The exemption set forth in this paragraph (e)(2) does not apply to solicitations and contracts:

(A) Entered into under the Javits-Wagner-O'Day Act, 41 U.S.C. 47;

(B) For the operation of a Government facility or portion thereof (but may be applicable to subcontracts for services set forth in paragraph (e)(2)(ii) that meet all of the criteria of paragraph (e)(2)(ii)); or

(C) Subject to section 4(c) of the Service Contract Act, as well as any options or extensions under such contract.

Signed at Washington, DC, on this 11th day of January, 2001.

T. Michael Kerr,

Administrator, Wage and Hour Division.

[FR Doc. 01–1337 Filed 1–17–01; 8:45 am]

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Federal Register

Thursday,
January 18, 2001

Part XI

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Parts 22 and 52
Federal Acquisition Regulation; Final Rules

Department of Labor

Bureau of International Labor Affairs; List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor; Notices

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DEPARTMENT OF DEFENSE
GENERAL SERVICES ADMINISTRATION
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 22 and 52

[FAC 97–23; FAR Case 1999–608]

RIN 9000–AI51

Federal Acquisition Regulation; Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) are issuing a final rule to amend the Federal Acquisition Regulation (FAR) to implement the specific requirements of Executive Order 13126, Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor, as well as to prescribe further appropriate actions to comply with the broad policy of the Executive Order (*i.e.*, to enforce laws prohibiting the manufacture or importation of products that have been mined, produced, or manufactured wholly or in part using forced or indentured child labor).

DATES: *Effective Date:* February 20, 2001.

Applicability Date: The FAR, as amended by this rule, is applicable to solicitations issued on or after February 20, 2001 per FAR 1.108(d).

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC, 20405, (202) 501–4755, for information pertaining to status or publication schedules. For clarification of content, contact Ms. Linda Nelson, Procurement Analyst, at (202) 501–3775. Please cite FAC 97–23, FAR case 1999–608.

SUPPLEMENTARY INFORMATION:

A. Background

This final rule amends the FAR by adding a new FAR subpart on prohibition of acquisition of products produced by forced or indentured child labor (Subpart 22.15), adding a new certification regarding knowledge of child labor for listed end products (FAR 52.212–3 and 52.222–18), and adding a clause at 52.222–19, that requires cooperation with authorities if the solicitation included the certification provision and provides remedies for violations relating to use of forced or indentured child labor.

On June 12, 1999, the President signed Executive Order 13126, Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor (the Executive Order). The Executive Order states a broad policy that executive agencies must take appropriate actions to enforce the laws prohibiting the manufacture or importation of products mined, produced, or manufactured wholly or in part by forced or indentured child labor.

Section 2 of the Executive Order directed the Department of Labor (DoL), in consultation with the Department of Treasury and the Department of State, to publish in the **Federal Register** a list of products (the List, identified by their country of origin, for which there is a reasonable basis to believe that such product may have been mined, produced, or manufactured by forced or indentured child labor. DoL published the preliminary List in the **Federal Register** on September 6, 2000 (65 FR 54108–54112), and solicited public comment. After receipt and consideration of the public comments, DoL is publishing the final List in today's **Federal Register**.

Section 3 of the Executive Order required the Councils to issue a proposed rule, amending the FAR to implement the policy expressed in the Executive Order. Accordingly, the Councils published a proposed rule in the **Federal Register** on September 6, 2000 (65 FR 54104–54107). Public comments on the proposed rule were due by November 6, 2000.

Ten respondents submitted public comments. Most comments received did not object to the basic policy but were outside the scope of the case, because they request FAR revisions that go beyond the scope of the Executive Order or are inconsistent with the requirements of the Executive Order.

For example, some suggested expanding the scope of the mandate of the Executive Order in the regulation to address products made by convict labor and forced or indentured labor by persons 18 or older—clearly outside the purview of this rulemaking. Other respondents suggested using a different definition of "forced or indentured child labor," a comment that has been addressed in the companion rule being issued simultaneously by the Department of Labor. The Councils carefully considered all comments in formulation of the final rule.

The Councils are issuing a final rule that is the same as the proposed rule, except for minor editorial changes. This is a significant regulatory action, and therefore, was subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because only a small percentage of acquisitions are for products on the DoL List, there is minimal impact on offerors providing a listed product that originates in a country other than the corresponding countries identified on the DoL List, and not all offerors responding to solicitations for these acquisitions are small entities. With regard to the clause that requires cooperation with authorities and provides remedies for violations relating to use of forced or indentured child labor, we expect that very few contractors are furnishing end products or components produced by forced or indentured child labor. The rule does not apply to micro-purchases.

The Councils did not receive any comments regarding the Regulatory Flexibility Act as a result of publication of the proposed rule in the **Federal Register** at 65 FR 54104.

C. Nonstatutory Certification Approval

In accordance with Section 29 of the Office of Federal Procurement Policy Act, 41 U.S.C. Section 425, the FAR Council has requested approval from the Administrator for Federal Procurement Policy for inclusion of a nonstatutory certification in the Federal Acquisition Regulation. In the absence of an Administrator, that approval has been granted by the Director of the Office of Management and Budget in accordance with the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3348(b)(2).

D. Paperwork Reduction Act

The Paperwork Reduction Act (Pub. L. 104–13) applies. This final rule contains information collection requirements that have been submitted to the Office of Management and Budget (OMB) which will not take effect prior to OMB approval of these provisions. Two respondents commented on the estimated burden of the information collection requirements.

The Councils note that the average response time reflects the average burden on all contractors, including those who must simply certify that they are not supplying products that were mined, produced, or manufactured in the corresponding country identified on the DoL List. We also anticipate that, given the need to comply with the Tariff Act of 1930, many offerors would already have taken steps that would enable them to make the necessary certification, before they sought to supply a product from a country identified on the DoL List.

The proposed rule erroneously stated the estimated hours per response as .30 hours rather than .5 hours (30 minutes). This does not change the total estimate of 250 response burden hours per year. The revised annual reporting burden is estimated as follows:

Respondents: 500.
Responses per respondent: 1.
Total annual responses: 500.
Preparation hours per response: .5.
Total response burden hours: 250.

List of Subjects in 48 CFR Parts 22 and 52

Government procurement.

Dated: January 12, 2001.

Al Matera,
Acting Director, Federal Acquisition Policy Division.

Federal Acquisition Circular

Federal Acquisition Circular (FAC) 97–23 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration.

All Federal Acquisition Regulation (FAR) changes and other directive material contained in FAC 97–23 are effective February 20, 2001.

Dated: January 11, 2001.

R.D. Kerrins, Jr.,
Acting Director, Defense Procurement, Department of Defense.

Dated: January 11, 2001.

David A. Drabkin,
Deputy Associate Administrator, Office of Acquisition Policy, General Services Administration.

Dated: January 12, 2001.

Anne Guenther,
Acting Associate Administrator for Procurement, National Aeronautics and Space Administration.

Therefore, DoD, GSA, and NASA amend 48 CFR Parts 22 and 52 as set forth below:

1. The authority citation for 48 CFR Parts 22 and 52 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

2. Add Subpart 22.15 to read as follows:

Subpart 22.15—Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor

Sec.
22.1500 Scope.
22.1501 Definitions.
22.1502 Policy.
22.1503 Procedures for acquiring end products on the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor.
22.1504 Violations and remedies.
22.1505 Solicitation provision and contract clause.

22.1500 Scope.

This subpart applies to acquisitions of supplies that exceed the micro-purchase threshold.

22.1501 Definitions.

As used in this subpart—

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor means the list published by the Department of Labor in accordance with Executive Order 13126 of June 12, 1999, Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor. The list identifies products, by their country of origin, that the Departments of Labor, Treasury, and State have a reasonable basis to believe might have been mined, produced, or manufactured by forced or indentured child labor.

22.1502 Policy.

Agencies must take appropriate action to enforce the laws prohibiting the manufacture or importation of products that have been mined, produced, or manufactured wholly or in part by forced or indentured child labor (19 U.S.C. 1307, 29 U.S.C. 201, *et seq.*, and 41 U.S.C. 35, *et seq.*). Agencies should make every effort to avoid acquiring such products.

22.1503 Procedures for acquiring end products on the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor.

(a) When issuing a solicitation for supplies expected to exceed the micro-purchase threshold, the contracting officer must check the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor (the List) (www.dol.gov/dol/ilab) (see 22.1505(a)). Appearance of a product on the List is not a bar to purchase of any such product mined, produced, or manufactured in the identified country, but rather is an alert that there is a reasonable basis to believe that such product may have been mined, produced, or manufactured by forced or indentured child labor.

(b) The requirements of this subpart that result from the appearance of any end product on the List do not apply to a solicitation or contract if the identified country of origin on the List is—

(1) Canada, and the anticipated value of the acquisition is $25,000 or more (see 25.405);

(2) Israel, and the anticipated value of the acquisition is $50,000 or more (see 25.406);

(3) Mexico, and the anticipated value of the acquisition is $54,372 or more (see 25.405); or

(4) Aruba, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, Korea, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Singapore, Spain, Sweden, Switzerland, or the United Kingdom and the anticipated value of the acquisition is $177,000 or more (see 25.403(b)).

(c) Except as provided in paragraph (b) of this section, before the contracting officer may make an award for an end product (regardless of country of origin) of a type identified by country of origin on the List the offeror must certify that—

(1) It will not supply any end product on the List that was mined, produced, or manufactured in a country identified on the List for that product, as specified in the solicitation by the contracting officer in the Certification Regarding Knowledge of Child Labor for Listed End Products; or

(2)(i) It has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any end product to be furnished under the contract that is on the List and was mined, produced, or manufactured in a country identified on the List for that product; and

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(ii) On the basis of those efforts, the offeror is unaware of any such use of child labor.

(d) Absent any actual knowledge that the certification is false, the contracting officer must rely on the offerors' certifications in making award decisions.

(e) Whenever a contracting officer has reason to believe that forced or indentured child labor was used to mine, produce, or manufacture an end product furnished pursuant to a contract awarded subject to the certification required in paragraph (c) of this section, the contracting officer must refer the matter for investigation by the agency's Inspector General, the Attorney General, or the Secretary of the Treasury, whichever is determined appropriate in accordance with agency procedures, except to the extent that the end product is from the country listed in paragraph (b) of this section, under a contract exceeding the applicable threshold.

(f) Proper certification will not prevent the head of an agency from imposing remedies in accordance with section 22.1504(a)(4) if it is later discovered that the contractor has furnished an end product or component that has in fact been mined, produced, or manufactured, wholly or in part, using forced or indentured child labor.

22.1504 Violations and remedies.

(a) *Violations.* The Government may impose remedies set forth in paragraph (b) of this section for the following violations (note that the violations in paragraphs (a)(3) and (a)(4) of this section go beyond violations of the requirements relating to certification of end products) (see 22.1503):

(1) The contractor has submitted a false certification regarding knowledge of the use of forced or indentured child labor.

(2) The contractor has failed to cooperate as required in accordance with the clause at 52.222–19, Child Labor Cooperation with Authorities and Remedies, with an investigation of the use of forced or indentured child labor by an Inspector General, the Attorney General, or the Secretary of the Treasury.

(3) The contractor uses forced or indentured child labor in its mining, production, or manufacturing processes.

(4) The contractor has furnished an end product or component mined, produced, or manufactured, wholly or in part, by forced or indentured child labor. Remedies in paragraphs (b)(2) and (b)(3) of this section are inappropriate unless the contractor knew of the violation.

(b) *Remedies.* (1) The contracting officer may terminate the contract.

(2) The suspending official may suspend the contractor in accordance with the procedures in subpart 9.4.

(3) The debarring official may debar the contractor for a period not to exceed 3 years in accordance with the procedures in subpart 9.4.

22.1505 Solicitation provision and contract clause.

(a) Except as provided in paragraph (b) of 22.1503, insert the provision at 52.222–18, Certification Regarding Knowledge of Child Labor for Listed End Products, in all solicitations that are expected to exceed the micro-purchase threshold and are for the acquisition of end products (regardless of country of origin) of a type identified by country of origin on the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, except solicitations for commercial items that include the provision at 52.212–3, Offeror Representations and Certifications—Commercial Items. The contracting officer must identify in paragraph (b) of the provision at 52.222–18, Certification Regarding Knowledge of Child Labor for Listed End Products, or paragraph (i)(1) of the provision at 52.212–3, any applicable end products and countries of origin from the List. For solicitations estimated to equal or exceed $25,000, the contracting officer must exclude from the List in the solicitation end products from any countries identified at 22.1503(b), in accordance with the specified thresholds.

(b) Insert the clause at 52.222–19, Child Labor—Cooperation with Authorities and Remedies, in all solicitations and contracts for the acquisition of supplies that are expected to exceed the micro-purchase threshold.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. In section 52.212–3, revise the date of the provision; add, in alphabetical order, in paragraph (a) the definition "Forced or indentured child labor"; and add paragraph (i) to read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

OFFEROR REPRESENTATIONS AND CERTIFICATIONS—COMMERCIAL ITEMS (February 2001)

(a) * * *

* * * * * *

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

* * * * *

(i) *Certification Regarding Knowledge of Child Labor for Listed End Products (Executive Order 13126). [The Contracting Officer must list in paragraph (i)(1) any end products being acquired under this solicitation that are included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, unless excluded at 22.1503(b).]*

(1) *Listed end products.*

Listed End Product

_____

Listed Countries of Origin

_____

(2) *Certification. [If the Contracting Officer has identified end products and countries of origin in paragraph (i)(1) of this provision, then the offeror must certify to either (i)(2)(i) or (i)(2)(ii) by checking the appropriate block.]*

☐ (i) The offeror will not supply any end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product.

☐ (ii) The offeror may supply an end product listed in paragraph (i)(1) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any such end product furnished under this contract. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

3a. Effective March 12, 2001, the date of the clause at 52.212–3 is amended by removing "(February 2001)" and adding (MAR 2001) in its place).

4. In section 52.212–5, revise the date of the clause and the introductory text of paragraph (b); redesignate paragraphs (b)(16) through (b)(27) as (b)(17) through (b)(28), respectively, and add new paragraph (b)(16) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required to Implement Statues or Executive Orders—Commercial Items (February 2001)

* * * * *

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items or components:

[Contracting Officer must check as appropriate.]

* * * * *

____(16) 52.222–19, Child Labor—Cooperation with Authorities and Remedies (E.O. 13126).

* * * * *

5. In section 52.213–4, revise the date of the clause; redesignate paragraphs (b)(1)(vii) through (xi) as (b)(1)(viii) through (xii), respectively, and add new paragraph (vii) to read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other than Commercial Items).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (February 2001)

* * * * *

(vii) 52.222–19, Child Labor—Cooperation with Authorities and Remedies (JAN 2001) (E.O. 13126). (Applies to contracts for supplies exceeding the micro-purchase threshold.)

* * * * *

5a. Effective March 12, 2001, the date of the clause at 52.213–4 is amended by removing "February 2001" and adding "(MAR 2001)" in its place).

6. Add new sections 52.222–18 and 52.222–19 to read as follows:

52.222–18 Certification Regarding Knowledge of Child Labor for Listed End Products.

As prescribed in 22.1505(a), insert the following provision:

Certification Regarding Knowledge of Child Labor for Listed End Products (February 2001)

(a) *Definition.*

Forced or indentured child labor means all work or service—

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

(b) *Listed end products.* The following end product(s) being acquired under this solicitation is (are) included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, identified by their country of origin. There is a reasonable basis to believe that listed endproducts from the listed countries of origin may have been mined, produced, or manufactured by forced or indentured child labor.

Listed End Product

_____

Listed Countries of Origin

_____

(c) *Certification.* The Government will not make award to an offeror unless the offeror, by checking the appropriate block, certifies to either paragraph (c)(1) or paragraph (c)(2) of this provision.

☐ (1) The offeror will not supply any end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in a corresponding country as listed for that end product.

☐ (2) The offeror may supply an end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture such end product. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

(End of provision)

52.222–19 Child Labor—Cooperation with Authorities and Remedies.

As prescribed in 22.1505(b), insert the following clause:

Child Labor—Cooperation With Authorities and Remedies (February 2001)

(a) *Applicability.* This clause does not apply to the extent that the Contractor is supplying end products mined, produced, or manufactured in—

(1) Canada, and the anticipated value of the acquisition is $25,000 or more;

(2) Israel, and the anticipated value of the acquisition is $50,000 or more;

(3) Mexico, and the anticipated value of the acquisition is $54,372 or more; or

(4) Aruba, Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, Korea, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Singapore, Spain, Sweden, Switzerland, or the United Kingdom and the anticipated value of the acquisition is $177,000 or more.

(b) *Cooperation with Authorities.* To enforce the laws prohibiting the manufacture or importation of products mined, produced, or manufactured by forced or indentured child labor, authorized officials may need to conduct investigations to determine whether forced or indentured child labor was used to mine, produce, or manufacture any product furnished under this contract. If the solicitation includes the provision 52.222–18, Certification Regarding Knowledge of Child Labor for Listed End Products, or the equivalent at 52.212–3(i), the Contractor agrees to cooperate fully with authorized officials of the contracting agency, the Department of the Treasury, or the Department of Justice by providing reasonable access to records, documents, persons, or premises upon reasonable request by the authorized officials.

(c) *Violations.* The Government may impose remedies set forth in paragraph (d) for the following violations:

(1) The Contractor has submitted a false certification regarding knowledge of the use of forced or indentured child labor for listed end products.

(2) The Contractor has failed to cooperate, if required, in accordance with paragraph (b) of this clause, with an investigation of the use of forced or indentured child labor by an Inspector General, Attorney General, or the Secretary of the Treasury.

(3) The Contractor uses forced or indentured child labor in its mining, production, or manufacturing processes.

(4) The Contractor has furnished under the contract end products or components that have been mined, produced, or manufactured wholly or in part by forced or indentured child labor. (The Government will not pursue remedies at paragraph (d)(2) or paragraph (d)(3) of this clause unless sufficient evidence indicates that the Contractor knew of the violation.)

(d) *Remedies.* (1) The Contracting Officer may terminate the contract.

(2) The suspending official may suspend the Contractor in accordance with procedures in FAR Subpart 9.4.

(3) The debarring official may debar the Contractor for a period not to exceed 3 years in accordance with the procedures in FAR Subpart 9.4.

(End of clause)

[FR Doc. 01–1503 Filed 1–17–01; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE GENERAL SERVICES ADMINISTRATION NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

Federal Acquisition Regulation; Small Entity Compliance Guide

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small entity compliance guide.

SUMMARY: This document is issued under the joint authority of the Secretary of Defense, the Administrator of General Services and the Administrator for the National Aeronautics and Space Administration. This *Small Entity Compliance Guide* has been prepared in accordance with Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121). It consists of a summary of the rule appearing in Federal Acquisition Circular (FAC) 97–23 which amends the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding this rule by

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referring to FAC 97–23 which precedes this document. This document is also available via the Internet at http://www.arnet.gov/far.

FOR FURTHER INFORMATION CONTACT: Laurie Duarte, FAR Secretariat, (202) 501–4225. For clarification of content, contact Ralph De Stefano, Procurement Analyst, General Services Administration, at (202) 501–1758.

Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor (FAC 97–23, FAR Case 1999–608)

This final rule amends the FAR by adding a new FAR subpart on prohibition of acquisition of products produced by forced or indentured child labor (Subpart 22.15), adding a new certification regarding knowledge of child labor for listed end products (FAR 52.212–3 and 52.222–18), and adding a clause at 52.222–19, which requires cooperation with authorities if the solicitation included the certification provision and provides remedies for violations relating to use of forced or indentured child labor.

Dated: January 12, 2001.

Al Matera,

Acting Director, Federal Acquisition Policy Division.

[FR Doc. 01–1504 Filed 1–17–01; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; Procedural Guidelines for the Maintenance of the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor Under 48 CFR Subpart 22.15 and E.O. 13126

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of procedural guidelines.

SUMMARY: This notice sets out procedural guidelines pertaining to the submission of information, review, and reporting process utilized by the Department of Labor's International Child Labor Program in maintaining and revising the list of products requiring certification as to forced or indentured child labor, pursuant to amendments to the Federal Acquisition Regulation (FAR), 48 CFR Subpart 22.15 and Executive Order No. 13126 ("Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor").

EFFECTIVE DATE: January 18, 2001.

FOR FURTHER INFORMATION CONTACT: Ami Thakkar, International Child Labor Program, Bureau of International Labor Affairs, Room S–5303, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 208–4843; fax: (202) 219–4923.

SUPPLEMENTARY INFORMATION: Executive Order No. 13126 ("Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor") was signed by President Clinton on June 12, 1999. The Executive Order declared that it was "the policy of the United States Government * * * that the executive agencies shall take appropriate actions to enforce the laws prohibiting the manufacture or importation of goods, wares, articles, and merchandise mined, produced, or manufactured wholly or in part by forced or indentured child labor."

Pursuant to Section 2 of the Executive Order, and following public notice and comment (including a public hearing held on August 10, 1999), the Department of Labor is publishing in today's **Federal Register** a final list of products, identified by their country of origin, that the Department, in consultation and cooperation with the Departments of State and Treasury, has a reasonable basis to believe might have mined, produced or manufactured with forced or indentured child labor. The List can be accessed on the Internet at www.dol.gov/dol/ilab or can be obtained from: International Child Labor Program, Bureau of International Labor Affairs, Room S–5303, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 208–4843; fax (202) 219–4923.

Pursuant to Section 3 of the Executive Order, in today's **Federal Register**, the Federal Acquisition Regulatory Councils published a final rule, pursuant to which federal contractors who supply products which appear on the list issued by the Department of Labor must certify to the contracting officer that the contractor or, in the case of an incorporated contractor, a responsible official of the contractor has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any product furnished under the contract and that, on the basis of those efforts, the contractor is unaware of any such use of child labor. The regulation also imposes other requirements with respect to contracts for products on the Department of Labor's list.

The Department of Labor expects that, over time, new information may become available with respect to the use of forced or indentured child labor and that other developments relevant to the list of products requiring certification as to forced or indentured child labor may occur. For example, new instances of the use of forced or indentured child labor may be discovered. Alternatively, the practice of using forced or indentured child labor in a particular country or industry may be effectively eliminated.

Accordingly, to carry out the purposes of FAR Subpart 22.15 and Executive Order No. 13126, the Department of Labor, may be required to examine and/or revise the list originally published today. The Department of Labor believes that it would be appropriate to establish a process by which members of the public may bring relevant information to the attention of the Department of Labor.

This Notice sets out the procedural guidelines that the Department of Labor intends to follow to maintain, examine, and, as appropriate, revise the list of products required by Executive Order No. 13126 and incorporated in 48 CFR Subpart 22.15. Under the guidelines, public notice and opportunity for comment will be provided before a product is added to, or deleted from, the Department of Labor's list.

Signed at Washington, DC, this 5th day of January, 2001.

Andrew J. Samet,

Deputy Under Secretary for International Affairs.

Notice of Procedural Guidelines

Section A. What Department of Labor Office Is Responsible for Maintaining the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor?

1. The International Child Labor Program, within the Bureau of International Labor Affairs of the U.S. Department of Labor, will review all submissions of information relevant to the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor, as published pursuant to Executive Order No. 13126 ("Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor"), and reflected in the FAR 48 CFR Subpart 22.15.

2. The International Child Labor Program, in consultation with the Departments of State and Treasury, will determine if such submissions may establish the need to add entries to, or delete entries from, the List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor.

Section B. What Do the Terms Used in These Procedural Guidelines Mean?

As used in these Guidelines:

"Adequate information" means information relevant to the development of a reasonable basis for belief that a particular product included or not included on the List might have been mined, produced, or manufactured wholly or in part by forced or indentured child labor;

"The List" means the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor as published in accordance with Executive Order 13126 and reflected in FAR 48 CFR Subpart 22.15;

"Non-governmental organization" means any scientific, professional, business, non-profit, or public interest organization or association which is neither affiliated with, nor under the direction of, a government;

"Office" means the International Child Labor Program of the Bureau of International Labor Affairs of the United States Department of Labor;

"Person" means one or more individuals, non-governmental organizations, labor organizations, partnerships, associations, corporations, governmental entities, or legal representatives.

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Section C. What Are the Functions of the Office With Respect to the List?

1. The Office shall—

(a) In consultation and cooperation with the Departments of State and Treasury, compile and maintain a current list of products and their countries of origin contained on the List;

(b) Periodically review and revise the List, as appropriate, either on the basis of information submissions from members of the public or on its own initiative, subject to public notice and comment;

(c) Receive, accept for review, and review information submissions pertaining to the inclusion on or deletion from the List, as set out in Sections D, E, and F;

(a) Consider and weigh several factors including: the nature of the information describing the use of forced or indentured child labor; the source of the information; the date of the information; the extent of corroboration of the information by appropriate sources; whether the information involved more than an isolated incident; and whether recent and credible efforts are being made to address forced or indentured child labor in a particular country and industry; and

(e) Include in the List the name and telephone number of the office responsible for its maintenance.

2. The List shall indicate—

(a) The names of products, identified by their country of origin, for which there is a reasonable basis to believe that the product might have been mined, produced, or manufactured wholly or in part by forced or indentured child labor;

(b) The date on which the product was included on the List.

3. Questions on the List—information is available by direct request to the Office by writing the International Child Labor Program, Bureau of International Labor Affairs, Rm. S–5303, U.S. Department of Labor, 200 Constitution Ave, NW., Washington, DC 20210.

Section D. How May a Person Submit Information to the Office Regarding Adding or Deleting a Product From the List?

1. Any person may file an information submission with the Office regarding either the inclusion of a product on the List or the deletion of a product from the List. A single copy is satisfactory for filing. Filing may be by hand delivery, mail delivery, or facsimile transmission.

2. The submission should identify clearly the person filing the submission and should be signed and dated. It should state with specificity the product and its country of origin which the submitter requests the Office to consider and should include relevant information available to the submitter.

Section E. How will the Office decide to accept a submission of information?

1. Within 60 days, unless there are good reasons for delay, the Office will decide whether to accept a submission of information for review. The Office may communicate with the submitter during this period regarding any matter relating to the decision.

2. In general, the Office may accept a submission of information if it provides adequate information and if a review would not be inconsistent with Executive Order No. 13126 or applicable laws or regulations.

3. The Office may decline to accept a submission for review if, in its discretion, it determines that:

(a) The submission does not identify clearly the person filing the submission or is not signed and dated;

(b) The submission does not provide adequate information;

(c) The matter raised is not within the scope of 48 CFR Subpart 22.15 or Executive Order No. 13126.

(d) The submission is substantially similar to a recent submission and significant new information has not been provided; or

(e) Review of the submission would otherwise be inappropriate.

4. If the Office declines to accept a submission for review, the Office promptly will notify the submitter in writing and will provide the reasons for the decision.

5. If the Office accepts a submission of information, review will follow those procedures described in Section F.

Section F. What review process will be followed after a submission of information is accepted by the Office?

1. Following a decision by the Office to accept a submission of information, the Office will conduct such further examination of the available information as necessary or appropriate to assist the Office in making a determination.

2. Except for information exempt from public inspection, information relevant to the review will be placed in a public file. Information exempt from public inspection will be placed in a separate file.

3. The Office, in its discretion, may hold a hearing regarding the product raised in the submission of information, for the purpose of receiving information from interested persons.

4. The Office, after consulting with the Departments of Treasury and State, will publish in the **Federal Register** a notice of initial determination, which will include any proposed alteration to be made to the List. Public comments will be accepted for at least 30 days following publication of the **Federal Register** notice. Submissions relating to the same product and country may be resolved by joint determinations.

5. Any person may submit, in person, in writing, or through a representative, information and argument in support of or in opposition to the proposed determination, including any additional specific information that relates to the proposed revision of the List. The Office will consider all comments prior to publication of a final determination, which will be made in consultation and cooperation with the Departments of State and Treasury.

Section G. What process will the Office use to update the List on its own initiative?

1. If the Office obtains adequate information, other than through public submission, it will publish in the **Federal Register** a notice of initial determination, which will include any proposed alteration to be made to the List. Public comments will be accepted for at least 30 days following publication of the notice of initial determination.

2. Any person may submit, in person, in writing, or through a representative, information and argument in support of or in opposition to the initial determination, including any additional specific information that relates to the proposed revision of the List. The Office will consider all comments prior to publication of a final determination, made in consultation and cooperation with the Departments of State and Treasury.

Section H. How will the Office communicate a final determination about a product's placement on the List?

1. A final determination on whether a product will be added to, or deleted from, the List will be published in the **Federal Register**.

2. The List will be revised in accordance with a final determination as to a particular product, identified by its country of origin. The Office will maintain a current copy of the List.

[FR Doc. 01–952 Filed 1–17–01; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; Notice of Final List of Products Requiring Federal Contractor Certification as to Forced or Indentured Child Labor Under Executive Order No. 13126

SUMMARY: As required by Executive Order No. 13126 ("Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor"), this notice sets forth a final list of products, by country of origin, which the Department of Labor, the Department of State, and the Department of the Treasury believe may have been mined, produced, or manufactured by forced or indentured child labor. Under a final rule by the Federal Acquisition Regulatory Council, published in today's issue of the **Federal Register**, which also implements Executive Order No. 13126, federal contractors who supply products on the list are required to certify, among other things, that they have made a good faith effort to determine whether forced or indentured child labor was used to produce the item. The Department of Labor is also publishing, in today's issue of the **Federal Register**, procedural guidelines that describe how the list of products will be updated in the future, through a public notice-and-comment process.

FOR FURTHER INFORMATION CONTACT: Ami Thakkar, International Child Labor Program, Bureau of International Labor Affairs, Room S–5303, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 208–4843; fax: (202) 219–4923.

SUPPLEMENTARY INFORMATION:

I. Background

Executive Order No. 13126, which was published in the **Federal Register** on June 19, 1999 (64 FR 32383–32385), required the Federal Acquisition Regulatory Council (the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council) to issue proposed rules to amend the Federal Acquisition Regulation (FAR), with respect to the procurement by federal agencies of products that may have been mined, produced, or manufactured with forced or indentured child labor. A proposed rule was published in the **Federal Register** on September 6, 2000 (65 FR 54104–54107), and public comment was invited. A final rule is being published in today's **Federal Register**.

Under that final rule, certain procurement related requirements will apply to products that appear on a list published by the Department of Labor, pursuant to Section 2 of Executive Order No. 13126, which required the Department of Labor, in consultation and cooperation with the Department of the Treasury and the Department of State, to "publish in the **Federal Register** a list of products, identified by their country of origin, that those Departments have a reasonable basis to believe might have been mined, produced, or manufactured by forced or indentured child labor."

As authorized by the Executive Order, the Department of Labor held a public hearing on August 10, 1999, at which several witnesses presented oral and written testimony concerning the development of a list of products. On September 6, 2000, in consultation and cooperation with the Department of State and the Department of the Treasury, the Department of Labor published a preliminary list of products in the **Federal Register** (65 FR 54108–54112), explained how the preliminary list was developed, and invited public comment. The public comment period closed on November 6, 2000.

II. Summary and Discussion of Significant Comments

Twenty-four comments were received. In developing the final list of products, the three Departments have carefully reviewed and considered the public comments received. The following is a summary of the significant comments and the three Departments' response.

A. Comments on the definition of "forced or indentured child labor"

Several comments raise issues related to the definition of "forced or indentured child labor" used in determining the proposed list of products that may be produced by forced or indentured child labor. Executive Order No. 13126 defines

> "forced or indentured child labor" as: all work or service (1) exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for the worker does not offer himself voluntarily; or (2) performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

As explained in the Department of Labor's September 6, 2000 **Federal Register** notice, the "two aspects of the definition represent alternatives which are not mutually exclusive." 65 FR 54109.

The definition of "forced or indentured child labor" in Executive Order No. 13126 is derived from, and generally consistent with, the Tariff Act of 1930, 19 U.S.C. 1307. That statute, enforced by the Customs Service of the Treasury Department, prohibits the importation into the United States of "all goods, wares, articles, and merchandise mined, produced, or manufactured wholly or in part in any foreign country by convict labor or/and forced labor or/and indentured labor under penal sanctions."

The Tariff Act specifically defines "forced labor" as "all work or service which is exacted from any person under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily." The first part of the Executive Order's definition of "forced or indentured child labor" incorporates this statutory language.

The Tariff Act does not specifically define "indentured labor under penal sanctions" (the term used in that statute). The second part of the Executive Order's definition of "forced or indentured child labor" is intended to incorporate the Tariff Act's concept of indentured labor, as it involves children. This part of the Executive Order definition is derived directly from the legislative history of the Tariff Act. See 71 Cong. Rec. 4488–4499 (daily ed. Oct. 14, 1929).

In comments on behalf of the organizations in the Child Labor Coalition, the International Labor Rights Fund questions the definition of "forced or indentured child labor" in the Executive Order and urges the development of a different, significantly broader definition. The Fund's comments identify various abusive working conditions that the Fund suggests "should be encompassed explicitly in the definition of 'forced or indentured child labor.'" The Fund's comments do not refer to any specific basis in U.S. or international law for such an expanded definition.

The Department of Labor's September 6, 2000 **Federal Register** notice explained how the Labor, State, and Treasury Departments have applied the definition in the Executive Order and have evaluated a wide range of working conditions for the possibility of coercion, the essential element of the first part of the definition. 65 FR 54109. The Department of Labor, in consultation and cooperation with the Departments of State and Treasury, is charged with implementing the Executive Order and its definition of "forced or indentured child labor." That definition is appropriately derived from the Tariff Act, as explained above, since the Executive Order embodies a procurement policy intended to be consistent with the Tariff Act. As has

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been previously noted, some child labor abuses may not meet the established definition of "forced or indentured child labor."

The United States Council for International Business, in a comment noting its strong support for international efforts to end forced and indentured child labor, asks for clarification concerning the second part of the definition of "forced or indentured child labor" in the Executive Order with respect to situations in which persons under age 18: (1) Work under a legally enforceable "collective bargaining agreement freely negotiated by the employer and the union representing workers in the bargaining unit;" or (2) work under individual employment contracts that contain a "penalty clause that is triggered by early termination," but where "excessive process or penalties" (as opposed to "customary cancellation penalties") are not involved.

The information provided by the U.S. Council is not detailed, especially with respect to individual employment contracts and the so-called "penalty clause." On the basis of the description provided by the U.S. Council, however, it appears possible, depending on the facts, that neither situation would come within the second part of the Executive Order's definition of "forced or indentured child labor," as interpreted consistently with the Tariff Act of 1930. As a general matter, there is no indication that Congress was concerned about legitimate collective bargaining agreements or legitimate employment contracts, providing for ordinary legal remedies, when it enacted the Tariff Act. In any case, neither situation described by the U.S. Council clearly implicates the concept of indentured labor under penal sanctions. For example, a child apparently would not be subject to criminal penalties, to a judicial order requiring the child to continue working, or to a state-sanctioned monetary penalty, as a means of enforcing the agreement or contract. With respect to employment contracts, the U.S. Council does not appear to be describing truly punitive provisions, designed to deter young workers from quitting employment in circumstances of exploitation or duress. Because there is no suggestion that children are being coerced to enter into a contract or to work under it, the first part of the Executive Order definition also may not apply to the situations described by the U.S. Council. The application of the Executive Order, of course, will depend on the specific factual circumstances of particular cases. Circumstances that suggest coercion, including coercion related to making or enforcing employment contracts, will be carefully examined.

In his comment, Senator Tom Harkin raises concerns about the application of the definition of "forced or indentured child labor" in the development of the list of products. The Departments have attempted to apply the definition in a way that is both consistent with the Tariff Act and takes into account the actual circumstances in which children work. We will continue to do so, based on available information, as the list of products is updated.

B. Comment on Statutory Authority

One comment questions the statutory authority for action by the three Departments to implement Executive Order 13126, since matters of federal acquisition policy are involved. The list of products called for in the Executive Order serves to trigger requirements for federal contractors under revisions to the Federal Acquisition Regulation, to be adopted by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council. The authority for the Executive Order, and for the regulations that implement it, derives in part from the Federal Property and Administrative Services Act of 1949 (also known as the Procurement Act), 40 U.S.C. 471 *et seq.*, which among other things authorizes the President to prescribe federal acquisition policy and directives.

C. Comment on the Burden of Proof Once a Product Is Listed

Senator Harkin expresses concern that products might be removed from the list, if new information demonstrating the continued use of forced or indentured child labor were not regularly supplied by non-governmental sources. He suggests instead that products should remain on the list, unless new information showed that the prior use of forced or indentured child labor had been effectively addressed. In fact, the list will be updated in line with the principle supported by Senator Harkin. Once a product is placed on the list, it will remain there, unless and until the three Departments have adequate information to justify removing the product from the list. The public notice-and-comment process by which the list will be updated is described in a separate notice in today's **Federal Register**.

D. Comment on the "Reasonable Basis to Believe" Standard

The International Labor Rights Fund, on behalf of the other organizations in the Child Labor Coalition, requests clarification of the Executive Order's standard for placing a product on the list: That the three Departments have a "reasonable basis to believe" that forced or indentured child labor was used. The Fund is correct in pointing out that this threshold is relatively low. The standard is appropriate, given the nature of the list. The list does not reflect a determination that forced or indentured child labor actually was used to produce a particular product. Rather, it establishes the need for further inquiry by a federal contractor who wishes to supply the product, in order to make sure that forced or indentured child labor was not, in fact, used.

As the September 6, 2000 **Federal Register** notice explained, the three Departments have applied the "reasonable basis to believe" standard to develop the list. There, we identified several factors that were considered and weighed: "the nature of the information describing the use of forced or indentured child labor; the source of the information; the date of the information; the extent of corroboration of the information by appropriate sources; and whether the information involved more than an isolated incident." 65 FR 54109. The three Departments have also taken into account "whether recent, credible efforts are being made to address forced or indentured child labor in a particular country." 65 FR 54109.

E. Comments on Effect of Prior Executive Branch Reports Addressing Child Labor

The International Labor Rights Fund, on behalf of the Child Labor Coalition, questions whether the three Departments gave sufficient weight to prior reports addressing the use of child labor, published by the Department of Labor and the Department of State. In particular, the Fund states that the Department of Labor's series By the Sweat and Toil of Children "should constitute prima facie evidence for purposes of identifying countries and products that should be identified pursuant to E.O. 13126." In fact, the three Departments did consider previously published reports and carefully reviewed information that was cited in those reports. The reports themselves, however, cannot serve as a substitute for the determination required by Executive Order. Moreover, in some instances, the reports completed in 1994 and 1995 relied upon information that may no longer be considered current, in a few cases the reports reflected information on isolated occurrences, and in others, there is information on more recent and credible efforts to eliminate child labor in the product identified.

F. Comments on the Inclusion of Products From Burma

Several comments were received supporting the inclusion of products from Burma on the preliminary list. These comments include a letter from a number of members of Congress, specifically Representatives Kucinich, Kaptur, McHugh, Evans, Slaughter, Nadler, Sanders, Waxman, George Miller, Payne, Ackerman, DeFazio, Abercrombie, Delahunt, McDermott, Tierney, McKinney, McGovern, Lee, Moakley, Carson, Doggett, Stark, Sandlin, Baldwin, and Sherrod Brown.

G. Comments on the Exclusion of Certain Products and Countries

Various comments express a concern that the list included an insufficient number of products and countries. For example, many of the comments, including those from Representatives Tom Campbell and Tom Tancredo, object to the exclusion of several countries, on the basis that these countries have well known "forced and indentured labor systems". Some comments refer to Congressional testimony where specific products were named by region as examples of products "flowing into America." One comment, discussed below, mentions a specific product and country.

As explained, in considering which products and countries would be placed on the preliminary list, the three Departments considered and weighed a number of factors including: The nature of the information describing the use of forced or indentured child labor; the source of the information; the date of the information; the extent of corroboration of information by appropriate sources; whether the information involved more than an isolated incident; and whether recent and credible efforts are being made to address forced or indentured child labor in a particular country or industry.

None of the comments described above provides additional information sufficient to support the inclusion of additional products and countries on the list. First, the Executive Order required the development of a list of products, by country of origin. Many of the comments named countries, but failed to identify specific products. In other cases, products were mentioned without reference to specific countries. Second, to satisfy the Executive Order standard, the Departments must have information on an individual product, in a particular country, which may be made with forced or indentured child labor. Such information was not provided in the comments received, with one exception. Third, the scope of the Executive Order is limited to forced and indentured child labor, that is labor by persons under the age of 18. The comments received refer to forced labor in a country and in some cases, sector. However, this alone does not provide sufficient information of forced or indentured child labor.

The Department of Labor welcomes future submissions providing information on specific products produced by forced or indentured child labor in specific countries. Submissions should follow the procedures outlined elsewhere in today's **Federal Register**.

As indicated, one comment did provide current and specific information: Professor Kevin Bales of Free the Slaves submitted new information concerning the use of forced or indentured child labor in the cocoa industry in the Ivory Coast. Since this product was not considered when creating the preliminary list, the International Child Labor Program of the Bureau of International Labor Affairs will consider the information as a submission for review pursuant to the newly-announced procedures for updating the current list.

H. Comments on Recent and Credible Efforts

Several comments question the factors which the three Departments took into consideration when determining which products and countries would be on the list. Senator Tom Harkin states that the presence of programs or the commitment to initiate programs aimed at eliminating child labor is not a justification to leave any product or country off the list.

The International Labor Rights Fund, on behalf of the Child Labor Coalition, makes a similar comment regarding carpets in South Asia, stating that efforts being undertaken in the industry to eliminate child labor did not justify their exclusion.

Again, in considering which products and countries would be placed on the preliminary list, the three Departments took into consideration a number of factors including the extent of recent and credible efforts undertaken in a particular country and industry aimed at addressing forced or indentured child labor. The Department of Labor will continue to assess the progress of these efforts and welcomes further information from the public on them.

I. Comments on Products From India

Senator Harkin and several other submitters specifically object to the failure to include any products from India on the list. The three Departments based their decision on the fact that the Government of India is now making extensive efforts, in collaboration with the International Labor Organization's International Program on the Elimination of Child Labor to prevent and eliminate child labor in the following sectors: hand-rolled beedi cigarettes, brassware, hand-made bricks, fireworks, footwear, hand-blown glass bangles, hand-made locks, hand-dipped matches, hand-broken quarried stones and hand-spun/hand-loomed silk. The Department of Labor will monitor the effectiveness of these efforts, and will welcome public comments on the credibility and progress of such efforts.

J. Other Comments

One comment states that the description of the products listed on the preliminary list were "vague" and that products should be identified by the standard category codes that are used by the Customs Service and Census Bureau. The three Departments believe that the descriptions are sufficiently specific. The Executive Order does not require the use of standard category codes in the products list. At this time, the Departments do not have reason to believe that the addition of standard category codes to the list would result in more efficient implementation of the Executive Order.

Another comment suggests that the inputs of the Department of State and Treasury into the Executive Order consultation process be described and that the joint determination process for compiling the list be disclosed. The Departments of Labor, State and Treasury consulted extensively before compiling the list, as mandated by the Executive Order. As a result, the preliminary list underwent a thorough interagency process.

Another similar comment suggests that the responsibility of implementing the Executive Order should rest with an acquisition policy agency, with advisory and support roles by the Departments of Labor, State and Treasury. In fact, as already described, the appropriate acquisition organizations are responsible for implementing the Executive Order, through revisions to the Federal Acquisition Regulation. Furthermore, the Executive Order mandates the Department of Labor, in coordination with the Departments of State and Treasury to publish a list of products.

Several comments suggest a broader scope for the Executive Order, rather than its current mandate to prohibit the acquisition of goods made with forced

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or indentured child labor by the federal government. These comments are beyond the scope of the present initiative, which is intended to implement the Executive Order, not to modify it. Development of a products list, and accompanying procurement regulations, based on standards broader than those in the Executive Order would require additional public notice-and-comment procedures, as well as significant additional research and investigation by the three Departments. These steps would unnecessarily delay the implementation of the Executive Order. Without ruling out the possibility of future steps, should they be determined to be appropriate, the three Departments have chosen to proceed to finalize the product list contemplated by the Executive Order.

K. Request for Information on Carpets

In the preliminary notice, the three Departments invited comment on the measures taken in South Asia to eliminate forced and indentured labor in the carpet sector, including labeling and monitoring initiatives that are currently in place. Specifically, the Department sought public comment on the sufficiency of these initiatives and whether or not a certification or label from a credible monitoring program could adequately serve the purposes of the Executive Order. The Departments received a comment from the International Labor Rights Fund, on behalf of the Child Labor Coalition, stating that there are impressive programs dealing with child labor in the carpet sector, particularly Rugmark. The submitter also said in order to avoid giving "a free pass" to producers who are not participating in the innovative programs, carpets should be included on the list. Although carpets are not being included in this final list, the Departments are considering how best to address the issue raised by the International Labor Rights Fund, while continuing to encourage innovative labeling and monitoring initiatives in the carpet sector. The Department of Labor requests additional public comment on the issue raised by the International Labor Rights Fund.

L. Request for Information on Cotton and Sugarcane

The Departments requested information on whether there was forced or indentured child labor in the production of cotton and sugarcane in Pakistan. No comments were received and existing information is insufficient; therefore, the Departments have not included these products on the final list.

III. Final List of Products

The three Departments have determined that it would be appropriate to publish a final list of products that comprises the products on the preliminary list. No comments objected to the inclusion of these products. The basis for including those products on the list is set forth in detail in the Department of Labor's September 6, 2000 notice in the **Federal Register** (65 FR 54108–54112). The final list of products appears below. In addition, in today's issue of the **Federal Register**, the Department of Labor is publishing procedural guidelines for updating the final list in the future.

Based on recent, credible, and appropriately corroborated information from various sources, the Department of Labor, the Department of State, and the Department of the Treasury have concluded that there is a reasonable basis to believe that the following products, identified by their country of origin, might have been mined, produced, or manufactured by forced or indentured child labor:

Bamboo(Burma)
Beans (including yellow, soya, and green beans) (Burma)
Bricks (hand-made) (Burma, Pakistan)
Chilies (Burma)
Corn (Burma)
Pineapples (Burma)
Rice (Burma)
Rubber (Burma)
Shrimp (aquaculture)(Burma)
Sugarcane (Burma)
Teak (Burma)

Signed at Washington, D.C., this 5th day of January, 2001.

Andrew J. Samet,

Deputy Under Secretary for International Affairs.

[FR Doc. 01–953 Filed 1–17–01; 8:45 am]
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Federal Register

Thursday,
January 18, 2001

Part XII

General Services Administration

41 CFR Parts 101–6, et al.
Real Property Policies; Final Rule

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101–6, 101–17, 101–18, 101–19, 101–20, 101–33, 101–47, 102–71, 102–72, 102–73, 102–74, 102–75, 102–76, 102–77, 102–78, 102–79, 102–80, 102–81, 102–82

[FPMR Amendment D–97]

RIN 3090–AF95

Real Property Policies

AGENCY: Office of Government-wide Policy, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is adding coverage on real property policies to the Federal Management Regulation (FMR). A section has been added to each affected Federal Property Management Regulations (FPMR) part to direct readers to the additional policy coverage contained in the FMR. The FMR coverage is written in plain language to provide agencies with updated regulatory material that is easy to read and understand.

EFFECTIVE DATE: January 18, 2001.

FOR FURTHER INFORMATION CONTACT: Stanley C. Langfeld, Director, Real Property Policy Division, at (202) 501–1737.

SUPPLEMENTARY INFORMATION:

A. Background

This final rule describes the current real property policies applicable to GSA and Federal agencies to whom GSA real property authority has been delegated. The policies contained in this rule reflect the way that real property operations are currently conducted and these policies have been separated from their procedural components resulting in a more efficient and easy to understand regulation.

The policies contained in this rule were published as a proposed rule at 62 FR 42444, August 7, 1997. GSA received several comments on the proposed rule. The comments were from an individual, special interest groups, and Federal agencies. All comments were considered in the formulation of the final rule. GSA believes the final regulation is responsive to the concerns raised by all parties providing comments.

B. Executive Order 12866

The General Services Administration (GSA) has determined that this final rule is not a significant regulatory action for the purposes of Executive Order 12866.

C. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for comment. Therefore, the Regulatory Flexibility Act does not apply.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not impose reporting, recordkeeping or information collection requirements which require the approval of the Office of Management and Budget pursuant to 44 U.S.C. 3501 *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from Congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Parts 101–6, 101–17, 101–18, 101–19, 101–20, 101–33, 101–47 and 102–71 Through 102–82

Administrative practice and procedure, Blind, Concessions, Federal buildings and facilities, Fire prevention, Government property management, Homeless, Individuals with disabilities, Occupational safety and health, Parking, Real property acquisition, Security measures, Surplus Government property, Utilities.

For the reasons set forth in the preamble, GSA amends 41 CFR chapters 101 and 102 as follows:

CHAPTER 101—[AMENDED]

PART 101–6—MISCELLANEOUS REGULATIONS

1. The authority citation for part 101–6 is revised to read as follows:

Authority: 31 U.S.C. 1344(e)(1); 40 U.S.C. 486(c).

2. Amend § 101–6.300 by adding paragraph (g) to read as follows:

§ 101–6.300 Federal facility ridesharing general policy.

* * * * *

(g) For more information on Federal facility ridesharing, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this subpart are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

3. Amend § 101–6.600 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–6.600 Scope of subpart.

* * * * *

(b) For more information on fire protection (firesafety) engineering, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this subpart are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

4. Part 101–17 is revised to read as follows:

PART 101–17—ASSIGNMENT AND UTILIZATION OF SPACE

Authority: 40 U.S.C. 285, 304c, 601 *et seq.*, 490 note; E.O. 12072, 43 FR 36869, 3 CFR, 1978 Comp., p. 213.

§ 101–17.0 Cross-reference to the Federal Management Regulation (FMR) (41 CFR chapter 102, parts 102–1 through 102–220).

For information on assignment and utilization of space, see FMR part 102–79 (41 CFR part 102–79).

PART 101–18—ACQUISITION OF REAL PROPERTY

5. The authority citation for part 101–18 is revised to read as follows:

Authority: Sec. 1–201(b), E.O. 12072, 43 FR 36869, 3 CFR, 1978 Comp., p. 213.

6. Amend § 101–18.000 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–18.000 Scope of part.

* * * * *

(b) For more information on the acquisition of real property, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

PART 101–19—CONSTRUCTION AND ALTERATION OF PUBLIC BUILDINGS

7. The authority citation for part 101–19 is revised to read as follows:

Authority: 40 U.S.C. 486(c), 490 and 601–619; 86 Stat. 216.

8. Amend § 101–19.000 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–19.000 Scope of part

* * * * *

(b) For more information on the construction and alteration of public buildings, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

PART 101–20—MANAGEMENT OF BUILDINGS AND GROUNDS

9. The authority citation for part 101–20 is revised to read as follows:

Authority: 40 U.S.C. 486(c).

10. Amend § 101–20.000 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–20.000 Scope of part.

* * * * *

(b) For more information on the management of buildings and grounds, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

11. The Appendix to Subchapter D is amended by adding § 101–17.000 to interim rule D–1 to read as follows:

Appendix to Subchapter D—Temporary Regulations

* * * * *

Federal Property Management Regulations; Interim Rule D–1

* * * * *

§ 101–17.000 Scope of part.

For more information on location of space, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statement in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

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PART 101–33—PUBLIC UTILITIES

12. The authority citation for part 101–33 is revised to read as follows:

Authority: 40 U.S.C. 486(c).

13. Amend § 101–33.000 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–33.000 Scope of part.

* * * * *

(b) For more information on the management of public utility services, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

PART 101–47—UTILIZATION AND DISPOSAL OF REAL PROPERTY

14. The authority for part 101–47 is revised to read as follows:

Authority: 40 U.S.C. 486(c).

15. Amend § 101–47.000 by designating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 101–47.000 Scope of part.

* * * * *

(b) For more information on the utilization and disposal of real property, see 41 CFR parts 102–71 through 102–82. To the extent that any policy statements in this part are inconsistent with the policy statements in 41 CFR parts 102–71 through 102–82, the policy statements in 41 CFR parts 102–71 through 102–82 are controlling.

CHAPTER 102—[AMENDED]

16. Parts 102–71 through 102–82 are added to subchapter C to read as follows:

PART 102–71—GENERAL

Sec.

102–71.5 What are the scope and philosophy of the General Services Administration's (GSA) real property policies?
102–71.10 How are these policies organized?
102–71.15 What happens if the policy statements in this part and parts 102–72 through 102–82 of this chapter conflict with policy statements in 41 CFR parts 101–6, 101–17 through 101–20, 101–33, and 101–47?
102–71,20 What definitions apply to GSA's real property policies?
102–71.25 Who must comply with GSA's real property policies?
102–71.30 How must these real property policies be implemented?
102–71.35 Are agencies allowed to deviate from GSA's real property policies?

Authority: 40 U.S.C. 486(c).

§ 102–71.5 What are the scope and philosophy of the General Services Administration's (GSA) real property policies?

GSA's real property policies contained in this part and parts 102–72 through 102–82 of this chapter apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services. These policies cover the acquisition, management, and utilization and disposal of real property by Federal agencies that initiate and have decisionmaking authority over actions for real property services. The detailed guidance implementing these policies is contained in separate customer service guides.

§ 102–71.10 How are these policies organized?

GSA has divided its real property policies into the following functional areas:

(a) Delegation of authority;
(b) Real estate acquisition;
(c) Facility management;
(d) Real property disposal;
(e) Design and construction;
(f) Art-in-architecture;
(g) Historic preservation;
(h) Assignment and utilization of space;
(i) Safety and environmental management;
(j) Security; and
(k) Utility services.

§ 102–71.15 What happens if the policy statements in this part and parts 102–72 through 102–82 of this chapter conflict with policy statements in 41 CFR parts 101–6, 101–17 through 101–20, 101–33, and 101–47?

The policies in this part and parts 102–72 through 102–82 of this chapter apply to 41 CFR parts 101–17 through 101–20, 101–33, and 101–47. To the extent that any policy statements elsewhere in 41 CFR parts 101–17 through 101–20, 101–33, and 101–47 are inconsistent with the policy statements in this part and parts 102–72 through 102–82 of this chapter, the policy statements in this chapter are controlling.

§ 102–71.20 What definitions apply to GSA's real property policies?

The following definitions apply to GSA's real property policies:

Executive agency means any Executive department or independent establishment in the Executive branch of the Government, including any wholly owned Government corporation.

Federal agency means any Executive agency or any establishment in the legislative or judicial branch of the Government (except the Senate, the House of Representatives, and the Architect of the Capitol and any activities under his or her direction).

Federal Government real property services provider means any Federal Government entity operating under, or subject to, the authorities of the Administrator of General Services, that provides real property services to Federal agencies. This definition also includes private sector firms under contract with Federal agencies that

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deliver real property services to Federal agencies. This definition excludes any entity operating under, or subject to, authorities other than those of the Administrator of General Services.

Public building means:

(1) Any building which is suitable for office and/or storage space for the use of one or more Federal agencies or mixed ownership corporations, such as Federal office buildings, post offices, customhouses, courthouses, border inspection facilities, warehouses, and any such building designated by the President. It also includes buildings of this sort that are acquired by the Federal Government under the Administrator's installment-purchase, lease-purchase, and purchase-contract authorities.

(2) *Public building* does not include buildings:

(i) On the public domain.

(ii) In foreign countries.

(iii) On Indian and native Eskimo properties held in trust by the United States.

(iv) On lands used in connection with Federal programs for agricultural, recreational, and conservation purposes.

(v) On or used in connection with river, harbor, flood control, reclamation or power projects, or for chemical manufacturing or development projects, or for nuclear production, research, or development projects.

(vi) On or used in connection with housing and residential projects.

(vii) On military installations.

(viii) On Department of Veteran's Affairs' installations used for hospital or domiciliary purposes.

(ix) Excluded by the President.

§ 102–71.25 Who must comply with GSA's real property policies?

Federal agencies operating under, or subject to, the authorities of the Administrator of General Services must comply with these policies.

§ 102–71.30 How must these real property policies be implemented?

Each Federal Government real property services provider must provide services that are in accord with the policies presented in parts 102–71 through 102–82 of this chapter. Also, Federal agencies must make the provisions of any contract with private sector real property services providers conform to the policies in parts 102–71 through 102–82 of this chapter.

§ 102–71.35 Are agencies allowed to deviate from GSA's real property policies?

Yes, see § § 102–2.60 through 102–2.110 of this chapter to request a deviation from the requirements of these real property policies.

PART 102–72—DELEGATION OF AUTHORITY

Sec.

102–72.5 What is the scope of this part?
102–72.10 What basic policy governs delegation of authority to Federal agencies?
102–72.15 What criteria must a delegation meet?
102–72.20 Are there limitations on this delegation of authority?
102–72.25 What are the different types of delegations of authority?
102–72.30 What are the different types delegations related to real estate leasing?
102–72.35 What are the requirements for obtaining an ACO delegation from GSA?
102–72.40 What are facility management delegations?
102–72.45 What are the different types of facility management delegations?
102–72.50 What are Executive agencies' responsibilities under a delegation of real property management and operation authority from GSA?
102–72.55 What are the requirements for obtaining a delegation of real property management and operation authority from GSA?
102–72.60 What are Executive agencies' responsibilities under a delegation of individual repair and alteration project authority from GSA?
102–72.65 What are the requirements for obtaining a delegation of individual repair and alteration project authority from GSA?
102–72.70 What are Executive agencies' responsibilities under a delegation of lease management authority (contracting officer representative authority) from GSA?
102–72.75 What are the requirements for obtaining a delegation of lease management authority (contracting officer representative authority) from GSA?
102–72.80 What are Executive agencies' responsibilities under a disposal of real property delegation of authority from GSA?
102–72.85 What are the requirements for obtaining a disposal of real property delegation of authority from GSA?
102–72.90 What are Executive agencies' responsibilities under a security delegation of authority from GSA?
102–72.95 What are the requirements for obtaining a security delegation of authority from GSA?
102–72.100 What are Executive agencies' responsibilities under a utility service delegation of authority from GSA?
102–72.105 What are the requirements for obtaining a utility services delegation of authority from GSA?

Authority: 40 U.S.C. 486(c), (d) and (e).

§ 102–72.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–72.10 What basic policy governs delegation of authority to Federal agencies?

The Administrator of General Services may delegate and may authorize successive redelegations of the real property authority vested in the Administrator to any Federal agency.

§ 102–72.15 What criteria must a delegation meet?

Delegations must be in the Government's best interest, which means that GSA must evaluate such factors as whether a delegation would be cost effective for the Government in the delivery of space.

§ 102–72.20 Are there limitations on this delegation of authority?

Federal agencies must exercise delegated real property authority and functions according to the parameters described in each delegation of authority document, and Federal agencies may only exercise the authority of the Administrator that is specifically provided within the delegation of authority document.

§ 102–72.25 What are the different types of delegations of authority?

The basic types of GSA Delegations of Authority are:

(a) Delegation of Leasing Authority;

(b) Delegation of Real Property Management and Operation Authority;

(c) Delegation of Individual Repair and Alteration Project Authority;

(d) Delegation of Lease Management Authority (Contracting Office Representative Authority);

(e) Delegation of Administrative Contracting Officer (ACO) Authority;

(f) Delegation of Real Property Disposal Authority;

(g) Security Delegation of Authority; and

(h) Utility Services Delegation of Authority.

§ 102–72.30 What are the different types of delegations related to real estate leasing?

Delegations related to real estate leasing include the following:

(a) Categorical space delegations, Agency special purpose space delegations, and delegations to specific agencies for certain space and lands outside urban areas (see § 101–18.104 of this title).

(b) The Administrator of General Services has issued a standing delegation of authority (under a program known as "Can't Beat GSA Leasing") to the heads of all Federal agencies to accomplish all functions relating to leasing of general purpose space for terms of up to 20 years regardless of geographic location. This delegation includes some conditions Federal agencies must meet when conducting the procurement themselves, such as training in lease contracting and reporting data to GSA.

(c) An Administrative Contracting Officer (ACO) delegation, in addition to lease management authority, provides Federal agencies with limited contracting officer authority to perform such duties as paying and withholding lessor rent and modifying lease provisions that don't change the lease term length or the amount of space under lease.

§ 102–72.35 What are the requirements for obtaining an ACO delegation from GSA?

When Federal agencies don't exercise the delegation of authority for general purpose space mentioned in § 102–72.30(b), GSA may consider granting an ACO delegation when Federal agencies:

(a) Occupy at least 90 percent of the building's GSA-controlled space or Federal agencies have the written concurrence of 100 percent of rent-paying occupants covered under the lease; and

(b) Have the technical capability to perform the leasing function.

§ 102–72.40 What are facility management delegations?

Facility management delegations give Executive agencies authority to operate and manage buildings day to day, to perform individual repair and alteration projects and manage real property leases.

§ 102–72.45 What are the different types of delegations related to facility management?

The principal types of delegations involved in the management of facilities are:

(a) Real property management and operation authority;

(b) Individual repair and alteration project authority; and

(c) Lease management authority (contracting officer representative authority).

§ 102–72.50 What are Executive agencies' responsibilities under a delegation of real property management and operation authority from GSA?

With this delegation, Executive agencies have the authority to operate and manage buildings day to day. Delegated functions may include building operations, maintenance, recurring repairs, minor alterations, historic preservation, concessions, and energy management of specified buildings subject to the conditions in the delegation document.

§ 102–72.55 What are the requirements for obtaining a delegation of real property management and operation authority from GSA?

An Executive agency may be delegated real property management and operation authority when it:

(a) Occupies at least 90 percent of the space in the Government-controlled facility or has the concurrence of 100 percent of the rent-paying occupants to perform these functions; and

(b) Demonstrates that it can perform the delegated real property management and operation responsibilities.

§ 102–72.60 What are Executive agencies' responsibilities under a delegation of individual repair and alteration project authority from GSA?

With this delegation of authority, Executive agencies have the responsibility to perform individual repair and alterations projects. Executive agencies are delegated repair and alterations authority for reimbursable space alteration projects up to the simplified acquisition threshold, under § 101–20.106 of this title.

§ 102–72.65 What are the requirements for obtaining a delegation of individual repair and alteration project authority from GSA?

Executive agencies may be delegated repair and alterations authority for other individual alteration projects when they demonstrate the ability to perform the delegated repair and alterations responsibilities and when such a delegation promotes efficiency and economy.

§ 102–72.70 What are Executive agencies' responsibilities under a delegation of lease management authority (contracting officer representative authority) from GSA?

When an Executive agency does not exercise the delegation of authority mentioned in § 102–72.30(b) to lease general purpose space itself, it may be delegated, upon request, lease management authority to manage the administration of one or more lease contracts awarded by GSA.

§ 102–72.75 What are the requirements for obtaining a delegation of lease management authority (contracting officer representative authority) from GSA?

An Executive agency may be delegated lease management authority when it:

(a) Occupies at least 90 percent of the building's GSA-controlled space or has the written concurrence of 100 percent of rent-paying occupants covered under the lease to perform this function; and

(b) Demonstrates the ability to perform the delegated lease management responsibilities.

§ 102–72.80 What are Executive agencies' responsibilities under a disposal of real property delegation of authority from GSA?

With this delegation, Executive agencies have the authority to utilize and dispose of excess or surplus real and related personal property and to grant approvals and make determinations subject to the conditions in the delegation document.

§ 102–72.85 What are the requirements for obtaining a disposal of real property delegation of authority from GSA?

While disposal delegations to Executive agencies are infrequent, GSA may delegate authority to them based on situations involving certain low-value properties and when they can demonstrate that they have the technical expertise to perform the disposition functions. GSA may grant special delegations of authority to Executive agencies for the utilization and disposal of certain real property through the procedures set forth in part 101–47, subpart 101–47.6, of this title.

§ 102–72.90 What are Executive agencies' responsibilities under a security delegation of authority from GSA?

With a security delegation, Executive agencies have the authority and responsibility to protect persons and property at the locations identified in the delegation document.

§ 102–72.95 What are the requirements for obtaining a security delegation of authority from GSA?

Executive agencies may be delegated security authority when any of the following conditions exist:

(a) A clear and unique security requirement;

(b) A critical national security issue;

(c) An intelligence or law enforcement mission; or

(d) The current security contractor is ineffective.

§ 102–72.100 What are Executive agencies' responsibilities under a utility service delegation of authority from GSA?

With this delegation, Executive agencies have the authority to negotiate and execute utility services contracts for periods over one year but not exceeding ten years for their use and benefit. Agencies also have the authority to intervene in utility rate proceedings to represent the consumer interests of the Federal Government, if so provided in the delegation of authority.

§ 102–72.105 What are the requirements for obtaining a utility services delegation of authority from GSA?

Executive agencies may be delegated utility services authority when they

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have the technical expertise and adequate staffing.

PART 102–73—REAL ESTATE ACQUISITION

Sec.

102–73.5 What is the scope of this part?
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102–73.15 What real estate acquisition and related services must Federal agencies provide?
102–73.20 When may Federal agencies consider leases of privately owned land and buildings to satisfy their space needs?
102–73.25 Are Federal agencies required to give priority consideration to space in buildings under the custody and control of the United States Postal Service in fulfilling Federal agency space needs?
102–73.30 On what basis must Federal agencies acquire leases?
102–73.35 Are Executive agencies required to acquire leased space by negotiation?
102–73.40 Is the CICA applicable to lease acquisition?
102–73.45 What policy must Executive agencies comply with in locating Federal facilities?
102–73.50 What historic preservation provisions must Federal agencies comply with when acquiring space by lease?
102–73.55 With whom may Federal agencies enter into lease agreements?
102–73.60 Are there any limitations on leasing certain space?
102–73.65 When may Federal agencies consider acquiring leases with purchase options?
102–73.70 What scoring rules must Federal agencies follow when considering leases and leases with purchase options?
102–73.75 When may Federal agencies consider purchase of buildings?
102–73.80 What factors must Executive agencies consider when purchasing sites?
102–73.85 What land acquisition policy must Federal agencies follow?
102–73.90 What relocation assistance policy must Federal agencies follow?
102–73.95 Is a prospectus required for all acquisition, construction or alteration projects?
102–73.100 What happens if the project exceeds the prospectus threshold?

Authority: 40 U.S.C. 486(c); Sec. 3(c), Reorganization Plan No. 18 of 1950 (40 U.S.C. 490 note); Sec. 1–201(b), E.O. 12072, 43 FR 36869, 3 CFR, 1978 Comp., p. 213.

§ 102–73.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–73.10 What is the basic real estate acquisition policy?

If suitable Government-controlled space is unavailable, Executive agencies must acquire real estate and related services in an efficient and cost effective manner.

§ 102–73.15 What real estate acquisition and related services must Federal agencies provide?

Federal agencies, upon approval from GSA, may provide real estate and related services, including leases (with and without purchase options), building purchase, purchase of sites, condemnation, and relocation assistance.

§ 102–73.20 When may Federal agencies consider leases of privately owned land and buildings to satisfy their space needs?

Federal agencies may consider leases of privately owned land and buildings only when needs cannot be satisfactorily met in Government-controlled space and one or more of the following conditions exist:

(a) Leasing is more advantageous to the Government than constructing a new building, or more advantageous than altering an existing Federal building;

(b) New construction or alteration is unwarranted because demand for space in the community is insufficient, or is indefinite in scope or duration; or

(c) Federal agencies cannot provide for the completion of a new building within a reasonable time.

§ 102–73.25 Are Federal agencies required to give priority consideration to space in buildings under the custody and control of the United States Postal Service in fulfilling Federal agency space needs?

Yes, after considering the availability of GSA-controlled space, Federal agencies must extend priority consideration to available space in buildings under the custody and control of the United States Postal Service (USPS) in fulfilling Federal agency space needs.

§ 102–73.30 On what basis must Federal agencies acquire leases?

Federal agencies must acquire leases on the most favorable basis to the Federal Government, with due consideration to maintenance and operational efficiency, and at charges consistent with prevailing market rates for comparable facilities in the community.

§ 102–73.35 Are Executive agencies required to acquire leased space by negotiation?

Yes, Executive agencies must acquire leased space by negotiation, except where the sealed bid procedure is required by the Competition in Contracting Act of 1984 (CICA), as amended (41 U.S.C. 253(a)). See also 40 U.S.C. 618(b) with respect to the use of competitive procedures for the acquisition of leaseholds in buildings constructed for Federal Government use.

§ 102–73.40 Is the CICA applicable to lease acquisition?

Yes, Executive agencies must obtain full and open competition among suitable locations meeting minimum Government requirements, except as otherwise provided by CICA.

§ 102–73.45 What policy must Executive agencies comply with in locating Federal facilities?

When acquiring space by lease, Executive agencies must comply with the location policies in § 101–17.205 and § 102–79.90 (E.O. 13006 (61 FR 26071, 3 CFR, 1996 Comp., p. 195)) of this title.

§ 102–73.50 What historic preservation provisions must Federal agencies comply with when acquiring space by lease?

When acquiring space by lease, Federal agencies must comply with the provisions of section 110(a) of the National Historic Preservation Act of 1966, as amended, (16 U.S.C. 470h–2(a)), regarding the use of historic properties.

§ 102–73.55 With whom may Federal agencies enter into lease agreements?

Federal agencies, upon approval from GSA, may enter into lease agreements with any person, copartnership, corporation, or other public or private entity, which do not bind the Government for periods in excess of twenty years (40 U.S.C. 490(h)(1)). This policy does not include persons who might otherwise be barred from contracting with the Federal Government (*e.g.*, debarred or suspended contractors or Members of Congress).

§ 102–73.60 Are there any limitations on leasing certain space?

Yes, the limitations on leasing certain space are as follows:

(a) In general, Federal agencies may not lease any space to accommodate computer and telecommunications operations; secure or sensitive activities related to the national defense or security; or a permanent courtroom, judicial chamber, or administrative office for any United States court, if the average annual net rental cost of leasing such space would exceed the prospectus threshold (40 U.S.C. 606(e)).

(b) Federal agencies may lease such space only if the Administrator of General Services first determines that leasing such space is necessary to meet requirements which cannot be met in public buildings and submits such reasons to the Committee on Environment and Public Works of the Senate and the Committee on Public Works and Transportation of the House of Representatives in accordance with 40 U.S.C. 606(e).

§ 102–73.65 When may Federal agencies consider acquiring leases with purchase options?

Agencies may consider leasing with a purchase option at or below fair market value when one or more of the following conditions exist:

(a) The purchase option offers economic and other advantages to the Government and is consistent with the Government's goals;

(b) The Government is the sole or major tenant of the building, and has a long-term need for the property; or

(c) Leasing with a purchase option is otherwise in the best interest of the Government.

§ 102–73.70 What scoring rules must Federal agencies follow when considering leases and leases with purchase options?

All Federal agencies must follow the budget scorekeeping rules for leases, capital leases, and lease-purchases identified in appendices A and B of OMB Circular A–11 (For availability, see 5 CFR 1310.3).

§ 102–73.75 When may Federal agencies consider purchase of buildings?

Agencies may consider purchase of buildings on a case-by-case basis when one or more of the following conditions exist:

(a) It is economically more beneficial to own and manage the property;

(b) There is a long-term need for the property;

(c) The property is an existing building, or a building nearing completion, that can be purchased and occupied within a reasonable time; or

(d) When otherwise in the best interests of the Government.

§ 102–73.80 What factors must Executive agencies consider when purchasing sites?

Agencies must locate proposed Federal buildings on sites that are most advantageous to the United States. Executive agencies must consider factors such as whether the site will contribute to economy and efficiency in the construction, maintenance and operation of the individual building, and how the proposed site relates to the Government's total space needs in the community. Prior to acquiring, constructing or leasing buildings (or sites for such buildings), Federal agencies must use, to the maximum extent feasible, historic properties available to the agency. In site selections, Executive agencies must consider Executive Orders 12072 (3 CFR, 1978 Comp., p. 213) and 13006 (40 U.S.C. 601a note). In addition, Executive agencies must consider all of the following:

(a) Maximum utilization of Government-owned land (including excess land) whenever it is adequate, economically adaptable to requirements and properly located, where such use is consistent with the provisions of part 101–47, subpart 101–47.8, of this title.

(b) A site adjacent to or in the proximity of an existing Federal building which is well located and is to be retained for long-term occupancy.

(c) The environmental condition of proposed sites prior to purchase: The sites must be free from contamination, unless it is otherwise determined to be in the best interests of the Government to purchase a contaminated site (*e.g.*, reuse of a site under an established "Brownsfields" program).

(d) Purchase options to secure the future availability of a site.

(e) All applicable policies concerning the location of Federal facilities (*e.g.*, to give first priority to locating facilities in rural areas under the Rural Development Act (7 U.S.C. 2204b–1)).

§ 102–73.85 What land acquisition policy must Federal agencies follow?

Federal agencies must follow a land acquisition policy that:

(a) Encourages and expedites the acquisition of real property by agreements with owners;

(b) Avoids litigation, including condemnation actions, where possible and relieves congestion in the courts;

(c) Provides for consistent treatment of owners; and

(d) Promotes public confidence in Federal land acquisition practices.

§ 102–73.90 What relocation assistance policy must Federal agencies follow?

Federal agencies, upon approval from GSA, must provide appropriate relocation assistance under the Uniform Relocation Assistance and Real Property Acquisition Policies Act (42 U.S.C. 4651–4655) to eligible owners and tenants of property purchased for use by Federal agencies. Appropriate relocation assistance means that the Federal agency must pay the displaced person for actual reasonable moving expenses (in moving himself, his family, business, etc.); actual direct losses of tangible personal property as a result of moving or discontinuing a business; actual reasonable expenses in searching for a replacement business or farm; and actual reasonable expenses necessary to reestablish a displaced farm, nonprofit organization, or small business at its new site, but not to exceed $10,000. The implementing regulations are found in 49 CFR part 24 (see § 105–51.000 of this title).

§ 102–73.95 Is a prospectus required for all acquisition, construction or alteration projects?

(a) No, a prospectus is not required if the dollar value of a project does not exceed the prospectus threshold. The Public Buildings Act of 1959, as amended, 40 U.S.C. 601–619, establishes a prospectus threshold, applicable to Federal agencies operating under, or subject to, the authorities of the Administrator of General Services, for the construction, alteration, purchase, and acquisition of any building to be used as a public building, and establishes a prospectus threshold to lease any space for use for public purposes. (Because of the important role the prospectus approval process plays in the budget preparation and planning process and with Congressional oversight responsibilities, Federal agencies must continue to prepare and submit prospectuses for all projects that exceed the prospectus threshold identified in § 102–73.55. All GSA delegations of leasing, alteration, and construction authority are subject to this policy.)

(b) Public Law 104–66, 109 Stat. 734, eliminated the prospectus submission requirement of the Public Buildings Act of 1959 (40 U.S.C. 606(a) and 610(b)).

§ 102–73.100 What happens if the project exceeds the prospectus threshold?

Such projects require approval by the Senate and the House of Representatives if the dollar value exceeds the prospectus threshold. In order to obtain this approval, prospectuses for such projects must be submitted to GSA and the Administrator of General Services will transmit the proposed prospectuses to Congress for consideration by the Senate and the House of Representatives.

PART 102–74—FACILITY MANAGEMENT

Sec.

102–74.5 What is the scope of this part?
102–74.10 What is the basic facility management policy?
102–74.15 What are occupancy services?
102–74.20 What responsibilities do Executive agencies have regarding occupancy services?
102–74.25 What standard in providing occupancy services must Executive agencies follow?

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102–74.30 What building services must Executive agencies provide?
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102–74.40 When must Federal agencies provide concessions services?
102–74.45 Are Federal agencies required to give blind vendors priority in operating vending facilities?
102–74.50 What are conservation programs?
102–74.55 What are asset services?
102–74.60 What asset services must an Executive agency provide?
102–74.65 What standard in providing asset services must Executive agencies follow?
102–74.70 What Federal facility ridesharing policy must Executive agencies follow?
102–74.75 What steps must Executive agencies take to promote ridesharing at Federal facilities?
102–74.80 What specific ridesharing information must Executive agencies report to the Administrator of General Services?
102–74.85 Where should Executive agencies send their Federal Facility Ridesharing Reports?
102–74.90 Are there any exceptions to these ridesharing reporting requirements?

Authority: 40 U.S.C. 486(c); E.O. 12191, 45 FR 7997, 3 CFR, 1980 Comp., p 138.

§ 102–74.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–74.10 What is the basic facility management policy?

Executive agencies must manage, operate, and maintain Government-owned and leased buildings in a manner that provides for quality space and services consistent with their operational needs and that accomplish overall Government objectives. The management, operation, and maintenance of buildings and building systems must:

(a) Be cost effective and energy efficient;

(b) Be adequate to meet the agencies' missions;

(c) Meet nationally recognized standards; and

(d) Be at an appropriate level to maintain and preserve the physical plant assets, consistent with available funding.

§ 102–74.15 What are occupancy services?

Occupancy services are:

(a) Building services (see § 102–74.30);

(b) Concession services; and

(c) Conservation programs.

§ 102–74.20 What responsibilities do Executive agencies have regarding occupancy services?

Executive agencies, upon approval from GSA, must manage, administer, and enforce the requirements of agreements (such as Memoranda of Understanding, etc.) and contracts that provide for the delivery of occupancy services.

§ 102–74.25 What standard in providing occupancy services must Executive agencies follow?

Executive agencies must provide occupancy services that substantially conform to nationally recognized standards. As needed, Executive agencies may adopt other standards for buildings and services in Federally-controlled facilities in order to conform to statutory requirements and to implement cost-reduction efforts.

§ 102–74.30 What building services must Executive agencies provide?

Executive agencies, upon approval from GSA, must provide:

(a) Building services such as custodial, solid waste management (including recycling), heating and cooling, landscaping and grounds maintenance, tenant alterations, minor repairs, building maintenance, integrated pest management, signage, parking, and snow removal, at appropriate levels to support Federal agency missions; and

(b) Arrangements for raising and lowering the United States flags at appropriate times. In addition, agencies must display P.O.W. and M.I.A. flags at locations specified in 36 U.S.C. 189a on P.O.W./M.I.A. flag display days.

§ 102–74.35 What are concessions services?

Concessions services are services such as dry cleaners, gift shops, vending facilities (onsite preparation facilities, prepackaged facilities, sundry facilities, and vending machines), cafeterias, employee health units, and public pay telephones.

§ 102–74.40 When must Federal agencies provide concessions services?

Federal agencies, upon approval from GSA, must provide concessions services where building population supports such services and when the availability of existing commercial services is insufficient to meet Federal agency needs. See the Randolph-Sheppard Act, as amended, 20 U.S.C. 107 *et seq.*, and part 101–20, subpart 101–20.2, of this title.

§ 102–74.45 Are Federal agencies required to give blind vendors priority in operating vending facilities?

With certain exceptions, the Randolph-Sheppard Act requires that blind persons licensed under the provisions of the Act be authorized to operate vending facilities on any Federal property, including leased buildings. The Act imposes a positive obligation on Federal agencies to have suitable sites for vending facilities in buildings that they acquire.

§ 102–74.50 What are conservation programs?

Conservation programs are programs that improve energy and water efficiency and promote the use of solar and other renewable energy. These programs must promote and maintain an effective source reduction activity (reducing consumption of resources such as energy, water and paper), resource recovery activity (obtaining materials from the waste stream that can be recycled into new products), and reuse activity (reusing same product before disposition, such as reusing unneeded memos for scratch paper).

§ 102–74.55 What are asset services?

Asset services include repairs (as opposed to those minor repairs identified in § 102–74.30(a)), alterations, and modernizations for real property assets. Typically, these are the type of repairs and alterations necessary to preserve or enhance the value of the real property asset.

§ 102–74.60 What asset services must Executive agencies provide?

Executive agencies, upon approval from GSA, must provide asset services such as repairs (in addition to those minor repairs identified in § 102–74.30(a)), alterations, and modernizations for real property assets. Federal agencies must follow the prospectus submission and approval policy identified in § § 102–73.95 and 102–73.100.

§ 102–74.65 What standard in providing asset services must Executive agencies follow?

Executive agencies must provide asset services that maintain continuity of Government operations, continue efficient building operations, extend the useful life of buildings and related building systems, and provide a quality workplace environment that enhances employee productivity.

§ 102–74.70 What Federal facility ridesharing policy must Executive agencies follow?

Executive agencies must actively promote the use of ridesharing (carpools, vanpools, privately leased buses, public transportation, and other multi-occupancy modes of travel) by personnel working at Federal facilities to conserve energy, reduce congestion, improve air quality, and provide an economical way for Federal employees to commute to work.

§ 102–74.75 What steps must Executive agencies take to promote ridesharing at Federal facilities?

Agencies must:

(a) Establish an annual ridesharing goal for each facility.

(b) Report to the Administrator of General Services by June 1 of each year the goals established, the means developed to achieve those goals, and the progress achieved.

(c) Cooperate with State and local ridesharing agencies where such agencies exist.

§ 102–74.80 What specific ridesharing information must Executive agencies report to the Administrator of General Services?

The head of each agency must submit to GSA by June 1 of each year a report which includes all of the following:

(a) The name, address, title, and telephone number of the agencywide Employee Transportation Coordinator (ETC).

(b) A narrative on actions taken and barriers encountered in promoting ridesharing within the agency.

(c) Information on any noticeable facility achievements.

(d) A copy of instructions issued to the agency's facility ETC's for implementing the Federal Facility Ridesharing Program.

§ 102–74.85 Where should Executive agencies send their Federal Facility Ridesharing Reports?

Agencies must send their Federal Facility Ridesharing Reports to the Real Property Policy Division (MPR), General Services Administration, 1800 F Street, NW., Washington, DC 20405.

§ 102–74.90 Are there any exceptions to these ridesharing reporting requirements?

Yes, facilities with less than 100 full-time employees or less than 100 full-time employees on the largest shift are not required to submit an annual report. Agencies must not subdivide buildings, groups of buildings, or worksites for the purpose of meeting the exception standards.

PART 102–75—REAL PROPERTY DISPOSAL

Sec.
102–75.5 What is the scope of this part?
102–75.10 What basic real property disposal policy governs Executive agencies?
102–75.15 What real property disposal services must Executive agencies provide?
102–75.20 What are Executive agencies' responsibilities concerning the utilization of excess property?
102–75.25 What are Executive agencies' responsibilities concerning real property surveys?
102–75.30 When may landholding Federal agencies grant rights for non-Federal interim use of excess property reported to GSA?
102–75.35 What are Executive agencies' responsibilities concerning the disposal of surplus property?
102–75.40 When may Executive agencies dispose of surplus real property by exchange for privately owned property?
102–75.45 When may Executive agencies outlease surplus real property for non-Federal interim use?
102–75.50 What are Federal agencies' reporting responsibilities under the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411)?
102–75.55 What are Executive agencies' responsibilities concerning public benefit conveyances?
102–75.60 When may Executive agencies conduct negotiated sales?
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102–75.75 What is a negotiated sale for economic development purposes?
102–75.80 What are Executive agencies' responsibilities concerning public sales?
102–75.85 How can Federal agencies obtain related disposal services?
102–75.90 What type of appraisal value must be obtained for real property disposal transactions?
102–75.95 Are appraisals required for all real property disposal transactions?
102–75.100 Who must appraise the real property?

Authority: 40 U.S.C. 486(c), 483(a), and 484; E.O. 12512, 50 FR 18453, 3 CFR, 1985 Comp., p. 340.

§ 102–75.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–75.10 What basic real property disposal policy governs Executive agencies?

Executive agencies must provide, in a timely, efficient, and cost effective manner, the full range of real estate services necessary to support their real property utilization and disposal needs. Landholding agencies must make surveys of real property under their jurisdiction to identify property that is unutilized, underutilized, or not being put to optimum use. Executive agencies must have adequate procedures in place to promote the effective utilization and disposal of such real property.

§ 102–75.15 What real property disposal services must Executive agencies provide?

Executive agencies must provide real property disposal services for real property assets under their custody and control. These real property disposal services include utilization of excess property, surveys, disposal of surplus property, public benefit conveyances, negotiated sales, public sales, related disposal services, and appraisals.

§ 102–75.20 What are Executive agencies' responsibilities concerning the utilization of excess property?

Executive agencies' responsibilities concerning the utilization of excess property are to:

(a) Increase the identification and reporting of their excess real property;

(b) Achieve maximum use of their excess real property, in terms of economy and efficiency, to minimize expenditures for the purchase of real property;

(c) Provide for the transfer of excess real property among Federal agencies, to mixed-ownership Government corporations, and to the municipal government of the District of Columbia; and

(d) Obtain assistance from GSA in resolving conflicting requests for transferring real property that the involved agencies cannot resolve.

§ 102–75.25 What are Executive agencies' responsibilities concerning real property surveys?

A landholding agency's responsibilities concerning real property surveys are to:

(a) Survey real property under its control (*i.e.*, that property reported on its financial statements) at least annually to identify property that is not needed, underutilized, or not being put to optimum use. When other needs for the property are identified or recognized, the agency must determine whether continuation of the current use or another use would better serve the public interest, considering both the Federal agency's needs and the property's location. In conducting annual reviews of their property holdings, § 101–47.801(b) of this title and other applicable GSA regulations provide guidelines for Executive agencies to consider in identifying unneeded Federal real property;

(b) Maintain its inventory of real property at the absolute minimum

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consistent with economical and efficient conduct of the affairs of the agency; and

(c) Promptly report to GSA real property that it has determined to be excess.

§ 102–75.30 When may landholding Federal agencies grant rights for non-Federal interim use of excess property reported to GSA?

Landholding Federal agencies may grant rights for non-Federal interim use of excess property reported to GSA, when it is determined that such excess property is not required for the needs of any Federal agency.

§ 102–75.35 What are Executive agencies' responsibilities concerning the disposal of surplus property?

Executive agencies must obtain from GSA a determination that their excess real property is not needed for Federal use and is surplus to the needs of the Federal Government. After receiving this determination, Executive agencies, upon approval from GSA, must expeditiously make the surplus property available for acquisition by State and local governmental units and nonprofit institutions (*see* § 102–75.55) or for sale by public advertising, negotiation, or other disposal action. Executive agencies must consider the availability of real property for public purposes on a case-by-case basis, based on highest and best use and estimated fair market value. See § 101–47.202–2(b) of this title for the requirements for reporting excess real property. Where hazardous substance activity is identified, see § 101–47.304–14 of this title for required information that the disposal agency must incorporate into Invitation for Bids/Offers to Purchase.

§ 102–75.40 When may Executive agencies dispose of surplus real property by exchange for privately owned property?

Executive agencies may dispose of surplus real property by exchange for privately owned property only:

(a) For property management considerations such as boundary realignment or provision of access; or

(b) Where authorized by law, when the requesting Federal agency receives approval from the Office of Management and Budget and the appropriate oversight committees, and where the transaction offers substantial economic or unique program advantages not otherwise obtainable by any othe. acquisition method.

§ 102–75.45 When may Executive agencies outlease surplus real property for non-Federal interim use?

Executive agencies may outlease surplus real property for non-Federal interim use, pending its disposition, when both of the following conditions exist:

(a) The lease or permit does not exceed one year and is revocable with not more than a 30-day notice by the disposal agency; and

(b) The use and occupancy will not interfere with, delay, or impede the disposal of the property.

§ 102–75.50 What are Federal agencies' reporting responsibilities under the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411)?

By December 31 of each year, each landholding agency responsible for reporting must notify the Department of Housing and Urban Development (HUD) regarding the current availability status and classification of each property controlled by the agency that:

(a) Was included in a list of suitable properties published that year by HUD; and

(b) Remains available for application for use to assist the homeless, or has become available for application during that year.

§ 102–75.55 What are Executive agencies' responsibilities concerning public benefit conveyances?

Based on a highest and best use analysis, Executive agencies, upon approval from GSA, may make surplus real property available to State and local governments and certain nonprofit institutions at up to 100 percent public benefit discount for public benefit purposes. Some examples of such purposes are education, health, park and recreation, the homeless, historic monuments, public airports, highways, correctional facilities, ports, and wildlife conservation. The implementing regulations are found at § 101–47.308 of this title.

§ 102–75.60 When may Executive agencies conduct negotiated sales?

Executive agencies may conduct negotiated sales only when:

(a) The estimated fair market value of the property does not exceed $15,000; or

(b) Bid prices after advertising are unreasonable (for all or part of the property) or were not independently arrived at in open competition; or

(c) The character or condition of the property or unusual circumstances make it impractical to advertise for competitive bids and the fair market value of the property and other satisfactory terms of disposal are obtainable by negotiation; or

(d) The disposals will be to States, Commonwealth of Puerto Rico, possessions, political subdivisions thereof, or tax-supported agencies therein, and the estimated fair market value of the property and other satisfactory terms of disposal are obtainable by negotiations. Such negotiated sales to public bodies must be limited to where a public benefit will result from a negotiated sale which would not be realized from a competitive sale disposal (some examples of such purposes are administrative offices and economic development); or

(e) Negotiation is otherwise authorized by the Federal Property and Administrative Services Act of 1949 or other law, such as disposals of power transmission lines for public or cooperative power projects.

§ 102–75.65 What are Executive agencies' responsibilities concerning negotiated sales?

Executive agencies must:

(a) Obtain such competition as is feasible in all negotiations of disposals and contracts for disposal of surplus property; and

(b) Prepare and transmit an explanatory statement, identifying the circumstances of each disposal by negotiation for any real property specified in 40 U.S.C. 484(e)(6)(A), to the appropriate committees of the Congress in advance of such disposal.

§ 102–75.70 What can Executive agencies do to eliminate the potential for windfall profits to public agencies in negotiated sales?

To eliminate the potential for windfall profits to public agencies, Executive agencies must include in negotiated sales to public agencies an excess profits clause, which usually runs for 3 years. This clause states that, if the purchaser should sell or enter into agreements to sell the property within 3 years from the date of title transfer by the Federal Government, all proceeds in excess of the purchasers costs will be remitted to the Federal Government. (Put the clause found in § 101–47.4908 of this title in the offer to purchase and in the conveyance document.)

§ 102–75.75 What is a negotiated sale for economic development purposes?

A negotiated sale for economic development purposes means that the public body purchasing the property will develop or make substantial improvements to the property with the intention of reselling or leasing the property in parcels to users to advance the community's economic benefit. This type of negotiated sale is acceptable where the expected public benefits to the community are greater than the anticipated proceeds derived from a competitive public sale.

§ 102–75.80 What are Executive agencies' responsibilities concerning public sales?

Executive agencies must make available by competitive public sale any surplus property that is not disposed of by public benefit discount conveyance or by negotiated sale. Awards must be made to the responsible bidder whose bid will be most advantageous to the Government, price and other factors considered.

§ 102–75.85 How can Federal agencies obtain related disposal services?

Federal agencies with independent disposal authority are encouraged to obtain disposal related services from those agencies with expertise in real property disposal, such as GSA, as allowed by 31 U.S.C. 1535 (the Economy Act), so that agencies may remain focused on their core mission.

§ 102–75.90 What type of appraisal value must be obtained for real property disposal transactions?

For all real property transactions requiring appraisals, Executive agencies must in all cases obtain, as appropriate, an appraisal of either the fair market value or the fair annual rental value of property available for disposal.

§ 102–75.95 Are appraisals required for all real property disposal transactions?

Generally, yes, appraisals are required for all real property disposal transactions. However, appraisals are not required when either of the following conditions exist:

(a) An appraisal will serve no useful purpose (*e.g.*, legislation authorizes conveyance without monetary consideration or at a fixed price). This exception does not apply to negotiated sales to public agencies intending to use the property for a public purpose not covered by any of the special disposal provisions in § 101–47.308 of this title.

(b) The estimated fair market value of property to be offered on a competitive sale basis does not exceed $50,000.

§ 102–75.100 Who must appraise the real property?

Executive agencies must use only experienced and qualified real estate appraisers familiar with types of property to be appraised when conducting the appraisal. When an appraisal is required for the purposes of disposing of surplus property by negotiation under § 102–75.60(c), (d), or (e), contract appraisers that meet this same standard must be used. However, Executive agencies may authorize any other method of obtaining an estimate of the fair market value or the fair annual rental when the cost of obtaining such data from a contract appraiser would be out of proportion to the expected recoverable value of the property.

PART 102–76—DESIGN AND CONSTRUCTION

Sec.

102–76.5 What is the scope of this part?
102–76.10 What basic design and construction policy governs Federal agencies?
102–76.15 What are design and construction services?
102–76.20 What issues must Federal agencies consider in providing site planning and landscape design services?
102–76.25 What standards must Federal agencies meet in providing architectural and interior design services?
102–76.30 Seismic safety. [Reserved]
102–76.35 Flood plains. [Reserved]

Authority: 40 U.S.C. 486(c) (in furtherance of the Administrator's authorities under 40 U.S.C. 601–619 and elsewhere as included under 40 U.S.C. 490(a) and (c)); E.O. 12411, 48 FR 13391, 3 CFR, 1983 Comp., p. 155; E.O. 12512, 50 FR 18453, 3 CFR, 1985 Comp., p. 340.

§ 102–76.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–76.10 What basic design and construction policy governs Federal agencies?

Federal agencies, upon approval from GSA, are bound by the following basic design and construction policies:

(a) Provide the highest quality services for designing and constructing new Federal facilities and for repairing and altering existing Federal facilities. These services must be timely, efficient, and cost effective.

(b) Use a distinguished architectural style and form in Federal facilities that reflects the dignity, enterprise, vigor and stability of the Federal Government.

(c) Follow nationally recognized model building codes and other applicable nationally recognized codes that govern Federal construction to the maximum extent feasible and consider local building code requirements. (See 40 U.S.C. 618 and 619.)

(d) Design Federal buildings to have a long life expectancy and accommodate periodic changes due to renovations.

(e) Make buildings cost effective, energy efficient, and accessible to and usable by the physically impaired.

(f) Provide for building service equipment that is accessible for maintenance, repair, or replacement without significantly disturbing occupied space.

(g) Consider ease of operation when selecting mechanical and electrical equipment.

(h) Agencies must follow the prospectus submission and approval policy identified in §§ 102–73.95 and 102–73.100 of this chapter.

§ 102–76.15 What are design and construction services?

Design and construction services are:

(a) Site planning and landscape design;

(b) Architectural and interior design; and

(c) Engineering systems design.

§ 102–76.20 What issues must Federal agencies consider in providing site planning and landscape design services?

In providing site planning and design services, Federal agencies must:

(a) Make the site planning and landscape design a direct extension of the building design;

(b) Make a positive contribution to the surrounding landscape;

(c) Consider requirements (other than procedural requirements) of local zoning laws and laws relating to setbacks, height, historic preservation and aesthetic qualities of a building;

(d) Identify areas for future building expansion in the architectural and site design concept for all buildings where an expansion need is identified to exist;

(e) Create a landscape design that is a pleasant, dynamic experience for occupants and visitors to Federal facilities and, where appropriate, encourage public access to and stimulate pedestrian traffic around the facilities. Coordinate the landscape design with the architectural characteristics of the building; and

(f) Comply with the requirements of the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4321 et seq., and the National Historic Preservation Act, as amended, 16 U.S.C. 470 et seq., for each project.

(g) Consider the vulnerability of the facility as well as the security needs of the occupying agencies.

§ 102–76.25 What standards must Federal agencies meet in providing architectural and interior design services?

Federal agencies must design distinctive and high quality Federal facilities that meet all of the following standards:

(a) Reflect the local architecture in buildings through the use of building form, materials, colors, or detail. Express a quality of permanence in the building interior similar to the building exterior.

(b) For new construction and major renovations, provide full access to and

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use of Federally-controlled facilities for physically impaired persons. Follow the Architectural Barriers Act of 1968, 42 U.S.C. 4151–4157 (Uniform Federal Accessibility Standards (UFAS)) or Americans with Disabilities Act of 1990, Public Law 101–336, 104 Stat. 327 (ADA accessibility guidelines), whichever is more stringent. For minor renovations in existing buildings, meet minimum UFAS requirements. A more detailed explanation of these standards can be found in part 101–19, subpart 101–19.6, of this title.

(c) Use metric specifications in construction where the metric system is the accepted industry standard, and to the extent that such usage is economically feasible and practical.

(d) Provide for the design of security systems to protect Federal workers and visitors and to safeguard facilities against criminal activity and/or terrorist activity. Security design must support the continuity of Government operations during civil disturbances, natural disasters and other emergency situations.

(e) Design and construct facilities that meet or exceed the energy performance standards applicable to Federal buildings in 10 CFR part 435.

§ 102–76.30 Seismic safety. [Reserved]

§ 102–76.35 Flood plains. [Reserved]

PART 102–77—ART-IN-ARCHITECTURE

Sec.

102–77.5 What is the scope of this part?
102–77.10 What basic Art-in-architecture policy governs Federal agencies?
102–77.15 Who funds the Art-in-architecture efforts?
102–77.20 Who should Federal agencies collaborate with when commissioning and selecting art for Federal buildings?
102–77.25 Do Federal agencies have responsibilities to provide national visibility for Art-in-architecture?

Authority: 40 U.S.C. 486(c) and 601a.

§ 102–77.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–77.10 What basic Art-in-architecture policy governs Federal agencies?

Federal agencies must incorporate fine arts as an integral part of the total building concept when designing new Federal buildings, and when making substantial repairs and alterations to existing Federal buildings, as appropriate. The selected fine arts, including painting, sculpture, and artistic work in other media, must reflect the national cultural heritage and emphasize the work of living American artists.

§ 102–77.15 Who funds the Art-in-architecture efforts?

To the extent not prohibited by law, Federal agencies must fund the Art-in-architecture efforts by allocating a portion of the estimated cost of constructing or purchasing new Federal buildings, or of completing major repairs and alterations of existing buildings. Funding for qualifying projects, including new construction, building purchases, other building acquisition, or prospectus-level repair and alteration projects, must be in a range determined by the Administrator of General Services.

§ 102–77.20 Who should Federal agencies collaborate with when commissioning and selecting art for Federal buildings?

To the maximum extent practicable, Federal agencies should seek the support and involvement of local citizens in selecting appropriate artwork. Federal agencies should collaborate with the artist and community to produce works of art that reflect the cultural, intellectual, and historic interests and values of a community. In addition, Federal agencies should work collaboratively with the architect of the building, art professionals, when commissioning and selecting art for Federal buildings. Federal agencies should commission artwork that is diverse in style and media.

§ 102–77.25 Do Federal agencies have responsibilities to provide national visibility for Art-in-architecture?

Yes, Federal agencies should provide Art-in-architecture that receives appropriate national and local visibility to facilitate participation by a large and diverse group of artists representing a wide variety of types of artwork.

PART 102–78—HISTORIC PRESERVATION

Sec.

102–78.5 What is the scope of this part?
102–78.10 What basic historic preservation policy governs Federal agencies?
102–78.15 What are historic properties?
102–78.20 Are Federal agencies required to identify historic properties?
102–78.25 What is an undertaking?
102–78.30 What are consulting parties?
102–78.35 Are Federal agencies required to involve consulting parties in their historic preservation activities?
102–78.40 What responsibilities do Federal agencies have when an undertaking adversely affects a historic or cultural property?
102–78.45 What are Federal agencies' responsibilities concerning nomination of properties to the National Register?
102–78.50 What historic preservation services must Federal agencies provide?
102–78.55 For which properties must Federal agencies provide historic preservation services?
102–78.60 What are Federal agencies' historic preservation responsibilities when acquiring leased space?
102–78.65 What are Federal agencies' historic preservation responsibilities when disposing of real property under their control?
102–78.70 What are an agency's historic preservation responsibilities when disposing of another Federal agency's real property?

Authority: 16 U.S.C. 470 h–2; 40 U.S.C. 486(c) and 490(a).

§ 102–78.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services. The policies in this part are in furtherance of GSA's preservation program under section 110 of the National Historic Preservation Act (16 U.S.C. 470) and apply to properties under the jurisdiction or control of the Administrator and to any Federal agencies operating, maintaining or protecting such properties under a delegation of authority from the Administrator.

§ 102–78.10 What basic historic preservation policy governs Federal agencies?

To protect, enhance and preserve historic and cultural property under their control, Federal agencies must consider the effects of their undertakings on historic and cultural properties and give the Advisory Council on Historic Preservation (Advisory Council), the State Historic Preservation Officer (SHPO), and other consulting parties a reasonable opportunity to comment regarding the proposed undertakings.

§ 102–78.15 What are historic properties?

Historic properties are those that are included in, or eligible for inclusion in, the National Register of Historic Places (National Register) as more specifically defined at 36 CFR 800.16.

§ 102–78.20 Are Federal agencies required to identify historic properties?

Yes, Federal agencies must identify all National Register or National Register-eligible historic properties under their control. In addition, Federal agencies must apply National Register Criteria (36 CFR part 63) to properties that have not been previously evaluated for National Register eligibility and that may be affected by the undertakings of Federally sponsored activities.

§ 102–78.25 What is an undertaking?

The term undertaking means a project, activity, or program under the direct or indirect jurisdiction of a Federal agency, including those:

(a) Carried out by or on behalf of the agency;

(b) Carried out with Federal financial assistance;

(c) Requiring a Federal permit, license, or approval; and

(d) Subject to State or local regulation administered pursuant to a delegation or approval by a Federal agency.

§ 102–78.30 What are consulting parties?

As more particularly described in 36 CFR 800.2(c), consulting parties are those parties having consultative roles in the Section 106 process (*i.e.*, Section 106 of the National Historic Preservation Act) that requires Federal agencies to take into account the effects of their undertakings on historic properties and afford the Council a reasonable opportunity to comment on such undertakings. Specifically, consulting parties include the State Historic Preservation Officer; Tribal Historic Preservation Officer; Indian tribes and Native Hawaiian organizations; Representatives of local governments; Applicants for Federal assistance, permits, licenses and other approvals; and other individuals and organizations with a demonstrated interest in the undertaking.

§ 102–78.35 Are Federal agencies required to involve consulting parties in their historic preservation activities?

Yes, Federal agencies must solicit information from consulting parties to carry out their responsibilities under historic and cultural preservation laws and regulations. Federal agencies must invite the participation of consulting parties through their normal public notification processes.

§ 102–78.40 What responsibilities do Federal agencies have when an undertaking adversely affects a historic or cultural property?

Federal agencies must not perform an undertaking that could alter, destroy, or modify an historic or cultural property until they have consulted with the SHPO and the Advisory Council. Federal agencies must minimize all adverse impacts of their undertakings on historic or cultural properties to the extent that is feasible and prudent. Federal agencies must follow the specific guidance on the protection of historic and cultural properties in 36 CFR part 800.

§ 102–78.45 What are Federal agencies' responsibilities concerning nomination of properties to the National Register?

Federal agencies must nominate to the National Register all properties under their control determined eligible for inclusion in the National Register.

§ 102–78.50 What historic preservation services must Federal agencies provide?

Federal agencies must provide the following historic preservation services:

(a) Prepare a Historic Building Preservation Plan for each National Register or National Register-eligible property under their control. When approved by consulting parties, such plans become a binding management plan for the property; and

(b) Investigate for historic and cultural factors all proposed sites for direct and leased construction.

§ 102–78.55 For which properties must Federal agencies assume historic preservation responsibilities?

Federal agencies must assume historic preservation responsibilities for real property assets under their custody and control. Federal agencies occupying space in buildings under the custody and control of other Federal agencies must obtain approval from the agency having custody and control of the building.

§ 102–78.60 What are Federal agencies historic preservation responsibilities when acquiring leased space?

In leasing historic property, Federal agencies must give a preference to such leasing actions in accordance with hierarchy of consideration identified in § 102–79.90 of this chapter.

§ 102–78.65 What are Federal agencies' historic preservation responsibilities when disposing of real property under their control?

Federal agencies must:

(a) To the extent practicable, establish and implement alternatives for historic properties, including adaptive reuse, that are not needed for current or projected agency purposes. Agencies are required to get the Secretary of Interior's approval of the plans of transferees of surplus Federally-owned historic properties.

(b) Review all proposed excess actions to identify any properties listed on or eligible for listing on the National Register. Federal agencies must not perform disposal actions that could result in the alteration, destruction, or modification of an historic or cultural property until Federal agencies have consulted with the SHPO and the Advisory Council.

§ 102–78.70 What are an agency's historic preservation responsibilities when disposing of another Federal agency's real property?

Federal agencies must not accept property declared excess by another Federal agency nor act as an agent for transfer or sale of such properties until the holding agency provides evidence that the Federal agency has met its National Historic Preservation Act responsibilities.

PART 102–79—ASSIGNMENT AND UTILIZATION OF SPACE

Sec.

102–79.5 What is the scope of this part?
102–79.10 What basic assignment and utilization of space policy governs an Executive agency?
102–79.15 What objectives must an Executive agency strive to meet in providing assignment and utilization of space services?
102–79.20 What standard must Executive agencies promote when assigning space?
102–79.25 Can Federal agencies allot space in Federal buildings for the provision of child care services?
102–79.30 Can Federal agencies allot space in Federal buildings for establishing fitness centers?
102–79.35 What elements must Federal agencies address in their planning effort for establishing fitness programs?
102–79.40 Can Federal agencies allot space in Federal buildings to Federal credit unions?
102–79.45 What type of services may Federal agencies provide without charge to Federal credit unions?
102–79.50 What standard must Executive agencies promote in their utilization of space?
102–79.55 Are agencies required to use historic properties available to the agency?
102–79.60 Are Executive agencies required to give first priority to the location of new offices and other facilities in rural areas?
102–79.65 When an agency's mission and program requirements call for the location in an urban area, are Executive agencies required to give first consideration to central business areas?
102–79.70 What is a central business area?
102–79.75 Who is responsible for identifying the delineated area within which a Federal agency wishes to locate specific activities?
102–79.80 Who must approve the final delineated area?
102–79.85 Are Executive agencies required to consider whether the central business area will provide for adequate competition when acquiring leased space?

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102–79.90 Are Executive agencies required to give preference to historic properties when acquiring leased space?
102–79.95 Automated external defibrillators. [Reserved]

Authority: 40 U.S.C. 486(c); E.O. 12411, 48 FR 13391, 3 CFR, 1983 Comp., p. 155; and E.O. 12512, 50 FR 18453, 3 CFR, 1985 Comp., p. 340.

§ 102–79.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–79.10 What basic assignment and utilization of space policy governs an Executive agency?

Executive agencies must provide a quality workplace environment that supports program operations, preserves the value of real property assets, meets the needs of the occupant agencies, and provides child care and physical fitness facilities in the workplace when adequately justified. An Executive agency must promote maximum utilization of Federal workspace, consistent with mission requirements, to maximize its value to the Government.

§ 102–79.15 What objectives must an Executive agency strive to meet in providing assignment and utilization of space services?

Executive agencies must provide assignment and utilization services that will maximize the value of Federal real property resources and improve the productivity of the workers housed therein.

§ 102–79.20 What standard must Executive agencies promote when assigning space?

Executive agencies must promote the optimum use of space for each assignment at the minimum cost to the Government, provide quality workspace that is delivered and occupied in a timely manner, and assign space based on mission requirements.

§ 102–79.25 Can Federal agencies allot space in Federal buildings for the provision of child care services?

Yes, in accordance with 40 U.S.C. 490b, Federal agencies can allot space in Federal buildings to individuals or entities who will provide child care services to Federal employees if:

(a) Such space is available;

(b) Such agency determines that such space will be used to provide child care services to children of whom at least 50 percent have one parent or guardian who is a Federal Government employee; and

(c) Such agency determines that such individual or entity will give priority for available child care services in such space to Federal employees.

§ 102–79.30 Can Federal agencies allot space in Federal buildings for establishing fitness centers?

Yes, in accordance with 5 U.S.C. 7901, Federal agencies can allot space in Federal buildings for establishing fitness programs.

§ 102–79.35 What elements must Federal agencies address in their planning effort for establishing fitness programs?

Federal agencies must address the following elements in their planning effort for establishing fitness programs:

(a) A survey indicating employee interest in the program;

(b) A three to five year implementation plan demonstrating long-term commitment to physical fitness/health for employees;

(c) A health related orientation, including screening procedures, individualized exercise programs, identification of high-risk individuals, and appropriate follow-up activities;

(d) Identification of a person skilled in prescribing exercise to direct the fitness program;

(e) An approach which will consider key health behavior related to degenerative disease, including smoking and nutrition;

(f) A modest facility that includes only the essentials necessary to conduct a program involving cardiovascular and muscular endurance, strength activities, and flexibility;

(g) Provision for equal opportunities for men and women, and all employees, regardless of grade level.

§ 102–79.40 Can Federal agencies allot space in Federal buildings to Federal credit unions?

Yes, in accordance with 12 U.S.C. 1770, Federal agencies may allot space in Federal buildings to Federal credit unions without charge for rent or services if:

(a) At least 95 percent of the membership of the credit union to be served by the allotment of space is composed of persons who either are presently Federal employees or were Federal employees at the time of admission into the credit union, and members of their families; and

(b) If space is available.

§ 102–79.45 What type of services may Federal agencies provide without charge to Federal credit unions?

Federal agencies may provide without charge to Federal credit union services such as:

(a) Lighting;

(b) Heating and cooling;

(c) Electricity;

(d) Office furniture;

(e) Office machines and equipment;

(f) Telephone service (including installation of lines and equipment and other expenses associated with telephone service); and

(g) Security systems (including installation and other expenses associated with security systems).

§ 102–79.50 What standard must Executive agencies promote in their utilization of space?

Executive agencies, acquiring or utilizing Federally owned and leased space under the Federal Property and Administrative Services Act of 1949, as amended, must promote efficient utilization of space according to GSA standards. In order to maximize the use of vacant space, use existing GSA-controlled space to the maximum extent practical. After considering the availability of GSA-controlled space, extend priority consideration to available space in buildings under the custody and control of the U.S. Postal Service before acquiring additional space. Where there is no Federal agency space need, Executive agencies must make every effort to maximize the productive use of vacant space through out-granting (for example, outlease, permit, license) to non-Federal entities to the extent authorized by law.

§ 102–79.55 Are agencies required to use historic properties available to the agency?

Yes, Federal agencies must assume responsibility for the preservation of the historic properties they own or control. Prior to acquiring, constructing or leasing buildings, agencies must use, to the maximum extent feasible, historic properties already owned or leased by the agency (16 U.S.C. 470h–2).

§ 102–79.60 Are Executive agencies required to give first priority to the location of new offices and other facilities in rural areas?

Yes, Executive agencies must give first priority to the location of new offices and other facilities in rural areas (7 U.S.C. 2204b–1), unless their mission or program requirements call for locations in an urban area.

§ 102–79.65 When an agency's mission and program requirements call for the location in an urban area, are Executive agencies required to give first consideration to central business areas?

Yes, when agency mission and program requirements call for location in an urban area and new space must be acquired, constructed or leased,

Executive agencies must give first consideration to central business areas (CBAs) and other areas designated by local officials (Executive Order 12072 (43 FR 36869, 3 CFR, 1978 Comp., p. 213.) and Executive Order 13006 (61 FR 26071, 3 CFR, 1996 Comp., p. 195)).

§ 102–79.70 What is a central business area?

Central business area means the centralized community business area and adjacent areas of similar character, including other specific areas which may be recommended by local officials in accordance with Executive Order 12072.

§ 102–79.75 Who is responsible for identifying the delineated area within which a Federal agency wishes to locate specific activities?

Each Federal agency is responsible for identifying the delineated area within which it wishes to locate specific activities, consistent with its mission and program requirements, and in accordance with all applicable laws, regulations, and Executive orders.

§ 102–79.80 Who must approve the final delineated area?

Federal agencies conducting the procurement must approve the final delineated area for site acquisitions and lease actions and must confirm that the final delineated area complies with the requirements of all applicable laws, regulations, and Executive orders.

§ 102–79.85 Are Executive agencies required to consider whether the central business area will provide for adequate competition when acquiring leased space?

In accordance with the Competition in Contracting Act of 1984 (CICA), as amended, (41 U.S.C. 253(a)) Executive agencies must consider whether restricting the delineated area for obtaining leased space to the central business area will provide for adequate competition when acquiring leased space. Where an Executive agency determines that the delineated area must be expanded beyond the CBA in order to provide adequate competition, the agency may expand the delineated area in consultation with local officials. Executive agencies must continue to include the CBA in such expanded areas.

§ 102–79.90 Are Executive agencies required to give preference to historic properties when acquiring leased space?

Yes, section 110 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470h–2), requires that agencies first consider historic properties already under agency control. However, the Act also provides that prior to acquiring, constructing or leasing new space, and subject to the requirements of Section 601 of Title VI of the Rural Development Act of 1972, as amended (7 U.S.C. 2204b–1), Executive Order 13006 and Executive Order 12072, Executive agencies must first consider historic properties within historic districts when locating Federal facilities. If no such suitable historic property is available, Executive agencies must then consider other developed or undeveloped sites within historic districts. Finally, Executive agencies must consider suitable historic properties outside of historic districts, if no suitable site exists within a historic district.

§ 102–79.95 Automated external defibrillators. [Reserved]

PART 102–80—SAFETY AND ENVIRONMENTAL MANAGEMENT

Sec.
102–80.5 What is the scope of this part?
102–80.10 What are the basic safety and environmental management policies for real property?
102–80.15 What are Federal agencies' responsibilities concerning the assessment and management of asbestos?
102–80.20 What are Federal agencies' responsibilities concerning the abatement of radon?
102–80.25 What are Federal agencies' responsibilities concerning the management of indoor air quality?
102–80.30 What are Federal agencies' responsibilities concerning lead?
102–80.35 What are Federal agencies' responsibilities concerning the monitoring of hazardous materials and wastes?
102–80.40 What are Federal agencies' responsibilities concerning the management of underground storage tanks?
102–80.45 What are Federal agencies' responsibilities concerning fire prevention and fire protection engineering?
102–80.50 Are Federal agencies responsible for identifying/estimating risks and for appropriate reduction strategies?
102–80.55 Are Federal agencies responsible for performing facility assessments?
102–80.60 Are Federal agencies responsible for managing the execution of risk reduction projects?
102–80.65 What are Federal agencies' responsibilities concerning the investigation of incidents, such as fires, accidents, injuries, and environmental incidents?
102–80.70 Are Federal agencies responsible for informing their tenants of the condition and management of their facility safety and environment?
102–80.75 Who assesses environmental issues in Federal construction and lease construction projects?

Authority: 40 U.S.C. 486(c) and 490.

§ 102–80.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services. The responsibilities for safety and environmental management under this part are intended to apply to GSA or those Federal agencies operating in GSA space pursuant to a GSA delegation of authority.

§ 102–80.10 What are the basic safety and environmental management policies for real property?

The basic safety and environmental management policies for real property are that Federal agencies must:

(a) Provide for a safe and healthful work environment for Federal employees and the visiting public;

(b) Protect Federal real and personal property;

(c) Promote mission continuity;

(d) Provide reasonable safeguards for emergency forces if an incident occurs;

(e) Assess risk;

(f) Make decisionmakers aware of risks; and

(g) Act promptly and appropriately in response to risk.

§ 102–80.15 What are Federal agencies' responsibilities concerning the assessment and management of asbestos?

Federal agencies have the following responsibilities concerning the assessment and management of asbestos:

(a) Inspect and assess buildings for the presence and condition of asbestos-containing materials. Space to be leased must be free of all asbestos containing materials, except undamaged asbestos flooring in the space or undamaged boiler or pipe insulation outside the space, in which case an asbestos

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management program conforming to Environmental Protection Agency (EPA) guidance must be implemented;

(b) Manage in-place asbestos that is in good condition and not likely to be disturbed;

(c) Abate damaged asbestos, and asbestos likely to be disturbed. Federal agencies must perform a pre-alteration asbestos assessment for activities that may disturb asbestos;

(d) Not use asbestos in new construction, renovation/modernization or repair of their owned or leased space. Unless approved by GSA, Federal agencies must not obtain space with asbestos through purchase, exchange, transfer, or lease, except as identified in paragraph (a) of this section; and

(e) Communicate all written and oral asbestos information about the leased space to tenants.

§ 102–80.20 What are Federal agencies' responsibilities concerning the abatement of radon?

Federal agencies have the following responsibilities concerning the abatement of radon in space when radon levels exceed current EPA standards:

(a) Retest abated areas and make lessors retest, as required, abated areas to adhere to EPA standards; and

(b) Test non-public water sources (in remote areas for projects such as border stations) for radon according to EPA guidance. Radon levels that exceed current applicable EPA standards must be mitigated. Federal agencies must retest, as required, to adhere to EPA standards.

§ 102–80.25 What are Federal agencies' responsibilities concerning the management of indoor air quality?

Federal agencies must assess indoor air quality of buildings as part of their safety and environmental facility assessments. Federal agencies must respond to tenant complaints on air quality and take appropriate corrective action where air quality does not meet applicable standards.

§ 102–80.30 What are Federal agencies' responsibilities concerning lead?

Federal agencies have the following responsibilities concerning lead in buildings:

(a) Test space for lead-based paint in renovation projects that require sanding, welding or scraping painted surfaces.

(b) Not remove lead based paint from surfaces in good condition.

(c) Test all painted surfaces for lead in proposed or existing child care centers.

(d) Abate lead-based paint found in accordance with Department of Housing and Urban Development (HUD) Lead-Based Paint Guidelines, available by writing to HUD USER, P.O. Box 6091, Rockville, MD, 20850.

(e) Test potable water for lead in all drinking water outlets in child care centers.

(f) Take corrective action when lead levels exceed the HUD Guidelines.

§ 102–80.35 What are Federal agencies' responsibilities concerning the monitoring of hazardous materials and wastes?

Federal agencies' responsibilities concerning the monitoring of hazardous materials and wastes are to:

(a) Monitor the transport, use, and disposition of hazardous materials and waste in buildings to provide for compliance with GSA, Occupational Safety and Health Administration (OSHA), Department of Transportation, EPA, and applicable State and local requirements. In addition to those operating in GSA space pursuant to a delegation of authority, tenants in GSA space must comply with these requirements.

(b) In leased space, include in all agreements with the lessor requirements that hazardous materials kept in leased space are kept and maintained according to applicable Federal, State, and local environmental regulations.

§ 102–80.40 What are Federal agencies' responsibilities concerning the management of underground storage tanks?

Federal agencies have the following responsibilities concerning the management of underground storage tanks in real property:

(a) Register, manage and close underground storage tanks, including heating oil and fuel oil tanks, in accordance with GSA, EPA, and applicable State and local requirements.

(b) Require the party responsible for tanks they use but don't own to follow these requirements and to be responsible for the cost of compliance.

§ 102–80.45 What are Federal agencies' responsibilities concerning fire prevention and fire protection engineering?

Federal agencies must follow accepted fire prevention practices in operating and managing buildings. Federally-owned buildings are generally exempt from State and local code requirements in fire protection; however, in accordance with 40 U.S.C. 619, each building constructed or altered by a Federal agency must be constructed or altered, to the maximum extent feasible, in compliance with one of the nationally recognized model building codes and with other nationally recognized codes. Leased buildings are subject to local requirements and inspection. Federal agencies must use the National Fire Protection Association (NFPA) codes and standards (obtained by writing to NFPA, 11 Tracy Drive, Avon, MA 02322.) as a guide for their building operations.

§ 102–80.50 Are Federal agencies responsible for identifying/estimating risks and for appropriate reduction strategies?

Yes, Federal agencies must identify and estimate safety and environmental management risks and appropriate reduction strategies for buildings. Federal agencies occupying as well as operating buildings must identify any safety and environmental management risks and report or correct the situation, as appropriate.

§ 102–80.55 Are Federal agencies responsible for performing facility assessments?

Yes, Federal agencies must evaluate facilities to comply with GSA's safety and environmental program and applicable Federal, State and local environmental laws and regulations. Federal agencies should conduct these evaluations in accordance with schedules that are compatible with repair and alteration and leasing operations.

§ 102–80.60 Are Federal agencies responsible for managing the execution of risk reduction projects?

Yes, Federal agencies must manage the execution of risk reduction projects in buildings they operate. Federal agencies must identify and take appropriate action to eliminate hazards and regulatory noncompliance.

§ 102–80.65 What are Federal agencies' responsibilities concerning the investigation of incidents, such as fires, accidents, injuries, and environmental incidents?

Federal agencies have the following responsibilities concerning the investigation of incidents, such as fires, accidents, injuries, and environmental incidents in buildings they operate:

(a) Investigate all incidents regardless of severity.

(b) Form Boards of Investigation for incidents resulting in serious injury, death, or significant property losses.

§ 102–80.70 Are Federal agencies responsible for informing their tenants of the condition and management of their facility safety and environment?

Yes, Federal agencies must inform their tenants of the condition and management of their facility safety and environment. Agencies operating GSA buildings must report any significant facility safety or environmental concerns to GSA.

§ 102–80.75 Who assesses environmental issues in Federal construction and lease construction projects?

Federal agencies must assess required environmental issues throughout planning and project development, so that the environmental impacts of a project are considered during the decisionmaking process.

PART 102–81—SECURITY

Sec.

102–81.5 What is the scope of this part?
102–81.10 What basic security policy governs Federal agencies?
102–81.15 Who is responsible for upgrading and maintaining security standards in each Federally-owned facility?

Authority: 40 U.S.C. 318a, 486(c) and 490.

§ 102–81.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–81.10 What basic security policy governs Federal agencies?

Federal agencies on Federal property under the charge and control of the Administrator and having a security delegation of authority from the Administrator must provide for the security and protection of the real estate they occupy, including the protection of persons within the property.

§ 102–81.15 Who is responsible for upgrading and maintaining security standards in each Federally-owned facility?

In a June 28, 1995, Presidential Policy Memorandum for Executive Departments and Agencies, entitled, "Upgrading Security at Federal Facilities" (see the Weekly Compilation of Presidential Documents, vol. 31, p. 1148), the President directed that Executive agencies must, where feasible, upgrade and maintain security in facilities they own or lease under their own authority to the minimum standards specified in the Department of Justice's June 28, 1995 study entitled "Vulnerability Assessment of Federal Facilities." The study may be obtained by writing to the Superintendent of Documents, P. O. Box 371954, Pittsburgh, PA, 15250–7954.

PART 102–82—UTILITY SERVICES

Sec.

102–82.5 What is the scope of this part?
102–82.10 What basic utility services policy govern Executive agencies?
102–82.15 What utility services must Executive agencies provide?
102–82.20 What are Executive agencies' rate intervention responsibilities?
102–82.25 What are Executive agencies' responsibilities concerning the procurement of utility services?

Authority: 40 U.S.C. 481(a) and 486(c).

§ 102–82.5 What is the scope of this part?

The real property policies contained in this part apply to Federal agencies, including the GSA/Public Buildings Service (PBS), operating under, or subject to, the authorities of the Administrator of General Services.

§ 102–82.10 What basic utility services policy govern Executive agencies?

Executive agencies procuring, managing or supplying utility services under the Federal Property and Administrative Services Act of 1949 must provide or procure services that promote economy and efficiency with due regard to the mission responsibilities of the agencies concerned.

§ 102–82.15 What utility services must Executive agencies provide?

Executive agencies must negotiate with public utilities to procure utility services and, where appropriate, provide rate intervention services in proceedings (see § § 102–72.100 and 102-72.105 of this chapter) before Federal and State utility regulatory bodies.

§ 102–82.20 What are Executive agencies' rate intervention responsibilities?

Where the consumer interests of the Federal Government will be significantly affected and upon receiving a delegation of authority from GSA, Executive agencies must provide representation in proceedings involving utility services before Federal and State regulatory bodies. Specifically, these responsibilities include instituting formal or informal action before Federal and State regulatory bodies to contest the level, structure, or applicability of rates or service terms of utility suppliers. The Secretary of Defense is independently authorized to take such actions without a delegation from GSA when the Secretary determines such actions to be in the best interests of national security.

§ 102–82.25 What are Executive agencies' responsibilities concerning the procurement of utility services?

Executive agencies, operating under a utility services delegation from GSA, or the Secretary of Defense when the Secretary determines it to be in the best interests of national security, must provide for the procurement of utility services (such as commodities and utility rebate programs), as required, and must procure from sources of supply that are the most advantageous to the Federal Government in terms of economy, efficiency, reliability, or quality of service. Executive agencies, upon receiving a delegation of authority from GSA, may enter into contracts for utility services for periods not exceeding ten years (40 U.S.C. 481).

Dated: December 21, 2000.

Thurman M. Davis, Sr.,

Acting Administrator of General Services.

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Part XIII

Department of Housing and Urban Development

Regulatory Waiver Requests Granted for the Third Quarter of Calendar Year 2000; Notice

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4591–N–03]

Regulatory Waiver Requests Granted for the Third Quarter of Calendar Year 2000

AGENCY: Office of the Secretary, HUD.

ACTION: Public Notice of the Granting of Regulatory Waivers from July 1, 2000 through September 30, 2000.

SUMMARY: Section 106 of the Department of Housing and Urban Development Reform Act of 1989 (the "HUD Reform Act"), requires HUD to publish quarterly **Federal Register** notices of all regulatory waivers that HUD has approved. Each notice must cover the quarterly period since the most recent **Federal Register** notice. The purpose of this notice is to comply with the requirements of section 106 of the HUD Reform Act. This notice contains a list of regulatory waivers granted by HUD during the quarter beginning on July 1, 2000 and ending on September 30, 2000.

FOR FURTHER INFORMATION CONTACT: For general information about this notice, contact Camille E. Acevedo, Associate General Counsel for Legislation and Regulations, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3055 (this is not a toll-free number). Hearing or speech-impaired persons may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8391.

For information concerning a particular waiver action for which public notice is provided in this document, contact the person whose name and address follows the description of the waiver granted in the accompanying list of waiver-grant actions.

SUPPLEMENTARY INFORMATION: As part of the Housing and Urban Development Reform Act of 1989 (the "HUD Reform Act"), the Congress adopted, at HUD's request, legislation to limit and control the granting of regulatory waivers by HUD. Section 106 of the HUD Reform Act added a new section 7(q) to the Department of Housing and Urban Development Act (42 U.S.C. 3535(q)), which provides that:

1. Any waiver of a regulation must be in writing and must specify the grounds for approving the waiver;

2. Authority to approve a waiver of a regulation may be delegated by the Secretary only to an individual of Assistant Secretary rank or equivalent rank, and the person to whom authority to waive is delegated must also have authority to issue the particular regulation to be waived;

3. Not less than quarterly, the Secretary must notify the public of all waivers of regulations that HUD has approved, by publishing a notice in the **Federal Register**. These notices (each covering the period since the most recent previous notification) shall:

a. Identify the project, activity, or undertaking involved;

b. Describe the nature of the provision waived, and the designation of the provision;

c. Indicate the name and title of the person who granted the waiver request;

d. Describe briefly the grounds for approval of the request;

e. State how additional information about a particular waiver grant action may be obtained.

Section 106 of the HUD Reform Act also contains requirements applicable to waivers of HUD handbook provisions that are not relevant to the purpose of this notice. Today's document follows publication of HUD's Statement of Policy on Waiver of Regulations and Directives issued by HUD on April 22, 1991 (56 FR 16337). This notice covers HUD's waiver-grant activity from July 1, 2000 through September 30, 2000. Additionally, this notice contains one report of a regulatory waiver granted from March 1, 2000 through June 30, 2000 that was inadvertently omitted from the last notice. The report can be found in Section IV of this notice with respect to a waiver granted in connection with 24 CFR 950.980.

For ease of reference, the waivers granted by HUD are listed by HUD program office (for example, the Office of Community Planning and Development, the Office of Housing, the Office of Public and Indian Housing, etc.). Within each program office grouping, the waivers are listed sequentially by the section of title 24 being waived. For example, a waiver-grant action involving the waiver of a provision in 24 CFR part 58 would come before a waiver of a provision in 24 CFR part 570.

Where more than one regulatory provision is involved in the grant of a particular waiver request, the action is listed under the section number of the first regulatory requirement in title 24 that is being waived as part of the waiver-grant action. For example, a waiver of both § 58.73 and § 58.74 would appear sequentially in the listing under § 58.73.

Waiver-grant actions involving the same initial regulatory citation are in time sequence beginning with the earliest-dated waiver grant action.

Should HUD receive additional reports of waiver actions taken during the period covered by this report before the next report is published, the next updated report will include these earlier actions, as well as those that occurred between October 1, 2000 through December 31, 2000.

Accordingly, information about approved waiver requests pertaining to HUD regulations is provided in the Appendix that follows this notice.

Dated: January 10, 2001.

Andrew Cuomo,

Secretary.

Appendix—Listing of Waivers of Regulatory Requirements Granted by Offices of the Department of Housing and Urban Development July 1, 2000 Through September 30, 2000

Note to Reader: More information about the granting of these waivers, including a copy of the waiver request and approval, may be obtained by contacting the person whose name is listed as the contact person directly before each set of waivers granted.

The regulatory waivers granted appear in the following order:

I. Regulatory Waivers granted by the Office of Community Planning and Development.

II. Regulatory Waivers granted by the Office of Community Planning and Development and the Office of Public and Indian Housing.

III. Regulatory Waivers granted by the Office of Housing.

IV. Regulatory Waivers granted by the Office of Multifamily Housing Assistance Restructuring.

V. Regulatory Waivers granted by the Office of Public and Indian Housing.

I. Regulatory Waivers Granted by the Office of Community Planning and Development:

For further information about the following waiver actions, please see the name of the person which immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 58.34(b) and 24 CFR 58.38.

Project/Activity: Housing rehabilitation and housing acquisition projects, Ohkay Owingeh Housing Authority and the San Juan Pueblo Tribe, San Juan Pueblo, New Mexico.

Nature of Requirement: HUD's regulation at 24 CFR 58.34(b) states that a recipient does not have to submit a Request for Release of Funds and certification, and that no further approval from HUD will be needed to carry out exempt activities and projects, provided the responsible entity documents its determination that each activity or project is exempt.

Additionally, 24 CFR 58.38 requires the responsible entity to maintain a written record of the environmental review for each project. This document will be designated the Environmental Review Record, which shall contain all environmental review documents, public notices and written determinations or environmental findings required by part 58, decision making and actions pertaining to a particular project.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: July 28, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The Ohkay Owingeh Housing Authority made several errors during the environmental review and clearance process required by 24 CFR part 58 that resulted in the Housing Authority obligating and expending grant funds for the project before a determination by the San Juan Pueblo that the activities were exempt. HUD made a determination that there was no statutory or regulatory provision that would have prevented conversion of these activities to exempt. Therefore, this waiver was needed in order to permit the San Juan Pueblo to complete the environmental review process by documenting that the activities are exempt under 24 CFR part 58, after the obligation of HUD funds. HUD also determined that no environmental degradation resulted from the regulatory noncompliance and that no mitigation activities would be necessary since no environmental damage or potential problems were identified. Considering the above, HUD determined that a waiver of the regulatory requirements would maintain the integrity of HUD's environmental review process and was consistent with Executive Order 12084 that encourages flexibility in the consideration of waiver requests from tribal governments.

Contact: Bruce Knott, Director, Office of Grants Evaluation, National Office of Native American Programs (ONAP), Department of Housing and Urban Development, 1999 Broadway—Suite 3390, Denver, Colorado 80202, Telephone: (303) 675–1600.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The County of Essex, New Jersey requested a waiver of the submission deadline for the County's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 25, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The County requested the waiver because of difficulties resulting from medical emergencies experienced by the Acting Director and staff responsible for Consolidated Annual Performance Evaluation Report (CAPER) preparation.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Cumberland, Maryland requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 25, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver because the lead person responsible for completing the CAPER, as well as inputting data in IDIS, has been summoned for jury duty in Federal District Court for the next four months.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The State of Nebraska requested a waiver of the submission deadline for the State's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 31, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The State requested the waiver because of staff turnover and IDIS development delays that impacted the ability to comply with beneficiary reporting requirements.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The County of Los Angeles, California requested a waiver of the submission deadline for the County's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 13, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The County requested the waiver because of technical problems with the Community Development Commission's financial management system.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: Baltimore County, Maryland requested a waiver of the submission deadline for the County's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 13, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The County requested the waiver because of staff turnover and the need for additional time to allow new staff to become familiar with the CAPER submission process.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of San Angelo, Texas requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

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Date Granted: September 13, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver because of staffing problems due to the resignation of one staff member and need for surgery by another staff member.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Hamden, Connecticut requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 14, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver because the City is rebuilding records to eliminate inconsistencies in its 1998 CAPER. This effort has not allowed the staff to focus on preparing the current 1999 CAPER.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Nashua, New Hampshire requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver because of staff turnover and the delay in receiving audited financial figures necessary for reconciliation.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Portland, Oregon requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver as a result of recent staff turnover in the Portland Development Commission's CDBG staff. This did not provide sufficient time for the staff to review the CAPER reporting information and reconcile it with the City's records before the submission deadline.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Vancouver, Washington requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested the waiver due to delays caused by changes in key personnel and the need to reprogram funds and correct data in IDIS to ensure accurate information.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Norwalk, California requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time for preparing the CAPER due to resignation of staff and unfilled vacancies.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Moreno Valley, California requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because its newly installed financial management system caused delays in the availability of the City's final expenditure data for reconciliation with data in IDIS.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Tulare, California requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of the office's recent move to a new facility that included relocating and upgrading the computer mainframe, the network, and personal computers. This move delayed computer operations needed to produce accurate IDIS data for the CAPER.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Modesto, California requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to vacancies and changes in key staff positions that are responsible for preparing the CAPER.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Napa, California requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because staff resources were diverted to cope with the aftermath of a serious earthquake that damaged many city businesses and residences.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Elizabeth, New Jersey requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of the delay in submitting its Consolidated Plan and to ensure that the required public comment period for the CAPER will be satisfied.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Camden, New Jersey requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to staff shortages.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of East Orange, New Jersey requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of staff difficulties resulting from the downsizing of the Planning Department, which is responsible for the preparation of the CAPER.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of Stamford, Connecticut requested a wdiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of a staff turnover, which resulted in a delay in generating IDIS reports.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
sbull Regulation: 24 CFR 91.520.
Project/Activity: The City of New Britain, Connecticut requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of renovation of the City's Office of Municipal Development and the reorganization of its staff. Office files have been moved and displaced making it difficult for the staff to have efficient access to information on grantee activities.
Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.
• *Regulation:* 24 CFR 91.520.
Project/Activity: The City of New London, Connecticut requested a waiver of the submission deadline for the City's 1999 CAPER.
Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.
Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.
Date Granted: September 27, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of the loss of two key finance staff. The two individuals provided the critical information required to

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complete the reconciliation of programmatic and financial records.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Weirton, West Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Petersburg, Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because of staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Virginia Beach, Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Charlottesville, Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Bristol, Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Portsmouth, Virginia requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to recent staff turnover.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Philadelphia, Pennsylvania requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because the City's fiscal year closing adjustments will not be released in sufficient time to allow the office responsible for report preparation to obtain information needed to complete the CAPER before the deadline.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Scranton, Pennsylvania requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time due to computer system failure.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Dover, Delaware requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City requested additional time because the staff person directly responsible for preparing the CAPER has been on sick leave.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 91.520.

Project/Activity: The City of Baltimore, Maryland requested a waiver of the submission deadline for the City's 1999 CAPER.

Nature of Requirement: HUD's regulation at 24 CFR 91.520 requires each grantee to submit a performance report to HUD within 90 days after the close of the grantee's program year.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reasons Waived: HUD determined that there was good cause for the waiver. The City requested additional time because the accounting records are not released in sufficient time to allow the City to complete the CAPER.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 92.205.

Project/Activity: The Kentucky Housing Corporation requested a waiver of the provision to permit less than a $1,000 minimum HOME investment per unit.

Nature of Requirement: HUD's regulation at 24 CFR 92.205 requires that the minimum of HOME funds that may be invested in a project is an average of $1,000 per unit.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 7, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. KHC provided justification that less than $1,000 was needed to assist homebuyers. Without a waiver these recipients would be either disqualified from becoming homebuyers or they would be over-subsidized in order to receive the HOME assistance.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulations:* 24 CFR 92.205, 92.503(b)(2).

Project/Activity: The Kentucky Housing Corporation requested a waiver of provisions regarding termination of a project prior to completion and the subsequent repayment requirement.

Nature of Requirement: HUD's regulations at 24 CFR 92.205 and 92.503(b)(2) require that a HOME unit that is terminated before completion, either voluntarily or otherwise, constitutes an ineligible activity and any HOME funds invested must be repaid.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: July 20, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The homeowner died prior to completion of construction and no further work on the home was done.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 92.214(a)(8).

Project/Activity: The City of Taylorsville, Utah requested permission to use HOME funds for acquisition of a parcel of land located within its boundaries, but owned by Salt Lake County. The City plans to move an existing home on the subject site which will be sold to a low income family.

Nature of Requirement: HUD's regulation at 24 CFR 92.214(a)(8) prohibits grantees from using HOME funds to pay for the acquisition of property owned by the participating jurisdiction, except for property acquired by the PJ with HOME funds, or property acquired in anticipation of carrying out a HOME project.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 31, 2000.

Reason Waived: HUD determined that there was good cause for the waiver since the transaction would assist the City in its effort to provide an affordable unit for a low income family.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 92.251.

Project/Activity: North Dakota counties and Indian reservation communities requested a waiver of the HOME provision which requires HOME-assisted housing to meet the applicable codes, standards, and ordinances specified.

Nature of Requirement: HUD's regulation at 24 CFR 92.251 requires that housing that is constructed or rehabilitated with HOME funds must meet all applicable local codes, rehabilitation standards, ordinances, and zoning ordinances at the time of project completion.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 31, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The State of North Dakota requested this waiver in order to allow for the use of HOME funds for emergency repairs on damaged housing within the disaster area. Funding sources are inadequate to address the housing needs that exist within the disaster area. The State would like to use HOME funds to assist in addressing this need. HUD therefore determined that this provision creates undue hardship for the communities and families in need of disaster-related assistance.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh

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Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 570.200(h)(1).

Project/Activity: The City of Coral Springs, Florida requested a waiver to allow the City to use CDBG funds to reimburse administrative costs incurred for the planning and preparation of its first Consolidated Plan as a new Entitlement community.

Nature of Requirement: HUD's regulation at 24 CFR 570.200(h)(1) states that a grantee may only use CDBG funds to pay pre-award costs if, among other things, the activity for which the costs are being incurred is included in a Consolidated Plan or an amended Consolidated Plan prior to the costs being incurred.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: July 28, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City is a new Entitlement community. Failure to grant the waiver would result in undue hardship and affect the benefits to the low- and moderate-income population of the City. Further, the authorization for new grantees to pay for planning and administrative start-up costs with CDBG funds was inadvertently omitted during the November 1995 revision to the CDBG regulations.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 570.200(h)(1).

Project/Activity: The City of Deerfield Beach, Florida requested a waiver to allow the City to use CDBG funds to reimburse administrative costs incurred for the planning and preparation of its first Consolidated Plan as a new Entitlement community.

Nature of Requirement: HUD's regulation at 24 CFR 570.200(h)(1) states that a grantee may only use CDBG funds to pay pre-award costs if, among other things, the activity for which the costs are being incurred is included in a Consolidated Plan or an amended Consolidated Plan prior to the costs being incurred.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 27, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City is a new Entitlement community. Failure to grant the waiver would result in undue hardship and affect the benefits to the low- and moderate-income population of the City. Further, the authorization for new grantees to pay for planning and administrative start-up costs with CDBG funds was inadvertently omitted during the November 1995 revision to the CDBG regulations.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 576.21(b)(2).

Project/Activity: Hennepin County, Minnesota requested a waiver of the 30 percent limitation on essential services in its ESG program.

Nature of Requirement: HUD's regulation at 24 CFR 576.21(b)(2) implements the statutory requirement that no more than thirty percent of the Emergency Shelter Grant funds be expended for essential services. This regulatory section also notes that the statute (42 U.S.C. 11374) also permits waiver of this requirement if the grantee demonstrates that other eligible activities are already being carried out in the locality with other resources.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: July 10, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Hennepin County provided documentation to support its claim that alternative funding for rehabilitation, operating costs and other eligible activities is available. The waiver allows Hennepin County to spend up to 100 percent of its FY 1999 and FY 2000 grants on essential services.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 576.21(b)(2).

Project/Activity: The Municipality of Caguas, Puerto Rico requested a waiver of the 30 percent limitation on essential services in its ESG program.

Nature of Requirement: HUD's regulation at 24 CFR 576.21(b)(2) implements the statutory requirement that no more than thirty percent of the Emergency Shelter Grant funds be expended for essential services. This regulatory section also notes that the statute (42 U.S.C. 11374) also permits waiver of this requirement if the grantee demonstrates that other eligible activities are already being carried out in the locality with other resources.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 25, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Caguas provided documentation to HUD to support the Municipality's claim that it is meeting its demand for other activities through funding from the United Way, the Department of Health, and local funds.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 576.21(b)(2).

Project/Activity: Onondago County, New York requested a waiver of the 30 percent limitation on essential services in its ESG program.

Nature of Requirement: HUD's regulation at 24 CFR 576.21(b)(2) requires that no more than 30 percent of ESG grant funds be expended for essential services.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 31, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Onondaga County provided documentation to HUD to support its claim of that other present needs for the County's ESG funds exist. The County may spend up to 58.67 percent of its funds for essential services.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 576.35(b).

Project/Activity: The City of Minneapolis, Minnesota requested a waiver regarding the time frame for expenditure of its FY 1998 Emergency Shelter Grant (ESG) funds.

Nature of Requirement: HUD's regulation at 24 CFR 576.35(b) requires recipients to expend ESG funds within two years of HUD's award.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: July 28, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City experienced unexpected delays in several rehabilitation projects. Failure to grant the waiver would adversely affect the City's ability to serve the homeless. HUD extended the date for the City to expend its 1998 funds to on or about July 15, 2000.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 882.408(b).

Project/Activity: The Metro Dade, Florida Housing Agency requested a waiver of the limitation on the initial Gross Rent for a Single Room Occupancy (SRO) property. The proposed rent would exceed the current Moderate Rehabilitation SRO Fair Market Rent (FMR) by more than 10%.

Nature of Requirement: HUD's regulation at 24 CFR 882.408(b) allows a housing agency to approve initial gross rents which exceed the applicable FMR by up to 10 percent for all units of a given size in specified areas.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: September 5, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Higher rents were necessitated by development obstacles such as change in sites, change in owner/developer and delay in obtaining financial resources.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

• *Regulation:* 24 CFR 882.805(d)(1)(ii)(B).

Project/Activity: The San Francisco, California Housing Authority requested a waiver of the Single Room Occupancy (SRO) requirement on the maximum amount allowed per unit for rehabilitation.

Nature of Requirement: HUD's regulation at 24 CFR 882.805(d)(1)(ii)(B) allows an SRO recipient to multiply the maximum per unit rehabilitation amount by 2.4 in areas where the Housing Authority has demonstrated to HUD's satisfaction that the increase is reasonable to accommodate special local conditions, including high construction costs. In the case of San Francisco, this would allow a maximum rehabilitation costs of $42,840.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development.

Date Granted: August 30, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City documented the high cost of the project and the difficulty in finding and acquiring suitable properties for the SRO program. The City further stated that the property is almost 90 years old and needs extensive rehabilitation to meet current building and accessibility code standards. The final per unit rehabilitation cost for this project is projected to be $69,311, well above the maximum approvable cost.

Contact: Cornelia Robertson-Terry, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7152, Washington, DC 20410; telephone (202) 708–2565.

II. Regulatory Waivers Granted by the Office of Community Planning and Development and the Office of Public and Indian Housing

For further information about the following waiver actions, please see the name of the person which immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 50.3(h)(3) and 1000.20(a).

Project/Activity: Acquisition of 10 Operation Walking Shield housing units, Flandreau Santee Sioux Tribe and Flandreau Santee Sioux Housing Authority, Flandreau, South Dakota.

Nature of Requirement: HUD's regulation at § 50.3(h) requires that for HUD grant programs in which funding approval for an applicant's program must occur before the applicant's selection of properties an applicant must agree to not acquire, rehabilitate, convert, lease, repair or construct property, nor commit or expend HUD or local funds until HUD approval of the property is obtained. HUD's regulation at § 1000.20(a) requires an environmental review be completed for any Native American Housing Assistance and Self-Determination Act project not excluded from review before a recipient may acquire, rehabilitate, convert, lease, repair or construct property, or commit HUD or local funds.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development and Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: July 31, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The Flandreau Santee Sioux Housing Authority used NAHASDA funds to acquire, rehabilitate and lease the subject Walking Shield units before receiving HUD approval of the property as required by 24 CFR 50.3(h)(3) and before HUD completed an environmental review. HUD has since completed the environmental review for the project. In order to satisfactorily resolve the issue, waivers of the provisions of 24 CFR 50.3(h)(3) and 1000.20(a) are necessary. HUD also determined that no environmental degradation resulted from the regulatory noncompliance and that no mitigation activities would be necessary since no environmental damage or potential problems were identified. Considering the above, HUD determined that a waiver of the regulatory requirements would maintain the integrity of HUD's environmental review process and was consistent with Executive Order 12084 that encourages flexibility in the consideration of waiver requests from tribal governments.

Contact: Bruce Knott, Director, Office of Grants Evaluation, National Office of Native American Programs (ONAP), Department of Housing and Urban Development, 1999 Broadway—Suite 3390, Denver, Colorado 80202, Telephone: (303) 675–1600.

sbull Regulation: 24 CFR 50.17 and 1000.20(a).

Project/Activity: Construction of 15 housing units with residual 1937 Housing Act funds under the Native American Housing Assistance and Self-Determination Act (NAHASDA), Upper Sioux Tribe, Granite Falls, Minnesota.

Nature of Requirement: HUD's regulation at § 50.17 requires that an environmental assessment and finding of no significant impact or an environmental impact statement be completed before the applicable decision points for projects not exempt or categorically excluded from environmental review requirements. HUD's regulation at § 1000.20(a) requires that an environmental review be completed for any NAHASDA project not excluded from review before a recipient may acquire, rehabilitate, convert, lease, repair or construct property, or commit HUD or local funds.

Granted By: Cardell Cooper, Assistant Secretary for Community Planning and Development and Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: Granted by Mr. Cooper on July 27, 2000 and by Mr. Lucas on July 28, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The Upper Sioux Tribe made several errors during the environmental review and clearance process required by 24 CFR part 58 that resulted in the tribe obligating and expending grant funds for the project before HUD's approval of the Request for Release of Funds and Certification, form HUD 7015.15. HUD made a determination based upon these actions to conduct an environmental review according to 24 CFR part 50. A HUD environmental review at this point would be after the execution of the Indian Housing Block Grant Agreement for this project. Therefore, a waiver is

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necessary to allow HUD to conduct the review and resolve the issue. HUD also determined that no environmental degradation resulted from the regulatory noncompliance and that no mitigation activities would be necessary since no environmental damage or potential problems were identified. Considering the above, HUD determined that a waiver of the regulatory requirements would maintain the integrity of HUD's environmental review process and was consistent with Executive Order 12084 that encourages flexibility in the consideration of waiver requests from tribal governments.

Contact: Bruce Knott, Director, Office of Grants Evaluation, National Office of Native American Programs (ONAP), Department of Housing and Urban Development, 1999 Broadway—Suite 3390, Denver, Colorado 80202, Telephone: (303) 675–1600.

III. Regulatory Waivers Granted by the Office of Housing

For further information about the following waiver actions, please see the name of the person which immediately follows the description of the waiver granted.

• *Regulation:* 24 CFR 202.3(c)(2)(iii).
Project/Activity: Credit Watch/ Termination Threshold.
Nature Of Requirement: HUD's regulation at 24 CFR 202.3(c)(2)(iii) establishes a default and claim rate threshold for HUD/FHA approved mortgagees on credit watch status.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner
Date Granted: August 21, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. Waiving the regulation permits HUD/ FHA to initially focus on those lenders originating the worst performing loans. The waiver will adjust the Credit Watch threshold from being between 150% and 200.9% of the HUD field office default and claim rate to being between 200% and 300.9% of that rate. This waiver is limited to Credit Watch reviews conducted in the third quarter of FY 2000.
Contact: Joy Hadley, Director, Quality Assurance Division, Department of Housing and Urban Development, 451 Seventh Street SW., Room B133–P3214, Washington, DC 20410, telephone (202) 708–2830.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Lakeview Senior Apartments, Carmel, New York, Project Number: 012–EE245/NY36–S981–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 4, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The owner had received a $65,000 grant from the Federal Housing Finance Board, the project was comparable in cost to similar projects, and the sponsor could not contribute any additional funds.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Centerplace III, New Albany, Indiana, Project Number: 073–HD048/IN36–Q981–002.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 8, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The development costs were comparable to other similar projects recently developed in Indiana and the project was of modest design.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Castleton Homes, Lanham, Maryland, Project Number: 000–HD041/MD39–Q981–003.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 11, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project required replacement of the HVAC systems in all three houses which had significantly increased costs.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Bishop Daly Gardens, Uniondale, New York, Project Number: 012–EE249/NY36–S981–005.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 16, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was economically designed and comparable in cost to similar projects, and the sponsor could not contribute any additional funds.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Turlock Silvercrest, Turlock, California, Project Number: 121–EE112/CA39–S981–005.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 21, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The contractor could not build the project within the fund reservation amount.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: VOA Riverside 10, Fort Worth, Texas, Project Number: 113–HD015/TX1–Q971–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 21, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was modestly designed and comparable to similar projects in the area, and the sponsor had exhausted all means of obtaining additional funds for the is project.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Saint Paul the Apostle Senior Housing, Corona, New York, Project Number: 012–EE254/ NY36–S981–010.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 21, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was modest in design, comparable to similar projects in the area, and the sponsor had made every attempt to secure additional funding from outside sources.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Cambridge Apartments, Rutledge, Tennessee, Project Number: 087–EE036/TN37–S981–004.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 22, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The owner had contributed the required minimum capital investment and purchased the site, the project was comparable in cost to similar projects, and the sponsor could not contribute any additional funds.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: St. Peter's Place II, Phoenixville, Pennsylvania, Project Number: 034–EE070/PA26–S971–002.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 25, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was modest in design, comparable to similar projects in the area and the owner had secured $230,000 from the Federal Home Loan Bank Board and $100,000 from the Chester County Office of Housing and Community Development.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulation:* 24 CFR 891.100(d).
Project/Activity: Homes With Hope, Westport, Connecticut, Project Number: 017–HD015/CT26–Q961–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: September 26, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was modest in design, comparable to similar projects in the area and the sponsor/owner had exhausted attempts in obtaining funds from other sources.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulations:* 24 CFR 891.100(d)and 891.165.
Project/Activity: Alice Williams Towers II, Atlanta, Georgia, Project Number: 061–EE065/GA06–S971–009.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 4, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was delayed to allow the sponsor and contractor time to prepare a new construction cost estimate and to obtain zoning approval. The project was also modest in design, comparable to similar projects developed in the area, the sponsor/owner had made every attempt to secure additional funding from outside sources, and the sponsor/ owner had exhausted their resources.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulations:* 24 CFR 891.100(d) and 891.165.
Project/Activity: HIS/Elois McCoy Village Apartments, Chicago, Illinois, Project Number: 071–EE115/IL06–S961–006.
Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 11, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The contractor increased his prices and the sponsor had exhausted all efforts to find additional funds from other sources. Additional time was needed to reprocess the firm commitment due to

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the increase in construction costs and to initially endorse the project.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulations:* 24 CFR 891.100(d) and 891.165.

Project/Activity: Selfhelp/United Help Kissena Apartments, Flushing, New York, Project Number: 012–EE224/NY36–S971–011.

Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 11, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The project encountered delays in securing zoning approvals, the project was economically designed, comparable to similar projects developed in the area, and the sponsor/owner had exhausted their resources.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone:(202) 708–3000.

• *Regulations:* 24 CFR 891.100(d) and 891.165.

Project/Activity: ASI-Missoula, Missoula, Montana, Project Number: 93–HD013/MY99–Q961–001.

Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted Ey: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 21, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The owner encountered delays due to the loss of two sites for the project and the death of the specialist who had been working very diligently on the project. The project was economically designed, comparable to other similar projects developed in the jurisdiction, and the owner had exhausted all possible efforts to obtain additional funds.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulations:* 24 CFR 891.100(d) and 891.165.

Project/Activity: Pomperaug Senior Housing, Southbury Twp., Connecticut, Project Number: 017–EE040/CT26–S971–008.

Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: September 26, 2000.

Reason Waived: HUD determined that there was good cause for the waivers. Delays were due to the owner obtaining design approval from the town of Southbury Planning and Zoning Commission. In addition, the project was modest in design, comparable to similar projects developed in the area, and the owner had made every attempt to secure additional funding from other sources.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulations:* 24 CFR 891.100(d) and 891.165.

Project/Activity: Cold Spring House, Forstburgh, New York, Project Number: 012–HD075/NY36–Q971–004.

Nature Of Requirement: HUD's regulation at 24 CFR 891.100(d) prohibits amendment of the capital advance fund reservation prior to initial closing. HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: September 26, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The owner was unable to obtain additional funds, and the project would receive complete property tax exemption from the locality as well as support service funding from the state. Additionally, a delay of over one year was encountered due to issues associated with the incorporation of the owner.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.105 and 891.410(c).

Project Activity: Sugarloaf Village, Diamond City, Arkansas, Project Number 082–EE091.

Nature of Requirement: HUD regulations at 24 CFR Part 891 require that occupancy be limited to Very Low Income (VLI) elderly persons (*i.e.*, households composed of one or more persons at least one of whom is 62 years of age at time of initial occupancy).

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: September 12, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The Little Rock Multifamily Program Center requested an age and income waiver for this Section 202/PRAC project. The project is only 4.3 percent occupied after 11 months of occupancy and is unable to attract sufficient elderly tenants because of insufficient local demand. These waivers will allow project management flexibility in attempting to rent up vacant units, thereby maintaining project viability and preventing foreclosure of the project. The waivers will allow elderly and near-elderly families and individuals who are at or over the age of 55 and low income to apply for admission to the project in addition to very low elderly families who will continue to receive an admissions preference.

Contact: Frank M. Malone, Director, Office of Asset Management, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410; telephone (202) 708–3730.

• *Regulation:* 24 CFR 891.120(b), 891.310(b)(1) and (b)(2).

Project/Activity: Options Supported Housing Project V, Scattered Site: Huntington, Huntington Sta., Centereach and Selden, New York, Project Number: 012–HD085/NY36–Q981–006.

Nature Of Requirement: HUD's regulations at 24 CFR 891.120(b), 891.310(b)(1) and (b)(2) govern accessibility standards for the Section 811 program.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 11, 2000.

Reason Waived: HUD determined there was good cause for the waiver. The project consisted of acquisition with rehabilitation of four group homes for persons with chronic mental illness. One of the sites was designed to be accessible for persons with mobility impairments. To make all units fully accessible for persons with mobility impairments would make the project, as a whole, financially unfeasible. The consumers served under the sponsor's existing programs did not generally require accessible housing, therefore accessibility of the one site was more than adequate for potential residents.

Contact: Willie Spearmon, Director, Office Of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–7000, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Abraham Lincoln Center, Chicago, Illinois, Project Number: 071–HD095/IL06–Q961–010.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: July 13, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The City had required the sponsor to obtain the approval of each alderman and the alderman had, in turn, required the approval of each of the communities involved.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Eaton Knolls, Town of Islip, New York, Project Number: 012–HD076/NY36–Q971–005.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: July 25, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Problems were discovered with the title policy which have subsequently been resolved to the satisfaction of all parties.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Accessible Space, Inc., Birmingham, Alabama, Project Number: 062–HD041/AL09–Q981–004.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 3, 2000.

Reason Waived: HUD determined that there was good cause to grant this waiver. The project had been delayed due to neighborhood opposition.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Ryder Assisted Care II, Humacao, Puerto Rico, Project Number: 065–HD010/RQ46–Q961–003.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 3, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Time delays were directly attributable to third parties since required local government endorsements took more than a year to be approved.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: St. Anthony Homes, Baltimore, Maryland, Project Number: 052–HD029/MD06–Q971–003.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 4, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Additional time was needed to prepare and submit the initial closing package.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Moorestown Consumer Home, Philadelphia, Pennsylvania, Project Number: 035–HD038/NJ39–Q971–077.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Granted: August 10, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The sponsor could not secure control of the site identified, had to secure bridge financing. Additionally, HUD required the sponsor to hire an architect due to the nature and amount of work involved.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.

• *Regulation:* 24 CFR 891.165.

Project/Activity: Royale Gardens, Chicago, Illinois, Project Number: 071–EE125/IL06–S961–016.

Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.

Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

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Date Granted: August 11, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project had been delayed due to the City of Chicago imposing new requirements regarding detailed breakdowns for landscaping costs.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Hogar Aurora, Aibonito, Puerto Rico, Project Number: 056–HD015/RQ46–Q971–002.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 11, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The delay in initial closing was directly attributable to the high cost of construction on the island and the lack of an available contractor to develop the project within the cost limits.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Three Bridges, Philadelphia, Pennsylvania, Project Number: 031–EE042/NJ39–S961–008.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 16, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was pending a judicial decision concerning settlement of a dispute regarding site control.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: ARC Housing, Wauwatosa, Wisconsin, Project Number: 075–HD053/WI39–Q971–004.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 16, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The sponsor needed additional time to work out the completion and submission of the closing documents. Additionally, the sponsor experienced problems with lead based paint removal, underground storage tanks, an elevator and relocation.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Absecon Consumer Home, Philadelphia, Pennsylvania, Project Number: 031–HD084/NJ39–Q971–009.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 16, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The sponsor had to locate a new site for the project and this was the sponsor's first experience with modular units (which it was using to replace the existing facility on the site and hoped to replicate in the future).
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Ft. Washington Adventist Apartments—New Life Homes, Albuquerque, New Mexico, Project Number: 116–HD015/NM16–Q001–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 30, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project had been delayed due to zoning issues and the need for local government approval of its water/sewer classification.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Ray Rawson Villa, Las Vegas, Nevada, Project Number: 125–HD064/NV25–Q971–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 30, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project experienced delays while the sponsor raised funds to meet the increased construction costs.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Timothy Place, Plum Borough, Allegheny County, Pennsylvania, Project Number: 033–HD048/PA28–Q971–010.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: August 30, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The first two approved sites were abandoned due to the sponsor's inability to secure additional sewer taps through the Department of Environmental Protection and to obtain a zoning variance from the local government.

Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Sumac Trail Apartments, Milwaukee, Wisconsin, Project Number: 075–HD050/WI39–Q971–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: September 8, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. Additional time was needed by the sponsor to correct deficiencies to their firm commitment application.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: New Opportunities For Waterbury, Waterbury, Connecticut, Project Number: 017–HD008.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary For Housing-Federal Housing Commissioner.
Date Granted: September 12, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. Additional time was needed by the sponsor to secure control of two of the four sites.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.165.
Project/Activity: Nashville Supportive Housing Development, Nashville, Tennessee, Project Number: 086–HD016/TN43–Q971–001.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary For Housing-Federal Housing Commissioner.
Date Granted: September 25, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The sponsor was unable to secure proper zoning on the original site and had to locate an alternate site.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.525.
Project/Activity: Brooklyn Home for Aged People, New York, New York, Project Number: 012–EH059/NY36–T781–032.
Nature Of Requirement: HUD's regulation at 24 CFR 891.165 provides that the duration of a capital advance fund reservation is 18 months from the date of issuance with limited exceptions up to 24 months as approved by HUD on a case-by-case basis.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: September 8, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The project was beset with problems, including the fact that the contractor took the project to arbitration over the slow rate of progress. The project was scheduled for completion on or before June 1984. In order to complete construction, the original mortgage was increased and the borrower arranged in 1988 for a second general contractor to complete construction. In an attempt to avoid any liability, the borrower filed for bankruptcy in 1989. The bankruptcy agreement stipulated that the supplemental loan be at 0 percent interest and this agreement was binding.
Contact: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone: (202) 708–3000.
• *Regulation:* 24 CFR 891.575 and 891.610(c).
Project/Activity: Northview Apartments, Okemah, Oklahoma, Project Number 117–EH089.
Nature of Requirement: HUD's regulations at 24 CFR part 891 limit occupancy to very low income (VLI) elderly households where or one or more persons is at least 62 years of age at the time of initial occupancy.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: July 20, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The Kansas City multifamily HUB requested waiver of this regulation due to the limited market of elderly individuals and families. This project is located in a small rural community and has historically been unable to attract elderly families to fill vacancies. This waiver will expand the number of eligible households who can be admitted to the property allowing the owner additional, necessary flexibility in renting up units.
Contact: Frank M. Malone, Director, Office of Asset Management, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410; telephone: (202) 708–3730.
• *Regulations:* 24 CFR 891.575 and 891.610(c).
Project/Activity: IOOF Tower, Salt Lake City, Utah, Project No: 105–EH050.
Nature of Requirement: HUD's regulations at 24 CFR part 891 limit occupancy to very low income households composed of two or more persons at least one of whom is 62 years of age or older at the time of initial occupancy.
Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.
Date Granted: September 12, 2000.
Reason Waived: HUD determined that there was good cause for the waiver. The Denver multifamily HUB requested an age waiver because the project had been unable to sustain occupancy due to the somewhat depressed surrounding neighborhood and declining demand for very low income elderly housing. The waiver allowed property management to rent up vacant units.
Contact: Frank M. Malone, Director, Office of Asset Management, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410; telephone: (202) 708–3730.
• *Regulation:* 24 CFR 891.575 and 610(c).
Project/Activity: Calvary Tower, Salt Lake City, Utah, Project Number: 105–EH048.
Nature Of Requirement: HUD's regulations at 24 CFR part 891 limit occupancy to very low income households composed of two or more persons at least one of whom is 62 years of age or older at the time of initial occupancy.

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Granted By: William C. Apgar, Assistant Secretary for Housing-Federal Housing Commissioner.

Date Waived: September 20, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The Denver Multifamily Hub requested an age waiver for the project due to the soft market for elderly properties in the Salt Lake City area. The surrounding neighborhood of Calvary Tower is somewhat depressed which also contributes to vacancy problems. Even though the property is currently full, any long term vacancies would pose a financial strain on this property and there is only one applicant on the waiting list. Lowering the age requirement from 62 to 55 and older will allow project management flexibility in attempting to alleviate vacancy problems.

Contact: Frank M. Malone, Director, Office of Asset Management, Department of Housing and Urban Development, 451 Seventh Street SW., Room 6160, Washington, DC 20410; telephone: (202) 708–3730.

IV. Regulatory Waivers Granted by the Office of Multifamily Housing Assistance Restructuring (OHMAR)

For further information about the following waiver actions, please see the name of the person which immediately follows the description of the waiver granted.

- *Regulation:* 24 CFR 401.600.

Project/Activity: The following projects requested waivers to the 12-month limit at above-market rents (24 CFR 401.600):

FHA No.	Project name	State
06235027	Alexander Court	AL
06235337	Monroe Avenue	AL
08235040	Harmony Homes Apartments	AR
08235018	North Acres Apartments	AR
01711020	New Era Court	CT
01735106	Old Middletown High School	CT
06635031	Central Area Apts.	FL
06335044	Pana Villa Gardens	FL
17135076	Johnson Manor	ID
07335270	Retired Tigers	IN
09244036	Torre de San Miguel	MN
11655006	Clovis II	NM
11635097	Four Seasons	NM
11644046	King Arthur's Court Apts.	NM
11644047	Tradewinds Carriage Apts.	NM
01435022	Lincoln Arms	NY
04644069	Albright	OH
04635027	Danner Park Apts.	OH
04335090	Fairview II	OH
04335125	Urbana Hollow	OH
11744077	Paradise Corners	OK
03435014	Beckett Gardens	PA
03344180	Bethesda Wilkinsburg	PA
03455033	Crosby	PA
03335006	Harriet Tubman Terrace	PA
03344157	Jeannette Gardens	PA
03355008	Liberty Park Apts.	PA
03344040	Palisades Manor	PA
03344119	Parkview Manor Apts.	PA
01644066	1890 House	RI
01635010	Roger & Roger	RI
05435075	St. Stephens Apts.	SC
08744033	Jaycee Progress, Inc.	TN
08744033	Jaycee Progress, Inc.	TN
08635039	Pulaski Terrace Apts. I	TN
11344036	Abilene North Apts.	TX
05935009	Belaire Manor	TX
11435063	Cleme Manor	TX
11335005	Prince Hall Garden II	TX
11435017	Prince Hall Plaza	TX
11435005	Prince Hall Village	TX
11435077	Rolland Hilliard	TX
11435046	Settegast	TX
13344034	Woodcrest Apartments	TX
05135040	Caru	VA
05135117	Caru East	VA
05135111	Dorchester Square	VA
05135034	Kings Court	VA
12735237	Burien Haus	WA
12735144	Omak Stampede	WA
17144040	Pine Villa	WA
07535078	Goodman Homes	WI
07535071	Oakwood Haven Vine Court Apts.	WI
07535077	Oakwood Haven Vine Court Apts.	WI
07535078	Pioneer Villa Goodman Homes	WI
07535076	Pioneer Villa Goodman Homes	WI
07535077	Vine Court Apts.	WI

FHA No.	Project name	State
10935035	Westgate Apartments	WY

Nature of Requirement: HUD's regulation at 24 CFR 401.600 requires that projects be marked down to market rents within 12 months of their first expiration date after January 1, 1998. The intent of this provision is to ensure timely processing of requests for restructuring, and that the properties will not default on their FHA insured mortgages during the restructuring process.

Granted By: Ira Peppercorn, Director of OMHAR.

Date Granted: July 11, 2000.

Reasons Waived: HUD determined that there was good cause for the waivers. The attached list of projects were not assigned to the PAEs in a timely manner or for which the restructuring analysis was unavoidably delayed due to no fault of the owner.

Contact: Dan Sullivan, Office of Multifamily Housing Assistance Restructuring, Department of Housing and Urban Development, Portals Building, Suite 400, 1280 Maryland Avenue SW., Washington, DC 20410; telephone (202) 708–0001.

- *Regulation:* 24 CFR 401.600.

Project/Activity: The following projects requested waivers to the 12-month limit at above-market rents (24 CFR 401.600):

FHA No.	Project name	State
06235045	Spring Creek	AL
08235039	Chicot Limited Partnership	AR
08235036	Haygood Neal Garden Apartments	AR
08235049	Pilgrim Rest Limited Partnership	AR
08235019	Smith Keys Village	AR
08244015	Village Park South I	AR
08244042	Village Park South II	AR
06735015	Shull Manor	FL
06344041	Sutton Place	FL
06344041	Sutton Place	FL
06344041	Sutton Place	FL
06344041	Sutton Place	FL
06735016	Tropical Manor	FL
06135006	Bethel Church Homes	GA
07435068	Benton Place	IA
07135341	Doyle family	IL
08335241	Lebanon Apts.	KY
08335251	Robinwood Park	KY
08335239	Sandefur Manor	KY
02355123	Park Gardens	MA
02344152	Rap-Up II B	MA
02238003	Dominican Court	ME
09235359	Falls South Apartments	MN
06535004	Canton Garden Apartments	MS
06535027	Eastview Apartments	MS
06535244	Hilldale Apartments	MS
06535159	Martin Luther King Memorial Apts.	MS
06535242	Oakdale Apartments	MS
09335068	Sherwood Inn	MT
01335060	Country Club Court	NY
01335048	Robinson Square	NY
01257044	Sumet I	NY
01335056	Summit Towers	NY
01332002	Woodburn Court	NY
11794009	Country Park	OK
11844025	Riverview Village	OK
05435037	Mt. Zion I	SC
05444005	Mt. Zion II	SC
11444026	Cedarwood Apartments	TX
10935028	Ranger Apartments	WY
10935040	Trails Apartments	WY

Nature of Requirement: HUD's regulation at 24 CFR 401.600 requires that projects be marked down to market rents within 12 months of their first expiration date after January 1, 1998. The intent of this provision is to ensure timely processing of requests for restructuring, and that the properties will not default on their FHA insured mortgages during the restructuring process.

Granted By: Ira Peppercorn, Director of OMHAR.

Date Granted: August 2, 2000.

Reason Waived: HUD determined that there was good cause for the waivers. The attached list of projects were not assigned to the PAEs in a timely manner and for which the restructuring analysis was unavoidably delayed due to no fault of the owner.

Contact: Dan Sullivan, Office of Multifamily Housing Assistance Restructuring, Department of Housing and Urban Development, Portals Building, Suite 400, 1280 Maryland

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Avenue SW., Washington, DC 20410; telephone (202) 708–0001.
• *Regulation:* 24 CFR 401.600.

Project/Activity: The following projects requested waivers to the 12-month limit at above-market rents (24 CFR 401.600):

FHA No.	Project name	State
00035113	Benning Courts	DC
06344037	Forest Green	FL
06692002	Harlem Gardens	FL
06335042	Hastings Apartments	FL
06335034	Marion Manor	FL
06344051	Springfield Res I	FL
07444052	Green Valley Manor	IA
07235053	Cougill Apts	IL
08335253	Regency Park-Louisville	KY
06535048	Northland Village Apartments	MS
09355004	Hillview Apartments	MT
03535026	Delsea Gardens	NJ
11692502	Hobbs Apts.	NM
11692506	Quay Apts.	NM
01355007	Eljay Apartments	NY
01444028	Fight Village	NY
01344008	Syracuse Apts.	NY
01344072	Syracuse Rehab V	NY
01444035	Whitney Neighborhood	NY
04335138	Discovery 76	OH
11735129	Arbuckle Ridge	OK
11735130	Arbuckle Ridge	OK
11835060	Autumn Wood Apartments	OK
11744006	London Square	OK
11744077	Paradise Corners	OK
11744106	Southgate	OK
11835093	Willow Gardens	OK
11838006	Willow Rock Apartments	OK
03344098	First Erie Better Housing West	PA
03444815	Geneva House	PA
03435130	Hampton House	PA
03344044	Monview Heights	PA
03335081	Penn Towers	PA
03335004	Punxsutawney Sycamore	PA
03444049	Wayneview Apartments	PA
08192503	Crestview Manor	TN
08192502	Parkway East I	TN
08135023	Parkway East II	TN
08135047	Ridgley Manor	TN
08135051	Somerville Apts.	TN
08135069	Southside Manor	TN
08135014	Tulane I Apts.	TN
11344036	Abilene North Apts.	TX
11435225	Beverly Place	TX
11235257	Lake June Village	TX
11535021	Lulac Village Park	TX
11335004	Prince Hall Garden I	TX
08244031	Town North Apartments	TX
08244031	Town North Apartments	TX
11544037	Villa Madre	TX
05155001	Brightwood Apts.	VA
17135178	Court Arthur	WA
17144046	Parkview Apartments	WA
07535291	Fordem Towers	WI
07535168	Pine Creek I Apartments	WI
07535117	Woodridge Gardens	WI
04535006	Rivermont Homes	WV

Nature of Requirement: HUD's regulation at 24 CFR 401.600 requires that projects be marked down to market rents within 12 months of their first expiration date after January 1, 1998. The intent of this provision is to ensure timely processing of requests for restructuring, and that the properties will not default on their FHA insured mortgages during the restructuring process.

Granted By: Ira Peppercorn, Director of OMHAR.

Date Granted: August 16, 2000.

Reason Waived: HUD determined that there was good cause for the waivers. The attached list of projects were not assigned to the PAEs in a timely manner or for which the restructuring analysis was unavoidably delayed due to no fault of the owner.

Contact: Dan Sullivan, Office of Multifamily Housing Assistance Restructuring, Department of Housing and Urban Development, Portals Building, Suite 400, 1280 Maryland

Avenue SW., Washington, DC 20410; telephone (202) 708–0001.
• *Regulation:* 24 CFR 401.600.

Project/Activity: The following projects requested waivers to the 12-month limit at above-market rents (24 CFR 401.600):

FHA No.	Project name	State
06292002	Stonegate Village	AL
10135207	Arvada House	CO
00044142	Brookland Manor Apartments	DC
00044142	Brookland Manor Apartments	DC
00035110	Fairmont I Apartments	DC
00055068	W Street Apartments	DC
03235003	Banneker Heights	DE
06735048	Central Court Apartments	FL
06335030	Eastside Garden Apartments	FL
06335031	Eastside Terrace Apartments	FL
06335101	Oakdale Garden Apartments	FL
06735035	Seminole Garden Apartments	FL
06344051	Springfield Residential One	FL
06344051	Springfield Residential One	FL
06192505	Etheridge Court Apartments I	GA
14035074	Hausten Gardens	HI
07435130	Autumn Park Apartments	IA
12435028	Pocatello Properties	ID
07135339	Countryside Manor	IL
07135369	Pullman Wheelworks	IL
07344455	Weyerbacher Terrace Apartments	IN
07344455	Weyerbacher Terrace Apartments	IN
02344152	Rap-Up II B	MA
09235299	Park Place Apartments	MN
09335007	Big Sky Apartments	MT
09335074	Grande Villa Apartments	MT
03135185	Baldwin Oaks Apartments	NJ
11635015	Santa Rosa Apartments	NM
11635056	Villa Del Sol Apts	NM
01235193	Belmont Apartments	NY
01257029	Parkview Apartments	NY
01255173	Siloam House	NY
01235306	St. Joseph's Village	NY
01255012	Towne Gardens Housing Development	NY
04335204	Cambridge Village	OH
04335173	Knollwood Commons	OH
04335197	Liberty Commons	OH
04335153	Momentum 75	OH
04635388	Parkview Arms II	OH
04335100	Rehab Unlimited	OH
04335107	Townhomes Properties, Ltd No. 1	OH
04335084	U.S. #51 Apartments	OH
11735013	Country Cove Housing	OK
11744115	Hillcrest Green Apartments	OK
11744077	Paradise Corner Apartments	OK
11835084	Willow Creek Apartments	OK
11835084	Willow Creek Apartments	OK
11835080	Willow Park Apartments	OK
03344045	Bedcliff Apartments	PA
03344071	Bethorne	PA
03344108	Colver Hotel Apartments	PA
03444808	Enon Toland Apartments	PA
03442029	Hedgerow Apartments	PA
03438017	Lincoln Towers	PA
03344050	Oliver Plaza Apartments	PA
03310002	Palisades Plaza	PA
01658501	Develco Apartments	RI
01644032	Develco Family Apartments	RI
08192504	Tulane II Apartments	TN
08135035	Warren Apartments	TN
11344036	Abilene North Apartments	TX
11435225	Beverly Place Apts	TX
11444026	Cedarwood Apartments	TX
11435023	Independent Missionary Village Apartments	TX
11535024	North Side Manor Apartments	TX
11492501	Oakhill Plaza Apartments	TX
11235070	Park Manor Apartments	TX
11235014	Prince Hall Chambre Apartments	TX
11235029	St. James Manor Apartments	TX
11344001	Villa Supreme Apartments	TX

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FHA No.	Project name	State
11344001	Villa Supreme Apartments	TX
13344034	Woodcrest Apartments	TX
17144086	Hillcrest Apartments	WA
17144046	Parkview Apartments	WA
17144022	Richard Allen Apartments	WA
07535072	Coleman Manor	WI
07535024	Fairfield Homes	WI
07535240	Housing Facilities of Monticello	WI
07535073	Laona Manor	WI
07535081	Lena Plaza	WI

Nature of Requirement: HUD's regulation at 24 CFR 401.600 requires that projects be marked down to market rents within 12 months of their first expiration date after January 1, 1998. The intent of this provision is to ensure timely processing of requests for restructuring, and that the properties will not default on their FHA insured mortgages during the restructuring process.

Granted By: Ira Peppercorn, Director of OMHAR.

Date Granted: August 31, 2000.

Reasons Waived: HUD determined that there was good cause for the waivers. The attached list of projects were not assigned to the PAEs in a timely manner or for which the restructuring analysis was unavoidably delayed due to no fault of the owner.

Contact: Dan Sullivan, Office of Multifamily Housing Assistance Restructuring, Department of Housing and Urban Development, Portals Building, Suite 400, 1280 Maryland Avenue SW., Washington, DC 20410; telephone (202) 708–0001.

- *Regulations:* 24 CFR 401.600.

Project/Activity: The following projects requested waivers to the 12-month limit at above-market rents (24 CFR 401.600):

FHA No.	Project name	State
10135218	High Country Apartments	CO
00044150	Eleventh Street Apartments	DC
06135053	Lakeview Apartments	GA
06135037	Pine Valley Apartments	GA
07344381	Caravelle Commons Cooperative	IN
00055019	Glenarden I Apartments	MD
00055019	Glenarden I Apartments	MD
00012005	Glenarden II Apartments	MD
00012005	Glenarden II Apartments	MD
00012005	Glenarden II Apartments	MD
00012005	Glenarden II Apartments	MD
00012005	Glenarden II Apartments	MD
05235079	Perrywood Garden Apartments	MD
02235011	Maple Knolls Apartments	ME
02235011	Maple Knolls Apartments	ME
08335056	Eagles Manor No. 2	MT
04235042	Chip Apartments II	OH
04244008	Ralston Square Apartments	OH
04235180	Rockefeller Park Towers	OH
11235145	Belle Oaks Apartments	TX
13355008	Villa Del Norte Apartments	TX
13355008	Villa Del Norte Apartments	TX
13344034	Woodcrest Apartments	TX
13344034	Woodcrest Apartments	TX
05135057	Rivermont Apartments	VA

Nature of Requirement: HUD's regulation at 24 CFR 401.600 requires that projects be marked down to market rents within 12 months of their first expiration date after January 1, 1998. The intent of this provision is to ensure timely processing of requests for restructuring, and that the properties will not default on their FHA insured mortgages during the restructuring process.

Granted By: Ira Peppercorn, Director of OMHAR.

Date Granted: September 22, 2000.

Reason Waived: HUD determined that there was good cause for the waivers. The attached list of projects were not assigned to the PAEs in a timely manner or for which the restructuring analysis was unavoidably delayed due to no fault of the owner.

Contact: Dan Sullivan, Office of Multifamily Housing Assistance Restructuring, Department of Housing and Urban Development, Portals Building, Suite 400, 1280 Maryland Avenue SW., Washington, DC 20410; telephone (202) 708–0001.

V. Regulatory Waivers Granted by the Office of Public and Indian Housing

For further information about the following waiver actions, please see the name of the person which immediately follows the description of the waiver granted.

- *Regulation:* 24 CFR 950.980 as in effect at the time of grant award.

Project/Activity: A request was made by the Cheyenne River Housing Authority (CRHA), Eagle Butte, South Dakota, for a one-year extension of their FY 1994 FIC grant to continue support and funding for their Single Mother's Self-Sufficiency Program.

Nature of Requirement: While no longer in effect, HUD's regulations at 24 CFR 950.980 governed the Family Investment Center (FIC) program at the time of the initial grant award. The FIC program does not have current regulations and the NOFA does not provide guidance on grant term extensions. The application kit states that the grant term will be of three to five years duration, depending upon the activities undertaken.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: June 19, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The FIC grant awarded to the CRHA has funded the Single Mother's Self-Sufficiency Program which has provided basic life skills, training and transitional housing for many homeless single mothers, as well as educational opportunities to seventy-four young women, thirty-three of which have completed their entire educational plan; forty-one of the participating that have not completed their goals will be able to achieve them during this additional year of operating the program; the success of the program has prompted the Board of Directors to approve a pilot program for single fathers, providing the same services to men in the area; and the CRHA has been highly competent in submitting their annual reports and financial status reports to the Northern Plains ONAP in a timely manner.

Contact: Tracy C. Outlaw, National Office of Native American Programs (ONAP), Department of Housing and Urban Development, 1999 Broadway—Suite 3390, Denver, Colorado 80202, telephone: (303) 675–1600.

- *Regulation:* 24 CFR 963.10(d).

Project/Activity: Tampa Housing Authority, Florida, Public Housing Program.

Nature of Requirement: HUD's regulation at 24 CFR 963.10(d) restricts a public housing agency (PHA) from contracting with a resident-owned business in excess of $1,000,000.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: July 26, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Approval of the waiver permitted the PHA to exceed the limit for contracting with resident-owned businesses and closed two Regional Inspector General Audit findings against the PHA.

Contact: Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh St. SW., Washington, DC 20410, telephone: (202) 708–0477.

- *Regulation:* 24 CFR 982.306(d).

Project/Activity: Vermont State Housing Authority, Vermont, Housing Choice Voucher Program.

Nature of Requirement: HUD's regulation at 24 CFR 982.306(d) limits the circumstances under which a public housing agency may approve the leasing of a unit if the owner of the unit is a close relative of the family.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: August 2, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Approval of the waiver permitted a voucher holder to lease a unit from a relative because of the unavailability of suitable vacant rental housing in the PHA's jurisdiction.

Contact: Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh St. SW., Washington, DC 20410, telephone: (202) 708–0477.

- *Regulation:* 24 CFR 982.306(d).

Project/Activity: Saint Paul Public Housing Agency, Minnesota, Housing Choice Voucher Program.

Nature of Requirement: HUD's regulation at 24 CFR 982.306(d) limits the circumstances under which a public housing agency may approve the leasing of a unit if the owner of the unit is a close relative of the family.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: August 7, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Approval of the waiver permitted a large family to find suitable housing to lease under the housing choice voucher program. The availability of vacant units with three or more bedrooms in the PHA's jurisdiction was extremely low. The market area vacancy rate was less than one percent.

Contact: Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh St. SW., Washington, DC 20410, telephone: (202) 708–0477.

- *Regulation:* 24 CFR 982.306(d).

Project/Activity: Northeast Nebraska Joint Housing Authority, Nebraska, Housing Choice Voucher Program

Nature of Requirement: HUD's regulation at 24 CFR 982.306(d) limits the circumstances under which a public housing agency (PHA) may approve the leasing of a unit if the owner of the unit is a close relative of the family.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: August 11, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Approval of the waiver permitted a voucher holder to lease a unit from a relative in a small rural area where there was limited availability of eligible housing units to lease under the program.

Contact: Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh St. SW., Washington, DC 20410, telephone: (202) 708–0477.

- *Regulation:* 24 CFR 983.4(a)(3).

Project/Activity: Burlington Housing Authority (BHA), Vermont, Project-Based Certificate Program.

Nature of Requirement: HUD's regulation at 24 CFR 983.4(a)(3) governs HUD approval of PHA submissions of intent to attach Project based assistance to units. Project-based units proposed for attachment may not be under a tenant-based or Project-based HAP contract or otherwise committed through issuance of certificates or under agreements to enter into HAP contract.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: July 20, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. Approval of the waiver permitted applicants on the BHA waiting list to be assisted sooner, since BHA will not be required to hold voucher assistance as long for future Project-based use, and the waiver also permitted improved utilization of BHA voucher funding during the ACC terms of voucher increments consistent with HUD policy to fully use units reserved under the ACC and allocated budget authority.

Contact: Gerald Benoit, Director, Real Estate and Housing Performance Division, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh St. SW., Washington, DC 20410, telephone: (202) 708–0477.

- *Regulation:* 24 CFR 1000.214.

Project/Activity: A request was made by the Match-E-Be-Nash-Shw-Wish band of Pottawatomi Indians (MBPI), Door, Michigan, to submit their Indian Housing Plan (IHP) to the Eastern Woodlands beyond the due date of July 1, 1999.

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Nature of Requirement: HUD's regulation at 24 CFR 1000.214 states that IHPs must be initially sent by the recipient to the Area ONAP no later than July 1. Section 1000.216 states that if the IHP is not initially sent by July 1, the recipient will not eligible for IHBG funds for that fiscal year.

Granted By: Harold Lucas, Assistant Secretary for Public and Indian Housing.

Date Granted: August 7, 2000.

Reason Waived: HUD determined that there was good cause for the waiver. The MBPI was unable to meet the submission date for the FY 2000 IHP due to circumstances beyond their control. The MBPI was federally recognized on August 23, 1999, and has spent most of the last year working to establish the basic elements for the MBPI's government and organization. Healthcare was the MBPI's first priority, so a health program was established. The small staff was unable to work on housing issues in addition to all other activities. The MBPI can now address the housing issues.

Contact: Tracy C. Outlaw, National Office of Native American Programs (ONAP), Department of Housing and Urban Development, 1999 Broadway—Suite 3390, Denver, Colorado 80202, Telephone: (303) 675–1600.

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Part XIV

Department of Justice

Executive Order 13160 Guidance Document: Ensuring Equal Opportunity in Federally Conducted Education and Training Programs; Notice

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DEPARTMENT OF JUSTICE

Executive Order 13160 Guidance Document: Ensuring Equal Opportunity in Federally Conducted Education and Training Programs

AGENCY: Department of Justice.

ACTION: Notice: Guidance document.

SUMMARY: This Guidance Document entitled "Executive Order 13160 Guidance Document" is being issued pursuant to Executive Order 13160, which was issued on June 23, 2000. Executive Order 13160 prohibits discrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent in federally conducted education and training programs. The Executive Order was issued in order to achieve equal opportunity in all federally conducted education and training programs and is premised upon the notion that the federal government should hold itself to at least the same principles of nondiscrimination in educational opportunities as it applies to the educational programs and activities of recipients of federal financial assistance. Toward that end, the Executive Order is intended to supplement existing laws and regulations that already prohibit many forms of discrimination in both federally conducted and federally assisted educational programs. The purpose of this Guidance Document is to assist all federal agencies in complying with the nondiscrimination mandates of Executive Order 13160 by providing a basic framework for implementation of the Executive Order. Among the topics addressed in this Guidance Document are the scope of covered educational programs, applicable legal principles, examples of discriminatory conduct, enforcement procedures, remedies, and agency reporting requirements. The text of the Guidance Document appears at the end of this Notice.

DATES: Effective January 18, 2001.

ADDRESSES: Coordination and Review Section, Civil Rights Division, P.O. Box 66560, Washington, D.C., 20035–6560.

FOR FURTHER INFORMATION CONTACT: Merrily A. Friedlander, Chief, Coordination and Review Section, Civil Rights Division, (202) 307–2222.

Dated: January 11, 2001.

Janet Reno,

Attorney General, Department of Justice.

Executive Order 13160 Guidance Document

I. Introduction

On June 23, 2000, the President of the United States issued Executive Order 13160 in order to achieve equal opportunity in all federally conducted education and training programs. More specifically, Executive Order 13160 was designed to ensure nondiscrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent in federally conducted education and training programs and activities.

Executive Order 13160 is premised upon the notion that the federal government should hold itself to at least the same principles of nondiscrimination in educational opportunities as it applies to the educational programs and activities of recipients of federal financial assistance. Toward that end, the Executive Order is intended to supplement existing laws and regulations that already prohibit many forms of discrimination in both federally conducted and federally assisted educational programs. Among the most significant of these nondiscrimination laws are the Rehabilitation Act of 1973, 29 U.S.C. 701 *et seq.*, as amended; the Age Discrimination in Employment Act of 1967, 29 U.S.C. 621, *et seq.*; Titles VI and VII of the Civil Rights Act of 1964, 42 U.S.C. 2000d, as amended; 42 U.S.C. 2000e-17, as amended; and Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.*

In order to achieve equal opportunity in all federally conducted education programs, Section 1–102 of Executive Order 13160 provides that:

> No individual, on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, or status as a parent, shall be excluded from participation in, be denied the benefits of, or be subjected to discrimination in, a federally conducted education or training program or activity.

All federal agencies that conduct education and training programs must therefore commit themselves to providing educational environments that are entirely free from discrimination based on race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent.

Pursuant to section 5–501 of Executive Order 13160, this Guidance Document has been developed to assist all federal agencies in complying with the nondiscrimination mandates of the Executive Order. Among the topics addressed herein are the scope of covered educational programs, applicable legal principles, examples of discriminatory conduct, enforcement procedures, remedies, and agency reporting requirements.

This Guidance Document is intended only to provide a basic framework for implementation of Executive Order 13160. This Guidance Document is not intended to be a comprehensive guide for compliance. Rather, this Guidance Document is designed only to provide a starting point for agency implementation, and this Document's failure to address a particular issue should in no way be interpreted to mean that such an issue falls outside the scope of the nondiscrimination protections established by the Executive Order or this Guidance.

In order to supplement the basic principles established in this Guidance Document, it is anticipated that, from time to time, the Department of Justice will publish additional policies or guidance documents to assist with the enforcement of this Executive Order. In addition, section 5–505 of the Executive Order provides that, "[u]pon request and to the extent practicable, the Attorney General shall provide advice and assistance to executive departments and agencies to assist in full compliance with this order." Responsibility for providing such advice and technical assistance is delegated to the Assistant Attorney General for Civil Rights, who shall conduct, handle, or supervise the performance of these functions.

II. Covered Education Programs and Activities

Executive Order 13160 applies to all federally conducted education and training programs and activities. Pursuant to section 2–201, "federally conducted education and training programs" include those that are "conducted, operated, or undertaken by" an executive department or agency.

Section 2–202 of the Executive Order provides that federally conducted "education and training programs and activities" may include, but are not limited to, the following:

(1) formal schools,
(2) extracurricular activities,
(3) academic programs,
(4) occupational training,
(5) scholarships and fellowships,
(6) student internships,
(7) training for industry members,
(8) summer enrichment camps, and
(9) teacher training programs.

As this definition makes clear, education programs covered by Executive Order 13160 may include both long-term, formal academic institutions (such as Department of Defense Dependents Schools, Department of Defense Domestic Dependent Elementary and Secondary Schools, and elementary or secondary schools operated by the Department of Interior, Bureau of Indian Affairs), as well as short-term job training programs (such as computer training courses for federal employees).

Some examples [1] of the types of education and training programs and activities that might be covered by Executive Order 13160 are discussed below:

Ex. 1. The Office of Government Ethics runs an agency ethics training course for federal employees from other agencies.

Ex. 2. The Federal Deposit Insurance Corporation operates a small computer school which teaches state examiners to analyze the weaknesses in the supervision of a small bank data processing operation.

Ex. 3. The Department of Veteran Affairs (VA) runs the VA Home Loan Training Program, which offers information and training to numerous private sector enterprises that cooperate in providing VA home loan benefits.

Ex. 4.The Nuclear Regulatory Commission provides radiation control training for state and local government personnel under the State Agreements Program.

Ex. 5. The Federal Bureau of Investigation (FBI) runs the FBI National Academy, an 11-week multi-disciplinary program in Quantico, Virginia, for federal, state, local, and foreign officers who are considered to have potential for further advancement in their careers.

Ex. 6. The Department of Housing and Urban Development operates the Community First Leadership Program, which provides in-depth training for representatives from state and local governments and non-profit organizations involved in housing and community development programs.

Ex. 7. The Maritime Administration conducts a Firefighting Training Program for private, licensed and unlicensed U.S. seafarers, who pay a fee for instruction in fire-fighting safety.

Ex. 8. The United States Department of Agriculture (USDA) operates the Graduate School, USDA, which provides career-related continuing education courses primarily designed to meet the educational needs of government employees.

Ex. 9. The Bureau of Alcohol, Tobacco, and Firearms operates the Anacostia Neighborhood Prevention Initiative, which provides crime prevention training to the public.

Ex. 10. The Peace Corps offers a World Wise Schools program to students interested in broadening their geographic and cultural horizons.

Ex. 11. The National Aeronautics and Space Administration conducts a tour of its facilities to educate the public about theSpace Shuttle Program.

Ex. 12. The Department of Justice conducts computer training courses to regularly update its employees on new software.

Ex. 13. The Federal Bureau of Prisons conducts an inmate boot camp to prepare inmates for reintegration into society.

Ex. 14. The U.S. Department of Agriculture conducts an annual Summer Intern Program for roughly 150 college students, who are hired to work with professional staff on projects related to the students' majors and career plans.

Ex. 15. The General Counsel's Office at the Federal Emergency Management Agency hires law students to work as-unpaid student interns during the school year.

[1] These examples were drawn from data provided by various federal agencies during the development of Executive Order 13160. The programs enumerated above, however, are not necessarily still in existence and, in some cases, are merely hypothetical examples.

III. Exemptions From Coverage

Although Executive Order 13160 is intended to provide broad-based coverage for federally conducted education and training programs, section 3 of the Executive Order does provide some exemptions from coverage. As discussed below, there are several circumstances under which the nondiscrimination prohibitions of the Executive Order do not apply to certain federally conducted education and training programs.

Military Programs

Section 3–301 explicitly states that the Executive Order does not apply to "members of the armed forces, military education or training programs, or authorized intelligence activities." Military education or training programs are defined as education programs conducted by the Department of Defense (or, where the Coast Guard is concerned, by the Department of Transportation) for the "primary purpose" of training members of the armed forces or meeting a statutory requirement to educate or train federal, state, or local civilian law enforcement officials pursuant to 10 U.S.C. chapter 18. This includes military academies, military programs that provide drug traffic prevention training to non-military law enforcement agencies, Department of Defense foreign language training and survival schools for non-military law enforcement agencies, and military training to non-military law enforcement agencies in the operation and maintenance of equipment used in the detection, monitoring, aerial reconnaissance, and communication intercepts of illegal drug trafficking.

Members of the armed forces, including students at military academies, are, however, protected from certain forms of discrimination pursuant to regulations currently enforced by the Department of Defense and individual service branches. *See, e.g.*, 32 CFR part 51, "Department of Defense Military Equal Opportunity Program," and 32 CFR part 56, "Nondiscrimination on the basis of Handicap in Programs and Activities Assisted or Conducted by Department of Defense." In addition, section 3–301 of Executive Order 13160 specifically provides that the Department of Defense shall develop procedures to protect the rights of, and to provide redress to, civilians involved in Department of Defense federally conducted military education and training programs if such civilians are not otherwise protected by existing federal law from discrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, or status as a parent.

Finally, it is important to emphasize that this exemption does not apply to the Department of Defense Dependent Schools and Department of Defense Domestic Dependent Elementary and Secondary Schools. These schools must comply with the Executive Order and with all applicable legal principles set forth in this Guidance Document.

Affirmative Action

Any otherwise lawful affirmative action plan or program is exempt from coverage under the Executive Order. Pursuant to section 3–302, the Executive Order "does not apply to, affect, interfere with, or modify the operation of any otherwise lawful affirmative action plan or program."

Programs Established Consistent With Federal Law

Section 3–303 of the Executive Order provides that an individual shall not be deemed subject to discrimination by virtue of his or her "exclusion from the benefits of a program established consistent with federal law or limited by federal law to individuals of a particular race, sex, color, disability, national origin, age, religion, sexual orientation, or status as a parent different from his or her own." For example, pursuant to 25 CFR §§ 31.1 and 31.3, education or training programs or activities conducted by the Department of Interior's Bureau of Indian Affairs are, subject to a few exceptions, limited to Native American students "of one-fourth or more degree of Indian blood."

Bureau of Indian Affairs Programs

Section 3–304 of the Executive Order exempts from coverage any ceremonial or similar education or training program or activity of a school conducted by the Department of Interior's Bureau of

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Indian Affairs, provided such program is "culturally relevant" to the children represented in the school. The Executive Order defines "culturally relevant" as any class, program, or activity that is "fundamental" to a tribe's "culture, customs, traditions, heritage, or religion." For example, certain educational classes involving traditional Native American dance instruction may be "culturally relevant" to the children represented in the school and therefore exempt from coverage under the Executive Order. In making determinations as to whether classes, programs, or activities are "culturally relevant," substantial deference shall be given to the views of the relevant tribes.

Selections of Foreign Nationals and Selections Made Outside the Executive Branch

Section 3–305 provides an exemption for selections of foreign nationals based on national origin if the selections pertain to participation in covered education programs or activities that "primarily concern national security or foreign policy matters." Thus, for example, the Executive Order would not cover the selection of participants, on the basis of national origin, for the Department of State's Antiterrorism Assistance training programs if the primary mission of these programs is to train foreign nationals in deterring and managing terrorist threats.

Section 3–305 further provides an exemption for "selections or other decisions made by entities outside the executive branch." For example, if a local school district selects students to participate in a federally conducted education program, the selection decisions of the local school district would not be subject to Executive Order 13160 as they represent selection decisions made by an entity outside the executive branch.[2] However, the students selected for participation in the federally conducted education program would be protected from discrimination under Executive Order 13160 during the duration of their participation in the federally education conducted program.

In addition, section 3–305 provides that it "shall be the policy of the executive branch that education or training programs or activities shall not be available to entities that select persons for participation in violation of Federal or State law." Thus, if a company responsible for selecting employees to participate in a federally conducted education program were to refuse to consider selecting members of a particular race in violation of Title VII of the Civil Rights Act of 1964, as amended, executive departments should, as a matter of policy, refrain from making their educational programs available to such a company.

Age-Based Admissions

Section 3–306 provides an exemption for age-based admissions to federally conducted education and training programs if such programs have "traditionally been age-specific" or "must be age-limited for reasons related to health or national security." *See* Section XI of this Guidance Document for further information regarding these age-related exemptions.

Final Determinations Regarding Coverage and Exemptions

As a general matter, Executive Order 13160 will apply to all federally conducted education and training programs or activities not subject to a specific exemption set forth in Section 3 of the Executive Order. Executive departments or agencies and individuals with questions regarding whether a particular program or activity is subject to Executive Order 13160 should contact the Department of Justice's Civil Rights Division.

Pursuant to section 2–203 of the Executive Order, the Attorney General is authorized to make final determinations as to whether a given program falls within the scope of covered education and training programs under section 2–202 or is excluded from coverage under section 3. *See* Section XIV(C), "Administrative Enforcement," for further information pertaining to applicable procedures for requesting a final determination from the Attorney General regarding coverage of a particular program.

IV. Applicable Legal Principles

Executive Order 13160 requires executive departments and agencies to ensure nondiscrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent in all federally conducted education and training programs. In order to comply with the antidiscrimination mandates of this Executive Order, agencies must ensure that individuals involved in federally conducted education and training programs and activities are not subjected to discrimination on the basis of any one of these protected characteristics. The most common forms of discrimination prohibited by the Executive Order are discussed below.

Disparate Treatment

Under Executive Order 13160, all individuals involved in federally conducted education or training programs or activities must be treated equally and not be subjected to discrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, or status as a parent. In order to comply with the Executive Order, all federal agencies that provide education or training programs or activities must ensure that individuals are not subjected to unjustified disparate treatment based on a protected status.[3] Examples of disparate treatment may include, but are not limited to:

- Selecting or failing to select an individual because of his or her protected status.
- Denying an individual any aid, benefit, or service offered in connection with a federally conducted education program because of his or her protected status.
- Failing to provide or allocate aid, benefits, or services as a result of an individual's protected status.
- Promoting or failing to promote an individual because of his or her protected status.
- Giving a positive or negative performance evaluation to an individual because of his or her protected status.
- Segregating an individual because of his or her protected status.
- Assigning an individual to a particular education or training program or activity, or a particular project, because of his or her protected status.
- Treating an individual less favorably with respect to the terms, conditions, or privileges of an education or training program or activity because of his or her protected status.

In addition to prohibiting individual instances of unjustified disparate treatment, the Executive Order also prohibits federal agencies from engaging in a "pattern or practice" of unlawful discrimination. Moreover, federal agencies may not rely on policies or practices that explicitly classify individuals on the basis of a protected characteristic absent a lawful justification for the use of such a classification.

It is important to note, however, that, under certain circumstances, compliance with the Executive Order may permit federal agencies to treat individuals differently on the basis of a protected characteristic. For example, under certain limited circumstances, agencies may legitimately treat individuals differently on the basis of sex if sex is a bona fide occupational qualification (BFOQ). Similarly, remedial situations may justify differential treatment. Moreover, in educational environments, narrowly-tailored measures designed to promote the educational benefits of diversity may lawfully treat individuals differently on the basis of a protected characteristic.

In some cases, the Executive Order may even require federal agencies to treat individuals differently in order to avoid discriminating against an individual on the basis of a protected characteristic. For example, the prohibition on religious discrimination may require an agency to provide an individual with a reasonable accommodation for religious practices as discussed in section X of this Guidance Document. Similarly, under many circumstances, federal agencies have an obligation to provide reasonable accommodations for individuals with disabilities. *See* Section IX of this Guidance Document. As such, the examples of disparate treatment enumerated above are designed merely to illustrate the types of conduct generally prohibited by this Executive Order and agencies must, of course, evaluate individual claims of disparate treatment on a case-by-case basis.

Hostile Environment

Pursuant to Executive Order 13160, a federal agency that provides education or training programs or activities must maintain a learning environment that is free of discrimination on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent.

- Federal agencies must ensure that the learning environment is free of harassment that is so severe, persistent, or pervasive that it alters the conditions of the federally conducted education or training program or activity for a participant on the basis of a protected status. Federal agencies should ensure that no individual is subject to a hostile environment that effectively denies or limits equal access to (*e.g.*, negatively affects an individual's participation or performance in) educational or training opportunities and benefits based on his or her protected status.
- Federal agencies should be aware that the sort of harassment that can create a hostile environment, when it is sufficiently severe, persistent, or pervasive, may take many forms including: slurs, epithets, jokes, cartoons, unwelcome advances, and other verbal or physical derogatory conduct that targets individuals on the basis of a protected status. Federal agencies should further be aware that hostile environments may be created by supervisors, instructors, administrators, other officials, or peers.

Disparate Impact

As a general matter, federally conducted education and training programs and activities may not utilize policies, procedures, criteria, or other methods of administration which, although facially neutral, have a disproportionate and adverse effect on certain individuals on the basis of a protected characteristic, unless:

(1) There is an educational or business necessity for the policy, procedure, criteria, or method of administration; and

(2) There are no equally effective alternative practices that would result in less adverse impact.

Retaliation

Federal agencies that operate education and training programs may not retaliate against any individual because he or she has raised concerns, reported claims, or filed complaints alleging discrimination. Federal agencies are similarly prohibited from retaliating against any individual who has testified, assisted, or participated in any manner in an investigation or other proceeding raising claims of discrimination.

Prohibited retaliation may take many forms including, but not limited to, intimidation, threats, coercion, harassment, discrimination, and adverse actions (*e.g.*, poor grades or performance evaluations) motivated by retaliatory purpose. Federal agencies must ensure that no individual is subject to any form of retaliation regardless of the merits (or lack thereof) of any underlying claim.

Specific Principles and Examples

The following sections address more specific applicable legal principles and examples of discriminatory conduct related to each of the nine protected bases covered by the Executive Order. It is important to note, however, that each of the following sections is intended merely to highlight certain specific forms of prohibited discrimination. The failure to include a particular legal principle (or a particular example of prohibited conduct) in one section of this Guidance Document should in no way be interpreted to mean that the legal principle (or prohibited conduct) is not covered with respect to another protected basis. Rather, all sections of this Guidance Document should be read in conjunction with each other to provide a fuller picture of the breadth and application of the Executive Order's antidiscrimination prohibitions.[4]

V. Discrimination on the Basis of Race

Federal agencies must ensure that no individual is discriminated against on the basis of his or her race in any federally conducted education or training program or activity.

- Federal agencies must ensure that all individuals are treated equally without regard to race in any federally conducted education or training program or activity.
- Federal agencies may not utilize policies, procedures, or methods of administration which, although facially neutral, have a disproportionate and adverse effect on participants or applicants on the basis of their race, unless there is an educational or business necessity for the use of such policies and there are no equally effective alternative practices that would result in less of a disproportionate impact.
- Federal agencies may not base any decisions regarding individuals in federally conducted education or training programs on race-based stereotypes or assumptions regarding interests, competency levels, or expectations of success.
- Federal agencies must take steps to ensure that no federally conducted education or training program takes place in an environment that is intimidating, abusive, offensive, or hostile on the basis of race.

Examples[5] of Prohibited Conduct:

- A federal law enforcement agency conducts an anti-terrorist training program in which it groups participants in various teams. Although the instructor generally makes random assignments for this exercise, he states that he has decided to assign all of the African-American participants to a single team because he believes that African-Americans work most effectively with members of their own race. The instructor's conduct violates the Executive Order.
- The Department of Justice offers an advanced prosecutorial course for its

[2] Such selection decisions might, however, be covered by other civil rights statutes, including Title VI of the Civil Rights Act of 1964, as amended, and Title IX of the Education Amendments of 1972, as amended.

[3] Throughout the remainder of this document, the term "protected status" may be used to refer generally to the nine protected characteristics which are the subject of this Executive Order: race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent.

[4] Of course, it is also true that not every principle will be applicable to every protected basis. For example, only certain protected characteristics trigger a reasonable accommodation requirement. Individuals or agencies with specific questions regarding the Executive Order's antidiscrimination provisions should contract the Department of Justice's civil Rights Division.

[5] All of the examples of discriminatory conduct set forth in this Guidance Document are hypothetical and are not intended to suggest that any federal agency actually engages in such discriminatory practices or necessarily even operates such an educational program.

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attorneys at the Department's National Advocacy Center in Columbia, South Carolina. Due to the high demand for this course, the limited number of openings available, and the difficulty the Department has had in determining which candidates should be selected, the Department decides to require candidates to take an aptitude test and to select candidates in descending rank order of their test scores. However, the test results in disparate impact upon members of a particular race. Further, the Department lacks evidence that the test is valid; namely, that it predicts success in the course or even that it is necessary to pass the test in order to satisfactorily complete the course. Accordingly, the Department's use of this test violates the Executive Order.

VI. Discrimination on the Basis of Sex

Federal agencies must ensure that no individual is discriminated against on the basis of sex in any federally conducted education or training program or activity.

• No executive agency may admit, refuse to admit, promote, refuse to promote, or otherwise favor or disfavor, a participant or prospective participant in a federally conducted education program on the basis of sex.

• An agency may not impose, explicitly or implicitly, stricter admission or completion requirements for one sex as compared to the other.

• Federal agencies operating education or training programs may not utilize policies, procedures, or methods of administration which, although facially neutral, have a disproportionate and adverse effect on participants or applicants on the basis of sex unless there is an educational or business necessity for the use of such policies and there are no equally effective alternative practices that would result in less of an impact on the basis of sex.

• Federal agencies should ensure that no individual is subjected to gender-based harassment, which may include harassment based on sex or sex-stereotyping, in any federally conducted education or training program. Gender-based harassment may be based upon stereotypical notions regarding how persons of each gender should act or look.

• Discrimination on the basis of sex includes discrimination on the basis of pregnancy. Federal agencies must ensure that no woman is discriminated against on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom, in any education or training program or activity.

Examples of prohibited conduct:

• The Director of Athletics at a Department of Defense School for dependent children of military personnel decides to allocate all of his annual athletics budget to male sports because he does not believe that female students need or want the same quality and variety of athletic services as males. Despite repeated requests from female students for a variety of programs and services, the Director refuses to consider the provision of any funding for co-ed or female sports. The Director's conduct would violate the Executive Order.[6]

• The Federal Bureau of Investigation conducts a firearms training program for state and local officials. The admissions director refuses to admit women because he believes that only men should be permitted to train for dangerous jobs. The director's refusal to consider women for participation in the program would violate the Executive Order.

• The Department of Health and Human Services conducts a nurses' training program on childhood vaccinations. One of the instructors requires the male participants to attend a seminar on infant care, but does not require the female students to attend the same seminar because she assumes that female students already possess such skills. The instructor's conduct would violate the Executive Order.

• A physical fitness instructor at the Federal Bureau of Prisons refuses to allow a pregnant inmate to participate in the physical fitness training program because he believes that pregnant women should not be physically active. Although the prison has a policy of permitting inmates with temporary disabilities to participate in physical fitness programs upon receipt of approval from a physician, the instructor refuses to consider a letter from the inmate's doctor explaining that physical activities pose no health risk to her. The instructor's decision to exclude the woman would violate the Executive Order.

• The Department of Labor conducts a week-long training seminar during which participants are evaluated for their approaches to management. Future promotion decisions are based on these evaluations. One of the evaluators gives high ratings to men who exhibit an aggressive interpersonal style, but deducts points for women who exhibit the same characteristics. The evaluator's judgments are based on sex-stereotypes and thus violate the Executive Order.

[6] Further information on the application of these nondiscrimination principles to athletic programs in educational institutions may be obtained by consulting Guidance Documents developed by the Department of Education's Office for Civil Rights, including *Policy Interpretation—Title IX and Intercollegiate Athletics*, 45 CFR part 26 (1979); *Equal Opportunity in Intercollegiate Athletics: Requirements under Title IX of the Education Amendments of 1972*, 34 CFR part 106; *Clarification of Intercollegiate Athletics Policy Guidance: The Three-Part Test* (January 16, 1998); and various other pamphlets, memoranda, and documents that may be found on the Department of Education's website at www.ed.gov./offices/OCR/ocrprod.html.

• The Department of Justice operates an advanced law enforcement training course on an annual basis for ten individuals. During one session of the course, nine of the ten participants are male. The only woman enrolled in the course is continually taunted and hazed by her male peers who do not believe that women are capable of serving as law enforcement officers. The male instructor not only fails to take appropriate corrective action, but joins the male students in subjecting the woman to a barrage of derogatory epithets. The gender-based harassment to which the woman is subjected violates the Executive Order.

Sexual Harassment

The Executive Order's prohibition on sex discrimination requires federal agencies to ensure that no individual is subjected to sexual harassment in any federally conducted education or training program.

• Sexual harassment entails unwanted or unwelcome sexual conduct including sexual advances, requests for sexual favors, or other verbal, nonverbal, or physical conduct of a sexual nature.

• Federal agencies must ensure that no individual involved in a federally conducted education or training program is subjected to any form of sexual harassment.

• No instructor, supervisor, administrator, or other official involved in a federally conducted education program may (1) Explicitly or implicitly make submission to sexual conduct a term or condition of an individual's participation in an education program, or (2) use submission to or rejection of such conduct as the basis for any decision affecting an individual. Sexual harassment of this type violates the Executive Order whether an individual resists and suffers the threatened harm or submits and thus avoids the threatened harm.

• Federal agencies must ensure that no individual involved in a federally conducted education or training program is subjected to a hostile environment on the basis of sex. An impermissible hostile environment may consist of unwelcome sexual conduct that is sufficiently severe, persistent, or pervasive so as to (1) Limit an individual's ability to participate in, or benefit from, an education or training program or activity, or (2) create a hostile or abusive educational environment. Hostile environments may be created by supervisors, instructors, administrators, other officials, or peers.

Examples of prohibited conduct:

• A male student attending a high school operated by the Bureau of Indian Affairs is told by a female teacher that he will fail algebra if he does not accompany her on a date. The student refuses the teacher's request and receives a failing grade as a result. The teacher's conduct violates the Executive Order.

• The Federal Emergency Management Agency conducts emergency preparedness training for local firefighters. A training supervisor refuses to certify that a trainee has completed the program until she accompanies him on a date. Fearing that she will lose her job if she is not certified, the trainee acquiesces to the supervisor's demand. The supervisor's behavior constitutes sexual harassment and violates the Executive Order.

• A volunteer student intern at the Department of Veterans Affairs has made repeated unwelcome sexual gestures of a graphic and physical nature toward a fellow intern. On several occasions, the intern has made such gestures while following the victim and threatening to "get her alone." The victim no longer feels that she can be by herself at the office. This conduct has been both severe and pervasive and has created a hostile educational environment. The intern tells her supervisor and the Senior Managers who oversee the program, but they refuse to investigate or otherwise stop or prevent the conduct. The failure to investigate and/or take appropriate corrective action violates the Executive Order.

VII. Discrimination on the Basis of Color

Federal agencies must ensure that no individual is discriminated against on the basis of color in any education or training program or activity.

• Discrimination on the basis of color may include, but is not limited to, discrimination on the basis of the appearance of an individual's skin tone, racial complexion, pigmentation, or hue.

• A federal agency may not, on the basis of color, admit, refuse to admit, promote, refuse to promote, or otherwise favor or disfavor, a participant or prospective participant in an education or training program or activity.

• A federal agency may not use color as a proxy for determining an individual's race or national origin.

• Federal agencies must ensure that participants in education or training programs or activities are not subjected to harassment, in the form of color-based animus, bias, hostility, stereotype, ridicule or insult, whether by instructors or fellow participants, that is sufficiently severe, persistent, or pervasive to create a hostile environment.

• Federal agencies may not utilize policies, procedures, criteria or methods of administration which, although facially neutral, have a disproportionate and adverse impact on the basis of color, unless there is an educational or business necessity for the use of such policies and there are no equally effective alternative practices that would result in less of an impact on the basis of color.

Examples of prohibited conduct:

• An executive agency conducts a vocational training program that includes an advanced course in media and broadcast education. The only criteria for admission is that the individual demonstrate a long-term interest in the field. After conducting interviews, however, a member of the admissions committee rejects an applicant with dark skin solely because she has seen statistical data that demonstrates that individuals with dark skin experience greater difficulty in finding permanent employment in these fields. The admissions committee member's conduct violates the Executive Order.

• A federal agency is planning an education seminar to address the Native American experience during the 20th Century. The program coordinator receives applications from numerous Native Americans who wish to participate as panelists. The program coordinator refuses to select any light-skinned applicants because he believes that such individuals do not appear to be "Native American" and thus cannot effectively address this topic. The coordinator's conduct violates the Executive Order.

VIII. Discrimination on the Basis of National Origin

Federal agencies must ensure that no individual is discriminated against on the basis of national origin in any federally conducted education or training program or activity.

• Discrimination on the basis of national origin may include discrimination based upon an individual's country of birth, ancestry, or accent.

• Federal agencies must ensure that individuals are not subjected to disparate treatment on the basis of national origin.

• Federal agencies may not utilize policies, procedures, criteria or methods of administration which, although facially neutral, have a disproportionate and adverse impact on the basis of national origin unless there is an educational or business necessity for the use of such policies and there are no equally effective alternative practices that would result in less of an impact on the basis of national origin.

• Participants in a federally conducted education or training program or activity must not be subjected to a hostile environment based upon national origin.

• Exempt from coverage under this Executive Order are selections based on national origin of foreign nationals to participate in covered education or training programs which primarily concern national security or foreign policy matters.

Examples of Prohibited Conduct:

• The Department of Health and Human Services decides to hold a conference focused on training community groups on Latino health issues. A non-Latino representative from one of these community groups wishes to attend the conference, but the Conference Coordinator denies the request because the individual is not Latino. The Conference Coordinator's conduct would violate the Executive Order.

• An agency plans to hold a training session in a large city. The conference is designed to help low-income and minority individuals across the city start their own small businesses. The agency decides to advertise the training session by posting announcements in all low-income areas of the city. An agency coordinator, however, decides not to post announcements in the Chinatown section, even though the area has a high population of low income and minority individuals, because the coordinator does not think people from that area will be interested and/or will understand the English-language training. The coordinator's decision would violate the Executive Order.

• A federal agency is conducting an educational program regarding citizenship and civic duty. An employee applies to be a member of the speakers' panel during the program, but her supervisor refuses to select her because he believes that she has a foreign accent which would undermine her credibility with the audience. The supervisor's conduct violates the Executive Order.

Limited English Proficiency

Under certain circumstances, a federal agency's failure to provide language assistance to an individual whose primary language is not English and who has a limited ability to read, write, speak, or understand English may constitute national origin discrimination. Agency obligations with respect to such individuals who are limited English proficient (LEP) are discussed below.[7]

• Agencies have an obligation to take reasonable steps to ensure that LEP

[7] Further guidance on these principles and agency obligations with respect to LEP issues may be found by consulting Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency," 65 FR 50121 (August 16, 2000), and the Department of Justice's Policy Document, "Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency," 65 FR 50123 (August 16, 2000).

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individuals have meaningful access to federally conducted education and training programs and activities.

• Agencies must determine what constitutes "reasonable steps" by considering a number of factors including: (1) the number or proportion of LEP persons in the eligible population to be served by the education or training program or activity; (2) the frequency with which LEP individuals come into contact with the program or activity; (3) the importance of the service provided by the program or activity; and (4) the resources available to the agency.

• If the federally conducted education program is an elementary or secondary school (*e.g.*, Department of Defense Dependent Schools or schools operated by the Department of Interior, Bureau of Indian Affairs), the executive department or agency should comply with the Department of Education's guidance on the provision of language services to elementary and secondary education LEP students.[8]

Examples of Prohibited Conduct:

• A prison operated by the Bureau of Prisons has a very large proportion of adult LEP inmates who speak the same native language. The prison has a drug and alcohol rehabilitation program for inmates who have drug or alcohol addictions. Due to the size of this single-language speaking LEP population, the fact that this population of inmates has the same percentage of drug and alcohol addictions as the rest of the inmate population, and the importance of the program, the prison's failure to provide this group of LEP inmates with access to the program (such as a separate class in their native language or a competent interpreter) would violate the Executive Order.

• Military parents have adopted a child who is limited English proficient. They decide to enroll her in the federally conducted K–12 school for children of military personnel. The school's refusal to consider providing the LEP child with any services to overcome language barriers would constitute a violation of the Executive Order.

IX. Discrimination on the Basis of Disability

Federal agencies must ensure that no individual is discriminated against on the basis of disability in any federally conducted education or training program or activity.

• Section 504 of the Rehabilitation Act already prohibits discrimination on the basis of disability in all federally conducted education and training programs as Section 504 applies to all federally conducted activities. Accordingly, executive departments and agencies may comply with the Executive Order by ensuring that all of their education and training programs are operated in accordance with their Section 504 regulations governing federally conducted activities.

• An individual with a disability refers to any person who has a physical or mental impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. Major life activities include walking, seeing, hearing, speaking, breathing, learning, performing manual tasks, caring for oneself, working, sitting, standing, lifting, and reading.

• Federal agencies must ensure that no otherwise qualified individual, on the basis of disability, is excluded from participation in, denied the benefits of, or subjected to discrimination in any federally conducted education or training program or activity.

• A qualified individual with a disability is any person who, with or without reasonable accommodation, can meet the essential eligibility requirements for involvement in the education or training program.

• Agencies must ensure that federally conducted education or training programs are readily accessible to qualified individuals with disabilities. In order to ensure accessibility, an agency may:

(i) Relocate the education or training program or activity to an accessible facility;

(ii) Provide the aid, benefit, or service in another manner; or

(iii) Make modifications to the building or facility itself.

• In determining how to achieve accessibility, agencies should attempt to provide aid, benefits, or services in the most integrated setting possible.

Examples of prohibited conduct:

• The National Endowment for the Arts conducts an education program on art history. The instructor has a limited number of tickets to a new movie regarding French impressionist works and decides to draw names randomly to decide which students can attend. When the instructor draws the name of a visually impaired participant, he reassigns the ticket because he believes that the visually impaired individual would not be able to enjoy the movie as much as a non-visually impaired participant. The instructor's conduct would violate the Executive Order.

• The Office of Government Ethics holds an ethics briefing for another agency's ethics officials in a building that has three stairs leading up the main entrance. There is no ramp, lift, or alternative accessible entrance. Several participants use wheelchairs and, thus, cannot get into the building. The instructor tells the participants that they will not be able to attend and refuses to relocate the briefing to an available and accessible facility, despite the fact that to do so would not constitute an undue burden. The instructor's refusal to relocate the briefing would violate the Executive Order.

Reasonable Accommodation

Agencies have an obligation to provide reasonable accommodation to the known physical or mental limitations of an otherwise qualified individual with a disability, unless the agency can demonstrate that the accommodation would impose an undue hardship.

• Agencies must furnish appropriate auxiliary aids and services when necessary to afford a qualified individual with a disability an equal opportunity to participate in a federally conducted education or training program or activity.

• Agencies must afford an individual with a disability an opportunity to request the auxiliary aid or service of his or her choice, and should honor that choice unless another effective aid or service is available.

• An agency may not charge an individual with a disability for the use of an auxiliary aid or service.

• The obligation to provide reasonable accommodations extends only to individuals with disabilities; an agency's failure to provide similar accommodations for individuals without disabilities does not constitute unlawful discrimination.

Examples of prohibited conduct:

• The Department of Justice conducts training seminars on compliance with civil rights laws for employees from other agencies. A prospective participant who is hearing impaired requests a sign language interpreter for an upcoming seminar. Although the agency employs a full-time sign language interpreter who is available to attend the seminar in question, the training coordinator refuses to enlist the interpreter's services and informs the participant that the agency will provide a video with closed-captioning that will be available ten days after the seminar is over. The coordinator's conduct would violate the Executive Order.

• A visually impaired student attending a high school operated by the Bureau of Indian Affairs requests that his class handouts be provided in Braille or on audio cassette. The principal refuses to translate any materials and urges that the student transfer to a private high school where such materials are more readily available. The principal's conduct would violate the Executive Order.

[8] *See*, for example, *Identification of Discrimination and Denial of Services on the Basis of National Origin* (May 1970), 35 FR 11595; "The Office for Civil Rights Title VI Language Minority Compliance Procedures" (Dec. 3, 1985); and *Policy Updates on Schools' Obligations Toward National Origin Minority Students with Limited-English Proficiency (LEP)* (Sept. 27, 1991).

X. Discrimination on the Basis of Religion

Federal agencies must ensure that no individual is discriminated against on the basis of religion in any education or training program or activity.

• Discrimination on the basis of religion may include discrimination on the basis of an individual's religion (or lack thereof), religious beliefs, religious expression, or religious practices. Religious practices may include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.[9]

• Discrimination on the basis of religion also may include discrimination on the basis of an individual's relationship with a person of a particular religion or an individual's affiliation with a group, including an employee or student organization, that is associated with religious issues or whose membership is composed largely of people of a particular religion.

• No executive agency may admit, refuse to admit, promote, refuse to promote, or otherwise favor or disfavor, a participant or prospective participant in a federally conducted education program because of his or her religion (or lack thereof), religious beliefs, religious expression, or religious practices.

• An agency may not impose, explicitly or implicitly, stricter admission or completion requirements for a particular religious group or an individual who espouses particular religious beliefs.

• Individuals involved in a federally conducted education program may not be subjected to a hostile environment in the form of religiously-based discriminatory intimidation, or pervasive or severe religious abuse, ridicule or insult, whether by instructors or fellow participants. A hostile environment is not created, however, simply by virtue of religious expression with which some participants might disagree.

Examples of prohibited conduct:

• An instructor in a Department of Justice computer training course requires a participant who is an atheist to complete five extra hours of training because that participant does not share the instructor's religious beliefs. The instructor's conduct would violate the Executive Order.

• A group of participants, attending a federally conducted training course, share a common faith. This group engages in a pattern of verbal attacks on other participants who do not share their religious views. These attacks occur repeatedly and are both severe and pervasive, creating a hostile educational environment. The agency is aware of this situation but fails to take effective corrective action. The agency's failure to take effective corrective action would violate the Executive Order.

Reasonable Accommodation of Religious Practices

The Executive Order's prohibition on religious discrimination also includes an obligation on the part of federal agencies to provide reasonable accommodation for religious practices. If an individual notifies an executive department or agency of his or her need for a religious accommodation with respect to a federally conducted education program, the agency has an obligation to reasonably accommodate the individual's religious observances or practices.

• Reasonable accommodations for religious observances or practices are those that do not impose an undue hardship. Though an agency need not make an accommodation that will result in more than a *de minimis* burden to the agency, the cost or other hardship nevertheless must be real rather than speculative or hypothetical. An accommodation should be made unless: (1) It would create an actual cost for the agency or other participants, (2) it would cause an actual disruption in the conduct of the education program, or (3) such accommodation is otherwise barred by law.

• Individuals involved in federally conducted education programs must be permitted to wear religious clothing, jewelry, or other accessories, if wearing such attire is part of an individual's religious practice or expression, so long as the wearing of such attire does not unduly interfere with the conduct of the education program.

• Agencies should be flexible in the scheduling of education and training courses when participants request scheduling changes in order to observe religious traditions, such as the Sabbath or particular holidays, unless to do so would result in more than a *de minimis* burden.

• Agencies should attempt to honor requests for alternative work assignments when completion of a particular work assignment would contravene an individual's religious practices or beliefs.

Examples of prohibited conduct:

• The National Aeronautics and Space Administration conducts a space camp program every Saturday and Sunday morning, and participants are randomly assigned to each session. The agency refuses to even consider a Catholic youth group's request to be placed in the Saturday morning program so that the group can participate without missing Mass. The agency's failure to even consider providing this religious accommodation would violate the Executive Order.

• The Department of Interior requires its national park service employees to wear uniforms during public instruction, and imposes sanctions for deviation from specific guidelines. A Muslim employee wishes to wear a head scarf or hijab during instruction, but her supervisor refuses to consider her request. The supervisor's refusal to consider the employee's request would violate the Executive Order.

XI. Discrimination on the Basis of Age

Federal agencies must ensure that no individual is discriminated against on the basis of age in any federally conducted education or training program or activity.

As a general matter, age may not be used as a basis upon which to condition the allocation of benefits within, or qualification for, or participation in, a federally conducted education or training program or activity. More specifically:

• Age distinctions may not be used to exclude individuals from a program or activity unless age is a bona fide qualification for participation in the program or activity, that is necessary to the achievement of a programmatic objective or necessary to the normal operation of the program or activity.

• Although agencies may, under certain circumstances, rely on age-based distinctions because it is impracticable to measure characteristics that are necessary to the achievement of an essential programmatic objective on an individualized basis, age may *not* be used as a proxy if it is not a substantially accurate measure of those characteristics.

• Age-based classifications may not be used to achieve any objective that is not essential to the achievement of a statutory objective or the normal operation of a program or activity.

Under certain circumstances, however, agencies may legitimately use age distinctions with respect to the operation of federally conducted education or training programs. For example:

• Agencies may use age-based admissions policies for education or training programs that have traditionally been age-specific.

• Agencies may use age-based admissions policies for education or training programs that must be age-limited for reasons related to health or national security.

• Agencies may rely on age when acting in accordance with laws designed

[9] *See* Equal Employment Opportunity Commission "Guidelines On Discrimination Because Of Religion," 29 CFR 1605.1.

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to provide special benefits or assistance to members of a particular age group, such as children or the elderly.

Examples of Prohibited Conduct:

• An executive agency conducts an education program through which it provides computer science training for high school graduates. The agency permits only individuals under the age of 30 to apply for, and participate in, the program. The agency's policy is based upon the belief that age can be used as an acceptable proxy for measuring an individual's likely long-term commitment to a career in computer science. The agency's policy would violate the Executive Order because age is not an accurate or acceptable measure of an individual's likely commitment to a long-term career in computer science.

• An executive agency operates a business development training program to train entrepreneurs starting new and novel businesses, The training program is only available to individuals under the age of 50. The agency claims that it uses this age requirement to measure characteristics, such as entrepreneurial ingenuity, that are essential to an individual's ability to start a novel business. The agency's conduct violates the Executive Order because age is not an accurate measure of entrepreneurial ingenuity—a characteristic which may be necessary to the achievement of an essential programmatic objective, but which is properly assessed on an individualized basis, such as by reviewing applicant business plans.

XII. Discrimination on the Basis of Sexual Orientation

Federal agencies must ensure that no individual is subjected to discrimination on the basis of his or her sexual orientation in any federally conducted education or training program or activity.

• "Sexual orientation" refers to heterosexuality, homosexuality, or bisexuality.

• Discrimination on the basis of sexual orientation includes discrimination on the basis of an individual's:

(i) Sexual orientation or perceived sexual orientation;

(ii) Relationship with an individual of a particular sexual orientation;

(iii) Affiliation with a group, including an employee or student organization, that is associated with sexual orientation issues or whose membership is composed largely of people of a particular sexual orientation.

• Federal agencies must ensure that all individuals involved in federally conducted education or training programs are treated without regard to sexual orientation.

• Federal agencies must ensure that no individual involved in a federally conducted education program is subjected to harassment based on his or her sexual orientation. Sexual orientation harassment may include slurs, epithets, unwelcome sexual advances, jokes, cartoons, or other derogatory behaviors that target individuals on the basis of sexual orientation and that are sufficiently severe, persistent, or pervasive to create a hostile educational environment.

Examples of Prohibited Conduct:

• A teacher in a Bureau of Indian Affairs federally conducted school is discharged on the basis of her sexual orientation. The discharge would violate the Executive Order.

• A student in a federally conducted school is harassed by his fellow students as a result of his perceived sexual orientation. The harassment causes him severe emotional distress and, as a result, his grades drop and he is often absent from school. The harassment creates a hostile educational environment, and the student notifies his teachers and the school principal. The failure of his teachers and the principal to investigate his claims and/or take appropriate corrective action would violate the Executive Order.

• A guidance counselor at a Department of Defense high school for the dependent children of military personnel refuses to permit a homosexual student to attend a training session on developing a career in business. The guidance counselor advises the student to consider a career as an interior decorator or a chef because she believes these professions are among the most suitable for gay men. The guidance counselor's conduct would violate the Executive Order.

• The internship coordinator at a federal agency refuses to select a heterosexual student as a summer intern because the student is being raised by two homosexual men. The coordinator's decision would violate the Executive Order.

• A federal agency holds an annual training retreat and invites the spouses or significant others of participating employees to accompany the group. However, when a homosexual employee arrives at the retreat with his partner, the retreat coordinator refuses to allow his partner to attend. The retreat coordinator's conduct violates the Executive Order.

XIII. Discrimination on the Basis of Status as a Parent

Federal agencies must ensure that no individual is discriminated against on the basis of his or her status as a parent in any federally conducted education or training program or activity.

• "Status as a Parent" refers to the status of any individual who, with respect to an individual who is under the age of 18 or who is 18 or older but is incapable of self-care because of a physical or mental disability, is:

(i) A biological parent;

(ii) An adoptive parent;

(iii) A foster parent;

(iv) A stepparent;

(v) A custodian of a legal ward;

(vi) In loco parentis over such an individual; or

(vii) Actively seeking legal custody or adoption of such an individual.

• The prohibition on discrimination based on status as a parent is designed to protect both men and women who become fathers and mothers through childbirth, foster parentage, adoption, legal guardianship, or marriage.

• Federal agencies may not rely on an individual's status as a parent in determining whether a person satisfies any policy or criterion for selection or admission to a federally conducted education program.

• Federal agencies may not rely on an individual's status as a parent in recruiting and/or selecting participants and instructors for federally conducted education programs.

• An individual may not be excluded from, denied the benefits of, or subjected to discrimination in any federally conducted education program as result of his or her perceived parental responsibilities.

Examples of prohibited conduct:

• The Admissions Committee for a summer training program operated by the Department of Health and Human Services refuses to admit mothers of young children because the committee members believe mothers should stay home and take care of their children. The Admissions Committee's conduct violates the Executive Order.

• The head of the French Department at the Department of Agriculture's Graduate Language Program twice passed over a single father with custody of two young children for promotion to a Senior Instructor position because she believed that the father would not be interested in a position with evening and weekend obligations due to his parental responsibilities. The failure to consider the father for promotion based upon his status as a parent violates the Executive Order.

• The Nuclear Regulatory Commission does not recruit graduate students with children for their Graduate Fellowship Program because the agency believes that the Graduate Fellowship Program is too rigorous for students with parental responsibilities. This recruitment practice constitutes discrimination on the basis of status as a parent and violates the Executive Order.

• An instructor for the VA Home Loan Training Program at the Department of Veterans Affairs is told by his supervisor that, if he proceeds to become a foster parent, he will not be eligible for a promotion to Senior Instructor because the new position will require too much travel. The instructor becomes a foster parent and is passed over for promotion as a result. The failure to consider the instructor for promotion based on his status as a foster parent violates the Executive Order.

• The Department of Justice is conducting a day-long training seminar for its employees and is planning to offer the course on three consecutive dates. Employees are assigned to dates alphabetically on the basis of their last names. One of the employees requests to take the training course on a different date as she is scheduled to attend a parent-teacher conference at her child's school. Although the training coordinator has honored other employee requests to switch dates, he refuses to grant the mother's request because he believes that she should prioritize work over her parental responsibilities. The training coordinator's conduct violates the Executive Order.

XIV. Administrative Enforcement

Section 4 provides for administrative enforcement of the antidiscrimination provisions of Executive Order 13160. General guidelines for administrative enforcement are discussed below. Before turning to these guidelines, however, it is important to address three preliminary matters.

First, Executive Order 13160 covers all individuals involved in federally conducted education and training programs. Although many such individuals are likely to be members of the general public, rather than federal employees, there will, of course, be many federal employees covered by the Executive Order by virtue of their employment-related participation in federally conducted educational programs. Such individuals, however, are already protected under a number of existing Equal Employment Opportunity (EEO) laws, regulations, and Executive Orders, including Title VII of the Civil Rights Act of 1964 (Title VII) (race, color, religion, sex, and national origin), sections 501 and 504 of the Rehabilitation Act (Sections 501 and 504) (disability), the Age Discrimination in Employment Act (ADEA) (age), the Equal Employment Opportunity Commission's Federal Sector Equal Employment Opportunity Regulations, 29 CFR 1614, and Executive Order 11478, as amended, (race, color, religion, sex, national origin, disability, age, sexual orientation, and status as a parent). Therefore, in order to promote the consistent and effective enforcement of equal employment opportunity mandates for all federal employees, and to preserve the integrity of statutorily protected equal employment opportunity rights, complaints filed under both this Executive Order and existing equal employment opportunity laws should be consolidated and adjudicated under the relevant equal employment opportunity statutes (*i.e.*, Title VII, sections 501/504, and/or the ADEA).[10] This approach will not only provide a streamlined procedure for resolving complaints, but will also protect an aggrieved employee's opportunity to recover any monetary damages that are available under the EEO statutes but not under this Executive Order.

As a practical matter, this means that a federal employee seeking to file a complaint under this Executive Order must indicate whether the complaint is related to his or her employment [11] and, if so, whether he or she has filed any other EEO claims arising out of the same circumstances. If so, the complaint filed under this Executive Order should be transferred to the office handling the related claim and the enforcement procedures set forth below will be deemed inapplicable. If a federal employee chooses to proceed solely under this Executive Order, the enforcement procedures set forth below will govern the disposition of his or her complaint.[12]

If a federal employee indicates that he or she has not filed any other EEO claims at the time of filing a complaint under this Executive Order, the employee may nevertheless subsequently elect to file a related claim under Title VII, section 504, the ADEA, or Executive Order 11478, provided the employee follows the appropriate EEO filing procedures and contacts an EEO counselor and files a complaint within the relevant statutory time limit. In such cases, the employee should notify the investigating office that he or she has decided to contact an EEO counselor and file a related EEO claim so that the Executive Order 13160 complaint may be transferred to the appropriate office as provided for above. Federal agencies must ensure that all federal employees filing Executive Order 13160 complaints have adequate notice that they should advise the investigating office handling the Executive Order 13160 complaint if they decide to pursue their claims through the EEO process.

Second, the enforcement procedures set forth below are designed solely to provide general guidance. Under Section 5–502 of the Executive Order, all executive departments and agencies must establish procedures to receive and review complaints within 90 days of January 18, 2001. As all executive departments and agencies already have procedures in place for adjudicating claims regarding federally conducted programs under Section 504 of the Rehabilitation Act, it is recommended that agencies consider utilizing the same investigative and adjudicative offices for handling complaints under Executive Order 13160. However, agencies are of course free to develop different procedures and to supplement or modify the following enforcement procedures as appropriate.

Third, after developing individual procedures to receive and review complaints, each executive department and agency should prepare some sort of outreach materials to ensure that all individuals involved in federally conducted education and training programs are aware of Executive Order 13160 and are advised as to the proper procedures for filing complaints. These outreach materials should provide individuals with specific information, including, but not limited to, the general antidiscrimination mandates of Executive Order 13160, details regarding how to obtain copies of this Guidance Document, timelines for filing complaints, the name(s) and address(es) of the office(s) to which such complaints should be sent, and specific procedures established by the relevant federal agency regarding the processing of complaints.

All executive departments and agencies should further ensure that these outreach materials provide clear instructions to federal employees regarding their respective rights under Executive Order 13160 and Title VII, sections 501/504, the ADEA, and Executive Order 11478. Specifically, these outreach materials should clearly state the differing timelines for filing claims under the Executive Order and

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[10] In cases where a complaint raises claims under both Executive Order 13160 and Executive Order 11478 (but does not raise statutory claims), the appropriate complaint processing procedures will depend upon whether the federal agency conducting the education program has an existing complaint process for handling claims filed under Executive Order 11478. If a federal agency has complaint procedures for claims filed under Executive Order 11478, claims filed under both Executive Order 13160 and Executive Order 11478 may be consolidated and adjudicated under Executive Order 11478. If a federal agency does not have a complaint procedure for claims arising under Executive Order 11478, and a complaint alleges a violation of Executive Order 13160 and Executive Order 11478 (but does not raise any statutory claims), the complaint should be processed in accordance with the procedures for Executive Order 13160 set forth below. If a complainant raises claims under Executive Order 13160, Executive Order 11478, and an EEO statute, the complaint should be consolidated and adjudicated under the relevant EEO processes.

[11] Federal employees participating as members of the general public in a federally conducted education program will, of course, be subject to the same enforcement procedures as outside participants.

[12] For instance, the enforcement procedures set forth in this Guidance Document may govern the resolution of a complaint filed by an employee involved in a training program conducted by a federal agency other than the federal agency for whom the employee works. For example, if an employee of the Department of Justice participates in a training course conducted by the Department of Education, the employee may choose to file an Executive Order 13160 claim directly against the Department of Education if he or she chooses not to, or is not able to, invoke existing EEO laws and regulations at the Department of Justice.

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these three statutes, as well as the availability (or unavailability) of different remedies. As discussed above, federal employees should also be clearly advised that claims filed under both the Executive Order and an equal employment opportunity statute will be adjudicated only under the relevant statute (or under Executive Order 11478, if an agency has existing procedures for receiving such complaints).

The development of these outreach materials should ensure that all individuals receive adequate notice of their rights under Executive Order 13160. These materials will also serve to ensure that individuals participating in federally conducted education and training programs are properly advised as to the appropriate procedures for filing complaints. Finally, these materials should assist in clarifying questions federal employees may have regarding the ramifications of filing a complaint under Executive Order 13160 versus filing a complaint under Title VII, sections 501/504, the ADEA, or Executive Order 11478.

A. Definitions

For purposes of this Guidance Document, the term—

Appropriate agency official means the officer or officers within an executive department or agency designated to determine what, if any, disciplinary action, remedial action, or corrective action should be taken as a result of a violation of the Executive Order.

Complete complaint means a written statement that contains the complainant's name, address, and phone number, describes the agency's alleged discriminatory action in sufficient detail to inform the agency of the nature and approximate date of the alleged violation, and identifies whether the complainant is an employee of the agency alleged to have committed the discrimination and whether the complainant's involvement in the relevant education or training program was related to his or her employment. A complete complaint must be signed by the complainant or by someone authorized by the complainant to sign on his or her behalf.

Investigating office means the office or offices within an executive department or agency that are designated to investigate complaints regarding violations of this Order or its implementing rules, regulations, policies, or guidance.

Respondent means the organizational unit in which the alleged discrimination occurred.

B. Filing a Complaint

Any individual who believes himself or herself to be aggrieved by a violation of Executive Order 13160 or its implementing regulations, rules, policies or guidance, including this Guidance Document, may, personally or through a representative, file a written complaint with the agency that he or she believes is in violation of this Order or any of its implementing regulations, rules, policies, or guidance. All written complaints should be filed with the appropriate Investigating Office as designated by the relevant agency.

1. Complete Complaints

In order to be accepted by an agency's Investigating Office, all written complaints must be "complete complaints." As defined above, a complete complaint must include the name, address, and phone number of the complainant, must identify whether the complainant is a federal employee and whether the complainant's involvement in the relevant education program was related to his or her employment, and must describe the alleged discriminatory conduct in sufficient detail to inform the agency as to the nature and approximate date of the alleged violation. A complete complaint also must be signed by the complainant or by someone authorized by the complainant to sign on his or her behalf.

2. Time Limits for Filing Complaints

As a general matter, all complaints must be filed within 180 days of the alleged discrimination. However, the appropriate Investigating Office may extend this time limit:

(a) If the complainant can demonstrate that he or she had no notice of the time limit and was not otherwise aware of it; or

(b) If the complainant can demonstrate that he or she was prevented by circumstances beyond his or her control from submitting the complaint in a timely fashion; or

(c) For other reasons, or under other circumstances, considered sufficient by the agency.

For purposes of determining when a complaint is timely filed, a complaint mailed to the agency will be deemed filed on the date that it is postmarked. Any other complaint will be deemed filed on the date that it is received by the appropriate Investigative Office, by any agency supervisor, or by any other agency employee designated by the agency to receive such complaints.

If a complaint is filed within 180 days of the alleged discrimination, but the agency subsequently determines that the complaint is not a "complete complaint," the complainant's claims shall nevertheless be deemed filed in a timely manner, and the complainant shall be given an appropriate opportunity to amend his or her original complaint. *See* Section C below for further information regarding the process for requesting additional information from a complainant in order to supplement an incomplete complaint.

3. Class Complaints

Any individual who believes that any specific class of persons has been subjected to discrimination prohibited by Executive Order 13160 or any of its implementing regulations, rules, policies, or guidance, including this Guidance Document, may file a class complaint with the appropriate Investigative Office, provided that individual is either a member of the allegedly aggrieved class of persons or a representative of a member of the allegedly aggrieved class of persons. Each executive department or agency should develop specific procedures to deal with the resolution of class complaints.

4. Legal Representation

Any individual filing a complaint under Executive Order 13160 or any of its implementing regulations, rules, policies, or guidance may be represented and assisted in all stages of these proceedings by an attorney or representative of his or her own choosing. An individual has a responsibility to promptly inform the agency if legal counsel is retained. In addition, an individual has an obligation to notify the appropriate Investigating Office if he or she wishes to have any other representative included in these proceedings. It is the responsibility of the complainant to provide the appropriate Investigating Office with the name, address, and phone number of any attorney or other representative. In addition, it is an ongoing responsibility of the complainant to advise the appropriate Investigating Office as to any changes with respect to the status of his or her legal and/or non-legal representation in any proceeding under this Executive Order or any of its implementing regulations, rules, policies, or guidance. Each federal agency has a duty to ensure that all complainants have adequate notice of these obligations.

C. Initial Review by the Investigating Office

Upon receipt of a complaint filed under this Executive Order, the investigating office must assess the complaint and determine how to proceed. The investigating office should

specifically consider whether the complaint is a complete complaint, whether it was filed in a timely manner, and, in the case of a federal employee, whether the complaint should be consolidated with another complaint and transferred, if necessary.

After reviewing the complaint, the investigating office may need to obtain additional information from the complainant. For example, the investigating office may ask the complainant to supply additional information if the complaint is not complete. Additional information also may be required by the investigating office to determine whether to waive the time limits for filing a complaint or whether to consolidate and transfer a federal employee's claim. If a complainant fails to provide additional information, or otherwise respond to the investigating office's request, within 30 days, without good cause shown, the investigating office may dismiss the complaint.

In certain instances, the investigating office may determine that a complaint should be dismissed because the alleged discriminatory conduct did not occur in a federally conducted education or training program. In such cases, the investigating office should issue a brief written determination setting forth the basis for the dismissal and advising the complainant of his or her right to appeal this decision to the Attorney General for a final determination regarding coverage pursuant to Section 2–203 of the Executive Order. Responsibility for issuing such final determinations regarding coverage is delegated to the Assistant Attorney General for Civil Rights, who shall conduct, handle, or supervise the performance of this function.

D. Informal Resolution or Formal Investigation

Before undertaking a formal investigation, agencies are strongly encouraged to pursue resolution of all complaints filed under this Executive Order through efforts to achieve voluntary compliance. Toward this end, agencies should make use of alternative dispute resolution techniques whenever appropriate.

If an informal resolution of a complaint between a complainant and respondent cannot be reached within a reasonable period of time (generally 45 days), or if efforts to achieve an informal resolution appear to become futile, the investigating office should initiate a formal investigation. However, efforts to achieve voluntary compliance should be undertaken whenever possible and should continue throughout the course of a formal investigation if and when appropriate opportunities arise.

If a decision is made to initiate a formal investigation, the investigating office must notify the complainant in writing. The investigating office should attempt to complete the investigation within 180 days of the agency's receipt of a complete complaint. The investigation should include a thorough review of the circumstances under which the alleged discrimination occurred and any other circumstances which may constitute, or appear to constitute, discrimination against the complainant.

A formal investigation may require the cooperation and participation of other agency employees. Employees who are required by the investigating office to participate in any investigation concerning violations of this Executive Order will do so as part of their official duties and during the course of regular working hours.

Upon completion of a formal investigation, the investigating office must prepare a written report setting forth the results of the investigation. If a determination is made that any agency employee has not complied with the Executive Order or any of its implementing rules, regulations, policies, or guidance, Section 4–402 requires the investigating office to complete a report and refer a copy of the report and any relevant findings or supporting evidence to the appropriate agency official. The investigating office also may make recommendations for any corrective and/or remedial action. A copy of the investigative report should be sent to both the complainant and the respondent, including the employee who is the subject of the report.

If a determination is made that there has been no violation of the Executive Order or any of its implementing rules, regulations, policies, or guidance, a copy of the report also shall be sent to both the complainant and the respondent. In such cases, although no action is required, a copy of the report should nevertheless be sent to the appropriate agency official.

E. Referral to the Appropriate Agency Official

Upon receipt of a report from an investigating office that indicates there has been a violation of the Executive Order or its implementing rules, regulations, policies, or guidance, the appropriate agency official shall review the report and all relevant supporting material in order to determine what, if any, disciplinary action is appropriate. Any action taken to discipline an employee, including removal, must be taken in compliance with otherwise applicable procedures, including the Civil Service Reform Act of 1978, Public Law No. 95–454, 92 Stat. 1111.

The appropriate agency official also shall review the report of the investigating office in order to determine whether any corrective or remedial action should be initiated. Pursuant to Section 4–402(b), however, nothing in the Executive Order authorizes monetary relief to the complainant as a form of remedial or corrective action. If the appropriate agency official does determine that the complainant is entitled to some form of remedial or corrective action, the appropriate agency official shall so notify the complainant in writing. The appropriate agency official also shall take all necessary steps to ensure that the corrective or remedial action ordered is implemented. If a determination is made that the complainant is not entitled to any corrective or remedial action, the appropriate agency official shall notify the complainant of this decision and the reasons for this determination.

Although agencies are free to designate any employee as the appropriate agency official, agencies should bear in mind that section 5–503 provides that the head of each executive department or agency shall be responsible for ensuring compliance with the Executive Order. As such, agencies should consider designating a senior level official for this important post.

XV. Remedies

As discussed above, in addition to making final decisions regarding disciplinary measures, the appropriate agency official shall have the authority to order corrective and/or remedial action, where appropriate. As a general matter, if there has been a violation of the Executive Order, the complainant shall be entitled to all appropriate, non-monetary, equitable relief. The appropriate agency official should attempt to ensure that the aggrieved individual ends up in the same position he or she would have occupied absent discrimination, or a substantially equivalent position. In the context of violations of this Executive Order, specific remedies are likely to include placement in the next available education or training program of a comparable nature; the development of an individualized training opportunity; the cancellation of an unwarranted personnel action or the expungement of adverse materials from agency records; the awarding of a diploma, other certificate, or specific grade; and the

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provision of reasonable accommodations.

Federal agencies must ensure that appropriate agency officials are accorded sufficient authority to provide all appropriate forms of relief. Complainants should be aware, though, that Section 8 of the Executive Order specifically provides that the Order "is not intended, and should not be construed, to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or its employees." Section 8 further provides, however, that the Order is not intended "to preclude judicial review of final decisions in accordance with the Administrative Procedures Act, 5 U.S.C. 701, *et seq.*"

XVI. Reporting Requirements

Section 6 of the Executive Order establishes reporting requirements for federal agencies. For the first three years following issuance of this Executive Order, all federal agencies shall file annual reports with the Attorney General that summarize the number, nature, and disposition of complaints filed under the Executive Order. Such reports are to be submitted to the Assistant Attorney General for Civil Rights within 90 days of the end of the preceding year's activities. Subsequent reports are to be submitted every three years and within 90 days of the end of each three year period.

XVII. Conclusion

As discussed above, this Guidance Document is intended to provide executive departments and agencies with a basic framework for ensuring compliance with Executive Order 13160. Pursuant to Section 5–502 of the Executive Order, each agency has 90 days from January 18, 2001 to establish procedures for receiving and addressing complaints. Each agency also shall take "all necessary steps" to effectuate any subsequent rules, regulations, policies, or guidance issued by the Attorney General or the Assistant Attorney General for Civil Rights in connection with this Executive Order within 90 days of issuance.

The mandate of Executive Order 13160 is clear: to ensure that all individuals, on the basis of race, sex, color, national origin, disability, religion, age, sexual orientation, and status as a parent, have an equal opportunity to participate in, enjoy the benefits of, and be free from discrimination in, federally conducted education and training programs. Federal agencies should strive to achieve these objectives to the fullest extent possible and are encouraged to use this Guidance Document as a starting point for achieving these important goals.

[FR Doc. 01–1494 Filed 1–17–01; 8:45 am]
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Federal Register

Thursday,
January 18, 2001

Part XV

Department of Justice

Guidance Concerning Redistricting and Retrogression Under Section 5 of the Voting Rights Act, 42 U.S.C. 1973c; Notice

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DEPARTMENT OF JUSTICE

Office of the Assistant Attorney General, Civil Rights Division; Guidance Concerning Redistricting and Retrogression Under Section 5 of the Voting Rights Act, 42 U.S.C. 1973c

AGENCY: Department of Justice.

ACTION: Notice.

SUMMARY: The Attorney General has delegated responsibility and authority for determinations under Section 5 of the Voting Rights Act to the Assistant Attorney General, Civil Rights Division, who finds that, in view of recent judicial decisions, it is appropriate to issue guidance concerning the review of redistricting plans submitted to the Attorney General for preclearance pursuant to Section 5 of the Voting Rights Act.

FOR FURTHER INFORMATION CONTACT: Joseph D. Rich, Acting Chief, Voting Section, Civil Rights Division, United States Department of Justice, Washington, D.C. 20530, (202) 514–6018.

SUPPLEMENTARY INFORMATION: Section 5 of the Voting Rights Act of 1965, 42 U.S.C. 1973c, requires jurisdictions covered by the Act's special provisions to obtain a determination from either the Attorney General or the United States District Court for the District of Columbia that any change affecting voting, which they seek to enforce, does not have a discriminatory purpose and will not have a discriminatory effect.

Beginning in April 2001, these jurisdictions will begin to seek preclearance of redistricting plans based on the 2000 Census. Based on past experience, the overwhelming majority of the covered jurisdiction will submit their redistricting plan to the Attorney General. As part of the Department's preparation for the upcoming redistricting cycle, Departmental representatives conducted a nation-wide outreach campaign to inform as many of the interested parties as possible of the manner in which it will analyze redistricting plans under section 5. Many of the contacts, both governmental entities and interested private citizens and groups, expressed the view that, in view of recent judicial decisions, it would be helpful for the Department to issue some general guidance in this area. These requests coincided with the Attorney General's view that, by identifying, in general terms, the Department's analytical approach, such guidance would serve a useful law enforcement purpose. This guidance is not legally binding; rather, it is intended only to provide assistance to entities and persons affected by the preclearance requirements of section 5. Approved OMB No. 1190–001 (expires December 31, 2001).

Guidance Concerning Redistricting and Retrogression Under Section 5 of the Voting Rights Act, as Amended, 42 U.S.C. 1973c

Following release of the 2000 Census data, the Department of Justice expects to receive several thousand submissions of redistricting plans pursuant to the preclearance provisions in Section 5 of the Voting Rights Act, 42 U.S.C. 1973c. The Civil Rights Division has received numerous requests for guidance concerning the procedures and standards that will be applied during review of these redistricting plans. Many of the requests relate to the role of the 2000 Census data in the Section 5 review process and to the Supreme Court's decisions in *Shaw* v. *Reno*, 509 U.S. 630 (1993), and later related cases.

The "Procedures for the Administration of Section 5 of the Voting Rights Act," 28 CFR Part 51, provide detailed information about the Section 5 review process. Copies of these Procedures are available upon request and through the Voting Section Web Site (*http://www.usdoj.gov/crt/voting*). This document is meant to provide additional guidance with regard to current issues of interest. Citations to judicial decisions are provided to assist the reader but are not intended to be comprehensive. The following discussion provides supplemental guidance concerning the following topics:

- The scope of Section 5 review;
- The Section 5 "benchmark";
- how the benchmark plan is compared with the proposed plan;
- The considerations leading to the decision to interpose a Section 5 retrogression objection;
- racially discriminatory purpose under Section 5; and
- The use of 2000 Census data and other information during Section 5 review.

The Scope of Section 5

The Supreme Court has held that under Section 5, a covered jurisdiction has the burden of establishing that a proposed redistricting plan does not have the purpose or effect of worsening the position of minority voters when compared to that jurisdiction's "benchmark" plan. *Reno* v. *Bossier Parish School Board*, 120 S. Ct. 866, 871–72 (2000). If the jurisdiction fails to show the absence of such purpose or effect, then Section 5 preclearance will be denied by the Department of Justice or the District Court for the District of Columbia.

The decision in the *Bossier Parish School Board* case addressed the scope of Section 5 review. Redistricting plans that are not retrogressive in purpose or effect must be precleared, even if they violate other provisions of the Voting Rights Act or the Constitution. The Department of Justice may not deny Section 5 preclearance on the grounds that a redistricting plan violates the one-person one-vote principle, on the grounds that it violates *Shaw* v. *Reno*, or on the grounds that it violates Section 2 of the Voting Rights Act. Therefore, jurisdictions should not regard Section 5 preclearance of a redistricting plan as preventing subsequent legal challenges to that plan by the Department of Justice. In addition, private plaintiffs may initiate litigation, claiming either constitutional or statutory violations.

Benchmark Plans

The last legally enforceable redistricting plan in force for a Section 5 covered jurisdiction is the "benchmark" against which a new plan is compared. *See* 28 CFR 51.54(b)(1). Generally, the most recent plan to have received Section 5 preclearance (or have been drawn by a federal court) is the last legally enforceable redistricting plan for Section 5 purposes. When a jurisdiction has received Section 5 preclearance for a new redistricting plan, or a federal court has drawn a new plan and ordered it into effect, that plan replaces the last legally enforceable plan as the Section 5 benchmark. *See McDaniel* v. *Sanchez*, 452 U.S. 130 (1981); *Texas* v. *United States*, 785 F. Supp. 201 (D.D.C. 1992); *Mississippi* v. *Smith*, 541 F. Supp. 1329, 1333 (D.D.C. 1982), appeal dismissed, 461 U.S. 912 (1983).

In *Abrams* v. *Johnson*, 521 U.S. 74 (1997), the Supreme Court held that a redistricting plan found to be unconstitutional under the principles of *Shaw* v. *Reno* and its progeny could not serve as the Section 5 benchmark. Therefore, a redistricting plan drawn to replace a plan found by a federal court to violate *Shaw* v. *Reno* will be compared with the last legally enforceable plan predating the unconstitutional plan. Absent such a finding of unconstitutionality under *Shaw* by a federal court, the last legally enforceable plan will serve as the benchmark for Section 5 review. Therefore, a jurisdiction is not required to address the constitutionality of its benchmark plan when submitting a redistricting plan and the question of whether the benchmark plan is constitutional will not be considered during the Department's Section 5 review.

Comparison of Plans

When the Department of Justice receives a Section 5 redistricting submission, several basic steps are taken to ensure a complete review. After the "benchmark" districting plan is identified, the staff inputs the boundaries of the benchmark and proposed plans into the Civil Rights Division's geographic information system. Then, using the most recent decennial census data, population data are calculated for each of the districts in the benchmark and proposed plans.

Division staff then analyzes the proposed plan to determine whether it will reduce minority voting strength when compared to the benchmark plan, considering all of the relevant, available information. Although comparison of the census population of districts in the benchmark and proposed plans is the important starting point of any retrogression analysis, our review and analysis will be greatly facilitated by inclusion of additional demographic and election data in the submission. *See* 28 CFR 51.28(a). For example, census population data may not reflect significant differences in group voting behavior.[1] Therefore, election history and voting patterns within the jurisdiction, voter registration and turnout information, and other similar information are very important to an assessment of the actual effect of a redistricting plan. This information is used to compare minority voting strength in the benchmark plan as a whole with minority voting strength in the proposed plan as a whole.

The Section 5 Procedures identify a number of factors that are considered in deciding whether or not a redistricting plan has a retrogressive purpose or effect. These factors include whether minority voting strength is reduced by the proposed redistricting; whether minority concentrations are fragmented among different districts; whether minorities are overconcentrated in one or more districts; whether available alternative plans satisfying the jurisdiction's legitimate governmental interests were considered; whether the proposed plan departs from objective redistricting criteria set by the submitting jurisdiction, ignores other relevant factors such as compactness and contiguity, or displays a configuration that inexplicably disregards available natural or artificial boundaries; and, whether the plan is inconsistent with the jurisdiction's stated redistricting standards. *See* 28 CFR 51.59; *see also* 28 CFR 51.56–51.58.

A proposed plan is retrogressive under the Section 5 "effect" prong if its net effect would be to reduce minority voters' "effective exercise of the electoral franchise" when compared to the benchmark plan. *See Beer* v. *United States*, 425 U.S. 130, 141 (1976). The effective exercise of the electoral franchise usually is assessed in redistricting submissions in terms of the opportunity for minority voters to elect candidates of their choice. The presence of racially polarized voting is an important factor considered by the Department of Justice in assessing minority voting strength. A proposed redistricting plan ordinarily will occasion an objection by the Department of Justice if the plan reduces minority voting strength relative to the benchmark plan and a fairly-drawn alternative plan could ameliorate or prevent that retrogression.

Alternatives to Retrogressive Plans

If a retrogressive redistricting plan is submitted, the jurisdiction seeking preclearance of such a plan bears the burden of demonstrating that a less-retrogressive plan cannot reasonably be drawn. In analyzing this issue, the Department takes into account constitutional principles as discussed below, the residential segregation and distribution of the minority population within the jurisdiction, demographic changes since the previous redistricting, the physical geography of the jurisdiction, the jurisdiction's historical redistricting practices, political boundaries such as cities and counties, and state redistricting requirements.

In considering whether less-retrogressive alternative plans are available, the Department of Justice looks to plans that were actually considered or drawn by the submitting jurisdiction, as well as alternative plans presented or made known to the submitting jurisdiction by interested citizens or others. In addition, the Department may develop illustrative alternative plans for use in its analysis, taking into consideration the jurisdiction's redistricting principles. If it is determined that a reasonable alternative plan exists that is non-retrogressive or less retrogressive than the submitted plan, the Department will interpose an objection.

Preventing retrogression under Section 5 does not require jurisdictions to violate the one-person one-vote principle. *See* 52 FR 488 (Jan. 6, 1987). Similarly, preventing retrogression under Section 5 does not require jurisdictions to violate *Shaw* v. *Reno* and related cases.

The one-person one-vote issue arises most commonly where substantial demographic changes have occurred in some, but not all, parts of a jurisdiction. Generally, a plan for congressional redistricting that would require a greater overall population deviation than the submitted plan is not considered a reasonable alternative by the Department. For state legislative and local redistricting, a plan that would require overall population deviations greater than 10 percent is not considered a reasonable alternative.

In assessing whether a less retrogressive alternative plan can reasonably be drawn, the geographic compactness of a jurisdiction's minority population will be a factor in the Department's analysis. This analysis will include a review of the submitting jurisdiction's historical redistricting practices and district configurations to determine whether the alternative plan would (a) abandon those practices and (b) require highly unusual features to link together widely separated minority concentrations.

At the same time, compliance with Section 5 of the Voting Rights Act may require the jurisdiction to depart from strict adherence to certain of its redistricting criteria. For example, criteria which require the jurisdiction to make the least change to existing district boundaries, follow county, city, or precinct boundaries, protect incumbents, preserve partisan balance, or in some cases, require a certain level of compactness of district boundaries may need to give way to some degree to avoid retrogression. In evaluating alternative plans, the Department of Justice relies upon plans that make the least departure from a jurisdiction's stated redistricting criteria needed to prevent retrogression.

Prohibited Purpose

In those instances in which a plan is found to have a retrogressive effect, as well as in those cases in which a proposed plan is alleged to have a retrogressive effect but a functional analysis does not yield clear conclusions about the plan's effect, the Department of Justice will closely examine the process by which the plan

[1] For example, within a particular jurisdiction there may be large differences between the rates of turnout among minority populations in different areas. Thus, a redistricting plan may result in a significant, objectionable reduction of effective minority voting strength if it changes district boundaries to substitute poorly-participating minority populations (for example, migrant worker housing or institutional populations) for active minority voters, even though the minority percentages for the benchmark and proposed plans are similar when measured by Census population data.

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was adopted to ascertain whether the plan was intended to reduce minority voting strength. This examination may include consideration of whether there is a purpose to retrogress in the future even though there is no retrogression at the time of the submission. If the jurisdiction has not provided sufficient evidence to demonstrate that the plan was not intended to reduce minority voting strength, either now or in the future, the proposed redistricting plan is subject to a Section 5 objection.

The 2000 Census

The most current population data are used to measure both the benchmark plan and the proposed redistricting plan. *See* 28 CFR 51.54(b)(2) (Department of Justice considers "the conditions existing at the time of the submission."); *City of Rome* v. *United States*, 446 U.S. 156, 186 (1980) ("most current available population data" to be used for measuring effect of annexations); *Reno* v. *Bossier Parish School Board*, 120 S. Ct. at 874 ("In § 5 preclearance proceedings * * * the baseline is the status quo that is proposed to be changed: If the change 'abridges the right to vote' relative to the status quo, preclearance is denied * * *").

For redistricting after the 2000 Census, the Department of Justice will, consistent with past practice, evaluate redistricting submissions using the 2000 Census population data released by the Bureau of the Census for redistricting pursuant to Public Law 94–171, 13 U.S.C. 141(c). Thus, our analysis of the effect of proposed redistricting plans includes a review and assessment of the Public Law 94–171 population data, even if those data are not included in the submission or were not used by the jurisdiction in drawing the plan. The failure to use the Public Law 94–171 population data in redistricting does not, by itself, constitute a reason for denial of preclearance. However, unless other population data can be shown to be more accurate and reliable than the Public Law 94–171 data, the Department of Justice will consider the Public Law 94–171 data to measure the total population and voting age population within a jurisdiction for purposes of its Section 5 analysis.

The 2000 Census Public Law 94–171 data for the first time will include counts of persons who have identified themselves as members of more than one racial category. This decision reflects the October 30, 1997 decision by the Office of Management and Budget [OMB] to incorporate multiple-race reporting into the federal statistical system. *See* 62 FR 58782–58790. On March 9, 2000, OMB issued Bulletin No. 00–02 addressing "Guidance on Aggregation and Allocation of Data on Race for Use in Civil Rights Enforcement." Part II of that Bulletin describes how such responses will be allocated for use in civil rights monitoring and enforcement.

For voting rights enforcement purposes, the Department of Justice will be guided by Part II of the Bulletin in its use of Census data. The following is an example, based on the data from the 1998 Dress Rehearsal Census in Columbia, South Carolina, of how such data will be allocated by the Department when analyzing redistricting submissions.

Total population	662,140	
Non-Hispanic	649,413	(98.1%)
White	374,291	(56.5%)
Black or African American	262,384	(39.6%)
Asian	6,161	(0.9%)
American Indian/Alaska Native	2,995	(0.5%)
Native Hawaiian or Other Pacific Uslander	375	(0.0%)
Some other race	882	(0.1%)
Other Multiple-Race (where more than one minority race is listed)	2,330	(0.4%)
Hispanic	12,727	(1.9%)

Pursuant to Part II of OMB Bulletin 00–02, any multiple-race response that included white and one of the five other race categories was allocated to the minority race listed in the response. Thus, the numbers above for Black/African American, Asian, American Indian/Alaska Native, Native Hawaiian or Other Pacific Islander and Some other race reflect the total of the single race responses and the multiple-race responses in which the minority race and white race were listed. For example, for the Black/African American category, there were 261,142 single race responses and 1,242 multiple-race responses in which the races listed were White and Black/African American. This adds up to the total calculated above of 262,384.

The Other Multiple-Race category is comprised of all multiple-race responses where there is more than one minority race listed. The number above (2,330) reflects the total number of responses of forty two such categories in the Columbia data where at least one response was indicated. In our analysis, we will examine this multiple-race data and if it appears that any one of these categories has significant numbers of responses (for example, if the Black/African American and American Indian/Alaska Native category, alone, indicates a significant number of responses), those responses will be allocated alternatively to each of the component single-race categories for analysis, as indicated in Part II of the OMB Bulletin. It is important to note that current research indicates that multiple-race responses are expected to be small. This is especially true with respect to multiple-race categories with two or more minority races. For example, in the Columbia data, the largest such groups are only 0.1 percent (American Indian/Alaska Native and Black/African/American; and Asian and Black/African American). In light of this, the impact of such multiple-race responses on the Department of Justice's analysis of census data pursuant to its responsibilities under the Voting Rights Act is expected to be minimal.

As in the past, the Department will analyze Hispanic voters as a separate group for purposes of enforcement of the Voting Rights Act. If there are significant numbers of responses which report Hispanics and one or more minority races (for example, Hispanics who list their race as Black/African-American), those responses will be allocated alternatively to the Hispanic category and the minority race category.

Dated: January 11, 2001.

Bill Lann Lee,

Assistant Attorney General, Civil Rights Division.

[FR Doc. 01–1488 Filed 1–17–01; 8:45 am]

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January 18, 2001

Part XVI

The President

Proclamation 7390—Martin Luther King, Jr., Federal Holiday, 2001

Executive Order 13188—Amendment to Executive Order 13111, Extension of the Advisory Committee on Expanding Training Opportunities

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Presidential Documents

Title 3—

The President

Proclamation 7390 of January 12, 2001

Martin Luther King, Jr., Federal Holiday, 2001

By the President of the United States of America

A Proclamation

Seventy-two years ago, Martin Luther King, Jr., was born into a sharply divided Nation, a place where the color of a child's skin too often determined that child's destiny. America was a place where segregation and discrimination put limits on a black child's dreams, opportunities, and future.

Dr. King led America to a better place. With eloquence, he articulated the struggles and hopes of generations of African Americans. With the power of his leadership, he rallied Americans of every race and creed to join together in the march for justice. With courage, conviction, and faith in God, he sought to make real in everyday practice—in schools, in the workplace, in public accommodations, and in the hearts and minds of his fellow citizens—the civil rights victories that had been won in the courts.

Although his life was cruelly cut short before his mission was complete, he helped put our Nation firmly on the right path, where the ideals of liberty, equality, brotherhood, and justice are not merely words on a page, but values honored by all. "Our freedom was not won a century ago," he said in 1968, "it is not won today; but some small part of it is in our hands, and we are marching no longer by ones and twos but in legions of thousands, convinced now it cannot be denied by any human force."

It is up to each of us to continue that march. The gallant freedom riders and freedom fighters of the civil rights era are growing older, and many, like Martin Luther King, Jr., are no longer among us. But their work must go on. There are still too many in our Nation who do not share equally in America's prosperity; minority unemployment and poverty rates, while decreasing, are still far above the national average; and the technical skills and resources needed for success in the global economy are still out of reach for hundreds of thousands of young Americans growing up in disadvantaged communities.

I encourage my fellow Americans to use this holiday, dedicated to the memory of Dr. Martin Luther King, Jr., and to his spirit of service, not as a day off, but rather as a day to make a difference in the lives of others—an opportunity to recognize where we have fallen short, to reach out to those who have been left behind, and to remove the barriers that keep us from becoming the promised land that Dr. King envisioned.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Monday, January 15, 2001, as the Martin Luther King, Jr., Federal Holiday. I call upon all Americans to observe this occasion with appropriate programs, ceremonies, and activities in honor of Dr. King's life and achievements and in response to his call to service.

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IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

[FR Doc. 01–1735
Filed 1–17–01; 8:45 am]
Billing code 3195–01–P

Presidential Documents

Executive Order 13188 of January 12, 2001

Amendment to Executive Order 13111, Extension of the Advisory Committee on Expanding Training Opportunities

By the authority vested in me as President by the Constitution and the laws of the United States, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and in order to extend the Advisory Committee on Expanding Training Opportunities for 2 years, it is hereby ordered that section 7(f) of Executive Order 13111 of January 12, 1999, is amended by deleting "2 years from the date of this order" and inserting "on January 11, 2003" in lieu thereof.

William J. Clinton

THE WHITE HOUSE,
January 12, 2001.

[FR Doc. 01–1736
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Title 3—

The President

Executive Order 13189 of January 15, 2001

Federal Interagency Task Force on the District of Columbia

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to further the revitalization of, and to improve prospects for the success of "home rule" in the District of Columbia, the Nation's Capital, it is hereby ordered as follows:

Section 1. *Background and Policy.* The District of Columbia is the Nation's Capital, and the Federal Government is the largest employer, landholder, and purchaser in the region. The Executive Office of the President has established and maintained an interest in fostering the Federal relationship with the District of Columbia since 1963. This Administration has long sought to strengthen the relationship between the Federal Government and the District of Columbia by initiating a historic restructuring of this relationship. At the request of the President, in 1995, the Federal D.C. Interagency Task Force, chaired by the Director of the Office of Management and Budget, and directed by the Special Advisor to the President and Executive Director of the Federal D.C. Interagency Task Force, was created to revitalize the District of Columbia and improve prospects for "home rule" to succeed in the Nation's Capital. The Federal D.C. Interagency Task Force Office has worked with Federal agencies, the Congress, and local officials to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia. In 1997, the President signed into law the National Capital Revitalization and Self-Government Improvement Act of 1997, under which the Federal Government undertook certain responsibilities and governmental functions befitting a State or county government. Also in 1997, the President signed into law tax incentives designed to spur economic growth in the District of Columbia.

It is the policy of this Administration, therefore, to build on the momentum of the accomplishments over the last 5 years by formally establishing the Federal D.C. Interagency Task Force to further assist the District of Columbia in achieving financial stability, economic growth, and improvement in management and service delivery.

Sec. 2. *Establishment of the Federal Interagency Task Force on the District of Columbia.*

(a) There is established the "Federal Interagency Task Force on the District of Columbia" (Task Force).

(b) The Task Force shall be composed of the following members:

(1) The Attorney General;

(2) The Secretary of Housing and Urban Development;

(3) The Secretary of Health and Human Services;

(4) The Secretary of Labor;

(5) The Secretary of Transportation;

(6) The Secretary of the Treasury;

(7) The Administrator of General Services;

(8) The Secretary of Education;

(9) The Secretary of the Interior;

(10) The Administrator of the Environmental Protection Agency;

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(11) The Secretary of Commerce;

(12) The Secretary of Agriculture;

(13) The Director of the Office of Management and Budget;

(14) The Administrator of the Small Business Administration;

(15) The Commissioner of the Social Security;

(16) The Secretary of Energy;

(17) The Director of the Office of Personnel Management; and

(18) Such other members as the Director of the Office of Management and Budget may provide (including the Director of the Court Services and Offender Supervision Agency, which office is located in the Department of Justice.)

(c) The Task Force shall be chaired by the Director of the Office of Management and Budget (Director). The Director may appoint an Assistant Director or other senior official to assist in the management of the Task Force.

(d) The Office of Management and Budget shall provide administrative support for the Task Force. To the extent permitted by law, other executive departments and agencies may provide such staff, resources, and information as may be required in carrying out the provisions of this order.

(e) The Director shall develop, review, modify, and, as appropriate, implement program recommendations, in cooperation with the appropriate elected Federal and local officials and agencies, to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia.

(f) To the extent permitted by law, the Task Force staff shall communicate with Federal and local elected officials as early in program planning cycles as reasonably feasible, to develop and explain specific Federal and local plans and program actions.

Sec. 3. *Purpose.* The purpose of the Interagency Task Force will be to coordinate and better leverage Administration efforts and initiatives for the District of Columbia in concert with local and regional initiatives to improve the long-term financial stability of the Nation's Capital and to improve self-governance. The Director's designee shall serve as liaison between the executive branch and the executive, legislative, and judicial branches of government of the District of Columbia, as well as the private sector.

Sec. 4. *Responsibilities.* To the extent permitted by law, the Interagency Task Force shall:

(a) formulate and recommend interagency compacts and cooperative agreements between Federal agencies and the District of Columbia;

(b) develop, on a continuing basis, a comprehensive and coordinated plan to establish priorities to promote long-term financial stability, economic growth, and opportunity for self-government for the District of Columbia;

(c) provide for an understanding by the public of the needs and assets of the District of Columbia;

(d) support District efforts to encourage economic growth in the District of Columbia;

(e) serve as the focal point and coordinating unit for Federal programs, technical assistance, and other support for the District of Columbia; and

(f) provide a forum for consideration of problems within the District of Columbia and propose and effectuate solutions.

Sec. 5. *Assistance to Economically Distressed Areas.* Members of the Task Force, to the extent permitted by law and within existing budgetary resources, shall provide targeted assistance to economically distressed areas within the District of Columbia and to projects that require economic development assistance. To the extent permitted by law, members of the Task Force shall also participate in comprehensive neighborhood revitalization initiatives requiring Federal assistance, including programs organized by the government of the District of Columbia, and collaborative efforts organized by private organizations, such as the Anacostia Best Practices initiative.

Sec. 6. *Local Accommodation.* To the extent permitted by law, the Federal Interagency Task Force shall make efforts to accommodate the concerns of local elected officials in proposing Federal technical or other assistance.

Sec. 7. *Judicial Review.* This order does not create any right or benefit, substantive or procedural, enforceable by law against the United States, its officers, its employees, or any other person.

William J. Clinton

THE WHITE HOUSE,
January 15, 2001.

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Presidential Documents

Executive Order 13190 of Janaury 15, 2001

President's Commission on Educational Resource Equity

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App.), it is hereby ordered as follows:

Section 1. *Policy.* A quality education is essential to the success of every child in the 21st century and to the continued strength and prosperity of our Nation. Our Nation has embraced the goal of promoting high educational standards for all children and increasing accountability in education. Although we know it is crucial that all children have access to the educational resources and opportunity necessary to achieve high standards, long-standing gaps in access to educational resources exist, including disparities based on race and ethnicity. These gaps limit the ability of individuals, as well as our Nation, to reach their full potential. Therefore, it is the policy of this Administration that our Nation undertake appropriate steps to understand fully the current status of resource equity in education and to identify and implement strategies at the local, State, and national levels that will ensure that all students have a full and equal opportunity to succeed.

Sec. 2. *Establishment.* To carry out this policy, there is established the "President's Commission on Educational Resource Equity" (Commission). The Commission shall be composed of not more than 13 members appointed by the President from the public and private sectors. The members may include current and former Federal, State, and local government officials, corporate and foundation leaders, recognized education and civil rights experts, educational practitioners, and others with experience and expertise in educational resource equity. The President shall designate from among the Commission members such official or officials to be chairperson or chairpersons, as he shall deem appropriate.

Sec. 3. *Duties and Commission Report.* (a) The Commission shall collect and review information about the current status of gaps in the availability of educational resources, including the underlying causes and effects of such resource gaps. The Commission shall, as appropriate, invite experts and communities to provide information and guidance in furtherance of their duties.

(b) Not later than August 31, 2001, the Commission shall prepare and submit a report for the President and the Congress on the issue of resource equity in education. The report shall include, but not be limited to:

(i) An analysis of the status of resource equity in education with regard to such factors as finances, staff, facilities, instructional programs, and support services, taking into account, as appropriate, differences in costs and needs for different students and communities;

(ii) An analysis of how resource gaps in education affect the success of individuals and our Nation;

(iii) An examination of the effectiveness of targeted Federal resources toward disadvantaged students and low-income schools as compared with the provision of State and local resources toward disadvantaged students and low-income schools;

(iv) A summary of best practices with regard to overcoming gaps in the availability of educational resources; and

(v) Short- and long-term recommendations for educational policy makers, including local, State, and Federal officials, to achieve resource equity in education.

Sec. 4. *Administration, Compensation, and Termination.* (a) The Department of Education shall, to the extent permitted by law, provide administrative support and funding for the Commission.

(b) Members of the Commission shall serve without compensation, but while engaged in the work of the Commission, members appointed from among private citizens of the United States shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707) to the extent funds are available for such purposes.

(c) The functions of the President under the Federal Advisory Committee Act, as amended, except that of reporting to the Congress, that are applicable to the Commission, shall be performed by the Department of Education in accordance with the guidelines that have been issued by the Administrator of General Services.

(d) The chairperson (or chairpersons) may from time to time prescribe such rules, procedures, and policies relating to the activities of the Commission as are not inconsistent with law or with the provisions of this order.

(e) The Commission shall terminate 30 days after submitting its final report, unless extended by the President.

William J. Clinton

THE WHITE HOUSE,
January 15, 2001.

[FR Doc. 01-1814
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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AG11

Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant. The final rule responds to petitions for rulemaking (PRM 50–63 and PRM 50–63A) submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

EFFECTIVE DATES: April 19, 2001.

FOR FURTHER INFORMATION CONTACT: Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: (301) 415–3224. Internet: MTJ1@nrc.gov.

SUPPLEMENTARY INFORMATION: Section 50.47 of the Commission's regulations establishes requirements for emergency plans for nuclear power reactors to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Section 50.47(b) contains 16 planning standards, and in particular, § 50.47(b)(10) requires that emergency plans include "a range of protective actions" for the plume exposure pathway emergency planning zone (EPZ) for emergency workers and the public. This provision does not identify specific protective actions that must be included in these emergency plans.

The Petitioner's Requested Amendment to the NRC Regulations

On November 27, 1995 (60 FR 58256), the NRC published a document announcing the receipt of a petition for rulemaking (PRM 50–63) filed by Mr. Peter G. Crane on his own behalf and requested public comment on the suggested action. In the original petition (PRM 50–63), submitted on September 9, 1995, the petitioner requested that 10 CFR part 50 be amended to include language taken from FEMA's Federal Radiological Emergency Response Plan of September 1994. The petitioner requested that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include the prophylactic use of potassium iodide (KI), which the petitioner stated prevents thyroid cancer after nuclear accidents.

The petitioner proposed that section 50.47(b)(10) be amended to read as follows:

(10) A range of protective actions *including sheltering, evacuation and prophylactic use of iodine* have been developed for the plume exposure pathway EPZ (emergency planning zone) for emergency workers and the public.

Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

In the September 9, 1995, petition (PRM 50–63), the petitioner stated that he believes that if his proposed rule change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission to stockpile KI will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM 50–63A). In the revised petition, the petitioner requested that 10 CFR 50.47(b) be amended to read: (10) "A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed."

The petitioner also provided a marked-up version of the NRC staff's proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) **Federal Register** document concerning a revision to the Federal policy relating to the use of KI by the general public. The NRC published a document announcing the receipt of the amended petition on December 17, 1997, (62 FR 66038) and requested public comment on the amended petition.

As part of the petitioner's comments on the proposed rule, the petitioner also stated that his original petition was incorporated by reference and resubmitted because the amended petition was based in part upon the June 30, 1997, Commission decision to fund State supplies for those States that request it.

The petitioner also requested in PRM 50–63 that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a sensible and prudent measure necessary to assure that the drug will be available in the event of a major accident. The petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

Commission Action Concerning the Petitions

By staff requirements memorandum (SRM) dated June 26, 1998, to SECY 98–061, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant," the Commission decided to grant the revised petition for rulemaking (PRM 50–63A). The Commission also directed that the

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preamble for the proposed rule include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions.

By SRM dated April 22, 1999, to SECY 98–264, "Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of Policy on the Use of Potassium Iodide (KI) After a Severe Accident at a Nuclear Power Plant," the Commission voted to approve publication in the **Federal Register** of a [7590–01–P] proposed rule that would grant in part both the original petition (PRM 50–63) and the revised petition for rulemaking (PRM 50–63A). The proposed rule was published for public comment on June 14, 1999 (64 FR 31737). That notice provides greater detail concerning the basis for the petition and the NRC's rationale for the proposed rule language put forth for comment.

Other Activities Related to the Rulemaking on KI

In its decision on June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States at their request. On June 26, 1998, in a decision on this rulemaking petition, the Commission again noted that the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request.[1] However, in its April 22, 1999, SRM, the Commission decided: (1) Not to fund State stockpiles of KI; (2) to direct the NRC staff to work with FEMA to establish and maintain regional KI stockpiles; and (3) to support NRC funding of the purchase and resupply of the regional KI stockpiles to the extent that this cannot be covered by FEMA under its initiatives. The Commission determined that notwithstanding the June 30, 1997, and June 26, 1998, intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, NRC was not prepared to fund State stockpiles of KI absent Congressional funding specifically for this purpose.

The Federal Radiological Preparedness Coordinating Committee (FRPCC) is responsible to coordinate all Federal responsibilities for assisting state and local governments in emergency planning and preparedness for peacetime radiological emergencies. Federal agencies which participate in the FRPCC include (among others): the Federal Emergency Management Agency (FEMA), NRC, the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). The 1985 Federal Policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public. In parallel with petitioning the NRC for rulemaking, Mr. Crane requested that the FRPCC policy be reconsidered. In early 1996, the FRPCC convened a subcommittee on Potassium Iodide. The subcommittee recommended the following to the FRPCC regarding the Federal KI policy: (1) Without changing the Federal policy that it is the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC through FEMA), should fund the purchase of a stockpile for a State that, hereafter, decides to incorporate KI as a protective measure for the general public; (2) the language in the 1985 policy should be softened to be more flexible and balanced, as for instance, rewording it to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments;" and (3) local jurisdictions that wish to use KI should consult with the State to determine if the arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

On June 16, 1997, the NRC staff forwarded to the Commission a staff version of the FRPCC-proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. In its SRM of June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States. On June 26, 1998, the Commission directed that the FRPCC proposed Policy be modified to include a statement to the effect that State and local decision makers, provided with proper information, may find the use of KI as a protective supplement is reasonable and prudent for specific local conditions. As noted above, the Commission also reiterated its endorsement of the Federal offer to fund KI stockpiles for States. Subsequently, on April 22, 1999, the Commission directed the staff to amend the draft FRN on the Federal KI Policy to conform to the Commission decision on the petitions for rulemaking, and the decision not to fund State KI stockpiles.

On April 29, 1999, the Director of FEMA, Mr. James Lee Witt, forwarded a letter to the Commission commenting on the issue of funding of stockpiles of KI for States. The letter objected to the Commission's "unilateral" decision on funding, and also noted "FEMA has always opposed the notion that Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles would complicate, not strengthen radiological emergency preparedness." FEMA believes that if a State opts to use KI as a supplemental protective measure, the NRC should provide the funds for such a purchase.

The NRC responded to Mr. Witt's letter on June 15, 1999. This letter noted the Commission's decision not to fund state stockpiles of KI as well as the reasons underlying that decision. The letter also referred to the Commission's direction to "the NRC staff to work with FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a state without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency." The letter expressed confidence that the staffs, working together would successfully resolve the KI supply issue. The status of the stockpile and funding issues are discussed later in this notice. NRC is working closely with the other Federal agencies to determine appropriate changes to the 1985 policy. A decision regarding policy changes will be reached after the conclusion of this rulemaking.

In accordance with a Memorandum of Understanding between NRC and FEMA, NRC sent draft versions of this **Federal Register** notice to FEMA for its review and comment. FEMA responded by letter dated January 12, 2000. That letter reiterated their previous comments opposing regional stockpiles and instead favoring NRC funding of State stockpiles. The letter also noted that the development of regional stockpiles of KI had not progressed.

As discussed in the public comment evaluation, the Commission, as part of its decision to grant in full the amended rulemaking petition, has withdrawn its support for the funding of regional KI stockpiles and has reinstated its offer to provide for NRC funding of State or, in some cases, local stockpiles. The Commission agrees to fund a State's

[1] This was in contrast to previous Commission statements, such as those made when the Commission amended its emergency planning regulations (45 FR 55402) on November 3, 1980, wherein the Commission stated that any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through the Federal Emergency Management Agency (FEMA).

stockpile of KI, subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). NRC intends to work closely with FEMA and the other Federal agencies in FRPCC to finalize the draft Federal Policy to replace the 1985 Federal Policy. A decision regarding changes to the draft policy will be reached after the conclusion of this rulemaking. The substance of the specific comments attached to the FEMA letter is addressed by the issues in the public comment evaluation.

On September 30, 1998, the Commission also directed the staff to withdraw its guidance document, NUREG–1633 and substantially revise it, in a number of respects, including an improved discussion on how the practical problems in KI stockpiling, distribution and use are handled by States and other nations who use KI as a supplement. To accomplish this task, the NRC formed a KI Core Group, consisting of representatives from those States that have KI as a supplemental protective action, the Conference of Radiation Control Program Directors, the National Emergency Management Association, the U.S. Food and Drug Administration (FDA), EPA and FEMA. The revised draft guidance document, NUREG–1633, "Assessment of the Use of KI as a Supplemental Protective Action During Severe Reactor Accidents", Rev. 2 is expected to be issued for comment following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI which was issued for public comment on January 4, 2001 (66 FR 801).

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50–63), and requested public comment on the suggested rule amendment. A total of 65 comment letters were received.[2] Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations, a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50–63A) in the **Federal Register**. In response to several requests, the comment period was extended until February 17, 1998, by a **Federal Register** notice published on January 21, 1998 (63 FR 3052). A total of 86 comment letters were received. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, one State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed analysis of the issues raised by the public comments with the response to those issues was published in the June 14, 1999, proposed rule **Federal Register** notice.

On June 14, 1999 (64 FR 31737), the Commission published a proposed rule in the **Federal Register**, based on the revised petition for rulemaking (PRM 50–63A) and requested public comment by September 14, 1999. A total of 77 comment letters were received.[3] The letters in favor of the proposed rulemaking and the revised petition for rulemaking originated from a United States Senator; a member of the U.S. House of Representatives; 3 State agencies; 4 public interest groups; 10 members of the public (including two from the petitioner); and one letter with 529 signatures. Letters that opposed the proposed rulemaking came from 14 utilities; 13 State or local government agencies; 1 utility interest association; one letter from the Conference of Radiation Control Program Directors Standards committee representing 5 committee members; a letter from the National Emergency Management Association representing emergency management directors in 50 states; a law firm representing 15 utilities; and a former Assistant Secretary of Nuclear Energy at DOE. The FEMA letter of April 29, 1999, was submitted before the rule was published and discussed KI stockpiles. Another 24 letters requested the Commission to grant the original petition (PRM 50–63) by *requiring* the use of KI rather than the *consideration* of KI in emergency planning. These letters originated from members of the public as well as public interest groups. As part of the petitioner's comment letter dated August 17, 1999, on the proposed rule the petitioner stated that, in light of the Commission's decision not to fund state stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted. He also requested the Commission to grant the petition as originally submitted.

The following discussion addresses the significant comments and issues raised in the three public comment periods for the original and amended petitions for rulemaking and the proposed rule.

Issue A: Should KI Be Considered as a Supplemental Protective Action to Evacuation and Sheltering

Several commenters on the proposed rule state that the rulemaking would not add significant public health and safety benefit beyond the current emergency plans, because evacuation and sheltering are the best means to protect the public in the event of a radiological emergency. According to these commenters, evacuation and sheltering are more effective at dose reduction because they reduce dose to all organs, not just to the thyroid.

Other comments express the view that the Chernobyl experience (including use of KI in Poland) shows that (1) thyroid cancer is a major result of reactor accidents, (2) the exposure can continue for days and thus the institution of KI blocking at any time is beneficial, (3) deployment of KI is safe, and (4) shelf life is extremely long. These commenters note that EPA Manual [Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA–400–R–92–001 (May 1992)] quotes the FDA as stating that potassium iodide "will have substantial benefit even if it is taken 3 or 4 hours after acute exposure." Thus, these commenters believe that the advantage of having a supply of KI on hand outweighs moderate cost and that KI should be a supplemental protective action. Further, these commenters note that just because there may be other radionuclides to which people are exposed is not a reason to deny them the availability of KI.

Commenters who favor the use of KI as a supplemental protective action conclude that evacuation and sheltering alone may not be sufficient safety actions in the event that evacuation is not feasible. They state that natural

[2] Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

[3] Three of the letters (those from FEMA, the senator and the congressional representative) were not submitted during the comment period in response to the notice, but are being treated as comment letters for purposes of this discussion.

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disasters could occur that would make evacuation difficult and time consuming at best, as for instance, earthquakes, hurricanes, blizzards, and ice storms. According to these commenters, a point against strong reliance upon evacuation is the evacuation routes themselves. As an example, a commenter cites the area around the Seabrook Nuclear Plant, noting that during the summer tourist season especially, it can be predicted that evacuees will be forced to wait in traffic for great lengths of time. This commenter believes that if KI were predistributed, instances of cancer, hypothyroidism and other thyroid disorders might be avoided.

Response. The Commission recognizes evacuation to be the most effective protective measure to be taken in the event of a radiological emergency because it protects the whole body (including the thyroid and other organs) from all radionuclides and all exposure pathways. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. However, it is important to note that the issue is not evacuation or sheltering *versus* KI. Rather, it is evacuation or sheltering *with* KI versus evacuation or sheltering *without* KI. The use of KI is intended to supplement, not to replace, other protective measures. This amendment represents no change in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. Depending on the circumstances, KI may offer additional protection for one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public but the use of KI can be a reasonable and prudent supplement. Therefore, it seems reasonable, while continuing to recognize the role of the State and local governments in matters of emergency planning, to require explicitly that emergency planners consider the use of KI.

Issue B: Is There a Need for New Regulation

Commenters in favor of the proposed rule note that a host of countries—France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Great Britain, Sweden, Slovakia, and others—protect themselves with stockpiles of KI. These commenters point to soaring rates of thyroid cancer appearing in children in the Soviet Union who were exposed to the Chernobyl nuclear accident and who received too little potassium iodide, and too late. Thus, these commenters support the view that there is new information that suggests the need for consideration by State and local governments. In addition, many of these commenters would go further than the proposed rule language and require the use of KI, not just its consideration.

In contrast to the above, letters from some state and local governments, and from utilities, say that the State and local governments have already considered the use of KI. They believe that the petitioner has not provided any compelling reasons why additional Federal requirements are needed or how they would benefit the health and safety of the public. These State and local government commenters reject the view that the States have not had access to sufficient technical information regarding potassium iodide, and that without accurate and current information on KI—including the Chernobyl experience and the consensus of international experts—States cannot make an informed judgment. They conclude that this assertion is without merit, as there has been no shortage of information related to the use of potassium iodide available to State radiological emergency planners, and oppose the implication that State and local governments, absent Federal actions, are incapable of making informed decisions regarding the protection of their citizens during a radiological emergency. One commenter stated that by issuing this rule, the Commission is ignoring the views of States where KI has been stockpiled or pre-distributed, and where experience shows the system is ineffective.

The commenters opposing the proposed rule on this basis also note that reliance on the Chernobyl experience discounts the vast technical, political, and socio-economic differences between the United States and Eastern European countries at the time of the Chernobyl accident. The efficacy of any protective measure will depend on a large number of factors, including but not limited to: the type of reactor involved; accident sequences and timing; source term; timeliness of notification; the manner in which protective action decisions are made and transmitted to the public; the mobility of the public; and the receptiveness of the general public to official instructions. These commenters believe that the above factors have already been considered by State and local governments in the development of existing emergency response plans.

Response. The Commission did not intend to imply that States are not capable of making informed decisions regarding the protection of their citizens during a radiological emergency. In fact, the final rule calls on offsite authorities to make their own decision on this matter. Additionally, the Commission recognizes that most State and local governments have already considered the use of KI in the event of an emergency as part of their planning. Nevertheless, the Commission believes it appropriate to provide information that may be of aid to offsite authorities in their consideration of this matter. Offsite authorities may, of course, use this information as they see fit.

Several States have welcomed the NRC's efforts in developing information relating to the benefits and risks associated with using KI as a supplemental protective measure for the general public. This information is intended to supplement and update information already available on this subject, including experience from State and foreign governments that have made KI available to the public. As noted earlier, this information will be in a revised NUREG–1633, which is scheduled for publication for comment after the FDA issues its draft guidance and in an information brochure.

The Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Through its decision to require that the use of KI be "considered" (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a State-by-State basis. As part of this consideration, State and local governments can weigh all relevant factors.

Issue C: The Importance of Information in the Decisionmaking Process Concerning the Public Use of KI

In the proposed rule, the Commission noted that NUREG–1633 was being revised to provide information about experience in the United States and abroad with distribution of KI, and that an information brochure was also being prepared. According to some commenters, distribution of information on the benefits and risks associated with the use of KI should not be limited to people living within nuclear power plant emergency planning zones. Further, commenters note that a comprehensive public information program outlining the potential range of benefits and risks of using KI and how to employ it most effectively in the event of a radiological emergency would be necessary to allow personal decisionmaking. Making the information and the KI itself available directly to members of the public provides them with the ability to decide for themselves how best to take advantage of the benefits associated with the use of KI as supplementary protection. One vehicle currently used for disseminating regular preparedness information which could be used to provide information on KI is the public information brochures and calendars already required to be distributed annually within each emergency planning zone. In this commenter's view, making information and KI available provides the greatest level of protection for the greatest number of people.

Some State government organizations were concerned that making provisions for KI might give the public a false sense of security that they are fully protected, and that the public might not evacuate. Thus, these organizations believe that there is a need for public information concerning the supplemental role that the use of KI could play.

Several of the commenters stated that it is desirable that the NRC would work with other appropriate Federal agencies to develop and promulgate clear and necessary guidance on the subject, similar to the guidance on sheltering and evacuation. These commenters also believe that the final decision should lie at the discretion of the State and local governments. A few commenters expressed the view that the rule puts the burden of assessment on States who have fewer technical resources than the NRC, the EPA or the FDA.

One commenter thought that the decisionmaking about stockpiling KI must include rigorous assessments to ensure sufficient quantities of KI will be available for distribution to members of the public, in both the plume exposure pathway and the ingestion exposure pathway.

Response. The Commission recognizes that once a State decides to include KI as a protective measure for the general public, it would be up to the State to decide how and when to conduct an educational program on the benefits and risks associated with using KI and to supply KI for appropriate distribution to the general public. Additionally, the Commission agrees that more detailed guidance on the use of KI would be useful in assisting States to assess the merits of stockpiling KI for the general public, including logistics, amounts and public information needs. The Commission has formed a KI "Core Group" consisting of representatives of State, local, and Federal agencies whose responsibility is to develop clear guidance relating to the use of KI. This guidance (NUREG–1633, Rev. 2) should be published for comment after FDA issues its draft guidance, which was issued for public comment on January 4, 2001 (66 FR 801). The NRC is continuing to work with other Federal agencies through the FRPCC to coordinate government policies concerning radiation protection and emergency planning. Further, a public information brochure to be published later will assist States and individuals in making an informed decision on KI.

Issue D: Making KI Available to the General Public

A range of comments were submitted concerning ways by which KI could be made available to the general public in the event of a radiological emergency. Many commenters simply asked NRC to "make KI available" without further detail. In the proposed rule, the NRC discussed Federal stockpiles of KI as part of Federal response to terrorist acts. One commenter indicated that expanding this supply may be the best approach. Another commenter stated that the public is not interested in stockpiles, but instead wants information to make their own decisions. Of those comments related to specific methods of availability, these can be generally grouped into individual availability, State stockpiles in the vicinity of nuclear power plants, or regional stockpiles.

Individual Availability

One State submitted, as part of its comments, a report that discussed a plan they have developed that would allow citizens to gain access to KI in advance of an accident. The plan calls for the State to secure agreements with KI manufacturers to sell the medication directly to individuals or retail outlets, and to urge local pharmacies to stock KI as an over-the-counter drug. Information concerning KI availability and use would be included in the annual emergency information mailings prepared by nuclear power plant staffs and distributed to every property owner within the emergency planning zones. The State concluded that this method would allow individuals to make their own decisions about the use of KI. This State noted that one can envision this activity being conducted in conjunction with existing programs designed to remind and encourage family members to periodically check home first aid kits, smoke detectors, spare batteries for flashlights and radios, and other items that they might employ for their comfort and protection in the event of any emergency. In addition, one commenter noted that KI is now available via the Internet from at least two vendors at an affordable price. (See also comments above in issue C about decisionmaking.)

State Stockpiles

A number of commenters believe that KI should be stockpiled in schools, fire houses or reception centers near nuclear power plants. These commenters state that this is the advice of the experts, for instance the World Health Organization and Dr. Jean Temeck, from FDA. These commenters believe that the young are the most vulnerable; and, in the words of Dr. Temeck, "in an emergency you want to get it to the children as quickly as possible and the teacher is right there on the spot. * * * You do not need to be medically trained to give KI. A permission slip to administer KI can be sent out by the school at the beginning of each year." Further, it makes sense to these commenters that this time-critical medicine be available nearby, such as in a local school, hospital, or fire-station. Thus, these commenters believe that State stockpiles are appropriate because regional stockpiles will not adequately protect the public since KI must be taken prior to exposure, or very shortly thereafter (within about six hours), to be an effective blocking agent.

Regional Stockpiles

A number of commenters, including emergency preparedness and response officials and FEMA, are concerned about the regional stockpiling and distribution process and its potential for reducing the effectiveness of measures which will provide much greater protection to the public. In their view, the complex logistics of storage and distribution of regional stockpiles far outweigh the usefulness of such a stockpile and that regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness. These commenters believe regional stockpiling has disadvantages as compared to State stockpiling. The administration of KI is time-critical and regional stockpiling means critical time will be spent transporting the drug from a regional stockpile to the area where it is needed. For these reasons, they believe that

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regional stockpiles should supplement, not substitute for State stockpiles.

Response. If a State decides to use KI as a supplemental protective measure, the Commission agrees that the State should focus on the early administration of KI to children. A decision to make KI available to the general public will require some planning by the State for its own supplies of KI and methods of distribution. Such planning (for implementation of protective actions) is a normal part of a State's emergency planning activities. As noted earlier, the NRC plans to issue a guidance document (NUREG–1633) to assist the States. The Commission recognizes the logistical challenges associated with the distribution of KI to the general public. For this reason, the staff intends to include a discussion of experience with KI distribution in the United States and abroad in the guidance document NUREG–1633.

There are different approaches that a State can use in incorporating KI as a supplemental protective measure for the general public. One approach is that mentioned by a commenter to distribute information about the over-the-counter availability of KI. Making KI available over the counter would provide members of the public with the opportunity to decide for themselves if they wanted to store and use KI. In fact, some KI manufacturers have indicated that they would make KI available to any person who requests it, at a fee. This approach would minimize the need for State stockpiles or predistribution and would put KI in the hands of the public before an accident occurs, rather than attempting to distribute the KI from stockpiles after an emergency is declared.

The concerns about the effectiveness of regional stockpiles for rapid deployment of KI to the public are also acknowledged. FEMA has stated that in its view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission agrees. As part of its decision on this final rule, the Commission has decided to provide funding for a supply of KI for States that request such funding through FEMA and to discontinue support of regional stockpiles. The Commission believes that in light of logistic difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue E: Requiring versus Considering Use of KI

Several commenters thought that the proposed rule should be modified to require the use of KI, not just the consideration by State and local officials. These commenters believe, for instance, that the tragic comedy of errors surrounding attempts to distribute KI in the wake of the Three Mile Island partial core melt accident only serves to highlight the need for pre-distribution. The health of our children is too important to leave their protection to the consideration of states. These commenters ask that if the U.S. system is adequate, why do other industrialized nations believe that sheltering and evacuation alone are insufficient? Some of these commenters want all commercial reactor licensees to distribute KI to all individuals within the EPZ and to make KI available to anyone within a 50-mile radius of the reactor upon request. These commenters believe that the prophylactic use of KI for the general public should be a *mandatory* emergency planning requirement and should not be merely an optional consideration, because, if given the choice, many States may not adequately protect their citizens. Another reason cited for wanting NRC to require KI is that "without a federal mandate for stockpiling KI, the nuclear industry will simply shift its fight against the policy to the State and local levels."

Response. Because the Commission believes that current emergency planning and protective measures—evacuation and sheltering—are adequate and protective of public health and safety, the Commission will not *require* use of KI by the general public. Rather, the Commission recognizes the *supplemental* value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters.

The use of KI is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave this decision to State and local emergency response planners, who may find that KI should be a supplementary protective measure, rather than to mandate its use. Additionally, the Commission's amendment to require explicitly that planners consider the use of KI, rather than require the use of KI, recognizes the important role of the States and local governments in matters of emergency planning and the use of medicinal protective measures by their citizens.

Issue F: Funding

Some commenters, including FEMA, state that the recent decision of the Commissioners *not* to fund the purchase of KI is an unfortunate reversal to the goal of providing supplementary protection for the general public. Thus, citing the Chernobyl accident, they urge the Commission to reconsider its position in light of the proven usefulness of KI in preventing childhood thyroid cancer. One State commenter was concerned that after two years of efforts made toward implementing this supplementary protection, the Commission's recent actions undermine that State's effort. While understanding the Commission's financial concerns leading to this decision, this commenter proposed that the Commission could approach Congress for a supplemental appropriation.

Another commenter stated that the Commission's withdrawal of the offer to pay for State KI stockpiles sends a message that KI preparedness is not important, and that States who were considering plans to establish stockpiles have dropped such plans. Further, some commenters believe that the NRC reversal of position regarding funding of KI for States that elect to stockpile it adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). [That draft policy currently provides that if a State chooses to add KI as a supplement to its evacuation and sheltering protective actions, the State will inform FEMA, which will forward the request to the NRC for payment.] Another commenter noted that the Kemeny Commission supported stockpiling KI, and that the Commission should fulfill an earlier NRC commitment to do so.

Several States expressed the view that the requirement that use of KI be considered is an unfunded State mandate and is contrary to an Executive Order of 8/5/99.

A number of commenters stated that they thought the utilities should pay for supplies of KI in the vicinity of the power plants. Some utilities expressed concern that the rulemaking might result in requests to the utilities from State and local organizations for such funding.

Response. The Commission decision not to fund State stockpiles has been reversed as the result of public comment on this rulemaking. Promulgation of this final rule underscores the Commission's views on the importance of emergency preparedness, including consideration of the use of KI. The Commission has decided to fund State and, in some cases, local stockpiles of KI, subject to certain restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant. The Commission's offer to fund the purchase of a supply of KI for a State choosing to use KI prophylaxis as a supplemental protective measure retains the FRPCC's proposal that the State remain responsible for all other funding connected with the incorporation of KI, such as preparing guidelines for its stockpiling, maintenance, distribution and use, and for all other ancillary costs.

The Commission agrees that, in the past, licensees may have found it in their own self interest to assist State and local governments by providing resources for emergency planning needs. The Commission expects that those States who decide to use KI for the general public will make suitable arrangements to fund costs other than the initial purchase of a supply of KI. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. As with other aspects of offsite emergency planning, the NRC will not require licensees to fund State activities, but the States can, of course, act in cooperation and coordination with licensees.

As to the issues whether the rule constitutes an "unfunded State mandate" or is contrary to an Executive Order of August 5, 1999, the Nuclear Regulatory Commission, as an independent regulatory agency, is not subject to the requirements of Title II of the Unfunded Mandates Reform Act of 1995 or Executive Order 13132, "Federalism," August 5, 1999.

Issue G: Whether This Rulemaking Is a Backfit

A commenter representing nuclear utilities raised a concern that if licensees would be required to expend significant resources in considering the use of KI in emergency plans, then the proposed rule is clearly a backfit and a backfitting analysis should be performed. Thus, the commenter requested that the NRC either limit the specific actions which would be required to be taken by licensees to demonstrate that the adequate consideration required by the proposed rule has been implemented, or the required backfitting analysis should be conducted and a suitably revised proposed rule should be published for comment.

Response. This notice contains a "Backfit Analysis" section, which notes that the Commission concludes that the rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to States or local governments, the entities with the responsibility to determine the appropriateness of the use of KI for their citizens, calling upon the governments to consider KI as one of the elements of their offsite emergency planning. The final rule imposes no binding requirement for State or local governments to alter emergency plans and procedures.

Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing § 50.47(b)(10). Once again, the rule does not impose new requirements on nuclear power plant licensees who are the intended beneficiaries of the Backfit Rule provisions. Therefore, no backfit is involved.

Issue H: State Liabilities in Providing KI for the General Public

State and local government organizations raised concerns about legal implications should a member of the general public be given KI at their directive or recommendation and the individual has an extreme allergic reaction. Commenters note that the **Federal Register** notice does not address legal issues for States who decide to adopt KI and for States who do not decide to adopt or administer KI to the public. Further, if the NRC decides to require stockpiling of KI for the general public, the commenters ask whether NRC has considered what liability may arise from any adverse health effects. Another concern was about who would assume liability if the KI was used prior to a Governor ordering its use.

Response. These comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. As stated in the proposed rule FR notice, the question of whether a State or locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular States. The NRC presumes that this would be part of the "consideration" that States and localities will undertake as a result of promulgation of this rule. To the extent that commenters are raising the potential for Federal government liability for the promulgation of this proposed rule, the proposed rule FRN notes NRC views that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require State and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the "discretionary function" exception to the Federal Tort Claims Act. 28 USC 2671, *et seq.*, which protects the Federal Government from liability. The Commission's offer to fund State stockpiles would similarly be subject to the "discretionary function" exception. The Commission has directed the staff to ensure that NRC funding for KI is accompanied by appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting, storing, distributing, administering, using, or determining proper doses of KI for adults and children.

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the

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current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, "FDA concludes in the final recommendations that risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem." That notice also provides recommended dosages for adults and children. New FDA guidance was published in the **Federal Register** for public comment on January 4, 2001 (66 FR 801). The Commission will incorporate it into its guidance documents.

Issue J: Original Petition Versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements— the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and the offer of Federally-funded State stockpiles. Since the promise of funding removed a major impediment to States adopting a pro-KI policy, the commenters believe that the petitioner felt that amending his petition to require only "consideration" of the use of KI would likely result in State decisions favorable to using KI. In their view, the amended PRM was premised on the now-withdrawn NRC offer of Federally-funded State stockpiles of KI, and therefore it would be entirely appropriate for the petitioner to rescind his amendment to PRM 50–63 and to insist that the NRC adopt what was requested in his original petition.

Response. The Commission agrees with this comment. Since the Commission has decided to reinstate its offer to fund a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans, the Commission believes that it is granting the amended petition (PRM–50–63A) in all respects.

Issue K: Meaning of "Consideration"

Several commenters stated that the proposed rule is vague in that it did not define "consideration." They believe that the rule should clarify that the KI "consideration" within the context of radiological emergency planning and preparedness needs to be performed only once by the responsible State agency, which would provide written notice of the consideration to the Commission. Thereafter, no further "consideration" should be required unless the State determines there is reason to reconsider its position and that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC, or any other federal agency.

Another commenter questioned whether a State that considered the issue in the early 1980s, and rejected the use of KI, could now claim that the Commission's current proposal has already been fulfilled. Reliance upon the earlier consideration would violate the intent of the petitioner's proposal.

Another commenter questioned whether the following scenario would be considered acceptable and in compliance with the rule: a State considered the use of KI, but found the licensee unwilling to pay for it, so the State decided that although use of KI might be a good idea, it couldn't afford it.

Response. The Commission would expect that a State's "consideration" would involve at least an internal review of this notice and brief deliberation on the State's position on the use of KI by the general public. In NRC's experience, States periodically review their emergency plans and preparedness, typically on an exercise frequency basis, to ensure that plans are up to date and account for local changed circumstances. For those States that conduct such periodic reviews, the Commission would expect the States to undertake their "consideration" of the use of KI during the first periodic review conducted by the State of offsite emergency plans and preparedness following the effective date of this rule amendment and issuance of revised NUREG–1633 guidance. For those States that do not routinely conduct periodic reviews, the Commission would expect the States to undertake their "consideration" of the use of KI on the same frequency as periodic emergency preparedness exercises following the effective date of this rule amendment and issuance of guidance. The rule does not require States to provide written notice of their "consideration." The Commission expects that States will inform FEMA and the NRC of the results of their consideration.

Additionally, the Commission agrees that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC or any other Federal agency.

By issuing this rule, the Commission is stating its conclusion that consideration of the use of KI that might have been performed many years ago, needs to be reexamined in light of new information. Thus reliance upon such earlier evaluations would not be consistent with the rule requirement.

Issue L: Federal Distribution of KI

One commenter noted that the Commission's proposed rule would seem to support the same techniques used for forced KI distribution that were dictated by governments in Eastern Europe during the Chernobyl accident. The commenter urged the Commission to consider whether this posture would be endorsed by any government, be it Federal, State, or local. This commenter believes the NRC staff ignores the testimony of those States where KI is stockpiled or pre-distributed for the public and where experience shows the system is ineffective. Additionally, a commenter thought that the proposed rule is predicated on the false assumption that even if States decide not to stockpile KI for the general public, they will have access to Federal reserves of the drug. By the Commission's own admission, such reserves have yet to be established nor has the funding mechanism to support such reserves been identified. The proposal suggests that states "consider" the availability of resources that do not exist.

Likewise, a commenter stated that the proposed rule implies that even when a State decides as a matter of public policy against distribution of KI for the general population, the Federal government will develop plans to override that decision. The purpose of such plans is unclear in the context of the proposed rule. Once a State has given due consideration to the use of KI stockpiling as a supplemental protective action and determined it to be unwarranted, the commenter seeks the basis on which the Commission proposes to develop a contingency plan.

Response. The Commission has never endorsed "forced KI distribution." Under this final rule the use of KI continues to be a State option. Moreover, revised NUREG–1633 will discuss the benefits and risks associated with using KI and the U.S. and foreign experience with public distribution. While the Commission has always recognized that distribution at the time of an accident will present difficulties if there has been no advance planning, the Commission believes that the States will take the distribution matters into account when they consider the use of KI for the general public under this rule.

The Commission has decided to withdraw its decision to provide funding for regional Federal KI stockpiles. However, it should be noted that Commission efforts in this regard were not intended to "override" a State decision not to use KI during an emergency; rather, they were intended to make KI available in the event that a particular State changed its views and decided to use KI in an actual emergency, and had nowhere else to go for KI. The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue M: Importance of Emergency Planning

A few commenters feel that safe siting and Design-Engineered features alone do not optimize protection of the public-health and safety and that the Commission should not rely upon probabilistic risk assessments to obviate the need for stockpiling and predistribution of KI. Another commenter is concerned that the premature aging of reactor components, the economics of utility restructuring, and the long-term storage of high-level waste at reactor sites all contribute to the need for KI stockpiling.

Response: The Commission agrees with the importance of emergency planning to complement site and design features and stated so in the August 19, 1980, **Federal Register** Notice (45 FR 55402) which codified the NRC's emergency planning regulations following the Three Mile Island accident: "The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear * * * that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident."

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

Issue N: Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner expressed the view that since the U.S. is currently engaged in a $15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

As noted earlier, the Commission has decided to offer to provide funding for a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans.

Issue O: Safety of KI

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse reactions. Specifically, 18 million individuals received prophylactic KI with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects.[4] Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident where people risk illness and death, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk.

Response. The Commission did consider the experience with mass distribution of KI during the Chernobyl radiological emergency (although the record on that distribution is not complete). That experience is still being investigated and evaluated by public health authorities worldwide. When the appropriate health agencies have established the applicability of the Polish experience to the United States, the findings will be followed in NRC guidance. The NRC acknowledges that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission guidance on emergency planning has long taken KI into consideration (see NUREG–0654/FEMA–REP–1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," Rev. 1, p. 63, items e and f). The FDA has approved KI as an over-the-counter medication and has found it effective and safe as discussed in the response to issue I.

Commission Decision on the Petitions for Rulemaking

Based on the foregoing, and as noted herein, the action by the Commission to approve this final rule grants in part and denies in part the original petition (PRM 50–63) and grants in all respects the amended petition (PRM 50–63A). The rule change, which requires "consideration" of the use of KI, is responsive to the amended petition. Further, including in this **Federal Register** notice for the final rule, a

[4] Comment letter from the Massachusetts Coalition To Stockpile KI dated September 10, 1999.

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statement that "KI is a reasonable, prudent, inexpensive supplement to evacuation and sheltering for specific local conditions," is also responsive to both petitions. This statement does not use the petitioner's exact language but is responsive to the petitioner's request. The Commission's final position on funding of State stockpiles grants that part of the original and amended petition to include a statement of such support in the Statement of Considerations for the rule. However, the final rulemaking would deny that part of the original petition requesting that the Commission amend 10 CFR 50.47(b)(10) to *require* that the range of protective actions developed for the plume exposure pathway EPZ include sheltering, evacuation, and the prophylactic use of iodine.

The Commission has found that "[I]n developing the range of actions for severe accidents at nuclear power plants, evacuation and sheltering provide adequate protection for the general public." (Proposed Rule, 64 FR at 31745). In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners to determine whether their emergency plans should include the use of KI as a supplementary protective measure for the general public. The Commission's decision is implemented through this final rule that changes 10 CFR 50.47(b)(10). This final rule completes NRC action on PRM 50–63 and PRM 50–63A.

Rationale for the Commission Decision

The Commission has considered the KI policy question on numerous occasions since 1984. The history of the Commission deliberations shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear-cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission agrees that its historical difficulty in reaching consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation.

After considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to amend 10 CFR 50.47(b)(10), by adding a sentence similar to the one suggested in the revised petition. Specifically the following sentence is inserted in § 50.47(b)(10), after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate."

The Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63, items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes few threatening side effects. Moreover, many nations in Europe and elsewhere—nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan—have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has significantly improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979.

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. The Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. In appropriate circumstances, KI can provide additional protection. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

The NRC recognizes that any decision to use KI as a supplemental protective measure for the general public presents issues of how best to position and distribute the medicine, to ensure: (1) That optimal distribution takes place in an emergency, with first priority given to protecting children; (2) that persons with known allergies to iodine not take it; and (3) that members of the public understand that KI is not a substitute for measures that protect the whole body. To date, these issues have been addressed in different ways in the numerous countries that currently use KI as a protective measure for their citizens. The NRC is working with States and other Federal agencies to develop guidance on these and other issues relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

Commission Decision on Funding of State Stockpiles or Supplies of KI

The **Federal Register** notice for the proposed rule (64 FR 31737) stated the Commission's then-held position only to support funding of regional stockpiles or other supplies of KI as opposed to funding of State stockpiling of KI. As described above, in its deliberations on this final rule, the Commission has withdrawn its support for funding of regional KI stockpiles and has reinstated its offer to provide NRC funding of State or, in some cases, local stockpiles, subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000).

In doing this, the Commission has responded to comments from FEMA and other commenters. The Commission is supporting the 1996 FRPCC's Ad Hoc Subcommittee on Potassium Iodide recommendation that the Federal government (NRC through FEMA) should fund the purchase of State, or in some cases local, KI stockpiles. The Commission recognizes that this policy contradicts the Commission's historical policy that funding for State and local emergency planning is the responsibility of those governments often working with licensees. The Commission is making this exception to the long-standing policy on the basis of the FRPCC's recommendation and recent petitions received. The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchase of KI for use by that State during a radiological emergency would directly contribute to fulfilling NRC's regulatory mission. The Commission also recognizes that any State choosing to incorporate KI prophylaxis as a supplemental protective action in its emergency planning will face costs, other than the cost of the purchase of KI. Consistent with the long-standing policy, these ancillary costs will remain the responsibility of the State government. Depending on how the State incorporates KI prophylaxis in its emergency plans, the ancillary costs could significantly exceed the cost of the purchase of the KI supply.

Metric Policy

On October 7, 1992, the Commission published its final Policy Statement on Metrication. According to that policy, after January 7, 1993, all new regulations and major amendments to existing regulations were to be presented in dual units. The amendment to the regulations contains no units.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its emergency planning regulations to require that consideration be given to including potassium iodide as a protective measure for the general public that would supplement sheltering and evacuation in the event of a severe reactor accident. This action does not constitute the establishment of a consensus standard that contains generally applicable requirements to which the provisions of the Act apply.

Environmental Assessment and Finding of No Significant Impact for Completing Action on the Petitions for Rulemaking Relating to the Use of Potassium Iodide (KI) for the General Public

I. Introduction

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration in order to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition PRM 50–63A, that requested two things:

1. A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and
2. A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

On June 26, 1998, the Commission disagreed with the NRC staff's recommendation in SECY–98–061 dated March 31, 1998, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant," to deny the revised petition for rulemaking (PRM 50–63A) and directed the NRC staff to grant the petition by revising 10 CFR 50.47 (b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 (June 16, 1997), "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents.

On April 22, 1999, the Commission voted to approve publication in the **Federal Register** of a proposed rule that would grant the revised petition for rulemaking (PRM 50–63A). The proposed rule was published on June 14, 1999 (64 FR 31737). In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this final rulemaking, is denying in part the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public. The Commission is granting in all respects the amended petition, including reinstating its support for funding State stockpiles of KI.

II. Need for Action

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. In an SRM on SECY–98–061, the Commission directed the NRC staff to proceed with the rulemaking. In so doing, the Commission found that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63 items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency. Although the record on that distribution is not complete, the indications thus far are that mass distribution is effective in

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preventing thyroid cancer and causes few threatening side effects. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it seems reasonable, while continuing to recognize the important role of the States in matters of offsite emergency planning, to explicitly require that planners consider the use of KI. The rule is needed to ensure that the States are aware of and take into consideration the costs, risks, and benefits of KI in their decision making process in order to optimize emergency planning for the public health and safety.

III. Environmental Impact of the Final Action

The environmental impacts of the final action and its alternative (deny the petitions in their entirety and take no action) are considered negligible by the NRC staff, given that the final action would only add the sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate." The NRC staff is not aware of any environmental impacts as a result of this final action.

IV. Alternative to the Final Action

The alternative to the final action at this time is to deny the petitions and take no action with respect to the use of KI by the public. Should this no-action alternative be pursued, the NRC staff is not aware of any resulting environmental impact.

V. Agencies and Persons Consulted

Cognizant personnel from the States, FEMA, and FDA were consulted, as was the petitioner, as part of this rulemaking activity.

VI. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendment is not a major Federal action significantly affecting the quality of human environment and; therefore, an environmental impact statement is not required. This amendment will require that consideration be given to evacuation, sheltering, and as a supplement to these, the prophylactic use of KI. This action will not have a significant impact upon the environment.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB) approval numbers 3150–0009 and 3150–0011.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis of the Final Rulemaking Completing Action on Petitions for Rulemaking (PRM 50–63) and (PRM 50–63A) Relating to the Use of Potassium Iodide (KI)

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition (PRM 50–63A), which requested two things:

A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure; and

A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this rulemaking, is granting the amended petition and is granting in part and denying in part the original petition. The Commission is denying that portion of the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State in matters of emergency planning by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public.

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. By SRM dated June 26, 1998, on SECY–97–245, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63) Relating to a Re-evaluation of the Policy Regarding use of Potassium Iodide (KI) after a Severe Accident at a Nuclear Power Plant," the Commission directed the NRC staff to revise 10 CFR 50.47(b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 dated June 16, 1997, "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents. Given that the Commission considered the options and directed the NRC staff to grant the amended petition, the only alternatives considered here are the Commission-approved option and the baseline, no-action alternative.

The final rule does not "require" any action of licensees. States are to "consider" the use of KI along with evacuation and sheltering as protective actions. It is estimated that no more than 30 States will need to make this consideration. The rule does not impose any substantive requirements on States to actually stockpile or plan for the use of KI. Therefore, States would not accrue the costs associated with such actions. However, the Commission recognizes that consideration of using KI as a supplemental protective measure may result in some State expenditures. The NRC staff estimates that the labor needed by the States could range from a staff-week, to half of a staff-year. The latter would be the case if a State decided to hold hearings on the issue.

If one assumes an average hourly salary of $70 (this estimate includes benefits, prorated secretarial and managerial assistance, but not overhead), the range of estimates would be from $2800 to $63,000 per State. Using a base of 30 States, the range of impacts for the States to make the KI consideration is from $84,000 to $1.9 million.

The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG–0654; FEMA–REP–1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment." This guidance was cited in the regulation and addresses the use of radioprotective drugs by the general public, including quantities, storage, and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987, but the guidance has continued in use for planning purposes by States and licensees and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the 30 affected States have at some point considered the use of KI. A few of the 30 affected States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not previously elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

It is difficult to estimate the benefit of a State's consideration to use KI for the general public. However, we believe the benefit of such an action by the States is summed up by the petitioner who stated that the decision to use KI for the general public should turn on whether, given the consequences of being without KI in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. As the petitioner further noted, "KI represents a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, can have such enormous consequences that it is sensible to take special precautions, especially where, as here, the cost of such additional precautions is relatively low."

Nonetheless, the Commission notes that this rule will introduce another element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. While this ultimate responsibility could have practical implications, with some associated burdens, the extent is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Additionally, the rule does not articulate any implementation date or inspection criteria.

As stated above, this analysis focuses on the rule being codified as the result of petitions for rulemaking and on the Commission direction to grant the amended petition in all respects and to grant in part the original petition.

This constitutes the regulatory analysis for this action.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule would affect only States and indirectly licensees of nuclear power plants. These States and licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, 5 U.S.C. 601, or the size standards adopted by the NRC (10 CFR 2.810).

Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" that was approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), Part 50 is classified as compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations.

Plain Language

The President's Memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the final revisions to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this notice.

Backfit Analysis

The definition of backfit, as set forth in 10 CFR 50.109(a)(1), is clearly directed at obligations imposed upon licensees (and applicants) and their facilities and procedures. Section 50.109(a)(1) defines a backfit as:

> * * * the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position * * *

Section 50.109 is replete with references to "facilities" and "licensees," which in their totality make clear that the rule is intended to apply to actions taken with respect to nuclear power plant licensees and the facilities they operate. *See* § 50.109(a)(7), "If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written *licensee* commitments * * * then ordinarily the applicant or *licensee* is free to choose the way that best suits its purposes [emphasis added]." This focus on licensees and their facilities is further confirmed by the Statement of Considerations accompanying the backfit rule (53 FR 20603; June 6, 1988), where the Commission stated that backfitting "means measures which are intended to improve the safety of nuclear power reactors * * *." (53 FR at 20604). The nine factors to be considered under 10 CFR 50.109(c) further make clear that the rule is aimed at requirements applicable to licensees and facilities. These include: "(2) General description of the activity that would be required by the *licensee* or *applicant* in order to complete the backfit; * * * (5) Installation and continuing costs associated with the backfit, including the cost of *facility* downtime or the cost of construction delay; [and] (6) The potential safety impact of changes in plant or operational complexity. * * * [emphasis added]."

The final rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to State or local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to

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"consider" KI as one of the elements of their offsite emergency planning. However, the rule imposes no binding requirement to alter plans and procedures on State or local governments. Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing wording of § 50.47(b)(10). On this basis, the final rule does not impose new substantive requirements on *anyone*. After consideration of these factors, no backfit is involved and no backfit analysis as defined in § 50.109 is required.

Commission precedent also makes clear that the amendment does not constitute a backfit. The Commission's position was stated explicitly in 1987, when the last major change took place in emergency planning regulations (52 FR 42078; November 3, 1987). The Commission's final rule involving the "Evaluation of the Adequacy of Off-Site Emergency Planning for Nuclear Power Plants at the Operating License Review Stage Where State and Local Governments Decline to Participate in Off-Site Emergency Planning" stated that the emergency planning rule change in question "does not impose any new requirements on production or utilization facilities; it only provides an alternative method to meet the Commission's emergency planning regulations. The amendment therefore is not a backfit under 10 CFR 50.109 and a backfit analysis is not required" (52 FR 42084). Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing for full participation emergency exercises (a change that, as a practical matter, could be expected to result in licensees' modifying emergency preparedness-related procedures to accommodate exercise frequency changes), it stated: "The final rule does not modify or add to systems, structures, components or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. Accordingly, no backfit analysis pursuant to 10 CFR 50.109 is required for this final rule" (52 FR 16828; May 6, 1987). The final emergency planning rule change is of a similar nature and similarly does not involve a backfit.

It has been argued by at least one commenter on the petition for rulemaking that, although licensees are not directly burdened by the final rule, they would be indirectly burdened because they would feel called upon to explain the new policy to their customers. By this logic, almost any Commission action that led an NRC licensee to issue a press release could be considered a backfit. Such a position is unsound law and policy. Here, the burden of public information on licensees or applicants, if any, appears *de minimis*. It plainly does not rise to the level of the type of concrete burden contemplated by the Commission when it enacted the backfit rule. It might also be argued that, if a State or local government were to decide to stockpile and use KI for the general public, it would undertake interactions with the affected licensee to coordinate offsite emergency planning. Although this could result in some voluntary action by the licensee to coordinate its planning, the final rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the final rule would not impose any backfits as defined in 10 CFR 50.109.

Nonetheless, the Commission notes that this rule will introduce another element in the context of the emergency planning requirements that licensees are ultimately responsible for, whereby licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. That ultimate responsibility could have practical implications, with some associated burdens, the extent of which is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 68 Stat. 1242, as amended 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. Law 95–601, sec. 10, 92 Stat. 2951, as amended by Pub. Law 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. Law 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.47, paragraph (b)(10) is revised to read as follows:

§ 50.47 Emergency plans.

* * * * *

(b) * * *

(10) A range of protective actions has been developed for the plume exposure pathway EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidance, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

* * * * *

Dated at Rockville, Maryland, this 9th day of January, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–1156 Filed 1–18–01; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 150

RIN 3150–AG60

Termination of Section 274i Agreement Between the State of Louisiana and the Nuclear Regulatory Commission

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is revising its regulations to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20 (c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking.

DATES: The final rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Stephanie P. Bush-Goddard, Ph.D., Office of Nuclear Material Safety and Safeguards, telephone (301) 415–6257, e-mail, SPB@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Background

In 1967, the State of Louisiana and the United States Atomic Energy Commission (now the U.S. Nuclear Regulatory Commission) entered into an agreement pursuant to section 274b of the Atomic Energy Act of 1954, as amended, to discontinue the Commission's regulatory responsibilities over the use and possession of certain types of radioactive material in Louisiana. The State of Louisiana, in turn, assumed authority (formerly exercised by the NRC) over these regulatory activities. This agreement was noticed in the **Federal Register** on May 3, 1967 (32 FR 6806). The discontinuance of the Commission's authority became effective May 1, 1967 and, at the same time, established Louisiana as an Agreement State. Additionally, on May 3, 1967 (32 FR 6807), the Commission published in the **Federal Register** a notice of an agreement between the State of Louisiana and the Commission that permitted the State to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the Commission. This inspection agreement, entered into pursuant to section 274i of the Act, did not expand the State's regulatory authority but rather specifically authorized the State to conduct inspection activities and other functions on the Commission's behalf.

The NRC received a letter from Louisiana Governor M. J. "Mike" Foster, Jr., dated March 22, 2000, which requested termination of the section 274i agreement. The Governor stated that the termination would become effective 30 days from receipt of the letter. The request was filed in accordance with section 6 of the inspection agreement, which states: "* * * This Agreement shall become effective on May 1, 1967, and shall remain in effect so long as the 274b Agreement remains in effect unless sooner terminated by either party on 30 days' prior written notice."

Governor Foster noted that difficulties arranging transportation and a lack of financial and personnel resources made it burdensome to conduct field activities for the NRC. The State concluded that the section 274i inspection agreement was no longer needed and should be terminated.

Effective April 26, 2000, the inspection agreement with the State of Louisiana and the NRC was terminated. Beginning April 26, 2000, the NRC, not the State, began conducting inspections of NRC-licensed activities in offshore waters adjacent to Louisiana. In this final rule, the NRC is issuing a conforming amendment to its reciprocity regulations in 10 CFR 150.20 (c) and (d). These sections provide that a licensee is not required to fulfill certain NRC reporting requirements for licensed activities performed in certain offshore waters. Under section 150.20 (c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana was the only Agreement State listed in the regulation because it was the only State which had entered into such an agreement with the NRC.

In a letter to Governor Foster acknowledging termination of the 274i Agreement, the NRC indicated it would remove from the regulation only the specific reference to the NRC's inspection agreement with Louisiana in section 150.20(d). However, to promote clarity in the regulations, these sections will be removed in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking. In a separate communication, the NRC will provide guidance to Louisiana licensees on the impacts that the termination of this agreement will have on the notification and fee requirements for activities conducted in offshore waters.

However, termination of the section 274i inspection agreement does not in any way affect the existing agreement between the Commission and the State of Louisiana entered into pursuant to section 274b of the Act. Accordingly, termination of the inspection agreement does not affect Louisiana's status as an Agreement State.

Procedural Background

This amendment involves a conforming change to NRC's regulations to reflect the fact that the State of Louisiana has terminated the section 274i inspection agreement. Accordingly, the NRC finds that, pursuant to 5 U.S.C. 553(b)(B), notice and comment is unnecessary. These amendments are effective upon publication in the **Federal Register**. Good cause exists to dispense with the usual 30-day delay in the effective date, because these amendments are of a minor and administrative nature, conforming the NRC's regulations as a result of the April 26, 2000 termination of the 274i agreement with the State of Louisiana.

Agreement State Compatibility

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and

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published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as compatibility Category "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

Voluntary Consensus Standards

The National Technology Transfer Act of 1995 (Public Law 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is revising its regulations to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20 (c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20 (c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking. This action does not constitute the establishment of a standard that establishes generally-applicable requirements.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(2). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget, Approval Number 3150–0032.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, collection of information unless it displays a currently valid OMB control number.

Regulatory Analysis

These minor amendments impose no new restrictions or requirements, and therefore, have no significant impact. Accordingly, a regulatory analysis is considered not necessary and has not been prepared.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This administrative rule is being revised to remove the reference to an inspection agreement, referred to as the 274i Agreement, with the State of Louisiana. The inspection agreement entered into pursuant to section 274i of the Atomic Energy Act allowed the State of Louisiana to perform inspections or other functions in offshore waters adjacent to Louisiana on behalf of the NRC. This reference is located in the reciprocity regulations in 10 CFR 150.20. Under section 150.20(c), certain general licensees are not required to file with the NRC if the licensee provides timely notification of its offshore activities to the Agreement State that issued the specific license, and that State is listed in 150.20(d) as agreeing to perform inspections for NRC under a 274i agreement. Louisiana is the only Agreement State listed in the regulation. This action responds to a request from the Governor of Louisiana to terminate the agreement. The NRC agreed that the 274i inspection agreement is no longer needed and should be terminated. Therefore, the NRC is revising the regulations by deleting 150.20(c) and (d) in their entirety. In the event NRC enters into a 274i inspection agreement with an Agreement State in the future, the provisions of 150.20(c) and (d), which were promulgated following notice and comment rulemaking, will be reinstated via direct final rulemaking.

Backfit Analysis

The NRC has determined that the backfit rule does not apply to this final rule because this amendment does not involve any provisions that would impose backfits as defined in 10 CFR Chapter 1. Therefore, a backfit analysis is not required for this final rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 150.

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

1. The authority citation for part 150 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841). Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.15 also issued under secs. 135, 141, Pub. Law 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec 234, 83 Stat. 444 (42 U.S.C. 2282).

§ 150.20 [Amended]

2. In § 150.20, paragraph (b)(1), first sentence, remove the words "Except as specified in paragraph (c) of this section, shall", add in their place "shall" and remove paragraphs (c) and (d).

Dated at Rockville, Maryland, this 28th day of December, 2000.

For the Nuclear Regulatory Commission.

Patricia G. Norry,

Acting Executive Director for Operations.

[FR Doc. 01–1079 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 740, 742, and 748

[Docket No. 010112014–1014–01]

RIN 0694–AC41

Implementation of Presidential Announcement of January 10, 2001: Revisions to License Exception CTP

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by revising License Exception CTP to reflect rapid technological advances in computing capability. This rule implements the President's sixth revision to U.S. export controls on high performance computers (HPCs), announced January 10, 2001. License Exception CTP is revised by removing Computer Tier 2 and merging its countries into Computer Tier 1. All HPCs continue to be eligible for export to a Computer Tier 1 country under License Exception CTP. Additionally, HPCs with CTP up to 85,000 MTOPS can be exported to Computer Tier 3 countries under License Exception CTP, and beginning March 20, 2001, exporters will no longer be required to submit National Defense Authorization Act (NDAA) advance notifications for HPCs with CTP exceeding 85,000 MTOPS. The NDAA advance notification will not be required for these computers, because exporters will be submitting a license for exports to Computer Tier 3 countries of HPCs with CTP exceeding 85,000 MTOPS. This rule also moves Lithuania from Computer Tier 3 to Computer Tier 1, effective May 19, 2001. The President's action will promote our national security, enhance the effectiveness of our export control system and ease unnecessary regulatory burdens on both government and industry.

DATES: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Tanya Hodge Mottley in the Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, at (202) 482–1837.

SUPPLEMENTARY INFORMATION:

Background

On January 10, 2001, the President announced significant changes to U.S. export control policy for HPCs. The new policy continues the Administration's commitment, as announced on July 1, 1999, to review and update its HPC policy every six months in order to reflect rapid advancements in computer hardware, as well as identify any risk posed by HPC exports to certain end-users and countries. This policy strengthens America's high tech competitiveness, while maintaining export controls to protect U.S. national security.

The Administration, in consultation with the national security community and industry, has determined that additional adjustments are warranted. Effective immediately, all countries in Computer Tier 2 have been moved to Computer Tier 1. Computer Tier 2 has been deleted. Those countries formerly in Computer Tier 2 do not pose proliferation or security threats to the United States.

This rule implements the Administration's decision to increase License Exception CTP eligibility for HPC exports to countries in Computer Tier 3 by raising the CTP level to 85,000 MTOPS, to reflect the widespread availability of computers, including high performance computing capability attained by clustering numerous lower level personal computers together.

Effective March 20, 2001, this rule raises the advance notification requirement level for HPC exports to Computer Tier 3 countries from 28,000 to 85,000 MTOPS. As required by the NDAA, changes in the advance notification level for HPC exports to Tier 3 destinations are only effective 60 days following the President's submission of a report to Congress. In addition, this rule revises the support documentation requirements for computers exported to the People's Republic of China.

This rule removes Lithuania from Computer Tier 3 and places it in Computer Tier 1. However, due to the requirements in the 1998 National Defense Authorization Act (NDAA), removing Lithuania from Computer Tier 3 is not effective until 120 days after the Congress receives a report justifying such a removal.

This rule revises the Export Administration Regulations by modifying computer exports under License Exception CTP, as follows:

1. Moving all Computer Tier 2 countries to Computer Tier 1;
2. Raising the CTP limit for computers eligible for License Exception CTP for exports and reexports to Computer Tier 3 destinations from "28,000 MTOPS" to "85,000 MTOPS";
3. Moving Lithuania to Tier 1 as of May 19, 2001;
4. Revising the CTP range for which NDAA notification is required for computers exported or reexported to Computer Tier 3 countries;
5. Revising the CTP level of computers for which PRC End-User Certificates are required as support documentation for export under License Exception CTP; and
6. Revising the CTP level of the computers that require post shipment verification reports for exports to Computer Tier 3 countries.

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This regulation involves collections previously approved by the Office of Management and Budget under control numbers 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 45 minutes per manual submission and 40 minutes per electronic submission. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Information is also collected under OMB control number 0694–0107, "National Defense Authorization Act," Advance Notifications and Post-Shipment Verification Reports, which carries a burden hour estimate of 15 minutes per report. This rule also involves collections of information under OMB control number 0694–0073, "Export Controls of High Performance Computers" and OMB control number 0694–0093, "Import Certificates and End-User Certificates."

3. This rule does not contain policies with Federalism implications as that

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term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rule making, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rule making and an opportunity for public comment be given for this rule. Because a notice of proposed rule making and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Foreign trade, Reporting and record keeping requirements.

15 CFR Part 742

Exports, Foreign trade.

Accordingly, parts 740, 742 and 748 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for 15 CFR Part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; Pub.L. No. 106–398; 50 U.S.C. 1701 *et seq.*; 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of November 10, 1999, 64 FR 61787, 3 CFR, 1999 Comp., p. 318; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

3. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 740—[AMENDED]

4. Part 740 is amended by revising section 740.7, to read as follows:

§ 740.7 Computers (CTP).

(a) *Scope.* License Exception CTP authorizes exports and reexports of computers and specially designed components therefor, exported or reexported separately or as part of a system for consumption in Computer Tier countries as provided by this section. (Related equipment controlled under 4A003.d and .g is authorized under this License Exception, only when exported or reexported with these computers as part of a system.) You may not use this License Exception to export or reexport items that you know will be used to enhance the CTP beyond the eligibility limit allowed to your country of destination. When evaluating your computer to determine License Exception CTP eligibility, use the CTP parameter to the exclusion of other technical parameters for computers classified under ECCN 4A003.a, .b and .c, *except* of parameters specified as Missile Technology (MT) concerns or 4A003.e (equipment performing analog-to-digital conversions exceeding the limits in ECCN 3A001.a.5.a). This License Exception does not authorize the export or reexport of graphic accelerators or coprocessors, or of computers controlled for MT reasons.

(b) *Computer Tier 1.* (1) *Eligible countries.* The countries that are eligible to receive exports under this License Exception include Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Barbados, Bangladesh, Belgium, Belize, Benin, Bhutan, Bolivia, Botswana, Brazil, Brunei, Burkina Faso, Burma, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Czech Republic, Chile, Colombia, Congo, Costa Rica, Cote d'Ivoire, Cyprus, Denmark, Dominica, Dominican Republic, Ecuador, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Gabon, Finland, France, Gambia (The), Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hong Kong, Hungary, Iceland, Indonesia, Ireland, Italy, Jamaica, Japan, Kenya, Kiribati, Korea (Republic of), Lesotho, Liberia, Liechtenstein, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritius, Mexico, Micronesia (Federated States of), Monaco, Mozambique, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Palau, Panama, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Portugal, Romania, Rwanda, St. Kitts & Nevis, St. Lucia, St. Vincent and Grenadines, Sao Tome & Principe, San Marino, Senegal, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, Spain, Sri Lanka, Surinam, Swaziland, Sweden, Switzerland, Taiwan, Tanzania, Togo, Tonga, Thailand, Trinidad and Tobago, Turkey, Tuvalu, Uganda, United Kingdom, Uruguay, Vatican City, Venezuela, Western Sahara, Western Samoa, Zaire, Zambia, and Zimbabwe. As of May 19, 2001, Lithuania is a Computer Tier 1 country.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 1 destinations are those having a Composite Theoretical Performance (CTP) greater than 6,500 Millions of Theoretical Operations Per Second (MTOPS).

(c) [Reserved]

(d) *Computer Tier 3.* (1) *Eligible countries.* The countries that are eligible to receive exports and reexports under this License Exception are Afghanistan, Albania, Algeria, Andorra, Angola, Armenia, Azerbaijan, Bahrain, Belarus, Bosnia & Herzegovina, Bulgaria, Cambodia, China (People's Republic of), Comoros, Croatia, Djibouti, Egypt, Georgia, India, Israel, Jordan, Kazakhstan, Kosovo (Serbian province of), Kuwait, Kyrgyzstan, Laos, Latvia, Lebanon, Lithuania, Macau, Macedonia (The Former Yugoslav Republic of), Mauritania, Moldova, Mongolia, Montenegro, Morocco, Oman, Pakistan, Qatar, Russia, Saudi Arabia, Serbia, Tajikistan, Tunisia, Turkmenistan, Ukraine, United Arab Emirates, Uzbekistan, Vanuatu, Vietnam, and Yemen. As of May 19, 2001, Lithuania is moved to Computer Tier 1.

(2) *Eligible computers.* The computers eligible for License Exception CTP to Tier 3 destinations are those having a CTP greater than 6,500 MTOPS, but less than or equal to 85,000 MTOPS, subject to the restrictions in paragraph (d)(3) of this section.

(3) *Eligible exports.* Only exports and reexports to permitted end-users and end-uses located in countries in Computer Tier 3. License Exception CTP does not authorize exports and reexports to Computer Tier 3 for nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR. Such exports and reexports will continue to require a license and will be considered on a case-by-case basis. Retransfers to these end-users and end-uses in eligible countries are strictly prohibited without prior authorization.

(4) *Supporting documentation.* Exporters are required to obtain a People's Republic of China (PRC) End-User Certificate before exporting computers described by paragraph (d)(2) of this section to the PRC, regardless of value. (See § 748.10(b)(3) of the EAR for information on obtaining the PRC End-User Certificate.) Exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see paragraph (d)(5)(v) of this section). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(5) *NDAA notification.* (i) *General requirement and procedures.* The National Defense Authorization Act (NDAA) of FY98 (Public Law 105–85, 111 Stat. 1629), enacted on November 18, 1997 requires advance notification of certain exports and reexports of computers to Computer Tier 3 countries. For each such transaction destined to Computer Tier 3, prior to using License Exception CTP, you must first notify BXA by submitting a completed Multipurpose Application Form (BXA–748P). The Multipurpose Application Form must be completed including all information required for a license application according to the instructions described in Supplement No. 1 to part 748 of the EAR, with two exceptions. You (the applicant as listed in Block 14) shall in Block 5 (Type of Application) mark the box "Other." This designator will permit BXA to route the NDAA notice into a special processing procedure. (Blocks 6 and 7, regarding support documentation, may be left blank.) BXA will not initiate the registration of an NDAA notice unless all information on the Multipurpose Application form is complete.

(A) *Prior to February 26, 2001,* advance notification is required for all exports and reexports of computers with a CTP greater than 12,500 but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 12,500 MTOPS, but less than or equal to 85,000 MTOPS.

(B) *Beginning on February 26, 2001 but prior to March 20, 2001,* advanced notification is required for export and reexport of computers with a CTP greater than 28,000 MTOPS, but less than or equal to 85,000 MTOPS to Computer Tier 3 destinations. You must also provide a notice using this procedure prior to exporting or reexporting items that you know will be used to enhance the CTP of a previously exported or reexported computer beyond 28,000 MTOPS, but less than or equal to 85,000 MTOPS.

(ii) *Action by BXA.* Within 24 hours of the registration of the NDAA notice, BXA will refer the notice for interagency review. Registration is defined as the point at which the notice is entered into BXA's electronic system.

(iii) *Review by other departments or agencies.* The Departments of Defense, Energy, and State have the authority to review the NDAA notice. Objections by any department or agency must be received by the Secretary of Commerce within nine days of the referral. Unlike the provisions described in § 750.4(b) of the EAR, there are no provisions for stopping the processing time of the NDAA notice. If, within 10 days after the date of registration, any reviewing agency provides a written objection to the export or reexport of a computer, License Exception CTP may not be used. In such cases, you will be notified that a license is required for the export or reexport. The NDAA notice will then be processed by BXA as a license application in accordance to the provisions described in § 750.4 of the EAR, and the licensing policies set forth in the Export Administration Regulations. Its NDAA notice number will be changed to a license application number. BXA may at this time request additional information to properly review the license application. If BXA confirms that no objection has been raised within the 10-day period (as described in paragraph (d)(5)(iv) of this section), you may proceed with the transaction on the eleventh day following date of registration. (Note that the fact that you have been advised to proceed with the transaction does not exempt you from other licensing requirements under the EAR, such as those based on knowledge of a prohibited end-use or end-user as referenced in general prohibition five (part 736 of the EAR) and set forth in part 744 of the EAR.)

(iv) *Status of pending advance notification requests.* You must contact BXA's System for Tracking Export License Applications ("STELA") at (202) 482–2752. (See § 750.5 of the EAR for procedures to access information on STELA.) STELA will provide the date of registration of the NDAA notice. If no departments or agencies raise objections within the 10-day period, STELA will provide you on the eleventh day following date of registration with confirmation that no objections have been raised and you may proceed with the transaction. BXA will subsequently issue written confirmation to you. If a license is required, STELA will notify you that an objection has been raised and a license is required. The NDAA notice will be processed as a license application. In addition, BXA may provide notice of an objection by telephone, fax, courier service, or other means.

(v) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (d)(5)(v), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(*1*) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS; and

(*2*) For exports on or after February 26, 2001, but prior to March 20, 2001, where the CTP is greater than 28,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (d)(5)(v)(C) of this section:

(*1*) Exporter name, address, and telephone number;

(*2*) NDAA notification number;

(*3*) Date of export;

(*4*) End-user name, point of contact, address, telephone number;

(*5*) Carrier;

(*6*) Air waybill or bill of lading number;

(*7*) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

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(8) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

Note to paragraph (d)(5)(v)(B) of this section: For exports authorized under License Exception CTP to the People's Republic of China (PRC), you must submit the PRC End-User Certificate Number identifying the transaction for which the End-User Certificate Number applies.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (d)(5)(v) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(1) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(2) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

(e) *Restrictions.* (1) *Access by certain foreign nationals.* Computers eligible for License Exception CTP may not be accessed either physically or computationally by nationals of Cuba, Iran, Iraq, Libya, North Korea, Sudan or Syria, except commercial consignees described in Supplement No. 3 to part 742 of the EAR are prohibited only from giving such nationals user-accessible programmability.

(2) *Reexport and retransfers.* Computers eligible for License Exception CTP may not be reexported/retransferred without prior authorization from BXA i.e., a license, a permissive reexport, another License Exception, or "No License Required". This restriction must be conveyed to the consignee, via the Destination Control Statement, see § 758.6 of the EAR. Additionally, the end-use and end-user restrictions in paragraph (d)(3) of this section must be conveyed to any consignee in Computer Tier 3.

(f) *Reporting requirements.* In addition to the reporting requirements set forth in paragraph (d) of this section, see § 743.1 of the EAR for additional reporting requirements of certain items under License Exception CTP.

PART 742—[AMENDED]

5. Section 742.12 is amended by removing the second sentence in paragraph (d); revising paragraph (a); removing and reserving paragraph (b)(2); and revising paragraph (b)(3) to read as follows:

§ 742.12 High performance computers.

(a) *License and recordkeeping requirements.* (1) This section contains special provisions for exports, reexports, and certain intra-country transfers of high performance computers, including software, and technology. This section affects the following ECCNs: 4A001; 4A002; 4A003; 4D001; 4D002; and 4E001. Licenses are required under this section for ECCN's having an "XP" under "Reason for Control" when License Exception CTP is not available (see § 740.7 of the EAR). License requirements reflected in this section are based on particular destinations, end-users, or end-uses. For the calculation of CTP, see the Technical Note that follows the Advisory Notes for Category 4 in the Commerce Control List. Note that License Exception CTP contains restrictions on access by nationals of certain countries, and on reexports and transfers of computers.

(2) In recognition of the strategic and proliferation significance of high performance computers, a license is required for the export or reexport of high performance computers to destinations, end-users, and end-uses, as specified in this section and on the CCL. These license requirements supplement requirements that apply for other control reasons, such as nuclear nonproliferation provided in section 742.3 of the EAR. The license requirements described in this section 742.12 are not reflected on the Country Chart (Supplement No. 1 to part 738 of the EAR). Three Computer Country Tiers have been established for the purposes of these controls. Countries included in Computer Tiers 1 and 3 are listed in License Exception CTP in section 740.7 of the EAR. As of January 19, 2001 there is no longer a Computer Tier 2, and countries that were in Tier 2 are incorporated into Computer Tier 1. Computer Tier 4 consists of Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria.

(3) Exporters must keep accurate records of each export to countries not included in Country Group A:1 (see Supplement No. 1 to part 740 of the EAR) of a computer with a CTP greater than 6,500 MTOPS. These records must be submitted semiannually to BXA and must contain the information as described in § 743.1 of the EAR.

(b) * * *

(1) * * *

(2) [Reserved]

(3) Computer Tier 3. (i) *License requirement.* (A) A license is required to export or reexport computers to countries in Computer Tier 3 to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in Computer Tier 3 countries.

(B) A license is required to export or reexport computers with a CTP greater than 85,000 MTOPS to a country in Computer Tier 3.

(C) Prior to February 26, 2001, a license may be required to export or reexport computers with a CTP greater than 12,500 MTOPS to countries in Computer Tier 3 pursuant to the NDAA (see § 740.7(d)(5) of the EAR). Beginning on February 26, 2001 but prior to March 20, 2001, a license may be required to export or reexport computers with a CTP greater than 28,000 MTOPS but less than or equal to 85,000 MTOPS to countries in Computer Tier 3 pursuant to the NDAA.

(ii) *Licensing policy for nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses.* License applications for exports and reexports to nuclear, chemical, biological, or missile end-users and end-uses and military end-users and end-uses subject to license requirements under § 744.2, § 744.3, § 744.4, § 744.5, and § 744.12 of the EAR in countries in Computer Tier 3 will be reviewed on a case-by-case basis using the following criteria:

(A) The presence and activities of countries and end-users of national security and proliferation concern and the relationships that exist between the government of the importing country and such countries and end-users;

(B) The ultimate consignee's participation in, or support of, any of the following:

(1) Activities that involve national security concerns; or

(2) Nuclear, chemical, biological or missile proliferation activities described in part 744 of the EAR;

(C) The extent to which the importing country is involved in nuclear, chemical, biological, or missile proliferation activities described in part 744 of the EAR;

(D) The end-user, whether the end-use is single-purpose or multiple-purpose.

(iii) *Licensing policy for other end-users and end-uses.* License applications for exports and reexports to other end-uses and end-users located in Computer Tier 3 countries will generally be approved, except there is a presumption of denial for all applications for exports and reexports of computers having a CTP greater than 6,500 MTOPS destined to Indian and Pakistani entities determined to be involved in nuclear, missile, or military activities included in Supplement No. 4 to part 744 (Entity List). All license applications for exports and reexports to India and Pakistan not meeting these criteria for presumption of denial will be considered on a case-by-case basis under other licensing policies set forth in the EAR applicable to such computers.

(iv) *Post-shipment verification.* This section outlines special post-shipment reporting requirements for exporters of certain computers to destinations in Computer Tier 3. Post-shipment reports must be submitted in accordance with the provisions of this paragraph (b)(3)(iv), and all relevant records of such exports must be kept in accordance with part 762 of the EAR.

(A) Exporters must file post-shipment reports for computer exports, as well as exports of items used to enhance previously exported or reexported computers, according to the following schedule:

(1) For exports occurring prior to February 26, 2001, where the CTP is greater than 12,500 MTOPS;

(2) For exports on or after February 26, 2001, but before March 20, 2001 where the CTP is greater than 28,000 MTOPS; and

(3) For exports on or after March 20, 2001 where the CTP is greater than 85,000 MTOPS.

(B) *Information that must be included in each post-shipment report.* No later than the last day of the month following the month in which the export takes place, the exporter must submit the following information to BXA at the address listed in paragraph (b)(3)(iv)(C) of this section:

(1) Exporter name, address, and telephone number;

(2) License number;

(3) Date of export;

(4) End-user name, point of contact, address, telephone number;

(5) Carrier;

(6) Air waybill or bill of lading number;

(7) Commodity description, quantities—listed by model numbers, serial numbers, and CTP level in MTOPS; and

(8) Certification line for exporters to sign and date. The exporter must certify that the information contained in the report is accurate to the best of his or her knowledge.

(C) *Mailing address.* A copy of the post-shipment report[s] required under paragraph (b)(3)(iv)(A) of this section shall be delivered to one of the following addresses. Note that BXA will not accept reports sent C.O.D.

(1) For deliveries by U.S. postal service: U.S. Department of Commerce, Bureau of Export Administration, P.O. Box 273, Washington, D.C. 20044, Attn: Office of Enforcement Analysis HPC Team, Room 4065.

(2) For courier deliveries: U.S. Department of Commerce, Office of Enforcement Analysis HPC Team, 14th Street and Constitution Ave., NW, Room 4065, Washington, DC 20230.

* * * * *

PART 748—[AMENDED]

6. Section 748.10 is amended by revising paragraph (b)(3) as follows:

§ 748.10 Import and end-user certificates.

* * * * *

(b) * * *

(3) Your transaction involves an export to the People's Republic of China (PRC) of a computer. You must obtain a PRC End-User Certificate, regardless of dollar value, as follows:

(i) For exports of computers as described by § 740.7(d)(2) of the EAR, regardless of value, to the People's Republic of China. (See paragraph (c) of this section for information on obtaining the PRC End-User Certificate.) Exporters are required to obtain a PRC End-User Certificate before exporting computers to the PRC. In addition, exporters are required to provide the PRC End-User Certificate Number to BXA as part of their post-shipment report (see § 740.7(d)(5)(v) of the EAR). When providing the PRC End-User Certificate Number to BXA, you must identify the transaction in the post shipment report to which that PRC End-User Certificate Number applies. The original PRC End-User Certificate shall be retained in the exporter's files in accordance with the recordkeeping provisions of § 762.2 of the EAR.

(ii) For exports of computers that require license applications.

* * * * *

Dated: January 16, 2001.

Matthew S. Borman,

Acting Deputy Assistant Secretary for Export Administration.

[FR Doc. 01–1623 Filed 1–16–01; 4:49 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N–484R]

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require human cells, tissue, and cellular and tissue-based product establishments to register with the agency and list their human cells, tissues, and cellular and tissue-based products. FDA is also amending the registration and listing regulations that currently apply to human cells, tissues, and cellular and tissue-based products regulated as drugs, devices, and/or biological products. These actions are being taken to establish a unified registration and listing program for human cells, tissues, and cellular and tissue-based products.

DATES: The regulation is effective April 4, 2001, except for 21 CFR 207.20(f), 807.20(d), and 1271.3(d)(2), which are effective on January 21, 2003.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

We, FDA, are putting in place a comprehensive new system of regulation for human cells, tissues, and cellular and tissue-based products. The goal of the new approach is to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products. Under the new system, the regulation of different types of human cells, tissues, and cellular and tissue-based products will be commensurate with the public health risks presented, enabling us to use our resources more effectively. Consolidating the regulation of human cells, tissues, and cellular and tissue-based products into one regulatory program is expected to lead to increased consistency and greater efficiency. Together, these planned improvements will increase the safety of human cells,

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tissues, and cellular and tissue-based products, and public confidence in their safety, while encouraging the development of new products.

A. Background

In 1997, we announced our regulatory plans for human cells, tissues, and cellular and tissue-based products in two documents:

- "A Proposed Approach to the Regulation of Cellular and Tissue-Based Products" (62 FR 9721, March 4, 1997) and
- "Reinventing the Regulation of Human Tissue" (Ref. 1).

The proposed approach described a comprehensive plan for regulating human cells, tissues, and cellular and tissue-based products that would include establishment registration and product listing, donor-suitability requirements, good tissue practice regulations, and other requirements. Under this tiered, risk-based approach, we proposed to exert only the type of government regulation necessary to protect the public health. To accomplish this goal, we planned to issue new regulations under the communicable disease provisions of the Public Health Service Act (the PHS Act). Some human cellular and tissue-based products would be regulated only under these new regulations, while other human cellular and tissue-based products would also be regulated as drugs, devices, and/or biological drugs. We requested written comments on the proposed approach and, on March 17, 1997, held a public meeting (62 FR 9721).

Since 1997, we have published three proposed rules to implement the proposed approach. In 1998, as a first step toward accomplishing these goals, we published the proposed rule, "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products" (63 FR 26744, May 14, 1998) (the "registration proposed rule"). That rule proposed to require cell and tissue establishments to register with us and submit a list of their human cellular and tissue-based products. We also proposed modifications to current registration and listing requirements for drugs and devices under which cell and tissue establishments already regulated under the Federal Food, Drug, and Cosmetic Act (the act) and/or section 351 of the PHS Act (42 U.S.C 262) would register and list following the new procedures.

In addition to the registration proposed rule, we published two more proposed rules:

- Suitability Determination for Donors of Human Cellular and Tissue-Based Products (64 FR 52696, September 30, 1999) (the "donor-suitability proposed rule"); and
- Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (66 FR 1508, January 8, 2000) (the "GTP proposed rule").

Together, these three rules when finalized would establish a comprehensive regulatory program for human cellular and tissue-based products, to be contained in part 1271 (21 CFR part 1271).

In the three proposed rules, we used the term "human cellular and tissue-based products." In this final rule, we have changed the term to "human cells, tissues, and cellular and tissue-based products" (abbreviated "HCT/P's"). This change in terminology is a clarification and does not affect the scope of the definition, which continues to encompass an array of articles containing or consisting of human cells or tissues, and intended for implantation, transplantation, infusion, or transfer into human recipients, including investigational products. The definition of "human cells, tissues, or cellular or tissue-based product" is intended to cover HCT/P's at all stages of their manufacture, from recovery through distribution. Some examples of HCT/P's include skin, tendons, bone, heart valves, corneas, hematopoietic stem cells, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue.

B. Implementation of the New Regulations

We had intended to finalize the registration proposed rule with the two other rules that would make up part 1271 in its entirety, and to implement all three rules together. However, we are now making the registration rule final, with staggered effective dates, before finalizing the two remaining portions of part 1271. We are taking this action because of recent concerns raised about the safety of tissue, which have led us to believe that accelerating the collection of basic information about the rapidly growing tissue industry is vital. This medical sector has grown rapidly, with a need for clearer standards and improved accountability. The Department of Health and Human Services met in mid-2000 with representatives of key tissue-related organizations, who supported finalization of this regulation as quickly as possible, instead of awaiting simultaneous publication with the other tissue regulations. For these reasons, we are going to begin collecting registration and listing information, while continuing to develop the remainder of the final rules that will complete part 1271, and we have changed the effective date of this rule from the proposed 180 days to 75 days after the date of publication in the **Federal Register**. As part of completing the rulemaking for part 1271, we would make any necessary conforming amendments to this regulation to make it consistent with any changes made in the remainder of the rulemaking process, and we would revoke part 1270.

Establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation currently regulated under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1270 (21 CFR part 1270) ("Human Tissue Intended for Transplantation") will be required to begin registering with the agency and listing their HCT/P's within 30 days after the effective date of this final rule. The effective date for all other human cells, tissues, and cellular and tissue-based products (as described in § 1271.3(d)(2)) is 2 years after publication, by which time we expect to have completed rulemaking for all the subparts of part 1271. (Some establishments that are not required to register and list until the second effective date have expressed a desire to submit registration and listing forms as soon as possible. In response, FDA is prepared to accept registration and listing forms submitted in advance of the second effective date. However, FDA is not soliciting this information.) Once the entire rulemaking is complete, the new regulatory approach would apply to a broad range of human cells, tissues, and cellular and tissue-based products, including reproductive cells and tissue; hematopoietic stem cells; and tissues and cells regulated as devices, drugs, and/or biological products.

Staggering the effective dates of this regulation permits us to begin collecting important registration and listing information soon from those establishments currently regulated under part 1270, while continuing to proceed through rulemaking to develop the remainder of part 1271. We believe that this action may prevent an unintentional gap in the regulation of certain currently regulated HCT/P's, permit an orderly implementation process, and avoid duplicative information collection. If we instead implemented the regulation immediately for all HCT/P's, this action could have the effect of shifting the regulation of certain products (e.g., HCT/P's currently regulated as devices that meet the criteria set out in § 1271.10 for regulation solely under section 361 of the PHS Act) into the new regulatory system before standards and enforcement provisions are in place. Staggering the effective dates also helps permit an orderly implementation process. Establishments that manufacture cells and tissues that will be regulated for the first time under new part 1271 may require more time than those currently regulated to implement the provisions of this final rule. However, we also recognize that unanticipated delays in completing the rulemaking for the remainder of part 1271 could occur. Should the rulemaking proceedings be delayed past the 2-year timeframe, we will consider whether to maintain the 2-year effective date for the HCT/P's described in § 1271.3(d)(2) or whether to extend that date for some or all of those HCT/P's.

C. Legal Authority

We are issuing this final rule under the authority of section 361 of the PHS Act. Under section 361 of the PHS Act, we may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for delegation of section 361 of the PHS Act authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) Intrastate transactions may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).)

HCT/P's are derivatives of the human body and thus pose a potential risk of transmitting infectious disease. We have determined that some HCT/P's may be effectively regulated solely by controlling the infectious disease risks they present. The regulation now being finalized forms the foundation for a regulatory program that will further the goal of preventing the transmission of communicable disease. To begin implementing this regulatory program, we are publishing the registration final rule, with staggered effective dates so that those HCT/P establishments not currently subject to regulation under section 361 of the PHS Act will have adequate preparation time and FDA can continue working towards finalizing the remainder of the program.

For this regulatory system to be effective in preventing the spread of disease, we must obtain basic information about the human cell and tissue industry and its HCT/P's. The information to be submitted in compliance with the registration and listing requirements in subpart B will provide baseline data on establishments that will be subject to part 1271. This information from the registration rule will assist us in reacting swiftly to newly discovered or understood risks by alerting members of the industry to our concerns and, when appropriate, by conducting establishment inspections. Without this information, we would not be able to effectively monitor compliance with the proposed donor-suitability, GTP, and other regulations that make up the rest of the regulatory program.

Authority for enforcement of section 361 of the PHS Act is provided by section 368 of the PHS Act (42 U.S.C. 271). Under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted (18 U.S.C. 3559 and 3571(c)). In addition, Federal District Courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. The regulations that we have proposed specific to enforcement appear in the GTP proposed rule.

HCT/P's that do not meet FDA's criteria set forth in part 1271 for regulation solely under section 361 of the PHS Act are regulated as drugs, devices, and/or biological products under the act and/or section 351 of the PHS Act, and their manufacturers are required to register with the agency under section 510 of the act (21 U.S.C. 360). Regulations implementing section 510 of the act are found in parts 207 and 807 (21 CFR parts 207 and 807), among other parts. In order to consolidate our data base on the cell and tissue industry and thus to improve our oversight functions, we are amending parts 207 and 807 to require registering establishments to follow the procedures set out in part 1271; these amendments are effective in 2 years, when we project the remaining two proposed tissue rules will be ready for implementation. Section 510 of the act remains the authority for the substantive registration requirement for products subject to parts 207 and 807. Because harmonizing the registration and listing procedures applicable to the various HCT/P's is intended to further the goal of preventing the spread of communicable disease, we are relying on the additional authority of section 361 of the PHS Act for the proposed amendments to parts 207 and 807.

II. Highlights of the Final Rule

A. Plain Language

On June 1, 1998, President Clinton directed Federal agencies to begin using "plain language" in regulations and other documents. The goal of the plain language initiative is to publish government documents that are easier to understand.

In response to this initiative, we have written the registration regulation in plain language. We have

- Written the regulation in question-and-answer format,
- Reorganized some regulatory sections for greater clarity, and
- Followed other plain-language conventions, such as using "must" instead of "shall."

The resulting codified language is easier to read and understand than the proposed regulation. These editorial changes are for clarity only and do not change the substance of the requirements.

B. Framework of the Final Regulation and Part 1271

When final, new part 1271 will be made up of six subparts. This final regulation contains subpart A (general provisions pertaining to the scope and applicability of part 1271; definitions); and subpart B (registration and listing procedures). The donor-suitability proposed rule contains subpart C of part 1271; and the GTP proposed rule contains subparts D, E, and F.

Section 1271.10, in subpart A, sets out the criteria that form the foundation of our tiered, risk-based approach to regulating HCT/P's. HCT/P's that meet these criteria are subject only to regulation under section 361 of the PHS Act. When all the proposed rules that will make up part 1271 become effective, these HCT/P's would be subject to the regulations in part 1271, and no premarket submissions would be required. (We sometimes refer to these HCT/P's as "361 HCT/P's." This term replaces "section 361 products," which was used in the registration proposed rule.) HCT/P's that do not meet the criteria for regulation as 361 HCT/P's will be regulated as drugs, devices, and/or biological products.

In September 1999, in the donor-suitability proposed rule, we modified proposed §§ 1271.1, 1271.3(e), 1271.10, and 1271.20 as they appeared in the registration proposed rule, and we added new § 1271.15. We made some of these changes to clarify our meaning.

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We made other changes so that the provisions on scope and applicability contained in subpart A would apply not only to the registration procedures in subpart B but more generally to the rest of the requirements in part 1271. These changes obviated the need for the addition, in later rulemaking, of new sections dealing with scope and applicability and were consistent with our original regulatory intent, as set out in the proposed approach.

We received comments on the registration proposed rule, and we received additional comments on subparts A and B of part 1271 in response to the donor-suitability proposed rule. To the extent possible we address these comments in this final rule; however, we recognize that additional discussion may be necessary as issues arise in the remaining rules that will makeup part 1271.

C. Staggered Effective Dates

In order to accomplish the goal of staggering the effective dates of the registration and listing regulation for different types of HCT/P's, we have divided the definition of "HCT/P" in § 1271.3(d) into two paragraphs. Paragraph (d)(1) of § 1271.3 identifies the subgroup of human tissues defined in part 1270. Paragraph (d)(2) provides the broader definition of HCT/P based on proposed § 1271.3(e). The definition of the subgroup in paragraph (d)(1) incorporates the definition of "human tissue" set out in § 1270.3(j) and thus identifies those tissues that are currently regulated under part 1270, including, for example, such tissues as corneas, bone, and skin. This represents the subgroup of human cells, tissues, and cellular and tissue-based products for which this final rule will first go into effect. Paragraph (d)(2) of § 1271.3 provides the broader definition of HCT/P and includes those HCT/P's described in paragraph (d)(1) as well as such additional HCT/P's as reproductive cells and tissues, hematopoietic stem cells, and cells and tissues currently regulated as drugs, devices, and/or biological products. The definition in paragraph (d)(2) of § 1271.3 will eventually replace paragraph (d)(1), as described below.

The effective date of § 1271.3(d)(1) is 75 days after the publication of this rule. The entire definition of HCT/P in § 1271.3(d)(2) is effective 2 years after the publication of this final rule in the **Federal Register**. The effect of this action is to make this final regulation applicable first to those HCT/P's currently regulated under part 1270, and later to the complete range of HCT/P's defined in § 1271.3(d)(2). When all of the regulations that make up part 1271 are final and have superseded part 1270, we will revoke § 1271(d)(1) and renumber (d)(2) as a conforming amendment. At that time the new regulatory framework contained in part 1271 will be instituted as a whole.

D. Other Highlights of This Final Rule

This final rule contains other changes from the proposed rule. Among these changes are the following:

- We have broadened "family-related allogeneic use," as used in proposed § 1271.10, to include first-degree and second-degree blood relatives.
- We have modified the definition of "homologous use."
- We have replaced the phrase "combined with or modified by the addition of a drug or a device" in § 1271.10 with new language.
- We have deleted the phrase "pending scheduled" from the exception in § 1271.15(d) for establishments that only receive or store HCT/P's.
- We have added an exception for establishments that only recovers reproductive cells or tissues for immediate transfer into a sexually intimate partner of the cell or tissue donor. (§ 1271.15(e)).

III. Comments on the Proposed Rule and FDA's Responses

We received 28 comments on the proposed rule as it was published in 1998. We received over 400 comments on the donor-suitability proposed rule; many of these raised issues related to subparts A and B of part 1271.

A. General Comments

(Comment 1) Many comments expressed general approval of the rule. One comment stated that the proposed rule addresses the public health needs for regulation in this area, helping to assure an adequate supply of safe and functional products without imposing unnecessary regulatory burdens or inhibitions to progress. Another comment, in support of registration, noted the importance of establishing a known data base of the industry. Another comment stated that creation of an official inventory of establishments subject to FDA regulation is important to determine the actual level of compliance and to develop reliable estimates of the cost of enforcement.

We acknowledge and appreciate these supportive comments. The new regulation on registration and listing will increase our knowledge and understanding of the HCT/P industry and will enable us to monitor industry developments and communicate with industry members. This final rule will enhance our compliance efforts in protecting the public from the spread of communicable diseases, when the remaining tissue regulations become effective.

(Comment 2) Some comments objected to the development of a comprehensive regulatory system. One of these comments objected that the approach is based on potential, not actual, concerns, is more applicable to new products than to such tissues as corneal tissue offered for transplant, and is unnecessary in light of quality assurance programs established by professional organizations.

We believe that this new regulatory program for HCT/P's, when it is in place, will be superior to the confusing patchwork of requirements that it will replace. We have created a simple registration system with uniform requirements for all HCT/P's and a one-page registration and listing form. The procedures in subpart B of part 1271 will be followed by all HCT/P establishments, along with those in proposed subparts C and D of part 1271. Together, they are intended to establish a communicable disease prevention program necessary to protect the public health.

In developing and issuing the registration rule, we have recognized that, because all HCT/P's are derived from the human body, they share certain common characteristics, among other things the ability to transmit infectious diseases. Thus, basic requirements such as registration, communicable disease screening and testing, and GTP's may reasonably be applied to all HCT/P's. However, we have also recognized that within the larger group of HCT/P's, certain products may present a greater degree of risk, and that these HCT/P's should be subject to additional premarket requirements.

With this tiered, risk-based approach, we will be putting in place a set of baseline requirements for all HCT/P's, while recognizing that different HCT/P's may present different concerns. As the comment points out, some concerns may be more applicable to new products than to such tissues as corneal tissue offered for transplant. We have identified criteria corresponding to the types of reduced risks that certain products may present. HCT/P's that do not meet all of these criteria will be regulated under the act and/or section 351 of the PHS Act (subject to subsequent effective dates). On the other hand, most HCT/P's, including cadaveric corneas, will be regulated solely under the communicable disease authority of section 361 of the PHS Act

and the regulations that will make up part 1271.

When implemented, the registration, donor-suitability, and GTP regulations are intended to reduce the risk of transmission of communicable disease by HCT/P's. The donor-suitability proposed rule incorporates and expands upon many of the requirements for human tissue intended for transplantation in part 1270. The part 1270 requirements were put into place to prevent the transmission of human immunodeficiency virus and hepatitis through the transplantation of tissue from domestic and foreign sources, "Human Tissue Intended for Transplantation," final rule (62 FR 40429, July 29, 1997).

Registration and listing are crucial components of a regulatory program to increase the safety of HCT/P's. Indeed, the United States General Accounting Office (GAO) has urged the agency to put a program in place in response to the potential transmission of infectious diseases from cell and tissue donors to recipients, GAO, "Human Tissue Banks, FDA Taking Steps to Improve Safety, but Some Concerns Remain" (December 1997).

We recognize the importance of voluntary quality assurance programs, and we respect the efforts and accomplishments of professional organizations. We have considered the efforts of professional organizations, and we will continue to do so as we implement the new regulations. However, not all HCT/P establishments belong to or are accredited by such groups, and voluntary programs are not enforceable.

(Comment 3) Another comment stated that we should finalize the registration rule as soon as possible, without waiting for the other rules.

We agree that there are benefits to publishing the registration final rule in advance of the other final rules, and we are doing so. However, as discussed earlier in this document, we are staggering the regulation's effective dates. Under this approach, we will be able to promptly begin receiving registration and listing information for HCT/P's currently subject to part 1270.

(Comment 4) One comment asserted that we should identify those tissues and entities subject to part 1271 that are not currently subject to part 1270, and initiate rulemaking to broaden the coverage of the substantive regulations codified in part 1270.

Rather than broaden the scope of the regulations in part 1270, we have earlier noted that we intend to replace part 1270 with the new regulations in part 1271 (donor-suitability proposed rule, 64 FR 52697). Revocation of part 1270 will occur at the time the GTP final rule becomes effective. We have earlier made clear (64 FR 52697 to 52698) that the new rules in part 1271, when complete, will be broader in scope than those in part 1270, will impose additional testing and screening requirements, and will cover more establishments and HCT/P's (e.g., hematopoietic stem cells, reproductive tissue). Thus, it is not necessary to initiate rulemaking to broaden the coverage of the regulations in part 1270.

(Comment 5) One comment asked the agency to clarify if it intends to require registered organizations to pass along any information the agency disseminates. Another comment counseled against depending on a secondary dissemination system, from those required to register to those with whom they interact who are not required to register, to get educational information to all of the tissue community.

We are not imposing a specific information-dissemination requirement at this time. The only members of the tissue community who would be subject to the rules in part 1271 and who are not required to register are those individuals who recover cells or tissue under contract, agreement, or other arrangement with a registered establishment, but who perform no other manufacturing step (except for sending the cells or tissue to the registered establishment). These individuals would be subject to the other requirements that will be contained in part 1271, when complete, and the establishments for whom they perform their services would be responsible for their work. (This exception is discussed in greater detail below.) Therefore, we believe that if we distribute information to registered establishments, we will be reaching the whole of the affected tissue community.

(Comment 6) One comment expressed concern that the proposed rule failed to identify the party ultimately responsible for the tissue or for the decisions required in the process of determining donor and tissue suitability.

We have addressed the question of responsibility in the GTP proposed rule.

(Comment 7) Several comments raised the issue of dispute resolution, particularly with respect to questions about homologous use and minimal manipulation. One of these comments urged us to develop and follow a process for resolving disputes in a prompt and efficient manner. One comment recommended that the Tissue Reference Group (TRG) serve as the forum for resolving any disagreements that arise with regard to the application of definitions.

We recognize that, as we implement this new regulation, there will be areas in which additional guidance may be desirable or interpretations may differ. To help answer questions about how a particular HCT/P will be regulated, the agency developed the TRG. If an establishment is not sure how its HCT/P may be regulated, it should contact the TRG.

The TRG provides a single reference point and makes recommendations to the Center Directors regarding regulation of specific HCT/P's, e.g., regulation solely under section 361 of the PHS Act or additionally under the act and/or section 351 of PHS Act. The TRG is composed of: (1) Three representatives from the Center for Biologics Evaluation and Research (CBER), including the product jurisdictional officer; (2) three representatives from the Center for Devices and Radiological Health (CDRH), including the product jurisdictional officer; and (3) a liaison from the agency's Office of the Chief Mediator and Ombudsman (OCMO), a nonvoting member. Other FDA staff attend the TRG meetings as needed to discuss issues related to products in their area of expertise. Further information about the TRG can be found on CBER's website at http://www.fda.gov/cber/tissue/trg.htm.

In some cases, a product regulated under the act will fall under the jurisdiction of more than one agency component, e.g., a combination device and biological product. Where the agency component with primary jurisdiction is unclear or in dispute, a sponsor may request designation from the product jurisdiction officer, who is the FDA Ombudsman, as detailed in 21 CFR part 3. In addition, the OCMO can assist in resolving disputes with the agency that may arise from decisions made by the Center Directors regarding the regulation of HCT/P's, after consideration of TRG recommendations, as described above.

In addition, we recognize that further public discussion of how tissue regulation would be applied to certain categories of human cells, tissues, and cellular and tissue-based products may be warranted due to the complexity or sensitivity of the issues. For example, we held a public meeting on August 2, 2000, to discuss how proposed definitions for "minimally manipulated" and "homologous use" should be applied to human bone allograft products (65 FR 44485, July 18, 2000). We intend to provide further opportunities for public discussion of

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how the regulatory approach should be applied to other HCT/P's. We anticipate that there may be additional needs for discussion through public meetings, public hearings, or guidance as we implement the new regulations.

(Comment 8) One comment asserted that we have published no document describing the TRG's current composition, authoritative status, procedures, whether its decisions are or will be made public, or how industry is expected to communicate with the group. The comment also suggested that we should consider making the TRG's policy decisions routinely available to the public.

We appreciate these comments and are committed to working on the issues raised. Among other things, the TRG is looking into mechanisms for increasing the transparency of its functions, while still protecting confidential information. Information about the TRG can be found on CBER's website at http://www.fda.gov/cber/tissue/trg.htm.

(Comment 9) Several comments asserted that we are proposing to regulate the practice of medicine, especially with respect to reproductive tissue and hematopoietic stem cells.

We disagree with this comment. This final rule sets out registration and listing requirements for establishments that recover, process, store, label, package, or distribute HCT/P's, or screen or test cell and tissue donors. HCT/P's, including hematopoietic stem cells and reproductive tissues, fall within our jurisdiction. Some HCT/P's will be regulated under the act and/or the PHS Act, while other HCT/P's will be effectively regulated solely by regulations issued under our authority to prevent the spread of communicable disease. We are not attempting to govern practitioners' use of HCT/P's, but rather to ensure that HCT/P's that would be used by practitioners in their treatment of patients are in compliance with applicable regulations, including regulations designed to prevent the transmission of spread of communicable disease.

(Comment 10) We received several comments on our proposed regulation of hematopoietic stem cells. One comment supported the proposal that all establishments involved with hematopoietic stem cell therapy register with FDA. Two comments asserted that the proposed regulation would jeopardize patient treatment, impede the development of new therapies, and increase the costs of treatment. One comment asserted that we lack the legal authority to regulate intrastate hematopoietic stem cell transplants. Another comment argued that clinical research involving the use of blood or bone marrow transplantation for treatment of human diseases, but not involving an investigational drug or device, should not require an investigational new drug application or investigational device exemption. This comment further requested the development of simplified procedures for evaluating those investigational devices or cellular biologic products that are more than minimally manipulated. Two comments argued that there is no need for FDA regulation as industry standards suffice and FDA requirements would be duplicative.

We believe that it is necessary to bring the regulation of hematopoietic stem cells in line with the regulation of other HCT/P's, and that we possess the legal authority to take this action. Like other HCT/P's, hematopoietic stem cells may transmit communicable diseases; thus, the basic communicable disease prevention requirements that will be contained in part 1271, including these registration and listing requirements, are as relevant to these cells as to any other HCT/P's. Intrastate activities involving hematopoietic stem cells, as well as other HCT/P s, can be regulated to prevent the interstate spread of communicable diseases under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).) The GAO has cited the lack of regulation of hematopoietic stem cells as a significant gap in our oversight, and urged us to proceed with implementing new regulations that would cover hematopoietic stem cells. We are now closing that gap.

Although we applaud the development of industry standards noted by the comments received, such standards are not followed by all HCT/P establishments. Moreover, voluntary standards differ significantly from enforceable regulations. We cannot take enforcement actions to ensure compliance with voluntary industry standards and thus would be limited in our ability to protect the public health if we relied on such standards alone. Establishments that comply with industry standards, however, should have little trouble adapting their practices to the new requirements. Thus, any additional burden should be minimal.

Rather than require data submission from each hematopoietic stem cell establishment, we have considered the development of standards for certain stem cell products. On January 20, 1998 (63 FR 2985), we published a notice in the **Federal Register** requesting the submission of proposed standards and supporting data relating to certain stem cell products by January 20, 2000, entitled "Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products." Later, we extended the deadline for submitting data to July 17, 2000 (65 FR 20825, April 18, 2000).

(Comment 11) One comment generally agreed with our proposal to require registration for certain reproductive tissue, but requested several clarifications and exceptions. Several comments questioned the need for the regulation of reproductive cells and tissues, citing current oversight from professional organizations, other Federal agencies, and States. Comments opposed registration for programs involved in egg donation, egg retrieval, semen processing, semen evaluation, or in vitro fertilization (IVF) in assisted reproductive technologies. One comment asserted that a large number of medical practitioners who perform inseminations would not be included in this new regulation, lessening their effectiveness. Another comment asserted that programs that manufacture tissue culture products for the growth of oocytes and sperm for sale should be required to register, but IVF programs making culture medium for their own uses should be exempt.

We stand by our decision to extend regulatory requirements to reproductive cells and tissue. Currently, FDA does not have regulations in place to address the infectious disease risk of donating, processing, and storing reproductive cells and tissue. Because there has been no registration or listing requirement, we have not had accurate information about the industry. We agree with the GAO that extending regulation to reproductive cells and tissues will remedy a significant gap in oversight.

Although we recognize the value of professional efforts to self-regulate, and of regulatory efforts of other agencies and the States, we disagree that these piecemeal, often voluntary, efforts are adequate. Nor will the new regulations in part 1271 be duplicative. State regulation varies from State to State and does not consistently address our concerns about the transmission of communicable disease. The model certification program for embryo laboratories developed by the Centers for Disease Control and Prevention (CDC) is a voluntary program that States may or may not choose to adopt; its primary focus is not on preventing the transmission of communicable disease. No State has yet adopted CDC's model certification program. Membership in professional societies is voluntary. Moreover, many establishments do not report to the Society for Assisted Reproductive Technology. The Clinical Laboratories Improvement Amendment of 1988 (CLIA) covers clinical laboratory testing, including certain procedures performed in embryo laboratories; however, as discussed later in this document, CLIA certification is not equivalent to the requirements we are putting in place.

We disagree that establishments that only deal with egg donation, retrieval, semen processing, or IVF should be exempt from the new regulations. These activities are vital to the handling of reproductive tissues. Performing these activities appropriately in order to prevent cross-contamination and mix-ups requires proper recordkeeping, storage practices, and accountability. Moreover, registration of these establishments is consistent with agency practice in other areas; e.g., establishments where only blood donation or processing occurs are required to register.

As discussed later in this document, however, this final rule contains a new exception for certain reproductive tissue establishments that perform only certain limited activities that raise limited communicable disease concerns. Under the exception, an establishment that only recovers reproductive cells or tissue for immediate transfer into a sexually intimate partner of the cell or tissue donor is not required to comply with the requirements that will be contained in part 1271, including registration and listing.

With respect to the comment about tissue culture media, these products are not considered HCT/P's. Rather, embryo culture media and other such products are regulated as medical devices by FDA, and establishments that manufacture embryo culture media are subject to the device regulations.

(Comment 12) Several comments responded to our discussion of regulating dura mater and human heart valve allografts as 361 HCT/P's rather than as devices, if they meet the criteria in § 1271.10 (63 FR 26744 at 26747). Three comments supported the regulation of heart valves as 361 HCT/P's. One comment suggested that, to prevent a regulatory "open window," the regulatory change should not take place until GTP requirements are effective or other steps are taken. One comment asked whether the transfer of heart valves would be reflected in a codified regulation. A fourth comment supported regulating dura mater as a 361 HCT/P and strongly suggested that "special controls" be included in the GTP requirements. No comments objected to regulating heart valve allografts and dura mater as 361 HCT/P's.

We agree that we should avoid an "open window" where possible. Therefore, we have staggered effective dates for this rule to prevent such an outcome. We do not intend to begin regulating human heart valve allografts and dura mater that meet the criteria in § 1271.10 as 361 HCT/P's until the donor-suitability and GTP components of part 1271 become effective, or other appropriate steps have been taken. The GTP proposed rule contains special requirements for dura mater intended to address the communicable disease concerns about that product. Because § 1271.10 contains the criteria for regulation of HCT/P's as 361 HCT/P's, and we are now reiterating our view that heart valves meeting those criteria will not be regulated as devices, we do not intend to issue a separate regulation to change regulatory authority on that specific point.

(Comment 13) One comment suggested that we consider voluntary accreditation and inspection programs in implementing our regulatory strategy. The comment further requested that we accord "deemed status" to certain accredited facilities.

We are exploring various options for inspections and compliance actions to enforce the new regulations. Among other ideas, we are looking into those suggested by this comment, including the legal issues raised. At present, we have in place a tiered inspection approach to enforce the regulations in part 1270 that takes into consideration such factors as professional accreditation. We intend to provide a more detailed discussion of our regulatory intentions after consideration of comments to the GTP proposed rule.

(Comment 14) One comment noted that tissue recovery is frequently performed by organ procurement organizations, and that the requirements with regard to the prevention of infectious disease transmission are appropriately much less stringent for organ donation than are comparable requirements for tissues. The comment asserted that exempting these organizations from regulation would immeasurably weaken the public health protection provided by this regulation.

An organ procurement organization that also recovers cells or tissues in addition to organs is not exempt from these regulations, and must register with the agency and follow all other regulations applicable to its actions with respect to HCT/P's. An organ procurement establishment is not required to submit a list of the vascularized human organs for transplantation that it recovers, because these organs are not covered by the definition of HCT/P (see § 1271.3(d)(2)(i)). However, such an organization must list with the agency any HCT/P's that fall within the scope of part 1271 that the organization recovers or otherwise manufactures.

B. Comments on Subpart A of Part 1271: Definitions

We received comments on many of the proposed definitions in § 1271.3(a) through (h). We did not receive comments on the definitions of "autologous" and "transfer." We address many of these comments below. Comments on the definitions of "homologous use" and "minimal manipulation" are addressed in section III.C of this document.

(Comment 15) The definition of *establishment* in proposed § 1271.3(b) reads as follows:

> *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cellular or tissue-based products. The term includes, among others, facilities that engage in contract manufacturing services for a manufacturer of human cellular or tissue-based products. The term also includes any individual partnership, corporation, association, or other legal entity engaged in the manufacture of human cellular or tissue-based products, *except that an individual engaged solely in the procurement or recovery of cells or tissues or under contract to a registered establishment is not required to independently register* (emphasis added).

Comments raised issues about the proposed exception in the last sentence of the definition. Some comments asserted that individuals or organizations engaged solely in procurement under contract should be required to register. One comment pointed to the critical role in the suitability assessment of a cell and tissue donor that such organizations play. Another comment asserted that registration and listing should be applied to those who screen donors and that procurement of tissue that is not done in an aseptic manner places tissue recipients at risk. One comment expressed confusion about the exception and suggested that "or under contract" should read "and under contract." This comment further suggested that individuals and other legal entities engaged solely in procurement or recovery be required to register unless contracted for that activity to a registered establishment.

Three comments argued for an expanded exception. One comment urged us to clarify that the "under

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contract to" language can apply to other contracting individuals, not just to contractors engaged in procurement or recovery (e.g., sales representatives who distribute HCT/P's). Two other comments requested clarification that clinical laboratories who perform testing are excluded from the registration and listing requirements.

We have rewritten the exception and moved it to § 1271.15(f). The relevant language now states:

> (f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

We believe this new language addresses many of the comments' concerns. We have replaced "or under contract" with "and under contract, agreement, or other arrangement." In addition, because "procurement" and "recovery" refer to the same action—the removal of cells or tissue from a donor—we have decided that it is redundant and possibly confusing to use both words. Instead, the exception now uses the term "recovery," the same term used in the definition of "manufacture" in § 1271.3(e). Therefore, the exception only applies to those individuals engaged solely in recovery of HCT/P's and who are under contract, agreement, or other arrangement with a registered establishment. We believe this is an appropriate way of easing the regulatory burden on individuals while ensuring the protection of the public health.

This exception does not extend to an individual who does more than recover tissue and send it to the contracting establishment. (Thus, for example, an individual engaged in any aspect of donor screening is not covered by the exception and must register.) Further, an individual who meets the terms of the exception would be excepted only from registration and listing requirements and would be required to comply with all other requirements to be contained in part 1271.

We are not extending the exception to "other legal entities." Only individuals are covered. Examples of such individuals not required to register might include certain medical examiners, morticians, or physicians who recover hematopoietic stem cells or tissues (e.g., corneas, cord blood). Laboratories that perform donor testing are not excluded from registration, listing, or other requirements in part 1271.

(Comment 16) We proposed to define *family-related allogeneic use* in proposed § 1271.3(c) as "the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product into a first-degree blood relative of the individual from whom cells or tissue comprising such product were removed." Under § 1271.10(d), as proposed, HCT/P's with a systemic effect that are for family-related allogeneic use would be regulated under section 361 of the PHS Act (provided that the HCT/P meets all other criteria set out in § 1271.10). This limited exception from the requirement for investigational use exemptions and premarketing submissions was first proposed in the proposed approach (62 FR 9721). In the registration proposed rule, we specifically requested further comments on the issue (63 FR 26744 at 26750).

We received approximately 13 comments on our proposed definition of "family-related allogeneic use," most from individuals and organizations involved in hematopoietic stem cell transplantation. One comment praised the proposed definition as clearer and more consistent than that used in the proposed approach, but cautioned that our terminology might create confusion. Other comments argued that we should expand the definition to more distantly related family members. Several comments suggested that the term include all ancestral relations, siblings, and collateral relations to the fourth degree by blood, marriage, or adoption. Another comment objected to distinguishing between family-related donors and other donors, stating that the same principles apply in both situations. This comment argued that the clinical use of unrelated versus related allogeneic transplants falls within the practice of medicine and should not be regulated by FDA.

We have decided to change the term from "family-related allogeneic use" to "allogeneic use in a first-degree or second-degree blood relative." Parents, children, and siblings are considered first-degree relatives. Aunts, uncles, nieces, nephews, first cousins, grandparents, and grandchildren are second-degree relatives. Relations by adoption or marriage are not included. Because we are using the phrase "first-degree or second-degree blood relative" in its ordinary sense, the final regulation does not contain a definition of this phrase.

Our decision to broaden the scope of related donors to include second-degree blood relatives, rather than just first-degree, is based upon several factors. In the absence of a human leukocyte antigen (HLA) identical sibling, the search for donors in extended families is occurring now to a very limited degree, but is likely to increase with the continuing advances in deoxyribonucleic acid technology. The likelihood of finding a donor with a haplotype identical to that of the recipient is greater among blood-related individuals than among unrelated individuals. Indeed, statistical methods have been proposed to measure this probability (Refs. 2 and 3).

In addition, for certain ethnic groups, it is extremely difficult to find an appropriate unrelated donor. Success at finding a match among the extended family can be equal to or even greater than the chance of finding a match using a single sibling search, if the haplotype is a common one within the patient's ethnic population, and the family members are of the same ethnic origin.

Registry outcome data for some hematologic malignancies suggest that peripheral blood and bone marrow transplant recipients may have a better survival rate when transplanted with hematopoietic stem cells from related donors. One possible reason is that a related donor is likely to share identical haplotypes with the patient (the genotypic level), whereas an unrelated donor is matched at the phenotypic level. Also, family donors may be better matched for minor histocompatability loci for which testing is not routinely performed.

We initially proposed a more limited exception. Having reviewed the comments on this issue, we believe there is some scientific merit in expanding the exception to second-degree blood relatives. This change is consistent with our goal of keeping regulatory burden to a minimum. The same scientific justification does not exist for expanding the exception to relatives by marriage or adoption, and is weaker for blood relatives beyond the second degree. In addition, the exception in § 1271.10(a)(4)(ii)(*b*) for allogeneic use in a first-degree or second-degree blood relative does not extend to those situations where the HCT/P is more than minimally manipulated, is advertised, labeled or otherwise objectively intended by the manufacturer for a nonhomologous use, or is combined with a drug or device (except as described in § 1271.10(a)(3)).

(Comment 17) One of the comments on "family-related allogeneic use" asserted that, in the context of reproductive medicine, the notion of appropriate use of family-related materials must include the close blood relatives of either partner. This comment proposed that those facilities collecting or using reproductive tissues from sexually intimate partners or close relatives should not be required to register.

Later in this document, we address the question of registration for reproductive tissue facilities. The change in terminology from "family-related allogeneic use" to "allogeneic use in first-degree or second-degree blood relatives" does not affect the registration of reproductive tissue establishments.

(Comment 18) Several comments objected to the word "product" in the term *human cellular or tissue-based product*, defined in proposed § 1271.3(e). These comments asserted that human cells and tissues are donations, not goods manufactured for sale. Some comments argued that the use of the word "product" might have legal implications; e.g., subjecting eye banks to inappropriate product liability litigation. Comments also noted that the word "product" is inconsistent with terms used in the tissue and eye banking field. We also received an objection to describing embryos and germ cells as "products."

In choosing "human cellular or tissue-based product," we were seeking a term that would describe everything that will be subject to the regulations in part 1271. We needed a term broad enough to cover both cells and tissues, and one that would include within its scope such diverse articles as unprocessed tissue, highly processed cells, and tissues that are combined with certain drugs or devices. Although we have considered removing the word "product" from the definition, we are concerned that another term (e.g., "human cells and tissues") would not be understood to include many of the highly manufactured products to which the regulations apply, or might be misconstrued to apply only to the cell or tissue component of such a product. Moreover, the term "product" is consistent with the language of the statutes under which we operate; for example, blood (which is also routinely donated) is a "biological product" under section 351 of the PHS Act. We do not believe that the use of the word "product" will affect the manner in which state laws apply to HCT/P's; our experience with the regulation of blood and blood products supports this view.

We recognize, however, that conceptual difficulties may arise in calling certain cells or tissues "products." Thus, as noted earlier in this document, we have expanded the term to "human cells, tissues, and cellular and tissue-based products," abbreviated as "HCT/P's." We have made appropriate substitutions throughout the regulation. The definition itself has not changed, and the scope of the term remains the same.

Proposed § 1271.3(e) has been redesignated as § 1271.3(d)(2).

(Comment 19) One comment stated that the proposed rule leaves vague peripheral blood lymphocytes that are not cultured or manipulated, but are used for their immunological effects for the treatment of disease. According to the comment, the definition in proposed § 1271.3(e)(2) (final § 1271.3(d)(2)(ii)) implies that these cells are subject to regulation under 21 CFR part 607. The comment recommends that these cells be specifically included in this proposal and not be considered mature blood cells subject to regulation under other sections of title 21 of the CFR.

We believe that the commenter is addressing donor lymphocytes (leukocytes) for infusion (DLI), which are the lymphocyte-rich cellular fractions obtained by leukapheresis of the peripheral blood of donors of bone marrow or peripheral blood hematopoietic stem/progenitor cells. Many DLI products are not further manipulated. These minimally manipulated products are administered to select patients to elicit a graft-versus-leukemia effect and to treat other transplant-associated complications.

DLI, regardless of the level of manipulation, meet the definition of HCT/P in this rule. FDA intends to regulate all DLI as HCT/P's, rather than as traditional blood products.

(Comment 20) One comment on proposed § 1271.3(e) requested clarification that an extract would not fall under the definition of human cellular or tissue-based product. The comment noted that the words "any cell or tissue-based component of such a product" may imply that an extract could fall within the definition.

We do not consider extracts to be HCT/P's. When we revised the definition of human cellular or tissue-based product in the donor-suitability proposed rule (64 FR 52696 at 52719), we deleted the phrase "or any cell or tissue-based component of such a product." Moreover, we listed "any secreted or extracted human products" as an exception to the definition of HCT/P in proposed § 1271.3(e)(3). These changes are codified in this rule at § 1271.3(d)(2)(iii).

(Comment 21) One comment on proposed § 1271.3(e)(4) objected to the exclusion of bone marrow from the definition of HCT/P, since all three sources of hematopoietic stem cells (cord, peripheral blood, bone marrow) have the same risk of infectious disease transmission.

Minimally manipulated bone marrow falls under the purview of the Health Resources and Services Administration (section 379 of the PHS Act (42 U.S.C. 274(k)). For this reason, we have excepted it from the definition of HCT/P's, and thus from the scope of this regulation issued under section 361 of the PHS Act authority.

The exception for bone marrow in final § 1271.3(d)(2)(iv) extends only to "minimally manipulated bone marrow for homologous use and not combined with a drug or a device (except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow)." Bone marrow would meet the definition of an HCT/P if it is: More than minimally manipulated; advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use, or combined with certain drugs or devices.

(Comment 22) In the proposed rule, we stated in proposed § 1271.3(f) that "*manufacture* means, but is not limited to, any or all steps in the recovery, screening, testing, processing, storage, labeling, packaging, or distribution of any human cellular or tissue-based product" (63 FR 26744 at 26754). Approximately 10 comments objected that the term "manufacture" is inappropriate. Some comments asserted that fertility clinics are not "manufacturers" of human tissue. Comments from the eye banks asserted that it is inaccurate to use the word "manufacture" with respect to corneal tissue; along with "product," the term could raise legal issues (e.g., subjecting eye banks to inappropriate product liability litigation). Another comment asserted that tissue banks do not manufacture tissue, but rather process it.

We have considered substituting a different term for "manufacture," but have been unable to find a satisfactory replacement. Most of the terms that we considered (e.g., produce, handle) were too limited in scope. Moreover, comments that objected to the term did not suggest alternatives. For these reasons, we continue to use the word "manufacture" as an umbrella term to capture the many different actions that HCT/P establishments might take in preparing HCT/P's for use. These steps may include, but are not limited to, recovery, screening, testing, processing, storage, labeling, packaging, and distribution. No comments disagreed with or objected to any of the actions listed in the definition of manufacture.

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Rather than list each of these activities repeatedly throughout this preamble and the regulation, we have decided to maintain the term "manufacture," as defined in this rule (proposed § 1271.3(f) is codified at § 1271.3(e)).

(Comment 23) One comment on *manufacture* questioned the rationale for requiring testing establishments to register. Three comments asserted that testing laboratories should not be required to register because CLIA certification is sufficient. One comment asked if labs that test for other diseases or that perform bacterial cultures need to register.

The definition of "manufacture" is intended to cover all steps in the process of handling HCT/P's. Testing donors for communicable diseases is a critical step in this process and for that reason is included the definition of manufacture. The registration requirement for testing laboratories enables us to have a list of all parties involved in manufacturing activities.

Having a list of testing laboratories enables us to inspect laboratories to ensure that testing is performed in a correct manner according to test kit instructions. The CLIA certification referred to in the comments is important, and in fact we are requiring CLIA certification. However, because there are differences between inspections under CLIA and inspections carried out by FDA, CLIA certification alone is not adequate for our purposes. CLIA requirements address only a limited spectrum of laboratory testing and personnel requirements and do not focus on donor testing. Moreover, our experience with inspecting testing laboratories indicates that significant violations have been found. To exclude testing laboratories from the scope of this regulation would not be consistent with our goal of preventing the transmission of communicable diseases.

The registration requirement for testing laboratories extends to those laboratories that test donor specimens for communicable disease. Only laboratories that test for relevant communicable diseases as defined in the proposed donor-suitability rule are required to register. We have clarified the definition of "manufacture" to refer to "screening or testing of the cell or tissue donor" rather than to screening or testing of the cell or tissue. In the situation where communicable disease testing to determine donor suitability might be appropriately performed on the cells or tissues, rather than on the donor (as might be the situation with cord blood), such testing would be included within the meaning of donor testing.

(Comment 24) One comment noted that entities engaged only in labeling and packaging are not explicitly within the scope of part 1270, but are covered by this new rule.

Part 1271 covers more activities than part 1270.

(Comment 25) In the preamble to the proposed rule, we noted that *distribution* "includes any conveyance or shipment of human cellular or tissue-based product (including importation and exportation), whether or not such conveyance or shipment is entirely intrastate and whether or not possession of the human cellular or tissue-based product is taken" (63 FR 26750). We have proposed a codified definition of "distribution" in the GTP proposed rule.

For purposes of the regulations in part 1271 only, we have proposed in the GTP rule to define "distribute" to mean the conveyance or shipment of an HCT/P. In other contexts, FDA has defined "distribution" more broadly. Under the act, FDA has interpreted the term "distribute" to include the delivery, transfer, and dispensing of products. Moreover, the ordinary, dictionary meaning of the term "distribute" includes acts such as delivering, dispensing, supplying, and giving out. In this rule, we do not intend the term to include the dispensing or the transfer of an HCT/P to or in a patient.

Two comments on the registration proposed rule disagreed with the phrase "whether or not possession is taken." They asserted that merely taking orders for a product should not be included within the meaning of "distribution," and thus should be excluded from "manufacture." One of these comments described its "service and distribution" agreement with a tissue processor, noting that although it does not ship or take possession of the product, its name appears on the product label along with that of the processor. A third comment recommended that the term "distributes" be clarified to exclude "distributors"; i.e., organizations that receive processed/manufactured allografts and ship them to hospitals. Another comment noted that hospitals and other establishments sometimes provide tissue to other institutions in emergencies or in cases of special need. The comment requested that these limited activities not be considered distribution.

We agree that an entity that does not take possession of HCT/P's is not distributing them for the purposes of this rule. However, we disagree that distributors should be excluded from the terms of the definition of "distribution." We agree that the occasional provision of HCT/P's to other institutions on an emergency basis does not fall within the meaning of "distribution."

We will consider any additional comments on the definition of "distribution" when finalizing the other proposed rules that will make up part 1271.

C. Comments on Subpart A: Proposed §§ 1271.10 and 1271.15 (Final §§ 1271.10 and 1271.20)

In proposed § 1271.10, we set out the criteria for regulating certain HCT/P's solely under section 361 of the PHS Act and the regulations to be contained in part 1271. An HCT/P would be subject to this level of regulation if it: (1) Was minimally manipulated; (2) was not promoted or labeled for any use other than a homologous use; (3) was not combined with or modified by the addition of any component that is a drug or a device; and (4) either does not have a systemic effect, or has a systemic effect and is for autologous, family-related allogeneic, or reproductive use (64 FR 52720).

Proposed § 1271.15 was intended to describe the HCT/P's that did not meet the criteria set out in § 1271.10 and for which we therefore did not consider regulation solely under section 361 of the PHS Act to be justified (64 FR 52699). The section set out the "mirror images" of the criteria in § 1271.10 to assist readers in understanding which HCT/P's would not be regulated solely under part 1271. However, rather than providing clarification, the proposed section could have been interpreted to create an additional hurdle for regulation of certain HCT/P's as drugs, devices, and/or biological products.

Our ability to regulate an HCT/P as a drug, device, and/or biological product derives from the act and section 351 of the PHS Act, authorities that are distinct from our authority to issue regulations to prevent the transmission of communicable disease under section 361 of the PHS Act. If an HCT/P does not meet the criteria in § 1271.10 for regulation solely under section 361 of the PHS Act, and the establishment does not qualify for any of the exceptions in final § 1271.15, the HCT/P will be regulated under the act and/or the PHS Act and applicable regulations. As part of this rulemaking process, we are amending certain drug and device regulations (e.g., §§ 207.20, 807.20) to require compliance with certain subparts of part 1271.

Therefore, we have modified proposed § 1271.15 and renumbered it § 1271.20. That section now refers to "an HCT/P that does not meet the criteria set out in § 1271.10(a)," rather than setting out the mirror images of those criteria. As before, the section contains cross-references to those drug and device regulations (e.g., §§ 207.20 and 807.20) that will direct establishments to follow the procedures set out in subparts B, C, and D of part 1271. The section now also clarifies that the referenced drug and device regulations apply if the establishment does not qualify for any of the exceptions in § 1271.15.

We address below the comments received on proposed § 1271.10 and on the proposed definitions of "homologous use" and "minimal manipulation."

(Comment 26) One comment requested that we schedule a public meeting to discuss the appropriateness, legality, and practicality of using the criteria in § 1271.10 to reach jurisdictional determinations.

We value public input on the criteria in § 1271.10. In February 1997 we made available the proposed approach, which among other things described the factors that we would consider in choosing to regulate certain HCT/P's solely under the authority of section 361 of the PHS Act rather than as drugs, devices, and/or biological products. On March 17, 1997, we held a public meeting to solicit information and views on the proposed approach from the interested public, and we opened a docket for the submission of comments (Docket No. 97N–0068).

We have published three proposed rules in the **Federal Register**. Two of those rules specifically solicited comments on the criteria for regulating certain HCT/P's solely under section 361 of the PHS Act. On August 2, 2000, we held an open public meeting to solicit information on current practices related to the manipulation and homologous use of human bone allograft in the spine and other orthopedic reconstruction and repair. Many of the comments presented at the meeting indicated that there were misunderstandings about how the criteria set out in § 1271.10 would be applied, and about the meaning of the terms "minimal manipulation" and "homologous use." This final rule contains clarifications and additional examples that we believe will clear up much of the confusion expressed at the meeting. We will consider issuing a guidance document if establishments need additional help in understanding the terms.

We intend to schedule additional public meetings as necessary. For example, FDA believes that additional public discussion of how the criteria in § 1271.10 would apply to reproductive tissues would be helpful, and further development of policy in this area may be warranted.

(Comment 27) We received numerous comments on the definition of *minimal manipulation*. The proposed definition reads as follows:

Minimal manipulation means:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells and nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

One comment urged us to state in the preamble of the final rule those activities that FDA presently considers to be minimal manipulation. Two comments recommended that the following procedures be considered minimal manipulation: Selective removal of B-cells, T-cells, or malignant cells; blood or platelet depletion; centrifugation; density gradient separation; and cryopreservation. Two comments supported the use of clinical and scientific data to determine whether a tissue-processing method is appropriately considered to be minimal manipulation or more than minimal manipulation.

Eight comments asserted that "minimal manipulation" is vague and open to subjective interpretation, and should be eliminated. Two comments asserted that it is difficult to draw a meaningful distinction between tissues that are minimally manipulated and those that are more than minimally manipulated. One of these comments suggested that instead of the minimal manipulation criterion, FDA should propose that tissue products labeled or promoted for tissue replacement, reconstruction, or restoration of function be regulated as tissue. Another comment requested the development of guidance and noted that, in light of future technological advances, a broader definition of minimal manipulation may be more appropriate. One comment recommended that the TRG serve as the liaison for communicating with manufacturers concerning FDA's intended application of the definition of minimal manipulation to particular tissues.

We received many comments on the regulation of bone allografts, INCLUDING bone dowels, submitted in response to the donor-suitability proposed rule. (The agency had previously considered regulating certain bone dowels as medical devices.) Many of these comments addressed the concept of minimal manipulation. Several comments supported regulating machined bone allografts as medical devices in order to evaluate their safety and efficacy and protect the public health. However, most comments opposed such regulation, pointing to the long history of safe use of bone allografts and citing concerns about decreased supply, among other issues.

Comments did not suggest changes to the definition of minimal manipulation, and we have not changed the regulation's wording. We disagree that the term should be eliminated, however, as it serves as a valid indicator of those HCT/P's that present fewer risks and that are most appropriately regulated solely under section 361 of the PHS Act and part 1271 (so long as other criteria are also met).

We agree that the TRG will continue to play a role in providing recommendations for certain decisions made by the Center director interpreting the term "minimal manipulation." At this time, examples of HCT/P's that we consider to be minimally manipulated include those that have been subjected to the following procedures: Density gradient separation; selective removal of B-cells, T-cells, malignant cells, red blood cells, or platelets; centrifugation; cutting, grinding, or shaping; soaking in antibiotic solution; sterilization by ethylene oxide treatment or irradiation; cell separation; lyophilization; cryopreservation; or freezing. We do not agree that the expansion of mesenchymal cells in culture or the use of growth factors to expand umbilical cord blood stem cells are minimal manipulation.

Most of the comments we received on the regulation of bone allografts and bone dowels assumed that we planned to regulate all bone allografts as medical devices. This is a misunderstanding. We are not considering regulating all bone allografts as medical devices. Like all other HCT/P's, the regulation of bone allografts depends on the four factors set out in § 1271.10. If the allograft is minimally manipulated, is not advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use, and is not combined with a drug or device (except as described in § 1271.10(a)(3)), then it will be regulated as a 361 HCT/P and subject only to the regulations in part 1271. (Bone allografts do not have a systemic effect, so the fourth factor is not at issue.) We consider cutting, shaping and grinding of bone minimal manipulation. Threading and other machining procedures that are performed to create bone dowels, screws, and pins are also considered minimal manipulation.

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(Comment 28) We received many comments on the term *homologous use*, which we defined in proposed § 1271.3(d) as follows:

Homologous use means the use of a cellular or tissue-based product for replacement or supplementation and:

(1) For structural tissue-based products, occurs when the tissue is used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs; or

(2) For cellular and nonstructural tissue-based products, occurs when the cells or tissue is used to perform the function(s) that they perform in the donor.

One comment praised the definition as reasonable, but urged us to develop a process for resolving differences of opinion between FDA and tissue manufacturers. Another comment supported our preamble statement that the "[b]asic function of a structural tissue is what the tissue does from a biological/physiological point of view, or is capable of doing when in its native state" (63 FR 26744 at 26749). As an example, this comment pointed to surgical use of fascia lata or pericardium allografts to replace or repair damaged dura mater or to construct a bladder support sling from a fascia lata allograft to prevent incontinence. Another comment questioned whether the homologous/nonhomologous criterion is a meaningful indicator of the need for premarket review; this comment cited fascia lata as an example of a tissue that has been used safely and effectively for years in ways that may be considered nonhomologous. One comment in response to our statement (63 FR 26744 at 26749) that the use of hematopoietic stem cells for treatment of adrenal leukodystrophy is an example of nonhomologous use stated that logical application of hematopoietic stem cells for their known hematologic, immunologic or metabolic effects as treatment of human disease should be considered within the practice of medicine and not subject to regulation by FDA.

Approximately 10 comments argued that the term "homologous use" should be eliminated. Many of these comments asserted that the term is vague and open to subjective interpretation. One comment stated that the phrase "fulfills in its native state" implies that tissue must be used in the identical place and for identical purposes, which ignores the realistic use of most tissue products. Many comments questioned the application of the term "homologous use" to bone allografts. One asserted that it is unusual for allograft tissues to be used in a homologous location, especially with regard to the spine.

Below, in comment 29, we discuss our decision to look not at the actual use of an HCT/P, but at the manufactuer's objective intent for a nonhomologous use. Under this approach, a practitioner could use an HCT/P, such as hematopoietic stem cells or fascia lata, for a nonhomologous use in the treatment of the physician's patients. Thus, we would not look at the surgical use of HCT/P's such as fascia lata or pericardium allografts, but instead at whether they were advertised, labeled, or otherwise objectively intended by the manufacturer for a nonhomologous use. In the absence of advertising, labeling, or other indications of the manufacturer's intent for such use, we would not require premarket submissions. Should such review be required for a product that has been used safely and effectively for years in nonhomologous ways, and that is intended for a nonhomologous use, we would expect that data would already exist to facilitate the review process.

We disagree that the term "homologous use" should be eliminated as a criterion for regulation of human cells or tissues under section 361 of the PHS Act. Regulation solely under section 361 and part 1271 is not warranted unless it is clearly demonstrated that the use of an HCT/P in the recipient is homologous to the function the HCT/P would carry out in the donor. We continue to consider nonhomologous use to be a meaningful indicator that regulation solely under section 361 of the PHS Act is not sufficient. For example, promotion of an HCT/P for an unproven therapeutic use, such as curing cancer, would clearly make it inappropriate to regulate the HCT/P solely under section 361 of the PHS Act and the regulations that will be in part 1271.

We have, however, rewritten the definition of homologous use in response to the comments' concerns. The new definition (codified at § 1271.3(c)) reads: "Homologous use means the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." The rewording eliminates the distinction between, on the one hand, structural tissues and, on the other, nonstructural tissues and cells. The new wording does not include the statement that, for structural tissues, homologous use occurs "in a location where such structural function normally occurs." This language was understood, contrary to our intention, to limit the use of structural tissue to the same location from which is was derived. However, a use of a structural tissue may be homologous even when it does not occur in the same location as it occurred in the donor. For example, the use of bone for repair, replacement, or reconstruction anywhere in the skeleton of the recipient (including the vertebral column) would be considered homologous use. However, it should be understood that, for the use of a structural tissue to be considered homologous, the HCT/P must perform the same basic function or functions in the recipient as it did in the donor; the use of structural tissue in a location where it does not perform the same basic function as it did in the donor would not be homologous.

We intend to interpret "nonhomologous" narrowly. Examples of uses that would be considered nonhomologous include: The use of dermis as a replacement for dura mater, the use of amniotic membrane in the eye, and the use of cartilage in the bladder. As noted above, an HCT/P that is intended by the manufacturer for one of these uses would not be regulated solely under section 361 of the PHS Act and these regulations, but as a drug, device, and/or biological product.

(Comment 29) We received approximately six comments agreeing with our focus in proposed § 1271.10(b) on the promotion or labeling of HCT/P's for nonhomologous uses, rather than on their actual use. One of these comments noted that the use of a product should be determined not by the practice of surgeons but by the promotion, labeling, and objective intent of the manufacturer. Another noted that the manner in which we intend to determine homologous use is consistent with the way we determine the intended use of other products under our jurisdiction. Two comments interpreted proposed § 1271.10(b) as relieving clinicians from restrictions on use of tissue, and one of these comments asserted that the exception should be extended to certain clinical transplant programs.

Another supportive comment questioned how we will regulate the labeling of 361 HCT/P's. Among other things, the comment asked whether we will require 361 HCT/P's to be labeled for their homologous use. The comment also queried whether cutting, shaping, or processing a product in a manner that makes it amenable to nonhomologous use would be considered promotion, in the absence of labeling or advertising.

We appreciate the comments on this issue, and we have decided to maintain the regulation's focus on the objective intent of the HCT/P's manufacturer for a nonhomologous use, rather than on

the intent of the practitioner who uses the HCT/P. We believe this approach will lead to more efficient use of our resources. The focus on labeling, advertising, and other indications of the manufacturer's objective intent does not relieve clinicians from all restrictions on the use of HCT/P's. However, it does mean that clinical use of an HCT/P in a nonhomologous manner, whether by an individual practitioner or a transplant program, can be consistent with regulation of the HCT/P solely under section 361 of the PHS Act and the regulations to be contained in part 1271. In order to clarify this provison, we are revising proposed § 1271.10(b) to read, in new § 1271.10(a)(2), as follows: "The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.

By labeling, we refer to the HCT/P label and any written, printed, or graphic materials that supplement, explain, or are textually related to the product, and which are disseminated by or on behalf of its manufacturer. We will address specific labeling requirements after reviewing comments to the GTP proposed rule.

In order to be more consistent with terminology used by the rest of the agency, we have replaced the word "promoted" with "advertised." The terms "advertised," "advertisement," and "advertising" include information, other than labeling, that originates from the same source as the product and that is intended to supplement, explain, or be textually related to the product (e.g., print advertising, broadcast advertising, electronic advertising (including the Internet), statements of company representatives).

(Comment 30) As originally proposed, § 1271.10(c) contained the following criterion for regulation of an HCT/P solely under section 361 of the PHS Act: "Not combined with or modified by the addition of any nontissue or noncellular component that is a drug or a device." We modified that wording in the donor-suitability proposed rule by deleting the phrase "nontissue or noncellular."

Two comments questioned the meaning of § 1271.10(c) and requested additional explanation. For example, the comments asked whether we would regard a component as being a drug or device based on its actual function in the product, or based on how the component is already regulated. The comments also questioned whether all products containing a "nontissue or noncellular component that is a drug or device" would automatically be subject to regulation and premarket review as drugs or devices, and expressed concern that application of the criterion might result in unnecessary regulation of HCT/P's as drugs or devices. Another comment asserted that we should not regulate a product containing a drug or device component unless it could affect recipient safety, and that the manufacturer should make the initial determination of whether this threshold has been crossed. One comment stated that hematopoietic stem cell components are routinely processed using centrifuges and other laboratory equipment, combined with dimethylsulfoxide (DMSO) and other reagents for cryopreservation, and separated using devices approved for the processing of hematopoietic stem cells components, and that we have previously classified these steps as minimal manipulation. The comment expressed concern that these steps might be considered to combine the cells with a drug or device component.

In response to the concerns expressed by these comments, we have rewritten the proposed language. Proposed § 1271.10(c) has been renumbered as § 1271.10(a)(3), and now reads: "The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P."

The addition of a drug or a device to the cell or tissue component of an HCT/P may ordinarily be expected to add a therapeutic effect and may also raise safety concerns. For these reasons, the addition of a drug or a device to a cell or tissue makes it no longer appropriate to regulate the HCT/P solely under section 361 of the PHS Act. (As used, the terms *drug* and *device* are defined in section 201(g) of the act (21 U.S.C. 321(g)).

However, we recognize that the use of certain sterilizing, preserving, and storage agents do not raise the same concerns. For this reason, we have excepted sterilizing, preserving, and storage agents, but only if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P. Examples of substances that would generally be acceptable include: (1) Cryoprotectants (e.g., DMSO); (2) chemicals used for sterilization (e.g., ethylene oxide); and (3) storage solutions. We encourage the development of industry standards that describe the safe use of sterilization, preserving, and storage agents.

Some drugs or devices that have as their principal purpose sterilizing, preserving, or storage may also have a therapeutic effect or may be claimed to have such an effect. The addition of such drugs or devices would not fall within the exception for sterilizing, preserving, and storage agents. We agree that the establishment that manufactures the HCT/P should make the initial determination of whether the addition of a drug or device that is a sterilizing, preserving, or storage agent to an HCT/P raises new clinical safety concerns.

(Comment 31) We received one comment in response to our request for comments on whether the term "systemic effect" adequately characterizes those HCT/P's that should be regulated under section 351 of the PHS Act, such as neural-derived tissues and cells used to replace or supplement neurons in the brain (donor suitability proposed rule, 64 FR 52699). This comment expressed concern that the intent of the proposed change is vague and that currently there is little or no evidence that supports such cells or tissues having any systemic effect when implanted in the brain.

After further consideration, we agree that the term "systemic effect" may not cover all of the HCT/P's that we intended to cover. Because the effect of implanted neurons or neural tissue into the brain would likely be restricted to the site where the tissue/cells were placed, this effect might not be included within the meaning of systemic. However, as discussed in the proposed approach, HCT/P's that rely on living cells for their primary function, such as neuronal tissue, raise clinical safety and effectiveness concerns that are not appropriately addressed solely under section 361 of the PHS Act. Such concerns include viability, efficacy, malignant transformation, or rejection after transplantation. Thus, although neuronal cells may not be considered to have a systemic effect, they nonetheless require regulation under the act and/or section 351 of the PHS Act.

Therefore, we have clarified § 1271.10(a)(4) to indicate that an HCT/P that either has systemic effect or depends upon the metabolic activity of living cells for its primary function would not be appropriately regulated solely under section 361 of the PHS Act, and therefore will be regulated as a drug, device, and/or biological product. Cells or tissues such as pancreatic islet cells, which have effects on many different organs throughout the body through the secretion of insulin, are appropriately characterized by the term "systemic effect." Neurons for implantation in the brain would fall into the category of HCT/P's that depend upon the metabolic activity of living

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cells for their primary function. In contrast, some HCT/P's (such as corneas, skin, or osteochondral allografts) may contain living cells, but do not depend on them for their primary function, which is structural.

(Comment 32) Two comments on proposed § 1271.10 suggested that isolated human hepatocytes intended for transplantation be considered to meet the criteria in § 1271.10 and therefore be regulated as 361 HCT/P's.

We do not consider human hepatocytes, isolated in tissue culture medium, infused into the spleen, and intended for temporary treatment of liver failure to be suitable for regulation solely under section 361 of the PHS Act. Human hepatocytes have a systemic effect. Therefore, regardless of the level of manipulation of the hepatocytes, these cells would be regulated under the act and section 351 of the PHS Act.

D. Comments on Subpart A: Proposed § 1271.20 (Final § 1271.15)

Proposed § 1271.20, as modified in the donor-suitability proposed rule, set out four specific exceptions from the requirements of part 1271. We address comments on these proposed exceptions below. In this final rule, we have renumbered proposed § 1271.20 as § 1271.15.

(Comment 33) We received one comment on the proposed exception in § 1271.20(b) for establishments that remove human cells or tissues from an individual and implant such cells or tissues into the same individual during the same surgical procedure. The comment assumed that hospitals retaining autologous tissue, not used in a scheduled surgical procedure, to be used in a subsequent application on the same patient, are exempt from registration and listing because the two applications are essentially a single continuous procedure.

We agree that, so long as the hospital does not engage in any other activity encompassed with in the definition of "manufacture," the hospital would not be required to register or comply with the other provisions to be codified in part 1271. For example, if the hospital expanded the cells or tissues, it would not meet the terms of the exception. In reaching this conclusion, we note that hospitals that store autologous cells or tissues for subsequent application in the same patient must follow the guidelines of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for tissue storage, monitoring of storage devices, and tracking in order to obtain or maintain accreditation.

(Comment 34) We received comments questioning the proposed exception in § 1271.20(d) for establishments that "receive or store human cellular or tissue-based products solely for pending scheduled implantation, transplantation, infusion, or transfer within the same facility." Approximately eight comments asserted that hospitals and other surgical facilities keep tissue allografts on hand for future use and suggested that the phrase "pending scheduled" be deleted from the exception. One comment projected that institutions would discontinue stocking tissue in order to avoid the registration requirement, leading to the denial to patients of appropriate implants. Another comment noted that thousands of hospitals and physician's offices store cells and tissue, and argued that registration could cause an unnecessary burden for facilities and FDA. One comment asserted that hospitals must follow the JCAHO guidelines for storage of tissues, monitoring of storage devices, and tracking of tissue use to provide for the safe storage of tissue. Another comment questioned whether physicians who receive sperm from a sperm bank and examine it for viability would be covered by the exception.

In response to many of these comments, we have deleted the phrase "pending scheduled." The exception, codified at § 1271.15(d), now reads:

> You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores human cells or tissue solely for implantation, transplantation, infusion, or transfer within your facility.

As we noted in the preamble to the registration proposed rule (63 FR 26744 at 26748), this exception is intended only for end-user establishments; that is, establishments that do not recover, distribute, or otherwise manufacture human cells or tissue. Examples of such establishments might include some hospitals, dental offices, and physicians' offices. Physicians who do not recover sperm from donors but only receive sperm from a sperm bank would fall within the exception; examining the received sperm sample for viability would not be considered screening.

We believe that expanding this exception will ease the regulatory burden without posing public health concerns. To date, we have not become aware of problems with the types of facilities that will fall under the exception. However, should that situation change—e.g., should we encounter problems with tracking systems or learn of storage problems—we will consider narrowing the exception through rulemaking to bring these establishments within the scope of the regulation.

(Comment 35) One comment argued that registration should not be required for facilities collecting or using reproductive tissues from sexually intimate partners or close relatives. The comment strongly urged us to expand proposed § 1271.20(d) to include establishments that collect reproductive materials for use between sexually intimate partners or close relatives.

We agree with this comment, in part, and have added new paragraph (e) to the exceptions in § 1271.15. This exception is limited to establishments that recover reproductive materials for immediate use between sexually intimate partners. (By "immediate use," we mean that the reproductive materials are used promptly enough that cryopreservation is not necessary and is not performed.) The exception is intended to cover an establishment that recovers semen for use in the artificial insemination of the donor's sexually intimate partner. We believe that this situation raises few new infectious disease concerns. For this reason, we are excepting these establishments from registering and from the other requirements that will be contained in part 1271. The exception does not extend to the recovery of cells or tissues from close relatives who are not sexually intimate partners, since an increased risk of communicable disease transmission exists in this situation.

E. Comments on Subpart B of Part 1271: Procedures for Registration and Listing

Many comments expressed general agreement with the proposed registration and listing procedures. One comment stated that the rule set forth a reasonable structure of requirements to be applied uniformly.

(Comment 36) One comment expressed concern that we might impose a registration fee.

We stated in the preamble to the registration proposed rule that we were evaluating our authority to assess a fee and the impacts of such a fee (63 FR 26744 at 26751). At this time, we have no plans to impose a registration fee.

(Comment 37) Comments opposed the proposed requirement in § 1271.21 for twice yearly reporting as excessive and supported annual listing updates instead. One comment noted that it is unlikely that the components processed by individual laboratories will change greatly over a 12-month period.

We disagree that the requirement for updating HCT/P lists is excessive. Establishments are required to update their listings with information on changes that have occurred since the previously submitted list. These changes include the introduction of new HCT/P's, the discontinuation of HCT/P's, the reintroduction of previously discontinued HCT/P's, and material changes in information previously submitted. However, if no such change has occurred since the previously submitted list, the establishment is not required to submit an update.

Those establishments that must update their lists will likely find the task relatively simple. As discussed in section III.G of this document, Form FDA 3356 was designed with ease of completion in mind. Yet the information to be submitted on those updates is crucial if we are to keep abreast of developments in the cell and tissue industry. Without current information, we will be restricted in our ability to understand the industry and achieve our public health goals.

In setting up a unified registration system for all HCT/P's, we incorporated certain components from current registration and listing regulations for drugs and devices, such as the update requirements. By doing so, we made it possible for establishments that manufacture HCT/P's regulated as devices, drugs, and/or biological drugs to register and list their products with the agency using the same form as manufacturers of 361 HCT/P's. Thus, the requirement for updating is similar to the requirements in §§ 207.30 and 807.30 and is consistent with the requirements of section 510(j)(2) of the act.

We have rewritten the requirement for updates for greater clarity. Section 1271.21(c) now contains timeframes for updating. Section 1271.25(c) lists the changes that must be reported. The listed events to be reported have been corrected to reflect the type of information required to be included in the initial listing. Thus, for example, just as a listing includes the names of HCT/P's that an establishment recovers, processes, stores, labels, packages, distributes, or for which it performs donor screening or testing, so the updated listing would reflect any changes in the HCT/P's for which any of these activities are performed.

We have made an additional change to proposed § 1271.25(c), which would have required that copies of all contract service agreements be available at the time of inspection of the establishment. In order to avoid duplicating a similar requirement proposed in the GTP regulations, we have deleted the requirement from § 1271.25(c).

(Comment 38) We earlier stated that we were developing an electronic version of Form FDA 3356 (registration proposed rule, 63 FR 26750). One comment strongly supported these efforts and asserted that manufacturers should also be able to submit registration and listing information electronically.

We understand that it would be convenient to submit registration and listing information electronically over the Internet. We intend to rely on our experience in developing electronic submission capability in other areas (e.g., biological product deviations in manufacturing reports) to develop an electronic submission process for HCT/P registration and listing. When electronic submissions of Form FDA 3356 are possible, we will make an announcement to that effect.

(Comment 39) Two comments disagreed with the requirement proposed in § 1271.25(a)(4) for a statement affirming the truth and accuracy of all information in the registration and listing form. The comments argued that no similar requirement exists in the registration and listing regulations for drugs and devices, parts 207 and 807. The comments proposed that, if the requirement is maintained, the statement be qualified with a phrase such as "to the best of my knowledge."

To be of use, information submitted on the registration and listing form must be truthful and accurate. Moreover, the reporting official who completes and signs the form should be aware of the obligation to report truthfully and accurately. Although, as the comment points out, the registration and listing regulations for drugs and devices do not contain a similar statement, the act specifically prohibits the submission of false or misleading reports with respect to any device (section 301(q)(2) of the act (21 U.S.C. 331(q)(2)). Furthermore, a willfully false statement to a Federal agency is a criminal offense, and it is not uncommon for forms submitted to the agency to so note (18 U.S.C. 1001).

For these reasons, we are maintaining the requirement for a statement affirming the truth and accuracy of the information submitted on the registration and listing form. However, the reporting official may reasonably obtain the reported information from reliable sources rather than firsthand. For this reason, we believe it is reasonable to modify the required statement with the language "to the best of my knowledge." We have made this change to the regulation and to the form.

(Comment 40) Two comments questioned the requirement proposed in § 1271.25(b) for a statement of whether each listed product meets the criteria set out in § 1271.10. One comment queried whether we plan to regard this statement as an admission that a product is or is not a 361 HCT/P. This comment suggested the addition of language consistent with that of other product registration and listing regulations clarifying that registration and listing under part 1271 does not constitute such an admission of product regulatory status. Both comments noted that only the statement is required, not an explanation or summary of why a product does or does not meet the criteria or which criteria are not met.

The categorization of HCT/P's as 361 HCT/P's or as drugs, devices, and/or biological products is a fundamental component of the new tiered, risk-based system. We are requiring this information for each HCT/P type to help us understand the HCT/P industry. Establishments need to know how their products are regulated in order to comply with appropriate requirements; therefore, the information required should be readily available. We understand that there may be instances where an establishment is unsure into which category its HCT/P falls; the establishment should contact the executive secretariat of the TRG in these situations. (For more information on the TRG, see CBER's website at http://www.fda.gov/cber/tissue/trg.htm.)

The requirement in § 1271.25(b) is for a statement only, not an explanation. The statement will inform the agency of the manufacturer's opinion, but will not be an "admission" with respect to how an HCT/P will be regulated. To be regulated solely under section 361 of the PHS Act and part 1271, an HCT/P must meet the criteria set forth under § 1271.10.

(Comment 41) Two comments requested that we clarify whether individual sizes or configurations of tissues should be listed separately, or instead under more general headings. One of these comments questioned whether a "new" product would include a new size of a product.

The information currently required on the registration and listing form is of a more general nature. Because the form does not ask for sizes, a new product would not include a new product size.

(Comment 42) One comment encouraged the use of standard product names for hematopoietic progenitor cell therapies in order to make product listing consistent.

We encourage the development of standard names. However, at this point we are requesting more general information on Form FDA 3356. In the

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future, we may ask for more detailed information.

(Comment 43) One comment recommended that required listing information include, with respect to each listed type of tissue, the specific manufacturing activities conducted at each registered establishment.

To simplify the registration and listing form, we are not asking for specific manufacturing information for each product but for the establishment in general. If there is a need, we may possibly ask for more specific information in the future.

(Comment 44) One comment questioned whether the addition of an adjacent building with a different address would be considered a new location, requiring an amendment to registration under § 1271.26.

No. Adding an adjacent building would not require an amendment to registration.

(Comment 45) No comments were received on proposed § 1271.27, which deals with the assignment of a registration number. We wish, however, to note that establishments that are currently registered under the drug or device registration and listing requirements, and who would in the future register and list using the procedures in part 1271, when that part is fully effective, would keep the same registration number that was issued previously. Those establishments should provide that number to us when registering for the first time using the new procedures.

(Comment 46) One comment supported the release of registration and listing information under § 1271.37, but questioned how we would determine which information to disclose to the public.

The information submitted on Form FDA 3356 is not proprietary or confidential in nature and may be released to the public. Section 1271.37(a)(4) notes that the agency may also release all data or information that has already become a matter of public record. The agency will follow the procedures and requirements set out in 21 CFR part 20 to determine which information has become a matter of public record and may be released.

F. Comments on the Proposed Amendments to §§ 207.20 and 807.20

(Comment 47) No comments were submitted on the proposed amendments to §§ 207.20 and 807.20.

We have modified the language proposed for §§ 207.20(f) and 807.20(e) to clarify that establishments that manufacture HCT/P's regulated as devices, drugs, and/or biological products will register and list their products following the procedures in part 1271 instead of the procedures in parts 207 and 807. Thus, when this rule is effective for HCT/P's regulated as devices, drugs, and or biological products, these establishments will submit Form FDA 3356 according to the procedures set out in subpart B of part 1271, at the same time as other cell and tissue establishments, and will no longer have to submit other registration and listing forms. We have also renumbered proposed § 807.20(e) as § 807.20(d).

The effective date of §§ 207.20(f) and 807.20(d) is 2 years after the publication of this rule.

G. Comments on the Registration and Listing Form (Form FDA 3356)

We asked nine manufacturers to participate in a pilot study to evaluate FDA Form 3356 in draft form, as allowed by the Office of Management and Budget (OMB) before we finalized the paperwork burden analysis. The pilot study had two purposes: To evaluate the ease of use of Form FDA 3356, and to validate the data base software developed for FDA under contract. The pilot study took place in May 1998, and in August 1998 we submitted to the docket a summary of the results of the study.

Six of the participating establishments noted that the draft form was easy to use and required less than 1 hour to complete. Other comments on the form noted several areas of potential confusion. We have addressed many of these issues elsewhere in this document, in response to comments submitted to the docket. We have addressed other issues by modifying the instructions for completing the form.

We have made minimal changes to Form FDA 3356 and its instructions to conform to the revised requirements in part 1271, subpart B. We have not added any additional information requirements.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121) and under the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes the final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. OMB has determined that the final rule is a significant action as defined in Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year. We have also determined that this rule will not result in aggregate expenditures for State, local, and tribal governments, or the private sector of $100 million in any one year (adjusted for inflation).

An analysis of available information suggests that costs to the entities most affected by this rule, including small entities, are not expected to be significant, as described in the analysis below. Therefore, the agency certifies that this rule will not have a significant impact on a substantial number of small entities.

A. Objective and Basis of the Action

This action is a first step in the regulation of the rapidly evolving industry of human cells and tissue. The entire industry has not been previously regulated under a single comprehensive regulatory program by FDA or other public health authorities. Lack of a single regulatory approach or registration system has prevented the agency from acquiring information regarding the full size of the cell and tissue industry and the scope of human cells, tissues, and cellular and tissue-based products (HCT/P's) that are used by the industry. The rule will require all manufacturers of HCT/P's to register with the agency and to submit to the agency a list of their HCT/P's. Through registration and listing, FDA will be able to identify industry participants and the scope of the HCT/P's produced. This will enable the agency to more efficiently monitor the industry, distribute new information such as guidances, policies, or requirements, and identify entities that may be subject to FDA oversight. This action is taken solely under the authority of section 361 of the PHS Act. Section 361 of the PHS Act is also used as authority to amend parts 207 and 807 so that the registration and data bases for all human cells, tissues, and cellular and tissue-based products may be consolidated. FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with the rule.

B. Small Entities Affected

This rule affects both establishments that currently register with FDA and submit product lists to the agency under applicable sections of the act (parts 207 and 807), and those establishments that are not presently required to register or list with the agency. FDA has structured registration and listing for HCT/P's to have a minimal impact on affected establishments. However, the agency anticipates that the impact will be greater for those establishments that do not currently register or list. Because the final rule is effective 75 days after publication of this document for those establishments currently regulated under part 1270, and is effective in 2 years for all other HCT/P establishments, the economic impact on the industry will be staggered.

The total number of establishments that are required to register and list under part 1271 in 2 years after the publication of this rule is estimated to be 1,225. The registration and listing initiative will, in part, help the agency obtain more accurate numbers of HCT/P's establishments. In calculating the burden, the agency has relied on information obtained from trade organizations related to the human cells, tissue, and cellular and tissue-based products industry, several of which also provided estimates of what portion of the industry their membership represented. Along with this information and from our own research, we determined that 65 manufacturers of human cells, tissue, and cellular and tissue-based products are registered with the agency as required by part 807. The agency also determined that one manufacturer of an HCT/P drug is registered as required by part 207

According to the U.S. Small Business Administration, a tissue bank is a small entity if it has annual revenues less than $5 million. FDA estimates that 110 tissue banks are involved in the manufacture of conventional tissue and that approximately 77.5 percent (or 85) of these banks are small entities. FDA estimates that there are 425 stem cell facilities (400 peripheral blood stem cell facilities and 25 cord blood facilities), and that all are small entities. FDA estimates that approximately 114 eye banks are currently operating in the United States, and industry experts estimate that virtually all facilities would be classified as small. FDA estimates that there are approximately 400 assisted reproductive technology (ART) facilities. This estimate is consistent with industry comments. Consultants estimate that two-thirds of all ART facilities (or 267 establishments) would be classified as small entities. In addition, the American Society of Reproductive Medicine (ASRM) has a 1996 list of approximately 110 sperm banks operating in the U.S. Information about sperm banks from a report by Eastern Research Group (ERG) indicates that 95 percent (or 105) of these sperm banks are small. Thus, approximately 996 (85 + 425 + 114 + 267 + 105) of all 1,225 establishments would be considered small entities. In addition, 66 establishments are currently regulated as drugs, devices, or biological products under parts 207 and 807. Approximately 90 percent of these (or 60 establishments) are small entities. Therefore, we estimate that a total 1,056 establishments (996 + 60) are small entities.

C. Nature of the Impact

The main cost in implementing this final rule is staff time, which we estimate to cost $38.00 per hour, based on 1997 Bureau of Labor Statistics estimates.

Out of a total 1,225 establishments affected by this rule, 66 HCT/P drug and device establishments currently submit registration and product listing information under parts 207 and 807. In the proposed rule, we incorrectly estimated both the time and the scope of annual information collection for these establishments. Our estimate inaccurately lumped the submission of all required information into one year and concluded that 2 hours would be needed annually to register and list initially, submit a subsequent annual registration, update HCT/P listings, and amend ownership or location information.

As proposed, however, this final rule requires that HCT/P drug and device manufacturers use a new, single form to register and list their HCT/P products. This rule does not impose any new registration or listing requirements for establishments regulated under parts 207 and 807. To avoid duplication, the rule provides HCT/P drug and device manufacturers a single, new form to replace the multiple forms currently required under parts 207 and 807. Therefore, we now estimate only the time needed to transition from the use of multiple forms to the use of the one form. Based on results from the pilot study described above in section III.G of this document, we estimate that establishments will need approximately 0.5 hour to transition to Form FDA 3356 at a one-time transition cost of approximately $19 [$38 x 0.5]. We estimate that the total impact for all 66 establishments will be approximately $1,254 [66 x $38 x 0.5].

For the 1,159 HCT/P manufacturers not regulated under parts 207 and 807, the costs are based upon the staff time needed to obtain the form, read the instructions, and complete and submit the form for the initial registration and HCP/T listing, subsequent annual registration, and, as needed, listing updates and location/ownership amendments. Based on the pilot study described above, FDA estimates that it will take an average of 0.75 hour of staff time per establishment for the initial submission. At $38.00 per hour of staff time, each establishment is expected to incur an initial one-time cost of approximately $28 [$38 x 0.75]. We estimate the total impact for all 1,159 establishments for the submission of initial registration and HCT/P listing to be approximately $33,032 [1,159 x $38 x 0.75].

After the initial registration, the final rule requires annual registration, which we estimate will take 0.5 hour to complete and submit to FDA. We estimate that the annual cost of these submissions will be approximately $22,021 [1,159 x $38 x 0.5] or $19 per establishment.

The final rule also requires HCT/P listing updates twice a year, a submission that is required only when a change has been made since the previous listing submission. FDA assumes that in any given year, 5 percent or 58 of the 1,159 establishments [1,159 x 0.05] will submit one listing. The listing update is estimated to take about 0.5 hours to complete and submit to FDA. We estimate that each establishment will incur an annual cost of approximately $19 [$38 x 0.5], for a total of $1,102 for all 58 establishments.

The rule also requires changes in ownership or location to be reported as an amendment within 5 days of such changes. FDA expects that this will be a rare event and that in any given year, no more than 5 percent or 58 of the 1,159 establishments [1,159 x 0.05] will change location or ownership and submit an amendment. This amendment is estimated to take 0.25 hours of staff time. We estimate that each establishment will incur a cost of approximately $10 [$38 x 0.25], totaling $580 for all 58 establishments.

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In sum, we estimate the total annual for all submissions subsequent to the initial registration and listing (annual registration and, as needed, listing updates and location/ownership amendments) to be $23,702 [$22,021 + $1,101 + $580].

There are no specific educational or technical skills required to complete and submit the registration and listing form. Trained and qualified employees of an establishment who are involved with its operations generally complete similar activities.

This final rule is the first step in creating a tiered, risk-based regulatory scheme that will tailor the degree of scrutiny afforded to different HCT/P's to the risks associated with each of them. Through registration and listing, FDA will acquire the information needed to characterize the nature and extent of HCT/P's. This information will enable FDA to efficiently and effectively respond to emerging public health concerns related to human cells or tissue. Lists of industry members and their HCT/P's will also help FDA disseminate educational materials and other important information regarding FDA policies, guidances, and requirements.

D. Minimizing the Impact on Small Entities

FDA recognizes that a large number of the establishments that would be required to register and list under the rule will be small entities with limited resources. In recognition of this, the agency is proposing that the information to be provided during registration and listing be only that which is necessary to achieve the agency's goals of industry characterization and identification of its participants. To alleviate the impact on entities, especially small entities, FDA will consider the use of electronic submissions (e-mail or Internet) and electronic signatures.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirements are shown below with an estimate of the initial one-time reporting burden and the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing each collection of information.

Title: Establishment Registration and Listing Requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products.

Description: The final rule requires establishments that recover, process, store, label, package, or distribute any human cell, tissue, and cellular and tissue-based product (HCT/P), or that perform donor screening or testing, to submit an initial establishment registration and HCT/P list to FDA. Subsequently, establishments must submit an annual update to their establishment registration. In addition, establishments are required to submit HCT/P list updates, if any, and amendments whenever an establishment changes ownership or locations. FDA provides a registration and listing form (Form FDA 3356) to facilitate the ease and speed of submissions. Form FDA 3356 is an approved information collection format under OMB control number 0910–0372. The approval expires July 31, 2001.

Description of Respondents: Establishments that recover, process, store, label, package, or distribute any human cells, tissue, and cellular and tissue-based product.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on May 14, 1998 (63 FR 26744), on the information collection requirements of the proposed rule.

Table 1 of this document lists the estimated one-time reporting burden for the initial establishment registration and HCT/P listing, which is required under § 1271.10(b). Section 1271.25(a) and (b) identify the initial establishment and HCT/P listing information required. Sections 207.20(f) and 807.20(d) require HCT/P establishments to use Form FDA 3356 for providing registration and listing information required under parts 207 and 807.

Table 2 of this document provides the estimate of the ongoing annual reporting burden for establishment registration. In addition, table 2 of this document sets out estimated reporting burdens for HCT/P listing updates and establishment location or ownership amendments that would occur during any given year. If there is no change to an HCT/P listing, establishment location or ownership, a submission is not required.

Sections 1271.21(b) and 1271.10(b) require the annual establishment registration by domestic and foreign HCT/P establishments that are solely regulated under section 361 of the PHS Act and this part.

Sections 1271.21(c)(ii), 1271.25(c), and 1271.10(b) require domestic and foreign HCT/P establishments to submit HCT/P listing updates only when an HCT/P is changed, added, or discontinued, and when there has been a material change to information submitted previously-to the agency. If no change has occurred since the previous submission, an update is not required.

Sections 1271.26 and 1271.10(b) require domestic and foreign HCT/P establishments to submit an amendment, but only when the establishment makes a change in location or ownership.

Sections 207.20, 207.26, 207.30, 807.20, 807.26, and 807.30 already require establishments that manufacture drug or device products to submit initial establishment registration and product listing, as well as annual establishment registration, product listing updates, and location and ownership amendments. This final rule adds §§ 207.20(f) and 807.20(d), which require that manufacturers of HCT/P drugs and devices submit this registration and listing information using Form FDA 3356 instead of the multiple forms identified under parts 207 and 807. Therefore, these establishments will incur only a one-time burden to transition from the use of several forms to the use of one form (see table 1 above). This rule adds no new registration and listing requirements.

This final rule is implemented according to the staggered effective dates. Human tissues intended for transplantation that are currently regulated under section 361 of the PHS Act and part 1270 are required to register with the agency and list their HCT/P's within 5 days of the first effective date. The effective date for all other HCT/P's is 2 years after publication of this rule in the **Federal Register**, about which time we expect that the remaining subparts of part 1271 will become effective.

In the proposed rule, FDA underestimated the number of respondents. Based on additional information provided to FDA by industry representatives, trade organizations, and professional societies, we have revised our estimate of establishments to approximately 1,225 (i.e., approximately 110 conventional tissue, 114 eye tissue banks, 400 peripheral blood stem cells, 25 stem cell products from cord blood, 400 reproductive tissue, 110 sperm banks, and 66 licensed biological products and approved devices).

Our burden estimates for the annual frequency per response and average hours per response are based on institutional experience with comparable reporting provisions for drugs, including biological products, and devices, information from industry representatives and trade organizations, and data provided by the Eastern Research Group (ERG), a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on sperm banks and other reproductive tissue facilities.

In the final rule, we have separated the initial, one-time reporting requirements (table 1 of this document) from the subsequent ongoing annual establishment registration, HCT/P updates and amendment requirements (table 2 of this document).

Table 1 of this document provides the initial, one-time estimated burden for HCT/P establishment registration and HCT/P listing. This information may be submitted simultaneously on the same form, Form FDA 3356. We estimate that 0.75 hour of staff time will be needed for each initial submission. This estimate is based on a pilot program described above in section III.G of this document conducted to evaluate Form FDA 3356.

In table 1 of this document we also include the one-time burden for HCT/P drug and device manufacturers regulated under parts 207 and 807. Parts 207 and 807 require that drug and device manufacturers submit initial establishment registration and product listing, annual establishment registration, product listing updates, and location/ownership amendments. New §§ 207.20(f) and 807.20(d) change only the reporting format and require use of only one form, new Form FDA 3356, in place of the multiple forms currently required, i.e., Forms FDA–2656 and FDA–2657 for drug manufacturers, and Forms FDA–2891, FDA–2891(a), and FDA–2892 for device manufacturers. Therefore, the one-time reporting burden estimate for §§ 207.20(f) and 807.20(d) in table 1 of this document reflects only the time necessary to transition from the use of current multiple forms to the use of Form FDA 3356. In the proposed rule, we incorrectly included the time needed to submit the registration and listing information already required under parts 207 and 807. As revised here, the reporting burden under new §§ 207.20(f) and 807.20(d) reflects only the time necessary to transition from the use of current multiple forms to the use of Form FDA 3356.

Table 2 of this document shows more accurately than in the proposed rule that on-going annual registration, updates and amendments require 0.50 hour, while the initial submission requires on average 0.75 hour. In addition, table 2 of this document shows that the average hours per response is less for the HCT/P listing updates and location/ownership amendments, which are required only when a change is made, than for the annual registration, which must be submitted every year. In table 2 of this document, we also estimate that approximately 5 percent of the 1,159 establishments, or 58 establishments, will make changes to HCT/P's, location, or ownership in any one year after the initial registration and listing. Based on additional information from industry representatives and from our own experiences, we estimate that annual registration, HCT/P listing updates, and location/ownership amendments will require 0.5, 0.5, and 0.25 hours, respectively, as opposed to the full hour estimated for every establishment submission in the proposed rule. The greater precision afforded by this breakout shows that, despite the increased number of total estimated respondents, the estimated total burden hours is lower than in the proposed rule. In table 2 of this document, the total annual burden of 623 hours for ongoing reporting is slightly less than the initial, one-time reporting burden total of 902.25 hours in table 1 of this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED INITIAL (ONE–TIME) REPORTING BURDEN [1]

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
207.20(f)	1	1	1	0.5	0.5
807.20(d)	65	1	65	0.5	32.50
Initial Registration and HCT/P Listing 1271.25(a), with 1271.25(b) and 1271.10(b)	1,159	1	1,159	0.75	869.25
TOTAL					902.25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN [2]

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
Annual Registration 1271.21(b) and 1271.10(b)	1,159	1	1,159	0.5	579.50
HCT/P Listing Update 1271.21(c), 1271.25(c), and 1271.10(b)	58	1	58	0.5	29.00

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TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[2]—Continued

21 CFR	No. of respondents	Annual frequency per response	Total annual responses	Hours per response (average)	Total hours
Location/Ownership Amendment 1271.26 and 1271.10(b)	58	1	58	0.25	14.50
TOTAL					623

[2] There are no capital costs or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection requirements, including suggestions for reducing the burden. Comments should be directed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Tissue Establishment Registration Coordinator (HFM–305), 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

The information collection requirements of the final rule have been submitted to OMB for review. Prior to the effective date of the final rule, FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection requirements in the final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Vice President's National Performance Review report, "Reinventing the Regulation of Human Tissue," February 1997.
2. Schipper, R. F., D'Amaro, J., and Oudshoorn, M., "The Probability of Finding a Suitable Related Donor for Bone Marrow Transplantation in Extended Families," *Blood*, 87:800–804, 1996.
3. Kaufman, R., "A Generalized HLA Prediction Model for Related Donor Matches," *Bone Marrow Transplantation*, 17:1013–1020, 1996.

List of Subjects

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 1271

Human cells, Reporting and recordkeeping requirements, tissue-based products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

1. The authority citation for 21 CFR part 207 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 356, 360, 360b, 371, 374; 42 U.S.C. 262, 264, 271.

2. Section 207.20 is amended by revising the heading and adding paragraph (f) to read as follows:

§ 207.20 Who must register and submit a drug list?

* * * * *

(f) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under section 351 of the Public Health Service Act and/or the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements in § 207.31 remain applicable.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES

3. The authority citation for 21 CFR part 807 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374; 42 U.S.C. 264, 271.

4. Section 807.20 is amended by revising the heading and adding paragraph (d) to read as follows:

§ 807.20 Who must register and submit a device list?

* * * * *

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in § 1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of § 807.31 remain applicable.

5. Part 1271 is added to read as follows:

PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE–BASED PRODUCTS

Subpart A—General Provisions

Sec.

1271.1 What are the purpose and scope of this part?
1271.3 How does FDA define important terms in this part?
1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?
1271.15 Are there any exceptions from the requirements of this part?
1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions in § 1271.15, what regulations apply?

Subpart B—Procedures for Registration and Listing

1271.21 When do I register, submit an HCT/P list, and submit updates?
1271.22 How and where do I register and submit an HCT/P list?
1271.25 What information is required for establishment registration and HCT/P listing?
1271.26 When must I amend my establishment registration?
1271.27 Will FDA assign me a registration number?
1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

Authority: 42 U.S.C. 216, 243, 264, 271.

Subpart A—General Provisions

§ 1271.1 What are the purpose and scope of this part?

(a) *Purpose.* The purpose of this part, in conjunction with §§ 207.20(f), 210.1(c), 210.2, 807.20(d), and 820.1(a) of this chapter, is to create a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-suitability, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope.* (1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, §§ 207.20(f) and 807.20(d) of this chapter require you to register and list your HCT/P's following the procedures in subpart B of this part. Sections 210.1(c), 210.2, 211.1(b), and 820.1(a) of this chapter require you to comply with the donor-suitability procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

§ 1271.3 How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

(b) *Establishment* means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. "Establishment" includes:

(1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and

(2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products.

(c) *Homologous use* means the replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d)(1) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means any human tissue derived from a human body and intended for transplantation into another human, as defined under § 1270.3(j). Examples of HCT/P's include, but are not limited to, bone, ligament, skin, and cornea.

(2) *Human cells, tissues, or cellular or tissue-based products (HCT/P's)* means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/P's include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/P's:

(i) Vascularized human organs for transplantation;

(ii) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(iii) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(iv) Minimally manipulated bone marrow for homologous use and not combined with a drug or a device (except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);

(v) Ancillary products used in the manufacture of HCT/P;

(vi) Cells, tissues, and organs derived from animals other than humans; and

(vii) In vitro diagnostic products as defined in § 809.3(a) of this chapter.

(e) *Manufacture means*, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.

(f) *Minimal manipulation* means:

(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

(g) *Transfer* means the placement of human reproductive cells or tissues into a human recipient.

§ 1271.10 Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

(3) The manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P; and

(4) Either:

(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

(*a*) Is for autologous use;

(*b*) Is for allogeneic use in a first-degree or second-degree blood relative; or

(*c*) Is for reproductive use.

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(b) If you are a domestic or foreign establishment that manufactures an HCT/P described in paragraph (a) of this section:

(1) You must register with FDA;

(2) You must submit to FDA a list of each HCT/P manufactured; and

(3) You must comply with the other requirements contained in this part.

§ 1271.15 Are there any exceptions from the requirements of this part?

(a) You are not required to comply with the requirements of this part if you are an establishment that uses HCT/P's solely for nonclinical scientific or educational purposes.

(b) You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure.

(c) You are not required to comply with the requirements of this part if you are a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier.

(d) You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within your facility.

(e) You are not required to comply with the requirements of this part if you are an establishment that only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

§ 1271.20 If my HCT/P's do not meet the criteria in § 1271.10, and I do not qualify for any of the exceptions in § 1271.15, what regulations apply?

If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in § 1271.10(a), and you do not qualify for any of the exceptions in § 1271.15, your HCT/P will be regulated as a drug, device, and/or biological product under the act and/or section 351 of the PHS Act, and applicable regulations in title 21, chapter I. Applicable regulations include, but are not limited to, §§ 207.20(f), 210.1(c), 210.2, 211.1(b), 807.20(d), and 820.1(a) of this chapter, which require you to follow the procedures in subparts B, C, and D of this part.

Subpart B—Procedures for Registration and Listing

§ 1271.21 When do I register, submit an HCT/P list, and submit updates?

(a) You must register and submit a list of every HCT/P that your establishment manufactures within 5 days after beginning operations or within 30 days of the effective date of this regulation, whichever is later.

(b) You must update your establishment registration annually in December, except as required by § 1271.26. You may accomplish your annual registration in conjunction with updating your HCT/P list under paragraph (c) of this section.

(c)(i) If no change described in § 1271.25(c) has occurred since youpreviously submitted an HCT/P list, you are not required to update your listing.

(ii) If a change described in § 1271.25(c) has occurred, you must update your HCT/P listing with the new information:

(*a*) At the time of the change, or

(*b*) Each June or December, whichever month occurs first after the change.

§ 1271.22 How and where do I register and submit an HCT/P list?

(a) You must use Form FDA 3356 for:

(i) Establishment registration,

(ii) HCT/P listings, and

(iii) Updates of registration and HCT/P listing.

(b) You may obtain Form FDA 3356:

(i) By writing to the Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator;

(ii) By contacting any Food and Drug Administration district office;

(iii) By calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800;

(iv) By calling the Fax Information System at 1–888–CBER–FAX or 301–827–3844; or

(v) By connecting to http://forms.psc.gov/forms/FDA/fda.html on the Internet.

(c)(i) You may submit Form FDA 3356 to the Center for BiologicsEvaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville, Pike, Rockville, MD 20852–1448, Attention: Tissue Establishment Registration Coordinator; or

(ii) You may submit Form FDA 3356 electronically in accordance with the instructions provided with the form.

§ 1271.25 What information is required for establishment registration and HCT/P listing?

(a) Your establishment registration Form FDA 3356 must include:

(1) The legal name(s) of the establishment;

(2) Each location, including the street address of the establishment and the postal service zip code;

(3) The name, address, and title of the reporting official; and

(4) A dated signature by the reporting official affirming that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

(b) Your HCT/P listing must include all HCT/P's (including the established name and the proprietary name) that you recover, process, store, label, package, distribute, or for which you perform donor screening or testing. You must also state whether each HCT/P meets the criteria set out in § 1271.10.

(c) Your HCT/P listing update must include:

(1) A list of each HCT/P that you have begun recovering, processing, storing, labeling, packaging, distributing, or for which you have begun donor screening or testing, that has not been included in any list previously submitted. You must provide all of the information required by § 1271.25(b) for each new HCT/P.

(2) A list of each HCT/P formerly listed in accordance with § 1271.21(a) for which you have discontinued recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including for each HCT/P so listed, the identity by established name and proprietary name, and the date of discontinuance. We request but do not require that you include the reason for discontinuance with this information.

(3) A list of each HCT/P for which a notice of discontinuance was submitted under paragraph (c)(2) of this section and for which you have resumed recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing, including the identity by established name and proprietary name, the date of resumption, and any other information required by § 1271.25(b) not previously submitted.

(4) Any material change in any information previously submitted. Material changes include any change in information submitted on Form FDA 3356, such as whether the HCT/P meets the criteria set out in § 1271.10.

§ 1271.26 When must I amend my establishment registration?

If the ownership or location of your establishment changes, you must submit an amendment to registration within 5 days of the change.

§ 1271.27 Will FDA assign me a registration number?

(a) FDA will assign each location a permanent registration number.

(b) FDA acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

§ 1271.37 Will establishment registrations and HCT/P listings be available for inspection, and how do I request information on registrations and listings?

(a) A copy of the Form FDA 3356 filed by each establishment will be available for public inspection at the Office of Communication, Training, and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request and receipt of a self-addressed stamped envelope, verification of a registration number or the location of a registered establishment will be provided. The following information submitted under the HCT/P requirements is illustrative of the type of information that will be available for public disclosure when it is compiled:

(1) A list of all HCT/P's;

(2) A list of all HCT/P's manufactured by each establishment;

(3) A list of all HCT/P's discontinued; and

(4) All data or information that has already become a matter of public record.

(b) You should direct your requests for information regarding HCT/P establishment registrations and HCT/P listings to the Office of Communication, Training and Manufacturers Assistance (HFM–48), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

Dated: January 2, 2001.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 01–1126 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 17 and 18

[T.D. ATF–436]

RIN 1512–AB99

Delegation of Authority for Parts 17 and 18

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: Authority delegation. This final rule places most ATF authorities contained in parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" and requires that persons file documents required by parts 17 and 18, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.13 is being published. Through this order, the Director has delegated most of the authorities in 27 CFR parts 17 and 18 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226 (202–927–8210).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Decision 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, in this final rule, the Director of ATF is rescinding all authorities of the Director in parts 17 and 18 which were previously delegated to a specified ATF officer and placing all authorities of the Director with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in parts 17 and 18, in which certain of these authorities are then delegated down to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 17 and 18 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the event of a change in delegation or in the event of a restructuring. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition to the above, this final rule also eliminates all references in the regulations which identify the ATF officer with whom an ATF form is filed. Thus, in lieu of identifying the authorized officer in the regulations, the form itself will indicate the officer with whom it shall be filed. Similarly, this final rule also amends parts 17 and 18 to provide that documents other than ATF forms (such as letterhead applications, notices and reports) will be filed with the "appropriate ATF officer." The "appropriate ATF officer" is the Director's delegate and will be identified in the accompanying ATF Order (ATF Order 1130.13, Delegation Order—Delegation of the Director's

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Authorities in part 17 and 18). These changes will facilitate the identification of the officer with whom forms and other required submissions are filed in the event that authority to receive such submissions, or the title of the officer, changes.

Consistent with the above, this final rule makes various technical amendments to subpart C—Administrative and Miscellaneous Provisions of 27 CFR parts 17 and 18. Specifically, new §§ 17.7 and 18.12 will be added to recognize the authority of the Director to delegate regulatory authorities in parts 17 and 18, respectively, and to identify ATF Order 1130.13 as the instrument reflecting such delegations. Also, §§ 17.2 and 18.16 are amended to provide that the instructions on an ATF form identify the ATF officer with whom it is filed.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 17

Alcohol and alcoholic beverages, Authority delegations, Claims, Drugs, Excise taxes, Foods, Reporting and recordkeeping requirements, Spices and flavorings, Surety bonds.

27 CFR Part 18

Administrative practice and procedure, Authority delegations, Excise taxes, Exports, Labeling, Reporting and recordkeeping requirements, Security measures, Spices and flavorings, Surety bonds.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 17—DRAWBACK ON TAXPAID DISTILLED SPIRITS USED IN MANUFACTURING NONBEVERAGE PRODUCTS

Paragraph 1. The authority citation for part 17 continues to read as follows:

Authority: 26 U.S.C. 5010, 5131–5134, 5143, 5146, 5206, 5273, 6011, 6065, 6091, 6109, 6151, 6402, 6511, 7011, 7213, 7652, 7805, 5062, 5081, 5111–5113, 5121, 5122, 5142, 5143, 5173, 5206; 31 U.S.C. 9301, 9303, 9304, 9306.

§§ 17.2, 17.3, 17.122 and 17.134 [Amended]

Par. 2. In part 17 remove the word "Director" each place it appears and add, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 17.2(a);

(b) Section 17.3(a), introductory text, and (c);

(c) Section 17.122; and

(d) Section 17.134.

Par. 3. In addition to the amendment made above, § 17.2 is amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 17.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or at the ATF web site (http://www.atf.treas.gov/).

Par. 4. The first sentence of paragraph (b) of § 17.3 is revised to read as follows:

§ 17.3 Alternate methods or procedures.

* * * * *

(b) Application. A letter of application to employ an alternate method or procedure must be submitted to the appropriate ATF officer. * * *

* * * * *

§§ 17.6, 17.55, 17.121, 17.161, 17.171, 17.182 and 17.183 [Amended]

Par. 5. Part 17 is further amended by adding the word "appropriate" before the words "ATF officer" each place it appears in the following places:

(a) Section 17.6;

(b) Section 17.55;

(c) Section 17.121(d);

(d) Section 17.161;

(e) Section 17.171;

(f) Section 17.182; and

(g) Section 17.183(a).

Par. 6. A new § 17.7 is added in Subpart A—General Provisions to read as follows:

§ 17.7 Delegations of the Director.

The regulatory authorities of the Director contained in this part 17 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 7. Section 17.11 is amended by removing the definitions of "Alcohol and Tobacco Laboratory", "ATF Officer", and "Regional director (compliance)", and by adding a new definition of "Appropriate ATF officer" and revising the definition of "Director" to read as follows:

§ 17.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Director. The Director, Bureau of Alcohol, Tobacco and Firearms, the Department of Treasury, Washington, DC 20226.

* * * * *

§§ 17.54, 17.101, 17.107, 17.108, 17.111, 17.112, 17.113, 17.114, 17.125, 17.141, 17.143, 17.147, 17.166, 17.167, 17.168, 17.170 and 17.183 [Amended]

Par. 8. Part 17 is further amended by removing the words "regional director (compliance)" or "regional directors (compliance)" each place it appears and adding, in substitution, the words "appropriate ATF officer" or "appropriate ATF officers", respectively, in the following places:

(a) Section 17.54;

(b) Section 17.101;

(c) Section 17.107;

(d) Section 17.108(c);

(e) Section 17.111 (a) introductory text and (b);

(f) Section 17.112;

(g) Section 17.113;

(h) Section 17.114;

(i) Section 17.125(a);

(j) Section 17.141;

(k) Section 17.143;

(l) Section 17.147(a);

(m) Section 17.166(c);

(n) Section 17.167(b);

(o) Section 17.168(a);

(p) Section 17.170; and

(q) Section 17.183(b) and (c).

Par. 9. The first three sentences of § 17.92 are revised into two sentences to read as follows:

Sec. 17.92 Filing of refund claim.

Claim for refund of special tax must be filed on ATF Form 2635 (5620.8), Claim—Alcohol, Tobacco and Firearms Taxes. The claim must set forth in detail sufficient reasons and supporting facts of the exact basis of the claim.* * *

* * * * *

Par. 10. The last sentence of § 17.101 is amended to remove the words "Regional directors (compliance)" and add, in substitution, the words "Appropriate ATF officers".

§§ 17.105, 17.144 and 17.145 [Amended]

Par. 11. Part 17 is further amended by removing the phrase "with the regional director (compliance)" each place it appears in the following places.

(a) Section 17.105(b);

(b) Section 17.144; and

(c) Section 17.145.

Par. 12. Paragraph (b) of § 17.121 is amended to remove the phrase "with the Alcohol and Tobacco Laboratory".

Par. 13. Section 17.122 is amended by removing the phrase "to the Alcohol and Tobacco Laboratory" and adding, in substitution, the phrase "appropriate ATF officer".

Par. 14. The third sentence of paragraph (b) of § 17.125 is revised to read as follows:

§ 17.125 Adoption of formulas and processes.

* * * * *

(b) Adoption of manufacturer's own forumulas from a different location. * * * A letterhead notice must be filed with the appropriate ATF officer and be accompanied by two photocopies of each formula to be adopted. * * *

* * * * *

§§ 17.126 and 17.136 [Amended]

Par. 15. Part 17 is further amended by removing the phrase "to the Alcohol and Tobacco Laboratory" each place it appears in the following places:

(a) Section 17.126(a); and

(b) Section 17.136.

Par. 16. Section 17.131 is amended by removing the phrase "by the Alcohol and Tobacco Laboratory" each place it appears.

Par. 17. The fifth sentence of paragraph (a) of § 17.142 is removed, and the first sentence of paragraph (a) of § 17.142 is revised to read as follows :

§ 17.142 Claims.

(a) General. The manufacturer must file claim for drawback with the appropriate ATF officer who has the authority to approve or disapprove claims. * * *

* * * * *

PART 18—PRODUCTION OF VOLATILE FRUIT FLAVOR CONCENTRATE

Par. 18. The authority citation for part 18 continues to read as follows:

Authority: 26 U.S.C. 5001, 5172, 5178, 5179, 5203, 5511, 5552, 6065, 7805; 44 U.S.C. 3504(h).

Par. 19. Section 18.11 is amended by removing the definitions of "ATF officer" and "Regional director (compliance) and by adding the definition of "Appropriate ATF officer" and revising the definition of "Registry number" to read as follows:

§ 18.11 Meaning of Terms.

* * * * *

Appropriate ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18.

* * * * *

Registry number. The number assigned to a concentrate plant or a bonded wine cellar for an approved application as required by Parts 18 and 24, respectively.

* * * * *

Par. 20. A new § 18.12 is added in subpart C—Administrative and Miscellaneous Provisions to read as follows:

§ 18.12 Delegations of the Director.

The regulatory authorities of the Director contained in this part 18 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.13, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 17 and 18. ATF delegation orders, such as ATF Order 1130.13, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, VA 22150–5190, or by accessing the ATF web site (http://www.atf.treas.gov/).

§§ 18.13, 18.16 and 18.52 [Amended]

Par. 21. Part 18 is further amended by removing the word "Director" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 18.13(a), introductory text;

(b) Section 18.16(a); and

(c) Section 18.52(b).

Par. 22. Paragraph (b) of § 18.13 is revised to read as follows:

§ 18.13 Alternate Methods or Procedures.

* * * * *

(b) *Application.* A proprietor who desires to employ an alternate method or procedure shall submit a written application to the appropriate ATF officer. The application will specifically describe the proposed alternate method or procedure and set forth the reasons therefor. Alternate methods or procedures may not be employed until the application has been approved by the appropriate ATF officer. Authorization for any alternate method or procedure may be withdrawn whenever in the judgment of the appropriate ATF officer the revenue is jeopardized or the effective

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administration of this part is hindered by the continuation of the authorization.

* * * * *

§§ 18.14, 18.22, 18.24 and 18.27 [Amended]

Par. 23. Part 18 is further amended by removing the words "regional director (compliance)" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 18.14(a), introductory text and (b);

(b) Section 18.22(b);

(c) Section 18.24; and

(d) Section 18.27(a).

§§ 18.15, 18.17, 18.19 and 18.61 [Amended]

Par. 24. Part 18 is further amended by adding the word "appropriate" before the phrase "ATF officers" or "ATF officer" each place it appears in the following places:

(a) Section 18.15;

(b) Section 18.17;

(c) Section 18.19; and

(d) Section 18.61(a) and (b).

Par. 25. Section 18.16 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 18.16 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5190, or at the ATF web site (http://www.atf.treas.gov/).

Par. 26. Section 18.21 is amended by removing the words "to the regional director (compliance)".

Par. 27. Section 18.26 is amended by removing the words "with the regional director (compliance)".

Par. 28. Section 18.65 is revised to read as follows:

Sec. 18.65 Annual report.

An annual report, on Form 1695(5520.2), of concentrate plant operations shall be prepared by each proprietor and forwarded in accordance with the instructions for the form. When a proprietor permanently discontinues the business of manufacturing concentrate, the proprietor shall submit the annual report in accordance with the instructions for the form.

Signed: July 13, 2000.

Bradley A. Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1162 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 20, 21 and 22

[T.D. ATF–435]

RIN 1512–AC13

Delegation of Authority for Parts 20, 21 and 22

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places all ATF authorities contained in parts 20, 21 and 22, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" and requires that persons file documents required by such parts, with the "appropriate ATF officer" or in accordance with the instructions for the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word "region." Concurrently with this Treasury Decision, ATF Order 1130.9 is being published. Through this order, the Director has delegated all of the authorities in 27 CFR parts 20, 21 and 22 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (telephone 202–927–8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of *chapter 51* of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in parts 20, 21 and 22 that were previously delegated and places those authorities with the "appropriate ATF officer." All of the authorities of the Director that were not previously delegated are also placed with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22, Distilled Spirits Plants, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in parts 20, 21 and 22 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends parts 20, 21 and 22 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the "appropriate ATF officer" identified in ATF Order 1130.9. These changes will facilitate the identification of the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to parts 20, 21 and 22 of Title 27 of the Code of Federal Regulations. First, new sections are added in each part to recognize the authority of the Director to delegate regulatory authorities and to identify ATF Order 1130.9 as the instrument reflecting such delegations. Second, § 20.21, 21.2, 22.21 of Title 27 of the Code of Federal Regulations are amended to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed. Third, this rule removes from part 22 of Title 27 of the Code of Federal Regulations the definition of the term "delegate." This term is used only in the definition of Secretary in part 22 of Title 27 of the Code of Federal Regulations. We have removed the definition of "delegate" to be consistent with most other parts of Title 27 of the Code of Federal Regulations and to minimize potential confusion and misunderstanding with the appropriate ATF officers to whom the Director has delegated authority.

ATF has begun to make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Pub. L. 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, we can issue this final rule without the notice and public procedure under 5 U.S.C. 553(b). For these same reasons, we are issuing this final rule effective on the same date of its publication in the **Federal Register**. This final rule is not subject to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information: The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 20

Administrative practice and procedure, Advertising, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Chemicals, Claims, Cosmetics, Excise taxes, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Transportation.

27 CFR Part 21

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Chemicals, Packaging and containers, Transportation.

27 CFR Part 22

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Claims, Excise taxes, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Science and technology, Surety bonds, Transportation.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 20—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

Paragraph 1. The authority citation for part 20 continues to read as follows:

Authority: 20 U.S.C. 5001, 5206, 5214, 5271–5275, 5311, 5552, 5555, 5607, 6065, 7805.

Par. 2. Section 20.11 is amended by removing the definitions of "Area supervisor", "ATF Officer", "Region", and "Regional director (compliance)", by adding a new definition of "Appropriate ATF officer", and by revising the definition of "Bulk conveyance" to read as follows:

§ 20.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Bulk conveyance. Any tank car, tank truck, tank ship, or tank barge, or a compartment of any such conveyance, or any other container approved by the appropriate ATF officer for the conveyance of comparable quantities of denatured spirits or articles.

* * * * *

Par. 3. In Subpart C—Administrative and Miscellaneous Provisions after the undesignated center heading "Authorities", a new § 20.20 is added as follows:

§ 20.20 Delegations of the Director.

All of the regulatory authorities of the Director contained in this Part 20 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

§§ 20.21, 20.22, 20.23, 20.48, 20.91, 20.92, 20.100, 20.103, 20.111, 20.144, 20.177, 20.211, 20.245 and 20.246 [Amended]

Par. 4. Part 20 is further amended by removing the word "Director" each place it appears and adding, in its place, the words "appropriate ATF officer" in the following places:

(a) Section 20.21(a);

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(b) Section 20.22(a)(2), (3) and (4), and (c);
(c) Section 20.23;
(d) Section 20.48(b) and (c);
(e) Section 20.91(a) and (c);
(f) Section 20.92(a) and (b);
(g) Section 20.100(a) introductory text;
(h) Section 20.103;
(i) Section 20.111;
(j) Section 20.144;
(k) Section 20.178(c)(1);
(l) Section 20.211(b);
(m) Section 20.245; and
(n) Section 20.246.

Par. 5. Section 20.21 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 20.21 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 6. The first and second sentences of § 20.22(a)(1) are revised to read as follows:

§ 20.22 Alternate methods or procedures; and emergency variations from requirements.

(a) *Alternate methods or procedures*—(1) *Application.* A permittee, after receiving approval from the appropriate ATF officer, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. A permittee wishing to use an alternate method or procedure may apply to the appropriate ATF officer. * * *

* * * * *

§ 20.22; 20.24, 20.26, 20.28, 20.41, 20.42, 20.43, 20.44, 20.48, 20.50, 20.51, 20.56, 20.57, 20.60, 20.61, 20.62, 20.63, 20.64, 20.68, 20.72, 20.74, 20.78, 20.80, 20.82, 20.132, 20.133, 20.134, 20.161, 20.163, 20.164, 20.181, 20.202, 20.204, 20.205, 20.213, 20.234, 20.235, 20.252, 20.261, 20.262, 20.263 and 20.265 [Amended]

Par. 7. Part 20 is further amended by removing the words "regional director (compliance)" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:
(a) Section 20.22(b)(1), (2) and (3);
(b) Section 20.24;
(c) Section 20.26;
(d) Section 20.28(b);
(e) Section 20.41(c) introductory text;
(f) Section 20.42(a)(11) and (b);
(g) Section 20.43(a) introductory text;
(h) Section 20.44 introductory text;
(i) Section 20.48(b);
(j) Section 20.50;
(k) Section 20.51 introductory text;
(l) Section 20.56(a)(1), (b) and (c)(1) and (3);
(m) Section 20.57(b)(1) and (2);
(n) Section 20.60;
(o) Section 20.61;
(p) Section 20.62(a);
(q) Section 20.63(a);
(r) Section 20.64;
(s) Section 20.68(a) introductory text;
(t) Section 20.72(b);
(u) Section 20.74;
(v) Section 20.79;
(w) Section 20.80;
(x) Section 20.82;
(y) Section 20.132(c);
(z) Section 20.133(a) introductory text and (b);
(aa) Section 20.134(c);
(bb) Section 20.161(c)(3);
(cc) Section 20.163(c)(2);
(dd) Section 20.164(e);
(ee) Section 20.181(a);
(ff) Section 20.202(a);
(gg) Section 20.204(b);
(hh) Section 20.205(f);
(ii) Section 20.213(a) and (b);
(jj) Section 20.234(b)(3);
(kk) Section 20.235(c);
(ll) Section 20.252(a);
(mm) Section 20.261;
(nn) Section 20.262(d);
(oo) Section 20.263(d); and
(pp) Section 20.265(b).

Par. 8. Section 20.22(c) is amended by removing the phrase "or the regional director (compliance)" each place it appears.

Par. 9. Section 20.25 is revised to read as follows:

§ 20.25 Permits.

The appropriate ATF officer must issue permits for the United States or a Governmental agency as provided in § 20.241 and industrial alcohol user permits, Form 5150.9, required under this part.

§ 20.27, 20.28, 20.37, 20.117, 20.166, 20.170, 20.213, 20.261, 20.262, 20.263 and 20.265 [Amended].

Par. 10. Part 20 is further amended by adding the word "appropriate" before the words "ATF officer" or "ATF officers" each place it appears in the following places:
(a) Section 20.27;
(b) Section 20.28(a);
(c) Section 20.37;
(d) Section 20.117(d)(2)(iv);
(e) Section 20.166;
(f) Section 20.170;
(g) Section 20.213(b);
(h) Section 20.261;
(i) Section 20.262(c);
(j) Section 20.263(c); and
(k) Section 20.265(a) introductory text.

Par. 11. The last sentence of § 20.45(c)(1) is revised to read as follows:

§ 20.45 Organizational Documents.

* * * * *

(c) *Statement of interest.* (1) * * * If a corporation is wholly owned or controlled by another corporation, persons owning 10% or more of each of the classes of stock of the parent corporation are considered to be the persons interested in the business of the subsidiary, and the names and addresses of such persons must be submitted to the appropriate ATF officer if specifically requested.

* * * * *

§§ 20.53 and 20.205 [Amended]

Par. 12. Part 20 is further amended by removing the phrase "with the regional director (compliance)" each place it appears in the following places:
(a) Section 20.53; and
(b) Section 20.205 introductory text.

Par. 13. The first sentence of § 20.62(a) is amended to remove the phrase "within the same region".

Par. 14. Paragraph (c) of § 20.92 is revised to read as follows:

§ 20.92 Samples.

* * * * *

(c) The appropriate ATF officer may, at any time, require submission of samples of:
(1) Any ingredient used in the manufacture of an article, or;
(2) Any article.

* * * * *

Par. 15. Paragraph (a) of § 20.95 is amended to remove the phrase "on request by the Director".

Par. 16. Paragraph (b) of § 20.100 is revised to read as follows:

§ 20.100 General.

* * * * *

(b) Approval by the appropriate ATF officer of formulas, samples, or statements of process means only that they meet the standards of the Bureau of Alcohol, Tobacco and Firearms. The approval does not require the issuance of a permit under subpart D of this part to withdraw and use specially denatured spirits in those formulas, articles, or statements of process.

* * * * *

Par. 17. Paragraph (d)(2)(v) of § 20.117 is amended by removing the phrase "which may be conditions of approval by the regional director (compliance)".

Par. 18. Paragraph (b)(1)(ii) of § 20.134 is amended by removing the phrase "regional director (compliance) of the region where the manufacturing site is located" and adding in substitution, the words "appropriate ATF officer".

Par. 19. Paragraph (b) of § 20.147 is amended by removing the word "Director's" and adding, in substitution, the words "appropriate ATF officer's."

Par. 20. Paragraph (e) of § 20.189 is amended by removing the phrase "by the Director" and adding, in substitution, the phrase "in accordance with subpart F of this part".

Par. 21. Section 20.190 is revised to read as follows:

§ 20.190 Diversion of articles for internal human use or beverage use.

An appropriate ATF officer who has reason to believe that the spirits in any article are being reclaimed or diverted to beverage or internal human use may direct the permittee to modify an approved formula to prevent the reclamation or diversion. The appropriate ATF officer may require the permittee to discontinue the use of the formula until it has been modified and again approved.

Par. 22. The second sentence of § 20.241 is amended to remove the phrase "from the Director" and adding, in substitution, the phrase "as provided in § 20.25".

Par. 23. The first sentence of § 20.242(b) is amended by removing the phrase "to the Director" and the preceding comma.

§§ 20.244 and 20.252 [Amended]

Par. 24. Part 20 is further amended by removing the phrase "regional director (compliance) of the region" and adding in substitution, the words "appropriate ATF officer" each place it appears in the following places:
(a) Section 20.244; and (b) Section 20.252(b).

Par. 25. The first sentence of § 20.251 is amended by removing the phrase "for submission on request by the Director" and adding, in substitution, the phrase "as required by § 20.92".

Par. 26. The first sentence of paragraph (a) of § 20.267 is amended by removing the phrase "submitted to the regional director (compliance)" and adding, in substitution, the phrase "as required by this part".

Par. 27. The second sentence of paragraph (a) of § 20.267 is amended by removing the words "regional director (compliance)" and adding, in substitution, the words "appropriate ATF officer".

PART 21—FORMULAS FOR DENATURED ALCOHOL AND RUM

Par. 28. The authority citation for part 21 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5242, 7805.

§§ 21.2, 21.3, 21.5, 21.31 and 21.91 [Amended]

Par. 29. Part 21 is further amended by removing the word "Director" each place it appears and adding, in its place, the words "appropriate ATF officer" in the following places:
(a) Section 21.2(a);
(b) Section 21.3(d);
(c) Section 21.5 introductory text;
(d) Section 21.31(b); and
(e) Section 21.91.

Par. 30. Section 21.2 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 21.2 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

21.3, 21.21, 21.31, 21.33, 21.34, 21.56 and 21.65 [Amended]

Par. 31. Part 21 is further amended by removing the words "Chief, Chemical Branch" each place it appears and, in substitution, adding the words "appropriate ATF officer" in the following places:
(a) Section 21.3(b);
(b) Section 21.21(b) and (c);
(c) Section 21.31(c);
(d) Section 21.33(c);
(e) Section 21.34(c);
(f) Section 21.56(a);
(g) Section 21.65(a);

Par. 32. Paragraph (c) of § 21.3 is revised to read as follows:

§ 21.3 Stocks of discontinued formulas.

* * * * *

(c) On approval of an application, filed with the appropriate ATF officer and approved by such officer, destroy those stocks under whatever supervision the appropriate ATF officer requires; or

* * * * *

Par. 33. Paragraph (d) of § 21.3 is further amended by removing the phrases "to be filed with the regional director (compliance) for transmittal to the Director" and the parentheses at the beginning and ending of these phrases.

Par. 34. In Subpart A—General Provisions, a new § 21.7 is added as follows:

§ 21.7 Delegations of the Director.

All of the regulatory authorities of the Director contained Part 21 of the regulations are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site ((http://www.atf.treas.gov/).

Par. 35. Section 21.11 is amended by removing the definitions of "Chief, Chemical Branch" and "Regional director (compliance)" and adding a new definition of "Appropriate ATF officer" to read as follows:

§ 21.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Par. 36. Footnote 1 of § 21.141 is amended by removing the phrase "by the Chief, Chemical Branch".

PART 22—DISTRIBUTION AND USE OF TAX-FREE ALCOHOL

Par. 37. The authority citation continues to read as follows:

Authority: 26 U.S.C. 5001, 5121.5142, 5143, 5146, 5206, 5214, 5271–5276, 5311, 5552, 5555, 6056, 6061, 6065, 6109, 6151, 6806, 7011, 7805; 31 U.S.C. 9304, 9306.

Par. 38. Section 22.11 is amended by removing the definitions of "Area supervisor", "ATF officer", "Delegate", "Region" and "Regional director (compliance)" and adding a new definition of "Appropriate ATF officer" as to read as follows:

§ 22.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.9, Delegation Order—Delegation of the Director's

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Authorities in 27 CFR Parts 20, 21 and 22.

* * * * *

Par. 39. In Subpart C—Administrative Provisions after the undesignated center heading "Authorities", a new § 22.20 is added as follows:

§ 22.20 Delegations of the Director.

All of the regulatory authorities of the Director contained in this Part 22 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.9, Delegation Order—Delegation of the Director's Authorities in 27 CFR Parts 20, 21 and 22. ATF delegation orders, such as ATF Order 1130.9, are available to any interested person by mailing a request to the ATF Distribution Center, PO Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site ((http://www.atf.treas.gov/).

§ 22.21, 22.22, 22.24, 22.171, 22.175 and 22.176 [Amended]

Par. 40. Part 22 is further amended by removing the word "Director" each place it appears and adding, in its place, the words "appropriate ATF officer" in the following places:

(a) Section 22.21(a);
(b) Section 22.22(a)(2),(3) and (4);
(c) Section 22.24(a);
(d) Section 22.171(a);
(e) Section 22.175; and
(f) Section 22.176(c).

Par. 41. Section 22.21 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:

§ 22.21 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 42. The first two sentences of § 22.22(a)(1) and paragraph (c) of § 22.22 are revised to read as follows:

§ 22.22 Alternate methods or procedures; and emergency variations from requirements.

(a) *Alternate methods or procedures*—(1) *Application.* A permittee, after receiving approval from the appropriate ATF officer, may use an alternate method or procedure (including alternate construction or equipment) in lieu of a method or procedure prescribed by this part. A permittee wishing to use an alternate method or procedure may apply to the appropriate ATF officer. * * *

* * * * *

(c) *Withdrawal of approval.* The appropriate ATF officer may withdraw approval for an alternate method or procedure or an emergency variation from requirements, approved under paragraph (a) or (b) of this section, if the appropriate ATF officer finds that the revenue is jeopardized or the effective administration of this part is hindered by the approval.

* * * * *

§§ 22.22, 22.23, 22.24, 22.25, 22.27, 22.41, 22.42, 22.42, 22.43, 22.44, 22.45, 22.50, 22.51, 22.57, 22.58, 22.61, 22.62, 22.63, 22.64, 22.68, 22.72, 22.74, 22.79, 22.80, 22.82, 22.102, 22.103, 22.111, 22.113, 22.122, 22.124, 22.125, 22.154, 22.162 and 22.164 [Amended]

Par. 43. Part 22 is further amended by removing the words "regional director (compliance)" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 22.22(b)(1), (2) and (3);
(b) Section 22.23;
(c) Section 22.24(b);
(d) Section 22.25;
(e) Section 22.27(b);
(f) Section 22.41(b);
(g) Section 22.42(a)(11);
(h) Section 22.42(b);
(i) Section 22.43(a) introductory text;
(j) Section 22.44 introductory text;
(k) Section 22.45(c)(1);
(l) Section 22.50;
(m) Section 22.51 introductory text;
(n) Section 22.57(a)(1), (b) and (c)(1) and (3);
(o) Section 22.58(b)(1) and (2);
(p) Section 22.61;
(q) Section 22.62;
(r) Section 22.63(a);
(s) Section 22.64;
(t) Section 22.68(a);
(u) Section 22.72(b);
(v) Section 22.74;
(w) Section 22.79;
(x) Section 22.80;
(y) Section 22.82;
(z) Section 22.102(c) introductory text;
(aa) Section 22.103;
(bb) Section 22.111(c)(3);
(cc) Section 22.113(a)(1);
(dd) Section 22.122(a);
(ee) Section 22.124(b);
(ff) Section 22.125(c);
(gg) Section 22.154(b)(3);
(hh) Section 22.162; and
(ii) Section 22.164(a).

§§ 22.26, 22.27, 22.36, 22.39, 22.113, 22.142 and 22.161 [Amended]

Par. 44. Part 22 is further amended by adding the word "appropriate" before the words "ATF officer" or "ATF officers" each place it appears in the following places:

(a) Section 22.26;
(b) Section 22.27(a);
(c) Section 22.36;
(d) Section 22.39(c);
(e) Section 22.113(c);
(f) Section 22.142(a) and (c); and
(g) Section 22.161(a) and (d).

Par. 45. The last sentence of § 22.45(c)(1) is revised to read as follows:

§ 22.45 Organizational Documents.

* * * * *

(c) *Statement of interest.* (1) * * * If a corporation is wholly owned or controlled by another corporation, persons owning 10% or more of each of the classes of stock of the parent corporation are considered to be the persons interested in the business of the subsidiary, and the names and addresses of such persons must be submitted to the appropriate ATF officer if specifically requested.

* * * * *

§§ 22.53 and 22.125 [Amended]

Par. 46. Part 22 is further amended by removing the phrase "with the regional director (compliance)" each place it appears in the following places:

(a) Section 22.53; and
(b) Section 22.125(a) introductory text.

§ 22.142 [Amended]

Par. 47. Part 22 is further amended by removing the words "area supervisor" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 22.142(a), (c) and (d).

Par. 48. The first sentence of § 22.63(a) is amended by removing the phrase "within the same region'.

Par. 49. The first sentence of § 22.172(b) is amended by removing the phrase "to the Director'.

Par. 50. The second sentence of § 22.174 is amended by removing the words "regional director (compliance) of the region from which the shipment was consigned" and adding, in substitution, the words "appropriate ATF officer."

Signed: July 13, 2000.

Bradley A, Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1163 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 25

[T.D. ATF–437]

RIN 1512–AC20

Delegation of Authority for Part 25

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places ATF authorities contained in part 25, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" and requires that persons file documents required by part 25, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer" or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word "region." Concurrently with this Treasury Decision, ATF Order 1130.10 is being published. Through this order, the Director has delegated most of the authorities in 27 CFR part 25 to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Room 5003, Washington, DC 20226 (telephone 202–927–8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 25 that were previously delegated and places those authorities with the "appropriate ATF officer." All of the authorities of the Director that were not previously delegated are also placed with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer, which delegates certain of these authorities to the appropriate organizational level. The effect of these changes is to consolidate all delegations of authority in part 25 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms will indicate the officer with whom they must be filed. Similarly, this final rule also amends part 25 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the "appropriate ATF officer" identified in ATF Order 1130.10. These changes will facilitate the identification of the officer with whom forms and other required submissions are filed.

This final rule also makes various technical amendments to Subpart A—Scope of Regulations of 27 CFR part 25. First, a new § 25.6 is added to recognize the authority of the Director to delegate regulatory authorities in part 25 and to identify ATF Order 1130.10 as the instrument reflecting such delegations. Second, § 25.3 is amended to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed. Third, this rule removes from part 25 of Title 27 of the Code of Federal Regulations the definition of the term "delegate." This term is used only in the definition of Secretary in part 25 of Title 27 of the Code of Federal Regulations. We have removed the definition of "delegate" to be consistent with most parts of title 27 of the Code of Federal Regulations and to minimize potential confusion and misunderstanding with the appropriate ATF officers to whom the Director has delegated authority.

ATF has made or will make similar changes in delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings. By amending the regulations part by part, rather than in one large rulemaking document and ATF Order, ATF minimizes the time expended in notifying interested parties of current delegations of authority.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Pub. L. 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

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Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 25

Administrative practice and procedure, Authority delegations, Beer, Claims, Custom duties and inspection, Electronic fund transfers, Excise taxes, Exports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Security measures, Surety bonds, Transportation.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 25—BEER

Paragraph 1. The authority citation for part 25 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5002, 5051–5054, 5056, 5061, 5091, 5111, 5113, 5142, 5143, 5146, 5222, 5401–5403, 5411–5417, 5551, 5552, 5555, 5556, 5671, 5673, 5684, 6011, 6061, 6065, 6091, 6109, 6151, 6301, 6302, 6311, 6313, 6402, 6651, 6656, 6676, 6806, 7011, 7342, 7606, 7805; 31 U.S.C. 9301, 9303–8.

§§ 25.3, 25.23, 25.52, 25.142 and 25.155 [Amended]

Par. 2. In part 25 remove the words "Director" each place it appears and add, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 25.3(a);
(b) Section 25.23(b) introductory text and (c);
(c) Section 25.52(a)(1), (3), (4) and (5);
(d) Section 25.142(c); and
(e) Section 25.155.

Par. 3. Part 25 is further amended by adding a sentence at the end of paragraph (a) and revising paragraph (b) of § 25.3 to read as follows:

§ 25.3 Forms prescribed.

(a) * * * The form will be filed in accordance with the instructions for the form.

(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 4. In Subpart A—Scope of Regulations, a new § 25.6 is added as follows:

§ 25.6 Delegations of the Director.

Most of the regulatory authorities of the Director contained in this part 25 are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer. ATF delegation orders, such as ATF Order 1130.10, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 5. Section 25.11 is amended by removing the definitions of "Area supervisor", "ATF officer", "Delegate", "Region" and "Regional director (compliance)" and by adding a new definition of "Appropriate ATF officer" to read as follows:

§ 25.11 Meaning of Terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.10, Delegation Order—Delegation of the Director's Authorities in 27 CFR part 25, Beer.

* * * * *

§§ 25.11, 25.22, 25.24, 25.25, 25.42, 25.52, 25.61, 25.63, 25.66, 25.71, 25.72, 25.74, 25.75, 25.77, 25.81, 25.91, 25.95, 25.96, 25.101, 25.103, 25.104, 25.106, 25.114, 25.144, 25.152, 25.156, 25.165, 25.167, 25.173, 25.182, 25.184, 25.196, 25.223, 25.225, 25.272, 25.274, 25.277, 25.281, 25.282, 25.283, 25.284, 25.291, 25.297 and 25.300 [Amended]

Par. 6. Part 25 is further amended by removing the words "regional director (compliance)" each place they appear and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) The definition of Barrel in § 25.11;
(b) Section 25.22;
(c) Section 25.24(a)(7);
(d) Section 25.25(a);
(e) Section 25.42(c);
(f) Section 25.52(a)(2) and (b)(1), (2), (3);
(g) Section 25.61(a) and (c);
(h) Section 25.63;
(i) Section 25.66(c)(1);
(j) Section 25.71(a)(2) and (b)(1);
(k) Section 25.72(b)(2);
(l) Section 25.74;
(m) Section 25.75;
(n) Section 25.77;
(o) Section 25.81(e);
(p) Section 25.91(c) and (d);
(q) Section 25.95;
(r) Section 25.96;
(s) Section 25.101(a) introductory text and (b);
(t) Section 25.103;
(u) Section 25.104;
(v) Section 25.105;
(w) Section 25.114(a);
(x) Section 25.144(b);
(y) Section 25.152(a) undesignated paragraph;
(z) Section 25.158(c);
(aa) Section 25.165(b)(3) and (e);
(bb) Section 25.167(a);
(cc) Section 25.173(a);
(dd) Section 25.182;
(ee) Section 25.184(d);
(ff) Section 25.196(b);
(gg) Section 25.223(a);
(hh) Section 25.225(b)(2);
(ii) Section 25.272(a) introductory text, (b), (c), (d) and (e);
(jj) Section 25.274(a);
(kk) Section 25.277;
(ll) Section 25.281(c);
(mm) Section 25.282(b), (c), (d) and (f);
(nn) Section 25.283(d);
(oo) Section 25.284(b);
(pp) Section 25.291(d)(3);
(qq) Section 25.297(b)(4); and
(rr) Section 25.300(c).

§§ 25.31, 25.42, 25.64, 25.66, 25.68, 25.127, 25.213, 25.251, 25.252, 25.291, 25.294 and 25.300 [Amended]

Par. 7. Part 25 is further amended by adding the word "appropriate" before the words "ATF officer" or "ATF officers" each place they appear in the following places:

(a) Section 25.31;
(b) Section 25.42 introductory text;
(c) Section 25.64;
(d) Section 25.66(d);
(e) Section 25.68(b);
(f) Section 25.127;
(g) Section 25.213(c);
(h) Section 25.251(c);
(i) Section 25.252(c);
(j) Section 25.291(c)(2)(ii);
(k) Section 25.294(c); and
(l) Section 25.300(a) and (d)(3).

Par. 8. Section 25.51 is revised to read as follows:

§ 25.51 Right of Entry and Examination.

An appropriate ATF officer may enter, during normal business hours, a brewery or other place where beer is stored and may, when the premises are open at other times, enter those premises in the performance of official duties. Appropriate ATF officers may make inspections as the appropriate ATF officer deems necessary to determine that operations are conducted in compliance with the law and this part. The owner of any building or place where beer is produced, made, or kept, or person having charge over such premises, who refuses to admit an appropriate ATF officer acting under 26 U.S.C. 7606, or who refuses to permit an appropriate ATF officer to examine beer must, for each refusal, forfeit $500.

Par. 9. Section 25.52(d) is revised to read as follows:

§ 25.52 Variations from requirements.

* * * * *

(d) *Withdrawal of approval.* The appropriate ATF officer may withdraw approval of an alternate method or procedure, approved under paragraph (a) or (b) of this section, if the appropriate ATF officer finds that the revenue is jeopardized or the effective administration of this part is hindered by the approval.

* * * * *

Par. 10. The first and second sentences of § 25.61(b) are revised to read as follows:

§ 25.61 General requirements for notice.

* * * * *

(b) *Brewer's Notice, Form 5130.10.* Each person must, before commencing business as a brewer, give notice on Form 5130.10. Each person continuing business as a brewer as provided in § 25.71 must give notice on Form 5130.10. * * *

* * * * *

§ 25.62 [Amended]

Par. 11. Section 25.62(b) is amended by removing the words "the regional director of any ATF region" and adding, in substitution, the words "an ATF office'.

§§ 25.65, 25.78, 25.81, 25.276 and 25.286 [Amended]

Par. 12. Part 25 is further amended by removing the phrase "with the regional director (compliance)" each place it appears in the following places:

(a) Section 25.65;
(b) Section 25.78;
(c) Section 25.81(b) introductory text;
(d) Section 25.276(b); and (e) The last sentence of § 25.286(a).

Par. 13. Section 25.71 (a)(1) is amended by removing the words "to the regional director (compliance)" from the first sentence.

§ 25.81 [Amended]

Par. 14. Section 25.81 (c) is amended by removing from the introductory text the words "regional director (compliance) through the ATF area supervisor" and adding, in substitution, the words "appropriate ATF officer".

Par. 15. The first through third sentences of § 25.85 are revised to read as follows:

§ 25.85 Notice of permanent discontinuance.

When a brewer desires to discontinue business permanently, he or she must file a notice on Form 5130.10. The brewer must state the purpose of the notice as "Discontinuance of business" and give the date of the discontinuance. When all beer has been lawfully disposed of, appropriate ATF officer will approve the Form 5130.10 and return a copy to the brewer. * * *

* * * * *

§ 25.91 [Amended]

Par. 16. Section 25.91(a) is amended by removing from the second sentence the phrase "with the regional director (compliance)" and the comma preceding this phrase.

Par. 17. Section 25.101(b) is revised to read as follows:

§ 25.101 Disapproval of bonds or consents of surety.

* * * * *

(b) *Appeal of disapproval.* If the bond or consent of surety is disapproved, the person giving the bond or consent of surety may appeal the disapproval to the appropriate ATF officer, who will grant a hearing in the matter if requested by the applicant or brewer, and whose decision will be final.

* * * * *

Par. 18. The second and last sentences of § 25.141(b)(2) are revised to read as follows:

§ 25.141 Barrels and kegs.

* * * * *

(b) * * *

(2) * * * The coding system employed will permit an appropriate ATF officer to determine the place of production (including street address if two or more breweries are located in the same city) of the beer. The brewer must notify the appropriate ATF officer prior to employing a coding system.

* * * * *

Par. 19. The second and last sentences of § 25.142(b)(2) are revised to read as follows:

§ 25.142 Bottles.

* * * * *

(b) * * *

(2) * * * The coding system employed will permit an appropriate ATF officer to determine the place of production (including street address if two or more breweries are located in the same city) of the beer. The brewer must notify the appropriate ATF officer prior to employing a coding system.

* * * * *

§ 25.165 [Amended]

Par. 20. Section 25.165(b)(1) is amended by removing the words "regional director (compliance), for each region in which taxes are paid" and adding, in substitution, the words "appropriate ATF officer".

§ 25.184 [Amended]

Par. 21. Section 25.184(c) is amended by removing the second sentence.

Par. 22. Section 25.213(b) is amended by revising the first and third sentences of the introductory text to read as follows:

§ 25.213 Beer returned to brewery other than that from which removed.

* * * * *

(b) *Notice.* A brewer need not file notice of intention to return beer to a brewery other than the one from which removed unless required by the appropriate ATF officer. * * * The brewer must file it with the appropriate ATF officer. * * *

* * * * *

Par. 23. Section 25.222 (a) is amended by revising the last sentence to read as follows:

§ 25.222 Notice of brewer.

(a) * * * The brewer must submit this notice to the appropriate ATF officer.

* * * * *

§§ 25.222 and 25.225 [Amended]

Par. 24. Part 25 is further amended by removing the words "area supervisor" each place they appear, and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) Section 25.222(b); and
(b) Section 25.225(b)(2).

Par. 25. Section 25.223(b) is revised to read as follows:

§ 25.223 Destruction of beer off brewery premises.

* * * * *

(b) *Destruction with supervision.* The appropriate ATF officer may require that an approriate ATF officer verify the information in the notice of destruction or witness the destruction of the beer. The appropriate ATF officer may also require a delay in the destruction of the beer or, if the place of destruction is not readily accessible to an appropriate ATF

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officer, may require that the beer be moved to a more convenient location. In this case, the brewer may not destroy the beer except under the conditions imposed by the appropriate ATF officer.

Par. 26. Section 25.273 is revised to read as follows:

§ 25.273 Action on application.

If the appropriate ATF officer approves the application for a pilot brewing plant, he or she will note approval on the application and forward a copy to the applicant. The applicant must file the copy of the approved application at the premises, available for inspection by an appropriate ATF officer.

Par. 27. Section 25.276 (c) amended by revising the first and last sentences to read as follows:

§ 25.276 Operations and records.

* * * * *

(c) *Records.* The operator of a pilot brewing plant must maintain records which, in the opinion of the appropriate ATF officer, are appropriate to the type of operation being conducted. * * * These records will be available for inspection by an appropriate ATF officer.

* * * * *

Par. 28. Section 25.282(e) is revised to read as follows:

§ 25.282 Beer lost by fire, theft, casualty, or act of God.

* * * * *

(e) *Notification of appropriate ATF officer.* (1) A brewer who sustains a loss of beer before transfer of title of the beer to another person and who desires to adjust the tax on the excise tax return or to file a claim for refund or for relief from liability of tax, must, on learning of the loss of beer, immediately notify in writing the appropriate ATF officer of the nature, cause, and extent of the loss, and the place where the loss occurred. Statements of witnesses or other supporting documents must be furnished if available.

(2) A brewer possessing unmerchantable beer and who desires to adjust the tax on the excise tax return or to file a claim for refund or for relief from liability must notify in writing the appropriate ATF officer, of the circumstances by which the beer became unmerchantable, and must state why the beer cannot be salvaged and returned to the market for consumption or sale.

§ 25.283 [Amended]

Par. 29. Section 25. 283(e) is amended by removing the words "with the regional director (compliance) of the region in which the beer was lost, returned, destroyed, or rendered unmerchantable".

Par. 30. Section 25.284(d) is amended by revising the third and last sentences to read as follows:

§ 25.284 Adjustment of tax.

* * * * *

(d) *Beer lost, destroyed or rendered unmerchantable.* * * * A brewer may not make an adjustment prior to notification required under § 25.282(e). When beer appears to have been lost due to theft, the brewer may not make an adjustment to the tax return until establishing to the satisfaction of the regional director (compliance) that the theft occurred before removal from the brewery and occurred without connivance, collusion, fraud, or negligence on the part of the brewer, consignor, consignee, bailee, or carrier, or the employees or agents of any of them.

* * * * *

§ 25.285 [Amended]

Par. 31. Section 25.285(a) is amended by removing from the third sentence the words "with regional director (compliance) in which the brewer's principal place of business is located" and the comma following these words.

§ 25.297 [Amended]

Par. 32. Section 25.297(a) is amended by removing the words "to the regional director (compliance) not later than the 15th day of the month following the close of the month for which prepared".

Par. 33. Section 25.297(b) is amended by removing from the first sentence the words "with the regional director (compliance) not later than the 15th day of the month following the close of the calendar quarter for which prepared".

Signed: July 19, 2000.

Bradley A. Buckles,

Director.

Approved: August 1, 2000.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1164 Filed 1–18–01; 8:45 am]

BILLING CODE 4810–31–U

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 30

[T.D. ATF–438]

RIN 1512–AC16

Delegation of Authority in 27 CFR Part 30

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: Authority delegation. This final rule places all ATF authorities contained in part 30, title 27 Code of Federal Regulations (CFR), with the "appropriate ATF officer." Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director. Concurrently with this Treasury Decision, ATF Order 1130.17 is being published. Through this order, the Director has delegated the authorities in 27 CFR part 30 to the appropriate ATF officers.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Lisa Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226, (202–927–9347) or e-mail at alctob@atfhq.atf.treas.gov.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120–01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC). The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 30 that were previously delegated and places those authorities with the "appropriate ATF officer." Most of the authorities of the Director that were not previously delegated are also placed with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.17, Delegation Order—Delegation of the Director's Authorities in part 30, Gauging Manual, which delegates certain of these authorities to the appropriate organizational level.

The effect of these changes is to consolidate all delegations of authority in part 30 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

Drafting Information

The principal author of this document is Lisa Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 30

Alcohol and alcoholic beverages, Measurement standards, Scientific equipment.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 30—GAUGING MANUAL

Paragraph 1. The authority citation for part 30 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 2. Section 30.11 is amended by removing the definitions of "ATF officer" and "Regional director" and by adding a new definition of "Appropriate ATF officer" to read as follows:

§ 30.11 Meaning of terms.

* * * * *

Appropriate ATF Officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.17, Delegation Order—Delegation of the Director's Authorities in 27 CFR Part 30—Gauging Manual.

* * * * *

§§ 30.11, 30.31, 30.36, 30.43, and 30.51 [Amended]

Par. 3. Part 30 is further amended by removing the words "Director" each place it appears and adding, in substitution, the words "appropriate ATF officer" in the following places:

(a) The definition of "Bulk conveyance" in § 30.11;

(b) Section 30.31(b);

(c) Section 30.36;

(d) The last sentence of § 30.43; and

(e) The first sentence of § 30.51.

Par. 4. Section 30.21(c) is revised to read as follows:

§ 30.21 Requirements.

* * * * *

(c) *Appropriate ATF Officers.* Appropriate ATF officers shall use only hydrometers and thermometers furnished by the Government. However, where this part requires the use of a specific gravity hydrometer, ATF officers shall use precision grade specific gravity hydrometers conforming to the provisions of § 30.24, furnished by the proprietor. However, the appropriate ATF officer may authorize the use of other instruments approved by the appropriate ATF officer as being equally satisfactory for determination of specific gravity and for gauging. From time to time appropriate ATF officers shall verify the accuracy of hydrometers and thermometers used by proprietors.

* * * * *

Par. 5. Section 30.24(a) is amended by adding the word "appropriate" before the words "ATF officers."

Par. 6. Section 30.24(b) is amended by adding the word "appropriate" before the words "ATF officer."

Bradley A. Buckles,

Director.

Approved: August 11, 2001.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 01–1165 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

29 CFR Part 552

RIN 1215–AA82

Application of the Fair Labor Standards Act to Domestic Service

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Department of Labor is proposing to amend several of the existing regulations under the Fair Labor Standards Act (FLSA) pertaining to the exemption for companionship

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services. Section 13(a)(15) exempts from the minimum wage and overtime provisions of the FLSA domestic service employees employed "to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary)." This exemption was enacted in 1974 at the same time that Congress amended the FLSA to cover domestic service employees generally. The pertinent regulations governing this exemption have been unchanged since they were promulgated in 1975. Due to significant changes in the home care industry over the last 25 years, workers who today provide in-home care to individuals needing assistance with activities of daily living are performing types of duties and working in situations that were not envisioned when the companionship services regulations were promulgated. The number of workers providing these services has also greatly increased, and most of these workers are being excluded from the FLSA under the companionship services exemption. The Department has reevaluated the regulations and determined that—as currently written—they exempt types of employees far beyond those whom Congress intended to exempt when it enacted section 13(a)(15). Therefore, the Department proposes to amend the regulations to revise the definition of "companionship services," which sets out the duties that a companion must be employed to perform in order to qualify for the exemption, to more closely mirror Congressional intent. The Department also proposes to amend the regulations to clarify the criteria used to judge whether employees qualify as trained personnel, who are not recognized as exempt companions. Finally, the Department proposes to amend the regulations pertaining to employment by a third party. This change would deny the companionship services exemption if the worker is employed by someone other than a member of the family in whose home he or she works. It would similarly deny the exemption for live-in domestics, who are exempt from the FLSA's overtime requirements pursuant to section 13(b)(21), if they are employed by someone other than a member of the family in whose home they reside and work.

DATES: Comments are due on or before March 20, 2001.

ADDRESSES: Submit written comments to T. Michael Kerr, Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Attention: Fair Labor Standards Team, Room S–3516, 200 Constitution Avenue NW., Washington, DC 20210. Commenters who wish to receive notification of receipt of comments are requested to include a self-addressed, stamped postcard, or to submit comments by certified mail, return receipt requested. As a convenience, commenters may transmit comments by facsimile ("FAX") machine to (202) 693–1432. This is not a toll free number. If comments are transmitted by FAX and a hard copy is also submitted by mail, please indicate on the hard copy that it is a duplicate copy of the FAX transmission.

FOR FURTHER INFORMATION CONTACT: Richard M. Brennan, Deputy Director, Office of Enforcement Policy, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3510, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–0745. This is not a toll free number. Copies of this proposed rulemaking may be obtained in alternative formats by calling (202) 693–0745 or (202) 693–1461 (TTY). The alternative formats available are large print electronic file on computer disk (Word Perfect, ASCII, Mates with Duxbury Braille System) and audiotape.

SUPPLEMENTARY INFORMATION

I. Background

Congress expressly extended coverage to "domestic service" workers under the FLSA in 1974, amending the law to apply to employees performing services of a household nature in or about the private home of the person by whom they are employed. 29 U.S.C. 202(a), 206(f), 207(l). Domestic service workers were made subject to the FLSA even though they worked for a private household and not for a covered enterprise. Domestic service workers include, for example, employees working as cooks, butlers, valets, maids, housekeepers, governesses, janitors, laundresses, caretakers, handymen, gardeners, and family chauffeurs. Senate Report No. 93–690, 93d Cong., 2d Sess. (1974), p. 20. Simultaneously with extending coverage under the FLSA to domestic service workers, Congress created a complete exemption from both the minimum wage and overtime requirements for casual babysitters and persons "employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary [of Labor])." 29 U.S.C. 213(a)(15). Congress also created a more limited exemption from the overtime requirements for domestic service employees in a household who reside in that household. 29 U.S.C. 213(b)(21).

Congressional committee reports describe the reasons for extending the minimum wage protections to domestics as "so compelling and generally recognized as to make it hardly necessary to cite them." Senate Report No. 93–690, p. 18. Private household work had been one of the least attractive fields of employment. Wages were low, work hours were highly irregular, and non-wage benefits were few. Senate Report No. 93–690, p. 18.

The U.S. House of Representatives, Committee on Education and Labor stated its expectation "that extending minimum wage and overtime protection to domestic workers will not only raise the wages of these workers but will improve the sorry image of household employment. * * * Including domestic workers under the protection of the Act should help to raise the status and dignity of this work." House Report No. 93–913, 93d Cong., 2d Sess., (1974), pp. 33–34. The legislative history states that the 1974 Amendments were intended to include all employees whose vocation was domestic service, but to exempt from coverage babysitters and companions who were not regular bread-winners or responsible for their families' support. It was not intended that the statute exclude trained personnel such as nurses, whether registered or practical, from the protections of the Act. Senate Report No. 93–690, p. 20. Senator Williams, Chairman of the Senate Subcommittee on Labor and the Senate floor manager of the 1974 FLSA Amendments, described companions as "elder sitters" whose main purpose of employment is to watch over an elderly or infirm person in the same manner that a babysitter watches over children. All other work (such as occasionally making a meal or washing clothes for the person) must be incidental to that main purpose. 119 Cong. Rec. 24773, 24801 (1973).

The Department promulgated implementing regulations in 1975 that define "companionship services" as including "fellowship, care, and protection" provided to a person who, because of advanced age or physical or mental infirmity, could not care for his or her own needs. The regulation defined such exempt services as including household work related to the person's care (such as meal preparation, bed making, washing of clothes, and other similar services). A companion could also perform additional general household work without losing the exemption if it was incidental and comprised not more than 20 percent of the total weekly hours worked. Finally, a companion could be exempt even if employed solely by a third-party employer or agency, rather than by an individual or family directly. 29 CFR 552.6; 552.109(a). Similarly, live-in domestic service workers could be exempt even if employed solely by a third-party employer or agency, rather than by the individual or family in whose home they resided and worked. 29 CFR 552.109(c).

The home care industry has changed dramatically since the Department published the 1975 regulations implementing the exemption for companionship services. There has been a growing demand for long-term in-home care for persons of all ages, in part because of the rising cost of and increasing dissatisfaction with traditional institutional care, and because of the availability of public funding assistance for in-home care under Medicare and Medicaid. According to the National Association of Home Care (NAHC) publication, *Basic Statistics About Home Care (March 2000)*, data from the Department of Health and Human Services' Health Care Financing Administration (HCFA) show that the number of Medicare-certified home care agencies increased over three-fold from 2,242 in 1975 to 7,747 in 1999. The number of for-profit agencies not associated with a hospital, rehabilitation facility, or skilled nursing facility, *i.e.*, freestanding agencies, increased more than any other category of agency from 47 in 1975 to 3,129 in 1999. These for-profit agencies grew from 2 percent of total Medicare-certified agencies to over 40 percent by 1999, and now represent the greatest percentage of certified agencies. Public health agencies, which constituted over half of the certified agencies in 1975, now represent only 12 percent.

The Federal Government pays for much of the cost of providing home care services to care recipients. Medicare provides a notable portion of the industry's total revenues; other payment sources include Medicaid, insurance plans, and direct pay. Based on data from "A Profile of Medicare Home Health"—a HCFA publication—Medicare and Medicaid together account for more than half of the revenues paid to freestanding agencies (40 and 15 percent, respectively). Other private funds (philanthropy) account for 12 percent, while private health insurance accounts for 11 percent. Out-of-pocket funds account for 22 percent of agency revenues.

There has been a similarly dramatic increase in the employment of home health aides and personal and home care aides in the private homes of individuals who need assistance with basic daily living or health maintenance activities. Bureau of Labor Statistics' (BLS) national occupational employment and wage estimates from the Occupational Employment Statistics (OES) survey show that the number of workers in these jobs tripled during the decade between 1988 and 1998, and by 1998 there were 430,440 people working as home health aides and 255,960 people working as personal and home care aides. The combined occupations of personal care and home health aides constitute the seventh most rapidly growing occupational group, and BLS estimates that their number will increase by another 150 percent from 1998 to 2008. The earnings of both categories of employees remain among the lowest in the service industry—a 1998 mean annual wage of $16,250 for home health aides and $14,920 for personal and home care aides according to the OES data. Based on the same data source, ten percent of home health aides and personal and home care aides earn below $12,300 a year—lower than the 1999 poverty threshold level of $13,880 for a family of three.

Home health aides generally received more than personal and home care aides—$7.51 per hour (mean hourly wage) for personal and home care aides, and $8.17 per hour for home health aides. However, 10 percent of home health aides were paid less than $5.87 an hour, while 10 percent of personal and home care aides received less than $5.60 per hour. Although 90 percent of home health aides and personal and home care aides received hourly wages at or above $5.87 or $5.60, nearly 70,000 of these workers received hourly wages at or below such rates, and possibly below the minimum wage.

According to the BLS National Industry-Occupation Employment Matrix (1998), the largest percentage (38 percent) of personal care and home health care aides are employed in the home health care services industry. Others are employed by miscellaneous social service agencies, residential care facilities, personnel supply service agencies, nursing homes and hospitals. Only about two percent were self-employed and another two percent were employed in private households.

Current data suggest that many workers in the home care industry are now employed in their primary occupation. BLS National Current Employment Statistics for 1999 show an average weekly number of hours worked among non-supervisory employees in the home health care services industry (SIC 808) of 29.1 hours. Workers in the individual and family social services industry (SIC 832) averaged 31.2 hours per week. In the residential care industry (SIC 836), workers averaged 32.4 weekly hours worked. To the extent that time spent traveling from one client to the next has not been considered hours worked and thus captured in the above data, home care workers may actually be working longer than revealed by the BLS statistics. As indicated earlier, it clearly was Congress' intent under the 1974 FLSA Amendments to cover all workers who performed domestic services as a *vocation*, excluding casual babysitters and providers of companionship services who were *not* regular bread winners or responsible for their families' support.

These workers perform a variety of housekeeping, personal care, and medical duties for individuals who need assistance with activities of daily living to enable them to remain in their homes. Home health aides perform duties such as preparing meals, dressing patients, administering medication and performing medical procedures under a doctor's or nurse's direction. Personal and home care aides perform a variety of tasks in the home, including household work and assistance with nutrition and cleanliness. Employers have generally treated workers employed as home health aides and personal and home care aides as exempt companions, based upon the Department's current regulations. To the extent that the current regulations allow for the exemption of an employee who provides very little fellowship, and whose duties involve almost exclusively the performance of household chores or medical services, they do not appropriately implement Congress' limited exemption for employees who provide companionship services. As a result, the Department believes it is necessary to amend the regulations to focus them on the fellowship and protection duties that Congress originally intended the companion exemption to cover.

II. Proposed Regulatory Revisions

A. Duties of a Companion (29 CFR 552.6)

The Department proposes to amend the definition of "companionship services" in section 552.6 to clarify the focus on the element of fellowship, to align the regulation more closely with Congressional intent. The dictionary definition of "companionship" is

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instructive in revising the regulation to conform to the concept of a companion as originally intended in the legislative history: someone in the home primarily to watch over and care for the elderly or infirm person, much as a neighbor or babysitter would. The dictionary defines companionship as the "relationship of companions; fellowship." And the term "companion" is defined as a "person who accompanies or associates with another; comrade" and as a person "employed to assist, live with, or travel with another." It further defines "fellowship" as including "the condition of being together," "friendship" and coming together "in a congenial atmosphere." The American Heritage Dictionary of the English Language, 1976 Edition. Thus, we propose a revision of the regulation that requires that fellowship be a significant, important and fundamental aspect of the job under the companionship services exemption. Only where the worker and the person being served or assisted interact on a close personal basis, for a significant percentage of the time, would the companionship services exemption be applicable. Of course, the precise nature of what activities constitute fellowship will vary, depending upon the needs, capabilities, and interests of the care recipient. For example, fellowship might involve reading a book or a newspaper to the person, chatting with him or her about family or other events, playing cards, watching television, or going for a walk. Whatever the specific activity, it must involve personal interaction between the in-home care provider and the care recipient in order for the proposed companionship services exemption to apply.

The regulatory definition of companionship services cannot be so broad as to include someone who essentially is serving as a maid or household worker. In 1974, Congress amended the FLSA specifically to include domestic service workers (such as maids, cooks, valets and laundresses) among those intended to be covered by the Act. Congress simultaneously created a narrowly-tailored exemption for casual babysitters and those providing companionship services to the elderly and infirm. The regulations implementing the exemption should strike a balance that implements Congress' twin goals by recognizing that the fellowship and protection provided by a companion are very different from the household chores performed by a maid or cook or laundress. Furthermore, the regulations should also reflect that coverage under the FLSA is construed broadly and exemptions narrowly to effectuate the Act's remedial purposes.

The Department recognizes that it is possible to define companionship services in several different ways, with the options arrayed along a spectrum. The definitions may vary in the degree to which they require the provision of fellowship only, or allow the provision of fellowship in conjunction with hands-on care. The percentage of time that must be spent in fellowship as compared to other care duties also may vary. The Department proposes three alternatives for defining companionship services and seeks comments on all three alternatives. The three possible definitions involve variations in the specific types of duties the employee may perform and the amount of time the employee may spend in performing such duties. All of the alternatives increase the emphasis on fellowship as a critical component of a companion's duties, and narrow or eliminate the type of care that may comprise a companion's duties. In all three alternatives, we also propose to eliminate the current regulatory provision that allows the exemption to apply when the worker spends up to 20 percent of his or her time performing general household work which is unrelated to the care of the person, such as general vacuuming and dusting. Such general household work is precisely the sort of work that Congress sought to cover when it amended the Act in 1974 to reach domestic service workers, and therefore would be precluded.

The first proposal requires that fellowship be a significant part of the person's duties for the companionship services exemption to apply, but does not require fellowship duties to occupy a set percentage of the worker's time. This proposal anticipates that fellowship would occur in conjunction with the performance of other intimate personal care chores, such as bathing, grooming, and dressing, which also would constitute exempt duties. The first proposal also would allow the exemption if the worker performs a limited amount (up to 20 percent of the hours worked per week) of work of a household nature that is directly related to the client's personal care, such as cooking the person's meal, making the person's bed, or washing the dishes for that person.

The second proposal focuses on fellowship and protection as the primary duties in order for the companionship services exemption to apply. Thus, an employee must spend more than 50 percent of his or her time engaging in fellowship or protection duties to be exempt. Such fellowship and protection duties would include activities providing only fellowship or protection as well as activities in which fellowship or protection is provided concurrently with the performance of other intimate personal care chores, such as bathing, grooming, and toileting. However, only one-half the time spent providing fellowship or protection simultaneously with such other intimate personal care chores would count when determining if the employee's primary duty was providing fellowship or protection. The second proposal also would allow the exemption if the worker performs a limited amount (up to 20 percent of the weekly hours) of work of a household nature that is directly related to the person's care.

The third proposal would require that fellowship and protection be the sole core duties in order for the exemption to apply. To qualify for the exemption, the individual would have to spend at least 80 percent of his or her time in activities that provide fellowship or protection, not in conjunction with other personal care duties. The 20 percent tolerance for other types of work would apply to other intimate care and related chores. Thus, under this proposal, time spent on intimate personal care chores (such as grooming, toileting, and feeding) and on directly related work for the person (such as cooking the person's meal) may not exceed 20 percent of the weekly hours worked for the companionship services exemption to apply.

B. Trained Personnel (29 CFR 552.6)

There has also been a dramatic change since the enactment of the 1974 FLSA Amendments in the nature of the duties performed by many employees classified as exempt under the companionship services exemption. Because many individuals who were formerly institutionalized or moved to nursing homes are able, with assistance, to stay in their homes, home care providers have taken on a broader range of medically-related duties. For example, individuals treated as exempt in providing companionship services may now perform duties such as medication management, taking vital signs (pulse, temperature, respiration), routine skin and back care, and assistance with exercise and the performance of simple procedures as an extension of physical therapy service.

The training necessary for an employee to perform such duties, while less than the training of a physician or nurse, means that such individuals are not acting simply as elder sitters or as babysitters watching over their charge.

Some courts, interpreting the current regulations, have allowed employees to qualify for exemption under the present regulatory definition of companionship services despite the fact that they had extensive training, on the theory that they did not have the two or more years of training generally required for LPNs and RNs. For example, in *McCune* v. *Oregon Senior Services Division*, 894 F.2d 1107 (9th Cir. 1990), the court found that certified nursing assistants who had to pass a 60-hour training class were exempt despite their extensive medical training. Similarly, in *Cox* v. *Acme Health Services, Inc.*, 55 F.3d 1304 (7th Cir. 1995), the court held that certified home health aides with 75 hours of state-required training were exempt. The court in *Terwilliger* v. *Home of Hope, Inc.*, 21 F. Supp. 2d 1294 (N.D. Okla. 1998), also found that employees with 160 hours of training, who had to obtain 40 additional hours of training each year, were exempt.

The Department believes that Congress did not intend for the companionship services exemption to apply to employees with the level of training necessary to perform medically-related duties such as medication management and assistance with physical therapy. Duties being performed that require such extensive training are beyond what Congress envisioned when it stated that persons providing companionship services are present in the home, as a neighbor might be, to watch over an elderly person the way a babysitter watches over a child. Thus, the Department proposes to clarify the regulatory definition of companionship services in section 552.6 to exclude personnel trained in the performance of such medically related duties from the companion exemption.

C. Third Party Employment (29 CFR 552.109)

The Department also proposes to amend section 552.109, the regulation pertaining to employment by a third party. People providing in-home care and assistance to individuals with activities of daily living may be employed, or jointly employed, by various parties such as the family or household using the companionship services, State or local governments, private for-profit agencies, and hospital-related and not-for-profit agencies.

Under the existing regulation, employees who are employed by an employer or agency other than the family or household using the companionship services may still qualify for the exemption. Similarly, under the current regulation live-in workers who are employed by a third party, rather than by the family in whose household they work and reside, nevertheless may qualify for an overtime exemption under section 13(b)(21) of the FLSA.

The Department believes that employment by a party other than the family or household using the companionship services is inconsistent with the status of a companion, because the exemption for companionship services in section 13(a)(15) of the FLSA is limited to employees who are domestic service employees. The overtime exemption in section 13(b)(21) for live-in employees who reside in the household is similarly limited to domestic service employees. While domestic service was not defined by Congress in the Act, the Senate report reflects Congress' view that "the generally accepted meaning of domestic service relates to service of a household nature performed by an employee in or about a private home of the person by whom he or she is employed." Senate Report No. 93–690, p. 20 (emphasis added). The regulations mirror Congressional intent in defining domestic service employment as services of a household nature performed by an "employee in or about a private home (permanent or temporary) of the person by whom he or she is employed." 29 CFR 552.3. Thus, the current regulations contain an internal inconsistency, because they allow the companion and live-in domestic exemptions to be applied to an employee employed by someone other than the person in whose private home the work is being performed.

In 1993, the Department published a proposal to amend this regulation in light of the statutory requirement that the exemptions for companionship services and live-ins only applied to domestic service employees. The proposal provided that the companionship services exemption would not apply unless the person receiving the companionship services acted, alone or jointly, as an employer. 58 FR 69310, December 30, 1993. The subsection pertaining to live-in employees was similarly proposed for amendment. In 1995 the rule was reproposed, suggesting that the exemption might apply if either the person receiving the services or a family member or state agency acted as an employer of the person providing companionship services, if the care recipient was unable to act on his or her own behalf. 60 FR 46797, September 8, 1995. The Department received very few comments on either of those proposals, and many of the comments indicated that there was confusion about the impact and effect of the proposals.

The Department continues to believe that the current regulation impermissibly extends the exemption for companionship services and for live-in workers to employees who do not qualify as domestic service employees, because they are not working *in* the home of their employer, *i.e.*, the third party employer. In addition, as discussed above, changes in the industry and in the nature of the duties being performed in peoples' homes by this segment of the work force have resulted in increasing numbers of employees working for third-party employers. Under the 1974 Amendments, Congress extended coverage of the FLSA to domestic service employees who were not previously covered, *i.e.*, those who worked only for a private family and not for a covered enterprise. Anyone who prior to 1974 had worked for a covered placement agency, for example, but who was assigned to work in someone's home, would have been covered previously by the FLSA. The Department believes that Congress did not intend the 1974 amendments to change the status of workers already covered by the FLSA, but only intended to exclude casual babysitters and companions from those newly covered by the law, that is, those exclusively employed by the homeowner or family member.

Accordingly, we propose to amend section 552.109 (a) and (c) to make the exemptions in sections 13(a)(15) and 13(b)(21) of the FLSA applicable only with respect to the family or household using the worker's services. For employees who are employed, whether solely or jointly, by an employer *other than* the family or household, such workers would *not* be engaged in "domestic service employment" with respect to those third party employers, and those third party employers, therefore, would *not* be able to avail themselves of the exemptions. A corresponding revision is made to the definition of *domestic service employment* in section 552.103.

III. Paperwork Reduction Act

This proposed regulation does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act.

IV. Executive Order 12866

The proposed rule is not an "economically significant" regulatory action within the meaning of section 3(f)(1) of Executive Order 12866 on

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"Regulatory Planning and Review." The rule is not likely to: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; or (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof. As a result, the Department concluded that a full economic impact and cost/benefit analysis was not required for the rule under Section 6(a)(3) of the Order. However, because of its importance to the public and to the Administration's priorities, the rule was treated as a significant regulatory action and it was, therefore, reviewed by the Office of Management and Budget.

Based on our preliminary analysis of the data, it is our conclusion that the proposals to change how the companionship services exemption is applied under the FLSA will not produce a significant economic or budgetary impact on affected entities. The data indicate that more than 90 percent of the workers employed in the potentially affected occupational categories already receive the current federal minimum wage of $5.15 an hour or higher, and changing their status under the FLSA from exempt to non-exempt would not impose any new wage costs to meet minimum wage requirements. Similarly, because it appears that most of the workers in these occupational categories do not regularly work overtime (*i.e.*, more than 40 hours per week), there would be little impact from overtime wage costs if their status were changed from exempt to non-exempt. Our analysis suggests that most of the likely impact, although small, will be limited to the less than 10 percent of workers who do not receive at least $5.15 an hour and to those workers who may be entitled to additional compensation (minimum wage or overtime) for time spent traveling between multiple client work sites during the day. Some employers may not now pay for such travel time. For those few workers who may be paid at or near the $5.15 minimum wage or who work overtime hours once the travel time is included, some employers could incur minor additional wage costs to meet FLSA's minimum wage or overtime requirements. However, there are many scheduling options available to employers to enable them in that event to limit the total hours worked by an employee to 40 or fewer hours per week to ensure that overtime costs are not incurred if paying overtime wages is not in their own economic self-interests.

The Department of Health and Human Services' Health Care Finance Administration informally estimates that the proposal will have a negligible effect on Medicare costs as the types of services at issue are not a significant component of the Medicare program. Annual Medicaid program expenditures may increase somewhere within a $30 to $40 million range, of which 57 percent would be the Federal share. An equivalent percent increase in private expenditures for home health services would suggest the possibility of a maximum additional increase of $35 million in total private expenditures. The combined private and public total would likely be no greater than $75 million.

Accordingly, it is our conclusion that this rulemaking is not an economically significant regulatory action for purposes of Executive Order 12866.

V. Small Business Regulatory Enforcement Fairness Act

For similar reasons as noted above, the Department has concluded that this proposed rule is not a "major" rule requiring approval by the Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*). It will not likely result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

VI. Unfunded Mandates Reform Act

For similar reasons for purposes of the Unfunded Mandates Reform Act of 1995, this rule does not include a Federal mandate that may result in increased expenditures by State, local, and tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million.

VII. Executive Order 13132 (Federalism)

The Department has reviewed this rule under the terms of Executive Order 13132 regarding federalism and has determined that it does not have federalism implications. Because the economic effects under the rule will not be substantial for the reasons noted above, the rule does not have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

VIII. Effects on Families

The Department has assessed this rule under section 654 of the Treasury and General Government Appropriations Act, 1999, for its effect on family well-being and hereby certifies that it will not adversely affect the well-being of families.

IX. Regulatory Flexibility Act

The Department has determined for similar reasons that this proposed regulation will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, and the Department has so certified to the Chief Counsel for Advocacy of the Small Business Administration. As discussed above in the analysis under Executive Order 12866, more than 90 percent of the workers employed in occupational categories addressed by this rulemaking already receive wages at rates above the current federal minimum wage, and they typically work fewer than 40 hours per week. Furthermore, employers are reimbursed by the Federal government or insurance companies for most of the cost of providing these benefits. Thus, even assuming that the alternative covering the most additional (and therefore exempting the fewest) workers is adopted, the rule will not have a significant economic impact. The following regulatory flexibility analysis supports this determination.

(1) Reasons Why Action is Being Considered

Section 13(a)(15) of the Fair Labor Standards Act (29 U.S.C. 213(a)(15)) contains an exemption from both the minimum wage and overtime pay requirements for "3 any employee employed in domestic service employment to provide companionship services for individuals who (because of age or infirmity) are unable to care for themselves (as such terms are defined and delimited by regulations of the Secretary)" (emphasis added). Due to considerable growth in home care and the home health care industry since the implementing regulations were promulgated in 1975, the Department's more recent experience indicates that the "companionship services" exemption is being asserted in an expansive way for many more workers than we believe the Congress originally intended based on a careful analysis of the background and legislative history to the exemption. Vast numbers of workers employed in regular vocations to provide domestic services and care for individuals in their private homes are being excluded from FLSA coverage as a result of this misapplication of this exemption, which we believe is contrary to the intent and specific purposes of the 1974 FLSA Amendments. The Department is therefore issuing this proposal to invite public comments on possible clarifications to the definitional terms describing the companionship services exemption to bring it more in line with original Congressional intent.

(2) Objectives of and Legal Basis for Rule

This proposed rule is issued under the authority provided by section 13(a)(15) of the FLSA (29 U.S.C. 213(a)(15)), which grants the Secretary of Labor legislative rulemaking authority to define and delimit the terms "employee employed in domestic service employment to provide companionship services" for purposes of exempting such workers from the minimum wage and overtime pay requirements of the FLSA.

(3) Number of Small Entities Covered Under the Rule

A small business profile obtained from the U.S. Small Business Administration's Office of Advocacy web site indicates that the health services industry is among the top small business industries in the United States according to employment figures. The SBA small business size standard for Home Health Care Services, NAICS 6216, applies a $10 million threshold in annual receipts for defining a small business. Based on data from the U.S. Census Bureau's 1997 Economic Census, there were 16,895 home health care establishments (both exempt from and subject to federal income tax) in 1997 that operated for the entire year. Of that number, 16,486 (or 98%) had revenues (in the case of tax exempt firms) or receipts (in the case of non-exempt firms) of less than $10,000,000. For purposes of this analysis, we have assumed that most of the entities potentially affected by this proposal would likely meet the applicable criteria defining a small business in the home health care industry.

(4) Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

The rule contains no reporting, recordkeeping or other compliance requirements. All employers covered by the FLSA must comply with its minimum wage, overtime pay, child labor, and generally applicable recordkeeping requirements with respect to each employee who is not otherwise exempt from the FLSA's requirements.

(5) Relevant Federal Rules Duplicating, Overlapping, or Conflicting With the Rule

There are no Federal rules that duplicate, overlap, or conflict with this rule governing the scope of the companionship services exemption under the FLSA. Regulations issued under the Medicare and Medicaid programs govern qualifying reimbursements for eligible expenses under those programs.

(6) Differing Compliance or Reporting Requirements for Small Entities

This proposed rule contains no reporting, recordkeeping, or other compliance requirements specifically applicable to small entities or that differ from FLSA requirements generally applicable to all employers subject to the FLSA. Furthermore, since this is a question of application of the basic minimum wage and overtime requirements of the Act, and most affected employers would be small, no special treatment would be appropriate for small entities. However, the Department has prepared three alternative definitions of the scope of exempt duties and requested comments on all three.

(7) Clarification, Consolidation, and Simplification of Compliance and Reporting Requirements

There is continuing confusion, among both employees and employers, over the scope of the companionship services exemption as it relates to the home health care industry. This proposal is intended to delimit how the exemption applies in a manner that conforms more fully with Congressional intent. Compliance requirements—*i.e.*, payment of not less than the minimum wage for all hours worked and overtime pay, computed at time-and-one-half the regular rate for hours worked over 40 per week to all covered employees—are imposed by statute but are also relatively simple and easy to comply with. Under the recordkeeping requirements generally applicable to all FLSA-covered employers, no particular order or form of records is prescribed by regulation and employers are free to use any format that assures the essential records are kept that meets compliance needs.

(8) Use of Other Standards

This proposed regulation addresses only statutory coverage and definitional terms used in applying the "companionship services" exemption. Different standards for a statutory exemption are not appropriate for small businesses. It should be noted, however, that the proposed modification to the exemption to exclude from the exemption those workers who are employed by an employer or agency other than the family or household using their services would have the effect of excluding all large employers (as well as small employers other than the family or household).

(9) Exemption of Small Entities From Coverage of the Rule

An exemption based on the size of the entity/employer would not be permitted by the terms of the statute. Coverage and applicability of the wage and hours provisions of the FLSA are based on engagement in interstate commerce, production of goods for interstate commerce, employment in domestic service employment in private households (per se), and employment by certain enterprises named in the statute as subject to its provisions.

X. Document Preparation

This document was prepared under the direction and control of Thomas M. Markey, Deputy Administrator for Operations, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 552

Domestic service workers, Employment, Labor, Minimum wages, Overtime pay, Wages.

Signed at Washington, DC on this 12th day of January, 2001.

T. Michael Kerr,

Administrator, Wage and Hour Division.

For the reasons set forth above, part 552 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 552—APPLICATION OF THE FAIR LABOR STANDARDS ACT TO DOMESTIC SERVICE

1. The authority citation for part 552 continues to read as follows:

Authority: Secs. 13(a)(15) and 13(b)(21) of the Fair Labor Standards Act, as amended (29 U.S.C. 213(a)(15), (b)(21)), 88 Stat. 62; Sec. 29(b) of the Fair Labor Standards

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Amendments of 1974 (Pub. L. 93–259, 88 Stat. 76), unless otherwise noted.

2. § 552.3 is proposed to be revised by adding a sentence to the end of the section to read as follows:

§ 552.3 Domestic service employment.

* * * Employees who are employed, whether solely or jointly, by an employer or agency other than the family or household using their services are not engaged in domestic service employment within the meaning of this part with respect to such third-party employer.

3. § 552.6 is proposed to be revised to read as follows:

Alternative 1 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship, care and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Although no specific percentage of time must be devoted exclusively to fellowship, fellowship must be a significant component of a companion's duties. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. Care generally involves providing intimate personal care services to that individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion may also perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person, provided, however, that such work is incidental, *i.e.*, does not exceed 20 percent of the total weekly hours worked. The term "companionship services" does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

Alternative 2 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship, care and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Fellowship and protection must be a companion's primary duties and the companion must spend at least 50% of his or her weekly hours worked providing fellowship or protection. A companion's time may be devoted exclusively to fellowship or protection, or fellowship and protection may be provided in conjunction with and concurrently with intimate personal care activities; however, only one-half of the time spent providing fellowship or protection in the context of and concurrently with intimate personal care activities may count towards the 50 percent requirement. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. Care generally involves providing intimate personal care services to that individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion may also perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person, provided, however, that such work is incidental, *i.e.*, does not exceed 20 percent of the total weekly hours worked. The term "companionship services" does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

Alternative 3 for § 552.6

§ 552.6 Companionship services for the aged or infirm.

As used in section 13(a)(15) of the Act, the term companionship services shall mean those services which provide fellowship and protection for a person who, because of advanced age or physical or mental infirmity, cannot care for his or her own needs. Fellowship and protection are a companion's sole core duties and a companion must spend at least 80% or his or her weekly hours worked exclusively providing fellowship or protection. Protection generally involves being present in the home of the individual to ensure the safety and well being of that individual. A companion may also perform duties that provide care, which generally involves providing intimate personal care services to the individual, such as feeding the person or assisting the person with bathing, dressing, grooming, or toileting. A companion also may perform household work but only insofar as it is directly related to the care of the individual, such as preparing the individual's meal, making the individual's bed, washing the individual's clothes and other similar services for the person. However, all intimate personal care services and household work directly related to the individual must be incidental, i.e., may not exceed 20 percent of the total weekly hours worked. The term "companionship services" does not include services relating to the care and protection of the individual which require and are performed by personnel with training in medical procedures, including, but not limited to, catheter and ostomy care, injections, and tube feeding, regardless of whether the caregiver is a registered or practical nurse. While such trained personnel do not qualify as companions, this fact does not remove them from the category of covered domestic service employees when employed in or about a private household.

4. In § 552.109, paragraphs (a) and (c) are proposed to be revised to read as follows:

§ 552.109 Third party employment.

(a) Employees who are employed, whether solely or jointly, by an employer or agency other than the family or household using their services are not engaged in "domestic service employment" within the meaning of these regulations with respect to such third party employer. Consequently, such a third party employer may not avail itself of the minimum wage and overtime pay exemption provided by section 13(a)(15) of the Act for employees employed in domestic service employment to provide companionship services.

(b) * * *

(c) Household workers who are employed, whether solely or jointly, by an employer or agency other than the family or household using their services are not engaged "in domestic service employment" within the meaning of these regulations with respect to such third party employer. Consequently, such a third party employer may not avail itself of the overtime pay exemption provided by section 13(b)(21) of the Act for employees employed in domestic service who reside in the household.

[FR Doc. 01–1590 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 001128334–0334–01; I.D. 111300E]

RIN 648–AN40

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Atlantic Large Whale Take Reduction Plan Regulations

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim final rule; delay of effective date.

SUMMARY: This interim final rule delays the effective date of an interim final rule amending the Atlantic Large Whale Take Reduction Plan (ALWTRP) from January 22, 2001, until February 21, 2001. Due to the rough January weather conditions in the Gulf of Maine, the affected fishers have not been able to implement the gear modifications in the interim final rule in time to meet the January 22, 2001 effective date. The intent of this delay of effective date is to allow fishers 30 additional days to implement the gear modifications.

DATES: The effective date of the interim final rule amending 50 CFR part 229 published at 65 FR 80368, December 21, 2000, is delayed until February 21, 2001.

ADDRESSES: Send comments on this interim final rule to the Chief, Marine Mammal Division, NMFS, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910. Copies of the Environmental Assessment, Atlantic Large Whale Take Reduction Team (ALWTRT) meeting summaries, progress reports on implementation of the ALWTRP, and a map and table of the changes to the ALWTRP may be obtained by writing Douglas Beach, NMFS/Northeast Region, 1 Blackburn Dr., Gloucester, MA 01930 or Katherine Wang, NMFS/Southeast Region, 9721 Executive Center Dr., St. Petersburg, Fl 33702–2432.

Send comments regarding any ambiguity or unnecessary complexity arising from the language used in this interim final rule to the Marine Mammal Division Chief at the previously listed address. See **SUPPLEMENTARY INFORMATION**, under the heading Electronic Access, for Internet addresses pertaining to this interim final rule.

FOR FURTHER INFORMATION CONTACT: Douglas Beach, NMFS, Northeast Region, 978–281–9254; Katherine Wang, NMFS, Southeast Region, 727–570–5312; or Patricia Lawson, NMFS, Office of Protected Resources, 301–713–2322.

SUPPLEMENTARY INFORMATION:

Electronic Access

Several of the background documents for this interim final rule and the take reduction planning process can be downloaded from the ALWTRP web site at http://www.nero.nmfs.gov/whaletrp/.

Background

The ALWTRP was developed pursuant to the Marine Mammal Protection Act (MMPA) to reduce the level of serious injury/mortality of all large whale species in East Coast lobster trap and finfish gillnet fisheries. The background for the take reduction planning process and development of the ALWTRP is set out in the preamble to the proposed (62 FR 16519, April 7, 1997), interim final (62 FR 39157, July 22, 1997), and final (64 FR 7529, February 16, 1999) rules implementing the ALWTRP. Additional information is available in the report from the ALWTRT after its recent series of meetings in 2000. Copies of these documents and supporting Environmental Assessments (EAs) are available from the NMFS/Northeast Region contact in the **ADDRESSES** section of this document.

Because of the status of the right whale population, there is a need to further reduce entanglement. The interim final rule published December 21, 2000, (65 FR 80368), with an effective date of January 22, 2001, implemented gear modifications (buoy line weak links, net panel weak links with anchoring systems, restrictions on number of buoy lines, and gear marking) that were initially discussed in the 1997 proposed and 1999 final rules and recommended by the TRT after the 2000 meetings. NMFS responded to these recommendations by promulgating the gear modifications in the December 21, 2000, interim final rule. It was agreed that the regulations implementing these gear modifications should be issued as soon as practicable. However, due to rough January weather conditions in the Gulf of Maine, effected fishers will be unable to retrieve and modify active gear by the January 22, 2001 effective date. This interim final rule delays the effective date until February 21, 2001, to allow fishers time to implement the gear modifications.

NMFS expects that a delay of the rule to February 21, 2001 will have minimal impact on the North Atlantic right whale population. Available sighting data for the January through February period suggests that most right whales in New England are congregated in Cape Cod Bay. Data reported by the NE Right Whale Alert System during 1999–2001, included only two sightings of right whales in New England waters outside of Cape Cod Bay. Whales do not begin to leave the Bay until late March (when they move to Stellwagen Bank and then perhaps on to the Great South Channel Area) by which time gear will have been modified as per the Interim Final Rule. Thus, the 30 day delay is not expected to adversely affect right whales in these waters.

Classification

An Environmental Assessment (EA) describing the impacts to the environment that would result from the implementation of the ALWTRP was prepared for the July 22, 1997, interim final rule (62 FR 39157). Supplemental EAs were also prepared for the April 9, 1999, final rule (64 FR 17292) and the December 21, 2000, interim final rule (65 FR 80368). The conclusion of those EAs was that the ALWTRP's actions would pose no significant adverse environmental impact. The delay of the effective date by 30 days does not change the determination of those EAs. This action is categorically excluded from further review because it is an action of limited size and magnitude that does not result in a significant change in the original action.

This interim final rule has been determined to be not significant for purposes of Executive Order 12866.

Given the status of the species to be protected and the fact that entanglements continue to occur under the existing regulations, the Assistant Administrator for Fisheries (AA) NOAA, for good cause under 5 U.S.C. 553(b)(3)(B), found that extending the December 21, 2000, interim final rule (65 FR 80368) to allow for prior notice and an opportunity for public comment

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would be contrary to the public interest. In addition, the AA finds for good cause under 5 U.S.C. 553(b)(3) that extending this interim final rule for prior notice and an opportunity for public comment would be contrary to the public interest. It would be unfair to subject fishers to changes in gear requirements under the December 21, 2000 interim final rule (65 FR 80368) when, due to weather, the affected fishers have been unable to implement these changes. Because prior notice and an opportunity for public comment are not required to be provided for this interim final rule by 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

This interim final rule delays implementation of a collection-of information requirement subject to the Paperwork Reduction Act that has already been approved by Office of Management and Budget (OMB control number: 0648–0364).

A biological opinion (BO) on the ALWTRP was finalized on July 15, 1997. That opinion concluded that implementation of the ALWTRP and continued operation of fisheries conducted under the American Lobster, Northeast Multispecies, and Shark Fishery Management Plans (FMPs), as modified by the ALWTRP, may adversely affect, but are not likely to jeopardize the continued existence of any listed species or adversely modify critical habitat. A further determination was made that the February 16, 1999, final rule (64 FR 7529) did not change the basis for that BO. NMFS also determined that the December 21, 2000, interim final rule (65 FR 80368) does not change the basis for the 1997 and 1999 ESA determinations. Because this interim final rule simply delays the effective date of the December 21, 2000, interim final rule, NMFS finds this action also does not change the basis for that BO.

This interim final rule should have no adverse impacts on marine mammals. Whale entanglement rates are not expected to increase significantly as a result of this action.

This interim final rule does not change the determination for the December 21, 2000, interim final rule (65 FR 80368) that the ALWTRP will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management programs of the U.S. Atlantic coastal states.

This interim final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

This interim final rule is promulgated in compliance with all procedural requirements established by the Administrative Procedure Act.

Plain Language Requirement for Rulemaking

The President has directed Federal agencies to use plain language in their communications with the public, including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this interim final rule. Send comments to the NMFS Marine Mammal Division Chief (see **ADDRESSES**).

List of Subjects in 50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: January 12, 2001.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1589 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register

Vol. 66, No. 13

Friday, January 19, 2001

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 575

RIN 3206–AJ08

Recruitment and Relocation Bonuses and Retention Allowances

AGENCY: Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing proposed regulations to provide agencies with greater flexibility to use recruitment and relocation bonuses and retention allowances. These proposed regulations would provide agencies with the flexibility to pay retention allowances to employees who are likely to leave their positions for other Federal employment under certain limited circumstances. This proposal also would allow agencies to pay recruitment and relocation bonuses and retention allowances to prevailing rate (wage) employees.

DATES: Comments must be received on or before March 20, 2001.

FOR FURTHER INFORMATION CONTACT: Jeanne Jacobson, (202) 606–2858; FAX: (202) 606–0824; email: payleave@opm.gov.

ADDRESSES: Comments may be sent or delivered to Donald J. Winstead, Assistant Director for Compensation Administration, Workforce Compensation and Performance Service, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415, FAX: (202) 606–0824, or email: *payleave@opm.gov.*

SUPPLEMENTARY INFORMATION: The Office of Personnel Management (OPM) is proposing to amend the recruitment and relocation bonus and retention allowance regulations in 5 CFR part 575, subparts A, B, and C, to provide agencies with additional flexibility to use these incentives. The proposed regulations would allow agencies to grant a retention allowance to a current employee likely to leave for other Federal employment under certain limited circumstances. The proposed regulations also would allow agencies to pay recruitment and relocation bonuses and retention allowances to prevailing rate (wage) employees.

Retention Allowances for Employees Likely To Leave for Other Federal Employment

Under current law (5 U.S.C. 5754), OPM may authorize agencies to grant a retention allowance to an employee if the unusually high or unique qualifications of the employee or a special need for the employee's services makes it essential to retain the employee, and the agency determines that the employee would be likely to leave in the absence of an allowance. Our regulations initially authorized agencies to grant retention allowances only if the employee was likely to leave the Federal service for employment outside the executive, legislative, or judicial branch of the Federal Government (60 FR 12833, March 28, 1991). Later, we broadened this authority to provide agencies with the flexibility to grant retention allowances to employees who were likely to leave the Federal service for any reason (60 FR 33323, June 28, 1995). We did not authorize agencies to pay retention allowances to employees likely to leave for other Federal employment because of concerns about potentially disruptive and costly bidding wars among Federal agencies competing for employees with highly desired skills or competencies.

Agencies have recently requested that OPM amend its regulations to authorize retention allowances for employees likely to leave for other Federal employment in certain limited circumstances. We recognize that agencies may experience significant staffing problems that hinder their ability to meet mission objectives when their employees leave for other Federal jobs. In some cases, the retention allowance authority may be the most effective way to resolve such problems. However, we must also continue to be cognizant of the potential costs of interagency competition.

We propose to amend the regulations at 5 CFR 575.304(b) to allow agencies to pay a retention allowance to an employee likely to leave for other Federal employment when (1) the other Federal position is under a different pay system (with certain exceptions) or (2) it is essential to retain the employee during a temporary but critical work situation. (Agencies would continue to have authority under § 575.304(b)(1) to pay retention allowances to employees who are likely to leave the Federal service for any reason.)

Section 575.304(b)(2) of the proposed regulations would authorize an agency to pay a retention allowance to an employee likely to leave for another Federal position that is under a pay system that is different from the pay system of the employee's current position. The proposed regulations would prohibit agencies from using this authority to pay retention allowances to an employee likely to leave for a General Schedule (GS), prevailing rate (wage), senior-level and scientific or professional (SL/ST), Senior Executive Service (SES), administrative law judge (ALJ), Executive Schedule (EX), or Board of Contract Appeals (BCA) position when his or her current position is also under any of these pay systems. (See proposed § 575.304(d).)

For example, using this new authority an agency could pay a retention allowance to a General Schedule employee likely to leave for a higher-paying position under a pay system outside of title 5, United States Code, (*e.g.*, the Federal Aviation Administration). In this situation, the recruiting agency may have independent statutory authority to offer salaries or other incentives that are greater than those available under the General Schedule, making it very difficult for the employee's current agency to compete effectively. We believe allowing agencies to grant retention allowances in such situations will help level the playing field among agencies with similar staffing needs.

Section 575.304(b)(3) of the proposed regulations would allow Federal agencies to grant retention allowances to an employee likely to leave for other Federal employment (under the same or different pay system) during temporary but critical staffing situations. Private sector organizations pay "staying-on" or "retention bonuses" to help retain employees and keep operations running smoothly during "crisis" situations, such as mergers, acquisitions, and plant closings. We believe it would be reasonable to allow Federal agencies to use the retention allowance authority on

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a temporary basis to help retain experienced employees who otherwise would be likely to leave during similar critical periods.

For example, an agency may need to retain an employee until the completion of a project critical to the mission of the agency or during the closure of a facility or office or the relocation of an office or facility to a different commuting area. Such employees may be likely to leave for other Federal employment if, for example, the agency has announced that it will eliminate or substantially change the duties of the employee's position as a result of the critical situation or upon completion of the important project or if the office relocation will compel the employee to change his or her residence to continue employment. A retention allowance may help entice an employee to stay through the temporary but critical work period.

To help ensure that agencies use this new authority only for temporary staffing difficulties, § 575.307(b) would limit payment of retention allowances to an employee working on a critical project to a period of no longer than 1 year. On a case-by-case basis, the head of an agency may ask OPM to extend this time limit. The proposed regulations would allow an agency to pay retention allowances to an employee likely to leave for other Federal employment prior to an office closure or relocation as long as the agency continues to have an essential need for the employee's services.

When authorizing a retention allowance for an employee likely to leave for other Federal employment under § 575.304(b)(2) and (3), the proposed regulations would require agencies to follow the payment criteria and documentation provisions currently prescribed in § 575.305(c). In addition, before approving a retention allowance for an employee who is likely to leave during a critical work period, § 575.305(c)(2) of the proposed regulations would require the agency to determine how the employee's departure would affect its ability to function effectively during the critical period.

The proposed regulations at § 575.305(c)(3)(iii) also would require agencies to consider other relevant factors when authorizing a retention allowance and determining the amount for an employee who is likely to leave for other Federal employment. These factors may include the likelihood of attracting candidates to fill the employee's position if the agency has announced that it will relocate the position, the cost and time required to hire and train a new employee to complete a critical project, or the salaries typically paid by another Federal agency.

To help avoid unwarranted and possibly costly interagency competition, § 575.305(c)(4) of the proposed regulations also would require agencies to consider the use of non-pay alternatives to help resolve staffing problems before paying a retention allowance to an employee likely to leave for another Federal position. Such non-pay alternatives may include alternative recruitment strategies; use of temporary or term appointments or appointments with varying work schedules, such as part-time, intermittent, and seasonal schedules; employment of experts and consultants; alternative work schedules (*i.e.*, flexible or compressed work schedules), job sharing, and telecommuting arrangements; paying or sharing the cost of employee training and higher education; or redesigning jobs so that a larger pool of candidates may qualify for a position or to make a job more appealing to candidates by adding desirable duties or eliminating undesirable duties.

All other conditions and requirements for paying a retention allowance under 5 CFR part 575, subpart C, would continue to apply to employees who receive an allowance on the basis of being likely to leave for other Federal employment. For example, §§ 575.306(c) and 575.307(b) would require agencies to reduce or terminate a retention allowance paid to an employee likely to leave for other Federal employment when the conditions giving rise to the original determination to pay the allowance have changed. In addition, under § 575.307(d)(4), an agency could authorize a retention allowance of up to 10 percent (or up to 25 percent with OPM approval) of an employee's rate of basic pay for a group or category of employees likely to leave for other Federal employment. (In response to agency inquiries, the proposed regulations at § 575.305(c)(1) clarify that, when the group retention allowance authority is not used, agencies must make likely-to-leave determinations (for any reason, including for other Federal employment) only on an individual, case-by-case basis.)

Recruitment, Relocation, and Retention Payments for Prevailing Rate (Wage) Employees

Sections 5753(e) and 5754(e) of title 5, United States Code, permit the President to authorize the application of recruitment, relocation, and retention payments to one or more categories of employees in an agency who would not otherwise be covered by these provisions of law upon the request of the head of the agency. Under section 6 of Executive Order 12748 of February 1, 1991, the President delegated this authority to the Director of OPM. In response to an agency request, these proposed regulations would provide agencies with discretionary authority to pay recruitment and relocation bonuses and retention allowances to an employee in a prevailing rate (wage) position, as defined in 5 U.S.C. 5342(a)(3). This would include Federal Wage System or "wage grade" employees. Under the proposed regulations, the same payment criteria, procedures, and documentation requirements that apply to other covered groups of employees also would apply to wage employees.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would apply only to Federal agencies and employees.

List of Subjects in 5 CFR Part 575

Government employees, Wages.

U.S. Office of Personnel Management.

Janice R. Lachance,

Director.

Accordingly, OPM is proposing to amend part 575 of title 5, Code of Federal Regulations, as follows:

PART 575—RECRUITMENT AND RELOCATION BONUSES; RETENTION ALLOWANCES; SUPERVISORY DIFFERENTIALS

1. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 5753, 5754, and 5755; secs. 302 and 404 of the Federal Employees Pay Comparability Act of 1990 (FEPCA) (Pub. L. 101–509), 104 Stat. 1462 and 1466, respectively; E.O. 12748, 3 CFR, 1992 Comp., p. 316.

Subpart A—Recruitment Bonuses

2. In § 575.102, paragraph (a)(5) is amended by removing "or"; paragraph (a)(6) is amended by removing "." and inserting in its place "; or"; and a new paragraph (a)(7) is added to read as follows:

§ 575.102 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

Subpart B—Relocation Bonuses

3. In § 575.202, paragraph (a)(5) is amended by removing "or"; paragraph (a)(6) is amended by removing "." and inserting in its place "; or"; and a new paragraph (a)(7) is added to read as follows:

§ 575.202 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

Subpart C—Retention Allowances

4. In § 575.302, paragraph (a)(5) is amended by removing "or"; paragraph (a)(6) is amended by removing "." and inserting in its place "; or"; and paragraph (a)(7) is added to read as follows:

§ 575.302 Delegation of authority.

(a) * * *

(7) A prevailing rate position, as defined in 5 U.S.C. 5342(a)(3).

* * * * *

5. In § 575.303, the definition of *commuting area* is added in alphabetical order to read as follows:

§ 575.303 Definitions.

* * * * *

Commuting area has the meaning given that term in § 575.203.

* * * * *

6. In § 575.304, paragraph (d) is redesignated as paragraph (e), paragraphs (b) and (c) are revised, and a new paragraph (d) is added, to read as follows:

§ 575.304 Conditions for payment.

* * * * *

(b) An agency may consider an employee likely to leave if he or she is—

(1) Likely to leave the Federal service for any reason;

(2) Likely to leave his or her position for another Federal position under a different pay system (except as provided in paragraph (c) of this section); or

(3) Likely to leave his or her position for a position under the same or different Federal pay system prior to the closure of the employee's office or facility; relocation of the employee's office or facility to a different commuting area; or the completion of a project critical to the mission of an agency.

(c) An agency may not pay a retention allowance under paragraph (b)(2) of this section to an employee likely to leave for a General Schedule, prevailing rate (wage), senior-level and scientific or professional, Senior Executive Service, administrative law judge, Executive Schedule, or Board of Contract Appeals position when his or her current position is also under any of these pay systems.

(d) An agency may not pay a retention allowance to an employee who is likely to leave his or her position for another Federal position other than under the conditions described in paragraphs (b)(2) and (3) of this section.

* * * * *

7. In § 575.305, paragraphs (a)(2)(iii), (c), and (d)(1)(i) are revised to read as follows:

§ 575.305 Agency retention allowance plans; higher level review and approval; and criteria for payment.

(a) * * *

(2) * * *

(iii) Procedures for paying allowances; and

* * * * *

(c) *Criteria for payment.* (1) An agency must base each allowance paid under this subpart on a written determination that the unusually high or unique qualifications of the employee or a special need of the agency for the employee's services makes it essential to retain the employee and that, in the absence of such an allowance, the employee would be likely to leave under one of the conditions specified in § 575.304(b). Except when using the group retention allowance authority under paragraph (d) of this section, an agency must make the determination that an employee is likely to leave on an individual, case-by-case basis.

(2) An agency must base the determination required by paragraph (c)(1) of this section on a written description of the extent to which the employee's departure would affect the agency's ability to carry out an activity or perform a function that the agency deems essential to its mission or to operate effectively during a critical period.

(3) An agency must consider the following factors, as applicable in the case at hand, in determining whether to pay a retention allowance and the amount of any such payment:

(i) The success of recent efforts to recruit candidates and retain employees with qualifications similar to those possessed by the employee for positions similar to the position held by the employee;

(ii) The availability in the labor market of candidates for employment who, with minimal training or disruption of service to the public, could perform the full range of duties and responsibilities of the employee's position; or

(iii) Other supporting factors, such as the likelihood of attracting candidates to fill the employee's position if the agency has announced that it will soon relocate the position, the cost and time required to hire and train a new employee to complete a critical, time-sensitive project, or the salaries typically paid by another Federal agency.

(4) For an employee likely to leave for other Federal employment under the conditions described in § 575.304(b)(2) and (3), the agency must consider the use of non-pay solutions to help retain the employee before authorizing a retention allowance. Such solutions may include conducting an aggressive recruiting program, using alternative appointing authorities, redesigning jobs, establishing training programs, implementing alternative work schedules, or improving working conditions.

(d) * * *

(1)(i) An agency may authorize a retention allowance of up to 10 percent of an employee's rate of basic pay for a group or category of employees (excluding individuals covered by § 575.302(a)(2), (3), (5), or (6) or those in similar positions to which OPM has delegated authority to approve retention allowances to agency heads under § 575.302(c)). An agency must determine in writing that the category of employees has unusually high or unique qualifications, or that the agency has a special need for the employees' services that makes it essential to retain the employees in that category. The agency must also determine in writing that it is reasonable to presume that there is a high risk that a significant number of employees in the targeted category are likely to leave under one of the conditions specified in § 575.304(b) in the absence of an allowance.

* * * * *

8. In § 575.306, paragraph (c) is revised to read as follows:

§ 575.306 Payment of retention allowance.

* * * * *

(c) An agency may continue paying a retention allowance as long as the conditions giving rise to the original determination to pay the allowance still exist, except as provided in § 575.307(a) and (b). However, at least annually, the agency must review each determination to pay an allowance to determine whether payment is still warranted. The agency approving official must certify this determination in writing.

* * * * *

9. In § 575.307, paragraphs (b) and (c) are redesignated as paragraphs (c) and

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(d), respectively, and a new paragraph (b) is added to read as follows:

§ 575.307 Reduction or termination of retention allowance.

* * * * *

(b) An agency must terminate a retention allowance paid to an employee (or group of employees) under § 575.304(b)(3) (for work on a project critical to the mission of the agency) not later than 1 year after the initial allowance payment. On a case-by-case basis, the head of an agency may ask OPM to extend this time limit.

* * * * *

[FR Doc. 01–1486 Filed 1–18–01; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 416, and 422

[Regulations Nos. 4 and 16]

RIN 0960–AF44

New Disability Claims Process

AGENCY: Social Security Administration (SSA).

ACTION: Notice of proposed rulemaking.

SUMMARY: We are proposing to revise our regulations that pertain to the processing of initial claims for disability benefits under title II (Social Security Disability Insurance) and title XVI (Supplemental Security Income) of the Social Security Act (the Act). The proposed rules would incorporate modifications to our administrative review process and disability determination procedures based on testing that we are conducting. The changes, which would apply to initial applications for disability benefits, would:

- First, permit disability examiners in our State agencies the flexibility to decide whether input from a medical or psychological consultant is needed to make a disability determination, so that our State agencies may use the expertise of the disability examiners and medical and psychological consultants more effectively;
- Second, provide claimants with an opportunity for an informal disability conference with the adjudicators of their claims at the initial level in cases in which it appears that the evidence does not support a fully favorable determination; and
- Third, eliminate the reconsideration step of the administrative review process.

We plan to phase in these changes over a period of 1 year until they apply in every State.

DATES: To be sure that your comments are considered, we must receive them no later than March 20, 2001.

ADDRESSES: Comments should be submitted to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703; sent by telefax to (410) 966–2830; sent by e-mail to *regulations@ssa.gov;* or delivered to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, between 8:00 a.m. and 4:30 p.m. on regular business days. During these same hours, you may inspect the comments that we receive by making arrangements with the contact person shown below.

FOR FURTHER INFORMATION CONTACT: Georgia E. Myers, Regulations Officer, Office of Process and Innovation Management, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–3632 or TTY (410) 966–5609, for information about this notice. For information on eligibility or claiming benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, Social Security Online, at www.ssa.gov.

SUPPLEMENTARY INFORMATION:

In Brief, What Are We Proposing To Do?

We are proposing to change our rules in three ways:

1. We are proposing to change our rules for how State agencies make disability determinations for us. The change would allow State agency adjudicators, called "disability examiners," to decide whether input from a medical or psychological consultant is needed to make a disability determination. The medical or psychological consultant would not be responsible for the determination; *i.e.,* would not be an adjudicator of the claim.
2. We are proposing to add rules providing that disability examiners will offer claimants an opportunity for an informal conference whenever it appears that the evidence does not support a fully favorable determination.
3. We are proposing to eliminate the reconsideration step of our administrative review process.

On August 30, 1999, we published a notice in the **Federal Register** announcing a "prototype" involving these three major modifications to our disability determination process for initial applications under titles II and XVI of the Act. (See 64 FR 47218.) In the notice, we stated that, before proceeding to national implementation, we expected that the prototype would provide a body of information about the impact of these modifications on agency operations, notice and other procedures, and the quality and timeliness of our determinations and decisions. Although the prototype is continuing and we continue to gather information and gain operational experience, we believe that we now have sufficient information to propose changes to our regulations. Public comments received on these proposed changes will assist us in fine-tuning these changes.

Because we now know that implementation of the process in each State agency requires support during the period of transition, we are considering a plan by which we would implement the process in groups of State agencies until all States use the new process. Our projected completion date will be in 2003. We explain our current plan in more detail later in this preamble, and invite public comment.

What Is the Current Process?

Sections 404.1503 and 416.903 of our regulations provide that State agencies make disability and blindness determinations, following rules that we provide. Sections 404.1615(c) and 416.1015(c) of our regulations provide with respect to initial disability claims that, in most cases, these disability determinations must be made by a State agency medical or psychological consultant and a State agency disability examiner, a lay adjudicator with expertise in evaluating disability. The medical or psychological consultant and the disability examiner work together as a team and are jointly responsible for the determination. Under current rules, a disability examiner alone may make a determination only in the very unusual circumstance in which:

- There is no medical evidence to be evaluated (*i.e.,* no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist); and
- The individual fails or refuses, without good reason, to attend a consultative examination.

State agency determinations in initial claims are generally based on review of the written information in a claimant's case record. Although our procedures permit disability examiners and medical and psychological consultants to speak to claimants to obtain more information, there are no formal requirements for such contact. Also, we have no procedures requiring a State agency adjudicator to explain and discuss our disability standards with claimants or to explain the determination, apart from the information that we provide in the written notice of determination; *i.e.,* after we have already made the determination.

Sections 205(b)(1) and 1631(c)(1)(A) of the Act provide that an individual who disagrees with our initial determination has a right to a hearing. However, §§ 404.900 and 404.907 (for title II) and 416.1400 and 416.1407 (for title XVI) of our regulations have long provided that, when an individual is dissatisfied with an initial determination, he or she may appeal the determination first to the "reconsideration" level of our administrative review process. In initial disability claims, the reconsideration determination consists of a case review of evidence from the initial claim as well as evidence obtained subsequently. Only after the reconsideration determination may individuals who are dissatisfied with their determinations appeal to a hearing before an administrative law judge.

What Led Us to These Proposed Rules?

For many years, we have been exploring methods for improving the disability determination process to make it more consistent, accurate, efficient, and timely. For example, for several years we have engaged in what we call "process unification" activities aimed at improving our ability to achieve similar results in similar cases at all stages of the administrative review process. In 1995, we also published §§ 404.906 and 416.1406, "Testing modifications to the disability determination procedures," which permitted us to test a number of variations to our current processes. We called the various test processes "models." (See 60 FR 20023, April 24, 1995.)

Among the models that we included in §§ 404.906 and 416.1406 were revisions to our current process that would permit a disability examiner in the State agency to assume sole authority for making disability determinations in certain cases, thereby giving examiners the flexibility to decide whether to obtain input from a medical or psychological consultant when making the disability determination. One of the models also included a "predecision interview" with the claimant to ensure that the case record was complete and that the claimant understood our disability standards. In the preamble to the Notice of Proposed Rulemaking (NPRM) for these rules, we indicated that in recent years we had conducted various studies on how to improve the disability determination process, and that we had a number of goals in proposing the models. We stated that our goals were:

- To provide assistance to the disability applicant by making the filing of a disability claim simpler;
- To promote fairness in each disability determination by ensuring that each disability applicant is given an opportunity to provide all of the necessary information to complete the claim and is aware of his or her rights under the program; and
- To ensure that our determination is equitable. (See 58 FR 54532, 54533, October 22, 1993.)

In 1994, we included a number of similar features in our proposal to redesign the disability claims process and the subsequent final redesign plan. (See 59 FR 18188, April 15, 1994, and 59 FR 47887, September 19, 1994.) Both the redesign proposal and the final plan were especially critical of:

- The time it takes for us to adjudicate some disability claims,
- The number of SSA and State agency employees who may be involved in processing a claim initially and throughout the appeals process,
- The lack of interaction between the claimant and the decisionmaker, and
- The lack of thorough explanations, in many cases, of the basis for the disability determinations.

Therefore, the redesign of the disability process included the following goals that are important to this NPRM:

- To ensure that claims that should be allowed are allowed at the earliest point in the process;
- To provide more opportunity for claimant interaction with the decisionmaker; and
- To reduce the amount of time required processing a claim to a final disability determination or decision.

Over the years since 1994, we have tested various ideas for addressing these goals and improving the claims process. For example, in 1997, we integrated several of the redesign proposals into what we called the "Full Process Model." We tested this model in eight States and got especially positive results from several features of the model:

- We allowed disability examiners the flexibility to decide whether to obtain medical or psychological consultant input in making a disability determination. (This did not apply to certain cases, described below, in which the Act requires a medical or psychological consultant or other health care professional to participate in making the determination.) This process change revised the role of the medical and psychological consultants to act as true consultants in these cases, to be used as needed.
- We provided claimants with an opportunity for a conference with the disability examiners who were deciding their claims when it appeared that the evidence was not sufficient to support a fully favorable determination. This gave claimants an opportunity to provide additional explanations and evidence, or sources of evidence. The disability examiners also explained the Social Security definition of disability and why it appeared that the claimants did not meet that definition or why it did not appear that the evidence supported a fully favorable determination.
- Finally, we eliminated the reconsideration step of the administrative review process. Claimants who were dissatisfied with their initial determinations appealed directly to the administrative law judge hearing level.

We found that these actions resulted in better determinations at the initial level, with more allowances of claims that should have been allowed. We believe that many claims that would have been allowed only after appeal under the old process were allowed at the initial step under the new process. These claimants were able to receive benefits months sooner than they otherwise would have, an important protection for individuals who are unable to work. By eliminating the reconsideration step, claimants who appealed reached the hearing level an average of 2 months sooner than claimants who went through the reconsideration step and therefore had an opportunity to receive their hearing decisions sooner. Also, the quality of our determinations improved. Reviews of disability determinations from the FPM by SSA's Office of Quality Assessment indicated that the new process improved the accuracy of initial decisions to deny claims from 92.6 percent to 94.8 percent. If implemented nationally, this would translate to approximately 34,000 fewer disabled claimants being erroneously denied benefits and facing the prospect of a lengthy appeal.

We believe that these positive results were due to a number of factors. For example, we know that removing the reconsideration step permitted the State agencies to redirect their resources so that the individuals who formerly worked on reconsideration claims could work on initial claims. This permitted increased contact with the claimants and improved documentation of the disability determinations.

The success of the Full Process Model provided the impetus for our current

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prototype, which includes the three most successful elements of the Full Process Model, the elements we are proposing in this Notice of Proposed Rulemaking (NPRM). We have been operating the prototype in 10 States since October 1999. The States are: Alabama, Alaska, California, Colorado, Louisiana, Michigan, Missouri, New Hampshire, New York, and Pennsylvania. In New York at this time, the prototype applies only to residents in areas served by the Albany and Brooklyn branches of the State agency. In California, it applies only to residents in areas served by the Los Angeles North and Los Angeles West branches of the State agency.

This notice pertains to features that have been used in these Prototype States. We continue testing other features that were part of the 1995 proposal separately from the prototype process, but this notice does not pertain to those features.

What Are the Key Features of the Proposed Rules?

The process we are proposing in this NPRM is similar to the prototype process with some modifications based on our experience with the Full Process Model and in the prototype States. The following are the key features and our reasons for proposing them. We explain the specific changes in the proposed rules in detail later in this preamble.

1. Enhanced Roles of State Agency Disability Examiners and Medical and Psychological Consultants

By "enhanced roles" of these individuals, we mean that disability examiners would be responsible for making the disability determination in many claims, and may decide whether medical consultant or psychological consultant input is needed. We also mean that medical or psychological consultants will serve as true consultants in these claims by providing review and advice in cases with difficult or complex medical issues. Medical and psychological consultants would be expected to participate in training and mentoring the disability examiners. This change would let us better use the expertise of our adjudicators and medical resources, minimize file handoffs and allow State agencies to make disability determinations in a more timely and cost-effective manner.

However, the proposed rules provide two situations in which a medical or psychological consultant must be involved in assessing disability because of requirements in the Act:

- Sections 221(h) and 1614(a)(3)(H) of the Act, and §§ 404.1503(e), 404.1615(d), 416.903(e), and 416.1015(e) of our regulations require that, before we may find an individual "not disabled" in any case in which there is evidence of a mental impairment, we will make every reasonable effort to ensure that a qualified psychiatrist or psychologist has completed the medical portion of the case review and any applicable residual functional capacity assessment. Therefore, the proposed rules provide that a disability examiner alone may make a fully favorable determination, but that any determination that is less than fully favorable must be made by a team that includes a medical or psychological consultant, as under current procedures. However, in these cases, the disability examiner will still offer a claimant conference, and the first stage of appeal will be to the administrative law judge hearing level.
- Section 1614(a)(3)(I) of the Act and §§ 416.903(f) and 416.1015(e) of our regulations require that, for all claims for childhood disability benefits under title XVI, we will make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in a field of medicine appropriate to the child's impairment(s) evaluates the case of the child. Therefore, the proposed rules provide that we must use disability examiners and medical or psychological consultants as a team in all determinations of childhood disability under title XVI, including fully favorable determinations. However, the disability examiner will still offer a claimant conference, and appeal will be to the administrative law judge hearing level.

We also provide that, in addition to these two mandatory situations in which a determination is made by a disability examiner and medical or psychological consultant team, State agencies may require medical or psychological consultant involvement in other cases. For example, we would expect a State agency to require its trainees and other less experienced disability examiners to work in teams with medical and psychological consultants until they have become sufficiently expert to determine cases alone.

- We are proposing this change because our experience in the prototype States continues to affirm the successes we had in the Full Process Model. We believe that enhancing the roles of disability examiners and medical and psychological consultants will maximize the effectiveness of adjudicative resources, focusing State agency medical and psychological consultants on duties and responsibilities commensurate with their training and experience. Furthermore, evidence from the Full Process Model as well as the prototype States shows that the accuracy of initial determinations improves, reducing the likelihood that a disabled claimant will have to go through the appeals process in order to receive benefits for which he or she is eligible.

2. Increased Contact Between Claimants and Adjudicators

The proposed rules would require disability examiners to provide claimants with an opportunity for an "informal disability conference" in any claim in which the evidence does not appear to support a fully favorable determination. By "fully favorable" we mean a determination that the claimant is (1) disabled and (2) that the determination matches the claimant's allegations about onset of disability and (3) that the claimant is still disabled at the time of the determination.

The purpose of the conference would be to:

- Explain our disability requirements to the claimant;
- Explain why the facts currently in the case record indicate that the determination should be less than fully favorable; and
- Ensure that we have identified and made every reasonable effort to obtain relevant evidence from all appropriate sources.

The proposed rules do not prohibit a disability examiner from contacting a claimant at other times. For example, a disability examiner may contact a claimant before he or she requests any evidence to ensure that the information in the case file about the claimant's medical sources is complete. However, under the proposed rules, the disability examiner must still make contact with the claimant at or near the end of the process, when the disability examiner believes that he or she has obtained sufficient evidence on which to base a determination and it appears that the determination will be less than fully favorable.

Our experience in the Full Process Model and the prototype States has shown that increased interaction between claimants and disability examiners makes the process more personal, and it changes the determinations in some claims because of new information provided by claimants during their conferences.

3. Eliminate the Reconsideration Step of the Administrative Review Process for Initial Disability Claims

We are proposing to remove the reconsideration step of our administrative review process in all determinations on initial disability applications except appeals of determinations based on a finding that the claimant is engaging in, or has engaged in, substantial gainful activity. Findings about substantial gainful activity are made in our field offices, not in the State agencies, and the appropriate appeal will continue to be to the reconsideration level.

We are proposing this change primarily because evidence indicates that the reconsideration step adds little value to the disability determination process, at a great cost of staffing resources and processing time. Eliminating the reconsideration step permits State agencies to use their resources to make better determinations at the initial level, thereby increasing the accuracy of initial determinations. It will also provide an opportunity for denied claimants to request a hearing sooner than under the current process and, therefore, result in earlier administrative law judge decisions in many claims.

How Do We Plan To Implement the New Disability Claims Process?

We have determined that it is not feasible to change over to the new process in all of our State agencies all at once. As we have already noted, it is clear from both the Full Process Model and the Prototype that each State will need substantial lead time for training and preparation, and we must retain our capacity to process new claims as timely as possible during implementation.

We believe that our only option for accomplishing this goal is to implement the redesigned process in smaller groups of States in several stages over approximately a 1-year period beginning with the publication of the final rules that result from this NPRM. This will permit us to plan and conduct critical activities in each group of States, such as training, systems enhancement, staffing, and workload management. Most importantly, a staged implementation will also allow us to minimize delays in processing claims. Our goal is to ensure to the extent possible that, while we implement the new process, we continue to make all of our disability determinations timely.

Therefore, the proposed rules explain that only individuals whose cases are adjudicated by State agencies that have implemented the new process will be subject to the new rules. In the proposed revisions, we have described which cases are subject to the new rules and which will continue to be adjudicated under the current rules.

To make clear which cases will be handled using the new rules, we are proposing to include a new temporary appendix 1 to subpart J of part 404 that lists participating State agencies and the criteria for identifying which cases will be handled under the proposed rules. We are printing the appendix only in part 404 to save space; the proposed rules in part 416 cross-refer to the appendix in part 404. As we add more State agencies, we will publish an appropriate notice in the **Federal Register** changing the appendix to include them.

When all State agencies are using the new rules, we will publish rules removing the appendix and all language in the proposed rules that indicates that there are two processes.

What Are the Specific Provisions of the Proposed Rules?

The following are the major revisions of the proposed rules:

Proposed §§ 404.904 and 416.1404 Informal Disability Conference

We are proposing to redesignate current §§ 404.904 and 416.1404, "Notice of the initial determination," as §§ 404.904a and 416.1404a so that we can insert these new provisions. Proposed §§ 404.904 and 416.1404 would provide our rules explaining:

- Who will be offered an informal disability conference;
- What a disability conference is; and
- The procedures associated with the informal disability conference.

Paragraph (a), "What is an informal disability conference?" explains that we will offer a claimant an informal disability conference in a case of an initial application for benefits if the individual meets all of the following factors:

1. Based on the evidence in the individual's case record, it appears that we will not be able to make a "fully favorable" determination, except if the determination will be based on a finding that the individual is, or was, engaging in substantial gainful activity. We provide an explanation of what we mean by a "fully favorable" determination and to specify what is "not fully favorable" for purposes of this section. We adopted the language for the definition of a "fully favorable" determination from §§ 404.948(a) and 416.1448(a).

2. The individual's case is being determined according to the identifying criteria listed in proposed appendix 1 to subpart J of part 404. These criteria involve people who have filed applications for benefits based on disability and whose claims are handled by one of the State agencies that is using the new rules. As already noted, we intend this proposed provision to be temporary. When all State agencies are participating in the new process, we will delete appendix 1 to subpart J.

Other paragraphs in these proposed sections provide more information about the procedures we would require in connection with the informal disability conference.

- In paragraph (b)—"How will I be contacted?"—we explain how we will notify the individual of the date, time, and place or method (*e.g.*, telephone) of the informal disability conference. We also explain that we will notify the claimant's representative when he or she is represented.

In paragraph (c)—"Where will my informal disability conference be held?—we explain that we may hold the conference by telephone, in person, or using videoconferencing technology but that in most cases we will hold the conference by telephone. We also explain that we will decide the method we will use for the conference.

- In paragraph (d)—"Can an attorney or other representative participate in the informal disability conference?"—we indicate that the individual has the right to have an attorney or other representative present at the informal disability conference.

Sections 404.908 and 416.1408 Parties to a Reconsideration

We propose to revise the first sentence of paragraph (a), "Who may request a reconsideration," to add an exception to the statement that the first level of appeal from an initial determination is a reconsideration. The proposed language includes cross-references to the new appendix and to § 404.930.

Sections 404.930 and 416.1430 Availability of a Hearing Before an Administrative Law Judge

We propose to add a new subparagraph (a)(2) to explain that individuals who meet the criteria in the new appendix appeal their initial determinations to the administrative law judge hearing level. Because of this, we would redesignate the numbers of the other subparagraphs within these paragraphs.

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Sections 404.948 and 416.1448 Deciding a Case Without an Oral Hearing Before an Administrative Law Judge

We propose to revise the heading of paragraph (a) from "Decision wholly favorable" to "Decision fully favorable." This will make the heading consistent with the text of current §§ 404.948(c) and 404.1448(c) and these proposed rules. The change is only editorial.

Proposed Appendix 1 to Subpart J of Part 404

As we explained earlier in this preamble, we are proposing to add this new appendix to list the types of claims that will be handled under the new disability claims process and the State agencies that will be using the new process. The proposed appendix includes three paragraphs. In paragraph (a)—"What is this appendix for?"—we briefly note the three major differences between the new process and the current process.

In paragraph (b)—"Why aren't all State agencies using the new disability claims process?"—we explain briefly how we are implementing the rules gradually in the States. We also explain that the appendix is temporary and that we will remove it when all State agencies are using the new process.

Paragraph (c)—"Which claims will be handled under the new disability claims process?"—explains that applications for benefits based on disability processed in certain state agencies come under the new rules. It is central to all of the other rules in this NPRM because we refer back to it to provide the basic criteria for all three of the major features of these proposed rules: The informal disability conference, no reconsideration appeal step, and permitting disability examiners the flexibility to decide whether to obtain medical or psychological consultant input when making the disability determination except in cases in which the Act requires that a medical or psychological consultant participate in making the determination. For example, in proposed §§ 404.930(a)(2) and 416.1430(a)(2), we explain that the first level of appeal for a person who meets the criteria in the proposed appendix is the administrative law judge hearing. (We also include this provision in proposed §§ 404.904(g) and 416.1404(g).) Likewise, we explain in proposed §§ 404.1615(c)(1) and 416.1015(c)(1) that a disability examiner may make the determination in the case of an individual who meets the criteria in the proposed appendix, except in cases requiring by statute participation by a medical or psychological consultant.

Paragraph (d)—"Which State agencies are using the new disability claims process?"—lists the participating State agencies. The State agencies listed in this NPRM are the same State agencies and branches of State agencies that have been participating in the Prototype test. When we decide which State agencies will be in the next group to begin using the new process, we will publish an appropriate notice in the **Federal Register** revising the list.

Sections 404.1512 and 416.912 Evidence of Your Impairment

We propose to revise paragraph (b)(6) of these sections for consistency with the changes we are proposing in §§ 404.1615 and 416.1015. In current §§ 404.1527(f) and 416.927(f), we recognize that State agency medical and psychological consultants are members of the teams that make determinations of disability under the current process. Therefore, we do not consider their administrative findings of fact (*e.g.*, about residual functional capacity) at the initial level to be medical opinions that must be weighed together with the evidence in the case record. However, our regulations have long provided that at the administrative law judge hearing and Appeals Council levels of administrative review, administrative law judges and administrative appeal judges must consider these findings as opinions of nonexamining sources. For this reason, current §§ 404.1512(b)(6) and 416.912(b)(6) provide that our term "evidence" includes opinions from State agency medical and psychological consultants when a case is at the administrative law judge hearing or Appeals Council level.

Under the proposed rules, there will now be cases in which disability examiners will make initial determinations when there are opinions from state agency medical or psychological consultants in the claims file. In these cases, we will expect disability examiners to consider these opinions as evidence from nonexamining sources in the same way as administrative law judges and administrative appeals judges. Therefore, we propose to revise §§ 404.1512(b)(6) and 416.912(b)(6) to include disability examiners who make decisions alone.

Sections 404.1526 and 416.926 Medical Equivalence

We propose to revise paragraph (b), "Medical equivalence must be based on medical findings," to be consistent with the changes in these proposed rules that provide an enhanced role for disability examiners in making disability determinations. The current provision requires that in every case we must consider the medical opinion given by one or more medical or psychological consultants designated by the Commissioner in deciding medical equivalence. Under the current process, this requirement is always satisfied at the initial level of administrative review because medical and psychological consultants are always members of teams that make the initial determination and are responsible for this finding.

In view of the changes we are proposing to our process, we now propose to remove this requirement for cases that are adjudicated under the new process. Proposed paragraph (b) would provide that we "may" consider the opinion of a medical or psychological consultant designated by the Commissioner, *i.e.*, when a medical consultant provides an opinion on equivalency we will consider it. Under the Full Process Model and the Prototype, we found no evidence that omitting a medical or psychological consultant's opinion from the determination whether an impairment(s) medically equaled a listing lowered the quality of the determinations.

The proposed change would also affect adjudication at the administrative law judge hearing and Appeals Council levels of administrative review (when the Appeals Council makes a decision). Under §§ 404.1526(b) and 416.926(b), and Social Security Ruling (SSR) 96–6p, we require that administrative law judges and administrative appeals judges (when the Appeals Council makes a decision) must also consider the opinion of a medical or psychological consultant designated by the Commissioner when they consider whether an individual's impairment or combination of impairments medically equals a listing. See SSR 96–6p, "Titles II and XVI: Consideration of Administrative Findings of Fact by State Agency Medical and Psychological Consultants and Other Program Physicians and Psychologists at the Administrative Law Judge and Appeals Council Levels of Administrative Review; Medical Equivalence," (61 FR 34466, July 2, 1996). In many cases, this requirement is satisfied because State agency medical and psychological consultants have already considered the issue and provided this opinion in connection with the initial and reconsideration determinations. SSR 96–6p provides that their signatures on the determinations satisfy the requirement to obtain an opinion from a medical or psychological consultant designated by the Commissioner at the administrative law judge hearing and Appeals Council levels of administrative review when an administrative law judge or the Appeals Council finds that an individual's impairment(s) does not medically equal a listing.

However, SSR 96–6p requires that, when an administrative law judge or administrative appeals judge determines that he or she may make a finding that an individual's impairment(s) medically equals a listing, he or she must obtain an updated medical opinion from a medical expert. If the proposed revision in §§ 404.1526(b) and 416.926(b) becomes final, we will remove this requirement for administrative law judges and the Appeals Council, in order to be consistent with the changes for disability examiners.

In current § 416.926, we include a paragraph (d), "Responsibility for determining medical equivalence," which we do not now include in § 404.1526. We propose to add a new paragraph (d) in § 404.1526 that is identical to the paragraph in § 416.926, and to revise the paragraph to incorporate reference to disability examiners who make determinations. The new language would explain that in such cases, the disability examiner is responsible for determining medical equivalence.

Sections 404.1527 and 416.927 Evaluating Opinion Evidence

We propose to revise paragraph (f), "Opinions of nonexamining sources," to include disability examiners when they make disability determinations. As we have already explained under the explanation of the proposed revisions to §§ 404.1512(b)(6) and 416.912(b)(6), these individuals must consider opinions from medical and psychological consultants to be opinion evidence from nonexamining sources in the same way that administrative law judges and the administrative appeals judges do (when the Appeals Council makes a decision).

To reflect this change, we propose to add a new paragraph (f)(2) for disability examiners who make disability determinations. The language in the proposed provision is similar to the provisions for administrative law judges in current paragraph (f)(2). Because we would add a new paragraph (f)(2), we would redesignate current paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4).

We propose minor revisions in paragraph (f)(1) to make clear that the current rules would continue to apply to cases that are adjudicated in State agencies that are not using the new process.

Sections 404.1546 and 416.946 Responsibility for Assessing and Determining Residual Functional Capacity

We propose to revise this section to clarify the responsibility for making assessments of a claimant's residual functional capacity.

The existing, unnumbered paragraph will be replaced by numbered paragraphs that will clarify the responsibility for making assessments of residual functional capacity in various types of claims. We will add a paragraph that will state that a State agency disability examiner may make assessments of residual functional capacity.

Sections 404.1615 and 416.1015 Making Disability Determinations

In paragraph (c) of these sections, we propose to add the rules that will permit disability examiners to make disability determinations in certain cases.

In proposed paragraph (c)(1)(i), we explain that a State agency disability examiner may make the disability determination in cases of individuals who meet the criteria in the appendix and that are not excluded in proposed paragraph (c)(2). We explain that this is not an absolute rule, because each State agency will have the option to decide whether to permit a disability examiner to make these determinations. Our intent is to provide each State agency with the authority to determine whether a given disability examiner is sufficiently skilled to make disability determinations without working in a team with a medical or psychological consultant.

We also provide in the third sentence of the proposed paragraph a reminder that a disability examiner may still request assistance from a medical or psychological consultant. In the prototype States, there have been many cases in which disability examiners sought opinions from medical and psychological consultants on various aspects of claims.

Proposed paragraph (c)(1)(ii) is the same as current paragraph (c)(2).

In the proposed rule, we would redesignate current paragraph (c)(1) as paragraph (c)(2). The current paragraph provides the requirement that a disability examiner and a medical or psychological consultant must make the determination in almost all cases. In the proposed paragraph, we would retain this provision for States that are not yet using the new process in proposed §§ 404.1615(c)(2)(iii) and 416.1015(c)(2)(iv). The reason the part 404 and part 416 sections have different numbers is that there is an additional section (proposed paragraph (c)(2)(iii)) containing the requirement of title XVI of the Act that in any case of a child claiming SSI disability benefits, we must make reasonable efforts to ensure that a qualified pediatrician or other individual who specializes in a field of medicine appropriate to a child's impairment(s) evaluates the case of the child. We decided to make the paragraphs providing the current rule for using teams last so that when we need to revise the rules again after all State agencies are using the new process, we can delete them without having to renumber the paragraphs.

In proposed paragraph (c)(2)(i), we would provide, as required by the Act, that a team must make the determination in any case in which the State agency determines that the individual is not disabled and there is evidence that indicates the existence of a mental impairment. In proposed paragraph (c)(2)(ii) we provide that a State agency may at its option require any disability examiner to work in a team with a medical or psychological consultant.

We are also proposing two changes to current paragraph (c) that are not related to the Prototype. At the end of § 404.1615(c), are two undesignated paragraphs. There is one undesignated paragraph at the end of § 416.1015(c) that contains the same text as the two undesignated paragraphs at the end of § 404.1615(c). The first sentence of both versions provides cross-references to the rules defining "medical or psychological consultant" and "disability hearing officer." In the proposed rules, we have moved those cross-references to the appropriate sections of paragraph (c) that address these individuals.

The second sentence explains that State agency disability examiners and disability hearing officers must be qualified to interpret and evaluate medical reports and other evidence as necessary to determine the capacities of the claimant to perform substantial gainful activity. We propose to designate this sentence as paragraph (d) so that it can be cited, and to redesignate all the subsequent paragraphs in the sections. We are not proposing any changes to this sentence.

The second undesignated paragraph at the end of current § 404.1615(c), which is the third sentence in the single undesignated paragraph in current § 416.1015(c), provides a cross-reference to § 404.1572 (in § 404.1615(c)) and to

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§ 416.972 (in § 416.1015(c)) "for what we mean by substantial gainful activity." Although these rules do in fact define the term "substantial gainful activity" for purposes of evaluating a person's earnings and work activity, the cross-references are misleading in the context of the preceding text. Disability examiners and disability hearing officers do not determine whether claimants who are working are engaging in "substantial gainful activity" and do not use the rules in §§ 404.1572 and 416.972. This determination is made in our field offices. Disability examiners and disability hearing officers make determinations about whether an individual is able to work using other rules regarding medical and vocational factors. Therefore, we propose to delete these sentences since they could be confusing.

Other Changes

We are proposing changes to other rules in subparts J, P, and Q of part 404, subparts I, J, and N of part 416, and subparts B and C of part 422. These changes are intended to make these other rules consistent with the proposed changes we have explained above.

Clarity of This Regulation

Executive Order (E.O.) 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that is unclear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** on the Internet site for the Government Printing Office: *http://www.access.gpo.gov/su_docs/aces/aces140.html*. It is also available on the Internet site for SSA (*i.e., Social Security Online*): *http://www.ssa.gov/*.

Regulatory Procedures

Executive Order 12866 and the Congressional Review Act

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed regulations meet the criteria of an economically significant regulatory action under E.O. 12866 because the impact in any single year exceeds $100 million. Thus, they were subject to OMB review. We have provided below an assessment of the costs and benefits of these proposed rules. It should also be noted that this proposed rule is a major rule under the criteria of the Congressional Review Act (Chapter 8 of 5 U.S.C.).

Program Savings

We do not expect any program savings to result from these regulations.

Program Costs

1. Title II

We estimate that these rules will result in increased program outlays resulting in the following costs (in millions of dollars) to the title II program:

[Million of dollars]

FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
70	155	360	751	1,247	2,583	17,105

Related Medicare Costs

[Millions of dollars]

FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
	3	26	75	174	277	4,420

2. Title XVI

We estimate that these rules will result in increased program outlays resulting in the following costs (in millions of dollars) to the title XVI program:

[Millions of dollars]

	FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
Federal	4	30	81	188	335	638	3,922
State		3	8	19	34	64	392

[Millions of dollars]

	FY2001	FY2002	FY2003	FY2004	FY2005	FY2001–2005	FY2001–2010
Federal	3	40	120	310	576	1,049	8,940
State	2	30	91	234	435	791	6,743

Administrative Savings

We do not expect any administrative savings to result from these regulations.

Administrative Costs

We expect there will be some administrative costs associated with the transition to these rules.

Policy Alternatives

We considered, but did not select, the following policy alternative:

Keep the Current Disability Claim Process

As noted above, the initiative to redesign the disability claim process was critical of several aspects of the current process, including: the time it takes for a final agency decision; the lack of interaction between the claimant and the decisionmaker; and the lack of thorough explanations, in many cases, of the basis for the disability determination. Based on the Full Process Model test and our experience with the prototype so far, we found that the proposed new process results in better determinations at the initial level, with more allowances of claims that should be allowed. Many claims that would have been allowed only after appeal under the old process, were allowed at the initial step of the new process. Eliminating the reconsideration step enables claimants who appeal to reach the hearing level sooner than under the old process, and the resources previously used at the reconsideration step can be used to ensure a more complete determination process at the initial level. These positive results support implementation of the redesigned claim process.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

We certify that these proposed rules will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed regulations would impose no new reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Programs No. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96–004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

20 CFR Part 422

Administrative practice and procedure, Freedom of information, Organization and functions (Government agencies), Social Security.

Dated: January 11, 2001.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subparts J, P, and Q of part 404, subparts I, J, and N of part 416, and subparts B and C of part 422 of 20 CFR, chapter III as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart J of part 404 continues to read as follows:

- **Authority:** Secs. 201(j), 204(f), 205(a), (b), (d)–(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 404(f), 405(a), (b), (d)–(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97–455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)–(e), and 15, Pub. L. 98–460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.900 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 404.900 Introduction.

(a) * * *

(2) *Reconsideration.* If you are dissatisfied with an initial determination, except for certain determinations about whether you are disabled (see paragraph (a)(3)(ii) of this section), you may ask us to reconsider it.

(3) *Hearing before an administrative law judge.* You may request a hearing before an administrative law judge if you are dissatisfied with:

(i) A reconsideration determination; or

(ii) Certain initial determinations on your application for benefits based on disability, if you are a person entitled to an informal disability conference, as explained in § 404.904 and appendix 1 to this subpart.

* * * * *

3. Section 404.901 is amended by adding the following definition to the alphabetical list of definitions:

§ 404.901 Definitions

* * * * *

"Fully favorable," with respect to a disability determination, means that we determine that: the claimant is disabled; the beginning date of disability is no later than the date alleged by the claimant; and either disability has not ended or, if the claimant alleges that disability has ended, it ended no earlier than the date alleged by the claimant.

* * * * *

4. Section 404.904 is redesignated as Section 404.904a and revised to read as follows:

§ 404.904a Notice of the initial determination.

We will mail a written notice of the initial determination to you at your last known address. The notice will state the reasons for the initial determination and the effect of the initial determination.

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The notice also will explain your right to appeal the determination and whether the appeal should be for a reconsideration or a hearing before an administrative law judge. (See §§ 404.900(a), 404.904(g), 404.907, and 404.930, and appendix 1 to this subpart.) We will not mail a notice if the beneficiary's entitlement to benefits has ended because of his or her death.

5. A new section 404.904 is added to read as follows:

§ 404.904 Informal disability conference.

(a) *What is an informal disability conference?* When you file an application for disability benefits, the disability examiner may offer you an opportunity to have an informal disability conference. If your claim is decided by a component of our office other than a State agency, the disability examiner in that component may offer you an opportunity to have an informal disability conference. The purpose of the informal disability conference is to explain how your medical condition relates to our disability requirements, and to make sure that we have all of the information we need to make a determination about whether you are disabled. We will offer you an informal disability conference if all of the following apply in your case:

(1) Based on the evidence in your case record, it appears that we will not be able to make a fully favorable disability determination. However, we will not offer you an informal disability conference if the determination is less than fully favorable because:

(i) You are, or were, engaging in substantial gainful activity; or

(ii) You fail to cooperate in the processing of your claim; or

(iii) You fail to meet one or more eligibility requirement that is not related to your medical condition (*e.g.*, insured status).

(2) Your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart (claims for disability being determined by certain State agencies).

(b) *Notification.* We will notify you in writing to offer you the conference. You may choose to have a conference or not have a conference. If you have an attorney or other representative, we will also notify that person about the conference. The attorney or representative may participate in the conference.

(c) *How will my informal disability conference be held?* In most cases, we will hold your informal disability conference by telephone. In some cases, we may ask you to come to the State agency for a conference in person. We may also ask you to go to a location near you for a videoconference. We will decide how your conference will be held.

(d) *What happens during the informal disability conference?* The disability examiner will have an informal conversation with you. If he or she has not already done so in earlier conversations, the disability examiner will explain our disability standard. He or she also will tell you why the evidence in your case does not appear to support a fully favorable determination. You will have a chance to give us any information that we may not have. If you want to give us information that we need to make a determination, we will give you a chance to get the information or we will try to get it for you, following our rules in § 404.1512.

(e) *What happens if I decide not to have an informal disability conference?* If you decide not to have a conference, we will make an initial determination based on the information that we have.

6. Section 404.905 is revised to read as follows:

§ 404.905 Effect of an initial determination.

Our initial determination is final unless you request appeal (see § 404.907) within the stated time period, or we revise the determination.

7. Section 404.907 is revised to read as follows:

§ 404.907 Reconsideration—general.

(a) If you are dissatisfied with the initial determination, reconsideration is the first step in the administrative review process that we provide, except for the following determinations. In these cases, the next step in the administrative review process is to the administrative law judge hearing level.

(1) Determinations described in §§ 404.930(a)(6) and (a)(7), where you appeal an initial determination denying your request for waiver or adjustment or recovery of an overpayment (see § 404.506).

(2) If you meet the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart, an initial determination about whether you are disabled that is not fully favorable to you, except for a determination based on a finding that you are, or were, engaging in substantial gainful activity. (See appendix 1 to this subpart.)

(b) If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

8. Section 404.908 is amended by revising paragraph (a) to read as follows:

§ 404.908 Parties to a reconsideration.

(a) *Who may request a reconsideration.* If you are dissatisfied with our initial determination, you may request that we reconsider it, unless you are entitled to request a hearing before an administrative law judge, as we explain in § 404.930 and Appendix 1 of this subpart. In addition, a person who shows in writing that his or her rights may be adversely affected by the initial determination may request a reconsideration.

* * * * *

9. Section 404.930 is amended by redesignating existing paragraphs (a)(2) through (a)(7) as paragraphs (a)(3) through (a)(8), and adding a new paragraph (a)(2) to read as follows:

§ 404.930 Availability of a hearing before an administrative law judge.

(a) * * *

(2) an initial determination about whether you are disabled that is not fully favorable to you, unless that determination was about whether you are engaging or were engaging in substantial gainful activity, if your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of this subpart;

* * * * *

10. Section 404.948 is amended by revising the heading of paragraph (a) to read as follows:

§ 404.948 Deciding a case without an oral hearing before an administrative law judge.

(a) *Decision fully favorable.* * * *

* * * * *

11. A new appendix 1 to subpart J is added to read as follows:

Appendix 1—Claims That Will Be Handled Under the New Disability Claims Process

(a) *What is this appendix for?* This appendix lists the types of claims that will be handled under the new disability claims process, and which State agencies will participate in the process. Individuals who meet the criteria in paragraphs (c) and (d) of this appendix, except for individuals whose determinations of disability are based on a finding that they are, or were, engaging in substantial gainful activity, may appeal to an administrative law judge hearing if they are dissatisfied with their initial determinations. In the States listed in paragraph (d), a disability examiner is responsible for making the disability determination in certain cases. The disability examiner will have the flexibility to decide whether input from a medical or psychological consultant is needed in making the disability determination. See §§ 404.1615 and 416.1015. Individuals who also meet the criteria in § 404.904(a) of this section or § 416.1404 of part 416 and whose State agencies are using the new claims process will be offered an informal disability conference.

(b) *Why aren't all State agencies using the new disability claims process?* We are phasing in the new process gradually, because each State will need substantial lead time for training and preparation, and we must retain our capacity to process new claims as timely as possible during implementation. This means that we will add more State agencies to this list from time-to-time until all State agencies are using the new process. When all State agencies are using the new process, we will delete this appendix and the new process will apply to everyone.

(c) *Which claims will be handled under the new disability claims process?* Your claim will be handled under the new process if you filed an application for benefits (disability insurance benefits or Supplemental Security Income) based on disability or blindness and if your case is processed in one of the State agencies listed in paragraph (d) of this appendix.

(d) *Which State agencies are using the new disability claims process?* The following State agencies are using the new process:

Alabama; Alaska; California (North Los Angeles and West Los Angeles branches); Colorado; Louisiana; Michigan; Missouri; New Hampshire; New York (Brooklyn and Albany branches); Pennsylvania.

12. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(l), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), 104–193, 110 Stat. 2105, 2189.

13. Section 404.1512 is amended by revising paragraph (b)(6) to read as follows:

§ 404.1512 Evidence of your impairment.

* * * * *

(b) * * *

(6) Findings, other than the ultimate determination about whether you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, and opinions expressed by medical experts we consult based on their review of the evidence in your case record. See § § 404.1527(f)(2) and (f)(3).

* * * * *

14. Section 404.1526 is amended by revising the last sentence of paragraph (b) and by adding a new paragraph (d) to read as follows:

§ 404.1526 Medical equivalence.

* * * * *

(b) * * * We may request, and will consider if requested, any medical opinion from one or more medical or psychological consultants designated by the Commissioner when we decide medical equivalence. (See § 404.1616.)

* * * * *

(d) *Responsibility for determining medical equivalence.* In cases where the State agency or other designee of the Commissioner makes the initial disability determination, a disability examiner is responsible for determining medical equivalence in cases in which a medical or psychological consultant does not make the determination together with the disability examiner (see § 404.1615 and Appendix 1 of subpart J). In cases in which a medical or psychological consultant makes the determination together with the disability examiner, the medical or psychological consultant is responsible for assessing medical severity, and the disability examiner and medical or psychological consultant are jointly responsible for determining medical equivalence. For cases in the disability hearing process or otherwise decided by a disability hearing officer, the responsibility for determining medical equivalence rests with either the disability hearing officer or, if the disability hearing officer's reconsideration determination is changed under § 404.918, with the Associate Commissioner for Disability or his or her delegate. For cases at the Administrative Law Judge or Appeals Council level, the responsibility for deciding medical equivalence rests with the administrative law judge or Appeals Council.

15. Section 404.1527 is amended by revising paragraph (f)(1), by redesignating existing paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4) and by adding a new paragraph (f)(2) to read as follows:

§ 404.1527 Evaluating opinion evidence.

* * * * *

(f) * * *

(1) In some cases, State agency medical and psychological consultants are members of teams that make initial determinations of disability (see § 404.1615(c)(2)). In these cases, a State agency medical or psychological consultant will consider the evidence in your case record and make findings of fact about the medical issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to this subpart, and your residual functional capacity. These administrative findings of fact are based on the evidence in your case record but they are not themselves evidence at this step.

(2) In other cases, a State agency disability examiner is responsible for making the initial determination (see § 404.1615(c)(1)). In these cases, the disability examiner may obtain the opinion of a State agency medical or psychological consultant with respect to issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to this subpart, and your residual functional capacity. In these cases, State agency disability examiners weigh any opinions provided by State agency medical or psychological consultants in accordance with these rules. State agency medical and psychological consultants are highly qualified and are also experts in Social Security disability evaluation. See § 404.1512(b)(6). When a State agency disability examiner considers findings of a State agency medical or psychological consultant, the State agency disability examiner will evaluate the findings using relevant factors in paragraphs (a) through (e) of this section, such as the medical or psychological consultant's medical specialty and expertise in our rules, the supporting explanations provided by the medical or psychological consultant, and any other factors relevant to the weighing of the opinions.

* * * * *

16. Section 404.1529 is amended by revising the third sentence of paragraph (b) and by adding a new fourth sentence to paragraph (b) to read as follows:

§ 404.1529 How we evaluate symptoms, including pain.

* * * * *

(b) *Need for medically determinable impairment that could reasonably be expected to produce your symptoms, such as pain.* * * * In some cases at the initial step in the administrative review process, and all cases at the reconsideration step, a State agency medical or psychological consultant (or other medical or psychological consultant designated by the Commissioner) directly participates in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 404.1615(c)(2)). In other cases at the initial step of the administrative review process, a State agency disability examiner may ask for and consider the opinion of a State agency medical or psychological consultant in determining whether your medically determinable impairment(s) could reasonably be expected to

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produce your alleged symptoms (see § 404.1615). * * *

* * * * *

17. Section 404.1546 is revised to read as follows:

§ 404.1546 Responsibility for assessing and determining residual functional capacity.

(a) *Initial determinations.* (1) In cases in which a State agency disability determination is made by a team consisting of a State agency disability examiner and a medical or psychological consultant, the medical or psychological consultant is responsible for assessing your residual functional capacity (see § 404.1615(c)(2)).

(2) In cases in which a State agency disability examiner makes the disability determination, the State agency disability examiner is responsible for assessing your residual functional capacity (see § 404.1615(c)(1)).

(b) *Disability hearing cases.* For cases in the disability hearing process, the responsibility for deciding your residual functional capacity rests with either the disability hearing officer or, if the disability hearing officer's reconsidered determination is changed under § 404.918, with the Associate Commissioner for Disability or his or her delegate.

(c) *Administrative law judge or Appeals Council cases.* For cases at the Administrative Law Judge or Appeals Council level, the administrative law judge or Appeals Council is responsible for assessing your residual functional capacity.

18. The authority citation for subpart Q of part 404 continues to read as follows:

Authority: Secs. 205(a), 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), 421, and 902(a)(5)).

19. Section 404.1615 is amended by revising paragraph (c), by redesignating the first undesignated paragraph following paragraph (c)(3) as paragraph (d), by removing the second undesignated paragraph following paragraph (c)(3), by revising new paragraph (d), and by redesignating existing paragraphs (d), (e), (f), and (g), as paragraphs (e), (f), (g), and (h), to read as follows:

§ 404.1615 Making disability determinations.

* * * * *

(c) The following individuals in the State agency will make disability determinations:

(1)(i) If your claim meets the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J, a State agency disability examiner is responsible for making the disability determination in your claim, unless it is a claim described in (c)(2) of this section. The State agency disability examiner may request advice from a State agency medical or psychological consultant on the medical aspects of your impairment.

(ii) In any State agency, a State agency disability examiner may make the disability determination when there is no medical evidence to be evaluated (i.e., no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist) and the individual fails or refuses, without a good reason, to attend a consultative examination (see § 404.1518).

(2) A State agency medical or psychological consultant (see § 404.1616) and a State agency disability examiner together will make the disability determination in the following situations:

(i) Any case in which the State agency determines that you are not disabled and there is evidence that indicates the existence of a mental impairment, as described in paragraph (e) of this section;

(ii) Any case in which the State agency decides to require a State agency medical or psychological consultant and a State agency disability examiner to make the disability determination together; and

(iii) Any case, if your claim does not meet the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J.

(3) A State agency disability hearing officer (see § 404.915).

(d) The State agency disability examiner and disability hearing officer must be qualified to interpret and evaluate medical reports and other evidence relating to the claimant's physical or mental impairments and as necessary to determine the capacities of the claimant to perform substantial gainful activity.

* * * * *

20. Section 404.1616 is amended by revising paragraph (a) to read as follows:

§ 404.1616 Medical or psychological consultants.

(a) *What is a medical consultant?* A medical consultant is a person who is a member of a team that makes disability determinations in a State agency, as explained in § 404.1615(c)(2), or who provides advice to a State agency disability examiner, as explained in § 404.1615(c)(1). A medical consultant may also be a person who serves the same functions for us when a federal component makes the disability determination.

* * * * *

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

21. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c), and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat.1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

22. Section 416.912 is amended by revising paragraph (b)(6) to read as follows:

§ 416.912 Evidence of your impairment.

* * * * *

(b) * * *

(6) Findings, other than the ultimate determination about whether you are disabled, made by State agency medical or psychological consultants and other program physicians or psychologists, and opinions expressed by medical experts we consult based on their review of the evidence in your case record. See §§ 416.1527(f)(2) and (f)(3).

* * * * *

23. Section 416.926 is amended by revising the last sentence of paragraph (b) and by adding a new paragraph (d) to read as follows:

§ 416.926 Medical equivalence for adults and children.

* * * * *

(b) * * * We may request, and will consider if requested, any medical opinion from one or more medical or psychological consultants designated by the Commissioner when we decide medical equivalence. (See § 416.1016.)

* * * * *

(d) *Responsibility for determining medical equivalence.* In cases where the State agency or other designee of the Commissioner makes the initial disability determination, a disability examiner is responsible for determining medical equivalence in cases in which a medical or psychological consultant does not make the determination together with the disability examiner (see § 416.1015 and Appendix 1 of subpart J). In cases in which a medical or psychological consultant makes the determination together with the disability examiner, the medical or psychological consultant is responsible for assessing medical severity, and the disability examiner and medical or psychological consultant are jointly responsible for determining medical equivalence. For cases in the disability hearing process or otherwise decided by a disability hearing officer, the responsibility for determining medical equivalence rests with either the disability hearing officer or, if the disability hearing officer's reconsideration determination is changed under § 416.1418, with the Associate Commissioner for Disability or his or her delegate. For cases at the Administrative Law Judge or Appeals Council level, the responsibility for deciding medical equivalence rests with the administrative law judge or Appeals Council.

24. Section 416.927 is amended by revising paragraph (f)(1), by redesignating existing paragraphs (f)(2) and (f)(3) as paragraphs (f)(3) and (f)(4) and by adding a new paragraph (f)(2) to read as follows:

§ 416.927 Evaluating opinion evidence.

* * * * *

(f) * * *

(1) In some cases, State agency medical and psychological consultants are members of teams that make initial determinations of disability (see § 416.1015(c)(2)). In these cases, a State agency medical or psychological consultant will consider the evidence in your case record and make findings of fact about the medical issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to subpart P of part 404 of this chapter, and your residual functional capacity. These administrative findings of fact are based on the evidence in your case record but they are not themselves evidence at this step.

(2) In other cases, a State agency disability examiner is responsible for making the initial determination (see § 416.1015(c)(1)). In these cases, the disability examiner may obtain the opinion of a State agency medical or psychological consultant with respect to issues, including, but not limited to, the existence and severity of your impairment(s), the existence and severity of your symptoms, whether your impairment(s) meets or equals the requirements for any impairment listed in appendix 1 to subpart P of part 404 of this chapter, and your residual functional capacity. In these cases, State agency disability examiners weigh any opinions provided by State agency medical or psychological consultants in accordance with these rules. State agency medical and psychological consultants are trained and are also experts in Social Security disability evaluation. See § 416.912(b)(6). When a State agency disability examiner considers findings of a State agency medical or psychological consultant, the State agency disability examiner will evaluate the findings using relevant factors in paragraphs (a) through (e) of this section, such as the medical or psychological consultant's medical specialty and expertise in our rules, the supporting explanations provided by the medical or psychological consultant, and any other factors relevant to the weighing of the opinions.

* * * * *

25. Section 416.929 is amended by revising the third sentence of paragraph (b) and by adding a new fourth sentence to paragraph (b) to read as follows:

§ 416.929 How we evaluate symptoms, including pain.

* * * * *

(b) *Need for medically determinable impairment that could reasonably be expected to produce your symptoms, such as pain.* * * * In some cases at the initial step in the administrative review process, and all cases at the reconsideration step, a State agency medical or psychological consultant (or other medical or psychological consultant designated by the Commissioner) directly participates in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 416.1015(c)(2)). In other cases at the initial step of the administrative review process, a State agency disability examiner may ask for and consider the opinion of a State agency medical or psychological consultant in determining whether your medically determinable impairment(s) could reasonably be expected to produce your alleged symptoms (see § 416.1015). * * *

* * * * *

26. Section 416.946 is revised to read as follows:

§ 416.946 Responsibility for assessing and determining residual functional capacity.

(a) *Initial determinations.* (1) In cases in which a State agency disability determination is made by a team consisting of a State agency disability examiner and a medical or psychological consultant, the medical or psychological consultant is responsible for assessing your residual functional capacity (see § 416.1015(c)(2)).

(2) In cases in which a State agency disability examiner makes the disability determination, the State agency disability examiner is responsible for assessing your residual functional capacity (see § 416.1015(c)(1)).

(b) *Disability hearing cases.* For cases in the disability hearing process, the responsibility for deciding your residual functional capacity rests with either the disability hearing officer or, if the disability hearing officer's reconsidered determination is changed under § 416.1418, with the Associate Commissioner for Disability or his or her delegate.

(c) *Administrative law judge or Appeals Council cases.* For cases at the Administrative Law Judge or Appeals Council level, the administrative law judge or Appeals Council is responsible for assessing your residual functional capacity.

27. The authority citation for subpart J of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1614, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382c, 1383, and 1383b).

28. Section 416.1015 is amended by redesignating paragraphs (d) through (h) as paragraphs (e) through (i), by redesignating the undesignated paragraph following paragraph (c)(3) as paragraph (d) and revising it, and by revising paragraph (c) to read as follows:

§ 416.1015 Making disability determinations.

* * * * *

(c) The following individuals in the State agency will make disability determinations:

(1) (i) If your claim meets the requirements of paragraphs (c) and (d) of Appendix 1 of subpart J, part 404 of this chapter, a State agency disability examiner is responsible for making the disability determination in your claim, unless it is a claim described in (c)(2) of this section. The State agency disability examiner may request advice from a State agency medical or psychological consultant on the medical aspects for your impairment.

(ii) In any State agency, a State agency disability examiner may make the disability determination when there is no medical evidence to be evaluated (*i.e.*, no medical evidence exists or we are unable, despite making every reasonable effort, to obtain any medical evidence that may exist) and the individual fails or refuses, without a good reason, to attend a consultative examination (see § 416.918).

(2) A State agency medical or psychological consultant (see § 416.1016) and a State agency disability examiner together will make the disability determination in the following situations:

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(i) Any case in which the State agency determines that you are not disabled and there is evidence that indicates the existence of a mental impairment, as described in paragraph (e) of this section;

(ii) Any case in which the State agency decides to require a State agency medical or psychological consultant and a State agency disability examiner to make the disability determination together; and

(iii) Any case of a child claiming disability benefits, as described in paragraph (f) of this section;

(iv) Any case, if your claim does not meet the requirements in paragraphs (c) and (d) of Appendix 1 of subpart J, part 404 of this chapter.

(3) A State agency disability hearing officer (see § 416.1015).

(d) The State agency disability examiner and disability hearing officer must be qualified to interpret and evaluate medical reports and other evidence relating to the claimant's physical or mental impairments and as necessary to determine the capacities of the claimant to perform substantial gainful activity.

* * * * *

29. Section 416.1016 is amended by revising paragraph (a) to read as follows:

§ 416.1016 Medical or psychological consultants.

(a) *What is a medical consultant?* A medical consultant is a person who is a member of a team that makes disability determinations in a State agency, as explained in § 416.1015(c)(2), or who provides advice to a State agency disability examiner, as explained in § 416.1015(c)(1). A medical consultant may also be a person who serves the same functions for us when a federal component makes the disability determination.

* * * * *

30. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); 31 U.S.C. 3720A.

31. Section 416.1400 is amended by revising paragraphs (a)(2) and (a)(3) to read as follows:

§ 416.1400 Introduction.

(a) * * *

(2) *Reconsideration.* If you are dissatisfied with an initial determination, except for certain determinations about whether you are disabled (see (a)(3)(ii) of this section), you may ask us to reconsider it.

(3) *Hearing before an administrative law judge.* You may request a hearing before an administrative law judge if you are dissatisfied with:

(i) A reconsideration determination; or

(ii) Certain initial determinations on your application for benefits based on disability, if you are a person entitled to an informal disability conference, as explained in § 416.1404 and appendix 1 to subpart J of part 404 of this chapter.

* * * * *

32. Section 416.1401 is amended by adding the following definition to the alphabetical listing of definitions in this section, to read as follows:

§ 416.1401 Definitions.

* * * * *

"Fully favorable" with respect to a disability determination, means that we determine that: the claimant is disabled; the beginning date of disability is no later than the date alleged by the claimant; and either disability has not ended or, if the claimant alleges that disability has ended, it ended no earlier than the date alleged by the claimant.

* * * * *

33. Section 416.1404 is redesignated as Section 416.1404a and revised to read as follows:

§ 416.1404a Notice of the initial determination.

(a) We will mail a written notice of the initial determination to you at your last known address. Generally, we will not send a notice if your benefits are stopped because of your death, or if the initial determination is a redetermination that your eligibility for benefits and the amount of your benefits have not changed.

(b) The written notice that we send will tell you:

(1) What our initial determination is;

(2) The reasons for our determination; and

(3) What rights you have to a reconsideration of the determination or a hearing before an administrative law judge. (See § § 416.1400(a), 416.1404(g), 416.1407, and 416.1430, and appendix 1 to subpart J of part 404 of this chapter.)

(c) If our initial determination is that we must suspend, reduce or terminate your benefits, the notice will also tell you that you have a right to a reconsideration before the determination takes effect (see § 416.1336).

34. A new section 416.1404 is added to read as follows:

§ 416.1404 Informal disability conference.

(a) *What is an informal disability conference?* When you file an application for disability benefits, the disability examiner may offer you an opportunity to have an informal disability conference. If your claim is decided by a component of our office other than a State agency, the disability examiner in that component may offer you an opportunity to have an informal disability conference. The purpose of the informal disability conference is to explain how your medical condition relates to our disability requirements, and to make sure that we have all of the information we need to make a determination about whether you are disabled. We will offer you an informal disability conference if all of the following apply in your case:

(1) Based on the evidence in your case record, it appears that we will not be able to make a fully favorable disability determination. However, we will not offer you an informal disability conference if the determination is less than fully favorable because:

(i) You are, or were, engaging in substantial gainful activity; or

(ii) You fail to cooperate in the processing of your claim; or

(iii) You fail to meet one or more eligibility requirement that is not related to your medical condition (e.g., limitations on income and resources).

(2) Your claim meets the requirements of paragraphs (c) and (d) of appendix 1, subpart J of part 404.

(b) *Notification* We will notify you in writing to offer you the conference. You may choose to have a conference or not have a conference. If you have an attorney or other representative, we will also notify that person. The attorney or representative may participate in the conference.

(c) How *will my informal disability conference be held?* In most cases, we will hold your informal disability conference by telephone. In some cases, we may ask you to come to the State agency for a conference in person. We may also ask you to go to a location near you for a videoconference. We will decide how your conference will be held.

(d) *What happens during the informal disability conference?* The disability examiner will have an informal conversation with you. If he or she has not already done so in earlier conversations, he or she will explain our disability standard. He or she also will tell you why the evidence in your case does not appear to support a fully favorable determination. You will have a chance to provide information that we may not have. If you want to give us information that we need to make a determination, we will give you a chance to get the information or we will try to get it for you, following our rules in § 416.912.

(e) *What happens if I decide not to have an informal disability conference?* If you decide not to have a conference, we will make an initial determination based on the information that we have.

35. Section 416.1405 is revised to read as follows:

§ 416.1405 Effect of an initial determination.

Our initial determination is final unless you request a reconsideration or an administrative law judge hearing within the stated time period, or we revise the determination.

36. Section 416.1407 is revised to read as follows:

§ 416.1407 Reconsideration—general.

If you are dissatisfied with the initial determination, reconsideration is the first step in the administrative review process that we provide, with one exception. If your claim meets the requirements of paragraphs (c) and (d) of Appendix 1, subpart J, part 404 of this chapter, and we make an initial determination about whether you are disabled that is not fully favorable to you, except for a determination based on a finding that you are, or were, engaging in substantial gainful activity, the next step in the administrative review process is to the administrative law judge hearing level. If you are dissatisfied with our reconsidered determination, you may request a hearing before an administrative law judge.

37. Section 416.1408 is amended by revising paragraph (a) to read as follows:

§ 416.1408 Parties to a reconsideration.

(a) *Who may request a reconsideration.* If you are dissatisfied with our initial determination, you may request that we reconsider it, unless you are entitled to request a hearing before an administrative law judge, as we explain in § 416.1430 and appendix 1 of subpart J, part 404 of this chapter. In addition, a person who shows in writing that his or her rights may be adversely affected by the initial determination may request a reconsideration.

* * * * *

38. Section 416.1430 is amended by redesignating existing paragraphs (a)(2), (a)(3), and (a)(4) as paragraphs (a)(3), (a)(4), and (a)(5), and by adding a new paragraph (a)(2) to read as follows:

§ 416.1430 Availability of a hearing before an administrative law judge.

(a) * * *

(2) An initial determination about whether you are disabled that is not fully favorable to you, unless that determination was about whether you are engaging or were engaging in substantial gainful activity, if your claim meets the requirements of paragraphs (c) and (d) of appendix 1 of subpart J, part 404 of this chapter;

* * * * *

39. Section 416.1448 is amended by revising the heading of paragraph (a) to read as follows:

§ 416.1448 Deciding a case without an oral hearing before an administrative law judge.

(a) *Decision fully favorable.* * * *

* * * * *

PART 422—ORGANIZATION AND PROCEDURES

40. The authority citation for subpart B of part 422 continues to read as follows:

Authority: Secs. 205, 232, and 702(a)(5), 1131, and 1143 of the Social Security Act (42 U.S.C. 405, 432, 902(a)(5), 1320b–l, and 1320b–13).

41. Section 422.140 is amended by revising the first sentence to read as follows:

§ 422.140 Reconsideration of initial determination.

Except in the case of certain determinations regarding disability (see § 404.930 and appendix 1 of subpart J, part 404 of this chapter), any party who is dissatisfied with an initial determination with respect to entitlement to monthly benefits, a lump-sum death payment, a period of disability, a revision of an earnings record, with respect to any other right under title II of the Social Security Act, or with respect to entitlement to hospital insurance benefits or supplementary medical insurance benefits, or the amount of hospital insurance benefits, may request that the Social Security Administration reconsider such determination. * * *

42. The authority citation for subpart C of part 422 continues to read as follows:

Authority: Secs. 205, 221, and 702(a)(5) of the Social Security Act (42 U.S.C. 405, 421, and 902(a)(5)); 30 U.S.C. 923(b).

43. Section 422.203 is amended by revising the first sentence of paragraph (a)(1), by redesignating paragraph (c) as paragraph (c)(1), and by adding paragraph (c)(2) to read as follows:

§ 422.203 Hearings.

(a) * * * (1) After certain determinations regarding disability (see § 404.930 and appendix 1 of subpart J, part 404 of this chapter), and after a reconsidered or a revised determination (i) of a claim for benefits or any other right under title II of the Social Security Act; or (ii) of eligibility or amount of benefits or any other matter under title XVI of the Act, except where an initial or reconsidered determination involving an adverse action is revised, after such revised determination has been reconsidered; or (iii) as to entitlement under part A or part B of title XVIII of the Act, or as to the amount of benefits under part A of such title XVIII (where the amount in controversy is $100 or more); or of health services to be provided by a health maintenance organization without additional costs (where the amount in controversy is $100 or more); or as to the amount of benefits under part B of title XVIII (where the amount in controversy is $500 or more); or as to a determination by a peer review organization (PRO) under title XI (where the amount in controversy is $200 or more); or as to certain determinations made under section 1154, 1842(1), 1866(f)(2), or 1879 of the Act; any party to such a determination may, pursuant to the applicable section of the Act, file a written request for a hearing on the determination. * * *

* * * * *

(c) * * *

(2) Unless for good cause shown on extension of time has been granted, a request for hearing must be filed within 60 days after the receipt of the notice of the reconsidered or revised determination, or after an initial determination described in § 404.900(a)(3)(ii), 42 CFR 498.3(b) and (c) (see §§ 404.933, 410.631, and 416.1433 of this chapter and 42 CFR 405,722, 498.40, and 417.260.)

* * * * *

[FR Doc. 01–1442 Filed 1–18–01; 8:45 am]

BILLING CODE 4191–02–P

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Notices

Federal Register
Vol. 66, No. 13
Friday, January 19, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Request for Comments; Improve Management of the Tongass National Forest and Service to Southeast Alaska Residents

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service announces its intention to establish a new information collection. The collected information will help the Forest Service identify and meet the needs of southeast Alaska residents who use, visit, or benefit in other ways from the Tongass National Forest in southeast Alaska. Information will be collected from southeast Alaska residents.

DATES: Comments must be received in writing on or before March 20, 2001.

ADDRESSES: All comments should be addressed to Robert F. Schroeder, Forestry Sciences Lab, Forest Service, USDA, 2770 Sherwood Lane, Suite 2A, Juneau, AK 99801.

Comments also may be submitted via facsimile to (907) 586–7848 or by email to: rschroeder@fs.fed.us.

The public may inspect comments received at the Office of the Forestry Sciences Lab, Forest Service, USDA, 2770 Sherwood Lane, Suite 2A, Juneau, Alaska. Visitors are asked to call (907) 586–8811, extension 240, to facilitate entrance into the building.

FOR FURTHER INFORMATION CONTACT: Robert F. Schroeder, Forestry Sciences Lab, at (907) 586–8811, extension 240.

SUPPLEMENTARY INFORMATION:

Background

The Tongass National Forest encompasses nearly 85 percent of the land in southeast Alaska, and activities conducted on the Forest form the basis for the regional economy. Commercial fishing, timber production, mineral extraction, and the quickly growing tourism industry depend on the renewable and non-renewable natural resources of this National Forest. The Forest Service completed a revision of the Tongass Land Management Plan in 1997 and published a revised Record of Decision in the **Federal Register** on May 11, 1999 (64 FR 25274). The Tongass Land Management Plan and Record of Decision will serve as a blueprint for how the Forest Service will manage the Tongass National Forest over the next 10 to 15 years.

While revising the Tongass Land Management Plan in 1997, the Forest Service identified critical information needs. Some of these information needs were associated with the human component of Tongass National Forest ecosystems, that is the people and social systems that benefit from these ecosystems.

The collected data, by addressing the human component, will provide the Forest Service with a better understanding of how forest management practices influence community well-being and social change within the southeast Alaska geographic area and will help the agency meet the needs of residents of southeast Alaska who are affected by forest management actions on a day-to-day basis.

The agency will gain a better understanding of the demands that southeast Alaska residents make on the Tongass National Forest programs and services, how well information about agency programs and services are communicated to southeast Alaska residents, and how well the agency meets the needs and expectations of the residents of southeast Alaska.

Forest Service personnel from the Pacific Northwest Research Station Forestry Sciences Lab in Juneau, Alaska, will work in cooperation with University of Alaska research staff to design, administer, and evaluate these surveys. Interviewers will conduct surveys by telephone. Persons interviewed will be asked to respond to questions that include their perceptions of how the Tongass National Forest is managed by the agency, their preferences for how this National Forest should be managed, their perceptions of Tongass National Forest ecosystems, their past and planned visits to the Tongass National Forest, their use of the forest's resources, their vision of the forest of the future, their household and community economic dependence on the forest, and their attitudes and values concerning timber management.

University of Alaska and Forestry Sciences Lab scientists will tabulate the results from this information collection. The results will be available to the public and to State and Federal agencies in printed and electronic formats. The results also will be published in the Pacific Northwest Research Station's General Technical Report series and in referenced journals.

This data collection will provide information on how southeast Alaska residents use the Tongass National Forest, the extent of their economic and subsistence reliance on the forest, and their attitudes and values concerning future management of the Tongass National Forest.

Description of Information Collection

The following describes the information collection to be established:

Title: The Tongass Southeast Alaska Resident Survey.

OMB Number: New.

Expiration Date of Approval: New.

Type of Request: This is a new information collection requirement and has not yet received approval from the Office of Management and Budget.

Abstract: The Forest Service, other Federal agencies, and the State of Alaska conducted a survey in 1979 to assess the interaction of the southeast Alaska residents with the Tongass National Forest. This survey also included the perceptions these residents had of the Tongass as a natural resource. The 1979 survey provided the most recent comprehensive information on southeast Alaska residents' subsistence and recreational use of the Tongass, their attitudes and values concerning the Tongass National Forest, their interest in the development of a regional timber economy, and their perceptions of Forest Service land management practices. This important benchmark survey is now 20 years old and may not be an accurate reflection of the views, perceptions, and activities of current southeast Alaska residents.

This new information collection will provide more current data and will identify issues that have become important to the southeast Alaska residents in the intervening years.

Respondents also will be asked questions that relate to issues that were not important at the time of the 1979 survey. These issues include large scale timber harvesting on national forest and private lands; a large increase in tourist and recreational use of the Tongass National Forest; expansion of tourist use into back-country areas; economic restructuring of the area that is moving away from timber, mining, and commercial fishing toward tourism and service industries; and an increasing resident and visitor population competing for limited fish and wildlife resources.

Forest Service personnel and University of Alaska research staff will conduct a random sample survey of southeast Alaska residents, through telephone interviews.

Data gathered in this information collection are not available from other sources.

Estimate of Annual Burden: 30 minutes per respondent.

Type of Respondents: Individual residents of southeast Alaska communities.

Estimated Annual Number of Respondents: 1600 per year.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 800 hours.

Comment Is Invited

The agency invites comments on the following: (a) Whether the proposed collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Use of Comments

All comments received in response to this notice, including names and addresses when provided, will become a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: January 9, 2001.

Barbara C. Weber,

Associate Deputy Chief for Research & Development.

[FR Doc. 01–1583 Filed 1–18–01; 8:45 am]

BILLING CODE 3410–11–U

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Export Administration (BXA).

Title: Short Supply Regulations—Unprocessed Western Red Cedar.

Agency Form Number: None.

OMB Approval Number: 0694–0025.

Type of Request: Extension of a currently approved collection of information.

Burden: 35 hours.

Average Time Per Response: 60 minutes per response.

Number of Respondents: 35 respondents.

Needs and Uses: The information is collected as supporting documentation for license applications to export western red cedar logs to enforce the Export Administration Act's prohibition against the export of such logs from State or Federal lands.

Affected Public: Individuals, businesses or other for-profit institutions.

Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Clearance Officer, Office of the Chief Information Officer, (202) 482–3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, D.C. 20230, or via e-mail at *MClayton@doc.gov*.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20230.

Dated: January 12, 2001.

Madeleine Clayton,

Departmental Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–1563 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 010111011–1011–01]

RIN 0648–AO99

Announcement of Intent To Initiate the Process To Designate the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve as a National Marine Sanctuary; Intent To Prepare a Draft Environmental Impact Statement and Management Plan

AGENCY: Marine Sanctuaries Division (MSD), National Ocean Service (NOS), National Oceanic and Atmospheric Administration, Department of Commerce (DOC).

ACTION: Notice

SUMMARY: On December 4, 2000, President William Clinton signed Executive Order 13178 establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve, pursuant to the National Marine Sanctuaries Amendments Act of 2000. The Reserve extends approximately 1200 nautical miles long and 100 nautical miles wide. Pursuant to this Act and the Executive Order, NOAA, on behalf of the Secretary is initiating the process to designate the Reserve as a national marine sanctuary and will proceed with the subsequent steps of the designation process. In designating the sanctuary, the Executive Order directs NOAA to supplement or compliment the existing Reserve.

NOAA will prepare an environmental impact statement and management plan which will examine the management, boundary and regulatory alternatives associated with sanctuary designation. NOAA will hold scoping meetings to solicit information and comments on the range and significance of issues related to sanctuary designation and management.

FOR FURTHER INFORMATION CONTACT: Helen Golde, (301) 713–3125, ext. 152 or helen.golde@noaa.gov.

SUPPLEMENTARY INFORMATION: The National Marine Sanctuaries Act (NMSA), 16 U.S.C. 1431 *et seq.*, authorizes the Secretary of Commerce (Secretary) to designate discrete areas of the marine environment as national marine sanctuaries to protect their special conservation, recreational, ecological, historical, cultural, archaeological, scientific, educational, or esthetic qualities. The NMSA is administered by the National Oceanic and Atmospheric Administration (NOAA) through the Marine Sanctuaries Division (MSD).

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On May 26, 2000, President Clinton directed the Secretaries of Commerce and the Interior, working cooperatively with the State of Hawaii and consulting with the Western Pacific Fishery Management Council, to develop recommendations for a new, coordinated management regime to increase protection of the coral reef ecosystem of the Northwestern Hawaiian Islands and provide for sustainable use of the area. Upon consideration of their recommendations and comments received during the public visioning process on this intiative, President Clinton issued Executive Order 13178 on December 4, 2000, establishing the Northwestern Hawaiian Islands Coral Reef Ecosystem Reserve (Reserve), pursuant to the National Marine Sanctuaries Amendments Act of 2000 (Act), Public Law 106–513.

As described in Executive Order 13178, the approximately 1,200 mile stretch of coral islands, seamounts, banks, and shoals of the Northwestern Hawaiian Islands are some of the healthiest and most extensive coral reefs in the United States. In their own right, the spectacular coral reefs and lands provide an amazing geological record of volcanic and erosive powers that have shaped this area. This vast area supports a dynamic reef ecosystem that supports more that 7,000 marine species, of which approximately half are unique to the Hawaiian Island chain. This incredibly diverse ecosystem is home to many species of coral, fish, birds, marine mammals, and other flora and fauna including the endangered Hawaiian monk seal, the threatened green sea turtle, and others. In addition, this area has great cultural significance to Native Hawaiian as well as linkages to early Polynesian culture—making it additionally worthy of protection and understanding. This is truly a unique and special place, a coral reef ecosystem like no place on earth, and a source of pride, inspiration, and satisfaction for all Americans, especially the people of Hawaii.

The purpose of the Reserve is to ensure the comprehensive, strong, and lasting protection of the coral reef ecosystem and related marine resource and species of the Northwestern Hawaiian Islands. The Reserve extends approximately 1200 nautical miles long and 100 nautical miles wide. The Reserve is adjacent to and seaward of the seaward boundaries of the State of Hawaii and the Midway Atoll National Wildlife Refuge, and overlays the Hawaiian Islands National Wildlife Refuge to the extent that it extends beyond the seaward boundaries of the State of Hawaii.

As required by the Act and Executive Order 13178, NOAA is initiating the process to designate the Reserve as a national marine sanctuary and will proceed with the steps of the designation process pursuant to the applicable provisions of sections 303 and 304 of the NMSA (16 U.S.C. 1433 and 1434). In designating the sanctuary, the Executive Order directs NOAA to supplement or compliment the existing Reserve. As part of the process, NOAA shall, in consultation with the Governor of the State of Hawaii, determine whether State submerged lands and waters should be included as part of the sanctuary. In designating and managing the sanctuary, the Secretary shall consider the advice and recommendations of the Reserve Council established pursuant to paragraph (f) of section 5 of E.O. 13178. The Reserve Council is expected to be established in January, 2001.

NOAA will prepare an environmental impact statement, pursuant to the National Environmental Policy Act, and management plan which will examine the management, boundary and regulatory alternatives associated with sanctuary designation. NOAA will hold scoping meetings, tentatively planned for spring 2001, to solicit information and comments on the range and significance of issues related to sanctuary designation and management. Individuals and representatives of interested organizations and government agencies are invited and encouraged to attend. Opportunities for comment will exist throughout this process and will be announced in the **Federal Register**, the local media, and other appropriate channels.

Authority: 16 U.S.C. Section 1431 *et seq.*, Pub. L. 106–513.

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: January 11, 2001.

John Oliver,

Chief Financial Officer/Chief Administrative Officer.

[FR Doc. 01–1475 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–08–U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 092500B]

Coral, Golden Crab, Shrimp, Spiny Lobster, Red Drum, Coastal Migratory Pelagic Resources, and Snapper-Grouper Fisheries of the South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of an exempted fishing permit.

SUMMARY: NMFS announces the issuance of an exempted fishing permit (EFP) for the North Carolina Aquariums (applicant), headquartered in Raleigh, NC. The EFP authorizes the applicant, with certain conditions, to collect for public display up to 60 red porgy and up to 500 lb (227 kg) of coral/live rock in Federal waters off North Carolina each year for 2 years. The three North Carolina Aquariums are located at Roanoke Island, Pine Knoll Shores, and Kure Beach, North Carolina. This EFP is similar to a previously approved EFP for North Carolina Aquariums that expired earlier this year.

DATES: The newly issued EFP is effective January 12, 2001, through December 31, 2002.

ADDRESSES: Copies of the EFP are available from Peter Eldridge, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

FOR FURTHER INFORMATION CONTACT: Peter Eldridge, 727-570-5305; fax 727-570-5583; e-mail: peter.eldridge@noaa.gov.

SUPPLEMENTARY INFORMATION: The EFP is issued under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*), and regulations at 50 CFR 600.745(b) concerning exempted fishing.

The EFP authorizes the applicant, with certain conditions, to collect for public display up to 60 red porgy and up to 500 lb (227 kg) of coral/live rock in Federal waters off North Carolina each year for 2 years.

The North Carolina Aquariums (NCA), with aquariums located at Roanoke Island, Pine Knoll Shores, and Kure Beach, is a public, non-profit, self-supporting institution established to promote an awareness, understanding, and appreciation of the diverse natural and cultural resources associated with North Carolina's ocean, estuaries, rivers, streams, and other aquatic environments. The several aquariums are major educational and conservation institutions with extensive field study and outreach programs. The specimens will be maintained in the various NCA facilities for public display.

The proposed collection involves activities otherwise prohibited by Federal regulations implementing the Fishery Management Plans for Coral, Coral Reefs, and Live/Hard Bottom Habitats, and the Fishery Management Plan for the Snapper-Grouper Fisheries of the South Atlantic Region. The applicant requests authorization in order to harvest and possess corals, live rock, and red porgy taken from Federal waters off North Carolina.

The EFP has a number of conditions concerning the harvest of prohibited species and corals, the gear that can be employed, and bycatch restrictions. The EFP requires an annual report to NMFS that lists taken specimens.

A notice of receipt of the application for this permit was published in the **Federal Register** on October 2, 2000 (65 FR 58745). In addition to announcing the receipt of the application, public comments were requested. No public comments were received. Also, consistent with the requirements of 50 CFR 600-745(b)(3)(1), NMFS provided copies of the EFP application to the State of North Carolina, the South Atlantic Fishery Management Council, and the U.S. Coast Guard along with information on the EFP's effects on target species. All of the consulted entities supported the issuance of the EFP.

Failure of the permittee to comply with the terms and conditions of the EFP may be grounds for revocation, suspension or modification of this permit, as well as civil or criminal sanctions.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 10, 2001.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1379 Filed 1–18–01; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Acting Leader, Regulatory Information Management, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: An emergency review has been requested in accordance with the Act (44 U.S.C. chapter 3507(j)), since public harm is reasonably likely to result if normal clearance procedures are followed. Approval by the Office of Management and Budget (OMB) has been requested by January 31, 2001. A regular clearance process is also beginning. Interested persons are invited to submit comments on or before March 20, 2001.

ADDRESSES: Written comments regarding the emergency review should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Desk Officer: Department of Education, Office of Management and Budget; 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren_Wittenberg@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) requires that the Director of OMB provide interested Federal agencies and the public an early opportunity to comment on information collection requests. The Office of Management and Budget (OMB) may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Acting Leader, Information Management Group, Office of the Chief Information Officer, publishes this notice containing proposed information collection requests at the beginning of the Departmental review of the information collection. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.*, new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. ED invites public comment. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on respondents, including through the use of information technology.

Dated: January 12, 2001.

Joe Schubart,

Acting Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: New.

Title: Performance Report—Training Personnel for the Education of Individuals with Disabilities Education Act (IDEA)

Abstract: This package contains instructions and the form necessary for grantees and contractors supported under Training Personnel for the Education of Individuals, CFDA No. 84.325. Data are obtained from grantees and are used to assess and monitor the implementation of IDEA and for Congressional reporting.

Additional Information: This program is a high priority initiative and an essential part of the Administration's overall strategy to allow the Department of Education to better facilitate the availability of an adequate amount of qualified personnel to better serve the needs of our children.

Frequency: Annually.

Affected Public: Not-for-profit institutions

Reporting and Recordkeeping Hour Burden:

Responses: 450

Burden Hours: 2,250

Requests for copies of the proposed information collection request should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW., Room 4050, Regional Office Building 3, Washington, DC 20202–4651, or should be electronically mailed to the internet address OCIO_IMG_Issues@ed.gov, or should be faxed to 202–708–9346.

Comments regarding burden and/or the collection activity requirements, contact Sheila Carey at (202) 708–6287 or via her internet address Sheila_Carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 01–1591 Filed 1–18–01; 8:45 am]

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DEPARTMENT OF EDUCATION

Revised Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties

AGENCY: Office for Civil Rights, Department of Education.

ACTION: Notice of availability.

SUMMARY: The Assistant Secretary for Civil Rights, U.S. Department of Education (Department), announces the availability of a document (revised sexual harassment guidance) that replaces the 1997 document entitled "Sexual Harassment Guidance: Harassment of Students by School Employees, Other Students, or Third Parties," issued by the Office for Civil Rights (OCR) on March 13, 1997 (1997 guidance). We revised the guidance in limited respects in light of subsequent Supreme Court cases relating to sexual harassment in schools.

The revised guidance reaffirms the compliance standards that OCR applies in investigations and administrative enforcement of Title IX of the Education Amendments of 1972 (Title IX) regarding sexual harassment. The revised guidance re-grounds these standards in the Title IX regulations, distinguishing them from the standards applicable to private litigation for money damages and clarifying their regulatory basis as distinct from Title VII of the Civil Rights Act of 1964 agency law. In most other respects the revised guidance is identical to the 1997 guidance. Thus, we intend the revised guidance to serve the same purpose as the 1997 guidance. It continues to provide the principles that a school should use to recognize and effectively respond to sexual harassment of students in its program as a condition of receiving Federal financial assistance.

FOR FURTHER INFORMATION CONTACT: Address requests for copies of the revised sexual harassment guidance to Jeanette J. Lim, U.S. Department of Education, 400 Maryland Avenue, SW., room 5212 Switzer Building, Washington, DC 20202–1100. Telephone: (202) 205–5557 or 1–800–421–3481. For all requests submitted by letter, you must include the term "Revised Sexual Harassment Guidance."

If you use a telecommunications device for the deaf (TDD), you may call the TDD number at (202) 260–0471. The document is also available through the Internet at the following site: *http://www.ed.gov/ocr/shguide*

If you prefer to send your request through the Internet, use the following address: ocr@ed.gov

You must include the term "Revised Sexual Harassment Guidance" in the subject line of your electronic message.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) by contacting the OCR Customer Service Team at 1–800–421–3481.

Electronic Access to This Document

You may view this notice, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF, you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this notice is the notice published in the **Federal Register**. Free Internet access to the official edition of the Federal Register and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html.

Dated: January 16, 2001.

Norma V. Cantú,

Assistant Secretary for Civil Rights.

[FR Doc. 01–1606 Filed 1–18–01; 8:45 am]

BILLING CODE 4000–01–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6833–6]

Agency Information Collection Activities: Proposed Collection; Comment Request; Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following proposed Information Collection Request (ICR) to the Office of Management and Budget (OMB): "Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities"; EPA ICR #2013.01. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before March 20, 2001.

ADDRESSES: Office of Enforcement and Compliance, EPA Region 10, 1200 6th Ave. (MS OEC–164), Seattle, WA 98101. Interested persons may obtain a copy of the ICR without charge; to do so, see the following Further Information Contact section.

FOR FURTHER INFORMATION CONTACT: Clark L. Gaulding; Academic Program Manager and Senior Policy Advisor; (206) 553–1849; fax (206) 553–7176. E-mail at <gaulding.clark@epa.gov>

SUPPLEMENTARY INFORMATION:

Affected entities: Entities potentially affected by this action are institutions providing college or university education leading to bachelors and graduate degrees.

Title: "Impact of Formal Environmental Policy Statements on the Teaching, Research and Operations of Colleges and Universities"; EPA ICR #2013.01.

Abstract: Many universities and colleges have adopted formal statements of environmental policy, and more are being adopted all the time. This is probably good, but little is known about the impacts that these statements have on the actual behavior of our academic institutions. Do they make a difference, and, if so, how? Where's the evidence? Is articulated environmental policy a prophesy of future behavior at the schools that adopt them, or is it rhetoric, however well intended?

This survey study is intended to develop some possible answers to these questions. Written surveys and selected follow-up interviews will be conducted on a representative number of the approximately 4,000 campuses across the U.S. Part of the inquiry is statistical in nature; how many schools have a formal policy on the environment, and how many do not; does it make a difference whether the school is public or private, large or small, urban or rural? Does region make a difference? Of the schools with policies, when were they adopted and is there a trend? Finally, can anything be made of the numbers?

Beyond the numbers, the survey, and especially the interviews, will focus on (1) substance and (2) impact. A random cross-section of written policy statements will be analyzed in comparative fashion to understand not only who wrote them, but what topics they literally address (especially,

teaching, research and operations) and what tone they impart (especially, how purely philosophical or action-oriented are they).

The impact of articulated environmental policy on institutional behavior will be weighed in two ways. The institutions themselves will be asked to explain and document the impacts across the full range of university activities. In parallel, EPA data will be used to look at environmental compliance at schools both with and without written policy to see whether there is any inferential relationship. Response to the study will be voluntary, and results will be reported in statistical fashion rather than with reference to any particular school. The analytical information and conclusions resulting from this study will be useful to academic institutions as they consider their role and responsibility toward society with respect to the natural environment, and to EPA in its policy deliberations regarding its relationship with higher education as an important element of society.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden statement: Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

There are two elements to this proposed study: a written survey questionnaire and a follow-up interview for a selected sub-set of those responding to the questionnaire. Using the burden definition above, it is estimated that the total hour burden for an institution to respond to the written survey questionnaire will be between five (5) and fifteen (15) hours depending on the size and organization of the respondent institution. The hour burden for an institution to participate in a follow-up interview is estimated not to exceed two (2) hours. It is not expected that any institution will incur any capital or recurring costs to participate in the study. Therefore, the dollar cost burden of participation will be directly related to the hour burden and the wage or salary rate of the individuals who handle the response at each institution.

Dated: January 8, 2001.

Laurie Davies,

Director, Office of Enforcement and Compliance, Region 10.

[FR Doc. 01–1345 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 14, 2000 (65 FR 20157).

Draft EISs

ERP No. D–AFS–L65367–AK Rating EC2, Chugach National Forest, Proposed Revised Land and Resource Management Plan, Implementation, Glacier, Seward and Cordova Ranger Districts, Kenai Peninsula Borough, AK.

Summary: EPA expressed environmental concerns with the lack of clarity in the direction and protections in the proposed Standards and Guidelines and the lack of detail in the proposed monitoring and evaluation plan. EPA recommended that the FEIS be revised clarifying how the new plan would conform with the new planning rule, clarify and strengthen the standards and guidelines, revise and refine the monitoring plan, and provide information to support conclusions of the predicted effects.

Final EISs

ERP No. F–AFS–L65327–WA Stimson Alaska National Interest Lands Conservation Act (ANILCA) Access Easement Project, Easement Authorization Grant for Construction, Reconstruction and Use of Seven Road Segments for Hauling Logs and Resource Management, Colville National Forest, Sullivan Ranger District, Pend Oreille County, WA.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–AFS–L65353–ID Lakeface-Lamb Fuel Reduction Project, To Reduce the Risk of Lethal Fires within a Wildland/Urban Interface, Implementation, Idaho Panhandle National Forests, Priest Lake Ranger District, Bonner County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–AFS–L65365–ID Swan Flat Timber Sale, Proposal to Cut and Haul Sawtimber, Caribou National Forest, Land Resource Management Plan (LRMP), Montpelier Ranger District, Bear Lake County, ID.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. F–BLM–K67040–CA Imperial Project, Open-Pit Precious Metal Mining Operation Utilizing Heap Leach Processes, Updated Information concerning "Endangered, Rare or Threatened" Biological Resources, Plan of Operations and Reclamation Plan Approvals, Right-of-Way Grants, Conditional Use/U.S. COE Permits, El Centro Resource Area, Desert District.

Summary: EPA commended BLM on its consideration of the unique characteristics of the project area within the California Desert Conservation Area, and the proposed project's potential irreparable degradation of sacred and historic values of the Indian Pass-Running Man Area of Traditional Cultural Concern, in identifying its preference for the No Action Alternative.

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ERP No. F–COE–H36110–NB Western Sarpy/Clear Creek Flood Reduction Study Including Environmental Restoration Component, Lower Platte River and Tributaries, Saunders and Sarpy Counties, NB.

Summary: EPA expressed its continuing objections to this levee project, as proposed, citing two significant environmental issues: (1) Project need and alternatives; and (2) economic analysis.

ERP No. F–SFW–K99029–CA San Joaquin County Multi-Species Habitat Conservation and Open Space Plan, Issuance of Incidental Take Permit, San Joaquin County, CA.

Summary: EPA expressed continued concern with the proposed SJMSCP's compliance with EPA's CWA Section 404(b)(1) guidelines. The Record of Decision (ROD) should state that CWA Section 404 coverage is not provided by the SJMSCP, describe Section 404(b)(1) requirements, and describe the measures that will be taken to ensure full compensation for temporal, spacial, and functional losses of open-space and multi-species habitat. EPA requested early notification and participation in the project's Regional General 404 Permit process.

ERP No. FS–FHW–A42026–NB US Highway 75 Roadway Improvement, Murray, Nebraska (Highway N–1) to Bellevue, Nebraska (Fairview Road), Updated Information concerning Project Changes and Changes to the Existing Environmental Setting, Funding, Cass and Sarpy Counties, NB.

Summary: EPA expressed no objections to the project as proposed.

Dated: January 16, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–1688 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6614–7]

Environmental Impact Statements; Notice of Availability

Responsible Agency:
Office of Federal Activities, General Information (202) 564–7167 or *www.epa.gov/oeca/ofa*
Weekly receipt of Environmental Impact Statements
Filed January 8, 2001 Through January 12, 2001
Pursuant to 40 CFR 1506.9.

EIS No. 010008, Final EIS, AFS, ID, East Beaver and Miner's Creek Timber Sales and Prescribed Burning Project, Implementation, Caribou-Targhee National Forest, Dubois Ranger District, Clark County, ID, Due: February 20, 2001, Contact: John Councilman (208) 558–7301.

EIS No. 010009, Final EIS, AFS, WY, Squirrel Meadows—Grand Targhee Land Exchange Proposal, Implementation, Targhee National Forest, Teton County, WY, Due: February 20, 2001, Contact: Patty Bates (208) 354–2312.

EIS No. 010010, Final EIS, FHW, LA, North-South Expressway Const. I–220 in Shreveport, LA to the Arkansas State Line, Funding and COE Section 404 Permit Issuance, Caddo Parish, LA, Due: February 20, 2001, Contact: William C. Farr (225) 757–7615.

EIS No. 010011, Final EIS, FHW, NY, Miller Highway Project (P.I.N. 103.27), Relocation of Miller Highway between West 59th Street to West 72nd Streets, on the Upper West Side of Manhattan, Funding and COE Section 404 Permit, New York County, NY, Due: February 20, 2001, Contact: Harold Brown (518) 431–4127.

EIS No. 010012, Final EIS, FHW, NV, AZ, US 93 Hoover Dam Bypass Project, Construction of a New Bridge and Highway, Funding, Right-of-Way Easement, U.S. Coast Guard, NPDES and COE Section 404 Permits, Federal Lands—Lake Mead National Recreation Area and Hoover Dam Reservation, Clark County, NV and Mohave County, AZ, Due: February 20, 2001, Contact: Dave Zanetell (303) 716–2167.

EIS No. 010013, Draft EIS, AFS, AK, Threemile Timber Sale, Implementation, Petersburg Ranger District, Tongass National Forest, AK, Due: March 12, 2001, Contact: Everett Kissinger (907) 772–5860.

EIS No. 010014, Draft EIS, AFS, AK, Gravina Island Timber Sale, Implementation, Timber Harvest and Related Activities, Ketchikan-Misty Fiords Ranger District, Tongass National Forest, AK, Due: March 5, 2001, Contact: Susan Marthaller (907) 225–2148.

EIS No. 010015, Draft EIS, BLM, CO, NM, Programmatic EIS—Southern Ute Indian Reservation Oil and Gas Development, Implementation, San Juan Basin, LaPlata, Archuleta, Montezuma Counties, CO and Rio Arriba and San Juan Counties, NM, Due: March 20, 2001, Contact: Don Englishman (970) 385–1346.

EIS No. 010016, Final EIS, AFS, OR, Triangle Land Exchange Project, Between Clearwater Land Exchange Oregon (Clearwater) an Oregon Partnership, Implementation, Malheur, Umatilla and Wallowa-Whitman National Forests, Baker, Grant, Harney and Wallowa Counties, OR, Due: February 20, 2001, Contact: John Day (541) 575–3000.

EIS No. 010017, Final EIS, NPS, CA, NV, Legislative EIS—Timbisha Shoshone Tribal Homeland, To Establish a Permanent Tribal Land Base and Related Cooperative Activities, The Transfer of Federal Land and Acquisition of Private Land, Death Valley National Park, Saline Valley, CA and Lida Ranch near Lida, NV, Due: February 20, 2001, Contact: Joan DeGraff (760) 255–8830.

EIS No. 010018, Draft EIS, FHW, OK, I–40 Crosstown Expressway Transportation Improvements, From I–235/I–35 Interchange West to Meridan Avenue, Funding, Oklahoma City, OK, Due: March 15, 2001, Contact: Lubin Quinones (405) 605–6011.

Dated: January 16, 2001.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 01–1689 Filed 1–18–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[OPP–42077A; FRL–6747–2]

Delaware State Plan for Certification of Applicators of Restricted Use Pesticides; Notice of Approval

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of approval.

SUMMARY: In the **Federal Register** of May 26, 2000 (65 FR 34178) (FRL–6488–6), EPA issued a notice of intent to approve an amended Delaware Plan for the certification of applicators of restricted use pesticides. In this notice EPA solicited comments from the public on the proposed action to approve the amended Delaware Plan. The amended Certification Plan Delaware submitted to EPA contained several statutory, regulatory, and programmatic changes to its current Certification Plan. The proposed amendments establish new requirements for the certification and recertification of pesticide applicators, requires training for registration of non-certified employees, adopts EPA's requirements for direct supervision, adds new commercial subcategories, and establishes the payment of fees for commercial applicators, issuance of business licenses, and dealer permits.

No comments were received and EPA hereby approves the amended Delaware Plan.

ADDRESSES: The amended Delaware Certification Plan can be reviewed at the locations listed under Unit I.B. of the **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Magda Rodriguez-Hunt, Pesticides/Asbestos Programs and Enforcement Branch (3WC32), Environmental Protection Agency, Region III, 1650 Arch St., Philadelphia, PA 19103; telephone number: 215–814–2128; fax number: 215–814–3113; e-mail address: rodriguez-hunt.magda.@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those involved in agriculture and anyone involved with the distribution and application of pesticides for agricultural purposes. Others involved with pesticides in a non-agricultural setting may also be affected. In addition, it may be of interest to others, such as, those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of the Amended State Plan, Other Related Documents, and Additional Information?

To obtain copies of the amended Delaware Certification Plan, other related documents, or additional information contact:

1. Magda Rodriguez-Hunt at the address listed under **FOR FURTHER INFORMATION CONTACT.**

2. Larry Towle, Delaware Department of Agriculture, Pesticides Compliance, 2320 Dupont Highway, Dover, DE 19901; telephone number: 302–739–4811; e-mail address: larry@smtp.dda.state.de.us.

3. John MacDonald, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.; telephone number: 703–305–7370; e-mail address: macdonald.john@epa.gov.

II. What Action is the Agency Taking?

EPA is approving the amended Delaware Certification Plan. This approval is based upon the EPA review of the Delaware Plan and finding it in compliance with FIFRA and 40 CFR part 171. Further, there were no public comments submitted to the earlier **Federal Register** Notice soliciting comments. The amended Delaware Certification Plan is therefore approved.

List of Subjects

Environmental protection.

Dated: January 2, 2001.

Bradley Campbell,

Regional Administrator, Region III.

[FR Doc. 01–1350 Filed 1–18–01 8:45 am]

BILLING CODE 6560–50–S

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System

TIME AND DATE: 11 a.m., Wednesday, January 24, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 17, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–1780 Filed 1–17–01; 11:13 am]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1168]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00–048N]

Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Availability

AGENCY: Food and Drug Administration, HHS, and Food Safety and Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) are announcing the availability of two documents: A draft risk assessment on the relationship between foodborne *Listeria monocytogenes* and human health that considers 20 ready-to-eat food categories, and a risk management action plan based on the *L. monocytogenes* risk assessment. We are making these documents available, and we are seeking public comment of a technical nature on the draft risk assessment. The risk management action plan identifies immediate actions as well as short-term and long-term activities targeted to reduce *L. monocytogenes* associated illnesses. This plan is intended to respond to the President's directive to reduce *L. monocytogenes* associated illnesses by 50 percent by the year 2005. HHS and USDA invite comments on the risk management strategies reflected in the action plan. A public meeting to discuss the draft risk assessment and the risk management plan will be announced in a future issue of the **Federal Register**.

DATES: Comments on the draft risk assessment and the HHS/USDA risk management action plan must be submitted by March 20, 2001.

ADDRESSES: Printed copies of the draft risk assessment and the risk management action plan may be requested by faxing your name and mailing address with the names of the documents you are requesting by faxing your name and mailing address with the names of the documents you are requesting to the CFSAN Outreach and Information Center at 1–877–366–3322. The documents may be reviewed at the

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FDA Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, and at the FSIS Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Submit written comments to the Dockets Management Branch (HFA–305), Docket No. 99N–1168, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy.

or

Submit one original and two copies of written comments to FSIS Docket Clerk, Docket No. 00–048N, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday. For electronic access to these documents see section III of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For information concerning the draft risk assessment document: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, or e-mail: sdennis@cfsan.fda.gov.

For information concerning the risk management action plan: Kathy Gombas, Center for Food Safety and Applied Nutrition (HFS–615), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202–205–4231; FAX 202–260–0136, e-mail: Kathy.Gombas@cfsan.fda.gov or Charles Edwards, Food Safety and Inspection Service, U.S. Department of Agriculture, rm. 405, Cotton Annex, 300 12th St. SW., Washington, DC 20250–3700; 202–205–0675; FAX 202–205–0080.

SUPPLEMENTARY INFORMATION:

I. Draft Risk Assessment

A. Background

The draft risk assessment was written by FDA's Center for Food Safety and Applied Nutrition (CFSAN) and USDA/FSIS, in consultation with the Centers for Disease Control and Prevention (CDC). These agencies began this comprehensive quantitative microbial risk assessment (QMRA) in 1999, and have held two public meetings to present the framework of the assessment, the assumptions, and the modeling procedures.

In the **Federal Register** of May 7, 1999 (64 FR 24661), FDA, in collaboration with USDA/FSIS, announced plans to conduct a risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes*. In the **Federal Register**s of May 7, 1999 (64 FR 24663), and August 13, 1999 (64 FR 44225), the agencies announced public meetings to discuss issues related to the risk models under development. You may refer to these notices for further background information.

B. The Listeria monocytogenes QMRA

The goal of this QMRA is to provide FDA and USDA/FSIS with information that will assist the agencies with the review of current programs and the development of new programs relating to the regulation of *L. monocytogenes* contamination in foods to ensure that such programs protect the public health. QMRA is a structured and systematic process of collecting and evaluating data and information to establish the risks to human health from consumption of pathogenic microorganisms. The draft risk assessment evaluates the available data on food consumption, contamination of various foods within 20 ready-to-eat food product categories by *L. monocytogenes*, growth of the pathogen in such foods, and the infectious dose. The draft risk assessment follows the framework recommended by both the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

(1) *Hazard identification.* The collection and critical review of data and information on *L. monocytogenes*.

(2) *Exposure assessment.* The determination of total exposure to *L. monocytogenes* from consumption of various foods using prevalence and food consumption data.

(3) *Hazard characterization/Dose-response.* The assessment of the potential for *L. monocytogenes* to cause illness in human populations using epidemiological investigations and data from animal studies.

(4) *Risk characterization.* The integration of the exposure and dose-response data into a complex model to estimate both the risk to the public health and the uncertainty associated with this estimate.

The risk assessment process also includes the identification of data gaps and the development of, and the reliance on, reasonable assumptions when data are unavailable.

As part of a peer evaluation of the draft risk assessment, FDA and USDA/FSIS are seeking comments that can be used to improve:

(1) The assumptions made,

(2) the modeling technique,

(3) the data used, and

(4) the transparency of the draft risk assessment document.

It is our intent to review and evaluate all public comments and make modifications to the assessment, as appropriate. As noted previously, the draft risk assessment is available electronically on websites listed in section III of the Supplementary Information section of this document and may be reviewed at the FDA's Dockets Management Branch and FSIS's Docket Clerk's Office (addresses above).

II. HHS/USDA Risk Management Action Plan

A. Background

On May 5, 2000, the President directed the Secretary of HHS and the Secretary of Agriculture to identify aggressive steps to reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President called for action to reduce the number of *L. monocytogenes* illnesses by 50 percent by the year 2005—5 years ahead of the previously established Healthy People 2010 target.

The President directed the Secretary of HHS to develop an action plan identifying additional steps necessary to reduce *L. monocytogenes* contamination. He specifically directed that the HHS plan include consideration of control measures for at-risk foods, publication of guidance for processors, retailers, and food service facilities, and consideration of enhanced labeling to provide additional safeguards for consumers. The President also directed the Secretary of Agriculture to report back on the actions that would reduce significantly the risk of illness and death from *L. monocytogenes* in ready-to-eat foods. The President in particular directed the Secretary of Agriculture to "complete proposed regulations that include any appropriate microbiological testing and other industry measures" to prevent cross-contamination in the processing environment; ensure that the processing of ready-to-eat products meets appropriate standards; and ensure that such products are safe throughout their shelf-life. Taken together, these actions are designed to reduce *L. monocytogenes*-related illnesses by 50 percent by 2005.

B. The L. Monocytogenes Action Plan

The action plan outlines the actions HHS and USDA intend to undertake to reduce *L. monocytogenes* illnesses from ready-to-eat foods. The plan focuses on those food categories identified in the draft risk assessment as either warranting additional measures to reduce *L. monocytogenes* contamination or warranting collection of additional data. Within HHS, FDA and CDC have the primary responsibility for implementation of this action plan. Within USDA, FSIS has the primary responsibility for implementation of this plan, working in concert with other USDA agencies through the Office of Food Safety.

The action plan contains the following eight action areas:

(1) Enhance consumer and health care provider information and education efforts;

(2) Develop and revise guidance for processors, retailers, and food service/institutional establishments that manufacture or prepare ready-to-eat foods;

(3) Develop and deliver training/technical assistance to the regulated industry and food safety regulatory employees;

(4) Review and redirect enforcement and regulatory strategies including microbial product sampling;

(5) Propose new regulations and revisions to existing regulations as needed;

(6) Enhance disease surveillance and outbreak response;

(7) Initiate projects with retail operations such as delicatessens and salad bars to pilot new *L. monocytogenes* control measures including employee practices; and

(8) Coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement, and educational activities.

As noted, the draft risk assessment will be available, along with other information, to assist HHS and USDA as they consider the specific means to implement the elements of the action plan.

III. Electronic Access

The draft risk assessment document and the risk management plan are available electronically as follows:

Draft Risk Assessment Document	www.cfsan.fda.gov www.fsis.usda.gov www.foodsafety.gov www.foodriskclearinghouse.umd.edu
The Risk Management Action Plan	www.cfsan.fda.gov www.foodsafety.gov www.fsis.usda.gov

Dated: January 11, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration, HHS.

Thomas J. Billy,

Administrator, Food Safety Inspection Service, USDA.

[FR Doc. 01–1439 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1075]

Public Health Impact of Vibrio Parahaemolyticus in Raw Molluscan Shellfish; Draft Risk Assessment Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft risk assessment on the relationship between *Vibrio parahaemolyticus* in raw molluscan shellfish, specifically oysters, and human health. FDA began this quantitative microbial risk assessment (QMRA) in 1999, and the agency has held three public meetings on the framework of the assessment, the assumptions, and the modeling procedures. As part of the review process, the agency is making this draft risk assessment available and is seeking comments on the technical aspects of the draft risk assessment. A public meeting to discuss the draft risk assessment will be announced in a future issue of the **Federal Register**.

DATES: Submit written comments on the draft risk assessment by March 20, 2001.

ADDRESSES: The draft risk assessment is available electronically on the FDA Internet at www.foodsafety.gov/dms/fs-toc.html. Hard copies of the draft risk assessment will be available upon request; fax requests to 1–877–366–3322. The draft risk assessment may also be reviewed at the Dockets Management Branch (address below) between 9 a.m. and 4 p.m., Monday through Friday.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of comments are to be submitted, except that individuals may submit one copy. Comments must be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For specific technical information contact: Marianne Miliotis, *Vibrio parahaemolyticus* Risk Assessment

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Team Leader, Center for Food Safety and Applied Nutrition (HFS–327), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4824, FAX 202–205–4939, or e-mail: mmilioti@cfsan.fda.gov.

For general information contact: Sherri B. Dennis, Risk Assessment Coordinator, Center for Food Safety and Applied Nutrition (HFS–032), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–3984, FAX 202–260–9653, or e-mail: sdennis@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 7, 1999 (64 FR 24664), FDA announced plans to conduct a risk assessment to determine the extent of exposure of consumers to *V. parahaemolyticus* in raw molluscan shellfish. On August 13, 1999 (64 FR 44226), FDA announced public meetings to discuss issues related to the risk models under development. You may refer to these notices for background.

II. The V. Parahaemolyticus QMRA

The goal of this QMRA is to provide FDA with information that will assist the agency with the review of current programs relating to the regulation of *V. parahaemolyticus* in raw molluscan shellfish to ensure that such programs protect the public health. QMRA is a structured and systematic process of collecting and evaluating data and information to determine the risks to human health from consumption of pathogenic microorganisms. This draft risk assessment evaluates factors that most influence the prevalence of *V. parahaemolyticus* in shellfish at harvest and after harvest handling practices. The draft risk assessment also evaluates preventive and intervention strategies, as well as the FDA and Interstate Shellfish Sanitation Conference guideline of up to 10,000 viable *V. parahaemolyticus* cells per gram of seafood. The draft risk assessment follows the framework recommended by both the National Academy of Sciences and the Codex Alimentarius Commission. This structured framework involves the following steps:

- *Hazard identification.* The collection and critical review of data and information on *V. parahaemolyticus.*
- *Exposure assessment.* The determination of the likelihood of ingesting pathogenic *V. parahaemolyticus* by eating raw molluscan shellfish harboring the organism and the amount of pathogenic *V. parahaemolyticus* present when consumed.
- *Hazard characterization/dose-response.* The relationship of the levels of *V. parahaemolyticus* ingested with the frequency and magnitude of illness using epidemiological investigations and clinical trials.
- *Risk characterization.* The integration of dose-response and exposure assessments into a complex model to estimate risk of illness and range of uncertainty associated with this estimate. The risk assessment process also involves the identification of data gaps and the development of reasonable assumptions if data are unavailable.

FDA began this QMRA in 1999. Recognizing the public health importance of this pathogen, the scientific knowledge and data currently available were rigorously evaluated to assure that this assessment will serve to facilitate several processes, including the formulation of effective guidance for the industry, regulators, and consumers and the evaluations of risk mitigation strategies.

As part of a peer evaluation of the draft risk assessment, FDA is seeking comments in the following areas: (1) The assumptions, (2) the modeling technique, (3) the data sets used, and (4) transparency of the document. FDA intends to review and evaluate all public comments and make modifications to the assessment, as appropriate.

As noted previously, the draft risk assessment is available electronically on FDA's website and may be reviewed in the agency's Dockets Management Branch.

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–1440 Filed 1–18–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4644–N–03]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Clifford Taffet, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 11, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 01–1398 Filed 1–18–01; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary; Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2002 or Calendar Year 2002

AGENCY: Office of Self-Governance, Interior.

ACTION: Notice of application deadline.

SUMMARY: In this notice, the Office of Self-Governance (OSG) establishes a March 1, 2001, deadline for tribes/consortia to submit completed applications to begin participation in the tribal self-governance program in fiscal year 2002 or calendar year 2002.

DATES: Completed application packages must be received by the Director, Office of Self-Governance by March 1, 2001.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to the Director, Office of Self-Governance, U.S. Department of the Interior, Mail Stop 2548, 1849 C Street, NW., Washington DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, U.S. Department of the Interior, Office of Self-Governance, 1849 C Street NW., Mail Stop 2548, Washington DC 20240; Telephone 202–208–5734.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Public Law 103–413), as amended by the Fiscal Year 1997 Omnibus Appropriations Bill (Public Law 104–208), the Director, Office of Self-Governance may select up to 50 additional participating tribes/consortia per year for the tribal self-governance program, and negotiate and enter into an annual written funding agreement with each participating tribe. The Act mandates that the Secretary submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each tribe that is served by the Bureau of Indian Affairs (BIA) agency that is serving the tribe that is a party to the funding agreement. Initial negotiations with a tribe/consortium located in a BIA region and/or agency which has not previously been involved with self-governance negotiations, will take approximately two months from start to finish. Agreements for an October 1 to September 30 fiscal year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 fiscal year need to be signed and submitted by October 1.

Background

On December 15, 2000, a final rule was published in the **Federal Register** implementing Tribal Self-Governance, as authorized by Title IV of the Indian Self-Determination and Education Assistance Act. This rule has been negotiated among representatives of Self-Governance and non-Self-Governance Tribes and the U.S. Department of the Interior. Selection of additional tribes for participation in tribal self-governance is governed by subparts 1000.10 to 1000.31.

Purpose of Notice

The final rule established at 25 CFR subparts 1000.10 to 1000.31 will be used to govern the application and selection process for tribes/consortia to begin their participation in the tribal self-governance program in fiscal year 2002 and calendar year 2002. Applicants should be guided by the requirements in these subparts in preparing their applications. Copies of these subparts may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the tribal self-governance program in fiscal year 2002 or calendar year 2002 must respond to this notice, except for those which are (1) currently involved with negotiations with the Department; (2) one of the 77 tribal entities with signed agreements; or (3) one of the tribal entities already included in the applicant pool as of the date of this notice.

Dated: December 22, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–396 Filed 1–18–01; 8:45 am]

BILLING CODE 4310–02–P

INTERNATIONAL TRADE COMMISSION

Sunshine Act Meeting; Emergency Notice of Change of Time of Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

DATE AND TIME: January 18, 2001 at 11 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

In accordance with 19 CFR § 201.35(d)(1), notice is hereby given that the Commission has determined to change the time of the meeting being held Thursday, January 18, 2001 from 2 p.m. to 11 a.m. Earlier notification of such change was not possible.

Issued: January 17, 2001.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 01–1815 Filed 1–17–01; 2:18 pm]

BILLING CODE 7020–02–M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and date made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of

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submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None

Volume II

None

Volume III

None

Volume IV

None

Volume V

None

Volume VI

None

Volume VII

None

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and Related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts." This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and Related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Dated: Signed at Washington, DC this 11th Day of January 2001.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 01–1444 Filed 1–18–01; 8:45 am]

BILLING CODE 4510–27–M

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of January 22, 2001.

A closed meeting will be held on Tuesday, January 23, 2001, at 10 a.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(A) and (10), permit consideration of the scheduled matters at the closed meeting.

The subject matters of the closed meeting will be:

institution and settlement of injunctive actions; and

institution and settlement of administrative proceedings of an enforcement nature.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 942–7070.

Dated: January 16, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1701 Filed 1–16–01; 4:20 pm]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Administrator's Line of Succession Designation, No. 1–A, Revision 23

This document replaces and supercedes "Line of Succession Designation No. 1–A, Revision 22."

Line of Succession Designation No. 1–A, Revision 23

Effective immediately, the Administrator's Line of Succession Designation is as follows:

(a) If I am absent from the office the Deputy Administrator will assume all functions and duties of the Administrator. In the event both I and the Deputy Administrator are absent from the office, I designate the officials in listed order below to serve as Acting Administrator with full authority to perform all acts which the Administrator is authorized to perform:

(1) Chief of Staff;

(2) General Counsel;

(3) Associate Deputy Administrator for Management and Administration;

(4) Associate Deputy Administrator for Capital Access;

(5) Associate Deputy Administrator for Government Contracting and Business Development;

(6) Associate Deputy Administrator for Entrepreneurial Development;

(7) Counselor to the Administrator;

(8) Chief Operating Officer;

(9) Deputy General Counsel;

(10) Chief Financial Officer.

(a) An individual serving in an acting capacity in any of the positions listed in paragraph (a)(1) through (10) is not also included in this Line of Succession. Instead, the next non-acting incumbent on the list shall serve as Acting Administrator.

(b) This designation shall remain in full force and effect until revoked or superceded in writing by the Administrator, or by the Deputy Administrator when serving as Acting Administrator.

(c) Serving as Acting Administrator has no effect on the officials listed in paragraph (a)(1) through (10), above, with respect to their full-time position's authorities, duties and responsibilities (except that such official cannot both recommend and approve an action).

Dated: January 5, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1584 Filed 1–18–01; 8:45 am]

BILLING CODE 8010–01–U

SOCIAL SECURITY ADMINISTRATION

Rate for Attorney Fee Assessment Beginning in 2001

AGENCY: Social Security Administration.

ACTION: Notice.

SUMMARY: The Social Security Administration is announcing that the attorney-fee assessment rate under section 206(d) of the Social Security Act, 42 U.S.C. 406(d), for 2001 is 6.3 percent.

FOR FURTHER INFORMATION CONTACT: John Watson, Social Security Administration, Office of the General Counsel, Phone: (410) 965–3137, email: *John.Watson@ssa.gov.*

SUPPLEMENTARY INFORMATION: Section 406 of Public Law No. 106–170, the Ticket to Work and Work Incentives Improvement Act of 1999, established an assessment for the services required to determine and certify payments to attorneys from the benefits due claimants under Title II of the Social Security Act. This provision is codified in section 206 of the Social Security Act (42 U.S.C. 406). The legislation set the assessment for the calendar year 2000 at 6.3 percent of the amount that would be required to be certified for direct payment to the attorney under either section 206(a)(4) or 206(b)(1) before the application of the assessment. For subsequent years, the legislation requires the Commissioner of Social Security to determine the percentage rate necessary to achieve full recovery of the costs of determining and certifying fees to attorneys, but not in excess of 6.3 percent.

The Commissioner of Social Security has determined, based on available data, that the current rate of 6.3 percent will continue. We based our decision to continue the 6.3 percent assessment rate on work sampling and management information data for performing these functions. We are continuing to review our data to determine if a change is appropriate subsequently.

Dated: January 16, 2001.

Yvette S. Jackson,

Deputy Commissioner for Finance, Assessment and Management.

[FR Doc. 01–1608 Filed 1–18–01; 8:45 am]

BILLING CODE 4191–02–U

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Generalized System of Preferences (GSP); Deadline for Submitting Public Comments on Modification of Duty-Free Treatment for Certain Products Imported From India.

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice of request for public comment

SUMMARY: This notice informs the public that the U.S. Government is considering whether to modify duty-free treatment accorded to certain imports from India under the U.S. Generalized System of Preferences (GSP). The review is being undertaken to determine whether India offers "equitable and reasonable market access for U.S. goods and services." If the conclusion is negative, the U.S. government is prepared to take steps that would lead to withdrawal of existing benefits on some products imported from India. Some or all of the products listed in the Annex may be affected. This notice sets forth the deadline for submitting public comments. A decision on this matter is expected on or about April 1, 2001.

FOR FURTHER INFORMATION CONTACT: GSP Subcommittee, Office of the United States Trade Representative, 600 17th Street, NW., Room 518, Washington, DC 20508 (Tel. 202/395–6971). Public versions of all documents relating to this review are available for public inspection by appointment in the USTR public reading room between 9:30–12 a.m. and 1–4 p.m. (Tel. 202/395–6186).

SUPPLEMENTARY INFORMATION: The GSP program is authorized pursuant to Title V of the Trade Act of 1974, as amended ("the Trade Act") (19 U.S.C. 2461 *et seq.*). The GSP program grants duty-free treatment to designated eligible articles that are imported from designated beneficiary developing countries. Once granted, GSP benefits may be withdrawn, suspended or limited by the President with respect to any article or with respect to any country. In determining whether to withdraw, suspend, or limit GSP benefits, the President must consider several factors, one of which is whether the country offers equitable and reasonable market access for U.S. goods and services (19 U.S.C. 2462(c)(4)). India is a beneficiary of the GSP program. In 1999, more than $1 billion in imports from India were granted duty-free treatment under the GSP program; through October 2000, more than $966 million in imports from India received duty-free treatment under GSP, an increase of over 13% over 1999.

On June 12, 1998, the American National Soda Ash Corporation (ANSAC) filed a petition in the 1998 GSP country review contending that the Government of India has failed to provide the United States equitable and reasonable access to India's soda ash market. ANSAC requested that India's benefits under the GSP program be withdrawn, suspended or limited. This petition was accepted for review and was the subject of public comment and hearings. The United States also raised these concerns with the Government of India over the course of two years without resolution. Accordingly, absent a substantial improvement in equitable and reasonable market access for U.S. goods and services in India, the TPSC may recommend that the President withdraw GSP benefits for India on some or all of the products identified in the Annex to this notice.

Opportunities for Public Comment and Inspection of Comments

The GSP Subcommittee of the TPSC invites comments in support of, or in opposition to, the withdrawal, suspension or limitation of duty-free treatment under the GSP program for certain products imported from India. The deadline for submissions is 5 p.m. on Friday, February 16, 2001.

Parties submitting comments must submit an original and 14 copies, in English, to the Chairman of the GSP Subcommittee, Trade Policy Staff Committee, 600 17th Street, NW., Room 518, Washington, DC 20508. Information and comments will be available for public inspection by appointment with the staff of the USTR public reading room, except for information submitted in confidence pursuant to 15 CFR 2007.7. If the document contains business confidential information, an original and 14 copies of a public version of the submission along with 15 copies of the confidential version must be also submitted. The business confidential version of the submission should be clearly marked "business confidential" at the top and bottom of each page of the document. A nonconfidential summary of the business confidential information must be included with the business confidential submission, along with a written explanation of why the business confidential material should be protected. The public version should also be clearly marked at the top and bottom of each and every page (either "public version" or "nonconfidential"). Submissions should comply with 15

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CFR part 2007, including sections 2007.0, and 2007.1.

Jon Rosenbaum,

Assistant U.S. Trade Representative for Trade and Development.

Annex

The products under consideration in this Annex encompass all articles that are classified under the specified numerical subheadings in the Harmonized Tariff Schedule of the United States listed below.

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Corrections

Federal Register
Vol. 66, No. 13
Friday, January 19, 2001

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 412

[FRL–6921–4]

RIN 2040–AD19

National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitations Guidelines and Standards for Concentrated Animal Feeding Operations

Correction

In proposed rule document 01–1 beginning on page 2960 in the issue of Friday, January 12, 2001, make the following correction:

On page 2960, in the second column, in the **DATES** section, "May 2, 2001" should read "May 14, 2001".

[FR Doc. C1–1 Filed 1–18–01; 8:45 am]

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Federal Register

Friday,
January 19, 2001

Part II

Department of Labor

Mine Safety and Health Administration

30 CFR Part 72

Diesel Particulate Matter Exposure of Underground Coal Miners; Final Rule

30 CFR Part 57

Diesel Particulate Matter Exposure of Undergound Metal and Nonmetal Miners; Final Rule

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 72

RIN 1219–AA74

Diesel Particulate Matter Exposure of Underground Coal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This rule establishes new health standards for underground coal mines that use equipment powered by diesel engines.

This rule is designed to reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers. The best available evidence indicates that such high exposures put these miners at excess risk of a variety of adverse health effects, including lung cancer.

The final rule for underground coal mines would require that the dpm emissions from certain pieces of equipment be restricted to prescribed levels. Underground coal mine operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA will publish a rule to reduce dpm exposures in underground coal mines.

DATES: The provisions of the final rule are effective March 20, 2001. However, § 72.500(b) will not apply until July 19, 2002; §72.501(b) will not apply until July 21, 2003; and, §72.501(c) will not apply until January 19, 2005.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Mr. Meyer can be reached at dmeyer@msha.gov (Internet E-mail), 703–235–1910 (voice), or 703–235–5551 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at http://www.msha.gov/REGSINFO.HTM.

SUPPLEMENTARY INFORMATION:

I. Key Features of MSHA's Final Rule Limiting the Concentration of Diesel Particulate Matter (DPM) in Underground Coal Mines

(1) What are the requirements for permissible equipment?

Permissible equipment must not emit more than 2.5 grams per hour of dpm, as measured in a laboratory test. Any permissible equipment that is added to a mine's inventory underground more than 60 days after the date this rule is published will have to meet this standard upon introduction. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

Within 18 months from the date the rule is issued, the entire permissible fleet must meet this standard.

The rule leaves the choice of controls used to achieve the emissions limit to operators. Operators may use any combination of controls (*e.g.*, cleaner engine, OCC, filter) to meet the emissions standard specified in this section.

As a practical matter, MSHA expects that to comply with this standard, most permissible equipment will be equipped with a paper filter. As explained in Part IV of this preamble, MSHA has verified that there are commercially available paper filters which will allow 99% of the existing 541 units in the permissible fleet to meet this requirement—including permissible units powered by the Deutz MWM 916, the Caterpillar 3304 and the Caterpillar 3306. Commercially available paper filters capable of bringing the emissions of these units into compliance include a model which can be installed directly on the exhaust coming from a water scrubber or on the exhaust coming from a heat exchanger, as well as the integrated DST® system. Other filters which use paper with the same performance characteristics will also be acceptable. Control devices whose dpm removal efficiency has not been demonstrated by laboratory testing on a diesel engine can be evaluated following the procedures in 30 CFR 72.503 of this part added by this rulemaking. Moreover, the rule provides that MSHA may rely upon the test results of other organizations who perform equivalent tests.

MSHA will publish on its web site a list of tested control devices and their performance. Compliance will be determined by reference to this data—there will be no in-mine testing.

The only engine which might not be able to meet these requirements for dpm emissions from permissible equipment with a paper filter is the Isuzu QD–100. MSHA's inventory indicates there are currently only two units of permissible equipment using this engine; however, these two units can comply at a derated power setting.

The engines currently approved for permissible use are generally high in particulate emissions. MSHA is committed to taking actions which will facilitate the approval for permissible use of the lower-emission engines which have become available in recent years. These actions could include waiving test fees, contracting for the performance of such tests, or on an interim basis permitting the use of an engine approved for nonpermissible use in a permissible package. MSHA will solicit input from the mining community, through a **Federal Register** notice as it considers how to proceed in this regard.

(2) What are the requirements for heavy-duty non-permissible equipment?

Non-permissible heavy duty equipment will ultimately not be permitted under the final rule to emit more than 2.5 grams per hour of dpm. For reasons of feasibility, this requirement will be implemented in phases.

Any heavy duty equipment added to a mine's inventory more than 60 days after the date of publication of this rule will have to comply with an interim emissions limit for that machine of 5.0 gr/hr. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

All heavy duty equipment in the fleet must meet the interim standard of 5.0 grams per hour of dpm in 30 months.

Finally, another 18 months later (4 years in all), all nonpermissible heavy duty equipment in the fleet will have to meet the final standard of 2.5 grams per hour of dpm.

As with permissible equipment, the rule leaves the choice of controls used to achieve the emissions limit to operators. Any combination of controls (*e.g.*, cleaner engine, OCC, filter) can be used as long as compliance with the standard specified in this section is met.

As a practical matter, MSHA believes that most existing heavy duty equipment will utilize commercially available hot gas filters (*e.g.*, ceramic cell, wound fiber, sintered metal, etc.) to comply with the final limit. All the existing fleet can reach the interim limit with such a filter; some will not need one. MSHA determined that all but a few can reach the final limit with such a filter.

The rule provides that MSHA may rely upon the test results of organizations who perform filtration efficiency tests. In this regard, MSHA will accept the results of filter tests performed by VERT. VERT is an acronym for Verminderung der Emissionen von Realmaschinen in Tunnelbau, a consortium of several European agencies conducting diesel emission research in connection with major planned tunneling projects in Austria, Switzerland and Germany. VERT was established to advance hot gas filter technology due to concerns in Europe about dpm levels. This gave VERT the opportunity to acquire the necessary filter evaluation expertise. A wide range of commercially available hot gas filters have been tested by VERT and the filtration efficiency determined. The Secretary may also accept filter efficiency test results from other testing organizations that can demonstrate a high level of expertise in filter evaluation (see § 72.503(c) of the final rule).

Operators using the DST" system with the catalytic convertor on heavy duty equipment, or the Jeffrey dry exhaust system, will also be deemed in compliance with the final rule, since test results conducted in the same manner as the requirement in the final rule demonstrate that those systems can reduce the emissions from all existing heavy duty engines to below the limit. Filtration devices whose filter efficiency has not been demonstrated by testing on a diesel engine can be evaluated following the procedures in 30 CFR 72.503 of this part added by this rulemaking.

MSHA will publish on its web site a list of tested control devices and their performance. Compliance will be determined by reference to this data—there will be no in-mine testing.

The standard may also be met through the use of newer, cleaner engines in some heavy duty equipment with low horsepower engines. There are already many engines approved for non-permissible use in underground coal mines that will enable heavy duty equipment to limit emissions, thus allowing the use of lower efficiency filters. MSHA is also considering approaches that would expedite the approval of additional engines based on evidence that such engines meet EPA standards which ensure the engines are at least as clean as required under MSHA approval standards.

(3) What are the requirements for generators and compressors?

The final rule provides that generators and compressors meet the same dpm emissions standards as heavy duty equipment. Thus, generators and compressors will ultimately not be permitted to emit more than 2.5 grams per hour of dpm. Generators and compressors introduced into the fleet of an underground coal mine more than 60 days after the final rule is published will have to meet an interim emissions limit of 5.0 g/hr. Generators and compressors in the existing fleet will have 30 months to meet the interim standard of 5.0 grams per hour of dpm. After an additional 18 months (4 years in all), all generators and compressors underground will have to meet the final standard of 2.5 grams per hour of dpm.

Although the proposed rule would not have covered generators and compressors, MSHA explicitly asked the mining community if there were types of light duty equipment that should, because of operating characteristics, be treated like heavy duty equipment. Generators and compressors generate more dpm emissions than other light-duty equipment based on their known duty cycle and type of work for which they are designed; indeed, they use engines whose horsepower often exceeds that in permissible equipment. Accordingly, MSHA has determined they should be covered by this rulemaking.

MSHA's inventory indicates that the 34 generators and 29 compressors constitute less than 3% of the underground light duty diesel fleet. The existing compressors are using engines which should meet the standard's interim and final requirements with a commercially available hot gas filter.

Generators and compressors will be able to utilize the same technologies as heavy duty machines to comply with this standard. This will include hot gas filters or paper filters, as appropriate. Smaller generators and compressors may utilize the clean engine technologies.

(4) What are the requirements for other nonpermissible equipment?

The final rule provides that any piece of nonpermissible light-duty equipment introduced into an underground coal mine more than 60 days after the date of publication of the rule must not emit more than 5.0 grams per hour of dpm. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

The final rule does not impose any new requirements on the existing nonpermissible light-duty fleet (except for generators and compressors as noted above).

While new light duty equipment would not have been covered by the proposed rule, MSHA explicitly asked the mining community if it would be feasible to cover such new light duty equipment, even if it were not feasible to set limits for all light duty equipment. MSHA has determined that it is feasible to require that newly introduced light duty equipment meet the same 5 gr/hr standard as new heavy duty equipment.

To facilitate compliance with this standard, light duty equipment which uses an engine meeting certain EPA standards listed in the MSHA rule will be deemed to automatically meet the MSHA dpm standard for newly introduced light-duty equipment. For example, any "heavy duty highway engine" produced after 1994 will be deemed to meet this dpm standard. The agency has determined that there are already MSHA approved engines available in a full range of horsepower sizes that can meet the EPA standards listed in this final rule.

In practice, what this rule does is simply ensure that very old engines with few, if any, emission controls are not added to a mine's current light duty fleet, thus accelerating the turnover to a newer generation of technology.

(5) Is there a summary of the applicable requirements and effective dates?

All of the emissions standards established by MSHA's final rule are summarized in Table I–1.

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Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
entire fleet	no requirements	

BILLING CODE 4510-43-C

(6) What other requirements are contained in the final rule for underground coal mines?

Miners have to be trained annually in the risks of dpm exposure and in control methods being used at the mine. Also, certain information about diesel engines and aftertreatment devices has to be added to the mine ventilation plan. The paperwork requirements added by this rule are small—on average, less than 7 hours in the first year and 4 hours per year thereafter for a mine operator that uses diesel powered equipment. Furthermore, manufacturers of diesel powered equipment will incur burden hours only during the first year that the rule is in effect in order to amend existing MSHA approvals. During the first year that the rule is in effect the average manufacturer will incur 70 paperwork burden hours.

(7) Will the final rule eliminate any health risks to miners resulting from the use of diesel powered equipment underground?

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented.

MSHA considered establishing stricter standards for certain types of equipment, and covering more light duty equipment, but concluded that such actions would either be technologically or economically infeasible for the coal mining industry as a whole at this time. As MSHA takes actions to facilitate the introduction of newer and cleaner engines underground, and as control technologies continue to develop, additional reductions in dpm levels may become feasible for the industry as a whole. MSHA will continue to monitor developments in this area.

(8) What are the costs and benefits of the final rule?

Costs

Table I–2 summarizes the compliance costs to mine operators that use diesel powered equipment for each section of the rule; total compliance costs are about $7 million a year. Table I–3 summarizes the compliance costs to mine operators that use diesel powered equipment by mine size (*i.e.*, mines employing fewer than 20 workers, mines employing between 20 and 500 workers, and mines employing more than 500 workers). In addition, there is a total annualized cost to diesel equipment manufacturers of $30,030.

MSHA's full Regulatory Economic Analysis, (REA) from which Tables I–2 and I–3 are derived, provides considerable detail on the assumptions MSHA used in developing these cost estimates, and on the costs associated with the controls required for particular engines in the current fleet. For example, MSHA is estimating that for a Caterpillar 3304 PCNA in a heavy duty piece of equipment, an operator will have to spend about $4,500 a year to achieve compliance with the limits for that equipment (hot gas filter, cost annualized, plus annual costs of regeneration). Copies of MSHA's full (REA) analysis are in the record and are available to the mining community upon request.

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Table I-2:
Total Yearly Compliance Costs for Mine Operators

Requirement	Total Yearly Industry Cost
Section 72.500 (Permissible Equipment)	$ 4,468,965
Section 72.501 (Heavy Duty Equipment)	$ 2,278,970
Section 72.502 (Light Duty Equipment)	$ 121,391
Section 72.503 (Filter Maintenance Training)	$ 2,971
Section 72.510 (Miner Health Training)	$ 196,209
Section 75.520 (Diesel Equipment Inventory)	$ 2,327
TOTAL	$ 7,070,833

Table I-3:
Total Cost By Mine Size Class

	Number of Employees		
	< 20	20 to 500	> 500
Compliance Costs	$7,411	$6,087,732	$975,690

BILLING CODE 4510-43-C

Benefits

Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 1.8 lung cancer deaths will be avoided per year.[1]

Benefits of the rule will also include reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and in sensory irritation and respiratory symptoms. MSHA does not believe that the available data can support reliable or precise quantitative estimates of these benefits. Nevertheless, the expected reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes appear to be significant, and the expected reductions in sensory irritation and respiratory symptoms appear to be rather large.

(9) What actions has MSHA taken, and what additional actions does it plan to take, to facilitate compliance with this rule?

This rule is a continuation of efforts by MSHA to help the mining community deal with the use of diesel engines in mining. The diesel equipment rule, now in effect, has itself contributed to the reduction of diesel exhaust emissions through the use of low sulfur diesel fuel, the requirement that all engines underground be approved, and improved maintenance. In one case, testimony was presented by a mine operator that timely engine maintenance, triggered by the weekly undiluted exhaust emissions test required by the new regulation, has greatly reduced carbon monoxide emissions from diesel equipment. These properly tuned engines will generate less particulate. MSHA has devoted workshops specifically to dpm control, issued a Toolbox of control methods to assist the mining community in this regard, and developed a computerized Estimator to help individual mines evaluate the impact of alternative approaches of controlling dpm emissions. The agency has verified the efficiency of the current generation of paper filters, and has sponsored work on the measurement of dpm in ambient mine atmospheres.

This final rule includes certain provisions to facilitate compliance—*e.g.*, authorizing MSHA to rely on the testing requirements of organizations like VERT, and permitting compliance with certain EPA requirements to be deemed as compliance with the requirements in this rule for newly introduced light duty equipment. The agency is, as described above, planning to take action in consultation with the mining community to facilitate the approval, and in particular the approval for permissible use, of a newer, cleaner generation of diesel engines. The agency will be preparing a compliance guide for this rule, and posting a variety of useful information on its web site. If necessary, additional workshops may be scheduled. In addition, MSHA is ready to provide special technical assistance to those who are planning to bring new engines or equipment underground in the next few months.

(10) Are surface mines addressed in this rule?

Surface areas of underground mines, and surface mines, are not covered by this rule. In certain situations the concentrations of dpm at surface mines may be a cause for concern: *e.g.*, production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, shops, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

II. Background Information

This part provides the context for this preamble. The nine topics covered are:

(1) The role of diesel-powered equipment in underground coal mining in the United States;

(2) The composition of diesel exhaust and diesel particulate matter (dpm);

(3) The difficulties in measuring ambient dpm in underground coal mines;

(4) Limiting the public's exposure to diesel and other fine particulates—ambient air quality standards;

(5) The impact on emissions of MSHA approval standards and environmental tailpipe standards;

(6) Methods for controlling dpm emissions in underground coal mines;

(7) Existing standards for underground coal mines that limit miner exposure to diesel emissions;

(8) Information on how certain states are restricting occupational exposure to diesel particulate matter; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule (63 FR 17501 *et seq.*). This version has been updated to reflect the record, to discuss certain issues relevant to underground coal mines in more detail, and reorganized as appropriate.

(1) The Role of Diesel-Powered Equipment in Underground Coal Mining in the United States

Diesel engines, first developed about a century ago, now power a full range of mining equipment. However at this time, less than 20% of underground coal mines (fewer than 150 underground coal mines) utilize this technology. Equipment powered by other sources (electrical power delivered by cable or trolley, and battery power) continues to predominate in this mining sector. Moreover, unlike in other mining sectors, most of the current diesel fleet in underground coal mines consists of light-duty support vehicles, and only limited numbers of the equipment used in digging or hauling coal is powered by diesel engines.

Many in the mining industry believe that diesel-powered equipment has productivity and safety advantages over equipment powered by other sources. Others cite evidence to the contrary, and several key underground coal mining states continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines. The use of diesel engines to power equipment in underground coal mining is increasing and appears likely to continue to do so absent significant improvement in other power technologies.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected

[1] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example, the estimate based on the mean value of all the studies examined is 13 lung cancer deaths avoided per year.

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into a prechamber or directly into the cylinder of the engine. Due to compression of air in the cylinder the temperature rises high enough in the cylinder to ignite the fuel.

The first diesel engines were not suited for many tasks because they were too large and heavy (weighing 450 lbs. per horsepower). It was not until the 1920's that an efficient lightweight diesel power unit was developed. Since diesel engines were built ruggedly and had few operational failures, they were used in the military, railway, farm, construction, trucking, and busing industries. The U.S. mining industry was slow to begin using these engines. Thus, when in 1935 the former U.S. Bureau of Mines published a comprehensive overview on metal mine ventilation (McElroy, 1935), it did not mention ventilation requirements for diesel-powered equipment. By contrast, the European mining community began using these engines in significant numbers, and various reports on the subject were published during the 1930's. According to a 1936 summary of these reports (Rice, 1936), the diesel engine had been introduced into German mines by 1927. By 1936, diesel engines were used extensively in coal mines in Germany, France, Belgium and Great Britain. Diesel engines were also used in potash, iron and other mines in Europe. Their primary use was in locomotives for hauling material.

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in coal mines. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining. Production equipment includes vehicles such as haultrucks and shuttle cars, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, crane trucks, ditch diggers, foam machines, forklifts, graders, locomotives, longwall component carriers, lube units, mine sealant machines, personnel carriers, hydraulic power units, rock dusting machines, roof drills, tractors, utility trucks, water spray units, and welders.

Current Patterns of Diesel Power Use in Underground Coal Mining. The underground coal mining sector is not as reliant upon diesel power as are other mining sectors. While nearly all underground metal and nonmetal mines, and nearly all surface mines, use diesel-powered equipment, less than 20% of underground coal mines use it. Table II–1 provides further information on the current inventory.

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Table II-1. Diesel Equipment in Underground Coal Mines

Mine size	# Mines	# Mines w/Diesel	# Engines
Small[a]	382	7	20
Large	528	138	3,101
All	910	145	3,121

Notes on Table II-1:
(a) A "small" mine is one with less than 20 miners.

BILLING CODE 4510–43–C

The great majority of the diesel engines used in underground coal mines are used to power support equipment, rather than production equipment. This is in sharp contrast to other sectors. For example, in underground metal and nonmetal mines, of the approximate 4,100 pieces of diesel equipment normally in use at the time of MSHA's proposal, nearly half of the units were estimated to be used for loading and hauling. By contrast, of the approximately 3,000 pieces of diesel equipment in use in underground coal mines, MSHA estimates that fewer than 10% are used for coal loading and haulage. Moreover, because of space constraints and other operating conditions in underground coal mines, virtually all coal loading and hauling equipment has engines less than 200 horsepower; by contrast, virtually all such equipment in metal and nonmetal mines has engines greater than 200 horsepower and ranging to more than 750 horsepower or greater. As a result, the average horsepower of diesel engines powering equipment in underground coal mines is much less than the average engine in underground metal and nonmetal mines and all surface mines. This is significant because, other things being equal, lower horsepower engines are going to produce less dpm emissions by mass than higher horsepower engines.

The engines in underground coal mines can be divided into three categories recognized under existing MSHA regulations: "permissible", "heavy-duty nonpermissible", and "light-duty nonpermissible." In this final dpm rule, MSHA is establishing different requirements for each of these categories. Accordingly, some background on this categorization is needed.

Use of Diesel Engines in Permissible Equipment. Under existing regulations, equipment, whether powered by diesel engines or electricity, that is used in areas of the mine where methane gas is likely to be present in dangerous concentrations must be MSHA-approved "permissible" equipment.

Permissible diesel powered equipment for use in coal mines is provided with special equipment to prevent the ignition of methane. This special equipment includes flame arresters and special treatment of flanges and joints. Since diesel engines normally have very hot surface temperatures and hot exhaust gas that can constitute an ignition source, permissible diesels must be provided with a means to maintain the temperatures of surfaces and the exhaust gas below 302°F.

MSHA regulations are very specific in defining those areas of the mine where permissible equipment is required. Generally, permissible equipment is required where the coal mining is actually being performed, because the mining process typically liberates methane. These areas are commonly referred to as "inby" areas. In some cases, however, permissible equipment is required to be used in other areas of the mine. For example, only permissible diesel-powered equipment may be used in return aircourses. The permissible equipment provides an additional level of fire protection because of the strict temperature controls on the equipment surface and exhaust. This increased protection is required because of the potential for the accumulation of dangerous levels of methane in these aircourses.

MSHA's January 2000 inventory indicates that of the 3,121 diesel powered pieces of equipment in underground coal mines, 528 units are permissible pieces. The emissions generated by permissible equipment make a significant contribution to dpm concentrations in the mines where they are functioning. This is because the equipment has large engines, works hard and continuously in locations generally far from ventilation sources, and in close quarters with miners.

Moreover, the engines which have to date been approved for permissible use are among those which emit the highest levels of dpm (in grams/hour): the Caterpillar 3304, Caterpillar 3306 (available in two horsepower sizes), the Deutz D916–6, and the Isuzu QD–100. The Deutz D916–6 is still used in underground coal mines, however, it is no longer in production. MSHA recently approved the Caterpillar 3306PCTA permissible, the first approved turbocharged engine.

Diesel engines in the horsepower ratings required to power permissible equipment are now available in new low emissions technology engines. However, none of them has been approved for use on permissible equipment because no applications for MSHA approval have been received. This situation may reflect a lack of adequate incentives for engine and equipment manufacturers to incur the development costs to meet MSHA permissibility requirements or to pay the fees required for approval.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain permissibility approval, previously approved, non-permissible engines that utilize low emissions technology engines, or waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. Under this program an equipment manufacturer could utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. Provisions of the two programs could be combined.

While the availability of cleaner engines would help reduce the dpm emissions from the permissible fleet, there are aftertreatment filters available for such equipment that are both highly efficient and relatively low cost. As discussed in more detail in section 6 of this part, because the exhaust temperature of these permissible pieces of equipment must be cooled for safety reasons, aftertreatment devices whose filtration media consists of paper can be directly installed on this equipment. Paper filters exposed to uncooled exhaust pose a fire and ignition hazard.

Use of Diesel Engines in Nonpermissible Equipment. In those areas of an underground coal mine where methane concentrations can be limited through the control of ventilation air, permissible equipment is not required. Generally, this is the case in areas away from the face, often referred to as "outby" areas. Most equipment operating in underground coal mines is "nonpermissible" equipment.

Nonpermissible equipment is divided into several categories for purposes of the diesel equipment rules that currently apply in underground coal mines (30 CFR part 75). In pertinent part, those rules provide:

§ 75.1908 Nonpermissible diesel-powered equipment; categories

(a) Heavy-duty diesel-powered equipment includes—
(1) Equipment that cuts or moves rock or coal;
(2) Equipment that performs drilling or bolting functions;
(3) Equipment that moves longwall components;
(4) Self-propelled diesel fuel transportation units and self-propelled lube units; or
(5) Machines used to transport portable diesel fuel transportation units or portable lube units.
(b) Light-duty diesel-powered equipment is any diesel-powered equipment that does not meet the criteria of paragraph (a) * * *
(c) * * *.
(d) Diesel-powered ambulances and fire fighting equipment are a special category of equipment that may be used underground only in accordance with the mine fire fighting and evacuation plan * * *.

MSHA's inventory indicates that of the 3,121 diesel powered pieces of equipment, 497 are heavy duty nonpermissible pieces, 66 are generators and air compressors, and 2,030—that is, about two-thirds of the total underground coal diesel fleet at present—are other light duty nonpermissible pieces.

The rationale for the division of nonpermissible dieselized equipment into these classes requires some background here because in this rulemaking on dpm, MSHA proposed making a significant distinction between the requirements applicable to each class.

The division resulted from MSHA's 1996 regulation establishing safety rules for the use of dieselized equipment in underground coal mines (the general history and purpose of which are summarized in section 9 of this Part). As discussed in the preamble to the final diesel safety rule (61 FR 55459–61), the purpose of the categorization was to take the diversity of nonpermissible equipment into account in establishing regulatory requirements relevant to safety. The final categorization scheme for nonpermissible equipment developed over the course of time in response to public comments to the proposed rule.

Equipment falling within the heavy duty category is typically used for extended periods during a shift on a continuous, rather than an intermittent,

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basis. Heavy duty equipment also moves heavy loads or performs considerable work. Accordingly, to ensure such equipment could operate in a safe manner, the safety rule required that each piece of heavy duty equipment:

* * * has to be equipped with an automatic fire suppression system addressing the additional fire risks resulting from the way this equipment is used. Heavy-duty equipment also produces greater levels of gaseous contaminants, and under the final rule is therefore subject to weekly undiluted exhaust emissions tests * * * and is included in the air quantity calculation of ventilation of diesel-powered equipment * * *. (61 FR 55461)

It is important to note that there are other types of underground coal mining equipment which, although they have operating characteristics much like heavy duty equipment, were not designated as such under the diesel equipment rule. That is because such equipment (*e.g.*, generators and compressors) is considered as portable equipment and special requirements were established in that rule to address the hazards presented by that equipment.

Ambulances and fire-fighting equipment which use diesel engines have operating characteristics like light-duty equipment, but under the diesel equipment rule are considered a special category of equipment that does not have to meet the requirements of that rule. The equipment in this category must only be used in emergencies or fire drills and in compliance with fire fighting and evaluation plan requirements. Consequently, such equipment is not required to have an approved engine or power package or comply with the design and performance requirements of §§ 75.1909 and 75.1910 (61 FR 55461).

Under the diesel equipment rule, heavy-duty equipment may be used to perform light-duty work; but equipment that is classified as light-duty may not be used, even intermittently, to perform the functions listed in paragraphs (a)(1) through (a)(5) of 30 CFR 75.1908 because it is not required to have the automatic fire suppression system that MSHA determined was necessary for such kinds of work. (Id.) As noted in the preamble, two machines of the same model could fall into different equipment categories depending on how they are used. Although of the same design, they do not present the same risk of fire because of the way in which they are used, nor do they produce the same quantities of exhaust contaminants:

"* * * machines that are operated for extended periods of time under heavy load generate more contaminants than machines that are not." (Id.)

It was for this reason—the rate of contaminant generation—that in proposing a rule to limit the concentration of dpm in underground coal mines, MSHA proposed making a distinction between heavy-duty equipment and light-duty equipment. MSHA proposed requiring heavy-duty nonpermissible equipment and permissible equipment to be equipped with filters capable of removing 95% of the dpm emitted by the engines in those pieces of equipment. The proposal did not include any controls for the dpm emitted from light-duty equipment nor for ambulances and fire-fighting equipment. As noted in section 9 of this part, the Agency asked the mining community to comment on the Agency's assumptions and consider some options in this regard. The record on this matter and MSHA's final decision are discussed in Part IV.

Whether categorized as heavy-duty or light-duty, the engine exhaust from nonpermissible equipment is not required to be cooled for safety reasons like exhaust from permissible equipment. Accordingly, this means that paper-type filters cannot be added directly to nonpermissible equipment without first adding a water scrubber or heat exchanger; otherwise, the paper would burn. As a result, control devices that are designed to filter hot exhaust gases (*e.g.*, ceramic filters) provide a cost effective alternative for dpm control with nonpermissible equipment.

Does Diesel Power Have Advantages Over Alternative Sources of Power for Equipment Used in Underground Coal Mines? As pointed out by a commenter, a number of power sources for mining equipment have been tried in the mining industry only to be rejected for various reasons (*e.g.*, gasoline engines, cables, and compressed air). Today, this commenter continued, there are three general ways of powering mining equipment: electric power (delivered by electric trailing cables or by trolley wires), on-board battery power, and diesel. Table II–2 reproduces a list provided by this commenter as to his view of some of the "advantages and challenges" of these power sources; MSHA is reproducing this list as a convenient summary, but does not necessarily agree or disagree with each specific entry.

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Table II-2
One Commenter's Comparison of Power Sources

Power Type	Electric w/trailing cable	Electric w/trolley wire	Battery	Diesel
Necessary infra-structure	electric power centers must be available at all areas where this type of electric trailing cable equipment is used	trolley wires and rails must be available at all areas where electric trolley wire equipment is used	battery charging stations must be available within the operating range of all battery powered equipment	refueling stations must be available within the operating reach of all diesel powered equipment
Availability of power source	the machine must be within reach and tethered to the electric power center	the machine must be connected to the energized electric trolley wire	the machine must be within reach of the charging station once the battery is depleted, usually at least once a shift	the vehicle is driven to a refueling station or a refueling vehicle is driven to the vehicle - refueling is typically performed every 1-3 shifts
Mobility	the range is limited by the reach of the trailing capable and is usually less than 500 feet	limited to areas with energized trolley wires	good as long as the battery is charged, weak when the battery charge is low	excellent and unlimited mobility in all properly ventilated areas of the mine
Operating time between service	uninterrupted until the trailing cable extent has been reached	uninterrupted as long as operating within reach of the trolley wire	may be less than a shift - multiple batteries are normally needed	at least one full shift, often several shifts
Safety concerns	electrocution hazard from damaged energized cables, back injuries from lifting and moving heavy cables	electrocution hazard from contact with energized trolley wires, open sparks	fire hazard during recharging the batteries; battery acid spills, hydrogen release	fuel spills, health concerns, acid exhaust emissions
Conclusions	prone to back injuries and electrocution risk	hazardous and prone to electrocution risk	prone to fire risk	requires emission controls

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Some in the mining industry strongly favor the use of diesel engines to power equipment in underground coal mines. A representative of a company with four underground coal mines testified that it has 200 pieces operated by diesel power, and is continuing to add more. Another commenter stated that diesel is the power source of choice for moving personnel and supplies in large underground mines where coal is moved by conveyor belt.

A number of commenters asserted that diesel-powered equipment has productivity and safety advantages over electrically-powered and battery-powered equipment.

One commenter argued that diesel reduces the risks associated with the use of electrical equipment by eliminating the need for trolley wires, trolley poles and trailing cables that cause injuries, accidents and fatalities—shocks, electrocutions, burns, fires, tripping or being struck by trolley poles, and also reduce the number of material handling injuries. This commenter also argued that unlike electrical power, diesel use does not restrict mining plans or the mining cycle because operations are not hampered by cable length or time consuming power moves, provide greater flexibility in underground travel routes, and make equipment moves from one area of a mine to another more efficient. This commenter further claimed that compared to battery-powered mining equipment (which arguably provides the same flexibility), diesels can haul coal more efficiently over longer distance, provide more power, and eliminate time-consuming battery change-out time.

Another commenter noted the increased potential for fatalities and injuries in underground coal mines when trolley wires are present, and further that trolley wires restrict ventilation in one entry.

Another commenter noted the difficulties of evacuating miners in the event of emergencies over the large distances in some underground mines using sources of power that were more prone to failure than diesel.

Another commenter asserted that all of the 18 employees who had died since 1972 as a result of exposed overhead direct current trolley lines could have lived if diesel power had been in use, and pointed to examples of fires initiated by trolley wires with associated loss of productivity. This commenter also noted that battery powered equipment has been known to cause injuries, and explosions both from its production of hydrogen gas and from sparks igniting methane in the mine atmosphere.

Commenters also note that many asserted safety risks associated with the use of diesel powered equipment in underground coal mines have now been addressed as a result of MSHA's safety rules.

Other commenters, however, pointed out that there are a number of the nation's most productive underground coal mines (including both those using longwall and those using room and pillar mining techniques) which do not use this technology. These commenters challenged industry claims that diesel power is necessary for business to survive. Some also noted that miners are trained to protect themselves better from safety hazards that accompany the use of electrical power, like tripping on cables and electrical hazards, but are not able to protect themselves from health hazards they cannot see. In this regard, the hearing transcripts are replete with reminders by underground coal miners of their concern about what they are breathing in light of the tragic experience with black lung disease.

As indicated by MSHA in the preamble to the proposed rule (63 FR 17503), not many studies done recently address the contentions that diesel power provides safety and/or productivity advantages, and the studies which have been reviewed by MSHA do not clearly support this hypothesis.

Outlook for Use of Diesel Engines To Power Equipment in Underground Coal Mines

The use of diesel engines to power equipment in underground coal mining is increasing. In fact, since this rulemaking was proposed, MSHA's inventory has recorded an increase of about 5% in the number of diesel-powered pieces of equipment at the roughly 145 coal mines using diesel power underground. This trend appears likely to continue, absent significant improvement in other power technologies.

Several key underground coal mining states—Ohio, Pennsylvania and West Virginia—continue to ban or significantly restrict the use of diesel-powered equipment in underground coal mines (as discussed in section 8 of this Part). There are 339 underground coal mines in these states. If the current restrictions in these States were relaxed, in accordance with the expressed interest of industry groups toward this end, many of these underground coal mines are likely to begin using diesel to power some equipment.

Full implementation of MSHA's recent rules for the safe use of diesel-powered equipment in underground coal mines (discussed in section 7 of this part), is also likely to lead to increased diesel use because they resolve certain safety concerns that discouraged the mining community from using such equipment more widely. Another factor suggesting that the use of diesel power will expand is that both miners and mine operators are concerned about the future of their industry.

On the other hand, operators as well as miners have acknowledged that potential health hazards associated with the use of diesel power must be addressed if its use is to become widespread. Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time. Nevertheless, the efforts by US and overseas environmental regulators to restrict dpm and other diesel emissions into the environment, discussed in sections 4, 5 and 6 of this Part, are leading to technological improvements in engines, fuel and filters that will help reduce this risk.

Currently, diesel power faces only a limited number of competitive power sources. It is unclear how quickly new ways to generate energy to run mobile vehicles will be available for use in underground mining activities. New hybrid electric automobiles have been introduced this year by two manufacturers (Honda and Toyota); these vehicles combine traditional internal combustion power sources (in this case gasoline) with electric storage and generating devices that can take over during part of the operating period. By reducing the time the vehicle is directly powered by combustion, such vehicles reduce emissions. Further developments in electric storage devices (batteries), and chemical systems that generate electricity (fuel cells) are being encouraged by government-private sector partnerships. For further information on recent developments, see the Department of Energy alternative fuels web site at http://www.afdc.doe.gov/altfuels.html., and "The Future of Fuel Cells" in the July 1999 issue of *Scientific American*. Until such new technologies mature, and are reviewed for safe use underground, MSHA assumes that the mining community's interest in the use underground of diesel-power as an alternative to direct electric power is likely to continue.

(2) The Composition of Diesel Exhaust and Diesel Particulate Matter (DPM)

The emissions from diesel engines are actually a complex mixture of compounds, containing gaseous and particulate fractions. The specific composition of the diesel exhaust in a mine will vary with the type of engines used and how they are used. Factors such as type of fuel, load cycle, engine maintenance, tuning, and exhaust treatment will affect the composition of both the gaseous and particulate fractions of the exhaust. This complexity is compounded by the multitude of environmental settings in which diesel-powered equipment is operated. Nevertheless, there are a few basic facts about diesel emissions that are of general applicability.

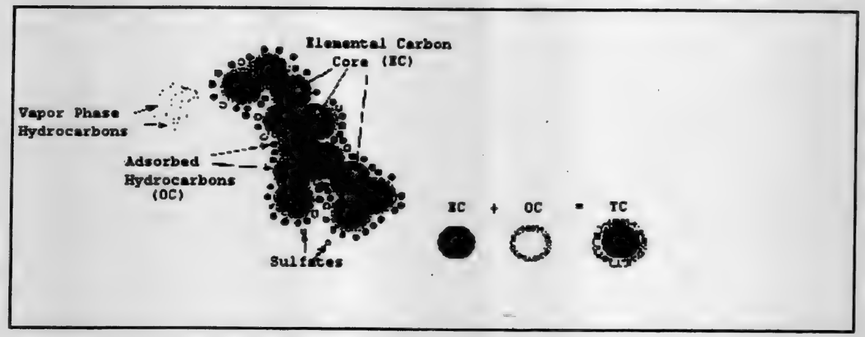
The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (*e.g.*, butadiene), aldehydes (*e.g.*, formaldehyde), monocyclic aromatics (*e.g.*, benzene, toluene), and polycyclic aromatic hydrocarbons (*e.g.*, phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) merit particular mention because in the atmosphere they can precipitate onto particulate matter. Thus, reducing the emissions of NO_X is a way that engine manufacturers can control particulate production indirectly. (See section 5 of this part).

The particulate components of the diesel exhaust gas include the so-called diesel soot and solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. Most of these particulates are in the invisible sub-micron range of 100nm.

The main particulate fraction of diesel exhaust is made up of very small individual particles. These particles have a solid core consisting mainly of elemental carbon. They also have a very surface-rich morphology. This extensive surface absorbs many other toxic substances, that are transported with the particulates, and can penetrate deep into the lungs. More than 1,800 different organic compounds have been identified as absorbed onto the elemental carbon core. A portion of this hydrocarbon material results from incomplete combustion of fuel; however, most is derived from engine lubrication. In addition, the diesel particles contain a fraction of non-organic adsorbed materials. Figure II–1 illustrates the composition of dpm.

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Figure II-1
DPM components



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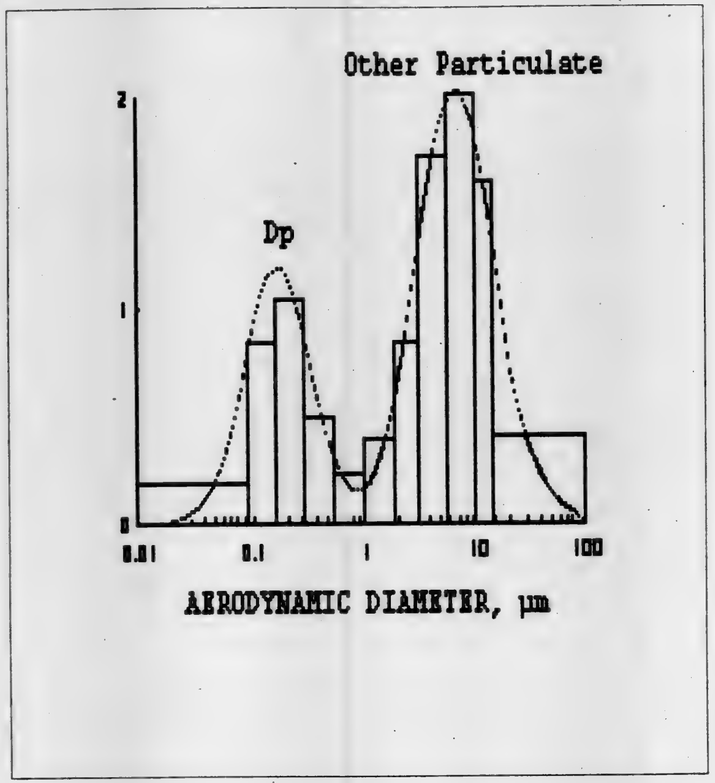
Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size—i.e., less than 1 micrometer (1 micron) in diameter. Dust generated by mining and crushing of material—*e.g.*, silica dust, coal dust, rock dust—is generally not submicrometer in size. Figure II–2 shows a typical size distribution of the particles found in the environment of a mine using equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative dpm concentration, and the horizontal axis the particle diameter.

As can be seen, the distribution is bimodal, with dpm generally less than 1 μm in size, and dust generated by the mining process greater than 1 μm.

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Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.

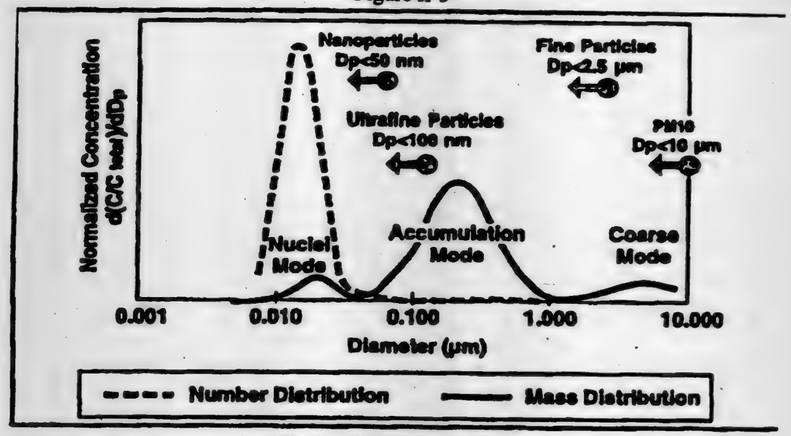


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As shown on Figure II–3 diesel particulates have a bimodal size distribution which includes small nuclei mode particles and larger accumulation mode particles. As further shown, most of diesel particle mass is contained in the accumulation mode but most of the particle number can be found in the nuclei mode.

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Figure II-3



Diesel particulate size distribution.

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The particles in the nuclei mode, also know as nanoparticles, are being investigated for their health hazard relevance. Interest in these particles has been sparked by the finding that newer "low polluting" engines emit higher numbers of small particles than the old engine technology engines. Although the exact composition of diesel nanoparticles is not known, it is thought that they may be composed of condensates (hydrocarbons, water, sulfuric acid). The amount of these condensates and the number of nanoparticles depends very significantly on the particulate sampling conditions, such as dilution ratios, which were applied during the measurement.

Both the maximum particle concentration and the position of the nuclei and accumulation mode peaks, however, depend on which representation is chosen. In mass distributions, the majority of the particulates (*i.e.*, the particulate mass) is found in the accumulation mode. The nuclei mode, depending on the engine technology and particle sampling technique, may be as low as a few percent, sometimes even less than 1%. A different picture is presented when the number distribution representation is used. Generally, the number of particles in the nuclei mode contributes to more than 50% of the total particle count. However, sometimes the nuclei mode particles represent as much as 99% of the total particulate number. The topic of dpm, with particular reference to very tiny particles known as nanoparticles, is discussed further in section 5 of this Part.

(3) The Difficulties of Measuring Ambient DPM in Underground Coal Mines.

As it indicated in its notice of proposed rulemaking to limit the concentrations of dpm in underground coal mines (63 FR 17498, 17500), MSHA decided not to propose a rule to require the measurement of ambient dpm levels in underground coal mines in order to determine compliance. The Agency observed that while there are a number of methods which can measure ambient dpm at high concentrations in underground coal mines with reasonable accuracy. When the purpose is exposure assessment, MSHA does not believe any of these methods provide the accuracy that would be required to measure ambient dpm levels in underground coal mines at lower concentrations.

In particular, MSHA expressed concern about potential difficulties in using the available methods to distinguish between dpm and submicron coal mine dust (63 FR 17506–17507). While the use of an available impactor device can prevent larger particles from entering the sampler (*e.g.*, carbonates), albeit at the expense of eliminating the larger fraction of dpm as well, there are limits on the extent to which it can help MSHA distinguish how much of the fine particulate reaching the sampler is coal dust and how much is dpm. To make the distinction analytically, NIOSH method 5040 would have to be adjusted so that only the elemental carbon is determined. However, as MSHA noted, there are no established relationships between the concentration of elemental carbon and total dpm under various operating conditions. The organic carbon component of dpm can vary with engine type and duty cycle; hence, the amount of whole dpm present for a measured amount of elemental carbon may vary. Accordingly, MSHA concluded that it was "not confident that there is a measurement method for dpm that will provide accurate, consistent and verifiable results at lower concentration levels in underground coal mines" (63 FR 17500).

Since there has been no disagreement with MSHA's initial conclusion about the current availability of an accurate, consistent and verifiable method of measuring dpm concentration levels in underground coal mines, the final rule is not dependent on ambient air measurements. MSHA has proposed using such a method for underground metal and nonmetal mines, and the validity of the measurement was the subject of much comment; accordingly, a more complete discussion of this topic will be found in the preamble of the final rule for underground metal and nonmetal mines.

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(4) Limiting the Public's Exposure to Diesel and Other Fine Particulates—Ambient Air Quality Standards

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which emits various types of particulate matter into the environment during mining operations, and a special impact on the coal mining industry whose product is used extensively in emission-generating power facilities. But those standards hold interest for the mining community in other ways as well, for underlying some of them is a large body of evidence on the harmful effects of airborne particulate matter on human health. Increasingly, that evidence has pointed toward the risks of the smallest particulates—including the particles generated by diesel engines.

This section provides an overview of EPA's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on an EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

EPA is also engaged in other work of interest to the mining community. Together with some state environmental agencies, EPA has actually established limits on the amount of particulate matter that can be emitted by diesel engines. This topic is discussed in the next section of this Part (section 5). Environmental regulations also establish the maximum sulfur content permitted in diesel fuel used in highway vehicles, and such sulfur content can be an important factor in dpm generation. This topic is discussed in section 6 of this Part. In addition, EPA and some state environmental agencies have also been exploring whether diesel particulate matter is a carcinogen or a toxic material at the concentrations in which it appears in the ambient atmosphere; discussion of these studies can be found in Part III of this preamble.

Background. Air quality standards involve a two-step process: Standard setting by EPA, and implementation by each State.

Under the law, EPA is specifically responsible for reviewing the scientific literature concerning air pollutants, and establishing and revising National Ambient Air Quality Standards (NAAQS) to minimize the risks to health and the environment associated with such pollutants. This review is to be conducted every five years. Feasibility of compliance by pollution sources is not supposed to be a factor in establishing NAAQS. Rather, EPA is required to set the level that provides "an adequate margin of safety" in protecting the health of the public.

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.*, mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take measurements of pollution to determine whether all counties within the state are meeting each ambient air quality standard. An area not meeting an NAAQS is known as a "nonattainment area".

Total Suspended Particulates (TSP). Particulate matter originates from all types of stationary, mobile and natural sources, and can also be created from the transformation of a variety of gaseous emissions from such sources. In the context of a global atmosphere, all these particles mix together, and both people and the environment are exposed to a "particulate soup," the chemical and physical properties of which vary greatly with time, region, meteorology, and source category.

The first ambient air quality standards dealing with particulate matter did not distinguish among these particles. Rather, the EPA established a single NAAQS for "total suspended particulates", known as "TSP." Under this approach, the states could come into compliance with the ambient air requirement by controlling any type or size of TSP. As long as the total TSP was under the NAAQS—which was established based on the science available in the 1970s—the state met the requirement.

Particulates Less than 10 Microns in Diameter (PM_{10}). When the EPA completed a new review of the scientific evidence in the mid-eighties, its conclusions led it to revise the particulate NAAQS to focus more narrowly on those particulates less than 10 microns in diameter, or PM_{10}. The standard issued in 1987 contained two components: an annual average PM_{10} limit of 50 $\mu g/m^3$, and a 24-hour PM_{10} limit of 150 $\mu g/m^3$. This new standard required the states to reevaluate their situations and, if they had areas that exceeded the new PM_{10} limit, to refocus their compliance plans on reducing the levels of particulates smaller than 10 microns in size. Sources of PM_{10} include power plants, iron and steel production, chemical and wood products manufacturing, wind-blown and roadway fugitive dust, secondary aerosols and many natural sources.

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—*e.g.*, by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards (Shea, 1995; comments of Newmont Gold Company, March 11, 1997, EPA docket number A–95–54, IV–D–2346).

Particulate Less than 2.5 Microns in Diameter ($PM_{2.5}$). The next EPA scientific review was completed in 1996. A proposed rule was published in November of 1996, and, after public hearings and review by the Office of Management and Budget, a final rule was promulgated on July 18, 1997 (62 FR 38651).

The new rule further modifies the standard for particulate matter. Under the new rule, the existing national ambient air quality standard for PM_{10} remains basically the same—an annual average limit of 50 $\mu g/m^3$ (with some adjustment as to how this is measured for compliance purposes), and a 24-hour ceiling of 150 $\mu g/m^3$. In addition, however, the new rule would establish a NAAQS for "fine particulate matter" that is less than 2.5 microns in size. The $PM_{2.5}$ annual limit was set at 15 $\mu g/m^3$, with a 24-hour ceiling of 65 $\mu g/m^3$.

The basis for the $PM_{2.5}$ NAAQS was a large body of scientific data indicating that particles in this size range are responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable public attention, and hearings by Congress, in which the scientific evidence was further discussed. Moreover, challenges to the EPA's determination that this size category warranted rulemaking were rejected by a three-judge panel of the DC Circuit Court. (*ATA* v. *EPA*, 175 F.3d 1027, D.C. Circuit 1999).

A majority of the DC Circuit Court, however, agreed with challenges to the EPA's determination to keep the existing requirements on PM_{10} as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the Court ordered EPA to develop a new standard for this size category.

Implications for the Mining Community. As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate; in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). As noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate, and did so in its risk assessment (see part III of this preamble). Comments on the appropriateness of this conclusion by MSHA, are reviewed in Part III.

(5) *The impact on emissions of MSHA approval standards and environmental tailpipe standards.*

MSHA requires that the gaseous emissions from all diesel engines used in underground coal mines meet certain minimum standards of cleanliness; only engines which meet those standards are "approved" for use in underground coal mines. The 1996 diesel equipment safety rule required that all engines in the underground mining fleet be approved engines. Thus, these rules set a ceiling for various types of diesel gas emissions. But diesel engines do not have to meet a dpm emissions standard to be "approved" for underground use.

Engine emissions of dpm are however, restricted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground coal mines, they can lead to a significant reduction in the amount of dpm emitted by the underground fleet.

This section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 17507), this review here updates the relevant information.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be "approved" by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer.

MSHA's 1996 diesel equipment rule (discussed in more detail in section 7 of this Part) made significant changes to diesel engine requirements for underground coal mines. The new rule required the entire underground coal fleet to convert to approved engines no later than November 1999. Accordingly, by the time this rule to limiting dpm exposure goes into effect, all diesel engines in underground coal mines are expected to be approved engines.

The new rule also required that during the approval process the agency determine the particulate index (PI) for the engine. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates the air quantity necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air.

Unlike the ventilation rate set for each engine, the PI does not appear on the engine's approval plate (61 FR 55421). Furthermore, the particulate index of an engine is not, under the diesel equipment rule, used to determine whether or not the engine can be used in an underground coal mine.

At the time the diesel equipment rule was issued, MSHA explicitly deferred the question of whether to require engines used in mining environments to meet a specific PI (61 FR 55420–21, 55437). While the matter was discussed during the diesel equipment rulemaking, the approach taken in the final rule was to adopt the multi-level aproach recommended by the Diesel Advisory Committee. This multi-level approach included the requirement to use clean fuel, low emission engines, equipment design, maintenance, and ventilation, all of which are included in the final rule. The requirement for determining the particulate index was included in the diesel equipment rule in order to provide information to the mining community in purchasing equipment—so that mine operators can compare the particulate levels generated by different engines. Mine operators and equipment manufacturers, can use the information along with consideration of the type of machine the engines would power and the area of the mine in which it would be used to make decisions concerning the engine's contribution of diesel particulate to the mine's total respirable dust. Equipment manufacturers can use the particulate index to design and install exhaust after-treatments (61 FR 55421). So that the PI for any engine is known to the mining community, MSHA reports the index in the approval letter, posts the PI and ventilating air requirement for all approved engines on its website, and publishes the index containing its lists of approved engines.

In the proposed dpm rule, MSHA indicated that given that the equipment rule was recently promulgated, it did not yet have enough information to determine the feasibility of a requirement that certain engines meet a specific PI in order to be used underground (63 FR 17564). MSHA received comments on this subject during the hearings and thereafter; the Agency's response to these comments is included in Part IV of this preamble.

Authority for Environmental Engine Emission Standards. The Clean Air Act authorizes the federal Environmental Protection Agency (EPA) to establish nationwide standards for mobile sources of air pollution, including those powered by diesel engines (often referred to in environmental regulations as "compression ignition" or "CI" engines). These standards are designed to reduce the amount of certain harmful atmospheric pollutants emanating from mobile sources: the mass of particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own engine emission standards. New engines destined for use in California must meet these standards. The standards are issued and administered by the California Air Resources Board (CARB). In many cases, the California standards are the same as the national standards; as noted herein, the EPA and CARB have worked on certain agreements with the industry toward that end. In other

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situations, the California standards may be more stringent than federal standards.

Regulatory responsibility for implementation of the Clean Air Act is vested in the Office of Transportation and Air Quality (formerly the Office of Mobile Sources), part of the Office of Air and Radiation of the EPA. Some of the discussion which follows was derived from materials which can be accessed from the agency's home page on the World Wide Web at (http://www.epa.gov/omswww/omshome.htm). Information about the California standards may be found at the CARB home page at (http://www.arb.ca.gov/homepage.htm).

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) Light duty vehicles and light duty trucks (*i.e.*, trucks under 8500 lbs GVWR, which include pick-up trucks and SUVs. EPA has also established a class of "medium duty passenger vehicles" which include passenger vehicles over 8500 lbs. These vehicles, mostly large SUVs, are treated like light-duty trucks for the purposes of emission standards; (2) heavy duty highway engines (*i.e.*, those designed primarily to power trucks) greater than 8500 lbs GVWR) which range from the largest pick-up trucks to over the road trucks); and (3) nonroad vehicles (*i.e.*, those engines designed primarily to power small equipment, construction equipment, locomotives, farm equipment and other non-highway uses).

The terms "heavy duty" and "light duty" are used differently by EPA and MSHA. The category of an engine for purposes of environmental regulations is not the same as the category of mining equipment in which it is used. The engine categories used by EPA have been established with reference to normal transportation uses. But as explained in section 1 of this Part, MSHA has established a classification system for underground coal mining equipment based on how that equipment is used in mining. This system includes "permissible" equipment (required where explosive methane gas may be present in significant quantities) and two categories of "nonpermissible" equipment known as "heavy duty nonpermissible" and "light duty nonpermissible". Accordingly, "heavy duty" engines might be used in "light duty" nonpermissible equipment.

The exact emission standards which a new diesel engine must meet varies with engine category and the date of manufacture. Through a series of regulatory actions, EPA has developed a detailed implementation schedule for each of the three engine categories. The schedule generally forces technology while taking into account certain technological realities.

Detailed information about each of the three engine categories is provided below; a summary table of particulate matter emission limits is included at the end of the discussion.

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks. Although vehicle engines in these categories are not currently approved for use in underground coal mines, it might be sought in the future. Accordingly, some information about the applicable environmental regulations is provided here.[2]

Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate-matter emission limits are found in 40 CFR part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2009, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO_X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in commercial mining pickup trucks.

New standards for this category of engines are gradually being put into place. On October 21, 1997, EPA issued a new rule for certain gaseous emissions from heavy duty highway engines that will take effect for engine model years starting in 2004 (62 FR 54693). The rule establishes a combined requirement for NO_X and Non-methane Hydrocarbon (NMHC). The combined standard is set at 2.5 g/bhp-hr, which includes a cap of 0.5g/bhp-hr for NMHC. EPA promulgated a rulemaking on December 22, 2000 (65 FR 80776) to adopt the next phase of new standards for these engines. EPA is taking an integrated approach to: (a) Reduce the content of sulfur in diesel fuel; and thereafter, (b) require heavy-duty highway engines to meet tighter emission standards, including standards for PM. The purpose of the diesel fuel component of the rulemaking is to make it technologically feasible for engine manufacturers and emissions control device makers to produce engines in which dpm emissions are limited to desired levels in this and other engine categories. The EPA's rule will reduce pm emissions from new heavy-duty engines to 0.01 g/bhp-hr, a reduction from the current 0.1 g/bhp-hr. MSHA assumes it will be some time before there is a significant supply of engines that can meet this standard, and the fuel supply to make that possible.

EPA Emissions Standards for Nonroad Engines. Nonroad engines are those designed primarily to power small portable equipment such as compressors and generators, large construction equipment such as haul trucks, loaders and graders, locomotives and other miscellaneous equipment with non-highway uses. Engines of this type are used most frequently in the underground coal mines to power equipment.

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in over model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

Particulate matter standards for locomotive engines were set subsequently (63 FR 18978, April, 1998). The standards are different for line-haul duty-cycle engine and switch duty-cycle engines. For model years from 2000 to 2004, the standards limit pm emissions to 0.45 g/bhp-hr and 0.54 g/bhp-hr respectively; after model year 2005, the limits drop to 0.20 g/bhp-hr and 0.24 g/bhp-hr respectively.

In October 1998, EPA established additional standards for nonroad engines (63 FR 56968). Among these are gaseous and particulate matter limits adopted for the first time (Tier 1 limits) for nonroad engines under 50 hp. Tier 2 emissions standards for engines between 50 and 175 hp include pm standards for the first time. Further, they establish Tier II particulate matter limits for all other land-based nonroad engines (other than locomotives which previously had Tier II standards). Some of the non-particulate emissions limits set by the 1998 rule are subject to a technology review in 2001 to ensure that the required levels are feasible; EPA has indicated that in the context of that review, it intends to consider further limits for particulate matter. Because of the phase-in of these Tier II pm standards, and the fact that some manufacturers will produce engines meeting the standard before the requirements go into effect, there are or soon will be some Tier II pm engines in some sizes available, but it is likely to be a few years before a full size range of Tier II pm nonroad engines is available.

Table II–3 provides a full list of the EPA required particulate matter limitations on nonroad diesel engines for tier 1 and 2. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

kW range	Tier	Year first applicable	PM limit (g/kW-hr)
kW<8	1	2000	1.00
	2	2005	0.80
8≤kW<19	1	2000	0.80
19≤kW<37	1	1999	0.80
	2	2004	0.60
37≤kW<75	1	1998	
	2	2004	0.40
75≤kW<130	1	1997	
	2	2003	0.30
130≤kW<225	1	1998	0.54
	2	2003	0.20
225≤kW<450	1	1996	0.54
	2	2001	0.20
450≤kW<560	1	1996	0.54
	2	2002	0.20
kW>560	1	2000	0.54
	2	2006	0.20

The Impact of MSHA and EPA Engine Emission Standards on the Underground Coal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition, and frequently rebuilt. Thus, many of the diesel engines in an underground coal mine's fleet today may only meet older environmental emission standards, or no environmental standards at all. Although the environmental tailpipe requirements on dpm are already bringing about a reduction in the overall contribution of dpm to the general atmosphere, the beneficial effects of the EPA regulations on mining atmospheres will be slower absent incentive or regulatory actions that accelerate the turnover of mining fleets to engines that emit less dpm. Moreover, while the requirement that all underground coal mine engines be "MSHA approved" is leading to a less polluting fleet than would otherwise be the case, there are many approved engines that do emit significant levels of pollution, and in particular dpm. As noted in the discussion of MSHA's approval requirements, the Agency is taking internal actions to ensure that these requirements do not inadvertently slow the introduction of cleaner engine technology.

It should be noted that in theory, underground mines can still purchase certain types of new engines that do not have to meet EPA standards. For example, the current rules on nonroad diesel engines state that they do not apply to engines intended to be used in underground coal and metal and nonmetal mines (40 CFR 89.1(b)). Moreover, it is not uncommon for engine manufacturers to take a model submitted for EPA testing and adjust the horsepower or other features for use in a mining application. In recent years, however, engine manufacturers have significantly cut back on such adjustments because the mining community is not a major market. Accordingly, MSHA believes that most of the diesel engines that will be available for underground mines in the future will meet the applicable EPA standard. In addition, many of the recently approved engines by MSHA currently meet the tier II nonroad pm standards.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to "nanoparticles;" i.e., particles found in the exhaust of diesel engines that are less than 50 nanometers (nm) in diameter.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating

[2] The discussion focuses on the particulate matter requirements for light duty trucks, although the current pm requirement for all light duty vehicles is the same. The EPA regulations for these categories apply to the unit, rather than just to the engine itself; for heavy-duty highway engines and nonroad engines, the regulations attach to the engines.

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that nanoparticles emitted from the engine could be removed effectively from the exhaust using aftertreatment devices such as ceramic traps.

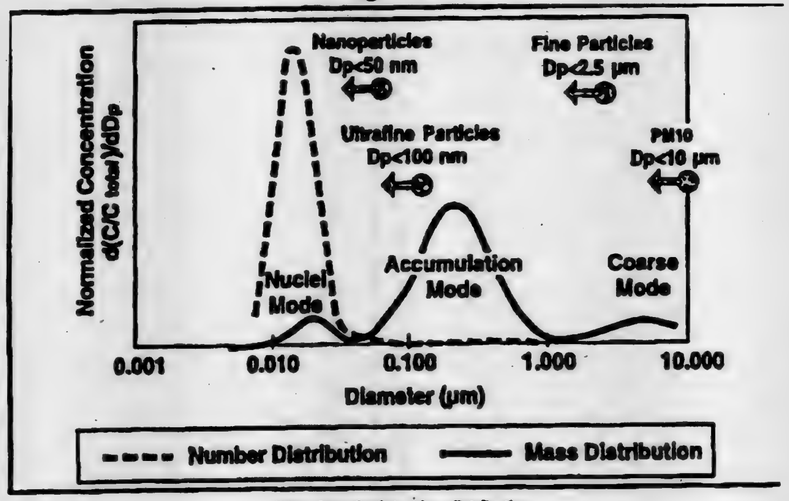
Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. He believed that this reduction in mass was attributed to those particles greater than 0.1μm but less than 1μm and did not address the recent scientific hypothesis that it may be the very small nanopaticles that are responsible for adverse health effects. Based on the recent scientific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that potential the risk of cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e. grams/brake-horsepower). Thus, the technology under development by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm emitted from the engine. There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles emitted from the engine.

Figure II–3, repeated here from section 2 of this Part, illustrates this situation (Majewski, W. Addy, Diesel Progress, June, 1998).

BILLING 4510–43–P

Figure II-3



Diesel particulate size distribution.

BILLING CODE 4510–43–C

The formation of particulates starts with particle nucleation followed by subsequent agglomeration of the nuclei particles into an accumulation mode. Thus, as illustrated in Figure II–3, the majority of the mass of dpm is found in the accumulation mode, where the particles are generally between 0.1 and 1 micron in diameter. However, when considering the number of particles emitted from the engine, more than half and sometimes almost all of the particles (by number) are in the nuclei mode.

A number of studies have demonstrated that the size of the particles emitted from the newer low emission diesel engines, has shifted toward the generation of nuclei mode particles. One study (cited by Majewski) compared a 1991 engine to its 1988 counterpart. The total PM mass in the newer engine was reduced by about 80%; but the new engine generated thousands of times more particles than the older engine (3000 times as much at 75 percent load and about 14,000 times as much at 25 percent load). One hypothesis offered for this phenomenon is that the cleaner engines produce less soot particles on which particulates can condense and accumulate, and hence they remain in nuclei mode. The accumulation particles act as a "sponge" for the condensation and/or adsorption of volatile materials. In the absence of that sponge, gas species which are to become liquid or solid will nucleate to form large numbers of small particles (see diesel.net technology guide). Mayer, while pointing out that nanoparticle production was a problem with older engines as well, concurs that the technology used to clean up pollution in newer engines is not having any positive impact on nanoparticle production. While there is scientific evidence that the newer engines, designed to reduce the mass of pollutants emitted from the diesel engine, emit more particles in the nuclei mode, quantifying the magnitude of these particles has been difficult. This is because as dpm is released into the atmosphere the diesel particulate undergoes very complex changes. In addition, current sampling procedures produce artificial particulates, which otherwise would not exist under atmospheric conditions. Experimental work conducted at West Virginia University (Bukarski) indicate that nanoparticles are not generated during the combustion process, but rather during other physical and chemical processes which the exhaust undergoes in aftertreatment systems.

While current medical research findings indicate that small particulates, particularly those below 2μm in diameter, may be more harmful to human health than the larger ones, much more medical research and diesel emission studies are needed to fully characterize diesel nanoparticles emissions and their influence on human health. If nanoparticles are found to have an adverse health impact by virtue of size or number, it could require significant adjustments in environmental engine emission regulation and technology. It could also have implications for the type of controls utilized, with some asserting that aftertreatment filters are the only effective way to limit the emission of nanoparticles and others asserting that aftertreatment filters can increase the number of nanoparticles.

As discussed in Part III, the available evidence on the risks for dpm exposure do not currently include enough data to draw conclusions about the risks of exposure to significant numbers of very small particles. Research on nanoparticles and their health effects is currently a topic of investigation. As there have been few measurements of the number of particles emitted (as opposed to mass), it will be very difficult for epidemiologists to extrapolate information in this regard.

Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be answered for some time because of the extensive research required to address the questions raised. MSHA's rules will require the application of exhaust aftertreatment devices on nearly all of the most polluting engines. The application of these measures will reduce the number of nanoparticles as well as the mass of the larger particles to which a miner will be exposed—miners wanted aftertreatment on all machines for this purpose.

(6) Other Methods for Controlling DPM in Underground Coal Mines

As discussed in the last section, the introduction of new engines underground will play a significant role in reducing the concentration of dpm in underground coal mines. There are, however, other approaches to reducing dpm concentrations in underground coal mines. Among these are: use of aftertreatment devices to eliminate particulates emitted by an engine; altering fuel composition to minimize engine particulate emission; use of maintenance practices and diagnostic systems to ensure that fuel, engine and aftertreatment technologies work as intended to minimize emissions; enhancing ventilation to reduce particulate concentrations in a work area; enclosing workers in cabs or other filtered areas to protect them from exposure; and use of work and fleet practices that reduce miner exposures to emissions.

As noted in section 9 of this Part, information about these approaches was solicited from the mining community in a series of workshops in 1995, and highlights were published by MSHA as an appendix to the proposed rule on dpm "Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox." During the hearings and in written comments on this rulemaking, these control methods were discussed.

This section provides updated information on two methods for controlling dpm emissions: aftertreatment devices and diesel fuel content. There was considerable comment on aftertreatment devices because MSHA's proposed rule would have required that certain equipment be equipped with high-efficiency particulate filters; the efficiency of such devices remains an important issue in determining the technological and economic feasibility of the final rule. Moreover, some commenters strongly favored the use of oxidation catalytic converters, a type of aftertreatment device used to reduce gaseous emission but which can also lessen dpm levels. Accordingly, information about them is reviewed here. With respect to diesel fuel composition, a recent rulemaking initiative by EPA, and actions taken by other countries in this regard, are discussed here because of their implications for the mining community.

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as "particle traps" or "soot traps," but the term filter is also used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment which have water scrubbers installed which cool the exhaust. However, another alternative that is now used in coal mines is "dry system technology" which cools the diesel exhaust with a heat exchanger and then uses a paper filter. In addition, "oxidation catalytic converters," devices used to limit the emission of diesel gases, and "water scrubbers," devices used to cool the emission of diesel gases, are discussed here as well, because they also can have effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas passes. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons is condensed and remains in the water with some of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. However, MSHA has no definitive evidence on the amount of dpm reduction that can be achieved with a particular water scrubber. The water scrubber does not remove the carbon monoxide, the oxides of nitrogen, or other gaseous emission that remains a gas at room temperature, so their effectiveness as aftertreatment devices is limited.

The water scrubber serves as an effective spark and flame arrester and as a means to cool the exhaust gas. Consequently, it is used in most of the permissible diesel equipment in mining as part of the safety components needed to gain MSHA approval.

The water scrubber has several operating characteristics which keep it from being a candidate for an aftertreatment device on nonpermissible equipment. The space required on the vehicle to store sufficient water for an 8 hour shift is not available on some equipment. Furthermore, the exhaust contains a great deal of water vapor which condenses under some mining conditions creating a fog which can adversely effect visibility. Also, operation of the equipment on slopes can cause the water level in the scrubber

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to change resulting in water blowing out the exhaust pipe. Control devices can be placed within the scrubber to maintain the appropriate water level. Because these devices are in contact with the water through which the exhaust gas has passed, they need frequent maintenance to insure that they are operating properly and have not been corroded by the acidic water created by the exhaust gas. The water scrubber must be flushed frequently to remove the acidic water and the dpm and other exhaust residue which forms a sludge that adversely effects the operation of the unit. These problems, coupled with the relatively low dpm removal efficiency, have prevented widespread use of water scrubbers as a primary dpm control device on nonpermissible equipment.

Oxidation Catalytic Converters (OCCs). Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor (Haney, Saseen, Waytulonis, 1997). Their use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the last several years (McKinnon, dpm Workshop, Beckley, WV, 1995).

Several of the harmful emissions in diesel exhaust are produced as a result of incomplete combustion of the diesel fuel in the combustion chamber of the engine. These include carbon monoxide and unburned hydrocarbons including harmful aldehydes. Catalytic converters, when operating properly, remove significant percentages of the carbon monoxide and unburned hydrocarbons. Higher operating temperatures, achieved by hotter exhaust gas, improve the conversion efficiency.

Oxidation catalytic converters operate, in effect, by continuing the combustion process outside the combustion chamber. This is accomplished by utilizing the oxygen in the exhaust gas to oxidize the contaminants. A very small amount of material with catalytic properties, usually platinum or a combination of the noble metals, is deposited on the surfaces of the catalytic converter over which the exhaust gas passes. This catalyst allows the chemical oxidation reaction to occur at a lower temperature than would normally be required.

For the catalytic converter to work effectively, the exhaust gas temperature must be above 370 degrees Fahrenheit for carbon monoxide and 500 degrees Fahrenheit for hydrocarbons. Most converters are installed as close to the exhaust manifold as possible to minimize the heat loss from the exhaust gas through the walls of the exhaust pipe. Insulating the segment of the exhaust pipe between the exhaust manifold and the catalytic converter extends the portion of the vehicle duty cycle in which the converter works effectively.

The earliest catalytic converters for mining use consisted of alumina pellets coated with the catalytic material and enclosed in a container. The exhaust gas flowed through the pellet bed where the exhaust gas came into contact with the catalyst. Designs have evolved, and now the most common design is a metallic substrate, formed to resemble a honeycomb, housed in a metal shell. The catalyst is deposited on the surfaces of the honeycomb. The exhaust gas flows through the honeycomb and comes into contact with the catalyst.

Soon after catalytic converters were introduced, it became apparent that there was a problem due to the sulfur found in diesel fuels in use at that time. Most diesel fuels in the United States contained anywhere from 0.25 to 0.50 percent sulfur or more on a mass basis. In the combustion chamber, this sulfur was converted to SO_2, SO_3, or SO_4 in various concentrations, depending on the engine operating conditions. In general, most of the sulfur was converted to gaseous SO_2. When exhaust containing the gaseous sulfur dioxide passed through the catalytic converter, a large proportion of it was converted to solid sulphates which are in fact, diesel particulate. Sulfates can "poison" the catalyst, severely reducing its life.

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm (0.05 percent) sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines required that this low sulfur fuel be used. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm (0.0015 percent) for on-highway use in 2006.

The particulate removal capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines (40 CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 20%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, or have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. He concludes that the negative effects outweigh the benefits (Mayer).

The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program established to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that testing of OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction. (DECSE Program Summary, Dec. 1999) Another commenter also notes that oxidation catalytic activity can increase sulfates under certain operating temperatures, and that oxidation is a part of aftertreatment systems approaches like the DST® and some ceramic traps. But this commenter asserts that the sulfate production occurs at an operating mode that is seldom seen in real operation.

Other commenters during the rulemaking strongly supported the use of OCCs to reduce particulate and other diesel emissions. They argue that the OCCs result in significant reductions in dpm and in dpm generating gases. One commenter noted that with a clean engine, an OCC might well reduce particulates enough to meet any requirements established by MSHA.

However, another commenter noted that OCCs and ceramic traps can fail when used at higher altitude mines due to the lower oxygen content in the exhaust system. Another commenter asserted that OCCs are not effective at low temperature, although they are improving. Accordingly, this commenter indicated that OCCs have an impact only on light duty equipment when the equipment is working, not when it is idling, and are virtually useless on permissible equipment because of the low exhaust temperatures achieved through cooling. Despite a specific request from MSHA at the rulemaking hearings, no data were provided by OCC advocates to demonstrate that they can perform well at the lower temperatures normally found in light duty equipment.

Hot gas particulate traps. Throughout this preamble, MSHA is referring to the particulate traps (filters) that can be used in the undiluted hot exhaust stream from the diesel engine as hot gas filter. Hot gas filter refers to the current commercially available particulate filters such as ceramic cell, woven fiber filter, sintered metal filter, etc.

Following publication of EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines, development of aftertreatment devices capable of more significant reductions in particulate levels began to be developed for Comerica applications.

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach (SAE, SP–735, 1988). This consisted of a ceramic substrate encased in a shock-and vibration-absorbing material covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without placing excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that exhaust from all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard. One commenter noted that a total exhaust, wall-flow, ceramic filter developed in Canada in collaboration with a US firm has been successfully demonstrated underground with a reduction of between 60% and 90% of particulate matter.

The development of these devices has proceeded in response to international and national efforts to regulate dpm emissions. However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps were found to be unnecessary for compliance with the EPA standards of the time for vehicle engines.

These devices proved to be quite effective in removing particulate, achieving particulate removal efficiencies of greater than 90 percent.

It was quickly recognized that this technology, while not immediately required for most vehicles, might be useful in mining applications. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The study demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles.

Canadian mines also began to experiment with ceramic traps in the 1980's with similar results (BOM, IC 9324, 1992). Work in Canada today continues under the auspices of the Diesel Emission Evaluation Program (DEEP), established by the Canadian Centre for Mineral and Energy Technology in 1996 (DEEP Plenary Proceedings, November 1996). The goals of DEEP are to: (1) evaluate aerosol sampling and analytical methods for dpm; and (2) evaluate the in-mine performance and costs of various diesel exhaust control strategies.

Reservations regarding their usefulness and practicality remain. One commenter stated at one of the MSHA workshops in 1995, "while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable." Another commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life. Another reported that ceramics would not work at higher altitudes because of lower oxygen content in the exhaust system. Another commenter pointed out that elevated operating temperatures in certain engine modes can result in sulfates adding as much as 50% to total particulate mass, and asserted that ceramic traps alone were unable to offset this effect on their own.

In response to the proposed rule, MSHA received information and claims about the current efficiency of such technologies. One commenter, representing those who manufacture emissions controls, and referring to technologies other than low temperature paper filters—such as higher temperature disposable paper filters, ceramic monolith diesel particulate filters, wound ceramic fiber filters, and metal fiber filters—asserted that there were technologies which could achieve in excess of 95% filtration efficiency under "many operating conditions." Another commenter submitted copies of information provided to that commenter by individual manufacturers of emission control systems, many of which made similar claims. Another commenter, however, questioned manufacturer claims, asserting big differences had been observed between such claims an independent 8-mode tests.

It appears that two groups in particular have been doing some research comparing the efficiency of recent ceramic models: the University of West Virginia, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling (in both cases, background on the regulatory efforts of the jurisdictions involved is discussed in section 8 of this part).

The legislature of the State of West Virginia enacted the West Virginia Diesel Act, which created the West Virginia Diesel Commission and set forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in that state. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of

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diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls.

The University provided data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system (a system which, first cools the exhaust, then runs it through a paper filter). The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system. The University reported problems with this system that would account for the lower than expected efficiency for a paper filter type system. A commenter who spoke for the Commission at MSHA's public hearing expressed serious reservations of the 95% collection efficiency of MSHA's proposed rule and believed it was not achievable with technology based on the University's current work. The WV Commission also provided MSHA a detailed proposal for setting a laboratory diesel particulate standard of 0.5 milligram per cubic meter. As discussed in part IV, this is similar to the Pennsylvania standard, but without a strict filter efficiency value, and as further discussed in part IV, MSHA's approach in this final rule is similar.

VERT's studies of particulate traps are detailed in two articles published in 1999 which have been widely disseminated to the diesel community here through www.DieselNet.com (Mayer et al., March 1999, and Mayer, April 1999). The March article focuses on the efficiency of the traps; the April article compares the efficiency of other approaches (OCCs, fuel reformulation, engine modifications to reduce ultra-fine particulates) with that of the traps. Here we focus only on the information about particulate traps.

The authors of the March article report that 29 particulate trap systems were tested using various ceramic, metal and fiber filter media and several regeneration systems. The authors of the March article summarize their conclusions as follows:

> The results of the 4-year investigations of construction site engines on test rigs and in the field are clear: particulate trap technology is the only acceptable choice among all available measures. Traps proved to be an extremely efficient method to curtail the finest particles. Several systems demonstrated a filtration rate of more than 99% for ultra-fine particulates. Specific development may further improve the filtration rate.
>
> A two-year field test, with subsequent trap inspection, confirmed the results pertaining to filtration characteristics of ultra-fine particles. No curtailment of the ultra-fine particles is obtained with any of the following: reformulated fuel, new lubricants, oxidation catalytic converters, and optimization of the engine combustion.
>
> Particulate traps represent the best available technology (BAT). Traps must therefore be employed to curtail the particulate emissions that the law demands are minimized. This technology was implemented in occupational health programs in Germany, Switzerland and Austria.

On the bench tests, it appears that the traps reduce the overall particulate matter by between 70 and 80%, with better results for solid ultrafine particulates; under hot gas conditions, it appears the non-solid components of particulate matter cannot be dependably retained by these traps. Consistent with this finding, it was found that polycyclic aromatic hydrocarbons (PAHs) decreased proportionately to the gravimetric decrease of carbon mass. The tests also explored the impact of additives on trap efficiency, and the impact of back pressure.

The field tests confirmed that the traps were easy to mount and retained their reliability over time, although regeneration using an external power source was required when low exhaust temperatures failed to do this automatically. Electronic monitoring of back pressure was recommended. In general, the tests confirmed that a whole series of trap systems have a high filtration rate and stable long time properties and are capable of performing under difficult construction site conditions. Again, the field tests indicated a very high reduction (97–99%) by particulate count, but a lower rate of reduction in terms of mass.

Subsequently, VERT has evaluated additional commerically available filter systems. A list of recently evaluated hot gas filters are shown in Table II–4. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed "PMAG—without additive". The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

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Table II-4
Efficiency of Diesel Particulate Traps VERT-Certification Test
Average 4 operation points, ISO 8187

Trap	Date	PMAG		PZAG		ECAG	
		without Additive	with Additive	without Additive	with Additive	without Additive	with Additive
3M	VERT-Certification Test Part 1 (new)	80.7	-	98.6	99.6	-	-
Oberland		90.5	-	98.4	99.4	-	-
JMC		94.5	-	99.3	-	-	-
IBIDEN		87.2	-	99.9	-	-	-
Corning		84.9	-	99.5	99.8	-	-
HJS/CRT		83.8	-	99.4	-	98.2	-
SHW(LIB1)	After VERT Field Test Part 3 (after 2000 hrs)	3.2	22.2	96.3	97.1	-	93.1
SHW(CAT1)		77.5	87.6	97.8	98.8	97.2	96.5
BUCK(LIB2)		76.5	81.0	95.4	97.8	94.0	95.5
BUCK(CAT3)		64.2	76.2	91.0	96.8	(87.0) [2]	95.3
ECS(LIB3)		12.4	43.0	99.9	99.9	99.3	99.0
DEUTZ(LIB4) [1]		(70.5)	(76.1)	(86.6)	(91.6)	(84.2)	
UNIKAT(CAT4)		54.7	76.2	99.0	99.6	98.1	98.4
AVERAGE		66.4		98.3		97.2	

[1] Small melting damage
[2] Uncertain data
[3] Coulometry is optional for VERT certification test

PMAG: Efficiency according to Total Particulate Mass PM
PZAG: Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ
ECAG: Efficiency according to Elementary Carbon EC (2 state Coulometry)

$$PMAG = \frac{PM_{\text{before trap}} - PM_{\text{after trapF}}}{PM_{\text{before trapF}}} = \frac{PM_{Ref} - PM_{\text{after trap}}}{PM_{Ref}} \quad (X\ 100\%)$$

$$PZAG = \frac{PZ_{\text{before trap}} - PZ_{\text{after trap}}}{PZ_{\text{before trap}}} = \frac{PZ_{Ref} - PZ_{\text{after trap}}}{PZ_{Ref}} \quad (X\ 100\%)$$

$$\text{Penetration} = 1 - \text{Efficiency} = = \frac{PZ_{\text{after PF}}}{PZ_{Ref}} \quad (X\ 100\%)$$

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Some commenters asserted that the VERT work was for relatively small engines and not for large engines, *i.e.* 600–700 hp, and hence could not be relied upon to demonstrate the availability of filters of such high efficiencies for the larger equipment used in some underground mines. MSHA believes this comment is misplaced. The efficiency of a filter is attributable to the design of the filter and not the size of the engine. VERT is documenting filter efficiencies of commercially available filters. It is customary in the industry, however, for the filter manufacturer to size the filter to fit the size of the engine. The mine operator must work with the filter manufacturer to verify that the filter needed will work for the intended machine. MSHA believes that this is no different for other types of options installed on machines for underground mining use.

More information about the results of the VERT tests on specific filters, and how MSHA intends to use this information to aid the mining industry in complying with the requirements of the standards for heavy duty equipment, generators and compressors, are discussed in Part IV of this preamble.

The accumulated dpm must be removed from particulate traps periodically. This is usually done by burning off the accumulated particulate in a controlled manner, called regeneration. If the diesel equipment on which the trap is installed has a duty cycle which creates an exhaust gas temperature greater than about 650 degrees Fahrenheit for more than 25 percent of the operating time, the unit will be self cleaning. That is, the hot exhaust gas will burn off the particulate as it accumulates. Unfortunately, only hard working equipment, such as load, haul, dump and haulage equipment usually satisfies the exhaust gas temperature and duration requirements to self regenerate.

Techniques are available to lower the temperature needed to initiate the regeneration. One technique under development is to use a fuel additive. A comparatively small amount of a chemical is added to the diesel fuel and burns along with the fuel in the combustion chamber. The additive is reported to lower the required regeneration temperature significantly. The additive combustion products are retained as a residue in the particulate trap. The trap must be removed from the equipment periodically to flush the residue. Another technique used to lower the regeneration temperature is to apply a catalyst to the surfaces of the trap material. The action of the catalyst is similar to that of the fuel additive. The catalyst also lowers the concentration of some gaseous emissions in the same manner as the oxidation catalytic converter described earlier.

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem does not occur in systems designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber. One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. In attempting to maintain a surface temperature less than the 300 degrees Fahrenheit (required for permissibility purposes) the exhaust gas was be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

If the machine on which the particulate trap is installed does not work hard enough to regenerate the trap with the hot exhaust gas and the option to use a fuel additive or catalyzed trap is not appropriate, the trap can still be regenerated while installed on the machine. Systems are available whereby air is heated by an externally applied heat source and caused to flow through the particle trap when the engine is stopped. The heat can be supplied by an electrical resistance element installed in front of the trap. The heat can also be supplied by a burner installed into the exhaust pipe in front of the trap. The burner is fueled by an auxiliary fuel line. The fuel is ignited creating large quantities of hot gas. With both systems, an air line is also connected to the exhaust pipe to create a flow of hot gases through the particulate trap. Both systems utilize operator panels to control the regeneration process.

Equipment owners may choose to remove the particle trap from the machine to perform the regeneration. Particle traps are available with quick release devices. The trap is then placed on a specially designed device that creates a controlled flow of heated air that is passed through the filter burning off the accumulated particulate.

The selection of the most appropriate means to regenerate the trap is dependent on the equipment type, the equipment duty cycle, and the equipment utilization practices at the mine.

A program under the Canadian DEEP project is field testing dpm filter systems in a New Brunswick Mine. Investigators are testing four filter systems on trucks and scoops. The initial feedback from Canada is very favorable concerning the performance of filters. Operators are very positive and are requesting the vehicles equipped with the filters because of the noticeable improvement in air quality and an absence of smoke even under transient load conditions. One system undergoing testing utilizes an electrical heating element installed in the filter system to provide the heated air for regeneration of the filter. This heating element requires connection of the filter to an external electrical source at the end of the shift. Initial tests have been successful.

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. MSHA believes this information is relevant to coal and metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment and can be applied to heavy duty equipment in coal mining operations. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany. Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The Oberland-Mangold company has approximately 1,000 systems in the field. They have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The Unikat company has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. In German industry, approximately 1,500 traps in forklifts are installed annually.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F, well below the ignition point of the filter material. Recognizing that under some operating modes, water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in-mine trials were conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared with the same machine without the filter. The test results showed that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines.

Despite the initial reports on the high efficiency of paper filters, during the hearings and in the comments on this rulemaking a number of commenters questioned whether, in practice, paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a paper filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification investigation are reviewed in Part IV of this preamble. They confirmed that commercially available paper filters are capable of achieving very high efficiencies.

Another commenter noted that the volatile fraction of particulate is not trapped by hot gas filters, but rather passes through the filter in gaseous form. The volatile fraction consists of, among other components, gaseous forms of sulfur compounds, lube oil and the high boiling point fraction of unburned fuel. These components condense in the mine atmosphere as diesel particulate. The commenter asserted that the process of volatilization is reduced in the water cooled exhaust, but it is present nevertheless.

MSHA recognizes that the volatile fraction of dpm passes through hot gas filters. This volatile fraction later condenses in the mine atmosphere and is collected on particulate samplers. This is not the case with hot gas filters that utilize a catalytic converter. The volatile fraction is oxidized in the catalytic converter and the gases produced do not condense as particulate. Paper filters are typically used with water scrubbers or heat exchangers, both of which condense the volatile fraction into dpm before the exhaust gas reaches the paper filter. This allows the paper filter to trap the condensed volatile fraction.

Dry systems technology. The recently developed means of achieving permissibility with diesel powered equipment in the United States is the dry exhaust conditioning system or dry system. This system combines several of the concepts described above as well as new, innovative approaches. The system also solves some of the problems encountered with older technologies.

The dry system in its most basic form consists of a heat exchanger to cool the exhaust gas, a mechanical flame arrestor to prevent the discharge of any flame from within the engine into the mine atmosphere, and a spark arrestor to prevent sparks from being discharged. The surfaces of these components and the piping connecting them are maintained below the 300 degrees F required by MSHA approval requirements. A filter, of the type normally used as an intake air filter element, is installed in the exhaust system as the spark arrestor. In terms of controlling dpm emissions, the most significant feature of the system is the use of this air filter element as a particulate filter. The filter media has an allowable operating temperature rating greater than the 300 degree F exhaust gas temperature allowed by MSHA approval regulations. These filters are reported to last up to sixteen hours, depending on how hard the machine operates.

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives. However, as pointed out by commenters, requiring the use of a dry system on all mining equipment would be expensive, cumbersome, and in many cases would require considerable engineering measures that might render them infeasible.

Although the dry systems were originally designed for permissible equipment applications, they can also be used directly on outby equipment (whose emissions are not already cooled), or to replace water scrubbers used to cool most permissible equipment with a system that includes additional aftertreatment.

Two manufacturers have received approval for diesel power packages that are configured as described above; Paas Technologies, (under various corporate designations including Minecraft and a registered trade name, Dry Systems Technology, or DST ®) and Jeffrey Mining Equipment Company (currently Long-Airdox-Jeffrey).

The design of the dry system manufactured by DST ® includes a catalytic converter. However, with respect to the basic Paas Technologies system, without a catalytic converter, the initial reported laboratory reductions in dpm were dramatic: up to 98%.

During the hearings, however, there were many questions about the applicability of the early results to MSHA's proposed requirement that emissions of certain equipment be reduced 95% by mass. It was indicated by a commenter that the original Paas Technology dry system tests with a paper filter were performed at West Virginia University used high sulfur fuel which is currently prohibited in underground coal mines. The commenter stated that the University tested different fuels containing varying sulfur contents and the results indicated a fluctuation in overall dpm emission results. The commenter stated the

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difference in dpm collection efficiency by the filter was on the order of 12 to 15%. Another commenter stated the difference in dpm reduction using a 0.37 percent fuel sulfur and a 0.04 percent fuel sulfur was about 22 percent. This commenter further stated that other published papers from Europe report the same dpm reductions with varying fuel sulfur levels, approximately 15 to 20 percent reduction.

As was stated ealier, Paas Technologies has further developed its system by the adding a catalytic converter in the exhaust before the particulate paper filter. Paas Technologies have developed a technique whereby the catalytic converter is mounted so that the exhaust gas temperature remains high enough for the converter to operate effectively while complying with the MSHA surface temperature requirement. In addition to removing most of the carbon monoxide, the catalytic converter removes most of the unburned hydrocarbons before they are cooled and condensed. This feature extends the operating life of the filter. Any sulfate formed in the catalytic converter or in the engine combustion process condenses to a solid form as the exhaust gas passes through the heat exchanger and is collected in the particulate filter.

Paas Technologies submitted a detailed set of test results on a 94hp MWM D–916–6 test engine equipped with a Model M38 DST® Management System, which included the catalytic converter, for the rulemaking record. These tests were conducted by Southwest Research Institute using an 8-mode test, with ASTM No. 2–D diesel fuel. Both the test cycle and test fuel (low sulfur) conformed with the test procedure detailed in the proposed rule and in this final rule. In idle mode, the dpm emissions were reduced about 90%; in mode 5, the dpm emissions were down 99%; on average of the 8 modes, the dpm emissions were reduced by 97%.

The Jeffrey system, which does not utilize a catalytic converter, was the subject of the MSHA verification initiative, noted in part IV. The verification was conducted in such a way as to test filter efficiency separately from whole system, with the low sulfur fuel required for coal mine use and without a catalytic converter. The verification confirmed that the paper filter has a dpm removal efficiency greater than 95 percent.

This data submitted to the rulemaking record demonstrates that paper filters used on dry systems can achieve a filtration efficiency that allows equipment to meet the 2.5 gm/hr standard with low sulfur diesel fuel both with and without a catalytic converter in the system.

Reformulated fuels. It has long been known that sulfur content can have a big effect on dpm emissions. In the diesel equipment rule, MSHA requires that fuel used in underground coal mines have less than 0.05% (500 ppm) sulfur. EPA regulations requiring that such low-sulfur fuel (less than 500 ppm) be used in highway engines, in order to limit air pollution, have in practice ensured that this is the type of diesel fuel available to mine operators, and they currently use this type of fuel for all engines.

EPA has proposed a rule which would require further reductions in the sulfur content of highway diesel fuel. Such an action was taken for gasoline fuel on December 21, 1999.

On May 13, 1999 (64 FR 26142) EPA published an Advance Notice of Proposed Rulemaking (ANPRM) relative to changes for diesel fuel. In explaining why it was initiating this action, EPA noted that diesel engines "contribute greatly" to a number of serious air pollution problems, and that diesel emissions account for a large portion of the country's particulate matter and nitrogen oxides-a key precursor to ozone. EPA noted that while these emissions come mostly from heavy-duty truck and nonroad engines, they expected the contribution to dpm emissions from light-duty equipment to grow due to manufacturers' plans to greatly increase the sale of light duty trucks. These vehicles are now subject to Tier 2 emission standards, whether powered by gasoline or diesel fuel. Such standards may be difficult to meet without advanced catalyst technologies that in turn are likely to require sulfur reductions in the fuel.

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). (For more information on the EPA planned engine standards, see section 5 of this Part). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148).

In the ANPRM, EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems were fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel was needed for effective PM control (64 FR 26150). EPA's proposed rule was published in May 2000 and EPA issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2009.

A joint government-industry partnership is also investigating the relationship between varying levels of sulfur content and emissions reduction performance on various control technologies, including particulate filters and oxidation catalytic convertors. This program is supported by the Department of Energy's Office of Heavy Vehicles Technologies, two national laboratories, the Engine Manufacturers Association, and the Manufacturers of Emission Controls Association. It is known as the Diesel Emission Control-Sulfur Effects (DECSE) Program; more information is available from its web site, http://www.ott.doe.gov/decse.

MSHA expects that once such cleaner fuel is required for transportation use, it will in practice become the fuel used in mining as well—directly reducing engine particulate emissions, increasing the efficiency of aftertreatment devices, and eventually through the introduction of new generation of cleaner equipment. Mayer states that reducing sulfur content, decreasing aromatic components and increasing the Cetane index of diesel fuel can generally result in a 5% to 15% reduction in total particulate emissions.

Several commenters in this rulemaking suggested other fuel formulations which could have a beneficial effect on dpm emissions. One commenter encouraged the use of FRF, Fire Resistant Fuel, which has various safety features as well as lower NO_X and PM, and noted it is under study for use by the military.

Another commenter noted the development of a catalytic ignition system that permits the engines to operate on alternative fuels which greatly reduce harmful emissions. For example, using a water-methanol mix, the commenter noted dramatic reductions in harmful emissions of NO_X, CO and HC over a gasoline, spark ignition engine. This commenter also noted that the ignition system could operate on a diesel engine, but provided no information about emissions reductions by its use.

Meyer reports the results of a test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it show any improvement in diminishing nonparticulate emissions.

Cabs. Even though cabs are not the type of control device that is attached to the exhaust of the diesel engine to reduce emissions, cabs can protect miners from environmental exposures to dpm. Both cabs and control booths are discussed in the context of reducing miners exposures to dpm.

A cab is an enclosure around the operator installed on a piece of mobile equipment. It can provide the same type of protection as a booth at a crusher station as found in some surface operations. While cabs are not available for all mining equipment, they are available for much of the larger equipment that also has application in the construction industry.

To be effective, a cab should be tightly sealed with windows and doors closed. Rubber seals around doors and windows should be in good condition. Door and window latches must operate properly. In addition to being well sealed, the cab should have an air filtration and pressurizing system. Air intake should be located away from engine exhaust. The airflow should provide one air change per minute for the cab and should pressurize the cab to 0.20 inches of water. While these are not absolute requirements, they do provide a guideline of how a cab should be designed. If a cab does not have an air filtration and pressurizing system, the diesel particulate concentration inside the cab will be similar to the diesel particulate concentration outside the cab.

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction. Several different types of filter media have been tested in underground mines. These include standard filter paper and high efficiency filter paper. Filter papers can reduce diesel particulate exposures by 60 percent to 90 percent. When changing filter media, it is necessary to make sure that the airflow into the cab is not reduced and that the airflow through an air conditioning system is not reduced.

Although the installation of a cab does not relieve the mine operator from the responsibility of complying with the equipment dpm limits, cabs provide assistance in complying with noise and respirable dust regulations. Cabs protect the equipment operator protection from dpm, respirable dust and noise exposures.

(7) Existing Standards for Underground Coal Mines That Assist in Limiting Miner Exposure to Diesel Emissions

MSHA already has in place various requirements that indirectly help to control miner exposure to diesel emissions in underground mines—including exposure to diesel particulate. The first such requirements were developed in the 1940's; the most recent went into full effect only in November, 1999. It is important to understand these requirements because they form the base upon which this new rule is overlaid.

Early developments. In 1944, part 31 established procedures for limiting the gaseous emissions from diesel powered equipment and establishing the recommended dilution air quantity for mine locomotives that use diesel fuel. In 1949, part 32 established procedures for testing of mobile diesel-powered equipment for non-coal mines. In 1961, part 36 was added to provide requirements for the use of diesel equipment in gassy noncoal mines, in which engines must be temperature controlled to prevent explosive hazards. These rules were drafted in response to research conducted by the former Bureau of Mines.

Continued research by the former Bureau of Mines in the 1950s and 1960s led to refinements of its ventilation recommendations, particularly when multiple engines are in use. An airflow of 100 to 250 cfm/bhp for engines that have a properly adjusted fuel to air ratio was recommended (Holtz, 1960). An additive ventilation requirement was recommended for operation of multiple diesel units, which could be relaxed based on the mine operating procedures. This approach was subsequently refined to become a 100–75–50 percent guideline (MSHA Policy Memorandum 81–19MM, 1981). Under this guideline, when multiple pieces of diesel equipment are operated, the required airflow on a split of air would be the sum of: (a) 100 percent of the approval plate quantity for the vehicle with the highest approval plate air quantity requirement; (b) 75 percent of the approval plate air quantity requirement of the vehicle with the next highest approval plate air quantity requirement; and (c) 50 percent of the approval plate airflow for each additional piece of diesel equipment.

Limitations on Diesel Gasses. MSHA has limits on some of the gasses produced in diesel exhaust. These are listed in Table II–5, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-5
GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of Limits Recommended		MSHA Limits	
			$Coal_A$	M/NM_B
HCHO	0.016_C	0.3_D	2	2
CO	25_D	50	50	50
CO_2	$5,000_C$	5,000	5,000	5,000
NO	$25_{C,D,E}$	25	25	25
NO_2	1_F	3_D	5	5
SO_2	$2_{C,D}$	5_E	2	5

Table Notes:
A) ACGIH, 1972
B) ACGIH, 1973
C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average
D) ACGIH, 1996
E) OSHA permissible exposure limit (PEL)
F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an MSHA exposure limit, regulatory action is required because the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed air quality rule (concerning control of drill dust and blasting) was promulgated. As a result of a recent legal action, MSHA's efforts to revise the specific limits for those gases emitted by diesel engines have been placed under the continued supervision of a federal court of appeals. This action is discussed in more detail in section 9 of this Part.

Diesel Equipment Rule for Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the "Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines" (61 FR 55412). The history of this "diesel equipment rule" (sometimes referred to here as the "diesel safety rule" to help distinguish it from this rulemaking which is oriented toward health) is set forth as part of the history of this rulemaking (see section 9 of this part).

The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

Certain requirements were included in the diesel equipment rule that are directly related to reducing diesel emissions. For example, the diesel equipment rule requires that the emissions of permissible and heavy duty equipment be tested weekly. The tests are conducted using instrumentation and the tests are conducted with the engines operated at a loaded condition which is representative of actual operation. The results are monitored and recorded. Higher than normal emissions readings indicate that the engines and equipment are not being maintained in approved condition. Although some of these requirements help reduce dpm emissions, they were not included in the rule for that specific purpose.

Lower-emission engines. The diesel equipment rule requires that virtually all diesel-powered engines used in underground coal mines be approved by MSHA; see 30 CFR part 7, (approval requirements), part 36 (permissible machines defined), and part 75 (use of such equipment in underground coal mines). The approval requirements, among other things, require clean-burning engines in diesel-powered equipment (61 FR 55417). In promulgating the final rule, MSHA recognized that clean-burning engines are "critically important" to reducing toxic gasses to levels that can be controlled through ventilation. To achieve the objective of clean-burning engines, the rule sets performance standards which must be met by virtually all diesel-powered equipment in underground coal mines.

As noted in section 5 of this part, the technical requirements for approved diesel engines focus on limiting the amount of various gases that an engine can emit, including undiluted exhaust limits for carbon monoxide and oxides of nitrogen (61 FR 55419). The limits for these gasses are derived from existing 30 CFR part 36.

The diesel equipment rule also provides that the particulate matter emitted by approved engines be determined during the testing required to gain approval. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates what air quantity is necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air. The purpose of the PI requirement is discussed in more detail in section 5 of this part.

Gas Monitoring. The diesel equipment rule also addresses the monitoring and control of gaseous diesel exhaust emissions (30 CFR part 70; 61 FR 55413). In this regard, the rule requires that mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations (61 FR 55413, 55430–55431). Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322 trigger corrective action by the mine operator (30 CFR part 70, 61 FR 55413).

Engine Maintenance. The diesel equipment rule requires that diesel-powered equipment be maintained in safe and approved condition (30 CFR 75.1914; 61 FR 55414). As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust (61 FR 55413–55414).

The rule also requires the weekly examination of diesel-powered equipment (30 CFR 75.1914(g)). To determine if more extensive maintenance is required, the rule further requires a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation.

In addition, operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified (61 FR 55414).

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less (30 CFR 75.1910(a); 61 FR 55413). Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment (30 CFR 75.1916(d).

Ventilation. The diesel equipment rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. The ventilating air quantities are required to appear on the engine's approval plate. The rule also requires generally that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. The engine's approval plate air quantity is also used to determine the minimum air quantity in areas where multiple units of diesel powered equipment are being operated. The minimum ventilating air quantity where multiple units of diesel powered equipment are operated on working sections and in areas where mechanized mining equipment is being installed or removed, must be the sum of 100 percent of the approval plate quantities of all of the equipment. As stated in the preamble of the diesel equipment rule, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment.

Impact of the diesel equipment rule on dpm. The diesel equipment rule is helping the mining community use diesel-powered equipment more safely in underground coal mines. Moreover, the diesel equipment rule has many features which reduce the emission and concentration of harmful diesel emissions in underground coal mines—including the particulate component of these emissions.

During the public hearings on the equipment rule, miners complained about the high concentrations of diesel emissions at the section loading point and in the areas of the mine where longwall equipment is being installed or removed. Accordingly, MSHA established, in that rule, provisions which would address miners' concerns.

The equipment rule required that the approval plate ventilation quantity be provided at the section loading point. The loading point is also identified as a location where regular air quality samples are required to be taken. Corrective action is required if the samples of CO and NO_2 exceeded more than one half the allowable concentration limit of these gases.

Longwall equipment installations and removals are handled in a similar manner. The diesel emissions from all of the equipment in the area of the mine where the longwall move is being made are required to be considered in establishing the amount of ventilation air to be provided. A specific location where that quantity is to be measured is established. Additionally, the same air quality sampling program required for section loading points is required for areas of the mine where the longwall move is to take place.

Permissible haulage vehicles contribute the largest quantities of emissions at the section loading point. Longwall moves are typically carried out by permissible and heavy duty equipment such as shield carriers, mules, and locomotives which produce large quantities of diesel emissions. Emissions from these vehicles are reduced by the use of approved engines, low sulfur fuel, the loaded repeatable engine condition testing, regular maintenance by trained personnel and the ventilation and sampling provisions of the diesel equipment rule.

Because the effective dates for provisions of the diesel equipment regulations are staggered, the full impact of the new rules was not known at the time the dpm hearings were held. MSHA expects that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look

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at the health risks of dpm exposure. (61 FR 55420).

(8) Information on How Certain States Are Restricting Occupational Exposure to DPM

As noted earlier in this part, the Federal government has long been involved in efforts to restrict diesel particulate emissions into the environment—both through ambient air quality standards, and through restrictions on diesel engine emissions. While MSHA's actions to limit the concentration of dpm in underground mines are the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job, several states have already taken actions in this regard with respect to underground coal mines.

This section reviews some of these actions, as they were the subject of considerable discussion and comment during this rulemaking.

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection but no request was ever approved.

In 1995, one company in the State submitted a plan for approval and started negotiations with its local union representatives. This led to statewide discussions and the adoption of a new law in the State that permits the use of diesel-powered equipment in deep coal mines under certain circumstances specified in the law (Act 182). As further noted by this commenter, the drafters of the law completed their work before the issuance of MSHA's new regulation on the safe use of diesel-powered equipment in underground coal mines. The Pennsylvania law, unlike MSHA's diesel equipment rule, specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

First, all diesel engines used in underground deep coal mines in Pennsylvania must be MSHA-approved engines with an "exhaust emissions control and conditioning system" that meets certain tests. (Article II–A, Section 203–A, Exhaust Emission Controls). Among these are dpm emissions from each engine no greater than "an average concentration of 0.12 mg/m^3 diluted by fifty percent of the MSHA approval plate ventilation for that diesel engine." In addition, any exhaust emissions control and conditioning system must include a "Diesel Particulate Matter (DPM) filter capable of an average of ninety-five percent or greater reduction of dpm emissions." It also requires the use of an oxidation catalytic converter. Thus, the Pennsylvania statute requires the use of low-emitting engines, and then the use of aftertreatment devices that significantly reduce the particulates emitted from these engines.

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's diesel equipment rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—*e.g.*, regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate.

While both mine operators and labor supported this approach, it remains controversial. During the hearings on this rulemaking, one commenter indicated that at the time the standards were established, it would have taken a 95% filter to reduce dpm from certain equipment to the 0.12 mg/m^3 emissions standard because 0.25 sulfur fuel was being utilized. This test reported by the commenter was completed prior to MSHA promulgating the diesel equipment rule that required the use of .05% sulfur fuel. Another commenter pointed out that as operators in the state began considering the use of newer, less polluting engines, achieving an efficiency of 95% reduction of the emissions from any such engines would become even more difficult. There was some disagreement among the commenters as to whether existing technology would permit operators to meet the 0.12 mg/m^3 emission standard in many situations.

One commenter described the difficulty in efforts to get a small outby unit approved under the current Pennsylvania law. Accordingly, the industry has indicated that it would seek additional changes in the Pennsylvania diesel law. Commenters representing miners indicated that they were also involved in these discussions.

West Virginia. Until 1997, West Virginia law banned the use of diesel-powered equipment in underground coal mines. In that year, the State created the joint labor-management West Virginia Diesel Equipment Commission (Commission) and charged it with developing regulations to permit and govern diesel engine use in underground coal mines. As explained by several commenters, the Commission, in collaboration with West Virginia University (WVU), developed a protocol for testing diesel engine exhaust controls, and the legislature appropriated more than $150,000 for WVU to test diesel exhaust controls and an array of diesel particulate filters.

There were a number of comments received by MSHA on the test protocols and results. These are discussed in appropriate parts in this preamble. One commenter noted that various manufacturers of products have been very interested in how their products compare to those of other manufacturers tested by the WVU. Another asserted that mine operators had been slowing the scheduling of tests by WVA.

Pursuant to the West Virginia law establishing the Commission, the Commission was given only a limited time to determine the applicable rules for the use of diesel engines underground, or the matter was required to be referred to an arbitrator for resolution. One commenter during the hearings noted that the Commission had not been able to reach resolution and that indeed arbitration was the next step. Other commenters described the proposal of the industry members of the Commission—0.5mg/m^3 for all equipment, as configured, before approval is granted. In this regard, the industry members of the West Virginia Commission said:

> "We urge you to accelerate the finalization of * * * these proposed rules. We believe that will aid our cause, as well as the other states that currently don't use diesel." (Id.)

Virginia. According to one commenter, diesel engine use in underground mining was legalized in Virginia in the mid-1980s. It was originally used on some heavy production equipment, but the haze it created was so thick it led to a drop in production. Thereafter, most diesel equipment has been used outby (805 pieces). The current state regulations consist of requiring that MSHA approved engines be used, and that the "most up-to-date, approved, available diesel engine exhaust aftertreatment package" be utilized. There are no distinctions between types of equipment. The commenter noted that more hearings were planned soon. Under a directive from the governor of Virginia, the state is reviewing its

regulations and making recommendations for revisions to sections of its law on diesels.

Ohio. The record of this rulemaking contains little specific information on the restrictions on the underground use of diesel-powered equipment in Ohio. MSHA understands, however, that in practice it is not used. According to a communication with the Division of Mines and Reclamation of the Ohio Division of Natural Resources, this outcome stems from a law enacted on October 29, 1995, now codified as section 1567.35 of Ohio Revised Code Title 15, which imposes strict safety restrictions on the use of various fuels underground.

(9) History of this Rulemaking

As discussed throughout this part, the Federal government has worked closely with the mining community to ascertain whether and how diesel-powered equipment might be used safety and healthfully in this industry. As the evidence began to grow that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions, including a number of non-regulatory initiatives taken by MSHA, are summarized here in chronological sequence.

Activities Prior to Proposed Rulemaking on DPM. In 1984, the National Institute for Occupational Safety and Health (NIOSH) established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that standing body established the Mine Health Research Advisory Committee Diesel Subgroup to determine if:

> * * * there is a scientific basis for developing a recommendation on the use of diesel equipment in underground mining operations and defining the limits of current knowledge, and recommending areas of research for NIOSH, if any, taking into account other investigators' ongoing and planned research. (49 FR 37174).

In 1985, MSHA established an Interagency Task Group with NIOSH and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines.

In April 1986, in part as a result of the recommendation of the Task Group, MSHA began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the Mine Health Research Advisory Committee Diesel Subgroup (which, as noted above, was created by a standing NIOSH committee) summarized the evidence available at that time as follows:

> It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust.

On October 6, 1987, pursuant to section 102(c) of the Mine Act, 30 U.S.C. 812(c), which authorizes MSHA to appoint such advisory committees as it deems appropriate, the agency appointed an advisory committee "to provide advice on the complex issues concerning the use of diesel-powered equipment in underground coal mines." (52 FR 37381). MSHA appointed nine members to this committee, officially known as The Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines (hereafter the MSHA Diesel Advisory Committee). As required by section 101(a)(1) of the Mine Act, MSHA provided the MSHA Diesel Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards would be promulgated.

In July 1988, the MSHA Diesel Advisory Committee completed its work with the issuance of a report entitled "Report of the Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines." It also recommended that MSHA promulgate standards governing the approval and use of diesel-powered equipment in underground coal mines. The MSHA Diesel Advisory Committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust.

With respect to diesel particulate, the MSHA Diesel Advisory Committee recommended that MSHA "set in motion a mechanism whereby a diesel particulate standard can be set." (MSHA, 1988). In this regard, the MSHA Diesel Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter in underground coal mines (*Id.* 64–65). Instead, the MSHA Diesel Advisory Committee recommended that MSHA ask NIOSH and the former Bureau of Mines to prioritize research in the development of sampling methods and devices for diesel particulate.

The MSHA Diesel Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id.*). In addition, the MSHA Diesel Advisory Committee recommended that the control of diesel particulate "be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements." The MSHA Diesel Advisory Committee further recommended that particulate emissions "be evaluated in the equipment approval process and a particulate emission index reported." (*Id.* at 9).

In addition, the MSHA Diesel Advisory Committee recommended that "the total respirable particulate, including diesel particulate, should not exceed the existing two milligrams per cubic meter respirable dust standard." (*Id.* at 9.) It should be noted that section 202(b)(2) of the Mine Act requires that coal mine operators maintain the average concentration of respirable dust at their mines at or below two milligrams per cubic meter which effectively prohibits diesel particulate matter in excess of two milligrams per cubic meter (30 U.S.C. 842(b)(2)).

As noted, the MSHA Diesel Advisory Committee issued its report in 1988. During that year, NIOSH issued a Current Intelligence Bulletin recommending that whole diesel exhaust be regarded as a potential carcinogen and controlled to the lowest feasible exposure level (NIOSH, 1988). In its bulletin, NIOSH concluded that although the excess risk of cancer in diesel exhaust exposed workers had not been quantitatively estimated, it is logical to assume that reductions in exposure to diesel exhaust in the workplace would reduce the excess risk. NIOSH stated that "[g]iven what we currently know, there is an urgent need for efforts to be made to reduce occupational exposures to DEP [dpm] in mines."

Consistent with the MSHA Diesel Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to

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perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the MSHA Diesel Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule, among other things, addressed, and in fact followed, the MSHA Diesel Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines (54 FR 40951), limiting gaseous pollutants from diesel equipment, (*Id.*), establishing ventilation requirements based on approval plate dilution air quantities (54 FR 40990), requiring equipment maintenance (54 FR 40958), requiring that trained personnel work on diesel-powered equipment, (54 FR 40995), establishing fuel requirements, (*Id.*), establishing gaseous contaminant monitoring (54 FR 40989), and requiring that a particulate index indicating the quantity of air needed to dilute particulate emissions from diesel engines be established. (54 FR 40953).

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) indicating it was in the early stages of developing a rule specifically addressing miners exposure to diesel particulate (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA (57 FR 501). The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule (57 FR 501). The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) Exposure limits, including the basis thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on "the need for a medical surveillance or screening program and on the use of respiratory equipment." (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a "comprehensive analysis of the comments and any other information received" in response to the ANPRM (57 FR 501), it took also several actions to encourage the mining community to begin to deal with the problems identified.

In 1995, MSHA sponsored three workshops "to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia." (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively.

The first workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: one by one miners, mining companies, and manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

In March of 1997, MSHA issued, in draft form, a publication entitled "Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox". The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site.

As explained in the publication, the Toolbox was designed to disseminate to the mining community information gained through the workshops about methods being used to reduce miner exposures to dpm. MSHA's Toolbox provided specific information about nine types of controls that can reduce dpm exposures: low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Some of these approaches reduce emissions from diesel engines; others focus on reducing miner exposure to whatever emissions are present. Quotations from workshop participants were used to illustrate when and how such controls might be helpful.

As it clearly stated in its introductory section entitled "How to Use This Publication," the Toolbox was not designed as a guide to existing or pending regulations. As MSHA noted in that regard:

> While the (regulatory) requirements that will ultimately be implemented, and the schedule of implementation, are of course uncertain at this time, MSHA encourages the mining community not to wait to protect miners' health. MSHA is confident that whatever the final requirements may be, the mining community will find this Toolbox information of significant value.

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines (61 FR 55412). The final rule addresses, and in large part is consistent with, the specific recommendations made by the MSHA Diesel Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. As noted in section 7 of this part, the diesel safety rule was implemented in steps concluding in late 1999. Aspects of this diesel safety rule had a significant impact on this rulemaking.

In the Fall of 1997, following comment, MSHA's Toolbox was finalized and disseminated to the mining community. At the same time, MSHA made available to the mining community a software modeling tool developed by the Agency to facilitate dpm control. This model enables an operator to evaluate the effect which various alternative combinations of controls would have on the dpm concentration in a particular mine—before making the investment. MSHA refers to this model as "the Estimator". The Estimator is in the form of a template that can be used on standard computer spreadsheet programs. As information about a new combination of controls is entered, the results are promptly displayed.

Proposed Rulemaking on Dpm. On April 9, 1998, MSHA published a proposed rule to "reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter" (63 FR 17492).

MSHA went to some lengths to ensure the mining community would be able to review and comment on the proposed rule. The agency made copies of the proposal available for review by the mining community at each district and field office location, at the National Mine Safety and Health Academy, and at each technical support center. MSHA also provided the opportunity for comments to be accepted from the mining community at each of those locations, as well as through mail, e-mail and fax to the national office. MSHA also distributed the proposal to all underground mines, to mining associations and other interested parties. A copy was also posted on MSHA's website.

In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule a "plain language" questions and answers section.

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 17512–17514). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 17580 *et seq.*). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed dpm rule (63 FR 17565 *et seq.*).

The proposed dpm rule was fairly simple. In addition to miner training, the proposed rule would have required aftertreatment filters on all permissible equipment and, subsequently, on all heavy duty nonpermissible equipment. Throughout the preamble, MSHA discussed a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines. MSHA made it very clear to the mining community that the rule being proposed represented only one of the approaches which might ultimately be required by the final rule and on which comment was being solicited by the proposed rulemaking notice.

For example, the agency noted the following:

> "MSHA recognizes that a specification standard does not allow for the use of future alternative technologies that might provide the same or enhanced protection at the same or lower cost. MSHA welcomes comment as to whether and how the proposed rule can be modified to enhance its flexibility in this regard * * *. (There are) two alternative specification standards which would provide somewhat more flexibility for coal mine operators. Alternative 1 would treat the filter and engine as a package that has to meet a particular emission standard. Instead of requiring that all engines be equipped with a high-efficiency filter, this approach would provide some credit for the use of lower-polluting engines. Alternative 2 would also provide credit for mine ventilation beyond that required." (63 FR 17498)

These alternatives were further discussed in a separate Question and Answer (#12). The agency was also clear it would welcome comment on "whether there are some types of light-duty equipment whose dpm emissions should, and could feasibly, be controlled", and "whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered" Question and Answer (#6) (63 FR 17556).

MSHA also discussed and welcomed comment on a number of other alternatives: *e.g.*, restricting the exposure of underground coal mines to all fine particulates regardless of source (63 FR 17495); and the use of administrative controls (*e.g.*, rotation of personnel) and personal protective equipment (*e.g.*, respirators) to reduce the dpm exposure of miners. The Agency also sought comments on its risk assessment, presented in full in the preamble to the proposed rule (Part III). As noted therein, this was the first risk assessment ever performed by the agency to be peer reviewed. Such a review is not required under the agency's statute, but MSHA took the time to obtain such a review in this instance due to significant disagreement within the mining community about the health risks of exposure to dpm (63 FR 17521).

MSHA also asked for comment on its economic assumptions in the preamble. Two of the Questions and Answers (#5 and #7) were specifically devoted to cost impacts, including those on small mines. MSHA also specifically requested all members of the mining community to consider using the Estimator in developing comments on the proposed rulemaking (63 FR 17565).

On July 14, 1998, in accordance with the National Environmental Protection Act, MSHA published a notice in the **Federal Register** seeking comment on its preliminary determination that the proposed rule would not have a significant environmental impact (63 FR 37796).

The initial comment period was scheduled to last for 120 days until August 7, 1998. In response to requests from the public, on August 5, 1998, MSHA extended the initial comment period on the proposed rule (and the comment period on its preliminary determination of no significant environmental impact) for an additional 60 days, until October 9, 1998 (63 FR 41755). That notice also announced MSHA's intent to hold public hearings on the proposal.

On October 19, 1998, MSHA announced in the **Federal Register** locations of four public hearings on the proposed rule. The agency further announced that the close of the post-hearing comment period and rulemaking record would be on February 16, 1999 (63 FR 55811).

In November 1998, MSHA held hearings in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

These hearings were well attended. Testimony was presented by individual miners, representatives of miners, individual coal companies, mining industry associations, representatives of engine and equipment manufacturers and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to engage in direct dialogue

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with members of MSHA's rulemaking committee-responding to questions and asking questions on their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches (including but not limited to those on which MSHA specifically sought comment), and the technological and economic feasibility of various alternatives.

During the hearings, MSHA made a number of requests that information provided at the hearing be supplemented by submission of cited sources, additional data, and in particular for data to support assertions made about various control technologies. MSHA again solicited information concerning the agency's cost assumptions, for the results of studies using MSHA's Estimator model, and also asked for any data on a number of other points. For example, the agency requested further information on the size distribution of particles from cleaner engines, on the viability of a fine particulate standard in lieu of a dpm standard, for a list of any studies concerning the risks of dpm or lack thereof, and data on equipment upgrades.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies discussed in the preamble of the proposed rule but not available at the time of publication; and (2) the extension of the post-hearing comment period and close of record for 60 additional days, until April 30, 1999.

On April 27, 1999, in response to requests from the public, MSHA extended the post-hearing comment period and close of record for 90 additional days, until July 26, 1999 (64 FR 22592).

On July 8, 1999, MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited by July 26, 1999, the close of the rulemaking record (64 FR 36826). The Estimator model was subsequently published in the literature.

The rulemaking record closed on July 26, 1999, fifteen months after the date the proposed rule was published for public notice. The comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were MSHA's paper filter verification studies and the recent information from VERT on the performance of hot gas filters mentioned in section 6 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for a related rulemaking for underground metal and nonmetal mines, and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

Other Related Activity. On September 3, 1999, the United States Court of Appeals for the District of Columbia Circuit issued its decision on writ of mandamus sought by the United Mine Workers to compel MSHA to issue final regulations controlling gaseous emissions in the exhaust of diesel engines used in underground coal mines. (190 F.3d 545.) The UMWA argued that such action should have been completed some years before as part of MSHA's air quality rulemaking to update emissions limits on hundreds of exposure limits. The Court found that the Agency was in violation of the statute's requirement that the Secretary must either promulgate final regulations, or explain her decision not to promulgate them, within ninety days of the certification of the record of a hearing if one is held or the close of the public comment period if a hearing is not held 30 U.S.C. 811(a)(4). However, the Court declined to immediately issue the mandamus order sought in this case because, among other factors: (a) The UMWA agreed that the diesel equipment rules alone may have the desired effect of reducing exposure to these gases; (b) the UMWA further agreed that the control of diesel particulate matter and respirable mine dust rank as higher rulemaking priorities for MSHA; and (c) MSHA submitted a tentative schedule for such rulemaking that the court found to be reasonable. However, the court retained jurisdiction of the case to ensure MSHA would move forward on this matter, and ordered several reports by the agency on its progress on December 31, 1999, June 30, 2000, December 31, 2000, and December 31, 2001.

III. Risk Assessment

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Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of occupational dpm exposures at levels encountered in the mining industry. This part of the preamble presents MSHA's review of the currently available information and MSHA's assessment of health risks associated with those exposures. All material submitted during the public comment periods was considered before MSHA drew its final conclusions.

The risk assessment begins in Section III.1, with a discussion of dpm exposure levels observed by MSHA in the mining industry. This is followed by a review, in Section III.2, of information available to MSHA on health effects that have been studied in association with dpm exposure. Finally, in Section III.3 entitled "Characterization of Risk," the Agency considers three questions that must be addressed for rulemaking under the Mine Act and relates the available information about risks of dpm exposure at current levels to the regulatory requirements.

A risk assessment must be technical enough to present the evidence and describe the main controversies surrounding it. At the same time, an overly technical presentation could cause stakeholders to lose sight of the main points. MSHA is guided by the first principle the National Research Council established for risk characterization, that the approach be:

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions, but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

Although the final rule covers only one sector, this portion of the preamble was intended to enable MSHA and other interested parties to assess risks throughout the coal and M/NM mining industries. Accordingly, the risk assessment includes information pertaining to all sectors of the mining industry. All public comments on the exposures of miners and the health effects of dpm exposure—whether submitted specifically for the coal rulemaking or for the metal/nonmetal rulemaking—were incorporated into the record for each rulemaking and have been considered for this assessment.

MSHA had an earlier version of this risk assessment independently peer reviewed. The risk assessment as proposed incorporated revisions made in accordance with the reviewers' recommendations, and the final version presented here contains clarifications and other responses to public comments. With regard to the risk assessment as published in the proposed preamble, the reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Some commenters generally agreed with this opinion. Dr. James Weeks, representing the UMWA, found the proposed risk assessment to be "balanced, thorough, and systematic." Dr. Paul Schulte, representing NIOSH, stated that "MSHA has prepared a thorough review of the health effects associated with exposure to high concentrations of dpm, and NIOSH concurs with the published [proposed] characterization of risks associated with these exposures." Dr. Michael Silverstein, representing the Washington State Dept. of Labor and Industries, found MSHA's "regulatory logic * * * thoroughly persuasive." He commented that "the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health * * * the evidence * * * is particularly strong and certainly provides a sufficient basis for regulatory action."

Many commenters, however, vigorously criticized various aspects of the proposed assessment and some of the scientific studies on which it was based. MSHA's final assessment, published here, was modified to respond to all of these criticisms. Also, in response to commenters' suggestions, this assessment incorporates some research studies and literature reviews not covered or inadequately discussed in the previous version.

Some commenters expressed the opinion that the proposed risk assessment should have been peer-reviewed by a group representing government, labor, industry, and independent scientists. Since the rulemaking process included a pre-hearing comment period, eight public hearings (four for coal and four for M/NM), and two post-hearing comment periods, these constituencies had ample opportunity to review and comment upon MSHA's proposed risk assessment. The length of the comment period for the Coal Dpm proposal was 15 months. The length of the comment period for the Metal/Nonmetal Dpm proposal was nine months.

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[3] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with

[3] MSHA has only limited information about miner exposures in other countries. Based on 223 personal and area samples, average exposures at 21 Canadian noncoal mines were reported to range from 170 to 1300 $\mu g/m^3$ (respirable combustible dust), with maximum measurements ranging from 1020 to 3100 $\mu g/m^3$ (Gangel and Dainty, 1993). Among 622 full shift measurements collected since 1989 in German underground noncoal mines, 91 (15%) exceeded 400 $\mu g/m^3$ (total carbon) (Dahmann et al., 1996). As explained elsewhere in this preamble, 400 $\mu g/m^3$ (total carbon) corresponds to approximately 500 $\mu g/m^3$ dpm.

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no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in coal and surface mines.[4] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

According to MSHA's experience, the dpm samples reflect exposures typical of mines known to use diesel equipment for face haulage in the U.S. However, they do not constitute a random sample of mines, and care was taken in the proposed risk assessment not to characterize results as necessarily representing conditions in all mines. Several commenters objected to MSHA's use of these exposure measurements in making comparisons to exposures reported in other industries and, for M/NM, in estimating the proposed rule's impact. These objections are addressed in Sections III.1.d and III.3.b.ii(3)(c) below. Comments related to the measurement methods used in underground coal and M/NM mines are addressed, respectively, in Sections III.1.b and III.1.c.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[5] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 $\mu g/m^3$ for coal and 808 $\mu g/m^3$ for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 $\mu g/m^3$ for M/NM and 103 $\mu g/m^3$ for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 $\mu g/m^3$ at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-SHIFT DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 50 DIESELIZED U.S. MINES

Mine type	Number of mines	Number of samples	Mean exposure ($\mu g/m^3$)	Standard error of mean ($\mu g/m^3$)	Exposure range ($\mu g/m^3$)
Surface	11	45	88	11	9–380
Underground Coal[a]	12	226	644	41	0–3,650
Underground Metal and Nonmetal	27	355	808	39	10–5,570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

Approximately 145 out of the 910 existing underground coal mines currently utilize diesel powered equipment. Of these 145 mines, 32 mines currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

Diesel particulate levels in underground mines depend on: (1) The amount, size, and workload of diesel equipment; (2) the rate of ventilation; and, (3) the effectiveness of whatever diesel particulate control technology may be in place. In the dieselized mines studied by MSHA, the sections used either two or three diesel coal haulage vehicles. In eastern mines, the haulage vehicles were equipped with a nominal 100 horsepower engine. In western mines, the haulage vehicles were equipped with a nominal 150 horsepower engine. Ventilation rates ranged from the approval plate requirement, based on the 100–75–50 percent rule (Holtz, 1960), to ten times the approval plate requirement. In most cases, the section airflow was approximately twice the approval plate requirement. Other control technology included aftertreatment filters and fuel. Two types of aftertreatment filters were used. These filters included a disposable diesel emission filter (DDEF) and a Wire Mesh Filter (WMF). The DDEF is a commercially available product; the WMF was developed by and only used at one mine. Both low sulfur and high sulfur fuels were used.

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

[4] The various methods of measuring dpm are explained in section 3 of Part II of the preamble to the proposed rule. This explanation, along with additional information on these methods, is also provided in section 3 of Part II of the preamble to the final M/NM rule.

[5] Since area samples in return airways do not necessarily represent locations where miners normally work or travel, they were excluded from the present analysis. A number of area samples were included, however, as described in Sections III.1.b and III.1.c. The included area samples were all taken in production areas and haulageways.

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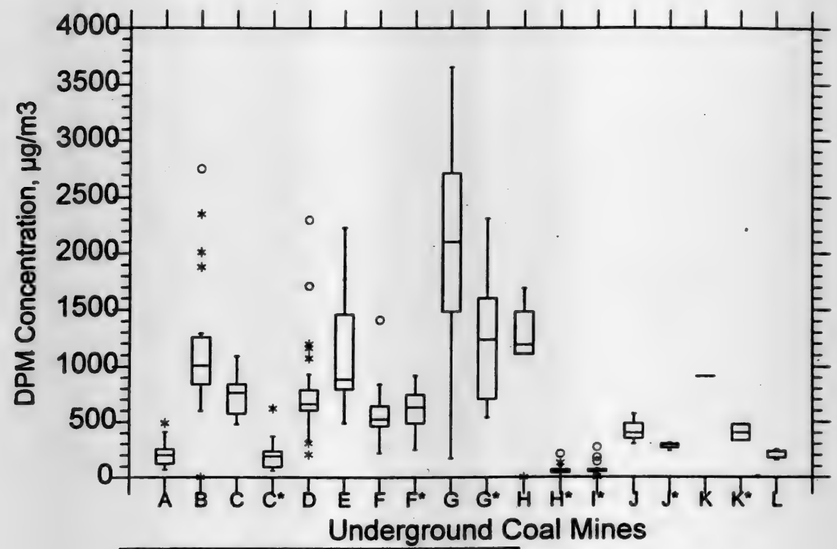


Figure 5 Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either * or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[6] A total of 19 individual measurements exceeded 1500 $\mu g/m^3$, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 $\mu g/m^3$ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 $\mu g/m^3$ in eight of the twelve mines and exceeded 1000 $\mu g/m^3$ in four.[7] At five of the twelve mines, all dpm measurements were 300 $\mu g/m^3$ or greater in the absence of after-treatment filters.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of WMFs, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 $\mu g/m^3$ (median = 2100 $\mu g/m^3$). With

[6] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 142 personal samples, the mean dpm concentration measurement was 608 $\mu g/m^3$, with a standard error of 42.5 $\mu g/m^3$. For the 84 area samples, the mean was 705 $\mu g/m^3$, with a standard error of 82.1 $\mu g/m^3$. The significance level (p-value) of a t-test comparing these means is 0.29 using a separate-variance test or 0.25 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at any confidence level greater than 75%. Here, and in other sections of this risk assessment, MSHA has employed standard statistical methods described in textbooks on elementary statistical inference.

[7] In coal mine E, the average as expressed by the mean exceeded 1000 $\mu g/m^3$, but the median did not.

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employment of WMFs, the mean dropped to 1241 µg/m³ (median = 1235 µg/m³).

Filters were employed during three of the four studies showing median dpm concentration at or below 200 µg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by approximately 50 percent in the mine using the WMF.

The higher dpm concentrations observed at the mine using the WMF (Mine "G*") are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 µg/m³ was conducted in a mine (Mine "A") which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

Some commenters [*e.g.*, WV Coal Assoc and Energy West] objected to MSHA's presentation of underground coal mine exposures based on measurements made using the size-selective method (gravimetric determination of the amount of submicrometer dust collected with an impactor). These commenters argued that the data were " * * * collected with emissions monitoring devices discredited by MSHA itself in the preamble * * *" and that these measurements do not reliably "* * * distinguish it [dpm] from other particles in coal mine dust, at the critical upper end range of submicron particles."

MSHA did not "discredit" use of the size-selective method for all purposes. As discussed elsewhere in this preamble, the size-selective method of measuring dpm was designed by the former BOM specifically for use in coal mines, and the size distribution of coal mine dust was taken into account in its development. Despite the recognized interference from a small fraction of coal mine dust particles, MSHA considers gravimetric size-selective measurements to be reasonably accurate in measuring dpm concentrations greater than 200 µg/m³, based on a full-shift sample, when coal mine dust concentrations are not excessive (*i.e.*, not greater than 2.0 mg/m³). Interference from submicrometer coal mine dust is counter-balanced, to some extent, by the fraction of larger size, uncaptured dpm. Coal mine dust concentrations were not excessive when MSHA collected its size-selective samples. Therefore, even if as much as 10 percent of the coal mine dust were submicrometer, this fraction would not have contributed significantly to the high concentrations observed at the sampled mines.

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[8] This does not mean, however, that MSHA has "discredited" this method for other purposes, including detection of very high dpm concentrations at coal mines (i.e., greater than 500 µg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[9] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the 27 underground M/NM mines studied. A total of 275 personal samples and 80 area samples were collected, excluding intake and return area samples. Personal exposures observed ranged from less than 100 µg/m³ to more than 3500 µg/m³. Exposure measurements based on area samples ranged from less than 100 µg/m³ to more than 3000 µg/m³. With the exception of Mine "V", personal exposures were for face workers. Mine "V" did not use dieselized face equipment.

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[8] MSHA has concluded that random weighing variability would make it impractical to use the size-selective method to enforce compliance with any dpm concentration limit less than about 300 µg/m³. MSHA believes that, at such levels, single-sample noncompliance determinations based on the size-selective method could not be made at a sufficiently high confidence level.

[9] The proposal discussed data from 25 underground M/NM mines. Studies at two additional mines, carried out too late to be included in the proposal, were placed into the public record along with the earlier studies. During the proceedings, MSHA provided copies of all of these studies to stakeholders requesting them.

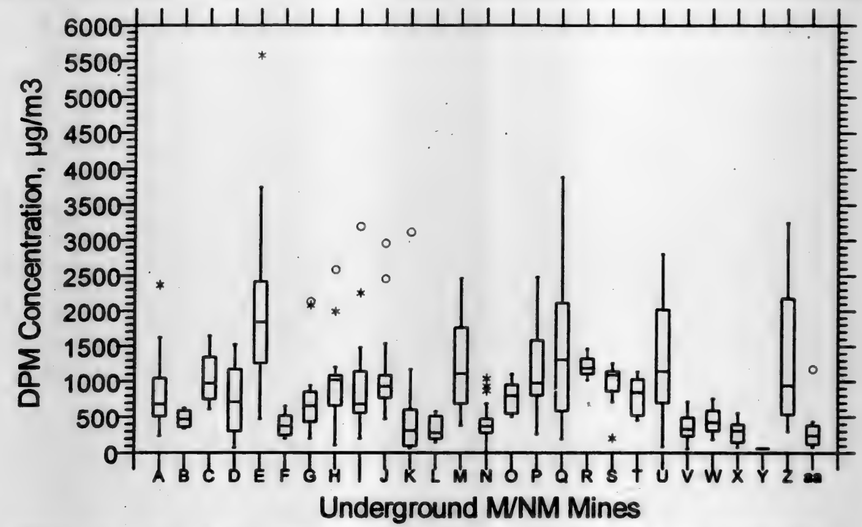


Figure 6 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either * or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[10] A total of 45 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 µg/m³, were from personal samples. Of the 45 measurements exceeding 1500 µg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 µg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 µg/m³ in 12.[11] At eight of the 27 mines, all dpm measurements exceeded 300 µg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine "E". Based on 16 samples, the mean dpm concentration observed at Mine "E" was 2008 µg/m³ (median = 1835 µg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 µg/m³. All four of these were based on personal samples.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore onto trucks or to haul and load ore onto belts. Additional pieces of diesel powered support equipment, such as bolters and mantrips, were also used at the mines. The typical piece of production equipment was rated at 150 to 350 horsepower. Ventilation rates in the M/NM mines studied mostly ranged from 100 to 200 cfm per horsepower of equipment. In only a few of the mines inventoried did ventilation exceed 200 cfm/hp. For single-level mines, working areas were ventilated in series (*i.e.*, the exhaust air from one area became the intake for the next working area). For multi-level mines, each level typically had a separate fresh air supply. One or two working areas could be on a level. Control technology used to reduce diesel particulate emissions in mines inventoried included oxidation catalytic converters and engine maintenance programs. Both low sulfur and high sulfur fuel were used; some mines used aviation grade low sulfur fuel.

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, "* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines." [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[12] then "if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities."[13] IMC Global went on to suggest that MSHA should "perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry."

As mentioned earlier, MSHA acknowledges that the mines for which dpm measurements are available do not comprise a statistically random sample of all underground M/NM mines. MSHA also acknowledges that the results obtained for these mines cannot be extrapolated in a statistically rigorous way to the entire population of underground M/NM mines. According to MSHA's experience, however, the selected mines (and sampling locations within those mines) represent typical diesel equipment use conditions at underground M/NM mines. MSHA believes that results at these mines, as depicted in Figure III–2, in fact fairly reflect the variety of diesel equipment used by the industry, regardless of type of M/NM mine. Based on its extensive experience with underground mines, MSHA believes that this body of data better represents those diverse diesel equipment use conditions, with respect to dpm exposures, than any other body of data currently available.

MSHA strongly disagrees with IMC Global's contention that, "* * * this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector." IMC Global apparently drew this conclusion from the fact that MSHA sampled approximately ten percent of all underground M/NM mines. This line of argument, however, depends on an unwarranted and highly unrealistic assumption: Namely, that all of the underground M/NM mines not included in the sampled group of 25 experience essentially no "potential [dpm] exposure problems." MSHA certainly did not go out and, by chance or design, pick for sampling just exactly those mines experiencing the highest dpm concentrations. IMC Global's argument fails to recognize that the sampled mines could be fairly representative without being randomly chosen.

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 µg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was

$$450/\sqrt{27} = 87\ \mu g/m^3.$$[14]

MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 µg/m³.

Several commenters questioned MSHA's use of the RCD and size-selective methods for measuring dpm exposures at underground M/NM mines. IMC Global indicated that MSHA's RCD measurements might systematically inflate the dpm concentrations presented in this section, because "* * * estimates for the non-diesel particulate component of RCD actually vary between 10% to 50%, *averaging 33%*."

[10] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 275 personal samples, the mean dpm concentration measurement was 770 µg/m³, with a standard error of 42.8 µg/m³. For the 80 area samples, the mean was 939 µg/m³, with a standard error of 86.6 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.06 using a separate-variance test or 0.07 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at a 95% confidence level.

[11] At M/NM mines C, I, J, P, and Z the average as expressed by the mean exceeded 1000 µg/m³ but the median did not. At M/NM mines H and S, the median exceeded 1000 µg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 µg/m³, but the median did not.

[12] Three underground M/NM mine surveys, carried out too late to be included in the discussion, were placed into the public record and provided to interested stakeholders. These surveys contained data from two additional underground M/NM mines ("Z" and "aa") and additional data for a mine ("d") that had previously been surveyed. The risk assessment has now been updated to include these data, representing a total of 27 underground M/NM mines.

[13] A breakdown by commodity is given at the end of this subsection.

[14] This quantity, 87 µg/m³, differs from the standard error of the mean of individual measurements for underground M/NM mines, presented in Table III–1. The tabled value is based on 355 measurements whose standard deviation is 727 µg/m³. Therefore, the standard error of the mean of all individual measurements is $_{727}/\sqrt{_{355}}$ = 39 µg/m², as shown in the table. Similarly, the mean of all individual measurements (listed in Table III–1 as 808 µg/m³) differs from the grand mean of individual mean concentrations observed within mines, which is 838 µg/m³.

MSHA considers the size-selective, gravimetric method capable of providing reasonably accurate measurements when the dpm concentration is greater than 200 µg/m³, interferences are adequately limited, and the measurement is based on a full-shift sample. Relatively few M/NM measurements were made using this method, and none at the mines showing the highest dpm concentrations. No evidence was presented that the size distribution of coal mine dust (for which the impactor was specifically developed) differs from that of other mineral dusts in a way that significantly alters the impactor's performance. Similarly, MSHA considers the RCD method, when properly applied, to be capable of providing reasonably accurate dpm measurements at concentrations greater than 200 µg/m³. As with the size selective method, however, random weighing errors can significantly reduce the precision of even full-shift RCD measurements at lower dpm concentrations. For this reason, in order to maintain a sufficiently high confidence level for its noncompliance determinations, MSHA will not use the RCD method for enforcement purposes. This does not mean, however, that MSHA has "discredited" the RCD measurements for all other purposes, including detection of very high dpm concentrations (i.e., greater than 300 µg/m³) and estimation of average concentrations based on multiple samples. On the contrary, MSHA considers the RCD method to be a useful tool for detecting and monitoring very high dpm concentrations in appropriate environments and for estimating average exposures when those exposures are excessive.

MSHA did not employ an impactor in its RCD measurements, and it is true that some of these measurements may have been subject to interference from lubrication oil mists. However, MSHA believes that the high estimates sometimes made of the non-dpm component of RCD (cited by IMC Global) do not apply to the RCD measurements depicted in Figure III–2. MSHA has three reasons for believing these RCD measurements consisted almost entirely of dpm:

(1) MSHA took special care to sample only environments where interferences would not be significant. No samples were taken near pneumatic drills or smoking miners.

(2) There was no interference from carbonates. The RCD analysis was performed at 500° C, and carbonates are not released below 1000° C. (Gangel and Dainty, 1993)

(3) Although high sulphur fuel was used in some mines, thereby adding sulfates to the RCD measurement, these sulfates are considered part of the dpm, as explained in section 2 of Part II of this preamble. Sulfates should not be regarded as an interference in RCD measurements of dpm.

Commenters presented no evidence that there were substantial interferences in MSHA's RCD measurements, and, as stated above, MSHA was careful to avoid them. Therefore, MSHA considers it reasonable, in the context of this risk assessment, to assume that all of the RCD was in fact dpm. Moreover, in the majority of underground M/NM mines sampled, even if the RCD measurements were reduced by ⅓, the mine's average would still be excessive: it would still exceed the maximum exposure level reported for non-mining occupations presented in Section III.1.d.

The breakdown, as suggested by IMC Global, of sampled underground M/NM mines by commodity is as follows:

Commodity	Number of mines
Copper	2
Gold	1
Lead/Zinc	6
Limestone	6
Potash	2
Salt	6
Trona (soda ash)	2
Other Nonmetal	2
Total	27

c. Surface Mines

Currently, there are approximately 12,620 surface mining operations in the United States. The total consists of approximately 1,550 coal mines and 11,070 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted dpm studies at eleven surface mining operations: eight coal mines and three M/NM mines. MSHA deliberately directed its surface sampling efforts toward occupations likely to experience high dpm concentrations. To help select such occupations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that relatively high surface mine dpm concentrations are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples was collected.

Figure III–3 displays the range of dpm concentrations measured at the eleven surface mines. The average dpm concentration observed was less than 200 µg/m³ at all mines sampled. The maximum dpm concentration observed was less than or equal to 200 µg/m³ in 8 of the 11 mines (73%). The surface mine studies suggest that even when sampling is performed at the areas of surface mines believed most likely to have high exposures, dpm concentrations are generally likely to be less than 200 µg/m³.

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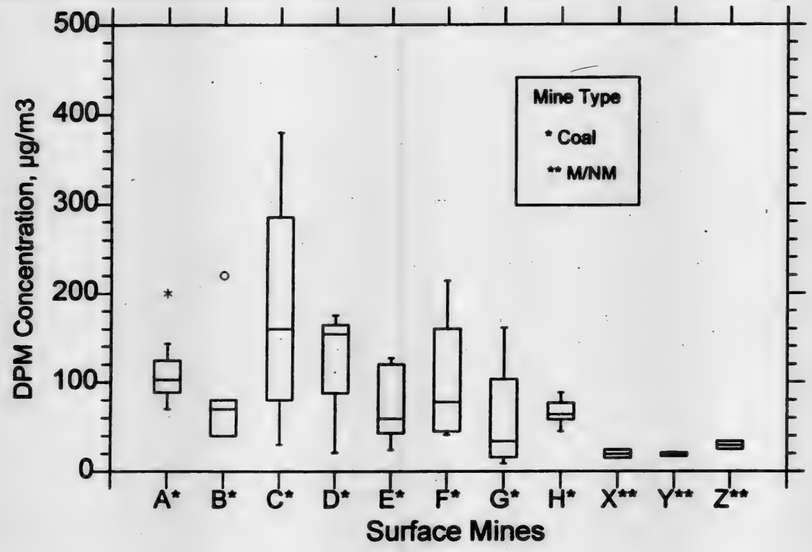


Figure 7 Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either ∗ or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH has estimated that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. (NIOSH 1988) Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include loading dock workers, truck drivers, and railroad workers.

As estimated by the reported geometric mean,[15] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 µg/m^3, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 µg/m^3 for truck drivers and from 4.8 to 28 µg/m^3 for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

Because these exposure averages, unlike those for railroad workers and miners, were reported in terms of EC, it is necessary, for purposes of comparison, to convert them to estimates of total dpm. Watts (1995) states that "elemental carbon generally accounts for about 40% to 60% of diesel particulate mass." Therefore, in earlier versions of this risk assessment, a 2.0 conversion factor was assumed for dock workers, truck drivers, and truck mechanics, based on the midpoint of the 40–60% range proposed by Watts.

Some commenters objected to MSHA's use of this conversion factor. IMC Global, for example, asserted that Watts' "* * * 40 to 60% relationship between elemental carbon and diesel particulate mass * * * applies only to underground coal mines where diesel haulage equipment is used." IMC Global, and other commenters, also objected to MSHA's use of a single conversion factor for "* * * different types of diesel engines under different duty cycles with different fuels and different types of emission control devices (if any) subjected to varying degrees of maintenance."

MSHA's quotation from Watts (1995) was taken from the "Summary" section of his paper. That paper covers a variety of occupational environments, and the summary makes no mention of coal mines. The sentence immediately preceding the quoted passage refers to the "occupational environment" in general, and there is no indication that Watts meant to restrict the 40- to 60-percent range to any specific environment. It seems clear that the 40- to 60-percent range refers to average values across a spectrum of occupational environments.

IMC Global mistakenly attributed to MSHA "the blanket statement" that the same ratio of elemental carbon to dpm applies "for all diesel engines in different industries for all patterns of use." MSHA made no such statement. On the contrary, MSHA agrees with Watts (and IMC Global) that "the percentage of elemental carbon in total diesel particulate matter fluctuates" depending on "engine type, duty cycle, fuel, lube oil consumption, state of engine maintenance, and the presence or absence of an emission control device." (Watts, op cit.) Indeed, MSHA acknowledges that, because of these factors, the percentage on a particular day in a particular environment may frequently fall outside the stated range. But MSHA is not applying a single conversion factor to individual elemental carbon measurements and claiming knowledge of the total dpm corresponding to each separate measurement. Instead, MSHA is applying an average conversion factor to an average of measurements in order to derive an estimate of an average dpm exposure. Averages are always less widely dispersed than individual values.

[15] Median concentrations were not reported. The geometric mean provides a smoothed estimate of the median.

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Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[16] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

It follows that the median mass concentration of dpm can be estimated as 2.64 (i.e., 1/(0.473×0.8)) times the geometric mean EC reported for dock workers, 3.42 times the geometric mean EC for truck drivers, and 3.65 times the geometric mean EC for truck mechanics. Applying the 2.64 conversion factor to the range of geometric mean EC concentrations reported for dock workers (i.e., 23 to 55 μg/m³) results in an estimated range of 61 to 145 μg/m³ in median dpm concentrations at various docks. Similarly, the estimated range of median dpm concentrations is calculated to be 6.8 to 24 μg/m³ for truck drivers and 18 to 102 μg/m³ for truck mechanics. It should be noted that MSHA is using conversion factors only for those occupational groups whose geometric mean exposures have been reported in terms of EC measurements.

Average exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m³.

For comparison with the exposures reported for these other industries, median dpm exposures measured within sampled mines were calculated directly from the data described in subsections a, b, and c above. The median within each mine is shown as the horizontal "belt" plotted for the mine in Figures III–1, III–2, and III–3.

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m³, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m³, 6.8 to 24 μg/m³, 18 to 102 μg/m³ and 49 to 191 μg/m³. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m³, with filters employed at mines showing the lower concentrations.[17] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m³, and for surface mines it is 19 to 160 μg/m³. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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[16] MSHA calculated the ratio for truck drivers by taking a weighted average of the ratios reported for "local drivers" and "road drivers."

[17] One commenter misinterpreted the tops of the ranges plotted in Figure III–4. This commenter apparently mistook the top of the range depicted for underground coal mines as the mean or median dpm exposure concentration measured across all underground coal mines. The top of this range (at 2100 μg/m³, actually represents the highest median concentration at any of the coal mines sampled. It corresponds to the "belt" plotted for Mine "G" (with no after-filters) in Figure III–1. The bottom of the same bar, at 55 μg/m³, corresponds to the "belt" plotted for Mine H ª (with after-filters) in Figure III–1.

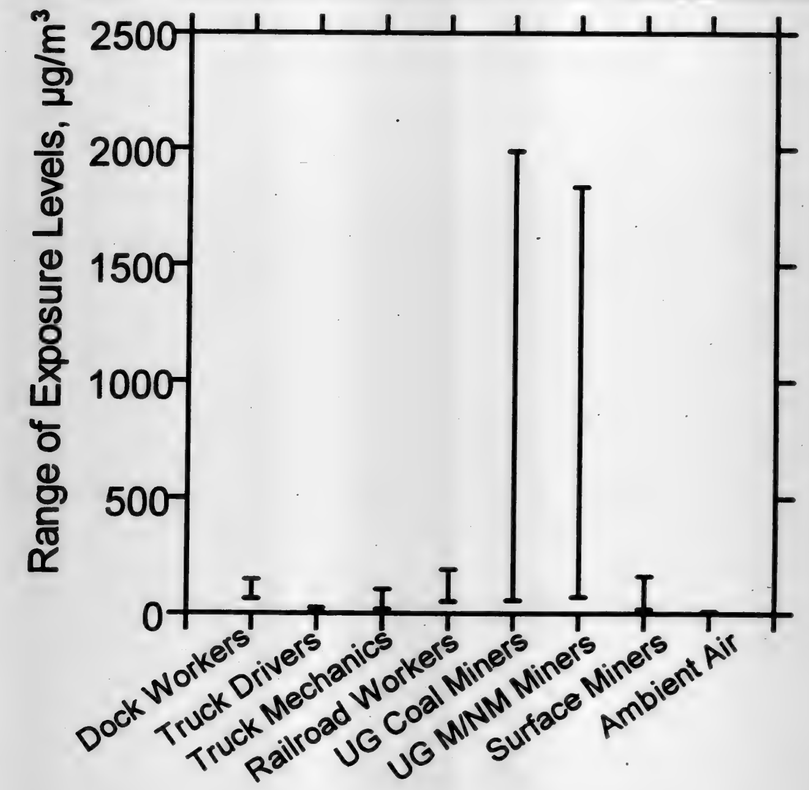


Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly mean for different months and locations in Southern California. Range for ambient air is roughly 1 to 10 μg/m³.

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urben areas,[18] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[19]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 $\mu g/m^3$ at underground M/NM mines "U" and "Z"—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

IMC Global further objected to Figure III–4 on the grounds that "* * * the assumptions that MSHA used to develop that figure are grossly inaccurate and do not make sense in the context of a dose-response relationship between lung cancer and Dpm exposure." IMC Global suggested that the comparison in Figure III–4 be deleted for this reason. MSHA believes that the comparison is informative and that empirical evidence should be used, when it is available, even though the evidence was not generated under ideal, theoretical dose-response model conditions. The issue of whether Figure III–4 is consistent with an exposure-response relationship for dpm is addressed in Subsection 3.a.iii(4) of this risk assessment.

2. Health Effects Associated With Dpm Exposures

This section reviews the various health effects (of which MSHA is aware) that may be associated with dpm exposures. The review is divided into three main sections: acute effects, such as diminished pulmonary function and eye irritation; chronic effects, such as lung cancer; and mechanisms of toxicity. Prior to that review, however, the relevance of certain types of information will be considered. This discussion will address the relevance of health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air.

Several commenters described medical surveillance studies that NIOSH and/or the former Bureau of Mines had carried out in the late 1970s and early 1980s on underground miners employed in western, dieselized coal mines. These commenters urged MSHA to make these studies available and to consider the results in this rulemaking. Some of these commenters also suggested that these data would provide a useful baseline for pulmonary function and lung diseases among miners exposed to dpm, and recommended that follow-up examinations now be conducted to evaluate the possible effects of chronic dpm exposure.

In response to such comments presented at some of the public hearings, another commenter wrote:

> First of all, MSHA is not a research agency, it is a regulatory agency, so that it would be inappropriate for MSHA to initiate research. MSHA did request that NIOSH conduct a risk assessment on the health effects of diesel exhaust and encouraged NIOSH and is currently collaborating with NIOSH (and NCI) on research of other underground miners exposed to diesel exhaust. And third, research on the possible carcinogenicity of diesel particulate matter was not undertaken on coal miners in the West or anywhere else because of the confounding exposure to crystalline silica, also considered a carcinogen, because too few coal miners have been exposed, and for too short a time to conduct a valid study. It was not arbitrariness or indifference on MSHA's part that it did not initiate research on coal miners; it was not within their mandate and it is inappropriate in any event. [UMWA]

Three reports summarizing and presenting results from these medical surveillance studies related to dpm exposures in coal mines were, in fact, utilized and cited in the proposed risk assessment (Ames *et al.*, 1982; Reger *et al.*, 1982; Ames *et al.*, 1984). Ames *et al.* (1982) evaluated acute respiratory effects, and their results are considered in Subsection 2.b.ii of this risk assessment. Reger *et al.* (1982) and Ames *et al.* (1984) evaluated chronic effects, and their results are considered in Subsection 2.c.i(1).

A fourth report (Glenn *et al.*, 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble *et al.* (1978) and are considered

[18] It should be noted, however, that 24-hour environmental exposures for a full lifetime are not directly comparable with workday exposures over an occupational lifetime. If it is assumed that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day, then the amount of air inhaled over the course of a 70-year lifetime is approximately 4.7 times the amount inhaled over a 45-year occupational lifetime with 240 working days per year.

[19] One commenter pointed out that the measurements for miners included both area and personal samples but provided no evidence that this would invalidate the comparison. As pointed out in Subsections 1.a and 1.b, area samples did not dominate the upper end of MSHA's dpm measurements. Furthermore, Figure III–4 presents a comparison of medians rather than means or individual measurements, so inclusion of the area samples has very little impact on the results.

in Subsection 2.b.ii of this risk assessment. Attfield (1979), Attfield *et al.* (1982), and Gamble *et al.* (1983) evaluated effects in M/NM mines, and their results are considered in Subsection 2.c.i(1). The general summary provided by Glenn *et al.* (1983) was among the reports that one commenter (MARG) listed as having received inadequate attention in the proposed risk assessment. In that context, the general results summarized in this report are discussed, under the heading of "Counter-Evidence," in Subsection 2.c.i(2)(a) of this risk assessment.

a. Relevancy Considerations

i. Animal Studies

Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable—both in helping to identify potential human health hazards and in providing a means for studying toxicological mechanisms. Respondents to MSHA's ANPRM who addressed the question of relevancy urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that exhibit relatively little biological variation prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled "Mechanisms of Toxicity" below.

Animal evidence also can help isolate the cause of adverse health effects observed among humans exposed to a variety of potentially hazardous substances. If, for example, the epidemiologic data are unable to distinguish between several possible causes of increased risk of disease in a certain population, then controlled animal studies may provide evidence useful in suggesting the most likely explanation—and provide that information years in advance of definitive evidence from human observations.

Furthermore, results from animal studies may also serve as a check on the credibility of observations from epidemiologic studies of human populations. If a particular health effect is observed in animals under controlled laboratory conditions, this tends to corroborate observations of similar effects in humans.

One commenter objected to MSHA's reference to using animal studies as a "check" on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researches use epidemiologic and animal studies "* * * to help understand different aspects of the carcinogenic process." [20] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled "Mechanisms of Toxicity." However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

Other commenters disputed the relevance of at least some animal data to human risk assessment. For example, The West Virginia Coal Association indicated the following comments by Dr. Peter Valberg:

> * * * scientists and scientific advisory groups have treated the rat bioassay for inhaled particles as unrepresentative of human lung-cancer risks. For example, the Presidential/Congressional Commission on Risk Assessment and Risk Management ("CCRARM") noted that the response of rat lungs to inhaled particulate in general is not likely to be predictive of human cancer risks. More specific to dpm, the Clean Air Scientific Advisory Committee ("CASAC"), a peer-review group for the U.S. EPA, has commented on two drafts (1995 and 1998) of the EPA's Health Assessment Document on Diesel Exhaust. On both occasions, CASAC emphasized that the data from rats are not relevant for human risk assessment. Likewise, the Health Effects Institute also has concluded that rat data should not be used for assessing human lung cancer risk.

Similarly, the NMA commented that the 1998 CASAC review "makes it crystal clear that the rat studies cited by MSHA should not be relied upon as a legitimate indicators of the carcinogenicity of Dpm in humans." The Nevada Mining Association, endorsing Dr. Valberg's comments, added:

> * * * to the extent that MSHA wishes to rest its case on rat studies, Dr. Valberg, among others, has impressively demonstrated that these studies are worthless for human comparison because of rats' unique and species-specific susceptibility to inhaled insoluble particles.

However, neither Dr. Valberg nor the Nevada Mining Association provided evidence that rats' susceptibility to inhaled insoluble particles was "unique" and that humans, for example, were not also susceptible to lung overload at sufficiently high concentrations of fine particles. Even if (as has apparently been demonstrated) some species (such as hamsters) do not exhibit susceptibility similar to rats, this by no means implies that rats are the only species exhibiting such susceptibility.

These commenters appear at times to be saying that, because studies of lung cancer in rats are (in the commenters' view) irrelevant to humans, MSHA should completely ignore all animal studies related to dpm. To the extent that this was the position advocated, the commenters' line of reasoning neglects several important points:

1. The animal studies under consideration are not restricted to studies of lung cancer responses in rats. They include studies of bioavailability and metabolism as well as studies of immunological and genotoxic responses in a variety of animal species.

2. The context for the determinations cited by Dr. Valberg was risk assessment at ambient levels, rather than the much higher dpm levels to which miners are exposed. The 1995 HEI report to which Dr. Valberg alludes acknowledged a potential mechanism of lung overload in humans at dpm concentrations exceeding 500 $\mu g/m^3$ (HEI, 1995). Since miners may concurrently be exposed to concentrations of mineral dusts significantly exceeding 500 $\mu g/m^3$, evidence related to the consequences of lung overload has special significance for mining environments.

3. The scientific authorities cited by Dr. Valberg and other commenters objected to using existing animal studies for quantitative human risk assessment. MSHA has not proposed doing that. There is an important distinction between extrapolating results from the rat studies to human populations and using them to confirm epidemiologic

[20] This risk assessment is not limited to cancer effects, but the commenter's point can be generalized.

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findings and to identify and explore potential mechanisms of toxicity.

MSHA by no means "wishes to rest its case on rat studies," and it has no intention of doing so. MSHA does believe, however, that judicious consideration of evidence from animal studies is appropriate. The extent to which MSHA utilizes such evidence to help draw specific conclusions will be clarified below in connection with those conclusions.

ii. Reversible Health Effects

Some reported health effects associated with dpm are apparently reversible—*i.e.*, if the worker is moved away from the source for a few days, the symptoms dissipate. A good example is eye irritation.

In response to the ANPRM, questions were raised as to whether so-called "reversible" effects can constitute a "material" impairment. For example, a predecessor constituent of the National Mining Association (NMA) argued that "it is totally inappropriate for the agency to set permissible exposure limits based on temporary, reversible sensory irritation" because such effects cannot be a "material" impairment of health or functional capacity within the definition of the Mine Act (American Mining Congress, 87–0–21, Executive Summary, p. 1, and Appendix A).

MSHA does not agree with this categorical view. Although the legislative history of the Mine Act is silent concerning the meaning of the term "material impairment of health or functional capacity," and the issue has not been litigated within the context of the Mine Act, the statutory language about risk in the Mine Act is similar to that under the OSH Act. A similar argument was dispositively resolved in favor of the Occupational Safety and Health Administration (OSHA) by the 11th Circuit Court of Appeals in *AFL–CIO* v. *OSHA*, 965 F.2d 962, 974 (1992).

In that case, OSHA proposed new limits on 428 diverse substances. It grouped these into 18 categories based upon the primary health effects of those substances: *e.g.*, neuropathic effects, sensory irritation, and cancer. (54 FR 2402). Challenges to this rule included the assertion that a "sensory irritation" was not a "material impairment of health or functional capacity" which could be regulated under the OSH Act. Industry petitioners argued that since irritant effects are transient in nature, they did not constitute a "material impairment." The Court of Appeals decisively rejected this argument.

The court noted OSHA's position that effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and be seriously disabling in some cases. Moreover, there was evidence that workers exposed to these sensory irritants could be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. (*Id.* at 974). This evidence included information from NIOSH about the general consequences of sensory irritants on job performance, as well as testimony by commenters on the proposed rule supporting the view that such health effects should be regarded as material health impairments. While acknowledging that "irritation" covers a spectrum of effects, some of which can be minor, OSHA had concluded that the health effects associated with exposure to these substances warranted action—to ensure timely medical treatment, reduce the risks from increased absorption, and avoid a decreased resistance to infection (*Id.* at 975). Finding OSHA's evaluation adequate, the Court of Appeals rejected petitioners' argument and stated the following:

> We interpret this explanation as indicating that OSHA finds that although minor irritation may not be a material impairment, there is a level at which such irritation becomes so severe that employee health and job performance are seriously threatened, even though those effects may be transitory. We find this explanation adequate. OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment. Moreover, section 6(b)(5) of the Act charges OSHA with addressing all forms of "material impairment of health or functional capacity," and not exclusively "death or serious physical harm" or "grave danger" from exposure to toxic substances. See 29 U.S.C. 654(a)(1), 655(c). [*Id.* at 974].

In its comments on the proposed rule, the NMA claimed that MSHA had overstated the court's holding. In making this claim, the NMA attributed to MSHA an interpretation of the holding that MSHA did not put forth. In fact, MSHA agrees with the NMA's interpretation as stated in the following paragraph and takes special note of the NMA's acknowledgment that transitory or reversible effects can sometimes be so severe as to seriously threaten miners' health and safety:

> NMA reads the Court's decision to mean (as it stated) that "minor irritation may not be a material impairment" * * * but that irritation can reach "a level at which [it] becomes so severe that employee health and job performance are seriously threatened even though those effects may be transitory." * * * AMC in 1992 and NMA today are fully in accord with the view of the 11th Circuit that when health effects, transitory or otherwise, become so "severe" as to "seriously threaten" a miner's health or job performance, the materiality threshold has been met.

The NMA, then, apparently agrees with MSHA that sensory irritations and respiratory symptoms can be so severe that they cross the material impairment threshold, regardless of whether they are "reversible." Therefore, as MSHA has maintained, such health effects are highly relevant to this risk assessment—especially since impairments of a miner's job performance in an underground mining environment could seriously threaten the safety of both the miner and his or her co-workers. Sensory irritations may also impede miners' ability to escape during emergencies.

The NMA, however, went on to emphasize that "* * * federal appeals courts have held that 'mild discomfort' or even 'moderate irritation' do not constitute 'significant' or 'material' health effects":

> In International Union v. Pendergrass, 878 F. 2d 389 (1989), the D.C. Circuit upheld OSHA's formaldehyde standard against a challenge that it did not adequately protect against significant noncarcinogenic health effects, even though OSHA had found that, at the permissible level of exposure, "20% of workers suffer 'mild discomfort', while 30% more experience 'slight discomfort'." Id. at 398. Likewise, in *Texas Independent Ginners Ass'n.* v. *Marshall*, 630 F, 2d 398 (1980), the Fifth Circuit Court of Appeals held that minor reversible symptoms do not constitute material impairment unless OSHA shows that those effects might develop into chronic disease. Id. at 408–09.

MSHA is fully aware of the distinction that courts have made between mild discomfort or irritation and transitory health effects that can seriously threaten a miner's health and safety. MSHA's position, after reviewing the scientific literature, public testimony, and comments, is that all of the health effects considered in this risk assessment fall into the latter category.

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air

There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that "fine" particulates (i.e., particles less than 2.5 μm in diameter) are more strongly associated than "coarse" respirable particulates (i.e., particles greater than 2.5 μm but less than 10 μm in diameter) with the adverse health effects observed (EPA, 1996).

MSHA recognizes that there are two difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational dpm exposures. First, although dpm is a fine particulate, ambient air also contains fine particulates other than dpm. Therefore, health effects associated with exposures to fine particulate matter in air pollution studies are not associated specifically with exposures to dpm or any other one kind of fine particulate matter. Second, observations of adverse health effects in segments of the general population do not necessarily apply to the population of miners. Since, due to age and selection factors, the health of miners differs from that of the public as a whole, it is possible that fine particles might not affect miners, as a group, to the same degree as the general population.

Some commenters reiterated these two points, recognized by MSHA in the proposal, without addressing MSHA's stated reasons for including health effects associated with fine particulates in this risk assessment. There are compelling reasons why MSHA considered this body of evidence in this rulemaking.

Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below the dpm concentrations studied in occupational settings. The potency of dpm differs from the total fine particulate found in ambient air. This makes it difficult to establish a specific exposure-response relationship for dpm that is based on fine particle results. However, this does not mean that these results should be ignored in a dpm risk assessment. The available evidence of adverse health effects associated with fine particulates is still highly relevant for dpm hazard identification. Furthermore, as shown in Subsection 3.c.ii of this risk assessment, the fine particle research findings can be used to construct a rough exposure-response relationship for dpm, showing significantly increased risks of material impairment among exposed miners. MSHA's estimates are based on the best available epidemiologic evidence and show risks high enough to warrant regulatory action.

Moreover, extensive scientific literature shows that occupational dust exposures contribute to the development of Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners. Miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). In addition, many miners also smoke tobacco. This places affected miners in subpopulations specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). Some commenters (*e.g.*, MARG) repeated MSHA's observation that the population of miners differs from the general population but failed to address MSHA's concern for miners' increased susceptibility due to COPD incidence and/or smoking habits. The Mine Act requires that standards "* * * most adequately assure on the basis of the best available evidence that no miner suffer material impairment of health or functional capacity * * *" (Section 101(a)(6), emphasis added). This most certainly authorizes MSHA to protect miners who have COPD and/or smoke tobacco.

MARG also submitted the opinion that if "* * * regulation of fine particulate matter is necessary, it [MSHA] should propose a rule dealing specifically with the issue of concern, rather than a rule that limits total airborne carbon or arbitrarily singles out diesel exhaust * * *." MSHA's concern is not with "total airborne carbon" but with dpm, which consists mostly of submicrometer airborne carbon. At issue here, however, are the adverse health effects associated with dpm exposure. Dpm is a type of fine particulate, and there is no evidence to suggest that the dpm fraction contributes less than other fine particulates to adverse health effects linked to exposures in ambient air.

For this reason, and because miners may be especially susceptible to fine particle effects, MSHA has concluded, after considering the public comments, that the body of evidence from air pollution studies is highly relevant to this risk assessment. The Agency is, therefore, taking the evidence fully into account.

b. Acute Health Effects

Information pertaining to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn. Subsection 2.a.iii of this risk assessment addressed the relevance to dpm of studies based on exposures to particulate matter in the ambient air.

Only the evidence from human studies will be addressed in this section. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Section 3.a and 3.b contain MSHA's interpretation of the evidence relating dpm exposures to acute health hazards.

i. Symptoms Reported by Exposed Miners

Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the dpm workshops conducted in 1995, a miner reported headaches and nausea experienced by several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that smoke from poorly maintained equipment, or from improper fuel use, irritates the eyes, nose, and throat. "We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again." (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

At the 1998 public hearings on MSHA's proposed dpm rule for coal mines, one miner, with work experience in a coal mine utilizing diesel haulage equipment at the face, testified that

> * * * unlike many, I have not experienced the headaches, the watering of the eyes, the cold-like symptoms and walking around in this cloud of smoke. Maybe it's because of the maintenance programs. Maybe it's because of complying with ventilation. * * * after 25 years, I have not shown any effects. [SLC, 1998]

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that "there had been a problem recognized in review with that exhaust system on that particular piece of equipment" and that the pneumonia may have

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developed due to "idiosyncracy of his lungs that respond to any type of a respiratory irritant." The manager suggested that this incident should not be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[21]

Another miner, who had worked at the same underground mine before and after diesel haulage equipment was introduced, indicated that he and his co-workers began experiencing acute symptoms after the diesel equipment was introduced. This miner suggested that these effects were linked to exposure, and referring to a co-worker stated:

> * * * had respiratory problems, after * * * diesel equipment was brought into that mine—he can take off for two weeks vacation, come back—after that two weeks, he felt pretty good, his respiratory problems would straighten up, but at the very instant that he gets back in the face of diesel-powered equipment, it starts up again, his respiratory problems will flare up again, coughing, sore throat, numerous problems in his chest. (Birm., 1998).

Several other underground miners asserted there was a correlation between diesel exposure levels and the frequency and/or intensity of respiratory symptoms, eye irritations, and chest ailments. One miner, for example, stated:

> I've experienced [these symptoms] myself. * * * other miners experience the same kind of distresses * * * Some of the stresses you actually can feel—you don't need a gauge to measure this—your burning eyes, nose, throat, your chest irritation. The more you're exposed to, the higher this goes. This includes headaches and nausea and some lasting congestion, depending on how long you've been exposed per shift or per week.
>
> The men I represent have experienced more cold-like symptoms, especially over the past, I would say, eight to ten years, when diesel has really peaked and we no longer really use much of anything else. [SLC, 1998]

Kahn *et al.* (1988) conducted a study of the prevalence and seriousness of such complaints, based on United Mine Workers of America records and subsequent interviews with the miners involved. The review involved reports at five underground coal mines in Utah and Colorado between 1974 and 1985. Of the 13 miners reporting symptoms: 12 reported mucous membrane irritation, headache and light-headiness; eight reported nausea; four reported heartburn; three reported vomiting and weakness, numbness, and tingling in extremities; two reported chest tightness; and two reported wheezing (although one of these complained of recurrent wheezing without exposure). All of these incidents were severe enough to result in lost work time due to the symptoms (which subsided within 24 to 48 hours).

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn *et al.* typified this kind of evidence in that it was "totally devoid of any correlation to actual exposure levels." A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[22]

With respect to the same article (Kahn *et al.*, 1988), and notwithstanding the NMA's claim that the article was totally devoid of any correlation to exposure levels, the NMA also stated that MSHA:

> * * * neglects to include in the preamble the article's description of the conditions under which the "overexposures" occurred, *e.g.*, "poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel. The NMA asserted that these conditions, cited in the article, "have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996."[23] Furthermore, despite its reservations about anecdotal evidence:
>
> NMA is mindful of the testimony of several miners in the coal proceeding who complained of transient irritation owing to exposure to diesel exhaust. * * * the October 1996 regulations together with the phased-in introduction of catalytic converters on all outby equipment and the introduction of such devices on permissible equipment when such technology becomes available will address the complaints raised by the miners.

The NMA provided no evidence, however, that elimination of the conditions described by Kahn *et al.*, or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. MSHA completed an analysis of the impact of the 1996 diesel regulations for underground coal mines (See Part II, Section 7). We do expect that the concentrations of diesel emissions at the section loading point and during longwall moves will be reduced as these provisions are fully implemented. These dpm levels, though reduced, are still above the exposures expected to cause sensory irritations and respiratory symptoms (See Section 3(d)(5)). MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines when developing the 1996 underground coal diesel regulations. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. In addition, the NMA did not provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposures under other conditions.

In the proposal for the present rule, MSHA requested additional information about such effects from medical personnel who have treated miners. IMC Global submitted letters from four healthcare practitioners in Carlsbad, NM, including three physicians. None of these practitioners attributed any cases of respiratory problems or other acute symptoms to dpm exposure. Three of the four practitioners noted that they had observed respiratory symptoms among exposed miners but attributed these symptoms to chronic lung conditions, smoking, or other factors. One physician stated that "[IMC Global], which has used diesel equipment in its mining operations for over 20 years, has never experienced a single case of injury or illness caused by exposures to diesel particulates."

ii. Studies Based on Exposures to Diesel Emissions

Several experimental and statistical studies have been conducted to investigate acute effects of exposure to diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that "levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops." No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced "intolerable" irritation in some subjects while the average irritation score was midway between "some" irritation and a "conspicuous but tolerable" irritation level. Diluting the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of "intolerable" eye irritation.

A study of underground iron ore miners exposed to diesel emissions found no difference in spirometry measurements taken before and after a work shift (Jörgensen and Svensson 1970). Similarly, another study of coal miners exposed to diesel emissions detected no statistically significant relationship between exposure and changes in pulmonary function (Ames *et al.* 1982). However, the authors noted that the lack of a statistically significant result might be due to the low concentrations of diesel emissions involved.

Gamble *et al.* (1978) observed decreases in pulmonary function over a single shift in salt miners exposed to diesel emissions. Pulmonary function appeared to deteriorate in relation to the concentration of diesel exhaust, as indicated by NO_2; but this effect was confounded by the presence of NO_2 due to the use of explosives.

Gamble *et al.* (1987a) assessed response to diesel exposure among 232 bus garage workers by means of a questionnaire and before- and after-shift spirometry. No significant relationship was detected between diesel exposure and change in pulmonary function. However, after adjusting for age and smoking status, a significantly elevated prevalence of reported symptoms was found in the high-exposure group. The strongest associations with exposure were found for eye irritation, labored breathing, chest tightness, and wheeze. The questionnaire was also used to compare various acute symptoms reported by the garage workers and a similar population of workers at a lead acid battery plant who were not exposed to diesel fumes. The prevalence of work-related eye irritations, headaches, difficult or labored breathing, nausea, and wheeze was significantly higher in the diesel bus garage workers, but the prevalence of work-related sneezing was significantly lower.

Ulfvarson *et al.* (1987) studied effects over a single shift on 47 stevedores exposed to dpm at particle concentrations ranging from 130 μ/m^3 to 1000 μ/m^3. Diesel particulate concentrations were determined by collecting particles on glass fiber filters of unspecified efficiency. A statistically significant loss of pulmonary function was observed, with recovery after 3 days of no occupational exposure.

To investigate whether removal of the particles from diesel exhaust might reduce the "acute irritative effect on the lungs" observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. The filters used were specially constructed from 144 layers of glass fiber with "99.97% degrees of retention of dioctylphthalate mist with particle size 0.3 µm." Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

In addition to confirming the earlier observation of significantly reduced pulmonary function after a single shift of occupational exposure, the study found that the stevedores in the group exposed only to filtered exhaust had 50–60% less of a decline in forced vital capacity (FVC) than did those stevedores who worked with unfiltered equipment. Similar results were observed for a subgroup of six stevedores who were exposed to filtered exhaust on one shift and unfiltered exhaust on another. No loss of pulmonary function was observed for the unexposed control group. The authors suggested that these results "support the idea that the irritative effect of diesel exhausts [sic] to the lungs is the result of an interaction between particles and gaseous components and not of the gaseous components alone." They concluded that "* * * it should be a useful practice to filter off particles from diesel exhausts in work places even if potentially irritant gases remain in the emissions" and that "removal of the particulate fraction by filtering is an important factor in reducing the adverse effect of diesel exhaust on pulmonary function."

Rudell *et al.* (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing. The most prominent symptoms were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased irritant symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46-percent reduction in median particle number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Asthma diagnosis was based on symptoms, pulmonary function tests, and measurement of airway hyperreactivity to methacholine or exercise.

Although MSHA is not aware of any other published report directly relating diesel emissions exposures to the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. Studies published through 1997 are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

Diaz-Sanchez *et al.* (1994) challenged healthy human volunteers by spraying

[21] MSHA realizes the incidents related in this subsection are anecdotal and draws no statistical conclusions from them. Since they pertain to specific experiences, however, they can be useful in identifying a potential hazard.

[22] MSHA sees potential value in anecdotal evidence when it relates to immediate experiences. MSHA regards anecdotal evidence to be less appropriate for identifying chronic health effects, since chronic effects cannot readily be linked to specific experiences. Accordingly, this risk assessment places little weight on anecdotal evidence for the chronic health hazards considered.

[23] The 1996 regulations to which the NMA was referring do not apply to M/NM mines.

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300 μg dpm into their nostrils.[24] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.*, histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[25] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez *et al.* (1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 μg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

Salvi *et al.* (1999) exposed healthy human volunteers to diluted diesel exhaust at a dpm concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Although there were no changes in pulmonary function, there were significant increases in various markers of allergic response in airway lavage fluid. Bronchial biopsies obtained six hours after exposure also showed significant increases in markers of immunologic response in the bronchial tissue. Significant increases in other markers of immunologic response were also observed in peripheral blood following exposure. A marked cellular inflammatory response in the airways was reported. The authors concluded that "at high ambient concentrations, acute short-term DE [diesel exhaust] exposure produces a well-defined and marked systemic and pulmonary inflammatory response in healthy human volunteers, which is underestimated by standard lung function measurements."

[24] Assuming that a working miner inhales approximately 1.25 m^3 of air per hour, this dose corresponds to a 1-hour exposure at a dpm concentration of 240 $\mu g/m^3$.

[25] IgE is one of five types of immunoglobulin, which are proteins produced in response to allergens. Cytokine (mentioned later) is a substance involved in regulating IgE production.

iii. Studies Based on Exposures to Particulate Matter in Ambient Air

Due to an incident in Belgium's industrial Meuse Valley, it was known as early as the 1930s that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that over 3,000 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

A significant elevation in particulate matter (along with SO_2 and its oxidation products) was measured during a 1948 incident in Donora, PA. Of the Donora population, 42.7 percent experienced some acute adverse health effect, mainly due to irritation of the respiratory tract. Twelve percent of the population reported difficulty in breathing, with a steep rise in frequency as age progressed to 55 years (Schrenk, 1949).

Approximately as projected by Firket (1931), an estimated 4,000 deaths occurred in response to a 1952 episode of extreme air pollution in London. The nature of these deaths is unknown, but there is clear evidence that bronchial irritation, dyspnea, bronchospasm, and, in some cases, cyanosis occurred with unusual prevalence (Martin, 1964).

These three episodes "left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures" and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 $\mu g/m^3$. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 $\mu g/m_3$, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

Subsequently, between 1986 and 1996, increasingly sophisticated techniques of particulate measurement and statistical analysis have enabled investigators to address these questions more quantitatively. The studies on acute effects carried out since 1986 are reviewed in the 1996 EPA Air Quality Criteria for Particulate Matter, which forms the basis for the discussion below (EPA, 1996).

At least 21 studies have been conducted that evaluate associations between acute mortality and morbidity effects and various measures of fine particulate levels in the ambient air. These studies are identified in Tables III–2 and III–3. Table III–2 lists 11 studies that measured primarily fine particulate matter using filter-based optical techniques and, therefore, provide mainly qualitative support for associating observed effects with fine particles. Table III–3 lists quantitative results from 10 studies that reported gravimetric measurements of either the fine particulate fraction or of components, such as sulfates, that serve as indicators or surrogates of fine particulate exposures.

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Table III-2. — Studies of acute health effects using filter based optical indicators of fine particles in the ambient air.

City	Study Years	Indicator*	Reference†
Acute Mortality			
London	1963-1972 (winters) 1965-1972 (winters)	BS	Thurston et al., 1989 Ito et al., 1993
Athens	1975-1987 July, 1987 1984-1988	BS	Katsouyanni et al., 1990 Katsouyanni et al., 1993 Touloumi et al., 1994
Los Angeles	1970-1979 1970-1979	KM	Shumway et al., 1988 Kinney and Ozkaynak, 1991
Santa Clara	1980-1986 (winters)	COH	Fairley, 1990
Increased Hospitalization			
Barcelona	1985-1989	BS	Sunyer et al., 1993
Acute Change in Pulmonary Function			
Wageningen, Netherlands		BS	Hoek and Brunkreef, 1993
Netherlands		BS	Roemer et al., 1993

† All references are from EPA, 1996

*BS (black smoke), KM (carbonaceous material), and COH (coefficient of haze) are optical measurements that are most directly related to elemental carbon concentrations, but only indirectly to mass. Site specific calibrations and/or comparisons of such optical measurements with gravimetric mass measurements in the same time and city are needed to make inferences about particle mass. However, all three of these indicators preferentially measure carbon particles found in the fine fraction of total airborne particulate matter. (EPA, 1996).

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Table III-3. —Studies of acute health effects using gravimetric indicators of fine particles in the ambient air.

Study	Indicator	RR per 25 μg/m³ $PM_{2.5}$ increase (95% Confidence Interval)	Mean $PM_{2.5}$ Levels (Min/Max)†
Acute Mortality			
Six Cities[A] (overall)	$PM_{2.5}$	1.038 (1.026, 1.055)	
Portage, WI	$PM_{2.5}$	1.030 (0.993, 1.071)	11.2 (±7.8)
Topeka, KS	$PM_{2.5}$	1.020 (0.961, 1.092)	12.2 (±7.4)
Boston, MA	$PM_{2.5}$	1.055 (1.038, 1.071)	15.7 (±9.2)
St. Louis, MO	$PM_{2.5}$	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	$PM_{2.5}$	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	$PM_{2.5}$	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN[B]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 3.1 - 8.2
Ontario, CAN[C]	$SO_4^=$ O_3	1.03 (1.02, 1.04) 1.03 (1.02, 1.05)	Min/Max = 2.0 - 7.7
NYC/Buffalo, NY[D]	$SO_4^=$	1.06 (1.01, 1.10)	NR
Toronto, CAN[D]	H⁺(Nmol/m³) $SO_4^=$ $PM_{2.5}$	1.16 (1.03, 1.30)* 1.12 (1.00, 1.24) 1.15 (1.02, 1.78)	28.8 (NR, 391) 7.6 (NR, 48.7) 18.6 (NR, 66.0)
Increased Respiratory Symptoms			
Southern California[F]	$SO_4^=$	1.48 (1.14, 1.91)	R = 2 - 37
Six Cities[G] (Cough)	$PM_{2.5}$ $PM_{2.5}$ Sulfur H⁺	1.19 (1.01, 1.42)** 1.23 (0.95, 1.59)** 1.06 (0.87, 1.29)**	18.0 (7.2, 37)*** 2.5 (3.1, 61)*** 18.1 (0.8, 5.9)***
Six Cities[G] (Lower Resp. Symp.)	$PM_{2.5}$ $PM_{2.5}$ Sulfur H⁺	1.44 (1.15 - 1.82)** 1.82 (1.28 - 2.59)** 1.05 (0.25 - 1.30)**	18.0 (7.2, 37)*** 2.5 (0.8, 5.9)*** 18.1 (3.1, 61)***
Denver, CO[P] (Cough, adult asthmatics)	$PM_{2.5}$ $SO_4^=$ H⁺	0.0012 (0.0043)**** 0.0042 (0.00035)**** 0.0076 (0.0038)****	0.41 - 73 0.12 - 12 2.0 - 41
Decreased Lung Function			
Uniontown, PA[E]	$PM_{2.5}$	PEFR 23.1 (-0.3,36.9) (per 25 μg/m³)	25/88 (NR/88)
Seattle, WA[Q] (Asthmatics)	b_{scat} calibrated by $PM_{2.5}$	FEV1 42 ml (12,73) FVC 45 ml (20,70)	5/45

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)
[B] Burnett et al. (1994)
[C] Burnett et al. (1995) O_3
[D] Thurston et al. (1992, 1994)
[E] Neas et al. (1995)
[F] Ostro et al. (1993)
[G] Schwartz et al. (1994)
[P] Ostro et al. (1991)
[Q] Koenig et al. (1993)

† Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).
* Change per 100 nmoles/m³.
** Change per 20 μg/m³ for $PM_{2.5}$; per 5 μg/m³ for $PM_{2.5}$ sulfur; per 25 nmoles/m³ for H⁺.
*** 50th percentile value (10,90 percentile).
**** Coefficient and SE in parenthesis.

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A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 μg/m³, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 μg/m³ in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population, excluding accidents, suicides, and homicides. Based on Schwartz et al. (1996), the relative risk of mortality in the general population increases by about 2.6 to 5.5 percent per 25 μg/m³ of fine particulate ($PM_{2.5}$) (EPA, 1996). More specifically, Schwartz *et al.* (1996) reported significantly elevated risks of mortality due to pneumonia, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD). For these three causes of death, the estimated increases in risk per incremental increase of 10 μg/m³ in the concentration of $PM_{2.5}$ were 4.0 percent, 3.3 percent, and 2.1 percent, respectively. Each of these three results was statistically significant at a 95-percent confidence level.

A total of 22 studies were published on associations between short-term particulate levels and hospital admissions, outpatient visits, and emergency room visits for respiratory disease, Chronic Obstructive Pulmonary Disease (COPD), pneumonia, and heart disease (EPA, 1996). Fifteen of these studies were focused on the elderly. Of the seven that dealt with all ages (or in one case, persons less than 65 years old), all showed positive results. All of the five studies relating fine particulate measurements to increased hospitalization, listed in Tables III–2 and III–3, dealt with general age populations and showed statistically significant associations. The estimated increase in risk ranges from 3 to 16 percent per 25 μg/m³ of fine particulate. Overall, these studies are indicative of acute morbidity effects being related to fine particulate matter and support the mortality findings.

Most of the 14 published quantitative studies on ambient particulate exposures and acute respiratory diseases were restricted to children (EPA, 1996, Table 12–12). Although they generally showed positive associations, and may be of considerable biological relevance, evidence of toxicity in children is not necessarily applicable to adults. The few studies on adults have not produced statistically significant evidence of a relationship.

Thirteen studies since 1982 have investigated associations between ambient particulate levels and loss of pulmonary function (EPA, 1996, Table 12–13). In general, these studies suggest a short term effect, especially in symptomatic groups such as asthmatics, but most were carried out on children only. In a study of adults with mild COPD, Pope and Kanner (1993) found a 29 ± 10 ml decrease in 1-second Forced Expiratory Volume (FEV_1) per 50 μg/m³ increase in PM_{10}, which is similar in magnitude to the change generally observed in the studies on children. In another study of adults, with PM_{10} ranging from 4 to 137 μg/m³, Dusseldorp et al. (1995) found 45 and 77 ml/sec decreases, respectively, for evening and morning Peak Expiratory Flow Rate (PEFR) per 50 μg/m³ increase in PM_{10} (EPA, 1996). In the only study carried out on adults that specifically measured fine particulate ($PM_{2.5}$), Perry et al. (1983) did not detect any association of exposure with loss of pulmonary function. This study, however, was conducted on only 24 adults (all asthmatics) exposed at relatively low concentrations of $PM_{2.5}$ and, therefore, had very little power to detect any such association.

c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel "have spit up black stuff every night, big black—what they call black (expletive) * * * [they] have the congestion every night * * * the 60-year-old man working there 40 years." Similarly, in comments submitted in response to MSHA's proposed dpm regulations, several miners reported cancers and chronic respiratory ailments they attributed to dpm exposure.

Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section of the risk assessment. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Subsection 3.a(iii) contains MSHA's interpretation of the evidence relating dpm exposures to one chronic health hazard: lung cancer.

i. Studies Based on Exposures to Diesel Emissions

The discussion will (1) summarize the epidemiologic literature on chronic effects other than cancer, and then (2) concentrate on the epidemiology of cancer in workers exposed to dpm.

(1) Chronic Effects Other Than Cancer

A number of epidemiologic studies have investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms (*i.e.*, chronic cough, chronic phlegm, and breathlessness) or measurable loss in lung function. Three studies involved coal miners (Reger *et al.*, 1982; Ames et al., 1984; Jacobsen *et al.*, 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield *et al.*, 1982; Gamble *et al.*, 1983). Three studies involved other groups of workers—railroad workers (Battigelli *et al.*, 1964), bus garage workers (Gamble *et al.*, 1987), and stevedores (Purdham *et al.*, 1987).

Reger et al. (1982) examined the prevalence of respiratory symptoms and the level of pulmonary function among more than 1,600 underground and surface U.S. coal miners, comparing results for workers (matched for smoking status, age, height, and years worked underground) at diesel and non-diesel mines. Those working at underground dieselized mines showed some increased respiratory symptoms and reduced lung function, but a similar pattern was found in surface miners who presumably would have experienced less diesel exposure. Miners in the dieselized mines, however, had worked underground for less than 5 years on average.

In a study of 1,118 U.S. coal miners, Ames et al. (1984) did not detect any pattern of chronic respiratory effects associated with exposure to diesel emissions. The analysis, however, took no account of baseline differences in lung function or symptom prevalence, and the authors noted a low level of exposure to diesel-exhaust contaminants in the exposed population.

In a cohort of 19,901 British coal miners investigated over a 5-year period, Jacobsen *et al.* (1988) found increased work absence due to self-reported chest illness in underground workers exposed to diesel exhaust, as compared to surface workers, but found

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no correlation with their estimated level of exposure.

Jörgenson & Svensson (1970) found higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among Swedish underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine. No significant difference was found in spirometry results.

Using questionnaires collected from 4,924 miners at 21 U.S. metal and nonmetal mines, Attfield (1979) evaluated the effects of exposure to silica dust and diesel exhaust and obtained inconclusive results with respect to diesel exposure. For both smokers and non-smokers, miners occupationally exposed to diesel for five or more years showed an elevated prevalence of persistent cough, persistent phlegm, and shortness of breath, as compared to miners exposed for less than five years, but the differences were not statistically significant. Four quantitative indicators of diesel use failed to show consistent trends with symptoms and lung function.

Attfield et al. (1982) reported on a medical surveillance study of 630 white male miners at 6 U.S. potash mines. No relationships were found between measures of diesel use or exposure and various health indices, based on self-reported respiratory symptoms, chest radiographs, and spirometry.

In a study of U.S. salt miners, Gamble and Jones (1983) observed some elevation in cough, phlegm, and dyspnea associated with mines ranked according to level of diesel exhaust exposure. No association between respiratory symptoms and estimated cumulative diesel exposure was found after adjusting for differences among mines. However, since the mines varied widely with respect to diesel exposure levels, this adjustment may have masked a relationship.

Battigelli et al. (1964) compared pulmonary function and complaints of respiratory symptoms in 210 U.S. railroad repair shop employees, exposed to diesel for an average of 10 years, to a control group of 154 unexposed railroad workers. Respiratory symptoms were less prevalent in the exposed group, and there was no difference in pulmonary function; but no adjustment was made for differences in smoking habits.

In a study of workers at four diesel bus garages in two U.S. cities, Gamble et al. (1987b) investigated relationships between job tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background. After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with job tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group. The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

Purdham et al. (1987) compared baseline pulmonary function and respiratory symptoms in 17 exposed Canadian stevedores to a control group of 11 port office workers. After adjustment for smoking, there was no statistically significant difference in self-reported respiratory symptoms between the two groups. However, after adjustment for smoking, age, and height, exposed workers showed lower baseline pulmonary function, consistent with an obstructive ventilatory defect, as compared to both the control group and the general metropolitan population.

In a review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that "several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis." Glenn et al (1983) noted that the studies of chronic respiratory effects carried out by NIOSH researchers in coal, salt, potash, and trona mines all "revealed an excess of cough and phlegm in the diesel exposed group." IPCS (1996) noted that "[a]lthough excess respiratory symptoms and reduced pulmonary function have been reported in some studies, it is not clear whether these are long-term effects of exposure." Similarly, Morgan et al. (1997) concluded that while there is "some evidence that the chronic inhalation of diesel fumes leads to the development of cough and sputum, that is chronic bronchitis, it is usually impossible to show a cause and effect relationship * * *." MSHA agrees that these dpm studies are not conclusive but considers them to be suggestive of adverse chronic, non-cancerous respiratory effects.

(2) Cancer

Because diesel exhaust has long been known to contain carcinogenic compounds (*e.g.*, benzene in the gaseous fraction and benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicity studies, and animal studies. In this risk assessment, MSHA has placed the most weight on evidence from the human epidemiologic studies and views the genotoxicity and animal studies as lending support to the epidemiologic evidence.

In the epidemiologic studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is usually assumed to be the agent associated with any excess prevalence of lung cancer observed in the epidemiologic studies. Subsection 2.d of this risk assessment contains a summary of evidence supporting this assumption.

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA's risk assessment as originally proposed.[26] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal–EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with

[26] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64 FR 7144. Säverin et al. (1999) is the published English version of a Germany study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews, including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical "meta-analyses"[27] of the epidemiologic literature: Lipsett and Campleman (1999) thru[28] and Bhatia et al. (1998).[29] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[30] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as "positive." The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a "positive" study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[31]

MSHA recognizes that these 47 studies are not of equal importance for determining whether dpm exposure leads to an increased risk of lung cancer. Some of the studies provide much better evidence than others. Furthermore, since no epidemiologic study can be perfectly controlled, the studies exhibit various strengths and weaknesses, as described by both this risk assessment and a number of commenters. Several commenters, and some of the reviewers cited above, focused on the weaknesses and argued that none of the existing studies is conclusive. MSHA, in accordance with other reviewers and commenters, maintains: (1) That the weaknesses identified in both negative and positive studies mainly cause underestimation of risks associated with high occupational dpm exposure; (2) that it is legitimate to base conclusions on the combined weight of all available evidence and that, therefore, it is not necessary for any individual study to be conclusive; and (3) that even though the 41 positive studies vary a great deal in strength, nearly all of them contribute something to the weight of positive evidence.

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[27] MSHA restricts the term "meta-analysis" to formal, statistical analyses of the pooled data taken from several studies. Some commenters (and Cox in the article itself) referred to the review by Cox (op.cit.) as a meta-analysis. Although this article seeks to identify characteristics of the individual studies that might account for the general pattern of results, it performs no statistical analysis on the pooled epidemiologic data. For this reason, MSHA does not regard the Cox article as a meta-analysis in the same sense as the two studies so identified. MSHA does, however, recognize that the Cox article evaluates and rejects the collective evidence for causality, based on the common characteristics identified. In that context, Cox's arguments and conclusions are addressed in Subsection 3.a.iii. Cox also presents a statistical analysis of data from one of the studies, and that portion of the article is considered here, along with his observations about other individual studies.

[28] MSHA's risk assessment as originally proposed cited an unpublished version, attributed to Lipsett and Alexeeff (1998), of essentially the same meta-analysis. Both the 1999 and 1998 versions are now in the public record.

[29] Silverman (1998) reviewed the meta-analysis by Bhatia et al. (op cit.) and discussed, in general terms, the body of available epidemiologic evidence on which it is based. Some commenters stated that MSHA had not sufficiently considered Silverman's views on the limitations of this evidence. MSHA has thoroughly considered these views and addresses them in Subsection 3.a.(iii).

[30] For simplicity, the epidemiologic studies considered here are placed into two broad categories. A *cohort study* compares the health of persons having different exposures, diets, etc. A *case-control study* starts with two defined groups known to differ in health and compares their exposure characteristics.

[31] The six entirely negative studies are: Kaplan (1959); DeCoufle et al. (1977); Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995).

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Table III-4. — Summary of information from 27 cohort studies on lung cancer and occupational exposure to diesel exhaust.

Study	Occupation	No. of Subjects	Follow-up period	Exposure Assessment	Smk. Adj.	Findings[a]	Stat. Sig.[b]	Comments
Ahlberg et al. (1981)	Male truck drivers	35,883	1961-73	Occupation only		RR = 1.33 for drivers of "ordinary" trucks.	*	Risk relative to males employed in trades thought to have no exposure to "petroleum products or other chemicals." Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.
Ahlman et al. (1991)	Underground sulfide ore miners	597	1968-86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45-64 age group. (calculated by MSHA)		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 338 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988)	Professional drivers	3,392	1950-84	Occupation only		SMR = 0.86 for taxi drivers. SMR = 1.42 for bus drivers. SMR = 1.59 for truck drivers.	*	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989)	Highway maintenance workers	4,849	1945-84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988)	Railroad worker Truck drivers Heavy Eq. Op's. Miners	2,973 16,208 855 2,034	1982-84	Occupation and diesel exposure by questionnaire	✔	RR = 1.24 for truck drivers. RR = 1.59 for railroad workers. RR = 2.60 for heavy Eq. Op's. RR = 2.67 for miners.	* *	Risk relative to workers reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
	All workers	476,648				RR = 1.05 for 1-15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995)	Coal miners	23,630	1973-92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.

Dubrow & Wegman (1984)	Truck & tractor drivers	not reported	1971-73	Occupation only		sMOR = 1.73 based on 176 deaths.	*	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951-83	Occupation only		SMR = 0.7 for overall cohort		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991)	Railroad workers	55,395 (1991 report)	1959-80	Job in 1959 & years of diesel exposure since 1959		RR = 1.31 for 1-4 years. RR = 1.28 for 5-9 years. RR = 1.19 for 10-14 years. RR = 1.40 for 15 or more years.	* * * *	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
Guberan et al. (1992)	Professional drivers	1,726	1961-86	Occupation only		SMR = 1.50	*	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986)	Dock workers	6,071	1961-80	Occupation only		SMR = 1.32 (mortality). SMR = 1.68 (morbidity).	* *	No adjustment for healthy worker effect.
Gustavsson et al. (1990)	Bus garage workers	708	1952-86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970-80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	*	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."

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Howe et al. (1983)	Railroad workers	43,826	1965-77	Jobs classified by diesel exposure		RR = 1.20 for "possibly exposed." RR = 1.35 for "probably exposed."	• •	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure. Possible confounding with asbestos and coal dust.
Johnston et al. (1997)	Underground coal miners	18,166	1950-85	Quantitative, based on detailed job history & surrogate dpm measurements	✔	mine-adjusted model: RR = 1.156 per g-hr/m³ mine-unadjusted model: RR = 1.227 per g-hr/m³		Risk is relative to unexposed workers in cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure. Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953-58	Jobs classified by diesel exposure		SMR=0.88 for operationally exposed. SMR = 0.72 for somewhat exposed. SMR = 0.80 for rarely exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers. No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978)	Truck drivers	183,791	May-July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1993)	Truck drivers	not reported	1965-79	Occupation only		SMR = 1.15	•	
Menck & Henderson (1976)	Truck drivers	34,800 estimated	1968-73	Occupation only		SMR = 1.65	•	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers	2,666 estimated from manyears at risk	1950-55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991)	Truck drivers	868	1951-88	Occupation only		SMR = 2.14	•	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

Rushton et al. (1983)	Bus maintenance workers	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	• •	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999)	Underground potash miners	5,536	1970-94	Quantitative, based on TC measurements & detailed job history		RR = 2.17 for highest compared to least exposed categories. RR=1.03 to 1.225 per mg-yr/m³, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984)	Railroad workers	2,519	1967-79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1.50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk	1950-74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973)	Potash miners	3,886	1941-67	Miners classified as underground or surface		SMR = 1.1 for both underground and surface miners.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
Wong et al. (1985)	Heavy equipment operators	34,156	1964-78	Job histories, latency, & years of union membership		SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member. SMR = 1.12 for ≥20 yr. latency. SMR = 1.30 for 4,075 "normal" retirees. SMR = 3.43 for "high exposure" dozer operators with 15-19 yr union membership & ≥20 yr latency.	• •	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

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Table III-5. — Summary of published information from 20 case-control studies on lung cancer and exposure to diesel exhaust.

Study	Cases	Controls	No. of Cases	No. of Controls	Exposure Assessment	Matching: Smk.	Matching: Additional	Findings[a]	Stat. Sig.[b]	Comments
Benhamou et al. (1988)	Histologically confirmed lung cancers	Non-tobacco related diseases	1,625	3,091	Occupational history by questionnaire.	✔	Sex, age at diagnosis, hospital, interviewer.	RR = 2.14 for miners RR = 1.42 for professional drivers.	• •	Mine type not reported. No evidence of an increase in risk with duration of exposure
Boffetta et al. (1990)	Hospitalized males with histologically confirmed lung cancer	Hospitalized males with no tobacco related disease	2,584	5,099	Occupation classified by probability of diesel exposure	✔	Sex, age within 2 yr, hospital, year of interview.	OR = 0.95 for 13 jobs with probable exposure. OR = 1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
			477	846	Occupational history & duration of diesel exposure by interview			OR = 1.21 for any self-reported diesel exposure. OR = 2.39 for more than 30 yr of self-reported diesel exposure.		
Brüske-Hohlfeld et al. (1999)	Cytologically and/or histologically confirmed lung cancers	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	✔	Sex, age, region of residence.	OR = 1.43 for any occupational diesel exposure during lifetime. OR = 1.56 for West German professional drivers post-1955. OR = 2.88 for > 20 yr in "traffic-related" jobs other than driving. OR = 6.81 for > 30 yr as full-time driver of farm tractors. OR = 4.30 for > 20 yr as heavy equipment operator.	• • • • •	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985)	Histologically confirmed lung cancers	Patients at same hospital	376	892	Occupational history from interview	✔	Sex, age, admission date.	OR = 1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.

Coggon et al. (1984)	Lung cancer deaths of males under 40	Deaths from other causes in males under 40	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure		Sex, death year, region, and birth year (approx.)	RR = 1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	•	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985)	Male patients with lung cancer	One living and one deceased without lung cancer	604	1,071	Job, with tenure, from mailed questionnaire	✔	Sex, death year, age, municipality	RR = 1.9 for non-smoking truck drivers aged <70 yr. RR = 4.5 for non-smoking truck drivers aged ≥70 yr.	•	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.
DeCoufle et al. (1977)	Male patients with lung cancer	Non-neoplastic disease patients	6,434	Not reported	Occupation only, from questionnaire	✔	Unmatched	RR = 0.92 for bus, taxi, and truck drivers. RR = 0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993)	Deaths from primary lung cancer among dock workers	Dock workers without lung cancer	50	154	Semi-quantitative from work history & records of diesel fuel usage	✔	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer	RR = 1.6 for "medium" duration of exposure. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987)	Deaths with primary lung cancer among railroad workers	Deaths from other than cancer, suicide, accidents, or unknown causes	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job	✔	Date of birth and death	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr. RR = 0.91 for 20+ diesel-years in workers aged ≥65 yr.	•	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990)	Deaths from lung cancer among bus garage workers	Non-cases within cohort mortality study	20	120	Semi-quantitative based on job, tenure, & exposure class for each job		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	•	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure
Hall & Wynder (1984)	Hospitalized males with lung cancer	Hospitalized males with no tobacco-related diseases	502	502	Usual occupation by interview	✔	Age, race, hospital, and hospital room status	RR = 1.4 for jobs with diesel exposure. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.

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Hayes et al. (1989)	Lung cancer deaths pooled from 3 studies	Various – lung disease excluded	2,291	2,570	Occupational history by interview	✔	Sex, age, and either race or area of residence	OR = 1.5 for ≥10 yr truck driving. OR = 2.1 for ≥10 yr operating heavy equipment. OR = 1.7 for ≥10 yr bus driving.	*	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for <10 yr in these jobs.
Lerchen et al. (1987)	New Mexico residents with lung cancer	Medicare recipients	506	771	Occupational history, industry, & self-reported exposure, by interview	✔	Sex; age, ethnicity	OR = 0.6 for ≥1 yr occupational exposure to diesel exhaust. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.
Milne et al. (1983)	Lung cancer deaths	Deaths from any other cancer	925	6,565	Occupation from death certificate		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	* *	Inadequate latency allowance.
Morabia et al. (1992)	Male lung cancer patients	Patients without lung cancer or other tobacco-related condition	1,793	3,228	Job, with coal and asbestos exposure durations, by interview	✔	Race, age, hospital, and smoking history	OR = 2.3 for miners. OR = 1.1 for bus drivers. OR = 1.0 for truck or tractor drivers.		Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994)	Professional drivers	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None.	OR = 1.48 for professional drivers.	*	Stratified by age. Indirectly adjusted for smoking, based on smoking-rate for occupation.
Siemiatycki et al. (1988)	Squamous cell lung cancer patients by type of lung cancer	Other cancer patients	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job	✔	None	OR = 1.2 for diesel exposure; OR = 2.8 for mining.		Stratified by age, socioeconomic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners "were exposed to diesel exhaust for short periods of time." Mining included quarrying, so result is likely to be confounded by silica exposure.

Steenland et al. (1990, 1992, 1998)	Deaths from lung CA among Teamsters	Deaths other than lung or bladder cancer or motor vehicle accidents	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data	✔	Time of death within 2 years	OR = 1.27 for diesel truck drivers with 1-24 yr tenure. OR = 1.26 for diesel truck drivers with 25-34 yr tenure. OR = 1.89 for diesel truck drivers with ≥35 yr tenure. OR = 1.50 for truck mechanics with ≥18 yr tenure after 1959.	* * *	Years of tenure not necessarily all at main job (i.e., diesel truck driver). OR adjusted for asbestos exposure.
Swanson et al. (1993) See also Burns & Swanson (1991)	Histologically confirmed Detroit metro area lung cancers	Colon or rectal cancer cases	3,792 males 5,935 total	1,966 males 3,956 total	Occupational history from interview	✔	None	OR = 1.4 for heavy truck drivers with 1-9 yr tenure. OR = 1.6 for heavy truck drivers with 10-19 yr tenure. OR = 2.5 for heavy truck drivers with ≥20 yr tenure. OR = 1.2 for railroad workers with 1-9 yr tenure. OR = 2.5 for railroad workers with ≥10 yr tenure. OR = 2.98 for mining industry workers. OR = 5.03 for mining machinery operators.	* * * *	OR for truck drivers & RR workers is for white males, relative to corresponding group with <1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report) OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by other occupational exposures. (1991 report)
Williams et al. (1977)	Male lung cancer patients	Other male cancer patients	432	2,617	Main lifetime occupation from interview	✔	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepencies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.

[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

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(i) Evaluation Criteria

Several commenters contended that MSHA paid more attention to positive studies than to negative ones and indicated that MSHA had not sufficiently explained its reasons for discounting studies they regarded as providing negative evidence. MSHA used five principal criteria to evaluate the strengths and weaknesses of the individual studies:

(1) power of the study to detect an exposure effect;
(2) composition of comparison groups;
(3) exposure assessment;
(4) statistical significance; and
(5) potential confounders.

These criteria are consistent with those proposed by the HEI Diesel Epidemiology Expert Panel (HEI, 1999). To help explain MSHA's reasons for valuing some studies over others, these five criteria will now be discussed in turn.

Power of the Study

There are several factors that contribute to a study's power, or ability to detect an increased risk of lung cancer in an exposed population. First is the study's size—i.e., the number of subjects in a cohort or the number of lung cancer cases in a case-control study. If few subjects or cases are included, then any statistical relationships are likely to go undetected. Second is the duration and intensity of exposure among members of the exposed group. The greater the exposure, the more likely it is that the study will detect an effect if it exists. Conversely, a study in which few members of the exposed group experienced cumulative exposures significantly greater than the background level is unlikely to detect an exposure effect. Third is the length of time the study allows for lung cancer to exhibit a statistical impact after exposure begins. This involves a latency period, which is the time required for lung cancer to develop in affected individuals, or (mainly pertaining to cohort studies) a follow-up period, which is the time allotted, including latency, for lung cancers in affected individuals to show up in the study. It is generally acknowledged that lung cancer studies should, at the very minimum, allow for a latency period of at least 10 years from the time exposure begins and that it is preferable to allow for latency periods of at least 20 years. The shorter the latency allowance, the less power the study has to detect any increased risk of lung cancer that may be associated with exposure.

As stated above, six of the 47 studies did not show positive results: One of these studies (Edling et al.) was based on a small cohort of 694 bus workers, thus having little statistical power. Three other of these studies (DeCoufle, Kaplan, and Christie) included exposed workers for whom there was an inadequate latency allowance (*i.e.*, less than 10 years). The entire period of follow-up in the Kaplan study was 1953–1958. The Christie study was designed in such a way as to provide for neither a minimum period of exposure nor a minimum period of latency: the report covers lung cancers diagnosed only through 1992, but the "exposed" cohort includes workers who may have entered the work force (and thus begun their exposure) as late as Dec. 31, 1992. Such workers would not be expected to develop lung cancer during the study period. The remaining two negative studies (Bender, 1989 and Waller, 1981) appear to have included a reasonably adequate number of exposed workers and to have allowed for an adequate latency period.

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.*, Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.*, Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[32] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed "general hand" job category. The Milne study did not control for potentially important "confounding" variables, as explained below in MSHA's discussion of that criterion.

[32] As noted in Table III–4, the underground sulfide ore miners studied by Ahlman et al. (1991) were exposed to radon in addition to diesel emissions. The total number of lung cancers observed, however, was greater than what was attributable to the radon exposure, based on a calculation by the authors. Therefore, the authors attributed a portion of the excess risk to diesel exposure.

Composition of Comparison Groups

This criterion addresses the question of how equitable is the comparison between the exposed and unexposed populations in a cohort study, or between the subjects with lung cancer (*i.e.*, the "cases") and the subjects without lung cancer (*i.e.*, the "controls") in a case-control study. MSHA includes bias due to confounding variables under this criterion if the groups differ systematically with respect to such factors as age or exposure to non-diesel carcinogens. For example, unless adequate adjustments are made, comparisons of underground miners to the general population may be systematically biased by the miners' greater exposure to radon gas. Confounding not built into a study's design or otherwise documented is considered potential rather than systematic and is considered under a separate criterion below. Other factors included under the present criterion are systematic (*i.e.*, "differential") misclassification of those placed into the "exposed" and "unexposed" groups, selection bias, and bias due to the "healthy worker effect."

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the "underground miner" subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[33] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of "Exposure Assessment" below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

[33] Furthermore, as pointed out in comments submitted by Dr. Peter Valberg through the NMA, the subgroup of underground miners working at mines with diesel engines was small, and the exposure duration in one of the mines with diesel engines was only ten years. Therefore, the power of the study was inadequate to detect an excess risk of lung cancer for that subgroup by itself.

Another type of selection bias may occur when members of the control group in a case-control study are non-randomly selected. This happens when cases and controls are selected from the same larger population of patients or death certificates, and the controls are simply selected (prior to case matching) from the group remaining after those with lung cancer are removed. Such selection can lead to a control group that is biased with respect to occupation and smoking habits. Specifically, "* * * a severely distorted estimate of the association between exposure to diesel exhaust and lung cancer, and a severely distorted picture of the direction and degree of confounding by cigarette smoking, can come from case-control studies in which the controls are a collection of 'other deaths'" when the cause of most "other deaths" is itself correlated with smoking or occupational choice (HEI, 1999). This selection bias can distort results in either direction.

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of "other deaths" or "other patients."[34] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

It is "well established that persons in the work force tend to be 'healthier' than persons not employed, and therefore healthier than the general population. Worker mortality tends to be below average for all major causes of death." (HEI, 1999) Because workers tend to be healthier than non-workers, the prevalence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of similar workers. This phenomenon is called the "healthy worker effect."

[34] These were: Buiatti et al. (1985), Coggan et al. (1984), DeCoufle et al. (1977), Garshick et al. (1987), Hayes et al. (1989), Lerchen et al. (1987), and Steenland et al. (1990).

All five cohort studies reporting entirely negative results drew comparisons against the general population and made no adjustments to take the healthy worker effect into account. (Kaplan, 1959; Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995)). The sixth negative study (DeCoufle, 1977) was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers. As mentioned earlier, this study did not meet the criterion for a minimum 10-year latency period. All other studies in which exposed workers were compared against similar but unexposed workers reported some degree of elevated lung cancer risk for exposed workers.

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively.[35]

Exposure Assessment

Many commenters suggested that a lack of concurrent exposure measurements in available studies limits their utility for quantitative risk assessment (QRA). MSHA is fully aware of these limitations but also recognizes that less desirable surrogates of exposure must frequently be employed out of practical necessity. As stated by HEI's expert panel on diesel epidemiology:

> Quantitative measures of exposures are important in any epidemiologic study used for QRA. The greater the detail regarding specific exposure, including how much, for how long, and at what concentration, the more useful the study is for this purpose. Frequently, however, individual measurements are not available, and surrogate measures or markers are used. For example, the most general surrogate measures of exposure in occupational epidemiologic studies are job classification and work location. (HEI, 1999)

It is important to distinguish, moreover, between studies used to identify a hazard (i.e., to establish that dpm exposure is associated with an excess risk of lung cancer) and studies used for QRA (i.e., to quantify the amount of excess risk corresponding to a given level of exposure). Although detailed exposure measurements are desirable in any epidemiologic study, they are more important for QRA than for identifying and characterizing a hazard. Conversely, epidemiologic studies can be highly useful for purposes of hazard identification and characterization even if a lack of personal exposure measurements renders them less than ideal for QRA.

Still, MSHA agrees that the quality of exposure assessment affects the value of a study for even hazard identification. Accordingly, MSHA has divided the 47 studies into four categories, depending on the degree to which exposures were quantified for the specific workers included. This ranking refers only to exposure assessment and does not necessarily correspond to the overall weight MSHA places on any of the studies.

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[36] Both of these recent cohort studies took smoking habits into account. These

[35] A similar adjustment was applied to the SMR for lung cancer reported in one of the negative studies (Edling et al., 1987). This raised the SMR from 0.67 to 0.80. Because of insufficient data, Bhatia et al. did not carry out the adjustment for the three other studies they considered with potentially important healthy worker effects. (Bhatia et al., 1998)

[36] The study of German potash miners by Säverin et al. was introduced by NIOSH at the Knoxville public hearing prior to publication. The study, as cited, was later published in English. Although the dpm measurements (total carbon) were all made in one year, the authors provide a justification for assuming that the mining technology and type of machinery used did not change substantially during the period miners were exposed (ibid., p.420).

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studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[37] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[38] With one exception (Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

The bottom rank, with respect to exposure assessment, consists of studies in which no exposure information was collected for individual workers. These studies used only job title to distinguish between exposed and unexposed workers. The remaining 32 studies, including five of the six with entirely negative results, fall into this category.

Studies basing exposure assessments on only a current job title (or even a history of job titles) are susceptible to significant misclassification of exposed and unexposed workers. Unless the study is poorly designed, this misclassification is "nondifferential" i.e., those who are misclassified are no more and no less likely to develop lung cancer (or to have been exposed to carcinogens such as tobacco smoke) than those who are correctly classified. If workers are sometimes misclassified nondifferentially, then this will tend to mask or dilute any excess risk attributable to exposure. Furthermore, differential misclassification in these studies usually consists of systematically including workers with little or no diesel exposure in a job category identified as "exposed." This too would generally mask or dilute any excess risk attributable to exposure. Therefore, MSHA assumes that in most of these studies, more rigorous and detailed exposure assessments would have resulted in somewhat higher estimates of excess risk.

IMC Global, MARG, and some other commenters expressed special concern about potential exposure misclassification and suggested that such misclassification might be partly responsible for results showing excess risk. IMC Global, for example, quoted a textbook observation that, contrary to popular misconceptions, nondifferential exposure misclassification can sometimes bias results away from the null. MSHA recognizes that this can happen under certain special conditions. However, there is an important distinction between "can sometimes" and "can frequently." There is an even more important distinction between "can sometimes" and "in this case does." As noted by the HEI Expert Panel on Diesel Epidemiology (HEI, 1999, p.48), "* * * nondifferential misclassification most often leads to an overall underestimation of effect." Similarly, Silverman (1998) noted, specifically with respect to the diesel studies, that "* * * this [exposure misclassification] bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates [of excess risk] toward the null value."

Statistical Significance

A "statistically significant" finding is a finding unlikely to have arisen by chance in the particular group, or statistical sample, of persons being studied. An association arising by chance would have no predictive value for exposed workers outside the sample. However, a specific epidemiologic study may fail to achieve statistical significance for two very different reasons: (1) there may be no real difference in risk between the two groups being compared, or (2) the study may lack the power needed to detect whatever difference actually exists. As described earlier, a lack of sufficient power comes largely from limitations such as a small number of subjects in the sample, low exposure and/or duration of exposure, or too short a period of latency or follow-up time. Therefore, a lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is statistically inconclusive.

As explained earlier, MSHA classifies a reported RR, SMR, or OR (i.e., the point estimate of relative risk) as "positive" if it exceeds 1.0 and "negative" if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount [39] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie et al., 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[40]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a sufficiently powerful study that failed to demonstrate a statistically significant positive relationship would, by its very failure, provide statistically significant evidence that an underlying relationship between an exposure and a specific disease was unlikely. It is important to note that MSHA regards a real 10-percent increase in the risk of lung cancer (i.e., a relative risk of 1.1) as constituting a clearly significant health hazard. Therefore, "sufficiently powerful" in this context means that the study would have to be of such scale and quality as to detect a 10-percent increase in risk if it existed. The outcome of such a study could plausibly be called "negative" even if the estimated RR slightly exceeded 1.0—so long as the lower confidence limit did not exceed 1.0 and the upper confidence limit did not exceed 1.05. Rarely does an epidemiological study fall into this "ideal" study category. MSHA reviewed the dpm epidemiologic studies to determine which of them could plausibly be considered to be negative.

For example, one study (Waxweiller et al., 1973) reported positive but statistically non-significant results corresponding to an RR of about 1.1. Among the studies MSHA counts as positive, this is the one that is numerically closest to being "negative". This study, however, relied on a relatively small cohort containing an indeterminate but probably substantial percentage of occupationally unexposed workers. Furthermore, there was no minimum latency allowance for the exposed workers. Therefore, even if MSHA were to use 1.1 rather than 1.05 as a threshold for significant relative risk, the study had insufficient statistical power to merit "negative" status.

One commenter (Dr. James Weeks, representing the UMWA) argued that "MSHA's reliance on * * * statistical significance is somewhat misplaced. Results that are not significant statistically * * * can nevertheless indicate that the exposure in question caused the outcome." MSHA agrees that an otherwise sound study may yield positive (or negative) results that provide valuable evidence for (or against) an underlying relationship but fail, because of an insufficient number of exposed study subjects, to achieve statistical significance. In the absence of other evidence to the contrary, a single positive but not statistically significant result could even show that a causal relationship is more likely than not. By definition, however, such a result would not be conclusive at a high level of confidence. A finding of even very high excess risk in a single, well-designed study would be far from conclusive if based on a very small number of observed lung cancer cases or if it were in conflict with evidence from toxicity studies.

MSHA agrees that evidence should not be ignored simply because it is not conclusive at a conventional but arbitrary 95-percent confidence level. Lower confidence levels may represent weaker but still important evidence. Nevertheless, to rule out chance effects, the statistical significance of individual studies merits serious consideration when only a few studies are available. That is not the case, however, for the epidemiology literature relating lung cancer to diesel exposure. Since many studies contribute to the overall weight of evidence, the statistical significance of individual studies is far less important than the statistical significance of all findings combined. Statistical significance of the combined findings is addressed in Subsection 3.a.iii of this risk assessment.

Potential Confounders

There are many variables, both known and unknown, that can potentially distort the results of an epidemiologic study. In studies involving lung cancer, the most important example is tobacco smoking. Smoking is highly correlated with the development of lung cancer. If the exposed workers in a study tend to smoke more (or less) than the population to which they are being compared, then smoking becomes what is called a "confounding variable" or "confounder" for the study. In general, any variable affecting the risk of lung cancer potentially confounds observed relationships between lung cancer and diesel exposure. Conspicuous examples are age, smoking habits, and exposure to airborne carcinogens such as asbestos or radon progeny. Diet and other lifestyle factors may also be potential confounders, but these are probably less important for lung cancer than for other forms of cancer, such as bladder cancer.

There are two ways to avoid distortion of study results by a potential confounder: (1) Design the study so that the populations being compared are essentially equivalent with respect to the potentially confounding variable; or (2) allow the confounding to take place, but adjust the results to compensate for its effects. Obviously, the second approach can be applied only to known confounders. Since no adjustment can be made for unknown confounders, it is important to minimize their effects by designing the comparison groups to be as similar as possible.

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[41] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

> * * * a study is open to criticism if no smoking data are collected and the association between exposure and outcome is weak. * * * When the magnitude of the association of interest is weak, uncontrolled confounding, particularly from a strong confounder such as cigarette smoking, can have a major impact on the study's results and on the credibility of their use. [HEI, 1999]

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity,

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[37] The cohort studies are Garshick et al. (1988) and Gustavsson et al. (1990). The case-control studies are Emmelin et al. (1993), Garshick et al.(1997), Gustavsson et al. (1990), Siemiatycki et al. (1988), and Steenland et al. (1990, 1992).

[38] The cohort study is Wong et al. (1985). The case-control studies are Brüske-Hohlfeld et al. (1999), Benhamou et al. (1988), Boffetta et al. (1990), Hayes et al. (1989), and Swanson et al. (1993).

[39] As a matter of practicality, MSHA places the threshold at 1.05.

[40] More detailed discussion of this study appears later in this subsection.

[41] If cases and controls cannot be closely matched on smoking or other potentially important confounder, then a hybrid approach is often taken. Cases and controls are matched as closely as possible, differences are quantified, and the study results are adjusted to account for the differences.

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demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[42] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

Stoäber and Abel (1996) argue, along with Morgan *et al.* (1997) and some commenters, that even in those epidemiologic studies that are adjusted for smoking and show a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining, smoking-adjusted studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[43] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia et al. (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

As shown in Tables III–4 and III–5, 18 of the published epidemiologic studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and five of these 18 also controlled or adjusted for exposure to asbestos and other carcinogenic substances (Garshick et al., 1987; Boffetta et al., 1988; Steenland et al., 1990; Morabia et al., 1992; Brüske-Hohlfeld et al., 1999). These results are less likely to be confounded than results from most of the studies with no adjustment. All but one of these 18 studies reported some degree of excess risk associated with occupational exposure to diesel particulate, with statistically significant results reported in eight.

In addition, several of the studies with no smoking adjustment took the first approach described above for preventing or substantially mitigating potential confounding by smoking habits: they drew comparisons against internal control groups or other control groups likely to have similar smoking habits as the exposed groups (*e.g.*, Garshick et al., 1988; Gustavsson et al., 1990; Hansen, 1993; and Säverin et al., 1999). Therefore, MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no smoking controls or adjustments. This emphasis is in accordance with the conclusion by Bhatia et al. (1998) that smoking homogeneity typically exists within cohorts and is associated with a uniform lifestyle and social class. Although it was not yet available at the time Bhatia et al. performed their analysis, an analysis of smoking patterns by Säverin et al. (op cit.) within the cohort they studied also supports this conclusion.

IMC Global and MARG objected to MSHA's position on potential confounders and submitted comments in general agreement with the views of Morgan et al. (op cit.) and Stöbel and Abel (op cit.). Specifically, they suggested that studies reporting relative risks solely between 1.0 and 2.0 should be discounted because of potential confounders. Of the 41 positive studies considered by MSHA, 22 fall into this category (16 cohort and 6 case-control). In support of their suggestion, IMC Global quoted Speizer (1986), Muscat and Wynder (1995), Lee (1989), WHO (1980), and NCI (1994). These authorities all urged great caution when interpreting the results of such studies, because of potential confounders. MSHA agrees that none of these studies, considered individually, is conclusive and that each result must be considered with due caution. None of the quoted authorities, however, proposed that such studies should automatically be counted as "negative" or that they could not add incrementally to an aggregate body of positive evidence.

IMC Global also submitted the following reference to two Federal Court decisions pertaining to estimated relative risks less than 2.0:

> The Ninth Circuit concluded in Daubert v. Merrell Dow Pharmaceuticals" that "for an epidemiologic study to show causation * * * the relative risk * * * arising from the epidemiologic data will, at a minimum, have to exceed 2." Similarly, a District Court stated in Hall v. Baxter Healthcare Corp.49: The threshold for concluding that an agent was more likely the cause of the disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no affect on the incidence of disease. When the relative risk reaches 2.0. the agent is responsible for an equal number of cases of disease as all other background causes. Thus a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. [IMC Global]

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was "more likely than not" caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

Furthermore, there is ample precedent for utilizing epidemiologic studies reporting relative risks less than 2.0 in making clinical and public policy decisions. For example, the following table contains the RR for death from cardiovascular disease associated with cigarette smoking reported in several prospective epidemiologic studies:

Study on cigarette smoking	Estimate of RR of death from cardiovascular disease
British doctors	1.6
Males in 25 states:	
Ages 45–64	2.08
Ages 65–79	1.36
U.S. Veterans	1.74
Japanese study	1.96
Canadian veterans	1.6
Males in nine states	1.70
Swedish males	1.7
Swedish females	1.3
California occupations	2.0

Source: U.S. Department of Health and Human Services (1989).

By IMC Global's rule of thumb, all but one or two of these studies would be discounted as evidence of increased risk attributable to smoking. These studies, however, have not been widely discounted by scientific authorities. To the contrary, they have been instrumental in establishing that cigarette smoking is a principal cause of heart disease.

A second example is provided by the increased risk of lung cancer found to be caused by residential exposure to radon progeny. As in the case of dpm, tobacco smoking has been an important potential confounder in epidemiological studies used to investigate whether exposures to radon concentrations at residential levels can cause lung cancer. Yet, in the eight largest residential epidemiological studies used to help establish the reality of this now widely accepted risk, the reported relative risks were all less than 2.0. Based on a meta-analysis of these eight studies, the combined relative risk of lung cancer attributable to residential radon exposure was 1.14. This elevation in the risk of lung cancer, though smaller than that reported in most studies of dpm effects, was found to be statistically significant at a 95-percent confidence level (National Research Council, 1999, Table G–25).

(ii) Studies Involving Miners

In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[44] MSHA placed two additional studies specific to exposed coal miners (Christie et al., 1995; Johnston et al.,1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[45] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin et al., 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[46] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

Five cohort studies (Waxweiler et al.,1973; Ahlman et al., 1991; Christie et al., 1996; Johnston et al., 1997; Saverin et al., 1999) were performed specifically on groups of miners, and one (Boffetta et al., 1988) addressed miners as a subgroup of a larger population. Except for the study by Christie et al., the cohort studies all showed elevated lung cancer rates for miners in general or for the most highly exposed miners within a cohort. In addition, all five case-control studies reported elevated rates of lung cancer for miners (Benhamou et al.,1988; Lerchen et al., 1987; Siemiatycki et al.,1988; Morabia et al., 1992; Burns and Swanson, 1991).

Despite the risk assessment's emphasis on human studies, some members of the mining community apparently believed that the risk assessment relied primarily on animal studies and that this was because studies on miners were unavailable. Canyon Fuels, for example, expressed concerns about relying on animal studies instead of studies on western diesel-exposed miners:

> Since there are over a thousand miners here in the West that have fifteen or more years of exposure to diesel exhaust, why has there been no study of the health status of those miners? Why must we rely on animal studies that are questionable and inconclusive?

Actually, western miners were involved in several studies of health effects other than cancer, as described earlier in this risk assessment. With respect to lung cancer, there are many reasons why workers from a particular group of mines might not be selected for study. Lung cancer often takes considerably more than 15 years to develop, and a valid study must allow not only for adequate duration of exposure but also for an adequate period of latency following exposure. Furthermore, many mines contain radioactive gases and/or

[42] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler et al. (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about ⅓ higher than the New Mexico rate, the reported SMRs were roughly ¾ of what they would have been if based on rates specific to New Mexico.

[43] The exception is DeCoufle *et al.* (1977), a case-control study that apparently did not match or otherwise adjust for age.

[44] In the proposed risk assessment, the studies identified as specifically investigating miners were Waxweiler et al. (1973) and Ahlman et al. (1991). At the Albuquerque public hearing, Mr. Bruce Watzman, representing the NMA, asked a member of the MSHA panel (Mr. Jon Kogut) to list six studies involving miners that he had cited earlier in the hearing and to identify those that were specific to miners. In both his response to Mr. Watzman, and in his earlier remarks, Mr. Kogut noted that the studies involving miners were listed in Tables III–4 and III–5. However, he inadvertently neglected to mention Ahlman et al. (op cit.) and Morabia et al. (1992). (The latter study addressed miners as a subgroup of a larger population.)

In his response to Mr. Watzman, Mr. Kogut cited Swanson *et al.* (1993) but not Burns and Swanson (1991), which he had mentioned earlier in the hearing in connection with the same study. These two reports are listed under a single entry in Table III–5 (Swanson et al.) because they both report findings based on the same body of data. Therefore, MSHA considers them to be two parts of the same study. The 5.03 odds ratio for mining machine operators mentioned by Mr. Kogut during the hearing was reported in Burns and Swanson (1991).

Only the six studies specified by Mr. Kogut in his response to Mr. Watzman were included in separate critiques by Dr. Peter Valberg and Dr. Jonathan Borak later submitted by the NMA and by MARG, respectively. Dr. Valberg did not address Burns and Swanson (1991), and he addressed a different report by Siemiatycki than the one listed in Table III–5 and cited during the hearing (i.e., Siemiatycki et al., 1988). Neither Dr. Valberg nor Dr. Borak addressed Ahlman et al. (op cit.) or Morabia et al. (op cit.). Also excluded were two additional miner-specific studies placed into the record on Feb. 12, 1999 (Fed Reg. 64:29 at 59258). Mr. Kogut did not include them in his response to Mr. Watzman, or in his prior remarks, because he was referring only to studies listed in Tables III–4 and III–5 of the published proposals. Mr. Kogut also did not include a study specific to German potash miners submitted by NIOSH at a subsequent public hearing, and this too was left out of both critiques. A published version of the study (Säverin et al., 1999) was placed into the record on June 30, 2000. All of the studies involving miners are in the public record and have been available for comment by interested parties throughout the posthearing comment periods.

[45] Some commenters suggested that MSHA "overlooked" a recently published study on NSW miners, Brown et al., 1997. This study evaluated the occurrence of forms of cancer other than lung cancer in the same cohort studied by Christie et al. (1995).

[46] This study was published in two separate reports on the same body of data: Burns and Swanson (1991) and Swanson et al. (1993). Both published reports are listed in Table III–5 under the entry for Swanson et al.

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respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

Similarly, at the public hearing in Albuquerque on May 13, 1999, a representative of Getchell Gold stated that he thought comparing miners to rats was irrational and that "there has not been a study on these miners as to what the effects are." To correct the impression that MSHA was basing its risk assessment primarily on laboratory animal studies, an MSHA panelist pointed out Tables III–4 and III–5 of the proposed preamble and identified six studies pertaining to miners that were listed in those tables. However, he placed no special weight on these studies and cited them only to illustrate the existence of epidemiologic studies reporting an elevated risk of lung cancer among miners.

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them "particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners." He concluded that they do not "implicate diesel exposure per se as strongly associated with lung cancer risk in miners." Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, "the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer."

MSHA agrees with Drs. Valberg and Borak that none of the studies they reviewed provides direct evidence of a link between dpm exposure and the excess risk of lung cancer reported for miners. (A few disagreements on details of the individual studies will be discussed below). As MSHA said at the Albuquerque hearing, the lack of exposure information on miners in these studies led MSHA to rely more heavily on associations reported for other occupations. MSHA also noted the limitations of these studies in the proposed risk assessment. MSHA explicitly stated that other epidemiologic studies exist which, though not pertaining specifically to mining environments, contain better diesel exposure information and are less susceptible to confounding by extraneous risk factors.

Inconclusive as they may be on their own, however, even studies involving miners with only presumed or sporadic occupational diesel exposure can contribute something to the weight of evidence. They can do this by corroborating evidence of increased lung cancer risk for other occupations with likely diesel exposures and by providing results that are at least consistent with an increased risk of lung cancer among miners exposed to dpm. Moreover, two newer studies pertaining specifically to miners do contain dpm exposure assessments based on concurrent exposure measurements (Johnston *et al.*, op cit.; Säverin et al.,op cit.). The major limitations pointed out by Drs. Valberg and Borak with respect to other studies involving miners do not apply to these two studies.

Case-Control Studies

Five case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer for miners, as shown in Table III–5. The results for miners in three of these studies (Benhamou *et al.*, 1988; Morabia *et al.*, 1992; Siemiatycki *et al.*, 1988) are given little weight, partly because of possible confounding by occupational exposure to radioactive gasses, asbestos, and silica dust. Also, Benhamou and Morabia did not verify occupational diesel exposure status for the miners. Siemiatycki performed a large number of multiple comparisons and reported that most of the miners "were exposed to diesel exhaust for short periods of time," Lerchen *et al.* (1987) showed a marginally significant result for underground non-uranium miners, but cases and controls were not matched on date of birth or death, and the frequency of diesel exposure and exposure to known occupational carcinogens among these miners was not reported.

Burns and Swanson (1991)[47] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the "occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators."

[47] This report is listed in Table III–5 under Swanson *et al.* (1993), which provides further analysis of the same body of data.

Cohort Studies

As shown in Table III–4, MSHA identified six cohort studies reporting results for miners likely to have been exposed to dpm. An elevated risk of lung cancer was reported in five of these six studies. These results will be discussed chronologically.

Waxweiller (1973) investigated a cohort of underground and surface potash miners. The authors noted that potash ore "is not embedded in siliceous rock" and that the "radon level in the air of potash mines is not significantly higher than in ambient air." Contrary to Dr. Valberg's review of this study, the number of lung cancer cases was reported to be slightly higher than expected, for both underground and surface miners, based on lung cancer rates in the general U.S. population (after adjustment for age, sex, race, and date of death). Although the excess was not statistically significant, the authors noted that lung cancer rates in the general population of New Mexico were about 25 percent lower than in the general U.S. population. They also noted that a higher than average percentage of the miners smoked and that this would "tend to counterbalance" the adjustment needed for geographic location. The authors did not, however, consider two other factors that would tend to obscure or deflate an excess risk of lung cancer, if it existed: (1) A healthy worker effect and (2) the absence of any occupational diesel exposure for a substantial percentage of the underground miners.

MSHA agrees with Dr. Valberg's conclusion that "low statistical power and indeterminate diesel-exhaust exposure render this study inadequate for assessing the effect of diesel exhaust on lung-cancer risk in miners." However, given the lack of any adjustment for a healthy worker effect, and the likelihood that many of the underground miners were occupationally unexposed, MSHA views the slightly elevated risk reported in this study as consistent with other studies showing significantly greater increases in risk for exposed workers.

Boffetta et al. (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations

identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[48] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

Although an adjustment was made for smoking patterns, the relative risk reported for mining did not control for exposures to radioactive gasses, silica dust, and asbestos. These lung carcinogens are probably present to a greater extent in mining environments than in most of the occupational environments used for comparison. Self-reported exposures to asbestos and stone dusts were taken into account in other parts of the study, but not in the calculation of excess lung cancer risks associated with specific occupations, including mining.

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however (Mr. Mark Kaszniak of IMC Global), argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

> In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the "no exposure to diesel exhaust group," their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[49] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the "miners" category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing "unknowns" from the "miner" group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that "[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *." He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman et al. (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (i.e., due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that "smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers. Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie et al. (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW)

[48] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that "smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers." The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

[49] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the "relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure." Contrary to Mr. Kaszniak's belief, however, the "miners" on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta et al., 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 "sometime" miners used in that calculation was 65 percent larger than the group of 1233 "mainly" miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members "with occupation different from those listed [i.e., railroad workers, truck drivers, heavy equipment operators, and miners] and not exposed [to diesel exhaust]." The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta et al., 1988).

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coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface ("open cut") miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie et al., 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie et al., 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that "it is likely that the well known 'healthy worker' effect * * * was operating" and that, instead of comparing to a general population, "a more appropriate comparison group is Australian petroleum industry workers." (Christie et al., 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—i.e., 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie et al., p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that "it is a relatively young cohort" and that "this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *." They further noted that "* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms." (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study "* * * reflects the latest and best scientific evidence, current technology, and the current health of miners" and that it "is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *." For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address Dpm exposure and the risk of lung cancer. Two of these studies (Johnston et al., 1997; Säverin et al., 1999), both incorporating a quantitative Dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld et al., 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston et al. (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 $\mu g/m^3$ to 370 $\mu g/m^3$ for locomotive drivers and from 1.6 $\mu g/m^3$ to 40 $\mu g/m^3$ for non-drivers at various mines and work locations (ibid.,Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m^3, some members had cumulative exposures that ranged as high as 11.6 g-hr/m^3 (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit, mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston et al. refer to as the "wider mortality study") was summarized in Section 1.2 (pp 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[50]

[50] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent "with other studies of occupational cohorts where a healthy worker effect is apparent." But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid.,p.5)

Contrary to the MARG and NMA characterization, Johnston et al. found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m^3 of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m^3 of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, RR = $(1.156)^{3.84}$ = 1.74 for a cumulative dpm exposure of 3.84 g-hr/m^3, and RR = $(1.156)^{7.68}$ = 3.04 for a cumulative dpm exposure of 7.68 g-hr/m^3.[51] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that "the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *." (ibid., pp. 71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was "* * * found to have generally the higher exposures to respirable quartz and low level radiation." Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin et al.(1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m^3 (i.e., the approximate equivalent of 4.9 mg-yr/m^3 TC).[52] At this exposure level, the mine-unadjusted model produces an estimated RR = $(1.227)^{11.7}$ = 11, and the mine-adjusted model produces an estimated RR = $(1.156)^{11.7}$ = 5.5.

Säverin et al. (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had "worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total."

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding

[51] Assuming an average dpm concentration of 200 $\mu g/m^3$ and 1920 work hours per year, 3.84 g-hr/m^3 and 7.68 g-hr/m^3 correspond to 10 and 20 years of occupational exposure, respectively.

[52] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m^3 presented by Säverin et al. must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m^3. To convert this result to the units used by Johnston et al., it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m^3. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston et al. (See Johnston et al., op cit., Table 9.1.)

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to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 µg/m³ for production, 230 µg/m³ for maintenance, and 120 µg/m³ for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because "the mining technology and the type of machinery used did not change substantially after 1970." This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m³.

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that "underground workers are heavily selected for health and sturdiness, making any surface control group incomparable." Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m³ of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [53]

Method	RR per mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m³ is $(1.225)^{3.5} = 2.03$.[54] The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m³, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 µg/m³. The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m³	
	Full cohort	Sub-cohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that "even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust." Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that "the results are unlikely to be substantially biased by confounding," and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of this study at the May 27, 1999, public

[53] MSHA *determined* these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m³ refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[54] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

hearing, NIOSH noted that the "lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up)." More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that "[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures." As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence

Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

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STUDY	STATISTICAL SIGNIFICANCE (at 95% Conf.)	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Boffetta et al. 1988 (cohort)	YES	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control)	NO	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control)	YES	Matched on sex, age, and region of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control)	YES	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort)	YES	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort)	NO (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort)	NO	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette - smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control)	YES	Matched within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

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Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

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STUDY	POWER	COMPARISON GROUPS	EXPOSURE ASSESSMENT	CONTROLS ON POTENTIAL CONFOUNDING
Bender et al. 1989 (cohort)	Relatively small cohort (N = 4849)	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment
DeCoufle et al. 1977 (case-control)	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N = 694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment
Waller 1981 (cohort)	Acceptable.	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers.	Disparate comparison groups with no smoking adjustment

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Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

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Main results from Boffetta et al., 1988

(RRs by duration adjusted for age, smoking, and other occupational exposures; Occupational RRs adjusted for age and smoking only)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer RR	95-Percent Confidence Interval
1 to 15	1.05	0.80 - 1.39
16 or more	1.21	0.94 - 1.56
Occupation		
Truck Drivers	1.24	0.93 - 1.66
Railroad Workers	1.59	0.94 - 2.69
Heavy Equipment Operators	2.60	1.12 - 6.06
Miners	2.67	1.63 - 4.37

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In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this "could introduce a substantial bias in the estimate of the association." (Boffetta et al., 1988, p.412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all "unknowns" were actually unexposed. Under this scenario, excluding the "unknowns" would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the "unknowns" who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (*ibid.*, pp. 410–411).

IMC Global also commented that the "* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol." They noted that this possibility "is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions."

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but "the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases." (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: "Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association."[55] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

[55] In his review of this study for the NMA, Dr. Peter Valberg stated: "This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated." Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were "statistically elevated." Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The "low exposure" group was used as the reference category for calculating odds ratios for the "possible" and "probable" job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (*ibid.*, p. 584).

Stöber and Abel (1996) identified this study as being "of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships." The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or "probable" diesel exposure. The authors repeated the occupational analysis using "ever" rather than "usual" employment in jobs classified as "probable" exposure, with "remarkably similar" results (*ibid.*, p. 584).

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Main results from Boffetta et al., 1990

(adjusted for age, race, education, smoking, and asbestos exposure)

Self-Reported Duration of Exposure to Diesel Exhaust (years)	Lung Cancer Odds Ratio	95-Percent Confidence Interval
1 to 15	0.90	0.40 - 1.99
16 to 30	1.04	0.44 - 2.48
31 or more	2.39	0.87 - 6.57
Likelihood of Exposure		
19 jobs with "possible" exposure	0.92	0.76 - 1.10
13 jobs with "probable" exposure	0.95	0.78 - 1.16
1 to 15 years in "probable" jobs	0.52	0.15 - 1.86
16 to 30 years in "probable" jobs	0.70	0.34 - 1.44
31 or more years in "probable" jobs	1.49	0.72 - 3.11

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The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure "to compare presumptive diesel truck drivers with nondiesel drivers." After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.*, p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other "traffic-related" jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as pack-years), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

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The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4†
11 to 20 years	2.49	1.1 - 5.6†
More than 20 years	2.88	1.1 - 7.2†
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8‡
21 to 30 years	3.67	1.0 - 13‡
More than 30 years	6.81	1.1 - 40‡
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

† Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

‡ Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

BILLING CODE 4510-43-C

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As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, "under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer." A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study "showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany."

Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as "exposed" or "unexposed" to diesel exhaust. For 39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as "diesel-years") for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that "this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk."

BILLING CODE 4510-43-P

Main results from Garshick et al., 1987, for workers aged less than 65 years at death

(controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure).

Diesel Exposure (no lag)	Lung Cancer Odds Ratio	95-Percent Confidence Interval
0 - 4 diesel-years	1	N/A (reference group)
5 - 19 diesel-years	1.02	0.72 - 1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06 - 1.88
20 or more diesel-years	1.64	1.18 - 2.29
Diesel Exposure (accumulated at least 5 years before death)		
0 - 4 diesel-years	1	N/A (reference group)
5 - 14 diesel-years	1.07	0.69 - 1.66
15 or more diesel-years	1.43	1.06 - 1.94

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In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that "compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer." (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination "generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked."

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between "public surveys" of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that "this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls." (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis

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of the type employed in this study, random errors in a multivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the date.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.*, that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op. cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form "Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.*, no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.*, Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (*i.e.*, a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is $p = 1 - (1 - 0.05)^{30} = 78\%$. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for tested from a pool of interchangeable possibilities and that the only thing distinguishing the combination of "65 years of age" and "20 diesel-years of exposure" from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959, who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and

1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as "unexposed" within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[56] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that "similar results were obtained." Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using "attained age," however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that "there appears to be an effect of diesel exposure on lung cancer mortality" but that "because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study."

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Main results from Garshick et al., 1988 and Garshick, 1991.

Exposure Duration (diesel-years, last 5 years excluded)	Full Cohort		Shopworkers & Hostlers Excluded	
	Relative Risk	95% Conf. Int.	Relative Risk	95% Conf. Int.
1 - 4	1.20	1.01 - 1.44	1.34	1.08 - 1.65
	1.31	1.09 - 1.57	N.R.	N.R.
5 - 9	1.24	1.06 - 1.44	1.33	1.12 - 1.58
	1.28	1.09 - 1.49	N.R.	N.R.
10 - 14	1.32	1.13 - 1.56	1.33	1.10 - 1.60
	1.19	1.002 - 1.41	N.R.	N.R.
15 or more	1.72	1.27 - 2.33	1.82	1.30 - 2.55
	1.40	1.03 - 1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up ("attained age"). N.R. means "not reported."

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Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this "paradoxical," since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

[1] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

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* * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump 1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for "train riders," who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that "lifestyle" factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this "has rendered its utility questionable at best." As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

* * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al.,1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al.,1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that "these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk." MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it "impossible to prove causation by eliminating plausible rival hypotheses based on this dataset." (Cox, 1997; p.826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any "rival hypotheses" were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident "because of weaknesses in exposure ascertainment." (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or "attained" age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: "In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures."

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

* * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [ibid., p.25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a "healthy worker survivor effect"; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p.32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. "* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm." At least one commenter [IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to "discount their results and not consider them in this rulemaking." On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

* * * have successfully controlled for severally [sic] potentially important confounding factors * * * Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Robert A. Michaels, RAM TRAC Corporation, submitted by National Coal Association].

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not "firmly" conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers.

Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m³ (i.e., 1 g-hr/m³) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m³ to mg-yr/m³ assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m³ Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Säverin et al. (1999).

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Main results from Johnston et al., 1997.

Cumulative dpm exposure	Mine-adjusted Model (15-yr lag)		Mine-unadjusted Model (15-yr lag)	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
1000 mg-hr/m³ (≈ 0.521 mg-yr/m³)	1.156	0.90 - 1.49	1.227	1.00 - 1.50
1920 mg-hr/m³ (= 1 mg-yr/m³)	1.321	Not Reported	1.479	Not Reported
11,700 mg-hr/m³ (≈ 6.1 mg-yr/m³)	5.5	Not Reported	11.0	Not Reported

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In its post-hearing comments, MARG acknowledged that this study "found a 'weak association' between lung cancer and respiratory diesel particulate exposure" but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was "deemed non-significant by the researchers" and that "no association was found among men with different exposures working in the same mines." Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m³ TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the

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published report (ibid., p.420). The approximate equivalency between 4.9 mg-yr/m³ TC and 6.1 mg-yr/m³ dpm assumes that, on average, TC comprises 80 percent of dpm.

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Main results from Säverin et al., 1999.

	Relative Risk	95% Confidence Interval
Highest Compared to Least Exposed Worker Category	2.17	0.79 - 5.99

Cumulative Total Carbon Exposure	Proportional Hazards (Cox) Model*		Poisson Model*	
	Relative Risk	95% Conf. Interval	Relative Risk	95% Conf. Interval
2.7 mg-yr/m³ TC (i.e., cohort mean)	1.33 1.73	0.67 - 2.64 0.70 - 4.30	1.08 1.42	0.59 - 1.99 0.65 - 3.92
4.9 mg-yr/m³ TC (= 6.1 mg-yr/m³ Dpm)	1.68 2.70	0.49 - 5.8 0.52 - 14.1	1.16 1.89	0.38 - 3.3 0.46 - 11.9

* Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

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These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide "some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects."

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that "many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later. * * *" Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of

improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on "very broad assumptions" used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

(1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate val e of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 μg-yr/m³, with a median value of 373 μg-yr/m³. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 μg-yr/m³, 1000 μg-yr/m³, and 2450 μ-yr/m³ were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration ($\mu g/m^3$)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40

Cumulative Occupational Exposure (μg-yr/m^3, lagged 5 years)**			Lung Cancer Odds Ratio	95-percent Conf. Interval
EC	TC* ≈ 2•EC	Dpm ≈ TC/0.8 ≈ 2.5•EC		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49
			Lung Cancer Odds Ratio‡	
		Logistic regression model →	Simple Cum. Exposure	Log of Cum. Exposure
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and Dpm assume that, on average, TC = 2•EC and TC = 0.8•DPM.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 μg-yr/m^3 assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 μg–yr/m^3 (≈ 6.1 mg–yr/m^3 Dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative Dpm exposure of approximately 6.1 mg—yr/m^3, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Säverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[57]

As mentioned above, the investigators recognized that these analyses rely on "broad assumptions rather than actual [concurrent] measurements," and they proposed that the "results should be regarded with appropriate caution." While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel "* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with "appropriate caution," it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that "no direct evidence of such bias is apparent" and emphasizing that "even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination." (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was "likely to be unreliable." By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of lung cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a "discrepancy" in the data, assuming that "cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years." (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics

[57] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of Dpm exclusively with elemental carbon. For example, NITC argued that "more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers." (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as "non-diesel," ignore the fact that Dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of Dpm would nonetheless be due to Dpm exposures.

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(Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that "the risk for mechanics did not appear to increase consistently with duration of employment," Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence

Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, "All of the studies showing negative or statistically insignificant positive associations * * * lacked good information about dpm exposure * * *" or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the "positive" studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin et al., 1999).

MSHA did not entirely "dismiss" the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of "Best Available Epidemiologic Evidence." The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of "Studies Involving Miners."

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as "examples of studies that reported negative associations between [dpm] exposure and lung cancer risk":

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as "possibly exposed" or "probably exposed" to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for "less than 5-year duration" is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for "normal" retirees (SMR = 1.30) and for "high exposure" dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.
- Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: "That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data." Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, "the overall risk of lung cancer was elevated among diesel-exposed workers" (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, "reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure." It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

- Ahlman et al. (1991). This study is discussed above, under the heading of "Studies Involving Miners." MSHA agrees with the commenter that this study did not "establish" a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.
- Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.
- Ames et al. (1983). As discussed later in this risk assessment, under the heading of "Mechanisms of Toxicity," this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.
- Ames et al. (1982). As noted earlier under the heading of "Acute Health Effects," this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.
- Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that "diesel emissions were not found to be related to increased health risks." However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.
- Attfield et al. (1982). MSHA has taken the results of this study into account, under the heading of "Chronic Effects other than Cancer."
- Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.
- Boffetta et al. (1988). This study is discussed in two places above, under the headings "Studies Involving Miners" and "Best Available Epidemiologic Evidence." The commenter stated that "the study obviously does not demonstrate risks from dpm exposure." If the word "demonstrate" is taken to mean "conclusively prove," then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.
- Costello *et al.* (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.
- Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." The commenter did not address MSHA's observation that the method of

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statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.

• Glenn *et al.* (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that "* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed." The authors noted that "results were rather mixed," but also noted that "levels of diesel exhaust contaminants were generally low," and that "overall tenure in these diesel equipped mines was fairly short." MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: "further research on this subject is needed." However, the authors also pointed out that "all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial." The miners included in the studies summarized by this report would not have been exposed to Dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.

• Johnston *et al.* (1997). This study is discussed in two places above, under the headings "Studies Involving Miners" and "Best Available Epidemiologic Evidence." MSHA disagrees with the commenter's assertion that "the study does not support a health risk from dpm." This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of "Mechanisms of Toxicity," these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld *et al.* (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of "Mechanisms of Toxicity." For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the "standard analysis" (*i.e.*, 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the "standard analysis" is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a "healthy-worker-survivor-effect," thereby masking the actual exposure effects in these workers. They found that "all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality." (Morfeld *et al.*, 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." As summarized by the commenter, "diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function," but the author found that "the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners." The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under "Mechanisms of Toxicity," showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that "the study does not establish a dpm-related health risk," but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under "Studies Involving Miners." As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

(v) Summation

Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under "Evaluation Criteria," weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), "* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding." Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that.

> In this field * * * epidemiology faces its limits (Taubes, 1995). * * * Many of these studies were doomed to failure from the very beginning.

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiologic case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air

Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[58] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the "Six Cities" study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[59] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[60] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution "contributes to excess mortality in certain U.S. cities." The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[61] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from measures of PM_{10} and measures of acid aerosols. The available studies, however, show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease. This is significant for miners occupationally exposed to fine particulates such as dpm because, as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity

As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are

[58] Unlike *longitudinal studies*, which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[59] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[60] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[61] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

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suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich *et al.*, 1986, 1995; Iwai *et al.*, 1986; Brightwell *et al.*, 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/nonmetal mines, to regulate total carbon ("TC") as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the "suspected carcinogens" in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the "suspected carcinogens" in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that "* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon." MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.*, 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention

As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli*. In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant*, which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained Dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of Dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of Dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called "overload" is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation,

epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that "particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust."

iii. Effects Other Than Cancer

A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.*, particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg·hr/m³ or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is "implicated in the increasing prevalence of allergic asthma in recent years." Similarly, Ichinose et al. (1997a) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that " * * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *."

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

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Table III-6. — Hypothesized mechanisms of particulate toxicity†

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).
Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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Deposition of particulates in the human respiratory tract may initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction can result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion can lead to mucus hypersecretion and, eventually, to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally-mediated bradycardia and hypertension (Widdicombe, 1988).

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are "scrubbed" from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (i.e., responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major

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polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that "[i]t therefore seems more likely that the particulate component of DE is responsible."

iv. Lung Cancer

(1) Genotoxicity Studies

Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of lung cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

One commenter (MARG) pointed out that "even assuming diesel exhaust contains particular genotoxic substances, the bioavailability of these genotoxins has been questioned." As acknowledged in the proposed risk assessment, a critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks et al., 1980; King et al., 1981; Siak et al., 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace et al., 1987; Keane et al., 1991; Gu et al., 1991; Gu et al., 1992). From these studies, NIOSH concluded in 1992 that:

> * * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

If this conclusion is correct, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

One commenter (IMC Global) noted that Wallace et al. (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu et al. involved "direct application of an unusually high concentration gradient" that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op cit) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai et al. (1996) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that "oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer."

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel exhaust.[62] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou et al. (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that "the studies conducted by Hemminiki [Hemminiki et al, 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers" but argued that "these elevations were at the borderline of statistical significance." Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that "the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded." As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.*, 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved "intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period." MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of "intensive" exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis "provides results in which the authors have a high level of confidence." They concluded that "given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, "longwall change out"] operations." Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that "* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small." According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 $\mu g/m^3$ of dpm would be equivalent in potency to smoking about one cigarette per month.[63] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose et al. (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the

[62] Some of these studies will be discussed in the next subsection of this risk assessment.

[63] The only details provided for this calculation pertained to ajusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 $\mu g/m^3$ concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 $\mu g/m^3$. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 $\mu g/m^3$) × (40 hours/week) is nearly 30 percent greater than (92 $\mu g/m^3$) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

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mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya et al., 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki et al., 1994; Hou et al., 1995; Nielsen et al., 1996; Qu et al., 1997).

(2) Animal Inhalation Studies

When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 $\mu g/m^3$ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon ("carbon black") particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[64]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al., 1996) did not pertain to questions of genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in "other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower." In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that "until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded."

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdorster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and TiO_2 rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: "Carbon black is possibly carcinogenic to humans (Group 2B)." (IARC, 1996)

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1996). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 $\mu g/m^3$. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a "quasi-threshold," or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions "produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randerath et al., 1995, p.55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly

[64] NIOSH commented as follows: "Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m^3 for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to TiO_2 at 250 mg/m^3 for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the TiO_2 exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations." In the reports cited by MSHA, levels of TiO_2 and/or carbon black were commensurate with dpm levels.

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inducing lung cancer by a mechanism similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 $\mu g/m^3$ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11)

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is "no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not." According to the NMA, this showed "* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment."

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m^3), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that "Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * * however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important."

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that "MSHA's contention that lung overload might "mask" tumor production by lower doses of Dpm has been convincingly rebutted by recognized experts in the field," but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to "derive a quantitative estimate of human lung cancer risk from the low-level rat data."

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a "meta-analysis" type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 $\mu g/m^3$ continuous lifetime exposure (approximately 2,500 $\mu g/m^3$ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats, a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that "[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals."

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

After reviewing the evidence of adverse health effects associated with exposure to dpm, MSHA evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (a) Whether health effects associated with dpm exposure constitute a "material impairment" to miner health or functional capacity; (b) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (c) whether the rule will substantially reduce such risks.

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that "[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence."[65] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *."

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is "inconclusive at best." Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a "mathematical straitjacket." [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the "Benzene" case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. [Id. at 656].

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[65] MARG supported this assertion by claiming that "[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]" Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its "scientific adequacy" is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

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Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the "best *available* evidence" (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

* * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that "[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal." Several commenters argued that evidence from within the mining industry itself was especially weak.[66] A representative of one mining company that had been using diesel equipment for many years commented: "[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry." This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combined weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded "it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation" and "a transient decline of ventilatory capacity has been noted following such exposures."

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, "acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *"; but asserted that "[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines]."

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called "reversible" health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute "material impairments" of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that "all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group." There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the

[66] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, "[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects." These studies drew comparisons against an external reference population and failed to adjust for the "healthy worker effect." (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

relationship between PAHs and other products of fossil fuel combustion found in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis ("hay fever") and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm "* * * are an important factor in the long-term increases in the prevalence in allergic airway disease." Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment "may play an important role in the increased incidence of allergic airway disease." Morgan et al. (1997) noted that dpm "* * * may be partly responsible for some of the exacerbations of asthma" and that "* * * it would be wise to err on the side of caution." Such health outcomes are clearly "material impairments" of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes

The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

* * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events * * *. There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels. [EPA, 1996]

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a "material impairment" of health or functional capacity within the meaning of the Act.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that "MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent." He argued that "dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples," that "chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects," and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5}$. Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (*i.e.*, $PM_{2.5}$), so the percentage of dpm in "total suspended particulate emissions" (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer

It is clear that lung cancer constitutes a "material impairment" of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (*i.e.*, enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan *et al.* (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: Even the strongest of

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the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia *et al.* (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence

As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that "* * * by its own admission in the preamble * * * most of the evidence in [the epidemiologic] studies is relatively weak" and argued that MSHA's conclusion was, therefore, unjustified.

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting "heads" on a single flip of a coin, or two "heads" out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 "heads" in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the "null hypothesis" that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

> [j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that—

> * * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between Dpm exposure and lung cancer.* * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational Dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[67] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) "examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups." Figures III–9 and III–10, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

[67] With respect to IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of "Potential Confounders," and in Subsection 3.a.iii(3) below, entitled "Potential Systematic Biases."

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Figure III-5

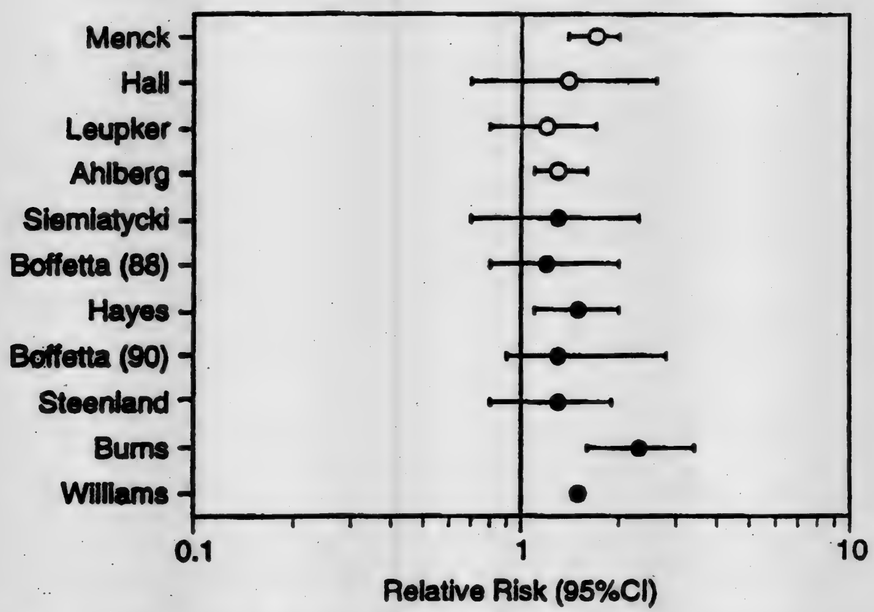


Figure . Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

Figure III-6

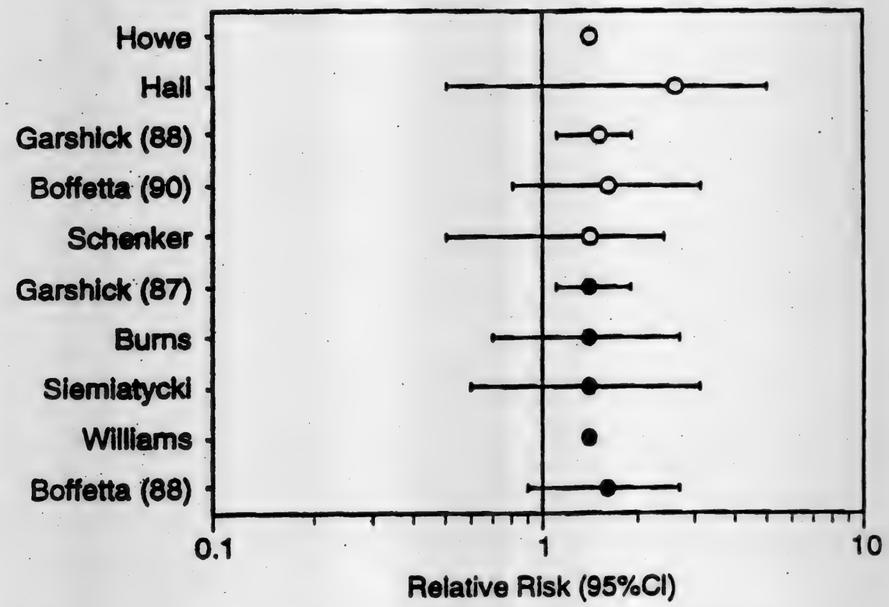


Figure . Lung cancer and exposure to diesel exhaust in railroad workers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the "positive" studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

* * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the "healthy worker effect."

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988,1991), Johnston et al. (1997), Steenland et al. (1990,1992,1998), and Säverin et al. (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2 \times 0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a "positive" exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.*, Cal-EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta et al. (1990) and Brüske-Hohlfeld et al. (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (i.e., dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland et al., 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

* * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule.* * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston et al., 1997 and Säverin et al., 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of

reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the "best available evidence" (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that "regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available" (HEI, 1999; p. 39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

* * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so,* * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia et al. (1998), Silverman (1998) proposed that "[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data." According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick et al. (1988), Gustavsson et al. (1990), Steenland et al. (1992), and Emmelin et al. (1993).[68] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston et al., 1997; Säverin et al., 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that "[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners." Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

[T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Saverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Saverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker

[68] Emmelin et al. (1993) was considered but excluded from the meta-analysis by Bhatia et al. (1998) for reasons explained by the authors.

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misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[69] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m³ is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m³ : RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m³ : RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple

[69] Listed in Table III–5 under Swanson et al., 1993.

comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia et al., 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (i.e., the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting "funnel plot" was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded "redundant" studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations "most likely to have had substantial exposure" to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia et al. (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment "could not be confirmed or reliably inferred" or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

To address potential publication bias, the investigators identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a "funnel plot" for the included studies, the authors concluded that there was no indication of publication bias.

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia et al. (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers, equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending

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from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia et al. (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that "this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust."

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[70] One commenter observed that—

> Lung cancer relative risks for occupational "control groups" vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the Dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses "presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail." IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[71] Dr. Silverman characterized Bhatia et al. (1998) as a "careful meta-analysis" and acknowledged that it "add[s] to the credibility that diesel exhaust is carcinogenic * * *." She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that "[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer." She suggested, however, that Bhatia et al. (1998) "ultimately do not resolve the question of causality." (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

> Has science proven causality beyond any reasonable doubt? Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality "beyond any reasonable doubt." The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof "beyond any reasonable doubt."[72]

The EMA objected to MSHA's reliance on the two meta-analyses because of "* * * serious deficiencies in each" but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that "most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis." MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

> [a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such "deficiencies" as lack of a smoking adjustment. For example, Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) publication bias

> * * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias.* * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia et al. (1998) found several unpublished studies of lung cancer among truck drivers that "* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers." (Bhatia et al., p. 90) Lipsett and Campleman (1999) checked "[s]moking-adjusted relative risks for several diesel-exposed occupations" in an unpublished report on U.S. veterans and found them "* * * consistent with those reported here." They remarked that "although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings." (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of "funnel plots" as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

> * * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]
>
> Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia et al. (1998) pointed out that "[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion." Even if studies on miners had been considered, Waxweiler et al. (1973) and Christie et al. (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

> * * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyzes won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that "[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects." However, as Dr. Silverman pointed out in her review, "* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure." (Silverman, 1998)

(4) Smoking as a Confounder

> * * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]
>
> * * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, metaanalyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as "flaws" in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia et al. (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the "small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding." Dr. Silverman concluded that "[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer." (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

> As noted by Lipsett and Campleman, "Diet may also confound the diesel-lung cancer association." The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that "diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations." Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences (and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a "deficiency" causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the

[70] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia et al. (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[71] Silverman (1998) reviewed Bhatia et al. (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[72] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that "underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups." (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin et al., 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston et al., 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

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possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery et al. 1993; Pope et al., 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[73] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as "negative." He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the possibility that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC Global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that "only a few of the studies have relative risks that exceed 2.0," Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that "residual smoking effects" could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking, come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a possible bias and an actual one.

[73] The term "residual smoking effects" refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using "funnel plots" and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a "potential" or "probable" human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[74] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

Results from the epidemiologic studies, the animal studies, and the genotoxicity studies are coherent and mutually supportive. After considering all these results, MSHA has concluded that the epidemiologic studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the

[74] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

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epidemiologic and toxicity studies were "coherent and mutually reinforcing" involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that "most of the individual [epidemiologic] studies are not very good" and that their suggestion of an association between dpm and lung cancer is "made credible in light of the animal data." To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an "absence of toxicological support for epidemiologic findings that are themselves inconclusive."

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as "not very good." Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that "none of the existing human studies is perfect" and that "no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *." That a study is not "perfect," however, does not imply that it is "not very good." MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the "coherency and reinforcement" arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on "broad assumptions" to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if Dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by Dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but Dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 μg/m³, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 μg/m³ exposure. Hence, dpm concentrations for miners in the range of 100–2,000 μg/m³ should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74 2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that "* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not make sense in the context of a dose-response relationship between lung cancer and Dpm exposure." This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. However, the truck drivers studied, due to their work conditions may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. Truck drivers commonly congregate in parking areas and sleep in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical "fit" to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p.190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 μg/m³ have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 μg/m³ and 644 μg/m³ for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 μg/m³—corresponding to a mean dpm concentration of about 490 μg/m³. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 μg/m³ to 370 μg/m³. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not "forty times larger" than the level imputed to truck drivers, but closer to seven times larger.[75] Applying Dr. Valberg's procedure, this yields an "expected" relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies (1 + 7 × (0.49)). Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an "utter lack of concordance" with the 4.4 "expected" value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

(5) Other Interpretations of the Evidence. After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks ("RR") that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or

[75] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner exposure to the average truck driver dpm exposure.

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placed it in a comparable category. These include:

Year

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA);
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000;
1998 California Environmental Protection Agency (Cal–EPA);
1998 Federal Republic of Germany;
1996 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH)

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the "causal link." To the contrary, the report explicitly states that the panel ". . . was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others." (HEI, 1999, p. 1) Furthermore, the HEI panel ". . . recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category." [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that "the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.'" (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in "[s]ome reviews critical of these data." (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had "discusse[d] this literature in depth" and had expressed no such opinions. In the same paragraph, the Panel confirmed that "[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time." (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as "highly likely" to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from "highly likely" to "likely," this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that "[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' in regard to environmental exposures." (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had "dismissed" opposing arguments critical of the positive studies, especially "regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * *. [IMC Global]"

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of "Potential Systematic Biases." Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of "Meta-Analyses."

IMC Global quoted Morgan et al. (1997) as concluding that "[a]lthough

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there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis." This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the "striking consistency" of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of "Consistency of Epidemiologic Evidence."

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: "* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure." (Cox, 1997, as quoted by EMA) The EMA, however, prematurely terminated this quotation. The quoted sentence continues: "* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung)." MSHA does not regard concentrations of dpm exceeding 200 $\mu g/m^3$ as "low to moderate," and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: "* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase." (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as "threats to causal inference." In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was "* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *." (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially "explain away" the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, "an unidentified negative confounder may have produced bias across studies, systematically diluting RRs."

b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial and persuasive evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments at a significant rate. This section will consider the significance of the risk faced by miners exposed to dpm.

i. Meaning of Significant Risk

(1) Legal Requirements

The benzene case, cited earlier in this risk assessment, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a "consensus" standard for exposure to benzene, as authorized by the OSH Act. The standard set an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.* at 619 *et seq.*). Although the "evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best," OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.*, at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires "safe or healthful employment," the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [Id., at 642, italics in original].

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

> First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe.' [*Id.*, at 655].

The court noted that the Agency's "* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations." (Id., note 62).

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

> * * * OSHA had contended in * * * [the benzene] case that "because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time". 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that "the benefits to be derived from lowering" the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'." 448 U.S. at 654.
>
> One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's "cotton dust" standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: "In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case." Id. at 505, n. 25. See also Public Citizen Research Group v. Tyson, 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); United Steelworkers of America v. Marshall, 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied , 453 U.S. 913 (1981) (where in promulgating a new lead standard "OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels"). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

> * * * the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or "black lung"), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a "qualitative" assessment "has no statistical meaning."

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a "perfect" risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: "The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to Dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–11 presents a similar comparison, based on the highest mean dpm level observed at

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any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[76] As shown in Figure III–11, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

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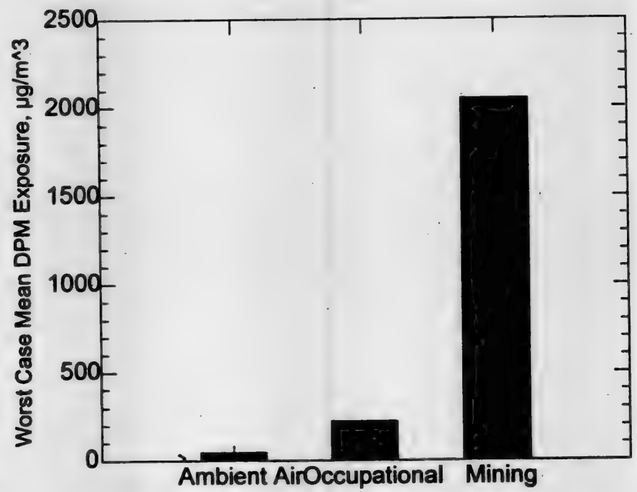


Figure III-11. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Given the significant increases in mortality and other acute health effects associated with increments of 25 µg/m³ in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground coal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that

[76] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.

can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. In 1996 MSHA published the diesel equipment safety rule that focused primarily on the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines. In developing this diesel equipment safety rule for underground coal mines, however, MSHA did not explicitly consider the health risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels. It was understood that the agency would be evaluating the health risks of dpm exposure at a later date. (61 FR 55420). With the implementation of the diesel safety rule in underground coal mines, MSHA believes that dpm concentrations may have declined, in the past two to three years. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 µg/m³—less than half of the average level that MSHA observed in its field studies. However, MSHA also believes that a reduction in exposure of more than 50 percent is highly implausible, even with the safety standard implemented. It is also important to note that the diesel equipment rule applied only to underground coal mines and not underground metal/nonmetal mines.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level*. The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 µg/m³ for tunneling and non-coal mining; 100 µg/m³ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 µg/m³ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 µg/m³ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 µg/m³ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (including allergenic responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms.

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This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute "material impairments" under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies.MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 $\mu g/m^3$ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 $\mu g/m^3$. For example, for a $PM_{2.5}$ concentration of 40 $\mu g/m^3$, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 $\mu g/m^3$ over an 8-hour workshift are at least as great as those at a concentration of 20 $\mu g/m^3$ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 $\mu g/m^3$ would correspond to a short-term occupational exposure to dpm at a concentration of 60 $\mu g/m^3$. Consequently, the RR at an occupational exposure level of Y $\mu g/m^3$ would equal the RR calculated for an ambient exposure level of $20 \times (Y/60)$ $\mu g/m^3$. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 $\mu g/m^3$ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 $\mu g/m^3$ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 $\mu g/m^3$ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 $\mu g/m^3$ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^5$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 $\mu g/m^3$ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 $\mu g/m^3$ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of "coarse" respirable particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute

mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 $\mu g/m^3$ in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 $\mu g/m^3$, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 $\mu g/m^3$. For a concentration of 300 $\mu g/m^3$, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1)(b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * * [U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were conducted on populations whose average exposure is estimated to be less than 200 $\mu g/m^3$—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 $\mu g/m^3$ EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to

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less than 150 µg/m³ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 µg/m³ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 µg/m³ for hostlers displayed in Figure III–11 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et.al. (1999), the mean TC concentration measured for production areas was 390 µg/m³—corresponding to a mean dpm concentration of about 490 µg/m³. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 µg/m³ for coal mines and 808 µg/m³ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
Geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

> Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]
>
> If Dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[77]

Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 µg/m³ yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

> The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

[77] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had "misrepresented the findings of a critical study" by stating that all methods showed an "unacceptably high risk" at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. "that reached an opposite conclusion." Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort, and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 µg/m³ for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

> At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

> What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have "very limited utility for QRA * * * at ambient levels" [emphasis added], this does not mean, even if true, that these data have "no relevance" to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 µg/m³ for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on "broad assumptions." The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results "should be viewed as exploratory." The commenter then asserted that MSHA had nevertheless used these results as "the basis for a major regulatory standard" and that "[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support." [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude "exploratory" results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

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Assuming that, on average, EC comprises 40 percent of total dpm,[78] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is

$$RR = \exp(0.4 \times 0.389 \times CumExp),$$

where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m³), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is

$$RR = \exp(0.1803 \times (\text{Log}(0.4 \times 1000 \times CumExp + BG) - \text{Log}(BG))),$$

still ignoring occupational dpm exposure in the most recent five years.[79]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m³ (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 μg/m³) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 μg-yr/m³). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 μg/m³ amounts to a cumulative dpm exposure of 36,360 μg-yr/m³, or about 36.4 mg-yr/m³. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

[78] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[79] BG, expressed in μg-yr/m³, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 μg/m³. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 μg-yr/m³. "Log" refers to the natural logarithm, and "exp" refers to the antilogarithm of the subsequent quantity.

(ii) Exposure-Response Relationships From Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Säverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m³.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a "mine-adjusted" and a "mine-unadjusted" statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[80] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m³ of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m³ by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Säverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m³ of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m³ of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m³ of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20} = 8.1$. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS

Study and statistical model	Unit RR per mg-yr/m³ dpm
Säverin et al. (1999):†	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997):‡	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

† Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.

‡ Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 μg/m³. Then each year of occupational exposure would contribute 0.5 mg-yr/m³ to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure

[80] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the "norm" for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m³ of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is $RR = (1.176)^{10} = 5.1$. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m³ accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is $RR = (1.321)^{7.5} = 8.1$. At age 80 or above, however, this model predicts that the relative risk would increase to $RR = (1.321)^{10} = 16.2$.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is $RR = (1.024)^{45 \times 0.644} = 2.0$ at a mean concentration of 644 μg/m³ or $RR = (1.024)^{45 \times 0.808} = 2.4$ at mean concentration of 808 μg/m³. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 μg/m³. The second-lowest estimate of relative risk, for example, is $RR = (1.089)^{45 \times 0.644} = 11.8$, predicted by Säverin's full cohort Cox model.[81]

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

[81] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 μg/m³. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston et al. (1997).

(iii) Excess Risk at Specific Dpm Exposure Levels

The "excess risk" discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 μg/m³, 500 μg/m³, 644 μg/m³ (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 μg/m³ (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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Table III-7. — Lifetime excess risk of lung cancer mortality at specific Dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers†			
	200 µg/m³	500 µg/m³	644 µg/m³	808 µg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

† Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 µg/m³, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 µg/m³) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 µg/m³), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 µg/m³), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum*; 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Even though the coal rule is an equipment based standard limiting emissions to 5.0 gm/hr and 2.5 gm/hr dpm output, MSHA estimates that these emissions limits will result in ambient dpm concentration in an underground coal mines of approximately 200 µg/m³. MSHA believes this is a reasonable estimate to use in light of several sample calculations which indicate that using available controls in underground mining sections with dirty equipment can reduce emissions to that level or further. For example, in part IV of this preamble, MSHA discusses the comparison of the machine-based standard in this final rule with the State of Pennsylvania's diesel law. MSHA provides data showing that a permissible engine equipped with a 95% filter and using the approval plate air quantity will result in a calculated ambient concentration of dpm of 142 µg/m³. In part V of this preamble, MSHA uses the "Estimator"—a computerized spreadsheet designed to calculate dpm ambient levels from given engine emissions and mine ventilation rates and the impact of various controls on those ambient levels. Table V–3 of part V presents Estimator results using another permissible engine to show that the ambient levels would be approximately 200 µg/m³ when applying various filters and using various intake dpm concentrations.

An alternative approach to estimating exposures once the rule is implemented is to look at the factors affecting dpm production. Dpm exposure is related to the emissions from engines, ventilation, and engine duty cycle. If emissions drop from 25 and 50 gm/hr (dpm concentration range emitted from current permissible engines) to 2.5 and 5.0 gm/hr (as required under the rule), there would be a ten-fold reduction in exposure. With current ventilation required for the diesel equipment, the ambient concentrations would also be reduced accordingly. Thus, assuming that emissions will be reduced down to 200 µg/m³ is a conservative approach in estimating benefits.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 µg/m³ may not have the same short-term effects as an 8-hour exposure at 60 µg/m³. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. As explained in Part IV of the preamble, the rule is expected to limit dpm concentrations to which miners in underground coal mines are exposed to approximately 200 µg/m³. Assuming that, in the absence of this rule, underground coal miners would be occupationally exposed to dpm for 45 years at a mean level of 644 µg/m³, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 644 µg/m³ and 200 µg/m³, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 644 µG/M³ TO 200µG/M³

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners†
Säverin et al. (1999):	
Poisson, full cohort	46
Cox, full cohort	352
Poisson, subcohort	470
Cox, subcohort	579
Johnston et al. (1997):	
15-year lag, mine-adjusted	457
15-year lag, mine-unadjusted	298

†Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground coal mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner Dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, "* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners," MSHA should "proceed with rulemaking based on the evidence currently available as presented in this

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FR notice." [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

* * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

* * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Discussion of Final Rule

This part of the preamble describes each of the provisions of the final rule. As appropriate, this part references discussions in other parts of this preamble: In particular, the background discussions and controls in part II, and the feasibility discussions in part V.

Table IV–1 will be referenced throughout this discussion. The table provides information about each engine approved by MSHA for use in underground coal mines. This table reflects the emission results based on the MSHA approval data.

The top rows of the table provide information about permissible configurations, designated by the MSHA approval numbers which contain an "A"; the remainder of the table provides information about nonpermissible configurations, designated by the MSHA approval numbers which contain a "B". Within each engine grouping, the permissible engines are listed in order of MSHA approval number, and the nonpermissible engines are listed in increasing "Rated Horsepower".

The table has ten columns. The first column gives the MSHA approval number. The second and third column lists the engine manufacturer and the engine model designation. The fourth column lists the rated horsepower of the engine as approved by MSHA. The fifth column gives the Particulate Index (PI) expressed in cubic feet per minute (cfm), the sixth column lists the DPM emissions expressed in gm/hr—weighted average over the 8 mode test cycle specified in 30 CFR 7.89, the seventh column weighted average horsepower, the eighth is the dpm expressed in grams per bhp-hr (calculated by dividing column six by column seven), the ninth column gives the filter efficiency needed to meet a 5.0 gm/hr standard, and the tenth column gives the filter efficiency needed to meet a 2.5 gm/hr standard.

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Table IV-1

MSHA Approved Diesel Engines under Part 7, subpart E

Approval No.	Manufacturer	Engine Model	Rated	PI	DPM gm/hr	Weighted Avg.	DPM	Filter Efficiency	Filter Efficiency
		* Meets EPA	Horsepower	CFM	Weighted Avg.	Horsepower	gr/bhp-hr	To Obtain 5.0gm/hr	To Obtain 2.5gm/hr
A001	DEUTZ	MWM 916	94	15000	25.49	51.1	0.50		90.2
A002	CATERPILLAR	3306 PCNA	150	27000	45.88	87.2	0.53		94.6
A003	CATERPILLAR	3304 PCNA	100	17500	29.74	58.1	0.51		91.6
A004	ISUZU	QD 100-306	70	50000	84.96	40.7	2.09		97.1
A004	ISUZU	QD 100-306	66	10000	16.99	34	0.50		85.3
A005	Caterpiller	3306PCTA	190	31000	52.68	95	0.55		95.3
B070	Farymann	43F	14	4000	6.80	7.00	0.97	26.4	63.2
B042	Lister Petter	LPU2 MKI	17.5	5000	8.50	9.1	0.93	41.2	70.6
B053	Kubota	V1200*	25.8	1500	2.55	13	0.20	0.0	1.9
B041	Lister Petter	LPU3 MKI	26.3	7000	11.89	13.7	0.87	58.0	79.0
B062	Deutz	F2L1011*	28.2	1000	1.70	14	0.12	0.0	0.0
B044	Lister Petter	LPU3 MKII	29	4500	7.65	15.1	0.51	34.6	67.3
B015	DEUTZ	F2L 1011F*	30	3500	5.95	15.6	0.38	15.9	58.0
B040	Lister Petter	LPU4 MKI	35	9500	16.14	18.2	0.89	69.0	84.5
B043	Lister Petter	LPU4 MKII	38.6	6000	10.20	20.1	0.51	51.0	75.5
B026	DEUTZ	F3L 912W*	40	2500	4.25	21.7	0.20	0.0	41.2
B061	Deutz	F3L1011*	41.6	1500	2.55	21	0.12	0.0	1.9
B033	PERKINS	104-19	42.5	7000	11.89	22.4	0.53	58.0	79.0
B014	DEUTZ	F3L 1011F*	44	5000	8.50	23.3	0.36	41.2	70.6
B054	Deutz	F3M1011F*	46	3500	5.95	24.2	0.25	15.9	58.0
B031	DEUTZ	F3L 912W *	47	2500	4.25	24.7	0.17	0.0	41.2
B025	DEUTZ	F4L 912W*	54	3500	5.95	28.9	0.21	15.9	58.0
B060	Deutz	F4L1011*	56.3	2000	3.40	28	0.12	0.0	26.4
B038	ISUZU	QD60 (C240)	57	5500	9.35	27.6	0.34	46.5	73.3
B027	PERKINS	704-26	58	8000	13.59	28.8	0.47	63.2	81.6
B013	DEUTZ	F4L 1011F	59	6500	11.05	31.1	0.36	54.7	77.4
B055	Deutz	F4M1011F*	61	4500	7.65	32.30	0.24	34.6	67.3
B029	DEUTZ	F4L 912W*	62	3500	5.95	32.9	0.18	15.9	58.0
B024	DEUTZ	F5L 912W*	67	4500	7.65	36.2	0.21	34.6	67.3
B019	DEUTZ	BF4L 1011F*	74	4500	7.65	40	0.19	34.6	67.3
B030	DEUTZ	F5L 912W *	76	4000	6.80	41.1	0.17	26.4	63.2
B006	ISUZU	QD 100-301	79	8500	14.44	43.5	0.33	65.4	82.7
B023	DEUTZ	F6L 912W*	80	5000	8.50	43.4	0.20	41.2	70.6
B056	Deutz	BF4M1011F*	82	5500	9.35	44.75	0.21	46.5	73.3
B028	DEUTZ	F6L 912W *	93	5000	8.50	49.3	0.17	41.2	70.6
B001	DEUTZ	MWM 916	94	11500	19.54	46.2	0.42	74.4	87.2

B004	CATERPILLAR	3304 PCNA	100	15000	25.49	52.8	0.48	80.4	90.2
B022	PERKINS	1004-40T	106	9000	15.29	55.4	0.28	67.3	83.7
B064	Caterpillar	3054DIT	108	9000	15.29	54.00	0.28	67.3	83.7
B045	ISUZU	4BG1T-MA	111	13000	22.09	57.7	0.38	77.4	88.7
B011	DEUTZ	BF4M 1012EC*	113	4000	6.80	59.1	0.12	26.4	63.2
B020	PERKINS	1004-40TW*	122	7500	12.74	62.6	0.20	60.8	80.4
B065	Caterpillar	3054DITA*	122	7500	12.74	61.00	0.21	60.8	80.4
B059	Deutz	BF4M1013*	127	4500	7.65	64	0.12	34.6	67.3
B046	ISUZU	6BG1-MA	129	16000	27.19	67.1	0.41	81.6	90.8
B039	ISUZU	QD145	135	12000	20.39	70.5	0.29	75.5	87.7
B034	DEUTZ	F6L 413FW*	137	7000	11.89	75.4	0.16	58.0	79.0
B003	CATERPILLAR	3306 PCNA	150	23000	39.08	79.2	0.49	87.2	93.6
B021	PERKINS	1006-60T	152	12000	20.39	82.6	0.25	75.5	87.7
B066	Caterpillar	3056DIT	152	12000	20.39	76.00	0.27	75.5	87.7
B008	DEUTZ	BF4M 1013EC*	158	7500	12.74	82.5	0.15	60.8	80.4
B005	GENERAL MOTORS	L57, 8.5L* - 1994	160	9500	16.14	83.5	0.19	69.0	84.5
B052	Cummins	5.9-175 w/cat* - 1994	175	3500	5.95	93.70	0.06	15.9	58.0
B052	Cummins	5.9-175 w/oat* - 1994	175	5000	8.50	93.70	0.09	41.2	70.6
B035	DEUTZ	F8L 413FW	182	9500	16.14	100.6	0.16	69.0	84.5
B067	Navistar	A185	185	15000	25.49	93.00	0.27	80.4	90.2
B058	Deutz	BF6M1013*	194	5500	9.35	97	0.10	46.5	73.3
B016	GENERAL MOTORS	L65, 6.5L - 1998	195	24000	40.78	101.8	0.40	87.7	93.9
B068	Navistar	A225* - 1994	215	11000	18.69	108.00	0.17	73.3	86.6
B063	Caterpillar	3306PCTA	215	31000	52.68	108.00	0.49	90.5	95.3
B036	DEUTZ	F10L 413FW	228	12000	20.39	125.7	0.16	75.5	87.7
B050	Detroit Diesel	Series 40 DDEC*	230	4500	7.65	118.6	0.06	34.6	67.3
B057	Deutz	BF6M1013C*	233	8500	14.44	117.00	0.12	65.4	82.7
B051	Cummins	ISB235* - 1998	235	6000	10.20	113.6	0.09	51.0	75.5
B069	Navistar	B250* - 1994	250	6000	10.20	125.00	0.08	51.0	75.5
B007	DEUTZ	BF6M 1013ECP	261	19000	32.29	136.2	0.24	84.5	92.3
B010	CATERPILLAR	3306 DITA*	270	6000	10.20	154.5	0.07	51.0	75.5
B037	DEUTZ	F12L 413FW	274	14000	23.79	150.8	0.16	79.0	89.5
B017	CATERPILLAR	3306 ATAAC*	300	12000	20.39	172.5	0.12	75.5	87.7
B047	Detroit Diesel	Series 50 DDEC*	315	5000	8.50	166.7	0.05	41.2	70.6
B048	Detroit Diesel	Series 60 11.1 DDEC*	325	5500	9.35	179.7	0.05	46.5	73.3
B012	CATERPILLAR	3176 ATAAC	335	8000	13.59	191	0.07	63.2	81.6
B002	DEUTZ	BF6M 1015C*	402	17500	29.74	219.1	0.14	83.2	91.6
B049	Detroit Diesel	Series 60 12.7 DDEC*	475	8500	14.44	249	0.06	65.4	82.7
B018	CATERPILLAR	3406E*	500	12500	21.24	274.8	0.08	76.5	88.2
B009	DEUTZ	BF8M 1015C*	536	18000	30.59	269.7	0.11	83.7	91.8
B032	Detroit Diesel	8V-2000TA DDEC*	650	10000	16.99	364.7	0.05	70.6	85.3

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The final rule would add six new sections to 30 CFR part 72 on March 20, 2001.

Section 72.500 Emission Limits for Permissible Diesel Powered Equipment.

Organization. As with the proposed rule, this section establishes the controls applicable to permissible equipment. As proposed, 30 CFR 72.500 also had included other requirements—controls for nonpermissible heavy-duty vehicles in 30 CFR 72.500(b) and requirements for the maintenance of such controls in 72.500(c). In this final rule, MSHA has retained the requirements for dpm reduction for permissible equipment in this section but has moved the requirements for nonpermissible heavy-duty vehicles to a new 30 CFR 72.501. MSHA has also moved the maintenance requirements for emission controls to a new 30 CFR 72.503. These organizational changes were made to make it easier for the mining community to locate specific requirements in the final rule.

Summary of final rule. The final rule requires all permissible equipment to meet an emissions limit of 2.5 grams of dpm per hour. The existing fleet has 18 months to meet this limit. In addition, any permissible engine introduced into the fleet of an underground coal mine after the effective date of this rule will have to meet that standard upon being introduced into the mine. MSHA means by "introduced" any equipment added to the mine's diesel equipment inventory. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing. It also includes engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

Infeasibility of a concentration limit for underground coal mines. The preamble accompanying the proposed rule explained why the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines. The Agency was not confident at the time the rule was proposed that there was a measurement method for dpm that provided accurate, consistent and verifiable results at lower concentration levels in underground coal mines. The available measurement methods for determining dpm concentrations in underground coal mines were carefully evaluated by the Agency, including field testing, before the Agency reached this conclusion. The Agency continued to collect data and has consulted with NIOSH in an attempt to resolve questions about the measurement of dpm in underground coal mines. There were no comments received that objected to the fact that the Agency was not proposing an ambient concentration limit for underground coal mines as it was proposing for underground metal and nonmetal mines.

Why dpm emissions from permissible equipment need to be controlled. The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from permissible equipment in particular. Dpm concentration samples taken in the field indicate that permissible equipment used for face haulage makes the largest contribution to high dpm levels. Dpm samples taken in the intake air to working sections where diesel face haulage was used showed relatively low dpm levels. When diesel particulate filters were not used, dpm samples taken on the working section and in returns from those sections generally showed dpm levels in excess of 500 μg/m³.

Other permissible equipment can also generate significant dpm emissions because this equipment utilizes the same engines as used in face haulage equipment. Since the time of the proposal, the diesel inventory for permissible machines has not changed significantly. The same four permissible engines that were available at the time the proposal was written continue to be the power source for the current permissible fleet. Table IV–1 shows that these four engines produce higher dpm emissions on a gm/hr basis than nonpermissible engines with the same horsepower. Commenters did not present evidence that dpm concentrations in areas where permissible equipment is used have decreased since the proposed rule was published.

Why the final rule uses a machine based emission limit instead of a requirement for the addition of a filter with a specified filtration efficiency. The final rule for permissible equipment is different from that proposed. As proposed by MSHA (63 FR 17491 et.seq.), 30 CFR 72.500(a) would have required mine operators to install on permissible vehicles a system capable of removing on average, at least 95% of dpm by mass. Operators were required to complete these filter installations within 18 months from the date of publication of the final rule; no action to control emissions from permissible equipment was required before that date.

The use of an emissions limit for permissible machines in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed. In that preamble, the agency also described a number of alternative approaches considered, and asked the mining community to comment on whether there were other approaches for the control of dpm from permissible equipment that might accomplish the same task with more flexibility. 63 FR 17498, 17499, 17556, 17563. The agency also described the approach being taken by the State of Pennsylvania that combined a filter efficiency standard with a tailpipe limit.

The Agency emphasized that it was particularly interested in comment on an alternative approach it described that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.*, 63 FR 17556, 17563). In fact, a separate "Question and Answer" was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653.

Based on the record, MSHA has concluded that the original proposal had deficiencies which are avoided by this alternative approach.

MSHA received many comments objecting to exclusive reliance on filters. Commenters stated that MSHA was denying operators the benefit of the full range of available dpm controls outlined in MSHA's Toolbox (the history and content of which are described in Part II of this preamble). These commenters stated that mine operators should be allowed to chose the combination of controls that best suit their operations.

On the other hand, other commenters favored requiring a filter on all underground mining equipment (including permissible equipment). Some of these commenters noted that controls are only effective if properly maintained, and some asserted that filters are easier to monitor in this regard than engines. Similarly, commenters argued that in the absence of a requirement for a filter on each piece of equipment, operators would rely primarily on increased ventilation to control dpm concentrations, and asserted that the industry had a very poor record of maintaining ventilation controls. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as reducing the mass of dpm discharged, whereas newer diesel engines designed to produce less dpm mass may actually

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increase the number of nanoparticles emitted.

A number of commenters pointed out that even if filters were required, relying on a filter-efficiency standard would be inappropriate. These commenters noted that even if a particular efficiency (*e.g.*, 95%) is achievable with a "dirty" engine like those currently composing the underground coal permissible fleet, such efficiency may not be feasible on the modern, clean burning engines that will eventually take their place. That is, if the emissions from a "cleaner" engine are lower to begin with, the filter mounted on a machine with such an engine would have to be much more efficient than the one mounted on a machine with a dirtier engine to remove the same percentage of dpm. Commenters stated that since it might not be possible to meet the proposed requirement for a 95% efficient filter with a newer engine, MSHA's proposed rule might well inhibit the introduction of cleaner engines into underground coal mines, and thus force operators to rely on older and dirtier engines which would require more maintenance.

There was also considerable discussion at the hearings and in the written comments about the experience of Pennsylvania, which has a 95% filter efficiency standard for permissible and other diesel equipment, as well as a requirement that each piece of equipment meet an emissions standard. Commenters clarified the development of that approach, its requirements and procedures, and implementation issues to date; many noted problems in meeting the standard as currently set forth. Other commenters noted that what might be feasible for Pennsylvania, a state which heretofore has not permitted diesel equipment underground, might not be feasible for operators in other states with existing fleets.

As proposed, the rule would have ensured that the emissions from the most polluting, commonly used engine (Caterpillar 3306PCNA, 150 horsepower, 45.88 gm/hr) would be reduced by 95%, resulting in tailpipe emissions of 2.29 gm/hr (5% of 44.88 gm/hr). After carefully considering all of the discussion at the hearings and the written comments, MSHA has concluded that the alternative approach on which it initially invited comment, a dpm emissions limit for each machine, has a number of advantages over the approach initially proposed. While MSHA has evidence that there are filters readily available for the existing permissible fleet which are 95% efficient it lacks evidence of the technological feasibility of filter performance at a 95% level for the cleaner engines which will eventually replace the current fleet. Moreover, the same problem exists at any filter efficiency rating. Changing the proposed rule to require that filters on permissible equipment must only be 70% efficient, as suggested by a commenter, does not guarantee they can provide this efficiency for future engines. At the same time it sets a limit for the current fleet that is far below what can be achieved. Thus, while a requirement for a high filter efficiency could have the perverse effect of inhibiting the introduction of cleaner engine technologies or other technologies that could be forthcoming that could make substantial reductions in dpm levels, a low filter efficiency requirement fails to provide protection for miners from dpm emissions from engines in today's fleet. Accordingly, MSHA has concluded that requiring a specific filter efficiency is not a good idea, either by itself or (as is the case in Pennsylvania) as a supplement to a machine emissions limit.

The machine emission limit specified in this final rule achieves the desired goal of significantly reducing the mass of dpm emitted from the permissible machines without specifying a filter efficiency. Using the 2.5 gm/hr emission limit provides a consistent target and resolves the issue relative to lower filter efficiency or cleaner engines.

With this final rule, MSHA is allowing the mine operator a wide choice of approaches from the toolbox to control dpm such as low emission diesel engines, aftertreatment controls (catalytic converters and/or dpm filters), fuel with a very low level sulfur content, alternative fuels, and fuel additives in order to meet the machine emission limit. Other aspects of the MSHA toolbox are already a requirement in underground coal mines such as the use of approved diesel engines, fuel with a sulfur content less than 500 ppm, optional EPA approved fuel additives, regular maintenance by qualified mechanics, prohibition of unnecessary idling, and training of mechanics and equipment operators. In practice, however, MSHA expects all permissible equipment to need filtration to achieve the required limit.

The final rule does not, however, permit operators to satisfy the requirements for permissible equipment by increasing ventilation or by using enclosed cabs, although the Toolbox describes both as methods for reducing miner exposure to dpm. While MSHA encourages operators to take such steps, the Agency concluded that it would not be appropriate to make an adjustment to or an exemption from the machine emissions limit when such controls are used.

In the case of ventilation, while increasing mine ventilation does reduce dpm concentrations in the ambient air, such a change does not impact a requirement based strictly on the emissions emitted from an individual machine. One variation of the alternative proposed by MSHA would have allowed a credit for added ventilation in determining whether a machine met the required emissions limit. However, after careful consideration the agency has concluded that this approach is inappropriate. It should be noted that while the agency acknowledges the evidence offered by many commenters that reliance upon ventilation as a primary dpm control is inappropriate in light of the record of violations of ventilation standards—even though not all of the data supplied supported the general conclusion being expressed and does not reflect the implementation of the new diesel equipment rule—this is not the basis on which the agency has determined not to allow operators a credit for increasing ventilation. Rather, MSHA concluded that such an approach would not be necessary in light of its conclusion about the capabilities of paper filters alone to enable the permissible fleet to meet the requirement. Controlling engine emissions to the required levels would have called for a ventilation rate of five times the engine particulate index air quantity. This quantity would have been specified in the Approved Ventilation Plan. Such a ventilation rate is achievable in only a few mines. At the same time, once the proper filter is installed, the emissions are controlled to the required levels; allowing a credit for ventilation makes no difference in practice given the range of available filters. While providing a ventilation credit would allow operators to use a less efficient filter, this would reduce dpm emissions less in such mines; and since the use of more efficient filters is feasible, the Act requires MSHA to pick the more protective approach. Moreover, due to the mobility of the equipment, a ventilation credit for outby equipment would be difficult to monitor and enforce. The Agency has indirectly allowed for ventilation by allowing a higher outby emission rate. The higher outby emission rate for light-duty equipment was based on the duty cycle and the normally higher ventilation rates in outby areas. Additionally, allowing for a ventilation credit based on the specific air volume would have become too complicated to administer in certain cases (for example, permissible equipment in multi-entry systems, or permissible equipment used in outby areas). Ventilation regulations for single and multiple units of permissible diesel equipment are based primarily on the approval plate quantity. Depending on a ventilation quantity other than that on the approval plate would have complicated an already complex issue.

While enclosed cabs or booths can be used to lower exposures for a machine operator, cabs do not currently exist for permissible underground coal mining equipment. Even if developed for permissible equipment, these enclosures would not provide protection for other miners working in that same area. Moreover, there will be no sampling to assure that the miners are protected. Consequently, the final rule requires that even if a cab were developed for permissible equipment, dpm emission limits would have to be maintained the same as other permissible equipment.

Having made the determination that an emissions limit is preferable to a filter efficiency requirement, and not to provide credit for ventilation or an exemption for the use of cabs, MSHA turned to the question of whether filters should always be required. Some commenters noted that controls are only effective if properly maintained, and asserted that filters are easier to monitor in this regard than engines. Also, one commenter asserted that filters were the only known control that would limit the number of nanoparticles emitted as well as dpm mass, whereas newer diesel engines designed to produce less dpm mass may actually increase the number of nanoparticles emitted.

With respect to maintenance, MSHA notes that while the provisions of the recently promulgated diesel equipment regulations dealing with maintenance and the training of qualified maintenance personnel were in effect at the time of the hearing, the full effect of implementation of these provisions may not have been apparent to the commenters. These regulations when fully implemented, should address many of the concerns expressed by the commenters in this regard.

With respect to nanoparticles, section 5 of Part II of this preamble notes that there is very little information at this time about the possible risk of such particles. Moreover, the evidence on whether filters can protect against such particles is unclear. In any event, it will be some time before the newest generation of diesel engines becomes commonplace in underground mines.

Accordingly, MSHA has concluded that at this time, it is not necessary to require filters that specifically limit nanoparticles. MSHA will, however, continue to monitor the situation. If it becomes apparent that the evidence warrants further action, the agency will not hesitate to act upon that information. In practice, as noted above, current permissible equipment will have to be filtered to meet the emissions standard.

In this regard, one commenter stated that if MSHA does not require filters on all equipment underground, it would be more difficult for the individual states to require filters on all diesel equipment. MSHA does not agree with the commentar. States can impose a more stringent standard than MSHA's requirements. While MSHA recognizes that Pennsylvania and West Virginia and other States are going to take a close look at the Federal government's standard, each State faces different circumstances—*e.g.*, the number and nature of diesel powered equipment already underground, the economic situation of the state's coal industry, etc. MSHA's discussion of the risks of dpm exposure in Part III suggest that further controls would be warranted where it is technologically and economically feasible for the underground coal mining industry as a whole to implement such controls; and while MSHA has concluded this is not feasible for the US industry as a whole, an individual State might well conclude it is feasible for the situation that exists in that State.

Some commenters requested that some or all of the State of Pennsylvania approach be adopted by MSHA. The Pennsylvania law requires an MSHA approved engine, a catalytic converter, and a 95% filter. Additionally, Pennsylvania establishes a ventilating air requirement calculated to dilute the dpm emitted from the filter to 120μ/m³. With respect to permissible equipment, MSHA's requirement for a machine dpm emission limit of 2.5 grams per hour is essentially equivalent to the emissions standard required under Pennsylvania law.

MSHA did not adopt a calculated ambient dpm concentration based on the approval plate air quantity. Instead, MSHA set the emission standard to represent the dpm emitted from the individual machine. However, since MSHA already requires an approval plate quantity based on the gaseous emissions, an ambient dpm concentration can be calculated from the engine's dpm emission data, the filter efficiency, and the approval plate air quantity. For example, as noted on Table IV–1, the Caterpillar 3306 PCNA engine produces 45.88 gm/hr of dpm from the Category A, permissible configuration. This engine has an approval plate quantity of 9500 cfm or 269m³/minute of air. When equipped with a 95% dpm filter, the resultant calculated laboratory ambient quantity for a single machine using the Caterpillar 3306 PCNA engine would be 142μ/m³. This is based on the following formula: (dpm,gm/hr) / 60 * ((100–95%)* 1000 / (approval plate quantity, m³/minute)* 1000. To reduce the emissions of this engine to the level specified in the Pennsylvania law would require additional air or a higher efficiency filter.

One commenter presented data from a laboratory test conducted on different filter media. The data indicated that the highest efficiency achieved was 81% using the ISO 8178, C1 test cycle. This commenter suggested that MSHA adopt an approach similar to the Pennsylvania approach but establish a 0.5 milligram per cubic meter (mg/m³) calculated ambient concentration instead of the 120μ/m³ (0.120 mg/m³). This commenter's approach included the use of a minimum 70% efficient filter and a recalculation of the approval plate air quantity to achieve the 500μ/m³ (0.5 mg/m3) concentration.

As with the Pennsylvania approach, MSHA basically agrees with the commenter's general approach. The dpm emission limits specified in this final rule limits the machine's dpm output, requiring the mine operator to choose an engine and aftertreatment device, if necessary, to meet the standard. This approach as previously stated significantly reduces dpm emissions and is based on laboratory testing of the engine and filter. However, since MSHA currently has a requirement for the use of approval plate air quantities in underground coal, MSHA did not impose an additional calculated approval plate air quantity as suggested by the commenters. MSHA is not imposing a minimum filter efficiency as suggested by the commenters because MSHA believes that the mine operator should be able to use all the available tools to meet the standards. MSHA believes that all of the current permissible engines will require filtration to meet the standard; however with this approach taken in the final rule, MSHA is not limiting future technologies.

A commenter asked why the Agency had not chosen to utilize the particulate index established during the MSHA approval process for each engine as the basis of any dpm regulation.

As discussed in Part II of this preamble, the requirement for determining the particulate index was

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contained in the Agency's diesel equipment regulations. It implemented a recommendation of the Diesel Advisory Committee which called for a particulate index to be set for approved diesel engines. The particulate index specifies the quantity of air needed to dilute the particulate generated by the engine to 1 milligram of diesel particulate matter per cubic meter of air and is based on data collected under the engine approval test described in 30 CFR 7.89.

MSHA established the particulate index to be used as a guide to the mining community in making certain decisions about the control of dpm while the Agency finalized regulations that specifically addressed dpm. This information is available to the mining industry from the manufacturer and MSHA. The particulate index enables the mining community to compare the particulate levels generated by different engines in terms of a ventilating air quantity. For example, if the particulate indices for diesel engines of the same horsepower were established as 7,500 cubic feet of air per minute (cfm) and 12,000 cfm respectively, an equipment manufacturer, mine operator, and MSHA personnel can use this information, along with consideration of the type of machine the engines would power and the area of the mine in which it would be used, to make certain decisions. A mine operator can use this information when choosing an engine to roughly estimate an engine's contribution of diesel particulate to the mine's total respirable dust. MSHA would use this information when evaluating mine dust control plans. Equipment manufacturers can use the particulate index to design and install exhaust after-treatments. MSHA posts this information on its website at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM for permissible engines and at *http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM* for nonpermissible engines.

Had the Agency decided to take an approach in this regulation similar to the approach taken by the state of Pennsylvania in its diesel law, or to establish an ambient dpm concentration limit, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. Instead, as was discussed above, the Agency chose to limit the quantity of dpm emitted from the machine, and is therefore expressing the standard in that fashion.

Nevertheless, there is a relationship between the PI and the machine limits established under this rule. The determination of the quantity of dpm emitted from the machine is based on the same information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine start with determining the permissible fleet. With the exception of the Isuzu QD100 engine which is only used in two machines in the permissible fleet, the Caterpillar 3306 PCNA meets this criteria. The Caterpillar engine emits approximately 46 grams of dpm per hour based on the MSHA approval test for part 7, Category A. Accordingly a 90% reduction would limit emissions to 5.0 grams an hour; and a 95% reduction would limit emissions to 2.5 grams an hour. If a filter could reduce the dpm emitted from the Caterpillar engine to these levels, it could reduce the emissions of any other permissible engine in the fleet to that level.

A number of commenters stated that they had been unable to substantiate the agency's contention that there are filters commercially available that meet such high efficiency requirements. Moreover they asserted that the only system which allegedly came close to this requirement, a system known as the DST®, was a system that would be economically infeasible to install on the entire current fleet of permissible equipment.

The DST® system is described in section 6 of Part II. Data was submitted for the record that the DST® system does indeed reduce the dpm emissions from an engine by more than 95% (*i.e.*, below 2.5 grams per hour) when tested on the ISO 8178,C1 test cycle. The engine tested with the DST® was a MWM916–6 diesel engine which emits 25.5 gm/hr based on the MSHA approval test for part 7, Category A. The system is composed of several components; a paper filter and a catalytic converter, with a heat exchanger used to reduce the temperature of the exhaust to the levels required by MSHA for permissible equipment. The low exhaust gas temperature enables the use of a paper filter without igniting the filter. Most permissible equipment uses water scrubbers to cool the exhaust temperature; hence, switching to the dry system would involve considerable expense.

The agency has reviewed the evidence to determine whether a commercially available paper type filter, mounted at the outlet of the water scrubber used to cool the exhaust of most permissible machines, can achieve comparable reductions in dpm emissions. Filter kits are readily available for most permissible machines, and the costs of equipping the fleet in this fashion is significantly lower than converting everything to a dry system.

MSHA had good reason to think that paper filters alone could do the job. In the early 1990's, equipment manufacturers along with the then Bureau of Mines installed paper filters to the exhaust of water scrubbers for dpm reduction. These systems proved to be very effective in dpm removal. Some mines have used these filters on permissible equipment successfully since the early 1980s. Anecdotal experience was also supportive. For example, a miner commented very favorably about improvement in emissions from a diesel equipped with a paper filter. The miner was referring to a dry system other than DST®. Moreover, based upon what it knows about the components of the DST® system discussed above, MSHA had reason to believe that based upon the extent to which the heat exchanger and catalytic convertor can themselves reduce dpm concentrations, that the main reason for the extensive dpm reduction of the system might well be the paper filter. However, although the record could support such a conclusion, the record contained no specific filter efficiency data. Moreover, some asserted that the DST® results were due to all of its components working together. Other commenters challenged the agency's assumption that a 95% reduction of emissions from the permissible engines that produce the highest dpm concentrations was feasible. Such a filter efficiency would be necessary to satisfy an emissions limit of 2.5 grams per hour.

In order to dispel any doubts about the matter and verify whether the addition of a paper filter alone could achieve such a significant reduction in dpm, MSHA had an analysis performed by an independent laboratory. MSHA has placed a full report of this verification analysis in the record. The analysis was performed on an engine that is representative of the permissible engines in the fleet that produce the most dpm.

The part 7 approval information indicates that three engines—the Caterpillar 3306 PCNA, 3304 PCNA, and the MWM 916–6—are basically of the same design. The Caterpillar 3306 PCNA used for the analysis is representative of the three engines' emissions performance. The Isuzu QD 100 is approved by MSHA and is used in a small number of permissible machines that can emit higher levels of dpm than the Caterpillar engine tested. This occurs when the Isuzu engine is adjusted to the highest horsepower rating approved by MSHA. However, this engine can be derated to an existing lower horsepower MSHA approval rating which is only 5.5% lower than maximum rating. The two machines of which MSHA is aware that are currently using this engine are operated in a two entry mine through a petition for modification. The petition for modification requires these machines to be permissible. If this was not the case, the two machines that are currently using this engine would be considered light-duty equipment. In a light-duty equipment application, the lower horsepower adjustment for this engine would not be as critical as when installed in a heavy duty machine.

MSHA contracted with Southwest Research Institute (SwRI) to determine the efficiency of a paper filter when installed on a Jeffrey dry system equipped with a Caterpillar 3306 PCNA diesel engine. Jeffrey's permissible system incorporates a heat exchanger and a synthetic type filter, but no oxidation catalytic converter. For the purpose of this verification test, a paper filter was substituted for the synthetic filter. In the setup for the verification test, as described below, the paper filter efficiency was determined.

Although most permissible equipment is cooled by a water scrubber, MSHA did not ask SwRI to verify filter performance with a water scrubber system actually in place. The agency has concluded that such verification is not feasible at this time. Laboratory testing of dpm removal efficiency with a water scrubber is very difficult due to the high moisture content of the exhaust. The high moisture content would cause interference in the measurement methods using laboratory dilution tunnels. Others have attempted this type of work on a limited basis, but in most cases, were not successful or the investigators did not repeat previous attempts. Accordingly, as noted under the next heading, MSHA will assume for compliance purposes that a paper filter whose efficiency is measured with a heat exchanger will work just as well when used with a water scrubber.

The paper filter installed on the Jeffery power package was acquired from Donaldson Filter Corporation. The filter paper was a standard primary air filter media, Donaldson Part No. EN0701026. When tested by Donaldson for use as a standard primary air filter media for many applications including diesel engine intake air filter, the paper has a particle removal efficiency of 32% for 0.5 micron particles, 60% for 1.0 micron particle, and 97% for 3.0 microns particles. This information was derived from data using neutralized KCL aerosol and on a test bench which complies with SAE J1669 requirements. The test was conducted on flatsheet media at 10.5 fpm face velocity. However, since the application of this paper filter media is unique to mining, the verification tests determined the efficiency when used in the cooled diesel exhaust stream (less than 300°F) to filter whole dpm (less than 1 micorn in size). The paper filter media used had performance specifications equivalent to the paper filter used on the DST® system. Moreover, it also is the same paper media which is used on the kits sold by Jeffrey and Wagner for installation of a paper filter on the exhaust of a water scrubber.

A standard ISO 8178, C1 eight-mode emission, test which is identical to the tests required by this final, rule was performed in three component configurations. The first configuration consisted of measuring engine-out emissions with no heat exchanger or filter attached to the engine. This was considered baseline dpm emission data. The second configuration consisted of routing the engine exhaust through the heat exchanger and filter housing with no filter installed. The third configuration consisted of installing a filter into the filter housing and routing the exhaust through the heat exchanger and then through the filter. The difference between the mass of diesel particulate measured at the outlet of the filter, and the baseline dpm emissions, enabled the collection efficiency of the filter to be determined.

The results of the verification conducted by Southwest Research Institute confirmed that a paper filter, without a catalytic converter, can reduce the dpm emissions of a Caterpillar 3306PCNA by 95%, down to a machine emissions rate of 2.3 gm/hr, thus meeting the 2.5 gm/hr standard. When the efficiency of the paper filter, as determined in the Southwest verification is applied to MSHA's approval data for these three permissible engines which make up almost all of the current permissible fleet, the 2.5 gm/hr standard is met. This is illustrated in the part of Table IV–1 dealing with permissible engines.

As can be seen in that table, machines equipped with the Isuzu QD–100 engine cannot meet the standard as currently operated. However, these engines can be derated from the highest power setting to a lower power setting and, with a paper filter, meet the emissions limit as shown by the second rating for that engine in the table. Since the paper filter used in the test has the same paper media as is generally used for dpm filters, MSHA has verified that the installation of a paper type filter alone will reduce the dpm concentration on all permissible machines currently in usage in underground coal mines.

A commenter who reviewed the report of the verification test conducted by SwRI raised two issues about relying upon the results.

One issue involves the dpm reduction from the heat exchanger. The results of the SwRI test indicated that there was a 9% reduction in dpm attributable to the heat exchanger. The commenter questioned whether the 9% attributed to the heat exchanger was also reported in the 95% reduction in dpm for the disposable paper filter. The test procedures required particulate measurements be made on bare engine emissions, with the heat exchanger in-line, and with the heat exchanger and disposable paper filter in-line. Comparing the particulate measurements made with the heat exchanger and filter installed to the measurements with only the heat exchanger installed, a 95% reduction in dpm concentration was observed.

The commenter also questioned the validity of the SwRI test because the results of two tests were different with the filter installed. MSHA is aware of the minor difference in test results. However, MSHA's interest is in the efficiency of a clean filter, not a used filter. The efficiency of a used filter is typically greater than the efficiency of a clean filter. The second test was the 8-mode test using the same filter tested in the first test. The filter was exposed to dpm for approximately four hours (time incurred in running the first test). MSHA expected this second test to perform similarly. In fact, on a percentage basis, the results were close, 94% versus 96%, as shown in figure 4 of the SwRI report. However, MSHA does agree with the commenter that the results would be expected to be closer. Although not documented on the SwRI report, the raw data did show an increase in the filter weight from the first 8 mode test. SwRI and MSHA hypothesize that a "chunk" of dpm may have dislodged from the filter paper during the test and biased the filter weight. As with any lab testing, further studies could have been done to investigate the difference. However, as noted in the next section, MSHA intends to use the results of this test as the basis for accepting as evidence of compliance with the standard for permissible equipment the use of a paper filter like that tested; accordingly, the agency believes it can proceed without this confirmatory data.

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One commenter suggested that a standard adopted by MSHA would have to be adjusted with respect to equipment used at high altitude. This commenter stated that high altitude has an extreme effect on these types of filtration systems. This commenter's experience appeared to be related to catalytic converters. The commenter did not supply any data in supporting his position.

MSHA is aware of the effect of altitude on engine performance. Engine deration must be performed on most engines to compensate for the decrease in the density of air at increasing altitudes to maintain the proper fuel-air ratio. However, the effect on aftertreatment controls specifically claimed by the commenter is not supported by any scientific principle. MSHA has experience with the former BOM on the use of paper filters on permissible machines at a high altitude mine. These were very successful tests. MSHA is not aware of any problems with other types of filters, including ceramic filters. If a self regeneration problem is noted by a mine, then the mine could use acceptable alternative regeneration devices to clean the ceramic filters. MSHA believes that the machine's dpm emission levels specified in this final rule are feasible at high altitude mines and the mine operator has many options available to meet the standards. Moreover, as discussed in the next section, if an operator is using a paper filter that is consistent with that already tested by MSHA, the agency will find the machine in compliance. There is no requirement in the final rule for an ambient air test; the laboratory test will be used.

MSHA wishes to note that it did receive comments from some in the industry acknowledging that it was appropriate for the agency to force technology; and also received some comments from filter manufacturers to the effect that they could meet whatever requirements MSHA set. Moreover, many miners commented that the costs of controlling dpm should not factor into the human cost of overexposure to dpm.

In light of these comments, and the statute, MSHA did consider whether it would be feasible for the underground coal mining industry to meet tighter requirements than the 2.5 gm/hr standard chosen. However, as discussed in Part V concerning feasibility, MSHA recognizes that the underground coal mining community has certain other relatively new standards with which to comply and others pending; moreover, the dpm exposure generated by permissible equipment is only one dpm source in many mines that needs to be addressed. Accordingly, the agency believes that an effort to force technology on paper filters at this time would not be warranted.

How the mining community can go about implementing this requirement, and how MSHA can help. As explained above, MSHA has verified that a commercially available paper filter can reduce the emissions of any permissible piece of equipment to 2.5 grams per hour, and so has set the limit at that point. But the rule itself provides flexibility of controls, and there are many aftertreatment products on the market. Thus both MSHA and operators need a way to know whether a particular combination of controls will limit emissions to 2.5 grams per hour.

The emission rate of a machine will be determined by the engine baseline dpm concentration determined during the MSHA engine approval process. The engine baseline dpm data for each MSHA approved engine is already known to the Agency. For the convenience of the mining community, the Agency is adding this information to its approval listings currently on the agency's web site. This information for permissible engines is located at http://www.msha.gov/S&HINFO/DESLREG/1907b5.HTM.

Under the final rule, an operator can purchase any commercially available aftertreatment device and would, upon a request from MSHA, have to provide evidence that the device would reduce the emissions of the machine on which it is to be installed to the emission standard. However, in a majority of cases the mine operator will not be required to submit any data nor have any aftertreatment device tested. This is because MSHA will accept as evidence of compliance the use of any paper filter which meets or exceeds the specifications of the paper filter used in the verification described above; and, as noted in the discussion of that test, it appears that *most current paper filters designed to reduce dpm use exactly the same paper as that used in the system tested.* Thus, a mine operator can add almost any current paper filter to permissible machines without additional filter tests and be in compliance with the machine emission limit.

It should be remembered, however, that the agency has established criteria for filter media intended for use on permissible equipment that go beyond filtration efficiency. These criteria were established to ensure that the addition of the filter would not compromise the permissibility features of the machine. MSHA will continue to apply these criteria in conjunction with this rule. A list of paper filters meeting the permissibility criteria and which have the required efficiency will be posted on the MSHA web site as this information becomes available.

As noted above, MSHA's verification was conducted on a system whose exhaust was cooled by a heat exchanger, not a system whose exhaust was cooled by a water scrubber. MSHA recognizes that most permissible equipment is cooled by a water scrubber, and that MSHA has not verified filter performance with a water scrubber system actually in place. For the reasons noted, the agency has concluded that such verification is not feasible at this time. Since such verification is not feasible at this time, for purposes of implementing the rule, MSHA will assume that the results achieved with a filter tested on a dry exhaust cooling system apply equally to a system in which the exhaust is cooled by a water scrubber.

The modifications required for the addition of a paper filter to the permissible machines can be made without any additional filter efficiency tests being conducted by the mine operator or machine manufacturer. The addition of a paper filter to the exhaust of the existing permissible machines would be evidence that those machines meet the 2.5 gm/hr standard. The mine operator would simply purchase a paper filter kit from the manufacturer of the permissible machine or perform a field modification to add an equivalent paper filter to the permissible machines. Since the machines are permissible, any modifications would have to be evaluated to make sure that the permissibility aspects of the diesel power package are not affected. This would normally involve evaluation of the machine's total backpressure and the addition of a high temperature exhaust gas sensor to the safety shutdown system.

The process that mine operators may elect to follow to demonstrate compliance with the dpm standard is very similar to the process MSHA established for existing permissible machines when the 1996 diesel equipment rule was implemented. MSHA had four engines tested to determine a gaseous ventilation rate and particulate index for those engines. Mine operators only needed to update the machine approval plate to show the newly determined gaseous ventilation rate to continue to operate the existing permissible machine. The machine manufacturer normally supplied the updated plate.

To demonstrate compliance with the dpm rule, the mine operator need only add a filter kit supplied by the equipment manufacturer. Filter kits which have been evaluated for permissibility are available from machine manufacturers for approximately 222 out of the 481 permissible machines that are not already equipped with filters. In the event that a kit is not available for a particular machine, the mine operator may work with the machine manufacturer to adapt an existing kit, or fabricate a special kit. MSHA will expedite the evaluation of field modifications submitted by mine operators to add such kits.

One commenter stated that MSHA has not done enough with its knowledgeable personnel and research facility, and indicated that industry would welcome the opportunity to develop with MSHA research and development programs in the area of dpm filtration. MSHA has worked with NIOSH, labor representatives, and the industry in the past and is committed to continue to work with these groups on projects which promote a safer mining environment. The Diesel Toolbox arose out of just such an effort, as described in part II. But the Agency must also act to require the use of existing technology when it determines that miners are at significant risk of a material impairment to their health.

One concern expressed by the mining community about more extensive reliance upon paper filtration systems is the increased potential for fires if, for example, water scrubbers run dry and the exhaust gases then become hot enough to ignite the paper filters. Several commenters expressed concerns about reports of fires that occurred on permissible diesel powered equipment on which paper particulate filters had been installed. Commenters told of fires on equipment in both western and eastern mines and further stated that the fires were the result of a lack of maintenance. While MSHA is concerned about all fires in underground mines, fires on permissible equipment are of particular concern because that equipment may operate in areas of the mine where methane may be present.

Shortly after particulate filters were introduced, MSHA received reports of a filter fire in an underground mine and at a surface facility of a second mine. In the latter incident, the machine operator was unaware that a filter had been installed and continued to operate the equipment on the surface without water in the water scrubber. After looking into the incidents, MSHA issued a Program Information Bulletin informing the mining community of the importance of maintaining those components of permissible diesel power packages that limit the exhaust gas temperature below 170 degrees Fahrenheit. This PIB, P92–17, was published on October 23, 1992, and was given wide distribution throughout the country.

Until the public hearings on this rule, MSHA was not aware of any additional filter fires. MSHA has no additional information concerning incidents of fires in mines involving permissible diesel equipment with particulate filters. Maintenance personnel at one mine had related that several filters had been exposed to high exhaust gas temperatures and that the filter media had started smoldering. The smoldering had been accompanied by significant amounts of smoke which alerted the equipment operators. The equipment operators removed the filters and extinguished the smoldering material before any actual fire broke out. According to mine maintenance personnel, these incidents had occurred several years ago, and since improved maintenance procedures were established and additional training had been provided, no additional problems had been noted.

MSHA has continued to investigate this matter because of the potential consequences of a filter fire underground. MSHA is aware of a filter media used in Australia for the same application on permissible diesel equipment. The media is called Filtrete and is manufactured by 3M. The media is polypropylene and when exposed to a heat source, the media reportedly melts away rather than burns. Reportedly, the filter media is as effective at removing diesel particulate as the filters currently used on diesels with water scrubber systems. MSHA is in contact with the filter manufacturer, and with Australian mine regulatory authorities, and mine operators concerning their experience with the filters. MSHA has also reviewed the flammability characteristics of the filter media used on dry type permissible diesels. One such media is a fiberglass/polyester fabric which seems to have flammability characteristics similar to the Filtrete media.

As noted by at least one commenter, observing the recent diesel equipment maintenance requirements should minimize the already small potential for any problems. Nevertheless, MSHA will continue to look at alternative media, if for no other reason that to ascertain if they perform better than paper filters in removing dpm from the engine emissions.

Although operators can comply with this requirement by using a paper filter, MSHA would like to encourage the introduction of cleaner engines in permissible equipment. The rule does not deal directly with factors which may be discouraging operators from using engines which incorporate the latest technologies to reduce dpm emissions. In order for an engine to be used in underground coal mines in permissible equipment, the engine has to be approved by MSHA for permissible applications, and this process operates at the initiative of engine manufacturers rather than mine operators. MSHA notes that even though engine manufacturers are producing significantly cleaner diesel engines, engine manufacturers have not submitted applications to MSHA to have these newer engines approved for permissible applications prior to this final rule. There are 528 permissible diesel powered machines in underground coal mines. The majority of the permissible machines use the Caterpillar 3306 PCNA, Caterpillar 3304 PCNA, or the Deutz-MWM 916–6 diesel engines as stated previously. These engines are of older technology design and produce almost 10 times the dpm emissions as modern engines. However, due to the costs of obtaining approval of an engine for permissible applications, which are borne by the applicant, and low sales volumes in underground coal for permissible machines, engine manufacturers are understandably reluctant to submit new technology engines for approval as permissible.

MSHA is developing programs that would facilitate the availability of engines that utilize the latest technologies to reduce gaseous and particulate emissions for use in permissible equipment. Current engine designs that utilize low emissions technologies are currently approved by MSHA in nonpermissible form. Particulate emissions are currently being determined by third parties testing under 30 CFR, Part 7. MSHA is in the process of purchasing an engine particulate testing system. Once this system is installed, MSHA will be able to facilitate testing and defer some of the cost of diesel engine particulate emission testing at its Approval and Testing Center. MSHA is considering a number of other programs that could aid the industry with emission tests.

One of the programs that MSHA is considering would follow the precedent established in the recently published diesel equipment rule. To facilitate compliance with this dpm rule, MSHA is considering funding the additional emissions testing needed to gain approval as permissible, certain

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previously approved, non-permissible engines that utilize low emissions technology engines. Additionally, MSHA is considering waiving the normal fees that the Agency charges for the administrative and technical evaluation portion of the approval process.

Alternatively, MSHA may relax, as an interim measure, the requirement that engine approvals be issued only to engine manufacturers. This requirement, stated in part 7, is intended to ensure that the party to whom the engine approval is granted has the ability to ensure that the engine is manufactured in the approved configuration. MSHA is considering a program in which an equipment manufacturer may utilize an engine, approved by MSHA as nonpermissible, in a permissible power package. MSHA would ensure that the additional emissions tests required for permissible engines are conducted as part of the power package approval process. The use of an engine previously approved as nonpermissible is a critical element of the program. For those engines, the engine manufacturer has already made the commitment to manufacture the engine in an approved configuration. The permissible configuration would be the same as the nonpermissible configuration. Provisions of the two programs could be combined. MSHA will solicit input from the mining community as it continues to develop these program concepts.

In response to comments, MSHA also took another look at the other components added to diesel engines of permissible equipment. One such control on permissible equipment is the device used to cool the hot gases emitted by diesel engines to the temperatures required for permissible applications. Specifically, in order to use a paper filter, a means of cooling the exhaust gas must be installed upstream of the paper filter to reduce the exhaust temperature below the ignition temperature of filter media. This is accomplished on permissible machines with either a water scrubber or a heat exchanger. The water scrubber allows the water to contact the exhaust, thus cooling the exhaust to less than 170° F. The heat exchanger cools without direct contact between water and the exhaust, thus providing a dryer exhaust. Research conducted by others has shown that water scrubbers can lower dpm concentrations by 20–30%. The Southwest verification showed that a heat exchanger can remove approximately 9% of the dpm. Either cooling method would reduce dpm to some degree; however MSHA is confident, and the SwRI tests clearly showed, that the majority of the filtering comes from the paper filter.

One commenter asserted that the most important emissions control that could be placed on a piece of diesel equipment is a catalytic converter. While there is some evidence in the record suggesting that OCCs can remove up to 20% of dpm emissions, this commenter's assertions about the importance of this control appear to stem from the view that the hazards to miners from diesel emissions come primarily from diesel gases rather than the particulate emissions. As indicated in MSHA's risk assessment, the risks which MSHA is acting to prevent in this case are from particulate emissions. Catalytic converters alone could not reduce dpm emissions from permissible equipment to levels that MSHA deems necessary.

Time frames for implementation. Commenters were also concerned that the 18-month time frame established in the proposed rule to bring existing fleets into compliance would not be feasible.

In part, these concerns stemmed from technological feasibility—that controls did not yet exist which would be available by the required time. Also, these concerns related to economic feasibility. As noted above, some commenters thought they would have to replace wet systems with a dry system package in order to comply with the proposed rule; such a changeover would be expensive and, given the amount of work involved, take time. Others were concerned about the availability of filtration systems that would fit existing systems and the time necessary to develop or rig systems to fit on a variety of existing machines underground.

The evidence discussed above addresses these concerns. MSHA is not pushing technology with the proposed emissions limit; rather, the technology is already here and for many pieces of equipment already in kit form for ready installation. The costs to the industry as a whole of adding paper filter to the permissible fleet after 18 months are economically feasible as well.

Moreover, the final rule requires that a permissible piece of equipment being "introduced" underground for the first time 60 days after this rule is promulgated will have to be so equipped.

MSHA means by "introduced" any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. "Introduced" means newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another. It does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt.

As a result of the information discussed above, MSHA has determined that this requirement is both technologically and economically feasible to require any newly introduced equipment to have the filter in place (see MSHA's REA for additional information). MSHA recognizes that in some areas, longwall moving equipment may be shared among mines, and that in one or two cases a scheduled longwall move could be impacted by this effective date; however, MSHA has concluded that by working with machine manufacturers, operators who find themselves in such a situation can avoid any disruptions.

72.501 Emission Limits for Nonpermissible Heavy Duty Diesel Powered Equipment, Generators, and Compressors

Organization. MSHA proposed limits on the dpm emitted by nonpermissible heavy-duty vehicles as part of 30 CFR 72.500, but in the final rule MSHA moved these requirements to a new 30 CFR 72.501. Also, this section now contains requirements for two types of light-duty equipment whose operating characteristics produce large quantities of dpm.

Summary of final rule. In the final rule, MSHA has adopted a machine emission limit for heavy duty diesel powered equipment, as defined by § 75.1908(a), just as it is doing with permissible equipment pursuant to § 72.500 of this final rule. It also applies this limit to generators and compressors.

Paragraph (a) specifies a machine emission limit for dpm at 5.0 gm/hr for heavy-duty equipment, generators or compressors introduced into an underground area of an underground coal mine more than 60 days after the date of publication of this final rule. "Introduced" means any equipment added to the mine's diesel equipment inventory.

Paragraph (b) provides that the fleet of such equipment already in a mine must reach a machine emission limit for dpm at 5.0 gm/hr within 30 months.

Paragraph (c) provides that the emission limit for all such equipment is further reduced to 2.5 gm/hr after 4 years.

Paragraph (d) exempts from the requirements of the rule any generator or compressor that discharges its exhaust directly into intake air that is coursed directly into a return air course, or discharges its exhaust directly into a return air course.

Why dpm emissions from heavy-duty equipment, generators and compressors need to be controlled.

As discussed in connection with § 72.500, MSHA determined that it could not establish a dpm concentration limit for underground coal mines, and therefore needed to focus its attention on the control of dpm emissions from specific types of equipment.

The preamble accompanying the proposed rule also explained why the agency was proposing to limit the emissions from heavy-duty equipment in particular. MSHA discussed earlier in the permissible section that engines used in permissible equipment generated large quantities of dpm. Many pieces of heavy-duty equipment utilize the same engines as permissible equipment and consequently produce similar high levels of dpm. MSHA closely examined the dpm emission rates from engines used in other heavy-duty equipment and found them to be as high as those rates found in permissible equipment. Furthermore, heavy-duty equipment is used in areas of the mine where the ventilation quantities may be less than those provided where permissible equipment is used. Equipment that moves long wall components is known to work at a high duty cycle, in close proximity to miners, and in areas of the mine where there are frequent ventilation interruptions. Numerous commenters stated that diesel emissions continue to be the cause of air quality problems during long wall moves. Even though newer engines are being added to the heavy duty fleet, additional controls are needed to further reduce the dpm levels to which miners are exposed. As shown in table IV–1, engines like the Deutz BF4M1012EC rated at 113hp and the Detroit Diesel Series 40 DDEC rated at 230 horsepower are low emission engines that have been designed to meet current EPA standards. However, the gm/hr levels are still higher than the MSHA standards and would require aftertreatment controls.

The proposed rule did not cover generators and compressors. However, the extension of the heavy duty requirements to generators and compressors stems directly from a question MSHA placed before the mining community. In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that light-duty equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2,030 engines out of the total MSHA inventory of 3121.

The Agency stated that it welcomed "information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule." The Agency went on to say that: "MSHA will consider including in the final rule filtration requirements that may be necessary to address any such identified problem." This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As discussed below, based on the record, MSHA has concluded that generators and compressors, while considered light-duty equipment for purposes of the diesel equipment rule, in fact have operating characteristics that produce large quantities of dpm, and should be controlled in the same manner as heavy-duty equipment.

Numerous commenters spoke on the issue of whether light-duty equipment, as defined by the diesel equipment rule, should be subject to dpm emissions standards. However, the record is divided between those who asserted that this type of equipment really operates much like heavy-duty equipment—*i.e.*, works many hours during a shift at high loads—and those who asserted that the equipment is normally used at low loads and very little during the day. Very limited data was provided by proponents of either position; not enough for MSHA to make a clear determination of which position to adopt when looking at light-duty equipment as a whole.

Based on the record, MSHA believes that light-duty equipment is used in a variety of ways dependent on individual mine situations. The engine loading dependent on mine conditions can play an important role in the emissions from the diesel. Two different mining conditions with identical equipment could experience vastly different emission levels from these engines due to the engine load that must be produced to complete the work. Therefore the commenters may be correct for their individual mines where the light-duty equipment must work at higher engine loads to complete the work. However, other miners with identical equipment may not experience the same degree of engine load which could result in lower levels of exhaust emissions.

However, the situation becomes much clearer when the focus narrows to specific types of light-duty equipment. For example, one commenter noted that some light-duty equipment (such as air compressors) which was exempt from requirements in the proposed rule, emitted high levels of dpm as determined by emission analyzers. Another commenter stated that larger engines that have heavy duty loads produce more dpm per hour and should be controlled. The commenter specifically recommended an OCC, adequate ventilation, and soot (dpm) filters.

After a review of the information available, MSHA has concluded that air compressors and generators emit more dpm in the mine environment than other light-duty equipment because their engines are operated continuously under high-load conditions when they are running. Generators are designed to run under a loaded condition to produce electricity and air compressors work at full load to produce compressed air. In both cases, these engines are operating at a high load, which contributes to high dpm emissions. Based on the information provided by a commenter that the gaseous emissions levels from air compressors were high, this would correlate with high engine load and also would be related to higher dpm emissions. In addition, generators and compressors can use very large horsepower engines, *i.e.* above 200 horsepower; by comparison, permissible equipment generally does not exceed 150 horsepower. In fact, some of the highest horsepower engines in underground coal mines are in generators and compressors. For example, in Table IV–1 engines that are known to be used in generators and compressors are represented by approval numbers B018, B037, and B036 and have horsepower ratings of 500, 275, and 220, respectively. Accordingly, in the final rule MSHA requires that air compressors and the generators meet the same engine emission limits as established for heavy-duty equipment. MSHA's inventory indicates that there are 66 air

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compressors and generators out of a total of 3,121 pieces of diesel-powered equipment in underground coal mines—about 3% of the 2,096 light duty units.

Why the final rule uses a machine-based emission limit instead of requiring for a high-efficiency filtration system.

The proposed rule would have required mine operators by 30 months from the date of publication of the final rule to install, on nonpermissible heavy-duty vehicles, a system capable of removing, on average, at least 95% of dpm by mass.

The use of a machine emissions limit in the final rule stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based proposed rule. In that preamble, the Agency requested comment on an alternative approach that would establish a machine based limit on emissions in lieu of a filter efficiency requirement (see, *e.g.*, 63 FR 17556, 17563). In fact, a separate "Question and Answer" was included in the preamble to highlight this alternative, immediately after the description of the proposed rule. 63 FR 17501, 17653. Based on the record, MSHA has concluded that the original proposal had deficiencies (such as a credit for clean engines and a variety of filter efficiencies) which are avoided by the alternative approach.

As explained in connection with § 72.500, based on the record developed, the Agency concluded that a machine based emissions limit avoids a number of problems with the approach initially proposed. The explanation provided in that discussion as to (1) why MSHA moved to a machine based emissions limit for permissible equipment; (2) why it decided not to make adjustments for ventilation or permit an exemption for enclosed cabs; and (3) the flexibility in choice of controls provided to operators, is fully applicable for heavy-duty equipment, and accordingly is not repeated.

Why MSHA concluded that the emissions limit for heavy-duty equipment, generators and compressors should ultimately be 2.5 grams per hour. As with permissible equipment, the emissions limit for this type of equipment was determined with reference to technological and economic feasibility. As is evident from the final rule, the emissions limit is 2.5 grams/hour, the same as the permissible limit; and, like permissible equipment, 2.5 grams/hour represents a 95% reduction in the dpm emissions of the engine that produced the most dpm emission in this category.

MSHA wishes to emphasize that despite this fact, the limit in the final rule was not merely a determination to use the proposed rule in another form, or to have an equivalency between permissible equipment and this equipment. Rather, once MSHA decided to use an emissions limit approach, it reviewed the record to determine what could feasibly be achieved with the controls available for this type of equipment. Instead of using paper filters as with permissible equipment, this kind of equipment would generally be filtered by ceramic or other hot gas filters—or systems that lower the temperature of the emissions so that paper filters can be used. Ceramic filters cost more than paper filters, require regeneration, and have certain other associated costs. On the other hand, unlike the permissible fleet, the fleet of heavy-duty equipment, generators and compressors has many choices of approved engines available for use, many of them modern technology engines with significantly lower emission rates than the engines currently utilized in this equipment.

Table IV–1 shows the current dpm emissions from MSHA's inventory of heavy-duty equipment, generators and compressors based on engine approval data, and shows the filter efficiency required to reduce those emissions to the interim and final limits required by the final rule. Based on information about the current efficiencies of hot gas filters (discussed in the next section), MSHA believes that a significant percentage of the current fleet can immediately meet a limit of 2.5 grams/hour with such filters alone—and all of the current fleet, except equipment powered by the Caterpillar 3306PCTA, can move immediately to meet a limit of 5.0 grams/hour with filters of only that efficiency. And even in the highly unlikely case that filter efficiency does not continue to improve to meet new demands in Europe and for over the road hauling in the United States, operators can bring the remainder of the fleet into compliance with new engines and filters with present day performance capabilities. In fact, the only reason for the two-tiered approach adopted in the final rule is to ensure that implementation of the rule will be economically feasible.

Some commenters stated that the proposed rule is technology forcing and would require manufacturers to conduct approval tests to market new products, although some commenters who made this observation conceded that MSHA had the legal right to force technology. Another commenter stated that all heavy-duty equipment would require heat exchangers or equivalent means to allow for the use of paper filters since these, in the views of that commenter, appear at present to have higher filter efficiencies.

These comments have some credibility with respect to the original proposal, which would in essence have required the engines that produce the most dpm emission in this category to achieve a limit of 2.5 grams/hour with filters alone; although as noted above, there are already some hot gas filters that are approaching this result. However, the machine emission limits set forth in this section are clearly feasible with current technology, as cleaner, approved nonpermissible engines are available should a piece of equipment not be able to reduce dpm to the required limit with filter alone.

A number of commenters argued that MSHA should not establish a rule which might rely heavily on the availability of ceramic filters because such systems have not performed well from either a practical or efficiency standpoint. MSHA has been aware that in many cases the industry, especially the metal/nonmetal mining sector, has had problems with the use of ceramic filters. However, these problems were reported over 10 years ago when the ceramic filter technology was originally being developed for the on-highway truck engines. When the highway truck sector did not need ceramic traps to comply with the on-highway EPA regulations, significant work on these trap systems was abandoned for the on-highway sector.

More recently, the European directive requiring filters on diesels in confined areas, Canadian mines research with dpm filters, and the continued US efforts to reduce dpm emissions in the environment, have led filter manufacturers to improve the performance and reliability of ceramic filters. Some M/NM mines have reported favorably on the use of ceramic traps. Aftertreatment control vendors, mine operators and VERT have reported filter life of over 8000 hours. After a review of the information in the record in this regard, as was described in more detail in section 6 of Part II, MSHA has concluded that the more recent work with ceramic traps has shown they are feasible for use by the underground coal mining industry.

How the mining community can go about implementing this requirement, and how MSHA can help. While the rule provides flexibility of controls to reach the required limit (controls that reduce engine emissions, that is), most operators are going to utilize hot gas (ceramic) filters to comply. In some cases, however, installation of a cleaner engine or the DST® or similar modified dry system (one without the permissibility components) may be more cost effective, and will be permitted under this machine based rule. Therefore to determine whether a particular machine is in compliance, MSHA will generally need to know the emissions from the engine in the equipment and the filtration efficiency of the filter.

The dpm emission rate of an engine will be established by the dpm concentration determined during the engine approval process. The engine baseline dpm data for each MSHA approved non-permissible engine will be posted on the MSHA homepage at http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Unlike the situation at present with permissible engines, in which none of the cleaner technology engines manufactured in recent years has been submitted for approval for permissible use, engine manufacturers have been submitting applications for approval of nonpermissible engines which meet EPA standards for both on road and nonroad applications. Thus, mine operators have the option of significantly reducing dpm emissions from heavy-duty equipment, generators and compressors by switching to cleaner approved engines. Moreover, MSHA is planning to accelerate the process of approving such engines so as to ensure that equipment of all sizes and shapes can utilize the cleanest engines available.

MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines.

In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized.

As noted in the prior section, MSHA expects that most operators will turn first to hot gas filters to reach the interim or even the final limit. Technically, an operator using a commercial filtration device would, upon a request from MSHA, have to provide evidence that the device is capable of reducing the emissions of the machine on which it is to be installed to the emission standard. The procedures by which a mine operator will demonstrate compliance with the rule are described in detail in the discussion of 30 CFR 72.503 of this part. However, the particulate removal efficiency of many commercially available hot gas filters is evaluated by VERT. VERT is a joint project of several European regulatory agencies, and private companies involved in the tunneling industry. VERT maintains facilities for the testing and evaluation of diesel engine aftertreatment devices for use on equipment used in tunneling. MSHA will accept dpm filtration efficiencies determined by VERT under the provisions of 30 CFR 72.503(c) of this rule.

VERT evaluates the filtration efficiency of candidate devices using a diesel engine with an average dpm production of 0.08 gr/hp-hr. This engine produces less dpm than the majority of engines approved by MSHA. As further discussed in section 72.503, the test must be conducted on an engine that emits no more dpm than the engine that the aftertreatment device will be used on in the machine. This is to ensure that "dirty" engines are not used to over estimate a filter efficiency. The VERT engine used is considered a clean engine by current production standards and clean when compared to many engines in the current underground fleet. The assigned filter efficiencies from VERT would not be considered over-rated and would be consistent with expected efficiencies when used on current underground engines. Consequently, the filter efficiency determined by VERT test can be used to establish the machine dpm level in order to comply with 72.503(b)(i).

MSHA received some comments suggesting the agency could not rely upon the most recent VERT test data (listed in Table II–4) because not enough is known about how those results were derived. MSHA agrees that more information about the test data would be useful; however, given the purposes for which the agency is relying upon the data, the agency believes the information it currently has on the test data are adequate. This information is discussed in section 6 of Part II. The VERT data is generated through procedures as stringent as those MSHA is requiring in the tests which are being established in the final rule for filters not tested by such an organization. While the results noted in Table II–4 have not been incorporated into a published article and has references that are in other sources, MSHA's review of other VERT papers shows that VERT is using the same nomenclature in all their reports and the pertinent information needed from the table is available from these other VERT papers. The table shows VERT results on filters tested "new" and after field test. MSHA is only concerned with the "new" filter efficiency data for applying a filter efficiency number to the baseline engine emission data in order to determine if the machine meets the machine emission limit specified in this final rule. The range of filter efficiencies is not critical since the operator can choose a filter system based on the need for the engine for each individual machine.

MSHA will maintain a list of dpm filtration devices and their filtration efficiencies on its website at www.msha.gov to assist the mining community. Where the particulate reduction capability of an aftertreatment device is not known, the operator would have to have the system tested at a laboratory capable of performing the tests as described in 30 CFR 72.503 of this rule to obtain the necessary data. However, in a majority of cases the mine operator will not be required to submit any data nor have the aftertreatment device tested. Since ceramic filters are used in general industry and automotive applications worldwide, extensive information on filter efficiency is available and a variety of hot gas filters are commercially available.

The two tier machine emission limits provide operators with a choice when making initial control decisions—whether to select a control that will bring the equipment into compliance with the interim limit first, or whether to go ahead and purchase controls that will be required in any event by the final emissions limit. MSHA envisions that the mine operator will in most cases make a single decision as to the options to select to bring the machine into compliance. If the machine is old

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and is expected to reach the end of its useful life in 4 years or less, the mine operator may choose a less costly set of options with the intention to scrap the machine when the lower emission level is effective. However, if the machine has a life expectancy beyond four years, then the mine operator may choose to install a filter system/engine combination that will meet the 2.5 gm/hr standard immediately. Moreover, MSHA has reviewed the VERT list and it identifies several filter systems that can be purchased that have sufficient efficiency ratings to meet the 2.5 gm/hr standard when matched to the majority of the MSHA approved engines in heavy-duty equipment, generators and compressors. MSHA anticipates that more such high efficiency filters will become available before the final emissions limit must be reached. Accordingly, some operators may be able to satisfy the requirements in this fashion.

Yet another alternative that can currently enable heavy-duty equipment to reach the 2.5 gm/hr final limit is the DST® system. Test data was submitted for the record showing an overall system efficiency of greater than 95%. While more costly than hot gas filters, this approach might in some cases be cheaper than a high efficiency hot gas filter and a new engine.

The final rule prohibits any piece of nonpermissible heavy duty diesel powered equipment, generator or compressor, from exceeding 5.0 grams per hour of diesel particulate emissions. MSHA believes that by working with manufacturers of aftertreatment systems, filters can be installed so that newly manufactured machines comply with this requirement. MSHA expects that new equipment, or any equipment with an expected service greater than four years will be provided with a filter capable of meeting the 2.5 gm/hr machine standard.

Section 72.502 Requirements for nonpermissible light-duty diesel powered equipment other than generators and compressors

Organization. The proposed rule did not contain specific provisions for light-duty diesel powered equipment. However, in the preamble to the rule, the agency asked the mining community if light-duty equipment should be subject to provisions that would address dpm emissions. This section is new in the final rule and is based on the large response from the mining community to that question.

Summary of final rule. Paragraph (a) of this section provides that light-duty equipment (other than generators or compressors, which are covered by 30 CFR 72.501) introduced into an underground area of an underground coal mine more than 60 days after the issuance of the final rule cannot emit more than 5.0 grams/hour of dpm. MSHA means by "introduced" any equipment added to the mine's diesel equipment inventory. That inventory, and any changes to it, must be recorded by an operator as a result of this rulemaking and be maintained pursuant to new 30 CFR 72.520. This includes newly purchased equipment, used equipment, or a piece of equipment receiving a replacement engine with a different serial number than the engine it is replacing, including engines or equipment coming from one mine into another, but it does not include a piece of equipment whose engine was previously part of the mine's inventory and rebuilt. MSHA will exempt newly manufactured light-duty equipment from meeting the requirements in 30 CFR 72.502, if the equipment is received after the 60 day time frame as long as a mine operator can present evidence that the equipment was ordered prior to the date of publication of this final rule.

Paragraph (b) provides that an engine will be deemed to be in compliance with this requirement if it meets or exceeds certain EPA dpm emission requirements listed in Table 72.502–1 which appears in the rule.

Paragraph (c) excludes any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan from the requirements of this section.

Why the final rule covers newly introduced light-duty equipment. The final rule's coverage of newly introduced light-duty equipment stems directly from an alternative which MSHA placed before the mining community in the preamble to the filter-efficiency based rule that was proposed.

In reviewing alternative approaches considered by the Agency, the preamble of the proposed rule (63 FR 17564) noted that light-duty equipment does contribute to the total particulate concentration in underground coal mines, and explored the possibility of requiring light-duty equipment to be treated like permissible and heavy-duty equipment. The agency noted that it had tentatively concluded that requiring controls for the whole light duty fleet may not be feasible for the underground coal sector at this time. In this regard, it should be noted that this type of equipment in underground coal mines makes up approximately ⅔ of the whole fleet: 2096 engines out of the total MSHA inventory of 3121.

The preamble further stated that the Agency welcomed "information about light-duty equipment which may be making a particularly significant contribution to dpm emissions in particular mines or particular situations, and which is likely to continue to do so after full implementation of the approval requirements of the diesel equipment rule". As noted in connection with 30 CFR 72.501, the record on this point led MSHA to treat light duty generators and compressors the same way as heavy duty nonpermissible equipment in the final rule.

The preamble to the proposed rule also indicated MSHA's specific interest in exploring whether it would be feasible to require controls on just the new equipment being added to the light duty fleet. "The Agency would also welcome comment on whether it would be feasible for this sector to implement a requirement that any new light-duty equipment added to a mine's fleet be filtered." The Agency further noted that limiting a filtering requirement to just this portion of the light duty fleet was a different issue in terms of economic feasibility than filtering the whole fleet. "By way of rough cost estimate, if turnover is only 10% a year, for example, the cost of such an approach would be only about a tenth of that for filtering all light-duty outby." 63 FR 17564. This discussion was repeated in the section by section review of the proposed rule. (63 FR 17556) The Agency reiterated its request for comments in this regard in its Questions and Answers (Q and A #10, 63 FR 17499).

As noted in the discussion of 30 CFR 72.501 of this part, MSHA received considerable comment on whether the light duty fleet as a whole should be covered. In a significant number of mines, the light duty fleet may work under heavy loads for considerable periods of time, resulting in localized intensive exposures. But it would also appear that in other mines this is not the case; moreover, many of the experiences with localized exposures may have been due to maintenance problems, as the diesel equipment rule with its requirements for maintenance had yet to go into effect.

Also, many miners commented that large numbers of light-duty equipment were in the same area of the mine on occasion and their emissions were not adequately diluted by the ventilation air provided. MSHA believes these comments were made based on experience gained before the effective date of the ventilation requirements under the diesel equipment rule.

Section 70.1900(a)(4) of the diesel equipment rule now allows the district manager to establish areas in the mine where air quality samples for gases must be collected to identify and correct problems such as those described. Even though the focus in 30 CFR 70.1900(a)(4) is on gaseous emissions, the point is that a buildup of gaseous emissions would be an indication of a build up of diesel emissions generally and thus, of the inadequate ventilation that was the concern of the commenters.

The comments about the light duty fleet as a whole were not particularly helpful in evaluating the agency's specific request for comment on whether it would be feasible for this sector to implement a requirement that the emissions from any new light-duty equipment added to a mine's fleet be limited. Nevertheless, as noted in Part III, the best available evidence is that a significant risk of adverse health effects due to dpm exposures will remain even after this rule will be implemented. Since the Agency is under a legal obligation to eliminate significant risks to the extent feasible, the Agency determined it should conduct a further analysis of the feasibility of limiting emissions from newly introduced light-duty equipment into underground coal mines. The service life of light-duty equipment (*e.g.*, pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. Accordingly, if the engines in the new equipment are cleaner than the ones in the old equipment, the dpm emissions in the mine can be lowered over this period of time without the need to place controls on the existing fleet.

MSHA then examined the kinds of engines that were likely to be in new light-duty equipment, as compared with the engines in the current light duty fleet. It turns out that there is likely to be a major difference. Many of the engines in the current fleet were designed and produced before the advent of EPA emission standards. Almost all of those engines likely to be available for introduction underground in the future will be subject to such standards. Accordingly, MSHA has determined that if newly introduced light duty engines or equipment are limited to more recent models, the dpm emissions from the new light duty fleet will eventually be significantly less than from the current fleet. The service life of light-duty equipment (*e.g.*, pickup trucks) is roughly ten years—much shorter than other types of equipment which is often rebuilt underground. As explained in the next section of this discussion, MSHA determined that requiring all light-duty equipment introduced underground in the future to comply with these standards is feasible; the engines required to meet the requirement are available in all types and sizes. Accordingly, the agency decided that the record warranted adoption of the alternative it had placed before the mining community, and the final rule establishes emission standards for newly introduced light-duty equipment.

How did MSHA determine the emissions limit for newly introduced light-duty equipment? MSHA examined whether it could establish the standard for newly introduced light-duty equipment at the same level as the standard it is establishing for newly introduced heavy-duty equipment, generators and compressors. In this regard, the agency looked at two sets of existing requirements to determine what types of engines used in light-duty equipment are readily available today, and then set the standard accordingly. First, the agency looked at current MSHA approval standards, and then it looked at current EPA standards.

The record indicated that equipment in the light duty fleet may be used to the extent that the dpm emissions from these vehicles could contribute to overall mine air quality in a manner similar to heavy-duty equipment. However, an equal number of commenters stated that light-duty vehicles are not used very much except for transporting miners in, out, and around the mine on a limited basis. MSHA believes that mines utilizes their light duty fleet in various ways depending on the individual mine conditions, fleet management, and standard operating practices. Also MSHA believes that many light-duty vehicles are operated in areas of the mine where the ventilation rate exceeds the approval plate quantities. Because MSHA did not receive sufficient information to establish the need to control dpm emissions from light-duty equipment to the same degree as required for heavy duty or permissible equipment, MSHA established a new approach. MSHA determined that no action needs to be taken to modify equipment in the existing light duty fleet. However, MHSA wanted to ensure that steps be taken to limit the dpm emissions from any light-duty equipment introduced into mines. The steps would include purchasing equipment that uses engines representative of the state-of-the-art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications. MSHA also recognized that manufacturers of mine specific vehicles currently utilize engines of older design that would not meet the EPA standards. Manufacturers of this equipment could continue to use these engines with appropriate after treatment of the exhaust to limit the dpm emissions.

In its deliberations to determine the emissions standard that was required to be met by heavy-duty equipment, MSHA also determined that engines in existing light-duty equipment could be provided with commercially available aftertreatment controls to reduce the dpm emissions to 5.0 gm/hr. In fact, some light-duty equipment with relatively low horsepower engines can meet a 5.0 gm/hr standard without any aftertreatment controls.

Some existing light-duty equipment built specifically for mine use is representative of equipment that will probably continue to be introduced into the mines. This type of light-duty equipment will continue to use engines that would not meet the EPA dpm standards. Hence for any such equipment introduced into an underground coal mine after the effective date, aftertreatment will be required.

Consequently, MSHA established the 5.0 gm/hr standard for any light-duty equipment introduced into mines after the effective date of the rule.

As stated above, part of the approach established by MSHA for light-duty equipment was to ensure that introduced light-duty equipment would be provided with engines representative of the state of the art in emission control that are commercially available. These engines would be the type that are being manufactured to comply with the current EPA standards for diesel engines for both on-highway and nonroad applications.

As noted in section 5 of Part II, the EPA emission standards are established for light-duty vehicles and trucks, heavy duty highway engines, and nonroad engines. These requirements take effect for new production runs of engines at various times depending on engine type and size. MSHA recognizes that introduced equipment provided with these engines may exceed the 5.0 gm/hr standard. However, the engines being built to meet the EPA standards represent the state of the art in emission controls that are feasible to limit diesel exhaust emissions for those sizes of engines. MSHA did not intend to require aftertreatment controls on introduced light-duty equipment. MSHA believes that as long as mine

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operators purchase equipment with these new engines, the in-mine dpm concentrations will be reduced as the existing light-duty equipment fleet is replaced.

MSHA has established an exception in 30 CFR 72.502(b) that would allow mine operators to introduce equipment powered by engines that meet the EPA standards listed in Table 72.502–1 in lieu of meeting the 5.0 gm/hr standard given in 72.502(a). MSHA also knows that the EPA intends to tighten the emission standards for new diesel engines. As engines meeting these future requirements are produced, they will also become available for use in mining equipment, thus the overall contribution of dpm from the in-mine light-duty equipment should decrease even further.

MSHA has already approved engines produced by a variety of engine manufacturers in a wide range of horsepowers that meet the EPA standards listed in Table 72.502–1 of this part. These engines are shown on Table IV–1 by an asterisk (*).

Many pickup trucks used in underground coal mines use engines that would be classified by the EPA as "heavy duty highway engines". Consequently, if the engine was produced after 1994, it has met the EPA emissions standard of 0.1 g/bhp-hr shown in table 72.502–1. MSHA believes that the mining community is not likely to have any problem finding a pickup truck that meets the standard. Many pickup trucks can be moved from mine to mine and meet the standard.

This is basically the same for any on-highway engine the EPA classifies as a "light-duty vehicle" or "light duty trucks". If manufactured in or after model year 1994, the vehicle or truck must be limited to a dpm output of 0.1 gr/mile and meets the EPA requirement. However, there are no such vehicles currently in use in mines.

Mine operators frequently purchase equipment for use in underground coal mines that come with engines which are categorized by EPA as nonroad engines for use in underground coal mines. This includes both industrial equipment and mine specific equipment such as forklifts, rockdusters, tractors, pumps, manlifts, personnel carriers, and welders. EPA's requirements on nonroad engines vary by horsepower. As discussed in part II of this preamble, EPA originally regulated these engines at standards referred to as tier 1. The most recent standards that are scheduled to become effective for these engines are designated as tier 2 standards. Many of the engines used in this equipment will soon be meeting the EPA tier 2 dpm limits as a result of the 1998 rulemaking by that agency. MSHA chose the tier 2 standards in 30 CFR 72.502(b) of this part since they will represent the most advanced technologies for emission controls. As previously stated, some nonroad engines are already being produced which meet the tier 2 requirements and have been approved by MSHA. Approximately two-thirds of the nonpermissible MSHA approved engines meet the tier 2 standards. The exact EPA emission limits for each tier for each engine size category are listed in Table 72.502–1 of the final rule which is reproduced here in the preamble for reference:

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TABLE 72.502-1: EPA's Requirements on Nonroad Engines

EPA Requirement	EPA Category		PM Limit
40 CFR 86.094-8(a)(1)(I)(A)(2)	light-duty vehicle		0.1 g/mile
40 CFR 86.094-9(a)(1)(I)(A)(2)	light duty truck		0.1 g/mile
40 CFR 86.094-11(a)(1)(iv)(B)	heavy duty highway engine		0.1 g/bhp-hr
40 CFR 89.112(a)	Tier 2 nonroad		varies by power:
	kW<8	(hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr)
	8≤kW<19	(11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr)
	19≤kW<37	(25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr)
	37≤kW<75	(50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr)
	75≤kW<130	(100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr)
	130≤kW<225	(175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr)
	225≤kW<450	(300≤hp<600)	0.20 g/kW-hr (0.15 g/bhp-hr)

Notes: "g" means grams "kW" means kilowatt
"hp" means horsepower "g/kW-hr" means grams/kilowatt-hour
"g/bhp-hr" means grams/brake horsepower-hour

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In this final rule, operators have the option to meet the requirements of the standard by installing filters on newly introduced light-duty equipment. For example, an operator wishing to take an existing piece of light-duty equipment whose emissions exceed 5.0 grams/hour from one mine and use it in another mine could do so if the machine is equipped with a filter or catalytic converter efficient enough to bring the emissions down to 5.0 grams/hour. MSHA anticipates that the majority of mine operators will choose to purchase equipment with MSHA approved engines meeting the EPA dpm standards. Some models of small utility equipment might be difficult to filter, so the mine operator will probably choose to introduce this type of equipment with an engine that meets EPA requirements. However in some cases where an engine which complies with the 5.0 g/hr standard or the EPA requirements is too expensive or hard to use for a specific machine application, a filter system can be designed in during the construction of the vehicle instead of a retrofit.

The Agency wishes to emphasize that it is not barring operators from introducing used equipment into an underground coal mine simply because it is used. As noted in the examples above, many of these EPA requirements have been in place for a while, so operators should have a wide choice of equipment from which to choose, and in other cases there are MSHA approved engines that will meet the standards.

MSHA will undertake other actions to further facilitate compliance with this standard. As noted above, MSHA is enabling operators to comply with this standard by selecting engines or equipment that comply with various EPA standards. However, under the diesel equipment rule, all engines used underground have to be approved by MSHA. Accordingly, MSHA is reviewing actions that could be taken to facilitate the approval process when an engine meets EPA standards.

As was described earlier in the discussion of the heavy-duty equipment requirements, MSHA is developing a program which will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA testing procedures (currently used only in the certification program for nonroad engines). MSHA will announce the specifics of the program when it is finalized. This program, when implemented, will assure mine operators and mining equipment manufacturers of the availability of low emissions engines, approved by both MSHA and EPA, in a wide range of horsepowers with which they can easily comply with the dpm requirements for light-duty equipment.

Exemption for ambulances and fire fighting equipment. Paragraph (c) of this section excludes from these requirements diesel powered ambulance and fire fighting equipment being used in accordance with the mine fire fighting and evacuation plan under 30 CFR 75.1101–23. This is done in the same manner as MSHA excluded this type of equipment in the diesel equipment rule. This exclusion ensures consistency between this rule and the diesel equipment rule.

Section 72.503 Determination of Emissions; Filter Maintenance

Organization. This section is added to the final rule to specify the means to determine and maintain compliance with the machine emission limits established in this part. The requirements of this section revise and refine provisions included in the proposal under 72.500(c) and (d). The requirements have been moved to a separate section because they are relevant to the requirements of several other sections—30 CFR 72.500, 72.501 and 72.502.

Engine emissions. Section 72.503(a) of the final rule specifies that the amount of dpm emitted by a particular engine shall be determined from the engine approval pursuant to 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A), except for those engines in light-duty equipment deemed to be in compliance with the requirements of this rule pursuant to 30 CFR 72.502(b).

This approach using part 7 engine approval data was inherent in the requirements of proposed 30 CFR 70.500(d). The current formulation refines the requirement to make it more clear and extends coverage to the EPA approval program.

MSHA currently lists all part 7 engine approvals on the Internet. The web addresses have been previously listed in this section. To assist mine operators in complying with the provisions of this rule, MSHA will add the dpm grams per hour number for each approved engine based on the approval test data. This number is calculated from the equations in 30 CFR 7.89(a)(9)(iii)(B) or 7.89(a)(9)(iv)(A) which are direct results of tests conducted for determination of the particulate index. This value will be used as an engine's baseline dpm concentration; the efficiency of the filter will then be multiplied by this baseline dpm number to establish compliance with the machine's emission limit under the appropriate section of this rule. MSHA will use the gm/hr data obtained from the MSHA approval data and not the gm/hr data determined from other filter tests that determine the efficiency of the filter being tested. Results from different engine configurations or different laboratories could give results that could prevent the mine operator from showing compliance. The data could also be different if the tests were run differently from the approval test.

Laboratory test procedures for testing aftertreatment devices; MSHA acceptance of results of other organizations. Section 72.503(b) of this final rule provides that the efficiency of an aftertreatment device is to be established by a laboratory test with a device representative of that to be used—and not by an actual test at the mine site on a particular filter. The test of the aftertreatment device is to be on an approved engine that emits no more dpm than the engine in the machine on which the aftertreatment device is to be used. If the filter test were run on an engine with higher emissions, the filter is likely to be rated as having a higher efficiency than it does when installed on an engine that produces lower emissions. This is consistent with the views of those commenters who objected to the proposal to establish a 95% efficient filter standard on the grounds that they would not be able to maintain such an efficiency as cleaner engines are introduced. The engine is to be run on the same test cycle used for MSHA approvals. The test procedure to follow must be appropriate to the filter media being tested. Furthermore the test is to be done by a laboratory capable of testing engines in accordance with MSHA approval requirements, to ensure consistency among testing and results.

Although these requirements provide the specifications for filter efficiency tests, MSHA does not believe that many filter tests will need to be run in order for mine operators to comply with the requirements of this rule. A key reason is that 30 CFR 72.503(c) allows the Secretary to accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth in 30 CFR 72.503(b). Also, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determined to be essentially identical to the one tested.

With respect to hot gas filters, the agency has already indicated (in the discussion of 30 CFR part 72.501) its intention to accept the efficiency results of any filter tested by VERT—

notwithstanding their use of somewhat different test procedures. MSHA will provide additional information on how mine operators can easily obtain the filter efficiency data from VERT in the compliance guide for this rule.

Moreover, the record of this rulemaking contains data establishing the efficiency of both the DST® system and paper filters. Both of these were tested by SwRI in tests meeting the requirements of this section. MSHA has indicated (in the discussion of proposed section 72.500 of this part) that it will accept as having the same efficiency as the paper filter it tested, any filter using the same or equivalent media. Such filter paper appears to be used for the production of a variety of filters. Consequently, effective filters will be readily available.

The filter efficiency test procedure stated in this final rule is basically the same as that procedure specified in the proposal. This test procedure follows the test cycle specified in part 7, subpart E, for determination of the particulate index. This test is similar to the test procedure used by VERT. VERT has streamlined their test procedure to minimize testing time but retained the main dpm producing modes on the steady state test cycle. The MSHA test procedures in part 7, subpart E were originally adapted from the ISO 8178 procedures. VERT actually follows the test procedures in ISO 8178.

Several commenters questioned whether the ISO 8178 is an appropriate test for performing the filter efficiency tests, but offered no suggestions as to a cycle which should be used. Other commenters stated that the ISO 8178 is the best test at this point in time for conducting the filter efficiency test since no other cycle is available. Because ISO 8178 is an internationally accepted test cycle for evaluating diesel engine emissions, MSHA is retaining the ISO 8178 test procedure in this final rule. However the rule does allow the Secretary to accept data from tests.

MSHA will maintain a list (posted on its web site) of additional sources from which mine operators and inspectors can obtain the necessary information, including aftertreatment manufacturers who follow testing procedures MSHA deems meet its requirements. Mine operators will have to show evidence that for each particular machine, the engine baseline data multiplied by the filter efficiency will meet the appropriate standard. Any questions on acceptance of a filter manufacturer should be made prior to purchasing of the filter media. The mine operator may want to contact MSHA's approval and certification center located at Triadelphia, WVA to determine that the filter efficiency data is acceptable prior to purchasing, especially if the filter data is not from VERT or from a source listed by MSHA.

One commenter stated that industry was concerned that laboratory tests of filters may give invalid indication of filter efficiency. MSHA believes that the filter test should be appropriate to the media; that is the aftertreatment device should be tested with the contaminant that is being controlled. The aftertreatment industry has been testing filters in the laboratory for many years in development of their products. In the case of ceramic type filters, MSHA is not aware of any types of tests performed on ceramics that does not use dpm from the diesel exhaust. Aftertreatment control manufacturers that build dpm control devices test their systems for various applications worldwide, through both laboratory and field work.

Other types of filter media (*e.g.*, paper) have been developed by the mining industry for use on permissible equipment which is specific to mining. General industry does not use paper for dpm reduction due to the high exhaust gas temperatures from diesels. Paper filters are mainly produced as intake air cleaners and industry test standards for determining air cleaner efficiency are followed. Since these filters are mainly used for intake air filters, MSHA believes that industry standard intake air filter tests could be representative tests for this type of filter media when used for dpm reduction. MSHA would compare the paper specifications to determine equivalency. If the papers were equivalent, then air filter type tests would be acceptable to the Secretary for this type of media.

Aftertreatment device maintenance requirements. Section 72.503(d) of this rule states that any aftertreatment device installed on a piece of diesel equipment, upon which the operator relies to remove dpm, shall be maintained in accordance with manufacturer specifications and shall be free of observable defects. Except for the last phrase, which was added by MSHA in order to clarify the requirement for the mining community, this requirement was specified in the proposal under section 72.500(d).

One commenter requested that MSHA also require an on board engine performance and diagnostic system. MSHA is aware that some permissible machines have added electronic type shut down systems and electronic controlled fire suppression systems. On some newer nonpermissible engines, especially larger engines, engine manufacturers use electronic controls to regulate the engine's fuel injection timing and governing. Engines equipped with these electronic devices typically have complete diagnostic capability. MSHA believes as engine technologies develop, more engines will have diagnostic systems built in from the manufacturer. MSHA is not requiring in this final rule on board engine performance and diagnostic systems on equipment. However, MSHA will work with engine manufacturers under the part 7 approval process to evaluate new electronic controls, especially for permissible engines.

Other commenters stated that maintenance is part of the toolbox approach, and therefore ought not to be specifically included. MSHA has a requirement in the current diesel equipment rule to maintain diesel powered equipment in approved and safe condition or be removed from service. This final rule is extending the requirements for maintenance specifically to aftertreatment controls added to the machines to reduce dpm.

Section 72.510 Miners Health Training

Paragraph (a) of this section requires annual hazard awareness training of underground coal miners who can reasonably be expected to be exposed to dpm. Paragraph (b) includes provisions on records retention, access and transfer.

Section 72.510(a) of this rule would require any underground coal miner "who can reasonably be expected to be exposed to diesel emissions" be trained annually in: (1) The health risk associated with exposure to diesel particulate matter; (2) the methods used in the mine to control diesel particulate matter concentrations; (3) identification of the person responsible for maintaining those controls; and (4) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk must be reminded of the dpm hazard to make them active and committed partners in implementing actions that will reduce that risk.

Several commenters expressed concern about which miners will be required to be trained. MSHA believes the rule is clear on this issue. The training need only be provided to underground miners who can reasonably be expected to be exposed to

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dpm at the mine. The training is to be provided by the operator; hence, it is to be without cost to the miner.

The rule places no constraints on how the operator should conduct this training. MSHA believes that the required training can be provided with minimal cost and with minimal disruption. This final rule does not require any special qualifications for instructors, nor does it specify the hours of instruction.

One-on-one discussions that cover the required topics is one approach that can be used. Alternatively, instruction could take place at safety meetings before the shift begins. Several of the training requirements can be covered by simply providing miners with a copy of MSHA's "toolbox." Operators may determine how the "toolbox" can be used at their mine.

The Agency requested comments concerning inclusion of dpm training in the required part 48 training plan. The only comment received suggested that this training be included in the part 48 training and removed from this rule. MSHA considered whether the requirements of part 48 were adequate to ensure the training required under the final diesel particulate standard. After careful consideration, MSHA concluded that available information provided to miners under current part 48 training would be inadequate to fully convey information under the diesel particulate final rule. MSHA will, however, accept part 48 training for compliance with diesel particulate training requirements under this section, provided mine operators fully integrate the requirements of diesel particulate training into their existing program.

Section 115 of the Federal Mine Safety and Health Act of 1977 and 30 CFR part 48, "Training and Retraining of Miners," requires operators to submit to MSHA and obtain its approval of training plans under which miners are provided training, primarily through initial and annual refresher training courses. Part 48, among other things, also specifies qualifications for training instructors, minimum training hours for miners and instruction on particular topics which must be covered within the specified minimum training time. Existing section 48.8(a) establishes a minimum of eight hours of annual refresher training for underground miners. Section 48.8(b), specifies that underground miners must be trained on a minimum of eleven different subjects, none of which MSHA believes would cover the specific requirements for diesel particulate training.

Nevertheless, MSHA believes compliance with this proposal can in many cases be fulfilled at the same time as scheduled part 48 training. The Agency, however, does not believe special language is required in this final rule to permit this action under part 48. If incorporated into part 48, mine operators would, however, be required to submit a revised training plan to the appropriate MSHA district office for approval. Some mine operators, however, may not be able to incorporate these topics in their part 48 plans. MSHA has endeavored to make the training requirements as simple as possible. If conducted separately from part 48 training, there are no specifications on trainer qualifications, no minimal training time, nor any training plans. If, however, the training is incorporated into part 48, then all applicable part 48 requirements will have to be met.

A commenter expressed concerns about individual MSHA inspectors determining their own set of health risks for training purposes and then trying to cite a company for not training on those health risks. They also suggested that the Agency develop a "Question and Answer" document to address this problem. To address the mine operators concern about the training requirements, MSHA intends to develop an instruction outline that mine operators can use as a guide for training personnel. Instruction materials will also be provided with the outline. MSHA believes this will not only provide guidance to the mining industry but also to MSHA inspectors.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice.

Section 72.510(a)(1) of this rule requires the operator to train underground miners who can reasonably be expected to be exposed to diesel emissions in the health risk associated with dpm exposure. Several commenters disagreed with this requirement. They do not believe the health risks associated with exposures to diesel emissions have been sufficiently identified. "If the health effects have not been identified, how can effective training be provided to the effected miners?" MSHA disagrees with this comment. MSHA believes, as throughly discussed in Part III of this preamble, that the health effects associated with diesel emissions have been well documented. Comments received during this rulemaking further support MSHA's position concerning health effects associated with diesel emissions. Therefore, the requirements for training underground miners who can be reasonably be expected to be exposed to diesel emissions have been retained in the final rule.

Section 72.510(a)(3) of this rule requires the operator to identify personnel responsible for maintaining the methods used to control dpm in the mine. Some commenters suggested removing this provision from the rule. These commenters objected to identifying the personnel responsible for maintaining the methods used to control dpm. Because they were concerned about having the employee, "singled out from the remaining workforce." Another commenter, asked how MSHA wanted the operator to identify the employee responsible for maintaining dpm controls; is the name to be posted, made available to interested persons, put in the training plan, etc? While there is no provision in this final rule for posting the information on the mine bulletin board or in any other location, this information is required to be presented to any underground miner who can reasonably be expected to be exposed to diesel emissions. The final rule requires this information to be presented at least annually but does not specify any specific method for presenting the information. The operator has the option of presenting this information orally or in written form.

The Agency believes this provision is consistent with the requirements contained in 30 CFR 75.1915(c). 30 CFR 75.1915(c) requires the operator to maintain a record of persons qualified to perform maintenance, repairs, examinations and tests on diesel-powered equipment. The operator is also required by § 75.1915(c) to include a copy of the training program used to qualify persons to perform maintenance, repairs, examinations and tests in their records. Section 75.1915(c) also requires the operator to make this record available for inspection by an authorized representative of the Secretary of Labor. All records that would need to be maintained concerning the qualification of personnel responsible for maintaining dpm controls are contained in § 75.1915(c). The individuals identified by § 75.1915(c) would also be the individuals identified in § 72.510(a)(3). The requirement to identify personnel qualified to perform specialized tasks is not a novel approach. Therefore, § 72.510(a)(3) has not been changed or deleted from the final rule.

Section 72.510(b)(1) of this rule requires that any log or record produced signifying that the training has taken place would be retained for one year. A commenter stated other records are not required to be maintained and should not be required by this rule. Numerous training records are required to be maintained for a variety of training requirements throughout 30 CFR, and MSHA believes that retention of the record for one year is important for documentation purposes. Therefore, § 72.510(b)(1) of this rule was not changed from the proposed rule and is incorporated in this final rule.

The training records need to be where an inspector can view them during the course of an inspection, as the information in the record may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, MSHA would permit the record to be maintained elsewhere so long as they are readily accessible. This approach is consistent with the Office of Management and Budget Circular A–130 and 30 CFR 75.1915(c).

Paragraph (b)(2) of section 72.510 of this rule requires mine operators to provide prompt access to the training records upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from an authorized representative of the miners. If an operator ceases to do business, all training records of employees are expected to be transferred to any successor operator. The successor operator is expected to maintain those training records for the required one year period unless the successor operator has undertaken to retrain the employees. There were no comments received concerning the maintenance of records by a successor operator. Therefore, the final rule has adopted the wording as published in the proposed rule.

Section 72.520 Diesel Equipment Inventory

Proposed § 75.371(qq) would have required, "A list of diesel-powered units used by the mine operator together with information about any unit's emission control or filtration system." One commenter stated that the proposal was vague and overly burdensome. The commenter also stated that exhaustive, detailed technical specifications were not needed in the approved ventilation plan. MSHA agrees with the comments and has changed the final rule to reflect what MSHA believes is necessary information to help evaluate the effectiveness of dpm controls in underground coal mines. By specifying the information required, MSHA has provided uniform guidance to the mining community as to the information required to be submitted in the diesel equipment inventory.

Another commenter suggested the information be provided and posted at the mine and made available to a representative of the Secretary and other interested person. Another commenter was concerned with the time delay in submitting an addendum to the ventilation plan and the approval of the plan. The commenter stated that this was not required of other equipment used underground and should not be required of diesel-powered equipment. Concerns were raised by several commenters about delays in the approval of revisions to the ventilation plan.

MSHA has taken these comments into consideration and in the final rule has removed the diesel equipment inventory provision from the Approved Ventilation Plan and established it as a separate requirement § 72.520. There was no intent to require that the inventory be approved, but rather to require the information to be provided to MSHA and the representatives of the miners. The final rule requires each mine operator to prepare and submit a diesel equipment inventory to the District Manager. It also clarifies the information that must be included in the inventory. This information must be accurate so that the appropriate emission controls can be matched with an engine and to ensure that the required emission rates during the phase-in period are met. If there are modifications to the inventory, such as equipment being added or deleted, or changes to emission control systems, these modification must be submitted to the District Manager within 6 months. If no changes to the inventory are made, there is no need to update the diesel equipment inventory. The final rule also requires that mine operators provide a copy the diesel equipment inventory to the representative of the miners within 3 days.

Effective Dates

The final rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation. Some provisions of the final rule contain delayed effective dates that provide more time for technical assistance to the operators. Table I–1 presents the effective dates of various provisions of the final rule is reproduced below for convenience.

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Table I-1

Type of Equipment	Emissions Limit	When Applicable (from date final rule published)
Permissible		
newly introduced	2.5 grams per hour	60 days
existing fleet	2.5 grams per hour	18 months
Heavy duty nonpermissible		
newly introduced	5.0 grams per hour	60 days
existing fleet (interim)	5.0 grams per hour	30 months
existing fleet (final)	2.5 grams per hour	4 years
Generators and compressors	same as heavy duty	same as heavy duty
Other light duty nonpermissible		
newly introduced	5.0 grams per hour (or listed EPA standards)	60 days
existing fleet	no requirements	

BILLING CODE 4510-43-C

The final rule stipulates that any piece of diesel-powered equipment introduced into an underground coal mine 60 days after the promulgation date of this final rule is required to meet specific emission limits. For equipment that is currently used in underground coal mines, the compliance dates vary with regards to the type of diesel-powered equipment used in underground coal mines. MSHA includes in the category of equipment currently in use in underground coal mines any equipment that is ordered on or before the promulgation date of this final rule, even if the delivery date is more that 60 days from the promulgation date. By treating equipment on order as equipment already in use, the Agency is allowing the operator to use the equipment as delivered by the equipment supplier. A valid purchase order would be required of the operator as evidence that the diesel-powered equipment was ordered on or before the promulgation date of the final rule.

The time frame of 60 days after the promulgation date of the final rule also applies to newly introduced diesel-powered equipment as a result of explicit effective dates in 30 CFR 72.500, 72.501, and 72.502 of this rule. Diesel-powered equipment that is introduced in an underground coal mine 60 days after the promulgation date of the final rule must emit no more than 2.5 grams per hour of dpm. The term "introduced" is defined in § 72.503(e) and is explained in the appropriate Section-by-Section discussion in this preamble.

Section 72.500(b) of this rule allows the operator 18 months from the promulgation date of the final rule to meet emission limits for permissible diesel-powered equipment currently in use in underground coal mines. Several commenters stated the 18 month time frame was insufficient to comply with the proposed rule. They suggested increasing the effective date to between 2 and 4 years from the promulgation date of the final rule. The proposed rule would have required, in part, a system capable of removing, on average, at least 95% of diesel particulate matter by mass. The only system reportedly available that achieved the filtration efficiency necessary, was the DST® system. As discussed elsewhere in this preamble, the final rule sets emission limits on diesel-powered equipment and allows the operator to use whatever diesel particulate reducing technologies available to meet the limits. Information submitted during the rule making process and verification testing conducted for MSHA, has identified that readily available paper filters can achieve the emission limits set for permissible diesel-powered equipment. Therefore, MSHA has retained the 18 month effective date for diesel-powered equipment currently in use in underground coal mines.

Section 72.501 of this rule addresses emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors. There are 3 time tables associated with these pieces of diesel-powered equipment. As with permissible diesel-powered equipment, all nonpermissible heavy-duty diesel powered equipment, generators and compressors introduced into an underground coal mine 60 days from the promulgation date of the final rule would be required to meet a specific dpm emission limit. As stated the final rule differs from the proposed rule, however, the compliance date for newly introduced diesel-powered equipment has not been changed.

The final rule allows 30 months from the promulgation date for the operator to reduce the emission levels to the levels required for newly introduced diesel-powered equipment. Some commenters believe this time frame should be increased to 3 to 4 years.

Another commenter stated the time frame for complying with the standard should be shortened. Based upon information obtained during the rule making process, MSHA believes the 30 month time table is adequate and reasonable to install the necessary particulate controls to comply with the required emission limits.

Section 72.501(c) of this final rule requires all nonpermissible heavy-duty diesel-powered equipment, generators and compressors to meet a stricter emission limit within 4 years after promulgation of the final rule. The proposed rule would have allowed 6 years to achieve these stricter limits. After reviewing the record, particularly information submitted by aftertreatment device manufacturers, MSHA has concluded that these stricter standards can be met in a shorter time frame. Discussions on these emission limits are covered in greater detail elsewhere in this preamble. Therefore, the effective date for the stricter emission limits was reduced from 6 years to 4 years.

Section 72.503 of this final rule addresses nonpermissible light-duty diesel-powered equipment other than generators and compressors. The proposed rule did not address nonpermissible light-duty diesel-powered equipment. As discussed earlier in the preamble, nonpermissible light-duty diesel-powered equipment has been included in this final rule. The final rule only addresses nonpermissible light-duty diesel-powered equipment that is introduced 60 days after the promulgation date of this final rule. Equipment currently in use in underground coal mines is excluded from meeting emission limits. Based upon information gathered during the rule making process, MSHA believes 60 days after the promulgation date of the final rule is reasonable and this requirement has been added to the final rule.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the coal mining industry.

The discussion then turns to the main component of the rule being promulgated by the Agency for underground coal mines. MSHA is requiring that mine operators limit the emissions of dpm to defined quantities for various categories of diesel equipment underground. This part evaluates the rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground coal miners that is both technologically and economically feasible for mine operators.

About half a dozen regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. After considerable study, the Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground coal mining industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that the Secretary of Labor (Secretary) in promulgating mandatory standards dealing with toxic materials or harmful physical agents under the Act, shall set standards when most:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary, in promulgating these mandatory standards, must base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition, to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * * This section further provides that "other considerations" in the setting of health standards are "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as "technology-forcing" legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL–CIO* v. *Brennan*, 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA*, 509 F.2d 1301, *cert. denied*, 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that the agency rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word "feasible" as "capable of being done, executed, or effected." The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the "arbitrary and capricious standard" to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce a reasonable assessment of the likely range of costs that a new standard will have on the industry. The agency must also show that a reasonable probability exists that the typical firm in the industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC*, 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.*, 463

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U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan*, 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied*, 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.*, 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA*, 577 F. 2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL–CIO* v. *Hodgson*, 499 F. 2d 467 (1974).

Industry Profile. The industry profile provides background information describing the structure and economic characteristics of the coal mining industry. This information was considered by MSHA in reaching its conclusions about the economic feasibility of various regulatory alternatives.

MSHA divides the mining industry into two major segments based on commodity: (1) coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.*, underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment.

MSHA also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity—for mining, 500 or fewer employees—when determining a rule's economic impact.

Table V–1 presents the total number of small and large coal mines and the corresponding number of miners, excluding contractors, for the coal mining segment. This table uses three mine size categories based on the number of employees: (1) fewer than 20 employees (MSHA's traditional definition of small), (2) 20 to 500 employees (small according to SBA's definition) and (3) more than 500 employees. Table V–1 further disaggregates data by surface mines and underground mines, as well as (for employees) office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the coal mining segment.

Although this particular rulemaking does not apply to the surface coal sector, information about surface coal mines is provided here in order to give context for the discussions on underground mining.

TABLE V–1.—DISTRIBUTION OF COAL MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of coal mine [b]		Mine type			
		Underground	Surface	Office workers	Total coal
Fewer Than 20 Employees	Mines	382	1,058	.....	1,438
	Employees	3,751	6,491	487	10,729
20 to 500 Employees	Mines	522	492	.....	1,014
	Employees	39,566	31,731	3,389	74,692
Over 500 Employees	Mines	6	1	.....	7
	Employees	3,459	510	189	4,158
All Coal Mines	Mines	910	1,549	.....	2,459
	Employees	46,776	38,738	4,065	89,579

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 1, p. 5.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractor [b]		Contractors			
		Underground	Surface	Office workers	Total
Fewer Than 20 Employees	Mines	1,077	2,403	.....	3,480
	Employees	4,078	9,969	1,064	15,111
20 to 500 Employees	Mines	79	242	.....	321
	Employees	4,131	11,618	1,192	16,941
Over 500 Employees	Mines	.....	.....	.....	.....
	Employees	.....	.....	.....	.....
Total Contractors	Mines	1,156	2,645	.....	3,801
	Employees	8,209	32,052	2,256	30,052

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 5, p. 20.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

Agency data (Table V–1) indicate that there were about 2,459 coal mines in 1998. When applying MSHA's definition of a small mine (fewer than 20 workers), 1,438 (about 58%) were small mines and 1,021 (about 42%) were large.[82] Using SBA's definition, only 7 coal mines (0.3 percent) were large. These data show that employment at coal mines in 1998 was about 89,600, of which (by MSHA's definition) about 10,700 (12 percent) worked at small mines and 78,900 (88 percent) worked at large mines.[83] Using SBA's definition, 95 percent of coal miners worked at small mines and 5 percent worked at large mines. Using MSHA's definition, small coal mine average 7 employees, and large coal mines average 77 employees. Using SBA's definition, there are, on average, 35 employees in each small coal mine and 594 employees in each large coal mine. MSHA classifies the U.S. coal mining segment into two major commodity groups: bituminous and anthracite. About 92 percent of total coal production is bituminous. The remaining 8 percent is the product of lignite and anthracite mines.[84]

Mines east of the Mississippi accounted for about 49% of coal production in 1998. For the period 1949 through 1998, coal production east of the Mississippi River fluctuated relatively little, from a low of 395 million tons in 1954 to a high of 630 million tons in 1990; 1998 production was estimated at 571 million tons. Coal production west of the Mississippi, by contrast, increased each year from a low of 20 million tons in 1959 to a record high of 548 million tons in 1998.[85] The growth in western coal has been due, in part, to environmental concerns that led to increased demand for low-sulfur coal, which is abundant in the West.

In addition, surface mining, with its higher average productivity, is much more prevalent in the West. Surface mining methods for coal, which include drilling and blasting, are also practiced in surface mines for other commodity types. Most surface mines use front-end loaders, bulldozers, shovels, or trucks for haulage.

The U.S. coal sector produced a record 1.12 billion short tons of coal in 1998, at an average price of $17.58 per ton. The total value of U.S. coal production in 1998 was estimated as $19.7 billion. Small mines (by MSHA's definition) produced about 4 percent (40 million tons) of domestic coal production valued at $0.7 billion, and large mines (by MSHA's definition) produced about 96 percent (1.08 billion tons) valued at $19.0 billion.[86]

The U.S. coal industry enjoys a fairly constant domestic demand. Over 90 percent of U.S. coal demand was accounted for by electric utilities in 1998.[87] Due to the high conversion costs of changing a fuel source, MSHA does not expect a substantial change in coal demand by utility power plants in the near future.[88]

Adequacy of Miner Protection Provided by the Rule for Underground Coal Mines. In evaluating the protection provided by the rule, it should be noted that MSHA has measured dpm concentrations in production areas and haulageways of underground coal mines which exceed 2500$_{DPM}$ µg/m^3 with a mean concentration of 644$_{DPM}$ µg/m^3. See Table III–1 and Figure III–1 in part III of this preamble. As discussed in detail in part III of this preamble, these concentrations place underground coal miners at significant risk of material impairment of their health, and the evidence supports the proposition that reducing the exposure reduces the risk.

The final rule would require operators to limit the emissions of dpm emitted by various categories of equipment in underground coal mines—permissible, heavy duty (and compressors and generators), and other light duty. Equipment added to a mine's inventory more than 60 days after the rule is promulgated (or equipment already in the inventory but equipped with a new engine after that time), would have to comply with the appropriate standard. In addition, operators would have 18 months to bring the existing fleet of permissible diesel equipment into compliance with a 2.5 gr/hr emission standard. Operators would have an additional year (30 months from date of promulgation) to bring the existing fleet of heavy duty equipment (and generators and compressors) into compliance with a 5.0 gr/hr emission standard, and up to 4 years in all to bring that fleet down to a standard of 2.5 gr/hr.

As an example of how these emission standards can reduce dpm concentration levels in a section of an underground coal mine, take the case of a single-section mine with three Ramcars (94hp, indirect injection) and a section airflow of 45,000 cfm. MSHA measured concentrations of dpm in this mine at 610$_{DPM}$ µg/m^3. Of this amount, 25$_{DPM}$ µg/m^3 was coming from the intake to the section, and the remaining 585 $_{DPM}$ µg/m^3 was emitted by the engines. Reducing the engine emissions by 95% through the use of commercially available paper filters would reduce the dpm emitted to 29$_{DPM}$ µg/m^3. With an intake amount of 25$_{DPM}$ µg/m^3, the ambient concentration would be about 54$_{DPM}$ µg/m^3. Similarly, dramatic results can be achieved in almost any situation by adding high efficiency aftertreatment filters or by replacing current engines in the fleet with a more recent generation.

While the reductions in section concentration from the controls required by the final rule can be significant, it is important to recognize that the actual reductions in a section will vary depending upon a number of factors.

In the first place, unlike the proposed rule, the final rule does not require current dpm emissions from each machine to be reduced by 95%. While the existing permissible fleet, and much of the existing heavy duty fleet, will need to reduce engine emissions significantly to come into compliance with the final standard, this will be feasible in many cases with a less efficient filter. A detailed table illustrating by how much the emissions from each current engine in the inventory must be reduced to achieve compliance is shown in table IV–1.

Second, while aftertreatment filters currently available are capable in laboratory tests of achieving a very significant reduction in dpm mass, and this has been confirmed in some field tests, the Agency has not tested filter efficiency under a variety of actual mining conditions. Therefore, actual performance may be different in the field due to individual mining

[82] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[83] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[84] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[85] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 191.

[86] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 203, U.S. Department of Energy, Energy Information Administration, *Coal Industry Annual 1997*, December 1998, pp. ix and 154, and U.S. Department of Labor, Mine Safety and Health Administration, Division of Mining Information Systems, 1998 Final MIS data (quarter 1–quarter 4) CM441 cycle 1998/198.

[87] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, p. 187.

[88] U.S. Department of Energy, Energy Information Administration, *Annual Energy Outlook 2000*, p. 68.

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conditions (*e.g.*, ventilation changes, changes of the equipment due to maintenance, and the type of engine used).

Third, the impact on a mine section of reduced emissions from a particular machine depends upon the ventilation rate and the ambient dpm intake into the section. If ventilation levels drop below the requirements established to control gaseous emissions, or if many pieces of equipment throughout the mine create a high ambient level of dpm, implementation of the rule may not bring concentrations down as effectively as suggested in the prior example. On the other hand, if the ventilation rate is maintained at a higher level, the emissions would be better diluted and the ambient concentration could offset any decrease in control efficiency under actual mining conditions. The intake of dpm to any section depends on what emissions are upstream. In this regard, it should be noted that the final rule does not require controls on the existing fleet of light-duty equipment, except for generators and compressors; hence, mines with significant light duty equipment will have this exhaust as an "intake" in such calculations.

Table V–3 summarizes information from a series of simulations designed to illustrate some of these variables. The simulations were performed using MSHA's "Estimator"—a computerized spreadsheet designed to calculate dpm ambient levels from given equipment, and the impact of various controls on those ambient levels. (The Estimator was discussed in detail in an Appendix to the preamble to the proposed rule and has since been published (Haney and Saseen, April 2000)). The example simulated here involves a mine section with a 94 horsepower engine, with a 0.3 gm/hp-hr dpm emission rate and a nameplate airflow, 5500 cfm. The engine was operated during an eight hour shift. The Estimator was used to calculate the section concentrations with a paper filter at full laboratory efficiency (95%) and two lower filter efficiencies. The same results would be obtained for multiple pieces of equipment provided that the nameplate airflow is additive for each piece of equipment.

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Table V-3: Section DPM Concentrations for Various Airflow Rates, Afterfilter Efficiencies and Intake DPM Concentrations

Airflow	Intake DPM ($\mu g/m^3$)	Resulting Section DPM Concentration ($\mu g/m^3$)		
		85 Percent After-filter	90 Percent After-filter	95 Percent After-filter
1.0 x Nameplate Airflow	0	452	302	151
2.0 x Nameplate Airflow	0	226	151	75
3.0 x Nameplate Airflow	0	151	101	50
4.0 x Nameplate Airflow	0	113	75	38
1.0 x Nameplate Airflow	25	477	327	176
2.0 x Nameplate Airflow	25	251	176	100
3.0 x Nameplate Airflow	25	176	126	75
4.0 x Nameplate Airflow	25	138	100	63
1.0 x Nameplate Airflow	50	502	352	201
2.0 x Nameplate Airflow	50	276	201	125
3.0 x Nameplate Airflow	50	201	151	100
4.0 x Nameplate Airflow	50	163	125	88
1.0 x Nameplate	75	527	377	226
2.0 x Nameplate Airflow	75	301	226	150
3.0 x Nameplate Airflow	75	226	176	125
4.0 x Nameplate Airflow	75	188	150	113

* Emission rate - 0.3 gm/hp-hr
Airflow - 5500 cfm

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In Table V–3, the intake dpm (second column) increases after every fourth row. Within each group of four rows, the ventilation (first column) increases

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from one row to the next. The last 3 columns display the ambient dpm concentration with a particular filter efficiency.

The first four rows represent a situation where there is no intake dpm. If the mine is ventilated with four times the nameplate airflow (row 4), the ambient dpm concentration using a filter operating at 95% (last column) is reduced to 38_{DPM} µg/m³. If the filter in this situation only works in practice at 85% efficiency in removing dpm, the ambient dpm concentration is only reduced to 113_{DPM} µg/m³. And if the ventilation is reduced to the nameplate airflow (first column) and the filter is only 85% efficient, the ambient dpm climbs to 452_{DPM} µg/m³.

The last four rows display the parallel situation but with an ambient intake concentration to the section of 75_{DPM} µg/m³. In this situation, depending on ventilation and filter effectiveness, the ambient dpm concentration ranges from 113_{DPM} to 527_{DPM} µg/m³.

In the example discussed above—a single section mine with three 94 hp Ramcars—the airflow of 45,000 cfm represents three times the current nameplate requirements. Many underground coal mines may use more than the nameplate ventilation to lower methane concentrations at the face. But if this airflow were reduced to the current nameplate requirements, the ambient dpm would have been 1620_{DPM} µg/m³, and would have been reduced by 95% effective filters to 105_{DPM} µg/m³.

Based on its experience as to the general effects of mining conditions on the expected efficiency of equipment, and on ventilation rates, MSHA has concluded that the rule for this sector will substantially reduce the concentrations of dpm to which underground coal miners are exposed.

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is provided, the Agency has considered some alternatives. Most are discussed elsewhere in this preamble, but are briefly repeated here and illustrate the extensive thought MSHA gave to this issue.

(1) *Establish a Concentration Limit.* MSHA considered establishing a dpm concentration limit for this sector, as it is doing for underground metal and nonmetal mines. A concentration limit provides operators with flexibility to select any combination of controls that keep ambient dpm concentrations below the limit.

The agency has concluded that it is not yet technologically feasible to establish a dpm concentration limit for underground coal mines. The problem is that significant questions remain as to whether there is a sampling and analytical system that can provide consistent and accurate measurements of dpm in areas of underground coal mines where there is a heavy concentration of coal dust. The Agency is continuing to work on the technical issues involved, and should it determine that these technological problems have been resolved, it will notify the mining community and proceed accordingly.

(2) *95% Filters on Defined Categories of Equipment.* This is what the agency initially proposed for this sector. It has the advantage of ensuring that all controlled equipment is filtered, which some assert is easier to keep in proper shape through observation, and others believe provides more protection against nanoparticles. On the other hand, such an approach may quickly become technologically infeasible as newer, cleaner engines are introduced underground; removing 95% (or any defined percentage) of the lower emissions of these engines is likely to prove much more difficult. Moreover, this approach could act as a disincentive to introduce cleaner engines underground, and thus slow the reduction of dpm that such a replacement fleet might make possible. Finally, the Agency determined that at this time, there is not enough evidence about the risks of nanoparticles to regulate on that basis. Accordingly, the agency rejected this approach in order to avoid the problems associated with its implementation over the long term.

(3) *A machine-based emissions limit with credit for extra ventilation used in the mine.* Under this approach, if the bench test of the combined engine and filter package was conducted at the approval plate ventilation, a mine's use of more than that level of ventilation would be factored into the calculation of what package would be acceptable. So if, for example, an engine equipped with a ceramic filter can reduce emissions to 5.0 grams/hour in a test using the approval plate ventilation, and the mine actually ventilates at twice the name plate ventilation, the system would be deemed to reach 2.5 grams/hour under that circumstance. This alternative, however, is less protective than the rule adopted by the agency, as it would not require dpm emissions to be reduced as much. Accordingly, since the more protective alternative is feasible as well, it would be inappropriate under the law for the agency to adopt this alternative.

(4) *Adjust the Time-Frame for Implementation of the Final Rule.* The final rule will not be fully implemented for several years. The existing permissible fleet is given a full 18 months to comply, even though the agency has determined that there are readily available paper filters which can bring this equipment into compliance. The implementation schedule for the existing heavy duty fleet (and compressors and generators) extends for 4 years from the date of promulgation, even though the agency has concluded that there are hot gas filters readily available which can bring most of this equipment into compliance with the final emissions limit. Accordingly, the agency has considered whether a faster implementation schedule is feasible.

Cutting the 18 month time-frame for permissible equipment does not appear to be practicable for the industry. Eighteen months to obtain and install a relatively new technology is a reasonable time. Time is needed for operators to familiarize themselves with this technology. Also, mine personnel have to be trained in how to maintain control devices in working order. Moreover, MSHA needs time to work with the mining community to develop a revised approach to approving engines for use in permissible equipment in order to accelerate the introduction of a cleaner generation of engines into the permissible fleet.

With respect to the heavy duty fleet, the four years permitted to meet the final emissions limit is actually two years faster than originally proposed by the agency when 95% filters were being proposed. As indicated in section 6 of Part II of this preamble, the development of high efficiency hot gas filters has proceeded much faster than expected, so that it is technologically feasible to comply more quickly with this requirement than originally proposed. Moreover, MSHA has determined that the cost differential to the industry of reaching the final 2.5 micrograms/hour emission limit in 4 years instead of 6 is minor (see REA). However, MSHA has concluded that moving up the timeline further would create unwarranted difficulties for operators in terms of installing the required engines and filters, and accordingly has determined that further acceleration of this schedule would be infeasible.

(5) *Require Machine Emission Limits on all Diesel Equipment in Underground Coal Mines.* The final rule would not immediately apply to more than 60% of the fleet—light-duty equipment other than generators and compressors. Over time, the final rule would have an impact on the remaining light duty fleet through controls on any new equipment introduced underground, but it will take many years before mine workers get the benefits of this approach. By contrast, the Commonwealth of Pennsylvania has recently adopted legislation for universal high-efficiency filtration based on an agreement in the mining community of that state. The Pennsylvania law requires that all diesel-powered equipment introduced into underground coal mines in that state (essentially all equipment, given the past ban), meet an emissions limit requirement (as well as a separate filter requirement).

One reason asserted for not covering all light duty equipment is that this equipment may run only intermittently, and under light loads, hence producing less dpm than other kinds of equipment. This proposition was supported by industry representatives during the rulemaking, and disputed by miners during the rulemaking proceedings. The Agency has not been able to draw any conclusions based on the mixed evidence as to the light duty fleet as a whole; as noted previously, it has carved out the 3% of the light duty fleet that clearly works like heavy duty equipment, and is covering them in this rule (generators and compressors).

A second issue is costs. The Agency decided to consider what it would take to bring the rest of the industry up to the standard established under the Pennsylvania agreement of universal coverage. MSHA has calculated that such a requirement would cost the underground coal industry an additional $9.7 to $17.4 million a year. This would be an increase of 135–240% of the cost of the rule for the underground coal mining industry. Since drawing conclusions concerning the level of dpm actually produced by light duty equipment in underground coal mines is difficult, the Agency has decided to take the approach of phasing in emission controls for light duty outby equipment over a period of five years. This approach significantly reduces the cost of the rule. Eventually, dpm exposures will be reduced for all miners in all areas of the mine.

(6) *Requiring certain engines to meet defined particulate emission standards.* As discussed in part II of this preamble, the Mine Safety and Health Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines recommended the establishment of a particulate index (PI), and MSHA did so in its diesel equipment rule. Under that rule, the PI establishes the amount of air required to dilute the dpm produced by an engine (as determined during its approval test under subpart E of part 7) to 1000 µg/m³.

In the preamble of the diesel equipment rule, MSHA noted that mine operators and machine manufacturers would find it useful to consider the engine PI in selecting and purchasing decisions. The agency explicitly deferred until this rulemaking the question of whether to require engines used in mining environments to meet a particular PI.

In its final rule, the Agency is, in fact, using a significant portion of the concepts embodied in the particulate index. The determination of the quantity of dpm emitted from the machine is based on the information from the engine approval tests in 30 CFR 7.89 as was used to establish the particulate index. Both means of expressing the dpm characteristics of the machine begin with determining the total amount of dpm, expressed in grams/hour, produced by the engine over the test cycle described in ISO 8178. The particulate index is determined by calculating the quantity of air required to dilute that particulate to a concentration of 1 mg/m³. The quantity of dpm emitted from the machine is determined by multiplying the quantity of dpm emitted from the engine by the filtration efficiency of the aftertreatment device.

Had the agency been able to utilize a concentration limit in this sector, the particulate index could have been used directly to compute an estimated level of dpm that could be achieved with various quantities of ventilation air. As noted above, however, that approach was found to be infeasible.

Feasibility of final rule for underground coal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule for the underground coal mining sector as a whole.

Although some doubts were expressed about this during the rulemaking proceedings, it is clear now that the technology exists to implement the final rule's requirements. As this preamble explains in overview in section 6 of Part II, and reiterates in connection with the specific requirements of the rule in Part IV, there are available emission controls which can bring all existing and contemplated future diesel equipment into compliance with the requirements of the rule. Paper filters have now been verified to reduce emissions from the dirtiest permissible engines to the required limit of 2.5 grams per hour. Ceramic filters have been certified by VERT to have the efficiency required to reduce emissions from the dirtiest heavy duty engines to the interim limit of 5.0 grams/hour, and for all but one engine to the final limit of 2.5 grams/hour. Approved engines that meet the emissions limit for newly introduced light duty equipment are available for all categories. And as MSHA and the mining industry work together to address aspects of the approval process that may be inhibiting the introduction of the newer generations of engines into underground mines, there should be no technological nor practical barriers to further emission limit reductions.

The economic feasibility of this rule has also been carefully considered by MSHA. The total for the final rule for underground coal mines will be about $7 million per year. The costs per dieselized mine are expected to be about $48,000 a year. MSHA has calculated that the costs of the final rule amount to less than one-quarter of one percent (0.23 percent) of the annual revenues of the dieselized underground coal mining sector. (The methodology for this calculation is discussed in Chapter IV of the Agency's REA). After reviewing the economic profile of that sector, and taking into account the cost of implementing the related diesel equipment rule, MSHA has concluded that the rule is economically feasible for this sector as a whole.

Conclusion: Underground Coal Mines. Based on the best evidence available to it at this time, the Agency has concluded that the final rule for the underground coal sector meets the statutory requirement that it attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground coal sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking "significant" under section 3(f) of Executive Order 12866, and has so

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designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an "economically significant" regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Certification.

The Regulatory Flexibility Act (RFA) requires regulatory agencies to consider a rule's economic impact on small entities. Under the RFA, MSHA must use the Small Business Administration's (SBA's) criterion for a small entity in determining a rule's economic impact unless, after consultation with the SBA Office of Advocacy, MSHA establishes an alternative definition for a small mine and publishes that definition in the **Federal Register** for notice and comment. For the mining industry, SBA defines "small" as a mine with 500 or fewer workers. MSHA traditionally has considered small mines to be those with fewer than 20 workers. To ensure that the final rule conforms with the RFA, MSHA has analyzed the economic impact of the final rule on mines with 500 or fewer workers (as well as on those with fewer than 20 workers).

MSHA has determined that the final rule would not have a significant economic impact on small mines, whether a small mine is defined as one with 500 or fewer workers or one with fewer than 20 workers.

Using the Agency's traditional definition of a small mine, which is one employing fewer than 20 workers, the estimated yearly cost of the final rule on small underground coal mines will be about $7,400. This estimated annualized cost for small mines compares to estimated annual revenues of approximately $9.1 million for the class of small underground coal mines.

Using SBA's definition of a small mine, which is one employing 500 or fewer workers, the estimated yearly cost of the final rule for all small underground coal mines would be about $6.1 million. This estimated cost for small mines compares to estimated annual revenues of approximately $2.95 billion for small underground coal mines, using SBA's criteria.

Based on its analysis, MSHA has determined that the final rule would not have a significant economic impact on a substantial number of small mines. MSHA has so certified these findings to the Small Business Administration. The factual basis for this certification is discussed in Chapter V of the REA for this rule.

(C) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(D) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose paperwork burden hours on underground coal mine operators that use diesel powered equipment and on manufacturers of diesel powered equipment. For mine operators that use diesel powered equipment, the final rule imposes two types of burden hours. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as "annual" burden hours). Manufacturers of diesel equipment that are affected by this rule, will incur only first year burden hours.

Mine operators

First Year Burden Hours

In the first year that the rule takes effect, mine operators will incur 997 burden hours, which is composed of 349 first year burden hours (from Table VI–1) and 648 annual burden hours (from Table VI–1(a)). The related costs to mine operators will be $33,049, of which $12,627 is related to first year burden hours (from Table VI–1) and $20,422 is related to annual burden hours (from Table VI–1(a)).

Burden Hours After the First Year

Beginning in the second year the rule takes effect and continuing every year thereafter, mine operators will incur 648 burden hours and related costs of $20,422 (from Table VI–1(a)).

Manufacturers

First Year Burden Hours

In the first year that the rule is in effect, manufacturers will incur 700 burden hours and related costs of $35,000 (from Table VI–2). After the first year, manufacturers will not incur any burden hours or related costs.

TABLE VI–1.—MINE OPERATORS—FIRST YEAR BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
75.1915/72.503	1.0	$28	50	$1,299	1.0	$14	52	$1,341
72.510	0.6	29	11	568	0.1	4	12	602
72.520	9.0	399	267	10,027	9.0	257	285	10,684
Total	11.0	456	329	11,895	10.0	276	349	12,627

TABLE VI–1(a).—MINE OPERATORS—ANNUAL BURDEN HOURS

Detail	<20 emp.		20 to 500 emp.		>500 emp.		Total	
	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs	Hrs.	Costs
72.510	5.0	$167	563	$17,971	28.0	$922	597	$19,061
72.1915/72.503	0	0	4	76	0.3	5	4	82
72.520	0.3	8	43	1,177	3.5	94	47	1,279
Total	5.0	176	610	19,225	32.0	1,021	648	20,422

TABLE VI–2.—MANUFACTURERS—ANNUAL BURDEN HOURS

Detail	Hrs.	Costs
Amended Applications	700	$35,000

The paperwork provisions for the proposed rule were approved under OMB Control Number 1219–0124. Our paperwork submission summarized above is explained in detail in the final REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. This final rule is being submitted to OMB under the same control number. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(E) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 *et seq.*), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(F) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(G) Executive Order 13045 Protection of Children from Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(H) Executive Order 12988 Civil Justice Reform

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

(I) Executive Order 13084 Consultation and Coordination with Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(J) Executive Order 13132 Federalism

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have "federalism implications." The final rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

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Supplementary References

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List of Subjects in 30 CFR Part 72

Coal, Health standards, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 72—[AMENDED]

1. The authority citation for Part 72 continues to read as follows:

Authority: 30 U.S.C. 811, 813(h), 957, 961.

2. Part 72 is amended by adding Subpart D to read as follows:

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

72.500 Emission limits for permissible diesel-powered equipment.
72.501 Emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors.
72.502 Requirements for nonpermissible light-duty diesel-powered equipment other than generators and compressors.
72.503 Determination of emissions; filter maintenance; definition of "introduced".
72.510 Miner health training.
72.520 Diesel equipment inventory.

Subpart D—Diesel Particulate Matter—Underground Areas of Underground Coal Mines

§ 72.500 Emission limits for permissible diesel-powered equipment.

(a) Each piece of permissible diesel-powered equipment introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 2.5 grams per hour of diesel particulate matter.

(b) As of July 19, 2002, each piece of permissible diesel-powered equipment operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

§ 72.501 Emission limits for nonpermissible heavy-duty diesel-powered equipment, generators and compressors.

(a) Each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) As of July 21, 2003, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 5.0 grams per hour of diesel particulate matter.

(c) As of January 19, 2005, each piece of nonpermissible heavy-duty diesel-powered equipment (as defined by § 75.1908(a) of this part), generator or compressor operated in an underground area of an underground coal mine must not emit no more than 2.5 grams per hour of diesel particulate matter.

(d) Notwithstanding the other provisions of this section, a generator or compressor that discharges its exhaust directly into intake air that is coursed directly to a return air course, or discharges its exhaust directly into a return air course, is not subject to the applicable requirements of this section.

§ 72.502 Requirements for nonpermissible light-duty diesel-powered equipment other than generators and compressors.

(a) Each piece of nonpermissible light-duty diesel-powered equipment (as defined by § 75.1908(b) of this part), other than generators and compressors, introduced into an underground area of an underground coal mine after March 20, 2001 must not emit no more than 5.0 grams per hour of diesel particulate matter.

(b) A piece of nonpermissible light-duty diesel-powered equipment must be deemed to be in compliance with the requirements of paragraph (a) of this section if it utilizes an engine which meets or exceeds the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 72.502–1, as follows:

TABLE 72.502–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(i)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(i)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	Tier 2 nonroad	Varies by power:
	kW< (hp<11)	0.80 g/kW-hr (0.60 g/bhp-hr).
	8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	19≤kW<37 (25≤hp<50)	0.60 g/kW-hr (0.45 g/bhp-hr).
	37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	130≤kW<225 (175≤hp<300)	0.20 g/kW-hr (0.15 g/bhp-hr).
	225≤kW<450 (300≤hp<800)	0.20 g/kW-hr (0.15 g/bhp-hr).

Notes: "g" means grams; "kW" means kilowatt; "hp" means horsepower; "g/kW-hr" means grams/kilowatt-hour; "g/bhp-hr" means grams/brake horsepower-hour.

(c) The requirements of this section do not apply to any diesel-powered ambulance or fire fighting equipment that is being used in accordance with the mine fire fighting and evacuation plan under § 75.1101–23.

§ 72.503 Determination of emissions; filter maintenance; definition of "introduced".

(a) MSHA will determine compliance with the emission requirements established by this part by using the amount of diesel particulate matter emitted by a particular engine determined from the engine approval pursuant to § 7.89(a)(9)(iii)(B) or § 7.89(a)(9)(iv)(A) of this title, with the exception of engines deemed to be in compliance by meeting the EPA requirements specified in Table 72.502–1 (§ 72.502(b)).

(b) Except as provided in paragraph (c) of this section, the amount by which an aftertreatment device can reduce engine emissions of diesel particulate matter as determined pursuant to paragraph (a) must be established by a laboratory test:

(1) on an approved engine which MSHA has determined, pursuant to paragraph (a) of this section, to emit no more diesel particulate matter than the engine being used in the piece of diesel-powered equipment in question;

(2) using the test cycle specified in Table E–3 of § 7.89 of this title, and following a test procedure appropriate for the filtration system, by a laboratory capable of testing engines in accordance with the requirements of Subpart E of part 7 of this title; and

(3) with an aftertreatment device representative of that being used on the piece of diesel-powered equipment in question.

(c) In lieu of the laboratory tests required by paragraph (b), the Secretary may accept the results of tests conducted or certified by an organization whose testing standards are deemed by the Secretary to be as rigorous as those set forth by paragraph (b) of this section; and further, the Secretary may accept the results of tests for one aftertreatment device as evidencing the efficiency of another aftertreatment device which the Secretary determines to be essentially identical to the one tested.

(d) Operators must maintain in accordance with manufacturer specifications and free of observable defects, any aftertreatment device installed on a piece of diesel equipment upon which the operator relies to remove diesel particulate matter from diesel emissions.

(e) For purposes of §§ 72.500(a), 72.501(a) and 72.502(a), the term "introduced" means any piece of equipment whose engine is a new addition to the underground inventory of engines of the mine in question, including newly purchased equipment, used equipment, and equipment receiving a replacement engine that has a different serial number than the engine it is replacing. "Introduced" does not include a piece of equipment whose engine was previously part of the mine inventory and rebuilt.

§ 72.510 Miner health training.

(a) Operators must provide annual training to all miners at a mine who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b)(1) An operator must keep a record of the training at the mine site for one year after completion of the training. An

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operator may keep the record elsewhere if the record is immediately accessible from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any such training record. Whenever an operator ceases to do business, that operator must transfer the training records, or a copy, to any successor operator who must maintain them for the required period.

§ 72.520 Diesel equipment inventory.

(a) The operator of each mine that utilizes diesel equipment underground, shall prepare and submit in writing to the District Manager, an inventory of diesel equipment used in the mine. The inventory shall include the number and type of diesel-powered units used underground, including make and model of unit, type of equipment, make and model of engine, serial number of engine, brake horsepower rating of engine, emissions of engine in grams per hour or grams per brake horsepower-hour, approval number of engine, make and model of aftertreatment device, serial number of aftertreatment device if available, and efficiency of aftertreatment device.

(b) The mine operator shall make changes to the diesel equipment inventory as equipment or emission control systems are added, deleted or modified and submit revisions, to the District Manager, within 7 calendar days.

(c) If requested, the mine operator shall provide a copy of the diesel equipment inventory to the representative of the miners within 3 days of the request.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 57

RIN 1219–AB11

Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This rule establishes new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

This rule is designed to reduce the risks to underground metal and nonmetal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter (dpm). DPM is a very small particle in diesel exhaust. Underground miners are exposed to far higher concentrations of this fine particulate than any other group of workers. The best available evidence indicates that such high exposures put these miners at excess risk of a variety of adverse health effects, including lung cancer.

The final rule for underground metal and nonmetal mines would establish a concentration limit for dpm, and require mine operators to use engineering and work practice controls to reduce dpm to that limit. Underground metal and nonmetal mine operators would also be required to implement certain "best practice" work controls similar to those already required of underground coal mine operators under MSHA's 1996 diesel equipment rule. These operators would also be required to train miners about the hazards of dpm exposure.

By separate notice, MSHA has published a rule to reduce dpm exposures in underground coal mines.

DATES: The provisions of the final rule are effective March 20, 2001. However, §57.5060 (a) will not apply until July 19, 2002 and §57.5060 (b) will not apply until January 19, 2006.

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Director, Office of Standards, Regulations, and Variances, MSHA, 4015 Wilson Boulevard, Arlington, VA 22203–1984. Mr. Meyer can be reached at dmeyer@msha.gov (Internet E-mail), 703–235–1910 (voice), or 703–235–5551 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at http://www.msha.gov/REGSINFO.HTM.

SUPPLEMENTARY INFORMATION:

I. Overview of the Final Rule

This Part: (1) Summarizes the key provisions of the final rule; and (2) summarizes MSHA's responses to some of the fundamental questions raised during the rulemaking proceeding—the need for the rule, the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments, and the feasibility of the requirements for this sector of the mining industry.

(1) Summary of Key Provisions of the Final Rule

The final rule applies only to underground areas of underground metal and nonmetal mines.

The final rule requires operators: (A) To observe a concentration limit where miners normally work or travel by the application of engineering controls, with certain limited exceptions, compliance with which will be determined by MSHA sampling; (B) to observe a set of best practices to minimize dpm generation; (C) to limit engines newly introduced underground to those meeting basic emissions standards; (D) to provide annual training to miners on dpm hazards and controls; and (E) to conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine. A list of effective dates for the provisions of the rule follows this summary.

(A) Observe a limit on the concentration of dpm in all areas of an underground metal or nonmetal mine where miners work or travel, with certain specific exceptions. The rule would limit dpm concentrations to which miners are exposed to about 200 micrograms per cubic meter of air—expressed as 200_{DPM} $\mu g/m^3$. However, the rule expresses the limit so as to reflect the measurement method MSHA will be using for compliance purposes to determine dpm concentrations. That method is specified in the rule itself. As discussed in detail in response to Question 2, the method analyzes a dust sample to determine the amount of total carbon present. Total carbon comprises 80–85% of the dpm emitted by diesel engines. Accordingly, using the lower boundary of 80%, a concentration limit of 200_{DPM} $\mu g/m^3$ can be achieved by restricting total carbon to 160_{TC} $\mu g/m^3$. This is the way the standard is expressed:

> After January 19, 2006 any mine operator covered by this part shall limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} $\mu g/m^3$).

All underground metal and nonmetal mines would be given a full five years to meet this limit, which is referred to in this preamble as the "final" concentration limit. However, starting July 19, 2002, underground metal and nonmetal mines have to observe an "interim" dpm concentration limit—expressed as a restriction on the concentration of total carbon of 400 micrograms per cubic meter (400_{TC} $\mu g/m^3$). The interim limit would bring the concentration of whole dpm in underground metal and nonmetal mines to which miners are exposed down to about 500 micrograms per cubic meter. No limit at all on the concentration of dpm is applicable for the first eighteen months following promulgation. Instead, this period would be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations.

In general, a mine operator has to use engineering or work practice controls to keep dpm concentrations below the applicable limit. The use of administrative controls (*e.g.*, the rotation of miners) is explicitly barred. The use of personal protective equipment (*e.g.*, respirators) is also explicitly barred except in two situations noted below. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls; the selection of controls is left to the operator's discretion.

Special extension. The rule provides that if an operator of a metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented by January 19, 2006, MSHA may approve an application for an additional extension of time to comply with the dpm concentration limit. Such a special extension is available only once, and is limited to 2 years. To obtain a special extension, an operator must provide information in the application adequate for MSHA to ensure that the operator will: (a) Maintain concentrations at the lowest limit which is technologically achievable; and (b) take appropriate actions to minimize miner exposure (*e.g.*, provide suitable respiratory protection during the extension period).

It is MSHA's intent that primary responsibility for analysis of the operator's application for a special extension will rest with MSHA's district managers. District managers are the most familiar with the conditions of mines in their districts, and have the best opportunity to consult with miners as well. At the same time, MSHA recognizes that district managers may need assistance with respect to the latest technologies and solutions being used in similar mines elsewhere in the country. Accordingly, the Agency intends to establish within its Technical Support directorate in Arlington, Va., a special panel to consult on these issues, to provide assistance to district managers, and to give final approval of any application for a special extension.

Special rule for employees engaged in inspection, maintenance or repair activities. The final rule provides that with the advance approval of the Secretary, employees engaged in such activities may work in concentrations of dpm exceeding the applicable concentration limit. However, the Secretary may only approve such work under three circumstances: when the activities are to be conducted are in areas where miners work or travel infrequently or for brief periods of time; when the miners work exclusively inside enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or when the miners work in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are used for access into the mine or egress from the mine. Moreover, to approve such an exception, the Secretary must determine that it is not feasible to reduce the concentration of dpm in these areas, and that adequate safeguards (including personal protective equipment) will be employed to minimize the dpm exposure of the miners involved.

An operator plan providing such details must be submitted; it is MSHA's intent to review these in the same manner as applications for a special extension. Such plans can only be approved for one year, but may be resubmitted each year.

Compliance determinations with concentration limit. Measurements to determine noncompliance with the dpm concentration limit will be made directly by MSHA, rather than having the Agency rely upon operator samples. Under the rule, a single Agency sample, using the sampling and analytical method prescribed by the rule, is explicitly deemed adequate to establish a violation.

The rule requires that if an underground metal or nonmetal mine exceeds the applicable limit on the concentration of dpm, a diesel particulate matter control plan must be established and remain in effect for 3 years. The purpose of such plans is to ensure that the mine has instituted practices that will demonstrably control dpm levels thereafter. Reflecting current practices in this sector, the plan does not have to be preapproved by MSHA. The plan must include information about the diesel-powered equipment in the mine and applicable controls. The rule requires operator sampling to verify that the plan is effective in bringing dpm levels down below the applicable limit, using the same sampling and analytical methods as MSHA, with the records kept at the mine site with the plan to facilitate review. Failure of an operator to comply with the requirements of the dpm control plan or to conduct adequate verification sampling is a violation of the rule; MSHA is not be required to sample to establish such a violation.

(B) *Observe best practices.* The rule requires that operators observe the following best practices to minimize the dpm generated by diesel-powered equipment in underground areas:

- Only low-sulfur (0.05% or less) diesel fuel may be used. The rule does not at this time require the use of ultra-low sulfur fuel by the mining community. MSHA is aware that the Environmental Protection Agency issued final regulations addressing emissions standards (December 2000) for new model year 2007 heavy-duty diesel engines and the low-sulfur fuel rule. The regulations require ultra-low sulfur fuel be phased in during 2006–2010.
- Only EPA-approved fuel additives may be used.
- Approved diesel engines have to be maintained in approved condition; the emission related components of non-approved engines have to be maintained in accordance with manufacturer specifications; and any installed emission devices have to be maintained in effective operating condition.
- Equipment operators are authorized and required to tag equipment with potential emissions-related problems, and tagged equipment has to be promptly referred for a maintenance check by persons qualified by virtue of training or experience to perform the maintenance.

(C) *Limit newly introduced engines to those meeting basic emission standards.* The rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine after January 19, 2001 must either be an engine approved by MSHA under Part 7 or Part 36, or an engine meeting certain EPA requirements on particulate matter specified in the rule. Since not all engines are MSHA approved, this ensures a wide variety of choice in meeting the engine requirements of this rule.

(D) *Provide annual training to miners on dpm hazards and controls.* Mines using diesel-powered equipment must annually train miners exposed to dpm

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in the hazards associated with that exposure, and in the controls being used by the operator to limit dpm concentrations. An operator may propose including this training in the Part 48 training plan.

(E) *Conduct sampling as often as necessary to effectively evaluate dpm concentrations at the mine.* The purpose of this requirement is to assure that operators are familiar with current dpm concentrations so as to be able to protect miners. Since mine conditions vary, MSHA is not requiring a specific schedule for operator sampling, nor a specific sampling method. The Agency will evaluate compliance with this sampling obligation by reviewing evidence of operator compliance with the concentration limit, as well as information retained by operators about their sampling. Consistent with the statute, the rule requires that miners and their representatives have the right to observe any operator monitoring—including any sampling required to verify the effectiveness of a dpm control plan.

Summary of Effective Dates. As of March 20, 2001, operators must comply with the requirement that new engines added to a mine's inventory be either MSHA approved or meet the listed EPA standards.

As of March 20, 2001, underground metal and nonmetal mine operators must comply with the requirement to provide basic hazard training to miners who are exposed underground to dpm and the best practice requirements listed above under (B).

As of July 19, 2002, underground metal and nonmetal mine operators must also comply with the interim dpm concentration limit of 400 micrograms of total carbon per cubic meter of air.

Finally, as of January 19, 2006, all underground metal and nonmetal mines have to comply with a final dpm concentration limit.

MSHA intends to provide considerable technical assistance and guidance to the mining community before the various requirements go into effect, and be sure MSHA personnel are fully trained in the requirements of the rule. A number of actions have already been taken toward this end. The Agency held workshops on this topic in 1995 which provided the mining community an opportunity to share advice on how to control dpm concentrations. The Agency has published a "toolbox" of methods available to mining operators to achieve reductions in dpm concentration, often referred to during the rulemaking proceedings. MSHA also developed a computer spreadsheet template which allows an operator to model the application of alternative engineering controls to reduce dpm, which it has published in the literature and disseminated to the mining community. The Agency is committed to issuing a compliance guide for mine operators providing additional advice on implementing the rule.

A note on surface mines. Surface areas of underground mines, and surface mines, are not covered by this rule. In certain situations the concentrations of dpm at surface mines may be a cause for concern: *e.g.*, production areas where miners work in the open air in close proximity to loader-haulers and trucks powered by older, out-of-tune diesel engines, shops, or other confined spaces where diesel engines are running. The Agency believes, however, that these problems are currently limited and readily controlled through education and technical assistance. The Agency would like to emphasize, however, that surface miners are entitled to the same level of protection as other miners; and the Agency's risk assessment indicates that even short-term exposures to concentrations of dpm like those observed may result in serious health problems. Accordingly, in addition to providing education and technical assistance to surface mines, the Agency will also continue to evaluate the hazards of diesel particulate exposure at surface mines and will take any necessary action, including regulatory action if warranted, to help the mining community minimize any hazards.

(2) Summary of MSHA's Responses to Several Fundamental Questions About This Rule

During the rulemaking proceeding, the mining community raised some fundamental questions about: (A) The need for the rule; (B) the ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments; and (C) the feasibility of the requirements for this sector of the mining industry. MSHA gave serious considerations to these questions, has made some adjustments in the final rule and its economic assessment as a result thereof, and has provided detailed responses in this preamble. These responses are briefly summarized here.

(A) *The need for the rule.* MSHA has to act in accordance with the requirements of the Mine Safety and Health Act. Section 101(a)(6)(A) of the Act specifies that any health standard must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration. (More information about what constitutes "feasibility" is discussed below in item C).

In proposing this rule, MSHA sought comment on its risk assessment, which it published in full as part of the preamble to the proposed rule. In that risk assessment, the agency carefully laid out the evidence available to it, including shortcomings inherent in that evidence. Although not required to do so by law, MSHA had this risk assessment independently peer reviewed, and incorporated the reviewers recommendations. The reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Based on the information in that risk assessment, the agency made some tentative conclusions. First, its tentative conclusion that miners are exposed to far higher concentrations of dpm than anybody else. The agency noted that median concentrations of dpm had been observed in individual dieselized metal and nonmetal underground mines up to 180 times as high as average environmental exposures in the most heavily polluted urban areas and up to 8 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups. Moreover, MSHA noted its tentative conclusion that exposure to high concentrations of dpm can result in a variety of serious health effects. These health effects include: (i) Sensory irritations and respiratory symptoms serious enough to distract or disable miners; (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. After a review of all the evidence, MSHA tentatively concluded that:

(1) The best available evidence is that the health effects associated with exposure to dpm can materially impair miner health or functional capacity.

(2) At levels of exposure currently observed in underground mining, many miners are presently at significant risk of incurring these material impairments over a working lifetime.

(3) The reduction in dpm exposures that is expected to result from implementation of the rule proposed by the agency for underground metal and nonmetal mines would substantially reduce the significant risks currently faced by underground metal and nonmetal miners exposed to dpm.

During the hearings and in written comments, some representatives of the mining industry raised a number of objections to parts of MSHA's proposed risk assessment, thus questioning the scientific basis for this rulemaking. It has been asserted that MSHA's observations of dpm concentrations in underground metal and nonmetal mines do not accurately represent exposures in the industry. It has been asserted that if dpm concentrations are not this high in general, or only on an intermittent basis, then the agency is incorrect in determining that the conditions in these mines put miners at significant risk of material impairment of their health. Moreover it has been asserted that there is insufficient evidence to establish a causal connection between dpm exposure and significant adverse health effects, that the agency has no hard evidence that reducing exposures to a particular level will in fact reduce the risks, and that it has no rational basis for selecting the concentration limit it did. In addition, it has been asserted that the risks of dpm exposure at any level are not well enough established to provide the basis for regulation at this time, and that action should be postponed pending the completion of various studies now underway that might shed more light on these risks.

MSHA has carefully evaluated all of these comments, and the evidence submitted in support of these positions. The agency's risk assessment has been modified as a result.

Exposures of underground metal and nonmetal miners. MSHA has clarified the charts of exposure measurements in Part III of this preamble to ensure that they fully reflect all studies in the record.

MSHA has not and does not claim that the actual exposure measurements in the record are a random or fully representative sample of the industry. What they do show is that exposures far higher than those which have been observed in other industries can and do occur in an underground mining environment.

Moreover, MSHA also placed into the record of the proposed rule several studies it had recently conducted in which dpm concentrations for several underground metal and nonmetal mines were estimated based upon the actual equipment and dpm controls currently available in those mines. Those simulations were performed using a software tool known as the Estimator (described in detail in an appendix to Part V of the preamble of the proposed rule, and since published in the literature (Haney and Saseen, April 2000). These studies of specific mines demonstrated that the type of equipment found in such mines, even after the application of current ventilation and controls, can be expected to produce localized high concentrations of dpm. The agency acknowledged that these simulations were conducted in mines that were not typical for the industry (they were chosen because the agency thought dpm concentrations might be particularly difficult to control in these mines, which turned out not to be the case); nevertheless, they indicate what is likely to be the case in at least some sections of many underground metal and nonmetal mines. To the extent that an individual mine has no covered mining areas with concentrations higher than those observed in other industries, it will not be impacted by the concentration limit established through this rulemaking. That is because the rule does not eliminate exposures, or even to reduce them to a safe level, but only to reduce them to the levels observed in other industries.

The nature of risks associated with dpm exposure. Although there were some commenters who suggested that symptoms reported by miners working around diesel equipment might be due to the gases present rather than dpm, there was nothing in the comments that changed MSHA's conclusions about the health problems associated with dpm exposure.

There are a number of studies quantifying significant adverse health effects—as measured by lost work days, hospitalization and increased mortality rates—suffered by the general public when exposed to concentrations of fine particulate matter like dpm far lower than concentrations to which some miners are exposed. The evidence from these fine particulate studies was the basis for recent rulemaking by the Environmental Protection Agency [1] to further restrict the exposure of the general public to fine particulates, and the evidence was given very widespread and close scrutiny before that action was made final. Of particular interest to the mining community is that these fine particulate studies indicate that smokers and those who have pre-existing pulmonary problems are particularly at risk. Many individual miners in fact have such pulmonary problems and are especially susceptible to the adverse health effects of inhaling fine particles.

Although no epidemiological study is flawless, numerous epidemiological studies have shown that long term exposure to diesel exhaust in a variety of occupational circumstances is associated with an increased risk of lung cancer. With only rare exceptions, involving relatively few workers and/or observation periods too short to reliably detect excess cancer risk, the human studies have consistently shown a greater risk of lung cancer among workers exposed to dpm than among comparable unexposed workers. When results from the human studies are combined, the risk is estimated to be 30–40 percent greater among exposed workers, if all other factors (such as smoking habits) are held constant. The consistency of the human study results, supported by experimental data establishing the plausibility of a causal connection, provides strong evidence that chronic dpm exposure at high levels significantly increases the risk of lung cancer in humans.

Moreover, all of the occupational studies indicating an increased frequency of lung cancer among workers exposed to dpm involved exposure levels estimated, on average, to be far below levels observed in underground mines. Except for miners, the workers

[1] The basis for the $PM_{2.5}$ NAAQS was a large body of scientific data indicating that particles in this size range are responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable public attention, and hearings by Congress, in which the scientific evidence was further discussed. Moreover, challenges to the EPA's determination that this size category warranted rulemaking were rejected by a three-judge panel of the DC Circuit Court. (ATA v. EPA, 175 F.3d 1027, D.C. Circuit 1999).

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included in these studies were exposed to average dpm levels below the limit established by this rule.

As noted in Part III, MSHA views extrapolations from animal experiments as subordinate to results obtained from human studies. However, it is noteworthy that dpm exposure levels recorded in some underground mines have been of the same order of magnitude that produced tumors in rats.

Based on the scientific data available in 1988, the National Institute for Occupational Safety and Health (NIOSH) identified dpm as a probable or potential human carcinogen and recommended that it be controlled. Other organizations have made similar recommendations. Most recently, the National Toxicology Program listed dpm as "reasonably anticipated to be a human carcinogen" in the Ninth Edition (Year 2000) of the National Report on Carcinogens.

The relationship between exposures and risks. Commenters noted MSHA's caution about trying to define a quantitative relationship between dpm exposure and particular health outcomes. They roundly attacked the agency's benefit analysis and a NIOSH paper reviewing quantification efforts as implying that such a relationship could be established in a valid way.

As MSHA acknowledged in the preamble to the proposed rule, the scientific community has not yet widely accepted any exposure-response relationship between the amount of dpm exposure and the likelihood of adverse health outcomes (63FR 58167). There are, however, two lung cancer studies in the record that show increasing risk of lung cancer with increasing levels of dpm exposure. Quantitative results from these studies, both conducted specifically on underground miners, can be used to estimate the reduction in lung cancer risk expected when dpm exposure is reduced in accordance with this rule. Depending on the study and method of statistical analysis used, these estimates range from 68 to 620 lung cancer deaths prevented, over an initial 65-year period, per 1000 affected miners with lifetime (45-year) exposure to dpm.

NIOSH and the National Cancer Institute (NCI) are collaborating on a cancer mortality study designed to provide additional information in this regard. The study is projected to take about seven years.

Notwithstanding this situation, MSHA believes the Agency is required under its statute to take action now to protect miners' health. As noted by the Supreme Court in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a "mathematical straightjacket." *Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980). The Court noted that when regulating on the edge of scientific knowledge, absolute scientific certainty may not be possible, and:

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. (Id. at 656).

This advice has special significance for the mining community, because a singular historical factor behind the enactment of the current Mine Act was the slowness of the mining community in coming to grips with the harmful effects of other respirable dust (coal dust).

It is worth noting that while the cohort selected for the NIOSH/NCI study consists of underground miners (specifically, underground metal and nonmetal miners), this choice is in no way linked to MSHA's regulatory framework or to miners in particular. This cohort was selected for the study because it provides the best population for scientists to study. For example, one part of the study would compare the health experiences of miners who have worked underground in mines with long histories of diesel use with the health experiences of similar miners who work in surface areas where exposure is significantly lower. Since the general health of these two groups is very similar, this will help researchers to quantify the impacts of diesel exposure. No other population is likely to be as easy to study for this purpose. But as with any such epidemiological study, the insights gained are not limited to the specific population used in the study. Rather, the study will provide information about the relationship between exposure and health effects that will be useful in assessing the risks to any group of workers in a dieselized industry.

Because of the lack of a generally accepted dose-response relationship, some commenters questioned the agency's rationale in picking a particular concentration limit: 160_{TC} µg/m³ or around 200_{DPM} µg/m³. Capping dpm concentrations at this level will eliminate the worst mining exposures, and bring miner exposures down to a level commensurate with those reported for other groups of workers who use diesel-powered equipment. The proposed rule would not bring concentrations down as far as the proposed ACGIH TLV^R of 150_{DPM} µg/m³. Nor does MSHA's risk assessment suggest that the proposed rule would completely eliminate the significant risks to miners of dpm exposure.

In setting the concentration limit at this particular value, the Agency is acting in accord with its statutory obligation to attain the highest degree of safety and health protection for miners that is feasible. The Agency's risk assessment supports reduction of dpm to the lowest level possible. But feasibility considerations dictated proposing a concentration limit that does not completely eliminate the significant risks that dpm exposure poses to miners.

The Agency specifically explored the implications of requiring mines in this sector to comply with a lower concentration limit than that being adopted. The results, discussed in Part V of this preamble, indicate that although the matter is not free from question, it still may not be feasible at this time for the underground metal and nonmetal mining industry as a whole to comply with a significantly lower limit than that being adopted. The Agency notes that since this rulemaking was initiated, the efficiency of hot gas filters has improved significantly, the dpm emissions from new engines continue to decline under EPA requirements, and the availability of ultra-low sulfur fuel should make controls even more efficient than at present.

The agency also explored the idea of bridging the gap between risk and feasibility by establishing an "action level". In the case of MSHA's noise rule, for example, MSHA adopted a "permissible exposure level" of a time-weighted 8-hour average (TWA_8) of 90 dBA (decibels, A-weighted), and an "action level" of half that amount—a TWA_8 of 85 dBA. In that case, MSHA determined that miners are at significant risk of material harm at a TWA_8 of 85 dBA, but technological and feasibility considerations preclude the industry as a whole, at this time, below a TWA_8 of 90 dBA. Accordingly, to limit miner exposure to noise at or above a TWA_8 of 85 dBA, MSHA requires that mine operators must take certain actions that are feasible (*e.g.*, provide hearing protectors).

MSHA considered the establishment of a similar "action level" for dpm—probably at half the proposed concentration limit, or 80_{TC} µg/m³. Under such an approach, mine operators whose dpm concentrations are above the "action level" would be required to implement a series of "best practices"—*e.g.*, limits on fuel types, idling, and engine maintenance. Only one commenter supported the creation of an Action Level for dpm. However, this commenter suggested that such an Action Level be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance. The agency determined it is feasible for the entire underground mining community to implement these best practices to minimize the risks of dpm exposure without the need for a trigger at an Action Level.

Some of the comments suggesting that the agency had no rational basis for setting the exposure limit at 160_{TC} µg/m³ seem to suggest that the statute itself does not provide the Agency with adequate guidance in this regard. The Agency recognizes that the Supreme Court has scheduled argument on a case that raises the question of how specific a regulatory statute must be with respect to how an agency must make standards determinations in order to be deemed a constitutional delegation of authority from the Congress. A decision is not expected until 2001. However, unless and until determined otherwise, MSHA presumes the Mine Act does pass constitutional muster in this regard, consistent with the existing case law concerning the very similar Occupational Safety and Health Act.

(B) The ability of the agency to accurately measure diesel particulate matter (dpm) in underground metal and nonmetal mine environments. As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration of 200_{DPM} µg/m³ or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether such any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the infrastructure (samplers and laboratories) existed to support such determinations. (See 63 FR 58127 *et seq.*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency tentatively concluded that by using a sampler developed by the Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH) to detect the total amount of carbon in a sample, MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself through provisions of the proposed rule to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis upon which determinations would be made of compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 provided as follows:

§ 57.5061 Compliance Determinations

(a) A single sample collected and analyzed by the Secretary in accordance with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the Bureau of Mines would provide an accurate sample to be analyzed, and whether such samplers and analytical procedures would be commercially available. Commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations. These comments are addressed elsewhere in this preamble (section 3 of Part II, and in connection with section 5061 in Part IV).

Here, MSHA summarizes its views on the most common assertion made by commenters: that the sampling and analytical methods the agency proposed to use are not able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke.

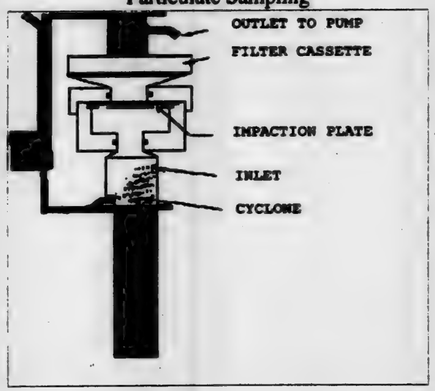
Interferences: what MSHA said in preamble to proposed rule. In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: "Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration." (63FR 58129)

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler—a submicron impactor—to eliminate certain other possible interferences (See Figure I–1). The submicron impactor stops particles larger than a micron from being collected by the sampler, while allowing the smaller dpm to be collected. Thus, an advantage of using the impactor would be to ensure that the sampler was not inadvertently collecting materials other than dpm. However MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present (63FR 58129). This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20% (Vuk, Jones, and Johnson, 1976).

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Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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Interferences: comments and MSHA efforts to verify. Many commenters asserted that no matter how it is performed in underground metal and nonmetal mines, the sampling and analysis proposed by MSHA to determine the amount of diesel particulate present would suffer from one or more of the aforementioned interferences. A number asserted that their own measurements using this approach provided clear evidence of such interferences. Although MSHA repeatedly asked for actual data and information about the procedures used to verify these assertions, very little was provided. Nevertheless, rather than conclude that these assertions were baseless, MSHA decided to attempt to verify these assertions itself. Accordingly, appropriate field and laboratory measurements were conducted toward this end, the results written up in appropriate fashion, and added to the record of this rulemaking. The agency has taken those results into account in ascertaining what weight to give to the assertions made by commenters and how to deal with those assertions supported by its measurements.

As described in detail in section 3 of Part II, MSHA's verifications demonstrate that the submicron impactor can eliminate any interferences from carbonates, carbonaceous minerals, and graphitic ores. Accordingly, although use of the impactor will result in an undercount of dpm, the final rule provides that MSHA will always use the submicron impactor in compliance sampling.

MSHA's verifications also demonstrated that oil mists as well as cigarette smoke, can in fact, under certain circumstances, create interferences even with the use of the impactor. MSHA presumes the same would happen with organic vapors. The verifications demonstrated that the problems occur in the immediate vicinity of the interferent (*e.g.*, close to a drill or smoker). However, the verifications also demonstrated that the interference dissipates when the sampling device is located a certain distance away from the interferent.

Accordingly, as detailed in the discussion of section 5061 in Part IV of this preamble, MSHA's sampling strategy for dpm will take these problems into account. For example, if a miner works in an enclosed cab all day and smokes, MSHA will not place a sampler in that cab or on that miner. If a miner works part of a day drilling, MSHA will not place a sampler on that miner. But MSHA can, for example, take an area sample in an area of a mine where drilling is being performed without concern about interferences from oil mists if it locates the sampler far enough away from the drill. MSHA's compliance manual will provide specific instructions to inspectors on how to avoid interferences.

The organic interferences (diesel mist, smoking) could be avoided by only analyzing a sample for elemental carbon, pursuant to the NIOSH method. As it indicated in the preamble to the proposed rule, however, MSHA does not at this time know the ratio between the amount of elemental carbon and the amount of dpm. Accordingly, rather than deal with the uncertainties in all samples which this approach would present, MSHA is going to use a method (i.e., sampling and analyzing for both organic carbon and elemental carbon) that, if properly applied, provides accurate results.

(C) The feasibility of the requirements for this sector of the mining industry. The Mine Act generally requires MSHA to set the standard that is most protective of miner health while still being technologically and economically feasible. In addition, consistent with the Regulatory Flexibility Act, the agency pays particular attention to the impact of any standard on small mining operations.

(1) Technological feasibility of the rule. It has been clear since the beginning of this rulemaking that if technological feasibility was an issue, it would be in the context of requiring all underground metal and nonmetal mines to meet a particular limit. While the Mine Act does not require that each mine be able to meet a standard for it to be considered technologically feasible—only that the standard be feasible for the industry as a whole—the extent to which various mines might have a problem complying is the evidence upon which this conclusion must be based.

Accordingly, MSHA evaluated the technological feasibility of the concentration limit in the underground metal and nonmetal sector by evaluating whether it was possible, using a combination of existing control approaches, to reach the concentration limit even in situations in which the Agency's engineers determined that compliance might be the most difficult. In this regard, the Agency examined how emissions generated by the actual equipment in four different underground mining operations could be controlled. The mines were very diverse—an underground limestone mine, an underground (and underwater) salt mine, and an underground gold mine. Yet in each case, the analysis revealed that there are available combinations of controls that can bring dpm concentrations down to well below the final limit—even when the controls that needed to be purchased were not as extensive as those which the Agency is assuming will be needed in determining the costs of the final rule. (The results of these analyses are discussed in Part V of the preamble, together with the methodology used in modeling the results—just as they were discussed in the preamble accompanying the proposed rule.) As a result of these studies, the Agency has concluded that there are engineering and work practice controls available to bring dpm concentrations in all underground metal and nonmetal mines down to the required levels.

The best actions for an individual operator to take to come into compliance with the interim and final concentration limits will depend upon an analysis of the unique conditions at the mine. The final rule provides 18 months after it is promulgated for MSHA to provide technical assistance to individual mine operators. It also gives all mine operators in this sector an additional three and a half years to bring dpm concentrations down to the proposed final concentration limit—using an interim concentration limit during this time which the Agency is confident every mine in this sector can timely meet. And the rule provides an opportunity for a special extension for an additional two years for mines that have unique technological problems meeting the final concentration limit.

As noted during 1995 workshops co-sponsored by MSHA on methods for controlling diesel particulate, many underground metal and nonmetal mine operators have already successfully determined how to reduce diesel particulate concentrations in their mines. MSHA has disseminated the ideas discussed at these workshops to the entire mining community in a publication, "Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox". The control methods are divided into eight categories: use of low emission engines; use of low sulfur fuel; use of aftertreatment devices; use of ventilation; use of enclosed cabs; diesel engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Moreover, MSHA designed a model in the form of a computer spreadsheet that can be used to simulate the effects of various controls on dpm concentrations. (This model is discussed in Part V of the preamble.) This makes it possible for individual underground mine operators to evaluate the impact on diesel particulate levels of various combinations of control methods, prior to making any investments, so each can select the most feasible approach for his or her mine.

(2) Economic Feasability of the Rule. The underground metal and nonmetal industry uses a lot of diesel-powered equipment, and it is widely distributed. Accordingly, MSHA recognizes that the costs of bringing mines into compliance with this rule will be widely felt in this sector (although, unlike underground coal mines, this sector did not have to comply with MSHA's 1996 diesel equipment rule).

In summary, the costs per year to the underground metal and nonmetal industry are about $25.1 million. The cost for an average underground metal and nonmetal mine is expected to be about $128,000 annually.

The Agency's initial cost estimates of $19.2 million a year were challenged during the rulemaking proceeding. As a result, the Agency reconsidered the costs.

In its initial estimate of the costs for the industry to comply with the concentration limit, MSHA assumed that a variety of engineering controls, such as low emission engines, ceramic filters, oxidation catalytic converters, and cabs would be needed on diesel powered equipment. Most of the engineering controls would be needed on diesel equipment used for production, while a small amount of diesel equipment that is used for support purposes would need engineering controls. In addition to these controls, MSHA assumed that some underground metal and nonmetal mines would need to make ventilation changes in order to meet the proposed concentration limits.

Specifically, in the PREA, MSHA assumed that: (1) the interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and (2) the final standard would be met by adding cabs and filters. Comments on the PREA and data collected by the Agency since publication of the proposed rule indicate that engine replacement is more expensive than originally thought and filters are more effective relative to engine replacement. The revised compliance strategy, upon which MSHA bases its revised estimates of compliance costs, reverses the two most widely used measures. MSHA now anticipates that: (1) the interim standard will be met with filters, cabs, and ventilation; and (2) the final standard will be met with more filters, ventilation, and such turnover in equipment and engines as will have occurred in the baseline. This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and cost estimated are different.

(3) Impact on small mines. As required by the Regulatory Flexibility Act, MSHA has performed a review of the effects of the proposed rule on "small entities".

The Small Business Administration generally considers a small mining entity to be one with less than 500 employees. MSHA has traditionally defined a small mine to be one with less than 20 miners, and has focused special attention on the problems experienced by such mines in implementing safety and health rules. Accordingly, MSHA has separately analyzed the impact of the rule on three categories of mines: large mines (more than 500 employees), middle size mines (20–500 employees), and small mines (those with less than 20 miners).

As required by law, MSHA has also developed a preliminary and final regulatory flexibility analysis. The Agency published its preliminary Regulatory Flexibility Analysis with its proposed rule and specifically requested comments thereon; the agency's final Regulatory Flexibility Analysis is included in the Agency's REA. In addition to a succinct statement of the objectives of the rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward the nature of small business entities.

In promulgating standards, MSHA is required to protect the health and safety of all the Nation's miners and may not include provisions that provide less protection for miners in small mines than for those in larger mines. But MSHA does consider the impact of its standards on even the smallest mines when it evaluates the feasibility of various alternatives. For example, a major reason why MSHA concluded it

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needed to stagger the effective dates of some of the requirements in the rule is to ensure that it would be feasible for the smallest mines to have adequate time to come into compliance.

MSHA recognizes that smaller mines may need particular assistance from the agency in coming into compliance with this standard. Before the dpm concentration goes into effect in 18 months, the Agency plans to provide extensive compliance assistance to the mining community. The metal and nonmetal community will also have an additional three and a half years to comply with the final concentration limit, which in many cases means these mines may have a full five years of technical assistance before any engineering controls are required. MSHA intends to focus its efforts on smaller operators in particular—training them in measuring dpm concentrations, and providing technical assistance on available controls. The Agency will also issue a compliance guide, and continue its current efforts to disseminate educational materials and software.

(4) Benefits of the final rule Benefits of the rule include reductions in lung cancer. In the long run, as the mining population turns over, MSHA estimates that a minimum of 8.5 lung cancer deaths will be avoided per year.[2]

Benefits of the rule will also include reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes and in sensory irritation and respiratory symptoms. MSHA does not believe that the available data can support reliable or precise quantitative estimates of these benefits. Nevertheless, the expected reductions in the risk of death from cardiovascular, cardiopulmonary, or respiratory causes appear to be significant, and the expected reductions in sensory irritation and respiratory symptoms appear to be rather large.

II. General Information

This part provides the context for this preamble. The nine topics covered are:

(1) The role of diesel-powered equipment in underground metal and nonmetal mining in the United States;

(2) The composition of diesel exhaust and diesel particulate matter (dpm);

(3) The sampling and analytical techniques for measuring ambient dpm in underground metal and nonmetal mines;

(4) Limiting the public's exposure to diesel and other final particulates—ambient air quality standards;

(5) The effects of existing standards—MSHA standards on diesel exhaust gases (CO, CO_2, NO, NO_2, and SO_2), and EPA diesel engine emission standards—on the concentration of dpm in underground metal and nonmetal mines;

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines;

(7) MSHA's approach to diesel safety and health in underground coal mines and its effect on dpm;

(8) Information on how certain states are restricting occupational exposure to dpm; and

(9) A history of this rulemaking.

Material on these subjects which was available to MSHA at the time of the proposed rulemaking was included in Part II of the preamble that accompanied the proposed rule. (63 FR 58123 et seq). Portions of that material relevant to underground metal and nonmetal mines is reiterated here (although somewhat reorganized), and the material is amended and supplemented where appropriate as a result of comments and additional information added to the record since the proposal was published.

(1) The Role of Diesel-Powered Equipment in Underground Metal and Nonmetal Mining in the United States

Diesel engines, first developed about a century ago, now power a full range of mining equipment in underground metal and nonmetal mines, and are used extensively in this sector. This sector's reliance upon diesel engines to power equipment in underground metal and nonmetal mines appears likely to continue for some time.

Historical Overview of Diesel Power Use in Mining. As discussed in the notice of proposed rulemaking, the diesel engine was developed in 1892 by the German engineer Rudolph Diesel. It was originally intended to burn coal dust with high thermodynamic efficiency. Later, the diesel engine was modified to burn middle distillate petroleum (diesel fuel). In diesel engines, liquid fuel droplets are injected into a prechamber or directly into the cylinder of the engine. Due to compression of air in the cylinder the temperature rises high enough in the cylinder to ignite the fuel.

The first diesel engines were not suited for many tasks because they were too large and heavy (weighing 450 lbs. per horsepower). It was not until the 1920's that the diesel engine became an efficient lightweight power unit. Since diesel engines were built ruggedly and had few operational failures, they were used in the military, railway, farm, construction, trucking, and busing industries. The U.S. mining industry was slow, however, to begin using these engines. Thus, when in 1935 the former U.S. Bureau of Mines published a comprehensive overview on metal mine ventilation (McElroy, 1935), it did not even mention ventilation requirements for diesel-powered equipment. By contrast, the European mining community began using these engines in significant numbers, and various reports on the subject were published during the 1930's. According to a 1936 summary of these reports (Rice, 1936), the diesel engine had been introduced into German mines by 1927. By 1936, diesel engines were used extensively in coal mines in Germany, France, Belgium and Great Britain. Diesel engines were also used in potash, iron and other mines in Europe. Their primary use was in locomotives for hauling material.

It was not until 1939 that the first diesel engine was used in the United States mining industry, when a diesel haulage truck was used in a limestone mine in Pennsylvania, and not until 1946 was a diesel engine used in a coal mine. Today, however, diesel engines are used to power a wide variety of equipment in all sectors of U.S. mining. Production equipment includes vehicles such as haultrucks and shuttle cars, front-end loaders, hydraulic shovels, load-haul-dump units, face drills, and explosives trucks. Diesel engines are also used in support equipment including generators and air compressors, ambulances, fire trucks, crane trucks, ditch diggers, forklifts, graders, locomotives, lube units, personnel carriers, hydraulic power units, longwall component carriers, scalers, bull dozers, pumps (fixed, mobile and portable), roof drills, elevating work platforms, tractors, utility trucks, water spray units and welders.

Current Patterns of Diesel Power Use in Underground Metal and Nonmetal Mining. Table II–1 provides information on the current utilization of diesel equipment in underground metal and nonmetal mines.

[2] This lower bound figure could significantly underestimate the magnitude of the health benefits. For example the estimate based on the mean value of all the studies examined is 49 lung cancer deaths avoided per year.

TABLE II–1.—DIESEL EQUIPMENT IN UNDERGROUND METAL AND NONMETAL MINES

Mine size	Number of underground mines [A]	Number of mines with diesels [B]	Number of Engines [B]
Small [C]	134	77	584
Large	130	119	3,414
All	264	196	3,998

(A) Number of underground mines is based on those reporting operations for FY1999 (preliminary data).
(B) Number of mines using diesels are based on January 1998 count, by MSHA inspectors, of underground metal and nonmetal mines that used diesel powered equipment, and the number of engines (the latter rounded to the nearest 25) was determined in the same count with reference to equipment normally in use.
(C) A "small" mine is one with less than 20 miners.

As noted in Table II–1, a majority of underground metal and nonmetal mines use diesel-powered equipment.

Diesel engines in metal and nonmetal underground mines, and in surface coal mines, range up to 750 HP or greater, although equipment size, and thus the size of the engine, can be limited by production requirements, the dimensions of mine openings, and other factors. By contrast, in underground coal mines, the average engine size is less than 150 HP. The reason for this disparity is the nature of the equipment powered by diesel engines. In underground metal and nonmetal mines, and surface mines, diesel engines are widely used in all types of equipment—both the equipment used under the heavy stresses of production and the equipment used for support. In underground metal and nonmetal mines, of the approximate 4,000 pieces of diesel equipment normally in use, about 1,800 units are used for loading and hauling. By contrast, the great majority of the diesel usage in underground coal mines is in support equipment.

This fact is significant for dpm control in underground metal and nonmetal mines. As the horsepower size of the engine increases, the mass of dpm emissions produced per hour increases. (A smaller engine may produce the same or higher levels of particulate emissions per volume of exhaust as a large engine, but the mass of particulate matter increases with the engine size). Accordingly, as engine size increases, control of emissions may require additional efforts.

Another factor relevant to control of dpm emissions in this sector is that fewer than 15 underground metal and nonmetal mines are required to use Part 36 permissible equipment because of the possibility of the presence of explosive mixtures of methane and air. The surface temperature of diesel powered equipment in underground metal and nonmetal mines classified as gassy must be controlled to less than 400°F. Such mines must use equipment approved as permissible under Part 36 if the equipment is utilized in areas where permissible equipment is required. These gassy metal and nonmetal mines have been using the same permissible engines and power packages as those approved for underground coal mines. (MSHA has not certified a diesel engine exclusively for a Part 36 permissible machine for the metal and nonmetal sector since 1985 and has certified only one permissible power package; however, that engine model has been retired and is no longer available as a new purchase to the industry). As a result, engine size (and thus dpm production of each engine) is more limited in these mines, and, as explained in section 6 of this part, the exhaust from these engines is cool enough to add a paper type of filtration device directly to the equipment.

By contrast, since in nongassy underground metal and nonmetal mines mine operators can use conventional construction equipment in their production sections without the need for modifications to the machines, they tend to do so. Two examples are haulage vehicles and front-end loaders. As a result, these mines can and do use engines with larger horsepower and hot exhaust. As explained in section 6 of this part, the exhaust from such engines must be cooled by a wet or dry device before a paper filter can be used, or high temperature filters (*e.g.*, ceramics) must be used.

At this time, diesel power faces little competition from other power sources in underground metal and nonmetal mines. As can be seen from the chart, there are some small metal and nonmetal mines (less than 20 employees) which do not use diesel-powered equipment; most of these used compressed air for drilling and battery-powered rail equipment for haulage.

It is unclear at this time, how quickly new ways to generate energy to run mobile vehicles will be available for use in a wide range of underground metal and nonmetal mining activities. New hybrid electric automobiles are being introduced this year by two manufacturers (Honda and Toyota); such vehicles combine traditional internal combustion power sources (in this case gasoline) with electric storage and generating devices that can take over during part of the operating period. By reducing the time the vehicle is directly powered by combustion, such vehicles reduce emissions. Further developments in electric storage devices (batteries), and chemical systems that generate electricity (fuel cells) are being encouraged by government-private sector partnerships. For further information on recent developments, see the Department of Energy alternative fuels web site at http://www.afdc.doe.gov/altfuels.html, and "The Future of Fuel Cells" in the July 1999 issue of *Scientific American*. Until such new technologies mature, are available for use in large equipment, and are reviewed for safe use underground, however, MSHA assumes that the underground metal and nonmetal mining community's significant reliance upon the use of diesel-power will continue.

(2) The Composition of Diesel Exhaust and Diesel Particulate Matter (DPM)

The emissions from diesel engines are actually a complex mixture of compounds, containing gaseous and particulate fractions. The specific composition of the diesel exhaust in a mine will vary with the type of engines being used and how they are used. Factors such as type of fuel, load cycle, engine maintenance, tuning, and exhaust treatment will affect the composition of both the gaseous and particulate fractions of the exhaust. This complexity is compounded by the multitude of environmental settings in which diesel-powered equipment is operated. Nevertheless, there are a few basic facts about diesel emissions that are of general applicability.

The gaseous constituents of diesel exhaust include oxides of carbon, nitrogen and sulfur, alkanes and alkenes (*e.g.*, butadiene), aldehydes (*e.g.*, formaldehyde), monocyclic aromatics (*e.g.*, benzene, toluene), and polycyclic aromatic hydrocarbons (*e.g.*,

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phenanthrene, fluoranthene). The oxides of nitrogen (NO_X) are worth particular mention because in the atmosphere they can precipitate into particulate matter. Thus, controlling the emissions of NO_X is one way that engine manufacturers can control particulate production indirectly. (See section 5 of this part).

The particulate components of the diesel exhaust gas include the so-called diesel soot and solid aerosols such as ash particulates, metallic abrasion particles, sulfates and silicates. The vast majority of these particulates are in the invisible sub-micron range of 100nm.

The main particulate fraction of diesel exhaust is made up of very small individual particles. These particles have a solid core mainly consisting of elemental carbon. They also have a very surface-rich morphology. This surface absorbs many other toxic substances, that are transported with the particulates, and can penetrate deep into the lungs. There can be up to 1,800 different organic compounds adsorbed onto the elemental carbon core. A portion of this hydrocarbon material is the result of incomplete combustion of fuel; however, the majority is derived from the engine lube oil. In addition, the diesel particles contain a fraction of non-organic adsorbed materials. Figure II–1 illustrates the composition of dpm.

Diesel particles released to the atmosphere can be in the form of individual particles or chain aggregates (Vuk, Jones, and Johnson, 1976). In underground coal mines, more than 90% of these particles and chain aggregates are submicrometer in size (i.e., less than 1 micrometer (1 micron) in diameter). Dust generated by mining and crushing of material—*e.g.*, silica dust, coal dust, rock dust—is generally not submicrometer in size. Figure II–2 shows a typical size distribution of the particles found in the environment of a mine that uses equipment powered by diesel engines (Cantrell and Rubow, 1992). The vertical axis represents relative concentration, and the horizontal axis the particle diameter. As can be seen, the distribution is bimodal, with dpm generally being well less than 1 μm in size and dust generated by the mining process being well greater than 1 μm.

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Figure II-1
DPM components

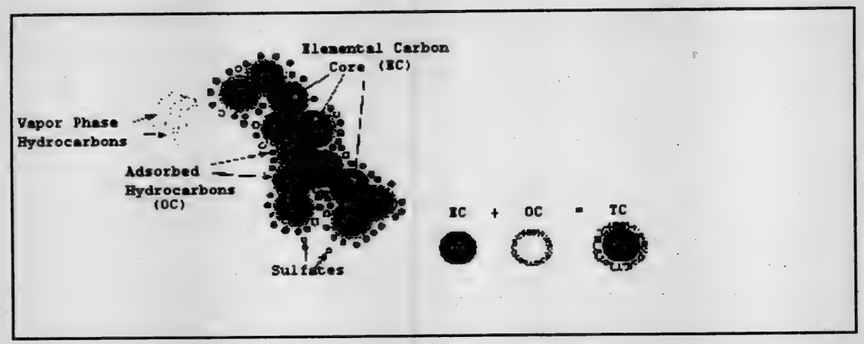
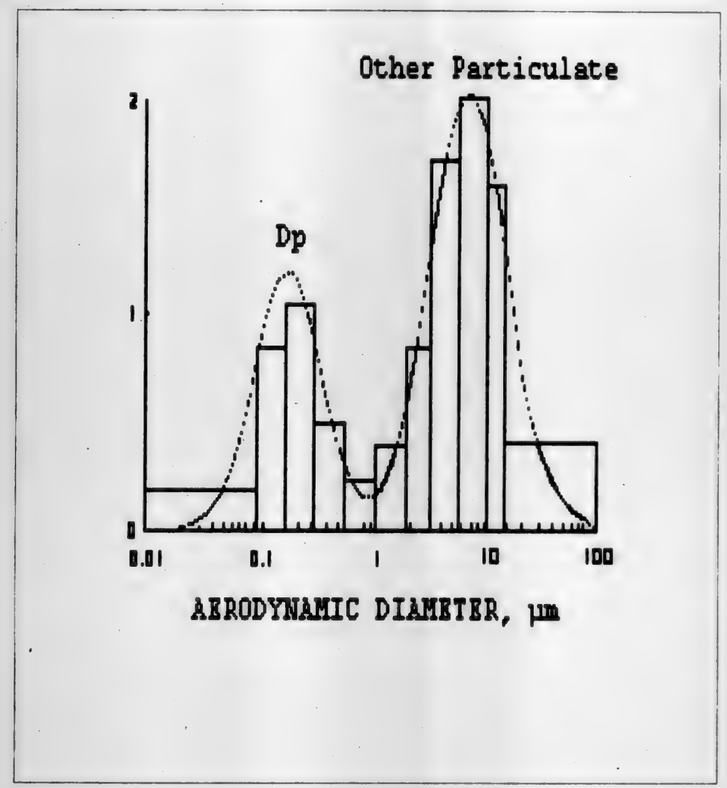
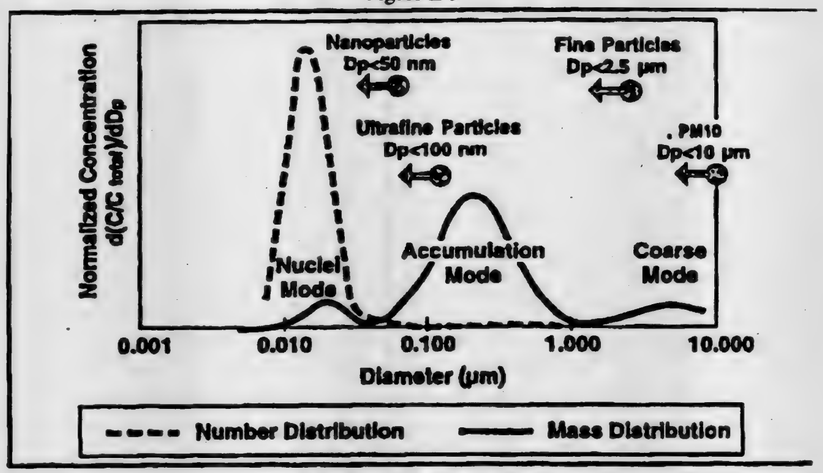


Figure II-2 -Typical distribution of dpm relative to distribution of other mining particulates.



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Figure II-3



Diesel particulate size distribution.

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As shown on Figure II–3 (Majewski, W. Addy, Diesel Progress June, 1998) diesel particulates have a bimodal size distribution which includes small nuclei mode particles and larger accumulation mode particles. As further shown, most of diesel particle mass is contained in the accumulation mode but most of the particle number can be found in the nuclei mode.

The particles in the nuclei mode, also known as nanoparticles, are being investigated as to their health hazard relevance. The interest in these particles has been sparked by the finding that newer "low polluting engines emit higher numbers of small particles than the old technology engines. Although the exact composition of diesel nanoparticles is not known, it was found that they may be composed of condensates (hydrocarbons, water, sulfuric acid). The amount of these condensates and the number of nanoparticles depends very significantly on the particulate sampling conditions, such as dilution ratios, which were applied during the measurement.

Both the maximum particle concentration and the position of the nuclei and accumulation mode peaks, however, depend on which representation is chosen. In mass distributions, the majority of the particulates (*i.e.*, the particulate mass) is found in the accumulation mode. The nuclei mode, depending on the engine technology and particle sampling technique, may be as low as a few percent, sometimes even less than 1%. A different picture is presented when the number distribution representation is used. Generally, the number of particles in the nuclei mode contributes to more than 50% of the total particle count. However, sometimes the nuclei mode particles represent as much as 99% of the total particulate number. The topic of nanoparticles is discussed further in section 5 of this Part.

(3) The Sampling and Analytical Techniques for Measuring Ambient dpm in Underground Metal and Nonmetal Mines

As MSHA noted in the preamble to the proposed rule, there are a number of methods which can measure dpm concentrations with reasonable accuracy when it is at high concentrations and when the purpose is exposure assessment. Measurements for the purpose of compliance determinations must be more accurate, especially if they are to measure compliance with a dpm concentration as low as 200 $\mu g/m^3$ or lower. Accordingly, MSHA noted that it needed to address a number of questions as to whether any existing method could produce accurate, reliable and reproducible results in the full variety of underground mines, and whether the samplers and laboratories existed to support such determinations. (See 63 FR 58127 *et.seq*).

MSHA concluded that there was no method suitable for such compliance measurements in underground coal mines, due to the inability of the available methods to distinguish between dpm and coal dust. Accordingly, the agency developed a rule for the coal mining sector that does not depend upon ambient dpm measurements.

By contrast, the agency concluded that by using a sampler developed by the former Bureau of Mines, and an analytical method developed by the National Institute for Occupational Safety and Health (NIOSH), MSHA could accurately measure dpm levels at the required concentrations in underground metal and nonmetal mines. While not requiring operators to use this method for their own sampling, MSHA did commit itself to use this approach (or a method subsequently determined by NIOSH to provide equal or improved accuracy) for its own sampling. Moreover the agency proposed that MSHA sampling be the sole basis for determining compliance by metal and nonmetal mine operators with applicable compliance limits, and that a single sample would be adequate for such purposes. Specifically, proposed § 57.5061 would have provided:

Section 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance with the procedure set forth in paragraph (b) of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect and analyze samples of diesel particulate matter by using the method described in NIOSH Analytical Method 5040 and determining the amount of total carbon, or by using any method subsequently determined by NIOSH to provide equal or improved accuracy in mines subject to this part.

This part of MSHA's proposed rule received considerable comment. Some commenters challenged the accuracy, precision and sensitivity of NIOSH Analytical Method 5040. Some challenged whether the amount of total carbon determined by the method is a reliable way to determine the amount of dpm. Others questioned whether the sampler developed by the former Bureau of Mines would provide an accurate sample to be analyzed. Many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. (It should be noted that commenters also questioned the use of a single sample as the basis for a compliance determination, and the use of area sampling in compliance determinations; these comments are reviewed and responded to in Part IV of this preamble in connection with the discussion of § 57.5061.)

The agency has carefully reviewed the information and data submitted by commenters. Where necessary to verify the validity of comments, MSHA collected additional information which it has placed in the record, and which in turn were the subject of an additional round of comments.

Background. As discussed in section 2 of this part, diesel particulate consists of a core of elemental carbon (EC), adsorbed organic carbon (OC) compounds, sulfates, vapor phase hydrocarbons and traces of other compounds. The method developed by NIOSH provides for the collection of a sample on a quartz fiber filter. As originally conceived, the filter is mounted in an open face filter holder that allows for the sample to be uniformly deposited on the filter surface. After sampling, a section of the filter is analyzed using a thermal-optical technique (Birch and Cary, 1996). This technique allows the EC and OC species to be separately identified and quantified. Adding the EC and OC species together provides a measure of the total carbon concentration in the environment.

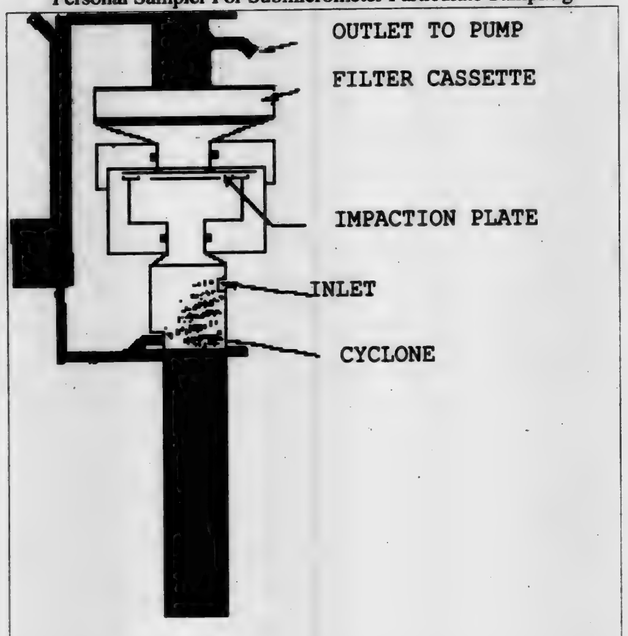
Studies have shown that the sum of the carbon (C) components (EC + OC) associated with dpm accounts for 80–85% of the total dpm concentration when low sulfur fuel is used (Birch and Cary, 1996). Therefore, in the preamble to the proposed rule, MSHA asserted that since the TC:DPM relationship is consistent, it provides a method for determining the amount of dpm. MSHA noted that the method can detect as little as 1 $\mu g/m^3$ of TC. Moreover, NIOSH has investigated the method and found it to meet NIOSH's accuracy criterion (NIOSH, 1995)—i.e., that measurements come within 25 percent of the true TC concentration at least 95 percent of the time.

In the preamble to the proposed rule, MSHA recognized that there might be some interferences from other common organic carbon sources in underground metal and nonmetal mines: specifically, oil mists and cigarette smoke. The agency noted it had no data on oil mists, but had not encountered the problem in its own sampling. With respect to cigarette smoke, the agency noted that: "Cigarette smoke is under the control of operators, during sampling times in particular, and hence should not be a consideration." (63 FR 58129).

The agency also discussed the potential advantages and disadvantages of using a special device on the sampler to eliminate certain other possible interferences. NIOSH had recommended the use of a submicron impactor when taking samples in coal mines to filter out particles more than one micron in size. See Figure III–3. The idea is to ensure that a sample taken in a coal mine does not include significant amounts of coal dust, since the analytical method would capture the organic carbon in the coal dust just like the carbon in dpm. Coal dust is generally larger than one micron, while dpm is generally smaller than one micron. However, MSHA pointed out that while samples in underground metal and nonmetal mines could be taken with a submicrometer impactor, this could lead to underestimating the total amount of dpm present. This is because the fraction of dpm particles greater than 1 micron in size in the environment of noncoal mines can be as great as 20%.

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Figure II- 3
Personal Sampler For Submicrometer Particulate Sampling



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MSHA also noted that while NIOSH Method 5040 requires no specialized equipment for collecting a dpm sample, the sample would most probably require analysis by a commercial laboratory. The agency noted it did not foresee the availability of qualified testing facilities as a problem. The agency likewise discussed the availability of the sampling device, and noted steps that were underway to develop a disposable sampler. (63 FR 58130)

Sample Collection Methods. Some commenters raised questions about how dpm samples should be taken: using open face sampling, respirable sampling and submicron sampling. All three are discussed in NIOSH Analytical Method 5040. Because diesel particulate matter is primarily submicron in size any of the three sampling methods could be used.

The choice of sample collection method considers the cost and potential interferences that the method can contribute. Regardless of the sampling method, the sampling media (filter) must be one that does not interfere with the analysis. For this reason a pre-fired quartz fiber filter has been chosen. The quartz fiber filter is capable of withstanding the temperatures from the analytical procedure. The filter is pre-fired to remove residual carbon, attached to the filter during manufacturing.

Total Dust Sampling. Total dust sampling is the least expensive method to collect an airborne dust sample. It is commonly used to collect a sample that is representative of all the dust in the environment; i.e., the particles are not preclassified during the collection process. Total dust sampling can be performed using a filter cassette that allows the whole face of the filter to be exposed during collection of the sample (open face) or using a filter cassette with a small inlet opening (referred to as a closed face filter cassette). The latter method is used by MSHA for compliance sampling for total dust in the metal and nonmetal sector. Because the sample collected is representative of all the particulate matter in the environment, there is the potential for interference from mineral contaminants when sampling for diesel particulate matter. While in many cases the analytical results can be corrected for these interferences, in some instances the interferences may be so large that they can not be quantified with the analytical procedure, thus preventing the analytical result to be corrected for the interference.

Additionally, MSHA has noted that in some cases when using the total dust sampler with the small inlet hole, distribution of the collected sample on the filter is not uniform. The distribution of sample is concentrated in the center of the filter. This can result in the effect of an interference being magnified. As a result, MSHA considers that total dust sampling is not an appropriate sampling method for the mining industry to use when sampling diesel particulate matter.

Respirable Dust Sample Collection. Respirable dust sampling is commonly used when a size selective criteria for dust is required. The mining industry is familiar with size selective sampling for the collection of coal mine dust samples in coal mines and for collecting respirable silica samples in metal and nonmetal mines. For respirable dust sampling MSHA uses a 10 millimeter, Dorr Oliver nylon cyclone as a particle classifier to separate the respirable fraction of the aerosol from the total aerosol sampled. The use of this particle classifier would be suitable when sampling diesel particulate, provided significant amounts of interfering minerals are not present. This is because 90 percent of the diesel particulate is typically less than 1 micrometer in size. Particles less than 1 micrometer in size pass through the cyclone and are deposited on the filter. While in many cases, these interferences could be removed during the analytical procedures, the analytical procedures alone can not be assured to remove the interferences when large amounts of mineral dust are present.

Additionally, MSHA has observed that in some sampling equipment the cyclone outlet hole has been reduced when interfacing it with the filter capsule. MSHA has further observed that where this has occurred, the distribution of sample on the collection filter may not be uniform. In this circumstance the sample is also concentrated in the center of the filter which can result in the effect of a mineral interference being magnified. As a result, MSHA considers that respirable dust sampling is not a universally applicable sampling method for the mining industry to use for sampling diesel particulate matter.

Submicron Dust Sample Collection. Since only a small fraction of a mineral dust aerosol is less than 1 micrometer in size, a submicrometer impactor (Cantrell and Rubow, 1992) was developed to permit the sampling of diesel particulate without sampling potential mineral interferences. The submicrometer impactor was initially developed to remove the interference from coal mine dust when sampling diesel particulate in coal mines. It was designed to remove the carbon coal particles, that are greater than 0.8 micrometer in size, when sampling for diesel particulate matter at a pump flowrate of 2.0 liters per minute. As a result the submicrometer impactor cleans potentially interfering mineral dust from the sample.

As noted in the preamble to the proposed rule, use of this method to measure dpm does result in the exclusion of that portion of dpm that is not submicron in size, and this can be significant. On the other hand, this method avoids problems associated with the other methods described above. Moreover, as discussed in more detail below under the topic of "interferences", the submicron impactor can eliminate certain substances that in metal and nonmetal mines would otherwise make it difficult for the analytical method to be used for compliance purposes.

Accuracy of Analytical Method, NIOSH Method 5040. Commenters challenged the accuracy, precision and sensitivity of the analytical method (NIOSH Method 5040) used for the diesel particulate analysis. MSHA has carefully reviewed these concerns, and has concluded that provided a submicron impactor is used with the sampling device in underground metal and nonmetal mines, NIOSH Method 5040 does provide the accuracy, precision and sensitivity necessary to use in compliance sampling for dpm in such mines.

As noted above, NIOSH Method 5040 is an analytical method that is used to determine elemental and organic carbon content from an airborne sample. It is more versatile than other carbon analytical methods in that it differentiates the carbon into its organic and elemental carbon components. The method accomplishes this through a thermal optical process. An airborne sample is collected on a quartz fiber filter. A portion of the filter, (approximately 2 square centimeters in area) is placed into an oven. The temperature of the oven is increased in increments. At certain oven temperature and atmospheric conditions (helium, helium-oxygen), carbon on the filter is oxidized into carbon dioxide. The carbon dioxide gas is then passed over a catalyst and reduced to methane. The methane concentration is measured and carbon content is determined. Separation of different types of organic carbon is accomplished through temperature and atmospheric control. The instrument is programmed to increase temperature in steps over time. This step by step increase in temperature allows for differentiation between various types of organic carbon.

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A laser is used to differentiate the organic carbon from the elemental carbon. The laser penetrates the filter and when the laser transmittance reaches its initial value this determines when elemental carbon begins to evolve. The computer software supplied with the instrumentation indicates this separation by a vertical line. The separation point can be adjusted by the analyst. As a result, there may be small differences in the determination of organic and elemental carbon between analysts, but the total carbon (sum of elemental and organic carbon) does not change. The software also allows the analyst to identify and quantify the different types of organic carbon using identifiable individual peaks. This permits the mathematical subtraction of a particular carbon peak. This feature is particularly useful in removing contributions from carbonates or other carbonaceous minerals. In other total carbon methods, samples have to be acidified to remove carbonate interference. A thermogram is produced with each analysis that shows the temperature ramps, oven atmospheric conditions and the amount of carbon evolved during each step.

A range of five separate sucrose standards between 10–100 $\mu g/cm^2$ carbon are initially analyzed to check the linearity of the internal calibration determined using a constant methane concentration. This constant methane concentration is injected at the end of each analysis. To monitor this methane constant, sucrose standards are analyzed several times during a run to determine that this constant does not deviate by more than 5–10%.

The method has the sensitivity to analyze environmental samples containing 1 to 10 $\mu g/m^3$ of elemental carbon. The method will be used in mining applications to determination total carbon contamination where the diesel particulate concentration will be limited to 400 $\mu g/m^3_{TC}$ and 160 $\mu g/m^3_{TC}$. NIOSH has reported that the lower limit of detection for the method is 0.1 $\mu g/cm^2$ elemental carbon for an oven pre-fired filter portion and 0.5 $\mu g/cm^2$ organic carbon for an oven pre-fired filter portion. For a full shift sample, this detection limit represents approximately 1 and 5 $\mu g/m^3$ of elemental and organic carbon, respectively. Additionally, NIOSH has conducted a round robin program to assess interlaboratory variability of the method. This study indicated a relative standard deviation for total carbon, of less than 15 percent.

A typical diesel particulate thermogram is shown in Figure II–4. The thermogram generally contains five or six carbon peaks, one for each temperature ramp on the analyzer. The first four peaks (occurring during a helium atmosphere ranging from a temperature of 210C to 870C) are associated with organic carbon determination and the fifth and/or sixth peak (occurring during a helium/oxygen atmosphere ranging in temperature from 610C to 890C) is the elemental carbon determination.

The fourth peak (temperature ~750C) is also where carbonate and other carbonaceous minerals are evolved in the analysis. For a diesel particulate sample without interferences present, this fourth peak is usually minimal as it is attributed to heavy distillant organics not normally associated with diesel operations in underground mining applications. If this peak is due to carbonate, the carbonate interference can be verified by analyzing a second portion of the sample after acidification as described in the NIOSH 5040 method. If the fourth peak is caused by some other carbonaceous mineral, the acidification process may not completely remove the interference and may, on occasion cause a positive bias to elemental carbon.

As explained below in the discussion of interferences, these analytical interferences from carbonaceous materials can be corrected by using the submicron impactor preceded by a cyclone (respirable classifier) to collect diesel particulate matter samples, since nearly all the particles of these minerals are greater than 1 micrometer in size. Accordingly, MSHA has determined it should utilize a submicron impactor in taking any samples in underground metal and nonmetal mines, and has included this requirement in the rule. Specifically, 57.5061(b) now provides:

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary may also use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter in mines subject to this part.

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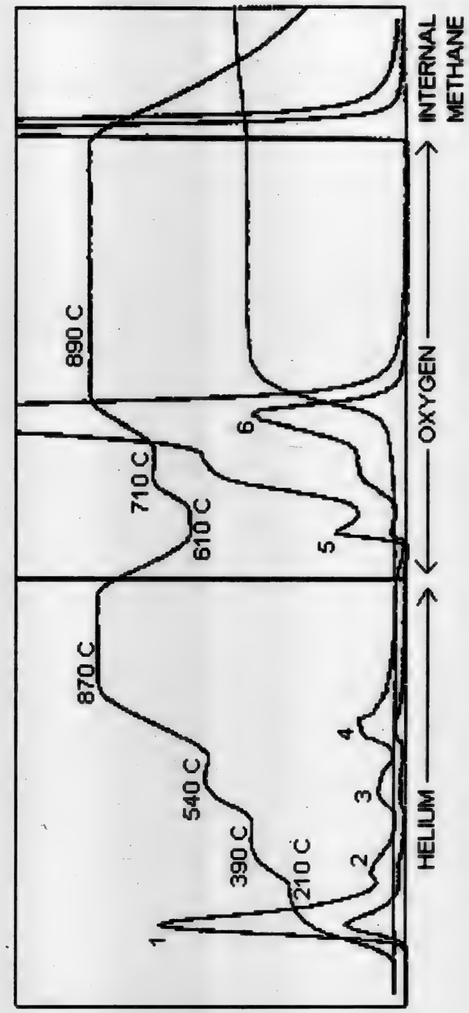


Figure II–4 Thermogram from analysis of a respirable dust sample.

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In keeping with established metal and nonmetal sampling protocol, the samplers will be operated at a flow rate of 1.7 LPM. At a flow rate of 1.7 LPM, the cut point for the impactor is 0.9 micrometers.

Any organic carbon detected at the fourth peak will be subtracted from the organic carbon portion of the sample analysis using the software supplied with the analytical program. The only samples that MSHA anticipates that will be acidified are those collected in trona mines. These samples contain a bicarbonate which evolves in several of the organic peaks but can be removed by acidification. Use of the submicron impactor will also insure a uniform distribution of diesel particulate and mineral dust on the filter.

Some Commenters indicated that a uniform deposit of mineral dust was sometimes not obtained with certain respirable dust sampler configurations. For some commodities such as salt and potash, where carbonate may not be an interference, it is probably not necessary to sample with the submicron impactor. However, in order to be consistent, MSHA will sample all commodities using a respirable dust sampler equipped with a submicrom impactor, and has so noted in the rule.

Proper use of sample blanks. Each set of samples collected to measure the diesel particulate concentration of a mine environment, must be accompanied by a field blank (a filter cassette that is treated and handled in the same manner as filters used to collect the samples) when submitted for analysis. The amount of total carbon determined from the analysis of the blank sample must be applied to (subtracted from) the carbon analysis of each individual sample. The field blank correction is applied to account for non-sampled carbon that attaches to the filter media. The blank correction is applied to the organic fraction as, typically, no elemental carbon is found on the blank filters.

Failure to adjust for the blanks can lead to incorrect results, as was the case with samples collected by some commenters. While field blanks were submitted and analyzed with their samples, the field blank analytical results were not used to correct the individual samples for nonsampled carbon content. Typically the carbon content on the reviewed field blanks ranged from 2 to 3 µg/square centimeter of filter area. For a one-hour sample, not using a blank correction of this magnitude, could result in an overestimate of 250 µg/m³ of dpm (3×8.55×1000/(1.7 * 60)=250). For an eight-hour sample, not using a blank correction, could result in an overestimate of 30 µg/m³ of dpm (3×8.55×1000/(1.7* 480)=30).

Variability of Sample Blanks

In response to the July 1, 2000, reopening of the record, one commenter submitted summary data from a study that examined diesel exposures in seven underground facilities where trona, salt, limestone, and potash were mined. The purpose of this study was to determine the precision and accuracy of the NIOSH 5040 method in these environments. According to the commenter, the study data "provide strong evidence that the NIOSH 5040 Method * * * is not feasible as a measure of DPM exposure." The commenter's conclusion was based on five "difficulties" that, according to the commenter, were documented when sampling for DPM using organic carbon or total carbon as a surrogate. These difficulties were:

(1) High and variable blank values from filters;

(2) High variability from duplicate punches from the same sampling filter;

(3) Consistently positive interference when open-faced monitors were sampled side-by-side with cyclones;

(4) Poor correlation of organic carbon to total carbon levels; and

(5) Interference from limestone that could not be adequately corrected with acid-washing.

As discussed elsewhere in this preamble, difficulties #3 and #5 will be resolved by the use of a submicrometer impactor sampler. Difficulty #4, the lack of a strong correlation between organic carbon and total carbon, has long been recognized by MSHA. That is one of the reasons MSHA chose total carbon (TC=EC+OC) as the best surrogate to use for assessing DPM levels in underground metal and nonmetal mines. MSHA has never proposed using organic carbon as a surrogate measure of DPM.

The summary data that the commenter submitted do not appear to demonstrate the first two items of "difficulties" with respect to TC measurements. Because MSHA has not experienced the difficulties of (1) high and variable blank values and (2) high variability between duplicate punches from the same sampling filter, MSHA also performed its own analysis of the data submitted by the commenter. MSHA's examination of the data included:

• Estimating the mean, within-mine standard deviation, and relative standard deviation (RSD) for blank TC values, based on the "Summary of Blank Sample Results" submitted; and

• Estimating the variability (expressed as RSD) associated with the TC analysis of duplicate punches from the same filter, based on individual sample data submitted earlier by the same commenter for five of the mines.

Based on the summary data, the overall average mean TC content per blank filter, weighted by the number of blank samples in each mine, was 16.9 µg TC. This represents the average value that would be subtracted from the TC measurement from an exposed sample before making a noncompliance determination. At a TC concentration of 160 µg/m³ (the final limit established by this rule), the TC accumulated on a filter after an 8-hour sampling period would be approximately 130 µg. Therefore, these data show that the mean TC value for a blank is less than 13 percent of TC accumulated at the concentration limit, and an even lower percentage of total TC accumulated at concentrations exceeding the limit. MSHA considers this to be acceptable for samples used to make noncompliance determinations. Based on the same summary data presented for TC measurements on blank samples, the weighted average of within-mine standard deviations is 6.4 µg. Compared to TC values greater than or equal to 130 µg, this corresponds to an RSD no greater than 6.4/130 = 4.9 percent. MSHA also regards this degree of variability in blank TC values to be acceptable for purposes of noncompliance determination.

To estimate the measurement variability associated with analytical errors in the TC measurements, MSHA examined the individual TC results from duplicate punches on the same filter. These data were submitted earlier by the same commenter for five mines. As shown, by the commenter's summary table, data obtained from the first mine were invalid, leaving data from four mines (2–5) for MSHA's data analysis. Data were provided on a total of 73 filters obtained from these four mines, yielding 73 pairs of duplicate TC measurements, using the initial and first repeated measurement provided for both elemental and organic carbon. MSHA calculated the mean percent difference within these 73 pairs of TC measurements (relative to the average for each pair) to be 8.2 percent (95-percent confidence interval = 5.6 to 10.9 percent). Based on the same data, MSHA calculated an estimated RSD = 10.0 percent for the analytical error in a single determination of TC.[1] Contrary to the commenter's conclusion, this result supports MSHA's position that TC measurements do not normally exhibit excessive analytical errors.

This estimate of the RSD = 10.0 percent for TC measurements is also consistent with the replicated area sample results submitted by the commenter for the seven mines. In this part of the study, designed to evaluate measurement precision, 69 sets of simultaneous samples were collected at the seven mines. Each set, or "basket," of samples normally consisted of five simultaneous samples taken at essentially the same location. Since the standard deviation of the TC measurements within each basket was based on a maximum of five samples, the standard deviation calculated within baskets is statistically unstable and does not provide a statistically reliable basis for estimating the RSD within individual baskets. However, as shown in the summary table submitted by the commenter, the mean RSD across all 69 baskets was 10.6 percent. This RSD, which includes the effects of normal analytical variability, variability in the volume of air pumped, and variability in the physical characteristics of individual sampler units, is not unusually high, in the context of standard industrial hygiene practice.

MSHA also examined data submitted by another commenter to estimate the total variability associated with TC sample analysis by different laboratories. Based on 25 pairs of simultaneous TC samples (using a cyclone) analyzed by different laboratories, this analysis showed a total RSD of approximately 20.6 percent. If the most extreme of three statistical outliers in these data is excluded, the result based on 24 pairs is an estimated RSD of 11.7 percent. Like the first commenter's estimate of RSD = 10.6 percent, based on simultaneous samples analyzed at the same laboratory, these RSD's include not only normal analytical variability in a TC determination, but also variability in the volume of air pumped and variability in the physical characteristics of individual sampler units. The higher estimates, however, also cover uncertainty in a TC measurement attributable to differences between laboratories.

[1] This estimate was obtained by first calculating the standard deviation of the differences between the natural logarithms of the TC measurements within each pair. Since each of these differences contains two TC determinations, and two corresponding analytical errors, this standard deviation was divided by the square root of 2. Using standard propagation of error formulas, the result provides a reasonably good estimate of the RSD over the range of TC values reported. MSHA used the same technique to estimate the RSD for the 25 pairs of TC samples analyzed at different laboratories, as described below.

Based on these analyses, MSHA has concluded that the data submitted to the record by commenters support the Agency's position that NIOSH Method 5040 is a feasible method for measuring DPM concentrations in underground M/NM mines.

Availability of analysis and samplers. One of the concerns expressed by commenters was the limited number of commercial laboratories available to analyze diesel particulate samples, and the availability of required samplers. While MSHA will be doing all compliance sampling itself, and running the analyses in its AIHA accredited laboratory in Pittsburgh, pursuant to § 57.5071 of the rule, operators in underground metal and nonmetal mines will be required to do environmental monitoring; and although they will not be required to use the same methods as MSHA to determine dpm concentrations, MSHA presumes that many will wish to do so. Moreover, there are certain situations (*e.g.*, verification that a dpm control plan is working) where the rule requires operators to use this method (§ 57.5062(c)).

Currently there are four commercial labs that have the capability to analyze for dpm using the NIOSH 5040 Method. These labs are: Sunset Laboratory, Forest Grove, Oregon and Chapel Hill, North Carolina; Data Chem, Salt Lake City, Utah; and Clayton Group Services, Detroit, MI. All of these labs, as well as including the NIOSH Laboratories in Cincinnati and Pittsburgh and the MSHA laboratory in Pittsburgh participate in a round robin analytical test to verify the accuracy and precision of the analytical method being used by each. As MSHA indicated in the preamble to its proposed rule, it believes that once there is a commercial demand for these tests, additional laboratories will offer such services.

The cost of the analysis from the commercial labs is approximately $30 to $50 for a single punch analysis and a report. This is about the same amount as a respirable silica analysis. The labs charge another $75 to acidify and analyze a second punch from the same filter and to prepare an analytical report. The labs report both organic and elemental carbon. By using the submicron impactor, operators can significantly reduce the number of situations where acidification is required, and thus reduce the cost of sample analysis.

The availability of samplers has been the subject of many comments—not so much because of concern about availability once the rule is in effect, but because of assertions that they are not available now. In particular, it has been alleged by some commenters that they have been unable to conduct their own "independent evaluation" of the NIOSH method because the agency has kept from them the samplers needed to properly conduct such testing. Some commenters even accused the agency of deliberately withholding the needed samplers.

As indicated in MSHA's toolbox and the preamble to the proposed rule, the former Bureau of Mines (BOM) submitted information on the development of a prototype dichotomous impactor sampling device that separates and collects the submicron respirable particulate from the respirable dust sampled. Information on this sampling device has been available to the industry since 1992. A picture of the sampler is shown above as Figure II–3. The impactor plate is made out of brass and the nozzles are drilled. The former BOM made available to all interested parties detailed design drawings that permitted construction of the dichotomous impactor sampler by any local machine shop. NIOSH and MSHA had hundreds of these sampling devices made for use in their programs to measure dpm concentrations. Anyone could have had impactor samplers built by a local machine shop at a cost ranging from $50 to $100.

In 1998, MSHA provided NIOSH with research funds for the development of a disposable sampling device that would have the same sampling characteristics as the BOM sampler, and including an impactor with the same sampling characteristics as the metal one. NIOSH awarded SKC the contract for the development of the disposable sampler. MSHA estimates the cost of the disposable sampler will be less than $50. The sampler is designed to interface with the standard 10 millimeter Dorr Oliver cyclone particle classifier and to fit in a standard MSHA respirable dust breast plate assembly. The quartz fiber filter used for the collection of diesel particulate in accordance with NIOSH Method 5040 has been encapsulated in an aluminum foil to make handling during the analytical procedure easier. To reduce manufacturing expense (and therefore, sampler cost), the nozzle plate in the SKC sampler is made of plastic instead of brass. In order to ensure that the nozzles in the impaction plate would hold their tolerances during manufacturing, the plastic nozzle plate for the SKC sampler is fitted with synthetic sapphire nozzles. This nozzle plate and nozzle assembly have the same performance as the BOM-designed sampler.

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As of the time MSHA conducted its verification sampling for interferences, SKC had developed several prototypes of the disposable unit. However, testing of the devices by NIOSH indicated that a minor design modification was needed to better secure the impaction plate and nozzle plate to the sampler housing for a production unit. In its verification sampling, MSHA used both BOM designed and SKC prototype samplers. Prior to its verification tests, MSHA replaced the brass nozzle plates in the BOM design impactors with plastic nozzle-plates fitted with sapphire nozzles, as used in the SKC prototype sampler. However, because there was no change in nozzle geometry, this change in the BOM impactors did not affect their performance. During MSHA's verifications testing, no problems were experienced with dislodgement of the impaction plates or nozzle plates. The impactors used by MSHA in its verification sampling were not defective in any way, as suggested by several Commenters.

Under the Mine Act, MSHA has no obligation to make devices available to the mining community to conduct its own test sampling or to verify MSHA's results, nor does the mining industry have any explicit authority under the Mine Act to "independently evaluate" MSHA's results. The responsibility for determining the accuracy of the device and method for sampling rests with the agency, not the mining community. Accordingly, although some commenters requested that MSHA remove its interference studies from the record, the agency declines to do so. These studies are discussed in more detail below; additional questions raised about the sampling devices used in the studies, and the procedures for that sampling, are discussed in that context.

Some commenters initially asserted that their inability to conduct their own testing would prevent them from making comments of MSHA's verification studies. Based on the detailed comments subsequently provided, this initial concern appears to have been overstated.

It appears from some of the comments on MSHA's studies that members of the mining community may have understood MSHA to say that use of an impactor sampler would remove all interferences. MSHA can find no such statement. As noted in more detail below, use of the impactor will remove most of the interferences (albeit at the cost of eliminating some dpm as well).

Choice of Total Carbon as Measurement of Diesel Particulate Matter. MSHA asserted that the amount of total carbon (determined by the sampling and analytical methods discussed above) would provided the agency with an accurate representation of the amount of dpm present in an underground metal and nonmetal mine atmosphere at the concentration levels which will have to be maintained under the new standard. Some commenters questioned MSHA's statements concerning the consistency of the ratio between total carbon and diesel particulate, and the amount of that ratio. Other commenters suggested that elemental carbon may be a better indicator of diesel particulate because it is not subject to the interference that could effect a total carbon measurement.

Under the approach incorporated into the final rule, the concentration of organic and elemental carbon (in µg per square centimeter) are separately determined from the sample analysis and added together to determine the amount of total carbon. The interference from carbonate or mineral dust quantified by the fourth organic carbon peak is subtracted from the organic carbon results. The field blank correction is then subtracted from the organic analysis (the blank does not typically contain elemental carbon). Concentrations (time weighted average) of carbon are calculated from the following formula:

$$\frac{C\left(\mu g/cm^2\right) * A\left(cm^2\right) * 1{,}000\ L/m^3}{1.7\ LPM * time\ (min)}$$

Where:

C=The Organic Carbon (OC) or Elemental Carbon (EC) concentration, in µg/m³, measured in the thermal/optical carbon analyzer (corrected for carbonate and field blank).

A=The surface area of the filter media used. The surface areas of the filters are as follows: quartz fiber filter without aluminum cover is 8.55 cm²; quartz fiber filter with aluminum cover is 8.04 cm².

The 80 percent factor MSHA used to establish the total carbon level equivalents of the 500 µg/m³ and 200 µg/m³ dpm concentration limits being set by the rule was based on information obtained from laboratory measurements conducted on diesel engines (Birch and Cary, 1996). Since the publishing of the proposed rule, this value has been confirmed by measurements collected in underground mines in Canada (Watts, 1999)

MSHA agrees that the total carbon measurement is more subject to interferences than the elemental carbon measurement. However, because the ratio of elemental carbon to total carbon in underground mines is dependent on the duty cycle at which the diesel engine is operated (found to vary between 0.2 and 0.7), MSHA believes that total carbon is the best indicator of diesel particulate for underground mines. Additionally, MSHA has observed that some controls, such as filtration systems on cabs can alter the ratio of elemental to total carbon. The ratio can be different inside and outside a cab on a piece of diesel equipment. MSHA notes that NIOSH has asserted that the ratio of elemental carbon to dpm is consistent enough to provide the basis for a standard based on elemental carbon ("* * * the literature and the MSHA laboratory tests support the assertion that DPM, on average, is approximately 60 to 80% elemental carbon, firmly establishing EC as a valid surrogate for DPM"). However, while an average value for elemental carbon percent may be a useful measure for research purposes, data submitted by commenters show that elemental carbon can range from 8 percent to 81 percent of total carbon.

MSHA does not believe elemental carbon is a valid surrogate for dpm in the context of a compliance determination that, like all other metal and nonmetal health standards, can be based on a single sample. By contrast, as noted above, studies have shown that there is a consistent ratio between total carbon and dpm (from 80 to 85%). Moreover, although the ratio of the elemental carbon to organic carbon components obtained using the NIOSH Method 5040 may vary, total carbon determinations obtained with this method are very consistent, and agree with other carbon methods (Birch, 1999). Accordingly, while total carbon sampling does necessitate sampling protocols to avoid interferences, of the sort discussed below, MSHA has concluded that it would not be suitable at this time to use elemental carbon as a surrogate for dpm.

Potential Sample Interferences/ Contributions. As noted in the introduction to this section, many commenters asserted that the analytical method would not be able to distinguish between dpm and various other substances in the atmosphere of underground metal and nonmetal mines—carbonates and carbonaceous minerals, graphitic materials, oil mists and organic vapors, and cigarette smoke. The agency carefully reviewed the information submitted by commenters, both during the hearings and in writing, and found that it was in general insufficient to establish that such interferences would be a problem. Limitations in the data submitted by the commenters included, for example, failure to utilize blanks, failure to blank correct sample results, open face and respirable samples that were collected in the presence of high levels of carbonate interference, the amount of carbonate interference was not quantified, dpm was not uniformly deposited on filters and sample punches were taken where the deposit was heaviest, failure to adjust sample results due to short sampling times, failure to consider the impact of interferences such as carbonate, oil mist, and cigarette smoke on dpm exposure.

Rather than dismiss these assertions, however, the agency decided to conduct some investigations to verify the validity of the comments. As a result of these tests, the agency has determined that certain interferences can exist, within certain parameters; and was also able to demonstrate how these interferences can be minimized or avoided. The material which follows reviews the information MSHA has on this topic, including representative comments MSHA received on these verification studies. Part IV of this preamble reviews in some detail the adjustments MSHA has made to the proposed rule, and the practices MSHA will follow in compliance sampling, to avoid these interferences.

General discussion of interference studies. As noted above, MSHA conducted the verifications to determine if the alleged interferences were in fact measurable in underground mining environments. At the same time, the studies gave MSHA an opportunity to identify sampling techniques that would minimize or eliminate the interferences, evaluate analytical techniques to minimize or eliminate the interferences from the samples, and develop a sampling and analytical strategy to assure reliable dpm measurements in underground mines.

A total of six studies were conducted. One field study was conducted at Homestake Mine, a gold mine in Lead, South Dakota, three field studies were conducted at gold mines near Carlin, Nevada. These included Newmont, South Area Carlin Mine and Barrick Goldstrike. One study was conducted in the NIOSH Research Laboratory's experimental mine in Pittsburgh, Pennsylvania and one study conducted in a laboratory dust chamber at the NIOSH Pittsburgh Research Laboratory. For example the studies conducted at Carlin and Homestake were to evaluate interference from oil mist and the studies conducted at Homestake, Newmont and Barrick were to assess interference from carbonaceous dust. These locations were carefully selected in light of the assertions about interferences which had been made by commenters.

Despite the care that went into designing where to conduct the verification samples, there were a number of comments asserting the samples were not representative. For example, it was asserted that MSHA did not sample a representative particle size distribution and sampled the wrong material (i.e., ores with the highest carbon content). On the contrary the samples that MSHA collected were representative of the respirable and submicron fractions of the dust in the environment as well as the total dust in the environment. Therefore, MSHA believes that the particle size distribution of the samples collected were representative. Also, MSHA obtained a bulk sample of the various ores tested. While the samples collected at the crushers were low carbon content (0–10.3%), the carbon content (30.3%) of the ore collected at the underground mining area sampled at Carlin was similar to the high carbon content (31.4%) ores obtained at Barrick. The sampling therefore included a cross section of the ores in question.

Some commenters objected to the fact that no personal samples were collected in these studies. Packages of samplers were placed in areas that were close to the breathing zone of the workers. Upwind and downwind samples were used to determine the extent of the interference. The regulation recognizes the validity of area samples. As a result these samples provided valid information on interferences that are likely to be encountered during sampling by MSHA inspectors.

More generally, commenters asserted that MSHA lacked enough studies for statistical analysis. MSHA notes again that the studies were conducted to verify specific industry assertions, and were properly designed to try and verify those assertions. However, the same studies which confirmed that such interferences could be measured in certain conditions were also able to determine that these interferences could not be measured, or were not significant in scope, if some of the conditions were changed. Part IV of this preamble discusses what actions the agency plans to take as a result of its current information on this matter.

Some commenters asserted that MSHA made certain incorrect technical assumptions in its verification sampling: about the sampling method used to conclude that overall dust levels would meet MSHA's standards; about the concentration of EC in submicrometer dust; and about the variability of carbonaceous ores. With respect to the first point, the final sampling strategy adopted by MSHA for dpm allows for either personal or area sampling using a submicrometer sampler preceded by a respirable cyclone. Because of the sampling and analytic procedures, the only potential mineral interferent would be the graphitic contribution (elemental carbon). The carbonate and carbonaceous contribution would be eliminated or reduced by the use of the impactor sampler and using the software integration procedure described in Method 5040.

With respect to the second point, the concentration of EC in the submicrometer dust, for personal and most area samples, the allowable silica exposure would limit the amount of submicrometer mineral dust sampled. This has been demonstrated for samples collected in coal mines where the coal dust contains high levels of elemental carbon, but the interference for EC from submicrometer samples has been less that 4 µg/m³.

With respect to the last point which addresses the geology of the ore, MSHA acknowledges that there would be variation in the carbon content of the ore. However, it would be unlikely that the carbon content would exceed that of coal mine dust where the elemental carbon interference has been found to be negligible.

The sampling was performed with the BOM designed or SKC prototype samplers as described in the prior section. All samplers used the more precise sapphire nozzles. Samples were collected using standard procedures developed by MSHA for assessing particulate concentrations in mine environments. Samples were analyzed for total carbon using NIOSH Method 5040. The analyses was performed by MSHA at the Pittsburgh Safety and Health Technology Center's Dust Division laboratory. For some samples a second analysis was performed using an acidification procedure.

Commenters alleged a number of technical problems with how the sampling was performed. Some asserted that defective devices were used for the sampling, or that MSHA did not properly calibrate its equipment. MSHA did not experience any problems with the samplers, and did calibrate its equipment according to standard procedures. Some pointed out that MSHA conducted the verifications with samplers different from those required by the rule. MSHA presumes this comment reflects the fact that the proposed rule did not require an

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impactor to be used; this is, however, the case with the final rule.

Some commenters noted that MSHA voided some sample results and that, lacking further explanation, it might be assumed the agency simply eliminated those samples which gave results that did not agree with the conclusions it sought. The only samples that were voided were chamber samples. Some voided samples were higher than, and some void samples were lower than, the sample used. These were duplicate samples collected for short time periods. Samples were voided because they were inconsistent with other samples in the set of six samples collected. These inconsistencies as-well-as variability between other duplicate samples were attributed to short sample times. Voided sample results are shown for Homestake (1 of 12 impactors). No impactor samples were voided at Barrick nor at the Newmont crusher. In the Jackleg drill tests conducted at Carlin Mine, there were 2 of 6 impactor samples voided.

Others asserted that MSHA failed to validate the design of the box which held the sampling equipment. In fact, all of the issues mentioned relative to the sampling box (i.e., pressure build up, leakage of chamber, impaction of particles, pump calibration) had been carefully examined by MSHA prior to the tests and found not to be a problem. Also, this sample chamber has been used extensively in other field tests where duplicate samples or a variety of samplers have been used and has worked extremely well.

One commenter stated that these studies confirm that measurement interference cannot be eliminated by blank correction and longer sample times, and that the proposed single sample enforcement policy would not be representative of typical mine conditions. MSHA disagrees with this conclusion from the verification tests. The MSHA tests demonstrated that blank correction does eliminate a source of interference. The residual organic carbon indicated in several of the samples collected at crushers were attributed to short sample time and normal variation in the range of blank values. The verification tests did not address sample time. However, when converting the mass collected to a concentration, the mass is divided by the sample time. Dividing by a longer time will always reduce an interference caused by a positive bias.

Other commenters alleged that there were problems with the MSHA personnel performing the studies. Some asserted these personnel failed to listen to suggestions made by representatives of mine companies who accompanied MSHA in their facilities during in-mine testing, suggestions which they assert would have corrected asserted problems in the testing procedure. Others simply assert that the MSHA personnel were biased, manipulated the data, and tried to conform the study results to those they wanted to find. It was also asserted that any potential for bias should have been removed through independent peer review of the results, or performance or confirmation of the studies by independent personnel or laboratories.

The tests were designed and conducted by personnel from MSHA's Pittsburgh Safety and Heath Technology's Dust Division. This laboratory at this facility is AIHA accreditated, and its personnel are among the foremost experts in particulate sampling analysis in the mining industry. They are widely published and are accustomed to performing work that must survive legal and scientific scrutiny. Moreover, the personnel designing and performing these studies have more experience than anybody else with dust sampling in general, and with this particular measurement application. While the agency welcomes scrutiny of its work, and repetition by others, it also recognizes that such efforts take time. In this case, the agency elected to conduct tests to address specific concerns, given its obligation to respond to the risks to miners reviewed in Part III of this preamble. It did so using a sound study design and expert personnel, and has made the detailed results of its studies a matter of public record.

In this regard, a number of commenters made reference to a study currently being conducted by NIOSH of possible interferences with the 5040 method. Some of these commenters provided MSHA with a copy of what is apparently the final protocol for the study, asserted that it would provide better information than the verification studies conducted by MSHA, and urged the agency to wait for completion of this study.

MSHA welcomes the NIOSH study, and will carefully consider its results—and the results of any other studies of this matter—in refining the compliance practices outlined in part IV of this preamble. But given the agency's obligation to respond to the risks to miners reviewed in Part III of this preamble, and the recommendations of NIOSH to take action in light of that risk, it would be inappropriate to await the results of another study.

Carbonates and Carbonaceous Minerals. As noted in the discussion of the analytical method (NIOSH Method 5040), carbonates have been known to cause an interference when determining the total carbon content of a diesel particulate sample. Carbonates are generally in two forms—carbonates such as limestone and dolomite and bicarbonate which is associated with trona (soda ash). As further noted, the amount of carbonate and bicarbonate collected on a sample can be significantly reduced or eliminated through the use of a submicrometer impactor. If the total carbon analysis of a sample indicates that a carbonate interference exists after the use of a submicrometer impactor, any remaining interfering effect may be removed or diminished using the acidification process described in NIOSH Method 5040.

Carbonate interference can also be removed during the analytical process by mathematically subtracting the organic carbon quantified by the fourth peak in the thermogram. Because bicarbonate is evolved over several temperature ranges, subtraction of only one peak does not remove all of the interference from bicarbonate. As a result, the sample needs to be acidified to remove all of the bicarbonate interference.

Commenters correctly pointed out that other carbonaceous minerals are not removed by the acidification process and in fact in some cases, the acidification process may cause a positive bias to the elemental carbon measurement. However, MSHA has verified that through the use of the submicrometer impactor, which reduces the mineral dust collected, combined with the subtraction of organic carbon quantified by the fourth organic carbon peak, this source of interference can be eliminated (PS&HTC–DD–505, PS&HTC–DD–509, PS&HTC–DD–510 and PS&HTC–DD–00–523).

MSHA has verified the use of a submicron impactor to remove carbonate interference through field and laboratory measurements. In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. In the laboratory measurements, a aerosol containing carbonate dust was introduced into a dust chamber and simultaneous submicron, respirable and total dust samples were collected. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, acidification of the sample removed the carbonate.

Carbonate was evolved in the fourth peak of the organic portion of the analysis. The carbon evolved by the analysis was approximately 10 percent of the carbonate collected on the gravimetric sample, roughly equating to 12 percent carbon contained in calcium carbonate tested (limestone). Sampling with the submicron impactor removed the carbonate and carbonaceous component from the sample. A commenter noted that in the dust chamber tests, organic carbon was reported, even though the carbonate was removed by sampling, acidification or software integration. This organic carbon was attributed to oil vapors leaking from the compressor that delivered the dust to the chamber. This oil leak was reported to MSHA after the tests were completed.

Sample results further indicated that the total carbon mass determined for the respirable diesel particulate samples was approximately 95 percent of the diesel particulate mass determined gravimetrically and the total carbon mass determined from the impactor diesel particulate samples was approximately 82 percent of the respirable value. Use of the impactor reduced the amounts of carbonate collected on the sample by 90 percent.

The difference between the respirable total carbon determinations and the gravimetric diesel particulate can be attributed to sulfates or other noncarbonaceous minerals in the diesel particulate. The difference between the submicron total carbon and the respirable total carbon determinations is attributed to the removal of diesel particulate particles that are greater than 0.9 micrometers in size. The difference between the carbonate measured by NIOSH Analytical Method 5040 and the gravimetric carbonate is attributed to impurities in the material. The expected ratio of evolved carbon from the carbonate to carbonate (C/CaCo3) would be 0.12 (12/(40 + 12 + 48)).

Graphitic Minerals. Commenters reported that several ores, primarily associated with gold mines, contain graphitic carbon, and that this carbon shows up as elemental carbon in an airborne dust sample. MSHA has collected samples of this ore and has found that in fact this is true (PS&HTC-DD–505, PS&HTC-DD–509, PS&HTC-DD–510). MSHA has verified the use of a submicron impactor to remove graphitic carbon interference through field measurements.

In the field measurements, simultaneous respirable and submicron dust samples were collected near crushing operations where there was no diesel equipment operating. For both the field and laboratory measurements, the samples were analyzed for carbon using NIOSH Method 5040. Results of analysis of these samples showed that for respirable dust samples, several µg/m³ of elemental carbon could be present in the sample.

However, MSHA has found this interference is very small, and can be reduced still further through the use of the submicron impactor on the sampler. The highest elemental carbon content of the ores was less than 5 percent. These ores also contain at least 20 percent respirable silica, as determined from samples collected near crushers where diesel particulate was not present. Based on a 20 percent respirable silica content in the dust in the environment, the allowable respirable dust exposure would be limited to 0.45 mg/m³. Based on a 5 percent elemental carbon content in the sample, this sample could contain 23 µg/m³ of elemental carbon. Typically 10 percent of mineral dust is less than one micron. By using the submicron impactor, the interference from graphitic carbon in the ore would be less than 3 µg/m³. Samples collected by MSHA, near crushing operations, using submicron impactors, did not contain elemental carbon.

Accordingly, MSHA plans to sample for diesel particulate matter using submicron impactors to reduce the potential interference from carbonates, carbonaceous minerals and graphitic ores. As noted previously, this requirement is being specifically added to the regulation.

Oil Mist and Organic Vapors. Commenters indicated that diesel particulate sample interference can occur from sampling around drilling operations and from organic solvents.

To verify the existence and extent of any such interference, MSHA collected samples at stoper drilling, jack leg drilling and face drilling operations. The stoper drill and jack leg drill were pneumatic. The face drill was electrohydraulic. Interference from drill oil mist was observed for both the stoper drill and jack leg drill operations (PS&HTC–DD–505, PS&HTC–DD–511). Respirable and submicron samples were collected in the stope, the intake air to the stope and the exhaust air from the stope. Interference from drill oil mist was not found in submicron samples collected on the electrohydraulic face drill (PS&HTC–DD–505). The oil mist interference for the stoper drill was confined to the drill location due to the use of a high viscosity lube grease. The amount of interference in the stope on a submicron sample for the stoper drill was 4.5 µg/m³ per hour of drilling. The interference from the oil mist on the jack leg operation extended throughout the mining stope area, but it did not extent into the main ventilation heading. The amount of interference in the stope on a submicron sample for the jack leg drill was 9 to 11 µg/m³ per hour of drilling. MSHA believes that similar interferences could occur when miners are working near organic solvents.

Accordingly, this is an interference that can be addressed by not sampling too close to the source of the interference. As discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples on drilling operations that produce an oil mist, or where organic solvents are used, personal samples will not be collected. Instead, an area sample will be collected, upwind of the driller or organic solvent source.

A commenter suggested that the lack of organic carbon reduction from outside to inside the cab at Homestake Mine indicated additional sources of organic carbon that have not been identified. MSHA believes that the reduction in elemental but not organic carbon from outside to inside the cab at Homestake Mine was attributed to size distribution. The organic carbon is small enough to pass through a filter. The organic carbon in the cab could not have been generated from a source inside the cab or attributed to residual cigarette smoke as the air exchange rate for the cab was one air change per minute. The cab operator did not smoke.

Cigarette Smoke. Cigarette smoke is a form of organic carbon. Commentors indicated that cigarette smoke can interfere with a diesel particulate measurement when total carbon is used as the indicator of dpm. Industry Commenters collected samples in a surface "smoke room" where the airflow and number of cigarettes were not monitored.

To verify the existence and the extent of any such interference, MSHA took samples in an underground mine where controlled smoking took place. Two series of cigarette tests were conducted. A test site was chosen in the NIOSH, PRL, Experimental Mine. The site consisted of approximately 75 feet of straight entry. The entry was approximately 18.5 feet wide and 6.2 feet high (115 square feet area). In the first test, the airflow rate through the test area was 6,000 cfm and 4 cigarettes were smoked over a 120 minute period. In the second test, the airflow was 3,000 cfm and 28 cigarettes were smoked over a 210 minute period. A control filter was used to adjust for organic carbon present on the filter media. MSHA collected samples on the smokers, twenty-five feet upwind of the smokers,

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twenty-five feet downwind of the smokers and fifty feet downwind of the smokers. Results of the underground test did verify that smoking could be an interference on a dpm measurement.

Analysis of the thermogram from the smoking test showed that cigarette smoke showed up only in the organic portion of the analysis. In this test with the cigarette smoke, a fifth organic peak was observed. This peak contributed approximately 0.5 $\mu g/m^2$ to the analysis. This would be equivalent to an 8 hour full shift concentration of 5 $\mu g/m^3$. The thermogram otherwise is not distinguishable from the organic portion of a thermogram for a diesel particulate sample. Analysis of the thermogram indicated that 30 percent of the organic carbon appeared in the first organic peak, 15 percent appeared in the second organic peak, 10 percent appeared in the third organic peak, 25 percent of the cigarette smoke appeared in the fourth organic peak, and 20 percent of the cigarette smoke appeared in the fifth organic peak. While the amount of carbon identified by the fourth organic peak can be quantified and mathematically subtracted from the amount of total carbon measured, the remaining three peaks, representing 83 percent of the total carbon associated with smoking, would be an interferrant to the diesel particulate matter measurement.

However, the effect of cigarette smoke was even more localized to the smoker than the oil mist was to the stoper or jack leg drill operator. Twenty five feet upwind of the smoker, no carbon attributed to cigarette smoke was detected. For the smoker, each cigarette smoked would add 5 to 10 $\mu g/m^3$ to the exposure, depending on the airflow. Smoking 10 cigarettes would add 50 to 100 $\mu g/m^3$ to a worker's exposure. At both twenty five feet and fifty feet downwind of the smoker, after mixing with the ventilating air, the contribution of carbon attributed to smoking was reduced to 0.3 $\mu g/m^3$ for each cigarette smoked. Sampling twenty-five to fifty feet down wind of a worker smoking 10 cigarettes per day would add no more than 3 $\mu g/m^3$ to the worker's exposure (PS&HTC–DD–518). The air velocities in this test (30 to 60 feet per minute) were relatively low compared to typical mine air velocities. The interference would be even less at the higher air velocities normally found in mines.

Accordingly, as discussed in more detail in Part IV of this preamble, when MSHA collects compliance samples, miners will be requested not to smoke. If a miner does want to smoke while being sampled, and is not prohibited from doing so by the mine operator, the inspector will collect an area sample a minimum of twenty-five feet upwind or downwind of the smoker. Smokers working inside cabs will not be sampled.

Summary of Conclusions from Verification Studies. In summary, MSHA was able to draw the following conclusions from these studies:

- As specified in NIOSH Method 5040, it is essential to use a blank to correct organic carbon measurements.
- Contamination (interference) from carbonate and carbonaceous minerals is evolved in the fourth organic peak of the thermogram.
- Interference from graphitic minerals may appear in the elemental carbon portion of the analysis.
- Interference from cigarette smoke and oil mist from pneumatic drills appears in several peaks of the organic analysis.
- Use of the submicron impactor removes the mineral interference from carbonate, carbonaceous minerals and graphitic minerals.
- Acidification is required to remove the interference from bicarbonate which maybe evolved in several of the organic peaks.
- Subtraction of the fourth organic peak by software integration can be used to correct for interference from carbonaceous minerals.
- Interference from cigarette smoke and oil mist from pneumatic drills is localized. It can be avoided by sampling upwind or downwind of the interfering source.
- Total carbon from cigarettes smoke and oil mist are small compared to emissions from a diesel engine.
- Sampling can be conducted down wind of the interfering source after the contaminated air current has been diluted with another air current.

The magnitude of interferences measured during the verifications were small compared to the levels of total carbon measured in underground mines (as reported in Part III of this preamble). The discussion of section 5061 in Part IV of this preamble provides further information on how MSHA will take this information about interferences into account in compliance sampling; in addition, MSHA will provide specific guidance to inspectors as to how to avoid interferences when taking compliance samples.

(4) Limiting the Public's Exposure to Diesel and Other Fine Particulates—Ambient Air Quality Standards.

Pursuant to the Clean Air Act, the Federal Environmental Protection Agency (EPA) is responsible for setting air pollution standards to protect the public from toxic air contaminants. These include standards to limit exposure to particulate matter. The pressures to comply with these limits have an impact upon the mining industry, which limits various types of particulate matter into the environment during mining operations, and a special impact on the coal mining industry whose product is used extensively in particulate emission generating power facilities. But those standards hold interest for the mining community in other ways as well, for underlying some of them is a large body of evidence on the harmful effects of airborne particulate matter on human health. Increasingly, that evidence has pointed toward the risks of the smallest particulates—including the particles generated by diesel engines.

This section provides an overview of EPA's rulemaking efforts to limit the ambient air concentration of particulate matter, including its recent particular focus on diesel and other fine particulates. Additional and up-to-date information about the most current rulemaking in this regard is available on EPA's Web site, http://www.epa.gov/ttn/oarpg/naaqsfin/.

EPA is also engaged in other work of interest to the mining community. Together with some state environmental agencies, EPA has actually established limits on the amount of particulate matter that can be emitted by diesel engines. This topic is discussed in the next section of this Part.(section 5). Environmental regulations also establish the maximum sulfur content permitted in diesel fuel, and such sulfur content can be an important factor in dpm generation. This topic is discussed in section 6 of this Part. In addition, EPA and some state environmental agencies have also been exploring whether diesel particulate matter is a carcinogen or a toxic material at the concentrations in which it appears in the ambient atmosphere. Discussion of these studies can be found in Part III of this preamble.

Background. Air quality standards involve a two-step process: standard setting by EPA, and implementation by each State.

Under the law, EPA is specifically responsible for reviewing the scientific literature concerning air pollutants, and establishing and revising National Ambient Air Quality Standards (NAAQS) to minimize the risks to health and the environment associated with such pollutants. This review is to be conducted every five years. Feasibility of compliance by pollution sources is not supposed to be a factor in establishing NAAQS. Rather, EPA is required to set the level that provides

"an adequate margin of safety" in protecting the health of the public.

Implementation of each national standard is the responsibility of the states. Each must develop a state implementation plan that ensures air quality in the state consistent with the ambient air quality standard. Thus, each state has a great deal of flexibility in targeting particular modes of emission (*e.g.*, mobile or stationary, specific industry or all, public sources of emissions vs. private-sector sources), and in what requirements to impose on polluters. However, EPA must approve the state plans pursuant to criteria it establishes, and then take pollution measurements to determine whether all counties within the state are meeting each ambient air quality standard. An area not meeting an NAAQS is known as a "nonattainment area".

TSP. Particulate matter originates from all types of stationary, mobile and natural sources, and can also be created from the transformation of a variety of gaseous emissions from such sources. In the context of a global atmosphere, all these particles are mixed together, and both people and the environment are exposed to a "particulate soup" the chemical and physical properties of which vary greatly with time, region, meteorology, and source category.

The first ambient air quality standards dealing with particulate matter did not distinguish among these particles. Rather, the EPA established a single NAAQS for "total suspended particulates", known as "TSP." Under this approach, the states could come into compliance with the ambient air requirement by controlling any type or size of TSP. As long as the total TSP was under the NAAQS—which was established based on the science available in the 1970s—the state met the requirement.

PM_{10}. When the EPA completed a new review of the scientific evidence in the mid-eighties, its conclusions led it to revise the particulate NAAQS to focus more narrowly on those particulates less than 10 microns in diameter, or PM_{10}. The standard issued in 1987 contained two components: an annual average limit of 50 $\mu g/m^3$, and a 24-hour limit of 150 $\mu g/m^3$. This new standard required the states to reevaluate their situations and, if they had areas that exceeded the new PM_{10} limit, to refocus their compliance plans on reducing those particulates smaller than 10 microns in size. Sources of PM_{10} include power plants, iron and steel production, chemical and wood products manufacturing, wind-blown and roadway fugitive dust, secondary aerosols and many natural sources.

Some state implementation plans required surface mines to take actions to help the state meet the PM_{10} standard. In particular, some surface mines in Western states were required to control the coarser particles—*e.g.*, by spraying water on roadways to limit dust. The mining industry has objected to such controls, arguing that the coarser particles do not adversely impact health, and has sought to have them excluded from the EPA ambient air standards.

$PM_{2.5}$. The next scientific review was completed in 1996, following suit by the American Lung Association and others. A proposed rule was published in November of 1996, and, after public hearings and review by the Office Management and Budget, a final rule was promulgated on July 18, 1997. (62 FR 38651).

The new rule further modifies the standard for particulate matter. Under the new rule, the existing national ambient air quality standard for PM_{10} remains basically the same—an annual average limit of 50 $\mu g/m^3$ (with some adjustment as to how this is measured for compliance purposes), and a 24-hour ceiling of 150 $\mu g/m^3$. In addition, however, a new NAAQS has now been established for "fine particulate matter" that is less than 2.5 microns in size. The $PM_{2.5}$ annual limit is set at 15 $\mu g/m^3$, with a 24-hour ceiling of 65 $\mu g/m^3$.

The basis for the $PM_{2.5}$ NAAQS is a large body of scientific data suggesting that particles in this size range are the ones responsible for the most serious health effects associated with particulate matter. The evidence was thoroughly reviewed by a number of scientific panels through an extended process. The proposed rule resulted in considerable press attention, and hearings by Congress, in which this scientific evidence was further discussed. Moreover, challenges to EPA's determination that this size category warranted rulemaking were rejected by a three judge panel of the DC Circuit Court. (American Trucking Association vs. EPA, 275 F.3d 1027).

Second, the majority of the panel agreed with challenges to the EPA's determination to keep the existing requirements on PM10 as a surrogate for the coarser particulates in this category (those particulates between 2.5 and 10 microns in diameter); instead, the panel ordered EPA to develop a new standard for this size category. (Op.Cit., *23.)

Implications for the Mining Community. As noted earlier in this part, diesel particulate matter is mostly less than 1.0 micron in size. It is, therefore, a fine particulate; indeed, in some regions of the country, diesel particulate generated by highway and off-road vehicles constitutes a significant portion of the ambient fine particulate (June 16, 1997, PM–2.5 Composition and Sources, Office of Air Quality Planning and Standards, EPA). Moreover, as noted in Part III of this preamble, some of the scientific studies of health risk from fine particulates used to support the EPA rulemaking were conducted in areas where the major fine particulate was from diesel emissions. Accordingly, MSHA has concluded that it must consider the body of evidence of human health risk from environmental exposure to fine particulates in assessing the risk of harm to miners of occupational exposure to diesel particulate. Comments on the appropriateness of the conclusion by MSHA, and whether MSHA should be working on a fine particulate standard rater than just one focused on diesel particulate are reviewed in Part III.

(5) The Effects of Existing Standards—MSHA Standards on Diesel Exhaust Gases (CO, CO_2, NO, NO_2, and SO_2), and EPA Diesel Engine Emission Standards—on the Concentration of dpm in Underground Metal and Nonmetal Mines

With the exception of diesel engines used in certain classifications of gassy mines, MSHA does not require that the emissions from diesel engines used in underground metal and nonmetal mines, as measured at the tailpipe, meet certain minimum standards of cleanliness. (Some states may require engines used in underground metal and nonmetal mines to be MSHA Approved.) This is in contrast to underground coal mines, where only engines which meet certain standards with respect to gaseous emissions are "approved" for use in underground coal mines. Indeed, as discussed in section 7 of this part, the whole underground coal mine fleet must now consist of approved engines, and the engines must be maintained in approved condition. While such restrictions do not directly control dpm emissions of underground coal equipment, they do have some indirect impact on them.

MSHA does have some requirements for underground metal and nonmetal mines that limit the exposure of miners to certain gases emitted by diesel engines. Accordingly, those requirements are discussed here.

Engine emissions of dpm in underground metal and nonmetal mines are gradually being impacted by Federal environmental regulations, supplemented in some cases by State restrictions. Over time, these regulations have required, and are continuing to

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require, that new diesel engines meet tighter and tighter standards on dpm emissions. As these cleaner engines replace or supplement older engines in underground metal and nonmetal mines, they can significantly reduce the amount of dpm emitted by the underground fleet. Much of this section reviews developments in this area. Although this subject was discussed in the preamble of the proposed dpm rule (63 FR 58130 *et seq.*), the review here updates the relevant information.

MSHA Limitations on Diesel Gases. MSHA limits on the exposure of miners to certain gases in underground mines are listed in Table II–2, for both coal mines and metal/nonmetal mines, together with information about the recommendations in this regard of other organizations. As indicated in the table, MSHA requires mine operators to comply with gas specific threshold limit values (TLV®s) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1972 (for coal mines) and in 1973 (for metal and nonmetal mines).

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TABLE II-2 GASEOUS EXPOSURE LIMITS (PPM)

Pollutant	Range of Limits Recommended		MSHA Limits	
			Coal[A]	M/NM[B]
HCHO (formaldehyde)	0.016[C]	0.3[D]	2	2
CO	25[D]	50	50	50
CO_2	5,000[C]	5,000	5,000	5,000
NO	25[C,D,E]	25	25	25
NO_2	1[F]	3[D]	5	5
SO_2	2[C,D]	5[E]	2	5

Table Notes:
A) ACGIH, 1972
B) ACGIH, 1973
C) NIOSH recommended exposure limit (REL), based on a 10-hour, time-weighted average
D) ACGIH, 1996
E) OSHA permissible exposure limit (PEL)
F) NIOSH recommends only a 1-ppm, 15-minutes, short-term exposure limit (STEL)

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To change an exposure limit at this point in time requires a regulatory action; the rule does not provide for their automatic updating. In 1989, MSHA proposed changing some of these gas limits in the context of a proposed rule on air quality standards. (54 FR 35760). Following opportunity for comment and hearings, a portion of that proposed rule, concerning control of drill dust and abrasive blasting, has been promulgated, but the other components are still under review.

One commenter expressed concern that MSHA would attempt to regulate dpm together with diesel exhaust gases based on their additive or combined effects. As discussed in greater detail in Part IV of this preamble, MSHA does not, at this time, have sufficient information upon which to enforcement limits for dpm and diesel exhaust gases on the basis of their additive or combined effects, if any.

Authority for Environmental Engine Emission Standards. The Clean Air Act authorizes the Federal Environmental Protection Agency (EPA) to establish nationwide standards for mobile vehicles, including those powered by diesel engines (often referred to in environmental regulations as "compression ignition" or "CI" engines). These standards are designed to reduce the amount of certain harmful atmospheric pollutants emanating from mobile sources: the mass of particulate matter, nitrogen oxides (which as previously noted, can result in the generation of particulates in the atmosphere), hydrocarbons and carbon monoxide.

California has its own engine emission standards. New engines destined for use in California must meet standards under the law of that State. The standards are issued and administered by the California Air Resources Board (CARB). In many cases, the California standards are the same as the national standards; as noted herein, the EPA and CARB have worked on certain agreements with the industry toward that end. In other situations, the California standards may be more stringent.

Regulatory responsibility for implementation of the Clean Air Act is vested in the Office of Transportation and Air Quality (formerly the Office of Mobile Sources), part of the Office of Air and Radiation of the EPA. Some of the discussion which follows was derived from materials which can be accessed from the agency's home page on the World Wide Web at (http://www.epa.gov/omswww/omshome.htm). Information about the California standards may be found at the CARB home page at (http://www.arb.ca.gov/homepage.htm).

Diesel engines are generally divided into three broad categories for purposes of engine emissions standards, in accordance with the primary use for which the type of engine is designed: (1) light duty vehicles and light duty trucks (i.e., those engines designed primarily to power passenger transport or transportation of property); (2) heavy duty highway engines (i.e., those designed primarily to power over-the-road truck hauling); and (3) nonroad vehicles (i.e., those engines designed primarily to power small equipment, construction equipment, locomotives and other non-highway uses).

The exact emission standards which a new diesel engine must meet varies with engine category and the date of manufacture. Through a series of regulatory actions, EPA has developed a detailed implementation schedule for each of the three engine categories noted. The schedule generally forces technology while taking into account certain technological realities.

Detailed information about each of the three engine categories is provided below; a summary table of particulate matter emission limits is included at the end of the discussion.

EPA Emission Standards for Light-Duty Vehicles and Light Duty Trucks.[2]

Current light-duty vehicles generally comply with the Tier 1 and National LEV emission standards. Particulate matter emission limits are found in 40 CFR Part 86. In 1999, EPA issued new Tier 2 standards that will be applicable to light-duty cars and trucks beginning in 2004. With respect to pm, the new rules phase in tighter emissions limits to parts of production runs for various subcategories of these engines over several years; by 2008, all light duty trucks must limit pm emissions to a maximum of 0.02 g/mi. (40 CFR 86.1811–04(c)). Engine manufacturers may, of course, produce complying engines before the various dates required.

EPA Emissions Standards for Heavy-Duty Highway Engines. In 1988, a standard limiting particulate matter emitted from the heavy duty highway diesel engines went into effect, limiting dpm emissions to 0.6 g/bhp-hr. The Clean Air Act Amendments of 1990 and associated regulations provided for phasing in even tighter controls on NO_X and particulate matter through 1998. Thus, engines had to meet ever tighter standards for NO^X in model years 1990, 1991 and 1998; and tighter standards for PM in 1991 (0.25 g/bhp-hr) and 1994 (0.10 g/bhp-hr). The latter remains the standard for PM from these engines for current production runs (40 CFR 86.094–11(a)(1)(iv)(B)). Since any heavy duty highway engine manufactured since 1994 must meet this standard, there is a supply of engines available today which meet this standard. These engines are used in mining in the commercial type pickup trucks.

New standards for this category of engines are gradually being put into place. On October 21, 1997, EPA issued a new rule for certain gaseous emissions from heavy duty highway engines that will take effect for engine model years starting in 2004 (62 FR 54693). The rule establishes a combined requirement for NO_X and Non-methane Hydrocarbon (NMHC). The combined standard is set at 2.5 g/bhp-hr, which includes a cap of 0.5 g/bhp-hr for NMHC. EPA promulgated a rulemaking on December 22, 2000 (65 FR 80776) to adopt the next phase of new standards for these engines. EPA is taking an integrated approach to: (a) Reduce the content of sulfur in diesel fuel; and thereafter, (b) require heavy-duty highway engines to meet tighter emission standards, including standards for PM. The purpose of the diesel fuel component of the rulemaking is to make it technologically feasible for engine manufacturers and emissions control device makers to produce engines in which dpm emissions are limited to desired levels in this and other engine categories. The EPA's rule will reduce pm emissions from new heavy-duty engines to 0.01 g/bhp-hr, a reduction from the current 0.1 g/bhp-hr. MSHA assumes it will be some time before there is a significant supply of engines that can meet this standard, and the fuel supply to make that possible.

EPA Emissions Standards for Nonroad Engines. Nonroad engines are those designed primarily to power small portable equipment such as compressors and generators, large construction equipment such as haul trucks, loaders and graders, locomotives and other miscellaneous equipment with non-highway uses. Engines of this type are the ones used most frequently in the underground coal mines to power equipment.

Nonroad diesel engines were not subjected to emission controls as early as other diesel engines. The 1990 Clean Air Act Amendments specifically directed EPA to study the contribution of nonroad engines to air pollution, and regulate them if warranted (Section 213 of the Clean Air Act). In 1991, EPA released a study that documented higher than expected emission levels across a broad spectrum of nonroad engines and equipment (EPA Fact Sheet, EPA420–F–96–009, 1996). In response, EPA initiated several regulatory programs. One of these set Tier 1 emission standards for larger land-based nonroad engines (other than for rail use). Limits were established for engine emissions of hydrocarbons, carbon monoxide, NO_X, and dpm. The limits were phased in with model years from 1996 to 2000. With respect to particulate matter, the rules required that starting in model year 1996, nonroad engines from 175 to 750 hp meet a limit on pm emissions of 0.4 g/bhp-hr, and that starting in model year 2000, nonroad engines over 750 hp meet the same limit.

Particulate matter standards for locomotive engines were set subsequently (63 FR 18978, April, 1998). The standards are different for line-haul duty-cycle engine and switch duty-cycle engines. For model years from 2000–2004, the standards limit pm emissions to 0.45 g/bhp-hr and 0.54 g/bhp-hr respectively for those engines; after model year 2005, the limits drop to 0.20 g/bhp-hr and 0.24 g/bhp-hr respectively.

In October 1998, EPA established additional standards for nonroad engines (63 FR 56968). Among these are gaseous and particulate matter limits for the first time (Tier 1 limits) for nonroad engines under 50 hp. Tier 2 emissions standards for engines between 50 and 175 hp include pm standards for the first time. Moreover, they establish Tier 2 particulate matter limits for all other land-based nonroad engines (other than locomotives which already had Tier 2 standards). Some of the non-particulate emissions limits set by the 1998 rule are subject to a technology review in 2001 to ensure that the levels required to be met are feasible; EPA has indicated that in the context of that review, it intends to consider further limits for particulate matter, including transient emission measurement procedures. Because of the phase-in of these Tier 2 pm standards, and the fact that some manufacturers will produce engines meeting the standard before the requirements go into effect, there are or soon will be some Tier 2 pm engines in some sizes available, but it is likely to be a few years before a full size range of Tier 2 pm nonroad engines is available.

Table II–3, EPA NonRoad Engine PM Requirements, provides a full list of the EPA required particulate matter limitations on nonroad diesel engines. For example, a nonroad engine of 175 hp produced in 2001 must meet a standard of 0.4 g/hp-hr; a similar engine produced in 2003 or thereafter must meet a standard of 0.15 g/hp-hr.

TABLE II–3.—EPA NONROAD ENGINE PM REQUIREMENTS

kW range	Tier	Year first applicable	PM limit (g/kW-hr)
kW<8	1	2000	1.00
	2	2005	0.80
8≤kW<19	1	2000	0.80
19≤kW<37	1	1999	0.80
	2	2004	0.60
37≤kW<75	1	1998	
	2	2004	0.40
75≤kW<130	1	1997	
	2	2003	0.30
130≤kW<225	1	1996	0.54
	2	2003	0.20
225≤kW<450	1	1996	0.54
	2	2001	0.20
450≤kW<560	1	1996	0.54
	2	2002	0.20
kW>560	1	2000	0.54
	2	2006	0.20

The Impact of EPA Engine Emission Standards on the Underground Metal and Nonmetal Mining Fleet. In the mining industry, engines and equipment are often purchased in used condition. Thus, many of the diesel engines in an underground mine's fleet may only meet older environmental emission standards, or no environmental standards at all.

By requiring that underground coal mine engines be approved, MSHA regulations have led to a less polluting fleet in that sector than would otherwise be the case. Many highly polluting engines have been barred or phased out as a result. As noted in Part IV of this preamble, such a requirement for the underground metal and nonmetal sector is being added by this rulemaking; however, it will be some time before its effects are felt. Moreover, although the environmental tailpipe requirements will bring about gradual reduction in the overall contribution of diesel pollution to the atmosphere, the beneficial effects on mining atmospheres may require a long timeframe absent actions that accelerate the turnover of mining fleets to engines that emit less dpm.

The Question of Nanoparticles. Comments received from several commenters on the proposed rule for diesel particulate matter exposure of underground coal miners raised questions relative to "nanoparticles"; i.e., particles found in the exhaust of diesel engines that are characterized by diameters less than 50 nanometers (nm). As the topic may be of interest to this sector as well, MSHA's discussion on the topic is being repeated in this preamble for informational purposes.

One commenter was concerned about recent indications that nanoparticles may pose more of a health risk than the larger particles that are emitted from a diesel engine. This commenter submitted information demonstrating that nanoparticles emitted from the engine could be effectively removed from the exhaust using aftertreatment devices such as ceramic traps. Another commenter was concerned that MSHA's proposed rule for underground coal mines is based on removing 95% of the particulate by mass. His concern was focused on the fact that this reduction in mass was attributed to those particles

[2] The discussion focuses on the particulate matter requirements for light duty trucks, although the current pm requirement for light duty vehicles is the same. The EPA regulations for these categories apply to the unit, rather than just to the engine itself; for heavy-duty highway engines and nonroad engines, the regulations attach to the engines.

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greater than 0.1μm but less than 1μm and did not address the recent scientific hypothesis that it may be the very small nanoparticles that are responsible for adverse health effects. Based on the recent specific information on the potential health effects resulting from exposure to nanoparticles, this commenter did not believe that the risk to cancer would be reduced if exposure levels to nanoparticles increased. He indicated that studies suggest that the increase in nanoparticles will exceed 6 times their current levels.

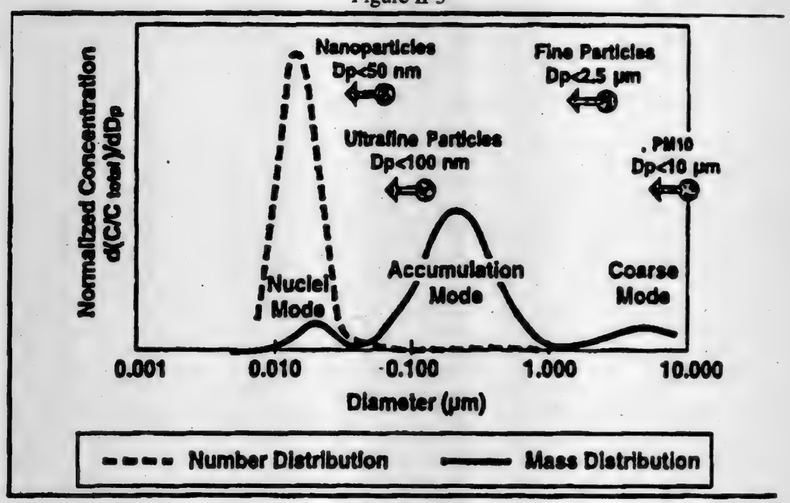
Current environmental emission standards established by EPA and CARB, and the particulate index calculated by MSHA, focus on the total mass of diesel particulate matter emitted by an engine—for example, the number of grams per some unit of measure (i.e., grams/brake-horsepower). Thus, the technology being developed by the engine industry to meet the standards accordingly focuses on reducing the mass of dpm being emitted from the engine.

There is some evidence, however, that some aspects of this new technology, particularly fuel injection, is resulting in an increase in the number of nanoparticles being emitted from the engine.

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Figure II-3, repeated here from section 2 of this Part, illustrates this situation (Majewski, W. Addy, Diesel Progress, June, 1998).

Figure II-3



Diesel particulate size distribution.

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The formation of particulates starts with particle nucleation followed by subsequent agglomeration of the nuclei particles into an accumulation mode. Thus, as illustrated in Figure II–3, the majority of the mass of dpm is found in the accumulation mode, where the particles are generally between 0.1 and 1 micron in diameter. However, when considering the number of particles emitted from the engine, more than half and sometimes almost all of the particles (by number) are in the nuclei mode.

Various studies have demonstrated that the size of the particles emitted from the new low emission diesel engines, has shifted toward the generation of nuclei mode particles. One study compared a comparable 1991 engine to its 1988 counterpart. The total PM mass in the newer engine was reduced by about 80%; but the new engine generated thousands of times more particles than the older engine (3000 times as much at 75 percent load and about 14,000 times as much at 25 percent load). One hypothesis offered for this phenomenon is that the cleaner engines produce less soot particles on which particulates can condense and accumulate, and hence they remain in nuclei mode. The accumulation particles act as a "sponge" for the condensation and/or adsorption of volatile materials. In the absence of that sponge, gas species which are to become liquid or solid will nucleate to form large numbers of small particles (diesel.net technology guide). Mayer, while pointing out that nanoparticle production was a problem with older engines as well, concurs that the technology being used to clean up pollution in newer engines is not having any positive impact on nanoparticle production. While there is scientific evidence that the newer engines, designed to reduce the mass of pollutants emitted from the diesel engine, emit more particles in the nuclei mode, quantifying the magnitude of these particles has been difficult because as dpm is released into the atmosphere the diesel particulate undergoes very complex changes. In addition, current testing procedures can produce spurious increases in the number of nanoparticles that would not necessarily occur under more realistic atmospheric conditions.

Experimental work conducted at WVU (Bukarski) indicate that nanoparticles are not generated during the combustion process, but rather during various physical and chemical processes which the exhaust undergoes in after treatment systems.

While current medical research findings indicate that small particulates, particularly those below 2μm in size, may be more harmful to humans than the larger ones, much more medical research and diesel emission studies are needed to fully characterize diesel nanoparticles emissions and their impact on human health. If nanoparticles are found to have an adverse health impact by virtue of size and number, it could require significant adjustments in environmental engine emission regulation and technology. It could also have implications for the type of controls utilized, with some asserting that aftertreatment filters are the only effective way to limit the emission of nanoparticles and others asserting that aftertreatment filters may under certain circumstances limit the number of nanoparticles.

Research on nanoparticles and their health effects is currently a topic of investigation. (Bagley et al., 1996, EPA Grant). Based on the comments received and a review of the literature currently available on the nanoparticle issue, MSHA believes that, at this time, promulgation of the final rules for underground coal and metal and nonmetal mines is necessary to protect miners. The nanoparticle issues discussed above will not be resolved for some time because of the extensive research required to address the questions raised.

(6) Methods for controlling dpm concentrations in underground metal and nonmetal mines

As discussed in the last section, the introduction of new engines underground will certainly play a significant role in reducing the concentration of dpm in underground metal/nonmetal mines. There are, however, many other approaches to reducing dpm concentrations and occupational exposures to dpm in underground metal/nonmetal mines. Among these are: aftertreatment devices to eliminate particulates emitted by an engine; altering fuel composition to minimize engine particulate emission; maintenance practices and diagnostic systems to ensure that fuel, engine and aftertreatment technologies work as intended to minimize emissions; enhancing ventilation to reduce particulate concentrations in a work area; enclosing workers in cabs or other filtered areas to protect them from exposure; and work and fleet practices that reduce miner exposures to emissions.

As noted in section 9 of this Part, information about these approaches was solicited from the mining community in a series of workshops in 1995, and highlights were published by MSHA as an appendix to the proposed rule on dpm "Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox." During the hearings and in written comments on this rulemaking, mention was made of all these control methods.

This section provides updated information on two methods for controlling dpm emissions: aftertreatment devices and diesel fuel content. There was considerable comment on aftertreatment devices because MSHA's proposed rule would require high-efficiency particulate filters be installed on a certain percentage of the fleet in order to meet both the interim and final dpm concentration; and the current and potential efficiency of such devices remains an important issue in determining the technological and economic feasibility of the final rule. Moreover, some commenters strongly favored the use of oxidation catalytic converters, a type of aftertreatment device used to reduce gaseous emission but which can also impact dpm levels. Accordingly, information about such devices is reviewed here. With respect to diesel fuel composition, a recent rulemaking initiative by EPA, and actions taken by other countries in this regard, are discussed here because of the implications of such developments for the mining community.

Emissions aftertreatment devices. One of the most discussed approaches to controlling dpm emissions involves the use of devices placed on the end of the tailpipe to physically trap diesel particulate emissions and thus limit their discharge into the mine atmosphere. These aftertreatment devices are often referred to as "particle traps" or "soot traps", but the term filter is often used. The two primary categories of particulate traps are those composed of ceramic materials (and thus capable of handling uncooled exhaust), and those composed of paper materials (which require the exhaust to first be cooled). Typically, the latter are designed for conventional permissible equipment mainly used in coal mining which have water scrubbers installed which cool the exhaust. However, another alternative that is now utilized in coal is the "dry system technology" which cools the diesel exhaust with a heat exchanger and then uses a paper filter. The dry system was first developed for oil shale mining applications where permissibility was required. However, when development of the oil shale industry faltered, manufacturers looked to coal mining for

application of the dry system technology. However, dry systems could be used as an alternative to the wet scrubbers for the relatively small number of permissible machines used in the metal/nonmetal industry. In addition, "oxidation catalytic converters," devices used to limit the emission of diesel gases, and "water scrubbers", devices used to cool the exhaust gases, are discussed here as well, because they also can have a significant effect on limiting particle emission.

Water Scrubbers. Water scrubbers are devices added to the exhaust system of certain diesel equipment. Water scrubbers are essentially metal boxes containing water through which the diesel exhaust gas is passed. The exhaust gas is cooled, generally to below 170 degrees F. A small fraction of the unburned hydrocarbons are condensed and remain in the water along with a portion of the dpm. Tests conducted by the former Bureau of Mines and others indicate that no more than 20 to 30 percent of the dpm is removed. This information was presented in the Toolbox publication. The water scrubber does not remove any of the carbon monoxide, the oxides of nitrogen, or any other gaseous emission that remains a gas at room temperature so their effectiveness as aftertreatment devices is questionable.

The water scrubber does serve as an effective spark and flame arrester and as a means to cool the exhaust gas when permissibility is required. Consequently, it is used in the majority of the permissible diesel equipment in mining as part of the safety components needed to gain MSHA approval.

The water scrubber has several operating characteristics which keep it from being a candidate for use as an aftertreatment device on nonpermissible equipment. The space required on the vehicle to store sufficient water for an 8 hour shift is not available on some equipment. Furthermore, the exhaust contains a great deal of water vapor which condenses under some mining conditions creating a fog which can adversely effect visibility. Also, operation of the equipment on slopes can cause the water level in the scrubber to change resulting in water being blown out the exhaust pipe. Control devices are sometimes placed within the scrubber to maintain the appropriate water level. Because these devices are in contact with the water through which the exhaust gas has passed, they need frequent maintenance to insure that they are operating properly and have not been corroded by the acidic water created by the exhaust gas. The water scrubber must be flushed frequently to remove the acidic water and the dpm and other exhaust residue which forms a sludge that adversely effects the operation of the unit. These problems, coupled with the relatively low dpm removal efficiency, have prevented widespread use of water scrubbers as a dpm control device on nonpermissible equipment.

Oxidation Catalytic Converters. Oxidation catalytic converters (OCCs) were among the first devices added to diesel engines in mines to reduce the concentration of harmful gaseous emissions discharged into the mine environment. OCCs began to be used in underground mines in the 1960's to control carbon monoxide, hydrocarbons and odor. That use has been widespread. It has been estimated that more than 10,000 OCCs have been put into the mining industry over the years.

Several of the harmful emissions in diesel exhaust are produced as a result of incomplete combustion of the diesel fuel in the combustion chamber of the engine. These include carbon monoxide and unburned hydrocarbons including harmful aldehydes. Catalytic converters, when operating properly, remove significant percentages of the carbon monoxide and unburned hydrocarbons. Higher operating temperatures, achieved by hotter exhaust gas, improve the conversion efficiency.

Oxidation catalytic converters operate by, in effect, continuing the combustion process outside the combustion chamber. This is accomplished by utilizing the oxygen in the exhaust gas to oxidize the contaminants. A very small amount of material with catalytic properties, usually platinum or some combination of the noble metals, is deposited on the surfaces of the catalytic converter over which the exhaust gas passes. This catalyst allows the chemical oxidation reaction to occur at a lower temperature than would normally be required.

For the catalytic converter to work effectively, the exhaust gas temperature must be above 370 degrees Fahrenheit for carbon monoxide and 500 degrees Fahrenheit for hydrocarbons. Most converters are installed as close to the exhaust manifold as possible to minimize the heat loss from the exhaust gas through the walls of the exhaust pipe. Insulating the segment of the exhaust pipe between the exhaust manifold and the catalytic converter extends the portion of the vehicle duty cycle in which the converter works effectively.

The earliest catalytic converters for mining use consisted of alumina pellets coated with the catalytic material and enclosed in a container. The exhaust gas flowed through the pellet bed and the exhaust gas came into contact with the catalyst. Designs have evolved, and the most common design is a metallic substrate, formed to resemble a honeycomb, housed in a metal shell. The catalyst is deposited on the surfaces of the honeycomb. The exhaust gas flows through the honeycomb and comes into contact with the catalyst.

Soon after catalytic converters were introduced, it became apparent that there was a problem brought about by the sulfur found in diesel fuels in use at that time. Most diesel fuels in the United States contained anywhere from 0.25 to 0.50 percent sulfur or more on a mass basis. In the combustion chamber, this sulfur was converted to SO_2, SO_3, or SO_4 in various concentrations, depending on the engine operating conditions. In general, most of the sulfur was converted to gaseous SO_2. When exhaust containing the gaseous sulfur dioxide passed through the catalytic converter, a large proportion of the SO_2 was converted to solid sulphates which are in fact, diesel particulate. Sulfates can "poison" the catalyst, severely reducing its life.

Recently, as described elsewhere in this preamble, the EPA required that diesel fuel used for over the road trucks contain no more than 500 ppm sulfur. This action made low sulfur fuel available throughout the United States. MSHA, in its recently promulgated regulations for the use of diesel powered equipment in underground coal mines requires that this low sulfur fuel be used. MSHA is now extending this requirement for low sulfur fuel (<500ppm) to underground metal/nonmetal mines in this final rule. When the low sulfur fuel is burned in an engine and passed through a converter with a moderately active catalyst, only small amounts of SO_2 and additional sulfate based particulate are created. However, when a very active catalyst is used, to lower the operating temperature of the converter or to enhance the CO removal efficiency, even the low sulfur fuel has sufficient sulfur present to create an SO_2 and sulfate based particulate problem. Consequently, as discussed later in this section, the EPA has notified the public of its intentions to promulgate regulations that would limit the sulfur content of future diesel fuel to 15 ppm for on-highway use in 2006.

The particulate reduction capabilities of some OCCs are significant in gravimetric terms. In 1995, the EPA implemented standards requiring older buses in urban areas to reduce the dpm emissions from rebuilt bus engines. (40

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CFR 85.1403). Aftertreatment manufacturers developed catalytic converter systems capable of reducing dpm by 25%. Such systems are available for larger diesel engines common in the underground metal and nonmetal sector. However, as has been pointed out by Mayer, the portion of particulate mass that seems to be impacted by OCCs is the soluble component, and this is a smaller percentage of particulate mass in utility vehicle engines than in automotive engines. Moreover, some measurements indicate that more than 40% of NO is converted to more toxic NO_2, and that particulate mass actually increases using an OCC at full load due to the formation of sulfates. In summation, Mayer concluded that the OCCs do not reduce the combustion particulates, produce sulfate particulates, have unfavorable gaseous phase reactions increasing toxicity, and that the positive effects are irrelevant for construction site diesel engines. Indeed, he indicates the negative effects outweigh the benefits. (Mayer, 1998. The Phase 1 interim data report of the Diesel Emission Control-Sulfur Effects (DECSE) Program (a joint government-industry program to explore lower sulfur content that is discussed in more detail later in this section) similarly indicates that using OCCs under certain operating conditions can increase dpm emissions due to an increase in the sulfate fraction (DECSE Program Summary, Dec. 1999). Another commenter also notes that oxidation catalytic activity can increase sulfates and submicron particles under certain operating conditions.

Other commenters during the rulemaking strongly supported the use of OCCs as an interim measure to reduce particulate and other diesel emission to address transitory employee effects that were mentioned in the proposed preamble. MSHA views the use of OCCs as one tool that mine operators can use to reduce the dpm emissions from certain vehicles alone or in combination of other aftertreatment controls to meet the interim and final dpm standards. The overall reduction in dpm emissions achieved with the exclusive use of an OCC is low compared to the reductions required to meet the standards. MSHA is aware of the negative effects produced by OCCs. However, with the use of low sulfur fuel and a catalyst that is formulated for low sulfate production, this problem can be resolved. Mine operators must work with aftertreatment manufacturers to come up with the best plan for their fleet for dpm control.

Hot gas filters. Throughout this preamble, MSHA is referring to the particulate traps (filters) that can be used in the undiluted hot exhaust stream from the diesel engine as hot gas filters. Hot gas filters refer to the current commercially available particulate filters, such as ceramic cell, woven fiber filters, sintered metal filters, etc.

Following publication of EPA rules in 1985 limiting diesel particulate emissions from heavy duty diesel engines, aftertreatment devices capable of significant reductions in particulate levels began to be developed for commercial applications.

The wall flow type ceramic honeycomb diesel particulate filter system was initially the most promising approach. These consisted of a ceramic substrate encased in a shock and vibration absorbing material and covered with a protective metal shell. The ceramic substrate is arranged in the shape of a honeycomb with the openings parallel to the centerline. The ends of the openings of the honeycomb cells are plugged alternately. When the exhaust gas flows through the particulate trap, it is forced by the plugged end to flow through the ceramic wall to the adjacent passage and then out into the mine atmosphere. The ceramic material is engineered with pores in the ceramic material sufficiently large to allow the gas to pass through without adding excessive back pressure on the engine, but small enough to trap the particulate on the wall of the ceramic material. Consequently, these units are called wall flow traps.

Work with ceramic filters in the last few years has led to the development of the ceramic fiber wound filter cartridge (SAE, SP–1073, 1995). The ceramic fiber has been reported by the manufacturer to have dpm reduction efficiencies up to 80 percent. This system has been used on vehicles to comply with German requirements that all diesel engines used in confined areas be filtered. Other manufacturers have made the wall flow type ceramic honeycomb dpm filter system commercially available to meet the German standard.

The development of these devices has proceeded in response to international and national efforts to regulate dpm emissions. However, due to the extensive work performed by the engine manufacturers on new technological designs of the diesel engine's combustion system, and the use of low sulfur fuel, particulate traps turned out to be unnecessary to comply with the EPA standards of the time for vehicle engines.

These devices proved to be very effective at removing particulate achieving particulate removal efficiencies of greater than 90 percent.

It was quickly recognized that this technology, while not immediately required for most vehicles, might be particularly useful in mining applications. The former Bureau of Mines investigated the use of catalyzed diesel particulate filters in underground mines in the United States (BOM, RI–9478, 1993). The investigation demonstrated that filters could work, but that there were problems associated with their use on individual unit installations, and the Bureau made recommendations for installation of ceramic filters on mining vehicles.

Canadian mines also began to experiment with ceramic traps in the 1980's with similar results (BOM, IC 9324, 1992). Work in Canada today continues under the auspices of the Diesel Emission Evaluation Program (DEEP), established by the Canadian Centre for Mineral and Energy Technology in 1996 (DEEP Plenary Proceedings, November 1996). The goals of DEEP are to: (1) Evaluate aerosol sampling and analytical methods for dpm; and (2) evaluate the in-mine performance and costs of various diesel exhaust control strategies.

Perhaps because experience is still limited, the general perception within the mining industry of the state of this technology in recent years is that it remains limited in certain respects; as expressed by one commenter at one of the MSHA workshops in 1995, "while ceramic filters give good results early in their life cycle, they have a relatively short life, are very expensive and unreliable."

One commenter reported unsuccessful experiments with ceramic filters in 1991 due to their inability to regenerate at low temperatures, lack of reliability, high cost of purchase and installation, and short life.

In response to the proposed rule, MSHA received a variety of information and claims about the current efficiency of such technologies. Commenters stated that in terms of technical feasibility to meet the standards, the appropriate aftertreament controls are not readily available on the market for the types and sizes of equipment used in underground mines. Another commenter stated that MSHA has not identified a technology capable of meeting the proposed standards at their mine and they were not aware of any technology currently available or on the horizon that would be capable of attaining the standards. Yet another commenter stated that both ceramic and paper filters are not technically feasible at their mine because of the high operating temperatures needed to regenerate filters or the difficulties presented by periodic removal of the filters for regeneration. Periodic removal of fragile ceramic filters subjects them to chipping and cracking and requires a large inventory of surplus filters. Commenter also stated that paper filters require exhaust gas cooling so that the paper filter does not burn. Commenter stated that they have been working with a manufacturer on installing one of these on a piece of equipment, but it is experimental and this installation was the first time a paper filter would be used on equipment of this size and type.

In response to the paper filter comment, dry system technology as described above was first tested on a large haul truck used in oil shale mining and then later applied to coal mining equipment. Paper filter systems have also been successfully installed on coal mining equipment that is identical to LHD machines used in metal/nonmetal mines. Therefore this technology has been applied to engine of the type and size used in metal/nonmetal mines. Commenters have stated that filters are not feasible at this time from the above comments. However, MSHA believes that the technology needed to reduce dpm emissions to both the interim and final standards is feasible. Much work has occurred in the development of aftertreatment controls, especially OCCs and hot gas filters. Aftertreatment control manufacturers have been improving both OCCs and ceramic type filters to provide better performance and reliability. New materials are currently available commercially and new filter systems are being developed especially in light of the recent requirements in Europe and the new proposals from the EPA. Consequently, MSHA does not agree with the commenter concerning chipping of the traps when removed. As stated, manufacturers have designed systems to either be removed easily or even regenerated on the vehicle by simply plugging the unit in without removing the filter.

Two groups in particular have been doing some research comparing the efficiency of recent ceramic models: West Virginia University, as part of that State's efforts to develop rules on the use of diesel-powered equipment underground; and VERT (Verminderung der Emissionen von Realmaschinen in Tunnelbau), a consortium of several European agencies conducting such research in connection with major planned tunneling projects in Austria, Switzerland and Germany to protect occupational health and subsequent legislation in each of the three countries restricting diesel emissions in tunneling.

The State of West Virginia legislature enacted the West Virginia Diesel Act, thereby creating the West Virginia Diesel Commission and setting forth an administrative vehicle to allow and regulate the use of diesel equipment in underground coal mines in West Virginia. West Virginia University was appropriated funds to test diesel exhaust controls, as well as an array of diesel particulate filters. The University was asked to provide technical support and data necessary for the Commission to make decisions on standards for emission controls. Even though the studies were intended for the Commission's work for underground coal, the control technologies tested are relevant to metal/nonmetal mines.

The University reported data on four different engines and an assortment of configurations of available control devices, both hot gas filters and the DST® system, a system which first cools the exhaust and then runs it through a paper filter. The range of collection efficiencies reported for the ceramic filters and oxidation catalysts combined fell between 65% and 78%. The highest collection efficiency obtained using the ISO 8 mode test cycle (test cycle described in rule) was 81% on the DST® system (intended for coal use). The University did report problems with this system that would account for the lower than expected efficiency for a paper filter type system.

VERT's studies of particulate traps are detailed in two articles published in 1999 which have been widely disseminated to the diesel community here through www.DieselNet.com. The March article focuses on the efficiency of the traps; the April article compares the efficiency of other approaches (OCCs, fuel reformulation, engine modifications to reduce ultra-fine particulates) with that of the traps. Here we focus only on the information about particulate traps.

The authors of the March article report that 29 particulate trap systems were tested using various ceramic, metal and fiber filter media and several regeneration systems. The authors of the March article summarize their conclusions as follows:

> The results of the 4-year investigations of construction site engines on test rigs and in the field are clear: particulate trap technology is the only acceptable choice among all available measures. Traps proved to be an extremely efficient method to curtail the finest particles. Several systems demonstrated a filtration rate of more than 99% for ultra-fine particulates. Specific development may further improve the filtration rate.
>
> A two-year field test, with subsequent trap inspection, confirmed the results pertaining to filtration characteristics of ultra-fine particles. No curtailment of the ultra-fine particles is obtained with any of the following: reformulated fuel, new lubricants, oxidation catalytic converters, and optimization of the engine combustion.
>
> Particulate traps represent the best available technology (BAT). Traps must therefore be employed to curtail the particulate emissions that the law demands are minimized. This technology was implemented in occupational health programs in Germany, Switzerland and Austria.

On the bench tests, it appears that the traps reduce the overall particulate matter by between 70 and 80%, with better results for solid ultrafine particulates; under hot gas conditions, it appears the non-solid components of particulate matter cannot be dependably retained by these traps. Consistent with this finding, it was found that polycyclic aromatic hydrocarbons (PAHs) decreased proportionately to the gravimetric decrease of carbon mass. The tests also explored the impact of additives on trap efficiency, and the impact of back pressure.

The field tests confirmed that the traps were easy to mount and retained their reliability over time, although regeneration was required when low exhaust temperatures failed to do this automatically. Electronic monitoring of back pressure was recommended. In general, the tests confirmed that a whole series of trap systems have a high filtration rate and stable long time properties and are capable of performing under difficult construction site conditions. Again, the field tests indicated a very high reduction (97–99%) of particulates by count, but a lower rate of reduction in terms of mass.

Subsequently, VERT has evaluated additional commercially available filter systems. The filtration efficiency, expressed on a gravimetric basis is shown in the column headed "PMAG—without additive". The filtration efficiencies determined by VERT for these 6 filter systems range from 80.7% to 94.5%. The average efficiency of these filters is 87%. MSHA will be updating the list of VERT's evaluated systems as they become available.

VERT has also published information on the extent of dpm filter usage in Europe as evidence that the filter technology has attained wide spread acceptance. This information is included in the record of the coal dpm rulemaking where it has particular significance; it is noted here for informational purposes. The information isn't critical in this case because operators have a choice of controls. MSHA didn't explicitly add the latest VERT data to the Metal/

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Nonmetal record during the latest reopening of the record. MSHA believes this information is relevant to metal/nonmetal mining because the tunneling equipment on which these filters are installed is similar to metal/nonmetal equipment. VERT stated that over 4,500 filter systems have been deployed in England, Scandinavia, and Germany.

Deutz Corporation has deployed 400 systems (Deutz's design) with full flow burners for regeneration of filters installed on engines between 50–600kw. The company Oberland-Mangold has approximately 1,000 systems in the field which have accumulated an average of 8,400 operating hours in forklift trucks, 10,600 operating hours in construction site engines, and 19,200 operating hours in stationary equipment. The company Unikat has introduced in Switzerland over 250 traps since 1989 and 3,000 worldwide with some operating more than 20,000 hours. German industry annually installs approximately 1,500 traps in forklifts.

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Table II-4

Efficiency of Diesel Particulate Traps VERT-Certification Test

Average 4 operation points, ISO 8187

Trap	Date	PMAG		PZAG		ECAG	
		without Additive	with Additive	without Additive	with Additive	without Additive	with Additive
3M	VERT-Certification Test Part 1 (new)	80.7	-	98.6	99.6	-	-
Oberland		90.5	-	98.4	99.4	-	-
JMC		94.5	-	99.3	-	-	-
IBIDEN		87.2	-	99.9	-	-	-
Corning		84.9	-	99.5	99.8	-	-
HJS/CRT		83.8	-	99.4	-	98.2	-
SHW(LIB1)	After VERT Field Test Part 3 (after 2000 hrs)	3.2	22.2	96.3	97.1	-	93.1
SHW(CAT1)		77.5	87.6	97.8	98.8	97.2	96.5
BUCK(LIB2)		76.5	81.0	95.4	97.8	94.0	95.5
BUCK(CAT3)		64.2	76.2	91.0	96.8	(87.0) [2]	95.3
ECS(LIB3)		12.4	43.0	99.9	99.9	99.3	99.0
DEUTZ(LIB4) [1]		(70.5)	(76.1)	(86.6)	(91.6)	(84.2)	
UNIKAT(CAT4)		54.7	76.2	99.0	99.6	98.1	98.4
AVERAGE		66.4		98.3		97.2	

[1] Small melting damage
[2] Uncertain data
[3] Coulometry is optional for VERT certification test

PMAG: Efficiency according to Total Particulate Mass PM
PZAG: Efficiency according to Integrated Particulate Count (20 - 300 nm) PZ
ECAG: Efficiency according to Elementary Carbon EC (2 state Coulometry)

$$PMAG = \frac{PM_{before\ trap} - PM_{after\ trapF}}{PM_{before\ trapF}} = \frac{PM_{Ref} - PM_{after\ trap}}{PM_{Ref}} \quad (X\ 100\%)$$

$$PZAG = \frac{PZ_{before\ trap} - PZ_{after\ trap}}{PZ_{before\ trap}} = \frac{PZ_{Ref} - PZ_{after\ trap}}{PZ_{Ref}} \quad (X\ 100\%)$$

$$Penetration = 1 - Efficiency = = \frac{PZ_{after\ PF}}{PZ_{Ref}} \quad (X\ 100\%)$$

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Some commenters asserted that the VERT work was for relatively small engines and not for large engines, *i.e.*, 600–700 hp, and hence could not be relied upon to demonstrate the availability of filters of such high efficiencies for the larger equipment used in some underground mines. MSHA believes this comment is misplaced. The efficiency of a filter is attributable to the design of the filter and not the size of the engine. VERT is documenting filter efficiencies of commercially available filters. It is customary in the industry, however, for the filter manufacturer to size the filter to fit the size of the engine. The mine operator must work with the filter manufacturer to verify that the filter needed will work for the intended machine. MSHA believes that this is no different for other types of options installed on machines for underground mining use.

More information about the results of the VERT tests on specific filters, and how MSHA intends to use this information to aid the mining industry to comply with the requirements of the standards are discussed in Part IV of this preamble.

The accumulated dpm must be removed from all particulate traps periodically. This is usually done by burning off the accumulated particulate in a controlled manner, called regeneration. If the diesel equipment on which the trap is installed has a duty cycle which creates an exhaust gas temperature greater than about 650 degrees Fahrenheit for more than 25 percent of the operating time, the unit will be self cleaning. That is, the hot exhaust gas will burn off the particulate as it accumulates. Unfortunately, only hard working equipment, such as load-haul-dump and haulage equipment usually satisfies the exhaust gas temperature and duration requirements.

Techniques are available to lower the temperature required to initiate the regeneration. One technique under development is to use a fuel additive. A comparatively small amount of a chemical is added to the diesel fuel and burns along with the fuel in the combustion chamber. The additive is reported to lower the required regeneration temperature significantly. The additive combustion products are retained as a residue in the particulate trap. The trap must be removed from the equipment periodically to flush the residue. Another technique used to lower the regeneration temperature is to apply a catalyst to the surfaces of the trap material. The action of the catalyst has a similar effect as the fuel additive. The catalyst also lowers the concentration of some gaseous emissions in the same manner as the oxidation catalytic converter described earlier.

A very active catalyst applied to the particulate trap surfaces and a very active catalyst in a catalytic converter installed upstream of the trap can create a situation in which the trap performs less efficiently than expected. Burning low sulfur diesel fuel, containing less than 500 ppm sulfur, will result in the creation of significant quantities of sulfates in the exhaust gas. These sulfates will still be in the gaseous state when they reach the ceramic trap and will pass through the trap. These sulfates will condense later forming diesel particulate. Special care must be taken in the selection of the catalyst formulation to ensure that sulfate formation is avoided. This problem is not present on systems which are designed with a catalytic converter upstream of a water scrubber. The gaseous phase sulfates will condense when contacting the water in the scrubber and will not be discharged into the mine atmosphere. Thus far, no permissible diesel packages have been approved which incorporate a catalytic converter upstream of the water scrubber.

One research project conducted by the former Bureau of Mines which attempted this arrangement was unsuccessful. The means selected to maintain a surface temperature less than the 300 degrees Fahrenheit required for permissibility purposes caused the exhaust gas to be cooled to the point that the catalytic converter did not reach the necessary operating temperature. It would appear that a means to isolate the catalytic converter from the exhaust gas water jacket is necessary for the arrangement to function as intended.

If the machine on which the particulate trap is installed does not work hard enough to regenerate the trap with the hot exhaust gas and the option to use a fuel additive or catalyzed trap is not appropriate, the trap can still be regenerated while installed on the machine. Systems are available whereby air is heated by an externally applied heat source and caused to flow through the particle trap with the engine stopped. The heat can be supplied by an electrical resistance element installed in front of the trap. The heat can also be supplied by a burner installed into the exhaust pipe in front of the trap fueled by an auxiliary fuel line. The fuel is ignited creating large quantities of hot gas. With both systems, an air line is also connected to the exhaust pipe to create a flow of hot gases through the particulate trap. Both systems utilize operator panels to control the regeneration process.

Some equipment owners may choose to remove the particle trap from the machine to perform the regeneration. Particle traps are available with quick release devices that allow maintenance personnel to readily remove the unit from the machine. The trap is then placed on a specially designed device that creates a controlled flow of heated air that is passed through the filter burning off the accumulated particulate.

The selection of the most appropriate means to regenerate the trap is dependent on the equipment type, the equipment duty cycle, and the equipment utilization practices at the mine.

A program under the Canadian DEEP project is field testing dpm filter systems in a New Brunswick Mine. The project is testing four filter systems on trucks and scoops. The initial feedback from Canada is very favorable concerning the performance of filters. Operators are very positive and are requesting the vehicles equipped with the filters because of the noticeable improvement in air quality and an absence of smoke even under transient load conditions. One system being tested utilizes an electrical heating element installed in the filter system to provide the heated air for regeneration of the filter. This heating element requires that the filter be connected to an external electrical source at the end of the shift. Initial results have been successful.

Paper filters. In 1990, the former Bureau of Mines conducted a project to develop a means to reduce the amount of dpm emitted from permissible diesel powered equipment using technologies that were available commercially and that could be applied to existing equipment. The project was conducted with the cooperation of an equipment manufacturer, a mine operator, and MSHA. In light of the fact that all permissible diesel powered equipment in coal and metal/nonmetal, at that time, utilized water scrubbers to meet the MSHA approval requirements, the physical characteristics of the exhaust from that type of equipment were the basis for the selection of candidate technologies. The technology selected for development was the pleated media filter or paper filter as it came to be called. The filter selected was an intake air cleaner normally used for over the road trucks. That filter was acceptable for use with permissible diesel equipment because the temperature of the exhaust gas from the water scrubber was less than 170 degrees F which was well below the ignition point of the filter material.

Recognizing that under some operating modes water would be discharged along with the exhaust, a water trap was installed in the exhaust stream before it passed through the filter. After MSHA conducted a thorough permissibility evaluation of the modified system, this filter was installed on a permissible diesel coal haulage vehicle and a series of in mine trials conducted. It was determined, by in mine ambient gravimetric sampling, that the particulate filter reduced dpm emissions by 95 percent compared to that same machine without the filter. The testing determined that the filters would last between one and two shifts, depending on how hard the equipment worked. (BOM, IC 9324).

Following the successful completion of the former Bureau of Mines mine trial, several equipment manufacturers applied for and received MSHA approval to offer the paper filter kits as options on a number of permissible diesel machines. These filter kits were installed on other machines at the mine where the original tests were conducted, and later, on machines at other mines. MSHA is not aware of any paper filters installed on permissible equipment in m/nm to date.

Despite the initial reports on the high efficiency of paper filters, during the coal public hearings and in the coal comments on this rulemaking a number of commenters at the coal public hearings questioned whether in practice paper filters could achieve efficiencies on the order of 95% when used on existing permissible equipment. In order to determine whether it could verify those concerns, MSHA contracted with the Southwest Research Institute to verify the ability of such a filter to reduce the dpm generated by a typical engine used in permissible equipment. The results of this verification effort confirmed that paper filters has a dpm removal efficiency greater than 95%. The information about MSHA's verification effort with respect to paper filters is discussed in detail in connection with the companion rule for the coal sector, where it has particular significance.

Dry systems technology. As mentioned earlier, the most recently developed means of achieving permissibility with diesel powered equipment in the United States is the dry exhaust conditioning system or dry system. This system combines several of the concepts described above as well as new, innovative approaches. The system also solves some of the problems encountered with older technologies.

The dry system in its most basic form consists of a heat exchanger to cool the exhaust gas, a mechanical flame arrestor to prevent the discharge of any flame from within the engine into the mine atmosphere, and a spark arrestor to prevent sparks for being discharged. The surfaces of all of these components and the piping connecting them are maintained below the 300 degrees F required by MSHA approval requirements. A filter, of the type normally used as an intake air filter element, is installed in the exhaust system as the spark arrestor. In terms of this dpm regulation, the most significant feature of the system is the use of this air filter element as a particulate filter. The filter media has an allowable operating temperature rating greater than the 300 degree F exhaust gas temperature allowed by MSHA approval regulations. These filters are reported to last up to sixteen hours, depending on how hard the machine operates.

The dry system can operate on any grade without the problems encountered by water scrubbers. Furthermore, there is no problem with fog created by operation of the water scrubber. Dry systems have been installed and are operating successfully in coal mines on diesel haulage equipment, longwall component carriers, longwall component extraction equipment, and in nonpermissible form, on locomotives.

Although the systems were originally designed for permissible equipment applications, they can also be used directly on nonpermissible equipment (whose emissions are not already cooled), or to replace water scrubbers used to cool most permissible equipment with a system that includes additional aftertreatment.

Reformulated fuels. It has long been known that sulfur content can have a significant effect on dpm emissions. In its diesel equipment rule for underground coal mines, MSHA requires that any fuel used in underground coal mines have less than 0.05% (500 ppm) sulfur. EPA regulations requiring that such low-sulfur fuel (less than 500 ppm) be used in highway engines, in order to limit air pollution, have in practice ensured that this type of diesel fuel is available to mine operators, and they currently use this type of fuel for all engines.

EPA has proposed a rule which would require further reductions in the sulfur content of highway diesel fuel. Such an action was taken for gasoline fuel on December 21, 1999.

On May 13, 1999 (64 FR 26142) EPA published an Advance Notice of Proposed Rulemaking (ANPRM) relative to changes for diesel fuel. In explaining why it was initiating this action, EPA noted that diesel engines "contribute greatly" to a number of serious air pollution problems, and that diesel emissions account for a large portion of the country's particulate matter and nitrogen oxides a key precursor to ozone. EPA noted that while these emissions come mostly from heavy-duty truck and nonroad engines, they expected the contribution to dpm emissions of light-duty equipment to grow due to manufacturers' plans to greatly increase the sale of light duty trucks. These vehicles are now subject to Tier 2 emission standards whether powered by gasoline or diesel fuel, and such standards may be difficult to meet without advanced catalyst technologies that in turn would seem to require sulfur reductions in the fuel.

Moreover, planned Tier 3 standards for nonroad vehicles would require similar action (64 FR 26143). The EPA noted that the European Union has adopted new specifications for diesel fuel that would limit it to 50 ppm by 2005, (an interim limit of 350 ppm by this year), that the entire diesel fuel supply in the United Kingdom should soon be at 50 ppm, and that Japan and other nations were working toward the same goal (64 FR 26148). In the ANPRM, the EPA specifically noted that while continuously regenerating ceramic filters have shown considerable promise for limiting dpm emissions even at fairly low exhaust temperatures, the systems are fairly intolerant of fuel sulfur. Accordingly, the agency hopes to gather information on whether or not low sulfur fuel is needed for effective PM control (64 FR 26150). EPA's proposed rule was published in June 2000, (65 FR 35430) and proposed a sulfur limit of 15 ppm for on-highway use in 2006–2009.

A joint government-industry partnership is also investigating the relationship between varying levels of sulfur content and emissions reduction performance on various control technologies, including particulate filters and oxidation catalytic convertors. This program is supported by the Department of Energy's Office of Heavy Vehicles Technologies, two national laboratories, the Engine Manufacturers Association, and the Manufacturers of Emission Controls Association. It is known as the Diesel Emission Control-Sulfur Effects (DECSE) Program; more information is available from its web site, http://www.ott.doe.gov/decse.

MSHA expects that once such cleaner fuel is required for transportation use, it will in practice become the fuel used in mining as well—directly reducing

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engine particulate emissions, increasing the efficiency of aftertreatment devices, and eventually through the introduction of new generation of cleaner equipment. Mayer states that reducing sulfur content, decreasing aromatic components and increasing the Cetane index of diesel fuel can generally result in a 5% to 15% reduction in total particulate emissions.

Meyer reports the test by VERT of a special synthetic fuel containing neither sulfur nor bound nitrogen nor aromatics, with a very high Cetane index. The fuel performed very well, but produced only abut 10% fewer particulates than low sulfur diesel fuel, nor did it have the slightest improvement in diminishing nonparticulate emissions.

NIOSH provided information on the work that has been done with Biodiesel fuel. Biodiesel fuel is a registered fuel and fuel additive with the EPA and meets clean diesel standards established by the California Air Resources Board. NIOSH stated that the undisputed consensus among the research conducted is that the use of biodiesel will significantly reduce dpm and other harmful emissions in underground mines. MSHA agrees that biodiesel fuel is an option that mine operators can use from the toolbox to meet the dpm standards.

Cabs. A cab is an enclosure around the operator installed on a piece of mobile equipment. It can provide the same type of protection as a booth at a crusher station. While cabs are not available for all mining equipment, they are available for much of the larger equipment that also has application in the construction industry.

Even though cabs are not the type of control device that is bolted onto the exhaust of the diesel engine to reduce emissions, cabs can protect miners from environmental exposures to dpm. Both cabs and control booths are discussed in the context of reducing miners exposures to dpm.

To be effective, a cab should be tightly sealed with windows and doors must be closed. Rubber seals around doors and windows should be in good conditions. Door and window latches should operate properly. In addition to being well sealed, the cab should have an air filtration and space pressurizing system. Air intake should be located away from engine exhaust. The airflow should provide one air change per minute for the cab and should pressurize the cab to 0.20 inches of water. While these are not absolute requirements, they do provide a guideline of how a cab should be designed. If a cab does not have an air filtration and pressurizing system, the diesel particulate concentration inside the cab will be similar to the diesel particulate concentration outside the cab.

MSHA has evaluated the efficiency of cab filters for diesel particulate reduction (Commercial Stone Study, PS&HTC–DD–98–346, Commercial Stone Study, PS&HTC–DD–99–402 and Homestake Mine Study, PS&HTC–DD–00–505.) Several different types of filter media have been tested in underground mines. Depending on the filter media, cabs can reduce diesel particulate exposures by 45 to 90 percent.

(7) MSHA's Diesel Safety Rule for Underground Coal Mines and its Effect on dpm

MSHA's proposed rule to limit the concentration of dpm in underground metal and nonmetal mines included a number of elements which have already proven successful in helping to reduce dpm concentrations in the coal sector. Accordingly, this section provides some background on the substance of the rules that have been in effect in underground coal mines (for more information cn the history of rulemaking in the coal sector, please refer to section 9 of this Part). It should be noted, however, that not all of the requirements discussed here are going to be required for underground metal and nonmetal mines; see Part IV of this preamble for details on what is included in the final rule.

Diesel Equipment Rule in Underground Coal Mines. On October 25, 1996, MSHA promulgated standards for the "Approval, Exhaust Gas Monitoring, and Safety Requirements for the Use of Diesel-Powered Equipment in Underground Coal Mines," sometimes referred to as the "diesel equipment rule" (61 FR 55412; the history of this rulemaking is briefly discussed in section 9 of this Part). The diesel equipment rule focuses on the safe use of diesels in underground coal mines. Integrated requirements are established for the safe storage, handling, and transport of diesel fuel underground, training of mine personnel, minimum ventilating air quantities for diesel powered equipment, monitoring of gaseous diesel exhaust emissions, maintenance requirements, incorporation of fire suppression systems, and design features for nonpermissible machines.

MSHA Approval Requirements for Engines Used in Underground Coal Mines. MSHA requires that all diesel engines used in underground coal mines be "approved" by MSHA for such use, and be maintained by operators in approved condition. Among other things, approval of an engine by MSHA ensures that engines exceeding certain pollutant standards are not used in underground coal mines. MSHA sets the standards for such approval, establishes the testing criteria for the approval process, and administers the tests. The costs to obtain approval of an engine are usually borne by the engine manufacturer or equipment manufacturer. MSHA's 1996 diesel equipment rule made some significant changes to the consequences of approval. The new rule required the whole underground coal fleet to convert to approved engines no later than November 1999.

The new rule also required that during the approval process the agency determine the particulate index (PI) for the engine. The particulate index (or PI), calculated under the provisions of 30 CFR 7.89, indicates the air quantity necessary to dilute the diesel particulate in the engine exhaust to 1 milligram of diesel particulate matter per cubic meter of air.

The PI does not appear on the engine's approval plate. (61 FR 55421). Furthermore, the particulate index of an engine is not, under the diesel equipment rule, used to determine whether or not the engine can be used in an underground coal mine.

At the time the equipment rule was issued, MSHA explicitly deferred the question of whether to require engines used in mining environments to meet a particular PI. (61 FR 55420–21, 55437). While there was some discussion of using it in this fashion during the diesel equipment rulemaking, the approach taken in the final rule was to adopt, instead, the multi-level approach recommended by the Diesel Advisory Committee. This multi-level approach included the requirement to use clean fuel, low emission engines, equipment design, maintenance, and ventilation, all of which appear in the final rule. The requirement for determining the particulate index was included in the diesel equipment rule in order to provide information to the mining community in purchasing equipment—so that mine operators can compare the particulate levels generated by different engines. Mine operators and equipment manufacturers can use the information along with consideration of the type of machine the engines would power and the area of the mine in which it would be used to make decisions concerning the engine's contribution of diesel particulate to the mine's total respirable dust. Equipment manufactures can use the particulate index to design and install exhaust after-treatments. (61 FR 55421). So that the PI for any engine is known to the mining community, MSHA reports the index in the approval letter, posted the PI and ventilating air requirement for all approved engines on its website, and publishes the index with its lists of approved engines.

Gas Monitoring. As discussed in section 5, there are limitations on the exposure of miners to various gases emitted from diesel engines in both underground coal mines and underground metal and nonmetal mines.

The 1996 diesel equipment rule for underground coal mines supplemented these protections in that sector by providing for the monitoring and control of gaseous diesel exhaust emissions. (30 CFR part 70; 61 FR 55413). The rule requires that underground coal mine operators take samples of carbon monoxide and nitrogen dioxide as part of existing onshift workplace examinations. Samples exceeding an action level of 50 percent of the threshold limits set forth in 30 CFR 75.322 trigger corrective action by the mine operator.

Engine Maintenance. The diesel equipment rule also requires that diesel-powered equipment be maintained in safe and approved condition. As explained in the preamble, maintenance requirements were included because of MSHA's recognition that inadequate equipment maintenance can, among other things, result in increased levels of harmful gaseous and particulate components from diesel exhaust.

Among other things, the rule requires the weekly examination of diesel-powered equipment in underground coal mines. To determine if more extensive maintenance is required, the rule further requires that a weekly check of the gaseous CO emission levels on permissible and heavy duty outby machines be made. The CO check requires that the engine be operated at a repeatable loaded condition and the CO measured. The carbon monoxide concentration in the exhaust provides a good indication of engine condition. If the CO measurement increases to a higher concentration than what was normally measured during the past weekly checks, then a maintenance person would know that a problem has developed that requires further investigation. In addition, underground coal mine operators are required to establish programs to ensure that those performing maintenance on diesel equipment are qualified.

Fuel. The diesel equipment rule also requires that underground coal mine operators use diesel fuel with a sulfur content of 0.05% (500 ppm) or less. Some types of exhaust aftertreatment technology designed to lower hazardous diesel emissions work more effectively when the sulfur content of the fuel is low. More effective aftertreatment devices will result in reduced hydrocarbons, carbon monoxide, and particulate levels. Low sulfur fuel also greatly reduces the sulfate production from the catalytic converters currently in use in underground coal mines, thereby decreasing exhaust particulate. To further reduce miners' exposure to diesel exhaust, the final rule prohibits operators from unnecessarily idling diesel-powered equipment.

Ventilation. The diesel equipment rule requires that as part of the approval process, ventilating air quantities necessary to maintain the gaseous emissions of diesel engines within existing required ambient limits be set. The ventilating air quantities are required to appear on the engine's approval plate. The rule also requires that mine operators maintain the approval plate quantity minimum airflow in areas of underground coal mines where diesel-powered equipment is operated. The engine's approval plate air quantity is also used to determine the minimum air quantity in areas where multiple units of diesel powered equipment are being operated. The minimum ventilating air quantity where multiple units of diesel powered equipment are operated on working sections and in areas where mechanized mining equipment is being installed or removed, must be the sum of 100 percent of the approval plate quantities of all of the equipment. As set forth in the preamble of the diesel equipment rule, MSHA believes that effective mine ventilation is a key component in the control of miners' exposure to gasses and particulate emissions generated by diesel equipment.

Impact of the diesel equipment rule on dpm levels in underground coal mines. The diesel equipment rule has many features which, by reducing the emission and concentration of harmful diesel emissions in underground coal mines, will indirectly reduce particulate emissions.

In developing the diesel equipment rule, however, MSHA did not explicitly consider the risks to miners of a working lifetime of dpm exposure at very high levels, nor the actions that could be taken to specifically reduce dpm exposure levels in underground coal mines. It was understood that the agency would be taking a separate look at the health risks of dpm exposure. For example, the agency explicitly deferred discussion of whether to make operators use only equipment that complied with a specific Particulate Index.

(8) Information on How Certain States are Restricting Occupational Exposure to DPM.

As noted earlier in this part, the Federal government has long been involved in efforts to restrict diesel particulate emissions into the environment—both through ambient air quality standards, and through restrictions on diesel engine emissions. While MSHA's actions to limit the concentration of dpm in underground mines are the first effort by the Federal government to deal with the special risks faced by workers exposed to diesel exhaust on the job, several states have already taken actions in this regard with respect to underground coal mines.

This section reviews some of these actions, as they were the subject of considerable discussion and comment during this rulemaking.

Pennsylvania. As indicated in section 1, Pennsylvania essentially had a ban on the use of diesel-powered equipment in underground coal mines for many years. As noted by one commenter, diesel engines were permitted provided the request was approved by the Secretary of the Department of Environmental Protection.

In 1995, one company in the State submitted a plan for approval and started negotiations with its local union representatives. This led to statewide discussions and the adoption of a new law in the State that permits the use of diesel-powered equipment in deep coal mines under certain circumstances specified in the law (Act 182). As further noted by this commenter, the drafters of the law completed their work before the issuance of MSHA's new regulation on the safe use of diesel-powered equipment in underground coal mines. The Pennsylvania law, unlike MSHA's diesel equipment rule, specifically addresses diesel particulate. The State did not set a limit on the exposure of miners to dpm, nor did it establish a limit on the concentration of dpm in deep coal mines. Rather, it approached the issue by imposing controls that will limit dpm emissions at the source.

First, all diesel engines used in underground deep coal mines in Pennsylvania must be MSHA-approved engines with an "exhaust emissions control and conditioning system" that meets certain tests. (Article II-A, Section 203-A, Exhaust Emission Controls). Among these are dpm emissions from each engine no greater than "an average concentration of 0.12 mg/m^3 diluted by fifty percent of the MSHA approval plate ventilation for that diesel engine." In addition, any exhaust emissions

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control and conditioning system must include a "Diesel Particulate Matter (DPM) filter capable of an average of ninety-five percent or greater reduction of dpm emissions." It also requires the use of an oxidation catalytic converter. Thus, the Pennsylvania statute requires the use of low-emitting engines, and then the use of aftertreatment devices that significantly reduce the particulates emitted from these engines.

The Pennsylvania law also has a number of other requirements for the safe use of diesel-powered equipment in the particularly hazardous environments of underground coal mines. Many of these parallel the requirements in MSHA's diesel equipment rule. Like MSHA's requirements, they too can result in reducing miner exposure to diesel particulate—*e.g.*, regular maintenance of diesel engines by qualified personnel and equipment operator examinations. The requirements in the Pennsylvania law take into account the need to maintain the aftertreatment devices required to control diesel particulate.

While both mine operators and labor supported this approach, it remains controversial. During the hearings on this rulemaking, one commenter indicated that at the time the standards were established, it would have taken a 95% filter to reduce dpm from certain equipment to the 0.12 mg/m³ emissions standard because 0.25 sulfur fuel was being utilized. This test reported by the commenter was completed prior to MSHA promulgating the diesel equipment rule that required the use of .05% sulfur fuel. Another commenter pointed out that as operators in the state began considering the use of newer, less polluting engines, achieving an efficiency of 95% reduction of the emissions from any such engines would become even more difficult. There was some disagreement among the commenters as to whether existing technology would permit operators to meet the 0.12 mg/m³ emission standard in many situations. One commenter described efforts to get a small outby unit approved under Pennsylvania law. Accordingly, the industry has indicated that it would seek changes to the Pennsylvania diesel law. Commenters representing miners indicated that they were involved in these discussions.

West Virginia. Until 1997, West Virginia law banned the use of diesel-powered equipment in underground coal mines. In that year, the State created the joint labor-management West Virginia Diesel Equipment Commission (Commission) and charged it with developing regulations to permit and govern diesel engine use in underground coal mines. As explained by several commenters, the Commission, in collaboration with West Virginia University (WVU), developed a protocol for testing diesel engine exhaust controls, and the legislature appropriated more than $150,000 for WVU to test diesel exhaust controls and an array of diesel particulate filters.

There were a number of comments received by MSHA on the test protocols and results. These are discussed in part IV this preamble. One commenter noted that various manufacturers of products have been very interested in how their products compare to those of other manufacturers tested by the WVU. Another asserted that mine operators had been slowing the scheduling of tests by WVA.

Pursuant to the West Virginia law establishing the Commission, the Commission was given only a limited time to determine the applicable rules for the use of diesel engines underground, or the matter was required to be referred to an arbitrator for resolution. One commenter during the hearings noted that the Commission had not been able to reach resolution and that indeed arbitration was the next step. Other commenters described the proposal of the industry members of the Commission—0.5mg/m³ for all equipment, as configured, before approval is granted. In this regard, the industry members of the West Virginia Commission said:

> "We urge you to accelerate the finalization of * * * these proposed rules. We believe that will aid our cause, as well as the other states that currently don't use diesel." (*Id*)

Virginia. According to one commenter, diesel engine use in underground mining was legalized in Virginia in the mid-1980s. It was originally used on some heavy production equipment, but the haze it created was so thick it led to a drop in production. Thereafter, most diesel equipment has been used outby (805 pieces). The current state regulations consist of requiring that MSHA approved engines be used, and that the "most up-to-date, approved, available diesel engine exhaust aftertreatment package" be utilized. There are no distinctions between types of equipment. The commenter noted that more hearings were planned soon. Under a directive from the governor of Virginia, the state is reviewing its regulations and making recommendations for revisions to sections of its law on diesels.

Ohio. The record of this rulemaking contains little specific information on the restrictions on the underground use of diesel-powered equipment in Ohio. MSHA understands, however, that in practice it is not used. According to a communication with the Division of Mines and Reclamation of the Ohio Division of Natural Resources, this outcome stems from a law enacted on October 29, 1995, now codified as section 1567.35 of Ohio Revised Code Title 15, which imposes strict safety restrictions on the use of various fuels underground.

(9) History of this Rulemaking.

As discussed throughout this part, the Federal government has worked closely with the mining community to ascertain whether and how diesel-powered equipment might be used safely and healthfully in this industry. As the evidence began to grow that exposure to diesel exhaust might be harmful to miners, particularly in underground mines, formal agency actions were initiated to investigate this possibility and to determine what, if any, actions might be appropriate. These actions, including a number of non-regulatory initiatives taken by MSHA, are summarized here in chronological sequence.

Activities Prior to Proposed Rulemaking on DPM. In 1984, the National Institute for Occupational Safety and Health (NIOSH) established a standing Mine Health Research Advisory Committee to advise it on matters involving or related to mine health research. In turn, that standing body established the Mine Health Research Advisory Committee Diesel Subgroup to determine if:

> * * * there is a scientific basis for developing a recommendation on the use of diesel equipment in underground mining operations and defining the limits of current knowledge, and recommending areas of research for NIOSH, if any, taking into account other investigators' ongoing and planned research. (49 FR 37174).

In 1985, MSHA established an Interagency Task Group with NIOSH and the former Bureau of Mines (BOM) to assess the health and safety implications of the use of diesel-powered equipment in underground coal mines.

In April 1986, in part as a result of the recommendation of the Task Group, MSHA began drafting proposed regulations on the approval and use of diesel-powered equipment in underground coal mines. Also in 1986, the Mine Health Research Advisory Committee Diesel Subgroup (which, as noted above, was created by a standing NIOSH committee) summarized the evidence available at that time as follows:

> It is our opinion that although there are some data suggesting a small excess risk of adverse health effects associated with exposure to diesel exhaust, these data are not compelling enough to exclude diesels from underground mines. In cases where diesel equipment is used in mines, controls should be employed to minimize exposure to diesel exhaust.

On October 6, 1987, pursuant to Section 102(c) of the Mine Act, 30 U.S.C. 812(c), which authorizes MSHA to appoint advisory committees as he deems appropriate, the agency appointed an advisory committee "to provide advice on the complex issues concerning the use of diesel-powered equipment in underground coal mines." (52 FR 37381). MSHA appointed nine members to this committee, officially known as The Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines (hereafter the MSHA Diesel Advisory Committee). As required by section 101(a)(1) of the Mine Act, MSHA provided the MSHA Diesel Advisory Committee with draft regulations on the approval and use of diesel-powered equipment in underground coal mines. The draft regulations did not include standards setting specific limitations on diesel particulate, nor had MSHA at that time determined that such standards would be promulgated.

In July 1988, the MSHA Diesel Advisory Committee completed its work with the issuance of a report entitled "Report of the Mine Safety and Health Administration Advisory Committee on Standards and Regulations for Diesel-Powered Equipment in Underground Coal Mines." It also recommended that MSHA promulgate standards governing the approval and use of diesel-powered equipment in underground coal mines. The MSHA Diesel Advisory Committee recommended that MSHA promulgate standards limiting underground coal miners' exposure to diesel exhaust.

With respect to diesel particulate, the MSHA Diesel Advisory Committee recommended that MSHA "set in motion a mechanism whereby a diesel particulate standard can be set." (MSHA, 1988). In this regard, the MSHA Diesel Advisory Committee determined that because of inadequacies in the data on the health effects of diesel particulate matter and inadequacies in the technology for monitoring the amount of diesel particulate matter at that time, it could not recommend that MSHA promulgate a standard specifically limiting the level of diesel particulate matter in underground coal mines (*Id.* 64–65). Instead, the MSHA Diesel Advisory Committee recommended that MSHA ask NIOSH and the former Bureau of Mines to prioritize research in the development of sampling methods and devices for diesel particulate.

The MSHA Diesel Advisory Committee also recommended that MSHA request a study on the chronic and acute effects of diesel emissions (*Id*). In addition, the MSHA Diesel Advisory Committee recommended that the control of diesel particulate "be accomplished through a combination of measures including fuel requirements, equipment design, and in-mine controls such as the ventilation system and equipment maintenance in conjunction with undiluted exhaust measurements." The MSHA Diesel Advisory Committee further recommended that particulate emissions "be evaluated in the equipment approval process and a particulate emission index reported." (*Id.* at 9).

In addition, the MSHA Diesel Advisory Committee recommended that "the total respirable particulate, including diesel particulate, should not exceed the existing two milligrams per cubic meter respirable dust standard." (*Id.* at 9.) It should be noted that section 202(b)(2) of the Mine Act requires that coal mine operators maintain the average concentration of respirable dust at their mines at or below two milligrams per cubic meter which effectively prohibits diesel particulate matter in excess of two milligrams per cubic meter (30 U.S.C. 842(b)(2)).

As noted, the MSHA Diesel Advisory Committee issued its report in 1988. During that year, NIOSH issued a Current Intelligence Bulletin recommending that whole diesel exhaust be regarded as a potential carcinogen and controlled to the lowest feasible exposure level (NIOSH, 1988). In its bulletin, NIOSH concluded that although the excess risk of cancer in diesel exhaust exposed workers has not been quantitatively estimated, it is logical to assume that reductions in exposure to diesel exhaust in the workplace would reduce the excess risk. NIOSH stated that "[g]iven what we currently know, there is an urgent need for efforts to be made to reduce occupational exposures to DEP [dpm] in mines."

Consistent with the MSHA Diesel Advisory Committee's research recommendations, MSHA, in September 1988, formally requested NIOSH to perform a risk assessment for exposure to diesel particulate. (57 FR 500). MSHA also requested assistance from NIOSH and the former BOM in developing sampling and analytical methodologies for assessing exposure to diesel particulate in mining operations. (*Id.*). In part, as a result of the MSHA Diesel Advisory Committee's recommendation, MSHA also participated in studies on diesel particulate sampling methodologies and determination of underground occupational exposure to diesel particulate.

On October 4, 1989, MSHA published a Notice of Proposed Rulemaking on approval requirements, exposure monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines. (54 FR 40950). The proposed rule followed the MSHA Diesel Advisory Committee's recommendation that MSHA promulgate regulations requiring the approval of diesel engines.

On January 6, 1992, MSHA published an Advance Notice of Proposed Rulemaking (ANPRM) (57 FR 500). In the ANPRM, MSHA, among other things, sought comment on specific reports on diesel particulate prepared by NIOSH and the former BOM. MSHA also sought comment on reports on diesel particulate which were prepared by or in conjunction with MSHA. The ANPRM also sought comments on the health effects, technological and economic feasibility, and provisions which should be considered for inclusion in a diesel particulate rule. The notice also identified five specific areas where the agency was particularly interested in comments, and about which it asked a number of detailed questions: (1) Exposure limits, including the basis thereof; (2) the validity of the NIOSH risk assessment model and the validity of various types of studies; (3) information about non-cancer risks, non-lung routes of entry, and the confounding effects of tobacco smoking; (4) the availability, accuracy and proper use of sampling and monitoring methods for diesel particulate; and (5) the technological and economic feasibility of various types of controls, including ventilation, diesel fuel, engine design, aftertreatment devices, and maintenance by mechanics with specialized training. The notice also solicited specific information from the mining community on "the need for a medical surveillance or screening program and on the use of respiratory equipment." (57 FR 500). The comment period on the ANPRM closed on July 10, 1992.

While MSHA was completing a "comprehensive analysis of the comments and any other information received" in response to the ANPRM (57 FR 501), it took also several actions to encourage the mining community to begin to deal with the problems identified.

In 1995, MSHA sponsored three workshops "to bring together in a forum format the U.S. organizations who have a stake in limiting the exposure of miners to diesel particulate (including) mine operators, labor unions, trade organizations, engine manufacturers, fuel producers, exhaust aftertreatment manufacturers, and academia." (McAteer, 1995). The sessions provided an overview of the literature and of diesel particulate exposures in the mining industry, state-of-the-art technologies available for reducing diesel particulate levels, presentations on engineering technologies toward that end, and identification of possible

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strategies whereby miners' exposure to diesel particulate matter can be limited both practically and effectively.

The first workshop was held in Beckley, West Virginia on September 12 and 13, and the other two were held on October 6, and October 12 and 13, 1995, in Mt Vernon, Illinois and Salt Lake City, Utah, respectively. A transcript was made. During a speech early the next year, the Deputy Assistant Secretary for MSHA characterized what took place at these workshops:

> The biggest debate at the workshops was whether or not diesel exhaust causes lung cancer and whether MSHA should move to regulate exposures. Despite this debate, what emerged at the workshops was a general recognition and agreement that a health problem seems to exist with the current high levels of diesel exhaust exposure in the mines. One could observe that while all the debate about the studies and the level of risk was going on, something else interesting was happening at the workshops: one by one miners, mining companies, and manufacturers began describing efforts already underway to reduce exposures. Many are actively trying to solve what they clearly recognize is a problem. Some mine operators had switched to low sulfur fuel that reduces particulate levels. Some had increased mine ventilation. One company had tried a soy-based fuel and found it lowered particulate levels. Several were instituting better maintenance techniques for equipment. Another had hired extra diesel mechanics. Several companies had purchased electronically controlled, cleaner, engines. Another was testing a prototype of a new filter system. Yet another was using disposable diesel exhaust filters. These were not all flawless attempts, nor were they all inexpensive. But one presenter after another described examples of serious efforts currently underway to reduce diesel emissions. (Hricko, 1996).

In March of 1997, MSHA issued, in draft form, a publication entitled "Practical Ways to Control Exposure to Diesel Exhaust in Mining—a Toolbox". The draft publication was disseminated by MSHA to all underground mines known to use diesel equipment and posted on MSHA's Web site.

As explained in the publication, the Toolbox was designed to disseminate to the mining community information gained through the workshops about methods being used to reduce miner exposures to dpm. MSHA's Toolbox provided specific information about nine types of controls that can reduce dpm exposures: low emission engines; fuels; aftertreatment devices; ventilation; enclosed cabs; engine maintenance; work practices and training; fleet management; and respiratory protective equipment. Some of these approaches reduce emissions from diesel engines; others focus on reducing miner exposure to whatever emissions are present. Quotations from workshop participants were used to illustrate when and how such controls might be helpful.

As it clearly stated in its introductory section entitled "How to Use This Publication," the Toolbox was not designed as a guide to existing or pending regulations. As MSHA noted in that regard:

> "While the (regulatory) requirements that will ultimately be implemented, and the schedule of implementation, are of course uncertain at this time, MSHA encourages the mining community not to wait to protect miners' health. MSHA is confident that whatever the final requirements may be, the mining community will find this Toolbox information of significant value."

On October 25, 1996, MSHA published a final rule addressing approval, exhaust monitoring, and safety requirements for the use of diesel-powered equipment in underground coal mines (61 FR 55412). The final rule addresses, and in large part is consistent with, the specific recommendations made by the MSHA Diesel Advisory Committee for limiting underground coal miners' exposure to diesel exhaust. As noted in section 7 of this part, the diesel safety rule was implemented in steps concluding in late 1999. Aspects of this diesel safety rule had a significant impact on this rulemaking.

In the Fall of 1997, following comment, MSHA's Toolbox was finalized and disseminated to the mining community. At the same time, MSHA made available to the mining community a software modeling tool developed by the Agency to facilitate dpm control. This model enables an operator to evaluate the effect which various alternative combinations of controls would have on the dpm concentration in a particular mine—before making the investment. MSHA refers to this model as "the Estimator." The Estimator is in the form of a template that can be used on standard computer spreadsheet programs. As information about a new combination of controls is entered, the results are promptly displayed.

On April 9, 1998, MSHA published a proposed rule to "reduce the risks to underground coal miners of serious health hazards that are associated with exposure to high concentrations of diesel particulate matter" (63 FR 17492). In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, a dozen "plain language" questions and answers.

The proposed rule to limit the concentration of dpm in underground coal mines (63 FR 17578) focused on the exclusive use of aftertreatment filters on permissible and heavy duty nonpermissible equipment to limit the concentration of dpm in underground coal mines. In its Questions and Answers, however, and throughout the preamble, MSHA presented considerable information on a number of other approaches that might have merit in limiting the concentration of dpm in underground coal mines, and drew special attention to the fact that the text of the rule being proposed represented only one of the approaches on which the agency was interested in receiving comment. Training of miners in the hazards of dpm was also proposed.

The Proposed Rule to Limit DPM Concentrations in Underground Metal and Nonmetal Mines and Related Actions. On October 29, 1998 (63 FR 58104), MSHA published a proposed rule establishing new health standards for underground metal and nonmetal mines that use equipment powered by diesel engines.

In order to further facilitate participation by the mining community, MSHA developed as an introduction to its preamble explaining the proposed rule, 30 "plain language" questions and answers.

The notice of proposed rulemaking reviewed and discussed the comments received in response to the ANPRM, including information on such control approaches as fuel type, fuel additives, and maintenance practices (63 FR 58134). For the convenience of the mining community, a copy of MSHA's Toolbox was also reprinted as an Appendix at the end of the notice of proposed rulemaking (63 FR 58223). A complete description of the Estimator, and several examples, were also presented in the preamble of the proposed rule.

MSHA proposed to adopt (63 FR 58104) a different rule to address dpm exposure in underground metal and nonmetal mines.

MSHA proposed a limit on the concentration of dpm to which underground metal and nonmetal miners would be exposed.

The proposed rule would have limited dpm concentrations in underground metal and nonmetal mines to about 200 micrograms per cubic meter of air. Operators would have been able to select whatever combination of engineering and work practice controls they wanted to keep the dpm concentration in the mine below this limit.

The concentration limit would have been implemented in two stages: an interim limit that would go into effect following 18 months of education and technical assistance by MSHA, and a final limit after 5 years. MSHA sampling would be used to determine compliance.

The proposal would also have required that all underground metal and nonmetal mines using diesel-powered equipment observe a set of "best practices" to reduce engine emissions—*e.g.*, to use low-sulfur fuel.

Additionally, the Agency also considered alternatives that would have led to a significantly lower-cost proposal, *e.g.*, establishing a less stringent concentration limit in underground metal and nonmetal mines, or increasing the time for mine operators to come into compliance. However, MSHA concluded at that time that such approaches would not be as protective, and that the approach proposed was both economically and technologically feasible.

MSHA also explored whether to permit the use of administrative controls (*e.g.*, rotation of personnel) and personal protective equipment (*e.g.*, respirators) to reduce the diesel particulate exposure of miners. It is generally accepted industrial hygiene practice, however, to eliminate or minimize hazards at the source before resorting to personal protective equipment. Moreover, such a practice is generally not considered acceptable in the case of carcinogens since it merely places more workers at risk. Accordingly, the proposal explicitly prohibited the use of such approaches, except in those limited cases where MSHA approves, due to technological constraints, a 2-year extension for an underground metal and nonmetal mine on the time to comply with the final concentration limit.

MSHA sought comments from the mining community on the proposed regulatory text as well as throughout the entire preamble.

In addition, the Agency specifically requested comments on the following issues:

(a) *Assessment of Risk/Benefits of the Rule.* The Agency welcomed comments on the significance of the material already in the record, and any information that could supplement the record. For example, information on the health risks associated with exposure to dpm—especially observations by trained observers or studies of acute or chronic effects of exposure to known levels of dpm or fine particles in general, information about pre-existing health conditions in individual miners or miners as a group that might affect their reactions to exposures to dpm or other fine particles; information about how dpm affects human health; information on the costs to miners, their families and their employers of the various health problems linked to dpm exposure, and the assumptions and approach to use in quantifying the benefits to be derived from this rule.

(b) *Proposed rule.* MSHA sought comments on specific alternative approaches discussed in Part V. The options discussed included: adjusting the concentration limit for dpm; adjusting the phase-in time for the concentration limit; and requiring that specific technology be used in lieu of establishing a concentration limit.

The Agency also requested comments on the composition of the diesel fleet, what controls cannot be utilized due to special conditions, and any studies of alternative controls using the computer spreadsheet described in the Appendix to Part V of the proposed rule preamble. The Agency also requested information about the availability and costs of various control technologies being developed (*e.g.*, high-efficiency ceramic filters), experience with the use of available controls, and information that would help the Agency evaluate alternative approaches for underground metal and nonmetal mines. In addition, the Agency requested comments from the underground coal sector on the implementation to date of diesel work practices (like the rule limiting idling, and the training of those who provide maintenance) to help evaluate related proposals for the underground metal and nonmetal sector. The Agency also asked for information about any unusual situations that might warrant the application of special provisions.

(c) *Compliance Guidance.* The Agency solicited comments on any topics on which initial guidance ought to be provided as well as any alternative practices which MSHA should accept for compliance before various provisions of the rule go into effect; and

(d) *Minimizing Adverse Impact of the Proposed Rule.* The Agency set forth assumptions about impacts (*e.g.*, costs, paperwork, and impact on smaller mines in particular) in some detail in the preamble and in the PREA. We sought comments on the methodology, and information on current operator equipment replacement planning cycles, tax, State requirements, or other information that might be relevant to purchasing new engines or control technology. The Agency also welcomed comments on the financial situation of the underground metal and nonmetal sector, including information that may be relevant to only certain commodities.

From this point on, the actions taken on the rulemakings in underground coal mines and underground metal and nonmetal mines began to overlap in chronology. There is considerable overlap between the coal and metal/nonmetal communities, and so their participation in these separate rulemakings was often intertwined.

In November 1998, MSHA held hearings on the proposed rule for underground coal mines in Salt Lake City, Utah and Beckley, West Virginia. In December 1998, hearings were held in Mt. Vernon, Illinois, and Birmingham, Alabama.

Hearings concerning the proposed rule for underground coal mines were well attended, including representatives from both the coal and metal and nonmetal sectors. Testimony was presented by individual miners, representatives of miners, mine operators, mining industry associations, representatives of engine and equipment manufacturers, and one individual manufacturer. Members of the mining community participating had an extensive opportunity to hear and respond to alternative views; some participated in several hearings. They also had an opportunity to exchange in direct dialogues with the members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about the need for diesel powered equipment in this sector, the risks associated with its use, the need for regulation in this sector, alternative approaches including those on which MSHA sought comment, and the technological and economic feasibility of various alternatives.

On February 12, 1999, (64 FR 7144) MSHA published a notice in the **Federal Register** announcing: (1) The availability of three additional studies applicable to the proposals; (2) the extension of the post-hearing comment period and close of record on the proposed rule for underground coal mines for 60 additional days, until April 30, 1999; (3) the extension of the comment period on the proposed rule for metal and nonmetal mines for an additional 60 days, until April 30, 1999; and (4) an announcement that the Agency would hold public hearings on the metal and nonmetal proposal.

On March 24, 1999, (64 FR 14200) MSHA published a notice in the **Federal Register** announcing the dates, time, and location of four public hearings for the metal and nonmetal proposed rule.

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The notice also announced that the close of the post-hearing comment period would be on July 26, 1999.

On April 27, 1999, (64 FR 22592) in response to requests from the public, MSHA extended the post-hearing comment period and close of record on the proposed rule for underground coal for 90 additional days, until July 26, 1999.

In May 1999, hearings on the metal and nonmetal proposed rule were held in Salt Lake City, Ut; Albuquerque, NM; St. Louis, MO and Knoxville, TN.

Hearings were well attended and testimony was presented by both labor (miners) and industry (mining associations, coal companies) and government (NIOSH). Testimony was presented by individual mining companies, mining industry associations, mining industry consultants and the National Institute of Occupational Safety and Health. The hearings were held for MSHA to obtain specific comments on the proposed rule for diesel particulate matter exposure of metal and nonmetal miners; additional information on existing and projected exposures to diesel particulate matter and to other fine particulates in various mining operations; information on the health risk associated with exposure to diesel particulate matter; information on the cost to miners, their families and their employers of the various health problems linked to diesel particulate matter; and information on additional benefits to be expected from reducing diesel particulate matter exposure.

Members of the mining community participating, had an extensive opportunity to hear and respond to alternative views; some participated in several of the hearings. They also had an opportunity to exchange in direct dialogues with members of MSHA's dpm rulemaking committee—responding to questions and asking questions of their own. There was extensive comment not only about the provisions of the proposed rule itself, but also about potential interferences with the method used to measure dpm, the studies that MSHA used to document the risk associated with exposure to dpm, the cost estimates derived by MSHA for industry implementation, and the technology and economic feasibility of various alternatives (specifically, industry use of a tool box approach without accountability for an exposure limit).

One commenter, at the Knoxville hearing, specifically requested that the credentials and experience (related to the medical field, epidemiology, metal and nonmetal mining, mining engineering, and diesel engineering) of the hearing panelists be made a part of the public record. The commenter was informed by one of the panelists at the hearing that if this information was wanted it should be requested under the Freedom Of Information Act (FOIA). Such a request was submitted to MSHA by the commenter and appropriately responded to by the Agency.

On July 8, 1999, (64 FR 36826) MSHA published a notice in the **Federal Register** correcting technical errors in the preamble discussion on the Diesel Emission Control Estimator formula in the Appendix to Part V of the proposed rulemaking notice, and correcting Figure V–5 of the preamble. Comments on these changes were solicited. (The Estimator model was subsequently published in the literature (Haney, R.A. and Saseen, G.P., "Estimation of diesel particulate concentrations in underground mines", Mining Engineering, Volume 52, Number 5, April 2000)).

The rulemaking records of both rules closed on July 26, 1999, nine months after the date the proposed rule on metal and nonmetal mines was published for public notice. The post-hearing comments, like the hearings, reflected extensive participation in this effort by the full range of interests in the mining community and covered a full range of ideas and alternatives.

On June 30, 2000, the rulemaking record was reopened for 30 days in order to obtain public comment on certain additional documents which the agency determined should be placed in the rulemaking record. Those documents were the verification studies concerning NIOSH Method 5040 mentioned in section 3 of this Part. In addition, the notice provided an opportunity for comment on additional documents being placed in the rulemaking record for the related rulemaking for underground coal mines (paper filter verification investigation and recent hot gas filter test results from VERT), and an opportunity to comment on some additional documents on risk being placed in both records. In this regard, the notice reassured the mining community that any comments filed on risk in either rulemaking proceeding would be placed in both records, since the two rulemakings utilize the same risk assessment.

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Introduction

MSHA has reviewed the scientific literature to evaluate the potential health effects of occupational dpm exposures at levels encountered in the mining industry. This part of the preamble presents MSHA's review of the currently available information and MSHA's assessment of health risks associated with those exposures. All material submitted during the public comment periods was considered before MSHA drew its final conclusions.

The risk assessment begins, in Section III.1, with a discussion of dpm exposure levels observed by MSHA in the mining industry. This is followed by a review, in Section III.2, of information available to MSHA on health effects that have been studied in association with dpm exposure. Finally, in Section III.3 entitled "Characterization of Risk," the Agency considers three questions that must be addressed for rulemaking under the Mine Act and relates the available information about risks of dpm exposure at current levels to the regulatory requirements.

A risk assessment must be technical enough to present the evidence and describe the main controversies surrounding it. At the same time, an overly technical presentation could cause stakeholders to lose sight of the main points. MSHA is guided by the first principle the National Research Council established for risk characterization, that the approach be:

> [a] decision driven activity, directed toward informing choices and solving problems * * * Oversimplifying the science or skewing the results through selectivity can lead to the inappropriate use of scientific information in risk management decisions, but providing full information, if it does not address key concerns of the intended audience, can undermine that audience's trust in the risk analysis.

Although the final rule covers only one sector, this portion of the preamble was intended to enable MSHA and other interested parties to assess risks throughout the coal and M/NM mining industries. Accordingly, the risk assessment includes information pertaining to all sectors of the mining industry. All public comments on the exposures of miners and the health effects of dpm exposure—whether submitted specifically for the coal rulemaking or for the metal/nonmetal rulemaking—were incorporated into the record for each rulemaking and have been considered for this assessment.

MSHA had an earlier version of this risk assessment independently peer reviewed. The risk assessment as proposed incorporated revisions made in accordance with the reviewers' recommendations, and the final version presented here contains clarifications and other responses to public comments. With regard to the risk assessment as published in the proposed preamble, the reviewers stated that:

> * * * principles for identifying evidence and characterizing risk are thoughtfully set out. The scope of the document is carefully described, addressing potential concerns about the scope of coverage. Reference citations are adequate and up to date. The document is written in a balanced fashion, addressing uncertainties and asking for additional information and comments as appropriate. (Samet and Burke, Nov. 1997).

Some commenters generally agreed with this opinion. Dr. James Weeks, representing the UMWA, found the proposed risk assessment to be "balanced, thorough, and systematic." Dr. Paul Schulte, representing NIOSH, stated that "MSHA has prepared a thorough review of the health effects associated with exposure to high concentrations of dpm, and NIOSH concurs with the published [proposed] characterization of risks associated with these exposures." Dr. Michael Silverstein, representing the Washington State Dept. of Labor and Industries, found MSHA's "regulatory logic * * * thoroughly persuasive." He commented that "the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health * * * the evidence * * * is particularly strong and certainly provides a sufficient basis for regulatory action."

Many commenters, however, vigorously criticized various aspects of the proposed assessment and some of the scientific studies on which it was based. MSHA's final assessment, published here, was modified to respond to all of these criticisms. Also, in response to commenters' suggestions, this assessment incorporates some research studies and literature reviews not covered or inadequately discussed in the previous version.

Some commenters expressed the opinion that the proposed risk assessment should have been peer-reviewed by a group representing government, labor, industry, and independent scientists. Since the rulemaking process included a pre-hearing comment period, eight public hearings (four for coal and four for M/NM), and two post-hearing comment periods, these constituencies had ample opportunity to review and comment upon MSHA's proposed risk assessment. The length of the comment period for the Coal Dpm proposal was 15 months. The length of the comment period for the Metal/Nonmetal Dpm proposal was nine months.

1. Exposures of U.S. Miners

Information about U.S. miner exposures comes from published studies and from additional mine investigations conducted by MSHA since 1993.[1] Previously published studies of exposures to dpm among U.S. miners are: Watts (1989, 1992), Cantrell (1992, 1993), Haney (1992), and Tomb and Haney (1995). MSHA has also conducted investigations subsequent to the period covered in Tomb and Haney (1995), and the previously unpublished data through mid-1998 are included here. Both the published and unpublished studies were placed in the record with the proposal, giving MSHA's stakeholders the opportunity to analyze and comment on all of the exposure data considered.

MSHA's field studies involved measuring dpm concentrations at a total of 50 mines: 27 underground metal and nonmetal (M/NM) mines, 12 underground coal mines, and 11 surface mining operations (both coal and M/NM). At all surface mines and all underground coal mines, dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. With few exceptions, dpm measurements at underground M/NM mines were made using the Respirable Combustible Dust (RCD) method (with no impactor). At two of the underground M/NM mines, measurements were made using the total carbon (TC) method, and at one, RCD measurements were made in one year and TC measurements in another. Measurements at the two remaining underground M/NM mines were made using the size-selective method, as in

[1] MSHA has only limited information about miner exposures in other countries. Based on 223 personal and area samples, average exposures at 21 Canadian noncoal mines were reported to range from 170 to 1300 $\mu g/m^3$ (respirable combustible dust), with maximum measurements ranging from 1020 to 3100 $\mu g/m^3$ (Gangel and Dainty, 1993). Among 622 full shift measurements collected since 1989 in German underground noncoal mines, 91 (15%) exceeded 400 $\mu g/m^3$ (total carbon) (Dahmann et al., 1996). As explained elsewhere in this preamble, 400 $\mu g/m^3$ (total carbon) corresponds to approximately 500 $\mu g/m^3$ dpm.

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coal and surface mines.[2] Weighing errors inherent in the gravimetric analysis required for both size-selective and RCD methods become statistically insignificant at the relatively high dpm concentrations observed.

According to MSHA's experience, the dpm samples reflect exposures typical of mines known to use diesel equipment for face haulage in the U.S. However, they do not constitute a random sample of mines, and care was taken in the proposed risk assessment not to characterize results as necessarily representing conditions in all mines. Several commenters objected to MSHA's use of these exposure measurements in making comparisons to exposures reported in other industries and, for M/NM, in estimating the proposed rule's impact. These objections are addressed in Sections III.1.d and III.3.b.ii(3)(c) below. Comments related to the measurement methods used in underground coal and M/NM mines are addressed, respectively, in Sections III.1.b and III.1.c.

Each underground study typically included personal dpm exposure measurements for approximately five production workers. Also, area samples were collected in return airways of underground mines to determine diesel particulate emission rates.[3] Operational information such as the amount and type of equipment, airflow rates, fuel, and maintenance was also recorded. Mines were selected to obtain a wide range of diesel equipment usage and mining methods. Mines with greater than 175 horsepower and less than 175 horsepower production equipment were sampled. Single and multiple level mines were sampled. Mine level heights ranged from eight to one-hundred feet. In general, MSHA's studies focused on face production areas of mines, where the highest concentrations of dpm could be expected; but, since some miners do not spend their time in face areas, samples were collected in other areas as well, to get a more complete picture of miner exposure. Because of potential interferences from tobacco smoke in underground M/NM mines, samples were not collected on or near smokers.

Table III–1 summarizes key results from MSHA's studies. The higher concentrations in underground mines were typically found in the haulageways and face areas where numerous pieces of equipment were operating, or where airflow was low relative to the amount of equipment operating. In production areas and haulageways of underground mines where diesel powered equipment was used, the mean dpm concentration observed was 644 μg/m³ for coal and 808 μg/m³ for M/NM. In travelways of underground mines where diesel powered equipment was used, the mean dpm concentration (based on 112 area samples not included in Table III–1) was 517 μg/m³ for M/NM and 103 μg/m³ for coal. In surface mines, the higher concentrations were generally associated with truck drivers and front-end loader operators. The mean dpm concentration observed was less than 200 μg/m³ at all eleven of the surface mines in which measurements were made. More information about the dpm concentrations observed in each sector is presented in the material that follows.

TABLE III–1.—FULL-SHIFT DIESEL PARTICULATE MATTER CONCENTRATIONS OBSERVED IN PRODUCTION AREAS AND HAULAGEWAYS OF 50 DIESELIZED U.S. MINES

Mine type	Number of mines	Number of samples	Mean exposure (μg/m³)	Standard error of mean (μg/m³)	Exposure range (μg/m³)
Surface	11	45	88	11	9–380
Underground coal	12	226	644	41	0–3,650
Underground metal and nonmetal	27	355	808	39	10–5,570

Note: Intake and return area samples are excluded.

a. Underground Coal Mines

Approximately 145 out of the 910 existing underground coal mines currently utilize diesel powered equipment. Of these 145 mines, 32 mines currently use diesel equipment for face coal haulage. The remaining mines use diesel equipment for transportation, materials handling and other support operations. MSHA focused its efforts in measuring dpm concentrations in coal mines on mines that use diesel powered equipment for face coal haulage. Twelve mines using diesel-powered face haulage were sampled. Mines with diesel powered face haulage were selected because the face is an area with a high concentration of vehicles operating at a heavy duty cycle at the furthest end of the mine's ventilation system.

Diesel particulate levels in underground mines depend on: (1) The amount, size, and workload of diesel equipment; (2) the rate of ventilation; and, (3) the effectiveness of whatever diesel particulate control technology may be in place. In the dieselized mines studied by MSHA, the sections used either two or three diesel coal haulage vehicles. In eastern mines, the haulage vehicles were equipped with a nominal 100 horsepower engine. In western mines, the haulage vehicles were equipped with a nominal 150 horsepower engine. Ventilation rates ranged from the approval plate requirement, based on the 100–75–50 percent rule (Holtz, 1960), to ten times the approval plate requirement. In most cases, the section airflow was approximately twice the approval plate requirement. Other control technology included aftertreatment filters and fuel. Two types of aftertreatment filters were used. These filters included a disposable diesel emission filter (DDEF) and a Wire Mesh Filter (WMF). The DDEF is a commercially available product; the WMF was developed by and only used at one mine. Both low sulfur and high sulfur fuels were used.

Figure III–1 displays the range of exposure measurements obtained by MSHA in the field studies it conducted in underground coal mines. A study normally consisted of collecting samples on the continuous miner operator and coal haulage vehicle operators for two to three shifts, along with area samples in the haulageways. A total of 142 personal samples and 84 area samples were collected, excluding any area samples taken in intake or return airways.

[2] The various methods of measuring dpm are explained in section 3 of Part II of the preamble to the proposed rule. This explanation, along with additional information on these methods, is also provided in section 3 of Part II of the preamble to the final M/NM rule.

[3] Since area samples in return airways do not necessarily represent locations where miners normally work or travel, they were excluded from the present analysis. A number of area samples were included, however, as described in Sections III.1.b and III.1.c. The included area samples were all taken in production areas and haulageways.

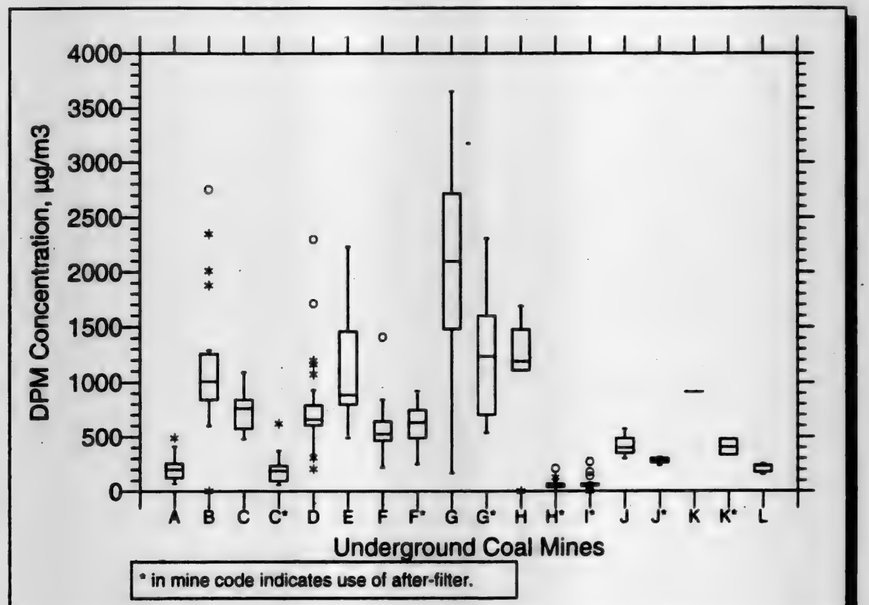


Figure 1Box plots (Tukey, 1977) for dpm concentrations observed at 12 underground coal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either * or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor.

As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[4] A total of 19 individual measurements exceeded 1500 μg/m³, still excluding intake and return area samples. Although the three highest of these were from area samples, nine of the 19 measurements exceeding 1500 μg/m³ were from personal samples.

In six mines, measurements were taken both with and without use of disposable after-treatment filters, so that a total of eighteen studies, carried out in twelve mines, are displayed. Without use of after-treatment filters, average observed dpm concentrations exceeded 500 μg/m³ in eight of the twelve mines and exceeded 1000 μg/m³ in four.[5] At five of the twelve mines, all dpm measurements were 300 μg/m³ or greater in the absence of after-treatment filters.

The highest dpm concentrations observed at coal mines were collected at Mine "G." Eight of these samples were collected during employment of WMFs, and eight were collected while filters were not being employed. Without filters, the mean dpm concentration observed at Mine "G" was 2052 μg/m³ (median = 2100 μg/m³). With employment of WMFs, the mean

[4] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 142 personal samples, the mean dpm concentration measurement was 608 μg/m³, with a standard error of 42.5 μg/m³. For the 84 area samples, the mean was 705 μg/m³, with a standard error of 82.1 μg/m³. The significance level (p-value) of a t-test comparing these means is 0.29 using a separate-variance test or 0.25 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at any confidence level greater than 75%.

Here, and in other sections of this risk assessment, MSHA has employed standard statistical methods described in textbooks on elementary statistical inference.

[5] In coal mine E, the average as expressed by the mean exceeded 1000 μg/m³, but the median did not.

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dropped to 1241 µg/m³ (median = 1235 µg/m³).

Filters were employed during three of the four studies showing median dpm concentration at or below 200 µg/m³. After adjusting for outby sources of dpm, exposures were found to be reduced by up to 95 percent in mines using the DDEF and by approximately 50 percent in the mine using the WMF.

The higher dpm concentrations observed at the mine using the WMF (Mine "G*") are attributable partly to the lower section airflow. The only study without filters showing a median concentration at or below 200 µg/m³ was conducted in a mine (Mine "A") which had section airflow approximately ten times the nameplate requirement. The section airflow at the mine using the WMF was approximately the nameplate requirement.

Some commenters [*e.g.*, WV Coal Assoc and Energy West] objected to MSHA's presentation of underground coal mine exposures based on measurements made using the size-selective method (gravimetric determination of the amount of submicrometer dust collected with an impactor). These commenters argued that the data were "* * * collected with emissions monitoring devices discredited by MSHA itself in the preamble * * *" and that these measurements do not reliably "* * * distinguish it [dpm] from other particles in coal mine dust, at the critical upper end range of submicron particles."

MSHA did not "discredit" use of the size-selective method for all purposes. As discussed elsewhere in this preamble, the size-selective method of measuring dpm was designed by the former BOM specifically for use in coal mines, and the size distribution of coal mine dust was taken into account in its development. Despite the recognized interference from a small fraction of coal mine dust particles, MSHA considers gravimetric size-selective measurements to be reasonably accurate in measuring dpm concentrations greater than 200 µg/m³, based on a full-shift sample, when coal mine dust concentrations are not excessive (i.e., not greater than 2.0 mg/m³). Interference from submicrometer coal mine dust is counter-balanced, to some extent, by the fraction of larger size, uncaptured dpm. Coal mine dust concentrations were not excessive when MSHA collected its size-selective samples. Therefore, even if as much as 10 percent of the coal mine dust were submicrometer, this fraction would not have contributed significantly to the high concentrations observed at the sampled mines.

At lower concentrations, or shorter sampling times, random variability in the gravimetric determination of weight gain becomes significant, compared to the weight of dust accumulated on the filter. For this reason, MSHA has rejected the use of the gravimetric size-selective method for enforcement purposes.[6] This does not mean, however, that MSHA has "discredited" this method for other purposes, including detection of very high dpm concentrations at coal mines (*i.e.*, greater than 500 µg/m³) and estimation of average dpm concentrations, based on multiple samples, when coal mine dust concentrations are not excessive. On the contrary, MSHA regards the gravimetric size-selective method as a useful tool for detecting and monitoring very high dpm concentrations and for estimating average exposures.

b. Underground Metal and Nonmetal Mines

Currently there are approximately 265 underground M/NM mines in the United States. Nearly all of these mines utilize diesel powered equipment, and 27 of those doing so were sampled by MSHA for dpm.[7] The M/NM studies typically included measurements of dpm exposure for dieselized production equipment operators (such as truck drivers, roof bolters, haulage vehicles) on two to three shifts. A number of area samples were also collected. None of the M/NM mines studied were using diesel particulate afterfilters.

Figure III–2 displays the range of dpm concentrations measured by MSHA in the 27 underground M/NM mines studied. A total of 275 personal samples and 80 area samples were collected, excluding intake and return area samples. Personal exposures observed ranged from less than 100 µg/m³ to more than 3500 µg/m³. Exposure measurements based on area samples ranged from less than 100 µg/m³ to more than 3000 µg/m³. With the exception of Mine "V", personal exposures were for face workers. Mine "V" did not use dieselized face equipment.

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[6] MSHA has concluded that random weighing variability would make it impractical to use the size-selective method to enforce compliance with any dpm concentration limit less than about 300 µg/m³. MSHA believes that, at such levels, single-sample noncompliance determinations based on the size-selective method could not be made at a sufficiently high confidence level.

[7] The proposal discussed data from 25 underground M/NM mines. Studies at two additional mines, carried out too late to be included in the proposal, were placed into the public record along with the earlier studies. During the proceedings, MSHA provided copies of all of these studies to stakeholders requesting them.

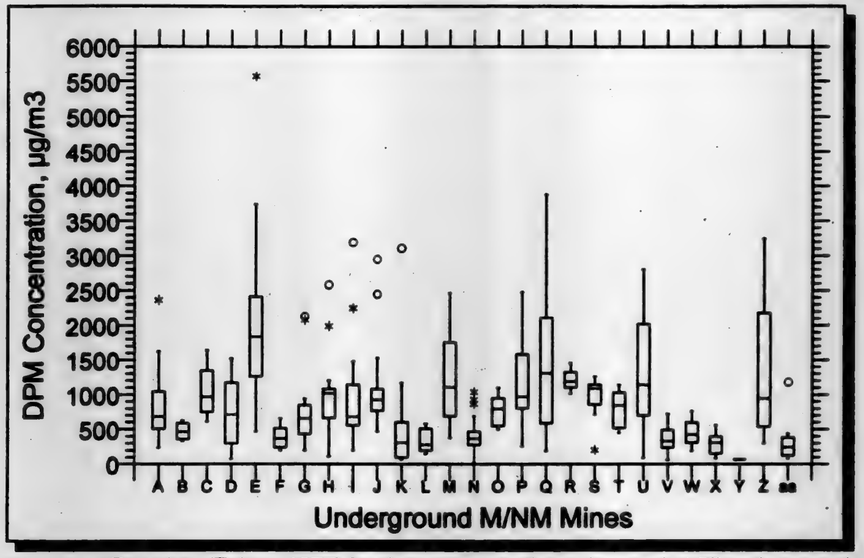


Figure 2 Box plots (Tukey, 1977) for dpm concentrations observed at 27 underground metal and nonmetal mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either * or ○) are outliers, representing unusually high or low measurements compared to other observations at same mine. Measurements at Mine "T" and on one visit to mine "D" were made using the size-selective method, based on gravimetric determinationof the amount of submicrometer dust collected with an impactor. Measurements on another visit to mine "D" and at Mines "Z" and "aa" were made using TC method. All other measurements were made using RCD method. Because of potential interferences from cigarette smoke, samples were not collected on or near smokers.

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As stated in the proposed risk assessment, no statistically significant difference was observed in mean dpm concentration between the personal and area samples.[8] A total of 45 individual measurements exceeded 1500 µg/m³, still excluding intake and return area samples. The three highest of these, all exceeding 3500 µg/m³, were from personal samples. Of the 45 measurements exceeding 1500 µg/m³, 30 were from personal samples and 15 were from area samples.

Average observed dpm concentrations exceeded 500 µg/m³ in 18 of the 27 underground M/NM mines and exceeded 1000 µg/m³ in 12.[9] At eight of the 27 mines, all dpm measurements exceeded 300 µg/m³. The highest dpm concentrations observed at M/NM mines were collected at Mine "E". Based on 16 samples, the mean dpm concentration observed at Mine "E" was 2008 µg/m³ (median = 1835 µg/m³). Twenty-five percent of the dpm measurements at this mine exceeded 2400 µg/m³. All four of these were based on personal samples.

As with underground coal mines, dpm levels in underground M/NM mines are related to the amount and size of equipment, to the ventilation rate, and to the effectiveness of the diesel particulate control technology employed. In the dieselized M/NM mines studied by MSHA, front-end-loaders were used either to load ore onto trucks or to haul and load ore onto belts. Additional pieces of diesel powered support equipment, such as bolters and mantrips, were also used at the mines. The typical piece of production equipment was rated at 150 to 350 horsepower. Ventilation rates in the M/NM mines studied mostly ranged from 100 to 200 cfm per horsepower of equipment. In only a few of the mines inventoried did ventilation exceed 200 cfm/hp. For single-level mines, working areas were ventilated in series (*i.e.*, the exhaust air from one area became the intake for the next working area). For multi-level mines, each level typically had a separate fresh air supply. One or two working areas could be on a level. Control technology used to reduce diesel particulate emissions in mines inventoried included oxidation catalytic converters and engine maintenance programs. Both low sulfur and high sulfur fuel were used; some mines used aviation grade low sulfur fuel.

Some commenters argued that, because of the limited number of underground M/NM mines sampled by MSHA, "* * * results of MSHA's admittedly non-random sample cannot be extrapolated to other mines." [MARG] More specifically, IMC Global claimed that since only 25 [now 27] of about 260 underground M/NM mines were sampled,[10] then "if the * * * measurements are correct, this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector and then only for certain unlisted commodities."[11] IMC Global went on to suggest that MSHA should "perform sufficient additional exposure monitoring * * * to show that the diesel particulate exposures are representative of the entire industry before promulgating regulations that will be applicable to the entire industry."

As mentioned earlier, MSHA acknowledges that the mines for which dpm measurements are available do not comprise a statistically random sample of all underground M/NM mines. MSHA also acknowledges that the results obtained for these mines cannot be extrapolated in a statistically rigorous way to the entire population of underground M/NM mines. According to MSHA's experience, however, the selected mines (and sampling locations within those mines) represent typical diesel equipment use condition at underground M/NM. MSHA believes that results at these mines, as depicted in Figure III–2, in fact fairly reflect the broad range of diesel equipment used by the industry, regardless of type of M/NM mine. Based on its extensive experience with underground mines, MSHA believes that this body of data better represents those diverse diesel equipment use conditions, with respect to dpm exposures, than any other body of data currently available.

MSHA strongly disagrees with IMC Global's contention that, "* * * this information shows at best potential exposure problems to diesel particulate in only 10% of the miners working in the metal-nonmetal mining sector." IMC Global apparently drew this conclusion from the fact that MSHA sampled approximately ten percent of all underground M/NM mines. This line of argument, however, depends on an unwarranted and highly unrealistic assumption: namely, that all of the underground M/NM mines not included in the sampled group of 25 experience essentially no "potential [dpm] exposure problems." MSHA certainly did not go out and, by chance or design, pick for sampling just exactly those mines experiencing the highest dpm concentrations. IMC Global's argument fails to recognize that the sampled mines could be fairly representative without being randomly chosen.

MSHA also disagrees with the premise that 27 [or 25 as in the proposal] is an inherently insufficient number of mines to sample for the purpose of identifying an industry-wide dpm exposure problem that would justify regulation. The between-mine standard deviation of the 27 mean concentrations observed within mines was 450 µg/m³. Therefore, the standard error of the estimated grand mean, based on the variability observed between mines, was $450/\sqrt{27} = 87$ µg/m³.[12] MSHA considers this degree of uncertainty to be acceptable, given that the overall mean concentration observed exceeded 800 µg/m³.

Several commenters questioned MSHA's use of the RCD and size-selective methods for measuring dpm exposures at underground M/NM mines. IMC Global indicated that MSHA's RCD measurements might systematically inflate the dpm concentrations presented in this section, because "* * * estimates for the non-diesel particulate component of RCD actually vary between 10% to 50%, *averaging 33%*."

MSHA considers the size-selective, gravimetric method capable of providing reasonably accurate measurements when the dpm concentration is greater than 200 µg/m³, interferences are adequately limited, and the measurement is based on a full-shift sample. Relatively few M/NM measurements were made using this method, and none at the mines showing the highest dpm concentrations. No evidence was presented that the size distribution of coal mine dust (for which the impactor was specifically developed) differs from that of other mineral dusts in a way that significantly alters the impactor's performance. Similarly, MSHA considers the RCD method, when properly applied, to be capable of providing reasonably accurate dpm measurements at concentrations greater than 200 µg/m³. As with the size selective method, however, random weighing errors can significantly reduce the precision of even full-shift RCD measurements at lower dpm concentrations. For this reason, in order to maintain a sufficiently high confidence level for its noncompliance determinations, MSHA will not use the RCD method for enforcement purposes. This does not mean, however, that MSHA has "discredited" the RCD measurements for all other purposes, including detection of very high dpm concentrations (i.e., greater than 300 µg/m³) and estimation of average concentrations based on multiple samples. On the contrary, MSHA considers the RCD method to be a useful tool for detecting and monitoring very high dpm concentrations in appropriate environments and for estimating average exposures when those exposures are excessive.

MSHA did not employ an impactor in its RCD measurements, and it is true that some of these measurements may have been subject to interference from lubrication oil mists. However, MSHA believes that the high estimates sometimes made of the non-dpm component of RCD (cited by IMC Global) do not apply to the RCD measurements depicted in Figure III–2. MSHA has three reasons for believing these RCD measurements consisted almost entirely of dpm:

(1) MSHA took special care to sample only environments where interferences would not be significant. No samples were taken near pneumatic drills or smoking miners.

(2) There was no interference from carbonates. The RCD analysis was performed at 500° C, and carbonates are not released below 1000° C. (Gangel and Dainty, 1993)

(3) Although high sulphur fuel was used in some mines, thereby adding sulfates to the RCD measurement, these sulfates are considered part of the dpm, as explained in section 2 of Part II of this preamble. Sulfates should not be regarded as an interference in RCD measurements of dpm.

Commenters presented no evidence that there were substantial interferences in MSHA's RCD measurements, and, as stated above, MSHA was careful to avoid them. Therefore, MSHA considers it reasonable, in the context of this risk assessment, to assume that all of the RCD was in fact dpm. Moreover, in the majority of underground M/NM mines sampled, even if the RCD measurements were reduced by ⅓, the mine's average would still be excessive: it would still exceed the maximum exposure level reported for non-mining occupations presented in section III.1.d.

The breakdown, as suggested by IMC Global, of sampled underground M/NM mines by commodity is as follows:

Commodity	Number of mines
Copper	2
Gold	1
Lead/Zinc	6
Limestone	6
Potash	2
Salt	6
Trona (soda ash)	2
Other Nonmetal	2
Total	27

c. Surface Mines

Currently, there are approximately 12,620 surface mining operations in the United States. The total consists of approximately 1,550 coal mines and 11,070 M/NM mines. Virtually all of these mines utilize diesel powered equipment.

MSHA conducted dpm studies at eleven surface mining operations: eight coal mines and three M/NM mines. MSHA deliberately directed its surface sampling efforts toward occupations likely to experience high dpm concentrations. To help select such occupations, MSHA first made a visual examination (based on blackness of the filter) of surface mine respirable dust samples collected during a November 1994 study of surface coal mines. This preliminary screening of samples indicated that relatively high surface mine dpm concentrations are typically associated with front-end-loader operators and haulage-truck operators; accordingly, sampling focused on these operations. A total of 45 samples was collected.

Figure III–3 displays the range of dpm concentrations measured at the eleven surface mines. The average dpm concentration observed was less than 200 µg/m³ at all mines sampled. The maximum dpm concentration observed was less than or equal to 200 µg/m³ in 8 of the 11 mines (73%). The surface mine studies suggest that even when sampling is performed at the areas of surface mines believed most likely to have high exposures, dpm concentrations are generally likely to be less than 200 µg/m³.

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[8] One commenter (IMC Global) noted that MSHA had provided no data verifying this statement. For the 275 personal samples, the mean dpm concentration measurement was 770 µg/m³, with a standard error of 42.8 µg/m³. For the 80 area samples, the mean was 939 µg/m³, with a standard error of 86.6 µg/m³. The significance level (p-value) of a t-test comparing these means is 0.08 using a separate-variance test or 0.07 using a pooled-variance test. Therefore, a difference in population means cannot be inferred at a 95% confidence level.

[9] At M/NM mines C, I, J, P, and Z the average as expressed by the mean exceeded 1000 µg/m³ but the median did not. At M/NM mines H and S, the median exceeded 1000 µg/m³ but the mean did not. At M/NM mine K, the mean exceeded 500 µg/m³, but the median did not.

[10] Three underground M/NM mine surveys, carried out too late to be included in the discussion, were placed into the public record and provided to interested stakeholders. These surveys contained data from two additional underground M/NM mines ("Z" and "ae") and additional data for a mine ("d") that had previously been surveyed. The risk assessment has now been updated to include these data, representing a total of 27 underground M/NM mines.

[11] A breakdown by commodity is given at the end of this subsection.

[12] This quantity, 87 µg/m³, differs from the standard error of the mean of individual measurements for underground M/NM mines, presented in Table III–1. The tabled value is based on 355 measurements whose standard deviation is 727µg/m³. Therefore, the standard error of the mean of all individual measurements is $727/\sqrt{355} = 39$ µg/m³, as shown in the table. Similarly, the mean of all individual measurements (listed in Table III–1 as 806 µg/m³) differs from the grand mean of individual mean concentrations observed within mines, which is 838 µg/m³.

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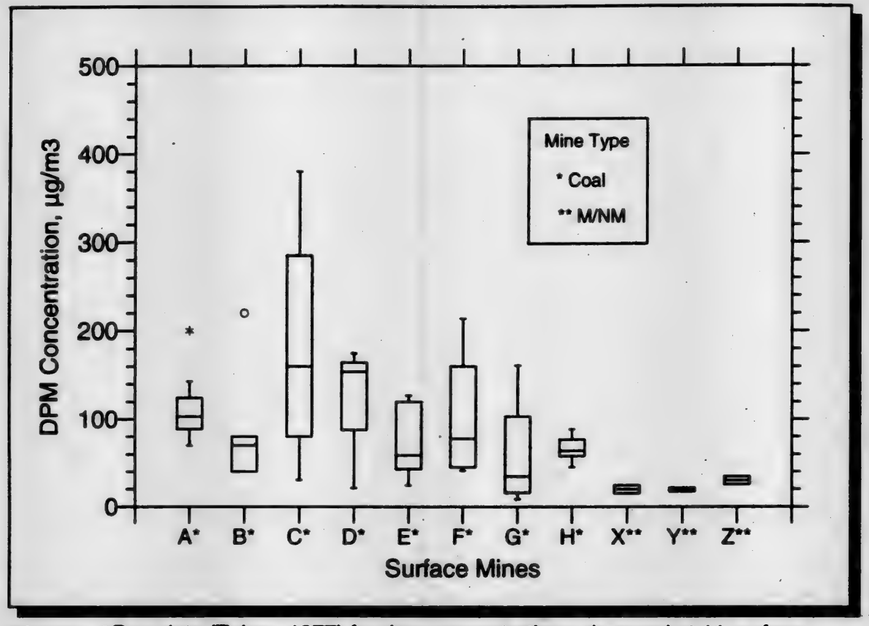


Figure 3 Box plots (Tukey, 1977) for dpm concentrations observed at 11 surface mines. Top and bottom of each box represent upper and lower quartiles, respectively. "Belt" inside box represents median. Vertical lines span nearly all measurements. Isolated points (either * or ○) are outliers, representing unusually high or low measurements compared to other observations at the same mine. All dpm measurements were made using the size-selective method, based on gravimetric determination of the amount of submicrometer dust collected with an impactor. Because of potential interferences from cigarette smoke, samples were not collected on smokeres who worked inside enclosures.

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d. Miner Exposures Compared to Exposures of Other Groups

Occupational exposure to diesel particulate primarily originates from industrial operations employing equipment powered with diesel engines. Diesel engines are used to power ships, locomotives, heavy duty trucks, heavy machinery, as well as a small number of light-duty passenger cars and trucks. NIOSH has estimated that approximately 1.35 million workers are occupationally exposed to the combustion products of diesel fuel in approximately 80,000 workplaces in the United States. (NIOSH 1988) Workers who are likely to be exposed to diesel emissions include: mine workers; bridge and tunnel workers; railroad workers; loading dock workers; truck drivers; fork-lift drivers; farm workers; and, auto, truck, and bus maintenance garage workers (NIOSH, 1988). Besides miners, groups for which occupational exposures have been reported and health effects have been studied include loading dock workers, truck drivers, and railroad workers.

As estimated by the reported geometric mean,[13] the median site-specific occupational exposures for loading dock workers operating or otherwise exposed to unfiltered diesel fork lift trucks ranged from 23 to 55 µg/m³, as measured by submicrometer elemental carbon (EC) (NIOSH, 1990). Reported geometric mean concentrations of submicrometer EC ranged from 2.0 to 7.0 µg/m³ for truck drivers and from 4.8 to 28 µg/m³ for truck mechanics, depending on weather conditions (Zaebst et al., 1991).

Because these exposure averages, unlike those for railroad workers and miners, were reported in terms of EC, it is necessary, for purposes of comparison, to convert them to estimates of total dpm. Watts (1995) states that "elemental carbon generally accounts for about 40% to 60% of diesel particulate mass." Therefore, in earlier versions of this risk assessment, a 2.0 conversion factor was assumed for dock workers, truck drivers, and truck mechanics, based on the midpoint of the 40–60% range proposed by Watts.

Some commenters objected to MSHA's use of this conversion factor. IMC Global, for example, asserted that Watts' "* * * 40 to 60% relationship between elemental carbon and diesel particulate mass * * * applies only to underground coal mines where diesel haulage equipment is used." IMC Global, and other commenters, also objected to MSHA's use of a single conversion factor for "* * * different types of diesel engines under different duty cycles with different fuels and different types of emission control devices (if any) subjected to varying degrees of maintenance."

MSHA's quotation from Watts (1995) was taken from the "Summary" section of his paper. That paper covers a variety of occupational environments, and the summary makes no mention of coal mines. The sentence immediately preceding the quoted passage refers to the "occupational environment" in general, and there is no indication that Watts meant to restrict the 40- to 60-percent range to any specific environment. It seems clear that the 40- to 60-percent range refers to average values across a spectrum of occupational environments.

IMC Global mistakenly attributed to MSHA "the blanket statement" that the same ratio of elemental carbon to dpm applies "for all diesel engines in different industries for all patterns of use." MSHA made no such statement. On the contrary, MSHA agrees with Watts (and IMC Global) that "the percentage of elemental carbon in total diesel particulate matter fluctuates" depending on "engine type, duty cycle, fuel, lube oil consumption, state of engine maintenance, and the presence or absence of an emission control device." (Watts, op cit.) Indeed, MSHA acknowledges that, because of these factors, the percentage on a particular day in a particular environment may frequently fall outside the stated range. But MSHA is not applying a single conversion factor to individual elemental carbon measurements and claiming knowledge of the total dpm corresponding to each separate measurement. Instead, MSHA is applying an average conversion factor to an average of measurements in order to derive an estimate of an average dpm exposure. Averages are always less widely dispersed than individual values.

[13] Median concentrations were not reported. The geometric mean provides a smoothed estimate of the median.

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Still, MSHA agrees with IMC Global that better estimates of dpm exposure levels are attainable by applying conversion factors more specifically related to the separate categories within the trucking industry: dock workers, truck drivers, and truck mechanics. Based on a total of 63 field measurements, the mean ratios (in percent) of EC to total carbon (TC) reported for these three categories were 47.3, 36.6, and 34.2, respectively (Zaebst et al., 1991).[14] As explained elsewhere in this preamble, TC amounts to approximately 80 percent, by weight, of total dpm. Therefore, each of these ratios must be multiplied by 0.8 in order to estimate the corresponding percentage of EC in dpm.

It follows that the median mass concentration of dpm can be estimated as 2.64 (i.e., 1/(0.473×0.8)) times the geometric mean EC reported for dock workers, 3.42 times the geometric mean EC for truck drivers, and 3.65 times the geometric mean EC for truck mechanics. Applying the 2.64 conversion factor to the range of geometric mean EC concentrations reported for dock workers (i.e, 23 to 55 μg/m³) results in an estimated range of 61 to 145 μg/m³ in median dpm concentrations at various docks. Similarly, the estimated range of median dpm concentrations is calculated to be 6.8 to 24 μg/m³ for truck drivers and 18 to 102 μg/m³ for truck mechanics. It should be noted that MSHA is using conversion factors only for those occupational groups whose geometric mean exposures have been reported in terms of EC measurements.

Average exposures of railroad workers to dpm were estimated by Woskie et al. (1988) and Schenker et al. (1990). As measured by total respirable particulate matter other than cigarette smoke, Woskie et al. reported geometric mean concentrations for various occupational categories of exposed railroad workers ranging from 49 to 191 μg/m³.

For comparison with the exposures reported for these other industries, median dpm exposures measured within sampled mines were calculated directly from the data described in subsections a, b, and c above. The median within each mine is shown as the horizontal "belt" plotted for the mine in Figures III–1, III–2, and III–3.

Figure III–4 compares the range of median dpm concentrations observed for mine workers within different mines to a range of dpm exposure levels estimated for urban ambient air and to the ranges of median dpm concentrations estimated for loading dock workers operating or otherwise exposed to diesel fork lift trucks, truck drivers, truck mechanics, and railroad workers. The range for ambient air, 1 to 10 μg/m³, was obtained from Cass and Gray (1995). For dock workers, truck drivers, truck mechanics, and railroad workers, the estimated ranges of median dpm exposures are, respectively: 61 to 145 μg/m³, 6.8 to 24 μg/m³, 18 to 102 μg/m³ and 49 to 191 μg/m³. The range of median dpm concentrations observed at different underground coal mines is 55 to 2100 μg/m³, with filters employed at mines showing the lower concentrations.[15] For underground M/NM mines, the corresponding range is 68 to 1835 μg/m³, and for surface mines it is 19 to 160 μg/m³. Since each range plotted is a range of median values or (for ambient air) mean values, the plots do not encompass all of the individual measurements reported.

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[14] MSHA calculated the ratio for truck drivers by taking a weighted average of the ratios reported for "local drivers" and "road drivers."

[15] One commenter misinterpreted the tops of the ranges plotted in Figure III–4. This commenter apparently mistook the top of the range depicted for underground coal mines as the mean or median dpm exposure concentration measured across all underground coal mines. The top of this range (at 2100 μg/m³, actually represents the highest median concentration at any of the coal mines sampled. It corresponds to the "belt" plotted for Mine "G" (with no after-filters) in Figure III–1. The bottom of the same bar, at 55 μg/m³, corresponds to the "belt" plotted for Mine H* (with after-filters) in Figure III–1.

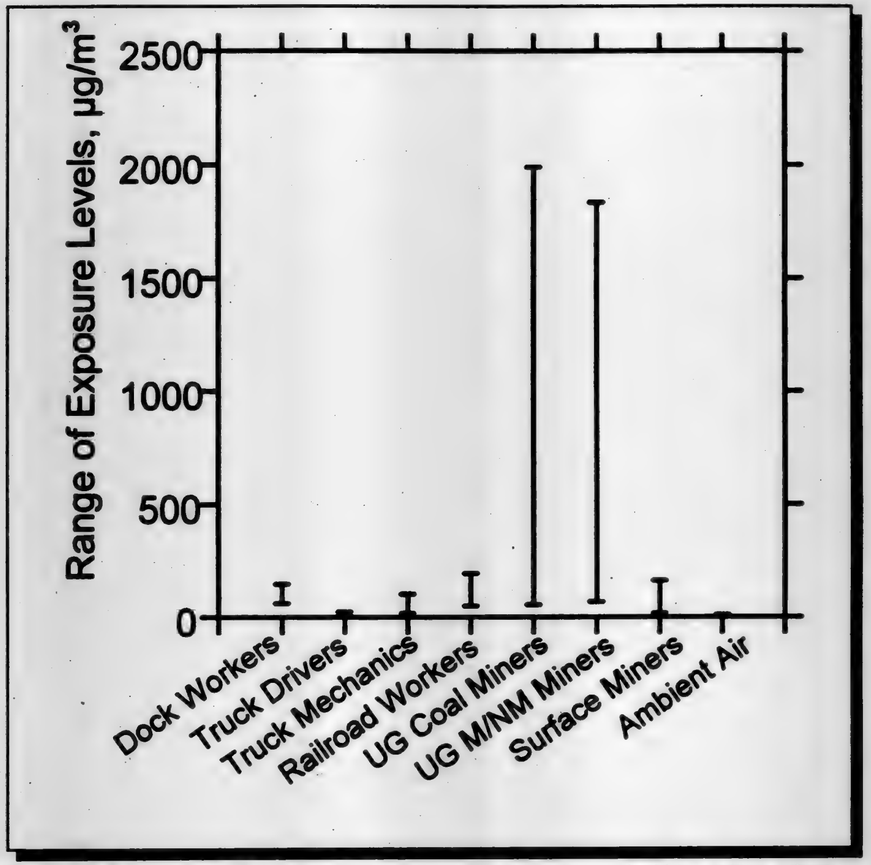


Figure III-4. — Range of median dpm exposure levels observed within various mines for underground and surface miners compared to range of median Dpm exposure levels estimated for other occupations. Range of dpm exposure levels for ambient air is for urban environments only and is based on the monthly mean for different months and locations in Southern California. Range for ambient air is roughly 1 to 10 $\mu g/m^3$.

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As shown in Figure III–4, some miners are exposed to far higher concentrations of dpm than are any other populations for which exposure data have been reported. Indeed, median dpm concentrations observed in some underground mines are up to 200 times as high as mean environmental exposures in the most heavily polluted urban areas,[16] and up to 10 times as high as median exposures estimated for the most heavily exposed workers in other occupational groups.

Several commenters objected to Figure III–4 and, more generally, to MSHA's comparison of dpm exposure levels for miners against the levels reported for other occupations. The objections to MSHA's method of estimating ranges of median dpm exposure for job categories within the trucking industry have already been discussed and addressed above. Other objections to the comparison were based on claims of insufficient accuracy in the RCD and gravimetric size selective measurements MSHA used to measure dpm levels for miners. MSHA considers its use of these methods appropriate for purposes of this comparison and has responded to criticisms of the dpm measurements for miners in Subsections 1.a and 1.b of this risk assessment.[17]

Some commenters objected to MSHA's basing a characterization of dpm exposures to miners on data spanning a ten-year period. These commenters contended that, in at least some M/NM mines, dpm levels had improved substantially during that period. No data were submitted, however, to support the premise that dpm exposures throughout the mining industry have declined to the levels reported for other occupations. As stated in the proposal and emphasized above, MSHA's dpm measurements were not technically designed as a random or statistically representative sample of the industry. They do show, however, that very high exposures have recently occurred in some mines. For example, as shown in Figure III–2, more than 25 percent of MSHA's dpm measurements exceeded 2000 $\mu g/m^3$ at underground M/NM mines "U" and "Z"—and these measurements were made in 1996–7. In M/NM mines where exposures are actually commensurate with other industries already, little or nothing would need to be changed to meet the exposure limits.

IMC Global further objected to Figure III–4 on the grounds that "* * * the assumptions that MSHA used to develop that figure are grossly inaccurate and do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure." IMC Global suggested that the comparison in Figure III–4 be deleted for this reason. MSHA believes that the comparison is informative and that empirical evidence should be used, when it is available, even though the evidence was not generated under ideal, theoretical dose-response model conditions. The issue of whether Figure III–4 is consistent with an exposure-response relationship for dpm is addressed in Subsection 3.a.iii(4) of this risk assessment.

2. Health Effects Associated With DPM Exposures

This section reviews the various health effects (of which MSHA is aware) that may be associated with dpm exposures. The review is divided into three main sections: acute effects, such as diminished pulmonary function and eye irritation; chronic effects, such as lung cancer; and mechanisms of toxicity. Prior to that review, however, the relevance of certain types of information will be considered. This discussion will address the relevance of health effects observed in animals, health effects that are reversible, and health effects associated with fine particulate matter in the ambient air.

Several commenters described medical surveillance studies that NIOSH and/or the former Bureau of Mines had carried out in the late 1970s and early 1980s on underground miners employed in western, dieselized coal mines. These commenters urged MSHA to make these studies available and to consider the results in this rulemaking. Some of these commenters also suggested that these data would provide a useful baseline for pulmonary function and lung diseases among miners exposed to dpm, and recommended that follow-up examinations now be conducted to evaluate the possible effects of chronic dpm exposure.

In response to such comments presented at some of the public hearings, another commenter wrote:

> First of all, MSHA is not a research agency, it is a regulatory agency, so that it would be inappropriate for MSHA to initiate research. MSHA did request that NIOSH conduct a risk assessment on the health effects of diesel exhaust and encouraged NIOSH and is currently collaborating with NIOSH (and NCI) on research of other underground miners exposed to diesel exhaust. And third, research on the possible carcinogenicity of diesel particulate matter was not undertaken on coal miners in the West or anywhere else because of the confounding exposure to crystalline silica, also considered a carcinogen, because too few coal miners have been exposed, and for too short a time to conduct a valid study. It was not arbitrariness or indifference on MSHA's part that it did not initiate research on coal miners; it was not within their mandate and it is inappropriate in any event. [UMWA]

Three reports summarizing and presenting results from these medical surveillance studies related to dpm exposures in coal mines were, in fact, utilized and cited in the proposed risk assessment (Ames et al., 1982; Reger et al., 1982; Ames et al., 1984). Ames et al. (1982) evaluated acute respiratory effects, and their results are considered in Subsection 2.b.ii of this risk assessment. Reger et al. (1982) and Ames et al. (1984) evaluated chronic effects, and their results are considered in Subsection 2.c.i(1).

A fourth report (Glenn et al., 1983) summarized results from the overall research program of which the coal mine studies were a part. This health and environmental research program included not only coal miners, but also workers at potash, trona, salt, and metal mines. All subjects were given chest radiographs and spirometric tests and were questioned about respiratory symptoms, smoking and occupational history. In conjunction with these medical evaluations, industrial hygiene surveys were conducted to characterize the mine environments where diesel equipment was used. Diesel exhaust exposure levels were characterized by area and personal samples of NO_2 (and, in some cases, additional gasses), aldehydes, and both respirable and total dust. For the evaluations of acute effects, exposure measures were based on the shift concentrations to which the examined workers were exposed. For the evaluations of chronic effects, exposures were usually estimated by summing the products of time spent in various locations by each miner by concentrations estimated for the various locations. Results of studies on acute effects in salt mines were reported by Gamble et al. (1978) and are considered in Subsection 2.b.ii of this risk assessment. Attfield (1979), Attfield et al. (1982), and Gamble et al. (1983) evaluated effects in M/NM mines, and their results are considered in Subsection 2.c.i(1). The general summary provided by Glenn et al. (1983) was among the reports that one commenter (MARG) listed as having received inadequate attention in the proposed risk assessment. In that context, the general results summarized in this report are discussed, under the heading of "Counter-Evidence," in Subsection 2.c.i(2)(a) of this risk assessment.

a. Relevancy Considerations

i. Animal Studies. Since the lungs of different species may react differently to particle inhalation, it is necessary to treat the results of animal studies with some caution. Evidence from animal studies can nevertheless be valuable—both in helping to identify potential human health hazards and in providing a means for studying toxicological mechanisms. Respondents to MSHA's ANPRM who addressed the question of relevancy urged consideration of all animal studies related to the health effects of diesel exhaust.

Unlike humans, laboratory animals are bred to be homogeneous and can be randomly selected for either non-exposure or exposure to varying levels of a potentially toxic agent. This permits setting up experimental and control groups of animals that exhibit relatively little biological variation prior to exposure. The consequences of exposure can then be determined by comparing responses in the experimental and control groups. After a prescribed duration of deliberate exposure, laboratory animals can also be sacrificed, dissected, and examined. This can contribute to an understanding of mechanisms by which inhaled particles may exert their effects on health. For this reason, discussion of the animal evidence is placed in the section entitled "Mechanisms of Toxicity" below.

Animal evidence also can help isolate the cause of adverse health effects observed among humans exposed to a variety of potentially hazardous substances. If, for example, the epidemiologic data are unable to distinguish between several possible causes of increased risk of disease in a certain population, then controlled animal studies may provide evidence useful in suggesting the most likely explanation—and provide that information years in advance of definitive evidence from human observations.

Furthermore, results from animal studies may also serve as a check on the credibility of observations from epidemiologic studies of human populations. If a particular health effect is observed in animals under controlled laboratory conditions, this tends to corroborate observations of similar effects in humans.

One commenter objected to MSHA's reference to using animal studies as a "check" on epidemiologic studies. This commenter emphasized that animal studies provide far more than just corroborative information and that researchers use epidemiologic and animal studies "* * * to help understand different aspects of the carcinogenic process." [18] MSHA does not dispute the utility of animal studies in helping to provide an understanding of toxicological processes and did not intend to belittle their importance for this purpose. In fact, MSHA places the bulk of its discussion of these studies in a section entitled "Mechanisms of Toxicity." However, MSHA considers the use of animal studies for corroborating epidemiologic associations to be also important—especially with respect to ruling out potential confounding effects and helping to establish causal linkages. Animal studies make possible a degree of experimental design and statistical rigor that is not attainable in human studies.

Other commenters disputed the relevance of at least some animal data to human risk assessment. For example, The West Virginia Coal Association indicated the following comments by Dr. Peter Valberg:

> * * * scientists and scientific advisory groups have treated the rat bioassay for inhaled particles as unrepresentative of human lung-cancer risks. For example, the Presidential/Congressional Commission on Risk Assessment and Risk Management ("CCRARM") noted that the response of rat lungs to inhaled particulate in general is not likely to be predictive of human cancer risks. More specific to dpm, the Clean Air Scientific Advisory Committee ("CASAC"), a peer-review group for the U.S. EPA, has commented on two drafts (1995 and 1998) of the EPA's Health Assessment Document on Diesel Exhaust. On both occasions, CASAC emphasized that the data from rats are not relevant for human risk assessment. Likewise, the Health Effects Institute also has concluded that rat data should not be used for assessing human lung cancer risk.

Similarly, the NMA commented that the 1998 CASAC review "makes it crystal clear that the rat studies cited by MSHA should not be relied upon as legitimate indicators of the carcinogenicity of Dpm in humans." The Nevada Mining Association, endorsing Dr. Valberg's comments, added:

> * * * to the extent that MSHA wishes to rest its case on rat studies, Dr. Valberg, among others, has impressively demonstrated that these studies are worthless for human comparison because of rats' unique and species-specific susceptibility to inhaled insoluble particles.

However, neither Dr. Valberg nor the Nevada Mining Association provided evidence that rats' susceptibility to inhaled insoluble particles was "unique" and that humans, for example, were not also susceptible to lung overload at sufficiently high concentrations of fine particles. Even if (as has apparently been demonstrated) some species (such as hamsters) do not exhibit susceptibility similar to rats, this by no means implies that rats are the only species exhibiting such susceptibility.

These commenters appear at times to be saying that, because studies of lung cancer in rats are (in the commenters' view) irrelevant to humans, MSHA should completely ignore all animal studies related to dpm. To the extent that this was the position advocated, the commenters' line of reasoning neglects several important points:

1. The animal studies under consideration are not restricted to studies of lung cancer responses in rats. They include studies of bioavailability and metabolism as well as studies of immunological and genotoxic responses in a variety of animal species.

2. The context for the determinations cited by Dr. Valberg was risk assessment at ambient levels, rather than the much higher dpm levels to which miners are exposed. The 1995 HEI report to which Dr. Valberg alludes acknowledged a potential mechanism of lung overload in humans at dpm concentrations exceeding 500 $\mu g/m^3$ (HEI, 1995). Since miners may concurrently be exposed to concentrations of mineral dusts significantly exceeding 500 $\mu g/m^3$, evidence related to the consequences of lung overload has special significance for mining environments.

3. The scientific authorities cited by Dr. Valberg and other commenters objected to using existing animal studies for quantitative human risk assessment. MSHA has not proposed doing that. There is an important distinction between extrapolating results from the rat studies to human populations and using them to confirm epidemiologic findings and to identify and explore potential mechanisms of toxicity.

[16] It should be noted, however, that 24-hour environmental exposures for a full lifetime are not directly comparable with workday exposures over an occupational lifetime. If it is assumed that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day, then the amount of air inhaled over the course of a 70-year lifetime is approximately 4.7 times the amount inhaled over a 45-year occupational lifetime with 240 working days per year.

[17] One commenter pointed out that the measurements for miners included both area and personal samples but provided no evidence that this would invalidate the comparison. As pointed out in Subsections 1.a and 1.b, area samples did not dominate the upper end of MSHA's dpm measurements. Furthermore, Figure III–4 presents a comparison of medians rather than means or individual measurements, so inclusion of the area samples has very little impact on the results.

[18] This risk assessment is not limited to cancer effects, but the commenter's point can be generalized.

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MSHA by no means "wishes to rest its case on rat studies," and it has no intention of doing so. MSHA does believe, however, that judicious consideration of evidence from animal studies is appropriate. The extent to which MSHA utilizes such evidence to help draw specific conclusions will be clarified below in connection with those conclusions.

ii. *Reversible Health Effects.* Some reported health effects associated with dpm are apparently reversible—*i.e.*, if the worker is moved away from the source for a few days, the symptoms dissipate. A good example is eye irritation.

In response to the ANPRM, questions were raised as to whether so-called "reversible" effects can constitute a "material" impairment. For example, a predecessor constituent of the National Mining Association (NMA) argued that "it is totally inappropriate for the agency to set permissible exposure limits based on temporary, reversible sensory irritation" because such effects cannot be a "material" impairment of health or functional capacity within the definition of the Mine Act (American Mining Congress, 87–0–21, Executive Summary, p. 1, and Appendix A).

MSHA does not agree with this categorical view. Although the legislative history of the Mine Act is silent concerning the meaning of the term "material impairment of health or functional capacity," and the issue has not been litigated within the context of the Mine Act, the statutory language about risk in the Mine Act is similar to that under the OSH Act. A similar argument was dispositively resolved in favor of the Occupational Safety and Health Administration (OSHA) by the 11th Circuit Court of Appeals in *AFL–CIO* v. *OSHA*, 965 F.2d 962, 974 (1992).

In that case, OSHA proposed new limits on 428 diverse substances. It grouped these into 18 categories based upon the primary health effects of those substances: *e.g.*, neuropathic effects, sensory irritation, and cancer. (54 FR 2402). Challenges to this rule included the assertion that a "sensory irritation" was not a "material impairment of health or functional capacity" which could be regulated under the OSH Act. Industry petitioners argued that since irritant effects are transient in nature, they did not constitute a "material impairment." The Court of Appeals decisively rejected this argument.

The court noted OSHA's position that effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and be seriously disabling in some cases. Moreover, there was evidence that workers exposed to these sensory irritants could be distracted as a result of their symptoms, thereby endangering other workers and increasing the risk of accidents. (*Id.* at 974). This evidence included information from NIOSH about the general consequences of sensory irritants on job performance, as well as testimony by commenters on the proposed rule supporting the view that such health effects should be regarded as material health impairments. While acknowledging that "irritation" covers a spectrum of effects, some of which can be minor, OSHA had concluded that the health effects associated with exposure to these substances warranted action—to ensure timely medical treatment, reduce the risks from increased absorption, and avoid a decreased resistance to infection (*Id* at 975). Finding OSHA's evaluation adequate, the Court of Appeals rejected petitioners' argument and stated the following:

> We interpret this explanation as indicating that OSHA finds that although minor irritation may not be a material impairment, there is a level at which such irritation becomes so severe that employee health and job performance are seriously threatened, even though those effects may be transitory. We find this explanation adequate. OSHA is not required to state with scientific certainty or precision the exact point at which each type of sensory or physical irritation becomes a material impairment. Moreover, section 6(b)(5) of the Act charges OSHA with addressing all forms of "material impairment of health or functional capacity," and not exclusively "death or serious physical harm" or "grave danger" from exposure to toxic substances. See 29 U.S.C. 654(a)(1), 655(c). [*Id.* at 974].

In its comments on the proposed rule, the NMA claimed that MSHA had overstated the court's holding. In making this claim, the NMA attributed to MSHA an interpretation of the holding that MSHA did not put forth. In fact, MSHA agrees with the NMA's interpretation as stated in the following paragraph and takes special note of the NMA's acknowledgment that transitory or reversible effects can sometimes be so severe as to seriously threaten miners' health and safety:

> NMA reads the Court's decision to mean (as it stated) that "minor irritation may not be a material impairment" * * * but that irritation can reach "a level at which [it] becomes so severe that employee health and job performance are seriously threatened even though those effects may be transitory." * * * AMC in 1992 and NMA today are fully in accord with the view of the 11th Circuit that when health effects, transitory or otherwise, become so "severe" as to "seriously threaten" a miner's health or job performance, the materiality threshold has been met.

The NMA, then, apparently agrees with MSHA that sensory irritations and respiratory symptoms can be so severe that they cross the material impairment threshold, regardless of whether they are "reversible." Therefore, as MSHA has maintained, such health effects are highly relevant to this risk assessment—especially since impairments of a miner's job performance in an underground mining environment could seriously threaten the safety of both the miner and his or her co-workers. Sensory irritations may also impede miners' ability to escape during emergencies.

The NMA, however, went on to emphasize that "* * * federal appeals courts have held that 'mild discomfort' or even 'moderate irritation' do not constitute 'significant' or 'material' health effects":

> In International Union v. Pendergrass, 878 F. 2d 389 (1989), the D.C. Circuit upheld OSHA's formaldehyde standard against a challenge that it did not adequately protect against significant noncarcinogenic health effects, even though OSHA had found that, at the permissible level of exposure, "20% of workers suffer 'mild discomfort', while 30% more experience 'slight discomfort'." *Id.* at 398. Likewise, in Texas Independent Ginners Ass'n. v. Marshall, 630 F. 2d 398 (1980), the Fifth Circuit Court of Appeals held that minor reversible symptoms do not constitute material impairment unless OSHA shows that those effects might develop into chronic disease. *Id.* at 408–09.

MSHA is fully aware of the distinction that courts have made between mild discomfort or irritation and transitory health effects that can seriously threaten a miner's health and safety. MSHA's position, after reviewing the scientific literature, public testimony, and comments, is that all of the health effects considered in this risk assessment fall into the latter category.

iii. Health Effects Associated with $PM_{2.5}$ in Ambient Air. There have been many studies in recent years designed to determine whether the mix of particulate matter in ambient air is harmful to health. The evidence linking particulates in air pollution to health problems has long been compelling enough to warrant direction from the Congress to limit the concentration of such particulates (see part II, section 5 of this preamble). In recent years, the evidence of harmful effects due to airborne particulates has increased, suggesting that "fine" particulates (*i.e.*, particles less than 2.5 μm in diameter) are more strongly associated than "coarse" respirable particulates (*i.e.*, particles greater than 2.5 μm but less than 10 μm in diameter) with the adverse health effects observed (EPA, 1996).

MSHA recognizes that there are two difficulties involved in utilizing the evidence from such studies in assessing risks to miners from occupational dpm exposures. First, although dpm is a fine particulate, ambient air also contains fine particulates other than dpm. Therefore, health effects associated with exposures to fine particulate matter in air pollution studies are not associated specifically with exposures to dpm or any other one kind of fine particulate matter. Second, observations of adverse health effects in segments of the general population do not necessarily apply to the population of miners. Since, due to age and selection factors, the health of miners differs from that of the public as a whole, it is possible that fine particles might not affect miners, as a group, to the same degree as the general population.

Some commenters reiterated these two points, recognized by MSHA in the proposal, without addressing MSHA's stated reasons for including health effects associated with fine particulates in this risk assessment. There are compelling reasons why MSHA considered this body of evidence in this rulemaking.

Since dpm is a type of respirable particle, information about health effects associated with exposures to respirable particles, and especially to fine particulate matter, is certainly relevant, even if difficult to apply directly to dpm exposures. Adverse health effects in the general population have been observed at ambient atmospheric particulate concentrations well below the dpm concentrations studied in occupational settings. The potency of dpm differs from the total fine particulate found in ambient air. This makes it difficult to establish a specific exposure-response relationship for dpm that is based on fine particle results. However, this does not mean that these results should be ignored in a dpm risk assessment. The available evidence of adverse health effects associated with fine particulates is still highly relevant for dpm hazard identification. Furthermore, as shown in Subsection 3.c.ii of this risk assessment, the fine particle research findings can be used to construct a rough exposure-response relationship for dpm, showing significantly increased risks of material impairment among exposed miners. MSHA's estimates are based on the best available epidemiologic evidence and show risks high enough to warrant regulatory action.

Moreover, extensive scientific literature shows that occupational dust exposures contribute to the development of Chronic Obstructive Pulmonary Diseases (COPD), thereby compromising the pulmonary reserve of some miners. Miners experience COPD at a significantly higher rate than the general population (Becklake 1989, 1992; Oxman 1993; NIOSH 1995). In addition, many miners also smoke tobacco. This places affected miners in subpopulations specifically identified as susceptible to the adverse health effects of respirable particle pollution (EPA, 1996). Some commenters (*e.g.*, MARG) repeated MSHA's observation that the population of miners differs from the general population but failed to address MSHA's concern for miners' increased susceptibility due to COPD incidence and/or smoking habits. The Mine Act requires that standards "* * * most adequately assure on the basis of the best available evidence that *no miner* suffer material impairment of health or functional capacity * * *" (Section 101(a)(6), emphasis added). This most certainly authorizes MSHA to protect miners who have COPD and/or smoke tobacco.

MARG also submitted the opinion that if "* * * regulation of fine particulate matter is necessary, it [MSHA] should propose a rule dealing specifically with the issue of concern, rather than a rule that limits total airborne carbon or arbitrarily singles out diesel exhaust * * *." MSHA's concern is not with "total airborne carbon" but with dpm, which consists mostly of submicrometer airborne carbon. At issue here, however, are the adverse health effects associated with dpm exposure. Dpm is a type of fine particulate, and there is no evidence to suggest that the dpm fraction contributes less than other fine particulates to adverse health effects linked to exposures in ambient air.

For this reason, and because miners may be especially susceptible to fine particle effects, MSHA has concluded, after considering the public comments, that the body of evidence from air pollution studies is highly relevant to this risk assessment. The Agency is, therefore, taking that evidence fully into account.

b. Acute Health Effects

Information pertaining to the acute health effects of dpm includes anecdotal reports of symptoms experienced by exposed miners, studies based on exposures to diesel emissions, and studies based on exposures to particulate matter in the ambient air. These will be discussed in turn. Subsection 2.a.iii of this risk assessment addressed the relevance to dpm of studies based on exposures to particulate matter in the ambient air.

Only the evidence from human studies will be addressed in this section. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Section 3.a and 3.b contain MSHA's interpretation of the evidence relating dpm exposures to acute health hazards.

i. Symptoms Reported by Exposed Miners. Miners working in mines with diesel equipment have long reported adverse effects after exposure to diesel exhaust. For example, at the dpm workshops conducted in 1995, a miner reported headaches and nausea experienced by several operators after short periods of exposure (dpm Workshop; Mt. Vernon, IL, 1995). Another miner reported that smoke from poorly maintained equipment, or from improper fuel use, irritates the eyes, nose, and throat. "We've had people sick time and time again * * * at times we've had to use oxygen for people to get them to come back around to where they can feel normal again." (dpm Workshop; Beckley, WV, 1995). Other miners (dpm Workshops; Beckley, WV, 1995; Salt Lake City, UT, 1995), reported similar symptoms in the various mines where they worked.

At the 1998 public hearings on MSHA's proposed dpm rule for coal mines, one miner, with work experience in a coal mine utilizing diesel haulage equipment at the face, testified that

> * * * unlike many, I have not experienced the headaches, the watering of the eyes, the cold-like symptoms and walking around in this cloud of smoke. Maybe it's because of the maintenance programs. Maybe it's because of complying with ventilation. * * * after 25 years, I have not shown any effects. [SLC, 1998].

Other miners working at dieselized coal mines testified at those hearings that they had personally experienced eye irritation and/or respiratory ailments immediately after exposure to diesel exhaust, and they attributed these ailments to their exposure. For example, one miner attributed a case of pneumonia to a specific episode of unusually high exposure. (Birm., 1998) The safety and training manager of the mining company involved noted that "there had been a problem recognized in review with that exhaust system on that particular piece of equipment" and that the pneumonia may have developed due to "idiosyncracy of his lungs that respond to any type of a respiratory irritant." The manager suggested that this incident should not

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be generalized to other situations but provided no evidence that the miner's lungs were unusually susceptible to irritation.[19]

Another miner, who had worked at the same underground mine before and after diesel haulage equipment was introduced, indicated that he and his co-workers began experiencing acute symptoms after the diesel equipment was introduced. This miner suggested that these effects were linked to exposure, and referring to a co-worker stated:

* * * had respiratory problems, after * * * diesel equipment was brought into that mine—he can take off for two weeks vacation, come back—after that two weeks, he felt pretty good, his respiratory problems would straighten up, but at the very instant that he gets back in the face of diesel-powered equipment, it starts up again, his respiratory problems will flare up again, coughing, sore throat, numerous problems in his chest. (Birm., 1998).

Several other underground miners asserted there was a correlation between diesel exposure levels and the frequency and/or intensity of respiratory symptoms, eye irritations, and chest ailments. One miner, for example, stated:

I've experienced [these symptoms] myself. * * * other miners experience the same kind of distresses * * * Some of the stresses you actually can feel—you don't need a gauge to measure this—your burning eyes, nose, throat, your chest irritation. The more you're exposed to, the higher this goes. This includes headaches and nausea and some lasting congestion, depending on how long you've been exposed per shift or per week.

The men I represent have experienced more cold-like symptoms, especially over the past, I would say, eight to ten years, when diesel has really peaked and we no longer really use much of anything else. [SLC, 1998].

Kahn et al. (1988) conducted a study of the prevalence and seriousness of such complaints, based on United Mine Workers of America records and subsequent interviews with the miners involved. The review involved reports at five underground coal mines in Utah and Colorado between 1974 and 1985. Of the 13 miners reporting symptoms: 12 reported mucous membrane irritation, headache and light-headiness; eight reported nausea; four reported heartburn; three reported vomiting and weakness, numbness, and tingling in extremities; two reported chest tightness; and two reported wheezing (although one of these complained of recurrent wheezing without exposure). All of these incidents were severe enough to result in lost work time due to the symptoms (which subsided within 24 to 48 hours).

In comments submitted for this rulemaking, the NMA pointed out, as has MSHA, that the evidence presented in this subsection is anecdotal. The NMA, further, suggested that the cited article by Kahn et al. typified this kind of evidence in that it was "totally devoid of any correlation to actual exposure levels." A lack of concurrent exposure measurements is, unfortunately, not restricted to anecdotal evidence; and MSHA must base its evaluation on the available evidence. MSHA recognizes the scientific limitations of anecdotal evidence and has, therefore, compiled and considered it separately from more formal evidence. MSHA nevertheless considers such evidence potentially valuable for identifying acute health hazards, with the understanding that confirmation requires more rigorous investigation.[20]

With respect to the same article (Kahn et al., 1988), and notwithstanding the NMA's claim that the article was totally devoid of any correlation to exposure levels, the NMA also stated that MSHA:

* * * neglects to include in the preamble the article's description of the conditions under which the "overexposures" occurred, *e.g.*, "poor engine maintenance, poor maintenance of emission controls, prolonged idling of machinery, engines pulling heavy loads, use of equipment during times when ventilation was disrupted (such as during a move of longwall machinery), use of several pieces of equipment exhausting into the fresh-air intake, and use of poor quality fuel.

The NMA asserted that these conditions, cited in the article, "have been addressed by MSHA's final standards for diesel equipment in underground coal mines issued October 25, 1996." [21] Furthermore, despite its reservations about anecdotal evidence:

NMA is mindful of the testimony of several miners in the coal proceeding who complained of transient irritation owing to exposure to diesel exhaust * * * the October 1996 regulations together with the phased-in introduction of catalytic converters on all outby equipment and the introduction of such devices on permissible equipment when such technology becomes available will address the complaints raised by the miners.

The NMA provided no evidence, however, that elimination of the conditions described by Kahn et al., or implementation of the 1996 diesel regulations for coal mines, would reduce dpm levels sufficiently to prevent the sensory irritations and respiratory symptoms described. Nor did the NMA provide evidence that these are the only conditions under which complaints of sensory irritations and respiratory symptoms occur, or explain why eliminating them would reduce the need to prevent excessive exposure under other conditions.

In the proposal for the present rule, MSHA requested additional information about such effects from medical personnel who have treated miners. IMC Global submitted letters from four healthcare practitioners in Carlsbad, NM, including three physicians. None of these practitioners attributed any cases of respiratory problems or other acute symptoms to dpm exposure. Three of the four practitioners noted that they had observed respiratory symptoms among exposed miners but attributed these symptoms to chronic lung conditions, smoking, or other factors. One physician stated that "[IMC Global], which has used diesel equipment in its mining operations for over 20 years, has never experienced a single case of injury or illness caused by exposures to diesel particulates."

ii. Studies Based on Exposures to Diesel Emissions. Several experimental and statistical studies have been conducted to investigate acute effects of exposure to diesel emissions. These more formal studies provide data that are more scientifically rigorous than the anecdotal evidence presented in the preceding subsection. Unless otherwise indicated, diesel exhaust exposures were determined qualitatively.

In a clinical study (Battigelli, 1965), volunteers were exposed to three concentrations of diluted diesel exhaust and then evaluated to determine the effects of exposure on pulmonary resistance and the degree of eye irritation. The investigators stated that "levels utilized for these controlled exposures are comparable to realistic values such as those found in railroad shops." No statistically significant change in pulmonary function was detected, but exposure for ten minutes to diesel exhaust diluted to the middle level produced "intolerable" irritation in some subjects while the average irritation score was midway between "some" irritation and a "conspicuous but tolerable" irritation level. Diluting the concentration by 50% substantially reduced the irritation. At the highest exposure level, more than 50 percent of the volunteers discontinued the experiment before 10 minutes because of "intolerable" eye irritation.

A study of underground iron ore miners exposed to diesel emissions found no difference in spirometry measurements taken before and after a work shift (Jörgensen and Svensson 1970). Similarly, another study of coal miners exposed to diesel emissions detected no statistically significant relationship between exposure and changes in pulmonary function (Ames et al. 1982). However, the authors noted that the lack of a statistically significant result might be due to the low concentrations of diesel emissions involved.

Gamble et al. (1978) observed decreases in pulmonary function over a single shift in salt miners exposed to diesel emissions. Pulmonary function appeared to deteriorate in relation to the concentration of diesel exhaust, as indicated by NO_2; but this effect was confounded by the presence of NO_2 due to the use of explosives.

Gamble et al. (1987a) assessed response to diesel exposure among 232 bus garage workers by means of a questionnaire and before- and after-shift spirometry. No significant relationship was detected between diesel exposure and change in pulmonary function. However, after adjusting for age and smoking status, a significantly elevated prevalence of reported symptoms was found in the high-exposure group. The strongest associations with exposure were found for eye irritation, labored breathing, chest tightness, and wheeze. The questionnaire was also used to compare various acute symptoms reported by the garage workers and a similar population of workers at a lead acid battery plant who were not exposed to diesel fumes. The prevalence of work-related eye irritations, headaches, difficult or labored breathing, nausea, and wheeze was significantly higher in the diesel bus garage workers, but the prevalence of work-related sneezing was significantly lower.

Ulfvarson et al. (1987) studied effects over a single shift on 47 stevedores exposed to dpm at particle concentrations ranging from 130 $\mu g/m^3$ to 1000 $\mu g/m^3$. Diesel particulate concentrations were determined by collecting particles on glass fiber filters of unspecified efficiency. A statistically significant loss of pulmonary function was observed, with recovery after 3 days of no occupational exposure.

To investigate whether removal of the particles from diesel exhaust might reduce the "acute irritative effect on the lungs" observed in their earlier study, Ulfvarson and Alexandersson (1990) compared pulmonary effects in a group of 24 stevedores exposed to unfiltered diesel exhaust to a group of 18 stevedores exposed to filtered exhaust, and to a control group of 17 occupationally unexposed workers. The filters used were specially constructed from 144 layers of glass fiber with "99.97% degrees of retention of dioctylphthalate mist with particle size 0.3 µm." Workers in all three groups were nonsmokers and had normal spirometry values, adjusted for sex, age, and height, prior to the experimental workshift.

In addition to confirming the earlier observation of significantly reduced pulmonary function after a single shift of occupational exposure, the study found that the stevedores in the group exposed only to filtered exhaust had 50–60% less of a decline in forced vital capacity (FVC) than did those stevedores who worked with unfiltered equipment. Similar results were observed for a subgroup of six stevedores who were exposed to filtered exhaust on one shift and unfiltered exhaust on another. No loss of pulmonary function was observed for the unexposed control group. The authors suggested that these results "support the idea that the irritative effect of diesel exhausts [sic] to the lungs is the result of an interaction between particles and gaseous components and not of the gaseous components alone." They concluded that "* * * it should be a useful practice to filter off particles from diesel exhausts in work places even if potentially irritant gases remain in the emissions" and that "removal of the particulate fraction by filtering is an important factor in reducing the adverse effect of diesel exhaust on pulmonary function."

Rudell et al. (1996) carried out a series of double-blind experiments on 12 healthy, non-smoking subjects to investigate whether a particle trap on the tailpipe of an idling diesel engine would reduce acute effects of diesel exhaust, compared with exposure to unfiltered exhaust. Symptoms associated with exposure included headache, dizziness, nausea, tiredness, tightness of chest, coughing, and difficulty in breathing. The most prominent symptoms were found to be irritation of the eyes and nose, and a sensation of unpleasant smell. Among the various pulmonary function tests performed, exposure was found to result in significant changes only as measured by increased airway resistance and specific airway resistance. The ceramic wall flow particle trap reduced the number of particles by 46 percent, but resulted in no significant attenuation of symptoms or lung function effects. The authors concluded that diluted diesel exhaust caused increased irritant symptoms of the eyes and nose, unpleasant smell, and bronchoconstriction, but that the 46-percent reduction in median particle number concentration observed was not sufficient to protect against these effects in the populations studied.

Wade and Newman (1993) documented three cases in which railroad workers developed persistent asthma following exposure to diesel emissions while riding immediately behind the lead engines of trains having no caboose. None of these workers were smokers or had any prior history of asthma or other respiratory disease. Asthma diagnosis was based on symptoms, pulmonary function tests, and measurement of airway hyperreactivity to methacholine or exercise.

Although MSHA is not aware of any other published report directly relating diesel emissions exposures to the development of asthma, there have been a number of recent studies indicating that dpm exposure can induce bronchial inflammation and respiratory immunological allergic responses in humans. Studies published through 1997 are reviewed in Peterson and Saxon (1996) and Diaz-Sanchez (1997).

Diaz-Sanchez et al.(1994) challenged healthy human volunteers by spraying 300 µg dpm into their nostrils.[22] Immunoglobulin E (IgE) binds to mast cells where it binds antigen leading to secretion of biologically active amines (*e.g.*, histamine) causing dilation and increased permeability of blood vessels. These amines are largely responsible for clinical manifestations of such allergic reactions as hay fever, asthma, and hives. Enhanced IgE levels were found in nasal washes in as little as 24 hours, with peak production observed 4 days after the dpm was administered.[23] No effect was observed on the levels of other immunoglobulin proteins. The selective enhancement of local IgE production was demonstrated by a dramatic increase in IgE-secreting cells. The authors suggested that dpm may augment human allergic disease

[19] MSHA realizes the incidents related in this subsection are anecdotal and draws no statistical conclusions from them. Since they pertain to specific experiences, however, they can be useful in identifying a potential hazard.

[20] MSHA sees potential value in anecdotal evidence when it relates to immediate experiences. MSHA regards anecdotal evidence to be less appropriate for identifying chronic health effects, since chronic effects cannot readily be linked to specific experiences. Accordingly, this risk assessment places little weight on anecdotal evidence for the chronic health hazards considered.

[21] The 1996 regulations to which the NMA was referring do not apply to M/NM mines.

[22] Assuming that a working miner inhales approximately 1.25 m^3 of air per hour, this dose corresponds to a 1-hour exposure at a dpm concentration of 240 $\mu g/m^3$.

[23] IgE is one of five types of immunoglobulin, which are proteins produced in response to allergens. Cytokine (mentioned later) is a substance involved in regulating IgE production.

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responses by enhancing the production of IgE antibodies. Building on these results, Diaz-Sanchez et al.(1996) measured cytokine production in nasal lavage cells from healthy human volunteers challenged with 150 µg dpm sprayed into each nostril. Based on the responses observed, including a broad increase in cytokine production, along with the results of the 1994 paper, the authors concluded that dpm exposure contributes to enhanced local IgE production and thus plays a role in allergic airway disease.

Salvi et al. (1999) exposed healthy human volunteers to diluted diesel exhaust at a dpm concentration of 300 µg/m^3 for one hour with intermittent exercise. Although there were no changes in pulmonary function, there were significant increases in various markers of allergic response in airway lavage fluid. Bronchial biopsies obtained six hours after exposure also showed significant increases in markers of immunologic response in the bronchial tissue. Significant increases in other markers of immunologic response were also observed in peripheral blood following exposure. A marked cellular inflammatory response in the airways was reported. The authors concluded that "at high ambient concentrations, acute short-term DE [diesel exhaust] exposure produces a well-defined and marked systemic and pulmonary inflammatory response in healthy human volunteers, which is underestimated by standard lung function measurements."

iii. Studies Based on Exposures to Particulate Matter in Ambient Air. Due to an incident in Belgium's industrial Meuse Valley, it was known as early as the 1930s that large increases in particulate air pollution, created by winter weather inversions, could be associated with large simultaneous increases in mortality and morbidity. More than 60 persons died from this incident, and several hundred suffered respiratory problems. The mortality rate during the episode was more than ten times higher than normal, and it was estimated that over 3,000 sudden deaths would occur if a similar incident occurred in London. Although no measurements of pollutants in the ambient air during the episode are available, high PM levels were obviously present (EPA, 1996).

A significant elevation in particulate matter (along with SO_2 and its oxidation products) was measured during a 1948 incident in Donora, PA. Of the Donora population, 42.7 percent experienced some acute adverse health effect, mainly due to irritation of the respiratory tract. Twelve percent of the population reported difficulty in breathing, with a steep rise in frequency as age progressed to 55 years (Schrenk, 1949).

Approximately as projected by Firket (1931), an estimated 4,000 deaths occurred in response to a 1952 episode of extreme air pollution in London. The nature of these deaths is unknown, but there is clear evidence that bronchial irritation, dyspnea, bronchospasm, and, in some cases, cyanosis occurred with unusual prevalence (Martin, 1964).

These three episodes "left little doubt about causality in regard to the induction of serious health effects by very high concentrations of particle-laden air pollutant mixtures" and stimulated additional research to characterize exposure-response relationships (EPA, 1996). Based on several analyses of the 1952 London data, along with several additional acute exposure mortality analyses of London data covering later time periods, the U.S. Environmental Protection Agency (EPA) concluded that increased risk of mortality is associated with exposure to combined particulate and SO_2 levels in the range of 500–1000 µg/m^3. The EPA also concluded that relatively small, but statistically significant increases in mortality risk exist at particulate (but not SO_2) levels below 500 µg/m^3, with no indications of a specific threshold level yet indicated at lower concentrations (EPA, 1986).

Subsequently, between 1986 and 1996, increasingly sophisticated techniques of particulate measurement and statistical analysis have enabled investigators to address these questions more quantitatively. The studies on acute effects carried out since 1986 are reviewed in the 1996 EPA Air Quality Criteria for Particulate Matter, which forms the basis for the discussion below (EPA, 1996).

At least 21 studies have been conducted that evaluate associations between acute mortality and morbidity effects and various measures of fine particulate levels in the ambient air. These studies are identified in Tables III–2 and III–3. Table III–2 lists 11 studies that measured primarily fine particulate matter using filter-based optical techniques and, therefore, provide mainly qualitative support for associating observed effects with fine particles. Table III–3 lists quantitative results from 10 studies that reported gravimetric measurements of either the fine particulate fraction or of components, such as sulfates, that serve as indicators or surrogates of fine particulate exposures.

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Table III-2. —Studies of acute health effects using filter based optical indicators of fine particles in the ambient air.

City	Study Years	Indicator*	Reference†
Acute Mortality			
London	1963-1972 (winters) 1965-1972 (winters)	BS	Thurston et al., 1989 Ito et al., 1993
Athens	1975-1987 July, 1987 1984-1988	BS	Katsouyanni et al., 1990 Katsouyanni et al., 1993 Touloumi et al., 1994
Los Angeles	1970-1979 1970-1979	KM	Shumway et al., 1988 Kinney and Ozkaynak, 1991
Santa Clara	1980-1986 (winters)	COH	Fairley, 1990
Increased Hospitalization			
Barcelona	1985-1989	BS	Sunyer et al., 1993
Acute Change in Pulmonary Function			
Wageningen, Netherlands		BS	Hoek and Brunkreef, 1993
Netherlands		BS	Roemer et al., 1993

† All references are from EPA, 1996

*BS (black smoke), KM (carbonaceous material), and COH (coefficient of haze) are optical measurements that are most directly related to elemental carbon concentrations, but only indirectly to mass. Site specific calibrations and/or comparisons of such optical measurements with gravimetric mass measurements in the same time and city are needed to make inferences about particle mass. However, all three of these indicators preferentially measure carbon particles found in the fine fraction of total airborne particulate matter. (EPA, 1996).

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Table III-3. —Studies of acute health effects using gravimetric indicators of fine particles in the ambient air.

Study	Indicator	RR per 25 $\mu g/m^3$ $PM_{2.5}$ Increase (95% Confidence Interval)	Mean $PM_{2.5}$ Levels (Min/Max)[†]
Acute Mortality			
Six Cities[A] (overall)	$PM_{2.5}$	1.036 (1.028, 1.056)	
Portage, WI	$PM_{2.5}$	1.030 (0.988, 1.071)	11.2 (±7.8)
Topeka, KS	$PM_{2.5}$	1.020 (0.951, 1.092)	12.2 (±7.4)
Boston, MA	$PM_{2.5}$	1.056 (1.038, 1.071)	16.7 (±9.2)
St. Louis, MO	$PM_{2.5}$	1.028 (1.010, 1.043)	18.7 (±10.5)
Kingston/Knoxville, TN	$PM_{2.5}$	1.035 (1.005, 1.066)	20.8 (±9.6)
Steubenville, OH	$PM_{2.5}$	1.025 (0.998, 1.053)	29.6 (±21.9)
Increased Hospitalization			
Ontario, CAN[B]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 3.1 - 8.2
Ontario, CAN[C]	$SO_4^=$	1.03 (1.02, 1.04)	Min/Max = 2.0 - 7.7
	O_3	1.03 (1.02, 1.05)	
NYC/Buffalo, NY[D]	$SO_4^=$	1.06 (1.01, 1.10)	NR
Toronto, CAN[E]	H^+(Nmol/m^3)	1.16 (1.03, 1.30)*	28.6 (NR, 391)
	$SO_4^=$	1.12 (1.00, 1.24)	7.6 (NR, 48.7)
	$PM_{2.5}$	1.15 (1.02, 1.78)	18.6 (NR, 86.0)
Increased Respiratory Symptoms			
Southern California[F]	$SO_4^=$	1.48 (1.14, 1.91)	R = 2 - 37
Six Cities[G] (Cough)	$PM_{2.5}$	1.19 (1.01, 1.42)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.23 (0.95, 1.59)**	2.5 (0.8, 5.9)***
	H^+	1.06 (0.87, 1.29)**	18.1 (3.1, 61)***
Six Cities[G] (Lower Resp. Symp.)	$PM_{2.5}$	1.44 (1.15 - 1.82)**	18.0 (7.2, 37)***
	$PM_{2.5}$ Sulfur	1.82 (1.28 - 2.59)**	2.5 (0.8, 5.9)***
	H^+	1.05 (0.25 - 1.30)**	18.1 (3.1, 61)***
Denver, CO[F] (Cough, adult asthmatics)	$PM_{2.5}$	0.0012 (0.0043)****	0.41 - 73
	$SO_4^=$	0.0042 (0.00035)****	0.12 - 12
	H^+	0.0076 (0.0038)****	2.0 - 41
Decreased Lung Function			
Uniontown, PA[F]	$PM_{2.5}$	PEFR 23.1 (-0.3,36.9) (per 25 $\mu g/m^3$)	25/88 (NR/88)
Seattle, WA[H] (Asthmatics)	b_{ext} calibrated by $PM_{2.5}$	FEV1 42 ml (12,73) FVC 45 ml (20,70)	5/45

References from EPA, 1996, Staff Report

[A] Schwartz et al. (1996a)

[B] Burnett et al. (1994)

[C] Burnett et al. (1995) O_3

[D] Thurston et al. (1992, 1994)

[E] Naes et al. (1995)

[F] Ostro et al. (1993)

[G] Schwartz et al. (1994)

[H] Ostro et al. (1991)

[I] Koenig et al. (1993)

[†] Min/Max 24-hr PM indicator level shown in parentheses unless otherwise noted as (±S.D.), 10 and 90 percentile (10,90).

* Change per 100 nmoles/m^3.

** Change per 20 $\mu g/m^3$ for $PM_{2.5}$; per 5 $\mu g/m^3$ for $PM_{2.5}$ sulfur; per 25 nmoles/m^3 for H^+.

*** 50th percentile value (10,90 percentile).

**** Coefficient and SE in parenthesis.

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A total of 38 studies examining relationships between short-term particulate levels and increased mortality, including nine with fine particulate measurements, were published between 1988 and 1996 (EPA, 1996). Most of these found statistically significant positive associations. Daily or several-day elevations of particulate concentrations, at average levels as low as 18–58 μ/m^3, were associated with increased mortality, with stronger relationships observed in those with preexisting respiratory and cardiovascular disease. Overall, these studies suggest that an increase of 50 $\mu g/m^3$ in the 24-hour average of PM_{10} is associated with a 2.5 to 5-percent increase in the risk of mortality in the general population, excluding accidents, suicides, and homicides. Based on Schwartz et al. (1996), the relative risk (RR) of mortality in the general population increases by about 2.6 to 5.5 percent per 25 $\mu g/m^3$ of fine particulate ($PM_{2.5}$) (EPA, 1996). More specifically, Schwartz et al. (1996) reported significantly elevated risks of mortality due to pneumonia, chronic obstructive pulmonary disease (COPD), and ischemic heart disease (IHD). For these three causes of death, the estimated increases in risk per incremental increase of 10 $\mu g/m^3$ in the concentration of $PM_{2.5}$ were 4.0 percent, 3.3 percent, and 2.1 percent, respectively. Each of these three results was statistically significant at a 95-percent confidence level.

A total of 22 studies were published on associations between short-term particulate levels and hospital admissions, outpatient visits, and emergency room visits for respiratory disease, Chronic Obstructive Pulmonary Disease (COPD), pneumonia, and heart disease (EPA, 1996). Fifteen of these studies were focused on the elderly. Of the seven that dealt with all ages (or in one case, persons less than 65 years old), all showed positive results. All of the five studies relating fine particulate measurements to increased hospitalization, listed in Tables III–2 and III–3, dealt with general age populations and showed statistically significant associations. The estimated increase in risk ranges from 3 to 16 percent per 25 $\mu g/m^3$ of fine particulate. Overall, these studies are indicative of acute morbidity effects being related to fine particulate matter and support the mortality findings.

Most of the 14 published quantitative studies on ambient particulate exposures and acute respiratory diseases were restricted to children (EPA, 1996, Table 12–12). Although they generally showed positive associations, and may be of considerable biological relevance, evidence of toxicity in children is not necessarily applicable to adults. The few studies on adults have not produced statistically significant evidence of a relationship.

Thirteen studies since 1982 have investigated associations between ambient particulate levels and loss of pulmonary function (EPA, 1996, Table 12–13). In general, these studies suggest a short term effect, especially in symptomatic groups such as asthmatics, but most were carried out on children only. In a study of adults with mild COPD, Pope and Kanner (1993) found a 29±10 ml decrease in 1-second Forced Expiratory Volume (FEV_1) per 50 $\mu g/m^3$ increase in PM_{10}, which is similar in magnitude to the change generally observed in the studies on children. In another study of adults, with PM_{10} ranging from 4 to 137 $\mu g/m^3$, Dusseldorp et al. (1995) found 45 and 77 ml/sec decreases, respectively, for evening and morning Peak Expiratory Flow Rate (PEFR) per 50 $\mu g/m^3$ increase in PM_{10} (EPA, 1996). In the only study carried out on adults that specifically measured fine particulate ($PM_{2.5}$), Perry et al. (1983) did not detect any association of exposure with loss of pulmonary function. This study, however, was conducted on only 24 adults (all asthmatics) exposed at relatively low concentrations of $PM_{2.5}$ and,therefore, had very little power to detect any such association.

c. Chronic Health Effects

During the 1995 dpm workshops, miners reported observable adverse health effects among those who have worked a long time in dieselized mines. For example, a miner (dpm Workshop; Salt Lake City, UT, 1995), stated that miners who work with diesel "have spit up black stuff every night, big black—what they call black (expletive) * * * [they] have the congestion every night * * * the 60-year-old man working there 40 years." Similarly, in comments submitted in response to MSHA's proposed dpm regulations, several miners reported cancers and chronic respiratory ailments they attributed to dpm exposure.

Scientific investigation of the chronic health effects of dpm exposure includes studies based specifically on exposures to diesel emissions and studies based more generally on exposures to fine particulate matter in the ambient air. Only the evidence from human studies will be addressed in this section of the risk assessment. Data from genotoxicity studies and studies on laboratory animals will be discussed later, in Subsection 2.d on mechanisms of toxicity. Subsection 3.a(iii) contains MSHA's interpretation of the evidence relating dpm exposures to one chronic health hazard: lung cancer.

i. Studies Based on Exposures to Diesel Emissions. The discussion will (1) summarize the epidemiologic literature on chronic effects other than cancer, and then (2) concentrate on the epidemiology of cancer in workers exposed to dpm.

(1) Chronic Effects other than Cancer

A number of epidemiologic studies have investigated relationships between diesel exposure and the risk of developing persistent respiratory symptoms (i.e., chronic cough, chronic phlegm, and breathlessness) or measurable loss in lung function. Three studies involved coal miners (Reger et al., 1982; Ames et al., 1984; Jacobsen et al., 1988); four studies involved metal and nonmetal miners (Jörgenson & Svensson, 1970; Attfield, 1979; Attfield et al., 1982; Gamble et al., 1983). Three studies involved other groups of workers—railroad workers (Battigelli et al., 1964), bus garage workers (Gamble et al., 1987), and stevedores (Purdham et al., 1987).

Reger et al. (1982) examined the prevalence of respiratory symptoms and the level of pulmonary function among more than 1,600 underground and surface U.S. coal miners, comparing results for workers (matched for smoking status, age, height, and years worked underground) at diesel and non-diesel mines. Those working at underground dieselized mines showed some increased respiratory symptoms and reduced lung function, but a similar pattern was found in surface miners who presumably would have experienced less diesel exposure. Miners in the dieselized mines, however, had worked underground for less than 5 years on average.

In a study of 1,118 U.S. coal miners, Ames et al. (1984) did not detect any pattern of chronic respiratory effects associated with exposure to diesel emissions. The analysis, however, took no account of baseline differences in lung function or symptom prevalence, and the authors noted a low level of exposure to diesel-exhaust contaminants in the exposed population.

In a cohort of 19,901 British coal miners investigated over a 5-year period, Jacobsen et al. (1988) found increased work absence due to self-reported chest illness in underground workers exposed to diesel exhaust, as compared to surface workers, but found no correlation with their estimated level of exposure.

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Jörgenson & Svensson (1970) found higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among Swedish underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine. No significant difference was found in spirometry results.

Using questionnaires collected from 4,924 miners at 21 U.S. metal and nonmetal mines, Attfield (1979) evaluated the effects of exposure to silica dust and diesel exhaust and obtained inconclusive results with respect to diesel exposure: For both smokers and non-smokers, miners occupationally exposed to diesel for five or more years showed an elevated prevalence of persistent cough, persistent phlegm, and shortness of breath, as compared to miners exposed for less than five years, but the differences were not statistically significant. Four quantitative indicators of diesel use failed to show consistent trends with symptoms and lung function.

Attfield et al. (1982) reported on a medical surveillance study of 630 white male miners at 6 U.S. potash mines. No relationships were found between measures of diesel use or exposure and various health indices, based on self-reported respiratory symptoms, chest radiographs, and spirometry.

In a study of U.S. salt miners, Gamble and Jones (1983) observed some elevation in cough, phlegm, and dyspnea associated with mines ranked according to level of diesel exhaust exposure. No association between respiratory symptoms and estimated cumulative diesel exposure was found after adjusting for differences among mines. However, since the mines varied widely with respect to diesel exposure levels, this adjustment may have masked a relationship.

Battigelli et al. (1964) compared pulmonary function and complaints of respiratory symptoms in 210 U.S. railroad repair shop employees, exposed to diesel for an average of 10 years, to a control group of 154 unexposed railroad workers. Respiratory symptoms were less prevalent in the exposed group, and there was no difference in pulmonary function; but no adjustment was made for differences in smoking habits.

In a study of workers at four diesel bus garages in two U.S. cities, Gamble et al. (1987b) investigated relationships between job tenure (as a surrogate for cumulative exposure) and respiratory symptoms, chest radiographs, and pulmonary function. The study population was also compared to an unexposed control group of workers with similar socioeconomic background. After indirect adjustment for age, race, and smoking, the exposed workers showed an increased prevalence of cough, phlegm, and wheezing, but no association was found with job tenure. Age- and height-adjusted pulmonary function was found to decline with duration of exposure, but was elevated on average, as compared to the control group. The number of positive radiographs was too small to support any conclusions. The authors concluded that the exposed workers may have experienced some chronic respiratory effects.

Purdham et al. (1987) compared baseline pulmonary function and respiratory symptoms in 17 exposed Canadian stevedores to a control group of 11 port office workers. After adjustment for smoking, there was no statistically significant difference in self-reported respiratory symptoms between the two groups. However, after adjustment for smoking, age, and height, exposed workers showed lower baseline pulmonary function, consistent with an obstructive ventilatory defect, as compared to both the control group and the general metropolitan population.

In a review of these studies, Cohen and Higgins (1995) concluded that they did not provide strong or consistent evidence for chronic, nonmalignant respiratory effects associated with occupational exposure to diesel exhaust. These reviewers stated, however, that "several studies are suggestive of such effects * * * particularly when viewed in the context of possible biases in study design and analysis." Glenn et al (1983) noted that the studies of chronic respiratory effects carried out by NIOSH researchers in coal, salt, potash, and trona mines all "revealed an excess of cough and phlegm in the diesel exposed group." IPCS (1996) noted that "[a]lthough excess respiratory symptoms and reduced pulmonary function have been reported in some studies, it is not clear whether these are long-term effects of exposure." Similarly, Morgan et al. (1997) concluded that while there is "some evidence that the chronic inhalation of diesel fumes leads to the development of cough and sputum, that is chronic bronchitis, it is usually impossible to show a cause and effect relationship * * *." MSHA agrees that these dpm studies considers them to be suggestive of adverse chronic, non-cancerous respiratory effects.

(2) Cancer

Because diesel exhaust has long been known to contain carcinogenic compounds (*e.g.*, benzene in the gaseous fraction and benzopyrene and nitropyrene in the dpm fraction), a great deal of research has been conducted to determine if occupational exposure to diesel exhaust actually results in an increased risk of cancer. Evidence that exposure to dpm increases the risk of developing cancer comes from three kinds of studies: human studies, genotoxicity studies, and animal studies. In this risk assessment, MSHA has placed the most weight on evidence from the human epidemiologic studies and views the genotoxicity and animal studies as lending support to the epidemiologic evidence.

In the epidemiologic studies, it is generally impossible to disassociate exposure to dpm from exposure to the gasses and vapors that form the remainder of whole diesel exhaust. However, the animal evidence shows no significant increase in the risk of lung cancer from exposure to the gaseous fraction alone (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). Therefore, dpm, rather than the gaseous fraction of diesel exhaust, is usually assumed to be the agent associated with any excess prevalence of lung cancer observed in the epidemiologic studies. Subsection 2.d of this risk assessment contains a summary of evidence supporting this assumption.

(a) Lung Cancer

MSHA evaluated 47 epidemiologic studies examining the prevalence of lung cancer within groups of workers occupationally exposed to dpm. This includes four studies not included in MSHA's risk assessment as originally proposed.[24] The earliest of these studies was published in 1957 and the latest in 1999. The most recent published reviews of these studies are by Mauderly (1992), Cohen and Higgins (1995), Muscat and Wynder (1995), IPCS (1996), Stöber and Abel (1996), Cox (1997), Morgan et al. (1997), Cal-EPA (1998), ACGIH (1998), and U.S. EPA (1999). In response to both the ANPRM and the 1998 proposals, several commenters also provided MSHA with their own reviews of many of these studies. In arriving at its conclusions, MSHA considered all of these reviews,

[24] One of these studies (Christie et al., 1995) was cited in the discussion on mechanisms of toxicity but not considered in connection with studies involving dpm exposures. Several commenters advocated that it be considered. The other three were published in 1997 or later. Johnston et al. (1997) was introduced to these proceedings in 64FR7144. Säverin et al. (1999) is the published English version of a German study submitted as part of the public comments by NIOSH on May 27, 1999. The remaining study is Brüske-Hohlfeld et al. (1999).

including those of the commenters, as well as the 47 source studies available to MSHA.

In addition, MSHA relied on two comprehensive statistical "meta-analyses" [25] of the epidemiologic literature: Lipsett and Campleman (1999)[26] and Bhatia et al. (1998).[27] These meta-analyses, which weight, combine, and analyze data from the various epidemiologic studies, were themselves the subject of considerable public comment and are discussed primarily in Subsection 3.a.iii of this risk assessment. The present section tabulates results of the studies and addresses their individual strengths and weaknesses. Interpretation and evaluation of the collective evidence, including discussion of potential publication bias or any other systematic biases, is deferred to Subsection 3.a.iii.

Tables III–4 (27 cohort studies) and III–5 (20 case-control studies) identify all 47 known epidemiologic studies that MSHA considers relevant to an assessment of lung cancer risk associated with dpm exposure.[28] These tables include, for each of the 47 studies listed, a brief description of the study and its findings, the method of exposure assessment, and comments on potential biases or other limitations. Presence or absence of an adjustment for smoking habits is highlighted, and adjustments for other potentially confounding factors are indicated when applicable. Although MSHA constructed these tables based primarily on its own reading of the 48 source publications, the tables also incorporate strengths and weaknesses noted in the literature reviews and/or in the public comments submitted.

Some degree of association between occupational dpm exposure and an excess prevalence of lung cancer was reported in 41 of the 47 studies reviewed by MSHA: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Despite some commenters' use of conflicting terminology, which will be addressed below, MSHA refers to these 41 studies as "positive." The 22 positive cohort studies in Table III–4 are identified as those reporting a relative risk (RR) or standardized mortality ratio (SMR) exceeding 1.0. The 19 positive case-control studies in Table III–5 are identified as those reporting an RR or odds ratio (OR) exceeding 1.0. A study does not need to be statistically significant (at the 0.05 level) or meet all criteria described, in order to be considered a "positive" study. The six remaining studies were entirely negative: they reported a deficit in the prevalence of lung cancer among exposed workers, relative to whatever population was used in the study as a basis for comparison. These six negative studies are identified as those reporting no relative risk (RR), standard mortality ratio (SMR), or odds ratio (OR) greater than 1.0.[29]

MSHA recognizes that these 47 studies are not of equal importance for determining whether dpm exposure leads to an increased risk of lung cancer. Some of the studies provide much better evidence than others. Furthermore, since no epidemiologic study can be perfectly controlled, the studies exhibit various strengths and weaknesses, as described by both this risk assessment and a number of commenters. Several commenters, and some of the reviewers cited above, focused on the weaknesses and argued that none of the existing studies is conclusive. MSHA, in accordance with other reviewers and commenters, maintains: (1) that the weaknesses identified in both negative and positive studies mainly cause underestimation of risks associated with high occupational dpm exposure; (2) that it is legitimate to base conclusions on the combined weight of all available evidence and that, therefore, it is not necessary for any individual study to be conclusive; and (3) that even though the 41 positive studies vary a great deal in strength, nearly all of them contribute something to the weight of positive evidence.

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings [a]	Stat. sig. [b]	Comments
Ahlberg et al. (1981).	Male truck drivers	35,883	1961–73	Occupation only		RR = 1.33 for drivers of "ordinary" trucks.	(*)	Risk relative to males employed in trades thought to have no exposure to "petroleum products or other chemicals." Comparison controlled for age and province of residence (Sweden). Based on comparison of smoking habits between truck drivers and general Stockholm population, authors concluded that excess rate of lung cancer could not be entirely attributed to smoking.

[25] MSHA restricts the term "meta-analysis" to formal, statistical analyses of the pooled data taken from several studies. Some commenters (and Cox in the article itself) referred to the review by Cox (op.cit.) as a meta-analysis. Although this article seeks to identify characteristics of the individual studies that might account for the general pattern of results, it performs no statistical analysis on the pooled epidemiologic data. For this reason, MSHA does not regard the Cox article as a meta-analysis in the same sense as the two studies so identified. MSHA does, however, recognize that the Cox article evaluates and rejects the collective evidence for causality, based on the common characteristics identified. In that context, Cox's arguments and conclusions are addressed in Subsection 3.a.iii. Cox also presents a statistical analysis of data from one of the studies, and that portion of the article is considered here, along with his observations about other individual studies.

[26] MSHA's risk assessment as originally proposed cited an unpublished version, attributed to Lipsett and Alexeeff (1998), of essentially the same meta-analysis. Both the 1999 and 1998 versions are now in the public record.

[27] Silverman (1998) reviewed the meta-analysis by Bhatia et al. (op cit.) and discussed, in general terms, the body of available epidemiologic evidence on which it is based. Some commenters stated that MSHA had not sufficiently considered Silverman's views on the limitations of this evidence. MSHA has thoroughly considered these views and addresses them in Subsection 3.a.(iii).

[28] For simplicity, the epidemiologic studies considered here are placed into two broad categories. A *cohort study* compares the health of persons having different exposures, diets, etc. A *case-control study* starts with two defined groups known to differ in health and compares their exposure characteristics.

[29] The six entirely negative studies are: Kaplan (1959); DeCoufle et al. (1977); Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995).

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TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings[a]	Stat. sig.[b]	Comments
Ahlman et al. (1991).	Underground sulfide ore miners.	597	1968–86	Job histories from personnel records. Measurements of alpha energy concentration from radon daughters at each mine worked.		RR = 1.45 overall. RR = 2.9 for 45–64 age group (calculated by MSHA).		Age-adjusted relative risk compared to males living in same area of Finland. No excess observed among 336 surface workers at same mines, with similar smoking and alcohol consumption, based on questionnaire. Based on calculation of expected lung cancers due to radon, excess risk attributed by author partly to radon exposure and partly to diesel exhaust & silica exposure.
Balarajan & McDowall (1988).	Professional drivers.	3,392	1950–84	Occupation only		SMR = 0.86 for taxi drivers.. SMR = 1.42 for bus drivers.. SMR = 1.59 for truck drivers.	(*)	Possibly higher rates of smoking among bus and truck drivers than among taxi drivers.
Bender et al. (1989).	Highway maintenance workers.	4,849	1945–84	Occupation only		SMR = 0.69		No adjustment for healthy worker effect.
Boffetta et al. (1988).	Railroad workers	2,973	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.24 for truck drivers.		Risk relative to reporting that they never worked in these four occupations and were never occupationally exposed to diesel exhaust. Adjusted for age and smoking only.
	Truck drivers	16,208						
	Heavy Eq. Op's	855				RR = 1.59 for railroad workers	(*)	
	Miners	2,034					(*)	
						RR = 2.60 for heavy Eq. Op's		
						RR = 2.67 for miners		
Do	All workers	476,648	1982–84	Occupation and diesel exposure by questionnaire.		RR = 1.05 for 1–15 years. RR = 1.21 for 16+ years.		Based on self-reported exposure, relative to unexposed workers. Adjusted for occupational exposures to asbestos, coal and stone dusts, coal tar & pitch, and gasoline exhaust (in addition to age and smoking). Possible biases due to volunteered participation and elevated lung cancer rate among 98,026 subjects with unknown dpm exposure.
Christie et al. (1994, 1995).	Coal miners	23,630	1973–92	Occupation only		SMR = 0.76		No adjustment for healthy worker effect. Cohort includes workers who entered workforce up through 1992. SMR reported to be greater than for occupationally unexposed petroleum workers.
Dubrow & Wegman (1984).	Truck & tractor drivers.	Not reported	1971–73	Occupation only		sMOR = 1.73 based on 176 deaths.	(*)	Excess cancers observed over the entire respiratory system and upper alimentary tract.
Edling et al. (1987)	Bus workers	694	1951–83	Occupation only		SMR = 0.7 for overall cohort.		Small size of cohort lacks statistical power to detect excess risk of lung cancer. No adjustment for healthy worker effect.
Garshick et al. (1988, 1991).	Railroad workers	55,395 (1991 report).	1959–80	Job in 1959 & years of diesel exposure since 1959.		RR = 1.31 for 1–4 years.	(*)	Adjusted for attained age (1991 report). Cumulative diesel exposure-years lagged by 5 years. Subjects with likely asbestos exposure excluded from cohort. Statistically significant results corroborated if 12,872 shopworkers and hostlers possibly exposed to asbestos are also excluded. Missing 12% of death certificates. Cigarette smoking judged to be uncorrelated with diesel exposure within cohort. Higher RR for each exposure group if shopworkers and hostlers are excluded.
						RR = 1.28 for 5–9 years.	(*)	
						RR = 1.19 for 10–14 years.	(*)	
						RR = 1.40 for 15 or more years.		
Guberan et al (1992).	Professional drivers.	1,726	1961–86	Occupation only		SMR = 1.50	(*)	Approximately 1/3 to 1/4 of cohort reported to be long-haul truck drivers. SMR based on regional lung cancer mortality rate.
Gustafsson et al. (1986).	Dock workers	6,071	1961–80	Occupation only		SMR = 1.32 (mortality).	(*)	No adjustment for healthy worker effect.
						SMR = 1.68 (morbidity)	(*)	

TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings[a]	Stat. sig.[b]	Comments
Gustavsson et al. (1990).	Bus garage workers.	708	1952–86	Semi-quantitative, based on job history & exposure intensity estimated for each job.		SMR = 1.22 for overall cohort. SMR = 1.27 for highest-exposed subgroup.		Lack of statistical significance may be attributed to small size of cohort.
Hansen (1993)	Truck drivers	14,225	1970–80	Occupation only		SMR = 1.60 for overall cohort. Some indication of increasing SMR with age (i.e., greater cumulative exposure).	(*)	Compared to unexposed control group of 38,301 laborers considered to "resemble the group of truck drivers in terms of work-related demands on physical strength and fitness, educational background, social class, and life style." Correction for estimated differences in smoking habits between cohort and control group reduces SMR from 1.60 to 1.52. Results judged "unlikely *** [to] have been seriously confounded by smoking habit differences."
Howe et al. (1983)	Railroad workers	43,826	1965–77	Jobs classified by diesel exposure.		RR = 1.20 for "possibly exposed.".	(*)	Risk is relative to unexposed subgroup of cohort. Similar results obtained for coal dust exposure.
						RR = 1.35 for "probably exposed.".	(*)	Possible confounding with asbestos and coal dust.
Johnston et al. (1997).	Underground coal miners.	18,166	1950–85	Quantitative, based on detailed job history & surrogate dpm measurements.		Mine-adjusted model: RR = 1.156 per g-hr/m^3.		Risk is relative to unexposed workers in coal miners based on cohort. Adjusted for age, smoking habit & intensity, mine site, and cohort entry date. Mine site highly correlated with dpm exposure.
						Mine-unadjusted model: RR = 1.227 per g-hr/m^3.		Both models lag exposure by 15 years.
Kaplan (1959)	Railroad workers	Approx. 32000	1953–58	Jobs classified by diesel exposure.		SMR=0.86 for operationally exposed.		No adjustment for healthy worker effect. Clerks (in rarely exposed group) found more likely to have had urban residence than occupationally exposed workers.
						SMR = 0.72 for somewha exposed SMR = 0.80 for rarely exposed.		No attempt to distinguish between diesel and coal-fired locomotives. Results may be attributable to short duration of exposure and/or inadequate follow-up time.
Leupker & Smith (1978).	Truck drivers	183,791	May–July, 1976	Occupation only		SMR = 1.21		Lack of statistical significance may be due to inadequate follow-up period. Retirees excluded from cohort, so lung cancers occurring after retirement were not included.
Lindsay et al. (1933).	Truck drivers	Not reported	1965–79	Occupation only		SMR = 1.15	(*)	
Menck & Henderson (1976).	Truck drivers	34,800 estimated	1968–73	Occupation only		SMR = 1.65	(*)	Number of subjects in cohort estimated from census data.
Raffle (1957)	Transport engineers.	2,666 estimated from manyears at risk.	1950–55	Occupation only		SMR = 1.42		SMR calculated by combining data presented for four quadrants of London. Excluded from most retirees and lung cancers occurring after retirement.
Rafnsson & Gunnarsdottir (1991).	Truck drivers	868	1951–88	Occupation only		SMR = 2.14	(*)	No trend of increasing risk with increased duration of employment or increased follow-up time. Based on survey of smoking habits in cohort compared to general male population, and fact that there were fewer than expected deaths from respiratory disease, authors concluded that differences in smoking habits were unlikely to be enough to explain excess rate of lung cancer. However, not all trucks were diesel prior to 1951, and there is possible confounding by asbestos exposure.

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TABLE III–4.—SUMMARY OF INFORMATION FROM 27 COHORT STUDIES ON LUNG CANCER AND OCCUPATIONAL EXPOSURE TO DIESEL EXHAUST—Continued

Study	Occupation	Number of subjects	Follow-up period	Exposure assessment	Smk. adj.	Findings[a]	Stat. sig.[b]	Comments
Rushton et al. (1983).	Bus maintenance workers.	8,480	5.9 yrs (mean)	Occupation only		SMR = 1.01 for overall cohort. SMR = 1.33 for "general hand" subgroup.	(*)	Short follow-up period. SMR based on comparison to national rates, with no adjustment for regional or socioeconomic differences, which could account for excess lung cancers observed among general hands. No adjustment for healthy worker effect.
Säverin et al. (1999).	Underground potash miners.	5,536	1970–94	Quantitative, based on TC measurements & detailed job history.		RR = 2.17 for highest compared to least exposed categories. RR = 1.03 to 1.225 per mg-yr/m³, depending on statistical model & inclusion criteria.		Based on routine measurements, miners determined to have had no occupational exposure to radon progeny. Authors judged asbestos exposure minor, with negligible effects. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Schenker et al. (1984).	Railroad workers	2,519	1967–79	Job histories, with exposure classified as unexposed, high, low, or undefined.		RR = 1,50 for low exposure subgroup. RR = 2.77 for high exposure subgroup.		Risk relative to unexposed subgroup. Jobs considered to have similar socioeconomic status. Differences in smoking calculated to be insufficient to explain findings. Possible confounding by asbestos exposure.
Waller (1981)	Bus workers	16,828 Est. from manyears at risk.	1950–74	Occupation only		SMR = 0.79 for overall cohort.		Lung cancers occurring after retirement or resignation from London Transport Authority were not counted. No adjustment for healthy worker effect.
Waxweiler et al. (1973).	Potash miners	3,886	1941–67	Miners classified as underground or surface.		SMR = 1.1 for both underground and surface miners.		No adjustment for healthy worker effect. SMR based on national lung cancer mortality, which is about 1/3 higher than lung cancer mortality rate in New Mexico, where miners resided. Authors judged this to be balanced by smoking among miners. A substantial percentage of the underground subgroup may have had little or no occupational exposure to diesel exhaust.
						SMR = 0.99 for overall cohort. SMR = 1.07 for ≥20 yr member SMR = 1.12 for ≥20 yr. latency.		
Wong et al. (1973)	Heavy equipment operators.	34,156	1964–78	Job histories, latency, & years of union membership.		SMR = 1.30 for 4,075 "normal" retirees.	(*)	Increasing trend in SMR with latency and (up to 15 yr) with duration of union membership. No adjustment for healthy worker effect.
						SMR = 3.43 for "high exposure" dozer operators with 15–19 yr union membership & ≥20 yr latency.	(*)	

[a] RR = Relative Risk; SMR = Standardized Mortality Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings[a]	Stat. sig.[b]	Comments
						Smk.	Additional			
Benhamou et al. (1988).	Histologically confirmed lung cancers.	Non-tobacco related diseases.	1,625	3,091	Occupational history by questionnaire.	√	sex, age at diagnosis, hospital, interviewer.	RR=2.14 for miners.	(*)	Mine type not reported.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching		Findings[a]	Stat. sig.[b]	Comments
						Smk.	Additional			
								RR=1.42 for professional drivers.	(*)	No evidence of an increase in risk with duration of exposure.
Boffetta et al. (1990).	Hospitalized males with histologically confirmed lung cancer.	Hospitalized males with no tobacco related disease.	2,584	5,099	Occupation classified by probability of diesel exposure.	√	Sex, age within 2 yr, hospital, year of interview.	OR=0.95 for 13 jobs with probable exposure. OR=1.49 for more than 30 yr in "probable" jobs.		Adjusted for race, asbestos exposure, education, & number of cigarettes per day.
Do			477	846	Occupational history & duration of diesel exposure by interview.	√	.....do	OR=1.21 for any self-reported diesel exposure. OR=2.39 for more than 30 yr of self-reported diesel exposure..		
Brüske-Hohlfeld et al. (1999).	Cytologically and/or histologically confirmed lung cancers.	Randomly selected from compulsory registries of residents.	3,498	3,541	Occupational history by interview; total duration of diesel exposure compiled from individual job episodes.	√	Sex, age, region of residence.	OR=1.43 for any occupational diesel exposure during lifetime. OR=1.56 for West German professional drivers post-1955. OR=2.88 for > 20 yr in "traffic-related" jobs other than driving. OR=6.81 for > 30 yr as full-time driver of farm tractors. OR=4.30 for > 20 yr as heavy equipment operator.	(*) (*) (*) (*) (*)	Adjusted for cumulative smoking & asbestos exposure. All interviews conducted directly with cases and controls. Lack of elevated risk for East German professional drivers attributed to relatively low traffic density & low proportion of vehicles with diesel engines in East Germany. Non-driving "traffic-related jobs" include switchmen & operators of diesel locomotives & forklifts.
Buiatti et al. (1985).	Histologically confirmed lung cancers.	Patients at same hospital.	376	892	Occupational history from interview.	√	Sex, age, admission date.	OR=1.8 for taxi drivers.		Adjusted for current and past smoking patterns and for asbestos exposure.
Coggon et al. (1984).	Lung cancer deaths of males under 40.	Deaths from other causes in males under 40.	598	1,180	Occupation from death certificate, classified as high, low, or no diesel exposure.		Sex, death year, region, and birth year (approx.).	RR=1.3 for all jobs with diesel exposure. RR=1.1 for jobs classified as high exposure.	(*)	Only most recent full-time occupation recorded on death certificate.
Damber & Larsson (1985).	Male patients with lung cancer.	One living and one deceased without lung cancer.	604	1,071	Job, with tenure, from mailed questionnaire.	√	Sex, death year, age, municipality.	RR=1.9 for non-smoking truck drivprs aged <70 yr. RR=4.5 for non-smoking truck drivers aged ≥70 yr.	(*)	Ex-smokers who did not smoke for at least last 10 years included with non-smokers.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching: Smk.	Matching: Additional	Findings[a]	Stat. sig.[b]	Comments
DeCoufle et al. (1997).	Male patients with lung cancer.	Non-neoplastic disease patients.	6,434	(c)	Occupation only, from questionnaire.	√	Unmatched	RR=0.92 for bus, taxi, and truck drivers. RR=0.94 for locomotive engineers.		Selected occupation compared to clerical workers. Positive associations found before smoking adjustment.
Emmelin et al. (1993).	Deaths from primary lung cancer among dock workers.	Dock workers without lung cancer.	50	154	Semi-quantitative from work history & records of diesel fuel usage.	√	Date of birth, port, and survival to within 2 years of case's diagnosis of lung cancer.	RR = 1.6 for "medium" duration of exposure.. RR = 2.9 for "high" duration of exposure.		Increasing relative risk also observed using exposure estimates based on machine usage & diesel fuel consumption. Confounding from asbestos may be significant.
Garshick et al. (1987).	Deaths with primary lung cancer among railroad workers.	Deaths from other than cancer, suicide, accidents, or unknown causes.	1,256	2,385	Job history and tenure combined with current exposure levels measured for each job.	√	Date of birth and death.	RR = 1.41 for 20+ diesel-years in workers aged ≤ 64 yr.. RR = 0.91 for 20+ diesel-years in workers aged ≥ 65 yr.	(*)	Adjusted for asbestos exposure. Older workers had relatively short diesel exposure, or none.
Gustavsson et al. (1990).	Deaths from lung cancer among bus garage workers.	Non-cases within cohort mortality study.	20	120	Semi-quantitative based on job, tenure, & exposure class for each job.		Born within two years of case.	RR = 1.34, 1.81, and 2.43 for increasing cumulative diesel exposure categories, relative to lowest exposure category.	(*)	Authors judged smoking habits to be similar for different exposure categories. RR did not increase with increasing asbestos exposure.
Hall & Wynder (1984).	Hospitalized males with lung cancer.	Hospitalized males with no tobacco-related diseases.	502	502	Usual occupation by interview.	√	Age, race, hospital, and hospital room status.	RR = 1.4 for jobs with diesel exposure.. RR = 1.9 for heavy equipment operators & repairmen.		Confounding with other occupational exposures possible.
Hayes et al. (1989).	Lung cancer deaths pooled from 3 studies.	Various—lung disease excluded.	2,291	2,570	Occupational history by interview.	√	Sex, age, and either race or area of residence.	OR = 1.5 for ≥ 10 yr truck driving. OR = 2.1 for ≥ 10 yr operating heavy equipment. OR = 1.7 for ≥ 10 yr bus driving.	(*)	OR adjusted for birth-year cohort and state of residence (FL, NJ, or LA), in addition to average cigarette use. Smaller OR for < 10 yr in these jobs.
Lerchen et al. (1987).	New Mexico residents with lung cancer.	Medicare recipients.	506	771	Occupational history, industry, & self-reported exposure, by interview.	√	Sex, age, ethnicity.	OR = 0.6 for ≥ 1 yr occupational exposure to diesel exhaust.. OR = 2.1 for underground non-uranium mining.		Small number of cases and controls in diesel-exposed jobs. Possibly insufficient exposure duration. Not matched on date of birth or death.

TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching: Smk.	Matching: Additional	Findings[a]	Stat. sig.[b]	Comments
Milne et al. (1983).	Lung cancer deaths.	Deaths from any other cancer.	925	6,565	Occupation from death certificate.		None	OR = 3.5 for bus drivers. OR = 1.6 for truck drivers.	(*)	Inadequate latency allowance.
Morabia et al. (1992).	Male lung cancer patients.	Patients without lung cancer or other tobacco-related condition.	1,793	3,228	Job, with coal and asbestos exposure durations, by interview.	√	Race, age, hospital, and smoking history.	OR=2.3 for miners.. OR=1.1 for bus drivers.. OR=1.0 for truck or tractor drivers.		Mine type not specified. Potential confounding by other occupational exposures for miners.
Pfluger and Minder (1994).	Professional drivers.	Workers in occupational categories with no known excess lung cancer risk.	284	1,301	Occupation only, from death certificate.		None	OR=1.48 for professional drivers.	(*)	Stratified by age. Indirectly adjusted for smoking, based-on smoking-rate for occupation.
Siemiatycki et al. (1988).	Squamous cell lung cancer patients by type of lung cancer.	Other cancer patients.	359	1,523	Semi-quantitative, from occupational history by interview, & exposure class for each job.	√	None	OR=1.2 for diesel exposure;. OR=2.8 for mining.		Stratified by age, socio-economic status, ethnicity, and blue- vs. white-collar job history. Examination of files indicated that most miners "were exposed to diesel exhaust for short periods of time." Mining included quarrying, so result is likely to be confounded by silica exposure.
Steenland et al. (1990, 1992, 1998).	Deaths from lung CA among Teamsters.	Deaths other than lung or bladder cancer or motor vehicle accidents.	996	1,085	Occupational history and tenure from next-of-kin, supplemented by IH data.	√	Time of death within 2 years.	OR=1.27 for diesel truck drivers with 1–24 yr tenure.. OR=1.26 for diesel truck drivers with 25–34 yr tenure.. OR=1.89 for diesel truck drivers with ≥35 yr tenure.. OR=1.50 for truck mechanics with ≥18 yr tenure after 1959.	(*)	Years of tenure not necessarily all at main job (i.e., diesel truck driver). OR adjusted for asbestos exposure.

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TABLE III–5.—SUMMARY OF PUBLISHED INFORMATION FROM 20 CASE-CONTROL STUDIES ON LUNG CANCER AND EXPOSURE TO DIESEL EXHAUST—Continued

Study	Cases	Controls	Number of cases	Number of controls	Exposure assessment	Matching: Smk.	Matching: Additional	Findings[a]	Stat. sig.[b]	Comments
Swanson et al. (1993) See also Burns & Swanson (1991).	Histologically confirmed Detroit metro area lung cancers.	Colon or rectal cancer cases.	[d]3,792 [e]5,935	[d]1,986 [e]3,956	Occupational history from interview.	√	None	OR = 1.4 for heavy truck drivers with 1–9 yr tenure. OR = 1.6 for heavy truck drivers with 10–19 yr tenure OR = 2.5 for heavy truck drivers with ≥20 yr tenure	(*)	OR for truck drivers & RR workers is for white males, relative to corresponding group with < 1 yr tenure, adjusted for age at diagnosis. Pattern of increasing risk with duration of employment also reported for black male railroad workers, based on fewer cases. (1993 report).
								OR = 1.2 for railroad workers with 1–9 yr tenure. OR = 2.5 for railroad workers with ≥10 yr tenure	(*)	
								OR = 2.98 for mining industry workers. OR = 5.03 for mining machinery operators	(*) (*)	OR for mining machinery operators and mining is for all males, adjusted for race and age at diagnosis. Type of mining not reported. Potential confounding by.
Williams et al. (1977).	Male lung cancer patients.	Other male cancer patients.	432	2,817	Main lifetime occupation from interview.	√	Sex	OR = 1.52 for male truck drivers.		Controlled for age, race, alcohol use, and socioeconomic status. Unexplained discrepancies in reported number of controls.

[a] RR = Relative Risk; OR = Odds Ratio. Values greater than 1.0 indicate excess prevalence of lung cancer associated with diesel exposure.
[b] An asterisk (*) indicates statistical significance based on 2-tailed test at confidence level of at least 95%.
[c] Not reported. [d] Males. [e] Total.

(i) Evaluation Criteria. Several commenters contended that MSHA paid more attention to positive studies than to negative ones and indicated that MSHA had not sufficiently explained its reasons for discounting studies they regarded as providing negative evidence. MSHA used five principal criteria to evaluate the strengths and weaknesses of the individual studies:

(1) power of the study to detect an exposure effect;
(2) composition of comparison groups;
(3) exposure assessment;
(4) statistical significance; and
(5) potential confounders.

These criteria are consistent with those proposed by the HEI Diesel Epidemiology Expert Panel (HEI, 1999). To help explain MSHA's reasons for valuing some studies over others, these five criteria will now be discussed in turn.

Power of The Study

There are several factors that contribute to a study's power, or ability to detect an increased risk of lung cancer in an exposed population. First is the study's size—i.e., the number of subjects in a cohort or the number of lung cancer cases in a case-control study. If few subjects or cases are included, then any statistical relationships are likely to go undetected. Second is the duration and intensity of exposure among members of the exposed group. The greater the exposure, the more likely it is that the study will detect an effect if it exists. Conversely, a study in which few members of the exposed group experienced cumulative exposures significantly greater than the background level is unlikely to detect an exposure effect. Third is the length of time the study allows for lung cancer to exhibit a statistical impact after exposure begins. This involves a latency period, which is the time required for lung cancer to develop in affected individuals, or (mainly pertaining to cohort studies) a follow-up period, which is the time allotted, including latency, for lung cancers in affected individuals to show up in the study. It is generally acknowledged that lung cancer studies should, at the very minimum, allow for a latency period of at least 10 years from the time exposure begins and that it is preferable to allow for latency periods of at least 20 years. The shorter the latency allowance, the less power the study has to detect any increased risk of lung cancer that may be associated with exposure.

As stated above, six of the 47 studies did not show positive results: One of these studies (Edling et al.) was based on a small cohort of 694 bus workers, thus having little statistical power. Three other of these studies (DeCoufle, Kaplan, and Christie) included exposed workers for whom there was an inadequate latency allowance (i.e., less than 10 years). The entire period of follow-up in the Kaplan study was 1953–1958. The Christie study was designed in such a way as to provide for neither a minimum period of exposure nor a minimum period of latency: the report covers lung cancers diagnosed only through 1992, but the "exposed" cohort includes workers who may have entered the work force (and thus begun their exposure) as late as Dec. 31, 1992. Such workers would not be expected to develop lung cancer during the study period. The remaining two negative studies (Bender, 1989 and Waller, 1981) appear to have been included a reasonably adequate number of exposed workers and to have allowed for an adequate latency period.

Some of the 41 positive studies also had little power, either because they included relatively few exposed workers (*e.g.*, Lerchen et al., 1987, Ahlman et al., 1991; Gustavsson et al., 1990) or an inadequate latency allowance or follow-up period (*e.g.*, Leupker and Smith (1978); Milne, 1983; Rushton et al., 1983). In those based on few exposed workers, there is a strong possibility that the positive association arose merely by chance.[30] The other studies, however, found increased prevalence of lung cancer despite the relatively short periods of latency and follow-up time involved. It should be noted that, for reasons other than lack of power, MSHA places very little weight on the Milne and Rushton studies. As mentioned in Table III–4, the Rushton study compared the cohort to the national population, with no adjustment for regional or socioeconomic differences. This may account for the excess rate of lung cancers reported for the exposed "general hand" job category. The Milne study did not control for potentially important "confounding" variables, as explained below in MSHA's discussion of that criterion.

Composition of Comparison Groups

This criterion addresses the question of how equitable is the comparison between the exposed and unexposed populations in a cohort study, or between the subjects with lung cancer (i.e., the "cases") and the subjects without lung cancer (i.e., the "controls") in a case-control study. MSHA includes bias due to confounding variables under this criterion if the groups differ systematically with respect to such factors as age or exposure to non-diesel carcinogens. For example, unless adequate adjustments are made, comparisons of underground miners to the general population may be systematically biased by the miners' greater exposure to radon gas. Confounding not built into a study's design or otherwise documented is considered potential rather than systematic and is considered under a separate criterion below. Other factors included under the present criterion are systematic (i.e., "differential") misclassification of those placed into the "exposed" and "unexposed" groups, selection bias, and bias due to the "healthy worker effect."

In several of the studies, a group identified with diesel exposure may have systematically included workers who, in fact, received little or no occupational diesel exposure. For example, a substantial percentage of the "underground miner" subgroup in Waxweiler et al. (1973) worked in underground mines with no diesel equipment. This would have diluted any effect of dpm exposure on the group of underground miners as a whole.[31] Similarly, the groups classified as miners in Benhamou et al. (1988), Boffetta et al. (1988), and Swanson et al. (1993) included substantial percentages of miners who were probably not occupationally exposed to diesel emissions. Potential effects of exposure misclassification are discussed further under the criterion of "Exposure Assessment" below.

Selection bias refers to systematic differences in characteristics of the comparison groups due to the criteria and/or methods used to select those included in the study. For example, three of the cohort studies (Raffle, 1957; Leupker and Smith, 1976; Waller, 1981) systematically excluded retirees from the cohort of exposed workers—but not from the population used for comparison. Therefore, cases of lung cancer that developed after retirement were counted against the comparison population but not against the cohort. This artificially reduced the SMR calculated for the exposed cohort in these three studies.

Another type of selection bias may occur when members of the control group in a case-control study are non-randomly selected. This happens when cases and controls are selected from the same larger population of patients or death certificates, and the controls are simply selected (prior to case matching) from the group remaining after those with lung cancer are removed. Such selection can lead to a control group that is biased with respect to occupation and smoking habits. Specifically, "* * * a severely distorted estimate of the association between exposure to diesel exhaust and lung cancer, and a severely distorted picture of the direction and degree of confounding by cigarette smoking, can come from case-control studies in which the controls are a collection of 'other deaths' " when the cause of most 'other deaths' is itself correlated with smoking or occupational choice (HEI, 1999). This selection bias can distort results in either direction.

MSHA judged that seven of the 20 available case-control studies were susceptible to this type of selection bias because controls were drawn from a population of "other deaths" or "other patients." [32] These control groups were likely to have over-represented cases of cardiovascular disease, which is known to be highly correlated with smoking and is possibly also correlated with

[30] As noted in Table III–4, the underground sulfide ore miners studied by Ahlman et al. (1991) were exposed to radon in addition to diesel emissions. The total number of lung cancers observed, however, was greater than what was attributable to the radon exposure, based on a calculation by the authors. Therefore, the authors attributed a portion of the excess risk to diesel exposure.

[31] Furthermore, as pointed out in comments submitted by Dr. Peter Valberg through the NMA, the subgroup of underground miners working at mines with diesel engines was small, and the exposure duration in one of the mines with diesel engines was only ten years. Therefore, the power of the study was inadequate to detect an excess risk of lung cancer for that subgroup by itself.

[32] These were: Buiatti et al. (1985), Coggan et al. (1984), DeCoufle et al. (1977), Garshick et al. (1987), Hayes et al. (1988), Lerchen et al. (1987), and Steenland et al. (1990).

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occupation. The only case-control study not reporting a positive result (DeCoufle et al., 1977) fell into this group of seven. The remaining 13 case-control studies all reported positive results.

It is "well established that persons in the work force tend to be 'healthier' than persons not employed, and therefore healthier than the general population. Worker mortality tends to be below average for all major causes of death." (HEI, 1999) Because workers tend to be healthier than non-workers, the prevalence of disease found among workers exposed to a toxic substance may be lower than the rate prevailing in the general population, but higher than the rate occurring in an unexposed population of similar workers. This phenomenon is called the "healthy worker effect."

All five cohort studies reporting entirely negative results drew comparisons against the general population and made no adjustments to take the healthy worker effect into account. (Kaplan, 1959; Waller (1981); Edling et al. (1987); Bender et al. (1989); Christie et al. (1995). The sixth negative study (DeCoufle, 1977) was a case-control study in which vehicle drivers and locomotive engineers were compared to clerical workers. As mentioned earlier, this study did not meet the criterion for a minimum 10-year latency period. All other studies in which exposed workers were compared against similar but unexposed workers reported some degree of elevated lung cancer risk for exposed workers.

Many of the 41 positive studies also drew comparisons against the general population with no compensating adjustment for the healthy worker effect. But the healthy worker effect can influence results even when the age-adjusted mortality or morbidity rate observed among exposed workers is greater than that found in the general population. In such studies, comparison with the general population tends to reduce the excess risk attributable to the substance being investigated. For example, Gustafsson et al. (1986), Rushton et al. (1983), and Wong et al. (1985) each reported an unadjusted SMR exceeding 1.0 for lung cancer in exposed workers and an SMR significantly less than 1.0 for all causes of death combined. Since the SMR for all causes is less than 1.0, there is evidence of a healthy worker effect. Therefore, the SMR reported for lung cancer was probably lower than if the comparison had been made against a more similar population of unexposed workers. Bhatia et al. (1998) constructed a simple estimate of the healthy worker effect evident in these studies, based on the SMR for all causes of death except lung cancer. This estimate was then used to adjust the SMR reported for lung cancer. For the three positive studies mentioned, the adjustment raised the SMR from 1.29 to 1.48, from 1.01 to 1.23, and from 1.07 to 1.34, respectively.[33]

Exposure Assessment

Many commenters suggested that a lack of concurrent exposure measurements in available studies limits their utility for quantitative risk assessment (QRA). MSHA is fully aware of these limitations but also recognizes that less desirable surrogates of exposure must frequently be employed out of practical necessity. As stated by HEI's expert panel on diesel epidemiology:

> Quantitative measures of exposures are important in any epidemiologic study used for QRA. The greater the detail regarding specific exposure, including how much, for how long, and at what concentration, the more useful the study is for this purpose. Frequently, however, individual measurements are not available, and surrogate measures or markers are used. For example, the most general surrogate measures of exposure in occupational epidemiologic studies are job classification and work location. (HEI, 1999)

It is important to distinguish, moreover, between studies used to identify a hazard (i.e., to establish that dpm exposure is associated with an excess risk of lung cancer) and studies used for QRA (i.e., to quantify the amount of excess risk corresponding to a given level of exposure). Although detailed exposure measurements are desirable in any epidemiologic study, they are more important for QRA than for identifying and characterizing a hazard. Conversely, epidemiologic studies can be highly useful for purposes of hazard identification and characterization even if a lack of personal exposure measurements renders them less than ideal for QRA.

Still, MSHA agrees that the quality of exposure assessment affects the value of a study for even hazard identification. Accordingly, MSHA has divided the 47 studies into four categories, depending on the degree to which exposures were quantified for the specific workers included. This ranking refers only to exposure assessment and does not necessarily correspond to the overall weight MSHA places on any of the studies.

The highest rank, with respect to this criterion, is reserved for studies having quantitative, concurrent exposure measurements for specific workers or for specific jobs coupled with detailed work histories. Only two studies (Johnston et al., 1997 and Säverin et al., 1999) fall into this category.[34] Both of these recent cohort studies took smoking habits into account. These studies both reported an excess risk of lung cancer associated with dpm exposure.

The second rank is defined by semi-quantitative exposure assessments, based on job history and an estimated exposure level for each job. The exposure estimates in these studies are crude, compared to those in the first rank, and they are subject to many more kinds of error. This severely restricts the utility of these studies for QRA (i.e., for quantifying the change in risk associated with various specified exposure levels). For purposes of hazard identification and characterization, however, crude exposure estimates are better than no exposure estimates at all. MSHA places two cohort studies and five case-control studies into this category.[35] All seven of these studies reported an excess risk of lung cancer risk associated with diesel exposure. Thus, results were positive in all nine studies with quantitative or semi-quantitative exposure assessments.

The next rank belongs to those studies with only enough information on individual workers to construct estimates of exposure duration. Although these studies present no data relating excess risk to specific exposure levels, they do provide excess risk estimates for those working a specified minimum number of years in a job associated with diesel exposure. One cohort study and five case-control studies fall into this category, and all six of them reported an excess risk of lung cancer.[36] With one exception

[33] A similar adjustment was applied to the SMR for lung cancer reported in one of the negative studies (Edling et al., 1987). This raised the SMR from 0.67 to 0.80. Because of insufficient data, Bhatia et al. did not carry out the adjustment for the three other studies they considered with potentially important healthy worker effects. (Bhatia et al., 1998)

[34] The study of German potash miners by Säverin et al. was introduced by NIOSH at the Knoxville public hearing prior to publication. The study, as cited, was later published in English. Although the dpm measurements (total carbon) were all made in one year, the authors provide a justification for assuming that the mining technology and type of machinery used did not change substantially during the period miners were exposed (ibid., p.420).

[35] The cohort studies are Garshick et al. (1988) and Gustavsson et al. (1990). The case-control studies are Emmelin et al. (1993), Garshick et al. (1997), Gustavsson et al. (1990), Siemiatycki et al. (1988), and Steenland et al. (1990, 1992).

[36] The cohort study is Wong et al. (1985). The case-control studies are Brüske-Hohlfeld et al. (1999), Benhamou et al. (1988), Boffetta et al. (1990), Hayes et al. (1989), and Swanson et al. (1993).

(Benhamou et al. 1988), these studies also presented evidence of increased age-adjusted risk for workers with longer exposures and/or latency periods.

The bottom rank, with respect to exposure assessment, consists of studies in which no exposure information was collected for individual workers. These studies used only job title to distinguish between exposed and unexposed workers. The remaining 32 studies, including five of the six with entirely negative results, fall into this category.

Studies basing exposure assessments on only a current job title (or even a history of job titles) are susceptible to significant misclassification of exposed and unexposed workers. Unless the study is poorly designed, this misclassification is "nondifferential"—i.e., those who are misclassified are no more and no less likely to develop lung cancer (or to have been exposed to carcinogens such as tobacco smoke) than those who are correctly classified. If workers are sometimes misclassified nondifferentially, then this will tend to mask or dilute any excess risk attributable to exposure. Furthermore, differential misclassification in these studies usually consists of systematically including workers with little or no diesel exposure in a job category identified as "exposed." This too would generally mask or dilute any excess risk attributable to exposure. Therefore, MSHA assumes that in most of these studies, more rigorous and detailed exposure assessments would have resulted in somewhat higher estimates of excess risk.

IMC Global, MARG, and some other commenters expressed special concern about potential exposure misclassification and suggested that such misclassification might be partly responsible for results showing excess risk. IMC Global, for example, quoted a textbook observation that, contrary to popular misconceptions, nondifferential exposure misclassification can sometimes bias results away from the null. MSHA recognizes that this can happen under certain special conditions. However, there is an important distinction between "can sometimes" and "can frequently." There is an even more important distinction between "can sometimes" and "in this case does." As noted by the HEI Expert Panel on Diesel Epidemiology (HEI, 1999, p. 48), "* * * nondifferential misclassification most often leads to an overall underestimation of effect." Similarly, Silverman (1998) noted, specifically with respect to the diesel studies, that "* * * this [exposure misclassification] bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates [of excess risk] toward the null value."

Statistical Significance

A "statistically significant" finding is a finding unlikely to have arisen by chance in the particular group, or statistical sample, of persons being studied. An association arising by chance would have no predictive value for exposed workers outside the sample. However, a specific epidemiologic study may fail to achieve statistical significance for two very different reasons: (1) there may be no real difference in risk between the two groups being compared, or (2) the study may lack the power needed to detect whatever difference actually exists. As described earlier, a lack of sufficient power comes largely from limitations such as a small number of subjects in the sample, low exposure and/or duration of exposure, or too short a period of latency or follow-up time. Therefore, a lack of statistical significance in an individual study does not demonstrate that the results of that study were due merely to chance—only that the study (viewed in isolation) is statistically inconclusive.

As explained earlier, MSHA classifies a reported RR, SMR, or OR (*i.e.*, the point estimate of relative risk) as "positive" if it exceeds 1.0 and "negative" if it is less than or equal to 1.0. By common convention, a positive result is considered statistically significant if its 95-percent confidence interval does not overlap 1.0. If all other relevant factors are equal, then a statistically significant positive result provides stronger evidence of an underlying relationship than one that is not statistically significant. On the other hand, a study must meet two requirements in order to provide statistically significant evidence of no positive relationship: (1) the upper limit of its 95-percent confidence interval must not exceed 1.0 by an appreciable amount[37] and (2) it must have allowed for sufficient exposure, latency, and follow-up time to have detected an existing relationship.

As shown in Tables III–4 and III–5, statistically significant positive results were reported in 25 of the 47 studies: 11 of the 19 positive case-control studies and 14 of the 22 positive cohort studies. In 16 of the 41 studies showing a positive association, the association observed was not statistically significant. Results in five of the six negative studies were not statistically significant. One of the six negative studies (Christie *et al.*, 1995, in full version), reported a statistically significant deficit in lung cancer for miners. This study, however, provided for no minimum period of exposure or latency and, therefore, lacked the power necessary to provide statistically significant evidence.[38]

Whether or not a study provides statistically significant evidence is dependent upon many variables, such as study size, adequate follow-up time (to account for enough exposure and latency), and adequate case ascertainment. In the ideal world, a sufficiently powerful study that failed to demonstrate a statistically significant positive relationship would, by its very failure, provide statistically significant evidence that an underlying relationship between an exposure and a specific disease was unlikely. It is important to note that MSHA regards a real 10-percent increase in the risk of lung cancer (*i.e.*, a relative risk of 1.1) as constituting a clearly significant health hazard. Therefore, "sufficiently powerful" in this context means that the study would have to be of such scale and quality as to detect a 10-percent increase in risk if it existed. The outcome of such a study could plausibly be called "negative" even if the estimated RR slightly exceeded 1.0—so long as the lower confidence limit did not exceed 1.0 and the upper confidence limit did not exceed 1.05. Rarely does an epidemiological study fall into this "ideal" study category. MSHA reviewed the dpm epidemiologic studies to determine which of them could plausibly be considered to be negative.

For example, one study (Waxweiller *et al.*, 1973) reported positive but statistically non-significant results corresponding to an RR of about 1.1. Among the studies MSHA counts as positive, this is the one that is numerically closest to being "negative". This study, however, relied on a relatively small cohort containing an indeterminate but probably substantial percentage of occupationally unexposed workers. Furthermore, there was no minimum latency allowance for the exposed workers. Therefore, even if MSHA were to use 1.1 rather than 1.05 as a threshold for significant relative risk, the study had insufficient statistical power to merit "negative" status.

One commenter (Dr. James Weeks, representing the UMWA) argued that "MSHA's reliance on * * * statistical

[37] As a matter of practicality, MSHA places the threshold at 1.05.

[38] More detailed discussion of this study appears later in this subsection.

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significance is somewhat misplaced. Results that are not significant statistically * * * can nevertheless indicate that the exposure in question caused the outcome." MSHA agrees that an otherwise sound study may yield positive (or negative) results that provide valuable evidence for (or against) an underlying relationship but fail, because of an insufficient number of exposed study subjects, to achieve statistical significance. In the absence of other evidence to the contrary, a single positive but not statistically significant result could even show that a causal relationship is more likely than not. By definition, however, such a result would not be conclusive at a high level of confidence. A finding of even very high excess risk in a single, well-designed study would be far from conclusive if based on a very small number of observed lung cancer cases or if it were in conflict with evidence from toxicity studies.

MSHA agrees that evidence should not be ignored simply because it is not conclusive at a conventional but arbitrary 95-percent confidence level. Lower confidence levels may represent weaker but still important evidence. Nevertheless, to rule out chance effects, the statistical significance of individual studies merits serious consideration when only a few studies are available. That is not the case, however, for the epidemiology literature relating lung cancer to diesel exposure. Since many studies contribute to the overall weight of evidence, the statistical significance of individual studies is far less important than the statistical significance of all findings combined. Statistical significance of the combined findings is addressed in Subsection 3.a.iii of this risk assessment.

Potential Confounders

There are many variables, both known and unknown, that can potentially distort the results of an epidemiologic study. In studies involving lung cancer, the most important example is tobacco smoking. Smoking is highly correlated with the development of lung cancer. If the exposed workers in a study tend to smoke more (or less) than the population to which they are being compared, then smoking becomes what is called a "confounding variable" or "confounder" for the study. In general, any variable affecting the risk of lung cancer potentially confounds observed relationships between lung cancer and diesel exposure. Conspicuous examples are age, smoking habits, and exposure to airborne carcinogens such as asbestos or radon progeny. Diet and other lifestyle factors may also be potential confounders, but these are probably less important for lung cancer than for other forms of cancer, such as bladder cancer.

There are two ways to avoid distortion of study results by a potential confounder: (1) design the study so that the populations being compared are essentially equivalent with respect to the potentially confounding variable; or (2) allow the confounding to take place, but adjust the results to compensate for its effects. Obviously, the second approach can be applied only to known confounders. Since no adjustment can be made for unknown confounders, it is important to minimize their effects by designing the comparison groups to be as similar as possible.

The first approach requires a high degree of control over the two groups being compared (exposed and unexposed in a cohort study; with and without lung cancer in a case-control study). For example, the effects of age in a case-control study can be controlled by matching each case of lung cancer with one or more controls having the same year of birth and age in year of diagnosis or death. Matching on age is never perfect, because it is generally not feasible to match within a day or even a month. Similarly, the effects of smoking in a case-control study can be imperfectly controlled by matching on smoking habits to the maximum extent possible.[39] In a cohort study, there is no confounding unless the exposed cohort and the comparison group differ with respect to a potential confounder. For example, if both groups consist entirely of never-smokers, then smoking is not a confounder in the study. If both groups contain the same percentage of smokers, then smoking is still an important confounder to the extent that smoking intensity and history differ between the two groups. In an attempt to minimize such differences (along with potentially important differences in diet and lifestyle) some studies restrict comparisons to workers of similar socioeconomic status and area of residence. Studies may also explicitly investigate smoking habits and histories and forego any adjustment of results if these factors are found to be homogeneously distributed across comparison groups. In that case, smoking would not actually appear to function as a confounder, and a smoking adjustment might not be required or even desirable. Nevertheless, a certain amount of smoking data is still necessary in order to check or verify homogeneity. The study's credibility may also be an important consideration. Therefore, MSHA agrees with the HEI's expert panel that even when smoking appears not to be a confounder,

> * * * a study is open to criticism if no smoking data are collected and the association between exposure and outcome is weak. * * * When the magnitude of the association of interest is weak, uncontrolled confounding, particularly from a strong confounder such as cigarette smoking, can have a major impact on the study's results and on the credibility of their use. [HEI, 1999]

However, this does not mean that a study cannot, by means of an efficient study design and/or statistical verification of homogeneity, demonstrate adequate control for smoking without applying a smoking adjustment.

The second approach to dealing with a confounder requires knowledge or estimation both of the differences in group composition with respect to the confounder and of the effect that the confounder has on lung cancer. Ideally, this would entail specific, quantitative knowledge of how the variable affects lung cancer risk for each member of both groups being compared. For example, a standardized mortality ratio (SMR) can be used to adjust for age differences when a cohort of exposed workers with known birth dates is compared to an unexposed reference population with known, age-dependent lung cancer rates.[40] In practice, it is not usually possible to obtain detailed information, and the effects of smoking and other known confounders cannot be precisely quantified.

Stöober and Abel (1996) argue, along with Morgan *et al.* (1997) and some commenters, that even in those epidemiologic studies that are adjusted for smoking and show a statistically significant association, the magnitude of relative or excess risk observed is too small to demonstrate any causal link between dpm exposure and cancer. Their reasoning is that in these studies, errors in the collection or interpretation of smoking data can create a bias in the results larger than any potential contribution attributable to diesel particulate. They propose that studies failing to account for smoking habits should be disqualified from consideration, and that evidence of an association from the remaining, smoking-adjusted studies should be discounted because of potential confounding due to erroneous, incomplete, or otherwise inadequate characterization of smoking histories.

It should be noted, first of all, that five of the six negative studies neither matched nor adjusted for smoking.[41] But more importantly, MSHA concurs with IARC (1989), Cohen and Higgins (1995), IPCS (1996), CAL–EPA (1998), ACGIH (1998), Bhatia *et al.* (1998), and Lipsett and Campleman (1999) in not accepting the view that studies should automatically be disqualified from consideration because of potential confounders. MSHA recognizes that unknown exposures to tobacco smoke or other human carcinogens can distort the results of some lung cancer studies. MSHA also recognizes, however, that it is not possible to design a human epidemiologic study that perfectly controls for all potential confounders. It is also important to note that a confounding variable does not necessarily inflate an observed association. For example, if the exposed members of a cohort smoke less than the reference group to which they are compared, then this will tend to reduce the apparent effects of exposure on lung cancer development. In the absence of evidence to the contrary, it is reasonable to assume that a confounder is equally likely to inflate or to deflate the results.

As shown in Tables III–4 and III–5, 18 of the published epidemiologic studies involving lung cancer did, in fact, control or adjust for exposure to tobacco smoke, and five of these 18 also controlled or adjusted for exposure to asbestos and other carcinogenic substances (Garshick *et al.*, 1987; Boffetta *et al.*, 1988; Steenland *et al.*, 1990; Morabia *et al.*, 1992; Brüske-Hohlfeld *et al.*, 1999). These results are less likely to be confounded than results from most of the studies with no adjustment. All but one of these 18 studies reported some degree of excess risk associated with occupational exposure to diesel particulate, with statistically significant results reported in eight.

In addition, several of the studies with no smoking adjustment took the first approach described above for preventing or substantially mitigating potential confounding by smoking habits: they drew comparisons against internal control groups or other control groups likely to have similar smoking habits as the exposed groups (*e.g.*, Garshick *et al.*, 1988; Gustavsson *et al.*, 1990; Hansen, 1993; and Säverin *et al.*, 1999). Therefore, MSHA places more weight on these studies than on studies drawing comparisons against dissimilar groups with no smoking controls or adjustments. This emphasis is in accordance with the conclusion by Bhatia *et al.* (1998) that smoking homogeneity typically exists within cohorts and is associated with a uniform lifestyle and social class. Although it was not yet available at the time Bhatia *et al.* performed their analysis, an analysis of smoking patterns by Säverin *et al.* (op cit.) within the cohort they studied also supports this conclusion.

IMC Global and MARG objected to MSHA's position on potential confounders and submitted comments in general agreement with the views of Morgan *et al.* (op cit.) and Stöbel and Abel (op cit.). Specifically, they suggested that studies reporting relative risks solely between 1.0 and 2.0 should be discounted because of potential confounders. Of the 41 positive studies considered by MSHA, 22 fall into this category (16 cohort and 6 case-control). In support of their suggestion, IMC Global quoted Speizer (1986), Muscat and Wynder (1995), Lee (1989), WHO (1980), and NCI (1994). These authorities all urged great caution when interpreting the results of such studies, because of potential confounders. MSHA agrees that none of these studies, considered individually, is conclusive and that each result must be considered with due caution. None of the quoted authorities, however, proposed that such studies should automatically be counted as "negative" or that they could not add incrementally to an aggregate body of positive evidence.

IMC Global also submitted the following reference to two Federal Court decisions pertaining to estimated relative risks less than 2.0:

> The Ninth Circuit concluded in Daubert v. Merrell Dow Pharmaceuticals" that "for an epidemiologic study to show causation * * * the relative risk * * * arising from the epidemiologic data will, at a minimum, have to exceed 2." Similarly, a District Court stated in Hall v. Baxter Healthcare Corp. 49: The threshold for concluding that an agent was more likely the cause of the disease than not is relative risk greater than 2.0. Recall that a relative risk of 1.0 means that the agent has no affect on the incidence of disease. When the relative risk reaches 2.0, the agent is responsible for an equal number of cases of disease as all other background causes. Thus a relative risk of 2.0 implies a 50% likelihood that an exposed individual's disease was caused by the agent. [IMC Global]

In contrast with the two cases cited, the purpose of this risk assessment is not to establish civil liabilities for personal injury. MSHA's concern is with reducing the risk of lung cancer, not with establishing the specific cause of lung cancer for an individual miner. The excess risk of an outcome, given an excessive exposure, is not the same thing as the likelihood that an excessive exposure caused the outcome in a given case. To understand the difference, it may be helpful to consider two analogies: (1) The likelihood that a given death was caused by a lightning strike is relatively low, yet exposure to lightning is rather hazardous; (2) a specific smoker may not be able to prove that his or her lung cancer was "more likely than not" caused by radon exposure, yet radon exposure significantly increases the risk—especially for smokers. Lung cancer has a variety of alternative causes, but this fact does not reduce the risk associated with any one of them.

Furthermore, there is ample precedent for utilizing epidemiologic studies reporting relative risks less than 2.0 in making clinical and public policy decisions. For example, the following table contains the RR for death from cardiovascular disease associated with cigarette smoking reported in several prospective epidemiologic studies:

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[39] If cases and controls cannot be closely matched on smoking or other potentially important confounder, then a hybrid approach is often taken. Cases and controls are matched as closely as possible, differences are quantified, and the study results are adjusted to account for the differences.

[40] Since these rates may vary by race, geographic region, or other factors, the validity of this adjustment depends heavily on choice of an appropriate reference population. For example, Waxweiler *et al.* (1973) based SMRs for a New Mexico cohort on national lung cancer mortality rates. Since the national age-adjusted rate of lung cancer is about 1/3 higher than the New Mexico rate, the reported SMRs were roughly 3/4 of what they would have been if based on rates specific to New Mexico.

[41] The exception is DeCoufle *et al.* (1977), a case-control study that apparently did not match or otherwise adjust for age.

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Study on cigarette smoking	Estimate of RR of death from cardiovascular disease
British doctors	1.6
Males in 25 states	
ages 45-64	2.08
ages 65-79	1.36
U.S. Veterans	1.74
Japanese study	1.96
Canadian veterans	1.6
Males in nine states	1.70
Swedish males	1.7
Swedish females	1.3
California occupations	2.0

Source: U.S. Department of Health and Human Services (1989)

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By IMC Global's rule of thumb, all but one or two of these studies would be discounted as evidence of increased risk attributable to smoking. These studies, however, have not been widely discounted by scientific authorities. To the contrary, they have been instrumental in establishing that cigarette smoking is a principal cause of heart disease.

A second example is provided by the increased risk of lung cancer found to be caused by residential exposure to radon progeny. As in the case of dpm, tobacco smoking has been an important potential confounder in epidemiological studies used to investigate whether exposures to radon concentrations at residential levels can cause lung cancer. Yet, in the eight largest residential epidemiological studies used to help establish the reality of this now widely accepted risk, the reported relative risks were all less than 2.0. Based on a meta-analysis of these eight studies, the combined relative risk of lung cancer attributable to residential radon exposure was 1.14. This elevation in the risk of lung cancer, though smaller than that reported in most studies of dpm effects, was found to be statistically significant at a 95-percent confidence level (National Research Council, 1999, Table G–25).

(ii) Studies Involving Miners. In the proposed risk assessment, MSHA identified seven epidemiologic studies reporting an excess risk of lung cancer among miners thought to have been exposed occupationally to diesel exhaust. As stated in the proposal, two of these studies specifically investigated miners, and the other five treated miners as a subgroup within a larger population of workers.[42] MSHA placed two additional studies specific to exposed coal miners (Christie *et al.*, 1995; Johnston *et al.*, 1997) into the public record with its Feb. 12, 1999 **Federal Register** notice. Another study,[43] investigating lung cancer in exposed potash miners, was introduced by NIOSH at the Knoxville public hearing on May 27, 1999 and later published as Säverin *et al.*, 1999. Finally, one study reporting an excess risk of lung cancer for presumably exposed miners was listed in Table III–5 as originally published, and considered by MSHA in its overall assessment, but inadvertently left out of the discussion on studies involving miners in the previous version of this risk assessment.[44] There are, therefore, available to MSHA a total of 11 epidemiologic studies addressing the risk of lung cancer for miners, and five of these studies are specific to miners.

Five cohort studies (Waxweiler *et al.*, 1973; Ahlman *et al.*, 1991; Christie *et al.*, 1996; Johnston *et al.*, 1997; Säverin *et al.*, 1999) were performed specifically on groups of miners, and one (Boffetta *et al.*, 1988) addressed miners as a subgroup of a larger population. Except for the study by Christie *et al.*, the cohort studies all showed elevated lung cancer rates for miners in general or for the most highly exposed miners within a cohort. In addition, all five case-control studies reported elevated rates of lung cancer for miners (Benhamou *et al.*, 1988; Lerchen *et al.*, 1987; Siemiatycki *et al.*, 1988; Morabia *et al.*, 1992; Burns and Swanson, 1991).

Despite the risk assessment's emphasis on human studies, some members of the mining community apparently believed that the risk assessment relied primarily on animal studies and that this was because studies on miners were unavailable. Canyon Fuels, for example, expressed concerns about relying on animal studies instead of studies on western diesel-exposed miners:

> Since there are over a thousand miners here in the West that have fifteen or more years of exposure to diesel exhaust, why has there been no study of the health status of those miners? Why must we rely on animal studies that are questionable and inconclusive?

Actually, western miners were involved in several studies of health effects other than cancer, as described earlier in this risk assessment. With respect to lung cancer, there are many reasons why workers from a particular group of mines might not be selected for study. Lung cancer often takes considerably more than 15 years to develop, and a valid study must allow not only for adequate duration of exposure but also for an adequate period of latency following exposure. Furthermore, many mines contain radioactive gases and/or respirable silica dust, making it difficult to isolate the effects of a potential carcinogen.

Similarly, at the public hearing in Albuquerque on May 13, 1999, a representative of Getchell Gold stated that he thought comparing miners to rats was irrational and that "there has not been a study on these miners as to what the effects are." To correct the impression that MSHA was basing its risk assessment primarily on laboratory animal studies, an MSHA panelist pointed out Tables III–4 and III–5 of the proposed preamble and identified six studies pertaining to miners that were listed in those tables. However, he placed no special weight on these studies and cited them only to illustrate the existence of epidemiologic studies reporting an elevated risk of lung cancer among miners.

With their post-hearing comments, the NMA and MARG submitted critiques by Dr. Peter Valberg and Dr. Jonathan Borak of six reports involving miners (see Footnote 42). Drs. Valberg and Borak both noted that the six studies reviewed lacked information on diesel exposure and were vulnerable to confounders and exposure misclassification. For these reasons, Dr. Valberg judged them "particularly poor in identifying what specific role, if any, diesel exhaust plays in lung cancer for miners." He concluded that they do not "implicate diesel exposure per se as

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[42] In the proposed risk assessment, the studies identified as specifically investigating miners were Waxweiler *et al.* (1973) and Ahlman *et al.* (1991). At the Albuquerque public hearing, Mr. Bruce Watzman, representing the NMA, asked a member of the MSHA panel (Mr. Jon Kogut) to list six studies involving miners that he had cited earlier in the hearing and to identify those that were specific to miners. In both his response to Mr. Watzman, and in his earlier remarks, Mr. Kogut noted that the studies involving miners were listed in Tables III–4 and III–5. However, he inadvertently neglected to mention Ahlman *et al.* (op cit.) and Morabia *et al.* (1992). (The latter study addressed miners as a subgroup of a larger population.)

In his response to Mr. Watzman, Mr. Kogut cited Swanson *et al.* (1993) but not Burns and Swanson (1991), which he had mentioned earlier in the hearing in connection with the same study. These two reports are listed under a single entry in Table III–5 (Swanson *et al.*) because they both report findings based on the same body of data. Therefore, MSHA considers them to be two parts of the same study. The 5.03 odds ratio for mining machine operators mentioned by Mr. Kogut during the hearing was reported in Burns and Swanson (1991).

Only the six studies specified by Mr. Kogut in his response to Mr. Watzman were included in separate critiques by Dr. Peter Valberg and Dr. Jonathan Borak later submitted by the NMA and by MARG, respectively. Dr. Valberg did not address Burns and Swanson (1991), and he addressed a different report by Siemiatycki than the one listed in Table III–5 and cited during the hearing (*i.e.*, Siemiatycki *et al.*, 1988). Neither Dr. Valberg nor Dr. Borak addressed Ahlman *et al.* (op cit.) or Morabia *et al.* (op cit.). Also excluded were two additional miner-specific studies placed into the record on Feb. 12, 1999 (Fed. Reg. 64:29 at 59258). Mr. Kogut did not include them in his response to Mr. Watzman, or in his prior remarks, because he was referring only to studies listed in Tables III–4 and III–5 of the published proposals. Mr. Kogut also did not include a study specific to German potash miners submitted by NIOSH at a subsequent public hearing, and this too was left out of both critiques. A published version of the study (Säverin *et al.*, 1999) was placed into the record on June 30, 2000. All of the studies involving miners are in the public record and have been available for comment by interested parties throughout the posthearing comment periods.

[43] Some commenters suggested that MSHA "overlooked" a recently published study on NSW miners, Brown *et al.*, 1997. This study evaluated the occurrence of forms of cancer other than lung cancer in the same cohort studied by Christie *et al.* (1995).

[44] This study was published in two seperate reports on the same body of data: Burns and Swanson (1991) and Swanson *et al.* (1993). Both published reports are listed in Table III–5 under the entry for Swanson *et al.*

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strongly associated with lung cancer risk in miners." Similarly, Dr. Borak suggested that, since they do not relate adverse health effects in miners to any particular industrial exposure, "the strongest conclusion that can be drawn from these six studies is that the miners in the studies had an increased risk of lung cancer."

MSHA agrees with Drs. Valberg and Borak that none of the studies they reviewed provides direct evidence of a link between dpm exposure and the excess risk of lung cancer reported for miners. (A few disagreements on details of the individual studies will be discussed below). As MSHA said at the Albuquerque hearing, the lack of exposure information on miners in these studies led MSHA to rely more heavily on associations reported for other occupations. MSHA also noted the limitations of these studies in the proposed risk assessment. MSHA explicitly stated that other epidemiologic studies exist which, though not pertaining specifically to mining environments, contain better diesel exposure information and are less susceptible to confounding by extraneous risk factors.

Inconclusive as they may be on their own, however, even studies involving miners with only presumed or sporadic occupational diesel exposure can contribute something to the weight of evidence. They can do this by corroborating evidence of increased lung cancer risk for other occupations with likely diesel exposures and by providing results that are at least consistent with an increased risk of lung cancer among miners exposed to dpm. Moreover, two newer studies pertaining specifically to miners do contain dpm exposure assessments based on concurrent exposure measurements (Johnston *et al., op cit.*; Säverin *et al., op cit.*). The major limitations pointed out by Drs. Valberg and Borak with respect to other studies involving miners do not apply to these two studies.

Case-Control Studies

Five case-control studies, all of which adjusted for smoking, found elevated rates of lung cancer for miners, as shown in Table III–5. The results for miners in three of these studies (Benhamou *et al.*, 1988; Morabia *et al.*, 1992; Siemiatycki *et al.*, 1988) are given little weight, partly because of possible confounding by occupational exposure to radioactive gasses, asbestos, and silica dust. Also, Benhamou and Morabia did not verify occupational diesel exposure status for the miners. Siemiatycki performed a large number of multiple comparisons and reported that most of the miners "were exposed to diesel exhaust for short periods of time," Lerchen *et al.* (1987) showed a marginally significant result for underground non-uranium miners, but cases and controls were not matched on date of birth or death, and the frequency of diesel exposure and exposure to known occupational carcinogens among these miners was not reported.

Burns and Swanson (1991)[45] reported elevated lung cancer risk for miners and especially mining machine operators, which the authors attributed to diesel exposure. Potential confounding by other carcinogens associated with mining make the results inconclusive, but the statistically significant odds ratio of 5.0 reported for mining machine operators is high enough to cause concern with respect to diesel exposures, especially in view of the significantly elevated risks reported in the same study for other diesel-exposed occupations. The authors noted that the "occupation most likely to have high levels of continuous exposure to diesel exhaust and to experience that exposure in a confined area has the highest elevated risks: mining machine operators."

Cohort Studies

As shown in Table III–4, MSHA identified six cohort studies reporting results for miners likely to have been exposed to dpm. An elevated risk of lung cancer was reported in five of these six studies. These results will be discussed chronologically.

Waxweiller (1973) investigated a cohort of underground and surface potash miners. The authors noted that potash ore "is not embedded in siliceous rock" and that the "radon level in the air of potash mines is not significantly higher than in ambient air." Contrary to Dr. Valberg's review of this study, the number of lung cancer cases was reported to be slightly higher than expected, for both underground and surface miners, based on lung cancer rates in the general U.S. population (after adjustment for age, sex, race, and date of death). Although the excess was not statistically significant, the authors noted that lung cancer rates in the general population of New Mexico were about 25 percent lower than in the general U.S. population. They also noted that a higher than average percentage of the miners smoked and that this would "tend to counterbalance" the adjustment needed for geographic location. The authors did not, however, consider two other factors that would tend to obscure or deflate an excess risk of lung cancer, if it existed: (1) a healthy worker effect and (2) the absence of any occupational diesel exposure for a substantial percentage of the underground miners.

MSHA agrees with Dr. Valberg's conclusion that "low statistical power and indeterminate diesel-exhaust exposure render this study inadequate for assessing the effect of diesel exhaust on lung-cancer risk in miners." However, given the lack of any adjustment for a healthy worker effect, and the likelihood that many of the underground miners were occupationally unexposed, MSHA views the slightly elevated risk reported in this study as consistent with other studies showing significantly greater increases in risk for exposed workers.

Boffetta *et al.* (1988) investigated mortality in a cohort of male volunteers who enrolled in a prospective study conducted by the American Cancer Society. Lung cancer mortality was analyzed in relation to self-reported diesel exhaust exposure and to employment in various occupations identified with diesel exhaust exposure, including mining. After adjusting for smoking patterns,[46] there was a statistically significant excess of 167 percent (RR = 2.67) in lung cancers among 2034 workers ever employed as miners, compared to workers never employed in occupations associated with diesel exposure. No analysis by type of mining was reported. Other findings reported from this study are discussed in the next subsection.

Although an adjustment was made for smoking patterns, the relative risk reported for mining did not control for exposures to radioactive gasses, silica dust, and asbestos. These lung carcinogens are probably present to a greater extent in mining environments than in most of the occupational environments used for comparison. Self-reported exposures to asbestos and stone dusts were taken into account in other parts of the study, but not in the calculation of excess lung cancer risks associated with specific occupations, including mining.

[45] This report is listed in Table III–5 under Swanson *et al.* (1993), which provides further analysis of the same body of data.

[46] During the public hearing on May 25, 1999, Mr. Mark Kaszniak of IMC Global incorrectly asserted that "smoking was treated in a simplistic way in this study by using three categories: smokers, ex-smokers, and non-smokers." The study actually used five categories, dividing smokers into separate categories for 1–20 cigarettes per day, 21 or more cigarettes per day, and exclusively pipe and/or cigar smoking.

Several commenters reiterated two caveats expressed by the study's authors and noted in Table III–4. These are (1) that the study is susceptible to selection biases because participants volunteered and because the age-adjusted mortality rates differed between those who provided exposure information and those who did not; and (2) that all exposure information was self-reported with no quantitative measurements. Since these caveats are not specific to mining and pertain to most of the study's findings, they will be addressed when this study's overall results are described in the next subsection.

One commenter, however, (Mr. Mark Kaszniak of IMC Global) argued that selection bias due to unknown diesel exposure status played an especially important role in the RR calculated for miners. About 21 percent of all participants provided no diesel exposure information. Mr. Kaszniak noted that diesel exposure status was unknown for an even larger percentage of miners and suggested that the RR calculated for miners was, therefore, inflated. He presented the following argument:

> In the miner category, this [unknown diesel exposure status] accounted for 44.2% of the study participants, higher than any other occupation studied. This is important as this group experienced a higher mortality for all causes as well as lung cancer than the analyzed remainder of the cohort. If these persons had been included in the "no exposure to diesel exhaust group," their inclusion would have lowered any risk estimates from diesel exposure because of their higher lung cancer rates. [IMC Global post-hearing comments]

This argument, which was endorsed by MARG, was apparently based on a misunderstanding of how the comparison groups used to generate the RR for mining were defined.[47] Actually, persons with unknown diesel exposure status were included among the miners, but excluded from the reference population. Including sometime miners with unknown diesel exposure status in the "miners" category would tend to mask or reduce any strong association that might exist between highly exposed miners and an increased risk of lung cancer. Excluding persons with unknown exposure status from the reference population had an opposing effect, since they happened to experience a higher rate of lung cancer than cohort members who said they were unexposed. Therefore, removing "unknowns" from the "miner" group and adding them to the reference group could conceivably shift the calculated RR for miners in either direction. However, the RR reported for persons with unknown diesel exposure status, compared to unexposed persons, was 1.4 (ibid., p. 412)—which is smaller than the 2.67 reported for miners. Therefore, it appears more likely that the RR for mining was deflated than inflated on account of persons with unknown exposure status.

Although confounders and selection effects may have contributed to the 2.67 RR reported for mining, MSHA believes this result was high enough to support a dpm effect, especially since elevated lung cancer rates were also reported for the three other occupations associated with diesel exhaust exposure. Dr. Borak stated without justification that "[the] association between dpm and lung cancer was confounded by age, smoking, and other occupational exposures * * *." He ignored the well-documented adjustments for age and smoking. Although it does not provide strong or direct evidence that dpm exposure was responsible for any of the increased risk of lung cancer observed among miners, the RR for miners is consistent with evidence provided by the rest of the study results.

Ahlman *et al.* (1991) studied cohorts of 597 surface miners and 338 surface workers employed at two sulfide ore mines using diesel powered front-end loaders and haulage equipment. Both of these mines (one copper and one zinc) were regularly monitored for alpha energy concentrations (*i.e.*, due to radon progeny), which were at or below the Finish limit of 0.3 WL throughout the study period. The ore in both mines contained arsenic only as a trace element (less than 0.005 percent). Lung cancer rates in the two cohorts were compared to rates for males in the same province of Finland. Age-adjusted excess mortality was reported for both lung cancer and cardiovascular disease among the underground miners, but not among the surface workers. None of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on the alpha energy concentration measurements made for the two mines, the authors calculated that not all of the excess lung cancer for the underground miners was attributable to radon exposure. Based on a questionnaire, the authors found similar underground and surface age-specific smoking habits and alcohol consumption and determined that "smoking alone cannot explain the difference in lung cancer mortality between the [underground] miners and surface workers." Due to the small size of the cohort, the excess lung cancer mortality for the underground miners was not statistically significant. However, the authors concluded that the portion of excess lung cancer not attributable to radon exposure could be explained by the combined effects of diesel exhaust and silica exposure. Three of the ten lung cancers reported for underground miners were experienced by conductors of diesel-powered ore trains.

Christie *et al.* (1994, 1995) studied mortality in a cohort of 23,630 male Australian (New South Wales, NSW) coal mine workers who entered the industry after 1972. Although the majority of these workers were underground miners, most of whom were presumably exposed to diesel emissions, the cohort included office workers and surface ("open cut") miners. The cohort was followed up through 1992. After adjusting for age, death rates were lower than those in the general male population for all major causes except accidents. This included the mortality rate for all cancers as a group (Christie *et al.*, 1995, Table 1). Lower-than-normal incidence rates were also reported for cancers as a group and for lung cancer specifically (Christie *et al.*, 1994, Table 10).

The investigators noted that the workers included in the cohort were all subject to pre-employment physical examinations. They concluded that "it is likely that the well known 'healthy worker' effect * * * was operating" and that, instead of comparing to a general population, "a more appropriate comparison group is Australian petroleum industry workers." (Christie *et al.*, 1995) In contrast to the comparison with the population of NSW, the all-cause standardized mortality ratio (SMR) for the cohort of coal miners was greater than for petroleum workers by a factor of over 20 percent—*i.e.*, 0.76 vs. 0.63 (ibid., p. 20). However, the investigators did not

[47] During the public hearing on May 25, 1999, Mr. Kaszniak stated his belief that, for miners, the "relative risk calculation excluded that 44% of folks who did not respond to the questionnaire with regards to diesel exposure." Contrary to Mr. Kaszniak's belief, however, the "miners" on which the 2.67 RR was based included all 2034 cohort members who had ever been a miner, regardless of whether they had provided diesel exposure information (see Boffetta *et al.*, 1988, p. 409).

Furthermore, the 44.2-percent nonrespondent figure is not pertinent to potential selection bias in the RR calculation reported for miners. The group of 2034 "sometime" miners used in that calculation was 65 percent larger than the group of 1233 "mainly" miners to which the 44-percent nonrespondent rate applies. The reference group used for comparison in the calculation consisted of all cohort members "with occupation different from those listed (*i.e.*, railroad workers, truck drivers, heavy equipment operators, and miners) and not exposed [to diesel exhaust]." The overall nonrespondent rate for occupations in the reference group was about 21 percent (calculated by MSHA from Table VII of Boffetta *et al.*, 1988).

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compare the cohort to petroleum workers specifically with respect to lung cancer or other causes of death. Nor did they adjust for a healthy worker effect or make any attempt to compare mortality or lung cancer rates among workers with varying degrees of diesel exposure within the cohort.

Despite the elevated SMR relative to petroleum workers, several commenters cited this study as evidence that exposure to diesel emissions was not causally associated with an increased risk of lung cancer (or with adverse health effects associated with fine particulates). These commenters apparently ignored the investigators' explanation that the low SMRs they reported were likely due to a healthy worker effect. Furthermore, since the cohort exhibited lower-than-normal mortality rates due to heart disease and non-cancerous respiratory disease, as well as to cancer, there may well have been less tobacco smoking in the cohort than in the general population. Therefore, it is reasonably likely that the age-adjusted lung cancer rate would have been elevated, if it had been adjusted for smoking and for a healthy worker effect based on mortality from causes other than accidents or respiratory disease. In addition, the cohort SMR for accidents (other than motor vehicle accidents) was significantly above that of the general population. Since the coal miners experienced an elevated rate of accidental death, they had a lower-than-normal chance to die from other causes or to develop lung cancer. The investigators made no attempt to adjust for the competing, elevated risk of death due to occupational accidents.

Given the lack of any adjustment for smoking, healthy worker effect, or the competing risk of accidental death, the utility of this study in evaluating health consequences of Dpm exposure is severely limited by its lack of any internal comparisons or comparisons to a comparable group of unexposed workers. Furthermore, even if such adjustments or comparisons were made, several other attributes of this study limit its usefulness for evaluating whether exposure to diesel emissions is associated with an increased risk of lung cancer. First, the study was designed in such a way as to allow inadequate latency for a substantial portion of the cohort. Although the cohort was followed up only through 1992, it includes workers who entered the workforce at the end of 1992. Therefore, there is no minimum duration of occupational exposure for members of the cohort. Approximately 30 percent of the cohort was employed in the industry for less than 10 years, and the maximum duration of employment and latency combined was 20 years. Second, average age for members of the cohort was only 40 to 50 years (Christie *et al.*, p. 7), and the rate of lung cancer was based on only 29 cases. The investigators acknowledged that "it is a relatively young cohort" and that "this means a small number of cancers available for analysis, because cancer is more common with advancing age * * *." They further noted that "* * * the number of cancers available for analysis is increasing very rapidly. As a consequence, every year that passes makes the cancer experience of the cohort more meaningful in statistical terms." (ibid., p. 27) Third, miners's work history was not tracked in detail, beyond identifying the first mine in which a worker was employed. Some of these workers may have been employed, for various lengths of time, in both underground and surface operations at very different levels of diesel exposure. Without detailed work histories, it is not possible to construct even semi-quantitative measures of diesel exposure for making internal comparisons within the cohort.

One commenter (MARG) claimed that this (NSW) study "* * * reflects the latest and best scientific evidence, current technology, and the current health of miners" and that it "is not rational to predicate regulations for the year 2000 and beyond upon older scientific studies * * *." For the reasons stated above, MSHA believes, to the contrary, that the NSW study contributes little or no information on the potential health effects of long-term dpm exposures and that whatever information it does contribute does not extend to effects, such as cancer, expected in later life.

Furthermore, three even more recent studies are available that MSHA regards as far more informative for the purposes of the present risk assessment. Unlike the NSW study, these directly address dpm exposure and the risk of lung cancer. Two of these studies (Johnston *et al.*, 1997; Säverin *et al.*, 1999), both incorporating a quantitative dpm exposure assessment, were carried out specifically on mining cohorts and will be discussed next. The third (Brüske-Hohlfeld *et al.*, 1999) is a case-control study not restricted to miners and will be discussed in the following subsection. In accordance with MARG's emphasis on the timeliness of scientific studies, MSHA places considerable weight on the fact that all three—the most recent epidemiologic studies available—reported an association between diesel exposure and an increased risk of lung cancer.

Johnston *et al.* (1997) studied a cohort of 18,166 coal miners employed in ten British coal mines over a 30-year period. Six of these coal mines used diesel locomotives, and the other four were used for comparison. Historical NO_X and respirable dust concentration measurements were available, having routinely been collected for monitoring purposes. Two separate approaches were taken to estimate dpm exposures, leading to two different sets of estimates. The first approach was based on NO_X measurements, combined with estimated ratios between dpm and NO_X. The second approach was based on complex calculations involving measurements of total respirable dust, ash content, and the ratio of quartz to dust for diesel locomotive drivers compared to the ratio for face workers (ibid., Figure 4.1 and pp. 25–46). These calculations were used to estimate dpm exposure concentrations for the drivers, and the estimates were then combined with traveling times and dispersion rates to form estimates of dpm concentration levels for other occupational groups. In four of the six dieselized mines, the NO_X-based and dust-based estimates of dpm were in generally good agreement, and they were combined to form time-independent estimates of shift average dpm concentration for individual seams and occupational groups within each mine. In the fifth mine, the PFR measurements were judged unreliable for reasons extensively discussed in the report, so the NO_X-based estimates were used. There was no NO_X exposure data for the sixth mine, so they used dust-based estimates of dpm exposure.

Final estimates of shift-average dpm concentrations ranged from 44 $\mu g/m^3$ to 370 $\mu g/m^3$ for locomotive drivers and from 1.6 $\mu g/m^3$ to 40 $\mu g/m^3$ for non-drivers at various mines and work locations (ibid., Tables 8.3 and 8.6, respectively). These were combined with detailed work histories, obtained from employment records, to provide an individual estimate of cumulative dpm exposure for each miner in the cohort. Although most cohort members (including non-drivers) had estimated cumulative exposures less than 1 g-hr/m^3, some members had cumulative exposures that ranged as high as 11.6 g-hr/m^3 (ibid., Figure 9.1 and Table 9.1).

A statistical analysis (time-dependent proportional hazards regression) was performed to examine the relationship between lung cancer risk and each miner's estimated cumulative dpm exposure (unlagged and lagged by 15 years), attained age, smoking habit, mine, and cohort entry date. Smoking habit was represented by non-smoker, ex-smoker, and smoker categories, along with the average number of cigarettes smoked per day for the smokers. Pipe tobacco consumption was expressed by an equivalent number of cigarettes per day.

In their written comments, MARG and the NMA both mischaracterized the results of this study, apparently confusing it with a preliminary analysis of the same cohort. The preliminary analysis (one part of what Johnston *et al.* refer to as the "wider mortality study") was summarized in Section 1.2 (pp. 3–5) of the 105-page report at issue, which may account for the confusion by MARG and the NMA.[48]

Contrary to the MARG and NMA characterization, Johnston *et al.* found a positive, quantitative relationship between cumulative dpm exposure (lagged by 15 years) and an excess risk of lung cancer, after controlling for age, smoking habit, and cohort entry date. For each incremental g-hr/m^3 of cumulative occupational dpm exposure, the relative risk of lung cancer was estimated to increase by a factor of 22.7 percent. Adjusting for mine-to-mine differences that may account for a portion of the elevated risk reduced the estimated RR factor to 15.6 percent. Therefore, with the mine-specific adjustment, the estimated RR was 1.156 per g-hr/m^3 of cumulative dpm exposure. It follows that, based on the mine-adjusted model, the estimated RR for a specified cumulative exposure is 1.156 raised to a power equal to that exposure. For example, RR = $(1.156)^{3.84}$ = 1.74 for a cumulative dpm exposure of 3.84 g-hr/m^3, and RR = $(1.156)^{7.68}$ = 3.04 for a cumulative dpm exposure of 7.68 g-hr/m^3.[49] Estimates of RR based on the mine-unadjusted model would substitute 1.227 for 1.156 in these calculations.

Two limitations of this study weaken the evidence it presents of an increasing exposure-response relationship. First, although the exposure assessment is quantitative and carefully done, it is indirect and depends heavily on assumptions linking surrogate measurements to dpm exposure levels. The authors, however, analyzed sources of inaccuracy in the exposure assessment and concluded that "the similarity between the estimated * * * [dpm] exposure concentrations derived by the two different methods give some degree of confidence in the accuracy of the final values * * *." (ibid., pp.71–75) Second, the highest estimated cumulative dpm exposures were clustered at a single coal mine, where the SMR was elevated relative to the regional norm. Therefore, as the authors pointed out, this one mine greatly influences the results and is a possible confounder in the study. The investigators also noted that this mine was "* * * found to have generally the higher exposures to respirable quartz and low level radiation." Nevertheless, MSHA regards it likely that the relatively high dpm exposures at this mine were responsible for at least some of the excess mortality. There is no apparent way, however, to ascertain just how much of the excess mortality (including lung cancer) at this coal mine should be attributed to high occupational dpm exposures and how much to confounding factors distinguishing it (and the employees working there) from other mines in the study.

The RR estimates based on the mine-unadjusted model assume that the excess lung cancer observed in the cohort is entirely attributable to dpm exposures, smoking habits, and age distribution. If some of the excess lung cancer is attributed to other differences between mines, then the dpm effect is estimated by the lower RR based on the mine-adjusted model.

For purposes of comparison with the findings of Säverin *et al.* (1999), it will be useful to calculate the RR for a cumulative dpm exposure of 11.7 g-hr/m^3 (*i.e.*, the approximate equivalent of 4.9 mg-yr/m^3 TC).[50] At this exposure level, the mine-unadjusted model produces an estimated RR = $(1.227)^{11.7}$ = 11, and the mine-adjusted model produces an estimated RR = $(1.156)^{11.7}$ = 5.5.

Säverin *et al.* (1999) studied a cohort of male potash miners in Germany who had worked underground for at least one year after 1969, when the mines involved began converting to diesel powered vehicles and loading equipment. Members of the cohort were selected based on company medical records, which also provided bi-annual information on work location for each miner and, routinely after 1982, the miner's smoking habits. After excluding miners whose workplace histories could not be reconstructed from the medical records (5.5 percent) and miners lost to follow-up (1.9 percent), 5,536 miners remained in the cohort. Within this full cohort, the authors defined a sub-cohort consisting of 3,258 miners who had "worked underground for at least ten years, held one single job during at least 80% of their underground time, and held not more than three underground jobs in total."

The authors divided workplaces into high, medium, and low diesel exposure categories, respectively corresponding to production, maintenance, and workshop areas of the mine. Each of these three categories was assigned a representative respirable TC concentration, based on an average of measurements made in 1992. These averages were 390 $\mu g/m^3$ for production, 230 $\mu g/m^3$ for maintenance, and 120 $\mu g/m^3$ for workshop. Some commenters expressed concern about using average exposures from 1992 to represent exposure throughout the study. The authors justified using these measurement averages to represent exposure levels throughout the study period because "the mining technology and the type of machinery used did not change substantially after 1970." This assumption was based on interviews with local engineers and industrial hygienists.

Thirty-one percent of the cohort consented to be interviewed, and information from these interviews was used to validate the work history and smoking data reconstructed from the medical records. The TC concentration assigned to each work location was combined with each miner's individual work history to form an estimate of cumulative exposure for each member of the cohort. Mean duration of exposure was 15 years. As of the end of follow-up in 1994, average age was 49 years, average time since first exposure was 19 years, and average cumulative exposure was 2.70 mg-y/m^3.

[48] Since MARG and the NMA both stressed the importance of a quantitative exposure assessment, it is puzzling that they focused on a crude SMR from the preliminary analysis and ignored the quantitative results from the subsequent analysis. Johnston et al. noted that SMRs from the preliminary analysis were consistent "with other studies of occupational cohorts where a healthy worker effect is apparent." But even the preliminary analysis explored a possible surrogate exposure-response relationship, rather than simply relying on SMRs. Unlike the analysis by Johnston et al., the preliminary analysis used travel time as a surrogate measure of dpm exposure and made no attempt to further quantify dpm exposure concentrations. (ibid., p. 5)

[49] Assuming an average dpm concentration of 200 $\mu g/m^3$ and 1920 work hours per year, 3.84 g-hr/m^3 and 7.68 g-hr/m^3 correspond to 10 and 20 years of occupational exposure, respectively.

[50] This value represents 20 years of cumulative exposure for the most highly exposed category of workers in the cohort studied by Säverin et al.

As explained elsewhere in this preamble, TC constitutes approximately 80 percent of total dpm. Therefore, the TC value of 4.9 mg-yr/m^3 presented by Säverin *et al.* must first be divided by 0.8 to produce a corresponding dpm value of 6.12 mg-yr/m^3. To convert this result to the units used by Johnston *et al.*, it is then multiplied by 1920 work hours per year and divided by 1000 mg/g to yield 11.7 g-hr/m^3. This is nearly identical to the maximum cumulative dpm exposure estimated for locomotive drivers in the study by Johnston *et al.* (See Johnston *et al.*, *op cit.*, Table 9.1.)

The authors performed an analysis (within each TC exposure category) of smoking patterns compared with cumulative TC exposure. They also analyzed smoking misclassification as estimated by comparing information from the interviews with medical records. From these analyses, the authors determined that the cohort was homogeneous with respect to smoking and that a smoking adjustment was neither necessary nor desirable for internal comparisons. However, they did not entirely rule out the possibility that smoking effects may have biased the results to some extent. On the other hand, the authors concluded that asbestos exposure was minor and restricted to jobs in the workshop category, with negligible effects. The miners were not occupationally exposed to radon progeny, as documented by routine measurement records.

As compared to the general male population of East Germany, the cohort SMR for all causes combined was less than 0.6 at a 95-percent confidence level. The authors interpreted this as demonstrating a healthy worker effect, noting that "underground workers are heavily selected for health and sturdiness, making any surface control group incomparable." Accordingly, they performed internal comparisons within the cohort of underground miners. The RR reported for lung cancer among miners in the high-exposure production category, compared to those in the low-exposure workshop category, was 2.17. The corresponding RR was not elevated for other cancers or for diseases of the circulatory system.

Two statistical methods were used to investigate the relationship between lung cancer RR and each miner's age and cumulative TC exposure: Poisson regression and time-dependent proportional hazards regression. These two statistical methods were applied to both the full cohort and the subcohort, yielding four different estimates characterizing the exposure-response relationship. Although a high confidence level was not achieved, all four of these results indicated that the RR increased with increasing cumulative TC exposure. For each incremental mg-yr/m³ of occupational TC exposure, the relative risk of lung cancer was estimated to increase by the following multiplicative factor: [51]

Method	RR per mg-yr/m³	
	Full cohort	Subcohort
Poisson	1.030	1.139
Proportional Hazards	1.112	1.225

Based on these estimates, the RR for a specified cumulative TC exposure (X) can be calculated by raising the tabled value to a power equal to X. For example, using the proportional hazards analysis of the subcohort, the RR for X = 3.5 mg-yr/m³ is $(1.225)^{3.5} = 2.03$.[52]

The authors calculated the RR expected for a cumulative TC exposure of 4.9 mg-yr/m3, which corresponds to 20 years of occupational exposure for miners in the production category of the cohort. These miners were exposed for five hours per 8-hour shift at an average TC concentration of 390 µg/m.³ The resulting RR values were reported as follows:

Method	RR for 4.9 mg-yr/m³	
	Full cohort	Subcohort
Poisson	1.16	1.89
Proportional Hazards	1.68	2.70

This study has two important limitations that weaken the evidence it presents of a positive correlation between cumulative TC exposure and the risk of lung cancer. These are (1) potential confounding due to tobacco smoking and (2) a significant probability (i.e., greater than 10 percent) that a correlation of the magnitude found could have arisen simply by chance, given that it were based on a relatively small number of lung cancer cases.

Although data on smoking habits were compiled from medical records for approximately 80 percent of the cohort, these data were not incorporated into the statistical regression models. The authors justified their exclusion of smoking from these models by showing that the likelihood of smoking was essentially unrelated to the cumulative TC exposure for cohort members. Based on the portion of the cohort that was interviewed, they also determined that the average number of cigarettes smoked per day was the same for smokers in the high and low TC exposure categories (production and workshop, respectively). However, these same interviews led them to question the accuracy of the smoking data that had been compiled from medical records. Despite the cohort's apparent homogeneity with respect to smoking, the authors noted that smoking was potentially such a strong confounder that "even small inaccuracies in smoking data could cause effects comparable in size to the weak carcinogenic effect of diesel exhaust." Therefore, they excluded the smoking data from the analysis and stated they could not entirely rule out the possibility of a smoking bias. MSHA agrees with the authors of this report and the HEI Expert Panel (op cit.) that even a high degree of cohort homogeneity does not rule out the possibility of a spurious correlation due to residual smoking effects. Nevertheless, because of the cohort's homogeneity, the authors concluded that "the results are unlikely to be substantially biased by confounding," and MSHA accepts this conclusion.

The second limitation of this study is related to the fact that the results are based on a total of only 38 cases of lung cancer for the full cohort and 21 cases for the subcohort. In their description of this study at the May 27, 1999, public hearing, NIOSH noted that the "lack of [statistical] significance may be a result of the study having a small cohort (approximately 5,500 workers), a limited time from first exposure (average of 19 years), and a young population (average age of 49 years at the end of follow-up)." More cases of lung cancer may be expected to occur within the cohort as its members grow older. The authors of the study addressed statistical significance as follows:

* * * the small number of lung cancer cases produced wide confidence intervals for all measures of effect and substantially limited the study power. We intend to extend the follow-up period in order to improve the statistical precision of the exposure-response relationship. [Säverin et al., op cit.]

Some commenters stated that due to these limitations, data from the Säverin et al. study should not be the basis of this rule. On the other hand, NIOSH commented that "[d]espite the limitations discussed * * * the findings from the Säverin et al. (1999) study should be used as an alternative source of data for quantifying the possible lung cancer risks associated with Dpm exposures." As stated earlier, MSHA is not relying on any single study but, instead, basing its evaluation on the weight of evidence from all available data.

(iii) Best Available Epidemiologic Evidence. Based on the evaluation criteria described earlier, and after considering all the public comment that was submitted, MSHA has identified four cohort studies (including two from U.S.) and four case-control studies (including three from U.S.) that provide the best currently available epidemiologic evidence relating dpm exposure to an increased risk of lung cancer. Three of the 11 studies involving miners fall into this select group. MSHA considers the statistical significance of the combined evidence far more important than confidence levels for individual studies. Therefore, in choosing the eight most informative studies, MSHA placed less weight on statistical significance than on the other criteria. The basis for MSHA's selection of these eight studies is summarized as follows:

Study	Statistical Significance (at 95% Conf.)	Comparison groups	Exposure assessment	Controls on potential confounding
Boffetta et al. 1988 (cohort).	Yes	Internal Comparison	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking, and, in some analyses, for occupational exposures to asbestos, coal & stone dusts, coal tar & pitch, and gasoline exhaust.
Boffetta et al. 1990 (case-control).	No	Matched within hospital on smoking, age, year of interview.	Job history and self-reported duration of occupational diesel exposure.	Adjustments for age, smoking habit and intensity, asbestos exposure, race, and education.
Brüske-Hohlfeld et al. 1999 (case-control).	Yes	Matched on sex, age, and region of residence of residence.	Total duration of occupational diesel exposure based on detailed job history.	Adjustments for current and past smoking patterns, cumulative amount smoked (packyears), and asbestos exposure.
Garshick et al. 1987 (case-control).	Yes	Matched within cohort on dates of birth and death.	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Adjustments for lifetime smoking and asbestos exposure.
Garshick et al. 1988, 1991 (cohort).	Yes	Internal Comparison	Semi-quantitative, based on job history and tenure combined with exposure status established later for each job.	Subjects with likely or possible asbestos exposure excluded from cohort. Cigarette smoking determined to be uncorrelated with diesel exposure within cohort.
Johnston et al. 1997 (cohort).	No (marginal)	Internal Comparison	Quantitative, based on surrogate exposure measurements and detailed employment records.	Adjustments for age, smoking habit & intensity, mine site, and cohort entry date.
Säverin et al. 1999 (cohort).	No	Internal Comparison	Quantitative, based on TC exposure measurements and detailed employment records.	Adjustment for age. Cigarette smoking determined to be uncorrelated with cumulative TC exposure within cohort.
Steenland et al. 1990, 1992, 1998 (case-control).	Yes	Matached within cohort on date of death within 2 years.	Semi-quantitative, based on job history and subsequent EC measurements.	Adjustments for age, smoking, and asbestos exposure. Dietary covariates were tested and found not to confound the analysis.

Six entirely negative studies were identified earlier in this risk assessment. Several commenters objected to MSHA's treatment of the negative studies, indicating that they had been discounted without sufficient justification. To put this in proper perspective, the six negative studies should be compared to those MSHA has identified as the best available epidemiologic evidence, with respect to the same evaluation criteria. (It should be noted that the statistical significance of a negative study is best represented by its power.) In accordance with those criteria, MSHA discounts the evidentiary significance of these six studies for the following reasons:

Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Bender et al. 1989 (cohort)	Relative small cohort (N=4849).	External comparison; No adjustment for healthy worker effect.	Job only: highway maintenance workers.	Disparate comparison groups with no smoking adjustment.

[51] MSHA determined these values by calculating the antilog, to the base e, of each corresponding estimate of α reported by Säverin et al. (op cit.) in their Tables III and IV. The cumulative exposure unit of mg-yr/m³ refers to the average TC concentration experienced over a year's worth of 8-hour shifts.

[52] This is the estimated risk relative not to miners in the workshop category but to a theoretical age-adjusted baseline risk for cohort members accumulating zero occupational TC exposure.

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Study	Power	Comparison groups	Exposure assessment	Controls on potential confounding
Christie et al. 1996 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Industry only: combined all underground and surface workers at coal mines.	Disparate comparison groups with no smoking adjustment.
DeCoufle et al. 1977 (case-control).	Inadequate latency allowance.	Cases not matched with controls.	Job only: (1) Combined bus, taxi, and truck drivers; (2) locomotive engineers.	Age differences not taken into account.
Edling et al. 1987 (cohort)	Small cohort (N=694)	External comparison; No adjustment for healthy worker effect.	Job only: bus workers	Disparate comparison groups with no smoking adjustment.
Kaplan 1959 (cohort)	Inadequate latency allowance.	External comparison; No adjustment for healthy worker effect.	Jobs classified by diesel exposure. No attempt to differentiate between diesel and coal-fired locomotives.	Disparate comparison groups with no smoking adjustment.
Waller 1981 (cohort)	Acceptable	External comparison; No adjustment for healthy worker effect; Selection bias due to excluding retirees from cohort.	Job only: bus workers	Disparate coparison groups with no smoking adjustment.

Other studies proposed as counter-evidence by some commenters will be addressed in the next subsection of this risk assessment.

The eight studies MSHA identified as representing the best available epidemiologic evidence all reported an elevated risk of lung cancer associated with diesel exposure. The results from these studies will now be reviewed, along with MSHA's response to public comments as appropriate.

Boffetta et al., 1988

The structure of this cohort study was summarized in the preceding subsection of this risk assessment. The following table contains the main results. The relative risks listed for duration of exposure were calculated with reference to all members of the cohort reporting no diesel exposure, regardless of occupation, and adjusted for age, smoking pattern, and other occupational exposures (asbestos, coal and stone dusts, coal tar and pitch, and gasoline exhausts). The relative risks listed for occupations were calculated for cohort members that ever worked in the occupation, compared to cohort members never working in any of the four occupations listed and reporting no diesel exposure. These four relative risks were adjusted for age and smoking pattern only. Smoking pattern was coded by 5 categories: never smoker; current 1–20 cigarettes per day; current 21 or more cigarettes per day; ex-smoker of cigarettes; current or past pipe and/or cigar smoker.

MAIN RESULTS FROM BOFFETTA ET AL., 1988

[RRs by duration adjusted for age, smoking, and other occupational exposures; Occupational RRs adjusted for age and smoking only]

Self-reported duration of exposure to diesel exhaust	Lung cancer RR	95-percent confidence interval
Years:		
1 to 15	1.05	0.80–1.39
16 or more	1.21	0.94–1.56
Occupation:		
Truck Drivers	1.24	0.93–1.66
Railroad Workers	1.59	0.94–2.69
Heavy Equipment Operators	2.60	1.12–6.06
Miners	2.67	1.63–4.37

In addition to comments (addressed earlier) on the RR for miners in this study, IMC Global submitted several comments pertaining to the RR calculated for persons who explicitly stated that they had been occupationally exposed to diesel emissions. This RR was 1.18 for persons reporting any exposure (regardless of duration) compared to all subjects reporting no exposure. MSHA considers the most important issue raised by IMC Global to be that 20.6 percent of all cohort members did not answer the question about occupational diesel exhaust exposure during their lifetimes, and these subjects experienced a higher age-adjusted mortality rate than the others. As the authors of this study acknowledged, this "could introduce a substantial bias in the estimate of the association." (Boffetta et al., 1988, p. 412).

To show that the impact of this bias could indeed be substantial, the authors of the study addressed one extreme possibility, in which all "unknowns" were actually unexposed. Under this scenario, excluding the "unknowns" would have biased the calculated RR upward by a sufficient amount to explain the entire 18-percent excess in RR. This would not, however, explain the higher RR for persons reporting more than 16 years exposure, compared to the RR for persons reporting 1 to 15 years. Moreover, the authors did not discuss the opposite extreme: if all or most of the "unknowns" who experienced lung cancer were actually exposed, then excluding them would have biased the calculated RR downward. There is little basis for favoring one of these extremes over the other.

Another objection to this study raised by IMC Global was:

> All exposure information in the study was self-reported and not validated. The authors of the study have no quantitative data or measurements of actual diesel exhaust exposures.

MSHA agrees with IMC Global and other commenters that a lack of quantitative exposure measurements limits the strength of the evidence this study presents. MSHA believes, however, that the evidence presented is nevertheless substantial. The possibility of random classification errors due to self-reporting of exposures does not explain why persons reporting 16 or more years of exposure would experience a higher relative risk of lung cancer than persons reporting 1 to 15 years of exposure. This difference is not statistically significant, but random exposure misclassification would tend to make the effects of exposure less conspicuous. Nor can self-reporting explain why an elevated risk of lung cancer would be observed for four occupations commonly associated with diesel exposure.

Furthermore, the study's authors did perform a rough check on the accuracy of the cohort's exposure information. First, they confirmed that, after controlling for age, smoking, and other occupational exposures, a statistically significant relationship was found between excess lung cancer and the cohort's self-reported exposures to asbestos. Second they found no such association for self-reported exposure to pesticides and herbicides, which they considered unrelated to lung cancer (ibid., pp. 410–411).

IMC Global also commented that the "* * * study may suffer from volunteer bias in that the cohort was healthier and less likely to be exposed to important risk factors, such as smoking or alcohol." They noted that this possibility "is supported by the U.S. EPA in their draft Health Assessment Document for Diesel Emissions."

The study's authors noted that enrollment in the cohort was nonrandom and that participants tended to be healthier and less exposed to various risk factors than the general population. These differences, however, would tend to reduce any relative risk for the cohort calculated in comparison to the external, general population. The authors pointed out that external comparisons were, therefore, inappropriate; but "the internal comparisons upon which the foregoing analyses are based are not affected strongly by selection biases." (ibid.)

Although the 1999 EPA draft notes potential volunteer bias, it concludes: "Given the fact that all diesel exhaust exposure occupations * * * showed elevated lung cancer risk, this study is suggestive of a causal association."[53] (EPA, 1999, p. 7–13) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

Boffetta et al., 1990

This case-control study was based on 2,584 male hospital patients with histologically confirmed lung cancer, matched with 5099 male patients with no tobacco-related diseases. Cases and controls were matched within each of 18 hospitals by age (within two years) and year of interview. Information on each patient, including medical and smoking history, occupation, and alcohol and coffee consumption, was obtained at the time of diagnosis in the hospital, using a structured questionnaire. For smokers, smoking data included the number of cigarettes per day. Prior to 1985, only the patient's usual job was recorded. In 1985, the questionnaire was expanded to include up to five other jobs and the length of time worked in each job. After 1985, information was also obtained on dietary habits, vitamin consumption, and exposure to 45 groups of chemicals, including diesel exhaust.

The authors categorized all occupations into three groups, representing low, possible, and probable diesel exhaust exposure. The "low exposure" group was used as the reference category for calculating odds ratios for the "possible" and "probable" job groups. These occupational comparisons were based on the full cohort of patients, enrolled both before and after 1985. A total of 35 cases and 49 controls (all enrolled after the questionnaire was expanded in 1985) reported a history of diesel exposure. The reference category for self-reported diesel exposure consisted of a corresponding subset of 442 cases and 897 controls reporting no diesel exposure on the expanded questionnaire. The authors made three comparisons to rule out bias due to self-reporting of exposure: (1) No difference was found between the average number of jobs reported by cases and controls; (2) the association between self-reported asbestos exposure was in agreement with previously published estimates; and (3) no association was found for two exposures (pesticides and fuel pumping) considered unrelated to lung cancer (ibid., p. 584).

Stöber and Abel (1996) identified this study as being "of eminent importance owing to the care taken in including the most influential confounding factors and analyses of dose-effect relationships." The main findings are presented in the following table. All of these results were obtained using logistic regression, factoring in the estimated effects of age, race, years of education, number of cigarettes per day, and asbestos exposure (yes or no). An elevated risk of lung cancer was reported for workers with more than 30 years of either self-reported or "probable" diesel exposure. The authors repeated the occupational analysis using "ever" rather than "usual" employment in jobs classified as "probable" exposure, with "remarkably similar" results (ibid., p. 584).

MAIN RESULTS FROM BOFFETTA ET AL., 1990

[Adjusted for age, race, education, smoking, and asbestos exposure]

Self-reported duration of exposure to diesel exhaust	Lung cancer odds ratio	95-percent confidence interval
Years:		
1 to 15	0.90	0.40–1.99
16 to 30	1.04	0.44–2.48
31 or more	2.39	0.87–6.57
Likelihood of Exposure:		
19 jobs with "possible" exposure	0.92	0.76–1.10
13 jobs with "probable" exposure	0.95	0.78–1.16
1 to 15 years in "probable" jobs	0.52	0.15–1.86
16 to 30 years in "probable" jobs	0.70	0.34–1.44
31 or more years in "probable" jobs	1.49	0.72–3.11

[53] In his review of this study for the NMA, Dr. Peter Valberg stated: "This last sentence reveals EPA's bias; the RRs for truck drivers and railroad workers were not statistically elevated." Contrary to Dr. Valberg's statement, the RRs were greater than 1.0 and, therefore, were "statistically elevated." Although the elevation for these two occupations was not statistically significant at a 95-percent confidence level, the EPA made no claim that it was. Under a null hypothesis of no real association, the probability should be ½ that the RR would exceed 1.0 for an occupation associated with diesel exposure. Therefore, under the null hypothesis, the probability that the RR would exceed 1.0 for all four such occupations is $(1/2)^4 = 0.06$. This corresponds to a 94-percent confidence level for rejecting the null hypothesis.

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The study's authors noted that most U.S. trucks did not have diesel engines until the late 1950s or early 1960s and that many smaller trucks are still powered by gasoline engines. Therefore, they performed a separate analysis of truck drivers cross-classified by self-reported diesel exposure "to compare presumptive diesel truck drivers with nondiesel drivers." After adjusting for smoking, the resulting OR for diesel drivers was 1.25, with a 95-percent confidence interval of 0.85 to 2.76 (*ibid.*, p. 585).

Brüske-Hohlfeld et al., 1999

This was a pooled analysis of two case-control studies on lung cancer in Germany. The data pool consisted of 3,498 male cases with histologically or cytologically confirmed lung cancer and 3,541 male controls randomly drawn from the general population. Cases and controls were matched for age and region of residence. For the pooled analysis, information on demographic characteristics, smoking, and detailed job and job-task history was collected by personal interviews with the cases and controls, using a standardized questionnaire.

Over their occupational lifetimes, cases and controls were employed in an average of 2.9 and 2.7 different jobs, respectively. Jobs considered to have had potential exposure to diesel exhaust were divided into four groups: Professional drivers (including trucks, buses, and taxis), other "traffic-related" jobs (including switchmen and operators of diesel locomotives or diesel forklift trucks), full-time drivers of farm tractors, and heavy equipment operators. Within these four groups, each episode of work in a particular job was classified as being exposed or not exposed to diesel exhaust, based on the written description of job tasks obtained during the interview. This exposure assessment was done without knowledge of the subject's case or control status. Each subject's lifetime duration of occupational exposure was compiled using only the jobs determined to have been diesel-exposed. There were 264 cases and 138 controls who accumulated diesel exposure exceeding 20 years, with 116 cases and 64 controls accumulating more than 30 years of occupational exposure.

For each case and control, detailed smoking histories from the questionnaire were used to establish smoking habit, including consumption of other tobacco products, cumulative smoking exposure (expressed as packyears), and years since quitting smoking. Cumulative asbestos exposure (expressed as the number of exposed working days) was assessed based on 17 job-specific questionnaires that supplemented the main questionnaire.

The main findings of this study, all adjusted for cumulative smoking and asbestos exposure, are presented in the following table. Although the odds ratio for West German professional drivers was a statistically significant 1.44, as shown, the odds ratio for East German professional drivers was not elevated. As a possible explanation, the authors noted that after 1960, the number of vehicles (cars, busses, and trucks) with diesel engines per unit area was about five times higher in West Germany than in East Germany. Also, the higher OR shown for professional drivers first exposed after 1955, compared to earlier years of first exposure, may have resulted from the higher density of diesel traffic in later years.

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Main results from Brüske-Hohlfeld et al., 1999

(controlled for age; adjusted for smoking and asbestos exposure)

Occupational Exposure to Diesel Exhaust	Lung Cancer Odds Ratio	95-Percent Confidence Interval
Any During Lifetime	1.43	1.23 - 1.67
West German Professional Drivers	*1.44*	*1.18 - 1.76*
First exposed before 1946	1.32	0.68 - 2.07
First exposed 1946 - 1955	1.49	0.96 - 1.88
First exposed after 1955	1.56	1.21 - 2.03
"Traffic-Related" Jobs other than Driving	*1.53*	*1.04-2.24*
4 to 10 years	1.18	0.6 - 2.4[†]
11 to 20 years	2.49	1.1 - 5.6[†]
More than 20 years	2.88	1.1 - 7.2[†]
Full-Time Drivers of Farm Tractors	*1.29*	*0.78 - 2.14*
11 to 20 years	1.51	0.4 - 3.8[‡]
21 to 30 years	3.67	1.0 - 13[‡]
More than 30 years	6.81	1.1 - 40[‡]
Heavy Equipment Operators	*2.31*	*1.44 - 3.70*
More than 20 years	4.30	statistically significant (interval not reported)

[†] Confidence limits estimated from Fig. 1 of Brüske-Hohlfeld et al. (1999).

[‡] Confidence limits estimated from Fig. 2 of Brüske-Hohlfeld et al. (1999).

BILLING CODE 4510-43-C

As the authors noted, a strength of this study is the good statistical power resulting from having a significant number of workers exposed to diesel emissions for more than 30 years. Another strength is the statistical treatment of potential confounders, using quantitative measures of cumulative smoking and asbestos exposures.

Although they did not rely solely on job title, and differentiated between diesel-exposed and unexposed work periods, the authors identified limitations in the assessment of diesel exposure, "under these circumstances leading to an odds ratio that is biased towards one and an underestimation of the true [relative] risk of lung cancer." A more quantitative assessment of diesel exposure would tend to remove this bias, thereby further elevating the relative risks. Therefore, the authors concluded that their study "showed a statistically significant increase in lung cancer risk for workers occupationally exposed to [diesel exhaust] in Germany with the exception of professional drivers in East Germany." Garshick et al., 1987

This case-control study was based on 1,256 primary lung cancer deaths and 2,385 controls whose cause of death was not cancer, suicide, accident, or unknown. Cases and controls were drawn from records of the U.S. Railroad Retirement Board (RRB) and matched within 2.5 years of birth date and 31 days of death date. Selected jobs, with and without regular diesel exposure, were identified by a review of job titles and duties and classified as "exposed" or "unexposed" to diesel exhaust. For

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39 jobs, this exposure classification was confirmed by personal sampling of current respirable dust concentrations, adjusted for cigarette smoke, at four different railroads. Jobs for which no personal sampling was available were classified based on similarities in location and activity to sampled jobs.

A detailed work history for each case and control was obtained from an annual report filed with the RRB. This was combined with the exposure classification for each job to estimate the lifetime total diesel exposure (expressed as "diesel-years") for each subject. Years spent not working for a railroad, or for which a job was not recorded, were considered to be unexposed. This amounted to 2.4% of the total worker-years from 1959 to death or retirement.

Because of the transition from steam to diesel locomotives in the 1950s, occupational lifetime exposures were accumulated beginning in 1959. Since many of the older workers retired not long after 1959 and received little or no diesel exposure, separate analyses were carried out for subjects above and below the age of 65 years at death. The group of younger workers was considered to be less susceptible to exposure misclassification.

Detailed smoking histories, including years smoked, cigarettes per day, and years between quitting and death, were obtained from next of kin. Based on job history, each case and control was also classified as having had regular, intermittent, or no occupational asbestos exposure.

The main results of this study, adjusted for smoking and asbestos exposure, are presented in the following table for workers aged less than 65 years at the time of their death. All of these results were obtained using logistic regression, conditioned on dates of birth and death. The odds ratio presented in the shaded cell for 20 years of unlagged exposure was derived from an analysis that modeled diesel-years as a continuous variable. All of the other odds ratios in the table were derived from analyses that modeled cumulative exposure categorically, using workers with less than five diesel-years of exposure as the reference group. Statistically significant elevations of lung cancer risk were reported for the younger workers with at least 20 diesel-years of exposure or at least 15 years accumulated five years prior to death. No elevated risk of lung cancer was observed for the older workers, who were 65 or more years old at the time of their death. The authors attributed this to the fact, mentioned above, that many of these older workers retired shortly after the transition to diesel-powered locomotives and, therefore, experienced little or no occupational diesel exposure. Based on the results for younger workers, they concluded that "this study supports the hypothesis that occupational exposure to diesel exhaust increases lung cancer risk."

MAIN RESULTS FROM GARSHICK ET AL., 1987, FOR WORKERS AGED LESS THAN 65 YEARS AT DEATH

[Controlled for dates of birth and death; adjusted for cigarette smoking and asbestos exposure]

Diesel exposure	Lung cancer odds ratio	95-percent confidence interval
No lag:		
0–4 diesel-years	1	N/A (reference group)
5–19 diesel-years	1.02	0.72–1.45
20 diesel-years (diesel exposure modeled as continuous variable)	1.41	1.06–1.88
20 or more diesel-years	1.64	1.18–2.29
Accumulated at least 5 years before death:		
0–4 diesel-years	1	N/A (reference group)
5–14 diesel-years	1.07	0.69– 1.66
15 or more diesel-years	1.43	1.06– 1.94

In its 1999 draft Health Assessment Document for Diesel Emissions, the U.S. EPA noted various limitations of this study but concluded that "compared with previous studies [i.e., prior to 1987] * * *, [it] provides the most valid evidence that occupational diesel exhaust emission exposure increases the risk of lung cancer." (EPA, 1999, p. 7–33) No objection to this conclusion was raised in the most recent CASAC review of the EPA draft (CASAC, 2000).

The EMA objected to this study's determination of smoking frequency based on interviews with next of kin, stating that such determination "generally results in an underestimate, as it has been shown that cigarette companies manufacture 60% more product than public surveys indicate are being smoked."

A tendency to mischaracterize smoking frequency would have biased the study's reported results if the degree of under- or over-estimation varied systematically with diesel exposure. The EMA, however, submitted no evidence that the smoking under-estimate, if it existed at all, was in any way correlated with cumulative duration of diesel exposure. In the absence of such evidence, MSHA finds no reason to assume differential mis-reporting of smoking frequency.

Even more importantly, the EMA failed to distinguish between "public surveys" of the smokers themselves (who may be inclined to understate their habit) and interviews with next of kin. The investigators specifically addressed the accuracy of smoking data obtained from next of kin, citing two studies on the subject. Both studies reported a tendency for surrogate respondents to overestimate, rather than underestimate, cigarette consumption. The authors concluded that "this could exaggerate the contribution of cigarette smoking to lung cancer risk if the next of kin of subjects dying of lung cancer were more likely to report smoking histories than were those of controls." (ibid, p.1246)

IMC Global, along with Cox (1997) objected to several methodological features of this study. MSHA's response to each of these criticisms appears immediately following a summary quotation from IMC Global's written comments:

(A) The regression models used to analyze the data assumed without justification that an excess risk at any exposure level implied an excess risk at all exposure levels.

The investigators did not extrapolate their regression models outside the range supported by the data. Furthermore, MSHA is using this study only for purposes of hazard identification at exposure levels at least as high as those experienced by workers in the study. Therefore, the possibility of a threshold effect at much lower levels is irrelevant.

(B) The regression model used did not specify that the exposure estimates were imperfect surrogates for true exposures. As a result, the regression coefficients do not bear any necessary relationship to the effects that they try to measure.

As noted by Cox (op cit.), random measurement errors for exposures in an univariate regression model will tend to bias results in the direction of no apparent association, thereby masking or reducing any apparent effects of exposure. The crux of Cox's criticism, however, is that, for statistical analysis of the type employed in this study, random errors in a mutivariate exposure (such as an interdependent combination of smoking, asbestos, and diesel exposure) can potentially bias results in either direction. This objection fails to consider the fact that a nearly identical regression result was obtained for the effect of diesel exposure when smoking and asbestos exposure were removed from the model: OR = 1.39 instead of 1.41. Furthermore, even with a multivariate exposure, measurement errors in the exposure being evaluated typically bias the estimate of relative risk downward toward a null result. Relative risk is biased upwards only when the various exposures are interrelated in a special way. No evidence was presented that the data of this study met the special conditions necessary for upward bias or that any such bias would be large enough to be of any practical significance.

(C) The * * * analysis used regression models without presenting diagnostics to show whether the models were appropriate for the data.

MSHA agrees that regression diagnostics are a valuable tool in assuring the validity of a statistical regression analysis. There is nothing at all unusual, however, about their not having been mentioned in the published report of this study. Regression diagnostics are rarely, if ever, published in epidemiologic studies making use of regression analysis. This does not imply that such diagnostics were not considered in the course of identifying an appropriate model or checking how well the data conform to a given model's underlying assumptions. Evaluation of the validity of any statistical analysis is (or should be) part of the peer-review process prior to publication.

(D) The * * * risk models assumed that 1959 was the effective year when DE exposure started for each worker. Thus, the analysis ignored the potentially large differences in pre-1959 exposures among workers. This modeling assumption makes it impossible to interpret the results of the study with confidence.

MSHA agrees that the lack of diesel exposure information on individual workers prior to 1959 represents an important limitation of this study. This limitation, along with a lack of quantitative exposure data even after 1959, may preclude using it to determine, with reasonable confidence, the shape or slope of a quantitative exposure-response relationship. Neither of these limitations, however, invalidates the study's finding of an elevated lung cancer risk for exposed workers. MSHA is not basing any quantitative risk assessment on this study and is relying on it, in conjunction with other evidence, only for purposes of hazard identification.

(E) The risk regression models * * * assume, without apparent justification, that all exposed individuals have identical dose-response model parameters (despite the potentially large differences in their pre-1959 exposure histories). This assumption was not tested against reasonable alternatives, *e.g.*, that individuals born in different years have different susceptibilities * * *

Cases and controls were matched on date of birth to within 2.5 years, and separate analyses were carried out for the two groups of younger and older workers. Furthermore, it is not true that the investigators performed no tests of reasonable alternatives even to the assumption that younger workers shared the same model parameters. They explored and tested potential interactions between smoking intensity and diesel exposure, with negative results. The presence of such interactions would have meant that the response to diesel exposure differed among individuals, depending on their smoking intensity.

One other objection that Cox (op cit.) raised specifically in connection with this study was apparently overlooked by IMC Global. To illustrate what he considered to be an improper evaluation of statistical significance when more than one hypothesis is tested in a study, Cox noted the finding that for workers aged less than 65 years at time of death, the odds ratio for lung cancer was significantly elevated at 20 diesel-years of exposure. He then asserted that this finding was merely

* * * an instance of a whole family of statements of the form "Workers who were A years or younger at the time of death and who were exposed to diesel exhaust for Y years had a significantly increased relative odds ratios for lung cancer. The probability of at least one false positive occurring among the multiple hypotheses in this family corresponding to different combinations of A (*e.g.*, no more than 54, 59, 64, 69, 74, 79, etc. years old at death) and durations of exposure (*e.g.*, Y = 5, 10, 15, 20, 25, etc. years) is not limited to 5% when each combination of A and Y values is tested at a p = 5% significance level. For example, if 30 different (A, Y) combinations are considered, each independently having a 5% probability of a false positive (i.e., a reported 5% significance level), then the probability of at least one false positive occurring in the study as a whole is p = 1 − (1 − 0.05) 30 = 78%. This p-value for the whole study is more than 15 times greater than the reported significance level of 5%.

MSHA is evaluating the cumulative weight of evidence from many studies and is not relying on the level of statistical significance attached to any single finding or study viewed in isolation. Furthermore, Cox's analysis of the statistical impact of multiple comparisons or hypothesis tests is flawed on several counts, especially with regard to this study in particular. First, the analysis relies on a highly unrealistic assumption that when several hypotheses are tested within the same study, the probabilities of false positives are statistically independent. Second, Cox fails to distinguish between those hypotheses or comparisons suggested by exploration of the data and those motivated by prior considerations. Third, Cox ignores the fact that the result in question was based on a statistical regression analysis in which diesel exposure duration was modeled as a single continuous variable. Therefore, this particular result does not depend on multiple hypothesis-testing with respect to exposure duration. Fourth, and most importantly, Cox assumes that age and exposure duration were randomly picked for testing from a pool of interchangeable possibilities and that the only thing distinguishing the combination of "65 years of age" and "20 diesel-years of exposure" from other random combinations was that it happened to yield an apparently significant result. This is clearly not the case. The investigators divided workers into only two age groups and explained that this division was based on the history of dieselization in the railroad industry—not on the results of their data analysis. Similarly, the result for 20 diesel-years of exposure was not favored over shorter exposure times simply because 20 years yielded a significant result and the shorter times did not. Lengthy exposure and latency periods are required for the expression of increased lung cancer risks, and this justifies a focus on the longest exposure periods for which sufficient data are available.

Garshick et al., 1988; Garshick, 1991

In this study, the investigators assessed the risk of lung cancer in a cohort of 55,407 white male railroad workers, aged 40 to 64 years in 1959,

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who had begun railroad work between 1939 and 1949 and were employed in one of 39 jobs later surveyed for exposure. Workers whose job history indicated likely occupational exposure to asbestos were excluded. Based on the subsequent exposure survey, each of the 39 jobs represented in the cohort was classified as either exposed or unexposed to diesel emissions. The cohort was followed through 1980, and 1,694 cases of death due to lung cancer were identified.

As in the 1987 study by the same investigators, detailed railroad job histories from 1959 to date of death or retirement were obtained from RRB records and combined with the exposure classification for each job to provide the years of diesel exposure accumulated since 1959 for each worker in the cohort. Using workers classified as "unexposed" within the cohort to establish a baseline, time-dependent proportional hazards regression models were employed to evaluate the relative risk of lung cancer for exposed workers. Although the investigators believed they had excluded most workers with significant past asbestos exposures from the cohort, based on job codes, they considered it possible that some workers classified as hostlers or shop workers may have been included in the cohort even if occupationally exposed to asbestos. Therefore, they carried out statistical analyses with and without shop workers and hostlers included.

The main results of this study are presented in the following table. Statistically significant elevations of lung cancer risk were found regardless of whether or not shop workers and hostlers were included. The 1988 analysis adjusted for age in 1959, and the 1991 analysis adjusted, instead, for age at death or end of follow-up (i.e., end of 1980).[54] In the 1988 analysis, any work during a year counted as a diesel-year if the work was in a diesel-exposed job category, and the results from the 1991 analysis presented here are based on this same method of compiling exposure durations. Exposure durations excluded the year of death and the four prior years, thereby allowing for some latency in exposure effects. Results for the analysis excluding shop workers and hostlers were not presented in the 1991 report, but the report stated that "similar results were obtained." Using either method of age adjustment, a statistically significant elevation of lung cancer risk was associated with each exposure duration category. Using "attained age," however, there was no strong indication that risk increased with increasing exposure duration. The 1991 report concluded that "there appears to be an effect of diesel exposure on lung cancer mortality" but that "because of weaknesses in exposure ascertainment * * *, the nature of the exposure-response relationship could not be found in this study."

MAIN RESULTS FROM GARSHICK ET AL., 1988 AND GARSHICK, 1991

Exposure duration (diesel-years, last 5 years excluded)	Full cohort		Shopworkers & hostlers excluded	
	Relative risk	95% conf. int.	Relative risk	95% conf. int.
1–4	1.20	1.01–1.44	1.34	1.08–1.65
	1.31	1.09–1.57	N.R.	N.R.
5–9	1.24	1.06–1.44	1.33	1.12–1.58
	1.28	1.09–1.49	N.R.	N.R.
10–14	1.32	1.13–1.56	1.33	1.10–1.60
	1.19	1.002–1.41	N.R.	N.R.
15 or more	1.72	1.27–2.33	1.82	1.30–2.55
	1.40	1.03–1.90	N.R.	N.R.

Top entry within each cell is from 1988 analysis, adjusted for age in 1959. Bottom entry is from 1991 analysis, adjusted for age at death or end of follow-up ("attained age"). N.R. means "not reported."

Some commenters noted that removing the shop workers and hostlers from the analysis increased the relative risk estimates. Dr. Peter Valberg found this "paradoxical," since workers in these categories had later been found to experience higher average levels of diesel exposure than other railroad workers.

This so-called paradox is likely to have resulted simply from exposure misclassification for a significant portion of the shop workers. The effect was explained by Garshick (1991) as follows:

* * * shop workers who worked in the diesel repair shops shared job codes with workers in non-diesel shops where there was no diesel exhaust * * *. Apparent exposure as a shop worker based on the job code was then diluted with workers with the same job code but without true exposure, making it less likely to see an effect in the shop worker group. In addition, workers in the shop worker group of job codes tended to have less stable career paths * * * compared to the other diesel exposure categories.

So although many of the shopworkers may have been exposed to relatively high dpm concentrations, many others were among the lowest-exposed workers or were even unexposed because they spent their entire occupational lifetimes in unexposed locations. This could readily account for the increase in relative risks calculated when shop workers were excluded from the analysis.

Dr. Valberg also noted that, according to Crump (1999), mortality rates for cirrhosis of the liver and heart disease were significantly elevated for "train riders," who were exposed to diesel emissions, as compared to other members of the cohort, who were less likely to be exposed. It is also the train riders who account, primarily, for the elevated risk of lung cancer associated with diesel exposure in the overall cohort. Dr. Valberg interpreted this as suggesting that "lifestyle" factors such as diet or smoking habits, rather than diesel exposure, were responsible for the increased risk of lung cancer observed among the diesel-exposed workers.

Dr. Valberg presented no evidence that, apart from diesel exposure, the train riders differed systematically from the other workers in their smoking habits or in other ways that would be expected to affect their risk of lung cancer. Therefore, MSHA views the suggestion of such a bias as speculative. Even if lifestyle factors associated with

[54] Also, the 1991 analysis excluded 12 members of the cohort due to discrepancies between work history and reported year of death, leaving 55,395 railroad workers included in the analysis.

train ridership were responsible for an increased risk of cirrhosis of the liver or heart disease, this would not necessarily mean that the same factors were also responsible for the increased risk of lung cancer. Still, it is hypothetically possible that systematic differences, other than diesel exposure, between train riders and other railroad workers could account for some or even all of the increased lung cancer risk. That is why MSHA does not rely on this, or any other, single study in isolation.

Some commenters, including the NMA, objected to this study on grounds that it failed to control for potentially confounding factors, principally smoking. The NMA stated that this "has rendered its utility questionable at best." As explained earlier, there is more than one way in which a study can control for smoking or other potential confounders. One of the ways is to make sure that groups being compared do not differ with respect to the potential confounder. In this study, workers with likely asbestos exposure were excluded from the cohort, stability of workers within job categories was well documented, and similar results were reported when job categories subject to asbestos exposure misclassification were excluded. In their 1988 report, the investigators provided the following reasons to believe that smoking did not seriously affect their findings:

* * * the cohort was selected to include only blue-collar workers of similar socioeconomic class, a known correlate of cigarette smoking * * *, in our case-control study [Garshick et al., 1987], when cigarette smoking was considered, there was little difference in the crude or adjusted estimates of diesel exhaust effects. Finally, in the group of 517 current railroad workers surveyed by us in 1982 * * *, we found no difference in cigarette smoking prevalence between workers with and without potential diesel exhaust exposure. [Garshick et al., 1988]

Since relative risks were based on internal comparisons, and the cohort appears to have been fairly homogeneous, MSHA regards it as unlikely that the association of lung cancer with diesel exposure in this study resulted entirely from uncontrolled asbestos or smoking effects. Nevertheless, MSHA recognizes that differential smoking patterns may have affected, in either direction, the degree of association reported in each of the exposure duration categories.

Cox (1997) re-analyzed the data of this study using exploratory, nonparametric statistical techniques. As quoted by IMC Global, Cox concluded that "these methods show that DE [i.e., dpm] concentration has no positive causal association with lung cancer mortality risk." MSHA believes this quotation (taken from the abstract of Cox's article) overstates the findings of his analysis. At most, Cox confirmed the conclusion by Garshick (1991) that these data do not support a positive exposure-response relationship. Specifically, Cox determined that inter-relationships among cumulative diesel exposure, age in 1959, and retirement year make it "impossible to prove causation by eliminating plausible rival hypotheses based on this dataset." (Cox, 1997; p. 826) Even if Cox's analysis were correct, it would not follow that there is no underlying causal connection between dpm exposure and lung cancer. It would merely mean that the data do not contain internal evidence implicating dpm exposure as the cause, rather than one or more of the variables with which exposure is correlated. Cox presented no evidence that any "rival hypotheses" were more plausible than causation by dpm exposure. Furthermore, it may simply be, as Garshick suggested, that an underlying exposure-response relationship is not evident "because of weaknesses in exposure ascertainment." (Garshick, 1991, op cit.) None of this negates the fact that, after adjusting for either age in 1959 or "attained" age, lung cancer was significantly more prevalent among the exposed workers.

Along similar lines, many commenters pointed out that an HEI expert panel examined the data of this study (HEI, 1999) and found that it had very limited use for quantitative risk assessment (QRA). Several of these commenters mischaracterized the panel's findings. The NMA, for example, drew the following unjustified conclusion from the panel's report: "In short, * * * the correct interpretation of the Garshick study is that any occupational increase in lung cancer among train workers was not due to diesel exposures."

Contrary to the NMA's characterization, the HEI Expert Panel's report stated that the data are

* * * consistent with findings of a weak association between death from lung cancer and occupational exposure to diesel exhaust. Although the secondary exposure-response analyses * * * are conflicting, the overall risk of lung cancer was elevated among diesel-exposed workers. [Ibid., p. 25]

The panel agreed with Garshick (1991) and Cox (1997) that the data of this study do not support a positive exposure-response relationship. Like Garshick and unlike Cox, however, the panel explicitly recognized that problems with the data could mask such a relationship and that this does not negate the statistically significant finding of elevated risk among exposed workers. Indeed, the panel even identified several factors, in addition to weak exposure assessment as suggested by Garshick, that could mask a positive relationship: unmeasured confounding variables such as cigarette smoking, previous occupational exposures, or other sources of pollution; a "healthy worker survivor effect"; and differential misclassification or incomplete ascertainment of lung cancer deaths. (HEI, 1999; p. 32)

Positive exposure-response relationships based on these data were reported by the California EPA (OEHHA, 1998). MSHA recognizes that those findings were sensitive to various assumptions and that other investigators have obtained contrary results. The West Virginia Coal Association, paraphrasing Dr. Peter Valberg, concluded that although the two studies by Garshick et al. "* * * may represent the best in the field, they fail to firmly support the proposition that lung cancer risk in workers derives from exposure to dpm." At least one commenter (IMC Global) apparently reached a considerably stronger conclusion that they were of no value whatsoever, and urged MSHA to "discount their results and not consider them in this rulemaking." On the other hand, in response to the ANPRM, a consultant to the National Coal Association who was critical of all other studies available at the time acknowledged that these two:

[* * * have successfully controlled for severally [sic] potentially important confounding factors * * *. Smoking represents so strong a potential confounding variable that its control must be nearly perfect if an observed association between cancer and diesel exhaust is * * * [inferred to be causal]. In this regard, two observations are relevant. First, both case-control [Garshick et al., 1987] and cohort [Garshick et al., 1988] study designs revealed consistent results. Second, an examination of smoking related causes of death other than lung cancer seemed to account for only a fraction of the association observed between diesel exposure and lung cancer. A high degree of success was apparently achieved in controlling for smoking as a potentially confounding variable. [Robert A. Michaels, RAM TRAC Corporation, submitted by National Coal Association].

To a limited extent, MSHA agrees with Dr. Valberg and the West Virginia Coal Association: these two studies—like every real-life epidemiologic study—are not "firmly" conclusive when viewed in isolation. Nevertheless, MSHA believes that they provide important contributions to the overall body of evidence. Whether or not they

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can be used to quantify an exposure-response relationship, these studies—among the most comprehensive and carefully controlled currently available—do show statistically significant increases in the risk of lung cancer among diesel-exposed workers. Johnston et al. (1997)

Since it focused on miners, this study has already been summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The tabled relative risk estimates presented for cumulative exposures greater than 1000 mg-hr/m³ (i.e., 1 g-hr/m³) were calculated by MSHA based on the regression coefficients reported by the authors. The conversion from mg-hr/m³ to mg-yr/m³ assumes 1,920 occupational exposure hours per year. Although 6.1 mg-yr/m³ Dpm roughly equals the cumulative exposure estimated for the most highly exposed locomotive drivers in the study, the relative risk associated with this exposure level is presented primarily for purposes of comparison with findings of Saverin et al. (1999).

MAIN RESULTS FROM JOHNSTON ET AL., 1997

Cumulative dpm exposure	Mine-adjusted model (15-yr lag)		Mine-unadjusted model (15-yr lag)	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
1000 mg-hr/m³ (= 0.521 mg-yr/m³)	1.156	0.90–1.49	1.227	1.00–1.50.
1920 mg-hr/m³ (= 1 mg-yr/m³)	1.321	Not reported	1.479	Not reported
11,700 mg-hr/m³ (= 6.1 mg-yr/m³)	5.5	Not reported	11.0	Not reported

In its post-hearing comments, MARG acknowledged that this study "found a 'weak association' between lung cancer and respiratory diesel particulate exposure" but failed to note that the estimated relative risk increased with increasing exposure. MARG also stated that the association was "deemed non-significant by the researchers" and that "no association was found among men with different exposures working in the same mines." Although the mine-adjusted model did not support 95-percent confidence for an increasing exposure-response relationship, the mine-unadjusted model yielded a statistically significant positive slope at this confidence level. Furthermore, since the mine-adjusted model adjusts for differences in lung cancer rates between mines, the fact that relative risk increased with increasing exposure under this model indicates (though not at a 95-percent confidence level) that the risk of lung cancer increased with exposure among men with different exposures working in the same mines.

Säverin et al. (1999)

Since this study, like the one by Johnston et al., was carried out on a cohort of miners, it too was summarized and discussed in the previous subsection of this risk assessment. The main results are presented in the following table. The relative risk estimates and confidence intervals at the mean exposure level of 2.7 mg-yr/m³ TC (total carbon) were calculated by MSHA, based on values of α and corresponding confidence intervals presented in Tables III and IV of the published report (ibid., p. 420). The approximate equivalency between 4.9 mg-yr/m³ TC and 6.1 mg-yr/m³ Dpm assumes that, on average, TC comprises 80 percent of Dpm.

MAIN RESULTS FROM SAVERIN ET AL., 1999

	Relative risk	95% confidence interval
Highest compared to least exposed worker category	2.17	0.79–5.99

Cumulative total carbon exposure	Proportional hazards (Cox) Model*		Poisson mode*	
	Relative risk	95% conf. interval	Relative risk	95% conf. interval
2.7 mg-yr/m³ TC (i.e., cohort mean)	1.33	0.67–2.64	1.08	0.59–1.99
	1.73	0.70–4.30	1.42	0.65–3.92
4.9 mg-yr/m³ TC (=6.1 mg-yr/m³ dpm)	1.68	0.49–5.8	1.16	0.38–3.3
	2.70	0.52–14.1	1.89	0.46–11.9

*Top entry in each cell is based on full cohort; bottom entry is based on subcohort, which was restricted to miners who worked underground at least ten years, with at least 80 percent of employment in same job, etc.

These results are not statistically significant at the conventional 95-percent confidence level. However, the authors noted that the relative risk calculated for the subcohort was consistently higher than that calculated for the full cohort. They also considered the subcohort to have a superior exposure assessment and a better latency allowance than the full cohort. According to the authors, these factors provide "some assurance that the observed risk elevation was not entirely due to chance since improving the exposure assessment and allowing for latency effects should, in general, enhance exposure effects."

Steenland et al., (1990, 1992, 1998)

The basis for the analyses in this series was a case-control study comparing the risk of lung cancer for diesel-exposed and unexposed workers who had belonged to the Teamsters Union for at least twenty years (Steenland et al., 1990). Drawing from union records, 996 cases of lung cancer were identified among more than 10,000 deaths in 1982 and 1983. For comparison to these cases, a total of 1,085 controls was selected (presumably at random) from the remaining deaths, restricted to those who died from causes other than lung cancer, bladder cancer, or motor vehicle accident. Information on work history, duration and intensity of cigarette smoking, diet, and asbestos exposure was obtained from next of kin. Detailed work histories were also obtained from pension applications on file with the Teamsters Union.

Both data sources were used to classify cases and controls according to a job category in which they had worked the longest. Based on the data obtained from next of kin, the job categories were diesel truck drivers, gasoline truck drivers, drivers of both truck types, truck mechanics, and dock workers. Based on the pension applications, the principal job categories were long-haul drivers, short-haul or city drivers, truck mechanics, and dock workers. Of the workers identified by next of kin as primarily diesel truck drivers, 90 percent were classified as long-haul drivers according to the Teamster data. The corresponding proportions were 82 percent for mechanics and 81 percent for dock workers. According to the investigators, most Teamsters had worked in only one exposed job category. However, because of the differences in job category definitions, and also because the next of kin data covered lifetimes whereas the pension applications covered only time in the Teamsters Union, the investigators found it problematic to fully evaluate the concordance between the two data sources.

In the 1990 report, separate analyses were conducted for each source of data used to compile work histories. The investigators noted that "many trucking companies (where most study subjects worked) had completed most of the dieselization of their fleets by 1960, while independent drivers and nontrucking firms may have obtained diesel trucks later * * *" Therefore, they specifically checked for associations between increased risk of lung cancer and occupational exposure after 1959 and, separately, after 1964. In the 1992 report, the investigators presented, for the Union's occupational categories used in the study, dpm exposure estimates based on subsequent measurements of submicrometer elemental carbon (EC) as reported by Zaebst et al. (1991). In the 1998 report, cumulative dpm exposure estimates for individual workers were compiled by combining the individual work histories obtained from the Union's records with the subsequently measured occupational exposure levels, along with an evaluation of historical changes in diesel engine emissions and patterns of diesel usage. Three alternative sets of cumulative exposure estimates were considered, based on alternative assumptions about the extent of improvement in diesel engine emissions between 1970 and 1990. A variety of statistical models and techniques were then employed to investigate the relationship between estimated cumulative dpm exposure (expressed as EC) and the risk of lung cancer. The authors pointed out that the results of these statistical analyses depended heavily on "very broad assumptions" used to generate the estimates of cumulative dpm exposure. While acknowledging this limitation, however, they also evaluated the sensitivity of their results to various changes in their assumptions and found these changes to have little impact on the results.

The investigators also identified and addressed several other limitations of this study as follows:

(1) possible misclassification smoking habits by next of kin, (2) misclassification of exposure by next of kin, (3) a relatively small non-exposed group (n = 120) which by chance may have had a low lung cancer risk, and (4) lack of sufficient latency (time since first exposure) to observe a lung cancer excess. On the other hand, next-of-kin data on smoking have been shown to be reasonably accurate, non-differential misclassification of exposure * * * would only bias our findings toward * * * no association, and the trends of increased risk with increased duration of employment in certain jobs would persist even if the non-exposed group had a higher lung cancer risk. Finally, the lack of potential latency would only make any positive results more striking. (Steenland et al., 1990)

The main results from the three reports covering this study are summarized in the following table. All of the analyses were controlled for age, race, smoking (five categories), diet, and asbestos exposure as reported by next of kin. Odds ratios for the occupations listed were calculated relative to the odds of lung cancer for occupations other than truck driver (all types), mechanic, dock worker, or other potentially diesel exposed jobs (Steenland et al., 1990, Appendix A). The exposure-response analyses were carried out using logistic regression. Although the investigators performed analyses under three different assumptions for the rate of engine emissions (gm/mile) in 1970, they considered the intermediate value of 4.5 gm/mile to be their best estimate, and this is the value on which the results shown here are based. Under this assumption, cumulative occupational EC exposure for all workers in the study was estimated to range from 0.45 to 2,440 μg-yr/m³, with a median value of 373 μg-yr/m³. The estimates of relative risk (expressed as odds ratios) presented for EC exposures of 373 μg-yr/m³, 1000 μg-yr/m³, and 2450 μg-yr/m³ were calculated by MSHA based on the regression coefficients reported by the authors for five-year lagged exposures (Steenland et al. 1998, Table II).

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Main results from Steenland et al., (1990, 1992, 1998)

Principal Occupation	Mean 1990 EC Concentration (µg/m³)	Duration of Employment	Lung Cancer Odds Ratio	95-percent Conf. Interval
Diesel truck driver	N.A.	35 or more years*	1.89	1.04 - 3.42
Short-haul driver	5.4	18 or more years after 1959	1.79	0.94 - 3.42
Long-haul driver	5.1	18 or more years after 1959	1.55	0.97 - 2.47
		13 or more years after 1964	1.64	1.05 - 2.57
Truck mechanic	26.6	18 or more years after 1959	1.50	0.59 - 3.40

Cumulative Occupational Exposure (µg-yr/m³, lagged 5 years)**			Lung Cancer Odds Ratio	95-percent Conf. Interval
EC	TC ≈ 2•EC	dpm ≈ TC/0.8 ≈ 2.5•EC		
0 - 169	0 - 338	0 - 422	1.08	0.72 - 1.63
169 - 257	338 - 514	422 - 642	1.10	0.74 - 1.65
257 - 331	514 - 662	642 - 827	1.36	0.90 - 2.04
more than 331	more than 662	more than 827	1.64	1.09 - 2.49

			Lung Cancer Odds Ratio‡	
		Logistic regression model →	Simple Cum. Exposure	Log of Cum. Exposure
373	746	932	1.16	1.41
1,000	2,000	2,500	1.48	1.66
2,450	4,900	6,100	2.59	1.93

*Although primary occupation was driving diesel trucks, employment duration includes years driving any type of truck.

**Conversions between EC, TC, and dpm assume that, on average, TC ≈ 2•EC and TC ≈ 0.8•dpm.

‡ Calculated by MSHA from regression coefficients presented by Steenland et al. (1990), Table II. Statistically significant regression coefficients reported for both models (95% Conf. level). Tabled results for Log(Cum. exposure) model have been adjusted for lifetime background exposure of 65 µg-yr/m³ assumed in regression analysis.

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Under the assumption of a 4.5 gm/mile emissions rate in 1970, the cumulative EC exposure of 2450 µg-yr/m³ (≃ 6.1 mg-yr/m³ dpm) shown in the table closely corresponds to the upper limit of the range of data on which the regression analyses were based (Steenland et al., 1998, p. 224). However, the relative risks (i.e., odds ratios) calculated for this level of occupational exposure are presented primarily for purposes of comparison with the findings of Johnston et al. (1997) and Säverin et al. (1999). At a cumulative dpm exposure of approximately 6.1 mg-yr/m³, it is evident that the Johnston models predict a far greater elevation in lung cancer risk than either the Säverin or Steenland models. A possible explanation for this is that the Johnston data included exposures of up to 30 years in duration, and the statistical models showing an exposure-response relationship allowed for a 15-year lag in exposure effects. The other two studies were based on generally shorter diesel exposures and allowed less time for latent effects. In Subsection 3.b.ii(3) of this risk assessment, the quantitative results of these three studies will be further compared with respect to

exposure levels found in underground mines.

Several commenters noted that the HEI Expert Panel (HEI, 1999) had identified uncertainties in the diesel exposure assessment as an important limitation of the exposure-response analyses by Steenland et al. (1998) and had recommended further investigation before the quantitative results of this study were accepted as conclusive. In addition, Navistar International Transportation (NITC) raised a number of objections to the methods by which diesel exposures were estimated for the period between 1949 and 1990 (NITC, 1999). In general, the thrust of these objections was that exposures to diesel engine emissions had been overestimated, while potentially relevant exposures to gasoline engine emissions had been underestimated and/or unduly discounted.[55]

As mentioned above, the investigators recognized that these analyses rely on "broad assumptions rather than actual [concurrent] measurements," and they proposed that the "results should be regarded with appropriate caution." While agreeing with both the investigators and the HEI Expert Panel that these results should be interpreted with appropriate caution, MSHA also agrees with the Panel "* * * that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999, p. 39) In this context, MSHA considers it appropriate to regard the 1998 exposure-response analyses as contributing to the weight of evidence that dpm exposure increases the risk of lung cancer, even if the results are not conclusive when viewed in isolation.

Some commenters also noted that the HEI Expert Panel raised the possibility that the method for selecting controls in this study could potentially have biased the results in an unpredictable direction. Such bias could have occurred because deaths among some of the controls were likely due to diseases (such as cardiovascular disease) that shared some of the same risk factors (such as tobacco smoking) with lung cancer. The Panel presented hypothetical examples of how this might bias results in either direction. Although the possibility of such bias further demonstrates why the results of this study should be regarded with "appropriate caution," it is important to distinguish between the mere possibility of a control-selection bias, evidence that such a bias actually exists in this particular study, and the further evidence required to show that such bias not only exists but is of sufficient magnitude to have produced seriously misleading results. Unlike the commenters who cited the HEI Expert Panel on this issue, the Panel itself clearly drew this distinction, stating that "no direct evidence of such bias is apparent" and emphasizing that "even though these examples [presented in HEI (1999), Appendix D] could produce misleading results, it is important to note that they are only hypothetical examples. Whether or not such bias is present will require further examination." (HEI, 1999, pp. 37–38) As the HEI showed in its examples, such bias (if it exists) could lead to underestimating the association between lung cancer and dpm exposure, as well as to overestimating it. Therefore, in the absence of evidence that control-selection bias actually distorted the results of this study one way or the other, MSHA considers it prudent to accept the study's finding of an association at face value.

One commenter (MARG) noted that information on cigarette smoking, asbestos exposure, and diet in the trucking industry study was obtained from next of kin and stated that such information was "likely to be unreliable." By increasing random variability in the data, such errors could widen the confidence intervals around an estimated odds ratio or reduce the confidence level at which a positive exposure-response relationship might be established. However, unless such errors were correlated with diesel exposure or lung cancer in such a way as to bias the results, they would not, on average, inflate the estimated degree of association between diesel exposure and an increased risk of ling cancer. The commenter provided no reason to suspect that errors with respect to these factors were in any way correlated with diesel exposure or with the development of lung cancer.

Some commenters pointed out that EC concentrations measured in 1990 for truck mechanics were higher, on average, than for truck drivers, but the mechanics, unlike the drivers, showed no evidence of increasing lung cancer risk with increasing duration of employment. NITC referred to this as a "discrepancy" in the data, assuming that "cumulative exposure increases with duration of employment such that mechanics who have been employed for 18 or more years would have greater cumulative exposure than workers who have been employed for 1–11 years." (NITC, 1999)

Mechanics were included in the logistic regression analyses (Steenland et al., 1998) showing an increase in lung cancer risk with increasing cumulative exposure. These analyses pooled the data for all occupations by estimating exposure for each worker based on the worker's occupation and the particular years in which the worker was employed. There are at least three reasons why, for mechanics viewed as a separate group, an increase in lung cancer risk with increasing dpm exposure may not have been reflected by increasing duration of employment.

First, relatively few truck mechanics were available for analyzing the relationship between length of employment and the risk of lung cancer. Based on the union records, 50 cases and 37 controls were so classified; based on the next-of-kin data, 43 cases and 41 controls were more specifically classified as diesel truck mechanics (Steenland et al., 1990). In contrast, 609 cases and 604 controls were classified as long-haul drivers (union records). This was both the largest occupational category and the only one showing statistically significant evidence of increasing risk with increasing employment duration. The number of mechanics included in the study population may simply not have been sufficient to detect a pattern of increasing risk with increasing length of employment, even if such a pattern existed.

The second part of the explanation as to why mechanics did not exhibit a pattern similar to truck drivers could be that the data on mechanics were more subject to confounding. After noting that "the risk for mechanics did not appear to increase consistently with duration of employment," Steenland et al. (1990) further noted that the mechanics may have been exposed to asbestos when working on brakes. The data used to adjust for asbestos exposure may have been inadequate to control for variability in asbestos exposure among the mechanics.

Third, as noted by NITC, the lung cancer risk for mechanics (adjusted for age, race, tobacco smoking, asbestos exposure, and diet) would be expected to increase with increasing duration of

[55] Many of the issues NITC raised in its critique of this study depend on a peculiar identification of dpm exclusively with elemental carbon. For example, NITC argued that "more than 65 percent of the total carbon to which road drivers (and mechanics) were exposed consisted of organic (i.e., non-diesel) carbon, further suggesting that some other etiology caused or contributed to excess lung cancer mortality in these workers." (NITC, 1999, p. 16) Such lines of argument, which depend on identifying organic carbon as "non-diesel," ignore the fact that dpm contains a large measure of organic carbon compounds (and also some sulfates), as well as elemental carbon. Any adverse health effects due to the organic carbon or sulfate constituents of dpm would nonetheless be due to dpm exposures.

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employment only if the mechanics' cumulative dpm exposure corresponded to the length of their employment. None of the commenters raising this issue, however, provided any support for this assumption, which fails to consider the particular calendar years in which mechanics included in the study were employed. In compiling cumulative exposure for an individual worker, the investigators took into account historical changes in both diesel emissions and the proportion of trucks with diesel engines—so the exposure level assigned to each occupational category was not the same in each year. In general, workers included in the study neither began nor ended their employment in the same year. Consequently, workers with the same duration of employment in the same occupational category could be assigned different cumulative exposures, depending on when they were employed. Similarly, workers in the same occupational category who were assigned the same cumulative exposure may not have worked the same length of time in that occupation. Therefore, it should not be assumed that duration of employment corresponds very well to the cumulative exposure estimated for workers within any of the occupational categories. Furthermore, in the case of mechanics, there is an additional historical variable that is especially relevant to actual cumulative exposure but was not considered in formulating exposure estimates: the degree of ventilation or other means of protection within repair shops. Historical changes in shop design and work practices, as well as differences between shops, may have caused more exposure misclassification among mechanics than among long-haul or diesel truck drivers. Such misclassification would tend to further obscure any relationship between mechanics' risk of lung cancer and either duration of employment or cumulative exposure.

(iv) Counter-Evidence. Several commenters stated that, in the proposal, MSHA had dismissed or not adequately addressed epidemiology studies showing no association between lung cancer and exposures to diesel exhaust. For example, the EMA wrote:

> MSHA's discussion of the negative studies generally consists of arguments to explain why those studies should be dismissed. For example, MSHA states that, "All of the studies showing negative or statistically insignificant positive associations . . . lacked good information about dpm exposure . . ." or showed similar shortcomings. 63 Fed. Reg. at 17533. The statement about exposure information is only partially true, for, in fact, very few of any of the cited studies (the "positive" studies as well) included any exposure measurements, and none included concurrent exposures.

It should, first of all, be noted that the statement in question on dpm exposure referred to the issue of any diesel exposure—not to quantitative exposure measurements, which MSHA acknowledges are lacking in most of the available studies. In the absence of quantitative measurements, however, studies comparing workers known to have been occupationally exposed to unexposed workers are preferable to studies not containing such comparisons. Furthermore, two of the studies now available (and discussed above) utilize essentially concurrent exposure measurements, and both show a positive association (Johnston et al., 1997; Säverin *et al.*, 1999).

MSHA did not entirely "dismiss" the negative studies. They were included in both MSHA's tabulation (see Tables III–4 and III–5) and (if they met the inclusion criteria) in the two meta-analyses cited both here and in the proposal (Lipsett and Campleman, 1999, and Bhatia et al., 1998). As noted by the commenter, MSHA presented reasons (such as an inadequate latency allowance) for why negative studies may have failed to detect an association. Similarly MSHA gave reasons for giving less weight to some of the positive studies, such as Benhamou et al. (1988), Morabia et al. (1992), and Siemiatycki et al., 1988. Additional reasons for giving less weight to the six entirely negative studies have been tabulated above, under the heading of "Best Available Epidemiologic Evidence." The most recent of these negative studies (Christie et al., 1994, 1995) is discussed in detail under the heading of "Studies Involving Miners."

One commenter (IMC Global) listed the following studies (all of which MSHA had considered in the proposed risk assessment) as "examples of studies that reported negative associations between [dpm] exposure and lung cancer risk":

- Waller (1981). This is one of the six negative studies discussed earlier. Results were likely to have been biased by excluding lung cancers occurring after retirement or resignation from employment with the London Transit Authority. Comparison was to a general population, and there was no adjustment for a healthy worker effect. Comparison groups were disparate, and there was no adjustment for possible differences in smoking frequency or intensity.
- Howe et al. (1983). Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risk for workers classified as "possibly exposed" or "probably exposed" to diesel exhaust. MSHA recognizes that these results may have been confounded by asbestos and coal dust exposures.
- Wong et al. (1985). The investigators reported a statistically insignificant deficit for lung cancer in the entire cohort and a statistically significant deficit for lung cancer in the less than 5-year duration group. However, since comparisons were to a general population, these deficits may be the result of a healthy worker effect, for which there was no adjustment. Because of the latency required for development of lung cancer, the result for "less than 5-year duration" is far less informative than the results for longer durations of employment and greater latency allowances. Contrary to the commenter's characterization of this study, the investigators reported statistically significant elevations of lung cancer risks for "normal" retirees (SMR = 1.30) and for "high exposure" dozer operators with 15–19 years of union membership and a latency allowance of at least 20 years (SMR = 3.43).
- Edling et al. (1987). This is one of the six negative studies discussed earlier. The cohort consisted of only 694 bus workers and, therefore, lacked statistical power. Furthermore, comparison was to a general, external population with no adjustment for a healthy worker effect.
- Garshick (1988). The reason the commenter (IMC Global) gave for characterizing this study as negative was: "That the sign of the association in this data set changes based on the models used suggests that the effect is not robust. It apparently reflects modeling assumptions more than data." Contrary to the commenter's characterization, however, the finding of increased lung cancer risk for workers classified as diesel-exposed did not change when different methods were used to analyze the data. What changed, depending on modeling assumptions, was the shape and direction of the exposure-response relationship among exposed workers (Cal-EPA, 1998; Stayner et al., 1998; Crump, 1999; HEI, 1999). MSHA agrees that the various exposure-response relationships that have been derived from this study are highly sensitive to data modeling assumptions. This includes assumptions about historical patterns of exposure, as well as assumptions related to technical aspects of the statistical analysis. However, as noted by the HEI Expert Panel, the study provides evidence of a positive association between exposure and lung cancer despite the conflicting exposure-response analyses. Even though different assumptions and methods of analysis have led to different conclusions about the utility of this study for quantifying an exposure-response relationship, "the overall risk of lung cancer was elevated among diesel-exposed workers" (HEI, 1999, p. 25).

Another commenter (MARG) cited a number of studies (all of which had already been placed in the public record by MSHA) that, according to the commenter, "reflect either negative health effects trends among miners or else failed to demonstrate a statistically significant positive trend correlated with dpm exposure." It should be noted that, as explained earlier, failure of an individual study to achieve statistical significance (i.e., a high confidence level for its results) does not necessarily prevent a study from contributing important information to a larger body of evidence. An epidemiologic study may fail to achieve statistical significance simply because it did not involve a sufficient number of subjects or because it did not allow for an adequate latency period. In addition to this general point, the following responses apply to the specific studies cited by the commenter.

- Ahlman et al. (1991). This study is discussed above, under the heading of "Studies Involving Miners." MSHA agrees with the commenter that this study did not "establish" a relationship between diesel exposure and the excess risk of lung cancer reported among the miners involved. Contrary to the commenter's characterization, however, the evidence presented by this study does incrementally point in the direction of such a relationship. As mentioned earlier, none of the underground miners who developed lung cancer had been occupationally exposed to asbestos, metal work, paper pulp, or organic dusts. Based on measurements of the alpha energy concentration at the mines, and a comparison of smoking habits between underground and surface miners, the authors concluded that not all of the excess lung cancer for the underground miners was attributable to radon daughter exposures and/or smoking. A stronger conclusion may have been possible if the cohort had been larger.
- Ames et al. (1984). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." The commenter repeated MSHA's statement (in the proposed risk assessment) that the investigators had not detected any association of chronic respiratory effects with diesel exposure, but ignored MSHA's observation that the analysis had failed to consider baseline differences in lung function or symptom prevalence. Furthermore, as acknowledged by the investigators, diesel exposure levels in the study population were low.
- Ames et al. (1983). As discussed later in this risk assessment, under the heading of "Mechanisms of Toxicity," this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Unlike the Australian mines studied by Christie et al. (1995), the coal mines included in this study were not extensively dieselized, and the investigators did not relate their findings to diesel exposures.
- Ames et al. (1982). As noted earlier under the heading of "Acute Health Effects," this study, which did not attempt to evaluate cancer or other chronic health effects, detected no statistically significant relationship between diesel exposure and pulmonary function. However, the authors noted that this might have been due to the low concentrations of diesel emissions involved.
- Armstrong et al. (1979). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. As pointed out by the commenter, comparisons were to a general population. Therefore, they were subject to a healthy worker effect for which no adjustment was made. The commenter further stated that "diesel emissions were not found to be related to increased health risks." However, diesel emissions were not mentioned in the report, and the investigators did not attempt to compare lung cancer rates in exposed and unexposed miners.
- Attfield et al (1982). MSHA has taken the results of this study into account, under the heading of "Chronic Effects other than Cancer."
- Attfield (1979). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." Although the results were not conclusive at a high confidence level, miners occupationally exposed to diesel exhaust for five or more years exhibited an increase in various respiratory symptoms, as compared to miners exposed for less than five years.
- Boffetta et al. (1988). This study is discussed in two places above, under the headings "Studies Involving Miners" and "Best Available Epidemiologic Evidence." The commenter stated that "the study obviously does not demonstrate risks from dpm exposure." If the word "demonstrate" is taken to mean "conclusively prove," then MSHA would agree that the study, viewed in isolation, does not do this. As explained in the earlier discussion, however, MSHA considers this study to contribute to the weight of evidence that dpm exposure increases the risk of lung cancer.
- Costello et al. (1974). As discussed later in this risk assessment, this study was among nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. Since comparisons were to a general population, they were subject to a healthy worker effect for which no adjustment was made. Diesel emissions were not mentioned in the report.
- Gamble and Jones (1983). MSHA has taken account of this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." The commenter did not address MSHA's observation that the method of statistical analysis used by the investigators may have masked an association of respiratory symptoms with diesel exposure.
- Glenn et al. (1983). As summarized by the commenter, this report reviewed NIOSH medical surveillance on miners exposed to dpm and found that "* * * neither consistent nor obvious trends implicating diesel exhaust in the mining atmosphere were revealed." The authors noted that "results were rather mixed," but also noted that "levels of diesel exhaust contaminants were generally low," and that "overall tenure in these diesel equipped mines was fairly short." MSHA acknowledges the commenter's emphasis on the report's 1983 conclusion: "further research on this subject is needed." However, the authors also pointed out that "all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group. In the potash, salt and trona groups, these excesses were substantial." The miners included in the studies summarized by this report would not have been exposed to dpm for sufficient time to exhibit a possible increase in the risk of lung cancer.
- Johnston et al. (1997). This study is discussed in two places above, under the headings "Studies Involving Miners" and "Best Available Epidemiologic Evidence." MSHA disagrees with the commenter's

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assertion that "the study does not support a health risk from dpm." This was not the conclusion drawn by the authors of the study. As explained in the earlier discussion, this study, one of the few containing quantitative estimates of cumulative dpm exposures, provides evidence of increasing lung cancer risk with increasing exposure.

• Jörgenson and Svensson (1970). MSHA discussed this study, which did not attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." Contrary to the commenter's characterization, the investigators reported higher rates of chronic productive bronchitis, for both smokers and nonsmokers, among the underground iron ore miners exposed to diesel exhaust as compared to surface workers at the same mine.

• Kuempel (1995); Lidell (1973); Miller and Jacobsen (1985). As discussed later in this risk assessment, under the heading of "Mechanisms of Toxicity," these three studies were among the nine (out of 17) that did not find evidence of a relationship between exposure to respirable coal mine dust and an increased risk of lung cancer. The extent, if any, to which workers involved in these studies were occupationally exposed to diesel emissions was not documented, and diesel emissions were not mentioned in any of these reports.

• Morfeld et al. (1997). The commenter's summary of this study distorted the investigators' conclusions. Contrary to the commenter's characterization, this is one of eight studies that showed an increased risk of lung cancer for coal miners, as discussed later in this risk assessment under the heading of "Mechanisms of Toxicity." For lung cancer, the relative SMR, which adjusts for the healthy worker effect, was 1.11. (The value of 0.70 cited by the commenter was the unadjusted SMR.) The authors acknowledged that the relative SMR obtained by the "standard analysis" (i.e., 1.11) was not statistically significant. However, the main object of the report was to demonstrate that the "standard analysis" is insufficient. The investigators presented evidence that the 1.11 value was biased downward by a "healthy-worker-survivor-effect," thereby masking the actual exposure effects in these workers. They found that "all the evidence points to the conclusion that a standard analysis suffers from a severe underestimate of the exposure effect on overall mortality, cancer mortality and lung cancer mortality." (Morfeld et al., 1997, p. 350)

• Reger (1982). MSHA has taken account of this study, which made no attempt to evaluate cancer effects, under the heading of "Chronic Effects other than Cancer." As summarized by the commenter, "diesel-exposed miners were found to have more cough and phlegm, and lower pulmonary function," but the author found that "the evidence would not allow for the rejection of the hypothesis of health equality between exposed and non-exposed miners." The commenter failed to note, however, that miners in the dieselized mines, had worked underground for less than 5 years on average.

• Rockette (1977). This is one of eight studies, discussed under "Mechanisms of Toxicity," showing an increased risk of lung cancer for coal miners. As described by the commenter, the author reported SMRs of 1.12 for respiratory cancers and 1.40 for stomach cancer. MSHA agrees with the commenter that "the study does not establish a dpm-related health risk," but notes that dpm effects were not under investigation. Diesel emissions were not mentioned in the report, and, given the study period, the miners involved may not have been occupationally exposed to diesel exhaust.

• Waxweiler (1972). MSHA's discussion of this study appears earlier in this risk assessment, under "Studies Involving Miners." As noted by the commenter, the slight excess in lung cancer, relative to the general population of New Mexico, was not statistically significant. The commenter failed to note, however, that no adjustment was made for a healthy worker effect and that a substantial percentage of the underground miners were not occupationally exposed to diesel emissions.

Summation. Limitations identified in both positive and negative studies include: lack of sufficient power, inappropriate comparison groups, exposure misclassification, statistically insignificant results, and potential confounders. As explained earlier, under "Evaluation Criteria," weaknesses of the first three of these types can reasonably be expected, for the most part, to artificially decrease the apparent strength of any observed association between diesel exposure and increased risk of lung cancer. Statistical insignificance and potential confounders may, in the absence of evidence to the contrary, be regarded as neutral on average. The weaknesses that have been identified in these studies are not unique to epidemiologic studies involving lung cancer and diesel exhaust. They are sources of uncertainty in virtually all epidemiologic research.

Even when there is a strong possibility that the results of a study have been affected by confounding variables, it does not follow that the effect has been to inflate rather than deflate the results or that the study cannot contribute to the weight of evidence supporting a putative association. As cogently stated by Stöber and Abel (op cit., p. 4), "* * * associations found in epidemiologic studies can always be, at least in part, attributed to confounding." Therefore, an objection grounded on potential confounding can always be raised against any epidemiologic study. It is well known that this same objection was, in the past, raised against epidemiologic studies linking lung cancer and radon exposure, lung cancer and asbestos dust exposure, and even lung cancer and tobacco smoking.

Some commenters, have now proposed that virtually every existing epidemiologic study relating lung cancer to dpm exposure be summarily discredited because of susceptibility to confounding or other perceived weaknesses. Given the practical difficulties of designing and executing an epidemiologic study, this is not so much an objection to any specific study as it is an attack on applied epidemiology in general. Indeed, in their review of these studies, Stöber and Abel (1996) conclude that

> In this field * * * epidemiology faces its limits (Taubes, 1995). * * * Many of these studies were doomed to failure from the very beginning.

For important ethical reasons, however, tightly controlled lung cancer experiments cannot be performed on humans. Therefore, despite their inherent limitations, MSHA must rely on the weight of evidence from epidemiologic studies, placing greatest weight on the most carefully designed and executed studies available.

(b) Bladder Cancer

With respect to cancers other than lung cancer, MSHA's review of the literature identified only bladder cancer as a possible candidate for a causal link to dpm. Cohen and Higgins (1995) identified and reviewed 14 epidemiologic case-control studies containing information related to dpm exposure and bladder cancer. All but one of these studies found elevated risks of bladder cancer among workers in jobs frequently associated with dpm exposure. Findings were statistically significant in at least four of the studies (statistical significance was not evaluated in three).

These studies point quite consistently toward an excess risk of bladder cancer among truck or bus drivers, railroad workers, and vehicle mechanics. However, the four available cohort studies do not support a conclusion that exposure to dpm is responsible for the excess risk of bladder cancer associated with these occupations. Furthermore, most of the case-control studies did not distinguish between exposure to diesel-powered equipment and exposure to gasoline-powered equipment for workers having the same occupation. When such a distinction was drawn, there was no evidence that the prevalence of bladder cancer was higher for workers exposed to the diesel-powered equipment.

This, along with the lack of corroboration from existing cohort studies, suggests that the excessive rates of bladder cancer observed may be a consequence of factors other than dpm exposure that are also associated with these occupations. For example, truck and bus drivers are subjected to vibrations while driving and may tend to have different dietary and sleeping habits than the general population. For these reasons, MSHA does not find that convincing evidence currently exists for a causal relationship between dpm exposure and bladder cancer. MSHA received no public comments objecting to this conclusion.

ii. Studies Based on Exposures to $PM_{2.5}$ in Ambient Air. Prior to 1990, the relationship between mortality and long-term exposure to particulate matter was generally investigated by means of cross-sectional studies, but unaddressed spatial confounders and other methodological problems inherent in such studies limited their usefulness (EPA, 1996).[56] Two more recent prospective cohort studies provide better evidence of a link between excess mortality rates and exposure to fine particulate, although some of the uncertainties here are greater than with the short-term studies conducted in single communities. The two studies are the "Six Cities" study (Dockery et al., 1993), and the American Cancer Society (ACS) study (Pope et al., 1995).[57] The first study followed about 8,000 adults in six U.S. cities over 14 years; the second looked at survival data for half a million adults in 151 U.S. cities for 7 years. After adjusting for potential confounders, including smoking habits, the studies considered differences in mortality rates between the most polluted and least polluted cities.

Both the Six Cities study and the ACS study found a significant association between chronically higher concentrations of $PM_{2.5}$ (which includes dpm) and age-adjusted total mortality.[58] The authors of the Six Cities Study concluded that the results suggest that exposures to fine particulate air pollution "contributes to excess mortality in certain U.S. cities." The ACS study, which not only controlled for smoking habits and various occupational exposures, but also, to some extent, for passive exposure to tobacco smoke, found results qualitatively consistent with those of the Six Cities Study.[59] In the ACS study, however, the estimated increase in mortality associated with a given increase in fine particulate exposure was lower, though still statistically significant. In both studies, the largest increase observed was for cardiopulmonary mortality.

Both studies also showed an increased risk of lung cancer associated with increased exposure to fine particulate. Although the lung cancer results were not statistically significant, they are consistent with reports of an increased risk of lung cancer among workers occupationally exposed to diesel emissions (discussed above).

The few studies on associations between chronic $PM_{2.5}$ exposure and morbidity in adults show effects that are difficult to separate from measures of PM_{10} and measures of acid aerosols. The available studies, however, show positive associations between particulate air pollution and adverse health effects for those with pre-existing respiratory or cardiovascular disease. This is significant for miners occupationally exposed to fine particulates such as dpm because, as mentioned earlier, there is a large body of evidence showing that respiratory diseases classified as COPD are significantly more prevalent among miners than in the general population. It also appears that PM exposure may exacerbate existing respiratory infections and asthma, increasing the risk of severe outcomes in individuals who have such conditions (EPA, 1996).

d. Mechanisms of Toxicity

Four topics will be addressed in this section of the risk assessment: (i) the agent of toxicity, (ii) clearance and deposition of dpm, (iii) effects other than cancer, and (iv) lung cancer. The section on lung cancer will include discussions of the evidence from (1) genotoxicity studies (including bioavailability of genotoxins) and (2) animal studies.

i. Agent of Toxicity. As described in Part II of this preamble, the particulate fraction of diesel exhaust is made up of aggregated soot particles, vapor phase hydrocarbons, and sulfates. Each soot particle consists of an insoluble, elemental carbon core and an adsorbed, surface coating of relatively soluble organic compounds, such as polycyclic aromatic hydrocarbons (PAHs). Many of these organic carbon compounds are suspected or known mutagens and/or carcinogens. For example, nitrated PAHs, which are present in dpm, are potent mutagens in microbial and human cell systems, and some are known to be carcinogenic to animals (IPCS, 1996, pp. 100–105).

When released into an atmosphere, the soot particles formed during combustion tend to aggregate into larger particles. The total organic and elemental carbon in these soot particles accounts for approximately 80 percent of the dpm mass. The remaining 20 percent consists mainly of sulfates, such as H_2SO_4 (sulfuric acid).

Several laboratory animal studies have been performed to ascertain whether the effects of diesel exhaust are attributable specifically to the particulate fraction. (Heinrich et al., 1986, 1995; Iwai et al., 1986; Brightwell et al., 1986). These studies compare the effects of chronic exposure to whole diesel exhaust with the effects of filtered exhaust containing no particles. The studies demonstrate that when the exhaust is sufficiently diluted to nullify the effects of gaseous irritants (NO_2 and SO_2), irritant vapors (aldehydes), CO, and other systemic toxicants, diesel particles are the prime etiologic agents of noncancer health effects. Exposure to dpm produced changes in the lung that were much more prominent than those evoked by the gaseous fraction alone. Marked differences in the effects of whole and filtered diesel exhaust were also evident from general toxicological

[56] Unlike *longitudinal studies*, which examine responses at given locations to changes in conditions over time, *cross-sectional studies* compare results from locations with different conditions at a given point in time.

[57] A third such study, the California Seventh Day Adventist study (Abbey et al., 1991), investigated only TSP, rather than fine particulate. It did not find significant excess mortality associated with chronic TSP exposures.

[58] The Six Cities study also found such relationships at elevated levels of PM_{10} and sulfates. The ACS study was designed to follow up on the fine particle results of the Six Cities Study, and also investigated sulfates separately. As explained earlier in this preamble, sulfates may be a significant constituent of dpm, depending on the type of diesel fuel used.

[59] The Six Cities study did not find a statistically significant increase in risk among non-smokers, suggesting that non-smokers might be less sensitive than smokers to adverse health effects from fine particulate exposures; however, the ACS study, with more statistical power, did find significantly increased risk even for non-smokers.

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indices, such as body weight, lung weight, and pulmonary histopathology.

These studies show that, when the exhaust is sufficiently diluted, it is the particles that are primarily responsible for the toxicity observed. However, the available studies do not completely settle the question of whether the particles might act additively or synergistically with the gases in diesel exhaust. Possible additivity or interaction effects with the gaseous portion of diesel exhaust cannot be completely ruled out.

One commenter (MARG) raised an issue with regard to the agent of toxicity in diesel exhaust as follows:

> MSHA has not attempted to regulate exposure to suspected carcinogens contained in dpm, but has opted instead, in metal/non-metal mines, to regulate total carbon ("TC") as a surrogate for diesel exhaust, without any evidence of adverse health effects from TC exposure. * * * Nor does the mere presence of suspected carcinogens, in minute quantities, in diesel exhaust require a 95 percent reduction of total diesel exhaust [sic] in coal mines. If there are small amounts of carcinogenic substances of concern in diesel exhaust, those substances, not TC, should be regulated directly on the basis of the risks (if any) posed by those substances in the quantities actually present in underground mines. [MARG]

First, it should be noted that the "suspected carcinogens" in diesel exhaust to which the commenter referred are part of the organic fraction of the total carbon. Therefore, limiting the concentration of airborne total carbon attributable to dpm, or removing the soot particles from the diesel exhaust by filtration, are both ways of effectively limiting exposures to these suspected carcinogens. Second, the commenter seems to have assumed that cancer is the only adverse health effect of concern and that the only agents in dpm that could cause cancer are the "suspected carcinogens" in the organic fraction. This not only ignores non-cancer health effects associated with exposures to dpm and other fine particles, but also the possibility (discussed below) that, with sufficient deposition and retention, soot particles themselves could promote or otherwise increase the risk of lung cancer—either directly or by stimulating the body's natural defenses against foreign substances.

The same commenter [MARG] also stated that "* * * airborne carbon has not been shown to be harmful at levels currently established in MSHA's dust rules. If the problem is dpm, as MSHA asserts, then it is not rationally addressed by regulating airborne carbon." MSHA's intent is to limit dpm exposures in M/NM mines by regulating the submicrometer carbon from diesel emissions—not any and all airborne carbon. MSHA considers its approach a rational means of limiting dpm exposures because most of the dpm consists of carbon (approximately 80 percent by weight), and because using low sulfur diesel fuel will effectively reduce the sulfates comprising most of the remaining portion. The commenter offered no practical suggestion of a more direct, effective, and rational way of limiting airborne dpm concentrations in M/NM mines. Furthermore, direct evidence exists that the risk of lung cancer increases with increasing cumulative occupational exposure to dpm as measured by total carbon (Säverin *et al.*, 1999, discussed earlier in this risk assessment).

ii. Deposition, Clearance, and Retention. As suggested by Figure II–1 of this preamble, most of the aggregated particles making up dpm are no larger than one micrometer in diameter. Particles this small are able to penetrate into the deepest regions of the lungs, called *alveoli*. In the alveoli, the particles can mix with and be dispersed by a substance called *surfactant*, which is secreted by cells lining the alveolar surfaces.

The literature on deposition of fine particles in the respiratory tract was reviewed in Green and Watson (1995) and U.S. EPA (1996). The mechanisms responsible for the broad range of potential particle-related health effects varies depending on the site of deposition. Once deposited, the particles may be cleared from the lung, translocated into the interstitium, sequestered in the lymph nodes, metabolized, or be otherwise chemically or physically changed by various mechanisms. Clearance of dpm from the alveoli is important in the long-term effects of the particles on cells, since it may be more than two orders of magnitude slower than mucociliary clearance (IPCS, 1996).

IARC (1989) and IPCS (1996) reviewed factors affecting the deposition and clearance of dpm in the respiratory tracts of experimental animals. Inhaled PAHs adhering to the carbon core of dpm are cleared from the lung at a significantly slower rate than unattached PAHs. Furthermore, there is evidence that inhalation of whole dpm may increase the retention of subsequently inhaled PAHs. IARC (op cit.) suggested that this can happen when newly introduced PAHs bind to dpm particles that have been retained in the lung.

The evidence points to significant differences in deposition and clearance for different animal species (IPCS, 1996). Under equivalent exposure regimens, hamsters exhibited lower levels of retained dpm in their lungs than rats or mice and consequently less pulmonary function impairment and pulmonary pathology. These differences may result from a lower intake rate of dpm, lower deposition rate and/or more rapid clearance rate, or lung tissue that is less susceptible to the cytotoxicity of dpm. Observations of a decreased respiration in hamsters when exposed by inhalation favor lower intake and deposition rates.

Retardation of lung clearance, called "overload" is not specific to dpm and may be caused by inhaling, at a sufficiently high rate, dpm in combination with other respirable particles, such as mineral dusts typical of mining environments. The effect is characterized by (1) an overwhelming of normal clearance processes, (2) disproportionately high retention and loading of the lung with particles, compared to what occurs at lower particle inhalation rates, (3) various pathological responses; generally including chronic inflammation, epithelial hyperplasia and metaplasia, and pulmonary fibrosis; and sometimes including lung tumors.

In the proposed risk assessment, MSHA requested additional information, not already covered in the sources cited above, on fine particle deposition in the respiratory tract, especially as it might pertain to lung loading in miners exposed to a combination of diesel particulate and other dusts. In response to this request, NIOSH submitted a study that investigated rat lung responses to chronic inhalation of a combination of coal dust and diesel exhaust, compared to coal dust or dpm alone (Castranova et al., 1985). Although this report did not directly address deposition or clearance, the investigators reported that another phase of the study had shown that "particulate clearance, as determined by particulate accumulation in the lung, is inhibited after two years of exposure to diesel exhaust but is not inhibited by exposure to coal dust."

iii. Effects other than Cancer. A number of controlled animal studies have been undertaken to ascertain the toxic effects of exposure to diesel exhaust and its components. Watson and Green (1995) reviewed approximately 50 reports describing noncancerous effects in animals resulting from the inhalation of diesel exhaust. While most of the studies were conducted with rats or hamsters, some information was also available from studies conducted using cats, guinea pigs, and monkeys. The authors also

correlated reported effects with different descriptors of dose, including both gravimetric and non-gravimetric (*e.g.*, particle surface area or volume) measures. From their review of these studies, Watson and Green concluded that:

(a) Animals exposed to diesel exhaust exhibit a number of noncancerous pulmonary effects, including chronic inflammation, epithelial cell hyperplasia, metaplasia, alterations in connective tissue, pulmonary fibrosis, and compromised pulmonary function.

(b) Cumulative weekly exposure to diesel exhaust of 70 to 80 mg• hr/m^3 or greater are associated with the presence of chronic inflammation, epithelial cell proliferation, and depressed alveolar clearance in chronically exposed rats.

(c) The extrapolation of responses in animals to noncancer endpoints in humans is uncertain. Rats were the most sensitive animal species studied.

Subsequent to the review by Watson and Green, there have been a number of animal studies on allergic immune responses to dpm. Takano et al. (1997) investigated the effects of dpm injected into mice through an intratracheal tube and found manifestations of allergic asthma, including enhanced antigen-induced airway inflammation, increased local expression of cytokine proteins, and increased production of antigen-specific immunoglobulins. The authors concluded that the study demonstrated dpm's enhancing effects on allergic asthma and that the results suggest that dpm is "implicated in the increasing prevalence of allergic asthma in recent years." Similarly, Ichinose et al. (1997a) found that five different strains of mice injected intratracheally with dpm exhibited manifestations of allergic asthma, as expressed by enhanced airway inflammation, which were correlated with an increased production of antigen-specific immunoglobulin due to the dpm. The authors concluded that dpm enhances manifestations of allergic airway inflammation and that "* * * the cause of individual differences in humans at the onset of allergic asthma may be related to differences in antigen-induced immune responses * * *."

The mechanisms that may lead to adverse health effects in humans from inhaling fine particulates are not fully understood, but potential mechanisms that have been hypothesized for non-cancerous outcomes are summarized in Table III–6. A comprehensive review of the toxicity literature is provided in U.S. EPA (1996).

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Table III-6. — Hypothesized mechanisms of particulate toxicity†

Response	Description
Increased Airflow Obstruction	PM exposure may aggravate existing respiratory symptoms which feature airway obstruction. PM-induced airway narrowing or airway obstruction from increased mucous secretion may increase abnormal ventilation/perfusion ratios in the lung and create hypoxia. Hypoxia may lead to cardiac arrhythmias and other cardiac electrophysiologic responses that in turn may lead to ventricular fibrillation and ultimately cardiac arrest. For those experiencing airflow obstruction, increased airflow into non-obstructed areas of the lung may lead to increased particle deposition and subsequent deleterious effects on remaining lung tissue, further exacerbating existing disease processes. More frequent and severe symptoms may be present or more rapid loss of function.
Impaired Clearance	PM exposure may impair clearance by promoting hypersecretion of mucus which in turn results in plugging of airways. Alterations in clearance may also extend the time that particles or potentially harmful biogenic aerosols reside in the tracheobronchial region of the lung. Consequently alterations in clearance from either disturbance of the mucociliary escalator or of macrophage function may increase susceptibility to infection, produce an inflammatory response, or amplify the response to increased burdens of PM. Acid aerosols impair mucociliary clearance.
Altered Host Defense	Responses to an immunological challenge (e.g., infection), may enhance the subsequent response to inhalation of nonspecific material (e.g., PM). PM exposure may also act directly on macrophage function which may not only affect clearance of particles but also increase susceptibility and severity of infection by altering their immunological function. Therefore, depression or over-activation of the immune system, caused by exposure to PM, may be involved in the pathogenesis of lung disease. Decreased respiratory defense may result in increased risk of mortality from pneumonia and increased morbidity (e.g., infection).
Cardiovascular Perturbation	Pulmonary responses to PM exposure may include hypoxia, bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators that can contribute to cardiovascular perturbation. Inhaled particles could act at the level of the pulmonary vasculature by increasing pulmonary vascular resistance and further increase ventilation/perfusion abnormalities and hypoxia. Generalized hypoxia could result in pulmonary hypertension and interstitial edema that would impose further workload on the heart. In addition, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to increased risk of thrombus formation in the vascular system. Finally, direct stimulation by PM of respiratory receptors found throughout the respiratory tract may have direct cardiovascular effects (e.g., bradycardia, hypertension, arrhythmia, apnea and cardiac arrest).
Epithelial Lining Changes	PM or its pathophysiological reaction products may act at the alveolar capillary membrane by increasing the diffusion distances across the respiratory membrane (by increasing its thickness) and causing abnormal ventilation/perfusion ratios. Inflammation caused by PM may increase "leakiness" in pulmonary capillaries leading eventually to increased fluid transudation and possibly to interstitial edema in susceptible individuals. PM induced changes in the surfactant layer leading to increased surface tension would have the same effect.
Inflammatory Response	Diseases which increase susceptibility to PM toxicity involve inflammatory response (e.g., asthma, COPD, and infection). PM may induce or enhance inflammatory responses in the lung which may lead to increased permeability, diffusion abnormality, or increased risk of thrombus formation in vascular system. Inflammation from PM exposure may also decrease phagocytosis by alveolar macrophages and therefore reduce particle clearance. (See discussions above for other inflammatory effects from PM exposure.)

† This table was derived from information in EPA (1996) 11:179-185; 13:67-72; and Appendix D of EPA staff report.

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Deposition of particulates in the human respiratory tract may initiate events leading to increased airflow obstruction, impaired clearance, impaired host defenses, or increased epithelial permeability. Airflow obstruction can result from laryngeal constriction or bronchoconstriction secondary to stimulation of receptors in extrathoracic or intrathoracic airways. In addition to reflex airway narrowing, reflex or local stimulation of mucus secretion can lead to mucus hypersecretion and, eventually, to mucus plugging in small airways.

Pulmonary changes that contribute to cardiovascular responses include a variety of mechanisms that can lead to hypoxemia, including bronchoconstriction, apnea, impaired diffusion, and production of inflammatory mediators. Hypoxia can lead to cardiac arrhythmias and other cardiac electrophysiologic responses that, in turn, may lead to ventricular fibrillation and ultimately cardiac arrest. Furthermore, many respiratory receptors have direct cardiovascular effects. For example, stimulation of C-fibers leads to bradycardia and hypertension, and stimulation of laryngeal receptors can result in hypertension, cardiac arrhythmia, bradycardia, apnea, and even cardiac arrest. Nasal receptor or pulmonary J-receptor stimulation can lead to vagally-mediated bradycardia and hypertension (Widdicombe, 1988).

Some commenters mistakenly attributed the sensory irritant effects of diesel exhaust entirely to its gaseous components. The mechanism by which constituents of dpm can cause sensory irritations in humans is much better understood than the mechanisms for other adverse health effects due to fine particulates. In essence, sensory irritants are "scrubbed" from air entering the upper respiratory tract, thereby preventing a portion from penetrating more deeply into the lower respiratory tract. However, the sensory irritants stimulate trigeminal nerve endings, which are located very close to the oro-nasal mucosa and also to the watery surfaces of the eye (cornea). This produces a burning, painful sensation. The intensity of the sensory irritant response is related to the irritant concentration and duration of exposure. Differences in relative potency are observed with different sensory irritants. Acrolein and formaldehyde are examples of highly potent sensory irritants which, along with others having low molecular weights (acids, aldehydes), are often found in the organic fraction of dpm (Nauss et al., 1995). They may be adsorbed onto the carbon-based core or released in a vapor phase. Thus, mixtures of sensory irritants in dpm may impinge upon the eyes and respiratory tract of miners and produce adverse health effects.

It is also important to note that mixtures of sensory irritants in dpm may produce responses that are not predicted solely on the basis of the individual chemical constituents. Instead, these irritants may interact at receptor sites to produce additive, synergistic, or antagonistic effects. For example, because of synergism, dpm containing a mixture of sensory irritants at relatively low concentrations may produce intense sensory responses (*i.e.*, responses far above those expected for the individual irritants). Therefore, the irritant effects of whole dpm cannot properly be evaluated by simply adding together the known effects of its individual components.

As part of its public comments on the proposed preamble, NIOSH submitted a study (Hahon et al., 1985) on the effects of diesel emissions on mice infected with influenza virus. The object of this study was to determine if exposure to diesel emissions (either alone or in combination with coal dust) could affect resistance to pulmonary infections. The investigators exposed groups of mice to either coal dust, diesel emissions, a combination of both, or filtered air (control group) for various durations, after which they were infected with influenza. Although not reflected by excess mortality, the severity of influenza infection was found to be more pronounced in mice previously exposed to diesel emissions than in control animals. The effect was not intensified by inhalation of coal dust in combination with those emissions.

In addition to possible acute toxicity of particles in the respiratory tract, chronic exposure to particles that deposit in the lung may induce inflammation. Inflammatory responses can lead to increased permeability and possibly diffusion abnormality. Furthermore, mediators released during an inflammatory response could cause release of factors in the clotting cascade that may lead to an increased risk of thrombus formation in the vascular system (Seaton, 1995). Persistent inflammation, or repeated cycles of acute lung injury and healing, can induce chronic lung injury. Retention of the particles may be associated with the initiation and/or progression of COPD.

Takenaka et al. (1995) investigated mechanisms by which dpm may act to cause allergenic effects in human cell cultures. The investigators reported that application of organic dpm extracts over a period of 10 to 14 days increased IgE production from the cells by a factor of up to 360 percent. They concluded that enhanced IgE production in the human airway resulting from the organic fraction of dpm may be an important factor in the increasing incidence of allergic airway disease. Similarly, Tsien et al. (1997) investigated the effects of the organic fraction of dpm on IgE production in human cell cultures and found that application of the organic extract doubled IgE production after three days in cells already producing IgE.

Sagai et al. (1996) investigated the potential role of dpm-induced oxygen radicals in causing pulmonary injuries. Repeated intratracheal instillation of dpm in mice caused marked infiltration of inflammatory cells, proliferation of goblet cells, increased mucus secretion, respiratory resistance, and airway constriction. The results indicated that oxygen radicals, induced by intratracheally instilled dpm, can cause responses characteristic of bronchial asthma.

Lovik et al. (1997) investigated inflammatory and systemic IgE responses to dpm, alone and in combination with the model allergen ovalbumin (OA), in mice. To determine whether it was the elemental carbon core or substances in the organic fraction of dpm that were responsible for observed allergenic effects, they compared the effects of whole dpm with those of carbon black (CB) particles of comparable size and specific surface area. Although the effects were slightly greater for dpm, both dpm and CB were found to cause significant, synergistic increases in allergenic responses to the OA, as expressed by inflammatory responses of the local lymph node and OA-specific IgE production. The investigators concluded that both dpm and CB synergistically enhance and prolong inflammatory responses in the lymph nodes that drain the site of allergen deposition. They further concluded that the elemental carbon core contributes substantially to the adjuvant activity of dpm.

Diaz-Sanchez et al. (1994, 1996, 1997) conducted a series of experiments on human subjects to investigate the effects of dpm on allergic inflammation as measured by IgE production. The studies by Takenaka et al. (op cit.) and Tsien et al. (op cit.) were also part of this series but were based on human cell cultures rather than live human volunteers. A principal objective of these experiments was to investigate the pathways and mechanisms by which dpm induces allergic inflammation. The investigators found that the organic fraction of dpm can enhance IgE production, but that the major

polyaromatic hydrocarbon in this fraction (phenanthrene) can enhance IgE without causing inflammation. On the other hand, when human volunteers were sprayed intranasally with carbon particles lacking the organic compounds, the investigators found a large influx of cells in the nasal mucosa but no increase in IgE. These results suggest that while the organic portion of dpm is not necessary for causing irritation and local inflammation, it is the organic compounds that act on the immune system to promote an allergic response.

Salvi et al. (1999) investigated the impact of diesel exhaust on human airways and peripheral blood by exposing healthy volunteers to diesel exhaust at a concentration of 300 $\mu g/m^3$ for one hour with intermittent exercise. Following exposure, they found significant evidence of acute inflammatory responses in airway lavage and also in the peripheral blood. Some commenters expressed a belief that the gaseous, rather than particulate, components of diesel exhaust caused these effects. The investigators noted that the inflammatory responses observed could not be attributed to NO_2 in the diesel exhaust because previous studies they had conducted, using a similar experimental protocol, had revealed no such responses in the airway tissues of volunteers exposed to a higher concentration of NO_2, for a longer duration, in the absence of dpm. They concluded that "[i]t therefore seems more likely that the particulate component of DE is responsible."

iv. *Lung Cancer.* (1) *Genotoxicity Studies.* Many studies have shown that diesel soot, or its organic component, can increase the likelihood of genetic mutations during the biological process of cell division and replication. A survey of the applicable scientific literature is provided in Shirnamé-Moré (1995). What makes this body of research relevant to the risk of lung cancer is that mutations in critical genes can sometimes initiate, promote, or advance a process of carcinogenesis.

The determination of genotoxicity has frequently been made by treating diesel soot with organic solvents such as dichloromethane and dimethyl sulfoxide. The solvent removes the organic compounds from the carbon core. After the solvent evaporates, the mutagenic potential of the extracted organic material is tested by applying it to bacterial, mammalian, or human cells propagated in a laboratory culture. In general, the results of these studies have shown that various components of the organic material can induce mutations and chromosomal aberrations.

One commenter (MARG) pointed out that "even assuming diesel exhaust contains particular genotoxic substances, the bioavailability of these genotoxins has been questioned." As acknowledged in the proposed risk assessment, a critical issue is whether whole diesel particulate is mutagenic when dispersed by substances present in the lung. Since the laboratory procedure for extracting organic material with solvents bears little resemblance to the physiological environment of the lung, it is important to establish whether dpm as a whole is genotoxic, without solvent extraction. Early research indicated that this was not the case and, therefore, that the active genotoxic materials adhering to the carbon core of diesel particles might not be biologically damaging or even available to cells in the lung (Brooks *et al.*, 1980; King *et al.*, 1981; Siak *et al.*, 1981). A number of more recent research papers, however, have shown that dpm, without solvent extraction, can cause DNA damage when the soot is dispersed in the pulmonary surfactant that coats the surface of the alveoli (Wallace *et al.*, 1987; Keane *et al.*, 1991; Gu *et al.*, 1991; Gu *et al.*, 1992). From these studies, NIOSH concluded in 1992 that:

* * * the solvent extract of diesel soot and the surfactant dispersion of diesel soot particles were found to be active in procaryotic cell and eukaryotic cell *in vitro* genotoxicity assays. The cited data indicate that respired diesel soot particles on the surface of the lung alveoli and respiratory bronchioles can be dispersed in the surfactant-rich aqueous phase lining the surfaces, and that genotoxic material associated with such dispersed soot particles is biologically available and genotoxically active. Therefore, this research demonstrates the biological availability of active genotoxic materials without organic solvent interaction. [Cover letter to NIOSH response to ANPRM, 1992].

If this conclusion is correct, it follows that dpm itself, and not only its organic extract, can cause genetic mutations when dispersed by a substance present in the lung.

One commenter (IMC Global) noted that Wallace *et al.* (1987) used aged dpm samples from scrapings inside an exhaust pipe and contended that this was not a realistic representation of dpm. The commenter further argued that the two studies cited by Gu *et al.* involved "direct application of an unusually high concentration gradient" that does not replicate normal conditions of dpm exposure.

MSHA agrees with this commenter's general point that conditions set up in such experiments do not duplicate actual exposure conditions. However, as a follow-up to the Wallace study, Keane *et al.* (op. cit.) demonstrated similar results with both exhaust pipe soot and particles obtained directly from an exhaust stream. With regard to the two Gu studies, MSHA recognizes that any well-controlled experiment serves only a limited purpose. Despite their limitations, however, these experiments provided valuable information. They avoided solvent extraction. By showing that solvent extraction is not a necessary condition of dpm mutagenicity, these studies provided incremental support to the hypothesis of bioavailability under more realistic conditions. This possibility was subsequently tested by a variety of other experiments, including experiments on live animals and humans.

For example, Sagai *et al.* (1993) showed that whole dpm produced active oxygen radicals in the trachea of live mice, but that dpm stripped of organic compounds did not. Whole dpm caused significant damage to the lungs and also high mortality at low doses. According to the investigators, most of the toxicity observed appeared to be due to the oxygen radicals, which can also have genotoxic effects. Subsequently, Ichinose *et al.* (1997b) examined the relationship between tumor response and the formation of oxygen radicals in the lungs of mice injected with dpm. The mice were treated with sufficiently high doses of dpm to produce tumors after 12 months. As in the earlier study, the investigators found that the dpm generated oxygen radicals, even in the absence of biologically activating systems (such as macrophages), and that these oxygen radicals were implicated in the lung toxicity of the dpm. The authors concluded that "oxidative DNA damage induced by the repeated DEP [*i.e.*, dpm] treatment could be an important factor in enhancing the mutation rate leading to lung cancer."

The formation of DNA adducts is an important indicator of genotoxicity and potential carcinogenicity. Adduct formation occurs when molecules, such as those in dpm, attach to the cellular DNA. These adducts can negatively affect DNA transcription and/or cellular duplication. If DNA adducts are not repaired, then a mutation or chromosomal aberration can occur during normal mitosis (*i.e.*, cell replication) eventually leading to cancer cell formation. IPCS (1996) contains a survey of animal experiments showing DNA adduct induction in the lungs of experimental animals exposed to diesel

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exhaust.[60] MSHA recognizes that such studies provide limited information regarding the bioavailability of organics, since positive results may well have been related to factors associated with lung particle overload. However, the bioavailability of genotoxic dpm components is also supported by human studies showing genotoxic effects of exposure to whole dpm. DNA adduct formation and/or mutations in blood cells following exposure to dpm, especially at levels insufficient to induce lung overload, can be presumed to result from organics diffusing into the blood.

Hemminki *et al.* (1994) found that DNA adducts were significantly elevated in lymphocytes of nonsmoking bus maintenance and truck terminal workers, as compared to a control group of hospital mechanics, with the highest adduct levels found among garage and forklift workers. Hou *et al.* (1995) reported significantly elevated levels of DNA adducts in lymphocytes of non-smoking diesel bus maintenance workers compared to a control group of unexposed workers. Similarly, Nielsen *et al.* (1996) found that DNA adducts were significantly increased in the blood and urine of bus garage workers and mechanics exposed to dpm as compared to a control group.

One commenter (IMC Global) acknowledged that "the studies conducted by Hemminiki [Hemminiki et al., 1994] showed elevations in lymphocyte DNA adducts in garage workers, bus maintenance workers and diesel forklift drivers" but argued that "these elevations were at the borderline of statistical significance." Although results at a higher level of confidence would have been more persuasive, this does not negate the value of the evidence as it stands. Furthermore, statistical significance in an individual study becomes less of an issue when, as in this case, the results are corroborated by other studies.

IMC Global also acknowledged that the Nielsen study found significant differences in DNA adduct formation between diesel-exposed workers and controls but argued that "the real source of genotoxins was unclear, and other sources of exposure, such as skin contact with lubricating oils could not be excluded." As is generally the case with studies involving human subjects, this study did not completely control for potential confounders. For this reason, MSHA considers it important that several human studies—not all subject to confounding by the same variables—found elevated adduct levels in diesel-exposed workers.

IMC Global cited another human study (Qu *et al.*, 1997) as casting doubt on the genotoxic effects of diesel exposure, even though this study (conducted on Australian coal miners) reported significant increases in DNA adducts immediately after a period of intense diesel exposure during a longwall move. As noted by the commenter, adduct levels of exposed miners and drivers were, prior to the longwall move, approximately 50% higher than for the unexposed control group; but differences by exposure category were not statistically significant. A more informative part of the study, however, consisted of comparing adducts in the same workers before and after a longwall move, which involved "intensive use of heavy equipment, diesel powered in these mines, over a 2–3 week period." MSHA emphasizes that the comparison was made on the same workers, because doing so largely controlled for potentially confounding variables, such as smoking habits, that may be a factor when making comparisons between different persons. After the period of "intensive" exposure, statistically significant increases were observed in both total and individual adducts. Contrary to the commenter's characterization of this study, the investigators stated that their analysis "provides results in which the authors have a high level of confidence." They concluded that "given the * * * apparent increase in adducts during a period of intense DEE [*i.e.*, diesel exhaust emissions] exposures it would be prudent to pay particular attention to keeping exposures as low as possible, especially during LWCO [*i.e.*, 'longwall change out'] operations." Although the commenter submitted this study as counter-evidence, it actually provides significant, positive evidence that high dpm exposures in a mining environment can produce genotoxic effects.

The West Virginia Coal Association submitted an analysis by Dr. Peter Valberg, purporting to show that "* * * the quantity of particle-bound mutagens that could potentially contact lung cells under human exposure scenarios is very small." According to Dr. Valberg's calculations, the dose of organic mutagens deposited in the lungs of a worker occupationally exposed (40 hours per week) to 500 µg/m³ of dpm would be equivalent in potency to smoking about one cigarette per month.[61] Dr. Valberg indicated that a person smoking at this level would generally be classified a nonsmoker, but he made no attempt to quantify the carcinogenic effects. Nor did he compare this exposure level with levels of exposures to environmental tobacco smoke that have been linked to lung cancer.

Since the commenter did not provide details of Dr. Valberg's calculation, MSHA was unable to verify its accuracy or evaluate the plausibility of key assumptions. However, even if the equivalence is approximately correct, using it to discount the possibility that dpm increases the risk of lung cancer relies on several questionable assumptions. Although their precise role in the analysis is unclear because it was not presented in detail, these assumptions apparently include:

(1) That there is a good correlation between genotoxicity dose-response and carcinogenicity dose-response. Although genotoxicity data can be very useful for identifying a carcinogenic hazard, carcinogenesis is a highly complex process that may involve the interaction of many mutagenic, physiological, and biochemical responses. Therefore, the shape and slope of a carcinogenic dose-response relationship cannot be readily predicted from a genotoxic dose-response relationship.

(2) That only the organic fraction of dpm contributes to carcinogenesis. This contradicts the findings reported by Ichinose *et al.* (1997b) and does not take into account the contribution that inflammation and active oxygen radicals induced by the inorganic carbon core of dpm may have in promoting lung cancers. Multiple routes of carcinogenesis may operate in human lungs—some requiring only the various organic mutagens in dpm and others involving induction of free radicals by the elemental carbon core, either alone or in combination with the organics.

(3) That the only mutagens in dpm are those that have been identified as mutagenic to bacteria and that the mutagenic constituents of dpm have all been identified. One of the most potent of all known mutagens (3-nitrobenzanthrone) was only recently isolated and identified in dpm (Enya *et al.*, 1997).

(4) That the mutagenic components of dpm have the same combined potency as those in cigarette smoke. This ignores the relative potency and amounts of the various mutagenic constituents. If the calculation did not take into account the relative amounts and potencies of all the individual mutagens in dpm and cigarette smoke, then it oversimplified the task of making such a comparison.

In sum, unlike the experimental findings of dpm genotoxicity discussed above, the analysis by Dr. Valberg is not based on empirical evidence from dpm experiments, and it appears to rely heavily on questionable assumptions. Moreover, the contention that active components of dpm are not available in sufficient quantities to cause significant mutagenic damage in humans appears to be directly contradicted by the empirical evidence of elevated DNA adduct levels in exposed workers (Hemminki *et al.*, 1994; Hou *et al.*, 1995; Nielsen *et al.*, 1996; Qu *et al.*, 1997).

(2) *Animal Inhalation Studies.* When dpm is inhaled, a number of adverse effects that may contribute to carcinogenesis are discernable by microscopic and biochemical analysis. For a comprehensive review of these effects, see Watson and Green (1995). In brief, these effects begin with phagocytosis, which is essentially an attack on the diesel particles by cells called alveolar macrophages. The macrophages engulf and ingest the diesel particles, subjecting them to detoxifying enzymes. Although this is a normal physiological response to the inhalation of foreign substances, the process can produce various chemical byproducts injurious to normal cells. In attacking the diesel particles, the activated macrophages release chemical agents that attract neutrophils (a type of white blood cell that destroys microorganisms) and additional alveolar macrophages. As the lung burden of diesel particles increases, aggregations of particle-laden macrophages form in alveoli adjacent to terminal bronchioles, the number of Type II cells lining particle-laden alveoli increases, and particles lodge within alveolar and peribronchial tissues and associated lymph nodes. The neutrophils and macrophages release mediators of inflammation and oxygen radicals, which have been implicated in causing various forms of chromosomal damage, genetic mutations, and malignant transformation of cells (Weitzman and Gordon, 1990). Eventually, the particle-laden macrophages are functionally altered, resulting in decreased viability and impaired phagocytosis and clearance of particles. This series of events may result in pulmonary inflammatory, fibrotic, or emphysematous lesions that can ultimately develop into cancerous tumors.

IARC (1989), Mauderly (1992), Busby and Newberne (1995), IPCS (1996), Cal-EPA (1998), and US EPA (1999) reviewed the scientific literature relating to excess lung cancers observed among laboratory animals chronically exposed to filtered and unfiltered diesel exhaust. The experimental data demonstrate that chronic exposure to whole diesel exhaust increases the risk of lung cancer in rats and that dpm is the causative agent. This carcinogenic effect has been confirmed in two strains of rats and in at least five laboratories. Experimental results for animal species other than the rat, however, are either inconclusive or, in the case of Syrian hamsters, suggestive of no carcinogenic effect. In two of three mouse studies reviewed by IARC (1989), lung tumor formation (including adenocarcinomas) was increased in the exposed animals as compared to concurrent controls; in the third study, the total incidence of lung tumors was not elevated compared to historical controls. Two more recent mouse studies (Heinrich et al., 1995; Mauderly et al., 1996) have both reported no statistically significant increase in lung cancer rates among exposed mice, as compared to contemporaneous controls. Monkeys exposed to diesel exhaust for two years did not develop lung tumors, but the short duration of exposure was judged inadequate for evaluating carcinogenicity in primates.

Bond et al. (1990a) investigated differences in peripheral lung DNA adduct formation among rats, hamsters, mice, and monkeys exposed to dpm at a concentration of 8100 µg/m³ for 12 weeks. Mice and hamsters showed no increase of DNA adducts in their peripheral lung tissue, whereas rats and monkeys showed a 60 to 80-percent increase. The increased prevalence of lung DNA adducts in monkeys suggests that, with respect to DNA adduct formation, the human lungs' response to dpm inhalation may more closely resemble that of rats than that of hamsters or mice.

The conflicting carcinogenic effects of chronic dpm inhalation reported in studies of rats, mice, and hamsters may be due to non-equivalent delivered doses or to differences in response among species. Indeed, monkey lungs have been reported to respond quite differently than rat lungs to both diesel exhaust and coal dust (Nikula, 1997). Therefore, the results from rat experiments do not, by themselves, establish that there is any excess risk due to dpm exposure for humans. However, the human epidemiologic and genotoxicity (DNA adduct) data indicate that humans comprise a species that, like rats, do suffer a carcinogenic response to dpm exposure. This would be consistent with the observation, mentioned above, that lung DNA adduct formation is increased among exposed rats but not among exposed hamsters or mice. Therefore, although MSHA recognizes that there are important differences between rats and humans (as there are also between rats and hamsters or mice), MSHA considers the rat studies relevant to an evaluation of human health risks.

Reactions similar to those observed in rats inhaling dpm have also been observed in rats inhaling fine particles with no organic component (Mauderly et al., 1994; Heinrich et al., 1994, 1995; Nikula et al., 1995). Rats exposed to titanium dioxide (TiO_2) or pure carbon ("carbon black") particles, which are not considered to be genotoxic, exhibited similar pathological responses and developed lung cancers at about the same rate as rats exposed to whole diesel exhaust. Carbon black particles were used in these experiments because they are physically similar to the inorganic carbon core of dpm but have negligible amounts of organic compounds adsorbed to their surface. Therefore, at least in some species, it appears that the lung cancer toxicity of dpm may result largely from a biochemical response to the core particle itself rather than from specific, genotoxic effects of the adsorbed organic compounds.[62]

One commenter stated that, in the proposed risk assessment, MSHA had neglected three additional studies suggesting that lung cancer risks in animals inhaling diesel exhaust are unrelated to genotoxic mechanisms. One of these studies (Mauderly et al., 1996) did not pertain to questions of

[60] Some of these studies will be discussed in the next subsection of this risk assessment.

[61] The only details provided for this calculation pertained to adjusting 8-hour occupational exposures. Dr. Valberg adjusted the 500 µg/m³ concentration for an 8-hour occupational exposure to a supposedly equivalent 24-hour continuous concentration of 92 µg/m³. This adjustment ignored differences in breathing rates between periods of sleep, leisure activities, and heavy work. Even under the unrealistic assumption of homogeneous breathing rates, the calculation appears to be erroneous, since (500 µg/m³) × (40 hours/week) is nearly 30 percent greater than (92 µg/m³) × (168 hours/week). Also, Dr. Valberg stated that the calculation assumed a deposition fraction of 20 percent for dpm but did not state what deposition fraction was being assumed for the particles in cigarette smoke.

[62] NIOSH commented as follows: "Data cited by MSHA in support of this statement are not comparable. Rats were exposed to dpm at 4 mg/m³ for 2 years (Mauderly et al. 1987; Brightwell et al. 1989), in contrast to rats exposed to TiO_2 at 250 mg/m³ for two years [reference to article (Lee et al. 1985) not cited by MSHA]. It is not apparent that the overload mechanism that is proposed to be responsible for tumors in the TiO_2 exposed rats could also have been responsible for the tumors seen in the dpm exposed rats at 62-fold lower exposure concentrations." In the reports cited by MSHA, levels of TiO_2 and/or carbon black were commensurate with dpm levels.

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genotoxicity but has been cited in the discussion of mouse studies above. The other two studies (Randerath et al., 1995 and Belinsky et al., 1995) were conducted as part of the cancer bioassay described in the 1994 article by Mauderly et al. (cited in the preceding paragraph). In the Randerath study, the investigators found that no DNA adducts specific to either diesel exhaust or carbon black were induced in the lungs of rats exposed to the corresponding substance. However, after three months of exposure, the total level of DNA adducts and the levels of some individual adducts were significantly higher in the diesel-exposed rats than in the controls. In contrast, multiple DNA adducts thought to be specific to diesel exhaust formed in the skin and lungs of mice treated topically with organic dpm extract. These results are consistent with the findings of Mauderly et al. (1994, op cit.). They imply that although the organic compounds of diesel exhaust are capable of damaging cellular DNA, they did not inflict such damage under the conditions of the inhalation experiment performed. The report noted that these results do not rule out the possibility of DNA damage by inhaled organics in "other species or * * * [in] exposure situations in which the concentrations of diesel exhaust particles are much lower." In the Belinsky study, the investigators measured mutations in selected genes in the tumors of those rats that had developed lung cancer. This study did not succeed in elucidating the mechanisms by which dpm and carbon black cause lung tumors in rats. The authors concluded that "until some of the genes involved in the carcinogenicity of diesel exhaust and carbon black are identified, a role for the organic compounds in tumor development cannot be excluded."

The carbon-black and TiO_2 studies discussed above indicate that lung cancers in rats exposed to dpm may be induced by a mechanism that does not require the bioavailability of genotoxic organic compounds adsorbed on the elemental carbon particles. Some researchers have interpreted these studies as also suggesting that (1) the carcinogenic mechanism in rats depends on massive overloading of the lung and (2) that this may provide a mechanism of carcinogenesis involving a threshold effect specific to rats, which has not been observed in other rodents or in humans (Oberdörster, 1994; Watson and Valberg, 1996). Some commenters on the ANPRM cited the lack of a link between lung cancer and coal dust or carbon black exposure as evidence that carbon particles, by themselves, are not carcinogenic in humans. Coal mine dust, however, consists almost entirely of particles larger than those forming the carbon core of dpm or used in the carbon black and TiO_2 rat studies. Furthermore, although there have been nine studies reporting no excess risk of lung cancer among coal miners (Liddell, 1973; Costello et al., 1974; Armstrong et al., 1979; Rooke et al., 1979; Ames et al., 1983; Atuhaire et al., 1985; Miller and Jacobsen, 1985; Kuempel et al., 1995; Christie et al., 1995), eight studies have reported an elevated risk of lung cancer for those exposed to coal dust (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Correa et al., 1984; Levin et al., 1988; Morabia et al., 1992; Swanson et al., 1993; Morfeld et al., 1997). The positive results in five of these studies (Enterline, 1972; Rockette, 1977; Howe et al., 1983; Morabia et al., 1992; Swanson et al., 1993) were statistically significant. Morabia et al. (op cit.) reported increased risk associated with duration of exposure, after adjusting for cigarette smoking, asbestos exposure, and geographic area. Furthermore, excess lung cancers have been reported among carbon black production workers (Hodgson and Jones, 1985; Siemiatycki, 1991; Parent et al., 1996). After a comprehensive evaluation of the available scientific evidence, the World Health Organization's International Agency for Research on Cancer concluded: "Carbon black is possibly carcinogenic to humans (Group 2B)." (IARC, 1996).

The carbon black and TiO_2 animal studies cited above do not prove there is a threshold below which dpm exposure poses no risk of causing lung cancer in humans. They also do not prove that dpm exposure has no incremental, genotoxic effects. Even if the genotoxic organic compounds in dpm were biologically unavailable and played no role in human carcinogenesis, this would not rule out the possibility of a genotoxic route to lung cancer (even for rats) due to the presence of the particles themselves. For example, as a byproduct of the biochemical response to the presence of particles in the alveoli, free oxidant radicals may be released as macrophages attempt to digest the particles. There is evidence that dpm can both induce production of reactive oxygen agents and also depress the activity of naturally occurring antioxidant enzymes (Mori, 1996; Ichinose et al., 1997; Sagai et al., 1993). Oxidants can induce carcinogenesis either by reacting directly with DNA, or by stimulating cell replication, or both (Weitzman and Gordon, 1990). Salvi et al. (1999) reported acute inflammatory responses in the airways of human exposed to dpm for one hour at a concentration of 300 $\mu g/m^3$. Such inflammation is associated with the production of free radicals and could provide routes to lung cancer with even when normal lung clearance is occurring. It could also give rise to a "quasi-threshold," or surge in response, corresponding to the exposure level at which the normal clearance rate becomes overwhelmed (lung overload).

Oxidant activity is not the only mechanism by which dpm could exert carcinogenic effects in the absence of mutagenic activity by its organic fraction. In its commentary on the Randerath study discussed above, the HEI's Health Review Committee suggested that dpm could both cause genetic damage by inducing free oxygen radicals and also enhance cell division by inducing cytokines or growth hormones:

> It is possible that diesel exhaust exerts its carcinogenic effects through a mechanism that does not involve direct genotoxicity (that is, formation of DNA adducts) but involves proliferative responses such as chronic inflammation and hyperplasia arising from high concentrations of particles deposited in the lungs of the exposed rats. * * * Phagocytes (macrophages and neutrophils) released during inflammatory reactions "produce reactive oxygen species that can damage DNA. * * * Particles (with or without adsorbed PAHs) may thus induce oxidative DNA damage via oxygen free radicals. * * * Alternatively, activated phagocytes may release cytokines or growth factors that are known to increase cell division. Increased cell division has been implicated in cancer causation. * * * Thus, in addition to oxidative DNA damage, increased cell proliferation may be an important mechanism by which diesel exhaust and other insoluble particles induce pulmonary carcinogenesis in the rat. [Randereth et al., 1995, p. 55]

Even if lung overload were the primary or sole route by which dpm induced lung cancer, this would not mean that the high dpm concentrations observed in some mines are without hazard. It is noteworthy, moreover, that dpm exposure levels recorded in some mines have been almost as high as laboratory exposures administered to rats showing a clearly positive response. Intermittent, occupational exposure levels greater than about 500 $\mu g/m^3$ dpm may overwhelm the human lung clearance mechanism (Nauss et al., 1995). Therefore, concentrations at the even higher levels currently observed in some mines could be expected to cause overload in some humans, possibly inducing lung cancer by a mechanism

similar to what occurs in rats. In addition, a proportion of exposed individuals can always be expected to be more susceptible than normal to clearance impairments and lung overload. Inhalation at even moderate levels may significantly impair clearance, especially in susceptible individuals. Exposures to cigarette smoke and respirable mineral dusts may further depress clearance mechanisms and reduce the threshold for overload. Consequently, even at dpm concentrations far lower than 500 $\mu g/m^3$ dpm, impaired clearance due to dpm inhalation may provide an important route to lung cancer in humans, especially if they are also inhaling cigarette smoke and other fine dusts simultaneously. (Hattis and Silver, 1992, Figures 9, 10, 11).

Furthermore, as suggested above, lung overload is not necessarily the only route to carcinogenesis in humans. Therefore, dpm concentrations too low to cause overload still may present a hazard. In humans exposed over a working lifetime to doses insufficient to cause overload, carcinogenic mechanisms unrelated to overload may operate, as indicated by the human epidemiologic studies and the data on human DNA adducts cited in the preceding subsection of this risk assessment. It is possible that overload provides the dominant route to lung cancer at high concentrations of fine particulate, while other mechanisms emerge as more relevant for humans under lower-level exposure conditions.

The NMA noted that, in 1998, the US EPA's Clean Air Scientific Advisory Committee (CASAC) concluded that there is "no evidence that the organic fraction of soot played a role in rat tumorigenesis at any exposure level, and considerable evidence that it did not." According to the NMA, this showed "* * * it is the rat data—not the hamster data—that lacks relevance for human health assessment."

It must first be noted that, in MSHA's view, all of the experimental animal data on health effects has relevance for human health risk assessment—whether the evidence is positive or negative and even if the positive results cannot be used to quantify human risk. The finding that different mammalian species exhibit important differences in response is itself relevant for human risk assessment. Second, the passage quoted from CASAC pertains to the route for tumorigenesis in rats and does not discuss whether this does or does not have relevance to humans exposed at high levels. The context for the CASAC deliberations was ambient exposure conditions in the general environment, rather than the higher occupational exposures that might impair clearance rates in susceptible individuals. Third, the comment assumes that only a finding of tumorigenesis attributable to the organic portion of dpm would elucidate mechanisms of potential health effects in humans. This ignores the possibility that a mechanism promoting tumors, but not involving the organics, could operate in both rats and humans. Induction of free oxygen radicals is an example. Fourth, although there may be little or no evidence that organics contributed to rat tumorigenesis in the studies performed, there is evidence that the organics contributed to increases in DNA adduct formation. This kind of activity could have tumorigenic consequences in humans who may be exposed for periods far longer than a rat's 3-year lifetime and who, as a consequence, have more time to accumulate genetic damage from a variety of sources.

Bond et al. (1990b) and Wolff et al. (1990) investigated adduct formation in rats exposed to various concentrations of either dpm or carbon black for 12 weeks. At the highest concentration (10 mg/m^3), DNA adduct levels in the lung were increased by exposure to either dpm or carbon black; but levels in the rats exposed to dpm were approximately 30 percent higher. Gallagher et al. (1994) exposed different groups of rats to diesel exhaust, carbon black, or TiO_2 and detected no significant difference in DNA adduct levels in the lung. However, the level of one type of adduct, thought to be derived from a PAH, was elevated in the dpm-exposed rats but not found in the control group or in rats exposed to carbon black or TiO_2.

These studies indicate that the inorganic carbon core of dpm is not the only possible agent of genetic damage in rats inhaling dpm. After a review of these and other studies involving DNA adducts, IPCS (1996) concluded that "Taken together, the studies of DNA adducts suggest that some organic chemicals in diesel exhaust can form DNA adducts in lung tissue and may play a role in the carcinogenic effects. * * *however, DNA adducts alone cannot explain the carcinogenicity of diesel exhaust, and other factors, such as chronic inflammation and cell proliferation, are also important."

Nauss et al. (1995, pp. 35–38) judged that the results observed in the carbon black and TiO_2 inhalation studies on rats do not preclude the possibility that the organic component of dpm has important genotoxic effects in humans. More generally, they also do not prove that lung overload is necessary for dpm-induced lung cancer. Because of the relatively high doses administered in some of the rat studies, it is conceivable that an overload phenomenon masked or even inhibited other potential cancer mechanisms. At dpm concentrations insufficient to impair clearance, carcinogenesis may have followed other routes, some possibly involving the organic compounds. At these lower concentrations, or among rats for which overload did not occur, tumor rates for dpm, carbon black, and TiO_2 may all have been too low to make statistically meaningful comparisons.

The NMA argued that "MSHA's contention that lung overload might "mask" tumor production by lower doses of dpm has been convincingly rebutted by recognized experts in the field," but provided no convincing explanation of why such masking could not occur. The NMA went on to say:

> The [CASAC] Panel viewed the premises that: a) a small tumor response at low exposure was overlooked due to statistical power; and b) soot-associated organic mutagens had a greater effect at low than at high exposure levels to be without foundation. In the absence of supporting evidence, the Panel did not view derivation of a quantitative estimate of human lung cancer risk from the low-level rat data as appropriate.

MSHA is not attempting to "derive a quantitative estimate of human lung cancer risk from the low-level rat data."

Dr. Peter Valberg, writing for the West Virginia Coal Association, provided the following argument for discounting the possibility of other carcinogenic mechanisms being masked by overload in the rat studies:

> Some regulatory agencies express concern about the mutagens bound to dpm. They hypothesize that, at high exposure levels, genotoxic mechanisms are overwhelmed (masked) by particle-overload conditions. However, they argue that at low-exposure concentrations, these organic compounds could represent a lung cancer risk. Tumor induction by mutagenic compounds would be characterized by a linear dose-response and should be detectable, given enough exposed rats. By using a "meta-analysis" type of approach and combining data from eight long-term rat inhalation studies, the lung tumor response can be analyzed. When all dpm-exposed rats from lifetime-exposure studies are combined, a threshold of response (noted above) occurs at approximately 600 $\mu g/m^3$ continuous lifetime exposure (approximately 2,500 $\mu g/m^3$ of occupational exposure). Additional statistical analysis of only those rats exposed to low concentrations of dpm confirms the absence of a tumorigenic effect below that threshold. Thus, even data in rats (the most sensitive laboratory species) do not support the hypothesis that particle-bound organics cause tumors.

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MSHA finds that this analysis relies on several questionable and unsupported assumptions and that, for the following reasons, the possibility remains that organic compounds in inhaled dpm may, under the right exposure conditions, contribute to its carcinogenic effects:

(1) The absence of evidence for an organic carbon effect is not equivalent to evidence of the absence of such an effect. Dr. Valberg did not demonstrate that enough rats were exposed, at levels insufficient to cause overload, to ensure detection of a 30- to 40-percent increase in the risk of lung cancer. Also, the normal lifespan of a rat whose lung is not overloaded with particles may, because of the lower concentrations involved, provide insufficient time for the organic compounds to express carcinogenic effects. Furthermore, low bioavailability of the organics could further reduce the likelihood that a carcinogenic sequence of mutations would occur within a rat's relatively short lifespan (i.e., at particle concentrations too low to cause overload).

(2) If the primary mechanism for carcinogenesis requires a reduced clearance rate (due to overload), then acute exposures are important, and it may not be appropriate to represent equivalent hazards by spreading an 8-hour occupational exposures over a 24-hour period. For example, eight hours at 600 $\mu g/m^3$ would have different implications for lung clearance than 24 hours at 200 $\mu g/m^3$.

(3) Granting that the rat data cannot be used to extrapolate risk for humans, these data should also not be used to rule out mechanisms of carcinogenesis that may operate in humans but not in rats. Clearance, for example, may operate differently in humans than in rats, and there may be a gradual rather than abrupt change in human overload conditions with increasing exposure. Also, at least some of the organic compounds in dpm may be more biologically available to the human lung than to that of the rat.

(4) For experimental purposes, laboratory rats are deliberately bred to be homogeneous. This is done, in part, to deliberately minimize differences in response between individuals. Therefore, individual differences in the threshold for lung overload would tend to be masked in experiments on laboratory rats. It is likely that human populations would exhibit, to a far greater extent than laboratory rats; a range of susceptibilities to lung overload. Also some humans, unlike the laboratory rats in these experiments, place additional burdens on their lung clearance by smoking.

One commenter (MARG) concluded that "[t]here is * * * no basis for extrapolating the rat results to human beings; the animal studies, taken together, do not justify MSHA's proposals."

MSHA is neither extrapolating the rat results to make quantitative risk estimates for humans nor using them, in isolation, as a justification for these regulations. MSHA does regard it as significant, however, that the evidence for an increased risk of lung cancer due to chronic dpm inhalation comes from both human and animal studies. MSHA agrees that the quantitative results observed for rats in existing studies should not be extrapolated to humans. Nevertheless, the fact that high dpm exposures for two or three years can induce lung cancer in rats enhances the epidemiologic evidence that much longer exposures to miners, at concentrations of the same order of magnitude, could also induce lung cancers.

3. Characterization of Risk

After reviewing the evidence of adverse health effects associated with exposure to dpm, MSHA evaluated that evidence to ascertain whether exposure levels currently existing in mines warrant regulatory action pursuant to the Mine Act. The criteria for this evaluation are established by the Mine Act and related court decisions. Section 101(a)(6)(A) provides that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

Based on court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that need to be addressed: (a) Whether health effects associated with dpm exposure constitute a "material impairment" to miner health or functional capacity; (b) whether exposed miners are at significant excess risk of incurring any of these material impairments; and (c) whether the rule will substantially reduce such risks.

Some commenters argued that the link between dpm exposure and material health impairments is questionable, and that MSHA should wait until additional scientific evidence becomes available before concluding that there are health risks due to such exposure warranting regulatory action. For example, MARG asserted that "[c]ontrary to the suggestions in the [proposed] preamble, a link between dpm exposure and serious illness has never been established by reliable scientific evidence."[63] MARG continued as follows:

> Precisely because the scientific evidence * * * is inconclusive at best, NIOSH and NCI are now conducting a * * * [study] to determine whether diesel exhaust is linked to illness, and if so, at what level of exposure. * * * MARG is also funding an independent parallel study.
>
> * * * Until data from the NIOSH/NCI study, and the parallel MARG study, are available, the answers to these important questions will not be known. Without credible answers to these and other questions, MSHA's regulatory proposals * * * are premature * * *."

For reasons explained below, MSHA does not agree that the collective weight of scientific evidence is "inconclusive at best." Furthermore, the criteria for evaluating the health effects evidence do not require scientific certainty. As noted by Justice Stevens in an important case on risk involving the Occupational Safety and Health Administration, the need to evaluate risk does not mean an agency is placed into a "mathematical straitjacket." [*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607, 100 S.Ct. 2844 (1980), hereinafter designated the "Benzene" case]. The Court recognized that regulation may be necessary even when scientific knowledge is not complete; and—

> so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data * * * risking error on the side of overprotection rather than underprotection. [Id. at 656].

[63] MARG supported this assertion by claiming that "[t]he EPA reports which MSHA references in its preamble were found 'not scientifically adequate for making regulatory decisions concerning the use of diesel-powered engines' by EPA's Clean Air Scientific Advisory Committee. [reference to CASAC (1998)]" Contrary to MARG's claim, CASAC (1998) did not review any of the 20 EPA documents MSHA cited in the proposed preamble. Instead, the document reviewed by CASAC (1998) was an unpublished draft of a health risk assessment on diesel exhaust (EPA, 1998), to which MSHA made no reference. Since MSHA has not relied in any way on this 1998 draft document, its "scientific adequacy" is entirely irrelevant to this rulemaking.

In response to the 1998 CASAC review, EPA modified its draft risk assessment (EPA, 1999), and CASAC subsequently reviewed the 1999 draft (CASAC, 2000). CASAC found the revised draft much improved over the previous version and agreed that even environmental exposure to diesel emissions is likely to increase the risk of lung cancer (CASAC, 2000). CASAC endorsed this conclusion for dpm concentrations in ambient air, which are lower, by a factor of more than 100, than the levels observed in some mines (see Fig. III–4).

Moreover, the statutory criteria for evaluating health effects do not require MSHA to wait for incontrovertible evidence. In fact, MSHA is required to set standards based on the "best *available* evidence" (emphasis added).

a. Material Impairments to Miners' Health or Functional Capacity

MSHA recognizes that there is considerable disagreement, among knowledgeable parties, in the interpretation of the overall body of scientific research and medical evidence related to human health effects of dpm exposures. One commenter for example, interpreted the collective evidence as follows:

> * * * the best available scientific evidence shows that diesel particulate exposure is associated with serious material impairment of health. * * * there is *clear* evidence that diesel particulate exposure can cause lung cancer (as well as other serious non-malignant diseases) among workers in a variety of occupational settings. While no body of scientific evidence is ever completely definitive, the evidence regarding diesel particulate is particularly strong * * *. [Michael Silverstein, MD, State of Washington Dept. of Labor and Industries]

Other commenters, including several national and regional organizations representing the mining industry, sharply disagreed with this interpretation. For example, one commenter stated that "[i]n our opinion, the best available evidence does not provide substantial or credible support for the proposal." Several commenters argued that evidence from within the mining industry itself was especially weak.[64] A representative of one mining company that had been using diesel equipment for many years commented: "[t]o date, the medical history of our employees does not indicate a single case of lung cancer, chronic illness, or material impairment of health due to exposure to diesel exhaust. This appears to be the established norm throughout the U.S. coal mining industry." This commenter, however, submitted no evidence comparing the rate of lung cancer or other material impairment among exposed miners to the rate for unexposed miners (or comparable workers) of similar age, smoking habits, and geographic location.

With due consideration to all oral and written testimony, comments, and evidence submitted during the rulemaking proceedings, MSHA conducted a review of the scientific literature cited in Part III.2. Based on the combinetl weight of the best available evidence, MSHA has concluded that underground miners exposed to current levels of dpm are at excess risk of incurring the following three kinds of material impairment: (i) Sensory irritations and respiratory symptoms (including allergenic responses); (ii) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (iii) lung cancer. The next three subsections will respectively explain MSHA's basis for linking these effects with dpm exposure.

i. Sensory Irritations and Respiratory Symptoms (including allergenic responses). Kahn et al. (1988), Battigelli (1965), Gamble et al. (1987a), and Rudell et al. (1996) identified a number of debilitating acute responses to diesel exhaust exposure. These responses included irritation of the eyes, nose and throat; headaches, nausea, and vomiting; chest tightness and wheeze. These symptoms were also reported by miners at the 1995 workshops and the public hearings held on these proceedings in 1998. In addition, Ulfvarson et al. (1987, 1990) reported evidence of reduced lung function in workers exposed to dpm for a single shift. The latter study supports attributing a portion of the reduction to the dpm in diesel exhaust. After reviewing this body of literature, Morgan et al. (1997) concluded "it is apparent that exposure to diesel fumes in sufficient concentrations may lead to [transient] eye and nasal irritation" and "a transient decline of ventilatory capacity has been noted following such exposures."

One commenter (Nevada Mining Association) acknowledged there was evidence that miners exposed to diesel exhaust experienced, as a possible consequence of their exposure, "acute, short-term or 'transitory' irritation, such as watering eyes, in susceptible individuals * * *"; but asserted that "[a]ddressing any such transient irritant effects does not require the Agency's sweeping, stringent PEL approach [in M/NM mines]."

Although there is evidence that such symptoms subside within one to three days of no occupational exposure, a miner who must be exposed to dpm day after day in order to earn a living may not have time to recover from such effects. Hence, the opportunity for a so-called "reversible" health effect to reverse itself may not be present for many miners. Furthermore, effects such as stinging, itching and burning of the eyes, tearing, wheezing, and other types of sensory irritation can cause severe discomfort and can, in some cases, be seriously disabling. Also, workers experiencing sufficiently severe sensory irritations can be incapacitated or distracted as a result of their symptoms, thereby endangering themselves and other workers and increasing the risk of accidents. For these reasons, MSHA considers such irritations to constitute "material impairments" of health or functional capacity within the meaning of the Act, regardless of whether or not they are reversible. Further discussion of why MSHA believes reversible effects can constitute material impairments can be found above, in Subsection 2.a.2 of this risk assessment.

The best available evidence also points to more severe respiratory consequences of exposure to dpm. Significant statistical associations have been detected between acute environmental exposures to fine particulates and debilitating respiratory impairments in adults, as measured by lost work days, hospital admissions, and emergency room visits (see Table III–3). Short-term exposures to fine particulates, or to particulate air pollution in general, have been associated with significant increases in the risk of hospitalization for both pneumonia and COPD (EPA, 1996).

The risk of severe respiratory effects is exemplified by specific cases of persistent asthma linked to diesel exposure (Wade and Newman, 1993). Glenn et al. (1983) summarized results of NIOSH health evaluations among coal, salt, trona, and potash miners and reported that "all four of the chronic effects analyses revealed an excess of cough and phlegm among the diesel exposed group." There is persuasive evidence for a causal connection between dpm exposure and increased manifestations of allergic asthma and other allergic respiratory diseases, coming from recent experiments on animals and human cells (Takenaka et al., 1995; Lovik et al., 1997; Takano et al., 1997; Ichinose et al., 1997a). Based on controlled experiments on healthy human volunteers, Diaz-Sanchez et al. (1994, 1996, 1997), Peterson and Saxon (1996), and Salvi et al. (1999) reported significant increases in various markers of allergic response resulting from exposure to dpm.

Peterson and Saxon (1996) reviewed the scientific literature on the relationship between PAHs and other products of fossil fuel combustion found

[64] At the public hearing on May 11, 1999, a commenter representing MARG suggested there is evidence that miners exposed to dpm experience adverse health effects at lower-than-normal rates. According to this commenter, "[s]ignificantly, the human studies conducted in the mining industry reveal a negative propensity for diesel particulate matter-related health effects." These studies drew comparisons against an external reference population and failed to adjust for the "healthy worker effect." (See MSHA's discussion of this effect, especially as manifested in the study by Christie et al., 1995, in Subsection 2.c.i(2)(a) of this risk assessment.)

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in dpm and trends in allergic respiratory disease. They found that the prevalences of allergic rhinitis ("hay fever") and allergic asthma have significantly increased with the historical increase in fossil fuel combustion and that laboratory data support the hypothesis that certain organic compounds found in dpm "* * * are an important factor in the long-term increases in the prevalence in allergic airway disease." Similarly, much of the research on allergenic responses to dpm was reviewed by Diaz-Sanchez (1997), who concluded that dpm pollution in the ambient environment "may play an important role in the increased incidence of allergic airway disease." Morgan et al. (1997) noted that dpm "* * * may be partly responsible for some of the exacerbations of asthma" and that "* * * it would be wise to err on the side of caution." Such health outcomes are clearly "material impairments" of health or functional capacity within the meaning of the Act.

ii. Premature Death from Cardiovascular, Cardiopulmonary, or Respiratory Causes. The evidence from air pollution studies identifies death, largely from cardiovascular, cardiopulmonary, or respiratory causes, as an endpoint significantly associated with acute exposures to fine particulates ($PM_{2.5}$—see Table III–3). The weight of epidemiologic evidence indicates that short-term ambient exposure to particulate air pollution contributes to an increased risk of daily mortality (EPA, 1996). Time-series analyses strongly suggest a positive effect on daily mortality across the entire range of ambient particulate pollution levels. Relative risk estimates for daily mortality in relation to daily ambient particulate concentration are consistently positive and statistically significant across a variety of statistical modeling approaches and methods of adjustment for effects of relevant covariates such as season, weather, and co-pollutants. The mortality effects of acute exposures appear to be primarily attributable to combustion-related particles in $PM_{2.5}$ (such as dpm) and are especially pronounced for death due to pneumonia, COPD, and IHD (Schwartz et al., 1996). After thoroughly reviewing this body of evidence, the U.S. Environmental Protection Agency (EPA) concluded:

> It is extremely unlikely that study designs not yet employed, covariates not yet identified, or statistical techniques not yet developed could wholly negate the large and consistent body of epidemiologic evidence * * *. [EPA, 1996]

There is also substantial evidence of a relationship between chronic exposure to fine particulates ($PM_{2.5}$) and an excess (age-adjusted) risk of mortality, especially from cardiopulmonary diseases. The Six Cities and ACS studies of ambient air particulates both found a significant association between chronic exposure to fine particles and excess mortality. In some of the areas studied, $PM_{2.5}$ is composed primarily of dpm; and significant mortality and morbidity effects were also noted in those areas. In both studies, after adjusting for smoking habits, a statistically significant excess risk of cardiopulmonary mortality was found in the city with the highest average concentration of $PM_{2.5}$ as compared to the city with the lowest. Both studies also found excess deaths due to lung cancer in the cities with the higher average level of $PM_{2.5}$, but these results were not statistically significant (EPA, 1996). The EPA concluded that—

> * * * the chronic exposure studies, taken together, suggest there may be increases in mortality in disease categories that are consistent with long-term exposure to airborne particles and that at least some fraction of these deaths reflect cumulative PM impacts above and beyond those exerted by acute exposure events * * * There tends to be an increasing correlation of long-term mortality with PM indicators as they become more reflective of fine particle levels. [EPA, 1996]

Whether associated with acute or chronic exposures, the excess risk of death that has been linked to pollution of the air with fine particles like dpm is clearly a "material impairment" of health or functional capacity within the meaning of the Act.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that "MSHA appears to regard all particulates smaller than 2.5 $\mu g/m^3$ as equivalent." He argued that "dpm and other ultra-fine particulates represents only a small proportion of ambient particulate samples," that "chronic cough, chronic phlegm, and chronic wheezing reflect mainly tracheobronchial effects," and that tracheobronchial deposition is highly dependent on particle size distribution.

No part of Dr. Borak's argument is directly relevant to MSHA's identification of the risk of death from cardiovascular, cardiopulmonary, or respiratory causes faced by miners exposed to high concentrations of dpm. First, MSHA does not regard all fine particulates as equivalent. However, dpm is a major constituent of $PM_{2.5}$ in many of the locations where increased mortality has been linked to $PM_{2.5}$ levels. MSHA regards dpm as presenting a risk by virtue of its comprising a type of $PM_{2.5}$. Second, the studies MSHA used to support the existence of this risk specifically implicate fine particles (i.e., $PM_{2.5}$), so the percentage of dpm in "total suspended particulate emissions" (which includes particles even larger than PM_{10}) is not relevant. Third, the chronic respiratory symptoms listed by Dr. Borak are not among the material impairments that MSHA has identified from the $PM_{2.5}$ studies. Much of the evidence pertaining to excess mortality is based on acute—not chronic—ambient exposures of relatively high intensity. In the preceding subsection of this risk assessment, MSHA identified various respiratory symptoms, including allergenic responses, but the evidence for these comes largely from studies on diesel emissions.

As discussed in Section 2.a.iii of this risk assessment, many miners smoke tobacco, and miners experience COPD at a significantly higher rate than the general population. This places many miners in two of the groups that EPA (1996) identified as being at greatest risk of premature mortality due to particulate exposures.

iii. Lung Cancer. It is clear that lung cancer constitutes a "material impairment" of health or functional capacity within the meaning of the Act. Therefore, the issue to be addressed in this section is whether there is sufficient evidence (i.e., enough to warrant regulatory action) that occupational exposure to dpm causes the risk of lung cancer to increase.

In the proposed risk assessment, MSHA noted that various national and international institutions and governmental agencies had already classified diesel exhaust or particulate as a probable human carcinogen. Considerable weight was also placed on two comprehensive meta-analyses of the epidemiologic literature, which had both found that the combined evidence supported a causal link. MSHA also acknowledged, however, that some reviewers of the evidence disagreed with MSHA's conclusion that, collectively, it strongly supports a causal connection. As examples of the opposing viewpoint, MSHA cited Stöber and Abel (1996), Watson and Valberg (1996), Cox (1997), Morgan et al. (1997), and Silverman (1998). As stated in the proposed risk assessment, MSHA considered the opinions of these reviewers and agreed that no individual study was perfect: even the strongest of the studies had limitations when viewed in isolation. MSHA nevertheless concluded (in the proposal) that the best available epidemiologic studies, supported by experimental data showing toxicity, collectively provide strong evidence that chronic dpm exposure (at occupational levels) actually does increase the risk of lung cancer in humans.

Although miners and labor representatives generally agreed with MSHA's interpretation of the collective evidence, many commenters representing the mining industry strongly objected to MSHA's conclusion. Some of these commenters also expressed dissatisfaction with MSHA's treatment, in the proposed risk assessment, of opposing interpretations of the collective evidence—saying that MSHA had dismissed these opposing views without sufficient explanation. Some commenters also submitted new critiques of the existing evidence and of the meta-analyses on which MSHA had relied. These commenters also emphasized the importance of two reports (CASAC, 1998 and HEI, 1999) that both became available after MSHA completed its proposed risk assessment.

MSHA has re-evaluated the scientific evidence relating lung cancer to diesel emissions in light of the comments, suggestions, and detailed critiques submitted during these proceedings. Although MSHA has not changed its conclusion that occupational dpm exposure increases the risk of lung cancer, MSHA believes that the public comments were extremely helpful in identifying areas of MSHA's discussion of lung cancer needing clarification, amplification, and/or additional supportive evidence.

Accordingly MSHA has re-organized this section of the risk assessment into five subsections. The first of these provides MSHA's summary of the collective epidemiologic evidence. Second is a description of results and conclusions from the only two existing peer-reviewed and published statistical meta-analyses of the epidemiologic studies: Bhatia et al. (1998) and Lipsett and Campleman (1999). The third subsection contains a discussion of potential systematic biases that might tend to shift all study results in the same direction. The fourth evaluates the overall weight of evidence for causality, considering not only the collective epidemiologic evidence but also the results of toxicity experiments. Within each of these first four subsections, MSHA will respond to the relevant issues and criticisms raised by commenters in these proceedings, as well as by other outside reviewers. The final subsection will describe general conclusions reached by other reviewers of this evidence, and present some responses by MSHA about opposing interpretations of the collective evidence.

(1) Summary of Collective Epidemiologic Evidence. As mentioned in Section III.2.c.i(2)(a) and listed in Tables III–4 and III–5, MSHA reviewed a total of 47 epidemiologic studies involving lung cancer and diesel exposure. Some degree of association between occupational dpm exposure and an excess rate of lung cancer was reported in 41 of these studies: 22 of the 27 cohort studies and 19 of the 20 case-control studies. Section III.2.c.1(2)(a) explains MSHA's criteria for evaluating these studies, summarizes those on which MSHA places greatest weight, and explains why MSHA places little weight on the six studies reporting no increased risk of lung cancer for exposed workers. It also contains summaries of the studies involving miners, addresses criticisms of individual studies by commenters and reviewers, and discusses studies that, according to some commenters, suggest that dpm exposure does not increase the risk of lung cancer.

Here, as in the earlier, proposed version of the risk assessment, MSHA was careful to note and consider limitations of the individual studies. Several commenters interpreted this as demonstrating a corresponding weakness in the overall body of epidemiologic evidence. For example, one commenter [Energy West] observed that "* * * by its own admission in the preamble * * *, most of the evidence in [the epidemiologic] studies is relatively weak" and argued that MSHA's conclusion was, therefore, unjustified:

It should first be noted that the three most recent epidemiologic studies became available too late for inclusion in the risk assessment as originally written. These three (Johnston et al., 1997; Säverin et al., 1999; Brüske-Hohlfeld, 1999) rank among the strongest eight studies available (see Section III.2.c.1(2)(a)) and do not have the same limitations identified in many of the other studies. Even so, MSHA recognizes that no single one of the existing epidemiologic studies, viewed in isolation, provides conclusive evidence of a causal connection between dpm exposure and an elevated risk of lung cancer in humans. Consistency and coherency of results, however, do provide such evidence. An appropriate analogy for the collective epidemiologic evidence is a braided steel cable, which is far stronger than any of the individual strands of wire making it up. Even the thinnest strands can contribute to the strength of the cable.

(a) Consistency of Epidemiologic Results

Although no epidemiologic study is flawless, studies of both cohort and case-control design have quite consistently shown that chronic exposure to diesel exhaust, in a variety of occupational circumstances, is associated with an increased risk of lung cancer. Furthermore, as explained earlier in this risk assessment, limitations such as small sample size, short latency, and (usually) exposure misclassification reduce the power of a study. These limitations make it more difficult to detect a relationship even when one exists. Therefore, the sheer number of studies showing a positive association readily distinguishes those studies criticized by Taubes (1995), where weak evidence is available from only a single study. With only rare exceptions, involving too few workers and/or observation periods too short to have a good chance of detecting excess cancer risk, the human studies have shown a greater risk of lung cancer among exposed workers than among comparable unexposed workers.

Moreover, the fact that 41 out of 47 studies showed an excess risk of lung cancer for exposed workers may itself be a significant result, even if the evidence in most of those 41 studies is relatively weak. Getting "heads" on a single flip of a coin, or two "heads" out of three flips, does not provide strong evidence that there is anything special about the coin. However, getting 41 "heads" in 47 flips would normally lead one to suspect that the coin was weighted in favor of heads. Similarly, results reported in the epidemiologic literature lead one to suspect that the underlying relationship between diesel exposure and an increased risk of lung cancer is indeed positive.

More formally, as MSHA pointed out in the earlier version of this risk assessment, the high proportion of positive studies is statistically significant according to the 2-tailed sign test. Under the "null hypothesis" that there is no systematic bias in one direction or the other, and assuming that the studies are independent, the probability of 41 or more out of 47 studies being either positive or negative is less than one per ten million. Therefore, the sign test rejects, at a very high confidence level, the null hypothesis that each study is equally likely to be positive or negative. This means that the collective results, showing increased risk for exposed workers, are statistically significant at a very high confidence level—regardless

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of the statistical significance of any individual study.

MSHA received no comments directly disputing its attribution of statistical significance to the collective epidemiologic evidence based the sign test. However, several commenters objected to the concept that a number of inconclusive studies can, when viewed collectively, provide stronger evidence than the studies considered in isolation. For example, the Engine Manufacturers Association (EMA) asserted that—

> [j]ust because a number of studies reach the same conclusion does not make the collective sum of those studies stronger or more conclusive, particularly where the associations are admittedly weak and scientific difficulties exist in each. [EMA]

Similarly, IMC Global stated that

> * * * IMC Global does not consider cancer studies with a relative risk of less than 2.0 as showing evidence of a casual relationship between dpm exposure and lung cancer. * * * Thus while MSHA states [in the proposed risk assessment; now updated to 41 out of 47] that 38 of 43 epidemiologic studies show some degree of association between occupational dpm exposures and lung cancer and considers that fact significant, IMC Global does not. [IMC Global]

Although MSHA agrees that even statistically significant consistency of epidemiologic results is not sufficient to establish causality, MSHA believes that consistency is an important part of establishing that a suspected association is causal.[65] Many of the commenters objecting to MSHA's emphasis on the collective evidence failed to distinguish the strength of evidence in each individual study from the strength of evidence in total.

Furthermore, weak evidence (from just one study) should not be confused with a weak effect. As Dr. James Weeks pointed out at the public hearing on Nov. 19, 1998, a 40-percent increase in lung cancer is a strong effect, even if it may be difficult to detect in an epidemiologic study.

Explicable differences, or heterogeneity, in the magnitudes of relative risk reported from different studies should not be confused with inconsistency of evidence. For example, as described by Silverman (1998), one of the available meta-analyses (Bhatia et al., 1998) "examined the primary sources of heterogeneity among studies and found that a main source of heterogeneity is the variation in diesel exhaust exposure across different occupational groups." Figures III–5 and III–6, taken from Cohen and Higgins (1995), respectively show relative risks reported for the two occupations on which the most studies are available: railroad workers and truck drivers.

Each of these two charts compares results from studies that adjusted for smoking to results from studies that did not make such an adjustment. For each study, the point plotted is the estimated relative risk or odds ratio, and the horizontal line surrounding it represents a 95-percent confidence interval. If the left endpoint of a confidence interval exceeds 1.0, then the corresponding result is statistically significant at a 95-percent confidence level.

The two charts show that the risk of lung cancer has consistently been elevated for exposed workers and that the results are not significantly different within each occupational category. Differences in the magnitude and statistical significance of results within occupation are not surprising, since the groups studied differed in size, average exposure intensity and duration, and the time allotted for latent effects.

[65] With respect to the IMC Global's blanket rejection of studies showing a relative risk less than 2.0, please see also the related discussions in Subsection 2.c.i(2)(a) above, under the heading of "Potential Confounders," and in Subsection 3.a.iii(3) below, entitled "Potential Systemic Biases."

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Figure III–5

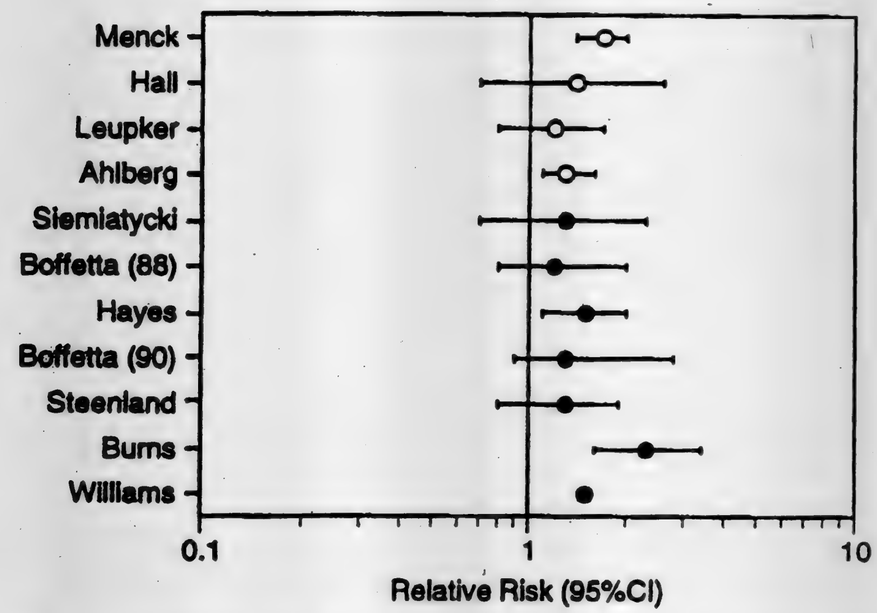


Figure . Lung cancer and exposure to diesel exhaust in truck drivers. ● = RR adjusted for cigarette smoking; O = RR not adjusted for cigarette smoking. For the study by Williams, CIs were not reported and could not be calculated. For the Steenland study, the data were gathered from union reports of long-haul truckers; for the Boffetta (1988) study, the data were self-reported by diesel truck drivers; and for the Siemiatycki study, they were self-reported by heavy-duty truck drivers (personal communication).

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Figure III–6

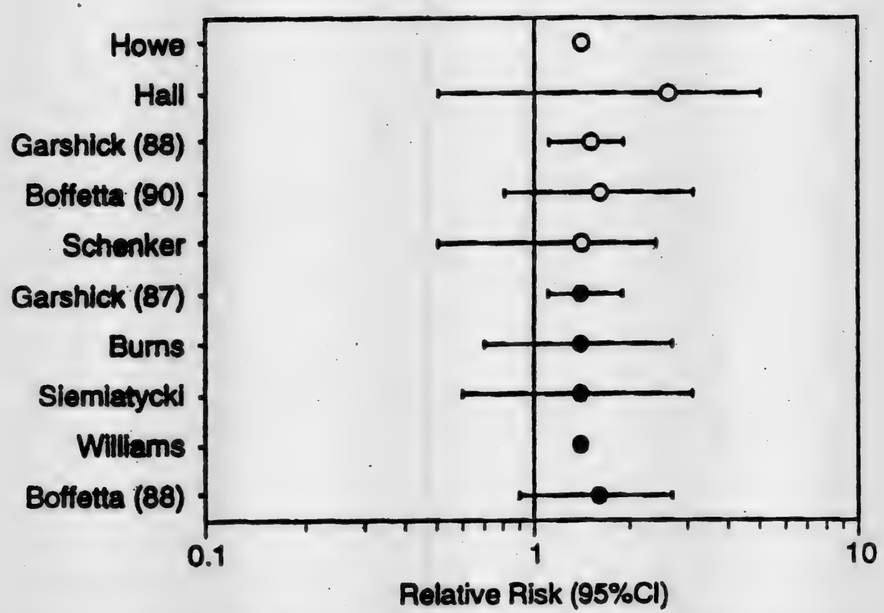


Figure . Lung cancer and exposure to diesel exhaust in railroad workers. ● = RR adjusted for cigarette smoking; ○ = RR not adjusted for cigarette smoking. For the two studies by Howe and Williams, CIs were not reported and could not be calculated.

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As documented in Subsection 2.c.i(2)(a) of this risk assessment, all of the studies showing negative associations were either based on relatively short observation or follow-up periods, lacked good information about dpm exposure, involved low duration or intensity of dpm exposure, or, because of inadequate sample size or latency allowance, lacked the power to detect effects of the magnitude found in the "positive" studies. Boffetta et al. (1988, p. 404) noted that, in addition, studies failing to show a statistically significant association—

> * * * often had low power to detect any association, had insufficient latency periods, or compared incidence or mortality rates among workers to national rates only, resulting in possible biases caused by the "healthy worker effect."

Some commenters noted that limitations such as insufficient duration of exposure, inadequate latency allowance, small worker populations, exposure misclassification, and comparison to external populations with no adjustment for a healthy worker effect may explain why not all of the studies showed a statistically significant association between dpm exposure and an increased prevalence of lung cancer. According to these commenters, if an epidemiologic study shows a statistically significant result, this often occurs in spite of methodological weaknesses rather than because of them. MSHA agrees that limitations such as those listed make it more difficult to obtain a statistically significant result when a real relationship exists.

(b) Best Available Epidemiologic Evidence

As explained above, it is statistically significant that 41 of the 47 available epidemiologic studies reported an elevated risk of lung cancer for workers exposed to dpm. MSHA finds it even more informative, however, to examine the collective results of the eight studies identified in Section III.2.c.i(2)(a) as providing the best currently available epidemiologic evidence. These studies, selected using the criteria described earlier, are: Boffetta et al. (1988), Boffetta et al. (1990), Brüske-Hohlfeld et al. (1999), Garshick et al. (1987), Garshick et al. (1988, 1991), Johnston et al. (1997), Steenland et al. (90, 92, 98), and Säverin *et al.*, (1999). All eight of these studies reported an increased risk of lung cancer for workers with the longest diesel exposures and for those most likely to have been exposed, compared to unexposed workers. Tables showing the results from each of these studies are provided in Section III.2.c.1(2)(a).

The sign test of statistical significance can also be applied to the collective results of these eight studies. If there were no underlying association between exposure to diesel exhaust and an increased risk of lung cancer, or anything else systematically favoring a positive result, then there should be equal probabilities (equal to one-half) that any one of these eight studies would turn out positive or negative. Therefore, under the null hypothesis that positive and negative results are equally likely, the probability that all eight studies would show either a positive or a negative association is $(0.5)^8 = 0.0039$, or 0.39 percent. This shows that the collective results of the eight studies comprising the best available epidemiologic evidence are statistically significant at a confidence level exceeding 99 percent (i.e., $100 - 2\times0.39$).

When the risk of disease or death increases in response to higher cumulative exposures, this is described by a "positive" exposure-response relationship. Like consistency of results, the existence of a positive exposure-response relationship is important in establishing that the exposures in question actually cause an increase in risk. Among the eight studies MSHA has identified as comprising the best available epidemiologic evidence, there are five that provide evidence of increasing lung cancer risk with increasing cumulative exposure: Boffetta, et al. (1990), Brüske-Hohlfeld et al. (1999), Johnston et al. (1997), Säverin et al. (1999), and Steenland et al. (1990, 1992, 1998). The results supporting such a relationship are provided in the table accompanying discussion of each of these studies in Section III.2.c.i(2)(a).

Although some have interpreted the results from the two studies by Garshick et al. as also providing evidence of a positive exposure-response relationship (*e.g.*, Cal–EPA, 1998), this interpretation is highly sensitive to the statistical models and techniques used to analyze the data (HEI, 1999; Crump 1999). Therefore, for purposes of this risk assessment, MSHA is not relying on Garshick et al. (1987) or Garshick et. al (1988, 1991) to demonstrate the existence of a positive exposure-response relationship. MSHA used the study for purposes of hazard identification only. The Garshick studies contributed to the weight of evidence favoring a causal interpretation, since they show statistically significant excesses in lung cancer risk for the exposed workers.

The relative importance of the five studies identified in demonstrating the existence of a positive exposure-response relationship varies with the quality of exposure assessment. Boffetta *et al.* (1990) and Brüske-Hohlfeld *et al.* (1999) were able to show such a relationship based on the estimated duration of occupational exposure for exposed workers, but quantitative measures of exposure intensity (*i.e.*, dpm concentration) were unavailable. Although duration of exposure is frequently used as a surrogate of cumulative exposure, it is clearly preferable, as many commenters pointed out, to base estimates of cumulative exposure and exposure-response analyses on quantitative measurements of exposure levels combined with detailed work histories. Positive exposure-response relationships based on such data were reported in all three studies: Johnston *et al.* (1997), Steenland *et al.* (1998), and Säverin *et al.* (1999).

(c) Studies With Quantitative or Semiquantitative Exposure Assessments

Several commenters stressed the fact that most of the available epidemiologic studies contained little or no quantitative information on diesel exposures and that those studies containing such information (such as Steenland *et al.*, 1998) generated it using questionable assumptions. Some commenters also faulted MSHA for insufficiently addressing this issue. For example, one commenter stated:

> * * * the Agency fails to highlight the lack of acceptable (or any) exposure measurements concurrent with the 43 epidemiology studies cited in the Proposed Rule. * * * the lack of concurrent exposure data is a significant deficiency of the epidemiology studies at issue and is a major factor that prevents application of those epidemiology results to risk assessment. [EMA]

MSHA agrees that the nature and quality of exposure information should be an important consideration in evaluating the strength of epidemiologic evidence. That is why MSHA included exposure assessment as one of the criteria used to evaluate and rank studies in Section 2.c.1(2)(a) of this risk assessment. Two of the most recent studies, both conducted specifically on miners, utilize concurrent, quantitative exposure data and are included among the eight in MSHA's selection of best available epidemiologic evidence (Johnston *et al.*, 1997 and Säverin *et al.*, 1999). As a practical matter, however, epidemiologic studies rarely have concurrent exposure measurements; and, therefore, the commenter's line of

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reasoning would exclude nearly all of the available studies from this risk assessment—including all six of the negative studies. Since Section 101(a)(6) of the Mine Act requires MSHA to consider the "best available evidence" (emphasis added), MSHA has not excluded studies with less-than-ideal exposure assessments, but, instead, has taken the quality of exposure assessment into account when evaluating them. This approach is also consistent with the recognition by the HEI Expert Panel on Diesel Emissions and Lung Cancer that "regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available" (HEI, 1999; p.39).

The degree of quantification, however, is not the only relevant consideration in evaluating studies with respect to exposure assessment. MSHA also considered the likely effects of potential exposure misclassification. As expressed by another commenter:

> * * * [S]tudies that * * * have poor measures of exposure to diesel exhaust have problems in classification and will have weaker results. In the absence of information that misclassification is systematic or differential, in which case study results would be biased towards either positive or no-effect level, it is reasonable to assume that misclassification is random or nondifferentiated. If so, * * * study results are biased towards a risk ratio of 1.0, a ratio showing no association between diesel exhaust exposure and the occurrence of lung cancer. [Dr. James Weeks, representing UMWA]

In her review of Bhatia *et al.* (1998), Silverman (1998) proposed that "[o]ne approach to assess the impact of misclassification would be to exclude studies without quantitative or semiquantitative exposure data." According to Dr. Silverman, this would leave only four studies among those considered by Dr. Bhatia: Garshick *et al.* (1988), Gustavsson *et al.* (1990), Steenland *et al.* (1992), and Emmelin *et al.* (1993).[66] All four of these studies showed higher rates of lung cancer for the workers estimated to have received the greatest cumulative exposure, as compared to workers who had accumulated little or no diesel exposure. Statistically significant results were reported in three of these four studies. Furthermore, the two more recent studies utilizing fully quantitative exposure assessments (Johnston *et al.*, 1997; Säverin *et al.*, 1999) were not evaluated or otherwise considered in the articles by Drs. Bhatia and Silverman. Like the other four studies, these too reported elevated rates of lung cancer for workers with the highest cumulative exposures. Specific results from all six of these studies are presented in Tables III–4 and III–5.

Once again, the sign test of statistical significance can be applied to the collective results of the four studies identified by Dr. Silverman plus the two more recent studies with quantitative exposure assessments. As before, under the null hypothesis of no underlying effect, the probability would equal one-half that any one of these six studies would turn out positive or negative. The probability that all six studies would show either a positive or a negative association would, under the null hypothesis, be $(0.5)^6 = 0.0156$, or 1.56 percent. This shows that the collective results of these six studies, showing an elevated risk of lung cancer for workers estimated to have the greatest cumulative exposure, are statistically significant at a confidence level exceeding 96 percent (i.e., $100 - 2 \times 1.56$).

As explained in the previous subsection, three studies showing evidence of increased risk with increasing exposure based on quantitative or semi-quantitative exposure assessments are included in MSHA's selection of best available epidemiologic evidence: Johnston et al. (1997), Steenland et al. (1998), and Säverin et al. (1999). Not only do these studies provide consistent evidence of elevated lung cancer risk for exposed workers, they also each provide evidence of a positive exposure-response relationship—thereby significantly strengthening the case for causality.

(d) Studies Involving Miners

Eleven studies involving miners are summarized and discussed in Section 2.c.i(2)(a) of this risk assessment. Commenters' observations and criticisms pertaining to the individual studies in this group are also addressed in that section. Three of these studies are among the eight in MSHA's selection of best available epidemiologic evidence: (Boffetta et al., 1988; Johnston et al., 1997; Säverin et al., 1999). All three of these studies provide evidence of an increased risk of lung cancer for exposed miners. Although MSHA places less weight on the remaining eight studies, seven of them show some evidence of an excess lung cancer risk among the miners involved. The remaining study (Christie et al., 1995) reported a greater all-cause SMR for the coal miners involved than for a comparable population of petroleum workers but did not compare the miners to a comparable group of workers with respect to lung cancer.

The NMA submitted a review of six of these studies by Dr. Peter Valberg, who concluded that "[t]hese articles do not implicate diesel exhaust, per se, as strongly associated with lung cancer in miners * * * The reviewed studies do not form a consistent and cohesive picture implicating diesel exhaust as a major risk factor for miners." Similarly, Dr. Jonathan Borak reviewed six of the studies on behalf of MARG and concluded:

> [T]he strongest conclusion that can be drawn from these six studies is that the miners in those studies had an increased risk of lung cancer. These studies cannot relate such increased [risk] to any particular industrial exposure, lifestyle or combination of such factors.

Apparently, neither Dr. Valberg nor Dr. Borak disputed MSHA's observation that the miners involved in the studies they reviewed exhibited, overall, an excess risk of lung cancer. It is possible that any excess risk found in epidemiologic studies may be due to extraneous unknown or uncontrolled risk factors (i.e., confounding variables). However, neither Drs. Valberg or Borak, nor the NMA or MARG, offered evidence, beyond a catalog of speculative possibilities, that the excess lung cancer risk for these miners was due to anything other than dpm exposure.

Nevertheless, MSHA agrees that the studies reviewed by Drs. Valberg and Borak do not, by themselves, conclusively implicate dpm exposure as the causal agent. Miners are frequently exposed to other occupational hazards associated with lung cancer, such as radon progeny, and it is not always possible to distinguish effects due to dpm exposure from effects due to these other occupational hazards. This is part of the reason why MSHA did not restrict its consideration of evidence to epidemiologic studies involving miners. What implicates exposure to diesel exhaust is the fact that diesel-exposed workers in a variety of different occupations, under a variety of different working conditions (including different types of mines), and in a variety of different geographical areas consistently exhibit an increased risk of lung cancer.

Drs. Valberg and Borak did not review the two studies that utilize quantitative dpm exposure assessments: Johnston et al. (1997) and Säverin et al. (1999). In recently received comments Dr. Valberg, writing for the NMA brought up four issues on the Säverin et al. 1999. These issues were potential exposure misclassification, potential flaws in the sampling method, potential smoker misclassification, and insufficient latency. Two of these issues have already been extensively discussed in section 2.c.i.2.a.ii and therefore will not be repeated here. Dr. Valberg suggested that the potential flaw in the sampling method would tend to over-estimate exposure and that there was insufficient latency. If, in fact, both of these issues are relevant, they would act to UNDERESTIMATE the lung cancer risk in this cohort instead of OVERESTIMATE it. MSHA regards these, along with Boffetta et al. (1988), Burns and Swanson (1991),[67] and Lerchen et al. (1987) to be the most informative of the available studies involving miners. Results on miners from these five studies are briefly summarized in the following table, with additional details provided in Section 2.c.1(2)(a) and Tables III–4 and III–5 of this risk assessment. The cumulative exposures at which relative risks from the Johnston and Säverin studies are presented are equivalent, assuming that TC constitutes 80 percent of total dpm. The cumulative dpm exposure of 6.1 mg-yr/m^3 is the multiplicative product of exposure duration and dpm concentration for the most highly exposed workers in each of these two studies.

[66] Emmelin *et al.* (1993) was considered but excluded from the meta-analysis by Bhatia *et al.* (1998) for reasons explained by the authors.

[67] Listed in Table III–5 under Swanson et al., 1993.

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Results from best available studies involving miners.

Study	Mine Type	Exposure Assessment	Smoking Adjustm't	Result
Boffetta et al. (1988)	various	Occupational history	yes	RR = 2.67 for miners, compared to workers never employed in diesel -exposed occupations.†
Burns and Swanson (1991)	unknown	Occupational history	yes	OR = 5.03 for mining machinery operators.†
Johnston et al. (1997)	UG coal	Occupational history & indirect dpm measurements	yes	For cumulative dpm exposure = 6.12 mg-yr/m³: RR = 5.5 using mine-adjusted statistical model; RR= 11.0 using mine-unadjusted statistical model.
Lerchen et al. (1987)	various	Occupational history	yes	OR = 2.1 for underground non-uranium mining.
Säverin et al. (1999)	UG potash	Occupational history & TC measurements	smoking uncorrelated with TC within cohort	RR = 2.17 for most highly exposed group, compared to least exposed group. For cumulative TC exposure = 4.9 mg-yr/m³: RR = 1.16 to 2.70 depending on statistical model.

†Statistically significant at a 95-percent confidence level.

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Although MSHA places less weight on the studies by Burns and Swanson and by Lerchen than on the other three, it is significant that the five best available studies involving miners all support an increased risk of lung cancer attributable to dpm exposure.

(2) Meta-Analyses

MSHA recognizes that simply tabulating epidemiologic studies as positive or negative can sometimes be misleading. There are generally a variety of outcomes that could render a study positive or negative, some studies contain different analyses of related data sets, some studies involve multiple comparisons of various subgroups, and the studies differ widely in the reliability of their results. Therefore, MSHA is not limiting its assessment of the epidemiologic evidence to such a tabulation or relying only on the sign test described above. MSHA has also considered the results of two statistical meta-analyses covering most of the available studies (Lipsett and Campleman, 1999; Bhatia *et al.*, 1998). These meta-analyses weighted and pooled independent results from those studies meeting certain inclusion requirements to form overall estimates of relative risk for exposed workers based on the combined body of data. In addition to forming pooled estimates of the effect of diesel exposure, both meta-analyses analyzed sources of heterogeneity in the individual results and investigated but rejected publication bias as an explanation for the generally positive results reported. Both meta-analyses derived a statistically significant increase of 30 to 40 percent in the risk of lung cancer, attributable to occupational dpm exposure.

Lipsett and Campleman (1999) systematically analyzed and combined results from most of the studies summarized in Tables III–4 and III–5. Forty-seven studies published between 1957 and 1995 were identified for initial consideration. Some studies were excluded from the pooled analysis because they did not allow for a period of at least 10 years for the development of clinically detectable lung cancer. Others were excluded because of bias resulting from incomplete ascertainment of lung cancer cases in cohort studies or because they examined the same cohort population as another study. One study was excluded because standard errors could not be calculated from the data presented. The remaining 30 studies, contributing a total of 39 separate estimates of exposure effect (for distinct occupational groups within studies), were analyzed using a random-effects analysis of variance (ANOVA) model.

Potential effects of publication bias (*i.e.*, the likelihood that papers with positive results may be more likely to be published than those with negative results) were investigated by plotting the logarithm of relative risk estimated from each study against its estimated precision, as expressed by the inverse of its standard error. According to the authors, the resulting "funnel plot" was generally consistent with the absence of significant publication bias, although there were relatively few small-scale, statistically insignificant studies. The investigators performed a further check of potential publication bias by comparing results of the included studies with the only relevant unpublished report that became available to them during the course of their analysis. Smoking-adjusted relative risks for several diesel-exposed occupations in the unpublished study were, according to the investigators, consistent with those found in the studies included in the meta-analysis.

Each of the 39 separate estimates of exposure effect was weighted by a factor proportional to its estimated precision. Sources of heterogeneity in results were investigated by subset analysis—using categorical variables to characterize each study's design, target population (general or industry-specific), occupational group, source of control or reference population, latency, duration of exposure, method of ascertaining occupation, location (North America or Europe), covariate adjustments (age, smoking, and/or asbestos exposure), and absence or presence of a clear healthy worker effect (as manifested by lower than expected all-cause mortality in the occupational population under study).

Sensitivity analyses were conducted to evaluate the sensitivity of results to inclusion criteria and to various assumptions used in the analysis. This included (1) substitution of excluded "redundant" studies of the same cohort population for the included studies and (2) exclusion of studies involving questionable exposure to dpm. An influence analysis was also conducted to examine the effect of dropping one study at a time, to determine if any individual study had a disproportionate effect on results of the ANOVA.

The pooled relative risk from all 39 exposure effects (estimated from 30 studies) was RR = 1.33, with a 95-percent confidence interval (CI) extending from 1.21 to 1.46. For the subgroup of 13 smoking-adjusted exposure effects (nine studies) from populations "most likely to have had substantial exposure" to dpm, the pooled effect was RR = 1.47, with a CI from 1.29 to 1.67. Based on the all of the various analyses they conducted, the authors concluded:

> Although substantial heterogeneity existed in the initial pooled analysis, stratification on several factors substantially reduced heterogeneity, producing subsets of studies with increased relative risk estimates that persisted through various influence and sensitivity analyses. * * *
>
> In studies that adjusted for confounding by cigarette smoking, not only did the positive association between diesel exhaust exposure and lung cancer persist but the pooled risk estimate showed a modest increase, with little evidence of heterogeneity.
>
> * * * [T]his meta-analysis provides quantitative evidence consistent with several prior reviews, which have concluded that the epidemiologic evidence supports a causal relationship between occupational exposure to diesel exhaust and lung cancer. [Lipsett and Campleman, 1999]

The other meta-analysis was conducted by Bhatia *et al.* (1998) on epidemiologic studies published in peer-reviewed journals between 1957 and 1993. In this analysis, studies were excluded if actual work with diesel equipment "could not be confirmed or reliably inferred" or if an inadequate latency period was allowed for cancer to develop, as indicated by less than 10 years from time of first exposure to end of follow-up. Studies of miners were also excluded, because of potential exposure to radon and silica. Likewise, studies were excluded if they exhibited selection bias or examined the same cohort population as a study published later. A total of 29 independent results on exposure effects from 23 published studies were identified as meeting the inclusion criteria.

To address potential publication bias, the investigators identified several unpublished studies on truck drivers and noted that elevated risks for exposed workers observed in these studies were similar to those in the published studies utilized. Based on this and a "funnel plot" for the included studies, the authors concluded that there was no indication of publication bias.

After assigning each of the 29 separate estimates of exposure effect a weight proportional to its estimated precision, Bhatia *et al.* (1998) used a fixed-effects ANOVA model to calculate pooled relative risks based on the following groupings: all 29 results; all case-control studies; all cohort studies; cohort studies using internal reference populations; cohort studies making external comparisons; studies adjusted for smoking; studies not adjusted for smoking; and studies grouped by occupation (railroad workers,

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equipment operators, truck drivers, and bus workers). Elevated risks of lung cancer were shown for exposed workers overall and within every individual group of studies analyzed. A positive duration-response relationship was observed in those studies presenting results according to employment duration. The weighted, pooled estimates of relative risk were identical for case-control and cohort studies and nearly identical for studies with or without smoking adjustments.

The pooled relative risk from all 29 exposure effects (estimated from 23 studies) was RR = 1.33, with a 95-percent confidence interval (CI), adjusted for heterogeneity, extending from 1.24 to 1.44. For just the smoking-adjusted studies, it was 1.35 (CI: 1.20 to 1.52); and for cohort studies making internal comparisons, it was 1.43 (CI: 1.29 to 1.58). Based on their evaluation of the all the analyses on various subgroups, Bhatia *et al.* (1998) concluded that the elevated risk of lung cancer observed among exposed workers was unlikely to be due to chance, that confounding from smoking was unlikely to explain all of the excess risk, and that "this meta-analysis supports a causal association between increased risks for lung cancer and exposure to diesel exhaust."

The pooled relative risks estimated in both meta-analyses equal 1.33 and exceed 1.4 for studies making internal comparisons, or comparisons to similar groups of workers. Both meta-analyses found these results to be statistically significant, meaning that they cannot be explained merely by random or unexplained variability in the risk of lung cancer that occurs among both exposed and unexposed workers. Although both meta-analyses relied, by necessity, on an overlapping selection of studies, the inclusion criteria were different and some studies included in one meta-analysis were excluded from the other. They used different statistical models for deriving a pooled estimate of relative risk, as well as different means of analyzing heterogeneity of effects. Nevertheless, they derived the same estimate of the overall exposure effect and found similar sources of heterogeneity in the results from individual studies.[68] One commenter observed that—

Lung cancer relative risks for occupational "control groups" vary over a range from 0.4 to 2.7 * * *. Therefore, the level of relative risks being reported in the dpm epidemiology fall within this level of natural variation. [IMC Global]

This argument is refuted by the statistical significance of the elevation in risk detected in both meta-analyses in combination with the analyses accounting for heterogeneity of exposure effects.

The EMA objected that MSHA's focus on these two meta-analyses "presents an incomplete picture because the counter-arguments of Silverman (1998) were not discussed in the same detail." IMC global also faulted MSHA for dismissing Dr. Silverman's views without adequate explanation.

In her review,[69] Dr. Silverman characterized Bhatia *et al.* (1998) as a "careful meta-analysis" and acknowledged that it "add[s] to the credibility that diesel exhaust is carcinogenic * * *." She also explicitly endorsed several of its most important conclusions. For example, Dr. Silverman stated that "[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer." She suggested, however, that Bhatia *et al.* (1998) "ultimately do not resolve the question of causality." (Silverman, 1998)

Dr. Silverman imposed an extremely high standard for what is needed to ultimately resolve the question of causality. The precise question she posed, along with her answer, was as follows:

Has science proven causality *beyond any reasonable doubt?* Probably not. [Silverman, 1998, emphasis added.]

Neither the Mine Act nor applicable case law requires MSHA to prove causality "beyond any reasonable doubt." The burden of proof that Dr. Silverman would require to close the case and terminate research is not the same burden of proof that the Mine Act requires to warrant protection of miners subjected to far higher levels of a probable carcinogen than any other occupational group. In this risk assessment, MSHA is evaluating the collective weight of the best available evidence—not seeking proof "beyond any reasonable doubt."[70]

The EMA objected to MSHA's reliance on the two meta-analyses because of "* * * serious deficiencies in each" but did not, in MSHA's opinion, identify any such deficiencies. The EMA pointed out that "most of the original studies in each were the same, and the few that were not common to each were not of significance to the outcome of either meta-analysis." MSHA does not regard this as a deficiency. Since the object of both meta-analyses was to analyze the available epidemiologic evidence linking dpm exposure with lung cancer, using defensible inclusion criteria, it is quite understandable that they would rely on overlapping information. The principal differences were in the types and methods of statistical analysis used, rather than in the data subjected to analysis; and MSHA considers it informative that different approaches yielded very similar results and conclusions. It is noteworthy, moreover, that both of the meta-analyses explicitly addressed the EMA's concern by performing analyses on various different sub-groupings of the available studies. The sensitivity of results to the inclusion criteria was also explicitly investigated and considered. MSHA believes that the conclusions of these meta-analyses did not depend on unreasonable inclusion or exclusion criteria.

The EMA also argued that—

[a] meta-analysis cannot compensate for basic deficiencies in the studies used to create the meta-analysis, and this fact is not clearly stated by MSHA. Instead, MSHA follows the tack of the meta-analysis authors, who claim that the meta-analysis somehow overcomes deficiencies of the individual studies selected and presents a stronger case. This is simply not true. [EMA]

MSHA agrees that a meta-analysis cannot correct for all deficiencies that may be present in individual studies. It can, however, correct for certain types of deficiencies. For example, individual studies may lack statistical power because of small study populations. By pooling results from several such studies, a meta-analysis may achieve a level of statistical significance not attainable by the individual studies. Furthermore, both of the meta-analyses used well-defined inclusion criteria to screen out those studies with the most severe deficiencies. In addition, they both found that it was the more rigorous and technically more valid studies that reported the strongest associations between excess lung cancer and dpm exposure. They also performed separate analyses that ruled out inflationary effects of such "deficiencies" as lack of a smoking adjustment. For example, Lipsett and Campleman (1999) reported a pooled RR = 1.43 for 20 smoking-adjusted results, as compared to a pooled RR = 1.25 for 19 results with no smoking adjustment.

IMC Global and MARG submitted five specific criticisms of the meta-analyses, to which MSHA will respond in turn.

(1) Publication Bias

* * * both studies * * * rely only on published studies. * * * the authors rely on statistical analysis in an attempt to uncover possible publication bias. * * * the only safeguard to protect against possible publication bias is to seek out unpublished results * * *. [IMC Global]

Both meta-analyses compared the results of published and unpublished studies and found them to be similar. Bhatia *et al.* (1998) found several unpublished studies of lung cancer among truck drivers that "* * * were not included in our analysis; however the risk ratios of these studies are similar to the [sic] those in published studies among truck drivers." (Bhatia *et al.*, p. 90) Lipsett and Campleman (1999) checked "[s]moking-adjusted relative risks for several diesel-exposed occupations" in an unpublished report on U.S. veterans and found them "* * * consistent with those reported here." They remarked that "although publication bias cannot be completely ruled out, it is an unlikely explanation for our findings." (Lipsett and Campleman, p. 1015) In addition to comparing results directly against unpublished studies, both meta-analyses used the statistical method of "funnel plots" as an indirect means of checking for the existence of significant publication bias. It should also be noted that MSHA did not exclude unpublished studies from this risk assessment.

(2) Selection Bias

* * * [the] meta-analyses have to provide a much more convincing rationale as to why all miners were excluded even when the confounders that are mentioned are not likely or important, for example in studies conducted in potash and salt mines. * * * IMC Global sees no reason why the older studies of potash workers [Waxweiler *et al.*, 1973] and more recent studies on New South Wales coal miners [Christie *et al.*, 1995] should not be included * * *. [IMC Global]

Studies were selectively included or excluded, without good or sufficient explanation. [MARG]

Contrary to the commenters' characterization, both meta-analyses listed each study excluded from the analysis of pooled relative risk and gave a good reason for its exclusion. For example, both meta-analyses excluded studies that failed to allow for a minimum 10-year latency period for lung cancer to develop after first exposure. With respect to the exclusion of all studies on miners, Bhatia *et al.* (1998) pointed out that "[s]ince studies of miners often indicate higher relative risks for lung cancer than those considered in this meta-analysis, this was a conservative exclusion." Even if studies on miners had been considered, Waxweiler *et al.* (1973) and Christie *et al.* (1995) would have been excluded from both meta-analyses because of their failure to meet the 10-year minimum latency requirement.

(3) Lack of Actual Exposure Data

* * * [N]ondifferential exposure or disease misclassification can sometimes produce bias away from the null * * * Thus, tests for heterogeneity performed in both these meta-analyses won't detect or correct this problem. [IMC Global]

Lipsett and Campleman acknowledged that "[e]xposure misclassification is a problem common to all studies of cancer and diesel emissions. In no case were there direct measurements of historical diesel exhaust exposures of the subjects." However, as Dr. Silverman pointed out in her review, "* * * this bias is most likely to be nondifferential, and the effect would probably have been to bias point estimates toward the null value. Thus the summary RR of 1.33 may be an underestimate of the true lung cancer effect associated with diesel exposure." (Silverman, 1998)

(4) Smoking as a Confounder

* * * The use of data manipulation and modeling adjustments in both these meta-analyses cannot rectify the flaws in the initial studies. [IMC Global]

* * * misclassification of this exposure [cigarette smoking] could result in residual confounding of individual studies and, consequently, meta-analyses, of those studies. [MARG]

Contrary to the commenter's suggestion, neither of the meta-analyses made any attempt to manipulate or adjust the data in order to rectify what the commenter regards as "flaws" in the way smoking or other potential confounders were treated in the initial studies. Both meta-analyses, however, compared the pooled RR for studies with a smoking adjustment to the pooled RR for studies without any such adjustment. Both meta-analysis calculated a pooled RR for the smoking-adjusted studies greater than or equal to that for the unadjusted studies. In addition, Bhatia *et al.* (1998) analyzed the impact of the smoking adjustment for the subgroup of studies reporting results both with and without such an adjustment and found that the "small reduction in the pooled RR estimates would not be consistent with a major effect from residual confounding." Dr. Silverman concluded that "[t]he authors convincingly show that potential confounding by cigarette smoking is likely to have little impact on the estimated RRs for diesel exhaust and lung cancer." (Silverman, 1998)

(5) Inadequate Control in the Underlying Studies for Diet

As noted by Lipsett and Campleman, "Diet may also confound the diesel-lung cancer association." The researchers also caution that this risk factor was not controlled for in the nearly 50 diesel studies they examined. [MARG]

Since inhalation is the primary route of dpm exposure, and the lung is the primary target organ, MSHA considers potential dietary confounding to be of minor importance in the diesel-lung cancer association. Lipsett and Campleman acknowledged that diet might be a relevant consideration for long-haul truck drivers, but stated that "diet would probably not be an important confounder in studies of other occupations, particularly those using internal or other occupationally active reference populations." Studies making internal comparisons, or comparisons to similar groups of workers, are unlikely to be seriously confounded by dietary differences, because the groups of workers being compared are likely to have very similar dietary habits, on average. The pooled relative risk for cohort studies making comparisons internally or to other active workers was 1.48 (95% CI = 1.28 to 1.70). (Lipsett and Campleman, 1999, Table 3) This was considerably higher than the pooled RRs for studies making comparisons against regional or national populations, where dietary differences

[68] Several commenters suggested that because the two meta-analyses both received direct or indirect funding from the same governmental agency, they were not independently conducted. These commenters speculated that Dr. Allan Smith, a co-author of Cal-EPA (1998) and Bhatia *et al.* (1998), contributed to both meta-analyses. Although an earlier version of Lipsett and Campleman (1999) appeared as an appendix to Cal-EPA (1998), commenters provided no evidence that Dr. Smith contributed anything to that appendix. Dr. Smith is not listed as a co-author of Lipsett and Campleman (1999).

[69] Silverman (1998) reviewed Bhatia *et al.* (1998) but not Lipsett and Campleman (1999) or the earlier version of that meta-analysis (Lipsett and Alexeeff, 1998) cited in MSHA's proposed preamble.

[70] It is noteworthy that, in describing research underway that might resolve the issue of causality, Dr. Silverman stressed the need for studies with quantitative exposure measurements and stated that "underground miners may, in fact, be the most attractive group for study because their exposure to diesel exhaust is at least five times greater than that of previously studied occupational groups." (Silverman, 1998) She then mentioned a study on underground miners in Germany that had recently been initiated. The study of German underground potash miners (Säverin *et al.*, 1999), published after Dr. Silverman's article, utilizes quantitative exposure measurements and is included in MSHA's selection of best available epidemiologic evidence (see Section 3.a.iii(1)(a) of this risk assessment). MSHA also includes in that selection another underground miner study utilizing quantitative exposure measurements (Johnston *et al.*, 1997). The 1997 study was available prior to Dr. Silverman's article but is not listed among her references.

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(and also differences with respect to other potential confounders) would be more important.

(3) Potential Systematic Biases

Citing failure to account for dietary differences as an example, some commenters argued that the meta-analyses may simply propagate weaknesses shared by the individual studies. These commenters contended that many of the studies MSHA considered in this risk assessment share methodological similarities and that, therefore, a "deficiency" causing bias in one study would probably also bias many other studies in the same direction. According to these commenters, no matter how great a majority of studies report a 30- to 40-percent increase in the risk of lung cancer for exposed workers, the possibility of systematic bias prevents the collective evidence from being strong or sufficient.

Although this point has some theoretical foundation, it has no basis in fact for the particular body of epidemiologic evidence relating lung cancer to diesel exposure. The studies considered were carried out by many different researchers, in different countries, using different methods, and involving a variety of different occupations. Elevated risk was found in cohort as well as case-control studies, and in studies explicitly adjusting for potential confounders as well as studies relying on internal comparisons within homogeneous populations. The possibility that systematic bias explains these results is also rendered less plausible by results from studies of a radically different type: the elevated risk of lung cancer associated with chronic environmental exposures to $PM_{2.5}$ (Dockery *et al.* 1993; Pope *et al.*, 1995).

Furthermore, the commenters advancing this argument presented no evidence that the studies shared any deficiencies of a type that would systematically shift results in the direction of showing a spurious association. As explained in Subsection 2.c.i(2)(a), exposure misclassification, healthy worker effect, and low power due to insufficient latency generally have the opposite effect—systematically diluting and masking results. Although many studies may share a similar susceptibility to bias by dietary differences or residual smoking effects,[71] there is no reason to expect that such effects will consistently bias results in the same direction, across all occupations and geographic regions.

Associations between dpm exposure and excess lung cancer are evident in a wide variety of occupational and geographical contexts, and it is unlikely that all (or most) would be biased in the same direction by lifestyle effects. There is no reason to suppose that, in nearly all of these studies, exposed subjects were more likely than unexposed subjects to have lifestyles (apart from their occupations) that increased their risk of lung cancer. On the other hand, exposures to other occupational carcinogens, such as asbestos dust, radon progeny, and silica, could systematically cause studies in which they are not taken into account to exhibit spurious associations between lung cancer and occupational diesel exhaust exposures. Silica dust and radon progeny are frequently present in mining environments (though not usually in potash mines), and this was the reason that studies on miners were excluded from the two meta-analyses.

IMC Global argued that because of the possibility of being misled by systematic biases, epidemiologic evidence can be used to identify only those hazards that, at a minimum, double the risk of disease (i.e., RR ≥ 2.0). IMC Global explained this viewpoint by quoting an epidemiologist as follows:

> * * * [E]pidemiologic methods can only yield valid documentation of large relative risks. Relative risks of low magnitude (say, less than 2) are virtually beyond the resolving power of the epidemiologic microscope. We can seldom demonstrably eliminate all sources of bias, and we can never exclude the possibility of unidentified and uncontrolled confounding. If many studies—preferably based on different methods—are nevertheless congruent in producing markedly elevated relative risks, we can set our misgivings aside. If however, many studies produce only modest increases, those increases may well be due to the same biases in all the studies. [Dr. Samuel Shapiro, quoted by IMC Global]

It is important to note that, unlike IMC Global, Dr. Shapiro did not suggest that results of RR < 2.0 be counted as "negative." He contended only that low RRs do not completely rule out the possibility of a spurious association due to unidentified or uncontrolled confounding. More importantly, however, this restriction would allow workers to be exposed to significant risks and is, therefore, unacceptable for regulatory purposes. For purposes of protecting miners from lung cancer, certainty is not required; and an increase in the relative risk of less than 100 percent can increase the absolute risk of lung cancer by a clearly unacceptable amount. For example, if the baseline risk of lung cancer is six per thousand, then increasing it by 33 percent amounts to an increase of two per thousand for exposed workers.

IMC Global went on to argue that—

> * * * only a few of these studies have relative risks that exceed 2.0, and some of the studies that do exceed 2.0 exhibit biases that make them unsuitable for rulemaking purposes in our opinion. * * * Thus, in IMC Global's opinion, the epidemiologic evidence demonstrates an artificial association that can be explained through common biases probably due to smoking habits and lifestyle factors. [IMC Global]

This line of reasoning leaps from the *possibility* that systematic biases might account for observed results to a conclusion that they actually do so. Furthermore, after proposing to allow for possible biases by requiring that only relative risks in excess of 2.0 be counted as positive evidence, IMC global has ignored its own criterion and discounted results greater than 2.0 for the same reason. Contrary to IMC Global's claim that "only a few of the studies have relative risks that exceed 2.0," Tables III–4 and III–5 show 23 separate results greater than 2.0, applying to independent categories of workers in 18 different studies.

According to Stöber and Abel (1996), the potential confounding effects of smoking are so strong that "residual smoking effects" could explain even statistically significant results observed in studies where smoking was explicitly taken into account. MSHA agrees that variable exposures to non-diesel lung carcinogens, including relatively small errors in smoking classification, could bias individual studies. However, the potential confounding effect of tobacco smoke and other carcinogens can cut in either direction. Spurious positive associations of dpm exposure with lung cancer would arise only if the group exposed to dpm had a greater exposure to these confounders than the unexposed control group used for comparison. If, on the contrary, the control group happened to be more exposed to confounders, then this would tend to make the association between dpm exposure and lung cancer appear negative. Therefore, although smoking effects could potentially distort the results of any single study, this effect could reasonably be expected to make only about half the studies that were explicitly adjusted for smoking come out positive. Smoking is unlikely to have been responsible for finding an excess prevalence of lung cancer in 17 out of 18 studies in which a smoking adjustment was applied. Based on a 2-tailed sign test, this possibility can be rejected at a confidence level greater than 99.9 percent.

Even in the 29 studies for which no smoking adjustment was made, tobacco smoke and other carcinogens were important confounders only to the extent that the populations exposed and unexposed to diesel exhaust differed systematically with respect to these other exposures. Twenty-four of these studies, however, reported some degree of excess lung cancer risk for the diesel-exposed workers. This result could be attributed to other occupational carcinogens only in the unlikely event that, in nearly all of these studies, diesel-exposed workers happened to be more highly exposed to these other carcinogens than the control groups of workers unexposed to diesel.

Like IMC Global, Stöber and Abel (1996) do not, in MSHA's opinion, adequately distinguish between a *possible* bias and an *actual* one. Potential biases due to extraneous risk factors are unlikely to account for a significant part of the excess risk in all studies showing an association. Excess rates of lung cancer were associated with dpm exposure in all epidemiologic studies of sufficient size and scope to detect such an excess. Although it is possible, in any individual study, that the potentially confounding effects of differential exposure to tobacco smoke or other carcinogens could account for the observed elevation in risk otherwise attributable to diesel exposure, it is unlikely that such effects would give rise to positive associations in 41 out of 47 studies. As stated by Cohen and Higgins (1995):

> * * * elevations [of lung cancer] do not appear to be fully explicable by confounding due to cigarette smoking or other sources of bias. Therefore, at present, exposure to diesel exhaust provides the most reasonable explanation for these elevations. The association is most apparent in studies of occupational cohorts, in which assessment of exposure is better and more detailed analyses have been performed. The largest relative risks are often seen in the categories of most probable, most intense, or longest duration of exposure. In general population studies, in which exposure prevalence is low and misclassification of exposure poses a particularly serious potential bias in the direction of observing no effect of exposure, most studies indicate increased risk, albeit with considerable imprecision. [Cohen and Higgins (1995), p. 269].

Several commenters identified publication bias as another possible explanation for the heavy preponderance of studies showing an elevated risk of lung cancer for exposed workers. As described earlier, both of the available meta-analyses investigated and rejected the hypothesis of significant publication bias affecting the overall results. This was based on both a statistical technique using "funnel plots" and a direct comparison between results of published and unpublished studies. Commenters presented no evidence that publication bias actually exists in this case. After the 1988 NIOSH and 1989 IARC determinations that diesel exhaust was a "potential" or "probable" human carcinogen, negative results would have been of considerable interest, and, in the absence of any evidence specifically applying to dpm studies, there is no reason to assume they would not have been published.

(4) Causality

MSHA must draw its conclusions based on the weight of evidence. In the absence of any statistical evidence for differential confounding or significant publication bias, the weight of epidemiologic evidence strongly favors a causal connection. On the one side, it is evident that virtually all of the studies that adjusted for smoking and other known confounders, or controlled for them by comparing against similar groups of workers, showed positive associations (i.e., relative risk or odds ratio > 1.0). Also on this side of the balance are all eight of the studies MSHA identified as comprising the best available human evidence. These include three studies reporting positive exposure-response relationships based on quantitative dpm exposure assessments: two recent studies specifically on underground miners (one coal and one potash) and one on trucking industry workers.[72] On the other side of the balance is the possibility that publication bias or other systematic biases may have been responsible for some unknown portion of the overall 30- to 40-percent elevation in lung cancer risk observed—a possibility that, while conceivable, is based on speculation. After considering other viewpoints (addressed here and in the next subsection), MSHA has accepted what in its view is the far more likely alternative: that the vast majority of epidemiologic studies showed an elevated risk in association with occupational exposures to diesel exhaust because such exposures cause the risk of lung cancer to increase. The toxicity experiments discussed in Subsection 2.d.iv of this risk assessment support the causal interpretation that MSHA has placed on the associations observed in epidemiologic studies.

In this risk assessment, MSHA is basing its conclusions primarily on epidemiologic studies. However, the results obtained from animal studies confirm that diesel exhaust can increase the risk of lung cancer in some species and help show that dpm (rather than the gaseous fraction of diesel exhaust) is the causal agent. The fact that dpm has been proven to cause lung cancer in laboratory rats only under conditions of lung overload does not make the rat studies irrelevant to miners. The very high dpm concentrations currently observed in some mines could impair or even overwhelm lung clearance for miners already burdened by respirable mineral dusts, thereby inducing lung cancer by a mechanism similar to what occurs in rats (Nauss et al., 1995). It must also be noted, however, that most of the human studies show an increased risk of lung cancer at dpm levels lower than what might be expected to cause overload. Therefore, the human studies suggest that overload is not a necessary condition for dpm to induce or promote lung cancer among humans. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 $\mu g/m^3$. Animal studies provide evidence that inhalation of dpm has related effects, such as induction of free oxygen radicals, that could promote the development of human lung cancers by mechanisms not requiring lung overload. (See Sec. III.2.d.iv(2).)

Similarly, the weight of genotoxicity evidence helps support a causal interpretation of the associations observed in the epidemiologic studies. This evidence shows that dpm dispersed by alveolar surfactant can have mutagenic effects, thereby providing a genotoxic route to carcinogenesis that is independent of overloading the lung with particles. After a comprehensive review of the evidence, IPCS (1996) concluded that both the particle core and the associated organic materials have biological activity. The biological availability of carcinogens present in the organic portion of dpm may, however, differ significantly in different species. Chemical byproducts of phagocytosis, which occurs even when the lung is not overloaded, may provide another genotoxic route. Inhalation of diesel emissions has been shown to cause DNA adduct formation in peripheral lung cells of rats and monkeys, and increased levels of human DNA adducts have been found in association with occupational exposures. (See Sec. III.2.d.iv(1)) None of this evidence

[71] The term "residual smoking effects" refers to the potentially confounding effects of smoking that may remain after a smoking adjustment has been made.

[72] These studies (respectively: Johnston et al., 1997; Säverin et al., 1999; Steenland et al., 1998) are discussed in detail in Subsection 2.c.i(2)(a) of this risk assessment.

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suggests that a lung cancer threshold exists for humans exposed to dpm, despite its importance in the rat model. Nor does this evidence suggest that lung overload is necessary for dpm to induce lung cancer in humans. Indeed, lung overload may be only one of many mechanisms through which lung cancer is produced in humans.

Results from the epidemiologic studies, the animal studies, and the genotoxicity studies are coherent and mutually supportive. After considering all these results, MSHA has concluded that the epidemiologic studies, supported by the experimental data establishing the plausibility of a causal connection, provide strong evidence that chronic occupational dpm exposure increases the risk of lung cancer in humans.

In a review, submitted by MARG, of MSHA's proposed risk assessment, Dr. Jonathan Borak asserted that MSHA's determination that results from the epidemiologic and toxicity studies were "coherent and mutually reinforcing" involved circular reasoning. He supported this assertion by incorrectly attributing to MSHA the view that "most of the individual [epidemiologic] studies are not very good" and that their suggestion of an association between dpm and lung cancer is "made credible in light of the animal data." To complete his argument that MSHA relied on circular reasoning, Dr. Borak then suggested that the epidemiologic data provided MSHA's sole basis for considering the animal data relevant to humans. In a similar vein, Kennecott Minerals claimed there was an "absence of toxicological support for epidemiologic findings that are themselves inconclusive."

Contrary to Dr. Borak's assertion, MSHA has not characterized most of the epidemiologic studies as "not very good." Nor has MSHA suggested that the epidemiologic evidence would not be credible or plausible in the absence of supporting animal data. As Dr. Borak correctly noted, MSHA acknowledged that "none of the existing human studies is perfect" and that "no single one of the existing epidemiological studies, viewed in isolation, provides conclusive evidence of a causal connection * * *." That a study is not "perfect," however, does not imply that it is "not very good." MSHA's position has consistently been that, as demonstrated by the two available meta-analyses, the collective epidemiologic evidence is not merely credible but statistically significant and indicative of a causal association. Although MSHA views the toxicity data as supporting and reinforcing the epidemiologic evidence, MSHA believes that the collective epidemiologic evidence is highly credible in its own right.

Furthermore, MSHA does not consider the animal data relevant to humans simply because of the positive epidemiologic evidence. The animal evidence is also credible in its own right. As MSHA has repeatedly pointed out, dust concentrations in some mines have been measured at levels of the same order of magnitude as those found to have caused lung cancer in rats. Such high exposures, especially when combined with occupational exposures to respirable mineral dusts and exposures to particles in tobacco smoke, could overload the human lung and promote lung cancer by a mechanism similar to that hypothesized for rats. (Hattis and Silver, 1992, Figures 9, 10, 11). Also, many of the animal experiments have elucidated genotoxic effects that, while apparently not responsible for the excess lung cancers observed for rats, may be responsible for some or all of the excess risk reported for humans.

MSHA has not relied on circular reasoning. If either the animal data or the toxicity data had failed to show any link between dpm and effects implicated in the induction or promotion of lung cancer, then MSHA's conclusion would have been weakened. The existence of experimental evidence confirming that there is such a link is not imaginary and is logically independent of the epidemiologic evidence. Therefore, contrary to Dr. Borak's characterization, the "coherency and reinforcement" arising from the epidemiologic, animal, and genotoxicity data are not the product of circular reasoning. A more apt description is that the three sources of evidence, like three legs of a tripod, support the same conclusion.

Many commenters argued that a causal connection between dpm exposure and an increased human risk of lung cancer should not be inferred unless there is epidemiologic evidence showing a positive exposure-response relationship based on quantitative measures of cumulative dpm exposure. MSHA does not agree that a quantitative exposure-response relationship is essential in establishing causality. Such a relationship is only one of several factors, such as consistency and biological plausibility, that epidemiologists examine to provide evidence of causality. As mentioned earlier, however, there are three studies providing quantitative exposure-response relationships. One of these studies (Steenland et al., 1998) controlled for age, race, smoking, diet, and asbestos exposure, but relied on "broad assumptions" to estimate historical exposure levels from later measurements. Two of the studies, however, (Johnston et al., 1997, and Säverin et al., 1999) utilized measurements that were either contemporaneous with the exposures (Johnston) or that were made under conditions very similar to those under which the exposures took place (Säverin). Both of these studies were conducted on underground miners. The Säverin study used exposure measurements of total carbon (TC). All three of the studies combined exposure measurements for each job with detailed occupational histories to form estimates of cumulative dpm exposure; and all three reported evidence of increasing lung cancer risk with increasing cumulative exposure.

Several commenters, expressing and endorsing the views of Dr. Peter Valberg, incorrectly asserted that the epidemiologic results obtained across different occupational categories were inconsistent with a biologically plausible exposure-response relationship. For example, MARG argued that—

> It is biologically implausible that, if dpm were (causally) increasing lung cancer risk by 50% for a low exposure (say, truck drivers), then the lung cancer risk produced by dpm exposure in more heavily exposed worker populations (railroad shop workers) would fall in this same range of added risk. The added lung-cancer risk for bus garage workers is half that of either railroad workers or truck drivers, but dpm concentrations are considerably higher. [MARG]

Earlier, MARG had argued to the contrary that, due to their lack of concurrent exposure measurements, these studies could not reliably be used for hazard identification. MARG then attempted to use them to perform the rather more difficult task of making quantitative comparisons of relative risk. If cumulative exposures are unknown, as MARG argued elsewhere, then there is little basis for comparing responses at different cumulative exposures.

In an analysis submitted by the West Virginia Coal Association, Dr. Valberg extended this argument to miners as follows:

> * * * If dpm concentrations for truck drivers is in the range of 5–50 μg/m³, then we can assign the 0.49 excess risk (Bhatia's meta-analysis result) to the 5–50 μg/m³ exposure. Hence, dpm concentrations for miners in the range of 100–2,000 μg/m³ should have yielded excess risks forty times larger, meaning that the RR for exposed miners would be expected to be about 21 (i.e., 1 + 19.6), whereas reported risk estimates are less than 3 (range from 0.74 2.67). Such an utter lack of concordance argues against a causal role for dpm in the reported epidemiologic associations.

Based on a similar line of reasoning, IMC Global asserted that "* * * the assumptions that MSHA used to develop [Figure III–4] * * * do not do make sense in the context of a dose-response relationship between lung cancer and dpm exposure." This was one of the reasons IMC Global gave for objecting to MSHA's comparison (in Section III.1.d) of exposure levels measured for miners to those reported for different occupations. IMC Global proposed that, as a consequence of this argument, MSHA should delete this comparison from its risk assessment.

MSHA sees three major flaws in Dr. Valberg's argument and rejects it for the following reasons:

(1) The argument glosses over the important distinction between exposure concentrations (intensity) and cumulative exposure (dose). Total cumulative exposure is the product of intensity and duration of exposure. Depending on duration, high intensity exposure may result in similar (or even lower) cumulative exposure than low intensity exposure. Furthermore, different industries, in different nations, introduced diesel equipment at different times. The studies being considered were carried out in a variety of different countries and covered a variety of different historical periods. Therefore, the same number of years in different studies can correspond to very different durations of occupational exposure.

Many of the miners in the studies Dr. Valberg considered may have been occupationally exposed to dpm for relatively short periods of time or even not at all. Various forms of exposure misclassification would tend to obscure any exposure-response relationship across industries. Such obscuring would result from both exposure misclassification within individual studies and also variability in the degree of exposure misclassification in different industries.

Furthermore, the exposure levels or intensities assigned to the various occupations would not necessarily be proportional to cumulative exposures, even if the average number of years of exposure were the same. Different job conditions, such as longer-than-average work hours, could have major, variable impacts on cumulative exposures. For example, lower dpm concentrations have been measured for truck drivers than for other occupationally-exposed workers. But as a group, the truck drivers who were studied, due to their work conditions, may have been in their trucks for longer than the standard 40-hour work week and therefore have larger cumulative dpm exposures. These truck drivers commonly congregated in parking areas and slept in their trucks with the engines idling, thereby disproportionately increasing their cumulative dpm exposures compared to miners and other types of workers.

(2) The commenters advancing this argument assumed that an exposure-response relationship spanning occupations at different levels of exposure intensity would take the form of a straight line. This assumption is unwarranted, since carcinogens do not necessarily follow such a simple pattern across a broad range of exposure levels. There is little basis for assuming that the relationship between cumulative dpm exposures and the relative risk of lung cancer would appear as a straight line when plotted against exposure levels that may differ by a factor of 100. Steenland et al. (1998) reported a better statistical "fit" to the data using a model based on the logarithm of cumulative exposure as compared to simple cumulative exposure. Even across the relatively limited range of exposures within the trucking industry, the logarithmic exposure model exhibits pronounced curvature towards the horizontal at the higher cumulative exposures (Steenland et al., 1998, Fig. 5). If this model is extrapolated out to the much higher exposures currently found in underground mining, then (as shown in Subsection 3.b.ii(3)(b) of this risk assessment) it diverges even more from a straight-line model. Toxicological evidence of curvature in the dose-response relationship has also been reported (Ichinose et al., 1997b, p. 190).

Furthermore, the exposure-response pattern may depend on other aspects of exposure, besides how much is accumulated. For example, the National Research Council (NRC) has adopted a risk model for radon-induced lung cancer in which the relative risk (RR) at any age depends on both accumulated exposure and the rate (reflecting the intensity of exposure) at which total exposure was accumulated. In this model, which was derived empirically from the epidemiologic data, exposures accumulated over long time periods at relatively low rates result in a greater risk of lung cancer than the same total exposures accumulated over shorter time periods at relatively higher rates (NRC, 1999). A similar effect for dpm could cause apparent anomalies in the pattern of relative risks observed for occupations ranked simply with respect to the intensity of their average exposures.

(3) Mean exposures and relative risks reported for miners involved in the available studies were mischaracterized. Although dpm levels as high as 2000 μg/m³ have been measured in some mines, the levels at most mines surveyed by MSHA were substantially lower (see Figures III–1 and III–2). The average levels MSHA measured at underground mines were 808 μg/m³ and 644 μg/m³ for M/NM and coal mines using diesel equipment for face haulage, respectively (Table III–1). However, these were not necessarily the levels experienced by miners involved in the available studies. The mean TC exposure concentration reported by Säverin et al. (1999), for work locations having the highest mean concentration, was 390 μg/m³—corresponding to a mean dpm concentration of about 490 μg/m³. In the only other study involving miners for which exposure measurements were available, Johnston et al. (1997) reported dpm concentrations for the most highly exposed category of workers (locomotive drivers), ranging from 44 μg/m³ to 370 μg/m³. Therefore, the mean dpm concentration experienced by the most highly exposed miners involved in these two studies was not "forty times larger" than the level imputed to truck drivers, but closer to seven times larger.[73] Applying Dr. Valberg's procedure, this yields an "expected" relative risk of about 4.4 for the underground miners who happened to work at mines included in these particular studies (1 + 7×(0.49)). Miners exposed at higher levels would, of course, face a greater risk.

Dr. Valberg asserted that the highest relative risk reported for miners was 2.67 (from Boffetta et al., 1988). Dr. Valberg failed to note, however, that the upper 95-percent confidence limit for miners' relative risk in this study was 4.37, so that this result hardly qualifies as an "utter lack of concordance" with the 4.4 "expected" value for miners. Furthermore, even higher relative risks for miners have been reported in other studies. Burns and Swanson (1991) reported 5.0 for operators of mining machinery, with an upper 95-percent confidence limit of 16.9. The relative risk estimated for the most highly exposed miners in the study by Johnston et al. (1997) was either 5.5 or 11.0, depending on the statistical model used. These results appear to be quite consistent with the data for truck drivers.

[73] The estimate of seven times larger dpm exposure in miners is the result of averaging data from Säverin et al. (1999) with data from Johnston et al. (1997) and comparing the combined average miner dpm exposure to the average truck driver dpm exposure.

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(5) Other Interpretations of the Evidence

After reviewing the same body of scientific evidence as MSHA, Dr. Peter Valberg came to a very different conclusion with respect to the likelihood of causality:

> Flawed methodology (lack of adequate control for smoking); values for relative risks ("RR") that are low and often not statistically elevated above 1.0; inadequate treatment of sources of variability; reliance on multiple comparisons; and inadequate control over how authors choose to define dpm exposure surrogates (that is, job category within a profession, cumulative years of work, age at time of exposure, etc.), all undermine the assignment of causality to dpm exposure.

On the other hand, many scientific organizations and governmental agencies have reviewed the available epidemiologic and toxicological evidence for carcinogenicity and, in accordance with MSHA's conclusion, identified dpm as a probable human carcinogen—at levels far lower than those measured in some mines—or placed it in a comparable category. These include:

YEAR

2000 National Toxicology Program (NTP);
1999 (tentative) U.S. Environmental Protection Agency (EPA)
1998 (tentative) (American Conference of Governmental Industrial Hygienists (ACGIH); Currently on Y2K NIC list. Probable vote in 10/2000.
1998 California Environmental Protection Agency (Cal-EPA);
1998 Federal Republic of Germany;
1998 International Programme on Chemical Safety (IPCS), a joint venture of the World Health Organization, the International Labour Organization, and the United Nations Environment Programme;
1989 International Agency for Research on Cancer (IARC);
1988 National Institute for Occupational Safety and Health (NIOSH).

Nevertheless, several commenters strongly objected to MSHA's conclusion, claiming that the evidence was obviously inadequate and citing scientific authorities who, they claimed, rejected MSHA's inference of a causal connection. In some cases, views were inaccurately attributed to these authorities, and misleading quotations were presented out of context. For example, the Nevada Mining Association stated that its own review of the scientific literature led to—

> * * * the only reasonable conclusion possible: there is no scientific consensus that there is a causal link between dpm exposure and lung cancer. The HEI [1999 Expert Panel] report concludes that the causal link between diesel exhaust and lung cancer remains unproven, and that further study and analysis are clearly required. [Nevada Mining Assoc.]

Although HEI (1999) recommended further study and analysis for purposes of quantitative risk assessment, the report contains no findings or conclusions about the "causal link." To the contrary, the report explicitly states that the panel "* * * was not charged to evaluate either the broad toxicologic or epidemiologic literature concerning exposure to diesel exhaust and lung cancer for hazard identification purposes, which has been done by others." (HEI, 1999, p. 1) Furthermore, the HEI panel "* * * recognize[d] that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999, p. 20)

MARG, along with the Nevada Mining Association and several other commenters, mischaracterized the Expert Panel's findings as extending beyond the subject matter of the report. This report was limited to evaluating the suitability of the data compiled by Garshick et al. (1987, 1988) and Steenland et al. (1990, 1992, 1998) for quantitative risk assessment. Contrary to the characterization by these commenters, HEI's Expert Panel explicitly stated:

> [The Panel] was not charged to evaluate the broad toxicologic or epidemiologic literature for hazard identification purposes, which has been done by others. State, national, and international agencies have all reviewed the broader animal and human evidence for carcinogenicity and, in either their draft or final reports, have all identified diesel exhaust as [a] probable human carcinogen or placed it in a comparable category." [HEI, 1999, p. 1]

The Panel then identified most of the organizations and governmental institutions listed above (HEI, 1999, p. 8).

One commenter (MARG) also grossly misrepresented HEI (1999) as having stated that "the available epidemiologic work has 'study design flaws, including uncontrolled, confounding and lack of exposure measures, leading to a lack of convincing evidence.'" (MARG post-hearing comments) The opinion falsely attributed to HEI was taken from a sentence in which HEI's Diesel Epidemiology Expert Panel was describing opinions expressed in "[s]ome reviews critical of these data." (HEI, 1999, p. 10) The Panel did not suggest that these opinions were shared by HEI or by any members of the Panel. In fact, the cited passage came at the end of a paragraph in which the Panel cited a larger number of other review articles that had "discusse[d] this literature in depth" and had expressed no such opinions. In the same paragraph, the Panel confirmed that "[t]he epidemiologic studies generally show higher risks of lung cancer among persons occupationally exposed to diesel exhaust than among persons who have not been exposed, or who have been exposed to lower levels or for shorter periods of time." (HEI, 1999, p. 10)

Several commenters noted that the U.S. EPA's Clean Air Scientific Advisory Committee (CASAC) issued a report (CASAC, 1998) critical of the EPA's 1998 draft Health Assessment Document for Diesel Emissions (EPA, 1998) and rejecting some of its conclusions. After the HEI (1999) Expert Panel report was published, the EPA distributed a revised draft of its Health Assessment Document (EPA, 1999). In the 1999 draft, the EPA characterized human exposures to diesel exhaust as "highly likely" to be carcinogenic to humans at ambient (i.e., environmental) exposure levels. After reviewing this draft, CASAC endorsed a conclusion that, at ambient levels, diesel exhaust is likely to be carcinogenic to humans. Although CASAC voted to recommend that the designation in the EPA document be changed from "highly likely" to "likely," this change was recommended specifically for ambient rather than occupational exposures. The CASAC report states that "[a]lthough there was mixed opinion regarding the characterization of diesel emissions as 'highly likely' to be a human carcinogen, the majority of the Panel did not agree that there was sufficient confidence (i.e., evidence) to use the descriptor 'highly' *in regard to environmental exposures.*" (CASAC, 2000, emphasis added)

MSHA recognizes that not everyone who has reviewed the literature on lung cancer and diesel exposure agrees about the collective weight of the evidence it presents or about its implications for regulatory decisions. IMC Global, for example, stated:

> After independently reviewing most [of the] * * * epidemiologic studies, the literature reviews and the two meta-analyzes, IMC Global believes * * * MSHA has misrepresented the epidemiologic evidence in the Proposed Rule. The best conclusion that we can reach based on our review of this information is that different reputable studies reach conflicting conclusions * * *. [IMC Global]

IMC Global continued by expressing concern that MSHA had "dismissed" opposing arguments critical of the positive studies, especially "regarding lack of statistical significance; small magnitudes of relative risk * * *; and the impact of confounding factors, especially smoking * * *. [IMC Global]"

MSHA has addressed these three issues, as they relate to the evaluation of individual studies, in Section 2.c.i(2)(a) of this preamble. The argument that confounding factors such as smoking may have been systematically responsible for the positive results was discussed above, under the heading of "Potential Systematic Biases." Statistical significance of the collective evidence is not the same thing as statistical significance of individual studies. Application of the sign test, as described Subsection 3.a.iii(1) above, is one way that MSHA has addressed statistical significance of the collective evidence. Another approach was also described above, under the heading of "Meta-Analyses."

IMC Global quoted Morgan et al. (1997) as concluding that "[a]lthough there have been a number of papers suggesting that diesel fumes may act as a carcinogen, the weight of the evidence is against this hypothesis." This conclusion was based largely on the authors' contention, shared by IMC Global, that the epidemiologic results were inconsistent and of insufficient strength (i.e., RR < 2.0) to rule out spurious associations due to potential confounders. MSHA, on the other hand, interprets the epidemiologic studies as remarkably consistent, given their various limitations, and has argued that the strength of evidence from individual studies is less important than the strength of evidence from all studies combined. Dr. Debra Silverman has referred to the "striking consistency" of this evidence. (Silverman, 1998)

Ironically, Morgan et al. point out many of the very limitations in individual studies that may actually explain why the studies do not yield entirely equivalent results. The 1997 Morgan article was written before the meta-analyses became available and resolved many, if not all, of the apparent inconsistencies in the epidemiologic results. Since none of the existing human studies is perfect and many contain important limitations, it is not surprising that reported results differ in magnitude and statistical significance. The meta-analyses described earlier showed that the more powerful and carefully designed studies tended to show greater degrees of association. MSHA has addressed the joint issues of consistency and strength of association above, under the heading of "Consistency of Epidemiologic Evidence."

The Engine Manufacturers Association (EMA) quoted Cox (1997) as concluding: "* * * there is no demonstrated biological basis for expecting increased risk at low to moderate levels of [diesel] exposure." (Cox, 1997, as quoted by EMA) The EMA, however, prematurely terminated this quotation. The quoted sentence continues: "* * * low to moderate levels of exposure (those that do not lead to lasting soot deposits, chronic irritation, and perhaps GSH enzyme depletion in the lung)." MSHA does not regard concentrations of dpm exceeding 200 µg/m³ as "low to moderate," and the EMA presented no evidence that the effects Dr. Cox listed do not occur at the high exposure levels observed at some mines. Salvi et al. (1999) reported marked inflammatory responses in the airways of healthy human volunteers after just one hour of exposure to dpm at a concentration of 300 µg/m³. The deleted caveat ending the quotation is especially important in a mining context, since mine atmospheres generally contain respirable mineral dusts that may diminish clearance rates and contribute to meeting thresholds for chronic irritation and inflammation leading to oxidative damage. Based on miners' testimony at the public hearings and workshops, there is, in fact, reason to believe that exposed miners experience lasting soot deposits and chronic irritation as a result of their exposures.

With respect to the epidemiologic evidence, the EMA quoted Dr. Cox as concluding: "* * * among studies that demonstrate an increased relative risk, it appears plausible that uncontrolled biases in study design and data analysis methods can explain the statistical increases in relative risk without there being a true causal increase." (Cox, 1997, quoted by EMA) Dr. Cox refers to non-causal explanations for positive epidemiologic results as "threats to causal inference." In considering Dr. Cox's discussion of the evidence, it is important to bear in mind that his purpose was "* * * not to establish that any (or all) of these threats do explain away the apparent positive associations between [dpm] and lung cancer risk * * * but only to point out that they plausibly could * * *." (Cox, 1997, p. 813) Dr. Cox's stated intent was to identify non-causal characteristics of positive studies that could potentially "explain away" the positive results. This is a relatively simple exercise that could misleadingly be applied to even the strongest of epidemiologic studies. As stated earlier, no epidemiologic study is perfect, and it is always possible that unknown or uncontrolled risk factors may have given rise to a spurious association. Neither the EMA nor Dr. Cox pointed out however, that there are characteristics common to the negative studies that plausibly explain why they came out negative: insufficient latency allowance, nondifferential exposure misclassification, inappropriate comparison groups (including healthy worker effect, negative confounding by smoking or other variables. A similar approach could also be used to explain why many of the positive studies did not exhibit stronger associations. As observed by Dr. Silverman, "an unidentified negative confounder may have produced bias across studies, systematically diluting RRs."

b. Significance of the Risk of Material Impairment to Miners

The fact that there is substantial and persuasive evidence that dpm exposure can materially impair miner health in several ways does not imply that miners will necessarily suffer such impairments at a significant rate. This section will consider the significance of the risk faced by miners exposed to dpm.

i. Meaning of Significant Risk

(1) Legal Requirements

The benzene case, cited earlier in this risk assessment, provides the starting point for MSHA's analysis of this issue. Soon after its enactment in 1970, OSHA adopted a "consensus" standard for exposure to benzene, as authorized by the OSH Act. The standard set an average exposure limit of 10 parts per million over an 8-hour workday. The consensus standard had been established over time to deal with concerns about poisoning from this substance (448 U.S. 607, 617). Several years later, NIOSH recommended that OSHA alter the standard to take into account evidence suggesting that benzene was also a carcinogen. (*Id.* at 619 et seq.). Although the "evidence in the administrative record of adverse effects of benzene exposure at 10 ppm is sketchy at best," OSHA was operating under a policy that there was no safe exposure level to a carcinogen. (*Id.*, at 631). Once the evidence was adequate to reach a conclusion that a substance was a carcinogen, the policy required the agency to set the limit at the lowest level feasible for the industry. (*Id.* at 613). Accordingly, the Agency proposed lowering the permissible exposure limit to 1 ppm.

The Supreme Court rejected this approach. Noting that the OSH Act requires "safe or healthful employment," the court stated that—

> * * * 'safe' is not the equivalent of 'risk-free' * * * a workplace can hardly be considered "unsafe" unless it threatens the

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workers with a significant risk of harm. Therefore, before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices. [*Id.*, at 642, italics in original].

The court went on to explain that it is the Agency that determines how to make such a threshold finding:

First, the requirement that a 'significant' risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a 'significant' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it. Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as "unsafe." [*Id.*, at 655].

The court noted that the Agency's "* * * determination that a particular level of risk is 'significant' will be based largely on policy considerations." (*Id.*, note 62).

Some commenters contended that the concept of significant risk, as enunciated by the Supreme Court in the Benzene case, requires support by a quantitative dose-response relationship. For example, one commenter argued as follows:

* * * OSHA had contended in * * * [the benzene] case that "because of the lack of data concerning the linkage between low-level exposures and blood abnormalities, it was impossible to construct a dose-response curve at this time". 448 U.S. at 632–633. The court rejected the Agency's attempt to support a standard based upon speculation that "the benefits to be derived from lowering" the permissible exposure level from 10 to 1 ppm were 'likely' to be 'appreciable'." 448 U.S. at 654.

One year after the Benzene case, the Court in American Textile Mfr's Inst. v. Donovan, 452 U.S. 490 (1981), upheld OSHA's "cotton dust" standard for which a dose-response curve had been established by the Agency. The Court relied upon the existence of such data to find that OSHA had complied with the Benzene mandate, stating: "In making its assessment of significant risk, OSHA relied on dose-response curve data * * * It is difficult to imagine what else the agency could do to comply with this Court's decision in the Benzene case." *Id.* at 505, n. 25. See also *Public Citizen Research Group* v. *Tyson*, 796 F. 2d 1479, 1496, 1499 (D.C. Cir. 1986) (where a dose response curve was constructed for the ethylene oxide standard and the agency [had] gone to great lengths to calculate, within the bounds of available scientific data, the significance of the risk); *United Steelworkers of America* v. *Marshall*, 647 F. 2d 1189, 1248 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (where in promulgating a new lead standard "OSHA amassed voluminous evidence of the specific harmful effects of lead at particular blood levels and correlated these blood lead levels with air lead levels"). [NMA]

A dose-response relationship has been established between exposure to $PM_{2.5}$ (of which dpm is a major constituent) and the risk of death from cardiovascular, cardiopulmonary, or respiratory causes (Schwartz et al.,1996; EPA, 1996). Furthermore, three different epidemiologic studies, including two carried out specifically on mine workers, have reported evidence of a quantitative relationship between dpm exposure and the risk of lung cancer (Johnston et al., 1997, Steenland et al., 1998, Säverin et al., 1999). However, the Secretary has carefully reviewed the legal references provided by the commenters and finds there is no requirement in the law that the determination of significant risk be based on such a relationship. The cited court rulings appear to describe sufficient means of establishing a significant risk, rather than necessary ones. Indeed, as stated earlier in this section, the Benzene court explained that:

* * * the requirement that a "significant" risk be identified is not a mathematical straitjacket. It is the Agency's responsibility to determine, in the first instance, what it considered to be a "significant" risk. * * * the Agency has no duty to calculate the exact probability of harm * * *.

The Agency has set forth the evidence and rationale behind its decision to propose a rule restricting miner exposure to dpm, obtained an independent peer review of its assessment of that evidence, published the evidence and tentative conclusions for public comment, held hearings, kept the record open for further comments for months after the hearings, and re-opened the record so that stakeholders could comment on the most recent evidence available. Throughout these proceedings, the Agency has carefully considered all public comments concerning the evidence of adverse health effects resulting from occupational dpm exposures. Based on that extensive record, and the considerations noted in this section, the Agency is authorized under the statute and relevant precedents to act on this matter—despite the fact that a more conclusive or definitively established exposure-response relationship might help address remaining doubts among some members of the mining community.

As the Supreme Court pointed out in the benzene case, the appropriate definition of significance also depends on policy considerations of the Agency involved. In the case of MSHA, those policy considerations include special attention to the history of extraordinary occupational risks leading to the Mine Act. That history is intertwined with the toll to the mining community of silicosis and coal workers' pneumoconiosis (CWP or "black lung"), along with billions of dollars in Federal expenditures.

(2) Standards and Guidelines for Risk Assessment

Several commenters suggested that this risk assessment, as originally proposed, deviated from established risk assessment guidelines, because it did not provide a sufficiently quantitative basis for evaluating the significance of miners's risks due to their dpm exposures. One of these commenters (Dr. Jonathan Borak) maintained that a determination of significant risk based on a "qualitative" assessment "has no statistical meaning."

MSHA recognizes that a risk assessment should strive to provide as high a degree of quantification and certainty as is possible, given the best available scientific evidence. However, in order to best protect miners' health, it is not prudent to insist on a "perfect" risk assessment. Nor is it prudent to delay assessing potentially grave risks simply because the available data may be insufficient for an ideal risk assessment. The need for regulatory agencies to act in the face of uncertainty was recognized by the HEI's Diesel Epidemiology Expert Panel as follows: "The Panel recognizes that regulatory decisions need to be made in spite of the limitations and uncertainties of the few studies with quantitative data currently available." (HEI, 1999) When there is good, qualitative evidence—such as the sight and smell of heavy smoke—that one's house is on fire, an inference of significant risk may be statistically meaningful even without quantitative measurements of the smoke's density and composition.

Moreover, as will be demonstrated below, the question of whether a quantitative assessment is or is not essential is, in this case, moot: this risk assessment does, in fact, provide a quantitative evaluation of how significant the risk is for miners occupationally exposed to dpm.

ii. Significance of Risk for Underground Miners Exposed to dpm

An important measure of the significance of a risk is the likelihood that an adverse effect actually will occur. A key factor in the significance of risks that dpm presents to miners is the very high dpm concentrations to which a number of those miners are currently exposed—compared to ambient atmospheric levels in even the most polluted urban environments, and to workers in diesel-related occupations for which positive epidemiologic results have been reported. Figure III–4 compared the range of median dpm exposure levels measured for mine workers at various mines to the range of medians estimated for other occupations, as well as to ambient environmental levels. Figure III–7 presents a similar comparison, based on the highest mean dpm level observed at any individual mine, the highest mean level reported for any occupational group other than mining, and the highest monthly mean concentration of dpm estimated for ambient air at any site in the Los Angeles basin.[74] As shown in Figure III–7, underground miners are currently exposed at mean levels up to 10 times higher than the highest mean exposure reported for other occupations, and up to 100 times higher than the highest mean environmental level even after adjusting the environmental level upwards to reflect an equivalent occupational exposure.

Given the significant increases in mortality and other acute health effects associated with increments of 25 $\mu g/m^3$ in fine particulate concentration (see Table III–3), the relative risk of acute effects for some miners (especially those already suffering respiratory problems) appears to be extremely high. Acute responses to dpm exposures have been detected in studies of stevedores, whose exposures were likely to have been less than one tenth the exposure of some miners on the job. Likewise, the risk of lung cancer due to dpm exposure would appear to be far greater for those underground miners who are exposed at such high levels than for other workers or general urban populations.

[74] For comparability with occupational lifetime exposure levels, the environmental ambient air concentration has been multiplied by a factor of approximately 4.7. This factor reflects a 45-year occupational lifetime with 240 working days per year, as opposed to a 70-year environmental lifetime with 365-days per year, and assumes that air inhaled during a work shift comprises half the total air inhaled during a 24-hour day.

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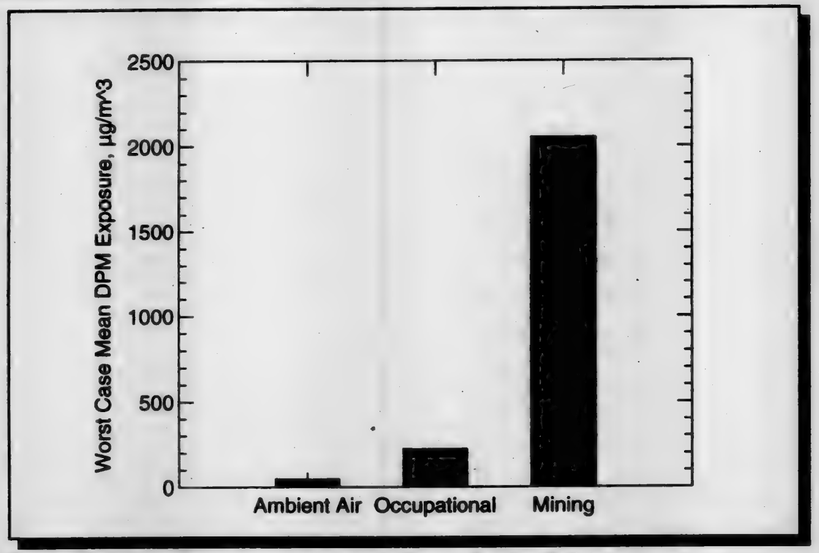


Figure III-7. — Worst case observed or reported mean diesel particulate exposure concentrations for urban ambient air, occupations other than mining, and mining. Worst case for mining is mean dpm measured within an underground mine. Worst case for occupations other than mining is mean respirable particulate matter, other than cigarette smoke, reported for railroad workers classified as hostlers (Woskie et al., 1988). Worst case for ambient air is mean estimated for peak months at most heavily polluted site in Los Angeles area (Cass and Gray, 1995), multiplied by 4.7 to adjust for comparability with occupational lifetime exposure levels. For additional information on means and ranges see Section III.1.d.

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Several commenters asserted that current dpm exposures in underground mines are lower than they were when MSHA conducted its field surveys and that MSHA had not taken this into account when assessing the significance of dpm risk to miners. A related comment was that MSHA had not designed its sampling studies to provide a statistically representative cross section of the entire industry but had nevertheless used the results in concluding that the risk to underground miners was significant.

In accordance with § 101.(a)(6) of the Mine Act, MSHA is basing this risk assessment on the best available evidence. None of the commenters provided evidence that dpm levels in underground metal/nonmetal mines had declined significantly since MSHA's field studies, or provided quantitative estimates of any purported decline in average dpm concentrations, or submitted data that would better represent the range of dpm concentrations to which underground miners are typically exposed at the present time. Although MSHA's field studies were not designed to be statistically representative in a way that can be readily quantified, they were performed at locations selected, according to MSHA's best engineering judgement, to be typical of the type of diesel equipment used. Furthermore, as will be shown below, MSHA's evaluation of the significance of risks presented to underground metal/nonmetal miners by their dpm exposures does not rely on the highest levels, or even the average levels, that MSHA has measured. As documented in Section 1.d of this risk assessment, some of the highest of MSHA's measurements were made as recently as 1996–1997. It is important to note, as is shown below, the cancer risks of dpm exposure are clearly significant even at a concentration of 300 µg/m³—less than half of the average level that MSHA observed in its field studies. Therefore, MSHA believes that a reduction in exposure of more than 50 percent in the last couple of years is highly implausible.

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A number of other governmental and nongovernmental bodies have concluded that, even at the far lower levels evident in other occupational environments or in ambient air, the health risks of dpm exposure are of sufficient significance that exposure should be limited:

(1) In 1988, after a thorough review of the scientific literature, the National Institute for Occupational Safety and Health (NIOSH) recommended that diesel exhaust be controlled to the *lowest feasible exposure level*. The document did not contain a recommended exposure limit.

(2) In 1996, the Federal Republic of Germany classified dpm as "probably carcinogenic for humans" and established legally binding technical limits on dpm concentrations in occupational environments. The classification requires that the "best available technology" be used for emission reduction. The technical concentration limits, applying to all workplaces except coal mines, are the lowest limits thought to be feasible in Germany with current technology. Expressed as limits on elemental carbon (EC), they are: 300 $\mu g/m^3$ for tunneling and non-coal mining; 100 $\mu g/m^3$ for all other workplaces (except coal mines).

(3) An ad hoc committee of the Canada Centre for Mineral and Energy Technology (CANMET) has recommended that a limit of 500 $\mu g/m^3$ RCD be adopted as a goal for underground mining environments.

(4) The International Programme on Chemical Safety (IPCS), which is a joint venture of the World Health Organization, the International Labour Organisation, and the United Nations Environment Programme, performed a comprehensive evaluation of the scientific evidence linking diesel exhaust with adverse health effects (IPCS, 1996). IPCS concluded that inhalation of diesel exhaust is of concern with respect to both neoplastic and non-neoplastic diseases and that the particulate phase appears to have the greatest effect on health. As a result of this evaluation, the IPCS recommended that "in the occupational environment, good work practices should be encouraged, and adequate ventilation must be provided to prevent excessive exposure."

(5) In light of the significant health risks associated with environmental exposures to fine particulates ($PM_{2.5}$), in 1997 the U.S. Environmental Protection Agency revised national air quality standards regulating PM to include $PM_{2.5}$ in the ambient air. Diesel particulate matter was a major constituent of $PM_{2.5}$ in many of the areas forming the basis of the EPA's health risk assessment. (EPA, 1996)

(6) In 1998, the California Environmental Protection Agency identified dpm as a toxic air contaminant, as defined in their Health and Safety Code, Section 39655. According to that section, a toxic air contaminant is an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health. This conclusion, unanimously adopted by the California Air Resources Board and its Scientific Review Panel on Toxic Air Contaminants, initiates a process of evaluating strategies for reducing dpm concentrations in California's ambient air.

(7) In 1999, the American Conference of Governmental Industrial Hygienists (ACGIH) proposed a Threshold Limit Value of 50 $\mu g/m^3$ for the dpm component of diesel exhaust and placed dpm on its Notice of Intended Changes. This ACGIH proposal was based on a determination that occupational exposure levels exceeding 50 $\mu g/m^3$ would present a significant "incremental" or excess risk of lung cancer.

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Earlier in this risk assessment, MSHA identified three types of material impairment that can result from occupational exposures to dpm. The next three subsections present the Agency's evaluation of how much of a risk there is that miners occupationally exposed to dpm will actually incur such consequences. Each part addresses the risk of incurring one of the three types of material impairment identified earlier.

(1) Sensory Irritations and Respiratory Symptoms (Including Allergenic Responses)

It is evident from the direct testimony of numerous miners working near diesel equipment that their exposures pose a significant risk of severe sensory irritations and respiratory symptoms. This was underscored during the workshops and public hearings by several miners who noted that such effects occurred immediately and consistently after episodes of intense exposure (Section 2.b.i). There is also persuasive experimental evidence that exposure at levels found in underground mines frequently cause eye and nose irritation (Rudell et al., 1996) and pulmonary inflammation (Salvi et al., 1999). Section 2.a.ii and 3.a.i of this risk assessment explain why these effects constitute "material impairments" under the Mine Act and why they threaten miners' safety as well as health. Therefore, it is clear that even short-term exposures to excessive concentrations of dpm pose significant risks.

MSHA's quantitative evaluation of how significant the risks of sensory irritations and respiratory symptoms are for miners is limited, by the quantitative evidence available, to acute respiratory symptoms linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. MSHA recognizes that, for miners exposed to dpm, this type of risk cannot be quantified with great confidence or precision based on the available evidence. This is because $PM_{2.5}$ is not solely comprised of dpm and also because miners, as a group, have different demographic and health characteristics from the general populations involved in the relevant studies. However, MSHA believes that the quantitative evidence suffices to establish a lower bound on the significance of this type of risk to miners exposed to dpm. Even at this lower bound, which is likely to substantially underestimate the degree of risk, the probability that a miner's occupational exposure to dpm will cause adverse respiratory effects is clearly significant.

As shown in Table III–3, the risk of acute lower respiratory tract symptoms has been reported to increase, at a 95-percent confidence level, by 15 to 82 percent (RR = 1.15 to 1.82) for each incremental increase of 20 $\mu g/m^3$ in the concentration of $PM_{2.5}$ in the ambient air. This means that the relative risk estimated for a given $PM_{2.5}$ concentration ranges between $(1.15)^k$ and $(1.82)^k$, where k = the concentration of $PM_{2.5}$ divided by 20 $\mu g/m^3$. For example, for a $PM_{2.5}$ concentration of 40 $\mu g/m^3$, the RR is estimated to be between $(1.15)^2$ and $(1.82)^2$, or 1.32 to 3.31. MSHA believes that part of the reason why the range is so wide is that the composition of $PM_{2.5}$ varied in the data from which the estimates were derived.

MSHA acknowledges that there are substantial uncertainties involved in converting 24-hour environmental exposures to 8-hour occupational exposures. However, since mining often involves vigorous physical activity (thereby increasing breathing depth and frequency) and sleep is characterized by reduced respiration, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. If it is assumed that the acute respiratory effects of inhaling dpm at a concentration of 60 $\mu g/m^3$ over an 8-hour workshift are at least as great as those at a concentration of 20 $\mu g/m^3$ over a 24-hour period, then it is possible to estimate a lower bound on the relative risk of such effects.

Based solely on the fact that dpm consists almost entirely of particles much smaller than 2.5 micrometers in diameter, the dpm would be expected to penetrate the lower respiratory tract at least as effectively as $PM_{2.5}$. Also, given the complex chemical composition of dpm, and its generation within a confined space, there is no reason to suspect that dpm in an underground mining environment is less potent than ambient $PM_{2.5}$ in inducing respiratory symptoms. Under these assumptions, a short-term environmental exposure to $PM_{2.5}$ at a concentration of 20 $\mu g/m^3$ would correspond to a short-term occupational exposure to dpm at a concentration of 60 $\mu g/m^3$. Consequently, the RR at an occupational exposure level of Y $\mu g/m^3$ would equal the RR calculated for an ambient exposure level of $20\times(Y/60)$ $\mu g/m^3$. For example, the relative risk (RR) of acute lower respiratory symptoms at an occupational exposure level of 300 $\mu g/m^3$ dpm would, at a minimum, correspond to the RR at an ambient exposure level equal to 5×20 $\mu g/m^3$ $PM_{2.5}$. (See Table III–3) A dpm concentration of 300 $\mu g/m^3$ happens to be the level at which Salvi et al. (1999) found a marked pulmonary inflammatory response in healthy human volunteers after just one hour of exposure.

Under these assumptions, the risk of lower respiratory tract symptoms for a miner exposed to dpm for a full shift at a concentration of 300 $\mu g/m^3$ or more, would be at least twice the risk of ambient exposure (i.e., RR = $(1.15)^8$ = 2.01). This would imply that for miners exposed to dpm at or above this level, the risk of acute lower respiratory symptoms would double, at a minimum. The Secretary considers such an increase in risk to be clearly significant.

(2) Premature Death From Cardiovascular, Cardiopulmonary, or Respiratory Causes

As in the case of respiratory symptoms, the nature of the best available evidence limits MSHA's quantitative evaluation of how large an excess risk of premature death, due to causes other than lung cancer, there is for miners exposed to dpm. As before, this evidence consists of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. Therefore, the analysis is subject to similar uncertainties. However, also as before, MSHA believes that the quantitative evidence suffices to place a lower bound on the increase in risk of premature mortality for miners occupationally exposed to dpm. As will be shown below, even this lower bound, which is likely to substantially underestimate the degree of increase, indicates that a miner's occupational exposure to dpm has a clearly significant impact on the likelihood of premature death.

Schwartz et al. (1996) found an average increase of 1.5 percent in daily mortality associated with each increment of 10 $\mu g/m^3$ in the daily concentration of fine particulates. Higher increases were estimated specifically for ischemic heart disease (IHD: 2.1 percent), chronic obstructive pulmonary disease (COPD: 3.3 percent), and pneumonia (4.0 percent). The corresponding 95-percent confidence intervals for the three specific estimates were, respectively, 1.4% to 2.8%, 1.0% to 5.7%, and 1.8% to 6.2%, per increment of 10 $\mu g/m^3$ in daily $PM_{2.5}$ exposure. Within the range of dust concentrations studied, the response appeared to be linear, with no threshold. The investigators checked for but did not find any consistent or statistically stable relationship between increased mortality and the atmospheric concentration of "course" respirable

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particles—i.e., those with aerodynamic diameter greater than 2.5 micrometers but less than 10 micrometers.

As explained earlier, it is highly likely that miners would inhale at least one-third of their total 24-hour intake of air during a standard 8-hour work shift. Therefore, under the same assumptions made in the previous subsection, the 24-hour average concentrations of $PM_{2.5}$ measured by Schwartz et al. are no more potent, in their impact on mortality risk, than eight-hour average concentrations that are three times as high. As discussed in Section 2.a.iii of this risk assessment, underground miners may be less, equally, or more susceptible than the general population to the acute mortality effects of fine particulates such as dpm. However, miners who smoke tobacco and/or suffer various respiratory ailments fall into groups identified as likely to be especially sensitive (EPA, 1996). Consequently, for such miners occupationally exposed to dpm, the relative risk of each type of premature mortality would be at least equal to the corresponding lower 95-percent confidence limit specified above.

Therefore, MSHA estimates that, on average, each increment of 30 $\mu g/m^3$ in the dpm concentration to which miners are exposed increases the risk of premature death due to IHD, COPD, and pneumonia by a factor of at least 1.4 percent, 1.0 percent, and 1.8 percent, respectively. As noted earlier, these estimates are based on the evidence of acute effects linked to fine particulate exposures ($PM_{2.5}$) in ambient air pollution studies. A lower bound on the increased risk expected at an occupational dpm concentration greater than 30 $\mu g/m^3$, is obtained by raising the relative risks equivalent to these factors (i.e., 1.014, 1.01, and 1.018) to a power, k, equal to the ratio of the concentration to 30 $\mu g/m^3$. For a concentration of 300 $\mu g/m^3$, k = 10; so MSHA estimates the lower bounds on relative risk to be: $(1.014)^{10} = 1.149$ for IHD; $(1.01)^{10} = 1.105$ for COPD; and $(1.018)^{10} = 1.195$ for pneumonia. This means that for miners exposed to dpm at or above this level, MSHA expects the risks to increase by at least 14.9 percent for IHD, 10.5 percent for COPD, and 19.5 percent for pneumonia. The Secretary considers increases of this magnitude to be clearly significant, since the causes of death to which they apply are not rare among miners.

(3) Lung Cancer

In contrast to the two types of risk discussed above, the available epidemiologic data can be used to relate the risk of lung cancer directly to dpm exposures. Therefore, the significance of the lung cancer risk can be evaluated without having to make assumptions about the relative potency of dpm compared to the remaining constituents of $PM_{2.5}$. This removes an important source of uncertainty present in the other two evaluations.

There are two different ways in which the significance of the lung cancer risk may be evaluated. The first way is based on the relative risk of lung cancer observed in the best available epidemiologic studies involving miners (identified as such in Subsections 3.a.iii(1) (b) and (d) of this risk assessment). As will be explained below, this approach leads to an estimated tripling of lung cancer risk for miners exposed to dpm, compared to a baseline risk for unexposed miners. The second way is to calculate the lung cancer risk expected at exposure levels MSHA has observed in underground mines, assuming a specified occupational lifetime and using the exposure-response relationships estimated for underground miners by Johnston et al. (1997) and Säverin et al. (1999). As will be explained further below, this second approach yields a wide range of estimates, depending on which exposure-response relationship and statistical model is used. All of the estimates, however, show at least a doubling of baseline lung cancer risk, assuming dpm exposure for a 45-year occupational lifetime at the average concentration MSHA has observed. Most of the estimates are much higher than this. If the exposure-response relationship estimated for workers in the trucking industry by Steenland et al. (1998) is extrapolated to the much higher exposure levels for miners, the resulting estimates fall within the range established by the two mine-specific studies, thereby providing a degree of corroboration. Since lung cancer is not a rare disease, the Secretary considers even the very lowest estimate—a doubling of baseline risk—to represent a clearly significant risk.

Both of these methods provide quantitative estimates of the degree by which miners' risk of lung cancer is increased by their occupational dpm exposures. The estimate based on exposure-response relationships is more refined, in that it ties the increased risk of lung cancer to specific levels of cumulative dpm exposure. However, this added refinement comes at the price of an additional source of uncertainty: the accuracy of the exposure-response relationship used to calculate the estimate. This additional uncertainty is reflected, in MSHA's evaluation, by a broad range of relative risk estimates, corresponding to the range of exposure-response relationships derived using different statistical models and epidemiologic data. The next two subsections present the details of MSHA's two approaches to analyzing lung cancer risk for miners exposed to dpm, along with MSHA's responses to the relevant public comments.

(a) Risk Assessment Based on Studies Involving Miners

As one commenter pointed out, the epidemiologic evidence showing an elevated risk of lung cancer for exposed workers is mostly based on occupations estimated to experience far lower exposure levels, on average, than those observed in many underground mines:

> * * *[U]nderground coal, metal and non-metal miners face a significant risk of lung cancer from occupational exposure to diesel particulate. Numerous epidemiologic studies of workers exposed to levels far below those experienced by coal, metal and non-metal miners have found the risk for exposed workers to be 30–50% greater than for unexposed workers. [Washington State Dept. of Labor and Industries]

Indeed, although MSHA recognizes that results from animal studies should be extrapolated to humans with caution, it is noteworthy that dpm exposure levels recorded in some underground mines (see Figures III–1 and III–2) have been well within the exposure range that produced tumors in rats (Nauss et al., 1995).

Both existing meta-analyses of the human studies relating dpm exposure and lung cancer excluded studies on miners but presented evidence showing that, averaged across all other occupations, dpm exposure is responsible for an increase of about 40 percent in lung cancer risk (See Section 3.a.iii(2) of this risk assessment). Even a 40-percent increase in the risk of lung cancer would clearly be significant, since this would amount to more than two cases of lung cancer per year per thousand miners at risk, and to an even greater risk for smoking miners. The best available evidence, however, indicates (1) that exposure levels in underground mines generally exceed exposures for occupations included in the meta-analyses and (2) that lung cancer risks for exposed miners are elevated to a greater extent than for other occupations.

As Dr. Valberg and other commenters pointed out, the epidemiologic studies used in the meta-analyses involved much lower exposure levels than those depicted for mines in Figures III–1 and III–2. The studies supporting a 40-percent excess risk of lung cancer were

conducted on populations whose average exposure is estimated to be less than 200 $\mu g/m^3$—less than one tenth the average concentration MSHA observed in some underground mines. More specifically, average exposure levels in the two most extensively studied industries—trucking (including loading dock workers) and railroads—have been reported to be far below the levels observed in underground mining environments. For workers at docks employing diesel forklifts—the occupational group estimated to be most highly exposed within the trucking industry—the highest average dpm concentration reported was about 55 $\mu g/m^3$ EC at an individual dock (NIOSH, 1990). As explained in Subsection 1.d of this risk assessment, this corresponds to less than 150 $\mu g/m^3$ of dpm, on average. Published dpm measurements for railworkers have generally also been less than 150 $\mu g/m^3$ (measured as respirable particulate matter other than cigarette smoke). The reported mean of 224 $\mu g/m^3$ for hostlers displayed in Figure III–7 represents only the worst-case occupational subgroup (Woskie et al., 1988). In contrast, in the study on underground potash miners by Säverin et al. (1999), the mean TC concentration measured for production areas was 390 $\mu g/m^3$—corresponding to a mean dpm concentration of about 490 $\mu g/m^3$. As shown in Table III–1, the mean dpm exposure level MSHA observed in underground production areas and haulageways was 644 $\mu g/m^3$ for coal mines and 808 $\mu g/m^3$ for M/NM.

In accordance with the higher exposure levels for underground miners, the five studies identified in Section III.3.a.iii(1)(d) as comprising the best available epidemiologic evidence on miners all show that the risk of lung cancer increased for occupationally exposed miners by substantially more than 40 percent. The following table presents the relative risk (RR) of lung cancer for miners in these studies, along with the geometric mean based on all five studies:

Study	Relative risk of lung cancer
Boffetta et al., 1988	2.67
Burns & Swanson, 1991	5.03
Johnston et al., 1997 (mine-adjusted model applied at highest cumulative exposure)	5.50
Lerchen et al., 1987	2.1
Säverin et al., 1999 (highest vs least exposed)	2.17
geometric mean	3.2

As shown in this table, the estimated RR based on these five studies is 3.2 for miners exposed to dpm. In other words, the risk of lung cancer for the highly exposed miners is estimated to be 3.2 times that of a comparable group of occupationally unexposed workers. The geometric mean RR remains 3.2 if the two studies on which MSHA places less weight (by Burns & Swanson and by Lerchen) are excluded from the calculation. This represents a 220-percent increase in the risk of lung cancer for exposed miners, in contrast to the 40-percent increase estimated, on average, for other occupationally exposed workers. The Secretary believes that a 40-percent increase in the risk of lung cancer already exceeds, by a wide margin, the threshold for a clearly significant risk. However, a 220-percent increase to more than three times the baseline rate is obviously of even greater concern.

Some commenters questioned whether increased lung cancer risks of this magnitude were plausible, since they were not aware of any unusually high lung cancer rates among workers at mines with which they were familiar and which used diesel equipment. There are several reasons why an elevated risk of lung cancer might not currently be conspicuous among U.S. miners exposed to dpm. Lung cancer not only may require a latency period of 30 or more years to develop, but it may also not develop until beyond the normal retirement age of 65 years. Cases of lung cancer developing after retirement may not all be known to members of the mining community. Also, in a population that includes many tobacco smokers, it may be difficult to discern cases of lung cancer specifically attributable to dpm exposure when they first begin to become prevalent. Two commenters expressed some of the relevant considerations as follows. Although they were referring to coal miners, the same points apply to M/NM miners.

> Because the latency period for lung cancer is so long, and diesel-powered equipment has only been used extensively in U.S. coal mines for about 25 years, the epidemic may well be progressing unnoticed. [UMWA]
>
> If dpm exposure will cause cancer, there is a huge population of miners here in the West that have already been exposed. Considering the latency periods indicated by MSHA, these miners should be beginning to develop cancers. [Canyon Fuels]

(b) Risk Assessment Based on Miners' Cumulative Exposure

Although it is evident that underground miners currently face a significant risk of lung cancer due to their occupational exposure to dpm, there are certain advantages in utilizing an exposure-response relationship to quantify the degree of risk at specific levels of cumulative exposure. As some commenters pointed out, for example, dpm exposure levels may change over time due to changes in diesel fuel and engine design. The extent and patterns of diesel equipment usage within mines also has changed significantly during the past 25 years, and this has affected dpm exposure levels as well. Furthermore, exposure levels at the mines involved in epidemiologic studies were not necessarily typical or representative of exposure levels at mines in general. A quantitative exposure-response relationship provides an estimate of the risk at any specified level of cumulative exposure. Therefore, using such a relationship to assess risk under current or anticipated conditions factors in whatever differences in exposure levels may be relevant, including those due to historical changes.

(i) Exposure-Response Relationships from Studies Outside Mining

Stayner et al. (1998) summarized quantitative risk assessments based on exposure-response relationships for dpm published through 1998. These assessments were broadly divided into those based on human studies and those based on animal studies. Depending on the particular studies, assumptions, statistical models, and methods of assessment used, estimates of the exact degree of risk varied widely even within each broad category. However, as presented in Tables III and IV of Stayner et al. (1998), all of the very different approaches and methods published through 1998 produced results indicating that levels of dpm exposure measured at some underground mines present an unacceptably high risk of lung cancer for miners—a risk significantly greater than the risk they would experience without the dpm exposure.[75]

[75] In comments submitted by MARG, Dr. Jonathan Borak asserted that MSHA had "misrepresented the findings of a critical study" by stating that all methods showed an "unacceptably high risk" at exposure levels found at some mines. Dr. Borak claimed that Stayner et al. (1998) had described an analysis by Crump et al. "that reached an opposite conclusion." Dr. Borak failed to distinguish between a finding of high risk and a finding of changes in that risk corresponding to changes in estimated exposures. The findings to which Dr. Borak referred pertained only to the exposure-response relationship within the group of exposed workers. Garshick (1981), Crump (1999), and HEI (1999) all noted that the risk of lung cancer was nevertheless elevated among the exposed workers, compared to unexposed workers in the same cohort.

Continued

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Quantitative risk estimates based on the human studies were generally higher than those based on analyses of the rat inhalation studies. As indicated by Tables 3 and 4 of Stayner et al. (1998), a working lifetime of exposure to dpm at 500 μg/m³ yielded estimates of excess lung cancer risk ranging from about 1 to 200 excess cases of lung cancer per thousand workers based on the rat inhalation studies and from about 50 to 800 per thousand based on the epidemiologic assessments. Stayner et al. (1998) concluded their report by stating:

> The risk estimates derived from these different models vary by approximately three orders of magnitude, and there are substantial uncertainties surrounding each of these approaches. Nonetheless, the results from applying these methods are consistent in predicting relatively large risks of lung cancer for miners who have long-term exposures to high concentrations of DEP [i.e., dpm]. This is not surprising given the fact that miners may be exposed to DEP [dpm] concentrations that are similar to those that induced lung cancer in rats and mice, and substantially higher than the exposure concentrations in the positive epidemiologic studies of other worker populations.

Restricting attention to the exposure-response relationships derived from human data, Table IV of Stayner et al. (1998) presented estimates of excess lung cancer risk based on exposure-response relationships derived from four different studies: Waller (1981) as analyzed by Harris (1983); Garshick et al. (1987) as analyzed by Smith and Stayner (1991); Garshick et al. (1988) as analyzed by California EPA (1998); and Steenland et al. (1998). Harris (1983) represented upper bounds on risk; and all of the other estimates represented the most likely value for risk, given the particular data and statistical modeling assumptions on which the estimate was based. Three different ranges of estimates were presented from the California EPA analysis, corresponding to various statistical models and assumptions about historical changes in dpm exposure among the railroad workers involved. As mentioned above and in the proposed version of this risk assessment, the low end of the range of estimates was 50 lung cancers per 1000 workers occupationally exposed at 500 μg/m³ for a 45-year working lifetime. This estimate was one of those based on railroad worker data from Garshick et al. (1988).

Several commenters objected to MSHA's reliance on any of the exposure-response relationships derived from the data compiled by Garshick et al. (1987) or Garshick et al. (1988). These objections were based on re-analyses of these data by Crump (1999) and HEI (1999), using different statistical methods and assumptions from those used by Cal-EPA (1998). For example, the NMA quoted HEI (1999) as concluding:

> At present, the railroad worker cohort study * * * has very limited utility for QRA [quantitative risk assessment] of lifetime lung cancer risk from exposure to ambient levels of diesel exhaust * * * [NMA, quoting HEI (1999)]

From this, the NMA argued as follows:

> What then is the relevance of this data to the proceedings at issue? Simply put, there is no relevance. The leading epidemiologist [sic], including Dr. Garshick himself, now agree that the data are inappropriate for conducting risk assessment. [NMA]

MSHA notes that the HEI (1999) conclusion cited by the NMA referred to quantitative risk assessments at ambient, not occupational, exposure levels. Also, HEI (1999) did not apply its approach (i.e., investigating the correlation between exposure and relative risk within separate job categories) to the Armitage-Doll model employed by Cal-EPA in some of its analyses. (Results using this model were among those summarized in Table IV of Stayner et al., 1998). Therefore, the statistical findings on which HEI (1999) based its conclusion do not apply to exposure-response relationships estimated using the Armitage-Doll model. Furthermore, although HEI concluded that the railroad worker data have "very limited utility for *QRA * * * at ambient levels*" [emphasis added], this does not mean, even if true, that these data have "no relevance" to this risk assessment, as the NMA asserted. Even if they do not reliably establish an exposure-response relationship suitable for use in a quantitative risk assessment, these data still show that the risk of lung cancer was significantly elevated among exposed workers. This is the only way in which MSHA is now using these data in this risk assessment.

In the proposed risk assessment, MSHA did not rely directly on the railroad worker data but did refer to the lowest published quantitative estimate of risk, which happened, as of 1998, to be based on those data. MSHA's reasoning was that, even based on the lowest published estimate, the excess risk of lung cancer attributable to dpm exposure was clearly sufficient to warrant regulation. If risk assessments derived from the railroad worker data are eliminated from consideration, the lowest estimate remaining in Table IV of Stayner et al. (1998) is obviously even higher than the one that MSHA used to make this determination in the proposed risk assessment. This estimate (based on one of the analyses performed by Steenland et al., 1998) is 89 excess cases of lung cancer per year per thousand workers exposed at 500 μg/m³ for a 45-year working lifetime.

HEI (1999) also evaluated the use of the Steenland data for quantitative risk assessment, but did not perform any independent statistical analysis of the data compiled in that study. Some commenters pointed out HEI's reiteration of the cautionary remark by Steenland et al. (1998) that their exposure assessment depended on "broad assumptions." The HEI report did not rule out the use of these data for quantitative risk assessment but suggested that additional statistical analyses and evaluations were desirable, along with further development of exposure estimates using alternative assumptions. MSHA has addressed comments on various aspects of the analysis by Steenland et al., including the exposure assumptions, in Section 2.c.i(2)(a) of this risk assessment.

One commenter noted that Steenland et al. (1998) had recognized the limitations of their analysis and had, therefore, advised that the results "should be viewed as exploratory." The commenter then asserted that MSHA had nevertheless used these results as "the basis for a major regulatory standard" and that "[t]his alone is sufficient to demonstrate that MSHA's proposal lacks the necessary scientific support." [Kennecott Minerals]

The Secretary does not accept the premise that MSHA should exclude "exploratory" results from its risk assessment, even if it is granted that those results depend on broad assumptions possibly requiring further research and validation before they are widely accepted by the scientific community. Steenland et al. (1998) estimated risks associated with specific cumulative exposures, based on estimates of historical exposure patterns combined with data originally described by Steenland et al., 1990 and 1992. Regardless of whether the cumulative exposure estimates used by Steenland et al. (1998) are sufficiently reliable to permit pinpointing the risk of lung cancer at any given exposure level, the quantitative analysis indicates that as cumulative exposure increases, so does the risk. Therefore, the 1998 analysis adds significantly to the weight of evidence supporting a causal

and they all identified reasons why the data used in this study might fail to detect a positive exposure-response relationship among the exposed workers.

relationship. However, MSHA did not use or propose to use exposure-response estimates derived by Steenland et al. (1998) as the sole basis for any regulatory standard.

The exposure-response relationships presented by Steenland et al. were derived from exposures estimated to be far below those found in underground mines. As Stayner et al. (1998) point out, questions are introduced by extrapolating an exposure-response relationship beyond the exposures used to determine the relationship. The uncertainties implicit in such extrapolation are demonstrated by comparing results from two statistical models based on five-year lagged exposures—one using simple cumulative exposure and the other using the natural logarithm of cumulative exposure (Steenland et al., 1998, Table II).

Assuming that, on average, EC comprises 40 percent of total dpm,[76] the formula for calculating a relative risk (RR) using Steenland's simple cumulative exposure model is RR = exp(0.4×0.389×CumExp), where CumExp is occupationally accumulated dpm exposure (expressed in mg-yr/m³), ignoring the most recent five years. Again assuming EC=0.4×dpm, the corresponding formula using Steenland's Log(CumExp) model is: RR = exp(0.1803×(Log(0.4×1000×CumExp + BG) − Log(BG))), still ignoring occupational dpm exposure in the most recent five years.[77]

The risk estimates from these two models are similar at the cumulative exposure levels estimated for workers involved in the study, but the projected risks diverge markedly at the higher exposures projected for underground miners exposed to dpm for a 45-year occupational lifetime. For example, a cumulative dpm exposure of 2.5 mg-yr/m³ (i.e., 45 years of occupational exposure at an average dpm concentration of about 55.6 μg/m³) is within the range of cumulative exposures from which these exposure-response relationships were estimated. At this level of cumulative exposure, the models (both lagged five years) yield relative risk estimates of 1.48 (based on simple cumulative exposure) and 1.64 (based on the logarithm of cumulative exposure, with BG=70 μg-yr/m³). On the other hand, 45 years of occupational exposure at an average dpm concentration of 808 μg/m³ amounts to a cumulative dpm exposure of 36,360 μg-yr/m³, or about 36.4 mg-yr/m³. At this level, which lies well beyond the range of data used by Steenland et al. (1998), the simple and logarithmic exposure models produce relative risk estimates of about 300 and 2.6, respectively.

Despite the divergence of these two models at high levels of cumulative exposure, they can provide a useful check of excess lung cancer risks estimated using exposure-response relationships developed from other studies. For highly exposed miners, the Steenland models both produce estimates of lung cancer risk within the range established by the two miner studies discussed below. This corroborates the upper and lower limits on such risk as estimated by the various statistical models used in those two studies.

(ii) Exposure-Response Relationships from Studies on Miners

As described in Section 2.c.i(2)(a) of this risk assessment, two epidemiologic studies, both conducted on underground miners, provide exposure-response relationships based on fully quantitative dpm exposure assessments. Johnston et al. (1997) conducted their study on a cohort of 18,166 underground coal miners, and Säverin et al. (1999) conducted theirs on a cohort of 5,536 underground potash miners. Each of these studies developed a number of possible exposure-response relationships, depending on the statistical model used for analysis and, in the case of Saverin et al. (1999), inclusion criteria for the cohort analyzed. For purposes of this risk assessment, MSHA has converted the units of cumulative exposure in all of these exposure-response relationships to mg-yr/m³.

Two exposure-response relationships derived by Johnston et al. (1997) are used in this risk assessment, based on a "mine-adjusted" and a "mine-unadjusted" statistical model. In both of these models, cumulative dpm exposure is lagged by 15 years.[78] This reflects the long latency period required for development of lung cancer and means that the most recent 15 years of exposure are ignored when the relative risk of lung cancer is estimated. The exposure-response relationships, as reported by the investigators, were expressed in terms of g-hr/m³ of cumulative dpm exposure. MSHA has converted the exposure units to mg-yr/m³ by assuming 1920 work hours per year.

Two different methods of statistical analysis were applied by Saüverin et al. (1999) to both the full cohort and to a subcohort of 3,258 miners who had worked underground, in relatively stable jobs, for at least ten years. Thus, the investigators developed a total of four possible exposure-response relationships from this study. Since they were based on measurements of total carbon (TC), these exposure-response relationships were expressed in terms mg-yr/m³ of cumulative TC exposure. MSHA has converted the exposure units to mg-yr/m³ of cumulative dpm exposure by assuming that, on average, TC comprises 80 percent of total dpm.

The following table summarizes the exposure-response relationships obtained from these two studies. Each of the quantitative relationships is specified by the unit relative risk (RR) per mg-yr/m³ of cumulative dpm exposure. To calculate the relative risk estimated for a given cumulative dpm exposure (CE), it is necessary to raise the unit RR to a power equal to CE. For example, if the unit RR is 1.11 and CE = 20, then the estimated relative risk is $(1.11)^{20} = 8.1$. Therefore, the estimated relative risk of lung cancer increases as CE increases. For the two Johnston models, CE does not include exposure accumulated during the 15 years immediately prior to the time in a miner's life at which the relative risk is calculated.

[76] The assumption is that, on average, EC = TC/2 and TC = 0.8×dpm.

[77] BG, expressed in μg-yr/m³, accounts for an assumed background (i.e., non-occupational) EC exposure level of 1.0 μg/m³. At age 70, after a 45-year worklife and an additional 5-year lag after retirement, BG is assumed to equal 70 μg-yr/m³. "Log" refers to the natural logarithm, and "exp" refers to the antilogarithm of the subsequent quantity.

[78] The 15-year lagged mine-unadjusted and mine-adjusted models are respectively denoted by M/03 and M/06 in Table 11.2 of Johnston et al. (1997). As explained earlier, the individual mines considered in this study differed significantly with respect to both dpm exposures and lung cancer experience. The investigators could not determine exactly how much, if any, of the increased lung cancer risk associated with dpm exposure depends on other, unknown factors differentiating the individual mines. The mine-adjusted model allocates a significant number of the lung cancers otherwise attributable to dpm exposure to the "norm" for specific mines. Therefore, if the differences in lung cancer prevalence between mines is actually due to corresponding differences in mean dpm exposure, then this model will mask a significant portion of the risk due to dpm exposure. After adjusting for miners' age and smoking habits, the mine-unadjusted model attributes differences in the prevalence of lung cancer between mines to corresponding differences in mean dpm exposure. However, the mine-adjusted model has the advantage of taking into account differences between mines with respect to potentially confounding factors, such as radon progeny and silica levels.

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EXPOSURE-RESPONSE RELATIONSHIPS OBTAINED FROM TWO STUDIES ON UNDERGROUND MINERS.

Study and statistical model	Unit RR per mg-yr/m³ dpm
Säverin et al. (1999)[1]:	
Poisson, full cohort	1.024
Cox, full cohort	1.089
Poisson, subcohort	1.110
Cox, subcohort	1.176
Johnston et al. (1997)[2]:	
15-year lag, mine-adjusted	1.321
15-year lag, mine-unadjusted	1.479

[1] Unit RR calculated from Tables III and IV, assuming TC = 0.8×dpm.
[2] Unit RR calculated from Table 11.2, assuming 1920 work hours per year.

For example, suppose a miner is occupationally exposed to dpm at an average level of 500 μg/m³. Then each year of occupational exposure would contribute 0.5 mg-yr/m³ to the miner's cumulative dpm exposure. Suppose also that this miner's occupational exposure begins at age 45 and continues for 20 years until retirement at age 65. Consequently, at or above age 65, this hypothetical miner would have accumulated a total of 10 mg-yr/m³ of occupational dpm exposure. According to the Säverin-Cox-subcohort model, the relative risk estimated for this miner after retirement is $RR = (1.176)^{10} = 5.1$. This means that, at or above age 65, the retired miner's risk of lung cancer is estimated (by this model) to be about five times that of another retired miner having the same age and smoking history but no occupational dpm exposure.

Since the two Johnston models exclude exposure within the last 15 years, it is instructive to calculate the relative risk using these models for the same hypothetical retiree at age 75. Since this miner retired at age 65, immediately after 20 years of occupational exposure, the cumulative exposure used in applying the Johnston models must be reduced by the 2.5 mg-yr/m³ accumulated from age 60 to age 65. Therefore, according to the Johnston mine-adjusted model, the relative risk estimated for this retired miner at age 75 is $RR = (1.321)^{7.5} = 8.1$. At age 80 or above, however, this model predicts that the relative risk would increase to $RR = (1.321)^{10} = 16.2$.

The six exposure-response relationships obtained from these two studies establish a range of quantitative risk estimates corresponding to a given level of cumulative dpm exposure. This range provides lower and upper limits on the risk of lung cancer for workers exposed at the given level, relative to similar workers who were not occupationally exposed. The lower limit of this range is established by Säverin's full cohort Poisson model. Therefore, the lowest estimate of relative risk after 45 years of occupational dpm exposure is $RR = (1.024)^{45 \times 0.644} = 2.0$ at a mean concentration of 644 μg/m³ or $RR = (1.024)^{45 \times 0.808} = 2.4$ at mean concentration of 808 μg/m³. These exposure levels correspond to the averages presented in Table III–1 for underground coal and underground M/NM mines, respectively.

A relative risk of 2.0 amounts to a doubling of the baseline lung cancer risk, and all of the models project relative risks of at least 2.0 after 45 years of exposure at these levels. Therefore, MSHA expects that underground miners exposed to dpm at these levels for a full 45-year occupational lifetime would, at a minimum, experience lung cancer at a rate twice that of unexposed but otherwise similar miners. Five of the six statistical models, however, predict a relative risk much greater than 2.0 after 45 years at a mean dpm concentration of 644 μg/m³. The second-lowest estimate of relative risk, for example, is $RR = (1.089)^{45 \times 0.644} = 11.8$, predicted by Säverin's full cohort Cox model.[79]

[79] Some commenters contended that MSHA cannot establish a reliable exposure-response relationship because of potential interferences in MSHA's dpm concentration measurements. More specifically, some of these commenters claimed that MSHA's dpm measurements in underground coal mines were significantly inflated by submicrometer coal dust.

As explained in Subsection 1.a of this risk assessment, the sampling device MSHA used to measure dpm in underground coal mines was designed specifically to allow for the submicrometer fraction of coal dust. Both the size-selective and RCD methods are reasonably accurate when dpm concentrations exceed 300 μg/m³. Moreover, neither of these methods was used to establish the exposure-response relationships presented by Säverin et al. (1999) or Johnston *et al.* (1997).

In the next subsection of this risk assessment, relative risks will be combined with baseline lung cancer and mortality data to estimate the lifetime probability of dying from lung cancer due to occupational dpm exposure.

(iii) Excess Risk at Specific dpm Exposure Levels. The "excess risk" discussed in this subsection refers to the lifetime probability of dying from lung cancer resulting from occupational exposure to dpm for 45 years. This probability is expressed as the expected excess number of lung cancer deaths per thousand miners occupationally exposed to dpm at a specified level. The excess is calculated relative to baseline, age-specific lung cancer mortality rates taken from standard mortality tables. In order to properly estimate this excess, it is necessary to calculate, at each year of life after occupational exposure begins, the expected number of persons surviving to that age with and without dpm exposure at the specified level. At each age, standard actuarial adjustments must be made in the number of survivors to account for the risk of dying from causes other than lung cancer.

Table III–7 shows the excess risk of death from lung cancer estimated across the range of exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). Estimates based on the 5-year lagged models from Steenland et al. (1998) fall within this range and are included for comparison. Based on each of the eight statistical models, the excess risk was estimated at four levels of dpm exposure: 200 μg/m³, 500 μg/m³, 644 μg/m³ (the mean dpm concentration observed by MSHA at underground coal mines, as shown in Table III–1), and 808 μg/m³ (the mean dpm concentration observed by MSHA at underground M/NM mines, as shown in Table III–1).

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Table III-7. — Lifetime excess risk of lung cancer mortality at specific dpm exposure levels.

Study and Statistical Model	Excess Lung Cancer Deaths per 1000 Occupationally Exposed Workers[1]			
	200 μg/m³	500 μg/m³	644 μg/m³	808 μg/m³
Säverin et al. (1999)				
Poisson, full cohort	15	44	61	83
Cox, full cohort	70	280	422	577
Poisson, subcohort	93	391	563	693
Cox, subcohort	182	677	761	802
Steenland et al. (1998)				
5-year lag, log of cumulative exposure	67	89	95	101
5-year lag, simple cumulative exposure	159	620	721	771
Johnston et al. (1997)				
15-year lag, mine-adjusted	313	724	770	800
15-year lag, mine-unadjusted	513	783	811	830

[1] Assumes 45-year occupational exposure at 1920 hours per year from age 20 to retirement at age 65. Lifetime risk of lung cancer adjusted for competing risk of death from other causes and calculated through age 85. Baseline lung cancer and overall mortality rates from NCHS (1996).

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All of the estimates in Table III–7 assume that occupational exposure begins at age 20 and continues until retirement at age 65. Excess risks were calculated through age 85 as in Table IV of Stayner et al. (1998). Table III–7 differs from Table IV of Stayner et al. in that results from Johnston et al. and Säverin et al. are substituted for results based on the two studies by Garshick et al. Nevertheless, at 500 $\mu g/m^3$, the range of excess risks shown in Table III–7 is nearly identical to the range (50 to 810 $\mu g/m^3$) presented in Table IV of Stayner et al. (1998).

MSHA considers the exposure levels shown in Table III–1 to be typical of current conditions in underground coal mines using diesel face equipment. At the mean dpm concentration observed by MSHA at underground M/NM mines (808 $\mu g/m^3$), the eight estimates range from 83 to 830 excess lung cancer deaths per 1000 affected miners. At the mean dpm concentration observed by MSHA at underground coal mines (644 $\mu g/m^3$), the estimates range from 61 to 811 excess lung cancer deaths per 1000 affected miners. MSHA recognizes that these risk estimates involved extrapolation beyond the exposure experience of the miner cohorts in Säverin et al. (1999) and Johnston et al. (1997). However, the degree of extrapolation was less for those two studies than the extrapolation that was necessary for the diesel-exposed truck drivers in Steenland et al. The lowest excess lung cancer risk in dpm exposed miners found in Table III–7 is 61/1000 per 45-year working lifetime. Based on the quantitative rule of thumb established in the benzene case, this estimate indicates a clearly significant risk of lung cancer attributable to dpm exposure at current levels. [*Industrial Union* vs. *American Petroleum;* 448 U.S. 607, 100 S.Ct. 2844 (1980)].

c. The Rule's Expected Impact on Risk

MSHA strongly disagrees with the views of some commenters who asserted that the proposed rules would provide no known or quantifiable health benefit to mine workers. On the contrary, MSHA's assessment of the best available evidence indicates that reducing the very high exposures currently existing in underground mines will significantly reduce the risk of three different kinds of material impairment to miners: (1) Acute sensory irritations and respiratory symptoms (including allergenic responses); (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes; and (3) lung cancer. Furthermore, as will be shown below, the reduction in lung cancer risk expected as a result of the rule can readily be quantified based on the estimates of excess risk at exposure levels given in Table III–7.

Using exposure-response relationships and assumptions described in Subsections 3.b.ii(1) and 3.b.ii(2) of this risk assessment, MSHA estimated lower bounds on the significance of risks faced by miners occupationally exposed to dpm with respect to (1) acute sensory irritations and respiratory symptoms or (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. MSHA expects the rules to significantly and substantially reduce all three kinds of risk. However, MSHA is unable, based on currently available data, to quantify with confidence the reductions expected for the first two kinds. A 24-hour exposure at 20 $\mu g/m^3$ may not have the same short-term effects as an 8-hour exposure at 60 $\mu g/m^3$. Furthermore, this concentration is only 30 percent of the maximum dpm concentration that MSHA expects once the rules are fully implemented and represents an even smaller fraction of average dpm concentrations many underground miners currently experience. It is unclear whether the same incremental effects on acute respiratory symptoms and premature mortality would apply at the much higher exposure levels found in underground mines. Additionally, as MSHA suggested in the proposed preamble and several commenters repeated, the toxicity of dpm and $PM_{2.5}$ may differ because of differences in composition. Finally, underground miners as a group may differ significantly from the populations for which the $PM_{2.5}$ exposure-response relationships were derived.

Therefore, MSHA's quantitative assessment of the rule's impact on risk is restricted to its expected impact on the third kind of risk—the risk of lung cancer. The rule will limit dpm concentrations to which miners in underground M/NM mines are exposed. The rule will limit these dpm concentrations to approximately 200 $\mu g/m^3$ by limiting the measured concentration of total carbon to 160 $\mu g/m^3$. Assuming that, in the absence of this rule, underground M/NM miners would be occupationally exposed to dpm for 45 years at a mean level of 808 $\mu g/m^3$, the following table contains the estimated reductions in lifetime risk expected to result from full implementation of the rule, based on the various exposure-response relationships obtained from Säverin et al. (1999) and Johnston et al. (1997). These estimates were obtained by calculating the difference between the corresponding estimates of excess lung cancer mortality, at 808 $\mu g/m^3$ and 200 $\mu g/m^3$, shown in Table III–7. The Regulatory Impact Analysis (RIA), presented later in this preamble, contains further quantitative discussion of the benefits anticipated from this rule.

REDUCTION IN LIFETIME RISK OF LUNG CANCER MORTALITY EXPECTED AS RESULT OF REDUCING EXPOSURE LEVEL FROM 808 $\mu G/M^3$ TO 200 $\mu G/M^3$.

Study and statistical model	Expected reduction in lung cancer deaths per 1000 affected miners[1]
Säverin et al. (1999):	
Poisson, full cohort	68
Cox, full cohort	507
Poisson, subcohort	600
Cox, subcohort	620
Johnston et al. (1997):	
15-year lag, mine-adjusted	487
15-year lag, mine-unadjusted	317

[1] Calculated from Table III–7.

Although the Agency expects that health risks will be substantially reduced by this rule, the best available evidence indicates that a significant risk of adverse health effects due to dpm exposures will remain even after the rule is fully implemented. As explained in Part V of this preamble, however, MSHA has concluded that, due to monetary costs and technological limitations, the underground M/NM mining sector as a whole cannot feasibly reduce dpm concentrations further at this time.

4. Conclusions

MSHA has carefully considered all of the evidence and public comment submitted during these proceedings to determine whether dpm exposures, at levels observed in some mines, present miners with significant health risks. This information was evaluated in light of the legal requirements governing regulatory action under the Mine Act. Particular attention was paid to issues and questions raised by the mining community in response to the Agency's ANPRM and NPRM and during workshops on dpm held in 1995. Based on its review of the record as a whole, the agency has determined that the best available evidence warrants the following conclusions:

1. Exposure to dpm can materially impair miner health or functional capacity. These material impairments include acute sensory irritations and respiratory symptoms (including allergenic responses); premature death from cardiovascular, cardiopulmonary, or respiratory causes; and lung cancer.

2. At dpm levels currently observed in underground mines, many miners are presently at significant risk of incurring these material impairments due to their occupational exposures to dpm over a working lifetime.

3. By reducing dpm concentrations in underground mines, the rule will substantially reduce the risks of material impairment faced by underground miners exposed to dpm at current levels.

In its response to MSHA's proposals, the NMA endorsed these conclusions to a certain extent, as follows:

> The members of NMA have come to recognize that it would be prudent to limit miners' exposure to the constituents of diesel exhaust in the underground environment. [NMA]

A number of commenters, however, urged MSHA to defer rulemaking for either the coal or M/NM sector, or both, until results were available from the NCI/NIOSH study currently underway. For example, referring to the M/NM proposal, one commenter stated:

> Vulcan agrees with MSHA that underground miner dpm exposure needs to be addressed by mine operators. Vulcan agrees with MSHA that a permissible exposure level (PEL) should be established, but disagrees that adequate information is currently available to set a PEL. [Vulcan Materials]

MSHA believes that expeditious rulemaking, in both underground mining sectors, is necessary for the following reasons:

(1) The NCI/NIOSH study currently in progress will eventually provide additional information on lung cancer mortality. Non-cancer health effects, such as sensory irritations, respiratory symptoms, or premature death from cardiovascular, cardiopulmonary, or respiratory causes will not be addressed. MSHA believes that these non-cancer effects constitute material impairments.

(2) NIOSH itself has recommended that, "* * * given the length of time to complete this study and the current state of knowledge regarding dpm exposures and health effects in miners," MSHA should "proceed with rulemaking based on the evidence currently available as presented in this FR notice." [NIOSH testimony by Paul Schulte, dated 5/27/99]

(3) Given the very high exposure levels measured at some underground mines, miners should not be required to serve as human guinea pigs in order to remove all doubts about the excess risks of dpm exposures in underground mines. While additional studies are in progress, miners should be protected by reducing dpm concentrations to a level more nearly commensurate with exposures in other industries.

Referring to some commenters' position that further scientific study was necessary before regulatory action could be justified, a miner at one of the dpm workshops held in 1995 said:

> * * * if I understand the Mine Act, it requires MSHA to set the rules based on the best set of available evidence, not possible evidence * * * Is it going to take us 10 more years before we kill out, or are we going to do something now * * *? (dpm Workshop; Beckley, WV, 1995).

Similar concern with the risk of waiting for additional scientific evidence was expressed by another miner, who testified:

> * * * I got the indication that the diesel studies in rats could no way be compared to humans because their lungs are not the same * * * But * * * if we don't set the limits, if you remember probably last year when these reports come out how the government used human guinea pigs for radiation, shots, and all this, and aren't we doing the same thing by using coal miners as guinea pigs to set the value? (dpm Workshop; Beckley, WV, 1995).

MSHA shares these sentiments. That is why MSHA considers it imperative to protect miners based on the weight of existing evidence, rather than to wait for the results of additional studies.

IV. Section by Section Discussion of Final Rule

This part of the preamble describes the provisions of the final rule on a section-by-section basis. As appropriate, this part references discussions in other parts of this preamble: in particular, the background discussions on measurement methods and controls in part II, and the feasibility discussions in part V.

The final rule would add nine new sections to 30 CFR Part 57 immediately following § 57.5015. It would not amend any existing sections of that part.

Many provisions of the final rule are identical to the proposed rule, but some provisions have been changed. The following table provides a quick overview of the key changes:

Section	Final rule (changes from proposal)
57.5060	When specified conditions have been met and various precautions have been taken (including use of proper PPE), miners performing certain inspection, maintenance and repair activities may be granted permission from MSHA to work in certain areas where miners normally work and travel, but where the dpm concentration limit is exceeded (not authorized in proposed rule)
57.5061	Compliance sampling must always be done with submicrometer impactor (unspecified in proposed rule)
57.5067	Engines meeting the applicable EPA requirements as per a table provided in the rule may be introduced underground after rule's effective date (under proposal, only MSHA approved engines were so allowed)

Section 57.5060 Limit on Concentration of Diesel Particulate Matter

Summary. This section of the final rule limits the concentration of dpm in underground metal and nonmetal mines. It has six subsections.

Subsection (a) provides that 18 months after the date of promulgation, dpm concentrations would be limited by restricting total carbon to 400 micrograms per cubic meter of air ($400_{TC}\mu g/m^3$). The reason why the concentration limit for dpm is expressed in terms of total carbon is explained below. A total carbon limit of $400_{TC}\mu g/m^3$ is the equivalent of about 500 micrograms per cubic meter of air of dpm ($500_{DPM}\mu g/m^3$). This limit would apply only for a period of 42 months; accordingly, it is sometimes referred to in this preamble as the "interim" concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (b) provides that five years after the date of promulgation, the concentration limit would be reduced, restricting total carbon to 160 micrograms per cubic meter of air ($160_{TC}\mu g/m^3$, or about $200_{DPM}\mu g/m^3$). This is sometimes referred to in this preamble as the "final" concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (c) provides for a special extension of up to two additional years in order for a mine to comply with the final concentration limit. This special extension is only available when the mine operator can establish that the final concentration limit cannot be met

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within the five years allotted due to technological constraints. The final rule establishes the information that must be contained in the application for an extension, the procedure to follow to make application, and the conditions that must be observed during the special extension period. Subsection (c) of the final rule refers to this extension as "special" because the final rule provides all mines in this sector with an extension of time (five years) to meet the final concentration limit. The final rule is the same as the proposed rule in this regard.

Subsection (d) provides that under certain conditions, a miner engaged in inspection, repair or maintenance activities in certain areas of a mine may work in concentrations of dpm in excess of the applicable concentration limit. Among the conditions that must be met in order for such work to be permitted is the use of proper personal protective equipment. This exception was not included in the proposed rule.

Subsection (e) provides that apart from the extraordinary circumstances where the use of such controls may be authorized under subsections (c) and (d), an operator must not utilize personal protective equipment to comply with either the interim or final concentration limit. The wording in the final rule clarifies the intent of the proposed rule, and accommodates new subsection (d).

Subsection (f) provides that an operator must not utilize administrative controls to comply with either the interim or final concentration limit. The proposed rule included the same requirement, but in the final rule this has been separated into a separate paragraph.

General Comments. Some commenters questioned MSHA's rationale for establishing concentration limits at this time. They pointed out that a large scale study by NIOSH of the health risks of dpm exposure is still on-going. Accordingly, they accused MSHA of acting prematurely, and urged delaying implementation of any limits until the health risks of dpm exposure are fully quantified. MSHA was also challenged to justify the specific numerical values chosen for the limits; several commenters suggested that these limits are based on unsubstantiated and unquantified health risks, and that therefore, the levels chosen cannot be justified. But another commenter suggested that the health risks are sufficiently documented to justify even lower limits than were contained in the proposed rule. This commenter suggested 100 µg and 50 µg for the interim and final limits, respectively. As these comments involve questions about the risk to underground metal and nonmetal miners, they are addressed in Part III of this preamble.

Some commenters also objected to the proposed concentration limits because they argued that MSHA lacked evidence that the limits were technologically feasible and economically feasible, and some objected to the use of unvalidated simulations to demonstrate the feasibility of compliance. An alternative to concentration limits was proposed wherein mine operators would "Examine and adopt technically and economically feasible methods of preventing potentially hazardous or irritating exposure to diesel exhaust." But another commenter argued that the metal and nonmetal industry could feasibly meet even lower concentration limits than those proposed. And another suggested that a concentration limit alone will not adequately protect miner health because, given the freedom to choose control options, mine operators may elect to boost ventilation rather than cut emissions. As these comments concern feasibility, they are generally discussed in part V of this preamble.

A number of commenters argued that MSHA should allow operators considerable additional flexibility dealing with dpm. Some felt operators should be left complete flexibility on controls, and that a concentration limit at all was inappropriate. Others argued that the range of operator choice of controls should include personal protective equipment as well as administrative controls. These comments are discussed below in connection with this section (§ 57.5060).

Still other commenters argued that concentration limits should not be proposed, or should be much higher, because they argue MSHA lacks a method to measure dpm concentrations in underground metal and nonmetal mines that provides the accuracy, consistency, and reliability that are needed for compliance determinations. These comments are discussed in this part in connection with § 57.5061.

Another commenter expressed concern about the interplay between this rule and those already in effect for diesel gases. This commenter expressed concern that, in addition to complying with the interim and final dpm concentration limits, mine operators would be required to comply with a concentration limit that considers the additive effect of diesel particulate matter and the principal gaseous emissions from a diesel engine (carbon monoxide, carbon dioxide, nitric oxide, and nitrogen dioxide).

MSHA's risk assessment in part III does not specifically evaluate the possible additive effects of diesel particulate matter and diesel gases. Accordingly, the agency does not at this time have a basis upon which to enforce either the interim or final dpm concentration limit in combination with any other substance or substances, including diesel exhaust gases. MSHA will, of course, continue to enforce the limits applicable to diesel gases, but this enforcement will be separate from the enforcement of the dpm concentration limits under the final dpm rule. The Agency understands that Canada does consider the additive effect of diesel exhaust gases and particulate, and will notify the mining community if it decides to look into this matter further based upon additional information.

Finally, the Agency notes it received only two comments on a related matter on which it specifically sought comment—whether to establish an "Action Level" for dpm (63FR 58119). An "Action Level" is a defined contaminant level (usually one-half of the compliance limit) which, if exceeded, triggers actions that must be taken to effectuate control of the contaminant. In the preamble to the proposed rule, MSHA noted it had considered the possibility of establishing an Action Level because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. If an Action Level were in place and compliance sampling results exceeded this level, certain remedial steps, or "best practices," would have to be initiated by management to reduce exposures, such as limits on fuel type, idling, and engine maintenance—whatever steps MSHA determined would be feasible at the Action Level for this sector as a whole. One comment that addressed this approach recommended against establishing an Action Level because the commenter was of the view that no limits at all could be justified at this time based on available health risk data. The other commenter suggested that an Action Level should be adopted in lieu of a rule incorporating a concentration limit requiring mandatory compliance.

After further consideration, MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Furthermore, MSHA determined that these "best practices" are technologically and economically feasible for all mines, so there is no reason to withhold their

implementation until an Action Level is reached. The rationale for requiring these "best practices" is discussed in more detail later in this section under "Meeting the concentration limit: operator choice of controls."

Concentration limit expressed as an "average eight-hour equivalent full shift airborne concentration." MSHA recognizes that work shifts longer than eight hours are common in the underground metal and nonmetal mining industry. It is for this reason that MSHA expressed its concentration limit as an "average eight-hour equivalent full shift airborne concentration." Health-related standards for airborne contaminants are typically established on the basis of an eight-hour work shift. Standard industrial hygiene practice, and MSHA's past practice for metal and nonmetal health sampling, involve adjusting the actual measured concentration of an airborne contaminant to an eight-hour equivalent concentration when work shifts are longer than eight hours. This adjusts an exposure occurring over an extended workshift (*e.g.*, 10 or 12 hours) to enable a valid comparison to an established exposure limit that is based on an 8-hr workshift.

The mathematical formula for making this adjustment is thoroughly described in the MSHA Metal and Nonmetal Health Inspection Procedures Handbook. This formula is as follows:

$$\frac{\text{Contaminant mass}}{(\text{sampling pump flow rate}) \times (480 \text{ minutes}) \times (0.001\ \text{m}^3/\text{l})}$$

When the sampling pump flow rate is expressed in units of liters per minute, the formula results in a contaminant concentration expressed in units of mg or µg per cubic meter. The factor of 480 minutes is used regardless of actual shift duration so as to adjust the actual concentration to an eight-hour equivalent concentration that can be appropriately compared to a standard limit.

MSHA specifically asked for comment on whether a more explicit definition is required in this regard (63 FR 58183). The agency did not receive any such suggestions. However, it is apparent that the term may be confusing to some. For example, one commenter observed that "miners working overtime hours would be exposed to more dpm than miners on a normal eight-hour shift," and that a formula to determine eight-hour equivalency should be included. Another commenter expressed concern that the final rule would place a restriction on the number of hours or overtime hours miners could work.

MSHA disagrees with these interpretations of the rule. The only impact of the rule relative to work hours is the aforementioned determination of "average eight-hour equivalent full shift airborne concentration" for dpm-exposed miners whose work shifts exceed eight hours. Although the Agency has no suggestions for a more clear formulation, it will endeavor to clarify this matter further for operators in its compliance guide.

Dpm concentration limits expressed in terms of total carbon. The purpose of the interim and final concentration limits is to limit the amount of diesel particulate matter; but the limit is being expressed in terms of a restriction on the amount of total carbon. The reason for this involves the measurement method that MSHA intends to utilize to determine the concentration of dpm. As discussed in connection with § 57.5061(a), the final rule specifies that MSHA will use a sampling and analytical method developed by NIOSH (NIOSH Method 5040) to measure dpm concentrations for compliance purposes. Using NIOSH's analytical method, the amount of total carbon (TC) contained in a dpm sample from any underground metal and nonmetal mine can be determined; the method does not directly yield the amount of dpm in a particular sample. However, as explained in detail in Part II of this preamble, TC represents approximately 80–85 percent of the total mass of dpm emitted in the exhaust of a diesel engine. The remaining 15–20 percent consists of sulfates and the various elements bound up with the organic carbon to form the adsorbed hydrocarbons. Using the lower boundary of this range, limiting the concentration of total carbon to 400 micrograms per cubic meter (400_{TC} µg/m³) effectively limits the concentration of whole diesel particulate to about 500_{DPM} µg/m³. Similarly, limiting the concentration of total carbon to 160_{TC} µg/m³ effectively limits the concentration of whole diesel particulate to about 200_{DPM} µg/m³. Expressing the concentration limit in terms of total carbon enables miners, mine operators and inspectors to directly compare a measurement result with the applicable limit.

Where the concentration limit applies. The concentration limits—both interim and final—would apply *only* in areas where miners normally work or travel. The purpose of this restriction is to ensure that mine operators do not have to monitor and control dpm concentrations in areas where miners do not normally work or travel—*e.g.*, abandoned areas of a mine where, for example, the roof may not be monitored for safety or ventilation may not be provided. At the same time, it should be noted that the interim and final concentration limits apply in any and all areas of a mine where miners *normally* work or travel—not just where miners might be present at any particular time.

MSHA generally intends for inspectors to determine which portions of a given mine are subject to the concentration limit based on whether normal work or travel activities routinely do, or could occur there, whether areas are designated as "abandoned" on mine maps, whether areas are made "off limits" through the use of signs or barricades, etc.

MSHA has, however, in the final rule (§ 57.5060(d)), explicitly authorized the Secretary, upon making certain findings and ensuring that certain protections are in place for miners, to allow miners engaged in certain inspection, maintenance or repair activities to work in areas of a mine which are considered areas in which miners normally work or travel but that exceed the concentration limits. These situations are discussed immediately below.

Exception: Specific mining activities which may be conducted in areas which exceed the concentration limit. Although feasible engineering and work practice controls were found to exist for most underground metal and nonmetal mining situations, MSHA did determine that certain maintenance and repair activities might have to be performed in areas where feasible engineering and work practice controls may not be capable of maintaining the dpm concentration at or below the applicable concentration limit. Therefore, in the final rule, § 57.5060(d) under certain conditions permits miners to work in areas where the concentration limit is exceeded, and only when specified precautions have been implemented to protect affected miners. As explained in

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detail below, principal among these precautions is the use by all affected miners, of proper personal protective equipment (*i.e.*, respiratory protection devices) within the context of a comprehensive respiratory protection program.

More specifically, § 57.5060(d)(1) permits, with the pre-approval of the Secretary, employees engaged in inspection, maintenance, or repair activities to work in concentrations of dpm exceeding the applicable limit if they are protected by appropriate respiratory protective equipment. This provision applies only to miners performing the identified activities, and only when certain mandatory protections are implemented. If respiratory protective equipment is used, the final rule requires implementation of a respiratory protection program consistent with the minimum requirements established in § 56/57.5005 (a) and (b), which address such factors as selection, maintenance, training, fitting, supervision, and cleaning. These requirements include by reference, the elements of a minimally acceptable respiratory protection program as delineated in the American National Standard on "Practices For Respiratory Protection" (ANSI Z88.2–1969).

The rule specifies that areas for which a request to allow employees to work in areas that exceed the concentration limit are limited to—areas where miners work or travel infrequently or for brief periods of time for equipment or mine inspection; areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

The standard applies in areas of the mine where miners "normally" work or travel. Normally does not equate to frequency, but rather to the nature of the area. Areas where miners work or travel infrequently are treated by the rule no differently than areas where miners work or travel frequently. For example, if a remote pump is checked on a weekly basis, the area in which that pump is located would be considered an area where miners normally work or travel, even though the area is visited infrequently.

Approval to allow miners to work in areas that exceed the concentration limit would be contingent on the Secretary determining that engineering controls are not feasible, and that adequate safeguards would be employed by the mine operator to prevent hazardous exposure to dpm. The final rule requires mine operators to submit a plan to the Secretary to justify the infeasibility of engineering controls, and to explain the circumstances of the job, the location where work will be performed, resulting dpm exposures, and controls to be used, including, but not necessarily limited to personal protective equipment.

In order for MSHA to determine the reasonableness of a mine operator's request for approval under 5060(d), certain details regarding the work need to be provided. These include the types of inspection, maintenance or repair activities planned, the locations of such activities, the dpm concentrations at these locations, the reasons why engineering controls would not be feasible, the anticipated frequency of these activities, the anticipated number of miners involved, and the safeguards the mine operator will employ to minimize dpm exposures. These factors will tend to change over time as the mine develops, as new equipment or procedures are introduced, as ventilation system parameters change, etc. MSHA believes that an annual updating of these factors is necessary to insure that approval is granted only where justified by the actual circumstances.

In essence, this exemption allows the use of personal protective equipment as a substitute for engineering controls under a limited number of circumstances. Many commenters suggested MSHA permit the use of PPE much more broadly in lieu of engineering controls; MSHA's review and reaction to these comments is discussed below.

One commenter, a mine operator, agreed with MSHA's approach that stresses engineering controls first and foremost. The commenter stated that, "engineering controls, as close to the source of the diesel emission as possible, must be the first line of DPM exposure control." The commenter further suggested that, "The proposed rule should allow personal protective equipment to be used as a last resort. The proposed rule should require written documentation explaining how the mine determined the appropriate exposure controls. This written documentation should clearly explain why engineering controls, commonly used in industry to control diesel emissions, are not technically or economically feasible."

Although MSHA has embraced the commenter's basic idea of requiring written documentation when personal protective equipment is proposed as an alternative to engineering controls, the final rule includes other necessary safeguards to insure that this option is used only when absolutely necessary and that appropriate steps are taken to insure that respirator wearers are adequately protected. The final rule requires such plans to identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which there are no feasible engineering controls sufficient to comply with the concentration limit, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency of such activities, the anticipated duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that will be employed to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment.

The final rule requires mine operators to utilize all feasible engineering and work practice controls, however, the exception under subsection (d) permits such controls to be supplemented with respirator use in certain limited situations where reliance solely on feasible engineering and work practice controls would be inadequate to control exposures below the applicable concentration limit. The proposal's prohibition on administrative controls under any and all circumstances is retained in the final rule in subsection (e).

Examples of situations where MSHA believes engineering controls might not be feasible include cleaning up a roof fall in an exhaust air course, replacing a conveyor belt idler in a conveyor tunnel that is carrying exhaust air, or shaft inspection in an exhaust air shaft. The provisions of subsection (d) are not intended to suggest that MSHA believes these and similar activities should automatically be considered exempt from the requirement to utilize engineering and work practice controls to comply with the concentration limit. Rather, MSHA recognizes that under certain site specific circumstances, feasible engineering and work practice controls alone may not be capable of achieving compliance with the concentration limit. Therefore, MSHA agrees that respirator use should be permitted if the applications are sufficiently justified and approved in advance.

MSHA does not intend that plans submitted for advance approval need to identify specifically and individually every activity for which advance approval is sought. The intent is that plans must identify, in a generic sense, the types of activities and related circumstances as can reasonably be anticipated, sufficient to enable the Secretary to determine whether advance approval is warranted.

Meeting the concentration limit: operator choice of engineering controls. The final rule contemplates that an operator of an underground metal or nonmetal mine have considerable discretion over the controls utilized to bring down dpm concentrations to the interim and final concentration limits. For example, an operator could filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, use traffic controls, or use a variety of other readily available controls. A combination of several control measures, including both engineering controls and work practices, may be necessary, depending on site specific conditions.

MSHA intends for engineering controls to refer to controls that remove the dpm hazard by applying such methods as substitution, isolation, enclosure, and ventilation. MSHA intends for work practice controls to refer to specified changes in the way work tasks are performed that reduce or eliminate a hazard, such as traffic controls (speed limits, one-way travel, etc.), prohibiting unnecessary engine idling, or designating areas that are off-limits for diesel equipment operations. As discussed below, the final rule does not permit utilization of administrative controls as a means of complying with the dpm concentration limit. In the context of this rule, MSHA intends for administrative controls to refer to controls that limit a miner's exposure to dpm by distributing the exposure among other miners through various work scheduling and worker rotation practices.

Some commenters asserted that implementation of certain dpm control measures may create other, unrelated health or safety problems. One example given concerned the complications and safety trade-offs of increasing ventilation to control dpm concentrations. The increased ventilation would tend to dry out roadways, causing increased problems with respirable silica bearing dust exposure. This problem, would, in turn, require application of greater amounts of water on the roadways for dust control, which, in turn, would create traction problems for vehicles. Increased ventilation might also accelerate the drying out of certain roof strata, creating roof control problems. Another commenter worried that enclosed cabs can reduce an equipment operator's field-of-view, and dirt or glare on windows can obscure visibility, possibly creating safety problems.

MSHA acknowledges that dpm control measures need to be selected and implemented carefully, both to insure they achieve the desired effect on dpm concentrations, and to minimize or avoid undesirable effects on other aspects of the mine's health and safety environment. In most cases, implementation of a given control will not have any undesirable effects. In other isolated cases, the undesirable effects of a given control can most likely be negated through additional work practice controls or other measures. For example, the increased application of water on roadways to reduce dust control problems caused by higher ventilation rates may require that equipment be operated at slower speeds. Roof control problems resulting from the accelerated drying out of strata may require a reassessment of the mine's roof control plan, such as its roof bolting practices. Vehicle operator field-of-view and visibility problems could be addressed by instituting new traffic controls, requiring slower speeds, and use of window washers. For these reasons, MSHA does not wish to explicitly deny operators a particular type of engineering control because in some circumstances an adjustment to customary mining practices may have to be made.

Because information on available controls has been described in other parts of this preamble (part II and part V), further discussion is not provided here. Mine operators are also directed to the MSHA "estimator" model to help them determine which control or combination of controls would be best able to produce the reduction in dpm concentrations necessary to comply with the appropriate concentration limit. The "estimator" mathematically calculates the effect of any combination of engineering and ventilation controls on existing dpm concentrations in a given production area of a mine. This model is in the form of a spreadsheet template permitting instant display of outcomes as inputs are altered. The model and some examples illustrating its potential utility are described in Part V of this preamble.

Several commenters expressed disappointment that the proposal did not embrace what they sometimes referred to as "MSHA's toolbox approach." In some cases, this appears to mean the commenters want operators to have the flexibility to use personal protective equipment and administrative controls, as well as engineering and work practice controls, to meet the required concentration limits. In other cases, however, it appears the commenters meant that MSHA should allow them the discretion not only to choose the controls they wish, but to choose whether or not to use controls at all. In other words, to these commenters, the "toolbox approach" means voluntary implementation of controls without enforcement of a concentration limit.

By way of background, in 1997, MSHA published a pocket-sized handbook called, "Practical Ways to Reduce Exposure to Diesel Exhaust in Mining—A Toolbox." This handbook describes and discusses a variety of emission control equipment, methods, and strategies, both in terms of laboratory emissions testing and in-mine experience. The rationale for a "toolbox approach" to controlling diesel emissions is explained in the handbook. "A toolbox offers a choice of tools, each with a specific purpose. One tool after another may be used to find a solution to a problem, or several tools may be tried at the same time.* * * Reducing exposure to diesel emissions lends itself to a toolbox approach because no single method or approach to reducing exposure may be suitable for every situation." Since its publication, this handbook, which is referred to simply as the "MSHA toolbox" or "toolbox" has become quite well known and is widely used in the mining industry.

Commenters who urged MSHA to adopt a "toolbox approach" in its rulemaking praised the approach taken in MSHA's publication, and indicated that they had successfully implemented some of the control strategies discussed. They urged MSHA to maintain this flexibility. One commenter suggested that, "The toolbox is just simply best practices, if you would. If we're doing this, this, and this, then we're doing all we can without enforcement.* * * That's what a toolbox is. A toolbox is not an enforcement tool."

The MSHA Toolbox was issued before this rulemaking, in which, after considering all the evidence, MSHA has concluded that miners are at significant risk of material impairment at the concentration levels still found in underground metal and nonmetal mines. When MSHA makes such a finding, it is required to act to protect miners to the extent feasible. MSHA has concluded that requiring operators to comply with a concentration limit using engineering controls is necessary to protect miners and feasible for the mining industry as a whole, while still

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providing underground metal and nonmetal mine operators with maximum flexibility to address this problem. Thus, MSHA believes the final rule does incorporate the "toolbox approach" by allowing mine operators to choose, from among numerous alternatives, the mix of control measures most suitable for the site specific conditions at a given mine—provided that the controls bring exposures down to the required limit.

MSHA has determined that certain types of controls discussed in the toolbox—PPE and administrative controls—are not considered acceptable ways to meet a concentration limit. PPE does not reduce the concentrations of a contaminant in the environment, though such equipment does offer limited protection to miners who must work in areas where the applicable concentration limit cannot be achieved using feasible engineering or work practice controls. The rule permits PPE to be used to protect miners in those limited situations where it permits work to take place despite dpm concentrations in excess of the concentration limit (special extension of time to meet final concentration limit under paragraph (c), discussed below, and special permission to perform inspection, maintenance and repair activities in areas that exceed the concentration limit under paragraph (d), discussed above.) Administrative controls (*e.g.*, limiting the hours worked by a particular miner in a high concentration area) simply spread risk among miners. The reasons for MSHA's position in this regard are discussed in detail below.

MSHA has also determined that certain other types of dpm control measures discussed in the toolbox must be implemented at all underground metal and nonmetal mines that use diesel equipment, regardless of the dpm concentration level, to minimize miner risks. These "best practices" include such requirements as low sulfur content diesel fuel, limits on unnecessary idling of diesel engines, maintenance standards, and a requirement for newly introduced engines to be MSHA approved or meet certain EPA standards. MSHA's rationale for why it is mandating such "best practices" is summarized below. Further detail is provided in the preamble to the proposal (63FR 58119), and in the sections of this Part which discuss the individual practices themselves (diesel fuel (§ 57.5065(a)), maintenance (§ 57.5066), and engines that are MSHA approved or meet EPA standards (§ 57.5067).

In the proposal, MSHA explained that it had considered implementing an "Action Level" for dpm, possibly at a level one-half of the final concentration limit, or 80$_{TC}$ μg/m^3 because the dpm concentration at which exposure does not result in adverse health effects is not known at this time. Under this approach, when dpm levels exceeded the Action Level, implementation of certain "best practice" controls, such as limits on fuel types, idling, and engine maintenance would have been required. However, this approach was not incorporated into the proposal, nor has it been incorporated into the final rule. MSHA determined it does not have enough information to proceed with an Action Level at this time, although it notes that the concept of an Action Level is well recognized in occupational health protection and included in many other standards. Instead, MSHA determined that these "best practices" would be required for all mines at all times.

MSHA followed this course for several reasons, including: (1) Sampling by both mine operators and MSHA would have been much more frequent under an approach incorporating an Action Level; (2) tracking equipment maintenance requirements would have been much more complicated, as diesel equipment could move from an area of the mine where the dpm concentration was less that the Action Level, to another area where the Action Level had been exceeded; (3) these "best practices" are already in place, and have proven to be workable and practical in coal mines; (4) given the history of lung problems associated with the mining industry, and considering that these practices were determined to be economically and technologically feasible for the industry as a whole, a more protective course seemed prudent; and (5) a number of the work practices appear to have significant benefits, such as improving the efficiency of maintenance operations.

One commenter suggested that other "best practices" related to mine ventilation should be mandated in the final rule. This commenter recommended requiring mine operators to provide details on the design and operating parameters of auxiliary ventilation systems, that they be required to utilize an appropriate air measurement and recording program, and that they properly attend to uncontrolled recirculations and leakages. MSHA believes that existing ventilation regulations adequately address these concerns, and that mine operators, in utilizing a "toolbox approach" to implement dpm control measures, have the option of incorporating ventilation system improvements if they are judged to be feasible, practical, desirable, and appropriate to the site specific conditions at a given mine. Thus, MSHA did not include a mandate to use such ventilation "best practices" in the final rule.

Concentration limit: time to meet. As noted, the dpm limitation requires metal and nonmetal mines to reduce total carbon concentrations in areas where miners normally work or travel to 160 micrograms per cubic meter of air (equating to about 200 micrograms of dpm per cubic meter of air.) § 57.5060 provides for an extension of time for underground metal and nonmetal mines to meet the concentration limit. Mines do not have to meet any limit for the first 18 months after the final rule is promulgated. Instead, this period will be used to provide compliance assistance to the metal and nonmetal mining community to ensure it understands how to measure and control diesel particulate matter concentrations in individual operations. Moreover, the rule provides all mines in this sector an extension of three and a half additional years to meet the final concentration limit established by § 57.5060(b). During this extension, however, all mines will have to bring total carbon concentrations down to 400 micrograms per cubic meter, equating to a limit of 500 micrograms per cubic meter in dpm.

Comments on the implementation schedule for the concentration limits focused on the technological and economic feasibility of complying within the time frames established. Commenters expressed the view that the rule is technology forcing, and that the mining sector of the economy is too small to justify the expense by manufacturers (mining equipment, diesel engines, aftertreatment devices, etc.) to develop the necessary products to enable mine operators to fully comply by the deadlines contained in the final rule.

MSHA provided these phase-in times for meeting the interim and final concentration limits after carefully reviewing comments on the economic and technological feasibility of requiring all mines in this sector to meet the applicable limits using available controls. This review is presented in Part V of this preamble. MSHA has studied a number of metal and nonmetal mines in which it believed dpm might be particularly difficult to control. The Agency has concluded that in combination with the "best practices" required under other provisions of the final rule (§§ 57.5065, 57.5066 and 57.5067), engineering and work practice controls are available that can bring dpm concentrations in all underground metal and nonmetal mines down to or below 400$_{TC}$ μg/m^3 within 18 months. Moreover, the Agency has concluded that controls are available to bring dpm concentrations in all underground metal and nonmetal mines down to or below 160$_{TC}$ μg/m^3 within 5 years. The Agency has concluded that it is not feasible to require this sector, as a whole, to lower dpm concentrations further, or to implement the required controls more swiftly.

Despite its conclusions on the feasibility of these timeframes for the underground metal and nonmetal industry as a whole, MSHA has included a provision in the final rule to allow an additional two years for mines experiencing difficulty in complying due to technological problems. A discussion of this special extension follows.

Special extension. Pursuant to § 5060(c), an operator may request more than five years to comply with the final concentration limit only in the case of technological problems. In light of the risks to miners posed by dpm, however, the Agency has concluded that the economic constraints of a particular operator are not an adequate basis for a further extension of time for that operator, and the final rule does not provide for any extension grounded in economic concerns. Moreover, if it is technologically feasible for an operator to reduce dpm concentrations to the final limit within the established five year compliance period, no extension would be permitted even if a more cost effective solution might be available in the future for that operator.

However, the Agency has determined that if an operator can actually demonstrate that there is no technological solution that could reduce the concentration of dpm to 160$_{TC}$ μg/m^3 within five years, a special extension would be warranted.

Extension application. § 57.5060(c)(1) provides that if an operator of an underground metal or nonmetal mine can demonstrate that there is no combination of controls that can, due to technological constraints, be implemented within five years to reduce the concentration of dpm to the limit, MSHA may approve an application for an extension of time to comply.

Such a special extension is available only once, and is limited to 2 years. In this regard, MSHA does not anticipate that an extension will automatically last 2 years, and the agency will closely scrutinize applications to determine how much time is really required to implement a technological solution. To obtain a special extension, an operator must show that diesel powered equipment was used in the mine prior to publication of the rule, demonstrate that there is no off-the-shelf technology available to reduce dpm to the limit specified in § 57.5060, and establish the lowest concentration of dpm attainable. In this regard, the Agency reiterates that cost is not a consideration; thus, simply because a more cost-effective solution will become available in the future is not an acceptable reason for an extension.

One commenter questioned whether it is reasonable to limit mine operators to one special extension when the necessary technology to comply with the concentration limits does not exist today. This commenter suggests a five to ten year compliance schedule is more realistic to allow time to develop the technology and to phase in the replacement of equipment. MSHA believes that very few, if any, underground metal and nonmetal mining operations should need a special extension, based on the feasibility information discussed in part V of this preamble. Despite this information, the final rule makes specific provision for a special extension for the very few mines that might experience technical problems that cannot be foreseen at this time. In the unlikely event any mines experience such technical problems, MSHA believes that a two year extension, in addition to the five years granted in the final rule for all mines, will be sufficient for them to achieve compliance.

The final rule further requires that to establish the lowest achievable concentration, the operator must provide sampling data obtained using NIOSH Method 5040 (the method MSHA will use when determining concentrations for compliance purposes; this sampling method is further discussed in connection with § 57.5061(a)).

The application would also require the mine operator to specify the actions that are to be taken to "maintain the lowest concentration of diesel particulate achievable" (such as ensuring strict adherence to an established control plan) and to minimize miner exposure to dpm (*e.g.*, such as providing and requiring the use of suitable respirators at mines or areas of mines under extension). MSHA's intent is to ensure that personal protective equipment is permitted only as a last and temporary resort to bridge the gap between what can be accomplished with engineering and work practice controls and the concentration limit. It is not the Agency's intent that personal protective equipment be permitted during the extension period as a substitute for engineering and work practice controls that can be implemented immediately.

Filing, posting and approval of extension application. The final rule requires that an application for an extension be filed no later than 6 months (180 days) in advance of the date of the final concentration limit (160$_{TC}$ μg/m^3), and a copy of the extension be posted at the mine site for the duration of the extension period. In addition, a copy of the application would also have to be provided to the designated representative of the miners.

The application must be approved by MSHA before it becomes effective. While pre-approval of plans is not the norm in this sector, an exception to the final concentration limit cannot be provided without careful scrutiny. Moreover in some cases, the examination of the application may enable MSHA to point out to the operator the availability of solutions not considered to date. MSHA notes that it received no comments on this requirement for pre-approval.

While the final rule is not explicit on the point, it is MSHA's intent (as set forth in the preamble to the proposed rule, 63 FR 58184) that primary responsibility for processing of the operator's application for an extension will rest with MSHA's District Managers. This ensures familiarity with the mine conditions, and provides an opportunity to consult with miners as well. At the same time, MSHA recognizes that District Managers may not have the expertise required to keep fully abreast of the latest technologies and of solutions being used in similar mines elsewhere in the country. Accordingly, and again consistent with the preamble to the proposed rule, the Agency intends to establish, within its Technical Support Directorate a special panel to consult on these issues and to provide assistance and guidance to its District Managers. In the preamble to the proposed rule (63 FR 58184) the Agency requested comment on whether further specifics regarding this approach to approving applications for special extensions should be incorporated into the final rule, however, no such comments were received.

The rule specifies that a mine operator shall comply with the terms of any approved application for a special extension, and provides that a copy of the approved application be posted at the mine site for the duration of the application.

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Personal protective equipment and administrative controls. In the proposal, mine operators were expressly forbidden to use personal protective equipment (*e.g.*, respirators) or administrative controls (*e.g.*, job rotation) to comply with either the interim or final dpm concentration limit. MSHA's rationale for these provisions was that limiting individual miner exposure through the use of respirators or job rotation would not reduce the airborne concentrations of dpm in the mine. Rather, in the proposal, MSHA chose to incorporate the widely accepted industrial hygiene concept of "hierarchy of controls" which places the highest priority on eliminating or minimizing hazards at the source through implementation of engineering and work practice controls.

The "hierarchy of controls" paradigm regards administrative controls and the use of personal protective equipment to be inherently inferior methods of controlling contaminant exposures in the workplace. Support for this position is virtually universal in the field of industrial hygiene. *Patty's Industrial Hygiene and Toxicology* (Vol I, General Principles) states, "Evidence of the importance of engineering control of the work environment among the various alternative solutions to industrial hygiene problems is found in every current industrial hygiene text: all list the possible solutions in priority fashion as engineering controls, administrative controls, and as a last resort, use of personal protective equipment." The National Safety Council's *Fundamentals of Industrial Hygiene* states, "Engineering controls should be used as the first line of defense against workplace hazards whenever feasible. Such built-in protection, inherent in the design of a process, is preferable to a method that depends on continual human implementation or intervention."

This text goes on to describe administrative controls as, "not as satisfactory as engineering controls," and notes that such controls "have been criticized by some as a means of spreading exposures instead of reducing or eliminating the exposure." This latter statement is particularly relevant to dpm, and to carcinogens in general, because administrative controls, such as job rotation, result in placing more workers at risk. Among the reasons *Patty's Industrial Hygiene and Toxicology* recommends that a given chemical should not be controlled by administrative reduction of exposure time is that it may be a carcinogen.

In the proposed rule, MSHA prohibited administrative controls as an acceptable dpm control method because they fail to eliminate the exposure hazard and result in placing more miners at risk. Since MSHA determined that compliance with the interim and final dpm concentration limits was feasible for the underground metal and nonmetal mining industry as a whole using exclusively engineering and work practice controls, the Agency logically chose to prohibit personal protective equipment as a compliance option as well.

In the Preamble to the proposed rule, MSHA stated that it intended that the normal meaning be given to the terms personal protective equipment and administrative controls, and asked for comment as to whether more specificity would be useful. MSHA noted that it assumed the mining community understands, for example, that an environmentally controlled cab for a piece of equipment is an engineering control and not a piece of personal protective equipment.

Numerous commenters took issue with the proposal's prohibition on administrative controls and personal protective equipment as compliance options. They noted that both administrative controls and personal protective equipment are accepted industrial hygiene exposure control methods that should be permitted under the rule. Most commenters agreed that engineering controls would be the preferred option for reducing an occupational health exposure, but that engineering controls sufficient to reduce dpm concentrations below the applicable concentration limit might not be the most cost-effective approach, and more importantly, that engineering controls may not be feasible in all situations. They argued that prohibiting administrative controls and personal protective equipment would, as a result, place mine operators in an impossible compliance dilemma.

It is significant to note that the commenters did not disagree with MSHA's fundamental reasoning for using the "hierarchy of controls" concept as the basis for prohibiting administrative controls and personal protective equipment. Likewise, there was no direct disagreement with MSHA's endorsement of the widely accepted industrial hygiene principle that administrative controls are inappropriate in the case of exposure to carcinogens because job rotation will expose more miners to the hazard.

Rather, commenters argued that administrative controls and personal protective equipment should be permitted simply to give mine operators greater flexibility in dealing cost effectively with a workplace contaminant, and because certain situations exist where no feasible engineering control would be available to enable compliance with the concentration limit.

Regarding the question of affording greater operator flexibility, a typical commenter observed that, "If MSHA's goal is protection of miners, in the context of a viable and profitable industry, it should encourage flexible control approaches to the control of dpm exposure, and not penalize operators for using all effective means available—including administrative controls and PPE." Another commenter asked MSHA to, "reconsider the use of personal protective equipment as a cost effective solution when appropriate." MSHA responds to these comments by noting that it did incorporate compliance flexibility into the requirements for this rule. As noted earlier under the discussion on "Meeting the concentration limit: operator choice of engineering controls," mine operators do have considerable freedom to choose the control, or combination of controls necessary to achieve and maintain compliance with the applicable concentration limit in their mines. However, this freedom is not total, particularly with respect to administrative controls and personal protective equipment. Operator flexibility, convenience, or cost effectiveness are not acceptable bases for permitting dpm control methods that are widely acknowledged to be inherently inferior to engineering and work practice controls.

Regarding the question of the feasibility of controls, several commenters argued that there are situations where engineering controls are either economically infeasible, technologically infeasible, or both. Some typical examples of these comments include a mining company that objected to, "the Agency's continued downgrading of administrative controls and the use of personal protective equipment in favor of considerably more expensive, presently infeasible, engineering controls." Another commenter complained that, "the standard must be attained with engineering controls alone," and that, "personal protective equipment and other means cannot be used even where compliance with engineering controls is not feasible." Still another commenter observed that, "The proposal is not [economically or technologically] feasible for metal mines * * * which are designed specifically for use of diesel equipment. In these mining scenarios, use of electric equipment is not cost-effective, and elimination of diesel equipment would eliminate the process for which the mines were designed."

The question of economic feasibility will be discussed separately from the question of technological feasibility. MSHA acknowledges that administrative controls or the use of personal protective equipment may be less costly than engineering or work practice controls in certain situations. However, a difference in cost between two approaches is simply that—a difference in cost. MSHA does not regard a cost difference per se as prima facia proof that an approach is economically infeasible simply because a less expensive alternative exists.

Commenters also questioned MSHA's compliance cost estimates, asserting that compliance costs will actually be much higher. MSHA's compliance cost estimates are discussed in the REA. However, in answer to this comment, MSHA determined that exclusive reliance on engineering and work practice controls are economically feasible for the underground metal and nonmetal mining industry as a whole (with the exception of the situations addressed in § 57.5050(d)). Thus, MSHA rejects the argument that administrative controls and the use of personal protective equipment should be permitted based on consideration for economic feasibility.

Regarding the question of the technological feasibility of engineering and work practice controls, the high number of comments addressing this issue suggested that the underground metal and nonmetal mining industry considered it to be of vital importance. Despite their number, however, none of these comments identified specific equipment or mining situations where exclusive reliance on engineering or work practice controls to achieve and maintain compliance with the applicable dpm concentration limit would be impossible due to technological infeasibility.

In the preamble to the proposed rule, MSHA provided extensive information on how mine operators might use a computer program known as the "Estimator" to conduct assessments of controls that might be necessary to deal with problems in individual mines, and requested comments based on such specific information. The comments that were received were critical of the "Estimator" because it produces an estimate of average dpm concentration in a given area, not the specific concentration that might exist at a specified sampling location; and because its accuracy depends on the quality of the input data, which is suspect due to the perceived inherent inaccuracy of the dpm sampling methods which must be used to obtain the input data.

Regarding the first criticism, MSHA notes that the average dpm concentration in a given area, which is the output obtained from the "Estimator," is a more accurate indicator of the potential dpm hazard than a specific concentration that might exist at a specified sampling location. Since compliance is based on a shift, weighted average concentration produced by diesel equipment that is normally in constant motion throughout the shift, the average dpm concentration in a given area is a better predictor of compliance or noncompliance than a determination of specific concentration that might exist at a specified sampling location. It might also be advisable to consider relocating a miner who, by virtue of their specific work location, is thought to be at risk of being exposed to a concentration of dpm that is greater than the average for that area (for example, move the miner from being in the direct line of the exhaust stream). Finally, MSHA notes that the "Estimator" is just that, a means of *estimating* dpm concentration. It was never claimed that this model could predict dpm concentrations with pinpoint accuracy. However, in verification testing of the model, MSHA has observed good agreement between predicted and measured dpm concentrations (as discussed in part II, section 3 of this preamble).

Regarding the second criticism, MSHA notes that users have the option of inputting actual dpm data, or estimating such values. If users desire to input in-mine measurements of dpm concentrations, MSHA is confident that dpm sampling and analysis using the NIOSH Method 5040, as described elsewhere in this preamble, will accurately represent actual dpm concentrations.

Nonetheless, MSHA reevaluated the feasibility of engineering and work practice controls as the exclusive means of complying with the applicable dpm concentration limits. This reevaluation identified potential compliance problems related to performing certain inspection, repair, and maintenance work if only engineering and work practice controls were permitted as means of achieving compliance. Therefore, the Agency has adjusted the final rule to allow such work, when sufficiently justified and preapproved by the Secretary, to be performed using personal protective equipment as a supplement to engineering and work practice controls. But apart from these very limited situations, the Agency has concluded that the use of engineering controls to meet the concentration limit is both economically and technologically feasible for the underground mining industry as a whole, and in light of the health risks to miners, and the superiority of engineering controls, the Agency has concluded that they (and not PPE or administrative controls) must be utilized to meet the concentration limit.

57.5061 Compliance Determinations

Summary. This section of the final rule establishes the criteria for determining compliance with the concentration limits. It has three subsections.

Subsection (a) provides for compliance sampling to be performed by MSHA directly, requires that such compliance sampling be done in accordance with the other requirements of this section, and further provides that a single such sample will be adequate to establish a violation. This is consistent with the proposed rule.

Subsection (b) provides that MSHA will collect dpm samples using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon (TC) using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of dpm in underground metal and nonmetal mines). This is like the proposed rule except that the final rule explicitly requires a submicrometer impactor to be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Subsection (c) provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations—personal sampling, occupational sampling, or area sampling—based on the circumstances of the particular exposure or exposures to be evaluated. This provision was not explicitly stated in the proposed rule; it was, however, stated in the preamble to the proposed rule as MSHA's intent. The final rule makes explicit MSHA's discretion in this regard.

As discussed in more detail in Part II, section 3, an important factor in the agency's decision as to which sampling practice to utilize in a particular situation, and how the sampling should be conducted (*e.g.*, how far away from a smoker or source of oil mist), is a careful review of other sources of total carbon in the environment to be

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sampled which could cast doubt on whether the sample result was based solely on the amount of dpm present. MSHA will provide guidance in this regard to metal and nonmetal inspectors and the mining community—based on the information noted already in Part II, section 3 of this preamble, such new information as may be developed, and continued experience in this regard—so as to avoid wasting the limited resources of the Agency and its counsel, the Mine Safety and Health Review Commission, and the underground metal and nonmetal mining community by taking compliance samples whose validity is questionable.

Numerous comments were received on this section—addressing the validity of single samples for determining compliance with an occupational health standard; the accuracy, precision, appropriateness, and practicality of using the NIOSH Method 5040 for determining dpm concentrations for enforcement purposes; and the legitimacy of using area sampling to determine compliance with a health standard. These comments, and MSHA's response to them, are discussed below.

Single sample compliance determination. Pursuant to § 57.5061(a), a single dpm sample showing that the applicable TC concentration limit has been exceeded on any individual shift will constitute a citable violation. Such a violation will also trigger further action pursuant to § 57.5062, as discussed below in connection with that section.

As is standard practice with other health compliance measurements, MSHA intends to account for normal variability in the sampling and analytical process by allowing a margin of error in the sampling result before issuing a citation. This margin of error will be based on the accuracy of the sampling and analytical method (Method 5040) used to measure the total carbon (TC) concentration in the mine environment, after correcting for potential interferences.

The variability associated with Method 5040, as expressed by the relative standard deviation (RSD), decreases with increased load on the filter. Based on a laboratory experiment, NIOSH has determined that, at a TC concentration as low as 23 $\mu g/m^3$, the variability associated with an 8-hour sample using Method 5040 and a pump flow rate of 2.0 L/min is approximately 8.5 percent. (NIOSH Manual of Analytical Methods, Method 5040, Issue 2, 1998)

MSHA will issue a citation for exceeding the applicable concentration limit only when such a citation can be issued at a confidence level of at least 95 percent. Each measurement made for purposes of compliance determination may be adjusted, if necessary, to compensate for any expected biases due to interferences such as tobacco smoke and oil mist. To account for sampling and analytical variability associated with Method 5040, the adjusted measurement will then be compared to the appropriate level established in § 57.5060 multiplied by an "error factor." The error factor will be calculated so as to achieve the required 95-percent confidence that a violation has actually occurred. Based on the standard normal distribution for measurement errors, this will be 1 + 1.645 times the variability of the sampling and analytical method, as expressed by its RSD.

For example, assuming the 8.5-percent limit on the RSD established by NIOSH under laboratory conditions, the error factor would be 1 + 1.645×.085 = 1.14. Suppose MSHA takes a sample during the interim period when the limit is 400_{TC} $\mu g/m^3$. Then, if expected interferences are negligible, MSHA would cite noncompliance only if the TC measurement exceeded 1.14×400 = 456 $\mu g/m^3$.

MSHA recognizes that measurement uncertainty may be higher for samples collected under mining conditions than under laboratory conditions. Therefore, MSHA intends to base the margin of error required to achieve a 95-percent confidence level for all noncompliance determinations on samples collected under field conditions. The Agency anticipates that the sampling and analytical error factor will be somewhere between 1.1 and 1.2. The Agency will, however, be governed by the actual data obtained to establish an appropriate margin of error.

Several comments were received regarding the value of the error factor for dpm sampling using NIOSH Method 5040. One commenter asserted that it will be impossible to establish a meaningful error factor, stating, "* * * there is insufficient information available to quantify the margin of error with any level of certainty." Another commenter expressed confusion with respect to the various ways in which measurement uncertainty was quantified in the proposal. This commenter argued as follows:

> MSHA states on page 58116 that the 5040 Method meets NIOSH's accuracy criteria that measurements come within 25% of the concentration at least 95% of the time. This standard is for a known particle size distribution in a laboratory setting, not a mine environment. Then on page 58184 states that, "the variability associated with the Method 5040 to be approximately 6% (one relative standard deviation)"! These do not compare! Then it states MSHA will issue a citation if the measured value was 10% over the established level! There is a contradiction somewhere in the MSHA proposal—how can MSHA take 25% NIOSH laboratory criteria and shrink it to 6% in a mining environment?

This commenter has apparently misunderstood the NIOSH Accuracy Criterion. Any unbiased method for which the RSD is known to be less than 12.75 percent meets the criterion, because any RSD less than 12.75 percent implies (assuming no measurement bias) that measurements will come within 25 percent of the true value at least 95 percent of the time. An RSD of 6 percent meets the NIOSH accuracy criterion, simply because 6 percent is less than 12.75 percent. In order to achieve 95-percent confidence that a specific measurement demonstrates noncompliance, a 6-percent RSD would, nevertheless, have to be multiplied by a 1-tailed 95-percent confidence coefficient of 1.645, yielding the 10-percent adjustment to which the commenter was referring. Therefore, these quantities are internally consistent. As stated earlier, however, MSHA intends to base its estimate of the RSD on data appropriate for field conditions in underground mining environments.

Another commenter suggested that the NIOSH Method 5040 is prone to excessive errors because it is "complex and requires highly skilled technicians." The inherent capacity of the method to produce accurate results was criticized by one commenter who stated, "* * * it is not possible to evaluate the accuracy of the method. In fact, the method has been shown to produce massive errors when side-by-side samples and control filters are analyzed. Even blank filters produce high and widely-varying readings for TC."

Based on MSHA's extensive experience using NIOSH Method 5040 and related sampling practices, the Agency is confident that such sampling and analysis will meet or exceed MSHA's accuracy criteria. This is discussed in detail in Part II, section 3, and later in this section under "Using NIOSH Method 5040 for compliance determinations."

Regarding the issue of uncertainty in the sampling and analytical process for field measurements, MSHA has not yet completed its determination of an appropriate error factor for this method. As noted above, MSHA will determine an appropriate factor and apply it when enforcing the applicable compliance limit. As a matter of general practice, however, the Agency does not include error factors in occupational health rules, since the accuracy of measurement methods may change over time. When this determination is made, the error factor, along with its derivation, will be promptly communicated to the underground metal and nonmetal mining industry through the appropriate channels.

MSHA recognizes that in recent years courts have closely scrutinized Agency actions to ensure they are consistent with the requirements of the Administrative Procedures Act and, in MSHA's case, with the requirements of the Mine Safety and Health Act as well. Courts have held that certain actions, traditionally regarded as enforcement policies issued at an agency's discretion, require notice and comment and even the development of feasibility analyses. MSHA has carefully considered its obligations in light of these precedents and has concluded that the determination of a margin of error to be allowed before issuing a citation remains among the type of actions left to Agency discretion. To require the Agency to go through rulemaking each time such an error factor is established or updated based upon improved sampling or analytical methods would not serve the best interests of the mining community. Therefore, MSHA wishes to emphasize that the Agency does not regard the determination of an appropriate margin of error as a necessary part of this rulemaking, but rather as strictly a matter of enforcement policy. As noted explicitly in the rule, the Agency is retaining discretion to switch to better techniques should NIOSH certify that they provide "equal or improved accuracy for the measurement of diesel particulate matter in" underground metal and nonmetal mines. (§ 57.5061(b))

Notwithstanding its decision not to be explicit in this standard about the error factor to be used, MSHA recognizes the strong interest the underground metal and nonmetal mining community has in this issue and will ensure the matter is fully discussed with that community before the concentration limits are scheduled to go into effect. In working with this community on diesel particulate matter controls (see the history of this rulemaking in Part II of this preamble), the Agency has repeatedly demonstrated its commitment to good communications in this regard—*e.g.*, the workshops, the advance and final circulation of the diesel toolbox, the use of the Agency's web site and direct notification in appropriate cases.

As explained elsewhere in this preamble, MSHA has determined that it is feasible for underground M/NM mines to maintain dpm concentrations at or below the limits specified in § 57.5060 on each and every shift, everywhere that miners normally work or travel, with the exception of the circumstances defined in § 57.5060(d). Therefore, MSHA will protect miners' health to the maximum extent feasible by citing a violation whenever a single sample demonstrates that the limit has been exceeded on a full shift at any appropriate sampling location. This single-sample enforcement strategy is consistent with all other occupational health enforcement practices in the metal and nonmetal sector. As per long-standing policy in this sector, single out-of-compliance samples for dust (*e.g.*, silica-bearing respirable dust, total nuisance particulate, etc.), gas (*e.g.*, CO, NO_2, solvent vapors, etc.), mist (*e.g.*, cutting oil mist, spray paint, etc.), fume (*e.g.*, welding fumes, fumes from melting furnaces, etc.), and noise are all considered citable violations of the respective standards. Nevertheless, the Agency decided it would be best, in this rulemaking, to avoid any possible ambiguity in this regard by explicitly stating in the rule itself that a single sample by the Agency would provide the basis for a citation. MSHA highlighted this matter in the preamble of its proposed rule (63 FR 58117, part of Question and Answer 12).

Some commenters suggested that MSHA should collect numerous samples and base noncompliance determinations on the average value of all samples collected. These commenters argued that a single sample is not a statistically valid representation of the subject's "typical" or "normal" exposure to the contaminant. The commenters noted that a single sample, if taken on a randomly selected work day, could result in an unusually high measurement (unusual with respect to a "typical" or "normal" day). Therefore, a single sample could give rise to a noncompliance determination, even if the environment being sampled is in compliance on most shifts. These commenters contended that such a sample was "unrepresentative" of typical exposure concentrations and should not, therefore, be used as a basis for a noncompliance determination.

MSHA recognizes that the day-to-day exposure of a miner will not be constant and that on some days the sample collected over a single shift may be lower than the miner's long term average and on other days higher. However, MSHA has several compelling reasons for considering noncompliance on any individual shift to be a citable violation of the dpm concentration limit.

First, MSHA has identified significant risks associated with short-term dpm exposures (i.e., exposures over a 24-hour period). As documented in Part III of this preamble, adverse health effects associated with short-term exposures include (1) acute sensory irritations and respiratory symptoms (including allergenic responses) and (2) premature death from cardiovascular, cardiopulmonary, or respiratory causes. These risks alone would fully justify enforcing the concentration limits established in § 57.5060 on each and every shift.

Second, the concentration limits that MSHA has established are not expected to fully protect miners from these risks or from the excess risk of lung cancer associated with chronic dpm exposure. Instead, they are based on what can be feasibly achieved at this time to control dpm. By requiring compliance with the concentration limit on each shift measurement, it is MSHA's intent to protect miners to the maximum extent feasible.

Third, it is not MSHA's objective, when sampling for compliance determination purposes, to estimate average dpm concentrations for any period greater than the shift sampled or for any mine location other than the location sampled. Some commenters confused the objective of estimating cumulative exposures for purposes of risk assessment with the objective of limiting cumulative exposures for purposes of risk management. MSHA's objective is to limit exposures to protect miners against both short- and long-term effects. It is not practical for MSHA to track miners' cumulative exposures over an occupational lifetime. Therefore, as a practical matter of enforcement policy, MSHA can best protect miners from both the health risks associated with acute exposures and from the excess lung cancer risk due to chronic dpm exposure by limiting exposure on each shift wherever miners normally work or travel.

In addition, MSHA wants to emphasize that compliance limits in the metal and nonmetal sector, whether personal exposure limits or concentration limits, apply to every individual work shift. Every full-shift exposure, not just the typical, or "average" exposure, must be in compliance with the limit. Basing compliance on the typical, or "average" shift would permit frequent or sustained exposures to the contaminant at concentrations significantly higher than the compliance limit.

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Although MSHA's dpm compliance limit was not derived from any corresponding ACGIH TLV®, the explanation of the proper interpretation and application of TLV®'s provided in the 1999 TLV®'s and BEI®'s booklet (American Conference of Governmental Industrial Hygienists, 1999), is relevant to this discussion. Compliance limits are specifically intended to be applied over a conventional eight-hour work day and forty-hour workweek, and not to the average exposure received during a series of consecutive work shifts or workweek. Although an allowance is made in some instances for calculating exposures on the basis of a workweek average concentration, MSHA believes such an exception should not apply to dpm because of (1) the seriousness of associated health risks (such as lung cancer and premature death from cardiovascular, cardiopulmonary, or respiratory causes) and (2) the significant risk of adverse health effects associated with short-term exposures).

The only circumstance in which a single, out-of-compliance sample would not be used as the basis for a non-compliance determination is if the sample itself were considered invalid; for example, an inspector following an improper sampling procedure. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a single out-of compliance sample will take into account the actual risk posed to miners.

MSHA's policy on health inspections requires inspectors to rigorously follow established sampling procedures to ensure the validity of samples collected. As a practical matter, MSHA will not sample for diesel particulate at the tailpipe of any diesel powered equipment in metal and nonmetal underground mines. As discussed below, MSHA's sampling strategy for determining operator compliance is established in paragraph (c) of Section 57.5062. That section specifically states that MSHA will conduct personal sampling, occupational sampling, and/or area sampling, depending upon the circumstances of the particular exposure. Because MSHA has an environmental exposure limit, MSHA is interested in obtaining the level of diesel particulate in the environment where miners normally work or travel. In the alternative, MSHA may conduct personal sampling where circumstances necessitate it. For example, if a mine operator has a miner working inside a cab and there are no other workers in that area working outside the cab, MSHA will conduct personal sampling of the cab operator and not conduct environmental sampling outside the cab in the same area of the mine. Moreover, MSHA's sampling would be conducted inside the cab rather than outside the cab. On the other hand, if there are miners working outside the enclosed cab, MSHA will sample the environment to determine the level of exposure to dpm for these miners. Also, if an operator has a miner who is operating a shuttle car, and that miner is replaced by another miner during that shift, MSHA intends to place the sampler on the shuttle car in the vicinity of the miner and not at the tailpipe. However, in no case will area sampling be performed closer than five feet to a piece of operating diesel equipment, and no tailpipe sampling will be performed to determine compliance with any concentration limit.

Among other precautions, sampling equipment is maintained and operated in strict accordance with manufacturer recommendations, and pumps are calibrated before and after samples are collected. Sampling media are blank-corrected, and all laboratory handling and analytic procedures are in accordance with AIHA laboratory certification. Sample integrity is ensured through chain-of-custody seals. If any breach in procedure occurs, all affected samples are invalidated.

In order to assure compliance with the limit, mine operators need to implement controls sufficient to ensure that the entire range of concentration values is always safely below the compliance limit. The purpose of both MSHA sampling and mine operator monitoring is to verify, on an on-going basis, that this limit is always met on every shift.

When mine operators implement effective engineering controls, the range of the concentration values becomes narrower so that once control of dpm is demonstrated, it is unlikely that the concentration limit will be exceeded.

MSHA believes the same justification for determining noncompliance based on a single sample applies to dpm as to other contaminants and noise. Therefore, MSHA has retained the provision permitting a noncompliance determination to be based on a single sample.

Using NIOSH Method 5040 for compliance determinations. Pursuant to paragraph (b) of section 5061 of the final rule, MSHA will collect dpm samples for compliance using a respirable dust sampler equipped with a submicrometer impactor, and analyze such samples for the amount of total carbon using NIOSH Method 5040 (or by using any method of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy) for the measurement of dpm in underground metal and nonmetal mines. As noted above, this is like the proposed rule except that the final rule explicitly requires that a submicrometer impactor be used in collecting all dpm compliance samples in underground metal and nonmetal mines.

Section 3 of part II of this preamble discusses alternative methods for measuring dpm concentrations, and reviews the many comments MSHA received on this topic. As noted in that discussion, methods other than NIOSH Method 5040 do not at this time provide the accuracy required to support compliance determinations at the concentration levels required to be achieved under this rule. Moreover, after a careful review of the comments and hearing record, the available technical information submitted in response to MSHA's proposed rule, and the results of studies performed by agency experts to ascertain the veracity of those comments and submissions, MSHA has determined that NIOSH method 5040 provides an accurate method of determining the total carbon content of a sample collected in any underground metal or nonmetal mine when a submicron impactor is used with the otherwise prescribed sampling procedure, and when sampling strategies avoid sampling under circumstances that could compromise the integrity of the analytical process. Accordingly, MSHA will use this method for determining TC concentrations for compliance purposes, and the rule has been specifically amended to require that such samples be taken with a submicron impactor.

As indicated in the discussion of the proposed rule (p. 58129), utilizing the submicron impactor—a device that limits particles entering the sampler to those less than 0.9 micron in size when operated at a flow rate of 1.7 LPM—does cause a reduction in the amount of dpm that can enter the sampler, since some dpm is larger than 0.9 microns. Thus, in making this amendment, MSHA recognizes that underground metal and nonmetal miners will be exposed to more dpm than will be ascertained by these compliance measurements. However, for the reasons noted in section 3 of Part II, MSHA has determined that requiring use of the impactor is the only way to ensure that certain potential interferences (sources of total carbon other than dpm) are avoided at this time. Thus, to ensure the integrity of the sampling method, the agency has determined that it must use such an impactor.

One commenter suggested that, in addition to basing concentration limit compliance determinations on samples collected pursuant to § 57.5061, samples collected and analyzed in accordance with § 7.89 should also be used as a basis for compliance determinations. Section 57.5061 is the compliance determination for the ambient concentrations in the mine. Based on the ventilation being supplied, the number of engines being used, the condition of the engines, the duty cycle of the machines, the sample will show if the mine is in compliance with the dpm standard. Section 7.89 is the laboratory test for the diesel in engine in the lab to measure the raw dpm from the engine. The § 7.89 test data is used to calculate the particulate index for a single engine. Section 7.89 data can give the mine operator an idea of the dpm being emitted from the single engine and can use this data in the "Estimator" to calculate an estimated dpm ambient concentration. However, as explained elsewhere in the preamble, this is an estimate to set up proper ventilation when adding other pieces of equipment or deciding on which engine to buy. The section 7.89 dpm concentration does not take into account the duty cycle of the engine. Section 7.89 tests all engines on a specific test cycle. Section 7.89 test data can only be used to estimate dpm, cannot be used to know exactly what the concentration is in a mine at any given time. The test in 57.5061 is used for that determination. MSHA believes this procedure is inappropriate for determining compliance with the concentration limits and provision for doing so has not been included in the final rule.

Sampling strategy—personal, occupational, and area sampling. Subsection (c) of section 5061 provides for MSHA inspectors to determine the appropriate sampling strategy for compliance determinations: personal sampling (attaching a sampler to an individual miner within the miner's breathing zone), area sampling (sampling at a fixed location where miners normally work or travel), or occupational sampling (locating the sampler on a piece of equipment where a miner may work).

Personal sampling is well understood in the metal and nonmetal sector because it is commonly used by MSHA to determine compliance with TLV®'s for silica-bearing respirable dust, welding fumes, and other airborne contaminants. Area sampling is less well known in this sector, but it is used by MSHA for compliance determinations in some situations, such as where miners are exposed to a contaminant having a ceiling limit. Occupational sampling is not well known in the metal and nonmetal sector because it is not currently used by MSHA for compliance determinations in this sector. However, MSHA does employ occupational sampling in the coal sector for compliance determinations.

Occupational sampling is a method which measures the exposure of an occupation to a given contaminant, as opposed to personal sampling, which measures the exposure of an individual, or area sampling, which measures the contaminant concentration at a fixed location throughout the working shift. All three methods determine contaminant concentration on a shift weighted average basis (see previous discussion of "Concentration limit expressed as an average eight hour equivalent full shift airborne concentration" under § 57.5060). In occupational sampling, a full-shift sample is collected from the working environment of the occupation. The sampling apparatus (sample pump, size selection devices, sample filter, etc.) remains in the environment of the work position being sampled rather than with the individual miner, even when miners change positions or alternate duties during the shift.

A very common example of where occupational sampling would be the appropriate sampling method is where the sampling objective is to determine the full shift exposure of the operator of a particular piece of equipment, but where two or more individuals alternate operating the equipment. Personal sampling would capture both the exposure received while the equipment is being operated, as well as the exposure received while performing other duties. Area sampling would be limited to measuring the contaminant concentration in the general area where the equipment is operated, but would not capture the operator's exposure. In this example, occupational sampling, with the sample apparatus remaining in the cab or operator's compartment of the equipment throughout the shift, would be the only sampling method that could satisfy the sampling objective.

As noted above, the provision for utilizing either personal sampling, area sampling, or occupational sampling was not explicitly stated in the proposed rule. It was, however, clearly stated in the preamble to the proposed rule as MSHA's intent; indeed, a specific Question and Answer was devoted to the topic. (63 FR 58117, Question and Answer 14; the topic is further explored at 63 FR 58185). Moreover, in explaining its adoption of a "concentration limit", MSHA noted that its intention was to emulate the approach taken with coal mine dust, where inspectors have similar discretion (63 FR 58184) in the preamble to the proposal). Accordingly, the mining community was fully informed in this regard. The topic was the subject of considerable discussion at the hearings and received considerable comment.

After evaluating the comments, and reviewing the verification data on possible interferences discussed in Part II of this preamble, MSHA determined that its proposed position in this regard should be explicitly incorporated into the final rule. At the same time, as a result of the comments, the Agency has refined its thinking as to when various types of sampling would be appropriate. The Agency will provide further information in this regard in its compliance guide, but is using this opportunity to inform the underground metal and nonmetal mining community of its current views on how it will initially approach this matter.

Numerous commenters expressed concern about the proposed rule's provision for using either personal sampling or area sampling for determining compliance with the concentration limit for dpm. They pointed out that area sampling was a departure from previous enforcement practice in metal and nonmetal mines. They also questioned whether it was appropriate to use area sampling to determine compliance when there may be no one exposed (or very limited miner exposure) to dpm at the time and in the location where the area sample is taken, as well as in situations where miners work in enclosed cabs with filtered breathing air, and in other areas where engineering controls are not feasible. One commenter also argued that sampling at a fixed location (area sampling) and then equating the results with a personal exposure was invalid.

Commenters also asserted that the superiority of personal sampling for quantifying worker exposures is a commonly accepted industrial hygiene principle. Some commenters noted that in underground mines which use mobile diesel equipment, the positions of diesel-powered vehicles with respect to intake and return air streams vary from hour to hour. Therefore, they asserted, it is virtually impossible to obtain meaningful information from stationary instruments. One commenter stated that area sampling was appropriate as a screening tool to determine whether personal sampling would be warranted, or to evaluate the effectiveness of controls, but that it

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should not be used to determine compliance with a mandatory limit.

In responding to these comments, MSHA would like to emphasize to the metal and nonmetal mining community, as it did in the preamble to the proposed rule, that while the concept of a concentration limit is new for this sector, it is a well established concept in the mining industry, and has been implemented for many years with respect to coal dust. Questions about whether a particular sampling method are appropriate in a given situation have been raised and resolved many times.

Moreover, the courts have upheld MSHA's use of area sampling for enforcing compliance. In a 1982 decision (*American Mining Congress* v. *Secretary of Labor*, Nos. 80–1581 and 80–2166), the U.S. Court of Appeals, Tenth Circuit ruled that the decision to employ area sampling for respirable dust compliance determinations was a reasonable exercise of MSHA's discretion and authority. The court stated:

"Nothing in the record supports the conclusion that either type of sampling provides a perfect measure of exposure to respirable dust. Since there is no perfect sampling method, the Secretary has discretion to adopt any sampling method that approximates exposure with reasonable accuracy. The Secretary is not required to impose an arguably superior sampling method as long as the one he imposes is reasonably calculated to prevent excessive exposure to respirable dust. On this record, the difference between area and personal sampling is not shown to be so great as to make Secretary's choice of an area sampling program irrational. Keeping in mind that our task is not to determine which method is better, we hold that the Secretary's choice of area sampling over personal sampling is not legally arbitrary and capricious."

"We are not unmindful that area sampling may effectively require lower dust levels than might be required under a personal sampling program."

"The fact that in theory the regulation may require operators to maintain a dust level below [the limit] in its person-by-person impact does not render the regulation arbitrary and capricious. We repeat that all proposed sampling methods are less than perfect and are designed to provide only estimates of actual exposure. Since measurement error is inherent in all sampling, the very fact that Congress authorized a sampling program indicates that it intended some error to be tolerated in enforcement of the dust standard. The method selected by the Secretary, while perhaps more burdensome in its impact on mine operators than other methods, is not beyond the scope of his discretion."

In addition to affirming MSHA's discretion to employ area sampling on the basis that it can be "reasonably calculated to prevent excessive exposure," the court also observed that area sampling can be considered superior to personal sampling for enforcement purposes:

"The area sampling program has several advantages over a personal sampling program. The most important advantage is that area sampling not only measures the concentration of respirable dust, it allows identification and thus control of dust generation sources. Control of dust at the source will obviously contribute to reducing the level of personal exposure. By contrast, the results of personal samples do not allow identification of dust sources due to the movement of miners through various areas of the mine during the course of a working shift. Thus, while a personal sampling system makes possible the identification of discrete individuals who have been overexposed, it does nothing to ensure reduction of dust generation because the source of the dust cannot be determined. Therefore, it clearly appears that area sampling can rationally be found to be superior to personal sampling as a means of enforcing (as opposed to merely measuring) compliance with [the standard]."

Although this decision relates specifically to respirable dust, it is clear that the Court of Appeals did not find that area sampling is inherently unreliable. Moreover, the logic expressed by the Court in describing the application of area sampling to respirable coal mine dust applies equally to dpm. Both are solid particulates that are produced from discrete sources during mining and are transported via the mine's ventilation system and inhaled by miners.

Accordingly, the fact that some in the metal and nonmetal sector, or some not engaged in mining at all, may not be familiar with this approach does not make it invalid or inappropriate.

Implementation by MSHA of its discretion. For the reasons noted above, MSHA has determined that personal sampling, occupational sampling, and area sampling are all viable sampling methods, and that inspectors should have the discretion to utilize whichever sampling strategy is appropriate in a given situation to determine compliance with the concentration limit for dpm. Accordingly, all three approaches are permitted in the final rule.

The Agency will provide further information about how these approaches should be used for dpm sampling in its compliance guide; however, it is using this opportunity to inform the underground metal and nonmetal mining community of its current views on some common situations.

For example, one commenter noted that an area sample could be taken adjacent to where a piece of diesel equipment was accelerating at low RPM, which is the time that an engine is working at its lowest efficiency. This commenter expressed concern that such a sample could indicate that the applicable dpm concentration was exceeded, even though the duty cycle as a whole for that equipment might be in compliance. MSHA believes this situation shouldn't result in a violation, because such an area sample would be taken for an entire shift, not just for the short time period when the piece of diesel equipment passes by the sampler.

Moreover, MSHA recognizes that it would not provide an accurate measure of the concentration of dpm to place a sampler in the area immediately around a machine's tailpipe when no workers would be in that location for any great length of time. An area sample would not be taken in that manner. But if a worker were assigned to work in a location on or immediately adjacent to diesel equipment, a personal or occupational sample might well be appropriate to determine if the limit is being exceeded for that worker or for such occupation.

Similarly, the agency would not consider it appropriate to conduct area sampling for compliance determinations in areas where dpm exposures, if any, would be infrequent and brief; in areas where miners work exclusively inside enclosed cabs; and in shafts, inclines, slopes, adits, tunnels and similar workings that are designated as return or exhaust air courses and that are also used for access into, or egress from an underground mine.

Examples of the first situation would be work areas that are visited infrequently and briefly, such as a remote pump that needs to be checked weekly, or a remote area where roof conditions need to be inspected at periodic intervals. These areas would clearly be subject to the concentration limit because miners "normally work or travel" there. Area sampling in such areas would be inconsistent with the regulation's intent to, "* * * limit the concentration of [dpm] to which miners are exposed * * *," because exposure would occur for only a few minutes per week, or possibly less.

Examples of the second situation would be production areas or haulageways where the only miners present work inside of enclosed and isolated cabs with appropriate filtration of breathing air, and underground crushing stations where crusher operator booths or similar fixed structures are provided with appropriately filtered breathing air. Area sampling outside such cabs or structures, which would have been permitted under the proposed rule, would be inconsistent with the regulation's intent to, "* * *limit the concentration of [dpm] to which miners are exposed * * *," because miners in these areas are not exposed; they are already protected by an accepted engineering control. This approach is consistent with MSHA's intent as stated in the preamble to the proposed rule (63 FR 58184). It also reflects MSHA's awareness that enclosed cabs may provide many other important health and safety benefits, such as reducing noise exposure and reducing exposure to silica bearing respirable dust.

However, as a result of the comments concerning whether NIOSH method 5040 can effectively be used to determine compliance when miners are smoking, the agency recognizes that it faces a particular difficulty in sampling miners when they smoke inside an enclosed cab or booth, whether such sampling is area, occupational, or personal. As noted in Part II, section 3, MSHA has verified that sampling using NIOSH method 5040 immediately adjacent to smokers can undermine the validity of the sample result—since some of the total carbon detected may be from the smoke). While MSHA can generally avoid this problem by not sampling immediately near smokers, as discussed in that section of this preamble, it does face a problem when the area to be sampled is an enclosed cab or booth: it can neither sample inside nor outside an enclosed cab or booth if the subject miner smokes. The Agency intends to address this problem by obtaining the concurrence of the miner not to smoke while sampling the environment of the cab.

MSHA is troubled that, under certain circumstances, it will need to rely on miners voluntarily refraining from smoking in order to perform compliance sampling for dpm. Since miners are usually free to choose to smoke if they wish, this need to rely on the voluntarily cooperation of miners could seriously limit the agency's ability to sample when and where it desires. Though MSHA has determined that sampling of nonsmokers would usually be unaffected by the presence of smokers elsewhere in the mine, there will be situations where sampling of a specifically targeted area, occupation, or person would be prevented due to the presence of a smoker at that immediate location. Therefore, MSHA intends to continue to search for a means to reliably measure dpm concentrations despite the presence of cigarette, cigar, and pipe smoke in close proximity to the sampling equipment.

As noted in Part II, section 3, MSHA has determined that samples analyzed only for elemental carbon are unaffected by the presence of cigarette smoke. At this time, however, MSHA cannot limit its analysis to elemental carbon, because no consistent quantitative relationship has been established between elemental carbon concentration and the concentration of whole dpm.

MSHA intends to implement any newly developed sampling procedure and/or analytical method that is capable of directly or indirectly measuring the concentration of whole dpm in the presence of cigarette, cigar, and pipe smoke, provided such procedure and/or method is determined by NIOSH to provide equal or improved accuracy compared to the NIOSH Method 5040. If MSHA decides that such a change in sampling procedure and/or analytic method should be adopted, the agency will utilize standard communication channels to provide specific notification of its intention in this regard to the underground metal and nonmetal mining industry. However, MSHA wishes to be clear that, in accordance with § 57.5061(b), implementing such a change does not require new rulemaking.

Examples of the third situation include return or exhaust air courses that are shafts, inclines, slopes, adits, tunnels, etc. which terminate on the surface, but which are also used for mine access or egress by mine personnel.

Since the purpose of a return or exhaust air course is to collect and remove contaminated air from the mine, one would expect such an air course could contain high dpm levels. However, being a major travelway, one would naturally consider them to be areas "where miners normally work or travel." As miners travel into the mine at the beginning of the shift and out of the mine at the end of the shift through these mine openings, relatively brief exposures to potentially high dpm levels could be expected. Full shift area sampling in such a location would likely indicate dpm levels in excess of the concentration limit. Should area sampling in such an air course result in a determination of noncompliance (which would be highly likely), the mine operator would be required to implement a change of some kind to bring the area into compliance, such as requiring that miners use a different access to the mine that is an intake or neutral air course, or that the ventilation system would need to be changed so that the access in question is no longer a return or exhaust air course. Since neither of these options may be feasible, the operator would be placed in an impossible compliance situation.

In such situations, MSHA believes that it would not be appropriate to use area sampling; rather, personal sampling would be more appropriate. Personal sampling would capture the exposure as miners travel into the mine at the beginning of the shift and depart at the end of the shift. Since the exposure time is brief, overexposure on a full-shift basis would be unlikely (assuming dpm levels in the working places are in compliance). Also, since exposure time is brief, the health risk associated with the exposure would be minimal.

It should be noted, however, that miners whose jobs require them to spend significant periods of time in these areas would continue to be at risk of overexposure if the dpm levels are high. For example, a haulage truck driver that spends much of the shift driving in and out of the mine through exhaust air hauling material to a surface dump point or crusher may need to be protected with an enclosed cab that is provided with filtered breathing air. Personal sampling on miners who engage in such activities would reveal the problem.

Another situation requiring clarification as to MSHA's intended compliance sampling procedures concerns miners who perform multiple work tasks during a shift. If a miner's work on a given shift includes a task or tasks for which the sampling procedures would not provide an accurate measurement of the dpm, MSHA would not use that measurement for the basis of a compliance determination. An example would be a miner who begins the shift operating a diesel-powered loader, and who finishes the shift operating a jack leg drill equipped with an in-line oil bowl. While operating the loader, MSHA would consider a personal or occupational sampling procedure to be acceptable for obtaining an accurate measurement for compliance purposes. However, as noted in Section II, MSHA would not consider personal or occupational sampling to be acceptable for sampling a miner who is operating a jack leg drill equipped with an in-line oil bowl, because there is the potential that oil mist emitted from the drill may be collected on the sample filter causing an inaccurate measurement of dpm to be made.

In this case, full shift area sampling would be performed at a location where the oil mist would not interfere with the measurement of dpm. If the drilling operation takes place in a different location from the loading operation (a different stope, for example), MSHA would consider full shift area sampling in both locations, if appropriate.

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However, if no source of dpm is present at the drilling location, the inspector would probably choose to sample only the location where the loader is operating.

The agency considered whether it would be appropriate to deal with these situations through an amendment of the rule, and decided this would not be appropriate. The specific facts in a specific situation should determine the appropriateness of the sampling approach; trying to lock down this situation or that in the rule would prove very complex and restrict the flexibility to react to developments in the industry. The rule reserves to MSHA the flexibility to adjust the use of sampling approaches for any situation where use of one or another method might not be appropriate.

At the same time, the Agency wishes to make it clear that in putting explicitly into the rule that the Agency can use any of the three methods specified, it intends by that action to ensure that any policy that would broadly restrict the use of one or another of these methods would have to be the subject of new rulemaking. Thus, for example, any policy to significantly restrict the use of area sampling to enforce compliance with this rule would have to be the subject of new rulemaking action, as the availability of that method was a key consideration in MSHA's decision that it could implement a concentration limit.

Section 57.5062 Diesel Particulate Matter Control Plan

Under the final rule, a determination of noncompliance with either the interim or final concentration limit prescribed by § 57.5060 would trigger two requirements: first, the operator must establish a diesel particulate matter control plan (dpm control plan) meeting certain basic requirements—or modify the plan if one is already in effect; and second, the operator must demonstrate that the new or modified plan will be effective in controlling the concentration of dpm to the applicable concentration limit. The final rule also sets forth a number of other specific details about such plans, and states that failure of an operator to comply with the provisions of a plan or to conduct required verification sampling will be a violation of Part 57 without regard for the concentration of dpm that may be present. In all respects, this section of the final rule is essentially the same as in the proposed rule.

Only a few comments were directed specifically at § 57.5062. Some of those were supportive of the concept, such as the remark by one mine operator that, "Generally, the Diesel Particulate Matter Control Plan (DPMCP) contained in § 57.5062 is well conceived." One commenter noted that once a plan is in place, failure to abide by its provisions is a citable violation, even if dpm levels are below the applicable concentration limit. Another commenter recommended that rather than a single out-of-compliance sample triggering the requirement to implement a plan, the provisions of § 57.5062 should not be triggered unless there is a significant history of non-compliance with the limit. Another commenter questioned why a determination of non-compliance requires MSHA to obtain only one non-compliant sample, whereas proof of operator compliance (both with respect to § 57.5062 and § 57.5071) requires multiple operator samples. A commenter also observed that a single sample is not "statistically significant or representative and cannot determine if the mine is out of compliance." The same commenter argued that the requirements for documenting dpm control plan effectiveness were unnecessary, burdensome, and duplicated other MSHA requirements.

Triggering plan. Under the final rule, a single out-of-compliance dpm sample constitutes a citable violation of the applicable concentration limit and triggers the requirement to implement a diesel particulate matter control plan. As noted above, one commenter recommended that a diesel particulate matter control plan should not be required unless a mine has a significant history of non-compliance with the applicable dpm concentration limit. MSHA disagrees with the commenter's position because MSHA does consider a single sample to be a valid means of determining compliance (see discussion under § 57.5060 on single sample), and because a "significant history of non-compliance" at a given mine, would almost certainly be accompanied by significant, prolonged, and repeated exposure of miners to dpm levels in excess of the applicable concentration limit. Such exposures cannot be tolerated. When sampling indicates non-compliance, remedial action consisting of the implementation of a dpm control plan, or modification of an existing plan, must be initiated without delay. This will insure a timely reduction in dpm levels, and will help prevent dpm levels from rising above the applicable concentration limit in the future.

No advance approval of plans required. § 57.5062 will maintain the Agency's metal and nonmetal mine plan tradition by not invoking a formal plan approval process. That is, the plan would not require advance approval of the MSHA District Manager. As noted in the discussion of § 57.5060(c) and (d), MSHA is requiring advance approval for an operator to obtain a special extension of up to 2 years to meet the final concentration limit, and/or to allow miners performing inspection, maintenance or repair work to conduct such activities in areas that exceed the concentration limit. But a plan required because the limit has been exceeded need not obtain such advance approval.

In the preamble to the proposal for this Part, MSHA requested comment from the mining industry as to whether dpm control plans should require pre-approval by the Agency (p. 58119). The only comment received was in support of the Agency's proposal that such plans not require pre-approval.

A dpm control plan would, however, have to meet certain requirements set forth in the final rule, and as noted in the preamble to the proposed rule, it would be a violation of § 57.5062 if MSHA determines that the operator has failed to adequately address each of the plan's required elements.

Moreover, as discussed subsequently in connection with paragraph (f) of this section, once in place, a dpm control plan becomes law for that mine, and an operator must comply with it.

Elements of plan. Under § 57.5062(b), a dpm control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan must also include a list of diesel-powered units maintained by the mine operator, together with information about any unit's emission control device and the parameters of any other methods used to control the concentration of diesel particulate matter.

Relationship to ventilation plan. At the discretion of the operator, the dpm control plan may be consolidated with the ventilation plan required by § 57.8520.

Demonstration of plan effectiveness. The final rule would require monitoring to verify that the dpm control plans are actually effective in reducing dpm concentrations in the mine to the applicable concentration limit. Because the dpm control plan was initiated as a result of a compliance action, the final rule would require the use of the same measurement method used by MSHA in compliance determinations—total carbon using NIOSH method 5040—to conduct verification sampling. As a result, mine operators who are required to establish a dpm control plan would need to acquire the necessary sampling equipment to conduct the verification sampling, or arrange for such sampling

to be conducted for them. As noted in Part II, the necessary sampling equipment is commercially available.

MSHA recognizes concerns about the commercial availability of the sampling equipment for NIOSH Method 5040. It is important that operators know whether they are in compliance with the standard. MSHA understands that the equipment will be available before this standard is in effect. MSHA will not use any equipment for sampling for compliance with this standard that is not commercially available. If the equipment is not commercially available by the effective date of the standard it is MSHA's intention not to enforce the dpm levels in the standard until the sampling equipment is available.

Effectiveness must be demonstrated by "sufficient" monitoring to confirm that the plan or amended plan will control the concentration of diesel particulate to the applicable limit under conditions that can be "reasonably anticipated" in the mine.

The final rule, like the proposed rule, does not specify that any defined number of samples must be taken—the intent is that the sampling provide a fair picture of whether the plan or amended plan is working. Instead, as indicated in the preamble to the proposed rule, MSHA will determine compliance with this obligation based on a review of the situation involved. While an MSHA compliance sample may be an indicator that the operator has not fulfilled the obligation under this section to undertake monitoring "sufficient" to verify plan effectiveness, it would not be conclusive on that point.

One commenter questioned the fairness of holding operators responsible for verifying plan effectiveness, the need for documentation to verify that plans will control dpm to the applicable limit, and for the requirement that such documentation must be provided upon request by MSHA. This commenter suggested that mine operators are already required to show compliance with air quality standards under § 57.5002, and that further documentation relating to the diesel particulate matter control plan therefore duplicates existing requirements.

While it is true that § 57.5002 requires mine operators to conduct "dust, gas, mist, and fume surveys" as frequently as necessary to determine the adequacy of control measures, this regulation does not specifically address diesel particulate matter, nor does it specify that dpm concentrations must be determined using the NIOSH Method 5040 (as is required in § 57.5062(c)). Thus, compliance with § 57.5002 will not insure compliance with the intent of § 57.5062. Section 57.5062(c) also requires that mine operators demonstrate that dpm concentrations will be controlled to applicable limits, not only under current conditions (*i.e.*, that a compliant sample be obtained), but also under reasonably anticipated conditions in the future.

MSHA disagrees with the commenter's suggestion that "rigorous enforcement of existing TLV©'s and air quality rules, and * * * utilization of recommendations in the 'Diesel Toolbox'" will result in "adequate safety levels." The 1973 Threshold Limit Values© or TLV©'s (the TLV©'s incorporated by reference in § 57.5001, and therefore currently enforceable in underground metal and nonmetal mines) do not include a limit of any kind for dpm. It is interesting to note that, as indicated in Table II–2 of Part II, section 5, the TLV©'s enforced by MSHA are derived from recommendations of the American Conference of Governmental Industrial Hygienists (ACGIH). That organization has recently proposed a limit for dpm (ACGIH Notice of Intended Changes for 1999) of $50_{DPM}\mu g/m^3$, well below what is being established by this rule. As noted in Part V of this preamble, MSHA has concluded that $50_{DPM}\mu g/m^3$ is an unreasonably low limit for dpm concentration in underground metal and nonmetal mines because MSHA's technological and economic feasibility assessment indicate that this level cannot be achieved using feasible control measures.

If a diesel particulate matter control plan is in effect, the final rule specifies that monitoring must be "sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine." Again, as conditions and circumstances in the mine change, the mine operator must demonstrate, on a continuing basis, through sampling results using NIOSH Method 5040, that compliance with the applicable concentration limit is consistently achieved.

MSHA believes that dpm control requires a holistic approach. A piecemeal solution to a dpm problem may result in shifting an overexposure from one area to another, but not eliminating the problem entirely. If an overexposure in one part of the mine is addressed by re-routing more ventilation air to that area, it means another part of the mine will have to give up some air, possibly causing an overexposure there. If an overexposure in one part of the mine is addressed by exchanging a dirty machine for a clean machine, it means the dirty machine is still polluting somewhere else. In these examples, the actions taken may simply move an overexposure to a different location, or they may result in overall compliance. The only way of knowing for sure whether the problem has actually been solved, is to consider the effects of a given action on the mine as a whole. That is what the regulation requires. MSHA does expect operators will focus their control plans on the areas of the mine in which dpm presents a hazard to miners.

The reason that MSHA can determine non-compliance based on a single sample whereas mine operators need multiple samples to demonstrate compliance is due to the fundamental difference between proving non-compliance versus proving compliance. For example, proving that at least one non-compliance condition exists somewhere in a mine requires only one non-compliant sample result. Proving conditions are fully compliant everywhere in a mine all the time requires more than one compliant sample result. The actual number of compliant samples necessary to prove that every location in the mine is fully compliant all the time would have to be determined, but it would rarely, if ever, be only one.

The differences between determining non-compliance versus determining compliance are incorporated into standard industrial hygiene practice. For example, regarding the evaluation of the exposure of a worker over a single day by means of a full-period measurement (which is MSHA's compliance sampling approach), *Patty's Industrial Hygiene and Toxicology* (3rd Edition, 1994) states, "In that case, the error variance is determined by only the sampling and analytical error, and confidence limits tend to be quite narrow." By appropriately accounting for sampling and analytic errors, MSHA will assure, at the 95% confidence level, that an out-of-compliance sample accurately reflects an out-of-compliance condition in the mine.

This contrasts with the mine operator's need to verify compliance. *Patty's* states, "Usually, however, our concern is with the totality of a workers exposure, and we wish to use the data collected to make inferences about other times not sampled. There is little choice; unless the universe of all exposure occasions is measured, we must "sample," that is, make statements about, the whole based on measurement of some parts."

"The American Industrial Hygiene Association has addressed the issue of

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appropriate sample size (Hawkins et al., 1991) and recommends in the range of 6–10 random samples per homogeneous exposure group. Fewer than 6 leaves a lot of uncertainty and more than 10 results in only marginal improvement in accuracy. Also, it is usually possible to make a reasonable approximation of the exposure distribution with 10 samples although a rigorous goodness-of-fit test often requires 30 or more." Although a single sample is not adequate to demonstrate compliance, MSHA does not specify in the final rule, a minimum number of samples that will constitute adequate verification of compliance in all cases. It is the mine operator's responsibility to determine the appropriate level of sampling effort and explain the rationale in the diesel particulate matter control plan.

Like the final rule, the proposed rule provided that verification sampling would be conducted under conditions that can be "reasonably anticipated" in the mine. The Agency very specifically solicited comment on "whether, and how, it should define the term 'reasonably anticipated.'" (63 FR 58185) The agency noted that with respect to coal dust, the Dust Advisory Committee recommended that "MSHA should define the range of production values which must be maintained during sampling to verify the plan. This value should be sufficiently close to maximum anticipated production." (MSHA, 1996) For dpm, the Agency suggested, the equivalent approach might be based on worst-case operating conditions of the diesel equipment—*e.g.*, all equipment is being operated simultaneously with the least ventilation. No comments were received on this point.

Recordkeeping retention and access. Pursuant to section 5062(b), a copy of the current dpm control plan is to be maintained at the mine site during the duration of the plan and for one year thereafter. Section 5062(c) requires that verification sample results be retained for 5 years. And, section 5062(d) provides that both the control plan and sampling records verifying effectiveness be made available for review, upon request, by the authorized representative of the Secretary, the Secretary of Health and Human Services, and/or the authorized representative of miners. Upon request of the District Manager or the authorized representative of miners, a copy of these records is to be provided by the operator.

Duration. The final rule requires the dpm control plan to remain in effect for three years from the date of the violation resulting in the establishment/ modification of the plan. Section 57.5062(e)(1) and (e)(2). MSHA has concluded that operators have sufficient time under the final rule to come into compliance with the concentration limits; if a problem exists, maintaining a plan in effect long enough to ensure that daily mine practices really change is an important safeguard. MSHA noted its view in this regard in the preamble to the proposed rule; no comments were received on this point.

Modification during plan lifetime. If a diesel particulate matter control plan is already in effect at a mine, section 57.5062(a) requires the mine operator to modify the current plan upon a subsequent violation of section 57.5060, and to demonstrate the effectiveness of the modified plan.

Section 57.5062(e)(3) would require the mine operator to independently initiate the modification of an existing dpm control plan to reflect changes in mining equipment and/or the mine environment, and requires the operator to demonstrate the effectiveness of the modified plan.

It should also be noted that a mine operator, based on dpm sampling data or other information or analysis, may at any time, modify the provisions of a dpm control plan to make it less restrictive, provided sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. A modification made in this manner does not affect the 3-year duration of the plan (end date unaffected). These plans made by the operator do not require advance approval by MSHA.

Compliance with plan requirements. Section 57.5062(f) states that failure by a mine operator to comply with the provisions of a diesel particulate matter control plan is a violation of the rule, regardless of the concentration of dpm that may be present at any time. Once an underground metal or nonmetal mine operator adopts a dpm control plan, it is considered law for the mine. Section 57.5062(f) specifically provides that MSHA would not need to establish (by sampling) that an operator is currently in violation of the applicable concentration limit under § 57.5060 in order to determine (by observation) that an operator has failed to comply with any requirement of the mine's dpm control plan.

One commenter observed that, "It does seem odd * * * that § 57.5062(f) contemplates that the mere failure to adhere to the [dpm control plan] itself is deemed a violation of the regulation—irrespective of the fact that the exposure to dpm may indeed be less than the [concentration limit]."

MSHA's rationale for making a mine's dpm control plan law for that mine derives from the rule's approach to setting control requirements. MSHA recognizes that every mine faces a unique set of conditions and circumstances relating to equipment, engines, emission controls, ventilation, etc. that would make uniform dpm control requirements across the entire underground metal and nonmetal mining industry unworkable, impractical, and ineffective. Hence, the final rule, with just a few exceptions, permits mine operators considerable freedom to select the mix of dpm control options they believe are necessary to comply with the applicable concentration limit. An operator can filter the emissions from diesel-powered equipment, install cleaner-burning engines, increase ventilation, improve fleet management, or use a variety of other readily available controls, all without consulting with, or seeking approval from MSHA.

However, if MSHA sampling indicates non-compliance with the applicable concentration limit, the rule requires the operator reduce to writing his or her specific plans for controlling dpm to the concentration limit and to adhere to that plan. MSHA considers miner exposure to dpm, a probable carcinogen, as a very serious matter, and has not established that exposures, even at the concentration limit, are safe. That is why a single non-compliant sample triggers the requirement for a compliance plan. The plan lays out the minimum steps the operator has determined must be followed in that mine to insure compliance. Failure to adhere to the requirements of the operator-developed plan must thus be viewed as a failure to take actions that are necessary for compliance with the concentration limit.

Because of the importance of adhering strictly to an effective dpm control plan, a means of enforcing such adherence is necessary. The plan is made law for that mine so that its provisions can be enforced by MSHA. The plan need not be approved by the MSHA District Manager, but it is, nonetheless, law for that mine, and any violation of the plan is therefore a violation of the regulation. As discussed above, an operator is free to modify a dpm control plan to make it less restrictive at any time during its life, and as often as desired, as long as sufficient sampling data confirm the plan's continuing effectiveness in controlling dpm to compliant levels. MSHA is of course concerned primarily with the health and safety of miners so the magnitude of any citation for a violation of the plan will take into account the actual risk posed to miners.

With respect to the required diesel particulate matter control plan, the mine operator is essentially telling MSHA what steps are necessary for that mine to comply with the applicable concentration limit. If MSHA observes a violation of the plan, it is only reasonable and proper for MSHA to conclude that full compliance is therefore not possible. If enforcement of the provisions of the dpm control plan depended upon obtaining an out-of-compliance dpm sample, plan enforcement would be greatly diminished, both in terms of timeliness and effectiveness. If such a sample were taken, and found to be out of compliance, implementation of needed corrective measures would be delayed because MSHA could not require the mine operator to take remedial actions until the sample results were obtained from the analytic laboratory, which could involve several weeks of time. If such a sample were taken, and found to be in compliance, that fact would not constitute conclusive evidence that the plan as a whole was fully effective (see earlier discussion on the need for multiple samples to establish continuing compliance). Thus, while providing inconclusive information at best, such a sampling outcome would prevent MSHA from enforcing a provision of the plan. Regardless of sampling outcome, it is important to remember that a violation of the plan means the mine operator did not adhere to the very requirements that were represented to MSHA by the operator as being necessary for compliance.

It should also be noted that MSHA already has similar enforcement authority relative to various other plans that are required in the underground metal and nonmetal sector. Mine operators are required to prepare plans for such purposes as escape and evacuation, rock bursts, ventilation, and training. MSHA has the authority to enforce the provisions of these plans without first verifying that the observed violation has caused an immediate outcome which itself, is prohibited by regulation. There is also ample precedent for citing health-related violations without sampling, such as § 58.620 on drill dust control, and § 57.5005 on respiratory protection.

The mine operator is required to modify dpm control plans to reflect changes in mining equipment or circumstances. The mine operator is also required to modify dpm control plans if the plan proves to be inadequate, as evidenced by a subsequent non-compliance determination during the three year period that the plan is in effect. In either case, the modifications to the original plan become law for that mine, and violations are subject to enforcement action by MSHA regardless of dpm concentration.

It is also important to remember that dpm levels are determined by the complex interaction of numerous factors, such as equipment type, engine size, type, and horsepower, duty cycles, engine maintenance, equipment operator training and work practices, fuel and fuel additives, the characteristics and performance of exhaust filtering systems, mine ventilation flows, and many others. Effectively controlling dpm levels throughout a mine requires a systematic approach that acknowledges the interrelationships and interactions between these factors to produce the desired end result, which is compliance with the applicable concentration limit. A determination of non-compliance indicates that the system of controls has failed. Thus, an effective permanent solution requires a comprehensive approach which not only corrects the immediate cause of the non-compliance (an out-of-tune engine, for example), but also addresses the underlying system failure (deficient maintenance management, inadequate dpm monitoring, ineffective equipment operator training, failure to tag equipment believed to require maintenance, etc.).

The implementation of a dpm control plan avoids piecemeal solutions that result in a repetitive pattern of mines being in and out of compliance without ever coming to grips with underlying problems. The required elements of a dpm control plan force a comprehensive approach, and facilitate effective, permanent solutions to systemic failures. The three year duration of such plans insures that the necessary system changes become institutionalized and integrated into daily mine practices. This, in turn, will increase the chances that mines will be in compliance with the applicable concentration limit on a continuous, on-going basis.

MSHA recognizes that some operators may want to supplement the compliance plans required by the regulation with additional internal instructions that provide supplementary protection—i.e., to achieve concentration levels below those required. MSHA does not want to discourage such supplemental plans; indeed, it would like to encourage them. Accordingly, MSHA will, upon request, work closely with mine operators to help avoid confusion by mine and Agency personnel between required compliance plans that contain the minimum elements considered essential to achieve compliance (and whose provisions are therefore enforceable by MSHA) and non-required supplemental plans that contain elements the mine operator wishes to implement as a matter of company policy (but whose provisions are not enforceable by MSHA).

Section 57.5065 Fueling Practices

Summary. This section of the final rule establishes the requirements for fueling practices in underground metal and nonmetal mines. Unlike the proposed rule, the final rule has two subsections.

Subsection (a) limits the amount of sulfur that may be contained in diesel fuel used to power equipment in underground areas, and requires mine operators to maintain purchase records that verify the sulfur content of the fuel they use.

Subsection (b) requires that fuel additives used in underground diesel-powered equipment be restricted to those registered by the U.S. Environmental Protection Agency.

These subsections of the final rule have not been changed from the proposed rule.

The practices being required by these two subsections are accepted industry practices to reduce dpm emissions. They are among the methods for reducing dpm explicitly included in MSHA's toolbox publication, and were made requirements for underground coal mines as part of MSHA's diesel equipment rulemaking. They are among the "best practices" for reducing dpm emissions that MSHA has determined are technologically and economically feasible for all underground metal and nonmetal mines. Part II of this preamble contains some background information on these practices together with information about the rules currently applicable in underground coal mines.

Low-sulfur fuel. In the final rule, § 57.5065(a) would require underground metal and nonmetal mine operators to use only low-sulfur fuel having a sulfur content of no greater than 0.05 percent. This requirement is identical to that currently required for diesel equipment used in underground coal mines [30 CFR 75.1901(a)]. Both number 1 and number 2 diesel fuel meeting the sulfur content requirement of this rule are commercially available.

Sulfur content can have a significant effect on diesel emissions. Use of low-sulfur diesel fuel reduces the sulfate fraction of dpm matter emissions, and

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reduces objectionable odors associated with diesel exhaust.

Another major benefit of using low-sulfur fuel is that the reduction of sulfur allows oxidation catalysts to perform properly. Some diesel emission aftertreatment devices, such as catalytic converters and catalyzed particulate traps, are "poisoned" with fuels having high-sulfur content (greater than 0.05 percent sulfur). MSHA believes the use of these aftertreatment devices is important to the mining industry because they will be necessary for many mines to meet the specified concentration limits. The requirement to use low-sulfur fuel will allow these devices to be used without additional adverse effects caused by the high-sulfur fuel.

Several commenters questioned why low-sulfur fuel was mandated, even for operators who could meet the applicable concentration limit using other means. MSHA responds by noting that the use of low-sulfur fuel is one of the "best practices" that MSHA requires all mines to follow, regardless of current dpm levels. Further elaboration on the rationale for mandating these "best practices" was included in the preamble to the proposed rule (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed "Meeting the concentration limit, operator choice of engineering controls." As noted in those discussions, MSHA is required by statute to reduce a significant risk to the extent feasible; the use of low-sulfur fuel is feasible, has not created any problems in the underground coal sector where it is required as a result of the diesel equipment rule, and its use will reduce dpm emissions from underground engines.

In the preamble to the proposal (63 FR 58186), MSHA indicated it did not believe a requirement mandating the use of low-sulfur fuel will add additional compliance costs. Several commenters contradicted this conclusion, arguing that the provision requiring low-sulfur fuel would have an adverse cost impact. One commenter supplied actual cost figures that showed their fuel costs increased over $18,000 per year after they switched to low-sulfur fuel. However, it is significant to note that this increase is quite small on both a cost per gallon of fuel basis (less than $0.03 per gallon), and a cost per ton basis (about $0.006 per ton), and that this mine had already made the switch to low-sulfur fuel, apparently because they perceived that the benefits justified the small additional expense.

As discussed in the Section IV of the PRIA, MSHA determined that the cost difference between high-sulfur and low-sulfur diesel fuel was less than $0.02 per gallon in many parts of the country, and in some areas, there was no difference at all, or a slight cost advantage to using low-sulfur fuel. Fuel used in over-the-road diesel engines is currently required by EPA regulations to meet the same 0.05% sulfur content limit that is being implemented for underground metal and nonmetal mines. Because over-the-road diesel engines represent the bulk of the diesel fuel market, such low-sulfur fuel is already readily available throughout the country. EPA has proposed regulations that would further reduce allowable fuel sulfur content to 0.0015% for over-the-road diesel engines. Current MSHA regulations limit the sulfur content of diesel fuel used in underground coal mines to 0.05%, and the availability of this fuel in remote coal mining areas has not been a problem for coal mine operators. As discussed above, MSHA has determined, based on extensive study of the metal and nonmetal mining industry, that compliance with the rule is economically feasible for the industry as a whole. Thus, although the provision requiring use of only low-sulfur fuel may, in some instances, result in a small cost increase for some operators, MSHA estimates that on average, the overall measurable impact is negligible. When they are measurable, it is because the mine is located in an area where heating fuel has relatively large market share compared to diesel fuel used for vehicles. This circumstance is unrelated to mine size. Most mines are not located in these regions and there is no evidence that small mines are disproportionately concentrated in these regions.

Fuel additives. Paragraph (b) of this section requires mine operators to use only diesel fuel additives that have been registered by the Environmental Protection Agency (40 CFR Part 79). Again, this rule is consistent with current requirements for diesel equipment used in underground coal mines [30 CFR 75.1901(c)], and is another of the "best practices" that MSHA considers to be feasible for all underground metal and nonmetal mines. The restricted use of additives would ensure that diesel particulate concentrations would not be inadvertently increased, while also protecting miners against the emission of other toxic contaminants. MSHA has published Program Information Bulletin No. P97–10, issued on May 5, 1997, that discusses the fuel additives list. The requirements of this paragraph do not place an undue burden on mine operators because operators need only verify with their fuel suppliers or distributors that the additive purchased is included on the EPA registration list. To assist mine operators in this regard, EPA's Internet site contains a current listing of additives registered with EPA. This site can be accessed at the following address: http://www.epa.gov/oms/regs/fuels/additive/web-dies.txt. No commenters objected to this requirement.

Idling practices. Proposed paragraph (c) of § 57.5021 would have prohibited idling of mobile diesel-powered equipment, except as required for normal mining operations. After further consideration of all comments received during the comment period, as well as testimony presented at the public hearings, MSHA has decided to delete this requirement from the final rule. Therefore, the final rule does not contain a restriction for operators on idling diesel-powered equipment. MSHA does, however, recommend as a best practice that mine operators do not allow miners to idle diesel-powered equipment unnecessarily.

Although commenters generally agreed with MSHA's statement in the proposal that this requirement would aid in the reduction of dpm concentrations at the mine, they pointed out that the total amount of diesel particulate matter emitted from this single source might have little effect on the levels of dpm in the overall mining environment. Also, several commenters questioned the need for an idling restriction in light of the proposed concentration limits established in the regulation. Additionally, another commenter indicated that the provision was not necessary because mine operators, in an effort to comply with the applicable concentration limits, would be forced to institute work rules to this effect anyway. Moreover, as pointed out by commenters, nothing in the regulatory language prohibits operators from voluntarily restricting idling at the mine, eliminating the need to include this provision. Accordingly, we have deleted proposed paragraph (c) from the final rule.

Section 57.5066 Maintenance standards.

Summary. This section of the final rule establishes maintenance standards for diesel-powered equipment operated in underground areas of metal and nonmetal mines. It has three subsections.

Subsection (a) addresses maintenance of diesel engines, emission related components, and emission or particulate control devices.

Subsection (b) institutes a mandatory procedure by which diesel equipment operators must be authorized and required to tag equipment they believe requires maintenance in order to comply with subsection (a) above, for mine operators to insure that equipment so tagged is promptly examined, and for mine operators to retain a log of tagged equipment and the corresponding equipment examinations.

Subsection (c) requires that persons maintaining diesel equipment in underground metal and nonmetal mines be appropriately qualified by virtue of training or experience, and that mine operators must retain evidence of the competence of such persons.

The provisions of this section in the final rule are unchanged from the proposal.

Maintain Approved engines in approved condition. § 57.5066(a)(1) requires that mine operators maintain any approved diesel engine in "approved" condition. Under MSHA's approval requirements, engine approval is tied to the use of certain parts and engine specifications. When these parts or specifications are changed (i.e., an incorrect part is used, or the engine timing is incorrectly set), the engine is no longer considered by MSHA to be in approved condition.

Often, engine exhaust emissions will deteriorate when this occurs. Maintaining approved engines in their approved condition will ensure near-original performance of an engine, and maximize vehicle productivity and engine life, while keeping exhaust emissions at approved levels. The maintenance requirements for approved engines in this rule are already applicable to underground coal mines. 30 CFR 75.1914.

Thus in practice, with respect to approved engines, mine maintenance personnel will have to maintain the following engine systems in near original condition: air intake, cooling, lubrication, fuel injection and exhaust. These systems shall be maintained on a regularly scheduled basis to keep the system in its "approved" condition and thus operating at its expected efficiency.

One of the best ways to ensure these standards are observed is to implement a proper maintenance program in the mine—but the final rule would not require operators to do this. A good program should include compliance with manufacturers' recommended maintenance schedules, maintenance of accurate records and the use of proper maintenance procedures. MSHA's diesel toolbox provides more information about the practices that should be followed in maintaining diesel engines in mines.

Maintain emissions related components of non-approved engines to manufacturer specifications. For any non-approved diesel engine, paragraph (a)(2) requires mine operators to maintain the emissions related components to manufacturer specifications.

The term "emission related components," refers to the parts of the engine that directly affect the emission characteristics of the raw exhaust. These are basically the same components which MSHA examines for "approved" engines. They are the piston, intake and exhaust valves, cylinder head, injector, fuel injection pump, governor, turbo charger, after cooler, injection timing and fuel pump calibration.

Engine manufacturers are required to build engines in a manner that ensures continued compliance with EPA emissions levels and to establish specifications for adjusting and maintaining these engines to the engine manufacturer's specifications to ensure that the engines continue to perform properly and emit acceptable levels of emissions.

As it indicated in the preamble to the proposed rule, the Agency does not intend that this requirement could be misconstrued as establishing the basis for "picky" citations. It is not MSHA's intent that engines be torn down and the engine components be compared against the specifications in manufacturer maintenance manuals (63 FR 58187). Primarily, the Agency is interested in ensuring that engines are maintained in accordance with the schedule recommended by the manufacturer. However, if it becomes evident that the engines are not being maintained to the correct specifications or are being rebuilt in a configuration not in line with manufacturers' specifications or approval requirements, an inspector may ask to see the manuals to confirm that the right manuals are being used, or call in MSHA experts to examine an engine to confirm whether basic specifications are being properly observed.

This explanation of MSHA's intent relative to its enforcement of this provision was included in the Preamble to the proposed rule, accompanied by an invitation for comment from the mining industry to suggest alternative ways to rephrase this requirement so the Agency has a basis for ensuring compliance while minimizing the opportunity for overprescriptiveness (63 FR 58187). However, no such suggestions were received.

Maintain emission or Particulate Control Devices in effective operating condition. Paragraph (a)(3) requires that any emission or particulate control device installed on diesel-powered equipment be maintained in effective operating condition. Depending on the type of devices installed on an engine, this would involve having trained personnel perform such basic tasks as regularly cleaning aftertreatment filters, using methods recommended by the manufacturer for that purpose, or inserting appropriate replacement filters when required, checking for and repairing any exhaust system leaks, and other appropriate actions. This explanation of MSHA's intent relative to subsection (a)(3) was contained in the preamble to the proposed rule (63 FR 58187). One comment was received on this subsection from a commenter who submitted a complete regulatory alternative to MSHA's proposed dpm rule. The section of this regulatory alternative that corresponds to subsection (a)(3) of both the proposed and final rules reads as follows: "Emission related components of diesel powered equipment shall be maintained in effective operating condition." This alternative language is functionally identical to both the proposed and final rules. It incorporates the phrase "Emission related components of diesel powered equipment * * *," whereas the rules incorporate the phrase, "Any emission or particulate control device installed on the equipment * * *," however, the requirement that such equipment, "shall be maintained in effective operating condition," is identical. Therefore, MSHA concluded that no change from the proposal was necessary.

Ensuring equipment that may be out of compliance with maintenance standards is attended to—Tagging. Section 57.5066(b)(1) of the final rule requires underground metal and nonmetal mine operators to authorize and require miners operating diesel powered equipment to affix a visible and dated tag to the equipment at any time the equipment operator "notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section." Moreover, § 57.5066 (b)(2) requires that the equipment be "promptly" examined by a person authorized by the mine operator to maintain diesel equipment, and prohibits removal of the tag until such examination has been completed. Section 57.5066 (b)(3) requires a log to be retained of all equipment tagged.

In proposing this approach, MSHA noted its view that tagging would

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provide an effective and efficient method of alerting all mine personnel that a piece of equipment needs to be checked by qualified service personnel for possible emission problems, and that such a check is performed in a timely way (63 FR 58187).

The agency noted that the presence of a tag serves as a caution sign to miners working on or near the equipment, as well as a reminder to mine management, as the equipment moves from task to task throughout the mine. While the equipment is not barred from service, operators would be expected to use common sense and not use it in locations in which diesel particulate concentrations are known to be high.

The agency noted it was not requiring that equipment tagged for potential emission problems be automatically taken out of service. The rule is not, therefore, directly comparable to a "tag-out" requirement such as OSHA's requirement for automatic powered machinery, nor is it as stringent as MSHA's requirement to remove from service certain equipment "when defects make continued operation hazardous to persons" (see 30 CFR 57.14100). In the Preamble to the proposed rule, MSHA indicated that it did not think there was a need for something as stringent as these requirements because, although exposure to dpm emissions does pose a serious health hazard for miners, the existence or scope of an equipment problem cannot be determined until the equipment is examined or tested by a person competent to assess the situation. Moreover, the danger is not as immediate as, for example, an explosive hazard.

In the preamble to the proposed rule, MSHA also provided additional insights into how this approach would be implemented. It noted, for example, that the tag may be affixed because the equipment operator detects a problem through a visual exam conducted before the equipment is started, or because of a problem that comes to the attention of the equipment operator during mining operations, (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.) MSHA also noted it had not defined the term "promptly" with respect to how quickly tagged equipment must be examined by a qualified person, and sought comment on whether it should define this term—for example, by limiting the number of shifts it could operate before the required examination is performed (63 FR 58187).

The equipment tagging requirement was the subject of numerous comments. Most commenters were concerned that equipment operators would be authorized and required to make judgements about equipment function (and malfunction) for which they are unqualified, namely, to tag equipment they believe requires maintenance due to a problem related to dpm emissions. The commenters argued that, although equipment operators may be highly skilled in operating equipment, they are not necessarily qualified to make judgements concerning equipment maintenance requirements. Even though the regulation would not require tagged equipment to be removed from service, the commenters were concerned that such tags would cause unnecessary "scurrying about of mechanics" whose time could be more productively spent performing actual needed maintenance, rather than reacting to tags affixed for reasons that might be dubious, at best.

Commenters noted that, in addition to unnecessary maintenance inspections and the possibility of unnecessarily removing equipment from service, this requirement could result in a safety hazard if a tag affixed under § 57.14100(c) is mistaken for a tag affixed under § 57.5066(b)(1). The former addresses safety defects that "make continued operation hazardous to persons," and it requires the equipment to be immediately removed from service. The latter relates to dpm emissions, and does not require the piece of equipment to be removed from service. If a tag under § 57.14100(c) is mistaken for a tag under § 57.5066(b)(1), the affected equipment would be allowed to remain in service, exposing the operator, and possibly others, to potentially dangerous conditions.

Some commenters suggested that the tagging requirement in the final rule was completely unnecessary because its intent is already satisfied by existing § 57.14100, and that for the sake of simplicity, § 57.5066(b)(1) should be eliminated. Another commenter noted that § 57.5066(b)(1) was unnecessary because mine operators already have effective mechanisms in place to identify and correct maintenance problems on diesel equipment, including emissions-related problems. Another commenter worried that a citation could be issued if an inspector believes an operator failed to tag a piece of diesel equipment with a "smoky" exhaust, even if the operator believes the exhaust is within the normal range. Several commenters speculated that disgruntled employees would deliberately shut down equipment by tagging it for an emissions check.

Several commenters suggested alternative requirements, including incorporating emissions checks into the pre-shift equipment inspection required under § 57.14100(a), requiring equipment operators to either inform their supervisors of any suspected emissions-related problems or note any suspected emissions-related problems in a log book provided in every piece of equipment for that purpose, and requiring the mine operator to insure that a qualified person examines any piece of equipment for which an emissions-related problem has been identified.

MSHA has considered these comments, and determined that the requirements contained in the proposal are both necessary, and more protective than the alternatives suggested by the commenters. For these reasons, the requirements contained in the proposal have been retained without change in the final rule.

MSHA believes that, since equipment operators spend more time running the equipment than other employees (such as mechanics), and are present when the equipment functions under the widest range of operating conditions, they are often better able to detect emissions-related problems than are mechanics. For this reason, the final rule requires that equipment operators be authorized and required to affix a visible and dated tag if they note any evidence that the equipment may need maintenance in order to comply with the rule's maintenance requirements. Even though equipment operators may not be trained or qualified as diesel mechanics, they often know the difference between normal and abnormal equipment performance, especially as it relates to diesel particulate matter generation, which is often plainly visible or apparent (i.e., black smoke while the equipment is under normal load, rough idling, unusual noises, backfiring, etc.).

MSHA acknowledges that an equipment operator's judgement should not necessarily be relied upon to remove a piece of diesel equipment from service, precisely because equipment operators are not specifically trained or qualified to make such a judgement. Accordingly, the final rule does not require equipment operators to be granted this authority; only that they be granted authority to visibly identify a potential problem machine by affixing a tag. It is then the responsibility of the mine operator to appropriately respond to the presence of a tag. Note that the response by the mine operator need not be immediate, nor does it necessarily require the affected equipment to be removed from service, as some commenters feared. Mine operators have the authority to establish work rules and procedures to prevent equipment from being removed from service unnecessarily. Equipment operators and mechanics simply need to be trained as to their respective authority and responsibility under this section; namely, that equipment operators need to tag equipment suspected of requiring maintenance attention, and that qualified mechanics need to follow up to determine if a problem actually exists, and if so, what corrective maintenance work is needed.

It is highly unlikely that a tag intended to indicate a suspected emissions-related problems, if properly designed, would be confused with a tag intended to indicate a safety problem as per § 57.14100(c). Such tags could be differentiated by size, color, or other obvious visual characteristics so that mistaking one for the other would be virtually impossible. As noted below, the final rule allows mine operators the freedom to develop a design that suits their circumstances. In contrast, a design mandated by MSHA might be too similar to a given mine's existing § 57.14100(c) safety tag.

MSHA believes that the equipment tagging requirements of § 57.14100(c) and § 57.5066(b)(1) are inherently and significantly different, to the extent that the § 57.14100(c) requirement, even if modified to include health hazards, could not achieve the desired effect of § 57.5066(b)(1). The purpose of § 57.14100(c) is to immediately remove equipment from service if it poses a safety hazard, whereas the purpose of § 57.5066(b)(1) is to identify a potential emissions-related problem that might require maintenance, but does not justify immediate removal from service. Another important difference is that examinations under § 57.14100(c) occur before a piece of equipment is placed in operation on that shift, whereas § 57.5066(b)(1) applies throughout a work shift. These fundamental differences would make any attempt to combine the rules overly complicated, which would defeat the commenter's purpose of simplifying the rule.

As discussed above, MSHA believes that equipment operators should be authorized and required to note emissions-related deficiencies at all times during a work shift, and not be limited to making such observations during a pre-shift equipment inspection or before the equipment is placed into operation. Some emissions-related problems may not become apparent until after the equipment has been fully engaged for some time in heavy duty cycle activities. If the only time emissions-related deficiencies could be identified is before the equipment is placed into operation, the mine operator might never learn about such problems, or the corresponding notification might be unnecessarily delayed.

MSHA acknowledges that many underground metal and nonmetal mine operators utilize effective maintenance programs to identify and correct emissions-related problems in a timely manner. However, MSHA believes that §§ 57.5066(b)(1) and (2) are "best practices" that should be implemented at all mines. At mines that already have an effective program, this provision would serve as a complementary element. At mines that have no effective program, this provision would create an important safeguard. Further elaboration on the rationale for mandating these "best practices" was included in the preamble to the proposal (p. 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed "Meeting the concentration limit, operator choice of engineering controls."

The tagging provision of § 57.5066(b) requires judgement on the parts of both the equipment operator and the MSHA inspector. There is no absolute standard which precisely defines the physical proof that constitutes, "evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section." Thus, MSHA inspectors will be guided by a standard of reasonableness, based on an equipment operator's ability to differentiate normal emissions from grossly abnormal emissions. MSHA does not expect operators to tag equipment whenever there is a minor aberration or excursion from an optimum or perfect emissions condition, or that an inspector should make a fine distinction between emissions that are "slightly too smoky" versus "barely acceptable." However, MSHA inspectors will not ignore an operator's failure to tag a piece of equipment suffering from a serious emissions-related problem that is so obvious as to suggest the mine operator is indifferent to, or even discourages such tagging.

MSHA believes that disgruntled employees' attempts to shut down equipment by affixing tags indicating possible emissions-related problems can be effectively controlled and prevented by mine operators through work rules and procedures, and employee discipline policies. Mine operators should treat the inappropriate exercise of this provision by a disgruntled employee no differently than any other disruptive or malicious behavior. In addition to being preventable, MSHA believes the inappropriate tagging of equipment would have minimal impact on mining operations because tagged equipment need not be immediately removed from service. The maintenance examination that is triggered by a tag might not take place until the next shift or the shift after, and if there is truly nothing wrong with the equipment, it would be obvious to the mechanic performing the examination, and would therefore only require a few minutes of a mechanic's time.

MSHA considers the provision for tagging equipment to be preferable to a system which permits equipment operators to simply notify their supervisor of a suspected emissions-related problem, because the presence of a tag serves as a caution sign to other miners working on or near the equipment, as well as a reminder to mine management that this piece of equipment needs to be examined. Simply informing the supervisor does not provide this ongoing visual indicator or reminder, and as miners and equipment are reassigned to different jobs in different parts of a mine, information that is communicated verbally can be easily forgotten. A major advantage of tagging is that the tag goes with the equipment throughout the mine, alerting all who come in contact with it of the potential dpm emissions problem. In this sense, tagging requirements are particularly valuable for mobile equipment that travels from place to place throughout the shift, and may have multiple operators over the course of several shifts.

Design of the tag. MSHA proposed that the design of the tag be left to the discretion of the mine operator, with the exception that the tag must be able to be marked with a date. MSHA sought comment on "whether some or all elements of the tag should be standardized to ensure its purpose is met".

Several commenters suggested that MSHA should design the tag to be used for indicating equipment suspected of needing emissions-related maintenance.

As noted above, the final rule leaves this decision to the discretion of the mine operator. Since the design of tags required under § 57.14100(c) is left to the discretion of the operator, it would be impossible for MSHA to insure that any mandated design for a tag under § 57.5066(b)(1) would be easily distinguishable from an existing § 57.14100(c) tag. However, MSHA strongly urges mine operators to adopt a design for their § 57.5066(b)(1) tags that is easily distinguishable from the design of their § 57.14100(c) tags, using, for example, different sizes, colors, or other obvious visual characteristics.

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Time to inspect equipment. As noted above, MSHA sought specific comment on whether to define the term "promptly." One commenter referred to "promptly examined" as, "whatever that is," indicating they believed the term "promptly examined" is too vague. Another commenter suggested that a definite time period for examining equipment should be specified; namely, "by the end of the next shift." However, another commenter agreed with MSHA that equipment tagged by an operator should be, "promptly examined" by an authorized diesel maintenance person. Another commenter proposed that, "the required examination be conducted during normally scheduled maintenance cycles."

The final rule, like the proposal, does not define the term "promptly". Operating and maintenance practices vary from mine to mine to such an extent that a proscriptive requirement mandating a specific time period within which an examination must be completed may be infeasibly short for some operators and unnecessarily long for other operators. However, MSHA's intent is that mine operators will insure such examinations are performed without undue delay. If a tag is affixed during a given shift, it would not be unreasonable to complete that shift before the maintenance examination. If no qualified mechanic is scheduled to work on the following shift, the equipment could be operated during that shift as well. However, if a qualified mechanic was scheduled to work on the next shift, the examination would be required before the equipment was used.

Tagged Equipment Log. Section 57.5066(b)(3) requires a log to be retained of all equipment tagged. Moreover, the log must include the date the equipment is tagged, the date the tagged equipment is examined, the name of the person making the examination, and the action taken as a result of the examination. Records in the log about a particular incident must be retained for at least one year after the equipment is tagged.

MSHA does not expect the log to be burdensome to the mine operator or mechanic examining or testing the engine. Based on MSHA's experience, it is common practice to maintain a log when equipment is serviced or repaired, consistent with any good maintenance program. The records of the tagging and servicing, although basic, provide mine operators, miners and MSHA with a history that will help in determining whether a maintenance program is being effectively implemented, and whether emissions-related components on the equipment are being maintained in a proper and timely fashion.

Several comments addressing the equipment log were received. Proposed revisions generally retained the requirement for an equipment log, but varied as to who would maintain the log (equipment operators, mechanics or supervisors), and how long they should be kept (one year versus until the condition is examined and remedied). It was also suggested that all record keeping could be accomplished under "existing mobile equipment examination standards and maintenance work order systems," and that additional standards were therefore not needed.

MSHA has concluded that the requirements in the proposal relative to tagged equipment logs are essential to effectively controlling dpm, and have therefore been retained in the final rule without change. They enable both the mine operator and MSHA to track emissions-related problems on equipment, and the actions taken by the mine operator to resolve the problems that occur. The logs are also important because they provide a written record documenting when equipment was tagged, and how the mine operator responded.

The log creates an accountability chain that clearly indicates the date the equipment was tagged, the date the tagged equipment was examined, the name of the person making the examination, and the action taken as a result of the examination. Without the written record, MSHA would be unable to ascertain the extent to which mine operators respond in a timely and appropriate manner to emissions-related problems on diesel equipment. The one-year record retention requirement is necessary so that MSHA can review the emissions-related maintenance history on a given piece of equipment over a meaningful time period. This will enable MSHA to judge the mine operator's on-going commitment to proper and timely maintenance of these components. If the log were kept only until a given maintenance operation was completed, MSHA's opportunity to assess the mine operator's on-going responsiveness to emissions-related problems would be limited to the few chance occasions where a piece of equipment is tagged during an MSHA inspection of the mine.

These requirements are protective to miners because they force mine operators to address dpm emissions problems through a systematic and effective program. The combination of equipment tagging and logging helps insure problems will be identified and resolved quickly. If either or both requirements were eliminated, mine operators would be less likely to receive timely notice of a potential problem, and once notified, would be less motivated to promptly initiate the required examination and corrective measures.

Persons qualified to perform maintenance. Section 57.5066(c) requires that persons who maintain diesel equipment in underground metal and nonmetal mines be "qualified," by virtue of training or experience, to ensure the maintenance standards of § 57.5066(a) are observed. Paragraph (c) also requires that an operator retain appropriate evidence of "the competence of any person to perform specific maintenance tasks" in compliance with the requirement's maintenance standards for one year.

The requirements being established in this regard are not as stringent as those in effect for the maintenance of diesel powered equipment in underground coal mines. Operators of underground coal mines where diesel-powered equipment is used are required, as of November 25, 1997, to establish programs to ensure that persons who perform maintenance, tests, examinations and repairs on diesel-powered equipment are qualified (30 CFR 75.1915). The unique conditions in underground coal mines require the use of specialized equipment. Accordingly, the persons who maintain this equipment generally must be appropriately qualified.

If repairs and adjustments to diesel engines used in underground metal and nonmetal mines are to be done properly, personnel performing such tasks must be properly trained. MSHA does not believe, however, that the qualifications required to perform this work in underground metal and nonmetal mines necessarily require the same level of training as is required for similar work in underground coal mines. Under the final rule, the training required would be that which is commensurate with the maintenance task involved. If examining and, if necessary, changing a filter or air cleaner is all that is required, a miner who has been shown how to do these tasks would be qualified by virtue of training or experience to do those tasks. For more detailed work, specialized training or additional experience would be required. Training by a manufacturer's representative, completion of a general diesel engine maintenance course, or practical experience performing such repairs could also serve as evidence of having the qualifications to perform the service.

In practice, the appropriateness of the training or experience of the maintenance personnel will be revealed by the performance of the equipment, both the diesel engine itself and any emission aftertreatment devices. If MSHA finds a situation where maintenance appears to be shoddy, where the log indicates an engine has been in for repair with more frequency than should be required, or where repairs have damaged engine approval status or emission control effectiveness, MSHA would ask the operator to provide evidence that the person(s) who worked on the equipment was properly qualified by virtue of training or experience.

It is MSHA's intent that equipment sent off-site for maintenance and repair is also subject to the requirement that the personnel performing the work be qualified by virtue of training or experience for the task involved. It is not MSHA's intent that a mine operator have to examine the training and experience record of off-site mechanics, but a mine operator will be expected to observe the same kind of caution as one would observe with a personal vehicle—*e.g.*, selecting the proper kind of shop for the nature of the work involved, and considering prior direct experience with the quality of the shop's work.

One commenter objected to the requirement that mine operators must retain evidence of the competence of such workers for one year after any applicable maintenance task is completed. MSHA believes the provision is important because the evidence retained by the mine operator is the only means by which MSHA can judge compliance with the competency requirement.

Another commenter recommended this provision be dropped from the final rule because it is unnecessary. This commenter argued that it is in a mine operator's self interest to employ only qualified diesel mechanics to perform maintenance on equipment that is critical to the productive capacity of the mine. Another commenter stated that the rule is unnecessary because they already keep a file on mechanic training. MSHA believes this provision is important because not all mine operators are as careful in employing only qualified persons to maintain the emissions-related components of their diesel equipment. For mine operators that do, this requirement should not be burdensome. For mine operators that don't, this requirement will prevent unqualified persons from performing improper maintenance procedures on this equipment, thereby preventing this equipment from generating potentially excessive diesel emissions.

Another commenter recommended that the final rule should include minimum qualifications for persons responsible for ventilation at underground metal and nonmetal mines. The recommendation applied to mines employing greater than 20 miners, and suggested that the minimum qualification should be a mining engineering degree from an accredited university having a program that includes training in the theory and practice of underground metal and nonmetal mine ventilation, and that qualified persons should also have some minimum level of operating experience in this field. MSHA believes that its existing ventilation regulations and this final dpm rule are appropriately performance oriented regarding the use of mine ventilation as a dpm control measure. Mine operators who rely on ventilation will be judged by MSHA according to their success in complying with the final concentration limit. Therefore, the final rule has not been changed to require persons who are responsible for ventilation at mines employing more than 20 miners to meet any minimum qualifications.

Section 57.5067 Engines

The final rule requires that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future have to either be engines approved by MSHA under part 7 or part 36 or engines that meet or exceed the applicable dpm emission requirements of the EPA explicitly incorporated into a table in the rule. This requirement takes effect 60 days after the date this rule is promulgated. Only engines approved by MSHA as permissible can be used in areas of the mine where permissible diesel equipment is required. The composition of the existing fleet in an underground metal and nonmetal mine is not impacted by this part of the final rule. However, after the rule's effective date, any engine introduced into the underground areas of the mine must be either MSHA approved or meet the applicable EPA requirements. The term "introduced" is explicitly defined in the final rule to eliminate uncertainty regarding MSHA's intent. Engines that are introduced means engines in newly purchased equipment, engines in used equipment brought into the mine, or replacement engines that have a different serial number than the engine it is replacing. The term introduced does not include engines that were previously part of the mine inventory and rebuilt.

The final rule reflects a change from the proposed rule. The proposed rule would have required that, with the exception of diesel engines used in ambulances and fire-fighting equipment, any diesel engines added to the fleet of an underground metal or nonmetal mine in the future would have to have been approved by MSHA under Part 7 or Part 36. As discussed below, after reviewing the comments on this topic, MSHA concluded that it could accomplish the same goal, while providing operators with considerable extra flexibility, by permitting engines compliant with applicable EPA standards as an alternative to MSHA approved engines.

Table § 57.5067–1 in the final rule lists the applicable EPA dpm standards for diesel engines. The EPA standards represent the dpm emission limits set by EPA for light duty vehicles, light duty trucks, heavy duty highway engines, and nonroad engines. MSHA believes that all engines used in underground M/NM mines would come from these categories. MSHA chose the current on-highway dpm standards that have been in effect since 1994 for any commercially available on-highway vehicle. For nonroad, MSHA mainly used the EPA tier 1 standards that have been in effect starting in 1996 through 2000.

MSHA did notice one gap in the EPA nonroad standards. For engines in the 50 to 175 horsepower range, EPA did not list a dpm standard for tier 1. A tier 2 standard is listed in the final rule table for this reason. Full EPA implementation of the tier 2 standard for this horsepower range will become effective in 2003 for engines from 50–100 horsepower and in 2004 for engines 100 to 175 horsepower. However, MSHA believes that engines in this horsepower range are available now to meet the standard. MSHA has approved many engines under part 7 in this horsepower range that would meet the standard, and engine manufacturers are also producing other engine models in this horsepower range that meet the standard. The dpm requirement is the same for this engine horsepower range as was specified for engines in light duty vehicles in the coal final rule. Therefore, MSHA does not believe that mine operators will have problems introducing engines that meet any of the requirements of this section.

Several commenters questioned the need for engine restrictions at all if the applicable concentration limit could be achieved through other means. The rationale for this requirement is to promote the gradual turnover of the

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existing fleet to better, less-polluting engines, thereby reducing dpm concentrations and attendant health risks. Without this requirement, there would be no constraint on the introduction of engines that are inherently higher polluting into underground metal and nonmetal mines. Such engines, regardless of the level of maintenance they receive, produce significantly higher dpm emissions than the low polluting engines mandated in the final rule. MSHA acknowledges that older, high polluting engines will eventually be replaced with low polluting engines through the normal equipment turnover process, because EPA emission requirements (and similar requirements imposed by foreign regulatory bodies) will make high polluting engines increasingly difficult for manufacturers to sell for any application. Even if a mine operator wanted to continue using high polluting engines, such engines will become more and more scarce over time. But in light of the risks of dpm exposure to miners, and the history of the underground mining industry to bring old engines underground and keep them operating for a long period of time, MSHA has concluded that a rule is required to bring about the transition to newer engines more quickly than would otherwise be the case. MSHA considers the gradual introduction of cleaner engines to be one of the "best practices" that is feasible for all underground metal and nonmetal mines. Further elaboration on the rationale for mandating these "best practices" was included in the preamble to the proposal (63 FR 58119), and a summary was provided in this Part under the portion of § 57.5060 that discussed "Meeting the concentration limit, operator choice of engineering controls."

Other commenters recommended that EPA certification be an acceptable alternative to MSHA approval. As noted above, after considering the matter, MSHA agrees that engines certified as meeting applicable EPA standards would provide an acceptable level of protection to miner health comparable to that which can be achieved by requiring MSHA approved engines. (For detailed information about the various "tiers" of EPA engine requirements, and the various types of engine categories, please see Part II, section 5). Therefore, under the final rule, engines meeting or exceeding applicable particulate emission requirements of the Environmental Protection Agency (as listed in the table in § 57.5067(b)) are an acceptable alternative to engines approved by MSHA as nonpermissible under subpart E of Part 7 of this title. This change in the final rule will provide mine operators with a wider choice of acceptable engines, and may reduce compliance costs.

MSHA is developing a program that will streamline the procedures by which manufacturers of diesel engines intended for use in outby areas of underground coal mines can gain Agency approval. The program will draw on the EPA approval programs for engines used in off-road applications. MSHA will continue to issue approvals for mining engines, but the application process will be abbreviated. Many of the provisions of part 7 are intended to ensure that engines continue to be manufactured in the same configuration and with the same emissions as the engine tested by MSHA. Procedures within the EPA approval programs reach the same end. Additionally, EPA has the resources and the regulatory authority to conduct an extensive quality assurance program to monitor emissions from production engines. In addition to streamlining the application process, MSHA will establish a program under which the engine emission tests conducted for EPA approval will satisfy the part 7 testing requirements. The test cycles under which emissions are tested for both MSHA and EPA are identical, and the gaseous emission results from the EPA tests can be used to establish the ventilating air quantity that appears on the engine approval plate and is referenced in mine ventilation regulations. MSHA will announce the specifics of the program when it is finalized. A listing of MSHA approved nonpermissible engines has been provided on MSHA's Internet web site. This listing can be accessed at the following address: http://www.msha.gov/S&HINFO/DESLREG/1909a.HTM.

Many underground metal and nonmetal mines are accustomed to employing front end loaders, haulage trucks, and other production equipment that is developed for, and primarily marketed to the surface mining and construction industries. Likewise, where conditions permit, underground metal and nonmetal mines often employ support vehicles such as pickup trucks, sport utility vehicles, and other small to medium sized trucks that are developed for, and primarily marketed to the surface over-the-road market. Mine operators employ this equipment because it is significantly less costly than purpose-built underground mining equipment, which has special mine-duty features and is produced in relatively low volume.

The engines in newly manufactured surface off-road equipment and over-the-road vehicles are already required to comply with EPA dpm emission regulations. EPA regulations are fashioned in a Tier structure whereby engines in designated horsepower ranges are required to meet increasingly stringent emissions levels. By changing the final rule as indicated above to accept engines meeting or exceeding applicable particulate emission requirements of the EPA, MSHA is, in essence, allowing mine operators to continue the long-standing and cost-effective practice of employing standard off-road equipment and over-the-road vehicles underground (if they are equipped with engines meeting the appropriate EPA requirements), without requiring potentially costly retrofits of approved engines. This change will enable mine operators and mine workers to gain the added benefits of engines that incorporate the most recent emission reducing technology.

Laboratory testing to certify that an engine meets the applicable EPA particulate matter limit or MSHA approval requirements is not the responsibility of the mine operator. MSHA approved engines carry an approval plate so they are easy to distinguish. Engines produced after the date indicated in the Table incorporated into 5067(b) will meet the EPA requirements for the listed category of engines.

Engines in diesel-powered ambulances and fire-fighting equipment are exempted from these requirements. This exemption is identical with that in the rule for diesel-powered equipment in underground coal mines. The rationale for this exemption is that the usage of these vehicles and equipment is so limited that their contribution to overall dpm levels in a mine is negligible. MSHA wishes to caution mine operators, however, that this exemption is intended to apply only to equipment that is used exclusively as an ambulance or fire fighting equipment. This exemption does not apply to vehicles and equipment that are normally used for other purposes, but serve as an ambulance or fire fighting equipment in the event of an accident or mine emergency.

Section 57.5070 Miner Training

Section 57.5070 requires any miner "who can reasonably be expected to be exposed to diesel emissions" be trained annually in: (a) The health risks associated with dpm exposure; (b) the methods used in the mine to control dpm concentrations; (c) identification of the personnel responsible for maintaining those controls; and (d) actions miners must take to ensure the controls operate as intended. The final rule is the same as that proposed, and is identical to the rule being established for underground coal miners through MSHA's rulemaking limiting dpm concentrations in underground coal mines.

The purpose of these requirements is to promote miner awareness. Exposure to diesel particulate is associated with a number of harmful effects as discussed in Part III of this preamble, and the safe level is unknown. Miners who work in mines where they are exposed to this risk ought to be reminded of the hazard often enough to make them active and committed partners in implementing actions that will reduce that risk.

The training need only be provided to miners who can reasonably be expected to be exposed at the mine. The training is to be provided by operators; hence, it is to be without fee to the miner.

The rule places no constraints on the operator as to how to accomplish this training. MSHA believes that the required training can be provided at minimal cost and minimal disruption. The proposal would not require any special qualifications for instructors, nor would it specify the hours of instruction.

Instruction could take place at safety meetings before the shift begins. Devoting one of those meetings to the topic of dpm would be a very easy way to convey the necessary information. Simply providing miners with a copy of MSHA's "Toolbox" and, a copy of the plan, if a control plan is in effect for the mine, and reviewing these documents, can cover several of the training requirements. One-on-one discussions that cover the required topics are another approach that can be used.

Operators could also choose to include a discussion on diesel particulate matter emissions in their Part 48 training, provided the plan is approved by MSHA. There is no existing requirement that Part 48 training include a discussion of the hazards and control of diesel emissions. While mine operators are free to cover additional topics during the Part 48 training sessions, the topics that must be covered during the required time frame may make it impracticable to cover the additional material on dpm. Where adequate time is available at mines using diesel-powered equipment, operators would be free to include the dpm instruction in their Part 48 training plans. Since inclusion of dpm-related training in Part 48 training plans is not explicitly prohibited in the final rule, MSHA does not believe special language is required to permit this practice.

The final rule does not require the mine operator to separately certify the completion of the dpm training, but some evidence that the training took place would have to be produced upon request. A serial log with the employee's signature is an acceptable practice. To assist mine operators with this training requirement, it is MSHA's intent to develop an instructor's guide and corresponding training materials.

A few comments were received on § 57.5070, including the suggestion that such training be included under Part 48, and the opposing view that such training be independent of Part 48. Arguments in favor of including the training under Part 48 focused on the need to simplify the rule by not requiring separate diesel particulate emissions training and training recordkeeping. Arguments opposed focused on the difficulty of including more subject matter into a Part 48 training plan that is already overfilled. It was also noted that Part 48 training requires MSHA-certified instructors. By separating Part 48 training from the training required under § 57.5070, mine operators would have greater flexibility in choosing instructors.

MSHA believes the final rule satisfies both positions because inclusion of the specified diesel particulate emissions training topics under Part 48 training is neither required nor prohibited. Mine operators wishing to incorporate diesel emissions training in their Part 48 training plan are free to do so, whereas those wishing to conduct diesel emissions training separate from Part 48 training are equally free to choose that option. MSHA believes it is significant that none of the commenters discounted the importance of providing dpm-exposed miners with such training; their comments only addressed the mechanics of how such training should be delivered.

In its preamble to the proposed rule, MSHA specifically invited comment as to whether special language should be included in the final rule that would expressly permit required dpm training to be incorporated into Part 48 training. Only one commenter responded, expressing the view that special language was not necessary. Therefore, MSHA did not change this provision in the final rule.

Another commenter suggested that training required under § 57.5070 incorporate mandatory coverage of underground metal and nonmetal mine ventilation, that such training address auxiliary ventilation and the use of elementary ventilation measurement instruments, and that similar training be mandatory for first and second line supervisors.

MSHA agrees that ventilation is an important topic and that ventilation can have a significant effect on dpm concentrations underground. However, MSHA believes it would be inappropriate to specify the content of dpm-related miner training to the level of detail suggested by the commenter. Since MSHA allows mine operators considerable freedom to choose dpm control measures, MSHA expects significant variability from mine to mine in the mix of controls selected. For example, some mines may rely heavily on ventilation to comply with the applicable concentration limit, but other mines may rely more on enclosed cabs or diesel particulate filters. As a result, the most important training subject or subjects at one mine could be quite different at another mine.

By requiring training in the health risks associated with dpm exposure, the methods used in the mine to control dpm concentrations, identification of the personnel responsible for maintaining those controls, and the actions miners must take to ensure the controls operate as intended, MSHA believes it has established performance-based training requirements that are applicable to all mines.

As with the proposed rule, the final rule does not require the mine operator to separately certify the completion of dpm training, but some evidence that the training took place will have to be produced upon MSHA request. In this regard, as noted in the preamble to the proposed rule, a serial log with the employee's signature is an acceptable practice. Nevertheless, some commenters complained that the recordkeeping requirements in the training provisions are burdensome, and don't reduce diesel emissions. MSHA believes that dpm training is an essential element of a comprehensive dpm control program because miners who are fully informed are more apt to become active and committed partners in implementing an effective dpm control strategy. In this way, training can have an indirect, yet substantive and positive influence on reducing dpm exposure. The corresponding recordkeeping requirements are important, because the records are the means by which MSHA can insure that the mine operator is complying with the training requirements.

As noted in the preamble to the proposed rule, to assist mine operators with this training requirement, it is MSHA's intent to develop an instruction outline that mine operators can use as

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a guide for training personnel. Instruction materials will be provided with the outline.

Section 57.5071 Environmental Monitoring

The final rule requires mine operators to monitor as often as necessary to effectively evaluate, under conditions that can be reasonably anticipated in the mine—(1) whether the concentration of dpm in an area where miners normally work or travel exceeds the applicable concentration limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary. This section also requires operators to provide affected miners and their representatives with notice and an opportunity to observe monitoring, to initiate corrective action by the next work shift should monitoring reveal a violation and to promptly complete such action, and requires certain posting and recordkeeping. The final rule is the same as the proposed rule.

Operator's Monitoring Responsibility. Section 57.5071(a) requires mine operators to monitor the underground mine environment to insure dpm concentrations are within compliance limits wherever the limits apply. Sampling, which could be area sampling, personal sampling, or occupational sampling, is required as often as necessary to "effectively determine"—under conditions that can be reasonably anticipated in the mine—(1) whether the dpm concentration in any area of the mine where miners normally work or travel exceeds the applicable limit; and (2) the average full shift airborne concentration at any position or on any person designated by the Secretary.

This requirement is similar to existing § 57.5002 which requires mine operators to conduct dust, gas, mist, and fume surveys as frequently as necessary to determine the adequacy of control measures, and to existing § 62.110(a) and (b) which requires mine operators to measure each miner's noise dose sufficient to determine continuing compliance with the established noise limits. Under § 57.5071(a), mine operators are required to monitor dpm concentrations in much the same way they are already required to monitor dust, gas, mist, fume, and noise.

There are three important aspects of this operator monitoring requirement.

First, the responsibility for dpm monitoring rests with the mine operator, not with MSHA. Mine operators cannot rely on MSHA inspectors to conduct dpm monitoring whenever and wherever necessary to ensure compliance with the applicable dpm concentration limit. The purpose of operator monitoring is to determine continuing compliance, whereas the purpose of MSHA sampling is to identify non-compliance. MSHA sampling is neither intended for, nor capable of determining continued compliance.

Second, the information gathered through operator monitoring is to be used by the operator to determine whether action is necessary to maintain compliance anywhere the applicable concentration limits apply in the mine. Gathering dpm concentration data, though necessary, is not the final goal in itself. The reason for gathering this information is so it can be used by the mine operator to assess the effectiveness of dpm control measures. Sampling results which indicate non-compliance should prompt the mine operator to initiate whatever actions are required (i.e., implementation of appropriate engineering controls and work practices) to achieve compliance wherever the applicable concentration limits apply.

Third, this requirement ensures special attention will be focused on locations or persons known to MSHA to have a significant potential for overexposure to dpm.

The obligation of operators to "effectively determine" dpm concentrations in a mine is a separate obligation from that to keep dpm levels below the established limit, and can be the basis of a separate citation from MSHA. The final rule is performance-oriented in that the regularity and methodology used to make this evaluation are not specified. However, MSHA expects mine operators to sample with such frequency that they and the miners working at the mine site are aware of dpm levels in their work environment. In this regard, MSHA's own measurements will assist the Agency in verifying the effectiveness of an operator's monitoring program. If an operator is "effectively determining" the concentration of dpm at designated positions, for example, MSHA would not expect to regularly record concentrations above the limit when it samples at that location. If MSHA does find such a problem, it will investigate to determine how frequently an operator is sampling, where the operator is sampling, and what methodology is being used, so as to determine whether the obligation in this section is being fulfilled. (See previous discussion in this Part in the portion of § 57.5062 that addressed "Demonstration of plan effectiveness" for further information on the number of samples required to demonstrate continuing compliance.)

Operator Monitoring Methods. The final rule requires that full-shift diesel particulate concentrations be determined during periods of normal production or normal work activity in areas where miners work or travel. The rule does not specify a particular monitoring method or frequency; rather, the rule is performance-oriented. Operators may, at their discretion, conduct their monitoring using the same sampling and analytical method as MSHA, or they may use any other method that enables that mine to "effectively determine" the concentrations of dpm.

As required by § 57.5061, MSHA will collect samples using a respirable dust sampler equipped with a submicrometer impactor, and use NIOSH Method 5040, the sampling and analytical method that NIOSH has developed for accurately determining the concentration of total carbon, to determine compliance. Operators who must comply with the terms of a diesel particulate control plan pursuant to § 57.5062 must, as noted in the requirements of that section, use the same sampling and analytical method as MSHA to verify plan effectiveness; monitoring performed for that purpose would probably meet the obligation under § 5071 if it is done with enough sufficiency to meet the obligation under § 57.5062(c). But the method may not be necessary to effectively determine dpm in some mines for purposes of § 57.5071(a). For example, dpm measurements in limestone, potash and salt mines could be determined using the RCD method, since there are no large carbonaceous particles present that would interfere with the analysis. For hydrated minerals such as gypsum and trona, a two-step RCD method would be necessary, wherein the first step would elevate the temperature of the sample sufficient to cause dehydration (105 °C). The sample is then reweighed, and the conventional RCD analysis procedure is followed. Such estimates can be useful in determining the effectiveness of controls and where more refined measurements may be required.

Of course, mine operators using the RCD or size-selective methods to monitor their diesel particulate concentrations would have to convert the results to a TC equivalent to ascertain their compliance status. At the present time, MSHA has no conversion tables for this purpose, however a simple conversion approach would be to adjust the sampling result to the corresponding estimated whole dpm concentration, then multiply that value by 0.8. In most cases, the other methods will provide a good indication of whether controls are working and whether further action is required.

Part II of this preamble provides information on monitoring methods and their constraints, and on laboratory and sampler availability.

One commenter observed that area sampling outside of an enclosed cab would defeat the purpose of installing the cab, and would diminish the status of such a cab, which is a recognized engineering control, to that of personal protective equipment, which is prohibited under the rule. MSHA agrees that area sampling is inappropriate where miners are protected by enclosed cabs with filtered breathing air and no other miners are required to work in the area outside of the cab. As discussed under section 5061(c)(3), area sampling by MSHA for compliance purposes would not be conducted outside of an enclosed cab unless miners are working in the area outside of such cabs, and MSHA would urge operators to follow the same approach. Also, as noted in discussing that section, personal sampling within cabs operated by smokers should only be conducted if the equipment operator agrees not to smoke during the sampling period.

Observation of Monitoring. Section 103(c) of the Mine Act requires that:

> The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act. Such regulations shall provide miners or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof.

In accordance with this legal requirement, § 57.5071(b) of the final rule requires a mine operator to provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice of the date and time of intended monitoring so that affected miners and their representatives can exercise their right to observe the monitoring if they so choose.

Comments addressing § 57.5071(b) questioned the meaning of the terms "miner's representative" and "affected miners," and objected to paying miners to observe dpm monitoring.

MSHA intends for miner's representative to mean any authorized representative of the miners. A representative of the miners could, but does not necessarily have to be, a representative of a certified union. Limiting representatives of miners to certified unions is a violation of the Mine Act and departs from previous MSHA practice.

MSHA intends for affected miners to mean the miners that are potentially exposed to the diesel particulate matter being monitored. The commenter suggested that this provision "* * * leaves too much for interpretation. How many employees may observe? For how long?" Consistent with the Mine Act, MSHA does not intend to limit the number of miners who may observe dpm monitoring, however, such miners need not be paid if, as a result of observing the monitoring, they are not performing their jobs.

Corrective Action if Concentration Is Exceeded. Section 57.5071(c) provides that if any monitoring performed under this section indicates that the applicable dpm concentration limit has been exceeded, an operator shall initiate corrective action by the next work shift, promptly post a notice of the corrective action being taken and promptly complete such corrective action.

The Agency wishes to emphasize that operator monitoring of dpm concentrations would not take the place of MSHA sampling for compliance purposes; rather, this requirement is designed to ensure the operator checks dpm concentrations on a more regular basis than is possible for MSHA to do. Paragraph (c) provides that if sampling results indicate the concentration limit has been exceeded in an area of a mine, an operator would initiate corrective action by the next work shift and promptly complete such action. Paragraph (c) does not require an operator to establish a dpm control plan. The establishment of a dpm control plan is triggered by a non-compliance determination based on sampling conducted by the Secretary.

In certain types of cases (*e.g.*, 30 CFR 75.323), MSHA has required that when monitoring detects a hazardous level of a substance, miners must be immediately withdrawn from an area until abatement action has been completed. Although MSHA did not include such a requirement in the final rule, MSHA in its proposal did solicit comment from the mining industry concerning this practice, especially in light of the evidence presented on the various risks posed by exposure to diesel particulate, including material presented in the preamble to the proposal that acute short-term increases in exposure can pose significant risks to miner health. The comments that were received in response to this solicitation were opposed to a provision requiring immediate withdrawal.

The agency also specifically asked for comments on three other points (63 FR 58189, 58190). First, the agency noted that it welcomed comments as to what guidance to provide with respect to corrective actions required where an operator is not using the total carbon analytical method. Second, the agency noted it welcomed comment as to whether personal notice of corrective action would be more appropriate than posting, given the health risks involved. Third, the agency solicited comment on whether clarification of the proposed requirement was needed in light of the fact that operators using more complex analytical procedures (*e.g.*, the total carbon method) may not receive the results for some time period after the posting has taken place.

No comments addressing these points were received.

Posting of Sample Results. Section 57.5071(d)(1) requires that monitoring results be posted on the mine bulletin board within 15 days of receipt, and remain posted for 30 days. A copy of the results must also be provided to the authorized miners' representative. Posting of the results will ensure that miners are kept aware of the hazard so they can actively participate in efforts to control dpm.

Comments that addressed this paragraph recommended that sampling results should not be given to the representative of the miners because this information is private, and recommended that mine operators should not be cited for posting sampling results that exceed the applicable concentration limit.

MSHA disagrees with the assertion that dpm sampling results are private, and therefore, such results should not be given the representative of the miners. The Mine Act clearly states that miners or their representatives have a legal right to access to exposure monitoring information.

Regarding the question of MSHA issuing a citation based on a mine operator posting sampling results that exceed the applicable concentration limit, it is not MSHA's intent to issue a citation under these circumstances. If such sampling indicates that dpm levels exceed the applicable concentration limit, a citation may be issued if the mine operator fails to initiate corrective action by the next work shift, as required under § 57.5071(c). However, mine operator sampling results that exceed the applicable limit is not, by itself, a violation.

MSHA recognizes that this is an important point, and reiterates that, as indicated in § 57.5061, MSHA itself is to conduct compliance sampling.

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Retention of Sample Results. Section 57.5071(d)(2) requires that records of the sampling method and the sample results themselves be retained by mine operators for five years. This is because the results from a monitoring program can provide insight as to the effectiveness of controls over time, and provide a history of occupational exposures at the mine.

In the preamble to the proposed rule, MSHA welcomed comments on the sample retention period appropriate for the risks involved. None were received.

In the preamble to the proposed rule, MSHA also asked for comments regarding the advisability of instituting a system of medical surveillance of miners exposed to dpm to identify miners suffering ill effects of dpm exposure, and the subsequent medical removal of miners who are determined to be suffering such ill effects. The comments received in response to this request suggested that medical surveillance for excessive dpm exposure is not feasible at this time because the appropriate biological tests or markers do not exist. One commenter observed that they were, "* * * unaware of any recognized or generally accepted examinations or tests for detecting whether miners are suffering from ill effects as a result of diesel particulate or exhaust exposure. This view is supported by EPA's Health Assessment Document for Diesel Emissions which states, 'There is no single medical test to determine if DP exposure has occurred. Many symptoms of episodic DP exposure are similar to symptoms caused by other agents or, in some cases, onset of a common cold. Invasive sampling of particle deposits in the upper respiratory tract or lung could be done, yet such particles may not be readily distinguishable from particulate matter from other sources' [EPA, 1998]." MSHA agrees with these commenters that appropriate medical testing protocols are not currently available. Therefore, provision for neither medical surveillance nor medical removal protections have been incorporated into the final rule.

Section 57.5075 Diesel Particulate Records

Various recordkeeping requirements are set forth in the provisions of the final rule. For the convenience of the mining community, these requirements are also listed in a table entitled "Diesel Particulate Recordkeeping Requirements," which can be found in § 57.5075(a). Each row involves a record that must be kept. The section requiring the record be kept is noted, along with the retention time.

This approach—having a summary table of recordkeeping requirements included in various sections of the rule—is identical to that taken in the proposed rule. MSHA indicated in the preamble to the proposed rule that it would welcome input from the mining community as to whether it liked this approach or found it duplicative or confusing, however, no comments were received.

Location of Records. Section 57.5075(b)(1) provides that any record which is required to be retained at the mine site may be retained elsewhere if it is immediately accessible from the mine site by electronic transmission. Compliance records need to be accessible to an inspector so they can be viewed during the course of an inspection, as the information in the records may determine how the inspection proceeds. If the mine site has a fax machine or computer terminal, there is no reason why the records cannot be maintained elsewhere. MSHA's approach in this regard is consistent with Office of Management and Budget Circular A–130.

One commenter, though supporting the concept of off-site electronic records storage, questioned MSHA's intent relative to the term "immediately accessible." As noted above, MSHA intends that records maintained off-site be made available to an MSHA inspector so the information can be used to guide inspection decisions. Thus, undue delay in retrieving this information from off site electronic storage would impede an inspection, and would not be permitted. If the records are maintained in hardcopy form at an off-site location, and considering the time required to contact off-site personnel to request the records, for those personnel to locate and remove the records from the files, and to fax the records to the mine site, a delay of one or two hours would not be unreasonable. If records are maintained in an off-site electronic database, it is reasonable to assume they could be electronically transmitted to the mine site even faster; perhaps one hour or less.

These time frames are in contrast to the requirement in MSHA's new noise regulation for noise records to be accessible to the MSHA inspector, but not "immediately accessible." The guideline established in the Preamble to the final noise rule states that records must be provided to the MSHA inspector within one business day or less (p. 49625).

The commenter notes further that, "Even with Y2K compliant systems, computer and electronic transmission equipment is not 100% reliable, especially in remote mining environments." MSHA agrees that an insistence on 100% reliability of computer and electronic transmission equipment is unreasonable. However, MSHA will not accept chronic computer or electronic transmission problems as a justification for the repeated denial of timely access to the required records. If chronic computer or electronic transmission problems make "immediate" access to records problematic, such records would have to be kept at the mine site.

Records Access. Section 57.5075(b) also covers records access. Consistent with the statute, upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators are to promptly provide access to any record listed in the table in this section. A miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, is to have access to any exposure record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. Upon request, the operator must provide the first copy of such record at no cost. Whenever an operator ceases to do business, that operator would be required to transfer all records required to be maintained by this part to any successor operator.

General Effective Date of Part 57. The rule provides that unless otherwise specified, its provisions take effect 60 days after the date of promulgation of the final rule. Thus, for example, the requirements to implement certain work practice controls (*e.g.*, fuel type) go into effect 60 days after the final rule is published.

A number of provisions of the final rule contain separate effective dates that provide more time for technical support. For example, the initial concentration limit for underground metal and nonmetal mines would be delayed for 18 months.

A general outline of effective dates is summarized in Part I of this preamble.

Additionally, the paperwork provisions will not become effective until approved by the Office of Management and Budget.

V. Adequacy of Protection and Feasibility of Final Rule; Alternatives Considered

The Mine Act requires that in promulgating a standard, the Secretary, based on the best available evidence, shall attain the highest degree of health and safety protection for the miner with feasibility a consideration.

Overview. This part begins with a summary of the pertinent legal requirements, followed by a general profile of the economic health and prospects of the metal and nonmetal mining industry.

The final rule establishes a concentration limit for dpm, supplemented by monitoring and training requirements. An operator in the metal and nonmetal sector would have the flexibility to choose any type or combination of engineering controls to keep dpm levels at or below the concentration limit. This part evaluates the final rule to ascertain if, as required by the statute, it achieves the highest degree of protection for underground metal and nonmetal miners that is feasible, both technologically and economically, for underground metal and nonmetal mine operators to provide.

Several regulatory alternatives to the final rule were also reviewed by MSHA in light of the record. The Agency has concluded that compliance with these alternatives either provide less protection than the feasible approach being adopted, or are not technologically or economically feasible for the underground metal and nonmetal industry as a whole at this time.

Pertinent Legal Requirements. Section 101(a)(6)(A) of the Federal Mine Safety and Health Act of 1977 (Mine Act) states that MSHA's promulgation of health standards must:

> * * * [A]dequately assure, on the basis of the best available evidence, that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life.

The Mine Act also specifies that the Secretary of Labor (Secretary), in promulgating mandatory standards pertaining to toxic materials or harmful physical agents, base such standards upon:

> * * * [R]esearch, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the mandatory health or safety standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 101(a)(6)(A)].

Thus, the Mine Act requires that the Secretary, in promulgating a standard, based on the best available evidence, attain the highest degree of health and safety protection for the miner with feasibility a consideration.

In relation to feasibility, the legislative history of the Mine Act states that:

> * * *Section further provides that "other considerations" in the setting of health standards are "the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While feasibility of the standard may be taken into consideration with respect to engineering controls, this factor should have a substantially less significant role. Thus, the Secretary may appropriately consider the state of the engineering art in industry at the time the standard is promulgated. However, as the circuit courts of appeal have recognized, occupational safety and health statutes should be viewed as "technology-forcing" legislation, and a proposed health standard should not be rejected as infeasible when the necessary technology looms in today's horizon. *AFL-CIO* v. *Brennan*, 530 F.2d 109 (1975); *Society of the Plastics Industry* v. *OSHA*, 509 F.2d 1301, *cert. denied*, 427 U.S. 992 (1975).

Similarly, information on the economic impact of a health standard which is provided to the Secretary of Labor at a hearing or during the public comment period, may be given weight by the Secretary. In adopting the language of [this section], the Committee wishes to emphasize that it rejects the view that cost benefit ratios alone may be the basis for depriving miners of the health protection which the law was intended to insure. S. Rep. No. 95–181, 95th Cong., 1st Sess. 21 (1977).

Court decisions have clarified the meaning of feasibility. The Supreme Court, in *American Textile Manufacturers' Institute* v. *Donovan* (OSHA Cotton Dust), 452 U.S. 490, 101 S.Ct. 2478 (1981), defined the word "feasible" as "capable of being done, executed, or effected." The Court stated that a standard would not be considered economically feasible if an entire industry's competitive structure was threatened. According to the Court, the appropriate inquiry into a standard's economic feasibility is whether the standard is capable of being achieved.

Courts do not expect hard and precise predictions from agencies regarding feasibility. Congress intended for the "arbitrary and capricious standard" to be applied in judicial review of MSHA rulemaking (S.Rep. No. 95–181, at 21.) Under this standard, MSHA need only base its predictions on reasonable inferences drawn from the existing facts. MSHA is required to produce reasonable assessment of the likely range of costs that a new standard will have on an industry. The agency must also show that a reasonable probability exists that the typical firm in an industry will be able to develop and install controls that will meet the standard. See, *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 91 S.Ct. 814 (1971); *Baltimore Gas & Electric Co.* v. *NRDC*, 462 U.S. 87 103 S.Ct. 2246, (1983); *Motor Vehicle Manufacturers Assn.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 103 S.Ct. 2856 (1983); *International Ladies' Garment Workers' Union* v. *Donovan*, 722 F.2d 795, 232 U.S. App. D.C. 309 (1983), *cert. denied*, 469 U.S. 820 (1984); *Bowen* v. *American Hospital Assn.*, 476 U.S. 610, 106 S.Ct. 2101 (1986).

In developing a health standard, MSHA must also show that modern technology has at least conceived some industrial strategies or devices that are likely to be capable of meeting the standard, and which industry is generally capable of adopting. *United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1272 (1980). If only the most technologically advanced companies in an industry are capable of meeting the standard, then that would be sufficient demonstration of feasibility (this would be true even if only some of the operations met the standard for some of the time). *American Iron and Steel Institute* v. *OSHA*, 577 F.2d 825, (3d Cir. 1978); see also, *Industrial Union Department, AFL-CIO* v. *Hodgson*, 499 F.2d 467 (1974).

Industry Profile. This industry profile provides background information about the structure and economic characteristics of the mining industry. It provides data on the number of mines, their size, the number of employees, and the diesel powered equipment used.

The Structure of the Metal/Nonmetal Mining Industry. MSHA divides the mining industry into two major segments based on commodity: (1) Coal mines and (2) metal and nonmetal (M/NM) mines. These segments are further divided based on type of operation (*e.g.*, underground mines or surface mines). MSHA maintains its own data on mine type, size, and employment, and the Agency also collects data on the number of independent contractors and contractor employees by major industry segment.

MSHA categorizes mines by size based on employment. For the past 20 years, for rulemaking purposes, MSHA has consistently defined a small mine to be one that employs fewer than 20 workers and a large mine to be one that employs 20 or more workers. To comply with the requirements of the Small

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Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), however, an agency must use the Small Business Administration's (SBA's) criteria for a small entity-¾ for mining, 500 or fewer employees ¾ when determining a rule's economic impact.

Table V–1 presents the total number of small and large mines and the corresponding number of miners, excluding contractors, for the M/NM mining segment. The M/NM mining segment consists of metal mines (copper, iron ore, gold, silver, etc.) and nonmetal mines (stone including granite, limestone, dolomite, sandstone, slate, and marble; sand and gravel; and others such as clays, potash, soda ash, salt, talc, and pyrophyllite.) As Table II–1 indicates, 98 percent of all M/NM mines are surface mines, and these mines employ some 90 percent of all M/NM miners, excluding office workers. Table V–2 presents corresponding data on the number of independent contractors and their employees working in the M/NM mining segment.

TABLE V–1.—DISTRIBUTION OF M/NM MINE OPERATIONS AND EMPLOYMENT (EXCLUDING CONTRACTORS) BY MINE TYPE AND SIZE [a]

Size of M/NM mine [b]	Mine type			
	Underground	Surface	Office workers	Total M/NM
Fewer than 20 employees:				
Mines	134	9,635	.....	9,769
Employees	1,054	54,356	9,160	64,570
20 to 500 employees:				
Mines	124	1,419	.....	1,543
Employees	11,299	79,675	15,040	106,014
Over 500 employees:				
Mines	7	18	.....	25
Employees	4,594	16,836	3,543	24,973
All M/NM mines:				
Mines	265	11,072	.....	11,337
Employees	16,947	150,867	27,743	195,557

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CM441/CM935LA cycle 1998/198. Data for Total Office workers from Mine Injury and Worktime Quarterly (1997 Closeout Edition) Table 2, p. 6.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

TABLE V–2.—DISTRIBUTION OF M/NM CONTRACTORS AND CONTRACTOR EMPLOYMENT BY SIZE OF OPERATION [a]

Size of contractors [b]	Contractors			
	Underground	Surface	Office workers	Total
Fewer than 20 employees:				
Mines	399	2,783	.....	3,182
Employees	1,717	14,155	649	16,521
20 to 500 employees:				
Mines	36	349	.....	384
Employees	1,639	17,979	802	20,420
Over 500 employees:				
Mines	.....	3	.....	3
Employees	.....	2,560	105	2,665
Total contractors:				
Mines	434	3,135	.....	3,569
Employees	3,356	34,694	1,556	39,606

[a] Source: U.S. Department of Labor, Mine Safety and Health Administration, Office of Standards, Regulations, and Variances based on 1998 MS data, CT441/CT935LA cycle 1998/198. Data for total office workers from Mine Injury and Worktime Quarterly (1998 Closeout Edition) Table 6, p. 21.

[b] Based on MSHA's traditional definition, large mines include all mines with 20 or more employees. Based on SBA's definition, as required by SBREFA, large mines include only mines with over 500 employees.

The M/NM mining sector consists of about 80 different commodities including industrial minerals. There were 11,337 M/NM mines in the U.S. in 1998, of which 9,769 (86%) were small mines and 1,568 (14%) were large mines, using MSHA's traditional definition of small and large mines. Based on SBA's definition, however, only 25 M/NM mines (0.2%) were large mines.[1]

The data in Table V–1 indicate that employment at M/NM mines in 1998 was 195,557, of which 64,570 workers (33%) were employed by small mines and 130,987 miners (67%) were employed by large mines, using MSHA's definition. Based on SBA's definition, however, 170,584 workers (87%) were employed by small mines and 24,973 workers (13%) were employed by large mines. Using MSHA's definition, the average employment is 7 workers at a small M/NM mine and 84 workers at a large M/NM mine.[2] Using SBA's definition, there are an average of 15 workers in each small M/NM mine and 888 workers in each large M/NM mine.

[1] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

Metal Mining. There are about 24 metal commodities mined in the U.S. Underground metal mines use a few basic mining methods, such as room and pillar and block caving. The larger mines rely more heavily on hydraulic drills and track-mounted haulage, and the smaller underground metal mines rely more heavily on hand-held pneumatic drills

Surface metal mines normally include drilling, blasting, and hauling; such processes are typical in all surface mines, irrespective of commodity types. Surface metal mines in the U.S. rank among some of the largest mines in the world.

Metal mines constitute 3 percent of all M/NM mines and employ 23 percent of all M/NM miners. Under MSHA's traditional definition of a small mine, 45 percent of metal mines are small, and these mines employ 2 percent of all miners working in metal mines. Using SBA's definition, 94 percent of metal mines are small, and they employ 53 percent of all miners working in metal mines.[3]

Stone Mining. In the stone mining subsector, there are eight different stone commodities, of which seven are further classified as either dimension stone or crushed and broken stone. Stone mining in the U.S. is predominantly by quarrying, with only a few slight variations. Crushed stone mines typically drill and blast, while dimension stone mines generally use channel burners, drills, or wire saws. Diesel powered-haulage is used to transfer the broken rock from the quarry to the mill where crushing and sizing are done.

Stone mines constitute 33 percent of all M/NM mines, and they employ 41 percent of all M/NM miners. Using MSHA's definition of a small mine, 71 percent of stone mines are small, and these mines employ 29 percent of all miners working in stone mines. Using SBA's definition, 99.9 percent of stone mines are small, and they employ 99 percent of all miners working in stone mines.[4]

Sand & Gravel Mining. Sand and gravel, for construction, is generally extracted from surface deposits using dredges or draglines. Further preparation involves washing and screening. As in other surface mining operations, sand and gravel uses diesel-driven machines, such as front-end loaders, trucks, and bulldozers, for haulage. The preparation of industrial sand and silica flour involves the use of crushers, ball mills, vibrating screens, and classifiers.

The sand and gravel subsector represents the single largest commodity group in the U.S. mining industry when the number of mining operations is being considered. Sand and gravel mines comprise 57 percent of all M/NM mines, and they employ 22 percent of all M/NM miners. Using MSHA's definition of a small mine, 95 percent of sand and gravel mines are small, and these mines employ 76 percent of all miners working in sand and gravel mines. Using SBA's definition, almost 100 percent of sand and gravel mines are small, and they employ approximately 42,800 miners.[5]

Other Nonmetal Mining. For enforcement and statistical purposes, MSHA separates stone and sand and gravel mining from other nonmetal mining. There are about 35 other nonmetal commodities, not including stone, and sand and gravel. Nonmetal mining uses a wide variety of underground mining methods such as continuous mining (similar to coal mining), in-situ retorting, block caving, and room and pillar. The mining method is dependent on the geologic characteristics of the ore and host rock. Some nonmetal operations use kilns and dryers in ore processing. Ore crushing and milling are processes common to both nonmetal and metal mining.

As with underground mining, there is a wide range of mining methods utilized in extracting minerals by surface mining. In addition to drilling and blasting, other mining methods, such as evaporation and dredging, are also utilized, depending on the ore formation.

"Other" nonmetal mines comprise 7 percent of all M/NM mines, and they employ 14 percent of all M/NM miners. Using MSHA's definition of a small mine, 66 percent of other nonmetal mines are small, and they employ 12 percent of all miners working in these nonmetal mines. Using SBA's definition, 99 percent of other nonmetal mines are small, and they employ 92 percent of all miners working in these nonmetal mines.[6]

Economic Characteristics of the Metal/nonmetal Mining Industry. The value of all M/NM mining output in 1998 was estimated at $40 billion.[7] Metal mines, which include copper, gold, iron, lead, silver, tin, and zinc mines, contributed $17.8 billion. Nonmetal production was valued at $22.2 billion: $9.0 billion from stone mining, $5.2 billion from sand and gravel, and $8 billion from other nonmetals such as potash, clay, and salt.

The end uses of M/NM mining output are diverse. For example, iron and aluminum are used to produce vehicles and other heavy duty equipment, as well as consumer goods such as household equipment and soft drink cans. Other metals, such as uranium and titanium, have more limited uses. Nonmetals, like cement, are used in construction while salt is used as a food additive and for road deicing in the winter. Soda ash, phosphate rock, and potash also have a wide variety of commercial uses. Stone and sand and gravel are used in numerous industries and extensively in the construction industry.

A detailed economic picture of the M/NM mining industry is difficult to develop because most mines are either privately held corporations or sole proprietorships, or subsidiaries of publicly owned companies. Privately held corporations and sole proprietorships are not required to make their financial data available to the public. Parent companies are not required to separate financial data for subsidiaries in their reports to the Securities and Exchange Commission. As a result, financial data are available for only a few M/NM companies, and these data are not representative of the entire industry.

Adequacy of Miner Protection Provided by the Final Rule in Underground Metal and Nonmetal Mines. In evaluating the rule for this purpose, it should be remembered that MSHA has measured dpm concentrations in this sector as high as $5{,}570_{DPM}$ µg/m³—a mean of 808_{DPM} µg/m³. See Table III–1 and Figure III–2 in part III of the preamble. As discussed in detail in part III of the preamble, these concentrations place underground metal and nonmetal miners at significant risk of material impairment of their health,

[2] U.S. Department of Labor, MSHA, 1998 final MIS data CM441 cycle 1998/198.

[3] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[4] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[5] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[6] U.S. Department of Labor, Mine Safety and Health Administration, Office of Program Policy Evaluation, Mine Employment Size-Average Employment 1998.

[7] U.S. Department of Energy, Energy Information Administration, *Annual Energy Review 1998*, July 1999, pp. 3, 6, 142, 158, and 160.

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and it does not appear there is any lower boundary to the risk. Accordingly, in accordance with the statute, the Agency has to set a standard which reduces these concentrations as much as is both technologically and economically feasible for this sector as a whole.

Specifically, the standard establishes a concentration limit on dpm. The concentration limit is the equivalent of about 200_{DPM} µg/m³ (as explained in Part IV, in the rule the concentration limit is expressed in terms of a restriction on the amount of total carbon because of the measurement system which MSHA will utilize for compliance sampling).

Alternatives considered. In order to ensure that the maximum protection that is feasible for the underground mining industry as a whole is being provided, the Agency has considered three alternatives that would provide greater protection: a lower concentration limit, a significantly shorter implementation period, and requiring certain categories of metal and nonmetal equipment to be filtered in addition to observing a concentration limit. In addition, the agency has considered whether the approach it is taking in underground coal mines would be feasible in this sector. Specific alternatives and approaches suggested by industry and labor are discussed in detail in part IV.

(1) *Establish a lower concentration limit for underground metal/nonmetal mines.* Based on the Agency's risk assessment, a lower concentration limit would provide more miner protection. The Agency has concluded, however, that at this time it would not be feasible for the underground metal and nonmetal sector to reach a lower concentration limit. The problem is not technological feasibility, but rather economic feasibility.

Technological feasibility of lower limit. In evaluating whether a lower concentration limit is technologically feasible for this sector, MSHA considered several examples of real-world situations. These examples, and a detailed description of the methodology by which they were developed, were published in the preamble to the proposed rule (65 FR 58198 *et seq.*). The examples were based on data about equipment and ventilation from several actual underground metal and nonmetal mines: a salt mine; an underground limestone mine that operates two completely different shifts, one for production, and one for support; and a multi-level underground gold mine. The data was placed into a computer model to estimate the ambient dpm that would remain in a mine section after the application of a particular combination of control technologies. The details of this computer model, referred to as "The Estimator", has subsequently been published in the literature (Haney and Saseen, *Mining Engineering,* April 2000). The results for the salt and limestone mines were written up in detail and placed into MSHA's record, with actual mine identifiers removed; the study of the underground gold mine is based on information supplied by inspectors, and all available data was presented in the preamble to the proposed rule.

MSHA had picked these mines because the Agency originally thought the conditions there were such that these mines would have great difficulty in controlling dpm concentrations. As the results indicated, however, even in these apparently difficult situations the concentration of dpm could be lowered to well below 200_{DPM} µg/m³ with readily available control techniques. Moreover as noted above, MSHA can adopt a rule which is not feasible for every mine; the standard is that the rule be feasible for the industry as a whole.

MSHA did receive comments on the Estimator. However, no specific examples of its application were received nor comments taking issue with the examples discussed above. Specific comments received on the Estimator are addressed in part IV.

Economic feasibility of lower concentration limit. MSHA estimates that it will cost the underground metal and nonmetal industry about $25.1 million a year to comply with a concentration limit of 160_{TC} µg/m³ (200_{DPM} µg/m³). For an average underground metal and nonmetal dieselized mine that uses diesel powered equipment, this amounts to about $128,000 per year.

The assumptions used in preparing the cost estimates for the final review are discussed in detail in the Agency's REA. They are based on a careful review of the evidence on the capabilities of various controls, and a careful review of an economic analysis submitted on behalf of several industry associations. That analysis estimated costs to be three times as high as MSHA's initial estimate. MSHA's analysis and the industry analysis agree on many of their assumptions; however, MSHA believes the industry analysis to be an overestimation primarily because it failed to properly optimize.

In general, MSHA has concluded that:

- The interim standard of 400_{TC} µg/m³ (500_{DPM} µg/m³) will be met primarily through the use of filters, but with cabs and ventilation in certain instances; and
- The final standard of 160_{TC} µg/m³ (200_{DPM} µg/m³) will be met through the use of more filters, ventilation changes, and the turnover in equipment and engines to less polluting models that will have occurred by the time the final standard goes into effect.

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. The incremental cost of additional controls would rise sharply if the industry were required to reach a substantially lower concentration level. It would begin to be necessary to retrofit cabs on equipment that was not designed with cabs and/or did not have off-the-shelf parts—at a cost per unit nearly three times as great as the costs for more limited retrofitting of suitably designed equipment. Additional ventilation improvements (*e.g.,* new shafts) could easily run into the millions of dollars—compared with the $300,000 estimate for more limited "major system improvements" used in the cost analysis. Additional replacement of engines beyond the natural turnover included in the baseline could run as high as $27,500 for the engine itself, with additional costs possibly as high as $65,000 for equipment modifications and installation.

(2) *Significantly shorten the phase-in time to reach the final concentration limit in underground metal/nonmetal mines.* Under the rule, there is a phase-in period for a dpm concentration limit. Operators have 18 months to reduce dpm concentrations in areas of the mine where miners work or travel to 400_{TC} µg/m³ (500_{DPM} µg/m³), and up to 60 months in all to reduce dpm concentrations in those areas to 160_{TC} µg/m³ (200_{DPM} µg/m³).

MSHA has established this phase-in period because it has concluded that it is economically infeasible for the underground metal and nonmetal mining industry as a whole to implement the requirements sooner. The costs of the rule would increase significantly were the final concentration limit to become effective significantly sooner. For example, the turnover of the fleet to less polluting engines would not be as complete by the time the final limit goes into effect; hence, operators would be required to purchase new engines ahead of schedule. Moreover, a substantial portion of the costs to implement these provisions were calculated using a 5-year discounting process to reflect the phase-in schedule.

Technological feasibility problems might also be more frequent with a quicker implementation schedule. The rule includes a provision for a special time extension to deal with unique situations; shortening the normal time frame available to this sector would tend to increase the frequency upon which operators would have to apply for such extensions.

Accordingly, MSHA has concluded that, for the underground metal and nonmetal sector as a whole, a significantly accelerated approach would not be feasible.

(3) *In addition to a concentration limit, require certain types of equipment to utilize an 80% efficiency filter.* This approach would help reduce dpm concentrations in localized areas of a mine, and ensure that problems with ventilation controls will have less of an impact on miner exposures. Most filters can meet the 80% requirement. The requirement could be applied: (a) just to loading and hauling equipment (*e.g.,* trucks and loaders); (b) to the equipment in (a) plus equipment used in the production process (*e.g.,* drills, powered trucks); (c) to the equipment in (a) and (b) and also direct support equipment (*e.g.,* scalers, lube trucks, generators, compressors and pumps); or (d) to all equipment except personnel carriers and supply trucks.

Such an approach would limit operator flexibility on controls—the broader the requirement, the less the flexibility. And it would increase expense, since the most efficient way to achieve compliance with the concentration limit might well be another type of control (*e.g.,* new engine, cab, ventilation, etc.). Accordingly, MSHA has determined that this approach would be infeasible for this sector at this time.

(4) *In lieu of a concentration limit, require certain types of equipment to reach tailpipe limits.* In the underground coal sector, MSHA is requiring various categories of equipment to meet specific tailpipe limits. Compliance with these limits is determined through laboratory tests of engines and control devices. This approach avoids questions about MSHA in-mine compliance sampling which have been the focus of much discussion in coal mining. Accordingly, MSHA considered requiring a similar approach in underground metal and nonmetal mines. However, the agency determined that this would not be practical, because the engines in the current fleet are not approved; hence, the agency lacks information on their emission rates, a key piece of information needed to implement a tailpipe standard. Moreover, in many cases a cab or ventilation change might be a more effective solution to a localized dpm concentration in an underground metal and nonmetal mine than a change in the engine or emission control device—and perhaps less expensive for equipment of this size. One of the advantages of a concentration limit is the flexibility of controls that the operator can apply to meet the limit.

Feasibility of the final rule for underground metal and nonmetal mining sector. The Agency has carefully considered both the technological and economic feasibility of the rule being promulgated for the underground metal and nonmetal mining sector as a whole.

Technological feasibility of final rule. There are arguably two separate issues with respect to technological feasibility—(a) the existence of technology that can accurately and reliably measure dpm concentration levels in all types of underground metal and nonmetal mines; and (b) the existence of control mechanisms that can bring dpm concentrations down to the proposed limit in all types of underground metal and nonmetal mines. Both have been addressed elsewhere in this preamble.

The first of these questions, concerning measurement, is reviewed in considerable detail in section 3 of Part II and in the discussion of section 57.5061 of the rule in Part IV. For the reasons set forth in those discussions, MSHA has concluded that with the use of a submicrometer sampler as required by the final rule, and with a sampling strategy that avoids the inteferences which can compromise individual samples in certain situations, it does have a technologically feasible measurement method that operators and the agency can use to determine if the limits established by the standard are in fact being met.

The second of these questions, concerning controls, is discussed earlier in this part [See "(1) *Establish a lower concentration limit for underground metal/nonmetal mines*"]. MSHA has performed various studies which suggest that even in the most difficult situations, it is technologically feasible for operators to meet the rule's final concentration limit. In fact, these studies suggest it is technologically feasible for operators in this sector to reduce their dpm concentrations to an even lower concentration limit. In addition, as discussed in section 6 of Part II of this preamble, considerable progress has been made in recent years on the effectiveness of filters and cabs. MSHA very carefully reviewed this information with reference to the kinds of engines and equipment found in underground metal and nonmetal mines, and their ventilation, and is confident that the final rule is technologically feasible.

Although the agency has reached this conclusion, and moreover knows of no mine that cannot accomplish the required reductions in the permitted time, it has nevertheless retained in the final rule a provision that any underground metal or nonmetal mine may have up to an additional two years to install the required controls should it find that there are unforseen technological barriers to timely completion. A detailed discussion of the requirements for obtaining approval for such an extension of time to comply is provided in part IV of the preamble.

Economic Feasibility. MSHA estimates that the rule would cost the underground metal and nonmetal sector about $25.1 million a year even with the extended phase-in time. The costs per underground dieselized metal or nonmetal mine are estimated to be about $128,000 annually. The yearly cost of the final rule represents about 0.67 percent of yearly industry revenue. MSHA uses a one-percent "screen" of costs relative to revenues as a presumptive benchmark of economic feasibility. Therefore, since the cost of the rule is less than one percent of revenues, MSHA anticipates that (subject to contrary evidence) the rule is economically feasible for the dieselized underground M/NM mining sector as a whole. Note, however, that the costs are sufficiently close to one percent of revenues that the rule could threaten the economic viability of affected mines on the economic margin and that more costly regulatory alternative could conceivably threaten the economic viability of a substantial fraction of this mining sector.

As explained in the REA, nearly all ($24.1 million) of the anticipated yearly costs would be investments in equipment to meet the interim and final concentration limits. While operators have complete flexibility as to what controls to use to meet the concentration limits, the Agency based its cost estimates on the assumption that operators will ultimately need the following to get to the final concentration limit: (a) Fifty percent of the fleet will have new engines (these new engines do not impact cost of the rule). It is expected that the new engines will be more expensive and technologically superior to the ones that they replace. One aspect of this technological superiority will be substantially lower DPM emissions. It does not follow, however, that the

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greater expense of these engines is an impact of this rule. Mine operators will not replace existing engines with the same type or model of engine. New engine technology makes engines much more efficient and productive than existing older engines. Particularly on larger equipment, greater productivity makes new engines an attractive investment that will pay back the greater costs. Moreover, due to EPA regulations which will limit DPM emissions from engines used in surface construction, surface mining, and over-the-road trucks (the major markets for heavy duty diesel engines), the market for low tech, "dirtier" engines will dry up. Underground mine operators will thus purchase high tech, cleaner engines because they will be the only engines available for purchase.

(b) One hundred percent of the production equipment and about fifty percent of the support equipment will be equipped with filters; (c) about thirty percent of all equipment will need to be equipped with environmentally controlled cabs; (d) twenty three percent of the mines will need new ventilation systems (fans and motors): (e) forty percent of the mines will need new motors on these fans; and (f) thirty two percent of the mines will need major ventilation upgrades.

The Agency is taking a number of steps to mitigate the impact of the rule for the underground metal and nonmetal sector, particularly on the smallest mines in this sector. These are described in detail in the Agency's Regulatory Flexibility Analysis, which the Agency is required to prepare under the Regulatory Flexibility Act in connection with the impact of the rule on small entities. (The regulatory flexibility analysis can be found in part VI of this preamble, or packaged with the Agency's REA.)

Based on its cost estimates, the Agency has concluded that this sector would not find it economically feasible to reduce dpm concentrations to a lower limit at this time. These assumptions and the rationale behind them are discussed in greater detail in the beginning of Chapter IV of the Regulatory Economic Analysis.

After a careful review of the information about this sector available from the industry economic profile, and the other obligations of this sector under the Mine Act, MSHA has concluded that a reasonable probability exists that the typical firm in this sector will be able at this time to afford the controls that will be necessary to meet the proposed standard.

Conclusion: metal and nonmetal mining sector. Based on the best evidence available at this time, the Agency has concluded that the final rule for the underground metal and nonmetal sector meets the statutory requirement that the Secretary attain the highest degree of health and safety protection for the miners in that sector, with feasibility a consideration.

VI. Regulatory Impact Analyses

This part of the preamble reviews several impact analyses which the Agency is required to provide in connection with its final rulemaking. The full text of these analyses can be found in the Agency's Regulatory Economic Analysis (REA).

(A) Costs and Benefits: Executive Order 12866

In accordance with Executive Order 12866, MSHA has prepared a Regulatory Economic Analysis (REA) of the estimated costs and benefits associated with the final rule for the underground metal and nonmetal mining sector.

The key conclusions of the REA are summarized, together with cost tables, in part I of this preamble (see Item number 7). The complete REA is part of the record of this rulemaking, and is available from MSHA.

The Agency considers this rulemaking "significant" under section 3(f) of Executive Order 12866, and has so designated the rule in its semiannual regulatory agenda (RIN 1219–AA74). However, based upon the REA, MSHA has determined that the final rule does not constitute an "economically significant" regulatory action pursuant to section 3(f)(1) of Executive Order 12866.

(B) Regulatory Flexibility Act (RFA)

Introduction

In accordance with section 605 of the Regulatory Flexibility Act of 1980 as amended, MSHA has analyzed the impact of the final rule on small businesses. Further, MSHA has made a determination with respect to whether or not it can certify that this final rule will not have a significant economic impact on a substantial number of small entities that are affected by this rulemaking. Under the Small Business Regulatory Enforcement Fairness Act (SBREFA) amendments to the Regulatory Flexibility Act (RFA), MSHA must include a factual basis for this certification. If the final rule does have a significant economic impact on a substantial number of small entities, then the Agency must develop a final regulatory flexibility analysis.

The Agency has, as required by law (5 U.S.C. 605), developed a final regulatory flexibility analysis which is set forth Chapter V of the REA. In addition to a succinct statement of the objectives of the final rule and other information required by the Regulatory Flexibility Act, the analysis reviews alternatives considered by the Agency with an eye toward minimizing the economic impact on small business entities.

Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the Small Business Administration (SBA) definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action, and hence is required to use the SBA definition.

The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees (13 CFR 121.201). Of the 196 underground M/NM mines that use diesel powered equipment and are therefore affected by this rulemaking, 189 (or all but 7) fall into this category and hence can be viewed as sharing the special regulatory concerns that the RFA was designed to address.

Traditionally, the Agency has also looked at the impacts of its rules on a subset of mines with 500 or fewer employees ¾ those with fewer than 20 employees, which the mining community refers to as "small mines." The way these small mines perform mining operations is generally recognized as being different from the way larger mines operate. These small mines differ from larger mines not only in the number of employees, but also, among other things, in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA rules and the impact of MSHA rules on them will also tend to be different. It is for this reason that "small mines," as traditionally defined by the mining community, are of special concern to MSHA.

This analysis complies with the legal requirements of the RFA for an analysis of the impacts on "small entities" while continuing MSHA's traditional look at "small mines." MSHA concludes that the final rule would not have a significant economic impact on small entities, as defined by SBA, *when considered as a group*. However, MSHA has determined that the final rule arguably would have a significant economic impact on a subset of small entities that are covered by this rulemaking. That subset is small underground M/NM mines as traditionally defined by MSHA, those mines with fewer than 20 employees. This subset of affected mines constitutes a substantial number of small entities.

Screening Analysis

General Approach. The Agency's analysis of impacts on "small entities" begins with a "screening" analysis. The screening compares the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for those small entities. When estimated compliance costs are less than 1 percent of the estimated revenues (for the size categories considered), the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed 1 percent of revenues, it tends to indicate that further analysis may be warranted.

Derivation of Costs and Revenues. The compliance costs presented here were previously introduced in Chapter IV of the REA along with an explanation of how they were derived. Table VI–1 summarizes the total yearly cost of the final rule by mine size.

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TABLE VI-1: Total Yearly Compliance Costs for M/NM Mine Operators by Mine Size Class

Requirement	Total Yearly Industry Cost By Mine Size Class		
	Under 20 Employees	20 to 500 Employees	Over 500 Employees
Section 57.5060(a)&(b) DPM Concentration Limits	$3,909,865	$17,068,073	$3,215,869
Section 57.5067 Newly Introduced Engines	$ -	$ 2,848	$ 712
Section 57.5060(c) Extension Application	$ 148	$ 401	$ 36
Section 57.5060(d) Respirator Protection	$ 67,247	$ 285,690	$ 17,855
Section 57.5062 DPM Control Plans	$ 1,408	$ 6,336	$ 704
Section 57.5066(c) Maintenance Training	$ 894	$ 2,384	$ 468
Section 57.5066(b) Tagging and Examination	$ 1,769	$ 6,178	$ 1,948
Section 57.5070 Miner Health Training	$ 5,226	$ 74,189	$ 42,005
Section 57.5071 Environmental Monitoring	$ 106,425	$ 297,213	$ 31,008
Section 57.5075 Diesel Particulate Records	$ 204	$ 1,639	$ 943
TOTAL COST	$4,093,186	$17,744,951	$3,311,548
COST PER MINE	$ 53,158	$ 158,437	$ 473,078

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Data on underground M/NM mines published by the U.S. Geological Survey [1] were used for tonnage and value of underground M/NM mines. These data, however, are not disaggregated by mine size class. MSHA collects data, by mine size, on both average employees and employee hours.[2] MSHA has used these data to estimate revenues by mine size class.

MSHA has assumed that tonnage is proportional to employee hours. This assumption (rather than proportionality with employees) implicitly adjusts for different shift lengths associated with different sizes of mines. MSHA has also assumed that all underground M/NM mines use diesel powered equipment.[3] Using these assumptions, MSHA has computed the percentages of employee hours of all underground M/NM mines that are accounted for by each size class. MSHA estimates that these percentages of total revenues are accounted for by the different mine size classes.

Results of the Screening Analysis. The final rule applies to underground M/NM mines that use diesel-powered equipment. Table VI–1 shows that the estimated yearly cost of the final rule as a percentage of yearly revenues is about 0.8 percent for the affected underground M/NM mines with 500 or fewer employees.

However, for a subset of affected underground M/NM mines, those with fewer than 20 employees, estimated yearly costs are equal to about 2.16 percent of yearly revenues for this subset of mines. The economic impact on these small mines, which constitute a substantial number of small entities affected by the final rule, is larger than one percent of their revenues. MSHA therefore cannot certify that the final rule would not have a significant impact on a substantial number of small entities.

The Agency has prepared a final regulatory flexibility analysis, as required by law, which explains the steps MSHA has taken to minimize the burden on these small entities and justifies the costs placed on them.

TABLE VI–2.—ESTIMATED YEARLY COSTS OF FINAL RULE RELATIVE TO YEARLY REVENUES FOR UNDERGROUND COAL MINES THAT USE DIESEL-POWERED EQUIPMENT

Mine size	Final rule yearly costs (In thousands)	Revenues[a] (In thousands)	Costs as Percentage of revenues
<20 emp.	$4,093	$189,305	2.16
≤500 emp.	21,837	2,745,137	0.80

[a] Source: Mine Safety and Health Administration, Office of Injury and Employment Information, Denver, Colorado. 1999, and U.S. Department of Energy, Energy Information Agency, *Annual Energy Review 1998*, DOE/EIA0384(98), July 1999, p.203.

Final Regulatory Flexibility Analysis

As indicated above, the estimated yearly cost of the final rule on a subset of small entities, those with fewer than 20 employees, is 2.16 percent of yearly revenue. This percentage is just over twice the value (1.0 percent) below which MSHA could say with reasonable confidence that the final rule does not have a significant economic impact on a substantial number of small entities. Accordingly, MSHA has prepared a final regulatory flexibility analysis.

Need for, and Objectives of, the Rule

Need. The rule is needed because underground miners in mines that use diesel powered equipment are currently exposed to extremely high concentrations of diesel particulate matter (DPM). Based on MSHA field studies, median DPM concentrations to which underground miners are exposed range up to 200 times as high as average environmental exposures in the most heavily polluted urban areas and up to 10 times as high as median exposures estimated for the most heavily exposed workers in any occupational group other than underground miners.

The available scientific information indicates that miners exposed to the extremely high DPM concentrations found in underground mines are at significant excess risk of experiencing three kinds of material impairment to their health:

- Increased risk of lung cancer has been linked to chronic occupational DPM exposure.
- Increased acute risk of death from cardiovascular, cardiopulmonary, or respiratory causes has been linked to short or long term DPM exposures.
- Sensory irritations and respiratory symptoms can result from even short term DPM exposures. Besides being potentially debilitating, such effects can distract miners from their responsibilities in ways that could pose safety hazards for everyone in the mine.

Although definitive dose-response relationships have not yet been established (especially for the acute effects), the best available evidence indicates that the risks are substantial.

Objective. The objective of the rule is to lower DPM exposures in underground M/NM mines to concentrations similar to the worst levels to which other occupational groups are exposed. By doing so, the rule is designed substantially to lower the health risks associated with DPM. Expected benefits include an estimated minimum of 8.5 lung cancer deaths avoided per year.

Significant Issues Raised in Response to the Initial RFA

Comments. The principal issue raised in comments on the PREA was that, for a variety of reasons, MSHA had substantially understated the costs of controlling DPM. The implication of these comments was that the rule was economically infeasible. The most comprehensive comments along these lines were by Head,[4] who argued (among other things) that MSHA had made the following errors and omissions in its analysis:

- MSHA had (according to Head) understated the numbers of machines and mines affected, including:

[1] U.S. Geological Survey, "Mineral Industry Surveys: Mining and Quarrying Trends, 1998 Annual Review, April 2000.

[2] U.S. Department of Labor, MSHA, 1998 Final MIS data CM441 cycle 1998/198.

[3] This assumption ignores the fact that some very small mines do not use diesel powered equipment. MSHA believes, however, that these mines are generally very small (even among the mines with fewer than 20 employees) and that many of them operate only intermittently. Thus they account for employee hours proportionately far less than their numbers. Accordingly, MSHA believes that the most accurate way to interpret the data is to disregard the fact that these mines do not use diesel powered equipment.

[4] H. John Head, Principal Mining Engineer, Harding Lawson Associates, "Review of Economic and Technical Feasibility of Compliance Issues Related to: Department of Labor—MSHA, 30 CFR Part 57—Proposed Rule for Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Miners," Report prepared under contract with the National Mining Association, July 21, 1999.

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- Understatement of the number of diesel units in underground M/NM mines by more than 50 percent, and
- Understatement of the number of ventilation upgrades needed by 20 percent to 40 percent
- MSHA had understated a number of costs, including:
- Understatement of the cost of replacement engines by up to one third,
- Understatement of the costs of filters on larger engines by 20 percent, and
- Understatement of the costs of vehicle cabs by about 60 percent.
- MSHA had omitted some costs entirely, including:
- Installation costs of retrofitting new engines in old equipment, which ran as high as three times the costs of the engines themselves, and
- Major ventilation improvements needed by about one third of the mines.

Based on his own numbers, Head estimated compliance costs to be three times as high as MSHA's estimate of the cost of the proposed rule of $19.2 million.

Analytical Assessment of Issues. MSHA considered the comments and reviewed its assessment of costs very carefully. The assessment focused on Head's comments, since his exposition was detailed enough for analysis of the basis of his estimates. MSHA responded in a variety of ways, which are summarized below.

The key to the issue of the number of diesel units affected by the rule was how one interpreted the number. MSHA resolved this issue by recognizing that not all diesel powered equipment would be affected in the same manner. In fact, the machines in Head's total count should be grouped into three categories: active, spares, and disused. Active diesel powered equipment (essentially MSHA's original count) needs to be fitted for everyday use. Spare equipment needs to be controlled for occasional use as back-up. Disused equipment is essentially not affected by the rule. A shift in the principal control strategy from engine replacement to ceramic filters (discussed further below) made these distinctions operational. With ceramic filters, both active and spare equipment can be fitted with filters (a relatively inexpensive operation), but filters need to be regenerated and changed (which encompasses most of the costs) only to the extent that the equipment is actually used.

MSHA believes that Head was simply wrong about the number of mines needing upgrades to their ventilation systems. Head appeared to believe that MSHA's count was arbitrary, and the basis for his proposed number was obscure. In fact, MSHA has based its count on mine-specific data on the existence and rate of air flow of ventilation systems. Thus, MSHA retained its original count.

MSHA's review of comments on costs produced different conclusions for different specific costs:

- MSHA accepted and used Head's estimate of costs of ceramic filters.
- MSHA does not entirely agree with Head's estimates of costs of new engines. Moreover, expensive new engines are technologically advanced and tend to produce substantial gains in productivity and savings in operating costs, which Head did not consider. The issue of engine costs became irrelevant, however, under a strategy of filters as the first-used control device.
- MSHA's re-examination of the costs of cabs indicated that MSHA's cost estimate is appropriate for equipment for which equipment manufacturers can provide off-the-shelf kits for retrofitting equipment, and Head's cost estimate is appropriate for equipment for which cabs have to be custom designed and retrofitted. Since the rule does not mandate cabs and MSHA expects cabs to be used on a relatively small proportion of equipment, however, MSHA believes that mine operators will not retrofit equipment for which cabs would need to be custom designed. Accordingly, MSHA has retained its original cost estimate.
- Head concurred with MSHA on the costs of ventilation improvements. While these costs appear to be an appropriate average estimate for M/NM mines as a whole, there is a distinct possibility that they may be too high for very small M/NM mines.[5] In the context of regulatory flexibility analysis, MSHA considers these cost estimates to be fairly conservative.

MSHA agrees that certain costs were omitted, but the conclusions of MSHA's reconsideration of these costs also vary with the cost:

- MSHA has accepted Head's estimates for major ventilation improvements and has included them in the analysis of costs.
- Head's comment that MSHA had omitted the costs of retrofitting new engines in old equipment is correct, although MSHA does not agree with the size of Head's cost estimates. The key issue, however, is that the strategy of relying primarily on filters does not entail retrofitting engines. Thus Head's comment is not germane.

Concentration Limits and the Toolbox. This standard for underground M/NM mines is a performance standard, with an interim DPM concentration limit of 500 micrograms/m^3, followed by a final DPM concentration limit of 200 micrograms/m^3. The rule encourages mine operators to use any combination of a "toolbox" of measures to meet these concentration limits. For cost estimation purposes, however, it is necessary to assume a specific set and sequence of control measures. Specifically, in the PREA MSHA assumed that:

- The interim standard would be met by replacing engines, installing oxidation catalytic converters, and improving ventilation; and
- The final standard would be met by adding cabs and filters.

Both the general strategy and the specific proportions of diesel powered equipment to be controlled by each measure were based on an optimizing approach, in which the most cost-effective additional measures were selected for additional DPM reductions at each stage.

In his comments, Head exactly replicated MSHA's assumptions about how many pieces of each kind of diesel equipment would be controlled, how they would be controlled, and the sequence in which controls would be used. Although his cost estimates differed substantially from MSHA's, Head made no attempt to optimize the use of DPM control "tools" from the toolbox.

Substantially the most important of Head's changes is to make filters much cheaper, relative to engine replacement. At the same time, data collected by MSHA since publication of the PREA indicate that filters are more effective than was previously understood. This finding has further enhanced the cost-effectiveness of filters, relative to engine replacement. These changes in information have caused MSHA to go back to the toolbox and rethink the optimized compliance strategy. The revised compliance strategy, upon which MSHA bases the revised estimates of compliance costs, reverses the two most widely used measures from the toolbox. MSHA now anticipates that:

- The interim DPM standard of 500 micrograms/m^3 will be met with filters, cabs, and ventilation; and
- The final DPM standard of 200 micrograms/m^3 will be met with more filters, ventilation, and such turnover in equipment and engines as will have occurred in the baseline.

This new approach uses the same toolbox and optimization strategy that was used in the PREA. Since relative costs are different, however, the tools used and costs estimated are quite different. The effects on costs is substantial. Most of the difference between Head's cost estimate and the cost estimate in the REA is attributable to this change in strategy.

Changes in the Rule. Because the rule is a performance standard that uses a tool-box approach, most modifications that MSHA made in response to comments involved changes in the mix of tools within the framework of the rule, rather than changes in the rule per se. MSHA did make one significant change in the rule itself, however, by allowing compliance with listed EPA standards as a substitute for MSHA approval of new engines. Because most engines used in underground M/NM mining equipment are essentially the same engines used on the surface, which fall under EPA regulations, MSHA believes that virtually all new engines used in mining equipment will meet EPA standards. Therefore, this change resulted in eliminating a cost of approval that was estimated in the PREA to average $2,500 per new engine.

Small Entities to Which the Rule Will Apply

For the purposes of this regulatory flexibility analysis, the working definition of "small" is MSHA's definition of fewer than 20 employees. (Although SBREFA requires use of the SBA's definition, the impacts on mines with 500 or fewer employees as a whole are not economically significant.) Correspondingly, one element of a regulatory flexibility analysis involves developing a more focused definition of "small."

There are 77 M/NM mines that are "small" by this definition. These mines fall in four commodity groups:

- Stone is the largest group, accounting for 54 small underground M/NM mines that use diesel equipment (70 percent). These mines include limestone (46 mines), marble (5 mines), lime (2 mines), and granite (1 mine).
- Precious metals account for 10 small underground M/NM mines that use diesel equipment (13 percent). Most of these (9 mines) are gold mines; one mines both gold and silver.
- Other metals account for 4 small underground M/NM mines that use diesel equipment (5 percent). These mines include zinc (2 mines), copper (1 mine), and a combination of copper and zinc (1 mine).
- The other 9 small underground M/NM mines that use diesel equipment (12 percent) are a miscellany that includes shale (3 mines) as well as calcite, clay, gemstone, perlite, sand (industrial), and talc (1 mine each).

Collectively, these 77 mines have estimated revenues of $189.3 million, or an average of $2.46 million per mine. The estimated total costs of the rule are $4.1 million, or an average of $53,160 per mine. Estimated costs of the rule are 2.16 percent of estimated revenues.

Costs by Commodity Group and Mine Size. Table VI–3 shows the estimated yearly cost by size class for each commodity group in M/NM mines. Costs for Section 57.5060(a) and Section 57.5060(b) were recalculated for each commodity group, based on the diesel powered equipment and air flow of the mines in each commodity group. All other costs were very small, probabilistically distributed among mines, and/or essentially constant for all mines or for all mines in a size class. For these costs, the average cost per mine in each size class (from Table VI–1) was used, as very little precision was lost through this simpler estimation procedure. Table VI–3 shows a fair degree of variation among commodity groups.

- For mines with fewer than 20 employees, the average cost per mine is estimated to be $53,158, and estimated costs per mine for commodity groups range from $31,500 to $60,500, with:
- Costs above average for stone mines ($60,500) and base metal ($54,400), and
- Costs below average for other M/NM mines ($31,500) and gold mines ($34,600).
- For mines with 20 to 500 employees, the average cost per mine is estimated to be $158,437, and estimated costs per mine for commodity groups range from $102,100 to $201,700, with:
- Costs above average for base metal mines ($201,700) and gold mines ($171,900),
- Costs roughly average for stone mines ($150,900) and evaporates mines ($149,100), and
- Costs below average for other M/NM mines ($102,100).
- For mines with over 500 employees, the average cost per mine is estimated to be $473,078, and estimated costs per mine for commodity groups range from $291,800 to $660,300, with:
- Costs above average for gold mines ($660,300) and base metal mines ($592,300), and
- Costs below average for evaporates mines ($291,800) and stone mines ($298,000).

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[5] The issue is further complicated by the fact that mines that are "small" in terms of employment vary considerably among commodities and mining techniques in their physical size and ventilation requirements. Accordingly, MSHA has not attempted to make a separate cost estimate of ventilation improvement costs for "small" M/NM mines as a group.

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Table VI-3: Yearly Compliance Costs by Commodity Group and Mine Size

Commodity Group	Mine Size	Total Yearly Industry Cost	Yearly Cost per Mine
Stone[a]	Under 20	$ 3,258,360	$ 60,340
	20 to 500	$ 6,330,996	$ 150,738
	Over 500	$ 297,691	$ 297,691
	All Mines	$ 9,887,047	$ 101,928
Precious Metals[b]	Under 20	$ 345,240	$ 34,524
	20 to 500	$ 3,263,782	$ 171,778
	Over 500	$ 659,978	$ 659,987
	All Mines	$ 4,269,000	$ 142,300
Other Metals[c]	Under 20	$ 217,104	$ 54,276
	20 to 500	$ 5,039,700	$ 201,588
	Over 500	$ 1,775,991	$ 591,997
	All Mines	$ 7,032,795	$ 219,775
Evaporates[d]	20 to 500	$ 3,724,100	$ 148,964
	Over 500	$ 582,990	$ 291,495
	All Mines	$ 4,307,090	$ 159,522
Other[e]	Under 20	$ 282,357	$ 31,373
	20 to 500	$ 101,950	$ 101,950
	All Mines	$ 384,307	$ 38,431

[a] Granite, lime, limestone, marble, and sandstone.

[b] Gold, Platinum, and silver.

[c] Copper, iron ore, lead, molybdenum, uranium, and zinc.

[d] Gypsum, potash, salt, and trona.

[e] Borate, calcite, clay, gemstones, perlite, sand (industrial), shale, and talc.

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Thus by overall commodity group:
- Compliance costs are relatively high in gold mines (except for small mines) and base metal mines,
- Compliance costs are relatively low in evaporates mines and other M/NM mines, and
- Compliance costs of stone mines show no consistent pattern relative to average costs for all M/NM mines.

The differences in cost per mine appear to be attributable to the interaction of three characteristics of the mines, which are included in Table VI–4:
- The percentage of mines that need new ventilation systems;
- The number of diesel powered machines per mine; and
- The proportion of diesel powered equipment that is large production equipment.

Table VI-4: Factors Contributing to Variability of Yearly Compliance Costs Across Commodity Groups

Commodity Group	Mine Size	Machines per Mine				Percent Needing Ventilation Improvements	
		Production		Sup.	Total		
		>150 h.p.	≤150 h.p.			New System	New Motor
Stone	Under 20	4.3	0.5	4.4	9.2	44%	30%
	20 to 500	8.5	1.0	7.6	17.1	33%	31%
	Over 500	16.0	1.0	23.0	40.0	0%	100%
	All Mines	6.3	0.7	6.0	12.9	39%	31%
Gold	Under 20	0.4	1.2	0.8	2.4	40%	40%
	20 to 500	6.6	5.8	11.7	24.1	0%	68%
	Over 500	26.0	12.0	95.0	133.0	0%	0%
	All Mines	5.2	4.5	10.9	20.5	13%	57%
Base Metal	Under 20	3.5	1.0	6.2	10.7	25%	50%
	20 to 500	10.3	2.8	16.6	29.8	0%	48%
	Over 500	17.3	29.3	68.0	114.7	0%	33%
	All Mines	10.1	5.1	20.2	35.3	3%	47%
Evaporate	20 to 500	5.2	4.6	21.1	30.9	4%	40%
	Over 500	1.5	11.5	80.0	93.0	0%	0%
	All Mines	4.9	5.1	25.5	35.5	4%	41%
Other	Under 20	1.2	0.8	0.2	2.2	11%	67%
	20 to 500	0.0	15.0	0.0	15.0	0%	100%
	All Mines	1.1	2.2	0.2	3.5	10%	70%

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These three characteristics interact in somewhat different ways in the different mine size classes:

- For mines with fewer than 20 employees, the cost per mine is:
- Relatively high (or just above average) in commodity groups where two or all three of these factors have relatively high values, and
- Relatively low when two of these factors have relatively low values.
- For mines with 20 to 500 employees, the cost per mine is:
- Relatively high in commodity groups where the number of machines per mine and the proportion of machines that are large production equipment are both relatively large,
- Average when one of these two factors is relatively high and the other is relatively small, and
- Relatively low when all three of the factors have relatively low values.
- For mines with over 500 employees (none of which need new ventilation systems), the cost per mine is:
- Relatively high in commodity groups where the number of machines per mine is relatively large, and
- Relatively low when the number of machines per mine or the proportion of machines that are large production equipment is relatively small.

Impacts on Small Mines by Commodity Group. The available data are not adequate to support a realistic estimate of impacts on small underground M/NM mines by commodity group, since revenues of individual commodities cannot be allocated to different size classes of mine. The analysis of costs per mine suggests, however, that stone is the only commodity group with impacts much above average. The costs per small stone mine are 13.6 percent higher than the average for all small underground M/NM mines. Impacts on small underground mines in other M/NM commodity groups appear to be about average or less.

Projected Reporting, Recordkeeping, and Other Requirements of the Rule

The rule requires several types of records and reports. Plans are required in conjunction with respirator use and DPM control if the concentration levels are violated, and these must be posted and provided to various parties. An extension may be applied for. Maintenance training, miner health training, and respirator training must be logged. Environmental monitoring results must be recorded and provided to miners upon request. While there are a number of reporting and recordkeeping requirements, however, each one is straightforward, and most are no more than the simplest form of documentation. Thus the total cost of recordkeeping is only about 0.35 percent of the compliance costs for small mines.

The principal source of costs of the rule is controls to reduce the DPM concentrations in underground mines. MSHA has adopted a flexible "toolbox" approach that allows mine operators to select the controls that will be most cost-effective for their mines. MSHA has based its cost estimates on extensive use of ceramic filters, less widespread use of cabs on equipment, and ventilation upgrades. MSHA also assumes that new diesel engines introduced into the mines as part of the baseline turnover of the fleet and its engines will be relatively clean and will contribute to reduced DPM levels. These control costs account for an estimated 95.6 percent of the yearly compliance costs of small mines. Of these costs, ventilation costs (47.1 percent) and filter costs (46.3 percent) account for nearly half each, while the cost of cabs (6.6 percent) is relatively minor.

Only two other requirements impose costs of any size. Environmental monitoring accounts for about 2.6 percent of the estimated compliance costs of small mines. Occasional use of respirators (equipment, training, inspection, etc.) accounts for about 1.6 percent of estimated compliance costs. Maintenance training and miner health training account for less than 0.2 percent of compliance costs. The non-control requirements of the rule are quite modest.

Steps Taken to Minimize Impacts on Small Entities

Constraints of the Mine Safety and Health Act. The Federal Mine Safety and Health Act of 1977 was enacted to protect miners. MSHA has always read the Act to prohibit discriminating among miners by providing different degrees of protection that varied systematically with the size of the mine in which they worked. Accordingly, the Mine Safety and Health Act rules out certain classes of regulatory flexibility alternatives, particularly exemption of small mines, but also any alternative that would result in systematically higher allowable DPM concentration levels in small mines. Because over 95 percent of the yearly costs to be incurred by small mines are directly related to protection, there is little scope for distinct provisions for small mines.

Built-In Flexibility. To minimize impacts on small entities, MSHA has taken steps to build as much flexibility into the rule itself as possible. The rule itself is a performance standard that allows mine operators to meet the DPM concentration limits with their own choice of "tools." While MSHA has selected a specific set of tools for the cost analysis, MSHA expects that operators of specific mines probably will often be able to come into compliance at lower costs by using a mix of techniques tailored to that specific mine.

Other parts of the rule provide similar flexibility. Training and recordkeeping requirements indicate the information to be imparted or retained, for example, but they do not spell out how this is to be done. Much of the reporting is required only upon request, rather than routinely. Where a requirement (*e.g.*, MSHA approval of new engines) appeared to be relatively expensive, MSHA added an alternative (compliance with listed EPA standards).

Phasing in over five years is another element that MSHA has incorporated to minimize impacts (albeit for all mines, not just for small ones). This not only defers costs, it allows impacts to be reduced in a number of ways. Mine operators can spread major expenses out to avoid a capital crunch. To a great degree, mine operators will be able to take advantage of the natural turnover of their fleets, rather than doing extensive (and more expensive) retrofitting. In extreme cases, if a mine is quite marginal and/or is likely to shut down in a few years anyway, the five-year phase-in allows an orderly closure that minimizes impacts.

Low Risk of Short-Term Closures. Ultimately, the issue of concern related to impacts whether mines may be forced to close. When costs are a significant but relatively small fraction of revenues (or profits), however, it is especially difficult to determine whether closure is an impact resulting from the rule or a baseline event that would have happened anyway. Given the fact that profits fluctuate widely over time, even the presence of losses is not necessarily a good indicator of whether businesses will recover or fail. In many cases where a business does fail, the true impact of a regulation is not causing its failure but rather hastening its failure. Because of the phasing of this rule, it affords an opportunity to consider the potential for hastening the failure of a small mine.

If a mine is likely to close within five to seven years without the regulation, the impacts of the rule are different from the above analysis. In order to stay open for five years, a mine need only comply with the interim DPM concentration level. To this end, it needs to incur the costs of:

- Control costs necessary for Section 57.5060(a);[6]
- Respirator protection costs of Section 57.5060(d);[7]
- DPM control plan costs of Section 57.5062;[8]
- Maintenance training, tagging, and examination costs of Section 57.5066(b) and Section 57.5066(c);[9]
- Miner Health Training costs of Section 57.5071;[10]
- Environmental monitoring costs of Section 57.5071;[11] and
- DPM record costs of Section 57.5075.[12]

Thus the yearly costs for small mines, amortized over 5 years at an annual discount rate of 7.0 percent, would be $1,554,086, or an average of $20,183 per mine. This is 0.82 percent of annual revenue, which is below the threshold for a significant economic impact. This is not the type of impact that would force a mine to close sooner rather than later. The conclusion is that any closure impacts would be mild and would occur foreseeably over time, rather than abruptly.

Compliance Assistance

The Agency plans to provide extensive compliance assistance to the mining community. MSHA intends to focus these efforts on smaller metal and nonmetal operators, including training them to measure DPM concentrations, providing technical assistance on available controls, and establishing a system for addressing compliance inquiries from small businesses. The Agency will also issue a compliance guide, continue its current efforts to disseminate educational materials and software, and hold workshops to inform the mining community.

In conclusion, MSHA believes that it has taken all of the steps consistent with the Mine Safety and Health Act that could substantially reduce the impacts of this rule on small entities.

(C) Alternatives Considered

MSHA did explore a variety of alternatives in its Initial Regulatory Flexibility Analysis. See 63 FR 58212. For example, it looked at a regulatory approach that would have focused on limiting workers exposure rather than limiting particulate concentration. Under such an approach, operators would have been able to use administrative controls and respiratory protection equipment to reduce diesel particulate exposure. For the reasons explained in that Initial Analysis, the Agency declined to take such an approach. For MSHA's response to comments on the specific topics of administrative controls and respiratory protection equipment, see Part IV's discussion of 57.5060(e) and 57.5060(f).

(D) Unfunded Mandates Reform Act of 1995

For purposes of the Unfunded Mandates Reform Act of 1995, the final rule does not include any Federal mandate that may result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private sector of more than $100 million.

(E) Paperwork Reduction Act of 1995

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA95). The final rule will impose two types of paperwork burden hours on underground M/NM mine operators that use diesel powered equipment. First, there are burden hours that will occur *only* in the first year the rule is in effect (hereafter known as first year burden hours). Second, there are burden hours that will occur *every* year that the rule is in effect, starting with the first year (hereafter known as "annual" burden hours).

In the first year, mine operators will incur 3,571 burden hours and associated burden costs of about $171,926. After the first year, mine operators will incur 526 burden hours annually and associated costs of about $21,871.

We have submitted a copy of this final rule to OMB for its review and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB New Executive Office Building, 725 17th St., NW, Rm. 10235, Washington, DC 20503, Attn: Desk Officer for MSHA. Submit written comments on the information collection not later than 60 days after date of publication in the **Federal Register**.

Our paperwork submission summarized above is explained in detail in the REA. The REA includes the estimated costs and assumptions for each final paperwork requirement related to this final rule. A copy of the REA is available from us. These paperwork requirements have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1995. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number.

(F) National Environmental Protection Act

The National Environmental Policy Act (NEPA) of 1969 requires each Federal agency to consider the environmental effects of final actions and to prepare an Environmental Impact Statement on major actions significantly affecting the quality of the environment. MSHA has reviewed the final rule in accordance with NEPA requirements (42 U.S.C. 4321 et. seq.), the regulations of the Council of Environmental Quality (40 CFR Part 1500), and the Department of Labor's NEPA procedures (29 CFR Part 11). As a result of this review, MSHA has determined that this rule will have no significant environmental impact.

(G) Executive Order 12360 Governmental Actions and Interference With Constitutionally Protected Property Rights

This final rule is not subject to Executive Order 12360, Governmental Actions and Interference with Constitutionally Protected Property Rights, because it does not involve implementation of a policy with takings implications.

(H) Executive Order 13045 Protection of Children From Environmental Health Risks and Safety Risks

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children. The Agency has determined that the rule will not have an adverse impact on children.

(I) Executive Order 12988 (Civil Justice)

The Agency has reviewed Executive Order 12988, Civil Justice Reform, and determined that the final rule will not unduly burden the Federal court system. The rule has been written so as to provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

[6] These controls include ceramic filters and cabs, but not ventilation (which MSHA did not estimate to be necessary for the interim DPM level. These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $1,119,800 for filters and $150,437 for cabs.

[7] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $164,845.

[8] Annual costs are $1,408.

[9] These costs, amortized over 5 years at an annual discount rate of 7.0 percent, are $5,681.

[10] Annual costs are $5,226.

[11] Annual costs are $106,425.

[12] Annual costs are $204.

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(J) Executive Order 13084 Consultation and Coordination With Indian Tribal Governments

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

(K) Executive Order 13132 (Federalism)

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it does not have "federalism implications." The final rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

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Supplementary References

Below is a list of supplemental references that MSHA reviewed and considered in the development of the proposed rule. These documents are not specifically cited in the preamble discussion, but are applicable to MSHA's findings:

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List of Subjects in 30 CFR Part 57

Metal and nonmetal, Mine safety and health, Underground mines, Diesel particulate matter.

Dated: January 8, 2001.

Robert A. Elam,

Acting Assistant Secretary for Mine Safety and Health.

Chapter I of Title 30 of the Code of Federal Regulations is hereby amended as follows:

PART 57—[AMENDED]

1. The authority citation for Part 57 continues to read as follows:

Authority: 30 U.S.C. 811, 957, 961.

2. The heading of Subpart D of Part 57 is revised to read as follows:

Subpart D—Air Quality, Radiation, Physical Agents, and Diesel Particulate Matter

3. A new undesignated center heading and §§ 57.5060 through 56.5075 are added to subpart D.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

Sec.

57.5060 Limit on concentration of diesel particulate matter.
57.5061 Compliance determinations.
57.5062 Diesel particulate matter control plan.
57.5065 Fueling and idling practices.
57.5066 Maintenance standards.
57.5067 Engines.
57.5070 Miner training.
57.5071 Environmental monitoring.
57.5075 Diesel particulate records.

DIESEL PARTICULATE MATTER—UNDERGROUND ONLY

§ 57.5060 Limit on concentration of diesel particulate matter.

(a) After July 19, 2002 and until January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 400 micrograms per cubic meter of air (400_{TC} µg/m³).

(b) After January 19, 2006, any mine operator covered by this part must limit the concentration of diesel particulate matter to which miners are exposed in underground areas of a mine by restricting the average eight-hour equivalent full shift airborne concentration of total carbon, where miners normally work or travel, to 160 micrograms per cubic meter of air (160_{TC} µg/m³).

(c)(1) If, as a result of technological constraints, a mine requires additional time to come into compliance with the limit specified in paragraph (b) of this section, the operator of the mine may file an application with the Secretary for a special extension.

(2) No mine may be granted more than one special extension, nor may the time otherwise available under this section to a mine to comply with the limit specified in paragraph (b) be extended by more than two years.

(3) The application for a special extension may be approved, and the additional time authorized, only if the application includes information adequate for the Secretary to ascertain:

(i) That diesel-powered equipment was used in the mine prior to October 29, 1998;

(ii) That there is no combination of controls that can, due to technological constraints, bring the mine into full compliance with the limit specified in paragraph (b) within the time otherwise specified in this section;

(iii) The lowest achievable concentration of diesel particulate, as demonstrated by data collected under conditions that are representative of mine conditions using the method specified in § 57.5061; and

(iv) The actions the operator will take during the duration of the extension to:

(A) Maintain the lowest concentration of diesel particulate; and

(B) Minimize the exposure of miners to diesel particulate.

(4) The Secretary may approve an application for a special extension only if:

(i) The mine operator files, the application at least 180 days prior to the date the mine must be in full compliance with the limit established by paragraph (b) of this section; and

(ii) The application certifies that the operator has posted one copy of the application, at the mine site for 30 days prior to the date of application, and has provided another copy to the authorized representative of miners.

(5) A mine operator must comply with the terms of any approved application for a special extension, and post a copy of an approved application for a special extension at the mine site for the duration of the special extension period.

(d)(1) Mine operators may permit miners engaged in inspection, maintenance, or repair activities, and only in such activities, with the advance approval of the Secretary under the circumstances and conditions defined in paragraphs (d)(2) through (d)(4) of this section, to work in concentrations of diesel particulate matter exceeding the applicable concentration limit under paragraph (a) or (b) of this section.

(2) The Secretary will only provide advance approval:

(i) For inspection, maintenance or repair activities to be conducted:

(A) In areas where miners work or travel infrequently or for brief periods of time;

(B) In areas where miners otherwise work exclusively inside of enclosed and environmentally controlled cabs, booths and similar structures with filtered breathing air; or

(C) In shafts, inclines, slopes, adits, tunnels and similar workings that the operator designates as return or exhaust air courses and that miners use for access into the mine or egress from the mine;

(ii) When the Secretary determines that it is not feasible to reduce the concentration of dpm in the areas where the inspection, maintenance or repair activities are to be conducted to those otherwise applicable under paragraph (a) or (b) of this section; and

(iii) When the Secretary determines that the mine operator will employ adequate safeguards to minimize the dpm exposure of the miners.

(3) The Secretary's determinations under paragraph (d)(2) of this section will be based on evaluating a plan prepared and submitted by the operator no less than 60 days before the commencement of any inspection, maintenance or repair activities. The mine operator must certify in the plan that one copy of the application has been posted at the mine site for 30 days prior to the date of submission, and another copy has been provided to the authorized representative of miners. The plan must identify, at a minimum, the types of anticipated inspection, maintenance, and repair activities that must be performed for which engineering controls sufficient to comply with the concentration limit are not feasible, the locations where such activities could take place, the concentration of dpm in these locations, the reasons why engineering controls are not feasible, the anticipated frequency and duration of such activities, the anticipated number of miners involved in such activities, and the safeguards that the operator will employ to limit miner exposure to dpm, including, but not limited to the use of respiratory protective equipment. The approved plan must include a program for selection, maintenance, training, fitting, supervision, cleaning and use of personal protective equipment and must meet the minimum requirements established in § 57.5005 (a) and (b).

(4) An advance approval by the Secretary for employees to engage in inspection, maintenance, or repair activities will be valid for no more than one year. A mine operator must comply with the conditions of the approved plan [which was the basis of the approval], and must post a copy of the approved plan at the mine site for the duration of its applicability.

(e) Other than pursuant to the conditions required in paragraphs (c) or (d) of this section, an operator must not

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utilize personal protective equipment to comply with the requirements of either paragraph (a) or paragraph (b) of this section.

(f) An operator must not utilize administrative controls to comply with the requirements of this section.

§ 57.5061 Compliance determinations.

(a) A single sample collected and analyzed by the Secretary in accordance with the requirements of this section shall be an adequate basis for a determination of noncompliance with an applicable limit on the concentration of diesel particulate matter pursuant to § 57.5060.

(b) The Secretary will collect samples of diesel particulate matter by using a respirable dust sampler equipped with a submicrometer impactor and analyze the samples for the amount of total carbon using the method described in NIOSH Analytical Method 5040, except that the Secretary also may use any methods of collection and analysis subsequently determined by NIOSH to provide equal or improved accuracy for the measurement of diesel particulate matter. Copies of the NIOSH 5040 Analytical Method are available by contacting MSHA's, Pittsburgh Safety and Health Technology Center, P.O. Box 18233, Cochrans Mill Road, Pittsburgh, PA 15236.

(c) The Secretary will determine the appropriate sampling strategy for compliance determination, utilizing personal sampling, occupational sampling, and/or area sampling, based on the circumstances of the particular exposure.

§ 57.5062 Diesel particulate matter control plan.

(a) In the event of a violation by the operator of an underground metal or nonmetal mine of the applicable concentration limit established by § 57.5060, the operator, in accordance with the requirements of this section, must—

(1) Establish a diesel particulate matter control plan for the mine if one is not already in effect, or modify the existing diesel particulate matter control plan, and

(2) Demonstrate that the new or modified diesel particulate matter control plan controls the concentration of diesel particulate matter to the applicable concentration limit specified in § 57.5060.

(b) A diesel particulate control plan must describe the controls the operator will utilize to maintain the concentration of diesel particulate matter to the applicable limit specified by § 57.5060. The plan also must include a list of diesel-powered units maintained by the mine operator, information about any unit's emission control device, and the parameters of any other methods used to control the concentration of diesel particulate matter. The operator may consolidate the plan with the ventilation plan required by § 57.8520. The operator must retain a copy of the current diesel particulate matter control plan at the mine site during its duration and for one year thereafter.

(c) An operator must demonstrate plan effectiveness by monitoring, using the measurement method specified by § 57.5061(b), sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine. The operator must retain a copy of each verification sample result at the mine site for five years. The operator monitoring must be in addition to, and not in lieu of, any sampling by the Secretary pursuant to § 57.5061.

(d) The records required by paragraphs (b) and (c) of this section must be available for review upon request by the authorized representative of the Secretary, the authorized representative of the Secretary of Health and Human Services, or the authorized representative of miners. In addition, upon request by the District Manager or the authorized representative of miners, the operator must provide a copy of any records required to be maintained pursuant to paragraph (b) or (c) of this section.

(e)(1) A control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused it to be established, except as provided in paragraph (e)(3) of this section.

(2) A modified control plan established as a result of this section must remain in effect for 3 years from the date of the violation which caused the plan to be modified, except as provided in paragraph (e)(3) of this section.

(3) An operator must modify a diesel particulate matter control plan during its duration as required to reflect changes in mining equipment or circumstances. Upon request from the Secretary, an operator must demonstrate the effectiveness of the modified plan by monitoring, using the measurement method specified by § 57.5061, sufficient to verify that the plan will control the concentration of diesel particulate matter to the applicable limit under conditions that can be reasonably anticipated in the mine.

(f) The Secretary will consider an operator's failure to comply with the provisions of the diesel particulate matter control plan in effect at a mine or to conduct required verification sampling to be a violation of this part without regard for the concentration of diesel particulate matter that may be present at any time.

§ 57.5065 Fueling and idling practices.

(a) Diesel fuel used to power equipment in underground areas must not have a sulfur content greater than 0.05 percent. The operator must retain purchase records that demonstrate compliance with this requirement for one year after the date of purchase.

(b) The operator must only use fuel additives registered by the U.S. Environmental Protection Agency in diesel powered equipment operated in underground areas.

(c) Idling of mobile diesel-powered equipment in underground areas is prohibited except as required for normal mining operations.

§ 57.5066 Maintenance standards.

(a) Any diesel powered equipment operated at any time in underground areas must meet the following maintenance standards:

(1) The operator must maintain any approved engine in approved condition;

(2) The operator must maintain the emission related components of any non-approved engine to manufacturer specifications; and

(3) The operator must maintain any emission or particulate control device installed on the equipment in effective operating condition.

(b)(1) A mine operator must authorize and require each miner operating diesel powered equipment underground to affix a visible and dated tag to the equipment at any time the miner notes any evidence that the equipment may require maintenance in order to comply with the maintenance standards of paragraph (a) of this section.

(2) A mine operator must ensure that any equipment tagged pursuant to this section is promptly examined by a person authorized by the mine operator to maintain diesel equipment, and that the affixed tag not be removed until the examination has been completed.

(3) A mine operator must retain a log of any equipment tagged pursuant to this section. The log must include the date the equipment is tagged, the date the equipment is examined, the name of the person examining the equipment, and any action taken as a result of the examination. The operator must retain the information in the log for one year after the date the tagged equipment was examined.

(c) Persons authorized by a mine operator to maintain diesel equipment covered by paragraph (a) of this section must be qualified, by virtue of training or experience, to ensure that the maintenance standards of paragraph (a) of this section are observed. An operator must retain appropriate evidence of the competence of any person to perform specific maintenance tasks in compliance with those standards for one year after the date of any maintenance, and upon request must provide the documentation to the authorized representative of the Secretary.

§ 57.5067 Engines.

(a) Any diesel engine introduced into an underground area of a mine covered by this part after March 20, 2001, other than an engine in an ambulance or fire fighting equipment which is utilized in accordance with mine fire fighting and evacuation plans, must either:

(1) Have affixed a plate evidencing approval of the engine pursuant to subpart E of Part 7 of this title or pursuant to Part 36 of this title; or

(2) Meet or exceed the applicable particulate matter emission requirements of the Environmental Protection Administration listed in Table 57.5067–1, as follows:

TABLE 57.5067–1

EPA requirement	EPA category	PM limit
40 CFR 86.094–8(a)(1)(i)(A)(2)	light duty vehicle	0.1 g/mile.
40 CFR 86.094–9(a)(1)(i)(A)(2)	light duty truck	0.1 g/mile.
40 CFR 86.094–11(a)(1)(iv)(B)	heavy duty highway engine	0.1 g/bhp-hr.
40 CFR 89.112(a)	nonroad (tier, power range)	varies by power range:
	tier 1 kW<8 (hp<11)	1.0 g/kW-hr (0.75 g/bhp-hr).
	tier 1 8≤kW<19 (11≤hp<25)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 1 19≤kW<37 (25≤hp<50)	0.80 g/kW-hr (0.60 g/bhp-hr).
	tier 2 37≤kW<75 (50≤hp<100)	0.40 g/kW-hr (0.30 g/bhp-hr).
	tier 2 75≤kW<130 (100≤hp<175)	0.30 g/kW-hr (0.22 g/bhp-hr).
	tier 1 130≤kW<225 (175≤hp<300)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 225≤kW<450 (300≤hp<600)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 450≤kW<560 (600≤hp<750)	0.54 g/kW-hr (0.40 g/bhp-hr).
	tier 1 kW≥560 (hp≥750)	0.54 g/kW-hr (0.40 g/bhp-hr).

Notes:
"g" means grams.
"hp" means horsepower.
"g/bhp-hr" means grams/brake horsepower-hour.
"kW" means kilowatt.
"g/kW-hr" means grams/kilowatt-hour.

(b) For purposes of paragraph (a):

(1) The term "introduced" means any engine added to the underground inventory of engines of the mine in question, including:

(i) An engine in newly purchased equipment;

(ii) An engine in used equipment brought into the mine; and

(iii) A replacement engine that has a different serial number than the engine it is replacing; but

(2) The term "introduced" does not include engines that were previously part of the mine inventory and rebuilt.

§ 57.5070 Miner training.

(a) Mine operators must provide annual training to all miners at a mine covered by this part who can reasonably be expected to be exposed to diesel emissions on that property. The training must include—

(1) The health risks associated with exposure to diesel particulate matter;

(2) The methods used in the mine to control diesel particulate matter concentrations;

(3) Identification of the personnel responsible for maintaining those controls; and

(4) Actions miners must take to ensure the controls operate as intended.

(b) An operator must retain a record at the mine site of the training required by this section for one year after completion of the training.

§ 57.5071 Environmental monitoring.

(a) Mine operators must monitor as often as necessary to effectively determine, under conditions that can be reasonably anticipated in the mine—

(1) Whether the concentration of diesel particulate matter in any area of the mine where miners normally work or travel exceeds the applicable limit specified in § 57.5060; and

(2) The average full shift airborne concentration of diesel particulate matter at any position or on any person designated by the Secretary.

(b) The mine operator must provide affected miners and their representatives with an opportunity to observe exposure monitoring required by this section. Mine operators must give prior notice to affected miners and their representatives of the date and time of intended monitoring.

(c) If any monitoring performed under this section indicates that the applicable concentration limit established by § 57.5060 has been exceeded, an operator must promptly post notice of the corrective action being taken, initiate corrective action by the next work shift, and promptly complete such corrective action.

(d)(1) The results of monitoring for diesel particulate matter, including any results received by a mine operator from sampling performed by the Secretary, must be posted on the mine bulletin board within 15 days of receipt and must remain posted for 30 days. The operator must provide a copy of the results to the authorized representative of miners.

(2) The mine operator must retain for five years (from the date of sampling), the results of any samples the operator collected as a result of monitoring under this section, and information about the sampling method used for obtaining the samples.

§ 57.5075 Diesel particulate records.

(a) The table entitled "Diesel Particulate Recordkeeping Requirements" lists the records the operator must retain pursuant to §§ 57.5060 through 57.5071, and the duration for which particular records need to be retained. The table follows:

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DIESEL PARTICULATE RECORDKEEPING REQUIREMENTS

Record	Section reference	Retention time
1. Approved application for extension of time to comply with final concentration limit.	§57.5060(c)	1 year beyond duration of extension.
2. Approved plan for miners to perform inspection, maintenance or repair actions in areas exceeding the concentration limit.	§57.5060(d)	For duration of plan.
3. Control plan	§57.5062(b)	1 year beyond duration of plan.
4. Compliance plan verification sample results	§57.5062(c)	5 years from sample date.
5. Purchase records noting sulfur content of diesel fuel.	§57.5065(a)	1 year beyond date of purchase.
6. Maintenance log	§57.5066(b)	1 year after date any equipment is tagged.
7. Evidence of competence to perform maintenance.	§57.5066(c)	1 year after date maintenance performed.
8. Annual training provided to potentially exposed miners.	§57.5070(b)	1 year beyond date training completed.
9. Sampling method used to effectively evaluate mine particulate concentration, and sample results.	§57.5071(d)	5 years from sample date.

(b)(1) Any record listed in this section which is required to be retained at the mine site may, notwithstanding such requirement, be retained elsewhere if the mine operator can immediately access the record from the mine site by electronic transmission.

(2) Upon request from an authorized representative of the Secretary of Labor, the Secretary of Health and Human Services, or from the authorized representative of miners, mine operators must promptly provide access to any record listed in the table in this section.

(3) An operator must provide access to a miner, former miner, or, with the miner's or former miner's written consent, a personal representative of a miner, to any record required to be maintained pursuant to § 57.5071 to the extent the information pertains to the miner or former miner. The operator must provide the first copy of a requested record at no cost, and any additional copies at reasonable cost.

(4) Whenever an operator ceases to do business, that operator must transfer all records required to be maintained by this part, or a copy thereof, to any successor operator who must maintain them for the required period.

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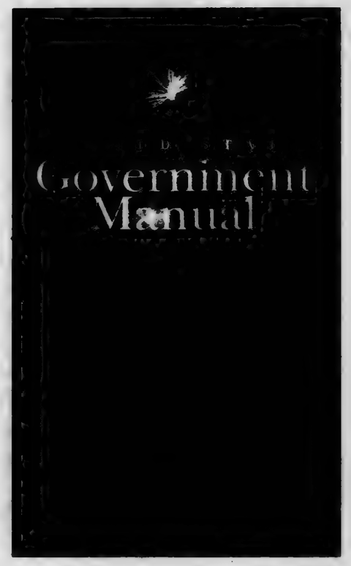
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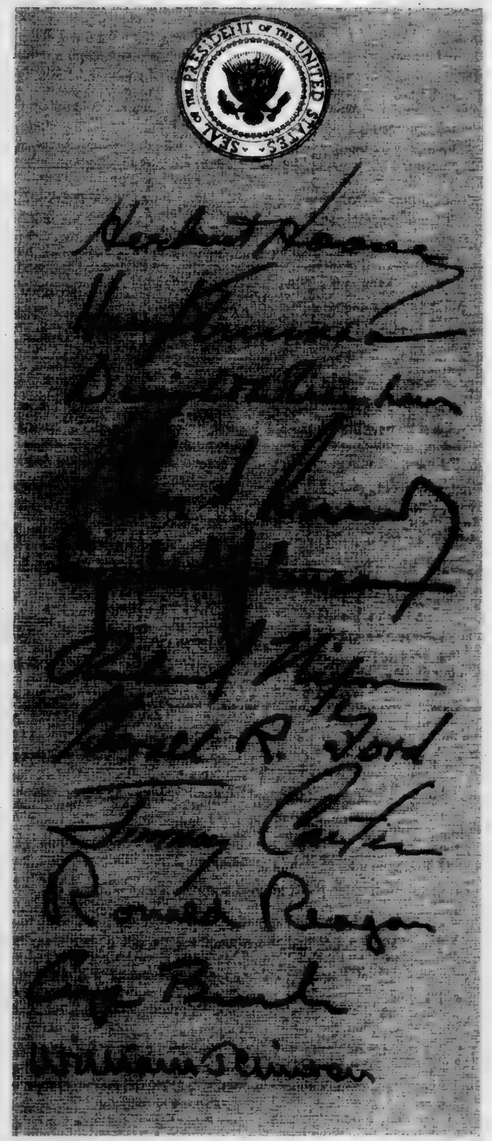
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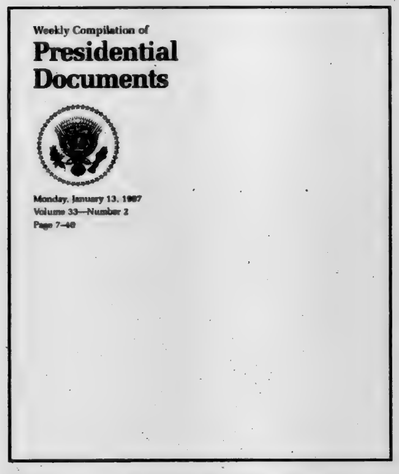
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Part III

Department of Housing and Urban Development

24 CFR Part 221
Discontinuation of the Section 221(d)(2) Mortgage Insurance Program; Final Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 221

[Docket No. FR-4588-F-02]

RIN 2502-AH50

Discontinuation of the Section 221(d)(2) Mortgage Insurance Program

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule discontinues HUD's section 221(d)(2) mortgage insurance program. The section 221(d)(2) program is rarely used by homebuyers, primarily due to its low mortgage limits. Accordingly, HUD will no longer enter into new contracts for mortgage insurance under the program. The final rule removes those provisions of the section 221(d)(2) regulations concerning eligibility for participation in the program, and replaces them with a savings clause. The rule, however, retains those regulatory provisions regarding the contract rights and servicing responsibilities for existing program participants. This final rule follows publication of a September 28, 2000 proposed rule. There were no public comments on the proposed rule, and HUD is adopting the proposed regulatory amendments without change.

DATES: *Effective Date:* February 20, 2001.

FOR FURTHER INFORMATION CONTACT: Vance T. Morris, Director, Office of Single Family Program Development, Office of Insured Single Family Housing, Room 9266, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–8000; telephone (202) 708–2121 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

Section 221(d)(2) of the National Housing Act (12 U.S.C. 1715l(d)(2)), authorizes HUD to insure private lenders against loss from default on mortgage loans made to finance the purchase, construction, or rehabilitation of low-cost, one- to four-family homes. HUD's regulations implementing the section 221(d)(2) program are located in 24 CFR part 221.

On September 28, 2000 (65 FR 58338), HUD published a proposed rule to discontinue the section 221(d)(2) mortgage insurance program. The program is rarely used by homebuyers, primarily due to its low mortgage limits. Moreover, the section 221(d)(2) program provides few homeownership opportunities not already made available by other HUD mortgage insurance programs, primarily the single family home mortgage insurance programs authorized by section 203 of the National Housing Act (12 U.S.C. 1709) (implemented by HUD in 24 CFR part 203), and the condominium mortgage insurance program authorized by section 234 of the National Housing Act (12 U.S.C. 1715y) (implemented by HUD in 24 CFR part 234). For these reasons, HUD has decided to discontinue the section 221(d)(2) program.

II. This Final Rule

This final rule adopts the policies and procedures of the September 28, 2000 proposed rule. The public comment period for the proposed rule closed on November 27, 2000. By close of business on that date, HUD had not received any public comments on the proposed rule. Accordingly, this final rule adopts the proposed regulatory amendments without change.

The final rule removes HUD's regulations establishing the eligibility requirements for section 221(d)(2) mortgage insurance in subpart A of 24 CFR part 221. A savings clause is retained in subpart A of the part 221 regulations, which provides that the authority to insure section 221(d)(2) mortgages is terminated, except that HUD will endorse for insurance validly processed mortgages under direct endorsement where the credit worksheet was signed by the mortgagee's underwriter before the effective date of the final rule. The savings clause also provides that subpart A, as it existed immediately before the termination date, will continue to govern the rights and obligations of insured mortgage lenders, mortgagors, and HUD with respect to section 221(d)(2) single family loans insured before the effective date of the final rule, and to the aforementioned direct endorsement loans.

III. Findings and Certifications

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made at the proposed rule stage, in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4223). That finding remains applicable to this final rule and is available for public inspection between the hours of 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC.

Regulatory Flexibility Act

The Secretary has reviewed this final rule before publication, and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this final rule will not have a significant economic impact on a substantial number of small entities. As noted above, the section 221(d)(2) program is rarely used by homebuyers. Mortgage lenders eligible to participate in the section 221(d)(2) program are also generally eligible to participate in other, alternative, FHA single family mortgage insurance programs that are preferred by homebuyers (such as the section 203 and section 234(c) programs). Accordingly, HUD's decision to discontinue the section 221(d)(2) program is not anticipated to have a significant economic impact on a substantial number of mortgage lenders participating in these FHA programs.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule would not have federalism implications and would not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule would not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance program number applicable to 24 CFR part 221 is 14.120: Mortgage Insurance—Homes for Low/Moderate Income Families.

List of Subjects in 24 CFR Part 221

Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, for the reasons described in the preamble, HUD amends 24 CFR part 221 to read as follows:

PART 221—LOW COST AND MODERATE INCOME MORTGAGE INSURANCE

1. The authority citation for part 221 is revised to read as follows:

Authority: 12 U.S.C. 1715b, 1715l; 42 U.S.C. 3535(d).

2. Subpart A is revised to read as follows:

Subpart A—Eligibility Requirements—Low Cost Homes—Savings Clause

§ 221.1 Savings clause.

(a) Effective February 20, 2001, the authority to insure mortgages under section 221(d)(2) of the National Housing Act (12 U.S.C. 1715l(d)(2)) for low cost and moderate income mortgage insurance is terminated, except that HUD will endorse for insurance validly processed mortgages under direct endorsement where the credit worksheet was signed by the mortgagee's underwriter before February 20, 2001.

(b) Subpart A of this part, as it existed immediately before February 20, 2001, will continue to govern the rights and obligations of insured mortgage lenders, mortgagors, and HUD with respect to section 221(d)(2) single family loans insured before February 20, 2001, or in accordance with paragraph (a) of this section, pursuant to the applicable provisions of this subpart.

Dated: January 9, 2001.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 01–1534 Filed 1–18–01; 8:45 am]

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Part IV

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1904 and 1952

Occupational Injury and Illness Recording and Reporting Requirements; Final Rule

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1904 and 1952

[Docket No. R–02]

RIN 1218–AB24

Occupational Injury and Illness Recording and Reporting Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is revising its rule addressing the recording and reporting of occupational injuries and illnesses (29 CFR parts 1904 and 1952), including the forms employers use to record those injuries and illnesses. The revisions to the final rule will produce more useful injury and illness records, collect better information about the incidence of occupational injuries and illnesses on a national basis, promote improved employee awareness and involvement in the recording and reporting of job-related injuries and illnesses, simplify the injury and illness recordkeeping system for employers, and permit increased use of computers and telecommunications technology for OSHA recordkeeping purposes.

This rulemaking completes a larger overall effort to revise Part 1904 of Title 29 of the Code of Federal Regulations. Two sections of Part 1904 have already been revised in earlier rulemakings. A rule titled Reporting fatalities and multiple hospitalization incidents to OSHA, became effective May 2, 1994 and has been incorporated into this final rule as § 1904.39. A second rule entitled Annual OSHA injury and illness survey of ten or more employers became effective on March 13, 1997 and has been incorporated into this final rule as § 1904.41.

The final rule being published today also revises 29 CFR 1952.4, Injury and Illness Recording and Reporting Requirements, which prescribes the recordkeeping and reporting requirements for States that have an occupational safety and health program approved by OSHA under § 18 of the Occupational Safety and Health Act (the "Act" or "OSH Act").

DATES: This final rule becomes effective January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Jim Maddux, Occupational Safety and Health Administration, U.S. Department of Labor, Directorate of Safety Standards Programs, Room N–3609, 200 Constitution Ave., NW, Washington, DC 20210. Telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Table of Contents

The following is a table of contents for this preamble. The regulatory text and appendices follow the preamble. Documents and testimony submitted to the docket (Docket R–02) of this rulemaking are cited throughout this preamble by the number that has been assigned to each such docket entry, preceded by the abbreviation "Ex.," for exhibit.

II. The Occupational Safety and Health Act and the Functions of the Recordkeeping System
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II. The Occupational Safety and Health Act and the Functions of the Recordkeeping System

Statutory Background

The Occupational Safety and Health Act (the "OSH Act" or "Act") requires the Secretary of Labor to adopt regulations pertaining to two areas of recordkeeping. First, section 8(c)(2) of the Act requires the Secretary to issue regulations requiring employers to "maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job."

Section 8(c)(1) of the Act also authorizes the Secretary of Labor to develop regulations requiring employers to keep and maintain records regarding the causes and prevention of occupational injuries and illnesses. Section (2)(b)(12) of the Act states Congress' findings with regard to achieving the goals of the Act and specifically notes that appropriate reporting procedures will help achieve the objectives of the Act.

Second, section 24(a) of the Act requires the Secretary to develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics. This section also directs the Secretary to "compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job."

After passage of the Act, OSHA issued the required occupational injury and illness recording and reporting regulations as 29 CFR part 1904. Since 1971, OSHA and the Bureau of Labor Statistics (BLS) have operated the injury and illness recordkeeping system as a cooperative effort. Under a Memorandum of Understanding dated July 11, 1990 (Ex. 6), BLS is now responsible for conducting the nationwide statistical compilation of occupational illnesses and injuries (called the Annual Survey of Occupational Injuries and Illnesses), while OSHA administers the regulatory components of the recordkeeping system.

Functions of the Recordkeeping System

This revision of the Agency's recordkeeping rule is firmly rooted in the statutory requirements of the OSH Act (see the Legal Authority section of the preamble, below). OSHA's reasons for revising this regulation to better achieve the goals of the Act are discussed in the following paragraphs.

Occupational injury and illness records have several distinct functions or uses. One use is to provide information to employers whose employees are being injured or made ill by hazards in their workplace. The information in OSHA records makes employers more aware of the kinds of injuries and illnesses occurring in the workplace and the hazards that cause or contribute to them. When employers analyze and review the information in their records, they can identify and correct hazardous workplace conditions on their own. Injury and illness records are also an essential tool to help employers manage their company safety and health programs effectively.

Employees who have information about the occupational injuries and illnesses occurring in their workplace are also better informed about the hazards they face. They are therefore more likely to follow safe work practices and to report workplace hazards to their employers. When employees are aware of workplace hazards and participate in the identification and control of those hazards, the overall level of safety and health in the workplace improves.

The records required by the recordkeeping rule are also an important source of information for OSHA. During the initial stages of an inspection, an OSHA representative reviews the injury and illness data for the establishment as an aid to focusing the inspection effort on the safety and health hazards suggested by the injury and illness records. OSHA also uses establishment-specific injury and illness information to help target its intervention efforts on the most dangerous worksites and the worst safety and health hazards. Injury and illness statistics help OSHA identify the scope of occupational safety and health problems and decide whether regulatory intervention, compliance assistance, or other measures are warranted.

Finally, the injury and illness records required by the OSHA recordkeeping rule are the source of the BLS-generated national statistics on workplace injuries and illnesses, as well as on the source, nature, and type of these injuries and illnesses. To obtain the data to develop national statistics, the BLS and participating State agencies conduct an annual survey of employers in almost all sectors of private industry. The BLS makes the aggregate survey results available both for research purposes and for public information. The BLS has published occupational safety and health statistics since 1971. These statistics chart the magnitude and nature of the occupational injury and illness problem across the country. Congress, OSHA, and safety and health policy makers in Federal, State and local governments use the BLS statistics to make decisions concerning safety and health legislation, programs, and standards. Employers and employees use them to compare their own injury and illness experience with the performance of other establishments within their industry and in other industries.

III. Overview of the Former OSHA Recordkeeping System

The OSH Act authorizes OSHA to require employers to keep records and to report the recorded information to OSHA. However, the Agency only requires some employers to create and maintain occupational injury and illness records. Those employers who are required to keep records must report on those records only when the government specifically asks for the information, which occurs exclusively under limited circumstances that are described below.

Employers covered by the recordkeeping regulations must keep records of the occupational injuries and illnesses that occur among their employees. To do so, covered employers must complete two forms. First, the employer must maintain a summary form (OSHA Form 200, commonly referred to as the "OSHA Log," or an equivalent form) that lists each injury and illness that occurred in each establishment during the year. For each case on the Log, the employer also prepares a supplementary record (OSHA Form 101, or an equivalent), that provides additional details about the injury or illness. Most employers use a workers' compensation First Report of Injury in place of the 101 form. The Log is available to employees, former employees, and their representatives. A Summary of the Log is posted in the workplace from February 1 to March 1 of the year following the year to which the records pertain. The Log and summary, as well as the more detailed supplementary record, are available to OSHA inspectors who visit the establishment.

The employer is only obligated to record work-related injuries and illnesses that meet one or more of certain recording criteria. In accordance with the OSH Act, OSHA does not require employers to record cases that only involve "minor" injuries or illnesses, *i.e.*, do not involve death, loss of consciousness, days away from work, restriction of work or motion, transfer to another job, medical treatment other than first aid, or diagnosis of a significant injury or illness by a physician or other licensed health care professional.

The language of the OSH Act also limits the recording requirements to injuries or illnesses that are "work-related." The Act uses, but does not define, this term. OSHA has interpreted the Act to mean that injuries and illnesses are work-related if events or exposures at work either caused or contributed to the problem. Work-related injuries or illnesses may (1) occur at the employer's premises, or (2) occur off the employer's premises when the employee was engaged in a work activity or was present as a condition of employment. Certain limited exceptions to this overriding geographic presumption were permitted by the former rule.

Although the Act gives OSHA the authority to require all employers covered by the OSH Act to keep records, two major classes of employers are not currently required regularly to keep records of the injuries and illnesses of their employees: employers with no more than 10 employees at any time during the previous calendar year, and employers in certain industries in the retail and service sectors.

Although the Act authorizes OSHA to require employers to submit reports on any or all injuries and illnesses occurring to their employees, there are currently only three situations where OSHA requires an employer to report occupational injury and illness records to the government. First, an employer must report to OSHA within eight hours any case involving a work-related fatality or the in-patient hospitalization of three or more employees as the result of a work-related incident (former 29 CFR 1904.8, final rule 1904.39). These provisions were revised in 1994 to reduce the reporting time for these incidents from 48 hours to 8 hours and reduce the number of hospitalized employees triggering a report from five workers to three workers (59 FR 15594 (April 1, 1994)). Changes made to this section in 1994 have largely been carried forward in the final rule being published today.

Second, an employer who receives an annual survey form from the Bureau of Labor Statistics must submit its annual injury and illness data to the BLS. The BLS conducts an annual survey of occupational injuries and illnesses under 29 CFR 1904.20–22 of the former rule (1904.41 of the final rule). Using a stratified sample, the BLS sends survey forms to randomly selected employers, including employers who, under Part 1904, would otherwise be exempt from the duty to keep the OSHA Log and Summary. These otherwise exempt employers are required to keep an annual record of the injuries and illnesses occurring among their employees that are recordable under Part 1904 if the BLS contacts them as part of the annual survey. At the end of the year, these employers must send the results of recordkeeping to the BLS. The BLS then tabulates the data and uses them to prepare national statistics on occupational injuries and illnesses. The

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BLS survey thus ensures that the injury and illness experience of employers otherwise exempted from the requirement to keep OSHA records—such as employers with 10 or fewer employees in the previous year and employers in certain Standard Industrial Classification (SIC) codes—is reflected in the national statistics. In accordance with its statistical confidentiality policy, the BLS does not make public the identities of individual employers.

Finally, OSHA may require employers to send occupational injury and illness data directly to OSHA under a regulation issued in 1997. That section of this regulation is entitled Annual OSHA Injury and Illness Survey of Ten or More Employers. It allows OSHA or the National Institute for Occupational Safety and Health (NIOSH) to collect data directly from employers. This section was published in the **Federal Register** on February 11, 1997 (62 FR 6434) and became effective on March 13, 1997. It has been included in this final rule as section 1904.41 without substantive change; however, this section has been rewritten in plain language for consistency with the remainder of Part 1904.

IV. OSHA's Reasons for Revising the Recordkeeping Rule

OSHA had several interrelated reasons for revising its recordkeeping rule. The overarching goal of this rulemaking has been to improve the quality of workplace injury and illness records. The records have several important purposes, and higher quality records will better serve those purposes. OSHA also believes that an improved recordkeeping system will raise employer awareness of workplace hazards and help employers and employees use and analyze these records more effectively. In revising its recordkeeping rule, the Agency also hopes to reduce underreporting and to remove obstacles to complete and accurate reporting by employers and employees.

A major goal of the revision has been to make the system simpler and easier to use and understand and to update the data on which the system is based. For example, OSHA has updated the list of partially exempt industries to reflect the most recent data available. The revisions to the final rule will also create more consistent statistics from employer to employer. Further, by providing more details about the system in the regulation itself and writing the rule in plain language, fewer unintentional errors will be made and the records will be more consistent. More consistent records will improve the quality of analyses comparing the injury and illness experience of establishments and companies with industry and national averages and of analyses looking for trends over several years.

Another objective of the rulemaking has been to lessen the recordkeeping burden on employers, reduce unnecessary paperwork, and enhance the cost-effectiveness of the rule. The final rule achieves this objective in several ways. It updates the partially exempt industry list, reduces the requirement to keep track of lengthy employee absences and work restrictions caused by work-related injuries and illnesses and, above all, greatly simplifies the forms, regulatory requirements, and instructions to make the system easier for employers and employees to manage and use.

In this rulemaking, OSHA has also addressed some of the objections employers have raised in the years since OSHA first implemented the injury and illness recordkeeping system. For example, the final rule includes a number of changes that will allow employers to exclude certain cases, eliminate the recording of minor illness cases, and allow employers maximum flexibility to use computer equipment to meet their OSHA recordkeeping obligations.

OSHA is also complying with the President's Executive Memorandum on plain language (issued June 1, 1998) by writing the rule's requirements in plain language and using the question-and-answer format to speak directly to the user. OSHA believes that employers, employees and others who compile and maintain OSHA records will find that the plain language of the final rule helps compliance and understanding.

Many of OSHA's goals and objectives in developing this final rule work together and reinforce each other. For example, writing the regulation in plain language makes the rule easier for employers and employees to use and improves the quality of the records by reducing the number of errors caused by ambiguity. In some cases, however, one objective had to be balanced against another. For example, the enhanced certification requirements in the final rule will improve the quality of the records, but they also slightly increase employer burden. Nevertheless, OSHA is confident that the final rule generally achieves the Agency's goals and objectives for this rulemaking and will result in a substantially strengthened and simplified recordkeeping and reporting system.

The Need To Improve the Quality of the Records

The quality of the records OSHA requires employers to keep is of crucial importance for anyone who uses the resulting data. Problems with completeness, accuracy, or consistency can compromise the data and reduce the quality of the decisions made on the basis of those data. Several government studies, as well as OSHA's own enforcement history, have revealed problems with employers' injury and illness recordkeeping practices and with the validity of the data based on those records.

A study conducted by the National Institute for Occupational Safety and Health (NIOSH) between 1981 and 1983 revealed that 25 percent of the 4,185 employers surveyed did not keep OSHA injury and illness records at all, although they were required by regulation to do so (Ex. 15:407–P).

A study of 192 employers in Massachusetts and Missouri conducted by the BLS in 1987 reported that an estimated 10 percent of covered employers did not maintain OSHA records at all, total injuries were underrecorded by approximately 10 percent (even though both overrecording and underrecording were discovered), lost workday injuries were undercounted by 25 percent, and lost workdays were undercounted by nearly 25 percent. Approximately half of the uncounted lost workdays were days of restricted work activity, and the other half were days away from work. Some of the underrecording was due to employers entering lost time cases on their records as no-lost-time cases (Exs. 72–1, 72–2).

Through its inspections of workplaces, OSHA has also discovered that some employers seriously underrecord injuries and illnesses. In cases where the inspector has found evidence that the employer willfully understated the establishment's injury and illness experience, OSHA has levied large penalties and fines under its special citation policy for egregious violations. OSHA has issued 48 egregious injury and illness recordkeeping citations since 1986 (Ex. 74).

As part of the OSHA Data Initiative (ODI), a survey allowing OSHA to collect injury and illness data from employers to direct OSHA's program activities, the Agency conducts Part 1904 records audits of 250 establishments each year. The following table shows the results of the audits conducted to date.

1996 THROUGH 1998 OSHA RECORDKEEPING AUDIT RESULTS*

Error type	Data reference year (percent)		
	1996	1997	1998
Cases not entered on employers Log	13.56	10.49	12.91
Lost workday cases recorded as non-lost workday cases	8.39	6.53	6.21
Non-lost workday cases recorded as lost workday cases	(**)	2.10	1.94
Total major recording errors	21.95	19.11	21.07
Total cases recorded without major errors	78.05	80.89	78.93

* The results were tabulated using unweighted data and should not be used to draw broad conclusions about the recordkeeping universe.
** Data not calculated for 1996.
Source: OSHA Data Initiative Collection Quality Control: Analysis of Audits on 1996–1998 Employer Injury and Illness Recordkeeping.

Explicit Rules Are Needed To Ensure Consistent Recording

When OSHA's recordkeeping regulation was first promulgated in 1971, many industry safety experts were concerned that the regulations and the instructions on the forms did not provide adequate guidance for employers. They requested that the Department of Labor provide additional instructions on employers' recordkeeping obligations and clarify several recordkeeping issues. The BLS responded in 1972 by publishing supplemental instructions to the recordkeeping forms, BLS Report 412, What Every Employer Needs To Know About OSHA Recordkeeping (Ex. 1). These supplemental instructions were designed to help employers by providing detailed information on when and how to record injury and illness cases on the recordkeeping forms. The supplemental instructions clarified numerous aspects of the rule, including the important recordability criteria that outline which injuries and illnesses are work-related and thus recordable. This BLS Report was revised and reissued in 1973, 1975, and 1978.

In response to requests from labor and industry, and after publication in the **Federal Register** and a public comment period, the BLS 412 report series was replaced in April of 1986 by the *Recordkeeping Guidelines For Occupational Injuries And Illnesses* (the *Guidelines*) (Ex. 2). The *Guidelines* contained an expanded question-and-answer format similar to that of the BLS 412 report and provided additional information on the legal basis for the requirements for recordkeeping under Part 1904. The *Guidelines* provided clearer definitions of the types of cases to be recorded and discussed employer recordkeeping obligations in greater detail. The *Guidelines* also introduced a number of exceptions to the general geographic presumption that injuries and illnesses that occurred "on-premises" were work-related to cover situations where the application of the geographic presumption was considered inappropriate. Further, the *Guidelines* updated the lists that distinguished medical treatment from first aid and addressed new recordkeeping issues. The BLS also published a shortened version of the *Guidelines*, entitled A Brief Guide to Recordkeeping Requirements for Occupational Injuries and Illnesses (Ex. 7).

Although the 1986 edition of the *Guidelines* clarified many aspects of the recordkeeping regulation, concerns persisted about the quality and utility of the injury and illness data. In response to inquiries from employers, unions, employees, BLS, and OSHA staff, the Agency issued many letters of interpretation. These letters restated the former rule's regulatory requirements, interpreted the rules as they applied to specific injury and illness cases, and clarified the application of those requirements. A number of these letters of interpretation have been compiled and entered into the docket of this rulemaking (Ex. 70). OSHA has incorporated many of the prior interpretations directly into the implementation questions and answers in the regulatory text of the final rule, so that all affected employers will be aware of these provisions.

External Critiques of the Former Recordkeeping System

Because of concern about the injury and illness records and the statistics derived from them, several organizations outside OSHA have studied the recordkeeping system. The National Research Council (NRC), the Keystone Center, and the General Accounting Office (GAO) each published reports that evaluated the recordkeeping system and made recommendations for improvements. OSHA has relied on these studies extensively in developing this final rule.

The NRC Report

In response to concern over the underreporting of occupational injuries and illnesses and inconsistencies in the national data collected by the BLS, Congress appropriated funds in 1984 for the BLS to conduct a quality assurance study of its Annual Survey of Occupational Injuries and Illnesses. The BLS asked the National Research Council (NRC) to convene an expert panel to analyze the validity of employer records and the BLS annual survey, to address any problems related to determining and reporting occupational diseases, and to consider other issues related to the collection and use of data on health and safety in the workplace.

In 1987, NRC issued its report, Counting Injuries and Illnesses in the Workplace: Proposals for a Better System (Ex. 4). The report contained 24 specific recommendations (Ex. 4, Ch. 8). In sum, the NRC panel recommended that BLS take the following steps to improve the recordkeeping system: (1) Modify the BLS Annual Survey to provide more information about the injuries and illnesses recorded; (2) discontinue the Supplementary Data System, replace it with a grant program for States and individual researchers, and develop criteria for the detail and quality of the data collected by the replacement system; (3) conduct an ongoing quality assurance program for the Annual Survey to identify underreporting by comparing the information on employers' logs with data from independent sources; (4) implement a system of surveillance for occupational disease, including the collection of data on exposure to workplace hazards; (5) improve the collection of national occupational fatality data; (6) implement an administrative data system that would allow OSHA to obtain individual establishment data to conduct an "effective program for the prevention of

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workplace injuries and illnesses * * *"; and (7) thoroughly evaluate recordkeeping practices in individual establishments, using additional resources requested from Congress for that purpose to avoid diverting resources from OSHA inspections of workplace hazards (Ex. 4, p. 10).

The Keystone Report

In 1987, The Keystone Center convened 46 representatives from labor unions, corporations, the health professions, government agencies, Congressional staff, and academia for a year-long dialogue to discuss occupational injury and illness recordkeeping. Two years later, Keystone issued its final report, Keystone National Policy Dialogue on Work-related Illness and Injury Recordkeeping, 1989 (Ex. 5). The report focused on four major topics: (1) Recordkeeping criteria; (2) OSHA enforcement procedures; (3) injury and illness data systems; and (4) occupational illnesses. The Keystone report recommended that: (1) OSHA and the BLS should revise various aspects of the recording criteria; (2) OSHA should use injury and illness data to target enforcement efforts; (3) the BLS should revise the *Guidelines* to make them easily and uniformly understood; (4) the BLS should develop a national system to collect and disseminate occupational injury and illness information; and (5) OSHA and the BLS should broaden the type of information collected concerning occupational illness and make the information available to employees and government agencies for appropriate purposes such as research and study.

The General Accounting Office (GAO) Study

An August 1990 report by the GAO, Options for Improving Safety and Health in the Workplace (Ex. 3), discussed the importance of employer injury and illness records. The GAO noted that these records have several major uses. They help employers, employees and others understand the nature and extent of occupational safety and health problems. They help employers and employees identify safety and health problems in their workplaces so that they can correct the problems. They also enable OSHA to conduct research, evaluate programs, allocate resources, and set and enforce standards. The report focused on the use of the records in OSHA enforcement, particularly in targeting industries and worksites for inspections and determining the scope of inspections.

The GAO report found that there was "possibly significant injury and illness underrecording and subsequent underreporting" (Ex. 3, p. 3). The GAO report gave three main reasons for inaccurate recording and reporting: (1) Employers intentionally underrecord injuries and illnesses in response to OSHA inspection policies or management safety competitions; (2) employers unintentionally underrecord injuries and illnesses because they do not understand the recording and reporting system; and (3) employers record injuries and illnesses inaccurately because they do not place a high priority on recordkeeping and do not supervise their recordkeepers properly. The GAO report noted that OSHA's revised enforcement procedures, which included increasing its fines for recordkeeping violations and modifying its records-review procedures, would likely help to improve the accuracy of recordkeeping. The GAO recommended that the Department of Labor study the accuracy of employers' records using independent data sources, evaluate how well employers understand the revised *Guidelines*, and audit employers' records in selected enforcement activities.

OSHA's Strategy for Improving the Quality of Records

OSHA has developed a four-part strategy to improve the quality of the injury and illness records maintained by employers. The first component is to provide information, outreach and training to employers to make them more aware of the recordkeeping requirements, thereby improving their compliance with these requirements. For example, information on injury and illness recordkeeping is included in many of OSHA's publications and pamphlets, on the OSHA CD–ROM, and on OSHA's Internet site. OSHA personnel answer thousands of recordkeeping questions each year in response to phone calls and letters. OSHA also trains employers at the OSHA Training Institute in recordkeeping procedures and provides speakers on this topic for numerous safety and health events.

The second component is improved enforcement of the recordkeeping requirements. OSHA continues to review employer records during many of its workplace inspections. OSHA also audits the records of some employers who submit data to OSHA under former section 1904.17 (recodified as section 1904.41 Requests from OSHA for Data in the final rule). Although OSHA does not issue citations for minor reporting and recording violations, the Agency does cite and fine employers when it encounters serious or willful injury and illness recordkeeping problems.

The third component of OSHA's overall plan is this revision of the injury and illness recordkeeping rule. The revised final rule will streamline the recordkeeping system by simplifying the forms and the logic used to record an individual case. It will also consolidate the instructions that were formerly contained in the rule itself, in the *Guidelines*, and in many interpretative letters and memoranda. In addition, the final rule will improve the quality of the injury and illness records by changing several requirements to ensure that data are entered correctly. OSHA has simplified and streamlined the recordkeeping forms and processes to reduce errors. Other changes include: (1) Simplifying and clarifying the definitions of terms such as "medical treatment," "first aid," and "restricted work" to reduce recording errors; (2) providing specific recordkeeping guidance for specific types of injuries and illnesses; (3) including a detailed discussion of the process of determining whether an injury or illness is work-related; (4) giving employees greater involvement by improving their access to records and providing a longer posting period for the annual summary; (5) requiring higher level management officials to certify the records; (6) adding a falsification/penalty statement to the Summary; (7) adding a disclaimer to the Log to clarify that an employer who records an injury or illness is not admitting fault, negligence or liability for workers' compensation or insurance purposes; and (8) requiring the employer to establish a process for employees to report injuries and illnesses and to tell employees about it, and explicitly prohibiting the employer from discriminating against employees who report injuries and illnesses.

V. The Present Rulemaking

In 1995, the Keystone Center reassembled a group of business, labor, and government representatives to discuss draft proposed changes to the recordkeeping rule. OSHA shared its draft proposed revision of the rule with the participants and the public. The draft was also reprinted in several national safety and health publications. Written comments generated by the on-going dialogue were used to help develop the proposal and the final rule, and they are in the rulemaking record (Ex. 12).

OSHA consulted with the Advisory Committee on Construction Safety and Health (ACCSH) before issuing the proposed rule. ACCSH made specific recommendations to OSHA for improving the recordkeeping system as it applied to the construction industry. OSHA gave the ACCSH recommendations careful consideration and responded by modifying the proposal in several areas. The ACCSH recommendations, OSHA's written briefing, and the relevant portions of the transcripts of the October and December 1994 ACCSH meetings are also part of the public record (Ex. 10).

OSHA published a Notice of Proposed Rulemaking (NPRM) on February 2, 1996 (61 FR 23), giving formal notice that the Agency proposed to revise the injury and illness recording and reporting regulations, forms, and supplemental instructions (Ex. 14). The proposed rule reflected a number of suggestions made by the Keystone participants and ACCSH.

The NPRM invited all interested parties to submit comments on the proposal to the docket by May 2, 1996. In response to requests from members of the public, OSHA held two public meetings during the comment period and extended the comment period to July 1, 1996.

OSHA received 449 written comments in response to the NPRM and compiled 1200 pages of transcripts from 60 presentations made at the public meeting. Comments and testimony were received from a broad range of interested parties, including corporations, small business entities, trade associations, unions, state and local governments, professional associations, citizens groups, and safety and health organizations. OSHA has carefully reviewed all of the comments and testimony in its preparation of the final rule.

As described in greater detail below, the final rule revises OSHA's regulation for the recording and reporting of work-related deaths, injuries and illnesses. The rule is part of a comprehensive revision of the OSHA injury and illness recordkeeping system.

The final rule becomes effective, on January 1, 2002. At that time, the following recordkeeping actions will occur:

(1) 29 CFR Part 1904, entitled Recording and Reporting Occupational Injuries and Illnesses, will be in effect.

(2) The State plan provisions in 29 CFR Part 1952, Section 1952.4, entitled Injury and Illness Recording and Reporting Requirements will be in effect.

(3) Three new recordkeeping forms will come into use:

(A) OSHA Form 300, OSHA Injury and Illness Log, and OSHA Form 300 A Summary, which will replace the former OSHA Form 200, Log and Summary of Occupational Injuries and Illnesses; and

(B) OSHA Form 301, OSHA Injury and Illness Incident Record, which will replace the former OSHA Form 101, Supplementary Record of Occupational Injuries and Illnesses.

(4) The following BLS/OSHA publications will be withdrawn:

(A) Recordkeeping Guidelines for Occupational Injuries and Illnesses, 1986; and

(B) A Brief Guide to Recordkeeping Requirements for Occupational Injuries and Illnesses, 1986.

(5) All letters of interpretation regarding the former rule's injury and illness recordkeeping requirements will be withdrawn and removed from the OSHA CD–ROM and the OSHA Internet site.

Provisions Not Carried Forward From the Proposal

Two proposed regulatory sections in OSHA's 1996 Notice of Proposed Rulemaking (NPRM) have not been carried forward in this rulemaking. They are: (1) Falsification of, or failure to keep records or provide reports (Proposed section 1904.16), and (2) Subcontractor records for major construction projects (Proposed section 1904.17).

Paragraphs (a) and (b) of proposed section 1904.16, "Falsification of, or failure to keep records or provide reports," were included in the proposal because they had been included in the former rule. The proposed section included a provision stating that employers may be subject to criminal fines under section 17(g) of the Act for falsifying injury and illness logs and may be cited and fined under sections 9, 10, and 17 of the Act for failure to comply with the recordkeeping rule. Several commenters favored retention of this proposed provision in the final rule because, in their view, OSHA needs strong enforcement of the recordkeeping rule to make sure that employers keep accurate records (see, *e.g.*, Exs. 15: 11, 289). Others, however, objected to the proposed provision (see, *e.g.*, Exs. 15: 22, 335, 375). The views of this latter group were reflected in a comment from the American Petroleum Institute (Ex. 15: 375), which urged OSHA to delete this section from the rule in its entirety because nothing like it is found in any other OSHA regulation or standard. In the final rule, OSHA has decided that this section is not needed to enforce the final rule, and when need be, to issue citations and levy penalties.

The Keystone report recommended, and OSHA proposed, to require construction employers to maintain "site logs," or comprehensive injury and illness records, for major construction projects. The Keystone report noted that construction sites are normally composed of multiple contractors and subcontractors, each of whom may be present at the site for a relatively short period of time, and that no records of the safety and health experience of the site are readily available, either to OSHA or to employers and employees.

In an attempt to address this problem, the proposed provision would have required site-controlling employers in the construction industry to maintain a separate record reflecting the overall injury and illness experience of employees working for sub-contract construction firms for any construction site having an initial construction contract value exceeding $1,000,000. The site-controlling employer would thus have been required to record the injuries and illnesses of subcontractor employees who were employed by construction employers with 11 or more employees working at the site at any time during the previous calendar year.

Many commenters strongly favored the addition of a construction site log provision to the final rule (see, *e.g.*, Exs. 20; 29; 35; 36; 45; 15: 48, 110, 113, 129, 136, 137, 141, 181, 224, 266, 278, 310, 350, 359, 369, 375, 394, 407, 413, 415, 418, 425, 438, 440). Several of these commenters urged OSHA to expand this "multi-employer" log concept to employers in other industries (see, *e.g.*, Exs. 35; 15: 48, 113, 129, 369, 415, 418, 438). For example, the AFL–CIO (Ex. 15: 418) encouraged OSHA to "[e]xpand this recommendation to all industries. As the Agency is well aware, safety and health problems related to multi-employer worksites and contract work are a major concern in many industries beyond construction. Many of the major chemical explosions and fatalities at steel mills, power plants and paper mills have been related to contract work. With more and more businesses contracting out services for on-site activities, the safety and health concern associated with these practices is growing."

Other commenters argued that the proposed site log provisions should be expanded to include injuries and illnesses to construction employees working for employers who would otherwise be exempt from OSHA recordkeeping requirements because they employ fewer than 11 workers (see, *e.g.*, Exs. 20; 15: 350, 359, 369, 407, 425). Two of these commenters recommended adding a requirement to the final rule requiring the site-controlling employer to assist smaller

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employers with their records (Exs. 15: 350, 359).

Several commenters recommended adding provisions to the final rule that would provide greater access to the construction site log by employees (see, *e.g.*, Exs. 15: 129, 310, 394) and by other employers (see, *e.g.*, Ex. 15: 310). Others recommended that OSHA include in the final rule a requirement for the site-controlling employer to collect the number of hours worked by each subcontractor to make it easier to calculate each subcontractor's injury and illness rates (see, *e.g.*, Exs. 15: 310, 369, 394), and some commenters recommended that the final rule contain a requirement for subcontractors to report work-related injuries and illnesses to the site-controlling employer (see, *e.g.*, Exs. 15: 359, 369, 440).

The Building and Construction Trades Department (BCTD), AFL–CIO discussed many of these issues while commenting in favor of site logs:

> On the project level, the fragmentation of employers on construction sites makes it impossible to assess fully safety and health on a particular project. Since the origins of OSHA, injury and illness recordkeeping has been the responsibility of each individual employer. Nevertheless, the hazards of construction activity are shared by employees across the site, and are not specific to a single employer. Employees are often injured or made ill by circumstances that are not under their own employer's full control. The balkanization of recordkeeping contributes to the failure of full and complete communication in construction.
>
> What is needed, at a national and the project level, is a way to record and count the injuries and illnesses that occur on specific projects. We need to know about illnesses and injuries that are associated with distinct types of construction activity, with the various phases of construction, and with the methods, materials, and hazards that are common to those types of work. Furthermore, we need to develop a measure of injury and illness that spans employers, to get a picture of the aggregate outcomes affecting all actors on a common site. Only with such a tool can the construction industry establish and meet performance benchmarks for safety and health.
>
> Site logs would be useful to all of the actors in the occupational safety and health arena. First, employers would benefit from the collection of this data. General contractors increasingly use safety and health information in selecting their subcontractors, and in evaluating projects. Site logs will give them a new tool for both self-evaluation and the evaluation of other contractors. Similarly, subcontractors are often ignorant of the safety and health performance of other contractors and the general contractor. Site logs will lead to better information for all contractors on the project.
>
> Second, employees will benefit from site logs. The site log will focus employers' attentions upon the risks and hazards that are encountered across the worksite. By concretely illustrating that hazards are everyone's problems, the site log will prompt employers and employees to minimize those hazards and to maximize site safety and health.
>
> Third, owners will benefit from site logs. Today, many owners are selecting contractors on the basis of the contractors' rates for lost work days and total recordables. In many cases, these rates are a poor measure for the owner's purpose. An owner's typical concern is with how well a general contractor manages safety and health on the entire site, not with how many injuries and illnesses occurred within that contractor's own workforce. Site logs can be used to measure the management performance of the general contractor, and will greatly assist the owners in their quest for construction safety.
>
> Finally, OSHA will find the site logs to be enormously useful in its efforts to become a "data-driven" agency. First, a project-centric focus will allow OSHA to focus its enforcement and consultation resources. Site logs will be useful to OSHA in scheduling inspections during the phases of construction which appear, through this data, to present the most risks, and in focusing its inspections at construction sites, since the recent illness and injury history of the entire site can be assayed by examining a single document. By the same token, the information revealed by the logs will assist OSHA in reaching out to employers to provide consultative services. Site specific data will also aid OSHA in developing safety and health standards that are appropriately tailored to the risks and hazards of specific types of construction.
>
> The BCTD is convinced that private actors will use site logs to improve safety and health performance. If OSHA establishes a requirement that site logs be kept, the private marketplace will use this new tool to the betterment of employee safety and health (Ex. 15: 394).

Other commenters opposed the addition of a site log provision to the final rule (see, *e.g.*, Exs. 43; 51; 15: 9, 17, 21, 38, 40, 43, 61, 67, 74, 77, 97, 111, 116, 119, 121, 126, 151, 155, 163, 170, 194, 195, 204, 213, 235, 242, 256, 260, 262, 263, 265, 269, 270, 281, 294, 298, 304, 305, 312, 314, 341, 342, 351, 356, 364, 377, 389, 395, 397, 401, 406, 412, 423, 433, 437, 443, 441). The most common argument presented by these commenters was that records should only be kept by the employer, and that one employer should not keep records for another employer's employees (see, *e.g.*, Exs. 15: 9, 116, 126, 163, 195, 204, 260, 262, 265, 281, 294, 304, 312, 314, 341, 342, 351, 364, 389, 395, 396, 397, 401, 406, 423, 433). The Jewell Coal and Coke Company (Ex. 15: 281) stated that:

> [t]he sub-contractor should be responsible for keeping up with their own employee injury/illness records as they are the ultimate responsible party for their own employees under worker's compensation regulations and in all other legal issues. This proposal would appear to be trying to switch total responsibility to the site controlling employer for that record keeping purpose and taking the responsibility off the subcontractor with whom the responsibility should lie. It is, we feel, unfairly discriminatory against the site-controlling employer in this case and we are strongly opposed to the wording of this proposal. Even the alternative proposal in this section places the ultimate responsibility upon the project owner for collection of accident and illness information and send it to OSHA. Again we are strongly opposed to the wording of this proposal because it takes the responsibility for record keeping off the subcontractor and places the ultimate responsibility on the project owner, a responsibility that we feel belongs to the subcontractor irregardless of their size.

Brown & Root, Inc. (Ex. 15: 423) added "A site controlling employer cannot be held responsible for determining which injuries and illnesses of a subcontractor's employees are recordable. A contractor cannot become involved in the medical records of employees who do not work for him or her. The subcontractor employer has to be held accountable and responsible for his own employees, this responsibility cannot be delegated to another contractor. The number of employees or the value of the construction project is irrelevant."

Some of the commenters who generally opposed this provision agreed that site-specific data would be useful if it could be collected by a method that allowed each employer to keep its own records (see, *e.g.*, Exs. 15: 9, 116, 195, 260, 262, 265, 304, 364, 401). Other commenters pointed out that there would be problems in getting accurate data from subcontractors (see, *e.g.*, Exs. 15: 242, 263, 269, 270, 310, 314, 377, 395, 397, 406) or suggested that the site-controlling employer should not be held responsible for the quality of the records received from subcontractors (see, *e.g.*, Exs. 33; 15: 176, 195, 231, 273, 294, 301, 305, 312, 351).

The Alabama Branch of the Associated General Contractors of America, Inc. (AGC) cited difficulties associated with other regulatory requirements that could result from the proposed OSHA site log requirement:

> This could place an undue hardship on the site controlling employer far beyond his ability to appoint and manage independent contractors and subcontractors without there being other entangling both federal and state obligations, which would lead to the subcontractor's employees being declared employees of the controlling contractor. Many states use the common law to make a determination of the employer/employee relationship, as well as the Internal Revenue Service. This employee/employer relationship under the common law usually says if a controlling contractor exercises any control as to time, place, method or result of a person's work that they are in fact defacto employees of the controlling contractor, for social security purposes and other state purposes. Therefore, I think it is shallow thinking to believe that the general contractor with 100 subcontractors should have all 5,500 employees under their control and avoid other legal entanglements, without the ability to actually control the subcontractor.

The National Federation of Independent Business (NFIB) expressed concern about the proposed site log provision as it would relate to OSHA's multi-employer citation policy (Ex. 15: 304), and the Small Business Administration (Exs. 51: 67, 437) argued that the proposed requirement would require competing employers to share sensitive business information.

A number of commenters objected to the requirement because of the additional burden it would place on employers (see, *e.g.*, Exs. 51; 15: 40, 43, 67, 77, 97, 119, 121, 163, 194, 204, 235, 242, 256, 263, 269, 270, 294, 298, 304, 312, 314, 356, 377, 389, 395, 397, 406, 412, 437, 441), arguing that the proposed requirement would result in duplication (see, *e.g.*, Exs. 51; 15: 9, 38, 67, 77, 119, 155, 204, 304, 312, 351, 356, 364, 377, 395, 397, 437). For example, the American Iron and Steel Institute (Ex. 15: 395) stated that the proposed requirement would place a "near impossible burden on the 'site controlling employer'" to determine the size of each subcontractor to decide which subcontractors would be required to keep records.

A number of commenters also questioned the value of the statistical data that would be produced by a site log requirement (see, *e.g.*, Exs. 51; 15: 61, 62, 67, 74, 77, 97, 121, 151, 194, 312, 314, 351, 389, 395, 433, 437, 433), and several participants were concerned that the records would not be useful for accident prevention purposes (see, *e.g.*, Exs. 15: 121, 151, 312, 351, 389, 433).

OSHA received many comments addressing miscellaneous points related to the proposed construction site log requirement. For example, some commenters suggested limiting the scope of the project records required to be maintained (see, *e.g.*, Exs. 15: 17, 21, 111, 116, 213, 155), while others argued that the proposed dollar threshold ($1 million) for a covered construction project was too low and should be raised (see, *e.g.*, Exs. 15: 17, 111, 116, 441). Others suggested that the site log requirement should be triggered by the time duration of the project (Ex. 15: 116); the number of construction workers at the site (Ex. 15: 111); or include only construction employers with more than 11 employees (see, *e.g.*, Exs. 15: 170, 213, 405). Some commenters urged the Agency not to expand the site log concept beyond the construction industry (see, *e.g.*, Exs. 33; 15: 176, 231, 273, 301, 397). Finally, several commenters urged OSHA to make any site log provision in the final rule compatible with the corresponding provisions of the Process Safety Management Standard (29 CFR 1910.119), especially if the site log requirement in the recordkeeping rule was expanded beyond construction (see, *e.g.*, Exs. 33; 15: 159, 176, 231, 273, 301, 335).

Based on a thorough review of the comments received, OSHA has decided not to include provisions in the final that require the site-controlling employer to keep a site log for all recordable injuries and illnesses occurring among employees on the site. OSHA has made this decision for several reasons. First, such a provision would not truly capture the site's injury and illness experience because many subcontractors employ 10 or fewer employees and are therefore exempt from keeping an OSHA Log. To require these very small employers to keep records under Part 1904 for the periods of time they worked on a construction site meeting the dollar threshold for this provision would be a new recordkeeping burden. This would create considerable complexity for these employers and for the site-controlling employer. Second, under the Data Initiative (section 1904.41 of the final rule), OSHA now has a means of targeting data requests for records of the safety and health experience of categories of employers and can therefore obtain the data it needs to establish inspection priorities in a less administratively complex and less burdensome way when the Agency needs such data. Third, OSHA was concerned with the utility of the data that would have been collected under the proposed site log approach, because of the time lag between collection of the data and its use in selecting employers for inspections or other interventions. In many cases work at the site would be complete before the data was collected and analyzed. Finally, a site log requirement is not necessary to enable general contractors to compare the safety records of potential subcontractors since they can require such information as a condition of their contractual arrangements without OSHA requirements. For these reasons, the final rule does not contain a site log provision.

The Use of Alternative Data Sources

Several commenters suggested that the Agency use data from existing data sources, such as state workers' compensation agencies, insurance companies, hospitals, or OSHA inspection files, instead of requiring separate data for OSHA recordkeeping purposes (see, *e.g.*, Exs. 15: 2, 28, 58, 63, 97, 184, 195, 289, 327, 341, 374, 444). For example, Alex F. Gimble observed:

> Since similar data are readily available from other sources, such as the National Safety Council, insurance carriers, etc., why not use these statistics, rather than go through this duplication of effort at taxpayer expense? Another approach would be to utilize data collected by OSHA and State Plan compliance officers during site visits over the past 25 years (Ex. 15: 28).

Several commenters suggested that OSHA use injury and illness data from the workers' compensation systems in lieu of employer records. The comments of the American Health Care Association (AHCA) are representative of the views of these commenters:

> AHCA encourages OSHA to consider the use of workers' compensation data in lieu of proposed OSHA 300 and 301 forms. Pursuing the enactment of legislation that would allow OSHA access to every state's workers' compensation data would eliminate the need for employers to maintain two sets of records, provide OSHA with necessary safety and health data, and ease administrative and cost burdens now associated with recordkeeping for employers in every industry across the country (Ex. 15: 341).

Ms. Diantha M. Goo recommended the use of injury and illness data obtained from treatment facilities rather than the OSHA records:

> The accuracy and usefulness of OSHA's reporting system would be vastly improved if it were to shift responsibility from employers (who have a vested interest in concealment) to the emergency rooms of hospitals and clinics. Hospitals are accustomed to reporting requirements, use the correct terminology in describing the accident and its subsequent treatment and are computerized (Ex. 15: 327).

In response to these comments, OSHA notes that the injury and illness information compiled pursuant to Part 1904 is much more reliable, consistent and comprehensive than data from any available alternative data source, including those recommended by commenters. This is the case because, although some State workers' compensation programs voluntarily provide injury and illness data to OSHA for various purposes, others do not. Further, workers' compensation data vary widely from state to state. Differing state workers' compensation laws and administrative systems have resulted in

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large variations in the content, format, accessibility, and computerization of that system's data. In addition, workers' compensation databases often do not include injury and illness data from employers who elect to self-insure.

Additionally, most workers' compensation databases do not include information on the number of workers employed or the number of hours worked by employees, which means that injury and illness incidence rates cannot be computed from the data. Workers' compensation data are also based on insurance accounts (i.e., filed claims), and not on the safety and health experience of individual workplaces. As a result, an individual account often reflects the experience of several corporate workplaces involved in differing business activities. Finally, as discussed below in the Legal Authority section of the preamble, the OSH Act specifically sets out the recordability criteria that must be included in the OSHA recordkeeping system envisioned by the Congress when the Act was passed. The Congress intended that all non-minor work-related injuries and illnesses be captured by the OSHA recordkeeping system, both so that individual establishments could evaluate their injury and illness experience and so that national statistics accurately reflecting the magnitude of the problem of occupational injury and illness would be available.

Although OSHA disagrees that any of the alternate sources of data are satisfactory substitutes for the information gathered under Part 1904, the Agency recognizes that data from these sources have value. To the extent that information from workers' compensation programs, the BLS statistics, insurance companies, trade associations, etc., are available and appropriate for OSHA's purposes, OSHA intends to continue to use them to supplement its own data systems and to assess the quality of its own data. However, consistent with the Congressional mandate of the OSH Act, OSHA must continue to maintain its own recordkeeping system and to gather data for this system through recording and reporting requirements applicable to covered employers.

Section 1952.4 Injury and Illness Recording and Reporting Requirements

The requirements of 29 CFR 1952.4 describe the duties of State-Plan states to implement the 29 CFR 1904 regulations. These requirements are discussed in Section IX of the preamble, State Plans, and in the preamble discussion for section 1904.37, State recordkeeping regulations.

General Issues Raised by Commenters

In addition to the issues discussed above, three issues concerning recordkeeping warrant discussion: analysis of the data, training and qualifications of recordkeepers, and recordkeeping software.

Analysis of the Data

During OSHA's public meetings, Eric Frumin of the Union of Needletrades, Industrial and Textile Employees, AFL–CIO (UNITE) urged OSHA to include a requirement for employers to analyze the OSHA 1904 data in depth to discover patterns and trends of occupational injury and illness, stating that:

[y]ou're telling the employers to evaluate information that's coming to them, and I say that to stress the point that's a very logical, common sense requirement and you're not generally speaking asking them to do that once they compile a log. You stop short of asking employers to evaluate the log in toto, to look for the kinds of trends and comparisons and so forth that we've been discussing here. I think it's important for OSHA to consider some—making such a requirement, particularly in light of a fairly consistent pattern of testimony in this proceeding, wherein employers now do not analyze what's on the log in much depth. * * * But what has emerged at the end of the day is not a whole lot of use of the information on the log for—in terms of analyzing it for trends and various associations or conclusions about how to protect people, how to stop the injuries and illness (Ex. 58X, pp. 372—375).

In the final rule, OSHA has not included any requirement for employers to analyze the data to identify patterns or trends of occupational injury and illness. OSHA agrees with Mr. Frumin that analysis of the data is a logical outgrowth of maintaining records. Employers and employees can use such analyses to identify patterns and trends in occupational injuries and illnesses, and use that information to correct safety and health problems in the workplace. OSHA encourages both employers and employees to use the data for these purposes. However, a requirement of this type would go beyond the scope of the recording and reporting rule, which simply requires employers to keep records of work-related injuries and illnesses, and report the data under certain circumstances. OSHA believes that requirements of this type are better addressed through an OSHA standard, rather than the 1904 recordkeeping regulation.

Training of Recordkeepers

The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) suggested that OSHA add requirements for the training of the individual who maintains the 1904 records for the employer, stating that:

[a]nother important issue relates to the qualifications and responsibilities of the individual filling out the 300 log and Form 301. Most workplaces generally have a non-safety and health professional entering this information in the 300 log after the decision of a recordable injury or illness has been made. In our view it is important that these individuals have proper training about the recordkeeping rule and the employer's recordkeeping system. In order to assure the most accurate and complete recording of work-related injuries and illnesses, we encourage the Agency to consider developing guidelines for the qualifications and training of these individuals (Ex. 15: 418).

OSHA has not included a training requirement for the person entering the information on the Part 1904 records in this final rule. The Agency believes that the Section 1904.32 provisions of the final rule calling for annual review of the records and certification of the annual summary by a company executive will ensure that employers assign qualified personnel to maintain the records and to see that they are trained in that task. Further, because OSHA did not include training requirements in its 1996 proposal, the Agency has not gathered sufficient information in the rulemaking docket about whether specific training provisions would have utility, as well as the appropriate qualifications and training levels that would assist in writing such provisions at this time.

As part of its outreach and training program accompanying this rule, OSHA will be providing speeches and seminars for employers to help them train their recordkeeping staff. OSHA will also be producing materials employers can use to help train their recordkeeping staff, including free software employers can use to keep records, training programs, presentations, course outlines, and a training video. All of these materials will be available through OSHA's Internet home page at www.osha.gov.

OSHA-Produced Recordkeeping Software

In its proposal (61 FR 4048), OSHA asked the public to comment on whether or not OSHA should develop computer software to make injury and illness recordkeeping easier for employers, and discussed the features that would be desirable for such software. Those features were:

—decision-making logic for determining if an injury or illness is recordable;

—automatic form(s) generation;

—the ability to assist the employer in evaluating the entered data through several preset analytical tools (*e.g.*, tables, charts, etc.); and

—computer based training tools to assist employers in training employees in proper recordkeeping procedures.

OSHA also suggested that any such software should be in the public domain and/or be available at cost to the public and asked the following questions: What percentage of employers have computers to assist them in their business? What percentage of employers currently use computers for tracking employee-related information (payroll, timekeeping, etc.)? Should the distribution be through the Government, public domain share-ware distribution, or other channels? Should OSHA develop the software or only provide specifications for its requirements?

Several commenters said that most business establishments had computers (see, *e.g.*, Exs. 15: 9, 95, 163, 281, 288, 375). The American Health Care Association (AHCA) estimated that 50% to 70% of their members used computers (Ex. 15: 341), and Raytheon Constructors, Inc. estimated that 60% of employers are using computers. OSHA agrees that computers are available in most businesses, although certainly not all of them. The agency also notes that these comments were made in 1996, and that businesses' computer usage has grown since that time.

A number of commenters urged OSHA to produce and distribute software to help employers keep the Part 1904 records (see, *e.g.*, Exs. 35; 36; 51; 15: 9, 26, 32, 34, 67, 68, 76, 87, 95, 105, 109, 111, 129, 154, 157, 170, 181, 182, 197, 225, 235, 239, 247, 272, 277, 281, 283, 288, 303, 313, 327, 341, 347, 350, 352, 353, 356, 394, 405, 406, 409, 418, 426, 437, 438). The commenters gave various reasons for favoring the provision of OSHA-provided software, including reducing the burden and cost of the rule for employers (see, *e.g.*, Exs. 15: 87, 95, 111, 170, 182, 197, 350), saving businesses programming costs (Ex. 15: 277), helping small businesses (Ex. 51; 15: 67), resulting in more uniform data (see, *e.g.*, Exs. 36; 15: 32, 153, 170, 181, 347, 409, 418), and facilitating analysis of the data (see, *e.g.*, Exs. 35; 15: 153, 418). For example, the Ford Motor Company stated that "Ford feels that the development of recordkeeping software by OSHA, which will employ a decision-making logic, automatic form generation, the ability to assist the employer in evaluating the entered data, and a tutorial section to assist employers in training is necessary. This will enhance the uniformity of data collection amongst all users, which is currently lacking" (Ex. 15: 347). The Muscatine Iowa Chamber of Commerce Safety Committee (Ex. 15: 87) added that:

"[e]very feature identified as a minimum requirement would be a great benefit to employers attempting to comply with the OSHA recordkeeping requirements. Prompts which would in any way aid in the determination of recordability would be appreciated by any person without a great deal of experience in filing OSHA reports. We feel these features are especially important now with the changes in forms and information to be collected."

Several of the commenters who urged OSHA to provide computer software tempered their support by asking that the use of such software should be optional and not mandatory (see, *e.g.*, Exs. 15: 60, 109, 154, 198, 225, 247, 272, 303, 394), and several other commenters recommended that OSHA provide both software and specifications so employers could use the OSHA product to build their own data systems (see, *e.g.*, Exs. 15: 170, 247, 283).

A number of commenters told OSHA that the Agency should not produce software to help employers with their 1904 recordkeeping obligations (see, *e.g.*, Exs. 15: 78, 82, 85, 156, 163, 324, 348, 359, 363, 374, 375, 378, 402, 414). Several of these commenters suggested OSHA produce software performance specifications for the industry (see, *e.g.*, Exs. 15: 156, 163, 357, 387). The commenters had various reasons for opposing the production of software. Several stated that each employer wants different data in its own unique form (see, *e.g.*, Exs. 15: 78, 85, 375, 414). For example, the Central Vermont Public Service Corporation (Ex. 15: 85) stated that "[b]usinesses using safety related software use programs that can perform OSHA recordkeeping and workers' compensation functions in one package. It is unlikely that software developed by OSHA will perform workers' compensation functions and therefore it will not be well received or utilized by business." Other commenters stated that OSHA should focus elsewhere, that the private sector could produce software more economically (see, *e.g.*, Exs. 15: 357, 375, 387), and that OSHA software is not needed (see, *e.g.*, Exs. 15: 363, 378). For example, the Synthetic Organic Chemical Manufacturers Association, Inc. (SOCMA) stated that "[a]n outside organization with software development expertise should develop the software. OSHA's limited resources should go directly toward improving safety and health in the workplace" (Ex. 15: 357). The Air Transport Association added: "[m]ost major companies have developed their own software to support required OSHA recordkeeping, and others have taken advantage of commercially available programs. We see no need for OSHA to enter this market" (Ex. 15: 378).

OSHA has decided that the Agency will produce software for employers to use for keeping their OSHA 1904 records. There is obviously a need for the Agency to provide outreach and assistance materials for employers, particularly small employers, to help them meet their obligations in the least burdensome way possible, and software will clearly help achieve this goal. In addition, computer software will improve the consistency of the records kept by employers, and will assist them with analysis of the data. At this time, OSHA has not developed the software or its specifications, but will make every effort to produce and distribute software to assist employers by the time this final rule becomes effective. Use of the OSHA produced software will be optional; employers are not required to use this software and may keep records using paper systems. Employers are also free to produce their own software, or to purchase software.

VI. Legal Authority

A. The Final Recordkeeping Rule Is a Regulation Authorized by Sections 8 and 24 of the Act

The Occupational Safety and Health Act authorizes the Secretary to issue two types of final rules, "standards" and "regulations." Occupational safety and health standards, issued pursuant to section 6 of the Act, specify the measures to be taken to remedy known occupational hazards. 29 U.S.C. 652(8), 655. Regulations, issued pursuant to general rulemaking authority found, inter alia, in section 8 of the Act, are the means to effectuate other statutory purposes, including the collection and dissemination of records on occupational injuries and illnesses. 29 U.S.C. 657(c)(2).

OSHA is issuing this final recordkeeping rule as a regulation pursuant to the authority expressly granted by sections 8 and 24 of the Occupational Safety and Health Act, 29 U.S.C. 657, 673. Section 8 authorizes the Secretary to issue regulations she determines to be necessary to carry out her statutory functions, including regulations requiring employers to record and report work-related deaths and non-minor injuries and illnesses.[1] Section 8(c)(1) of the Act requires each

[1] This rule excludes minor or insignificant injuries and illnesses from reporting requirements. The exclusion of minor illnesses represents a change from the former rule, and is discussed *infra*.

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employer to "make, keep and preserve, and make available to the Secretary [of Labor] or the Secretary of Health [and Human Services], such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health and Human Services, may prescribe by regulation as necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses." Section 8(c)(2) further provides that the "Secretary, in cooperation with the Secretary of Health and Human Services, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job." Section 8(c)(3) empowers the Secretary to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under Section 6."

Section 8(g)(1) authorizes the Secretary "to compile, analyze, and publish, whether in summary or detailed form, all reports or information obtained under this section." Section 8(g)(2) of the Act empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out his responsibilities under the Act."

Section 24 contains a similar grant of regulatory authority. It requires the Secretary to "develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics * * * The Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job." Section 24 also empowers the Secretary to "promote, encourage, or directly engage in programs of studies, information and communication concerning occupational safety and health statistics." Finally, Section 24 requires employers to "file such reports with the Secretary as he shall prescribe by regulation, as necessary to carry out his functions under this chapter."

Section 20 of the Act, 29 U.S.C. 669, contains additional implicit authority for collecting and disseminating data on occupational injuries and illnesses. Section 20(a) empowers the Secretaries of Labor and Health and Human Services to consult on research concerning occupational safety and health problems, and provides for the use of such research, "and other information available," in developing criteria on toxic materials and harmful physical agents. Section 20(d) states that "[i]nformation obtained by the Secretary and the Secretary of [HHS] under this section shall be disseminated by the Secretary to employers and employees and organizations thereof."

Two federal circuit Courts of Appeals have held that rules imposing recordkeeping requirements are regulations and not standards, and are thus reviewable initially in the district courts, rather than the Courts of Appeals. *Louisiana Chemical Assn.* v. *Bingham*, 657 F.2d 777, 782–785 (5th Cir. 1981) (OSHA rule on Access to Employee Exposure and Medical Records); *Workplace Health & Safety Council* v. *Reich*, 56 F.3d 1465, 1467–1469 (D.C. Cir. 1995) (OSHA rule on Reporting of Fatality or Multiple Hospitalization Incidents). These courts applied a functional test to differentiate between standards and regulations: standards aim toward correction of identified hazards, while regulations serve general enforcement and detection purposes, including those outlined in section 8. E.g., *Workplace Health & Safety Council*, 56 F.3d at 1468. See also *United Steelworkers of America* v. *Reich*, 763 F.2d 728, 735 (3d Cir. 1985) (Hazard Communication rule is a standard because it aims to ameliorate the significant risk of inadequate communication about hazardous chemicals). Clearly, the recordkeeping requirements in this final rule serve general administrative functions: They are intended to "aid OSHA's effort to identify the scope of occupational safety and health problems," to "serve as the foundation for national statistics on the number and rate of workplace injuries and illnesses" and "to raise employers' awareness of the kinds of injuries and illnesses occurring in their workplaces." See *Functions of the Recordkeeping System, supra*. Therefore, the final rule falls squarely within the mandate of sections 8 and 24 of the Act and is properly characterized as a regulation.

B. The Legal Standard: The Regulation Must Be Reasonably Related to the Purposes of the Enabling Legislation

Under section 8, the Secretary is empowered to issue "such * * * regulations as [s]he may deem necessary to carry out [her] responsibilities under this Act[,]" including regulations requiring employers to record and to make reports on "work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion or transfer to another job." 29 U.S.C. 657(g)(2), (c)(2). Similarly, section 24 directs the Secretary to compile accurate statistics on "all disabling serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries. * * *" 29 U.S.C. 673(a). Where an agency is authorized to prescribe regulations "necessary" to implement a statutory provision or purpose, a regulation promulgated under such authority is valid "so long as it is reasonably related to the enabling legislation." *Mourning* v. *Family Publications Service, Inc.*, 411 U.S. 356, 369 (1973).

Section 8(g)(2) is functionally equivalent to the enabling legislation at issue in *Mourning*; therefore a reviewing court must examine the final recordkeeping rule's relationship to the purposes of section 8. Cf. *Louisiana Chemical Assn.* v. *Bingham*, 550 F. Supp. 1136, 1138–1140 (W.D. La. 1982), *aff'd*, 731 F.2d 280 (5th Cir. 1984) (records access rule is directly related to the goals stated in the Act and supported by the language of section 8).

C. The Final Recordkeeping Rule's Key Provisions Are Reasonably Related to the Purposes of the OSH Act

The goal of this final rule, as stated in the Summary, is to improve the quality and consistency of injury and illness data while simplifying the recordkeeping system to the extent consistent with the statutory mandate. To achieve this purpose, the final rule carries forward the key elements of the existing recordkeeping scheme, with changes designed to improve efficiency, equity, and flexibility while reducing, to the extent practicable, the economic burden on individual establishments. The central requirements in the final rule may be summarized as follows: All non-exempt employers must record all work-related, significant injuries and illnesses. As discussed below, OSHA's approach to each of these elements—the scope of the exemptions from recording requirements, the meaning of "work-relationship," and the criteria for determining whether an injury or illness is "significant"—is reasonable and directly related to the statutory language and purpose. .

1. Exemptions From Recordkeeping Requirements

The final rule contains two categories of exemptions that, together, relieve most employers of the obligation routinely to record injuries and illnesses sustained by their employees. Section 1904.1 contains a "very small-employer" exemption: Employers need not record injuries or illnesses in the current year if they had 10 or fewer employees at all times during the previous year, unless required to do so pursuant to Sections 1904.41 or 1904.42. Section 1904.2 contains a "low-hazard industry" exemption: Individual business establishments are not required to keep records if they are classified in specific low-hazard retail, service, finance, insurance, or real estate industries.

a. The size-based exemption. Section 8(d) of the Act expresses Congress' intent to minimize, where feasible, the burden of recordkeeping requirements on employers, particularly small businesses: "Any information obtained by the Secretary, the Secretary of [HHS], or a State agency under this Act shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible." 29 U.S.C. 657(d).

Since 1972, the Secretary has exempted very small businesses from most recordkeeping requirements. On October 4, 1972, OSHA issued a provision, codified at 29 CFR 1904.15(a), exempting employers from routine injury and illness reporting requirements for the current year if they had no more than seven employees during the previous year. The exemption did not relieve these businesses from the obligation to report fatality and multiple hospitalization incidents to OSHA and to participate in the BLS annual survey when selected to do so. 37 FR 20823 (October 4, 1972). In 1977, the Secretary amended section 1904.15 to make it applicable to businesses having ten or fewer employees during the year preceding the current reporting year. 42 FR 38568 (July 29, 1977). As support, the amendment cited the Department of Labor appropriations acts for fiscal years 1975 and 1976, which exempted employers having ten or fewer employees from most routine recordkeeping requirements, and Section 8(d) of the Act. *Id.* The Secretary determined that the amendment appropriately balanced the interest of very small businesses while preserving the essential purposes of the recordkeeping scheme:

> The [exemption] has been carefully designed to carry out the mandate of section 8(d) without impairing the Act's basic purpose. Thus, the [exemption] will not diminish the protections afforded employees under the Act because all employers * * * remain subject to the enforcement provisions of the Act. The [exemption] will continue to require * * * small employers * * * to report fatalities and multiple hospitalizations and to participate in the BLS annual survey when selected to do so.

42 FR 10016 (February 18, 1977).

In the present rulemaking, the Secretary proposed to enlarge the scope of the exemption to include employers, in industries other than construction, having 19 or fewer employees during the entire previous calendar year. 61 FR 4057 (February 2, 1996). At the same time, the proposal asked for public comment on whether "the small employer partial exemption [should] remain the same, be eliminated, or be expanded?" 61 FR 4043. In reaching a final decision on this matter, the Secretary resolved two interrelated questions. First, she determined that there is no sound basis for departing from OSHA's prior interpretation that the Act permits a carefully crafted exemption for very small employers. Second, she determined that limiting the exemption to employers with ten or fewer employees effectuates Congress' intent with the minimum degree of impairment to the overall recordkeeping scheme. The first question is essentially one of statutory construction, and is therefore considered below. The second question calls for an analysis of the record and is addressed in the preamble explanation for section 1904.1 of the final rule.

It is a fundamental principle of administrative law that an agency which chooses to reverse a previously held position must supply a "reasoned analysis" of its decision. *Motor Vehicle Mfgrs Assn.* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 27, 42 (1983). After careful consideration, the Secretary finds no persuasive basis for eliminating the small-employer exemption in this rule. As a threshold matter, nothing has changed the agency's long-held view that section 8(d) permits a carefully tailored exemption from recordkeeping requirements for very small businesses. 42 FR 10016 (February 18, 1977). This interpretation is consistent with the literal wording of the statute and is further confirmed by the provisions in the Department's appropriations acts for FY 1975 and 1976, exempting employers with ten or fewer employees from routine recordkeeping and reporting requirements. See 42 FR 5356 (January 28, 1977) (noting restriction in FY 1975 and 1976 appropriations acts and stating OSHA would continue to treat firms of up to 10 employees as exempt pending permanent change in the regulations to expand the small-employer exemption).

OSHA also concludes that a very small business exemption limited to the routine recording and reporting of non-fatal injuries and illnesses will not seriously undermine the recordkeeping system. OSHA explained in Section I. of the preamble that there are three primary purposes for recordkeeping and reporting requirements. First, the records are the foundation for national statistics published by the BLS on the number and rate of workplace injuries and illnesses, as well as their source, nature and type. Second, the records provide information useful to employers and employees in their efforts voluntarily to locate and eliminate workplace safety and health hazards. Finally, the records are useful to OSHA in targeting its enforcement efforts and in efficiently conducting its safety and health inspections.

Exempting very small businesses from routine recordkeeping will not significantly compromise these goals. The exemption has no effect upon the obligation of these businesses to participate in the national statistical survey administered by the BLS. See the discussion of § 1904.42 in Section V. Summary and Explanation. If a small business is selected for participation in the survey, it must keep a log of injuries and illnesses and make reports as required by the BLS. *Id.* Thus, even the smallest firms continue to be represented in the national injury and illness statistics.

The second purpose is not seriously compromised by the exemption because injury and illness records are less necessary as an aid to voluntary compliance efforts by very small employers and their employees than they are for larger employers. OSHA's experience is that, in establishments with only a few employees, management and production personnel typically work in close concert. Because of their size, such establishments also tend to record fewer occupational injuries and illnesses. Accordingly, in very small firms, managers are likely to have first-hand knowledge of those occupational injuries and illnesses that occur in their workplaces. By the same token, it is reasonable to believe that employees in very small firms are generally aware of the injuries that occur in their workplaces and do not

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rely heavily upon access to employer records to inform themselves about occupational hazards. In short, review and analysis of injury and illness records by very small business employers, or by their employees, may not be required for awareness of workplace conditions.

Finally, routine injury and illness records are of limited usefulness to OSHA in targeting and conducting inspections. Many OSHA inspections are conducted in response to a specific complaint or referral alleging unsafe conditions, or in response to a workplace catastrophe or fatality. A large number of inspections are also conducted under special emphasis programs at the national and local level. The remaining inspections are conducted at specific worksites in the construction industry and in other non-construction industries selected under a planned schedule. Construction inspections are selected using an econometric model that predicts the best time to conduct an inspection at a specific construction project. The general industry scheduled inspections are targeted primarily toward employers with extremely high rates of occupational injury and illness, using data supplied by employers to the OSHA Data Initiative (ODI) under the requirements of former section 1904.17, *Annual OSHA Injury and Illness Survey of Ten or More Employers (now section 1904.41)*. Due to budget, paperwork burden and logistical constraints, OSHA collects data only from employers in high hazard industries, and has generally not collected data from employers with fewer than 40 workers.

OSHA is also prohibited from conducting scheduled inspections of employers with 10 or fewer employees in low hazard industries by an annual rider on OSHA's appropriations bills which has been renewed annually for many years. Thus, OSHA does not collect data from very small employers, and they are excluded from the general industry scheduled inspection program. Because very small firms have been wholly excluded from the general schedule inspection program, the routine injury and illness records of very small businesses have been of little use to OSHA in targeting inspections. Should OSHA wish to include very smaller employers in a special emphasis inspection program or other initiative, the agency may require any business, regardless of its size, to keep records and make reports as necessary. See 29 CFR 1904.41.

OSHA also finds that access to the Log and Incident Report would be of little value to compliance officers in conducting inspections of very small businesses initiated by a complaint or report of a fatality or an accident resulting in multiple hospitalizations. OSHA has long acknowledged that while injury and illness records are frequently useful in identifying hazardous areas or operations within larger establishments subject to programmed inspections, they are significantly less important in the conduct of inspections in the smallest businesses. As OSHA has stated, "experience has shown that when dealing with small employers, the injury and illness records * * * are normally not needed by the CSHO to locate hazards during an inspection. In those cases where log information may be needed, the CSHO can easily obtain the information by interviewing the employees." 42 FR 10016 (February 18, 1977). See also 47 FR 57699, 5700 (December 28, 1982) (in conducting complaint or fatality inspections, the hazard information is usually provided by the complaint itself, or through prompt investigation.) For these reasons, the Secretary believes that an exemption for very small employers, reasonably tailored to the purposes served by recordkeeping requirements, is appropriate.

b. The hazard-based exemption. Since 1982, OSHA has exempted from routine recordkeeping requirements certain industries classified in OMB's Standard Industrial Classification (SIC) Manual. The 1982 exemption was limited to establishments in SIC Industry Groups that (1) were not subject to general schedule inspections, and (2) had average lost workday case injury rates, as published by the BLS, at or below 75% of the national average. In 1982, the industry groups that met these criteria were those classified as retail trade, finance, insurance, real estate, and services—SIC codes 52–89, excluding 52–54, 70, 75, 76, 79, and 80. 47 FR 57899–57,700 (December 28, 1982).

The purpose of the exemption "was to further OSHA's continuing effort under section 8(d) of the Act to reduce the paperwork burden on employers without compromising worker safety and health." 47 FR 57700. Exempting low-hazard industries from routine record-keeping was justified, OSHA explained, for the same reasons that warranted exempting very small businesses. Injury and illness records from establishments in the affected SIC codes were not of significant benefit to OSHA because these industry groups were not then targeted for general schedule inspections. *Id.* The records were not a significant source of information for employers and employees because BLS data showed that approximately 94% of all establishments in the affected industry groups could be expected to have fewer than two injuries per establishment on an annual basis. *Id.* Finally, the exemption would not affect the reliability of safety and health statistics because the affected establishments would continue to participate in the BLS annual survey of occupational injuries and illnesses. *Id.*

OSHA continues to believe that a properly tailored exemption for low-hazard industries is appropriate. Congress intended in section 8(d) to minimize the recordkeeping burden on all employers, not only small businesses. Exempting from routine injury and illness reporting requirements those employers whose records are unlikely to be of significant benefit to OSHA, or to the employers and their employees, serves this important interest. However, OSHA recognizes that the balance between the interest of minimizing recordkeeping burdens and that of ensuring accurate, reliable and useful information is a delicate one. In the final rule, OSHA has substantially revised the list of exempt low-hazard industries based upon more reliable three-digit industry classification data. See the discussion of § 1904.1, in the following Summary and Explanation. With these changes, OSHA believes that the rule strikes the appropriate balance.

2. The Meaning of "Work-Relationship"

Section 8 of the Act directs the Secretary to prescribe regulations requiring employers to "maintain accurate records of * * * work-related deaths injuries and illnesses [of a non-minor nature]. 29 U.S.C. 657(c)(2). The definition of work-relationship in section 1904.5 of the final rule is consistent, in all but one respect, with the definition in the *Guidelines* to the former rule. The final rule states that an injury or illness is work-related "if an event or exposure in the work environment either *caused or contributed to* [it] or significantly aggravated a pre-existing injury or illness. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception listed in section 1904.5(b)(2) specifically applies" (emphasis added).

The *Guidelines* state that, "[i]f an event * * * occurred in the work environment *that caused or contributed to the* injury", the case would be recordable, assuming it meets the other requirements for recordability. Ex. 2 at p. 32 (original emphasis). Further instructions in the *Guidelines* provided that:

> The general rule is that all injuries and illnesses which result from events or exposures occurring to employees on the employer's premises are *presumed* to be work related. This presumption is rebuttable. * * * However, the nature of the activity which the employee is engaged in at the time of the event or exposure, the degree of employer control over the employee's activity, the preventability of the incident, or the concept of fault do not affect the determination.

Ex. 2 at p. 34 (original emphasis). The only significant difference between the final rule and the former rule is that the final rule requires that work "significantly" aggravate a pre-existing injury or illness before the case is recordable.

OSHA's approach to work-relationship in both the former and the final recordkeeping rules reflects two important principles. The first is that work need only be a causal factor for an injury or illness to be work-related. The rule requires neither precise quantification of the occupational cause, nor an assessment of the relative weight of occupational and non-occupational causal factors. If work is a tangible, discernible causal factor, the injury or illness is work-related. The second principle is that a "geographic presumption" applies for injuries and illnesses caused by events or exposures that occur in the work environment. These injuries and illnesses must be considered work-related unless an exception to the presumption specifically applies.

The final rule's geographic presumption reflects a theory of causation similar to that applied by courts in some workers' compensation cases. Under the "positional-risk" test, an injury may be found to "arise out of" employment for compensation purposes if it would not have occurred but for the fact that the conditions and obligations of employment placed the claimant in the position where he or she was injured. See 1 Larson's Workers' Compensation Law section 6.50 (1977). *Accord, Odyssey/Americare of Oklahoma* v. *Worden*, 948 P.2d 309, 311 (Okla. 1997). Under this "but for" approach to work-relationship, it is not necessary that the injury or illness result from conditions, activities or hazards that are uniquely occupational in nature. Accordingly, the presumption encompasses cases in which an injury or illness results from an event at work that is outside the employer's control, such as a lightning strike, or involves activities that occur at work but that are not directly productive, such as horseplay.

The proposed rule asked for comment on whether OSHA should abandon its historic approach and adopt a new test for determining work-relationship. 61 FR 4044, 4045. The proposal outlined three alternative tests in which the determination of work-relationship turned on the degree to which the injury or illness was linked to occupational causes, as compared with personal factors such as off-the job activities, aging, or pre-existing medical conditions. Two of these alternative tests required evidence of a high degree of work causation to establish work-relationship. Alternative 1 required that occupational factors be the "sole cause" of the injury or illness; any evidence of non-work related causal factors was sufficient to exclude the case. Alternative 2 required that occupational factors be the "predominant cause" before the case could be considered work-related. See 61 FR 4044. Some commenters suggested a modification to Alternative 2 that would have involved substitution of the word "substantial" or "significant" for "predominant."

The third alternative test was significantly more expansive than that adopted in the final rule. Under Alternative 3, an injury or illness would be considered work-related if the work environment had any possibility of playing a causal role. 61 FR 4044.

Some commenters favored a somewhat different test for work-relationship that focused on the nature of the injury-causing event in the workplace. This test would include in the OSHA records only those cases resulting from uniquely occupational or job-related activities or processes. Supporters of this approach argued that it would exclude injuries and illnesses caused by factors at work that are unrelated to production tasks, or that are unpreventable by the employer's safety and health program.

After careful consideration of the record, OSHA believes that the final rule's test for work-relationship is both more consistent with the Act's purpose and more practical than the "quantified occupational cause" tests or the "unique occupational conditions" test. The language of the statute itself indicates that Congress did not intend to give "work-related" a narrow or technical meaning, but rather sought to cover a variety of causal relationships that might exist in workplaces. Section 2 of the Act addresses injuries and illnesses arising out of "work situations." Sections 2(b)(1), 2(b)(2), and 2(b)(4) refer to "places of employment," and to the achievement of safe and healthful "working conditions." Section 2(b)(7) seeks to assure that no employee will suffer diminished health or life expectancy as a result of his "work experience." Section 2(b)(12) states that one of the Act's purposes is to provide for reporting procedures which "accurately describe the nature of the occupational safety and health problem." Section 2(b)(13) encourages joint labor-management efforts to reduce injuries and disease "arising out of employment."

This conclusion is further supported by the Act's stated purpose to promote research into the causes and prevention of occupational injuries and illnesses. Section 2 of the Act establishes Congress' intent to improve occupational safety and health, *inter alia*, by:

> Providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques and approaches for dealing with occupational safety and health problems. 29 U.S.C. § 651(b)(5)

> [E]xploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems. * * * 29 U.S.C. § 651(b)(6).

> Providing for appropriate reporting procedures with respect to occupational safety and health which will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problems. 29 U.S.C. § 651(b)(12).

The legislative history of the Act demonstrates Congress' awareness of the importance of developing information for future scientific use. The Committee Report accompanying the Senate bill reported to the floor noted that,

> [i]n the field of occupational health, the view is particularly bleak, and due to the lack of information and records, may well be considerably worse than we currently know. * * * Recent scientific knowledge points to hitherto unsuspected cause-and-effect relationships between occupational exposures and many of the so-called chronic diseases—cancer, respiratory ailments, allergies, heart disease, and others. In some instances, the relationship appears to be direct: asbestos, ionizing radiation, chromates, and certain dye intermediaries, among others, are directly involved in the genesis of cancer. In other cases, occupational exposures are implicated as contributory factors. The distinction between occupational and non-occupational illnesses is growing increasingly difficult to define.

S. Rep. No. 1282, 91st Cong., 2d Sess. 2 (1970), *reprinted in* Subcommittee on Labor of the Senate Committee on Labor and Public Welfare, *Legislative History of the Occupational Safety and Health Act of 1970* (Committee Print 1971) at

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142 (Leg. Hist.). With this background in mind, the committee stated that it "expects the Secretary of Labor and the Secretary of [HHS] will make every effort through the authority to issue regulations and other means, to obtain complete data regarding the occurrence of illnesses, including those resulting from occupational exposure which may not be manifested until after the termination of such exposure." Leg. Hist. at 157.

Both the Senate and the House Committees expressed concern that the statute not be interpreted in a way that would result in under-reporting of injuries and illnesses. The Senate report states:

> The committee recognizes that some work-related injuries or ailments may involve only a minimal loss of work time or perhaps none at all, and may not be of sufficient significance to the Government to require their being recorded or reported. However, the committee was also unwilling to adopt statutory language which, in practice might result in under-reporting. The committee believes that records and reports prescribed by the Secretary should include such occurrences as work-related injuries and illnesses requiring medical treatment or restriction or reassignment of work activity, as well as work-related loss of consciousness.

Leg. Hist. at 157. The House Report similarly noted that while some injuries and illnesses might not be of enough value to require recordation, "the greater peril" lay in allowing under reporting. Leg. Hist. at 860. Therefore, the report added, "[the] language 'all work-related injuries, [and illnesses]' should be treated as a minimum floor. * * *"

In light of these purposes, it is apparent that Congress did not, in Section 8, mean to limit recordable "work-related" injuries and illnesses only to those caused primarily or substantially by work. It is evident from the statute that Congress wanted employers to keep accurate records of non-minor injuries and illnesses, in part, to serve as a basis for research on the causes and prevention of industrial accidents and diseases. This research is needed, among other reasons, to further examine and understand those occupational factors implicated as contributory causes in injuries and diseases. To serve this purpose, the records should include cases in which there is a tangible connection between work and an injury or illness, even if the causal effect cannot be precisely quantified, or weighed against non-occupational factors.

The first two alternative quantification theories outlined in the preamble would exclude important information from the records. These theories would eliminate cases in which the work environment is believed to have played a definite role in the accident or the onset of disease, but not enough is known to quantify the effect of work factors or to assess the relative contribution of work and non-work factors. However, the information provided by cases having a tangible, yet unquantifiable, connection with the work environment is useful to employers, employees and researchers and thus serves the recordkeeping purposes envisioned by Congress.

On the other hand, the third alternative theory in the proposal would sweep too broadly. A work-relationship test that is met if work has "any possibility of playing a role in the case" would include virtually every injury or illness occurring in the work environment. 61 Fed. Reg. 4044. Recording cases in which the causal connection to work is so vague and indefinite as to exist only in theory would not meaningfully advance research, or serve the other purposes for requiring recordkeeping. For these reasons, OSHA has rejected the three alternative theories outlined in the proposal.

The "unique occupational activity" test, which some commenters favored instead of the geographic presumption, would limit recorded injuries and illnesses to those caused by an activity or process peculiarly occupational in nature. Supporters of this approach identified several types of cases that would be work-related under the geographic presumption, but not recordable under an activities-based approach. These include cases in which the injury or illness was not caused by the physical forces or hazards unique to industrial processes, cases in which the employee was not injured while performing an activity or task directly related to production, and cases in which the injury or illness was not preventable by the employer.

The "unique occupational activity" test is unsuitable for essentially the same reasons that militate against the first two alternatives described in the proposal. The statutory language and purpose do not reflect a Congressional intent to limit recording only to those cases resulting from uniquely occupational hazards or activities. Rather, the statute shows that Congress knew that employees were being injured and made ill in a variety of ways and under a variety of circumstances, and wanted employers to record all cases causally related to the work environment. The "but-for" theory underlying the geographic presumption is a widely accepted legal test for causation and is consistent with the statutory language and purpose.

The "unique occupational activities" test, like the "quantification" tests, would likely result in exclusion of important information from the records. An activity-based test for work-relationship could obscure the role of factors in the work environment not directly linked to production, such as violence perpetrated by employees and others or tuberculosis outbreaks. In addition, the precise causal mechanism by which an employee has been injured or made ill at work may not be known at the time of the accident, or may be misunderstood. To serve the statute's research purposes, the records must reflect not only those injuries and illnesses for which the precise causal mechanism is apparent at the time of recordation, but also those for which the mechanism is imperfectly understood. The alternative approaches to work-relationship would severely limit the usefulness of injury and illness data for research purposes, particularly research to uncover latent patterns of health impairment and disease and to establish causal connections between diseases and exposure to particular hazards.

The Occupational Safety and Health Review Commission has affirmed the approach to work-relationship taken in the former rule. *General Motors Corp., Inland Div.*, 8 O.S.H. Cas. (BNA) 2036, 2039–2040 (August 29, 1980). The issue in *General Motors* was whether the employer was required to record respiratory ailments of three employees, based on notations from the employees' treating physicians that their ailments were probably related to exposure to a chemical substance at work. The Commission rejected the employer's argument that the recordkeeping rule required recording only of illnesses directly caused by work activities, stating:

> To accept Respondent's interpretation would impose a static view of scientific knowledge. Only illnesses in which the known cause was the occupational environment would be recorded. Unknown medical correlations between disease and the workplace would be obscured by this inadequate recording obligation. Under this interpretation of the statute and regulations, OSHA and NIOSH would be significantly restrained from fulfilling their statutory obligation of making the workplace healthier. * * * [T]he primary purpose of the recording obligation is to develop information for future scientific use.

8 O.S.H. Cas. at 2040. Accordingly, OSHA believes that there is a sound legal basis for the definition of work-relationship in the final rule.

There are also sound policy justifications. The approach to "work-relationship" adopted in the final rule is more cost-effective than the alternative approaches and will result in more accurate injury and illness data. OSHA expects that for each reported injury or illness, employers generally will be able to apply the geographic presumption more easily and quickly than a test requiring an assessment of the relative contribution of employment and personal causes. The incremental reduction in the time necessary to complete each entry, when multiplied by the total number of entries per year, will result in a substantial cumulative saving in paperwork burden in comparison to the burden that would be imposed by the alternatives.

The geographic presumption will also produce more consistent and accurate reporting. OSHA believes that it would be difficult to measure the precise degree to which personal and occupational factors cause accidents or illnesses. Accordingly, any test requiring that job duties or tasks be "significant" or "predominant" causative factors would necessarily involve a high degree of subjective judgment. There is likely to be substantial inconsistency, both in the treatment of successive, similar cases by the same employer, and in the treatment of such cases among different employers. Moreover, such a test would fail to capture cases in which the workplace contribution to an injury or illness was imperfectly known or misunderstood at the time the case was reported. Recording all cases caused by events or exposures at work, with only limited exceptions, produces data that enables OSHA, employers and others to better understand the causal relationships present in the work environment. Although OSHA has not adopted a test for determining significant contribution by work, the final rule does include provisions to make sure that workplace aggravation of a pre-existing injury must be significant before work relationship is established (see discussion of 1904.5(b)(4)).

A number of commenters argued that because OSHA's mission is to eliminate preventable occupational injuries and illnesses, the determination of work-relatedness must turn upon whether the case could have been prevented by the employer's safety and health program. Dow expressed this view as follows:

> [T]he goal of this recordkeeping system should be to accurately measure the effectiveness of safety and health programs in the workplace. Activities where safety and health programs could have no impact on preventing or mitigating the condition should not be logged and included in the Log and Summary nor used by OSHA to determine its inspection schedule. If the event was caused by something beyond the employer's control, it should not be considered a recordable event that calls into question a facility's safety and health program. * * * Credibility in this regulation rests on whether the recorded data accurately reflects the safety and health of the workplace. Including events where the workplace had virtually no involvement undermines the credibility of the system and results in continued resistance to this regulation.

Ex. 15–335B. The law firm of Constangy, Brooks and Smith, LLC, urged OSHA to adopt the second alternative definition in the proposal because cases that are "predominantly caused by workplace conditions" are the ones most likely to be preventable by workplace controls. They stated, "[s]ince OSHA's ultimate mission is the prevention of workplace injuries and illnesses, it is reasonably necessary to require recording only when the injury or illness can be prevented by the employer." Ex. 15–345.

OSHA believes that these comments reflect too narrow a reading of the purposes served by injury and illness records. Certainly one important purpose for recordkeeping requirements is to enable employers, employees and OSHA to identify hazards that can be prevented by compliance with existing standards or recognized safety practices. However, the records serve other purposes as well, including facilitating the research necessary to support new occupational safety and health standards and to better understand causal connections between the work environment and the injuries and illnesses sustained by employees. As discussed above, these purposes militate in favor of a general presumption of work-relationship for injuries and illnesses that result from events or exposures at the worksite, with exceptions for specific types of cases that can be safely excluded without significantly impairing the usefulness of the database.

3. The Criteria for Determining the Significance of an Injury or Illness

Section 1904.7 of the final rule sets forth the criteria to be used by employers in determining whether work-related occupational injuries and illnesses are significant, and therefore recordable. Under § 1904.7, a work-related injury or illness is significant for recordkeeping purposes if it results in any of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. Employers must also record any significant injury or illness diagnosed by a physician or other licensed health care professional even if it does not does not result in the one of the listed outcomes. OSHA's definition of a "significant" injury or illness in this context is based on two key principles discussed below. The first is that the requirement for recording only significant cases applies equally to "injuries" and "illnesses" for recordkeeping purposes. The second principle is that the criteria expressly mentioned in the Act, such as death, loss of consciousness or restriction of work, are mandatory but not exclusive indicia of significance; any significant injury or illness diagnosed by a physician or other licensed health care professional must also be recorded. These two principles are addressed below, while the definitions applicable to the specific criteria themselves, and related evidentiary issues, are discussed in the preamble explanation for section 1904.7.

a. The significant case requirement applies equally to injuries and illnesses; employers are no longer to report insignificant illnesses. OSHA distinguishes between injuries and illnesses based on the nature of the precipitating event or exposure. Cases which result from instantaneous events are generally considered injuries, while cases which result from non-instantaneous events, such as a latent disease or cumulative trauma disorder, are considered illnesses. *Id.*

Under the former recordkeeping regulations, occupational injuries had to be recorded if they were non-minor in nature; that is, if they resulted in loss of consciousness, or required medical treatment, time off work, restriction of work, lost time, or transfer to another job. 61 FR 4036. However, all occupational illnesses had to be reported, regardless of severity. *Id.* This difference in the severity threshold for recording injuries and illnesses had, in the past, been based upon the particular phrasing of section 8(c)(2) of the Act:

> The Secretary * * * shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses, other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job."

29 U.S.C. 657(c)(2). Because the severity criteria appear in the clause defining "minor injuries," OSHA had construed the section to require recordation of all work-related illnesses, even those that do not meet the severity

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characteristics expressly applicable to "injuries."

OSHA has reconsidered its position in this rulemaking, and has concluded that the former rule was inappropriate in several respects. First, although the severity characteristics listed in section 8(c)(2) of the Act apply expressly to "injuries," the Act contains persuasive indications that Congress also meant to require recordation only of "significant" illnesses, as determined by reasonable criteria. Section 24(a) states that "[t]he Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses * * * other than minor injuries requiring only first aid treatment and which do not involve medical treatment * * * ." 29 U.S.C. 673 (a). The legislative history also supports this view. The statement of the House managers on the resolution of conflicting House and Senate bills states that:

> A Senate bill provision without a counterpart in the House amendment permitted the Secretary to require an employer to keep records and make reports on "all work-related deaths, injuries and illnesses." The House receded with an amendment limiting the reporting requirement to injuries and illnesses other than of a minor nature, with a specific definition of what is not of a minor nature.

Leg. Hist. at 1190 (emphasis supplied). The former rule did not appropriately implement this intent. In the first place, OSHA's prior interpretation that section 8(c)(2) limits the applicability of the listed severity criteria only to injuries does not necessarily mean that illnesses must be recorded without regard to their significance. As a textual matter, such a reading simply leaves open the question of what, if any, severity criteria apply to illnesses.

OSHA believes that the Act does not support a different severity threshold for injuries than for illnesses. OSHA is now persuaded that its prior reading of section 8(c)(2) placed too much emphasis on the fact that the severity criteria modify the word "injuries" in the clause, "other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion or transfer to another job." 29 U.S.C. 657(c)(2). Congress' failure to list specific severity criteria for illnesses, as it did for injuries, does not, in itself, compel the inference that two different sets of criteria must apply. Congress meant to limit recordation to significant injuries and illnesses alike, and absent strong indications to the contrary, it is reasonable to presume that Congress meant the same severity threshold to apply to both conditions.

In addition, there are strong policy reasons for avoiding a distinction between injuries and illnesses based on severity. OSHA explained in the proposal that the current distinction between injuries and illnesses based on the nature of the precipitating event has caused some degree of confusion and uncertainty. Using one set of criteria for severity means that employers will not have to decide whether a case is an injury or an illness in determining its recordability. This simplifies the recordkeeping system, resulting in more accurate injury and illness data while reducing the recordkeeping burden for employers who are required to maintain records (61 FR 4036). Employers will continue to classify each recordable case as either an injury or an illness on the OSHA 300 Log, but the decision no longer has any effect on whether or not the case must be recorded.

b. The criteria listed in the Act are mandatory but not exclusive indicia of significance. A final issue relating to significance is the effect to be given a finding that an injury or illness results in, or does not result in, one of the outcomes listed in the statute: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. The implication arising from the wording of section 8(c)(2) and section 24 is that if an injury or illness results in one of the listed outcomes, it must be deemed significant for recordkeeping purposes. This position, which reflects OSHA's longstanding, consistent interpretation of the statute, was not seriously questioned in the rulemaking. Accordingly, the final rule requires that a work-related injury or illness be recorded if it results in one of the outcomes mentioned in the statute.

The final rule also requires that a case be recorded, whether or not it results in one of the listed outcomes, if it involves a significant injury or illness diagnosed by a physician or other licensed health care professional. 29 CFR 1904.10(b). Nothing in the statute compels the conclusion that the criteria mentioned in sections 8 and 24 are the exclusive indicia of severity for recordkeeping purposes. Congress directed the Secretary to collect data on "all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work," other than minor injuries * * * which [do not result in one of the listed outcomes]. 29 U.S.C. 673(a). A reasonable reading of this language is that while an injury that meets one of the listed criteria is non-minor and must be recorded, the converse does not necessarily follow. An injury or illness may reasonably be viewed as significant, and therefore recordable, even if it is not immediately followed by death, loss of consciousness, or job-related disability. For example, an employee diagnosed with an unquestionably serious work-related disease, such as asbestosis or mesothelioma, may forego or postpone medical treatment and continue temporarily to perform his or her normal job duties. Focusing exclusively on the basic criteria listed in the statute in cases such as these could result in underrecording of serious cases. Accordingly, the final rule requires employers to record any significant injury or illness that is diagnosed. A thorough discussion of this requirement, including a definition of what constitutes a "significant" injury or illness for this purpose, is contained in the preamble discussion of section 1904.7.

Because the provisions of the final recordkeeping rule, as explained above and in the subsequent sections of this preamble, are reasonably related to the statutory purposes, the Secretary finds that the rule is necessary to carry out her responsibilities under the Act. The rule is therefore a valid exercise of the Secretary's general rulemaking authority under Section 8. Cf. *Mourning* v. *Family Publications Services*, 411 U.S. 356.

VII. Summary and Explanation

The following sections discuss the contents of the final 29 CFR Part 1904 and section 1952.4 regulations. OSHA has written these regulations using the plain language guidance set out in a Presidential Memo to the heads of executive departments and agencies on June 1, 1998. The Agency also used guidance from the Plain Language Action Network (PLAN), which is a government-wide group working to improve communications from the Federal government to the public, with the goals of increasing trust in government, reducing government costs, and reducing the burden on the public. For more information on PLAN, see their Internet site at http://www.plainlanguage.gov/.

The plain language concepts encourage government agencies to adopt a first person question and answer format, which OSHA used for the Part 1904 rule. The rule contains several types of provisions. Requirements are described using the "you must * * *" construction, prohibitions are described using "you may not * * *", and optional actions that are not

requirements or prohibitions are preceded by "you may * * *." OSHA has also included provisions to provide information to the public in the rule.

Subpart A. Purpose

The Purpose section of the final rule explains why OSHA is promulgating this rule. The Purpose section contains no regulatory requirements and is intended merely to provide information. A Note to this section informs employers and employees that recording a case on the OSHA recordkeeping forms does not indicate either that the employer or the employee was at fault in the incident or that an OSHA rule has been violated. Recording an injury or illness on the Log also does not, in and of itself, indicate that the case qualifies for workers' compensation or other benefits. Although any specific work-related injury or illness may involve some or all of these factors, the record made of that injury or illness on the OSHA recordkeeping forms only shows three things: (1) that an injury or illness has occurred; (2) that the employer has determined that the case is work-related (using OSHA's definition of that term); and (3) that the case is non-minor, *i.e.*, that it meets one or more of the OSHA injury and illness recording criteria. OSHA has added the Note to this first subpart of the rule because employers and employees have frequently requested clarification on these points.

The following paragraphs describe the changes OSHA has made to the Purpose provisions in Subpart A of the final rule, and discusses the Agency's reasons for these changes. Proposed section 1904.1 of Subpart A contained three separate paragraphs. Proposed paragraph (a) stated that the purpose of the recordkeeping rule (Part 1904) was "to require employers to record and report work-related injuries, illness and fatalities." It also described several ways in which such records were useful to employers, employees, OSHA officials, and researchers evaluating and identifying occupational safety and health issues.

Proposed paragraph (b) noted that the recording of a job-related injury, illness or fatality did not necessarily impute fault to the employer or the employee, did not necessarily mean that an OSHA rule had been violated when the incident occurred, and did not mean that the case was one for which workers' compensation or any other insurance-related benefit was appropriate. The third paragraph in proposed section 1904.1, proposed paragraph (c), stated that the regulations in Part 1904 had been developed "in consultation with the Secretary of Health and Human Services" (HHS), as required by Section 24(a) of the Act.

In the final rule, OSHA has moved much of this material, which was explanatory in nature, from the regulatory text to the preamble. This move has simplified and clarified the regulatory text. The final rule's Purpose paragraph simply states that: "The purpose of this rule (Part 1904) is to require employers to record and report work-related fatalities, injuries and illnesses." This final rule statement is essentially identical to the first sentence of the proposed Purpose section. It clearly and succinctly states OSHA's reasons for issuing the final rule.

A number of commenters (see, *e.g.*, Exs. 25; 15: 199, 305, 313, 346, 348, 352, 353, 375, 418, 420) specifically addressed proposed section 1904.1. The principal points raised by these commenters concerned: (1) Statements in proposed paragraph (a) about the quality of the data captured by the records; (2) proposed paragraph (b)'s discussion of the relationship between OSHA recordkeeping and employer/employee fault, violations of OSHA rules, and the workers' compensation system, and (3) the statement in proposed paragraph (c) that discussed OSHA's consultation with the Secretary of Health and Human Services in developing this rule. Each of these issues is discussed in detail below.

Most comments on proposed paragraph (a) took issue with the language that OSHA used to describe the statistical use of the records (see, *e.g.*, Exs. 25, 15: 305, 346, 348, 375, 420). Typical of these comments is one from the National Association of Manufacturers: "We urge OSHA to remove the following unverified and conclusory statement from § 1904.1(a): '"The records: * * * accurately describe the nature of occupational safety and health problems for the Nation, State or establishment" (Exs. 25, 15: 305). OSHA did not intend this statement to attest with certainty to the validity of national occupational statistics. Proposed section 1904.1(a) merely paraphrased section 2(b) of the Act, which states that such records "will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem." In response to commenters, OSHA has simplified the final rule by deleting the proposed listing of the functions of the records required by this rule.

As discussed earlier, proposed paragraph (b) stated that the recording of a case did not "necessarily mean that the employer or employee was at fault, that an OSHA standard was violated, or that the employee is eligible for workers' compensation or other insurance benefits." The last sentence of proposed paragraph (b) described the various types of workplace events or exposures that may lead to a recordable injury or illness.

A number of commenters agreed with the proposed statements on fault, compliance, and the relationship between the recording of a case and workers' compensation or other insurance (see, *e.g.*, Exs. 25, 15: 305, 346, 420). Employers have frequently asked OSHA to explain the relationship between workers' compensation reporting systems and the OSHA injury and illness recording and reporting requirements. As NYNEX (Ex. 15: 199) noted,

> [t]he issue of confusion between OSHA recordkeeping and workers' compensation/insurance requirements cannot be totally eliminated as the workers' compensation criteria vary somewhat from state to state. There will always be some differences between OSHA recordability and compensable injuries and illnesses. The potential consequences of these differences can be minimized, however, if all stakeholders in the recordkeeping process (i.e., employers, employees, labor unions, OSHA compliance officials) are well informed that OSHA recordability does not equate to compensation eligibility. This can be facilitated by printed reminders on all of the OSHA recordkeeping documents (*e.g.*, forms, instructions, pamphlets, compliance directives, etc.).

As NYNEX observed, employers must document work-related injuries and illnesses for both OSHA recordkeeping and workers' compensation purposes. Many cases that are recorded in the OSHA system are also compensable under the State workers' compensation system, but many others are not. However, the two systems have different purposes and scopes. The OSHA recordkeeping system is intended to collect, compile and analyze uniform and consistent nationwide data on occupational injuries and illnesses. The workers' compensation system, in contrast, is not designed primarily to generate and collect data but is intended primarily to provide medical coverage and compensation for workers who are killed, injured or made ill at work, and varies in coverage from one State to another.

Although the cases captured by the OSHA system and workers' compensation sometimes overlap, they often do not. For example, many injuries and illnesses covered by workers' compensation are not required to be recorded in the OSHA records. Such a situation would arise, for example, if an employee were injured on the job, sent to a hospital emergency

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room, and was examined and x-rayed by a physician, but was then told that the injury was minor and required no treatment. In this case, the employee's medical bills would be covered by workers' compensation insurance, but the case would not be recordable under Part 1904.

Conversely, an injury may be recordable for OSHA's purposes but not be covered by workers' compensation. For example, in some states, workers' compensation does not cover certain types of injuries (*e.g.*, certain musculoskeletal disorders) and certain classes of workers (*e.g.*, farm workers, contingent workers). However, if the injury meets OSHA recordability criteria it must be recorded even if the particular injury would not be compensable or the worker not be covered. Similarly, some injuries, although technically compensable under the state compensation system, do not result in the payment of workers' compensation benefits. For example, a worker who is injured on the job, receives treatment from the company physician, and returns to work without loss of wages would generally not receive workers' compensation because the company would usually absorb the costs. However, if the case meets the OSHA recording criteria, the employer would nevertheless be required to record the injury on the OSHA forms.

As a result of these differences between the two systems, recording a case does not mean that the case is compensable, or vice versa. When an injury or illness occurs to an employee, the employer must independently analyze the case in light of both the OSHA recording criteria and the requirements of the State workers' compensation system to determine whether the case is recordable or compensable, or both.

The American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) urged OSHA to emphasize the no-fault philosophy of the Agency's recordkeeping system, stating:

> The AFL–CIO is encouraged by some provisions currently in the proposed rulemaking which indirectly address underreporting. But, we believe the Agency must take it one step further. To adequately address this problem, the Agency must encourage employers to adopt a "no fault system" philosophy in the workplace and remove barriers which discourage the reporting of injuries and illnesses by employees. This philosophy will not only encourage workers to report injuries and illnesses, but also encourage those individuals (*e.g.*, supervisors, safety personnel) responsible for recording this data to report all recordable incidents (Ex. 15: 418).

OSHA believes that the note to the Purpose paragraph of the final rule will allay any fears employers and employees may have about recording injuries and illnesses, and thus will encourage more accurate reporting. Both the Note to Subpart A of the final rule and the new OSHA Form 300 expressly state that recording a case does not indicate fault, negligence, or compensability.

The Workplace Health and Safety Council, the American Coke and Coal Chemicals Institute, and the National Oilseed Processors Association (Exs. 15: 313, 352, 353) all urged OSHA to improve on this paragraph of the proposed rule in two ways. First, these commenters asked OSHA to remove the word "necessarily" from the language of proposed paragraph (b), which stated that recording did not "necessarily mean" that anyone was at fault, that a standard had been violated, or that the case was compensable:

> The qualification "necessarily" robs the [proposed] sentences of their meaning and makes them inaccurate. Using the word erroneously implies that merely listing an injury sometimes does mean that the employer or employee was at fault, that an OSHA standard was violated, or that the employee is eligible for workers' compensation. Clearly, this is not what OSHA intended to convey. Indeed, the word "necessarily" may actually worsen the problem OSHA seeks to solve, for attorneys and consultants reading the proposed provision might well advise employers that the provision actually endorses some uses of a listing against an employer.
>
> OSHA should, therefore, delete the word "necessarily. * * *" Alternatively, the sentence in the regulation should read: "That an injury or illness is recordable has no bearing on whether the employer or employee was at fault, an OSHA standard violated, or the employee is eligible for workers' compensation. * * *" The legend in the form would be similarly changed (Exs. 15: 313, 352, 353).

These three commenters (Exs. 15: 313, 352, 353) also suggested the following:

> (a) much preferred additional solution, would be for OSHA to promulgate in the final version a provision that makes inadmissible in all proceedings, both those under the OSH Act and those under any state or federal law, the entries in Form OSHA 300 and 301 as evidence of fault or culpability. Such a regulation would give employers the necessary assurance that their recordkeeping forms would not be used against them. Injured employees would lose nothing by this, for they could still be permitted to prove the fact of injury, its work-relatedness, and its consequence, with normal proof. They would simply not be permitted to introduce the forms as evidence of culpability. Such a rule would implement, be consistent with, and be authorized by Section 4(b)(4) of the Act, which prohibits the Act from affecting workers' compensation and tort schemes.

OSHA agrees with the point made by these commenters about the proposed rule's use of the word "necessarily." Accordingly, the word necessarily has been deleted from the Note to the Purpose paragraph of the final rule. However, OSHA has rejected the suggestion made by these commenters to limit the admissibility of the forms as evidence in a court proceeding. Such action is beyond the statutory authority of the agency, because OSHA has no authority over the courts, either Federal or State.

In the proposal, the no-fault statement was followed by a listing of the various causes of recordable injuries and illnesses: "Recordable workplace injuries and illnesses result from a variety of workplace events or exposures, including but not limited to: accidents, exposure to toxic materials or harmful physical agents, intentional acts of violence, or naturally occurring events such as a tornado or earthquake." The American Petroleum Institute (API) (Ex. 15: 375) objected to this proposed sentence describing the various examples of injury and illness causality, stating:

> To help the system have much-needed credibility, "regardless of fault or preventability" should not be applied beyond reasonable limits. Specifically, it shouldn't mean "tornado or earthquake" or other sudden, unforeseen catastrophic events over which the employer clearly could not have any control. Employers can, however, exercise control to prevent injury from some types of naturally occurring events. The terms "tornado or earthquake" should be replaced with more reasonable examples.

In the final rule, OSHA has decided to eliminate the sentence of examples to make the regulatory text clearer and more concise. However, OSHA notes that many circumstances that lead to a recordable work-related injury or illness are "beyond the employer's control," at least as that phrase is commonly interpreted. Nevertheless, because such an injury or illness was caused, contributed to, or significantly aggravated by an event or exposure at work, it must be recorded on the OSHA form (assuming that it meets one or more of the recording criteria and does not qualify for an exemption to the geographic presumption). This approach is consistent with the no-fault recordkeeping system OSHA has adopted, which includes work-related injuries and illnesses, regardless of the level of employer control or non-control involved. The issue of whether different types of cases are deemed work-related under the OSHA recordkeeping rule is discussed in the Legal Authority section, above, and in the work-relationship section (section 1904.5) of this preamble.

In a comment on proposed paragraph (a), the National Association of Manufacturers (NAM) (Exs. 25, 15: 305) argued that the OSHA recordkeeping system should only collect information on

> "the most significant hazards, those that lead to the most significant injuries and illnesses * * *" and that the purpose paragraph of the final rule be revised to state "The purpose of this Part is to require employers to record and report disabling, serious and significant work-related injuries and illnesses, and work-related fatalities."

OSHA does not agree with this interpretation of the OSH Act. As discussed in the Legal Authority section, above, Congress stated clearly that the OSHA recordkeeping system was intended to capture "work-related deaths, injuries and illnesses, *other than minor injuries* requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job" (Sec. 8(c)(2)) (emphasis added). The words "disabling, serious, and significant," suggested by NAM, are at variance with Congress' clear intent. OSHA concludes that the guidance given by Congress—that employers should record and report on work-related deaths, and on injuries and illnesses other than minor injuries, establishes the appropriate recording threshold for cases entered into the OSHA recordkeeping system.

A few commenters recommended that OSHA delete paragraph (c) of the proposed Purpose section (see, *e.g.*, Exs. 25, 15: 305, 346, 348, 420), and in the final rule, OSHA has done so because the paragraph merely attested to OSHA's cooperation with other agencies on this rule. Although the rule has, in fact, been developed in cooperation with the Department of Health and Human Services, and specifically with the National Institute for Occupational Safety and Health (NIOSH), there is no need to include this information in the regulatory text itself.

Subpart B. Scope

The coverage and partial exemption provisions in Subpart B of the final rule establish which employers must keep OSHA injury and illness records at all times, and which employers are generally exempt but must keep records under specific circumstances. This subpart contains sections 1904.1 through 1904.3 of the final rule.

OSHA's recordkeeping rule covers many employers in OSHA's jurisdiction but continues to exempt many employers from the need to keep occupational injury and illness records routinely. This approach to the scope of the rule is consistent with that taken in the former recordkeeping rule. Whether a particular employer must keep these records routinely depends on the number of employees in the firm and on the Standard Industrial Classification, or SIC code, of each of the employer's establishments. Employers with 10 or fewer employees are not required to keep OSHA records routinely. In addition, employers whose establishments are classified in certain industries are not required to keep OSHA records under most circumstances. OSHA refers to establishments exempted by reason of size or industry classification as "partially exempt," for reasons explained below.

The final rule's size exemption and the industry exemptions listed in non-mandatory Appendix A to Subpart B of the final rule do not relieve employers with 10 or fewer employees or employers in these industries from *all* of their recordkeeping obligations under 29 CFR Part 1904. Employers qualifying for either the industry exemption or the employment size exemption are not routinely required to record work-related injuries and illnesses occurring to their employees, that is, they are not normally required to keep the OSHA Log or OSHA Form 301. However, as sections 1904.1(a)(1) and 1904.2 of this final recordkeeping rule make clear, these employers must still comply with three discrete provisions of Part 1904. First, all employers covered by the Act must report work-related fatalities or multiple hospitalizations to OSHA under § 1904.39. Second, under § 1904.41, any employer may be required to provide occupational injury and illness reports to OSHA or OSHA's designee upon written request. Finally, under § 1904.42, any employer may be required to respond to the Survey of Occupational Injuries and Illnesses conducted by the Bureau of Labor Statistics (BLS) if asked to do so. Each of these requirements is discussed in greater detail in the relevant portion of this summary and explanation.

Section 1904.1 Partial Exemption for Employers With 10 or Fewer Employees

In § 1904.1 of the final rule, OSHA has retained the former rule's size-based exemption, which exempts employers with 10 or fewer employees in all industries covered by OSHA from most recordkeeping requirements. Section 1904.1, "Partial exemption for employers with 10 or fewer employees," states that:

> (a) Basic requirement.
>
> (1) If your company had ten (10) or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA or the BLS informs you in writing that you must keep records under § 1904.41 or § 1904.42. However, as required by § 1904.39, all employers covered by the OSH Act must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees.
>
> (2) If your company had more than ten (10) employees at any time during the last calendar year, you must keep OSHA injury and illness records unless your establishment is classified as a partially exempt industry under § 1904.2.
>
> (b) Implementation.
>
> (1) Is the partial exemption for size based on the size of my entire company or on the size of an individual business establishment?
>
> The partial exemption for size is based on the number of employees in the entire company.
>
> (2) How do I determine the size of my company to find out if I qualify for the partial exemption for size?
>
> To determine if you are exempt because of size, you need to determine your company's peak employment during the last calendar year. If you had no more than 10 employees at any time in the last calendar year, your company qualifies for the partial exemption for size.

The Size-Based Exemption in the Former Rule

The original OSHA injury and illness recording and reporting rule issued in July 1971 required all employers covered by the OSH Act to maintain injury and illness records. In October 1972, an exemption from most of the recordkeeping requirements was put in place for employers with seven or fewer employees. In 1977, OSHA amended the rule to exempt employers with 10 or fewer employees, and that exemption has continued in effect to this day. All employers, however, have always been required to report fatalities and catastrophes to OSHA and to participate in the BLS survey, if requested to do so.

As discussed in the Legal Authority section of this preamble, the 10 or fewer employee threshold is consistent with Congressional intent: the 1977 **Federal Register** notice announcing the new exemption cited the Department of Labor appropriations acts for fiscal years 1975 and 1976, which exempted employers having 10 or fewer employees from most routine recordkeeping requirements, and Section 8(d) of the Act, as the major reasons for raising the exemption size threshold from seven to 10 employees. The 1977 Notice stated that the new size

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threshold appropriately balanced the interest of small businesses while preserving the essential purposes of the recordkeeping scheme:

> The [exemption] has been carefully designed to carry out the mandate of section 8(d) without impairing the Act's basic purpose. Thus, the [exemption] will not diminish the protections afforded employees under the Act because all employers * * * remain subject to the enforcement provisions of the Act. The [exemption] will continue to require * * * small employers * * * to report fatalities and multiple hospitalizations and to participate in the BLS annual survey when selected to do so (42 FR 38568 (July 29, 1977)).

The Size-Based Exemption in the Final Rule

The final rule published today maintains the former rule's partial exemption for employers in all covered industries who have 10 or fewer employees. Under the final rule (and the former rule), an employer in any industry who employed no more than 10 employees at any time during the preceding calendar year is not required to maintain OSHA records of occupational illnesses and injuries during the current year unless requested to do so in writing by OSHA (under § 1904.41) or the BLS (under § 1904.42). If an employer employed 11 or more people at a given time during the year, however, that employer is not eligible for the size-based partial exemption.

The Size-Based Exemption in the Proposed Rule

In the 1996 proposal, OSHA contemplated raising the threshold for the size-based exemption to 19 employees for all employers except those in the construction industry. In proposing this more extensive exemption, OSHA stated that BLS Annual Survey data appeared to indicate that small businesses in this size category had proportionately fewer injuries and illnesses and were thus safer places to work. However, since the proposal, OSHA has analyzed the record evidence on this point and now believes that small businesses are not generally likely to be less hazardous than larger businesses and, in fact, are likely, as a general matter, to be more hazardous than large businesses. OSHA's reasoning is described below.

Comments to the record make clear that the recording of fewer injuries and illnesses by very small firms could have many causes other than a lower level of hazards. For example, the National Institute for Occupational Safety and Health (NIOSH) submitted a comment to the record that described numerous studies based on fatality and workers' compensation data that suggest that smaller businesses are at least as hazardous as larger businesses (Ex. 15: 407). NIOSH also argued that the BLS estimated injury and illness incidence rates for small employers may be erroneously low, i.e., may be the result of underreporting rather than a lower injury rate. The following comment from NIOSH explains these concerns:

> From a public standpoint, NIOSH does not support a partial exemption from recordkeeping requirements for employers in the construction industry with 10 or fewer employees, and non-construction employers with 19 or fewer employees. Research indicates significant safety and health problems in "small" establishments which employ a substantial proportion of the workforce. One-quarter of the civilian, full-time workforce is employed in establishments with fewer than 25 employees (Oleinick et al. 1995).
>
> The Occupational Safety and Health Administration (OSHA) notes [in the proposal to the recordkeeping rule] that "the Annual Survey data show that small employers generally experience much lower patterns of injuries and illnesses than medium size firms." However, recent literature comparing Annual Survey data and workers compensation data questions the validity of the estimated rates for small employers obtained through the Bureau of Labor Statistics (BLS) Annual Survey. Moreover, fatal and nonfatal work injuries are a significant risk among small businesses in hazardous industries and many industries with high fatal and nonfatal injury rates are comprised primarily of small companies. In addition, NIOSH research indicates that small companies have less access to safety and health programs that might reduce injuries and illnesses than larger companies [NIOSH 1988a].
>
> Though the Annual Survey of Occupational Injuries and Illnesses has consistently reported that employers with fewer than 20 employees have significantly lower rates of injuries and illnesses, there is concern that these low incidence rates are an artifact of the reporting system. Analysis of compensable injuries with >7 missed workdays in Michigan indicates that the pattern of lower injury rates among small employers is not consistent across industry divisions. Though the services and trade industry divisions show a marked decline in compensable injury rate for small size firms, the higher risk industries of construction and transportation/utilities show relatively little decline in the compensable injury rate for employers with fewer than 25 employees. Comparison of the demographic characteristics of the Michigan work force with the demographic characteristics of injured workers suggest that high risk groups (*e.g.*, males, younger workers [<35 years of age], construction, manufacturing, transportation, and blue collar workers) are over-represented among workers injured in small size firms (<25 workers). Using cumulative lost work time as a surrogate for severity of injury, the Michigan study also found that with one exception (construction), compensable injuries to workers in small firms were at least as serious as compensable injuries in larger firms [Oleinick et al. 1995] (Ex. 15: 407).
>
> Since publication of the recordkeeping proposal, OSHA has done considerable research into the issue of fatality, injury, and illness rates in small companies. The results of this research also point to underreporting, rather than safer workplaces, as a likely reason for the lower-than-average injury and illness numbers reported by small employers. The most telling evidence that injury and illness underreporting is prevalent among small firms is the substantial discrepancy between the fatality rates in these firms and their injury and illness rates.
>
> Most professionals agree that occupational fatality data are more reliable than occupational injury and illness data, primarily because fatalities are more likely to be reported than injuries. The work-related BLS fatality data appear to confirm this belief, showing that although businesses with fewer than 10 employees account for only 4% of the total workforce, they account for 28% of occupational fatalities. Furthermore, although businesses with fewer than 20 employees comprise only 26% of the total workforce, they account for 36% of all occupational fatalities (see Mendeloff, "Using OSHA Accident Investigations to Study Patterns in Work Fatalities," *J. Occup. Med* 32: 1117, 1119 (1990) (Ex. 15: 407 F)). These data strongly suggest that very small businesses are disproportionately hazardous places to work.
>
> Many safety and health professionals also believe that injuries and illnesses are substantially underreported by small employers (see, *e.g.*, Exs. 4, 5, 15: 407). However, the occupational injury and illness data reported by employers to the BLS in connection with its Annual Survey of Occupational Injuries and Illnesses show lower rates of injuries and illnesses for firms in the smallest size classes than for those in larger classes. In an effort to understand why smaller firms might have lower injury and illness incidence rates, the authors of one study found that: (1) occupational fatality rates were highest in businesses with fewer than 50 employees; (2) businesses with fewer than 50 employees were least likely to have occupational health services available; and (3) lost workday injury rates in several major industry categories are highest (i.e., the injuries are most severe) in these facilities. From these findings, the authors concluded:

> It is difficult to imagine a set of workplace conditions in small establishments that would lead simultaneously to lower injury rates, higher fatality rates, and equal, or greater, injury severity measured by missed work time, especially since these establishments were less likely to provide injury prevention and safety services (Oleinick *et al.*, "Establishment Size and Risk of Occupational Injury," *Am. J. Med.* 28(1): 2–3 (1995) (Ex. 15: 407 N)).

After considering a number of explanations that might explain this apparent incongruity, these authors rejected all explanations except one—underreporting by small firms:

> With the rejection of alternative explanations, there is a strong likelihood of underreporting as the explanation, and we estimate that the annual [BLS] survey substantially undercounts injuries in small establishments (Oleinick et al., 1995 (Ex. 15: 407 N)).

NIOSH agrees, noting that "recent literature comparing Annual Survey data and workers compensation data questions the validity of the estimated rates for small employers obtained through the BLS Annual Survey" (Ex.15: 407). Thus, the apparent discrepancy between the high fatality rate in the smallest firms (i.e., those with fewer than 20 employees) and the low rates of injuries and illnesses reported by those same firms is likely to be the result of underreporting rather than lower relative hazards.

A *Wall Street Journal* (Feb. 3, 1994) computer analysis of more than 500,000 Federal and State safety-inspection records came to the same conclusions, i.e., that employees of small businesses are at greater risk of exposure to workplace hazards than employees of larger businesses, and that BLS data for small firms seriously understate injuries and illnesses in such firms. From 1988 through 1992, the analysis found an incidence of 1.97 deaths per 1,000 workers at workplaces with fewer than 20 employees, compared with an incidence of just 0.004 deaths per 1,000 workers at workplaces with more than 2,500 workers. Thus, an employee's risk of death was approximately 500 times higher at the smallest businesses compared with the risk at the largest businesses. Similarly, while one in six employees at small businesses worked in an area cited for a serious safety violation, only one in 600 did so at the largest businesses. This means that employees in small businesses are 100 times more likely to be exposed to a serious hazard at work than those in the largest businesses, a finding that is consistent with the higher fatality rates in very small workplaces (*Wall Street Journal*, February 3, 1994).

In the final rule, OSHA has decided to continue the Agency's longstanding practice of partially exempting employers with 10 or fewer employees from most recordkeeping requirements, but not to extend the exemption to non-construction businesses with 19 or fewer employees, as was proposed. OSHA has determined that increasing the number of employers partially exempted is not in the best interests of the safety and health of their employees. First, as NIOSH's comments (Ex. 15: 407), the Oleinick et al. study (1995), the Mendeloff article (1990), and the *Wall Street Journal* study (1994) all indicate, businesses with 20 or fewer employees tend to be relatively hazardous places to work, and their employees have a disproportionately high risk of work-related death. Second, as NIOSH and others point out, there is reason to believe that these very small workplaces also experience disproportionately high numbers of injuries and illnesses, and that the BLS statistics for these workplaces substantially underreport the extent of job-related incidents at these establishments (Ex. 15: 407, Oleinick et al. 1995, *Wall Street Journal* 1994 (Ex. 15: 407 N). Finally, under the 10 or fewer employee partial exemption threshold, more than 80% of employers in OSHA's jurisdiction are exempted from routinely keeping records. Increasing the threshold for the size exemption would deprive even more employers and employees of the benefits of the information provided by these injury and illness records and reduce the number of establishments where the records can be of use to the government during an on-site visit. OSHA also believes that keeping the OSHA Log and Incident Report is important for national statistical purposes.

Size Exemption Threshold for Construction Companies

The final rule also retains the former rule's size exemption threshold (10 or fewer employees) for construction employers. OSHA proposed separate size thresholds for construction and nonconstruction firms, i.e., the Agency proposed to exempt firms in construction with 10 or fewer employees and non-construction firms with 19 or fewer employees from routine recordkeeping requirements. Comments on this aspect of the proposal were mixed. Some commenters agreed that OSHA should continue the exemption for construction employers with ten or fewer employees (see, *e.g.*, Exs. 15: 145, 170, 197, 288). Other commenters urged that employers in the construction industry not be exempted from recordkeeping at all (see, *e.g.*, Exs. 15: 62, 74, 414). For example, Robert L. Rowan, Jr. stated that:

> [s]mall contractors often lack adequate safety knowledge, programs and safeguards to prevent injuries and illnesses. I believe that data obtained from these small contractors will point to a trend that these employees have a relatively high frequency of injuries that are related to tasks involving construction work such as excavations and fall hazards. I suggest that there be no exemptions for recordkeeping for any construction employer (Ex. 15: 62).

Other commenters asked OSHA to use a single size threshold for employees in all industries and to raise the size exemption threshold to more than 19 employees across the board (see, *e.g.*, Exs. 15: 67, 304, 312, 344, 437). For example, the Sheet Metal and Air Conditioning Contractors' National Association (SMACNA) remarked:

> The recordkeeping standard is considered to be a horizontal standard, which by definition, means that it covers all industries. SMACNA members own and operate sheet metal fabrication shops where they design and create the products which are then installed in the construction process, including duct work and all types of specialty and architectural sheet metal. Sheet metal fabrication shops fall under the manufacturing classification and are therefore subject to general industry standards. SMACNA contractors also construct with the components that they fabricate. Therefore, as contractors they must also comply with the OSHA standards for construction.
>
> OSHA's arbitrary two tier record keeping requirement will cause confusion among SMACNA contractors as to which classification they are under and when they have to maintain records. With the volumes of regulations that contractors already must comply with, it is only logical that if OSHA truly wishes to simplify its recordkeeping requirements it would create a uniform standard for all industries. * * *
>
> SMACNA urges OSHA to create a uniform horizontal standard and increase the exemption for the construction industry to cover employers with 19 or fewer employees (Ex. 15: 116).

After a review of the record and reconsideration of this issue, OSHA agrees that there should be only one size exemption threshold across all industries and finds that the threshold should be 10 or fewer employees. This threshold comports both with longstanding Agency practice and Congressional intent. Further, as discussed above, OSHA finds that extending this threshold to include firms with 11 to 19 employees is not warranted by the evidence. Firms in this size range have a disproportionately large number of fatalities, and their

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lower reported injury and illness rates are likely to be the result of underreporting rather than fewer hazards. Thus, companies in this size class need the information their OSHA records provide to improve conditions in their workplaces and to protect their employees from job-related injuries, illnesses, and deaths. Likewise, OSHA does not believe that it would be appropriate to remove the partial exemption for construction employers with 10 or fewer employees, as some commenters suggested (see, *e.g.*, Exs. 15: 67, 304, 312, 344, 437). Using the same size threshold for all OSHA-covered industries also makes the rule simpler and is more equitable from industry to industry.

Comments on Raising the Size-Based Exemption

Many commenters supported raising the size-based exemption threshold (see, *e.g.*, Exs. 27, 15: 26, 27, 67, 102, 123, 145, 170, 173, 182, 198, 247, 288, 304, 359, 375, 378, 392, 401, 437). For example, the American Society of Safety Engineers (ASSE) remarked:

> ASSE supports exempting businesses under twenty (20) employees from the standard with some specific industry exemptions. Enforcing this regulation for businesses of less than twenty (20) employees would be detrimental to small business from the recordkeeping/bureaucracy perspective, and may not generate any significant data. ASSE wishes to clarify, however, that this position should not be interpreted to mean that small businesses should be exempted from safety and health laws. We believe that all employees are entitled to an equal level of safety and health regardless of the size of their place of employment. Exempting a paperwork requirement does not change this level of commitment (Ex. 15: 182).

Two commenters suggested that OSHA use an even higher threshold for determining the size-based exemption (Exs. 15: 357, 408). The Synthetic Organic Chemical Manufacturers Association (SOCMA) stated "* * * SOCMA believes that OSHA should modify the small employer exemption by increasing it to 40 employees. This alternative approach would reduce the employer paperwork burden while improving the accuracy of injury and illness information" (Ex. 15:357). Similarly, the American Dental Association (ADA) commented "The ADA suggests that OSHA expand the proposed exemption from 'fewer than 20 employees' to 'fewer than 25 employees.' This would bring the small-employer exception into conformity with many federal and state employment laws. It would also serve as a more reasonable dividing line between small employers and others" (Ex. 15:408).

Some commenters, however, objected to OSHA's proposed exemption of employers in the 11 to 20 employee size range (see, *e.g.*, Exs. 15:62, 369, 379, 407, 415, 418). Among these was the International Brotherhood of Teamsters (IBT), which stated:

> IBT maintains the importance of recording of all occupational injuries and illnesses. For that same reason, International Brotherhood of Teamsters does not support increasing the trigger for non-construction employers from ten to nineteen employees. Although injuries due to preventable causes occur in all types and sizes [of businesses], a disproportionately high number of fatalities occur in the smallest businesses. According to an analysis of BLS and OSHA data, then assistant secretary of labor, Joe Dear, told the House of Representative's Small Business Committee, "Businesses with fewer than eleven workers account for 33 percent of all fatalities even though they account for less than 20 percent of employees." According to a study by the National Federation of Independent Businesses, "generally businesses with fewer employees do less to improve safety than those with more." Large corporations can afford the full-time services of a safety engineer and industrial hygienist, whereas often small firms cannot. IBT contends that it is up to OSHA to protect the workers and institute prevention measures. The use of required recordkeeping of data helps to reach that aim by providing hard data. If the data is going to be used as a prevention tool, it must be collected from the entire workforce not just a subgroup (Ex. 15:369).

Reliance on a single size exemption threshold also addresses the point made by SMACNA: that many small employers perform construction work and also manufacture products and would therefore be uncertain, if the rule contained two size exemption thresholds, as to whether they are required to keep records or not.

OSHA's proposed rule stated that the size exemption would apply to employers based on the number of employees employed by the employer "for the entire previous calendar year." The Office of Advocacy of the Small Business Administration (SBA) observed (Ex. 15:67, p. 4) that this statement could be interpreted in various ways, and expressed concern that it could be taken to refer to the total number of employees who had been employed at one time or another during the year rather than the total employed at any one time of the year. The SBA office recommended that OSHA provide clearer guidance. OSHA agrees with the SBA that the proposed regulatory language was ambiguous. Accordingly, the final rule clarifies that the 10 or fewer size exemption is applicable only if the employer had fewer than 11 employees at all times during the previous calendar year. Thus, if an employer employs 11 or more people at any given time during that year, the employer is not eligible for the small employer exemption in the following year. This total includes all workers employed by the business. All individuals who are "employees" under the OSH Act are counted in the total; the count includes all full time, part time, temporary, and seasonal employees. For businesses that are sole proprietorships or partnerships, the owners and partners would not be considered employees and would not be counted. Similarly, for family farms, family members are not counted as employees. However, in a corporation, corporate officers who receive payment for their services are considered employees.

Consistent with the former rule, the final rule applies the size exemption based on the total number of employees in the firm, rather than the number of employees at any particular location or establishment. Some commenters suggested that the size exemption should be based on the number of employees in each separate establishment rather than the entire firm (see, *e.g.*, Exs. 15: 67, 201, 437). For example, Caterpillar Inc. (Ex. 15: 201) noted:

> We do object to the note to [proposed] paragraph 1904.2(b)(2) which bases size exemptions on the total number of employees in a firm rather than the establishment size. Size exemptions must be based upon individual establishment size. The factors that make recordkeeping difficult and unproductive for small facilities are not eliminated by adding small facilities together. Small facilities are usually unique and adding together the injury and illness experience of different small facilities will not produce a valid database for accident analysis or accident prevention planning. Injury and illness data collection is difficult because of small facility size and lack of recordkeeping expertise and resources. The benefits of collecting information in small facilities does not justify the costs. It is illogical to base the size exemption on anything other than the size of each separate establishment.

OSHA does not agree with this comment because the resources available in a given business depend on the size of the firm as a whole, not on the size of individual establishments owned by the firm. In addition, the analysis of injury records should be of value to the firm as a whole, regardless of the size of individual establishments. Further, an exemption based on individual establishments would be difficult to administer, especially in

cases where an individual employee, such as a maintenance worker, regularly reports to work at several establishments.

Section 1904.2 Partial Exemption for Establishments in Certain Industries

Section 1904.2 of the final rule partially exempts employers with establishments classified in certain lower-hazard industries. The final rule updates the former rule's listing of partially exempted lower-hazard industries. Lower-hazard industries are those Standard Industrial Classification (SIC) code industries within SICs 52–89 that have an average Days Away, Restricted, or Transferred (DART) rate at or below 75% of the national average DART rate. The former rule also contained such a list based on data from 1978–1980. The final rule's list differs from that of the former rule in two respects: (1) the hazard information supporting the final rule's lower-hazard industry exemptions is based on the most recent three years of BLS statistics (1996, 1997, 1998), and (2) the exception is calculated at the 3-digit rather than 2-digit level.

The changes in the final rule's industry exemptions are designed to require more employers in higher-hazard industries to keep records all of the time and to exempt employers in certain lower-hazard industries from keeping OSHA injury and illness records routinely. For example, compared with the former rule, the final rule requires many employers in the 3-digit industries within retail and service sector industries that have higher rates of occupational injuries and illnesses to keep these records but exempts employers in 3-digit industries within those industries that report a lower rate of occupational injury and illness. Section 1904.2 of the final rule, "Partial exemption for establishments in certain industries," states:

> (a) Basic requirement.
> (1) If your business establishment is classified in a specific low hazard retail, service, finance, insurance or real estate industry listed in Appendix A to this Subpart B, you do not need to keep OSHA injury and illness records unless the government asks you to keep the records under § 1904.41 or § 1904.42. However, all employers must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).
> (2) If one or more of your company's establishments are classified in a non-exempt industry, you must keep OSHA injury and illness records for all of such establishments unless your company is partially exempted because of size under § 1904.1.
> (b) Implementation.
> (1) Does the partial industry classification exemption apply only to business establishments in the retail, services, finance, insurance or real estate industries (SICs 52–89)?
> Yes. Business establishments classified in agriculture; mining; construction; manufacturing; transportation; communication, electric, gas and sanitary services; or wholesale trade are not eligible for the partial industry classification exemption.
> (2) Is the partial industry classification exemption based on the industry classification of my entire company or on the classification of individual business establishments operated by my company?
> The partial industry classification exemption applies to individual business establishments. If a company has several business establishments engaged in different classes of business activities, some of the company's establishments may be required to keep records, while others may be exempt.
> (3) How do I determine the Standard Industrial Classification code for my company or for individual establishments?
> You determine your Standard Industrial Classification (SIC) code by using the Standard Industrial Classification Manual, Executive Office of the President, Office of Management and Budget. You may contact your nearest OSHA office or State agency for help in determining your SIC.

Employers with establishments in those industry sectors shown in Appendix A are not required routinely to keep OSHA records for their establishments. They must, however, keep records if requested to do so by the Bureau of Labor Statistics in connection with its Annual Survey (section 1904.42) or by OSHA in connection with its Data Initiative (section 1904.41). In addition, all employers covered by the OSH Act must report a work-related fatality, or an accident that results in the hospitalization of three or more employees, to OSHA within 8 hours (section 1904.39).

In 1982, OSHA exempted establishments in a number of service, finance and retail industries from the duty to regularly maintain the OSHA Log and Incident Report (47 FR 57699 (Dec. 28, 1982)). This industry exemption to the Part 1904 rule was intended to "reduce paperwork burden on employers without compromising worker safety and health."

The 1982 list of partially exempt industries was established by identifying lower hazard major industry groups in the SIC Divisions encompassing retail trade, finance, insurance and real estate, and the service industries (SICs 52–89). Major industry groups were defined as the 2-digit level industries from the SIC manual published by the U.S. Office of Management and Budget (OMB). Industries in these major industry groups were partially exempted from coverage by Part 1904 if their average lost workday injury rate (LWDI) for 1978–80 was at or below 75% of the overall private sector LWDI average rate for that year. Industries traditionally targeted for OSHA enforcement (those in SICs 01 through 51, comprising the industry divisions of agriculture, construction, manufacturing, transportation and public utilities, mining, and wholesale trade) remained subject to the full recordkeeping requirements. Although the 1982 **Federal Register** notice discussed the possibility of revising the exempt industry list on a routine basis, the list of partially exempt industries compiled in 1982 has remained unchanged until this revision of the Part 1904 rule.

The proposed rule would have updated the industry exemption based on more current data, and would have relied on 3-digit SIC code data to do so. The only change from the former rule taken in the proposal would have been reliance on LWDI rates for industries at the 3-digit, rather than 2-digit, level.

Evaluating industries at the 3-digit level allows OSHA to identify 3-digit industries with high LWDI rates (DART rates in the terminology of the final rule) that are located within 2-digit industries with relatively low rates. Conversely, use of this approach allows OSHA to identify lower-hazard 3-digit industries within a 2-digit industry that have relatively high LWDI (DART) rates. Use of LWDI (DART) rates at the more detailed level of SIC coding increases the specificity of the targeting of the exemptions and makes the rule more equitable by exempting workplaces in lower-hazard industries and requiring employers in more hazardous industries to keep records.

Under the proposal, based on their LWDI (DART) rates, the following industries would have been required to keep records for the first time since 1982:

SIC 553	Auto and Home Supply Stores
SIC 555	Boat Dealers
SIC 571	Home Furniture and Furnishings Stores
SIC 581	Eating Places
SIC 582	Drinking Places
SIC 596	Nonstore Retailers
SIC 598	Fuel Dealers
SIC 651	Real Estate Operators and Lessors
SIC 655	Land Subdividers and Developers
SIC 721	Laundry, Cleaning, and Garment Services
SIC 734	Services to Dwellings and Other Buildings
SIC 735	Miscellaneous Equipment Rental and Leasing
SIC 736	Personnel Supply Services
SIC 833	Job Training and Vocational Rehabilitation Services
SIC 836	Residential Care

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SIC 842 Arboreta and Botanical or Zoological Gardens, and
SIC 869 Membership Organizations Not Elsewhere Classified

The following industries would have been newly exempted by the proposal:

SIC 525 Hardware Stores
SIC 752 Automobile Parking
SIC 764 Reupholstery and Furniture Repair
SIC 793 Bowling Centers
SIC 801 Offices and Clinics of Doctors of Medicine
SIC 807 Medical and Dental Laboratories, and
SIC 809 Miscellaneous Health and Allied Services, Not Elsewhere Classified

In the Issues section of the preamble to the proposed rule, OSHA asked the public to comment on the appropriateness of the proposed exemption procedure, and on whether or not OSHA should expand this approach to industries in SICs 01 through 51. The Agency also asked for alternative approaches that would reduce employer paperwork burden while retaining needed injury and illness information, and for estimates of the costs and benefits associated with these alternatives. OSHA notes that the final rule is based on the most recent data available (1996–1998). Although it has relied on the methodologies proposed (3-digit SIC codes, industries below 75% of the national average LWDI rate), there have been a few shifts in the industries proposed to be covered and those actually covered by the final rule. Thus this final rule will continue to exempt eating and drinking places (SICs 581 and 582) but will not exempt automobile parking (SIC 752).

Comments on the Proposed Industry Exemptions

A number of commenters supported OSHA's proposal to apply the 1982 exemption criteria to the service and retail industries at the three-digit SIC level (see, *e.g.*, Exs. 27; 15: 26, 199, 229, 247, 272, 299, 359, 375, 378, 392). However, a number of commenters opposed any exemptions from the Part 1904 requirements on the basis of industry classification (see, *e.g.*, Exs. 15: 9, 13, 31, 62, 78, 83, 129, 153, 154, 163, 186, 197, 204, 234, 350, 379, 399, 414). The International Paper Company explained its reasons for opposing industry exemptions as follows:

> Exempting employers with low incidence rates is inconsistent with a major objective of the recordkeeping rules; specifically, measuring the magnitude of work-related injuries and illnesses. Exemption of specific industrial classifications or small employers may bias statistics which are used by OSHA for identifying industries for inspections. These exemptions may also impact statistics related to less traditional, but increasingly more frequent exposures such as bloodborne pathogens, tuberculosis, motor vehicle incidents or workplace violence.
>
> Exempting employers with low incidence rates does not provide any measurable relief from paperwork requirements. Time spent on recordkeeping is primarily dedicated to decision making regarding work relationship and recordability, not actual Log entries or completing supplemental reports. Simplifying the decision making process is the best way to reduce the burden of recordkeeping, not exempting employers (Ex. 15:399).

The Service Employees International Union (SEIU) agreed:

> Injury and illness recordkeeping is the most basic step an employer must take in order to begin to address workplace hazards. Responsible employers recognize that injury and illness records are a useful tool for development of sound company safety and health programs. This information is also critical to the workers themselves, by raising awareness about how and where people are getting hurt, they in turn use this information to work to eliminate the causes of such injuries and illnesses. Therefore it is disturbing that in the proposed revised standard, there still exist industry exemptions for recordkeeping and reporting. Prior to 1983, all employers covered by OSHA with more than ten employees were required to maintain injury and illness records.
>
> * * * SEIU believes that such exemptions are unwarranted and violate the specific language of the Occupational Safety and Health Act. * * * The Act does not provide for excluding entire classes of occupationally injured and sick workers. Furthermore, little recordkeeping will be required for industries that are safe and experience low rates of injuries and illnesses. It is critical that OSHA require recordkeeping for all industries, especially since many previously exempt sectors now experience increasing rates of injury and illness. Many of these industry sectors are also dramatically expanding—therefore, continued recordkeeping is even more critical (Ex. 15:379).

The National Safety Council (Ex. 15:359) cautioned:

> From the point of view of injury and illness prevention. * * * an establishment that does not track its injury and illness experience cannot effectively administer a prevention program. * * *

Although OSHA encourages employers to track the occupational injuries and illnesses occurring among their employees and agrees that doing so is important for safety and health prevention efforts, OSHA has decided in the final rule to continue the long-established practice of exempting employers in industries with lower average lost workday incidence rates from most OSHA recordkeeping requirements but to tie the exemption as closely as possible to specific 3-digit SIC code data.

Accordingly, non-mandatory Appendix A of the final rule identifies industries for exemption at the 3-digit SIC code level. Although this approach does make the list of exempt industries longer and more detailed, it also targets the exemption more effectively than did the former rule's list. For example, the final rule does not exempt firms in many of the more hazardous 3-digit SIC industries that are embedded within lower rate 2-digit SIC industries. It does, however, exempt firms in relatively low-hazard 3-digit SIC industries, even though they are classified in higher hazard 2-digit SIC industries. Where Days Away, Restricted, or Transferred (DART, formerly LWDI) rate calculations exempt all of the 3-digit SIC industries within a given 2-digit industry, the exempt industry list in Appendix A displays only the 2-digit SIC classification. This approach merely provides a shorter, simpler list.

For multi-establishment firms, the industry exemption is based on the SIC code of each establishment, rather than the industrial classification of a firm as a whole. For example, some larger corporations have establishments that engage in different business activities. Where this is the case, each establishment could fall into a different SIC code, based on its business activity. The Standard Industrial Classification manual states that the establishment, rather than the firm, is the appropriate unit for determining the SIC code. Thus, depending on the SIC code of the establishment, one establishment of a firm may be exempt from routine recordkeeping under Part 1904, while another establishment in the same company may not be exempt.

Several commenters suggested that OSHA use an alternate method for determining exemptions (see, *e.g.*, Exs. 15: 97, 201, 359). The National Safety Council (Ex. 15: 359), for example, urged OSHA to "evaluate other exemption procedures before incorporating one into proposed section 1904.2."

OSHA has evaluated other approaches but has decided that the 3-digit DART rate method is both simpler and more equitable than the former 2-digit method. By exempting lower-hazard industry sectors within SICs 52–89, OSHA hopes both to concentrate its recordkeeping requirements in sectors that will provide the most useful data and to minimize paperwork burden. No exemption method is perfect: any method that exempts broad classes of employers from recordkeeping obligations will exempt some more hazardous workplaces and cover some less hazardous workplaces. OSHA has attempted to minimize both of these problems by using the most current injury and illness statistics available, and by applying them to a more detailed industry level within the retail, financial and service sectors than was formerly the case. OSHA has also limited the scope of the exemptions by using an exemption threshold that is well below the national average, including only those industries that have average DART rates that are at or below 75% of the national average DART rate. The rule also limits the exempt industries to the retail, financial and service sectors, which are generally less hazardous than the manufacturing industry sector.

The Orlando Occupational Safety and Health Customer Council asked: "What is the criteria for exemptions? For example, large auto dealers who also perform auto repair work are exempt, while smaller auto repair shops are not exempt. Why not classify the organization by the most hazardous occupation [within that organization]?" (Ex. 15: 97).

In response to this query, OSHA notes that the exemption procedure is reasonably straightforward, as the following example illustrates: the automobile dealer industry is exempt because its DART rate, as indicated by its average over three years of BLS data, is below 75% of the national average rate. Automobile repair shops are not exempted, however, because their rate is higher than the 75% cutoff. If OSHA were to base its recordkeeping requirements on the most hazardous occupation within a given industry, assuming that occupation-specific within-industry injury and illness data were available, as this commenter suggests, the number of establishments in individual industries that would have to keep records would greatly increase. This is because even relatively safe industries have some number of employees who engage in relatively hazardous occupations. For example, workers who transport currency, coins, and documents for banks and other financial institutions are engaged in a fairly hazardous occupation. They may be injured in many different ways, ranging from highway accidents, to lifting of heavy parcels, to robberies. However, the experience of these few employees within the industry does not accurately reflect the relative degree of hazard confronting the vast majority of employees in the financial industries. Although it is certainly not perfect, OSHA believes that the BLS lost workday injury rate (DART rate) is a better comparative statistic than the injury rate for a particular occupation because it reflects the risk to the average worker within the particular industry. Moreover, while it is relatively easy to classify employees according to occupation, it is unclear how to classify individual employers with regard to detailed occupation, and OSHA is also not aware of data that would permit such classification.

The Caterpillar Corporation (Ex. 15: 201) suggested that OSHA adjust the formula used to determine which industries are exempted:

> You propose to base your exemption on achieving less than 75% of the average private sector lost workday injury rate; however, we would recommend expanding the size of the exemption to include all industries below the private sector average. We have no objection to your proposal to eliminate the "nesting" problem within 2-digit SIC code groups, as long as the exemption size is maximized. The recordkeeping paperwork burden for small and relatively safe industries is significant and not justified based upon the benefits received.

OSHA has decided in the final rule to continue to use a formula that will exempt retail, finance and services industries from most recordkeeping requirements if they have a Days Away, Restricted, or Transferred (DART) rate that is at or below 75% of the national average rate. OSHA believes that the 75% threshold will ensure that only industries with relatively low injury and illness rates are exempted from these requirements. Using the national average DART rate, rather than 75% of the national DART rate, as the threshold for exemption purposes would exempt employers whose industries were merely average in terms of their DART rate.

OSHA received many comments from firms in industries that have been exempt from most OSHA recordkeeping requirements since 1982 but that would have been required by the proposed rule to keep records. Most of these commenters opposed their industry's inclusion within the scope of the proposed rule. For example, several commenters from the restaurant industry objected to the fact that SICs 581 and 582, eating and drinking places, would have been covered (see, *e.g.*, Exs. 15: 3, 4, 5, 6, 7, 8, 12, 20, 22, 55, 96, 125, 202, 311). The National Restaurant Association remarked:

> The Association opposes elimination of this exemption on the bases that:
> —the proposal, if promulgated, will cost eating and drinking establishments an estimated $17 million in the first year alone;
> —the additional recordkeeping obligations under the proposed rule duplicate data already available to OSHA from other sources; and
> —the current data does not justify removal of the partial recordkeeping exemption for eating and drinking establishments (Ex. 15: 96).

In the final rule, the exemption for eating and drinking places is retained, because the recent data indicate that these industries have DART rates that are below 75% of the national rate.

Two commenters addressed the proposed removal of the exemption for SIC 553, auto and home supply stores (Ex. 15: 367, 402). For example, the Automotive Parts and Accessories Association (APAA) stated:

> The vast majority of auto parts stores are similar to other retailers which would still be exempt under this proposal. * * * [m]ore than three quarters of the automotive parts retailers which are proposed to be saddled with the full Log requirements would have little or no potential injury or illness experience to justify the added mandate (Ex. 15: 367).

Several commenters discussed the proposed removal of the exemption for SIC 721, laundry, dry cleaning and textile rental services (see, *e.g.*, Exs. 15: 183, 244, 326). Typical of the views expressed by these commenters was the comment of the Textile Rental Services Association of America (TRSA):

> TRSA is strongly opposed to OSHA's proposal to eliminate the partial exemption from recordkeeping and reporting requirements for laundry, cleaning, and garments services for Standard Industrial Classification (SIC) 721. TRSA believes that the proposed inclusion of the textile rental industry is unjustified. Because the textile rental industry has historically been proactive when it comes to workplace safety and has been 75% below the industry average for lost work days, we contend that OSHA's plan to eliminate the partial exemption from injury/illness recordkeeping requirements is unwarranted (Ex. 15: 183).

The National Association of Home Builders (NAHB) commented on the proposed inclusion in the recordkeeping system of a variety of industries closely associated with the home building industry:

> As a result of using a 3 digit Standard Industrial Classification (SIC), "Real Estate Offices" (SIC 651) will now be required to report and record injury and illness data if they have more than 19 workers during the year. A cursory analysis of the hazards associated with real estate offices seems to indicate limited exposure to high hazards (Ex. 15: 323).

The primary arguments put forth by these commenters are as follows: (1) The occupational injury and illness data collected under Part 1904 are available to OSHA from other sources; (2) OSHA's data requirements are burdensome; (3) the use of even more current data would change the list of exempted industries;

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and (4) some of the individual industries that would be covered are relatively safe.

In response, OSHA notes that, although statistical information on average work-related injury and illness rates in industries is available from the BLS and other sources, information about the hazards present at specific workplaces is not available to OSHA from those same sources. OSHA recognizes that the maintenance of these records imposes some burden on businesses in the form of paperwork. However, the benefits of keeping records are also clearly substantial: informed employers can use the data to provide greater protection for their employees and to receive the benefits that accrue from prevention efforts in the form of fewer injuries and illnesses. In addition, the records are useful to OSHA in the inspection process. OSHA also believes that the process for selecting exempt industries must be as objective as possible, and that exemptions must rely upon timely and objective information about the safety and health experience of a given industry. The lost workday injury rates published by the Bureau of Labor Statistics provide the most consistent and reliable nationwide statistics available for this purpose, and OSHA is therefore relying on these data. The 75% of the national rate cutoff strikes a reasonable balance between collecting data likely to be useful and avoiding unnecessary burden. OSHA has used the most recent data available at this time in establishing the final list of partially exempt industries. OSHA also has used data from a three-year period (1996–1998) rather than a one-year period to reduce year-to-year variation in the data.

Other commenters argued that their industry should not be exempt because their workplaces continue to pose risk to the workers in them. For example, the American Nurses Association (ANA) opposed the partial exemption of doctor's offices and health services:

> ANA urges OSHA to remember the purpose of the Act, to protect the health and safety of ALL workers, when deliberating on exempting employers from this standard. As stated before, health care workers risk of exposure to injury and illness is not limited to one setting. Therefore, the Standard Industrial Classifications (SICs) 801 Offices and Clinics of Doctors of Medicine and SIC 809 Miscellaneous Health and Allied Services should not be exempt from this standard (Ex. 15: 376).

The International Brotherhood of Teamsters (IBT) also argued against excluding certain health care service industries:

> IBT has concerns when the use of this analysis will grant partial exemptions to SIC codes 801 (offices and clinics of doctors), 807 (medical and dental offices), and 809 (miscellaneous health and allied services). All three of these SIC codes are covered under other OSHA rules (such as the bloodborne pathogen standard and ethylene oxide standard) and have medical surveillance requirements to detect adverse health effects. OSHA should require that these workplaces keep records of work related illnesses or injuries that occur. Especially, since OSHA has already determined that there is a significant risk of harm from exposures in these workplaces (Ex. 15: 369).

OSHA recognizes that workers in establishments that are exempt under the 75% DART rate criterion will continue to be exposed to job-related hazards and to experience workplace injuries and illnesses. However, because these industries' overall injury rate is below the 75% cutoff, they qualify for exemption, along with other financial, service and retail industries that fall below that injury rate threshold. Exemption of an industry on the basis of its lower-than-average DART rate does not mean that all establishments within that industry have such rates or that workers in that industry will not experience injuries and illnesses. The 1904 partial exemption does not exempt employers from any other OSHA regulation or standard, so employees in these industries will continue to benefit from the protection offered by the OSHA standards. For example, while doctors' and dentists' offices are partially exempt under the 1904 regulation, they are still required to comply with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). Use of the 75% criterion merely provides a cutoff point, based on BLS injury and illness rates, for different industry sectors. OSHA believes that it is appropriate to use the 75% cutoff point because, in general, it is an appropriate overall indicator of the relative hazard rank of an industry. OSHA recognizes that no average across-establishment statistic can capture the injury and illness experience of all occupations or establishments within that industry.

For some SIC codes, the BLS Annual Survey does not publish data at the three-digit level. The survey is designed to provide data at the four-digit level in the manufacturing industries and at the three-digit level in all other industries, primarily because of budget constraints that limit the amount of data the BLS can collect and process. However, the survey has other publication criteria that make some of the data at this detailed level unpublishable. Under the proposal, coverage would have been based on the industry's LWDI rate. If a 3-digit sector did not have published data, OSHA proposed to use the data for the two-digit industry group for that sector.

One 3-digit sector affected by this approach was dental offices (SIC 802), which the proposal would have covered because the entire 2-digit health care sector has a relatively high injury and illness rate. The American Dental Association (ADA) suggested that OSHA use an alternative approach to exempt dentists from coverage rather than rely on a strict data protocol for making the decision:

> [d]ental offices are very much like physicians' offices in terms of size, scope of activity, and degree of occupational health risk. For purposes of this rulemaking, however, physicians' offices have been granted a categorical exemption while dentists' offices (SIC Code 802) have not. Even dental laboratories (SIC Code 807) have been granted a categorical exemption from this rule, although it is unlikely that anyone would assert that dental laboratories are safer and more healthful places to work than dental offices. The ADA is unaware of any data suggesting that dental offices should be treated differently than either physicians' offices or dental laboratories (Ex. 15: 408).

The more recent data published by the BLS for the years 1996, 1997, and 1998 include specific estimates of the injury and illness experience for SIC 802 (dental offices) in that period. The dental office industry experienced a 3-year average rate of days away, restricted, or transferred injuries of 0.2 per 100 workers in those years, a rate well below 75% of the national average. Therefore, the final rule exempts employers classified in SIC 802 from routine recordkeeping requirements.

The proposed rule would have removed SIC 736 (personnel supply services) from the list of exempted industry sectors; however, because this industry's more recent average DART (formerly LWDI) rate (for the years 1996, 1997, and 1998, the base years OSHA is using to determine lower-hazard industry exemptions) is above 75% of the national average cutoff, SIC 736 is not exempted under the final rule. The final rule (see section 1904.31(b)(2)) requires the "using firm" to record the injuries and illnesses of temporary workers that are "leased" from a personnel supply service, providing that the using firm supervises these workers on a day-to-day basis.

The National Association of Temporary and Staffing Services commented on the proposed removal of the exemption for SIC 736:

> The proposed rules also would lift the partial exemption for employers classified under SIC Code 7363 (help supply services). Those employers, among others, were exempted from injury and illness record keeping requirements in 1982 because they had low work place injury rates. The proposal to lift the exemption is based on reported increased injury rates for these employers. However, since records for the vast majority of staffing firm employees are maintained by the worksite employer as explained above, the practical effect of lifting the exemption for staffing firms would be to require them to maintain records for their home office clerical and administrative workers—for whom there is no evidence of increased work place illnesses or injuries. Hence, we urge OSHA to retain the partial exemption for SIC 7363.
>
> If the exemption is not retained in the case of SIC 7363 employers, it would be especially important for the final rules to expressly provide, as set forth above, that there is no intent to impose a dual reporting requirement. At least one state OSH office already has construed the proposed lifting of the partial exemption as creating an obligation on the part of staffing firms to maintain records for all of its employees, including temporary employees supervised by the worksite employer. This is clearly inconsistent with the intent of the proposed rule and should be clarified (Ex. 15: 333).

The final rule makes clear that, when a "leased" or "temporary" employee is supervised on a day-to-day basis by the using firm, the using firm must enter that employee's injuries and illnesses on the using firm's establishment Log and other records. Injuries and illnesses occurring to a given employee should only be recorded once, either by the temporary staffing firm or the using firm, depending on which firm actually supervises the temporary employees on a day-to-day basis. (see the discussion for § 1904.31, Covered employees, for an in-depth explanation of these requirements.)

Some commenters suggested that OSHA should grant partial exemptions to specific industries within SICs 01 through 51 (agriculture, forestry and fishing; mining; construction; manufacturing; transportation, communications, electric, gas and sanitary services; and wholesale trade) that had lost workday incidence rates that were below 75% of the average rate for all industries instead of limiting such exemptions to industries in SICs 52–89 (see, *e.g.*, Exs. 15: 77, 95, 184, 201, 357, 359, 374, 375). Typical of these comments was one from the Synthetic Organic Chemical Manufacturers Association (SOCMA):

> SOCMA believes that the partial exemption from recordkeeping requirements should be consistent for all standard industrial classifications. SOCMA supports the use of injury rates, rather than SIC Codes, as a criterion for partial exemption from recordkeeping requirements, provided the same criterion is applied to all work sites. For example, if the performance measure was 75 percent of the private sector average, then all industries with injury rates below this average should be exempt.
>
> There is sound basis for this shift in OSHA's approach. It has been found in the past that some industries in partially exempt SIC Codes 52—89 have had high injury rates while some in the "manufacturing" SIC Codes 01–51 have had low injury rates. This has resulted in insufficient or unavailable injury and illness information for some facilities in SIC Codes 52–89 with high injury rates. Inspection resources are wasted if injury and illness information is not available during the inspection of high injury rate facilities. Conversely, requiring full recordkeeping for facilities with low injury rates results in a facility wasting resources on unnecessary recordkeeping. All businesses, regardless of SIC Code, should be treated equally and should have the opportunity to be exempt based on injury rates (Ex. 15: 357).

The National Automobile Dealers Association (NADA) urged OSHA to exempt truck dealerships [classified in SIC 50], even though they are considered wholesale rather than retail establishments, because of their similarity to automobile dealerships [SIC 551], which are exempted:

> NADA strongly urges OSHA to exempt truck dealerships (SIC 5012), the overwhelming majority of whom are small businesses as recognized by the Small Business Administration (SBA).* * * A limited exemption for truck dealerships is justified under the same criteria used for automobile dealerships (Ex. 15: 280).

On the other hand, some commenters agreed with OSHA's proposal to require all businesses in SICs 01–51 to keep injury and illness records (see, *e.g.*, Exs. 15: 170, 199, 369). The International Brotherhood of Teamsters (IBT) remarked: "IBT does not support using the same analysis of data at the three digit level of those industries in SIC 01 through 51 (industries historically not exempted from recordkeeping requirements). IBT maintains the importance of recording of all occupational injuries and illnesses" (Ex. 15: 369). A major utility, New England Power, agreed: "We believe that the existing exemption criteria for SICs 52–89 should remain the same. Although many industries would fall within the exemption criteria in SICs 01–51, they are still higher hazard industries producing valuable data on injury/illness experience" (Ex. 15: 170). The NYNEX Corporation also agreed with OSHA's proposed approach:

> We are not in favor of extending the concept of industry-wide recordkeeping exemptions to the list of three digit codes in the group 01–51 that were identified in the proposal. Even though these groups have average injury and illness case rates that are less than 75% of the private sector average, the nature of the work operations performed within these industries suggests that the variation above and below average for individual establishments could be much greater than with SIC Codes 52–89. An exemption for this group of establishments could mask the existence of some very high case rates within this group (Ex. 15: 199).

After a review of the recent BLS data, OSHA's own experience, and the record of this rulemaking, OSHA has decided that it is appropriate to require firms in industries within the SIC 01 through 51 codes to comply with OSHA's requirements to keep records. Thus, the final rule, like the proposed rule and the rule published in 1982, does not exempt firms with more than 10 employees in the industry divisions of agriculture, mining, construction, manufacturing, wholesale trade, transportation and public utilities (SICs 01—52) from routine recordkeeping.

Although OSHA no longer restricts its inspection targeting schemes to employers in these SICs, these industries have traditionally been, and continue to be, the focus of many of the Agency's enforcement programs. OSHA believes that it is important for larger employers (i.e., those with more than 10 employees) in these industries to continue to collect and maintain injury and illness records for use by the employer, employees and the government. As noted in the comments there is a wide variation in injury/illness rates among establishments classified in these industries. Further, as a whole, these industries continue to have injury and illness rates that are generally higher than the private sector average and will thus benefit from the information that OSHA-mandated records can provide about safety and health conditions in the workplace. In 1998, the lost workday injury and illness rate for the entire private sector was 3.1. As can be seen in the following table of lost workday injury and illness rates by industry division, all of the covered divisions exceeded 75% of the national average LWDI rate (2.325) for the private sector as a whole, while the exempted industry divisions had substantially lower rates.

Industry sector	1998 lost workday injury and illness rate
Agriculture, forestry and fishing (SIC 01–09)	3.9
Mining (SIC 10–14)	2.9
Construction (SIC 15–17)	4.0
Manufacturing (SIC 20–39)	4.7

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Industry sector	1998 lost workday injury and illness rate
Transportation, communications, electric, gas and sanitary services (SIC 40–49)	4.3
Wholesale trade (SIC 50 & 51)	3.3
Retail trade (SIC 52–59)	2.7
Finance, Insurance & Real Estate (SIC 60–67)	0.7
Services (SIC 70–87)	2.4

(U.S. Department of Labor Press Release USDL 98–494, December 16, 1999)

The problems that may be encountered by exempting additional industries are exemplified by an analysis of the petrochemical industry and the manufacturers of chemicals and petroleum products, classified in SICs 28 and 29. If the industry exemption were applied to these industries, injury and illness records would not be required for highly specialized plants that make industrial inorganic chemicals, plastics materials and synthetic resins, pharmaceuticals, industrial organic chemicals, and petroleum refineries. These industries have relatively low occupational injury and illness rates, but they are not truly low-hazard industries. All of these facilities make, use and handle highly toxic chemicals and consequently have the potential for both acute overexposure and chronic exposures of their employees to these substances. These industries, for example, are the industries to which OSHA health standards, such as the benzene, ethylene oxide, and methylene chloride standards, apply. Because occupational illnesses, particularly chronic illnesses, are notoriously underreported (see, *e.g.*, Exs. 15: 407, 4, 5), the LWDI rates for these industries do not accurately reflect the level of hazard present in these facilities. In addition, these types of facilities are prone to major safety and health problems, including explosions, toxic releases and other events that often lead to fatalities and serious injuries. The safety and health problems of these facilities are not limited to workers, but extend to hazards posed to the general public. In addition, OSHA frequently inspects these facilities because of their potential for catastrophic releases, fires, and explosions, and the Part 1904 injury and illness records have been extremely useful for this purpose.

The Agency finds that continuing, and improving on, the Agency's longstanding approach of partially exempting those industries in SIC codes 52–89 that have DART rates, based on 3 years of BLS data, below 75% of the private-sector average strikes the appropriate balance between the need for injury and illness information on the one hand, and the paperwork burdens created by recording obligations, on the other. The BLS Annual Survey will, of course, continue to provide national job-related statistics for all industries and all sizes of businesses. As it has done in the past, the BLS will sample employers in the partially exempt industries and ask each sampled employer to keep OSHA records for one year. In the following year, BLS will collect the records to generate estimates of occupational injury and illness for firms in the partially exempt industries and size classes, and combine those data with data for other industries to generate estimates for the entire U.S. private sector. These procedures ensure the integrity of the national statistics on occupational safety and health.

The list of partially exempted industry sectors in this rule is based on the current (1987) revision of the SIC manual. The Office of Management and Budget (OMB) is charged with maintaining and revising the system of industrial classification that will replace the SIC. The new system is used by U.S. statistical agencies (including the BLS). Under the direction of OMB, the U.S. government has adopted a new, comprehensive system of industrial classification that will replace the SIC. The new system is called the North American Industrial Classification System (NAICS). NAICS will harmonize the U.S. classification system with those of Canada and Mexico and make it easier to compare various economic and labor statistics among the three countries. Several commenters expressed concern about this change in industrial classification systems (see, *e.g.*, Exs. 15: 70, 182, 183, 379). For example, the American Society of Safety Engineers (ASSE) stated:

> The Society is concerned with the recent Office of Management Budget (OMB), proposal to change the Economic Classification Policy from the Standard Industrial Classification System to the North American Industry Classification System. We recommend that OSHA study what the effect would be of promulgating a new regulation partially based on SIC codes when these codes could be potentially replaced/revised with a new classification system (Ex. 15: 182).

Although the NAIC industry classification system has been formally adopted by the United States, the individual U.S. statistical agencies (including the BLS) are still converting their statistical systems to reflect the new codes and have not begun to publish statistics using the new industry classifications. The new system will be phased into the nation's various statistical systems over the next several years. The BLS does not expect to publish the first occupational injury and illness rates under the new system until the reference year 2003. Given the lag time between the end of the year and the publication of the statistics, data for a full three-year period will not be available before December of 2006.

Because data to revise the Part 1904 industry exemption based on the NAIC system will not be available for another five years, OSHA has decided to update the industry exemption list now based on the most recent SIC-based information available from BLS for the years 1996, 1997 and 1998. OSHA will conduct a future rulemaking to update the industry classifications to the NAIC system when BLS publishes injury and illness data that can be used to make appropriate industry-by-industry decisions.

The proposal inquired whether OSHA should adopt a procedure for adjusting the industry exemption lists as the injury and illness rates of various industries change over time. A number of commenters urged OSHA to update the exemption list periodically (see, *e.g.*, Exs. 15: 27, 87, 170, 181, 199, 272, 280, 359, 374, 375, 392, 407). Some commenters suggested various time periods, such as annually (Ex. 15: 374), every 3 years (see, *e.g.*, Exs. 15: 87, 181, 199, 407), every 5 years (see, *e.g.*, Exs. 15: 170, 181, 262, 272, 359, 375), or every 5 to 10 years (Ex. 15: 392). Southwestern Bell Telephone suggested that the list should be modified whenever changes in the injury and illness rates warrant a change (Ex. 15: 27). In the opinion of the National Safety Council, "How often the SIC exemption should be updated depends on how well and how quickly OSHA can communicate changes in the exempt industry list to those affected. The Council recommends updating the list every 3 to 5 years" (Ex. 15: 280).

Several commenters, however, opposed frequent updating of the SIC exemption list. For example, the Orlando Safety and Health Customer Council stated: "Changes to SIC exemptions should be limited to a minimum of every 5 years. This would reduce confusion" (Ex. 15: 97). The National Institute for Occupational Safety and Health (NIOSH) generally opposed industry exemptions but recommended that, if they were continued, they be updated as follows:

> If OSHA continues to provide this exemption for low injury rate SICs, NIOSH recommends that the list of partially exempt SICs be placed in an Appendix. Because the injury and illness experience of an industry can change over time (*e.g.*, SIC 58 and SIC 84 had injury rates at or below 75% of the private sector average in 1983, but above 75% of the private sector average in 1990 and 1992), OSHA should periodically review and modify the list of partially exempt industries. NIOSH recommends that the criteria for partial exemptions be placed in the regulatory text, while placing the list of partially exempt industries in an Appendix as noted so that the list could be updated periodically by administrative means rather than by changing the regulation. In addition to the partial exemption criteria, the regulatory text should specify the interval (in years) for reviewing and revising the list of those industries that qualify. NIOSH recommends an interval of 3 years for the review and revision process (Ex. 15: 407).

OSHA agrees with those commenters who favored regular updating of the SIC code exemption list. For the list to focus Agency resources most effectively on the most hazardous industries, it must be up-to-date. Industries that are successful in lowering their rates to levels below the exemption threshold should be exempted, while those whose rates rise sufficiently to exceed the criterion should receive additional attention. Unfortunately, the change in industry coding systems from the Standard Industrial Classification (SIC) system to the North American Industry Classification (NAIC) system will require a future rulemaking to shift to that system. Therefore, there is no value in adding an updating mechanism at this time. The automatic updating issue will be addressed in the same future rulemaking that addresses the NAIC system conversion.

Partial Exemptions for Employers Under the Jurisdiction of OSHA-Approved State Occupational Safety and Health Plans

Robert L. Rowan, Jr. expressed a concern that the OSHA State-Plan States could have differing industry exemptions from those applying to federal OSHA states, commenting:

> In regard to the note in OSHA's Coverage and Exemption Table that "some states with their own occupational safety and health programs do not recognize the federal record keeping exemptions". I am deeply concerned. I would prefer that all jurisdictions enforce the same requirements. This will be confusing and create needless problems for businesses with sites in numerous states if requirements are not enforced equally (Ex. 15: 62).

For those States with OSHA-approved State plans, the state is generally required to adopt Federal OSHA rules, or a State rule that is at least as effective as the Federal OSHA rule. States with approved plans do not need to exempt employers from recordkeeping, either by employer size or by industry classification, as the final Federal OSHA rule does, although they may choose to do so. For example, States with approved plans may require records from a wider universe of employers than Federal OSHA does. These States cannot exempt *more* industries or employers than Federal OSHA does, however, because doing so would result in a State rule that is not as effective as the Federal rule. A larger discussion of the effect on the State plans can be found in Section VIII of this preamble, State Plans.

Recordkeeping Under the Requirements of Other Federal Agencies

Section 1904.3 of the final rule provides guidance for employers who are subject to the occupational injury and illness recording and reporting requirements of other Federal agencies. Several other Federal agencies have similar requirements, such as the Mine Safety and Health Administration (MSHA), the Department of Energy (DOE), and the Federal Railroad Administration (FRA). The final rule at section 1904.3 tells the employer that OSHA will accept these records in place of the employer's Part 1904 records under two circumstances: (1) if OSHA has entered into a memorandum of understanding (MOU) with that agency that specifically accepts the other agency's records, the employer may use them in place of the OSHA records, or (2) if the other agency's records include the same information required by Part 1904, OSHA would consider them an acceptable substitute.

OSHA received very few comments on the issue of duplicate recordkeeping under different agency rules. The Fertilizer Institute (TFI) recommended that OSHA make the data mandated by OSHA and MSHA more consistent (Ex. 15:154). However, MSHA and OSHA have different recordkeeping requirements because the agencies' mandate and uses of the data differ. The approach OSHA takes in the final rule, which is to continue to accept data kept by employers under other Federal requirements if the two federal agencies have made an agreement to do so, or if the data are equivalent to the data required to be kept by Part 1904, appears to be the best way to handle the problem raised by the TFI.

Subpart C. Recordkeeping Forms and Recording Criteria

Subpart C of the final rule sets out the requirements of the rule for recording cases in the recordkeeping system. It contains provisions directing employers to keep records of the recordable occupational injuries and illnesses experienced by their employees, describes the forms the employer must use, and establishes the criteria that employers must follow to determine which work-related injury and illness cases must be entered onto the forms. Subpart C contains sections 1904.4 through 1904.29.

Section 1904.4 provides an overview of the requirements in Subpart C and contains a flowchart describing the recording process. How employers are to determine whether a given injury or illness is work-related is set out in section 1904.5. Section 1904.6 provides the requirements employers must follow to determine whether or not a work-related injury or illness is a new case or the continuation of a previously recorded injury or illness. Sections 1904.7 through 1904.12 contain the recording criteria for determining which new work-related injuries and illnesses must be recorded on the OSHA forms. Section 1904.29 explains which forms must be used and indicates the circumstances under which the employer may use substitute forms.

Section 1904.4 Recording Criteria

Section 1904.4 of the final rule contains provisions mandating the recording of work-related injuries and illnesses that must be entered on the OSHA 300 (Log) and 301 (Incident Report) forms. It sets out the recording requirements that employers are required to follow in recording cases.

Paragraph 1904.4(a) of the final rule mandates that each employer who is required by OSHA to keep records must record each fatality, injury or illness that is work-related, is a new case and not a continuation of an old case, and meets one or more of the general recording criteria in section 1904.7 or the additional criteria for specific cases found in sections 1904.8 through 1904.12. Paragraph (b) contains provisions implementing this basic requirement.

Paragraph 1904.4(b)(1) contains a table that points employers and their recordkeepers to the various sections of the rule that determine which work-related injuries and illnesses are to be recorded. These sections lay out the requirements for determining whether an injury or illness is work-related, if it is a new case, and if it meets one or more of the general recording criteria. In addition, the table contains a row addressing the application of these and additional criteria to specific kinds of cases (needlestick and sharps injury cases, tuberculosis cases, hearing loss

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cases, medical removal cases, and musculoskeletal disorder cases). The table in paragraph 1904.4(b)(1) is intended to guide employers through the recording process and to act as a table of contents to the sections of Subpart C.

Paragraph (b)(2) is a decision tree, or flowchart, that shows the steps involved in determining whether or not a particular injury or illness case must be recorded on the OSHA forms. It essentially reflects the same information as is in the table in paragraph 1904.4(b)(1), except that it presents this information graphically.

The former rule had no tables or flowcharts that served this purpose. However, the former *Recordkeeping Guidelines* (Ex. 2) contained several flowcharts to help employers make decisions and understand the overall recording process. The proposed rule included a flowchart as Appendix C to Part 1904—Decision Tree for Recording Occupational Injuries and Illnesses. OSHA received very few comments in response to proposed Appendix C, and no commenters objected to the decision tree concept. The commenters who discussed the decision tree supported it, and many suggested that it should be incorporated into the computer software OSHA develops to assist employers with keeping the records (see, *e.g.*, Exs. 51, 15: 38, 67, 335, 407, 438).

In the final rule, OSHA has decided to include the flowchart because of its usefulness in depicting the overall recording process. OSHA has not labeled the flowchart non-mandatory, as some commenters (see, *e.g.*, Ex. 15: 335) suggested, because the recording of injuries and illnesses is a mandatory requirement and labeling the flowchart as non-mandatory could be confusing.

Section 1904.5 Determination of Work-Relatedness

This section of the final rule sets out the requirements employers must follow in determining whether a given injury or illness is work-related. Paragraph 1904.5(a) states that an injury or illness must be considered work-related if an event or exposure in the work environment caused or contributed to the injury or illness or significantly aggravated a pre-existing injury or illness. It stipulates that, for OSHA recordkeeping purposes, work relationship is presumed for such injuries and illnesses unless an exception listed in paragraph 1904.5(b)(2) specifically applies.

Implementation requirements are set forth in paragraph (b) of the final rule. Paragraph (b)(1) defines "work environment" for recordkeeping purposes and makes clear that the work environment includes the physical locations where employees are working as well as the equipment and materials used by the employee to perform work.

Paragraph (b)(2) lists the exceptions to the presumption of work-relatedness permitted by the final rule; cases meeting the conditions of any of the listed exceptions are not considered work-related and are therefore not recordable in the OSHA recordkeeping system.

This section of the preamble first explains OSHA's reasoning on the issue of work relationship, then discusses the exceptions to the general presumption and the comments received on the exceptions proposed, and then presents OSHA's rationale for including paragraphs (b)(3) through (b)(7) of the final rule, and the record evidence pertaining to each.

Section 8(c)(2) of the OSH Act directs the Secretary to issue regulations requiring employers to record "work-related" injuries and illnesses. It is implicit in this wording that there must be a causal connection between the employment and the injury or illness before the case is recordable. For most types of industrial accidents involving traumatic injuries, such as amputations, fractures, burns and electrocutions, a causal connection is easily determined because the injury arises from forces, equipment, activities, or conditions inherent in the employment environment. Thus, there is general agreement that when an employee is struck by or caught in moving machinery, or is crushed in a construction cave-in, the case is work-related. It is also accepted that a variety of illnesses are associated with exposure to toxic substances, such as lead and cadmium, used in industrial processes. Accordingly, there is little question that cases of lead or cadmium poisoning are work-related if the employee is exposed to these substances at work.

On the other hand, a number of injuries and illnesses that occur, or manifest themselves, at work are caused by a combination of occupational factors, such as performing job-related bending and lifting motions, and factors personal to the employee, such as the effects of a pre-existing medical condition. In many such cases, it is likely that occupational factors have played a tangible role in causing the injury or illness, but one that cannot be readily quantified as "significant" or "predominant" in comparison with the personal factors involved.

Injuries and illnesses also occur at work that do not have a clear connection to a specific work activity, condition, or substance that is peculiar to the employment environment. For example, an employee may trip for no apparent reason while walking across a level factory floor; be sexually assaulted by a co-worker; or be injured accidentally as a result of an act of violence perpetrated by one co-worker against a third party. In these and similar cases, the employee's job-related tasks or exposures did not create or contribute to the risk that such an injury would occur. Instead, a causal connection is established by the fact that the injury would not have occurred but for the conditions and obligations of employment that placed the employee in the position in which he or she was injured or made ill.

The theory of causation OSHA should require employers to use in determining the work-relationship of injuries and illnesses was perhaps the most important issue raised in this rulemaking. Put simply, the issue is essentially whether OSHA should view cases as being work-related under a "geographic" or "positional" theory of causation, or should adopt a more restrictive test requiring that the occupational cause be quantified as "predominant," or "significant," or that the injury or illness result from activities uniquely occupational in nature. This issue generated substantial comment during this rulemaking, and the Agency's evaluation of the various alternative tests, and its decision to continue its historic test, are discussed below.

The final rule's test for work-relationship and its similarity to the former and proposed rules.—The final rule requires that employers consider an injury or illness to be "work-related" if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness. Work relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception in § 1904.5(b)(2) specifically applies.

Under paragraph 1904.5(b)(1), the "work environment" means "the establishment and other locations where one or more employees are working or are present as a condition of their employment. The work environment includes not only physical locations, but also equipment or materials used by the employee during the course of his or her work."

The final rule's definition of work-relationship is essentially the same as that in both the former and proposed rules except for the final rule's requirement that the work event or exposure "significantly" aggravate a pre-existing injury or illness. The *Guidelines* interpreting the former rule stated that

> Work-relationship is established under the OSHA recordkeeping system when the injury or illness results from an event or exposure in the work environment. The work environment is primarily composed of: (1) The employer's premises, and (2) other locations where employees are engaged in work-related activities or are present as a condition of their employment. (Ex. 2 at p. 32).

The proposed rule also contained a similar definition of "work-related" and "work environment." The only significant difference between the proposed and the final rule definitions is that the proposed rule also would not have required a "significant" aggravation of a pre-existing condition before it became recordable; under the proposal, any aggravation would have been sufficient (see 61 FR 4059).

The Alternative Tests for Work-Relationship

Although OSHA proposed to continue its existing definition of work-relationship, it sought comment on the following three alternative tests:

1. Exclude cases with any evidence of non-work etiology. Only cases where the work event or exposure was the *sole* causative factor would be recorded;
2. Record only cases where work was the *predominant* causative factor;
3. Record all cases where the work event or exposure had *any possibility* of contributing to the case (emphasis added). (61 FR 4045)

Comments on the "Quantified Occupational Cause" Test

The first two alternative tests described in the proposal would have required the employer to quantify the contribution of occupational factors as compared to that of personal factors. These tests are referred to in the Legal Authority section, and in this preamble, as the "quantified occupational cause" tests. Of these tests, Alternative 2—record only injuries and illnesses predominantly caused by occupational factors—received the most comment. Typical of these comments were those of the Dow Chemical Company, which expressed the view of many in industry that "[a] system that labels an injury or illness attributable to the workplace even though the workplace contribution may be insignificant does not lead to an effective, credible or accurate program" (Ex. 15: 335). Other commenters stated that recording only those cases where work was the predominant cause would improve the system by focusing attention on cases that are amenable to employer abatement (see, *e.g.*, Exs. 22, 15: 13, 27, 34, 38, 52, 60, 69, 71, 72, 82, 97, 102, 108, 109, 122, 136, 137, 141, 146, 147, 149, 152, 154, 159, 163, 169, 171, 174, 176, 181, 197, 198, 199, 200, 201, 214, 218, 224, 230, 231, 238, 239, 260, 262, 265, 266, 272, 273, 277, 278, 287, 288, 290, 297, 301, 302, 303, 307, 313, 317, 318, 330, 335, 346, 352, 353, 370, 375, 382, 378, 383, 384, 386, 388, 396, 401, 402, 404, 405, 425, 426, 430).

Some commenters (see, *e.g.*, Exs. 15: 185, 199, 205, 332, 338, 349, 354, 358, 375, 421, 440) offered a slight modification on Alternative 2. They suggested that using a term other than predominant, such as "substantial" or "significant," would avoid the need to define "predominant" as a percentage. For example, United Technologies (Ex. 15: 440) opposed "placing a percentage on the degree of contribution" because doing so would not be practical. Further, according to this commenter, "work relationship should be established in cases where the workplace contributed substantially to the injury or illness, as determined by an occupational physician." Arguing along the same lines, the American Petroleum Institute (API) (Ex. 15: 375) stated that it supported "in principle the work-relatedness concept presented by OSHA as Alternative 2, but feels "predominant" might be too difficult to administer as a fundamental criterion. API proposes that work-relatedness should exist when an event or exposure in the workplace is a significant factor resulting in an injury or illness. * * *" Organization Resource Counselors, Inc. (Ex. 15: 358) added: "[T]he Congressional intent in drafting these sections was to require the collection of work-related information about significant work-related injuries and illnesses." The General Electric Company (Ex. 15: 349) said that "OSHA needs to allow the facility the flexibility to record only those cases that are "more likely than not" related to workplace exposure or tasks. This determination can be made during the incident investigation. A good test of work-relatedness is whether the injury would have been prevented by full compliance with the applicable OSHA standard."

Proposed Alternative 1, which would have required the recording only of cases where work was the sole cause, was also supported by a large number of commenters (see, *e.g.*, Exs. 15: 9, 39, 87, 95, 119, 123, 145, 151, 152, 179, 180, 183, 185, 204, 205, 225, 229, 234, 242, 259, 263, 269, 270, 304, 341, 363, 377, 389, 393, 414, 433, 443). Typical of this view was the comment of the American Health Care Association (Ex. 15: 341):

> If OSHA's primary concern is to address those workplace hazards or risks that cause or may cause employee injury/illness then the agency should confine recordability to those injuries and illnesses that are directly caused by a workplace event or exposure. This approach, in turn, will focus the employer's attention on those unsafe workplace conditions that need to be corrected to protect all workers exposed to or at risk from the unsafe conditions.

The National Federation of Independent Business (Ex. 15: 304) supported Alternative 1 "because under such a system evidence of non-work-related factors is excluded thus the decision-making process is dramatically simplified and the tally is very credible." The Painting and Decorator Contractors of America (Ex. 15: 433) added: "[T]his approach is also consistent with OSHA's intent (and the Congressional mandate in the Paperwork Reduction Act of 1995) to reduce compliance burdens as this would be the simplest method for employers to apply."

Comments on the "Unique Occupational Activities" Test

Some commenters favored a closely related test for work relationship that would place primary emphasis on the nature of the activity that the employee was engaged in when injured or made ill. This test is referred to the Legal Authority section and in this preamble section as the "unique occupational activities" test. Its supporters argued that whether an injury or illness occurs or manifests itself at work is less important than whether or not the harm has been caused by activities or processes peculiar to the workplace. The AISI argued that:

> [I]t is clear that Congress intended OSHA's authority to regulate to be limited to "occupational hazards" and conceived of such hazards as "processes and materials" peculiar to the workplace. * * * Congress did not give OSHA the authority to regulate hazards if they "grow out of economic and social factors which operate primarily outside the workplace. The employer neither controls nor creates these factors as he controls or creates work processes and materials." Congress was concerned with dangerous conditions peculiar to the workplace; it did not have in mind the recording of illnesses simply because they appear at work (internal citations omitted) (Ex. 15: 395).

Dow Chemical made a similar point in arguing that the criteria for determining work-relationship should include whether the activity the employee was engaged in at the time of the injury or onset of illness was for the direct benefit of the employer or was a required part of the job (Ex. 15: 335B).

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According to Dow, the activity-based test would be more accurate than the geographic presumption (OSHA's historic test) because it would omit injuries due to hazards beyond the employer's control:

> Examples to illustrate this point include the employee who during his break attempts to remove a plastic insert in a condiment container with a knife and ends up cutting himself which requires three stitches. This activity, while it happened on company grounds, was not for the direct benefit of the company nor a requirement of his job, and there was no way for the employer to prevent it (Ex. 15: 335B).

Comments on OSHA's Historical Test

A significant number of commenters supported OSHA's long-standing test in which work factors must be a cause, but not necessarily a "significant" or "predominant" cause, and a geographic presumption applies if "events or exposures" in the work environment either caused or contributed to the resulting condition, or aggravated a pre-existing condition (see, *e.g.*, Exs. 15: 74, 153, 362, 369, 394, 407, 418, 429). For example, NIOSH (Ex. 15: 407) favored this approach because "[o]verreported cases can be identified and accounted for in data analysis, in contrast to the other alternatives which stress specificity at the expense of sensitivity and would result in unreported cases." The AFL–CIO argued that:

> * * * [c]apturing all workplace illnesses and injuries, even those for which the predominant cause cannot be proven to be work-related, can lead to early recognition of problems and abatement of hazardous conditions. Our experience has shown us that when comprehensive records of all possible cases are kept, patterns of injury and illness emerge, enabling us to target problem areas/factors that previously may not have been associated with that specific work environment. The inclusion of all cases will lead to prevention strategies that can reduce the risk of serious illness and injury to workers. Inclusion of all cases that have a workplace link will also assist in the recognition of diseases that are caused by synergistic effects. (Ex. 15: 418)

The American Industrial Hygiene Association (AIHA) argued that continuing OSHA's historic approach to work-relationship is particularly important in the case of occupational illnesses because:

> Occupational illnesses differ from injuries in that minor or early symptoms of illness are often an important indicator of a more serious disease state, while a minor injury usually goes away without further developments. By the time serious disabling symptoms have surfaced, a disease may be very far progressed and irreversible. Training courses such as Hazard Communication are geared toward educating the workforce to recognize and report symptoms of overexposure, presumably for disease prevention. AIHA does not want this information to be de-emphasized or lost (Ex. 15: 153).

Comments on the "Mere Possibility" Test

Alternative 3 described in the proposal would have required that an injury or illness be considered work related "if the worker ever experienced a workplace event or exposure that had any possibility of playing a role in the case." This "mere possibility" test is substantially different than OSHA's historical definition of work-relationship, which required that the injury or illness have a tangible connection with the work environment. Although some commenters supported Alternative 3, apparently on the assumption that it was in fact OSHA's proposed definition, analysis of these comments suggests that the parties involved recognized that an injury must have a real, not merely theoretical, link to work to be work-related. No commenter suggested a rationale for recording cases having only a theoretical or speculative link to work.

OSHA's Reasons for Rejecting the Alternative Tests for Work-Relationship

OSHA has given careful consideration to all of the comments and testimony received in this rulemaking and has decided to continue to rely in the final rule on the Agency's longstanding definition of work-relationship, with one modification. That modification is the addition of the word "significantly" before "aggravation" in the definition of work-relatedness set forth in final rule section 1904.5. The relevant portion of the section now states "an injury or illness is to be considered work-related if an event or exposure in the work environment either caused or contributed to the injury or illness or *significantly* aggravated a pre-existing injury or illness" (emphasis added).

In the final rule, OSHA has restated the presumption of work-relationship to clarify that it includes any non-minor injury or illness occurring as a result of an event or exposure in the work environment, unless an exception in paragraph 1904.5(b)(2) specifically applies. OSHA believes that the final rule's approach of relying on the geographic presumption, with a limited number of exceptions, is more appropriate than the alternative approaches, for the following reasons.

The Geographic Presumption Is Supported by the Statute

One important distinction between the geographic test for causation and the alternative causation tests is that the geographic test treats a case as work-related if it results in whole or in part from an event or exposure occurring in the work environment, while the alternative tests would only cover cases in which the employer can determine the degree to which work factors played a causal role. Reliance on the geographic presumption thus covers cases in which an event in the work environment is believed likely to be a causal factor in an injury or illness but the effect of work cannot be quantified. It also covers cases in which the injury or illness is not caused by uniquely occupational activities or processes. These cases may arise, for example, when: (a) an accident at work results in an injury, but the cause of the accident cannot be determined; (b) an injury or illness results from an event that occurs at work but is not caused by an activity peculiar to work, such as a random assault or an instance of horseplay; (c) an injury or illness results from a number of factors, including both occupational and personal causes, and the relative contribution of the occupational factor cannot be readily measured; or (d) a pre-existing injury or illness is significantly aggravated by an event or exposure at work.

As discussed in the Legal Authority section, the statute's language and the Legislative History support a definition of work-relationship that encompasses all injuries and illnesses resulting from harmful events and exposures in the work environment, not only those caused by uniquely occupational activities or processes. A number of commenters acknowledged the broad purposes served by OSHA's recordkeeping requirements and urged continued reliance on the former rule's definition of "work-related" (see, *e.g.*, Exs. 15: 65, 198, 350, 369, 418). For example, the AFL–CIO noted, "[o]ur experience has shown us that when comprehensive records of all possible cases are kept, patterns of injury and illness emerge, enabling us to target problem areas/factors that previously may not have been associated with that specific work environment" (Ex. 15: 418) (emphasis added).

On the other hand, those commenters favoring the "quantified occupational cause" test or the "unique occupational activity" test maintained that injury and illness records have more limited functions. Some commenters argued that because OSHA's mission is to eliminate preventable occupational injuries and illnesses, the determination of work-relationship must turn on whether the case could have been prevented by the employer's safety and health program. The Dow Chemical Company expressed this view as follows:

> [T]he goal of this recordkeeping system should be to accurately measure the effectiveness of safety and health programs in the workplace. Activities where safety and health programs could have no impact on preventing or mitigating the condition should not be logged and included in the Log and Summary nor used by OSHA to determine its inspection schedule. If the event was caused by something beyond the employer's control it should not be considered a recordable event that calls into question a facility's safety and health program.
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> . . . Credibility in this regulation rests on whether the recorded data accurately reflects the safety and health of the workplace. Including events where the workplace had virtually no involvement undermines the credibility of the system and results in continued resistance to this regulation (Ex. 15: 335B).

The law firm of Constangy, Brooks and Smith, LLC, urged OSHA to adopt the proposal's second alternative ("predominant cause") because cases that are "predominantly caused by workplace conditions" are the ones most likely to be preventable by workplace controls. Their comment stated, "[s]ince OSHA's ultimate mission is the prevention of workplace injuries and illnesses, it is reasonably necessary to require recording only when the injury or illness can be prevented by the employer" (Ex. 15–345). Other commenters opposed the recording of cases in which the injury or illness arises while the employee is on break, in the rest room, or in storage areas located on the employer's premises. These commenters claimed that use of the geographic presumption results in recording many injuries and illnesses that have little or no relationship to the work environment (see, *e.g.*, Exs. 15: 231, 423, 424G).

OSHA believes that the views of Dow Chemical and others in support of the proposal's alternative tests for work-relationship reflect too narrow a reading of the purposes served by the OSHA injury and illness records. Certainly, one important purpose for recordkeeping requirements is to enable employers, employees, and OSHA to identify hazards that can be prevented by compliance with existing standards or recognized safety practices. However, the records serve other purposes as well, including providing information for future scientific research on the nature of causal connections between the work environment and the injuries and illnesses sustained by employees. For example, the records kept by employers under Part 1904 produced useful data on workplace assaults and murders, which has permitted OSHA, employers, and others to focus on the issue of violence in the workplace. This has led, in turn, to efforts to reduce the number of such cases by implementing preventive measures. Although this issue was not anticipated by the 1904 system, the broad collection of injury, illness and fatality data allowed useful information to be extracted from the 1904 data. As discussed in the Legal Authority section, these purposes militate in favor of a general presumption of work-relationship for injuries and illnesses that result from events or exposures occurring in the work environment, with exceptions for specific types of cases that may safely be excluded without significantly impairing the usefulness of the national job-related injury and illness database.

At the same time, OSHA is sensitive to the concerns of some commenters that the injury and illness records are perceived as a measure of the effectiveness of the employer's compliance with the Act and OSHA standards. OSHA emphasizes that the recording of an injury or illness on the Log does not mean that a violation has occurred. The explanatory materials accompanying the revised OSHA Forms 300 and 301 contain the following statement emphasizing this point: "Cases listed on the Log of Work-Related Injuries and Illnesses are not necessarily eligible for Workers Compensation or other insurance benefits. Listing a case on the Log does not mean that the employer or worker was at fault or that an OSHA standard was violated."

The Alternative Tests for Work-Relationship Will Likely Lead Both to Inconsistent Determinations and to Underreporting of Cases

Under the first two alternative tests for work-relationship described in the proposal, the decision on work-relationship would depend upon the degree to which the injury or illness resulted from distinctly occupational causes. Whether labeled "sole cause," "predominant cause," or "significant cause," these alternative tests would require the employer, in each case, to distinguish between the occupational and non-occupational causal factors involved, and to weigh the contribution of the occupational factor or factors. Requiring the occupational cause to be quantified in this way creates practical problems militating against the use of these alternative tests in the final recordkeeping rule.

The most serious problem is that there is no reliable, objective method of measuring the degree of contribution of occupational factors. The absence of a uniform methodology for assessing the extent of work contribution caused several industry commenters to endorse the former rule's position on work-relationship. For example, the American Automobile Manufacturers Association (AAMA) noted that an ideal system would focus on cases in which the work environment was a major contributor to the injury or illness. Nevertheless, the AAMA argued against adopting the predominant cause test, stating: "until a system is developed in which employers can measure objectively and consistently whether or not the work environment is a major contributor to a workplace injury or illness, we favor continuing the definition of work-relationship as it currently exists" (Ex. 15: 409). The Ford Motor Co. also argued in favor of continuing the existing definition:

> Ford feels that the work environment should be a major contributor to an injury or illness for the case to be considered work-related. However, we are unsure how employers can measure objectively, consistently and equally whether the work environment is a major contributor. The use of a checklist by a health care provider to determine whether the work environment was a major contributor for a case to be considered work-related would be overly burdensome and subjective. Until a system is developed by which employers can measure objectively, consistently and equally whether or not the work environment is a major contributor to a workplace injury or illness, we favor continuing the definition of work relationship as it currently exists (Ex. 15: 347).

Based on a review of the record, OSHA agrees with those commenters who supported a continuation of the Agency's prior practice with regard to reliance on the geographic presumption for determinations of work-relatedness. OSHA finds that this approach, which includes all cases with a tangible connection with work, better serves the purposes of recordkeeping. Accordingly, the final rule relies on the geographic presumption, with a few limited exceptions, as the recordkeeping system's test for work-relationship.

Who Makes the Determination?

In addition to the definition of work-relatedness, commenters addressed the issue of who should make the determination of work-relatedness in a given case (see, *e.g.*, Exs. 15: 27, 35, 102, 105, 127, 193, 221, 281, 305, 308, 324, 325, 341, 345, 347, 385, 387, 390, 392,

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397, 420). Some commenters believed that a trained medical professional should make this determination, while others argued that the employer should make the ultimate decision about the work-relatedness of occupational injuries and illnesses. Some supported the use of the work-relatedness checklist for specific disorders included by OSHA in the proposal. For example, the American Public Health Association (Ex. 15: 341) commented:

> We also believe that work-relatedness should only be established by the documented determination of a qualified health care provider with specific training related to the type of case reported. OSHA's checklist for determining work-relatedness. . . .should be used and expanded to include potentially recordable cases, i.e., excluding first aid treatment.

The Dow Corning Corporation (Ex. 15: 374) argued that the employer should make the determination, albeit with the assistance of a health care professional:

> This assessment process should include interviews with knowledgeable people regarding the duties and hazards of the employee's job tasks in addition to the employee interview. If inaccurate or misleading information is given to the health care provider improper or inaccurate conclusions may be reached with regard to the incident cause. A health care provider's assessment of work-relationship is typically viewed as difficult to overcome, even if it is made with incomplete information. We recommend that the health care provider's checklist be used as only one input in the work-relationship decision and that the final decision should still rest with the employer.

Deere and Company (Ex. 15: 253) opposed leaving the determination of work-relatedness to a health care professional:

> We strongly disagree with any provision that would allow a physician to make a final determination of work-relatedness. The only time a physician should have any input into the actual determination of work-relatedness is if they are knowledgeable of the employer's workplace environment and the specific job tasks performed by employees. Frequently, physicians will state that a condition was caused by an employee's job without having any knowledge of the specific tasks being performed by the employee. This is an unacceptable usurpation of employers' rights and we oppose any attempt to codify it in a federal regulation.

However, several participants opposed making any work-relatedness checklist mandatory (such as the one OSHA proposed) (see, *e.g.*, Exs. 15: 68, 170, 201, 283, 434). The American Trucking Association's comment (Ex. 15: 397) was typical of this view:

> We do not, however, support a requirement that employers must use a mandatory checklist to determine work-relatedness. . . . Because the checklist asks for medical information, the employer would find itself in conflict with the confidentiality requirements imposed under the Americans With Disabilities Act. 29 C.F.R. § 1630.14. Moreover, a mandatory checklist would be unnecessarily time-consuming and subjective. Finally, we note that inclusion of item 5(b), "possible work contribution," biases the checklist in favor of work-relatedness. In the absence of a clear indication of whether or not the workplace caused or substantially caused the condition, asking a provider or employee if it were "possible" that the workplace contributed to or aggravated the injury/illness invites an affirmative response.

OSHA has concluded that requiring employers to rely on a health care professional for the determination of the work-relatedness of occupational injuries and illnesses would be burdensome, impractical, and unnecessary. Small employers, in particular, would be burdened by such a provision. Further, if the professional is not familiar with the injured worker's job duties and work environment, he or she will not have sufficient information to make a decision about the work-relatedness of the case. OSHA also does not agree that health care professional involvement is necessary in the overwhelming majority of cases. Employers have been making work-relatedness determinations for more than 20 years and have performed this responsibility well in that time. This does not mean that employers may not, if they choose, seek the advice of a physician or other licensed health care professional to help them understand the link between workplace factors and injuries and illnesses in particular cases; it simply means that OSHA does not believe that most employers will need to avail themselves of the services of such a professional in most cases.

Accordingly, OSHA has concluded that the determination of work-relatedness is best made by the employer, as it has been in the past. Employers are in the best position to obtain the information, both from the employee and the workplace, that is necessary to make this determination. Although expert advice may occasionally be sought by employers in particularly complex cases, the final rule provides that the determination of work-relatedness ultimately rests with the employer.

The Final Rule's Exceptions to the Geographic Presumption

Paragraph 1904.5(b)(2) of the final rule contains eight exceptions to the work environment presumption that are intended to exclude from the recordkeeping system those injuries and illnesses that occur or manifest in the work environment, but have been identified by OSHA, based on its years of experience with recordkeeping, as cases that do not provide information useful to the identification of occupational injuries and illnesses and would thus tend to skew national injury and illness statistics. These eight exceptions are the only exceptions to the presumption permitted by the final rule.

(i) *Injuries or illnesses will not be considered work-related if, at the time of the injury or illness, the employee was present in the work environment as a member of the general public rather than as an employee.* This exception, which is codified at paragraph 1904.5(b)(2)(i), is based on the fact that no employment relationship is in place at the time an injury or illness of this type occurs. A case exemplifying this exception would occur if an employee of a retail store patronized that store as a customer on a non-work day and was injured in a fall. This exception allows the employer not to record cases that occur outside of the employment relationship when his or her establishment is also a public place and a worker happens to be using the facility as a member of the general public. In these situations, the injury or illness has nothing to do with the employee's work or the employee's status as an employee, and it would therefore be inappropriate for the recordkeeping system to capture the case. This exception was included in the proposal, and OSHA received no comments opposing its adoption.

(ii) *Injuries or illnesses will not be considered work-related if they involve symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.* OSHA's recordkeeping system is intended only to capture cases that are caused by conditions or exposures arising in the work environment. It is not designed to capture cases that have no relationship with the work environment. For this exception to apply, the work environment cannot have caused, contributed to, or significantly aggravated the injury or illness. This exception is consistent with the position followed by OSHA for many years and reiterated in the final rule: that any job-related contribution to the injury or illness makes the incident work-related, and its corollary—that any injury or illness to which work makes no actual contribution is not work-related. An example of this type of injury would be a diabetic incident that occurs while an employee is working. Because no event or exposure at work contributed in any way to the diabetic incident, the case is not recordable. This exception allows the employer to exclude cases where an employee's non-work activities are the sole cause of the injury or illness. The exception was included in the proposal, and OSHA received no comments opposing its adoption.

(iii) *Injuries and illnesses will not be considered work-related if they result solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical, flu shot, exercise classes, racquetball, or baseball.* This exception allows the employer to exclude certain injury or illness cases that are related to personal medical care, physical fitness activities and voluntary blood donations. The key words here are "solely" and "voluntary." The work environment cannot have contributed to the injury or illness in any way for this exception to apply, and participation in the wellness, fitness or recreational activities must be voluntary and not a condition of employment.

This exception allows the employer to exclude cases that are related to personal matters of exercise, recreation, medical examinations or participation in blood donation programs when they are voluntary and are not being undertaken as a condition of work. For example, if a clerical worker was injured while performing aerobics in the company gymnasium during his or her lunch hour, the case would not be work-related. On the other hand, if an employee who was assigned to manage the gymnasium was injured while teaching an aerobics class, the injury would be work-related because the employee was working at the time of the injury and the activity was not voluntary. Similarly, if an employee suffered a severe reaction to a flu shot that was administered as part of a voluntary inoculation program, the case would not be considered work-related; however, if an employee suffered a reaction to medications administered to enable the employee to travel overseas on business, or the employee had an illness reaction to a medication administered to treat a work-related injury, the case would be considered work-related.

This exception was included in the proposal, and received support from a number of commenters (see, *e.g.*, Exs. 15: 147, 181, 188, 226, 281, 304, 341, 345, 363, 348, 373). Other commenters supported this proposal but suggested consolidating it with the proposed exception for voluntary activities away from the employer's establishment (see, *e.g.*, Exs. 15–176, 231, 248, 249, 250, 273, 301). OSHA has decided not to combine this exception with another exception because questions are often asked about injuries and illnesses that arise at the employer's establishment and the Agency believes that a separate exception addressing voluntary wellness programs and other activities will provide clearer direction to employers.

(iv) *Injuries and illnesses will not be considered work-related if they are solely the result of an employee eating, drinking, or preparing food or drink for personal consumption (whether bought on the premises or brought in).* This exception responds to a situation that has given rise to many letters of interpretation and caused employer concern over the years. An example of the application of this exception would be a case where the employee injured himself or herself by choking on a sandwich brought from home but eaten in the employer's establishment; such a case would not be considered work-related under this exception. On the other hand, if the employee was injured by a trip or fall hazard present in the employer's lunchroom, the case would be considered work-related. In addition, a note to the exception makes clear that if an employee becomes ill as a result of ingesting food contaminated by workplace contaminants such as lead, or contracts food poisoning from food items provided by the employer, the case would be considered work-related. As a result, if an employee contracts food poisoning from a sandwich brought from home or purchased in the company cafeteria and must take time off to recover, the case is not considered work related. On the other hand, if an employee contracts food poisoning from a meal provided by the employer at a business meeting or company function and takes time off to recover, the case would be considered work related. Food provided or supplied by the employer does not include food purchased by the employee from the company cafeteria, but does include food purchased by the employer from the company cafeteria for business meetings or other company functions. OSHA believes that the number of cases to which this exception applies will be few. This exception was included in the proposal and received generally favorable comments (see, *e.g.*, Exs. 15: 31, 78, 105, 159, 176, 181, 184, 188, 345, 359, 428).

(v) *Injuries and illnesses will not be considered work-related if they are solely the result of employees doing personal tasks (unrelated to their employment) at the establishment outside of their assigned working hours.* This exception, which responds to inquiries received over the years, allows employers limited flexibility to exclude from the recordkeeping system situations where the employee is using the employer's establishment for purely personal reasons during his or her off-shift time. For example, if an employee were using a meeting room at the employer's establishment outside of his or her assigned working hours to hold a meeting for a civic group to which he or she belonged, and slipped and fell in the hallway, the injury would not be considered work-related. On the other hand, if the employee were at the employer's establishment outside his or her assigned working hours to attend a company business meeting or a company training session, such a slip or fall would be work-related. OSHA also expects the number of cases affected by this exception to be small. The comments on this exception are discussed in more detail in the section concerning proposed Exception B–5, Personal Tasks Unrelated To Employment Outside of Normal Working Hours, found later in this document.

(vi) *Injuries and illnesses will not be considered work-related if they are solely the result of personal grooming, self-medication for a non-work-related condition, or are intentionally self-inflicted.* This exception allows the employer to exclude from the Log cases related to personal hygiene, self-administered medications and intentional self-inflicted injuries, such as attempted suicide. For example, a burn injury from a hair dryer used at work to dry the employee's hair would not be work-related. Similarly, a negative reaction to a medication brought from home to treat a non-work condition would not be considered a work-related illness, even though it first manifested at work. OSHA also expects that few cases will be affected by this exception.

(vii) *Injuries will not be considered work-related if they are caused by motor vehicle accidents occurring in company parking lots or on company access roads while employees are commuting to or from work.* This exception allows the employer to exclude cases where an employee is injured in a motor vehicle accident while commuting from work to home or from home to work or while on a personal errand. For example, if an employee was injured in a car accident while arriving at work or while leaving the company's property at the end of the day, or while driving on his or her lunch hour to run an errand, the case would not be considered work-related. On the other hand, if an employee was injured in a car accident while leaving

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the property to purchase supplies for the employer, the case would be work-related. This exception represents a change from the position taken under the former rule, which was that *no* injury or illness occurring in a company parking lot was considered work-related. As explained further below, OSHA has concluded, based on the evidence in the record, that some injuries and illnesses that occur in company parking lots are clearly caused by work conditions or activities—*e.g.*, being struck by a car while painting parking space indicators on the pavement of the lot, slipping on ice permitted to accumulate in the lot by the employer—and by their nature point to conditions that could be corrected to improve workplace safety and health.

(viii) *Common colds and flu will not be considered work-related.*

Paragraph 1904.5(b)(2)(viii) allows the employer to exclude cases of common cold or flu, even if contracted while the employee was at work. However, in the case of other infectious diseases such as tuberculosis, brucellosis, and hepatitis C, employers must evaluate reports of such illnesses for work relationship, just as they would any other type of injury or illness.

(ix) *Mental illness will not be considered work-related unless the employee voluntarily provides the employer with an opinion from a physician or other licensed health care professional with appropriate training and experience (psychiatrist, psychologist, psychiatric nurse practitioner, etc.) stating that the employee has a mental illness that is work-related.*

Exception (ix) is an outgrowth of proposed Exception B–11—Mental illness, unless associated with post-traumatic stress. There were more than 70 comments that addressed the issue of mental illness recordkeeping. Two commenters suggested that OSHA postpone any decision on the issue: the National Safety Council (Ex. 15: 359) recommended further study, and the AFL–CIO (Ex. 15: 418) stated that the problem of mental illness in the workplace was so prevalent and so important that it should be handled in a separate rulemaking devoted to this issue.

A few commenters, including NIOSH (Ex. 15: 407), the American Psychological Association (Ex. 15: 411), the AFL–CIO (Ex. 14: 418), the United Steelworkers of America (Ex. 15: 429), and the United Brotherhood of Carpenters Health and Safety Fund of North America (Ex. 15: 350) argued that recording should not be limited to post-traumatic stress as OSHA had proposed but should instead include a broader range of mental disorders. The primary arguments of this group of comments were:

- Workers are afflicted with a number of mental disorders caused or exacerbated by work, and the statistics should include those disorders just as they include physical disorders;
- If the records include only post-traumatic stress as a mental disorder, many work-related cases of mental illness will go unreported (6,000 mental illness cases are reported to the BLS and involve days away from work, but less than 10% of these are post-traumatic stress cases), and the statistics will be skewed and misinterpreted;
- Workers' compensation does not restrict compensable mental illnesses to post-traumatic stress cases;
- Employers are recording and reporting all mental disorders now and thus would not be burdened by continuing the practice.

Arguments in support of treating mental illnesses no differently from any other injury or illness were made by the American Psychological Association (Ex. 15: 411):

> The American Psychological Association strongly opposes OSHA's proposal to consider a mental illness to be work related only if it is "associated with post-traumatic stress." We feel that this proposal disregards an accumulating body of research showing the relationship between mental health/illness and workplace stressors. Mental illness associated with post traumatic stress is only one form of mental illness and use of this singular definition would exclude much of the mental illness affecting our nation's workforce.
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> Job stress is perhaps the most pervasive occupational health problem in the workplace today. There are a number of emotional and behavioral results and manifestations of job stress, including depression and anxiety. These mental disorders have usually been captured under the "mental illness" category but would no longer be recognized if the proposed reporting guidelines were enacted.
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> The 1985 National Health Interview Survey (Shilling & Brackbill, 1987) indicated that approximately 11 million workers reported health-endangering levels of "mental stress" at work. A large and growing body of literature on occupational stress has identified certain job and organizational characteristics as having deleterious effects on the psychological and physical health of workers, including their mental health. These include high workload demands coupled with low job control, role ambiguity and conflict, lack of job security, poor relationships with coworkers and supervisors, and repetitive, narrow tasks (American Psychological Association, 1996). These include role stressors and demands in excess of control. More precise analyses reveal that specific occupations and job factors present particular risks. For example, machine-paced workers (involving limited worker control of job demands) have one of the highest levels of anxiety, depression, and irritation of 24 occupations studied (Caplan et al., 1975). Health professionals (*e.g.*, physicians, dentists, nurses, and health technologists) have higher than expected rates of suicide which is most often related to depression (Milham, 1983) and of alcohol and drug abuse (Hoiberg, 1982). Nurses and other health care workers have increased rates of hospitalizations for mental disorders (Gundersson & Colcord, 1982; Hoiberg, 1982). This information about specific risks within different occupations provides important information for possible intervention and training to improve conditions while at the same time, indicating the possibility of specific stressors that need to be addressed within the job. This type information would be lost with the proposed reporting guidelines.

Fourteen commenters opposed having to record mental illness cases of any kind (Exs. 15: 78, 133, 184, 248, 249, 250, 304, 348, 378, 395, 406, 409, 412, 424). Their primary arguments were:

- The diagnosis of mental illnesses is subjective and unreliable;
- It is often impossible, even for a health care professional, to determine objectively which mental disorders are work-related and which are not;
- Workers have a right to privacy about mental conditions that should not be violated; employers fear the risk of invasion of privacy lawsuits if they record these cases on "public records"; because of confidentiality concerns, workers are unlikely to disclose mental illnesses, and employers will therefore be unable to obtain sufficient information to make recordability determinations;
- Mental illnesses are beyond the scope of the OSHA Act; Congress intended to include only "recognized injuries or illnesses";
- Recording mental disorders opens the door to abuse; workers may "fake" mental illnesses, and unions may encourage workers to report mental problems as a harassment tactic; and
- No useful statistics will be generated by such recording.

The American Iron and Steel Institute (AISI) (Ex.15: 395) expressed the concerns of the group of employers opposed to any recording of mental conditions:

> OSHA should eliminate its proposed recording requirements for mental illness. OSHA's proposed rule includes changes in an employee's psychological condition as an "injury or illness," and [proposed] Appendix A presumes that mental illness "associated with post-traumatic stress" is work related. Employers, employees, and OSHA have been wrestling for 25 years with the proper recording of fairly simple injuries like back injuries, sprains, and illnesses caused by chemical exposures. Requiring employers to record something as vague as psychological conditions will impose impossible burdens on employers (and compliance officers) and thus will create an unworkable recordkeeping scheme.
>
> Moreover, too little is known about the etiology of most mental conditions to justify any presumption or conclusion that a condition that surfaces at work was "caused" by something in the work environment. It is hard to imagine a mental illness appearing at work that is not a manifestation of a preexisting condition or predisposition. Thus, the only sensible approach is to exclude all mental illnesses from recording requirements.

Many commenters from business and trade associations either agreed with OSHA's proposal or recommended an even stricter limitation on recordable mental disorders (see, *e.g.*, Exs. 33, 15: 27, 31, 38, 46, 79, 122, 127, 132, 153, 170, 176, 181, 199, 203, 226, 230, 231, 273, 277, 289, 301, 305, 307, 308, 313, 325, 332, 352, 353, 368, 384, 387, 389, 392, 410, 427, 430, 434). Points raised by these commenters included recommendations that OSHA should require:

- Recording only of those mental illnesses that arise from a single, work-related traumatic or catastrophic event, such as a workplace explosion or an armed robbery;
- Recording only of those mental illnesses that are directly and substantially caused by a workplace incident;
- Recording only of diagnosed mental illnesses resulting from a single workplace event that is recognized as having the potential to cause a significant and severe emotional response;
- Recognition only of post-traumatic stress cases or related disorders that include physical manifestations of illness and that are directly related to specific, objectively documented, catastrophic work-related events; and
- Recording only of diagnosed conditions directly attributable to a traumatic event in the workplace, involving either death or severe physical injury to the individual or a co-worker.

Several commenters suggested the use of a medical evaluation to determine diagnosis and/or work-relationship in cases of mental illness (see, *e.g.*, Exs. 15: 65, 78, 105, 127, 170, 181, 184, 226, 230). For example, the Aluminum Company of America (Ex. 15: 65) stated that:

> OSHA should define mental health conditions for recordkeeping purposes as conditions diagnosed by a licensed physician or advanced health care practitioner with specialized psychiatric training (*i.e.*, psychiatric nurse practitioner). Work-relatedness of the mental health condition should be determined by a psychiatric independent medical evaluation.

A comment from the Department of Energy (Ex. 15: 163) stated that any diagnosis of mental illness should be made by at least two qualified physicians, and CONSOL Inc. (Ex. 15: 332) and Akzo Nobel (Ex. 15: 387) wanted the rule to require that any such diagnosis meet the criteria of the Diagnostic and Statistical Manual, Version IV (DSM–IV). Commenters had different opinions about the minimum qualifications necessary for a health care professional to make decisions about mental health conditions; specifically, some commenters urged OSHA to exclude "counselors" (Ex. 15: 226) or to include "only psychiatrists and Ph.D. psychologists" (Ex. 15: 184).

A number of commenters suggested excluding from the requirement to record any mental illness related to personnel actions such as termination, job transfer, demotions, or disciplinary actions (see, *e.g.*, Exs. 15: 68, 127, 136, 137, 141, 176, 184, 224, 231, 266, 273, 278, 301, 395, 424). The New York Compensation Board (Ex. 15: 68) noted that New York's workers' compensation law excludes such cases by specifying that mental injuries are compensable with the exception of injuries that are the "direct consequence of a lawful personnel decision involving a disciplinary action, work evaluation, job transfer, demotion, or termination taken in good faith by the employer."

Finally, several employers raised the issues of the privacy of an employee with a mental disorder, the need to protect doctor-patient confidentiality, and the potential legal repercussions of employers breaching confidentiality in an effort to obtain injury and illness information and in recording that information (see, *e.g.*, Exs. 15: 78, 153, 170, 195, 260, 262, 265, 277, 348, 392, 401, 406, 409). Some of these commenters suggested that an employer should only have the obligation to record after the employee has brought the condition to the attention of the employer, either directly or through medical or workers' compensation claims, and in no case should doctor-patient confidentiality be breached. (Issues related to confidentiality of the Log are discussed in detail in the summary and explanation of § 1904.35, *Employee Involvement.*)

After a review of the comments and the record on this issue, OSHA has decided that the proposed exception, which would have limited the work-relatedness (and thus recordability) of mental illness cases to those involving post-traumatic stress, is not consistent with the statute or the objectives of the recordkeeping system, and is not in the best interest of employee health. The OSH Act is concerned with both physical and mental injuries and illnesses, and in fact refers to "psychological factors" in the statement of Congressional purpose in section 2 of the Act (29 U.S.C. 651(b)(5)).

In addition, discontinuing the recording of mental illnesses would deprive OSHA, employers and employees, and safety and health professionals of valuable information with which to assess occupational hazards and would additionally skew the statistics that have been kept for many years. Therefore, the final rule does not limit recordable mental disorders to post traumatic stress syndrome or any other specific list of mental disorders. OSHA also does not agree that recording mental illnesses will lead to abuse by employees or others. OSHA has required the recording of these illnesses since the inception of the OSH Act, and there is no evidence that such abuse has occurred.

However, OSHA agrees that recording work-related mental illnesses involves several unique issues, including the difficulty of detecting, diagnosing and verifying mental illnesses; and the sensitivity and privacy concerns raised by mental illnesses. Therefore, the final rule requires employers to record only those mental illnesses verified by a health care professional with appropriate training and experience in the treatment of mental illness, such as a psychiatrist, psychologist, or psychiatric nurse practitioner. The employer is under no obligation to seek out information on mental illnesses from its employees, and employers are required to consider mental illness cases only when an employee voluntarily presents the employer with an opinion from the health care professional that the employee has a mental illness and that it is work related. In the event that the employer does not believe the reported mental illness is work-related, the employer may refer the case to a physician or other licensed health care professional for a second opinion.

OSHA also emphasizes that work-related mental illnesses, like other illnesses, must be recorded only when they meet the severity criteria outlined in § 1904.7. In addition, for mental illnesses, the employee's identity must be protected by omitting the employee's name from the OSHA 300 Log and instead entering "privacy concern case" as required by § 1904.29.

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Exceptions Proposed but Not Adopted

The proposed rule contained eleven exceptions to the geographic presumption. Some of these exceptions are included in the final rule, and therefore are discussed above, while others were rejected for various reasons. The following discussion addresses those proposed exemptions not adopted in the final rule, or not adopted in their entirety.

Proposed Exception B–5. Personal Tasks Unrelated To Employment Outside of Normal Working Hours. The proposed rule included an exception for injuries and illnesses caused solely by employees performing personal tasks at the establishment outside of their normal working hours. Some aspects of this proposed exception have been adopted in the final, but others have not. Almost all the comments on this proposed exception supported it (see, *e.g.*, Exs. 15: 31, 78, 105, 121, 159, 281, 297, 336, 341, 350), and many suggested that the exception be expanded to include personal tasks conducted *during* work hours (see, *e.g.*, Exs. 15: 176, 184, 201, 231, 248, 249, 250, 273, 301, 335, 348, 374). Caterpillar, Inc. (Ex. 15: 201) offered an opinion representative of the views of these commenters: "We agree with this exception but it should be expanded to include any personal tasks performed during work hours if the work environment did not cause the injury or illness. Expanding this exemption will be consistent with the exemptions for voluntary wellness program participation and eating, drinking, and preparing one's own food."

One commenter disagreed with the proposed exception (the Laborers Safety and Health Fund of North America (Ex. 15: 310)) and cited as a reason the difficulty of determining the extent to which, for example, a case involving an employee misusing a hazardous chemical after hours because he or she did not receive the necessary Right-to-Know training from the employer would qualify for this exception.

Several commenters suggested that OSHA clarify what it meant by the terms "personal tasks" and "normal working hours" (see, *e.g.*, Exs. 15: 102, 304, 345). For example, a representative of Constangy, Brooks & Smith recommended that:

> More explanation be provided regarding the further limitation on this exclusion. For example, does this section of the proposal envision the exclusion of injuries and illnesses resulting from personal tasks performed during overtime (i.e., outside of normal working hours)? If I am injured while talking to my spouse on the phone during regular business hours, must the case be recorded, while if the same injury occurs during overtime, the case is non-recordable? Also, how are injuries to salaried employees (who are exempt from overtime) treated under this aspect of the proposal? I submit that if these issues are not fully "fleshed out" in the proposal or its preamble, this subparagraph will result in the creation of more questions than it resolves.

The National Federation of Independent Business (NFIB) (Ex. 15: 304) asked OSHA "to specify that the 'normal working hours' refers to the work schedule of the employee not the employer. If this distinction is not made clear, this proposal arguably could deny this exemption to establishments which operate during non-standard operating hours (*e.g.*, 24 hours a day, weekends, after 5 PM, etc.)—and we assume this is not OSHA's intent."

OSHA believes that injuries and illnesses sustained by employees engaged in purely personal tasks at the workplace, outside of their assigned working hours, are not relevant for statistical purposes and that information about such injuries and illnesses would not be useful for research or other purposes underlying the recordkeeping requirements. OSHA has therefore decided to include some parts of the proposed exception in the final rule. Additional language has been added to the exception since the proposal to clarify that the exception also applies when the employee is on the premises outside of his or her assigned working hours, as the NFIB pointed out.

OSHA does not agree, however, with those commenters who suggested that the exception be expanded to include personal tasks performed by employees during work hours. As discussed in preceding sections of this summary and explanation and in the Legal Authority discussion, there are strong legal and policy reasons for treating an injury or illness as work-related if an event or exposure in the work environment caused or contributed to the condition or significantly aggravated a pre-existing condition. Under this "but-for" approach, the nature of the activity the employee was engaged in at the time of the incident is not relevant, except in certain limited circumstances. Moreover, OSHA believes that it would be difficult in many cases for employers to distinguish between work activities and personal activities that occur while the employee is on-shift. Accordingly, the final rule codifies parts of this proposed exception in paragraph 1904.5(b)(v) in the following form: "The injury or illness is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours."

Proposed Exception B–6. Cases Resulting From Acts of Violence by Family Members or Ex-spouses When Unrelated to Employment, Including Self-inflicted Injuries. The final rule does not exempt workplace violence cases from the Log, although it does allow employers to exclude cases that involve intentionally self-inflicted injuries. The final rule thus departs substantially from the proposal in this respect. The proposed exception, which would have exempted domestic violence and self-inflicted cases from the Log, drew many comments. The comments generally fell into four categories: (1) those urging OSHA to require the recording of all cases of violence occurring at the establishment; (2) those recommending that no violence cases at the establishment be recorded; (3) those recommending recordation only of violence cases perpetrated by certain classes of individuals; and (4) those urging OSHA to require the recording of cases involving violence related to employment without regard to the perpetrator. The comments on the proposed exception are discussed below.

No exemption/record all injuries and illnesses arising from violent acts. A number of commenters objected to OSHA's proposed exemption of domestic violence cases from the list of recordable injuries, arguing that all acts of violence occurring at the workplace should be recorded (see, *e.g.*, Exs. 15: 31, 54, 56, 88, 90, 91, 93, 94, 99, 101, 103, 104, 106, 111, 114, 115, 144, 186, 187, 238, 345, 362, 407, 418, 439). For example, the North Carolina Department of Labor stated that "if an employer must log the injuries sustained as a result of workplace violence then the employer may also institute needed security measures to protect the employees at the establishment. An employer should be required to log any 'preventable' injury (above first aid) that an employee sustains at the establishment" (Ex. 15: 186). The Miller Brewing Company also supported recording all acts of workplace violence, based on the following rationale: "I envision a scenario involving an angry husband attempting to kill his wife but, because he is a "bad shot," another employee is killed. Why should killing an innocent bystander be a reportable event, whereas a fatality involving a spouse is excluded?" (Ex. 15: 442).

Exception for all violent acts. There were commenters who thought injuries and illnesses resulting from violence were outside of OSHA's purview and should not be recorded at all (see, *e.g.*, Exs. 15: 28, 75, 96, 107, 203, 254, 289). For example, the Quaker Oats Company (Ex. 15: 289) stated that "[w]orkplace violence in any form is a personal criminal act, and in no way, shape or form should violence be labeled under hazards in the workplace or even [be] monitored by OSHA. A person who may turn to violent behavior from family, personal, or job dispute is a matter of NLRB [National Labor Relations Board], law enforcement or state employment statutes, not industrial safety." The National Restaurant Association (Ex. 15: 96) agreed:

> Congress passed the Occupational Safety and Health Act to regulate workplace hazards dealing with the workplace environment or processes that employers could identify and possibly protect. The Congress did not contemplate that this statute would be used to redress incidents over which the employer has no ability to control, such as the unpredictability of workers or nonworkers committing violent, tortuous acts towards others. This issue was litigated unsuccessfully by OSHA in Secretary of Labor v. Megawest Financial, Inc., OSHRC Doc. No. 93–2879 (June 19, 1995). OSHA apparently is attempting in this NPR to obtain by regulatory fiat what was rejected by case law and to displace state tort law actions by using the OSH Act to police social behavior.

Recording work-related violence except acts of certain classes of individuals. There were many commenters who supported the proposed exception, which would only have excluded acts of violence on employees committed by family members and ex-spouses and self-inflicted injuries and illnesses. The proposed exception as drafted was supported by some commenters (see, *e.g.*, Exs. 15: 78, 198, 350, 359). Others thought the exception should be expanded to include not only family members and ex-spouses, but also live-in partners, friends, and other intimates (see, *e.g.*, Exs. 15: 80, 122, 153, 181, 213, 325, 363, 401), while others argued that the exemption should apply to the general public, i.e., to all people (see, *e.g.*, Exs. 15: 9, 111, 119, 151, 152, 179, 180, 239, 260, 262, 265, 272, 303, 304, 341, 356, 375, 401, 430).

Typical of comments in support of a broader exception were the remarks of the National Oilseed Processors Association (Ex. 15: 119):

> The only time violence in the work place should be considered work-related is when it is associated with a work issue and committed by an employee or other person linked to the business, *e.g.*, a customer. Any other act of violence is not under the control of the employer and should not be considered work-related.

Alabama Shipyard Inc. (Ex. 15: 152) added:

> Exempting acts of violence based strictly on acts committed by family members, a spouse, or when self-inflicted is too limited. Instead, the exemption should be based on the relationship of the perpetrator to the employer. The employer should be no more responsible for some random act of violence by a crazy individual walking in off the street who is in no way associated with the employer than it should be for an act of violence by a family member.

Southern California Edison (Ex. 15: 111) stated that "violence is another example that should be excluded from being work-related if the employee personally knows the attacker. This would include family members or coworkers. Only those acts of violence that result from random criminal activity should be included (i.e., robbery, murder, etc.)." TU Services (Ex. 15: 262) recommended "that only cases that involve acts of violence that are the result of random criminal activity should be recorded. Cases that involve anyone with a personal relationship with the employee should be excluded." The American Feed Industry Association (Ex. 15: 204) and United Parcel Service (Ex. 15: 424), on the other hand, argued that cases involving workplace violence should only be recorded if the perpetrator was a fellow employee.

Record all violent acts directly related to employment regardless of who commits the act. Commenters favoring this approach suggested that violence by family members or others should be recorded if linked to work, but that all personal disputes should be exempt (see, *e.g.*, Exs. 15: 105, 146, 176, 184, 231, 273, 297, 301, 313, 336, 348, 352, 353, 374, 389, 392). The Workplace Health and Safety Council (Ex. 15: 313) proposed the following exception:

> Cases will not be considered work-related if they result solely from acts of violence committed by one's family, or ex-spouse, or other persons when unrelated to the worker's employment, including intentionally self-inflicted injuries. Violence by persons on the premises in connection with the employer's business (including thieves and former employees) is considered work related even if committed by one's family or ex-spouse.

The American Ambulance Association (Ex. 15: 226) stated simply: "AAA believes that OSHA should define what is work-related violence and assume that all other acts are not work-related, and eliminate the family and non-family distinction." The United Auto Workers (Ex. 15: 438) agreed:

> Incidents of intentional violence should be recorded only if they arise from employment activities. Incidents between employees, or between employees and non-employees which rise from personal disputes should not be recorded. Existing data show that the number of incidents of interpersonal violence between coworkers or workers and intimates is small, although these incidents do get high visibility. Therefore, exclusion of these small number of cases will have little effect on statistical measures.

Some commenters urged OSHA to place some restrictions on the proposed exception. For example, two commenters argued that cases involving violence should only be recorded for occupations where there is a reasonable potential of encountering violence (Exs. 15: 335, 409). The American Automobile Manufacturers Association (AAMA) stated that:

> Workplace violence as a reasonable function of an employee's employment should be recorded, for example: a cashier injured in a robbery attempt at a 24-hour retail establishment. An example of "unreasonable" recordable workplace violence that should not be recordable (i.e., where an employee was simply "in the wrong place at the wrong time") would be a flight crew that perishes mid-flight from a terrorist's bomb. These cases have nothing to do with the individual's employer, only that they happened to be victims at the employer's place of employment. It is AAMA's understanding that the purpose of the subject standard is to collect information pertaining to injuries and illnesses that arise out of conditions in the workplace, with the end objective being to use that information to correct or mitigate these conditions so as to prevent additional injuries or illnesses.

Caterpillar Inc. (Ex. 15: 201) suggested that "a predominant contributor concept, similar to that being proposed to help establish work-relatedness, could be utilized in cases where the clear cause of violence is not readily apparent."

In the final rule, OSHA has decided not to exclude from recording those injury and illness cases involving acts of violence against employees by family members or ex-spouses that occur in the work environment or cases involving other types of violence-related injuries and illnesses. The final rule does exempt from recording those cases resulting from intentionally self-inflicted injuries and illnesses; these cases represent only a small fraction of the total number of workplace fatalities (three percent of all 1997 workplace violence fatalities) (BLS press release USDL 98–336, August 12, 1998). OSHA believes that injuries and illnesses resulting from acts of violence against employees at work are work-related under the positional theory of causation. The causal connection is usually established by the fact that the assault or other harmful event would not have

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occurred had the employee not, as a condition of his or her employment, been in the position where he or she was victimized. Moreover, occupational factors are directly involved in many types of workplace violence, such as assaults engendered by disputes about working conditions or practices, or assaults on security guards or cashiers and other employees, who face a heightened risk of violence at work. Accordingly, OSHA does not accept the premise, advanced by some commenters, that workplace violence is outside the purview of the statute.

In some cases, acts of violence committed by a family member or ex-spouse at the workplace may be prevented by appropriate security measures enforced by employers. Moreover, information about workplace injuries due to assaults by family members or ex-spouses is relevant and should be included in the overall injury and illness data for statistical and research purposes. Omitting the proposed exception also obviates the need for employers to make distinctions among various degrees of personal relationships. Accordingly, the final rule does not allow employers to exclude injuries and illnesses resulting from violence occurring in the workplace from their Logs. However, some cases of violence will be excluded under § 1904.5(b)(2)(v), which exempts an injury or ilness that is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours. For example, if an employee arrives at work early to use a company conference room for a civic club meeting, and is injured by some violent act, the case would not be considered work related.

OSHA has decided to maintain the exclusion for intentionally self-inflicted injuries that occur in the work environment in the final rule. The Agency believes that when a self-inflicted injury occurs in the work environment, the case is analogous to one in which the signs or symptoms of a pre-existing, non-occupational injury or illness happen to arise at work, and that such cases should be excluded for the same reasons. (see paragraph 1904.5(b)(2)(ii)). The final rule at paragraph 1904.5(b)(2)(vi) therefore includes that the part of exception proposed that applied to injuries and illnesses that are intentionally self-inflicted.

Proposed Exception B–7. Parking Lots and Access Roads. This proposed exception, which in effect would have narrowed the definition of "establishment" to exclude company parking lots, had approximately equal numbers of commenters in favor and opposed. The final rule includes some aspects of the proposed exemption. In favor of recording injuries in parking lots and on access roads were the commenters represented by Exs. 24, 15: 41, 72, 310, 362. Typical of the views of this group was that of the Association of Operating Room Nurses (AORN) (Ex. 15: 72), which noted that:

> [e]mployee parking lots should be included in defining "work-related." Perioperative nurses and other surgical service providers may be required on a "call" basis during the night hours. Consequently they enter and leave parking lots at unusual times when traffic in the lots is minimal. These providers may be at increased risk for random violence. Absent the "call" requirement, the employee would not be in the parking lot at the time of the injury. Further, if the employee is paid for travel time to and/or from the facility, injuries occurring during that period should be considered "work-related."

The AFL-CIO (Ex. 15: 362) added that employers may be less likely to provide lighting, security and other controls that could prevent violent assaults in parking lots and access roads if injuries occurring there are not recordable.

The opposite view, in support of the proposed exception for parking lots, was expressed by several employers (see, *e.g.*, Exs. 15: 27, 45, 176, 185, 195, 231, 248, 249, 250, 273, 289, 301, 304, 341, 363). The National Wholesale Druggists Association (NWDA) (Ex. 15: 185) supported the proposed exclusion:

> [i]nevitably, activities that take place in the company parking lot or on the company access road are not only outside of the employer's dominion and control but also are most often not related in any way to the employee's work. Including injuries that occur in these locations as part of the OSHA log would lead to an inaccurate reflection of injury data as a whole. OSHA should retain this exemption. An employer has no control over an employee's commute to and from the workplace, with the exception of arrival and departure times for the work day. If OSHA requires the reporting of injuries that occur during the employee's commute, the number of injuries reported would increase dramatically.

The National Federation of Independent Business (Ex. 15: 304) stated that the proposed exception would be consistent with workers' compensation rules.

OSHA has concluded that a limited exception for cases occurring on parking lots is appropriate but that the broader exception proposed is not. The final rule thus provides an exception for motor vehicle injury cases occurring when employees are commuting to and from work. As discussed in the preamble that accompanies the definition of "establishment" (see Subpart G of the final rule), OSHA has decided to rely on activity-based rather than location-based exemptions in the final rule. The parking lot exception in the final rule applies to cases in which employees are injured in motor vehicle accidents commuting to and from work and running personal errands (and thus such cases are not recordable), but does not apply to cases in which an employee slips in the parking lot or is injured in a motor vehicle accident while conducting company business (and thus such cases are recordable). This exception is codified at paragraph 1904.5(b)(2)(vii) of the final rule.

Proposed Exception B–8. Never Engaged in an Activity That Could Have Placed Stress On the Affected Body Part. This proposed exception would have allowed employers not to record cases if no aspect of the worker's job placed stress on the affected body part or exposed the worker to any chemical or physical agent at work that could be associated with the observed injury or illness. This proposed exception received support from a number of employers (see, *e.g.*, Exs. 15: 176, 185, 231, 273, 301, 341, 359, 406). For example, the National Wholesale Druggists' Association stated that "Such injuries or illnesses are obviously not caused by any work-related activities and should therefore be excluded from any reporting and recording requirements' (Ex. 15: 185).

Deleting the word "never" from the proposed exception was also supported by many respondents (see, *e.g.*, Exs. 15: 146, 279, 304, 335, 374, 392, 395, 430, 431, 442). Representative of the latter group is the following comment by the BF Goodrich Company (Ex. 15: 146):

> The use of the term "never" in this exemption requires too harsh a test for case evaluation. A back injury should not be recordable because the employee lifted a box 10 years previous to the injury. A more reasonable evaluation criteria meeting the same intent could be stated as below: The injury or illness is not work-related if it cannot be associated with the employee's duties or exposures at work.

Taking an opposing view to the proposed exception were the AFL-CIO (Ex. 15: 418), the United Steelworkers of America (Ex. 15: 429), and the United Brotherhood of Carpenters Health and Safety Fund of North America (Ex. 15: 350). The AFL-CIO stated that:

> We believe when evaluating injuries this approach could logically work in most cases, but in cases of chemical exposures and musculoskeletal disorders this logic does not hold merit. If the Agency attempts to apply this approach to the aforementioned types of cases, the employer will have to become an epidemiologist, ergonomist or toxicologist to determine if these cases meet the recordability criteria set forth in this proposal . . . . We encourage the Agency to omit this provision from the final standard. Because of the increasing numbers of workers being medically diagnosed for multiple chemical sensitivity and the exposures some workers receive without any knowledge until years after the incident, the Agency must carefully think about the inclusion of this provision to the final standard.

Similarly, the Carpenters Fund (UBC H&SF) argued that:

> [T]his [exception] would exclude those cases where symptoms arise at work, but are caused by accidents or exposures away from work. The UBC H&SF agrees with the theory of this provision, but emphasizes that the task placed on employers to determine causation by exposures away from work would in many cases be impossible. Also the apportionment of causation is not discussed in this analysis and would allow some to record cases .01 percent caused by work and others to not record cases 99 percent caused by work. For the foregoing reasons, that this requirement is unworkable, we urge it be dropped from the final rule.

Based on a review of the record on this issue, OSHA has decided not to include this proposed exception in the final rule. On reflection, the proposed language is confusing and would be difficult to apply. The underlying concept, to the extent it has merit, is better covered in the exemption paragraph 1904.5(b)(2)(ii). As discussed in preceding sections of this summary and explanation for section 1904.5, there are sound legal and policy justifications for defining work-relationship broadly to include injuries and illnesses that result from events or exposures in the work environment. The proposed exception would effectively "swallow" the geographic presumption theory of causation underpinning the rule by shifting the focus of enquiry in every case to the employee's specific job duties. As OSHA has noted, the geographic presumption includes some cases in which the illness or injury cannot be directly linked to the stresses imposed by job duties. For example, if an employee trips while walking on a level factory floor and breaks his arm, the injury should be recordable. The comments supporting the proposed exemption do not, in OSHA's view, provide a basis for excluding these types of cases from recording on the Log.

Proposed Exception B–9. Voluntary Community Activities Away From The Employer's Establishment. This proposed exemption drew two comments supporting it as written (Exs. 15: 78, 304), and several other participants recommended that it be expanded to exclude injuries and illnesses that arise from voluntary community activities wherever they occur (see, *e.g.*, Exs. 15: 146, 184, 272, 303, 359). Typical of these comments is one from U.S. West (Ex. 15: 184), which stated that "[e]mphasis should be on the activity that occurred, not the location of the activity."

The United Brotherhood of Carpenters, Health & Safety Fund of North America (Ex. 15: 350) agreed with the proposed exception, except for cases where the employee is present as a condition of employment or in the employer's interest. It commented:

> [A]t the surface this exception seems to make perfect sense. However, real employment relationships and real employer-community relationships do not fit such clean characterizations. Many times employees are forced to become "team players" and volunteer for unpaid off-establishment activities. Many employers engage in community "good will" generating activities by having their employees volunteer. For the above reasons we urge that cases occurring away from the employer's establishment be considered work-related if the employee is engaged in any activity in the interest of the employer or is there as a condition of employment.

OSHA has decided not to include this proposed exception in the final rule because the final rule's overall definition of work-environment addresses this situation in a simple and straightforward way. If the employee is taking part in the activity and is either working or present as a condition of employment, he or she is in the work environment and any injury or illness that arises is presumed to be work-related and must then be evaluated for its recordability under the general recording criteria. Thus, if the employee is engaged in an activity at a location away from the establishment, any injury or illness occurring during that activity is considered work-related if the worker is present as a condition of employment (for example, the worker is assigned to represent the company at a local charity event). For those situations where the employee is engaged in volunteer work away from the establishment and is not working or present as a condition of employment, the case is not considered work-related under the general definition of work-relationship. There is thus no need for a special exception.

Proposed Exception B–10. The Case Results Solely From Normal Body Movements, not Job-Related Motions or Contribution from the Work Environment. This proposed exception generated some support (see, *e.g.*, Exs. 15: 107, 147, 173, 185, 341, 348, 373, 392) but also caused much confusion about the meaning of the phrases "normal body movement" and "job-related" (see, *e.g.*, Exs. 15: 80, 83, 89, 98, 146, 176, 225, 226, 231, 239, 273, 301, 304, 313, 352, 353, 355, 359, 406, 424). The following comment by the American Gas Association (Ex. 15: 225) is representative of those in this group:

> '[N]ormal body movements' needs clarification since OSHA has not set forth any reasons for excluding it. OSHA's language states that there is an exclusion "* * * provided that activity does not involve a job related motion and the work environment does not contribute to the injury or illness". OSHA goes on to elaborate that illnesses or injuries should not be recorded if they are not related to an identifiable work activity. However, OSHA also states the exclusion would not apply if it involved repetitive motion or if the work environment either caused or contributed to the injury or illness. This language is ambiguous and redundant. Repetitive motion injury/illness conditions should be treated in the same way as any other condition. There should be a work-related exclusion if the work environment did not cause or contribute to the injury/illness.

LeRoy E. Euvard, Jr., Safety and Environmental Staff (Ex. 15: 80) added:

> [T]he definition of work-related resulting from normal body movements is too broad. The definition excludes walking, talking, etc. 'provided the activity does not involve a job-related motion.' Does that mean that if an employee is walking to the rest room and becomes ill, the illness is not work-related, but, if he/she is walking from the rest room back to his/her work station, it is work-related? If the employee is engaged in social talk, the illness is not work-related, but, if he/she is engaged in a conversation regarding some aspect of work, the illness is work-related?

Other commenters objected to the concept of excluding cases resulting from normal body movements from the Log (Ex. 56X, pp. 51, 52; Ex. 15: 418). Walter Jones of the International Brotherhood of Teamsters used the following example:

> We do take opposition to some of the exceptions. For cases that result in normal body movement, I'd like to just bring another example up. We have a member who after spending most of his morning sorting about 700 different boxes, on break in a normal, unencumbered motion, dropped his pencil and picked it up, had a back spasm and his back went out. And I know that according to the way the standard is written, or the regulation is written, that this can be attributed to work activity. But the reason we bring it up is we need to be careful in trying to be that exact because an employer will take an uninformed employee and may take liberties (Ex. 56X, pp. 51, 52).

OSHA has decided not to include a recordkeeping exception for injuries or illnesses associated with normal body movements in the final rule. The

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proposed provision was intended to exclude the recording of cases that happened to occur in the work environment without any real work contribution. However, the comments on this issue have convinced OSHA that the proposed provision is unnecessary, would be unworkable, and would result in incomplete and inconsistent data. The case cited by the Teamsters is but one example of a legitimate work-related injury that could go unrecorded if OSHA were to adopt this provision in the final rule. Further, the final rule already makes clear that injuries and illnesses that result solely from non-work causes are not considered work-related and therefore are excluded from the Log, and establishes the requirements employers must follow to determine work-relationship for an injury or illness when it is unclear whether the precipitating event occurred in the workplace or elsewhere (see paragraph 1904.5(b)(3)). According to the requirements in that section, the employer must evaluate the employee's work duties and the work environment to decide whether it is more likely than not that events or exposures in the work environment either caused or contributed to the condition or significantly aggravated a pre-existing condition. If so, the case is work-related.

Additional Exemptions Suggested by Commenters but Not Adopted

In addition to commenting on the eleven proposed exceptions, interested parties suggested adding some exceptions to the final rule. This section contains a discussion of those additional exemptions suggested by commenters but not adopted in the final rule.

Acts of God: The International Dairy Foods Association (IDFA) suggested that OSHA exclude any injury or illness that was "the result of an "Act of God," such as, but not limited to, an earthquake or a tornado" (Ex. 15: 203). OSHA has not adopted such an exception because doing so would not be in keeping with the geographic presumption underpinning this final rule, and would exclude cases that are in fact work-related. For example, if a worker was injured in a flood while at work, the case would be work-related, even though the flood could be considered an act of God. Accordingly, if workplace injuries and illnesses result from these events, they must be entered into the records (for a more detailed discussion of this point, see the Legal Authority section, above).

Phobias: The American Crystal Sugar Company (Ex. 15: 363) suggested that OSHA add an exception from recording for cases involving phobias:

> I would also like to suggest exempting an employee's loss of consciousness based on a fear-based phobia, i.e., fainting at the sight of blood. Occasionally an OSHA regulation may require blood tests, such as checking lead levels in blood. There are a few employees that will lose consciousness at the sight of a needle. These phobias are not limited to medical procedures, but may include spiders, snakes, etc. In several of our factories, the occupational health nurse will administer tetanus boosters as a service to our employees. Employees that have a phobia about injections can (and do) lose consciousness, which now makes what was intended as a service an OSHA recordable accident.

OSHA has not included an exception from recording in the final recordkeeping regulation for phobias or any other type of mental illness. The scenario described by the American Crystal Sugar Company, which involved fainting from fear of an injection offered as a service to employees, might be considered non-work-related under the exception codified at paragraph 1904.5(b)(2)(iii), Voluntary participation in a medical activity. OSHA also believes that it would be unreasonable to omit a case of loss of consciousness resulting from the administration of a blood test for lead exposure at work. These tests are necessitated by the employee's exposure to lead at work and are required by OSHA's lead standard (29 CFR 1910.1025). The other scenarios presented by these commenters, involving spiders, snakes, etc., would also be work-related under the geographic presumption.

Illegal activities and horseplay: Several commenters suggested an exception for an employee engaging in illegal activities, horseplay, or failing to follow established work rules or procedures (see, *e.g.*, Exs. 15: 49, 69, 117, 151, 152, 179, 180, 203, 368, 393). The comment of the American Network of Community Options and Resources (ANCOR) (Ex. 15: 393) is representative of those on this issue:

> Employees who fail to follow employer training and best practices or violate established policy present a threat not only to other employees and consumers/customers, but also to employers held responsible for the consequences of their actions. For example, ANCOR does not believe that employers should have to use these recording and reporting procedures when illnesses and injuries are a result of an employee engaged in illegal activities or fails/violates established procedures.

OSHA has not adopted any of these recommended exceptions in the final recordkeeping rule because excluding these injuries and illnesses would be inconsistent with OSHA's longstanding reliance on the geographic presumption to establish work-relatedness. Furthermore, the Agency believes that many of the working conditions pointed to in these comments involve occupational factors, such the effectiveness of disciplinary policies and supervision. Thus, recording such incidents may serve to alert both the employer and employees to workplace safety and health issues.

Non-occupational degenerative conditions: Two commenters also asked OSHA to include in the final rule a recording exception for non-occupational degenerative conditions (Exs. 15: 176, 248) such as high blood pressure, arthritis, coronary artery disease, heart attacks, and cancer that can develop regardless of workplace exposure. OSHA has not added such an exception to the rule, but the Agency believes that the fact that the rule expects employers confronted with such cases to make a determination about the extent to which, if at all, work contributed to the observed condition will provide direction about how to determine the work-relatedness of such cases. For example, if work contributes to the illness in some way, then it is work-related and must be evaluated for its recordability. On the other hand, if the case is wholly caused by non-work factors, then it is not work-related and will not be recorded in the OSHA records.

Determining Whether the Precipitating Event or Exposure Occurred in the Work Environment or Elsewhere

Paragraph 1904.5(b)(3) of the final rule provides guidance on applying the geographic presumption when it is not clear whether the event or exposure that precipitated the injury or illness occurred in the work environment or elsewhere. If an employee reports pain and swelling in a joint but cannot say whether the symptoms first arose during work or during recreational activities at home, it may be difficult for the employer to decide whether the case is work-related. The same problem arises when an employee reports symptoms of a contagious disease that affects the public at large, such as a staphylococcus infection ("staph" infection) or Lyme disease, and the workplace is only one possible source of the infection. In these situations, the employer must examine the employee's work duties and environment to determine whether it is more likely than not that one or more events or exposures at work caused or contributed to the condition. If the employer determines that it is unlikely that the precipitating event or exposure occurred in the work environment, the employer would not record the case. In the staph infection example given above, the employer would consider the case work-related, for example, if another employee with whom the newly infected employee had contact at work had been out with a staph infection. In the Lyme disease example, the employer would determine the case to be work-related if, for example, the employee was a groundskeeper with regular exposure to outdoor conditions likely to result in contact with deer ticks.

In applying paragraph 1904.5(b)(3), the question employers must answer is whether the precipitating event or exposure occurred in the work environment. If an event, such as a fall, an awkward motion or lift, an assault, or an instance of horseplay, occurs at work, the geographic presumption applies and the case is work-related unless it otherwise falls within an exception. Thus, if an employee trips while walking across a level factory floor, the resulting injury is considered work-related under the geographic presumption because the precipitating event—the tripping accident—occurred in the workplace. The case is work-related even if the employer cannot determine why the employee tripped, or whether any particular workplace hazard caused the accident to occur. However, if the employee reports an injury at work but cannot say whether it resulted from an event that occurred at work or at home, as in the example of the swollen joint, the employer might determine that the case is not work-related because the employee's work duties were unlikely to have caused, contributed to, or significantly aggravated such an injury.

Significant Workplace Aggravation of a Pre-existing Condition

In paragraph 1904.5(b)(4), the final rule makes an important change to the former rule's position on the extent of the workplace aggravation of a preexisting injury or illness that must occur before the case is considered work-related. In the past, any amount of aggravation of such an injury or illness was considered sufficient for this purpose. The final rule, however, requires that the amount of aggravation of the injury or illness that work contributes must be "significant," *i.e.*, non-minor, before work-relatedness is established. The preexisting injury or illness must be one caused entirely by non-occupational factors.

A number of commenters on OSHA's proposed rule raised the issue of recording injuries that were incurred off the job and then were aggravated on the job (see, *e.g.*, Exs. 15: 60, 80, 95, 107, 176, 201, 204, 213, 281, 308, 313, 338, 368, 375, 395, 396, 406, 424, 427, 428, 441). The National Roofing Contractors Association (NRCA) commented that "[t]his definition [includes] aggravating a pre-existing condition. While NRCA believes that the exemptions provided [in the proposed rule] are a step in the right direction, this provision could require that an employer record an injury that originally occurred outside the employer's workplace. The motion or activity that aggravated the injury may not represent any substantial hazard, yet would still be recorded" (Ex. 15: 441). The United Parcel Service (Ex. 15: 424) objected to the inclusion of the concept of aggravation in the definition of work-relatedness:

> [a]nother flaw in the proposal arises from its proposed recording requirement in the case of "aggravation" of prior conditions. As drafted, the rule would require reporting as an occupational injury or illness a musculoskeletal condition arising away from work which becomes aggravated by performing job duties (i.e., the job increases discomfort), when accompanied by swelling or inflammation. Thus, an employee who hurts his wrist playing tennis on the weekend and who returns to his word processing job Monday would have a reportable MSD under the rule. With such criteria for recordation, reported occupational injuries and illnesses would skyrocket, and yet most often these reports would reflect conditions arising away from work.

The Food Distributors International (Ex. 15: 368) recommended:

> [i]t is very important that injuries that are not truly work-related not be the subject of mandatory recording. For example, if an employee were injured off the job and came to work to "try it out" (i.e., to see if he or she was capable of performing the normal job functions), resulting pain might be seen as "aggravation" and become recordable on that basis. The true source of injury, however, would be outside the workplace, and recording would produce an artificially inflated rate of injuries and illnesses, and a profile that was inaccurate.

Several commenters were concerned about the aggravation of preexisting injuries in the context of recurrences or new cases (see, *e.g.*, Exs. 15: 210, 204, 338) . For example, Caterpillar Inc. (Ex. 15: 201) stated that:

> [b]lack injuries, repetitive motion injuries, and other chronic conditions which have degenerative or aging causal factors often recur without a new work accident and further without a new work accident capable of causing the underlying condition. Even if a new work accident occurs, the accident should be serious enough to cause the underlying condition before the new case presumption is applicable. The effect of this would be to eliminate minor aggravation of preexisting conditions from consideration as new injuries.

LeRoy E. Euvard, Jr., of the Safety and Environmental Staff Company (Ex. 15: 80), suggested that:

> [a]ggravation of a pre-existing condition should not be recordable if normal body movements or events cause the aggravation. For example, a smoker with asthma or other obstructive airway disease may experience shortness of breath while climbing a flight of stairs. A person with degenerative disk disease may experience pain while lifting a normal bag of groceries. If performing similar activities at work likewise aggravates the condition, it should not be recordable.

As discussed above, OSHA agrees that non-work-related injuries and illnesses should not be recorded on the OSHA Log. To ensure that non-work-related cases are not entered on the Log, paragraph 1904.5(b)(2)(ii) requires employers to consider as non-work-related any injury or illness that "involves signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment."

The Agency also believes that preexisting injury or illness cases that have been aggravated by events or exposures in the work environment represent cases that should be recorded on the Log, because work has clearly worsened the injury or illness. OSHA is concerned, however, that there are some cases where work-related aggravation affects the preexisting case only in a minor way, i.e., in a way that does not appreciably worsen the preexisting condition, alter its nature, change the extent of the medical treatment, trigger lost time, or require job transfer. Accordingly, the final rule requires that workplace events or exposures must "significantly" aggravate a pre-existing injury or illness case before the case is presumed to be work-related. Paragraph 1904.5(a) states that an injury or illness is considered work-related if "an event or exposure in the work environment either caused or contributed to the resulting condition or *significantly aggravated* a pre-existing injury or illness."

Paragraph 1904.5(b)(4) of the final rule defines aggravation as significant if the contribution of the aggravation at work is such that it results in tangible consequences that go beyond those that the worker would have experienced as a result of the preexisting injury or illness alone, absent the aggravating effects of the workplace. Under the final rule, a preexisting injury or illness will be considered to have been significantly aggravated, for the purposes of OSHA injury and illness recordkeeping, when an event or exposure in the work

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environment results in: (i) Death, providing that the preexisting injury or illness would likely not have resulted in death but for the occupational event or exposure; (ii) Loss of consciousness, providing that the preexisting injury or illness would likely not have resulted in loss of consciousness but for the occupational event or exposure; (iii) A day or days away from work or of restricted work, or a job transfer that otherwise would not have occurred but for the occupational event or exposure; or (iv) Medical treatment where no medical treatment was needed for the injury or illness before the workplace event or exposure, or a change in the course of medical treatment that was being provided before the workplace event or exposure. OSHA's decision not to require the recording of cases involving only minor aggravation of preexisting conditions is consistent with the Agency's efforts in this rulemaking to require the recording only of non-minor injuries and illnesses; for example, the final rule also no longer requires employers to record minor illnesses on the Log.

Preexisting Conditions

Paragraph 1904.5(b)(5) stipulates that pre-existing conditions, for recordkeeping purposes, are conditions that resulted solely from a non-work-related event or exposure that occurs outside the employer's work environment. Pre-existing conditions also include any injury or illness that the employee experienced while working for another employer.

Off Premises Determinations

Employees may be injured or become ill as a result of events or exposures away from the employer's establishment. In these cases, OSHA proposed to consider the case work-related only if the employee was engaged in a work activity or was present as a condition of employment (61 FR 4063). In the final rule, (paragraph 1904.5(b)(1)) the same concept is carried forward in the definition of the work environment, which defines the environment as including the establishment and any other location where one or more employees are working or are present as a condition of their employment.

Thus, when employees are working or conducting other tasks in the interest of their employer but at a location away from the employer's establishment, the work-relatedness of an injury or illness that arises is subject to the same decision making process that would occur if the case had occurred at the establishment itself. The case is work-related if one or more events or exposures in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition, as stated in paragraph 1904.5(a). In addition, the exceptions for determining work relationship at paragraph 1904.5(b)(2) and the requirements at paragraph 1904.5(b)(3) apply equally to cases that occur at or away from the establishment.

As an example, the work-environment presumption clearly applies to the case of a delivery driver who experiences an injury to his or her back while loading boxes and transporting them into a building. The worker is engaged in a work activity and the injury resulted from an event—loading/unloading—occurring in the work environment. Similarly, if an employee is injured in an automobile accident while running errands for the company or traveling to make a speech on behalf of the company, the employee is present at the scene as a condition of employment, and any resulting injury would be work-related.

Employees on Travel Status

The final rule continues (at § 1904.5(b)(6)) OSHA's longstanding practice of treating injuries and illnesses that occur to an employee on travel status as work-related if, at the time of the injury or illness, the employee was engaged in work activities "in the interest of the employer." Examples of such activities include travel to and from customer contacts, conducting job tasks, and entertaining or being entertained if the activity is conducted at the direction of the employer.

The final rule contains three exceptions for travel-status situations. The rule describes situations in which injuries or illnesses sustained by traveling employees are not considered work-related for OSHA recordkeeping purposes and therefore do not have to be recorded on the OSHA 300 Log. First, when a traveling employee checks into a hotel, motel, or other temporary residence, he or she is considered to have established a "home away from home." At this time, the status of the employee is the same as that of an employee working at an establishment who leaves work and is essentially "at home". Injuries and illnesses that occur at home are generally not considered work related. However, just as an employer may sometimes be required to record an injury or illness occurring to an employee working in his or her home, the employer is required to record an injury or illness occurring to an employee who is working in his or her hotel room (see the discussion of working at home, below).

Second, if an employee has established a "home away from home" and is reporting to a fixed worksite each day, the employer does not consider injuries or illnesses work-related if they occur while the employee is commuting between the temporary residence and the job location. These cases are parallel to those involving employees commuting to and from work when they are at their home location, and do not have to be recorded, just as injuries and illnesses that occur during normal commuting are not required to be recorded.

Third, the employer is not required to consider an injury or illness to be work-related if it occurs while the employee is on a personal detour from the route of business travel. This exception allows the employer to exclude injuries and illnesses that occur when the worker has taken a side trip for personal reasons while on a business trip, such as a vacation or sight-seeing excursion, to visit relatives, or for some other personal purpose.

The final rule's travel-related provisions (at paragraph 1904.5(b)(6)) are essentially identical to those proposed (63 FR 4063), with only minor editorial changes, and are also parallel to those for determining the work-relationship of traveling employees under the former recordkeeping system (Ex. 2, pp. 36, 37). OSHA received various comments and suggestions about how best to determine work relationship for traveling employees. A few commenters endorsed OSHA's proposed approach (see, *e.g.*, Exs. 15: 199, 396, 406). Other commenters believe, however, that employer control of, or the authority to control, the work environment should be determinative because activities outside the employer's control fall outside the scope of the employer's safety and health program (see, *e.g.*, Exs. 15: 335, 396, 409, 424). The comments of the Dow Chemical Company (Ex. 15: 335) are typical of these views:

[t]ravel on public carriers such as commercial airlines, trains, and taxi services or pre-existing conditions that are aggravated during normal unencumbered body motions, or injuries that occur off-the-job but do not impair someone until they arrive at work are all beyond the control of the employer and the scope of any safety and health program. The commercial plane that crashes while the employee was flying on company business or the taxi accident while the employee was trying to get to the airport to fly on company business are events which, while tragic, are beyond the scope of an employer's control and beyond the reasonable reach of that employer's safety and health program.

However, as discussed in the Legal Authority section and the introduction to the work-relationship section of the preamble, OSHA has decided not to limit the recording of occupational injuries and illnesses to those cases that are preventable, fall within the employer's control, or are covered by the employer's safety and health program. The issue is not whether the conditions could have, or should have, been prevented or whether they were controllable, but simply whether they are occupational, i.e., are related to work. This is true regardless of whether the employee is injured while on travel or while present at the employer's workplace. An employee who is injured in an automobile accident or killed in an airline crash while traveling for the company has clearly experienced a work-related injury that is rightfully included in the OSHA injury and illness records and the Nation's occupational injury and illness statistics. As the American Industrial Hygiene Association (Ex. 15: 153) remarked:

The workforce is increasingly made up of service sector jobs. Computers, materials movement, travel, violence are all emerging and increasing sources of occupational injury and illness. Many of these newer trends in cases may not involve lost workdays, but are recordable and significant to the workforce none the less. Many of the clean, non-manufacturing employers who were traditionally exempt from recordkeeping have risk in these and other emerging areas about which OSHA should be collecting data.

Two commenters specifically objected to the inclusion of cases involving client entertainment (Ex. 15: 409, 424). The American Association of Automobile Manufacturers (AAMA) remarked:

AAMA agrees with OSHA that injuries/illnesses to employees during travel status are work-related and recordable. However, AAMA takes strong exception to the inclusion of 'entertaining or being entertained for the purpose of transacting, discussing, or promoting business.' We find the notion of recording an illness for an employee, while he/she was engaged in a business related dinner, and subsequently suffering acute onset of diarrhea leading to hospitalization for gastroenteritis, to be inappropriate. OSHA needs to remove this obligation from the final rule. (Ex. 15: 409)

OSHA does not agree with this comment, because the Agency believes that employees who are engaged in management, sales, customer service and similar jobs must often entertain clients, and that doing so is a business activity that requires the employee to work at the direction of the employer while conducting such tasks. If the employee is injured or becomes ill while engaged in such work, the injury or illness is work-related and should be recorded if it meets one or more of the other criteria (death, medical treatment, etc.). The gastroenteritis example provided by the AAMA is one type of injury or illness that may occur in this situation, but employees are also injured in accidents while transporting clients to business-related events at the direction of the employer or by other events or exposures arising in the work environment.

On the other hand, not all injuries and illnesses sustained in the course of business-related entertainment are reportable. To be recordable, the entertainment activity must be one that the employee engages in at the direction of the employer. Business-related entertainment activities that are undertaken voluntarily by an employee in the exercise of his or her discretion are not covered by the rule. For example, if an employee attending a professional conference at the direction of the employer goes out for an evening of entertainment with friends, some of whom happen to be clients or customers, any injury or illness resulting from the entertainment activities would not be recordable. In this case, the employee was socializing after work, not entertaining at the direction of the employer. Similarly, the fact that an employee joins a private club or organization, perhaps to "network" or make business contacts, does not make any injury that occurs there work-related.

Two commenters recommended that OSHA eliminate the exceptions for determining work-relationship while employees are on travel and simply require all injuries and illnesses occurring while an employee is on travel status to be considered work-related (Exs. 15: 350, 418). For example, the AFL–CIO (Ex. 15: 418) suggested:

We would also strongly encourage the Agency to re-evaluate [proposed] Appendix A Section C "Travel Status". The AFL–CIO believes that employees in "travel status" (*e.g.*, traveling on company business) should be considered engaged in work-related activities during ALL of their time spent on the trip. This includes all travel, job tasks, entertaining and other activities occurring during "travel status."

OSHA believes that expanding the concept of work-related travel to include all of the time the worker spends on a trip would be inconsistent with the tests of work-relationship governing the recording of other injuries and illnesses and would therefore skew the statistics and confuse employers. As the Dow Chemical Company (Ex. 15: 335) stated:

While the employee is traveling for the benefit of the company, it cannot be said that 100% of their time is engaged in work-related activities. Employees engage in personal and social activities while traveling on company business that is not for the direct benefit of the company nor a condition of employment and which cannot be impacted by an employer's safety or health program. Often there is "free time" while traveling and employees engage in a myriad of activities such as shopping, sightseeing, dining out with friends or family that may be in the area, and the like. These are activities that do not benefit the company and are outside the company's control or reasonable reach of its safety and health programs. These are activities which, if the employee were engaged in them at their normal work location, would not be recordable; but just by the fact that they happen to be traveling for business purposes raises these otherwise non-recordable cases into those subject to the recordkeeping rule.

OSHA agrees with Dow that there are situations where an injury or illness case involving an employee who is on travel status should be excluded from the records. There is no value in recording injuries and illnesses that would not be recorded under non-travel circumstances. For example, there is no value to including in the statistics an injury sustained by an employee who slips and falls in a motel room shower or who is injured in an automobile accident while on personal business, or becomes the victim of random street violence while doing personal shopping on a business trip. OSHA is therefore continuing the Agency's practice of excluding certain cases while employees are in travel status and applying the exceptions to the geographic presumption in the final rule to those occurring while the worker is traveling.

The Department of Energy (Ex. 15: 163) expressed a concern about overseas travel, remarking "For employees who travel in the U.S., the standard makes sense. For employees who travel out of the country, additional burdens to them are generally incurred. Travelers to tropical locations or other areas with different fauna and microbes may incur diseases that are not indigenous to the U.S." In response, OSHA notes that the recordkeeping regulation does not apply to travel outside the United States because the OSH Act applies only to the confines of the United States (29 U.S.C. § 652(4)) and not to foreign operations. Therefore, the OSHA recordkeeping regulation does not apply to non-U.S. operations, and injuries or illnesses that may occur to a worker traveling outside the United States need not be recorded on the OSHA 300 Log.

Working at Home

The final rule also includes provisions at § 1904.5(b)(7) for

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determining the work-relatedness of injuries and illnesses that may arise when employees are working at home. When an employee is working on company business in his or her home and reports an injury or illness to his or her employer, and the employee's work activities caused or contributed to the injury or illness, or significantly aggravated a pre-existing injury, the case is considered work-related and must be further evaluated to determine whether it meets the recording criteria. If the injury or illness is related to non-work activities or to the general home environment, the case is not considered work-related.

The final rule includes examples to illustrate how employers are required to record injuries and illnesses occurring at home. If an employee drops a box of work documents and injures his or her foot, the case would be considered work-related. If an employee's fingernail was punctured and became infected by a needle from a sewing machine used to perform garment work at home, the injury would be considered work-related . If an employee was injured because he or she tripped on the family dog while rushing to answer a work phone call, the case would not be considered work-related. If an employee working at home is electrocuted because of faulty home wiring, the injury would not be considered work-related.

This provision is consistent with longstanding Agency practice under the former recordkeeping system. It was also included in the proposed rule (63 FR 4063), which read "An injury or illness will be considered work-related if it occurs while the employee is performing work for pay or compensation in the home, if the injury or illness is directly related to the performance of work rather than the general home environment or setting."

A number of commenters supported OSHA's proposed approach to recording the injuries and illnesses of employees who work at home (see, *e.g.*, Exs. 15: 31, 146, 176, 231, 273, 301, 336, 348, 375, 406, 409, 413, 427, 429). The comments of the Council of Community Blood Centers (CCBC) (Ex. 15: 336) are typical of the views of these participants:

> CCBC believes this is a good rule and should stay on the books. Accident or illness should be work-related if it occurs at home and is related to performance of the work, not the general home environment or setting. Workers often are off the premises in a variety of situations, such as travel, providing repair services, or consultation. Just as injuries in these situations are reportable, so should those during work at home, if authorized by the employer.

A large number of commenters objected to the proposed approach, however (see, *e.g.*, Exs. 65, 66, 78, 89, 105, 111, 123, 194, 200, 225, 239, 260, 262, 265, 277, 288, 330, 335, 341, 345, 360, 387, 393, 401, 406, 409, 430, 434, 440). Most of these commenters objected because of the employer's perceived inability to control working conditions in the home environment (see, *e.g.*, Exs. 15: 89, 163, 194, 239, 262, 288, 330, 345, 360). For example, the Fort Howard Corporation commented:

> Fort Howard strongly opposes OSHA's proposal to consider any injuries and illnesses as "work-related" if it occurs while the employee is performing work for pay or compensation in the home if the injury or illness is directly related to the performance of the work. Employers have absolutely no control over employees' homes. They cannot oversee employees who are doing the work nor can they effectively monitor the manner the work is conducted or the environment in which it is conducted. OSHA's proposal could place employers in the role of insuring the home as a safe work environment. (Ex. 15: 194)

Again, as discussed above, OSHA is concerned that all non-minor work-related cases be recorded on the Log and become part of the national statistics, both because these injuries and illnesses provide information about the safety and health of the work environment to employers, employees, and safety and health professionals and because collecting them may allow previously obscured safety and health issues to be identified. Injuries and illnesses occurring while the employee is working for pay or compensation at home should be treated like injuries and illnesses sustained by employees while traveling on business. The relevant question is whether or not the injury or illness is work-related, not whether there is some element of employer control. The mere recording of these injuries and illnesses as work-related cases does not place the employer in the role of insuring the safety of the home environment.

The law firm of Leonard, Ralston, Stanton & Remington, Chartered (Ex. 15: 430) raised questions about OSHA's role when employees perform office work activities in a home office:

> The increasing incidence of home work (or "telecommuting") raises some interesting issues. For example, does OSHA assume that its right of inspection extends to an employee's private home? If so, has the Agency examined the constitutionality of this position? What control does the Agency assume an employer has over working conditions in a private home? Does the Agency expect the employer to inspect its employees' homes to identify unsafe conditions? Must the employer require an employee to correct unsafe conditions in the home (*e.g.*, frayed carpet which presents a tripping hazard; overloaded electrical wiring or use of extension cords; etc.) as a condition of employment? If so, who must pay the cost of necessary home improvements?

OSHA has recently issued a compliance directive (CPL 2–0.125) containing the Agency's response to many of the questions raised by this commenter. That document clarifies that OSHA will not conduct inspections of home offices and does not hold employers liable for employees' home offices. The compliance directive also notes that employers required by the recordkeeping rule to keep records "will continue to be responsible for keeping such records, regardless of whether the injuries occur in the factory, in a home office, or elsewhere, as long as they are work-related, and meet the recordability criteria of 29 CFR Part 1904."

With more employees working at home under various telecommuting and flexible workplace arrangements, OSHA believes that it is important to record injuries and illnesses attributable to work tasks performed at home. If these cases are not recorded, the Nation's injury and illness statistics could be skewed. For example, placing such an exclusion in the final rule would make it difficult to determine if a decline in the overall number or rate of occupational injuries and illnesses is attributable to a trend toward working at home or to a change in the Nation's actual injury and illness experience. Further, excluding these work-related injuries and illnesses from the recordkeeping system could potentially obscure previously unidentified causal connections between events or exposures in the work environment and these incidents. OSHA is unwilling to adopt an exception that would have these potential effects. As the BF Goodrich Company (Ex. 15: 146) said, "[s]pecific criteria to address employee work-at-home situations is appropriate to assure consistent reporting in our changing work environment."

Section 1904.6 Determination of New Cases

Employers may occasionally have difficulty in determining whether new signs or symptoms are due to a new event or exposure in the workplace or whether they are the continuation of an existing work-related injury or illness. Most occupational injury and illness cases are fairly discrete events, i.e., events in which an injury or acute illness occurs, is treated, and then resolves completely. For example, a worker may suffer a cut, bruise, or rash from a clearly recognized event in the workplace, receive treatment, and recover fully within a few weeks. At some future time, the worker may suffer another cut, bruise or rash from another workplace event. In such cases, it is clear that the two injuries or illnesses are unrelated events, and that each represents an injury or illness that must be separately evaluated for its recordability.

However, it is sometimes difficult to determine whether signs or symptoms are due to a new event or exposure, or are a continuance of an injury or illness that has already been recorded. This is an important distinction, because a new injury or illness requires the employer to make a new entry on the OSHA 300 Log, while a continuation of an old recorded case requires, at most, an updating of the original entry. Section 1904.6 of the final rule being published today explains what employers must do to determine whether or not an injury or illness is a new case for recordkeeping purposes.

The basic requirement at § 1904.6(a) states that the employer must consider an injury or illness a new case to be evaluated for recordability if (1) the employee has not previously experienced a recorded injury or illness of the same type that affects the same part of the body, or (2) the employee previously experienced a recorded injury or illness of the same type that affected the same part of the body but had recovered completely (all signs and symptoms of the previous injury or illness had disappeared) and an event or exposure in the work environment caused the injury or illness, or its signs or symptoms, to reappear.

The implementation question at § 1904.6(b)(1) addresses chronic work-related cases that have already been recorded once and distinguishes between those conditions that will progress even in the absence of workplace exposure and those that are triggered by events in the workplace. There are some conditions that will progress even in the absence of further exposure, such as some occupational cancers, advanced asbestosis, tuberculosis disease, advanced byssinosis, advanced silicosis, etc. These conditions are chronic; once the disease is contracted it may never be cured or completely resolved, and therefore the case is never "closed" under the OSHA recordkeeping system, even though the signs and symptoms of the condition may alternate between remission and active disease.

However, there are other chronic work-related illness conditions, such as occupational asthma, reactive airways dysfunction syndrome (RADs), and sensitization (contact) dermatitis, that recur if the ill individual is exposed to the agent (or agents, in the case of cross-reactivities or RADs) that triggers the illness again. It is typical, but not always the case, for individuals with these conditions to be symptom-free if exposure to the sensitizing or precipitating agent does not occur.

The final rule provides, at paragraph (b)(1), that the employer is not required to record as a new case a previously recorded case of chronic work-related illness where the signs or symptoms have recurred or continued in the absence of exposure in the workplace. This paragraph recognizes that there are occupational illnesses that may be diagnosed at some stage of the disease and may then progress without regard to workplace events or exposures. Such diseases, in other words, will progress without further workplace exposure to the toxic substance(s) that caused the disease. Examples of such chronic work-related diseases are silicosis, tuberculosis, and asbestosis. With these conditions, the ill worker will show signs (such as a positive TB skin test, a positive chest roentgenogram, etc.) at every medical examination, and may experience symptomatic bouts as the disease progresses.

Paragraph 1904.6(b)(2) recognizes that many chronic occupational illnesses, however, such as occupational asthma, RADs, and contact dermatitis, are triggered by exposures in the workplace. The difference between these conditions and those addressed in paragraph 1904.6(b)(1) is that in these cases exposure triggers the recurrence of symptoms and signs, while in the chronic cases covered in the previous paragraph, the symptoms and signs recur even in the absence of exposure in the workplace. This distinction is consistent with the position taken by OSHA interpretations issued under the former recordkeeping rule (see the *Guidelines* discussion below). The Agency has included provisions related to new cases/continuations of old cases in the final rule to clarify its position and ensure consistent reporting.

Paragraph 1904.6(b)(3) addresses how to record a case for which the employer requests a physician or other licensed health care professional (HCP) to make a new case/continuation of an old case determination. Paragraph (b)(3) makes clear that employers are to follow the guidance provided by the HCP for OSHA recordkeeping purposes. In cases where two or more HCPs make conflicting or differing recommendations, the employer is required to base his or her decision about recordation based on the most authoritative (best documented, best reasoned, or most persuasive) evidence or recommendation.

The final rule's provisions on the recording of new cases are nearly identical to interpretations of new case recordability under the former rule. OSHA has historically recognized that it is generally an easier matter to differentiate between old and new cases that involve injuries than those involving illnesses: the *Guidelines* stated that "the aggravation of a previous injury almost always results from some new incident involving the employee * * * [w]hen work-related, these new incidents should be recorded as new cases on the OSHA forms, assuming they meet the criteria for recordability * * *" (Ex. 2, p. 31). However, the *Guidelines* also stated that "certain illnesses, such as silicosis, may have prolonged effects which recur over time. The recurrence of these symptoms should not be recorded as a new case on the OSHA forms. * * * Some occupational illnesses, such as certain dermatitis or respiratory conditions, may recur as the result of new exposures to sensitizing agents, and should be recorded as new cases."

OSHA developed and included specific guidance for evaluating when cumulative trauma disorders (CTDs) (ergonomic injuries and illnesses, now known as musculoskeletal disorders, or MSDs) should be recorded as new cases in the *Ergonomics Program Management Guidelines For Meatpacking Plants* (Ex. 11, p. 15) which were published in 1990. These *Guidelines* provided:

> If and when an employee who has experienced a recordable CTD becomes symptom free (including both subjective symptoms and physical findings), any recurrence of symptoms establishes a new case. Furthermore, if the worker fails to return for medical care within 30 days, the case is presumed to be resolved. Any visit to a health care provider for similar complaints after the 30-day interval "implies reinjury or reexposure to a workplace hazard and would represent a new case."

Thus, the former rule had different "new case" criteria for musculoskeletal disorders than for other injuries and illnesses. (For the final rule's recording criteria for musculoskeletal disorders, see Section 1904.12.)

OSHA's recordkeeping NPRM proposed a single approach to the identification of new cases for all injuries and illnesses, including musculoskeletal disorders. The proposal would have required the recurrence of a pre-existing injury or illness to be considered a new case to evaluate for recordability if (1) it resulted from a

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new work event or exposure, or (2) 45 days had elapsed since medical treatment, work restriction, or days away from work had ceased, and the last sign or symptom had been experienced. The proposed approach would, in effect, have extended the recurrence criteria for musculoskeletal disorders to all injury and illness cases, but would have increased the no-medical-intervention interval from 30 to 45 days. A recurrence of a previous work-related injury or illness would have been presumed, under the proposed approach, to be a new case if (1) it resulted from a new work accident or exposure, or (2) 45 days had elapsed since medical treatment had been administered or restricted work activity or days away had occurred and since the last sign or symptom had been experienced. This proposed presumption would have been rebuttable if there was medical evidence indicating that the prior case had not been resolved. In the proposal, OSHA also asked for input on the following questions related to new case recording:

> OSHA solicits comment on the appropriateness of the 45-day interval. Is 45 days too short or long of a period? If so, should the period be 30 days? 60 days? 90 days? or some other time period? Should different conditions (*e.g.* back cases, asthma cases etc.) have different time intervals for evaluating new cases?
>
> OSHA is also seeking input for an improved way to evaluate new cases. Should a new category of cases be created to capture information on recurring injuries and illnesses? One option is to add an additional "check box" column to the proposed OSHA Form 300 for identifying those cases that are recurrences of previously recorded injuries and illnesses. This would allow employers, employees and OSHA inspectors to differentiate between one time cases and those that are recurrent, chronic conditions. This approach may help to remove some of the stigma of recording these types of disorders and lead to more complete records. OSHA solicits input on this approach. Will a recurrence column reduce the stigma of recording these types of cases? Should recurrences be included in the annual summaries? Should a time limit be used to limit the use of a recurrence column?

In response to the views and evidence presented by commenters to the record, OSHA has decided not to adopt the proposed approach to the recording of new/recurring cases in the final rule. Commenters expressed a wide variety of views about the recording of recurring injury and illness cases. Some commenters favored the proposed approach as drafted. Others, however, objected to it on many grounds: (1) the time limit should be longer or shorter than the 45 days proposed; (2) the proposed approach would result in under- or overreporting; (3) it would conflict with workers' compensation requirements; (4) it was too restrictive (5) it would encourage excessive use of the health care system; and (6) it should be replaced by a physician or other licensed health care professional's opinion.

A number of commenters supported OSHA's proposed approach (see, *e.g.*, Exs. 15: 27, 65, 70, 151, 152, 154, 179, 180, 181, 185, 186, 188, 214, 331, 332, 336, 359, 387, 396, 424, 428). Representative of these comments was one from The Fertilizer Institute (TFI):

> TFI agrees with OSHA's proposed 45 day criterion for the recording of new cases. Concerning OSHA's solicitation of comments on whether different conditions should have different evaluation periods, TFI encourages OSHA to adopt a single time period for all conditions. Different evaluation periods for different conditions will lead to complexity and confusion without any resulting benefit to recordkeeping (Ex. 15: 154).

Other commenters supported the concept of using a time limit for determining new cases, but thought the number of days should be higher (see, *e.g.*, Exs. 15: 45, 49, 61, 82, 89, 131, 147, 184, 235, 331, 389). Some commenters generally opposed the time limit concept but made recommendations for longer time periods if OSHA decided in the final rule to adopt a time limit (see, *e.g.*, Exs. 15: 38, 79, 89, 111, 136, 137, 141, 194, 224, 246, 266, 278, 288, 299, 313, 335, 352, 353, 430). The longer intervals suggested by commenters included 60 days (see, *e.g.*, Exs. 15: 82, 389); 90 days (see, *e.g.*, Exs. 15: 38, 49, 79, 147, 184, 246, 299, 313, 331, 335, 352, 353, 430); 120 days (Ex. 15: 194); 180 days (see, *e.g.*, Exs. 15: 61, 111, 136, 137, 141, 224, 266, 278, 288); one year (Ex. 15: 131); and five years (Ex. 15: 89).

A large number of commenters opposed the proposed approach for identifying new cases that would then be tested for their recordability (see, *e.g.*, Exs. 15: 33, 38, 39, 41, 78, 79, 89, 95, 102, 107, 111, 119, 127, 133, 136, 137, 141, 153, 171, 176, 194, 199, 203, 224, 225, 231, 246, 266, 273, 278, 281, 288, 289, 299, 301, 305, 307, 308, 313, 335, 337, 341, 346, 348, 352, 353, 375, 395, 405, 410, 413, 424, 425, 428, 430, 440). Some commenters argued that the proposed 45-day interval was arbitrary (see, *e.g.*, Exs. 15: 119, 203, 289, 313, 352, 353, 395), that it conflicted with workers' compensation new case determinations (see, *e.g.*, Exs. 15: 38, 119, 136, 137, 141, 224, 266, 278), that the approach would not work in the case of chronic injury (see, *e.g.*, Exs. 33; 15: 176, 199, 231, 273, 299, 301, 305, 308, 337, 346, 348, 375), or that the proposed 45-day rule would result in over-reporting of occupational injuries and illnesses (see, *e.g.*, Exs. 15: 119, 127, 136, 137, 141, 171, 199, 224, 266, 278, 305, 337, 424, 425). The comments of the NYNEX Corporation (Ex. 15: 199) illustrate the general concerns of these commenters:

> We do not agree, however, with the second criterion of a symptom free 45 day period following medical treatment, restriction, or days away from work. This criterion fails to take into account the persistent nature of many chronic or recurring conditions, i.e., back strains, musculoskeletal disorders, where the symptoms may disappear for a period of time, but the underlying conditions are still present. If adopted, this criterion could cause injury and illness data to be artificially inflated with the onset of "new" cases, which in fact are recurrences of existing conditions. This in turn could lead to false epidemics and a diversion of resources from more legitimate workplace concerns.

On the other hand, William K. Principe of Constangy, Brooks & Smith, LLC (Ex. 15: 428) was concerned that the proposed method would result in fewer recordable cases:

> Since many employees will report that they continued to experience symptoms or that they continue to have good days and bad days, the new rule will result in many fewer recordable CTD [cumulative trauma disorder] cases. In fact, at some hand-intensive manual operations, the number of CTD cases should be drastically reduced under the proposal that 45 days must elapse since the last symptom. There is something fundamentally wrong with a recordkeeping system that one year shows a high incidence of CTDs and the next shows a dramatic decline, when the underlying conditions remain virtually identical.

United Parcel Service (Ex. 15: 424) stated that there should be no time limit to determining whether or not a case is a recurrence:

> In UPS's experience, however, it is a simple process to determine, by medical referral or by examining prior medical history, whether a condition is a recurrence. This has long been the practice, and indeed the [proposal] contemplates it will remain the practice through the first 44 days. It does not become any more complex on the 45th, 50th, or 100th day; and if in an individual employer's judgment it does, then the employer may of course report the condition as a new injury.

Three commenters disapproved of OSHA's approach because it would have been applicable to all recurrences and they believe that each case must be evaluated on its own merits (Exs. 15: 78, 184, 203). The International Dairy Foods Association (IDFA) described this concern succinctly: "Each injury has its own resolution based on the injury, illness, degree, and numerous other factors that are characteristic of the

individual. As such, it is impossible for OSHA or anyone else to set a valid number of days even if the resolution period is set on the basis of the type of illness/injury" (Ex. 15: 203).

In addition, the proposed 45-day approach was interpreted differently by different commenters. For example, David E. Jones of the law firm Ogletree, Deakins, Nash, Smoak & Stewart (ODNSS) suggested:

> The words "either" and "or" * * * should be deleted because an aggravation of the previously recorded injury or illness brought about within the 45-day period would require the entry of a new case at that time, thus negating the 45-day rule, leading to the adverse result that the 45-day rule otherwise would rectify. Accordingly, ODNSS recommends * * * "A recurrence of a previous work-related injury or illness is a new case when it (1) results from a new work event or exposure *and* (2) 45 days have elapsed since medical treatment, restricted work activity, or days away from work (as applicable) were discontinued and the employee has been symptom-free (including both subjective symptoms and physical findings) (emphasis added) (Ex. 15: 406).

In the final rule, OSHA has decided against the proposed approach of determining case resolution based on a certain number of days during which the injured or ill employee did not lose time, receive treatment, have signs or symptoms, or be restricted to light duty. OSHA agrees with those commenters who argued that the proposed approach was too prescriptive and did not allow for the variations that naturally exist from one injury and illness case to the next. Further, the record contains no convincing evidence to support a set number of days as appropriate. OSHA thus agrees with those commenters who pointed out that adoption of a fixed time interval would result in the overrecording of some injury and illness cases and the underrecording of others, and thus would impair the quality of the records.

Further, OSHA did not intend to create an "injury free" time zone during which an injury or illness would not be considered a new case, regardless of cause, as ODNSS suggested. Instead, OSHA proposed that a case be considered a new case if *either* condition applied: the case resulted from a new event or exposure *or* 45 days had elapsed without signs, symptoms, or medical treatment, restricted work, or days away from work. There are clearly cases where an event or exposure in the workplace would be cause for recording a new case. A new injury may manifest the same signs and symptoms as the previous injury but still be a new injury and not a continuation of the old case if, for example, an employee sustains a fall and fractures his or her wrist, and four months later falls again and fractures the wrist in the same place. This occurrence is not a continuation of the fracture but rather a new injury whose recordability must be evaluated. The final rule's approach to recurrence/new case determinations avoids this and other recording problems because it includes no day count limit and relies on one of the basic principles of the recordkeeping system, i.e., that injuries or illnesses arising from events or exposures in the workplace must be evaluated for recordability.

In response to those commenters who raised issues about inconsistency between the OSHA system and workers' compensation, OSHA notes that there is no reason for the two systems, which serve different purposes (recording injuries and illnesses for national statistical purposes and indemnifying workers for job-related injuries and illnesses) to use the same definitions. Accordingly, the final rule does not rely on workers' compensation determinations to identify injuries or illness cases that are to be considered new cases for recordkeeping purposes.

Another group of commenters argued that the 45-day recording requirement would lead employers to spend money on unnecessary and costly health care (see, *e.g.*, Exs. 15: 136, 137, 141, 224, 266, 278, 305, 346, 348, 375). The views of the American Petroleum Institute (API) are representative: "OSHA's proposal would also add substantially to employers' costs since it could require employees to make frequent trips to a health care professional, even if symptom free, just to avoid being recorded repeatedly on the OSHA log as new cases" (Ex. 15: 375). Union Carbide Corporation (Ex. 15: 396) also remarked on the proposed approach's potential incentive for medical follow-up, but viewed such an incentive as a positive phenomenon, stating "One benefit [of the proposed approach] is that it encourages medical follow-up for the employee." Although the proposed approach would not have "required" an employer to send a worker to a physician or other licensed health care professional, and OSHA is not persuaded that employers would choose to spend money in this way merely to avoid recording an occasional case as a new case, elimination of any set day-count interval from the final rule will also have made the concerns of these commenters moot.

OSHA also received a number of suggestions about the role of physicians and other licensed health care professionals (HCP) in new case determinations. A number of commenters recommended that the decision to record should be based solely on the opinions of a physician or other licensed health care professional (see, *e.g.*, Exs. 33: 15: 39, 95, 107, 119, 127, 133, 225, 289, 332, 335, 341, 387, 424, 440). The National Grain and Feed Association, the National Oilseed Processors Association, and the Grain Elevator and Processing Society (Ex. 15: 119) commented as a group and recommended that "[r]elying on a physician's opinion rather than an arbitrary timeframe would simplify recordkeeping and help ensure that the records are consistent with existing and accepted workers' compensation plans."

Other commenters recommended that, if OSHA adopted a day count time limit, the rule should specifically allow a physician's opinion to be used to refute a new case determination (see, *e.g.*, Exs. 15: 65, 181, 184, 203). Several others simply asked OSHA to provide more guidance on what type of medical evidence could be used in new case determinations (see, *e.g.*, Exs. 15: 176, 231, 273, 301, 430). The National Wholesale Druggists' Association (NWDA) suggested that "OSHA should also include a provision that the employee obtain written approval from a doctor that the employee's condition has been resolved before going back to work. Determining the end of treatment should be left in the hands of a medical professional and OSHA should require some type of documentation to that effect" (Ex. 15: 185).

OSHA has not included any provisions in the final rule that require an employer to rely on a physician or other licensed health care professional or that tell a physician or other licensed health care professional how to treat an injured or ill worker, or when to begin or end such treatment. In the final rule OSHA does require the employer to follow any determination a physician or other licensed health care professional has made about the status of a new case. That is, if such a professional has determined that a case is a new case, the employer must record it as such. If the professional determines that the case is a recurrence, rather than a new case, the employer is not to record it a second time. In addition, the rule does not require the employee, or the employer, to obtain permission from the physician or other licensed health care professional before the employee can return to work. OSHA believes that the employer is capable of, and often in the best position to, make return-to-work decisions.

Southern California Edison (Ex. 15: 111) expressed concern that imposing a day limit would not take differences

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between types of injuries and illnesses into account, stating "A recurrence of a previous work-related injury or illness should only be considered a new case when the injury or illness has completely healed. Severe muscle and nerve damage can take many weeks or months to properly heal." The final rule takes such differences into account, as follows. If the previous injury or illness has not healed (signs and symptoms have not resolved), then the case cannot be considered resolved. The employer may make this determination or may rely on the recommendation of a physician or other licensed health care professional when doing so. Clearly, if the injured or ill employee is still exhibiting signs or symptoms of the previous injury or illness, the malady has not healed, and a new case does not have to be recorded. Similarly, if work activities aggravate a previously recorded case, there is no need to consider recording it again (although there may be a need to update the case information if the aggravation causes a more severe outcome than the original case, such as days away from work).

The Quaker Oats Company (Ex. 15: 289) suggested that employers should be permitted by the rule to decide whether a given case was a new case or not, without requirements in the rule:

> The 45 day interval on determining if a case is a new one or should be counted under a previous injury should be left to the discretion of the employer. They have the most intimate knowledge of the work environment, medical treatment of the affected employee and the status of their work-related injury or illness. I will agree that it is a difficult matter to decide and to assure consistency throughout industry * * * I believe that any number of days would simply be an arbitrary attempt at quantifying something that is best left to the medical judgment of a healthcare professional.

Under the OSHA recordkeeping system, the employer is always the responsible party when it comes to making the determination of the recordability of a given case. However, if OSHA did not establish consistent new case determination criteria, a substantial amount of variability would be introduced into the system, which would undermine the Agency's goals of improving the accuracy and consistency of the Nation's occupational injury and illness data. Accordingly, OSHA has not adopted this suggested approach in the final rule.

A number of commenters argued that the occurrence of a new event, exposure, or incident should be required to trigger the recording of a new case (see, *e.g.*, Exs. 33, 15: 102, 171, 176, 231, 273, 301, 307, 308, 405, 410, 413, 425). Representative of these comments was one from the Voluntary Protection Programs Participants' Association (VPPPA), which recommended that OSHA "adopt a definition for new case that requires the occurrence of a new work-related event to trigger a new case. In the absence of this, the case would be considered recurring" (Ex. 15: 425). OSHA agrees with the VPPPA that if no further event or exposure occurs in the workplace to aggravate a previous injury or illness, a new case need not be recorded. However, if events or exposures at work cause the same symptoms or signs to recur, the final rule requires employers to evaluate the injury or illness to see if it is a new case and is thus recordable.

The OSHA statistical system is designed to measure the incidence, rather than prevalence, of occupational injury and illness. Incidence measures capture the number of new occupational injuries and illnesses occurring in a given year, while prevalence measures capture the number of such cases existing in a given year (prevalence measures thus capture cases without regard to the year in which they onset). Prevalence measures would therefore capture all injuries and illnesses that occurred in a given year as well as those unresolved injuries and illnesses that persist from previous years. The difference is illustrated by the following cases: (1) A worker experiences a cut that requires sutures and heals completely before the year ends; this injury would be captured both by an incidence or prevalence measure for that particular year. (2) Another worker retired last year but continues to receive medical treatment for a work-related respiratory illness that was first recognized two years ago. This case would be captured in the year of onset and each year thereafter until it resolves if a prevalence measure is used, but would be counted only once (in the year of onset) if an incidence measure is used.

Because the OSHA system is intended to measure the incidence of occupational injury and illness, each individual injury or illness should be recorded only once in the system. However, an employee can experience the same type of injury or illness more than once. For example, if a worker cuts a finger on a machine in March, and is then unfortunate enough to cut the same finger again in October, this worker has clearly experienced two separate occupational injuries, each of which must be evaluated for its recordability. In other cases, this evaluation is not as simple. For example, a worker who performs forceful manual handling injures his or her back in 1998, resulting in days away from work, and the case is entered into the records. In 1999 this worker has another episode of severe work-related back pain and must once again take time off for treatment and recuperation. The question is whether or not the new symptoms, back pain, are continuing symptoms of the old injury, or whether they represent a new injury that should be evaluated for its recordability as a new case. The answer in this case lies in an analysis of whether or not the injured or ill worker has recovered fully between episodes, and whether or not the back pain is the result of a second event or exposure in the workplace, *e.g.*, continued manual handling. If the worker has not fully recovered and no new event or exposure has occurred in the workplace, the case is considered a continuation of the previous injury or illness and is not recordable.

One reason for the confusion that is apparent in some of the comments on the proposal's approach to the recording of recurrences may be the custom that developed over the years of referring to recordable recurrences of work-related injuries and illnesses as "new cases." See for example, 61 FR 4037/1 ("employers may be dealing with a re-injury or recurrence of a previous case and must decide whether the recurrence is a "new case" or a continuation of the original case.") The term "new case" tends to suggest to some that the case is totally original, when in fact new cases for OSHA recordkeeping purposes include three categories of cases; (1) totally new cases where the employee has never suffered similar signs or symptoms while in the employ of that employer, (2) cases where the employee has a preexisting condition that is significantly aggravated by activities at work and the significant aggravation reaches the level requiring recordation, and (3) previously recorded conditions that have healed (all symptoms and signs have resolved) and then have subsequently been triggered by events or exposures at work.

Under the former rule and the final rule, both new injuries and recurrences must be evaluated for their work-relatedness and then for whether they meet one or more of the recording criteria; when these criteria are met, the case must be recorded. If the case is a continuation of a previously recorded case but does not meet the "new case" criteria, the employer may have to update the OSHA 300 Log entry if the original case continues to progress, i.e., if the status of the case worsens. For example, consider a case where an employee has injured his or her back lifting a heavy object, the injury resulted in medical treatment, and the case was recorded as a case without restricted work or days away. If the injury does not heal and the employer subsequently decides to assign the worker to restricted work activity, the employer is required by the final rule to change the case classification and to track the number of days of restricted work. If the case is a previous work-related injury that did not meet the recording criteria and thus was not recorded, future developments in the case may require it to be recorded. For example, an employee may suffer an ankle sprain tripping on a step. The employee is sent to a health care professional, who does not recommend medical treatment or restrictions, so the case is not recorded at that time. If the injury does not heal, however, and a subsequent visit to a physician results in medical treatment, the case must then be recorded.

OSHA and employers and employees need data on recurring cases because recurrence is an important indicator of severity over the long term. Just as the number of days away is a useful indicator of health and safety risk at a particular establishment, so is the total number of injury and illness events and of exposures resulting in health consequences that occur in an establishment or industry. Further, any realistic assessment of occupational safety and health conditions should reflect the fact that some but not all injuries and illnesses have long-term consequences. In other words, a safety and health analysis should give less weight to an injury or illness that has a clear and relatively quick recovery without impairment of any kind and an injury or illness that is chronic in nature or one that involves recurring episodes that are retriggered by workplace events or exposures.

Ignoring the fact that an occupational injury or illness is a recurrence occasioned by an event or exposure in the workplace would result in an underestimate of the true extent of occupational injury and illness and deprive employers, employees, and safety and health professionals of essential information of use in illness prevention. The other extreme, requiring employers to record on-going signs or symptoms repeatedly, even in the absence of an event or exposure in the workplace, would result in overstating the extent of illness. In terms of the recordkeeping system, deciding how most appropriately to handle new cases requires a balanced approach that minimizes both overrecording and underrecording. OSHA has dealt with this problem in the final rule by carefully defining the circumstances under which a chronic and previously recorded injury or illness must be considered closed and defining the circumstances under which a recurrence is to be considered a new case and then evaluated to determine whether it meets one or more of the recordability criteria.

OSHA's proposal to apply a single criterion to the determination of the recordability of all recurrences of previously recorded injuries and illnesses received support from several commenters (see, *e.g.*, Exs. 15: 31, 61, 70, 154, 203, 396). The final rule uses one set of criteria for determining whether any injury or illness, including a musculoskeletal disorder, is to be treated as a new case or as the continuation of an "old" injury or illness. First, if the employee has never had a recorded injury or illness of the same type and affecting the same part of the body, the case is automatically considered a new case and must be evaluated for recordability. This provision will handle the vast majority of injury and illness cases, which are new cases rather than recurrences or case continuations. Second, if the employee has previously had a recorded injury or illness of the same type and affecting the same body part, but the employee has completely recovered from the previous injury or illness, and a new workplace event or exposure causes the injury or illness (or its signs or symptoms) to reappear, the case is a recurrence that the employer must evaluate for recordability.

The implementation section of § 1904.6 describes these requirements and includes explanations applying to two special circumstances. In the first case, paragraph 1904.6(b)(1) the employee has experienced a chronic injury or illness of a type that will progress regardless of further workplace exposure. Cases to which this provision applies are serious, chronic illness conditions such as occupational cancer, asbestosis, silicosis, chronic beryllium disease, etc. These occupational conditions generally continue to progress even though the worker is removed from further exposure. These conditions may change over time and be associated with recurrences of symptoms, or remissions, but the signs (*e.g.*, positive chest roentgenogram, positive blood test) generally continue to be present throughout the course of the disease.

The second kind of case, addressed in paragraph 1904.6(b)(b)(2), requires employers to record chronic illness cases that recur as a result of exposures in the workplace. These conditions might include episodes of occupational asthma, reactive airways dysfunction syndrome (RADS), or contact allergic dermatitis, for example.

Paragraph 1904.6(b)(3) recognizes the role of physicians and other licensed health care professionals that the employer may choose to rely on when tracking a "new case" or making a continuation of an old case determination. If a physician or other licensed health care professional determines that an injury or illness has been resolved, the employer must consider the case to be resolved and record as a new case any episode that causes the signs and symptoms to recur as a result of exposure in the workplace. On the other hand, if the HCP consulted by the employer determines that the case is a chronic illness of the type addressed by paragraph 1904.6(b)(1), the employer would not record the case again. In either case, the employer would evaluate it for work-relatedness and then determine whether the original entry requires updating or the case meets the recording criteria. Paragraph (b)(3) also recognizes that the employer may ask for input from more than one HCP, or the employer and employee may each do so, and in such cases, the rule requires the employer to rely on the one judged by the employer to be most authoritative.

Adding a Recurrence Column to the OSHA 300 Log

In the proposal, OSHA asked commenters whether the Log should include a column with a check-box that could be marked if a case was a recurrence of a pre-existing condition (61 FR 4037). Some commenters supported the proposed approach (see, *e.g.*, Exs. 15: 27, 39, 61, 65, 89, 154, 186, 214, 235, 277, 299, 305, 332, 336). For example, the National Association of Manufacturers (NAM) suggested that, in lieu of adopting a 45-day time limit, OSHA should add a column to the Log: "If the Agency believes there is a need to track the number of recurring cases, we believe the better approach would be to add a column to the log which would permit the original entry for each injury or illness to be updated in the event of a recurrence" (Ex. 15: 305). The American Association of Homes and Services for the Aging (AAHSA) agreed:

> [t]here should be a column on the injury and illness log for employers to check for reoccurring injuries. This addition would help the employer to identify possible patterns or problems associated with a specific job and find solutions. Recommendation: Add a column to the injury and illness log allowing the employer

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to check when an employee is having a repetitive injury or illness (Ex. 15: 214).

Other commenters did not support the proposal's approach to tracking recurrences (see, *e.g.*, Exs. 15: 70, 78, 136, 137, 141, 151, 152, 179, 180, 194, 224, 266, 278). The comments of Kathy Lehrman, RN, Occupational Health Nurse (Ex. 15: 136) are representative of these comments:

> The addition of a column to record recurrent conditions would not reduce the stigma and would lead to increased health care provider visits to avoid having an ongoing case labeled as a new case. * * * I do not see the value of including a new category of case designation. This runs counter to the simplification objective.

After a review of the comments on this issue, OSHA has decided not to include such a check-box on the Log. The final rule adds several columns to the OSHA 300 form to collect data on the number of restricted workdays and on various types of occupational injuries and illnesses. The addition of these columns, and the decision to provide more space on the Log to add information on the case, has used up the available space on the form. Requiring employers to record recurrences would also be burdensome and make the rule more complex. Further, OSHA did not propose such a requirement, and this issue raises questions not adequately aired in the record. For example, if an employee has recurring episodes of low back pain, should the employer be required to record each day the employee experiences such pain as a recurring injury? OSHA is also unsure how recurrence data should be captured and used in the Nation's injury and illness statistics. For example, would a separate data set on recurrences, similar to data on injuries and illnesses, be produced by the BLS?

OSHA has therefore decided that it is not appropriate to add a column to the Log to capture data on recurring injuries and illnesses. However, OSHA recognizes that data on injury and illness recurrence may be useful to employers and employees at individual worksites and encourages employers who wish to collect this additional information to do so; however, the final rule does not require employers to provide recurrence data on the Log.

Section 1904.7 General Recording Criteria

Section 1904.7 contains the general recording criteria for recording work-related injuries and illnesses. This section describes the recording of cases that meet one or more of the following six criteria: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, loss of consciousness, or diagnosis as a significant injury or illness by a physician or other licensed health care professional.

Paragraph 1904.7(a)

Paragraph 1904.7(a) describes the basic requirement for recording an injury or illness in the OSHA recordkeeping system. It states that employers must record any work-related injury or illness that meets one or more of the final rule's general recording criteria. There are six such criteria: death, days away from work, days on restricted work or on job transfer, medical treatment beyond first aid, loss of consciousness, or diagnosis by a physician or other licensed heath care professional as a significant injury or illness. Although most cases are recorded because they meet one of these criteria, some cases may meet more than one criterion as the case continues. For example, an injured worker may initially be sent home to recuperate (making the case recordable as a "days away" case) and then subsequently return to work on a restricted ("light duty") basis (meeting a second criterion, that for restricted work). (see the discussion in Section 1904.29 for information on how to record such cases.)

Paragraph 1904.7(b)

Paragraph 1904.7(b) tells employers how to record cases meeting each of the six general recording criteria and states how each case is to be entered on the OSHA 300 Log. Paragraph 1904.7(b)(1) provides a simple decision table listing the six general recording criteria and the paragraph number of each in the final rule. It is included to aid employers and recordkeepers in recording these cases.

1904.7(b)(2) Death

Paragraph 1904.7(b)(2) requires the employer to record an injury or illness that results in death by entering a check mark on the OSHA 300 Log in the space for fatal cases. This paragraph also directs employers to report work-related fatalities to OSHA within 8 hours and cross references the fatality and catastrophe reporting requirements in § 1904.39 of the final rule, Reporting fatalities and multiple hospitalizations to OSHA.

Paragraph 1904.7(b)(2) implements the OSH Act's requirements to record all cases resulting in work-related deaths. There were no comments opposing the recording of cases resulting in death. However, there were several comments questioning the determination of work-relatedness for certain fatality cases and the appropriateness of reporting certain kinds of fatalities to OSHA. These comments are addressed in the sections of this preamble devoted to work-relationship and fatality reporting (sections 1904.5 and 1904.39, respectively).

Paragraph 1904.7(b)(3) Days Away From Work

Paragraph 1904.7(b)(3) contains the requirements for recording work-related injuries and illnesses that result in days away from work and for counting the total number of days away associated with a given case. Paragraph 1904.7(b)(3) requires the employer to record an injury or illness that involves one or more days away from work by placing a check mark on the OSHA 300 Log in the space reserved for day(s) away cases and entering the number of calendar days away from work in the column reserved for that purpose. This paragraph also states that, if the employee is away from work for an extended time, the employer must update the day count when the actual number of days away becomes known. This requirement continues the day counting requirements of the former rule and revises the days away requirements in response to comments in the record.

Paragraphs 1904.7(b)(3)(i) through (vi) implement the basic requirements. Paragraph 1904.7(b)(3)(i) states that the employer is not to count the day of the injury or illness as a day away, but is to begin counting days away on the following day. Thus, even though an injury or illness may result in some loss of time on the day of the injurious event or exposure because, for example, the employee seeks treatment or is sent home, the case is not considered a days-away-from-work case unless the employee does not work on at least one subsequent day because of the injury or illness. The employer is to begin counting days away on the day following the injury or onset of illness. This policy is a continuation of OSHA's practice under the former rule, which also excluded the day of injury or onset of illness from the day counts.

Paragraphs 1904.7(b)(3)(ii) and (iii) direct employers how to record days-away cases when a physician or other licensed health care professional (HCP) recommends that the injured or ill worker stay at home or that he or she return to work but the employee chooses not to do so. As these paragraphs make clear, OSHA requires employers to follow the physician's or HCP's recommendation when recording the case. Further, whether the employee works or not is in the control of the

employer, not the employee. That is, if an HCP recommends that the employee remain away from work for one or more days, the employer is required to record the injury or illness as a case involving days away from work and to keep track of the days; the employee's wishes in this case are not relevant, since it is the employer who controls the conditions of work. Similarly, if the HCP tells the employee that he or she can return to work, the employer is required by the rule to stop counting the days away from work, even if the employee chooses not to return to work. These policies are a continuation of OSHA's previous policy of requiring employees to follow the recommendations of health care professionals when recording cases in the OSHA system. OSHA is aware that there may be situations where the employer obtains an opinion from a physician or other health care professional and a subsequent HCP's opinion differs from the first. (The subsequent opinion could be that of an HCP retained by the employer or the employee.) In this case, the employer is the ultimate recordkeeping decision-maker and must resolve the differences in opinion; he or she may turn to a third HCP for this purpose, or may make the recordability decision himself or herself.

Paragraph 1904.7(b)(3)(iv) specifies how the employer is to account for weekends, holidays, and other days during which the employee was unable to work because of a work-related injury or illness during a period in which the employee was not scheduled to work. The rule requires the employer to count the number of calendar days the employee was unable to work because of the work-related injury or illness, regardless of whether or not the employee would have been scheduled to work on those calendar days. This provision will ensure that a measure of the length of disability is available, regardless of the employee's work schedule. This requirement is a change from the former policy, which focused on scheduled workdays missed due to injury or illness and excluded from the days away count any normal days off, holidays, and other days the employee would not have worked.

Paragraph 1904.7(b)(3)(v) tells the employer how to count days away for a case where the employee is injured or becomes ill on the last day of work before some scheduled time off, such as on the Friday before the weekend or the day before a scheduled vacation, and returns to work on the next day that he or she was scheduled to work. In this situation, the employer must decide if the worker would have been able to work on the days when he or she was not at work. In other words, the employer is not required to count as days away any of the days on which the employee would have been able to work but did not because the facility was closed, the employee was not scheduled to work, or for other reasons unrelated to the injury or illness. However, if the employer determines that the employee's injury or illness would have kept the employee from being able to work for part or all of time the employee was away, those days must be counted toward the days away total.

Paragraph 1904.7(b)(3)(vi) allows the employer to stop counting the days away from work when the injury or illness has resulted in 180 calendar days away from work. When the injury or illness results in an absence of more than 180 days, the employer may enter 180 (or 180+) on the Log. This is a new provision of the final rule; it is included because OSHA believes that the "180" notation indicates a case of exceptional severity and that counting days away beyond that point would provide little if any additional information.

Paragraph 1904.7(b)(3)(vii) specifies that employers whose employees are away from work because of a work-related injury or illness and who then decide to leave the company's employ or to retire must determine whether the employee is leaving or retiring because of the injury or illness and record the case accordingly. If the employee's decision to leave or retire is a result of the injury or illness, this paragraph requires the employer to estimate and record the number of calendar days away or on restricted work/job transfer the worker would have experienced if he or she had remained on the employer's payroll. This provision also states that, if the employee's decision was unrelated to the injury or illness, the employer is not required to continue to count and record days away or on restricted work/job transfer.

Paragraph 1904.(b)(3)(viii) directs employers how to handle a case that carries over from one year to the next. Some cases occur in one calendar year and then result in days away from work in the next year. For example, a worker may be injured on December 20th and be away from work until January 10th. The final rule directs the employer only to record this type of case once, in the year that it occurred. If the employee is still away from work when the annual summary is prepared (before February 1), the employer must either count the number of days the employee was away or estimate the total days away that are expected to occur, use this estimate to calculate the total days away during the year for the annual summary, and then update the Log entry later when the actual number of days is known or the case reaches the 180-day cap allowed in § 1904.7(b)(3)(v).

Comments on the Recording of Days Away From Work

OSHA received a large number of comments on how days away should be counted. The issues addressed by commenters included (1) whether to count scheduled workdays or calendar days, (2) whether the day counts should be "capped," and, if so, at what level, (3) how to count days away or restricted when employees are terminated or become permanently disabled, and (4) how to handle cases that continue to have days away/restricted from one year to the next.

Scheduled or calendar work days. OSHA proposed to count scheduled workdays, consistent with its long-standing policy of excluding normal days off such as weekends, holidays, days the facility is closed, and prescheduled vacation days (61 FR 4033). The proposal asked the public for input on which counting method—calendar days or scheduled work days—would be better, stating that "OSHA is considering a modification to the concept of days away from work to include days the employee would normally not have worked (*e.g.* weekends, holidays, etc.). OSHA believes this change to calendar days would greatly simplify the method of counting days away by eliminating the need to keep track of, and subtract out, scheduled days off from the total time between the employee's first day away and the time the employee was able to return to full duty" (61 FR 4033). The proposal also discussed the potential benefits and pitfalls of counting calendar days:

> Another potential benefit of changing to calendar days would be that the day count would more accurately reflect the severity of the injury or illness. The day count would capture all the days the employee would not have been able to work at full capacity regardless of work schedules. For example, if an employee, who normally does not work weekends, is injured on a Friday and is unable to work until the following Tuesday, the "days away from work" would be three (3), using calendar days, rather than one (1) day, using work days. If the same injury occurred on a Monday, the day count would be three (3) using either calendar or workdays. Changing the day count to calendar days would eliminate discrepancies based upon work schedules. Thus, the day counts would be easier to calculate and potentially more meaningful.
>
> One of the potential problems with this change would be that economic information on lost work time as a measure of the impact of job related injuries and illnesses on work

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life would no longer be available. Employers could, however, estimate work time lost by applying a work day/calendar day factor to the recorded day counts. OSHA solicits comment on the idea of counting calendar days rather than work days, in particular, what potential do these methods have for overstating (i.e. counting calendar days) or understating (i.e. counting work days) the severity of injuries and illnesses? (61 FR 4034)

OSHA received a large number of comments on the calendar day/scheduled day issue. Many commenters suggested that OSHA track days away from work using its former method of counting scheduled workdays (see, *e.g.*, Exs. 21; 30; 37; 15: 10, 16, 30, 42, 44, 48, 61, 66, 69, 78, 79, 89, 100, 107, 108, 119, 121, 122, 127, 130, 133, 146, 151, 152, 154, 159, 163, 170, 172, 179, 180, 200, 203, 204, 213, 214, 219, 226, 246, 260, 262, 265, 281, 287, 297, 299, 300, 304, 305, 307, 308, 341, 346, 356, 363, 364, 368, 373, 378, 384, 385, 387, 389, 390, 397, 401, 404, 410, 413, 414, 424, 426, 427, 431, 440, 443). Many commenters also suggested that OSHA use calendar days instead of scheduled workdays to track days away from work (see, *e.g.*, Exs. 19; 44; 15: 26, 27, 31, 34, 44, 71, 75, 82, 105, 111, 119, 127, 136, 137, 138, 141, 153, 181, 182, 188, 198, 205, 218, 224, 233, 242, 263, 266, 269, 270, 271, 278, 310, 316, 326, 337, 345, 347, 350, 359, 369, 377, 391, 396, 405, 407, 409, 415, 418, 423, 425, 428, 429, 434, 438). The arguments of each group fall loosely into two categories: which counting method provides the most meaningful data and which method is least burdensome.

Arguing against counting calendar days, a number of commenters stated that calendar days would overstate lost workdays and artificially inflate or distort severity rates (see, *e.g.*, Exs. 15: 10, 16, 42, 44, 69, 108, 119, 127, 130, 133, 146, 159, 163, 170, 195, 203, 213, 219, 281, 287, 297, 300, 304, 305, 307, 341, 356, 364, 373, 385, 389, 390, 397, 404, 410, 414, 424, 426, 431, 440, 443). Some commenters also argued that the information would be "false and misleading" (see, *e.g.*, Exs. 15: 287, 443), "would not indicate true severity" (Ex. 15: 108), or would make it difficult to compare data from the old rule with data kept under the new rules (see, *e.g.*, Exs. 37; 15: 44, 61, 130, 146, 226, 281, 297, 299, 300, 304, 341, 378, 384, 385, 397, 404, 426, 440). Typical of these views was the one expressed by the American Trucking Associations (Ex. 15: 397), which stated that:

> This provision serves no useful purpose. Its proponents exaggerate the difficulty in computing days away from work under the current regulation. Instead, it will only serve the purpose of artificially increasing incidence and severity rates which would falsely designate a given worksite as unsafe or delineate it as a high hazard workplace. This false delineation of high hazardousness would also result in the workplace being unfairly targeted by OSHA for enforcement activities. In addition, this change would make it difficult, if not impossible, for employers to compare previous lost work day incidence rates with current rates. Such trend data is invaluable to employers in tracking progress made in eliminating workplace injuries and illnesses.

Other commenters, however, argued that calendar days would be a better statistical measure (see, *e.g.*, Exs. 15: 71, 75, 347, 425, 434, 438). For example, the American Waterways Shipyard Conference (Ex. 15: 75) stated:

> AWSC would also urge that "days away from work" be counted by calendar days rather than work days. This would ease the burden on establishments in their recordkeeping and would also make the data more useful. For example, an employee injured on Friday who does not return to work until Tuesday is currently counted as one-day off the job. If "days away from work" are calculated by calendar days, then this same injury would be counted as three days. The three day injury ruling is a more accurate indicator of the seriousness of the injury.

The United Auto Workers (UAW) argued that: "Calendar days are a much better measure of severity or disability than actual days which are adjusted for work schedule, vacations, layoffs and other extraneous disruptions. Frankly, counting actual days is a waste of effort, subject to manipulation and serves no public health purpose. It is relic and should be eliminated. The only reason some employers might wish to retain this measure is because they can generate a lower number" (Ex. 15: 438).

Other commenters were concerned that the change to counting calendar days would have an unfair effect on firms that rely more heavily on part-time workers, use alternative schedules, and/or use planned plant shutdowns (see, *e.g.*, Exs. 15: 42, 96, 121, 159, 163, 213, 219, 200, 262, 281, 299). For example, Dayton Hudson Corporation (Ex. 15: 121) stated that:

> DHC questions the concept of counting calendar days versus the proposed scheduled work days in documenting days away from work. Both methods have their value and also potential problems. The calendar method would make it much easier for a company to record the severity of an accident. However, this method would have a significant effect on an industry such as retailing, since the majority of our work force is part-time. If OSHA decides to go with the calendar method, there needs to be clearly defined examples referenced in the standard dealing with part-time workers.

Northrop Grumman Corporation (Ex. 15: 42) asserted that: "[c]ounting calendar days for days away from work would have an adverse impact on those companies, such as aerospace companies, which routinely have shut downs for one or more weeks at a time. Employees injured on the day prior to shut down would have to be recorded as being injured, off work, for the entire time of the shut down." The Texas Chemical Council (Ex. 15: 159) expressed concern about the impact the change to calendar days might have on day counts involving alternative schedules:

> We believe the value of the reduced burden is not worth the skewed data that may result. OSHA's proposal may yield accurate data and better reflect severity when applied to work schedules following an 8 hour day, Monday through Friday. However, many industries utilize a 12 hour shift that provides periods of time off longer than the normal two day weekends. The proposed method of counting days could, for example, turn an injury requiring two days recuperation time into a case requiring four or more days to be counted. This would skew severity analysis utilizing days off data.

However, the Eli Lilly Company (Ex. 15: 434) argued that calendar days would help equalize day counts: "[a] calendar day count would ensure employer consistency and comparability even when employers have unique and variable shift works."

Other commenters argued that scheduled workdays are a better measurement because they measure economic impact and lost productivity (see, *e.g.*, Exs. 15: 154, 172, 203, 204, 226, 262, 304, 341, 356, 364, 367, 397). The Fertilizer Institute (Ex. 15: 154) argued that: "Although such a change might simplify the counting of days, it will make comparisons difficult for companies, trade and professional associations, and government agencies that are trying to measure the severity of injuries and illnesses in terms of productivity. In addition to the health and safety of its employees, industry is primarily concerned with the cost of work-related injuries and illnesses, as they relate to lost productivity. Thus, the basis of the lost work day, not the lost calendar day, is the most appropriate measurement to use." The Society of the Plastics Industry, Inc. (Ex. 15: 364) urged OSHA to retain the scheduled days system because of its usefulness in measuring the economic impact of job-related accidents and the incentive such information provides for prevention efforts.

In addition to arguments about the preferred way of counting days away, commenters discussed the issues of simplification and the burden of counting days away from work with both methods. A number of commenters supported using calendar days because doing so would simplify the process and reduce burden (see, *e.g.*, Exs. 15: 71, 75, 82, 136, 137, 141, 224, 242, 263, 266, 269, 270, 278, 347, 377, 415, 418, 423, 434). Two commenters made the point that using calendar days would make it easier to use computer software to calculate days away from work (Exs. 15: 347, 423). Representative of the comments supporting the use of calendar days to reduce the recording burden was the view of the Ford Motor Company (Ex. 15: 347):

> The single most significant change that could be made to simplify and reduce the burden of the current recordkeeping system would be a change to a calendar count for days away from work. This would eliminate the need to keep track of and subtract out any scheduled days off from the time of the employee's first day away until the time the employee was able to return to work. Of additional importance, a calendar count approach would provide a more accurate reflection of the severity of injuries and illnesses.
>
> Currently, tracking days away from work is a particular problem in that many individuals no longer work a traditional eight hours a day, Monday through Friday. Some individuals work four days a week, ten hours a day, others work every Saturday and/or Sunday, and some individuals have their scheduled days off during the week. Different employees in the same establishment commonly have different work schedules. Different departments are commonly on "down time" while the rest of the establishment may be in full operation. A calendar count will simplify the calculation of days away from work for alternative work schedules.
>
> In comparison to the current system, a calendar count will provide meaningful, consistent, and useful data, as well as provide an accurate reflection of severity. The calendar day count will also enhance the ability to develop software to standardize the recordkeeping process.
>
> In addition, the change to a calendar day count would enable Ford Motor Company to free up highly trained personnel for more productive and effective pursuits rather than tracking lost workdays under the current system. The cost of these resources to track lost workdays cases exceeds one million dollars per year.

Even some of the commenters who argued against OSHA's adoption of a calendar day approach in the final rule acknowledged that counting calendar days would be simpler but emphasized that this added simplicity and reduction in burden would not offset the deleterious effect of this change on the data (see, *e.g.*, Exs. 15: 44, 61, 69, 121, 154, 159, 170, 195). The Institute for Interconnecting and Packaging Electronic Circuits (IPC) said that: "According to IPC member companies, the potential simplification gains that may be achieved by this proposal would not outweigh the gross overreporting and, therefore, inaccurate data that would result" (Ex. 15: 69).

Other commenters arguing against calendar days stated that counting scheduled workdays is not difficult or onerous (see, *e.g.*, Exs. 15: 107, 146, 387), that counting calendar days would not simplify the counting of lost workdays (see, *e.g.*, Exs. 15: 16, 119, 146, 281, 299, 304, 308, 341, 364, 367, 424), that counting calendar days would add to the administrative burden (see, *e.g.*, Exs. 15: 42, 146, 304, 308, 341, 364, 367, 431), that counting calendar days would add confusion (see, *e.g.*, Exs. 15: 204, 431), or that employers already report scheduled workdays to workers' compensation and thus this information is already available (see, *e.g.*, Exs. 15: 367, 384). Commenters also cited the need to change computer software systems if a shift to calendar days was made (Ex. 15: 122) and argued that retaining scheduled workdays would require less training than moving to calendar days (see, *e.g.*, Exs. 15: 37, 122, 133, 304, 384). The BF Goodrich Company (Ex. 15: 146) summed up these views:

> BF Goodrich's business systems are set up to count and track work days and work hours. We do not agree with the suggestion of counting calendar days rather than actual work days for Days Away From Work cases. Counting calendar days would improperly inflate the severity incidence rates which are calculated based on actual hours worked and defeat any efforts to perform trend analysis against previous years. Use of calendar days would also require unnecessary analysis of work capability for days that would not be worked anyway. There would be no reduction in burden in a calendar day system and there would be loss of severity trend analysis capability.

A number of commenters pointed to the difficulty of analyzing days away for injuries that occur just before scheduled time off, such as before the weekend (see, *e.g.*, Exs. 15: 16, 42, 44, 69, 79, 130, 179, 226, 281, 299, 341, 363, 389, 414, 424). The Institute for Interconnecting and Packaging Electronic Circuits (IPC) described the following scenario:

> [i]f a worker is injured on Friday, is sent home, and returns to work on Monday, the alternative [calendar day] proposal would require employers to count weekend days in the lost workday count. IPC believes that this alternative proposal would not accurately reflect the severity of the injury since, if the same injury had occurred on a Monday, the worker might have been able to return to work on Tuesday. (Ex. 15: 69)

United Parcel Service (UPS) was concerned about the accuracy of employee reporting of injuries and illnesses under the calendar day system:

> [t]he cessation of the effects of an employee's injury or illness cannot reliably be determined in the case of a worker who "heals" on the weekend. Thus, the number of days away from work and their impact on the perception of serious incidents will be substantially inflated. Indeed, it has been UPS's experience that a disproportionate number of injuries are reported on Friday and Monday; inclusion of claimed weekend injury, therefore, would greatly inflate OSHA statistics with factors that honest observers know to be linked, to some degree, with the universal attraction of an extended weekend. The risk, moreover, is not merely inflated numbers, but inflation of the apparent severity of those conditions that are difficult to verify and that are therefore the most likely resort of employees who would misreport a condition for time off (Ex. 15: 424).

Another issue noted by commenters was the difficulty of getting medical attention over the weekend. For example, the American Ambulance Association (Ex. 15: 226) cautioned that "The common practice of a health care provider is to defer an employee's return to work until after a weekend or holiday, due to limited staff resources for evaluating employee status on those days," and the Sandoz Corporation (Ex. 15: 299) noted that "This change [to calendar days] would lead to overstatement of the severity in cases of part-time employees due to the difficulty of getting return-to-work clearance from medical personnel."

Two commenters (Exs. 15: 69, 15: 363) objected to counting calendar days based on a belief that counting these days would raise their workers' compensation insurance rates. For example, the Institute for Interconnecting and Packaging Electronic Circuits (IPC) stated that "Lost time is a major factor in insurance premiums for facilities. As a result, a definition that would over-estimate lost time would significantly raise facility insurance costs" (Ex. 15: 69).

Patrick R. Tyson, a partner in the law firm of Constangy, Brooks & Smith, LLC (Ex. 55X, pp. 99–100), strongly favored moving to a calendar-day-count system, for the following reason:

> [w]hat we've seen in some audits is companies that attempt to try to control the number of days that would be counted as lost work days by controlling the number of days that otherwise would be worked. * * *
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> We * * * encountered one company that announced proudly in its newsletter that one particular employee should be congratulated because when she had to have surgery for carpal tunnel syndrome, clearly work related * * * she chose to have that surgery during

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her vacation so that the company's million man hours of work without a lost time accident would not be interrupted. That doesn't make any sense where we encourage those kinds of things * * * We ought to consider a calendar count if only to address those kinds of situations. I understand that would cause problems with respect to those companies who use lost work days as a measure of the economic impact of injuries and illnesses in the workplace, but I suspect that a better measure of that would be worker's compensation. If it's a lost work day, you're going to pay comp on it. * * *

OSHA agrees with some of the points made by those in favor of, and those opposed to, changing over to calendar day counts. After a thorough review of the arguments for each alternative, however, OSHA has decided to require employers to count calendar days, both for the totals for days away from work and the count of restricted workdays. OSHA does not agree with those commenters who argued that the counting of calendar days away from work would be a significant burden. The Agency finds that counting calendar days is administratively simpler than counting scheduled days away and thus will provide employers who keep records some relief from the complexities of counting days away from work (and days of restricted work) under the old system. For the relatively simple injury or illness cases (which make up the great majority of recorded cases) that involve a one-time absence from work of several days, the calendar-day approach makes it much easier to compare the injury/illness date with the return-to-work date and compute the difference. This process is easier than determining each employee's normal schedule and adjusting for normal days away, scheduled vacations, and days the facility was not open. The calendar method also facilitates computerized day counts. OSHA recognizes that, for those injuries and illnesses that require two or more absences, with periods of work between, the advantages of the calendar day system are not as significant; OSHA notes, however, that injuries and illnesses following this pattern are not common.

Changing to a calendar day counting system will also make it easier to count days away or restricted for part-time workers, because the difficulties of counting scheduled time off for part-time workers will be eliminated. This will, in turn, mean that the data for part-time workers will be comparable to that for full-time workers, i.e., days away will be comparable for both kinds of workers, because scheduled time will not bias the counting method. Calendar day counts will also be a better measure of severity, because they will be based on the length of disability instead of being dependent on the individual employee's work schedule. This policy will thus create more complete and consistent data and help to realize one of the major goals of this rulemaking: to improve the quality of the injury and illness data.

OSHA recognizes that moving to calendar day counts will have two effects on the data. First, it will be difficult to compare injury and illness data gathered under the former rule with data collected under the new rule. This is true for day counts as well as the overall number and rate of occupational injuries and illnesses. Second, it will be more difficult for employers to estimate the economic impacts of lost time. Calendar day counts will have to be adjusted to accommodate for days away from work that the employee would not have worked even if he or she was not injured or ill. This does not mean that calendar day counts are not appropriate in these situations, but it does mean that their use is more complicated in such cases. Those employers who wish to continue to collect additional data, including scheduled workdays lost, may continue to do so. However, employers must count and record calendar days for the OSHA injury and illness Log.

Thus, on balance, OSHA believes that any problems introduced by moving to a calendar-day system will be more than offset by the improvements in the data from one case to the next and from one employer to another, and by the resulting improvements in year-to-year analysis made possible by this change in the future, i.e., by the improved consistency and quality of the data.

The more difficult problem raised by the shift to calendar days occurs in the case of the injury or illness that results on the day just before a weekend or some other prescheduled time off. Where the worker continues to be off work for the entire time because of the injury or illness, these days are clearly appropriately included in the day count. As previously discussed, if a physician or other licensed health care professional issues a medical release at some point when the employee is off work, the employer may stop counting days at that point in the prescheduled absence. Similarly, if the HCP tells the injured or ill worker not to work over the scheduled time off, the injury was severe enough to require days away and these must all be counted. In the event that the worker was injured or became ill on the last day before the weekend or other scheduled time off and returns on the scheduled return date, the employer must make a reasonable effort to determine whether or not the employee would have been able to work on any or all of those days, and must count the days and enter them on the Log based on that determination. In this situation, the employer need not count days on which the employee would have been able to work, but did not, because the facility was closed, or the employee was not scheduled to work, or for other reasons unrelated to the injury or illness.

Accordingly, the final rule adopts the counting of calendar days because this approach provides a more accurate and consistent measure of disability duration resulting from occupational injury and illness and thus will generate more reliable data. This method will also be easier and less burdensome for employers who keep OSHA records and make it easier to use computer programs to keep track of the data.

Capping the Count of Lost Workdays

OSHA proposed to limit, or cap, the total number of days away from work the employer would be required to record. This would have been a departure from OSHA's former guidance for counting both days away from work and restricted workdays. The former rule required the employer to maintain a count of lost workdays until the worker returned to work, was permanently reassigned to new duties, had permanent work restrictions, or was terminated (or retired) for reasons unrelated to the workplace injury or illness (Ex. 2, pp. 47–50).

OSHA's proposed regulatory text stated that "[f]or extended cases that result in 180 or more days away from work, an entry of "180" or "180+" in the days away from work column shall be considered an accurate count" (61 FR 4058). In the preamble to the proposal, OSHA explained that day counts of more than 180 days would add negligible information for the purpose of injury and illness case analysis but would involve burden when updating the OSHA records. The proposed preamble also asked several questions: "Should the days away from work be capped? Is 180 days too short or long of a period? If so, should the count be capped at 60 days? 90 days? 365 days? or some other time period?" (61 FR 4033)

A large number of commenters supported a cap on day counts (see, *e.g.*, Exs. 21; 27; 33; 51; 15: 26, 67, 72, 82, 85, 89, 95, 105, 108, 111, 119, 120, 121, 127, 132, 133, 136, 137, 141, 146, 153, 159, 170, 173, 176, 180, 182, 185, 188, 194, 195, 198, 199, 203, 205, 213, 224, 231, 233, 239, 242, 260, 262, 263, 265, 266, 269, 270, 271, 273, 278, 283, 287, 288, 289, 297, 298, 301, 304, 307, 310, 316, 317, 321, 332, 334, 335, 336, 341, 345, 346, 347, 348, 351, 368, 373, 374, 375, 377, 378, 384, 385, 387, 389, 390, 392, 397, 401, 404, 405, 434, 437, 440, 442). The most common argument was that capping the counts would reduce the burden on employers (see, *e.g.*, Exs. 21; 33; 15: 82, 95, 111, 146, 154, 159, 170, 176, 182, 188, 213, 231, 260, 262, 265, 273, 288, 289, 297, 301, 304, 305, 310, 341, 345, 346, 373, 389, 390, 401, 442) and simplify the OSHA recordkeeping system (see, *e.g.*, Exs. 21; 15: 188, 297, 373). Several commenters argued that such a change would produce a "significant" reduction in burden and cost (see, *e.g.*, Exs. 15: 154, 159, 203, 297). The Miller Brewing Company comment (Ex. 15: 442) was representative: "We endorse this cap on the days away from work (DAFW) calculation. Once a case reaches 180 days, it is clearly recognized as a serious case. The requirement to calculate days away from work beyond 180 is a time consuming administrative exercise which provides no value-added information relative to the severity of a given case. Again, we support this rule change and OSHA's attempt to simplify the recordkeeping process."

Commenters also pointed out that limiting the day counts would make it easier to count days for cases that span two calendar years (see, *e.g.*, Exs. 15: 153, 194, 195, 289). Other commenters stated that it was difficult to modify the former year's records (Ex. 15: 153) and that the day count cap would ease the burden of tracking cases that span two calendar years (Ex. 15: 289).

Several commenters stated that the benefits of recording extended day counts were insignificant (see, *e.g.*, Exs. 15: 111, 159, 176, 184, 260, 262, 265, 288, 297, 373, 401, 430, 434, 442), that they added negligible information for case analysis or safety and health program evaluation (Ex. 15: 434), and that there was no "value added information" from high day counts (see, *e.g.*, Exs. 15: 260, 262, 265, 401, 442). Others stated that capping the day counts would provide "adequate data" (see, *e.g.*, Exs. 15: 111, 159, 304, 345) and that there would be no loss of significant data for analysis (see, *e.g.*, Exs. 15: 170, 184, 297, 341, 373). The McDonnell Douglas Corporation (Ex. 15: 297) argued that a cap "[w]ould allow industry to avoid the significant and costly paperwork burdens associated with tracking lost workdays, without any appreciable reduction in OSHA's ability to identify significant workplace injuries and illnesses or to assure continuing improvement in workplace safety and health."

Support for capping the count of days away from work was not unanimous, and several commenters opposed a day count cap (see, *e.g.*, Exs. 15: 31, 62, 197, 204, 225, 277, 294, 302, 350, 359, 369, 379). The National Safety Council stated that "[n]o cap on counting lost workdays is necessary provided that the count automatically ends with termination, retirement, or entry into long-term disability. Only a small proportion of cases have extended lost workday counts so there is little additional recordkeeping burden. The additional information gained about long-term lost workday cases is important and keeps employers aware of such cases" (Ex. 15: 359). Other commenters stressed that it was important to obtain an accurate accounting of days away to assess the severity of the case (see, *e.g.*, Exs. 15: 294, 379, 429, 440), that the counts were needed to make these cases visible (see, *e.g.*, Exs. 15: 294, 440), and that the counts demonstrate the impact of long term absences (Ex. 15: 62). For example, the Boeing Company (Ex. 15: 294) argued that

> If the count is suspended after 180 days (or any other arbitrary number), an employer will lose valuable information regarding the true amount of lost work days and their associated costs. The experience of The Boeing Company indicates that there are a small number of cases that have many more than 180 days. The result is a disproportionate amount of total costs. Not having visibility of these cases would be a mistake.

The United Steelworkers of America (USWA) offered several reasons for not adopting a day count cap: "The USWA also strongly opposes capping lost work day cases at 180. We believe that no cap is necessary or desirable. Only a very small proportion of cases have extended lost workdays recorded so there is little additional recordkeeping burden. The additional information gained about long-term lost workday cases is important in evaluating the severity of the injury and it keeps attention on such cases" (Ex. 15: 429).

The International Brotherhood of Teamsters (IBT) opposed the capping of day counts on the basis that the OSH Act requires "accurate" records, stating that:

> The IBT opposes the elimination of counting the days of restricted work activity and opposes capping the count of "days away from work" at 180 days. The IBT uses the restricted work activity day count to gauge the severity of an injury or illness. We are supported by the OSH Act, section 24(a) "the Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries or illnesses. * * *. The International Brotherhood of Teamsters maintains that the recording of restricted work activity day counts and counting of days away from work enables OSHA to compile accurate data on serious and significant injuries. (Ex. 15: 369)

After a review of the evidence submitted to the record, OSHA has decided to include in the final rule a provision that allows the employer to stop counting days away from work or restricted workdays when the case has reached 180 days. OSHA's primary reason for this decision is that very few cases involve more than 180 days away or days of restricted work, and that a cap of 180 days clearly indicates that such a case is very severe. Continuing to count days past the 180-day cap thus adds little additional information beyond that already indicated by the 180-day cap.

Selection of the Day Count Cap

A large number of commenters specifically supported the 180 day cap proposed by OSHA (see, *e.g.*, Exs. 51; 15: 26, 27, 67, 70, 89, 111, 121, 127, 136, 137, 141, 153, 154, 159, 170, 176, 184, 224, 233, 242, 260, 262, 263, 265, 266, 269, 270, 278, 283, 288, 298, 316, 335, 341, 368, 377, 385, 401, 404, 423, 430, 437, 442). The Chemical Manufacturers Association (CMA) stated that "CMA supports the use of a cap on the number of days away from work that must be counted. Once an employee misses more than 180 days from work * * * due a workplace injury or illness, the relative seriousness of the incident is determined and little benefit is derived from continuing to count the number of days for OSHA's recordkeeping system." The Fertilizer Institute (Ex. 15: 154) supported 180 days because it "is consistent with most corporate long-term disability plans."

Many commenters who supported a cap on counting days away recommended that OSHA adopt a number of days other than 180 (see, *e.g.*, Exs. 21; 37; 15: 60, 71, 75, 82, 85, 105, 108, 119, 122, 132, 180, 182, 185, 188, 194, 195, 198, 199, 203, 213, 239, 246, 271, 272, 287, 289, 297, 303, 304, 305, 307, 308, 317, 336, 347, 348, 351, 375, 378, 384, 385, 404, 405, 407, 409, 410, 414, 425, 431, 434). The most common argument against capping at 180 days was that a few very serious cases would skew the statistical data (see, *e.g.*, Exs. 15: 75, 180, 246, 271, 385, 409). Hoffman-La Roche, Inc. argued for 90 days on the grounds that "90 days is more than sufficient to get a read on the severity of the injury/illness. This would enable employers to obtain meaningful data that is not skewed by one or two cases" (Ex. 15: 271).

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Commenters suggested a number of alternatives, including 30 days (see, *e.g.*, Ex. 15: 414); 60 days (see, *e.g.*, Exs. 15: 60, 108, 119, 194, 203, 246, 287, 405); 60 or 90 (Ex. 15: 407); 90 days (see, *e.g.*, Exs. 21; 15: 75, 85, 105, 132, 182, 185, 239, 271, 272, 289, 297, 303, 317, 336, 347, 378, 409, 410, 425, 431); 50 to 100 days (see, *e.g.*, Exs. 37; 15: 384); 90 to 120 days (Ex. 15: 71); 90 or 180 days (Ex. 15: 434); 120 days (Ex. 15: 198); the equivalent of six months (see, *e.g.*, Exs. 15: 82, 188, 199, 213, 304, 307, 308, 351, 375); one year (Ex. 15: 122); and 60 days after the beginning of the new year (see, *e.g.*, Ex. 15: 195).

The most common alternative recommended by commenters was 90 days (see, *e.g.*, Exs. 21; 15: 75, 85, 105, 132, 182, 185, 239, 271, 272, 289, 297, 303, 317, 336, 347, 378, 409, 410, 425, 431). These commenters argued that 90 days would reduce the burden without a loss of information (see, *e.g.*, Exs. 15: 75, 85, 239, 297, 425), that 90 days is sufficient to determine severity (see, *e.g.*, Exs. 15: 85, 105, 271 272, 289, 303, 410), that 90 days matches existing labor agreements (see, *e.g.*, Exs. 15: 378), and that 90 days limits the problems caused by a case that extends over 2 years (see, *e.g.*, Exs. 15: 407, 431).

NIOSH (Ex. 15: 407) commented that:

NIOSH agrees with OSHA that "day counts greater than 180 days add negligible information while entailing significant burden on employers when updating OSHA records." Therefore, NIOSH agrees with the concept of capping the count of days away from work at a maximum of 180 days, and recommends that OSHA also consider caps of 60 or 90 days away from work.

Currently, the Annual Survey of Occupational Injuries and Illnesses reports distributional data for the number of days away from work and the median number of days away from work for demographic (age, sex, race, industry, and occupation) and injury/illness (nature, part of body, source, and event) characteristics. The largest category of days away from work reported by the BLS for days away from work is "31 days or more." In 1992, the Annual Survey reported median days away from work that ranged from 1 day to 236 days [U.S. Department of Labor 1995]. For most demographic and injury/illness categories, capping the count of days away from work at 180 days will not alter the values for either the percent of injuries in the "31 days or more" category or median days away from work.

OSHA may wish to consider capping the count of days away from work at either the 60 or the 90 day level. Employers could be instructed to enter a value of 61+(or 91+) to indicate that the recorded injury or illness condition existed beyond the cap on the count of days away from were based on the 1992 Annual Survey data, no reported industry and only one reported occupation had a median of greater than 60 days (dental hygienist, median = 71). There was also a very small number of injury/illness characteristics with medians between 60 and 90 days or with medians exceeding 90 days. Eleven of the 13 instances in which the median exceeded 60 days away from work were based on distributions involving a small number of estimated cases i.e., only 100 to 400 nationally. Capping the count of days away from work at either 60 or 90 days would still allow the reporting of the proportion of cases involving days away from work in the "31 days or more category" that is currently being reported by the BLS. A minor limitation of capping the count of days away from work at 60 or 90 days is that for a very small number of characteristics, the median would have to be reported as exceeding the cap.

Two commenters suggested that OSHA use months instead of days as the measurement (Exs. 15: 304, 404), and a number of commenters pointed out that OSHA's proposed 180 days should be 125 if based on 6 months of actual workdays instead of calendar days (see, *e.g.*, Exs. 15: 199, 213, 307, 308, 348).

After careful consideration, OSHA has decided to cap the day counts at 180 days and to express the count as days rather than months. The calendar month is simply too large and unwieldy a unit of measurement for this purpose. The calendar-day method is the simplest method and will thus produce the most consistent data.

OSHA has decided to cap the counts at 180 days to eliminate any effect such capping might have on the median days away from work data reported by BLS. This cap will continue to highlight cases with long periods of disability, and will also reduce the burden on employers of counting days in excess of 180. Using a shorter threshold, such as 90 or even 120 days, could impact the injury and illness statistics published by the BLS, and could thus undermine the primary purpose of this regulation: to improve the quality and utility of the injury and illness data. Using a shorter time frame would also make it harder to readily identify injuries and illnesses involving very long term absences. The rule also does not require the employer to use the designation of 180+ or otherwise require cases extending beyond 180 days to be marked with an asterisk or any other symbol, as suggested by various commenters (see, *e.g.*, Exs. 15: 31, 62, 153, 289, 374, 407, 425). Employers who wish to attach such designations are free to do so, but OSHA does not believe such designations are needed.

Counting Lost Workdays When Employees Are No Longer Employed by the Company

The proposed rule contained a provision that would have allowed the employer to stop counting the days away from work when the worker was terminated for reasons unrelated to an injury or illness (61 FR 4058). This provision would have continued OSHA's former policy on this matter, which allowed the employer to stop counting days away or restricted workdays when the employee's employment was terminated by retirement, plant closings, or like events unrelated to the employee's work-related injury or illness (Ex. 2, pp. 49, 50). The final rule, at paragraph 1904.7(b)(3)(vii), permits employers to stop counting days away if an injured or ill employee leaves employment with the company for a reason unrelated to the injury or illness. Examples of such situations include retirement, closing of the business, or the employee's decision to move to a new job.

Paragraph 1904.7(b)(3)(vii) also requires employers whose employees have left the company because of the injury or illness to make an estimate of the total days that the injured or ill employee would have taken off work to recuperate. The provisions in paragraph 1904.7(b)(3)(vii) also apply to the counting of restricted or transferred days, to ensure that days are counted consistently and to provide the simplest counting method that will collect accurate data. OSHA's reasoning is that day counts continue to be relevant indicators of severity in cases where the employee was forced to leave work because of the injury or illness.

Handling Cases That Cross Over From One Year to the Next

A special recording problem is created by injury and illness cases that begin in one year but result in days away from work or days of restricted work in the next year. Under the former rule, the employer was to record the case once, in the year it occurred, and assign all days away and restricted days to that case in that year (Ex. 2, p. 48). Under the rule being published today, this policy still applies. If the case extends beyond the time when the employer summarizes the records following the end of the year as required by § 1904.32, the employer is required by paragraph 1904.7(b)(3)(viii) to update the records when the final day count is known. In other words, the case is entered only in the year in which it occurs, but the original Log entry must subsequently be updated if the day count extends into the following year.

In addition to the NIOSH (Ex. 15: 407) comments on the day counts summarized above, the Society for Human Resource Management (Ex. 15: 431) urged OSHA to adopt a lower day

count cap to limit the "crossover" problem. Two commenters urged OSHA to take a new approach to cases that extend over two or more years. Both the Laborers' Health & Safety Fund of North America (Ex. 15: 310) and the Service Employees International Union (Ex. 15: 379) recommended that these cases be recorded in each year, with the days for each year assigned to the appropriate case. The Laborers' Health & Safety Fund of North America (Ex. 15: 310) stated:

One concern with a large number of days away from work is how to record the lost days which begin in one calendar year and end in a following calendar year. We suggest that it is best to record the number of days lost from the date of the injury to the end of the calendar year, and to enter the injury again on the following year's OSHA 300 with the remaining days of lost time up to the 180 day maximum. A box should be available to indicate that the entry is a continuation from the prior year.

As stated earlier, OSHA has decided on the 180 day cap for both days away and days of restricted work cases to ensure the visibility of work-related injuries and illnesses with long periods of disability. The final rule also requires the employer to summarize and post the records by February 1 of the year following the reference year. Therefore, there will be some cases that have not been closed when the records are summarized. Although OSHA expects that the number of cases extending over two years will be quite small, it does not believe that these cases warrant special treatment. A policy that would require the same case to be recorded in two years would result in inaccurate data for the following year, unless special instructions were provided. Accordingly, the final rule requires the employer to update the Log when the final day count is known (or exceeds 180 days), but to record the injury or illness case only once. This approach is consistent with OSHA's longstanding practice and is thus familiar to employers.

Miscellaneous Day Counting Issues

Two commenters provided additional comments for OSHA to consider on the issue of counting days away from work. The Laborers' Health & Safety Fund of North America (Ex. 15: 310) recommended that OSHA require employers to enter a count of 365 days away from work on the Log for any fatality case:

In a recent project we used OSHA 200 data from road construction and maintenance employers to determine the causes and relative severities of serious injuries. The number of lost workdays plus restricted work activity days for an injury event or type was used as a measure of severity. In quite a few individual injury cases, the number of days away from work entry was not available because of the severity of the injury or because the injury resulted in a fatality. For recordkeeping purposes, we would suggest a maximum cap of 180 days for a non-fatal serious injury of long duration, and an automatic entry of 365 for fatalities. Using this method, the most severe cases would be weighted appropriately, with fatalities carrying the heaviest weight. Also, entering a lost workday number for fatalities would enable fatalities to count in a single and simple "severity-weighted Lost Work Day Injury and Fatality (LWDIF) rate".

OSHA has not adopted the Laborers' Health & Safety Fund of North America recommendation. OSHA believes that fatalities must be considered separately from non-fatal cases, however severe the latter may be. When an employee dies due to a work-related injury or illness, the outcome is so severe and so important that it must be treated separately. Merging the two types of cases would diminish the importance of fatality entries and make the days away data less useful for determining the severity of days away injury cases. Accordingly, the final rule being published today does not reflect this recommendation.

The Westinghouse Corporation (Ex. 15: 405) suggested that OSHA look at days of hospitalization as a measure of severity, stating "[t]he number of days hospitalized does provide a more objective indication of the seriousness of injury or illness, if for no other reason than cost control by insurance companies. If OSHA can document a legitimate use for an indicator of the "seriousness" of an injury, it may want to consider hospital stay time." OSHA has considered the use of hospitalized days, but has rejected them as a measure of injury or illness severity. Although these day counts may be a reasonable proxy for severity, they are applicable only in a relatively small number of cases.

Paragraph 1904.7(b)(4) Restricted Work or Transfer to Another Job

Another class of work-related injuries and illnesses that Section 8(c) of the Act identifies as non-minor and thus recordable includes any case that results in restriction of work or motion[2] or transfer to another job. Congress clearly identified restricted work activity and job transfer as indicators of injury and illness severity.

In the years since OSHA has been enforcing the recordkeeping rule, however, there has been considerable misunderstanding of the meaning of the term "restricted work," and, as a result, the recording of these cases has often been inconsistent. The Keystone Report (Ex. 5), which summarized the recommendations of OSHA stakeholders on ways to improve the OSHA recordkeeping system, noted that restricted work was perhaps the least understood of the elements of the system.

This section of the Summary and Explanation first discusses the former recordkeeping system's interpretation of the term restricted work, describes how the proposed rule attempted to revise that interpretation, and then summarizes and responds to the comments OSHA received on the proposed approach to the recording of work restriction and job transfer cases. Finally, this section explains the final rule's restricted work and job transfer requirements and OSHA's reasons for adopting them.

The Former Rule

The former recordkeeping rule did not include a definition of restricted work or job transfer; instead, the definition of these terms evolved on the basis of interpretations in the BLS *Guidelines* (Ex. 2, p. 48). The *Guidelines* stated that restricted work cases were those cases "where, because of injury or illness, (1) the employee was assigned to another job on a temporary basis; or (2) the employee worked at a permanent job less than full time; or (3) the employee worked at his or her permanently assigned job but could not perform all the duties connected with it." The key concepts in this interpretation were that work was to be considered restricted when an employee experienced a work-related injury or illness and was then unable, as a result of that injury or illness, to work as many hours as he or she would have been able to work before the incident, or was unable to perform all the duties formerly connected with that employee's job. "All duties" were interpreted by OSHA as including any work activity the employee would have performed over the course of a year on the job.

OSHA's experience with recordkeeping under the former system indicated that employers had difficulty with the restricted work concept. They questioned the need for keeping a tally of restricted work cases, disagreed with the "less than full time" concept, or

[2] The term *restricted motion* has been interpreted to mean restricted work motion and to be essentially synonymous with *restricted work*. OSHA does not distinguish between the two terms. OSHA's former *Guidelines* (Ex. 2, p. 43) clearly stated that a restriction of work or motion, such as that resulting from a bandaged finger, that did not also impair work was not recordable, and that is also the interpretation of the final rule.

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were unsure about the meaning of "all the duties connected with [the job]." (In OSHA's experience, employers have not generally had difficulty understanding the concept of temporary job transfer, which are treated in the same way as restricted work cases for recordkeeping purposes. The following discussion thus focuses on restricted work issues.) The changes OSHA proposed to make to the work restriction concept (61 FR 4033) were intended to address these employer concerns.

The Proposed Rule

The proposal would have changed restricted work recordkeeping practices markedly. For example, the proposal would have required employers to acknowledge that the case involved restricted work by placing a check in the restricted work column on the Log but would no longer have required them to count the number of restricted work days associated with a particular case. At the time of the proposal, OSHA believed that dropping the requirement to count restricted days was appropriate because the Agency lacked data showing that restricted work day counts were being used by employers in their safety and health programs. In addition, the proposal would have limited the work activities to be considered by the employer in determining whether the injured or ill worker was on restricted work. Under the former rule, employers had to consider whether an injured or ill employee was able to perform "all the duties" normally connected with his or her job when deciding if the worker's job was restricted; OSHA interpreted "all the duties" to include any work activity the employee performed at any time within a year. Under the proposal, the duties that the employer would have been required to consider were narrowed to include only (1) those work activities the employee was engaged in at the time of injury or illness onset, or (2) those activities the employee would have been expected to perform on that day (61 FR 4059). OSHA also requested comment in the proposal on the appropriateness of limiting the activities to be considered and on other definitions of work activities that should be considered, *e.g.*, would it be appropriate not to consider an employee to be on restricted work if he or she is able to perform any of his or her former job activities? (61 FR 4059).

Comments on the Proposed Rule's Restricted Work and Job Transfer Provisions

The comments OSHA received on these provisions were extensive. Commenters offered a wide variety of suggestions, including that OSHA eliminate restricted work activity cases from the recordkeeping system altogether, that the proposed definition of restricted work activity be changed, that the proposed approach be rejected, that it be adopted, and many other recommendations. These comments are grouped under topic headings and are discussed below.

Eliminate the Recording of Restricted Work Cases

Several commenters recommended that OSHA completely eliminate the recording of restricted work cases because, in the opinion of these commenters, the concept confused employers, created disincentives to providing light duty work or return-to-work programs, and provided no useful information (see, *e.g.*, Exs. 15: 119, 203, 235, 259, 336, 414, 427). For example, the American Bakers Association said, "We believe that the concept and definitions of 'restricted work activity' should be eliminated. That term and its proposed definition is so ambiguous as to be unworkable, and information gleaned from that terminology would have little reliability or usefulness" (Ex. 15: 427).

The National Grain and Feed Association agreed, arguing that the recording of restricted work cases should be eliminated on the following grounds:

[w]e agree with the conclusion of the Keystone Report that "the recording of restricted work is perhaps the least understood and least accepted concept in the recordkeeping system." We disagree with OSHA, however, that the concept of restricted work is meaningful. For example, there is a wide range of restrictions that may be placed on an injured employee's activity after returning to work depending on the nature of the injury (*e.g.*, the range of work possible for an employee who has experienced a slight sprain versus an employee with a broken bone). Additionally, the concept of restricted work is greatly dependent on individual employee motivation and job description. * * * Importantly, we believe the concepts embodied in the proposed restricted work definition run counter to modern work practices that encourage workers to return to productive work at the worksite. Workers who have experienced minor injuries on the job can return to productive work under employer "return-to-work" programs. For this reason, the concept of restricted work is arbitrary and ultimately of little use to either evaluating the effectiveness of an employer's safety and health programs or determining the exposure of workers to a hazard at a specific worksite. We, therefore, recommend that the Agency delete the category of restricted work injuries from the proposed changes to 29 CFR 1904. Removal of this section will simplify the recordkeeping system and make it more "user friendly." We support deletion of this category of injury because we think it will make the system more complex and is inconsistent with current practices of returning employees back to productive work at the earliest date (Ex. 15: 119).

Revise the Proposed Definition of a Restricted Work Case

Most of the remaining comments recommended either that the definition of restricted work in the final rule be revised to include a more inclusive set of job activities or functions or a less inclusive set. For example, the Small Business Administration (Ex. 51) was concerned that:

[t]he new definition for classifying "restricted work activity" could increase the number of cases that would be subject to this standard, and subsequently, classified as a recordable incident. Small businesses would face increased recordkeeping. Under the proposed definition, a case would be determined as a "restricted work activity" if the employee cannot perform what he or she was doing at the time of the illness or injury, or he or she could not perform the activities scheduled for that day. While this would be a very simple method, it would encompass more recordable incidents. Many workers have a myriad of tasks associated with their job. If an employee can return to work and perform functions within their job description, this should not be considered "restricted work activity". * * *

Several commenters recommended that OSHA rely on a definition of restricted work that would focus on "non productive work" and exclude the recording of any case where the employee was still productive (see, *e.g.*, Exs. 15: 9, 45, 46, 67, 80, 89, 247, 437). For example, Countrymark Cooperative, Inc. (Ex. 15: 9) stated:

[w]e disagree with a portion of the definition for restricted work activity. We agree that this should include injuries or illnesses where the worker is not capable of performing at full capacity for a full shift. However, by addressing the task that they were engaged in at the time of the injury will create problems. Most employees today have numerous assignments and responsibilities. They move from one task to another during a given day and during a given week. What they are doing at the time they are injured may not be the assignment for the next day or the next week. In these cases, they may be back at work in a fully productive role, but not doing the same task as when they were hurt. If they are performing a fully productive role within the same job description, but cannot perform the role of the job they were doing at the time, they should not be penalized. In many cases, this job task may not be active at the time they return. * * * It should be very clear that the ability to return an employee to a productive role (whether 50% or 100%) is extremely important to any "Return-to-Work" Program. If that person is returned to work and is performing at full capacity in a given task within their job description, this should not be recorded unless it meets other criteria such as medical treatment. If we return to the days of recording these and penalizing the employer, they may be inclined to return to the days of only allowing employees to return to work when they are 100% in all given tasks within their job description. If this occurs, we all lose. * * * We do agree that any time an employee is returned to work and is restricted to only perform certain jobs, can only return for a limited duration, or must be reassigned to another task, this should be recorded as a restricted work case (Ex. 15: 9).

Others recommended that OSHA adopt the Keystone Report's definition of restricted work (see, *e.g.*, Exs. 15: 123, 129, 145, 225, 359, 379, 418). For example, the National Safety Council recommended:

[t]he concept of restricted work activity as described on page 4046 [of the **Federal Register**] is one with which the Council concurs, but the specific wording in proposed section 1904.3 is less clear. The colon following the opening clause of the definition "at full capacity for a full shift:" seems to mean that the employee must be able to perform the task during which he/she was injured and the other tasks he/she performed or would have performed that day not only for the normal frequency or duration, but "at full capacity for a full shift." For example, if the employee were required to open a valve at the start of a shift and close it at the end of the shift, the current wording seems to say that if the employee could not spend the entire shift opening and closing the valve, then his/her work activity is restricted. * * * The Council also believes that the concept of restricted work activity as formulated by the Keystone Report is appropriate in that it represents a consensus among the various stakeholder groups. For this reason, we also recommend that the task limitations refer to the week's activities rather than the day's activities (Ex. 15: 359).

The Union of Needletrades, Industrial and Textile Employees (UNITE) agreed with the National Safety Council that a different time period should be used in determining what job activities to consider. UNITE suggested that OSHA use the employee's monthly, rather than daily or weekly, duties to define restricted work activity (Ex. 15: 380).

A few commenters expressed concern that use of the proposed restricted work definition could lead employers to include unusual, extraordinary or rarely performed duties in the "work activities" to be considered when determining whether a case was a restricted work case (see, *e.g.*, Exs. 15: 80, 247). For example, the Arizona Public Service Company said:

[d]etermining restricted duty days should remain as it currently is in the Guidelines. The restriction should focus on the ability of the employee to perform all or any part of his or her normal job duties. Focusing on what specifically they were doing at the time of injury could incorrectly base this determination on an activity that is performed rarely. Also, focusing on what they were scheduled to do for that week would not be useful for those whose schedules can change daily (Ex. 15: 247).

Adopt the Americans With Disabilities Act Definition of Essential Duties

The Laboratory Corporation of America's comment (Ex. 15: 127) was typical of those of several commenters who suggested that OSHA use the concept of essential job duties that is also used for the administration of the Americans with Disabilities Act (ADA) (see, *e.g.*, Exs. 15: 127, 136, 137, 141, 224, 266, 278, 431):

[t]he definition used by the Americans with Disability Act (ADA) would be very useful here. That definition indicates that restricted work exists if an employee is unable to perform the essential functions of his/her job. Since these essential functions are identified in the employee's job description, the employer would have a consistent "yardstick" with which to make this determination for each employee.

Adoption of the Proposed Approach Will Lead to Underreporting

Some commenters, such as the AFL–CIO, opposed the proposed approach to restricted work on the grounds that it would result in underreporting:

[w]e believe this proposed provision would entice employers to manipulate records and lead to further under-reporting. We strongly suggest that the Agency adopt the Keystone Report recommendation of restricted work which requires an employer to record if the employee is (1) unable to perform the task he or she was engaged in at the time of injury or onset of illness (task includes all facets of the assignment the employee was to perform); or (2) unable to perform any activity that he or she would have performed during the week (Ex. 15: 418).

Other commenters agreed (see, *e.g.*, Exs. 20, 15: 17, 129, 418). For example, the United Brotherhood of Carpenters (UBC) Health & Safety Fund of North America argued in favor of a broader definition to avoid this problem:

[t]he majority of workers represented by the UBC, such as carpenters and millwrights, routinely perform a wide variety of tasks during their normal workdays in either construction or industrial settings. Therefore, OSHA should not limit the classification of "restricted work activity" to either "the task he or she was engaged in at the time of the injury" or his or her daily work activity (daily work activity includes all assignments the employee was expected to perform on the day of the injury or onset of illness)" as proposed. The UBC feels that the current proposal would allow for manipulation of the records and will lead to serious under reporting. Many workplaces have armies of "walking wounded" rather than reporting lost or restricted work activity. OSHA should at the very least adopt the position of the Keystone Report which recommended that restricted work activity should be recorded if the employee is "(1) unable to perform the task he or she was engaged in at the time of the injury or onset of illness, or (2) unable to perform any activity that he or she would have performed during the week." The UBC believes that the best definition of restricted work activity would be any illness or injury which inhibits, interferes with, or prevents a worker from performing any or all of the functions considered to be a normal part of his or her trade or occupation as defined in the applicable job description (Ex. 20).

Do Not Count Incidents Involving Only One or a Few Days as Restricted Work

A number of commenters recommended that restricted work activity involving only the day of injury/illness onset should not trigger an OSHA recordable case (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391). Typical of these comments is one from the Society of the Plastics Industry, Inc.:

[e]mployers have had problems with OSHA's definition of restricted work activity because OSHA's interpretation that having any work restriction, even one which lasts only for the remainder of the shift and which imposes no significant limitations on the employee's ability to perform his or her job, makes a case recordable. OSHA should adopt the administratively simple and common-sense rule that restricted work activity on the day of the case report does not make the case recordable. . . . The definition of "restricted work activity" should be clarified to state that the criteria apply only to days following the day of injury or onset of the illness. An employee's inability to work a full shift on the actual date of injury or onset of illness should not require recording as a restricted work case. As noted above, because OSHA's interpretation that having any work restriction, even one which lasts only for the remainder of the shift and which imposes no significant limitations on the employee's ability to perform his or her job, makes a case recordable, many non-serious, non-disabling cases are now recorded. Cases which do not otherwise meet the recordability criteria should not be recordable. Therefore, as recommended above, OSHA should eliminate the current requirement to record cases in which restricted work activity occurs only on the day of the case report (Ex. 15: 364).

The Kodak Company urged OSHA not to count cases involving restrictions lasting only for three days as restricted work cases on the grounds that such cases are "minor": "Restricted work activity allows employers and employees to remain at work. This is a win-win situation for both. Kodak suggests restricted work activity be counted only if the restriction lasts

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longer than 3 working days. Hence, only serious cases would be recorded" (Ex. 15: 322).

Adopt the Proposed Approach

A large number of commenters supported OSHA's proposed definition, however (see, *e.g.*, Exs. 27, 15: 26, 61, 70, 133, 159, 171, 185, 199, 204, 242, 263, 269, 270, 272, 283, 303, 305, 307, 317, 318, 324, 334, 347, 351, 373, 375, 377, 378, 384, 390, 392, 405, 409, 413, 425, 430). Typical of these were comments from the New Jersey Department of Labor (Ex. 15: 70), which commented:

[p]roviding a clear definition of what constitutes restricted work and an item to indicate that an injured employee has been shifted to restricted work activity should improve the accuracy and completeness of case reporting. Identifying the actual number of cases in which employees are shifted to alternate work, which are thought to be under reported, and adding the date when the employee returned to his/her usual work will help to assess the impact of these incidents.

The American Petroleum Institute, which believed that the proposed definition would be easy to interpret and would therefore improve recording consistency, stated: "API strongly supports OSHA's proposed definition of restricted activity. Because it is much more logical and easy to understand than the current definition, API believes it will lead to greater consistency" (Ex. 15: 375).

Use Different Triggers Than Those Proposed

The Commonwealth Edison Company recommended that restricted work be defined only in terms of the hours the employee is able to work, not the functions the employee is able to perform:

[C]omEd disagrees with OSHA on its definition of "restricted work activity". We propose that OSHA consider that restricted work activity simply state "Restricted work activity means the worker, due to his or her injury or illness, is unable to work a full shift." OSHA's proposed definition of restricted work activity is even more confusing than the current one. ComEd's proposed definition will allow quantifiable, direct cost tracking for this category of injury or illness. Workers will more than likely have some kind of meaningful work waiting for them if the injury is not disabling. If he or she is able to work the required normal shift hours, don't count the case as restricted. If they miss the entire shift, count is as a day away from work. If they miss part of the shift, count it as restricted (Ex. 15: 277).

Two commenters suggested that a case should only be considered restricted when it involves both medical treatment *and* work restrictions (Exs. 15: 9, 348). For example, the E. I. du Pont de Nemours & Company (DuPont) said that the

"Restricted Work Activity" definition is a definite improvement over the current one. Suggest making treatment AND restriction the criteria. An insignificant injury can result in being told not to climb ladders. This does not negate the ability to do the job; it just limits the job to levels where ladder climbing is not required. * * * Restricted work activity is more dependent on timing and job than on injury severity. It doesn't necessarily focus on hazardous conditions. Certainly the definition in the proposed guidelines is far more specific and appropriate than the current one. We suggest consideration be given to dropping the Restricted category where medical treatment is not also given. For example, a slight muscle strain will result in advice not to climb ladders. The case would be in the restricted category although the treatment, if any, would be at the first aid level. Injury severity is the equivalent of a cut finger" (Ex. 15: 348).

Other comments sought a broader, more inclusive definition of restricted work, one that relies on job descriptions (see, *e.g.*, Exs. 15: 41, 62, 198, 426). For example, Robert L. Rowan, Jr. stated:

[t]he definition of "restricted work activity" also concerns me and I believe it is unsuitable. The definition refers to an employee who is not capable of performing at full capacity for a full shift the "task" that he or she was engaged in at the time of the injury or onset of illness. The definition should include "any and all tasks" within the employee's clearly defined job description" (Ex. 15: 62).

The Maine Department of Labor, however, preferred the former rule's interpretation, with some modifications:

[w]e agree that there should be no mention of "normal" duties in the definition. Include: temporary transfer to a position or department other than the position or department the worker was working at when he/she was injured. Some of these can be detected on payroll records; only being able to work part of their workday. Time forms could raise suspicion here; a health care provider puts the person on written restrictions unless the employer can show that the restrictions listed do not impact the employee's ability to do his or her scheduled job during the time period of the restrictions. Keep a copy of the restrictions in the file. The doctor's name on the OSHA 301 serves as another possible check (Ex. 15:41).

Miscellaneous Comments and Questions

There were also a variety of miscellaneous comments and questions about the proposed approach to the recording of restricted work cases. For example, Bob Evans Farms suggested that:

[w]hen considering this proposal, OSHA needs to keep in mind the special nature of the restaurant business. It is not uncommon for a cook to cut himself or herself, apply a Band-Aid, and then temporarily be reassigned to janitorial work for a day or two to keep the cut dry while it heals. This could be considered work duty modification and would then need to be reported to OSHA. As you can see, this type of minor occurrence would clog the system with needless paper (Exs. 15: 3, 4, 5, 6).

Phibro-Tech, Inc. offered this comment:

[a] factory employee who normally performs heavy labor may be assigned office work as a restricted work activity, and may not actually be contributing anything meaningful to the job. Will employers be required to limit what is considered "light duty" tasks? Will there be directives as to when an employee should really be off work or when he can be on "light duty"? Occupational physicians all have different opinions as to when an employee can return for light or full duty. It would be helpful to have more direction on this issue so employees aren't sent back to work too soon or kept off on lost time too long (Ex. 15: 35).

The law firm of Constangy, Brooks & Smith, LLC, asked, "[w]ould a restriction of piece rate or production rate be considered restricted duty under the proposed definition even though it is not considered restricted duty under the present guidelines?" (Ex. 15: 428). Miller Brewing Company added, "[w]ould also recommend that OSHA attempt to clarify whether a treating physician's [non-specific] return to work instructions such as "8 hours only," "self restrict as needed," and "work at your own pace" will constitute restricted work activity under the proposed recordkeeping rule" (Ex. 15: 442).

The Pacific Maritime Association stated:

This is another example where the ILWU/PMA workforce does not fit into the proposed recordkeeping system. The regulation as written pertains to employers who assign their employees to work tasks. As previously mentioned, in our industry it is the employee who selects the job they will perform. This dispatch system, or job selection process, presents many problems when the maritime industry is required to conform to requirements established for traditional employee/employer relationships found in general industry. At the present time there is no method available to determine why an individual longshoreman selects a specific job. Therefore, the requirement to identify, track, and record "restricted work activity" may be impossible to accomplish [in the maritime industry] (Ex. 15: 95).

Preventive Job Transfers

Several commenters (see, *e.g.*, Exs. 25; 15: 69, 156, 406) urged OSHA to make some accommodation for "preventive transfers" and medical removals. Many transfers and removals of this nature are related to work-related musculoskeletal disorders and are used to prevent minor musculoskeletal soreness from becoming worse. The following comments are representative of the views of these commenters. The Ogletree, Deakins, Nash, Smoak & Stewart (ODNSS) coalition commented:

[t]his definition [the proposed definition of restricted work] is overly broad, penalizes employers who have a light duty program in place, and fails to take into account that (1) today's employees increasingly are cross trained and perform varied tasks, and (2) the ability of an employee to perform alternative meaningful work mitigates the seriousness of the inability to perform work in the two categories set out in the definition as proposed. The ODNSS Coalition recommends curing these defects by adding the following proviso to the proposed definition: "The case should be recorded as a restricted work case UNLESS the restrictive work activity is undertaken to relieve minor soreness experienced by a newly hired or transferred employee during a break-in phase to prevent the soreness from worsening, or the employee otherwise is able to perform other existing full-time duties." The appropriate nature of the recommended proviso is underscored by a baseball analogy where the right fielder and the center fielder change positions. They both continue to play on the same team and make substantial contributions, but the strain on the new right fielder is less because he doesn't have as much ground to cover (Ex. 15: 406).

The National Association of Manufacturers (NAM) summed up its views as follows:

[a] preventive or prophylactic measure such as medical removal (as opposed to a restorative or curative measure) is not and should not be deemed medical treatment, a job transfer or restricted activity for purposes of recordability, in the absence of a substantial impairment of a bodily function (Ex. 25).

Although Organization Resource Counselors (ORC) generally endorsed the proposed approach to the treatment of restricted work cases, it did express concern about how medical removal cases would be treated under the proposed definition:

[t]he proposed definition of restricted work is a significant improvement over the current [former] one, which was considered by many employers to be unfair and confusing. It is no secret that many employers did not understand the current restricted work rules and, as a result, did not follow them consistently. Additionally, the [proposed] elimination of the count of restricted workdays is appropriate and is a recognition by OSHA that the recording of this count is of little value to either the Agency or employers in program evaluation or program development. * * * Additionally, requirements for the recording of either voluntary or mandatory medical removals where no additional symptoms are present are examples of appropriate action taken by employers to prevent harm to employees and not of a recordable injury or illness. * * *" (Ex. 15: 358).

Final Rule's Restricted Work and Job Transfer Provisions, and OSHA's Reasons for Adopting Them

Paragraph 1904.7(b)(4) contains the restricted work and job transfer provisions of the final rule. These provisions clarify the definition of restricted work in light of the comments received and continue, with a few exceptions, most of the former rule's requirements with regard to these kinds of cases. OSHA finds, based on a review of the record, that these provisions of the final rule will increase awareness among employers of the importance of recording restricted work activity and job transfer cases and make the recordkeeping system more accurate and the process more efficient.

OSHA believes that it is even more important today than formerly that the definition of restricted work included in the final rule be clear and widely understood, because employers have recently been relying on restricted work (or "light duty") with increasing frequency, largely in an effort to encourage injured or ill employees to return to work as soon as possible. According to BLS data, this category of cases has grown by nearly 70% in the last six years. In 1992, for example, 9% of all injuries and illnesses (or a total of 622,300 cases) recorded as lost workday cases were classified in this way solely because of restricted work days, while in 1998, nearly 18% of all injury and illness cases (or a total of 1,050,200 cases) were recorded as lost workday cases only because they involved restricted work [BLS Press Release 99–358, 12–16–99). The return-to-work programs increasingly being relied on by employers (often at the recommendation of their workers' compensation insurers) are designed to prevent exacerbation of, or to allow recuperation from, the injury or illness, rehabilitate employees more effectively, reintegrate injured or ill workers into the workplace more rapidly, limit workers' compensation costs, and retain productive workers. In addition, many employees are eager to accept restricted work when it is available and prefer returning to work to recuperating at home.

The final rule's requirements in paragraph 1904.10(b)(4) of the final rule state:

(4) How do I record a work-related injury or illness that involves restricted work or job transfer?

When an injury or illness involves restricted work or job transfer but does not involve death or days away from work, you must record the injury or illness on the OSHA 300 Log by placing a check mark in the space for job transfer or restricted work and entering the number of restricted or transferred days in the restricted work column.

(i) How do I decide if the injury or illness resulted in restricted work?

Restricted work occurs when, as the result of a work-related injury or illness:

(A) You keep the employee from performing one or more of the routine functions of his or her job, or from working the full workday that he or she would otherwise have been scheduled to work; or

(B) A physician or other licensed health care professional recommends that the employee not perform one or more of the routine functions of his or her job, or not work the full workday that he or she would otherwise have been scheduled to work.

(ii) What is meant by "routine functions"?

For recordkeeping purposes, an employee's routine functions are those work activities the employee regularly performs at least once per week.

(iii) Do I have to record restricted work or job transfer if it applies only to the day on which the injury occurred or the illness began?

No. You do not have to record restricted work or job transfers if you, or the physician or other licensed health care professional, impose the restriction or transfer only for the day on which the injury occurred or the illness began.

(iv) If you or a physician or other licensed health care professional recommends a work restriction, is the injury or illness automatically recordable as a "restricted work" case?

No. A recommended work restriction is recordable only if it affects one or more of the employee's routine job functions. To determine whether this is the case, you must evaluate the restriction in light of the routine functions of the injured or ill employee's job. If the restriction from you or the physician or other licensed health care professional keeps the employee from performing one or more of his or her routine job functions, or from working the full workday the injured or ill employee would otherwise have worked, the employee's work has been restricted and you must record the case.

(v) How do I record a case where the worker works only for a partial work shift because of a work-related injury or illness?

A partial day of work is recorded as a day of job transfer or restriction for recordkeeping purposes, except for the day on which the injury occurred or the illness began.

(vi) If the injured or ill worker produces fewer goods or services than he or she would have produced prior to the injury or illness but otherwise performs all of the activities of his or her work, is the case considered a restricted work case?

No. The case is considered restricted work only if the worker does not perform all of the

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routine functions of his or her job or does not work the full shift that he or she would otherwise have worked.

(vii) How do I handle vague restrictions from a physician or other licensed health care professional, such as that the employee engage only in "light duty" or "take it easy for a week"?

If you are not clear about a physician or other licensed health care professional's recommendation, you may ask that person whether the employee can perform all of his or her routine job functions and work all of his or her normally assigned work shift. If the answer to both of these questions is "Yes," then the case does not involve a work restriction and does not have to be recorded as such. If the answer to one or both of these questions is "No," the case involves restricted work and must be recorded as a restricted work case. If you are unable to obtain this additional information from the physician or other licensed health care professional who recommended the restriction, record the injury or illness as a case involving job transfer or restricted work.

(viii) What do I do if a physician or other licensed health care professional recommends a job restriction meeting OSHA's definition but the employee does all of his or her routine job functions anyway?

You must record the injury or illness on the OSHA 300 Log as a restricted work case. If a physician or other licensed health care professional recommends a job restriction, you should ensure that the employee complies with that restriction. If you receive recommendations from two or more physicians or other licensed health care providers, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

The concept of restricted work activity in the final rule falls somewhere between the commenters' broadest and narrowest definitions of the work activities that should be considered in determining whether a particular case involves work restriction. The final rule's concept of restricted work is based both on the type of work activities the injured or ill worker is able to perform and the length of time the employee is able to perform these activities. The term "routine functions of the job" in paragraphs 1904.7(b)(4)(i) and (b)(4)(ii) clarifies that OSHA considers an employee who is unable, because of a work-related injury or illness, to perform the job activities he or she usually performs to be restricted in the work he or she may perform. Use of the term "routine functions of the job" should eliminate the concern of some commenters who read the proposed definition as meaning that an employee had to be able to perform every possible work activity, including those that are highly unusual or performed only very rarely, in order for the employer to avoid recording the case as a restricted work case (see, *e.g.*, Exs. 15: 80, 247). In other words, OSHA agrees that it makes little sense to consider an employee who is prevented by an injury or illness from performing a particular job function he or she never or rarely performed to be restricted (see, *e.g.*, Exs. 15: 80, 247). For example, OSHA finds that, for the purposes of recordkeeping, an activity that is performed only once per month is not performed "regularly." This approach is consistent with OSHA interpretations under the former rule. Limiting the definition to "essential functions," the ADA term recommended by several commenters (see, *e.g.*, Exs. 15: 127, 136, 137, 141, 224, 266, 278, 431), would be inappropriate, because OSHA needs information on all restricted work cases, not just those that interfere with the essential functions of the job (29 U.S.C. 657(c)(2)).

On the other hand, OSHA agrees with those commenters who argued that the proposed definition, to limit the definition of restricted activity to the specific functions or tasks the employee was engaged in on the day of injury or onset of illness would be unsatisfactory, because doing so could fail to capture activities that an employee regularly performs (see, *e.g.*, Exs. 20; 15: 17, 129, 380, 418). In the final rule, OSHA has decided that defining restricted work as work that an employee would regularly have performed at least once per week is appropriate, i.e., OSHA believes that the range of activities captured by this interval of time will generally reflect the range of an employee's usual work activities. Activities performed less frequently than once per week reflect more uncommon work activities that are not considered routine duties for the purposes of this rule. However, the final rule does not rely on the duties the employee actually performed during the week when he or she was injured or became ill. Thus, even if an employee did not perform the activity within the last week, but usually performs the activity once a week, the activity will be included. OSHA believes that this change in definition will foster greater acceptance of the concept of restricted work among employers and employees because of its common sense approach.

Use of the term "partial work shift" in paragraph 1904.7(b)(4)(v) covers restrictions on the amount of time an employee is permitted to work because of the injury or illness. This interpretation of restricted work was not generally disputed by commenters, although some argued that the restriction on the hours worked should last for a specific number of days before the case becomes recordable as a restricted work case (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391).

The final rule's restricted work provisions also clarify that work restriction must be imposed by the employer or be recommended by a health care professional before the case is recordable. Only the employer has the ultimate authority to restrict an employee's work, so the definition is clear that, although a health care professional may recommend the restriction, the employer makes the final determination of whether or not the health care professional's recommended restriction involves the employee's routine functions. Restricted work assignments may involve several steps: an HCP's recommendation, or employer's determination to restrict the employee's work, the employers analysis of jobs to determine whether a suitable job is available, and assignment of the employee to that job. All such restricted work cases are recordable, even if the health care professional allows some discretion in defining the type or duration of the restriction, an occurrence noted by one commenter (Ex. 15:442). However, the final rule's provisions make it clear that the employee is not the person making the determination about being placed on restricted work, as one commenter (Ex. 15: 97) feared.

A number of commenters suggested that OSHA cease to require the recording of restricted work cases entirely (see, *e.g.*, Exs. 15: 119, 427). However, the Congress has directed that the recordkeeping system capture data on non-minor work-related injuries and illnesses and specifically on restricted work cases, both so that the national statistics on such injuries and illnesses will be complete and so that links between the causes and contributing factors to such injuries and illnesses will be identified (29 U.S.C. 651(b)). Days away and restricted work/job transfer cases together constitute two of the most important kinds of job-related injuries and illnesses, and it would be inappropriate not to record these serious cases. OSHA also cannot narrow the definition of restricted work to those cases where the employee is at work but cannot do productive work, as several commenters suggested (see, *e.g.*, Exs. 15: 9, 45, 46, 89, 437), because the Congress clearly intended that workers whose work-related injuries and illnesses were so severe as to prevent them from doing their former work or from working for a full shift had experienced an injury or illness that was non-minor and thus worthy of being recorded. OSHA does not believe that requiring employers to record such injuries and illnesses as restricted work cases will in any way discourage the use of restricted work or return-to-work programs, and the marked shift in the number of restricted work cases reported to the BLS in the last few years bears this out. It would also not be appropriate for OSHA to require that employers only record as restricted work cases those cases in which the injured or ill worker requires medical treatment *and* is placed on restricted work, as some commenters suggested (see, *e.g.*, Exs. 15: 9, 348). The OSH Act clearly requires the recording of all work-related cases that require either medical treatment or restricted work.

Under the final rule, employers are not required to record a case as a restricted work case if the restriction is imposed on the employee only for the day of the injury or onset of illness. OSHA thus agrees with a number of commenters (see, *e.g.*, Exs. 15: 19, 44, 146, 154, 156, 198, 364, 374, 391) that restricted activity only on the day the injury occurred or the illness began does not justify recording. This represents a change in the treatment of restricted work cases from OSHA's practice under the former rule. OSHA has made this change to bring the recording of restricted work cases into line with that for days away cases: under the final rule, employers are not required to record as days away or restricted work cases those injuries and illnesses that result in time away or time on restriction or job transfer lasting only for the day of injury of illness onset.

Several commenters recommended that cases involving medical removal under the lead or cadmium standards or cases involving "voluntary" preventive actions, such as cases involving job transfer or restricted work activity, not be considered recordable under the final rule; these participants argued that requiring employers to record voluntary transfers or removals would create a disincentive for employers to take these protective actions (see, *e.g.*, Exs. 25, 15: 69, 156, 358, 406). Under the final rule (see section 1904.9), mandated removals made in accordance with an OSHA health standard must be recorded either as days away from work or as days of restricted work activity, depending on the specific action an employer takes. Since these actions are mandated, no disincentive to record is created by this recordkeeping rule.

Some commenters, however, urged OSHA to make an exception from the recording requirements for cases where the employer voluntarily, or for preventive purposes, temporarily transfers an employee to another job or restricts an employee's work activities. OSHA does not believe that this concept is relevant to the recordkeeping rule, for the following reasons. Transfers or restrictions taken *before* the employee has experienced an injury or illness do not meet the first recording requirement of the recordkeeping rule, i.e., that a work-related injury or illness must have occurred for recording to be considered at all. A truly preventive medical treatment, for example, would be a tetanus vaccination administered routinely to an outdoor worker. However, transfers or restrictions whose purpose is to allow an employee to recover from an injury or illness as well as to keep the injury or illness from becoming worse are recordable because they involve restriction or work transfer caused by the injury or illness. All restricted work cases and job transfer cases that result from an injury or illness that is work-related are recordable on the employer's Log.

As the regulatory text for paragraph (b)(4) makes clear, the final rule's requirements for the recording of restricted work cases are similar in many ways to those pertaining to restricted work under the former rule. First, like the former rule, the final rule only requires employers to record as restricted work cases those cases in which restrictions are imposed or recommended as a result of a work-related injury or illness. A work restriction that is made for another reason, such as to meet reduced production demands, is not a recordable restricted work case. For example, an employer might "restrict" employees from entering the area in which a toxic chemical spill has occurred or make an accommodation for an employee who is disabled as a result of a non-work-related injury or illness. These cases would not be recordable as restricted work cases because they are not associated with a work-related injury or illness. However, if an employee has a work-related injury or illness, and that employee's work is restricted by the employer to prevent exacerbation of, or to allow recuperation from, that injury or illness, the case is recordable as a restricted work case because the restriction was necessitated by the work-related injury or illness. In some cases, there may be more than one reason for imposing or recommending a work restriction, *e.g.*, to prevent an injury or illness from becoming worse or to prevent entry into a contaminated area. In such cases, if the employee's work-related illness or injury played *any* role in the restriction, OSHA considers the case to be a restricted work case.

Second, for the definition of restricted work to apply, the work restriction must be decided on by the employer, based on his or her best judgment or on the recommendation of a physician or other licensed health care professional. If a work restriction is not followed or implemented by the employee, the injury or illness must nevertheless be recorded on the Log as a restricted case. This was also the case under the former rule.

Third, like the former rule, the final rule's definition of restricted work relies on two components: whether the employee is able to perform the duties of his or her pre-injury job, and whether the employee is able to perform those duties for the same period of time as before.

The principal differences between the final and former rules' concept of restricted work cases are these: (1) the final rule permits employers to cap the total number of restricted work days for a particular case at 180 days, while the former rule required all restricted days for a given case to be recorded; (2) the final rule does not require employers to count the restriction of an employee's duties on the day the injury occurred or the illness began as restricted work, providing that the day the incident occurred is the only day on which work is restricted; and (3) the final rule defines work as restricted if the injured or ill employee is restricted from performing any job activity the employee would have regularly performed at least once per week before the injury or illness, while the former rule counted work as restricted if the employee was restricted in performing any activity he or she would have performed at least once per year.

In all other respects, the final rule continues to treat restricted work and job transfer cases in the same manner as they were treated under the former rule, including the counting of restricted days. Paragraph 1904.7(b)(4)(xi) requires the employer to count restricted days using the same rules as those for counting days away from work, using § 1904.7(b)(3)(i) to (viii), with one exception. Like the former rule, the final rule allows the employer to stop counting restricted days if the employee's job has been permanently modified in a manner that eliminates the routine functions the employee has been restricted from performing. Examples of permanent modifications would include reassigning an employee with a respiratory allergy to a job where such allergens are not present, or adding a mechanical assist to a job that formerly required manual lifting. To make it clear that employers may stop

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counting restricted days when a job has been permanently changed, but not to eliminate the count of restricted work altogether, the rule makes it clear that at least one restricted workday must be counted, even if the restriction is imposed immediately. A discussion of the desirability of counting days of restricted work and job transfer at all is included in the explanation for the OSHA 300 form and the § 1904.29 requirements. The revisions to this category of cases that have been made in the final rule reflect the views of commenters, suggestions made by the Keystone report (Ex. 5), and OSHA's experience in enforcing the former recordkeeping rule.

Paragraph 1904.7(b)(5) Medical Treatment Beyond First Aid

The definitions of first aid and medical treatment have been central to the OSHA recordkeeping scheme since 1971, when the Agency's first recordkeeping rule was issued. Sections 8(c)(2) and 24(a) of the OSH Act specifically require employers to record all injuries and illnesses other than those "requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job." Many injuries and illnesses sustained at work do not result in death, loss of consciousness, days away from work or restricted work or job transfer. Accordingly, the first aid and medical treatment criteria may be the criteria most frequently evaluated by employers when deciding whether a given work-related injury must be recorded.

In the past, OSHA has not interpreted the distinction made by the Act between minor (i.e., first aid only) injuries and non-minor injuries as applying to occupational illnesses, and employers have therefore been required to record all occupational illnesses, regardless of severity. As a result of this final rule, OSHA will now apply the same recordability criteria to both injuries and illnesses (see the discussion of this issue in the Legal Authority section of this preamble). The Agency believes that doing so will simplify the decision-making process that employers carry out when determining which work-related injuries and illnesses to record and will also result in more complete data on occupational illness, because employers will know that they must record these cases when they result in medical treatment beyond first aid, regardless of whether or not a physician or other licensed health care professional has made a diagnosis.

The former recordkeeping rule defined first aid as "any one-time treatment and any follow-up visit for the purpose of observation, of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care." Medical treatment was formerly defined as "treatment administered by a physician or by registered professional personnel under the standing orders of a physician."

To help employers determine the recordability of a given injury, the *Recordkeeping Guidelines*, issued by the Bureau of Labor Statistics (BLS) in 1986, provided numerous examples of medical treatments and of first aid treatments (Ex. 2). These examples were published as mutually exclusive lists, i.e., a treatment listed as a medical treatment did not also appear on the first-aid list. Thus, for example, a positive x-ray diagnosis (fractures, broken bones, etc.) was included among the treatments generally considered medical treatment, while a negative x-ray diagnosis (showing no fractures) was generally considered first aid. Despite the guidance provided by the *Guidelines*, OSHA continued to receive requests from employers for interpretations of the recordability of specific cases, and a large number of letters of interpretation addressing the distinction between first aid and medical treatment have been issued. The following sections discuss the definitions of medical treatment and first aid proposed by OSHA, the comments received in response to the proposal, and the definition of medical treatment that OSHA has decided to include in the final rule.

In the proposed rule, OSHA presented a simplified approach: to define as first aid anything on a list of first aid treatments, and to define as medical treatment any treatment not on that list. Specifically, medical treatment was defined as "any medical cure or treatment beyond first aid" (61 FR 4059).

The proposal contained a comprehensive list of all treatments that would be considered "first aid" regardless of the provider:

(1) Visit(s) to a health care provider limited to observation

(2) Diagnostic procedures, including the use of prescription medications solely for diagnostic purposes (*e.g.* eye drops to dilate pupils)

(3) Use of nonprescription medications, including antiseptics

(4) Simple administration of oxygen

(5) Administration of tetanus or diphtheria shot(s) or booster(s)

(6) Cleaning, flushing or soaking wounds on skin surface

(7) Use of wound coverings such as bandages, gauze pads, etc.

(8) Use of any hot/cold therapy (*e.g.* compresses, soaking, whirlpools, non-prescription skin creams/lotions for local relief, etc.) except for musculoskeletal disorders (see Mandatory Appendix B to Part 1904)

(9) Use of any totally non-rigid, non-immobilizing means of support (*e.g.* elastic bandages)

(10) Drilling of a nail to relieve pressure for subungual hematoma

(11) Use of eye patches

(12) Removal of foreign bodies not embedded in the eye if only irrigation or removal with a cotton swab is required

(13) Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or other simple means (61 FR 4059)

OSHA also solicited comment on three specific definitional questions:

(A) Should any treatments on the proposed first aid list be excluded and should any treatments be added?

(B) Should a list of medical treatments also be provided? Which treatments?

(C) Should simple administration of oxygen be defined to exclude more severe procedures such as Intermittent Positive Pressure Breathing (IPPB)? If so, how?

OSHA received many comments on the general approach taken in the proposal, i.e., that employers rely on a comprehensive list of first aid treatment and define any treatment not on that list as medical treatment. The Agency also received many comments on the individual items on the proposed first aid list. The following discussion addresses comments on the general approach adopted in the final rule and then deals with comments on specific items and OSHA's responses to each issue.

A large number of commenters agreed with OSHA's proposal to rely on a finite list of treatments considered first aid and to consider all other treatments medical treatment (see, *e.g.*, Exs. 15: 9, 13, 26, 27, 74, 76, 87, 95, 122, 127, 156, 163, 185, 188, 199, 204, 218, 242, 263, 269, 270, 283, 297, 324, 332, 338, 347, 357, 359, 377, 378, 385, 386, 387, 395, 397, 405, 407, 414, 434). Several commenters wanted no change to the proposal (see, *e.g.*, Exs. 15: 26, 76, 204, 385, 378), while others agreed with the general approach but stated that the first aid list should be more comprehensive (see, *e.g.*, Exs. 15: 199, 332, 338, 357, 386, 387).

Commenters supported the proposed approach for a variety of reasons. For example, some stated that a finite list would improve the clarity of the definition, reduce confusion for employers, and reduce inaccuracy in the data (see, *e.g.*, Exs. 15: 87, 95, 122, 127, 163, 185, 188, 395, 338, 242, 270, 269, 263, 347, 377, 386). The statement of the American Iron and Steel Institute exemplified these comments:

> Consistent with its statutory mandate, OSHA's proposal would also require the recording of all work-related injuries and illnesses that result in medical treatment beyond first aid. The expanded and finite list of treatments that constitute first aid would clarify the task of deciding what to record, because any treatment that does not appear on this list will be considered a medical treatment. (Ex. 15: 395)

The Ford Motor Company agreed, stating:

> Ford supports that the definition of first aid be modified to consist of a comprehensive list of treatments. Treatments not found on the first aid list would be considered medical treatment for recordkeeping purposes. Assuming that the list will be comprehensive, it will reduce confusion, lead to consistent recordkeeping, and greatly simplify the decision making process (Ex. 15: 347).

Some commenters stated that the proposed approach would be simpler for employers, generate more consistent records, and facilitate better comparisons of injury and illness data over time (see, *e.g.*, Exs. 15: 13, 122, 127, 242, 270, 269, 263, 283, 297, 347, 359, 377, 405, 407). According to the Southern Nuclear Operating Company: "Providing a comprehensive list of all first-aid treatments will remove the current ambiguity in deciding if a case involves first aid only or if it is medical treatment. This should provide more consistent recordkeeping and allow for more meaningful comparisons of accident histories" (Ex. 15: 242, p. 2).

A number of commenters, however, disagreed that defining first aid by listing first aid treatments was appropriate (see, *e.g.*, Exs. 15: 18, 63, 83, 87, 96, 119, 123, 129, 145, 159, 171, 173, 176, 182, 201, 225, 229, 247, 260, 262, 265, 272, 281, 303, 307, 308, 335, 337, 338, 341, 348, 349, 357, 364, 375, 380, 382, 389, 396, 401, 413, 418, 430, 434). Several of these commenters argued that it would not be possible to list every first aid treatment (see, *e.g.*, Exs. 15: 225, 335, 337, 396, 430). Some commenters stated that the proposed approach would not provide sufficient clarity, would involve a definition of medical treatment that was overly vague, and would not be helpful to employers without additional definitions (see, *e.g.*, Exs. 15: 159, 171, 176, 229, 281, 348, 357, 396). Another group of commenters stated that the approach did not provide flexibility to adapt to changing medical practice, and would not be capable of responding to changes in technology (see, *e.g.*, Exs. 15: 18, 63, 96, 335, 348). The comments of the Dow Chemical Corporation are representative of these views:

> Dow believes that OSHA should provide non-exhaustive lists for both first aid and medical treatment, rather than defining one solely by the exclusion of the other. Dow believes this suggested approach is necessary to take into account that these lists cannot be comprehensive or all-inclusive as it is impossible to list every possible contingency. Moreover, technology is constantly changing and cannot be accounted for in a static list. For example, one can now obtain Steri-Strips over the counter where previously it would have been considered "medical treatment." Since exhaustive lists do not allow the flexibility to take these technologies into account nor capture every possible situation, much would still be left to supposition. By providing an illustrative list for both first aid and medical treatment, OSHA would be giving adequate guidance for the regulated community. Dow recommends OSHA make this modification in the final rule. (Ex. 15: 335)

A number of commenters urged OSHA to use the definition of medical treatment as a way to focus primarily on the seriousness of the injury or illness (see, *e.g.*, Exs. 15: 147, 201, 308, 341, 375, 395, 418). For example, the American Petroleum Institute remarked "* * * the fundamental issue is the seriousness of the injury or illness, not the treatment" (Ex. 375–A, p. 7). The Caterpillar Corporation provided lengthy comments on the definition of medical treatment, including the following criticism of the proposed approach:

> Insignificant injuries for which medical treatment is provided do not provide valuable information for safety and health analysis. This proposal attempts to oversimplify the recordkeeping process which will result in many insignificant injuries and illnesses being recorded because of the unnecessarily restrictive definitions for first aid and medical treatment. The definition and listing of first aid cannot be a comprehensive or exclusive listing and definition. Medical treatment may be provided for insignificant injuries and significant injuries may receive little or no medical treatment. The medical treatment process and options are too complicated to be adequately described by one list which makes the treatments mutually exclusive. OSHA should continue the current practice with lists for both first aid and medical treatment. Further, the treatments cannot be mutually exclusive since treatment does not necessarily recognize the severity of the injury or illness (Ex. 15: 201, p. 4).

Some commenters who disagreed with the proposed approach provided suggestions and alternative definitions. A number of commenters suggested that OSHA keep its former definitions of first aid and medical treatment (see, *e.g.*, Exs. 15: 83, 119, 123, 129, 145, 225, 337, 380, 389, 418, 430). Several commenters urged OSHA to update the former rule's definitions using the proposed rule's listing of first aid treatments (see, *e.g.*, Exs. 15: 83, 380, 418). Other commenters urged OSHA not to change the definition in any way because it would produce a break in the historical series of occupational injury and illness data (see, *e.g.*, Exs. 15: 123, 145, 389).

Several commenters made suggestions that they believed would introduce flexibility into the proposed rule's first aid definition. The National Restaurant Association suggested that OSHA add a "catchall" category to the list to include "any similar type of treatment" (Ex. 15: 96, p. 5). The General Electric Company urged that the following language be added: "Other treatments may be considered first aid so long as they are recognized as first aid actions and [are] not listed in the definition of medical treatment" (Ex. 15: 349, p. 8). Some commenters suggested allowing the health care professional to determine whether the activity was properly classified as first aid or medical treatment (see, *e.g.*, Exs. 27; 15: 131, 173, 176, 201, 334, 382, 392, 434). A typical comment along these lines was one from the American Forest and Paper Association, which stated that "* * * we believe a qualified health care professional should have the authority to determine what is properly characterized as first aid and what should be properly characterized as medical treatment" (Ex. 15:334, p. 7). Two commenters suggested that the health care professional be allowed to decide whether an action constituted first aid or medical treatment only if the treatment was not on either the first aid or medical treatment lists (see, *e.g.*, Exs. 27; 15: 382, 392, 434).

One commenter, the American Network of Community Options and Resources, supported the development of a finite first aid list, but suggested that OSHA define medical treatment as "any treatment that requires professional medical intervention" (Ex. 15: 393, p. 8).

A number of commenters agreed with OSHA that the first aid definition should focus on the type of treatment given, and not on the provider (see, *e.g.*, Exs. 15: 185, 308, 338, 349, 364, 443). Other comments argued that a distinction between first aid and medical treatment could be made on the basis of the number of times a particular treatment had been given. The AFL–CIO expressed a concern that, absent some

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consideration of the number of times a treatment was administered, many serious injuries and illnesses would no longer be recordable and valuable data would be lost. The AFL–CIO stated that longer term treatments are more likely than shorter ones to be indicative of medical treatment:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. Those conditions which require continued treatments, including continued use of non-prescription drugs and repeated cleaning, flushing or soaking of wounds would no longer be recordable. The AFL–CIO believes that first aid should be limited to one time treatments as is the current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid. (Ex. 15: 418).

Similarly, the TIMEC group of companies believed that any one-time treatment should be considered first aid, saying:

> It is also TIMEC's perspective that the exclusion of a "one time medical treatment" provision from the list of first aids is unduly restrictive. Any condition that can be resolved or treated in one visit to the doctor should be considered minimal or negligible in the context of record keeping for industrial injuries. Under the proposed regulation, a condition that results in a one time medical treatment theoretically could be given the same weight, in terms of OSHA recordability, as a broken or severed limb. This seems unduly restrictive. Further, it may inhibit some employers from taking injured employees to the doctor in the first instance, in order to avoid a "OSHA recordable injury." An employer may otherwise hope that the matter will heal itself without infection. This seems contrary to the goal of the Occupational Safety and Health Act, to ensure appropriate and prompt medical treatment and safety services to employees (Ex. 15: 18, p. 2).

In response to these comments and the evidence in the record of this rulemaking, the final rule essentially continues the proposed approach, i.e., it includes a list of first-aid treatments that is inclusive, and defines as medical treatment any treatment not on that list. OSHA recognizes, as several commenters pointed out, that no one can predict how medical care will change in the future. However, using a finite list of first aid treatments—knowing that it may have to be amended later based on new information—helps to limit the need for individual judgment about what constitutes first aid treatment. If OSHA adopted a more open-ended definition or one that relied on the judgment of a health care professional, employers and health care professionals would inevitably interpret different cases differently, which would compromise the consistency of the data. Under the system adopted in the final rule, once the employer has decided that a particular response to a work-related illness or injury is in fact treatment, he or she can simply turn to the first aid list to determine, without elaborate analysis, whether the treatment is first aid and thus not recordable. OSHA finds that this simple approach, by providing clear, unambiguous guidance, will reduce confusion for employers and improve the accuracy and consistency of the data.

The need for clear and unambiguous guidance is also OSHA's reason for not considering treatments from the first aid list to be medical treatment if carried out for a lengthier time, as suggested by the AFL–CIO. If an injured or ill employee is given first-aid treatment, such as non-prescription medications (at non-prescription strength), hot or cold therapy, massage therapy, or some other treatment on the first aid list, the treatment should not be considered medical treatment for OSHA recordkeeping purposes, regardless of the length of time or number of applications used. This approach will ensure that the recordkeeping system excludes truly minor injuries and illnesses, and capture the more serious cases that require treatment beyond first aid.

In the final rule, OSHA has adopted the approach taken in the proposal, in a slightly modified form. Under the final rule, employers will be able to rely on a single list of 14 first aid treatments. These treatments will be considered first aid whether they are provided by a lay person or a licensed health care professional. However, the final rule includes the following definition of medical treatment; "management and care of a patient for the purpose of combating disease or disorder;" this definition excludes observation and counseling, diagnostic procedures, and the listed first aid items. OSHA believes that providing a definition of medical treatment for recordkeeping purposes will help employers who are uncertain about what constitutes medical treatment. OSHA will also provide examples of medical treatments covered by this definition in compliance assistance documents designed to help smaller businesses comply with the rule. The following discussion describes the definitions of first aid and medical treatment in the final rule and explains the Agency's reasons for including each item on the first aid list.

Final Rule

The final rule, at § 1904.7(b)(5)(i), defines medical treatment as the management and care of a patient for the purpose of combating disease or disorder. For the purposes of Part 1904, medical treatment does not include:

(A) Visits to a physician or other licensed health care professional solely for observation or counseling;

(B) The conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or

(C) "first aid" as defined in paragraph (b)(5)(ii) of this section.

The final rule, at paragraph (b)(5)(ii), defines first aid as follows:

(A) Using a nonprescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes).

(B) administering tetanus immunizations (other immunizations, such as hepatitis B vaccine or rabies vaccine, are considered medical treatment).

(C) Cleaning, flushing or soaking wounds on the surface of the skin;

(D) Using wound coverings, such as bandages, Band-Aids®, gauze pads, etc.; or using butterfly bandages or Steri-Strips® (other wound closing devices, such as sutures, staples, etc. are considered medical treatment);

(E) Using hot or cold therapy;

(F) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);

(G) Using temporary immobilization devices while transporting an accident victim (*e.g.* splints, slings, neck collars, back boards, etc.)

(H) Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;

(I) Using eye patches;

(J) Removing foreign bodies from the eye using only irrigation or a cotton swab;

(K) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs, or other simple means;

(L) Using finger guards;

(M) Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes);

(N) Drinking fluids for relief of heat stress.

This list of first aid treatments is comprehensive, i.e., any treatment not included on this list is not considered first aid for OSHA recordkeeping purposes. OSHA considers the listed treatments to be first aid regardless of the professional qualifications of the person providing the treatment; even when these treatments are provided by a physician, nurse, or other health care professional, they are considered first aid for recordkeeping purposes.

The definition of medical treatment in the final rule differs both from the definition used in the former rule ("treatment administered by a physician or by registered professional personnel under the standing orders of a physician") and the proposed definition ("medical treatment includes any medical care or treatment beyond first aid"). The medical treatment definition in the final rule is taken from *Dorland's Illustrated Medical Dictionary*, and is thus consistent with usage in the medical community.

The three listed exclusions from the definition—visits to a health care professional solely for observation or counseling; diagnostic procedures, including prescribing or administering of prescription medications used solely for diagnostic purposes; and procedures defined in the final rule as first aid—clarify the applicability of the definition and are designed to help employers in their determinations of recordability.

OSHA received several comments on the proposed definition of medical treatment. These dealt primarily with the general approach OSHA was proposing, i.e., the use of an all-inclusive list of first aid applications, and defining any treatment not on the list as medical treatment. The remaining comments (see, *e.g.*, Exs. 15: 87, 171, 173, 176, 182, 229, 247, 260, 262, 265, 272, 303, 307, 357, 338, 375, 382, 396, 401, 413) urged OSHA to develop an all-inclusive list of medical treatments, to provide examples of some medical treatments, or to provide a non-mandatory appendix with such examples.

OSHA has not adopted the suggestions made by these commenters because the Agency finds that simplicity and clarity are best served by adopting a single, all-inclusive first aid list and explicitly stating that any treatment not on the list is considered, for recordkeeping purposes, to be medical treatment. Employers will thus be clear that any condition that is treated, or that should have been treated, with a treatment not on the first aid list is a recordable injury or illness for recordkeeping purposes.

This simplified approach addresses the concerns expressed by several commenters, who emphasized that the distinction between first aid and medical treatment made in the Act was meant to ensure that all occupational injuries and illnesses that were other than minor be captured by OSHA's recordkeeping system but that minor conditions not be recorded (see, *e.g.*, Exs. 15–308, 375A, p. 7). As the American Petroleum Institute commented (Ex. 375A), "* * * the fundamental issue is the seriousness of the injury or illness, not the treatment." OSHA concludes, based on its review of the record, that the final rule's definitions of medical treatment and first aid will work together to achieve Congress's intent, as specified in sections 8 and 24 of the Act.

In making its decisions about the items to be included on the list of first aid treatments, OSHA relied on its experience with the former rule, the advice of the Agency's occupational medicine and occupational nursing staff, and a thorough review of the record comments. In general, first aid treatment can be distinguished from medical treatment as follows:

- First aid is usually administered after the injury or illness occurs and at the location (*e.g.*, workplace) where the injury or illness occurred.
- First aid generally consists of one-time or short-term treatment.
- First aid treatments are usually simple and require little or no technology.
- First aid can be administered by people with little training (beyond first aid training) and even by the injured or ill person.
- First aid is usually administered to keep the condition from worsening, while the injured or ill person is awaiting medical treatment.

The final rule's list of treatments considered first aid is based on the record of the rulemaking, OSHA's experience in implementing the recordkeeping rule since 1986, a review of the BLS *Recordkeeping Guidelines*, letters of interpretation, and the professional judgment of the Agency's occupational physicians and nurses.

Specific Items on the Proposed First Aid List in the NPRM

Item 1 listed in the NPRM definition of first aid was "Visit(s) to a health care provider limited to observation." Two commenters raised the issue of counseling with regard to the recording of mental disorders (Exs. 15: 226, 395). The American Ambulance Association (AAA) stated that: "This is and should be considered preventive treatment aimed at preventing stress-related illnesses. OSHA's adoption of such a policy will allow and encourage employers to provide CISD (critical incident stress debriefing) counseling" (Ex. 15: 226, p. 3). The AAA recommended that OSHA add preventive counseling, such as critical incident stress debriefing, to the first aid listing.

OSHA agrees that counseling should not be considered medical treatment and has expressly excluded it from the definition of medical treatment. Counseling is often provided to large groups of workers who have been exposed to potentially traumatic events. Counseling may be provided on a short-term basis by either a licensed health care professional or an unlicensed person with limited training. OSHA believes that capturing cases where counseling was the only treatment provided do not rise to the level of recording; other counseling cases, where prescription medications, days away from work, or restricted work activity is involved, would be captured under those criteria.

The Brookhaven National Laboratory recommended that the first aid list include any return visit to evaluate diagnostic decisions (Ex. 15: 163). Caterpillar, Inc. suggested that visits for observation, testing or diagnosis of injuries should also be considered first aid (Ex. 15: 201). The Chemical Manufacturers Association and Marathon Oil Company encouraged OSHA to add visits to the hospital for observation to the first-aid list (Exs. 15: 308, 310)

OSHA generally agrees with these commenters. OSHA believes that visits to a health care professional for observation, testing, diagnosis, or to evaluate diagnostic decisions should be excluded from the definition of medical treatment in the final rule. Visits to a hospital, clinic, emergency room, physician's office or other facility for the purpose of seeking the advice of a health care professional do not themselves constitute treatment. OSHA believes that visits to a hospital for observation or counseling are not, of and by themselves, medical treatment. Accordingly, the final rule excludes these activities from the definition of medical treatment.

Item 2 listed in the NPRM definition of first aid was "Diagnostic procedures, including the use of prescription medications solely for diagnostic purposes (*e.g.* eye drops to dilate pupils)." Several commenters believed that diagnostic procedures such as x-rays and blood tests should not be considered medical treatment (see, *e.g.*, Exs. 15: 176, 301, 347, 349, 375, 443). For example, General Electric (GE) stated "Diagnostic tests should not be considered medical treatment.

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Considering a diagnostic test to be a recordable injury without consideration of the test results is illogical and will establish a disincentive to test. GE's position is that a definition of medical treatment should also be included in the proposed regulation. Proposed wording is as follows: "Medical treatment" includes any medical care or treatment beyond "first aid" and does not include diagnostic procedures."

Two commenters opposed the exclusion of diagnostic procedures. The National Institute for Occupational Safety and Health (NIOSH) said "the term diagnostic procedures" in item #2 is too broad, and the example given is vague. These procedures should not be considered first aid" (Ex. 15: 407, p. 17). The United Steelworkers of America stated " * * * delete the use of prescription drugs for diagnostic purposes. This will be abused by the company" (Ex. 15: 429).

OSHA disagrees with NIOSH that the exclusion for diagnostic procedures is overly vague. It is the experience of the Agency that employers generally understand the difference between procedures used to combat an injury or illness and those used to diagnose or assess an injury or illness. In the event that the employer does not have this knowledge, he or she may contact the health care professional to obtain help with this decision. If the employer does not have this knowledge, and elects not to contact the health care professional, OSHA would expect the employer to refer to the first aid list and, if the procedure is not on the list, to presume that the procedure is medical treatment and record the case. OSHA also does not believe that this provision will be subject to abuse, because the procedures used for diagnosis are generally quite different from those involving treatment.

OSHA agrees with those commenters who recommended the exclusion of diagnostic procedures from the definition of medical treatment. Diagnostic procedures are used to determine whether or not an injury or illness exists, and do not encompass therapeutic treatment of the patient. OSHA has included such procedures on the first aid list in the final rule with two examples of diagnostic procedures to help reduce confusion about the types of procedures that are excluded.

Item 3 listed in the NPRM definition of first aid was "Use of nonprescription medications, including antiseptics." This issue received a large number of comments, more than any other issue related to the proposed definition of medical treatment and first aid. Most of the comments requested that OSHA consider some uses of prescription drugs to be first aid treatment (see, *e.g.*, Exs. 15: 13, 60, 147, 159, 201, 218, 225, 246, 247, 297, 308, 332, 335, 336, 348, 349, 359, 374, 375, 386, 387, 395, 405, 414, 430, 434). The most common reason given by commenters for treating some prescription drugs as first aid was their use when they were given for preventive rather than therapeutic intervention. Several commenters asked for a broad exception from medical treatment for prescription drugs taken for preventive or prophylactic purposes (see, *e.g.*, Exs. 55X 15: 247, 336, 375, 395). For example, the American Iron and Steel Institute stated "AISI encourages OSHA to make one change: add the use of prescription medications for prophylactic reasons to the first aid list. In many instances, a health care professional will prescribe antibiotics as a precaution against a possible infection. An employer should not be required to record a minor injury solely because a health care professional opted to respond aggressively" (Exs. 15: 395; 55X).

Several commenters asked for an exception from the medical treatment for antibiotics and antiseptics (see, *e.g.*, Exs. 15: 218, 246, 332, 349, 375, 395, 414, 430). Raytheon Constructors, Inc. commented: "We believe the following treatments should be added [to the first aid list]: Application of antiseptics, as often as needed. This is for prevention of infection after an injury. Infection is not caused by the work environment. Treatment for an infection, such as prescription drugs. Again, infection is not the result of the work environment" (Ex. 15: 414).

A number of employers asked OSHA to define the use of prescription drugs for comfort, or to relieve pain or inflammation, as first aid (see, *e.g.*, Exs. 15: 60, 147, 201, 225, 247, 308, 348, 349). The American Gas Association stated that: we propose that 'prescription medications for comfort' be added to the list. Medical practitioners frequently "prescribe drugs to comfort people after an injury" (Ex. 15: 225), and the Proctor and Gamble Company stated "[p]rescription medication to prevent complications or reduce pain should not be a sole basis for recording injuries and illnesses. It is our view that preventive measures or action taken to reduce pain should not in themselves be the basis for recording" (Ex. 15: 147). Entergy Services Inc. suggested that OSHA include Benadryl shots as first aid since they are often given to prevent allergic reactions to insect bites and poison oak/ivy/sumac (Ex. 15: 13). The Arizona Public Service Company remarked: "Treatment for bee stings should be addressed (perhaps listed on the First Aid list). For instance, if a doctor administers the same treatment that an employee could have administered themselves it should not be considered medical treatment" (Ex. 15: 247).

Another set of comments suggested that prescription medications should be considered first aid if they were used only once or for a limited period of time. A number of comments requested that OSHA continue to treat a single dose of prescription medication as first aid. (see, *e.g.*, Exs. 15: 201, 332, 348, 349, 359, 374, 386, 387, 405, 430, 434). Typical of these comments was one from the National Safety Council:

> [t]hat administration of a single dose of prescription medication on first visit for minor injury or discomfort remain first aid. For example, minor muscle aches and pains may occasionally be eased with a single dose of 800 mg ibuprofen. This is currently considered first aid and should remain so. Another example would be the treatment of first degree burns. This is currently considered first aid treatment, even though treatment frequently involves the application of a single dose of prescription-strength ointment. (Ex.15: 359, p. 12)

Other commenters suggested that prescription medications used for 24 hours, 48 hours, or five days be considered first aid (see, *e.g.*, Exs. 15: 159, 246, 297, 308, 335, 375).

In the final rule, OSHA has not included prescription medications, whether given once or over a longer period of time, in the list of first aid treatments. The Agency believes that the use of prescription medications is not first aid because prescription medications are powerful substances that can only be prescribed by a licensed health care professional, and for the majority of medications in the majority of states, by a licensed physician. The availability of these substances is carefully controlled and limited because they must be prescribed and administered by a highly trained and knowledgeable professional, can have detrimental side effects, and should not be self-administered.

Some commenters asked whether a case where a prescription was written by a physician and given to the injured or ill employee but was not actually filled or taken would be recordable. In some instances the employee, for religious or other reasons, refuses to fill the prescription and take the medicine. In other cases, the prescriptions are issued on a "take-as-needed" basis. In these cases, the health care professional gives the patient a prescription, often for pain medication, and tells the patient to fill and take the prescription if he or she needs pain relief. OSHA's long-standing policy has been that if a prescription of this type has been issued, medical treatment has been provided and the case must therefore be recorded. Numerous commenters asked OSHA to reverse or clarify its policy and consider these prescriptions to be first aid in the final rule (see, *e.g.*, Exs. 15: 13, 105, 247, 260, 262, 279, 281, 295, 300, 308, 359, 362, 386, 414). For example, the National Safety Council requested that "OSHA should specify whether the treatment must actually be given or merely be appropriate or normal for the injury or illness. For example, is medical treatment given when a prescription is written or when it is filled or when it is taken by the employee" (Ex. 15: 359).

OSHA has decided to retain its long-standing policy of requiring the recording of cases in which a health care professional issues a prescription, whether that prescription is filled or taken or not. The patient's acceptance or refusal of the treatment does not alter the fact that, in the health care professional's judgment, the case warrants medical treatment. In addition, a rule that relied on whether a prescription is filled or taken, rather than on whether the medicine was prescribed, would create administrative difficulties for employers, because such a rule would mean that the employer would have to investigate whether a given prescription had been filled or the medicine had actually been taken. Finally, many employers and employees might well consider an employer's inquiry about the filling of a prescription an invasion of the employee's privacy. For these reasons, the final rule continues OSHA's longstanding policy of considering the giving of a prescription medical treatment. It departs from former practice with regard to the administration of a single dose of a prescription medicine, however, because there is no medical reason for differentiating medical treatment from first aid on the basis of the number of doses involved. This is particularly well illustrated by the recent trend toward giving a single large dose of antibiotics instead of the more traditional pattern involving several smaller doses given over several days.

Yet another issue raised by commenters about medications involved the use of non-prescription medications at prescription strength. In recent years, many drugs have been made available both as prescription and "over-the-counter" medications, depending on the strength or dosage of the product. Some examples include various non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, and cortisone creams. OSHA's policy has been that if these drugs are used in the over-the-counter form they are first aid, but if they are used in prescription form, they are medical treatment. Some commenters stated that these drugs should always be considered first aid (see, *e.g.*, Exs. 15: 300, 308, 414). For example, Heritage Environmental Services, Inc. stated:

> While the proposed rule includes the use of non-prescription medications in the definition of first aid, it fails to address the use of prescription quantities of over-the-counter medications (i.e., Tylenol, Motrin). It has been Heritage's experience that the requirement of the current rule to record cases where physicians have prescribed over the counter medications has resulted in the inclusion of a broad range of minor cases, that in all other respects would not have been recordable. In working with occupational health care providers for many years, Heritage has found that frequently, physicians prescribe prescription quantities of over the counter medications for reasons other than the severity of the injury. Many physicians are unaware that the distribution of OTC medications in such a manner results in an OSHA recordable injury/illness." * * * Heritage strongly favors the inclusion of a statement within the definition of first aid that eliminates the need to record cases where the sole reason for the recording of the case is the administration of prescription quantities of over-the-counter medications. (Ex. 15: 300)

Other commenters stated that the use of nonprescription medications should be considered medical treatment if they are used at prescription strength (Ex. 15: 279) or that the continued use of non-prescription drugs, especially anti-inflammatory drugs, should be considered medical treatment (see, *e.g.*, Exs. 15: 362, 371, 380, 418). The Union of Needletrades, Industrial and Textile Employees (UNITE) stated that "the self-administration of medication, when used on a recurring basis, should trigger the recording of cases" (Ex. 15: 380), and the United Food and Commercial Workers Union, pointed out that "When the employee reports pain that has lasted for over a week, they are given over-the-counter medication for as long as they ask. These cases, which can go on for a month or longer, are never recorded" (Ex. 15: 371).

One commenter suggested that health care professionals might prescribe over-the-counter medications rather than prescription medications for economic reasons (Ex. 15: 279).

The final rule does not consider the prescribing of non-prescription medications, such as aspirin or over-the-counter skin creams, as medical treatment. However, if the drug is one that is available both in prescription and nonprescription strengths, such as ibuprofen, and is used or recommended for use by a physician or other licensed health care professional at prescription strength, the medical treatment criterion is met and the case must be recorded. There is no reason for one case to be recorded and another not to be recorded simply because one physician issued a prescription and another told the employee to use the same medication at prescription strength but to obtain it over the counter. Both cases received equal treatment and should be recorded equally. This relatively small change in the recordkeeping rule will improve the consistency and accuracy of the data on occupational injuries and illnesses and simplify the system as well.

Two commenters asked OSHA to add non-prescription ointments to item 3 on the first aid list (Exs. 15: 308, 443). The final rule simply lists non-prescription medications, and expects non-prescription medications to be included regardless of form. Therefore, non-prescription medicines at non-prescription strength, whether in ointment, cream, pill, liquid, spray, or any other form are considered first aid. OSHA has also removed antiseptics from the description of non-prescription medications. Following the same logic used for ointments, there is no need to list the variety of possible uses of non-prescription medications. Non-prescription medicines are first aid regardless of the way in which they are used.

Item 4 listed in the NPRM definition of first aid was "Simple administration of oxygen." Some commenters agreed with OSHA's proposal to define the giving of oxygen as first aid (see, *e.g.*, Exs. 15: 34, 74, 78, 201, 281, 378, 414).

Several commenters, however, asked OSHA to provide more guidance as to what qualified as the "simple" administration of oxygen (see, *e.g.*, Exs. 15: 13, 170, 188, 229, 260, 262, 265, 272, 303, 374, 401, 405), while others suggested alternatives that would make some uses of oxygen first aid and other uses medical treatment. The American Petroleum Institute recommended: "Simple oxygen administration is standard operating procedure for EMTs and should remain first aid. Oxygen therapy, if prescribed, should be considered medical treatment" (15: 375). A group of utilities said "Simple administration of oxygen should be defined to include the preventive aspects following an injury. This would include, for example, administration at the pre-hospital site or while in the emergency room or hospital for observation. Identifying oxygen administration in this manner would

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eliminate the need to identify which of the more advanced uses of oxygen should be considered as medical treatment" (see, *e.g.*, Exs. 15: 260, 262, 265, 401).

A number of commenters opposed the inclusion of oxygen as a first aid treatment (see, *e.g.*, Exs. 15: 9, 87, 156, 290, 350, 395, 415, 429). The American Red Cross stated:

> The simple administration of oxygen * * * is inappropriately considered first aid. Simple administration of oxygen is not so simple. If oxygen is administered to someone with chronic pulmonary disease (a medical condition not generally recognized by untrained individuals), the victim could die. Carbon dioxide build-up in the blood forces an individual with this condition to breathe; therefore, administration of oxygen would obstruct the involuntary breathing action, resulting in pulmonary arrest. Red Cross would argue that no administration of oxygen is "simple" (Ex. 15: 290).

The United Brotherhood of Carpenters Health & Safety Fund of North America (USC H&SF) remarked, "[w]e urge that OSHA remove the simple administration of oxygen from first aid treatment. This procedure requires considerable training above what is recognized as First Aid by either the Red Cross's or National Safety Council's First Aid training courses" (Ex. 15: 350). The Muscatine Iowa Chamber of Commerce Safety Committee added:

> We feel that oxygen administration, as a first aid treatment would extend beyond the intent of the standards. The training and equipment requirements for the delivery of oxygen are extensive and beyond the simple first aid kits. We believe that the delivery of even the most minimal amount of oxygen constitutes an advanced level of care to an employee. All oxygen administration should be considered as medical treatment, no matter how delivered or how much is used, for whatever the reason" (Ex. 15: 87, p. 4).

OSHA is persuaded by the views of the Red Cross and others, which point to the potential complexities and consequences of the administration of oxygen. Accordingly, the Agency has decided to remove the use of oxygen from the first aid list and to consider any use of oxygen medical treatment. Oxygen administration is a treatment that can only be provided by trained medical personnel, uses relatively complex technology, and is used to treat serious injuries and illnesses. The use of any artificial respiration technology, such as Intermittent Positive Pressure Breathing (IPPB), would also clearly be considered medical treatment under the final rule.

Item 5 listed in the NPRM definition of first aid was "administration of tetanus or diphtheria shot(s) or booster(s)." These treatments have been considered first aid by OSHA for some time when they are administered routinely, *i.e.*, in the absence of an injury or illness (see the Recordkeeping Guidelines (Ex. 2, p. 43)). Several commenters expressed their support for continuing to include tetanus and diphtheria shots and boosters as first aid (see, *e.g.*, Exs. 15: 197, 201, 218, 247, 302, 308, 348, 385, 386, 393). Bell Atlantic commented that "Bell Atlantic supports the proposed inclusion of tetanus/diphtheria shots on the first aid list. Such preventative actions should not be considered medical treatment" (Ex. 15: 218). One commenter, Countrymark Cooperative, Inc., agreed that tetanus shots or boosters should be considered first aid, but did not believe diphtheria shots or boosters should be (Ex. 15: 9).

Two commenters recommended that tetanus and diphtheria shots be considered medical treatment, whether or not they are administered in connection with a work-related injury or illness. The American Red Cross stated, "inappropriately considered * * * administration of diphtheria and tetanus shots or boosters cannot be performed without a prescription from a physician. The person administering the shots must also be cognizant of potential side effects, *i.e.*, anaphylactic shock, which can result from such an action, and be prepared to address them" (Ex. 15: 290). The International Brotherhood of Teamsters added "International Brotherhood of Teamsters encourages OSHA to discontinue tetanus and diphtheria booster shots as first aid. They should be considered medical treatment. They are usually administered both after exposure and before diagnosis. The International Brotherhood of Teamsters considers it similar to the prophylaxis medical treatment given after exposure to Hepatitis B Virus" (Ex. 15: 369).

A number of commenters recommended the addition to the first aid list of other immunizations, including gamma globulin; vaccines for hepatitis B, hepatitis C, and rabies; or other prophylactic immunizations (see, *e.g.*, Exs. 15: 197, 201, 218, 302, 308, 347, 348, 386). Caterpillar, Inc. recommended, "[c]learly exclude any immunizations and inoculations which are preventative in nature. Immunizations and inoculations are not usually provided in response to a specific injury or illness and should be excluded from OSHA records" (Ex. 15: 201).

In the final rule, tetanus immunizations are included as item B on the first aid list. These immunizations are often administered to a worker routinely to maintain the required level of immunity to the tetanus bacillus. These immunizations are thus based not on the severity of the injury but on the length of time since the worker has last been immunized.

The issue of whether or not immunizations and inoculations are first aid or medical treatment is irrelevant for recordkeeping purposes unless a work-related injury or illness has occurred. Immunizations and inoculations that are provided for public health or other purposes, where there is no work-related injury or illness, are not first aid or medical treatment, and do not in themselves make the case recordable. However, when inoculations such as gamma globulin, rabies, etc. are given to treat a specific injury or illness, or in response to workplace exposure, medical treatment has been rendered and the case must be recorded. The following example illustrates the distinction OSHA is making about inoculations and immunizations: if a health care worker is given a hepatitis B shot when he or she is first hired, the action is considered first aid and the case would not be recordable; on the other hand, if the same health care worker has been occupationally exposed to a splash of potentially contaminated blood and a hepatitis B shot is administered as prophylaxis, the shot constitutes medical treatment and the case is recordable.

Item 6 listed in the NPRM definition of first aid was "cleaning, flushing or soaking wounds on skin surface." OSHA received only one specific comment on this item. The American Federation of State, County, and Municipal Employees (AFSCME) commented: "Cleaning, flushing or soaking wounds on skin surfaces. This is the initial treatment for needle stick injuries. AFSCME requests that OSHA clarify its position that cleaning, flushing or soaking of sharps injuries is considered a medical treatment" (Ex. 15: 362).

The AFL–CIO disagreed with OSHA's proposed approach to skin surface wounds, based on the belief that valuable information about serious work-related injuries would be lost if the approach were adopted:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. Those conditions which require continued treatments, including continued use of non-prescription drugs and repeated cleaning, flushing or soaking of wounds would no longer be recordable. The AFL–CIO believes that first aid should be limited to one time treatments as is the current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid (Ex. 15: 418).

OSHA believes that cleaning, flushing or soaking of wounds on the skin surface is the initial emergency treatment for almost all surface wounds and that these procedures do not rise to the level of medical treatment. This relatively simple type of treatment does not require technology, training, or even a visit to a health care professional. More serious wounds will be captured as recordable cases because they will meet other recording criteria, such as prescription medications, sutures, restricted work, or days away from work. Therefore, OSHA has included cleaning, flushing or soaking of wounds on the skin surface as an item on the first aid list. As stated previously, OSHA does not believe that multiple applications of first aid should constitute medical treatment; it is the nature of the treatment, not how many times it is applied, that determines whether it is first aid or medical treatment.

Item 7 listed in the NPRM definition of first aid was "Use of wound coverings, such as bandages, gauze pads, etc." These treatments were considered first aid treatments by the *Recordkeeping Guidelines* (Ex. 2, p. 43). OSHA received no comments opposing the proposed definition of wound coverings as first aid. However, the issue of whether or not butterfly bandages and Steri-strips™ are first aid was raised. Steri-strips™ are a product of the 3M Company, which advertises them as a comfortable adhesive strip used to secure, close and support small cuts, wounds and surgical incisions. "Butterfly bandages" is a generic term used for similar adhesive strips designed for small wounds.

All of the commenters who raised the issue suggested that OSHA add Steri-strips and butterfly bandages to this first aid item (see, *e.g.*, Exs. 15: 45, 108, 163, 201, 247, 308, 332, 349, 387, 405). Some commenters believed that the use of Steri-strips™ and butterfly bandages should always be considered first aid (see, *e.g.*, Exs. 15: 45, 247, 332, 349, 387), while others believed they should be considered medical treatment only when used as a replacement for, or in lieu of, sutures (see, *e.g.*, Exs. 15: 108, 163, 201, 308, 405). The Westinghouse Electric Corporation stated, "Steri-strips should be added to the list of first-aid treatments, when determined by the attending medical provider that the Steri-strip™ was not applied in lieu of sutures. Often medical care providers use a Steri-strip™ rather than a bandage, even though the injury does not require closure of any type" (Ex. 15: 405).

These treatments were listed in the 1986 *Recordkeeping Guidelines* as medical treatment when applied "in lieu of sutures" (Ex. 2, p. 43). In the past, this provision in the *Guidelines* has been the subject of several letters of interpretation. For example, in a 1993 letter from Ms. Monica Verros, R.N., C.O.H.N, of the IBP company, Ms. Verros asked, "[a]re all applications of butterfly adhesive dressing(s) and Steri-strip(s) considered medical treatment?" OSHA's answer was simply "yes" (Ex. 70: 136).

OSHA agrees with the commenters who suggested that these devices be considered first aid treatment. They are included in item D of the first aid list. Steri strips and butterfly bandages are relatively simple and require little or no training to apply, and thus are appropriately considered first aid.

Two commenters also raised the issue of whether or not sutures or stitches should be considered first aid (Exs. 15: 229, 348). The National Pest Control Association (NPCA) stated:

> NPCA believes cuts requiring five or less external stitches should also be categorized as first aid as well unless the employee has to go back to the medical provider because of the cut or there are more than five external stitches. Some of the examples the agency has included in its list of first aid, such as drilling of a nail to relieve pressure for subungual hematoma and removal of splinters or foreign material from areas other than eyes by irrigation, tweezers, cotton, swabs or other simple means, seems to be comparable to cuts requiring a minimal amount of stitches. Therefore, we believe it should be added to the list (Ex. 15: 229, p. 4).

The Dupont Company suggested: "Expand the 'suture' category to say that any device used for closure for therapeutic reasons is an automatic MTC (medical treatment case). Leeway should be given for when a care provider gives 'unnecessary' treatment, for example, sutures for cosmetic reasons instead of for therapeutic closure, where the doctor provides the documentation" (Ex. 15: 348).

OSHA believes that including sutures or stitches in the first aid list would not be appropriate. Performing these procedures requires substantial medical training, and they are used only for more serious wounds and are generally considered to go beyond first aid. OSHA has also decided not to provide exclusions for first aid items based on their purpose or intent. If the medical professional decides stitches or sutures are necessary and proper for the given injury, they are medical treatment.

Because OSHA has decided not to include a list of medical treatments in the final rule, there is no need to articulate that the use of other wound closing devices, such as surgical staples, tapes, glues or other means are medical treatment. Because they are not included on the first aid list, they are by definition medical treatment.

Item 8 listed in the proposed definition of first aid was "[u]se of any hot/cold therapy (*e.g.* compresses, soaking, whirlpools, non prescription skin creams/lotions for local relief, etc.) except for musculoskeletal disorders" (61 FR 4059). *The Recordkeeping Guidelines* defined heat therapy, hot or cold therapy compresses or soaking therapy, or whirlpool bath therapy on a second or subsequent visit to be medical treatment (Ex. 2, p. 43). OSHA has restated this guidance in numerous letters of interpretation, most of them related to the issue of the recording of musculoskeletal disorders (MSDs).

A number of commenters recommended that hot or cold therapy be defined as first aid regardless of the number of times it is administered or the type of condition for which it is used (see, *e.g.*, Exs. 15: 39, 45, 95, 109, 156, 163, 199, 201, 218, 246, 308, 347, 348, 359, 386, 414, 430, 443). Several of the comments cited consistency as an issue (see, *e.g.*, Exs. 15: 39, 109, 347, 348, 430). For example, the Dupont Company stated that "Item 8 on the 'First Aid Treatment' list considers the same treatment as either first aid or medical treatment depending on the condition for which it is applied. The treatment is used for reduction of swelling and discomfort. The condition for which it is used should not matter. * * * Exclude the 'except for musculoskeletal disorders * * *' clause from item 8 (Ex. 15: 348, p. 9).

Another issue raised was that hot and cold treatments do not require special training (Ex. 15: 414). For example, Raytheon Constructors stated "[w]e believe the following treatments should be added: Soaking, whirlpool and hot/cold therapy with no limit on the number of times. Many physicians choose this conservative treatment, plus, any first aid trained person and/or the injured person can do this" (Ex. 15: 414). Other commenters stated that serious musculoskeletal disorders would be captured more consistently by other recording criteria (see, *e.g.*, Exs. 15: 199, 347). The Ford Motor Company stated:

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We have a major disagreement with the proposed rule that the use of any hot or cold therapy is first aid, except for musculoskeletal disorders. The use of hot or cold therapy should always be considered first aid. If an individual has a significant or serious musculoskeletal disorder, it would require prescription medicine, restriction of work or motion, transfer to another job, a day away from work, or medical treatment. Considering hot or cold therapy to always be first aid simplifies the system, reduces confusion, and does not discourage practitioners from using hot or cold therapy for minor or insignificant musculoskeletal disorders. If all musculoskeletal disorders which include two or more applications of hot or cold therapy as directed by a health care provider are recordable, the data on musculoskeletal disorders will be absolutely useless (Ex. 15: 347).

Several commenters believed that multiple hot or cold treatments should be considered medical treatment (see, *e.g.*, Exs. 15: 371, 418). The AFL–CIO disagreed with OSHA's proposal; it recommended that multiple treatments of all types be considered medical treatment, based on the belief that valuable information about serious work-related injuries would otherwise be lost. The AFL–CIO said:

> The proposed change in definition would seem to exclude cases where there are continued instances of the listed first aid treatments from the recordkeeping requirements. * * * The AFL–CIO believes that first aid should be limited to one time treatments as is the current practice, so that serious conditions which require multiple treatments are recorded on the log. We strongly urge OSHA to maintain the definition of first aid in the current recordkeeping guidelines and to use the listed conditions as examples of first aid (15: 418).

The Tosco Corporation proposed an alternative, recommending that hot/cold treatments for musculoskeletal disorders be considered first aid for the first four treatments (Ex. 15: 246).

In the final rule, OSHA has included hot and cold treatment as first aid treatment, regardless of the number of times it is applied, where it is applied, or the injury or illness to which it is applied. The Agency has decided that hot or cold therapy must be defined as either first aid or medical treatment regardless of the condition being treated, a decision that departs from the proposal. It is OSHA's judgment that hot and cold treatment is simple to apply, does not require special training, and is rarely used as the only treatment for any significant injury or illness. If the worker has sustained a significant injury or illness, the case almost always involves some other form of medical treatment (such as prescription drugs, physical therapy, or chiropractic treatment); restricted work; or days away from work. Therefore, there is no need to consider hot and cold therapy to be medical treatment, in and of itself. Considering hot and cold therapy to be first aid also clarifies and simplifies the rule, because it means that employers will not need to consider whether to record when an employee uses hot or cold therapy without the direction or guidance of a physician or other licensed health care professional.

Item 9 listed in the NPRM definition of first aid was "[u]se of any totally non-rigid, non-immobilizing means of support (*e.g.* elastic bandages)." The proposal reflected OSHA's guidance to employers under past interpretations. The *Recordkeeping Guidelines* defined first aid treatment as "use of elastic bandage(s) during first visit to medical personnel" (Ex. 2, p. 43). The *Guidelines* do not provide specific guidance on the use of other types of orthopedic devices such as splints, casts, or braces. In response to requests from the public to clarify the issue of which devices are medical treatment and which are first aid treatment, OSHA issued several letters of interpretation stating that the use of wraps or non-constraining devices such as wristlets, tennis elbow bands or elastic bandages are first aid treatment, regardless of how long or how often they are used. The use of casts, splints, or orthopedic devices designed to immobilize a body part to permit it to rest and recover is considered medical treatment. Generally, orthopedic devices used for immobilization are made rigid, in whole or in part, through the use of stays or non-bending supports (see, *e.g.*, Exs. 70: 40, 158).

OSHA received several comments recommending that it provide additional clarification of this issue (see, *e.g.*, Exs. 15: 176, 290). Several commenters suggested that OSHA include wrist splints as first aid, on the grounds that wrist splints are used as a prophylactic treatment (see, *e.g.*, Exs. 15: 332, 349, 386, 387). Other commenters recommended that finger splints be considered first aid (see, *e.g.*, Exs. 15: 201, 349, 386). The Caterpillar Company suggested that OSHA "[e]xpand item 9 to include rigid finger splints, which are used only to prevent further injury or to maintain the cleanliness of finger lacerations and other minor wounds, rather than as part of the required medical treatment. Only splints that are used to provide rigidity as part of the required medical treatment should trigger recordability" (Ex. 15: 201).

Several comments centered on the issue of immobilization for injuries while the worker is being transported to a medical care facility (see, *e.g.*, Exs. 15: 290, 347, 434). The Ford Motor Company remarked, "[t]he first aid list should be expanded to include the use of any partially or totally rigid immobilizing means of support when used solely for the purpose of immobilization during initial transport for medical evaluation. For example, the use of a back board, stiff neck collar, or air splint" (Ex. 15: 347). The American Red Cross added:

> While Red Cross would agree that this is "first aid," it is unclear whether OSHA intends for use of rigid support to be considered "medical treatment." In most traditional first aid classes, including those taught by Red Cross, students are taught that if, for example, a victim has broken a bone, any rigid means of support that would immobilize the limb until further medical care can be obtained should be utilized. Examples of rigid support include newspapers, magazines, sticks, boards, splints, etc., anything that is available to prevent further injury. This action may be performed by anyone who has been trained in first aid, and Red Cross does not believe that "rigidity" is the appropriate qualification to consider this action "medical treatment" (15: 290).

The General Electric Corporation (GE) recommended that OSHA rely, not on the design of the device but on whether or not the device resulted in restricted activity. GE recommended "the following additions to the list: Use of rigid or non-rigid immobilization devices, if they don't result in restricted activity, *e.g.* wrist braces, finger splints, immobilization for transport" (Ex. 15: 349).

OSHA has included two items related to orthopedic devices in the final definition of first aid. Item F includes "[u]sing any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes)." OSHA has included more examples of the devices (wraps and non-rigid back belts) to help make the definition clearer. However, OSHA believes that the use of orthopedic devices such as splints or casts should be considered medical treatment and not first aid. They are typically prescribed by licensed health care professionals for long term use, are typically used for serious injuries and illnesses, and are beyond the everyday definition of first aid. OSHA believes that it would be inappropriate to rely on "restricted activity," as recommended by GE, because there may be situations where orthopedic devices are prescribed, the worker is not placed on

restrictions, but an injury or illness warranting recording has occurred.

However, OSHA agrees with those commenters who stated that the use of these devices during an emergency to stabilize an accident victim during transport to a medical facility is not medical treatment. In this specific situation, a splint or other device is used as temporary first aid treatment, may be applied by non-licensed personnel using common materials at hand, and often does not reflect the severity of the injury. OSHA has included this item as G on the first aid list: "[u]sing temporary immobilization devices while transporting an accident victim (*e.g.* splints, slings, neck collars, etc.)"

Item 10 listed in the proposed definition of first aid was "drilling of a nail to relieve pressure for subungual hematoma." A subungual hematoma is an accumulation of blood underneath a finger or toenail that is normally caused by a sharp blow to the nail. When pressure builds beneath the nail, pain results. The normal course of treatment for this injury is to drill a small hole through the nail to relieve the pressure. In the past, OSHA considered such treatment to be medical treatment and not first aid. For example, a 1993 letter from IBP, Inc. asked whether "[d]rilling a hole through a fingernail to relieve pressure (subungual hematoma) is considered medical treatment?" OSHA's answer was "Yes, the draining of any fluids or blood is to be considered medical treatment" (Ex. 70: 136).

OSHA received very few comments on this first aid item. Linda Ballas & Associates stated "The drilling of a nail to relieve pressure for subungual hematoma should be included as medical treatment and not first aid" (Ex. 15: 31, p. 5). The American Textile Manufacturers Institute recommended that OSHA change the item to: "Simple relieving of the pressure of a subungual hematoma. The use of the word drilling is too restrictive. There are a number of simple procedures to relieve pressure that are considered first aid" (Ex. 15:156). OSHA also received a similar comment from Oxychem Corporation stating that lancing a blister should be considered first aid (Ex. 15: 386).

OSHA has decided to retain this item on the first aid list and to add the lancing of blisters as well. These are both one time treatments provided to relieve minor soreness caused by the pressure beneath the nail or in the blister. These are relatively minor procedures that are often performed by licensed personnel but may also be performed by the injured worker. More serious injuries of this type will continue to be captured if they meet one or more of the other recording criteria. OSHA has specifically mentioned finger nails and toenails to provide clarity. These treatments are now included as item H on the first aid list.

Item 11 listed in the proposed definition of first aid was "Use of eye patches." The *Recordkeeping Guidelines* did not provide specific guidance about eye patches. However, in a 1992 letter, OSHA provided an interpretation that the use of eye patches was first aid treatment; in that letter, ELB Inc. asked OSHA to "[e]xplain if pressure patches on eyes are recordable or if a patch over an eye to prevent light from entering is recordable? Is the use of an eye patch recordable?" OSHA answered " The use of a normal eye patch is considered to be first aid. However, if the employee is unable to perform all of his/her normal job duties because of the patch, the case should be recorded based on restricted work activity. The use of a pressure eye patch is medical treatment" (Ex. 70: 161) .

OSHA received only one comment specific to this item. The National Institute for Occupational Safety and Health (NIOSH) stated that the initial use of an eye patch would generally require medical evaluation and should not be considered first aid (Ex. 15: 407). In the final rule, OSHA has included the use of eye patches as first aid in item I of the first aid list. Eye patches can be purchased without a prescription, and are used for both serious and non-serious injuries and illnesses. OSHA believes that the more serious injuries to the eyes will that NIOSH refers to require medical treatment, such as prescription drugs or removal of foreign material by means other than irrigation or a cotton swab, and will thus be recordable.

Item 12 listed in the proposed definition of first aid was "removal of foreign bodies not embedded in the eye if only irrigation or removal with a cotton swab is required." The effect of including this item in the list of first aid treatments would be to make any case involving a foreign body embedded in the eye a recordable injury.

The *Recordkeeping Guidelines* listed "removal of foreign bodies embedded in the eye" as medical treatment and "removal of foreign bodies not embedded in eye if only irrigation is required" as first aid (Ex. 2, p. 43). In subsequent letters of interpretation, the use of a cotton swab to remove a foreign body from the eye was interpreted to be first aid; injuries requiring any removal method other than irrigation or a cotton swab made the case recordable (Ex. 70: 92).

OSHA received few comments on this first aid item. NIOSH stated that any case involving a foreign body in the eye should be recorded, because "even though removal of a foreign body from the eye may be a first aid procedure, the presence of a work-related foreign body in the eye should be recordable. These procedures should not be considered first aid" (Ex. 15: 407). The Ford Motor Company asked OSHA to clarify that a foreign body "embedded in or adhered to" the eye and removed by the methods proposed would be considered first aid. Ford added that "[t]he use of a prescription medication to anesthetize the eye for a diagnostic procedure, an assessment procedure, or flushing to remove a loose foreign body should not be considered medical treatment" (Ex. 15: 347). Countrymark Cooperative, Inc. asked that the definition of this item be expanded to include other means of removal, stating: "We suggest wording such as * * * Removal of foreign bodies not embedded in the eye if only irrigation or simple removal techniques are required, or comparable" (Ex. 15: 9).

In the final rule, OSHA has included as item J "Removing foreign bodies from the eye using only irrigation or a cotton swab." OSHA believes that it is often difficult for the health care professional to determine if the object is embedded or adhered to the eye, and has not included this suggested language in the final rule. In all probability, if the object is embedded or adhered, it will not be removed simply with irrigation or a cotton swab, and the case will be recorded because it will require additional treatment.

OSHA believes that it is appropriate to exclude those cases from the Log that involve a foreign body in the eye of a worker that can be removed from the eye merely by rinsing it with water (irrigation) or touching it with a cotton swab. These cases represent minor injuries that do not rise to the level requiring recording. More significant eye injuries will be captured by the records because they involve medical treatment, result in work restrictions, or cause days away from work.

Item 13, the last item listed in the proposed definition of first aid, was "Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or other simple means." The *Recordkeeping Guidelines* distinguished between foreign body removal cases on the basis of the complexity of the removal technique used. According to the *Guidelines*, the "removal of foreign bodies from a wound if the procedure is

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complicated because of depth of embedment, size or location" was medical treatment, while "removal of foreign bodies from wound, if procedure is uncomplicated, and is, for example, by tweezers or other simple technique" was first aid (Ex. 2, p. 43).

OSHA received one comment specific to this proposed first aid item. The Muscatine Iowa Chamber of Commerce Safety Committee stated "The list appears to be very inclusive of what items are currently understood as first aid treatments. Our only concern is the ambiguous ending of Number 13. "* * * or other simple means." This should be further defined. Change number 13 to read: "Removal of splinters or foreign material from areas other than the eyes by irrigation, tweezers, cotton swabs or by excision not to exceed the depth of the outer layer of skin" (Ex. 15: 87).

In the final rule, OSHA has decided to retain item 13 essentially as proposed, and this first aid treatment appears as item K on the first aid list. The inclusion of the phrase "other simple means" will provide some flexibility and permit simple means other than those listed to be considered first aid. Cases involving more complicated removal procedures will be captured on the Log because they will require medical treatment such as prescription drugs or stitches or will involve restricted work or days away from work. OSHA believes that cases involving the excision of the outer layer of skin are not appropriately considered first aid, as suggested by the Muscatine Iowa Chamber of Commerce; excision of tissue requires training and the use of surgical instruments.

Additions to the First Aid List Suggested by Commenters

In addition to comments about the first aid items OSHA proposed to consider first aid, a number of commenters asked for additional clarifications or recommended additions to the first aid list. The items suggested included exercise, chiropractic treatment, massage, debridement, poison ivy, bee stings, heat disorders, and burns.

Exercise: Several commenters requested adding exercise, performed either at home or at work, to the list (see, *e.g.*, Exs. 15: 201, 308, 349, 396). For example, Caterpillar suggested that OSHA "[a]dd a listing for range of motion exercises and minor physical therapy performed at home" (Ex. 15: 201). These comments described exercises that amount to self-administered physical therapy, and are normally recommended by a health care professional who trains the worker in the proper frequency, duration and intensity of the exercise. Physical therapy treatments are normally provided over an extended time as therapy for a serious injury or illness, and OSHA believes that such treatments are beyond first aid and that cases requiring them involve medical treatment.

Chiropractic treatment: A few commenters believe that chiropractic treatment should be treated as first aid (see, *e.g.*, Exs. 15: 154, 299, 396). For example, the Sandoz Corporation stated "[i]t would simplify our record keeping if there were better definition of the use of chiropractors. Is one visit counted or do you have to have multiple visits" (Ex. 15: 299). OSHA does not distinguish, for recordkeeping purposes, between first aid and medical treatment cases on the basis of number of treatments administered. OSHA also does not distinguish between various kinds of health care professionals, assuming they are operating within their scope of practice. If a chiropractor provides observation, counseling, diagnostic procedures, or first aid procedures for a work-related injury or illness, the case would not be recordable. On the other hand, if a chiropractor provides medical treatment or prescribes work restrictions, the case would be recordable.

Massage therapy: The Union Carbide company recommended the addition of massages and prescribed physical therapy to the first aid list (Ex. 15: 396). OSHA believes that massages are appropriately considered first aid and has included them as item M in the final rule's first aid list. However, physical therapy or chiropractic manipulation are treatments used for more serious injuries, and are provided by licensed personnel with advanced training and therefore rise to the level of medical treatment beyond first aid.

Debridement: Several commenters recommended that OSHA include debridement as a first aid treatment (see, *e.g.*, Exs. 15: 201, 332, 349, 387). Debridement is the surgical excision, or cutting away, of dead or contaminated tissue from a wound. The *Recordkeeping Guidelines* listed "cutting away dead skin (surgical debridement)" as an example of medical treatment (Ex. 2, p. 43). The Caterpillar Company recommended that OSHA "[a]dd to the [first aid] listing provisions for the minor removal of nonviable tissue as first aid treatment" (Ex. 15: 201).

OSHA has decided not to include debridement as a first aid treatment. This procedure must be performed by a highly trained professional using surgical instruments. Debridement is also usually performed in conjunction with other forms of medical treatment, such as sutures, prescription drugs, etc.

Intravenous (IV) administration of glucose and saline: Two commenters (Exs. 15: 154, 395) argued that the intravenous administration of saline (salt) and glucose (sugar) should be considered first aid. In former letters of interpretation, OSHA considered these treatments first aid in injury cases (see, *e.g.*, Exs. 15: 154, 395). In the final rule, however, OSHA has decided not to include the IV administration of fluids on the first aid list because these treatments are used for serious medical events, such as post-shock, dehydration or heat stroke. The administration of IVs is an advanced procedure that can only be administered by a person with advanced medical training, and is usually performed under the supervision of a physician.

The Union Carbide Corporation (Ex. 15: 396) also recommended three additions to the first aid list: UV treatment of blisters, rashes and dermatitis; acupuncture, when administered by a licensed health care professional; and electronic stimulation. After careful consideration, OSHA has decided not to include these treatments as first aid. Each of these treatments must be provided by a person with specialized training, and is usually administered only after recommendation by a physician or other licensed health care professional.

Several commenters asked that treatments for two specific types of disorders be added to the list: heat disorders and burns. OSHA has not added these types of conditions to the first aid list because the list includes treatments rather than conditions. However, OSHA has added fluids given by mouth for the relief of heat disorders to the list, in response to comments received.

Two commenters asked about the recording of heat disorders and how they relate to the definition of first aid and medical treatment. Union Carbide recommended an addition to the first aid list to state "fluids taken internally for heat stress" (Ex. 15: 396). The Arizona Public Service Company remarked: "Recordability of heat stress and heat rash should be addressed based on classification of treatment (first aid vs. medical)" (Ex. 15: 247). Under OSHA's former recordkeeping system, heat stress was recordable as an occupational illness because it results from non-instantaneous exposures that occur over time and all occupational illnesses, including minor ones, were considered recordable.

In the final rule, OSHA agrees with Union Carbide that drinking fluids for the relief of heat disorders is a first aid rather than medical treatment and item N on the final first aid list is "drinking fluids for relief of heat stress." However, as discussed above, OSHA believes that more extensive treatment, including the administration of fluids by intravenous injections (IV), are medical treatment, and more serious cases of heat disorders involving them must be entered into the records. In addition, any diagnosis by a physician or other licensed health care professional of heat syncope (fainting due to heat) is recordable under paragraph 1904.7(b)(6), Loss of Consciousness.

Burns: Many commenters recommended that OSHA include the treatment of burns on the first aid list (see, *e.g.*, Exs. 45, 170, 260, 262, 265, 288, 301, 401, 414, 443). Teepak Inc. stated "[s]econd degree burns treated by first aid measures only, with no infection or complication or prescription medication, should be considered first aid" (Ex. 15: 45). The Georgia Power Company argued that "[t]reatment of all first degree burns should be added to the list of first aid treatments because they are minor injuries that are exempt from the requirements of the Act. Omission of first degree and second degree burns receiving only first aid treatment from this list is inconsistent with the recording criteria listed for burns of the skin in [proposed] Appendix B" (Ex. 15: 260). The Chemical Manufacturers Association recommended that OSHA add "[b]urns that require only one-time treatment. Subsequent observations and changing of bandages does not constitute medical treatment" (Ex. 15: 301).

The former *Recordkeeping Guidelines* listed the treatment of first degree burns as an example of first aid treatment and did not consider such treatment to be recordable (Ex. 2, p. 43). In the final rule, OSHA has decided not to include burn treatments on the first aid list. If first, second, or third degree burns result in days away from work, restricted work activity, or medical treatment beyond first aid, such as prescription drugs or complex removal of foreign material from the wound, they will rise to the level that requires recording.

Taking this approach means that burns will be treated just as other types of injury are, *i.e.*, minor burn injuries will not be recordable, while more serious burns will be recorded because they will involve medical treatment. For example, a small second degree burn to the forearm that is treated with nothing more than a bandage is not recordable. A larger or more severe second degree burn that is treated with prescription creams or antibiotics, or results in restricted work, job transfer, or days away from work is recordable. The vast majority of first degree burns and minor second degree burns will not be recorded because they will not meet the recording criteria, including medical treatment. However, more serious first and second degree burns that receive medical treatment will be recorded, and third degree burns should always be recorded because they require medical treatment.

Miscellaneous First Aid and Medical Treatment Issues

The American Association of Occupational Health Nurses (AAOHN) was concerned that the public might interpret the fact that treatments were listed as first aid to mean that they did not have to be administered, in some cases, by a health care professional:

> OSHA must clarify that categorizing certain actions as first aid does not necessarily imply that these actions can be delegated to a non-health care professional. While a list of actions considered first aid treatment will offer guidance for employers in determining recordability of incidents, situations exist that will require the professional judgment of a health care professional. One example is the administration of tetanus/diphtheria shots. While it is appropriate to consider these treatments first aid for recordability, injections pose issues that require the judgment and expertise of a health care professional. One potential hazard of this treatment is the risk of side effects. The ability to identify the reaction and take appropriate measures should be handled by a qualified health care professional (Ex. 15: 181).

OSHA agrees with the AAOHN that certain treatments and interventions require the professional judgment of a health care professional. The Agency believes that these matters are best left to state agencies and licensing boards, and the final rule's definition of health care professional (see Subpart G) makes this clear.

The State of New York expressed a concern about the possible confusion some employers might experience between OSHA's requirements and those of the state workers' compensation systems. The New York Workers' Compensation Board stated:

> The proposed rule contains a broad list of treatments which will qualify as first aid, with less emphasis on the number of treatments or the resulting amount of lost time from work. It is possible that many of the items listed in the OSHA rule as first-aid treatments which do not require reporting under the proposed OSHA standard (*i.e.* use of splints, drilling a nail in a hematoma, use of compresses and non-prescription medications), may still require reporting under the WCL because in a particular case the treatment qualifies as medical treatment or because it has caused lost time from work beyond the working day. The only problem would be if employers, in complying with proposed OSHA requirements, failed to continue to comply with New York's recording and reporting requirements (Ex. 15: 68).

OSHA's reporting requirements do not in any way interfere with or have any impact on state workers compensation reporting requirements. Employers are required to record certain injuries and illnesses under the OSHA recordkeeping regulation and to observe certain other requirements under workers' compensation law. The two laws have separate functions: workers' compensation is designed to compensate injured or ill workers, while the OSH Act is designed to prevent injuries and illnesses and to create a body of information to improve understanding of their causes. Thus, certain injuries and illnesses may be reportable under state workers' compensation law but not under the OSHA recordkeeping rule, and certain injuries and illnesses may be reportable under the OSHA rule but not under one or more workers' compensation statutes. OSHA notes that employers have been following the requirements of both systems for years, and have generally not experienced difficulty in doing so.

Several commenters remarked on the need for OSHA to update the first aid list in the future (see, *e.g.*, Exs. 234, 247, 384, 407). One commenter remarked: "The suggested first aid list adds and clarifies some treatments as first aid. There should be a mechanism for adding or removing treatments to first aid and medical treatment lists as new information becomes available" (Ex. 15: 234). The Akzo Nobel Company suggested that "[w]ith the assistance of occupational physicians, updates could be made quarterly and distributed via the Internet" (Ex. 15: 384). The National Institute for Occupational Safety and Health (NIOSH) recommended "[t]he first aid list, however, should be included as an appendix, rather than in the rule itself, in order to allow revisions to be made more easily as medical practice evolves" (Ex. 15: 407).

In response, OSHA notes that the list is part of a definition that sets mandatory recording and reporting requirements and is a part of the regulation itself. Including the first aid list as a non-mandatory appendix would

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provide additional flexibility for future updates, but doing so would not meet the purposes for which the list is intended. The list is mandatory, and making it non-mandatory would only introduce additional confusion about what is or is not to be entered into the records. As a result, the mechanism OSHA will use to update or modify the first aid list will be to pursue a future rulemaking, if and when such a rulemaking is needed. OSHA will continue to issue letters of interpretation to help employers understand the requirements as they apply to specific situations.

Paragraph 1904.7(b)(6) Loss of Consciousness

The final rule, like the former rule, requires the employer to record any work-related injury or illness resulting in a loss of consciousness. The recording of occupational injuries and illnesses resulting in loss of consciousness is clearly required by Sections 8(c) and 24 of the OSH Act. The new rule differs from the former rule only in clearly applying the loss of consciousness criterion to illnesses as well as injuries. Since the former rule required the recording of all illnesses, illnesses involving loss of consciousness were recordable, and thus OSHA expects that this clarification will not change recording practices. Thus, any time a worker becomes unconscious as a result of a workplace exposure to chemicals, heat, an oxygen deficient environment, a blow to the head, or some other workplace hazard that causes loss of consciousness, the employer must record the case.

Very few commenters addressed the issue of loss of consciousness. Three commenters asked OSHA to make sure that these cases are not recordable unless they are the result of a work-related injury or illness (see, *e.g.*, Exs. 15: 102, 159, 176). The American Frozen Food Institute (AFFI) stated that "[l]oss of consciousness should not be reported unless it is the clear result of a work related injury or illness" (Ex. 15: 102). The Chemical Manufacturers Association added "OSHA must clearly indicate in the final recordkeeping rule that loss of consciousness must be induced by an occupational exposure. For example, if someone faints at work due to pregnancy or has an epileptic seizure, such loss of consciousness should not be recordable" (Ex. 15: 176).

OSHA agrees with these commenters that, in order to be a recordable event, a loss of consciousness must be the result of a workplace event or exposure. Loss of consciousness is no different, in this respect, from any other injury or illness. The exceptions to the presumption of work-relationship at § 1904.5(b)(2)(ii) allow the employer to exclude cases that "involve signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment." This exception allows the employer to exclude cases where a loss of consciousness is due solely to a personal health condition, such as epilepsy, diabetes, or narcolepsy.

The American Crystal Sugar Company (Ex. 15: 363) raised the issue of phobias resulting in loss of consciousness:

> I would also like to suggest exempting an employee's loss of consciousness based on a fear-based phobia, i.e., fainting at the sight of blood. Occasionally an OSHA regulation may require blood tests, such as checking lead levels in blood. There are a few employees that will lose consciousness at the sight of a needle. These phobias are not limited to medical procedures, but may include spiders, snakes, etc. In several of our factories, the occupational health nurse will administer tetanus boosters as a service to our employees. Employees that have a phobia about injections can (and do) lose consciousness, which now makes what was intended as a service an OSHA recordable accident.

The final rule does not contain an exception for loss of consciousness associated with phobias or first aid treatment. OSHA notes, however, that the exception at paragraph 1904.5(b)(2)(iii) allows the employer to rebut the presumption of work relationship if "the injury or illness results solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical, flu shot, exercise class, racquetball, or baseball." This exception would eliminate the recording of fainting episodes involving voluntary vaccination programs, blood donations and the like. However, episodes of fainting from mandatory medical procedures such as blood tests mandated by OSHA standards, mandatory physicals, and so on would be considered work-related events, and would be recordable on the Log if they meet one or more of the recording criteria. Similarly, a fainting episode involving a phobia stemming from an event or exposure in the work environment would be recordable.

The Union Carbide Corporation (Ex. 15: 398) asked OSHA to be more precise about the definition of loss of consciousness, stating that "[m]ost people generally understand this term without a definition, but it can be open to interpretation. For example, is 'feeling woozy' for a few seconds considered to be a loss of consciousness? Perhaps OSHA should define the term to avoid any confusion." In this final rule, OSHA has not included a separate definition for the term "loss of consciousness." However, the language of paragraph 1904.7(b)(6) has been carefully crafted to address two issues. First, the paragraph refers to a worker becoming "unconscious," which means a complete loss of consciousness and not a sense of disorientation, "feeling woozy," or a other diminished level of awareness. Second, the final rule makes it clear that loss of consciousness does not depend on the amount of time the employee is unconscious. If the employee is rendered unconscious for any length of time, no matter how brief, the case must be recorded on the OSHA 300 Log.

Paragraph 1904.7(b)(7) Recording Significant Work-Related Injuries and Illnesses Diagnosed by a Physician or Other Licensed Health Care Professional

Paragraph 1904.7(b)(7) of this final rule requires the recording of any significant work-related injury or illness diagnosed by a physician or other licensed health care professional. Paragraph 1904.7(b)(7) clarifies which significant, diagnosed work-related injuries and illnesses OSHA requires the employer to record in those rare cases where a significant work-related injury or illness has not triggered recording under one or more of the general recording criteria, i.e, has not resulted in death, loss of consciousness, medical treatment beyond first aid, restricted work or job transfer, or days away from work. Based on the Agency's prior recordkeeping experience, OSHA believes that the great majority of significant occupational injuries and illnesses will be captured by one or more of the other general recording criteria in Section 1904.7. However, OSHA has found that there is a limited class of significant work-related injuries and illnesses that may not be captured under the other § 1904.7 criteria. Therefore, the final rule stipulates at paragraph 1904.7(b)(7) that any significant work-related occupational injury or illness that is not captured by any of the general recording criteria but is diagnosed by a physician or other licensed health care professional be recorded in the employer's records.

Under the final rule, an injury or illness case is considered significant if it is a work-related case involving occupational cancer (*e.g.*, mesothelioma), chronic irreversible disease (*e.g.*, chronic beryllium disease), a fractured or cracked bone (*e.g.*, broken arm, cracked rib), or a punctured eardrum. The employer must record such cases within 7 days of receiving a diagnosis from a physician or other licensed health care professional that an injury or illness of this kind has occurred. As explained in the note to paragraph 1904.7(b)(7), OSHA believes that the great majority of significant work-related injuries and illnesses will be recorded because they meet one or more of the other recording criteria listed in § 1904.7(a): death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. However, there are some significant injuries, such as a punctured eardrum or a fractured toe or rib, for which neither medical treatment nor work restrictions may be administered or recommended.

There are also a number of significant occupational diseases that progress once the disease process begins or reaches a certain point, such as byssinosis, silicosis, and some types of cancer, for which medical treatment or work restrictions may not be recommended at the time of diagnosis, although medical treatment and loss of work certainly will occur at later stages. This provision of the final rule is designed to capture this small group of significant work-related cases. Although the employer is required to record these illnesses even if they manifest themselves after the employee leaves employment (assuming the illness meets the standards for work-relatedness that apply to all recordable incidents), these cases are less likely to be recorded once the employee has left employment. OSHA believes that work-related cancer, chronic irreversible diseases, fractures of bones or teeth and punctured eardrums are generally recognized as constituting significant diagnoses and, if the condition is work-related, are appropriately recorded at the time of initial diagnosis even if, at that time, medical treatment or work restrictions are not recommended.

As discussed in the Legal Authority section, above, OSHA has modified the Agency's prior position so that, under the final rule, minor occupational illnesses no longer are required to be recorded on the Log. The requirement pertaining to the recording of all significant diagnosed injuries and illnesses in this paragraph of the final rule, on the other hand, will ensure that all significant (non-minor) injuries and illnesses are in fact captured on the Log, as required by the OSH Act. Requiring significant cases involving diagnosis to be recorded will help to achieve several of the goals of this rulemaking. First, adherence to this requirement will produce better data on occupational injury and illness by providing for more complete recording of significant occupational conditions. Second, this requirement will produce more timely records because it provides for the immediate recording of significant disorders on first diagnosis. Many occupational illnesses manifest themselves through gradual onset and worsening of the condition. In some cases, a worker could be diagnosed with a significant illness, such as an irreversible respiratory disorder, not be given medical treatment because no effective treatment was available, not lose time from work because the illness was not debilitating at the time, and not have his or her case recorded on the Log because none of the recording criteria had been met. If such a worker left employment or changed employers before one of the other recording criteria had been met, this serious occupational illness case would never be recorded. The requirements in paragraph 1904.7(b)(7) remedy this deficiency and will thus ensure the capture of more complete and timely data on these injuries and illnesses.

The provisions of paragraph 1904.7(b)(7) are an outgrowth of Appendix B of the proposed rule, which included provisions for the recording of individual conditions, such as blood lead levels, musculoskeletal disorders, and various respiratory ailments. As OSHA explained in the preamble to the proposed rule (61 FR 4039–4042), the proposed requirements were intended to ensure the recording of significant non-fatal cases that did not meet the general criteria (days away, restricted work, medical treatment, etc.).

Proposed Appendix B has not been included in the final rule, which instead includes additional separate criteria for several of the conditions proposed to be included in Appendix B; these criteria, which cover tuberculosis cases, hearing loss cases, and so on, appear in the final rule at § 1904.8 through § 1904.12. The requirements at paragraph 1904.7(b)(7) of the final rule, which require the recording of significant injuries and illnesses not meeting one or more of the general recording criteria, will ensure the recording of the small number of significant conditions that would have been covered by proposed Appendix B and are not elsewhere addressed in the final rule. Thus, OSHA believes that cases involving the conditions listed in proposed Appendix B will be captured either by the requirements in this significant diagnosed case section or by the other general recording criteria.

In developing the text of paragraph 1904.7(b)(7) of the final rule, OSHA reviewed the following questions as they related to proposed Appendix B. Each of these questions, and the comments received, are discussed in greater detail below: (1) Are additional recording criteria beyond loss of consciousness, medical treatment, restricted work, job transfer, days away, or death needed in the final rule?; (2) if so, should these additional criteria address a finite list of specific conditions or address a broader range of disorders?; (3) how should the agency define "significant" injuries and illnesses?; and (4) how should the final rule ensure the work-relatedness of these cases?

Are Additional Recording Criteria Needed?

Many commenters viewed proposed Appendix B as an unnecessary addition to the other general recording criteria and argued that OSHA should use the general criteria listed in the OSH Act itself for most if not all of the listed conditions (see, *e.g.*, Exs. 15: 52, 146, 200, 203, 219, 260, 262, 265, 271, 272, 303, 313, 329, 348, 352, 353, 368, 401, 427). For example, the Atlantic Richfield Company (ARCO) stated that:

> [t]his broadening of the recordability criteria particularly as detailed in [proposed] mandatory Appendix B dilutes the significant data with marginal data and does not, in our view, fit with OSHA's stated goals for improved Log accuracy and utility. ARCO believes that for almost all of these specific exposures, the appropriate data can be captured through the normal performance criteria of whether the condition or exposure has caused a day away from work, restriction on activity, or resulted in medical treatment. It is, therefore, our opinion that Appendix B is unnecessary and appropriate for deletion (Ex. 15: 329).

However, other commenters saw a need for and supported the inclusion of additional recording criteria in the final rule (see, *e.g.*, Exs. 15: 201, 301, 304, 318). For example, the National Federation of Independent Business (NFIB) agreed that "[t]here are some conditions which are serious enough to be recorded, but could escape the proposed recordkeeping criteria of medical treatment, restricted or loss workdays or job transfer" (Ex. 15: 304). Caterpillar agreed "[w]ith the basic concept proposed in Appendix B that additional guidelines are needed to capture some injuries and illnesses serious enough to be recorded, which may not be captured by the basic recordkeeping criteria" (Ex. 15: 201).

OSHA agrees with those commenters who supported the inclusion in the final rule of an additional mechanism to ensure the capture of significant work-related injuries and illnesses that are diagnosed by a physician or other licensed health care professional but do

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not, at least at the time of diagnosis, meet the criteria of death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. The recording of *all* non-minor injuries and illnesses is consistent with the OSH Act (see the Legal Authority section) and has been the intent of the recordkeeping system for many years. The primary goal of the requirement at paragraph 1904.7(b)(7) is to produce more accurate and complete data on non-minor work-related injuries and illnesses. Because the number of significant work-related injuries and illnesses may not be captured by one or more of the other general recording criteria, OSHA finds that this additional criterion is needed. However, OSHA believes that most cases will be captured by the general recording criteria.

Should Additional Criteria Address a Finite List of Specific Conditions or Address a Broader Range of Disorders?

Proposed Appendix B was composed of a finite list of disorders and their associated recording criteria. A number of commenters were concerned that an inclusive list would overlook other conditions that did not meet the general recording criteria and were not included in proposed Appendix B. For example, OxyChem wrote:

[f]or example, aniline is a substance having specific effects from occupational exposure, but it is not listed in Appendix B. How will occupational illness cases related to aniline be treated? Under OSHA's proposal, employers will apply the general recordability criteria to make a decision, and the case will very likely not be recorded unless it involves medical treatment, loss of consciousness, etc. (Ex. 15: 386)

This issue was also raised by the International Chemical Workers, who wrote that "[a]ppendix B limits the types of illnesses which are recordable. It needs to be textually and visually clear that this list is not an all inclusive list of recordable illnesses " (Ex. 15: 415). Additionally, the American Industrial Hygiene Association had the following thoughts on this subject:

[a]n addition should be made to the end of Appendix B to clarify and expand on the recording of new or emerging occupational illnesses as introduced by OSHA in Appendix B, second paragraph at the end of page 4063: "Conditions not included in this Appendix that otherwise meet the criteria in the § 1904.4.(c) must be recorded." Medical diagnoses, including laboratory and diagnostic tests should be the principal criteria for recording occupational illnesses.

The above quotation "Conditions not included in this Appendix * * * must be recorded" should be reworded to include the statement "including symptomology with a clear workplace link" (Ex. 15: 153).

OSHA generally agrees with these points. Limiting the recording of non-minor occupational injuries and illnesses to a finite list runs counter to the goal of this rule, which is to capture comprehensive data on all non-minor work-related injuries and illnesses, and thus including such a list would not meet the Agency's statutory mandate to collect such data. OSHA believes there will be very few injuries and illnesses that are not captured by the general recording criteria. For example, non-minor acute illnesses, such as the skin disorders potentially associated with aniline exposure, will be captured by the other criteria, particularly medical treatment beyond first aid, restricted work or job transfer, or days away from work. However, to address the gap in case capture presented by significant injury and illness cases that escape the general recording criteria, OSHA is requiring employers to record cases of chronic, irreversible disease under the § 1904.7(b)(7) criterion. This means that if long-term workplace exposure to aniline results in a chronic, irreversible liver or kidney disease, the case would be recordable at the time of diagnosis, even if no medical treatment is administered at that time and no time is lost from work. The regulatory text of paragraph 1904.7(b)(7) limits the types of conditions that are recordable, however, to significant diagnosed injury and illness cases, which are defined as cancer, chronic irreversible diseases, fractured or cracked bones, and punctured eardrums.

How Should the Agency Define "Significant" Injury or Illness?

Although there was considerable support in the record for the final rule to include a list of conditions that might not be captured under the general recordkeeping criteria, there was far less agreement among commenters on the specific conditions that should be listed. Many commenters agreed with Amoco, which testified that "[t]he criteria currently listed in the proposed rule would require recording of signs, symptoms and laboratory abnormalities; situations which are not disabling, serious, or significant" (Ex. 22). Waste Management, Inc., commented that "[t]he definition of an illness [in the proposal] or injury refers to an adverse change in the individual. This is interpreted to mean a change which is permanent or a change which is clinically demonstrable to be adverse to the individual as a result of occupational exposure in the workplace. Some of the guidance provided in Appendix B does not meet these criteria" (Ex. 15: 389). The Chemical Manufacturers Association suggested that only those conditions "[w]hose seriousness is approximately equal to that of conditions captured by traditional criteria" be included in Appendix B (Ex. 15: 301), and the Dupont Company proposed that the conditions listed in Appendix B "[i]nclude only situations that cause a permanent change to the body structure where medical treatment may not be given" (Ex. 15: 348). Dupont also stated that "[O]SHA should provide scientific evidence that a change in a lab reading [laboratory tests results were also included in proposed Appendix B] is the equivalent of a serious or significant change to the body structure" (Ex. 15: 348). Other commenters such as the Marathon Oil Company questioned whether OSHA had the legal authority "[t]o require employers to record these non-serious exposures. The OSHA proposed criteria do not represent serious, significant or disabling injuries/illnesses as required by Section 24(a) of the Act" (Ex. 15: 308).

OSHA believes that the conditions that are required to be recorded under § 1904.7(b)(7) of the final rule represent significant occupational injuries and illnesses as described in the OSH Act. Some clearly significant injuries or illnesses are not amenable to medical treatment, at least at the time of initial diagnosis. For example, a fractured rib, a broken toe, or a punctured eardrum are often, after being diagnosed, left to heal on their own without medical treatment and may not result in days away from work, but they are clearly significant injuries. Similarly, an untreatable occupational cancer is clearly a significant injury or illness. The second set of conditions identified in paragraph 1904.7(b)(7), chronic irreversible diseases, are cases that would clearly become recordable at some point in the future (unless the employee leaves employment before medical treatment is provided), when the employee's condition worsens to a point where medical treatment, time away from work, or restricted work are needed. By providing for recording at the time of diagnosis, paragraph 1904.7(b)(7) of the final rule makes the significant, work-related condition recordable on discovery, a method that ensures the collection of timely data. This approach will result in better injury and illness data and also is likely to be more straightforward for employers to comply with, since there is no further need to track the case to determine whether, and at what point, it becomes recordable.

The core of the recording requirement codified at § 1904.7(b)(7) is the employer's determination that a "significant" injury or illness has been diagnosed. The Agency's former *Recordkeeping Guidelines* addressed this issue in interpretations about "non minor" injuries that did not meet the general recording criteria of death, days away, restricted work, transfer to another job, medical treatment or loss of consciousness. The *Guidelines* stated (Ex. 2, p. 42) that:

The distinction between medical treatment and first aid depends not only on the treatment provided, but also on the severity of the injury being treated. First aid is: (1) Limited to one-time treatment and subsequent observation; and (2) involves treatment of only minor injuries, not emergency treatment of serious injuries. Injuries are not minor if:

(a) They must be treated only by a physician or licensed medical personnel;

(b) They impair bodily function (*i.e.*, normal use of senses, limbs, etc.);

(c) They result in damage to the physical structure of a nonsuperficial nature (*e.g.*, fractures); or

(d) They involve complications requiring followup medical treatment.

Many commenters on the proposal simply stated that the system must include all serious, significant or disabling injuries, and exclude cases that did not rise to that level (see, *e.g.*, Exs. 25; 15: 55, 135, 144, 154, 158, 162, 165, 193, 201, 206, 207, 211, 212, 220, 228, 238, 240, 243, 252, 253, 257, 258, 261, 264, 267, 272, 274, 276, 286, 293, 303, 305, 306, 309, 318, 320, 346, 354, 358, 365, 368, 375, 382, 383, 395, 397, 408, 412, 420, 421, 427, 434). The comments of the American Petroleum Institute (API) reflect this view: "[A]PI is strongly opposed to any provision which would require a case to be recorded which is not serious or which is not likely to become serious. API strongly disagrees that non-serious subjective signs, symptoms, abnormal health test results, or evidence of exposure in and of themselves should be recorded on the OSHA log—unless the case otherwise meets one of the traditional criteria (*e.g.*, medical treatment, *et al.*) or results in, or is expected to result in a serious impairment" (Ex. 15: 375).

Many comments believed that the recordability of occupational illnesses should rely on the diagnosis of a health care professional. For example, the U.S. Small Business Administration recommended that "[a] recordable incident under the [proposed] 'Specific Conditions' should be subject to a health care provider's clinical diagnosis" (Ed. 15: 67); Fort Howard recommended that "[t]he Company disagrees with the [proposed] Mandatory Appendix B concept particularly in light of the statement in the Proposal that an employer can not rely solely on the clinical diagnosis of an injury or illness by a physician. Fort Howard recommends that an employer be allowed to specifically rely on the conclusions of those trained in this field, namely physicians" (Ex. 15: 194); and Country Mark Cooperative recommended that " [i]f an illness is diagnosed by a medical provider as linked to the cause agent, then it would be recorded as 'otherwise recordable' until such time as other recordable criteria are met such as days unable to work" (Ex. 15: 9). BASF commented that "[proposed] Appendix B should not require the recording of merely signs, symptoms, or laboratory abnormalities. Instead, it should also include objective findings or observations on the part of health care providers regarding the diagnosis of a serious illness or effect not otherwise subject to recording requirements" (Ex. 15: 403).

Only a few commenters suggested methods for differentiating between serious and non-serious cases, in the context of conditions that should be listed in the final rule (see, *e.g.*, Exs. 15: 135, 176, 193, 199, 258, 375, 396). The API suggested that, if OSHA identifies a need to define "disabling, serious or significant" explicitly, the Agency should consider the following criteria:

[a]ny other case which results in a serious impairment or significant injury for which no effective treatment exists, or

involves a diagnosis of a condition which in time is expected to result in a serious impairment (or death), *e.g.*, certain asbestos-related diseases; or

involves evidence of a chemical exposure at biological levels where criteria in an OSHA standard requires medical removal (Ex. 15: 375).

Elsewhere in their comments, the API recommended criteria for selecting which conditions would be listed in proposed Appendix B as follows:

[t]he purpose of this appendix [proposed Appendix B] is to provide for the mandatory recording of occupational injuries and illnesses which are also serious or significant—but which do not immediately result in medical treatment, restricted work * * *

Such cases fall into three broad categories. They occur when the injury or illness either

Results in a serious impairment (unable to perform any normal life activity such as walking, eating, thinking, talking, breathing, seeing, smelling, hearing, driving a car. Incontinence and impotence would also be included)

Involves a diagnosis of a condition which in time is expected to result in serious impairment (or death), *e.g.* certain asbestos related diseases,

or

Involved evidence of a chemical exposure at biological levels where criteria in an OSHA standard requires medical removal (Ex. 15: 375).

Adapto, Inc. (Ex. 15: 258) focused on the major life activity concept, stating that:

[a]s mentioned previously, Congress intended that the statistical data compiled under this rule be limited to cases involving disabling, serious, or significant injuries or illness. Adapto, Inc. believes this phrase generally refers to a work-related condition that results in a physical or mental impairment that substantially limits a major life activity.

Union Carbide (Ex. 15: 396) urged that the following factors be used for determining the conditions that should be included in the final rule:

Serious illnesses caused by exposures which are chronic and cumulative in nature

Serious illnesses with a long latency period between exposure and recognition of the significant illness condition

Serious illnesses which are likely to result in significant impairment

Serious illnesses without a known or widely recognized medical treatment until advanced stages.

The Chemical Manufacturing Association (Ex. 15: 176) restated the same factors articulated by Union Carbide and added another factor: "[s]erious illnesses that are not treatable." The NYNEX Corporation (Ex. 15: 199), the National Broiler Council (NBC), and the National Turkey Federation (Ex. 15: 193), in identical comments, focused on the idea of cases with an expectation of serious impairment or death, stating:

[w]e do recognize, however, that there are some cases that do not meet this criteria that do have the expectation of resulting in serious impairment or even death. We are in agreement that cases of this potential seriousness should be recorded when they are diagnosed by a competent physician or medical professional as work-related.

The Macon Corporation (Ex. 15: 135) suggested using a material impairment test, suggesting that "[w]e need to establish an effective system for the collection of data on serious work related injuries and illnesses which, at the time of recording, represent a material impairment to the health or functional capacity [of the injured or ill worker]." OSHA has not adopted the material impairment alternative in the final rule because the term has specific meaning in the context of OSHA rulemaking. Section 6(b)(5) of the Act,

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which sets forth the criteria for promulgating standards dealing with toxic substances or harmful physical agents, states that OSHA shall "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer *material impairment of health or functional capacity even* if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life (emphasis added)." OSHA believes that use of this term in the recordkeeping rule could cause confusion among employers.

In the final rule, OSHA has adopted an approach similar to that suggested by the American Petroleum Institute, *i.e.*, focusing on two types of injury and illness: those that may be essentially untreatable, at least in the early stages and perhaps never (fractured and cracked bones, certain types of occupational cancer, and punctured eardrums) and those expected to progressively worsen and become serious over time (chronic irreversible diseases). The final rule is also responsive to the many commenters who urged OSHA to adopt a definition of severity for this requirement that would include all serious and significant injuries and illnesses, while excluding less serious cases. The language of paragraph 1904.(b)(7) of the final rule also responds to comments presented by commenters on the proposal who argued that relying on test results or other measures as indicators of serious occupational injury or illness was inappropriate. Instead, the final rule relies exclusively on the diagnosis of a limited class of injuries and illnesses by a physician or other licensed health care professional.

Clarifying That Cases Captured by Paragraph 1904.7(b)(7) Must Be Work Related

A number of commenters on the proposal expressed concern that proposed Appendix B was not clear enough about the fact that conditions must be work-related to be recordable on the OSHA forms. For example, several commenters asked OSHA to make sure that recordable cases of asthma are work-related (see, *e.g.*, Exs. 15: 38, 78, 80, 83, 89, 105, 157, 163, 188, 197, 203, 239, 279, 281, 297, 299, 302, 337, 345, 378, 395, 414). The Jewel Coal and Coke Company (Ex. 15: 281) stated that "[asthma, in nearly all cases, is genetic and, to be recordable, we feel must be a direct result of something in the working OSHA environment. To require anything else would cause the unnecessary recording of cases of genetic asthma with no relationship to the working environment and would serve no purpose other than to balloon the statistics."

OSHA wishes to reiterate that *any* condition that is recordable on the OSHA injury and illness recordkeeping forms must be work-related, and § 1904.7(b)(7) includes the term "work-related" to make this fact clear. In addition, because the employer will be dealing with a physician or other licensed health care professional, he or she may also be able to consult with the health care professional about the work-relatedness of the particular case. If the employer determines, based either on his or her own findings or those of the professional, that the symptoms are merely arising at work, but are caused by some non-work illness, then the case would not be recorded, under exception (b)(2)(ii) to the work-relatedness presumption at § 1904.5(b)(2) of the final rule. Similarly, if workplace events or exposures contributed only insignificantly to the aggravation of a worker's preexisting condition, the case need not be recorded under § 1904.5(a) and § 1904.5(b)(3) of the final rule.

The provisions of § 1904.7(b)(7) of the final rule thus meet the objectives of (1) capturing significant injuries and illnesses that do not meet the other general recording criteria of death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; (2) excluding minor injuries and illnesses; (3) addressing a limited range of disorders; and (4) making it clear that these injuries and illnesses must be work-related before they must be recorded.

Section 1904.8 Additional Recording Criteria for Needlestick and Sharps Injuries

Section 1904.8 of the final rule being published today deals with the recording of a specific class of occupational injuries involving punctures, cuts and lacerations caused by needles or other sharp objects contaminated or reasonably anticipated to be contaminated with blood or other potentially infectious materials that may lead to bloodborne diseases, such as Acquired Immunodeficiency Syndrome (AIDs), hepatitis B or hepatitis C. The final rule uses the terms "contaminated," "other potentially infectious material," and "occupational exposure" as these terms are defined in OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030). These injuries are of special concern to healthcare workers because they use needles and other sharp devices in the performance of their work duties and are therefore at risk of bloodborne infections caused by exposures involving contaminated needles and other sharps. Although healthcare workers are at particular risk of bloodborne infection from these injuries, other workers may also be at risk of contracting potentially fatal bloodborne disease. For example, a worker in a hospital laundry could be stuck by a contaminated needle left in a patient's bedding, or a worker in a hazardous waste treatment facility could be occupationally exposed to bloodborne pathogens if contaminated waste from a medical facility was not treated before being sent to waste treatment.

Section 1904.8(a) requires employers to record on the OSHA Log all work-related needlestick and sharps injuries involving objects contaminated (or reasonably anticipated to be contaminated) with another person's blood or other potentially infectious material (OPIM). The rule prohibits the employer from entering the name of the affected employee on the Log to protect the individual's privacy; employees are understandably sensitive about others knowing that they may have contracted a bloodborne disease. For these cases, and other types of privacy concern cases, the employer simply enters "privacy concern case" in the space reserved for the employee's name. The employer then keeps a separate, confidential list of privacy concern cases with the case number from the Log and the employee's name; this list is used by the employer to keep track of the injury or illness so that the Log can later be updated, if necessary, and to ensure that the information will be available if a government representative needs information about injured or ill employees during a workplace inspection (see § 1904.40). The regulatory text of § 1904.8 refers recordkeepers and others to § 1904.29(b)(6) through § 1904.29(b)(10) of the rule for more information about how to record privacy concern cases of all types, including those involving needlesticks and sharps injuries. The implementation section of § 1904.8(b)(1) defines "other potentially infectious material" as it is defined in OSHA's Bloodborne Pathogens Standard (29 CFR § 1910.1030, paragraph (b)). Other potentially infectious materials include (i) human bodily fluids, human tissues and organs, and (ii) other materials infected with the HIV or hepatitis B (HBV) virus such as laboratory cultures or tissues from experimental animals. (For a complete list of OPIM, see paragraph (b) of 29 CFR 1910.1030.)

Although the final rule requires the recording of all workplace cut and puncture injuries resulting from an event involving contaminated sharps, it does not require the recording of all cuts and punctures. For example, a cut made by a knife or other sharp instrument that was not contaminated by blood or OPIM would not generally be recordable, and a laceration made by a dirty tin can or greasy tool would also generally not be recordable, providing that the injury did not result from a contaminated sharp and did not meet one of the general recording criteria of medical treatment, restricted work, etc. Paragraph (b)(2) of § 1904.8 contains provisions indicating which cuts and punctures must be recorded because they involve contaminated sharps and which must be recorded only if they meet the general recording criteria.

Paragraph (b)(3) of § 1904.8 contains requirements for updating the OSHA 300 Log when a worker experiences a wound caused by a contaminated needle or sharp and is later diagnosed as having a bloodborne illness, such as AIDS, hepatitis B or hepatitis C. The final rule requires the employer to update the classification of such a privacy concern case on the OSHA 300 Log if the outcome of the case changes, i.e., if it subsequently results in death, days away from work, restricted work, or job transfer. The employer must also update the case description on the Log to indicate the name of the bloodborne illness and to change the classification of the case from an injury (i.e., the needlestick) to an illness (i.e., the illness that resulted from the needlestick). In no case may the employer enter the employee's name on the Log itself, whether when initially recording the needlestick or sharp injury or when subsequently updating the record.

The privacy concern provisions of the final rule make it possible, for the first time, for the identity of the bloodborne illness caused by the needlestick or sharps injury to be included on the Log. By excluding the name of the injured or ill employee throughout the recordkeeping process, employee privacy is assured. This approach will allow OSHA to gather valuable data about the kinds of bloodborne illnesses healthcare and other workers are contracting as a result of these occupational injuries, and will provide the most accurate and informative data possible, including the seroconversion status of the affected worker, the name of the illness he or she contracted, and, on the OSHA 301 Form for the original case, more detailed information about how the injury occurred, the equipment and materials involved, and so forth. Use of the privacy case concept thus meets the primary objective of this rulemaking, providing the best data possible, while simultaneously ensuring that an important public policy goal—the protection of privacy about medical matters—is met. OSHA recognizes that requiring employers to treat privacy cases differently from other cases adds some complexity to the recordkeeping system and imposes a burden on those employers whose employees experience such injuries and illnesses, but believes that the gain in data quality and employee privacy outweigh these disadvantages considerably.

The last paragraph (paragraph (c)) of § 1904.8 deals with the recording of cases involving workplace contact with blood or other potentially infectious materials that do not involve needlesticks or sharps, such as splashes to the eye, mucous membranes, or non-intact skin. The final recordkeeping rule does not require employers to record these incidents unless they meet the final rule's general recording criteria (i.e., death, medical treatment, loss of consciousness, restricted work or motion, days away from work, diagnosis by an HCP) or the employee subsequently develops an illness caused by bloodborne pathogens. The final rule thus provides employers, for the first time, with regulatory language delineating how they are to record injuries caused by contaminated needles and other sharps, and how they are to treat other exposure incidents (as defined in the Bloodborne Pathogens standard) involving blood or OPIM. "Contaminated" is defined just as it is in the Bloodborne Pathogens standard: "Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface."

Before issuance of this final recordkeeping rule, the OSHA compliance directive CPL 2–2.44C for the Bloodborne Pathogens standard, "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030" provided recording guidance to employers of occupationally exposed employees. The CPL 2–2.44C guidance treated cuts, lacerations and exposure incidents identically, classifying all of the events as injuries because they usually result from instantaneous events or exposures. The employer was required to record an incident when it met one of the following requirements:

1. The incident is a work-related injury that involves loss of consciousness, transfer to another job, or restriction of work or motion.

2. The incident results in the recommendation of medical treatment beyond first aid (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, or zidovudine) regardless of dosage.

3. The incident results in a diagnosis of seroconversion. The serological status of the employee shall not be recorded on the OSHA 200. If a case of seroconversion is known, it shall be recorded on the OSHA 200 as an injury (*e.g.*, "needlestick" rather than "seroconversion") in the following manner:

a. If the date of the event or exposure is known, the original injury shall be recorded with the date of the event or exposure in column B.

b. If there are multiple events or exposures, the most recent injury shall be recorded with the date that seroconversion is determined in column B.

In 1999, OSHA updated CPL 2–2.44 and changed this language to simply refer to the Part 1904 regulation, in anticipation of the publication of this final recordkeeping rule.

The proposal

In the 1996 **Federal Register** notice, OSHA proposed recording criteria for needlestick and sharps injuries that were the same as the criteria being set forth in this final rule. The requirements in the final rule have been stated in slightly different language from those in the proposal to be consistent with the format of the remainder of the rule. The only substantive difference between the approach taken in the proposal and that in the final rule is the way that cases are handled to protect the privacy of the injured or ill worker. Appendix B of the proposed rule (61 FR 4065) included requirements to record the following:

"any workplace bloodborne pathogen exposure incident (as defined in 1910.1030(b)) that results in a positive blood test or diagnosis by a health care provider indicating AIDS, HIV seroconversion, hepatitis B or hepatitis C.

OR

any laceration or puncture wound that involves contact with another person's blood or other potentially infectious materials.

Note: to protect employee confidentiality, employers shall record occupationally acquired bloodborne pathogen diseases, such as hepatitis B, simply as the initial bloodborne exposure incident and note the exposure type (e.g. needlestick). Seroconversion and specific type of bloodborne disease shall not be recorded."

OSHA explained in its proposal that recording these incidents was appropriate because these injuries are clearly non-minor, and recording them would be consistent with the Agency's mandate to collect information related to the death, illness, and injury of workers (61 FR 4041). OSHA then requested comment on whether it would be appropriate to record small puncture

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wounds and lacerations that do not lead to disease, and whether OSHA should require employers to record all "exposure incidents" involving exposure to blood or OPIM, not just *injuries* involving contaminated needles and sharps. The proposal also asked for comment about the special privacy concerns potentially associated with bloodborne pathogen injuries and illnesses, and asked the following questions: "What data is useful to collect? Are there other criteria for the recording of bloodborne infectious diseases which should be considered? What experience do employers have in data collection systems for this hazard?"

These proposed recording criteria for needlesticks and sharps injury cases prompted many comments to the rulemaking record. Very few of the comments supported OSHA's proposed position on this issue. Commenters either recommended recording all bloodborne pathogen exposure incidents or sharply limiting the recording of these events. A large number of commenters either objected specifically to the recording of all bloodborne pathogen exposure incidents or objected to the entire contents of proposed Appendix B (see, *e.g.*, Exs. 15: 1, 37, 38, 39, 44, 48, 52, 61, 66, 69, 74, 78, 82, 89, 100, 119, 121, 122, 126, 133, 146, 151, 152, 154, 156, 179, 193, 197, 200, 201, 203, 204, 213, 218, 219, 239, 254, 260, 262, 265, 271, 272, 277, 287, 297, 299, 301, 303, 305, 308, 310, 313, 317, 322, 329, 335, 345, 346, 347, 348, 349, 351, 352, 353, 361, 364, 373, 374, 375, 378, 392, 393, 395, 396, 398, 401, 403, 405, 407, 408, 409, 425, 434, 435). The most frequent suggestion made by commenters was that the only criterion for recording bloodborne pathogen diseases should be a positive blood test or diagnosis by a health care professional (see, *e.g.*, Exs. 15: 1, 38, 61, 65, 78, 82, 119, 122, 133, 151, 152, 179, 201, 213, 260, 262, 265, 290, 299, 301, 317, 345, 347, 373, 374, 393, 401, 407, 408, 435, 442). Many of the commenters who objected to recording all bloodborne incidents on the Log argued that these cases reflect exposure only and do not usually reflect cases that rise to the level of an injury or illness (see, *e.g.*, Exs. 15: 44, 69, 78, 151, 152, 179, 197, 201, 239, 272, 277, 287, 303, 308, 313, 345, 347, 348, 349, 351, 352, 353, 364, 373, 374, 375, 386, 392, 395, 396, 403, 405, 423, 425, 442). Other commenters urged OSHA to consider these cases minor injuries if they do not result in disease (see, *e.g.*, Exs. 15: 52, 290, 317, 403, 409, 434). Many agreed with the comments submitted by Bellin Hospital, which stated "[r]ecording of all Significant Exposures is unnecessary. Seroconversions after exposure, regardless of mode of exposure is appropriate recordkeeping only" (Ex. 15: 38). Several commenters made similar points. For example, Atlantic Dry Dock (Ex. 15: 179) wrote that "[n]ot all contact [with blood or other potentially infectious materials] will result in an infection. There is no injury/illness unless an infection has actually resulted from the contact."

Some commenters suggested that only those cases that resulted in either medical treatment or seroconversion should be recorded on the Log (see, *e.g.*, Exs. 15: 48, 100, 213, 310, 395, 416, 423), while others advocated recording lacerations and puncture wounds only if they met the rule's general recording criteria (see, *e.g.*, Exs. 15: 52, 200, 203, 219, 260, 262, 265, 271, 313, 329, 348, 352, 353, 401). As Bell Atlantic (Ex. 15: 128) commented, "[s]erious lacerations and puncture wounds involving contact with bloodborne pathogens should be reported. But the mechanism driving such reporting is the severity of the wound and NOT the presence of bloodborne pathogens. Even with the absence of bloodborne pathogens, such serious injuries would be recorded."

The American Hospital Association and the Georgia Hospital Association expressed concern that bloodborne pathogen disease criteria require "the recording of all instances of certain conditions that meet specific criteria, whether or not they meet OSHA's established criteria for recordability (work-relationship; involves medical treatment or death, loss of consciousness, or in-patient hospitalization, or days away from work restricted work activity, or job transfer)" (Exs. 15: 100, 219).

Several commenters stated that the recording of all bloodborne pathogen incidents would be redundant and unnecessary (see, *e.g.*, Exs. 15: 66, 121, 299, 322, 408, 435). Some commenters said that OSHA's bloodborne pathogen standard already requires recordkeeping and tracking of bloodborne pathogen exposure incidents (see, *e.g.*, Exs. 15:39, 89, 121, 310, 351, 378, 393, 405, 416), and others remarked that general medical records already contained adequate data (see, *e.g.*, Exs. 15: 151, 152, 179).

A number of commenters discussed the effect on injury and illness statistics that would be caused by recording all bloodborne pathogen incidents (see, *e.g.*, Exs. 15: 39, 44, 48, 61, 66, 69, 126, 146, 151, 152, 179, 201, 239, 287, 290, 308, 313, 329, 345, 352, 353, 364, 405). The Society of the Plastics Industry, Inc. (Ex. 15: 364) said that "Requiring recording of exposure incidents rather than actual illnesses will improperly inflate the statistics regarding these diseases." Patrick Tyson, a partner at Constangy, Brooks & Smith, LLC, (Ex. 15: 345) stated:

> In effect, the Proposed Recordkeeping Rule would include on the Log those exposure incidents where a medical follow-up examination actually rules out the resulting illness. I believe that the Logs should not be used in this fashion any more than they should be used to record incidents of high levels of workplace noise in the absence of actual hearing loss, or incidents of employee exposure to highly repetitive jobs in the absence of resulting musculo-skeletal disorders. Simply stated, the OSH Act does not contemplate or intend the recording of mere exposure incidents on the OSHA Log. To do so would artificially overstate the relative safety and health risk in the American workplace.

On the other hand, a number of commenters recommended that OSHA require the recording of all bloodborne pathogen incidents as defined in the bloodborne pathogens standard (see, *e.g.*, Exs. 24, 15: 72, 153, 181, 196, 198, 289, 379, 380, 418). Several of these commenters urged the recording of all exposure incidents to improve the information on these injuries and promote better protection for workers (see, *e.g.*, Exs. 24, 15: 72, 153, 181, 196, 289, 379, 380). The American Association of Occupational Health Nurses (AAOHN) remarked "The benefit in keeping these detailed records of bloodborne pathogen exposures will be the ability to track the root cause of resultant injuries and illnesses, regardless of latency" (Ex. 15: 181). The National Association of Operating Room Nurses (Ex. 15: 72) added "Reporting exposures may raise consciousness resulting in work practice changes and decreased hazard."

Two commenters cited the severity of these incidents as a reason for requiring the recording of all exposure incidents (Exs. 24; 15: 379). The American Nurses Association based its arguments on the severity of the risk, stating "While the Center for Disease Control and Prevention (CDC) Cooperative Needlestick Surveillance Group reported no seroconversions to HIV positive from mucous membrane or skin exposure, Hepatitis infections have been reported following exposures via these routes. The nature of the risk to HIV however small is very severe, deadly in fact; and the risk of Hepatitis is even greater. Because of the severity of the risk, we believe that all exposures must be recorded" (Ex. 24). The Service Employees International Union (SEIU) added "The lives of thousands of health

care workers each year are unnecessarily devastated by occupational exposure to hepatitis B, hepatitis C and HIV. A workplace exposure to blood or other potentially infectious materials represents a significant event in the life of a health care worker, regardless of whether or not the exposure results in infection with hepatitis B, hepatitis C or HIV" (Ex. 15: 379).

A few commenters remarked on the need for consistency between the bloodborne pathogens standard and the recordkeeping requirements (see, *e.g.*, Exs. 15: 153, 198, 379). The National Association for Home Care (NAHC) stated "NAHC believes that OSHA should maintain consistency between individual OSHA bloodborne pathogen requirements and general OSHA reporting requirements. Reporting of all exposure incidents is consistent with OSHA's bloodborne pathogen regulations for health care settings which require medical follow-up of employees for all exposure incidents" (Ex. 15: 198).

Several commenters suggested recording all incidents as a method for masking the identity of workers who actually contract disease as a result of their injury (see, *e.g.*, Exs. 15: 379, 380, 418). The AFL–CIO (Ex. 15: 418) stated:

> The AFL–CIO believes that exposures to bloodborne pathogens pose a unique case with respect to confidentiality and privacy concerns. As the Agency has recognized in the Bloodborne Pathogen Standard, 29 CFR 1910.1030, there are real and legitimate concerns about discrimination against individuals who have tested positive for HIV and other bloodborne infectious diseases. To address these legitimate confidentiality concerns, the AFL–CIO believes that a different approach to recording cases related to bloodborne pathogens is required. For these cases, we recommend that the Agency require the recording of needlestick injuries and all exposures to blood or blood contaminated body fluids on the Log 300 and on the 301. Cases involving actual seroconversions should be recorded in the confidential medical record. This approach would be consistent with the approach and language in the bloodborne pathogen standard. It would permit the log to be used to track individual cases of exposure for prevention purposes, while at the same time maintaining the confidentiality of individuals whose health status had changed as a result of exposure. The AFL–CIO recognizes that this approach will require the recording of exposure incidents which do not result in the change of health status and sets different criteria for recording cases related to bloodborne pathogens. Given the unique confidentiality concerns associated with this set of conditions, we believe that this special treatment for these conditions is warranted.

After a review of the many comments in the record on this issue, OSHA has decided to require the recording of all workplace injuries from needlesticks and sharp objects that are contaminated with another person's blood or other potentially infectious material (OPIM) on the OSHA Log. These cases must be recorded, as described above, as privacy concern cases, and the employer must keep a separate list of the injured employees' names to enable government personnel to track these cases. OSHA does not agree with those commenters who were of the opinion that contaminated needlestick and sharps injuries are minor injuries comparable in importance to a puncture by a sewing needle or leather punch. OSHA also disagrees with those commenters who believed these incidents are merely exposure incidents roughly comparable with exposure to loud noises. These incidents are clearly injuries, where the worker has experienced a cut or laceration wound.

OSHA recognizes that these injuries are different from most workplace cuts and lacerations, whose seriousness depends largely on the size, location, jaggedness, or degree of contamination of the cut, which determines the need for medical treatment, restricted work, or time away for recuperation and thus the recordability of the incident. In contrast, all injuries from contaminated needles and sharps are serious because of the risk of contracting a potentially fatal bloodborne disease that is associated with them.

Many commenters argued that needlestick and sharps injuries are not the kinds of injuries that Congress intended employers to record, as articulated in the OSH Act (see, *e.g.*, Exs. 15: 239, 308, 313, 345, 352, 353, 375, 395). As discussed earlier in the Legal Authority section, OSHA disagrees, believing that Congress mandated the recording of all non-minor injuries and illnesses as well as all injuries resulting in medical treatment or one of the other general recording criteria. OSHA finds that needlestick and sharps injuries involving blood or other potentially infectious materials are non-minor injuries, and therefore must be recorded. This conclusion is consistent with the Senate Committee on Appropriations report accompanying the fiscal year 1999 *Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriation Bill, 1999* (S. 2440) which included the following language:

> Accidental injuries from contaminated needles and other sharps jeopardize the well-being of our Nation's health care workers and result in preventable transmission of devastating bloodborne illnesses, including HIV, hepatitis B, and hepatitis C. The committee is concerned that the OSHA 200 Log does not accurately reflect the occurrence of these injuries. The committee understands that the reporting and recordkeeping standard (29 CFR 1904) requires the recording on the OSHA 200 Log of injuries from potentially contaminated needles and other sharps that result in: the recommendation or administration of medical treatment beyond first aid; death, restriction of work or motion; loss of consciousness, transfer to another job, or seroconversion in the worker. Accidental injuries with potentially contaminated needles or other sharps require treatment beyond first aid. Therefore, the Committee urges OSHA to require the recording on the OSHA 200 log of injuries from needles and other sharps potentially contaminated with bloodborne pathogens (Senate Report 105–300).

OSHA finds that these injuries are significant injuries because of the risk of seroconversion, disease, and death, they pose (see the preamble to the OSHA Bloodborne Pathogens Standard at 56 FR 64004).

OSHA recognizes that requiring the recording of all injuries from contaminated needles and sharps will result in more cases being recorded on employers' Logs and will increase the number of such injuries reflected in the Nation's statistics. However, the Agency does not agree that the statistics will be inappropriately inflated. Instead, OSHA believes that the statistics will henceforth include, for the first time, cases that reflect the incidence of these significant injuries accurately. Adding these cases to the Nation's statistics will create a more accurate accounting of work-related injury and illness cases, information that will be useful to employers, employees, the government and the public. In addition, the collection of this information at the establishment level will generate data employers and employees can use to analyze injury and illness patterns and make improvements in work practices and equipment. Recording these injuries will thus help to realize one of this rulemaking's primary goals, to improve the utility and quality of the information in the records.

If OSHA were to adopt a final rule that only required the recording of seroconversion cases and cases that met the general recording criteria, as many commenters suggested (see, *e.g.*, Exs. 15: 52, 200. 203, 219, 260, 262, 265, 271, 313, 329, 348, 352, 353, 401), the Nation's statistics would not be as complete and accurate, and workplace records would not have the same preventive value for employees and employers. In addition, that approach would be more complex because it

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would require employers to evaluate each case against several criteria before recording it. The approach taken in the final rule is considerably simpler. Recording all such injuries also helps to protect the privacy of workers who have been injured in this way. Needlestick and sharps injuries raise special privacy concerns. The comments on this subject show a universal concern for the privacy of a worker's medical information and disease status, and OSHA has taken several special precautions, discussed elsewhere in the preamble, to protect this privacy. Several commenters suggested recording all needlesticks and sharps incidents as a method for masking the identify of workers who actually contract disease (see, *e.g.*, Exs. 15: 379, 380, 418). OSHA has adopted this practice in the final rule because recording all of these injuries will help to protect the privacy of individual workers as well as produce higher quality data.

OSHA disagrees with those commenters who argued that the § 1904.8 recording requirement would be duplicative or redundant with the requirements in the Bloodborne Pathogens standard (29 CFR 1910.1030). That standard requires the employer to document the route(s) of exposure and the circumstances under which the exposure incident occurred, but does not require that it be recorded on the Log (instead, the standard requires only that such documentation be maintained with an employee's medical records). The standard also has no provisions requiring an employer to aggregate such information so that it can be analyzed and used to correct hazardous conditions before they result in additional exposures and/or infections. The same is true for other medical records kept by employers: they do not substitute for the OSHA Log or meet the purposes of the Log, even though they may contain information about a case that is also recorded on the Log.

OSHA is requiring only that lacerations and puncture wounds that involve contact with another person's blood or other potentially infectious materials be recorded on the Log. Exposure incidents involving exposure of the eyes, mouth, other mucous membranes or non-intact skin to another person's blood or OPIM need not be recorded unless they meet one or more of the general recording criteria, result in a positive blood test (seroconversion), or result in the diagnosis of a significant illness by a health care professional. Otherwise, these exposure incidents are considered only to involve exposure and not to constitute an injury or illness. In contrast, a needlestick laceration or puncture wound is clearly an injury and, if it involves exposure to human blood or other potentially infectious materials, it rises to the level of seriousness that requires recording. For splashes and other exposure incidents, the case does not rise to this level any more than a chemical exposure does. If an employee who has been exposed via a splash in the eye from the blood or OPIM of a person with a bloodborne disease actually contracts an illness, or seroconverts, the case would be recorded (provided that it meets one or more of the general recording criteria).

Privacy Issues

There was support in the record for OSHA's proposal to record occupationally acquired bloodborne pathogen diseases simply as the initial bloodborne exposure incident to protect employee confidentiality. Eli Lilly and Company (Ex. 15: 434) commented:

> Lilly agrees with the Agency's proposed method of recording exposure incidents that result in disease. All of these recordable incidents should be recorded simply as the type of bloodborne exposure incident (*e.g.* needlestick) with no reference to the type of disease. While Lilly is concerned about protecting the privacy of every individual employee's medical information, Lilly concedes that the current social stigma resulting from bloodborne pathogen diseases demands a more simple recordkeeping requirement.

Privacy issues, however, concerned many of the commenters to the rulemaking record. Metropolitan Edison/Pennsylvania Electric Company (M/P), for example, was so concerned with employee privacy that "[d]ue to the sensitivity of Bloodborne Pathogenic diseases and related confidentiality concerns, M/P disagrees with recording these types of incidents" (Ex. 15: 254). The American Automobile Manufacturers Association (AAMA), among others, expressed concern that the recording requirement for bloodborne pathogen diseases would discourage employees from reporting exposures and might also discourage individuals from seeking treatment. AAMA wrote:

> [m]any individuals who contract an infectious disease from a workplace event or exposure will be against having their names on the OSHA log for scrutiny by any employee or former employee of the establishment. To openly list (on the OSHA log) an individual with an infectious disease will discourage some employees from reporting exposures. It may also discourage individuals from seeking treatment, which may be lifesaving or which may limit the spread of the disease. We oppose the development of any system which directly or indirectly discourages individuals from seeking medical evaluation or treatment, for the sake of data collection (Ex. 15: 409).

The AAMA proposed as an alternative "to remove all personal identifiers for infectious disease cases from the OSHA log. Some type of employer created coding system could be instituted, as long as the code was consistently applied. Authorized medical personnel and government representatives would be the only individuals permitted access to the personal identifiers and/or key to the coding system" (Ex. 15: 409). The Quaker Oats Company and the Ford Motor Company supported similar alternatives (Exs. 15: 289, 347). A number of commenters specifically supported the use of a coding system (see, *e.g.*, Exs. 15: 146, 213, 260, 262, 265, 345, 347, 409).

OSHA shares these commenters' concern about the privacy of employees who seroconvert as the result of a bloodborne pathogens-related needlestick or sharps incident and finds that these incidents are clearly the type of non-minor occupational injury and illness Congress intended to be included in the OSHA recordkeeping system. If the Agency were to exclude these cases categorically from the records, it would not be meeting the requirements of the OSH Act to produce accurate statistics on occupational death, injury and illness.

The final recordkeeping rule addresses this issue by prohibiting the entry of the employee's name on the OSHA 300 Log for injury and illness cases involving blood and other potentially infectious material. Further, by requiring employers to record all needlestick and sharps incidents, regardless of the seroconversion status of the employee, coworkers and representatives who have access to the Log will be unable to ascertain the disease status of the injured worker. OSHA believes that the privacy concern case approach of the final rule obviates the need for a coding system because the case number assigned to the recorded injury will serve the purpose of a code, without adding additional complexity or burden. A discussion of access to the records is contained in the portion of the preamble associated with section 1904.35, Employee Involvement.

The College of American Pathologists objected to the inclusion of hepatitis C in the list of bloodborne pathogen diseases. They commented that "the great majority of cases of hepatitis C lack any identifiable source of exposure. More cases of HCV infection occur among non-health care workers than among health care workers. To presume that an individual who is infected with HCV acquired it on the job just because they work in a health care setting is unjustified" (Ex. 15: 37). On the other hand, a commenter from Waukesha Memorial Hospital suggested that OSHA "should include all blood borne pathogen disease that develops as a result of an exposure incident, not just HIV, Hep B, Hep C, even though those are the major players in a hospital setting. Since we must teach that there are many bloodborne pathogens, it doesn't make sense to me to only record some and not all" (Ex. 15: 436). OSHA believes that hepatitis C cases should, like other illness cases, be tested for recordability using the geographic presumption that provides the principal rationale for determining work-relatedness throughout this rule. OSHA also agrees with the commenter from Waukesha Memorial Hospital that *all* bloodborne pathogen diseases resulting from events or exposures in the workplace should be recorded. Therefore, OSHA has modified the final regulatory text of paragraph 1904.8(b)(4)(i) to reflect this decision.

Section 1904.9 Additional Recording Criteria for Cases Involving Medical Removal Under OSHA Standards

The final rule, in paragraph 1904.9(a), requires an employer to record an injury or illness case on the OSHA 300 Log when the employee is medically removed under the medical surveillance requirements of any OSHA standard. Paragraph 1904.9(b)(1) requires each such case to be recorded as a case involving days away from work (if the employee does not work during the medical removal) or as a case involving restricted work activity (if the employee continues to work but in an area where exposures are not present.) This paragraph also requires any medical removal related to chemical exposure to be recorded as a poisoning illness.

Paragraph 1904.9(b)(2) informs employers that some OSHA standards have medical removal provisions and others do not. For example, the Bloodborne Pathogen Standard (29 CFR 1910.1030) and the Occupational Noise Standard (29 CFR 1910.95) do not require medical removal. Many of the OSHA standards that contain medical removal provisions are related to specific chemical substances, such as lead (29 CFR 1901.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), formaldehyde (29 CFR 1910.1048), and benzene (29 CFR 1910.1028).

Paragraph 1904.9(b)(3) addresses the issue of medical removals that are not required by an OSHA standard. In some cases employers voluntarily rotate employees from one job to another to reduce exposure to hazardous substances; job rotation is an administrative method of reducing exposure that is permitted in some OSHA standards. Removal (job transfer) of an asymptomatic employee for administrative exposure control reasons does not require the case to be recorded on the OSHA 300 Log because no injury or illness—the first step in the recordkeeping process—exists. Paragraph 1904.9(b)(3) only applies to those substances with OSHA mandated medical removal criteria. For injuries or illnesses caused by exposure to other substances or hazards, the employer must look to the general requirements of paragraphs 1910.7(b)(3) and (4) to determine how to record the days away or days of restricted work.

The provisions of § 1904.9 are not the only recording criteria for recording injuries and illnesses from these occupational exposures. These provisions merely clarify the need to record specific cases, which are often established with medical test results, that result in days away from work, restricted work, or job transfer. The § 1904.9 provisions are included to produce more consistent data and provide needed interpretation of the requirements for employers. However, if an injury or illness results in the other criteria of § 1904.7 (death, medical treatment, loss of consciousness, days away from work, restricted work, transfer to another job, or diagnosis as a significant illness or injury by a physician or other licensed health care professional) the case must be recorded whether or not the medical removal provisions of an OSHA standard have been met.

The recording of OSHA mandated medical removals was not addressed in the 1996 recordkeeping proposal. OSHA has included the provisions of § 1904.9 in the final rule to address a deficiency noted by a number of commenters, and as a replacement for criteria that were contemplated for the recording of various ailments in proposed Appendix B (61 FR 4063–4065). For example, R. L. Powell, Personnel Safety Manager for Union Carbide Corporation, (Ex. 15: 396) asked about medical removal and restricted work:

> How does this criteria [restricted work] apply to "medical removal?" Medical removal is sometimes mandated by other OSHA standards under certain conditions. A similar technique may also be used by a physician to conduct controlled tests to assess the impact of workplace factors on a condition such as a chemical sensitivity.

A number of commenters recommended the use of medical removal criteria as the correct recording level for various substances listed in proposed Appendix B (see, *e.g.*, Exs. 22; 15: 113, 155, 192, 199, 213, 242, 262, 272, 303, 304, 307, 326, 338, 340, 349). Many of these commenters suggested the medical removal criteria as a substitute for the proposed recording levels for lead and cadmium (Ex. 22; 15: 113, 155, 192, 340, 349). For example, Newport News Shipbuilding (Ex. 15: 113) said:

> The proposed regulation requires recording lead and cadmium cases based on biological action levels rather than on the onset of illness. The purpose of the biological action level is to identify those employees who are at greater risk of reaching the limits for medical removal, so that onset of illness may be prevented. The use of biological action levels as the basis of defining and recording illness is inappropriate. Rather, lead and cadmium cases should be recorded when medical removal is required by the specific standard.

The Institute of Scrap Recycling Industries, Inc. (Ex. 15: 192) added:

> This [proposed] statement clearly subverts the clear intent of the OSHA lead standard that a blood lead level of 50 µg/100 g of whole blood and not 40 µg/100 g of whole blood is the criteria for medical removal and therefore also the criteria for documentation on the OSHA injury and illness log. Had the scientific evidence on which the OSHA lead standard was based pointed clearly to 40 µg/100 g of whole blood as the medical removal standard and therefore the standard for documentation on the OSHA injury and illness log the standard would have reflected this. Therefore it would clearly subvert the purpose and scope of the OSHA lead standard, that was based on scientific evidence and an exhaustive public comment period on the scientific data, to establish a clear benchmark for a recordable event on the injury and illness log without the benefit of supporting scientific study and data and a public comment period on such information.

The Institute of Scrap Recycling Industries, Inc is incorrect about the lead standard's determination of recording criteria on the OSHA injury and illness log. The lead standard (§ 1910.1025) does not specifically address the recording issue, but the lead standard does address the medical removal issue. The Institute points to the benefit of using medical removal criteria for recording purposes, and OSHA agrees that these criteria are useful for recordkeeping purposes. The medical removal provisions of each standard were set using scientific evidence established in the record devoted to that rulemaking. OSHA takes care when setting the medical removal provisions of standards to ensure that these provision reflect a material harm, *i.e.*, the existence of an abnormal condition that is non-minor and thus

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worthy of entry in the OSHA injury and illness records.

Other commenters urged OSHA to use the medical removal criteria as a replacement for all of proposed Appendix B. (see, *e.g.*, Exs. 15: 199, 213, 242, 262, 303, 304, 307, 326, 338, 375). For example, Southern Nuclear Operating Company (Ex. 15: 242) stated that:

> Mercury, Lead, Cadmium, Benzene: In these cases, it is appropriate to distinguish between biological markers that merely point to exposure versus those that relate to illness or disease. All of the recordability criteria for these substances are based on various "action" levels stated in their respective OSHA regulations. Southern Nuclear Operating Company believes that the appropriate criteria for recording these cases as illnesses should be the "medical removal" criteria stated in their respective regulations coupled with a physician's diagnosis of disease rather that the "action" levels as stated in the proposal. These "medical removal" criteria are more indicative of disease or illness. If the "action" levels for these substances are used as the recording criteria, the number of illnesses recorded on the OSHA log would more accurately reflect the numbers of workers covered by a given exposure control program as opposed to the number of illnesses that result from an inadequate program.

The American Petroleum Institute (API) argued that:

> API incorporates in its recommended Appendix B the recording of cases when medical removal is required by a specific OSHA standard. API concedes this is inconsistent with the concept of "serious or significant"—and inconsistent with API's fundamental belief that actions by employers to prevent cases from becoming serious should not be recorded—because such medical removals are by design preventive; that is, intended to occur before a case becomes serious. However, API acknowledges that it is extremely difficult to define and get substantial agreement on any straight-forward and verifiable criteria when such cases are indeed "serious". Therefore, API has decided to recommend the medical-removal criterion for Appendix B as the best on-balance solution for situations involving toxic substance adsorption. (Ex. 15: 375)

A number of commenters opposed the use of mandatory medical removal levels for injury and illness recording purposes (see, *e.g.*, Exs. 25; 15: 146, 193, 258, 261, 304, 305, 318, 346, 358). Many argued that the OSH Act did not support the use of medical removals (see, *e.g.*, Exs. 25; 15: 258, 261, 304, 358). For example, the National Association of Manufacturers (NAM) commented:

> There is no reference in Section 24(a) or Section 8(c)(2) of the OSH Act to recording exposure incidents that do not result in disabling, serious or significant injuries or illnesses; or is there any reference in those sections to medical removal provisions or other action levels that do not result in disabling, serious or significant injuries or illnesses. On the other hand, Section 8(c)(3) does discuss—as a separate component of OSHA's occupational safety and health statistics program—maintaining records of employee exposures to toxic materials and harmful physical agents pursuant to standards issued under Section 6 of the OSH Act.
>
> This is a rulemaking about the statistical program for tracking disabling, serious or significant injuries and illnesses—nothing more and nothing less. We believe Congress determined that those are the criteria that OSHA should utilize for this particular component of its statistical program. A statistical program that aggregates disabling, serious or significant injuries and illnesses with other conditions and exposure incidents, is contrary to both the congressional directive and the goal of this recordkeeping system.

While these commenters are correct in noting that the OSH Act does not specifically address medical removal levels and whether or not cases meeting these levels should be recorded, the Act also does not exclude them. The Act does require the recording of injuries and illnesses that result in "restriction of work or motion" or "transfer to another job." OSHA finds that cases involving a mandatory medical removal are cases that involve serious, significant, disabling illnesses resulting in restriction of work and transfer to another job, or both. These medical restrictions result either in days away from work (form of restriction) or days when the worker can work but is restricted from performing his or her customary duties.

Other commenters objected to recording medical removals because they are precautionary in nature (Ex. 15: 146, 193, 258, 261, 305, 318, 346). The American Foundrymen's Society, Inc. (Ex. 15: 346) argued that:

> An abnormally high level of a toxic material in an individual's blood (*e.g.*, a lead level at or above the action level or the level requiring "medical removal" under OSHA's Lead Standard) is not and should not, in itself, be considered a recordable injury or illness. A preventive or prophylactic measure such as medical removal (as opposed to a restorative or curative measure) is not and should not be deemed medical treatment, a job transfer or restricted activity for purposes of recordability in the absence of a diagnosis of a substantial impairment of a bodily function.

As stated previously, a "diagnosis of substantial impairment of a bodily function" is not required for a case to meet OSHA recordkeeping criteria, nor is it a limitation to recordability under the OSH Act. Many injuries and illnesses meet the recording criteria of the Act but lack diagnosis of a substantial impairment of a bodily function. Although the medical removal provisions are included in OSHA's standards to encourage participation in the medical program by employees and to prevent progression to serious and perhaps irreversible illness, they also reflect illnesses caused by exposures in the workplace and are thus themselves recordable. The workers are being removed not only to prevent illness, but to prevent further damage beyond what has already been done. Thus OSHA does not agree that medical removal measures are purely preventive in nature; instead, they are also remedial measures taken when specific biological test results indicate that a worker has been made ill by workplace exposures.

OSHA has therefore included section 1904.9 in the final rule to provide a uniform, simple method for recording a variety of serious disorders that have been addressed by OSHA standards. The § 1904.9 provisions of the final rule cover all of the OSHA standards with medical removal provisions, regardless of whether or not those provisions are based on medical tests, physicians' opinions, or a combination of the two. Finally, by relying on the medical removal provisions in any OSHA standard, section 1904.9 of the final rule establishes recording criteria for future standards, and avoids the need to amend the recordkeeping rule whenever OSHA issues a standard containing a medical removal level.

Section 1904.10 Recording Criteria for Cases Involving Occupational Hearing Loss

The recording criteria employers should use to record occupational hearing loss on the OSHA recordkeeping forms have been an issue since OSHA first proposed to require hearing conservation programs for general industry employers (39 FR 37775, October 24, 1974). Job-related hearing loss is a significant occupational safety and health issue because millions of workers are employed in noisy workplaces and thousands of workers experience noise-induced hearing loss each year. Noise-induced hearing loss is a serious and irreversible condition that may affect the safety and well-being of workers for the rest of their lives.

For the nation as a whole in 1997, the BLS reported only 495 cases of occupational hearing loss resulting in days away from work (http://stats.bls.gov/case/ostb0684.txt; BLS Characteristics Data Table R15 of 04/22/1999). Hearing loss is not the type of occupational injury or illness that typically requires days away from work for recuperation, as is often the case for a fracture, fall, or carpal tunnel syndrome case. OSHA believes that there are many cases of hearing loss—probably numbering in the thousands—that occur every year as a result of job-related noise exposure but do not result in days away from work and are thus not captured in the BLS statistics. Because these hearing losses are often permanent, a large number of Americans, both working and retired, are currently suffering the effects of hearing loss due to occupational exposure.

The changes being made to the OSHA 300 form in the final rule will improve the quality of the data collected nationally on this important occupational condition by providing consistent hearing loss recording criteria, thus improving the consistency of the hearing loss statistics generated by the BLS occupational injury and illness collection program. National hearing loss statistics will also be improved because OSHA has added a column to the OSHA 300 Log that will require employers, for the first time, to separately collect and summarize data specific to occupational hearing loss. These changes mean that the BLS will collect hearing loss data in future years, both for cases with and without days away from work, which will allow for more reliable published statistics concerning this widespread occupational disorder.

Paragraph 1904.10(a) of the final rule being published today requires an employer to record an employee's hearing test (audiogram) result if that result reveals that a Standard Threshold Shift (STS) for that employee has occurred. If the employee is one who is covered by the medical surveillance requirements of OSHA's Occupational Noise standard (29 CFR 1910.95), compliance with the standard will generate the information necessary to make recording decisions.

If the employee is not covered by the 29 CFR 1910.95 noise standard, OSHA rules do not require the employer to administer baseline or periodic audiograms, and the 1904 rule does not impose any new requirements for employers to obtain baseline information where it is not already required. However, some employers conduct such tests and acquire such information for other reasons. If the employer's workplace is a high noise environment (i.e., has noise levels that exceed 85 dBA) and the employer has the relevant audiogram information for an employee, the employer must record any identified work-related hearing loss equal to or greater than an OSHA-defined STS on the Log. This means that an employer in the construction industry, for example, who is aware that his or her work activities regularly generate high noise levels and who has audiometric data on the hearing level of the employees exposed to those noise levels must record on the Log any STS detected in those workers. OSHA believes that this approach to the recording of work-related hearing loss cases among these workers not covered by the noise standard is appropriate because it is reasonable, protective, and administratively straightforward.

Paragraph 1904.10(b)(1) of the final rule defines an STS as that term is defined in the Occupational Noise Standard: as a change in an employee's hearing threshold, relative to the baseline audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears. The Noise standard, at paragraph 1910.95(c)(1), describes the employees in general industry who are covered by the required hearing conservation program as follows:

> The employer shall administer a continuing, effective hearing conservation program, as described in paragraphs (c) through (o) of this section, whenever employee noise exposures equal or exceed an 8-hour time-weighted average sound level (TWA) of 85 decibels measured on the A scale (slow response) or, equivalently, a dose of fifty percent. For purposes of the hearing conservation program, employee noise exposures shall be computed in accordance with appendix A and Table G–16a, and without regard to any attenuation provided by the use of personal protective equipment.

Paragraph 1904.10(b)(2) of the final recordkeeping rule directs employers how to determine whether a recordable STS has occurred. The paragraph deals with two situations: (1) where the employee has not previously experienced such a hearing loss, and (2) where the employee has experienced a past recordable hearing loss. If the employee has never previously experienced a recordable hearing loss, the employer must compare the results of the employee's current audiogram with the employee's baseline audiogram, if the employee has a baseline audiogram. The employee's baseline audiogram could either be that employee's original baseline audiogram or a revised baseline audiogram adopted in accordance with paragraph (g)(9) of 29 CFR 1910.95. For employees who have not previously had a recordable hearing loss with that employer, the loss in hearing is computed using the preemployment hearing test result so that any hearing loss the employee may have experienced before obtaining employment with the employer is not attributed to noise exposure in that employer's workplace.

If the employee has previously experienced a recordable hearing loss, the employer must compare the employee's current audiogram with the employee's revised baseline audiogram (i.e., the audiogram reflecting the prior recorded hearing loss). For employees who have had a previously recordable hearing loss with that employer, the final recordkeeping rule thus ensures that the employer does not record the same case of hearing loss twice, but that if a second STS occurs, the employer will record that additional hearing loss.

Paragraphs 1904.10(b)(3) and (4) of the final rule allow the employer to take into account the hearing loss that occurs as a result of the aging process and to retest an employee who has an STS on an audiogram to ensure that the STS is permanent before recording it. The employer may correct the employee's audiogram results for aging, using the same methods allowed by the OSHA Noise standard (29 CFR 1910.95). Appendix F of § 1910.95 provides age correction for presbycusis (age-induced hearing loss) in Tables F–1 (for males) and F–2 (for females). Further, as permitted by the Noise standard, the employer may obtain a second audiogram for employees whose first audiogram registers an STS if the second audiogram is taken within 30 days of the first audiogram. The employer may delay recording of the hearing loss case until the STS is confirmed by the second audiogram and is, or course, not required to record the case if the second audiogram reveals that the STS was not permanent.

Paragraph 1904.10(b)(5) of the final rule establishes how employers are to determine the work-relatedness of hearing loss cases. This paragraph specifies that, in accordance with the recordkeeping rule's definition of work-relationship, hearing loss is presumed to be work-related for recordkeeping purposes if the employee is exposed to noise in the workplace at an 8-hour time-weighted average of 85 dB(A) or greater, or to a total noise dose of 50 percent, as defined in 29 CFR 1910.95. (Noise dose is defined as the amount of actual employee exposure to noise relative to the permissible exposure limit for noise; a dose greater than 100% represents exposure above the limit.) For hearing loss cases where the employee is not exposed to this level of workplace noise, or where the employee is not covered by the Occupational Noise standard, the employer must use the rules set out in § 1904.5 to determine if the hearing loss is to be

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considered work related for recordkeeping purposes.

Paragraph 1904.10(b)(6) allows the employer not to record a hearing loss case if physician or other licensed health care professional determines that the hearing loss is not work-related or has not been aggravated by occupational noise exposure. This provision is consistent with the Occupational Noise standard, and it allows the employer not to record a hearing loss case that is not related to workplace events or exposures; examples of such cases are hearing loss cases occurring before the employee is hired or those unrelated to workplace noise.

The recordkeeping provisions in section 1904.10 of the final recordkeeping rule thus match the provisions of the Occupational Noise standard by (1) covering the same employers and employees (with the exception of cases occurring among employees not covered by that standard whose employers have audiometric test results and high-noise workplaces); (2) using the same measurements of workplace noise; (3) using a common definition of hearing loss, i.e., the STS; (4) using the same hearing loss measurement methods; (5) using the same definitions of baseline audiogram and revised baseline audiogram; (6) using the same method to account for age correction in audiogram results; and (7) allowing certain temporary threshold shifts to be set aside if a subsequent audiogram demonstrates that they are not permanent or a physician or other licensed health care professional finds they are not related to workplace noise exposure.

The Former Rule

The regulatory text of OSHA's former recordkeeping rule did not specifically address the recording of hearing loss cases, and the § 1910.95 Occupational Noise Standard does not address the recording of hearing loss cases on the OSHA Log. However, the 1986 *Recordkeeping Guidelines* provided clear advice to employers to the effect that work-related hearing loss was a recordable disorder, that it could be either an injury or illness, depending on the events and exposures causing the hearing loss, and that all hearing loss illnesses were required to be recorded, regardless of the industry in which the employer worked (Ex. 2, p. 4). However, the *Guidelines* did not provide specific guidance on the kinds of hearing test or audiogram results that would constitute a recordable, work-related hearing loss.

In 1990, OSHA considered issuing a Compliance Directive addressing the recording of hearing loss cases on employers' OSHA 200 Logs, but decided that the issue of the recording of hearing loss cases should be addressed through notice-and-comment rulemaking at the time of the revision of the recordkeeping rule. To address this topic in the interim before the final recordkeeping rule was issued, OSHA sent a memorandum to its field staff (June 4, 1991) to clarify its enforcement policy on the recording of occupational hearing loss and cumulative trauma disorders on the OSHA 200 Log, on the grounds that these cases "have received national attention and require immediate clarification." The memorandum specified that "OSHA will issue citations to employers for failing to record work related shifts in hearing of an average of 25 dB or more at 2000, 3000, and 4000 hertz (Hz) in either ear on the OSHA 200 Log." The interim enforcement policy was intended to provide a conservative approach to the issue until the recordkeeping rulemaking was completed. The interim policy stated that "The upcoming revision of the recordkeeping regulations, guidelines and related instructional materials will address the recordability criteria for all work related injuries and illnesses." The memo also mentioned the use of standard threshold shifts (STS) results, saying:

> Employers are presently required by 29 CFR 1910.95 to inform employees in writing within 21 days of the determination of a Standard Threshold Shift (an average of 10 dB or more at 2000, 3000 and 4000 Hz in either ear) and to conduct specific follow-up procedures as required in paragraph (g) of the standard. Employers should be encouraged to use this information as a tracking tool for focusing noise reduction and hearing protection efforts.

The Proposal

The proposed recordkeeping criterion for recording a case of hearing loss (61 FR 4064) was an average shift of 15 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears after the employee's hearing loss had been adjusted for presbycusis (age-related hearing loss). OSHA proposed to permit employers to delete the record of the hearing loss injury or illness if a retest performed within 30 days indicated that the original shift was not permanent. Once a 15 dB work-related shift had occurred, however, OSHA proposed that the employee's baseline audiogram (for recordkeeping purposes) be adjusted to reflect that loss. A subsequent audiogram would have to reveal an additional 15 dB shift from the new or revised baseline value to be considered a new hearing loss injury or illness. OSHA proposed to presume work-relationship if an employee was exposed on the job to an 8-hour time-weighted average noise level equaling 85 dB(A) (61 FR 4064).

OSHA also raised several issues related to hearing loss recording in the proposal (61 FR 4064):

> The lowest action level in the noise standard is an average shift of 10 decibels or more at 2000, 3000 and 4000 hertz. OSHA is proposing the 15 decibel criteria for recordkeeping purposes to account for variations in the reliability of individual audiometric testing results.
>
> OSHA asks for input on which level of a shift in hearing should be used as a recording criteria; 10 decibels? 20 decibels? 25 decibels? For each level, what baseline should be used? Preemployment (original) baseline? Audiometric zero? Is adjusting for presbycusis appropriate?

Comments on the Proposal

OSHA's proposed recording criterion for hearing loss received more comments than the proposed criterion for any other type of injury or illness other than musculoskeletal disorders. The hearing loss comments cover a wide variety of issues, including which hearing test results should or should not be considered an OSHA recordable illness, the choice of baseline audiograms, retesting and persistence of hearing loss, determining work relatedness, the appropriateness of correcting audiograms for aging (presbycusis), and the role of physicians and other licensed health care professionals in the determination of recordable hearing loss cases. The issues raised by commenters are organized by topic and discussed below.

The Definition of Recordable Hearing Loss

There was limited support among commenters for OSHA's proposed 15 dB shift recording criterion (see, *e.g.*, Exs. 15: 50, 61, 84, 111, 113, 156, 188, 233, 281, 289, 349, 407). However, many of these commenters supported the use of a 15 dB shift as the recording criterion only if the final recordkeeping rule also reflected other changes, such as eliminating the correction for aging (see, *e.g.*, Exs. 15: 50, 188, 407) or limiting the recording of hearing loss to one case per worker per lifetime (Ex. 15: 349). For example, General Electric (Ex. 15: 349) suggested limiting the recording of hearing loss to one case per employee:

> GE supports recording an average standard threshold shift of 15 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears, adjusted for presbycusis and with a deletion upon retest as described. The establishment of the recording criteria at a level slightly higher than STS requiring action in the noise standards allows the employer the opportunity to take action before the STS progresses to a recordable injury. GE recommends, however, that, to reduce the administrative burden, the baseline not be revised after the shift, that the original baseline be maintained and the hearing loss only be recorded on the initial occasion of the 15 dB shift.

George R. Cook and Omar Jaurez, occupational audiologists (Ex. 15: 50), supported the 15dB level only if no adjustment for aging was allowed:

> [t]he Noise Standard has two loopholes in the identification of STS. First it allows for revision of baseline when the loss is persistent. The Standard does not identify persistence and it is possible to revise a baseline early and subsequent STSs would be postponed. The second loophole is the allowance of presbycusis which hides changes in hearing. Therefore, a criteria which separates the recording criteria from STS and protects the required STS follow-up is necessary. A 20 or 25 dB criteria is felt to be too much change.

Most of the commenters, however, did not support the proposed 15 dB criterion (see, *e.g.*, Exs. 22; 26; 15: 25, 45, 108, 110, 119, 137, 146, 154, 171, 177, 201, 203, 213, 218, 246, 251, 262, 278, 295, 310, 329, 331, 334, 343, 347, 348, 350, 358, 369, 394, 396, 405, 424). Most of these commenters recommended a recording criterion of a 25 dB shift, i.e., the criterion used in OSHA's interim enforcement policy (see, *e.g.*, Exs. 22; 15: 45, 119, 137, 146, 154, 171, 177, 201, 203, 218, 246, 262, 278, 329, 331, 334, 343, 348, 358, 395, 424). Con Edison wrote "[l]owering the dB shift criteria to 15 dB [from 25 dB] would result in recording cases which do not meet the clinical definition of hearing loss" (Ex. 15: 213), and the Amoco Corporation testified that OSHA should "[r]aise the hearing loss limit to a more appropriate indication of material impairment" (Ex. 22). The American Iron and Steel Institute (Ex. 15: 395) commented:

> The appropriate recording trigger should be the loss of hearing recognized by the American Medical Association (AMA) as the lowest indicator of any material impairment to the employee's hearing. According to the AMA, a person has suffered material impairment when testing reveals a 25 dB average hearing loss from audiometric zero at 500, 1000, 2000, and 3000 hertz. OSHA itself has recognized that this is the lowest level of hearing loss that constitutes any material hearing impairment. see 46 Fed. Reg. 4083 (Jan. 18, 1981). Below that level, an employee has suffered no noticeable injury or illness.

The American Iron and Steel Institute disagreed that a 10 or a 15 dB shift in hearing should be recorded, stating that "While a 15 dB shift is arguably closer to a serious injury than a 10 dB shift, neither is a principled approximation of the onset of any disabling illness or injury, and each is inconsistent with OSHA's acknowledgment in Forging Indus. Ass'n v. Secretary of Labor, 773 F.2d 1436, 1447 n.18 (4th Cir. 1985), that no injury results until a person experiences a 25 dB loss." (OSHA does not agree with this characterization of its position.)

Similarly, the Monsanto Company commented "OSHA acknowledges in the Hearing Conservation Amendment Standard that STS will occur and nothing is required to be done to prevent it from occurring. Therefore, it cannot be a measure of significantly impaired functional hearing capacity. In the preamble to this rule, OSHA cites several excerpts of testimony supporting this position" (Ex. 15: 295).

Vulcan Chemicals commented that it "believes the present requirement [of a hearing level shift of 25 dB for recordkeeping] is protective and recommends that the recordable criteria should remain at 25 decibels" (Ex. 15: 171). New England Power justified its support for a 25 dB shift as the recording criteria with the comment that there "is far too much variability with an individual subject and the equipment to ensure accuracy" (Ex. 15: 170), and Tosco, arguing in a similar vein, commented that the "existing 25 dB shift provides an easily identifiable measurement for determining injuries, and also provides for variation in background noise during testing, variability of the employee's health/hearing capability on the day being tested, as well as variation in the employee's home/social lifestyle which may contribute to hearing loss" (Ex. 15: 246). The Can Manufacturers Institute commented that a 25 dB shift criterion "would identify as consequential change in hearing acuity that is irreversible and minimize multiple recording of change over time" (Ex. 15: 331).

There was also support in the rulemaking record for using a 20 dB shift as a criterion for recording hearing loss (see, *e.g.*, Exs. 15: 108, 295, 396, 405, 423). Most of the reasons given for supporting this level were the same as those provided as support for a 25 dB shift recording criterion. For example, the Westinghouse Electric Corporation commented that a "20 decibel shift would not only allow for variances in individual audiometric tests, but would also allow for the fact that workplace noise levels are quite often more controlled and less severe than noise levels in the home environment (*e.g.*, trap shooting, stereo sound levels, lawn mowing, and other types of non job-related activities)" (Ex. 15: 405).

Commenting that a 20 dB shift is two times the action level of a 10 dB shift prescribed by OSHA's Occupational Noise standard (29 CFR 1910.95), Brown and Root, Inc. suggested that this level "would allow for a program to be initiated [at the action level] and working before a case becomes recordable. If the program, however, is not as effective as desired, the recordable level would require that the case be logged" (Ex. 15: 423). Finally, Union Carbide Corporation argued that using a 20 dB shift as a recording criterion.

> [i]s in the direction of simplicity since this is an even multiple of 10 dB, which is the standard threshold shift and the action level for triggering certain hearing conservation requirements. Having an even multiple makes it much easier to track two different baselines one for the hearing conservation requirements and one for recordkeeping requirements. Our experience has shown that it is an administrative nightmare to track 10 dB baselines for hearing conservation and 25 dB baselines for recordkeeping (Ex. 15: 396).

Industrial Health, Inc. (Ex. 15: 84), a mobile audiometry vendor, supported either a 10 dB or 15 dB persistent shift as the recording criterion and provided an analysis, using their data base of over 4 million audiograms. Their comments on the merits of the 10 dB and 15 dB options, and whether each change is significant and noise related, are:

> Noise relatedness: Using the OSHA shift formula across 2, 3 & 4 KHz (including OSHA's corrections for aging), a persistent shift of either 10dB or 15dB shows a strong correlation with audiogram patterns typical of exposure to noise (our samples showed more than 85 percent of such shifts appeared to be noise related, and most of the remainder had been flagged by the reviewing audiologist as either medical referrals or cases where the employee had given a medically related explanation for the shift in hearing). Hence, we conclude that a persistent shift based on the OSHA shift formula with age correction, whether 10 dB or 15 dB, is a reasonably accurate indication of a hearing change due to noise exposure provided that medically related shifts are excluded.
>
> Significance of change: We calculated historic shifts based on both a 10 dB shift and a 15 dB shift on a sample industrial database. The following results are for persistent shifts only. The results showed that 15 dB shifts occurred less often than 10 dB shifts (as would be expected), with approximately 70% as many 15 dB shifts as 10 dB shifts. When both shifts occurred for an employee, most (over 80%) of the 15 dB shifts occurred at exactly the same test dates as did the 10 dB shifts, although in some cases (less than 20%) the 15 dB shifts occurred at later times. In general, the agreement was surprisingly good—much better than we had expected. In most (about 80%) of the instances where a 10 dB shift occurred but a 15 dB shift did not,

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the significance of the 10 dB shift was questionable when the actual data were examined. Less than 5% of what we judged to be significant 10 dB shifts were missed by the 15 dB rule.

As a result, our analysis indicates the following (based again on all shifts having been demonstrated to be persistent):

a. A persistent 10 dB shift with age correction is a reasonably good yardstick for significant change due to noise, although it does flag some changes which are of questionable significance (perhaps as high as 20% of the shifts).

b. A persistent 15 dB shift with age correction is a better yardstick for significant change due to noise. In our tests it produced roughly 70 percent as many shifts as the 10 dB rule, but the difference was largely 10 dB shifts of questionable significance. It did report some changes later than the 10 dB rule and missed a few shifts (about 5%) which we judged to be of significance.

Finally, there was strong support in the rulemaking record for using a 10 dB shift (also identified as a standard threshold shift or STS in the OSHA Noise standard) as a recording criterion for hearing loss (see, *e.g.*, Exs. 26; 42; 15: 25, 110, 251, 310, 347, 350, 369, 394). For example, the American College of Occupational and Environmental Medicine noted that the "STS is the earliest reliable indication of measurable hearing loss for practical purposes. This is the earliest practical level of early detection and prevention of further loss is quite possible if the correct measures are taken" (Ex. 15: 251). The Ford Motor Company agreed. Commenting that it currently records any work-related hearing loss that results in an average loss of 10 dB or more, the company noted that "[r]ecording hearing loss in its early stage provides Ford the information to correct hazardous conditions and prevent serious impairment to an employee" (Ex. 15: 347). Ford further stated that its "method of recording occupational hearing loss is consistent with the requirement of the Hearing Conservation Amendment which requires notification to the employee." The Laborer's Health and Safety Fund of North America also pointed out the inconsistency between OSHA's proposed recording criterion in the recordkeeping rule and the criterion in OSHA's occupational noise exposure standard. The Fund commented:

"The noise standard defines a 10 dB shift at 2, 3, and 4K as a standard threshold shift and allows a revision of the baseline should the shift persist. Along comes the recordkeeping rule which says that a 15 dB shift is recordable, and a baseline revision (for recordkeeping purposes) can be made when a 15 dB shift occurs. This situation is an administrative nightmare. It is possible that a hearing loss will never be recordable because the 'baseline' is revised at a 10 dB shift. To avoid this situation, an employer would have to establish 2 different baselines, one for the noise standard provisions, and one for the recordkeeping rule provisions. This situation is unacceptable. We recommend that standard threshold shifts of 10 dB be used as the recordability criteria, since it is consistent with the 1910.95 noise standard" (Ex. 15: 310).

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26, 42) recommended a recording policy that would capture instances of age-corrected STS, as defined in the OSHA noise standard, that are confirmed as persistent and that are determined to be work-related. The Coalition's comments are of particular interest because its members include professional and scientific organizations dedicated to the issue of studying and preventing hearing loss. Member associations include the American Speech-Language-Hearing Association, the American Industrial Hygiene Association, the National Hearing Conservation Association, the Acoustical Society of America, the Council for Accreditation in Occupational Hearing Conservation, Self Help for Hard of Hearing People, Inc. and the Institute for Noise Control Engineering. These groups represent well over 100,000 audiologists, acousticians, speech-language pathologists, industrial hygienists, safety and health professionals, and persons with hearing loss (Ex. 42, page 1).

The Coalition provided the following reasons for relying on a 10 dB shift in hearing as an OSHA recordable condition (Ex. 42, pp. 9–13).

1. An allowance in the recording criteria for test-retest variability is inappropriate (i.e. OSHA proposed the 15 dB criterion rather than the 10 dB criterion "to account for variations in the reliability of individual audiometric results."
2. An age-corrected STS is a large hearing change that can affect communicative competence.
3. Typical occupational noise exposures do not justify a larger shift criterion.
4. Recording OSHA STSs reduces the recordkeeping burden to industry.
5. Current OSHA STS rates are not high.
6. Recording OSHA STSs will promote effective hearing conservation programs.

Other commenters proposed still other criteria for recording hearing loss. For example, Detroit Edison stated that a shift in hearing level should not be used as a recording criterion for hearing loss because this "is not indicative of an illness or injury, but only an indication that someone has had a slight change in their ability to hear" and proposed instead that "the level of hearing impairment should be used in recording hearing losses versus a threshold shift as compared to a baseline" (Ex. 15: 377). OSHA does not agree with this commenter, however, because, as the record in the Noise standard rulemaking indicates, permanent threshold shifts do indicate a non-minor impairment, although not all STSs are disabling.

As is the case for many OSHA rules, the 1981 Noise standard was challenged in the courts, which stayed several provisions. In 1983, OSHA revised the hearing conservation amendment to revoke many of the provisions stayed by the court, lift an administrative stay implemented by OSHA, and make technical corrections (48 FR 9738). One of those provisions involved the definition of STS, which was renamed a "standard" rather than "significant" threshold shift to help differentiate the two separate methods used to calculate the STS in the 1981 and 1983 rules. Although OSHA changed the calculation method used to establish an STS in 1983, the role and importance of the STS concept in the context of a hearing conservation program was unchanged. The main reason for changing the definition of STS in the 1983 standard was to simplify the original calculation and address the concerns of employers and audiology professionals who wished to avoid using a computer to calculate an STS. The standard requires employers to take follow-up actions when an STS is identified, notify the affected employee, evaluate and refit hearing protectors, retrain the employee, and, if necessary, refer the employee for medical evaluation.

The arguments put forward by the Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26, 42) are, in OSHA's view, compelling reasons for requiring employers to record on their Logs any case of work-related hearing loss that reaches the level of an STS. OSHA is particularly persuaded by the Coalition's argument that "An age-corrected STS is a large hearing change that can affect communicative competence" because an age-corrected STS represents a significant amount of cumulative hearing change from baseline hearing levels. In the words of the Coalition, "For an individual with normal hearing on the baseline audiogram, STS usually involves age-corrected shifts of 15–20 dB at 3000 and 4000 Hz. For an individual with pre-existing high-frequency hearing loss on the baseline, STS usually involves substantial progression of the hearing loss into the critical speech frequencies. The absolute shift values before age corrections are considerably larger." The Coalition also stressed that the method of averaging hearing loss at several frequencies, as is required to determine an STS under the OSHA Noise standard, tends to "obscure the large hearing shifts at individual frequencies which usually occur before the average changes by a specified amount" (Ex. 42, p. 10).

OSHA has rejected, for recordkeeping purposes, the use of the 25 dB shift from audiometric zero prescribed by the American Medical Association Guidelines for Material Impairment. The AMA's 25 dB criterion is intended to be used to determine the level at which the employee should be compensated for hearing loss-related medical bills or lost time. In the context of occupational noise exposure, hearing loss of this magnitude reflects a serious impairment of health or functional capacity. As discussed in the Legal Authority section, however, the Congress intended the OSHA recordkeeping system to capture all non-minor occupational injuries and illnesses, and OSHA believes that an STS loss of hearing represents such an injury. An STS is an abnormal condition that should be recorded because it represents a material loss in hearing ability, beyond the normal effects of aging.

OSHA has also rejected the 15 dB and 20 dB shift recording options, for several reasons. First, although OSHA suggested in the proposal that an additional 5 dB beyond the 10-dB STS shift was needed to account for variability in testing, this has not been supported by the record. As the Medical Educational Development Institute (Ex. 15: 25) stated: "[t]est/re-test reliability of 5 dB is well established in hearing testing. For example, the Council on Accrediting Occupational Hearing Conservationists maintain this range of reliability in their training guidelines and this is recognized in American National Standard Method for Manual Pure-Tone Threshold Audiometry, S3.21—1978 (R1992)."

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Ex. 26) provided additional justification for dropping the proposed rule's 5 dB reliability margin: "The allowance for a retest (or even multiple retests) should largely eliminate spurious shifts due to measurement error in audiometry. In fact, one of OSHA's original reasons for choosing a frequency-averaged shift (the OSHA STS) as a trigger level for employee follow-up was that the frequency averaging process reduces the influence of random audiometric variability." Because reliance on a frequency-averaged rather than single frequency shift increases the reliability of audiometric measurements, OSHA has not adopted NIOSH's recommendation that the hearing loss criterion should be a 15 dB shift at *any* frequency (Ex. 15: 407). Single frequency calculations are less reliable and may therefore lead to the under- or over-recording of hearing loss cases compared with the STS method of averaging loss over several frequencies.

In the final recordkeeping rule, OSHA has chosen to use the Occupational Noise standard's STS—an average shift in either ear of 10 dB or more at 2000, 3000, and 4000 hertz—as the shift in hearing that must be recorded by an employer on the OSHA log as a hearing loss case. An STS clearly represents a non-minor injury or illness of the type Congress identified as appropriate for recordkeeping purposes. The final rule allows the employer to adjust an employee's hearing test results for presbycusis (age), to retest within 30 days (the employer is not required to record if there is a retest within 30 days and the retest refutes the original test), and to have the test results evaluated by a physician or other licensed health care professional. Using the STS as the recording criterion also meets one of the primary purposes of this rulemaking, to improve the simplicity of the overall recordkeeping system. Relying on the Noise standard's STS shifts avoids the complexity referred to by many commenters (see, *e.g.*, Exs. 15: 310, 396) of maintaining multiple baselines for the Noise standard and the OSHA recordkeeping rule. As the Laborers' Health & Safety Fund of North America (Ex. 15: 310) commented:

The noise standard defines a 10 dB shift at 2,3, and 4K as a standard threshold shift and allows a revision of the baseline should the shift persist. Along comes the recordkeeping rule which says that a 15 dB shift is recordable, and a baseline revision (for recordkeeping purposes) can be made when a 15 dB shift occurs. This situation is an administrative nightmare. It is possible that a hearing loss will never be recordable because the baseline is revised at a 10 dB shift. To avoid this situation, an employer would have to establish 2 different baselines, one for the noise standard provisions, and one for the recordkeeping rule provisions. This situation is unacceptable. We recommend that standard threshold shifts of 10 dB be used as the recordability criteria, since it is consistent with the 1910.95 noise standard.

Several commenters (see, *e.g.*, Exs. 15: 295, 395) argued that OSHA itself had discounted the significance of the 10 dB STS during the 29 CFR 1910.95 rulemaking. OSHA disagrees with this assessment of the Agency's position on the importance of an STS. In the 1981 preamble to the Hearing Conservation Amendment, OSHA found that a 10 dB shift in hearing threshold is significant because it is outside the range of audiometric error and "it is serious enough to warrant prompt attention" (46 FR 4144). The 1983 preamble reinforces these findings. It states that:

Correctly identifying standard threshold shifts will enable employers and employees to take corrective action so that the progression of hearing loss may be stopped before it becomes handicapping. Moreover, a standardized definition of STS will ensure that the protection afforded to exposed employees is uniform in regard to follow-up procedures. * * *

OSHA reaffirms its position on the ideal criterion for STS which was articulated in the January 16, 1981 promulgation (see 46 FR 4144). The criterion must be sensitive enough to identify meaningful changes in hearing level so that follow-up procedures can be implemented to prevent further deterioration of hearing but must not be so sensitive as to pick up spurious shifts (sometimes referred to as "false positives"). In other words, the criterion selected must be outside the range of audiometric error (48 FR 9760).

The Fourth Circuit rejected an employer's argument that a 10 dB shift in hearing threshold is insignificant. In its decision upholding OSHA's use of a 10 dB STS as an action level in the Hearing Conservation Amendment, the court found that:

[t]he amendment is concerned with protecting workers before they sustain an irreversible shift. Consequently, it was incumbent upon the Agency to select a trigger level that would protect workers by providing an early warning yet not to be so low as to be insignificant or within the range of audiometric error. We find that the Agency struck a reasonable balance between those concerns. * * *

Forging Indus. Ass'n v. *Secretary of Labor*, 773 F.2d 1436, 1450 (1985)(en banc).

OSHA believes that many of the reasons stated in the 1983 preamble make the STS an appropriate recording criterion for recordkeeping purposes. For example, employers are familiar with the STS definition, which is also sensitive enough to identify a non-minor change in hearing. Use of the STS also reduces the confusion that would arise were OSHA to require employers to maintain two baselines: one required by the Occupational Noise standard and one required for recordkeeping purposes.

Baseline Audiogram

In its proposal, OSHA also asked for comment on which baseline should be used as the starting point in determining recordable hearing loss. There was strong support in the record for using

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the preemployment or original baseline for this purpose (see, *e.g.*, Exs. 26; 15: 25, 50, 78, 108, 110, 111, 113, 146, 154, 163, 181, 188, 218, 233, 262, 281, 295, 308, 348, 354, 402, 405), although a few commenters proposed using audiometric zero (see, *e.g.*, Ex. 15: 395). One commenter prpposed that the reviewing professional should determine the appropriate baseline on a case-by-case basis (Ex. 15: 175), and another proposed that an audiologist should determine when a change in baseline audiograms is warranted (Ex. 15: 203). Some commenters supported adjusting the employee's baseline audiogram when a recordable hearing loss case has been identified (see, *e.g.*, Exs. 26; 15: 25, 108, 111, 146, 163, 290, 354, 405, 407).

OSHA agrees with those commenters who argued that the preemployment or original baseline should be used as the benchmark from which to determine recordable hearing loss. Using the preemployment or original baseline automatically corrects for any hearing loss that may have occurred before the worker was employed with his or her current employer and will prevent the recording of cases of nonoccupational hearing loss. This policy is also consistent with OSHA's Occupational Noise standard and therefore increases the simplicity of the recording system.

OSHA also agrees that an employee's baseline audiogram should be adjusted if that employee experiences a recordable hearing loss. Revising the baseline by substituting the revised audiogram for the original audiogram after an STS has occurred will avoid a second or third recording of the same STS. On the other hand, recording hearing loss in a given worker only once would overlook the additional hearing lc :s that may occur, either in the same or the other ear, and would not be consistent with the definition of a "new" case in Section 1904.6 of this rule, which requires employers to evaluate any "new" case that results from exposure in the workplace for recordability. Subsequent STS findings, i.e., further 10-dB shifts in hearing level, are more serious events than the first STS, because of the nonlinearity of the dB rating system and the progressive severity of increasing hearing loss. A second or third STS in a given worker is therefore also treated under the recordkeeping system as a recordable illness on the OSHA 300 Log. The final rule makes this clear by requiring the employee's audiogram to be compared to the preemployment baseline audiogram when the worker has not experienced a recordable hearing loss, and to the audiogram reflecting the most recent recorded hearing loss if the worker has experienced a prior recorded hearing loss case.

Correction for Aging

In its proposal, OSHA included provisions allowing the employer to adjust the results of audiograms for presbycusis (age-related hearing loss), and asked for comment on whether an age correction is appropriate. The vast majority of commenters agreed that it was (see, *e.g.*, Exs. 26; 42; 15: 39, 45, 84, 113, 137, 163, 175, 201, 203, 262, 278, 281, 283, 331, 347, 348, 396, 405). As the Westinghouse Hanford Company commented, "[t]he adjusting for presbycusis is appropriate as the deterioration of the hearing related to age is an important factor in determining the amount of hearing loss related to workplace hazards" (Ex. 15: 108). Julia Royster, Ph.D. CC-A/SLP, agreed with this view, stating that "Age-related hearing loss is inevitable. There are individual differences in the rate of age-related hearing change and the amount of hearing loss eventually shown due to presbycusis. However, most people will eventually develop age-related hearing changes equivalent to one or more OSHA STSs. Therefore, presbycusis corrections are necessary to avoid attributing age-related hearing change to occupational causes" (Ex. 26, Appendix C).

However, some commenters did not agree that the use of age corrections was appropriate (see, *e.g.*, Exs. 15: 50, 110, 188, 233, 407). For example, Occupational Audiologists (Ex. 15: 50) pointed out that "[w]hen the tables [in 29 CFR 1910.95] are applied they ignore any hearing loss that may be present as a result of medical pathology or noise exposure prior to the baseline hearing test," and therefore the "use of the presbycusis tables hides significant changes in hearing thus delaying the STS required procedures of follow-up, notification, fitting/re-fitting, educating and requiring the wearing of hearing protection for some individuals." Similarly, John P. Barry (Ex. 15: 110), commented:

> At the 4000 Hz test frequency where occupational hearing loss first occurs, application of the presbycusis correction may significantly reduce the noted threshold shift relative to the employee's baseline audiogram. However, the changes at 2000 and 3000 Hz often are equal to or less than the presbycusis corrections. When these corrections are applied to actual audiometric data, they mask the effects of occupational noise and hinder early detection of noise-induced hearing loss. While hearing loss due to aging (presbycusis) and hearing loss due to the non occupational environment (sociocusis) may account for some of hearing loss noted in serial audiograms, there is no scientifically valid way to correct the data for non occupational hearing loss. * * * It is inappropriate use of statistics to apply median values from one population on a different population when no foundation has been developed to justify such manipulation of data.

OSHA recognizes that using the correction for presbycusis when interpreting audiogram results is controversial among experts in the field of audiology and that NIOSH has developed a new criteria document on occupational noise exposure ("Criteria for a Recommended Standard; Occupational Noise Exposure, Revised Criteria, 1998; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health; June 1998) which at present does not recommend applying presbycusis correction values to actual employee audiometric data. However, since the Occupational Noise standard itself permits employers to adjust the interpretation of audiograms for the effects of aging, it would be inconsistent and administratively complex to prohibit this practice in the recordkeeping rule. Accordingly, § 1904.10(b)(3) allows the employer to adjust for aging when determining the recordability of hearing loss. The adjustment is made using Tables F–1 or F–2, as appropriate (table F–1 applies to men and F–2 applies to women), in Appendix F of 29 CFR 1910.95. However, use of the correction for aging is not mandatory, just as it is not mandatory in the Noise standard itself.

Persistence of Hearing Loss

Yet another issue surrounding the recording of hearing loss involves the timing of the recording of a case on the OSHA forms when an audiogram has been performed on an employee. The issue is whether the results of an audiogram should be recorded within the interval for recording all cases, or whether the audiogram should be verified with a retest before recording is required. The proposed rule would have required the recording of hearing loss cases within 7 calendar days of the first audiogram, but then would have permitted employers to remove, or line out, a hearing loss case on the Log if a second audiogram taken on that employee within 30 days failed to show that the STS was persistent. Several commenters supported immediate recording with the 30 day retest provision (see, *e.g.*, Exs. 15: 295, 350, 394, 407). The Building and Construction Trades Department of the AFL–CIO (Ex. 15: 394) noted that if a

retest was not performed the case would never be recorded:

> We support OSHA, however, on requiring cases to be recorded and then lined out later if the loss does not persist. In construction, where a worker may never get a follow-up test because they have moved to a different worksite, the case needs to be recorded and presumed work-related. For construction workers that is a very good presumption to make. These changes should lead to more accurate reporting of hearing loss among construction workers.

Other commenters, however, did not agree with OSHA's proposal and believed the shifts should be confirmed before recording on the Log is required (see, *e.g.*, Exs. 26; 42; 15: 50, 84, 175, 181, 188, 201, 203, 331). Impact Health Services (Ex. 15: 175) expressed its opinion that

> The new hearing loss criterion should require recording of only confirmed work-related shifts in hearing. * * * There is no question that it is in the best interest of the hearing conservation program to identify shifts in hearing while they are still temporary so that follow-up action can be taken immediately to prevent permanent hearing loss. * * * However, requiring companies to record all shifts (both temporary and persistent) within six (proposed seven) days may have an unintended punitive effect. Companies are usually hesitant to record any incidents on Form 200 (proposed Form 300), even if lining-out the event at a later date is an option. Therefore, disallowing the OSHA 30-day retest for recording purposes may have a negative impact on programs which are designed to prevent hearing loss. By requiring recording of all shifts within seven days, companies may actually discontinue programs of conducting annual testing during the work shift, due to a reluctance to identify (and record) temporary threshold shift.

To address the problem identified by the Building and Construction Trades Department of the AFL–CIO, Impact Health Services recommended that "[i]f a follow-up audiogram is not administered within 30 days of determination, or if the follow-up audiogram confirms the shift, then the shift is considered persistent and if determined to be work related, must be recorded on Form 300" (Ex. 15: 175). The American Association of Occupational Health Nurses (Ex. 15: 181) noted that it "would require less paperwork to record the hearing loss after confirmation by a re-test in thirty days, rather that recording the initial shift and then having to 'line out' the entry if the re-test was not indicative of any hearing loss."

The Coalition to Preserve OSHA and NIOSH and Protect Workers' Hearing (Exs. 26; 42) stated:

> This urgency [as reflected in the proposal's provision requiring recording within 7 days] in recording unconfirmed shifts does not appear justified and creates additional burdens for the employer. The coalition recommends the following more efficient and suitably protective approach:
> —Only confirmed (i.e., persistent) work-related STSs are to be recorded on Form 300, unless a follow-up audiogram is not administered.
> —If a follow-up audiogram is not administered within 30 days of the initial determination of STS, or if the follow-up audiogram confirms the STS, then the shift is considered persistent, and if determined to be work-related, must be recorded on Form 300. * * *
> —If a follow-up audiogram given within 30 days of the initial determination of the STS does not confirm the STS, nothing is to be recorded on Form 300.

The Coalition also recommended that employers be allowed to remove, or line-out, recorded hearing losses that are not confirmed by subsequent retesting, or are found not to be work-related, within 15 months of the initial STS identification, at the discretion of the reviewing professional. Such a provision would allow employers to remove cases if the next annual audiogram showed an improvement in hearing (Exs. 26; 42).

Several commenters discussed the length of time OSHA should allow between the audiogram on which the STS was first detected and the confirmatory retest. The International Dairy Food Association suggested that allowing only a 30-day period "may not be feasible in many situations where mobile van testing is utilized. * * * Thirty days are easily consumed during the compiling, mailing, interpreting, mailing, evaluation process" (Ex. 15: 203). The Association recommended instead that "OSHA increase the current requirement of 30 days to 45 days to allow employers and employees to obtain a re-test following an annual audiogram" (Ex. 15: 403). For the same reasons, the Can Manufacturers Institute recommended that retests be permitted within 90 days of the original test, noting that "[t]here is no magic regarding the current 30 day span" (Ex. 15: 331). Industrial Health Inc. commented that "there's no rush" to retest and stated its preference for a time lapse longer than 30 days "[i]n order to allow temporary [hearing loss] effects to subside" (Ex. 15: 84). NIOSH (Ex. 15: 407) proposed that a confirmatory retest be permitted at any time provided that the retest was preceded by a 14-hour period of quiet.

After a review of the record on this point, OSHA has decided to require that any retest the employer chooses to perform be conducted within 30 days. Accordingly, in the final rule, at paragraph 1904.10(b)(4), employers are permitted, if they choose, to retest the employee to confirm or disprove that an STS reflected on the first audiogram was attributable to a cold or some other extraneous factor and was not persistent. If the employer elects to retest, the employer need not record the case until the retest is completed. If the retest confirms the hearing loss results, the case must be recorded within 7 calendar days. If the retest refutes the original test, the case is not recordable, and the employer does not have to take further action for OSHA recordkeeping purposes. The 30 day limit in the final recordkeeping rule is consistent with the 30 day retest provision of § 1910.95(g)(5)(ii), which allows the employer to obtain a retest within 30 days and consider the results of the retest as the annual audiogram if the STS recorded on the first test is determined not to persist.

OSHA believes that the 30 day retest option allows the employer to exclude false positive results and temporary threshold shifts from the data while ensuring the timely and appropriate recording of true positive results. Adding language to the final recordkeeping rule to specify different procedures, depending on whether the employer chooses to conduct a re-test within 30 days, adds some complexity to the final rule, but OSHA finds that this added complexity is appropriate because it will reduce burden for some employers and improve the accuracy of the hearing loss data.

Work-Relationship

One of the greatest sources of controversy in the record concerning OSHA's proposed criterion for recording hearing loss relates to the presumption of work-relationship in cases where an employee is exposed to an 8-hour time-weighted average sound level of noise equaling or exceeding 85 dB(A) (61 FR 4064). One commenter supported the recordkeeping proposal's approach on this matter. NIOSH (Ex. 15: 407) recommended that work-relationship be presumed "if an employee is exposed to an 8-hour time-weighted sound level of noise equaling or exceeding 85 dB(A) or to peak sound levels equaling or exceeding 115 dB(A) regardless of brevity or infrequency." Several commenters advocated presuming work-relatedness if the employee experienced occupational exposures to 85 dB unless medical evidence showed that the hearing loss was not related to work (see, *e.g.*, Exs. 15: 39, 50, 146, 171, 188). For example, BF Goodrich (Ex. 15: 146) asked that "[O]SHA give employers the opportunity to refute the work

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relationship for employees found to have other than noise-induced hearing loss. If the employee is examined by an otolaryngologist or other qualified health professional and found to have a medical condition that causes hearing loss, the case should not be recordable."

Several commenters objected to the proposed presumption of work-relationship (see, *e.g.*, Exs.15: 201, 263, 283, 289, 305, 318, 334, 390). The National Association of Manufacturers commented that "There is no justification for presuming that hearing loss is work-related simply because an employee is exposed to an 8-hour time weighted average sound level of noise of 85 dB(A) or higher, even if it were a daily exposure and particularly where it could be as infrequent as once per year" (Ex. 15: 305). Many commenters agreed with Mississippi Power, which wrote "[t]he presumption of work relationship does not consider other potentially significant noise exposures such as noisy hobbies, or other noisy activities not associated with occupational noise exposures" (Ex. 15: 263). Deere & Company argued that "OSHA is not taking into account the noise-reducing effect of an effective hearing conservation program nor does it take into account the often significant noise exposure that many employees have away from the workplace " (Ex, 15: 283).

There are numerous suggestions in the record on how best to deal with the presumption of work-relationship. Impact Health Services Inc., and others suggested that a case be considered work-related "when in the judgement of the supervising audiologist or physician, the shift is due in full or in part to excessive noise exposure in the workplace" (Ex. 15: 175). Akzo Nobel Chemicals proposed that work-relationship be presumed when "there is no other reasonable non-work related explanation" (Ex. 37), and the National Grain and Feed Association suggested "that if an employer has an active and an enforceable hearing conservation program in place, the presumption should be that any hearing loss experienced by an employee is not work related unless it can be shown to be otherwise" (Ex. 15: 119). A number of commenters agreed with the comment of the Edison Electric Group that "OSHA should also establish a criteria of exposure to noise at or above the 85 dB(a) TWA action level of 30 or more days per year before the case is recordable" because "[a] single day's exposure at or below the PEL will not cause hearing loss" (Ex. 15: 401), and NIOSH proposed that work-relationship be presumed "if an employee is exposed to an 8-hour time-weighted sound level of noise equaling or exceeding 85 dB(A) or to peak sound levels equaling or exceeding 115 dB(A) regardless of brevity or infrequency" (Ex. 15: 407).

In the final rule, OSHA has continued to rely on a presumption of work-relationship for workers who are exposed to noise at or above the action levels specified in the Occupational Noise standard (29 CFR 1910.95). In line with the overall concept of work relationship adopted in this final rule for all conditions, an injury or illness is considered work related if it occurs in the work environment. For workers who are exposed to the noise levels that require medical surveillance under § 1910.95 (an 8-hour time-weighted average of 85 dB(A) or greater, or a total noise dose of 50 percent), it is highly likely that workplace noise is the cause of or, at a minimum, has contributed to the observed STS. It is not necessary for the workplace to be the sole cause, or even the predominant cause, of the hearing loss in order for it to be work-related. Because the final recordkeeping rule relies upon the coverage of the Occupational Noise standard, it is also not necessary for OSHA to include a minimum time of exposure provision. The Occupational Noise standard does not require a baseline audiogram to be taken for up to six months after the employee is first exposed to noise in the workplace, and the next annual audiogram would not be taken until a year after that. For any worker to have an applicable change in audiogram results under the Occupational Noise standard, the worker would have been exposed to levels of noise exceeding 85 dB(A) for at least a year, and possibly even for 18 months.

In addition, the provisions allowing for review by a physician or other licensed health care professional allow for the exclusion of hearing loss cases that are not caused by noise exposure, such as off the job traumatic injury to the ear, infections, and the like. OSHA notes that this presumption is consistent with a similar presumption in OSHA's Occupational Noise standard (in both cases, an employer is permitted to rebut this presumption if he or she suspects that the hearing loss shown on an employer's audiogram in fact has a medical etiology and this is confirmed by a physician or other licensed health care professional).

Miscellaneous Issues

Other issues addressed by commenters to the rulemaking record on OSHA's proposed criterion for recording hearing loss included whether OSHA should treat hearing levels for each ear separately for recording purposes. Impact Health Services, Inc. (Ex. 15: 175) recommended that proposed Appendix B specify that shifts in hearing be calculated separately for each ear:

> Because an individual's left and right ears may be affected differently by noise or other occupational injury, it is important that Appendix B specifies that shifts in hearing are to be calculated separately for each ear.

Arguing along similar lines, the Chevron Companies raised the issue of revising baselines for both ears when a standard threshold shift is recorded in only one ear. They commented:

> The proposed rule discusses an average shift in one or both ears and establishing a new or revised baseline for future tests to be evaluated against. In discussing the new or revised baseline however the proposed rule does not give guidance on revision when only one ear meets the revision criteria (15 dB or 25 dB or whatever the final rule states). Are the baselines for both ears revised or only the ear meeting the criteria? This issue should be clearly addressed in the final rule. Usually noise induced hearing loss is a symmetrical event so it would be reasonable to revise the baselines for both ears. If the baselines are to be revised individually one could anticipate more hearing losses being recorded than if they are revised in unison. Therefore, for Hearing Conservation Program statistics to be meaningful and comparable, baseline revision must be handled the same across industries (Ex. 15: 343).

Shifts in hearing must be calculated separately for each ear, in accordance with the requirements of § 1910.95. However, if a single audiogram reflects a loss of hearing in both ears, only one hearing loss case must be entered into the records. The issue of revising baseline audiograms to evaluate the extent of future hearing loss pertains to a hearing loss case that has been entered on the Log. If a single-ear STS loss has been recorded on the Log, then the baseline audiogram should be adjusted for that ear, and that ear only. If an STS affecting both ears has been recorded on the Log, then the baseline audiogram may be revised and applied to both ears. This means that there should be no cases where the baseline audiogram has been adjusted and the case has not been recorded on the Log.

The Medical Educational Development Institute (Ex. 15: 25) made several recommendations for changing OSHA's noise standard, 29 CFR 1910.95, to add specific steps to be taken when a 10 dB STS occurs, such as employee interviews, reevaluations with medical personnel, physician referral, labeling of revised baseline audiograms, and reassignment to quieter work for workers with a second or subsequent STS. These are interesting recommendations, but they address issues that are beyond the scope of this rulemaking. This rulemaking is concerned only with the Part 1904 requirements for recording occupational hearing loss on the OSHA 300 Log, and does not affect any provision of the OSHA Occupational Noise standard.

Phillips Petroleum (Ex. 15: 354) raised another miscellaneous issue when it suggested that OSHA phase in the recording of audiometric tests if a more protective definition of hearing loss was adopted in the final rule:

> [i]f OSHA insists on the recording of hearing loss at the 15 dB, it would artificially inflate the number of recordable hearing-loss cases and have a similar effect as that of the severity issue. We recommend that if the recordability bar is lowered from 25 dB), OSHA allow a transition period where a 15 dB shift is listed on the log, but is not counted in the recordable total. This should continue for a transition period of three years to allow facilities to identify all employees affected. Any employees who were not identified during the transition period would become recordables with a 15 dB hearing loss after the transition period.

OSHA does not believe that a transition period is needed for the recording of occupational hearing loss or any other type of injury or illness included in the records. Adding such a provision would add unnecessary complexity to the rule, and would also create an additional change in the data that would make it difficult to compare data between the two years at the end of the transition. OSHA finds that it is better to implement the recordkeeping changes as a single event and reduce the impacts on the data in future years.

As noted previously, OSHA is not making any changes to its noise standards in this Part 1904 rulemaking, and thus no additional protections are being provided in this final rule.

Section 1904.11 Additional Recording Criteria for Work-Related Tuberculosis Cases

Section 1904.11 of the final rule being published today addresses the recording of tuberculosis (TB) infections that may occur to workers occupationally exposed to TB. TB is a major health concern, and nearly one-third of the world's population may be infected with the TB bacterium at the present time. There are two general stages of TB, tuberculosis infection and active tuberculosis disease. Individuals with tuberculosis infection and no active disease are not infectious; tuberculosis infections are asymptomatic and are only detected by a positive response to a tuberculin skin test. Workers in many settings are at risk of contracting TB infection from their clients or patients, and some workers are at greatly increased risk, such as workers exposed to TB patients in health care settings. Outbreaks have also occurred in a variety of workplaces, including hospitals, prisons, homeless shelters, nursing homes, and manufacturing facilities (62 FR 54159).

The text of § 1904.11 of the final rule states:

(a) Basic requirement. If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis (TB), and that employee subsequently develops a tuberculosis infection, as evidenced by a positive skin test or diagnosis by a physician or other licensed health care professional, you must record the case on the OSHA 300 Log by checking the "respiratory condition" column.

(b) Implementation.

(1) Do I have to record, on the Log, a positive TB skin test result obtained at a pre-employment physical?

No, because the employee was not occupationally exposed to a known case of active tuberculosis in your workplace.

(2) May I line-out or erase a recorded TB case if I obtain evidence that the case was not caused by occupational exposure?

Yes. you may line-out or erase the case from the Log under the following circumstances:

(i) The worker is living in a household with a person who has been diagnosed with active TB;

(ii) The Public Health Department has identified the worker as a contact of an individual with a case of active TB unrelated to the workplace; or

(iii) A medical investigation shows that the employee's infection was caused by exposure to TB away from work, or proves that the case was not related to the workplace TB exposure.

The Proposal

The proposed rule included criteria for the recording of TB cases in proposed Appendix B. In that appendix, OSHA proposed to require the recording of cases of TB infection or disease at the time an employee first had a positive tuberculin skin test, except in those cases where the skin test result occurred before the employee was assigned to work with patients or clients. The proposal stated that cases of TB disease or TB infection would be presumed to be work-related if they occurred in an employee employed in one of the following industries: correctional facilities, health care facilities, homeless shelters, long-term care facilities for the elderly, and drug treatment centers. In other words, the proposal contained a "special industries" presumption for those industries known to have higher rates of occupational TB transmission. OSHA proposed to allow employers to rebut the presumption of work-relatedness if they could provide evidence that the employee had been exposed to active TB outside the work environment. Examples of such evidence would have included (1) the employee was living in a household with a person who had been diagnosed with active TB, or (2) the Public Health Department had identified the employee as a contact of an individual with a case of active TB. For employees working in industries other than the "special" industries, OSHA proposed that a positive skin test result be considered work-related when the employee had been exposed to a person within the work environment who was known to have TB disease. Under the proposal, an employee exhibiting a positive skin test and working in industries other than those listed would otherwise not be presumed to have acquired the infection in the work environment (61 FR 4041). As noted in the proposal, these recording criteria for TB were consistent with those published previously in OSHA directives to the field (February 26, 1993 memo to Regional Administrators). The final rule permits employers to rebut the presumption of work-relatedness in cases of TB infection among employees but does not rely on the "special industries" approach taken by OSHA in the proposal, for reasons explained below.

Positive Skin Tests

Several comments in the record supported OSHA's proposed recording criteria for occupational TB cases (see, *e.g.*, Exs. 15: 72, 133, 198). A number of commenters, however, questioned whether a positive tuberculin skin test reaction should be considered a recordable occupational illness (Ex. 15: 146, 188, 200). For example, BF Goodrich wrote:

> We disagree with a positive skin test reaction as the criterion for recording a TB case. Such tests are only indicative of a past exposure, not necessarily an illness or a condition. OSHA should allow diagnosing medical professionals to use their professional judgement to confirm active TB cases and restrict recordability to those cases (Ex. 15: 146).

Kaiser Permanente (Ex. 15: 200) argued:

> The presumption that an initial positive skin test result or diagnosed tuberculosis in a health care employee is occupationally based is not warranted. While there have been outbreaks in health care facilities

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documented in the literature, and while skin test conversion does occur in health care workers and may in given cases be occupationally related, the Kaiser Permanente experience has not been characterized by outbreaks or significant rates of skin test conversion. Diagnosed cases of tuberculosis among Kaiser Permanente health care workers are extremely rare.

OSHA views the situation differently. A positive tuberculin skin test indicates that the employee has been exposed to Mycobacterium tuberculosis *and* has been infected with the bacterium. Although the worker may or may not have active tuberculosis disease, the worker has become infected. Otherwise, his or her body would not have formed antibodies against these pathogens. (OSHA is aware that, in rare situations, a positive skin test result may indicate a prior inoculation against TB rather than an infection.)

OSHA believes that TB infection is a significant change in the health status of an individual, and, if occupational in origin, is precisely the type of illness Congress envisioned including in the OSHA injury and illness statistics. Contracting a TB infection from a patient, client, detainee, or other person in the workplace would cause serious concern, in OSHA's view, in any reasonable person. Once a worker has contracted the TB infection, he or she will harbor the infection for life. At some time in the future, the infection can progress to become active disease, with pulmonary infiltration, cavitation, and fibrosis, and may lead to permanent lung damage and death. An employee harboring TB infection is particularly likely to develop the full-blown disease if he or she must undergo chemotherapy, contracts another disease, or experiences poor health. According to OSHA's proposed TB rule (62 FR 54159), approximately 10% of all TB infections progress at some point to active disease, and it is not possible to predict in advance which individuals will do so.

OSHA also believes that it is important to require employers to record TB cases when an employee experiences a positive skin test because doing so will create more timely and complete statistics. If, for example, OSHA were to require recording only when the worker develops active TB, many cases that were in fact occupational in origin would go unrecorded. In such cases, if the worker had retired or moved on to other employment, the employer would generally not know that the employee had contracted active TB disease, and the case would never be included in the Nation's occupational injury and illness statistics and important information would be lost. Thus, requiring the recording of a case at the infection stage will create more accurate, complete and useful statistics, one of the major goals of this rulemaking.

Several commenters suggested that TB should not be recorded at all because, in their view, acquiring TB infection is not within the control of the employer and is not amenable to control by an employer's safety and health program (see, *e.g.*, Exs. 15: 316, 348, 414, 423). For example, Raytheon Engineers & Constructors (Ex. 15: 414) argued that TB infection and disease should not be recorded because it "is not due to a condition of the work environment under the control of the employer." Dupont argued along similar lines:

> It does not make sense to record tuberculosis cases where an infectious worker infects co-workers. That has nothing to do with job activity or with the workplace except as an accidental exposure. The same type of thinking could apply to flu symptoms, "colds", conjunctivitis, etc., where lack of personal hygiene or a strong "germ" migrated through the workplace. If the exposure is not part of the job activity, none of the cases mentioned, including tuberculosis, should be recorded (Ex. 15: 348).

As discussed elsewhere in this document (see the Legal Authority section above), Congress did not intend OSHA's recordkeeping system only to capture conditions over which the employer has complete control or the ability to prevent the condition. The Act thus supports a presumption of work-relatedness for illnesses resulting from exposure in the workplace, and the OSHA recordkeeping system has always reflected this position (although a few specific exceptions to that presumption are permitted, including an exception for common colds and flu). In accordance with that presumption, when an employee is exposed to an infectious agent in the workplace, such as TB, chicken pox, etc., either by a co-worker, client, patient, or any other person, and the employee becomes ill, workplace conditions have either caused or contributed to the illness and it is therefore work-related. Since, as discussed above, TB infection is clearly a serious condition, it is non-minor and must be recorded.

Employee-to-Employee Transmission

Two commenters argued that transmission from employee to employee should not be considered work-related (Exs. 15: 39, 348). The RR Donnelley & Sons Company (Ex. 15: 39) pointed out that an employer "may never know that a fellow employee has tuberculosis. To record personal transmission from one employee to another goes beyond the scope of work relatedness." Other commenters agreed with OSHA that, at least under certain circumstances, employee-to-employee transmission should be considered work-related (see, *e.g.*, Exs. 15: 78, 218, 361, 398, 407). For example, Alliant Techsystems (Ex. 15: 78) stated that "[i]f a worker with infectious tuberculosis disease infected their co-worker, the co-workers' infection/disease would be recordable."

Again, as discussed above, OSHA believes, under the positional theory of causality, that non-minor illnesses resulting from an exposure in the work environment are work-related and therefore recordable unless a specific exemption to the presumption applies. Infection from exposure to another employee at work is no different, in terms of the geographic presumption, from infection resulting from exposure to a client, patient, or any other person who is present in the workplace. The transmission of TB infection from one employee to another person at work, including a co-worker, clearly is non-minor and is squarely within the presumption.

Special Industry Presumptions

Many of the commenters supported OSHA's proposed approach of assuming work-relatedness for TB cases if the infection occurred in workers employed in certain special industries (see, *e.g.*, Exs. 24, 15: 78, 345, 376, 407). Other commenters suggested that OSHA abandon the proposed special industry presumption (see, *e.g.*, Exs. 15: 197, 200, 225, 259, 279, 302, 341, 431, 436). In the proposed rule, OSHA proposed different work-relatedness criteria for different work environments, *i.e.*, in industries in which published reports of TB outbreaks were available from the Centers for Disease Control and Prevention (CDC), a special presumption would prevail, while in industries in which occupational transmission had not been documented it would not.

Kaiser Permanente commented that the CDC "Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities establish facility risk levels for occupational transmission of tuberculosis based upon assessment of a range of relevant criteria such as job duties, incidence of TB patients treated, and community TB rates" and urged OSHA to follow these in the final rule (Ex. 15: 200).

Two commenters objected to the inclusion of nursing homes in the list of industries in which the special industry presumption would apply (Exs. 15: 259, 341). For example, the American Health Care Association (AHCA) suggested:

> [i]t should not be presumed that exposure is work-related in all long term care facilities for the elderly. Depending upon the facility and/or its location, the incidence of TB infection/disease in the facility may be less than that of the general public. The Centers for Disease Control and Prevention recognizes that even within certain settings, there are varying levels of risk (minimal to high). TB linkage to the facility should be based on the level of risk using the CDC assessment system, with work relatedness assigned to facilities within the moderate to high risk classification (Ex. 15: 341).

Two commenters suggested OSHA add more industries to the proposed list of industries to which the special industry presumption would apply. The American Nurses Association (ANA) told the Agency that "There should be no question on the inclusion of the home health arena under the rubric of health care facilities. The risk of transmission exists in all health care work sites including home health sites and must not be limited to traditional health care facilities' (Ex. 15: 376). Alliant Techsystems (Ex. 15: 78) suggested adding "Industries that causes exposure outside the United States such as the airline sector."

Some commenters argued that recording should be limited only to TB cases occurring in workers in specific industries, *i.e.*, that no case of TB in other industries, no matter how transmitted or when diagnosed, should be recordable (see, *e.g.*, Exs. 15: 351, 378, 396). Westinghouse Electric Corporation recommended that "Tuberculosis exposure or disease cases outside of listed industries where cases would be prevalent (such as health care facilities, long-term care facilities, etc.) should not be recordable as an occupational illness. The logical source of exposure would be non work-related and outside the premises of the employer's establishment." Likewise, the Air Transport Association (Ex. 15: 378) suggested that TB recording "[s]hould be limited to medical work environments rather than general industry. The administrative burden far exceeds the expected benefits."

OSHA is aware that the relative risk of TB, and of all occupational injuries and illnesses, varies widely from industry to industry and from occupation to occupation. However, OSHA does not consider this circumstance relevant for recordkeeping purposes. The fact that ironworkers experience a higher incidence of falls from elevation than do carpenters does not mean that carpenters' injuries from such falls should not be recorded. Congress clearly intended information such as this to be used by individual employers and to be captured in the national statistical program. Again, because TB infection is a significant illness wherever in the workplace it occurs, and because no exemption applies, it must be recorded in all covered workplaces. Accordingly, in the final rule being published today, TB cases are recordable without regard to the relative risk present in a given industry, providing only that the employee with the infection has been occupationally exposed to someone with a known case of active tuberculosis. Employers may rebut the presumption only if a medical investigation or other special circumstances reveal that the case is not work-related.

In the final rule, OSHA has not adopted the "special industries" presumption, for several reasons. First, doing so would be inconsistent with the approach taken by the Agency in other parts of the rule, *i.e.*, specific industries have not been singled out for special treatment elsewhere. Second, a "special industries" presumption is not needed because the approach OSHA has taken in this section will provide employers with better ways of rebutting work-relatedness when that is appropriate. Finally, the special industries approach is not sufficiently accurate or well enough targeted to achieve the intended goal. Many cases of occupationally transmitted TB occur among employees in industries other than the "special industries," and evidence shows that the risk of TB infection varies greatly among facilities in the special industries.

Other Suggestions for Determining the Work-Relatedness of TB Cases

A number of commenters provided other suggestions for determining the work-relatedness of TB cases (see, *e.g.*, Exs. 15: 39, 154, 181, 188, 200, 218, 226, 335, 393, 407, 431, 436).

The Society for Human Resource Management stated:

> Workers are exposed to tuberculosis in many places other than the work site: it would be unduly burdensome to require employers to provide evidence that the employee has had non-work exposure. Since the employee is in the best position to retrace his or her activities, he or she should be required to provide evidence to establish work-relatedness (Ex. 15: 431).

OSHA does not agree that the employee is in a better position than the employer to know whether an employee has been exposed to TB at work. For example, the worker is not as likely to know whether a co-worker, patient, client, or other work contact has an active TB case. To determine whether exposure to an active case of TB has occurred at work, the employer may interview the employee to obtain additional information, or initiate a medical investigation of the case, but it would be inappropriate to place the burden of providing evidence of work-relationship on the employee.

The American Ambulance Association (Ex. 15: 226) did not support the proposed approach of reporting an employee's positive tuberculin skin test reaction "unless there has [also] been documentation of a work-related exposure." The American Network of Community Options and Resources (ANCOR) argued "ANCOR strongly opposes the inclusion of tuberculosis unless the infection is known to have been caused at work due to a known, active carrier" (Ex. 15: 393). The American Association of Occupational Health Nurses (AAOHN) proposed that the criteria for recording TB infection or illness be "[a]n employee tests positive for tuberculosis infection after being exposed to a person within the work environment known to have tuberculosis disease and the positive test results are determined to be caused by the person in the workplace with tuberculosis disease" (Ex. 15: 188).

Several commenters suggested that the first case of TB occurring in the workplace should not be recordable (see, *e.g.*, Exs. 15: 218, 361, 398). In two separate comments, the Association for Professionals in Infection Control (APIC) recommended:

> [a]s an acceptable rebuttal to the presumption of work relationship when an employee is found to be infected with tuberculosis or to have active disease. The employer is able to demonstrate that no other employee with similar duties and patient assignments as the infected employee was found to have tuberculosis infection or active disease (Exs. 15: 361, 398).

In addition, Bell Atlantic (Ex. 15: 218) proposed that public health agencies be charged with determining the work-relationship of cases of TB in the workplace. Bell Atlantic's comments to the rulemaking record were as follows:

> Bell Atlantic does not agree that tuberculosis cases should be inherently reported. The first identified incidence of tuberculosis in an employee group probably was not contracted in the workplace. However, if Public Health Officials deem it necessary to require TB testing in the facility as a preventive measure, and new cases are found, these may be recordable. The criteria here is one of public health, and where the disease initiated. The Public Health Agencies

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would be charged with investigation of family members, friends, and the community away from work.

A number of commenters misunderstood the proposal as allowing the geographic presumption of work-relationship only to be rebutted in certain "high risk" industries. For example, Alcoa commented that "OSHA seems to conclude * * * that if someone in your workforce has TB then each person in the workplace who tests positive is now considered as having work-related TB due to the incidental exposure potential" (Ex. 15: 65). ALCOA suggested that the final rule allow the geographic presumption of work-relationship to be rebutted for "all other industries."

OSHA agrees that a case of TB should be recorded only when an employee has been exposed to TB in the workplace (*i.e.*, that the positional theory of causation applies to these cases just as it does to all others). OSHA has added an additional recording criterion in this case: for a TB case occurring in an employee to be recordable, that employee must have been exposed at work to someone with a known case of active tuberculosis. The language of the final rule addresses these concerns: "If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis, * * *" Under the final rule, if a worker reports a case of TB but the worker has not been exposed to an active case of the disease at work, the case is not recordable. However, OSHA sees no need for the employer to document such workplace exposure, or for the Agency to require a higher level of proof that workplace exposure has occurred in these compared with other cases. Further, OSHA knows of no justification for excluding cases simply because they are the first or only case discovered in the workplace. If a worker contracted the disease from contact with a co-worker, patient, client, customer or other work contact, the case would be work-related, even though it was the first case detected. Many work-related injury and illness cases would be excluded from the recordkeeping system if cases were only considered to be work-related when they occurred in clusters or epidemics. This was clearly not Congress's intent.

The final rule's criteria for recording TB cases include three provisions designed to help employers rule out cases where occupational exposure is not the cause of the infection in the employee (*i.e.*, where the infection was caused by exposure outside the work environment). An employer is not required to record a case involving an employee who has a positive skin test and who is exposed at work if (1) the worker is living in a household with a person who has been diagnosed with active TB, (2) the Public Health Department has identified the worker as a contact of a case of active TB unrelated to the workplace, or (3) a medical investigation shows that the employee's infection was caused by exposure to TB away from work or proves that the case was not related to the workplace TB exposure.

The final rule thus envisions a special role for public health departments that may investigate TB outbreaks but does not permit employers to wait to record a case until a public health department confirms the work-relatedness of the case. In addition, the final rule's provisions for excluding cases apply in all industries covered by the recordkeeping rule, just as the recording requirements apply to all industries. The final rule thus does not include the "special industries" approach of the proposal. As discussed above, the Agency has rejected this proposed approach because it would not have been consistent with the approach OSHA has taken elsewhere in the rule, which is not industry-specific; it is not necessary to attain the intended goal; and it would not, in any case, have achieved that goal with the appropriate degree of accuracy or specificity.

A few commenters stressed that employers should not be required to record cases where the employee was infected with TB before employment (see, *e.g.*, Exs. 15: 65, 407, 414). For example, Alcoa (Ex. 15: 65) proposed that employers not be required to consider as work-related any case where "the employee has previously had a positive PPD [Purified Protein Derivative] test result." In response to this suggestion, OSHA has added an implementation question to the final rule to make sure that employers understand that pre-employment skin test results for TB are not work-related and do not have to be recorded. These results are not considered work-related for the purposes of the current employer's Log because the test result cannot be the result of an event or exposure in the current employer's work environment.

NIOSH proposed to expand the recording criteria for TB infection or disease to include the criterion that "regardless of the industry or source of infection, a case of active TB disease is presumed to be work-related if the affected employee has silicosis attributable to crystalline silica exposure in the employer's establishment" (Ex. 15: 407). OSHA has chosen not to include this criterion in the final rule because in NIOSH's example the case would previously have been entered into the records as a case of silicosis. Adopting the NIOSH criterion would result in the same illness being recorded twice.

Kaiser Permanente recommended that OSHA adopt a method for determining the work relationship of TB cases that Kaiser Permanente currently uses in California to evaluate whether cases are recordable, in accordance with an agreement with the California Division of Occupational Safety and Health (Ex. 15: 200):

1. The employer shall promptly investigate all tuberculin skin test conversions according to the "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities" published by the Centers for Disease Control and Prevention (CDC Guidelines).

2. Probable exposure to Mycobacterium tuberculosis unrelated to work environment. The conversion shall not be recorded on the log if, after investigation, the employer reasonably determines that the employee probably converted as a result of exposure unrelated to the employee's work duties.

3. Probable exposure to Mycobacterium tuberculosis related to work environment. The conversion shall be recorded on the log if, after investigation, the employer reasonably determines that the employee probably converted as a result of exposure related to the employee's work duties.

4. Inability to determine probable cause of exposure. If, after reasonably thorough investigation, the employer is unable to determine whether the employee probably converted as a result of exposure related to the employee's work duties, the following shall be done:

a. The conversion shall not be recorded on the log if the employee was, at all times during which the conversion could have occurred, assigned to a unit or job classification, which met the minimal risk, low risk, or very low risk criteria specified in the CDC Guidelines.

b. In all other cases, the conversion shall be recorded on the log.

As an initial matter, OSHA notes that the States are not authorized to provide employers with variances to the Part 1904 regulations, under either the rule being published today or the former rule. The issuing of such variances is exclusively reserved to Federal OSHA, to help ensure the consistency of the data nationwide and to make the data comparable from state-to-state. OSHA has not adopted the approach suggested by Kaiser Permanente because the approach is too complex, does not apply equally to health care and non-health care settings, and does not provide the clear guidance needed for a regulatory requirement. However, because the final rule allows employers to rebut the presumption of work-relatedness if a medical evaluation concludes that the TB infection did not arise as a result of occupational exposure, a physician or other licensed health care professional could use the CDC Guidelines or another method to investigate the origin of the case. If such an investigation resulted in information that demonstrates that the case is not related to a workplace exposure, the employer need not record the case. For example, such an investigation might reveal that the employee had been vaccinated in childhood with the BCG vaccine. The employer may wish, in such cases, to keep records of the investigation and determination.

Section 1904.12 Recording Criteria for Cases Involving Work-Related Musculoskeletal Disorders

Section 1904.12, entitled "Recording criteria for cases involving work-related musculoskeletal disorders," provides requirements for recording work-related musculoskeletal disorders (MSDs). MSDs are defined in the final recordkeeping rule as "injuries and disorders of the muscles, nerves, tendons, ligaments, joints, cartilage, and spinal discs."

Paragraph 1904.12(a) establishes the employer's basic obligation to enter recordable musculoskeletal disorders on the Log and to check the musculoskeletal disorder column on the right side of the Log when such a case occurs. The paragraph states that, "[i]f any of your employees experiences a recordable work-related musculoskeletal disorder (MSD), you must record it on the OSHA 300 Log by checking the "musculoskeletal disorder" column." Paragraph 1904.12(b)(1) contains the definition of 'musculoskeletal disorder' used for recordkeeping purposes. Paragraphs 1904.12(b)(2) and 1904.12(b)(3) provide answers to questions that may arise in implementing the basic requirement, including questions on the work-relatedness of MSDs.

The Proposal

The proposal defined MSDs as "injuries and illnesses * * * result[ing] from ergonomic hazards," such as lifting, repeated motion, and repetitive strain and stress on the musculoskeletal system. (61 FR 4046) This language was derived, in part, from the definition of the term "cumulative trauma disorders (CTDs)," used in OSHA's *Ergonomics Program Management Guidelines For Meatpacking Plants* (hereafter "*Meatpacking Guidelines*"). The 1990 *Meatpacking Guidelines* used the term CTDs to cover "health disorders arising from repeated biomechanical stress due to ergonomic hazards." (Ex. 11 at p. 20.)

Appendix B to the recordkeeping rule proposed requirements for employers to follow when recording MSDs. The proposed requirements would have required recording: (1) whenever an MSD was diagnosed by a health care provider, or (2) whenever an employee presented with one or more of the objective signs of such disorders, such as swelling, redness indicative of inflammation, or deformity. When either of these two criteria was met, or when an employee experienced subjective symptoms, such as pain, and one or more of the general criteria for recording injuries and illnesses (i.e., death, loss of consciousness, days away from work, restricted work, job transfer, or medical treatment) were met, an MSD case would have been recordable under the proposal.

The proposal also contained special provisions for determining whether hot and cold treatments administered to alleviate the signs and symptoms of MSDs would be considered first aid or medical treatment. Under the former recordkeeping rule, the application of hot and cold treatment on the first visit to medical personnel was considered first aid, while the application of such treatment on the second or subsequent visit was considered to constitute medical treatment. OSHA proposed to revise this provision to consider hot or cold therapy to be first aid for all injuries and illnesses except MSDs, but to consider two or more applications of such therapy medical treatment if used for an MSD case (61 FR 4064). Whether hot and cold therapies constitute first aid or medical treatment is addressed in detail in section 1904.7 of the final recordkeeping rule. As discussed in that section, under the final rule, hot and cold therapies are considered first aid, regardless of the type of injury or illness to which they are applied or the number of times such therapy is applied.

The Final Rule's Definition of Musculoskeletal Disorder

The preamble to the proposal described an MSD as an injury or disorder "resulting from" ergonomic hazards. However, OSHA has not carried this approach forward in the final rule because it would rely on an assessment of the cause of the injury, rather than the nature of the injury or illness itself.

Paragraph 1904.12(b)(1) of the final rule therefore states, in pertinent part, that MSDs "are injuries and disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs. MSDs do not include injuries caused by slips, trips, falls, or other similar accidents." This language clarifies that, for recordkeeping purposes, OSHA is not defining MSDs as injuries or disorders caused by particular risk factors in the workplace. Instead, the Agency defines MSDs as including all injuries to the listed soft tissues and structures of the body regardless of physical cause, unless those injuries resulted from slips, trips, falls, motor vehicle accidents, or similar accidents. To provide examples of injuries and disorders that are included in the definition of MSD used in the final rule, Section 1904.12(b)(1) contains a list of examples of MSDs; however, musculoskeletal conditions not on this list may also meet the final rule's definition of MSD.

Determining the Work-Relatedness of MSDs

Section 1904.12(b)(2) provides that "[t]here are no special criteria for determining which musculoskeletal disorders to record. An MSD case is recorded using the same process you would use for any other injury or illness." This means that employers must apply the criteria set out in sections 1904.5–1904.7 of the final rule to determine whether a reported MSD is "work-related," is a "new case," and then meets one or more of the general recording criteria. The following discussion supplements the information provided in the summary and explanation accompanying section 1904.5, to assist employers in deciding which MSDs are work-related.

For MSDs, as for all other types of injuries and illnesses, the threshold question is whether the geographic presumption established in paragraph 1904.5(a) applies. The presumption applies whenever an MSD or other type of injury or illness "results from an event or exposure in the work environment." For recordkeeping purposes, an "event" or "exposure" includes any identifiable incident, occurrence, activity, or bodily movement that occurs in the work environment. If an MSD can be attributed to such an event or exposure, the case is work related, regardless of the nature or extent of the ergonomic risk factors present in the workplace or the worker's job.

This position is not new to the final rule; it is clearly reflected in the 1986 BLS *Recordkeeping Guidelines*. The *Guidelines* contain the following discussion of the applicability of the work-relatedness presumption to back injuries and hernia cases, which reflects OSHA's position under this final rule:

Back and hernia cases should be evaluated in the same manner as any other case.

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Questions concerning the recordability of these cases usually revolve around: (1) The impact of a previous back or hernia condition on the recordability of the case, or (2) whether or not the back injury or hernia was work-related.

Preexisting conditions generally do not impact the recordability of cases under the OSHA system. * * * For a back or hernia case to be considered work-related, it must have resulted from a work-related event or exposure in the work environment. Employers may sometimes be able to distinguish between back injuries that result from an event in the work environment, and back injuries that are caused elsewhere and merely surface in the work environment. The former are recordable; the latter are not. This test should be applied to all injuries and illnesses, not just back and hernia cases. *Guidelines* at p. 32 (emphasis in original).

The *Guidelines* provide the following question and answer to illustrate that MSDs may be attributable to events or exposures in the work environment that pose little apparent ergonomic risk:

B–16 Q. An employee's back goes out while performing routine activity at work. Assuming the employee was not involved in any stressful activity, such as lifting a heavy object, is the case recordable?

A. Particularly stressful activity is not required. If an event (such as a * * * sharp twist, etc.) occurred in the work environment that caused or contributed to the injury, the case would be recordable, assuming it meets the other requirements for recordability. *Guidelines* at p. 32 (emphasis in original).

OSHA believes that, in most cases, an employee who reports an MSD at work will be able to identify the activity or bodily movements (such as lifting, twisting, or repetitive motions) that produced the MSD. If the activity or movements that precipitated the disorder occurred at work, the presumption of work-relatedness is established without the need for further analysis. However, cases may arise in which it is unclear whether the MSD results from an event or exposure in the work environment. In these cases, paragraph 1904.5(b)(3) of the final rule directs the employer to evaluate the employee's work activities to determine whether it is likely that one or more events or exposures in the work environment caused or contributed to the disorder. In this situation the employer would consider the employee report, the ergonomic risk factors present in the employee's job, and other available information to determine work-relationship.

In evaluating job activities and work conditions to identify whether ergonomic risk factors are present, employers may turn to readily available sources of information for assistance, such as materials made available by OSHA on its web site, current scientific evidence, available industry guidelines, and other pertinent sources. This final rule does not establish new or different criteria for determining whether an MSD is more likely than not to have resulted from work activities or job conditions, i.e., from exposure to ergonomic risk factors at work. As is the case for all injuries and illnesses, the employer must make a good faith determination about work-relatedness in each case, based on the available evidence.

The preamble discussion for paragraph 1904.5(b)(3) contains some examples to assist employers in making this determination. In addition, the BLS *Guidelines* contain the following examples:

Q. Must there be an identifiable event or exposure in the work environment for there to be a recordable case? What if someone experiences a backache, but cannot identify the particular movement which caused the injury?

A. Usually, there will be an identifiable event or exposure to which the employer or employee can attribute the injury or illness. However, this is not necessary for recordkeeping purposes. If it seems likely that an event or exposure in the work environment either caused or contributed to the case, the case is recordable, even though the exact time or location of the particular event or exposure cannot be identified.

If the backache is known to result from some nonwork-related activity outside the work environment and merely surfaces at work, then the employer need not record the case. In these situations, employers may want to document the reasons they feel the case is not work related. (BLS *Guidelines*, p. 32.)

Comments on Other Approaches to Recording MSDs

Commenters provided OSHA with several suggestions for recording musculoskeletal disorders: requiring diagnosis by a health care professional, recording symptoms lasting seven days, and eliminating special criteria for recording MSD cases. These are discussed below.

Eliminating Special Criteria for Recording MSD Cases

A large number of commenters suggested that the recordkeeping rule should not contain criteria for recording MSD cases that were different from those for recording all injuries and illnesses, arguing that they should be captured using the criteria for all other types of injuries and illnesses (see, *e.g.*, Exs. 15: 9, 44, 76, 109, 122, 123, 130, 145, 146, 176, 188, 199, 201, 218, 235, 272, 273, 288, 289, 301, 303, 304, 347, 351, 359, 368, 386, 392, 395, 396, 409, 425, 427). The comments of PPG Industries, Inc. (Ex. 15: 109) are representative of these views: "The system for evaluating all cases should be consistent. When evaluating musculoskeletal disorders, the normal recordkeeping criteria should be used." The Voluntary Protection Programs Participants' Association (VPPPA) also recommended that "MSDs should be treated as any other injury or illness. If the problem arises to the level of seriousness that it is a recordable injury or illness, then it should be recorded on the log" (Ex. 15: 425). The National Safety Council (Ex. 15: 359) recommended that "if an employee has pain, he or she should report it. It then becomes recordable or not recordable based on the usual criteria. The employer makes a decision on a case by case basis."

OSHA agrees with these commenters that MSD cases should be recorded in the same way as other injuries and illnesses, and should not have separate recordability criteria. Using the same criteria for these cases, which constitute one-third of all occupational injuries and illnesses, simplifies the final rule and makes the system easier for employers and employees to use. Employing consistent recording criteria thus helps to achieve one of OSHA's major goals in this rulemaking, simplification. Section 1904.12 has been included in the final rule not to impose different recording criteria on MSDs, but to emphasize that employers are to record MSD cases like all other injuries and illnesses. OSHA believes that this approach to the recording of MSDs will yield statistics on musculoskeletal disorders that are reliable and complete.

Requiring Diagnosis by a Health Care Professional

A number of commenters recommended that OSHA require the recording of musculoskeletal disorders only when they are diagnosed by a health care professional or identified by a medical test result (see, *e.g.*, Exs. 15: 20, 22, 39, 42, 44, 57, 60, 78, 82, 121, 126, 146, 173, 199, 201, 218, 225, 242, 246, 247, 248, 259, 272, 288, 289, 303, 318, 324, 332, 335, 341, 342, 348, 351, 355, 356, 357, 364, 366, 378, 384, 397, 414, 424, 440, 441). The National Electrical Contractors Association (NECA) requested that "OSHA modify the current criteria to state "Positive x-ray showing broken bones or fracture, diagnosis of broken teeth, or diagnosis of acute soft tissue damages" (Ex. 15: 126). The United Technologies Company (UTC) agreed that "MSDs should only be recorded if the diagnosis is made by a health care provider operating within the scope of his or her specialty" (Ex. 15: 440). The National Coalition on Ergonomics (Ex. 15: 366) urged OSHA to limit the recording of MSD cases to those diagnosed by highly qualified health care professionals:

> [O]SHA should not encourage unqualified individuals to "diagnose" musculoskeletal disorders given the present state of medical knowledge of their causes and cures. * * * Therefore, OSHA should limit in the definition of musculoskeletal disorders the diagnosis to qualified and trained physicians, and such other practitioners as are accepted by the medical community as having the training and skill necessary to adequately and appropriately treat these cases.

Other commenters expressed similar opinions, arguing that the work relationship of a given case should be determined by a health care professional (see, *e.g.*, Exs. 15: 9, 105, 248, 249, 250, 262, 272, 288, 303, 304, 324, 366, 397, 408, 440). The Footwear Industries of America (Ex. 15: 249) recommended that "An MSD should be recordable only if it is diagnosed by a health-care provider based on a determination that the MSD is clearly work-related—that is, caused by the work environment." The American Dental Association (Ex. 15: 408) suggested that "OSHA should not require employers to keep records of musculoskeletal disorders unless and until a physician identifies work as the "predominant cause" in a given case." United Technologies Company recommended that the health care provider use a check list to make this determination: "UTC also believes that the provider should be required to complete a check list regarding work relatedness with the language changed to include predominantly caused by the work environment and the submittal of information by the employer" (Ex. 15: 440).

The Northrop Grumman Association (Ex. 15: 42) suggested that "Recordability should only be based on objective, documented findings by a licensed physician. In [proposed] mandatory Appendix B, recordability is defined as diagnosis by a health care provider and/or objective findings. The 'or' should be deleted. Only positive test findings should denote recordability. There are physicians who diagnose cases without any objective tests to confirm their diagnosis." Other commenters (see, *e.g.*, Exs. 15: 44, 386, 330, 332) recommended that MSD cases be recorded only when they are diagnosed by a health care provider and/or are identified by a positive test result *and* meet the general recording criteria.

A few commenters argued that a health care professional's diagnosis should not be considered evidence of work-relatedness (see, *e.g.*, Exs. 15: 347, 363, 409). For example, the American Automobile Manufacturers Association (AAMA) remarked that "[w]e strongly oppose the recording of a musculoskeletal disorder based solely on the diagnosis by a health care provider. A diagnosis, in and of itself, does not reflect whether a musculoskeletal disorder is significant or serious in nature. Health care providers record a description or diagnosis of an employee's complaint whether minor or serious." On the other hand, the American Federation of State, County, and Municipal Employees (Ex. 15: 362) argued that "[w]orkers may not see a health care professional until after they have endured symptoms for an extended period * * * The reality of the situation is that a great number of workers who suffer from symptoms will not be diagnosed by a health care provider unless or until their condition becomes severe and/or disabling."

As discussed in the preamble to the work relationship section of the final rule (§ 1904.5), an employer is always free to consult a physician or other licensed health care professional to assist in making the determination of work relationship in individual injury or illness cases, including musculoskeletal disorders. If a physician or other licensed health care professional has knowledge of the employee's current job activities and work conditions, work history, and the work environment, he or she can often use that information, along with the results of a medical evaluation of the worker, to reach a conclusion about the work-relatedness of the condition. Relying on the expertise of a knowledgeable health care professional can be invaluable to the employer in those infrequent cases for which it is not clear whether workplace events or exposures caused or contributed to the MSD or significantly aggravated pre-existing symptoms. Employers may also obtain useful information from ergonomists, industrial engineers, or other safety and health professionals who have training and experience in relevant fields and can evaluate the workplace for the presence of ergonomic risk factors.

However, OSHA does not require employers to consult with a physician or other licensed health care professional or to have the employee undergo medical tests when making work-relationship determinations. The Agency finds that doing so would be both unnecessary and impractical in the great majority of cases and would result both in delaying the recording of occupational MSD cases and increasing medical costs for employers.

In most situations, an evaluation by a physician or other licensed health care professional is simply not needed in order to make a recording decision. For example, if a worker strains a muscle in his or her back lifting a heavy object, and the back injury results in days away from work, there is no doubt either about the work-relationship of the case or its meeting of the recording criteria. Similarly, if a worker performing a job that has resulted in MSDs of the wrist in other employees reports wrist pain and restricted motion, and the employer places the employee on restricted work, the case is recordable and there is no need to await a clinical diagnosis.

Recording of MSD Symptoms

In the preamble to the proposed rule (61 FR 4047), OSHA asked:

> There is a concern that the proposed criteria [for recording MSDs] will result in a situation where workers could be working with significant pain for an extended period of time, without their case being entered into the records. OSHA has been asked to consider an additional recording criterion for these cases: record when the employee reports symptoms (pain, tingling, numbness, etc.) persisting for at least 7 calendar days from the date of onset. OSHA asks for input on this criterion.

Some commenters urged OSHA to require employers to record MSD cases where an employee reports symptoms that have persisted for at least 7 calendar days (see, *e.g.*, Exs. 15: 87, 129, 186, 362, 369, 371, 374, 380). The American Federation of State County and Municipal Employees, AFL–CIO (AFSCME) recommended:

> Under-reporting of MSDs will increase if OSHA adopts this proposal. It has been AFSCME's experience that workers experiencing pain, soreness, tenderness, numbness, tingling and other sensations in their extremities or back do not immediately report these symptoms to their employer. Rather, most employees first attempt to alleviate their symptoms on their own: they ingest medications, use topical solutions, apply heat or cold to affected areas, or utilize other remedies in their attempt to relieve pain, aches, stiffness, or other symptoms. OSHA should require that these cases be recorded when symptoms last for seven consecutive days.
>
> Investigations conducted by AFSCME repeatedly demonstrate that inclusion of the additional criterion is necessary in order to ascertain accurately the number of work-related MSDs. Employer records typically show MSD rates at or even well below ten percent of employees at risk for these injuries. However, results of AFSCME-conducted symptom surveys show that it is common for a third or more of the employees to respond that they have felt pain, numbness, tingling, or other symptoms that have persisted for more than seven days.* * *

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AFSCME wishes to emphasize that accurate and complete recording of MSDs is critically important. Early detection, proper medical intervention, and appropriate measures to address ergonomic risk factors in the workplace are all necessary to prevent and manage MSDs (Ex. 15: 362).

Many commenters objected to the proposed 7-day symptom recording concept (see, *e.g.*, Exs. 15: 9, 20, 39, 122, 127, 128, 170, 230, 246, 248, 281, 289, 324, 330, 332, 341, 359, 378, 397, 406, 434). David E. Jones of the law firm of Ogletree, Deakins, Nash, Smoak & Stewart (Ex. 15: 406) stated that this provision was unnecessary because "[t]he prevalent experience has shown that employers typically record those symptoms when they result in medical treatment, restricted work activity, or days away from work." The Eli Lilly Company (Ex. 15: 434) also observed that "[b]ased on input from [our] occupational health physicians, the vast majority of MSD-type cases would manifest into objective findings or a MSD diagnosis after 7 calendar days of legitimate subjective symptoms."

Other objections to the proposal's 7-day symptom trigger were based on practical considerations. Many commenters were opposed to recording undiagnosed conditions that persist for seven days on the grounds that the seriousness or veracity of the complaint of pain or other symptoms could not be established by the employer (see, *e.g.*, Exs. 15: 9, 20, 39, 121, 122, 127, 128, 170, 218, 230, 246, 248, 281, 289, 359, 366, 397). For example, the Dayton Hudson Corporation (Ex. 15: 121) stated: "[s]elf-reporting of symptoms with no medical findings or evaluation is an invitation for abuse. Are these cases work-related or serious? Are they even real?" Clariant Corporation held the view that "[d]isgruntled employees could use subjective findings as a means of avoidance. It could be used to prevent them from doing a job or task they do not like" (Ex. 15: 217). The National Coalition on Ergonomics (Ex. 15: 366) opposed any recordation based on symptoms alone, stating:

> First, persistent pain is a symptom, not a disorder, and therefore cannot be a case. There is often no indication that persistent pain is work-related, except that as the person becomes more fatigued, the pain may appear or become more intense. Further, because pain is subjective, there is no way to quantify it so as to focus only on serious cases. Finally, pain can exist without an underlying pathology. Pain in and of itself cannot be a case in the absence of a diagnosis by a qualified medical practitioner, provided that the case is serious, disabling or significant.
>
> Second, other symptoms mentioned in OSHA's question do not represent cases either. As we discuss below, individual symptoms are not illnesses; symptoms, in conjunction with appropriate signs and/or laboratory results are essential to diagnose specific conditions.
>
> Since symptoms do not define cases, OSHA cannot—indeed, should not—require employers to record complaints of uncertain validity and non-specific origin. It is perhaps true that such employees should see a trained physician or other practitioner, but only after this event will there be a case to record, if one exists at all.

Linda Ballas & Associates (Ex. 15: 31) expressed a different concern, namely that "[i]f an employee is experiencing pain, or reports symptoms—the clock should not have to click to 7 days before the case is recordable. This will lead to under recording and under reporting * * *."

In response to the comments on this issue, OSHA finds that pain and/or other MSD symptoms, of and by themselves, may indicate an injury or illness. In this regard, MSD cases are not different from other types of injury or illness. As discussed in the preamble to the definitions section of the final rule (Subpart G), symptoms such as pain are one of the primary ways that injuries and illnesses manifest themselves. If an employee reports pain or other symptoms affecting the muscles, nerves, tendons, etc., the incident must be evaluated for work-relatedness, and, if determined by the employer to be work-related, must be tested against the recording criteria to determine its recordability. If it is determined by the employer to be recordable, it must be recorded as an MSD on the OSHA 300 Log.

The ICD–9–CM manual, the *International Classification of Diseases, Clinical Modification* (ICD–CM), the official system of assigning codes to diagnoses of disease, injury and illness, lists several MSD conditions that consist only of pain. That is, when health care professionals diagnose these disease states, they do so on the basis of employee-reported pain (health care professionals often evaluate and confirm such reports by physical examination when making a diagnosis). According to the National Center for Health Statistics (NCHS), the agency responsible for the coordination of all official disease classification activities in the United States relating to the International Classification of Diseases (ICD), the ICD–CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States, and is used to code and classify morbidity data from inpatient and outpatient records, physicians' offices, and most NCHS surveys. The following table includes a few illustrative examples of ICD illness codes for pain-related disorders that would be considered MSD cases under OSHA's definition and would thus warrant an evaluation of work-relatedness by the employer.

ICD code	Name and description
723.1	Cervicalgia—Pain in neck.
724.1	Pain in thoracic spine.
724.2	Lumbago—Low back pain.
724.5	Backache, unspecified.

(NCHS Internet home page, http://www.cdc.gov/nchswww/about/otheract/icd9)

Pain is a symptom that generally indicates the existence of some underlying physiological condition, such as inflammation, damage to a spinal disc, or other biomechanical damage. The occurrence of pain or other symptoms (such as, in the case of MSDs, tingling, burning, numbness, etc.) is thus indicative of an incident that warrants investigation by the employer for work-relatedness, the first step in the injury and illness reporting and recording process. The occurrence of pain or other symptoms, however, is not enough, in the absence of an injury or illness that meets one or more of the recording criteria, to make any injury or illness (including an MSD case) recordable under Part 1904. Employers are not required to record symptoms unless they are work-related and the injury or illness reaches the seriousness indicated by the general recording criteria, which for MSD cases will almost always be days away from work, restricted work, medical treatment, or job transfer. Thus, the requirements governing the recording of all injuries and illnesses will work to ensure that symptoms such as the aches and pains that most people experience from time to time during their lives, are not automatically recorded on the OSHA Log. These same recording requirements will also ensure that those MSDs that are determined by the employer to be work-related and that also meet one or more of the recording criteria will be captured in the national statistics.

If the employer is concerned that the case is not work-related, he or she can refer the employee to a health care professional for a determination, evaluation, or treatment. In this situation, or when the employee has already obtained medical attention, the physician or other licensed health care professional can help to differentiate between work-related and non-work-related cases, minor aches and pains, or inappropriate employee reports. This is no different for MSD cases than for other types of injuries and illnesses, and does not represent a new problem in the determination of work-related injury and illness. There have always been disputes between workers and employers over the existence of an injury or illness and whether it is work-related. If an employer subsequently demonstrates that a worker is malingering or determines that an injury or illness is or is not work-related (using OSHA's definition of work-related), the employer may remove the recorded entry from the OSHA 300 Log.

Although OSHA believes that pain or other symptoms indicate an injury or illness that warrants additional analysis, the final rule has not adopted persistent symptoms alone, whether lasting for 7 days or any other set time period, as an automatic recording criterion. OSHA is concerned about workers who experience persistent pain for any reason, and such pain, if work-related, may well warrant an inquiry into the employee's work conditions and the taking of administrative actions. However, pain or other symptoms, standing alone, have not ordinarily been captured by the OSHA recordkeeping system, and OSHA has accordingly not adopted persistent musculoskeletal pain as a recording criterion, for the following reasons.

First, as discussed earlier, OSHA does not believe that MSD cases should receive differential treatment for recording purposes, and the final rule does not contain different criteria for recording MSD cases; instead, it relies on the general criteria of § 1904.7 to capture MSD cases. OSHA finds that, for recordkeeping purposes, MSD pain is no different in nature than the pain caused by a bruise, cut, burn or any other type of occupational injury or illness. For example, the OSHA rule does not contain a criterion requiring that if a burn, cut or bruise results in pain for seven days it is automatically recordable. Creating a special provision for MSD pain would create an inconsistency in the rule.

Further, OSHA believes that the provisions of the final recordkeeping rule, taken together will appropriately capture reliable, consistent, and accurate data on MSD cases. Incorporating a clear definition of MSDs, clarifying the rule's requirements for determining work-relatedness; and refining the definitions of restricted work, first aid and medical treatment; will all work together to improve the quality of the Log data on MSDs. OSHA concludes, based on an analysis of the record evidence on MSDs, that the general recording criteria will enhance the data on work-related, non-minor MSDs occurring in the workplace, and that an additional "persistent pain" criterion is unnecessary for purposes of the recordkeeping system.

New hires

Some commenters encouraged OSHA to find a way to exclude MSD cases that involve minor muscle soreness in newly hired employees, i.e., to allow employers to not record MSDs occurring during a "break-in" period (see, *e.g.*, Exs. 15: 27, 31, 39, 82, 87, 105, 186, 198, 204, 221, 239, 272, 283, 289, 303, 330, 359, 374, 412, 440). For example, the American Meat Institute (Ex. 15: 330) remarked: "Employees returning from vacation, or other extended break periods from the job function, could have normal muscle aches to which hot/cold packs could provide relief. Recording such cases would not meet the purpose [of the OSHA Act] either." On the same topic, the National Safety Council (Ex. 15: 359) wrote:

> The concept of forgiveness for a short period of adjustment to return to work makes good sense in industries that are traditionally very resistant to early return to work programs. If allowing for a short "break-in" period helps get workers safely and comfortably back to full productivity and earning capacity it should be seriously considered. The Council recommends, however, that no specific method be developed in the proposed rule because situations may vary greatly from industry to industry.

The Harsco Corporation (Ex. 15: 105) suggested "Construction activities can be a physically demanding occupation. If a person hasn't worked in a period of time, the first couple of days can be very tough. To transfer a person to a different task which would allow for the affected body part to rest should have no bearing on recordability if no other treatment is required?"

Other commenters disagreed, however, that a recording exemption for injuries occurring during a break-in period was appropriate (see, *e.g.*, Exs. 15: 68, 359, 371). For example, the State of New York Workers' Compensation Board (Ex. 15: 68) stated that:

> As to the exclusion of minor soreness commonly occurring to newly hired employees or employees on a rehab assignment during a "break-in stage", we do not envision any reason to exclude reporting solely on this basis. The criteria should not be to whom the injury happens, but rather whether the injury would otherwise be reportable regardless of who is injured.

The United Food and Commercial Workers Union (UFCW) argued:

> We could not disagree more with the agency. The current proposal in fact screens out all fleeting cases, and includes only those cases that are serious, have progressed and become debilitating. Only those cases with serious medical findings, lost workdays, restricted days and those receiving medical treatment are currently recordable—not those with fleeting pain that goes away with a good nights rest (Ex. 15: 371).

After a review of the record on this topic, OSHA finds that no special provision for newly hired or transferred workers should be included in the final rule. As the National Safety Council stated, it would be very difficult to identify a single industry-wide method for dealing with break-in or work conditioning periods. Any method of exempting such cases would risk excluding legitimate work-related, serious MSD cases. A newly hired employee can be injured just as easily as a worker who has been on the job for many years. In fact, inexperience on the job may contribute to an MSD injury or illness. For example, a new worker who is not aware of the need to get assistance to move a heavy load or perform a strenuous function may attempt to do the task without help and be hurt in the process. Cases of this type, if determined to be work-related, are appropriately included in national statistics on occupational injuries and illnesses.

OSHA notes that minor muscle soreness, aches, or pains that do not meet one or more of the general recording criteria will not be recorded on the OSHA 300 Log. Therefore, the system already excludes minor aches and pains that may occur when employees are newly hired, change jobs, or return from an extended absence. These cases will be recorded only if they reach the level of seriousness that requires recording. The final rule's definition of first aid includes hot/cold treatments and the administration of non-prescription strength analgesics, two of the most common and conservative methods for treating minor muscle soreness. Thus, the final rule allows newly hired workers to receive these first aid treatments for minor soreness without the case being recordable.

The Ergonomics Rulemaking

Many of the comments OSHA received on the proposed recordkeeping rule referred to OSHA's efforts to develop an ergonomics standard. Several commenters argued that OSHA was trying, through the recordkeeping rule, to collect data to support an ergonomics standard (see, *e.g.*, Exs. 22, 183, 215, 304, 346, 397). Typical of these views was that of the National Beer Wholesalers Association (NBWA) (Ex. 15: 215):

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NBWA is especially troubled by the likelihood that the new definitions of what injuries must be recorded and reported in the current proposed rule are intended artificially to inflate the number of reported musculoskeletal disorders, whether work-related or not. Such a surge in MSDs could be used to justify additional work on a workplace ergonomics rule despite the notable lack of a scientific basis for regulation in this area.

Other commenters believed that OSHA was using the recordkeeping rule to conduct a "backdoor rulemaking" to control ergonomics hazards in the workplace (see, *e.g.*, Exs. 15: 86, 215, 287, 304, 404, 412, 426). For example, the Reynolds Aluminum Company stated that:

Reynolds supports the inclusion of musculo-skeletal disorders (MSDs) on the OSHA log, but does not support the industry-wide application of the Ergonomics Program Management Guidelines For Meatpacking Plants as the criteria for determining recordability. By incorporating these guidelines into Appendix B, OSHA would be implementing an ergonomics program. It would be inappropriate and without legal or scientific basis to burden all industries with ergonomic guidelines designed for a specific, unique industry (Ex. 15: 426).

Several commenters stated that the injury and illness recordkeeping rules should not address musculoskeletal disorders until after an ergonomics standard has been completed (see, *e.g.*, Exs. 15: 13, 95, 393). For example, Entergy Services, Inc. (Ex. 15: 13) expressed the following concerns:

This area is of concern since there is no standard that really covers this issue except the meat packers standard * * * It is believed that to record this type case, a standard should be in place or language should be written to look at true disorders with long term effect as compared to short term symptoms.

Many commenters also made comments on the overall debate about ergonomics, *i.e.*, that the medical community has not reached consensus on what constitutes an MSD (see, *e.g.*, Exs. 15: 116, 1267, 323, 355), that there is too much scientific uncertainty about the issue of ergonomics (see, *e.g.*, Exs. 15: 57, 215, 304, 312, 342, 344, 355, 393, 397, 412, 424), that science and medicine cannot tell what is work-related and what is not (see, *e.g.*, Exs. 15: 204, 207, 218, 323, 341, 342, 3546, 408, 412, 424, 443), that OSHA needs to do more research before issuing a rule (Ex. 15: 234), that "musculoskeletal disorder" is a vague category (Ex. 15: 393), and that OSHA should drop the issue until the science is better (Ex. 15: 204).

OSHA does not agree that the provisions on the recording of MSDs contained in this recordkeeping rule would conflict in any way with OSHA's ergonomics rulemaking. Unlike the proposed ergonomics standard, the final ergonomics standard does not use an OSHA recordable case as a "trigger" that would require an employer to implement an ergonomics program. As a result, a recordable musculoskeletal disorder does not necessarily mean that the employer is required to implement an ergonomics program. The recordkeeping rule's provisions on the reporting of MSDs simply address the most consistent and appropriate way to record injury and illness data on these disorders. MSDs, like all other injuries and illnesses, must be evaluated for their work-relatedness and their recordability under the recordkeeping rule's general recording criteria; only if the MSD meets these tests is the case recordable. Additionally, OSHA has required the recording of MSDs for many years.

The recordkeeping rule and the ergonomics standard treat MSDs somewhat differently because the purpose of the two rules is different. Thus, although many of the requirements in the two rules are the same, some requirements reflect the different purposes of the two rulemakings. For example, the recordkeeping rule defines MSDs more broadly than the ergonomics rule because one of the purposes of the Part 1904 recordkeeping system is to gather broad information about injuries and illnesses; the ergonomics standard, in contrast, is designed to protect workers from those MSD hazards the employer has identified in their job. Another difference between the two rules is that the ergonomics standard requires employers to evaluate employee reports of MSD signs and symptoms that last for seven consecutive days, although the recordkeeping rule does not require employers to record signs and symptoms that last for seven consecutive days unless such signs or symptoms involve medical treatment, days of restricted work, or days away from work. The record in the ergonomics rulemaking strongly supported early reporting of MSD signs and symptoms because such early reporting reduces disability, medical costs, and lost productivity. However, evidence in the recordkeeping rulemaking did not support a requirement that persistent signs and symptoms of all occupational injuries and illnesses be recorded on the OSHA Log, and the final recordkeeping rule accordingly contains no such requirement.

Section 1904.29 Forms

Section 1904.29, titled "Forms," establishes the requirements for the forms (OSHA 300 Log, OSHA 300A Annual Summary, and OSHA 301 Incident Report) an employer must use to keep OSHA Part 1904 injury and illness records, the time limit for recording an injury or illness case, the use of substitute forms, the use of computer equipment to keep the records, and privacy protections for certain information recorded on the OSHA 300 Log.

Paragraph 1904.29(a) sets out the basic requirements of this section. It directs the employer to use the OSHA 300 (Log), 300A (Summary), and 301 (Incident Report) forms, or equivalent forms, to record all recordable occupational injuries and illnesses. Paragraph 1904.29(b) contains requirements in the form of questions and answers to explain how employers are to implement this basic requirement. Paragraph 1904.29(b)(1) states the requirements for: (1) Completing the establishment information at the top of the OSHA 300 Log, (2) making a one- or two-line entry for each recordable injury and illness case, and (3) summarizing the data at the end of the year. Paragraph 1904.29(b)(2) sets out the requirements for employers to complete the OSHA 301 Incident Report form (or equivalent) for each recordable case entered on the OSHA 300 Log. The requirements for completing the annual summary on the Form 300A are found at Section 1904.32 of the final rule.

Required Forms

OSHA proposed to continue to require employers to keep both a Log (Form 300) and an Incident Report form (Form 301) for recordkeeping purposes, just as they have been doing under the former rule. OSHA received no comments on the use of two forms for recordkeeping purposes, i.e., a Log with a one-line entry for each case and a supplemental report that requires greater detail about each injury or illness case. OSHA has therefore continued to require two recordkeeping forms in the final rule, although these have been renumbered (they were formerly designated as the OSHA 200 Log and the OSHA 101 Supplementary Report).

In addition to establishing the basic requirements for employers to keep records on the OSHA 300 Log and OSHA 301 Incident Report and providing basic instructions on how to complete these forms, this section of the rule states that employers may use two lines of the OSHA 300 Log to describe an injury or illness, if necessary. Permitting employers to use two lines when they need more space and specifying this information in the rule and on the Log responds to several comments (see, *e.g.*, Exs. 37; 15: 138, 389) about the lack of adequate space for descriptive information on the proposed OSHA 300 Log form. OSHA believes that most injury and illness cases can be recorded using only one line of the Log. However, for those cases requiring more space, this addition to the Log makes it clear that two lines may be used to describe the case. The OSHA 300 Log is designed to be a scannable document that employers, employees and government representatives can use to review a fairly large number of cases in a brief time, and OSHA believes that employers will not need more than two lines to describe a given case. Employers should enter more detailed information about each case on the OSHA 301 form, which is designed to accommodate lengthier information.

Deadline for Entering a Case

Paragraph 1904.29(b)(3) establishes the requirement for how quickly each recordable injury or illness must be recorded into the records. It states that the employer must enter each case on the OSHA 300 Log and OSHA 301 Form within 7 calendar days of receiving information that a recordable injury or illness has occurred. In the vast majority of cases, employers know immediately or within a short time that a recordable case has occurred. In a few cases, however, it may be several days before the employer is informed that an employee's injury or illness meets one or more of the recording criteria.

The former recordkeeping rule required each injury or illness to be entered on the OSHA Log and Summary no later than six working days after the employer received information about the case. OSHA proposed to change this interval to 7 calendar days. Several commenters agreed that allowing 7 calendar days would simplify the reporting time requirement and reduce confusion for employers (see, *e.g.*, Exs. 36; 15: 9, 36, 65, 107, 154, 179, 181, 203, 332, 369, 387). Other commenters (see, *e.g.*, Exs. 15: 46, 60, 82, 89, 184, 204, 225, 230, 239, 283, 288, 305, 348, 375, 390, 346, 347, 348, 358, 389, 409, 423, 424, 431) objected to the proposed 7 calendar-day requirement, principally on the grounds that the proposed 7 calendar-day time limit would actually be shorter than the former rule's 6 working-day limit in some situations, such as if a long holiday weekend intervened (see, *e.g.*, Exs. 15: 9, 60, 230, 272, 375).

One commenter urged OSHA to adopt a 21-day period because conducting a thorough investigation to determine whether a case is work-related or a recurrence of an old case can sometimes take longer than 7 or even 10 days (Ex. 15: 184). In the final rule, OSHA is adopting a 7 calendar-day time limit for the recording of an injury or illness that meets the rule's recording criteria. For many employers, the 7 day calendar period will be longer than the former 6 working day period. Although it is true that, in other cases, a 7 calendar-day limit may be slightly shorter than the former rule's 6 working-day limit, the Agency believes that the 7 calendar-day rule will provide employers sufficient time to receive information and record the case. In addition, a simple "within a week" rule will be easier for employers to remember and apply, and is consistent with OSHA's decision, in this rule, to move from workdays to calendar days whenever possible. The Agency believes that 7 calendar days is ample time for recording, particularly since the final rule, like the former rule, allows employers to revise an entry simply by lining it out or amending it if further information justifying the revision becomes available. The final rule does contain one exception for the 7 day recording period: if an employee experiences a recordable hearing loss, and the employer elects to retest the employee's hearing within 30 days, the employer can wait for the results of the retest before recording.

Equivalent Forms and Computerized Records

Commenters were unanimous in urging OSHA to facilitate the use of computers and to allow the use of alternative forms in OSHA recordkeeping (see, *e.g.*, Exs. 21, 22, 15:9, 11, 45, 72, 95, 111, 184, 262, 271, 288, 305, 318, 341, 346, 389, 390, 396, 405, 424, 434, 438). The comments of the U.S. West Company (Ex. 15:184) are representative of these views:

U S WEST strongly supports provisions in the proposed rule that allow "equivalent" forms instead of the OSHA Forms 300 and 301. U S WEST also supports the provisions that would allow use of data processing equipment and computer printouts of equivalent forms. These provisions allow employers considerable flexibility and greatly reduced paperwork burdens and costs, especially for larger multi-site employers.

Accordingly, paragraphs 1904.29(b)(4) and (b)(5) of the final rule make clear that employers are permitted to record the required information on electronic media or on paper forms that are different from the OSHA 300 Log, provided that the electronic record or paper forms are equivalent to the OSHA 300 Log. A form is deemed to be "equivalent" to the OSHA 300 Log if it can be read and understood as easily as the OSHA form and contains at least as much information as the OSHA 300 Log. In addition, the equivalent form must be completed in accordance with the instructions used to complete the OSHA 300 Log. These provisions are intended to balance OSHA's obligation, as set forth in Section 8(d) of the OSH Act, to reduce information collection burdens on employers as much as possible, on the one hand, with the need, on the other hand, to maintain uniformity of the data recorded and provide employers flexibility in meeting OSHA's recordkeeping requirements. These provisions also help to achieve one of OSHA's goals for this rulemaking: to allow employers to take full advantage of modern technology and computers to meet their OSHA recordkeeping obligations.

Several commenters were concerned that computerized records would make it more difficult for employees to access the records (see, *e.g.*, Exs. 15:379, 380, 418, 438). Representative of these views is a comment from the United Auto Workers (UAW):

Electronic data collection is an essential step to moving forward, especially regarding data analysis for large worksites. However, as it works today electronic collection can also be an obstacle to prompt availability to persons without direct access to the computer system. For this reason, OSHA should require the availability of electronic information to employees and employee representatives in the same time interval as hard copy information, regardless of whether the computer system is maintained at the site (Ex. 15: 438).

OSHA does not believe that computerization of the records will compromise timely employee, employer or government representative access to the records. To ensure that this is the case, paragraph § 1904.29(b)(5) of the final rule allows the employer to keep records on computer equipment only if the computer system can produce paper copies of equivalent forms when access to them is needed by a government representative, an employee or former employee, or an employee representative, as required by §§ 1904.35 or 1904.40, respectively. Of course, if the employee requesting access to the information agrees to receive it by e-mail, this is acceptable under the 1904 rule.

OSHA also proposed specifically to require that, on any equivalent form, three of the questions on the form asking for details of the injury or illness

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(proposed questions 16, 17, and 18) be positioned on the form in the same order and be phrased in identical language to that used on the OSHA 301 Incident Report. The three questions were all designed to obtain more detailed information about how the injury or illness occurred, what equipment or materials the employee was using at the time of the injury or illness, and the activity the employee was engaged in at the time of the injury or illness.

A number of commenters objected to the proposed requirement that, on any equivalent form, these three questions be asked in the same order and be phrased in the same language as on the OSHA Incident Report (see, *e.g.*, Exs. 33; 37; 15: 9, 41, 44, 59, 60, 119, 132, 156, 176, 201, 231, 281, 283, 301, 312, 318, 322, 329, 334, 335, 346). In addition to arguing that such a requirement would be burdensome and prescriptive, these commenters pointed out that the proposed OSHA recordkeeping form was not identical to many State workers' compensation forms (the forms most often used as alternatives to the OSHA forms), which would mean that employers in these States would, in effect, be forced to use the OSHA forms (Ex. 15: 334). Other commenters argued that being required to use a certain format would hamper employers' internal accident investigations (see, *e.g.*, Exs. 15: 44, 176, 322). For example, the Kodak Company remarked:

> In [proposed] section 1904.5(b)(2)—"Questions 16, 17 & 18 must be asked in the same order and using identical language from the Form 301." Companies, like Kodak, have well established techniques to ascertain the cause of the injury and illness. This requirement would actually hamper our ability to find the root cause of an accident. This requirement should be eliminated from the rule. (Ex. 15: 322)

The final rule does not include a requirement that certain questions on an equivalent form be asked in the same order and be phrased in language identical to that used on the OSHA 301 form. Instead, OSHA has decided, based on a review of the record evidence, that employers may use any substitute form that contains the same information and follows the same recording directions as the OSHA 301 form, and the final rule clearly allows this. Although the consistency of the data on the OSHA 301 form might be improved somewhat if the questions asking for further details were phrased and positioned in an identical way on all employers' forms, OSHA has concluded that the additional burden such a requirement would impose on employers and workers' compensation agencies outweighs this consideration.

OSHA has revised the wording of these three questions on the final OSHA 301 form to match the phraseology used by the Bureau of Labor Statistics (BLS) in its Annual Survey of Occupational Injuries and Illnesses. By ensuring consistency across both the BLS and OSHA forms, this change will help those employers who respond both to the BLS Annual Survey and keep OSHA records.

Handling of Privacy Concern Cases

Paragraphs 1904.29(b)(6) through (b)(10) of the final rule are new and are designed to address privacy concerns raised by many commenters to the record. Paragraph 1904.29(b)(6) requires the employer to withhold the injured or ill employee's name from the OSHA 300 Log for injuries and illnesses defined by the rule as "privacy concern cases" and instead to enter "privacy concern case" in the space where the employee's name would normally be entered if an injury or illness meeting the definition of a privacy concern case occurs. This approach will allow the employer to provide OSHA 300 Log data to employees, former employees and employee representatives, as required by § 1904.35, while at the same time protecting the privacy of workers who have experienced occupational injuries and illnesses that raise privacy concerns. The employer must also keep a separate, confidential list of these privacy concern cases, and the list must include the employee's name and the case number from the OSHA 300 Log. This separate listing is needed to allow a government representative to obtain the employee's name during a workplace inspection in case further investigation is warranted and to assist employers to keep track of such cases in the event that future revisions to the entry become necessary.

Paragraph 1904.29(b)(7) defines "privacy concern cases" as those involving: (i) An injury or illness to an intimate body part or the reproductive system; (ii) an injury or illness resulting from a sexual assault; (iii) a mental illness; (iv) a work-related HIV infection, hepatitis case, or tuberculosis case; (v) needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material, or (vi) any other illness, if the employee independently and voluntarily requests that his or her name not be entered on the log. Paragraph 1904.29(b)(8) establishes that these are the only types of occupational injuries and illnesses that the employer may consider privacy concern cases for recordkeeping purposes.

Paragraph 1904.29(b)(9) permits employers discretion in recording case information if the employer believes that doing so could compromise the privacy of the employee's identity, even though the employee's name has not been entered. This clause has been added because OSHA recognizes that, for specific situations, coworkers who are allowed to access the log may be able to deduce the identity of the injured or ill worker and obtain innapropriate knowledge of a privacy-sensitive injury or illness. OSHA believes that these situations are relatively infrequent, but still exist. For example, if knowing the department in which the employee works would inadvertently divulge the person's identity, or recording the gender of the injured employee would identifying that person (because, for example, only one woman works at the plant), the employer has discretion to mask or withhold this information both on the Log and Incident Report.

The rule requires the employer to enter enough information to identify the cause of the incident and the general severity of the injury or illness, but allows the employer to exclude details of an intimate or private nature. The rule includes two examples; a sexual assault case could be described simply as "injury from assault," or an injury to a reproductive organ could be described as "lower abdominal injury." Likewise, a work-related diagnosis of post traumatic stress disorder could be described as "emotional difficulty." Reproductive disorders, certain cancers, contagious diseases and other disorders that are intimate and private in nature may also be described in a general way to avoid privacy concerns. This allows the employer to avoid overly graphic descriptions that may be offensive, without sacrificing the descriptive value of the recorded information.

Paragraph 1904.29(b)(10) protects employee privacy if the employer decides voluntarily to disclose the OSHA 300 and 301 forms to persons other than those who have a mandatory right of access under the final rule. The paragraph requires the employer to remove or hide employees' names or other personally identifying information before disclosing the forms to persons other than government representatives, employees, former employees or authorized representatives, as required by paragraphs 1904.40 and 1904.35, except in three cases. The employer may disclose the forms, complete with personally identifying information, (2) only: (i) to an auditor or consultant

hired by the employer to evaluate the safety and health program; (ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or (iii) to a public health authority or law enforcement agency for uses and disclosures for which consent , an authorization, or opportunity to agree or object is not required under section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

These requirements have been included in § 1904.29 rather than in § 1904.35, which establishes requirements for records access, because waiting until access is requested to remove identifying information from the OSHA 300 Log could unwittingly compromise the injured or ill worker's privacy and result in unnecessary delays. The final rule's overall approach to handling privacy issues is discussed more fully in the preamble discussion of the employee access provisions in § 1904.35.

The Treatment of Occupational Illness and Injury Data on the Forms

The treatment of occupational injury and illness data on the OSHA forms is a key issue in this rulemaking. Although the forms themselves are not printed in the Code of Federal Regulations (CFR), they are the method OSHA's recordkeeping regulation uses to meet the Agency's goal of tracking and reporting occupational injury and illness data. As such, the forms are a central component of the recordkeeping system and mirror the requirements of the Part 1904 regulation. The final Part 1904 rule requires employers to use three forms to track occupational injuries and illnesses: the OSHA 300, 300A, and 301 forms, which replace the OSHA 200 and 101 forms called for under the former recordkeeping rule, as follows:

1. The OSHA Form 300, Log of Work-Related Injuries and Illnesses, replaces the Log portion of the former OSHA Form 200 Log and Summary of Occupational Injuries and Illnesses. The OSHA 300 Log contains space for a description of the establishment name, city and state, followed by a one-line space for the entry for each recordable injury and illness.

2. The OSHA Form 300A, Summary of Work-Related Injuries and Illnesses, replaces the Summary portion of the former OSHA Form 200 Log and Summary of Occupational Injuries and Illnesses. The Form 300A is used to summarize the entries from the Form 300 Log at the end of the year and is then posted from February 1 through April 30 of the following year so that employees can be aware of the occupational injury and illness experience of the establishment in which they work. The form contains space for entries for each of the columns from the Form 300, along with information about the establishment, and the average number of employees who worked there the previous year, and the recordkeeper's and corporate officer's certification of the accuracy of the data recorded on the summary. (These requirements are addressed further in Section 1904.32 of the final rule and its associated preamble.)

3. The OSHA Form 301, Injury and Illness Report, replaces the former OSHA 101 Form. Covered employers are required to fill out a one-page form for each injury and illness recorded on the Form 300. The form contains space for more detailed information about the injured or ill employee, the physician or other health care professional who cared for the employee (if medical treatment was necessary), the treatment (if any) of the employee at an emergency room or hospital, and descriptive information telling what the employee was doing when injured or ill, how the incident occurred, the specific details of the injury or illness, and the object or substance that harmed the employee. (Most employers use a workers' compensation form as a replacement for the OSHA 301 Incident Report.)

The use of a three-form system for recordkeeping is not a new concept. The OSHA recordkeeping system used a separate summary form from 1972 to 1977, when the Log and Summary forms were combined into the former OSHA Form 200 (42 FR 65165). OSHA has decided that the three-form system (the 300 Log, the 300A summary, and the 301 Incident Report) has several advantages. First, it provides space for more cases to be entered on the Log but keeps the Log to a manageable size. Second, it helps to ensure that an injured or ill employee's name is not posted in a public place. When the forms were combined in 1977 into a single form, employers occasionally neglected to shield an employee's name on the final sheet of the 200 Log, even though the annual summary form was designed to mask personal identifiers. The use of a separate 300A summary form precludes this possibility. Third, the use of a separate summary form (the final rule's Form 300A) allows the data to be posted in a user-friendly format that will be easy for employees and employers to use. Fourth, a separate 300A Form provides extra space for information about an employee's right to access the Log, information about the establishment and its employees, and the dual certifications required by § 1904.32 of the rule. Finally, a separate 300A Form makes it easier to attach to the reverse side of the form worksheets that are designed to help the employer calculate the average number of employees and hours worked by all employees during the year.

The majority of the changes to the final forms (compared with the forms used with the former rule and the proposed forms) have been made to reflect the requirements of the final rule and are needed to align the forms with the final regulatory requirements. All of the other changes to the forms reflect formatting and editorial changes made to simplify the forms, make them easier to understand and complete, and facilitate use of the data. The forms have been incorporated into an information package that provides individual employers with several copies of the OSHA 300, 300A, and 301 forms; general instructions for filling out the forms and definitions of key terms; an example showing how to fill out the 300 Log; a worksheet to assist employers in computing the average number of employees and the total number of hours worked by employees at the establishment in the previous year; a non-mandatory worksheet to help the employer compute an occupational injury and illness rate; and instructions telling an employer how to get additional help by (1) accessing the OSHA Internet home page, or (2) by calling the appropriate Federal OSHA regional office or the OSHA approved State-Plan with jurisdiction. The package is included in final rule Section VI, Forms, later in this preamble.

The Size of the OSHA Recordkeeping Forms

The OSHA recordkeeping forms required by the final Part 1904 recordkeeping rule are printed on legal size paper (8½" x 14"). The former rule's Log was an 11 by 17-inch form, the equivalent of two standard 8½ by 11-inch pages. The former 200 Log was criticized because it was unwieldy to copy and file and contained 12 columns for recording occupational injury and occupational illness cases. The proposed OSHA 300 Log and Summary would have fit on a single 8½ by 11-inch sheet of paper (61 FR 4050), a change that would have been made possible by the proposed elimination of redundancies on the former 200 Log and of certain data elements that provided counts of restricted workdays and separate data on occupational injury and illness cases. The proposed OSHA 300 Form was favorably received by a

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large number of commenters (see, *e.g.*, Exs. 19, 44, 15: 48, 157, 246, 307, 347, 351, 373, 374, 378, 384, 391, 395, 396, 427, 434, 441, 443). For example, the National Association of Plumbing-Heating-Cooling Contractors (NAPHCC) stated:

> NAPHCC applauds the Agency's efforts to simplify the Injury and Illness Log and Summary in the form of a new Form 300 and Form 301. Employers will be more comfortable with the one-page forms—they appear less ominous than the oversized 200 Form and therefore have a better chance of being completed in a timely and accurate manner (Ex. 15: 443, p. 6).

A number of commenters were concerned that proposed the 300 form would fail to capture important data and argued that the former Log should be retained (see, *e.g.*, Exs. 15:15, 47, 283, 369, 429, 438). The primary argument of this group of commenters was that the size of the form should not determine which data elements were included on the Log and which were not. The comment of the International Union, United Automobile, Aerospace & Agricultural Implement Workers of America—UAW summed up this position: "The UAW uses this data on a yearly basis when it becomes available at the national level, and on a daily basis at the plant level. Compared to the value of the summary data and data series, the goal of reducing the size of the form to something easily Xeroxed is silly" (Ex. 15: 438, p. 2). The International Brotherhood of Teamsters commented "OSHA believes the change results in a simplified form that fits on a standard sheet of paper that can be easily copied and kept on a personal computer. * * * The storage capacity of an additional page in a personal computer is hardly burdensome. The amount of information that can be collected should always be need based, and never be limited to what an 8½" x 11" sheet of paper can hold" (Ex. 15: 369, p. 49).

OSHA agrees that the proposed Log would have resulted in a significant loss of useful data and has therefore maintained several data fields on the final OSHA 300 Log to capture counts of restricted work days and collect separate data on occupational injuries and several types of occupational illness. However, there is a limit to the information that can be collected by any one form. OSHA wishes to continue to make it possible for those employers, especially smaller employers, who wish to keep records in paper form to do so. It is also important that the Log be user-friendly, easily copied and filed, and otherwise manageable. Although a form 8½ x 11 inches in size would be even easier to manage, OSHA has concluded that a form of that size is too small to accommodate the data fields required for complete and accurate reporting.

Accordingly, OSHA has redesigned the OSHA 300 Log to fit on a legal size (8½ x 14 inches) piece of paper and to clarify that employers may use two lines to enter a case if the information does not fit easily on one line. The OSHA forms 300A and 301, and the remainder of the recordkeeping package, have also been designed to fit on the same-size paper as the OSHA 300 Log. For those employers who use computerized systems (where handwriting space is not as important) equivalent computer-generated forms can be printed out on 8½ x 11 sheets of paper if the printed copies are legible and are as readable as the OSHA forms.

Commenters raised four major issues concerning the OSHA 300 Log: (1) Defining lost workdays (discussed below); (2) collecting separate data on occupational injury and occupational illness (discussed below); (3) collecting separate data on musculoskeletal disorders (discussed below and in the summary and explanation associated with § 1904.12; and (4) recurrences (discussed in the summary and explanation associated with § 1904.6, Determination of new cases). In addition, commenters raised numerous minor issues concerning the 300 Log data elements and forms design; these are discussed later in this section.

Defining Lost Workdays

OSHA proposed to eliminate the term "lost workdays," by replacing it with "days away from work" (61 FR 4033). The OSHA recordkeeping system has historically defined lost workdays as including both days away from work and days of restricted work activity, and the *Recordkeeping Guidelines* discussed how to properly record lost workday cases with days away from work and lost workday cases with days of restricted work activity (Ex. 2, p. 47, 48). However, many use the term "lost workday" in a manner that is synonymous with "day away from work," and the term has been used inconsistently for many years. Many commenters on the proposal agreed that the term "lost workday" should be deleted from the forms and the recordkeeping system because of this confusion (see, *e.g.*, Exs. 33; 37; 15: 9, 26, 69, 70, 105, 107, 136, 137, 141, 146, 176, 184, 204, 224, 231, 266, 271, 272, 273, 278, 281, 287, 288, 301, 303, 305, 347, 384, 414, 428). The Akzo Nobel Chemicals Company (Ex. 37) simply commented "[a] big ATTA BOY for removing restricted work cases from under the lost time umbrella. They never really belonged there." William K. Principe of the law firm of Constangy, Brooks & Smith, LLC, stated that:

> The elimination of the term "lost work days" is a good idea, because its use under the existing recordkeeping regulations has been confusing. Recordkeepers have equated "lost work days" with "days away from work," but have not thought that "lost work days" included days of "restricted work activity." Thus, the elimination of "lost work days" will result in more understandable terminology.

The Hoffman-La Roche, Inc. company agreed with OSHA's proposal to eliminate the term lost workdays from the system, stating that "[t]he term "lost workdays" is confusing and does not clearly define whether the case involved days away from work or restricted days. However, the term "lost workday case" still has a place in defining a case that has either days away from work or restricted days." The Jewel Coal and Coke Company (Ex. 15: 281) remarked that:

> [w]e believe that the listing of restricted work injuries/illnesses has its purpose as to the consideration of the seriousness of the injury or illness. However, we believe that restricted work duty injuries/illnesses should be placed in a separate category from days away from work and should not be considered as serious as accidents with days away from work but are in fact more serious than first Aid cases or other medically reportable cases. We believe that the listing of the date of return of the employee to full work activities may very well have it's place on the OSHA Form 301 or other supplemental forms.

In the final rule, OSHA has eliminated the term "lost workdays" on the forms and in the regulatory text. The use of the term has been confusing for many years because many people equated the terms "lost workday" with "days away from work" and failed to recognize that the former OSHA term included restricted days. OSHA finds that deleting this term from the final rule and the forms will improve clarity and the consistency of the data.

The 300 Log has four check boxes to be used to classify the case: death, day(s) away from work, days of restricted work or job transfer; and case meeting other recording criteria. The employer must check the single box that reflects the most severe outcome associated with a given injury or illness. Thus, for an injury or illness where the injured worker first stayed home to recuperate and then was assigned to restricted work for several days, the employer is required only to check the box for days away from work (column I). For a case with only job transfer or restriction, the employer must check the box for days of restricted work or job transfer (Column H). However, the final Log still allows employers to calculate the incidence rate formerly referred to as a "lost workday injury and illness rate" despite the fact that it separates the data formerly captured under this heading into two separate categories. Because the OSHA Form 300 has separate check boxes for days away from work cases and cases where the employee remained at work but was temporarily transferred to another job or assigned to restricted duty, it is easy to add the totals from these two columns together to obtain a single total to use in calculating an injury and illness incidence rate for total days away from work and restricted work cases.

Counting Days of Restricted Work or Job Transfer

Although the final rule does not use the term "lost workday" (which formerly applied both to days away from work and days of restricted or transferred work), the rule continues OSHA's longstanding practice of requiring employers to keep track of the number of days on which an employee is placed on restricted work or is on job transfer because of an injury or illness. OSHA proposed to eliminate the counting of the number of days of restricted work from the proposed 300 Log (61 FR 4046). The proposal also asked whether the elimination of the restricted work day count would provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work (61 FR 4046).

A large number of commenters supported OSHA's proposal to eliminate the counting of restricted work days (see, *e.g.*, Exs. 21; 26; 27; 28; 33; 37; 51; 15: 9, 19, 26, 39, 44, 60, 65, 67, 69, 70, 76, 79, 82, 83, 85, 87, 100, 105, 107, 111, 119, 121, 123, 136, 137, 141, 145, 146, 154, 156, 159, 170, 171, 173, 176, 184, 188, 194, 199, 203, 204, 205, 218, 224, 225, 229, 230, 231, 234, 235, 239, 246, 247, 260, 262, 265, 266, 271, 272, 273, 278, 281, 283, 287, 288, 289, 298, 301, 303, 304, 305, 307, 317, 321, 332, 334, 336, 337, 341, 345, 346, 347, 351, 364, 368, 373, 384, 390, 391, 392, 401, 405, 409, 413, 414, 423, 424, 426, 427, 428, 430, 434, 437, 440, 442). For example, the Union Carbide Corporation (Ex. 15: 391) argued that their:

> [e]xperience with tracking lost or restricted workdays the way it is being done today indicates that it is fruitless. The interest is in the number of lost workday or restricted workday cases with only minor attention being given to the number of days involved. Elimination of the term "lost workdays" in regard to restricted workdays would surely be a step in the direction of simplicity and focus. The severity of an injury/illness is more clearly indicated by the number of days away from work than by any other means. The inclusion of cases involving restricted work only clouds the issue.

The Monsanto Corporation (Ex. 28) urged the Agency to do away with *all* day counts, noting that Monsanto:

> [u]ses the recordable case as the basis of our performance measurement system. We measure the number of days away and restricted but rarely look at them. We agree that OSHA should eliminate the number of days of restricted work from the requirements but we would also delete the number of days away as well. While the number of days are some measure of "severity", we think a better and simpler measure is just the cases rate for fatalities and/or days away cases.

The commenters who argued for eliminating the counting of restricted workdays offered several reasons: (1) Doing away with the counting would simplify the recordkeeping system and reduce burden on employers (see, *e.g.*, Exs. 33; 15: 69, 105, 136, 137, 141, 146, 156, 176, 184, 188, 203, 224, 231, 239, 266, 272, 273, 278, 288, 289, 301, 303, 304, 336, 337, 345, 346, 347, 390, 391, 409, 424, 426, 428, 430, 442); (2) eliminating the day counts would make it easier to computerize the records (see, *e.g.*, Exs. 15: 136, 137, 141, 224, 266, 278); (3) limiting counts of restricted work would match workers' compensation insurance requirements, which typically count only days away from work (see, *e.g.*, Exs. 15: 225, 336); (4) counts of restricted work have little or no value (see, *e.g.*, Exs. 21; 15: 65, 105, 119, 154, 170, 203, 205, 235, 260, 262, 265, 332, 347, 391, 401, 405, 409, 430); (5) restricted workday counts are not used in safety and health programs and their evaluation (see, *e.g.*, Exs. 15: 65, 119, 154, 159, 194, 239, 271, 347, 409, 426, 428); (6) restricted workday counts are not a good measure of injury and illness severity (see, *e.g.*, Exs. 15: 336, 345); and (7) restricted workday counts are not a uniform or consistent measure (see, *e.g.*, Exs. 15: 235, 288, 289, 347, 409, 442).

For example, the National Grain and Feed Association (Ex. 15: 119) argued that "[t]here is no evidence that the current restricted work activity day counts are being used in safety and health programs and there is no purpose in continuing the restricted work activity count requirement." The Tennessee Valley Authority (Ex. 15: 235) argued that "[o]nly days away from work or death should be recorded on the 300 log. Recording of restricted work-day cases is difficult to consistently record, thereby, not providing a good data base for comparison."

However, a number of commenters opposed the proposal to eliminate the counting of restricted days (see, *e.g.*, Exs. 35; 15: 31, 34, 41, 61, 72, 74, 181, 186, 281, 310, 350, 359, 369, 371, 380, 438). For example, Linda Ballas & Associates (Ex. 15: 31) argued that:

> [r]estricted work days should be counted. A restricted case with 1 restricted day would be less severe than a restricted work case with 30 days. The elimination of the restricted work activity day count will provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work.* * *

Most of these commenters argued that restricted work day data are needed to gauge the severity of an occupational injury or illness (see, *e.g.*, Exs. 15: 31, 34, 41, 181, 186, 310, 369, 371, 438) or that such data are a measure of lost productivity (see, *e.g.*, Exs. 15: 41, 61, 281). The American Association of Occupational Health Nurses stated that "[O]SHA should be aware that modifications to recording restricted work days will result in the loss of valuable information related to the severity of the injuries/illnesses." The Jewel Coal and Coke Company (Ex. 15: 281) stated that:

> We believe that the listing of restricted work injuries/illnesses has its purpose as to the consideration of the seriousness of the injury or illness. However, we believe that restricted work duty injuries/illnesses should be placed in a separate category from days away from work and should not be considered as serious as accidents with days away from work but are in fact more serious than first Aid cases or other medically reportable cases.* * *

The North Carolina Department of Labor (Ex. 15: 186) recommended that:

> [r]estricted work day counts as well as lost work day counts can be measures of the severity of individual illnesses/injuries. In addition through trend analysis lost work day rates and restricted work day rates may be calculated by job, department, etc. to identify higher risk jobs, departments, etc. and/or measure the effectiveness of interventions and progress in the development of a comprehensive ergonomics program.

As to OSHA's question in the proposal about the incentive for employers to offer restricted work to employee's in order to avoid recording a case with days away from work, a number of commenters questioned whether such an incentive exists (see, *e.g.*, Exs. 15: 13, 26, 27, 39, 79, 136, 137, 141, 156, 181, 199, 218, 224, 229, 242, 263, 266, 269, 270, 278, 283, 341, 364, 377, 409, 426, 434, 440). For example,

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the United Technologies Company (UTC) stated that "[U]TC does not believe that the recording or not recording of restricted days will influence management's decision to temporarily assign employees to restricted work. The decision to place an employee on restricted work is driven by workers' compensation costs rather than OSHA incidence rates" (Ex. 15: 440). The American Textile Manufacturers Association (ATMI) agreed:

> [A]TMI believes that this will not provide an incentive for employers to temporarily assign injured or ill workers to jobs with little or no productive value to avoid recording a case as one involving days away from work. The restricted work activity day count is in no way related to an employer wanting to avoid having days away from work. Workers' compensation claims and, for the most part, company safety awards are based on the number of "lost-time accidents." The counting of restricted work days has never been an incentive or disincentive for these two key employer safety measures and ATMI believes that this will not change. (Ex. 15: 156)

Other commenters, however, believed there could be incentive effects (see, *e.g.*, Exs. 15: 13, 31, 74, 111, 359, 369).

In the final rule, OSHA has decided to require employers to record the number of days of restriction or transfer on the OSHA 300 Log. From the comments received, and based on OSHA's own experience, the Agency finds that counts of restricted days are a useful and needed measure of injury and illness severity. OSHA's decision to require the recording of restricted and transferred work cases on the Log was also influenced by the trend toward restricted work and away from days away from work. In a recent article, the BLS noted that occupational injuries and illnesses are more likely to result in days of restricted work than was the case in the past. From 1978 to 1986, the annual rate in private industry for cases involving only restricted work remained constant, at 0.3 cases per 100 full-time workers. Since 1986, the rate has risen steadily to 1.2 cases per 100 workers in 1997, a fourfold increase. At the same time, cases with days away from work declined from 3.3 in 1986 to 2.1 in 1997 (Monthly Labor Review, June 1999, Vol. 122. No. 6, pp. 11–17). It is clear that employers have caused this shift by modifying their return-to-work policies and offering more restricted work opportunities to injured or ill employees. Therefore, in order to get an accurate picture of the extent of occupational injuries and illnesses, it is necessary for the OSHA Log to capture counts of days away from work *and* days of job transfer or restriction.

The final rule thus carries forward OSHA's longstanding requirement for employers to count and record the number of restricted days on the OSHA Log. On the Log, restricted work counts are separated from days away from work counts, and the term "lost workday" is no longer used. OSHA believes that the burden on employers of counting these days will be reduced somewhat by the simplified definition of restricted work, the counting of calendar days rather than work days, capping of the counts at 180 days, and allowing the employer to stop counting restricted days when the employees job has been permanently modified to eliminate the routine job functions being restricted (see the preamble discussion for 1904.7 General Recording Criteria).

Separate 300 Log Data on Occupational Injury and Occupational Illness

OSHA proposed (61 FR 4036–4037) to eliminate any differences in the way occupational injuries, as opposed to occupational illnesses, were recorded on the forms. The proposed approach would not, as many commenters believed, have made it impossible to determine the types and number of cases of occupational illnesses at the aggregated national level, although it would have eliminated the distinction between injuries and illnesses at the individual establishment level. In other words, the proposed approach would have involved a coding system that the BLS could use to project the incidences of several types of occupational illnesses nationally, but would not have permitted individual employers to calculate the incidence of illness cases at their establishments.

Many commenters reacted with concern to the proposal to eliminate, for recording purposes, the distinction between occupational injuries and occupational illnesses, and to delete the columns on the Log used to record specific categories of illnesses (see, *e.g.*, Exs. 15: 213, 288, 359, 369, 407, 418, 429, 438). For example, Con Edison stated that "Distinguishing between injuries and illness is a fundamental and essential part of recordkeeping" (Ex. 15: 21), and the National Institute for Occupational Safety and Health (NIOSH) discussed the potentially detrimental effects on the Nation's occupational injury and illness statistics of such a move, stating "For occupational health surveillance purposes * * * NIOSH recommends that entries on the OSHA log continue to be categorized separately as illnesses and injuries" (Ex. 15: 407).

Many commenters also criticized OSHA's proposal to delete from the Log the separate columns for 7 categories of occupational illnesses (see, *e.g.*, Exs. 20, 35, 15: 27, 283, 371). These commenters pointed out that these categories of illnesses have been part of the recordkeeping system for many years and that they captured data on illness cases in 7 categories: occupational skin diseases or disorders, dust diseases of the lungs, respiratory conditions due to toxic agents, poisoning (systemic effects of toxic materials), disorders due to physical agents, disorders associated with repeated trauma, and all other occupational illnesses. Typical of the views of commenters concerned about the proposal to delete these columns from the Log was the comment of the United Auto Workers: "OSHA should abandon the plan to change the OSHA 200 form to eliminate illness categories. The illness categories in the summary presently provide critically necessary information about cumulative trauma disorders, and useful information about respiratory conditions" (Ex: 15: 348).

Several commenters supported the proposed concept of adding a single column to the form on which employers would enter illness codes that would correspond to the illness conditions listed in proposed Appendix B, which could then be decoded by government classifiers to project national illness incidence rates for coded conditions (see, *e.g.*, Exs. 20, 15: 27, 369, 371). For example, the United Brotherhood of Carpenters and Joiners of America stated:

> The UBC would recommend [that].* * * A column should be added for an identification code for recordable conditions from Appendix B. (Eg. 1 = hearings loss, 2 = CTD's. 3 = blood lead. Etc.) (Ex. 20).

After a thorough review of the comments in the record, however, OSHA has concluded that the proposed approach, which would have eliminated, for recording purposes, the distinction between work-related injuries and illnesses, is not workable in the final rule. The Agency finds that there is a continuing need for separately identifiable information on occupational illnesses and injuries, as well as on certain specific categories of occupational illnesses. The published BLS statistics have included separate estimates of the rate and number of occupational injuries and illnesses for many years, as well as the rate and number of different types of occupational illnesses, and employers, employees, the government, and the public have found this information useful and worthwhile. Separate illness and injury data are particularly useful at the establishment level, where employers and employees can use them to evaluate the establishment's health experience and compare it to the national experience or to the experience of other employers in their industry or their own prior experience. The data are also useful to OSHA personnel performing worksite inspections, who can use this information to identify potential health hazards at the establishment.

Under the final rule, the OSHA 300 form has therefore been modified specifically to collect information on five types of occupational health conditions: musculoskeletal disorders, skin diseases or disorders, respiratory conditions, poisoning, and hearing loss. There is also an "all other illness" column on the Log. To record cases falling into one of these categories, the employer simply enters a check mark in the appropriate column, which will allow these cases to be separately counted to generate establishment-level summary information at the end of the year.

OSHA rejected the option suggested by the UBC and others (see, *e.g.*, Exs. 20, 15: 27, 369, 371)—to add a single column that would include a code for different types of conditions—because such an approach could require employers to scan and separately tally entries from the column to determine the total number of each kind of illness case, an additional step that OSHA believes would be unduly burdensome. Because the scanning and tallying are complex, this approach also would be likely to result in computational errors.

In the final rule, two of the illness case columns on the OSHA 300 Log are identical to those on the former OSHA Log: a column to capture cases of skin diseases or disorders and one to capture cases of systemic poisoning. The single column for respiratory conditions on the new OSHA Form 300 will capture data on respiratory conditions that were formerly captured in two separate columns, i.e., the columns for respiratory conditions due to toxic agents (formerly column 7c) and for dust diseases of the lungs (formerly column 7b). Column 7g of the former OSHA Log provided space for data on all other occupational illnesses, and that column has also been continued on the new OSHA 300 Log. On the other hand, column 7e from the former OSHA Log, which captured cases of disorders due to physical agents, is not included on the new OSHA Log form. The cases recorded in former column 7e primarily addressed heat and cold disorders, such as heat stroke and hypothermia; hyperbaric effects, such as caisson disease; and the effects of radiation, including occupational illnesses caused by x-ray exposure, sun exposure and welder's flash. Because space on the form is at a premium, and because column 7e was not used extensively in the past (recorded column 7e cases accounted only for approximately five percent of all occupational illness cases), OSHA has not continued this column on the new OSHA 300 Log.

OSHA has, however, added a new column specifically to capture hearing loss cases on the OSHA 300 Log. The former Log included a column devoted to repeated trauma cases, which were defined as including noise-induced hearing loss cases as well as cases involving a variety of other conditions, including certain musculoskeletal disorders. Several commenters recommended that separate data be collected on hearing loss (see, *e.g.*, Exs. 20, 53X, p.76, 15: 31). Dedicating a column to occupational hearing loss cases will provide a valuable new source of information on this prevalent and often disabling condition. Although precise estimates of the number of noise-exposed workers vary widely by industry and the definition of noise dose used, the EPA estimated in 1981 that about 9 million workers in the manufacturing sector alone were occupationally exposed to noise levels above 85 dBA. Recent risk estimates suggest that exposure to this level of noise over a working lifetime would cause material hearing impairment in about 9 percent, or approximately 720,000, U.S. workers (NIOSH, 1998). A separate column for occupational hearing loss is also appropriate because the BLS occupational injury and illness statistics only report detailed injury characteristics information for those illness cases that result in days away from work. Because most hearing loss cases do not result in time off the job, the extent of occupational hearing loss has not previously been accurately reflected in the national statistics. By creating a separate column for occupational hearing loss cases, and clearly articulating in section 1904.10 of the final rule the level of hearing loss that must be recorded, OSHA believes that the recordkeeping system will, in the future, provide accurate estimates of the incidence of work-related loss of hearing among America's workers.

Column on the Log for Musculoskeletal Disorders

Column 7f of the former Log also was intended to capture cases involving repetitive motion conditions, such as carpal tunnel syndrome, tendinitis, etc. These conditions have been called by many names, including repetitive stress injuries, cumulative trauma disorders, and overuse injuries. OSHA has decided to include a separate column on the Log for musculoskeletal disorders (MSDs), the preferred term for injuries and illnesses of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs, including those of the upper extremities, lower extremities, and back. Many MSDs are caused by workplace risk factors, such as lifting, repetitive motion, vibration, overexertion, contact stress, awkward or static postures, and/or excessive force. The repeated trauma column on the former OSHA Log did not permit an accurate count of musculoskeletal disorders, both because other conditions, such as occupational hearing loss, were included in the definition of repeated trauma and because many musculoskeletal disorders—including lower back injuries—were excluded. The column was limited to disorders classified as illnesses, but OSHA instructed employers to record all back cases as injuries rather than illnesses, even though back disorders are frequently associated with exposure to occupational stresses over time (Ex. 2, p. 38).

In its proposal, OSHA asked for comment on the need for a separate column containing information on musculoskeletal disorder (MSD) cases such as low back pain, tendinitis and carpal tunnel syndrome. OSHA received numerous comments opposing the addition of an MSD column to the Log (see, *e.g.*, Exs. 15: 9, 60, 78, 105, 122, 136, 137, 141, 201, 218, 221, 224, 266, 278, 305, 308, 318, 346, 395, 397, 406, 414, 430). These commenters objected on several grounds: because they believed that including such a column would make the forms more complex (Ex. 15: 414), because the column would have "no utility" (Ex. 15: 397), or because the column would only capture a small percentage of total MSD cases (Ex. 15: 210). Several commenters objected because they believed that an MSD column would duplicate information already obtained through the case description (see, *e.g.*, Exs. 15: 9, 105, 210, 221, 406). For example, the law firm of Ogletree, Deakins, Nash, Smoak & Stewart offered comments on behalf of a group of employers known as the ODNSS Coalition, remarking that "The log and system of OSHA recordkeeping would not benefit from a separate column for musculoskeletal disorders. The proposed rules for recording these disorders are clear, and

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the revisions to the "case description" column appearing on the OSHA Form 300 provide for the ample identification of the disorders, which will enable all interested parties to track and analyze entries of that nature" (Ex. 15: 406). Another group of commenters contended that a separate MSD column would result in an inaccurate picture of MSD incidence because the numbers recorded would increase as a result of the inclusion of lower back MSDs in the cases to be entered in the column (see, *e.g.*, Exs. 15: 305, 308, 318, 346). Representative of these comments is one from the National Association of Manufacturers (NAM):

> Given the over-inclusive definitions of the terms "work-related," "injury or illness," "medical treatment" and "MSDs" (in Appendix B), and the fact that, for the first time, back injuries would be included as MSDs, we strongly objected to that idea. Under that approach, the MSD numbers probably would have been huge, would have painted a grossly inaccurate and misleading picture as to the current prevalence of MSDs, and would have been cited as justification for an ergonomics standard. Unless and until those deficiencies are completely eliminated, the NAM remains unalterably opposed to the inclusion of an MSD column on the OSHA Form 300 (Ex. 15: 305).

OSHA also received numerous comments supporting the addition of a separate MSD column on the Log (see, *e.g.*, Exs. 35; 15: 32, 156, 371, 379, 380, 415, 418, 438). For example, the United Food and Commercial Workers stated that:

> Of key concern to our membership is the lack of any categorization for musculoskeletal disorders (MSD). A major concern in meatpacking and poultry plants, our committees will now be forced to spend endless hours poring over the logs, reading each individual definition and deciding whether it is a MSD. The logs are often hand written and xerox copies of these are difficult to read. This is a real burden for workers, companies, joint committees and anyone using the logs (Ex. 15: 371).

After a thorough review of the record, and extensive consultation with NIOSH and the BLS to establish the need for such statistics, OSHA has concluded that including a separate column on the final OSHA 300 Log for MSD cases is essential to obtain an accurate picture of the MSD problem in the United States. In 1997, more than 600,000 MSDs resulting in days away from work were reported to the BLS by employers, although determining this number has required close cooperation between OSHA and the BLS and several "special runs" by the BLS (i.e., computer analyses performed especially for OSHA) (see on the Internet at ftp://146.142.4.23/pub/special.requests/ocwc/osh/). OSHA believes that such a column on the OSHA 300 Log will not only permit more complete and accurate reporting of these disorders and provide information on the overall incidence of MSDs in the workplace, it will provide a useful analytical tool at the establishment level. OSHA recognizes that the column will add some complexity to the form, but believes that the additional complexity will be more than offset by the fact that all recordable MSDs will be captured in a single entry on the Log. Thus, the total count of cases in the MSD column will allow employers, employees, authorized representatives, and government representatives to determine, at a glance, what the incidence of these disorders in the establishment is. OSHA does not agree with those commenters who stated that entries in the MSD column will duplicate information recorded in the injury/illness description; the case description column will include additional information, *e.g.*, on the particular type of MSD (back strain, carpal tunnel syndrome, wrist pain, tendinitis, etc.).

OSHA also does not agree with those commenters who argued that including a separate column for MSDs would introduce error into the national statistics on the incidence of MSDs. The views of these commenters are not persuasive because the number of reportable lost-workday MSDs is already being captured in national statistics, albeit under two categories ("injuries" and "illnesses") that are difficult to interpret. In response to comments that including a separate column on the Log will provide OSHA with "justification for an ergonomics standard," the Agency notes that it has already developed and proposed an ergonomics standard despite the absence of a single MSD column on employers' Logs.

Miscellaneous 300 Form Issues

The proposed OSHA Form 300 contained a column designated as the "Employer Use" column. Many employers keep two sets of injury and illness records; one for OSHA Part 1904 purposes and another for internal safety management system purposes. OSHA envisioned that the proposed Employer Use column would be used to tailor the Log to meet the needs of the establishment's particular safety and health program and reduce the practice some employers have adopted of keeping multiple sets of occupational injury and illness records for various purposes. For example, OSHA envisioned that an employer could enter codes in this column to collect data on occupational injuries and illnesses beyond what is required by the OSHA Part 1904 regulation, such as the results of accident investigations, whether the case was accepted by workers' compensation, or whether or not the employee was hospitalized for treatment.

A number of commenters supported the proposed Employer Use column (see, *e.g.*, Exs. 15: 87, 136, 137, 141, 170, 224, 266, 278, 359). Some stated that employers could utilize the column to identify cases based on specific criteria that could be used in their internal safety and health evaluations (see, *e.g.*, Exs. 15: 136, 137, 141, 170, 224, 266, 278, 359). For example, the National Safety Council stated "The Council believes that adding the employer use column to the log will effectively reduce the adverse effects of accountability systems. This will allow employers to identify cases for which supervisors and managers should be held accountable, using company specific criteria" (Ex. 15: 359, p. 14). Another commenter, Kathy Mull, stated "The comment on possible use of the 'employer use column' to note cases not included in internal safety statistics is a possible mechanism to defer pressures on internal performance measures as tied strictly to OSHA recordkeeping" (Ex. 15: 278, p. 4).

Several commenters opposed the addition to the Log of an Employer Use column, however (see, *e.g.*, Exs. 15: 28, 82, 109, 132, 375). Among these was the American Petroleum Institute, which stated "If the revised regulation meets API's recommended system objectives, the 'employer use' column would not be needed. Cases recorded would then be credible, reasonable and meaningful to employers, employees (and to OSHA). * * * OSHA should consider the employer as the primary user of the system" (Ex. 15: 375A, p. 55). Commenters also expressed concern that an Employer Use column could have a negative effect on the use of the data. For example, the Sherman Williams Company stated "It is not necessary to provide column j, for "other" information that may be provided by the employer. It will lead to inconsistent utilization of the proposed form. Delete column j of the proposed Form 300" (Ex. 15: 132, p. 1).

Several other commenters argued for the addition of new data requirements to the OSHA 300 Log, as follows:

Commenter	Suggested addition to the 300 Log
G. Neil Companies (Ex. 15: 29)	Information explaining which employers must keep the Log should be added to the form.
Atlantic Dry Dock Corp. (Ex. 15: 179)	A line to carry over the totals from previous page should be added at the top of the form.
Maine Department of Labor (Ex. 15: 41)	The form should include three columns for case type: a column for days away only, a column for days away and restricted, and a column for restricted only to differentiate the three different types of cases.
Ford Motor Company (Ex. 15: 347)	"To facilitate identification, Ford proposes that the employee's last four numbers of his or her social security number be included on the OSHA 300 and 301 Forms * * * The last four numbers of the social security number will greatly assist in employee identification and at the same time offer some measure of confidentiality."
American Trucking Associations (Ex. 15: 397)	"OSHA should add a new column to the proposed OSHA 300 form allowing employers to indicate whether an injury occurred off-site. This recommendation is not novel [ ] the current OSHA 101 form asks if the injury or illness occurred on the employer's premises * * * the inclusion of the 'off-site' column is crucial in determining which fixed facilities maintain abnormally high rates of workplace injuries/illnesses. In addition, this recommendation furthers the goal of requiring motor carriers to record injuries and illnesses to their employees as well as provides valuable information to OSHA and others regarding the employer's lack of control over the site of the injury."

OSHA has not added the fields or columns suggested by commenters to the final 300 or 301 forms because the available space on the form has been allocated to other data that OSHA considers more valuable. In addition, there is no requirement in the final rule for employers to enter any part of an employee's social security number because of the special privacy concerns that would be associated with that entry and employee access to the forms. However, employers are, of course, free to collect additional data on occupational injury and illness beyond the data required by the Agency's Part 1904 regulation.

The OSHA 301 Form

Although the final OSHA 300 Log presents information on injuries and illnesses in a condensed format, the final OSHA 301 Incident Record allows space for employers to provide more detailed information about the affected worker, the injury or illness, the workplace factors associated with the accident, and a brief description of how the injury or illness occurred. Many employers use an equivalent workers' compensation form or internal reporting form for the purpose of recording more detailed information on each case, and this practice is allowed under paragraph 1904.29(b)(4) of the final rule.

The OSHA Form 301 differs in several ways from the former OSHA 101 form it replaces, although much of the information is the same as the information on the former 101 Form, although it has been reworded and reformatted for clarity and simplicity. The final Form 301 does not require the following data items that were included on the former OSHA 101 to be recorded:

—The employer name and address;
—Employee social security number;
—Employee occupation;
—Department where employee normally works;
—Place of accident;
—Whether the accident occurred on the employer's premises; and
—Name and address of hospital.

OSHA's reasons for deleting these data items from the final 301 form is that most are included on the OSHA Form 300 and are therefore not necessary on the 301 form. Eliminating duplicate information between the two forms decreases the redundancy of the data collected and the burden on employers of recording the data twice. The employee social security number has been removed for privacy reasons. OSHA believes that the information found in several other data fields on the 301 Form (*e.g.*, the employee's name, address, and date of birth) provides sufficient information to identify injured or ill individuals while protecting the confidentiality of social security numbers.

OSHA has also added several items to the OSHA Form 301 that were not on the former OSHA No. 101:

—The date the employee was hired;
—The time the employee began work;
—The time the event occurred;
—Whether the employee was treated at an emergency room; and
—Whether the employee was hospitalized overnight as an in-patient (the form now requires a check box entry rather than the name and address of the hospital).

OSHA concludes that these data fields will provide safety and health professionals and researchers with important information regarding the occurrence of occupational injuries and illnesses. The questions pertaining to what the employee was doing, how the injury or illness occurred, what the injury or illness was, and what object or substance was involved have been reworded somewhat from those contained on the former OSHA No. 101, but do not require employers or employees to provide additional information.

Proposed Form 301

The proposed OSHA 301 Injury and Illness Incident Record differed in minor respects from the former OSHA 101. For example, a number of fields would have been eliminated to reduce redundancy between the Log and the Incident Report, and several items would have been added to the Incident Report to obtain additional information about occupational injuries and illnesses. OSHA proposed to add to the Form 301 the following:

—The date the employee was hired;
—The time the employee began work;
—The time the event occurred;
—Whether the employee was treated at an emergency room;
—Whether the employee was hospitalized overnight as an in-patient;
—The equipment, materials or chemicals the employee was using when the event occurred; and
—The activity the employee was engaged in when the event occurred.

In addition, the proposed regulation would have required the employer to ask several questions (questions 16 through 18) in the same order and using the same language as used on the OSHA forms, in order to obtain more consistent and accurate data about these data items.

A number of commenters approved of the proposed Form 301 (see, *e.g.*, Exs. 21; 15: 32, 153, 246, 324, 369, 374, 380, 396, 427, 441). For example, the International Brotherhood of Teamsters (Ex. 15: 369) stated that the union "[s]upports the [proposed] modifications of the OSHA Injury and Illness Incident Record (OSHA Form

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301) to collect more useful information." Other commenters preferred the former OSHA 101 form and urged OSHA to retain it (see, *e.g.*, Exs. 15: 47, 48, 122, 242). For example, the Boiling Springs Fire District (Ex. 15: 47) opposed any changes to the Log or 101 forms, stating "[W]e like the forms we are presently using and feel that the information in these forms is adequate. I am a great believer in the old saying 'if it is not broke—why fix it'?"

Many of the commenters who specifically addressed the proposed 301 form were concerned about the privacy implications of providing employees, former employees, and employee representatives with access to the OSHA 301 forms. These concerns are addressed in detail in the section of this summary and explanation associated with section 1904.35, Employee involvement. Many other commenters were concerned with the use of equivalent forms (discussed above) and with the requirement to ask certain questions in the same order and using the same language (also discussed above). The remaining comments relating to the proposed forms are grouped into three categories: comments about the proposed case detail questions (proposed questions 9, 10, 16, 17 and18) and the data they would collect; the other fields OSHA proposed to add to the form 101/301; and comments urging the Agency to place additional data fields on the 301 form.

Rewording of the Proposed Case Detail Questions (questions 9, 10, 16, 17, and 18)

OSHA proposed to include five questions on the final OSHA 301 form to gather information about the details of each work-related injury or illness case:

—Proposed question 9 asked for information about the specific injury or illness (*e.g.*, second degree burn or toxic hepatitis);
—Proposed question 10 asked for information on the body part or parts affected (*e.g.*, lower right forearm);
—Proposed question 16 asked for information on all equipment, materials or chemicals the employee was using when the event occurred;
—Proposed question 17 asked for information on the specific activity the employee was engaged in when the event occurred;
—Proposed question 18 asked for information on how the injury or illness occurred, including a description of the sequence of events that led up to the incident and the objects or substances that directly injured or made the employee ill.

OSHA received only one comment about the contents of the proposed questions: George R. Cook, Jr., of the Hearing Conservation Services Company, stated:

> Questions 9, 10, and 16 on the OSHA 301 form should be worded so that the combination of the answers to these three questions could be used as the answer to Question F. on the OSHA 300. Therefore, if a form 301 is filled out in computerized form, that information could then be carried over to the form 300 thus eliminating the need for duplicate entry (Ex. 15: 188).

As discussed above, final Form 301 no longer requires the employer to include these questions on any equivalent form in the same format or language as that used by the OSHA 301 form. However, any employer wishing to take the approach suggested by Mr. Cook is free to do so.

Several commenters objected to proposed question 16 and questioned why information on all of the materials, equipment or chemicals the employee was using when the event occurred was needed (see, *e.g.*, Exs. 15: 35, 205, 318, 334, 375, 424). For example, the Chocolate Manufacturers Association and the National Confectioners Association, in a joint comment (Ex. 15: 318, p. 9) , stated:

> [W]e strongly disagree with the approach reflected in Question 16. We believe the additional information sought by Question 16 (and not by Question 18) is irrelevant and would not, in any event, justify a second set of reporting forms for every recordable incident subject to federal or state OSHA jurisdiction. Requiring a listing of "all" equipment, materials or chemicals an employee might have been using—without regard to whether they contributed to the injury or illness—would serve no useful purpose.

OSHA agrees with this assessment and has not included this question from the final 301 form.

The final form solicits information only on the object or substance that directly harmed the employee. The final 301 form contains four questions eliciting case detail information (*i.e.*, what was the employee doing just before the incident occurred?, what happened?, what was the injury or illness?, and what object or substance directly harmed the employee?). The language of these questions on the final 301 form has been modified slightly from that used in the proposed questions to be consistent with the language used on the BLS Survey of Occupational Injuries and Illnesses collection form. The BLS performed extensive testing of the language used in these questions while developing its survey form and has subsequently used these questions to collect data for many years. The BLS has found that the order in which these questions are presented and the wording of the questions on the survey form elicit the most complete answers to the relevant questions. OSHA believes that using the time-tested language and ordering of these four questions will have the same benefits for employers using the OSHA Form 301 as they have had for employers responding to the BLS Annual Survey. Matching the BLS wording and order will also result in benefits for those employers selected to participate in the BLS Annual Survey. To complete the BLS survey forms, employers will only need to copy information from the OSHA Injury and Illness Incident Report to the BLS survey form. This should be easier and less confusing than researching and rewording responses to the questions on two separate forms.

The Data Fields OSHA Proposed to Change on the Proposed 301 Form

Proposed field 5, Date hired. OSHA proposed to add this data field to collect additional data about the work experience of the injured or ill worker. Such data can be very useful for employers, employees, and OSHA because it enables researchers to discover, for example, whether newly hired or inexperienced workers experience relatively more injuries and illnesses than more experienced workers. Several commenters questioned the value of the data OSHA proposed to collect in field 5 (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 201, 347, 409). For example, Caterpillar Inc. (Ex. 15: 201) recommended that "[i]tem 5 of Form 301 be deleted. The date hired is not a significant factor in analyzing injury causation. If any similar data is necessary, it should be the time on the current job, which is a better indicator of relative job skills or work experience." Several commenters asked for clarification of the "date hired" phrase (see, *e.g.*, Exs. 15: 151, 152, 179, 180). For example, Atlantic Marine, Inc. (Ex. 15: 180) asked "What date shall be recorded as the "Date Hired" if an employee is laid off, is terminated, or resigns and then is rehired? Should the date of initial hire or the date of rehire be recorded?"

OSHA continues to believe that the data gathered by means of the "date hired" field will have value for analyzing occupational injury and illness data and has therefore included this data field on the final OSHA 301 form. These data are useful for analyzing the incidence of occupational injury and illness among newly hired workers and those with longer tenure. OSHA is aware that the data collected are not a perfect measure of job experience because, for example, an employee may have years of experience doing the same type of work for a previous employer, and that prior experience will not be captured by this data field. Another case where this data field may fail to capture perfect data could occur in the case of an employee who has worked for the same employer for many years but was only recently reassigned to new duties. Despite cases such as these, inclusion of this data field on the Form 301 will allow the Agency to collect valid data on length of time on the job for most employment situations.

For the relatively infrequent situation where employees are hired, terminated, and then rehired, the employer can, at his or her discretion, enter the date the employee was originally hired, or the date of rehire.

Proposed field 6, Name of health care provider; proposed field 7, If treatment off site, facility name and address; and proposed field 8, Hospitalized overnight as in-patient? The former OSHA Form 101 included similar data fields: former field 18 collected the "name and address of physician," while former field 19 collected data on "if hospitalized, name and address of hospital." Several commenters discussed these data fields and questioned their usefulness for analytical purposes (see, *e.g.*, Exs. 15: 95, 151, 152, 179, 180, 347, 409). The Pacific Maritime Association (Ex. 15: 95) noted the difficulty of collecting the data requested by proposed data fields 5, 6, 7, and 13 as they pertain to longshoremen:

> Items 5, 6, 7, and 13 on the OSHA Form 301 presents problems for direct employers of longshoremen. Longshoremen are hired on a daily basis, select their own health care provider; may be treated at a facility of their choice, and may not return to the same employer when returning to work.

Several commenters asked OSHA to clarify the data that OSHA was asking for in these data fields (see, *e.g.*, Exs. 15: 51, 152, 179, 180, 347, 409). For example, the Ford Motor Company (Ex. 15: 347) asked:

> [I]tem 6, "Name of health care provider" is unclear in terms of the general instructions. Who is considered the primary health care provider? Is it the individual who sees the employee on the initial medical visit, the individual who renders the majority of care for a case, or the individual who renders care if the employee is referred to an off-site provider on the initial visit? We feel that the last choice is the correct response. We also question the benefit of providing this information. The criteria for OSHA recordability focuses on the care provided, and not on the individual providing the care.
>
> Item 7, "If treated off-site, facility name and address" requires more specific instructions as to when this field must be completed. Is this to be completed if the employee is referred to an outside provider on the initial visit, or is this to be completed should the individual be referred out later in the course of the injury or illness? We feel that the former is the correct response. We also question the benefit of providing this information.

OSHA has decided to continue to collect information on final Form 301 concerning the treatment provided to the employee (proposed data field 7). OSHA's experience indicates that employers have not generally had difficulty in providing this information, either in the longshoring or any other industry. The data in this field is particularly useful to an OSHA inspector needing additional information about the medical condition of injured or ill employees. (OSHA does not request this medical information without first obtaining a medical access order under the provisions of 29 CFR part 1913, Rules Concerning OSHA Access to Employee Medical Records.) The final OSHA 301 Form therefore includes a data field for information on the off-site treating facility.

The final 301 Form also includes a data field requesting the name of the health care professional seen by the injured or ill employee. The employer may enter the name either of the physician or other health care professional who provided the initial treatment or the off-site treatment. If OSHA needs additional data on this point, the records of the health care professional listed will include both the name of the referring physician or other health care professional as well as the name of the health care professional to whom the employee was referred for specialized treatment.

Several commenters asked OSHA to collect data on whether a hospitalization involved in-patient treatment or was limited to out-patient treatment (see, *e.g.*, Exs. 15: 151, 152, 179, 180). For example, Alabama Shipyard, Inc. recommended "Instead of asking in [proposed] item 8 if an employee is hospitalized overnight as in-patient, have a check box to record whether the treatment was as an in-patient or outpatient status" (Ex. 15: 152). OSHA agrees that the additional information suggested by this commenter would be useful, and final OSHA Form 301 asks two hospitalization-related questions: Was employee treated in an emergency room?, and Was employee hospitalized overnight as an in-patient?

Proposed question 13, date of return to work at full capacity: The proposed Injury and Illness Incident Report (Form 301) contained a data field requiring the date the employee returned to work at full capacity if the case involved restricted work activity or days away from work. This field was included to provide information regarding the length of time the employee was partially or fully incapacitated by the injury or illness. However, because the final rule requires employers to record day counts both for cases involving days away from work and cases involving job transfer or restriction (see discussion above), the date at which an employee returned to work at full capacity field is no longer necessary and does not appear on the final form.

Proposed questions 14, Time of event and 15, Time employee began work: No commenter objected to the inclusion of proposed data field 14, Time of event, and only two commenters objected to proposed data field 15, Time employee began work (see, *e.g.*, Exs. 15: 347, 409). Both of these commenters, the Ford Motor Company and the American Automobile Manufacturers Association, stated that:

> "Time employee began work," is of questionable benefit. Many employees perform a variety of jobs during the day or may have their job changed during the day (work added or subtracted). This question is burdensome and offers little benefit for data analysis.

Several commenters discussed the way the proposed form collected the new information on the time of the accident (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 260, 262, 265, 347, 401, 409). Several of these commenters suggested that OSHA do away with the am/pm designation and use a 24-hour clock instead (see, *e.g.*, Exs. 15: 151, 152, 179, 180). The comments of Atlantic Marine (Ex. 15: 152) are representative:

> Change the form from using A.M. or P.M. to using a 24-hour clock. A 24-hour clock is much easier to use in drawing conclusions on the relationship between injuries/illnesses and the time of day that they occurred. OSHA may find that many employers are currently using a 24-hour clock system.

Another group of commenters suggested that OSHA add am/pm boxes the employer could simply check off as an easier way to collect the data (see, *e.g.*, Exs. 15: 260, 262, 265, 401). For example, the Edison Electric Institute (Ex. 15: 401) suggested that "Questions 14 and 15 should include a box which can be checked for AM and PM to reduce the possibility that this information will be omitted."

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OSHA has included on the final 301 form the two questions asking for data on the time of the event and the time the employee began work so that employers, employees and the government can obtain information on the role fatigue plays in occupational injuries and illness. Both questions (*i.e.*, on time of event and time employee began work) must be included to conduct this analysis. Thus, OSHA has included both fields on the final Form 301. In addition, the form has been designed so that the employer can simply circle the a.m. or p.m. designation. OSHA believes that this approach will provide the simplest, least burdensome method for capturing these data, and that using a 24 hour clock system would be cumbersome or confusing for most employers.

Data fields for the name and phone number of the person completing the form. Both the former and proposed Incident Report forms included fields designed to obtain information on the person who completed the form. The former OSHA 101 form asked for the date of report, the name of the preparer, and that person's official position. The proposed form would have carried forward the name and title of the preparer and the date, and added the person's phone number. OSHA received very little comment on these proposed data fields. The Ford Motor Company (Ex. 15: 347) and the American Automobile Manufacturers Association (Ex. 15: 409) both made the following comment:

> The "Completed by" field could be modified to consolidate name and title. This would be consistent with the manner in which most health care professionals routinely sign their name.
>
> The "Phone number required" item should refer to the medical department's number or the general number of the establishment, and be included with the establishment's name and address at the top of the form. This would decrease the paperwork burden by allowing the use of a stamp or a pre-typed format as opposed to completing a phone number on each OSHA Form 301.

The final OSHA Form 301 permits the employer to include the name and title in either field, as long as the information is available. As to the phone number, the employer may use whatever number is appropriate that would allow a government representative accessing the data to contact the individual who prepared the form.

Case File number: The former OSHA 101 form did not include a method for linking the OSHA 300 and 301 forms. Any linking had to be accomplished via the employee's name, department, occupation, and the other information from the forms. OSHA proposed to add a field to the OSHA 301 form that would use the same case number as that on the OSHA 300 form, thus making it easier for employers, employees and government representatives to match the data from the two forms. Two commenters objected to the addition of such a case file number (Exs. 15: 217, 334). The American Forest & Paper Association (AF&PA) argued:

> Another issue of concern to AF&PA is the requirement for a unique case or file number on the Form 300 and Form 301 to facilitate cross-referencing between the forms. We believe there is sufficient data (employee name, date of birth, date of injury) on all existing state First Report of Injury forms to readily cross-reference the First Report to the entry on the Form 300. A uniform requirement for employers to create an indexing system would serve no useful purpose. Furthermore, it would be unduly burdensome for many affected companies except in those cases when there is a reason to maintain the confidentiality of the affected employee's name (Ex. 15: 334).

OSHA continues to believe that easy linkage of the Forms 300 and 301 will be beneficial to all users of these data. Thus, the final Form 301 contains a space for the case file number. The file/case number is required on both forms to allow persons reviewing the forms to match an individual OSHA Form 301 with a specific entry on the OSHA Form 300. Access by authorized employee representatives to the information contained on the OSHA Form 301 is limited to the information on the right side of the form (see § 1904.35(b)(2)(v)(B) of the final rule). The case/file number is the data element that makes a link to the OSHA Form 300 possible. OSHA believes that this requirement will add very little burden to the recordkeeping process, because the OSHA Log has always required a unique file or case number. The final Form 301 requirement simply requires the employer to place the same number on the OSHA 301 form.

Suggested Fields

Commenters submitted suggestions for other data fields that they believed should be included on the OSHA Form 301, as follows.

Commenter(s)	Suggested addition to the 301 incident report, and OSHA response
American Industrial Hygiene Association (AIHA) (Ex. 15: 153).	"AIHA suggests a corrective action box on the OSHA 301. This form is often used as an employer's accident report, and this would encourage employers to seek action as appropriate to prevent reoccurrence." OSHA has not included this suggested change because the 301 form is not designed to be an accident investigation form, but is used to gather information on occupational injuries and illnesses. Corrective actions would thus not be an appropriate data field for this form.
(Exs. 15: 179, 180, 151, 152).	"A space is needed for recording an employee identification number. This number is important for maintaining records. Some employers use the employee's social security number, while others have a unique, employer generated identifier for each employee." OSHA believes the combination of other data fields (case number, employee name, address and date of birth) provides the user the ability to identify individuals when necessary.
Ogletree, Deakins, Nash, Smoak & Stewart (Ex. 15: 406).	Substituting "regular job title" would provide for effective use of Form 301 in conducting safety and health analysis of the workplace. The OSHA 300 Log asks for the employee's job title. OSHA does not believe there is a need to ask for the data on both forms.

Commenter(s)	Suggested addition to the 301 incident report, and OSHA response
American Petroleum Institute (Ex. 15: 375).	"[t]he supplemental data should contain all information necessary to make recordkeeping decisions, and to facilitate certification of the logs at year end. For this reason, the following should be added to what OSHA proposes for the supplemental data: company name, establishment name, employee social security number, regular job title, "new injury or illness?", "loss of consciousness?", days away from work, first date absent, est. duration of absence, "date days-away cases returned to work?," "result in restricted activity?", "job transfer?", "termination of employment?" OSHA has not included these data fields on the final form because the Agency believes that doing so would duplicate the information on the OSHA 300 form. There is also no need to use the OSHA 301 form to document all the employer's recordkeeping decisions.
Ford Motor Company and the American Automobile Manufacturers Association (Exs. 15: 347, 409).	"AAMA proposes the OSHA Form 301 include the establishment name and address at the top of the form. This will assist not only the employer, but OSHA as well, to avoid any confusion over records in which one medical department may serve several establishments. Also, it will be helpful in those cases where a company employee, who works predominately at one particular facility, sustains an injury or illness at another company establishment." The establishment name and location are included on the OSHA Form 300. In an effort to identify and eliminate duplication of data, OSHA has not included this data item on the OSHA Form 301.
Building and Construction Trades Department, AFL–CIO (Ex.15: 394).	For every potentially recordable injury or illness, the employer shall record: case number, date case reported and name of employee. —Job title of employee. —Date of injury or illness. —Time of event or exposure. —Time employee began work. —Specific description of injury or illness. —Location where the accident or exposure occurred (*e.g.* loading dock). —Facility or Project (*e.g.* Hackensack factory, or Dreamwood Subdevelopment). —Body part affected. —Equipment, tools, materials, or chemicals being used. —Specific activity when injured or upon onset of illness. —How injury or illness occurred. OSHA notes that the final OSHA 301 form contains many of these data elements. The Agency believes that the remaining fields are unnecessary or duplicative of information already found on the OSHA 300 Log.

Summary

The final forms employers will use to keep the records of those occupational injuries and illnesses required by the final rule to be recorded have been revised to reflect the changes made to the final rule, the record evidence gathered in the course of this rulemaking, and a number of changes designed to simplify recordkeeping for employers. In addition, the forms have been revised to facilitate the use of equivalent forms and employers' ability to computerize their records.

Subpart D. Other OSHA injury and illness recordkeeping requirements

Subpart D of the final rule contains all of the 29 CFR Part 1904 requirements for keeping OSHA injury and illness records that do not actually pertain to entering the injury and illness data on the forms. The nine sections of Subpart D are:

—Section 1904.30, which contains the requirements for dealing with multiple business establishments;

—Section 1904.31, which contains the requirements for determining which employees' occupational injuries and illnesses must be recorded by the employer;

—Section 1904.32, which requires the employer to prepare and post the annual summary;

—Section 1904.33, which requires the employer to retain and update the injury and illness records;

—Section 1904.34, which requires the employer to transfer the records if the business changes owners;

—Section 1904.35, which includes requirements for employee involvement, including employees' rights to access the OSHA injury and illness information;

—Section 1904.36, which prohibits an employer from discriminating against employees for exercising their rights under the Act;

—Section 1904.37, which sets out the state recordkeeping regulations in OSHA approved State-Plan states; and

—Section 1904.38, which explains how an employer may seek a variance from the recordkeeping rule.

Section 1904.30 Multiple Establishments

Section 1904.30 covers the procedures for recording injuries and illnesses occurring in separate establishments operated by the same business. For many businesses, these provisions are irrelevant because the business has only one establishment. However, many businesses have two or more establishments, and thus need to know how to apply the recordkeeping rule to multiple establishments. In particular, this section applies to businesses where separate work sites create confusion as to where injury and illness records should be kept and when separate records must be kept for separate work locations, or establishments. OSHA recognizes that the recordkeeping system must accommodate operations of this type, and has adopted language in the final rule to provide some flexibility for employers in the construction, transportation, communications, electric and gas utility, and sanitary services industries, as well as other employers with geographically dispersed operations. The final rule provides, in part, that operations are not considered separate establishments unless they continue to be in operation for a year or more. This length-of-site-operation provision increases the chances of discovering patterns of occupational injury and illness, eliminates the burden of creating OSHA 300 Logs for transient work sites, and ensures that useful records are generated for more permanent facilities.

OSHA's proposed rule defined an establishment as a single physical location that is in operation for 60 calendar days or longer (61 FR 4059), but did not provide specific provisions covering multiple establishments. In the final rule, the definition of

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establishment is included in Subpart G, Definitions.

The basic requirement of § 1904.30(a) of this final rule states that employers are required to keep separate OSHA 300 Logs for each establishment that is expected to be in business for one year or longer. Paragraph 1904.30(b)(1) states that for short-term establishments, i.e., those that will exist for less than a year, employers are required to keep injury and illness records, but are not required to keep separate OSHA 300 Logs. They may keep one OSHA 300 Log covering all short-term establishments, or may include the short-term establishment records in logs that cover individual company divisions or geographic regions. For example, a construction company with multi-state operations might have separate OSHA 300 Logs for each state to show the injuries and illnesses of its employees engaged in short-term projects, as well as a separate OSHA 300 Log for each construction project expected to last for more than one year. If the same company had only one office location and none of its projects lasted for more than one year, the company would only be required to have one OSHA 300 Log.

Paragraph 1904.30(b)(2) allows the employer to keep records for separate establishments at the business' headquarters or another central location, provided that information can be transmitted from the establishment to headquarters or the central location within 7 days of the occurrence of the injury or illness, and provided that the employer is able to produce and send the OSHA records to each establishment when § 1904.35 or § 1904.40 requires such transmission. The sections of the final rule are consistent with the corresponding provisions of the proposed rule.

Paragraph 1904.30(b)(3) states that each employee must be linked, for recordkeeping purposes, with one of the employer's establishments. Any injuries or illnesses sustained by the employee must be recorded on his or her home establishment's OSHA 300 Log, or on a general OSHA 300 Log for short-term establishments. This provision ensures that all employees are included in a company's records. If the establishment is in an industry classification partially exempted under § 1904.2 of the final rule, records are not required. Under paragraph 1904.30(b)(4), if an employee is injured or made ill while visiting or working at another of the employer's establishments, then the injury or illness must be recorded on the 300 Log of the establishment at which the injury or illness occurred.

How Long Must an Establishment Exist to Have a Separate OSHA Log

As previously stated, the final rule provides that an establishment must be one that is expected to exist for a year or longer before a separate OSHA log is required. Employers are permitted to keep separate OSHA logs for shorter term establishments if they wish to do so, but the rule does not require them to do so. This is a change from the proposed rule, which would have required an establishment to be in operation for 60 days to be considered an "establishment" for recordkeeping purposes. The proposed 60-day threshold would have changed the definition of "establishment" used in OSHA's former recordkeeping rule, because that rule included a one-year-in-operation threshold for defining a fixed establishment required to keep a separate OSHA Log (Ex. 2, p. 21). The effect of the proposed change in the threshold would have been to increase the number of short-duration operations required to maintain separate injury and illnesses records.

The majority of the comments OSHA received on this issue opposed the decrease in the duration of the threshold from one year to 60 calendar days, primarily because commenters felt that requiring temporary facilities to maintain records would be burdensome, costly and would not increase the utility of the records (see, *e.g.*, Exs. 21, 15: 21, 43, 78, 116, 122, 123, 145, 170, 199, 213, 225, 254, 272, 288, 303, 304, 305, 308, 338, 346, 349, 350, 356, 358, 359, 363, 364, 375, 389, 392, 404, 412, 413, 423, 424, 433, 437, 443, 475). For example, the Associated Builders and Contractors, Inc. (ABC):

> [d]isagrees that sites in existence for as little as 60 days need separate injury and illness records. The redefinition of "establishment" will cause enormous problems for subcontractors in a variety of construction industries. Even employers with small workforces could be on the site of several projects at any one time, and in the course of the year could have sent crews to hundreds of sites. Though they may be on such sites for only brief periods of time, they will be required under this proposal to create separate logs for each site, increasing greatly their paperwork requirements without increasing the amount of information available to their employees (Ex. 15: 412).

In addition, many of these commenters argued that a 60-day threshold would be especially burdensome because it would capture small work sites where posting of the annual summary or mailing the summary to employees would make little sense because so few cases would be captured on each Log. The majority of these commenters suggested that OSHA retain the former one-year duration threshold in the definition of establishment (see, *e.g.*, Exs. 15: 78, 123, 225, 254, 305, 356, 389, 404).

Other commenters expressed concern that the proposed 60-day threshold would create an unreasonable burden on employers in service industries like telecommunications and other utilities, whose employees typically report to a fixed location, such as a service center or garage, but perform tasks at transient locations that remain in existence for more than 60 days. These commenters felt that classifying such locations as "establishments" and creating thousands of new OSHA Logs, would have "no benefit to anyone" (Ex. 15: 199) (*see also* Exs. 15: 65, 170, 213, 218, 332, 336, 409, 424).

In contrast, commenters who supported the 60-day threshold worried that injuries and illnesses occurring at transient locations would never be accounted for without such a provision (see, *e.g.*, Exs. 15: 9, 133, 310, 369, 425). Some urged OSHA to adopt an even shorter time-in-operation threshold (see, *e.g.*, Exs. 15: 369, 418, 429). For example, the International Brotherhood of Teamsters (IBT) stated that they "[w]ould strongly support reducing the requirement to thirty days to cover many low level housing construction sites, and transient operations, similar to mobile amusement parks" (Ex. 15: 369). The AFL–CIO agreed: "* * * the 60-day time period is still too long. We believe that to truly capture a majority of these transient work sites, a 30-day time period would be more realistic. A 30-day time period as the trigger would capture construction activities such as trenching, roofing, and painting projects which will continue to be missed if a 60-day time period is used" (Ex. 15: 418). OSHA agrees that under the proposed provisions there was a potential for injuries and illnesses to be missed at short term establishments and for employees who did not report to fixed establishments. Therefore, §§ 1904.30(b)(1) and (b)(3) have been added to make it clear that records (but not a *separate* log) must be kept for short-term establishments lasting less than one year, and that each employee must be linked to an establishment.

The United Parcel Service (UPS) recommended that OSHA craft its rule to coincide with a company's personnel records system, stating "[t]he unit for which an employer maintains personnel records is presumptively appropriate and efficient; accordingly, OSHA should not mandate a rule that conflicts with a company's current personnel units policy" (Ex. 15: 424). OSHA recognizes

that employers would prefer OSHA to allow companies to keep records in any way they choose. However, OSHA believes that allowing each company to decide how and in what format to keep injury and illness records would erode the value of the injury and illness records in describing the safety and health experience of individual workplaces and across different workplaces and industries. OSHA has therefore decided not to adopt this approach in the final rule, but to continue its longstanding requirement requiring records to be kept by establishment.

OSHA has reviewed all of the comments on this issue and has responded by deleting any reference to a time-in-operation threshold in the definition of establishment but specifying a one-year threshold in section 1904.30(a) of the final rule. OSHA finds, based on the record evidence, that the one-year threshold will create useful records for stable establishments without imposing an unnecessary burden on the many establishments that remain in existence for only a few months.

Centralized Recordkeeping

As previously stated, the proposed rule did not include a specific section covering multiple establishments. The proposal did require that records for employees not reporting to any single establishment on a regular basis should be kept at each transient work site, or at an established central location, provided that records could be obtained within 4 hours if requested as proposed.

Most commenters supported provisions that would allow the employer to keep records at a centralized location (see, *e.g.*, Exs. 20, 21, 15: 9, 38, 48, 136, 137, 141, 154, 173, 203, 213, 224, 234, 235, 254, 260, 262, 265, 266, 272, 277, 278, 288, 303, 321, 336, 350, 367, 373, 375, 401, 409). Many, however, disagreed with the requirement that records be produced within 4 hours if requested by an authorized government official. Those comments are discussed in the preamble for § 1904.40, Providing records to government representatives. The only other concern commenters expressed about centralized recordkeeping was that centralized records, like computerized records, would make it more difficult for employees to access the records (see, *e.g.*, Exs. 15:379, 380, 418, 438).

OSHA does not believe that centralization of the records will compromise timely employee or government representative access to the records. To ensure that this is the case, centralization under § 1904.30(b)(2) is allowed only if the employer can produce copies of the forms when access to them is needed by a government representative, an employee or former employee, or an employee representative, as required by §§ 1904.35 and 40.

Recording Injuries and Illnesses Where They Occur

Proposed section 1904.7, Location of records, and section 1904.11, Access to records, covered recordkeeping requirements for employees who report to one establishment but are injured or made ill at other locations of the same company. Specifically, these sections required that records for employees reporting to a particular establishment but becoming ill or injured at another establishment within the same company be kept at the establishment in which they became injured or ill. This was derived from OSHA's longstanding interpretation that employees' cases should be recorded where they occur, if it is at a company establishment (April 24, 1992 letter of interpretation to Valorie A. Ferrara of Public Service Electric and Gas Company). Several commenters objected to the proposed requirement that an employee's injury or illness be recorded on the log of the establishment where the injury occurred, rather than on the log of the establishment they normally report to (see, *e.g.*, Exs.15: 60, 107, 146, 184, 199, 200, 232, 242, 263, 269, 270, 329, 335, 343, 356, 375, 377). The comments of the B.F. Goodrich Company (Ex. 15: 146) are representative:

> [t]he requirement for a company to log a visiting employee's injury or illness on the log of the company establishment that they are visiting rather than on the log of their normal work establishment, is not consistent with the data collection process. As proposed, the rule requires the facility to record the injury or illness and not the hours worked by the visiting employee. These individuals would not normally be counted in the number of employees at the visited site nor in the manhours worked at that site. Recording of cases from visiting employees would improperly skew the incidence rates of both facilities. This approach is particularly inappropriate in the case of an illness, since the case may be a result of accumulated exposures which have nothing to do with the site visited during the onset of the illness. Alternately, an injury or illness could manifest after the visitor leaves the facility.

OSHA disagrees with these commenters about where the injuries and illnesses should be recorded. For the vast majority of cases, the place where the injury or illness occurred is the most useful recording location. The events or exposures that caused the case are most likely to be present at that location, so the data are most useful for analysis of that location's records. If the case is recorded at the employee's home base, the injury or illness data have been disconnected from the place where the case occurred, and where analysis of the data may help reveal a workplace hazard. Therefore, OSHA finds that it is most useful to record the injury or illness at the location where the case occurred. Of course, if the injury or illness occurs at another employer's workplace, or while the employee is in transit, the case would be recorded on the OSHA 300 Log of the employee's home establishment.

For cases of illness, two types of cases must be considered. The first is the case of an illness condition caused by an acute, or short term workplace exposure, such as skin rashes, respiratory ailments, and heat disorders. These illnesses generally manifest themselves quickly and can be linked to the workplace where they occur, which is no different than most injury cases. For illnesses that are caused by long-term exposures or which have long latency periods, the illness will most likely be detected during a visit to a physician or other health care professional, and the employee is most likely to report it to his or her supervisor at the home work location.

Recording these injuries and illnesses could potentially present a problem with incidence rate calculations. In many situations, visiting employees are a minority of the workforce, their hours worked are relatively inconsequential, and rates are thus unaffected to any meaningful extent. However, if an employer relies on visiting labor to perform a larger amount of the work, rates could be affected. In these situations, the hours of these personnel should be added to the establishment's hours of work for rate calculation purposes.

Section 1904.31 Covered employees

Final Rule Requirements and Legal Background

Section 1904.31 requires employers to record the injuries and illnesses of all their employees, whether classified as labor, executive, hourly, salaried, part-time, seasonal, or migrant workers. The section also requires the employer to record the injuries and illnesses of employees they supervise on a day-to-day basis, even if these workers are not carried on the employer's payroll.

Implementing these requirements requires an understanding of the Act's definitions of "employer" and

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"employee." The statute defines "employer," in relevant part, to mean "a person engaged in a business affecting interstate commerce who has employees." 29 U.S.C. 652 (5). The term "person" includes "one or more individuals, partnerships, associations, corporations, business trusts, legal representatives, or any organized group of persons." 29 U.S.C. 652 (4). The term "employee" means "an employee of an employer who is employed in a business of his employer which affects interstate commerce." 29 U.S.C. 652(6). Thus, any individual or entity having an employment relationship with even one worker is an employer for purposes of this final rule, and must fulfill the recording requirements for each employee.

The application of the coverage principles in this section presents few issues for employees who are carried on the employer's payroll, because the employment relationship is usually well established in these cases. However, issues sometimes arise when an individual or entity enters into a temporary relationship with a worker. The first question is whether the worker is an employee of the hiring party. If an employment relationship exists, even if temporary in duration, the employee's injuries and illnesses must be recorded on the OSHA 300 Log and 301 form. The second question, arising in connection with employees provided by a temporary help service or leasing agency, is which employer—the host firm or the temporary help service—is responsible for recordkeeping.

Whether an employment relationship exists under the Act is determined in accordance with established common law principles of agency. At common law, a self-employed "independent contractor" is not an employee; therefore, injuries and illnesses sustained by independent contractors are not recordable under the final Recordkeeping rule. To determine whether a hired party is an employee or an independent contractor under the common law test, the hiring party must consider a number of factors, including the degree of control the hiring party asserts over the manner in which the work is done, and the degree of skill and independent judgment the hired party is expected to apply. *Loomis Cabinet Co.* v. *OSHRC*, 20 F.3d 938, 942 (9th Cir. 1994).

Other individuals, besides independent contractors, who are not considered to be employees under the OSH Act are unpaid volunteers, sole proprietors, partners, family members of farm employers, and domestic workers in a residential setting. See 29 CFR § 1975.4(b)(2) and § 1975.6 for a discussion of the latter two categories of workers. As is the case with independent contractors, no employment relationship exists between these individuals and the hiring party, and consequently, no recording obligation arises.

A related coverage question sometimes arises when an employer obtains labor from a temporary help service, employee leasing firm or other personnel supply service. Frequently the temporary workers are on the payroll of the temporary help service or leasing firm, but are under the day-to-day supervision of the host party. In these cases, Section 1904.31 places the recordkeeping obligation upon the host, or utilizing, employer. The final rule's allocation of recordkeeping responsibility to the host employer in these circumstances is consistent with the Act for several reasons.

First, the host employer's exercise of day-to-day supervision of the temporary workers and its control over the work environment demonstrates a high degree of control over the temporary workers consistent with the presence of an employment relationship at common law. See *Loomis Cabinet Co.*, 20 F.3d at 942. Thus, the temporary workers will ordinarily be the employees of the party exercising day-to-day control over them, and the supervising party will be their employer.

Even if daily supervision is not sufficient alone to establish that the host party is the employer of the temporary workers, there are other reasons for the final rule's allocation of recordkeeping responsibility. Under the OSH Act, an employer's duties and responsibilities are not limited only to his own employees. Cf. *Universal Constr. Co.* v. *OSHRC*, 182 F.3d 726, 728–731 (10th Cir. 1999). Assuming that the host is *an* employer under the Act (because it has an employment relationship with someone) it reasonably should record the injuries of all employees, whether or not its own, that it supervises on a daily basis. This follows because the supervising employer is in the best position to obtain the necessary injury and illness information due to its control over the worksite and its familiarity with the work tasks and the work environment. As discussed further below, the final rule is sensible and will likely result in more accurate and timely recordkeeping.

The Proposed Rule

The final rule's coverage rules are consistent with the basic principles embodied in the former rule and in the proposal. The proposed rule would have continued to require employers to record the injuries and illnesses of employees over whose work they exert "day-to-day supervision" (61 FR 4058/3). OSHA proposed to codify this longstanding interpretation by adding a definition of "employee" together with a note explaining its application to Part 1904 recordkeeping. The proposed definition restated the definition of employee in the OSH Act. It then explained that, for recordkeeping purposes, an employer should consider as its employees any persons who are supervised on a day-to-day basis at the establishment. The proposal noted that this was the test regardless of whether the persons were labeled as "independent contractors," "migrant workers," or workers provided by a temporary help service.

The proposal further explained that day-to-day supervision occurs "when, in addition to specifying the output, product or result to be accomplished by the person's work, the employer supervises the details, means, methods and processes by which the work is to be accomplished" (61 FR 4059/1). OSHA also noted that other classes of workers would not be covered because they were not considered employees, either as defined in the OSH Act or as set forth in regulatory interpretations. These included sole proprietors, partners, family members of farm employers, and domestic workers in a residential setting.

Response To the Proposal

A number of commenters agreed with OSHA's approach to differentiate between employees and true independent contractors, and to require employers to keep records for employees they supervise on a day-to-day basis (see, *e.g.*, Exs. 15: 61, 65, 205, 305, 322, 333, 346, 348, 351, 369, 390, 429). The National Association of Manufacturers (NAM) stated:

> [f]or purposes of recordkeeping, OSHA has consistently taken the position that the term "employee" includes all personnel who are supervised on a day-to-day basis by the employer using their services (not only with respect to the result to be achieved, but also the means, methods and processes by which the work is to be accomplished). While this is a fact-intensive determination that must be made on a case-by-case basis, we commend the Agency for attempting to clarify the matter by making that approach an explicit part of the rule, presumably for purposes of both recordkeeping and records access (Ex. 15: 305).

The National Association of Temporary Staffing Services (NATSS)) supported:

> [c]ontinuation of "utilizing employer" rule for maintaining records for temporary employees. Temporary help and staffing service firms recruit individuals with a broad range of training, education and skills, and then assign them to work at customer locations on a variety of assignments and projects. The fundamental nature of the service relationship is such that while staffing service firms are the general employers of their workers and assume a broad range of employer responsibilities, those responsibilities generally do not include direct supervision of the employees at the worksite. Hence, staffing firms have a limited ability to affect conditions at the worksite.
>
> In recognition of the above, OSHA's long-standing policy has been to require the worksite employer, not the staffing firm, to maintain illness and injury records of temporary workers supervised by the worksite employer. The proposed rules continue this policy. In a special "note" in section 1904.3, "employee" for record keeping purposes is defined to include temporary workers "when they are supervised on a day-to-day basis by the employer utilizing their services." Under this definition, the worksite employer, not the staffing firm, would be required to maintain records for temporary employees supplied by a staffing firm, provided they are supervised by the worksite employer. As stated in the background section of the proposed rule, "this is consistent with case law and the interpretation currently used by OSHA" (61 F.R. 4034). NATSS strongly supports this proposed definition. (Ex. 15: 333)

A number of commenters opposed OSHA's proposed approach on this issue (see, *e.g.*, Exs. 15: 9, 23, 26, 64, 67, 82, 92, 119, 154, 159, 161, 184, 185, 198, 203, 204, 225, 259, 287, 297, 299, 312, 335, 336, 338, 341, 356, 363, 364, 370, 404, 423, 424, 427, 431, 437, 443). Several of these commenters thought that including temporary employees from temporary services, independent contractors and other leased personnel within the definition of employee would impose new burdens on employers (see, *e.g.*, Exs. 15: 35, 67, 356, 423, 437). However, the proposal did not alter the long-standing meanings of the terms employee, employer or employment relationship. The day-to-day supervision test for identifying the employer who is responsible for compliance with Part 1904 is a continuation of OSHA's former policy, and is consistent with the common law test. The comments indicate that many employers are not aware that they need to keep records for leased workers, temporary workers, and workers who are inaccurately labeled "independent contractors" but are in fact employees. However, these workers are employees under both the former rule and the final rule. Incorporating these requirements into the regulatory text can only help to improve the consistency of the data by clarifying the employer's responsibilities.

Several commenters erroneously believed that they might need to keep records for all employees of independent contractors performing work in their establishment (see, *e.g.*, Exs. 15: 161, 203, 312). The Battery Council International remarked:

> [i]t is unclear how this clarification would apply to employers in the battery industry who hire independent contractors to perform construction and other activities on their manufacturing facilities. Often times, battery manufacturers will provide the contractors with an orientation to the facility (which includes the facility's safety and health rules and location of MSDSs) [material safety data sheets], and monitor the work of the contractor to ensure that work contracted for has been completed, but do not otherwise supervise the details, means, methods and processes by which the work is to be accomplished. In these relationships, the contractors certify to the battery manufacturers that they comply with all OSHA requirements including training, which must be completed as part of the work contract.
>
> If the intent of the proposed clarification is to not require the reporting of injuries and illnesses to independent contractors under similar conditions as described above, then BCI supports this concept and requests further clarification on this issue. BCI will oppose, however, any attempt by OSHA to require the reporting of injuries or illnesses that occur to "independent contractors" where the employer has not otherwise supervised the details, means, methods and processes by which the work was accomplished (Ex. 15: 161).

The International Dairy Foods Association (IDFA) was concerned that if a dairy processing facility hired an electrical contractor to install new lighting and the electrical contractor's employee were injured while installing the lighting, the dairy might have to record the incident in its Part 1904 records (Ex. 15: 203).

The 1904 rule does not require an employer to record injuries and illnesses that occur to workers supervised by independent contractors. However, the label assigned to a worker is immaterial if it does not reflect the economic realities of the relationship. For example, an employment contract that labels a hired worker as an independent contractor will have no legal significance for Part 1904 purposes if in fact the hiring employer exercises day-to-day supervision over that worker, including directing the worker as to the manner in which the details of the work are to be performed. If the contractor actually provides day-to-day supervision for the employee, then the contractor is responsible for compliance with Part 1904 as to that employee. In the IDFA example, unless the dairy exercised supervisory control over the time and manner of the electrician's work, the dairy would not be considered the electrician's employer and would not be required to record the incident.

Some commenters argued that the injury and illness statistics would be more accurate or useful if the payroll employer recorded the injuries and illnesses, regardless of which employer controlled the work or the hazard (see, *e.g.*, Exs. 15: 9, 26, 92, 161, 198, 259, 287, 297, 299, 333, 341, 356, 364, 443). The Sandoz Corporation stated that "[t]he control and responsibility for reporting these injuries should be with the employer, i.e. the establishment that pays the employee. This simplifies the control and reporting. It also allows a company that utilizes temporary or contract services to look at the OSHA record of the supplier as part of the purchasing decision and thus put pressure on the supplier for better safety performance, thus using market forces to improve safety" (Ex. 15: 299). The Battery Council International added "[r]equiring employers to record the injuries and illnesses of independent contractors under such circumstances is unfair and will result in the over recording of injuries and illnesses by the battery industry. This will result in more OSHA inspections on the lead battery industry, which will in turn impose additional costs and burdens on BCI members" (Ex. 15: 161). The Fertilizer Institute stated "[a]dopting compensation as the basis for determining the employer/employee relationship results in simplification that is not afforded when one must look at day-to-day supervision" (Ex. 15: 154).

A few commenters recommended that the employer responsible for workers' compensation insurance also be required to record the injuries and illnesses (Ex. 15: 204, 225, 336, 364). The American Gas Association (Ex. 15: 225) stated that OSHA should:

> [s]trive to parallel Workers' Compensation law. The employer may have supervision of some types of temporary workers, *e.g.*, daily office workers. However, the employer may have no control over a crew of construction contractors. In this case, the employer does not supervise the details, means, methods and processes by which the work accomplished. The definition of employee, along with the note to the definition proposed by OSHA requires a subjective determination to be made. 61 Fed. Reg. at 4058. We recommend OSHA follow a more objective test. The responsibility of reporting injuries and illnesses should turn on the fact of who provides the Workers' Compensation insurance, not necessarily daily supervision. This would then be an objective, rather than

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subjective test, less likely open to interpretation and mistakes.

OSHA has rejected the suggestions that either the payroll or workers' compensation employer keep the OSHA 1904 records. The Agency believes that in the majority of circumstances the payroll employer will also be the workers' compensation employer and there is no difference in the two suggestions. Temporary help services typically provide the workers' compensation insurance coverage for the employees they provide to other employers. Therefore, our reasons for rejecting these suggestions are the same. OSHA agrees that there are good arguments for both scenarios: 1. Including injuries and illnesses in the records of the leasing employer (the payroll or workers' compensation employer and 2. For including these cases in the records of the controlling employer. Requiring the payroll or workers' compensation employer to keep the OSHA records would certainly be a simple and objective method. There would be no doubt about who keeps the records. However, including the cases in the records of the temporary help agency erodes the value of the injury and illness records for statistical purposes, for administering safety and health programs at individual worksites, and for government inspectors conducting safety and health inspections or consultations. The benefits of simplification and clarity do not outweigh the potential damage to the informational value of the records, for the reasons discussed below.

First, the employer who controls the workers and the work environment is in the best position to learn about all the injuries and illnesses that occur to those workers. Second, when the data are collected for enforcement and research use and for priority setting, the injury and illness data are clearly linked to the industrial setting that gave rise to them. Most important, transferring the recording/reporting function from the supervising employer to the leasing firm would undermine rather than facilitate one of the most important goals of Part 1904—to assure that work-related injury and illness information gets to the employer who can use it to abate work-related hazards. If OSHA were to shift the recordkeeping responsibility from the controlling employer to the leasing firm, the records would not be readily available to the employer who can make best use of them. OSHA would need to require the leasing firm to provide the controlling employer with copies of the injury and illness logs and other reports to meet this purpose. This would be both burdensome and duplicative.

Requiring the controlling (host) employer to record injuries and illnesses for employees that they control has several advantages. First, it assigns the injuries and illnesses to the individual workplace with the greatest amount of control over the working conditions that led to the worker's injury or illness. Although both the host employer and the payroll employer have safety and health responsibilities, the host employer generally has more control over the safety and health conditions where the employee is working. To the extent that the records connect the occupational injuries and illnesses to the working conditions in a given workplace, the host employer must include these cases to provide a full and accurate safety and health record for that workplace.

If this policy were not in place, industry-wide statistics would be skewed. Two workplaces with identical numbers of injuries and illnesses would report different statistics if one relied on temporary help services to provide workers, while the other did not. Under OSHA's policy, when records are collected to generate national injury and illness statistics, the cases are properly assigned to the industry where they occurred. Assigning these injuries and illnesses to temporary help services would not accurately reflect the type of workplace that produced the injuries and illnesses. It would also be more difficult to compare industries. To illustrate this point, consider a hypothetical industry that relies on temporary help services to provide 10% of its labor force. Assuming that the temporary workers experience workplace injury and illness at the same rate as traditional employees, the Nation's statistics would underrepresent that industry's injury and illness numbers by 10%. If another industry only used temporary help services for 1% of the labor force, its statistics would be closer to the real number, but comparisons to the 10% industry would be highly suspect.

The policy also makes it easier to use an industry's data to measure differences that occur in that industry over time. Over the last 20 years, the business community has relied increasingly on workers from temporary help services, employee leasing companies, and other temporary employees. If an industry sector as a whole changed its practices to include either more or fewer temporary workers over time, comparisons of the statistics over several years might show trends in injury and illness experience that simply reflected changing business practices rather than real changes in safety and health conditions.

Some commenters objected to this aspect of the proposal because they thought it would require both the personnel leasing firm and the host employer to record injuries and illnesses. Double recording would lead to inaccurate statistics when both employers reported their data to BLS (see, *e.g.*, Exs. 15: 9, 26, 92, 198, 259, 287, 297, 333, 341, 356, 364, 443). The National Association of Temporary Staffing Services Stated:

> [i]f the exemption is not retained in the case of SIC 7363 [Help Supply Services] employers, it would be especially important for the final rules to expressly provide * * * that there is no intent to impose a dual reporting requirement. At least one state OSH office already has construed the proposed lifting of the partial exemption as creating an obligation on the part of staffing firms to maintain records for all of its employees, including temporary employees supervised by the worksite employer. This is clearly inconsistent with the intent of the proposed rule and should be clarified (Ex. 15: 333).

The Society of the Plastics Industry added:

> [b]ecause statistics are required to be collected for several years, it would take a significant effort to contact several independent companies on a continual basis to obtain such information. This would only result in a serious duplication of records, as both the host employer and the temporary leasing employer record the case. This will increase the recordkeeping burden for both the employer and those independent companies hired for a specific job by that employer (Ex. 15: 364).

OSHA agrees with these commenters that there is a potential for double counting of injuries and illnesses for workers provided by a personnel supply service. We do not intend to require both employers to record each injury or illness. To solve this problem, the rule, at § 1904.31(b)(4), specifically states that both employers are not required to record the case, and that the employers may coordinate their efforts so that each case is recorded only once—by the employer who provides day-to-day supervision. When the employers involved choose to work with each other, or when both employers understand the Part 1904 regulations as to who is required to record the cases and who is not, there will not be duplicative recording and reporting. This policy will not completely eliminate double recording of these injuries and illnesses, but it provides a mechanism for minimizing the error in the BLS statistics.

OSHA believes that many employers already share information about these injuries and illnesses to help each other with their own respective safety and health responsibilities. For example, personnel service employers need information to process workers' compensation claims and to determine how well their safety and health efforts are working, especially those involving training and the use of personal protective equipment. The host employer needs information on conditions in the workplace that may have caused the injuries or illnesses.

Many commenters objected to the requirement that the employer who controls the work environment record injuries and illnesses of temporary workers because that employer does not have adequate information to record the cases accurately (see, *e.g.*, Exs. 15: 9, 23, 184, 341, 363, 364, 370). These commenters contended that temporary workers supplied by personnel agencies may not have been at any given assignment long enough for the controlling employer to count days away from work accurately or to make informed judgments about the recordability of ongoing or recurring cases. The comments also contended that the controlling employer may have difficulty judging whether an injury or illness is related to that employer's work environment, to other places of employment, or is totally non-work related. These drawbacks in turn affect the recording employer's ability to certify to the completeness and accuracy of the annual summary of the Log. U.S. West, Inc. (Ex. 15: 184) remarked:

> [e]mployers should not be responsible for recordkeeping involving independent contractors, workers from temporary agencies, etc. A major reason for this would be the difficulties presented when trying to track such individuals for injuries/illnesses that have long periods of days away from work. In addition, it is often difficult to assign work relatedness for cases to a specific employer—an example would be upper extremity repetitive motion disorders for an individual from a temporary agency that works for several different employers in the course of a week or month. To avoid such problems, recordkeeping should be the responsibility of the individual's actual employer.

OSHA agrees with these commenters that recording work-related injuries and illnesses for temporary, leased employees will sometimes present these difficulties. However, the solution is not, as some commenters urge, to require the personnel leasing agency to assume responsibility for Part 1904 recording and reporting. The personnel leasing firm will not necessarily have better information than the host employer about the worker's exposures or accidents in previous assignments, previously recorded injuries or illnesses, or the aftermath of an injury or illness. And the personnel leasing firm will certainly have less knowledge of and control over the work environment that may have caused, contributed to, or significantly aggravated an injury or illness. As described above, the two employers have shared responsibilities and may share information when there is a need to do so.

If Part 1904 records are inaccurate due to lack of reasonably reliable data about leased employees, there are ways for OSHA to address the problem. First, the OSH Act does not impose absolutely strict liability on employers. The controlling employer must make reasonable efforts to acquire necessary information in order to satisfy Part 1904, but may be able to show that it is not feasible to comply with an OSHA recordkeeping requirement. If entries for temporary workers are deficient in some way, the employer can always defend against citation by showing that it made the efforts that a reasonable employer would have made under the particular circumstances to obtain more complete or accurate data.

A few commenters suggested that OSHA should link the recording requirement to the duration of time that the contract or temporary employee works at a specific location (see, *e.g.*, Exs. 15: 185, 259, 341, 364). The National Wholesale Druggists Association (NWDA) believed that:

> [t]here should be a length-of-employment delineation to determine whether a temporary or contract employee illness or injury should be included in the OSHA log. OSHA should set a length of time that the contract or temporary employee must work in a location before requirements for OSHA log reporting are triggered. By setting a length of employment standard, OSHA will not only eliminate the possibility of duplicative reporting of injuries and illnesses but will also eliminate the reporting of those short-term temporary employee assignments that may be covered by the temporary agency (Ex. 15: 185).

The Society of the Plastics Industry (SPI) recommended that the controlling firm should only keep records for permanently leased workers, stating "[f]or temporary employees, the employer who pays an employee (with the presumption that this is for whom they work) should be required to keep the records. For permanently assigned, leased employees, SPI agrees that such cases should be recorded by the leasing employer" (Ex. 15: 364). The Iowa Health Care Association asked whether a temporary nurse's aide who works in a facility for seven days to cover a vacationing permanent employee would be considered to be under the day-to-day supervision of the host facility (Ex. 15: 259).

OSHA has decided not to base recording obligations on the temporary employee's length of employment. Recording the injuries and illnesses of some temporary employees and not others would not improve the value or accuracy of the statistics, and would make the system even more inconsistent and complex. In OSHA's view, the duration of the relationship is much less important than the element of control. In the example of the temporary nurse's aide, for OSHA recordkeeping purposes the worker would be considered an employee of the facility for the days he or she works under the day-to-day supervision of the host facility.

Several commenters questioned whether or not temporary workers would be included in the total number of employees of that employer (see, *e.g.*, Exs. 15: 67, 356, 375, 437). The number of employees is used in two separate areas of the recordkeeping system. The number of employees is used to determine the exemption for smaller employers, and is entered on the annual summary of occupational injuries and illnesses. The Small Business Administration expressed concern over whether counting these workers as employees would affect the exemption for smaller employers, stating "[t]he definition of "employee" goes beyond the statutory intent * * * Small businesses would not only have new obligations for coverage, but this methodology for counting employees would impact the opportunity for an exemption under this standard" (Exs. 15: 67, 437). The American Petroleum Institute (API) was concerned about how the employee count affects the way that the host employer completes the annual summary, particularly the entries for hours worked by all employees and the average number of employees:

> [u]sing the OSHA-specified approach for determining the number of employees and hours worked, particularly for temporary employees and/or smaller establishments, is not often feasible. Assumption (1) [that the employer already has this data] is not true for temporary employees. Their hours worked are maintained by their contract employers. Host employers have dollar costs paid to each contractor employer. Therefore, getting employee counts and hours worked for temporaries requires making assumptions and estimating (Ex. 15: 375).

Because OSHA is using the common law concepts to determine which workers are to be included in the records, a worker who is covered in

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terms of recording an injury or illness is also covered for counting purposes and for the annual summary. If a given worker is an employee under the common law test, he or she is an employee for all OSHA recordkeeping purposes. Therefore, an employer must consider all of its employees when determining its eligibility for the small employer exemption, and must provide reasonable estimates for hours worked and average employment on the annual summary. OSHA has included instructions on the back of the annual summary to help with these calculations.

The Texas Chemical Council argued that supervising employers should not have to record injuries or illnesses of agency-supplied workers unless the supervising employer has authority to hold these workers accountable for safety performance (Ex. 15: 159). According to this commenter, most temporary agencies limit the contracting employer to following the agencies' policies for corrective action for unacceptable performance. OSHA would simply point out that this is a matter within the contract arrangements between the two employers, and that OSHA intervention in this area is not necessary or appropriate. In any event, we believe that this should not determine who records occupational injuries and illnesses.

The Phibro-Tech company asked "[i]f the facility is now responsible for tracking these injuries on their Form 300, will this affect the Worker's Compensation liability?" (Ex. 15: 35). Tracking injuries and illnesses for OSHA purposes does not affect an employer's workers' compensation liability. An employer's liability for workers' compensation is a separate matter that is covered by state law. Employers who maintain workers' compensation coverage will be responsible for injuries and illnesses regardless of which employer records them for OSHA purposes.

Bell Atlantic Network Services asked "[a]re contract employee OSHA recordable injury/illness incidents to be recorded on the same OSHA 300 log as employer's full-time employees? Are they to be identified as "Contract/Temporary" employees on the OSHA 300 Log, i.e., under the column E—Job Title?" (Ex. 15: 218). OSHA's view is that a given establishment should have one OSHA Log and only one Log. Injuries and illnesses for all the employees at the establishment are entered into that record to create a single summary at the end of the year. OSHA does not require temporary workers or any other types of workers to be identified with special titles in the job title column, but also does not prohibit the practice. This column is used to list the occupation of the injured or ill worker, such as laborer, machine operator, or nursing aide. However, OSHA does encourage employers to analyze their injury and illness data to improve safety and health at the establishment. In some cases, identifying temporary or contract workers may help an employer to manage safety and health more effectively. Thus an employer may supplement the OSHA Log to identify temporary or contract workers, although the rule does not require it.

OSHA received two suggestions that would provide an OSHA inspector with injury and illness data for temporary workers without putting their injuries on the host employer's OSHA 300 Log. The National Grain and Feed Association, Grain Elevator and Processing Society, and National Oilseed Processors Association jointly recommended:

> [e]mployers with employees who work under contract at a site other than the employer's should be required to provide a copy of the appropriate first report of injury or OSHA 301 to the site controlling employer. The site controlling employer can then maintain a file of Form 301's to facilitate OSHA's evaluation of workplace hazards (Ex. 15: 119).

The Douglas Battery Manufacturing (Ex. 15: 82) company suggested the following alternative:

> [a]n option that would allow an employer of temporary workers to determine the incident rate of the temporaries, would be to require the temporary agency/ contractor to forward a copy of its OSHA log for workers at a particular facility, to that facility by February of the next calendar year. The names and other personal identifiers of the temporary/contract workers could be removed prior to submittal but the data would be available on site for agency inspection purposes.

OSHA believes that neither of these alternatives would be an acceptable substitute for completing the 300 Log and 301 form for injured workers. The information would not be entered into the annual summary, so the establishment's statistics would not be complete. While these options would create a method (although a cumbersome method) for providing the information to a government inspector, the data would not be collected for statistical purposes.

Some commenters asked OSHA about how they should deal with a variety of other types of workers. The American Ambulance Association suggested that OSHA "[s]pecifically exclude from the definition of employee, students who are unpaid by the company/institution which is providing a clinical or practice setting" (Ex. 15: 226). The Maine Department of Labor (Ex. 15: 41) asked the following question:

> [q]uestions about how to report people such as Interns, Aspire (welfare) program participants, prison release workers and volunteers are now being asked. A clear definition needs to be established to account for all kinds of employees. Our Public Sector law requires us to count all people who are permitted to work. Maybe you don't want that inclusive a definition, but it is something to consider. We had to come up with a specific definition of volunteers to exclude sporadic volunteers (essentially those not working at a specific place at a specific time on a regular basis). With some workplaces utilizing volunteers and with welfare reform changes expected, you may want to prepare for these questions now.

These workers should be evaluated just as any other worker. If a student or intern is working as an unpaid volunteer, he or she would not be an employee under the OSH Act and an injury or illness of that employee would not be entered into the Part 1904 records. If the worker is receiving compensation for services, and meets the common law test discussed earlier, then there is an employer-employee relationship for the purposes of OSHA recordkeeping. The employer in that relationship must evaluate any injury or illness at the establishment and enter it into the records if it meets the recording criteria.

Section 1904.32 Annual Summary

At the end of each calendar year, section 1904.32 of the final rule requires each covered employer to review his or her OSHA 300 Log for completeness and accuracy and to prepare an Annual Summary of the OSHA 300 Log using the form OSHA 300–A, Summary of Work-Related Injuries and Illnesses, or an equivalent form. The summary must be certified for accuracy and completeness and be posted in the workplace by February 1 of the year following the year covered by the summary. The summary must remain posted until April 30 of the year in which it was posted.

Preparing the Annual Summary requires four steps: reviewing the OSHA 300 Log, computing and entering the summary information on the Form 300–A, certification, and posting. First, the employer must review the Log as extensively as necessary to make sure it is accurate and complete. Second, the employer must total the columns on the Log; transfer them to the summary form; and enter the calendar year covered, the name of the employer, the name and address of the establishment, the average number of employees on the establishment's payroll for the calendar year, and the total hours worked by the covered employees. If there were no recordable cases at the establishment for the year covered, the summary must nevertheless be completed by entering zeros in the total for each column of the OSHA 300 Log. If a form other than the OSHA 300–A is used, as permitted by paragraph 1904.29(b)(4), the alternate form must contain the same information as the OSHA 300–A form and include identical statements concerning employee access to the Log and Summary and employer penalties for falsifying the document as are found on the OSHA 300–A form.

Third, the employer must certify to the accuracy and completeness of the Log and Summary, using a two-step process. The person or persons who supervise the preparation and maintenance of the Log and Summary (usually the person who keeps the OSHA records) must sign the certification statement on the form, based on their direct knowledge of the data on which it was based. Then, to ensure greater awareness and accountability of the recordkeeping process, a company executive, who may be an owner, a corporate officer, the highest ranking official working at the establishment, or that person's immediate supervisor, must also sign the form to certify to its accuracy and completeness. Certification of the summary attests that the individual making the certification has a reasonable belief, derived from his or her knowledge of the process by which the information in the Log was reported and recorded, that the Log and summary are "true" and "complete."

Fourth, the Summary must be posted no later than February 1 of the year following the year covered in the Summary and remain posted until April 30 of that year in a conspicuous place where notices are customarily posted. The employer must ensure that the Summary is not defaced or altered during the 3 month posting period.

Changes from the former rule. Although the final rule's requirements for preparing the Annual Summary are generally similar to those of the former rule, the final rule incorporates four important changes that OSHA believes will strengthen the recordkeeping process by ensuring greater completeness and accuracy of the Log and Summary, providing employers and employees with better information to understand and evaluate the injury and illness data on the Annual Summary, and facilitating greater employer and employee awareness of the recordkeeping process.

1. Company Executive Certification of the Annual Summary. The final rule carries forward the proposed rule's requirement for certification by a higher ranking company official, with minor revision. OSHA concludes that the company executive certification process will ensure greater completeness and accuracy of the Summary by raising accountability for OSHA recordkeeping to a higher managerial level than existed under the former rule. OSHA believes that senior management accountability is essential if the Log and Annual Summary are to be accurate and complete. The integrity of the OSHA recordkeeping system, which is relied on by the BLS for national injury and illness statistics, by OSHA and employers to understand hazards in the workplaces, by employees to assist in the identification and control of the hazards identified, and by safety and health professionals everywhere to analyze trends, identify emerging hazards, and develop solutions, is essential to these objectives. Because OSHA cannot oversee the preparation of the Log and Summary at each establishment and cannot audit more than a small sample of all covered employers' records, this goal is accomplished by requiring employers or company executives to certify the accuracy and completeness of the Log and Summary.

The company executive certification requirement imposes different obligations depending on the structure of the company. If the company is a sole proprietorship or partnership, the certification may be made by the owner. If the company is a corporation, the certification may be made by a corporate officer. For any management structure, the certification may be made by the highest ranking company official working at the establishment covered by the Log (for example, the plant manager or site supervisor), or the latter official's supervisor (for example, a corporate or regional director who works at a different establishment, such as company headquarters).

The company executive certification is intended to ensure that a high ranking company official with responsibility for the recordkeeping activity and the authority to ensure that the recordkeeping function is performed appropriately has examined the records and has a reasonable belief, based on his or her knowledge of that process, that the records are accurate and complete.

The final rule does not specify how employers are to evaluate their recordkeeping systems to ensure their accuracy and completeness or what steps an employer must follow to certify the accuracy and completeness of the Log and Summary with confidence. However, to be able to certify that one has a reasonable belief that the records are complete and accurate would suggest, at a minimum, that the certifier is familiar with OSHA's recordkeeping requirements, and the company's recordkeeping practices and policies, has read the Log and Summary, and has obtained assurance from the staff responsible for maintaining the records (if the certifier does not personally keep the records) that all of OSHA's requirements have been met and all practices and policies followed. In most if not all cases, the certifier will be familiar with the details of some of the injuries and illnesses that have occurred at the establishment and will therefore be able to spot check the OSHA 300 Log to see if those cases have been entered correctly. In many cases, especially in small to medium establishments, the certifier will be aware of all of the injuries and illnesses that have been reported at the establishment and will thus be able to inspect the forms to make sure all of the cases that should have been entered have in fact been recorded.

The certification required by the final rule may be made by signing and dating the certification section of the OSHA 300–A form, which replaces the summary portion of the former OSHA 200 form, or by signing and dating a separate certification statement and appending it to the OSHA Form 300–A. A separate certification statement must contain the identical penalty warnings and employee access information as found on the OSHA Form 300–A. A separate statement may be needed when the certifier works at another location and the certification is mailed or faxed to the location where the Summary is posted.

The certification requirement modifies the certification provision of the former rule (former paragraph 1904.5(c)), which required a certification of the Annual Summary by the employer or an officer or employee who supervised the preparation of the Log and Summary. The former rule required that individual to sign and date the year-end summary on the OSHA Form 200 and to certify that the summary was true and complete. Alternatively, the recordkeeper could, under the former rule, sign a separate certification statement rather than signing the OSHA form.

Both the former rule (paragraph 1904.9 (a) and (b)) and the proposed rule (paragraph 1904.16(a) and (b))

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contained penalty provisions for the falsification of OSHA records or for the failure to record recordable cases; these provisions do not appear in the final rule. OSHA believes, based on the record and the Agency's own recordkeeping and audit experience, that this deletion will not affect the accuracy or completeness of the records, employers' recording obligations, or OSHA's enforcement powers. The criminal penalties referred to in paragraph 1904.9(a) of the former rule are authorized by section 17(g) of the OSH Act and do not need to be repeated in the final rule to be enforced. Similarly, the administrative citations and penalties referred to in paragraph 1904.9(b) of the former rule are authorized by sections 9 and 17 of the OSH Act. The warning statement on the final OSHA 300–A form or its equivalent should be sufficient to remind those who certify the forms of their legal obligations under the Act.

OSHA has revised the final rule's certification requirement in response to questions about its usefulness raised in the preamble to the proposal (61 FR 4047). In particular, the proposal noted that the person responsible for preparing the Log and Summary might, in some cases, have an incentive not to report injuries and illnesses, which would, of course, impair the accuracy of the Log. OSHA stated that "some employers mistakenly believe that recording a case implies fault on the part of the employer" and thus has the potential to adversely affect their ability to defend workers' compensation claims or lawsuits. Some employers also have established "accountability systems" that are based on the number of OSHA recordables, *i.e.*, that evaluate the safety performance of managers by the number of injuries and illnesses reported by workers in the departments or organizational units under their control. OSHA noted that individuals whose performance, promotions, compensation, and/or bonuses depend on the achievement of reduced injury and illness rates "may be discouraged from fully and accurately recording injuries and illnesses (61 FR 4047) * * *" Managers and supervisors being evaluated by the numbers" also may have an incentive to avoid recording as many cases as possible.

OSHA proposed to change the former rule's certification requirements. In the proposed rule, OSHA proposed to require that a responsible company official certify to the accuracy and completeness of the Log and Summary. According to the proposal, that person would sign the summary to certify that "he or she has examined the OSHA Injury and Illness Log and Summary and that the entries on the form and the year-end summary are true, accurate, and complete" (61 FR 4060). "Responsible company official" was defined in the proposal as "an owner of the company, the highest ranking company official working at the establishment, or the immediate supervisor of the highest ranking company official working at the establishment" (61 FR 4059). By requiring a high level individual to sign each establishment Log certification, the proposal sought to create an incentive for that official to take steps to ensure the accuracy and completeness of the information on the log or face penalties for failing to do so.

Several commenters (see, *e.g.*, Exs. 15: 50, 105, 415) confirmed that an underreporting incentive did exist under the former rule's certification system. For example, the International Chemical Workers' Union (Ex. 15: 415) and Mr. George Cook (Ex. 15: 50) noted the potential for this problem to arise in their comments to the record. Harsco Corporation (Ex. 15: 105) pointed out that a contractor's accident rate will affect its ability to bid for jobs, and there is thus an incentive to keep rates low by not recording all injuries and illnesses.

There were many responses to the proposed change in the certification requirement. In general, a broad cross-section of commenters (see, *e.g.*, Exs. 15: 70, 127, 136, 137, 141, 153, 163, 170, 224, 266, 278, 324, 371, 407, 418, 429) gave unqualified support to the proposal's certification by a "responsible corporate official." Typical of these comments was the New Jersey Department of Labor's statement that the proposed change would result in heightened awareness of health and safety problems by management, enhanced efforts to reduce workplace injuries and illnesses, and more accurate reporting (Ex. 15: 70). The AFL–CIO noted that requiring top corporate officials to be responsible "represents a fundamental change in the importance of data gathering in the workplace" (Ex. 15: 418).

A number of commenters expressed reservations about the definition of "responsible corporate official" and the extent of the responsibility and/or legal liability such certification might impose on certifying officials. Some commenters argued that it was unreasonable for a high corporate official, who might not be familiar with the recordkeeping function and its legal requirements, to certify to the accuracy and completeness of the Log and Summary. These commenters argued that it would be more appropriate for a high level management official, industrial hygienist, or director of health and safety to certify the Log and Summary because these individuals are already responsible for ensuring the accuracy and completeness of the Log, especially in multi-establishment businesses where recordkeeping is centralized (see, *e.g.*, Exs. 21; 25; 27; 33; 15: 44, 48, 65, 122, 132, 133, 147, 154, 161, 169, 174, 176, 193, 194, 199, 203, 231, 242, 263, 269, 270, 272, 273, 283, 284, 289, 290, 292, 295, 297, 299, 301, 304, 305, 317, 325, 329, 332, 341, 345, 346, 348, 364, 368, 377, 385, 386, 387, 403, 405, 410, 412, 413, 420, 425, 442). Two commenters suggested that, if a high level official were to be responsible for the certification, he or she should only be required to certify that the "[c]ompany has * * * taken reasonable steps to ensure the accuracy of the logs" (Exs. 15: 200, 442). Several representatives from the construction industry (see, *e.g.*, Exs. 15: 126, 342, 355) urged OSHA to make sure that any certification provision reflect the operation of multi-employer construction sites. These commenters recommended that the certifying official either be the senior official on-site or that person's immediate superior.

Other employer representatives believed that the broad nature of the proposed certification could make the certification vulnerable to legal liability (see, *e.g.*, Exs. 20; 33; 15: 122, 133, 147, 149, 176, 193, 199, 201, 205, 220, 231, 236, 272, 273, 284, 290, 292, 297, 301, 304, 313, 318, 320, 335, 345, 346, 352, 353, 368, 373, 375, 389, 396, 424, 425, 427, 428, 430). The National Association of Manufacturers (Ex. 15: 305), in a statement that is representative of the views of these commenters, said that:

> [t]he language of the certification is totally impractical and unreasonable in that it is written as a certification of absolute completeness and accuracy. This creates such an unreasonably high standard that no one should legitimately be asked or required to sign it. As a general rule, we believe an individual would be expected to have significantly better knowledge of the information on his/her personal income tax return than on the OSHA Form 300; yet even the certification on the personal income tax return includes the language "to the best of my knowledge and belief." This clause must be added to the certifying language.

Numerous commenters favored a dual level of accountability, with a first level certification by the "responsible company official," as defined in the proposal, and a second level certification required by a high level corporate official with safety and health responsibilities (see, *e.g.*, Exs. 20, 15: 65, 89, 182, 369, 380, 409, 415). These participants recommended that OSHA require a more senior official, at a corporate level beyond the establishment keeping the records, additionally certify that the company had made a good faith effort to ensure accurate and complete records for all of the employer's establishments. The American Automobile Manufacturers Association (AAMA) stated that it:

> [a]grees that a corporate official responsible for health and safety and the highest ranking company official at an establishment should certify that a good faith effort for proper recordkeeping has taken place, and the individual responsible for day-to-day OSHA recordkeeping should certify the accuracy and completeness of the log (Ex. 15–409).

OSHA has not adopted a dual certification requirement because one certification should be enough to make sure that the records are accurate. In addition, a dual certification requirement would increase the complexity and burdens of the final rule, without significantly adding incentives for employers to keep better records.

Some commenters wished OSHA to maintain the former rule's approach to certification. These participants were generally skeptical of senior management certification, characterizing it as impractical, onerous, burdensome, unrealistic, intrusive, and infringing on the prerogative of management to designate the appropriate person(s) to certify the Log (see, *e.g.*, Exs. 15: 9, 15, 39, 45, 60, 89, 96, 132, 149, 156, 183, 184, 185, 195, 200, 201, 203, 204, 213, 218, 225, 239, 259, 260, 262, 265, 271, 272, 303, 304, 313, 317, 318, 320, 332, 335, 338, 344, 352, 353, 360, 373, 378, 389, 390, 392, 401, 406, 414, 423, 424, 427, 428, 430, 431). According to the Battery Council International, "[t]he threat of civil and criminal liability provides more than enough incentive to ensure the accuracy of the recordkeeping Log and Summary" (Ex. 15: 161). Mallinckrodt Chemical, Inc., and the Interconnecting and Packaging Electronic Circuits Corporation echoed this belief (Exs. 15: 69, 172). The Vulcan Chemical Company went so far as to recommend that OSHA delete certification requirements completely and rely only on the proposed penalty provisions (Ex. 15: 171).

Most commenters opposing high-level management certification argued that management-designated, well-qualified, lower level administrative personnel perform the recordkeeping function and can therefore best certify to the accuracy of the OSHA 300 Log (see, *e.g.*, Exs. 15: 69, 220, 225, 227, 281, 297, 305, 313, 352, 353). According to the American Textile Manufacturers Institute (Ex. 15: 156), "[a] corporate official (*i.e.*, safety director, human resources director, Chief Executive Officer) should never be required to certify the accuracy of the logs. Commenters also stated that placing the responsibility on senior management would increase the economic and paperwork burden of the rule because these individuals would need additional training and would conduct audits, particularly at businesses with many work locations (see, *e.g.*, Exs. 15 : 213, 259, 375, 395). A few commenters stated that none of OSHA's proposed approaches, including the Log and Summary certification, would significantly decrease the financial incentives employers have for underreporting (see, *e.g.*, Exs. 15: 39, 199, 406). The Ogletree, Deakins, Nash, Smoak & Stewart Coalition (ODNSSC) said that "[i]n the final analysis, the one measure that will have the greatest effect in fostering the maintenance of accurate logs is finally within the grasp of all interested parties: the promulgation of a final rule * * * that is well conceived, makes intuitive and analytical sense, and as such is largely accepted within the regulated community" (Ex. 15: 406).

Although OSHA believes that the final rule has many features that will enhance the accuracy and completeness of reporting, the Agency has included a company executive level of certification in the final rule. OSHA believes that company executive certification will raise employer awareness of the importance of the OSHA records, improve their accuracy and completeness (and thus utility), and decrease any underreporting incentive.

The final rule therefore requires a higher level company official to certify to their accuracy and completeness. Thus the final rule reflects OSHA's agreement with those commenters who stated that the Log and Summary must be actively overseen by higher level management and that certification by such an official would make management's responsibility for the accuracy and completeness of the system clear (see, *e.g.*, Exs. 20; 15: 31, 65, 70, 89, 127, 136, 137, 141, 153, 163, 170, 182, 224, 266, 278, 324, 369, 371, 380, 396, 407, 409, 415, 418, 429). As the Union Carbide Company stated, having a higher authority sign a qualified certification of the summary "[w]ould encourage activities, such as training and periodic reviews/audits of the logs, to improve the accuracy and completeness of the data" (Ex. 15: 396). In the words of one safety consultant, "[u]ntil there is a Corporate Commitment the information will be suspect" (Ex. 15: 31).

OSHA has slightly modified the proposed definition of responsible company official in the text of the final rule. In the final rule, the person who must perform the certification must be a company executive. OSHA does not believe that an industrial hygienist or a safety officer is likely to have sufficient authority to ensure the integrity of a company's recordkeeping process. Therefore, the final rule requires that the certification be provided by an owner of a sole proprietorship or partnership, an officer of the corporation, the highest-ranking official at the establishment, or that person's supervisor. OSHA believes that this definition takes into account and addresses the concerns of the comments received from construction employers (see, *e.g.*, Exs. 15: 105, 126.342, 355).

OSHA is also aware that senior management officials cannot be expected to have hands-on experience in the details of the logs and summaries and therefore that their certification attests to the overall integrity of the recordkeeping process. In response to numerous comments that certification by the responsible company official be qualified by the addition to the certification of a clause such as "to the best of my knowledge and belief" (see, *e.g.*, Exs. 20, 15: 122, 193, 199, 205, 220, 272, 273, 290, 305, 320, 335, 375, 396, 424, 425, 427, 428, 430), OSHA has added that the certification required by the final rule must be based on the official's "reasonable belief" that the Log and Summary are accurate and complete. Certification thus means that the certifying official has a general understanding of the OSHA recordkeeping requirements, is familiar with the company's recordkeeping process, and knows that the company has effective recordkeeping procedures and uses those procedures to produce accurate and complete records. The precise meaning of "reasonable belief" will be determined on a case-by-case basis because circumstances vary from establishment to establishment and decisions about the recordability of individual cases may differ, depending upon case-specific details.

2. Number of employees and hours worked. Injury and illness records provide a valuable tool for OSHA, employers, and employees to determine where and why injuries and illnesses occur, and they are crucial in the development of prevention strategies. The final rule requires employers to include in the Annual Summary (the OSHA Form 300–A) the annual average number of employees covered by the

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Log and the total hours worked by all covered employees. In the proposal (61 FR 4037), OSHA stated that this information would facilitate hazard analysis and incidence rate calculations for each covered establishment. A number of commenters supported the proposed approach and felt that it would not be a burden on employers, as long as OSHA granted some flexibility to employers who did not have sophisticated recordkeeping systems (see, *e.g.*, Exs. 15: 48, 61, 70, 78, 153, 163, 181, 262, 310, 350, 369, 429). For example, the Safety Services Administration of the City of Mesa, Arizona, a small employer, stated:

> [f]or most employers, the average number of employees is readily available; the work hour totals may, or may not be so easily obtained, depending upon the book keeping methodology. For salaried employees, where detailed hourly records are not maintained, the 2,000 hr/yr would be used in any case. In our case, both employee numbers and total hours worked is available and presents no problem (Ex. 15: 48).

Other commenters stated that the total number of hours worked was readily available through payroll records and that calculating it would present only a minimal burden, but were opposed to the required inclusion of the annual average number of employees because this number is highly variable, difficult to assess where employment is seasonal and subject to high turnover, and not important to incidence calculations (see, *e.g.*, Exs. 15: 123, 145, 170, 225, 359, 375).

Other commenters opposed including in the summary the average number of employees and the total number of hours worked because they believed the costs of compiling this information would outweigh its benefits, which they believed to be minimal (see, *e.g.*, Exs. 15: 9, 44, 184, 195, 205, 214, 247, 272, 303, 308, 313, 335, 341, 352, 353, 412, 423, 431), especially in industries, like health care, with high turnover rates (Ex. 15: 341). One company estimated its cost of collecting data on total hours worked to be $200,000 to $300,000 and to take four to six months (Ex. 15: 423). Sprint Corporation proposed that "[i]ncidence rates continue to be calculated on an exception basis by the compliance officer at the time of the inspection. Larger employers, like Sprint, maintain such incidence rates by department or business unit and not by physical location as broken out on the OSHA log" (Ex. 15: 133).

Some commenters recommended alternatives, including permitting employers to estimate the total number of hours worked, possibly by using the ANSI Z16.4 standard of 173.33 hours per month per employee, to minimize the burden (see, *e.g.*, Exs. 15: 272, 303, 335, 359) or excluding establishments with fewer than 100 employees from the requirement altogether (Ex. 15: 375).

OSHA's view is that the value of the total hours worked and average number of employees information requires its inclusion in the Summary, and the final rule reflects this determination. Having this information will enable employers and employees to calculate injury and illness incidence rates, which are widely regarded as the best statistical measure for the purpose of comparing an establishment's injury and illness experience with national statistics, the records of other establishment, or trends over several years. Having the data available on the Form 300–A will also make it easier for the employer to respond to government requests for the data, which occurs when the BLS and OSHA collect the data by mail, and when an OSHA or State inspector visits the facility. In particular, it will be easier for the employer to provide the OSHA inspector with the hours worked and employment data for past years.

OSHA does not believe that this requirement creates the time and cost burden some commenters to the record suggested, because the information is readily available in payroll or other records required to be kept for other purposes, such as income tax, unemployment, and workers' compensation insurance records. For the approximately 10% of covered employers who participate in the BLS's Annual Survey of Occupational Injuries and Illnesses, there will be no additional burden because this information must already be provided to the BLS. Moreover, the rule does not require employers to use any particular method of calculating the totals, thus providing employers who do not maintain certain records—for example the total hours worked by salaried employees—or employers without sophisticated computer systems, the flexibility to obtain the information in any reasonable manner that meets the objectives of the rule. Employers who do not have the ability to generate precise numbers can use various estimation methods. For example, employers typically must estimate hours worked for workers who are paid on a commission or salary basis. Additionally, the instructions for the OSHA 300–A Summary form include a worksheet to help the employer calculate the total numbers of hours worked and the average number of.

3. Extended posting period. The final rule's requirement increasing the summary Form 300–A posting period from one month to three months is intended to raise employee awareness of the recordkeeping process (especially that of new employees hired during the posting period) by providing greater access to the previous year's summary without having to request it from management. The additional two months of posting will triple the time employees have to observe the data without imposing additional burdens on the employer. The importance of employee awareness of and participation in the recordkeeping process is discussed in the preamble to sections 1904.35 and 1904.36.

The requirement to post the Summary on February 1 is unchanged from the posting date required by the former rule. As OSHA stated in the proposal (61 FR 4037) "one month (January) is a reasonable time period for completing the summary section of the form." Only three commenters disagreed (see, *e.g.*, Exs. 15: 347, 402, 409); two of these commenters suggested that 60 days were required to do so (Exs. 15: 347, 409). OSHA believes that, since the required process is simple and straightforward, 30 days will be sufficient. Delaying the posting any further would mean that employers would not have access to the Summary for a longer period, thus diminishing the timeliness of the posted information.

OSHA's proposal would have required employers to post the summary for one year, based on the Agency's preliminary conclusion that continuous posting presented no additional burden for employers and would be beneficial to employees (61 FR 4037–4038). The one-year posting period was unconditionally supported by a number of commenters (see, *e.g.*, Exs. 15: 70, 153, 154, 199, 277) and was supported by others on the condition that no updating of the posted summary be required (see, *e.g.*, Exs. 15: 262, 288, 435). The AAMA and the Ford Motor Co. supported a ten-month posting period (from March 1 to December 31) (Exs. 15: 347, 409).

A number of commenters stated that a one-year posting period was too long and would not be justified by the minimal benefits to be achieved by such year-long posting. Some of these participants contended that the Annual Summary does not continue to provide useful, accurate information after its initial posting and will not enhance employee awareness because, although posting of a new summary is noticed when it is done, it becomes "wallpaper" shortly thereafter, especially if it is on a cluttered bulletin board (see, *e.g.*, Exs. 33; 15: 9, 23, 39, 40, 45, 60, 66, 98, 107, 119, 121, 122, 176, 203, 204, 231, 232, 273, 281, 289, 301, 317, 322, 329, 335, 341, 344, 347, 348, 356, 358, 381, 389, 399, 405, 409, 414, 428, 430, 431, 434, 441). For example, the Witco Corporation predicted that the 12-month posting requirement "[w]ill result in no one noticing the old Log's removal and the posting of a new one" (Ex. 15: 107). One commenter even suggested that continuous posting "[u]ndermines the Agency's intent in bringing the information to employees" attention" (Ex. 15: 428).

Other commenters argued that year-long posting was excessive because it created too great a burden on employers. They stated that extended posting would require employers to make periodic inspections to ensure that the summary had not been taken down, covered, or defaced (see, *e.g.*, Exs. 37, 15: 57, 80, 97, 151, 152, 179, 180, 272, 303, 335, 346, 381, 410, 431), and that this additional administrative burden, especially to employers with large establishments that now voluntarily post Logs in multiple locations, could be significant (see, *e.g.*, Exs. 15: 97, 184, 239, 272, 283, 297, 303, 304, 305, 348, 395, 396, 410, 424, 430). One suggestion made by commenters to minimize this burden was to post the Summary for one month at the establishment and then at a central location for the remaining eleven months (see, *e.g.*, Exs. 15: 151, 152, 179, 180) or to permit electronic posting (Ex. 15: 184). Other employers opposed the extended posting-period on the grounds that a one-month period posting was sufficient to achieve OSHA's objectives (see, *e.g.*, Exs. 15: 9, 15, 39, 45, 49, 57, 69, 74, 80, 89, 97, 98, 116, 119, 133, 163, 182, 184, 195, 203, 287, 289, 335, 356, 396, 424, 427, 428, 441, 443), especially since employees have access to the summary at any time during the retention period (see, *e.g.*, Exs. 15: 9, 15, 69, 80, 98, 119, 136, 137, 141, 161, 200, 204, 224, 225, 266, 272, 278, 303, 312, 317, 324, 348, 374, 395, 405, 406, 410, 412, 431). Still other commenters thought the one-year period was too long but supported a two or even three-month posting period as adding little, if any, additional burden (see, *e.g.*, Exs. 37, 15: 78, 89, 199, 235, 256, 277).

After a review of all the comments received and its own extensive experience with the recordkeeping system and its implementation in a variety of workplaces, OSHA has decided to adopt a 3-month posting period. The additional posting period will provide employees with additional opportunity to review the summary information, raise employee awareness of the records and their right to access them, and generally improve employee participation in the recordkeeping system without creating a "wallpaper" posting of untimely data. In addition, OSHA has concluded that any additional burden on employers will be minimal at best and, in most cases, insignificant. All the final rule requires the employer to do is to leave the posting on the bulletin board instead of removing it at the end of the one-month period. In fact, many employers preferred to leave the posting on the bulletin board for longer than the required one-month period in the past, simply to provide workers with the opportunity to view the Annual Summary and increase their awareness of the recordkeeping system in general and the previous year's injury and illness data in particular. OSHA agrees that the 3-month posting period required by the final rule will have these benefits which, in the Agency's view, greatly outweigh any minimal burden that may be associated with such posting. The final rule thus requires that the Summary be posted from February 1 until April 30, a period of three months; OSHA believes that the 30 days in January will be ample, as it has been in the past, for preparing the current year's Summary preparatory to posting.

4. Review of the records. The provisions of the final rule requiring the employer to review the Log entries before totaling them for the Annual Summary are intended as an additional quality control measure that will improve the accuracy of the information in the Annual Summary, which is posted to provide information to employees and is also used as a data source by OSHA and the BLS. Depending on the size of the establishment and the number of injuries and illnesses on the OSHA 300 Log, the employer may wish to cross-check with any other relevant records to make sure that all the recordable injuries and illnesses have been included on the Summary. These records may include workers' compensation injury reports, medical records, company accident reports, and/or time and attendance records.

OSHA did not propose that any auditing or review provisions be included in the final rule. However, several commenters suggested that OSHA include requirements that would require employers to audit the OSHA 300 Log information (see, *e.g.*, Exs. 35; 36; 15: 31, 310, 418, 438). For example, the United Auto Workers (Ex. 15: 438) stated:

> [t]he most important change OSHA could make in recordkeeping rules would be to require employers to conduct an independent audit of the completeness of the record. The purpose of the audit would be to determine that no case went unrecorded, and that no disabling injury or illness was mislabeled as non lost workday. Such requirements were not in the proposal, but are desperately needed.

Linda Ballas (Ex. 15: 31), a safety consultant who performs audits of OSHA injury and illness records for employers, added [u]ntil there is Corporate Commitment the information will be suspect. * * * Audits are necessary." In fact, the Laborers' Health & Safety Fund of North America (Ex. 15: 310) recommended biennial third-party audits.

In the final rule, OSHA has not adopted regulatory language that requires formal audits of the OSHA Part 1904 records. However, the final rule does require employers to review the OSHA records as extensively as necessary to ensure their accuracy. The Agency believes that including audit provisions is not necessary because the high-level certification requirement will ensure that recordkeeping receives the appropriate level of management attention.

Some companies, especially larger ones, may choose to conduct audits, however, to ensure that the records are accurate and complete; many companies commented that they already perform records audits as part of their company's safety and health program. For example, the Ford Motor Company (Ex. 15: 347), Dow Chemical Company (Ex. 15: 335), and Brown & Root (Ex. 15: 423) reported that they audit their injury and illness records on a regular basis. Also, three commenters to the record were safety and health consultants who provide injury and illness auditing services to employers, in addition to other safety and health services (Exs. 15: 31, 345, 406). In the past, OSHA has entered into a number of corporate-wide settlement agreements with individual companies that included third-party audits of the employers' injury and illness records (*e.g.*, Ford, General Motors, Union Carbide). OSHA expects that many of these companies will continue to audit their injury and illness records and their recordkeeping procedures, and to take any other quality control measures they believe to be necessary to ensure the quality of the records. However, OSHA has not required records audits in the final rule because the Agency believes that the combination of final rule requirements providing for employee participation (§ 1904.35), protecting employees against discrimination for reporting work-related injuries and illnesses to their employer (section

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1904.36), requiring review by employers of the records at the end of the year, and mandating two level certification of the records will provide the quality control mechanisms needed to improve the quality of the OSHA records.

Deletions from the former rule. Except for the foregoing changes discussed above, the final rule is generally similar to the former rule in its requirements for preparing, certifying and posting of the year-end Summary. However, some provisions of the former rule related to the Summary have not been included in the final rule. For example, the former rule required employers with employees who did not report to or work at a single establishment, or who did not report to a fixed establishment on a regular basis, to hand-deliver or mail a copy of the Summary to those employees. OSHA proposed to maintain this requirement, which was supported by one commenter (Ex. 15: 298) but opposed by many others because of the administrative cost of preparing such mailings, especially in high turnover industries like construction (see, *e.g.*, Exs. 15: 116, 132, 199, 200, 201, 312, 322, 329, 335, 342, 344, 355, 375, 395, 430, 440, 441). These commenters pointed out that employees who do not report to a single establishment still have the right to view the summary at a central location and to obtain copies of it.

In the final rule, OSHA has decided not to include the proposed requirement for individual mailings as unnecessary because final paragraph 1904.30(b)(3) requires that every employee be linked, for recordkeeping purposes, to at least one establishment keeping a Log and Summary that will be prepared and posted. In other words, every employee covered by the rule will have his or her injuries or illnesses recorded on a particular establishment's Log, even if that employee does not routinely report to that establishment or is temporarily working there. Thus every employee will have 3-month access to the Log and Summary at the posted location or may obtain a copy the next business day under paragraph 1904.35(b)(2)(iii), making the need for hand-delivery or mailing unnecessary.

Under the former rule, multi-establishment employers who closed an establishment during the year were not obligated to post an Annual Summary for that establishment. OSHA believes that this requirement is also unnecessary because it is obvious in such cases that there is no physical location at which to post the Summary. Closing an establishment does not, however, relieve an employer of the obligation to prepare and certify the Summary for whatever portion of the calendar year the establishment was operating, retain the Summary, and make the Summary accessible to employees and government officials.

Other comments. Some commenters availed themselves of the opportunity to comment on portions of the recordkeeping rule that OSHA did not propose to change. Some of these comments addressed the issue of whether to post a year-end Summary at all. Posting the Summary was almost unanimously supported, but a few commenters opposed posting on the grounds that posting had "[a] de minimus effect on employee safety and accident prevention" (Ex. 15: 46), was not an accurate measure of current safety and health conditions (see, *e.g.*, Exs. 15: 95, 126), or was unnecessary and burdensome for their industry (*e.g.* the maritime industry (Ex. 15: 95), construction industry (Ex. 15: 126), and retail store industry (Ex. 15: 367)). Although opposed to the posting of a year-end summary, one company urged OSHA to require that year-end summaries be submitted to OSHA (Ex. 15: 63).

Alternatives to posting were suggested by some commenters. One advocated annual informational meetings with employees instead (Ex. 15: 126), while others supported mailing the summary to each employee and providing the summary to new employees at orientation (Ex. 15: 154) or by e-mail (Ex. 15: 156). Three employers recommended excluding small establishments (fewer than 20, 50 or 100 employees) from posting if all column totals on the Log were zero (see, *e.g.*, Exs. 15: 304, 358, 375).

OSHA believes, based on the record evidence and its own extensive recordkeeping experience, that posting the Summary is important to safety and health for all the reasons described above. Some of the suggested alternatives may be useful, and OSHA encourages employers to use any practices that they believe will enhance their own and employee awareness of safety and health issues, provided that they also comply fully with the final rule's posting requirements.

Another issue raised by commenters was whether multi-establishment employers should be required to post their summaries in each establishment, as required by the former rule. Employers generally supported posting at each establishment, although one commenter opposed posting at each establishment in multi-establishment companies as overly burdensome and without benefit (Ex. 15: 356). One construction employer argued that construction companies should be allowed to post their summaries at a centralized location and only be required to do so at the establishment if it was a major construction site in operation for at least one year (Ex. 15: 116).

OSHA believes that permitting centralized posting only would substantially interfere with ready employee access to the Log, especially for employers operating many different sites. The record does not suggest that retaining the requirement for posting summaries at each establishment will be burdensome to employers and the final rule accordingly requires that multi-establishment employers post a Summary in each establishment relating that establishment's injury and illness experience for the preceding year.

Section 1904.33 Retention and Updating

Section 1904.33 of the final rule deals with the retention and updating of the OSHA Part 1904 records after they have been created and summarized. The final rule requires the employer to save the OSHA 300 Log, the Annual Summary, and the OSHA 301 Incident Report forms for five years following the end of the calendar year covered by the records. The final rule also requires the employer to update the entries on the OSHA 300 Log to include newly discovered cases and show changes that have occurred to previously recorded cases. The provisions in section 1904.33 state that the employer is not required to update the 300A Annual Summary or the 301 Incident Reports, although the employer is permitted to update these forms if he or she wishes to do so.

As this section makes clear, the final rule requires employers to retain their OSHA 300 and 301 records for five years following the end of the year to which the records apply. Additionally, employers must update their OSHA 300 Logs under two circumstances. First, if the employer discovers a recordable injury or illness that has not previously been recorded, the case must be entered on the forms. Second, if a previously recorded injury or illness turns out, based on later information, not to have been recorded properly, the employer must modify the previous entry. For example, if the description or outcome of a case changes (a case requiring medical treatment becomes worse and the employee must take days off work to recuperate), the employer must remove or line out the original entry and enter the new information. The employer also has a duty to enter the date of an employee's return to work or the date of an injured worker's death on the Form 301; OSHA considers the entering of this information an integral part of the recordkeeping for such cases. The Annual Summary and the Form 301 need not be updated, unless the employer wishes to do so. The requirements in this section 1904.33 do not affect or supersede any longer retention periods specified in other OSHA standards and regulations, *e.g.*, in OSHA health standards such as Cadmium, Benzene, or Lead (29 CFR 1910.1027, 1910.1028, and 1910.1025, respectively).

The proposed rule (61 FR 4030, at 4061) would have reduced the retention and updating periods for these records to three years. The language of the proposal was as follows:

> (a) Retention. OSHA Forms 300 and 301 or equivalents, year-end summaries, and injury and illness records for "subcontractor employees" as required under Sec. 1904.17 of this Part shall be retained for 3 years following the end of the year to which they relate.
>
> (b) Updating. During the retention period, employers must revise the OSHA Form 300 or equivalent to include newly discovered recordable injuries or illnesses. Employers must revise the OSHA Form 300 to reflect changes which occur in previously recorded injuries and illnesses. If the description or outcome of a case changes, remove the original entry and enter the new information to reflect the more severe consequence. Employers must revise the year-end summary at least quarterly if such changes have occurred.
>
> **Note to Sec. 1904.9:** Employers are not required to update OSHA Form 301 to reflect changes in previously recorded cases.

A number of commenters supported the proposed reduction in the retention period from five years to three years on the ground that it would reduce administrative burdens and costs without having any demonstrable effect on safety and health (see, *e.g.*, Exs. 22, 33, 37, 15: 9, 39, 61, 69, 82, 89, 95, 107, 121, 133, 136, 137, 141, 154, 173, 179, 181, 184, 201, 204, 213, 224, 225, 239, 242, 263, 266, 269, 270, 272, 278, 283, 288, 304, 307, 321, 322, 332, 334, 341, 347, 348, 368, 375, 377, 384, 387, 390, 392, 395, 396, 397, 409, 413, 424, 425, 427, 443). According to the American Iron and Steel Institute (AISI), whose views were typical of those of this group of commenters, a three-year retention period:

> [s]hould reduce employers' administrative costs without sacrificing any accuracy in the records of serious illnesses and injuries. Additional cost savings could be accomplished by limiting the time period during which an employer must update its injury and illness records to one year. Such a change would allow employers to close the books sooner on the health and safety data for a particular year, without resulting in any loss of accuracy. In AISI's experience, it is extremely rare that any new information on an illness or injury surfaces more than a few months after an injury is recorded, while the administrative cost of having to update a log and summary is significant for the rare cases that yield information after one year (Ex. 15: 395).

Several commenters, however, opposed the three-year retention period and favored the former rule's five-year retention period (see, *e.g.*, Exs. 20, 24, 15: 153, 350, 359, 379, 407, 415, 429). For example, the American Industrial Hygiene Association (AIHA) opposed the shorter retention period, stating:

> [A]IHA opposes OSHA's proposed change of OSHA recordkeeping record retention from 5 to 3 years. There is little work in record retention, and much information lost if they are discarded. We recommend maintaining the 5 year retention for OSHA Logs and supporting 301 forms (Ex. 15: 153.)

According to NIOSH, which favored the longer retention period, retaining records for five years:

> [a]llows the aggregation of data over time that is important for evaluating distributions of illnesses and injuries in small establishments with few employees in each department/job title. Also, the longer retention period is important for the observation of trends over time in the recognition of new problems and the evaluation of the effectiveness of intervention in large companies. In addition, the longer retention period makes possible the assessment of trends over time or to determine if a current cluster of cases is unusual for that industry. Reducing the retention period would thus have a detrimental effect on these types of analysis, which are frequently used by NIOSH in field studies (Ex. 15: 407).

The American Industrial Hygiene Association recommended a longer retention period (up to 30 years) for the OSHA 301 form to accommodate occupational diseases with long latency periods (Ex. 15: 153).

In this final rule, OSHA has decided to retain the five-year retention requirement for OSHA injury and illness records because the longer time period will enable employers, employees, and researchers to obtain sufficient data to discover patterns and trends of illnesses and injuries and, in many cases, to demonstrate the statistical significance of such data.

In addition, OSHA has concluded that the five-year retention period will add little additional cost or administrative burden, since relatively few cases will surface more than three years after the injury and illness occurred, and the vast majority of cases are resolved in a short time and do not require updating. In addition, OSHA believes that other provisions of the final rule (*e.g.*, computerization of records, centralized recordkeeping, and the capping of day counts) will significantly reduce the recordkeeping costs and administrative burden associated with the tracking of long-term cases.

The comments on the proposed rule's updating requirements for individual entries on the OSHA Form 300 reflected a considerable amount of confusion about the proposed rule's requirements for updating. Because the proposed rule did not state how frequently the form was to be updated, some employers interpreted the proposed rule as permitting quarterly updates (proposed by OSHA for year-end summaries only) during the retention period (see, *e.g.*, Exs. 15: 9, 61, 89, 170, 181, 288, 389). Some participants argued for even less frequent updating (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 317, 348). Several employers recognized that the Log is an ongoing document and that information must be updated on a regular basis, preferably at the same frequency as required for initial recording (see, *e.g.* Exs. 15: 65, 201, 313, 346, 352, 353, 430). The final rule requires Log updates to be made on a continuing basis, *i.e.*, as new information is discovered. For example, if a new case is discovered during the retention period, it must be recorded within 7 calendar days of discovery, the same interval required for the recording of any new case. If new information about an existing case is discovered, it should be entered within 7 days of receiving the new information. OSHA has also decided to require updating over the entire five-year retention period. OSHA believes that maintaining consistency in the length of the retention and updating periods will simplify the recordkeeping process without imposing additional burdens on employers, because most updating of the records occurs during the first year following an injury or illness.

The comments OSHA received on the proposed quarterly updating of year-end summaries were mixed. Some thought that such updating would provide timely and accurate information to employees at little cost (see, *e.g.* Exs. 15: 9, 89, 170, 260, 262, 265, 401), while others saw the requirement as burdensome and costly and without commensurate value (see, *e.g.* Exs. 15: 78, 225, 289, 337, 406, 412). Typical of those commenters who viewed such a requirement as burdensome was the American Automobile Manufacturing Association (AAMA), which stated "[u]pdating prior year totals on the annual summary(s) once posted, is of little value. The increase in total numbers is generally so modest as to not affect the overall magnitude of problems within an establishment" (Ex. 15: 409).

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Some commenters recommended that the summaries be updated less frequently, such as semi-annually (see, *e.g.*, Exs. 37, 15: 163). The National Safety Council (Ex. 15: 359) recommended quarterly updates the first year and annual updates thereafter. Others interpreted the proposed rule as requiring quarterly updates and re-certification and re-posting of the year-end summaries after the posting period had ended; these commenters opposed such a requirement as being overly burdensome (see, *e.g.*, Exs. 15: 181, 199, 201, 225, 272, 288, 303, 308, 351). Lucent Technologies (Ex. 15: 272), one of these commenters, urged OSHA to add the following qualifier to any requirement for the updating of the annual summary: "[t]he quarterly update of the summary is for tracking purposes only and will not require re-certification or posting."

After reviewing these comments and the evidence in the record, OSHA has decided not to require the updating of annual summaries. Eliminating this requirement from the final rule will minimize employers' administrative burdens and costs, avoid duplication, and avoid the complications associated with the certification of updated summaries, the replacement of posted summaries, and the transmission of summaries to remote sites. The Agency concludes that updating the OSHA Form 300 or its equivalent for a period of five years will provide a sufficient amount of accurate information for recordkeeping purposes. OSHA is persuaded that updating the year-end summary would provide little benefit as long as the information from which the summaries are derived (the OSHA Form 300) is updated for a full five-year period.

Very few comments were received on OSHA's proposed position not to require the updating of the 301 form. All of the comments received supported OSHA's proposed approach (see, *e.g.*, Exs. 15: 260, 262, 265, 401). OSHA does not believe that updating the OSHA Form 301 will enhance the information available to employers, employees, and others sufficiently to warrant including such a requirement in the final rule. However, the final rule makes it clear that employers may, if they choose, update either the Summary or the Form 301.

Section 1904.34 Change in Business Ownership

Section 1904.34 of the final rule addresses the situation that arises when a particular employer ceases operations at an establishment during a calendar year, and the establishment is then operated by a new employer for the remainder of the year. The phrase "change of ownership," for the purposes of this section, is relevant only to the transfer of the responsibility to make and retain OSHA-required injury and illness records. In other words, if one employer, as defined by the OSH Act, transfers ownership of an establishment to a different employer, the new entity becomes responsible for retaining the previous employer's past OSHA-required records and for creating all new records required by this rule.

The final rule requires the previous owner to transfer these records to the new owner, and it limits the recording and recordkeeping responsibilities of the previous employer only to the period of the prior owner. Specifically, section 1904.34 provides that if the business changes ownership, each employer is responsible for recording and reporting work-related injuries and illnesses only for that period of the year during which each employer owned the establishment. The selling employer is required to transfer his or her Part 1904 records to the new owner, and the new owner must save all records of the establishment kept by the prior owner. However, the new owner is not required to update or correct the records of the prior owner, even if new information about old cases becomes available.

The former OSHA injury and illness recording and reporting rule also required both the selling and buying employers to record and report data for the portion of the year for which they owned the establishment. Although the former rule required the purchasing employer to preserve the records of the prior employer, it did not require the prior employer to transfer the OSHA injury and illness records to the new employer. Section 1904.11 of the former rule stated:

> Where an establishment has changed ownership, the employer shall be responsible for maintaining records and filing reports only for that period of the year during which he owned such establishment. However, in the case of any change in ownership, the employer shall preserve those records, if any, of the prior ownership which are required to be kept under this part. These records shall be retained at each establishment to which they relate, for the period, or remainder thereof, required under § 1904.6.

The section of OSHA's proposed rule addressing "change of ownership" mirrored the former rule with only slight language changes, as follows:

> Where an establishment has changed ownership, each employer shall be responsible for recording and reporting occupational injuries and illnesses only for that period of the year during which he or she owned such establishment, but the new owner shall retain all records of the establishment kept by the prior owner, as required by § 1904.9(a) of this Part.

Some commenters felt that this proposed section suggested that new owners could be held responsible for obtaining OSHA injury and illness records, but that the former owners were not required to provide them (see, *e.g.*, Exs. 15: 119 298, 323, 356, 397, 323). This interpretation, which would clearly place the new owner in an untenable position, was not accurate. Consequently, to avoid confusion in the future, the final rule requires former owners to transfer their Part 1904 records to the new owner. This requirement ensures that the continuity of the records is maintained when a business changes hands.

Sections 1904.35 Employee Involvement, and 1904.36, Prohibition Against Discrimination

One of the goals of the final rule is to enhance employee involvement in the recordkeeping process. OSHA believes that employee involvement is essential to the success of all aspects of an employer's safety and health program. This is especially true in the area of recordkeeping, because free and frank reporting by employees is the cornerstone of the system. If employees fail to report their injuries and illnesses, the "picture" of the workplace that the employer's OSHA forms 300 and 301 reveal will be inaccurate and misleading. This means, in turn, that employers and employees will not have the information they need to improve safety and health in the workplace.

Section 1904.35 of the final rule therefore establishes an affirmative requirement for employers to involve their employees and employee representatives in the recordkeeping process. The employer must inform each employee of how to report an injury or illness, and must provide limited access to the injury and illness records for employees and their representatives. Section 1904.36 of the final rule makes clear that § 11(c) of the Act prohibits employers from discriminating against employees for reporting work-related injuries and illnesses. Section 1904.36 does not create a new obligation on employers. Instead, it clarifies that the OSH Act's anti-discrimination protection applies to employees who seek to participate in the recordkeeping process.[3]

[3] The relevant language of Section 11(c) that "No person shall discharge or in any manner discriminate against any employee * * * because of the exercise by such employee on behalf of himself or others of any rights afforded by this Act."

Under the employee involvement provisions of the final rule, employers are required to let employees know how and when to report work-related injuries and illnesses. This means that the employer must establish a procedure for the reporting of work-related injuries and illnesses and train its employees to use that procedure. The rule does not specify how the employer must accomplish these objectives. The size of the workforce, employees' language proficiency and literacy levels, the workplace culture, and other factors will determine what will be effective for any particular workplace.

Employee involvement also requires that employees and their representatives have access to the establishment's injury and illness records. Employee involvement is further enhanced by other parts of the final rule, such as the extended posting period provided in section 1904.32 and the access statements on the new 300 and 301 forms.

These requirements are a direct outgrowth of the issues framed by OSHA in the 1996 proposal. In that **Federal Register** notice, OSHA proposed an employee access provision, § 1904.11(b), and discussed the issue at length in the preamble (61 FR 4038, 4047, and 4048). OSHA did not propose a specific provision for employee involvement in the reporting process, but raised the issue for discussion in the preamble (61 FR 4047–48) (*see* Issue 7. Improving employee involvement). The proposed rule did contain a reference to section 11(c) of the OSH Act and its applicability to retaliatory discrimination by employers against employees who report injuries or illnesses (61 FR 4062).

Specifically, OSHA noted in the NPRM that the Keystone Dialogue report (Ex. 5) advocated greater employee awareness and involvement in the recordkeeping process to improve the process and enhance safety and health efforts in general. There was agreement among members of the Dialogue group that, for a number of reasons, among them lack of knowledge, fear of reprisal, and apathy, "employees often do not seek access to injury/illness logs (to a sufficient extent) * * * [and] that overall workplace safety and health would benefit if the information in the logs were more widely known. * * *" In this regard, the group made several recommendations to modify the recordkeeping process and to involve employees in accident prevention efforts:

- OSHA should require employers to notify employees individually of log entries for each recordable case and their right to access the records, either by providing them with a copy of the 101 form or the log, by having the employee initial or otherwise acknowledge the log entry, or by other means negotiated with a designated employee representative;
- Employers should inform employees of an affirmative duty to bring cases to the employer's attention;
- OSHA should add statements to the OSHA recordkeeping forms 101 and 200 that inform employees of their right to access the 200 form;
- OSHA should extend the posting period for the 200 form from one month to 12 months;
- Employers should share data with employees and members of safety committees;
- Employers should include more employees in accident investigations and analyses; and
- Detailed survey data systems should be developed so those employees could assist employers in evaluating accident and exposure risks associated with their work processes.

OSHA also noted that the General Accounting Office (GAO) report (Ex. 3) identified employee lack of knowledge and understanding of the recordkeeping system as one cause of the underreporting of occupational injuries and illnesses. Based on these and other reports and OSHA's compliance experience, OSHA requested comment in the proposal on (1) whether employers should notify employees that their injuries or illnesses have been entered into the records, (2) if so, how employers could meet such a requirement and the degree of flexibility OSHA should give employers, (3) any other ideas for improving employee involvement in the recordkeeping system, and (4) the costs and benefits of alternate proposals.

These issues drew considerable comment during the rulemaking. With few exceptions (see, *e.g.*, Exs. 15: 13, 78, 201, 389, 406), commenters generally supported increasing employee awareness and involvement in the recordkeeping process in some form (see, *e.g.*, Exs. 15: 26, 85, 87, 154, 170, 199, 234, 310, 341, 357, 378, 414, 415, 418, 426). For example, some commenters supported increasing employee awareness by requiring year-round posting of the OSHA 300 Log (see, *e.g.*, Exs. 15: 154, 170, 199, 415, 426), adding an employee accessibility statement to the OSHA 300 Log (Ex. 15: 418) , and requiring employee training on recordkeeping issues and procedures (Ex. 15: 418). A number of commenters also discussed their own efforts to involve employees in various recordkeeping activities, such as in filling out accident forms (see, *e.g.*, Exs. 15: 23, 87, 225), assisting in accident investigations (see, *e.g.*, Exs. 15: 170, 357, 425), and reviewing accident data (see, *e.g.*, Exs. 15: 260, 262, 265, 310, 357, 401, 414).

However, most employers, including many who supported various methods to increase employee awareness and involvement in the process, opposed a provision requiring employers to notify individual employees that their injuries have been recorded on the Log because, in their views, such a requirement would not be likely to achieve OSHA's stated objective and would be too burdensome and costly for employers (see, *e.g.*, Exs. 15: 9, 49, 60, 76, 82, 85, 95, 109, 123, 145, 154, 170, 172, 199, 204, 218, 225, 262, 281, 283, 288, 324, 341, 357, 374, 393, 406, 426). Representative of these comments were those of AT&T and Lucent Technologies, which pointed out that workers are currently required to be notified about the status of job-related incidents by workers' compensation regulations and company benefit programs and that separate notification of an OSHA 300 Log entry would therefore be confusing and redundant (Exs. 15: 272 and 15: 303).

On the other hand, individual notification of employees was supported by commenters from the unions and professional organizations, as well as by some employers (see, *e.g.*, Exs. 15: 156, 181, 233, 247, 310, 350, 369, 414). For example, the American Association of Occupational Health Nurses (Ex. 15: 181) supported notification "[a]s a means of improving employee cooperation and helping employees recognize their role in working safely and promoting a safe workplace." Those supporting notification suggested that reasonable means of providing such notification would be direct mail, including a notice in a pay envelope, or e-mailing a notice and/or the OSHA 301 form to affected employees (see, *e.g.*, Exs. 15: 310, 350).

The National Safety Council's comment (Ex. 15: 359) typifies the views of these commenters:

> [w]e believe that employee involvement in occupational safety and health issues is highly desirable and that notification is one aspect of employee involvement. * * * If OSHA were to require notification, then OSHA should require each employer to create and comply with its own written notification policy—perhaps subject to some limitation such as notification within 7–14 days of entry on the Log. The OSHA compliance officer can verify compliance with the company's policy on a test basis during an inspection.

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Other commenters (see, *e.g.*, Exs. 15: 234, 283, 348, 426) agreed that the final rule should not specify how employee notification should be accomplished. For example, E. I. du Pont de Nemours Corporation (Ex. 15: 348) stated:

[l]egislating how people communicate is confining. Many companies do a fine job of notifying employees about injuries, investigation findings, hazard reduction, and ways to contribute to a safer workplace. Mandating a particular method would be counterproductive to those organizations already doing a good job. * * * We suggest that unless full implications of involving employees in the process are clearly understood (and are not prohibited by any other federal agency) no guideline should be written—but perhaps suggestions of ways successful companies have worked with their employees to improve safety performance could be provided and would be useful.

One participant suggested a policy of having the injured employee view the Log to verify its accuracy, noting that "[t]his procedure * * * does not appear to place additional costs or undue burden on the employer" (Ex. 15: 163). Another recommended a "face-to-face advisory" after an investigation of the accident had been completed (Ex. 15: 414). The American Textile Manufacturers Institute (Ex. 15: 156) suggested more proactive approaches:

[o]ther methods for improving employee involvement in the injury and illness recordkeeping system include giving employees accident causation and prevention information from the records. In addition, information about departments, accident types, injury types, hazards and contributing factors, etc., could and should be shared for the benefit of employer and employees.

The AFL–CIO, United Auto Workers (UAW), Services Employees International Union (SEIU), and MassCOSH addressed the reporting disincentive that occurs when employees are threatened, disciplined, or discriminated against for reporting injuries or illnesses (Exs. 58X, 15: 79, 418, 438). MassCOSH recounted how health care workers were disciplined for reporting multiple needle stick injuries, and the United Auto Workers noted that some injury victims were subject to drug testing (Ex. 15: 438). The unions recommended that discriminatory treatment of employees who report injuries should be presumed to be a violation of section 11(c), the anti-discrimination provision of the OSH Act (see, *e.g.*, Exs. 48, 58X, 15: 379, 418, 438). Specifically, the UAW (Ex. 15: 438) recommended that the following regulatory text be added to the final rule:

[r]eporting * * * an injury or illness to management is an activity in support of the purposes of the Act. Since an injury report may trigger an employer's responsibility to abate a hazard, such report is an exercise of an employee's right under the Act and therefore protected activity under Section 11(c) of the Act. Adverse action by an employer following such a report shall be presumed to be discrimination. Examples of adverse action are verbal warnings, disparate treatment, additional training provided only to injury victims, disciplinary action of any kind, or drug testing. Suffering an injury or illness by itself shall not be considered probable cause to trigger a drug test. An employer may rebut the presumption of discrimination by showing substantial evidence that injured employees receive consistent treatment to those who have not suffered injuries. Granting of prizes or compensation to employees or groups of employees who do not report injuries is discrimination against those employees who do report injuries. Therefore, such programs are violations of Section 11(c) of the Act.

The AFL–CIO (Ex. 15: 4218) supported this language and, along with the Union of Needletrades, Industrial and Textile Employees (UNITE) (Ex. 15: 380), also recommended that the rule include a prohibition against retaliation or discrimination that would be enforced in the same manner as other violations of the recordkeeping rule (Ex. 15: 418). The AFL–CIO (Ex. 15: 418) also requested that OSHA include in the final rule:

[a]n affirmative obligation on employers to inform employees of their right to report injuries or illnesses without fear of reprisal and to gain access to the Log 300 and to the Form 301 with certain limitations. At a minimum, the Log 300 should contain a statement, which informs employees of their rights and protections afforded under the rule. We recommend the following language be added to the log: 'Employees have a right to report work-related injuries and illnesses to their employer and to gain access to the Log 300 and Form 301.'

OSHA has concluded that the rulemaking record overwhelmingly demonstrates that employee awareness and involvement is a crucial part of an effective recordkeeping program, as well as an overall safety and health program. There was little disagreement over this point among participants in the rulemaking, whether they represented management, labor, government or professional associations (see, *e.g.*, Exs. 15: 26, 85, 87, 154, 170, 199, 234, 310, 341, 357, 378, 414, 415, 426). There was also no disagreement with the unions' contention that employees should not be retaliated against for reporting work-related injuries and illnesses and for exercising their right of access to the Log and Incident Report forms. The prominent employee involvement issues in the rulemaking were thus not whether employee involvement should be strengthened but to what extent and in what ways employees should be brought into the process.

In response to this support in the record, OSHA has strengthened the final rule to promote better injury and illness information by increasing employees' knowledge of their employers' recordkeeping program and by removing barriers that may exist to the reporting of work-related injuries and illnesses. To achieve this goal, the final rule establishes a simple two-part process for each employer who is required to keep records, as follows:

—Set up a way for employees to report work-related injuries and illnesses promptly; and
—Inform each employee of how to report work-related injuries and illnesses.

OSHA agrees with commenters that employees must know and understand that they have an affirmative obligation to report injuries and illnesses. Additionally, OSHA believes that many employers already take these actions as a common sense approach to discovering workplace problems, and that the rule will thus, to a large extent, be codifying current industry practice, rather than breaking new ground.

OSHA is convinced that a performance requirement, rather than specific requirements, will achieve this objective effectively, while still giving employers the flexibility they need to tailor their programs to the needs of their workplaces (see, *e.g.*, Exs. 15: 234, 283, 348, 359, 426). The Agency finds that employee awareness and participation in the recordkeeping process is best achieved by such provisions of the final rule as the requirement to extend the posting period for the OSHA 300 summary, the addition of accessibility statements on the OSHA Summary, and requirements designed to facilitate employee access to records.

Many of the specific suggestions made by commenters have not been adopted in the final rule in favor of the more performance-based approach to employee involvement supported by so many commenters. For example, OSHA has decided not to require employers to devise a method of notifying individual employees when a case involving them has been entered on the OSHA 300 Log. An employee notification requirement would be very burdensome and costly, and the potential advantages of an employee notification system have not been shown in the record for this rule. Thus, OSHA is not sure that employee notification would improve the quality of the records enough to justify the added burdens. Additionally, employees and their representatives have a right to access the records under the final rule, if they wish to review the employer's recording of a given occupational injury or illness case. OSHA believes that the improved recordkeeping that will result from the changes being made to the final rule, the enhanced employee involvement reflected in many of the rule's provisions, and the prohibition against discrimination will all work in concert to achieve the goal envisioned by those commenters who urged OSHA to require employee notification: more and better reporting and recording.

Several of the other suggestions made by participants—such as including employees in accident investigations and involving employees in program evaluation—are beyond the scope of the Part 1904 regulation, which simply requires employers to record and report occupational deaths, injuries and illnesses. OSHA encourages employers and employees to work together to determine how best to communicate the information that workers need in the context of each specific workplace. Moreover, OSHA encourages employers to involve their workers in activities such as accident investigations and the analysis of accident, injury and illness data, as suggested by some commenters, but believes that requiring these activities is beyond the scope of this rule.

OSHA has also included in the final rule, in section 1904.36, a statement that section 11(c) of the OSH Act protects workers from employer retaliation for filing a complaint, reporting an injury or illness, seeking access to records to which they are entitled, or otherwise exercising their rights under the rule. This section of the rule does not impose any new obligations on employers or create new rights for employees that did not previously exist. In view of the evidence that retaliation against employees for reporting injuries is not uncommon and may be "growing" (see, *e.g.*, Ex. 58X, p. 214), this section is intended to serve the informational needs of employees who might not otherwise be aware of their rights and to remind employers of their obligation not to discriminate. OSHA concurs with the International Chemical Workers Union, which, while discussing the issue of whether personal identifiers should be used on the Log, stated (Ex. 15: 415), "We have never heard of [personal identifiers] being an issue for our members, except when management used the reports as an excuse to discipline 'unsafe' workers. The addition of language notifying workers of their rights to 11(c) protection * * * should help alleviate any such concerns."

Employee access to OSHA injury and illness records

The Part 1904 final rule continues OSHA's long-standing policy of allowing employees and their representatives access to the occupational injury and illness information kept by their employers, with some limitations. However, the final rule includes several changes to improve employees' access to the information, while at the same time implementing several measures to protect the privacy interests of injured and ill employees. Section 1904.35 requires an employer covered by the Part 1904 regulation to provide limited access to the OSHA recordkeeping forms to current and former employees, as well as to two types of employee representatives. The first is a personal representative of an employee or former employee, who is a person that the employee or former employee designates, in writing, as his or her personal representative, or is the legal representative of a deceased or legally incapacitated employee or former employee. The second is an authorized employee representative, which is defined as an authorized collective bargaining agent of one or more employees working at the employer's establishment.

Section 1904.35 accords employees and their representatives three separate access rights. First, it gives any employee, former employee, personal representative, or authorized employee representative the right to a copy of the current OSHA 300 Log, and to any stored OSHA 300 Log(s), for any establishment in which the employee or former employee has worked. The employer must provide one free copy of the OSHA 300 Log(s) by the end of the next business day. The employee, former employee, personal representative or authorized employee representative is not entitled to see, or to obtain a copy of, the confidential list of names and case numbers for privacy cases. Second, any employee, former employee, or personal representative is entitled to one free copy of the OSHA 301 Incident Report describing an injury or illness to that employee by the end of the next business day. Finally, an authorized employee representative is entitled to copies of the right-hand portion of all OSHA 301 forms for the establishment(s) where the agent represents one or more employees under a collective bargaining agreement. The right-hand portion of the 301 form contains the heading "Tell us about the case," and elicits information about how the injury occurred, including the employee's actions just prior to the incident, the materials and tools involved, and how the incident occurred, but does not contain the employee's name. No information other than that on the right-hand portion of the form may be disclosed to an authorized employee representative. The employer must provide the authorized employee representative with one free copy of all the 301 forms for the establishment within 7 calendar days.

Employee privacy is protected in the final rule in paragraphs 1904.29(b)(7) to (10). Paragraph 1904.29(b)(7) requires the employer to enter the words "privacy case" on the OSHA 300 Log, in lieu of the employee's name, for recordable privacy concern cases involving the following types of injuries and illnesses: (i) an injury from a needle or sharp object contaminated by another person's blood or other potentially infectious material; (ii) an injury or illness to an intimate body part or to the reproductive system; (iii) an injury or illness resulting from a sexual assault; (iv) a mental illness; (v) an illness involving HIV, hepatitis; or tuberculosis, or (vi) any other illness, if the employee independently and voluntarily requests that his or her name not be entered on the log. Musculoskeletal disorders (MSDs) are not considered privacy concern cases, and thus employers are required to enter the names of employees experiencing these disorders on the log. The employer must keep a separate, confidential list of the case numbers and employee names for privacy cases.

The employer may take additional action in privacy concern cases if warranted. Paragraph 1904.29(b)(9) allows the employer to use discretion in describing the nature of the injury or illness in a privacy concern case, if the employer has a reasonable basis to believe that the injured or ill employee may be identified from the records even though the employee's name has been removed. Only the six types of injuries and illnesses listed in Paragraph 1904.29(b)(7) may be considered privacy concern cases, and thus the additional protection offered by paragraph 1904.29(b)(9) applies only to such cases.

Paragraph 1904.29(b)(10) protects employee privacy if the employer decides voluntarily to disclose the OSHA 300 and 301 forms to persons other than those who have a mandatory right of access under the final rule. The paragraph requires the employer to remove or hide employees' names or

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other personally identifying information before disclosing the forms to persons other than government representatives, employees, former employees or authorized representatives, as required by paragraphs 1904.40 and 1904.35, except in three cases. The employer may disclose the forms, complete with personally identifying information, (2) only: (i) to an auditor or consultant hired by the employer to evaluate the safety and health program; (ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or (iii) to a public health authority or law enforcement agency for uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required under section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

The former rule. The access provisions of the former recordkeeping regulation required employers to provide government representatives, as well as employees, former employees, and their representatives, with access to the OSHA Logs and year-end summaries, including the names of all injured and ill employees. The former regulation permitted only government representatives to have access to the supplemental incident reports (the former Form 101). *Id.* Employees, former employees and their representatives had no right to inspect and copy the incident reports, although employers were permitted to disclose these forms if doing so was included in the terms of a collective bargaining agreement. *Id.*

The proposed rule. The proposed rule would have required employers to provide government representatives, and employees, former employees, and their representatives, with access to the unredacted OSHA Logs and summaries (61 FR 4061). The proposal would have expanded the scope of the former rule's access provisions by requiring employers to make available the incident reports (former OSHA Form 101, renumbered Form 301 in the final rule) to employees, former employees, and their designated representatives. *Id.* At the same time, OSHA did not intend to provide access to the general public. The proposed standard stated: "OSHA asks for input on possible methodologies for providing easy access to workers while restricting access to the general public" (61 FR 4048).

The access provisions of the proposed rule attracted considerable comment. Many industry representatives argued that disclosure of information contained in the injury and illness records to employees, former employees and their representatives would violate an injured or ill employee's right, under the Constitution and several statutes, to privacy. On the other hand, a number of commenters emphasized the importance of the information contained in the records to employees and unions in their voluntary efforts to uncover and eliminate workplace safety and health hazards. The following paragraphs discuss privacy and access issues, and their relationship to the recordkeeping rule.

The Privacy Interest of the Injured or Ill Employee

Whether, and to what extent, the U.S. Constitution grants individuals a right of privacy in personal information has not been firmly established. In *Whalen* v. *Roe*, 429 U.S. 589 (1977), the Supreme Court considered whether a New York law creating a central computer record of the names and addresses of persons taking certain dangerous but lawful drugs violated the constitutional privacy interest of those taking the drugs. The Court rejected the claim, primarily because the state statute required that government employees with access keep the information confidential and there was no basis to assume that the requirement would be violated. 429 U.S. at 601, 605–606. Although the decision does not say whether the Constitution affords protection against disclosure of personal information, some language suggests that it does, at least in some circumstances. The Court stated:

> The cases sometimes characterized as protecting "privacy" have in fact involved at least two different kinds of interests. One is the individual interest in avoiding disclosure of personal matters, and another is the interest in independence in making certain kinds of decisions. 429 U.S. at 598, 599.
>
> Recognizing that in some circumstances th[e] duty [to avoid unwarranted disclosure of personal matters] arguably has its roots in the Constitution, nevertheless New York's statutory scheme, and its implementing administrative procedures, evidence a proper concern with, and protection of, the individual's interest in privacy. 429 U.S. at 605

A subsequent case, *Nixon* v. *Administrator of General Services*, 433 U.S. 425 (1977), lends further support to the existence of a constitutional right of privacy in personal information. At issue in *Nixon* was a statute that required the former president to turn over both public and private papers to an archivist who would review them and return any personal materials. The Court appeared to acknowledge that Nixon had a Constitutionally protected privacy right in personal information. 433 U.S. at 457. It upheld the statute because of the strong public interest in preserving the documents and because the statute's procedural safeguards made it unlikely that truly private materials would be disclosed to the public.

A number of federal circuit courts of appeals, building on *Whalen* and *Nixon*, have held that individuals possess a qualified constitutional right to confidentiality of personal information, including medical information. See, *e.g.*, *Paul* v. *Verniero*, 170 F.3d 396, 402 (3d Cir. 1999); *Norman-Bloodsay* v. *Lawrence Berkeley Laboratory*, 135 F.3d 1260, 1269 (9th Cir. 1998); *F.E.R.* v. *Valdez*, 58 F.3d 1530, 1535 (10th Cir. 1995); *John Doe* v. *City of New York*, 15 F.3d 264, 267 (2d Cir. 1994); *Fadjo* v. *Coon*, 633 F.2d 1172, 1175 (5th Cir. 1981). See also *Anderson* v. *Romero*, 72 F.3d 518, 522 (7th Cir. 1995) (noting holdings of federal circuits, including seventh circuit, recognizing qualified constitutional right to confidentiality in medical records, but finding it "not clearly established" that prison inmate enjoyed such right in 1992).

Of the remaining circuits that have addressed the issue, only the Sixth has squarely rejected a general constitutional right to nondisclosure of personal information. *E.g.*, *J.P.* v. *DeSanti*, 653 F.2d 1080, 1089 (6th Cir. 1981). Two circuits have expressed skepticism as to the existence of such a right. See *American Federation of Government Employees, AFL–CIO* v. *Department of Housing and Urban Development*, 118 F.3d 786, 788 (D.C. Cir. 1987) (expressing "grave doubt" whether the Constitution protects against disclosure of personal information); *Borucki* v. *Ryan*, 827 F.2d 836, 845–846 (1st Cir. 1987) (noting lack of concrete guidance by Supreme Court and disagreement among circuits on constitutional right of confidentiality). See also *Ferguson* v. *City of Charleston, S.C.*, 186 F.3d 469, 483 (4th Cir.1999) (declining to decide whether individuals possess a general constitutional right to privacy, noting circuit conflict).

Where the right to privacy is recognized, protection extends to information that the individual would reasonably expect to remain confidential. *Fraternal Order of Police Lodge No. 5* v. *City of Philadelphia*, 812 F.2d 105, 112 (3d Cir. 1987); *Mangels* v. *Pena*, 789 F.2d 836, 839 (10th Cir. 1986). "The more intimate or personal the information, the more justified is the expectation that it will not be subject to public scrutiny." *Fraternal Order of Police*, 812 F.2d at 105. Thus, information about the state of a person's health, including his or her medical

treatment, prescription drug use, HIV status and related matters, is entitled to privacy protection. See *Paul* v. *Verniero*, 170 F.3d at 401–402 (collecting cases). See also *Doe* v. *City of New York*, 15 F.3d at 267 ("[T]here are few matters that are quite so personal as the status of one's health, and few matters the dissemination of which one would prefer to maintain greater control over.")

The right to privacy is not limited only to medical records. Other types of records containing medical information are also covered. See, *e.g.*, *Whalen*, (computer tapes containing prescription drug information); *Fraternal Order of Police*, 812 F.2d at 112 (police questionnaire eliciting information about employee's physical and mental condition); *Doe* v. *SEPTA*, 72 F.3d 1133 (3d Cir. 1995) (utilization report listing prescription drugs dispensed to employees under employer health plan). Moreover, personal financial data and other types of private information may be subject to privacy protection in certain cases. See *Nixon* v. *Administrator of General Services*, 433 U.S. 425, 455 (1977) (personal matters, including personal finances, reflected in presidential papers); *Paul* v. *Verniero*, 170 F.3d at 404 (home address of sex offender subject to disclosure under "Megan's Law"); *Fadjo* v. *Coon*, 633 F.2d at 1175 (private details contained in subpoenaed testimony).

A finding that information is entitled to privacy protection is only the first step in determining whether a disclosure requirement is valid. A balancing test must be applied, which weighs the individual's interest in confidentiality against the public interest in disclosure. *Fraternal Order of Police*, 812 F.2d at 113. In evaluating the government's interest, at least two factors must be considered; the purpose to be served by disclosure of personal information to individuals authorized by law to receive it, and the adverse effect of unauthorized public disclosure of such information. *Id.* at 117, 118. *Accord*, *Barry* v. *City of New York*, 712 F.2d 1554, 1561–5162 (2d Cir. 1983). Thus, the fact that disclosure of highly personal information to parties who have need for it serves an important public interest is not sufficient justification for a disclosure requirement in the absence of adequate safeguards against broader public access. *Fraternal Order of Police*, 812 F.2d at 118 ("It would be incompatible with the concept of privacy to permit protected information and material to be publicly disclosed. The fact that protected information must be disclosed to a party who has need for it * * * does not strip the information of its protection against disclosure to those who have no similar need.")

Balancing the Interests of Privacy and Access

OSHA historically has recognized that the Log and Incident Report (Forms 300 and 301, respectively) may contain information of a sufficiently intimate and personal nature that a reasonable person would wish it to remain confidential. In its 1978 records access regulation (29 CFR 1910.1020), OSHA addressed the privacy implications of its decision to grant employee access to the Log. The agency noted that while Log entries are intended to be brief, they may contain medical information, including diagnoses of specific illnesses, and that disclosure to other employees, former employees or their representatives raised a sensitive privacy issue. 43 FR 31327 (1978). However, OSHA concluded that disclosure of the Log to current and former employees and their representatives benefits these employees generally by increasing their awareness and understanding of the health and safety hazards to which they are, or have been, exposed. OSHA found that this knowledge "will help employees to protect themselves from future occurrences," and that "[i]n such cases, the right of privacy must be tempered by the obvious exigencies of informing employees about the effects of workplace hazards." *Id.* at 31327, 31328.

The proposed rule would have expanded the right of access of employees, former employees, and their designated representatives beyond the Log to include the Incident Report (Form 301) (61 FR 4061). OSHA discussed the potentially conflicting interests involved, and explained its preliminary balancing of these interests, as follows:

> OSHA's historical practice of allowing employee access to all of the information on the log permits employees and their designated representatives to be totally informed about the employer's recordkeeping practices, and the occupational injuries and illnesses recorded in the workplace. However, this total accessibility may infringe on an individual employee's privacy interest. At the same time, the need to access individual's Incident Records to adequately evaluate the safety and health environment of the establishment has been expressed.
>
> These two interests—the privacy interests of the individual employee versus the interest in access to health and safety information concerning one's own workplace—are potentially at odds with one another. For injury and illness recordkeeping purposes, OSHA has taken the position that an employee's interest in access to health and safety information on the OSHA forms concerning one's own workplace carries greater weight than an individual's right to privacy. More complete access to the detailed injury and illness records has the potential for increasing employee involvement in workplace safety and health programs and therefore has the potential for improving working conditions. Analysis of injury and illness data provides a wealth of information for injury and illness prevention programs. Analysis by workers, in addition to analyses by the employer, lead to the potential of developing methods to diminish workplace hazards through additional or different perspectives (61 FR 4048).

The proposal asked for comment on alternatives that would preserve broad access rights while protecting fundamental privacy interests, including requiring omission of personal identifying information for certain specific injury and illness cases recorded on the Log, and restricting non-government access to the Incident Reports to that portion of the Form 301 that does not contain personal information. *Ibid.*

OSHA continues to believe that granting employees a broad right of access to injury and illness records serves important public interests. There is persuasive evidence that access by employees and their representatives to the Log and the Incident Report serves as a useful check on the accuracy of the employer's recordkeeping and promotes greater employee involvement in prevention programs that contribute to safer, more healthful workplaces. For example, the Building and Construction Trades Department, AFL–CIO stated that:

> In the main, the name of the employee is critically important to understanding and verifying recordable cases. It is often necessary to speak with the employee to explore the conditions that lead to the injury or illness, and this is impossible without employee names. In addition, employees and unions play an important role in assuring the proper administration of the recordkeeping rule, and they cannot audit an employer's recordkeeping performance without having access to employee names, which are necessary to verify that all properly recordable cases are actually on the log, and to verify that recorded cases are properly classified. (Ex. 15: 394, p. 35)

Similarly, the American Federation of State, County and Municipal Employees, AFL–CIO stated that "[w]hen employees and their representatives have complete access to the detailed injury and illness records, employee involvement in workplace safety and health programs increases. Worker representatives use the data on the forms to assist in the identification of specific hazards, as well as other

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factors affecting workplace safety" (Ex.15: 362, p. 7).

The United Auto Workers (Ex. 15: 438) argued that the OSHA 301 incident reports are as valuable as the log is in aiding voluntary enforcement efforts. The UAW stated:

> The OSHA 101 (proposed 301) form is an available data source on circumstances of an injury or illness. The collected data contains information for prevention, and also indicates the effectiveness of management's health and safety program. The information on the OSHA [301] relevant to hazard identification and control should be made available to employee representatives on the same basis as they are made available to OSHA compliance officers. Personal data on treatment details, physician's name, personal information on employee can be recorded on the "other" side of the form and blanked out.

The Laborers' Health and Safety Fund (Ex. 15: 310) also emphasized the practical value of the information contained in the Form 301:

> We wholeheartedly support the specific language in the proposed rule allowing designated representatives access to the OSHA 300 and 301 forms. In a project we administered to determine the major causes of serious injuries and illnesses in road construction under a Federal Highway Administration grant, several employers would not allow access to even information from the injured person's 101 workers compensation equivalent form, because the form contained other information such as the employee's age and salary. The event information contained in the 301 form is critical in determining the hazards and possible preventive measures.

Other commenters also supported the proposal's approach of broadening employee access to records (see, *e.g.* Exs. 24; 36; 15: 350, 380, 418).

Recognition of the important purpose served by granting access to injury and illness records does not end the analysis. The public interest that is served when information contained in the records is used to promote safety and health must be balanced against the possible harm that would result from the misuse of private information. There are two ways in which harm could occur. First, the information could be used for unauthorized purposes, such as to harass or embarrass employees. Second, employees and their representatives with access to records could, deliberately or inadvertently, disclose private information to others who have no need for it.

Several commenters indicated concern about the unauthorized disclosure of private material contained in the injury and illness records. The joint comments filed by the National Broiler Council and the National Turkey Council express the view shared by many employers:

> There is universal support among employees and employers for the communication of information about workplace illnesses and injuries. It also seems apparent that there is universal opposition to the communication of personal information about individuals involved in those incidents. There are many circumstances in the workplace where employees have no desire for fellow employees to know the extent, description, or type of injury or illness they have incurred. The reasons for an employee's concern about his or her personal privacy may vary but almost always find their foundation in very strong and personal emotions. One example that clearly illustrates this point would be the employee who has experienced an exposure incident under the bloodborne pathogens standard. Most people would not want it to be known that they may have been exposed to HIV, let alone if they tested positive for HIV. * * * In addition to the concerns about how this information could be used by other individuals, employers also have very serious concerns about the misuse of this information by individuals or organizations for purposes in no way related to the issue of workplace health and safety (Ex. 15: 193, pp. 4–5).

A number of commenters argued that granting access to the Log and Incident Report to employees, former employees and their representatives will deter employees from reporting their injuries and illnesses, especially in cases involving exposure to bloodborne pathogens and injuries and illnesses involving reproductive organs (see, *e.g.*, Exs. 15–185, 15–193, 15–238, 15–239, 15–305). A representative of the Middlesex Convalescent Center wrote:

> [R]equiring employers to disclose personal identifiers (which include name and occupation) will result in *fewer* people reporting injuries and illnesses because employees will feel shame or embarrassment for being involved in an accident. * * * Additionally, employees who do not want co-workers to know their physical handicaps and other personal business will choose not to report accidents, including those in which the employee is not at fault (Ex. 15: 23 (emphasis in original)).

There exist at present no mechanisms to protect against unwarranted disclosure of private information contained in OSHA records. While Agency policy is that employees and their representatives with access to records should treat the information contained therein as confidential except as necessary to further the purposes of the Act, the Secretary lacks statutory authority to enforce such a policy against employees and representatives (*e.g.* 29 U.S.C. §§ 658, 659) (Act's enforcement mechanisms directed solely at employers). Nor are there present here other types of safeguards that have been held to be adequate to protect against misuse of private material. See *Whalen*, 589 U.S. at 605 ("The right to collect and use [private] data for public purposes is typically accompanied by a concomitant statutory or regulatory duty to avoid unwarranted disclosures.") See also *Fraternal Order of Police*, 812 F.2d at 118 (appropriate safeguards could include statutory sanctions for unauthorized disclosures, security provisions to prevent mishandling of files, coupled with express regulatory prohibition on disclosure, or procedures such as storage of private material in locked cabinets with automatic removal and destruction within six months); *In re Search Warrant (Sealed)*, 810 F.2d 67, 72 (3d Cir. 1987) (district court order that medical records and related information be kept confidential except as disclosure was reasonably required in connection with criminal investigation).

The degree of harm that could result from unauthorized use or disclosure of information on the Log and Incident Report varies depending upon the nature and sensitivity of the injury or illness involved. An employee might reasonably have little to fear from disclosure of a garden-variety injury or illness of the kind that one might sustain in everyday life. Cf. *Wilson* v. *Pennsylvania State Police Department*, 1999 WL 179692 (E.D.Pa) (vision-related information not as intimate as other types of medical information, and less likely to result in harm if disclosed to the public). However, there is a much greater risk that social stigma, harassment and discrimination could result from public knowledge that one has, or may have, AIDS, has been the victim of a sexual assault, or has suffered an injury to a reproductive organ or other intimate body part. See, *e.g. Doe* v. *SEPTA*, 712 F.2d at 1140 (AIDS); *New Jersey Bell Telephone Co.* v. *NLRB*, 720 F.2d 789, 790 (3d Cir. 1983) (reasons given by employees for absence or tardiness included colitis, insertion of urethral tubes, vaginal infections, scalded rectal areas, and heart problems).

OSHA has concluded that the disclosure of occupational injury and illness records to employees and their representatives serves important public policy interests. These interests support a requirement for access by employees and their representatives to personally identifiable information for all but a limited number of cases recorded on the Log, and to all information on the right-hand side of the Form 301. However, OSHA also concludes that prior Agency access policies may not have given

adequate consideration to the harm which could result from disclosure of intimate medical information. In the absence of effective safeguards against unwarranted use or disclosure of private information in the injury and illness records, confidentiality must be preserved for particularly sensitive cases. These "privacy concern cases" listed in paragraph 1904.29 (b)(7) of the final rule involve diseases, such as AIDS and hepatitis, other illnesses if the employee voluntarily requests confidentiality, as well as certain types of injuries, the disclosure of which could be particularly damaging or embarrassing to the affected employee. MSDs are not included in privacy concern cases because OSHA's ergonomics rule independently provides for access by employees and their representatives to the names of workers who report work-related MSDs. (See 29 CFR 1910.900(v)(1) and (2.)

The record supports this approach. For example, API recommended that OSHA protect employee confidentiality for cases involving HIV, fertility problems, bloodborne pathogens, seroconversions, and impotence (Ex. 15: 375). OSHA agrees that employee confidentiality should be protected in these and similar cases. Therefore, the final rule requires that the employer withhold the employee's name from the OSHA 300 Log for each "privacy concern case," and maintain a separate confidential list of employee names and case numbers. In all other respects, the final rule ensures full access to the OSHA Log by employees, former employees, personal representatives and authorized employee representatives.

Protections Against Broad Public Access

In the proposal, OHSA noted that the access requirements were intended as a tool for employees and their representatives to affect safety and health conditions at the workplace, not as a mechanism for broad public disclosure of injury and illness information. (61 FR 4048.) A number of commenters suggested that OSHA should include specific language in the final rule protecting employee confidentiality whenever injury and illness data are disclosed for other than safety or health purposes, or to persons other than those who have a legitimate need to know. Dow argued that:

> OSHA should allow an employer to develop a system that will protect personal identifiers and other non-safety or health related information. Further, such information should only be available for the specific use by an OSHA inspector who is reviewing an employer's logs during an inspection, medical personnel, the employer's incident investigation designated officials, and the individual's supervisor. Outside of these individuals, access should be granted only after written authorization from the injured or ill employee has been obtained. This approach would allow those individuals who have a legitimate "need to know" limited access to the information (Ex.. 15: 335).

Other commenters suggested requiring that employee names be shielded if the forms are disclosed to third parties (see, *e.g.*, Exs. 15: 374, 375).

OSHA agrees that confidentiality of injury and illness records should be maintained except for those persons with a legitimate need to know the information. This is a logical extension of the agency's position that a balancing test is appropriate in determining the scope of access to be granted employees and their representatives. Under this test, "the fact that protected information must be disclosed to a party who has need for it* * * does not strip the information of its protection against disclosure to those who have no similar need." *Fraternal Order of Police*, 812 F2d at 118.

OSHA has determined that employees, former employees and authorized employee representatives have a need for the information that justifies their access to records, including employee names, for all except privacy concern cases. While the possibility exists that employees and their representatives with access to the records could disclose the information to the general public, OSHA does not believe that this risk is sufficient to justify restrictions on the use of the records by persons granted access under sections 1904.40 and 1904.35. As discussed in the following section, strong policy and legal considerations militate against placing restrictions on employees' and employee representatives' use of the injury and illness information.

There is also a concern that employers may voluntarily grant access to OSHA records to persons outside their organization, who do not need the information for safety and health purposes. To protect employee confidentiality in these circumstances, paragraph 1904.29(b)(10) requires employers generally to remove or shield employee names and other personally identifying information when they disclose the OSHA forms to persons other than government representatives, employees, former employees or authorized employee representatives. Employers remain free to disclose unredacted records for purposes of evaluating a safety and health program or safety and health conditions at the workplace, processing a claim for workers' compensation or insurance benefits, or carrying out the public health or law enforcement functions described in section 164.512 of the final rule on Standards for Privacy of Individually Identifiable Health Information.

OSHA believes that this provision protects employee privacy to a reasonable degree consistent with the legitimate business needs of employers and sound public policy considerations. The record does not demonstrate that routine access by the general public to personally identifiable injury and illness data is necessary or useful. Indeed, several prominent industry representatives stated that the OSHA log should not be made available to the general public. See Ex. 335 (Dow); Ex. 15–375 (API). Furthermore, employers are always free to seek authorization from employees to disclose their names in particular cases. Thus, employers retain a degree of flexibility to tailor their voluntary disclosure policies to meet exigent circumstances.

Misuse of the Records by Employees and Their Representatives

Several commenters were concerned about inappropriate uses of the records once they are released to employees (see, *e.g.*, Exs. 15: 9, 39, 102, 185, 193, 201, 304, 305, 317, 321, 330, 341, 346, 359, 363, 375, 389, 397, 412, 413, 423, 424, 431). The American Petroleum Institute stated: "API has concerns about potentials for uncontrolled and unscrupulous use of these data for purposes unrelated to safety and health—uses such as for plaintiff-lawyer "fishing expeditions", in union organizing attempts, to create adverse publicity as contracts expire, or to foster other special interests" (Ex. 15: 375). Several commenters stated that information requests could be used as a harassment by unions (see, *e.g.*, Exs. 15: 9, 201, 317, 423, 424), and the Caterpillar Corporation (Ex. 15: 201) related its labor management difficulties during a recent strike (Ex. 15: 201). The American Crystal Sugar Company (Ex. 15 363) expressed concern that "there have been instances where an employee is paid a finder's fee to identify possible cases for personal injury lawyers." A few commenters suggested methods to solve these potential misuse problems, including a requirement for all information requests to be made in writing (see, *e.g.*, Exs. 15: 163, 235, 281, 397). Two commenters suggested requirements for the employee or employee representative to sign a pledge not to misuse the information (Exs. 15: 359, 389). For example, the Waste

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Management, Inc. Company suggested that "OSHA should require the individual(s) obtaining a copy of the log or record to certify that the information will be maintained in confidence and will not be released to a third party under any circumstances under penalty of law. OSHA shall also promulgate severe penalties for violation" (Ex. 15: 389).

While there may be instances where employees share the data with third parties who normally would not be allowed to access the data directly, the final rule contains no enforceable restrictions on use by employees or their representatives. Employees and their representatives might reasonably fear that they could be found personally liable for violations of such restrictions. This would have a chilling effect on employees' willingness to use the records for safety and health purposes, since few employees would voluntarily risk such liability. Moreover, despite the concerns of commenters about abuse problems, OSHA has not noted any significant problems of this type in the past. This suggests that, if such problems exist, they are infrequent. In addition, as noted in the privacy discussion above, a prohibition on the use of the data by employees or their representatives is beyond the scope of OSHA's enforcement authority. For these reasons, the employer may not require an employee, former employee or designated employee representative to agree to limit the use of the records as a condition for viewing or obtaining copies of records.

OSHA has added a statement to the Log and Incident Report forms indicating that these records contain information related to employee health and must be used in a manner that protects the confidentiality of employees to the extent possible while the information is used for occupational safety and health purposes. This statement is intended to inform employees and their representatives of the potentially sensitive nature of the information in the OSHA records and to encourage them to maintain employee confidentiality if compatible with the safety and health uses of the information. Encouraging parties with access to the forms to keep the information confidential where possible is reasonable and should not discourage the use of the information for safety and health purposes. OSHA stresses, however, that the statement does not reflect a regulatory requirement limiting the use of records by those with access under sections 1904.35 and 1904.40.

The Records Access Requirement and the ADA

Several commenters alleged that a requirement that individually identifiable injury and illness records be disclosed to employees and union representatives would conflict with the confidentiality provisions of the Americans With Disabilities Act, 42 U.S.C. §§ 12112 (d)(3)(B), (d)(4)(C) (1994 ed. and Supp. III) (ADA) (see, *e.g.*, Exs. 15: 64, 290, 304, 315, 397).

Section 12112(d)(3)(B) of the ADA permits an employer to require a job applicant to submit to a medical examination after an offer of employment has been made but before commencement of employment duties, provided that medical information obtained from the examination is kept in a confidential medical file and not disclosed except as necessary to inform supervisors, first aid and safety personnel, and government officials investigating compliance with the ADA. Section 12112(d)(4)(C) requires that the same confidentiality protection be accorded health information obtained from a voluntary medical examination that is part of an employee health program.

By its terms, the ADA requires confidentiality for information obtained from medical examinations given to prospective employees, and from medical examinations given as part of a voluntary employee health program. The OSHA injury and illness records are not derived from pre-employment or voluntary health programs. The information in the OSHA injury and illness records is similar to that found in workers' compensation forms, and may be obtained by employers by the same process used to record needed information for workers' compensation and insurance purposes. The Equal Employment Opportunity Commission (EEOC) recognizes a partial exception to the ADA's strict confidentiality requirements for medical information regarding an employee's occupational injury or workers' compensation claim. See *EEOC Enforcement Guidance: Workers' Compensation and the ADA*, 5 (September 3, 1996). Therefore, it is not clear that the ADA applies to the OSHA injury and illness records.

Even assuming that the OSHA injury and illness records fall within the literal scope of the ADA's confidentiality provisions, it does not follow that a conflict arises. The ADA states that "nothing in this Act shall be construed to invalidate or limit the remedies, rights, and procedures of any Federal law. * * *" 29 U.S.C. 12201(b). In enacting the ADA, Congress was aware that other federal standards imposed requirements for testing an employee's health, and for disseminating information about an employee's medical condition or history, determined to be necessary to preserve the health and safety of employees and the public. See H.R. Rep. No. 101–485 pt. 2, 101st Cong., 2d Sess. 74–75 (1990), *reprinted in* 1990 U.S.C.C.A.N. 356, 357 (noting, *e.g.* medical surveillance requirements of standards promulgated under OSH Act and Federal Mine Safety and Health Act, and stating "[t]he Committee does not intend for [the ADA] to override any medical standard or requirement established by Federal * * * law * * * that is job-related and consistent with business necessity"). See also 29 CFR part 1630 App. p. 356. The ADA recognizes the primacy of federal safety and health regulations; therefore such regulations, including mandatory OSHA recordkeeping requirements, pose no conflict with the ADA. Cf. *Albertsons, Inc.* v. *Kirkingburg*, 527 U.S. 555, (1999) ("When Congress enacted the ADA, it recognized that federal safety and health rules would limit application of the ADA as a matter of law.")

The EEOC, the agency responsible for administering the ADA, has recognized both in the implementing regulations at 29 CFR part 1630, and in interpretive guidelines, that the ADA yields to the requirements of other federal safety and health standards. The implementing regulation codified at 29 CFR 1630.15(e) explicitly states that an employer's compliance with another federal law or regulation may be a defense to a charge of violating the the ADA:

> (e) Conflict with other Federal laws. It may be a defense to a charge of discrimination under this part that a challenged action is required or necessitated by another Federal law or regulation, or that another Federal law or regulation prohibits an action (including the provision of a particular reasonable accommodation) that would otherwise be required by this part.

Interpretive guidance provided by the EEOC further underscores this point. The 1992 Technical Assistance Manual on Title I of the ADA states as follows:

> *4.6 Health and Safety Requirements of Other Federal or State Laws*
>
> The ADA recognizes employers' obligations to comply with requirements of other laws that establish health and safety standards. However, the [ADA] gives greater weight to Federal than to state or local law.
>
> 1. Federal Laws and Regulations
>
> The ADA does not override health and safety requirements established under other Federal laws If a standard is required by another Federal law, an employer must comply with it and does not have to show that the standard is job related and consistent with business necessity (emphasis added).

U.S. Equal Employment Opportunity Commission, *A Technical Assistance Manual on the Employment Provisions (Title I) of the Americans With Disabilities Act*, IV–16 (1992) (Technical Assistance Manual). The Technical Assistance Manual also states that, while medical-related information about employees must generally be kept confidential, an exception applies where "[o]ther Federal laws and regulations * * * require disclosure of relevant medical information." Assistance Manual at VI–12. See also Assistance Manual at VI–14–15 (actions taken by employers to comply with requirements imposed under the OSH Act are job related and consistent with business necessity). For these reasons, OSHA does not believe that the mandatory employee access provisions of the final recordkeeping rule conflict with the provisions of the ADA.

Times Allowed To Provide Records

In its proposal, OSHA would have required the employer to allow the employee to view the 300 Log and the Form 301 records by the end of the next business day and provide copies within seven calendar days. An employer would have been required to provide access to the 301 forms for all injuries and illnesses "in a reasonable time" (61 FR 4061). Several commenters agreed with OSHA's proposed times for providing copies of the records to employees and their representatives (see, *e.g.*, Exs. 15: 213, 277, 359). For example, Consolidated Edison (Ex. 15: 213) stated that "[t]he time limits in the proposal are acceptable but [Con Ed] recommends that a time limit of seven days be included at [proposed] paragraph 1904.11(b)(5) [which addressed the copying of 301 forms] rather than the vague "reasonable time" included in the text."

A number of commenters disagreed with OSHA's proposed times for providing copies of the records (see, *e.g.*, Exs. 15: 195, 201, 213, 218, 226, 235, 326, 347, 369, 370, 389, 409, 423, 425, 440). These commenters suggested a variety of times, including four hours (Ex. 15: 369), 24 hours (Ex. 15: 425), two workdays (Ex. 15: 226), five working days (Ex. 15: 235), within seven calendar days or one week (Ex. 15: 195, 370), 15 days to match the requirements of the OSHA medical records access rule (Ex. 15: 218, 347, 409, 423), and 21 days (Ex. 15: 389). The International Brotherhood of Teamsters (Ex. 15: 369) suggested that "[e]mployees and their designated representatives be provided with the same access rule as proposed for governmental officials, RE: obtain copies of logs four hours after the request."

The Tennessee Valley Authority (TVA) argued that "[a]ll requests for records should be made in writing and the information provided to the authorized requester within five working days. This provides the documentation for who received the information and reduces the burden on the employer" (Ex. 15: 235). Bell Atlantic Network Services, Inc. (Ex. 15: 218) recommended that "OSHA should simplify the very confusing and differing "access" and "copies" schedule to an uniform 15 working days as is the requirement in 29 CFR 1910.20, Access to Employee Exposure and Medical Records."

In addition, the Caterpillar Company (Ex. 15: 201) recommended that the final rule should not establish time frames at all, stating that "The time limit of providing access by the close of business on the next scheduled workday is unnecessarily restrictive. Noncompliance situations could be generated by simple work schedule conflicts or other minor difficulties. The access period should be stated as a reasonable time period allowing employees and employers adequate flexibility."

Under the final rule, an employer must provide a copy of the 300 Log to an employee, former employee, personal representative or authorized employee representative on the business day following the day on which an oral or written request for records is received. Likewise, when an employee, former employee or personal representative asks for copies of the 301 form for an injury or illness to that employee, the employer must provide a copy by the end of the next business day. OSHA finds that these are appropriate time frames for supplying a copy of the existing forms, which in the case of the Form 301 is a single page. The average 300 Log is also only one page, although employers who have a larger number of occupational injuries and illnesses will have more than one page.

The final rule allows the employer seven business days to provide copies of the OSHA 301 forms for all occupational injuries and illnesses that occur at the establishment. Several commenters stated that there is additional burden for these large requests (see, *e.g.*, Exs. 15: 172, 260, 262, 265, 294, 297, 401). For example, the Boeing Corporation stated that "[s]ince Boeing is a large employer with several thousand employees at several sites, (up to 30,000 at one site), the administrative burden could be immense, particularly, if large numbers of records are requested by several employees. For example, if 100 employees requested ten thousand 301 forms, one million records would have to be available. This requirement is simply not administratively realistic." OSHA agrees that, because these records may involve more copying, the employer needs more time to produce copies of the 301 forms. In addition, as stated in the final rule, the employer may not provide the authorized employee representative with the information on the left side of the 301 form, so the employer needs additional time to redact this information. Because the final rule only provides a right of access to an authorized employee representative (authorized collective bargaining agent), the number of requests should not exceed the number of unions representing employees at the establishment. Thus, the multiple request problem envisioned by Boeing should not surface. In addition, OSHA expects that, in large plants such as the one described by Boeing, the authorized employee representatives will ask for the data on a periodic basis, either monthly or quarterly, so the data requested at one time will be limited. In addition, the employer must provide only one free copy. If additional copies are requested, the employer may charge for the copies.

Charging Employees for Copies of the OSHA Records

The proposal also required the employer to provide copies without cost, or provide access to copying facilities without charge, or allow the employee or representative to take the records off site to make copies (61 FR 4061). Linda Ballas (Ex. 15: 31) commented that the copies should be provided at no cost to the employee. Several commenters stated that employees who access the records should pay for them (see, *e.g.*, Exs. 15: 151, 152, 179, 180, 201, 226, 317, 397, 424). Atlantic Marine, Inc. stated: "Providing copies of records without cost to individuals may produce an undue administrative and financial burden for some employers. Although there is merit to providing information access to employees, the charging of a fee not to exceed the actual cost for duplicating the documents may deter unnecessary or frivolous requests" (Ex. 15: 151). The United Parcel Service Company (Ex. 15: 424) stated that:

> [i]f expanded access to safety and health records is afforded, certainly such access should not be at the employer's cost. This is an unfair burden on the employer, and will

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encourage improper, harassing requests. These risks are not alleviated by the alternative of permitting the employer to give its records to the requesting party to copy. Proposed § 1904.11(b)(3)(iii), 61 Fed. Reg. at 4061, since employers often will be reluctant to entrust their only original copies to a current or former employee. (Ex. 15: 424)

In the final rule, OSHA has implemented the proposed provision requiring employers to provide copies free of charge to employees who ask for the records. The costs of providing copies is a minimal expense, and employees are more likely to access the data if it is without cost. In addition, allowing the employer to charge for copies of the OSHA records would only serve to delay production of the records. Providing free copies for employees thus helps meet one of the major goals of this rulemaking; to improve employee involvement. However, OSHA agrees that there are some circumstances where employers should have the option of charging for records. After receiving an initial, free copy of requested records, an employee, former employee, or designated representative may be charged a reasonable search and copying fee for duplicate copies of the records. However, no fee may be charged for an update of a previously requested record.

Section 1904.37 State Recordkeeping Regulations

Section 1904.37 addresses the consistency of the recordkeeping and reporting requirements between Federal OSHA and those States where occupational safety and health enforcement is provided by an OSHA-approved State Plan. Currently, in 21 States and 2 territories, the State government has been granted authority to operate a State OSHA Plan covering both the private and public (State and local government) sectors under section 18 of the OSH Act (see the State Plan section of this preamble for a listing of these States). Two additional States currently operate programs limited in scope to State and local government employees only. State Plans, once approved, operate under authority of State law and provide programs of standards, regulations and enforcement which must be "at least as effective" as the Federal program. (State Plans must extend their coverage to State and local government employees, workers not otherwise covered by Federal OSHA regulations.) Section 1904.37 of the final rule describes what State Plan recordkeeping requirements must be identical to the Federal requirements, which State regulations may be different, and provides cross references to the State Plan regulations codified in Section 1902.3(k), 1952.4, and 1956.10(i). The provisions of Subpart A of 29 CFR part 1952 specify the regulatory discretion of the State Plans in general, and section 1952.4 spells out the regulatory discretion of the State Plans specifically for the recordkeeping regulation.

In the final rule, OSHA has rewritten the text of the corresponding proposed section and moved it into Subpart D of the final rule. Under Section 18 of the OSH Act, a State Plan must require employers in the State to make reports to the Secretary in the same manner and to the same extent as if the Plan were not in effect. Final section 1904.37 makes clear that States with approved State Plans must promulgate new regulations that are substantially identical to the final Federal rule. State Plans must have recording and reporting regulations that impose identical requirements for the recordability of occupational injuries and illnesses and the manner in which they are entered. These requirements must be the same for employers in all the States, whether under Federal or State Plan jurisdiction, and for State and local government employers covered only through State Plans, to ensure that the occupational injury and illness data for the entire nation are uniform and consistent so that statistics that allow comparisons between the States and between employers located in different States are created.

For all of the other requirements of the Part 1904 regulations, the regulations adopted by the State Plans may be more stringent than or supplemental to the Federal regulations, pursuant to paragraph 1952.4(b). This means that the States' recording and reporting regulations could differ in several ways from their Federal Part 1904 counterparts. For example, a State Plan could require employers to keep records for the State, even though those employers are within an industry exempted by the Federal rule. A State Plan could also require employers to keep additional supplementary injury and illness information, require employers to report fatality and multiple hospitalization incidents within a shorter timeframe than Federal OSHA does, require other types of incidents to be reported as they occur, or impose other requirements. While a State Plan must assure that all employee participation and access rights are assured, the State may provide broader access to records by employees and their representatives. However, because of the unique nature of the national recordkeeping program, States must secure Federal OSHA approval for these enhancements.

The final rule eliminates paragraph (b) of section 1904.14 of the proposed rule. Proposed paragraph (b) stated that records maintained under State Plan rules would be considered to be in compliance with the Federal rule. OSHA has eliminated paragraph (b) as unnecessary because it is redundant to state that the records kept under State law will be acceptable; since State regulations must be identical to, or more stringent than the Federal regulations, compliance by private sector employers with approved State laws would by definition constitute compliance with the Federal regulations. Paragraph (c), which deals with public sector recording and reporting requirements in both comprehensive State Plans (those covering both the private and public sector employees) and those which are limited to the public sector (State and local government), has been reworded and moved to 1904.37(b)(3).

Because Federal OSHA does not provide coverage to State and local government employees, the State-Plan States may grant State recordkeeping variances to the State and local governments under their jurisdiction. However, the State must obtain concurrence from Federal OSHA prior to issuing any such variances. In addition, the State-Plan States may not grant variances to any other employers and must recognize all 1904 variances granted by Federal OSHA. These steps are necessary to ensure that the injury and illness data requirements are consistent from State to State.

Rulemaking comments on this issue were unanimous in supporting identical State and Federal regulations for recordkeeping. Multi-State employers and their representatives, such as US West, Lucent Technologies, AT&T, and the National Association of Manufacturers, thought that identical State regulations would simplify and reduce their recordkeeping burdens (see, *e.g.*, Exs. 15: 194, 272, 303, 305, 346, 348, 358, 375).

OSHA understands the advantages to multi-State businesses of following identical OSHA rules in both Federal and State Plan jurisdictions, but also recognizes the value of allowing the States to have different rules to meet the needs of each State, as well as the States' right to impose different rules as long as the State rule is at least as effective as the Federal rule. Accordingly, the Part 1904 rules impose identical requirements where they are needed to create consistent injury and illness statistics for the nation and allows the States to impose supplemental or more stringent requirements where doing so will not interfere with the maintenance of comprehensive and uniform national statistics on workplace fatalities, injuries and illnesses.

Section 1904.38 Variances From the Recordkeeping Rule

Section 1904.38 of the final rule explains the procedures employers must follow in those rare instances where they request that OSHA grant them a variance or exception to the recordkeeping rules in Part 1904. The rule contains these procedures to allow an employer who wishes to maintain records in a manner that is different from the approach required by the rules in Part 1904 to petition the Assistant Secretary. Section 1904.8 allows the employer to apply to the Assistant Secretary for OSHA and request a Part 1904 variance if he or she can show that the alternative recordkeeping system: (1) Collects the same information as this Part requires; (2) Meets the purposes of the Act; and (3) Does not interfere with the administration of the Act.

The variance petition must include several items, namely the employer's name and address; a list of the State(s) where the variance would be used; the addresses of the business establishments involved; a description of why the employer is seeking a variance; a description of the different recordkeeping procedures the employer is proposing to use; a description of how the employer's proposed procedures will collect the same information as would be collected by the Part 1904 requirements and achieve the purpose of the Act; and a statement that the employer has informed its employees of the petition by giving them or their authorized representative a copy of the petition and by posting a statement summarizing the petition in the same way notices are posted under paragraph 1903.2(a).

The final rule the describes how the Assistant Secretary will handle the variance petition by taking the following steps:

—The Assistant Secretary will offer employees and their authorized representatives an opportunity to comment on the variance petition. The employees and their authorized representatives will be allowed to submit written data, views, and arguments about the petition.

—The Assistant Secretary may allow the public to comment on the variance petition by publishing the petition in the **Federal Register**. If the petition is published, the notice will establish a public comment period and may include a schedule for a public meeting on the petition.

—After reviewing the variance petition and any comments from employees and the public, the Assistant Secretary will decide whether or not the proposed recordkeeping procedures will meet the purposes of the Act, will not otherwise interfere with the Act, and will provide the same information as the Part 1904 regulations provide. If the procedures meet these criteria, the Assistant Secretary may grant the variance subject to such conditions as he or she finds appropriate.

—If the Assistant Secretary grants the variance petition, OSHA will publish a notice in the **Federal Register** to announce the variance. The notice will include the practices the variance allows, any conditions that apply, and the reasons for allowing the variance.

The final rule makes clear that the employer may not use the proposed recordkeeping procedures while the Assistant Secretary is processing the variance petition and must wait until the variance is approved. The rule also provides that, if the Assistant Secretary denies the petition, the employer will receive notice of the denial within a reasonable time and establishes that a variance petition has no effect on the citation and penalty for a citation that has been previously issued by OSHA and that the Assistant Secretary may elect not to review a variance petition if it includes an element which has been cited and the citation is still under review by a court, an Administrative Law Judge (ALJ), or the OSH Review Commission.

The final rule also states that the Assistant Secretary may revoke a variance at a later date if the Assistant Secretary has good cause to do so, and that the procedures for revoking a variance will follow the same process as OSHA uses for reviewing variance petitions. Except in cases of willfulness or where necessary for public safety, the Assistant Secretary will: Notify the employer in writing of the facts or conduct that may warrant revocation of a variance and provide the employer, employees, and authorized employee representatives with an opportunity to participate in the revocation procedures.

The final rule differs somewhat from the variance section of the former rule. The text of the previous rule gave the Bureau of Labor Statistics authority to grant, deny, and revoke recordkeeping variances and exceptions. Under the former rule, applicants were required to petition the Regional Commissioner of the Department of Labor's Bureau of Labor Statistics (BLS) for the region where the establishment was located. Petitions that stretched beyond the regional boundary were referred to the BLS Assistant Commissioner. These responsibilities were transferred to OSHA in 1990 (Memorandum of Understanding between OSHA and BLS, 7/11/90) (Ex. 6), but the variance section of the rule itself was not amended at that time. This section of the final rule codifies the shift in responsibilities from the BLS to OSHA with regard to variances.

Like the former variance section of the rule, the final rule does not specifically note that the states operating OSHA-approved state plans are not permitted to grant recordkeeping variances. Paragraph (b) of former section 1952.4, OSHA's rule governing the operation of the State plans, prohibited the states from granting variances, and paragraph (c) of that rule required the State plans to recognize any Federal recordkeeping variances. The same procedures continue to apply to variances under section 1904.37 and section 1952.4 of this final rule. OSHA has not included the provisions from these two sections in the variance sections of this recordkeeping rule, because doing so would be repetitive.

The final rule adds several provisions to those of the former rule. They include (1) the identification of petitioning employers' pending citations in State plan states, (2) the discretion given to OSHA not to consider a petition if a citation on the same subject matter is pending, (3) the clarification that OSHA may provide additional notice via the **Federal Register** and opportunity for comment, (4) the clarification that variances have only prospective effect, (5) the opportunity of employees and their representatives to participate in revocation procedures, and (6) the voiding of all previous variances and exceptions.

Variance procedures were not discussed in the *Recordkeeping Guidelines* (Ex. 2), nor have there been any letters of interpretations or OSHRC or court decisions on recordkeeping variances. As noted in the proposal, at 61 FR 4039, only one recordkeeping variance has ever been granted by OSHA. This variance was granted to AT&T and subsequently expanded to its Bell subsidiaries to enable them to centralize records maintenance for workers in the field.

The final rule does not adopt the approach to variances proposed by OSHA in 1996 (see section 1904.15 of the proposal). OSHA proposed to eliminate the variance and exception procedure from the recordkeeping rules

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altogether and instead to require all variances and exceptions to the recordkeeping rule to be processed under OSHA's general variance regulations, which are codified at 29 CFR Part 1905. As stated in the proposal, OSHA believed that this change would streamline the final recordkeeping rule and eliminate duplicate procedures for obtaining variances. OSHA also proposed to amend paragraph 1952.4(c) to make clear that employers were required to obtain all recordkeeping variances or exceptions from OSHA instead of from the BLS.

OSHA received very few comments on the proposed changes to the variance procedures. Some commenters approved the proposed approach but did not comment on its merits (see, *e.g.*, Exs. 15: 133, 136, 137, 141, 224, 266, 278). The International Dairy Foods Association (IDFA) supported the change if "it is indeed * * * a duplicative section" and "no significant change will occur by deleting the provision" (Ex. 15: 203). Another commenter stated that "no employer should be exempt from record keeping and I cannot imagine what kind of variance for record keeping exceptions could exist. I am requesting that this proposal be removed from the standard" (Ex. 15: 62). The Air Transport Association urged "OSHA * * * [to] permit [airline] companies to keep records according to location or division * * * and without the need to seek and acquire variances, so long as records can be retrieved in a reasonable time for OSHA oversight purposes" (Ex. 15: 378).

OSHA has decided, after further consideration, to continue to include a specific recordkeeping variance section in the final rule, and not to require employers who wish a recordkeeping variance or exception to follow the more rigorous procedures in 29 CFR part 1905. The procedures in Part 1905, which were developed for rules issued under sections 6 and 16 of the OSH Act, may not be appropriate for rules issued under section 8 of the Act, such as this recordkeeping rule.

The final rule thus retains a section on variance procedures for the recordkeeping rule. OSHA believes that few variances or exceptions will be granted under the variance procedures of the final rule because other provisions of the final rule already reflect many of the alternative recordkeeping procedures that employers have asked to use over the years, such as electronic storage and transmission of data, centralized record maintenance, and the use of alternative recordkeeping forms. Because these changes have been made to other sections of the final rule, there should be little demand for variances or exceptions. As OSHA noted in the proposal (61 FR 4039) in relation to the AT&T variance, "[t]he centralization of records provision contained in this proposal [and subsequently adopted in the final rule] will eliminate the continued need for this variance." Similarly, the changes in paragraphs 1904.3(e) and (f) of the final rule that permit substitute forms and computerization of recordkeeping by employers, combined with the changes in paragraph 1904.30(c) that allow for recordkeeping at a central location will accommodate the Air Transport Association's request that OSHA "permit airline companies to keep records according to location or division * * * without the need to seek and acquire variances" (Ex. 15: 378). Under the final rule, companies are still required to summarize their injury and illness records for individual establishments, but may also produce records for separate administrative units if they wish to do so. Centralized and computerized recordkeeping systems make this a relatively simple task when compared to paper-driven and decentralized systems.

The final changes to the variance section of the former rule are minor. The primary change is to make clear that OSHA, rather than the BLS, has the responsibility for granting recordkeeping variances or exceptions. The other changes reflected in the final rule follow from the proposed rule and are intended to add several provisions from OSHA's general variance procedures in Part 1905. For example, paragraph (e) of section 1904.38 of the final rule is a modification of § 1905.11(b)(8), and paragraph (i) of this section of the final rule derives from section 1905.5. The objective of this paragraph is to give OSHA discretionary authority to decline to act on a petition where the petitioner has a pending citation. OSHA concludes that it would not be appropriate to consider granting a recordkeeping variance to an employer who has a pending recordkeeping violation before OSHRC or a State agency.

Paragraph (i) of the final rule supports paragraph (c)(7) from this same section because it provides a mechanism for giving OSHA notice of a citation pending before a state agency. Paragraph (i) also clarifies that variances only apply to future events, not to past practices. Paragraph (j) of section 1904.38 of the final rule nullifies all prior variances and exceptions. OSHA believes that it is important to begin with a "clean slate" when the final recordkeeping rule goes into effect. Employers with existing variances can re-petition the agency if the final rule does not address their needs. Another addition to the final rule makes explicit that OSHA can provide additional public notice via the **Federal Register** and may offer additional opportunity for public comment. A final addition recognizes and makes clear that employees can participate in variance revocation proceedings.

Subpart E. Reporting Fatality, Injury and Illness Information to the Government

Subpart E of this final rule consolidates those sections of the rule that require employers to give recordkeeping information to the government. In the proposed rule, these sections were not grouped together. OSHA believes that grouping these sections into one Subpart improves the overall organization of the rule and will make it easier for employers to find the information when needed. The four sections of this subpart of the final rule are:

(a) Section 1904.39, which requires employers to report fatality and multiple hospitalization incidents to OSHA.

(b) Section 1904.40, which requires an employer to provide his or her occupational illness and injury records to a government inspector during the course of a safety and health inspection.

(c) Section 1904.41, which requires employers to send their occupational illness and injury records to OSHA when the Agency sends a written request asking for specific types of information.

(d) Section 1904.42, which requires employers to send their occupational illness and injury records to the Bureau of Labor Statistics (BLS) when the BLS sends a survey form asking for information from these records.

Each of these sections, and the record evidence pertaining to them, is discussed below.

Section 1904.39 Reporting Fatality or Multiple Hospitalization Incidents to OSHA

Paragraph (a) of section 1904.39 of the final rule requires an employer to report work-related events or exposures involving fatalities or the in-patient hospitalization of three or more employees to OSHA. The final rule requires the employer, within 8 hours after the death of any employee from a work-related incident or the in-patient hospitalization of three or more employees as a result of a work-related incident, to orally report the fatality/multiple hospitalization by telephone or in person to the Area Office of the Occupational Safety and Health Administration (OSHA), or to OSHA via the OSHA toll-free central telephone number, 1–800–321–6742.

The final rule makes clear in paragraph 1904.39(b)(1) that an employer may not report the incident by leaving a message on OSHA's answering machine, faxing the Area Office, or sending an e-mail, but may report the fatality or multiple hospitalization incident using the OSHA 800 number. The employer is required by paragraph 1904.39(b)(2) to report several items of information for each fatality or multiple hospitalization incident: the establishment name, the location of the incident, the time of the incident, the number of fatalities or hospitalized employees, the names of any injured employees, the employer's contact person and his or her phone number, and a brief description of the incident.

As stipulated in paragraph 1904.39(b)(3), the final rule does not require an employer to call OSHA to report a fatality or multiple hospitalization incident if it involves a motor vehicle accident that occurs on a public street or highway and does not occur in a construction work zone. Employers are also not required to report a commercial airplane, train, subway or bus accident (paragraph 1904.39(b)(4)). However, these injuries must still be recorded on the employer's OSHA 300 and 301 forms, if the employer is required to keep such forms. Because employers are often unsure about whether they must report a fatality caused by a heart attack at work, the final rule stipulates, at paragraph 1904.39(b)(5), that such heart attacks must be reported, and states that the local OSHA Area Office director will decide whether to investigate the incident, depending on the circumstances of the heart attack.

Paragraph 1904.39(b)(6) of the final rule clarifies that the employer is not required to report a fatality or hospitalization that occurs more than thirty (30) days after an incident, and paragraph 1904.39(b)(7) states that, if the employer does not learn about a reportable incident when it occurs, the employer must make the report within 8 hours of the time the incident is reported to the employer or to any of the employer's agents or employees.

Section 1904.39 of the final rule includes several changes from the proposed rule and section 1904.17 of the former rule. First, OSHA has rewritten the requirements of the former rule using the same plain-language question-and-answer format that is used throughout the rest of the rule. Second, this section clarifies that the report an employer makes to OSHA on a workplace fatality or multiple hospitalization incident must be an oral report. As the regulatory text makes clear, the employer must make such reports to OSHA by telephone (either to the nearest Area Office or to the toll-free 800 number) or in person. Third, the employer may not merely leave a message at the OSHA Area Office; instead, the employer must actually speak to an OSHA representative. Fourth, this section of the rule lists OSHA's 800 number for the convenience of employers and to allow flexibility in the event that the employer has difficulty reaching the OSHA Area Office. Fifth, this section eliminates the former requirement that employers report fatalities or multiple hospitalizations that result from an accident on a commercial or public transportation system, such as an airplane accident or one that occurs in a motor vehicle accident on a public highway or street (except for those occurring in a construction work zone, which must still be reported).

OSHA's proposal would have made three changes to the former rule: (1) it would have clarified the need for employers to make oral reports, (2) it would have included OSHA's 800 number in the text of the regulation, and (3) it would have required a site-controlling employer at a major construction site to report a multiple hospitalization incident if the injured workers were working at that site under the control of that employer.

A number of commenters supported all three of these proposed changes (see, *e.g.*, Exs. 15: 133, 136, 137, 141, 204, 224, 266, 278, 369, 378, 429). However, many commenters discussed the changes OSHA proposed, raised additional issues not raised in the proposal, and made various suggestions for the final rule. Comments are discussed below for each of the proposed changes.

Making oral reports of fatalities or multiple hospitalization incidents and the OSHA 800 number. The former rule required an employer to "orally report" fatality or multiple hospitalization incidents to OSHA by telephone or in person, although the rule did not specify that messages left on the Area Office answering machine or sent by e-mail would not suffice. Since the purpose of this notification is to alert OSHA to the occurrence of an accident that may warrant immediate investigation, such notification must be made orally to a "live" person. The changes made to the final rule are consistent with those proposed, except that the proposal would have required employers to report to the Area Office either by telephone or in person during normal business hours and to limit use of the toll-free 800 number to non-business hours.

A few commenters suggested ways for OSHA to make the 800 number more available to employers and to ensure that reports are made orally (see, *e.g.*, Exs. 15: 9, 154, 203, 229, 238, 239, 389). For example, the National Pest Control Association suggested that:

> [t]he agency print OSHA's emergency toll free number on the OSHA 300 and 301 forms and explain that employers are to call the number in the case of a fatality or multiple hospitalization during non-business hours. We would also urge OSHA to define "non-business" hours both in the regulatory text and on the forms (Ex. 15: 229).

Waste Management, Inc. (WMI) (Ex. 15: 389) recommended full reliance on the 800 number, proposing that:

> [t]he 800 number be used at all times. A recent event entailing an attempt to report to the local area office illustrates the difficulty in complying with this proposal. The caller was away from the office out-of-town and attempted to rely on information obtained from the local telephone information service. No local OSHA telephone number was identified as the local emergency number. The city had multiple area offices and telephone numbers without adequate identification at the telephone company information desk. The local number which was finally identified as the local OSHA emergency number could not be accessed from outside the calling area even if the caller was willing to pay the charges. After numerous calls and involvement of several levels of telephone management, the normal business day was completed and so the 800 number in Washington was called. The use of a single, nationwide 800 number has worked for EPA and other agencies. WMI believes it would simplify reporting requirements and ensure more timely reporting.

Houston Lighting and Power (Ex. 15: 239) suggested that OSHA allow employers to report either to the local OSHA Office or to the 800 number:

> [r]eporting of an incident either to the nearest Area Office or through the use of the 1–800 number should be available alternatives to the reporting requirement. The proposal limits when the 1–800 number may be used. In many cases the person reporting the incident may not be at the incident site. It is much more efficient to use a number that does not change from location to location than to attempt to identify each area office.

Tri/Mark Corporation (Ex. 15: 238) asked about reporting using fax or e-mail: "If a live person is available to answer the 800 number, there is no

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problem with this item. Could a fax or e-mail message be an appropriate notification tool?"

It is essential for OSHA to speak promptly to any employer whose employee(s) have experienced a fatality or multiple hospitalization incident to determine whether the Agency needs to begin an investigation. Therefore, the final rule does not permit employers merely to leave a message on an answering machine, send a fax, or transmit an e-mail message. None of these options allows an Agency representative to interact with the employer to clarify the particulars of the catastrophic incident. Additionally, if the Area Office were closed for the weekend, a holiday, or for some other reason, OSHA might not learn of the incident for several days if electronic or facsimile transmission were permitted. Paragraph 1904.39(b)(1) of the final rule makes this clear.

As noted, OSHA allows the employer to report a fatality or multiple hospitalization incident by speaking to an OSHA representative at the local Area Office either on the phone or in person, or by using the 800 number. This policy gives the employer flexibility to report using whatever mechanism is most convenient. The employer may use whatever method he or she chooses, at any time, as long as he or she is able to speak in person to an OSHA representative or the 800 number operator. Therefore, there is no need to define business hours or otherwise add additional information about when to use the 800 number; it is always an acceptable option for complying with this reporting requirement.

This final rule also includes the 800 number in the text of the regulation. OSHA has decided to include the number in the regulatory text at this time to provide an easy reference for employers. OSHA will also continue to include the 800 number in any interpretive materials, guidelines or outreach materials that it publishes to help employers comply with the reporting requirement.

Reporting by a site-controlling employer at a major construction site. The proposed rule would have required a "site controlling employer or designee" to report a case to OSHA "if no more than two employees of a single employer were hospitalized but, collectively, three or more workers were hospitalized as in-patients." This provision was designed to capture those cases where three or more employees of different employers were injured and hospitalized in a single incident. Because a site-controlling employer was defined in the proposed rule as a construction firm with control of a project valued at $1,000,000 or more, the proposed rule would have applied only to those employers. Under the former rule, employers only needed to report if three of their own employees were hospitalized.

A number of commenters opposed the proposed change (see, *e.g.*, Exs. 25, 15: 9, 126, 199, 289, 305, 312, 335, 346, 356, 389, 406, 420). Several commenters argued that the provision would be unworkable because individual employers often do not know about the post-accident condition of the injured employees of other employers (see, *e.g.*, Exs. 15: 126, 346). Other commenters objected to placing the burden of such reporting on the general contractor on a construction site rather than on the individual employers of the affected employees (see, *e.g.*, Exs. 15: 312, 356). Still other commenters noted that, since the term "site-controlling employer" is defined by OSHA as an employer in the construction industry, this provision would have no apparent application in multi-employer settings outside the construction industry (see, *e.g.*, Exs. 15: 199, 335, 346).

After considering the issue further, OSHA agrees that it would be impractical to impose on one employer a duty to report cases of multiple hospitalizations of employees who work for other employers. Although such a reporting requirement would provide OSHA with information that the Agency could use to inspect some incidents that it might otherwise not know about, OSHA believes that the fatality and catastrophe provisions of the final rule will capture most such incidents. Accordingly, OSHA has not included this proposed provision in the final rule.

Eight hours to report. A number of commenters asked OSHA to extend the 8-hour period allowed for employers to report a fatality or a multiple hospitalization incident to OSHA. Most of the commenters who believe that this interval is too short recommended a 24- or 48-hour reporting time (see, *e.g.*, Exs. 33, 15: 35, 37, 176, 203, 218, 229, 231, 273, 301, 335, 341, 423, 425). For example, the International Dairy Foods Association (IDFA) (Ex. 15: 203) recommended that "the reporting period be extended from 8 hours to 24 hours after the event. We feel this is appropriate because the resultant devastation in this type of situation would clearly overshadow the need to inform OSHA of an event that, with all due respect, could not be remedied by reporting it within 8 hours or less." The American Health Care Association (AHCA) (Ex. 15: 341) stated:

> [r]eporting workplace fatalities or multiple employee hospitalization within 8 hours is unrealistic and unreasonable because the employer's first concern should be to the employee(s) injured or killed, his/her family or damage to the building when others may be in imminent danger (*e.g.*, a fire in a health care facility may require evacuating and finding alternative placement for frail, elderly residents). AHCA recommends that OSHA revise the regulation by extending the time period for reporting fatalities or hospitalization of 3 or more employees to "within 48 hours."

After considering these comments, and reviewing the comments received during the comment period for the April 1, 1994 rulemaking on this issue (59 FR 15594–15600), OSHA has decided to continue the 8-hour requirement. The 1994 rulemaking noted the support of many commenters for the 8-hour rule, as well as support for 4-hours, 24 hours, and 48 hours. As OSHA discussed in the April 1, 1994 rulemaking, prompt reporting enables OSHA to inspect the site of the incident and interview personnel while their recollections are immediate, fresh and untainted by other events, thus providing more timely and accurate information about the possible causes of the incident. The 8-hour reporting time also makes it more likely that the incident site will be undisturbed, affording the investigating compliance officer a better view of the worksite as it appeared at the time of the incident. Further, from its enforcement experience, OSHA is not aware that employers have had difficulty complying with the 8-hour reporting requirement.

Motor vehicle and public transportation accidents. Several commenters recommended that OSHA not require employers to report to OSHA fatalities and multiple hospitalization catastrophes caused by public transportation accidents and motor vehicle accidents (see, *e.g.*, Exs. 33, 15: 176, 199, 231, 272, 273, 301, 303, 375). The comments of NYNEX (Ex. 15: 199) are typical:

> [t]he primary purpose of this section is to provide OSHA with timely information necessary to make a determination whether or not to investigate the scene of an incident. To NYNEX's knowledge, OSHA has not investigated public transportation accidents or motor vehicle accidents occurring on public streets or highways. In order to reduce unnecessary costs for both employers and OSHA, NYNEX recommends that fatalities and multiple hospitalizations resulting from these types of accidents be exempt from the reporting requirement.

OSHA agrees with these commenters that there is no need for an employer to report a fatality or multiple hospitalization incident when OSHA is clearly not going to make an investigation. When a worker is killed or injured in a motor vehicle accident on a public highway or street, OSHA is only likely to investigate the incident if it occurred in a highway construction zone. Likewise, when a worker is killed or injured in an airplane crash, a train wreck, or a subway accident, OSHA does not investigate, and there is thus no need for the employer to report the incident to OSHA. The text of paragraphs 1904.39(b)(3) and (4) of the final rule clarifies that an employer is not required to report these incidents to OSHA. These incidents are normally investigated by other agencies, including local transit authorities, local or State police, State transportation officials, and the U.S. Department of Transportation.

However, although there is no need to *report* these incidents to OSHA under the 8-hour reporting requirement, any fatalities and hospitalizations caused by motor vehicle accidents, as well as commercial or public transportation accidents, are *recordable* if they meet OSHA's recordability criteria. These cases should be captured by the Nation's occupational fatality and injury statistics and be included on the employer's injury and illness forms. The statistics need to be complete, so that OSHA, BLS, and the public can see where and how employees are being made ill, injured and killed. Accordingly, the final rule includes a sentence clarifying that employers are still required to record work-related fatalities and injuries that occur as a result of public transportation accidents and injuries.

Although commenters are correct that OSHA only rarely investigates motor vehicle accidents, the Agency does investigate motor vehicle accidents that occur at street or highway construction sites. Such accidents are of concern to the Agency, and OSHA seeks to learn new ways to prevent these accidents and protect employees who are exposed to them. For example, OSHA is currently participating in a Local Emphasis Program in the State of New Jersey that is designed to protect highway construction workers who are exposed to traffic hazards while performing construction work. Therefore, the final rule provides provisions that require an employer to report a fatality or multiple hospitalization incident that occurs in a construction zone on a public highway or street.

Other issues related to the reporting of fatalities and multiple hospitalization incidents. Commenters also raised several issues not addressed in the proposed rule. The National Pest Control Association (NPCA) (Ex. 15: 229) asked OSHA to allow for a longer reporting time in those rare cases where the owner of a small business was himself or herself incapacitated in the accident, suggesting that:

> [l]anguage be included in the rule revisions to provide for additional time to report fatalities and multiple hospitalizations if the employer is hospitalized or otherwise incapacitated. * * * Typically, pest control companies are very small operations. Many employ five or less employees. Often times the business owner is out in the field as much as the employees. So, let's say an employer is hospitalized during a work-related incident that also claimed the life of an employee, who happened to be the lone employee. Can the employer really be expected to report the fatality within eight hours? In most instances the eight hour requirement is rather reasonable, however, in this circumstance it is not. NPCA asks that the agency consider adding language allowing small employers who are hospitalized additional time to report a multiple hospitalization or fatality.

OSHA has decided that there is no need to include language to address this very rare occurrence. If such an unfortunate event were to occur, OSHA would certainly allow a certain amount of leeway for the employer or a representative to report the case. The OSHA inspector can, for good cause, provide the employer with reasonable relief from citation and penalty for failing to report the incident within 8 hours, especially if the employer reports it as soon as possible.

Bell Atlantic (Ex. 15: 218) and the Dow Chemical Company (Ex. 15: 335) recommended that OSHA include additional provisions for employees who are admitted to the hospital for observation only. Bell Atlantic's comments were: "Bell Atlantic also recommends that the hospitalization requirement [for reporting multiple hospitalizations] be limited to those workers that are hospitalized overnight for treatment. The current proposal does not address hospitalization for observation, only that they are non-recordable."

OSHA disagrees with these comments, as it did when similar comments were submitted to the record in the 1994 rulemaking on this provision [59 FR 15596–15597]. If three or more workers are hospitalized overnight, whether for treatment or observation, the accident is clearly of a catastrophic nature, and OSHA needs to learn about it promptly. Additionally, the inpatient distinction provides an easy-to-understand trigger for reporting. In many instances, a patient who is admitted for observation as an inpatient later receives treatment after the true nature and extent of the injury becomes known. At the time of the incident, when reporting is most useful, the employer is unlikely to know the details about the treatment that the worker is receiving (*e.g.*, observation only or medical treatment). However, the employer will probably know that the employee has been admitted to the hospital as an inpatient.

The United Parcel Service (UPS) (Ex. 15: 424) suggested that the 8-hour time period for reporting apply only when a higher ranking official of the company learns of the fatality or catastrophe, stating:

> [U]PS supports this proposal, with one modification: the provision that the eight-hour limit begins to run on notice to an employee or agent is over broad. It may happen that workers who learn of the death or hospitalization of a co-worker do not notify the employer in sufficient time to enable the manager in charge of contacting OSHA to meet the deadline. The better rule, therefore, is to require OSHA modification within eight hours of the incident's being reported to a supervisor, manager, or company official. This allowance is particularly necessary for incidents occurring away from the work site.

The issue of who within the company must learn of the incident before the reporting deadline was also discussed in the 1994 rulemaking [59 FR 15597]. As in the former rule, the final rule requires reporting within 8 hours of the time any agent or employee of the employer becomes aware of the incident. It is the employer's responsibility to ensure that appropriate instructions and procedures are in place so that corporate officers, managers, supervisors, medical/health personnel, safety officers, receptionists, switchboard personnel, and other employees or agents of the company who learn of employee deaths or multiple hospitalizations know that the company must make a timely report to OSHA.

Section 1904.40 Providing Records to Government Representatives

Under the final rule, employers must provide a complete copy of any records required by Part 1904 to an authorized government representative, including the Form 300 (Log), the Form 300A(Summary), the confidential listing of privacy concern cases along with the names of the injured or ill privacy case workers, and the Form 301 (Incident Report), when the representative asks for the records during a workplace safety and health inspection. This requirement is unchanged from the corresponding requirement in OSHA's former recordkeeping rule. However, the

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former rule combined the requirements governing both government inspectors' and employers' rights of access to the records into a single section, section 1904.7 "Access to Records." The final rule separates the two. It places the requirements governing access to the records by government inspectors in Subpart E, along with other provisions requiring employers to submit their occupational injury and illness records to the government or to provide government personnel access to them. Provisions for employee access to records are now in section 1904.35, Employee Involvement, in Subpart D of this final rule.

The final regulatory text of paragraph (a) of section 1904.40 requires an employer to provide an authorized government representative with records kept under Part 1904 within four business hours. As stated in paragraph 1904.40(b)(1), the authorized government representatives who have a right to obtain the Part 1904 records are a representative of the Secretary of Labor conducting an inspection or investigation under the Act, a representative of the Secretary of Health and Human Services (including the National Institute for Occupational Safety and Health (NIOSH) conducting an investigation under Section 20(b) of the Act, or a representative of a State agency responsible for administering a State plan approved under section 18 of the Act. The government's right to ask for such records is limited by the jurisdiction of that Agency. For example, a representative of an OSHA approved State plan could only ask for the records when visiting an establishment within that state.

The final rule allows the employer to take into account difficulties that may be encountered if the records are kept at a location in a different time zone from the establishment where the government representative has asked for the records. If the employer maintains the records at a location in a different time zone, OSHA will use the business hours of the establishment at which the records are located when calculating the deadline, as permitted by paragraph 1904.40(b)(2).

The former rule. Paragraph 1904.7(a) of the former OSHA recordkeeping rule required employers to provide authorized government representatives with access to the complete Form 200, without the removal of any information (unredacted). That paragraph read as follows:

> Each employer shall provide, upon request, records provided for in §§ 1904.2, 1904.4, and 1904.5, for inspection and copying by any representative of the Secretary of Labor for the purpose of carrying out the provisions of the Act, and by representatives of the Secretary of Health, Education, and Welfare during any investigation under section 20(b) of the Act, or by any representative of a State accorded jurisdiction for occupational safety and health inspections or for statistical compilation under sections 18 and 24 of the Act.

The proposal. The proposed regulation was consistent with OSHA's former recordkeeping regulation in that it continued to require employers to provide government representatives with access to the entire OSHA injury and illness Log and Summary (Forms 300 and 300A) and OSHA Incident Record (Form 301). Proposed paragraph 1904.11(a), "Access to Records," read as follows:

> *Government Representatives.* Each employer shall provide, upon a request made in person or in writing, copies of the OSHA Forms 300 and 301 or equivalents, and year-end summaries for their own employees, and injury and illness records for "subcontractor employees" as required under this Part to any authorized representative of the Secretary of Labor or Secretary of Health and Human Services or to any authorized representative of a State accorded jurisdiction for occupational safety and health for the purposes of carrying out the Act.
>
> (1) When the request is made in person, the information must be provided in hard copy (paper printout) within 4 hours. If the information is being transmitted to the establishment from some other location, using telefax or other electronic transmission, the employer may provide a copy to the government representative present at the establishment or to the government representative's office.
>
> (2) When the request is made in writing, the information must be provided within 21 days of receipt of the written request, unless the Secretary requests otherwise.

The proposal thus would have continued to combine the records access provisions for government personnel with the access provisions for employees, former employees and employee representatives. The proposed rule would have modified the former rule in several ways, however (61 FR 4038). First, it would have required the employer to provide copies of the forms, while the former rule simply required the employer to provide records for inspection and copying. Second, the proposal would have required the employer to produce the records within 4 hours, while the former rule did not specify any time period. Third, the proposed rule would have allowed an employer either to provide the records at the inspection location, or to fax the records to the government inspector's home office. This would allow employers to keep their records at a centralized location as long as the government inspector could obtain the information promptly. Fourth, the proposed rule would have required the employer to send Part 1904 information to OSHA within 21 days of the date on which a written request was received from the Agency. This time limit for mailed survey forms was established in section 1904.17 of the former rule and is carried forward in this final rule at section 1904.40.

The proposal also requested comment on situations where the 4-hour requirement might be infeasible and posed several questions for the public to consider:

> OSHA solicits input on these time limitations. Are they reasonable? Should they be shortened or extended? Should the requirement be restricted to business hours, and if so, to the business hours of the establishment to which the records pertain or the establishment where the records are maintained?

Many commenters agreed with OSHA that government representatives should have access to the records themselves (see, *e.g.*, Exs. 15: 78, 163, 218, 359, 369, 405). For example, Alliant Techsystems remarked "[c]opies of this data should be given to OSHA personnel" (Ex. 15: 78). A number of commenters agreed that OSHA personnel should have access to the OSHA 301 records, even though they did not think that employees and their representatives should have access to the Form 301 (see, *e.g.*, Exs. 33, 15: 1, 39, 76, 82, 83, 159, 183, 185, 193, 226, 330, 335, 338, 359, 373, 383, 385, 389, 399, 409, 423). For example, the American Meat Institute (AMI) (Ex. 15: 330) "[b]elieves that it is imperative that personal identifiers be explicitly excluded from information that would be readily available to anyone, with the single exception of an interested government regulator." The Texas Chemical Council (Ex. 15: 159) argued: "[L]ogs with employees" names should only be accessed by selected individuals (i.e., OSHA inspectors, medical personnel, etc.). Posting or viewing of OSHA 300 log or 301 reports without names should be the avenue for employees to access information."

Other commenters disagreed with one or more of the proposed access provisions (see, *e.g.*, Exs. 25, 27, 15: 13, 22, 39, 60, 82, 100, 102, 105, 111, 117, 119, 124, 139, 142, 154, 170, 174, 181, 182, 183, 193, 215, 239, 258, 277, 294, 297, 305, 313, 315, 317, 318, 346, 347, 352, 353, 359, 375, 378, 390, 392, 393, 395, 397, 399, 409, 425, 430, 440.) These commenters raised a wide range of issues. These included the right of OSHA inspectors to access the records; employers' Fourth Amendment rights; the way the government handles

information in its possession; employee privacy concerns; and the proposed requirement to produce the records within 4 hours. On the right of OSHA inspectors to access the records, for example, the Douglas Battery Manufacturing Company (Ex. 15: 82) stated:

> [n]one of these records should be * * * used to conduct an OSHA compliance inspection. Such action would be in direct conflict with the purpose of the OSHA log which is to track injury and illness trends so corrective action can be taken by the employer.

OSHA does not agree with this view, because government inspectors conducting workplace safety and health inspections need these records to carry out the purposes of the Act, i.e., to identify hazards that may harm the employees working there. The Part 1904 records provide information about how workers are injured or made ill at work and help guide the inspector to the hazards in the workplace that are causing injury and illness. Although these records may not cover all hazards that exist in a particular workplace, they help the inspector to identify hazards more completely during an inspection.

Fourth amendment issues. A number of commenters argued that the regulatory requirement to provide records to a government inspector violated Fourth Amendment guarantees against unreasonable searches and the right to demand a warrant or subpoena before the government can search a citizen's property (see, *e.g.*, Exs. 25, 27, 15: 124, 139, 154, 174, 193, 215, 258, 305, 315, 318, 346, 375, 390, 392 395, 397). For example, the Workplace Safety and Health Council (Ex. 15: 313) stated:

> [t]his provision would require employers to give OSHA a copy of a Form 300 and 301. This proposal flies in the face of court decisions holding that employers may not be penalized for declining to provide current Form 101 upon request and that, to gain access to them, OSHA must proceed by subpoena or inspection warrant. Secretary v. Taft Broadcasting Co., 849 F.2d 990 (6th Cir. 1988); *Brock* v. *Emerson Electric Co.*, 834 F.2d 994 (11th Cir. 1987). These decisions are based on an employer's constitutional rights and they are not subject to change by OSHA regulation.

These commenters appear to be arguing that including a subpoena or warrant enforcement mechanism in the text of the rule is necessary to adequately protect their Fourth Amendment right to privacy. This is not the case, however. The Fourth Amendment protects against "unreasonable" intrusions by the government into private places and things. Reporting rules that do not depend on subpoena or warrant powers are not "unreasonable" per se. *See e.g., California Bankers Ass'n* v. *Shultz*, 416 U.S. 21, 67 (1974) (upholding reporting regulation issued under the Bank Secrecy Act of 1970 that did not provide for subpoenas or warrants where the "information was sufficiently described and limited in nature and sufficiently related to a tenable Congressional determination" that the information would have a high degree of usefulness in criminal, tax, or regulatory investigations or proceedings).

In any event, the text of the rule is silent as to the enforcement mechanism OSHA will use in what OSHA hopes will be the rare case in which an employer does not provide a copy of the records on request. OSHA may proceed by applying for a warrant, or by administrative subpoena, or by citation where doing so is consistent with the Fourth Amendment. OSHA notes that employers have a Fourth Amendment right to require a warrant before an OSHA representative may physically enter a business establishment for an inspection.

The totality of circumstances surrounding a warrantless or "subpoena-less" administrative investigation or investigation program determines its reasonableness. For example, in *McLaughlin* v. *A.B. Chance*, 842 F.2d at 727 (4th Cir. 1988), the Fourth Circuit upheld a records access citation against an employer who refused an OSHA inspector access to its OSHA Logs and forms on the ground that it had a right to insist on a warrant or subpoena; the Court held that the inspector had such a right because a summary of the information was posted annually on the employee bulletin board and the inspector was lawfully on the premises to investigate a safety complaint. In *New York* v. *Burger*, 482 U.S. 691, 702–703 (1987), the Supreme Court noted that agencies may gather information without a warrant, subpoena, or consent if the information would serve a substantial governmental interest, a warrantless (or subpoena-less) inspection is necessary to further the regulatory scheme, and the agency acts pursuant to an inspection program that is limited in time, place, and scope. The *Burger* court upheld a warrantless inspection of records during an administrative inspection of business premises. See also *Kings Island* (noting that under *Burger* a warrantless or subpoena-less inspection of records might be reasonable, but concluding that the facts of the case did not satisfy *Burger* analysis); *Emerson Electric* (noting that under *California Bankers* an agency may gain access to information without a subpoena or warrant but concluding that the facts of that case were not comparable to those reviewed in *California Bankers*).

Given that some warrantless and subpoena-less searches during an OSHA inspection may be reasonable while others may not, depending on the circumstances of the individual inspection, OSHA has decided not to include a subpoena or warrant enforcement mechanism in the text of the rule. However, OSHA will continue to enforce the rule within the parameters of applicable court decisions.

Privacy of medical records. A number of commenters questioned the right of the government to access information in the records because of privacy concerns about medical records (see, *e.g.*, Exs. 27, 15: 13, 22, 39, 60, 82, 117, 119, 142, 183, 359, 378, 392, 399.) The National Association of Manufacturers (NAM) (Ex. 15: 142) stated that "[t]he privacy interference as proposed that opens up medical records to most anyone is inconceivable, and should be eliminated." The National Oilseed Processors Association (Ex. 15: 119) recommended:

> [t]he issue of privacy is an important one that should be handled carefully and with sensitivity to individual rights. We believe that the release of medical records of a specific employee should only be done after the employee whose records may be released has provided written permission to the employer to do so.

This section of the final rule does not give unfettered access to the records by the public, but simply allows a government inspector to use the records during the course of a safety and health inspection. As discussed above in the section covering access to the records for employees, former employees, and employee representatives (Section 1904.35), OSHA does not consider the Forms 300 and 301 to be medical records, for the following reasons. First, they do not have to be completed by a physician or other licensed health care professional. Second, they do not contain the detailed diagnostic and treatment information usually found in medical records. Finally, the injuries and illnesses found in the records are usually widely known among other employees at the workplace where the injured or ill worker works; in fact, these co-workers may even have witnessed the accident that gave rise to the injury or illness.

OSHA does not agree that its inspectors should be required to obtain permission from all injured or ill employees before accessing the full records. Gaining this permission would make it essentially impossible to obtain

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full access to the records, which is needed to perform a meaningful workplace investigation. For example, an inspector would not be able to obtain the names of employees who were no longer working for the company to perform follow-up interviews about the specifics of their injuries and illnesses. The names of the injured or ill workers are needed to allow the government inspector to interview the injured and ill workers and determine the hazardous circumstances that led to their injury or illness. The government inspector may also need the employee's names to access personnel and medical records if needed (medical records can only be accessed after the inspector obtains a medical access order). Additionally, refusing the inspector access to the names of the injured and ill workers would effectively prohibit any audit of the Part 1904 records by the government, a practice necessary to verify the accuracy of employer recordkeeping in general and to identify problems that employers may be having in keeping records under OSHA's recordkeeping rules. Adopting the inefficient access method suggested by these commenters would also place a substantial administrative burden on the employer, the employees, and the government. Further, since OSHA inspectors do not allow others to see the medical records they have accessed, the privacy of employees is not compromised by CSHO access to the records.

Time for response to requests for records. Paragraphs 1904.40(a) and (b) of the final rule require records to be made available to a government inspector within 4 business hours of an oral request for the records, using the business hours of the establishment at which the records are located.

A number of commenters opposed the proposed 4-hour records production requirement as being unreasonable and burdensome (see, *e.g.*, Exs. 15: 89, 182, 185, 204, 213, 226, 260, 262, 265, 277, 294, 297, 317, 324, 348, 392, 401, 409, 425). Several of these commenters recommended longer intervals, ranging from 8 hours (see, *e.g.*, Exs. 15: 9, 133, 204, 271, 294, 343), the "next business day," or 24 hours (see, *e.g.*, Exs. 15: 200, 225, 277, 394, 425), 72 hours (see, *e.g.*, Exs. 15: 65, 154), 6 days (Ex. 15: 226), and 21 days (Ex. 15: 317). On the other hand, some commenters were concerned that access not be unduly delayed (see, *e.g.*, Exs. 15: 350, 369, 418, 429). Two commenters (Exs. 15: 418, 429) recommended that the 4-hour requirement be reduced to two hours, except when the request would extend the reply period beyond regular business hours, when 4 hours would be acceptable.

OSHA has concluded that 4 hours is a reasonable and workable length of time for employers to respond to governmental requests for records. The 4-hour time period for providing records from a centralized source strikes a balance between the practical limitations inherent in record maintenance and the government official's need to obtain these records and use the information to conduct a workplace inspection.

Some commenters noted that temporary computer or fax failures could interfere with an employer's ability to comply with the 4-hour requirement (see, *e.g.*, Exs. 15: 203, 254, 423). One commenter felt that additional time should be given to employers if equipment failure prevented the retrieval of the records within four hours (Ex. 15: 423). The American Society of Safety Engineers (ASSE) questioned whether four hours is a reasonable time frame for employers who use independent third parties to maintain their records (Ex. 15: 182).

Several commenters raised concerns that other difficulties might make it difficult to produce the records in the allotted time. Some noted that the 4-hour time limit might not be adequate for large facilities with voluminous records (see, *e.g.*, Exs. 15: 181, 297, 425). For example, the American Automobile Manufacturers Association (AAMA) (Ex. 15: 409) stated:

> [m]any of our members' locations have only one medical person working, and to disrupt the normal medical care of injured or ill employees to produce records within a four hour period is not in the best interests of the health and safety of all concerned. Many additional factors must be taken into account in terms of the production of records such as locating the files, copying the files, having appropriate staffing to do the copying, and if the records are on a computer, the computer must not be on down time.

OSHA believes that it is essential for employers to have systems and procedures that can produce the records within the 4-hour time. However, the Agency realizes that there may be unusual or unique circumstances where the employer cannot comply. For example, if the records are kept by a health care professional and that person is providing emergency care to an injured worker, the employer may need to delay production of the records. In such a situation, the OSHA inspector may allow the employer additional time.

If a government representative requests records of an establishment, but those records are kept at another location, the 4-hour period can be measured in accordance with the normal business hours at the location where the records are being kept. Some commenters observed that personnel at the centralized location might not be available to respond to requests if the 4-hour period extended outside the regular business hours of that location (see, *e.g.*, Exs. 15: 105, 111, 159, 170, 225, 239, 272, 294, 303, 332, 336, 343, 356, 359, 389, 393, 430). This problem could arise under two different scenarios. First, if the centralized location were in a different time zone than the site whose records are requested, the business hours of the respective locations may differ by three or even more hours. Second, the business hours of a manufacturing plant or a construction site might differ from the business hours of the company's central offices, even if the operations are in the same time zone. Under the final rule, the employer has 4 regular business hours at the location at which the records are kept in which to comply with the request of a government representative.

OSHA has designed the final rule to give each employer considerable flexibility in maintaining records. It permits an employer to centralize its records, to use computer and facsimile technologies, and to hire a third party to keep its records. However, an employer who chooses these options must also ensure that they are sufficiently reliable to comply with this rule. In other words, the flexibility provided to employers for recordkeeping must not impede the Agency's ability to obtain and use the records.

Provide copies. Several commenters objected to the proposed requirement that employers provide copies of the records to government personnel without charging the government to do so (see, *e.g.*, Exs. 15: 69, 86, 100, 179, 347, 389, 397, 409). Most of these commenters cited the paperwork burden on employers as the primary reason for objecting. Several suggested that the employer be allowed to charge for copies, or that the government representative make their own copies (see, *e.g.*, Exs. 15: 179, 347, 389, 409). This view was expressed in a comment from the Ford Motor Company (Ex. 15: 347):

> [a]n undue burden may be placed on the establishment should a compliance officer ask for an inordinate amount of records or records which will not be utilized. Authorized government representatives should make their own copies and therefore will be diligent in asking only for those materials they will be utilizing.

OSHA's experience has been that the vast majority of employers willingly provide copies to government representatives during safety and health inspections. Making copies is a routine office function in almost every modern workplace. With the widespread availability of copying technology, most workplaces have copy machines on-site or readily available. The cost of providing copies is minimal, usually less than five cents per copy. In addition, the government representative needs to obtain copes of records promptly, so that he or she can analyze the data and identify workplace hazards. Therefore, in this final rule, OSHA requires the employer to provide copies of the records requested to authorized government representatives.

Other Section 1904.40 issues. Commenters raised additional issues about providing occupational illness and injury information to OSHA during an inspection. The American Ambulance Association (Ex. 15: 226) recommended that OSHA "[p]lace greater emphasis on the fact that employers do not have to provide Forms 300 and 301 unless OSHA specifically asks for their submission." OSHA believes that the final rule is clear on this point, because it states that the employer must provide the records only when asked by an authorized government representative to do so.

Several commenters stated that all requests for occupational safety and health information should be made in writing (see, *e.g.*, Exs. 15: 69, 317, 397). OSHA believes that it is neither appropriate nor necessary to require a government representative to request the information in writing. Government officials who are conducting workplace inspections may ask for any number of materials or ask verbally for information about various matters during the course of an inspection. Putting these requests in writing would impede workplace inspections and delay efforts to address workplace hazards.

Section 1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers

Section 1904.41 of this final rule replaces section 1904.17, "Annual OSHA Injury and Illness Survey of Ten or More Employers," of the former rule issued on February 11, 1997. The final rule does not change the contents or policies of the corresponding section of the former rule in any way. Instead, the final rule simply rephrases the language of the former rule in the plain language question-and-answer format used in the rest of this rule. The following table shows the text of Section 1904.17 of the former rule, followed by the text of Section 1904.41 of this final rule.

Former sections 1904.17	New section 1904.41
"Annual OSHA Injury and Illness Survey of Ten or More Employers"	"Annual OSHA Injury and Illness Survey of Ten or more Employers"
1904.17(a) Each employer shall, upon receipt of OSHA's Annual Survey Form, report to OSHA or OSHA's designee the number of workers it employed and number of hours worked by its employees for periods designated in the Survey Form and such information as OSHA may request from records required to be created and maintained pursuant to 29 CFR Part 1904.	1904.41(a) Basic Requirement. If you receive OSHA's annual survey from, you must fill it out and send it to OSHA or OSHA's designee, as stated on the survey form. You must report the following information for the year described on the form: (1) the number of workers you employed; (2) the number of hours worked by your employees; and (3) the requested information from the records that you keep under Part 1904.
No comparable provision	1904.41(b)(1) Does every employer have to send data to OSHA? No. Each year, OSHA sends injury and illness survey forms to employers in certain industries. In any year, some employers will receive an OSHA survey form and others will not. You do not have to send injury and illness data to OSHA unless you receive a survey form.
1904.17(b) Survey reports shall be transmitted to OSHA by mail or other remote transmission authorized by the Survey Form within the time period specified in the Survey Form, or 30 calendar days, whichever is longer..	1904.41(b)(2) How quickly do I need to respond to an OSHA survey form? You must send the survey reports to OSHA, or OSHA's designee, by mail or other means described in the survey form, within 30 calendar days, or by the date stated in the survey form, whichever is later.
1904.17(c) Employers exempted from keeping injury and illness records under §§ 1904.15 and 1904.16 shall maintain injury and illness records required by §§ 1904.2 and 1904.4, and make Survey Reports pursuant to this Section, upon being notified in writing by OSHA, in advance of the year for which injury and illness records will be required, that the employer has been selected to participate in an information collection.".	1904.41(b)(3) Do I have to respond to an OSHA survey form if I am normally exempt from keeping OSHA injury and illness records? Yes. Even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, OSHA may inform you in writing that it will be collecting injury and illness information from you in the following year. If you receive such a survey form, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make survey reports for the year covered by the survey.
1904.17(d) Nothing in any State plan approved under Section 18 of the Act shall affect the duties of employers to comply with this section..	1904.41(b)(4) Do I have to answer the OSHA survey form if I am located in a State-Plan State? Yes. All employers who receive survey forms must respond to the survey, even those in State-Plan States
1904.17(e) Nothing in this section shall affect OSHA's exercise of its statutory authorities to investigate conditions related to occupational safety and health.	1904.41(b)(5) Does this section affect OSHA's authority to inspect my workplace? No. Nothing in this section affects OSHA's statutory authority to investigate conditions related to occupational safety and health.

Thus, section 1904.41 of the final rule merely restates, in a plain language question-and-answer format, the requirements of former rule section 1904.17, with one minor change. The final rule adds paragraph 1904.41(b)(1), which contains no requirements or prohibitions but simply informs the employer that there is no need to send in the Part 1904 injury and illness data until the government asks for it.

Section 1904.42 Requests From the Bureau of Labor Statistics for Data

Section 1904.42 of the final rule derives from the subpart of the former rule titled "Statistical Reporting of Occupational Injuries and Illnesses." The former rule described the Bureau of Labor Statistics annual survey of occupational injuries and illnesses, discussed the duty of employers to answer the survey, and explained the effect of the BLS survey on the States operating their own State plans.

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Both OSHA and the BLS collect occupational injury and illness information, each for separate purposes. The BLS collects data from a statistical sample of employers in all industries and across all size classes, using the data to compile the occupational injury and illness statistics for the Nation. The Bureau gives each respondent a pledge of confidentiality (as it does on all BLS surveys), and the establishment-specific injury and illness data are not shared with the public, other government agencies, or OSHA. The BLS's sole purpose is to create statistical data.

OSHA collects data from employers from specific size and industry classes, but collects from each and every employer within those parameters. The establishment-specific data collected by OSHA are used to administer OSHA's various programs and to measure the performance of those programs at individual workplaces.

OSHA proposed to replace sections 1904.20, .21, and .22 of the former rule with a single reporting provision that would combine the requirements for BLS and OSHA survey reports into a single section (61 FR 4039). However, since the time of the proposal, OSHA has determined that the BLS and OSHA information collections warrant separate coverage because they occur at different times and collect data for different purposes. When OSHA published final Section 1904.17, Annual OSHA Injury and Illness Surveys (62 FR 6434, Feb. 11, 1997), the Agency made clear that its surveys are separate from any collections of injury and illness data by the BLS. Accordingly, the final rule includes two separate sections: section 1904.41, which is devoted entirely to the collection of employer-generated injury and illness data by OSHA, and section 1904.42, which is devoted to the collection of such data by the Bureau of Labor Statistics.

Many commenters discussed the need for accurate government statistics about occupational death, injury and illness; however, very few of the comments specifically addressed the proposed provisions relating to employer participation in the BLS survey. The comments OSHA did receive on this point addressed the burden imposed by requests for employer records and the potential duplication between the data collections of OSHA and the BLS (see, *e.g.*, Exs. 15: 9, 163, 184, 390, 402). The comments of the U.S. West Company (Ex. 15: 184) are typical:

> [U]S WEST acknowledges the need for the Secretary of Labor to periodically request reports, including recordkeeping data, from employers. However, US WEST does ask that OSHA carefully consider the need for such reports and work to streamline the process and reduce redundancies. Specifically, US WEST requests that OSHA move to implement systems that will allow employers to electronically provide data, such as the data requested in the BLS Survey of Occupational Injuries and Illnesses. Such a method will be more effective, in terms of receiving consistently formatted data, and will be more cost efficient for both employers and the Department of Labor.
>
> In addition, the DOL should work to avoid duplicate internal efforts that are costly and time-consuming for the government and employers. By way of example, US WEST has in the past received requests from BLS to complete the Survey and from OSHA to complete the Occupational Injury and Illness Report (Form 196B) for the same facility. Both surveys collect similar information.

OSHA and the BLS have worked together for many years to reduce the number of establishments that receive both surveys. These efforts have largely been successful. However, OSHA and BLS use different databases to select employers for their surveys. This makes it difficult to eliminate the overlap completely. We are continuing to work on methods to reduce further the numbers of employers who receive both BLS and OSHA survey requests.

OSHA and BLS are also pursuing ways to allow employers to submit occupational injury and illness data electronically. In 1998, the OSHA survey allowed employers for the first time to submit their data electronically, and this practice will continue in future OSHA surveys. The BLS has not yet allowed electronic submission of these data due to security concerns, but continues to search for appropriate methods of electronic submission, and hopes to allow it in the near future.

In this final rule, OSHA has replaced former sections 1904.20 to 1904.22 with a new section 1904.42, which is stated in the form of a basic requirement and four implementing questions and answers about the BLS survey. Former section 1904.20 "Description of statistical program," is not carried forward in the final rule because it merely described BLS's general legal authority and sampling methodology and contained no regulatory requirements.

Section 1904.21 of the former rule, titled "Duties of employers," required an employer to respond to the BLS annual survey: "Upon receipt of an Occupational Injuries and Illnesses Survey Form, the employer shall promptly complete the form in accordance with the instructions contained therein, and return it in accordance with the aforesaid instructions."

Paragraphs 1904.42(a), (b)(1) and (b)(2) of the final rule being published today replace former section 1904.21. Paragraph 1904.42(a) states the general obligation of employers to report data to the BLS or a BLS designee. Paragraph 1904.42(b)(1) states that some employers will receive a BLS survey form and others will not, and that the employer should not send data unless asked to do so. Paragraph 1904.42(b)(2) directs the employer to follow the instructions on the survey form when completing the information and return it promptly.

Paragraph 1904.42(b)(3) of this final rule notes that the BLS is authorized to collect data from all employers, even those who would otherwise be exempt, under section 1904.1 to section 1904.3, from keeping OSHA injury and illness records. This enables the BLS to produce comprehensive injury and illness statistics for the entire private sector. Paragraph 1904.42(b)(3) combines the requirements of former rule paragraphs 1904.15(b) and 1904.16(b) into this paragraph of the final rule.

In response to the question "Am I required to respond to a BLS survey form if I am normally exempt from keeping OSHA injury and illness records?," the final rule states "Yes. Even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, the BLS may inform you in writing that it will be collecting injury and illness information from you in the coming year. If you receive such a survey form, you must keep the injury and illness records required by § 1904.4 to § 1904.12 and make survey reports for the year covered by the survey."

Paragraph 1904.42(b)(4) of this final rule replaces section 1904.22 of the former rule. It provides that employers in the State-plan States are also required to fill out and submit survey forms if the BLS requests that they do so. The final rule thus specifies that the BLS has the authority to collect information on occupational fatalities, injuries and illnesses from: (1) employers who are required to keep records at all times; (2) employers who are normally exempt from keeping records; and (3) employers under both Federal and State plan jurisdiction. The information collected in the annual survey enables BLS to generate consistent statistics on occupational death, injury and illness for the entire Nation.

Subpart F. Transition From the Former Rule to the New Rule

The transition interval from the former rule to the new rule involves several issues, including training and outreach to familiarize employers and employees about the now forms and requirements, and informing employers in newly covered industries that they are now required to keep OSHA Part 1904 records. OSHA intends to make a major outreach effort, including the development of an expert software system, a forms package, and a compliance assistance guide, to assist employers and recordkeepers with the transition to the new rule. An additional transition issue for employers who kept records under the former system and will also keep records under the new system is how to handle the data collected under the former system during the transition year. Subpart F of the final rule addresses some of these transition issues.

Subpart F of the new rule (sections 1904.43 and 1904.44), addresses what employers must do to keep the required OSHA records during the first five years the new system required by this final rule is in effect. This five-year period is called the transition period in this subpart. The majority of the transition requirements apply only to the first year, when the data from the previous year (collected under the former rule) must be summarized and posted during the month of February. For the remainder of the transition period, the employer is simply required to retain the records created under the former rule for five years and provide access to those records for the government, the employer's employees, and employee representatives, as required by the final rule at sections 1904.43 and 44.

The proposal did not spell out the procedures that the employer would have to follow in the transition from the former recordkeeping rule to the new rule. OSHA realizes that employers will have questions about how they are required to handle the data collected under the former system during this transition interval. The final rule maintains the basic structure and recordkeeping practices of the former system, but it employs new forms and somewhat different requirements for recording, maintaining, posting, retaining and reporting occupational injury and illness information. Information collection and reporting under the final rule will continue to be done on a calendar year basis. The effective date for the new rule is January 1, 2001. OSHA agrees with the commenter who stated that beginning the new recordkeeping system on "Any other date [but January 1] would create an insurmountable number of problems * * *" (Ex. 27). Accordingly, employers must begin to use the new OSHA 300 and 301 forms and to comply with the requirements of this final rule on January 1, 2002.

Some commenters stressed the need for an orderly transition from the former system to the new system, and pointed out that adequate lead time is needed to understand and assimilate the changes, make adjustments in their data management systems, and train personnel who have recordkeeping responsibilities (see, *e.g.*, Exs. 15: 9, 36, 119, 347, 409).

The transition also raises questions about what should be done in the year 2002 with respect to posting, updating, and retaining the records employers compiled in 2001 and previous years. In the transition from the former rule to the present rule, OSHA intends employers to make a clean break with the former system. The new rule will replace the old rule on the effective date of the new rule, and OSHA will discontinue the use of all previous forms, interpretations and guidance on that date (see, *e.g.*, Exs. 21, 22, 15: 184, 423). Employers will be required to prepare a summary of the OSHA Form 200 for the year 2001 and to certify and post it in the same manner and for the same time (one month) as they have in the past. The following time table shows the sequence of events and postings that will occur:

Date	Activity
2001	Employers keep injury and illness information on the OSHA 200 form
January 1, 2002	Employers begin keeping data on the OSHA 300 form
February 1, 2002	Employers post the 2001 data on the OSHA 200 Form
March 1, 2002	Employers may remove the 2001 posting
February 1, 2003	Employers post the 2002 data on the OSHA 300A form
May 1, 2003	Employers may remove the 2002 posting

The final rule's new requirements for dual certification and a 3-month posting period will not apply to the Year 2000 Log and summary. Employers still must retain the OSHA records from 2001 and previous years for five years from the end of the year to which they refer. The employer must provide copies of the retained records to authorized government representatives, and to his or her employees and employee representatives, as required by the new rule.

However, OSHA will no longer require employers to update the OSHA Log and summary forms for years before the year 2002. The former rule required employers to correct errors to the data on the OSHA 200 Logs during the five-year retention period and to add new information about recorded cases. The former rule also required the employer to adjust the totals on the Logs if changes were made to cases on them (Ex. 2, p. 23). OSHA believes it would be confusing and burdensome for employers to update and adjust previous years' Logs and Summaries under the former system at the same time as they are learning to use the new OSHA occupational injury and illness recordkeeping system.

Subpart G. Definitions

The Definitions section of the final rule contains definitions for five terms: "the Act," "establishment," "health care professional," "injury and illness," and "you." To reduce the need for readers to move back and forth from the regulatory text to the Definitions section of this preamble, all other definitions used in the final rule are defined in the regulatory text as the term is used. OSHA defines the five terms in this section here because they are used in several places in the regulatory text.

The Act

The Occupational Safety and Health Act of 1970 (the "OSH Act") is defined because the term is used in many places in the regulatory text. The final rule's definition is essentially identical to the definition in the proposal. OSHA received no comments on this definition. The definition of "the Act" follows:

The Act means the Occupational Safety and Health Act of 1970 (84 Stat. 1590 et seq., 29 U.S. 651 et seq.), as amended. The definitions contained in section (3) of the Act and related interpretations shall be applicable to such terms when used in this Part 1904.

Employee

The proposed rule defined "employee" as that term is defined in section 3 of the Act and added a Note describing the various types of employees covered by this

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recordkeeping rule (*e.g.*, "leased employees," "seasonal employees"). In the final rule, OSHA has decided that it is not necessary to define "employee" because the term is defined in section 3 of the Act and is used in this rule in accordance with that definition.

Employer

The proposed rule included a definition of "employer" that was taken from section 3 of the Act's definition of that term. Because the final rule uses the term "employer" just as it is defined in the Act, no separate definition is included in the final rule.

Establishment

The final rule defines an establishment as a single physical location where business is conducted or where services or industrial operations are performed. For activities where employees do not work at a single physical location, such as construction; transportation; communications, electric, gas and sanitary services; and similar operations, the establishment is represented by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities.

The final rule also addresses whether one business location can include two or more establishments. Normally, one business location has only one establishment. However, under limited conditions, the employer may consider two or more separate businesses that share a single location to be separate establishments for recordkeeping purposes. An employer may divide one location into two or more establishments only when: each of the proposed establishments represents a distinctly separate business; each business is engaged in a different economic activity; no one industry description in the Standard Industrial Classification Manual (1987) applies to the joint activities of the proposed establishments; and separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information. For example, if an employer operates a construction company at the same location as a lumber yard, the employer may consider each business to be a separate establishment.

The final rule also deals with the opposite situation, and explains when an establishment includes more than one physical location. An employer may combine two or more physical locations into a single establishment only when the employer operates the locations as a single business operation under common management; the locations are all located in close proximity to each other; and the employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other kinds of business information. For example, one manufacturing establishment might include the main plant, a warehouse serving the plant a block away, and an administrative services building across the street. The final rule also makes it clear that when an employee telecommutes from home, the employee's home is not a business establishment for recordkeeping purposes, and a separate OSHA 300 Log is not required.

The definition of "establishment" is important in OSHA's recordkeeping system for many reasons. First, the establishment is the basic unit for which records are maintained and summarized. The employer must keep a separate injury and illness Log (the OSHA Form 300), and prepare a single summary (Form 300A), for each establishment. Establishment-specific records are a key component of the recordkeeping system because each separate record represents the injury and illness experience of a given location, and therefore reflects the particular circumstances and hazards that led to the injuries and illnesses at that location. The establishment-specific summary, which totals the establishment's injury and illness experience for the preceding year, is posted for employees at that establishment and may also be collected by the government for statistical or administrative purposes.

Second, the definition of establishment is important because injuries and illnesses are presumed to be work-related if they result from events or exposures occurring in the work environment, which includes the employer's establishment. The presumption that injuries and illnesses occurring in the work environment are by definition work-related may be rebutted under certain circumstances, which are listed in the final rule and discussed in the section of this preamble devoted to section 1904.5, Determination of work-relatedness. Third, the establishment is the unit that determines whether the partial exemption from recordkeeping requirements permitted by the final rule for establishments of certain sizes or in certain industry sectors applies (see Subpart B of the final rule). Under the final rule's partial exemption, establishments classified in certain Standard Industrial Classification codes (SIC codes) are not required to keep injury and illness records except when asked by the government to do so. Because a given employer may operate establishments that are classified in different SIC codes, some employers may be required to keep OSHA injury and illness records for some establishments but not for others, *e.g.* if one or more of the employer's establishments falls under the final rule's partial exemption but others do not.

Fourth, the definition of establishment is used to determine which records an employee, former employee, or authorized employee representative may access. According to the final rule, employees may ask for, and must be given, injury and illness records for the establishment they currently work in, or one they have worked in, during their employment.

The proposed rule defined an establishment as:

(1) A single physical location that is in operation for 60 calendar days or longer where business is conducted or where services or industrial operations are performed. (For example: A factory, mill, grocery store, construction site, hotel, farm, ranch, hospital, central administrative office, or warehouse.) The establishment includes the primary work facility and other areas such as recreational and storage facilities, restrooms, hallways, etc. The establishment does not include company parking lots.

(2) When distinct and separate economic activities are performed at a single physical location, each activity may represent a separate establishment. For example, contract construction activities conducted at the same physical location as a lumber yard may be treated as separate establishments. According to the Standard Industrial Classification (SIC) Manual, Executive Office of the President, Office of Management and Budget, (1987) each distinct and separate activity should be considered an establishment when no one industry description from the SIC manual includes such combined activities, and the employment in each such economic activity is significant, and separate reports can be prepared on the number of employees, their wages and salaries, sales or receipts, or other types of establishment information.

The final rule modifies this definition in several ways: it deletes the "60 days in operation" threshold, adds language to the definition to address the concerns of employers who operate geographically dispersed establishments, describes in greater detail what OSHA means by separate establishments at one location, and defines which locations must be considered part of the establishment, and which employee activities must be considered work-related, for

recordkeeping purposes. Each of these topics is discussed below.

Subpart G of the final rule defines "establishment" as "a single physical location where business is conducted or where services or industrial operations are performed. For activities such as construction; transportation; communications, electric and gas utility, and sanitary services; and similar operations, the establishment is represented for recordkeeping purposes by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities." This part of the definition of "establishment" provides flexibility for employers whose employees (such as repairmen, meter readers, and construction superintendents) do not work at the same workplace but instead move between many different workplaces, often in the course of a single day.

How the definition of "establishment" must be used by employers for recordkeeping purposes is set forth in the answers to the questions posed in this paragraph of Subpart G:

(1) Can one business location include two or more establishments?

(2) Can an establishment include more than one physical location?

(3) If an employee telecommutes from home, is his or her home considered a separate establishment?

The employer may consider two or more economic activities at a single location to be separate establishments (and thus keep separate OSHA Form 300s and Form 301s for each activity) only when: (1) Each such economic activity represents a separate business, (2) no one industry description in the Standard Industrial Classification Manual (1987) applies to the activities carried out at the separate locations; and (3) separate reports are routinely prepared on the number of employees, their wages and salaries, sales or receipts, and other business information. This part of the definition of "establishment" allows for separate establishments when an employer uses a common facility to house two or more separate businesses, but does not allow different departments or divisions of a single business to be considered separate establishments. However, even if the establishment meets the three criteria above, the employer may, if it chooses, consider the physical location to be one establishment.

The definition also permits an employer to combine two or more physical locations into a single establishment for recordkeeping purposes (and thus to keep only one Form 300 and Form 301 for all of the locations) only when (1) the locations are all geographically close to each other, (2) the employer operates the locations as a single business operation under common management, and (3) the employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other business information. However, even for locations meeting these three criteria, the employer may, if it chooses, consider the separate physical locations to be separate establishments. This part of the definition allows an employer to consider a single business operation to be a single establishment even when some of his or her business operations are carried out on separate properties, but does not allow for separate businesses to be joined together. For example, an employer operating a manufacturing business would not be allowed to consider a nearby storage facility to be a separate establishment, while an employer who operates two separate retail outlets would be required to consider each to be a separate establishment.

OSHA received many comments on the proposed definition of "establishment." These are organized by topic and discussed below.

How long must an establishment exist to have a separate OSHA Log. The proposed rule would have required an establishment to be in operation for 60 days to be considered an "establishment" for recordkeeping purposes. Under the proposed definition, employers with establishments in operation for a lesser period would not have been required to keep a log for that operation. The proposed 60-day threshold would have changed the definition of "establishment" used in OSHA's former recordkeeping rule, because that rule included a one-year-in-operation threshold for defining establishments required to keep a separate OSHA log (Ex. 2, p. 21). The effect of the proposed change in the threshold would have been to increase the number of short-duration operations required to maintain separate injury and illnesses records. In particular, the proposed change would have affected construction employers and utility companies.

The majority of the comments OSHA received on this issue opposed the decrease in the duration of the threshold from one year to 60 calendar days. A few commenters, however, supported the proposed 60-day rule (see, *e.g.*, Exs. 15: 9, 133, 310, 369, 425), and some urged OSHA to adopt an even shorter time-in-operation threshold (see, *e.g.*, Exs. 15: 369, 418, 429). Typical of the comments favoring an even shorter period was one from the International Brotherhood of Teamsters (IBT):

> [t]he International Brotherhood of Teamsters is encouraged by OSHA's modification to the definition of an establishment, especially reducing the requirement for an operation in a particular location from one year to sixty days. The IBT would strongly support reducing the requirement to thirty days to cover many low level housing construction sites, and transient operations, similar to mobile amusement parks (Ex. 15: 369).

The AFL–CIO agreed: "* * * [t]he 60-day time period is still too long. We believe that to truly capture a majority of these transient worksites, a 30-day time period would be more realistic. A 30-day time period as the trigger would capture construction activities such as trenching, roofing, and painting projects which will continue to be missed if a 60-day time period is used" (Ex. 15: 418).

Those commenters objecting to the proposed 60-day threshold usually did so on grounds that requiring temporary facilities to maintain records would be burdensome and costly and would not increase the utility of the records (see, *e.g.*, Exs. 21, 15: 21, 43, 78, 116, 122, 123, 145, 170, 199, 213, 225, 254, 272, 288, 303, 304, 305, 308, 338, 346, 349, 350, 356, 358, 359, 363, 364, 375, 389, 392, 404, 412, 413, 423, 424, 433, 437, 443, 475). For example, the Associated Builders and Contractors, Inc. (ABC) remarked:

> ABC agrees with OSHA's sentiment of making injury and illness records useful, but disagrees that sites in existence for as little as 60 days need separate injury and illness records. The redefinition of "establishment" will cause enormous problems for subcontractors in a variety of construction industries. Even employers with small workforces could be on the site of several projects at any one time, and in the course of the year could have sent crews to hundreds of sites. Though they may be on such sites for only brief periods of time, they will be required under this proposal to create separate logs for each site, increasing greatly their paperwork requirements without increasing the amount of information available to their employees. Projects which last less than 90 days do not need separate logs. Requiring separate logs for short-term projects only increases inefficiency and costs, while doing nothing for safety (Ex. 15: 412).

Many of these commenters argued that a 60-day threshold would be especially burdensome if it captured small work sites where posting of the annual summary or mailing the summary to employees would make little sense because so few cases would

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be captured on each Log. The majority of these commenters suggested that OSHA retain the former one-year duration threshold in the definition of establishment (see, *e.g.*, Exs. 15: 78, 123, 225, 254, 305, 356, 389, 404).

Other commenters expressed concern that the proposed 60-day threshold would create an unreasonable burden on employers in service industries like telecommunications and other utilities, whose employees typically report to a fixed location but perform tasks at transient locations that remain in existence for more than 60 days and would thus be classified as new "establishments" for OSHA recordkeeping purposes (see, *e.g.*, Exs. 15: 65, 170, 199, 213, 218, 332, 336, 409, 424).

OSHA has reviewed all of the comments on this issue and has responded by deleting any reference to a time-in-operation threshold in the definition of establishment but specifying a one-year threshold in section 1904.30 of the final rule. In response to comments, OSHA has thus continued the former one-year threshold rather than adopting the 60-day threshold proposed. Under the final rule, employers will be required to maintain establishment-specific records for any workplace that is, or is expected to be, in operation for one year or longer. Employers may group injuries and illnesses occurring to workers who are employed at shorter term establishments onto one or more consolidated logs. These logs may cover the entire company; geographic regions such as a county, state or multi-state area; or individual divisions of the company. For example, a construction company with multi-state operations might have separate logs for each state to show the injuries and illnesses of short-term projects, as well as separate logs for each construction project expected to last for more than one year.

OSHA finds, based on the record evidence, that the one-year threshold will create useful records for stable establishments without imposing an unnecessary burden on the many establishments that remain in existence for only a few months. OSHA concludes that the one-year threshold and permitting employers to keep one Log for geographically dispersed or short-term facilities will also provide more useful injury and illness records for workers employed in transient establishments. This will be the case because the records will capture more cases, which enhances the informational value of the data and permits analysis of trends.

Geographically Dispersed Workplaces. A number of commenters raised issues of particular importance to the construction and utility industries (see, *e.g.*, Exs. 15: 43, 116, 122, 123, 145, 170, 199, 213, 225, 272, 288, 303, 305, 350, 359, 364, 392, 412, 433, 443). In addition to objections about the 60-days-in-operation threshold in the definition of establishment, these commenters raised concerns about the difficulty of keeping records for a mobile and dispersed workforce. Representative of these comments is the statement by Con Edison (Ex. 15: 213):

> Con Edison believes that OSHA's proposal to tie its redefinition of a permanent establishment to a 60-day time frame, as opposed to the present one-year limit, would be costly, overly burdensome and in some cases unworkable. On many occasions work must be performed on city streets or in out of the way areas during the erection of overhead transmission and distribution lines. These projects may carry on for periods greater than the 60-day period specified above for designation as an establishment. No permanent structures are erected at these sites and to require maintenance of records there is impractical. Con Edison believes that the definition of establishment as set forth in the 1987 Standard Industrial Classification Manual (see below) should apply.
>
> "For activities such as * * * electric * * * and similar physically dispersed operations, establishments are represented by those relatively permanent main or branch offices, terminals, stations, etc. that are (2) the base from which personnel operate to carry out these activities. Hence, the individual sites, projects, fields, networks, lines, or system of such dispersed activities are not ordinarily considered to be establishments." (SIC Manual, 1987, p. 265).

OSHA agrees that the recordkeeping system must recognize the needs of operations of this type and has adopted language in the final rule to provide some flexibility for employers in the construction, transportation, communications, electric and gas utility, and sanitary services industries, as well as other employers with geographically dispersed operations. The final rule specifies, in Subpart G, that employers may consider main or branch offices, terminals, stations, etc. that are either (1) responsible for supervising such activities, or (2) the base from which personnel operate to carry out these activities, as individual establishments for recordkeeping purposes. This addition to the final rule's definition of establishment allows an employer to keep records for geographically dispersed operations using the existing management structure of the company as the recording unit. Use of this option will also mean that each Log will capture more cases, which will, as discussed above, improve the chances of discovering patterns of occupational injury and illness that can be used to make safety and health improvements. At the same time, by requiring records to be kept for any individual construction project that is expected to last for one year or longer, the final rule ensures that useful records are generated for more permanent facilities.

More than one establishment at a single location. OSHA's former rule recognized, for recordkeeping purposes, that more than one establishment can exist at a single location, although most workplaces consist of a single establishment at a single location. The final rule also recognizes that, in some narrowly defined situations, a business may have side-by-side operations at a single location that are operated as separate businesses because they are engaged in different lines of business. In these situations, the Standard Industrial Classification Manual (OMB 1987) allows a single business location to be classified as two separate establishments, each with its own SIC code. Like all government agencies, OSHA follows the OMB classification method and makes allowances for such circumstances.

The proposal stated that distinct, separate economic activities performed at a single physical location may each be classified, for recordkeeping purposes, as a separate establishment. The proposed definition stated that each distinct and separate economic activity may be considered an establishment when (1) no one industry description from the Standard Industrial Classification (SIC) manual includes such combined activities, (2) the employment in each economic activity is significant, and (3) separate reports can be prepared on the number of employees, their wages and salaries, sales or receipts, or other types of establishment information. The final rule is essentially unchanged from the proposal on this point, but the language has been modified to make it clear that the employer may employ this option only in the enumerated circumstances.

Several commenters were in favor of OSHA's proposed definition of separate establishments as places engaged in separate economic activities (see, *e.g.*, Exs. 15: 185, 297, 375) and agreed that when distinct and separate economic activities are performed at a single physical location, each activity should be considered a separate establishment.

Others, however, disagreed with the proposed definition of multiple establishments at a single location (see, *e.g.*, Exs. 15: 194, 305, 322, 346, 347, 348, 389, 409, 424, 431). The comments

of the Ford Motor Company (Ex. 15: 347) and the American Automobile Manufacturing Association (AAMA) (Ex. 15: 409) are representative:

> [a]ll economic activities performed at a single location should be allowed to be placed on a single log. Many of these locations have only one medical department, payroll, or management. At many of these locations, separate reports cannot be prepared on the number of employees per establishment, and at times many of the employees will work at separate sites within the same single physical location. To break down the economic activities to record injuries and illness on different logs is confusing, difficult, and overly burdensome.

United Parcel Service (UPS) (Ex. 15: 424) added:

> [t]he proposal should be amended to make clear that treatment of a different activity as a separate establishment is optional, not mandatory—the proposal currently results in unnecessary ambiguity by saying first that separate activities "may" be separate establishments, and then describing situations in which they "should be" considered an establishment. A requirement that such vaguely defined "economic activities" be treated as separate "establishments" would be mistaken: employers would be left to guess what is an "economic activity" and when it is "separate" from another. Moreover, such mandatory separate recordkeeping would unnecessarily burden employers with determining when separate records are required, and with maintaining such separate records.

These commenters understood the proposed language as requiring employers to keep separate logs if separate economic activities were being conducted at a single establishment; what OSHA intended, and the final rule makes clear in Subpart G, is that an employer whose activities meet the final rule's definition may keep separate logs if he or she chooses to do so. Thus the final rule includes a provision that allows an employer to define a single business location as two separate establishments only under specific, narrow conditions. The final rule allows the employer to keep separate records only when the location is shared by completely separate business operations involved in different business activities (Standard Industrial Classifications) for which separate business records are available. By providing specific, narrow criteria, the final rule reduces ambiguity and confusion about what is required and sets out the conditions that must be met in order for employers to deviate from the one place-one establishment concept.

OSHA expects that the overwhelming majority of workplaces will continue to be classified as one establishment for recordkeeping purposes, and will keep just one Log. However, allowing some flexibility for the rare cases that meet the specified criteria is appropriate. The employer is responsible for determining whether a given workplace meets the criteria; OSHA will consider an employer meeting these criteria to be in compliance with the final rule if he or she keeps one set of records per facility. This policy allows an employer to keep one set of records for a given location and avoid the additional burden or inconvenience associated with keeping separate records.

The McDonnell Douglas Corporation (Ex. 15: 297) and the American Textile Manufacturers Institute (ATMI) (Ex. 15: 156) commented on a different scenario, one in which a single establishment could encompass more than one physical location. ATMI remarked that:

> [O]SHA's definition of establishment as "a single physical location" is too restrictive. We believe that OSHA should be more flexible since many industries have primary facilities with secondary work facilities that have the same local management. For example, in the textile industry, a plant may use a warehouse that is not physically attached but the plant manager is responsible for the both facilities. We suggest that the text of the rule be modified to read: "A single physical location or multiple physical locations under the same management * * *."

OSHA agrees that there are situations where a single establishment that has a satellite operation in close physical proximity to the primary operation may together constitute a single business operation and thus be a single establishment. For example, a business may have a storage facility in a nearby building that is simply an adjunct to the business operation and is not a separate business location.

OSHA believes that there are situations where establishments in separate physical locations constitute a single establishment. However, under the final rule, employers will only be allowed to combine separated physical locations into a single establishment when they operate the combined locations as a single business operation under common management and keep a single set of business records for the combined locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other types of business information.

How OSHA defines an establishment also has implications for the way company parking lots and recreation facilities, such as company-provided gymnasiums, ball fields, and the like are treated for recordkeeping purposes. The 1986 *Guidelines* excluded these areas from the definition of establishment and thus did not require injuries and illnesses occurring to employees at these locations to be recorded unless the employee was actually performing work in those areas (Ex. 2, p. 33). The final rule includes these areas in the definition of establishment but does not require employers to record cases occurring to employees engaged in certain activities at these locations. For example, injuries and illnesses occurring at the establishment while the employee is voluntarily engaged in recreation activities or resulting from a motor vehicle accident while the employee is commuting to or from work would not have to be recorded (see section 1904.5). The following paragraphs discuss OSHA's reasons for taking this approach to the recording of injuries and illnesses occurring in these locations.

Company Parking Lots and Access Roads. Because the former rule excluded company parking lots and access roads from the definition of establishment, injuries and illnesses that occurred to their employees while on such parking lots and access roads were not considered work-related and did not have to be recorded on the Log; the proposed rule would have continued this practice. Many commenters urged OSHA not to consider injuries and illnesses occurring in these locations work-related, principally because, in the view of these commenters, employers have little control over safety and health conditions in their parking lots (see, *e.g.*, Exs. 15: 9, 65, 78, 95, 105, 107, 111, 119, 136, 137, 141, 154, 159, 194, 203, 204, 218, 224, 225, 260, 262, 265, 266, 277, 278, 288, 304, 337, 389, 401). The comments of the American Gas Association (AGA) are representative: "AGA agrees with OSHA that parking lots and access roads should be excluded from the definition of establishment and therefore injuries occurring there are not work-related. Likewise, injuries and illnesses that occur during commuting must also continue to be excluded" (Ex. 15: 225). The Texas Chemical Council (TCC) agreed with this position: "[T]CC supports continuing these exceptions. Employers have limited to no control over variables that contribute to incidents occurring in parking lots or during commutes to and from work" (Ex. 15: 159).

Other commenters, however, argued that cases occurring on company parking lots and access roads should be included in the establishment's Log (see, *e.g.*, Exs. 15: 61, 157, 310, 407, 432). The Laborer's Health and Safety

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Fund of North America pointed to the difficulty of separating cases occurring on the parking lot from those occurring at other locations within the establishment:

[w]e do not believe that company parking lots should be excluded from the definition of establishment. The parking lot exclusion seems to be based on the assumption that parking lots are separate from loading dock and other work areas. On road construction sites, "parking lots" are sometimes right in the middle of the work zones where heavy equipment is operating. Pedestrian employees being hit by traffic and moving machinery are responsible for about 41.5% of the yearly fatalities in road construction and maintenance work. We believe that excluding parking lots from the definition of establishment would open the door to under reporting of workplace fatalities on construction sites, and discourage construction employers from establishing safe parking areas for their employees (Ex. 15: 310).

The National Institute for Occupational Safety and Health (NIOSH) presented statistical data demonstrating the importance of safety and health measures in employer-owned parking lots:

[N]IOSH does not support continuing the exemption of employer-owned parking lots from the definition of an establishment. NIOSH recommends that OSHA require employers to record cases meeting the work relationship criteria that occur in employer-owned parking areas. Employers have extensive control over the environmental conditions in their own parking areas. Environmental conditions that are under employer control include snow and ice accumulation in walk areas, vicinity lighting around parked cars and entrance ways, and security provisions in parking areas. In 1993, parking lots and garages were identified in a study of violence in the workplace as the location where 211 fatal injuries occurred [Toscano and Weber 1995]. Eighty-two of these deaths were homicides. Parking lots and garages accounted for 3.4% of fatal injuries and 7.8% of homicides. Data on the total number of injuries and illnesses occurring in parking lots and garages is unknown. However, in 1992 the category "parking lots" was listed as the source of injury or illness for 10,000 cases involving days away from work [U.S. Department of Labor 1995a]. The proportion of parking lots and garages owned by the employer where fatal and nonfatal injuries occurred is not known (Ex. 15: 407).

OSHA agrees with NIOSH that company parking lots can be highly hazardous and that employers have considerable control over conditions in such lots. In addition, OSHA believes that having data on the kinds of injuries and illnesses occurring on company parking lots and access roads will permit employers to address the causes of these injuries and illnesses and thus to provide their employees with better protection. Accordingly, for recordkeeping purposes, the final rule includes company parking lots and access roads in the definition of establishment. However, the final rule recognizes that some injuries and illnesses occurring on company parking lots and access roads are not work-related and delineates those that are work-related from those that are not work-related on the basis of the activity the employee was performing at the time the injury or illness occurred. For example, when an employee is injured in a motor vehicle accident that occurs during that employee's commute to or from work, the injury is not considered work-related. Thus, the final rule allows the employer to exclude from the Log injuries and illnesses occurring on company parking lots and access roads while employees are commuting to or from work or running personal errands in their motor vehicles (see section 1904.5). However, other injuries and illnesses occurring in parking lots and on access roads (such as accidents at loading docks, while removing snow, falls on ice, assaults, etc.) are considered work-related and must be recorded on the establishment's Log if they meet the other recording criteria of the final rule (*e.g.*, if they involve medical treatment, lost time, etc.).

OSHA concludes that the activity-based approach taken in the final rule will be simpler for employers to use than the former rule's location-based approach and will result in the collection of better data. First, the activity-based approach eliminates the need for employers to determine where a parking lot begins and ends, i.e., what specific areas constitute the parking lot, which can be difficult in the case of combined, interspersed, or poorly defined parking areas. Second, it ensures the recording of those injuries and illnesses that are work-related but simply happen to occur in these areas. If parking lots and access roads are totally excluded from the definition of establishment, employers would not record *any* injury or illness occurring in such locations. For example, employers could fail to record an injury occurring to an employee performing work, such as building an attendant's booth or demarcating parking spaces, from the Log.

Recreation facilities. Although the proposed rule would have included recreational facilities in the definition of establishment, it would have excluded, for recordkeeping purposes, injuries and illnesses occurring to employees who were voluntarily participating in wellness activities at fitness or recreational facilities maintained by the employer. As discussed above, OSHA believes that including in the final rule a list of activities that employers can use to rebut the presumption of work-relatedness for recordkeeping purposes will greatly simplify the system for employers and result in the collection of more meaningful data. Including a list of such activities in the final rule was supported by many commenters (see, *e.g.*, Exs. 15: 65, 151, 152, 170, 179, 180, 204, 246, 350, 392). The comments of the Tosco Corporation are representative: "[w]e agree that the recreational facilities should not be automatically excluded, but rather that the voluntary use of the facilities govern the work relatedness as OSHA has indicated. This will make the OSHA regulation consistent with workers compensation rulings" (Ex. 15: 246).

An even larger number of commenters disagreed with OSHA's proposed approach, however, arguing that a location-based, rather than activity-based, exclusion was more appropriate for recordkeeping purposes (see, *e.g.*, Exs. 15: 9, 95, 111, 119, 136, 137, 141, 154, 156, 184, 194, 203, 213, 218, 224, 232, 266, 271, 277, 278, 288, 304, 317, 345, 347, 389, 409, 414, 423, 428, 431). For example, the law firm of Constangy, Brooks & Smith, LLC, argued that excluding facilities is simpler than excluding activities: "* * * [t]he current requirements allow a more simplified analysis of the recreational facility issue and this analysis should be retained in place of the more complicated analysis that would be imposed under the Proposed Recordkeeping Rule" (Ex. 15: 345).

Other employers stressed the concept that changing the exclusion for recreational facilities would reduce the incentive for employers to provide such facilities for their employees' use (see, *e.g.*, Exs. 15: 136, 137, 141, 213, 224, 266, 278). The remarks of the Society for Human Resource Management (SHRM) are typical: "[t]o presume that the employee's usage of weight room facilities is involuntary may be unrealistic and would likely result in the closure of employer provided weight rooms, golf courses, and other facilities which benefit the employees * * *" (Ex. 15: 431).

In the final rule, OSHA has decided to include recreational areas in the definition of establishment but to include voluntary fitness and recreational activities, and other wellness activities, on the list of excepted activities employers may use to rebut the presumption of work-relatedness in paragraph 1904.5(b)(2). OSHA finds that this approach is simpler and will provide better injury and illness data because recreational facilities are often multi-use areas that are sometimes used as work zones and sometimes as recreational areas. Several of the interpretations OSHA has provided over the years address this problem. For example, the loading dock or warehouse at some establishments has an area with a basketball hoop that is used for impromptu ball games during breaks, while at other establishments employees may use a grassy area to play softball, an empty meeting room for aerobics classes, or the perimeter of the property as a jogging or bicycling track. Providing an exception based on activity will make it easier for employers to evaluate injuries and illnesses that occur in mixed-use areas of the facility.

This approach is also consistent with OSHA's overall approach in the final rule of using specific activity-based exemptions to allow the employer to rebut the presumption of work relationship rather than providing exemptions by modifying the definition of establishment. OSHA also does not believe that this approach will provide an incentive for employers to eliminate recreational and fitness opportunities for their employees. Both approaches exempt the same injuries from recording, but the final rule's approach provides employers with a more straightforward mechanism for rebutting the presumption of work relationship.

OSHA believes that injuries and illnesses occurring to employees who are present in recreational areas as part of their assigned work duties should be recorded on the Log; the final rule thus only permits employers to exclude recreational activities that are being performed by the employee voluntarily from their Logs. For example, an injury to an exercise instructor hired by the company to conduct classes and demonstrate exercises would be considered work related, as would an injury or illness sustained by an employee who is required to exercise to maintain specific fitness levels, such as a security guard.

Private homes as an establishment. Two commenters raised the issue of whether or not private homes could constitute an establishment (see, *e.g.*, Exs. 21, 15: 304, 358). The National Federation of Independent Business (NFIB) stated: "[N]FIB believes that the definition of establishment as applied to extremely small work sites, including private homes, needs to be reexamined" (Ex. 15: 304). The Organization Resource Counselors (ORC) added: "[d]efinition of establishment as applied to extremely small work sites including private homes needs to be reexamined. The sixty day rule by itself does not seem unreasonable except that it captures these small work sites where the requirements for posting or mailing summaries make little sense" (Ex. 21).

In the final rule, OSHA has not excluded private homes from the definition of establishment because many private homes contain home offices or other home-based worksites, and injuries and illnesses occurring to employees during work activities performed there on behalf of their employer are recordable if the employer is required to keep a Log. However, the final rule makes clear that, in the case of an employee who telecommutes from his or her home, the home is not considered an establishment for OSHA recordkeeping purposes and the employer is not required to keep a separate Log for the home office. For these workers, the worker's establishment is the office to which they report, receive direction or supervision, collect pay, and otherwise stay in contact with their employer, and it is at this establishment that the Log is kept. For workers who are simply working at home instead of at the company's office, i.e., for employees who are telecommuting, OSHA does not consider the worker's home to be an establishment for recordkeeping purposes, and the definition of establishment makes this fact clear. OSHA has recently issued a compliance directive clarifying that OSHA does not and will not inspect home offices in the employee's home and would inspect a home-based worksite other than a home office only if the Agency received a complaint or referral. A fuller discussion concerning the determination of the work-relatedness of injuries and illnesses that occur when employees are working in their homes can be found in the discussion of § 1904.5 Determination of work-relatedness.

Miscellaneous issues. Two commenters recommended that OSHA consider excluding injuries and illnesses occurring to employees while they were present in other areas as well (Exs. 15: 203, 389). The International Dairy Foods Association (IDFA) suggested:

[i]n addition, facilities such as cafeterias/lunch/break/rest/locker rooms should be exempted except for the employees who work in those areas. While it is true that other workers may occasionally be injured in these areas, the inclusion of all injury/illness information that occurs in these areas only distorts the data. OSHA should be concerned with the accuracy of any information it requires and/or collects and should eliminate any non-relevant or extraneous information. We believe that this anomaly is easily correctable, and the result will be a more accurate assessment of hazards associated with a specific workplace (Ex. 15: 203).

OSHA does not agree with this commenter that injuries and illnesses occurring in such areas are not work-related. For example, many injuries occurring in lunch rooms involve slippery floors, which the employer can address by establishing a system for immediate spill cleanup. However, the final rule does contain an exception from recordability of cases where the employee, for example, chokes on his or her food, is burned by spilling hot coffee, etc. (see paragraph 1904.5(b)).

The United Parcel Service (UPS) recommended that OSHA craft its rule to coincide with the company's personnel records system, stating "[t]he unit for which an employer maintains personnel records is presumptively appropriate and efficient; accordingly, OSHA should not mandate a rule that conflicts with a company's current personnel units policy" (Ex. 15: 424). OSHA recognizes that employers would prefer OSHA to allow companies to keep records in any way they choose. However, OSHA believes that allowing each company to decide how and in what format to keep injury and illness records would erode the value of the injury and illness records in describing the safety and health experience of individual workplaces and across different workplaces and industries. OSHA has therefore decided not to adopt this approach in the final rule.

Two commenters raised the issue of centralized recordkeeping as it related to the proposed definition of establishment. The General Electric Company (GE) stated:

[G]E does not support the redefinition of establishment to mean a single physical location that is in operation for 60 calendar days or longer. GE field staff frequently establish such establishments and the illness and injury recording and reporting for these sites has been done at central locations. The required data therefore is already collected but the new definition would substantially increase the administrative burden for employers, without providing any additional value. Currently, field employees can report an injury to one well-trained individual who is able to properly administer the program and keep all required documentation. Under this new rule, the employer would need to train a significantly greater number of employees on the proper method for recording injuries and illnesses, keeping documentation, and ensuring the submission of this information to the central office for long-term retention. Further, turnover in the field service operations necessitates an ongoing training program. GE would prefer to train field service employees on GE's

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expectations for safe performance and how to perform their jobs safely, rather then training field service employees on OSHA recordkeeping regulations (Ex. 15: 349).

OSHA will continue to allow employers to keep their records centrally and on computer equipment, and nothing in the final rule would preclude such electronic centralization. OSHA believes that the defipition of establishment in the final rule will have no impact on the ability of the employer to keep records centrally; however, the final rule does continue to require employers to summarize and post the records for each establishment at the end of the year.

The North Carolina Department of Labor (Ex. 15: 186) suggested that OSHA add a note cross-referencing the rule's exceptions for work relationship in parking lots, to assist readers in locating them. OSHA has not added a note to the definition but believes that the list of exceptions to the presumption of work-relationship will achieve the objective this commenter intended. In addition, OSHA has included a table showing changes from the former system to the new system in the compliance assistance and training materials it is distributing to employers and employees.

Health Care Professional

The final rule defines health care professional (HCP) as "a physician or other state licensed health care professional whose legally permitted scope of practice (i.e. license, registration or certification) allows the professional independently to provide or be delegated the responsibility to provide some or all of the health care services described by this regulation."

The proposed rule used the term "health care provider," defined as a person operating within the scope of his or her health care license, registration or certification. The final rule uses the term "health care professional" to be consistent with definitions used in the medical surveillance provisions of other OSHA standards (see, *e.g.*, the methylene chloride final rule (29 CFR 1910.1052).

OSHA recognizes that injured employees may be treated by a broad range of health care practitioners, especially if the establishment is located in a rural area or if the worker is employed by a small company that does not have the means to provide on-site access to an occupational nurse or a physician. Although the rule does not specify what medical specialty or training is necessary to provide care for injured or ill employees, the rule's use of the term health care professional is intended to ensure that those professionals providing treatment and making determinations about the recordability of certain complex cases are operating within the scope of their license, as defined by the appropriate state licensing agency.

The rulemaking record reflects a wide diversity of views on this topic. Many commenters thought the proposed definition was much too broad, leaving "[t]he door open for unqualified individuals to make medical diagnoses" (see, *e.g.*, Exs. 15: 342, 201). Many commenters also argued that the proposed definition could be misinterpreted (see, *e.g.*, Exs. 31, 15: 131, 342, 397). Specifically, many employers thought the definition could be interpreted to permit untrained or unlicensed individuals to treat employees or to make medical diagnoses that would determine the recordability of certain an injuries or illnesses (see, *e.g.*, Exs. 15: 304, 355, 433). Additionally, some commenters interpreted the proposed definition to mean that any time an individual who was certified or trained in cardiopulmonary resuscitation (CPR) or first aid administered treatment, the case would automatically be recordable (see, *e.g.*, Exs. 15: 116, 132, 323, 341, 356). For example, the National Federation of Independent Business noted:

> [u]nlike licensed practitioners, those who are registered or certified are not consistently judged against stringent objective criteria. Oftentimes registration is obtained by paying a fee and certification usually entails attending training courses on how to administer first aid. In any given place of employment it is common to find at least one employee who is trained and certified in first aid care. Simple actions on the part of such an employee could become recordable instances under this proposal. This would only serve to erroneously inflate statistics thus making the work site log an inaccurate reflection of occupational injuries and illnesses (Ex. 15: 304).

Consequently, many commenters advocated qualifying the proposed definition by limiting it to providers with specific types of training, such as licensed physicians (see, *e.g.*, Exs. 15: 42, 105) or other providers, such as dentists, psychiatrists, or clinical psychologists (see, *e.g.*, Exs. 15: 126, 312, 342, 410, 433, 443) and/or practitioners operating under their direction, such as physician assistants and nurses (see, *e.g.*, Exs. 15: 116, 131, 334, 344, 441).

Some commenters proposed eliminating the words "registration" and "certification" from the definition because these terms have different meanings in different states, and in some states, some providers can pay to be certified or registered even though their credentials are inadequate (see, *e.g.*, Exs. 15: 199, 272, 303, 375). A few commenters also noted that some registrations and certifications are given by professional associations rather than state agencies. For example, according to the American Academy of Physician Assistants:

> [w]hile many health care providers receive professional certification through a private certifying body (*e.g.* board certification in cardiology for a doctor), this "certificate" is not automatically tied to any state recognized credential or scope of practice permitting the provision of health care services. PAs, for example, are certified by the National Commission on Certification of Physician Assistants. This certification is not synonymous with a state certificate or license. As the proposed rule is currently worded, an NCCPA-certified PA or a physician who is board certified in cardiology would qualify as a "health care provider." However, OSHA would not be assured that the PA or physician was practicing medicine with a license and in compliance with their state scope of practice. Further, it would be illegal in all states for a PA or a physician to provide health care services based solely on their professional certification (Ex. 15: 81).

Still others feared that registered or certified "alternative medicine" providers, such as acupuncturists and massage therapists, might influence an employer's recordkeeping decision (see, *e.g.*, Exs. 15: 184, 317, 430).

The proposed definition was, however, supported by several unions, large and small employers, and professional associations representing those health care personnel who might be excluded by a more restrictive definition (see, *e.g.*, Exs. 15: 9, 72, 137, 170, 204, 278). These commenters generally advocated a broader definition because such a definition would recognize the various types of health care personnel who may be called on to attend an injured employee (see, *e.g.*, Exs. 15: 181, 350, 376, 392, 417). Typical of these comments was one from The Fertilizer Institute:

> [O]SHA should not qualify and limit this definition to personnel with specific training due to the wide variation in health care support and training available throughout the country. Because not all facilities are located in large metropolitan areas where a wide variety of medical training is available, it may be difficult, if not impossible to satisfy Administration-specified minimal training (Ex. 15: 154).

These commenters did agree, however, that to ensure the availability of quality health care to employees, health care professionals must be licensed or certified by the state(s) in which they practice and must operate within the scope of that license or certification (see, *e.g.*, Exs. 24, 15: 81, 181, 350, 417). In particular, several commenters stressed the need to define the term "health care professional" as one practicing "in accordance with the laws of the applicable jurisdiction" (Ex. 15: 409; see also Exs. 15: 308, 349).

Additionally, the AFL–CIO cautioned that using a broad definition of the term "health care provider" in this recordkeeping rule should not supersede or in any way affect the provisions of many OSHA health standards that specifically require a physician to perform medical surveillance of occupationally exposed employees:

> [a]ll of OSHA's 6(b) health standards, except for Bloodborne Pathogens, require that the medical examinations required by the rules be carried out by a physician or under the supervision of a licensed physician. Many of these standards further require that a physician evaluate the results of the exam and provide a diagnosis and opinion as to whether any adverse medical condition has been detected. Some standards such as lead, benzene, and formaldehyde also require the physician to determine whether or not an employee should be removed from his or her job due to occupational exposures.
>
> [In contrast], the proposed recordkeeping rule would allow diagnoses for conditions covered by these standards (*e.g.*, lead poisoning, asbestosis, byssinosis) to be made by any health care provider operating within the scope of their license. We are concerned that this discrepancy and inconsistency may lead to confusion about the requirements for medical surveillance under OSHA's health standards (Ex. 15: 418).

Therefore, the AFL–CIO recommended that OSHA insert a provision in the proposed recordkeeping rule that would ensure that it is not interpreted as superseding the requirements of those standards. OSHA shares this concern and does not intend the use of the term "health care professional" in this rule to modify or supersede any requirement of any other OSHA regulation or standard.

On the basis of the record, OSHA finds that there is a broad consensus among commenters that only qualified health care professionals should make diagnoses and treat injured employees, and that state licensing agencies are best suited to determine who may practice and the legal scope of that practice (see, *e.g.*, Exs. 15: 31, 65, 95, 154, 184, 201, 288, 308, 335, 349, 409, 425). The definition in the final rule ensures that, although decisions about the recordability of a particular case may be made by a wide range of health care professionals, the professionals making those decisions must be operating within the scope of their license or certification when they make such decisions.

Injury or Illness

The final rule's definition of injury or illness is based on the definitions of injury and illness used under the former recordkeeping regulation, except that it combines both definitions into a single term "injury or illness." Under the final rule, an injury or illness is an abnormal condition or disorder. Injuries include cases such as, but not limited to, a cut, fracture, sprain, or amputation. Illnesses include both acute and chronic illnesses, such as, but not limited to, a skin disease, respiratory disorder, or systemic poisoning. The definition also includes a note to inform employers that some injuries and illnesses are recordable and others are not, and that injuries and illnesses are recordable only if they are new, work-related cases that meet one or more of the final rule's recording criteria.

Former rule's definition. The former rule also defined these terms broadly, as did the proposal. The text of the former recordkeeping rule did not include a definition of injury or illness; instead, the definitions for these terms were found on the back of the OSHA 200 Log and in the former *Recordkeeping Guidelines* (Ex. 2, p. 37). The definition of occupational injury found in the *Guidelines* was:

> Occupational injury is any injury such as a cut, fracture, sprain, amputation, etc., which results from a work accident or from an exposure involving a single incident in the work environment.
>
> **Note:** Conditions resulting from animal bites, such as insect or snake bites, or from one-time exposure to chemicals are considered to be injuries.

An occupational illness was defined as:

> [a]ny abnormal condition or disorder, other than one resulting from an occupational injury, caused by exposure to environmental factors associated with employment. It includes acute and chronic illnesses or diseases which may be caused by inhalation, absorption, ingestion, or direct contact.

The former rule's definitions of injury and illness captured a very broad range of injuries, including minor injuries such as scratches, bruises and so forth, which the employer then tested for work-relatedness and their relationship to the recording criteria. The former rule's definition of illness was even broader, including virtually any abnormal occupational condition or disorder that was not an occupational injury. However, the recording of illnesses under the former rule was more inclusive than is the case for the final rule being published today because the former rule required employers to record every occupational illness, regardless of severity. The final rule applies the same recording criteria to occupational illnesses as to occupational injuries, and thus rules out minor illnesses (see the Legal Authority section and the preamble discussion accompanying section1904.4).

The former rule's broad definition of illness was upheld in a 1989 Occupational Safety and Health Review Commission decision concerning the recording of elevated levels of lead in the blood of workers employed at a battery plant operated by the Johnson Controls Company. In that decision (OSHRC 89–2614), the Occupational Safety and Health Review Commission found that:

> [a]s the Secretary states in his brief on review "The broad applicability of the term "illness" adopted in the BLS Guidelines serves this purpose [to set explicit and comprehensive recording requirements designed to obtain accurate and beneficial statistics regarding the causes of occupational disease] by including health related conditions which may not look like, or may not yet be, treatable illnesses." Accordingly, for the purposes of the Secretary's recordkeeping regulations promulgated pursuant to sections 8(c)(1) and (2) of the Act, we accept the Secretary's interpretation of "illness" that includes blood lead levels at or above 50 ug/100g.

Proposed rule's definition. OSHA proposed a new, broad definition that encompassed both occupational injury and occupational illness. This approach was consistent with one of the goals of the proposal, to eliminate the distinction between injury and illness entirely for recordkeeping purposes. OSHA's proposed definition of an injury or illness was:

> "Injury or illness" is any sign, symptom, or laboratory abnormality which indicates an adverse change in an employee's anatomical, biochemical, physiological, functional, or psychological condition (61 FR 4058).

Comments on the proposed definition. Many commenters remarked that the proposed definition of injury and illness was too broad and all encompassing (see, *e.g.*, Exs. 25, 33, 15: 95, 120, 156, 174, 176, 199, 201, 213, 231, 273, 282, 301, 305, 318, 331, 346, 348, 375, 383, 386, 395, 420, 424, 425, 430). The views of the National Association of Manufacturers (NAM) are representative of this view:

> [a] second option is to re-examine the scope of the proposed definition of the term "injury or illness," which appears to go well beyond the normal understanding of the medical profession. That definition is so broad it includes virtually any change in the status of the employee. In contrast, Dorland's

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Illustrated Medical Dictionary defines the term "illness" as a condition marked by "pronounced deviation from the normal healthy state." Accordingly, the NAM believes the proposed definition of the term "injury or illness" would be far more accurate and credible if it were modified to read substantially as follows "Any sign, symptom, or laboratory abnormality which evidences a significant adverse change in an employee's anatomical, biochemical, physiological, functional, or psychological condition, and which evidences a state of ill-health or a reasonable probability that ill-health will result (Exs. 25, 15: 305).

The American Iron and Steel Instute (AISI) also objected to the definition, stating that:

OSHA also fails to provide any guidance as to what constitutes a "change" in an employee's condition. If a person is tired at the end of the day, does that constitute a change in his physical condition? If a person is grumpy at the end of a long shift, has he undergone a change in his psychological condition? If a person gains weight, has his "anatomical" condition "changed"? OSHA's proposed definition would force employers to address these questions but provides none of the answers. * * * Finally, in addition to inviting gross intrusions into employees' lives, the concept of an "adverse" psychological change is so vague and burdened with value judgments that it simply is beyond definition.

Several other commenters urged OSHA to add the word "significant" and the phrase "and which evidences a state of ill-health or a reasonable probability that ill-health will result" to the final rule's definition of injury or illness (see, *e.g.*, Exs. 15: 169, 174, 199, 282, 305, 318, 346, 348, 375, 386, 420, 425).

A number of commenters stated that they did not understand the word "functional" in the definition, and particularly how its meaning differs from that of the word "physiological" in the definition (see, *e.g.*, Exs. 15: 313, 352, 353, 424). Several commenters also suggested the deletion from the definition of an occupational injury or illness any reference to signs, symptoms or laboratory abnormalities (see, *e.g.*, Exs. 33, 15: 176, 231, 273, 301). The Pacific Maritime Association (Ex. 15: 95) suggested that OSHA delete the proposed definition of injury or illness and replace it with the following: "[an injury or illness] is any condition diagnosed by a health care provider." Two commonters suggested excluding psychological conditions from the definition of injury or illness (Exs. 15: 395, 424). A discussion of mental conditions and OSHA's reasons for including them in the definition is included in the preamble discussion of work-relationship at section 1904.5, Determination of work relatedness. OSHA has decided to continue to include psychological conditions in the final rule's definition of injury and illness because many such conditions are caused, contributed to, or significantly aggravated by events or exposures in the work environment, and the Agency would be remiss if it did not collect injury and illness information about conditions of these types that meet one or more of the final rule's recording criteria.

In the final rule, OSHA has relied primarily on the former rule's concept of an abnormal condition or disorder. Although injury and illness are broadly defined, they capture only those changes that reflect an adverse change in the employee's condition that is of some significance i.e. that reach the level of an abnormal condition or disorder. For example, a mere change in mood or experiencing normal end-of-the-day tiredness would not be considered an abnormal condition or disorder. Similarly, a cut or obvious wound, breathing problems, skin rashes, blood tests with abnormal results, and the like are clearly abnormal conditions and disorders. Pain and other symptoms that are wholly subjective are also considered an abnormal condition or disorder. There is no need for the abnormal condition to include objective signs to be considered an injury or illness. However, it is important for employers to remember that identifying a workplace incident as an occupational injury or illness is only the first step in the determination an employer makes about the recordability of a given case.

OSHA finds that this definition provides an appropriate starting point for decision-making about recordability, and that the requirements for determining which cases are work-related and which are not (section 1904.5), for determining which work-related cases reflect new injuries or illnesses rather than recurrences (section 1904.6), and for determining which new, work-related cases meet one or more of the general recording criteria or the additional criteria (sections 1904.7 to 1904.12) together constitute a system that ensures that those cases that should be recorded are captured and that minor injuries and illnesses are excluded. In response to the desire of many commenters for greater clarity, OSHA has added language to the definition of injury and illness to make it clear that many injuries and illnesses are not recordable, either because they are not work-related or because they do not meet any of the final rule's recording criteria.

In general, all of those commenters who opposed the proposed definition wished OSHA to revise the definition so that it would provide an initial screening mechanism for excluding minor injuries and illnesses, even before the status of the case vis-a-vis the geographic presumption or recording criteria was assessed. OSHA recognizes that the proposed language referring to any adverse change was too broad, and has returned to the former language requiring that the change reach the "abnormal condition" level. OSHA recognizes that this is still a broad definition—deliberately so. After reviewing this issue thoroughly, OSHA finds that a system that initially defines injury and illness broadly and then applies a series of screening mechanisms to narrow the number of recordable incidents to those meeting OSHA and statutory criteria has several advantages. First, by being inclusive, this system avoids the problem associated with any "narrow gate" approach: that some cases that should be evaluated are lost even before the evaluation process begins. Second, this approach is consistent with the broad definitions of these terms that OSHA has used for more than 20 years, which means that the approach is already familiar to employers and their recordkeepers. Third, adding terminology like "significant" and "reasonable probability that ill-health will result," as commenters suggested, would unnecessarily complicate the first step in the evaluation process.

Accordingly, the definition of injury and illness in the final rule differs from the former definition only in minor respects. The definition is based on the former rule's definitions, simply combining the separate definitions of injury and illness into a single category, to be consistent with the elimination of separate recording thresholds for occupational injuries and occupational illnesses. As discussed above, OSHA has elected to continue to use a broad definition of illness or injury. The definition in the final rule also makes it clear that each injury and illness must be evaluated for work-relatedness, to decide if it a new case, and to determine if it is recordable before a covered employer must enter the case in the OSHA recordkeeping system.

"You"

The last definition in the final rule, of the pronoun "you," has been added because the final rule uses the "you" form of the question-and-answer plain-language format recommended in Federal plain-language guidance. "You," as used in this rule, mean the employer, as that term is defined in the Act. This definition makes it clear that employers are responsible for implementing the requirements of this final rule, as mandated by the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*)

VIII. Forms

This section of the preamble includes a copy of the final forms package. For a discussion of the contents, the old forms, the proposed forms, and comments to the proposed forms, refer to the preamble discussion of Subpart C. 1904.6 Forms. The forms fit on 11" by 14" legal sized paper. The forms do not appear in the **Federal Register** due to printing considerations. To obtain a copy contact OSHA's Publications Office at (202) 693–1888, order the forms from the OSHA Internet home page *(http://www.osha.gov)* or download the forms from the OSHA home page.

IX. State Plans

The 25 States and territories with their own OSHA approved occupational safety and health plans must adopt a rule comparable to the 29 CFR part 1904 recordkeeping and reporting occupational injuries and illnesses regulation being published today, with the exception of the requirements of § 1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers. These 25 States are: Alaska, Arizona, California, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming; and Connecticut and New York (for State and local Government employees only).

The former 29 CFR 1952.4 regulation required that States with approved State-Plans under section 18 of the OSH Act (29 U.S.C. 667) must adopt occupational injury and illness recording and reporting regulations which were "substantially identical" to those set forth in 29 CFR part 1904 because the definitions used by the Federal and State governments for recordkeeping purposes must be identical to ensure the uniformity of the collected information. In addition, former § 1952.4 provided that employer variances or exceptions to State recordkeeping or reporting requirements in a State-Plan State would be approved by the Bureau of Labor Statistics. Similarly, a State was permitted to require supplemental reporting or recordkeeping data, but that State was required to obtain approval from the Bureau of Labor Statistics to ensure that the additional data would not interfere with "the primary uniform reporting objectives."

The proposed revision of 29 CFR 1952.4 would have retained the same substantive requirements for the State-Plan States, but reflected the organizational shift of some recordkeeping responsibilities from the Bureau of Labor Statistics to OSHA in 1990. See also the memorandum of understanding between OSHA and BLS effective July, 1990 (Ex. 6).

OSHA received no comments directed specifically to proposed section 1952.4. Section 1952.4 of the final rule parallels the provisions of § 1904.37, State Recordkeeping Regulations, the section of the final rule implementing the requirements proposed as § 1904.14, Recordkeeping Under Approved State Plans. The discussion of the comments and OSHA's decisions on the few issues associated with this section can be found in the preamble discussion for § 1904.37, State Recordkeeping Regulations. Section 1952.4 of the final regulation differs from that of the former regulation in that (1) the final rule requires the States to consult with and obtain approval from OSHA rather than BLS when promulgating supplementary fatality, injury or illness recording and reporting requirements; (2) the final rule allows the State to grant variances from the fatality, injury and illness reporting and recording requirements for State and local governments with Federal approval; and (3) Federal OSHA rather than the BLS is responsible for issuing all private sector and federal variances from the 29 CFR part 1904 requirements.

OSHA Data Initiative Surveys

In 1997, OSHA issued a final rule at § 1904.17, OSHA Surveys of 10 or More Employers that required employers to submit occupational injury and illness data to OSHA when sent a survey form. The 1904.17 rule enabled the Agency to conduct a mandatory survey of the 1904 data, which has been named the OSHA Data Initiative. Section 1904.41 of the final rule, Annual OSHA Injury and Illness Survey of Ten or More Employers, simply carries forward the employer reporting requirements of the former § 1904.17, with only minor editorial changes.

When OSHA issued the 1997 rule, the Agency determined that the States were not required to adopt a rule comparable to the federal § 1904.17 rule (62 FR 6441). Paragraph 1952.4(d) has been added to the final rule to continue to provide the States with the flexibility to participate in the OSHA Data Initiative under the Federal requirements or the State's own regulation. At its outset, Federal OSHA conducted the OSHA data collection in all of the states, including those which administer approved State-Plans. However, in recent years, Federal OSHA has collected data only in the State-Plan States that wish to participate. For example, in 2000, the states of Oregon, South Carolina, Washington, and Wyoming elected not to participate in the annual OSHA survey and employers in those States were not surveyed. OSHA plans to continue to allow the individual States to decide, on an annual basis, whether or not they will participate in the OSHA data collection.

If a State elects to participate, the State may either adopt and enforce the requirements of section 1904.41 as an identical or more stringent State regulation, or may defer to the Federal regulation and Federal enforcement with regard to the mandatory nature of the survey. If the State defers to the Federal section 1904.41 regulation, OSHA's authority to implement the survey is not affected either by operational agreement with a State-Plan State or by the granting of final State-Plan approval under section 18(e). OSHA's authority under the Act to take appropriate enforcement action if necessary to compel responses to the survey and to ensure the accuracy of the data submitted by employers will be exercised in consultation with the State in State-Plan states.

X. Final Economic Analysis

1. Introduction

A. Background

OSHA is revising its regulation on Recording and Reporting Occupational Injuries and Illnesses, which is codified at 29 CFR part 1904. Executive Order 12866, issued by President Clinton on September 30, 1993, requires OSHA to assess the benefits and costs of regulations, and to design regulations to impose the least burden on society consistent with achieving the Agency's regulatory objective. This economic analysis, therefore, was developed to describe the potential impacts of the final revisions to 29 CFR part 1904.

The final revisions to 29 CFR part 1904 reflect the results of studies of occupational injury and illness reporting and recordkeeping. One study of the accuracy and quality of occupational safety and health statistics was conducted by the National Research Council of the National Academy of Sciences (NAS), under contract to the Bureau of Labor Statistics (BLS).[4] The NAS report focused on changes to the

[4] National Research Council of the National Academy of Sciences, *Counting Injuries and Illnesses in the Workplace: Proposal for a Better System*, 1987.

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overall strategy for occupational health and safety statistics and reporting, rather than on specific methods for improving the existing recordkeeping system. Reform of the occupational health and safety recordkeeping system was also the topic of a conference convened by the Keystone Center, an independent, non-profit organization that specializes in mediating multi-party disputes in the areas of science, technology, environmental, and health concerns. The Keystone Conference brought together 46 representatives from labor unions, corporations, the health professions, government agencies, Congressional staff, and academia to engage in a year-long dialogue. The Conference's final report[5] was an important source of ideas for some of the changes being made in OSHA's final recordkeeping rule.

In 1990, the Department of Labor transferred from the Bureau of Labor Statistics (BLS) to OSHA the responsibility for developing recordkeeping regulations and their accompanying guidelines. Although BLS continues to compile occupational injury and illness statistics, OSHA determines what information needs to be recorded by employers.

This economic analysis measures the potential regulatory impacts of the final revisions to 29 CFR part 1904. Much of the data for this analysis derives from a study conducted for OSHA by Meridian Research.[6] The data in the Meridian study, however, have been updated to reflect more recent data on the numbers of establishments affected and on rates of occupational illnesses and injuries, as well as the evidence submitted to the record in the course of this rulemaking.

B. Overview of the Final Regulation

The final regulation revises an existing rule, Recording and Reporting Occupational Injuries and Illnesses (29 CFR part 1904). Specific changes include changes in coverage, editorial and formatting changes, and changes in specific provisions that affect the requirements for recording and reporting. Changes are summarized in Table X–1.

(1) Editing and Format Changes

Language and Structure of the Rule. The final regulation reflects a complete rewriting of 29 CFR part 1904. The new version of the rule is written in plain language, using a question and answer format. This style is designed to make the rule clearer, more accessible, and easier to understand. In addition, the final rule contains many questions that employers frequently ask about recordkeeping, and it provides answers to those questions. By including these questions and answers in the rule itself, OSHA has provided employers with a readily available source of information on how to record particular cases. This means that the quality of the data being recorded will be higher than was the case in the past.

TABLE X–1: CHANGES IN RECORDKEEPING REQUIREMENTS

Section of final rule	Section of former or other source	Rule change
1904.2	1904.16	Cover parts of SICs 55, 57, 59, 65, 72, 73, 83, & 84; Exempt parts of SICs 52, 54, 76, 79, & 80.
1904.5	Guidelines	Include specific exemptions from recording for certain cases, such as common cold or flu.
		Limit parking lot exemption to commuting.
		Require recording of preexisting injury or illness only if workplace exposure "significantly" aggravates the injury or illness.
1904.7	1904.12	Replace term "lost workdays" in recording criteria with "days away" or "days restricted or transferred"; count days as calendar days, rather than scheduled work days; cap count at 180 days; do not record restricted, transferred, or lost time occurring only on day of injury or illness as restricted work, job transfer, or a day away. Define routine duties for restricted work purposes as work activities done at least once per week. Define medical treatment beyond first aid to include all non-prescription drugs given at prescription strength and first and subsequent physical therapy or chiropractic treatment and to exclude use of Steri-Strips™ and hot or cold therapy.
1904.7	(New)	Narrow criteria for recording illnesses by excluding minor illnesses.
1904.8	(New)	Record all needlestick/sharps injury cases involving exposure to blood or other potentially infectious materials.
1904.10	Interpretation	Record all hearing loss cases at 10 dB shift, rather than 25 dB shift.
1904.11	Interpretation	Narrow criteria for recording positive tuberculosis test.
1904.12	1904.12	Make criteria for recording MSD cases the same as those for all other injuries and illnesses.
1904.29	1904.2	Replace old Log form with simplified Form 300.
		Require that cases be recorded within 7 calendar days rather than 6 working days.
1904.29	1904.4	Require more information on new Form 301 than on former Form 101.
1904.29	(New)	Define new category of "privacy concern cases" and require maintenance of separate, confidential list of names for such.
1904.29	(New)	Require employer to protect privacy of injured or ill workers by withholding names, with certain exceptions.
1904.32	1904.5 (New)	Post Annual Summary for 3 months rather than 1 month.
		Review records for accuracy at end of year.
		Require descriptive and statistical totals in Annual Summary.
		Require certification of accuracy of the Log by responsible company official.
1904.34	1904.11	With change of ownership, require seller to turn over OSHA records to buyer.
1904.35	(New)	Inform employees how to report injuries or illnesses to employer.
		Provide union representative access to some, but not all, Form 301 information.
1904.39	1904.8	Delete requirement for common carrier and motor vehicle incidents to be reported.

[5] Keystone Center, *Keystone National Policy Dialogue on Work-Related Illness and Injury Recording*, 1989.

[6] Meridian Research, Inc., Economic Analysis of Proposed Changes to OSHA's Recordkeeping Requirements (29 CFR 1904), 1991.

The rule also has been completely restructured. Its provisions have been put into a logical sequence, with topics addressed as an employer would encounter them when complying with the rule. The numbering of sections within 29 CFR part 1904 has been entirely revised.

The final rule includes considerable detail not found in the former rule. This detail generally reflects interpretations that OSHA has made over time. By including these in the rule itself, OSHA intends to make the rule far clearer. Interpretations and related details are formatted as check lists, for ease of interpretation.

(2) Specific Changes in Regulatory Provisions

(a) Changes in Coverage

Former rule. The former rule exempted all employers with 10 or fewer employees and all employers in specific low-hazard retail and service industry sectors from routinely keeping OSHA records. The industry exemptions were based on injury and illness data at the 2-digit SIC code level.

Final rule. The final rule continues the former rule's exemption of all employers with 10 or fewer employees from routine recordkeeping requirements. The final rule also exempts all employers in specific low-hazard retail and service industry sectors, as the former rule did, from maintaining OSHA records routinely. The final rule exempts 3-digit SIC industries if their average lost workday injury (LWDI) rate was at or below 75% of the overall private sector LWDI average rate in the most recent BLS occupational injury and illness data.

Change. Updating the list of exempted industry categories by relying on 3-digit, rather than 2-digit, data in the final rule results in 17 formerly exempt industries being covered under the final rule (see Table X–2). Employers in 16 industries that were covered by the former rule are exempted by the final rule (see Table X–3). The exemptions in the final rule are better targeted than those in the former rule, because high-hazard 3-digit industries embedded within lower-hazard 2-digit industries are not exempted, while low-hazard 3-digit industries embedded within higher-hazard 2-digit industries are exempted. Employers in the newly covered industries will experience additional costs and benefits from these new requirements, while newly exempted employers will also experience changes in costs and benefits. These costs and benefits are quantified in this economic analysis.

(b) Changes to the OSHA Forms

Former rule. The former rule required the employer to maintain two forms, the OSHA 200 Log and Summary of Occupational Injuries and Illnesses (one form including both a Log and Summary), and the OSHA 101 Supplementary Record of Occupational Injuries and Illnesses. The employee who supervised the production of the annual summary was required to certify it.

Final rule. The final rule requires the employer to maintain up to four records: the OSHA 300 Log of Work-Related Injuries and Illnesses, the OSHA 300-A Summary of Work-Related Injuries and Illnesses, the OSHA 301 Injury and Illness Incident Report, and, if one or more employees experiences an injury or illness case classified as a "privacy concern" case, a confidential list of those employees. (See discussion of privacy provisions below.)

Change. The new OSHA 300 Log is smaller than the Former OSHA 200 Log, fits on legal sized pages (8 ½" x 14"), has fewer columns and a more logical, user friendly design. Each injury and illness must be recorded within 7 calendar days, rather than the 6 working days allowed under the former rule. Although the 300 Log requires essentially the same information as the former 200 Log, it is easier to complete, which will result in cost savings for employers. These savings are quantified in this economic analysis.

The OSHA 300–A Summary Form replaces the summary portion of the former OSHA 200 Log and Summary Form. Each covered employer must complete the summary at the end of the year and post it for 3 months, while the former rule required posting for one month. The longer posting period will result in only minimal additional costs. The final rule also requires the employer to review the records at year end for accuracy before summarizing them, requires additional certification of accuracy by a company executive, and requires additional data on the average employment and hours worked at the establishment. These changes will result in higher quality data, and will also add costs for employers. These costs are quantified in this economic analysis.

The OSHA 301 Incident Report is only slightly different from the OSHA 101 Form that it replaces. Some data elements have been added to the form. In addition, the form has been redesigned to obtain better responses to the questions and to accommodate employee access to the forms while still protecting privacy (see discussion below). Costs of recording additional data elements are quantified in this economic analysis.

(c) Changes in the Recording Criteria

The final rule includes a number of changes that will affect the number of recorded cases, and thus potentially affect the costs and costs savings associated with the regulation. Some of these changes will result in more cases being recorded, as follows: (1) Changes to the definitions of medical treatment and first aid, (2) change to the criterion for recording cases of hearing loss, and (3) change to the criterion for recording needlestick and sharps injuries.

Other changes will result in fewer cases being recorded, as follows: (1) Exemptions from the requirement to consider certain cases work-related, (2) elimination of different recording criteria for injuries and illnesses, (3) changes to the requirements for recording injuries and illnesses with days away or job restriction/transfer, (4) changes to the criteria for recording cases of tuberculosis, and (5) elimination of separate recording criteria for musculoskeletal disorders.

Because the final rule makes a number of changes, some of which increase the number of recordable injuries and illnesses and some of which decrease the number of recordable cases, it is difficult to estimate the precise impact of each change. OSHA expects that these changes, with two exceptions, will generally have the effect of offsetting each other, with the result that approximately the same number of injury and illness cases will be recorded under the final rule as were recorded under the former rule. The costs and cost savings associated with each small definitional change have not been quantified in this economic analysis. However, the changes made in the recording of hearing loss cases and the recording of needlestick and sharps injury cases will result in quantifiable increases in the number of recorded injuries. The cost effects of these changes are specifically identified in this economic analysis.

OSHA recognizes that individual employers will be affected differently by the changes made in the final rule and that some employers will record more cases under the final rule while others will record fewer. OSHA also finds that the overall effect of the changes made to the final rule is to greatly ease the determination of recordability, and has quantified these cost savings in this economic analysis.

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(i) Changes to the Determination of Work-Relationship

Former rule. Under the former rule, work-relationship was established if work either caused or contributed to the injury or illness, or aggravated a pre-existing condition. Injuries and illnesses that occurred on the employer's premises were presumed to be work-related, with three exceptions: cases that occurred in a parking lot or recreational facility, cases that occurred while the employee was present at the workplace as a member of the general public and not as an employee, and cases where injury or illness symptoms arose at work but were the result of a non-work-related injury or illness were not required to be recorded.

Final rule. Work relationship is established if work either caused or contributed to the injury or illness, or significantly aggravated a pre-existing condition. The final rule continues the former rule's geographic presumption of work relationship but adds several additional exceptions to the need to record cases involving: voluntary participation in wellness programs, eating and drinking food or beverages for personal consumption, intentionally self-inflicted wounds, personal grooming, or the common cold or flu. The final rule also contains an exception that limits the recording of mental illness cases.

Change. The final rule changes the requirement to record cases in which any degree of aggravation of a preexisting injury or illness has occurred; now, the work environment must have significantly aggravated a pre-existing injury or illness before the case becomes work-related. The final rule also adds several new exceptions to the geographic presumption of work relationship. Both of these changes will result in fewer cases being recorded under the final rule.

(ii) Elimination of Different Recording Criteria for Injuries and Illnesses

Former rule. Under the former rule, employers were required to record all work-related deaths, all illnesses, and injuries that resulted in days away from work, restricted work, transfer to another job, medical treatment beyond first aid, or loss of consciousness. The employer was required to decide if the case was either an injury or illness; injuries included all back cases and any case caused by an instantaneous event, while illnesses were any abnormal condition or disorder caused by a non-instantaneous event. The employer was required to record every illness case, regardless of severity.

Final rule. Under the final rule, the employer is not required to determine whether a case is an injury or illness to decide whether or not to record the case. A case is recordable if it results in death, days away from work, job restriction or transfer, medical treatment beyond first aid, loss of consciousness, or if the case is a significant injury or illness diagnosed by a physician or other licensed health care professional. Additional criteria are included for cases of hearing loss, tuberculosis, and needlestick injuries and the rule clarifies how to record musculoskeletal disorders and cases involving medical removal or work restriction under OSHA's standards.

Change. The new general recording criteria eliminate the recording of minor illness cases, which will result in fewer cases being recorded by employers, and lower costs. The new criteria for recording hearing loss and needlestick cases will increase the number of cases and the costs associated with recording.

(iii) Days Away and Job Restriction/Transfer

Former rule. Under the former rule, employers were required to record lost workday cases, which were defined as any case that resulted in days away from work and/or days of restricted work or job transfer. Restricted work included any case when because of injury or illness (1) the employee was assigned to another job on a temporary basis, (2) the employee worked at a permanent job less than full time, or (3) the employee worked at his or her permanently assigned job but could not perform his or her routine duties. Routine duties were defined as any activity the employee would be expected to perform even once during the course of the year. The employer was required to record any case that involved restricted work, even if the restriction occurred only on the day the injury or illness occurred.

Employers were also required to count days as the number of scheduled days away or restricted, i.e., to use a counting system that included only scheduled work days and excluded any days off, such as weekends and days the plant was closed.

Final Rule. The final rule continues to require employers to record cases with days away from work, restricted work or transfer to another job. For restricted work/job transfer, the final rule focuses on whether or not the employee is permitted to perform his or her routine job functions, defined as the duties he or she would have performed at least once per week before the injury or illness. If the work restriction is limited to the day of the injury or illness, and none of the other recording criteria are met, the case is not recordable.

The final rule continues to require the employer to count days away from work and days of restricted work/job transfer. However, the days are counted using calendar days, and employers may stop the count at 180 days. The employer also may stop counting restricted days if the employer permanently modifies the employee's job in a way that eliminate the routine functions the employee was restricted from performing.

Change. The final rule shifts the focus of the definition of restricted work to the routine functions of the job and away from the former rule's focus on any activity the injured or ill employee might have performed during the work year, and eliminates the requirement to record cases that involve restrictions only on the day of injury or illness. These changes will result in fewer cases being recorded, and will have the effect of reducing costs for employers.

The final rule's changes to the method of counting days, i.e., relying on calendar days instead of scheduled work days, will simplify the counting requirements and produce more reliable information on injury and illness severity. Both the change to the calendar day counting method and the capping of days away and days restricted or transferred at 180 days will have the effect of reducing costs for employers.

(iv) Changes to the Definitions of Medical Treatment and First Aid

Former rule. The former rule defined medical treatment as any treatment, other than first aid treatment, administered to injured or ill employees. Medical treatment involved the provision of medical or surgical care for injuries through the application of procedures or systematic therapeutic measures.

The former regulation defined first aid as "any one-time treatment, and any follow up visit for the purpose of observation, of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care. Such one-time treatment, and follow up visits for the purpose of observation are considered first aid even though provided by a physician or registered professional personnel."

The former *Recordkeeping Guidelines* provided two lists of treatments employers could use to determine whether a particular treatment was first aid or medical treatment for recordkeeping purposes. For example, the use of prescription drugs was generally considered medical treatment, except when only a single dose was prescribed. Physical therapy, hot or cold therapy, or soaking therapy was considered medical treatment if it was used on a second or subsequent visit to medical personnel. Treatment of any third or second degree burn was considered medical treatment. The former rule's lists provided a useful starting point for determining which treatments were first aid or medical treatment, but also caused some confusion because, if a particular treatment was not on either list, the employer was not sure how to classify the treatment.

Final rule. The final rule defines medical treatment as the management and care of a patient to combat disease or disorder. For the purposes of Part 1904, medical treatment does not include: visits to a physician or other licensed health care professional solely for observation or counseling; the conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or first aid.

The final rule then defines first aid by listing 14 first aid treatments, such as using non-prescription drugs at non-prescription strength, using bandages or butterfly bandages, using hot or cold therapy, using splints or slings to transport an accident victim, and drinking liquids for relief of heat stress.

Change. The final rule changes the definitions of which treatments are considered first aid and medical treatment. Each change will result in some change in the number of cases that are recorded, as shown in the following table.

Changes from the former rule to the final rule	Impact on number of cases recorded
Medical treatment now includes all non-prescription drugs at prescription strength and any dose of a prescription drug.	More cases
First aid now includes hot or cold therapy, regardless of how often applied.	Fewer cases
Medical treatment now includes any physical therapy/chiropractic treatment.	More cases
First aid now includes use of butterfly bandages and Steri-Strips for any purpose.	Fewer cases
Medical treatment now includes any use of oxygen.	More cases
Second degree burns are now not automatically recordable.	Fewer cases

The overall effect of the changes to the definitions of medical treatment and first aid is difficult to determine. OSHA believes that they generally offset each other, but data to confirm this are not available.

(v) Changes in the Recording of Needlestick and Sharps Injuries

Former rule. Under the former rule, an employer was required to record a needlestick or sharps injury involving human blood or other potentially infectious material if the case resulted in death, days away from work, restricted work, medical treatment beyond first aid, or loss of consciousness, or if the employee seroconverted (contracted HIV or hepatitis infection).

Final rule. Under the final rule, an employer is required to record *all* needlestick or sharps injuries involving human blood or other potentially infectious material. These cases are recorded as privacy concern cases.

Change. The final rule will require the recording of an additional estimated 501,640 needlestick and sharps injury cases. The costs associated with this change have been quantified in this economic analysis. This change will also significantly simplify recording for those employers who recorded 88,925 needlestick and sharps injuries under the former rule, resulting in cost savings for those cases. These cost savings have been quantified in this economic analysis.

(vi) Changes in the Recording of Hearing Loss

Former rule. Under OSHA's interpretations of the former rule, an employer was required to record a hearing loss of 25 decibels in one or both ears, averaged over three frequencies, compared to the employee's baseline audiogram. Work-relatedness was presumed if the employee was exposed to noise at or above an 8-hour time weighted average of 85 decibels.

Final rule. The final rule requires an employer to record any hearing loss that reaches the level of a standard threshold shift (STS), defined by the occupational noise standard as a 10 decibel shift in hearing, averaged over three frequencies, in one or both ears, compared to the employee's baseline audiogram. Work-relatedness is presumed if the employee was exposed to noise at or above an 8-hour time weighted average of 85 decibels.

The employer must check a separate box on the OSHA Log to identify hearing loss cases.

Change. The additional check box will result in improved statistical data on occupational hearing loss. The change to a more sensitive threshold (10 decibel shift rather than 25 decibel shift) for recording occupational hearing loss will result in the recording of additional cases. Based on audiometric data collected from 22 companies in SICs 20 through 29, 33, 34, 35, 39, 49, and 90, OSHA estimated that, with the new threshold, 250,000 more workers in manufacturing and 25,000 more workers elsewhere in general industry would sustain recordable hearing loss annually. The costs associated with this increase have been quantified in this economic analysis.

(vii) Changes in the Recording of Tuberculosis

Former rule. Under OSHA's interpretation of the former rule, an employer was required to record an active case of tuberculosis (TB) or a positive TB skin test. If the employee was employed in one of five high risk industries, as defined by the Centers for Disease Control and Prevention (CDC), the case was presumed to be work related.

Final rule. Under the final rule, a case of tuberculosis is recorded if the employee has active TB or has a positive skin test. The case is considered work-related if the employee has been occupationally exposed at work to another person (client, patient, co-worker) with a known, active case of tuberculosis. The employer may subsequently remove or line out the case if a medical investigation shows that the case was caused by a non-occupational exposure.

Change. The final rule eliminates the "special industries" presumption of work-relatedness. OSHA believes that this change will reduce the number of recorded TB cases, and thus reduce costs somewhat. However, data to estimate the cost savings associated with this change are not available.

(viii) Changes in the Recording of Musculoskeletal Disorders (MSD)

Former rule. Under the former rule, MSD cases were recorded differently based on whether they were occupational injuries or occupational illnesses. If the case was an MSD *injury*, it was recorded if it resulted in days away from work, restricted work, job transfer, or medical treatment beyond

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first aid. If the case was an MSD *illness*, it was recorded if it resulted in:

(1) Objective findings:
—A diagnosis by a health care provider (carpal tunnel, tendinitis, etc.)
—Positive test results (Tinel's, Finkelstein's, Phalen's, EMG)
—Signs (redness, swelling, loss of motion, deformity)

OR

(2) Symptoms combined with days away from work, restricted work, or medical treatment beyond first aid.

Injury MSD cases were considered to be "new cases" if they resulted from new (additional) workplace events or exposures. Illness MSD cases were treated in the same way or were subjected to a "30 day rule" whereby if an ill employee did not return to the health care provider for care after 30 days the case was considered resolved. If the same employee reported later with additional MSD problems, the case was evaluated for recordability as a new illness.

Final rule. Under the final rule, MSD cases are recorded using the same criteria as those for other injuries and illnesses. Cases are recorded if they result in days away from work, restricted work/job transfer, or medical treatment beyond first aid. Recurrences are also handled just as other types of injuries and illnesses are.

The employer must check a separate box on the Log for MSD cases to permit separate data on these disorders to be collected.

Change. The final rule simplifies the recording of MSDs and collects improved statistical information on these disorders on the 300 Log. Because the final rule does not require the automatic recording of diagnosed disorders, physical signs, and positive test results, it will generally require employers to record fewer MSD cases, resulting in some cost savings. However, the magnitude of these cost savings is not known.

(d) Change in Ownership

Former rule. Under the former rule an employer who acquired a business establishment was required to retain the OSHA records of the prior owner. Each owner was responsible for the records only for that period of the year that each owned the business.

Final rule. Under the final rule, when a business establishment changes owners, each owner is responsible for the OSHA records only for that period of the year that each owned the business. The prior owner is required to transfer the records to the new owner, and the new owner is responsible for retaining those records.

Change. The final rule differs from the former rule by requiring the prior owner to transfer the records to the new owner. Any new costs imposed by this requirement are extremely small and have not been quantified in this economic analysis.

(e) Employee Involvement

Former rule. The former rule involved employees in the recordkeeping process in two ways: through posting of the annual summary of occupational injuries and illnesses for one month, and by allowing access to the OSHA 200 Log by employees, former employees, and their representatives.

Final rule. The final rule involves employees in the process to a greater extent than formerly: it requires the employer to set up a system for accepting injury and illness reports from employees and requires the employer to tell each employee how to report a work-related injury or illness. The final rule also requires the employer to post the annual summary for three months. Employees, former employees, and their representatives have the right to one free copy of the 300 Log, the injured or ill employee or a personal representative has a right to one free copy of the 301 (Incident Report) for his or her case, and authorized employee representatives have a right to one free copy of a portion of the 301 form for all injuries and illnesses at the establishment he or she represents.

Change. The final rule will improve employee reporting of work-related injuries and illnesses and allow improved access to the information in the records, including one free copy of each record requested. OSHA finds that these provisions will increase costs for employers, and these costs have been quantified in the economic analysis.

(f) Privacy Protections

Former rule. The former rule had no provisions to protect the privacy of injured or ill workers when a coworker or employee representative was allowed access to the OSHA 200 Log. The employer was required to provide the Log with names intact.

Final rule. The final rule protects the privacy of injured or ill workers when a coworker or employee representative accesses the records by prohibiting the employer from entering the employee's name for certain "privacy concern" cases. A separate, confidential list of case numbers and employee names must be kept for these cases. An employee representative can access only part of the information from the 301 form, and the employer must withhold the remainder of the information when providing copies. With certain exceptions, if the employer provides the information to anyone other than a government representative, an employee, a former employee, or an employee representative, the names and other personally identifying information must be removed from the forms. In addition, separation of the summary form will eliminate accidental disclosure of employee names during the posting of the summary information.

Change. The final rule protects injured or ill employees' privacy in several ways, *e.g.*, by limiting the distribution of injured or ill employees' names, by not recording the employee's name in privacy concern cases, and by providing employee representatives access to only part of the Form 301. The costs of keeping a separate, confidential list for privacy concern cases have been quantified in the economic analysis.

(g) Computerized and Centralized Records

Former rule. The former rule allowed the employer to keep the OSHA 200 Log on computer equipment or at a location other than the establishment, and required that the employer have available a copy of the Log current to within 45 calendar days. The former rule had no provisions for keeping the OSHA 101 form off site or on computer equipment.

Final rule. The final rule allows all forms to be kept on computer equipment or at an alternate location, providing the employer can produce the data when it is needed to provide access to a government inspector, employee, or an employee representative. There is no need to keep records at the establishment at all times.

Change. The final rule provides the employer with greater flexibility for keeping records on computer equipment and at off-site locations. These costs savings have been quantified in the economic analysis.

Reporting of Fatality and Catastrophe Incidents

Former rule. The former rule required the employer to report any workplace fatality, or any incident involving the hospitalization of 3 or more employees to OSHA within 8 hours.

Final rule. The final rule requires the employer to report any workplace fatality, or any incident involving the hospitalization of 3 or more employees to OSHA within 8 hours. The final rule does not require the employer to report to OSHA fatal or multiple hospitalization incidents that occur on commercial airlines, trains and buses; or fatality/catastrophe incidents from a motor vehicle accident on a public highway.

Change. The final rule requires employers to report fewer incidents to OSHA, which will result in cost savings. These cost savings have not been quantified in the economic analysis.

(3) Qualitative Overview of Impacts

Forms

The largest impact of the final rule's revised provisions on recordkeeping at the individual establishment will be in the direction of cost savings and will come from the plain language rewriting of the rule itself and the new forms. These changes in language, organization, and format will reduce the burden on employers and recordkeepers in several ways. The clearer language and streamlining will allow the entire rule to be read more quickly and with greater comprehension. It will also be possible to obtain a good understanding of the rule in a single reading (which will be particularly helpful for establishments with very few or no recordable incidents). Finally, the organization and format make it far easier to get quick answers to specific questions, because the answers are part of the final rule itself rather than being included in a separate document, the *Recordkeeping Guidelines for Occupational Injuries and Illnesses* (the "Blue Book").

2. Industry Profile

OSHA's former regulation for Recording and Reporting Occupational Injuries and Illnesses, 29 CFR part 1904, covered most industries in the economy. The principal exceptions were the finance, insurance, and real estate sector, some retail trade industries, and some service industries. This chapter describes the changes in coverage, as well as key characteristics of the industries that will be covered under the final rule.

A. Changes in Industries Covered

The former rule (with one exception) covered or exempted industries at the two-digit SIC level. The final rule fine tunes this coverage in the finance, insurance, and real estate, retail trade, and service sectors by extending coverage to some high-hazard three-digit SICs in two-digit SICs that were not covered by the former rule and exempting some low-hazard three-digit SICs in two-digit industries that were covered by the former rule. These changes, by two-digit SICs, are as follows:

Industries covered under the former rule that would continue to be covered under the final rule:[7]
Agriculture (SIC 01–02),
Forestry, and Fishing (SIC 07–09),
Oil & Gas Extraction (SIC 13),
Sulfur Mining (SIC 1479, part),
Construction (SIC 15–17),
Manufacturing (SIC 20–39),
Transportation (SIC 41–42),
United States Postal Service (SIC 43),
Public Utilities (SIC 44–49),
Wholesale Trade (SIC 50–51),
General Merchandise Stores (SIC 53),
Hotels and Other Lodging Places (SIC 70), and
Automotive Repair, Services, and Parking (SIC 75).

Industries exempted under the former rule that would continue to be exempted:
Apparel and Accessory Stores (SIC 56),
Eating and Drinking Places (SIC 58),
Depository Institutions (SIC 60),
Nondepository Institutions (SIC 61),
Security and Commodity Brokers (SIC 62),
Insurance Carriers (SIC 63),
Insurance Agents, Brokers, and Services (SIC 64),
Holding and Other Investment Offices (SIC 67),
Motion Pictures (SIC 78),
Legal Services (SIC 81),
Educational Services (SIC 82),
Membership Organizations (SIC 86),
Engineering, Accounting, Research, Management & Related Services (SIC 87), and
Services, not elsewhere classified (SIC 89).

Two-digit industries that were not covered under the former rule but will have some three-digit industries within them covered under the final rule:
Automobile Dealers (SIC 55),
Furniture Stores (SIC 57),
Miscellaneous Retail Stores (SIC 59),
Real Estate (SIC 65),
Personal Services (SIC 72),
Business Services (SIC 73),
Social Services (SIC 83), and
Museums (SIC 84).

Two-digit industries that were covered under the former rule but will have some or all three-digit industries within them exempted under the final rule:
Building Materials & Garden Supplies (SIC 52),
Food Stores (SIC 54),
Miscellaneous Repair Services (SIC 76),
Amusement and Recreation Services (SIC 79), and
Health Services (SIC 80).

Table X–2 shows the specific three-digit industries that were formerly exempted and to which the final rule will extend coverage. Table X–3 shows the specific three-digit industries that were formerly covered and which the final rule will exempt.

Exempting an industry means that employers with establishments in that industry do not have to keep the OSHA Form 300 (the Log of Occupational Injuries and Illnesses), the Annual Summary (OSHA 300-A), and OSHA Form 301 (the Incident Record) or their equivalents. The final rule does not exempt establishments from the obligation to report fatalities or multiple hospitalization accidents to OSHA, nor does it exempt an employer from the requirement to maintain records if notified by the Bureau of Labor Statistics that it is a participant in the annual Occupational Injuries and Illnesses Survey or by OSHA that it has been selected to report under the OSHA Data Initiative.

B. Characteristics of Covered Establishments

(1) Number of Establishments

Table X–4 shows the estimated number of establishments, by industry, covered by the final regulation. Data for agriculture (SICs 01 and 02) are taken from the 1997 Census of Agriculture. Data for the remaining SICs are taken from a compilation of 1996 data by the U.S. Census Bureau for the Small Business Administration (SBA) to reflect parent company control of establishments. Firms that have 10 or fewer employees,[8] which are exempt from the final regulation because of their size, are excluded from Table X–4.

[7] In addition, state and local government employers will continue to be covered in State Plan states.

[8] The SBA data have size classes of 5–9 employees and 10–19 employees. Establishments with 10 employees were assumed to account for ten percent of the 10–19-employee size class. Since the distribution is skewed by size, rather than being uniform, this assumption slightly overstates the number of establishments covered by the regulation.

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TABLE X–2.—FORMERLY EXEMPT INDUSTRIES THAT THE FINAL RECORDKEEPING RULE COVERS

Two-digit industry*	Three-digit industry that OSHA's final rule covers
SIC 55	SIC 553, Auto and Home Supply Stores
	SIC 555, Boat Dealers
	SIC 556, Recreational Vehicle Dealers
SIC 57	SIC 571, Home Furniture and Furnishings Stores
	SIC 572, Household Appliance Stores
SIC 59	SIC 593, Used Merchandise Stores
	SIC 596, Nonstore Retailers
	SIC 598, Fuel Dealers
SIC 65	SIC 651, Real Estate Operators and Lessors
	SIC 655, Subdividers and Developers
SIC 72	SIC 721, Laundry, Cleaning, and Garment Service
SIC 73	SIC 734, Services to Buildings
	SIC 735, Miscellaneous Equipment Rental/Leasing
	SIC 736, Personnel
SIC 83	SIC 833, Job Training and Related Services
	SIC 836, Residential Care
SIC 84	SIC 842, Botanical and Zoological Gardens

*Only the 3-digit SICs shown in the second column are covered by the rule; those within the 2-digit SIC that are not listed are still exempt from the requirement to keep OSHA records routinely.

TABLE X–3.—FORMERLY COVERED INDUSTRIES EXEMPTED BY THE FINAL RULE

Two-digit industry	Three-digit industry that OSHA's final rule exempts
SIC 52	SIC 525, Hardware Stores
SIC 54	SIC 542, Meat and Fish Markets
	SIC 544, Candy, Nut, and Confectionery Stores
	SIC 545, Dairy Product Stores
	SIC 546, Retail Bakeries
	SIC 549, Miscellaneous Food Stores
SIC 76	SIC 764, Reupholstry and Furniture Repair
SIC 79	SIC 791, Dance Studios, Schools, and Halls
	SIC 792, Producers, Orchestras, and Entertainers
	SIC 793, Bowling Centers
SIC 80	SIC 801, Offices and Clinics of Medical Doctors
	SIC 802, Offices and Clinics of Dentists
	SIC 803, Offices of Osteopathic Physicians
	SIC 804, Offices of Other Health Practitioners
	SIC 807, Medical and Dental Laboratories
	SIC 809, Health and Allied Services, nec

TABLE X–4—ESTABLISHMENTS REQUIRED BY THE FINAL RULE ROUTINELY TO KEEP OCCUPATIONAL INJURY/ILLNESS RECORDS

Industry establishments		Estimated number of establishments required to keep records	Estimated number of recordable cases annually in these
Agricultural Production	SIC 01–02	56,367	46,770
Agricultural Svcs, Forestry, Fishing	SIC 07–09	16,271	54,022
Oil and Gas Extraction	SIC 13	5,367	13,851
Construction	SIC 15–17	114,470	415,500
Manufacturing	SIC 20–39	196,643	2,060,900
Transportation, Postal, Utilities	SIC 41–49	157,390	516,653
Wholesale Trade	SIC 50–51	219,678	403,240
Building Materials/Garden Supplies	SIC 52[a]	22,339	56,091
General Merchandise Stores	SIC 53	28,519	180,909
Food Stores	SIC 54[b]	64,443	126,780
Automotive Dealers	SIC 55[c]	23,342	22,662
Furniture Stores	SIC 57[d]	25,580	24,302
Miscellaneous Retail Stores	SIC 59[e]	19,913	23,750
Real Estate	SIC 65[f]	17,925	22,702
Hotels and Other Lodging Places	SIC 70	23,956	103,423
Personal Services	SIC 72[g]	14,768	18,072
Business Services	SIC 73[h]	51,525	58,659
Automotive Repair, Svcs, Parking	SIC 75	41,575	40,359
Miscellaneous Repair Services	SIC 76[i]	12,294	17,686
Amusement and Recreation Services	SIC 79[j]	20,602	79,623
Health Services	SIC 80[k]	38,996	995,122[l]
Social Services	SIC 83[m]	25,998	25,349
Museums	SIC 84[n]	236	2,408
State and Local Government Employers in State Plan States		167,788	519,646
TOTAL: Final Rule[o]		1,365,985	5,828,477
TOTAL: Former Rule[o]		1,306,418	4,907,081

[a] Consists of Lumber & Other Building Materials (SIC 521); Paint, Glass, & Wallpaper Stores (SIC 523); Retail Nurseries & Garden Stores (SIC 526); and Mobile Home Dealers (SIC 527).
[b] Consists of Grocery Stores (SIC 541) and Fruit and Vegetable Markets (SIC 543).
[c] Consists of Auto and Home Supply Stores (SIC 553); Boat Dealers (SIC 555); and Recreational Vehicle Dealers (SIC 556).
[d] Consists of Furniture & Homefurnishings Stores (SIC 571) and Household Appliance Stores (SIC 572).
[e] Consists of Used Merchandise Stores (SIC 593); Nonstore Retailers (SIC 596); and Fuel Dealers (SIC 598).
[f] Consists of Real Estate Operators and Lessors (SIC 651) and Subdividers and Developers (SIC 655).
[g] Consists of Laundry, Cleaning, and Garment Services (SIC 721).
[h] Consists of Services to Buildings (SIC 734); Miscellaneous Equipment Rental and Leasing (SIC 735); and Personnel Supply Services (SIC 736).
[i] Consists of Electrical Repair Shops (SIC 762); Watch, Clock and Jewelry Repair (SIC 763); and Miscellaneous Repair Shops (SIC 769).
[j] Consists of Commercial Sports (SIC 794) and Miscellaneous Amusement & Recreation Services (SIC 799).
[k] Consists of Nursing and Personal Care Facilities (SIC 805); Hospitals (SIC 806); and Home Health Care Services (SIC 808).
[l] Includes estimated 501,640 needlesticks and sharps not now recordable that are covered by the final rule.
[m] Consists of Job Training and Related Services (SIC 833) and Residential Care (SIC 836).
[n] Consists of Botanical and Zoological Gardens (SIC 842).
[o] Sulfur mining (part of SIC 1479) is excluded because information is not available.
Sources: U.S. Census Bureau compilation of 1996 establishment and employment data by parent firm, performed for the Small Business Administration; Bureau of Labor Statistics 1998 Survey of Occupational Injuries and Illnesses.

The final regulation covers an estimated total of 1,365,985 establishments belonging to 699,712 employers. The number of establishments covered by the rule represents a net increase of 4.6 percent over the 1,306,418 establishments covered by the former regulation. This increase in the number of establishments covered results from the changes made to the scope of the final rule.

(2) Number of Recordable Cases

Table X–4 also shows the number of recordable cases of occupational injury and illness, by industry, covered by the final regulation. These are taken from unpublished data from the 1998 BLS Survey of Occupational Injury and Illness.

The final regulation will annually capture an estimated total of 5,828,477 occupational injury and illness cases. Of these cases, 275,000 represent additional hearing loss cases and 501,640 represent additional needlestick and sharps injuries anticipated to occur in SIC 80. The needlestick and sharps number represents 85 percent of the estimated 590,165 needlestick and sharps injuries occurring in SIC 80 (63 FR 48250, September 9, 1998; Ex. 3–172V, Docket No. H370A), since OSHA estimates that approximately 15 percent of such injuries were being recorded under the former rule. Since not all of SIC 80 is covered by the final rule, this figure is likely to overstate the number of recordable cases to some extent.

Exclusive of the 275,000 additional hearing loss cases and the 501,640 additional needlestick and sharps injuries, the final regulation will capture an estimated 5,051,837 cases annually. This is an increase of 3 percent over the 4,907,081 cases captured by the former rule. This increase in capture reflects changes in the scope of the rule that are designed to target the regulation more precisely to high-risk industries in the retail and service sectors of the economy. This increase in the rule's capture efficiency, or cost-effectiveness, is reflected by the fact that the industries that are newly covered under the final rule average 2.6 times as many cases per covered establishment as the industries the final rule would newly exempt.

3. Costs

A. Overview of the Analysis

(1) Background

This chapter assesses the changes in compliance costs associated with the changes the Occupational Safety and Health Administration (OSHA) is making to 29 CFR part 1904, the Agency's Recording and Reporting Occupational Injuries and Illnesses rule, and its associated forms and instructions. The analysis relies in part on methodology and estimates provided in a study conducted for OSHA by Meridian Research, Inc. The Meridian analysis has been updated to reflect more recent data as well as changes that OSHA has made to the regulation in the interval since the Meridian report was prepared, and to reflect comments on the proposed rule.

The great majority of the establishments covered by the rule are small, i.e., have fewer than 20 employees. On average, a covered establishment records 4 occupational injury and illness cases per year, and the recordkeeping decisions involved in these cases are generally straightforward and easy to make (*e.g.*, the injuries involve lacerations, slips and falls, or fractures). Unlike other OSHA rules, the recordkeeping rule does not require employers to implement engineering controls, change employee work practices, provide protective equipment, or take other costly actions to protect their employees' safety and health. Instead, the costs of this rule are based on the costs associated with the time the recordkeeper and others spend in maintaining the records and overseeing the recordkeeping system. OSHA's estimates of the time necessary to perform each step of the recordkeeping process, including the time to consider and record each case, maintain the Log, and perform other recordkeeping tasks, have been reviewed and commented on

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by the public and approved by the Office of Management and Budget in connection with the process required by the Paperwork Reduction Act of 1995. Even if OSHA's estimates of the time involved in making, determining, and overseeing the records involved in the recordkeeping system are low, for example, by a factor of two or so, the costs imposed by the final rule are low in comparison with the benefits of the system and are readily affordable by covered establishments. (See the Impacts section of this economic analysis.)

Because the final regulation makes a number of changes, some of which increase the amount of information employers must maintain and others that simplify recordkeeping and reduce the burden, it is difficult to estimate the precise impact of a given change on establishments in particular industries. Moreover, most individual changes have only a minor impact on burdens, whether positive or negative. Accordingly, the analysis groups together changes to a specific portion of the recordkeeping activities, such as maintaining the Log or filling out the individual report of injury, and (for the most part) assesses the net impact of the group of provisions, rather than the impact of each provision individually.

The analysis reflects the fact that the final regulation is a revision of a former regulation. Thus many of the impacts are changes in the burden of doing something that is already required. Wherever this is the case, the burden under the former and final regulations will be the same if the activities are unchanged. In addition, small changes in burden estimates, both positive and negative, may offset each other.

(2) Analytical Approach

Scope. The costs of the final rule depend in part on the scope of the rule, i.e., on the industries that are covered. As noted in Chapter II, affected industries fall into three groups, depending on their inclusion or exemption under the former and final rules. Impacts differ for each of these three groups:

—For industries covered under the former rule and the final rule, impacts are the costs employers will incur to comply with changes made in a regulatory provision.

—For industries covered by the former rule but exempted under the final rule, impacts consist of cost savings equal to the cost of compliance employers incurred under the former rule.

—For industries exempted under the former rule but covered by the final rule, impacts are the total cost of compliance employers will incur under the final rule.

In examining the costs of this rule, it is critical to remember certain basic characteristics of affected facilities. On average, facilities subject to recordkeeping have about 50 employees and record about four injuries and illnesses a year. Because the size distribution of facilities is somewhat skewed, the majority of establishments record fewer than four injuries and illnesses a year and have fewer than 20 employees. Some commenters appeared to be unaware of the small number of injuries and illnesses recorded by the typical affected establishment when commenting on the proposal. For example, the comment of one commenter that the typical establishment will need to train 2 to 4 recordkeepers (Ex. 15–375) is clearly not reasonable because the typical establishment covered by this rule employs about 50 employees and records a total of four injuries and illnesses a year.

The impacts of changes in specific regulatory provisions are generally related to one of two factors:

- Costs that are essentially fixed costs for an establishment are estimated on a per-establishment basis and multiplied by the number of affected establishments.
- Costs that vary with the number of cases recorded are estimated on a per-case-recorded basis and multiplied by the number of such cases recorded.

Other Parameters. Burdens are estimated as number of minutes (per establishment or per case) to comply with each provision. Most of the costs are based on the assumption that recordkeeping tasks will be conducted by someone with the skill level of a personnel specialist who would be qualified both to obtain and to enter the necessary data. The wage rate for a Personnel Training and Labor Relations Specialist—$19.03, or $26.32 including fringe benefits [9]—is used for this cost. Where the time of a company official is called upon, the estimated labor cost is based on the hourly rate for an Industrial Production Manager—$26.38, or $36.48 including fringe benefits.

Cost estimates for many specific tasks are also influenced by the fact that almost all establishments will also have to gather information on work-related injuries and illnesses for insurance and workers' compensation purposes. In many cases, the data that employers must collect and provide for these purposes are considerably more detailed than those required by OSHA. Even OSHA recordable injuries and illnesses that turn out, in the end, not to be workers' compensation claims are likely to be investigated to determine their status in relation to the workers' compensation system. As a result, much of the basic data gathering necessary to the recording of injuries and illnesses has already been done independent of the OSHA recordkeeping requirements, and, in most cases, making the OSHA record simply involves copying information from other sources to the OSHA form.

(3) Overview of Estimates

The estimated net impact of the revisions to the recordkeeping rule is a cost of $38.6 million per year. Estimated net costs for establishments covered by the former rule that will continue to be covered by the final rule are relatively minor, and the estimated 119,720 establishments that OSHA has exempted from the final rule will incur substantial savings. The chief cost increases will be to the 179,287 establishments brought under the scope of OSHA's recordkeeping rule for the first time.

B. Initial Costs of Learning the Recordkeeping System

(1) Initial Costs to Establishments Already Covered of Becoming Familiar With the Revised Recordkeeping System

Recordkeepers in establishments that were covered by the former regulation and that will continue to be covered under the final regulation will need to become familiar with the changes in the recordkeeping system associated with the final rule even before an injury or illness occurs. OSHA originally estimated that this initial familiarization would require 15 minutes per such establishment. Some commenters objected to this estimate as too low. (See, for example, Exs. 15: 119, 15: 357, 15: 375, 15: 395.) For example, one commenter (Ex. 15: 395) stated that "No person could give even a superficial reading to this material [the proposed rule] in 15 minutes." Another commenter (Ex. 15: 375) stated that this was "not enough time for one person to even read through the rule and the preamble one time." OSHA does not believe that experienced recordkeepers will need to read the entire preamble, or even the entire rule, in order to familiarize themselves with the new recordkeeping changes. For the most part, the new system continues the concepts, practices, and interpretations developed under the former rule and thus is well known to recordkeepers. OSHA believes that most recordkeepers will avail themselves of the summaries of the changes in the rule provided by OSHA or by a wide variety of other sources. The recordkeepers' thorough knowledge of the recordkeeping system will suffice to cover most aspects of the rule. Nor does OSHA agree that the typical recordkeeper, who needs to record only 4 injuries and/or illnesses a year, needs to study every change. For example, a recordkeeper relying on OSHA's summary information on the differences between the former and the revised rule only needs to make a mental note to the effect that injuries and illnesses occurring in parking lots are treated differently under the revised rule, but would not have to know the details of the changes until (if ever) the recordkeeper actually has an injury or illness that occurred in a parking lot. Nevertheless, as a result of the comments received on the prior proposed time estimates, OSHA has raised its familiarization estimate to 20 minutes per establishment for facilities with prior OSHA recordkeeping experience. This estimate covers the time needed for an experienced recordkeeper to learn the basics of the new system, but assumes that such a recordkeeper, who records an average of four cases per year, need not learn the details of the system for dealing with unusual cases until, and if, they arise; instead, this recordkeeper is assumed to examine specific issues later and as needed, when issues arise in the course of the recording of actual cases. The time attributed in this analysis to the recording of individual cases (discussed below) includes the time needed to understand the details of the individual case. It is assumed that this subsequent learning will occur as recordkeepers enter the data; that is, the time that OSHA estimates will be initially required to complete both Form 300 and Form 301 entries includes the time that the Agency estimates will be needed for additional familiarization with issues related to the entry being made. The costs for this subsequent recording activity are discussed in Part D of this section of the economic analysis. The initial familiarization cost is a one-time cost that will not recur. Accordingly, this cost was annualized over ten years using a 7 percent discount rate. The net annualized costs of this initial familiarization activity are $1,482,384.[10]

(2) Costs of Learning the Basics of the Recordkeeping System *De Novo*

Establishments required to keep OSHA records will incur the costs associated with learning about the recordkeeping system from scratch whenever a new person takes over the recordkeeping job as a result of staff turnover. OSHA assumes that 20 percent of covered establishments will experience such staff turnover in any given year. Establishments that are newly covered by the regulation will also incur the costs of learning the recordkeeping system *de novo*. Establishments that are newly exempted under the regulation, of course, will save the staff turnover costs formerly associated with recordkeeping.

At the time of the proposal, OSHA estimated that, under the former regulation, new personnel would require a 30-minute orientation to learn the basics of the recordkeeping system and 25 minutes to learn the newer, simpler recordkeeping system. Many commenters believed that these estimates were too low. (See, for example, Exs. 15: 119, 15: 170, 15: 357, 15: 375.) After reviewing the record, OSHA agrees that the estimates in the Preliminary Economic Analysis did not adequately capture the average amount of time required to learn the system for a person without previous knowledge of OSHA recordkeeping. OSHA has revised its average estimate of the time for learning the new recordkeeping system *de novo* to one hour and has revised the average estimate of the time it would have taken a recordkeeper to learn the previous recordkeeping system to 1.5 hours. (In other words, OSHA believes that its prior estimate of the average amount of time required to learn the former recordkeeping system—30 minutes—was too low.)

Although OSHA's revised average estimates are lower than the estimates made by some commenters, OSHA believes that the Agency's estimates appropriately reflect the average amount of time new recordkeepers will need to learn the basics of the system. Again, new recordkeepers are assumed not to learn all the details of the new system up front, such as exactly when an off-site injury is considered work-related or how to classify injuries occurring in lunch rooms, until such a case actually arises in the workplace. Since unusual cases and those falling within the exceptions are relatively rare, recordkeepers will generally choose to obtain detailed case-specific information only when it is needed. New recordkeepers need only to know that such exceptions exist and that further study of the rule will be necessary in the relatively unlikely event that such an injury or illness occurs. OSHA's estimates of the time required to record each case (discussed further below) include the time for the recordkeeper to study the instructions to learn how to address specific issues that may arise when recording specific types of injuries or illnesses (*e.g.*, noise-induced hearing loss or work-related TB cases).

OSHA believes that the new system is much simpler than the old. Many simplifications, *e.g.*, the use of calendar days, capping of days away cases, have been made to the rule to save effort. This additional simplicity, as well as improved outreach materials to explain the new regulation, will, OSHA believes, result in significantly reducing the length of time required to learn the system. OSHA estimates that learning the basics will take, on average, one hour. This will save 30 minutes compared to the learning time that would have been required for the former system.

Continuously Covered Establishments. Establishments that were covered under the former regulation and continue to be covered under the final regulation will save 30 minutes, compared with the time needed under the former rule, whenever staff turnover requires a new recordkeeper. At a 20 percent turnover rate, the net annualized savings for this learning activity under the final rule are $3,123,394.[11]

Newly Exempted Establishments. Establishments that were covered under the former regulation but are exempted under the final regulation will incur a saving of 90 minutes whenever staff turnover would have required a new recordkeeper. At a 20 percent turnover rate, the net annualized savings of eliminating the need for this learning activity are $945,309.[12]

Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered under the final regulation will incur two types of costs: All establishments will incur an initial learning cost of one hour per establishment. Since this is a one-time cost that will not recur, the cost was annualized over ten years using a 7 percent discount rate. In addition, these establishments will incur an ongoing cost of 60 minutes whenever staff turnover requires a new recordkeeper to become familiar with the system. The net annualized costs of this learning activity are $671,856 + $943,756 = $1,615,612.[13]

[9] Benefits and overhead are computed at 38.3 percent of the hourly wage.

[10] $1,482,384 = (1,186,698 Establishments) × (20 Minutes/Establishment) × ($26.32/Hr.) × {0.07/(1 − (1/(1.07)[10]))}

[11] $3,123,394 = (1,186,698 Establishments) × (0.2) × (30 Minutes/Establishment) × ($26.32/Hour)

[12] $945,309 = (119,720 Establishments) × (0.2) × (90 Minutes/Establishment) × ($26.32/Hour)

[13] $1,615,612 = {(179,287 Establishments) × (60 Minutes/Establishment) × ($26.32/Hour) × {0.07/(1 − (1/(1.07)[10]))} + (179,287 Establishments) × (0.2) × (60 Minutes/Establishment) × ($26.32/Hour)

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(3) Total Cost Impact

Table X–5 summarizes the total annualized cost impacts of initially learning the recordkeeping system under the final regulation. The total net annualized impact is estimated to be a saving of $970,757.

C. Fixed Costs of Recordkeeping

A number of the cost items associated with the final rule do not vary with the size of the establishment or the number of cases reported. These include the costs of setting up the Log, posting the Summary, certifying the Summary, and providing data from the Log to OSHA inspectors. Impacts in this category are related to the number of establishments covered and the specific changes in recordkeeping requirements.

TABLE X–5—FAMILIARIZATION COSTS ASSOCIATED WITH THE FINAL RULE

Cost element/industry status under the final rule	Estimated number of establishments	Change in level of effort		Total cost
		(Minutes)	Hours	
Shift to the New Recordkeeping System:				
Formerly & Still Covered	1,186,698	20	395,566	[a,b]$1,482,384
Initally Learn the Basics of the Recordkeeping System:				
Newly Covered	179,287	60	179,287	[a,b]671,856
Re-learn the Basics of the Recordkeeping System:				
Formerly & Still Covered	237,340	−30	-118,670	[a] −3,123,394
Newly Exempted	23,944	−90	−35,916	[a] −945,309
Newly Covered	35,857	60	35,857	[a]943,756
Total Annual Cost			[c]456,124	970,757

[a] Based on an hourly cost of $26.32.
[b] One-time cost that is annualized over 10 years at a discount rate of 7 percent.
[c] Includes 574,853 hours that will be required in the first year only.

(1) Setting Up the Log and Posting the Summary

Both the former rule and the final rule require that the Log be set up at the beginning of the year and that the Annual Summary be posted on February 1 of the year following the year to which the data pertain. The final regulation requires that the Summary remain posted for three months, while the former regulation required that it remain posted for only one month.

OSHA estimates that the process of setting up the Log and filling out and posting the Summary under the former regulation required 8 minutes. OSHA has no reason to believe that this burden will change as a result of the final rule. Most of the concern expressed in the comments on the proposed recordkeeping rule related to the burden commenters perceived to be associated with updating the posted Summary form when revisions were made and mailing out the Summary as an alternative to posting (see, *e.g.*, Exs. 15: 288, 303, 395). Updating the posted Summary was never OSHA's intent, and the final rule has dropped the mailing alternative, so that both of these concerns are now moot. Any possible increase in burden due to the longer posting periods for the Summary (posting for 3 months rather than 1 month) should be offset by greater simplicity in keeping the Log using the new forms.

The final rule's changes in posting requirements will have no impact on establishments that were covered under the former rule and will be covered under the final rule. Establishments that are newly exempted by the final rule will have an annual savings of 8 minutes each, however. Establishments that are newly covered will incur an annual cost of 8 minutes each. The total estimated impact of these changes in scope is a net cost of −$420,146 + $629,180 = $209,034.[14]

(2) The Annual Summary

The final rule adds a requirement for employers to record on the Log Summary the average number of employees working in the establishment over the past year and the total hours worked by all employees during that year. OSHA initially estimated that recording these data on the Summary would add 5 minutes of labor per establishment to the cost of maintaining each Log. Many commenters noted that this step might be difficult, and some stated that it might be more time consuming than estimated. (See, *e.g.*, Ex. 15: 170.) One commenter stated that this information was sufficiently valuable for management purposes that firms would benefit from having the data if they did not already compile these data (Ex. 15: 395). The commenters who argued that this requirement would be burdensome were generally large multi-establishment firms (see, *e.g.*, Exs. 15: 218, 15: 423). Since OSHA's estimate of this cost is per establishment, these firms would indeed bear higher costs. OSHA does not believe that this requirement will necessitate modifications to data systems for the vast majority of firms; finding where the data are on existing systems should suffice. OSHA also believes that the final rule has clarified that the average number of employees and hours worked need not be precise and can simply be an estimate, which should reduce the amount of effort required to generate this number. The Agency thus finds that this procedure will be relatively simple for most single-establishment firms that maintain personnel records that already have this information for a variety of other purposes. However, OSHA also recognizes that firms with more than one establishment may keep this information only on a firm, not establishment, basis, and may need to perform calculations to compile or revise the data available from their management systems. To account for this, OSHA has raised its average estimate of the time required for the additional information to 20 minutes.

This burden is estimated to fall on all establishments covered by the rule, but not on newly exempted establishments. The total estimated cost of this additional data requirement is $10,411,297 + $1,572,936 = $11,984,233.[15]

The former rule required the recordkeeper to certify that the entries on the Summary were true, accurate, and complete. The final rule requires a company executive to certify that he or she has examined this document and "reasonably believes, based on his or her knowledge of the process by which the information was recorded, that the annual summary is correct and complete."

OSHA estimated, at the time of the proposal, that the former requirement that the recordkeeper certify the Summary cost an average of 2 minutes, because all the recordkeeper had to do was sign the form. The final rule drops the requirement for recordkeeper certification.

Having the Summary certified by a company executive was estimated at the time of the proposal to require only 5 minutes.[16] OSHA now estimates that certification by a company executive will require 30 minutes, because the Agency believes that the company executive will briefly review the records, perhaps speak with the recordkeeper, and generally take whatever steps are necessary to assure himself/herself that the records are accurate. Although, as noted above, the typical firm covered by the rule only records 4 cases per year and these cases are generally straightforward, OSHA believes that the certifying executive will need this amount of time, on average, to perform this task thoughtfully. Again, this estimate is an average estimate—it will take longer for some very large firms and less time for small firms. Estimated impacts on the different classes of establishments are as follows:

- Continuously Covered Establishments. Establishments that were covered by the former rule and will be covered by the final regulation will save the costs for certification by the recordkeeper, but will incur new costs for certification by a responsible company official. This change in requirements results in an estimated total annual cost of $20,604,232.[17]

Newly Exempted Establishments. Establishments that were covered by the former regulation but are exempted from the final regulation will realize a cost saving of 2 minutes of recordkeeper time. The estimated total annual savings will be $105,043.[18]

Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered by the final regulation will incur costs of 30 minutes of company official time. The total annual cost is estimated to be $3,270,213.[19]

The total impact of the final rule's certification requirement is estimated to be $23,769,204.

(3) Provision of Data to OSHA Inspectors

Like the former rule, the final rule requires employers to provide the Log and Incident Reports to an OSHA inspector during a compliance visit. Employers are now required by the final rule to provide a copy of these forms to the inspector on request. OSHA believes that providing copies has in fact been the practice in the past, even though the former rule did not spell this out specifically. OSHA thus does not believe that this small change in the regulation will result in burdens or costs for employers.

(4) Informing Employees How To Report Occupational Injuries and Illnesses

The final regulation requires employers to set up a way for employees to report work-related injuries and illnesses and inform employees about the approach they have chosen. OSHA assumes that it will take a Personnel Training and Labor Relations Specialist (or equivalent) at each establishment an average of twenty minutes to decide on a system and inform employees of it. The "way" will usually simply involve directing supervisors to inform their subordinates, as part of their usual communication with them, to report work-related injuries and illnesses to their supervisor. Most, if not all, establishments require employees routinely to report problems of any kind to their supervisors, and reporting injuries and illnesses is simply one of the kinds of things employees report. OSHA believes there will be no additional cost associated with the supervisors' forwarding of these reports to the person in charge of recordkeeping, because this is already part of supervisors' duties. This is a one-time cost, which OSHA has annualized over ten years using a 7 percent discount rate. The net annualized costs of setting up the system are $1,706,285.[20]

(5) Total Cost Impact

Table X–6 summarizes the total annualized cost impacts of fixed, establishment-level costs resulting from the final regulation. The total net annualized costs are estimated to be $37,668,954.

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[14] $209,034 = (−119,720 + 179,287 Establishments) × (8 Minutes/Establishment) × ($26.32/Hour)

[15] $11,984,233 = (1,186,698 + 179,287 Establishments) × (20 Minutes/Establishment) × ($26.32/Hour)

[16] The proposal would have replaced certification by the recordkeeper with certification by a plant manager. Many commenters stated that this would have required the plant to become personally familiar with the information being certified, and that this would have entailed considerably more time than 5 minutes (see, *e.g.*, Exs. 15–9, 15–355, 15–428, 15–395).

[17] $20,604,232=(1,186,698 Establishments) × (−2 Minutes/Establishment) × ($26.32/Hour) + (30 Minutes/Establishment) × ($36.48/Hour)

[18] $105,043=(119,720 Establishments) × (2 Minutes/Establishment) × ($26.32/Hour)

[19] $3,270,213=(179,287 Establishments) × (30 Minutes/Establishment) × ($36.28/Hour)

[20] $1,706,285=(1,365,985 Establishment) × (20 Minutes/Establishment) × ($26.32/Hr.) × [0.07/(1 − (1/(1.07)[10]))]

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TABLE X-6
FIXED ANNUAL COSTS TO ESTABLISHMENTS

Cost Element/ Industry Status under Final Rule	Estimated Number of Establishments	Change in Level of Effort (Minutes)	Total Hours	Total Cost
Set Up Log and Post Summary				
Newly Exempted	119,720	- 8	-15,963	-$ 420,146[a]
Newly Covered	179,287	8	23,905	$ 629,180[a]
Additional Data Requirements on Summary				
Formerly & Still Covered	1,186,698	20	395,566	$10,411,297[a]
Newly Covered	179,287	20	59,762	$ 1,572,936[a]
Certification of Summary				
Formerly & Still Covered	1,186,698	- 2	- 39,557	$ 1,041,140[a]
		30	593,349	$21,645,372[b]
Newly Exempted	119,720	- 2	- 3,991	-$ 105,043[a]
Newly Covered	179,287	30	89,644	$ 3,270,213[b]
Way to Inform Employees	1,365,985	20	455,328	$ 1,706,285 [a,c]
TOTAL ANNUAL COST			1,588,043[d]	$37,668,954

[a] Based on an hourly cost of $26.32.

[b] Based on an hourly cost of $36.48.

[c] One-time cost that is annualized over 10 years at a discount rate of 7 percent.

[d] Includes 227,664 hours that will be required in the first year only.

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D. Costs of Maintaining Records

The costs of maintaining the Log and Incident Reports are related to the number of cases recorded. There are numerous changes to the final rule that result in very small increases or decreases in the number of cases that will need to be recorded. With two exceptions, OSHA concludes that the average establishment keeping records under both the former rule and the final rule will experience an overall decrease in the number of occupational injury and illness cases entered into its OSHA records. These decreases will result from the addition of several exemptions to the presumption of work-relatedness for cases occurring in the work environment and from definitional changes (*e.g.*, medical treatment, first aid, restricted work, aggravation) that will make fewer cases recordable. However, for this analysis, OSHA makes the conservative assumption that these will net out to a zero change. This assumption means that the costs presented in this economic analysis are somewhat overstated.

The two exceptions to the overall decrease in the number of cases recorded are the result of the change to a more sensitive standard threshold shift for recording hearing loss, which will increase the number of cases in all industries except construction, and the new requirement to record needlesticks and sharps injuries, which will result in a relatively large increase in the number of cases recorded in SIC 80.

The costs for SIC 80 are analyzed separately. The analysis uses the following classes of industries:

For industries covered by the former regulation and now covered by the new regulation, except for SIC 80, OSHA assumes that the number of needlestick cases recorded will essentially be unchanged by the final regulation.

For industries (except in SIC 80) covered by the former regulation, but exempted under the final regulation, recorded cases will fall to zero, resulting in commensurate savings.

For industries exempted under the former regulation but covered by the final regulation, the impact will be the full cost of recording such cases.

In SIC 80, recorded cases in three-digit industries that are newly exempted (see Table X–3) will fall to zero, resulting in commensurate savings. The industries that will continue to be covered (SIC 805, Nursing and Personal Care Facilities, SIC 806, Hospitals, and SIC 808, Home Health Care Services) will bear the full cost of recording the expected increase in needlesticks and sharps cases. This increase in cases will be analyzed in the same manner as cases in newly covered industries.

(1) Impacts on Costs of the Final Rule's Changes in Scope

The changes in the scope of the final rule's industry coverage will bring commensurate changes in the costs of the regulation. OSHA estimates that, under the former regulation, it required an average of 15 minutes per recorded case to maintain the Log, plus 20 minutes to fill out a 101 form, for those employers who did not use an equivalent form.

The addition of new elements to Form 301, as will be described shortly, raises OSHA's estimate of the total time required to fill out an individual report of injury or illness to 22 minutes. Based on data collected during approximately 400 recordkeeping audit inspections, OSHA assumes that 82 percent of incidents will be recorded on forms other than the new Form 301, such as workers' compensation forms.

The average for the Log takes into account a wide range of cases. For clearly work-related injuries involving an absence of 10 work days and involving no additional restricted time, for example, essentially all of the necessary information can be obtained from workers' compensation-related files. In such a case, entering the data on the Log will simply require pulling the workers' compensation file and entering the key information on the Log—a three minute task. OSHA assumes that the time required to make an entry will increase when either (1) information is not already kept for other purposes, or (2) making the entry requires the recordkeeper to study the regulation. Examples of situations where the necessary information would not already have been recorded elsewhere are cases that are not recorded as workers' compensation cases, or cases involving restricted work days (which are not recorded in workers' compensation data and may not be part of the affected worker's payroll or personnel files). Examples of situations where it would be necessary to study the regulation are those involving questions about the recordability of the incident or its work-relatedness. Changes in scope will have different impacts on the different classes of industries, as follows:

- Continuously Covered Establishments. By definition, establishments in industries formerly covered and still covered by the final regulation will have no changes in costs related to industry scope.
- Newly Exempted Establishments. Establishments that were covered by the former regulation but are exempt from the final regulation will realize for each currently recorded case a cost saving of 15 minutes for the Log entry plus, for 18% of the cases, a saving of 20 minutes for the 301 form. The estimated total annual savings will be $405,499.[21]
- Newly Covered Establishments. Establishments that were exempt under the former regulation but are covered by the final regulation will incur for each currently recorded case costs of 15 minutes for the Log entry plus, for 18% of the cases, 22 minutes for the 301 form. The total annual cost is estimated to be $1,646,000.[22]
- Additional Hearing Loss Cases. Establishments will incur for each additional hearing loss case costs of 15 minutes for the Log entry plus, for 18% of the cases, 22 minutes for the 301 form, or an estimated total annual cost of $2,287,208.[23]
- SIC 80. Establishments in SIC 80 will incur for each additional needlesticks and sharps case costs of 5 minutes for the Log entry [24] plus, for 18% of the cases, 22 minutes for the 301 form, or an estimated total annual cost of $1,971,664.[25]

(The costs of the "log of percutaneous injuries from contaminated sharps" specified in the revision of the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act have been captured in the analysis of that rule. No offset has been taken in the economic analysis of this rule for costs common to these two rules for recording needlestick injuries.)

The estimated total cost impact related to changes in scope of the recordkeeping rule is $5,499,373.

(2) Maintenance of the Log

Form 300 will replace Form 200 as the Log of injuries and illnesses. The revisions to this form represent the greatest source of cost savings to employers required to record work-related injuries and illnesses. The major modifications that result in time and cost savings are simplifications of Form 300 and changes and simplifications in the criteria for recordable cases.

Simplification of the Log. Compared to the form that it will replace, Form 300 has a more logical progression, makes available considerably more space, and eliminates unnecessary columns. OSHA estimates that this will take an average of one minute off the time required to record cases (except for

[21] $405,499 = ((49,698 Cases) × (15 Minutes/Case) + (8,946 Cases) × (20 Minutes/Case)) × ($26.32/Hours).

[22] $1,646,000 = ((197,904 Cases) × (15 Minutes/Case) + ($35,623 Cases) × (22 Minutes/Case)) × ($26.32/Hours).

[23] $2,287,208 = (275,000 Cases) × (15 Minutes/Case) × ($26.32/Hour) + (49,500 Cases) × (22 Minutes/Case)) × ($26.32/Hour).

[24] Under the simplified criteria of the final rule, needlesticks and sharps cases are among the very easiest cases to document and record.

[25] $1,971,664 = ((501,640 Cases) × (5 Minutes/Case) + (90,295 Cases) × (22 Minutes/Case)) × ($26.32/Hour).

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those that involve needlesticks or sharps, which will be analyzed separately in this analysis). This simplification of the Log will produce a saving of $2,177,240.[26]

Simplification of Decisionmaking about Recordability. In estimating the savings in time associated with the simplification of recordability decisionmaking, OSHA focused primarily on the simplification of the steps needed to determine whether an injury or illness is serious enough to be recorded. When a work-related injury or illness results in days away from work or restricted workdays, then it is obvious under both the former and final regulations that the injury or illness must be recorded. Under the former regulation, however, the employer was required to consult several paragraphs of the Recordkeeping Guidelines to determine whether an injury that did not result in lost or restricted workdays would need to be counted. The final regulation will allow the employer to settle the issue quickly by looking at the list of first aid treatments in Section 1904.7(b)(4).

Of the cases in the 1998 BLS Survey of Occupational Injury and Illness that did not involve needlesticks or sharps, 52.34 percent did not involve lost or restricted workdays. In addition to the one minute saved for each case because of the forms simplification discussed on the previous page, OSHA estimates that the simplification of recordability decisionmaking under the final rule will save approximately 2 minutes for each such injury or illness case. Applying this unit cost saving to all industries covered by the final rule produces estimated total savings of $2,279,080.[27]

Under the final rule there will no longer be any need to examine in any detail the recordability of any cases involving needlesticks or sharps, since all such cases will have to be recorded. OSHA estimates that the average time required to record such cases will change from 15 minutes under the former rule to 5 minutes under the final rule. This would save covered establishments in SIC 80 an estimated $388,329.[28]

OSHA has also clarified the requirement to record medical removal cases by stating in the regulatory text that any case involving medical removal required by an OSHA health standard must be recorded as a case involving days away from work or restricted work/job transfer (as appropriate). OSHA had interpreted the former rule to have the same effect, but the former regulatory text did not clearly state the requirement. This clarification makes overall compliance with OSHA's rules simpler, because both the recordkeeping rule and the OSHA standards will rely on the same criteria, such as biological monitoring test results, employers' determinations, and physician's opinions, and the recording requirements are clearly stated in the regulatory text.

Under the final rule, days away from work and days of restricted work will be counted by calendar days rather than according to scheduled work days. One commenter (Ex. 57X, pp. 97–101, 117–118) argued that, in the automobile manufacturing industry alone, this could free up $5,000,000 to $6,000,000 worth of human resources per year for more productive uses of time. However, OSHA has not taken cost savings for this change because no data in the record suggest that the projections for this industry will be typical of other industries.

Privacy Concern Cases. The final rule requires maintenance of a separate, confidential list of case numbers and employee names for "privacy concern cases," so that an employee's name does not appear on the Form 300. Privacy concern cases include injury or illness to an intimate body part or the reproductive system; injury or illness resulting from a sexual assault; mental illness; HIV infection, hepatitis, or tuberculosis; needlesticks and sharps injuries; and other illnesses (except MSD illnesses) that the employee requests be treated as a privacy concern case.

In 1997 BLS estimated that there were 621 days away from work cases involving the reproductive tract, 18 rapes, 5,542 mental disorders, and no hepatitis cases. (Data are available at www.bls.gov.) In 1997, OSHA estimated that there were approximately 34,630 occupational TB infections annually. It appears that TB cases have declined somewhat since then, but OSHA uses this number in this analysis as a conservative estimate.

The time to record HIV infection cases is included in the estimate of the time associated with recording 590,165 needlestick and sharps cases, but each of these cases will also require time for making an entry in the confidential list of case numbers and employee names. OSHA also assumes that employees in 10,000 other illness cases will ask that their names not appear on the Form 300.

OSHA estimates that it will take an average of 3 minutes to record each "privacy concern case" on the required separate, confidential list of case numbers and employee names. The estimated annual cost of this provision is thus $843,524.[29]

(3) Maintenance of Individual Reports of Injury and Illness

The final regulation substitutes the new Form 301 for the former Form 101 and provides other options.

New Elements on Individual Reports. The new form requires employers to record such additional items as the injured or ill employee's date of hire, emergency room visits, the starting time of the employee's shift, and time of the accident. OSHA estimates that these additional elements will raise time required to fill out an individual report of injury or illness from 20 minutes for the old Form 101 to 22 minutes for the new Form 301. This change will cost employers in industries formerly covered and still covered by the final regulation an estimated $889,169.[30]

Changes that will reduce burden include:

An option to keep Form 301s off-site; and

An option to keep Form 301s on electronic media.

Keeping Form 301s Off-site. Keeping Form 301s off-site will provide the greatest cost savings to small, isolated establishments that are owned by larger firms that already keep personnel data at headquarters or at another site. For such firms, OSHA estimates that the ability to maintain records off-site could save as much as 5 minutes per record. These savings in time and effort would result from reductions in the amount of time necessary to copy the Form 301 at headquarters, send it to the small establishment, receive it there, and file it. There would also be a saving in postage. Under the final rule, such small establishments would have to go through all of these steps only when an inspection occurred. Even if only 2 percent of the estimated recordable cases in establishments that are covered under the final regulation were affected by this provision (which OSHA believes is likely to be an underestimate), the resulting cost savings would be $294,141.[31]

Storing Form 301s on Electronic Media. The final rule permits employers to store Form 301s on electronic media, provided that they are able to produce the records in hard copy within four hours of a request by a government representative permitted access under the regulation. OSHA estimated that electronic storage would be advantageous for establishments that handle more than 100 cases per year. OSHA used as a proxy variable for this number the number of establishments with 1,000 or more employees. In the 1998 BLS survey, establishments in this size category had a total of 899,700 recordable cases. OSHA estimates that for each case the ability to store case information electronically would save 2 minutes of time, plus $.05, for making a paper copy. The estimated cost savings from this change would amount to approximately $825,027 per year.[32] OSHA believes that this may be an underestimate, because having even as few as 30 to 40 cases a year might be enough incentive to prompt a firm to keep its records electronically. To the extent that these much smaller firms turn to electronic storage, the cost savings associated with this provision could be many times greater than the estimate.

(4) Employee and Employee Representative Access

The final regulation requires employers to provide employees and their representatives access to Form 301s and to pay the cost of one copy. (It also requires them to allow access to the Log, but this is not a change from the former rule.) OSHA assumes that employers would require five minutes to pull, copy (at $0.05), and replace the relevant form. OSHA assumes that (a) at one-tenth of covered establishments, one employee would request access to his or her own Form 301, and (b) at one percent of covered establishments, a union representative would request access to all Form 301s at the establishment. OSHA further assumes that there would be an average of ten Form 301s at such establishments.[33] The estimated total cost of this provision is $612,860.[34]

(5) Access to Other Parties

The final regulation requires that if employers voluntarily disclose Forms 300 or 301 to persons other than government representatives, employees, former employees, of authorized representatives, they must remove or hide the employees' names, with certain exceptions. Since employers may accomplish this by simply covering part of the form before they copy it, OSHA considers this requirement to impose no costs.

(6) Total Cost Impact

Table X–7 summarizes the cost impacts of maintaining records attributable to the final regulation. The net impact is an estimated annual cost of $1,881,080.

E. Summary of Costs

Table X–8 summarizes the total annualized cost impacts of the entire final rule. This summary indicates that:

The largest sources of costs are: New certification requirements ($23.8 million), additional data requirements ($12.0 million), expansion in the scope of the rule ($5.5 million), and transitional costs of the new rule ($1.5 million).

The largest sources of savings are: Simplified maintenance of the Log ($4.8 million), less time required to relearn the recordkeeping system ($3.1 million), simplified maintenance of individual reports ($1.1 million).

The net impact of these changes is an estimated annual cost of about $38.6 million.

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[26] $2,177,240 = (4,963,312 Cases) × (1 Minute/Case) × ($26.32/Hour).

[27] $2,279,080 = (2,597,736 Cases) × (2 Minutes/Case) × ($26.32/Hour).

[28] $388,329 = (88,525 Cases) × (10 Minutes/Case) × ($26.32/Hour).

[29] $843,524 = (640,976 Cases) × (3 Minutes/Case) × ($26.32/Hour).

[30] $889,169 = (1,013,503 Cases) × (2 Minutes/Case) × ($26.32/Hour).

[31] $294,141 = (5,630,573 Cases) × (0.02) × [(5 Minutes/Case) × ($26.32/Hour) + ($0.33/Case)].

[32] $825,027 = (889,700 Cases × [(2 Minutes/Case) × ($26.32/Hour) + ($0.05/Case)].

[33] This is a conservative estimate. The average number of cases per covered establishment was only about 4 in 1998. Further, some employers already provide copies of Form 301s to union representatives. [Transcript, March 29, 1996, p. 14].

[34] $612,860 = (273,197 Forms × [(5 Minutes × ($26.32/Hour) + $.05/Copy)].

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TABLE X-7
ANNUAL COSTS OF MAINTAINING RECORDS

Cost Element/ Industry Status Under the Final Rule	Estimated Number of Recorded Cases	Change in Level of Effort (Minutes)	Total Hours	Total Cost
Changes in Scope				
Effects on Number of Log Entries:				
Newly Exempted	49,698	- 15	- 12,425	- $ 327,013[a]
Newly Covered	197,904	15	49,476	$1,302,208[a]
Additional Hearing Cases	275,000	15	68,750	$1,809,500[a]
Additional Needlestick Cases	501,640	5	41,803	$1,100,255[a]
Effects on Number of 301 Forms:				
Newly Exempted	8,946	- 20	- 2,982	- $ 78,486[a]
Newly Covered	35,623	22	13,062	$ 343,792[a]
Additional Hearing Cases	49,500	22	18,150	$ 477,708[a]
Additional Needlestick Cases	90,295	22	33,108	$ 871,409[a]
Maintenance of the Log				
Covered under Final Rule[b]	4,963,312	- 1	- 82,722	- $2,177,240[a]
Non- Lost Work Day Cases				
Covered under Final Rule[b]	2,597,736	- 2	- 86,591	- $2,279,080[a]
Previous Needlestick Cases	88,525	- 10	- 14,754	- $ 388,329[a]
Privacy Concern Cases				
Covered under Final Rule	640,976	3	32,049	$ 843,524[a]
Maintenance of Individual Reports:				
New Elements on Form 301				
Formerly & Still Covered	1,013,503	2	33,783	$ 889,169[a]
Form 301 Off-Site				
Covered under New Rule	116,569	- 5	- 9,714	- $ 294,141[a]
Electronic Media				
Covered under New Rule	889,700	- 2	- 29,657	- $ 825,057[a]
Employee Access				
Covered under New Rule	273,197	5	22,766	$ 612,860[a]
TOTAL ANNUAL COST			109,138	$1,881,080

[a] Based on an hourly cost of $26.32
[b] Except needlesticks and additional hearing loss cases

TABLE X-8
NET ANNUAL COSTS ASSOCIATED WITH THE FINAL RULE, BY PROVISION

Cost Element	Total Net Hours	Total Net Cost
Initial Familiarization Costs		
Shift to the New Recordkeeping System	395,566[a]	$ 1,482,384
Initially Learn the Recordkeeping System	179,287[a]	$ 671,856
Relearn the Recordkeeping System	- 118,729	- $ 3,124,947
Fixed Recordkeeping Costs		
Set Up Log and Post Summary	7,942	$ 209,034
Additional Data Requirements	455,328	$11,984,233
Certification	639,445	$23,769,402
Way to Inform Employees	455,328	$ 1,706,285
Costs of Maintaining Records		
Changes in Scope	208,943	$ 5,499,373
Maintenance of the Log	- 184,067	- $ 4,844,648
Privacy Concern Cases	32,049	$ 843,524
New Elements on Individual Reports	33,783	$ 889,169
Maintenance of Individual Reports	- 39,371	- $ 1,119,198
Employee Access	22,766	$ 612,860
TOTAL ANNUAL COST	2,088,269[b]	$38,246,377

[a] One-time costs only.
[b] Includes 1,030,181 hours that will be required in the first year only.

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4. Benefits

OSHA's final Recording and Reporting Occupational Injuries and Illnesses rule is designed to provide an information base to assist employers and employees to maintain safe and healthy working conditions that protect workers. The importance of the contribution of accurate recordkeeping to lower injury and illness rates is indicated by experience with OSHA's Voluntary Protection Program (VPP), a program that recognizes employers with exemplary safety and health programs. VPP worksites, which have comprehensive safety and health management programs that include effective injury, illness, and accident recordkeeping, generally have lost-workday case rates ranging from one-fifth to one-third the rates experienced by most worksites in the same industry.[35] These sites also routinely rely on the Logs and other worksite data sources to evaluate their programs and correct deficiencies. This chapter describes the potential benefits associated with the changes OSHA is making to the recordkeeping requirements in 29 CFR 1904.

A. Overview of Benefits

The benefits of improved recordkeeping fall into two groups. Improved recordkeeping enhances the ability of employers and employees to prevent occupational injuries and illnesses. Improved recordkeeping and reporting also increases the utility of injury and illness records for OSHA's purposes.

(1) Enhanced Ability of Employers and Employees to Prevent Injuries and Illnesses

The additional or improved information about events and exposures to be collected on Form 301, including information on the location, the equipment, materials or chemicals being used, and the specific activity being performed, will increase the ability of employers and employees to identify hazardous conditions and to take remedial action to prevent future injuries and illnesses. Identifying the irritating substance that has caused an employee to experience a recordable case of occupational dermatitis, for example, could prompt an employer to re-examine available Material Safety Data Sheets to identify a non-irritating substitute material. On Form 301, details will be recorded in a logical sequence that will help structure the information and focus attention on problem processes and activities. Thus the establishment's records of injuries and illnesses will provide management with an analytical tool that can be used to control or eliminate hazards.

The process of using recorded information to control or eliminate hazards was well illustrated in a comment on the proposed rule.[36] This testimony described a training exercise where trainees used Log data to plot MSD injuries on a floor plan; went into the plant to look for risk factors and interview workers; formulated specific workplace design and work organization changes to eliminate or reduce risk factors; and refined their findings into an action plan.

If this enhanced ability to identify (and thus address) hazards translates into a reduction even as small as 0.5 to 1 percent of the estimated number of recordable cases, it would mean the prevention of 29,147 to 58,285 injuries and illnesses per year.[37]

(2) Increased Utility of Data to OSHA

The final rule's changes will also make injury records more useful to OSHA, as well as to employers and employees. Improvements in the quality and usefulness of the records being kept by employers would enhance OSHA's capacity to:

Focus compliance outreach efforts on the most significant hazards;

Identify types or patterns of injuries and illnesses whose investigation might lead to regulatory changes or other types of prevention efforts, such as enforcement strategies, information and training, or technology development; and

Set priorities among establishments for inspection purposes.

Employers and employees both stand to benefit from the more effective use of OSHA's resources. The enhanced ability of compliance officers to identify patterns of injuries will enable OSHA to focus on more serious problems. Identification of such patterns will also increase the ability of employers to control these hazards and prevent other similar injuries. To the extent that employers take advantage of this information, the burden of OSHA inspections should be reduced in the long run. Employees clearly will also benefit from these reductions in injuries.

B. Specific Benefits of the Final Regulation

(1) Changes in Scope of the Regulation

The changes in the scope of the final regulation in the retail and service sectors represent a refinement in coverage. The scope of the former rule is defined at the two-digit SIC level; the scope of the final rule is defined at the three-digit SIC level. OSHA is expanding the scope to include high-risk three-digit industries that were previously exempt and to reduce the scope to exempt low-risk three-digit industries that were previously covered.

The effect of this change is to make the regulation more cost-effective. This retargeting shifts the burden from industries with relatively few injuries and illnesses per establishment to industries with substantially larger numbers of injuries and illnesses per establishment. Thus the final rule will result in higher hazard identification benefits per dollar of regulatory burden. It is also likely to lead to a small reduction in injuries and illnesses at newly covered establishments that had not been keeping records at all.

The final rule's changes in scope will similarly increase the cost-effectiveness of OSHA's compliance activities. With the same expenditure of resources, OSHA will be better able to detect injury and illness trends and to assist employers to address the causes of these trends. OSHA expects this more efficient use of Agency resources to translate directly into reduced worker injuries and illnesses, reductions in costs to employers, and increased productivity.

(2) Forms Simplification and Definitions

The general reduction in burden associated with changes in the forms and in the data reported was discussed in the previous chapter under cost savings. The simplification of the forms also will have benefits in the form of improved information. The same is true of definitional changes, such as counting lost workdays or restricted work days as calendar days and capping the count at 180 days. Easier recording of data will make records of individual cases more complete and consistent. It is also possible that simplified recording will encourage more complete recording of job-related injuries and illnesses.

This process is illustrated by the change from days away from work to calendar days. This change represents an explicit decision to shift the emphasis from lost productivity to the seriousness of the injury or illness. Calendar days are a more accurate and consistent reflection of seriousness than

[35] **Federal Register**, January 26, 1989, p. 3904.

[36] Nancy Lessin, Testimony on behalf of Massachusetts Coalition for Occupational Safety and Health, May 3, 1996, Transcript, p. 48.

[37] (0.005 to .01) × 5,828,477.

are lost scheduled workdays. They are also directly comparable across establishments and industries, while days away from work are not. Thus, calendar days produce more useful information for the purpose of assessing patterns of injuries and illnesses. This variable is also generally much simpler to determine and record, so that the information is more likely to be complete and accurate. This combination of attributes, OSHA believes, will substantially improve the quality of the information available for analysis and enhance the resulting actions taken to reduce job-related injuries and illness.

(3) Recordable Injuries/Illnesses

The changes in the definition of the injuries and illnesses that are recordable have several different types of benefits. In general, they follow a pattern of simplification and/or more cost-effective targeting of recording requirements, which should produce the types of benefits discussed above. Changes that add to the information recorded have other benefits as well.

Specified Recording Thresholds. One change involves identifying the threshold at which a medical removal condition or restriction is to be recorded, and tying this to the level in a specific OSHA standard (lead, cadmium, ergonomics, etc.). This requirement involves no increase in cost, since the pre-removal or restriction conditions are already required under the specific OSHA standard.

Needlesticks and Sharps Injuries and Hearing Loss Cases. By far the most extensive change in recording is the requirement to report *all* needlesticks and sharps injuries involving exposure to blood or other potentially infectious materials in the covered industries. The benefits of this change are also quite extensive, however, and the costs are less than they might at first seem. In effect, OSHA is changing the emphasis on these injuries from the effects (the injury's medical treatment) to the actual injury caused by the incident (i.e., the needlestick or sharps injury).

Recording all needlesticks and sharps injuries will provide far more useful information for illness prevention purposes. Unlike many other conditions (*e.g.*, blood poisoning and hearing loss) that are progressive, AIDS and hepatitis are either present or they are not. In any given work setting, the risk is probabilistic and bimodally distributed; either one is infected by an injury or one is not. Under these circumstances, it is important to prevent all injuries that might lead to illness. For that prevention strategy to be successful, however, it is necessary to get a complete picture of the overall pattern of all needlesticks and sharps injuries. This requires recording all such injuries, whether or not they result in AIDS, hepatitis, or other bloodborne illness. The final regulation accomplishes this.

Because of their high mortality and disability potentials, AIDS and hepatitis are particularly frightening illnesses. One implication of this fact, however, is that the benefits per case of prevention are large. Another implication is that there are substantial employee morale benefits to a prevention program that is comprehensive and well informed. Recording all risky wounds and then using the data for prevention are actions that are reasonable. These provisions of the final rule are likely also to result in indirect benefits in the form of improved patient care.

Hearing loss cases also result in substantial disability and lead to safety accidents as well. OSHA believes that aligning the recording threshold for such cases with the Standard Threshold Shift criterion in the Agency's occupational Noise Standard will simplify recording for many employers who are already familiar with this criterion. The shift in this recording criterion will also increase the number of hearing loss cases captured by the recordkeeping system and provide more opportunities for employers to intervene to prevent other hearing loss cases.

(4) Procedural Changes and Informational Requirements

The relationship between costs and benefits varies for the final rule's procedural changes and for its requirements for additional information. Some provisions have positive but trivial costs. Others have more significant costs but substantial benefits.

De Minimis Costs. A number of changes have costs that are so low that the benefits of the change are clearly greater. Examples include the provisions discussed below.

Recording incidents within seven calendar days, rather than six working days, will impose costs for more rapid recording on establishments that work only five days a week. The reduced burden resulting from a simpler deadline—one week later—almost certainly outweighs this minuscule cost, however. Moreover, for establishments that operate six or seven days a week, this change does not impose any costs at all.

The requirement, upon change of ownership, for the seller to hand over records to the buyer of the business has extremely small costs. The seller, after all, is already required to maintain those records, and the buyer is required to take them over. The benefits of continuity of information are clearly much greater than this trivial cost.

The cost, if any, for posting (but not revising) the Annual Summary for three months, rather than one month, is extremely small—particularly considering that quite a number of other certificates and information (*e.g.*, elevator certificates, minimum wage information, etc.) must be posted at all times. The ability of employees to refer back to the Annual Summary information, as well as the availability of the information to new employees when they are hired, clearly produces benefits that exceed the costs.

Certification by a Company Executive. The requirement that a company executive certify the Summary will have the effect of increasing the oversight and accountability of higher management in health and safety activities. The certifying official will be responsible for ensuring that systems and processes are in place and for holding the recordkeeper accountable. OSHA believes that this increased awareness of job-related injuries and illnesses, and of their prevention, will translate into fewer accidents and injuries because the certifying executive will have a heightened sense of responsibility for safety and health, although quantifying this benefit is not possible at this time.

Additional Data Requirements for Form 301 and Form 300–A. The final rule will require employers to provide several additional pieces of information, at an estimated cost of two minutes per Form 301 and twenty minutes per Form 300–A.

Additional information related to incidents (on Form 301) includes: Employee's date of hire, emergency room visits, time the employee began work (starting time of the shift), and time of the accident.

Additional establishment information (on the Form 300–A Summary) includes:

Annual average number of employees employed in that year, and Total hours worked by all employees during the year.

Information on the injured employee's date of hire can provide insight into a number of factors that have been shown to relate to injury rates. Such factors may include inadequate training, inexperience on the job, etc. If OSHA were to link its injury data with information on the distribution of job tenure, for example, it could then calculate injury rates by job tenure category for different jobs. That information would help to identify areas

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where better training would have the greatest potential to reduce injuries.

Data on starting times of shifts and the time of occurrence of the accident will facilitate research on whether accident rates vary by shift, and whether certain portions of a shift are particularly dangerous. This information will be helpful to OSHA as well as to the employer's own assessment of workplace safety and health. Most importantly, employees will receive the information they need to understand both the absolute and relative incidence of injuries and illnesses in their establishment. Such information is essential both for market-based mechanisms to influence safety and health and for meaningful employee participation in safety and health.

The inclusion of information concerning the average number of employees and total hours worked by all employees during the year will enable OSHA inspectors to calculate incidence rates directly from the posted summary. Employers will also benefit from their ability to obtain incidence information quickly and easily.

At the establishment level, occupational injury and illness records are examined at the beginning of an OSHA inspection and are used by compliance officers to identify safety and health problems that deserve to be focused on. The data on Form 300 and Form 301 will also be used to determine what areas of the site, if any, warrant particular attention during the inspection. Again, access to this improved information will be of direct benefit to employers and employees, who will be able to act on it to control hazards.

Employee Access to Form 301. Providing employees with access to the Form 301, as well as the Form 300, will allow them to monitor the accuracy of the data and to identify possible patterns of injuries and illnesses. Access to Form 301 is important because this form contains enough detailed information about the events surrounding the occurrence to enable workers analyzing it to identify the appropriate protective measures to prevent future accidents.

(5) Summary

Taken together, the changes that OSHA is making to its recording and reporting requirements are designed to achieve the Agency's primary goal of reducing job-related injuries, illnesses, and fatalities. The link between more accurate and better-targeted injury and illness recordkeeping and accident prevention has repeatedly been established and emphasized by the National Academy of Sciences, the Keystone Report, the testimony of safety and health professionals, and the Agency's own experience. The final rule's changes will thus benefit workers, their employers, and the Agency's accident prevention efforts.

5. Economic Feasibility and Small Business Impacts

Introduction

This section assesses the impact on affected firms of the costs of implementing the final recordkeeping rule. It is divided into four parts. The first part analyzes the economic feasibility of the rule for firms in all affected industries. The second part analyzes the economic impacts of the rule on small entities in the affected industries. The third part presents an Unfunded Mandates Analysis, which OSHA has conducted in accordance with the Unfunded Mandates Reform Act. The fourth part examines the potential environmental impacts of the regulation.

Analysis of Economic Feasibility

The final 1904 rule is a regulation promulgated under sections 8 and 24 of the OSH Act, and is not a standard, which would be promulgated under Section 6 of the Act. Nevertheless, OSHA has performed an analysis of the economic feasibility of the rule.

The courts have held that, to demonstrate that a standard is economically feasible, OSHA "must construct a reasonable estimate of compliance costs and demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry, even if it does portend disaster for some marginal firms" [*United Steelworkers of America* v. *Marshall*, 647 F.2d 1189, 1272 (D.C. Cir. 1980) (the "Lead decision")]. In assessing the economic feasibility of the final recordkeeping rule, OSHA has followed the decisions of the courts in the Lead case and other OSHA cases, and has relied on information and data in the record to determine that the final standard is economically feasible for firms in all affected industries.

OSHA's estimates of the number of covered establishments in each affected industry are presented in Section 2 of this economic analysis, and the results of the Agency's analysis of annualized compliance costs are presented in Section 3. The Agency's analysis is based on comments to the record, supplemented, where needed, by public information sources such as the Census Bureau's *County Business Patterns*.

In this section, for each affected industry, estimates of per-firm annualized compliance costs are compared with (a) per-firm estimates of sales from a compilation of 1996 data performed by the U.S. Census Bureau for the Small Business Administration to reflect parent company control of establishments, and (b) per-firm estimates of profits derived from information in Dun & Bradstreet's "Industry Norms and Key Business Ratios" database for 1996 or by applying 1996 profit percentages from Robert Morris Associates to the Agency's per-firm estimates of sales. Based on the results of these comparisons, which identify the magnitude of the potential impacts of the final rule, OSHA then assesses the rule's economic feasibility for establishments in all affected industries.

To estimate the sales and profits of covered firms, OSHA identified the Standard Industrial Classifications (SICs) of every industry under the scope of the rulemaking. For each industry, OSHA then calculated the average sales per firm in the relevant SIC(s). The average rate of return on sales (from Dun and Bradstreet or, if necessary, from Robert Morris Associates) was used to estimate average profit per firm. (Throughout this section, the term "average" is used to mean the arithmetic mean.)

The cost estimates compared with estimated sales and profit data for firms in each affected industry "screen" for potential impacts. If sizeable impacts were identified by this screening analysis, additional analysis would be necessary.

Table X–9 shows compliance costs as a percentage of before-tax profits and of sales. This table presents the results of the screening analysis, which simply measures costs as a percentage of before-tax profits and sales; the screening analysis is used to determine whether the compliance costs potentially associated with the rule could lead to significant impacts on the affected firms under worst-case scenarios. Whether or not the costs of compliance actually lead to a significant impact on the profit and/or sales of firms in a given industry will depend on the price elasticity of demand for the products or services of firms in that industry.

Price elasticity refers to the relationship between the price charged for a product and the demand for that product: the more elastic the relationship, the less able firms are to pass the costs of compliance through to their customers in the form of a price increase and the more they must absorb the costs of compliance from their

profits. When demand is inelastic, firms can absorb all the costs of compliance simply by raising the prices they charge for that product; under this scenario, profits are untouched. On the other hand, when demand is elastic, firms cannot cover the costs simply by passing the cost increase through in the form of a price increase; instead, they must absorb some of the increase from their profits. In general, "when an industry is subjected to a higher cost, it does not simply swallow it; it raises its price and reduces its output, and in this way shifts a part of the cost to its consumers and a part to its suppliers," in the words of the court in *American Dental Association* v. *Secretary of Labor*, [984 F.2d 823, 829 (Seventh Cir. 1993)] (the "ADA decision").

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TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$ 26.27	$1,643,011	0.0016%	$98,581	0.027%
08	Forestry	$ 34.18	$4,517,500	0.0008%	$140,043	0.024%
09	Fishing, Hunting, & Trapping	$ 28.24	$6,318,183	0.0004%	$315,909	0.009%
13	Oil and Gas Extraction	$ 45.83	$34,757,006	0.0001%	$1,772,607	0.003%
15	Gen. Contractors & Op. Builders	$ 25.16	$8,733,493	0.0003%	$227,071	0.011%
16	Heavy Constr., except Building	$ 24.61	$8,891,657	0.0003%	$337,883	0.007%
17	Special Trade Contractors	$ 24.83	$3,021,903	0.0008%	$114,832	0.022%
20	Food and Kindred Products	$ 39.45	$55,449,039	0.0001%	$1,108,981	0.004%
21	Tobacco Products	$109.19	$611,873,720	*	$23,863,075	**
22	Textile Mill Products	$ 53.53	$27,804,977	0.0002%	$722,929	0.007%
23	Apparel & Other textile Products	$ 37.80	$6,533,106	0.0006%	$163,328	0.023%
24	Lumber and Wood Products	$ 31.92	$8,476,937	0.0004%	$305,170	0.010%
25	Furniture and Fixtures	$ 32.73	$10,819,231	0.0003%	$335,396	0.010%
26	Paper and Allied Products	$ 60.90	$50,060,367	0.0001%	$1,902,294	0.003%
27	Printing and Publishing	$ 41.86	$10,140,518	0.0004%	$415,761	0.010%
28	Chemicals & Allied Products	$ 78.02	$88,199,672	0.0001%	$3,704,386	0.003%
29	Petroleum & Coal Products	$ 96.77	$240,889,238	*	$7,467,566	0.001%
30	Rubber & Misc. Plastics Pdts	$ 40.67	$17,053,410	0.0002%	$613,923	0.007%
31	Leather and Leather Products	$ 38.35	$11,516,441	0.0003%	$207,296	0.018%
32	Stone, Clay, & Glass Products	$ 49.98	$12,963,602	0.0004%	$635,216	0.008%
33	Primary Metal. Industries	$ 33.15	$48,966,680	0.0001%	$2,301,434	0.001%
34	Fabricated Metal Products	$ 32.19	$11,131,190	0.0003%	$478,641	0.007%
35	Industrial Machinery & Equipment	$ 32.47	$13,603,234	0.0002%	$557,733	0.006%

TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
36	Electronic & Other Electrical Equip.	$ 49.71	$34,672,510	0.0001%	$1,733,626	0.003%
37	Transportation Equipment	$ (6.32)	$107,210,814	- *	$4,288,433	- **
38	Instruments & Related Products	$ 50.12	$29,545,846	0.0002%	$1,625,022	0.003%
39	Misc. Manufacturing Industries	$ 32.37	$7,712,561	0.0004%	$254,515	0.013%
41	Local & Interurban Pass. Transit	$ 34.78	$2,782,251	0.0012%	$164,153	0.021%
42	Trucking and Warehousing	$ 40.54	$6,828,568	0.0006%	$245,828	0.016%
43	United States Postal Service	$776,159	$60,005,000,00	0.0013%	N/A	N/A
44	Water Transportation	$ 38.83	$16,550,772	0.0002%	$827,539	0.005%
45	Transportation by Air	$ 20.57	$77,701,749	*	$3,185,772	0.001%
46	Pipelines, except Natural Gas	$350.74	$123,685,486	0.0003%	$6,060,589	0.006%
47	Transportation Services	$ 68.59	$4,212,194	0.0016%	$134,790	0.051%
48	Communication	$133.35	$45,842,134	0.0003%	$3,071,423	0.004%
49	Electric, Gas, & Sanitary Svs	$111.93	$112,358,783	0.0001%	$10,112,290	0.001%
50	Wholesale Trade - Durables	$ 51.39	$25,279,114	0.0002%	$606,699	0.008%
51	Wholesale Trade - Nondurables	$ 49.58	$42,689,772	0.0001%	$768,416	0.006%
521	Lumber & Other Bldg Materials	$ 52.26	$15,180,822	0.0003%	$288,436	0.018%
523	Paint, Glass & Wallpaper Stores	$142.20	$5,388,504	0.0026%	$48,497	0.293%
526	Retail Nurseries & Garden Stores	$ 38.87	$2,528,349	0.0015%	$55,624	0.070%
527	Mobile Home Dealers	$ 52.29	$8,631,626	0.0006%	$250,317	0.021%
53	General Merchandise Stores	$301.14	$141,333,177	0.0002%	$3,391,996	0.009%
541	Grocery Stores	$ 76.04	$18,148,027	0.0004%	$217,776	0.035%
543	Fruit & Vegetable Markets	$ 32.32	$3,033,727	0.0011%	$39,438	0.082%

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TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
553	Auto & Home Supply Stores	$207.49	$6,295,269	0.0033%	$119,610	0.173%
555	Boat Dealers	$ 65.37	$5,020,251	0.0013%	$110,446	0.059%
556	Recreational Vehicle Dealers	$ 72.19	$9,137,789	0.0008%	$155,342	0.046%
571	Furniture & Furnishings Stores	$131.57	$5,126,403	0.0026%	$117,907	0.112%
572	Household Appliance Stores	$ 89.23	$5,087,527	0.0018%	$117,013	0.076%
593	Used Merchandise Stores	$143.80	$2,423,691	0.0059%	$111,490	0.129%
596	Nonstore Retailers	$103.25	$13,330,037	0.0008%	$266,601	0.039%
598	Fuel Dealers	$128.25	$6,046,113	0.0021%	$48,369	0.265%
651	Real Estate Oprs &Lessors	$ 81.54	$5,093,830	0.0016%	$784,450	0.010%
655	Subdividers & Developers	$ 84.66	$5,577,710	0.0015%	$507,572	0.017%
70	Hotels & Other Lodging Places	$ 34.95	$5,334,743	0.0007%	$373,432	0.009%
721	Laundry, Cleaning & Garment Svcs	$ 88.69	$1,661,452	0.0053%	$63,135	0.140%
734	Services to Buildings	$ 58.48	$1,486,505	0.0039%	$55,001	0.106%
735	Misc. Equip. Rental & Leasing	$140.26	$5,665,544	0.0025%	$521,230	0.027%
736	Personal Supply Services	$122.03	$6,371,536	0.0019%	$191,146	0.064%
751	Automotive Rental & Leasing	$122.70	$20,477,609	0.0006%	$1,167,224	0.011%
752	Automobile Parking	$346.96	$7,956,476	0.0044%	$381,911	0.091%
753	Automotive Repair Shops	$ 39.47	$1,712,369	0.0023%	$66,782	0.059%
754	Automotive Svs, except Repair	$ 45.15	$1,218,918	0.0037%	$79,230	0.057%
762	Electrical Repair Shops	$ 52.11	$4,100,382	0.0013%	$106,610	0.049%

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TABLE X-9

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR ALL COVERED FIRMS, UNDER TWO WORST-CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
763	Watch, Clock & Jewelry Repair	$ 83.20	$1,714,533	0.0049%	$58,294	0.143%
769	Miscellaneous Repair Shops	$ 32.68	$2,867,239	0.0011%	$169,167	0.019%
794	Commercial Sports	$ 19.62	$10,882,419	0.0002%	$391,767	0.005%
799	Misc. Amusement & Rec. Svcs	$ 29.18	$3,061,718	0.0010%	$128,592	0.023%
805	Nursing & Personal Care Facilities	$ 86.55	$6,269,041	0.0014%	$269,569	0.032%
806	Hospitals	$256.90	$75,848,928	0.0003%	$3,868,295	0.007%
808	Home Health Care Services	$ 90.38	$4,861,272	0.0019%	$170,145	0.053%
833	Job Training & Related Svcs	$108.09	$2,420,399	0.0045%	$60,510	0.179%
836	Residential Care	$107.87	$2,223,194	0.0049%	$57,803	0.187%
842	Botanical & Zoological Gardens	$166.25	$4,411,468	0.0038%	$269,100	0.062%
All Covered Firms		$ 57.82				

* indicates absolute value is less than .00005%
** indicates absolute value is less than .0005%

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

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Specifically, if demand is completely inelastic (i.e., the price elasticity is 0), then the impact of compliance costs that amount to 1 percent of revenues would be a 1 percent increase in the price of the product, with no decline in demand or in profits. Such a situation would be most likely when there are few, if any, substitutes for the product or services offered by the affected firms and the products or services of the affected firms account only for a small portion of the income of their consumers. If demand is perfectly elastic (i.e., the price elasticity is infinitely large), then no increase in price is possible, and before-tax profits would be reduced by an amount equal to the costs of compliance (minus any savings resulting from improved worker health and reduced insurance costs). Under this scenario, if the costs of compliance represent a large percentage of the firm's profits, some firms might be forced to close. This scenario is highly unlikely to occur, however, because it can only arise when there are other goods or services that are, in the eyes of consumers, perfect substitutes for the goods produced by the affected firms.

A common intermediate case would be a price elasticity of one. In this situation, if the costs of compliance amount to 1 percent of revenues, and prices are raised by 1 percent, then production would decline by 1 percent. In this situation, firms would remain in business and maintain the same profit as before, but would produce 1 percent less product. Consumers would effectively absorb the costs through a combination of increased prices and reduced consumption; this, as the court described in the ADA decision, is the more typical case.

As Table X–9 shows, the impacts potentially imposed by the final rule are not sizeable. On average, annual costs per firm are less than $58. (In one industry, Transportation Equipment, characterized by large workplaces, the potential reduction in costs that vary with the number of cases actually outweighs the potential increase in essentially fixed costs associated with the number of establishments, producing an average reduction in costs per firm.) In no industry do average compliance costs per firm amount to more than .006 percent of sales or 0.3 percent of profits. Even if no price increase were possible, a 0.3 percent decline in profits would not threaten the viability of any firm. For example, a firm with before-tax profits of 10 percent of sales would still have profits of 9.97 percent of sales, even under this extreme scenario. Thus, the final rule is clearly economically feasible in all industry groups.

Among the covered SICs, average compliance costs as a percent of sales range from less than .00005% in several industries, such as SIC 29, Petroleum and Coal Products, to .0059% in SIC 593, Used Merchandise Stores. Average compliance costs as a percent of profits ranges from less than .0005% in several industries, such as SIC 37, Transportation Equipment manufacturing, to .293% in SIC 523, Paint, Glass, and Wallpaper Stores.

Potential Economic Impacts of the Rule on Small Firms

As required by the Regulatory Flexibility Act (as amended in 1996), this section measures the potential economic impacts of the final rule on small businesses in the regulated community to determine whether the rule has a significant impact on a substantial number of small firms. It builds on the analysis of economic impacts developed in the Economic Feasibility part of this section. The Agency has analyzed the impact of the final recordkeeping rule on small entities, as defined by the Small Business Administration and in accordance with the Regulatory Flexibility Act.

Data on receipts were provided by the Commerce Department, in a data table specially commissioned by the Small Business Administration. Since the size definitions SBA has established do not precisely match the categories provided in these data, the Agency approximated the nearest data grouping, where necessary. The SBA-commissioned data were broken into size categories of firms defined by numbers of employees (1–4, 5–9, 10–19, 20–99, 100–499, >500). Where these size categories did not match SBA's assigned "small" firm definitions, the Agency approximated them to the closest category. For those industries where an "annual receipts" SBA definition was used, the Agency projected the analogous employment break by examining the ratio of employment to receipts per firm. For example, in Heavy Construction, SIC 16, the ratio of employment to receipts suggested that a $17 million firm would have approximately 104 employees. The Agency therefore examined firms with fewer than 100 employees. This process is shown in Table X–10.

The results of this analysis are shown in Table X–11. Over the entire range of SICs affected by the final rule, estimated cost per small firm averages only $31.63.

In order to ensure that even the smallest entities would not be significantly impacted, the Agency performed an analysis of impacts on very small firms, i.e., those with fewer than 20 employees. This analysis used the same sources for sales and profit data as Table X–11. The results of this analysis are shown in Table X–12.

Regardless of whether the SBA definitions or the fewer-than-20-employee definition was used, the results were the same—no significant impact. For the purposes of small-business impact assessment, OSHA defines as potentially significant annualized costs of compliance that amount to 1 percent of sales or 5 percent of profits. The impacts of the rule on sales and profits did not exceed 1 percent for firms in any covered industry, whether the analysis used the SBA's definitions or the fewer-than-20-employee size class definition. No small firm in any industry would need to increase its prices by more than 0.0105 percent, even under a full cost pass-through scenario. Alternatively, if a small firm had to pay for the costs of compliance entirely from profits, costs would account for no more than 0.406 percent of profits [38] in any industry. Impacts of this magnitude would not affect the viability of even the smallest firm.

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[38] It should be emphasized that a one percent decrease in profits represents a one percent decrease in profits, not in profit rate.

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
07	Agricultural Services	$5 million	$ 51,635	97	99
08	Forestry	$5 million	$ 79,190	63	99
09	Fishing, Hunting, and Trapping	$3 million	$128,436	23	19
13	Oil and Gas Extraction	500 employees	NA	500	499
15	General Contractors & Operative Builders	$17 million	$246,233	69	99
16	Heavy Construction, except Building	$17 million	$163,694	104	99
17	Special trade Contractors	$ 7 million	$ 95,231	74	99
20	Food and Kindred Products	500 employees	NA	500	499
21	Tobacco Products	500 employees	NA	500	499
22	Textile Mill Products	500 employees	NA	500	499
23	Apparel and Other textile Products	500 employees	NA	500	499
24	Lumber and Wood Products	500 employees	NA	500	499
25	Furniture and Fixtures	500 employees	NA	500	499
26	Paper and Allied Products	500 employees	NA	500	499
27	Printing and Publishing	500 employees	NA	500	499
28	Chemicals and Allied Products	500 employees	NA	500	499
29	Petroleum and Coal Products	500 employees	NA	500	499
30	Rubber and Miscellaneous Plastics Pdts	500 employees	NA	500	499
31	Leather and Leather Products	500 employees	NA	500	499

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TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
32	Stone, Clay, and Glass products	500 employees	NA	500	499
33	Primary Metal. Industries	500 employees	NA	500	499
34	Fabricated Metal Products	500 employees	NA	500	499
35	Industrial Machinery and Equipment	500 employees	NA	500	499
36	Electronic & Other Electrical Equipment	500 employees	NA	500	499
37	Transportation Equipment	500 employees	NA	500	499
38	Instruments and Related Products	500 employees	NA	500	499
39	Miscellaneous Manufacturing Industries	500 employees	NA	500	499
41	Local and Interurban Passenger Transit	$ 5 million	$ 38,970	128	99
42	Trucking and Warehousing	$18.5 million	$ 93,596	198	99
44	Water Transportation	500 employees	NA	500	499
45	Transportation by Air	1500 employees	NA	1500	499
46	Pipelines, except Natural Gas	1500 employees	NA	1500	499
47	Transportation Services	$ 5 million	$ 73,838	68	99
48	Communication	1500 employees	NA	1500	499
49	Electric, Gas, and Sanitary Services	$ 5 million	$301,546	17	19
50	Wholesale Trade - Durable Goods	100 employees	NA	100	99
51	Wholesale trade - Nondurable Goods	100 employees	NA	100	99
521	Lumber and Other Building Materials	$ 5 million	$225,654	22	19
523	Paint,, Glass, and Wallpaper Stores	$ 5 million	$136,892	37	19
526	Retail Nurseries and Garden Stores	$ 5 million	$ 92,622	54	19

TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee in 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
527	Mobile Home Dealers	$ 9.5 million	$286,529	33	19
53	General Merchandise Stores	$ 5 million	$138,035	36	19
541	Grocery Stores	$20 million	$118,116	169	99
543	Fruit and Vegetable Markets	$ 5 million	$103,003	49	19
553	Auto and Home Supply Stores	$ 5 million	$137,449	36	19
555	Boat Dealers	$ 5 million	$228,912	22	19
556	Recreational Vehicle Dealers	$ 5 million	$367,035	14	19
571	Furniture and Homefurnishings Stores	$ 5 million	$143,728	35	19
572	Household Appliance Stores	$ 5 million	$188,677	34	19
593	Used Merchandise Stores	$ 5 million	$ 52,924	94	99
596	Nonstore Retailers	$ 5 million	$144,160	35	19
598	Fuel Dealers	$ 5 million	$185,718	27	19
651	Real Estate Operators and Lessors	$ 5 million	$155,042	32	19
655	Subdividers and Developers	$ 5 million	$155,425	32	19
70	Hotels and Other Lodging Places	$ 5 million	$ 44,641	112	99
721	Laundry, Cleaning, and Garment Svcs	$ 5 million	$ 38,848	129	99
734	Services to Buildings	$12 million	$ 23,274	537	499
735	Misc. Equipment Rental & Leasing	$ 5 million	$ 38,848	129	99
736	Personal Supply Services	$ 5 million	$ 32,785	153	99
751	Automotive Rental & Leasing, w/o Drivers	$18.5 million	$172,688	107	99
752	Automobile Parking	$ 5 million	$ 75,807	66	99

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TABLE X-10

CONVERSION OF SBA SIZE DEFINITIONS TO CONFORM TO AVAILABLE DATA

SIC	Industry	Affected Firm Size Class *	Sales per Employee In 20-99 Employee Group	Estimated Number of Employees at Class Limit	Approximated Class Size Limit
753	Automotive Repair Shops	$ 5 million	$ 89,691	56	19
754	Automotive Services, except Repair	$ 5 million	$ 33,092	151	99
762	Electrical Repair Shops	$ 5 million	$ 86,830	58	19
763	Watch, Clock, and Jewelry Repair	$ 5 million	NA	NA	19
769	Miscellaneous Repair Shops	$ 5 million	$ 91,007	55	19
794	Commercial Sports	$ 5 million	$176,962	28	19
799	Misc. Amusement & Recreation Svcs	$ 5 million	$ 42,873	117	99
805	Nursing and Personal Care Facilities	$ 5 million	$ 31,102	161	99
806	Hospitals	$ 5 million	$ 50,315	99	99
808	Home Health Care Services	$ 5 million	$ 39,175	128	99
833	Job Training and Related Services	$ 5 million	$ 35,204	142	99
836	Residential Care	$ 5 million	$ 34,361	146	99
842	Botanical and Zoological Gardens	$ 5 million	$ 48,064	104	99

* Dollar figures are for annual receipts.

NA = Not Applicable

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$5 million	13,670	$24.73	$987,190	0.0025%	$59,231	0.042%
08	Forestry	$5 million	336	$26.21	$2,105,842	0.0012%	$65,281	0.040%
09	Fishing, Hunting, & Trapping	$3 million	161	$27.04	$2,584,497	0.0026%	$129,225	0.052%
13	Oil and Gas Extraction	500 employees	2,710	$31.36	$9,591,457	0.0003%	$489,164	0.006%
15	Gen. Contractors & Op. Builders	$17 million	23,352	$24.77	$5,151,861	0.0005%	$133,948	0.018%
16	Heavy Constr., except Building	$17 million	10,323	$24.56	$4,503,478	0.0005%	$171,132	0.014%
17	Special Trade Contractors	$7 million	69,229	$24.46	$2,124,066	0.0012%	$80,715	0.030%
20	Food and Kindred Products	500 employees	7,458	$29.91	$14,986,974	0.0002%	$299,739	0.010%
21	Tobacco Products	500 employees	34	$35.06	$29,572,735	*	$1,153,337	0.003%
22	Textile Mill Products	500 employees	2,432	$33.25	$8,159,577	0.0004%	$212,149	0.016%
23	Apparel & Other textile Products	500 employees	9,351	$31.31	$3,510,089	0.0009%	$87,752	0.036%
24	Lumber and Wood Products	500 employees	10,560	$27.92	$4,708,398	0.0006%	$169,502	0.016%
25	Furniture and Fixtures	500 employees	4,515	$28.67	$5,096,930	0.0006%	$158,005	0.018%
26	Paper and Allied Products	500 employees	2,724	$33.54	$12,075,394	0.0003%	$458,865	0.007%
27	Printing and Publishing	500 employees	16,857	$31.98	$4,442,306	0.0007%	$168,775	0.019%
28	Chemicals & Allied Products	500 employees	3,468	$37.29	$17,866,831	0.0002%	$750,407	0.005%
29	Petroleum & Coal Products	500 employees	530	$45.57	$28,919,179	0.0002%	$896,495	0.005%
30	Rubber & Misc. Plastics Pds	500 employees	7,432	$31.24	$7,522,338	0.0004%	$270,804	0.012%
31	Leather and Leather Products	500 employees	695	$30.88	$4,943,160	0.0006%	$88,977	0.035%
32	Stone, Clay, & Glass Products	500 employees	5,293	$36.46	$5,529,515	0.0007%	$270,946	0.013%
33	Primary Metal Industries	500 employees	2,948	$29.62	$11,867,260	0.0002%	$557,761	0.005%
34	Fabricated Metal Products	500 employees	16,731	$28.41	$5,979,978	0.0005%	$257,139	0.011%

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TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
35	Industrial Machinery & Equipment	500 employees	21,451	$28.78	$5,070,462	0.0006%	$207,889	0.014%
36	Electronic and Other Electrical Equipment	500 employees	7,163	$32.43	$8,379,085	0.0004%	$428,954	0.008%
37	Transportation Equipment	500 employees	4,015	$ 26.52	$8,870,271	0.0003%	$354,811	0.007%
38	Instruments & Related Products	500 employees	4,213	$ 32.47	$7,392,197	0.0004%	$406,571	0.008%
39	Misc. Manufacturing Industries	500 employees	5,379	$ 29.47	$4,621,281	0.0006%	$152,502	0.019%
41	Local & Interurban Pass. Transit	$5 million	4,986	$ 27.09	$1,107,785	0.0024%	$65,359	0.041%
42	Trucking and Warehousing	$18.5 million	20,099	$27.34	$2,393,091	0.0011%	$86,151	0.032%
44	Water Transportation	500 employees	1,751	$32.20	$6,533,938	0.0005%	$326,697	0.010%
45	Transportation by Air	1500 employees	1,660	$35.67	$3,558,061	0.0010%	$145,880	0.024%
46	Pipelines, except Natural Gas	1500 employees	21	$101.30	$26,554,857	0.0004%	$1,301,188	0.008%
47	Transportation Services	$5 million	5,506	$36.47	$1,698,837	0.0021%	$54,363	0.067%
48	Communication	1500 employees	6,042	$36.51	$5,716,356	0.0006%	$382,996	0.010%
49	Electric, Gas, & Sanitary Svcs	$5 million	947	$28.00	$2,984,573	0.0009%	$268,612	0.010%
50	Wholesale Trade - Durables	100 employees	62,307	$32.89	$11,930,304	0.0003%	$286,327	0.011%
51	Wholesale Trade - Nondurables	100 employees	34,374	$30.78	$16,844,265	0.0002%	$303,197	0.010%
521	Lumber & Other Bldg Materials	$5 million	2,741	$26.94	$2,603,069	0.0010%	$49,458	0.054%
523	Paint, Glass & Wallpaper Stores	$5 million	577	$31.14	$1,722,688	0.0018%	$15,504	0.201%
526	Retail Nurseries & Garden Stores	$5 million	1,797	$26.58	$1,905,264	0.0020%	$41,916	0.092%
527	Mobile Home Dealers	$9.5 million	557	$28.98	$3,627,901	0.0008%	$105,209	0.027%
53	General Merchandise Stores	$5 million	986	$27.76	$4,174,173	0.0007%	$100,180	0.028%
541	Grocery Stores	$20 million	18,877	$30.99	$2,902,882	0.0011%	$34,835	0.089%
543	Fruit & Vegetable Markets	$5 million	237	$28.46	$2,771,857	0.0010%	$36,034	0.079%
553	Auto & Home Supply Stores	$5 million	3,264	$23.36	$1,453,195	0.0016%	$27,611	0.085%
555	Boat Dealers	$5 million	592	$27.02	$4,343,588	0.0006%	$95,559	0.028%
556	Recreational Vehicle Dealers	$5 million	448	$36.04	$3,801,888	0.0009%	$64,632	0.056%
571	Furniture & Furnishings Stores	$5 million	5,174	$24.38	$1,731,758	0.0014%	$39,830	0.061%
572	Household Appliance Stores	$5 million	892	$25.13	$1,931,969	0.0013%	$44,435	0.057%
593	Used Merchandise Stores	$5 million	1,486	$63.93	$1,151,431	0.0056%	$52,966	0.121%
596	Nonstore Retailers	$5 million	2,234	$28.17	$1,738,348	0.0016%	$34,767	0.081%
598	Fuel Dealers	$5 million	1,156	$29.90	$2,380,413	0.0013%	$19,043	0.157%
651	Real Estate Opts &Lessors	$5 million	4,854	$19.27	$2,113,760	0.0009%	$325,519	0.006%
655	Subdividers & Developers	$5 million	946	$21.16	$1,811,582	0.0012%	$164,854	0.013%
70	Hotels & Other Lodging Places	$5 million	13,280	$27.33	$1,213,073	0.0023%	$84,915	0.032%
721	Laundry, Cleaning & Garment Svcs	$5 million	8,218	$66.92	$823,024	0.0081%	$31,275	0.214%
734	Services to Buildings	$12 million	12,156	$46.16	$869,064	0.0053%	$32,155	0.144%
735	Misc. Equip. Rental & Leasing	$5 million	3,879	$73.79	$2,917,151	0.0025%	$268,378	0.027%
736	Personal Supply Services	$5 million	6,277	$47.92	$1,334,065	0.0036%	$40,022	0.120%
751	Automotive Rental & Leasing	$18.5 million	998	$35.46	$3,950,718	0.0009%	$225,191	0.016%
752	Automobile Parking	$5 million	438	$58.71	$1,946,436	0.0030%	$93,429	0.063%
753	Automotive Repair Shops	$5 million	12,372	$27.42	$1,405,287	0.0028%	$54,806	0.071%
754	Automotive Svcs, except Repair	$5 million	4,643	$31.54	$873,101	0.0036%	$56,752	0.056%
762	Electrical Repair Shops	$5 million	1,994	$27.68	$1,698,049	0.0026%	$44,149	0.099%
763	Watch, Clock & Jewelry Repair	$5 million	59	$32.89	$2,673,508	0.0012%	$90,899	0.036%
769	Miscellaneous Repair Shops	$5 million	5,231	$26.52	$1,772,231	0.0024%	$104,562	0.040%
794	Commercial Sports	$5 million	347	$25.93	$1,408,876	0.0018%	$50,720	0.051%
799	Misc. Amusement & Rec. Svcs	$5 million	13,777	$26.31	$1,235,992	0.0021%	$52,752	0.050%
805	Nursing & Personal Care Facilities	$5 million	5,202	$38.04	$1,597,604	0.0024%	$68,697	0.055%

TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
555	Boat Dealers	$5 million	592	$27.02	$4,343,588	0.0006%	$95,559	0.028%
556	Recreational Vehicle Dealers	$5 million	448	$36.04	$3,801,888	0.0009%	$64,632	0.056%
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572	Household Appliance Stores	$5 million	892	$25.13	$1,931,969	0.0013%	$44,435	0.057%
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736	Personal Supply Services	$5 million	6,277	$47.92	$1,334,065	0.0036%	$40,022	0.120%
751	Automotive Rental & Leasing	$18.5 million	998	$35.46	$3,950,718	0.0009%	$225,191	0.016%
752	Automobile Parking	$5 million	438	$58.71	$1,946,436	0.0030%	$93,429	0.063%
753	Automotive Repair Shops	$5 million	12,372	$27.42	$1,405,287	0.0028%	$54,806	0.071%
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762	Electrical Repair Shops	$5 million	1,994	$27.68	$1,698,049	0.0026%	$44,149	0.099%
763	Watch, Clock & Jewelry Repair	$5 million	59	$32.89	$2,673,508	0.0012%	$90,899	0.036%
769	Miscellaneous Repair Shops	$5 million	5,231	$26.52	$1,772,231	0.0024%	$104,562	0.040%
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799	Misc. Amusement & Rec. Svcs	$5 million	13,777	$26.31	$1,235,992	0.0021%	$52,752	0.050%
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TABLE X-11

ANNUAL COST OF THE FINAL RULE AS A PERCENT OF SALES AND PROFITS FOR COVERED SMALL FIRMS, UNDER WORST CASE SCENARIOS

SIC	Industry	Small Business Definition*	Number of Affected Firms	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
806	Hospitals	$5 million	580	$41.62	$3,146,674	0.0013%	$160,480	0.026%
808	Home Health Care Services	$5 million	3,834	$36.50	$1,508,924	0.0024%	$52,812	0.069%
833	Job Training & Related Svcs	$5 million	2,086	$64.80	$1,230,974	0.0053%	$30,774	0.211%
836	Residential Care	$5 million	6,253	$60.64	$1,003,036	0.0060%	$26,079	0.233%
842	Botanical & Zoological Gardens	$5 million	147	$88.76	$1,494,510	0.0059%	$91,165	0.097%
	All Covered Industries		541,988	$31.66				

* Dollar figures are for annual receipts.

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
07	Agricultural Services	$ 25.15	$621,820	0.0040%	$37,309	0.067%
08	Forestry	$ 25.71	$1,393,764	0.0018%	$43,207	0.060%
09	Fishing, Hunting, & Trapping	$ 27.04	$1,038,708	0.0026%	$51,935	0.052%
13	Oil and Gas Extraction	$ 27.34	$2,868,080	0.0010%	$146,272	0.019%
15	Gen Contractors & Op Builders	$ 25.41	$2,580,143	0.0010%	$67,084	0.038%
16	Heavy Constr., except Building	$ 25.50	$2,090,243	0.0012%	$79,429	0.032%
17	Special Trade Contractors	$ 25.23	$1,131,469	0.0022%	$42,996	0.059%
20	Food and Kindred Pdts	$ 26.18	$2,531,479	0.0010%	$50,630	0.052%
22	Textile Mill Products	$ 27.09	$1,515,715	0.0018%	$39,409	0.069%
23	Apparel & Textile Pdts	$ 27.34	$938,592	0.0029%	$23,465	0.117%
24	Lumber and Wood Pdts	$ 25.94	$1,422,378	0.0018%	$51,206	0.051%
25	Furniture and Fixtures	$ 26.30	$1,115,791	0.0024%	$34,590	0.076%
26	Paper and Allied Pdts	$ 26.95	$1,936,363	0.0014%	$73,582	0.037%
27	Printing and Publishing	$ 27.33	$1,172,319	0.0023%	$48,065	0.057%
28	Chemicals & Allied Pdts	$ 27.73	$4,032,271	0.0007%	$169,355	0.016%
29	Petroleum & Coal Pdts	$ 28.84	$6,336,307	0.0005%	$196,426	0.015%
30	Rubber & Misc Plastics Pdts	$ 26.50	$1,679,865	0.0016%	$60,475	0.044%
32	Stone, Clay, & Glass Pdts	$ 26.50	$1,681,495	0.0016%	$82,393	0.032%
33	Primary Metal Industries	$ 25.94	$1,814,577	0.0014%	$85,285	0.030%
34	Fabricated Metal Pdts	$ 26.05	$1,444,760	0.0018%	$62,125	0.042%
35	Industrial Machinery & Equ't	$ 26.51	$1,279,056	0.0021%	$52,441	0.051%

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TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
36	Electronic & Electrical Equ't	$ 27.24	$1,603,741	0.0017%	$80,187	0.034%
37	Transportation Equipment	$ 25.65	$1,568,481	0.0016%	$62,739	0.041%
38	Instruments & Related Pdts	$ 27.70	$1,691,768	0.0016%	$93,047	0.030%
39	Misc. Mfg Industries	$ 26.89	$1,297,254	0.0021%	$42,809	0.063%
41	Local Passenger. Transit	$ 26.11	$483,512	0.0054%	$28,527	0.092%
42	Trucking & Warehousing	$ 26.29	$1,289,953	0.0020%	$46,438	0.057%
44	Water Transportation	$ 27.15	$1,849,451	0.0015%	$92,473	0.029%
47	Transportation Svs	$ 30.57	$932,566	0.0033%	$29,842	0.102%
48	Communication	$ 27.69	$1,590,405	0.0017%	$106,557	0.026%
49	Electric, Gas, & Sanitary Svs	$ 28.00	$2,984,573	0.0009%	$268,612	0.010%
50	Wholesale Trade - Durables	$ 28.01	$5,528,464	0.0005%	$132,683	0.021%
51	Wholesale Trade - Nondurables	$ 27.69	$8,321,447	0.0003%	$149,786	0.018%
521	Lumber & Other Bldg Mat'ls	$ 26.94	$2,603,069	0.0010%	$49,458	0.054%
523	Paint, Glass & Wallpaper Stores	$ 31.14	$1,722,688	0.0018%	$15,504	0.201%
526	Retail Nurseries & Gdn Stores	$ 26.58	$1,314,022	0.0020%	$28,908	0.092%
527	Mobile Home Dealers	$ 28.70	$3,627,901	0.0008%	$105,209	0.027%
53	General Merchandise Stores	$ 27.76	$1,322,364	0.0021%	$31,737	0.087%
541	Grocery Stores	$ 27.50	$1,415,207	0.0019%	$16,982	0.162%
543	Fruit & Vegetable Markets	$ 28.46	$2,771,857	0.0010%	$36,034	0.079%
553	Auto & Home Supply Stores	$ 23.36	$1,453,195	0.0016%	$27,611	0.085%
555	Boat Dealers	$ 27.02	$4,343,588	0.0006%	$95,559	0.028%

TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
556	Recreational Vehicle Dealers	$36.04	$3,801,888	0.0009%	$64,632	0.056%
571	Furniture & Furnishings Stores	$24.38	$1,731,758	0.0014%	$39,830	0.061%
572	Household Appliance Stores	$25.13	$1,931,969	0.0013%	$44,435	0.057%
593	Used Merchandise Stores	$16.15	$818,933	0.0020%	$37,671	0.043%
596	Nonstore Retailers	$28.17	$1,738,348	0.0016%	$34,767	0.081%
598	Fuel Dealers	$29.90	$2,380,413	0.0013%	$19,043	0.157%
651	Real Estate Oprs & Lessors	$19.27	$2,113,760	0.0009%	$325,519	0.006%
655	Subdividers & Developers	$21.16	$1,811,582	0.0012%	$164,854	0.013%
70	Hotels & Other Lodging Places	$26.54	$613,072	0.0043%	$42,915	0.062%
721	Laundry, Cleaning Svcs	$27.51	$444,393	0.0062%	$16,887	0.163%
734	Services to Buildings	$24.14	$390,494	0.0062%	$14,448	0.167%
735	Misc. Equ't. Rental & Leasing	$34.05	$1,552,492	0.0022%	$142,829	0.024%
736	Personal Supply Services	$32.04	$835,157	0.0038%	$25,055	0.128%
751	Automotive Rental & Leasing	$29.52	$2,284,946	0.0013%	$130,242	0.023%
752	Automobile Parking	$36.38	$1,050,921	0.0035%	$50,444	0.072%
753	Automotive Repair Shops	$27.42	$992,563	0.0028%	$38,710	0.071%
754	Automotive Svs, exc Repair	$28.35	$596,943	0.0048%	$38,801	0.073%
762	Electrical Repair Shops	$27.68	$1,073,521	0.0026%	$27,912	0.099%
763	Watch, Clock, Jewelry Repair	$32.89	$2,673,508	0.0012%	$90,899	0.036%
769	Miscellaneous Repair Shops	$26.52	$1,111,697	0.0024%	$65,590	0.040%
794	Commercial Sports	$25.93	$1,408,876	0.0018%	$50,720	0.051%

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TABLE X-12

ANNUAL COST AS A PERCENT OF SALES AND PROFITS FOR FIRMS WITH 11-19 EMPLOYEES UNDER WORST CASE SCENARIOS

SIC	Industry	Average Cost per Firm	Average Sales per Firm	Cost as a Percent of Sales	Average Profit per Firm	Cost as a Percent of Profits
799	Misc Amusement & Rec. Svcs	$26.28	$654,250	0.0040%	$27,478	0.096%
805	Nursing & Personal Care Fac's	$29.68	$577,018	0.0051%	$24,812	0.120%
806	Hospitals	$32.49	$732,676	0.0044%	$37,366	0.087%
808	Home Health Care Svcs	$30.07	$758,133	0.0040%	$26,535	0.113%
833	Job Training & Related Svcs	$42.69	$643,890	0.0066%	$16,097	0.265%
836	Residential Care	$40.83	$388,540	0.0105%	$10,102	0.404%
842	Botanical & Zoological Gdns	$43.84	$722,554	0.0061%	$44,076	0.099%
	All Covered Industries	$29.99				

Source: Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

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Regulatory Flexibility Analysis

Although a Final Regulatory Flexibility Analysis is not required in this case, OSHA has chosen to include the elements of a final regulatory flexibility analysis in this document. The elements of a Final Regulatory Flexibility Analysis are:

- A succinct statement of the need for, and the objective of, the rule;
- A summary of significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the Agency of such issues, and a statement of any changes made to the proposed rule as a result of such comments;
- A description of and estimate of the number of small entities to which the rule will apply or an explanation of why no such explanation is available;
- A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the rule's requirements and the types of professional skills necessary for preparation of the record or report;
- A description of the steps the Agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives considered by the agency was rejected.

The Regulatory Flexibility Act states that the Regulatory Flexibility Analysis (RFA) need not contain all of the above elements *in toto* if these elements are presented elsewhere in the documentation and analysis of the regulation. This analysis will follow this approach and refer the reader to other documentation for some of the above elements.

Need for and objectives of the rule. The need for the final rule and its objectives are discussed in the introductory sections of the preamble.

The number of small entities to which the rule will apply. As shown in Table X–11, the final rule will impact 541,988 firms defined as small firms by the SBA.

The compliance requirements of the final rule. The compliance requirements of the final rule are discussed in the summary and explanation section of the preamble, which discusses each requirement in detail.

Steps taken to minimize the impact of the rule on small entities. The final Part 1904 rule minimizes the impact on small entities in two ways. First, all employers who had fewer than 11 workers at all times during the previous year are exempt from keeping Part 1904 records of occupational injuries and illnesses, unless specifically asked to do so by the government. Second, the final rule exempts employers classified in certain industries in the services and retail sectors. These industry-exempt employers are also not required to keep records unless asked to do so by the government. The effect of the size and industry exemptions is that more than 4.5 million of the Nation's 6 million business establishments are exempted from keeping OSHA Part 1904 records on a routine basis.

OSHA considered several alternatives to exempting employers based on size and/or industry classification. A discussion of these alternatives, and why OSHA chose the alternative in the final rule, can be found in the preamble discussion for Subpart B, Scope.

XI. Regulatory Flexibility Certification

Based on OSHA's analysis of small business impacts (Tables X–11 and X–12), OSHA certifies that this final rule will not have a significant impact on a substantial number of small entities. OSHA makes this certification to fulfill its obligations under the Regulatory Flexibility Act (as amended in 1996).

XII. Environmental Impact Assessment

In accordance with the requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), Council on Environmental Quality NEPA regulations (40 CFR part 1500 *et seq.*), and the Department of Labor's NEPA regulations (29 CFR part 11), the Assistant Secretary has determined that this final rule will not have a significant impact on the external environment.

XIII. Federalism

This final rule has been reviewed in accordance with Executive Order 13132 (52 FR 41685), regarding Federalism. Because this rulemaking action involves a "regulation" issued under section 8 of the OSH Act, and not a "standard" issued under section 6 of the Act, the rule does not preempt State law, see 29 U.S.C. § 667 (a). The effect of the final rule on States is discussed above in Section VI, *State Plans*.

XIV. Paperwork Reduction Act of 1995

The final regulation contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. Most of the provisions of the final rule contain collection of information requirements, either to keep records or to report information from the records to the government. In addition, the effort employers are required to put forth to learn the requirements are considered information requirements.

In response to OSHA's 1996 proposal, the public submitted 450 written comments . The Agency also held two public meetings where it collected oral comments from 43 individuals and groups during six days of informal meetings.

In summary, OSHA estimates that there are 1,365,985 establishments that will be required to keep records of occupational injuries and illnesses under the provisions. A total of approximately 4,500,000 hours will be needed for employers to comply with the information collection requirements for the first year, and 3,500,000 hours in each subsequent year. This represents an increase of 1,060,000 hours from the previous paperwork burden estimates. OSHA has recently recognized that previous estimates of the burden associated with becoming familiar with the 1904 rule have been understated, and recently corrected those estimates, as noted in OSHA's Final Economic Analysis for the Part 1904 rule.

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), OSHA has requested OMB approval of the collection of information requirement described above. The information collection provisions will take effect when OMB approves them under the PRA.

XV. Authority

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, DC 20210.

List of Subjects

29 CFR Part 1904

Health statistics, Occupational safety and health, Reporting and recordkeeping requirements, State plans.

29 CFR Part 1952

Health statistics, Intergovernmental relations, Occupational safety and health, Reporting and recordkeeping requirements, State plans.

Accordingly, pursuant to sections 8(c), 8(g), 20 and 24 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 673), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 5 U.S.C. 553, the Department amends 29 CFR Chapter XVII as set forth below.

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Signed in Washington, D.C., this 5th day of January, 2001.

Charles N. Jeffress,

Assistant Secretary of Labor.

1. 29 CFR Part 1904 is revised to read as follows:

Part 1904—Recording and Reporting Occupational Injuries and Illnesses

Sec.

Subpart A—Purpose

1904.0 Purpose

Subpart B—Scope

1904.1 Partial exemption for employers with 10 or fewer employees.
1904.2 Partial exemption for establishments in certain industries.
1904.3 Keeping records for more than one agency.
Non-mandatory Appendix A to Subpart B—Partially Exempt Industries.

Subpart C—Recordkeeping Forms and Recording Criteria

1904.4 Recording criteria.
1904.5 Determination of work-relatedness.
1904.6 Determination of new cases.
1904.7 General recording criteria.
1904.8 Recording criteria for needlestick and sharps injuries.
1904.9 Recording criteria for cases involving medical removal under OSHA standards.
1904.10 Recording criteria for cases involving occupational hearing loss.
1904.11 Recording criteria for work-related tuberculosis cases.
1904.12 Recording criteria for cases involving work-related musculoskeletal disorders.
1904.13–1904.28 [Reserved]
1904.29 Forms.

Subpart D—Other OSHA Injury and Illness Recordkeeping Requirements

1904.30 Multiple business establishments.
1904.31 Covered employees.
1904.32 Annual summary.
1904.33 Retention and updating.
1904.34 Change in business ownership.
1904.35 Employee involvement.
1904.36 Prohibition against discrimination.
1904.37 State recordkeeping regulations.
1904.38 Variances from the recordkeeping rule.

Subpart E—Reporting Fatality, Injury and Illness Information to the Government

1904.39 Reporting fatalities and multiple hospitalization incidents to OSHA.
1904.40 Providing records to government representatives.
1904.41 Annual OSHA Injury and Illness Survey of Ten or More Employers.
1904.42 Requests from the Bureau of Labor Statistics for data.

Subpart F—Transition From the Former Rule

1904.43 Summary and posting of year 2000 data.
1904.44 Retention and updating of old forms.
1904.45 OMB control numbers under the Paperwork Reduction Act

Subpart G—Definitions

1904.46 Definitions.

Authority: 29 U.S.C. 657, 658, 660, 666, 669, 673, Secretary of Labor's Order No. 1–90 (55 FR 9033), and 5 U.S.C. 553.

Subpart A—Purpose

§ 1904.0 Purpose.

The purpose of this rule (Part 1904) is to require employers to record and report work-related fatalities, injuries and illnesses.

Note to § 1904.0: Recording or reporting a work-related injury, illness, or fatality does not mean that the employer or employee was at fault, that an OSHA rule has been violated, or that the employee is eligible for workers' compensation or other benefits.

Subpart B—Scope

Note to Subpart B: All employers covered by the Occupational Safety and Health Act (OSH Act) are covered by these Part 1904 regulations. However, most employers do not have to keep OSHA injury and illness records unless OSHA or the Bureau of Labor Statistics (BLS) informs them in writing that they must keep records. For example, employers with 10 or fewer employees and business establishments in certain industry classifications are partially exempt from keeping OSHA injury and illness records.

§ 1904.1 Partial exemption for employers with 10 or fewer employees.

(a) *Basic requirement.* (1) If your company had ten (10) or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA or the BLS informs you in writing that you must keep records under § 1904.41 or § 1904.42. However, as required by § 1904.39, all employers covered by the OSH Act must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees.

(2) If your company had more than ten (10) employees at any time during the last calendar year, you must keep OSHA injury and illness records unless your establishment is classified as a partially exempt industry under § 1904.2.

(b) *Implementation.* (1) *Is the partial exemption for size based on the size of my entire company or on the size of an individual business establishment?* The partial exemption for size is based on the number of employees in the entire company.

(2) *How do I determine the size of my company to find out if I qualify for the partial exemption for size?* To determine if you are exempt because of size, you need to determine your company's peak employment during the last calendar year. If you had no more than 10 employees at any time in the last calendar year, your company qualifies for the partial exemption for size.

§ 1904.2 Partial exemption for establishments in certain industries.

(a) *Basic requirement.* (1) If your business establishment is classified in a specific low hazard retail, service, finance, insurance or real estate industry listed in Appendix A to this Subpart B, you do not need to keep OSHA injury and illness records unless the government asks you to keep the records under § 1904.41 or § 1904.42. However, all employers must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).

(2) If one or more of your company's establishments are classified in a non-exempt industry, you must keep OSHA injury and illness records for all of such establishments unless your company is partially exempted because of size under § 1904.1.

(b) *Implementation.* (1) *Does the partial industry classification exemption apply only to business establishments in the retail, services, finance, insurance or real estate industries (SICs 52–89)?* Yes, business establishments classified in agriculture; mining; construction; manufacturing; transportation; communication, electric, gas and sanitary services; or wholesale trade are not eligible for the partial industry classification exemption.

(2) *Is the partial industry classification exemption based on the industry classification of my entire company or on the classification of individual business establishments operated by my company?* The partial industry classification exemption applies to individual business establishments. If a company has several business establishments engaged in different classes of business activities, some of the company's establishments may be required to keep records, while others may be exempt.

(3) *How do I determine the Standard Industrial Classification code for my company or for individual establishments?* You determine your Standard Industrial Classification (SIC) code by using the Standard Industrial Classification Manual, Executive Office of the President, Office of Management and Budget. You may contact your nearest OSHA office or State agency for help in determining your SIC.

§ 1904.3 Keeping records for more than one agency.

If you create records to comply with another government agency's injury and illness recordkeeping requirements, OSHA will consider those records as meeting OSHA's Part 1904 recordkeeping requirements if OSHA accepts the other agency's records under a memorandum of understanding with that agency, or if the other agency's records contain the same information as this Part 1904 requires you to record. You may contact your nearest OSHA office or State agency for help in determining whether your records meet OSHA's requirements.

Non-Mandatory Appendix A to Subpart B—Partially Exempt Industries

Employers are not required to keep OSHA injury and illness records for any establishment classified in the following Standard Industrial Classification (SIC) codes, unless they are asked in writing to do so by OSHA, the Bureau of Labor Statistics (BLS), or a state agency operating under the authority of OSHA or the BLS. All employers, including those partially exempted by reason of company size or industry classification, must report to OSHA any workplace incident that results in a fatality or the hospitalization of three or more employees (see § 1904.39).

SIC code	Industry description	SIC code	Industry description
525	Hardware Stores	725	Shoe Repair and Shoeshine Parlors.
542	Meat and Fish Markets	726	Funeral Service and Crematories.
544	Candy, Nut, and Confectionery Stores	729	Miscellaneous Personal Services.
545	Dairy Products Stores	731	Advertising Services.
546	Retail Bakeries	732	Credit Reporting and Collection Services.
549	Miscellaneous Food Stores	733	Mailing, Reproduction, & Stenographic Services.
551	New and Used Car Dealers	737	Computer and Data Processing Services.
552	Used Car Dealers	738	Miscellaneous Business Services.
554	Gasoline Service Stations	764	Reupholstery and Furniture Repair.
557	Motorcycle Dealers	78	Motion Picture.
56	Apparel and Accessory Stores	791	Dance Studios, Schools, and Halls.
573	Radio, Television, & Computer Stores	792	Producers, Orchestras, Entertainers.
58	Eating and Drinking Places	793	Bowling Centers.
591	Drug Stores and Proprietary Stores	801	Offices & Clinics Of Medical Doctors.
592	Liquor Stores	802	Offices and Clinics Of Dentists.
594	Miscellaneous Shopping Goods Stores	803	Offices Of Osteopathic.
599	Retail Stores, Not Elsewhere Classified	804	Offices Of Other Health Practitioners.
60	Depository Institutions (banks & savings institutions)	807	Medical and Dental Laboratories.
61	Nondepository	809	Health and Allied Services, Not Elsewhere Classified.
62	Security and Commodity Brokers	81	Legal Services.
63	Insurance Carriers	82	Educational Services (schools, colleges, universities and libraries).
64	Insurance Agents, Brokers & Services	832	Individual and Family Services.
653	Real Estate Agents and Managers	835	Child Day Care Services.
654	Title Abstract Offices	839	Social Services, Not Elsewhere Classified.
67	Holding and Other Investment Offices	841	Museums and Art Galleries.
722	Photographic Studios, Portrait	86	Membership Organizations.
723	Beauty Shops	87	Engineering, Accounting, Research, Management, and Related Services.
724	Barber Shops	899	Services, not elsewhere classified.

Subpart C—Recordkeeping Forms and Recording Criteria

Note to Subpart C: This Subpart describes the work-related injuries and illnesses that an employer must enter into the OSHA records and explains the OSHA forms that employers must use to record work-related fatalities, injuries, and illnesses.

§ 1904.4 Recording criteria.

(a) *Basic requirement.* Each employer required by this Part to keep records of fatalities, injuries, and illnesses must record each fatality, injury and illness that:

(1) Is work-related; and

(2) Is a new case; and

(3) Meets one or more of the general recording criteria of § 1904.7 or the application to specific cases of § 1904.8 through § 1904.12.

(b) *Implementation.* (1) *What sections of this rule describe recording criteria for recording work-related injuries and illnesses?* The table below indicates which sections of the rule address each topic.

(i) Determination of work-relatedness. See § 1904.5.

(ii) Determination of a new case. See § 1904.6.

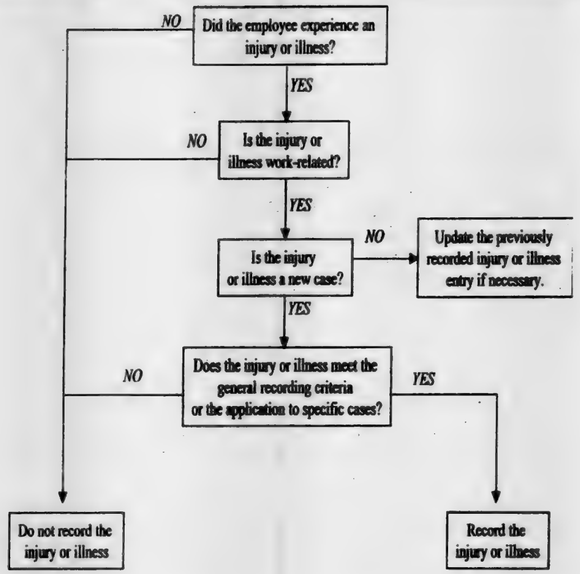
(iii) General recording criteria. See § 1904.7.

(iv) Additional criteria. (Needlestick and sharps injury cases, tuberculosis cases, hearing loss cases, medical removal cases, and musculoskeletal disorder cases). See § 1904.8 through § 1904.12.

(2) *How do I decide whether a particular injury or illness is recordable?* The decision tree for recording work-related injuries and illnesses below shows the steps involved in making this determination.

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§ 1904.5 Determination of work-relatedness.

(a) *Basic requirement.* You must consider an injury or illness to be work-related if an event or exposure in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing injury or illness. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the work environment, unless an exception in § 1904.5(b)(2) specifically applies.

(b) *Implementation.* (1) What is the "work environment"? OSHA defines the work environment as "the establishment and other locations where one or more employees are working or are present as a condition of their employment. The work environment includes not only physical locations, but also the equipment or materials used by the employee during the course of his or her work."

(2) *Are there situations where an injury or illness occurs in the work environment and is not considered work-related?* Yes, an injury or illness occurring in the work environment that falls under one of the following exceptions is not work-related, and therefore is not recordable.

1904.5(b)(2)	You are not required to record injuries and illnesses if . . .
(i)	At the time of the injury or illness, the employee was present in the work environment as a member of the general public rather than as an employee.
(ii)	The injury or illness involves signs or symptoms that surface at work but result solely from a non-work-related event or exposure that occurs outside the work environment.
(iii)	The injury or illness results solely from voluntary participation in a wellness program or in a medical, fitness, or recreational activity such as blood donation, physical examination, flu shot, exercise class, racquetball, or baseball.
(iv)	The injury or illness is solely the result of an employee eating, drinking, or preparing food or drink for personal consumption (whether bought on the employer's premises or brought in). For example, if the employee is injured by choking on a sandwich while in the employer's establishment, the case would not be considered work-related. **Note:** If the employee is made ill by ingesting food contaminated by workplace contaminants (such as lead), or gets food poisoning from food supplied by the employer, the case would be considered work-related.
(v)	The injury or illness is solely the result of an employee doing personal tasks (unrelated to their employment) at the establishment outside of the employee's assigned working hours.
(vi)	The injury or illness is solely the result of personal grooming, self medication for a non-work-related condition, or is intentionally self-inflicted.
(vii)	The injury or illness is caused by a motor vehicle accident and occurs on a company parking lot or company access road while the employee is commuting to or from work.
(viii)	The illness is the common cold or flu (Note: contagious diseases such as tuberculosis, brucellosis, hepatitis A, or plague are considered work-related if the employee is infected at work).

1904.5(b)(2)	You are not required to record injuries and illnesses if . . .
(ix)	The illness is a mental illness. Mental illness will not be considered work-related unless the employee voluntarily provides the employer with an opinion from a physician or other licensed health care professional with appropriate training and experience (psychiatrist, psychologist, psychiatric nurse practitioner, etc.) stating that the employee has a mental illness that is work-related.

(3) *How do I handle a case if it is not obvious whether the precipitating event or exposure occurred in the work environment or occurred away from work?* In these situations, you must evaluate the employee's work duties and environment to decide whether or not one or more events or exposures in the work environment either caused or contributed to the resulting condition or significantly aggravated a pre-existing condition.

(4) *How do I know if an event or exposure in the work environment "significantly aggravated" a preexisting injury or illness?* A preexisting injury or illness has been significantly aggravated, for purposes of OSHA injury and illness recordkeeping, when an event or exposure in the work environment results in any of the following:

(i) Death, provided that the preexisting injury or illness would likely not have resulted in death but for the occupational event or exposure.

(ii) Loss of consciousness, provided that the preexisting injury or illness would likely not have resulted in loss of consciousness but for the occupational event or exposure.

(iii) One or more days away from work, or days of restricted work, or days of job transfer that otherwise would not have occurred but for the occupational event or exposure.

(iv) Medical treatment in a case where no medical treatment was needed for the injury or illness before the workplace event or exposure, or a change in medical treatment was necessitated by the workplace event or exposure.

(5) *Which injuries and illnesses are considered pre-existing conditions?* An injury or illness is a preexisting condition if it resulted solely from a non-work-related event or exposure that occured outside the work environment.

(6) *How do I decide whether an injury or illness is work-related if the employee is on travel status at the time the injury or illness occurs?* Injuries and illnesses that occur while an employee is on travel status are work-related if, at the time of the injury or illness, the employee was engaged in work activities "in the interest of the employer." Examples of such activities include travel to and from customer contacts, conducting job tasks, and entertaining or being entertained to transact, discuss, or promote business (work-related entertainment includes only entertainment activities being engaged in at the direction of the employer).

Injuries or illnesses that occur when the employee is on travel status do not have to be recorded if they meet one of the exceptions listed below.

1904.5 (b)(6)	If the employee has . . .	You may use the following to determine if an injury or illness is work-related
(i)	checked into a hotel or motel for one or more days.	When a traveling employee checks into a hotel, motel, or into a other temporary residence, he or she establishes a "home away from home." You must evaluate the employee's activities after he or she checks into the hotel, motel, or other temporary residence for their work-relatedness in the same manner as you evaluate the activities of a non-traveling employee. When the employee checks into the temporary residence, he or she is considered to have left the work environment. When the employee begins work each day, he or she re-enters the work environment. If the employee has established a "home away from home" and is reporting to a fixed worksite each day, you also do not consider injuries or illnesses work-related if they occur while the employee is commuting between the temporary residence and the job location.
(ii)	taken a detour for personal reasons.	Injuries or illnesses are not considered work-related if they occur while the employee is on a personal detour from a reasonably direct route of travel (*e.g.*, has taken a side trip for personal reasons).

(7) *How do I decide if a case is work-related when the employee is working at home?* Injuries and illnesses that occur while an employee is working at home, including work in a home office, will be considered work-related if the injury or illness occurs while the employee is performing work for pay or compensation in the home, and the injury or illness is directly related to the performance of work rather than to the general home environment or setting. For example, if an employee drops a box of work documents and injures his or her foot, the case is considered work-related. If an employee's fingernail is punctured by a needle from a sewing machine used to perform garment work at home, becomes infected and requires medical treatment, the injury is considered work-related. If an employee is injured because he or she trips on the family dog while rushing to answer a work phone call, the case is not considered work-related. If an employee working at home is electrocuted because of faulty home wiring, the injury is not considered work-related.

§ 1904.6 Determination of new cases.

(a) *Basic requirement.* You must consider an injury or illness to be a "new case" if:

(1) The employee has not previously experienced a recorded injury or illness of the same type that affects the same part of the body, or

(2) The employee previously experienced a recorded injury or illness of the same type that affected the same part of the body but had recovered completely (all signs and symptoms had disappeared) from the previous injury or illness and an event or exposure in the work environment caused the signs or symptoms to reappear.

(b) *Implementation.* (1) *When an employee experiences the signs or symptoms of a chronic work-related illness, do I need to consider each recurrence of signs or symptoms to be a new case?* No, for occupational illnesses where the signs or symptoms may recur or continue in the absence of an exposure in the workplace, the case must only be recorded once. Examples

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may include occupational cancer, asbestosis, byssinosis and silicosis.

(2) *When an employee experiences the signs or symptoms of an injury or illness as a result of an event or exposure in the workplace, such as an episode of occupational asthma, must I treat the episode as a new case?* Yes, because the episode or recurrence was caused by an event or exposure in the workplace, the incident must be treated as a new case.

(3) *May I rely on a physician or other licensed health care professional to determine whether a case is a new case or a recurrence of an old case?* You are not required to seek the advice of a physician or other licensed health care professional. However, if you do seek such advice, you must follow the physician or other licensed health care professional's recommendation about whether the case is a new case or a recurrence. If you receive recommendations from two or more physicians or other licensed health care professionals, you must make a decision as to which recommendation is the most authoritative (best documented, best reasoned, or most authoritative), and record the case based upon that recommendation.

§ 1904.7 General recording criteria.

(a) *Basic requirement.* You must consider an injury or illness to meet the general recording criteria, and therefore to be recordable, if it results in any of the following: death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness. You must also consider a case to meet the general recording criteria if it involves a significant injury or illness diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness.

(b) *Implementation.* (1) *How do I decide if a case meets one or more of the general recording criteria?* A work-related injury or illness must be recorded if it results in one or more of the following:

(i) Death. See § 1904.7(b)(2).

(ii) Days away from work. See § 1904.7(b)(3).

(iii) Restricted work or transfer to another job. See § 1904.7(b)(4).

(iv) Medical treatment beyond first aid. See § 1904.7(b)(5).

(v) Loss of consciousness. See § 1904.7(b)(6).

(vi) A significant injury or illness diagnosed by a physician or other licensed health care professional. See § 1904.7(b)(7).

(2) *How do I record a work-related injury or illness that results in the employee's death?* You must record an injury or illness that results in death by entering a check mark on the OSHA 300 Log in the space for cases resulting in death. You must also report any work-related fatality to OSHA within eight (8) hours, as required by § 1904.39.

(3) *How do I record a work-related injury or illness that results in days away from work?* When an injury or illness involves one or more days away from work, you must record the injury or illness on the OSHA 300 Log with a check mark in the space for cases involving days away and an entry of the number of calendar days away from work in the number of days column. If the employee is out for an extended period of time, you must enter an estimate of the days that the employee will be away, and update the day count when the actual number of days is known.

(i) *Do I count the day on which the injury occurred or the illness began?* No, you begin counting days away on the day after the injury occurred or the illness began.

(ii) *How do I record an injury or illness when a physician or other licensed health care professional recommends that the worker stay at home but the employee comes to work anyway?* You must record these injuries and illnesses on the OSHA 300 Log using the check box for cases with days away from work and enter the number of calendar days away recommended by the physician or other licensed health care professional. If a physician or other licensed health care professional recommends days away, you should encourage your employee to follow that recommendation. However, the days away must be recorded whether the injured or ill employee follows the physician or licensed health care professional's recommendation or not. If you receive recommendations from two or more physicians or other licensed health care professionals, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

(iii) *How do I handle a case when a physician or other licensed health care professional recommends that the worker return to work but the employee stays at home anyway?* In this situation, you must end the count of days away from work on the date the physician or other licensed health care professional recommends that the employee return to work.

(iv) *How do I count weekends, holidays, or other days the employee would not have worked anyway?* You must count the number of calendar days the employee was unable to work as a result of the injury or illness, regardless of whether or not the employee was scheduled to work on those day(s). Weekend days, holidays, vacation days or other days off are included in the total number of days recorded if the employee would not have been able to work on those days because of a work-related injury or illness.

(v) *How do I record a case in which a worker is injured or becomes ill on a Friday and reports to work on a Monday, and was not scheduled to work on the weekend?* You need to record this case only if you receive information from a physician or other licensed health care professional indicating that the employee should not have worked, or should have performed only restricted work, during the weekend. If so, you must record the injury or illness as a case with days away from work or restricted work, and enter the day counts, as appropriate.

(vi) *How do I record a case in which a worker is injured or becomes ill on the day before scheduled time off such as a holiday, a planned vacation, or a temporary plant closing?* You need to record a case of this type only if you receive information from a physician or other licensed health care professional indicating that the employee should not have worked, or should have performed only restricted work, during the scheduled time off. If so, you must record the injury or illness as a case with days away from work or restricted work, and enter the day counts, as appropriate.

(vii) *Is there a limit to the number of days away from work I must count?* Yes, you may "cap" the total days away at 180 calendar days. You are not required to keep track of the number of calendar days away from work if the injury or illness resulted in more than 180 calendar days away from work and/or days of job transfer or restriction. In such a case, entering 180 in the total days away column will be considered adequate.

(viii) *May I stop counting days if an employee who is away from work because of an injury or illness retires or leaves my company?* Yes, if the employee leaves your company for some reason unrelated to the injury or illness, such as retirement, a plant closing, or to take another job, you may stop counting days away from work or days of restriction/job transfer. If the employee leaves your company because of the injury or illness, you must estimate the total number of days away or days of restriction/job transfer and enter the day count on the 300 Log.

(ix) *If a case occurs in one year but results in days away during the next calendar year, do I record the case in both years?* No, you only record the injury or illness once. You must enter the number of calendar days away for the injury or illness on the OSHA 300 Log for the year in which the injury or illness occurred. If the employee is still away from work because of the injury or illness when you prepare the annual summary, estimate the total number of calendar days you expect the employee to be away from work, use this number to calculate the total for the annual summary, and then update the initial log entry later when the day count is known or reaches the 180-day cap.

(4) *How do I record a work-related injury or illness that results in restricted work or job transfer?* When an injury or illness involves restricted work or job transfer but does not involve death or days away from work, you must record the injury or illness on the OSHA 300 Log by placing a check mark in the space for job transfer or restriction and an entry of the number of restricted or transferred days in the restricted workdays column.

(i) *How do I decide if the injury or illness resulted in restricted work?* Restricted work occurs when, as the result of a work-related injury or illness:

(A) You keep the employee from performing one or more of the routine functions of his or her job, or from working the full workday that he or she would otherwise have been scheduled to work; or

(B) A physician or other licensed health care professional recommends that the employee not perform one or more of the routine functions of his or her job, or not work the full workday that he or she would otherwise have been scheduled to work.

(ii) *What is meant by "routine functions"?* For recordkeeping purposes, an employee's routine functions are those work activities the employee regularly performs at least once per week.

(iii) *Do I have to record restricted work or job transfer if it applies only to the day on which the injury occurred or the illness began?* No, you do not have to record restricted work or job transfers if you, or the physician or other licensed health care professional, impose the restriction or transfer only for the day on which the injury occurred or the illness began.

(iv) *If you or a physician or other licensed health care professional recommends a work restriction, is the injury or illness automatically recordable as a "restricted work" case?* No, a recommended work restriction is recordable only if it affects one or more of the employee's routine job functions. To determine whether this is the case, you must evaluate the restriction in light of the routine functions of the injured or ill employee's job. If the restriction from you or the physician or other licensed health care professional keeps the employee from performing one or more of his or her routine job functions, or from working the full workday the injured or ill employee would otherwise have worked, the employee's work has been restricted and you must record the case.

(v) *How do I record a case where the worker works only for a partial work shift because of a work-related injury or illness?* A partial day of work is recorded as a day of job transfer or restriction for recordkeeping purposes, except for the day on which the injury occurred or the illness began.

(vi) *If the injured or ill worker produces fewer goods or services than he or she would have produced prior to the injury or illness but otherwise performs all of the routine functions of his or her work, is the case considered a restricted work case?* No, the case is considered restricted work only if the worker does not perform all of the routine functions of his or her job or does not work the full shift that he or she would otherwise have worked.

(vii) *How do I handle vague restrictions from a physician or other licensed health care professional, such as that the employee engage only in "light duty" or "take it easy for a week"?* If you are not clear about the physician or other licensed health care professional's recommendation, you may ask that person whether the employee can do all of his or her routine job functions and work all of his or her normally assigned work shift. If the answer to both of these questions is "Yes," then the case does not involve a work restriction and does not have to be recorded as such. If the answer to one or both of these questions is "No," the case involves restricted work and must be recorded as a restricted work case. If you are unable to obtain this additional information from the physician or other licensed health care professional who recommended the restriction, record the injury or illness as a case involving restricted work.

(viii) *What do I do if a physician or other licensed health care professional recommends a job restriction meeting OSHA's definition, but the employee does all of his or her routine job functions anyway?* You must record the injury or illness on the OSHA 300 Log as a restricted work case. If a physician or other licensed health care professional recommends a job restriction, you should ensure that the employee complies with that restriction. If you receive recommendations from two or more physicians or other licensed health care professionals, you may make a decision as to which recommendation is the most authoritative, and record the case based upon that recommendation.

(ix) *How do I decide if an injury or illness involved a transfer to another job?* If you assign an injured or ill employee to a job other than his or her regular job for part of the day, the case involves transfer to another job. Note: This does not include the day on which the injury or illness occurred.

(x) *Are transfers to another job recorded in the same way as restricted work cases?* Yes, both job transfer and restricted work cases are recorded in the same box on the OSHA 300 Log. For example, if you assign, or a physician or other licensed health care professional recommends that you assign, an injured or ill worker to his or her routine job duties for part of the day and to another job for the rest of the day, the injury or illness involves a job transfer. You must record an injury or illness that involves a job transfer by placing a check in the box for job transfer.

(xi) *How do I count days of job transfer or restriction?* You count days of job transfer or restriction in the same way you count days away from work, using § 1904.7(b)(3)(i) to (viii), above. The only difference is that, if you permanently assign the injured or ill employee to a job that has been modified or permanently changed in a manner that eliminates the routine functions the employee was restricted from performing, you may stop the day count when the modification or change is made permanent. You must count at least one day of restricted work or job transfer for such cases.

(5) *How do I record an injury or illness that involves medical treatment beyond first aid?* If a work-related injury or illness results in medical treatment beyond first aid, you must record it on the OSHA 300 Log. If the injury or illness did not involve death, one or more days away from work, one or more days of restricted work, or one or more days of job transfer, you enter a check mark in the box for cases where the employee received medical treatment but remained at work and was not transferred or restricted.

(i) *What is the definition of medical treatment?* "Medical treatment" means the management and care of a patient to

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combat disease or disorder. For the purposes of Part 1904, medical treatment does not include:

(A) Visits to a physician or other licensed health care professional solely for observation or counseling;

(B) The conduct of diagnostic procedures, such as x-rays and blood tests, including the administration of prescription medications used solely for diagnostic purposes (*e.g.*, eye drops to dilate pupils); or

(C) "First aid" as defined in paragraph (b)(5)(ii) of this section.

(ii) *What is "first aid"?* For the purposes of Part 1904, "first aid" means the following:

(A) Using a non-prescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes);

(B) Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment);

(C) Cleaning, flushing or soaking wounds on the surface of the skin;

(D) Using wound coverings such as bandages, Band-Aids™, gauze pads, etc.; or using butterfly bandages or Steri-Strips™ (other wound closing devices such as sutures, staples, etc., are considered medical treatment);

(E) Using hot or cold therapy;

(F) Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes);

(G) Using temporary immobilization devices while transporting an accident victim (*e.g.*, splints, slings, neck collars, back boards, etc.).

(H) Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister;

(I) Using eye patches;

(J) Removing foreign bodies from the eye using only irrigation or a cotton swab;

(K) Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means;

(L) Using finger guards;

(M) Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes); or

(N) Drinking fluids for relief of heat stress.

(iii) *Are any other procedures included in first aid?* No, this is a complete list of all treatments considered first aid for Part 1904 purposes.

(iv) *Does the professional status of the person providing the treatment have any effect on what is considered first aid or medical treatment?* No, OSHA considers the treatments listed in § 1904.7(b)(5)(ii) of this Part to be first aid regardless of the professional status of the person providing the treatment. Even when these treatments are provided by a physician or other licensed health care professional, they are considered first aid for the purposes of Part 1904. Similarly, OSHA considers treatment beyond first aid to be medical treatment even when it is provided by someone other than a physician or other licensed health care professional.

(v) *What if a physician or other licensed health care professional recommends medical treatment but the employee does not follow the recommendation?* If a physician or other licensed health care professional recommends medical treatment, you should encourage the injured or ill employee to follow that recommendation. However, you must record the case even if the injured or ill employee does not follow the physician or other licensed health care professional's recommendation.

(6) *Is every work-related injury or illness case involving a loss of consciousness recordable?* Yes, you must record a work-related injury or illness if the worker becomes unconscious, regardless of the length of time the employee remains unconscious.

(7) *What is a "significant" diagnosed injury or illness that is recordable under the general criteria even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness?* Work-related cases involving cancer, chronic irreversible disease, a fractured or cracked bone, or a punctured eardrum must always be recorded under the general criteria at the time of diagnosis by a physician or other licensed health care professional.

Note to § 1904.7: OSHA believes that most significant injuries and illnesses will result in one of the criteria listed in § 1904.7(a): death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness. However, there are some significant injuries, such as a punctured eardrum or a fractured toe or rib, for which neither medical treatment nor work restrictions may be recommended. In addition, there are some significant progressive diseases, such as byssinosis, silicosis, and some types of cancer, for which medical treatment or work restrictions may not be recommended at the time of diagnosis but are likely to be recommended as the disease progresses. OSHA believes that cancer, chronic irreversible diseases, fractured or cracked bones, and punctured eardrums are generally considered significant injuries and illnesses, and must be recorded at the initial diagnosis even if medical treatment or work restrictions are not recommended, or are postponed, in a particular case.

§ 1904.8 Recording criteria for needlestick and sharps injuries.

(a) *Basic requirement.* You must record all work-related needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material (as defined by 29 CFR 1910.1030). You must enter the case on the OSHA 300 Log as an injury. To protect the employee's privacy, you may not enter the employee's name on the OSHA 300 Log (see the requirements for privacy cases in paragraphs 1904.29(b)(6) through 1904.29(b)(9)).

(b) *Implementation.* (1) *What does "other potentially infectious material" mean?* The term "other potentially infectious materials" is defined in the OSHA Bloodborne Pathogens standard at § 1910.1030(b). These materials include:

(i) Human bodily fluids, tissues and organs, and

(ii) Other materials infected with the HIV or hepatitis B (HBV) virus such as laboratory cultures or tissues from experimental animals.

(2) *Does this mean that I must record all cuts, lacerations, punctures, and scratches?* No, you need to record cuts, lacerations, punctures, and scratches only if they are work-related and involve contamination with another person's blood or other potentially infectious material. If the cut, laceration, or scratch involves a clean object, or a contaminant other than blood or other potentially infectious material, you need to record the case only if it meets one or more of the recording criteria in § 1904.7.

(3) *If I record an injury and the employee is later diagnosed with an infectious bloodborne disease, do I need to update the OSHA 300 Log?* Yes, you must update the classification of the case on the OSHA 300 Log if the case results in death, days away from work, restricted work, or job transfer. You must also update the description to identify the infectious disease and change the classification of the case from an injury to an illness.

(4) *What if one of my employees is splashed or exposed to blood or other potentially infectious material without being cut or scratched? Do I need to record this incident?* You need to record such an incident on the OSHA 300 Log as an illness if:

(i) It results in the diagnosis of a bloodborne illness, such as HIV, hepatitis B, or hepatitis C; or

(ii) It meets one or more of the recording criteria in § 1904.7.

§ 1904.9 Recording criteria for cases involving medical removal under OSHA standards.

(a) *Basic requirement.* If an employee is medically removed under the medical surveillance requirements of an OSHA standard, you must record the case on the OSHA 300 Log.

(b) *Implementation.* (1) *How do I classify medical removal cases on the OSHA 300 Log?* You must enter each medical removal case on the OSHA 300 Log as either a case involving days away from work or a case involving restricted work activity, depending on how you decide to comply with the medical removal requirement. If the medical removal is the result of a chemical exposure, you must enter the case on the OSHA 300 Log by checking the "poisoning" column.

(2) *Do all of OSHA's standards have medical removal provisions?* No, some OSHA standards, such as the standards covering bloodborne pathogens and noise, do not have medical removal provisions. Many OSHA standards that cover specific chemical substances have medical removal provisions. These standards include, but are not limited to, lead, cadmium, methylene chloride, formaldehyde, and benzene.

(3) *Do I have to record a case where I voluntarily removed the employee from exposure before the medical removal criteria in an OSHA standard are met?* No, if the case involves voluntary medical removal before the medical removal levels required by an OSHA standard, you do not need to record the case on the OSHA 300 Log.

§ 1904.10 Recording criteria for cases involving occupational hearing loss.

(a) *Basic requirement.* If an employee's hearing test (audiogram) reveals that a Standard Threshold Shift (STS) has occurred, you must record the case on the OSHA 300 Log by checking the "hearing loss" column.

(b) *Implementation.* (1) *What is a Standard Threshold Shift?* A Standard Threshold Shift, or STS, is defined in the occupational noise exposure standard at 29 CFR 1910.95(c)(10)(i) as a change in hearing threshold, relative to the most recent audiogram for that employee, of an average of 10 decibels (dB) or more at 2000, 3000, and 4000 hertz in one or both ears.

(2) *How do I determine whether an STS has occurred?* If the employee has never previously experienced a recordable hearing loss, you must compare the employee's current audiogram with that employee's baseline audiogram. If the employee has previously experienced a recordable hearing loss, you must compare the employee's current audiogram with the employee's revised baseline audiogram (the audiogram reflecting the employee's previous recordable hearing loss case).

(3) *May I adjust the audiogram results to reflect the effects of aging on hearing?* Yes, when comparing audiogram results, you may adjust the results for the employee's age when the audiogram was taken using Tables F–1 or F–2, as appropriate, in Appendix F of 29 CFR 1910.95.

(4) *Do I have to record the hearing loss if I am going to retest the employee's hearing?* No, if you retest the employee's hearing within 30 days of the first test, and the retest does not confirm the STS, you are not required to record the hearing loss case on the OSHA 300 Log. If the retest confirms the STS, you must record the hearing loss illness within seven (7) calendar days of the retest.

(5) *Are there any special rules for determining whether a hearing loss case is work-related?* Yes, hearing loss is presumed to be work-related if the employee is exposed to noise in the workplace at an 8-hour time-weighted average of 85 dBA or greater, or to a total noise dose of 50 percent, as defined in 29 CFR 1910.95. For hearing loss cases where the employee is not exposed to this level of noise, you must use the rules in § 1904.5 to determine if the hearing loss is work-related.

(6) *If a physician or other licensed health care professional determines the hearing loss is not work-related, do I still need to record the case?* If a physician or other licensed health care professional determines that the hearing loss is not work-related or has not been significantly aggravated by occupational noise exposure, you are not required to consider the case work-related or to record the case on the OSHA 300 Log.

§ 1904.11 Recording criteria for work-related tuberculosis cases.

(a) *Basic requirement.* If any of your employees has been occupationally exposed to anyone with a known case of active tuberculosis (TB), and that employee subsequently develops a tuberculosis infection, as evidenced by a positive skin test or diagnosis by a physician or other licensed health care professional, you must record the case on the OSHA 300 Log by checking the "respiratory condition" column.

(b) *Implementation.* (1) *Do I have to record, on the Log, a positive TB skin test result obtained at a pre-employment physical?* No, you do not have to record it because the employee was not occupationally exposed to a known case of active tuberculosis in your workplace.

(2) *May I line-out or erase a recorded TB case if I obtain evidence that the case was not caused by occupational exposure?* Yes, you may line-out or erase the case from the Log under the following circumstances:

(i) The worker is living in a household with a person who has been diagnosed with active TB;

(ii) The Public Health Department has identified the worker as a contact of an individual with a case of active TB unrelated to the workplace; or

(iii) A medical investigation shows that the employee's infection was caused by exposure to TB away from work, or proves that the case was not related to the workplace TB exposure.

§ 1904.12 Recording criteria for cases involving work-related musculoskeletal disorders.

(a) *Basic requirement.* If any of your employees experiences a recordable work-related musculoskeletal disorder (MSD), you must record it on the OSHA 300 Log by checking the "musculoskeletal disorder" column.

(b) *Implementation.* (1) *What is a "musculoskeletal disorder" or MSD?* Musculoskeletal disorders (MSDs) are disorders of the muscles, nerves, tendons, ligaments, joints, cartilage and spinal discs. MSDs do not include disorders caused by slips, trips, falls, motor vehicle accidents, or other similar accidents. Examples of MSDs include: Carpal tunnel syndrome, Rotator cuff syndrome, De Quervain's disease, Trigger finger, Tarsal tunnel syndrome, Sciatica, Epicondylitis, Tendinitis, Raynaud's phenomenon, Carpet layers knee, Herniated spinal disc, and Low back pain.

(2) *How do I decide which musculoskeletal disorders to record?* There are no special criteria for determining which musculoskeletal disorders to record. An MSD case is recorded using the same process you would use for any other injury or illness. If a musculoskeletal disorder is work-related, and is a new case, and meets one or more of the general recording criteria, you must record the musculoskeletal disorder. The following table will guide you to the appropriate

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section of the rule for guidance on recording MSD cases.

(i) Determining if the MSD is work-related. See § 1904.5.

(ii) Determining if the MSD is a new case. See § 1904.6.

(iii) Determining if the MSD meets one or more of the general recording criteria:

(A) Days away from work, see § 1904.7(b)(3).

(B) Restricted work or transfer to another job, or see § 1904.7(b)(4).

(C) Medical treatment beyond first aid. See § 1904.7(b)(5).

(3) *If a work-related MSD case involves only subjective symptoms like pain or tingling, do I have to record it as a musculoskeletal disorder?* The symptoms of an MSD are treated the same as symptoms for any other injury or illness. If an employee has pain, tingling, burning, numbness or any other subjective symptom of an MSD, and the symptoms are work-related, and the case is a new case that meets the recording criteria, you must record the case on the OSHA 300 Log as a musculoskeletal disorder.

§§ 1904.13–1904.28 [Reserved]

§ 1904.29 Forms

(a) *Basic requirement.* You must use OSHA 300, 300–A, and 301 forms, or equivalent forms, for recordable injuries and illnesses. The OSHA 300 form is called the Log of Work-Related Injuries and Illnesses, the 300–A is the Summary of Work-Related Injuries and Illnesses, and the OSHA 301 form is called the Injury and Illness Incident Report.

(b) *Implementation.* (1) *What do I need to do to complete the OSHA 300 Log?* You must enter information about your business at the top of the OSHA 300 Log, enter a one or two line description for each recordable injury or illness, and summarize this information on the OSHA 300–A at the end of the year.

(2) *What do I need to do to complete the OSHA 301 Incident Report?* You must complete an OSHA 301 Incident Report form, or an equivalent form, for each recordable injury or illness entered on the OSHA 300 Log.

(3) *How quickly must each injury or illness be recorded?* You must enter each recordable injury or illness on the OSHA 300 Log and 301 Incident Report within seven (7) calendar days of receiving information that a recordable injury or illness has occurred.

(4) *What is an equivalent form?* An equivalent form is one that has the same information, is as readable and understandable, and is completed using the same instructions as the OSHA form it replaces. Many employers use an insurance form instead of the OSHA 301 Incident Report, or supplement an insurance form by adding any additional information required by OSHA.

(5) *May I keep my records on a computer?* Yes, if the computer can produce equivalent forms when they are needed, as described under §§ 1904.35 and 1904.40, you may keep your records using the computer system.

(6) *Are there situations where I do not put the employee's name on the forms for privacy reasons?* Yes, if you have a "privacy concern case," you may not enter the employee's name on the OSHA 300 Log. Instead, enter "privacy case" in the space normally used for the employee's name. This will protect the privacy of the injured or ill employee when another employee, a former employee, or an authorized employee representative is provided access to the OSHA 300 Log under § 1904.35(b)(2). You must keep a separate, confidential list of the case numbers and employee names for your privacy concern cases so you can update the cases and provide the information to the government if asked to do so.

(7) *How do I determine if an injury or illness is a privacy concern case?* You must consider the following injuries or illnesses to be privacy concern cases:

(i) An injury or illness to an intimate body part or the reproductive system;

(ii) An injury or illness resulting from a sexual assault;

(iii) Mental illnesses;

(iv) HIV infection, hepatitis, or tuberculosis;

(v) Needlestick injuries and cuts from sharp objects that are contaminated with another person's blood or other potentially infectious material (see § 1904.8 for definitions); and

(vi) Other illnesses, if the employee independently and voluntarily requests that his or her name not be entered on the log. Musculoskeletal disorders (MSDs) are not considered privacy concern cases.

(8) *May I classify any other types of injuries and illnesses as privacy concern cases?* No, this is a complete list of all injuries and illnesses considered privacy concern cases for Part 1904 purposes.

(9) *If I have removed the employee's name, but still believe that the employee may be identified from the information on the forms, is there anything else that I can do to further protect the employee's privacy?* Yes, if you have a reasonable basis to believe that information describing the privacy concern case may be personally identifiable even though the employee's name has been omitted, you may use discretion in describing the injury or illness on both the OSHA 300 and 301 forms. You must enter enough information to identify the cause of the incident and the general severity of the injury or illness, but you do not need to include details of an intimate or private nature. For example, a sexual assault case could be described as "injury from assault," or an injury to a reproductive organ could be described as "lower abdominal injury."

(10) *What must I do to protect employee privacy if I wish to provide access to the OSHA Forms 300 and 301 to persons other than government representatives, employees, former employees or authorized representatives?* If you decide to voluntarily disclose the Forms to persons other than government representatives, employees, former employees or authorized representatives (as required by §§ 1904.35 and 1904.40), you must remove or hide the employees' names and other personally identifying information, except for the following cases. You may disclose the Forms with personally identifying information only:

(i) to an auditor or consultant hired by the employer to evaluate the safety and health program;

(ii) to the extent necessary for processing a claim for workers' compensation or other insurance benefits; or

(iii) to a public health authority or law enforcement agency for uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required under Department of Health and Human Services Standards for Privacy of Individually Identifiable Health Information, 45 CFR 164.512.

Subpart D—Other OSHA Injury and Illness Recordkeeping Requirements

§ 1904.30 Multiple business establishments.

(a) *Basic requirement.* You must keep a separate OSHA 300 Log for each establishment that is expected to be in operation for one year or longer.

(b) *Implementation.* (1) *Do I need to keep OSHA injury and illness records for short-term establishments (i.e., establishments that will exist for less than a year)?* Yes, however, you do not have to keep a separate OSHA 300 Log for each such establishment. You may keep one OSHA 300 Log that covers all of your short-term establishments. You may also include the short-term establishments' recordable injuries and illnesses on an OSHA 300 Log that covers short-term establishments for individual company divisions or geographic regions.

(2) *May I keep the records for all of my establishments at my headquarters location or at some other central location?* Yes, you may keep the records for an establishment at your headquarters or other central location if you can:

(i) Transmit information about the injuries and illnesses from the establishment to the central location within seven (7) calendar days of receiving information that a recordable injury or illness has occurred; and

(ii) Produce and send the records from the central location to the establishment within the time frames required by § 1904.35 and § 1904.40 when you are required to provide records to a government representative, employees, former employees or employee representatives.

(3) *Some of my employees work at several different locations or do not work at any of my establishments at all. How do I record cases for these employees?* You must link each of your employees with one of your establishments, for recordkeeping purposes. You must record the injury and illness on the OSHA 300 Log of the injured or ill employee's establishment, or on an OSHA 300 Log that covers that employee's short-term establishment.

(4) *How do I record an injury or illness when an employee of one of my establishments is injured or becomes ill while visiting or working at another of my establishments, or while working away from any of my establishments?* If the injury or illness occurs at one of your establishments, you must record the injury or illness on the OSHA 300 Log of the establishment at which the injury or illness occurred. If the employee is injured or becomes ill and is not at one of your establishments, you must record the case on the OSHA 300 Log at the establishment at which the employee normally works.

§ 1904.31 Covered employees.

(a) *Basic requirement.* You must record on the OSHA 300 Log the recordable injuries and illnesses of all employees on your payroll, whether they are labor, executive, hourly, salary, part-time, seasonal, or migrant workers. You also must record the recordable injuries and illnesses that occur to employees who are not on your payroll if you supervise these employees on a day-to-day basis. If your business is organized as a sole proprietorship or partnership, the owner or partners are not considered employees for recordkeeping purposes.

(b) *Implementation.* (1) *If a self-employed person is injured or becomes ill while doing work at my business, do I need to record the injury or illness?* No, self-employed individuals are not covered by the OSH Act or this regulation.

(2) *If I obtain employees from a temporary help service, employee leasing service, or personnel supply service, do I have to record an injury or illness occurring to one of those employees?* You must record these injuries and illnesses if you supervise these employees on a day-to-day basis.

(3) *If an employee in my establishment is a contractor's employee, must I record an injury or illness occurring to that employee?* If the contractor's employee is under the day-to-day supervision of the contractor, the contractor is responsible for recording the injury or illness. If you supervise the contractor employee's work on a day-to-day basis, you must record the injury or illness.

(4) *Must the personnel supply service, temporary help service, employee leasing service, or contractor also record the injuries or illnesses occurring to temporary, leased or contract employees that I supervise on a day-to-day basis?* No, you and the temporary help service, employee leasing service, personnel supply service, or contractor should coordinate your efforts to make sure that each injury and illness is recorded only once: either on your OSHA 300 Log (if you provide day-to-day supervision) or on the other employer's OSHA 300 Log (if that company provides day-to-day supervision).

§ 1904.32 Annual summary.

(a) *Basic requirement.* At the end of each calendar year, you must:

(1) Review the OSHA 300 Log to verify that the entries are complete and accurate, and correct any deficiencies identified;

(2) Create an annual summary of injuries and illnesses recorded on the OSHA 300 Log;

(3) Certify the summary; and

(4) Post the annual summary.

(b) *Implementation.* (1) *How extensively do I have to review the OSHA 300 Log entries at the end of the year?* You must review the entries as extensively as necessary to make sure that they are complete and correct.

(2) *How do I complete the annual summary?* You must:

(i) Total the columns on the OSHA 300 Log (if you had no recordable cases, enter zeros for each column total); and

(ii) Enter the calendar year covered, the company's name, establishment name, establishment address, annual average number of employees covered by the OSHA 300 Log, and the total hours worked by all employees covered by the OSHA 300 Log.

(iii) If you are using an equivalent form other than the OSHA 300-A summary form, as permitted under § 1904.6(b)(4), the summary you use must also include the employee access and employer penalty statements found on the OSHA 300-A Summary form.

(3) *How do I certify the annual summary?* A company executive must certify that he or she has examined the OSHA 300 Log and that he or she reasonably believes, based on his or her knowledge of the process by which the information was recorded, that the annual summary is correct and complete.

(4) *Who is considered a company executive?* The company executive who certifies the log must be one of the following persons:

(i) An owner of the company (only if the company is a sole proprietorship or partnership);

(ii) An officer of the corporation;

(iii) The highest ranking company official working at the establishment; or

(iv) The immediate supervisor of the highest ranking company official working at the establishment.

(5) *How do I post the annual summary?* You must post a copy of the annual summary in each establishment in a conspicuous place or places where notices to employees are customarily posted. You must ensure that the posted annual summary is not altered, defaced or covered by other material.

(6) *When do I have to post the annual summary?* You must post the summary no later than February 1 of the year following the year covered by the records and keep the posting in place until April 30.

§ 1904.33 Retention and updating.

(a) *Basic requirement.* You must save the OSHA 300 Log, the privacy case list (if one exists), the annual summary, and the OSHA 301 Incident Report forms for five (5) years following the end of the calendar year that these records cover.

(b) *Implementation.* (1) *Do I have to update the OSHA 300 Log during the five-year storage period?* Yes, during the storage period, you must update your stored OSHA 300 Logs to include newly discovered recordable injuries or illnesses and to show any changes that have occurred in the classification of previously recorded injuries and illnesses. If the description or outcome of a case changes, you must remove or line out the original entry and enter the new information.

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(2) *Do I have to update the annual summary?* No, you are not required to update the annual summary, but you may do so if you wish.

(3) *Do I have to update the OSHA 301 Incident Reports?* No, you are not required to update the OSHA 301 Incident Reports, but you may do so if you wish.

§ 1904.34 Change in business ownership.

If your business changes ownership, you are responsible for recording and reporting work-related injuries and illnesses only for that period of the year during which you owned the establishment. You must transfer the Part 1904 records to the new owner. The new owner must save all records of the establishment kept by the prior owner, as required by § 1904.33 of this Part, but need not update or correct the records of the prior owner.

§ 1904.35 Employee involvement.

(a) *Basic requirement.* Your employees and their representatives must be involved in the recordkeeping system in several ways.

(1) You must inform each employee of how he or she is to report an injury or illness to you.

(2) You must provide limited access to your injury and illness records for your employees and their representatives.

(b) *Implementation.* (1) *What must I do to make sure that employees report work-related injuries and illnesses to me?*

(i) You must set up a way for employees to report work-related injuries and illnesses promptly; and

(ii) You must tell each employee how to report work-related injuries and illnesses to you.

(2) *Do I have to give my employees and their representatives access to the OSHA injury and illness records?* Yes, your employees, former employees, their personal representatives, and their authorized employee representatives have the right to access the OSHA injury and illness records, with some limitations, as discussed below.

(i) *Who is an authorized employee representative?* An authorized employee representative is an authorized collective bargaining agent of employees.

(ii) *Who is a "personal representative" of an employee or former employee?* A personal representative is:

(A) Any person that the employee or former employee designates as such, in writing; or

(B) The legal representative of a deceased or legally incapacitated employee or former employee.

(iii) *If an employee or representative asks for access to the OSHA 300 Log, when do I have to provide it?* When an employee, former employee, personal representative, or authorized employee representative asks for copies of your current or stored OSHA 300 Log(s) for an establishment the employee or former employee has worked in, you must give the requester a copy of the relevant OSHA 300 Log(s) by the end of the next business day.

(iv) *May I remove the names of the employees or any other information from the OSHA 300 Log before I give copies to an employee, former employee, or employee representative?* No, you must leave the names on the 300 Log. However, to protect the privacy of injured and ill employees, you may not record the employee's name on the OSHA 300 Log for certain "privacy concern cases," as specified in paragraphs 1904.29(b)(6) through 1904.29(b)(9).

(v) *If an employee or representative asks for access to the OSHA 301 Incident Report, when do I have to provide it?*

(A) When an employee, former employee, or personal representative asks for a copy of the OSHA 301 Incident Report describing an injury or illness to that employee or former employee, you must give the requester a copy of the OSHA 301 Incident Report containing that information by the end of the next business day.

(B) When an authorized employee representative asks for a copies of the OSHA 301 Incident Reports for an establishment where the agent represents employees under a collective bargaining agreement, you must give copies of those forms to the authorized employee representative within 7 calendar days. You are only required to give the authorized employee representative information from the OSHA 301 Incident Report section titled "Tell us about the case." You must remove all other information from the copy of the OSHA 301 Incident Report or the equivalent substitute form that you give to the authorized employee representative.

(vi) *May I charge for the copies?* No, you may not charge for these copies the first time they are provided. However, if one of the designated persons asks for additional copies, you may assess a reasonable charge for retrieving and copying the records.

§ 1904.36 Prohibition against discrimination.

Section 11(c) of the Act prohibits you from discriminating against an employee for reporting a work-related fatality, injury or illness. That provision of the Act also protects the employee who files a safety and health complaint, asks for access to the Part 1904 records, or otherwise exercises any rights afforded by the OSH Act.

§ 1904.37 State recordkeeping regulations.

(a) *Basic requirement.* Some States operate their own OSHA programs, under the authority of a State Plan approved by OSHA. States operating OSHA-approved State Plans must have occupational injury and illness recording and reporting requirements that are substantially identical to the requirements in this Part (see 29 CFR 1902.3(k), 29 CFR 1952.4 and 29 CFR 1956.10(i)).

(b) *Implementation.* (1) State-Plan States must have the same requirements as Federal OSHA for determining which injuries and illnesses are recordable and how they are recorded.

(2) For other Part 1904 provisions (for example, industry exemptions, reporting of fatalities and hospitalizations, record retention, or employee involvement), State-Plan State requirements may be more stringent than or supplemental to the Federal requirements, but because of the unique nature of the national recordkeeping program, States must consult with and obtain approval of any such requirements.

(3) Although State and local government employees are not covered Federally, all State-Plan States must provide coverage, and must develop injury and illness statistics, for these workers. State Plan recording and reporting requirements for State and local government entities may differ from those for the private sector but must meet the requirements of paragraphs 1904.37(b)(1) and (b)(2).

(4) A State-Plan State may not issue a variance to a private sector employer and must recognize all variances issued by Federal OSHA.

(5) A State Plan State may only grant an injury and illness recording and reporting variance to a State or local government employer within the State after obtaining approval to grant the variance from Federal OSHA.

§ 1904.38 Variances from the recordkeeping rule.

(a) *Basic requirement.* If you wish to keep records in a different manner from the manner prescribed by the Part 1904 regulations, you may submit a variance petition to the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, DC 20210. You can obtain a variance only if you can show that your alternative recordkeeping system:

(1) Collects the same information as this Part requires;

(2) Meets the purposes of the Act; and

(3) Does not interfere with the administration of the Act.

(b) *Implementation.* (1) *What do I need to include in my variance petition?* You must include the following items in your petition:

(i) Your name and address;

(ii) A list of the State(s) where the variance would be used;

(iii) The address(es) of the business establishment(s) involved;

(iv) A description of why you are seeking a variance;

(v) A description of the different recordkeeping procedures you propose to use;

(vi) A description of how your proposed procedures will collect the same information as would be collected by this Part and achieve the purpose of the Act; and

(vii) A statement that you have informed your employees of the petition by giving them or their authorized representative a copy of the petition and by posting a statement summarizing the petition in the same way as notices are posted under § 1903.2(a).

(2) *How will the Assistant Secretary handle my variance petition?* The Assistant Secretary will take the following steps to process your variance petition.

(i) The Assistant Secretary will offer your employees and their authorized representatives an opportunity to submit written data, views, and arguments about your variance petition.

(ii) The Assistant Secretary may allow the public to comment on your variance petition by publishing the petition in the **Federal Register**. If the petition is published, the notice will establish a public comment period and may include a schedule for a public meeting on the petition.

(iii) After reviewing your variance petition and any comments from your employees and the public, the Assistant Secretary will decide whether or not your proposed recordkeeping procedures will meet the purposes of the Act, will not otherwise interfere with the Act, and will provide the same information as the Part 1904 regulations provide. If your procedures meet these criteria, the Assistant Secretary may grant the variance subject to such conditions as he or she finds appropriate.

(iv) If the Assistant Secretary grants your variance petition, OSHA will publish a notice in the **Federal Register** to announce the variance. The notice will include the practices the variance allows you to use, any conditions that apply, and the reasons for allowing the variance.

(3) *If I apply for a variance, may I use my proposed recordkeeping procedures while the Assistant Secretary is processing the variance petition?* No, alternative recordkeeping practices are only allowed after the variance is approved. You must comply with the Part 1904 regulations while the Assistant Secretary is reviewing your variance petition.

(4) *If I have already been cited by OSHA for not following the Part 1904 regulations, will my variance petition have any effect on the citation and penalty?* No, in addition, the Assistant Secretary may elect not to review your variance petition if it includes an element for which you have been cited and the citation is still under review by a court, an Administrative Law Judge (ALJ), or the OSH Review Commission.

(5) *If I receive a variance, may the Assistant Secretary revoke the variance at a later date?* Yes, the Assistant Secretary may revoke your variance if he or she has good cause. The procedures revoking a variance will follow the same process as OSHA uses for reviewing variance petitions, as outlined in paragraph 1904.38(b)(2). Except in cases of willfulness or where necessary for public safety, the Assistant Secretary will:

(i) Notify you in writing of the facts or conduct that may warrant revocation of your variance; and

(ii) Provide you, your employees, and authorized employee representatives with an opportunity to participate in the revocation procedures.

Subpart E—Reporting Fatality, Injury and Illness Information to the Government

§ 1904.39 Reporting fatalities and multiple hospitalization incidents to OSHA.

(a) *Basic requirement.* Within eight (8) hours after the death of any employee from a work-related incident or the in-patient hospitalization of three or more employees as a result of a work-related incident, you must orally report the fatality/multiple hospitalization by telephone or in person to the Area Office of the Occupational Safety and Health Administration (OSHA), U.S. Department of Labor, that is nearest to the site of the incident. You may also use the OSHA toll-free central telephone number, 1–800–321–OSHA (1–800–321–6742).

(b) *Implementation.* (1) *If the Area Office is closed, may I report the incident by leaving a message on OSHA's answering machine, faxing the area office, or sending an e-mail?* No, if you can't talk to a person at the Area Office, you must report the fatality or multiple hospitalization incident using the 800 number.

(2) *What information do I need to give to OSHA about the incident?* You must give OSHA the following information for each fatality or multiple hospitalization incident:

(i) The establishment name;

(ii) The location of the incident;

(iii) The time of the incident;

(iv) The number of fatalities or hospitalized employees;

(v) The names of any injured employees;

(vi) Your contact person and his or her phone number; and

(vii) A brief description of the incident.

(3) *Do I have to report every fatality or multiple hospitalization incident resulting from a motor vehicle accident?* No, you do not have to report all of these incidents. If the motor vehicle accident occurs on a public street or highway, and does not occur in a construction work zone, you do not have to report the incident to OSHA. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

(4) *Do I have to report a fatality or multiple hospitalization incident that occurs on a commercial or public transportation system?* No, you do not have to call OSHA to report a fatality or multiple hospitalization incident if it involves a commercial airplane, train, subway or bus accident. However, these injuries must be recorded on your OSHA injury and illness records, if you are required to keep such records.

(5) *Do I have to report a fatality caused by a heart attack at work?* Yes, your local OSHA Area Office director will decide whether to investigate the incident, depending on the circumstances of the heart attack.

(6) *Do I have to report a fatality or hospitalization that occurs long after the incident?* No, you must only report each fatality or multiple hospitalization incident that occurs within thirty (30) days of an incident.

(7) *What if I don't learn about an incident right away?* If you do not learn of a reportable incident at the time it occurs and the incident would otherwise be reportable under paragraphs (a) and (b) of this section, you must make the report within eight (8) hours of the time the incident is reported to you or to any of your agent(s) or employee(s).

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§ 1904.40 Providing records to government representatives.

(a) *Basic requirement.* When an authorized government representative asks for the records you keep under Part 1904, you must provide copies of the records within four (4) business hours.

(b) *Implementation.* (1) *What government representatives have the right to get copies of my Part 1904 records?* The government representatives authorized to receive the records are:

(i) A representative of the Secretary of Labor conducting an inspection or investigation under the Act;

(ii) A representative of the Secretary of Health and Human Services (including the National Institute for Occupational Safety and Health—NIOSH) conducting an investigation under section 20(b) of the Act, or

(iii) A representative of a State agency responsible for administering a State plan approved under section 18 of the Act.

(2) *Do I have to produce the records within four (4) hours if my records are kept at a location in a different time zone?* OSHA will consider your response to be timely if you give the records to the government representative within four (4) business hours of the request. If you maintain the records at a location in a different time zone, you may use the business hours of the establishment at which the records are located when calculating the deadline.

§ 1904.41 Annual OSHA injury and illness survey of ten or more employers.

(a) *Basic requirement.* If you receive OSHA's annual survey form, you must fill it out and send it to OSHA or OSHA's designee, as stated on the survey form. You must report the following information for the year described on the form:

(1) the number of workers you employed;

(2) the number of hours worked by your employees; and

(3) the requested information from the records that you keep under Part 1904.

(b) *Implementation.* (1) *Does every employer have to send data to OSHA?* No, each year, OSHA sends injury and illness survey forms to employers in certain industries. In any year, some employers will receive an OSHA survey form and others will not. You do not have to send injury and illness data to OSHA unless you receive a survey form.

(2) *How quickly do I need to respond to an OSHA survey form?* You must send the survey reports to OSHA, or OSHA's designee, by mail or other means described in the survey form, within 30 calendar days, or by the date stated in the survey form, whichever is later.

(3) *Do I have to respond to an OSHA survey form if I am normally exempt from keeping OSHA injury and illness records?* Yes, even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, OSHA may inform you in writing that it will be collecting injury and illness information from you in the following year. If you receive such a letter, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make a survey report for the year covered by the survey.

(4) *Do I have to answer the OSHA survey form if I am located in a State-Plan State?* Yes, all employers who receive survey forms must respond to the survey, even those in State-Plan States.

(5) *Does this section affect OSHA's authority to inspect my workplace?* No, nothing in this section affects OSHA's statutory authority to investigate conditions related to occupational safety and health.

§ 1904.42 Requests from the Bureau of Labor Statistics for data.

(a) *Basic requirement.* If you receive a Survey of Occupational Injuries and Illnesses Form from the Bureau of Labor Statistics (BLS), or a BLS designee, you must promptly complete the form and return it following the instructions contained on the survey form.

(b) *Implementation.* (1) *Does every employer have to send data to the BLS?* No, each year, the BLS sends injury and illness survey forms to randomly selected employers and uses the information to create the Nation's occupational injury and illness statistics. In any year, some employers will receive a BLS survey form and others will not. You do not have to send injury and illness data to the BLS unless you receive a survey form.

(2) *If I get a survey form from the BLS, what do I have to do?* If you receive a Survey of Occupational Injuries and Illnesses Form from the Bureau of Labor Statistics (BLS), or a BLS designee, you must promptly complete the form and return it, following the instructions contained on the survey form.

(3) *Do I have to respond to a BLS survey form if I am normally exempt from keeping OSHA injury and illness records?* Yes, even if you are exempt from keeping injury and illness records under § 1904.1 to § 1904.3, the BLS may inform you in writing that it will be collecting injury and illness information from you in the coming year. If you receive such a letter, you must keep the injury and illness records required by § 1904.5 to § 1904.15 and make a survey report for the year covered by the survey.

(4) *Do I have to answer the BLS survey form if I am located in a State-Plan State?* Yes, all employers who receive a survey form must respond to the survey, even those in State-Plan States.

Subpart F—Transition From the Former Rule

§ 1904.43 Summary and posting of the 2001 data.

(a) *Basic requirement.* If you were required to keep OSHA 200 Logs in 2001, you must post a 2000 annual summary from the OSHA 200 Log of occupational injuries and illnesses for each establishment.

(b) *Implementation.* (1) *What do I have to include in the summary?*

(i) You must include a copy of the totals from the 2001 OSHA 200 Log and the following information from that form:

(A) The calendar year covered;

(B) Your company name;

(C) The name and address of the establishment; and

(D) The certification signature, title and date.

(ii) If no injuries or illnesses occurred at your establishment in 2001, you must enter zeros on the totals line and post the 2001 summary.

(2) *When am I required to summarize and post the 2001 information?*

(i) You must complete the summary by February 1, 2002; and

(ii) You must post a copy of the summary in each establishment in a conspicuous place or places where notices to employees are customarily posted. You must ensure that the summary is not altered, defaced or covered by other material.

(3) You must post the 2001 summary from February 1, 2002 to March 1, 2002.

§ 1904.44 Retention and updating of old forms.

You must save your copies of the OSHA 200 and 101 forms for five years following the year to which they relate and continue to provide access to the data as though these forms were the OSHA 300 and 301 forms. You are not required to update your old 200 and 101 forms.

§ 1904.45 OMB control numbers under the Paperwork Reduction Act

The following sections each contain a collection of information requirement which has been approved by the Office of Management and Budget under the control number listed

29 CFR citation	OMB Control No.
1904.4–35	1218–0176
1904.39–41	1218–0176
1904.42	1220–0045
1904.43–44	1218–0176

Subpart G—Definitions

§ 1904.46 Definitions

The Act. The Act means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*). The definitions contained in section 3 of the Act (29 U.S.C. 652) and related interpretations apply to such terms when used in this Part 1904.

Establishment. An establishment is a single physical location where business is conducted or where services or industrial operations are performed. For activities where employees do not work at a single physical location, such as construction; transportation; communications, electric, gas and sanitary services; and similar operations, the establishment is represented by main or branch offices, terminals, stations, etc. that either supervise such activities or are the base from which personnel carry out these activities.

(1) *Can one business location include two or more establishments?* Normally, one business location has only one establishment. Under limited conditions, the employer may consider two or more separate businesses that share a single location to be separate establishments. An employer may divide one location into two or more establishments only when:

(i) Each of the establishments represents a distinctly separate business;

(ii) Each business is engaged in a different economic activity;

(iii) No one industry description in the Standard Industrial Classification Manual (1987) applies to the joint activities of the establishments; and

(iv) Separate reports are routinely prepared for each establishment on the number of employees, their wages and salaries, sales or receipts, and other business information. For example, if an employer operates a construction company at the same location as a lumber yard, the employer may consider each business to be a separate establishment.

(2) *Can an establishment include more than one physical location?* Yes, but only under certain conditions. An employer may combine two or more physical locations into a single establishment only when:

(i) The employer operates the locations as a single business operation under common management;

(ii) The locations are all located in close proximity to each other; and

(iii) The employer keeps one set of business records for the locations, such as records on the number of employees, their wages and salaries, sales or receipts, and other kinds of business information. For example, one manufacturing establishment might include the main plant, a warehouse a few blocks away, and an administrative services building across the street.

(3) *If an employee telecommutes from home, is his or her home considered a separate establishment?* No, for employees who telecommute from home, the employee's home is not a business establishment and a separate 300 Log is not required. Employees who telecommute must be linked to one of your establishments under § 1904.30(b)(3).

Injury or illness. An injury or illness is an abnormal condition or disorder. Injuries include cases such as, but not limited to, a cut, fracture, sprain, or amputation. Illnesses include both acute and chronic illnesses, such as, but not limited to, a skin disease, respiratory disorder, or poisoning. (Note: Injuries and illnesses are recordable only if they are new, work-related cases that meet one or more of the Part 1904 recording criteria.)

Physician or Other Licensed Health Care Professional. A physician or other licensed health care professional is an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows him or her to independently perform, or be delegated the responsibility to perform, the activities described by this regulation.

You. "You" means an employer as defined in Section 3 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 652).

PART 1952—[AMENDED]

2. The authority citation for Part 1952 is revised to read as follows:

Authority: 29 U.S.C. 667; 29 CFR part 1902, Secretary of Labor's Order No. 1–90 (55 FR 9033) and 6–96 (62 FR 111).

3. Section 1952.4 is revised to read as follows:

§ 1952.4 Injury and illness recording and reporting requirements.

(a) Injury and illness recording and reporting requirements promulgated by State-Plan States must be substantially identical to those in 29 CFR part 1904 "Recording and Reporting Occupational Injuries and Illnesses." State-Plan States must promulgate recording and reporting requirements that are the same as the Federal requirements for determining which injuries and illnesses will be entered into the records and how they are entered. All other injury and illness recording and reporting requirements that are promulgated by State-Plan States may be more stringent than, or supplemental to, the Federal requirements, but, because of the unique nature of the national recordkeeping program, States must consult with OSHA and obtain approval of such additional or more stringent reporting and recording requirements to ensure that they will not interfere with uniform reporting objectives. State-Plan States must extend the scope of their regulation to State and local government employers.

(b) A State may not grant a variance to the injury and illness recording and reporting requirements for private sector employers. Such variances may only be granted by Federal OSHA to assure nationally consistent workplace injury and illness statistics. A State may only grant a variance to the injury and illness recording and reporting requirements for State or local government entities in that State after obtaining approval from Federal OSHA.

(c) A State must recognize any variance issued by Federal OSHA.

(d) A State may, but is not required, to participate in the Annual OSHA Injury/Illness Survey as authorized by 29 CFR 1904.41. A participating State may either adopt requirements identical to 1904.41 in its recording and reporting regulation as an enforceable State requirement, or may defer to the Federal regulation for enforcement. Nothing in any State plan shall affect the duties of employers to comply with 1904.41, when surveyed, as provided by section 18(c)(7) of the Act.

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 120
Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the agency) is adopting final regulations to ensure the safe and sanitary processing of fruit and vegetable juices. The regulations mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of these foods. HACCP is a preventive system of hazard control. FDA is taking this action because there have been a number of food hazards associated with juice products and because a system of preventive control measures is the most effective and efficient way to ensure that these products are safe.

DATES: Effective Dates: This rule is effective January 22, 2002.

Compliance Date: For small businesses as defined in 21 CFR 120.1(b)(1), the final rule will be binding January 21, 2003. For very small businesses as defined in 21 CFR 120.1(b)(2), the final rule will be binding January 20, 2004.

FOR FURTHER INFORMATION CONTACT: Shellee Anderson, Center for Food Safety and Applied Nutrition (HFS–366), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5023.

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I. Background

A. Notice of Intent

In the **Federal Register** of August 28, 1997 (62 FR 45593)(Ref. 1), FDA published a notice of intent (hereinafter referred to as the notice of intent) that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and ultimately to address the safety of all juice products. In the notice of intent, the agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products; (2) propose that the labels or the labeling of juice products not specifically processed to prevent, reduce, or eliminate pathogens bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and (3) initiate several educational programs to minimize the hazards associated with consumption of fresh juices. The agency stated that it would address comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency. FDA also stated that it would consider all comments to the notice of intent received after 15 days in any final rulemaking. FDA reviewed all of the comments received within 15 days of publication and found that they provided no information that would cause the agency to conclude that the HACCP proposal was inappropriate. Comments received 15 days after publication of the notice of intent are discussed in this final rule.

B. The Proposal

In the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), FDA published a proposed rule to establish requirements relating to the processing of juice and juice products (hereinafter referred to as the HACCP proposal).[1] The proposal would have required the application of HACCP principles by processors and importers to ensure juice safety to the maximum extent practicable. FDA proposed these regulations because there had been a number of food hazards, including some directly affecting children, associated with juice products. The agency tentatively concluded that the most effective way to ensure the safety of juice products is to process the products under a system of preventive control measures based on HACCP principles. Interested persons were given until July 8, 1998, to comment on the HACCP proposal. The agency subsequently extended the comment period to August 7, 1998 (63 FR 37057; July 8, 1998) (Ref. 3).

In addition to publishing the HACCP proposal, FDA published in the same issue of the **Federal Register** (63 FR 20486) (Ref. 4) a proposed rule (the juice labeling proposal) to require warning labels on juice that has not been processed to prevent, reduce to acceptable levels, or eliminate pathogens that may be present. As fully discussed in the juice labeling proposal, FDA proposed that untreated juice products bear a warning statement informing at risk consumers of the hazard posed by untreated juices to allow them to make informed decisions on whether to purchase and consume such products. The labeling proposal was finalized on July 8, 1998 (63 FR 37030) (Ref. 5).

FDA issued in the **Federal Register** of May 1, 1998 (63 FR 24254) (Ref. 6) a single Preliminary Regulatory Impact Analysis (PRIA) that addressed both the juice labeling proposal and the juice HACCP proposal. Interested parties were given until May 26, 1998, to comment on aspects of the PRIA relating to the juice labeling proposal and until July 8, 1998, to comment on aspects of the PRIA relating to the juice HACCP proposal.

[1] As defined in § 120.1 (21 CFR 120.1) "juice" refers both to beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables and to the juice ingredient in those beverages that contain other ingredients in addition to juice. In this document, the term "juice product" refers both to beverages that contain only juice and to the juice ingredient of beverages that are composed of juice and other ingredients.

In the remainder of this document, products not processed to prevent, reduce, or eliminate hazards will be referred to as "untreated juice products." In addition, processing to "prevent, reduce, or eliminate" hazards will be referred to as processing to "control" hazards.

C. Additional Opportunities for Public Participation

Under the juice labeling rule (§ 101.17(g) (21 CFR 101.17(g))), juice and juice products that have not been specifically processed to attain a 5-log reduction in the pertinent pathogen must bear a warning label. Similarly, under the juice HACCP proposal (proposed § 120.24), covered processors must attain a 5-log reduction in the pertinent pathogen in their HACCP systems. Accordingly, in November 1998, FDA held two technical workshops on how processors could attain a 5-log (*i.e.*, 10^5) reduction in the pertinent pathogen in citrus juices (63 FR 57594; October 28, 1998) (Ref. 7). The transcripts from the two workshops were placed on display in the docket for the juice HACCP proposal and on the FDA/CFSAN website http://www.fda.gov/). On December 17, 1998 (63 FR 69579) (Ref. 8), the comment period for the juice HACCP proposal was reopened until January 19, 1999, to allow public comment on data and other information that were presented at or developed as a result of these workshops. In addition, FDA expressly sought comments on the following four specific topics related to the application of the 5-log pathogen reduction standard: (1) Appropriate baselines for the calculation of the 5-log pathogen reduction; (2) feasible interventions or practices for the cultivation and harvest of fruits and vegetables, and acquisition of supplies and materials that may contribute to achieving a 5-log pathogen reduction; (3) feasible interventions for the production process that may contribute to achieving a 5-log pathogen reduction; and (4) acceptable methods for measuring and validating 5-log reductions.

On July 15 and 16, 1999, FDA held a workshop on food safety controls for the apple cider[2] industry (64 FR 34125; June 25, 1999) (Ref. 9). The workshop dealt with issues related to the implementation of the agency's regulations requiring a warning statement for certain juice products. Specifically, the workshop addressed pathogen reduction interventions that may be effective for apple cider production and the methods used to measure and validate such interventions. Results of research conducted by Federal, State, private, and academic institutions were presented.

In the **Federal Register** of November 23, 1999 (64 FR 65669) (Ref. 10), FDA announced the availability of new data and information regarding the safe processing of citrus juice and juice products, and reopened the comment period for the juice HACCP proposal until January 24, 2000, in order to receive comment on the new data and other information. In that same notice, in order to develop the most complete administrative record possible, FDA requested additional data and information relating to four separate areas: Internalization and survival of pathogens in produce used to produce juice, especially citrus fruit; application and measurement of the 5-log reduction standard; current methods used by juice processors to monitor the application of heat treatment to juice; and certain economic matters related to juice regulation. The notice discussed in detail the particular issues in each of the four areas in which the agency was seeking comments (64 FR 65669 at 65670 through 65671). Two of these areas (internalization and survival of pathogens and application and measurement of the 5-log reduction standard) were also to be the subject of the December 8 to 9, 1999, public meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) (discussed in more detail below), and the comment period extension was established so as to permit comments on the identified issues in light of any information or recommendations coming out of that meeting of the NACMCF.

D. NACMCF Public Meeting

NACMCF is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and has members from USDA (Food Safety and Inspection Service), the Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention (CDC)), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and State agencies. The NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

The NACMCF held a public meeting on December 8 to 9, 1999 (64 FR 63281; November 19, 1999) (Refs. 11 and 12) to discuss recent research and other information related to performance criteria for fresh citrus juices. FDA sought advice from the NACMCF on two issues. In addition, the meeting agenda provided an opportunity for public comment.

First, FDA asked the NACMCF about the potential internalization and survival of pathogens in citrus fruits and citrus juices. The NACMCF members generally agreed that it is theoretically possible for microorganisms to enter the interior of apparently sound, intact citrus fruit under certain conditions (*e.g.*, temperature difference between fruit and wash water), and that human pathogens appear to be able to survive, at least under defined laboratory conditions, in the fruit itself (Ref. 12). However, the NACMCF members concluded, based on the current information, that the potential for microorganisms to enter and survive in intact fruit is not likely to result in a significant public health risk. In particular, the Committee members concluded, based upon the limited data available, including data presented by the industry, that although it is theoretically possible, it is unlikely that pathogens will enter and grow in sound, intact fruit under actual current industry processing practices.

Second, the agency asked the NACMCF about the application and measurement of the 5-log pathogen reduction standard to citrus fruit. In response, the NACMCF outlined the following five basic consensus decisions related to the application and measurement of the 5-log reduction standard to citrus juices:

1. The 5-log reduction need not start with the extracted juice but may begin with the exterior decontamination of citrus fruit. However, processors should not start a cumulative 5-log reduction until after the fruit is cleaned (*i.e.*, washed) and culled (*i.e.*, damaged or dropped fruit is removed so that the remaining fruit is USDA choice level or higher quality).

2. One possible method to minimize potential microbial infiltration into the fruit would be by controlling fruit and wash water temperatures, as well as excluding fruit that is split, punctured, or otherwise not intact. Laboratory studies indicate that microbial infiltration of fruit occurred when warm fruit was washed or submerged into cold water (Refs. 13 and 14).

3. The entire 5-log process must occur under one firm's control and in one processing facility, *i.e.*, all steps from

[2] Although the terms "apple cider" and "apple juice" may have different meanings throughout the United States, these terms are used interchangeably throughout this final rule.

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fruit receiving to final juice packaging (and all points included in the 5-log reduction process) must occur at one facility. If processors transport fruit or juice to another facility for extraction, blending, or final packaging, the 5-log reduction must be accomplished in the second facility.

4. If the expressed juice is aseptically packaged in a single-use sanitary non-reusable tote (sterile bag in box type package form) and the bulk packed juice will be repackaged at another facility, a 5-log reduction process must be performed on that juice prior to final fill and packaging. If the juice is used directly from the tote (*e.g.*, used to dispense juice and juice beverages at retail), the 5-log reduction process need not be repeated. Because juice in tanker trucks is not juice in a final package form, juice shipped in bulk tankers must undergo a 5-log reduction process after transport and prior to final fill and packaging.

5. As part of a HACCP verification program, firms should conduct microbial testing on the final product if the 5-log reduction process relies in part on fruit surface treatment. This testing would not be batch-by-batch testing for lot acceptance prior to shipping, but would be used to verify the 5-log reduction process. The testing should use generic *E. coli* as a means to assess the control of the process and should be conducted as specified in the HACCP plan, utilizing an appropriate sampling plan. However, if results indicate (*i.e.*, the presence of generic *E. coli*) that the 5-log reduction has not been achieved, processors should consider testing the juice for specific pathogens of concern, such as *Salmonella* or any other microorganisms of concern, according to an appropriate sampling plan and processors should take suitable corrective actions. If the 5-log reduction is applied after the juice is expressed, microbiological testing would not be required as part of a HACCP verification program.

II. Response to the Comments

FDA received approximately 85 responses, each containing one or more comments, to the notice of intent. FDA addressed some of these comments in the juice HACCP proposal. FDA subsequently received approximately 800 responses, each containing one or more comments, to the juice HACCP proposal. Comments received in response to the notice of intent and to the juice HACCP proposal came from industry, trade organizations, consumers, consumer interest groups, academia, and State government agencies. Comments concerning labeling issues are discussed to the extent that they fall within the scope of issues presented by the juice HACCP proposal. Some of the comments supported the proposal. Other comments opposed, or suggested modifications of various provisions of, the proposal. The agency discusses below the significant comments bearing on the proposed HACCP regulation and, when applicable, any revisions to the proposed regulation made in response to these comments. Responses to the notice of intent that bear on the juice HACCP proposal and that were not addressed in that proposal also are addressed in this document. For simplicity, the agency's discussion does not identify comments as to whether they were received in response to the notice of intent or in response to the juice HACCP proposal.

A. Alternatives to HACCP Considered by the Agency

In developing a strategy to address the hazards associated with juice, FDA considered the following alternatives to HACCP: (1) Increased inspections, (2) current good manufacturing practices (CGMP's), (3) mandatory pasteurization, (4) labeling as a long-term solution, (5) education, and (6) an approach that would draw a distinction between untreated apple cider and all other juices. The agency discussed each alternative in the HACCP proposed rule (63 FR 20450 at 20454) and its reasons for proposing the use of HACCP systems rather than the alternatives (Ref. 2). FDA received a number of comments questioning the agency's rejection of certain alternatives. The agency's responses to those comments are set forth in this section (section II.A). To provide a meaningful context for the discussion of the alternatives, FDA is providing the following discussion of HACCP.

HACCP is a focused, efficient, preventive system that minimizes the chance that foods contaminated with hazardous materials or microorganisms will be consumed. The strength of HACCP lies in its ability to enable the processor to identify, systematically and scientifically, the primary food safety hazards of concern for the specific products, the specific processes, and the specific manufacturing facilities in question, and then to implement on a focused, consistent basis, steps (critical control points (CCP's)) in food production, processing, or preparation that are critical to prevent, reduce to acceptable levels, or eliminate hazards from the particular food being processed. Flexibility in how to address identified hazards is inherent in HACCP systems. Even when producing comparable products, no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities. Each of these factors (and their many combinations) presents potential opportunities for contamination of the food. HACCP focuses the processor on understanding his own process and the hazards that may be introduced during that process, and identifying specific controls to prevent, reduce, or eliminate the identified hazards.

The flexibility of the HACCP approach is a critically important attribute. This flexibility allows manufacturers to adjust CCP's, adjust techniques used to address CCP's when changes occur in the system (*e.g.*, use of new ingredients), and readily incorporate new scientific developments (*e.g.*, use of new control techniques, new preventive technologies, identification of new hazards). Another important strength of HACCP is the development of a plan written by the processor detailing the control measures to be used at CCP's. By developing a written plan, juice processors gain a working knowledge of their processing system, its effect on the food, and where in the system potential contamination may occur. Both the processor and the agency are able to derive the full benefits of a HACCP system. The hazard analysis and HACCP plan allow both the processor and the agency to verify and validate the operation of the system. HACCP's flexibility also permits processors to select the appropriate control measures in the context of how the whole system functions, allowing processors to use the most appropriate and economical methods to control food hazards that are reasonably likely to occur in their operation. The ability to choose among various control methods encourages research on and development of new and innovative technologies to better address individual situations. Because of its flexibility, HACCP is particularly advantageous to small businesses and seasonal processors.

HACCP provides the processor with a record of identified food hazards. It allows quick identification of a breakdown in the processing system and thus, prevents products with food hazards from entering the marketplace and causing illness. Moreover, review of records over a longer period of time (days or weeks) may reveal a trend toward a breakdown in the system, such as a critical processing temperature that is slowly drifting down. HACCP records allow evaluation of whether changes in the processing system require changes

in CCP's or their critical limits (CL's), thus ensuring that the HACCP system is up-to-date and adequate to control all food hazards that are reasonably likely to occur. This recordkeeping also allows regulatory investigators to readily review the long term performance of a firm's processing system, rather than relying on a time-limited inspection, which provides only a snapshot of how well the firm is doing in producing and distributing safe product on any given day.

HACCP is ideally suited to respond to emerging problems because a HACCP system is a dynamic system that must be validated periodically to ensure that all hazards reasonably likely to occur are identified and controlled via CCP's. Validation of both the hazard analysis and the HACCP plan entails a thorough review to ensure that all hazards that are reasonably likely to occur are addressed in the HACCP system.

Because of its preventive yet flexible nature, HACCP is recognized by food safety professionals as the single most effective means to assure the safety of foods. It has been endorsed by the National Academy of Sciences (Ref. 15), the Codex Alimentarius Commission (an international food standard-setting organization) (Ref. 16), and the NACMCF (Ref. 17). Increasingly, use of HACCP systems is an indication to importing countries that food safety systems that provide a standardized level of public health protection are in place and being used by producers in exporting countries.

1. Increased Inspection

(Comment 1) Several comments suggested that the increased FDA inspection approach would be preferable to HACCP.

The agency disagrees. FDA's responsibility is to implement and enforce the Federal Food, Drug, and Cosmetic Act (the act), *i.e.*, to oversee the manufacture of safe food. Increased inspection by FDA is a resource-intensive activity that puts the responsibility and burden for ensuring food safety on the agency rather than on the juice processors. Inspections can, of course, provide food processors with valuable information about improving the safety of their products. However, safety cannot be effectively inspected into foods. Rather, food processing systems themselves must be designed and implemented in a manner that results in the production of safe food. Part 120 (21 CFR part 120) provides a flexible standard that both the juice industry and the agency will use to determine the adequacy of a process. HACCP has been shown to be an approach that effectively ensures the production of food that is safe and wholesome (Ref. 17). Importantly, the HACCP approach clearly delineates the processor's responsibility to make safe products and FDA's responsibility to monitor conformance with the act through inspections and record review.

(Comment 2) One comment advocated a short-term solution of increased inspections for adherence to sanitation standard operating procedures (SSOP's) and CGMP's with zero tolerance for noncompliance. Another comment stated that the juice industry would welcome increased inspections as it implements new safety measures.

The agency has been actively monitoring the juice industry, especially the fresh juice industry, in response to recent outbreaks. In addition, FDA has conducted inspections to determine compliance with the label warning statement required by § 101.17(g). The agency will continue this additional oversight of the juice industry during implementation of part 120 until it has assurance that the industry is in compliance.

(Comment 3) One comment suggested that cider operations be inspected and graded for cleanliness by the States, like restaurants.

The agency disagrees with the comment. Although sanitation (*i.e.*, cleanliness) is important in cider and all other food production operations, it is only a starting point for ensuring that safe food is produced and distributed to consumers. This limitation exists regardless of the regulatory agency inspecting for sanitation.

(Comment 4) Several comments suggested that industry-funded inspections could be used to ensure safe juice.

FDA disagrees with these comments. As discussed above, inspections are not an adequate substitute for HACCP. Moreover, the agency does not have the authority to require or accept funds from the industry for inspections of juice processors.

2. Current Good Manufacturing Practices

(Comment 5) Comments maintained that a survey of several small citrus producers and juice bars showed that SSOP's and CGMP's are sufficient to produce safe juice. One comment stated that no additional regulations are needed for dairies that process juice because dairies follow sanitation and other procedures outlined by the National Conference on Interstate Milk Shipments (NCIMS) and the application of these principles affects other products made in these facilities.

The agency disagrees that CGMP's and SSOP's alone are adequate to control microbial hazards in juice although it does believe that CGMP's play an important role in juice safety. The survey referenced by the comment, was conducted by the Florida Department of Agriculture & Consumer Services and found that 17 out of 383 samples analyzed (4.4 percent) were positive for generic *E. coli* and did not indicate what, if any, other microorganisms were present. While generic *E. coli* are not pathogens, their presence is indicative of fecal contamination and may be indicative of the presence of pathogens such as *E. coli* O157:H7. (The significance of fecal contamination is discussed in more detail in the response to comment 143.) Therefore, it is unclear how the comments concluded that CGMP's and SSOP's provide adequate control of potential food hazards to assure the safety of the food by relying on the survey data.

The NCIMS procedures (*i.e.*, the Pasteurized Milk Ordinance (PMO) (Ref.18)) were developed to assure the safety of milk. While there may be some fundamental principles, such as basic sanitation procedures, that apply to both the production of milk and juice, the products are vulnerable to different hazards. Moreover, States administer the PMO, and the agency has no information indicating consistency in the application of the PMO to juice inspections in dairies. Thus, investigators in some States may use the PMO as a guide in conducting dairy juice operations and others may not. Therefore, the agency does not believe that application of NCIMS procedures in some dairies that process juice negates the need for juice-specific HACCP regulations.

(Comment 6) Several comments argued that the examples of nonmicrobial hazards (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) cited in the juice HACCP proposal are CGMP violations and would not be included in a processor's HACCP plan.

The agency does not agree with the comments. Whether or not a nonmicrobial food hazard jeopardizes the safety of a juice product is determined by the processor during the hazard analysis of his process. If potential nonmicrobial food hazards are not reasonably likely to occur, then the HACCP plan does not need to address these hazards with CCP's. Thus, FDA does not believe that it is reasonable to make a global statement that CGMP's in part 110 (21 CFR part 110) are adequate

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to control nonmicrobial hazards in all systems, because that determination must be made by each individual processor through a hazard analysis of the individual system.

(Comment 7) Several comments noted that the risks posed by the nonmicrobial hazards identified by FDA cannot be quantified for economic purposes, that microbial hazards alone are not an adequate basis on which to mandate HACCP, and that CGMP's are adequate.

FDA disagrees with these comments. There are nonmicrobial food hazards that may be reasonably likely to occur in juice. Some non-microbial hazards, such as glass, tin, and copper, present acute risks (Ref. 6), and result in acute illnesses or injuries that generate medical and hospital costs, as well as lost productivity costs.

The adverse health effects of other nonmicrobial hazards are chronic (long-term) in nature. For example, long-term exposure to the mycotoxin, patulin, has been shown to be toxic in safety assessments conducted in the United States (Refs. 19 and 20) and by international organizations (Refs. 21 and 22). Patulin is produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged, and has been found to occur at high levels in some apple juice products. The long-term toxic effects in young children are of particular concern because children consume larger quantities of apple juice relative to body weight than other age groups. A compilation of data from three surveys showed that nearly one-fifth of the samples of apple juice contained levels of patulin in excess of 50 microgram/liter (μg/L) (Ref. 23), the level recently established by FDA in draft guidance as the maximum level that should be present in foods (Ref. 24).

The agency recognizes that quantifying the economic effects of chronic non-microbial hazards is difficult. Given the difficulties in quantification, FDA chose to not include nonmicrobial hazards with chronic health risks in the PRIA, thereby underestimating the benefits of the proposal. Nevertheless, hazards with chronic health risks exist and the potential effects on health are real. Thus, hazards with chronic health risks must be considered, along with nonmicrobial hazards with acute health consequences and microbial hazards, during the hazard analysis and a determination made as to whether the potential hazard is reasonably likely to occur (comment 63 discusses how a hazard analysis must be conducted) and thus, must be included in the HACCP plan.

(Comment 8) Several comments maintained that the enforcement of CGMP's or sanitation standards would ensure the safety of all juices.

The agency disagrees with the comments. Outbreaks of foodborne disease have been associated with juice despite the fact that the processors appear to have been actively implementing CGMP's. Increased compliance with the CGMP regulations in part 110, including all sanitation provisions, is certainly desirable. However, CGMP's are general in nature and apply to all types of facilities that process all types of food products from highly processed foods to raw foods that are merely packaged and labeled. CGMP's were not designed specifically to address individual production facilities (for juice or any other commodity) or the unique attributes associated with specific foodborne hazards. HACCP systems, as discussed in section II.A of this document, provide focused, product- and process-specific prevention and control of potential hazards. HACCP augments the controls established through CGMP's by: (1) Determining the food hazards that are reasonably likely to occur in a specific facility and process and thus, warrant extra consideration beyond application of routine food safety measures, (2) identifying a specific CGMP or additional control measure that must be undertaken to prevent this food hazard that is reasonably likely to occur from reaching the consumer, and (3) developing a verifiable procedure for assuring that each control measure was applied and was effective. This focused consideration of hazards and their prevention provides a higher degree of safety assurance than application of CGMP's.

3. Mandatory Pasteurization

(Comment 9) Several comments requested that the agency mandate pasteurization or use of a universal thermal process (thermal kill) to ensure juice safety. The comments maintained that mandatory pasteurization is a reasonable, science-based solution that would ensure safe juice, is consistent with FDA's mission to protect the public health, and would assure consumers and regulators that the microbial hazards associated with juice are being prevented in the most effective manner. Conversely, a number of comments opposed mandatory pasteurization. They argued that nutritional value is lost from heat treatment; some consumers prefer unpasteurized juice; pasteurized juice may become contaminated after treatment and still put consumers at risk; and the apple cider and fresh juice industry would be destroyed.

Based upon the available information, FDA does not believe that it is necessary or appropriate to mandate pasteurization or other thermal treatment of juice. The agency is aware of the reasons why processors pasteurize or elect not to pasteurize their juice products. Pasteurization, a heat treatment sufficient to destroy pathogens, is an effective and proven technology that will attain the 5-log reduction in pathogens and, thus ensure microbiologically safe juice. Pasteurization also results in a longer shelf-life of refrigerated juices. With proper post-processing handling, pasteurization assures consumers and regulators that the potential microbial hazards associated with juice are prevented. However, pasteurization is not the only method for addressing potential microbial contamination. This was discussed extensively in the juice HACCP proposal (63 FR 20450 at 20454) (Ref. 2) and again in the juice labeling final rule (63 FR 37030 at 37041) (Ref. 5). This approach is supported by the NACMCF recommendation that FDA establish safety performance criteria for appropriate target organisms rather than mandating a specific intervention technology (Ref. 25). Mandating a specific intervention technology such as pasteurization would limit the development of new, potentially less costly technologies that may be as effective as pasteurization. New nonthermal technologies (*e.g.*, UV irradiation and pulsed light, as approved by FDA; high pressure) may be able to achieve the required pathogen reduction. The use of non-thermal technologies will provide consumers with a greater selection of safe products to purchase. Furthermore, mandatory pasteurization would not control non-microbial hazards in juice. Therefore, FDA is declining to mandate pasteurization for juice.

(Comment 10) One comment stated that pasteurization should be mandatory for apple cider to eliminate a major source of health risks.

FDA disagrees with the comment. Under § 120.24, apple cider processors must treat their juice to achieve a 5-log reduction in the pertinent pathogen. At the present time, the agency is not aware of any technology that can accomplish the 5-log reduction in apple juice products except by treating the extracted juice with a "kill step." However the "kill step" does not necessarily have to be pasteurization. This approach allows for innovation in the development of new processes to achieve the 5-log pathogen reduction.

4. Labeling

(Comment 11) Two comments suggested that FDA require either pasteurization or a permanent warning label statement for producers who do not pasteurize. One comment stated that FDA should require HACCP with a CCP of either a 5-log performance standard for pathogen reduction or a warning label.

FDA disagrees with the comments. Under § 120.24, juice processors must achieve the 5-log reduction in their juice. As discussed in both the HACCP proposal and in this final rule, it is possible for firms to manufacture juice to achieve this reduction by means other than pasteurization. The alternative presented in the comments, labeling, has some limitations as a public health measure. The effectiveness of labeling untreated juice to alert consumers to possible harmful effects from its consumption relies on consumers' reading, comprehending, and acting on the information in the labeling. Although labeling can provide consumers with the information to make food safety related choices, education is an important factor in a consumer's choice. Therefore, there are limitations to the effectiveness of labeling.

The agency mandated the use of warning label statements on juice largely as an interim step to establishing the HACCP regulation. For most juice products, the warning label is a short term solution. While FDA is reluctant to rely on labeling as the sole safety measure, the agency recognizes that in certain circumstances, labeling may, on balance, provide the most reasonable approach to protect the public health. FDA believes that HAACP, as required in this final rule, is a reasonable approach because, in contrast to some other food safety problems, the facts show that, for juice, processor control of pathogens is reasonably achievable. Moreover, a warning label does not substitute for adequate processing of juice, is not an appropriate substitute for the 5-log performance standard, and would not be considered a CCP for juice under part 120.

For juice produced by retailers (as defined in the rule), however, the warning statement is a long term solution. The agency discussed its reasons for exempting retail establishments from part 120 in the juice HACCP proposal (63 FR 20450 at 20464) (Ref. 2), and these reasons are further discussed in section III.B.2.b of this document. The agency intends to work closely with the States to provide recommendations for implementing measures that will assure safe juice at retail. Therefore, the agency concludes that its current regulations and programs are balanced and appropriate for juice and juice products.

(Comment 12) Several comments asked that FDA make the warning label statement a permanent option because, if it is adequate to ensure consumer safety with products exempt from HACCP, it should be adequate for all juice products.

FDA disagrees with the comments. As noted in the previous response, while the warning label statement may be effective, particularly with consumers aware of juice safety problems, it has limitations as a public health measure. The warning label statement simply informs consumers that the juice bearing the statement has not been treated to control pathogens and that the consumption of untreated juice may pose a risk of illness. As noted, the effectiveness of any warning label relies on consumer education and action. FDA is not changing the warning label statement requirements in this rulemaking.

5. Education

(Comment 13) Several comments maintained that increasing industry education is all that is needed to ensure the safety of all juices.

The agency disagrees. While FDA supports and encourages processor education as a way to improve the safety of the food supply, such measures alone, without being teamed with implementation of an effective food safety control program, such as HACCP, and government oversight, will not ensure consumer protection from hazards that may be present in juice. Training and education is only one step in the effective implementation of any food safety system, including HACCP. Effectively, this final rule requires the industry to improve their education in food safety in order to implement effective HACCP systems. Implementation of an effective HACCP system demonstrates a processor's understanding of HACCP principles and the ability to translate theory into production of safer food. Therefore, the agency concludes that increased industry education alone would not be sufficient to ensure the safety of all juices.

6. Alternative Approach

(Comment 14) Many comments supported the alternative approach outlined in the proposed rule (63 FR 20450 at 20456) (Ref. 2) that would: (1) Require producers of apple cider to choose between HACCP with a performance standard and labeling and (2) require processors of all other juices to choose between HACCP, a performance standard, and labeling.

The agency has evaluated the alternative approaches and concludes that HACCP with a performance standard is the most effective and efficient approach to ensure safe juice. FDA notes that no data or other information were submitted to persuade the agency that the alternative approach described in the proposal would provide adequate public health assurance as would be provided by the HACCP regulation set forth below. Although more outbreaks have been traced to the consumption of apple juice than other juices, a fact reflected in the proposed alternative approach, the agency concludes that, because microbial, chemical, and physical hazards may occur in all juices, and outbreaks have been associated with a variety of juices, there is a need to regulate all juices in the same general manner. Furthermore, the performance standard and the label warning statement only address microbial hazards. In contrast, HACCP systems address physical and chemical, as well as microbiological, hazards, thus providing greater assurance that juice is safe. Therefore, the agency is requiring that all juice processors with the exception of those specifically exempted by § 120.3(j)(2) use HACCP systems as set forth in part 120.

B. Response to the Decision to Propose HACCP

FDA proposed to require HACCP for juice products because it had tentatively concluded that HACCP was an appropriate system of preventive controls necessary to produce safe juice products. The evidence presented in the proposal demonstrated that juice has been a vehicle for pathogens that have caused a number of foodborne illness outbreaks. While pathogens can be controlled through heat treatment, the data (Ref. 2) clearly demonstrate that there are potential nonmicrobiological hazards associated with juice that cannot be controlled through heat treatment. For these reasons, FDA tentatively concluded that a HACCP program that addresses all potential hazards (*i.e.*, microbiological, chemical, and physical), allows each juice manufacturer to evaluate its own process, and to institute appropriate controls for all hazards identified as reasonably likely to occur in that manufacturer's process should be established.

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(Comment 15) Several comments advocated HACCP limited to pathogen control.

The agency disagrees with the comments. While pathogen control is a significant part of any HACCP system for juice, there are potential chemical and physical hazards that can occur in juice, with significant public health implications, and these hazards may be most effectively controlled through application of HACCP (Ref. 2). HACCP provides a way to focus on specific CCP's addressing specific hazards, both microbial and non-microbial (*e.g.*, tin, lead, nitrates, patulin, glass, or plastic) that are relevant to juice processing operations and products. These hazards may be appropriately identified in the hazard analysis as hazards that are reasonably likely to occur and controlled through a HACCP plan.

There are a number of potential hazards for juice that are nonmicrobial in nature. For example, juice products have become contaminated with cleaning solution. If this contamination is a hazard that is reasonably likely to occur in a particular process (*e.g.*, there is a repeated history of its occurrence), the processor must establish controls in its HACCP plan to prevent the contamination rather than address the contamination in their SSOP's.

Similarly, some juice products have been recalled due to the presence of glass. Glass shards in juice represent a severe and acute public health threat. Processors who package in glass must consider whether glass in their final product is reasonably likely to occur in the absence of control. If so, processors must establish controls for glass in their HACCP plans.

Excess detinning represents another potential nonmicrobial hazard for juice. Certain juices are purposely packaged to allow some detinning of the can in order to protect the color quality of the product. However, detinning can be accelerated by unusually high nitrate content in the product or by elevated temperatures during storage or shipping (Refs. 26). Excessive detinning has resulted in consumer illness (Refs. 26 and 27). Thus, processors of juice products that employ detinning as a means of color protection must determine whether it is necessary to establish specific control measures, *i.e.*, a CCP, because excessive detinning is reasonably likely to occur.

Potential hazards may also be caused by the nature of incoming materials. Patulin in apple juice products is one such example. Patulin is a mycotoxin produced by several species of mold that can grow on apples, particularly if bruised or otherwise damaged. A compilation of data from three surveys showed that 19 percent of samples of apple juice contained levels of patulin in excess of 50 µg/L (Ref. 23). FDA has recently issued guidance describing 50 parts per billion (ppb) as a recommended level for patulin (Refs. 19 and 24). For apple juice processors, patulin may represent a hazard that is reasonably likely to occur when juice is made from bruised or damaged fruit, as even moderate bruising can result in mold growth on apples. Moreover, patulin may be a chronic potential hazard and therefore particular attention must be given to the frequency of occurrence. Therefore, a prudent processor must determine whether the frequency of occurrence of this potential hazard in juice is unacceptable without controls. If patulin is reasonably likely to occur at unacceptably high levels, processors must include it as a hazard in their HACCP plans. Patulin is not the sole mycotoxin that may be a hazard in juice. There is evidence that other mycotoxins, such as ochratoxin in grapes and *Alternaria* toxins in fruit and vegetable products (Ref. 28), may be emerging public health problems in juices and at least warrant monitoring of future developments.

Lead contamination has also been associated with juices. In 1996, infant apple prune and prune juices were recalled for unacceptable levels of lead (Refs. 29 and 30). More recently, unacceptable levels of lead have been found in babyfood containing carrots and in carrots in frozen mixed vegetables as a result of lead contamination in the soil (Refs. 31 and 32). Juice made from produce with high lead levels will also be high in lead. A German survey of lead in foods found that 12 percent of fruit juices contained elevated levels of lead and over 5 percent of fruits had elevated levels of lead (Ref. 33). It is well recognized that lead has no known "no-effect level" and consumption of lead-contaminated food is a recognized health problem, particularly for children in their developmental stages. Responsible processors should exercise control to ensure that their juice products do not contain lead at harmful levels. Again, HACCP provides both the necessary control and flexibility to address the problem of lead contamination. If a processor is importing juice from a geographic region known to have a problem with lead contamination in foods, that processor should identify lead as a hazard in their HACCP plan. However, if a juice processor determines through its hazard analysis that, given their source, incoming materials are not reasonably likely to be contaminated with lead, that processor would not need to identify lead as a hazard in its HACCP plan. Importantly, processors who are currently implementing HACCP to address microbial hazards only already have the infrastructure in place to analyze their processing system and can then determine if there are chemical or physical hazards that are reasonably likely to occur. Therefore, with minimal effort, these processors can readily expand the scope of their HACCP system to include consideration of all potential hazards.

Based upon the foregoing, the agency concludes that chemical and physical hazards, as well as pathogens, may pose public health risks in juice products. These hazards, when they are reasonably likely to occur, require specific preventive controls. HACCP is the most appropriate system to control both microbial and nonmicrobial hazards that are reasonably likely to occur in juice products.

(Comment 16) Several comments suggested that quality assurance systems devised specifically for juices would be appropriate alternatives to mandatory HACCP with a performance standard. The comments contended that the quality assurance systems developed by and for the citrus industry in conjunction with the University of Florida (Ref. 34) are adequate to ensure the safety of citrus juices and that the Apple Hill Quality Assurance Program (Ref. 35) is adequate to ensure the safety of apple juice. Some comments asserted that these programs are just as effective as HACCP, while being less expensive to implement.

FDA encourages the efforts by industry, universities, State and local government agencies, and others to develop programs to ensure the safety and quality of the food supply and is aware of several such programs. The agency has reviewed the quality assurance programs mentioned by the comments and finds that the HACCP system in part 120 provides a greater level of public health assurance. If a processor can implement a quality assurance program that also meets the requirements of part 120, then FDA does not object to the processor using that program for its HACCP system. However, quality and safety are not necessarily synonymous. Quality programs focus on the combination of attributes or characteristics of a product that have significance in determining the degree of acceptability of that product by consumers. Safety programs focus on hazards and public health assurance. Quality assurance systems may not address all public health hazards just as safety programs may not address all quality issues.

(Comment 17) Several comments requested that FDA exempt from the HACCP regulation processors who pasteurize their product, make shelf-stable product, or meet the 5-log performance standard because the aim of the rule should be pathogen control. The comments said that HACCP is regulatory overkill and it is unfair to impose HACCP on the 98 percent who pasteurize in order to control the real risk from the 2 percent who do not. The comments noted that illness outbreak evidence only supports the need for interventions to control pathogens in unpasteurized juice because there have been no reported outbreaks of illness from consumption of pasteurized juice.

The agency agrees that, when used with appropriate times and temperatures, thermal pasteurization [3] is a proven and effective method for controlling pathogens. However, the effectiveness of pasteurization is dependent on implementation of an integrated system that validates and verifies the efficacy of the pasteurization process. It is likely that processors who make concentrated, shelf-stable, or pasteurized juices have already incorporated HACCP principles, aimed at control of pathogens, into their processing operations (Ref. 36). Processors already attaining the 5-log reduction performance standard are likely to have established process parameters (*i.e.*, critical limits), are monitoring the process, and are keeping records of their monitoring. Therefore, it should require minimal effort for processors that make concentrated, shelf-stable, or pasteurized juices to satisfy the requirements of part 120 relating to pathogen control. Moreover, as discussed in section L of this document "Process Controls," in recognition of the effectiveness of thermal treatments for pathogen control, FDA is providing in part 120 an alternative method for processors making shelf-stable juices or certain juice concentrates to comply with the 5-log reduction in the pertinent pathogen. The agency believes that the alternative method is reasonable because the processes for shelf-stable juices and concentrates are so rigorous that they exceed the minimum requirements for control of microbiological hazards. A copy of the thermal process in a processor's hazard analysis will provide evidence that the process is adequate.

Importantly, pathogen control is not the only problem with juice safety. As discussed in the juice HACCP proposal (63 FR 20450 at 20451) (Ref. 2) and in the response to comment 15, there are also established chemical and physical risks with juice. A juice product can only be considered safe if all hazards (*i.e.*, microbial, chemical, and physical) are considered and, if these hazards are reasonably likely to occur, are controlled. Therefore, FDA concludes that processors of thermally processed juice must comply completely with this HACCP regulation, but can do so with minimal added effort.

(Comment 18) Some comments contended that the HACCP proposal goes way beyond establishing necessary measures to ensure juice safety and is neither reasonable nor economically feasible for an industry characterized by small producers, family businesses, seasonal production, and very little prior experience in food safety management. Comments also noted that there is a low level of compliance with seafood HACCP among small producers and the success of juice HACCP will depend upon small processors complying with costly regulations. Conversely, several comments argued that HACCP is the appropriate food safety system for small producers because it can be implemented without being overly burdensome and forcing them out of business.

The flexibility of HACCP allows the processor to control hazards identified in the hazard analysis in a manner that best fits an individual operation, large or small. In addition, if small producers actually have very little prior experience or knowledge in food safety management, as some comments asserted, then HACCP training and consultation are very much needed by this group and will provide specific food safety goals customized to their individual operations.

Thus, features of the agency's regulatory strategy will accommodate small processors. First, FDA intends to provide a juice HACCP hazards and controls guidance that will assist processors. Second, this final rule has a staggered compliance schedule (§ 120.1(b)(1) and (b)(2)), which provides small and very small juice processors additional time to implement fully the final rule.

The agency's HACCP strategy for the seafood industry, which is dominated by small processors, has been to acknowledge that the implementation of HACCP can be an educational process, especially with regard to science-based analysis, and thus to allow for the progression in mastering the HACCP system that accompanies that process. The progress in implementing HACCP systems that the seafood industry is making suggests that other segments of the food industry, including those populated by small businesses, can also benefit from a HACCP program, even if complete understanding of what constitutes full implementation of a HACCP system is not immediate.

(Comment 19) Several comments stated that HACCP presents an undue burden to the pasteurized juice industry with no consumer benefits. The comments stated that the chemical hazards cited by FDA are not reasonably likely to occur and that there has never been a foodborne illness outbreak associated with pasteurized juice.

The agency does not agree. The preamble to the proposed rule described incidents of illness associated with chemical contaminants in juice (63 FR 20450 at 20451) (Ref. 2). Chemical hazards can occur in juice regardless of pasteurization. Moreover, for some juices, the risk of chemical contamination can be high, depending on the quality of the incoming produce and the chosen processing steps. In fact, in two recent incidents, juice was recalled by the processor in one case due to the presence of dairy and egg allergens (Refs. 37 and 38), and in the other, due to the presence of cleaning solution (Refs. 39, 40, and 41). As discussed earlier in comment 15, the risk of patulin contamination in apple juice is high if the processor uses bruised apples.

The agency does not agree that HACCP for the pasteurized juice industry does not convey benefits to consumers. While the classic definition of pasteurization is a heat-treatment to destroy pathogens, the agency has no assurance that all juice processors who believe they are pasteurizing their products actually have all the controls in place to assure that every particle of the juice is receiving sufficient heat to destroy pathogens. Moreover, pasteurization alone does not assure the safety of juice products. Proper handling of the product after pasteurization is required to prevent post-process contamination. A HACCP system based on CGMP's provides assurance to the processor, as well as to the agency and the consumer, that pasteurized products are safe.

The agency is required, by Executive Order and law, to consider both the costs and benefits to consumers and industry. This analysis can be found in the PRIA, and the Regulatory Flexibility

[3] FDA has not defined what pasteurization means in terms of juice and juice products because of the unique characteristics of the many various types of juice and juice products. The scientific literature provides data on adequate pasteurization times and temperatures. Prudent processors using pasteurization rely on this research data for their particular types of juices.

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Analysis in sections V and VI of this final rule. Based on FDA's analysis, the benefits (*i.e.*, prevention of illness) of this final rule outweigh the costs to industry.

A few comments expressed concern that HACCP regulations may be enforced at the expense of CGMP's.

The agency does not agree with the comments. In fact, FDA expects that the opposite will be true. A HACCP system cannot be operating properly if a processor is not following CGMP's because CGMP's provide the foundation for an adequate and appropriate HACCP system. Therefore, to evaluate the effectiveness of a HACCP system, processors and agency inspectors must also evaluate processors' adherence to CGMP's.

(Comment 20) One comment stated that HACCP as set forth in the proposal places the responsibility for product safety on the government rather than the processor.

FDA does not agree with this comment. Each juice processor is responsible for developing a system of preventive controls by adapting the HACCP principles in new part 120 to its specific operation and needs. Under HACCP, the manufacturer is responsible for knowing and understanding its manufacturing process, identifying points where contamination can occur, and implementing control measures in order to produce safe food. To accomplish this, the processor must: (1) Have an individual who is trained in HACCP conduct a hazard analysis, determine where controls are needed, and validate the adequacy of any HACCP plan that is developed; (2) put those controls in place and verify that they are working through monitoring and recordkeeping; and (3) revalidate the HACCP plan at least annually or any time there is a significant change in the process or whenever scientific information demonstrates a new risk that processors have not previously considered in their hazard analysis. FDA's responsibility is to conduct oversight to ensure that HACCP is properly implemented and is effective.

(Comment 21) Several comments stated that HACCP's cost is not justified because most foodborne illness occurs as a result of problems that originate after juice leaves the processor and HACCP will not remedy these problems. One comment cited a source that estimated that food manufacturers are involved in less than 10 percent of foodborne disease outbreaks of known origin (Ref. 42).

FDA maintains that all steps in juice production and handling are potential points of contamination in the absence of adequate controls, not just post-process handling. Processors must consider prevention of post-process contamination to the extent feasible. For example, post-process piping must prevent contamination from occurring prior to packaging. HACCP systems are implemented to assure the safety of food when it leaves the processor's control and under normal handling conditions after that. The agency points out that the CAST report cited by the comment includes all foods (not just juice) and all food sources (processors, food service, institutions) and is limited to microbial contamination of foods. The majority of juice outbreaks have not been caused by post-process contamination but rather by contaminated incoming product or contamination during processing (Ref. 43). Thus, the performance standard (5-log reduction in pathogen level) established by this rulemaking is set to ensure that the final product is not contaminated with illness-causing bacteria that may have been present on incoming fruit. In addition, processors must use CGMP's, SSOP's, and HACCP to ensure that product is not contaminated with pathogens while in the processing facility.

(Comment 22) Several comments stated that hazards in juice are adequately dealt with under State laws (*i.e.*, Connecticut, Florida, Illinois, Maryland, Massachusetts, Michigan, New Jersey, New Hampshire, Wisconsin).

The agency applauds State efforts to ensure the safety of juice produced and sold in their States. However, while there may be some State laws that govern the manufacture of juices, these laws are generally not as comprehensive as this HACCP rule. In addition, not all juice producing States have applicable State laws. This HACCP final rule provides a uniform minimum level of public health protection across the country for juices. FDA believes that this final rule will enhance State efforts and help extend the food safety efforts of some States to all States.

C. Significance of Illness Data

The preamble to the proposed regulation described occurrences of juice-related foodborne illness in the United States. It is well recognized that foodborne illnesses are significantly underreported to public health authorities (Ref. 44). Consequently, precise data on the numbers and causes of foodborne illness do not exist. The primary purpose of these regulations is to ensure that juice is safe through the use of preventive controls that are systematically and routinely applied in juice processing, and applied in a way that can be verified as effective by company management as well as regulatory authorities.

(Comment 23) Many comments questioned the validity of FDA's risk assessment on juice. They stated that it was not scientific and sound, not probabilistic, didn't include pasteurized juice, and contains inaccuracies. However, comments did not specifically identify the inaccuracies.

FDA maintains that its "Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices" is sound. As outlined in the juice labeling final rule (63 FR 37030 at 37031) (Ref. 5), the agency performed a detailed evaluation of the potential hazards posed by untreated juices. This evaluation is part of the record of the HACCP proposal and was included as an appendix to the PRIA (63 FR 24292; May 1, 1998) (Ref. 6). The evaluation was based on available scientific information, included pasteurized juice, and examined both heat-treatable microbial hazards and non-heat-treatable hazards. Non-heat-treatable hazards are discussed in section VII and the evidence is summarized in table 7 of FDA's Investigation. The conclusion that the most significant juice-borne hazards are associated with non-heat-treated juice was based on this investigation.

(Comment 24) One comment stated that all outbreaks in cider have been traced to using dropped apples or unsanitary processing conditions and that eliminating these circumstances will stop outbreaks in cider.

FDA disagrees with the comment because the causes of cider-related outbreaks are not limited to using drops or processing in an insanitary facility. In fact, from a structural standpoint, apples are susceptible to contamination because they have an open blossom end, and thus, the interior of the fruit can be contaminated while the exterior appears clean and blemish free (Ref. 45). This potential for contamination is confirmed by data that show that cider, even when it is made from tree-picked fruit and processed under CGMP's, can contain pathogens and provide an environment conducive to the survival of pathogens of public health significance (Ref. 13).

(Comment 25) Several comments maintained that the risk from juice is low and does not warrant a HACCP regulation.

The agency does not agree with the comments. There are documented cases of lifethreatening foodborne illness associated with the consumption of various juice products contaminated with pathogens such as *E. coli* O157:H7, *Salmonella* species, *Cryptosporidium*, and *Vibrio cholerae*. Some of the illnesses associated with juices have been very severe (*e.g.*, cases of long-term reactive arthritis and severe chronic illness) (Ref. 2). In one case, consumption of contaminated juice resulted in the death of a child and in another case, consumption of contaminated juice contributed to the death of an elderly man. These reported outbreaks likely represent only a fraction of the outbreaks and sporadic cases that actually occur (Ref. 44).

Chemical and physical hazards have also been associated with juices. Examples of these hazards were included in the proposal (63 FR 20450 at 20451) (Ref. 2) and are discussed in detail in the response to comment 15.

The evidence demonstrates that hazards can be present in juice. The comments did not provide the agency with additional data that either contradict FDA's hazard evaluation (Ref. 6) or that can be used to reevaluate the health risks associated with consumption of juice products. Therefore, FDA believes that the public health risk associated with consumption of juices is sufficiently high to justify mandating use of HACCP systems.

(Comment 26) Many comments argued that HACCP is no longer necessary for juice because of the safety improvements made by the juice industry since the 1996 outbreak of *E. coli* O157:H7 in apple juice. They stated that these improvements are evidenced by the fact that there has not been an outbreak associated with juice since 1997.

FDA disagrees with the comments. There have been documented outbreaks of juice-associated foodborne illness since 1997. The agency acknowledges the recent steps taken by the industry to address microbial contamination of juice. Nevertheless, while there were no reported outbreaks attributed to juice in the United States in 1997 and 1998, there were several outbreaks in 1999 and 2000. These outbreaks are discussed below.

In early 1999 in south Florida, there were 16 reported cases from *Salmonella typhi* linked to the consumption of frozen mamey, a product often used to make juice beverages (Ref. 46).

During June 1999, there was an outbreak of *Salmonella* serotype Muenchen infection associated with consumption of unpasteurized orange juice (Ref. 47). As of April 2000, a total of 423 cases, including one that contributed to a death, from S. Muenchen infection had been reported. Nine additional *Salmonella* serotypes were identified from orange juice collected from the implicated firm.

In October 1999, there was an outbreak of *E. coli* O157:H7 in commercially-processed unpasteurized apple cider in Oklahoma with 9 illnesses (7 children) and 6 hospitalizations (4 cases of hemolytic uremic syndrome (HUS)) (Ref. 48).

While no illnesses were reported in October 1998, the State of Florida found *Salmonella* Manhattan in an unpasteurized juice blend containing strawberry, apple, and papaya juice (Ref. 49).

In November 1999, the same firm involved in the June 1999 outbreak initiated and subsequently expanded a recall because their routine testing found *Salmonella* in samples of unpasteurized orange juice (Ref. 50). The product had been distributed to restaurants and other food service establishments in eight U.S. States and one Canadian Province and to one retail store in Oregon. No known illnesses were associated with this incident.

In April 2000, there was an outbreak of *Salmonella* Enteritidis associated with unpasteurized orange juice (Ref. 51). As of May 2000, 143 cases traced to this orange juice had been identified in Arizona, California, Colorado, Minnesota, Nevada, Washington, and Wyoming.

Also in April 2000, 24 people who attended a conference in Atlanta, Georgia, were reported ill with viral gastroenteritis (Ref. 52). Fresh-squeezed unpasteurized fruit smoothies were implicated in this outbreak. CDC detected Norwalk-like virus in three patient stools.

Thus, the potential for juice-related illness still exists, although the number of illness outbreaks linked to juice may vary from year to year. In addition, the agency has no information indicating that all members of the juice industry have implemented adequate safety improvements to address the potential for microbial contamination and other potential hazards in their products. The fact that outbreaks continue to occur is evidence to the contrary.

(Comment 27) One comment asserted that most problems associated with citrus juices were a result of insanitary processing conditions at small or very small businesses or contamination by asymptomatic food handlers, and HACCP would not prevent problems in either situation.

The agency disagrees with this comment. FDA often finds in their investigations into outbreaks that the exact cause of the outbreak is unknown. The agency may find various possible causes that include those mentioned by the comment. However, as discussed throughout this preamble, insanitary conditions and workers' health are not the only source of food hazards in juice. For example, if juice is made from contaminated fruit and the 5-log reduction is not accomplished, an outbreak could occur. HACCP systems do provide greater assurance than CGMP's and SSOP's alone that juice is safe. HACCP recordkeeping provisions allow processors and regulators to detect process deviations and stop distribution of or recall product before it results in an outbreak.

(Comment 28) Several comments stated that the rules should cover apple products only, asserting this is where problems have occurred.

The agency disagrees that only apple juice should be covered by part 120, and all other juices should be exempt. There have been illness outbreaks from other types of juice, *e.g.*, orange juice. Some of these were cited in the proposal (63 FR 20450) (Ref. 2). As discussed in comment 27, additional outbreaks since publication of the proposal have occurred. Therefore, FDA concludes that because there are documented foodborne illness risks associated with juices other than apple juice, all types of juice must be covered under part 120.

(Comment 29) Many comments argued that juice regulations should not be more stringent than regulations for other foods that are more hazardous, such as seafood or meat and poultry. Many comments noted that seafood HACCP has no performance standard but is a much higher risk food than juice.

The agency disagrees that juice is being regulated more stringently than warranted. HACCP for juice mirrors FDA's HACCP regulations for seafood and USDA's regulations for meat and poultry. In contrast to most seafood and meat and poultry, juice is generally consumed as sold. The record of this proceeding demonstrates that microbial contamination of juice is a substantial public health risk and that a performance standard is achievable as a practical matter. Thus, to ensure the safety of juice products, FDA is establishing a mandatory HACCP program that includes a performance standard to prevent, reduce, or eliminate levels of pathogens known to cause foodborne illness. The performance standard ensures that controls within the HACCP system are working effectively to reduce the risk of illness and that the final product is safe.

(Comment 30) One comment maintained that the physical hazards related to juice are a result of metal cans

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and glass, both of which are not used by the fresh juice industry.

FDA recognizes that juices that are minimally processed usually are packaged in plastic to provide for expansion of the product. Whether or not packaging materials are included in a processor's HACCP plan will be determined in the processor's hazard analysis. If the hazard analysis shows that a particular operation has no physical hazards, such as metal or glass, that are reasonably likely to occur, no control measures are required for such hazards. Even if there are no physical hazards in fresh juice that require controls, the risk of microbial contamination of fresh juice is well-documented and a HACCP approach is needed to address these risks.

(Comment 31) One comment stated that the *Bacillus cereus* incident cited by FDA is not significant and any final rule should clearly state that sporeformers are not a problem that needs to be considered in a treatment system for juice.

The agency has considered the issues surrounding hazards from spore forming bacteria. Regulations in parts 113 and 114 (21 CFR parts 113 and 114) already address the hazard from *Clostridium botulinum* in low acid canned foods and acidified foods. Spore forming bacteria have not been associated with public health problems in juice that has been properly handled (*e.g.*, refrigerated) after leaving the processing plant. Therefore, FDA does not anticipate that processors' hazard analyses will establish that spore forming bacteria are a hazard that is reasonably likely to occur.

D. Comparison of the Proposal and This Final Regulation

The comments received generated some clarifications of and changes in provisions of the proposed regulation. These are discussed in detail in the comments noted after each item. Among the most significant clarifications and changes are the following:

- Clarification that the regulation covers intrastate, as well as interstate juice (discussed in comments 33 and 74)
- Adoption of the most recent NACMCF definition of "food hazard" (comment 39)
- Elimination of the proposed exemption from the regulation for retail establishments that produce juice on their premises and sell 40,000 or less gallons of juice per year (comment 47)
- Addition of a definition of "retail establishment" (comment 48)
- Clarification of how a hazard analysis is conducted (comments 63 to 70)
- Clarification of application of the 5-log pathogen reduction performance standard (comments 115 and 131 to 139)
- Creation of an exemption for shelf-stable juice processors and concentrated juice processors from the requirement for a pathogen reduction critical control point, under specific conditions (comment 140)
- Establishment of a process verification sampling and testing procedure for citrus juices that use surface treatment as part of the 5-log pathogen reduction process (comment 142 to 143)

III. The Final Regulation

A. Applicability

The agency proposed in § 120.1(a) that any juice sold as such or used as an ingredient in beverages be processed in accordance with the requirements of part 120 (63 FR 20450 at 20462) (Ref. 2). As proposed, juice is the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

(Comment 32) One comment requested that FDA define juice as the aqueous liquid expressed or otherwise extracted from food and that this definition should be synonymous with juice definitions in other regulations, *i.e.*, food standards. One comment noted that food products (*e.g.*, fruit cocktail) other than beverages contain fruit juice.

FDA advises that the purpose of § 120.1(a) is to define the scope of what is covered under part 120 rather than to provide a general definition for the term "juice." Part 120 only covers products sold as juice or used as an ingredient in beverages. The agency recognizes that products other than beverages, *e.g.*, canned fruit cocktail, may contain fruit or vegetable juice. However, the foodborne illness outbreaks prompting the juice HACCP proposal were associated with juices and juice products that were beverages rather than juice ingredients contained in non-beverage products. Therefore, FDA is not defining "juice" in the general sense requested by the comment.

(Comment 33) Several comments requested that FDA clarify whether the juice HACCP regulation covers only interstate commerce.

FDA intends that this final rule cover both "interstate juice" (*i.e.*, juice that is shipped in interstate commerce or that is made using one or more components that were shipped in interstate commerce) and "intrastate juice" (*i.e.*, juice that is made entirely from components grown within a single State and then sold to the ultimate consumer within the same State).

As noted in the proposal, FDA is relying upon both its authority under the act, 21 U.S.C. 321 *et seq.*, and the Public Health Service Act, 42 U.S.C. 241, 242l, 264. FDA's authority to regulate "interstate juice" is discussed in detail below in comment 74. Under section 361 of the Public Health Service Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State. (This authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4).) Activities that are wholly intrastate in character, such as the production and final sale to consumers of a regulated article within one State, are subject to regulation under section 361 of the PHS Act *State of Louisiana* v. *Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977). The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting foodborne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Similarly, the record (Ref. 53) demonstrates that consumers (particularly out-of-State tourists and other travelers) are likely to purchase and/or consume "intrastate" juice. These consumers subsequently take the juice back to their home State where the juice is consumed or carry a communicable disease back to their home State, thereby creating the risk that foodborne illness may occur in the home State as a result of such consumption.

The agency believes that its intent to regulate both "interstate" and "intrastate" juice was evident from § 120.1(a) of the proposal, which stated that the requirements of part 120 would apply to "any juice" without qualification as to its "interstate" or "intrastate" character. However, to clarify further the products to which this final rule applies, FDA is adding a sentence to § 120.1(a) as follows: "The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b))."

(Comment 34) Some comments requested that FDA exempt citrus juices from the HACCP regulation because these juices contain organic acids that stop microbial growth, the pH of citrus juices is too low for pathogen growth, and peel oil contains an antimicrobial agent. One comment included data

indicating that *Listeria* and *E. coli* O157:H7 cannot survive in lemon and lime juices under normal storage conditions and requested that these two juices be exempted from the HACCP rule.

The agency disagrees that citrus juices should be exempt from the requirements of part 120. Although the organic acids, pH, and peel oil in citrus juice may inhibit (*i.e.*, prevent or slow down) the growth of pathogens, such organisms can still be present in citrus juice and may cause illness if consumed. Fruits and vegetables differ in their inherent chemical composition; even within varieties of particular fruits or vegetables, there can be some variation in composition depending on growing conditions. However, the comments provided no data to show how the chemical composition of a citrus juice (pH or antimicrobial compounds in peel oil) will ensure the safety of fresh citrus juice. In fact, because the amount of peel oil in juice will vary from process to process, the agency disagrees that the antimicrobial effects of citrus peel oil can adequately control pathogens in juice. Similarly, the organic acid in citrus juice (*i.e.*, citric acid) has not been shown to provide any additional protection against pathogen contamination and survival compared to the acid found in apple juice (Refs. 54, 55, and 56).

A 1997 study of *E. coli* O157:H7 behavior in apple juice and orange juice, particularly under refrigerated conditions, demonstrated that even in the relatively acidic environment of these juices, this organism can survive (Ref. 57). In the study, juice was inoculated with *E. coli* O157:H7. After a 24-day period at refrigeration temperatures, there was only a small decline in numbers of *E. coli* O157:H7. The fact that *E. coli* O157:H7 can survive in orange juice and that human illnesses from other pathogens, such as *S. Muenchen* and other *Salmonella* species, have been traced to orange juice demonstrates that, if contaminated, orange juice has the potential to cause human illness.

Lemon and lime juices are more acidic than other types of citrus juice. The strong acidity of these juices does have an antimicrobial effect as the comment's data demonstrated. However, the resistance of oocysts to the strong acidity of these juices is not known. In addition, there can be differences in acidity between varieties of lemons and limes, and thus, differences in their inherent antimicrobial effects. These juices may be diluted and sweetened to make them palatable as beverages, thus changing antimicrobial parameters. In addition, there may be chemical and physical hazards that are reasonably likely to occur in these types of juices that pH and acids cannot control. Therefore, FDA concludes that the chemical composition of lemon and lime juices does not justify exempting these juices from this rule. If processors can demonstrate that the inherent antimicrobial qualities of a juice are adequate to accomplish the 5-log reduction in the pertinent pathogen under refrigerated conditions (or freezing conditions, if the product is frozen) prior to the product leaving the processing facility, then the antimicrobial parameters, along with the necessary time to accomplish the 5-log reduction, could constitute CCP's. FDA notes, however, that under the final rule, processors must establish critical limits and monitor each of the CCP's as part of their HACCP systems.

(Comment 35) Some comments maintained that there is less inherent risk from citrus juices because citrus processing limits contact time of peel and juice. The comments included data from citrus processors that separate the peel from the juice with only a small fraction of peel contacting the juice.

The agency disagrees that there is less risk from citrus juices such that these juices should not be subject to part 120. The significance of peel/juice contact as a source of pathogens in the juice depends on several factors, including the microbial load on the peel and the amount of contact of the peel with the juice. If the small fraction of peel, as described by the comments, is contaminated and comes into contact with the juice, that contact is significant. As discussed in the proposed rule (63 FR 20450) (Ref. 2) and also in the response to comment 26, there have been outbreaks of food borne illness associated with orange juice.

(Comment 36) A few comments requested that FDA exempt apple cider from the HACCP regulation because the agency found no pathogen contamination in the 1997 cider survey, which, according to the comment, indicates that there is no real risk from pathogens in cider.

FDA's 1997 survey involved inspection of fresh unpasteurized apple cider operations at 237 processors in 32 States (Ref. 45) during which the agency collected samples at various processing steps. These samples were analyzed for *E. coli* O157:H7, *Salmonella*, *Staphylococcus aureus*, fecal coliforms, and generic *E. coli*. Although the survey did not detect any pathogens in finished juice products, one firm's apples tested positive for *Salmonella*, demonstrating that pathogens can occur on incoming apples. (The analytical method used for *Salmonella* has since been improved to better detect low levels of this pathogen in acidic foods, such as apple juice.) Results also showed that samples of wash water from several firms tested positive for generic *E. coli* and fecal coliforms; overall, generic *E. coli* was found in 15 percent of the finished product samples. The presence of fecal coliforms and generic *E. coli* are widely recognized as indicators of fecal contamination (Ref. 58). Further, the survey concluded that it is likely that any microbial hazards that are introduced at the beginning of processing will be carried through to the finished product; no microbial reduction will occur during the process (Ref. 45).

The agency disagrees that these results indicate there is no real risk from pathogens in cider. Contrary to the comments' contention, the cider survey results affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, as well as pathogenic bacteria, such as *Salmonella*, are present in cider processing operations and could give rise to microbiological safety hazards in finished cider products.

Finally, illness outbreaks associated with apple cider continue to occur. In particular, in October 1999 in Oklahoma, there was an outbreak related to *E. coli* O157:H7 in a commercially produced, unpasteurized apple cider, that resulted in nine reported illnesses. The agency, therefore, is not granting the requested exemption.

(Comment 37) Several comments requested that FDA clarify whether concentrates are covered under the rule.

The agency advises that under the final rule, a juice concentrate satisfies the definition of "juice" in § 120.1, and thus, producers of concentrates are required to comply with part 120.

(Comment 38) One comment requested that FDA clarify whether processors of beverages that include juice as an ingredient but do not produce the juice itself are covered under the juice HACCP regulation. One comment stated that dairies using concentrates that are processed to meet the 5-log requirement or untreated juices that are further pasteurized should not be subject to the HACCP regulation.

The agency advises that any juice processing activity, including juice ingredient processing, must comply with the provisions of part 120. Dairies making juice, regardless of whether they use concentrates, must comply with part

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120. However, dairies producing a non-juice beverage that contains a juice ingredient (*e.g.*, a dairy-based beverage containing orange juice) are not required to comply with part 120 in terms of the process for producing that non-juice beverage. Processors of juice used as a beverage ingredient must comply with the provisions of part 120.

B. Definitions

1. Food Hazard

FDA proposed in § 120.3(e) (finalized as § 120.3(g)) that "food hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(Comment 39) One comment requested that FDA adopt the most recent NACMCF definition of a food hazard to clarify the mechanism by which a hazard analysis is conducted.

The agency agrees with this comment. The NACMCF currently defines "hazard" as a "biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control" (Ref. 17). The definition differs from, but is not inconsistent with, the definitions for food hazards used in the seafood HACCP and meat and poultry HACCP regulations. Adopting the most recent NACMCF recommendations to the extent feasible will allow the HACCP regulation to remain current with the science of HACCP.

In the first step of a hazard analysis, processors must identify all the hazards that could potentially occur in the juice. Potential hazards are those microbial, chemical, and physical agents that are reasonably likely to cause illness or injury regardless of the likelihood of their occurrence. FDA intends to publish a juice HACCP hazards and controls guidance to assist processors in this step of the hazard analysis.

Second, processors must determine whether the potential hazards identified are "reasonably likely to occur" in their particular process. Under § 120.7(b), a hazard is "reasonably likely to occur" if a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed.

In the NACMCF's view, if a hazard has a severe, acute public health impact (*e.g.*, illness caused by a pathogen, injury caused by ingestion of glass), that hazard presents a significant risk even at an extremely low frequency of occurrence and must be appropriately identified as a hazard that is "reasonably likely to occur" (Ref. 17). FDA concurs in this view. On the other hand, chronic hazards would need to occur at a higher frequency to be identified as a hazard that is "reasonably likely to occur." In the case of chronic hazards, it must be understood that the illness or injury need not be caused by any specific occurrence of the hazard but may occur with exposure to the hazard over time. Each hazard identified in the hazard analysis as "reasonably likely to occur" requires the identification of at least one CCP, the critical step or steps in the process that must be controlled to prevent, reduce to acceptable levels, or eliminate the hazard.

Because hazards can be either acute or chronic (*i.e.*, having short-term or long-term effects, respectively) and the purpose of HACCP is to focus on public health hazards that are "reasonably likely to occur," FDA finds that the NACMCF definition better describes what must be considered in a hazard analysis. Therefore, the agency is modifying § 120.3(g) to state that a "food hazard" means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

2. Processing

The agency proposed in § 120.3(h)(1) (finalized as § 120.3(j)(1)) to define "processing" as activities that are directly related to the production of juice products. However, for purposes of proposed part 120, certain activities were proposed to be exempted by § 120.3(h)(2) (finalized as § 120.3(j)(2)). These are: (1) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; (2) the operation of a retail establishment; and (3) the operation of a retail establishment that is a very small business and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and that sells the juice (a) directly to consumers or (b) directly to consumers and other retail establishments.

a. Harvesting, Picking, and Transporting Raw Agricultural Products.

(Comment 40) Several comments objected to the definition of processing in proposed § 120.3(h)(2)(i) (finalized as 120.3(j)(2)(i)) excluding harvesting, picking, and transporting raw agricultural ingredients of juice products because this will leave a big gap in the farm to table system and contamination is very likely to occur in this gap. One comment advocated mandatory HACCP that either begins at the farm including harvesting, picking, and transport or includes a "kill step."

The agency has concluded that it would be unduly burdensome to require that harvesting, picking, and transportation be included as part of a processor's HACCP system or to require a kill step. Under HACCP, processors are responsible for evaluating their production system for hazards and establishing CCP's. This includes the quality of incoming raw materials. FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (Ref. 59). This guidance document is based upon certain basic principles and practices associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables. Farmers should take all steps to ensure their products are safe for the intended food use, but safe juice can be produced without these activities at the farm level coming under the processor's HACCP system. Processors can control hazards that may be present on incoming produce by: (1) Rejecting produce at receipt that does not meet processor specifications; (2) removing contaminated produce during initial processing; (3) cleaning and sanitizing produce; (4) using, as a minimum standard, the 5-log reduction in the pertinent pathogen as set forth in § 120.24; and (5) using any other effective method.

The agency does not believe it is appropriate to mandate a "kill step" in the absence of HACCP at the farm. It is the processor's decision, based on its hazard analysis whether or not the first CCP in its HACCP system is at the point of receipt of raw materials, to control hazards that may have occurred earlier. The hazard analysis must be based on experience, illness data, scientific reports, or other information that provide a basis to conclude that there is a reasonable possibility that, in the absence of HACCP controls, the food hazard will occur in the particular type of product being processed. The performance standard establishes the minimum level of microbial pathogen reduction the process must be able to provide to produce safe juice and this may be met by a "kill step" or any other appropriate method. The 5-log reduction in the pertinent pathogen is adequate to ensure that the juice is safe when done under a HACCP system with a foundation of CGMP's and SSOP's.

(Comment 41) One comment suggested that the definition of processing should at least mention FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" (GAP's).

FDA has considered the comment's suggestion and believes that reference to the GAP's in part 120 would be useful. However, the agency finds that it is more appropriate to discuss the GAP's in terms of the application of part 120. Therefore, FDA is modifying § 120.1(a) to state that raw agricultural ingredients are not subject to the requirements of this part and that processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

b. Retail.

(Comment 42) Several comments were opposed to excluding retail establishments from the definition of processing in proposed § 120.3(h)(2)(ii) (finalized as § 120.3(j)(2)(ii)). The comments expressed concern because outbreaks associated with products processed in retail establishments will be equally devastating to the industry as a whole. One comment stated that relying on the Food Code and State regulators is inadequate because: (1) The adoption of Food Code provisions is voluntary and varies widely on a State-by-State basis and (2) State regulators do not have the resources to inspect retail establishments on a regular basis.

The agency recognizes that retail is an important segment of the juice industry and that retailers may also mishandle products. FDA is concerned that juice sold at retail be safe. However, retail establishments pose a unique situation for the implementation of HACCP. Retail establishments, in general, deal with a greater variety of products and processes at relatively lower volumes than non-retail producers. For example, cider retailers at farmers' markets will generally sell other products, including fresh produce, as well as apple cider. Therefore, because retail establishments handle lower volumes of a variety of products, HACCP systems at retail are significantly different from HACCP systems in processing plants. Because of the wide variety of products and processes used by retail establishments, the relatively low volumes of juices produced, the normally small area of product distribution, and the large number of retail establishments, FDA has chosen to focus its regulatory resources on manufacturers that produce larger quantities of widely distributed products.

Even though retail establishments are not included in this rulemaking, prudent retailers should take steps to ensure the safety of their products. FDA traditionally provides guidance to the retail industry through the Food Code and works with the States to implement Food Code provisions. The States should be aware that the Food Code is responsive to many of the concerns raised in the comment. FDA encourages juice retailers to implement Food Code provisions. Also, FDA provides training and other forms of technical assistance to States and local Governments who inspect retail food establishments through the agency's retail Federal/State cooperative program. The agency will continue to provide this support through the Federal/State cooperative mechanism. FDA recognizes that not all States have adopted the Food Code.

Finally, more than 25 States have adopted the Food Code as law with most other States in the process of adopting the Code. However, retail establishments pose an inspection burden well beyond the capacity of FDA. There are not sufficient resources to adequately inspect the many retail establishments in the United States.

Although retail establishments are not covered in this final rule, they are subject to § 101.17(g), which requires that packaged untreated juice products carry a statement informing consumers that the product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

(Comment 43) One comment suggested that, rather than exempting all retail establishments from the definition for processors, only retailers who produce in batches of less than 32 ounces at a time or who sell product in glass containers that can be washed and reused might be exempted because the less fruit and vegetables that go into a batch, the lower the risk.

The agency agrees with the concept that the smaller the batch, the lower the microbial risk. Larger establishments produce larger quantities of juice that are often widely distributed. Retail establishments produce much smaller quantities of juice that are more likely (but not always) consumed locally. Thus, the public health impact of a foodborne illness outbreak associated with larger firms is likely to be greater. However, the special considerations discussed in the response to the previous comment still exist for retail firms, regardless of batch size. Therefore, FDA concludes that it is appropriate that part 120 excludes operators of retail establishments from the definition of processor.

(Comment 44) One comment requested that FDA establish national standards for juice processors in the Food Code if the agency excludes retail establishments from the definition for processing. Conversely, several comments stated that the provisions of the Food Code adequately ensure juice safety at retail. A few comments stated that the guidelines developed by the Fresh Citrus Juice Task Force in combination with Food Code provisions are adequate to ensure the safety of citrus juice without mandatory HACCP for retailers.

FDA agrees with the comments that maintain that the Food Code describes appropriate controls that can be applied to reduce juice hazards at retail. The agency has traditionally relied on the Food Code to provide guidance to retail establishments. As noted in the response to comment 42, FDA will work with the States through its Federal/State mechanism. The agency urges retailers to implement State and industry guidance in their establishments to ensure the safety of juice.

(Comment 45) One comment suggested that all juice, like milk, should be pasteurized and FDA should not permit the sale of untreated juice since raw milk sales are not allowed.

The agency agrees. Under § 120.24(a), processors must include in their HACCP plans control measures that will produce, at a minimum, a 5-log reduction in the pertinent pathogen. Thus, all juice subject to part 120 will be treated to control microorganisms.

(Comment 46) One comment requested information on which processors will not be covered under either the juice labeling rule or the juice HACCP rule and which processors, if any, have a permanent labeling option.

The agency advises that § 101.17(g) requires that any packaged juice in interstate commerce that has not been specifically processed to prevent, reduce, or eliminate the presence of pathogens must bear the warning statement. Under this final rule, a juice retailer as defined in § 120.3(l) is not required to establish a HACCP system; however, any juice produced by that retailer that includes an interstate ingredient or is shipped in interstate commerce must bear the warning label statement. Such a retailer may avoid the labeling requirements by treating its product to achieve a 5-log reduction in the pertinent microorganism.

c. 40,000 gallon exemption.

(Comment 47) Most of the comments on the 40,000 gallon exemption from both large and small processors requested that FDA withdraw the exemption in proposed § 120.3(h)(2)(iii)

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(the definition of "processing"). The comments stated that small processors are just as likely to produce contaminated juice as larger processors and that company size should not dictate compliance with regulations when public safety is at stake. The comments also noted that this exemption does not maximize public health protection.

The comments have persuaded the agency to exclude from this final rule the exemption proposed for very small retail businesses who sell less than 40,000 gallons of juice annually either to consumers directly or to other retailers. FDA agrees that company size should not dictate compliance with food safety rules. The agency also agrees with comments that stated that this exemption does not protect the public health. Although large processing firms can be responsible for more widespread outbreaks than the firms in the proposed exemption because of their broader product distribution, those smaller businesses can make juice that may cause an outbreak. Further, other regulations addressing public health concerns (*e.g.*, seafood HACCP in part 123 (21 CFR part 123) mandatory pasteurization of milk and milk products in 21 CFR 1240.61) do not contain such exemptions. Therefore, the agency is removing the exemption from this final rule. FDA notes that those producers who would have been covered by the 40,000 gallon exemption and who are strictly engaged in retail sales would not be required to comply with this final rule consistent with § 120.3(j)(2)(ii). Juice produced by these retailers would be required to bear the label warning statement as described in the response to comment 46.

3. Retail Establishment

(Comment 48) Several comments requested that FDA define "retail establishment" for clarity. One comment requested that FDA revise proposed § 120.3(h) so that retailers who sell to other retailers are covered by the definition for processors.

FDA agrees with the comment that recommended establishing a definition of "retail establishment." The FDA Food Code has a definition of " food establishment", which, given the purpose and scope of the Food Code, is essentially a definition of a retail establishment. In establishing a definition for "retail establishment" in this final rule, FDA is relying on this Food Code definition. The Food Code definition of " food establishment" has been in existence for many years, and is recognized by the States. The Food Code definition includes establishments in which juice is produced and sold directly to consumers in stores, from roadside stands, at farmers' markets, and in food service operations (such as juice bars and restaurants).

FDA also agrees with the comment that requested that juice retailers who sell to other retailers be subject to the HACCP regulation. FDA believes that this approach will contribute to public health protection. Accordingly, under this final rule, only a retail establishment that limits its juice business to direct consumer sales would qualify for exemption from the requirements of this HACCP regulation, and would be subject to regulation by the State in which it operates. Thus, the "retail establishment" definition in this regulation is consistent with the Food Code, and also describes establishments that are included and excluded specifically for the purpose of this regulation. For example, a retail establishment, central kitchen, or processing facility that provides juice to more than one retail operation (e.g., juice production operation that provides juice to outlets of a chain supermarket) would not be considered a retail establishment that is exempt from this regulation. However, a retail establishment that produces juice for sale directly to consumers at that location and at other locations under the same ownership would be considered a retail establishment exempt from this regulation. Therefore, the agency is adding a § 120.3(l) to define a "retail establishment" as an operation that provides juice directly to consumers, and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending. (Because the agency is establishing an additional definition in § 120.3, it is recodifying the other terms in § 120.3 so that they continue to appear in alphabetical order.)

4. Verification and Validation

(Comment 49) Several comments requested that the terms "validation" and "verification" be defined and be used consistent with NACMCF principles.

FDA agrees with the comments. The agency intends that the terms "validation" and "verification" be used consistent with NACMCF principles throughout this final rule. The NACMCF has established definitions for these terms that the agency finds useful (Ref. 17). According to the NACMCF definition, validation is a subset of verification (Ref. 17). Therefore, in this final rule the agency is amending § 120.3(p) and (q) to include the NACMCF definitions of both validation and verification as follows:

Validation means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified hazards;

Verification means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

C. Prerequisite Program Standard Operating Procedures

The HACCP proposal discussed two types of prerequisite program standard operating procedures (SOP's). FDA proposed to require the first type, SSOP's, in § 120.6. SSOP's cover sanitary conditions and practices before, during, and after processing. The agency requested comment (63 FR 20450 at 20466) (Ref. 2) on a second prerequisite program to provide control over materials as they enter the plant. However, the agency did not propose to require incoming material SOP's in part 120.

(Comment 50) One comment asked that if FDA requires prerequisite program SOP's, the agency should be more specific about what is to be included in the prerequisite program SOP's. It stated that some SOP's ensure wholesomeness and quality and should not be a part of HACCP.

The agency advises that it is requiring that processors implement SSOP's in part 120 at this time and not any other type of SOP. The SSOP's in § 120.6 do include specific standards that must be maintained. The SSOP's as described in § 120.6(a) address insanitary conditions and are not directed to ensure wholesomeness and quality although they may have a beneficial effect on these attributes.

1. SSOP's

(Comment 51) Several comments stated that SSOP's are covered under CGMP's and should not also be covered in HACCP and neither SSOP's nor CGMP's should be a written requirement for HACCP. One comment stated that SSOP's should not be written for the same reasons that SSOP's are not written for seafood HACCP. One comment stated that prerequisite program SSOP's should not be mandated and that CGMP's provide an adequate basis for HACCP. However, other comments maintained that SSOP's and CGMP's should be a part of written HACCP programs.

It is important to understand the difference between CGMP's, SSOP's, and HACCP. The agency has established CGMP's in part 110. These regulations provide general guidance on such matters as facility design, materials, personnel practices, and cleaning and sanitation procedures. In § 120.5, FDA requires that part 110 apply in determining whether the facilities, methods, practices, and controls used to process food are safe, and whether the food has been processed under sanitary conditions. Processors do not need to make a record of these activities for FDA review. However, the agency will continue to include in its inspections determinations of processor compliance with CGMP's. All appropriate CGMP's must be implemented, whether they are incorporated into a processor's HACCP system or not, because they reflect norms of good processing.

SSOP's are specific sanitation CGMP's that FDA has found are key to the successful implementation of a HACCP system. Not all CGMP's deal with sanitation issues (e.g., contamination with aflatoxin or other natural toxins in § 110.80(a)(3)). As required by § 120.6(a), SSOP's emphasize sanitation conditions and practices before, during, and after processing. Because of the importance of sanitation to a facility, processors must monitor SSOP conditions and practices during processing to at least ensure compliance with part 110. If sanitation conditions and practices are not met, processors must take corrective actions (§ 120.6((b)). Insanitary conditions can directly result in food hazards, especially microbiological hazards. Inadequate sanitation has a direct effect on whether the HACCP plan can adequately control food hazards. For example, insanitary conditions can cause post process contamination.

Both CGMP's and SSOP's have a broad scope. As noted in section II.A, HACCP is a system to identify specific points in a particular manufacturers process where risks exist and critical controls are needed to control the identified risks. CGMP's and SSOP's both play an important role in HACCP in that they form the foundation upon which the HACCP system is built.

FDA stated in the proposal (63 FR 20450 at 20467) (Ref. 2) that the records bearing on the monitoring of relevant sanitation conditions and practices and the agency's access to such records are essential if SSOP's are to be part of an effective regulatory strategy. Although the agency elected not to require written SSOP's under the seafood HACCP regulation, it required that seafood processors establish SSOP's and maintain records monitoring and documenting corrective actions. Juice is significantly different than seafood in that juice is generally consumed as sold whereas seafood is generally cooked, thus sanitation takes on increased importance. Because of the significance of sanitary conditions, the agency concludes that juice processors must maintain SSOP records in the same manner as that required for other HACCP records.

(Comment 52) One comment requested that FDA require that the quality and safety of water used in juice processing plants be verified.

The agency agrees that water used in juice processing plants must be safe and of an adequate sanitary quality for its intended use. This is consistent with the CGMP requirements in § 110.37(a). Section 120.6(a)(1) of this final rule requires that juice processors have SSOP's that address the safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice. Processors must examine the source of the water used in their facilities and determine the necessary provisions to ensure the water's safety. The processor's particular obligations may vary, depending on the source of the water. Water from community water supplies is tested for many substances and the processor can obtain the results of that testing from the local water authority. In the case of well water, processors must know that the water they use is safe because such water could present potential hazards. Thus, processors using well water need to test the water. Moreover, if substances in the water are hazards that are reasonably likely to occur, one or more CCP's must be established and included in the HACCP plan.

(Comment 53) One comment requested that FDA require processors to monitor for water and cleaning solution contamination.

FDA believes that, given the regulation as proposed, the requested revision is unnecessary. Section 120.6(a)(1) already requires processors to have and implement SSOP's relating to water quality and § 120.6(a)(5) requires processors to have and implement SSOP's relating to the protection of food from cleaning compounds. Processors must monitor their SSOP's and take corrective actions for sanitation conditions and practices where the specified conditions are not met (§ 120.6(b)). In addition, processors must maintain records that document monitoring and any corrective actions taken (§ 120.6(c)). If either water or cleaning solution contamination is a hazard that is reasonably likely to occur, one or more control measures must be included in the HACCP plan for each hazard identified.

(Comment 54) One comment requested that FDA clarify whether § 120.6(a)(5) permits certain amounts of "no rinse" sanitizers to come into contact with product.

The agency advises that "no rinse" sanitizers used according to product directions do not present a contamination problem and, with appropriate use, their presence would not be considered a violation of § 120.6(a)(5).

(Comment 55) One comment requested that FDA set an "acceptable level of infestation" for insect control and require that processors use insect light traps as monitoring devices. Another comment requested that FDA revise § 120.6(a)(8) to read as follows: "Exclusion of pests from the food plant and prevention of contamination from pests within the plant, as well as in packaging and raw materials delivered to the plant."

FDA disagrees that it should establish an "acceptable level of infestation" for insects or that it should revise § 120.6(a)(8) as the comment requested. Exclusion of pests from the food plant is included as a necessary part of SSOP's in § 120.6(a)(8). The comment's requested modification is already implied in § 120.6(a)(8). Pests are recognized sources of microbial contamination, as well as filth, in foods. The agency believes that generally no unusual pest control requirements are necessary for juice processing operations beyond the general requirements for pest control in all food processing facilities, as laid out in part 110. However, if, during its hazard analysis, a processor identifies pests or contamination from pests as a food hazard that is reasonably likely to occur in its particular system, the processor will need to establish a control measure, critical limits, and a means of monitoring.

(Comment 56) One comment requested that FDA add the following to § 120.6(b): "The requirements under this section shall apply both to the processor's own premises and the premises of any supplier of raw materials and packaging, as far as this is relevant." The comment concluded that this is necessary because packaging and raw materials are particular sources of contamination in most food processing plants.

FDA agrees that incoming materials can be a possible source of contamination in juice processing plants but points out that the focus of this

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regulation is the production of safe juice by juice processors. Nevertheless, processors are urged to take steps to control hazards before the hazards enter the processing facility. Under part 120, processors must control food hazards in the juice products they make. If a processor's hazard analysis indicates that a hazard is reasonably likely to occur in incoming materials, then an appropriate control (such as a supplier agreement concerning that hazard) must be a part of the processor's HACCP plan, and the processor must monitor the CCP and verify supplier performance. Thus, FDA concludes that raw materials and packaging are already covered adequately and is not modifying § 120.6(b) as the comment requested.

(Comment 57) One comment stated that corrective actions should not be required for CGMP's and SSOP's.

FDA advises that there are no corrective actions specifically required for CGMP's in these HACCP regulations. However, part 120 sets forth monitoring and corrective action requirements for SSOP's. Insanitary conditions create an environment in which products may become contaminated with pathogens or other substances. If a product becomes contaminated because of insanitary conditions, it is important that corrections be made as quickly as possible so as not to subject subsequently processed product to conditions that could introduce food hazards. Therefore, processors need to monitor the performance of SSOP's to ensure that the SSOP's are functioning as designed, and that any problems that arise are corrected. The comment did not provide data to persuade the agency to conclude otherwise.

(Comment 58) One comment suggested that FDA only require SSOP's in a HACCP plan if their control is essential to eliminate or control a public health risk, as determined in the hazard analysis. The comment contended that a distinction must be made between failure to meet sanitation requirements and failure to meet a food safety/HACCP requirement. The comment further stated that singling out items to be included in SSOP's implies that the other sanitation requirements in part 110 are not that important, and this is not the case. It stated that if FDA establishes SSOP's that, at the very least, no recordkeeping requirements should be associated with SSOP's.

FDA advises that processors are not required to include sanitation controls in their HACCP plans. Section 120.6(d) allows processors the option of including sanitation controls in the HACCP plan, but they are under no obligation to do so as long as the sanitation controls are being implemented through the SSOP. Insanitary facilities or equipment, poor food handling, improper personal hygiene, and similar insanitary conditions create an environment in which products may become contaminated with pathogens and other substances. A processor may determine that a task normally covered by SSOP's may be of such importance that it must be included in the HACCP plan because it controls a hazard that is reasonably likely to occur. Similarly, an SSOP task may simply be more efficiently or effectively performed under the HACCP plan rather than SSOP controls, and thus, a processor may choose to incorporate the SSOP task into the HACCP system. However, HACCP controls generally focus on discrete steps or "points" in a processing system, while sanitation and sanitation controls generally have broader, plantwide applicability. Thus, sanitation does not always lend itself well to HACCP controls. Therefore, the agency is not modifying § 120.6(d) as requested.

FDA disagrees that singling out items to be included in SSOP's implies that the other provisions of part 110 are not important. Rather, the items listed in § 120.6(a) are to assist processors in identifying and implementing key sanitation activities. Sanitation controls, such as controls preventing use of contaminated water in juice making, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. No matter how reliable the process is, insanitary conditions can cause the product to become contaminated with pathogens. It is because of the critical role that sanitation plays in the production of safe juice that FDA is requiring SSOP's, identifying specific items to be included, and requiring recordkeeping. However, processors must comply with all provisions of part 110 in addition to having SSOP's as required under § 120.5.

2. Other SOP's

(Comment 59) Several comments requested that FDA require written, monitored, and verified SOP's for incoming materials. One comment contended that reasonable procedures for these SOP's should include no use of dropped apples, no contact with water that could contain pathogens, no manure as fertilizer, steam cleaning of crates in contact with fruit between lots, and regular inspections of source farms and orchards. Another comment suggested that incoming material SOP's be required only for producers that do not pasteurize their product.

The agency is not convinced of the need for mandatory incoming material SOP's because these activities may be adequately controlled under the CGMP's in part 110. However, FDA does recognize the value of incoming material SOP's, and it encourages processors to establish and monitor incoming material conditions and practices and to take corrective actions when needed. Processors must evaluate the need for controls at all points in their process, including incoming materials. If incoming materials are reasonably likely to present a hazard, then the hazard must be controlled by one or more CCP's in the HACCP plan, even if a processor has an incoming material SOP.

Many of the controls mentioned in the comments are addressed in FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." As noted earlier, FDA encourages farmers and processors to evaluate and modify their agricultural practices in accordance with GAP guidance. Processors may include GAP's in any SOP's for incoming materials that they may establish.

Finally, because all processors, regardless of whether or not they pasteurize, must meet the performance standard required under § 120.24, as well as the other requirements of part 120, there is no need to differentiate between processors for the purposes of requiring incoming material SOP's, and thus, to require more SSOP's from a processor that does not pasteurize.

(Comment 60) One comment requested that FDA hold a public meeting for input on incoming material SOP's.

The agency does not believe that such a public meeting is necessary. There have been many opportunities for interested parties to comment on all issues related to HACCP, including incoming material SOP's (see section I.B of this final rule). FDA requested public input in the HACCP proposed rule (63 FR 20450 at 20466) (Ref. 2) and in this final rule has considered all significant comments received. In addition, some issues surrounding incoming materials for citrus juices were discussed at the public NACMCF meeting in December, 1999 (Ref. 12). Finally, FDA intends to issue a juice HACCP hazards and controls guidance, which will provide another opportunity for public input on the incoming materials issue.

(Comment 61) One comment suggested that the GAP's for fresh produce can be used in conjunction with SOP's to ensure the safety of incoming material.

FDA agrees that the use of GAP's in combination with SOP's may enhance the safety of incoming materials. FDA's GAP's for fresh produce provide valuable guidance for use in the production and post harvest handling of raw agricultural commodities. As noted, the agency also intends to publish a juice HACCP hazards and controls guidance that will provide additional guidance on ensuring the safety of incoming materials.

(Comment 62) One comment stated that HACCP should include a requirement for incoming materials testing to prevent another outbreak like the one in 1996.

The agency disagrees that it should require incoming materials testing in part 120, although it encourages processors to test incoming materials as appropriate. Testing may be used as a control measure for a hazard that is reasonably likely to occur and it may also be used to gather information on a product or supplier for use in the hazard analysis. However, testing may not be useful in all cases. Microbial contamination of fresh produce is usually at low levels and is not uniformly distributed throughout a lot. Thus, while detecting a pathogen, such as *E. coli* O157:H7, would allow a processor to avoid using contaminated produce, failure to detect pathogens by testing does not provide assurance that the hazard is not present in incoming materials. The 5-log reduction in the pertinent pathogen as implemented in a HACCP system provides the assurance that microbial hazards are under control throughout the process. Therefore, the agency is not requiring the testing of incoming materials.

D. Hazard Analysis

The agency proposed in § 120.7 that processors develop a written hazard analysis to determine whether there are hazards that are reasonably likely to occur for each type of juice produced by a processor and to identify the control measures that the processor can apply to control those hazards.

(Comment 63) One comment requested that FDA clarify how a hazard analysis is conducted. The comment suggested that FDA emphasize the NACMCF recommendations, including consideration of both likelihood of occurrence and severity of hazards. The comment expressed concern that without considering both the likelihood of occurrence and severity of hazards, HACCP plans would not be consistent with international practice and World Trade Organization (WTO) obligations, which state that scientific determinations of risk are needed to form a sound basis for food safety standards.

The agency agrees that the approach outlined by the NACMCF will best assist processors in conducting a hazard analysis. First, processors will benefit from using the five preliminary steps set forth by the NACMCF, which are to assemble a HACCP team, describe the food and its distribution, identify the intended use and consumers of the food, develop a flow diagram that describes the process, and verify the flow diagram (Ref. 17). Although the agency is not specifically requiring that processors use these preliminary steps, these steps will aid processors in focusing on their specific product and process.

According to the NACMCF, processors must accomplish three objectives in the hazard analysis: (1) Identify hazards that are reasonably likely to occur and their associated control measures; (2) identify needed modifications to a process or product so that product safety is further assured or improved; and (3) provide a basis for determining CCP's in the HACCP plan (Ref. 17). FDA agrees with these objectives.

The first NACMCF objective is accomplished in three steps. First, processors must list all the potential hazards that could be present in the juice. During this step, the processor's HACCP expert or team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. A list of categories of potential food hazards is found in § 120.7(c). Based on this review, the processor's HACCP team develops a list of potential biological, chemical, or physical food hazards that may be introduced, increased, or controlled at each step in the production process. A hazard analysis must be conducted for each type of juice product manufactured by the processor because different hazards may be associated with different juice products. (For example, patulin need only be considered in apple juice products.)

The processor must then identify those food hazards that are reasonably likely to occur. According to NACMCF, this step takes into account both the consequences of exposure (i.e., severity) and the probability of occurrence (i.e., frequency) of the health impact of the potential hazards in question (Ref. 17). FDA agrees with the NACMCF approach. Accordingly, when applying the phrase "reasonably likely to occur," a processor must consider both severity and frequency of potential hazards. The NACMCF stated that consideration of the likelihood of the hazard's occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature (Ref. 17). The NACMCF also stated that consideration should be given to the effects of short term, as well as long-term, exposure to the potential hazards. Because this process takes into consideration both frequency and severity, a potential hazard may be identified as reasonably likely to occur even though it occurs infrequently because the public health consequences when it does occur are so severe, *e.g.*, HUS in small children from *E. coli* O157:H7 in juice. This approach also provides greater harmony for international trade because it is the same approach recommended by the Codex Alimentarius Commission, which is a recognized standard setting body by the WTO. Hazards that are not reasonably likely to occur do not require further consideration within a HACCP plan but are controlled under CGMP's.

Identification of control measures is a third step in the first NACMCF objective in developing a hazard analysis. For example, juice processors must identify the process they will use to achieve the 5-log reduction in the pertinent pathogen. This may be pasteurization, surface treatments for citrus, or other effective methods. Therefore, § 120.7 requires that processors identify the measures that they will apply to control the hazards that have been identified as reasonably likely to occur. These control measures must be included in the HACCP plan as well as the hazard analysis.

Under the second NACMCF objective, processors must review their current process to determine deficiencies in controlling food hazards and then identify the changes that must be made to ensure that food hazards are controlled. For example, some juice beverages may be thinner or thicker than others, a characteristic that may affect how fast the product flows through the pasteurizer; in this stage of the hazard analysis, the processor must review its process to determine whether the product is flowing through the pasteurizer at a rate sufficient to ensure that all particles of the juice receive the appropriate treatment in terms of both time and temperature to achieve, at a minimum, the 5-log reduction in the pertinent pathogen.

The third NACMCF objective requires that processors use the hazard analysis to provide a basis for determining CCP's in the HACCP plan. For example, some

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processors may run different juice beverages on the same line during the same day with only a water flush between products. If one juice product contains a potential allergen, such as a soy ingredient, then a possible control measure is that this product be run last in the day with a thorough cleaning of the system before the next day's startup.

To clarify the necessary steps in developing a hazard analysis, as the comment requested, the agency is codifying them in § 120.7(a). (Because the agency is adding these steps to § 120.7, it is recodifying the other paragraphs in § 120.7 for clarity.)

(Comment 64) A few comments objected to the requirement of a written hazard analysis because the seafood HACCP regulation does not require a written hazard analysis. However, some comments supported such a requirement.

FDA acknowledges that a written hazard analysis is not required by the seafood HACCP regulation and believes that, at the time that the regulation was established, this was appropriate. Although the seafood HACCP regulation does not require a written hazard analysis for agency record review, seafood processors are strongly urged to have a written hazard analysis to resolve differences between the processor and the agency about whether a HACCP plan is needed and about the selection of hazards, CCP's, and CL's.

Since the issuance of the seafood HACCP regulation, the HACCP concept and how best to implement HACCP has evolved in step with industry's increasing experience with HACCP; part of that evolution is the idea that the hazard analysis should be written. Processors will have a better HACCP system if they document the hazard analysis process. A thorough hazard analysis is the key to preparing an effective HACCP plan. According to the NACMCF, if the hazard analysis is not done correctly and the hazards warranting control are not properly identified, the plan will not be effective regardless of how well it is followed (Ref. 17).

Another aspect of HACCP implementation that affects the need for a written hazard analysis is the availability of specially trained investigators. At the time the seafood HACCP program was established, FDA had sufficient resources to hire and specifically train investigators in seafood HACCP, as well as to provide assistance to the industry in implementing HACCP. With expansion of HACCP into other commodity areas, the agency does not have the resources to develop cadres of investigators with expertise in a single commodity, such as juice. With a written hazard analysis, investigators can more easily determine whether processors have adequately considered all juice hazards and have adequately identified those hazards that are reasonably likely to occur.

Even though a written hazard analysis is not required by the seafood HACCP regulation, that regulation, as well as USDA's meat and poultry HACCP regulations, require a systematic and comprehensive hazard analysis. In addition, USDA's meat and poultry HACCP regulations require a written hazard analysis. Thus, the only difference in the juice final rule and the seafood HACCP regulation is that the analysis is written, not that it is or is not required. FDA believes that the additional step of recording the hazard analysis poses no significant burden, economic or otherwise, to juice processors and, on the contrary, has advantages for the processor. A written hazard analysis provides processors with a ready record of the decisions made in conducting a safety analysis of their process, which they may use in evaluating potential changes to the system and for discussions with regulatory officials. Further, written hazard analyses are useful to processors in that they help provide the rationale for the establishment of critical limits and other plan components. Having the basis for these decisions available will be helpful when processors experience changes in personnel, especially those associated with the HACCP process, and in responding to unanticipated CL deviations.

A written hazard analysis need not be a highly detailed document, but it must reflect consideration of all the potential hazards that could occur in a processor's system for a product and the processor's decisions about whether these hazards are reasonably likely to occur. The hazard analysis may be as simple as a checklist of potential hazards and the reason why certain decisions were made. A written hazard analysis clearly and rationally demonstrates that processors have considered all potential hazards, identified those hazards that are reasonably likely to occur and are associated with their product and process, and identified CCP's and CL's in their HACCP plan.

(Comment 65) Several comments stated that HACCP should only cover hazards that are reasonably likely to occur and that have been documented.

FDA agrees that processors need only control in their HACCP plan those hazards that are reasonably likely to occur and that have been documented. The hazard analysis is where processors differentiate between unlikely hazards and hazards that are reasonably likely to occur in the absence of controls. This determination is made for each type of juice processed in a particular facility. Data such as experience, illness data, scientific reports, or other information may be used as documentation as to whether the hazard is reasonably likely to occur in juice and, if so, how the hazard is best controlled.

(Comment 66) One comment requested that the agency revise proposed § 120.7(a) to state generally that all physical, chemical, and microbiological hazards be considered, instead of providing a numbered list of potential hazards to be considered in the hazard analysis.

FDA disagrees that all physical, chemical, and microbiological hazards must be considered, but only those that can be introduced both within and outside the particular processing environment, including hazards that can occur before, during, and after harvest. The agency points out that the provision now codified as § 120.7(c), simply provides guidance in the form of a minimum list of potential physical, chemical, and microbiological hazards that processors should consider. The list is not intended to be all-encompassing, and is not so constructed. FDA believes that this guidance is useful because it provides detail about the types of potential hazards that fall into the more general categories of physical, chemical, and microbiological hazards. For these reasons, FDA declines to revise § 120.7(c) as requested.

(Comment 67) Several comments argued that unapproved pesticide residues, unapproved food and color additives, and food allergens are not appropriate for inclusion in HACCP because, categorically, they are not a significant threat to public health and are already covered by other regulations. One of the comments supported its claim of inappropriateness by pointing out that FDA failed to give any examples of problems caused by unlawful pesticide residues or unapproved food and color additives. Therefore, it stated, these are not problems that should be covered by HACCP, but addressed under CGMP's.

FDA disagrees that certain types of potential hazards, such as those mentioned in § 120.7(c), need not be considered in a hazard analysis. For example, pesticide residues above tolerance may be potential hazards. However, it is unlikely that pesticide residues above tolerance will need to be identified during a hazard analysis as hazards that must be included in the HACCP plan because they occur infrequently and the public health impact of infrequent exposure is not severe.

The agency recognizes that there are effective governmental control programs in place in the United States to assure generally that unlawful pesticide residues are unlikely to occur. For pesticides, these controls include pesticide registration, applicator licensure, and government sampling and enforcement programs. Likewise, unapproved food and color additives are generally unlikely to occur in juice products because prudent processors would not intentionally add them to their products. Thus, for crops grown in the United States, a processor may ordinarily conclude that the controls for pesticide use are such that it is not reasonably likely that unlawful pesticide residues will be present in crops (including residues at levels above tolerance). A processor is responsible for assessing the adequacy of control for pesticide use for crops grown outside the United States and determining whether such controls are sufficient to make it unlikely that unlawful pesticide residues will be present. If foreign governmental controls are sufficient, HACCP controls would not likely be necessary in the processor's HACCP plan. If foreign governmental controls are not sufficient, the processor may need to include appropriate controls in its HACCP plan.

Similarly, unapproved food and color additives would be reasonably likely to occur only if, because of their presence in the production plant and the potential for formulation errors, there was a real likelihood that they may be inadvertently added to the product or added at higher than the allowable rate. A food or color additive may also be used on the product by a processor's supplier. This may pose a hazard where the food or color additive is a potential allergen or causes sensitivity reactions in susceptible individuals. For example, a processor may make several types of juice drinks, some containing FD&C Yellow No. 5. The likelihood and severity of a reaction to Yellow No. 5 is a factor that must be considered in determining whether the unintended presence, whether by misformulation or cross contamination, of the ingredient or additive in a food is reasonably likely to occur and, therefore, constitutes a potential hazard.

Therefore, the agency concludes that if unlawful pesticide residues and unapproved food and color additives are hazards that are reasonably likely to occur, it is appropriate that a processor identify them in its hazard analysis and include them in its HACCP plan.

(Comment 68) Several comments suggested that pesticide control should be handled as an agreement between processor and grower, not as a CCP.

The agency advises that if an agreement between a processor and a grower adequately assures that unlawful pesticide residues will not be a hazard that is reasonably likely to occur, then controls for that particular hazard need not be included in the HACCP plan. Agreements between processors and growers on pesticide issues may be particularly useful for produce grown in areas where government controls may not be sufficient to ensure that unlawful pesticide residues are not a hazard that is reasonably likely to occur.

(Comment 69) One comment noted that unapproved food and color additives are not an issue for orange juice because it has a standard of identity.

The existence of a standard of identity, such as for orange juice or tomato juice, is no guarantee that an unapproved food or color additive has not been intentionally or inadvertently added to the juice product. However, as noted previously, if a processor's hazard analysis establishes that unapproved food and color additives are not a hazard that is reasonably likely to occur, such additives do not need to be controlled as part of a HACCP plan.

(Comment 70) One comment requested that proposed § 120.7(b) be withdrawn as the list of what a processor should evaluate because it is already covered under part 110 and can be addressed by prerequisite programs.

The agency stated in the proposal that it was including in proposed § 120.7(b) (now codified as § 120.7(d)) some elements that would be useful for juice processors to consider in a hazard analysis (63 FR 20450 at 20468) (Ref. 2). Although CGMP's and SSOP's address a wide variety of situations and hazards, a particular food hazard may be reasonably likely to occur in the absence of its control and, therefore, necessitate HACCP controls. To assist processors in identifying all hazards that are reasonably likely to occur in their products, and their public health impact, FDA is, therefore, retaining the list in § 120.7(d) to guide processors in their hazard analyses.

(Comment 71) One comment requested that FDA revise the list of what processors should consider in evaluating the safety of their products to include cooling, ice, and water quality specifically.

The list in § 120.7(c) simply provides examples to guide processors and is not intended to be all inclusive. Ice and water quality are issues that generally will be addressed in the SSOP requirement in § 120.6(a)(1). Therefore, the agency is not modifying § 120.7(c) as requested. However, because the list in § 120.7(c) is guidance for processors, it does not preclude a processor from considering ice and water quality in its hazard analysis. If ice or water quality poses a hazard that is reasonably likely to occur, then the hazard must be addressed in the HACCP plan.

E. HACCP Plan

The agency proposed that processors have and implement a written HACCP plan for a given process whenever a hazard analysis of that process establishes that there are one or more food hazards that are reasonably likely to occur during such processing. The written HACCP plan is to include the following seven principles: (1) Conduct a hazard analysis, (2) determine the critical control points, (3) establish critical limits, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures. These seven elements are derived from the NACMCF principles of HACCP.

(Comment 72) One comment requested that FDA delete the term "during processing" in § 120.8(a) because some of the problems in the past have come from fruit contaminated on receipt and the term could be read to mean that only hazards that could occur during processing should be considered in the hazard analysis.

The agency does not agree with the comment. Section 120.7 requires that processors conduct a hazard analysis to determine the hazards that are reasonably likely to occur in their juice. If a hazard is reasonably likely to occur in the juice, the source of the hazard is immaterial. Therefore, FDA is not revising § 120.8(a) to delete the term "during processing."

(Comment 73) One comment requested that FDA delete proposed § 120.8(b)(2)(ii) because it appears to contradict the definition for processing in proposed § 120.3(h)(1) (finalized as § 120.3(j)(1)). The comment asserted that § 120.8(b)(2)(ii) states that CCP's should include food hazards that occur before, during, and after harvesting, yet processing is defined as excluding harvesting, picking, or transporting raw materials, which places it beyond the control of a processor.

The agency is not making the requested change because the language in question, along with the definition of

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processor in § 120.3(k), serves to identify those who are required to comply with part 120 and is not a basis for excluding potential food hazards from consideration. Specifically, the definition of processing in § 120.3(j)(1) excludes the activities of harvesting, picking, or transporting raw materials even if these materials may be intended for use in juice processing under § 120.3(k). Only those engaged in "processing" juice are "processors" and are subject to the requirements in part 120. However, juice processors are responsible for addressing the hazards that may be present in/on the foods produced during their process, including hazards that result from characteristics of the incoming produce. One way to address potential hazards presented by incoming materials is by examining those materials when received and rejecting those that may contain hazards. Another way is to process juice in a manner to control pathogens or other hazards that may have been present on incoming materials. Therefore, FDA believes that the definition of "processing" does not conflict with § 120.8(b)(2)(ii) and is not making the requested change.

F. Legal Basis

The agency proposed in § 120.9 that failure of a processor to have and to implement a HACCP system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, renders the juice products of that processor adulterated under section 402(a)(4) of the act (21 U.S.C. 342(a)(4)).

(Comment 74) A number of comments asserted that FDA lacks the statutory authority to require juice processors to establish HACCP programs. Several comments claimed that section 402(a)(4) of the act cannot be read to authorize a broad range of HACCP controls and to provide that the failure to observe any of those controls would render food prepared under such conditions adulterated within the meaning of section 402(a)(4) of the act.

FDA disagrees with these comments. As shown below, the agency has ample authority to require juice processors to establish HACCP systems.[4]

[4] Comments on the seafood HACCP final rule raised similar questions as to FDA's authority to require seafood processors to establish HACCP systems and to require recordkeeping and record access. In response to the proposed juice HACCP rule, one trade associations filed a copy of its comments on the seafood HACCP proposal. The agency's detailed response to the comments on the seafood proposal, set out at 60 FR 65098–65012, is incorporated by reference into the preamble of this final rule.

FDA is issuing these regulations under the authority of the act and the Public Health Service Act (PHS Act). Specifically, FDA is relying on sections 402(a)(4) of the act and 701(a) of the act (21 U.S.C. 371(a)) and section 361 of the PHS Act (42 U.S.C. 264).

Under section 402(a)(4) of the act, a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. It is important to recognize that section 402(a)(4) of the act addresses conditions that may render a food injurious to health, rather than conditions that have actually caused the food to be injurious. See *United States* v. *1,200 Cans, Pasteurized Whole Eggs, Etc.*, 339 F. Supp. 131, 141 (N.D. Ga. 1972). *See also United States* v. *H.B. Gregory, Co.*, 502 F.2d 700, 705 (7th Cir. 1974), *cert. den.* 422 U.S. 1007 (1975). As noted in the notice of proposed rulemaking, 63 FR 20450 and 20457 (Ref. 2), the question is whether the conditions of a juice processing operation are such that it is reasonably possible that the juice produced by that operation may be rendered injurious to health. Based upon the information available to the agency and filed in the record of this proceeding, FDA has concluded that, if a juice processor does not incorporate certain basic controls into its procedures for preparing, packing, and holding juice, it is reasonably possible that the juice may be rendered injurious to health and, therefore, adulterated under the act. FDA is authorized by 21 U.S.C. 371 to adopt regulations for the efficient enforcement of the act.

FDA believes that the comments disputing the agency's authority to issue these regulations advocate an unduly narrow interpretation of the act generally and of section 342(a)(4) specifically. It is well-settled that the act is to be interpreted broadly so as to achieve its goal of public health protection. *United States* v. *Bacto-Unidisk*, 393 U.S. 784, 798 (1969). Section 402(a)(4) of the act deems adulterated food that is prepared, packed, or held under "insanitary" *conditions*. The term "insanitary" is not defined in the act. "Sanitary" describes that which "pertains to health, with especial [sic] reference to cleanliness and freedom from infective and deleterious influences," Black's Law Dictionary, 6th Ed.(1990); use of the prefix "in" denotes the absence or opposite of sanitary. Thus, "unsanitary conditions" are those that contribute to unhealthiness generally, including unclean conditions or those that promote infection or disease.

The case law interpreting section 402(a)(4) of the act is consistent with this broad reading of "insanitary conditions." In particular, in *United States* v. *Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977), the Second Circuit rejected a restrictive reading of 402(a)(4) of the act, concluding that this section provided the FDA with authority to establish by regulation processing parameters to control or eliminate harmful substances present in food intended for further processing. *See United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–1369 (E.D.N.Y. 1976), *aff'd supra*, 568 F.2d 240. At issue in *Nova Scotia* were FDA's regulations governing the time, temperature, and salinity for processing smoked fish, 568 F.2d at 243, 247 to 248, and provisions designed to minimize the outgrowth and toxin formation of *Clostridium botulinum Type E*, 568 F.2d at 243. The regulations in question defined sanitary conditions for processing such fish; fish processed under conditions not complying with the regulation were deemed adulterated within the meaning of section 402(a)(4) of the act, 21 CFR 128a.2 (1971); 35 FR 17401 (November 13, 1970) (Ref. 60). Although the Court posited that "insanitary conditions" could be narrowly interpreted to refer to insanitary conditions in the plant, such as the presence of insects and rodents, the Court rejected this narrow interpretation, 568 F.2d at 245 to 246, and held that under section 402(a)(4) of the act, "insanitary conditions" may include "inadequate sanitary conditions of prevention" (568 F.2d at 247). In rejecting the narrower reading of 402(a)(4) of the act, the Court recognized a "larger general purpose on the part of Congress in protecting the public health" (568 F.2d at 248).

This final rule requires that juice processors implement and maintain HACCP systems. As discussed in detail above, HACCP systems are designed to prevent, control, or eliminate hazards that are reasonably likely to occur during food production, including hazards that are present in in-coming materials, such as pathogens and other contaminants. Under the final rule, § 120.9, the failure of a juice processor to establish and maintain an adequate HACCP system renders juice produced under that system adulterated within the meaning of section 402(a)(4) of the act. Thus, the provisions of this final rule are essentially comparable to those addressed in *Nova Scotia*.

In addition, FDA relies on its authority under the Public Health

Service Act in issuing this regulation to the extent that the regulation seeks to control illnesses caused by pathogenic microorganisms. Under section 361 of the PHS Act (42 U.S.C. 264), the Surgeon General is authorized to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another State; this authority has been delegated to the Commissioner of Food and Drugs, 5 CFR 5.10(a)(4). See *State of Louisiana* v. *Mathews*, 427 *F. Supp. 174, 176 (E.D. La. 1977)*. The record in this rulemaking amply demonstrates that juice can function as a vehicle for transmitting food-borne illness caused by pathogens such as *Salmonella* and *E. coli* O157:H7. Juice produced in one State and shipped and sold in another State may be contaminated with pathogens and thus may result in the transmission of food-borne illness from State to State. The record similarly establishes that juice may be produced and sold to a visiting consumer in one State, with the consumer subsequently taking the juice to a second State. Given that juice can function as a vehicle for transmitting human pathogens, this situation creates the possibility that food-borne illness will be transmitted from one State to another. In light of the record of this proceeding, FDA has concluded that a system of HACCP controls is necessary to prevent the spread of communicable disease via consumption of contaminated juice, and that the PHS Act provides the agency with the authority to establish such HACCP requirements for juice.

(Comment 75) Several comments challenged the agency's authority to require that certain records be maintained and that FDA be granted access to those records. The thrust of these comments is that the act does not explicitly authorize the agency to require food processors to maintain records or to require access to records maintained by food processors. The comments observed that section 704 of the act (21 U.S.C. 374), the act's general records access provision, contains specific authorization for agency access to records relating to drugs and restricted medical devices but that, by its terms, the authority of section 704 does not extend to records relating to foods. Thus, the comments conclude that the records access provisions of the juice HACCP proposal are unlawful.

FDA disagrees with this comment because the agency has adequate authority under the act and the PHS Act both to require the maintenance of records and to compel official access to such records for the efficient enforcement of the act. Importantly, FDA is not relying on its authority in section 704 of the act to require the keeping of HACCP records and to require official access to such records. As discussed in the response to the previous comment, in terms of the act, this final rule implements section 402(a)(4) and utilizes FDA's authority in section 701(a) of the act to issue regulations for the efficient enforcement of the act. FDA is similarly relying on sections 402(a)(4) and 701 to establish the recordkeeping and access to records requirements of this rule. That this is sufficient authority is established in the caselaw.

In particular, in *National Confectioners Assoc.* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978), the D.C. Circuit held that FDA had authority to establish recordkeeping requirements for food processors. In *Confectioners*, the recordkeeping provisions of the regulations were challenged on the grounds that they would permit prosecution where processing conditions were completely sanitary, but required records were deficient. Such an outcome, it was argued, would be beyond the scope of section 402(a)(4) of the act, one of the particular sections relied upon as authority for the regulation as a whole. The court rejected this argument, holding that the principal consideration was whether the statutory scheme as a whole justified the regulations. Although the records in question in Confectioners were coding and distribution records that FDA desired in order to facilitate recalls, the court's ruling as to the validity of the regulations was not limited to recalls or shipping records. Indeed, *Confectioners* is appropriately read to authorize FDA to establish regulations that have a limited scope, are not unreasonably onerous, and clearly assist in the efficient enforcement of the act (569 F.2d 693 n. 9). In addition, the *Confectioners* court recognized that FDA has a role both in preventing and in remedying commerce in adulterated foods, and that the act imposes on the FDA an equal duty to perform each role (569 F.2d at 694).

It is widely accepted that recordkeeping and inspectional access to records are essential components of a HACCP-type system. Through records maintenance and review, a processor can, over time, develop a comprehensive picture of its process and identify shortcomings or potential shortcomings. Similarly, records maintenance and access provide the appropriate regulatory authorities with the opportunity to oversee, in a comprehensive way, the operation of the processor's HACCP plan, thereby ensuring that contaminated juice products will not enter the marketplace.

Like the records at issue in *Confectioners*, the records at issue with respect to this final rule are designed to prevent the introduction into commerce of adulterated foods (569 F.2d at 694). In this case, the recordkeeping and access required under this final rule meet the *Confectioners* test. First, the requirements are limited. The HACCP recordkeeping and record access requirements in the final rule are tied specifically to the CCP's, i.e., those points in the process at which control is essential if there is to be assurance that the resultant product will not be injurious to health is to be achieved. Second, this limited amount of recordkeeping assists FDA in the efficient enforcement of the act. By focusing on the CCP's, the requirements ensure that the processor and the agency focus on those aspects of processing that present the greatest threat to food safety; by documenting whether the HACCP plan and its preventive controls are being followed, these records enable regulators to verify proper operation of the HACCP system or identify malfunctioning of the system, again ensuring that adulterated foods are not produced and distributed to consumers. As such, the record-keeping requirements assist in the effective and efficient enforcement of the act. Finally, the HACCP recordkeeping burden is not unduly onerous because the required records are limited to the development of appropriate controls and documenting those aspects of processing that are critical to food safety. The documentation required in the final rule is narrowly tailored to ensure that only essential information needs to be recorded and maintained. Because the preventive controls required by HACCP are essential to the production of safe food as a matter of design, the statutory scheme is benefited by agency access to records that demonstrate that these controls are being systematically applied.

Similarly, FDA's authority under the PHS Act (42 U.S.C. 264), provides a separate and sufficient basis for the recordkeeping and records access provisions of this rule, at least to the extent that these requirements relate to the transmission of communicable disease. The record of this proceeding clearly shows that juice can function as a transmitter of human disease caused by foodborne pathogens, such as *Salmonella* and *E. coli* O157:H7. Likewise, the record demonstrates that a system of preventative controls, such as those based upon HACCP, will control or eliminate this risk from juice

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consumption. As discussed in more detail below, records for the HACCP operation, and official access to these records, are central to the effectiveness of HACCP. Thus, the PHS Act clearly authorizes the records maintenance and access requirements of this final rule.

(Comment 76) A few comments stated that the factual and legal justifications for mandatory HACCP relate to the presence of pathogens in the final product, which is not true of the pasteurized juice industry. Comments maintained that section 402(a)(4) of the act does not authorize a broad range of controls and that seafood HACCP was predicated on the conclusion that there were sufficient hazards in all fishery products. One comment stated that the factual predicate relied upon in the seafood rule does not exist for juice. The comment maintained that a review of the data in the proposed rule indicates that microbiological hazards gave rise to the entire HACCP proceeding and these hazards do not exist in pasteurized and shelf stable juices.

The agency addressed the legal authority for this rule in the response to comment 74. FDA disagrees that the factual predicate for juice HACCP is not adequate. The record demonstrates that there are significant potential hazards in the production of juice, including pasteurized and shelf stable juices. These potential hazards in juice can be divided along the lines of the NACMCF food hazard definition: Microbiological, chemical, and physical. Microbiological hazards can be controlled with some type of heat treatment or other process that prevents, reduces, or eliminates the pathogens. Chemical hazards are not normally affected by heat and other treatments that are used to reduce the microbial contamination of foods and thus, must be controlled by other means (*e.g.*, rejection of incoming materials with high lead levels). Likewise, physical hazards must be controlled in some manner other than by thermal or equivalent treatments. All three types of hazards require that the specific hazard be identified (*e.g.*, bacterial species; mycotoxin identity; foreign matter present, such as glass), a means for preventing or controlling the hazard identified, and the means of control consistently and effectively used. The public health effects of microbial hazards are most often acute, although long-term, chronic effects have been identified (*e.g.*, arthritis). Chemical hazards are most often associated with chronic adverse health affects, although they may also have immediate, acute affects (*e.g.*, excess tin leaching from container lining can cause vomiting). Physical hazards cause acute health affects, such as cuts in the mouth from glass or metal fragments in the food. These hazards are discussed in more detail below.

Microbial hazards—There is a long history of foodborne illness outbreaks associated with microbial contamination of a variety of juices. The public health consequences may be minimal (some gastrointestinal distress), severe (hospitalization, HUS), or fatal. Among the pathogens that have been associated with juices are *E. coli* O157:H7, *Salmonella*, *Cryptosporidium*, and certain viruses. Identified sources of pathogens include water, fruit, processing under insanitary conditions, and infected workers and food handlers.

Juices, particularly fruit juices, have traditionally not been considered vehicles for human pathogens. Fruit juices, in particular, are acidic, and such acidity generally would inhibit the growth of most pathogens. Over the past few decades, however, it has become well documented that some pathogens have adapted to this acidic environment, making juices susceptible to microbial contamination and subsequent survival of the pathogens in the juice products.

Regarding the comment that pasteurized juices should not be subject to HACCP, is without foundation because "pasteurized" products may potentially contain chemical or physical hazards. HACCP systems control all types of food hazards, not just the microbial hazards that adequate heat treatments will control. In recognition of the lethality of the heat treatment that shelf stable and concentrated juice products receive, FDA has modified the pathogen control requirements in § 120.24 for these product groups. This modification to the proposed rule is discussed in detail in the response to comment 140.

Chemical hazards—There is also a history of foodborne illness outbreaks caused by a variety of chemical hazards in foods. These hazards include the presence of tin, lead, and poisonous plant materials. FDA recall data show that additional types of chemical substances with the potential to cause illness or injury have triggered recalls of products from the market (*e.g.*, food ingredients that cause allergic-type reactions such as FD&C Yellow No. 5), cleaning solutions, copper from copper pipe fittings on processing equipment. Symptoms of reported juice outbreaks usually are limited to acute gastrointestinal effects. Chronic effects of chemical contaminants are difficult to assess because long-term monitoring of the health of individuals that experience illness or injury caused by chemical hazards is required and there are no data indicating that this type of monitoring occurs. Some chemical hazards, such as patulin, have known chronic effects of sufficient public health concern that FDA is in the process of issuing guidance documents concerning maximum levels that should be present in foods (Refs. 19 and 24).

Sources of chemical contaminants in juices include packaging materials, plant (botanical) material, processing and cleaning equipment, formulation errors, contaminated ingredients, and contaminated fruit (*e.g.*, patulin in apples). Unlike microbial contaminants, chemical contaminants cannot be destroyed or easily removed from contaminated foods, and thus, appropriate controls must be established to prevent the contamination in the first instance.

Physical hazards—FDA recall data indicate that glass and fragments of other packaging materials frequently cause companies to recall juice products. However, the agency has no data on illnesses or injuries caused by those packaging materials.

(Comment 77) One comment stated that *United States* vs. *Nova Scotia Foods Products Corporation* cannot be read to authorize HACCP controls. The comment maintained that this case cannot be said to support FDA's proposal to impose a complex and detailed regulatory scheme on pasteurized products. Additionally, the comment stated that since FDA cannot demonstrate a need or legal justification for HACCP for pasteurized products, its authority to require recordkeeping and record inspection under such a HACCP program has no statutory basis.

In the response to comment 74, the agency has explained at some length the basis for its reliance on *United States* v. *Nova Scotia Foods*, 417 F.S. 1364, 1368–69 (E.D.N.Y. 1976), *aff'd supra, 568 F.2d 240*. Similarly, in the response to comment 75, FDA has explained at length the legal basis for the recordkeeping and records access provisions of this final rule. In sum, both the rule itself and the recordkeeping provisions are clearly authorized by the act and the PHS Act.

G. Corrective Actions

FDA proposed to require in § 120.10 that processors take appropriate corrective actions whenever a deviation from a critical limit occurs. All corrective actions must be fully documented in records and are subject to verification under § 120.11(a)(iv)(B).

(Comment 78) One comment requested that FDA revise § 120.10(a)(1) and (b)(3) to remove the wording "otherwise adulterated" because it broadens the scope of the rule beyond food safety and the focus of HACCP should be on food safety. The comment further stated that adulteration is covered in part 110 and should not also be covered in part 120.

The agency disagrees that the requested revisions are necessary. HACCP plans only address food hazards that are reasonably likely to occur. Under § 120.3(g) a "food hazard" is defined as "any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control." Thus, a HACCP plan is already focused on food safety. FDA also disagrees that adulteration is addressed exclusively by part 110. In fact, the legal basis for this final rule is, in part an adulteration provision, 402(a)(4) of the act and juice not processed under conditions not complying with this final rule is adulterated (see § 120.9).

(Comment 79) A few comments suggested that in § 120.10(b)(5) the words "timely validation" probably should be "timely verification" or "timely review" and that in § 120.13(a)(3) the term "verifying" should be used in place of "validating" to be consistent with NACMCF's HACCP guidelines.

The agency agrees with the comments. When there is a process deviation, processors must undertake a review to see if there have been sufficient changes such that a revalidation of the HACCP plan is warranted. The fact that processors have discovered a deviation indicates that the HACCP plan is working. Therefore, FDA is modifying § 120.10(b)(5) to use the term "timely verification" and § 120.13(a)(3) to use the term "verifying." As noted previously, the agency is defining the terms "validation" and "verification," in § 120.3(p) and (q), respectively.

H. Verification and Validation

(Comment 80) One comment requested that FDA not require a review of consumer complaints in the HACCP program. The comment maintained that review of consumer complaints is untimely because the product has already been processed and reached the consumer. Additionally, the comment stated that consumer complaints, or lack thereof, cannot attest to the effectiveness of a process. Another comment suggested that it should be up to the management to determine which consumer complaints need followup in relation to HACCP compliance. One comment stated that only consumer complaints that indicate a deviation should be held for HACCP review.

The agency disagrees that processors should not review consumer complaints as part of their HACCP programs. The agency recognizes that review of consumer complaints is of limited use as a preventive tool because the consumer making the complaint already has the product. However, such review may alert the processor to a problem that, if resolved, would prevent recurrence of the problem with other consumers. The agency also recognizes that the receipt or absence of complaints does not alone attest to the adequacy of a HACCP system. However, it is FDA's experience that consumer injury or illness complaints can identify problems traceable to inadequate controls at the food processing facility (Ref. 61). Where information that has potential relevance to food safety is available to a processor as a result of its own consumer complaint system, it is entirely appropriate for the processor to consider that information in assessing the adequacy of its HACCP program. FDA concludes, therefore, that processors should evaluate, as part of their HACCP verification procedures, the consumer complaints that they receive to determine whether the complaints relate to the adequate performance of control measures or reveal unidentified hazards.

FDA agrees that it is up to management to determine which consumer complaints need followup in relation to HACCP compliance as part of its verification procedures. This final rule does not require that processors hold consumer complaints for HACCP record review, except as the processor deems necessary as documentation of verification procedures.

(Comment 81) One comment requested that FDA revise § 120.11(a)(1)(iii) by adding at the end of the sentence "where these are other than standard operating procedures or CCP's" to clarify that testing required under standard operating procedures or CCP's is not optional.

The agency disagrees that the requested revision of § 120.11(a)(1)(iii) is appropriate. The requested revision would make the testing mandatory as part of verification activities for SOP's and CCP's. This was not the intent of the provision. In the preamble to the proposal, the agency acknowledged the shortcomings of end-product testing as a process control, especially microbiological testing, but encouraged inclusion of testing in HACCP systems where it is appropriate. SOP's and CCP monitoring requirements do not necessarily need to be end-product or in-process tested, except where FDA is requiring end-product testing. Monitoring could consist of ensuring that the product was processed within time/temperature parameters or time/sanitizer concentration parameters. Therefore, FDA is not making the requested modification.

(Comment 82) One comment suggested that verification should include actual times and temperatures taken and recorded and that there should be penalties for noncompliance.

The agency agrees with the comment. Verification activities include timely review of monitoring records in accordance with § 120.11(a)(1)(iv). Monitoring records must include actual measurements (*e.g.*, times and temperatures) in accordance with § 120.8(b)(7), except as exempted by § 120.24. Consequently, verification must include checking the actual measurements that are recorded in the monitoring records. As proposed, the rule has an enforcement mechanism. Specifically, under § 120.9, failure of a juice processor to have and to implement a HACCP system in accordance with part 120 will render the juice products of that processor adulterated under section 402(a)(4) of the act. Penalties for noncompliance are FDA refusing entry to imported products and instituting legal actions such as seizure, multiple seizures, or injunction, against unlawful products or their producers.

(Comment 83) One comment maintained that weekly review of production records is inadequate and suggested that records be reviewed before each batch of product leaves the plant.

FDA disagrees with the comment. The agency stated in the proposed rule that weekly review of HACCP monitoring and corrective action records would provide the industry with the necessary flexibility to move a highly perishable commodity like fresh juice through processing and distribution without interruption, while still facilitating timely feedback of information. FDA notes that the comment provided no information to demonstrate that weekly review of records is inadequate. In fact, weekly record review will quickly indicate whether the HACCP system is out of control on a regular basis, which is a sign that the system is not adequate to assure safety and that revalidation of the system is required. Thus, the agency concludes that weekly review of monitoring and corrective action records is adequate for verification purposes. FDA notes that the requirement for weekly review does not preclude a processor from reviewing

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production records on a more frequent basis if the processor wishes to do so.

(Comment 84) One comment suggested that FDA revise § 120.11(a)(1)(iv)(A) to provide for values that are outside critical limits and for which corrective actions are taken (covered in § 120.11(a)(1)(iv)(B)).

The agency disagrees that the requested revision of § 120.11(a)(1)(iv)(A) is necessary because under § 120.11(a)(1)(iv)(B) processors must review records to ensure that the records are complete and to verify that appropriate corrective actions were taken. Therefore, FDA is not making the requested modification.

(Comment 85) Several comments pointed out that the proposed annual validation requirement in § 120.11(b) is not consistent with NACMCF HACCP guidelines. The comments requested that, instead, FDA require validation whenever there are significant process changes or equipment/system failures.

The agency is not persuaded that it should modify the requirement for annual validation. Section 120.11(b) is consistent with the NACMCF HACCP guidelines in that processors must validate their process as needed (Ref. 17). The NACMCF provided as examples whenever there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized. FDA has simply defined "as needed" as at least annually or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Therefore, FDA is not modifying § 120.11(b) as the comments requested.

(Comment 86) One comment requested that FDA not require a processor to validate the HACCP plan any time changes occur in the prerequisite programs. The comment requested that FDA revise § 120.11(b) to delete this requirement.

The agency agrees with the comment. It is rare that a change in SSOP's will make the HACCP plan ineffective. Validation is not a paper exercise and may be time consuming and expensive. Therefore, FDA is modifying § 120.11(b) to delete the proposed requirement. FDA notes that the final rule requires revalidation when there is any change in the process, including a change in the SSOP's, that decreases the effectiveness of the HACCP plan.

(Comment 87) One comment expressed concern that the proposed validation requirements would have the effect of locking producers into one supplier and that this would stop product development and innovation.

The agency does not agree with the comment. All food processors must take safety considerations into account when contemplating changes in their processes, regardless of whether they are operating under a HACCP system. The agency recognizes that validation could be costly if frequent changes are made in the process that could affect the hazard analysis or alter the HACCP plan and, thus, processors may be reluctant to make changes, even if the changes have the potential to improve the process or the safety of the final product. A change in the supplier of raw ingredients may be a change requiring revalidation. However, a prudent processor will check new suppliers before making any changes to determine that the supplier will not be a source of any safety concerns. Because HACCP systems need to be revalidated only when changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way, not every change will require revalidation. Similarly, because a hazard analysis needs to be revalidated only when there are process changes that could reasonably be expected to affect whether a food hazard exists, not every process change will require revalidation of the hazard analysis. Therefore, FDA concludes that the requirements of § 120.11(b) and (c) are important for the public safety and will have minimum impact on conscientious processors.

I. Records

The agency proposed that processors maintain records documenting their HACCP system. FDA also proposed general record requirements, and other provisions or requirements dealing with documentation, record retention, official review, public disclosure, and records maintained on computers.

(Comment 88) One comment was concerned that the agency was trying to get access to processors' CGMP records under § 120.12(a)(1) and that this could be a disincentive for companies to keep thorough records.

The agency disagrees with the comment. Section 120.12(a)(1) requires that processors maintain records documenting the implementation of the SSOP's in § 120.6. SSOP'S are select CGMP sanitation requirements that the agency believes are so important to the effective implementation of HACCP that they require separate, specific provisions. The agency believes that the sanitation controls in § 120.6 are of significant importance to the proper implementation of HACCP because sanitation controls, such as controls preventing contamination from pests, have a direct impact on the presence or absence of pathogens during processing, which in turn, directly affects the effectiveness of the HACCP plan. Access to specific SSOP records is important to investigators making reasonable judgements about whether the HACCP plan is working properly. Accordingly, the final rule requires that SSOP records must be maintained and made available during inspections. However, the agency has no intention of requiring, and processors need not make available to FDA, any other CGMP-related records.

(Comment 89) One comment recommended that the agency delete from the regulation any reference to records for end-product or in-process testing. The comment stated that individual processors would keep testing records for FDA review only if it is part of the verification of their HACCP plan.

The agency disagrees that any modification of the regulation is necessary and is not making the requested change. The regulation only requires that end-product or in-process testing records associated with verification of the HACCP plan be available for FDA review and thus, is consistent with the comment. As discussed in section III.L.6, the agency is establishing periodic end-product testing requirements for purposes of process verification of citrus juices that use fruit surface treatment to achieve the 5-log reduction in the pertinent pathogen; processors are required to provide FDA with access to these records.

(Comment 90) One comment stated that a processor with only one location should not have to provide its location on all records, as required in § 120.12(b)(1).

The agency agrees with the comment and is modifying § 120.12(b)(1) to read as follows: "The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location."

(Comment 91) Two comments stated that date and time may not be necessary on all records. One comment contended that the date and time are only important on monitoring and corrective action records and, therefore, should only be required on these records.

The agency believes that the date of the activity is important on all HACCP records. The date allows the processor and the FDA investigator to assess whether the record is current, to identify when any deviation occurred, and to track corrective actions. However, the time of an activity is not necessary on records other than

monitoring and corrective action records (*i.e.*, it is not necessary on the hazard analysis or HACCP plan). Therefore, the agency is modifying § 120.12(b)(2) to state that the time of the activity need not be included on records required under § 120.12(a)(2), (a)(3), and (a)(5).

(Comment 92) One comment suggested that there is no need for the hazard analysis to be signed unless there is no HACCP plan because the hazard analysis did not indicate the need for a HACCP plan.

FDA disagrees with the comment. The signature of the most responsible individual onsite at the processing facility or by a higher level official of the company is important for both the hazard analysis and the HACCP plan. The signature reflects the fact that management has reviewed, accepted, and is responsible for the content of the hazard analysis and any resulting plan. Therefore, the agency concludes that both the hazard analysis and any resulting HACCP plan must be signed.

(Comment 93) One comment suggested that the final rule should allow initialing of records instead of a signature, as is done with low acid canned foods.

The agency disagrees with the comment. The food canning establishment registration and the food process filing form for low acid canned foods both require the signature of an authorized individual. Other low acid canned food records must be signed or initialed (§ 113.100). Part 120 has similar requirements for juice product records. Section 120.12(b)(3) states that all records shall include the signature or initials of the person performing the operation or creating the record. However, given their centrality in a HACCP program, it is important that the hazard analysis and the HACCP plan be reviewed and authorized by the most responsible individual onsite at the processing facility or by a higher level official of the processor so as to signify that management of the firm is aware of and has accepted these records (§ 120.12(c)). Therefore, the agency is not modifying part 120 to permit the initialing of the hazard analysis and the HACCP plan.

(Comment 94) One comment argued that consumer complaints often involve quality issues and are primarily handled at headquarters facilities, not processing plants. Therefore, the comment stated that consumer complaint records should not be part of HACCP recordkeeping requirements.

The agency points out that consumer complaint records are not required to be maintained or access given to them under part 120. Processors are required to review consumer complaints as a part of their verification procedures (§ 120.11(a)(1)(i)) to determine whether complaints relate to the performance of the HACCP plan or to reveal previously unidentified hazards. Processors may choose to include consumer complaints in their HACCP records to document verification of the HACCP system, but it is not required.

(Comment 95) One comment stated that the period that records must be held is out of line with product shelf life because fresh juice only lasts 14 days. The comment suggested that records could be kept for 3 months rather than 1 to 2 years.

FDA disagrees with the comment. Some problems, such as trends in the frequency of process deviations, may not be easily recognized in a "snapshot" record review. By reviewing records covering a longer period of time, a processor may be able to identify certain process deviations. Moreover, while it may be true that most fresh products will be unusable within 3 months, some products are processed for longer shelf-life (such as flash pasteurized, refrigerated juices), and retention times of less than 1 year do not provide for sufficient information for the processor's or FDA's verification activities. (See § 120.11(b).) Therefore, FDA has made no changes to § 120.12(d)(1).

(Comment 96) One comment requested that FDA revise § 120.12(d)(1) to read "Subject to part § 120.14, all records required by this part * * *," because there are other importer requirements for recordkeeping outlined in § 120.14.

The agency disagrees with the comment. Section 120.12(d)(1) requires both processors and importers to retain all records required by part 120. Under § 120.12(d)(1), importers must retain the records required under § 120.14 at the importer's place of business in the United States. Therefore, the agency concludes that the modification is not necessary.

(Comment 97) One comment noted that proposed § 120.12(d)(2) requires processors to maintain records related to the adequacy of equipment or processes. The comment stated that if equipment is old or modifications have been made to it, firms may have trouble getting a letter to that effect from the manufacturer. Therefore, the comment stated, scientific studies will have to be performed to determine adequacy, which will be costly, especially for small processors. The comment stated that the requirement is not consistent with parts 113 and 114. It stated that a written communication summarizing requirements to achieve an adequate process would be adequate.

FDA has reevaluated the provision in § 120.12(d)(2) and concludes that it does not afford any additional significant protection to consumers and may add unnecessary burdens for processors. Therefore, the agency is deleting § 120.12(d)(2) and recodifying paragraphs § 120.12(d)(3) and (d)(4) as § 120.12(d)(2) and (d)(3), respectively.

(Comment 98) One comment suggested that FDA restrict recordkeeping requirements to records produced at the manufacturing facility. The comment stated that data used to establish processes should be maintained by the individual or organization that developed the record, not by the processing plant.

FDA disagrees with the comment. It is vital that each processing plant maintain or have access to all records required under part 120, that pertain to products produced by that plant for purposes of both processor review and FDA inspections. The agency has made provision for offsite storage of records, to the extent feasible, to reduce plant storage burden. Specifically, under § 120.12(d)(2), electronic records are considered to be onsite if they are accessible from an onsite location and comply with § 120.12(g). In addition, under § 120.12(d)(2), offsite storage is allowed for certain monitoring records after 6 months following the date that the monitoring occurred as long as the records can be retrieved and provided onsite within 24 hours. Finally, under § 120.12(d)(3), seasonal processors may store records at a reasonably accessible location at the end of the seasonal pack.

Records (such as the hazard analysis, HACCP plans, and verification, including validation, records for products processed in the plant) are needed by both the processor and FDA to determine whether the HACCP system or systems are properly implemented and effective. HACCP systems and associated records may be tailored to each specific processing facility and for different products processed in the facility. Therefore, the agency concludes that all records required by part 120 must be retained at the processing facility to which they relate (or reasonably accessible when offsite storage is permitted) or at the importer's place of business in the United States. As discussed in previous comments, FDA recognizes that processors may review information (*e.g.*, consumer complaints) to develop/evaluate their systems that is not required to be maintained and to which processors are not required to grant FDA

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access. Processors may maintain this information at any location that is convenient for the processor.

(Comment 99) One comment pointed out an inconsistency between the preamble to the proposed rule that stated that after 6 months the SSOP and HACCP monitoring and corrective action records could be stored offsite, and the codified language in proposed § 120.12(d)(3) that refers to the storage of SSOP records and the HACCP plan offsite.

FDA agrees that the proposal's preamble and codified were inconsistent. The agency realizes that some juice processors may be required to store records that could require a great deal of space (*e.g.*, the SSOP and HACCP monitoring and corrective action records) and that there may not be adequate storage space in the processing facility for all of these records. However, because of their direct relevance to ensuring safe processing operations at a facility, FDA has concluded that records dealing with the HACCP plan must remain on site for at least 6 months. After that period, such records may be stored off-site if they can be retrieved and returned on-site to the plant within 24 hours so that plant managers and FDA investigators have ready access to the records for use in evaluating the effectiveness of the HACCP plan. Therefore, FDA is modifying § 120.12(d)(2) to refer to paragraphs (a)(1) and (a)(4) instead of (a)(1) and (a)(3).

(Comment 100) One comment requested that FDA delete § 120.12(e) because the agency does not have the statutory authority to see consumer complaints.

The agency advises that consumer complaints are not required records under § 120.12(a) and the rule does not seek to require that FDA be given access to such records. Thus, the agency concludes that no action is necessary in response to this comment.

(Comment 101) Several comments expressed concern about the confidentiality of records associated with an abandoned process. They stated that a manufacturer's processing methods are often considered trade secret even for products that have been abandoned. The comments suggested that the agency make provisions for this in the final rule and handle abandoned product records in the same manner as existing product information. One comment added that current process lines may use technology similar to that used for an abandoned product and that abandoned products may be brought back into production.

The agency advises that the agency intended that proposed § 120.12(f) not permit public disclosure of processing records except where they have been previously disclosed to the public or where they relate to an abandoned product or ingredient and are no longer trade secret or confidential commercial or financial information. FDA acknowledges that the proposal was less than clear as to the status of an abandoned product process. To clarify the final rule, FDA is striking the work "thus" from § 120.12(f) so that the trade secret status of a product process may be maintained by the processor and the information not necessarily subject to public disclosure even though the particular product has been abandoned. The public availability of such information will be evaluated by FDA on a case-by-case basis.

(Comment 102) Several comments requested that HACCP documents in FDA's possession not be made available under the Freedom of Information Act (FOIA).

FOIA provides consumers and others with the opportunity to obtain records in the possession of Federal agencies, including FDA, upon request. There are, however, some restrictions on the types of records available under FOIA. For example, confidential commercial information and trade secrets are exempt from disclosure 5 U.S.C. 552(b)(4). The agency concluded in the seafood HACCP final rule (60 FR 65096 at 65138) (Ref. 62), that HACCP plans, as a general rule, meet the definition of trade secret information, and thus, even if these plans are in agency files, they likely would not be available under FOIA. However, because FDA is bound by FOIA and the agency's implementing regulation in 21 CFR part 20, the agency is unable to exclude categorically all HACCP records in agency files from public disclosure.

J. Training

The agency proposed that only individuals trained in HACCP be responsible for certain key functions in a HACCP system. The agency is correcting an error in § 120.13(a)(3), as proposed, so that the section references § 120.10(b)(5) instead of § 120.10(c)(5) because there is no paragraph (c)(5).

(Comment 103) Several comments requested that FDA provide training for the juice industry.

FDA has limited resources to use for training. Therefore, the agency has no plans at present to provide specific HACCP training for the juice industry. However, the agency is interested in cooperating with States and the industry in the development of training programs. FDA worked with the Seafood Alliance to develop a seafood HACCP curriculum and training courses. A similar cooperative effort would be very beneficial in juice processing. Also, the agency is in the process of developing a juice HACCP hazards and controls guide, which will assist juice processors in the development of their HACCP systems.

(Comment 104) One comment questioned whether the agency will acknowledge the equivalency of juice HACCP training, as mentioned in § 120.13(b), offered by other parties (such as a trade association or academic institution) as it did for seafood HACCP. The comment asked how and who would determine training adequacy. Another comment suggested that equivalency of training programs would be better dealt with by establishing training objectives, such as the system used in meat and poultry HACCP, rather than specific materials and curricula.

FDA believes that the development of seafood HACCP training, through the Seafood Alliance, was beneficial for all parties. A basic curriculum was developed, which the agency reviewed, that was available for the industry's use. The agency has encouraged trainers to evaluate their courses against the materials developed by the Alliance and to make modifications necessary to ensure that programs were consistent with and provided at least an equivalent level of instruction to the Alliance course. FDA is very interested in cooperating with all interested parties, including academia, consumer groups, and the juice industry, to develop training programs that incorporate the most appropriate objectives and materials. FDA will acknowledge the equivalency of training in the same manner as is done for seafood HACCP.

(Comment 105) One comment argued that criteria for adequate HACCP training should be left up to the States to determine, but did not provide any support for this opinion. The comment also asked that FDA provide States with guidance and funding to carry out HACCP training for existing State personnel and to certify HACCP specialists.

The agency currently intends to provide training to States, through contracts and State partnerships. The agency recognizes that the effectiveness of juice HACCP hinges on consistent implementation and regulation throughout the United States and training, particularly for investigators, plays an important role in such consistency. As noted above, FDA is interested in cooperative work with

States, academia, and industry to develop training programs.

(Comment 106) One comment stated that individual companies should be permitted to determine when experience can substitute for HACCP training. Another comment argued that experience can never substitute for training, although the comment contained no data or other information to support the claim.

FDA believes that in certain circumstances, appropriate job experience can be an adequate substitute for formal HACCP training. FDA is aware that some juice processors have had successful HACCP programs in place for a long period of time and, as a result, employees working with those systems have gained a working knowledge about HACCP that is more than adequate to meet the training requirement. Moreover, FDA's experience is that other segments of the food industry have HACCP programs in place and employee experience gained working with those systems may be transferred successfully to juice processing. It is the responsibility of processors to determine that their HACCP system is functioning appropriately and is in compliance with part 120, a responsibility that includes ensuring that those individuals involved in designing and implementing the HACCP system are qualified.

(Comment 107) One comment suggested that FDA develop a test to determine whether particular job experience can substitute for HACCP training. The comment asked if FDA is developing such a test.

FDA has no plans to develop a test to determine whether job experience can substitute for HACCP training. Job experience that is equivalent to training gained under an adequate standardized HACCP curriculum is certainly one way that individuals may gain the training required in § 120.13(a). However, as noted, it is the responsibility of individual companies to ensure that qualified individuals conduct the hazard analysis and develop the HACCP plan, whether such individual is qualified through training or job experience.

K. Application of Requirements to Imported Products

The agency proposed in § 120.14 specific requirements for importers of juice products because FDA typically does not inspect foreign food establishments. Under § 120.14 of the proposed rule, importers of juice either must ensure that all juice offered for entry into the United States has been processed in compliance with part 120 or import such juice from a country that has an appropriate memorandum of understanding (MOU) with the United States. In addition, importers must maintain records that document the performance and results of the affirmative steps taken to demonstrate compliance with § 120.14.

(Comment 108) Several comments contended that the juice HACCP regulation should not apply to imports. However, other comments disagreed. A few comments suggested that only imported fresh juice be covered, not juices that have been documented to have been thermally processed to meet the 5-log performance standard.

The agency advises that this final rule will cover all imported and domestic fresh or processed juices. First, under the act, all products in interstate commerce, whether imported or domestic, must adhere to the same standards. Moreover, imported juices may have many of the same potential food hazards as domestic products. FDA discussed outbreaks associated with imported juices in the proposed rule (63 FR 20450 at 20450) (Ref. 2), and some of the recent outbreaks discussed in response to comment 26 were associated with imported juice (Refs. 46 and 47). In addition, imported juices may contain food hazards not normally associated with domestic products. The differences in the types of food hazards may be the function of a number of factors, including differences in processing systems and sources of raw ingredients. The fact that HACCP is based on prevention of specific hazards makes it applicable, in general, to food processing wherever the processing occurs. Therefore, the agency agrees with those comments that stated that the rule must apply equally to imported and domestic juice products, because the potential risks are the comparable. The safety of juice must be ensured regardless of where it is produced.

(Comment 109) One comment suggested that FDA clarify the reference to "imported food" in the introductory sentence of § 120.14 to identify that juice is the specifically covered product.

The agency agrees with this suggestion and has revised the introductory sentence of § 120.14 by replacing the word "food" with the word "juice."

L. Process Controls

1. Performance Standard

The agency proposed to require that juice processors, except those that are subject to part 113 or part 114, include in their HACCP plans control measures that will produce at least a 5-log (10^5) reduction in the pertinent microorganism. As proposed, the pertinent microorganism means the pathogen that is likely to occur in juice and that is most resistant to the pathogen reduction technology used and, if it occurs, is likely to be of public health significance. The proposed reduction must be for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions.

(Comment 110) Several comments advocated a regulatory scheme of HACCP without the performance standard proposed by FDA. The comments argued that a performance standard is not necessary to ensure the safety of all products (*e.g.*, citrus). Comments stated that requiring a performance standard negates the strength and function of HACCP and indicates that FDA does not trust HACCP alone. The comments asserted that FDA should require either the performance standard or HACCP, but not both.

The agency disagrees that having the performance standard as an integral part of HACCP weakens the HACCP system. As NACMCF has pointed out, the performance standard enhances HACCP by establishing the appropriate level of health protection that must be achieved (Ref. 25). The 5-log reduction performance standard assures public health protection for consumers and assists processors by establishing a minimum microbial standard for safe juice. Particularly for non-heat treated juice, the 5-log reduction requirement provides a standard against which processors can measure the effectiveness of combinations of HACCP controls. Including a performance standard as part of HACCP sets a goal for processors without mandating the means by which they must achieve that goal and also provides a means of determining the equivalence of alternative strategies for controlling pathogens. Finally, FDA disagrees with the suggestion that a performance standard alone will ensure safe juice. As noted previously, there are hazards in addition to microbial contamination, and a performance standard alone does not address the chemical and physical hazards that may be present in juice.

(Comment 111) Many comments stated that the final rule should identify a safety goal instead of a performance standard and let industry decide how to meet it.

FDA points out that the performance standard in § 120.24 is a microbial safety goal and that the final rule allows the industry to decide how to achieve the safety goal. Elsewhere in this

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preamble, FDA has included guidance on the application of the 5-log standard, and FDA also intends to issue a juice HACCP hazards and controls guidance. Both of these forms of guidance are available to the juice industry to help in deciding how to achieve the safety goal. Therefore, the agency concludes that no modification is necessary in response to this comment.

(Comment 112) A few comments suggested that producers who do not use dropped fruit should be able to use HACCP without a performance standard. One comment contended that a 5-log reduction is not necessary when the source of the fruit is known and processors follow CGMP's.

This comment did not provide evidence to persuade FDA that using tree-picked fruit, along with HACCP, would make the 5-log performance standard unnecessary. In fact, produce, in general, including tree picked fruit, may not be pathogen free. Agricultural water, birds, insects, and harvesters are vectors that can potentially contaminate produce even though the produce has not come into contact with the ground. Even if pathogens are present on or in the produce used to make juice, processors can make safe juice by attaining the 5-log reduction performance standard.

(Comment 113) Many comments stated that the 5-log performance standard was not appropriate because processors would have to pasteurize their juice to meet the standard. A few comments stated that the 5-log performance standard is unreasonable, counterproductive, and precludes consideration of harvesting and farming practices that help ensure safety.

The agency disagrees with the comments. The performance standard in § 120.24 allows for the use of alternative technologies. The basis for 5-log is discussed in response to comment 124. As noted in section III.L.4, application of 5-log must occur where the treatment has direct contact with any and all pathogens that may be present. For most juices, this will entail direct treatment of the juice after extraction. For citrus juice only, the available data and information show that surface treatments can be used to meet all or part of the performance standard. In either case, treatments should be applied at a single location under the processor's control and immediately before packaging, in order to prevent post-process contamination of the juice. Although fruit producers and juice manufacturers are encouraged to follow GAP's, GAP's such as water and manure management are generally aimed at minimizing the potential for contamination rather than eliminating pathogens that may be present. Thus, use of GAP's would not be a substitute for the 5-log reduction treatment.

(Comment 114) A few comments suggested that, in addition to the 5-log reduction performance standard, producers should be given the option that Food Safety and Inspection Service (FSIS) gives for fermented sausage, which is batch testing to determine that the product contains less than a certain level of pertinent pathogens and then use a 2-log reduction on the batch tested.

FDA disagrees with the comments' suggestion. Juice is significantly different from a fermented meat product in that a fermented meat product is typically inoculated with bacterial cultures as part of the production process. The growth of the added microorganisms modifies the food environment so that pathogenic bacteria are inhibited or inactivated; there is no comparable inoculation and inhibition activity with juice. Moreover, this process occurs over an extended period of time (3 to 6 weeks is common), which allows time for test results to be completed. Juice, especially juice that is minimally processed, must be processed and consumed within a significantly shorter period than fermented products and, thus, extensive microbial testing of finished, processed products is not practical. Therefore, because there is no counterpart in juice processing to the inhibition or inactivation of pathogens by an added bacterial culture, the agency concludes that batch testing to establish that juice contains a minimum level of pertinent pathogens followed by a 2-log reduction in the pertinent pathogen is not an appropriate substitute for the 5-log reduction performance standard.

(Comment 115) Several comments maintained that there are no data to show that certain combinations of preventive steps are not adequate to ensure juice safety. One comment argued that a combination of grading, washing, sanitation, and current extraction techniques are sufficient to meet the 5-log reduction.

FDA is not prohibiting the use of appropriate cumulative controls to attain the 5-log reduction for citrus products. However, as discussed in section III.L.4, FDA has determined that the 5-log reduction must occur where the treatment has direct contact with all pathogens, if they are present. Further, cumulative controls must be completed in a single production facility under the control of the processor, be effective against the pertinent pathogen, be validated, and be vigorously implemented to ensure that the full 5-log reduction is consistently achieved under commercial processing conditions. GAP's and CGMP's that do not meet these criteria would be in addition to, but not count as part of, the 5-log reduction. The agency notes that it is the responsibility of the processor to demonstrate that combinations of preventive steps are adequate to achieve the 5-log pathogen reduction standard.

(Comment 116) A few comments expressed concern that no attention was being given to preventing the presence of pathogens in juice.

Prevention of pathogens in juice is the reason HACCP was proposed and is being finalized. The agency has always taken the position that food safety is enhanced by the use of the highest quality incoming materials. The agency strongly encourages growers to implement preventive controls and has issued GAP guidance to assist growers in the production of safe produce that is not contaminated. FDA is issuing part 120 to assist processors in establishing preventive controls. Specifically, § 120.7(b) provides that the hazard analysis shall include hazards that can be introduced both within and outside the processing plant environment, including hazards that can occur before, during, and after harvest. In addition, § 120.7(d) requires that processors evaluate product ingredients to determine their potential effect on the safety of the finished food.

(Comment 117) One comment requested that FDA explain how the performance standard applies to each different juice (apple, citrus, vegetable, and blends).

FDA advises that the performance standard in § 120.24 applies to all juice, including blends of more than one type of juice. Processes for attaining a 5-log reduction will vary significantly depending on the target pathogen and the type of juice produced. Therefore, it is up to each processor to determine how best to apply the performance standard to its process. FDA intends to develop a juice HACCP hazards and controls guidance for juice that will provide processors information on the application of the performance standard in addition to that provided in this final rule. The scientific literature is another source of information for processors on recent developments to attain the 5-log reduction for various types of fruits and vegetable juices. Guidance documents from State agencies may also provide information.

(Comment 118) One comment suggested that all processors should be required to meet the chosen performance standard the same way.

The agency disagrees with the comment. FDA specifically chose not to mandate that processors use a particular method to meet the performance standard in order to provide flexibility and to encourage innovation. Different methods that have been validated to meet the 5-log reduction standard can be effective in controlling pathogens to the appropriate level, which is the goal of the performance standard. Mandating a specific technology for processors to use would eliminate the incentive for processors to develop new and possibly improved alternative methods. FDA does not want to limit innovative approaches to achieving food safety or the flexibility for processors to choose the most appropriate method for a particular operation.

(Comment 119) Some comments requested a zero tolerance for *E. coli* O157:H7 in juice. One comment was concerned that the NACMCF may have recommended a higher threshold of risk than consumers would consider acceptable. It stated that there is no acceptable level of risk with regards to *E. coli* O157:H7 because it is so virulent that a single organism could be deadly. The comment sought scientific evidence that the 5-log performance standard will truly kill these organisms, as opposed to represent a reasonable number of organisms killed.

The agency disagrees with the comments. FDA notes that no food processing method can be shown scientifically to achieve a "zero" level for a pathogen or any other contaminant potentially present in the processed food due to the detection limits of the relevant analytical methods. For example, the methods used to detect *E. coli* in juice in several State surveys had a detection limit of < 1 cell per 3.33 milliliter (mL) juice. Thus, a negative result does not necessarily mean that the microorganism is not present, just that it is not present at detectable levels. Furthermore, if pathogens are not distributed homogeneously throughout a product, they may be present in the product but not in the sample tested. Conversely, food processing methods can be shown scientifically to reduce, by mathematical increments (*i.e.*, by "logs"), the level of pathogens that may be present in juice and, as a result, to reduce the risk of illness from juice. FDA has received no comments to undermine the assumption based on the NACMCF recommendation that the 5-log performance standard will adequately protect consumers from *E. coli* O157:H7 and other pathogens.

(Comment 120) One comment contended that a 5-log performance standard is unenforceable and that FDA should set pathogen reduction goals similar to those established for meat and poultry.

FDA disagrees that the 5-log performance standard is unenforceable. The reasons FDA did not set a zero tolerance for pathogens, as was done for certain pathogens in meat and poultry, already have been discussed in the response to comment 114. By virtue of the requirements of part 120, FDA believes that the performance standard is enforceable. That is, as part of their HACCP plan, processors must have a validated procedure for achieving a 5-log reduction in the pertinent pathogen for their process and also must have documentation to demonstrate to FDA that the standard is being achieved. Processors who cannot meet these requirements will not be in compliance with part 120 and thus, will be subject to regulatory action.

(Comment 121) A few comments suggested that FDA use "safe harbor" guidelines rather than require the 5-log reduction to ensure juice safety.

The comment did not define the term "safe harbor." FDA assumes, however, that by "safe harbor", the comment means that FDA would provide guidance, such as times and temperatures for thermal treatments, that, if complied with, would be deemed to achieve the 5-log reduction, thus providing a basis to conclude that the processor is in compliance with § 120.24. FDA is currently working with industry to develop guidance on how to achieve the 5-log reduction, and has already met with the apple industry and citrus juice industry to discuss technological options for achieving the performance standard. Although the agency is developing guidance to assist processors in achieving the 5-log reduction, FDA does not intend such guidance to provide a "safe harbor". Thus, juice processors will not be absolved from adopting HACCP and demonstrating through validation and verification that they have met the performance standard.

(Comment 122) One comment noted the statement in the agency's PRIA statement (63 FR 24254 at 24264) (Ref. 6) that other methods of meeting the performance standard may not be as effective as pasteurization or prevent as much illness seems to indicate an agency lack of confidence in methods other than pasteurization.

FDA disagrees with the interpretation of the PRIA statement. The statement referenced from the PRIA reads "To the extent that processors adopt controls for these hazards other than flash pasteurization which are less effective, the percentage of cases prevented may be smaller than those estimated here." The benefits of the rule with regard to illness prevention were developed based on the amount of illness that would be prevented if all juices were pasteurized because, at the time the proposal was published, pasteurization was the primary effective, commercially implemented method for controlling pathogens in juice that had been validated to meet the performance standard. Since the publication of the proposal, it has become evident that there may be methods other than pasteurization, some of which may require FDA approval for their use, that could be used to treat juice (*e.g.*, use of UV irradiation, high pressure). While it is true that pasteurization treatments significantly exceed the 5-log pathogen reduction performance standard, the statement in the PRIA was not intended to imply that methods other than pasteurization are not effective at preventing illness or that these other methods cannot meet the 5-log reduction performance standard.

(Comment 123) One comment noted that pasteurization would add a complicated and unnecessary step to cider production that will take time and require documentation.

FDA is not requiring in this rulemaking that juice be pasteurized. This rulemaking requires that juice be processed under a HACCP system that contains a control or controls that have been validated to achieve a 5-log reduction in the target pathogen. A juice processor may choose to meet the 5-log reduction requirement by pasteurizing product or by any other validated means. Although pasteurization is the primary option available for cider at this time, this final rule does not preclude the development or use of alternative technologies to achieve a 5-log reduction. For example, FDA recently amended the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products (65 FR 71056, November 29, 2000) (Ref. 75). Importantly, however, the processor chooses to meet the 5-log reduction requirement, the process utilized by the processor must be validated and verified as achieving a 5-log reduction in the pertinent microorganism. The risks associated with consumption of cider and other juices are well established (see 63 FR 20450 (Ref. 2) and section II.C of this final rule) and justify regulatory requirements that processors establish controls for pathogens and the other hazards associated with juice.

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2. Magnitude of Reduction

(Comment 124) Many comments questioned the scientific basis for the 5-log reduction performance standard. A few comments contended that it was too stringent based on actual numbers of ubiquitous coliform bacteria found in cider in State surveys. In support, a survey submitted as part of a comment questioning the basis of a 5-log reduction standard showed that samples of apples in cider mills in Maryland contained an average of only 3-logs of ubiquitous coliform bacteria and no generic *E. coli* or *E. coli* O157:H7. Some comments asserted that a 5-log performance standard is premature considering that the source of *E. coli* O157:H7 contamination in apple juice is not known and suggested that FDA adopt a 3-log performance standard until scientific data are developed to support the need for a 5-log standard. The comments stated that without data to provide baseline numbers for contamination of juice, any performance standard selected might be inappropriately stringent or lax. The comments maintained that the 5-log standard is particularly excessive if a processor is using CGMP's and only uses prime fruit.

Conversely, one comment suggested that the 7-log performance standard used by other high risk food processors would afford more consumer protection. It suggested that the agency compare the protection offered by 5, 6, and 7 log performance standards because *E. coli* keeps proving to be more resistant to controls than previously thought and because a 5-log reduction may not be adequate for all strains of *E. coli*.

FDA discussed the cider survey results in the response to comment 36. In that discussion, the agency noted the limitations of the analytical methods and advised that the survey results did in fact affirm that risk factors such as fecal coliforms, an indicator of the possible presence of pathogens, are present in cider operations and could give rise to microbial food safety hazards in the finished juice.

In establishing the 5-log standard, FDA is relying on the advice of a panel of recognized food safety experts, the NACMCF. In making this recommendation, the Fresh Produce Working Group of the NACMCF considered various situations that could occur with juice (Ref. 63). First, they considered what levels of *E. coli* might typically occur in juice and added a standard 100-fold safety margin. The Working Group then considered a worst case scenario where produce could be contaminated with bovine feces, a source of *E. coli* O157:H7. They determined that a 5-log reduction would both eliminate the *E. coli* O157:H7 contamination and provide a safety margin. In addition to the information factored into determination of the 5-log reduction performance standard, regulatory precedents were considered. The 5-log pathogen reduction performance standard is used by FDA for *Salmonella* inactivation for in-shell egg pasteurization and by FSIS for inactivation of *E. coli* O157:H7 in fermented sausage. The agency has evaluated the NACMCF advice and concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to ensure that juice is safe.

This pathogen reduction performance standard, in combination with the requirement that measurement of the 5-log reduction begins after cleaning and culling of citrus fruits and, for all other juices, when the treatment has direct contact with any pathogens in the juice (discussed in the response to comment 131), provides adequate public health assurance while minimizing the impact of treatments on the sensory attributes of the juices (Ref. 64). While a 3-log reduction could be adequate under certain circumstances, it does not ensure that juice is safe under all circumstances that may occur. In contrast, the 5-log reduction performance standard has a built-in safety factor that provides additional consumer protection.

In light of the comments, FDA has considered a 6- or 7-log reduction standard and concluded this additional level of reduction is not necessary to compensate for possible future microbial resistance. The 5-log reduction refers to numbers of microorganisms, not resistance of microorganisms. Strains of microorganisms may become more resistant to heat, acid, sanitizers or other controls over time. Because microorganisms are capable of developing resistance, it is critical that juice processors periodically verify and validate their process to determine the continued effectiveness of the process. If resistance occurs, processors may need to make appropriate changes in their process so that their process continues to attain a 5-log reduction in pathogens. Therefore, the agency concludes that increasing the performance standard to attain a greater log reduction is not necessary to compensate for possible future increased resistance of pathogens.

(Comment 125) One comment asserted that a 1000-fold safety factor is not consistent with other performance standards set by FDA, although the comment did not reference any specific performance standards. The comment maintained that a performance standard should be based on actual levels of pathogens found in or on fruit plus a 1- or 2-log safety factor.

FDA has concluded that the 5-log performance standard recommended by the NACMCF is the most appropriate standard to assure that juice is safe. In the response to comment 124, FDA discussed how the Fresh Produce Working Group of the NACMCF arrived at the 5-log pathogen reduction performance standard. This performance standard includes the customary 100-fold safety factor, not a 1,000-fold safety factor as asserted by the comment. Therefore, the agency concludes that the 5-log value is consistent with other performance standards set by FDA and, in fact, was arrived at using the 100-fold (2 log) safety factor the comment suggested.

(Comment 126) Several comments stated that 5-log is not an appropriate performance standard for citrus juice because, in trial studies, researchers have not been able to inoculate fruit with sufficient numbers of microorganisms to measure a 5-log reduction. One comment stated that minimum safety performance criteria should be established for citrus because the likelihood of contamination in citrus juices is not high. However, another comment suggested that a 5-log performance standard would be appropriate for orange juice because it can be attained without heat and a 3-log performance standard would be appropriate for apple juice because this may be the maximum attainable without heat treatment.

FDA proposed the 5-log performance standard based on safety considerations and on the recommendation of the NACMCF (Ref. 63). As mentioned in the response to comment 124, while a 3-log reduction could be adequate under certain circumstances to ensure that juice is safe, the 5-log performance standard has a 2-log safety factor that offers additional consumer protection. In addition, the agency found in its review of performance criteria for other foods, that a 5-log reduction in pathogens is the standard for product safety in several cases (Ref. 63). Although the target pathogen may differ among juice types and, thus, change the specific processing parameters (*e.g.*, temperature, processing time) for attaining a 5-log reduction, FDA maintains that the 5-log performance standard is appropriate for all juices. The one area where FDA has data to suggest differences between citrus juice and other juices is with respect to the potential for pathogen infiltration. Specifically, the available data show that the potential internalization of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk (see the response to 132). Thus, for citrus juice only, the agency has determined that surface treatments may be used to achieve the 5-log reduction standard. Accordingly, citrus juice processors have an additional option in how to achieve the performance standard (*i.e.*, 5-log reduction), but the standard is the same.

FDA also rejects the comment's implicit suggestion that the performance standard should be based on what is technically feasible. In order to assure safe food, a performance standard must be based on safety, not on whether it is attainable using only certain technologies, such as heat treatment. Presenters at the Florida and California FDA workshops on the 5-log pathogen reduction (November 12, 1998 and November 19, 1998) and FDA research presented at the December 8 to 10, 1999, NACMCF meeting demonstrated that researchers could and had inoculated fruit with pathogens to a level that permits measurement of a 5-log reduction. Therefore, FDA is not persuaded that the performance standard should be different for different produce used to make juice.

(Comment 127) Several comments noted that the 5-log performance standard was chosen by NACMCF and that there was no representative of the fresh juice industry on the Committee. The comments maintained that NACMCF may not have considered written comments that were submitted after the public meeting when making its recommendation.

The NACMCF based its recommendation for a 5-log performance standard for juice on safety considerations, which included a scientific evaluation and rationale for a 5-log reduction standard. FDA reviewed the advice from NACMCF and chose to propose the same standard for HACCP systems for juice because the agency determined that the 5-log standard is supported scientifically. The structure of the NACMCF and the way it functions allow for public comment during the meeting, which comments the Committee considers in developing its recommendations. The fresh juice industry presented their views to the NACMCF during the meeting in question. FDA, on the other hand, typically announces a period of time during which comments related to the public NACMCF meeting may be submitted. In reaching its conclusion to propose a 5-log reduction standard, the agency considered written comments, including comments submitted after the meeting, on the appropriateness of the 5-log reduction standard, along with comments presented at the NACMCF meetings and the NACMCF recommendations.

(Comment 128) A few comments requested that FDA not require small producers to meet the 5-log performance standard until alternatives to pasteurization are validated. The comments argued that pasteurization is too costly for small producers.

The agency understands the small processors' concerns. However, the 5-log reduction is based on safety, and therefore, processors must meet the standard in § 120.24, in their HACCP systems in order for public health to be protected. FDA has documented outbreaks that have been attributed to small processors (Ref. 65). In recognition of the circumstances of small processors, however, the agency is establishing staggered compliance dates such that there is an additional 1 year for small processors and an additional 2 years for very small processors to comply with the HACCP final rule. Importantly, such processors must use the label warning statement if they are not processing their product to achieve the 5-log reduction. FDA believes that this approach does not substantially compromise safety and at the same time provides accommodation to small and very small processors. Therefore, the agency declines to modify the regulation to exempt small producers from the 5-log performance standard.

3. Pertinent Pathogens

(Comment 129) Some comments provided views on the types of microorganisms that should be considered the pertinent microorganism for measuring the 5-log reduction. One comment contended that the chosen target organism must make scientific sense based on their extremes of pathogenic viability across multiple reduction steps. A few comments stated that *Listeria monocytogenes* should not be a target pathogen for the performance standard because there is no history of problems with *Listeria* in juice. However, other comments stated that *E. coli* O157:H7 and *L. monocytogenes* are both appropriate target pathogens, especially because *Listeria* contamination is a risk to pregnant women. One comment also stated that *Salmonella* is not an appropriate target microorganism because it is not as acid-resistant as *E. coli* O157:H7.

FDA has concluded that target pathogens must be chosen on the basis of historical association with a product and the way in which the product is processed. For example, there have been apple juice outbreaks associated with *E. coli* O157:H7, *Salmonella* spp., and *Cryptosporidium parvum*. *Salmonella species* have been associated with outbreaks from orange juice. The NACMCF recommended the use of *E. coli* O157:H7 or *Listeria monocytogenes* as the target organism, as appropriate. This recommendation is based on the number of known outbreaks of *E. coli* O157:H7 in juice and the ubiquitous nature of *L. monocytogenes*. FDA advises that if *L. monocytogenes* becomes a source of outbreaks in the future, especially affecting pregnant women, then processors must consider whether *L. monocytogenes* should serve as the pertinent microorganism for their product.

Processors must also consider the manner in which they are achieving the 5-log reduction and the microbial resistance to the process. For example, a new technology may be effective in attaining a 5-log reduction of *E. coli* O157:H7 in apple juice, but may allow the survival of *Cryptosporidium*. *E. coli* O157:H7 is known to be unusually acid-resistant and *L. monocytogenes* is relatively heat-resistant. The 5-log pathogen reduction standard applies to the most resistant microorganism of concern under the processing conditions used. If the microorganism is resistant to a particular treatment and the treatment does not therefore deliver a 5-log reduction in the microorganism, then, obviously, the 5-log reduction standard has not been met. FDA plans to provide additional information in its Juice HACCP hazards and controls guidance to assist producers in identifying the pertinent microorganism for measuring the 5-log standard.

(Comment 130) Several comments requested that FDA clarify how surrogate microorganisms should be chosen to validate cumulative steps used to achieve a 5-log reduction (*e.g.*, use of sanitizers). One comment requested that FDA require industry to use an agreed upon "cocktail" of surrogates to validate processes.

FDA advises that surrogates should be equally or more resistant to the processing conditions than is the target pathogen to assure that the process also destroys the pathogen. As noted in the response to comment 129, one treatment may be effective in reducing one type of pathogen but have less or no effect on another. FDA will be providing additional guidance on the selection and effective use of surrogate microorganisms for process validation in its juice HACCP hazards and controls guidance. FDA believes that it is the

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responsibility of the producer to validate the processes it chooses to use in manufacturing juice products, including determining appropriate surrogate microorganisms. Therefore, FDA is not requiring use of a "cocktail" of surrogates to validate processes.

In choosing and using surrogates, it is important to remember that a cumulative 5-log reduction must be achieved. Therefore, a processor must have evidence that there is a total reduction of 5 logs in the surrogate population and that the same 1- or 2-log reduction is not being counted repeatedly. In other words, if one step reduces the surrogate by 2 logs, the next step must reduce the surrogate by an additional number of microorganisms. In addition, care must be taken that there is no growth of microorganisms between steps.

4. Application of the Performance Standard

(Comment 131) Several comments maintained that, because of the possibility that pathogens may become internalized into fruit (or vegetables), the treatment(s) will need to be applied after the juice has been extracted so that the treatment has intimate (*i.e.*, direct) contact with pathogens. One comment suggested that FDA require at least part of the treatment be applied directly to the juice. Conversely, another comment maintained that, except for warm apples in cold water, the potential for pathogen infiltration is hypothetical. Even then, according to the comment, use of potable water and hygienically maintained tanks could control pathogen internalization despite a temperature differential that could cause water to be pulled into the fruit.

As stated previously, FDA believes that, for all fruits and vegetables, the pathogen reduction control process must begin at the point where the pathogen reduction treatment directly contacts the pathogens. Inherent in the NACMCF recommendation of the 5-log pathogen reduction standard was the assumption that the treatment(s) would be applied in a way that would effectively reduce the entire population of the microorganism of concern by 5-log. In making this recommendation, NACMCF did not contemplate treatments that may eliminate some pathogens while not reaching others, as would be the case for surface treatment of produce susceptible to pathogen internalization. In fact, the NACMCF specifically advised that surface treatments would have little effect on pathogens if they are internalized.

Contrary to the comment, the potential for infiltration is not hypothetical because information and data from the scientific literature demonstrate that, under certain conditions, microorganisms can become internalized. (Refs. 13 and 14) Such internalization may occur through natural plant structures or through decayed or damaged sites on the fruit or vegetable. Water, insects, and birds, all of which may carry human pathogens, can serve as pathogen vectors, resulting in contamination of fruits and vegetables. Internalization may occur before or after harvest although submerging warm harvested fruit in cold water (such as dump tanks and flumes) increases the potential for infiltration into susceptible produce. Similarly, exposing vulnerable external points of fruit or vegetables may also cause water to be taken-up along with pathogens if they are present. Accordingly, for most fruits and vegetables, this means that the pathogen reduction treatment must be applied to the juice after extraction. Moreover, processors should include in their HACCP plans, where appropriate, precautions to avoid or minimize the potential for infiltration (such as by avoiding submerging warm fruit in colder water). In addition, while CGMP's and SSOP's, such as using potable water and sanitary operating conditions during washing, are a base for HACCP, they will not necessarily prevent or correct pathogen infiltration into fruits and vegetables. If pathogens have become internalized in fruit or vegetables, wash treatments, even if conducted consistent with CGMP's, will not eliminate them.

In the case of citrus fruits, FDA considered in the preamble to the proposed rule that the structure of citrus fruits prevented internalization of microorganisms, and thus, for citrus fruits, pathogenic microorganisms are likely to be restricted to the surface of the fruit. As such, FDA tentatively concluded that surface treatments of citrus fruit would satisfy the criterion for direct contact with all pathogens and could, therefore, be counted towards the 5-log reduction standard (see also the response to comment 132).

In response to comments challenging this agency conclusion and in the absence of scientific studies directly on this topic, FDA conducted two studies to determine the validity of its assumption, and made the results available for public comment. The results of one study provided evidence that internalization, survival, and growth of human bacterial pathogens may occur inside oranges. The results of the second study demonstrated that there is uptake of water by oranges and grapefruit when there is a transitory pressure differential between the interior and exterior of the fruit. At the December 1999 NACMCF meeting, FDA asked the NACMCF to consider the potential for internalization of microorganisms by citrus fruits. The NACMCF concluded that it is theoretically possible for microorganisms to internalize in sound, intact citrus fruit under conditions where a temperature differential between fruit and wash water may cause water to be drawn into the fruit. The Committee stated that while this was demonstrated in laboratory conditions, the probability of its actual occurrence under current industry practices was not demonstrated. Accordingly, the NACMCF concluded, based on the available evidence, that the potential internalization and survival of pathogens in sound, intact citrus fruit is not likely to present a significant public health risk.

FDA agrees with the NACMCF conclusion. Importantly, the comments did not provide any data for FDA to conclude otherwise. Thus, the agency is requiring in § 120.24 that the 5-log standard be met by treatments applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided the 5-log reduction process for citrus begins after cleaning and culling and is accomplished in a single production facility under the control of the processor. (The terms "cleaning" and "culling" are discussed below in the response to comment 132.)

At the present time, FDA believes that only citrus fruits have been demonstrated to be adequately impervious to internal contamination such that it is reasonable to rely on surface treatments of these fruits, and therefore, use of surface treatments to achieve all or part of the required 5-log pathogen reduction is restricted to citrus fruit. Whenever sufficient scientific data are provided to the agency to establish that, for other fruits and vegetables, it is appropriate to begin the 5-log reduction process at other points than the extracted juice or that establish that surface treatment is no longer an acceptable method to contribute to the 5-log reduction for citrus fruit, FDA will review this conclusion.

(Comment 132) A number of comments contained suggestions or asked for clarification about where to start treatment for purposes of calculating the 5-log pathogen reduction. A few comments maintained that processors grading fruit to reduce potential contamination, and processors using other best management practices, should be able to count these practices towards the 5-log reduction standard. One comment claimed that FDA should allow the measuring of pathogen reduction to begin prior to processing to achieve and count reductions in pathogens from proven sources, such as by cleaning and culling dirty or damaged fruit. Another comment maintained that a 2-log reduction is possible from using tree picked apples instead of drops and that this practice (i.e., excluding drops) should be counted towards achieving the 5-log reduction.

In contrast, several comments stated that the earliest possible point to start counting the 5-log reduction is with clean, sound fruit. One comment maintained that, while overtly damaged fruit carry a greater risk of contamination, apparently sound fruit may also be contaminated and that, therefore, culling is not a screen for microbial contamination.

FDA agrees that food safety is enhanced by the highest quality incoming materials. However, as noted in response to comment 112, FDA does not believe that GAP's (such as using tree picked fruit) or CGMP's (such as washing and culling fruit) are a replacement for the 5-log reduction. Nor can these practices substitute for a portion of the 5-log treatment. Establishment of the 5-log pathogen reduction standard as adequate public health protection was based upon certain starting conditions, including cleaning and culling the produce, and the principal that the pathogen reduction treatment must directly contact the microbiological hazard. As noted, for juice made from fruits and vegetables in which there is a potential for pathogen infiltration, such contact is likely to occur only after the juice has been extracted; for citrus, where pathogen internalization is unlikely under current industry conditions, the 5-log reduction process does not need to start with the extracted juice but may begin with exterior decontamination of fruit after cleaning and culling.

FDA is defining in § 123.3(a) and (f) the terms "cleaned" and "culled" as described by NACMCF to establish the starting point for surface treatments for citrus. *Cleaned* means washed with water of adequate sanitary quality. *Culled* means separation of damaged fruit from undamaged. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit (*i.e.*, USDA choice or higher quality). For all juices, cleaning and culling operations would be part of CGMP's, and fruit being tree-picked is not applicable to the 5-log reduction. This is consistent with the NACMCF recommendation that cleaning and culling of citrus fruits not be considered part of the 5-log reduction of pathogens. The agency notes that all produce used for making juice must be cleaned and culled prior to the start of the 5-log reduction according to CGMP's. However, FDA is defining these terms to clearly set forth the basic starting conditions for the 5-log reduction, especially in regard to surface treated citrus.

(Comment 133) One comment suggested developing a standard for fruit for juicing that includes no dropped fruit, no blemishes or dimples, and rinsing with pathogen-free water. The comment suggested that beginning with fruit of a standardized quality would not count toward the 5-log reduction, but would ensure that all processors start with fruit of the same high quality. One comment argued that treatments that can achieve a 5-log reduction in pathogens when applied to sound, clean fruit may be adequate for producing safe product but questioned whether a greater reduction might be necessary if starting with fruit that was dirty or damaged.

FDA is not setting a standard for fruit quality or expressly prohibiting the use of drops in most juices. As with any food, FDA encourages the highest possible quality incoming materials in the production of juice. The Produce Working Group of the NACMCF arrived at the 5-log reduction recommendation by considering a "worse case" scenario where fruit was heavily contaminated with feces, as might occur with the use of drops. The Committee concluded that a 5-log reduction treatment would eliminate pathogens and provide a 100-fold safety margin. Thus, FDA concludes that the 5-log reduction applied directly to the juice will eliminate pathogens that may otherwise be introduced by the use of drops. FDA cautions, however, that juice producers that are exempt from or that have not yet adopted HACCP, including the 5-log reduction standard, can reduce their risk of producing contaminated product by avoiding drops and by culling tree picked fruit before extraction.

The agency is establishing a standard for citrus fruit that is treated only with surface treatment. For these juices, drops may not be used. The NACMCF suggested, and FDA agrees, that for citrus juices, only tree-picked fruit should be used, and fruit should be cleaned and culled to be USDA choice or higher quality. Although pathogen infiltration is unlikely in sound, intact citrus fruit, drops and damaged fruit are likely to be more susceptible to pathogen infiltration and, therefore, should not be used for juice that relies on surface treatment.

Furthermore, in some cases, damage incurred when fruit drops to the ground may foster nonmicrobial contamination such as the mycotoxin patulin, which may occur in damaged apples. Patulin, if present in the apples, will not be decreased by the 5-log performance standard. In these cases, the processor must have controls in place to ensure that the final juice does not contain unsafe levels of the mycotoxin.

(Comment 134) Several comments urged FDA to define sound fruit. A few comments noted that culling is a subjective process and therefore may not be consistently applied. One comment suggested that the agency establish mandatory common minimum standards and technologies (*e.g.*, black lighting) to ensure consistency in culling operations. Another comment suggested that FDA specify that fruit be culled of unsound fruit before dirty fruit is placed into a flume where it might contaminate sound fruit.

In the case of citrus juice where a surface treatment is used to achieve, at least in part, the 5-log reduction, the agency has specified that the fruit shall be "culled" and "cleaned." As noted, these terms are defined in § 120.3. Fruit and vegetable grading criteria (*e.g.*, for USDA choice level or higher, as will be required for surface treated citrus fruit) have been established by USDA. Although there may be some degree of subjectivity in culling citrus fruit, visibly damaged fruit is apparent and is unlikely to meet the requirements for USDA choice level or higher. Application of CGMP's, along with the 5-log performance standard beginning at a point after cleaning and culling of citrus fruit, should overcome any potential risks that may result from subjective processes such as culling.

As stated in response to comment 132, FDA is not setting a standard for fruit where the juice is treated after extraction to achieve a 5-log reduction, although processors may consider including standards for incoming fruit as appropriate to their operations in establishing a HACCP plan. Additional guidance will be provided in the agency's juice HACCP hazards and controls guidance.

(Comment 135) Several comments requested that FDA develop a guide for industry that states the log reduction achieved for each potential processing step. A few comments requested that pasteurization guidelines for juice be published in a guide, and one comment asked whether or not heat treatment at

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161 °F for 15 seconds results in the appropriate 5-log reduction in juice. Another comment questioned how to calculate a 5-log reduction for banana juice.

FDA plans to publish a juice HACCP hazards and controls guidance to assist the juice industry in implementing these regulations. FDA intends that the guidance will contain pasteurization guidelines and information about achieving the performance standard in other ways. The agency is unable to comment on whether a heat treatment of 161 °F for 15 seconds results in a 5-log pathogen reduction without information about the characteristics of the juice as well as the thermal resistance characteristics of the pathogen of concern. Appropriate 5-log pathogen reduction treatments for specific juices (such as banana juice) will vary, depending on the characteristics of the juice (*e.g.*, acidity, viscosity, percentage of pulp) and processing conditions. Processors may find it necessary to consult additional resources to determine and implement the most appropriate process to achieve the 5-log pathogen reduction, such as information from State public health or agriculture agencies, universities, extension services, and private consultants. The agency emphasizes that it is the processor's responsibility to validate the chosen pathogen reduction process to assure its effectiveness in consistently achieving a 5-log or greater reduction.

(Comment 136) Many comments expressed confusion about the use of cumulative steps to reach the 5-log pathogen reduction requirement. A few comments also requested that FDA clarify exactly what would be required if two different processors perform steps that in the final product add up to a 5-log reduction. A number of comments stated that separating cumulative pathogen reduction steps by time and or by location is not acceptable. These comments argued that such separation provided opportunities for recontamination of product and regrowth of any existing pathogens that had not yet been eliminated in the product, that any multiple step intervention should take place in a single location, and urged FDA to ensure time between treatments is kept to a minimum once an intervention sequence is begun. Several comments on transporting juice between facilities suggested that FDA require that bulk transport juice (*e.g.*, juice shipped in tanker trucks) be pasteurized upon arrival at the final facility because of the potential for contamination during transport.

FDA agrees with the comments expressing concern about the potential for recontamination or regrowth of surviving pathogens if individual treatments designed to achieve a 5-log reduction are separated by time or space. At the December 8 to 9, 1999, meeting of the NACMCF, FDA asked the Committee to consider certain questions about the application of the 5-log reduction standard, focusing on citrus juices. Questions included the impact of separation in time and space between cumulative steps in the 5-log reduction process. The Committee members agreed that separating steps in the 5-log reduction by time, and especially by location, is likely to increase the risk of failure of the pathogen reduction process (Ref. 12). Thus, the NACMCF recommended that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. These restrictions are designed to reduce the risk of recontamination of juice already processed to achieve all or part of the 5-log reduction. Both time and the act of transportation, between processors, present an opportunity for recontamination. Even if a processor moves product from one building to another within the same facility, this movement must be accomplished under CGMP's and the processor must insure that recontamination does not occur. As noted, there have been several recent outbreaks of microbially contaminated fresh juice; investigation of these outbreaks establish that the concern about recontamination is not just theoretical because the evidence suggests that transportation may have played a role in these outbreaks. In April 2000, FDA was notified by CDC of a foodborne disease outbreak involving over 140 reported cases from 10 States. CDC determined that the illness was caused by *Salmonella* Enteritidis in unpasteruized orange juice, a component of which had been imported in bulk. Previously, in July 1999, an outbreak of *Salmonella* Serotype Muenchen occurred in 15 States and 2 Canadian provinces with over 300 cases reported. Again, the product was fresh orange juice, a portion of which was imported. In this second outbreak, several serotypes of *Salmonella* were isolated from tanker truckloads of juice tested at the United States/Mexican border (Ref. 67).

FDA agrees with the NACMCF recommendations that all the steps needed to achieve the required 5-log reduction should occur under one firm's control and within a single production facility. Although the NACMCF recommendation focused on citrus juice, based on the comments, FDA believes that this recommendation should be extended to all juices. Because of the potential for contamination at a facility over which the final processor/packager has little or no control and because of the potential for contamination during bulk transport, FDA has concluded that there should not be any carryover from one facility to another of any portion of pathogen reduction that contributes to a total 5-log pathogen reduction. If a treated juice is transported to another facility for final packaging or blending and packaging operations, the entire 5-log reduction must be repeated. To clarify this point, the agency is adding paragraph (c) to § 120.24 to state that processors must complete the 5-log performance standard and final product packaging within a single processing facility under CGMP's.

FDA also notes that, for citrus juice producers relying on surface treatments for the 5-log reduction, the single facility criterion also applies to the requirement that processors start with clean, choice or higher grade fruit. Although some juice processors may receive fruit that has been cleaned and graded at another facility, fruit may require additional cleaning and culling to remove any fruit damaged in storage or transit. It is the responsibility of the final juice processor (*i.e.*, the processor at the location where the 5-log treatment will be applied) to ensure that fruit is clean and of appropriate grade before beginning the 5-log reduction.

Even within a single production facility, time between cumulative steps may provide an opportunity for growth or recontamination. Therefore, processors should include in their HACCP plans controls to protect against regrowth of pathogens between steps (*e.g.*, limiting hold time and/or temperature) and to prevent recontamination of the juice during or after processing (*e.g.*, aseptic handling between steps or between treatment and packaging).

FDA also agrees with the concern expressed by comments on the potential for juice to be contaminated during bulk transport. This is an area of particular concern to the agency because, as mentioned above, bulk transport appears to be a common factor in several recent outbreaks. However, the agency has no information nor was any information submitted by comments that the 5-log reduction standard applied to juice in general would not be sufficient to ensure the safety of juice that is shipped in bulk, provided that the transported juice receive the entire

5-log reduction at the facility where it will be packaged. Therefore, FDA is not requiring at this time that juice shipped in bulk between facilities be subject to additional treatment.

(Comment 137) One comment expressed concern that a cumulative process will be more easily overwhelmed by especially dirty fruit than would a single kill-step process. The comment contended that the risk of contamination in a multi-step process is increased over the risk in a single kill-step process because of the potential that contamination can be introduced between steps. One comment expressed concern that validation studies on a cumulative 5-log reduction cannot account for all variables and, thus, meeting the performance standard cannot be guaranteed.

HACCP principles and this final rule require that a processor validate the HACCP plan for its particular process under commercial operating conditions. This validation requirement exists for plans utilizing both single-step and cumulative pathogen reduction controls. FDA recognizes that within a processing system time delays may occur between stages of the treatment; the processor must take any delays into consideration, establish appropriate controls, and validate the HACCP plan for that system. The 5-log reduction performance standard was established to ensure the safety of juice regardless of the pathogen reduction system chosen or the microbial load of the incoming fruit. Furthermore, as discussed in response to comment 132, citrus juice processors using surface disinfection to achieve all or part of the 5-log reduction must start with cleaned and culled fruit as defined in § 120.3 (a) and (f).

(Comment 138) Several comments maintained that juice should be packaged immediately before or after the intervention treatment. One comment stated that a processor could hold and cool a heat treated product before packaging if sufficient controls were in place to preclude recontamination of the product.

As noted earlier, time between cumulative steps and between application of the 5-log reduction and packaging increases the risk of failure (see response to comment 136). Therefore, to reduce the risk of recontamination, juice should be packaged immediately before or after application of the 5-log pathogen reduction treatment. The potential for recontamination between application of the 5-log reduction treatment and packaging (such as might occur when product is held and cooled) should be considered in the development of the HACCP plan and appropriate controls established that are designed to prevent recontamination. Processors not packaging juice immediately after treatment should have sufficient controls in place (*e.g.*, aseptic equipment) to ensure the safety achieved by the 5-log reduction can be consistently maintained.

(Comment 139) One comment asked if the regulation allowed for the application of 5-log reduction to a juice ingredient at any time (*e.g.*, before or after blending). The comment argued that the juice ingredient used to manufacture dairy beverages usually receives a 5-log treatment by the supplier and that the finished beverage is often pasteurized at the dairy.

Juice that is intended for use in further manufacturing is generally shipped in bulk. As discussed in the response to comment 136, the NACMCF recommended and FDA agrees that if bulk transport juice will be repackaged at another facility, the 5-log reduction process must be performed on the juice at the facility where it is packed into final packages. If treated juice is packaged into a bulk-type sterile package, such as a single use sanitary tote, then reprocessing is not necessary unless it is repackaged. If juice shipped in sterile totes is to be repackaged at a different facility, the juice product sold to consumers must be retreated to attain the 5-log reduction at the facility where final packaging is performed. As discussed earlier, separation in time and location increases the risk of failure of the HACCP system, including the 5-log reduction. Therefore, FDA is not providing for carryover of any part of the 5-log reduction when juice, not in its final packaged form, is transported between two facilities.

Juice destined for use as an ingredient in another juice beverage must also undergo a 5-log reduction process. The processor may choose either to treat the juice ingredients before blending or to treat the final product, so long as the entire 5-log reduction is completed in a single production facility under the control of the processor and the processor minimizes time between treatment and packaging.

(Comment 140) Several comments noted that shelf-stable juices are processed well in excess of the 5-log reduction necessary for pathogen control. The comments requested that FDA exempt shelf-stable juice producers from a CCP for pathogen reduction because the shelf-stability of the product is proof that their process greatly exceeds safety performance criteria. Comments also requested that the same consideration be given to concentrated juices.

The agency agrees with the comments and is providing an exemption from the requirements of § 120.24 for shelf-stable and concentrated juices, under specific conditions. Shelf-stable juice products are generally processed at high temperatures in a single step to destroy spoilage microorganisms and enzymes (Ref. 68). These temperatures far exceed what is needed to attain the 5-log reduction in the pertinent pathogen. Therefore, FDA concludes that it is reasonable to exempt a processor of shelf-stable juices from the requirements of § 120.24, if the firm uses a single thermal processing step to attain shelf-stability.

FDA also recognizes that the production of thermally concentrated juice utilizes thermal treatments similar to those used for the production of shelf-stable juices (Ref. 68). A thermal concentration process generally consists of an initial thermal treatment, similar to that used for shelf-stable juices, followed by several thermal evaporation steps. For this reason, the agency has concluded that when a thermal processing step is used before a thermal evaporation process, the processor should be exempt from the 5-log reduction requirement.

Accordingly, FDA is adding § 120.24(a)(2) exempting juice processors using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients from the requirements of § 120.24 (the 5-log reduction requirement). When completing the written hazard analysis as required by § 120.7, processors of shelf-stable and concentrated products using a thermal treatment need not identify pathogens as a hazard that is reasonably likely to occur. To demonstrate that its process is sufficient for the exemption, a processor must include a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis as required by § 120.7.

Shelf-stable or concentrated juice processors are not exempt from the requirement to conduct a written hazard analysis because of the possibility that chemical or physical hazards may be reasonably likely to occur. However, if, based on its hazard analysis a processor exempt from § 120.24 determines that there are no chemical or physical hazards that are reasonably likely to occur in its juice product, then that processor is not required to have a HACCP plan. Juice processors that do not have a HACCP plan need not

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comply with the following provisions of part 120:

- § 120.8, HACCP plan
- § 120.10, Corrective actions
- § 120.11(a) (except paragraph (a)(1)(i)), Verification
- § 120.11(b), Validation of the HACCP plan
- § 120.12(a)(3) and (a)(4), Required records
- § 120.24(a) (except paragraph (a)(2)), Process controls
- § 120.25, Process verification for certain processors

FDA anticipates that, in the future, processors making shelf-stable or concentrated juice may use alternative nonthermal processing technologies. While the control mechanism of these nonthermal technologies may eliminate spoilage microorganisms, the effect on pathogens is uncertain. Therefore, the exemption under § 120.24(a)(2) does not extend to nonthermal processes.

5. Validation of the Performance Standard

(Comment 141) One comment stated that the cost of validating a 5-log reduction procedure would be prohibitive to small producers because the validation studies would have to take place in a pilot plant. Another comment stated that processors should be able to validate procedures and critical control limits based on literature reviews, in-plant experience, recommendations from consultants, and routine testing.

The agency disagrees with the comment that argued that validation would be too expensive for small processors because it would have to take place in a pilot plant. FDA notes that validation studies need not occur in a pilot plant. There are several options available to a processor in validating its 5-log reduction procedure and in establishing critical limits. Although it is preferable to establish limits for CCP's and validate individual processes in a pilot plant or in the processing facility where they will be carried out, FDA recognizes that this may not be feasible for small processors. As suggested by the second comment, many alternatives are available. For example, small processors that use identical procedures for producing juice could validate these processes cooperatively. It is also acceptable to use referenced procedures for achieving a particular log reduction provided a processor can demonstrate that the referenced procedure is being followed exactly (or more stringently), as outlined in the literature, and is effective in the processor's operation. Small producers may also elect to use proven technologies (*e.g.*, thermal treatments) that have been extensively validated, and as such can be readily adopted with minimal need to conduct in depth microbiological validation testing.

FDA was unsure what the second comment meant when referring to "routine testing" as a way to validate HACCP. It may be that the comment was referring to "verification" (*e.g.*, routine testing and monitoring) to ensure that the HACCP plan is functioning correctly, rather than "validation". Verification and validation are further discussed in the following section.

6. Process Verification

(Comment 142) Several comments expressed concern about the effectiveness of cumulative steps in meeting the 5-log reduction. One comment pointed out that the efficacy of a cumulative step process for citrus assumes perfect grading and that the interior of citrus is sterile. The comment stated that perfect grading is not possible because pathogens that may have entered the fruit through a microperforation may not be detected and the fruit could have a contaminated interior. The comment also maintained that no steps in the cumulative process described in the proposed rule were designed to prevent reproduction of pathogens in the juice during storage. A few comments concerned about the effectiveness of cumulative treatments argued that FDA should require end-product testing to verify HACCP for all non-pasteurized juice. One comment advocated continuous testing for unpasteurized juice and periodic testing for pasteurized juice. Conversely, one comment maintained that, in most cases, microbial testing is not necessary nor is it the best method for verifying HACCP. However, this comment suggested that microbial testing be required for citrus juice using surface treatments to achieve 5-log since, according to the comment, there are few other steps that can be used to verify cumulative processes that include surface treatment.

FDA's response to these comments requires an understanding of the differences between two HACCP concepts: validation and verification. Verification includes all activities, except monitoring, that establish the soundness of the HACCP plan and that the system is operating according to the plan. Many verification activities, such as process verification, are an on-going (*e.g.*, daily or weekly) part of operating under a HACCP plan. Validation is a subset of verification activities that occurs when a HACCP plan is first set up and whenever significant changes are made that may have an impact on the effectiveness of the system. Validation focuses on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control all hazards that are reasonably likely to occur. In contrast, verification assesses whether the HACCP plan, once established, is working properly.

FDA disagrees that microbiological testing of the final juice should be required of all juice manufacturers. If juice is treated to achieve a 5-log reduction in a target pathogen after the juice is expressed, the extent of the reduction (>100,000-fold) in combination with the low levels of pathogens that have been detected in untreated juice would likely result in a post-treatment level of microorganisms that is too low to be detected using reasonable sampling and analytical methods. Moreover, microorganisms are not likely to be uniformly distributed throughout the juice and, accordingly, may not be present in the sample tested even though they are in the juice. This can result in false negative test results. Determination that the product has been adequately treated is more effectively verified by review of the monitoring records for the appropriate CCP. Thus, as a general rule, FDA is not requiring end product testing as part of verification for processes where the juice itself has been directly treated. The exception to this general rule is that processors of citrus juice that use surface treatments to achieve the 5-log reduction performance standard will be required to conduct end product testing to verify that their HACCP system, including the cumulative step 5-log reduction, is operating as it is designed to operate. This verification testing is discussed in more detail below. Of course, even where not required, processors may elect to use end product testing as part of the verification of the HACCP plan.

Conversely, except for techniques like pasteurization, where industry has a long history and experience of using time-temperature parameters as an indicator of microbial destruction, a processor will likely need to conduct studies using samples inoculated with pathogens (or surrogates) to confirm that their HACCP process does result in a 5-log reduction in the pertinent pathogen.

In light of comments expressing concern about the efficacy of cumulative steps, including surface treatment of cleaned and culled citrus fruit, FDA has evaluated the need for additional forms of process verification for some

products. As noted, verification is designed to demonstrate that the HACCP plan is achieving the level of process control intended and thus producing safe food on a continuing basis. Verification is broader than ongoing process monitoring alone. The purpose of monitoring is to measure and document that those identified steps that must operate within specified limits on a continuing basis in order to control a foodborne hazard (*i.e.*, CCP's) are in fact operating within specifications. Ideally, monitoring involves continuous, "real-time" measurements so that process deviations can be detected and corrected immediately.

Conversely, verification entails both the periodic review of monitoring data and the acquisition of additional data to assess whether the HACCP plan is functioning as intended. The additional data are not necessarily data relating to a CCP, but could be data relating to another step in a process that reflects the effectiveness of a prior CCP(s) (*e.g.*, sampling of citrus fruit surfaces for levels of acid resistant mesophilic aerobic microorganisms after treatment of the fruit with an acidic antimicrobial wash). Furthermore, since verification data are only acquired on a periodic basis, types of analyses that require too much time to be effective means for monitoring CCP's can nevertheless be highly effective tools for verifying a HACCP plan. Verification activities may include review of CCP-monitoring records; collection of either in-line or finished product samples for microbiological, chemical, or physical analysis; and direct observations of monitoring activities and corrective actions. The frequency of verification activities will vary depending on factors such as the type of process, volume of product, the results of prior monitoring and verification activities, and past frequency of process deviations.

As discussed in detail previously, at its December 1999 meeting, the NACMCF considered at length the effectiveness of surface treatment to eliminate microbiological concerns related to citrus fruits. There has been a continuing question of whether the integrity of the outer surface of citrus fruit is sufficiently impervious such that pathogenic microorganisms cannot enter the fruit. If the surface were sufficiently impervious, surface treatments might effectively reduce the risk from microbiological hazards. The NACMCF (1999) concluded that the potential for the uptake and growth of bacterial pathogens such as *Salmonella* Hartford and *E. coli* O157:H7 by intact citrus fruit is unlikely, given current industry practices, and that surface treatment of intact, healthy citrus fruit should adequately reduce microbiological risks. However, the NACMCF also concluded that under certain limited conditions, internalization of pathogenic bacteria is possible. Further, the NACMCF noted that surface treatments of fruits would have little effect on internalized pathogenic microorganisms (Ref. 12). In addition, although the NACMCF concluded internalization of pathogens in sound citrus is unlikely under current industry practices, FDA research confirmed that if a temperature differential exists between the fruit and wash water, washing may cause internalization of pathogens in citrus and other produce through indiscernible punctures of the skin.

The NACMCF observed that while microbiological testing is seldom effective as a means of monitoring a CCP, such testing can play a role in verifying HACCP programs (Ref. 17). Similarly, the International Commission on Microbiological Specifications for Foods (Ref. 69) has recognized microbiological testing of product as one type of HACCP verification.

In relation to HACCP and citrus juice manufacture, the NACMCF (Ref. 12) recommended that periodic microbiological testing of juice be a component of the HACCP verification activities undertaken by those citrus juice manufacturers who rely on surface treatment of fruit to achieve all or part of the microbiological performance standard (5-log reduction).

Because of continuing questions about the possibility of pathogen internalization and because of the lack of alternative verification steps available for processors using cumulative steps, including surface treatments, to achieve the 5-log reduction, FDA concludes that, for citrus juices that rely solely or in part on surface treatments, periodic microbial testing to verify the effectiveness of cumulative processes is integral to the process control verification. Therefore, in § 120.25, FDA is requiring microbial testing for such juice products. This testing is in addition to verification and validation requirements set forth in § 120.11.

(Comment 143) As noted above, several comments argued that FDA should require microbial testing for some or all juices. Some comments favored microbial testing of finished product but did not specify sampling plans or methods. A few comments suggested that FDA could permit companies to test for indicator organisms because *E. coli* O157:H7 is hard to detect. One comment argued that such a requirement would eliminate the need for a HACCP system.

FDA disagrees with the comment that maintained that end product testing would eliminate the need for HACCP for juice. As discussed in response to comment 142, microbial testing is limited in its ability to detect process deviations in a timely manner, especially for products with a short shelf-life, such as fresh juice.

FDA agrees with the comment that suggested that indicator organisms could be used for process verification. While microbiological testing for specific pathogens might be a direct means of verifying that a surface treatment is effective and that pathogens have not been internalized in the fruit, analyses for individual pathogens can be highly complex. Testing for pathogens also has limitations, including the potential for pathogens to be present at low levels compared to other microorganisms and the detection limit of the test. There is also the question of which pathogens that may be present on the surface of the fruit should be the focus of any testing. For example, testing for *Salmonella*, *E. coli* O157:H7, and *Cryptosporidium parvum* might be appropriate since all three have been implicated in disease outbreaks related to juices. Another limitation of testing for pathogens is that testing for one pathogen (*e.g. Salmonella*) will not detect another (*e.g., E. coli* O157:H7), even if the second pathogen is present. An alternative would be to select a microorganism whose presence is indicative of a loss of process control. Since all three of the pathogens above are fecal in origin, the ideal indicator microorganism would be one that is indicative of fecal contamination.

FDA has considered several different possible indicator microorganisms and has concluded that biotype I *Escherichia coli* (*i.e.*, generic *E. coli*) is the most suitable indicator microorganism for verifying the effectiveness of surface treatments in attaining the 5-log reduction standard. This microorganism is generally regarded by the scientific community as the best indicator microorganism for processes intended to control fecal contamination (Refs. 15 and 70). When present, generic *E. coli* generally occurs at levels several magnitudes greater than the levels of enteric pathogens that are associated with fecal contamination. Consequently, testing for generic *E. coli* is more likely to detect product where the 5-log reduction standard has not been achieved. Thus, FDA concludes that any citrus juice manufacturer that relies solely or in part on surface treatment of

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the fruit to achieve the 5-log reduction performance standard shall, for each different type of juice product produced, conduct analyses of the final product for biotype I *Escherichia coli*.

The next issue is how the analysis should be performed. Historically, the juice industry has used the standard 3-tube MPN (most probable number) method in FDA's Bacteriological Analytical Manual (BAM) for analysis of coliform and *E. coli* in juices. However, this method has several limitations. First, as noted in a paper entitled "Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard" ("Surface Treatment Sampling Plan") (Ref. 71), the BAM method can only analyze a small sample size of 3.33 mL with a detection limit of 0.3 *E. coli*/mL. In addition, the high acidity of some juices, including most citrus juices, can interfere with the detection efficiency of the test. Using an analytical method that can test a larger sample size (*i.e.*, 20 mL) and by including an enrichment step to reduce interference by acidity should improve an analysis for generic *E. coli* and thus assist a citrus juice processor using surface treatments to verify whether the process is achieving the 5-log reduction. Consequently, FDA has developed the method, "Analysis for *Escherichia coli* in Juices—Modification of AOAC Official Method 992.30," to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples) (Ref. 72). In the future, FDA intends to place this method in the BAM. After publication of this final rule, the method will be available on FDA's Internet site at www.cfsan.fda.gov.

In order to facilitate uniform and effective application of this requirement, FDA has added to § 120.25, specific requirements for sample collection and testing. Under this provision, one 20 mL sample, consisting of two 10 mL subsamples, of finished juice shall be analyzed for the presence of generic *E. coli* from each 1,000 gallons of juice produced per day. If less than 1,000 gallons of juice are produced per day, samples must be taken for each 1,000 gallons produced, or once every 5 working days that the facility is producing that juice, whichever comes first. If either 10 mL subsample is positive for *E. coli*, then the 20 mL sample is recorded as being positive for generic *E. coli*.

In addition to the general corrective action requirements in § 120.10, FDA is also adding requirements in § 120.25 to spell out the specific steps that should be taken if a processor subject to the requirements of § 120.25 finds one or more juice samples positive for *E. coli*. Generic *E. coli* is relatively ubiquitous. Thus, the occasional sample that is positive for *E. coli* does not necessarily indicate that microorganisms of fecal origin are not restricted to the surface of the fruit or that surface treatments are insufficient to assure product safety. Nevertheless, an occasional positive sample should prompt a review of the monitoring records relating to the 5-log reduction standard to determine whether pathogen reduction treatments and post process controls designed to prevent re-contamination are being properly delivered. Because generic *E. coli* is an indicator of fecal contamination, processors finding generic *E. coli* in a single sample may consider testing another sample of the same juice for specific pathogens of concern, such as *Salmonella* and *E. coli* O157:H7, to determine whether, in fact, pathogens are present in the juice. FDA is not requiring pathogen testing for the occasional, single positive for *E. coli*. However, if the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is found, the processor shall take corrective action as set forth in § 120.10 of this final rule. Corrective action requirements for a single positive generic *E. coli* are set forth in 120.25(d).

More than an occasional 20 mL sample positive for generic *E. coli* is an indication that the HACCP process is not sufficient to assure product safety. Under § 120.25, processors relying in whole or in part on surface treatments of the fruit shall have in place a sampling and testing plan sufficient to distinguish between the occasional positive sample and more frequent positives that are indicative of a failure to deliver the 5-log reduction. One way to distinguish between a chance event and an event that results from other factors (such as a failure to deliver the 5-log reduction) is to examine a defined series of tests and assess whether the unusual happens too frequently to be due to chance alone. FDA has evaluated the available data and information, and based on that analysis, has determined that two positives in any series of seven contiguous tests is an appropriate criterion in a sampling plan designed to signal a citrus juice processor relying on surface treatments that its 5-log reduction standard has not been achieved. This standard would alert processors relatively quickly that their system is not delivering the 5-log reduction and, at the same time, would have a relatively small incidence of "false alarms" for processors who are achieving a 5-log reduction. The statistical basis for this criterion is described in the paper entitled "Derivation of Sampling Plan to Meet the Testing Requirement in the Juice HACCP Final Rule for Citrus Juices That Rely Solely Or in Part on Surface Treatments to Achieve the 5-Log Reduction Standard" (Surface Treatment Sampling Plan) (Ref. 71).

FDA acknowledges that there were certain limitations in the data it had available to estimate *E. coli* levels that would be expected in juice not treated to reduce pathogenic microorganisms. For example, available data on *E. coli* levels in citrus juice were limited to orange juice. However, FDA believes that the sampling plan set out in the Surface Treatment Sampling Plan (Ref. 71) can appropriately be applied to all types of citrus juice. Orange juice represents a significant portion of the citrus juice market. For those citrus juices that have a lower occurrence of *E. coli* compared to orange juice, using the same sampling plan will provide an equivalent or greater level of food safety assurance for consumers without increasing any burden, such as the risk of false alarms, for processors. Moreover, a single standard sampling plan will simplify implementation and evaluation of HACCP for citrus juice processors using surface treatments. Other aspects of the data, including its limitations, are discussed in the Surface Treatment Sampling Plan (Ref. 71). FDA believes that the assumptions made, based on its review of available data, were sufficiently sound and reasonable to support this sampling plan. Therefore, FDA is specifying in § 120.25(e) that finding two samples positive for *E. coli* out of a series of seven sequential tests indicates that the 5-log reduction was not achieved. As additional data become available, the agency will consider those data and make adjustments in the HACCP regulation or in the Juice HACCP hazards and controls guide as appropriate.

Under § 120.25(e), if a processor finds two positives out of seven tests, the control measures to achieve the 5-log reduction would no longer be considered adequate. This would require immediate action to ensure that no product enters commerce that was produced where the 5-log reduction was not achieved, because inadequately processed juice creates the potential for the transmission of foodbourne illnesses. In addition, the processors would need to determine the source of the failure and to take steps to correct the failure. Corrective actions must include a review of the monitoring records for control measures to attain the 5-log reduction standard, and the processor must correct those conditions and practices that are not met. If the review of monitoring records or the additional testing shows that the 5-log reduction has not been achieved, such as a deviation in the process or its delivery, the processor shall take corrective action as set forth in § 120.10 of this final rule. The processor should also review the aspects of the HACCP plan relating to the 5-log reduction standard to determine whether the conditions and practices specified in the plan relating to the 5-log reduction standard are being met. If those conditions and practices are being met, and no other source of the problem can be found (*e.g.*, post process contamination), the processor should conclude that the treatment, although delivered as intended, was not able to achieve the intended 5-log pathogen reduction. In such case, the processor shall revalidate its HACCP plan in relation to the 5-log reduction standard.

While the control measures relating to the 5-log reduction standard are being evaluated, and until all corrective actions have been completed, including, if necessary, revalidation of those aspects of the HACCP plan relating to the 5-log reduction standard, the processor must use an alternative process or processes to achieve the 5-log reduction after the juice has been expressed. Processors should consider why the monitoring and verification results are not in accord, such as through an inadequate process or a failure in process delivery, and whether an alternate approach to achieving the 5-log reduction is needed. Once these steps have been taken, processors may again use the validated approach that relies solely or in part on surface treatments rather than the alternative process.

FDA has concluded that two positive *E. coli* samples in a series of seven tests indicate that the control measures to attain the 5-log reduction standard are inadequate and immediate corrective actions are necessary. Two positives in a window larger than seven tests may be due to chance rather than a failure to deliver the 5-log reduction. However, processors may wish to review test results over a larger window as a possible early warning that the process may be approaching failure. FDA intends to provide additional information in its Juice HACCP hazards and controls guide to assist processors in ensuring their review is sufficiently extensive to determine that no trends towards loss of control are occurring.

The agency concludes that new § 120.25 is a highly effective tool for verifying the 5-log reduction standard for processors using surface treatments. In addition, FDA is modifying § 120.11(a)(1) to include new paragraph (vi) to clarify that the activities in § 120.25 are part of the processor's verification activities.

7. Other Issues

(Comment 144) One comment requested that FDA clarify what is meant by moderate abuse conditions. The comment stated that *E. coli* may be less tolerant under these conditions, so moderate abuse could be a kill step for *E. coli*.

FDA discussed what it considered to be moderate abuse in the proposal (63 FR 20450 at 20478) (Ref. 2). FDA acknowledges that in some circumstances moderate abuse such as slightly elevated temperature in an acidic juice may actually decrease the numbers of certain microorganisms. If a processor intends to use a specific period of elevated holding temperature as a treatment, then the processor must validate the treatment as required for any CCP.

(Comment 145) A few comments asked that FDA eliminate the requirement that the 5-log reduction be maintained throughout shelf-life of the product. The comments maintained that there is no risk of recontamination once the juice is bottled.

FDA agrees that there is little risk of recontamination after a juice is bottled if the container is not damaged and the juice is handled under CGMP's. However, because of the importance of attaining the 5-log reduction for juice to be safe, it is reasonable that juice retain this characteristic throughout the period that it is available for consumption by consumers. Therefore, FDA is not amending § 120.24.

(Comment 146) One comment suggested that the performance standard should be phased in as data on meeting the performance standard becomes available. Another comment suggested that initially, a 3-log reduction could be required, then the following year a 4-log reduction would be required and finally a 5-log reduction.

The agency does not agree. FDA is providing ample opportunity to accommodate processors that may have difficulty implementing the 5-log reduction performance standard. First, the agency has required, since the effective date of the juice labeling final rule, that juice be treated to control pathogens (*i.e.*, meet a 5-log reduction performance standard) or bear a warning label statement. Since that same time, FDA also has been working with the juice industry, through workshops and programs, on the development of techniques that meet the performance standard. Finally, depending on their size, processors will have 1 to 3 years to implement this rule because the agency is providing additional time for small and very small businesses to implement their HACCP systems. Therefore, FDA concludes that it has already provided the means and reasonable time for processors to identify and implement available means to meet the 5-log reduction performance standard.

M. HACCP Enforcement Issues

(Comment 147) One comment requested that FDA establish a preapproval system for HACCP including plant registration, filing of HACCP plans, regular inspections, validation and verification of HACCP plans with microbial testing and tracebacks.

FDA believes that a preapproval system for HACCP plans would unduly burden the agency's resources without substantially increasing public health benefits. The effectiveness of a HACCP plan, including monitoring, recordkeeping, and verification, can best be evaluated under actual operating conditions. Therefore, as part of its enforcement plan for juice HACCP, FDA plans to do inspections of juice processing facilities to ensure compliance with the HACCP regulations after they become effective. These inspections will include collection and analysis of product samples for pathogens and other contaminants.

The agency is putting juice processors on notice that FDA is committed to inspecting all high risk firms annually, even before the effective date of this final rule, and intends to include sample collection and analysis as an integral part of that process. In the agency's view, processors of untreated juices, including firms producing citrus juices using surface treatments, fall into the category of high risk firms.

(Comment 148) One comment stated that tracebacks are very important and the need for information relating to origin of the product was not covered in the proposed rule.

FDA agrees that tracebacks are important and believes that the ability to traceback from a foodborne illness outbreak to the source is critical to controlling the size and duration of the outbreak. The source of an outbreak may

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be contaminated raw produce or contamination of product during production and distribution. Processors must implement CGMP's to address raw produce suitability for processing and, if there are hazards that are reasonably likely to occur in raw produce, implement HACCP controls for such hazards. The recordkeeping requirements of this rule mandate that all records include the identity of the product and the production code where appropriate. The purpose of these requirements is to ensure that records maintained under part 120 can be readily linked to a product and to the timeframe in which the product was manufactured. Linking a record to a specific product will be especially important when a product must be isolated or recalled. The information required in § 120.12 will help ensure that, when tracebacks are necessary, they can be carried out efficiently.

(Comment 149) One comment suggested that third party inspections should be done to validate HACCP and the results should be publicized.

FDA encourages such self-regulated programs within industry as third party inspections. Validation of the HACCP plan may be done by any individual, including a third party, that has been trained in accordance with § 120.13. The validity of the HACCP plan will ultimately affect the overall compliance status of firms, as determined through the inspection process. This status is public information.

(Comment 150) One comment suggested that FDA should model its HACCP regulation after that of FSIS with more frequent and less lenient inspections and validation testing.

Differences in the way FDA and FSIS implement their HACCP programs are due to differences in the products being regulated. Also, FSIS's authority and funding provides for the presence of inspectors in meat and poultry plants on a daily basis, whereas FDA's authority and resources do not require or allow for such frequent inspections. FDA, to the extent it is able, will work with juice processors during inspections to properly implement part 120.

(Comment 151) A few comments questioned whether FDA was planning to ask states to enforce the HACCP regulations in light of the agency's limited resources. Another comment stated that the States should verify compliance with any applicable safety regulations.

FDA cannot mandate that a State ensure that a firm is complying with FDA regulations. However, FDA has a long history of working cooperatively with the States to enforce food safety regulations, and the agency hopes to continue these cooperative relationships with States in the context of juice HACCP. FDA notes that some States adopt FDA requirements as their own laws and regulations; with those States, the final rule will effectively be enforced by the States.

(Comment 152) One comment requested that first inspections of HACCP systems be nonregulatory.

The agency recognizes the benefits of a nonregulatory (*i.e.*, educational) first inspection of implementation of a new HACCP system. For the seafood HACCP program, FDA elected to make the first inspection educational, rather than regulatory, as long as there were no urgent public health problems. FDA chose that approach because, for most processors, the first inspection provided the first direct feedback from the agency on the status of the firm's HACCP system. FDA will consider whether the same approach is warranted for some or all juice processors.

(Comment 153) One comment questioned the type of training that FDA would be providing its investigators to ensure that they understand the relevance of microbial data and that they will not go on "witch hunts" to find something wrong with the facility.

FDA's food processor investigators have considerable experience with HACCP in that most are currently conducting seafood HACCP inspections. Investigators are trained to look for violations of FDA regulations and to employ discretion and good judgment (*e.g.*, consider the significance of the violation) in determining how inspectional findings are handled. Further, an investigator's significant inspectional findings are reviewed by multiple higher level FDA employees to confirm the violation prior to the initiation of any regulatory action by the agency.

N. Miscellaneous Issues

(Comment 154) One comment suggested that FDA develop a juice HACCP pilot program.

FDA currently has a HACCP pilot program that includes juice processors. To date, two pasteurized juice processors and one fresh juice processor have completed the HACCP pilot program. FDA has used experience gained from the participation of these juice processors in the HACCP pilot program in proposing and finalizing this rule (Ref. 73).

(Comment 155) Several comments stated that FDA should not impose regulations on industry that will scare consumers into buying only certain foods (i.e., pasteurized juices).

It is not the aim of this rulemaking to scare consumers into buying only certain foods, such as pasteurized juices. However, juices have been the source of a number of outbreaks of illness and the death of one child, as well as have contributed to the death of an elderly man. Juices have also been the source of chemical and physical contaminants that have adverse public health effects, such as high lead levels, the presence of patulin, and the presence of glass pieces. For these reasons, the agency has determined that measures are necessary to ensure that juice is safe and to prevent additional illnesses and deaths, particularly among at risk groups. The primary purpose of this rulemaking is to protect the public, not scare them. FDA believes that these measures will promote public confidence in the safety of juice products.

IV. Effective Date

FDA proposed that any final rule based on the proposal become effective 1 year after its date of publication in the **Federal Register**. Further, FDA proposed that any final rule based on the proposal would not be binding on small businesses as defined in § 120.1(b)(1) until 2 years after publication in the **Federal Register**; and for very small businesses as defined in § 120.1(b)(2), the final rule would not be binding until 3 years after publication in the **Federal Register**.

(Comment 156) Many comments expressed concern that small businesses have the longest time to comply with the rules, even though outbreak data indicate that these producers are most likely responsible for producing contaminated juice.

The agency considered, in the HACCP proposal, the various issues surrounding the need for processors to immediately implement HACCP programs and the need to consider options to minimize the burden of the cost of implementation to small businesses (63 FR 20450 at 20463) (Ref. 2). To address the most immediate concerns (*i.e.*, pathogens) with juice, FDA has since finalized the warning label statement regulation in § 101.17(g) and has engaged in extensive education to alert consumers to the problems of consuming untreated juice. All juice shipped in interstate commerce or made from ingredients shipped in interstate commerce, including that produced by small businesses, that has not been processed to achieve a 5-log reduction in pathogens must be labeled with a warning for consumers (§ 101.17(g)). Thus, even if not produced under a HACCP system, the products of these small businesses will have some safeguards to protect public health. In addition to the label warning requirement, FDA encourages processors to implement a HACCP system as soon as possible to reduce hazards in juice rather than use the warning label statement. Consequently, the agency has decided to focus initial implementation of HACCP on processors that produce the largest quantity of juice and thus have the potential of affecting the largest number of consumers should contaminated product reach the marketplace.

(Comment 157) Several comments requested that the regulations become effective for all processors 1 year after the rule is finalized and several comments requested that the regulations become effective for all processors 2 years after the rule is finalized.

The agency disagrees with the comments. As noted, FDA considered various options for the implementation of the effective date in the proposed rule. The final rule requires that the bulk of juice produced in the United States will be processed under a HACCP system within 1 year. The agency realizes that it may take longer for small and very small businesses to fully implement HACCP systems and has extended the effective date for one or 2 years, respectively, to give them adequate time to comply.

V. Final Regulatory Impact Analysis

A. Introduction

FDA has examined the impact of this final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Under the Executive Order, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting some sector of the economy in a material way; or adversely affecting competition or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA finds that this final rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this final rule is a major rule for the purpose of congressional review.

In addition, FDA has determined that this rule is not a significant rule under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring benefit-cost and other analyses. Under UMRA a significant rule is defined as "a Federal mandate that may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year".

This Final Regulatory Impact Analysis reflects changes made in the regulation from the proposed rule to the final rule and changes in estimates as a response to comments. It also includes responses to comments on the PRIA. Where there were no changes in the estimates provided in the PRIA, the estimates are summarized here. Interested persons are directed to the text of the PRIA (Ref. 6) for a fuller explanation of the estimates over which there was no controversy or changes. The PRIA discussed a number of regulatory alternatives. FDA received some comments on these alternatives, however, none were specifically economic in nature. Thus, FDA's responses to comments on these alternatives are given in section III.1. There were no specific economic comments on the regulatory alternatives outlined in the PRIA.

B. Factors Considered in Developing This Analysis

This final rule requires all juice processors (as defined in the rule), regardless of size, to implement a HACCP program with a 5-log reduction (that is, a 100,000-fold reduction in pathogens) performance criterion. In the proposed rule, FDA tentatively exempted retailers. In addition, FDA tentatively decided to exempt as retailers very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers and other retailers. Based on the comments and other information, FDA has determined that it is necessary to cover such very small businesses. The estimated benefits and costs for this final rule reflect this change in the coverage of the rule.

Table 1 gives the time to the effective dates by size of firm in terms of time from the date of publication of this final rule.

TABLE 1.—TIME TO EFFECTIVE DATE BY SIZE OF FIRM

Firm size	Time to effective date
Large firms	12 months.
Small firms	24 months.
Very small firms	36 months.

For purposes of this rule, the agency is defining large processors as those who have more than 500 employees, small processors as those who have less than 500 employees and very small processors as those who have: (1) Total annual sales of less than $500,000, or (2) that have total annual sales of greater than $500,000 but total annual food sales of less than $50,000, or (3) that employ fewer than 100 full-time equivalent employees and annually sell less than 100,000 units of the juice in the United States.

This rule follows the implementation of the juice labeling rule, which covers juice that is packaged and has not been subjected to a 5-log reduction treatment. Because the coverage of the juice labeling rule and this juice HACCP rule overlap, and because to some extent both rules address microbial hazards associated with juice, it is necessary to take into account the benefits and costs estimated for juice labeling to avoid double-counting benefits and costs for juice HACCP.

C. Benefits

This analysis provides estimated benefits due to reduced adverse health effects. Presented here is a summary of the analysis provided for the proposed rule. Comments are addressed, and any changes from the analysis for the proposed rule are detailed in each section as appropriate.

FDA uses the following steps to estimate health benefits:

1. The most significant hazards in juice are described in terms of severity and duration;

2. The hazards are described in terms of resulting health effects and symptoms when they cause illness;

3. The health effects and symptoms are translated into consumer utility losses;

4. The utility losses are translated into values in terms of lost dollars (this gives the cost per case for every combination

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of level of severity and for the specified duration for each hazard);

5. The average annual number of reported cases associated with juice covered by this final rule are listed;

6. The factors used to account for under reporting of foodborne illness are explained;

7. The estimates of the average annual number of cases are given;

8. The estimated number of cases is divided according to level of severity;

9. The percentages of each type of hazard expected to be prevented by the proposal are listed; and

10. The total health benefits of the proposal are derived by multiplying steps 4, 7, and 8.

That is, TB = RC x CF x CR x V, where
TB = total health benefits in dollars,
RC = number of reported cases,
CF = under reporting correction factor,
CR = percent of cases reduced,
V = dollar value per case averted (medical costs + value of pain and lost function).

One comment stated that FDA had underestimated the amount of untreated juice consumed and, therefore, had underestimated the number of cases of illness associated with juice. FDA disagrees that the cases of illness addressed by the rule have been underestimated due to incorrect consumption estimates. FDA did not estimate the number of illnesses based on consumption. Instead, the agency estimated the number of illnesses by multiplying confirmed illnesses associated with juice by factors accounting for under-reporting of foodborne illness. Thus, FDA does not agree with this comment.

One comment questioned the model used to calculate benefits and asked if it has been "calibrated." The comment did not explain how the word calibrated is used in this case. FDA assumed that it meant to compare the estimates obtained using this model with the actual number of illnesses related to juice. FDA has used this model to calculate benefits for rules involving microbial hazards since 1994. The model is an adaptation of peer-reviewed research on estimating the costs of illness and injury (Ref. 74). The model is the best method known to FDA for estimating the benefits of rules involving microbial hazards, and is similar to that used by FSIS for similar rules. Because the actual number of cases of illness is not observable, it is not possible to compare the model's estimates to the actual number of illnesses.

1. Description of Microbial Hazards in Juice

The most significant health risks associated with juice products are those that result from microbial contamination. There are other non-microbial potential hazards related to juice that this rule is designed to control. FDA does not have enough data to quantify benefits for these non-microbial hazards. From 1992 to 1998 the hazards associated with commercially processed, packaged juice produced by nonretail establishments included *Bacillus cereus*, *Cryptosporidium parvum*, *E. coli* O157:H7, and *Salmonella* non *typhi*. Most of the information in section C of this document (Benefits) is taken from "Appendix: Preliminary Investigation into the Morbidity and Mortality Associated with the Consumption of Fruit and Vegetable Juices" (Ref. 6, the Appendix). The Appendix includes hazards other than those for which benefits have been estimated in this analysis. The hazards considered in section C of this document are those for which the risk is highest, meaning that they are the most significant in terms of probability of occurrence and/or severity of outcome.

Some comments stated that *C. parvum* should have been included in the estimate of benefits for the HACCP proposal. The comments cite FDA's inclusion of *C. parvum* in the list of hazards in the Appendix. FDA included *C. parvum* as a hazard addressed by the labeling rule but not as a hazard addressed by the proposed HACCP rule. The only documented cases of juice-related *C. parvum* illnesses from commercially produced products from 1992 to 1996 were from juice produced by processors making less than 40,000 gallons per year. Because these processors were included under the retail exemption from the proposed HACCP rule, the proposed HACCP rule would not have addressed the *C. parvum* hazard. Because this final HACCP rule covers all processors regardless of the volume of juice they produce, *C. parvum* is a hazard addressed by this final rule.

2. Description of Health Effects and Symptoms of Microbial Hazards in Juice

In order to quantify the loss (disutility) that individuals experience from becoming ill, the pain, suffering, and mobility loss must be scaled. Individuals who become ill suffer losses of functional status in terms of mobility, ability to do other physical activity, and ability to engage in social activities. Individuals who become ill also experience additional losses from the symptoms of the illness.

One comment stated that symptoms and functional effects associated with some cases are more severe than those described by FDA. FDA agrees with this comment. However, it is equally true that symptoms and functional effects associated with some cases are less severe than those described by FDA. The symptoms and functional effects described by FDA were developed with the assistance of medical doctors at FDA and are those of a typical case for each level of severity for each hazard. Effects vary to a considerable degree across cases of any illness or disease. Such variance is not captured by this analysis. However, FDA believes that the use of typical cases is appropriate for this analysis.

3. Utility Losses From Microbial Hazards in Juice

Decreases in functional status and symptoms and problems associated with illness translate into values of disutility. Utility losses for survivors are derived by multiplying the total disutility per day by the number of days that symptoms of the illness persists. This gives the utility loss for survivors in terms of the number of quality adjusted life days (QALD's) for each case of the categories of severity for each hazard. A QALD is a day of perfect health.

4. Value of Losses From Microbial Hazards in Juice

FDA values a QALD at $630. The value of utility losses for survivors comes from multiplying the number of QALD's lost due to the illness by the value of a QALD. This represents the value of pain and function losses that individuals experience. Additionally, there are the societal costs of medical treatment. These costs are shared generally between insurance companies and individuals. They include all aspects of medical expenses (*e.g.*, physician visits, laboratory tests, prescriptions and therapies, hospital stays). The value of losses per case is the sum of the value of utility losses for survivors and the medical costs for the categories of severity for each hazard.

5. Distribution of the Reported Cases per Year for Microbial Hazards in Juice

The analysis for the proposed rule used the average number of reported cases from 1992 through 1996 for each hazard for the types of products covered by the rule.

Some comments claimed that FDA had miscalculated the benefits of the HACCP proposal by including outbreaks associated with non-commercially produced juice. Although other parts of the proposed rule and the Appendix refer to outbreaks associated with non-commercially produced juice, the estimate of the benefits of the HACCP rule was based only on outbreaks associated with commercially produced juice.

Some comments stated that FDA had miscalculated the average number of cases per year. These comments used data presented in the Appendix to recalculate the average number of cases per year. The comments were confused because the Appendix lists several outbreaks that were associated with non-commercially produced juice. Because this regulation covers only commercially produced juice, outbreaks associated with non-commercially produced juice were not included in the calculation of the average annual number of cases. Thus, the average annual number of cases was properly calculated.

Tables 2 and 3 should clarify which outbreaks FDA has used in this analysis, and why some outbreaks were not used.

TABLE 2.—JUICE OUTBREAKS (1992 TO 2000) USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event
Orange juice, 1994	*B. cereus*	85	FDA recall data.
Orange juice, 1995	*Salmonella spp.*	62	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	70	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	14	Outbreak data.
Apple juice, 1996	*C. parvum*	31	Outbreak data.
Apple juice, 1996	*E. coli* O157:H7	1	Pennsylvania State Health Dept.
Orange juice, 1999	*Salmonella muenchen*	423	Outbreak data.
Apple juice, 1999	*E. coli* O157:H7	9	Oklahoma State Health Dept.
Orange juice, 2000	*Salmonella enteritidis*	88	Outbreak data.

TABLE 3.—JUICE OUTBREAKS (1992 TO 2000) NOT USED TO CALCULATE BENEFITS

Product and year of event	Hazard	Number of cases	Source of data on event	Reason not included
Orange juice Mixing Compound, 1992.	*Salmonella agona*	25	FDA recall Data	Orange Julius compound is mixed with juice at the retail location but does not contain juice.
Apple juice, 1993	*C. parvum*	160	Outbreak Data	Juice not made by commercial establishment.
Juice flavored Drinks, 1993.	*C. parvum*	Unknown	FDA recall Data	Approved municipal water supply was contaminated, rule not expected to prevent such occurrences.
Carrot juice, 1993	*Clostridium botulinum*	1	Washington State Health Dept.	Home-made product.
Orange juice, 1993	Unknown	23	Ohio State Health Dept.	Contamination likely caused by consumer.
Watermelon Juice, 1993.	*S. spp.*	18	Florida State Health Dept.	Home-made product.
Apple juice, 1996	*E. coli* 157:H7	6	Outbreak data	Juice not made by Commercial establishment.

Some comments claimed that FDA's analysis had not taken into account the efforts to control hazards made by the industry after the October 1996 outbreak. To estimate the number of illnesses that the proposed rule would prevent, FDA used the most recent 5-year period for which final CDC numbers were available. In the analysis of the proposed rule, FDA did not include 1997 in the estimate of illnesses that the rule would prevent because there was too great of a possibility that illnesses that had actually occurred had not yet been reported. FDA can now add the 1997 to 2000 experience to the 1992 to 1996 experience. By doing so FDA addresses this comments concern. The average number of cases reported per year for each hazard is described in table 4.

TABLE 4.—AVERAGE REPORTED CASES PER YEAR FOR MICROBIAL HAZARDS IN JUICE (1992 TO 2000)

Hazard	Average No. of cases reported per year
B. cereus	2
C. parvum	3
E. coli O157:H7	10
Salmonella (non-typhi)	64

6. Estimates of Factors Needed To Offset Underreporting of Foodborne Illness

It is widely recognized that the total number of foodborne illnesses is much greater than those numbers reported to the CDC. In order to compensate for the rate of underreporting, the number of known cases associated with a hazard (*i.e.*, reported to CDC) is multiplied by factors that are estimated to account for underreporting.

One comment took issue with the underreporting correction factors used by FDA. The comment stated that no underreporting correction factor should ever exceed 100. In the analysis accompanying the proposed rule, FDA used two estimates of underreporting correction factors that have been widely cited on this issue. FDA does not agree that underreporting correction factors should never exceed 100. The appropriate correction factors are those based on the best information available, without any limit created by a predetermined number.

Since the PRIA, CDC has published estimates of foodborne illness; in this final estimate of costs and benefits, FDA

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is relying on these recent CDC estimates. The estimates of underreporting correction factors used in the PRIA relied heavily on research that was over 20 years old. In some cases, the research preceded the recognition that *E. coli* O157:H7 was a pathogen. The correction factors based on this research required a significant amount of adaptation, extrapolation and interpolation by FDA. By relying on the recent CDC estimates of foodborne illness to determine correction factors, FDA is reducing its reliance on dated research and its own extrapolations. FDA believes that the estimates of benefits based on CDC estimates of foodborne illness should be more objective.

The underreporting correctiion factors calculated from the CDC reported by Mead et al, show the relationship between estimated total cases and culture-confirmed total cases. The factors are based on surveys estimating the probability that: (1) A person who becomes ill seeks medical care, and (2) the probability that the physician will obtain a stool culture from the person, and (3) the probability that the laboratory will test for the pathogen. The factor for a particular pathogen is the inverse of the multiplicative product of those three probabilities. FDA is relying on the CDC point estimates of the average number of cases per year and the CDC underreporting factor. Because CDC did not provide ranges for these estimates, FDA has insufficient information to probide a range of estimates for the benefits of this rule. FDA's use of a point estimate for the number of illnesses should not, however, be interpreted as implying the absence of uncertainty about these estimates.

For two of the hazards in this analysis, *E. coli* O157:H7 and *Salmonella*, FDA has used correction factors based on the ratio of total estimated cases to active surveillance cases estimated. FDA has used these factors for these hazards because the juice outbreaks for these hazards associated with this rule were discovered through the active surveillance of the FoodNet system. The FoodNet system is designed to identify interstate outbreaks and to more thoroughly discover cases associated with an outbreak.

For *B. cereus* FDA has used a correction factor based on the ratio of total estimated cases to reported outbreak cases. FDA has used this factor for this hazard because the juice outbreaks for this hazard associated with this rule were discovered through the standard outbreak reporting process. *B. cereus* is not a hazard tested for in the FoodNet system, and because of its mild symptoms is very likely to be underreported.

For *C. parvum* FDA has used a correction factor based on the ratio of total estimated cases to 10 percent of the estimated passive surveillance cases. According to CDC, reported outbreak cases account for only 10 percent of the cases accounted for through passive surveillance. FDA has used this factor for *C. parvum* because the juice outbreaks for this hazard associated with this rule were discovered through the standard passive surveillance process. *C. parvum* is not a hazard tested for in the FoodNet system, nor is it on the list of hazards reportable to CDC. Because of its mild symptoms it is very likely to be underreported.

The correction factors used in this analysis are given in table 5.

TABLE 5.—ESTIMATES OF FACTORS NEEDED TO OFFSET UNDERREPORTING OF FOODBORNE ILLNESS

Hazard	Correction factor
B. cereus	380
C. parvum	1,071
E. coli O157:H7	20
Salmonella (non-typhi)	38

7. Estimates of Juice-Associated Cases Per Year

In table 6, FDA has estimated ranges of the likely annual number of cases that occur for each of the four pathogens studied.

TABLE 6.—ESTIMATE OF JUICE-ASSOCIATED CASES COVERED PER YEAR

Hazard	Case
B. cereus	3,420
C. parvum	3,210
E. coli O157:H7	200
Salmonella (non-typhi)	2,430

8. Estimate of Juice-Associated Cases per Year Not Prevented by Labeling Rule

FDA estimated that the juice labeling rule would prevent up to 140 juice-associated illnesses (10 *C. parvum*, 40 *E. coli*, 90 *Salmonella*) as consumers avoid consumption of untreated juice. This HACCP rule will effectively supersede the labeling rule for all those processing establishments covered by the labeling rule. Therefore, once it goes into effect, the HACCP rule will be responsible for prevented juice-related illnesses and not the labeling rule. However, this analysis should attribute to the juice HACCP rule prevention of only those illnesses that would not have been prevented by the juice labeling rule had this rule not superseded it. To estimate the potential benefits of this HACCP final rule, FDA subtracted 140 cases that were estimated to be prevented by the labeling rule (assuming that 16 percent of consumers read the label and do not consume untreated juice) from the estimates provided in table 6. The 16 percent consumer response estimates are the largest estimates of consumer response that FDA has made for the juice labeling rule. Therefore, subtracting the 16 percent consumer response estimates from the estimates of the total number of juice-related illnesses yields the lowest number of illnesses that may be prevented by this juice HACCP final rule. Table 7 gives estimates of the number of juice-related illnesses per year not prevented by the juice labeling rule. The estimates in table 7 come from subtracting the estimated 140 cases prevented by the labeling rule from the estimated cases in table 6.

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY

Hazard	Severity	Percent	Cases
B. cereus	Mild	99	3,390
	Moderate	1	30
	Severe	.03	1
	Total cases	100	3,421
C. parvum	Mild	90	2,890
	Moderate	9	290
	Severe	.7	20
	Death	.02	1
	Total cases	100	3,200

TABLE 7.—THE ESTIMATED NUMBER OF JUICE-ASSOCIATED CASES NOT PREVENTED BY THE LABELING RULE DIVIDED ACCORDING TO LEVEL OF SEVERITY—Continued

Hazard	Severity	Percent	Cases
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.0	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA-short term	2	50
	ReA-long term	5	120
	Death	5	120
Salmonella (non typhi)	Total cases	100	2,340

9. Percent of Cases Preventable by HACCP Proposal

Table 8 indicates the percent of cases for each hazard expected to be prevented by the rule. In general, most pathogens will be eliminated when a 5-log treatment is applied. For example, *E. coli* O157:H7, *C. parvum* and *Salmonella* should all be completely eliminated from juice by standard methods of flash pasteurization (in the absence of extraordinarily high counts, detrimental human intervention, or equipment failure). However, hazards associated with *B. cereus* will not necessarily be eliminated by heat treatment. This bacterium forms spores that are more difficult to kill by the usual heat process applied to juice.

In the proposed rule, FDA tentatively exempted certain small retail processors. FDA estimated that the exemption for small retail processors would affect 14 percent of the volume of unpasteurized juice. Therefore, the agency estimated that though pathogen controls may be 100 percent effective in controlling some hazards, such controls would only prevent 86 percent of the cases of illness from these hazards, because of the 14 percent of juice not covered. The final rule covers all processors of juice as defined in the final rule; therefore, controls will affect the full volume of juice made by processors. (Retailers are not covered by this rule. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and eating places.)

TABLE 8.—PERCENT OF CASES PREVENTABLE BY HACCP PROPOSAL

Hazard	Percent of cases preventable by HAACP proposal
B. cereus	10
C. parvum	100
E. coli O157:H7	100
Salmonella (non typhi)	100

Table 9 indicates the number of cases for each hazard expected to be prevented by the rule.

TABLE 9.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTED BY HACCP RULE

Hazard	Severity	Percent of cases	Cases
	Mild	99	340
	Moderate	1	0
	Severe	.3	0
B. cereus	Total case	100	340
	Mild	90	2,890
	Moderate	9	290
	Severe	7	20
	Death	.02	1
C. parvum	Total cases	100	3,200
	Mild	59	95
	Moderate	38	60
	Severe-acute	3	5
	Severe-chronic	4	10
	Death	.08	0
E. coli O157:H7	Total cases	100	160
	Mild	68	1,590
	Moderate	31	730
	Severe	1	20
	ReA–short term	2	50
	ReA–long term	5	120
	Death	.04	1
Salmonella (non typhi)	Total cases	100	2,340

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10. Estimates of Annual Benefits for HACCP Proposal

The total benefits for the categories of severity for each hazard are derived by multiplying the number of cases prevented by this rule by the estimates of the value of utility losses and medical costs per case. The sum of those benefits for each hazard is the total benefits of this rule for pathogen control. Table 10 gives the estimate of benefits for each hazard.

TABLE 10.—ESTIMATES OF JUICE-ASSOCIATED CASES PER YEAR PREVENTABLE BY HACCP RULE

Hazard	Severity	Dollars
	Mild	$102,000
B. cereus	Total	102,000
	Mild	5,780,000
	Moderate	1,450,000
	Severe	360,000
	Death	5,000,000
C. parvum	Total	12,590,000
	Mild	190,000
	Moderate	240,000
	Severe-acute	165,000
	Severe-chronic.	12,210,000
E. coli O157:H7.	Total	12,805,000
	Mild	1,590,000
	Moderate	1,460,000
	Severe	320,000
	ReA-short term.	350,000
	ReA-long term.	117,120,000
	Death	5,000,000
Salmonella (non typhi).	Total	$125,840,000

Table 11 presents the estimate of annual benefits based on table 10.

TABLE 11.—ESTIMATES OF ANNUAL MICROBIALLY RELATED BENEFITS FOR HACCP PROPOSAL

Hazard	Dollars
B. cereus	$102,000
C. parvum	12,590,000
E. coli O157:H7	12,805,000
Salmonella (non typhi)	$125,840,000
Total	151,000,000

11. Pesticide Residues

There are two potential benefits associated with the regulation of pesticides: (1) Decreases in cancer and other illness caused by chronic consumption of pesticide residues and, (2) social benefits associated with reductions in the costs of recapturing firm goodwill. FDA cannot quantify the cost savings that will occur because of more vigilant monitoring of pesticide residues by firms under a HACCP rule.

12. Summary of Benefits

Table 12 summarizes the benefits of this rule.

TABLE 12.—BENEFITS OF JUICE HACCP RULE

Type of benefit	Annual value
Reduced illness and death from Controlling pathogens.	$151 million.
Reduced harm from physical and chemical hazards.	Not quantified, effects often long-term and probably small.
Total Quantified Benefits.	$151 million

D. Costs

The costs of these rules have been estimated by multiplying the costs for each proposed requirement on a per-plant basis by the number of plants affected by each requirement. Cost per plant will vary by current practice, product, and size.

1. Coverage

In the proposal, FDA tentatively decided that retailers would include processors that are very small businesses, that make juice on their premises, and that directly sell juice or juice products to consumers and other retailers—provided that retail sales of juice and juice products do not exceed 40,000 gallons per year. As noted, FDA has decided in the final rule not to exclude such processors from the rule's requirements. The final rule covers all processors of juice except those who are retailers. Retailers are those businesses that sell only direct to consumers and include grocery stores, supermarkets, farms, roadside stands, restaurants, and other eating places.

Since FDA published the proposed rule, it collected data showing that 24 percent of very small apple juice processors only sell juice direct to consumers. FDA assumes that the same percentage of very small orange juice processors only sell juice direct to consumers. Therefore, about 380 very small apple and 70 very small orange juice processors are exempted from the rule as retailers.

FDA estimated that 5 percent (about 50 plants) of the 900 plants in the FDA Official Establishment Inventory (OEI) would have implemented HACCP as required by this rule by the effective date of the rule even if FDA had not done this rulemaking. No HACCP costs are attributable to this rule for these plants.

Table 13 shows the estimated number of establishments affected by the rule. These numbers exclude the retailers and the 5 percent of plants already doing HACCP.

TABLE 13.—NUMBER OF PLANTS AFFECTED BY THE RULE

Plant type	Number of establishments affected
Juice manufacturers in the OEI	850
Very small apple juice makers	1,220
Very small orange juice makers	230
Total	2,300

2. Length of Production Period

The agency has assumed that 50 percent of the 850 plants in the OEI plus all of the 1,450 very small juice makers affected by the HACCP rule produce seasonally. Table 14 shows the length of the production period for plants producing seasonally and year round.

TABLE 14.—PLANTS' PRODUCTION PERIOD

	Weeks of operation per year	Hours of operation per day	Number of plants
Seasonal	16	12	1,875
Year Round	52	24	425
Total			2,300

3. Cost Estimates by Requirement

a. HACCP costs.
i. CGMP's (§ 120.5)
ii. Prerequisite Program SOP's (§ 120.6)
iii. Hazard Analysis (§ 120.7)
iv. HACCP Plan (§ 120.8)
v. Corrective Actions (§ 120.10)
vi. Verification and Validation (§ 120.11)
vii. Process Verification for Certain Citrus Processors(§ 120.25)
viii. HACCP Records (§ 120.12)
ix. Training (§ 120.13)
x. Imports and Foreign Processors (§ 120.14)
b. Summary of Costs.
c. Take First Year and Recurring Cost Per Activity.

a. *HACCP costs.*—i. *CGMP's (§ 120.5).* No costs are attributed to this section for this rulemaking. In 1996, only 6 percent of the plants inspected were cited for official action. Thus, an overwhelming majority of firms are complying with part 110. Therefore, there is no additional cost of complying with this provision because plants are already complying with part 110. Therefore, FDA assumed that this rule will have no effect on the enforcement of the CGMP's for juice products.

ii. *Prerequisite program SOP's (§ 120.6).—Developing SOP's.* The cost per plant of developing SOP's is approximately $260. If one half of the 850 domestic plants in the OEI and all of the 1,450 very small juice processors do not currently have SOP's, then they will have to develop them to comply with this regulation. Under these assumptions, the total cost for the industry to develop SOP's is approximately $488,000 ($260 x 1,875 plants).

Implementing sanitation controls with corrections of deviations from SOP's. Based on information from inspection reports, FDA assumes that about 30 percent of all 2,300 covered juice plants (about 690 plants) are likely to have sanitation controls that are insufficiently implemented, but which do not warrant administrative or regulatory action. If it costs each of these 690 plants $500 to implement sanitation controls and to correct deviations from SOP's earlier than they would do otherwise, then the total cost for this requirement is $345,000. Because this cost is discounted, it is added as a one-time expenditure in the total costs.

Monitoring and documenting of SOP's. Table 15 shows the distribution of per plant and total industry costs based on the estimate in table 25 for SOP monitoring and documenting needed to comply with this rule.

TABLE 15.—TOTAL ANNUAL COST OF SOP MONITORING AND DOCUMENTING

	Annual per plant SOP monitoring and documenting cost	Number of plants	Annual SOP monitoring and documenting cost
Seasonal	$100	1,662	$166,000
Year round	340	213	72,000
Totals		1,875	238,000

iii. *Hazard analysis (§ 120.7).* FDA estimates that performing a hazard analysis takes 20 labor hours. At $13 per labor hour the cost of performing a hazard analysis is about $250 per plant. Approximately 2,300 plants will need to perform a hazard analysis to comply with this rule. Therefore, the total cost to perform a hazard analysis is approximately $575,000.

iv. *HACCP plan (§ 120.8)—HACCP plan development.* FDA estimates that developing a HACCP plan takes 60 labor hours. At $13 per labor hour the cost of developing a HACCP plan is about $750 per plant. Only those plants that determine from their hazard analysis that they have hazards that are reasonably likely to occur will have to develop a HACCP plan.

Processors that produce shelf-stable or juice concentrate may conclude after their hazard analysis that they need not include pathogen control in any HACCP plan as required by § 120.24(a), if they include a copy of the thermal process in their written hazard analysis. These processors only need a HACCP plan if they have other hazards that are reasonably likely to occur.

Table 16 shows those processors expected to develop HACCP plans.

Adding the categories of processors that develop HACCP plans yields a total of about 1,560 out of the original 2,300 processors that perform a hazard analysis. This may be a small overestimate because some of the citrus processors that now do not make self-stable products may begin to do so because of this rule. It also may be a small overestimate because of the small potential for overlap among the categories.

TABLE 16.—NUMBER OF PLANTS WITH HACCP PLANS

Processors with pathogen Hazards	1,460
Processors with natural toxin Hazards	20
Processors with pesticide Hazards	80
Total processors with HACCP Plans	1,560

Approximately 1,560 plants will need to develop a HACCP plan at a cost of $750 each to comply with this rule. Therefore, the total cost to develop HACCP plans is approximately $1,170,000.

Pathogen controls. In response to this rule, many processors that are not now heat-treating their products are likely to begin doing so. Processors may choose any lawful means to achieve the required 5-log reduction. However, costs here are estimated for pasteurization as the lowest-cost technology now available.

In the PRIA FDA estimated that costs for initiating pasteurization range from $18,000 for a very small seasonal operation to $35,000 for a larger year round operation. FDA received many comments claiming that the initial cost for initiating pasteurization was $30,000 even for a small operation. Because of the number of comments claiming that the initiation of pasteurization would cost $30,000 for a small operation, FDA has used a range for its estimate of the cost of initiating pasteurization for very small processors.

Of the 2,300 processors covered by the HACCP rule only a portion of these will need to initiate pasteurization. In this final rule, processors of shelf-stable juice and juice concentrate will not need to incur additional costs for the control of pathogens. FDA estimates that this new provision in the final rule applies to about 600 processors (70 percent of the processors listed in the OEI) affected by this rule.

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FDA estimates that all but 20 of the rest of the affected processors listed in the OEI (230 plants) and 30 percent of the 1,220 very small apple juice processors (370 plants) are already operating pasteurization equipment. Therefore, 600 plants do not need to implement additional pathogen controls.

For the purpose of this analysis, FDA has concluded that it is unlikely that fresh orange juice processors will have to pasteurize their products to achieve a 5-log reduction when a HACCP program is adopted because of the nature of the fruits, the availability of effective surface treatments and the methods of juice extraction commonly used by industry. However, given the information gained from the December 1999 NACMCF meeting on citrus juice and the several recent outbreaks associated with fresh citrus juice, it is clear that most fresh orange processors will need to incur additional costs to implement effective 5-log pathogen reduction controls. In the PRIA, FDA estimated that costs for these processors were limited to the costs of creating and operating a HACCP system with appropriate monitoring and recordkeeping of the necessary CCP's, not to purchasing pasteurizing equipment. In this final analysis, FDA is estimating costs for fresh orange juice processors to improve pathogen controls. Although the measures to improve such controls will not necessarily be pasteurization, FDA is estimating these costs to be equivalent to the costs for initiating pasteurization. FDA only has cost data for pasteurization which is also the only widely-adopted commerical technology for controlling pathogens in juice. Citrus processors may choose to adopt a technology more expensive that the $18,000 to $30,000 estimated here for the implementation of pasteurization. However, the more expensive technologies would likely be adopted for reasons other than compliance with this rule.

Therefore, 20 affected processors listed in the OEI, 300 very small citrus processors and 850 very small apple juice processors (a total of 1,170 plants) will incur costs to implement additional pathogen controls. Table 17 shows the first year total cost of pathogen control attributable to the HACCP rule.

TABLE 17.—FIRST YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP PROPOSAL

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$18,000–$30,000	850	$15,300,000–25,500,000
Very small orange juice processors	18,000–30,000	300	5,400,000–9,000,000
Juice processors in the OEI	35,000–58,000	20	700,000–1,160,000
Total		1,170	21,400,000–35,660,000

Pasteurization will require ongoing costs for operation and maintenance. FDA estimates these annual costs for labor, utilities, and materials subsequent to the first year to be $7,000 per year for very small processors and $8,000 per year for processors in the OEI. The total cost of pathogen control in subsequent years is given in table 18.

TABLE 18.—SUBSEQUENT YEAR COST OF PATHOGEN CONTROL ATTRIBUTABLE TO HACCP RULE

Processor type	Cost per plant	Number of plants	Total
Very small apple juice processors	$7,000	850	$5,950,000
Very small orange juice Processors	7,000	300	2,100,000
Juice processors in the OEI	8,000	20	160,000
Total		1,170	8,210,000

Other costs are related to processing for pathogen control. The pasteurization of juice causes changes in the characteristics of the products, primarily in terms of texture and taste. Some current consumers of nonheat-treated juice will bear the costs of losing a particular product as well as costs of searching for products with the characteristics that they prefer. Thus, one cost of these regulations is the limited loss of "fresh" juice: that is, juice that is not heat (or otherwise) processed.

Some consumer comments indicated a strong preference for fresh juice; however, although FDA expressly asked for comments on this issue in its November 1999 notice, no comments suggested any means of estimating this cost. FDA has no information on how readily consumers will accept pasteurized juice in the place of fresh juice nor does FDA have any other information that could be used to estimate that cost.

Glass and direct food additive HACCP controls. FDA has not attributed any costs for control of glass or unapproved direct food additives although these potential hazards are among those that are likely to be relevant for juice. The agency believes that even if broken glass is determined to be a hazard to processors packing juice in glass, these processors are already currently implementing every feasible control for this potential hazard in order to limit their liability and to provide consumer protection. Additionally, although approximately 25 percent of the processing plants pack juice in glass containers, this number is diminishing rapidly for economic and safety reasons.

Regarding food additives, many juice products contain food or color additives for the purpose of coloring or extending product shelf life. However the agency believes that even if unapproved food additives are determined to be a hazard, these processors using direct food additives in juice are already currently implementing sufficient controls for these potential hazards as FDA strictly regulates them.

Natural toxin controls. FDA believes that in most every case processors of domestic apples should be able to control natural toxin hazards such as patulin, by processing controls such as washing and culling. This can be accomplished at no additional cost.

Processors using imported juice concentrate are likely to need to initiate a sampling regime for natural toxins. FDA assumes that the 23 large plants will randomly sample 30 shipments per year at a cost of $150 per sample. The total marginal cost of patulin testing is approximately $104,000 (30 tests x $150/test x 23 firms). Costs per plant are $4,500. If any lots are found positive, costs will be incurred for taking corrective action.

Pesticide controls. FDA believes that all 175 affected plants operated by large firms are currently doing a sufficient amount of sampling and monitoring (or receiving supplier certificates) for pesticides residues. Therefore, FDA assumed that there are no additional costs for large firms to control this potential hazard. This does not mean that FDA believes that no large firms will identify pesticides as a hazard that needs to be controlled under HACCP. Large and small firms are more likely than very small firms to use imported produce, which may not be subjected to as strict controls as U.S. produce in all cases. FDA believes that 10 percent of all large and small firms (80 plants total) will determine that pesticide hazards are reasonably likely to occur. However, FDA believes that all large firms are already sufficiently addressing this issue with present expenditures. FDA made this estimate based on its knowledge of the magnitude of the pesticide problem in juice.

If processors determine that pesticide residues are hazards for their product, then they must run pesticide residue tests to ensure that there are no pesticides either over tolerance or used on products for which there is no tolerance. FDA believes that 10 percent of the shipments received by small processors must be covered by a sampling plan. Sixty-five small plants are believed to cover their shipments with a pesticide-sampling plan. Average cost per plant is estimated to be $1,500. The total annual marginal cost of pesticide testing is approximately $98,000 (10 tests x $150/test x 65 firms).

v. *Corrective actions (§ 120.10).—Corrective action plan.* The development of a corrective action plan for juice products is less expensive than revalidation after each deviation from a CL. FDA estimates that a corrective action plan for juice products can be developed in 4 hours with a cost per plant of approximately $50 (about 4 hours of management time).

All of the plants that develop HACCP plans as a result of this rule will develop corrective action plans to comply with this rule. The total cost for 1,560 plants at $50 each to develop corrective action plans is approximately $78,000.

Corrective actions. Plants operating under HACCP plans will take corrective actions when CL's are exceeded for hazards such as pesticide residues, unacceptable fruit for pathogen controls, and presence of natural toxins. Costs of corrective actions are expected to decline as processors gain more experience under a HACCP system and as the number of corrective actions decreases. Tables 19 and 20 show the estimated first year and subsequent year costs of corrective actions per plant.

TABLE 19.—COST OF FIRST YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$450	1,490	$671,000
Year round	1,460	70	102,000
Totals		1,560	773,000

TABLE 20.—COST OF SUBSEQUENT YEAR CORRECTIVE ACTIONS

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$110	1,490	$164,000
Year round	340	70	24,000
Totals		1,560	188,000

Verification and validation (§ 120.11).—Verification. The record verification cost per plant per production cycle is given in table 21.

TABLE 21.—COST OF RECORD VERIFICATION

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$420	1,490	$626,000
Year Round	1,350	70	95,000
Totals		1,560	721,000

Validation. Processors with HACCP plans must validate their HACCP plans during the first year after implementation and at least annually, or whenever any changes occur that could affect or alter the hazard analysis, or

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HACCP plan. Further, processors who have no HACCP plans because there are no hazards that are reasonably likely to occur in that process (as may be the case with processors of shelf-stable or concentrated juice), the processor must reassess their hazard analysis when any significant change occurs. Examples of things that may change include: (1) Raw material specifications or sources of raw materials, (2) product formulation, (3) processing methods or systems, (4) packaging, (5) finished product distribution systems, or (6) intended consumers or use by consumers.

Tables 22 and 23 give the estimated cost for validation in the first and subsequent years.

TABLE 22.—COST OF FIRST YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1,640	$1,640,000
Year Round Business	2	1,000	120	240,000
Year Round Small Shelf-Stable or Concentrate Business	1	1,000	130	130,000
Year Round Large Business	2	600	80	96,000
Year Round Large Shelf-Stable or Concentrate Business	1	600	95	57,000
Totals	2,265		2,065	$2,163,000

TABLE 23.—COST OF SUBSEQUENT YEAR VALIDATION

Plant type	Number of validations	Cost per validation	Number of plants	Total cost
Seasonal Small Business	1	$1,000	1,490	$1,490,000
Year Round Small Business	2	1,000	35	70,000
Year Round Large Business	2	600	35	42,000
Totals	1,630		1,560	1,602,000

vii. *Process verification for certain citrus processors (§ 120.25).* Citrus processors that decide to rely on surface treatments of the fruit to achieve the requisite 5-log reduction (rather than treating the juice directly) are required to sample their final product to verify the effectiveness of the HACCP plan. These processors are required to test two 10 mL subsamples for generic *E. coli* every 1,000 gallons or every 5 days whichever is more frequent. FDA assumes that the cost of testing two 10 mL subsamples for generic *E. coli* is $50. FDA estimates that there are 240 citrus processors that will be affected by this section. To estimate the number of samples, FDA began with the estimated annual U.S. untreated orange juice consumption estimate of 11,700,000 gallons. FDA then assumed that 10 million gallons were packaged for resale and therefore covered by this rule. FDA then assumed that the 180 processors that would sample at a frequency of once every 5 days on average process 750 gallons during that time. These processors are assumed to be seasonal processors operating for only 16 weeks a year. FDA made these assumptions based on its knowledge of microbial testing and beliefs about the volume of untreated packaged juice sold by small processors. That set of processors accounts for 2,160,000 gallons annually. The remaining 60 processors share production of the remaining 7,840,000 gallons resulting in about 130 samples per year per processor.

Table 24 shows the estimated cost for process verification sampling for these citrus processors.

TABLE 24.—ESTIMATED COST FOR VERIFICATION SAMPLING

Sample frequency	Number of samples	Number of processors	Cost per sample cost	Total
Every 5 days	16	180	$50	$144,000
Every 1,000 Gallons	130	60	50	390,000
Total	10,720	240		$534,000

Also, any time that 2 process-verification samples test positive for generic *E. coli* in a series of 7 samples there is a process verification failure. The processor must not sell the product without further processing and must review its monitoring records, reevaluate its HACCP plan, and if no obvious deficiencies in the HACCP plan are discovered, must revalidate its HACCP plan. FDA estimates that even if all citrus processors that rely on surface treatments to achieve a 5-log reduction are fully successful in achieving the 5-log reduction, 2 samples in a series of 7 will test positive for generic *E. coli* once in every 1,000 samples. Based on an estimate of 10,720 samples taken per year, this will occur about 11 times per year. FDA assumes that the cost of further processing of the product will be more expensive than withdrawing and destroying the product, which should not exceed 1,000 gallons. FDA assumes that the cost of withdrawing and destroying the product plus the cost of reviewing monitoring records, reevaluating and revalidating HACCP plan is $20,000. FDA made this assumption based on its experience with such small lot market withdrawls. Therefore, the additional cost of a process verification failure is $220,000 per year. The annualized cost of a process verification failure is $320 for a seasonal processor sampling every 5 days ((16/1,000) × $20,000 = $320) and $2,600 for a year round processor sampling every 1,000 gallons ((130/1,000) × $20,000 = $2,600).

The total cost of process verification testing for untreated citrus juice is $764,000 per year ($534,000 + $220,000 = $764,000).

viii. *HACCP records (§ 120.12).—Monitoring and recordkeeping.* The additional monitoring and recordkeeping that needs to be done throughout the entire plant is estimated to be equivalent to 5 percent of one worker's time (3 minutes per hour of operation per plant). Table 25 shows the annual cost of additional monitoring and recordkeeping per plant. It also shows the distribution of per plant costs and total industry costs for the additional monitoring and recordkeeping needed to comply with this final rule.

TABLE 25.—COST OF MONITORING AND RECORDKEEPING

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$900	1,490	$1,341,000
Year Round	5,600	70	392,000
Totals		1,560	$1,733,000

Record maintenance and storage. The annual cost of record maintenance and storage per plant is described in table 26.

TABLE 26.—COST OF RECORD MAINTENANCE

Plant type	Cost per plant	Number of plants	Total cost
Seasonal	$360	1,490	$536,000
Year Round	830	70	58,000
Totals		1,560	$894,000

ix. *Training (§ 120.13).—HACCP coordinator training.* Processors may need to employ a HACCP coordinator to carry out the duties specified for such a person. FDA estimates that the cost of HACCP coordinator training is $1,300 for each of the 2,300 processing plants, or a total industry cost of $2,990,000.

Employee training in HACCP. Each processor with a HACCP plan will need to train employees in their HACCP-related activities. This analysis assumes that each plant must train 5 employees or 10 percent of their employees in HACCP-related responsibilities, whichever is greater. Table 27 describes the cost of training each employee for 8 hours annually (the equivalent of 40 minutes per month for 10 percent of the employees) and the total cost of this level of training.

TABLE 27.—COST OF EMPLOYEE TRAINING

Average plant employment	Number of employees trained	Cost per employee	Number of plants	Total cost
3	3	$100	1,459	$437,700
7	5	100	10	5,000
15	5	100	19	9,500
35	5	100	28	14,000
75	8	100	29	23,200
175	16	100	15	27,000
Totals	5,160		1,560	$516,000

x. *Imports and foreign processors (§ 120.14).—Importers.* The agency estimates that the cost of these activities will be $10,000 for each of the 120 importers in the first year, decreasing to $5,000 in subsequent years. Total costs for importers is $1,200,000 in the first year and $600,000 in subsequent years.

Foreign juice processors. The estimated first year cost per foreign juice exporter is approximately $26,000, and the cost in subsequent years is $22,000. Therefore the total cost in the first year for 300 foreign processors is approximately $8 million and approximately $7 million in subsequent years. Tables 33 and 34 in the Regulatory Flexibility Analysis, which follows, shows typical costs for large plants that have not already implemented HACCP. The agency assumes that these costs are representative of foreign plants exporting to the United States.

b. *Summary of Costs*—The total quantified costs are approximately $44 to $58 million in the first year and $23 million in all subsequent years. Table 28 summarizes costs of the rule by provision.

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C. TABLE 28.—TOTAL FIRST YEAR AND RECURRING COST PER ACTIVITY

Activity	First year costs	Recurring costs
Develop SOP's	$488,000	
Prerequisite Program SOP's	345,000	
Monitoring and Documenting for SOP	238,000	238,000
Hazard analysis	575,000	
HACCP plan	1,170,000	
Pathogen controls	21,400,000–35,660,000	8,210,000
Natural toxin controls	104,000	104,000
Pesticide controls	98,000	98,000
Corrective action plan	78,000	
Corrective actions	773,000	188,000
Verification	721,000	721,000
Validation	2,163,000	1,602,000
Process verification	764,000	764,000
HACCP monitoring and recordkeeping	1,733,000	1,733,000
Record maintenance and storage	694,000	694,000
HACCP coordinator training	2,990,000	
Employee training	516,000	516,000
Importers	1,200,000	600,000
Foreign processors	8,000,000	7,000,000
Totals	44,000,000–58,000,000	23,000,000

E. Summary of Benefits and Costs

FDA has examined the benefits and costs of this rule as required under Executive Order 12866. Over time, the relationship between benefits and costs changes, so that, to compare them properly, benefits and costs must be discounted to the present year (the time at which the decisions are being made). The quantified benefits (discounted annually over an infinite time horizon at 7 percent) are expected to be about $2 billion ($151 million/7 percent) and the quantified costs (discounted annually over an infinite time horizon at 7 percent) are expected to be about $400 million.

VI. Regulatory Flexibility Analysis

FDA has examined the impact of this rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the RFA requires agencies to analyze options that would minimize the economic impact of that rule on small entities. The agency acknowledges that this rule is likely to have a significant impact on a substantial number of small entities.

A. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that will have a significant impact on a substantial number of small entities. The HACCP rule is being issued to ensure that juice processors control all physical, chemical, and microbial hazards in their products.

B. Definition of Small Business and Number of Small Businesses Affected

The RFA requires a statement of the definition of small business used in the analysis and a description of the number of small entities affected.

Table 29 shows the definition of small business for each type of establishment affected and a description of the number of small entities affected by the rule. The agency has accepted the Small Business Administration (SBA) definitions of small business for this analysis.

TABLE 29.—APPROXIMATE NUMBER OF SMALL PLANTS COVERED BY THESE RULES

Type of establishment	North American industry classification system codes	SBA definition of small by category	Category defined as small by SBA	Percent of No. of small businesses covered
Juice manufacturers in the OEI	311421, 311411	Less than 500 employees	75%	675
Roadside-type apple juice Makers	311421, 311411	Less than 500 employees	100%	1,220
Roadside orange juice Makers	311421, 311411	Less than 500 employees	100%	230
Totals				2,125

C. Description of the Impact on Small Entities

1. Costs to Small Entities

Because there is a broad distribution of products covered, firm types, current processing practices and sizes, it would be misleading to report average per firm costs. However, some idea of the costs can be gained from the following examples. The impacts that the costs will have on a firm will vary depending on the total revenue derived from juice by a firm and the profit (return on sales) associated with juice production. Data on food manufacturing firms indicates that 75 percent of firms have return on sales of less than 5 percent.

The first example (table 30) is of a small seasonal apple cider plant that is now producing nonheat-treated juice, with fruit from a known source, and that has not developed or implemented sanitation SOP's. This plant will need to buy a pasteurizer (or find and validate a different process that achieves a 5-log reduction). The next example (table 31)

is a small plant that is producing orange juice concentrate year round with fruit from a known source, and that has already developed and implemented sanitation SOP's (except that records have not been kept on SOP's). The third example (table 32) is a small plant operating year round producing unpasteurized orange juice, using commingled fruit, and that has not developed or implemented sanitation SOP's.

These three illustrative small plants can be compared to two illustrative large plants. The first large plant (table 33) is a large shelf-stable apple juice plant with many employees that operates year round and that imports some apples and therefore must test for patulin, and has not developed or implemented sanitation SOP's. The second large plant (table 34) is a large shelf-stable tomato juice processor using fruit from a known source and with sanitation SOP's fully implemented.

TABLE 30.—COSTS FOR ILLUSTRATIVE SMALL SEASONAL APPLE CIDER PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Sanitation SOP's	500	
Monitoring and Documenting of SOP's	100	$100
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action plan	50	
Corrective actions	450	110
Verification	420	420
Validation	1,000	500
HACCP monitoring and recordkeeping	900	900
Record maintenance & storage	360	360
Training of coordinator	1,300	
Employee training	300	300
Totals	24,700–36,700	10,600

TABLE 31.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND CONCENTRATED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Monitoring and documenting of SOP's	$340	$340
Hazard analysis	250	
Validation	1,000	
Training of coordinator	1,300	
Totals	2,900	300

TABLE 32.—COST FOR ILLUSTRATIVE SMALL YEAR ROUND UNPASTEURIZED ORANGE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	
Monitoring and documenting of SOP's	340	$340
Hazard analysis	250	
HACCP plan	750	
Pathogen controls	18,000–30,000	7,900
Corrective action Plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	2,000	1,000
Process verification testing	7,800	7,800
Annualized cost of Process Verification Failure	2,600	2,600
HACCP monitoring and Recordkeeping	5,600	5,600
Record maintenance & storage	830	830
Training of coordinator	1,300	
Employee training	500	500
Totals	43,100–55,100	28,300

TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Develop SOP's	$260	

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TABLE 33.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND APPLE JUICE PROCESSOR—Continued

Type of cost	Cost in first year	Cost in subsequent years
Sanitation SOP's	500	
Monitoring and documenting of SOP's	340	$340
Hazard analysis	250	
HACCP plan	750	
Natural toxin control	4,500	4,500
Corrective action plan	50	
Corrective actions	1,460	340
Verification	1,350	1,350
Validation	1,200	1,200
HACCP monitoring and recordkeeping	5,600	5,600
Record maintenance	680	680
Record storage	150	
Training of coordinator	1,300	
Employee training	8,300	8,300
Totals	24,000	20,000

TABLE 34.—COSTS FOR ILLUSTRATIVE LARGE YEAR ROUND SHELF-STABLE TOMATO JUICE PROCESSOR

Type of cost	Cost in first year	Cost in subsequent years
Hazard analysis	$250	
Validation	600	
Training of coordinator	1,300	
Totals	2,000	$0

Some comments stated that the rule would be burdensome on small juice processors and that some processors would have to cease producing juice. FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases. One effect of the cost savings will be to reduce small firm failure. FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making necessary changes to comply with this rule.

2. Professional Skills Required for Compliance

The RFA requires a description of the professional skills required for compliance with this rule. Table 35 describes the professional skills required for compliance with the various activities required by this rule.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE

Required activity	Section of rule	Professional skills required for compliance
Developing prerequisite program SOP's	§ 120.6	Managers familiar with incoming materials and plant sanitation.
Implementing sanitation controls with corrections of deviations from prerequisite program SOP's.	§ 120.6	Production workers who are able to maintain the sanitation controls as described in the sanitation SOP's and supervisors or managers who can determine what corrective actions are necessary for deviations from SOP's.
Monitoring and documenting of prerequisite Program SOP's.	§ 120.6	Production workers who are appropriately trained to monitor and keep records on observations and measurements for prerequisite program SOP's.
Developing hazard analysis and HACCP plan..	§§ 120.7 and 120.8	Supervisors or managers who fulfill the role of HACCP coordinator as well as microbiologists, chemists, and attorneys.
Implementing pathogen controls	§ 120.8	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP's.
Implementing pesticide controls	§ 120.8	Production workers who are appropriately trained to carry out tests, to monitor, and to keep records on observations and measurements at CCP's.
Tracking corrective actions	§ 120.10	Production workers who are trained to take corrective action described in corrective action plans and supervisors or managers who can determine what corrective actions are necessary for deviations from CL's.
Verification	§ 120.11	Supervisors or managers who fulfill the role of HACCP coordinator.
Validation	§ 120.11	Food scientists or food technologists who can perform a scientific review of the process.
Process verification	§ 120.25	Microbiologists and production workers who are trained to take process verification samples and food scientists or food technologists who can perform a scientific review of the process in the event of a process verification failure.

TABLE 35.—PROFESSIONAL SKILLS REQUIRED FOR COMPLIANCE—Continued

Required activity	Section of rule	Professional skills required for compliance
Monitoring and recordkeeping	§ 120.12	Production workers who are appropriately trained to monitor and keep records on observations and measurements at CCP's.
Record maintenance	§ 120.12	Clerical or production workers.
HACCP coordinator training coordinator	§ 120.13	Supervisors or managers who fulfill the role of HACCP.
HACCP employee training	§ 120.13	Clerical and production workers.
Imports	§ 120.14	Clerical workers as well as supervisors or managers who fulfill the role of HACCP coordinator.

3. Recordkeeping requirements

The RFA requires a description of the recordkeeping requirements of the proposed rule. Table 36 shows the provisions for which records need to be made and kept by small businesses, the number of small businesses affected, the annual frequency that the records need to be made, the amount of time needed for making each record, and the total number of hours for each provision in the first year and then in subsequent years.

TABLE 36.—SMALL BUSINESS RECORDKEEPING REQUIREMENTS

21 CFR provisions	Number of small entities keeping records	Annual frequency	Hours per record per small entity	Total hours first year	Total subsequent years
120.6 Monitoring and Recordkeeping of SOP's	1,660	16	0.5	13,300	13,300
	210	52		5,500	5,500
120.7 Hazard analysis	2,125	1	20	42,500	0
120.8 HACCP plan	1,930	1	60	115,800	0
120.8 Pesticide Controls by Supplier Certificate	1,700	160	.02	5,400	5,400
120.11 Verification	1,450	16	2	48,400	48,400
	380	52	[1]8	39,500	39,500
120.11 Validation	1,450	1	[2]4	11,600	5,800
	380	2		6,100	3,000
120.12 HACCP records	1,450	1,440	.05	104,400	104,400
	380	8,640		164,200	164,200
120.12 Record maintenance	1,450	16	1	23,200	23,200
Totals				598,000	431,000

[1]First year. [2]Subsequent year.

D. Minimizing the Burden on Small Entities

The RFA requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities.

There are two alternatives that the agency has considered to provide regulatory relief for small entities. First, FDA considered and is proposing the option of exempting some small entities from the requirements of these rules. Second, FDA considered and is proposing the option of lengthening the compliance period for small entities.

1. Exempt Small Entities

One alternative for alleviating the burden for small entities would be to exempt them from the provisions of this rule. FDA proposed to exempt retailers who, for the purposes of this rule, the agency tentatively decided would include very small businesses that make juice on their premises and whose total sales of juice and juice products do not exceed 40,000 gallons per year and who sell directly to consumers or directly to consumers and other retailers.

Revenue from sales of 40,000 gallons of nonheat treated juice may be approximately $160,000 with annual profits ranging from $1,600 to $16,000 per year (1 percent to 10 percent). This exemption covered most of the very small businesses, although less than 15 percent of the volume of unpasteurized juice. However, packaged products sold by these types of processors are covered under the labeling rule.

As detailed in response to comment 47, the comments that FDA received on this exemption were almost entirely critical of the exemption. Based upon the comments and other information available to the agency, FDA has decided not to finalize this proposed exemption.

2. Extend Compliance Period

FDA is issuing a tiered, extended compliance period giving the smallest firms the most time to comply with the rule. Extending the compliance period by 1 year for small firms could save each one $500 to $31,600 (using a 7 percent discount rate). Extending the compliance period by 2 years for very small firms could save each one $900 to $61,000 (using a 7 percent discount rate). These savings accrue just from delaying the time at which the expenditures for compliance must take place. The amount of savings increases as the cost of compliance increases.

Additional savings may come as smaller firms learn more efficient compliance strategies from larger firms that must comply earlier and as new, less costly technologies that may be employed by small firms are developed during the extended compliance period. FDA is unable to quantify these additional savings of the extended compliance period although one effect of the cost savings will be to reduce small firm failure.

FDA believes that this extended compliance period will provide small firms with significant relief in the cost of preparing for HACCP and making

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necessary changes to comply with this rule.

E. Summary

FDA has examined the impact of this rule on small businesses in accordance with the RFA. This analysis, together with the rest of the preamble constitutes the final RFA. FDA has determined that this rule is likely to have a significant impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these information provisions is given below with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Hazard Analysis and Critical Control Point (HACCP) Procedures for the Safe and Sanitary Processing of Juice—Recordkeeping requirements for processors of fruit and vegetable juices

Description: This final rule mandates the application of HACCP procedures to fruit and vegetable juice processing. HACCP is a preventative system of hazard control that can be used by all food processors to ensure the safety of their products to consumers. FDA is finalizing these regulations because a system of preventative control is the most effective and efficient way to ensure that these food products are safe. FDA's mandate to ensure the safety of the nation's food supply is derived principally from the act (21 U.S.C. 321 *et seq.*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced and held under sanitary conditions, and are not misbranded or deceptively packaged; under 21 U.S.C. 371, the act authorizes the agency to issue regulations for its efficient enforcement. The agency also has authority under the Public Health Service Act (42 U.S.C. 264) to issue and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases from one State to another other State. Information development and recordkeeping are essential parts of any HACCP system. The information collection requirements of this rule are narrowly tailored to focus on the development of appropriate controls and documenting those aspects of processing that are critical to food safety. Through this final rule, FDA is implementing its authority under section 402(a)(4) of the act. The information development and recordkeeping requirements of this final rule are likewise an implementation of section 402(a)(4) of the act.

Description of Respondents: Businesses and other for-profit institutions.

In the **Federal Register** of April 24, 1998, the agency requested comments on the proposed collection of information provisions contained in the HACCP proposal. One comment was received. This comment asserted that the change in sequence in the proposed rule for the last two steps of the seven principles of HACCP is a change that will result in many paperwork changes. The seven principles of HACCP have been articulated by the NACMCF.

The agency does not agree with this comment. Prior to 1997, the NACMCF listed establishing recordkeeping and documentation procedures and establishing verification procedures as the sixth and seventh principles of HACCP; this is the order in which the principles are reflected in FDA's seafood HACCP regulation, part 123. When the NACMCF revised its HACCP principles and application guidelines in 1997, it reversed the order of the last two steps. Thus, the sequence in part 120 for the seven principles of HACCP is identical to the sequence most recently outlined by NACMCF. The 1997 change does not require a change in the analytical approach or in the information to be assembled by juice processors as they apply the HACCP principles to their process. The agency does not anticipate that there will be a need for processors to complete additional paperwork simply because there has been a change in the order of the seven principles of HACCP or because there will be a slight difference in the juice HACCP regulation and the seafood HACCP regulation. It is FDA's position that as long as all the essential elements are present in the written HACCP plan, the plan will be complete.

FDA estimates the burden of this collection of information as follows:

TABLE 37.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR sections	Number of recordkeepers	Annual frequency of records	Total annual records	Hours per record	Total hours
120.6(a) & 120.12(a)(1) & (b)	1,875	1	1,875	4	[2] 7,500
120.6(c) & 120.12(a)(1) & (b)	1,875	365	684,375	0.1	68,437.5
120.7; 120.10 (a); & 120.12(a)(2), (b) & (c)	2,300	1.1	2,530	20	50,600
120.8 (except monitoring records required under 120.8(b)(7)); & 120.12(a)(3),(b)& (c)	1,840	1	1,840	60	[2] 110,400
120.8(b)(7) & 120.12(a)(4)(i), & (b)	1,450	14,600	21,170,000	0.01	211,700
120.10(c) & 120.12(a)(4)(ii), & (b)	1,840	12	22,080	0.1	2,208
120.11(a)(1)(iv); 120.11(a)(2); 120.12(a)(5)	1,840	52	95,680	0.1	9,568
120.11(b) & 120.12(a)(5), & (b)	1,840	1	1,840	4	7,360
120.11 (c) & 120.12(a)(5) & (b)	1,840	1	1,840	4	7,360
120.14(a)(2); & 120.14 (c) & (d)	308	1	308	4	1,232
Totals	First year—476,365.5		Subsequent years—358,465.5		

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] First year only.

The burden estimates in table 37 above are based on an estimate of the total number of juice manufacturing plants (*i.e.*, 2,300) affected by this final rule. Included in this total are 850 plants currently identified in FDA's OEI plus 1,220 very small apple juice manufacturers and 230 very small orange juice manufacturers (see table 13 in section V). The figures in table 36 are derived by estimating the number of plants affected by each portion of this final rule and multiplying the corresponding number by the number of records required annually and the hours needed to complete the record. These numbers were obtained from the agency's final RIA prepared for this final rule.

Moreover, these estimates assume that every processor will prepare SSOP's and a HACCP plan and maintain the associated monitoring records and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have a HACCP plan under this final rule.

Table 37 provides a breakdown of the total estimated recordkeeping burden for the first year and subsequent years. The estimates in this table have been reviewed by the agency's HACCP experts, who have practical experience in observing various processing operations and related recordkeeping activities.

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Environmental Impact

The agency has previously considered the environmental effects of the action being taken in this final rule. As announced in the proposed rule published in the **Federal Register** of April 24, 1998 (63 FR 20450) (Ref. 2), the agency determined that under 21 CFR 25.30(j) this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

(Comment 158) Two comments were received in response to the potential environmental impact of this rule. One comment stated that "* * * the extensive recordkeeping requirements under the juice proposal will increase paper consumption significantly, which will not be considered 'environmentally friendly.'" This comment did not provide evidence to support this assertion.

FDA agrees that the recordkeeping requirement in the HACCP final rule may increase paper consumption. However, the agency disagrees that this increase will be significant. The agency believes that the paper used for the required recordkeeping will be a very small fraction of the overall amount of paper used in the United States. Therefore, this use will not significantly increase the production, use and disposal of paper and, thus, will not result in significant adverse impacts on the environment. Additionally, FDA notes that § 120.12(g) of the final rule permits records to be maintained electronically. When the regulated entities maintain records electronically, the need for paper is reduced.

(Comment 159) One comment on the proposed rule stated that efforts to achieve 5-log reduction will lead to possible excessive pollution of the environment from disposal of unessential sanitizers. This comment did not provide evidence to support this assertion.

The agency has concluded that even if some increase in the use of sanitizing products should result, the products used would be either registered with the U.S. EPA or regulated by FDA for use on food contact articles under § 178.1010 (21 CFR 178.1010) or both. Environmental review is part of EPA's pesticide registration process and is part of FDA's process for listing sanitizing solutions under § 178.1010. FDA expects processors to use all sanitizing products according to directions on product labels and under the supervision of experienced persons. Use of the sanitizing products in this manner should ensure that any increased use will not result in adverse effects on the environment.

The agency has concluded that these comments on the potential for adverse environmental effects will not affect its previous determination that this action will not have a significant impact on the human environment and that an environmental impact statement is not required.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government (Ref. 75). Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

X. References

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List of Subjects in 21 CFR Part 120

Foods, Fruit juices, Imports, Reporting and recordkeeping requirements, Vegetable juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, under the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Part 120 is added to read as follows:

PART 120—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A—General Provisions

Sec.
120.1 Applicability.
120.3 Definitions.
120.5 Current good manufacturing practice.
120.6 Sanitation standard operating procedures.
120.7 Hazard analysis.
120.8 Hazard Analysis and Critical Control Point (HACCP) plan.
120.9 Legal basis.
120.10 Corrective actions.
120.11 Verification and validation.
120.12 Records.
120.13 Training.
120.14 Application of requirements to imported products.

Subpart B—Pathogen Reduction

120.20 General.
120.24 Process controls.
120.25 Process verification for certain processors.

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

Subpart A—General Provisions

§ 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.

(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.

(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

§ 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, § 101.9(j)(18)(vi), and part 110 of this chapter are applicable to

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such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.

(b) *Control* means to prevent, eliminate, or reduce.

(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.

(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.

(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.

(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with § 120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.

(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.

(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

(j)(1) *Processing* means activities that are directly related to the production of juice products.

(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and

(ii) The operation of a retail establishment.

(k) Processor means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

(o) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

§ 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

§ 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and

(8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the recordkeeping requirements of § 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Sanitation standard operating procedure controls may be included in the HACCP plan required under § 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

§ 120.7 Hazard analysis.

(a) Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control those hazards. The written hazard analysis shall consist of at least the following:

(1) Identification of food hazards;

(2) An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. This evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs;

(3) Identification of the control measures that the processor can apply to control the food hazards identified as reasonably likely to occur in paragraph (a)(2) of this section;

(4) Review of the current process to determine whether modifications are necessary; and

(5) Identification of critical control points.

(b) The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. The hazard analysis shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.

•(c) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:

(1) Microbiological contamination;

(2) Parasites;

(3) Chemical contamination;

(4) Unlawful pesticides residues;

(5) Decomposition in food where a food hazard has been associated with decomposition;

(6) Natural toxins;

(7) Unapproved use of food or color additives;

(8) Presence of undeclared ingredients that may be allergens; and

(9) Physical hazards.

(d) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer.

(e) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or part 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

§ 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. A HACCP plan shall be specific to:

(1) Each location where juice is processed by that processor; and

(2) Each type of juice processed by the processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List all food hazards that are reasonably likely to occur as identified in accordance with § 120.7, and that thus must be controlled for each type of product;

(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate:

(i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and

(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;

(3) List the critical limits that shall be met at each of the critical control points;

(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with § 120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;

(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with § 120.11; and

(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with § 120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 120.6, they are not required to be included in the HACCP plan.

§ 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with §§ 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

§ 120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with § 120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;

(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(4) Take corrective action, when necessary, to correct the cause of the deviation; and

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(5) Perform or obtain timely verification in accordance with § 120.11, by an individual or individuals who have been trained in accordance with § 120.13, to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with § 120.11(a)(1)(iv)(B) and the recordkeeping requirements of § 120.12.

§ 120.11 Verification and validation.

(a) *Verification.* Each processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.

(1) Verification activities shall include:

(i) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(ii) The calibration of process monitoring instruments;

(iii) At the option of the processor, the performance of periodic end-product or in-process testing; except that processors of citrus juice that rely in whole or in part on surface treatment of fruit shall perform end-product testing in accordance with § 120.25.

(iv) A review, including signing and dating, by an individual who has been trained in accordance with § 120.13, of the records that document:

(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within 1 week (7 days) of the day that the records are made;

(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with § 120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and

(C) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in § 120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(vi) Additional process verification if required by § 120.25.

(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of this section, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of this section, are subject to the recordkeeping requirements of § 120.12.

(b) *Validation of the HACCP plan.* Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) *Validation of the hazard analysis.* Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with § 120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of § 120.12.

§ 120.12 Records.

(a) *Required records.* Each processor shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:

(1) Records documenting the implementation of the sanitation standard operating procedures (SSOP's) (see § 120.6);

(2) The written hazard analysis required by § 120.7;

(3) The written HACCP plan required by § 120.8;

(4) Records documenting the ongoing application of the HACCP plan that include:

(i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and

(ii) Corrective actions, including all actions taken in response to a deviation; and

(5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.

(b) *General requirements.* All records required by this part shall include:

(1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;

(2) The date and time of the activity that the record reflects, except that records required by paragraphs (a)(2), (a)(3), and (a)(5) of this section need not include the time;

(3) The signature or initials of the person performing the operation or creating the record; and

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

(c) *Documentation.* (1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification and validation in accordance with § 120.11.

(d) *Record retention.* (1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) *Official review.* All records required by this part shall be available for review and copying at reasonable times.

(f) *Public disclosure.* (1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in § 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.

(g) *Records maintained on computers.* The maintenance of computerized records, in accordance with part 11 of this chapter, is acceptable. § 120.13 *Training.*

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by § 120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of § 120.8;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in § 120.10(b)(5) and the validation activities specified in § 120.11(b) and (c); and § 120.7;

(4) Performing the record review required by § 120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

§ 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported juice.

(a) *Importer requirements.* Every importer of juice shall either:

(1) Obtain the juice from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written procedures for ensuring that the juice that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:

(i) Product specifications that are designed to ensure that the juice is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and

(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:

(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure records required by this part that relate to the specific lot of food being offered for import;

(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;

(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 120.12.

(d) *Determination of compliance.* The importer shall provide evidence that all juice offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported juice has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

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Subpart B—Pathogen Reduction

§ 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

§ 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (*i.e.*, 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:

(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and

(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by § 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in § 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

§ 120.25 Process verification for certain processors.

Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of § 120.24 shall analyze the finished product for biotype I *Escherichia coli* as follows:

(a) One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced shall be sampled each production day. If less than 1,000 gallons of juice is produced per day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.

(b) If the facility is producing more than one type of juice covered by this section, processors shall take subsamples according to paragraph (a) of this section for each of the covered juice products produced.

(c) Processors shall analyze each subsample for the presence of *E. coli* by the method entitled "Analysis for *Escherichia coli* in Citrus Juices—Modification of AOAC Official Method 992.30" or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting *E. coli*. This method is designed to detect the presence or absence of *E. coli* in a 20 mL sample of juice (consisting of two 10 mL subsamples). The method is as follows:

(1) *Sample size.* Total-20 mL of juice; perform analysis using two 10 mL aliquots.

(2) *Media.* Universal Preenrichment Broth (Difco, Detroit, MI), EC Broth (various manufacturers).

(3) *Method.* ColiComplete (AOAC Official Method 992.30—modified).

(4) *Procedure.* Perform the following procedure two times:

(i) Aseptically inoculate 10 mL of juice into 90 mL of Universal Preenrichment Broth (Difco) and incubate at 35 °C for 18 to 24 hours.

(ii) Next day, transfer 1 mL of preenriched sample into 10 mL of EC Broth, without durham gas vials. After inoculation, aseptically add a ColiComplete SSD disc into each tube.

(iii) Incubate at 44.5 °C for 18 to 24 hours.

(iv) Examine the tubes under longwave ultra violet light (366 nm). Fluorescent tubes indicate presence of *E. coli*.

(v) MUG positive and negative controls should be used as reference in interpreting fluorescence reactions. Use an *E. coli* for positive control and 2 negative controls—a MUG negative strain and an uninoculated tube media.

(d) If either 10 mL subsample is positive for *E. coli*, the 20 mL sample is recorded as positive and the processor shall:

(1) Review monitoring records for the control measures to attain the 5-log reduction standard and correct those conditions and practices that are not met. In addition, the processor may choose to test the sample for the presence of pathogens of concern.

(2) If the review of monitoring records or the additional testing indicates that the 5-log reduction standard was not achieved (*e.g.*, a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is identified), the processor shall take corrective action as set forth in § 120.10.

(e) If two samples in a series of seven tests are positive for *E. coli*, the control measures to attain the 5-log reduction standard shall be deemed to be inadequate and the processor shall immediately:

(1) Until corrective actions are completed, use an alternative process or processes that achieve the 5-log reduction after the juice has been expressed;

(2) Perform a review of the monitoring records for control measures to attain the 5-log reduction standard. The review shall be sufficiently extensive to determine that there are no trends towards loss of control;

(i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or

(ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the 5-log reduction standard; and

(3) Take corrective action as set forth in § 120.10. Corrective actions shall include ensuring no product enters commerce that is injurious to health as set forth in § 120.10(a)(1).

Dated: December 20, 2000.

Jane E. Henny,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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January 19, 2001

Part VI

Department of Agriculture

Cooperative State Research, Education and Extension Service

Requests for Proposals (RFP): Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years 2001 and 2002; and Special Research Grants Programs, Citrus Tristeza Research; Notice

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DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Request for Proposals (RFP): Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years 2001 and 2002

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) announces the availability of grant funds and requests proposals for the Food and Agricultural Sciences National Needs Graduate Fellowship Grants Program for Fiscal Years (FYs) 2001 and 2002, and for 2001 Supplemental Grants for Special International Study or Thesis/Dissertation Research Travel Allowances. Proposals are hereby requested from eligible institutions as identified herein for competitive consideration for Food and Agricultural Sciences National Needs Graduate Fellowship Grant awards. In addition, CSREES seeks proposals from recipients of currently active Food and Agricultural Sciences National Needs Fellowship Grants for supplemental grants to support special international study or thesis/dissertation research experiences for current Fellows.

CSREES also is soliciting comments regarding this RFP from any interested party. Such comments will be considered in the development of any future requests for proposals for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (AREERA).

DATES: All proposals for Food and Agricultural Sciences National Needs Graduate Fellowship Grants must be received on or before July 10, 2001. Supplemental Grant proposals to support special international study or thesis/dissertation research for current Fellows must be received by October 1, 2001. Proposals not received on or before these dates, as appropriate, will not be considered for funding.

Comments are requested within six months from the issuance of this RFP. Comments received after that date will be considered to the extent practicable.

ADDRESSES: For Food and Agricultural Sciences National Needs Graduate Fellowship Grant proposals, hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before July 10, 2001, at the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit Office of Extramural Programs Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via facsimile (fax) machine will not be accepted. Proposals submitted by mail must be received on or before July 10, 2001. Proposals submitted by mail should be sent to the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

For International Study or Thesis/Dissertation Research Supplemental Grant proposals, hand-delivered proposals (brought in person by the applicant or through a courier service) must be received prior to October 1, 2001, at the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted. Proposals submitted by mail must be received prior to October 1, 2001. Proposals submitted by mail should be sent to the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA–CSREES; STOP 2299; 1400 Independence Avenue, SW.; Washington, DC 20250–2299; or via e-mail to: *RFP–OEP@reeusda.gov.* (This e-mail address is intended only for receiving stakeholder input comments regarding this RFP, and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT: Dr. Howard Sandberg; Higher Education Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture, STOP 2251; 1400 Independence Avenue, SW.; Washington, DC 20250–2251; Telephone: (202) 720–2193; E-mail: *hsandberg@reeusda.gov.*

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Stakeholder Input

CSREES is requesting comments regarding this FY 2001 RFP from any interested party. In your comments, please include the name of the program and the fiscal year solicitation for applications to which you are responding. These comments will be considered in the development of the next solicitation for applications for the program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(c). Comments should be submitted as provided for in the **ADDRESSES** and **DATES** portions of this notice.

Catalog of Federal Domestic Assistance

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.210, Food and Agricultural Sciences National Needs Graduate Fellowship Grants.

Part I. Food and Agricultural Sciences National Needs Graduate Fellowship Grants

A. Administrative Provisions and Legislative Authority

This Program is subject to the provisions found at 7 CFR part 3402. 7 CFR part 3402 sets forth procedures to be followed when submitting grant proposals for food and agricultural sciences national needs graduate fellowship grants, rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of such grant projects.

Legislative authority for this program is contained in section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. 3152(b)(6)).

In accordance with the statutory authority, subject to the availability of funds, the Secretary of Agriculture, who has delegated the authority to the Administrator of CSREES, may make competitive grants, for periods not to exceed five years, to land-grant colleges and universities, to colleges and universities having significant minority enrollments and a demonstrable capacity to carry out the teaching of food and agricultural sciences, and to other colleges and universities having a demonstrable capacity to carry out the teaching of food and agricultural sciences, to administer and conduct graduate fellowship programs to help meet the Nation's needs for development of scientific and professional expertise in the food and agricultural sciences. For this program, the term "food and agricultural sciences" means basic, applied, and developmental research, extension, and teaching activities in food and fiber, agriculture, renewable natural resources, forestry, and physical and social sciences, including activities related to subject areas defined in section 1404(8) of NARETPA, 7 U.S.C. 3103(8).

B. Program Description

1. Purpose of the Program

This program seeks to award grants for training students for a doctoral degree at colleges and universities which have demonstrable teaching and research competencies in the food and agricultural sciences. The grants are specifically intended to support fellowship programs that encourage outstanding students to pursue and complete their degree at such institutions in an area of the food and agricultural sciences for which there is a national need for the development of scientific and professional expertise.

2. Targeted National Need Areas

Food and agricultural science areas appropriate for fellowship grant applications are those which are directly related to one of the following: (1) Animal, microbial, or plant molecular biology including genomics or bioinformatics; (2) natural resources and environment; (3) agricultural systems or natural resource engineering; (4) marketing or management; (5) food science or human nutrition; or (6) human sciences. A proposal is restricted to one national need area.

3. Eligibility

Proposals may be submitted by institutions that confer a doctoral degree in a national need area. For proposals involving more than one institution, all institutions must meet the eligibility requirements. Proposals also may be submitted by a research foundation maintained by an eligible college or university. Eligibility requirements are discussed further in 7 CFR 3402.3.

4. Degree Level Supported

In FYs 2001 and 2002, only the doctoral level of study will be supported.

5. Proposal Submission Limitations

No limitations are placed on the number of proposals which can be submitted by a college or university.

6. Limitations on Number of Fellowships

There is no limit on the number of fellowships in the single national need area which can be requested in the proposal. While proposals must document institution willingness to recruit and train the number of fellows requested, CSREES may fund fewer fellows than requested in a proposal. Also, the maximum total amount of funds from this program that may be awarded to an institution in FYs 2001 and 2002 is limited to $276,000.

7. Available Funding

Subject to the enactment of the appropriations acts that will provide funds to CSREES for this program in FYs 2001 and 2002, CSREES anticipates that approximately $5.6 million will be available for fellowship grants for the FYs 2001 and 2002 combined competition, including approximately $2.8 million in anticipated FY 2001 appropriations and approximately $2.8 million in anticipated FY 2002 appropriations. Contingent on the availability of these funds, approximately $934,000 will be allocated to each of the six national need areas. This program is highly competitive, and it is anticipated that available funding will support approximately 81 doctoral fellows. No-year funds drawn from expired fellowship grants with unspent funds remaining may be used to fund additional fellows. Please note that Congress has not enacted the FY 2002 appropriation bills for the Department. Therefore, the $5.6 million cited for FYs 2001 and 2002 grants is only tentative, and USDA is not bound by this estimate.

8. Stipend Level

Each institution funded will receive $69,000 for each doctoral fellowship awarded. However, it is anticipated that total program funds available will not be evenly divisible by $69,000. Therefore, one fellowship may be supported on a partial basis with a lesser amount of funds, or one fellowship may be supported fully by a combination of FYs 2001 and 2002 funds and unspent funds remaining from expired fellowship grants. Except in the case of a partially funded fellowship, fellowship monies must be used to: (1) Support the same doctoral fellow for three years at $22,000 per year; and (2) provide for an institution annual cost-of-education allowance of $1,000. Total funds awarded to an institution under the program in FYs 2001 and 2002 shall not exceed $276,000.

C. Selection Process and Evaluation Criteria

Section 223 of the Agricultural Research, Extension, and Education Reform Act of 1998, Pub. L. No. 105–185, amended section 1417 of NARETPA to require that priorities be given in awarding grants for certain teaching enhancement projects under section 1417(b) of NARETPA. This program is authorized under section 1417(b). CSREES considers all applications received in response to this solicitation as teaching enhancement project applications. To implement the new priorities for proposals submitted for the FYs 2001 and 2002 competition, the evaluation criteria used to evaluate proposals, as provided in the administrative provisions for this program (7 CFR 3402.19), have been

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modified to include new criteria for proposals demonstrating enhanced coordination among eligible institutions and focusing on innovative, multidisciplinary education programs, material, or curricula. The following criteria and weights will be used to evaluate proposals submitted for funding to the FYs 2001 and 2002 competition:

(A) 25 points—The degree to which the proposal establishes clearly that the proposed program of graduate study will result in the development of outstanding scientific/professional expertise related to a national need area and will do so in a reasonable period of time.

(B) 25 points—The degree to which the proposal contains any special features such as a focus on innovative, multidisciplinary education programs, material, or curricula; enhanced coordination among institutions eligible for grants under the Food and Agricultural National Needs Fellowship Grant Program; an inter-disciplinary, multi-disciplinary, or cross-disciplinary approach, an unusual collateral specialization in a related discipline, experiential learning opportunities, unique mentoring programs, seminars, or a multi-university collaborative approach.

(C) 20 points—The degree to which the proposal substantiates clearly that the institution's faculty, facilities and equipment, instructional support resources, and other academic attributes are excellent for providing outstanding graduate study and research at the forefront of science and technology related to the chosen area of national need.

(D) 20 points—The degree to which the institution's plans and procedures for recruiting and selecting academically outstanding Fellows and for advising and guiding Fellows through a program of study reflect excellence as documented in the proposal.

(E) 5 points—The degree to which supplementary summary data substantiate program quality in the targeted need area.

(F) 5 points—The quality of the proposal as reflected by its substantive content, organization, clarity, and accuracy.

D. How To Obtain Application Materials

An Application Kit containing program application materials can be downloaded from the CSREES, Office of Higher Education Programs (HEP) web site at http://www.reeusda.gov/serd/hep/hep.htm or will be made available to eligible institutions upon request. These materials include the administrative provisions, this Request for Proposals, Summary Information, forms, instructions, and other relevant information needed to prepare and submit grant proposals. Copies of the Application Kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Deparment of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245. The telephone number is 202–401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting forms for the FYs 2001 and 2002 National Needs Graduate Fellowship Grants Program.

Application materials also may be requested via Internet by sending a message which states that you want to receive a copy of the application materials for the FY 2001/2002 National Needs Graduate Fellowship Grants Program with your name, mailing address (not e-mail) and phone number to psb@reeusda.gov. The materials will then be mailed to you (not e-mailed) as quickly as possible.

E. Submission of a Proposal

1. Intent To Submit a Proposal

Submission of an Intent to Submit a Proposal (Form CSREES–706) is requested for the FYs 2001 and 2002 competition and is due May 11, 2001. Form CSREES–706 can be sent by FAX to 202–720–2030; by courier to Graduate Fellowship Program; CSREES/SERD/HEP; Waterfront Centre; 3rd Floor, Room 3251; 800 9th Street, SW.; Washington, DC 20024; or by mail to Graduate Fellowship Program, USDA/CSREES/SERD/HEP, 1400 Independence Ave., SW.; STOP 2251; Washington, DC 20250–2251.

2. What To Submit

An original and six (6) copies of a proposal must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½" x 11" white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. All copies of the proposal must be submitted in one package. Each copy of the proposal must be stapled securely in the upper left-hand corner (DO NOT BIND).

The proposal should be paginated and a Table of Contents should be included preceding the proposal narrative. Applicants are cautioned to comply with the 20-page limitation for the narrative section of the proposal. Applicants also are cautioned to include *summary* faculty vitae using Summary Vita—Teaching Proposal (Form CSREES–708). More detailed information on the narrative, summary vita, and other portions of a proposal is provided in subpart C of 7 CFR part 3402.

3. Where and When To Submit

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received on or before July 10, 2001, at the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The telephone number is (202) 401–5048. Proposals transmitted via facsimile (fax) machine will not be accepted.

Proposals submitted through the mail must be received on or before July 10, 2001. Proposals submitted through the mail should be sent to the following address: National Needs Graduate Fellowship Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW., Washington, DC 20250–2245.

4. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged via e-mail. Therefore it is important to include an e-mail address on the Proposal Cover Page (Form CSREES–701) when applicable. This acknowledgment will contain a proposal identification number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

F. Current Research Information System (CRIS) Reports and Impact Reports

Institutions will be asked to submit annual CRIS Reports in partial fulfillment of the reporting requirements of 7 CFR 3402.25(a). Also, institutions will be asked to submit reports describing significant impacts generated by the activities and accomplishments of the fellows in partial fulfillment of the reporting requirements of 7 CFR 3402.25.

Part II. 2001 Special International Study or Thesis/Dissertation Research Travel Allowances

A. Administrative Provisions and Legislative Authority

This Program is subject to the provisions found at 7 CFR part 3402. 7 CFR 3402.5(e) sets forth procedures to be followed when submitting supplemental grant proposals for special international study or thesis/dissertation research travel allowances. 7 CFR part 3402, subparts E and F set forth rules governing the evaluation of proposals and the awarding of grants, and regulations relating to the post-award administration of such grant projects.

Legislative authority for this program is contained in section 1417(b)(6) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended (NARETPA) (7 U.S.C. 3152(b)(6)).

B. Program Description

CSREES has determined that a new competition for special international study or thesis/dissertation research travel allowances will be held during FY 2001, and hereby solicits proposals for competitive supplemental grants. Proposals may be submitted by universities or colleges who currently have active Food and Agricultural Sciences National Needs Graduate Fellowship Grants. Eligibility for this opportunity is limited to any current Fellow with sufficient time to complete the international experience before the termination date of the fellowship grant under which he/she is supported. These supplementary grants provide support for a Fellow to conduct thesis/dissertation research or to undertake studies at a site outside of the United States. Before the international study or thesis/dissertation research travel may commence, a Fellow must have completed one academic year of full-time study, as defined by the institution, under the fellowship appointment and arrangements must have been formalized for the Fellow to study and/or conduct research in the foreign location(s).

Estimated funds for supplemental grants in FY 2001 are approximately $60,000. These funds are obtained from no-year funds drawn from expired fellowship grants with unspent funds remaining. CSREES has determined that no FY 2001 appropriations will be targeted to supplemental grants supporting special international study or thesis/dissertation research travel allowances. For each travel allowance, the institution may request up to $10,000. Travel allowance monies may be used only to pay travel and living expenses for the Fellow while the Fellow is on the specific international assignment as proposed in the application for the special international study or thesis/dissertation research travel allowance. No limitation is placed on the number of applications an institution may submit. Awards will be made to the extent possible based on the review of the proposal and subject to the availability of funds.

C. Selection Process and Evaluation Criteria

Applications for the special international travel allowances will be evaluated as they are received until available funds for the supplemental grants are exhausted. Upon receipt of an application, CSREES staff will first determine the eligibility of the Fellow for whom the application was submitted for an international travel experience. Eligible and complete requests then will be reviewed by professional staff from USDA or other Federal agencies, as appropriate. Since awards for supplemental grants will be made as reviews are completed, there is no assurance funds will be available late in the application period for every acceptable proposal.

The six evaluation criteria are:

1. 10 points—Destination and duration—the degree to which the destination and duration of the travel experience is appropriate for enhancing the Fellow's academic program.

2. 30 points—Travel experience activities—the degree to which the specific international experiences contribute to the Fellow's program of study.

3. 20 points—Advance preparations—the degree to which the proposed study or research activities are well-planned, including the likelihood that these activities will come to fruition and that the participation of identified personnel will materialize.

4. 10 points—Budget—the degree to which the budget for the international experience is justified.

5. 20 points—Personnel—the degree to which the personnel, both U.S. and international, involved with the travel experience have the appropriate credentials and experience to direct the Fellow's international experience, and the likelihood that their participation as mentors, trainers, advisors, or teachers will contribute to the educational value of the travel experiences.

6. 10 points—Supporting documentation—the degree to which letters from the dean of the college (or equivalent administrative unit) and the fellowship grant project director support the application.

D. How To Obtain Application Materials

An Application Kit containing program application materials can be downloaded from the HEP web site at *http://www.reeusda.gov/serd/hep/hep.htm* or will be made available to eligible institutions upon request. These materials include the administrative provisions, Request for Proposals, Summary Information, forms, instructions, and other relevant information needed to prepare and submit grant applications. Copies of the Application Kit may be requested from the Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245. The telephone number is (202) 401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting the Application Kit for the FY 2001 Graduate Fellowship (International) Supplemental Grants Program.

Application materials may also be requested via Internet by sending a message, that states that you wish to receive a copy of the application materials for the 2001 Graduate Fellowship (International) Supplemental Grants Program with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov. The materials will then be mailed to you (not e-mailed) as quickly as possible.

E. What To Submit

An original plus six (6) copies of each application must be submitted. Proposals should contain all requested information when submitted. Each proposal should be typed on 8½" × 11" white paper, double-spaced, and on one side of the page only. Please note that the text of the proposal should be prepared using a font no smaller than 12 point and one-inch margins. Each copy of the application should be stapled securely in the upper left-hand corner (DO NOT BIND). All copies of the application must be submitted in one package. Applications transmitted via a facsimile (FAX) machine will not be accepted.

A separate application must be submitted by a fellowship grant project director at an eligible institution on behalf of each Fellow for which a special international study or thesis/dissertation research travel allowance is requested.

Each application must include an "Application for Funding," Form

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CSREES–661, and a "Budget," Form CSREES–55. To provide HEP with sufficient information upon which to evaluate the merits of the requests for a special international study or thesis/dissertation research travel allowance, each application for a supplemental grant must contain a narrative which provides the following: (1) The specific destination(s) and duration of the travel; (2) the specific study or thesis/dissertation research activities in which the Fellow will be engaged; (3) how the international experience will contribute to the Fellow's program of study; (4) a budget narrative specifying and justifying the dollar amount requested for the travel; (5) summary credentials of both the U.S. and international faculty or other professionals with whom the Fellow will be working during the international experience (summary credentials must not exceed three pages per person; "Summary Vita—Teaching Proposal," Form CSREES–708, may be used for this purpose); (6) a letter from the dean of the Fellow's college or equivalent administrative unit supporting the Fellow's travel request and certifying that the travel experience will not jeopardize the Fellow's satisfactory progress toward degree completion; and (7) a letter from the fellowship grant project director certifying the Fellow's eligibility, the accuracy of the Fellow's travel request, and the relevance of the travel to the Fellow's advanced degree objectives.

The narrative portion of the application must not exceed 10 pages, excluding the summary vita/vitae.

F. Where and When To Submit

Applications for the special international study or thesis/dissertation research travel allowance supplemental grants may be submitted at any time prior to October 1, 2001. However, to allow time for CSREES to process the applications, proposals should be submitted at least three months prior to the proposed beginning date of the international research project. Applicants are urged to submit their proposals early.

Note: Proposals for these special supplemental awards should *not* be submitted as part of the application for a FY 2001/2002 Graduate Fellowship grant.)

Hand-delivered proposals (brought in person by the applicant or through a courier service) must be received prior to October 1, 2001, at the following address: Special International Study or Thesis/Dissertation Research Supplemental Grant; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. The phone number is 202–401–5048. Proposals transmitted via a facsimile (fax) machine will not be accepted.

Proposals submitted through the U.S. mail must be received prior to October 1, 2001. Proposals submitted through the U.S. mail should be sent to the following address: Graduate Fellowship (International) Supplemental Grants Program; c/o Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

G. Impact Reports

Awardees will be asked to submit an impact report at the conclusion of the international research experience. The impact report describes the accomplishments made by the Fellow as a result of the international research experience. This report should be submitted to: Graduate Fellowship Program; CSREES/SERD/HEP, USDA; STOP 2251; 1400 Independence Ave., SW.; Washington, DC 20250–2251.

Done at Washington, DC, this 11th day of January, 2001.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. 01–1492 Filed 1–18–01; 8:45 am]

BILLING CODE 3410–22–P

DEPARTMENT OF AGRICULTURE

Cooperative State Research, Education, and Extension Service

Request for Proposals: Special Research Grants Program, Citrus Tristeza Research

AGENCY: Cooperative State Research, Education, and Extension Service, Department of Agriculture.

ACTION: Notice of request for proposals and request for input.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) announces the availability of grant funds and requests proposals for the Special Research Grants Program, Citrus Tristeza Research for fiscal year (FY) 2001. The purpose of the program is to support research that focuses on problems caused by Citrus Tristeza Virus (CTV) and the Brown Citrus Aphid. This request for proposals (RFP) sets forth procedures to be followed when submitting grant proposals, rules governing the evaluation of proposals, the awarding of grants, and regulations relating to the post-award administration of such grants.

CSREES also is requesting comments regarding this RFP from any interested party. These comments will be considered in the development of the next RFP for this program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998.

DATES: All proposals must be received at USDA on or before February 15, 2001. Proposals not received on or before this date will not be considered for funding.

User comments are requested within six months from the issuance of this RFP. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Proposals should be submitted to the following mailing address: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245.

The address for hand-delivered proposals or proposals submitted using an express mail or overnight courier service is: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024. Telephone: (202) 401–5048.

Written user comments should be submitted by mail to: Policy and Program Liaison Staff; Office of Extramural Programs; USDA–CSREES; STOP 2299; 1400 Independence Avenue, SW.; Washington, DC 20250–2299; or via e-mail to: *RFP-OEP@reeusda.gov*. (This e-mail address is intended only for receiving comments regarding this solicitation and not for requesting information or forms.)

FOR FURTHER INFORMATION CONTACT: Dr. Tom Bewick, Manager, Citrus Tristeza Research Program; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2220; 1400 Independence Avenue, SW.; Washington, DC 20250–2220; telephone (202) 401–3356; fax (202) 401–6869; e-mail: tbewick@reeusda.gov.

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Stakeholder Input

CSREES is requesting comments regarding the FY 2001 Special Research Grants Program, Citrus Tristeza Research RFP from any interested party. In your comments, please include the name of the program and the fiscal year solicitation for applications to which you are responding. These comments will be considered in the development of the next RFP for the program. Such comments will be used in meeting the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998, 7 U.S.C. 7613(c). Comments should be submitted as provided for in the **ADDRESSES** and **DATES** portions of this notice.

Part I—General Information

A. Legislative Authority

The authority for this program is contained in section (c)(1)(A) of the Competitive, Special, and Facilities Research Grant Act, section 2 of Pub. L. 89–106, as amended (7 U.S.C. 450i(c)(1)(A)). This program is subject to the administrative regulations found in 7 CFR Part 3400.

In accordance with the statutory authority, the Secretary may make grants for the purpose of conducting research to facilitate or expand promising breakthroughs in areas of the food and agricultural sciences of importance to the United States.

B. Definitions

For the purpose of awarding grants under this program, the following definitions are applicable:

(1) *Administrator* means the Administrator of the Cooperative State Research, Education, and Extension Service and any other officer or employee of the Department to whom the authority involved may be delegated.

(2) *Authorized departmental officer* or *awarding official* means the Secretary or any employee of the Department who has the authority to issue or modify grant instruments on behalf of the Secretary.

(3) *Authorized organizational representative* means the president, director, chief executive officer, or other designated official of the applicant organization who has the authority to commit the resources of the organization.

(4) *Budget period* means the interval of time (usually 12 months) into which the project period is divided for budgetary and reporting purposes.

(5) *Department* or *USDA* means the United States Department of Agriculture.

(6) *Grantee* means the organization or entity designated in the grant award document as the responsible legal entity to which a grant is awarded.

(7) *Peer review panel* or *group* means an assembled group of experts or consultants qualified by training and experience in particular scientific or technical fields to give expert advice on the scientific and technical merit of grant applications in those fields. The panel members will evaluate eligible proposals submitted to this program in their personal and professional area(s) of expertise.

(8) *Prior approval* means written approval evidencing prior consent by an authorized departmental officer as defined in (2) above.

(9) *Project* means the particular activity within the scope of the program supported by a grant award.

(10) *Principal Investigator* means the single individual designated by the grantee in the grant application and approved by the Administrator who is responsible for the scientific and technical direction of the project.

(11) *Project period* means the total length of time that is approved by the Administrator for conducting the research project as outlined in an approved grant application.

(12) *Secretary* means the Secretary of Agriculture and any other officer or employee of the Department to whom the authority involved may be delegated.

C. Eligibility

Proposals may be submitted by State agricultural experiment stations, all colleges and universities, other research institutions and organizations, Federal agencies, private organizations or corporations, and individuals. Although an applicant may be eligible based on its status as one of these entities, other factors may exclude an applicant from receiving Federal assistance under this program (*e.g.*, debarment or suspension, a determination of non-responsibility based on submitted organizational management information).

Part II—Program Description

A. Purpose and Scope of the Program

Proposals are invited for competitive grant awards under the Special Research Grants Program, Citrus Tristeza Research for fiscal year (FY) 2001. The purpose of this grant program is to support research that focuses on problems caused by CTV and the Brown Citrus Aphid. This research should aim to facilitate promising breakthroughs in this important area of the food and agricultural sciences.

CTV is a pathogen of citrus vectored by several aphid species. This disease has been found in all the citrus producing regions of the United States and is of world-wide importance. The virus strain complex can cause a variety of symptoms, from mild to severe, depending upon the host and its environment. A new aphid vector, the Brown Citrus Aphid was introduced in Florida. This vector is capable of transmitting a severe stem-pitting form of the virus. The Brown Citrus Aphid also occurs in Central America and the Caribbean Basin and thus poses a threat to citrus in other citrus producing areas in the United States (*e.g.*, Louisiana, Texas, Arizona, and California).

The research priority areas that have been identified are (1) characterization and detection of CTV strains; (2) biology and control of the Brown Citrus Aphid; (3) host plant resistance, including scion and rootstock development; (4) epidemiology and crop loss assessment; and (5) development of cross-protecting CTV strains.

B. Available Funds and Award Limitations

Funds will be awarded on a competitive basis to support research projects that focus on solving problems caused by the CTV and Brown Citrus Aphid. The total amount of funds available in FY 2001 for support of this program is approximately $595,000. Each proposal submitted in FY 2001 shall request funding for a period not to

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exceed two years. FY 2001 awardees must submit new proposals and recompete to receive additional funding at the expiration of their current grant.

C. Applicant Peer Review Requirements

Subsection (c)(5)(A) of the Competitive, Special, and Facilities Research Grant Act, as amended (7 U.S.C. 450i(c)(5)(A)) requires applicants to conduct a scientific peer review of a proposed research project in accordance with regulations promulgated by the Secretary prior to the Secretary making a grant award under this authority. Regulations implementing this requirement are set forth in 7 CFR 3400.20 and 3400.21. The regulations impose the following requirements for scientific peer review by applicants of proposed research projects:

1. Credible and independent. Review arranged by the grantee must provide for a credible and independent assessment of the proposed project. A credible review is one that provides an appraisal of technical quality and relevance sufficient for an organizational representative to make an informed judgment as to whether the proposal is appropriate for submission for Federal support. To provide for an independent review, such review may include USDA employees, but should not be conducted solely by USDA employees.

2. Notice of completion and retention of records. A notice of completion of the review shall be conveyed in writing to CSREES either as part of the submitted proposal or prior to the issuance of an award, at the option of CSREES (see Part III. B.(2)(i). The written notice constitutes certification by the applicant that a review in compliance with these regulations has occurred. Applicants are not required to submit results of the review to CSREES; however, proper documentation of the review process and results should be retained by the applicant.

3. Renewal and supplemental grants. Review by the grantee is not automatically required for renewal or supplemental grants as defined in 7 CFR 3400.6. A subsequent grant award will require a new review if, according to CSREES, either the funded project has changed significantly, other scientific discoveries have affected the project, or the need for the project has changed. Note that a new review is necessary when applying for another standard or continuation grant after expiration of the grant term.

Part III—Preparation of a Proposal

A. Program Application Materials

Program application materials will be made available to interested entities upon request. These materials include information about the purpose of the program, how the program will be conducted, and the required contents of a proposal, as well as the forms needed to prepare and submit grant applications under the program. The application kit can be downloaded from the Internet at the following website: http://www.reeusda.gov/1700/funding/ourfund.htm or may be obtained by writing or calling the following office: Proposal Services Unit; Office of Extramural Programs; Cooperative State Research, Education, and Extension Service; U.S. Department of Agriculture; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245; Telephone: (202) 401–5048. When contacting the Proposal Services Unit, please indicate that you are requesting application materials for the FY 2001 Special Research Grants Program, Citrus Tristeza Research. Application materials also may be requested via Internet by sending a message with your name, mailing address (not e-mail) and telephone number to psb@reeusda.gov that states that you wish to receive a copy of the application materials for the FY 2001 Special Research Grants Program, Citrus Tristeza Research. The materials will then be mailed to you (not e-mailed) as quickly as possible.

B. Content of a Proposal

(1) General

The proposal should follow these guidelines, enabling reviewers to more easily evaluate the merits of each proposal in a systematic, consistent fashion:

(a) The proposal should be prepared on only one side of the page using standard size (8 ½" x 11") white paper, one inch margins, typed or word processed using no type smaller than 12 point font regardless of whether it is single or double spaced. Use an easily readable font face (*e.g.*, Geneva, Helvetica, CG Times). Once accepted for review, your proposal will be read by at least three expert reviewers. Thus it is to your advantage to ensure that your proposal is not difficult to read.

(b) Each page of the proposal, including the Project Summary, budget pages, required forms, and appendices, should be numbered sequentially in the upper right-hand corner.

(c) The proposal should be stapled in the upper left-hand corner. Do not bind. An original and 9 copies (10 total) must be submitted in one package, along with 20 copies of the Project Summary as a separate attachment.

(2) Cover Page

Complete Form CSREES–661, Application for Funding, in its entirety. This form is to be utilized as the Cover Page. Form CSREES–661 serves as a source document for the CSREES grant database; it is therefore important that it be completed accurately.

(a) In Block 6, complete the title of the project. The project title must be brief (80-character maximum), yet represent the major thrust of the effort being proposed. Project titles are read by a variety of nonscientific people; therefore, highly technical words or phraseology should be avoided where possible. In addition, introductory phrases such as "investigation of" or "research on" should not be used.

(b) Blocks 7 and 8 should be completed to read "Special Research Grants Program, Citrus Tristeza Research."

(c) In Block 13, the Type of Award Request is "new."

(d) In Block 14, note the total amount of Federal dollars being requested.

(e) In Block 15, designate Principal Investigator(s)/Project Directors(s) (PI/PD). Listing multiple co-PIs beyond those required for genuine collaboration is discouraged. Note that providing a Social Security Number is voluntary, but is an integral part of the CSREES information system and will assist in the processing of the proposal.

(f) Type of Performing Organization (Block 18). A check should be placed in the box beside the type of organization which actually will carry out the effort. For example, if the proposal is being submitted by an 1862 Land-Grant institution but the work will be performed in a department, laboratory, or other organizational unit of an agricultural experiment station, box "03" should be checked. If portions of the effort are to be performed in several departments, check the box that applies to the individual listed as PI/PD #1 in Block 15.a.

(g) In Block 22 list the names or acronyms of all other public or private sponsors including other agencies within USDA and other programs funded by CSREES to whom your application has been or will be sent. In the event you decide to send your application to another organization or agency at a later date, you must inform the identified CSREES program manager as soon as practicable. Submitting your proposal to other potential sponsors will not prejudice its review by CSREES; however, duplicate support for the same project will not be provided.

(h) The original copy of the Application for Funding form must contain the pen-and-ink signatures of the PI/PD(s) and authorized organizational representative for the applicant organization.

(i) By signing the Application for Funding form, the AOR of the applicant institution is providing the required certification that the full proposal has received a credible and independent peer review arranged by the institution (see Part II. C.).

(j) Note that by signing the Application for Funding form, the applicant is also providing the required certifications set forth in 7 CFR Part 3017, regarding Debarment and Suspension and Drug-Free Workplace, and 7 CFR Part 3018, regarding Lobbying. The three certification forms are included in this application package for informational purposes only. It is not necessary to sign and submit the forms to USDA as part of the proposal.

(3) Table of Contents

For consistency and ease in locating information, each proposal must contain a detailed Table of Contents just after the Cover Page. The Table of Contents should include page numbers for each component of the proposal. Page numbers, shown in the upper right-hand corner, should begin with the first page of the Project Summary.

(4) Project Summary

The proposal must contain a Project Summary of 250 words or less on a separate page. The summary must be self-contained and describe the overall goals and relevance of the project. The summary should also contain a listing of the major organizations participating in the project. The Project Summary should immediately follow the Table of Contents. In addition to the summary, this page must include the title of the project, the name of the applicant organization, the authorized organizational representative, and the PI(s), followed by the summary.

(5) Project Narrative

Note: The Project Narrative shall not exceed 10 pages. To ensure fair and equitable competition, reviewers are instructed that they need to read only the first 10 pages of the Project Narrative and to ignore information on additional pages. The Project Narrative should contain the following items:

(a) Objectives—Clear, concise, complete, and logically arranged statement(s) of the specific aims of the proposed effort must be included in all proposals.

(b) Procedures—The procedures or methodology to be applied to the proposed effort should be explicitly stated. This section should include but not necessarily be limited to a description of the proposed investigations and/or experiments in the sequence in which it is planned to carry them out; techniques to be employed, including their feasibility; kinds of results expected; means by which data will be analyzed or interpreted; pitfalls which might be encountered; and limitations to proposed procedures.

(c) Justification—This section should include in-depth information on the magnitude of the problem and its relevance to ongoing food and agricultural research programs; the importance of starting the work during the current fiscal year, and reasons for having the work performed by the proposing institution.

(d) Cooperation and Institutional Units Involved—Cooperative and multi-State applications are encouraged. Identify each institutional unit contributing to the project. Identify each State in a multiple-State proposal and designate the lead State. When appropriate, the project should be coordinated with the efforts of other State and/or national programs. Clearly define the roles and responsibilities of each institutional unit of the project team, if applicable.

If it will be necessary to enter into formal consulting or collaborative arrangements with other individuals or organizations, such arrangements should be fully explained and justified. For purposes of proposal development, informal day-to-day contacts between key project personnel and outside experts are not considered to be collaborative arrangements and thus do not need to be detailed.

All anticipated subcontractual arrangements also should be explained and justified in this section. A proposed statement of work, budget, and budget narrative for each arrangement involving the transfer of substantive programmatic work or the providing of financial assistance to a third party must be provided. Agreements between departments or other units of your own institution and minor arrangements with entities outside of your institution (*e.g.*, requests for outside laboratory analyses) are excluded from this requirement. If you expect to enter into subcontractual arrangements, please note that the provisions contained in 7 CFR Part 3019, USDA Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations, and the general provisions contained in 7 CFR 3015.205, USDA Uniform Federal Assistance Regulations, flow down to subcontractors. In addition, when applicable, required clauses from 7 CFR 3019.40 through 3019.48 ("Procurement Standards") and appendix A ("Contract Provisions") should be included in final contractual documents, and it is necessary for the subcontractor to make a certification relating to debarment/suspension.

(e) Literature Review—A summary of pertinent publications with emphasis on their relationship to the effort being proposed should be provided and should include all important and recent publications from other institutions, as well as those from the applicant institution. The citations themselves should be accurate, complete, and written in an acceptable journal format.

(f) Current Work—Current unpublished institutional activities to date in the program area under which the proposal is being submitted should be described.

(g) Facilities and Equipment—All facilities which are available for use or assignment to the project during the requested period of support should be reported and described briefly. Any potentially hazardous materials, procedures, situations, or activities, whether or not directly related to a particular phase of the effort, must be explained fully, along with an outline of precautions to be exercised. Examples include work with toxic chemicals and experiments that may put human subjects or animals at risk.

All items of major instrumentation available for use or assignment to the proposed project should be itemized. In addition, items of nonexpendable equipment not currently accessible and needed to conduct and bring the project to a successful conclusion should be listed, including dollar amounts and, if funds are requested for their acquisition, justified.

(h) Project Timetable—The proposal should outline all important phases as a function of time, year by year, for the entire project, including periods beyond the grant funding period.

(6) Key Personnel

All senior personnel who are expected to be involved in the effort must be clearly identified. For each person, the following should be included:

(a) An estimate of the time commitment involved; and

(b) vitae of all key persons who are expected to work on the project.

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whether or not CSREES funds are sought for their support. Each vitae should be limited to two (2) pages in length, excluding publications listings. A chronological list of the most representative publications during the past five (5) years must be provided for each professional project member for whom a vitae appears. Authors should be listed in the same order as they appear on each paper cited, along with the title and complete reference as these usually appear in journals.

(7) Conflict-of-Interest List

A separate Conflict-of Interest List form (Form CSREES–1233) must be submitted for each investigator for whom a curriculum vitae is required. This form is necessary to assist program staff in excluding from proposal review those individuals who have conflicts-of-interest with the project personnel in the grant proposal. The Program Manager must be informed of additional conflicts-of-interest that arise after the proposal has been submitted.

(8) Budget

A detailed budget for each year of requested support must be submitted. In addition, a cumulative budget is required detailing requested support for the overall project period. The budget form may be reproduced as needed by applicants. Funds may be requested under any of the categories listed on the form, provided that the item or service for which support is requested is allowable under the authorizing legislation, the applicable Federal cost principles, and these program guidelines, and can be justified as necessary for the successful conduct of the proposed project. Applicants must also include a budget narrative to explain and justify their budgets. The following guidelines should be used in developing the proposal budget(s):

(a) Salaries and Wages—Salaries and wages are allowable charges and may be requested for personnel who will be working on the project in proportion to the time such personnel will devote to the project. If salary funds are requested, the number of Senior and Other Personnel and the number of CSREES Funded Work Months must be shown in the spaces provided. Grant funds may not be used to augment the total salary or rate of salary of project personnel or to reimburse them for time in addition to a regular full-time salary covering the same general period of employment. Salary funds requested must be consistent with the normal policies of the institution and with the applicable OMB Cost Principles. Administrative and clerical salaries are normally classified as indirect costs. (See Item i. below.) However, if requested under A.2.e., they must be fully justified.

(b) Fringe Benefits—Funds may be requested for fringe benefit costs if the usual accounting practices of your institution provide that institutional contributions to employee benefits (social security, retirement, etc.) be treated as direct costs. Fringe benefit costs may be included only for those personnel whose salaries are charged as a direct cost to the project. See, *e.g.*, OMB Circular No. A–21, Cost Principles for Educational Institutions, for further guidance in this area.

(c) Nonexpendable Equipment—Nonexpendable equipment means tangible nonexpendable personal property including exempt property charged directly to the award having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. (However, institutions may establish lower limits.) As such, items of necessary instrumentation or other nonexpendable equipment should be listed individually by description and estimated cost in the budget narrative. This applies to revised budgets as well, as the equipment item(s) and amount(s) may change.

Note: For projects awarded under the authority of subsection (c)(1)(A) of the Competitive, Special, and Facilities Research Grant Act, no funds will be awarded for the renovation or refurbishment of research spaces; the purchase or installation of fixed equipment in such spaces; or for the planning, repair, rehabilitation, acquisition, or construction of a building or facility.

(d) Materials and Supplies—The types of expendable materials and supplies which are required to carry out the project should be indicated in general terms with estimated costs in the budget narrative.

(e) Travel—The type and extent of travel and its relationship to project objectives should be described briefly and justified. If travel is proposed, provide the purpose, the destination, method of travel, number of persons traveling, number of days, and estimated cost for each trip. If details of a trip are not known at the time of proposal submission, provide a basis for determining the amount requested. Airfare allowances normally will not exceed round-trip jet economy air accommodations. U.S. flag carriers must be used when available. See 7 CFR 3015.205(b)(4) for further guidance.

(f) Publication Costs/Page Charges—Anticipated costs of preparing and publishing results of the research being proposed (including page charges, necessary illustrations, and the cost of a reasonable number of coverless reprints) may be estimated and charged against the grant.

(g) Computer (ADPE) Costs—Reimbursement for the costs of using specialized facilities (such as a university or department-controlled computer mainframe or data processing center) may be requested if such services are required for completion of the work.

(h) All Other Direct Costs—Anticipated direct project charges not included in other budget categories must be itemized with estimated costs and justified in the budget narrative. This applies to revised budgets as well, as the item(s) and dollar amount(s) may change. Examples include space rental at remote locations, subcontractual costs, charges for consulting services, telephone, facsimile, e-mail, shipping costs, and fees for necessary laboratory analyses. You are encouraged to consult the "Instructions for Completing Form CSREES–55, Budget," of the Application Kit for detailed guidance relating to this budget category.

(i) Indirect Costs—The recovery of indirect costs under this program may not exceed the lesser of the grantee institution's official negotiated indirect cost rate or pursuant to section 1462 of National Agricultural Research, Extension, and Teaching Policy Act, 7 U.S.C. 3310, the equivalent of 19 percent of total Federal funds awarded. (An alternative method to calculate this limitation is to multiply total direct costs by 23.456 percent.) This limitation also applies to any subcontractor, and should be reflected in the subcontractor's budget.

(j) Cost-sharing—Cost-sharing is encouraged; however, cost-sharing is not required.

(9) Budget Narrative

All budget categories for which support is requested, must be individually listed (with costs) and justified on a separate sheet of paper and placed immediately behind the Budget Form.

(10) Current and Pending Support

All proposals must list any other current public or private support (including in-house support) to which key personnel identified in the proposal have committed portions of their time, whether or not salary support for person(s) involved is included in the budget for each project. Analogous information must be provided for any pending proposals that are being considered by, or that will be submitted in the near future to, other possible sponsors, including other USDA programs or agencies. Concurrent submission of identical or similar proposals to other possible sponsors will not prejudice proposal review or evaluation by the Administrator for this purpose. However, a proposal that duplicates or overlaps substantially with a proposal already reviewed and funded (or that will be funded) by another organization or agency will not be funded under this program. The application material includes Form CSREES–663, Current and Pending Support, which should be used for listing current and pending support. Note that the project being proposed should be included in the pending section of the form.

(11) Assurance Statement(s) (Form CSREES–662)

A number of situations encountered in the conduct of projects require special assurance, supporting documentation, etc., before funding can be approved for the project. In addition to any other situation that may exist with regard to a particular project, it is expected that some applications submitted in response to these guidelines will include the following:

(a) Recombinant DNA or RNA Research. As stated in 7 CFR 3015.205(b)(3), all key personnel identified in the proposal and all endorsing officials of the proposing organization are required to comply with the guidelines established by the National Institutes of Health entitled, "Guidelines for Research Involving Recombinant DNA Molecules," as revised. If your project proposes to use recombinant DNA or RNA techniques, the application must so indicate by checking the "yes" box in Block 19 of Form CSREES–661 and by completing Section A of Form CSREES–662. For applicable proposals recommended for funding, Institutional Biosafety Committee approval is required before CSREES funds will be released.

(b) Animal Care. Responsibility for the humane care and treatment of live vertebrate animals used in any grant project supported with funds provided by CSREES rests with the performing organization. Where a project involves the use of living vertebrate animals for experimental purposes, all key project personnel and all endorsing officials of the proposing organization are required to comply with the applicable provisions of the Animal Welfare Act, as amended (7 U.S.C. 2131 *et seq.*) and the regulations promulgated thereunder by the Secretary in 9 CFR parts 1, 2, 3, and 4 pertaining to the care, handling, and treatment of these animals. If your project will involve these animals or activities, you must check the "yes" box in Block 20 of Form CSREES–661 and complete Section B of Form CSREES–662. In the event a project involving the use of live vertebrate animals results in a grant award, funds will be released only after the Institutional Animal Care and Use Committee has approved the project.

(c) Protection of Human Subjects. Responsibility for safeguarding the rights and welfare of human subjects used in any grant project supported with funds provided by CSREES rests with the performing organization. Guidance on this issue is contained in the National Research Act, Pub. L. 93–348, as amended, and implementing regulations established by the Department under 7 CFR part 1c. If you propose to use human subjects for experimental purposes in your project, you should check the "yes" box in Block 21 of Form CSREES–661 and complete Section C of Form CSREES–662. In the event a project involving human subjects results in a grant award, funds will be released only after the appropriate Institutional Review Board has approved the project.

(12) Compliance With the National Environmental Policy Act (NEPA)

As outlined in 7 CFR part 3407 (the Cooperative State Research, Education, and Extension Service regulations implementing NEPA), the environmental data for any proposed project is to be provided to CSREES so that CSREES may determine whether any further action is needed. In most cases, based on previously funded projects, the preparation of environmental data is not usually required. Certain categories of actions are excluded from the requirements of NEPA.

In order for CSREES to determine whether any further action is needed with respect to NEPA, pertinent information regarding the possible environmental impacts of a particular project is necessary; therefore, Form CSREES–1234, NEPA Exclusions Form, must be included in the proposal indicating whether the applicant is of the opinion that the project falls within a categorical exclusion and the reasons therefor. If it is the applicant's opinion that the proposed project falls within the categorical exclusions, the specific exclusion must be identified. Form CSREES–1234 and supporting documentation should be the last page of the proposal.

Even though a project may fall within the categorical exclusions, CSREES may determine that an Environmental Assessment or an Environmental Impact Statement is necessary for an activity. This will be the case if substantial controversy on environmental grounds exists or if other extraordinary conditions or circumstances are present which may cause such activity to have a significant environmental effect. However, this rarely occurs.

Part IV—Submission of a Proposal

A. What To Submit

An original and nine copies of the complete proposal must be submitted. Each copy of the proposal must be stapled in the upper left-hand corner. DO NOT BIND. In addition, submit 20 copies of the proposal's Project Summary. All copies of the proposal and Project Summary must be submitted in one package.

B. Where and When To Submit

Proposals must be received on or before February 15, 2001. Proposals that are hand-delivered, delivered by courier, or sent via overnight delivery services must be sent or delivered to: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Office of Extramural Programs; USDA/CSREES; Room 1307, Waterfront Centre; 800 9th Street, SW.; Washington, DC 20024; Telephone: (202) 401–5048.

Note: Applicants are strongly encouraged to submit their completed proposals via overnight mail or delivery services to ensure timely receipt by the USDA.

Proposals sent via the U.S. Postal Service must be sent to the following address: Special Research Grants Program, Citrus Tristeza Research; c/o Proposal Services Unit; Office of Extramural Programs; USDA/CSREES; STOP 2245; 1400 Independence Avenue, SW.; Washington, DC 20250–2245; Telephone: (202) 401–5048.

C. Acknowledgment of Proposals

The receipt of all proposals will be acknowledged by e-mail, therefore applicants are encouraged to provide e-mail addresses, where designated, on the Form CSREES–661. The acknowledgment will contain an identifying proposal number. Once your proposal has been assigned a proposal number, please cite that number in future correspondence.

Part V—Selection Process and Evaluation Criteria

A. Selection Process

Applicants should submit fully developed proposals that meet all the requirements set forth in this RFP.

Each proposal will be evaluated in a two-part process. First, each proposal will be screened to ensure it meets the

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requirements as set forth in this RFP. Proposals not meeting the requirements as set forth in this RFP will not be considered for funding. However, USDA retains the right to conduct discussions with applicants to resolve technical and/or budget issues as it deems necessary. Second, each proposal that meets the requirements will be technically evaluated by a peer review panel.

The individual peer panel members will be selected from among those recognized as specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals being reviewed. The individual reviews of the panel members will be used to determine which proposals should be recommended to the Administrator (or his designee) for final funding decisions.

There is no commitment by USDA to fund any particular proposal or to make a specific number of awards. Care will be taken to avoid actual, potential, and/or the appearance of conflicts of interest among reviewers. Evaluations will be confidential to USDA staff members, peer reviewers, and the principal investigator(s), to the extent permitted by law.

The specificity of these organisms and their host limits the areas in which relevant research can be carried out. The brown citrus aphid has recently been introduced into the citrus growing areas of Florida. Research on both the virus/aphid and on field biology of the aphid is largely conducted in the areas of Florida and Puerto Rico where it is established. CSREES anticipates that the expertise necessary to review proposals will be found at organizations in these geographic areas. Therefore, conflict-of-interest rules will be amended to allow reviewers to evaluate submitted proposals from their own university as long as the applicant and reviewer do not work on the same campus. Thus, for this program, the scientists from the University of Florida but from other campuses (*i.e.*, Research and Education Centers) are not considered to be in conflict.

B. Evaluation Criteria

The evaluation of proposals will be based on the following criteria, weighted relative to each other as noted in the parentheses following each criterion listed.

(1) Overall scientific and technical quality of the proposal (15 points);

(2) Scientific and technical quality of the approach (10 points);

(3) Relevance and importance of proposed research to solution of specific areas of inquiry, and application of expected results for States in which the grantee resides and will perform the work (30 points);

(4) Feasibility of attaining objectives; adequacy of professional training and experience, facilities and equipment (40 points);

(5) The appropriateness of the level of funding requested (5 points).

Part VI—Supplementary Information

A. Access To Review Information

Copies of summary reviews will be sent to the applicant principle investigator automatically, as soon as possible after the review process has been completed. The identity of the individual peer reviewers will not be provided.

B. Grant Awards

(1) General

Within the limit of funds available for such purpose, the awarding official of CSREES shall make grants to those responsible, eligible applicants whose proposals are judged most meritorious under the procedures set forth in this RFP. The date specified by the Administrator as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by CSREES under this RFP shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015, 3016, and 3019 of 7 CFR).

(2) Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one-time basis as part of the responsibility determination prior to the award of a grant identified under this part if such information has not been provided previously under this or another program for which the sponsoring agency is responsible. Copies of forms recommended for use in fulfilling the requirements contained in this section will be provided by the sponsoring agency as part of the preaward process.

(3) Grant Award Document and Notice of Grant Award

The grant award document shall include at a minimum the following:

(a) Legal name and address of performing organization or institution to whom the Administrator has awarded a grant under the terms of this RFP;

(b) Title of project;

(c) Name(s) and address(es) of principal investigator(s) chosen to direct and control approved activities;

(d) Identifying grant number assigned by the Department;

(e) Project period, specifying the amount of time the Department intends to support the project without requiring recompetition for funds;

(f) Total amount of Departmental financial assistance approved by the Administrator during the project period;

(g) Legal authority(ies) under which the grant is awarded;

(h) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the grant award; and

(i) Other information or provisions deemed necessary by CSREES to carry out its respective granting activities or to accomplish the purpose of a particular grant.

The notice of grant award, in the form of a letter, will be prepared and will provide pertinent instructions or information to the grantee that is not included in the grant award document.

CSREES will award standard grants to carry out this program. A standard grant is a funding mechanism whereby CSREES agrees to support a specified level of effort for a predetermined time period without additional support at a future date.

C. Use of Funds; Changes

(1) Delegation of Fiscal Responsibility

Unless the terms and conditions of the grant state otherwise, the grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

(2) Changes in Project Plans

(a) The permissible changes by the grantee, principal investigator(s), or other key project personnel in the approved project grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the project's approved goals. If the grantee and/or the principal investigator(s) are uncertain as to whether a change complies with this provision, the question must be referred to the CSREES Authorized Departmental Officer (ADO) for a final determination.

(b) Changes in approved goals or objectives shall be requested by the grantee and approved in writing by the CSREES ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

(c) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and approved in writing by the awarding official of CSREES prior to effecting such changes.

D. Applicable Federal Statutes and Regulations

This program is subject to the administrative provisions for the Special Research Grants Program found in 7 CFR part 3400, which set forth procedures to be followed when submitting grant proposals, the processes regarding the awarding of grants, and regulations relating to the post-award administration of such grants. However, where there are differences between this RFP and the administrative provisions, this RFP shall take precedence to the extent that the administrative provisions authorize such deviations.

Several other Federal statutes and regulations apply to grant proposals considered for review and to project grants awarded under this program. These include but are not limited to:

7 CFR part 3019—USDA implementation of OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR part 3052—USDA implementation of OMB Circular No. A–133, Audits of States, Local Governments, and Non-profit Organizations.

E. Confidential Aspects of Proposals and Awards

When a proposal results in a grant, it becomes a part of the record of the Agency's transactions, available to the public upon specific request. Information that the Secretary determines to be of a privileged nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as privileged should be clearly marked as such and sent in a separate statement, two copies of which should accompany the proposal. The original copy of a proposal that does not result in a grant will be retained by the Agency for a period of one year. Other copies will be destroyed. Such a proposal will be released only with the consent of the applicant or to the extent required by law. A proposal may be withdrawn at any time prior to the final action thereon.

F. Regulatory Information

For the reasons set forth in the final Rule-related Notice to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995, as amended (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524–0022.

Done at Washington, DC, this 11th day of January 2001.

Colien Hefferan,

Administrator, Cooperative State Research, Education, and Extension Service.

[FR Doc. 01–1493 Filed 1–18–01; 8:45 am]

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Part VII

Department of Housing and Urban Development

24 CFR Parts 5, 92, et al.

Determining Adjusted Income in HUD Programs Serving Persons with Disabilities: Requiring Mandatory Deductions for Certain Expenses; and Disallowance for Earned Income; Final Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5, 92, 200, 236, 574, 582, 583, 891, 982

[Docket No. FR–4606–F–02]

RIN 2501–AC72

Determining Adjusted Income in HUD Programs Serving Persons with Disabilities: Requiring Mandatory Deductions for Certain Expenses; and Disallowance for Earned Income

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's regulations in part 5, subpart F, to include additional HUD programs in the list of programs that must make certain deductions in calculating a family's adjusted income. These deductions primarily address expenses related to a person's disability, for example medical expenses or attendant care expenses. The purpose of this amendment is to expand the benefits of these deductions to persons with disabilities served by HUD programs not currently covered by part 5, subpart F. Second, this rule adds a new regulatory section to part 5 to require for some but not all of these same programs the disallowance of increases in income as a result of earnings by persons with disabilities. HUD believes that making these deductions and disallowance available to persons with disabilities through as many HUD programs as possible will assist persons with disabilities in obtaining and retaining employment, which is an important step toward economic self-sufficiency.

This rule follows publication of a August 21, 2000 proposed rule, and takes into consideration public comments received on the rule.

DATES: Effective Date: February 20, 2001.

FOR FURTHER INFORMATION CONTACT: For the HOME Investment Partnerships Program, contact Mary Kolesar, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2470.

For the Housing Choice Voucher Program, contact Patricia Arnaudo, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–0744.

For the Housing Opportunities for Persons with AIDS Program, contact David Vos, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–1934.

For the Rent Supplement Program, contact, Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Rental Assistance Payment (RAP) Program, contact Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Section 202 Supportive Housing Program for the Elderly (including Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities), contact Aretha Williams, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2866.

For Section 8 Project-Based, contact Willie Spearmon, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–3000.

For the Section 811 Supportive Housing Program for Persons with Disabilities, contact Gail Williamson, Office of Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2866.

For the Shelter Plus Care Program, contact the State Assistance Division, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–2140.

For the Supportive Housing Program (McKinney-Vento Act Homeless Assistance), contact Clifford Taffet, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 708–1234.

For all of the above telephone numbers, persons with hearing or speech-impairments may call 1–800–877–8339 (Federal Information Relay Service TTY). (Other than the "800" number, the telephone numbers are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

I. Background

HUD's FY 1999 Appropriations Act, which included the Quality Housing and Work Responsibility Act of 1998 (as title V of the FY 1999 HUD Appropriations Act) (the entire FY 1999 Appropriations Act, including title V, is Public Law 105–276, approved October 21, 1998, and frequently referred to as the "Public Housing Reform Act") enacted landmark measures in HUD programs, including many of the reforms sought by Secretary Cuomo, such as transforming public housing, creating additional housing assistance vouchers, merging the Section 8 certificate and voucher programs, and enabling more families to obtain FHA mortgages to become homeowners. Since the Public Housing Reform Act became law, HUD has published many rules and notices implementing the important changes in HUD programs required by the Act. While the majority of these changes are applicable to HUD's public housing and Section 8 programs, HUD has been able to extend, administratively at times, the benefits of some of these landmark measures to HUD programs not specifically identified by the statute.

On August 21, 2000 (65 FR 50842), HUD published a proposed rule that proposed to extend the benefits of (1) deducting certain expenses as provided by the Public Housing Reform Act (currently applicable only to public housing and Section 8 housing (tenant-based and project-based)); and (2) disregarding certain increases in earned income as provided by the Public Housing Reform Act (currently applicable only to public housing) to persons with disabilities served by the following HUD programs—HOME Investment Partnerships, Housing Opportunities for Persons with AIDS, Supportive Housing, and Housing Choice Voucher.

HUD proposed these benefit extensions to persons with disabilities because HUD believes that these deductions and the disregard of earned income constitute an important step in helping persons with disabilities find employment and retain employment. HUD is aware that the lack of accessible, affordable housing continues to be a barrier to the ability of persons with disabilities to take advantage of economic opportunities in many communities across the country. The availability of accessible, affordable housing and the location of that housing can be the key to persons with disabilities in obtaining employment. The August 21, 2000 proposed rule provides more detailed information on the two amendments made by the proposed rule (the extension of certain mandatory deductions of expenses, and the disregard of earned income) and HUD refers the reader to the earlier rulemaking for more detailed information.

II. Discussion of Public Comments on the Proposed Rule

The public comment period for the August 21, 2000, proposed rule closed on October 20, 2000. HUD received 26 comments. The commenters represented a broad cross-section of affected entities. Commenters included a wide spectrum of individuals and entities affected by or interested in this rulemaking. The majority of the commenters expressed support for the rule's proposals. Notwithstanding widespread support of the rule's proposals, commenters raised certain concerns about the rule, primarily with respect to HUD's proposal to expand the earned income disregard. The following presents a discussion of the significant comments and questions raised by the commenters and HUD's responses to these comments and questions.

A. Mandatory Expense Deduction From Gross Income

Comment: This proposal is a positive step in helping persons with disabilities become economically self sufficient. The following comments reflect the types of comments submitted in support for this proposal.

The expense deduction will help people with disabilities to obtain and keep employment.

The expense deduction will increase the opportunity for persons with disabilities to access many HUD programs.

The expense deduction will have a positive effect on persons with disabilities.

The expense deduction creates incentives for residents in HUD-assisted programs to return to the work force by adjusting their rent to reflect increased expenses.

Many poor people must spend a large portion of their income on required services. The rule represents a positive step by ensuring that money spent on care for persons with disabilities and child care expenses is not counted as income.

The more uniform standard of income deductions as proposed by the rule will simplify program administration at the local level.

HUD Response. HUD appreciates the comments in support of the proposal to deduct certain expenses from gross income.

Comment. The rule should allow for the deduction of expenses incurred to prevent institutionalization of a person with disabilities.

HUD Response. The rule provides for deduction of unreimbursed reasonable attendant care expenses. (See § 5.611(a)(3)(ii).)

Comment. Since the intention of the rule is self-sufficiency, the rule should not limit the exclusion of certain expenses only to the extent they exceed three percent of gross income. The rule would better serve families if it allows for a complete exclusion of the listed expenses.

HUD Response. The three percent cap is imposed by statute, and therefore cannot be revised by HUD through regulation. (See 42 U.S.C. 1437a(b)(5).)

Comment. The definition of "adjusted income" in § 5.611 provides the basis for determining the amount of rent to be charged to an eligible household *after* the initial determination of eligibility is made. As amended by the proposed rule, § 5.611 ensures that adjustments to income for persons with disabilities would be taken into account in determining rent. However, if § 5.609 is not similarly amended, some persons with disabilities whose gross incomes slightly exceed the program limits, but who would be eligible for substantial deductions for expenses of care, would be excluded from program eligibility.

HUD Response. The statutory provision for these deductions relates to adjusted income, not income for eligibility purposes. There is no indication of Congressional intent to adjust eligibility limits, which most applicants are considerably below in any event, for such purposes.

B. Mandatory Earned Income Disregard

Comment: This proposal is a positive step in helping persons with disabilities become economically self sufficient. The following comments reflect the types of comments submitted in support for this proposal.

Persons with disabilities often have difficulty transitioning to employment. The earned income disregard will support these families in their quest for independence, and ease the transition to self-sufficiency.

The earned income disregard concept has worked well in conjunction with the Temporary Assistance for Needy Families (TANF) program. It should be equally valuable in helping persons with disabilities residing in HUD-assisted housing move toward self-sufficiency.

Counting all income from earnings is tantamount to removing any incentive to work and be a contributing citizen when it would result in the loss or significant reduction in housing assistance benefits.

The more residents who work, the greater the income to HUD and those involved in operating HUD assisted housing.

The earned income disregard helps qualified families negotiate the transition from public assistance to employment. Any negative budget impacts caused by the disregard will be short-term in nature and will be offset by increased rental income (or lower subsidy levels) as families are able to stay successfully employed.

HUD Response. HUD appreciates the comments in support of this proposal.

Comment. Broader application of the earned income disregard may diminish funds available for other programs. A mandatory earned income disregard will, in some cases, limit housing choice. It will force agencies to disallow earned income that would otherwise enable families to qualify for better housing under the Section 8 voucher program. The impact of this proposed policy on the Housing Choice Voucher Program must be considered before finalizing the rule. The final rule needs to address all these concerns.

HUD Response. HUD took these concerns into consideration in developing the proposed rule, and determined that any fiscal impact will not be significant and will be short-term. HUD believes that the long term benefits of this proposal—helping persons with disabilities obtain and retain employment—outweigh any initial short term impact. As several commenters pointed out, this proposal will help persons with disabilities move toward self-sufficiency, which will increase available funds for other families.

Comment. The earned income disregard should be coordinated with other federal agencies (*e.g.*, SSA, HHS, DOL) to ensure that there are no overlaps or inconsistencies with other applicable programs. The rule does not take into account the way the earned income disregard interfaces other federal programs affecting persons with disabilities.

HUD Response. HUD undertook this coordination when developing its proposed and final rules on "Changes in Admissions and Occupancy Requirements," published on April 30, 1999 (64 FR 23460) and March 29, 2000 (61 FR 16692), which implemented the earned income disregard for public housing (see 24 CFR 960.255). The earned income disregard in § 5.617 is modeled on § 960.255.

Comment. HUD should evaluate the effectiveness of the earned income disregard as an incentive for employment based on the historical

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experience of the public housing program before extending it to additional programs. Empirical studies are needed to validate the effectiveness of rent-based work incentives such as the mandatory earned income disregard.

HUD Response. HUD believes that at this time the expansion of earned income disregard to persons with disabilities is an appropriate incentive for employment, and has determined that the costs of implementation of this expanded benefit to persons with disabilities are not significant.

Comment. The Public Housing Reform Act specifically directs that the earned income disregard be applied to public housing. HUD must articulate in the final rule a sufficient justification for interpreting the statute so broadly as to allow extension of the earned income disregard to other programs as contemplated by the rule. The proposed rule did not provide this justification.

HUD Response. Section 3(b) of the U.S. Housing Act of 1937 gives the Secretary the authority to define "income" and therefore through this definition of income allows the Secretary to apply the earned income disregard to HUD's housing voucher program. For the HOME Program, section 104(9) and (1) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12704) states that the varying median income definitions of low-and very low-income families shall be determined by the Secretary. For the HOPWA program, Section 859(a) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12908) cites to section 8 of the U.S. Housing Act of 1937 to the end that rental assistance "shall be provided to the extent practicable in the manner provided for under section." This provision refers to rental assistance, not income, and vests in the administrator discretion whether it would be practicable to follow the temporary ineligibility of section 8 income disregards. For the Supportive Housing for the Homeless program, the authorizing statute contains no income limitations. Section 426(d) of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11386) states that assisted tenants may be required to pay an occupancy charge in an amount determined by the recipient providing the project, which may not exceed the amount determined under section 3(a) of the U.S. Housing of Act of 1937. Therefore, HUD can amend the regulations for this program to provide for use by the housing provider of earned income disregards in establishing its occupancy charges.

Comment. Several commenters requested that HUD extend the earned income disregard to programs other than the four programs provided in the August 21, 2000 proposed rule. Their comments included the following:

The earned income disregard should be extended to all Section 8 participants, including those receiving Moderate Rehabilitation and Project Based assistance.

The earned income disregard should be extended to all Section 8 program participants, regardless of how the actual program title is styled. Program administration will be much easier if the earned income disregard is made applicable to all Section 8 programs.

The earned income disregard should be extended to persons participating in the Section 811 program.

The earned income disregard should be extended to all households served under Section 202.

The earned income disregard should be extended to Shelter Plus Care recipients.

The earned income disregard should be extended to all persons with disabilities, regardless of the program under which they are participating.

The income disregard should be extended to all persons with disabilities in all types of HUD housing.

HUD Response. As discussed in the preamble to the August 21, 2000, proposed rule, HUD extended the earned income disregard to persons with disabilities in four programs (the HOME Investment Partnerships Program, the Housing Opportunities for Persons with AIDS, Supportive Housing Program, and the Housing Choice Voucher Program) because HUD had the requisite statutory authority to do so. At this time, HUD does not have the statutory authority to extend the earned income disregard to other programs but is seeking such authority.

Comment. The rule does not contain a suitable implementation strategy. There are many questions with regard to implementation of the earned income disregard. HUD should postpone the effective date of any proposed extension of the earned income disregard until HUD can provide additional guidance to PHAs.

HUD Response. As is appropriate for rules, the rule establishes the requirements for application of the earned income disregard. The specifics of how this is to be implemented by public housing agencies (PHAs) will be set out in guidance issued by HUD. HUD issued guidance to PHAs on this subject in connection with the publication of the final rule on Admissions and Occupancy. HUD expects to issue further guidance.

Comment. The Federal government should not substitute its own judgment for that of local housing providers since only at the local level can the costs and benefits of the mandatory income disregard be effectively weighed. Whether or not to incorporate the income disregard into specific programs is a matter best reserved to local discretion.

HUD Response. Consistent with the Public Housing Reform Act, HUD has left considerable discretion to PHAs on the manner of implementation of various requirements imposed by the statute. However, it is primarily the responsibility of Congress and HUD to determine which categories of families will be eligible for certain benefits. Determining whether persons with disabilities will be eligible for the earned income disregard is a determination that should be made by HUD to ensure consistency and fairness in application across the nation, and not a decision that should be made solely at the local level.

Comment. Notwithstanding its beneficial effect on program participants, an expanded earned income disregard will have a negative fiscal impact on local housing providers. HUD should raise administrative allowances to compensate agencies for the increased cost of managing earned income disregard provisions. The expanded earned income disregard will force housing providers to incur greater administrative costs. HUD should therefore include provisions in the rule to "make them whole." Additionally, the use of a selective earned income disregard based on disability and specific program participation status places an undue administrative burden on housing providers since they must compute the earned income disregard in some cases, but not in others. Agencies that administer both Section 8 and Public Housing Programs will find it very difficult to train staff to compute rent one way for Section 8 and another way for Public Housing.

HUD Response. HUD believes that any negative fiscal impact on local housing providers will not be significant. HUD recognizes that with the start-up of implementation of any new requirement or responsibility, there is an increase in administrative burden, but as the processes for implementation are established and once those processes are underway, the administrative burden lessens.

Comment. The proposed earned income disregard will likely result in some individuals in a building receiving a benefit while others do not. This will lead to friction between tenants and increase management difficulty.

HUD Response. HUD believes that any friction that may be voiced by tenants will be minimal. As HUD noted in the preamble to the August 21, 2000 proposed rule, estimates concerning unemployment indicate that the unemployment rate among persons with significant disabilities is in the range of 70% to 75%, among the highest of disadvantaged groups in the nation. HUD believes that the amendments made by this rule may help to lower this rate for persons residing in HUD assisted housing.

Comment. HUD's earned income disregard policy needs to go further by expanding the amount of income that is excluded and graduating the level of the disregard to allow for a transitional period. The earned income disregard should incorporate a transition period and be applicable to other forms of public assistance. The time period under which earned income may be disregarded is too short since many persons with disabilities cycle in and out of employment. The 48 month, once in a lifetime exclusion contained in the rule should be modified to address the cyclical employment pattern of many persons with disabilities.

HUD Response. The amount of income that is eligible for exclusion is established by statute (see 42 U.S.C. 1437a(b)(5)). The 48 month period arose from considerable public comment on the comparable regulatory provision for public housing (§ 960.255) in the rule on Admissions and Occupancy (see 61 FR 16704). Given the considerable public comment on the period of time in which earned income may be disregarded, HUD declines to modify that period at this time.

Comment. The rule should allow child support paid by a non-custodial parent who earns income or is engaged in educational activities to be excluded from income.

HUD Response. The commenter makes a valid point, but such a change is outside the scope of this rulemaking and needs to be addressed in separate rulemaking.

Comment. While the earned income disregard is an incentive for persons to become employed who are not working, the rule is a disincentive for persons working part-time to become employed full-time. Social Security payment restrictions also compound this problem. More needs to be done to provide income disallowances to help part-time workers become employed full-time.

HUD Response. HUD recognizes that the earned income disregard provided by statute will not serve as an incentive to all families in all situations. The statutory earned income disregard is limited to income increases as a result of employment of a member of the family who was previously unemployed for one or more years. (See section 3(d) of the U.S. Housing Act of 1937; 42 U.S.C. 1437a(d).) HUD, however, recognizes that some part-time employment should not be considered "previous employment" and has defined by regulation the term "previously unemployed" to include a person who has earned, in the twelve months previous to employment no more than would be received for 10 hours of work per week for 50 weeks at the established minimum wage. (See § 5.617 of this rule, and § 960.255 of the public housing regulations.)

Comment. In determining if a person with a disability is previously unemployed for the mandatory period prior to beginning employment, the rule should specifically include time during which the person received public assistance.

HUD Response. Consistent with the statutory language, the rule includes increases in annual incomes resulting during or within six months after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under part A of title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and welfare-to-work programs. (See § 5.617 of this rule, and § 960.255 of the public housing regulations.)

Comment. The earned income disregard should contain a grandfather clause to allow individuals that are employed at the time of their admission to subsidized housing to take advantage of the offset. The earned income disregard should not be available to persons who are employed at the time they enter assisted housing.

HUD Response. The statute establishes the requirements for eligibility of the earned income disregard and the rule in defining "qualified family" and "previously unemployed" reflects the statutory eligibility requirements. (See § 5.617(a).)

Comment. The definition of "qualified family" in the rule is inconsistent with other regulatory provisions. Section 5.617(b) should be changed to make clear that it includes a family with any adult member with a disability, not just the head of household or spouse, as eligible for the income disregard.

HUD Response. HUD believes that there is no ambiguity here. The definition of "qualified family" in § 5.617 makes no reference to the head of household or spouse, but simply "a family member." Section 960.255, upon which § 5.617 is modeled, also does not refer to the head of household or spouse. HUD believes both regulations are clear and no further modification is needed.

Comment. HUD's income disregard program should dovetail with the Plan to Achieve Self-Sufficiency (PASS) program so that persons with disabilities continue to receive the disregard benefit even after they are no longer participating in PASS. The income disregard should apply to all families with a member participating in the PASS program. The earned income disregard should apply as long as any household member, not just a family member with a disability, is receiving TANF benefits. The earned income disregard should specifically allow eligibility when any family member receives any type of government support, not limited to TANF. The earned income disregard should be applicable to those families receiving "welfare to work" funds.

HUD Response. The contours of the earned income disregard are established by statute. The statute, however, includes as eligible for the earned income disregard a family whose annual income increases, during or within six months, after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under part A of title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and welfare-to-work programs.

C. Specific Issue for Comment

Expansion of the earned income disregard to all families. In the August 21, 2000 proposed rule, HUD advised that although this rule limited the extension of the earned income disregard to persons with disabilities, HUD is analyzing the extension of the earned income disregard to all families served by HUD and HUD specifically solicited comment on this issue. (See 65 FR 50844, column one.)

Comment. A few commenters submitted comments on this issue and their comments were as follows:

The Public Housing Reform Act does not limit the earned income disregard strictly to persons with disabilities. If HUD is going to extend the income disregard to other programs, it should

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not be restricted solely to persons with disabilities.

The earned income disregard should be extended to all families not only families with persons with disabilities. However, application of the earned income disregard to all families may diminish the availability of funds for expanding the number of families participating in the Section 8 or other HUD programs. For this reason, we urge HUD to seek the necessary appropriations from Congress to ensure the expansion of this disregard to all programs.

The earned income disregard should be extended to all households served under HOPWA.

HUD Response. HUD appreciates the comments on this issue, and is continuing to study this matter.

III. Findings and Certifications

Environmental Impact

In accordance with 24 CFR 50.19(c)(1) of HUD's regulations, this rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, or manufactured housing. Therefore, this rule is categorically excluded from the requirements of the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*).

Regulatory Planning and Review

The Office of Management and Budget has reviewed this proposed rule under Executive Order 12866 (captioned "Regulatory Planning and Review") and determined that this rule is a "significant regulatory action" as defined in section 3(f) of the Order (although not an economically significant regulatory action under the Order). Any changes made to this rule as a result of that review are identified in the docket file, which is available for public inspection during regular business hours (7:30 a.m. to 5:30 p.m.) at the Office of the General Counsel, Rules Docket Clerk, Room 10276, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500.

Regulatory Flexibility Act

The Secretary has reviewed this rule before publication and by approving it certifies, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), that this rule would not have a significant economic impact on a substantial number of small entities. This rule is limited to expanding existing mandatory expense deductions and earned income disregard to the calculation of income for persons with disabilities in other HUD programs by which the program participants will benefit, and the owners of the housing assisted by these programs will benefit from the uniformity in the program administration this rule presents.

Executive Order 13132, Federalism

This rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of Executive Order 13132 (entitled "Federalism").

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) requires Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and on the private sector. This rule does not impose, within the meaning of the UMRA, any Federal mandates on any State, local, or tribal governments or on the private sector.

List of Subjects

24 CFR Part 5

Administrative practice and procedure, Aged, Claims, Drug abuse, Drug traffic control, Grant programs—housing and community development, Grant programs—Indians, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Pets, Public housing, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 92

Administrative practice and procedure, Grant programs—housing and community development, Grant programs—Indians, Low and moderate income housing, Manufactured homes, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

24 CFR Part 236

Grant programs—housing and community development, Low and moderate income housing, Mortgage insurance, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 574

AIDS/HIV, Community facilities, Disabled, Grant programs—health programs, Grant programs—housing and community development, Grant programs—social programs, Homeless, Housing, Low and moderate income housing, Nonprofit organizations, Rent subsidies, Reporting and recordkeeping requirements, Technical assistance.

24 CFR Part 582

Homeless, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 583

Homeless, Rent subsidies, Reporting and recordkeeping requirements.

4 CFR Part 891

Aged, Civil rights, Grant programs—housing and community development, Individuals with disabilities, Loan programs—housing and community development, Low and moderate income housing, Mental health programs, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 982

Grant programs—Housing and community development, Housing, Rent subsidies.

Accordingly, HUD amends parts 5, 92, 200, 236, 574, 582, 583, 891 and 982 of title 24 of the Code of Federal Regulations as follows:

PART 5—GENERAL HUD PROGRAM REQUIREMENTS; WAIVERS

1. The authority citation for part 5 continues to read as follows:

Authority: 42 U.S.C. 3535(d), unless otherwise noted.

2. The heading for subpart F is revised to read as follows:

Subpart F—Section 8 and Public Housing, and Other HUD Assisted Housing Serving Persons with Disabilities: Family Income and Family Payment; Occupancy Requirements for Section 8 Project-Based Assistance

3. Section 5.601 is revised to read as follows:

§ 5.601 Purpose and applicability.

This subpart states HUD requirements on the following subjects:

(a) Determining annual and adjusted income of families who apply for or receive assistance in the Section 8 (tenant-based and project-based) and public housing programs;

(b) Determining payments by and utility reimbursements to families assisted in these programs;

(c) Additional occupancy requirements that apply to the Section 8 project-based assistance programs. These additional requirements concern:

(1) Income-eligibility and income-targeting when a Section 8 owner admits families to a Section 8 project or unit;

(2) Owner selection preferences; and

(3) Owner reexamination of family income and composition;

(d) Determining adjusted income, as provided in § 5.611(a) and (b), for families who apply for or receive assistance under the following programs: HOME Investment Partnerships Program (24 CFR part 92); Rent Supplement Payments Program (24 CFR part 200, subpart W); Rental Assistance Payments Program (24 CFR part 236, subpart D); Housing Opportunities for Persons with AIDS (24 CFR part 574); Shelter Plus Care Program (24 CFR part 582); Supportive Housing Program (McKinney Act Homeless Assistance) (24 CFR part 583); Section 202 Supportive Housing Program for the Elderly (24 CFR 891, subpart B); Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities (24 CFR part 891, subpart E) and the Section 811 Supportive Housing for Persons with Disabilities (24 CFR part 891, subpart C). Unless specified in the regulations for each of the programs listed in paragraph (d) of this section or in another regulatory section of this part 5, subpart F, the regulations in part 5, subpart F, generally are not applicable to these programs; and

(e) Determining earned income disregard for persons with disabilities, as provided in § 5.617, for the following programs: HOME Investment Partnerships Program (24 CFR part 92); Housing Opportunities for Persons with AIDS (24 CFR part 574); Supportive Housing Program (McKinney Act Homeless Assistance) (24 CFR part 583); and the Housing Choice Voucher Program (24 CFR part 982).

4. In § 5.603, paragraph (a)(1) is revised and a new definition of "responsible entity" is added to paragraph (b) to read as follows:

§ 5.603 Definitions.

* * * * *

(a) *Terms found elsewhere in part 5.*

(1) *Subpart A.* The terms *1937 Act, elderly person, public housing, public housing agency (PHA), responsible entity* and *Section 8* are defined in § 5.100.

* * * * *

(b) * * *

Responsible entity. For § 5.611, in addition to the definition of "responsible entity" in § 5.100, and for § 5.617, in addition to only that part of the definition of "responsible entity" in § 5.100 which addresses the Section 8 program covered by § 5.617 (public housing is not covered by § 5.617), "responsible entity" means:

(1) For the HOME Investment Partnerships Program, the participating jurisdiction, as defined in 24 CFR 92.2;

(2) For the Rent Supplement Payments Program, the owner of the multifamily project;

(3) For the Rental Assistance Payments Program, the owner of the Section 236 project;

(4) For the Housing Opportunities for Persons with AIDS (HOPWA) program, the applicable "State" or "unit of general local government" or "nonprofit organization" as these terms are defined in 24 CFR 574.3, that administers the HOPWA Program;

(5) For the Shelter Plus Care Program, the "Recipient" as defined in 24 CFR 582.5;

(6) For the Supportive Housing Program, the "recipient" as defined in 24 CFR 583.5;

(7) For the Section 202 Supportive Housing Program for the Elderly, the "Owner" as defined in 24 CFR 891.205;

(8) For the Section 202 Direct Loans for Housing for the Elderly and Persons with Disabilities), the "Borrower" as defined in 24 CFR 891.505; and

(9) For the Section 811 Supportive Housing Program for Persons with Disabilities, the "owner" as defined in 24 CFR 891.305.

* * * * *

5. Revise § 5.611 to read as follows:

§ 5.611 Adjusted income.

Adjusted income means annual income (as determined by the responsible entity, defined in § 5.100 and § 5.603) of the members of the family residing or intending to reside in the dwelling unit, after making the following deductions:

(a) *Mandatory deductions.* In determining adjusted income, the responsible entity must deduct the following amounts from annual income:

(1) $480 for each dependent;

(2) $400 for any elderly family or disabled family;

(3) The sum of the following, to the extent the sum exceeds three percent of annual income:

(i) Unreimbursed medical expenses of any elderly family or disabled family; and

(ii) Unreimbursed reasonable attendant care and auxiliary apparatus expenses for each member of the family who is a person with disabilities, to the extent necessary to enable any member of the family (including the member who is a person with disabilities) to be employed. This deduction may not exceed the earned income received by family members who are 18 years of age or older and who are able to work because of such attendant care or auxiliary apparatus; and

(4) Any reasonable child care expenses necessary to enable a member of the family to be employed or to further his or her education.

(b) *Additional deductions.* (1) For public housing, a PHA may adopt additional deductions from annual income. The PHA must establish a written policy for such deductions.

(2) For the HUD programs listed in § 5.601(d), the responsible entity shall calculate such other deductions as required and permitted by the applicable program regulations.

6. A new § 5.617 is added to read as follows:

§ 5.617 Self-sufficiency incentives for persons with disabilities—Disallowance of increase in annual income.

(a) *Applicable programs.* The disallowance of increase in annual income provided by this section is applicable only to the following programs: HOME Investment Partnerships Program (24 CFR part 92); Housing Opportunities for Persons with AIDS (24 CFR part 574); Supportive Housing Program (24 CFR part 583); and the Housing Choice Voucher Program (24 CFR part 982).

(b) *Definitions.* The following definitions apply for purposes of this section.

Disallowance. Exclusion from annual income.

Previously unemployed includes a person with disabilities who has earned, in the twelve months previous to employment, no more than would be received for 10 hours of work per week for 50 weeks at the established minimum wage.

Qualified family. A disabled family residing in housing assisted under one of the programs listed in paragraph (a) of this section or receiving tenant-based rental assistance under one of the programs listed in paragraph (a) of this section:

(1) Whose annual income increases as a result of employment of a family member who is a person with

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disabilities and who was previously unemployed for one or more years prior to employment;

(2) Whose annual income increases as a result of increased earnings by a family member who is a person with disabilities during participation in any economic self-sufficiency or other job training program; or

(3) Whose annual income increases, as a result of new employment or increased earnings of a family member who is a person with disabilities, during or within six months after receiving assistance, benefits or services under any state program for temporary assistance for needy families funded under Part A of Title IV of the Social Security Act, as determined by the responsible entity in consultation with the local agencies administering temporary assistance for needy families (TANF) and Welfare-to-Work (WTW) programs. The TANF program is not limited to monthly income maintenance, but also includes such benefits and services as one-time payments, wage subsidies and transportation assistance—provided that the total amount over a six-month period is at least $500.

(c) *Disallowance of increase in annual income.*—(1) *Initial twelve month exclusion.* During the cumulative twelve month period beginning on the date a member who is a person with disabilities of a qualified family is first employed or the family first experiences an increase in annual income attributable to employment, the responsible entity must exclude from annual income (as defined in the regulations governing the applicable program listed in paragraph (a) of this section) of a qualified family any increase in income of the family member who is a person with disabilities as a result of employment over prior income of that family member.

(2) *Second twelve month exclusion and phase-in.* During the second cumulative twelve month period after the date a member who is a person with disabilities of a qualified family is first employed or the family first experiences an increase in annual income attributable to employment, the responsible entity must exclude from annual income of a qualified family fifty percent of any increase in income of such family member as a result of employment over income of that family member prior to the beginning of such employment.

(3) *Maximum four year disallowance.* The disallowance of increased income of an individual family member who is a person with disabilities as provided in paragraph (c)(1) or (c)(2) is limited to a lifetime 48 month period. The disallowance only applies for a maximum of twelve months for disallowance under paragraph (c)(1) and a maximum of twelve months for disallowance under paragraph (c)(2), during the 48 month period starting from the initial exclusion under paragraph (c)(1) of this section.

(d) *Inapplicability to admission.* The disallowance of increases in income as a result of employment of persons with disabilities under this section does not apply for purposes of admission to the program (including the determination of income eligibility or any income targeting that may be applicable).

PART 92—HOME INVESTMENT PARTNERSHIPS PROGRAM

7. The authority citation for part 92 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12701–12839.

8. In § 92.203, a new paragraph (d)(3) is added to read as follows:

§ 92.203 Income determinations.

* * * * *

(d) * * *

(3) The participating jurisdiction must follow the requirements in § 5.617 when making subsequent income determinations of persons with disabilities who are tenants in HOME-assisted rental housing or who receive tenant-based rental assistance.

PART 200—INTRODUCTION TO FHA PROGRAMS

9. The authority citation for part 200 continues to read as follows:

Authority: 12 U.S.C. 1701–1715z–18; 42 U.S.C. 3535(d).

10. Section 200.1303 is revised to read as follows;

§ 200.1303 Annual income exclusions for the Rent Supplement Program.

(a) The exclusions to annual income described in 24 CFR 5.609(c) apply to those rent supplement contracts governed by the regulations at 24 CFR part 215 in effect immediately before May 1, 1996 (contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219), in lieu of the annual income exclusions described in 24 CFR 215.21(c) (contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219).

(b) The mandatory deductions described in 24 CFR 5.611(a) also apply to the rent supplement contracts described in paragraph (a) of this section in lieu of the deductions provided in the definition of "adjusted income" in 24 CFR 215.1 (as contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219).

(c) The definition of "persons with disabilities" in paragraph (c) of this section replaces the terms "disabled person" and "handicapped person" used in the regulations in 24 CFR part 215, subpart A (as contained in the April 1, 1995 edition of 24 CFR, parts 200 to 219). *Person with disabilities,* as used in this part, has the same meaning as provided in 24 CFR 891.305.

PART 236—MORTGAGE INSURANCE AND INTEREST REDUCTION PAYMENT FOR RENTAL PROJECTS

11. The authority citation for part 236 continues to read as follows:

Authority: 12 U.S.C. 1701–1715z–1; 42 U.S.C. 3535(d).

Subpart D—Rental Assistance Payments

12. Section 236.710 is revised to read as follows;

§ 236.710 Qualified tenant.

(a) The benefits of rental assistance payments are available only to an individual or a family who is renting a dwelling unit in a project that is subject to a contract entered into under the requirements of this subpart or who is occupying such a dwelling unit as a cooperative member. To qualify for the benefits of rental assistance payments, the individual or family must satisfy the definition of Qualified Tenant found in § 236.2 of subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)).

(b) To receive rental assistance under this subpart, the income of the individual or family must be determined to be too low to permit the individual or family to pay the approved Gross Rent with 30 percent of the individual's or family's Adjusted Monthly Income, as defined in § 236.2 of subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499). Determination of the Adjusted Monthly Income must include the deductions required for adjusted income in 24 CFR 5.611(a) in lieu of the deductions provided in the definition of "adjusted income" in 24 CFR 236.2 (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)).

(c) For requirements concerning the disclosure and certification of Social Security Numbers, see 24 CFR part 5, subpart B. For requirements regarding the signing and submitting of consent forms for the obtaining of wage and claim information from State Wage Information Collection Agencies, see 24 CFR part 5, subpart B. For restrictions on financial assistance to noncitizens with ineligible immigration status, see 24 CFR part 5, subpart E.

(d) The definition of "persons with disabilities" in paragraph (d) of this section replaces the terms "disabled person" and "handicapped person" used in the regulations in 24 CFR part 236, subpart A (contained in the April 1, 1995 edition of 24 CFR, parts 220 to 499; see the Savings clause at § 236.1(c)). *Person with disabilities,* as used in this part, has the same meaning as provided in 24 CFR 891.305.

PART 574—HOUSING OPPORTUNITIES FOR PERSONS WITH AIDS

13. The authority citation for part 574 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 12901–12912.

14. Paragraphs (d)(1) and (d)(3) of § 574.310 are revised to read as follows:

§ 574.310 General standards for eligible housing activities.

* * * * *

(d) *Resident rent payment.* * * *

(1) 30 percent of the family's monthly adjusted income (adjustment factors include the age of the individual, medical expenses, size of family and child care expenses and are described in detail in 24 CFR 5.609). The calculation of the family's monthly adjusted income must include the expense deductions provided in 24 CFR 5.611(a), and for eligible persons, the calculation of monthly adjusted income also must include the disallowance of earned income as provided in 24 CFR 5.617, if applicable;

* * * * *

(3) If the family is receiving payments for welfare assistance from a public agency and a part of the payments, adjusted in accordance with the family's actual housing costs, is specifically designated by the agency to meet the family's housing costs, the portion of the payment that is designated for housing costs.

* * * * *

PART 582—SHELTER PLUS CARE

15. The authority citation for part 582 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 11403–11407b.

16. Section 582.310 is revised to read as follows:

§ 582.310 Resident rent.

(a) *Amount of rent.* Each participant must pay rent in accordance with section 3(a)(1) of the U.S. Housing Act of 1937 (42 U.S.C. 1437a(a)(1)), except that in determining the rent of a person occupying an intermediate care facility assisted under title XIX of the Social Security Act, the gross income of this person is the same as if the person were being assisted under title XVI of the Social Security Act.

(b) *Calculating income.* (1) Income of participants must be calculated in accordance with 24 CFR 5.609 and 24 CFR 5.611(a).

(2) Recipients must examine a participant's income initially, and at least annually thereafter, to determine the amount of rent payable by the participant. Adjustments to a participant's rental payment must be made as necessary.

(3) As a condition of participation in the program, each participant must agree to supply the information or documentation necessary to verify the participant's income. Participants must provide the recipient information at any time regarding changes in income or other circumstances that may result in changes to a participant's rental payment.

PART 583—SUPPORTIVE HOUSING PROGRAM

17. The authority citation for part 583 continues to read as follows:

Authority: 42 U.S.C. 3535(d) and 11389.

18. In § 583.315, paragraph (a) is revised to read as follows:

§ 583.315 Resident rent.

(a) *Calculation of resident rent.* Each resident of supportive housing may be required to pay as rent an amount determined by the recipient which may not exceed the highest of:

(1) 30 percent of the family's monthly adjusted income (adjustment factors include the number of people in the family, age of family members, medical expenses and child care expenses). The calculation of the family's monthly adjusted income must include the expense deductions provided in 24 CFR 5.611(a), and for persons with disabilities, the calculation of the family's monthly adjusted income also must include the disallowance of earned income as provided in 24 CFR 5.617, if applicable;

(2) 10 percent of the family's monthly gross income; or

(3) If the family is receiving payments for welfare assistance from a public agency and a part of the payments, adjusted in accordance with the family's actual housing costs, is specifically designated by the agency to meet the family's housing costs, the portion of the payment that is designated for housing costs.

* * * * *

PART 891—SUPPORTIVE HOUSING FOR THE ELDERLY AND PERSONS WITH DISABILITIES

19. The authority citation for part 891 continues to read as follows:

Authority: 12 U.S.C. 1701q, 42 U.S.C. 1437f, 3535(d) and 8013.

20. In § 891.105, the definitions of *Annual Income, Total Tenant Payment,* and *Utility Allowance* are revised and a new definition of *Adjusted Income* is added to read as follows:

§ 891.105 Definitions.

* * * * *

Adjusted income as defined in part 5, subpart F of subtitle A of this title.

Annual income as defined in part 5, subpart F of subtitle A of this title. In the case of an individual residing in an intermediate care facility for the developmentally disabled that is assisted under title XIX of the Social Security Act and this part, the annual income of the individual shall exclude protected personal income as provided under that Act. For purposes of determining the total tenant payment, the income of such individuals shall be imputed to be the amount that the household would receive if assisted under title XVI of the Social Security Act.

* * * * *

Total tenant payment means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Utility allowance is defined in part 5, subpart F of this subtitle A of this title and is determined or approved by HUD.

* * * * *

21. In part 891, revise the heading of subpart E to read as follows:

Subpart E—Loans for Housing for the Elderly and Persons with Disabilities

22. In § 891.520, the definitions of *Gross Rent, Tenant Rent, Total Tenant Payment, Utility Allowance,* and *Utility Reimbursement* are revised and a new definition of *Adjusted Income* is added to read as follows:

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§ 891.520 Definitions applicable to 202/8 projects.

* * * * *

Adjusted income as defined in part 5, subpart F of subtitle A of this title.

* * * * *

Gross rent is defined in part 5, subpart F of subtitle A of this title.

* * * * *

Tenant rent means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Total tenant payment means the monthly amount defined in, and determined in accordance with part 5, subpart F of subtitle A of this title.

Utility allowance is defined in part 5, subpart F of subtitle A of this title and is determined or approved by HUD.

Utility reimbursement is defined in part 5, subpart F of subtitle A of this title.

* * * * *

PART 982—SECTION 8 TENANT BASED ASSISTANCE: HOUSING CHOICE VOUCHER PROGRAM

23. The authority citation for part 982 continues to read as follows:

Authority: 42 U.S.C. 1437f and 3535(d).

24. In § 982.201, paragraph (b)(3) is revised to read as follows:

§ 982.201 Eligibility and targeting.

* * * * *

(b) * * *

(3) The annual income (gross income) of an applicant family is used both for determination of income-eligibility under paragraph (b)(1) of this section and for targeting under paragraph (b)(2)(i) of this section. In determining annual income of an applicant family which includes persons with disabilities, the determination must include the disallowance of increase in annual income as provided in 24 CFR 5.617, if applicable.

* * * * *

Dated: January 10, 2001.

Andrew Cuomo,

Secretary.

[FR Doc. 01–1536 Filed 1–18–01; 8:45 am]

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Federal Register

Friday,
January 19, 2001

Part VIII

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 400, et al.
Medicaid Program; Medicaid Managed Care; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 400, 430, 431,434, 435, 438, 440, and 447

[HCFA–2001–FC]

RIN 0938–AI70

Medicaid Program; Medicaid Managed Care

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period amends the Medicaid regulations to implement provisions of the Balanced Budget Act of 1997 (BBA) that allow the States greater flexibility by permitting them to amend their State plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers if beneficiary choice is provided; establish new beneficiary protections in areas such as quality assurance, grievance rights, and coverage of emergency services; eliminate certain requirements viewed by State agencies as impediments to the growth of managed care programs, such as the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing. In addition, this final rule expands on regulatory beneficiary protections provided to enrollees of prepaid health plans (PHPs) by requiring that PHPs comply with specified BBA requirements that would not otherwise apply to PHPs.

DATES: Effective Date: These regulations are effective on April 19, 2001. Provisions that must be implemented thorough contracts with managed care organizations, prepaid health plans, health insuring organizations, or enrollment brokers are effective with respect to contracts that are up for renewal or renegotiation on or after April 19, 2001, but no longer than April 19, 2002.

Comment Date: We will consider comments on the upper payment limits in § 438.(c) if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 20, 2001.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2001–FC, P.O. Box 8010, Baltimore, MD 21244–8010 .

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–8010.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2001–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT:
Subparts A and B—Bruce Johnson: (410) 786–0615
Subpart C—Tim Roe: (410) 786–6647
Subpart D—Ann Page: (410) 786–0083
Subpart F—Tim Roe: (410) 786–2006
Subpart H—Tim Roe: (410) 786–2006
Subpart I—Tim Roe: (410) 786–2006
Subpart J—Bruce Johnson: (410) 786–0615

SUPPLEMENTARY INFORMATION:

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I. Background

Title XIX of the Social Security Act (the Act) established the Medicaid program, under which matching Federal funds are provided to State agencies to pay for coverage of health care services to low-income pregnant women, families and aged, blind, and disabled individuals. The Medicaid program is administered by States according to Federal statutory and regulatory requirements, under the aegis of a "State plan" that must be approved by the Health Care Financing Administration (HCFA). At the program' s inception, most health coverage under the Medicaid program was provided by reimbursing health care providers on a fee-for-service basis for services furnished to Medicaid beneficiaries. (Note: The term "beneficiaries" is used throughout the preamble to refer to individuals eligible for and receiving Medicaid benefits. The term "recipients" is used in the text of the regulation and is synonymous with "beneficiary").

Increasingly, however, State agencies have provided Medicaid coverage through managed care contracts, under which a managed care organization (MCO) or other similar entity is paid a fixed monthly capitation payment for each beneficiary enrolled with the entity for health coverage. Enrolled beneficiaries are required to receive the majority of health care services through the managed care entity. In most States, enrollment in these managed care arrangements is currently mandatory for at least certain categories of beneficiaries. Prior to the enactment of the Balanced Budget Act of 1997 (BBA), State agencies were required to obtain a waiver of a statutory "freedom of choice requirement" in order to operate these mandatory managed care programs. No such waiver was required for arrangements involving voluntary enrollment in managed care.

The Balanced Budget Act of 1997

Chapter One of the Medicaid provisions (Subtitle H) of the BBA significantly strengthens Medicaid managed care programs by modifying prior law to: (1) reflect the more widespread use of managed care by State agencies to serve Medicaid beneficiaries; (2) build on the increased expertise acquired by HCFA and the State agencies in the administration of managed care programs; (3) incorporate the knowledge that has been learned from Medicaid, Medicare and private sector managed care programs and their oversight organizations; and (4) provide a framework that will allow HCFA and

State agencies to continue to incorporate further advances in the oversight of managed care, particularly as it pertains to the protection of beneficiaries and the quality of care delivered to Medicaid enrollees. This final rule with comment period implements most of the provisions of that chapter (that is, sections 4701 through 4710). It addresses BBA provisions that reduce the need for State agencies to obtain waivers to implement certain managed care programs; eliminate enrollment composition requirements for managed care contracts; increase beneficiary protections for enrollees in Medicaid managed care entities; improve quality assurance; establish solvency standards; protect against fraud and abuse; permit a period of guaranteed eligibility for Medicaid beneficiaries; and improve certain administrative features of State managed care programs. It also strengthens existing regulatory requirements that apply to prepaid health plans (PHPs) by applying to PHPs certain requirements that the BBA imposes on MCOs.

Several principles guided the development of the final rule. First, the rule was developed with a clear emphasis on consumer protections. We have addressed the issues identified by advocates regarding the rights of Medicaid beneficiaries, particularly vulnerable populations, and how they can be protected as State agencies increasingly replace fee-for-service Medicaid delivery systems with managed care programs. In doing so, we have been guided by the Consumers Bill of Rights and Responsibilities (CBRR) issued in November 1997 by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. A Presidential directive ordered the Medicaid program to comply, to the extent permitted by law, with the recommendations in the CBRR. As a result, when writing this regulation, we incorporated the CBRR recommendations whenever authorized by law.

Second, we attempted to provide State agencies with sufficient flexibility to continue to be innovative in the development and improvement of their State Medicaid managed care programs. We recognized that uniform, national standards were not always appropriate in all instances and tried to identify areas where States needed flexibility to develop their own standards, unless an overriding beneficiary interest needed to be taken into account. The regulations were also written to support State agencies in their role as "health care purchasers," in addition to their role as "health care regulators." State agencies, like group purchasers in the private sector, are continuing to seek better value for their health care dollars, when "value" means the best possible combination of both quality and price. Relevant subparts of this final rule attempt to provide State agencies with the tools needed to become better purchasers.

Third, wherever we determined it was appropriate to develop Medicaid regulatory language that is parallel to the language used in the final Medicare+Choice (M+C) regulations published on June 9, 2000 (65 FR 40170), we did so. The latter M+C final rule implements Medicare managed care provisions in the BBA, many of which are similar to the Medicaid provisions implemented in this final rule.

Fourth, with respect to the quality-related provisions, we opted to take a more conservative approach and not impose greater regulatory burden without a strong evidence base.

Finally, the BBA directed the Secretary of the Department of Health and Human Services to:

> conduct a study concerning the safeguards (if any) that may be needed to ensure that the health care needs of individuals with special health care needs and chronic conditions who are enrolled with Medicaid managed care organizations are adequately met. (Section 4705(c)(2) of the Balanced Budget Act of 1997.)

In response to this charge from the Congress, during October 1998 to August 1999, HCFA conducted a study of existing research, data, and other information in a variety of areas related to the needs of special populations. HCFA has already taken steps to address many of these recommendations through revisions to the 1915(b) waiver process and provision of technical assistance and training activities to States. HCFA's responses in this final rule with comment period to comments on the proposed rule pertaining to safeguards for populations with special health care needs have been informed by our analysis of information gathered for the report to Congress. The final rule reflects revisions in response to comments based on this analysis.

This final rule with comment period creates a new part 438 in title 42 of the Code of Federal Regulations. All new managed care regulations created under the authority of the BBA, other sections of existing Medicaid regulations pertaining to managed care, and appropriate cross references appear in the new part 438. By creating this new part, we are attempting to help users of the regulations to better comprehend the overall regulatory framework for Medicaid managed care. More detailed discussions of the content of each of the subparts of this final rule are found at the beginning of the section of the preamble discussing each subpart.

Statutory Basis

Section 4701 of the BBA creates section 1932 of the Act, changes terminology in title XIX of the Act (most significantly, the BBA uses the term "managed care organization" to refer to entities previously labeled "health maintenance organizations"), and amends section 1903(m) of the Act to require that contracts under that section and contracting MCOs comply with applicable requirements in new section 1932. Among other things, section 1932 of the Act permits State agencies to require most groups of Medicaid beneficiaries to enroll in managed care arrangements without waiver authority under sections 1915(b) or 1115 of the Act. Under the law prior to the BBA, a State agency was required to request Federal waiver authority under section 1915(b) or pursuant to a demonstration authority under section 1115 in order to restrict beneficiaries' Medicaid coverage to managed care arrangements. Section 1932 of the Act also defines the term "managed care entity" (MCE) to include MCOs and primary care case managers meeting a new definition in section 1905(t) of the Act; establishes new requirements for managed care enrollment and choice of coverage; and requires MCOs, primary care case managers (PCCMs), and State agencies to provide specified information to enrollees and potential enrollees.

Section 4702 of the BBA amends section 1905 of the Act to permit State agencies to provide primary care case management services without waiver authority. Instead, primary care case management services may be made available under a State's Medicaid plan as an optional service.

Section 4703 of the BBA eliminates a former statutory requirement that no more than 75 percent of the enrollees in an MCO be Medicaid or Medicare beneficiaries.

Section 4704 of the BBA creates section 1932(b) of the Act to add increased protections for those enrolled in managed care arrangements. These include, among others, the application of a "prudent layperson's" standard to determine whether emergency room use by a beneficiary was appropriate and must be covered; criteria for showing adequate capacity and services; grievance procedures; and protections for enrollees against liability for payment of an organization's or provider's debts in the case of insolvency.

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Section 4705 of the BBA creates section 1932(c) of the Act, which requires State agencies to develop and implement quality assessment and improvement strategies for their managed care arrangements and to provide for external, independent review of managed care activities.

Section 4706 of the BBA provides that, with limited exceptions, an MCO must meet the same solvency standards set by State agencies for private HMOs or be licensed or certified by the State as a risk-bearing entity.

Section 4707 of the BBA creates section 1932(d) of the Act to add protections against fraud and abuse, such as restrictions on marketing and sanctions for noncompliance.

Section 4708 of the BBA adds a number of provisions to improve the administration of managed care arrangements. These include, among others, provisions raising the threshold value of managed care contracts that require the Secretary's prior approval, and permitting the same copayments in MCOs as apply to fee-for-service arrangements.

Section 4709 of the BBA allows State agencies the option to provide 6 months of guaranteed eligibility for all individuals enrolled in an MCE.

Section 4710 of the BBA specifies the effective dates for all the provisions identified in sections 4701 through 4709.

Proposed Rule

On September 29, 1998, we published a proposed rule setting forth proposed regulations implementing the above statutory provisions, as well as proposing to strengthen regulatory PHP requirements by incorporating by regulation requirements that would otherwise apply only to MCOs. (63 FR 52022) A summary of the specific provisions of the proposed regulations upon which we received public comments is set forth at the beginning of the discussion below of the comments we received. For a fuller discussion of our basis and purpose for the approach taken in the September 29, 1998 proposed rule, see the preamble to that document, at 63 FR 52022 through 52074.

We received 305 comments on the September 29, 1998 proposed rule. The comments were extensive and generally pertained to all the sections contained in the proposed rule. We carefully reviewed all of the comments and revisited the policies contained in the proposed rule that related to the comments.

II. Analysis of and Response to Public Comments on the Proposed Rule

A. General Provisions of the Proposed Rule (Subpart A)

1. Basis and Scope (Proposed § 438.1)

Section 438.1 of the proposed regulation set forth the basis and scope of part 438 including the fact that regulations in this part implement authority in sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act. Proposed § 438.1 also briefly described these statutory provisions.

2. Definitions (Proposed §§ 438.2, 430.5)

Section 438.2 of the proposed rule included definitions of terms that would apply for purposes of proposed part 438. The proposed definitions and relevant comments and our responses are provided below. As used in this part—

Authorized representative means an individual authorized by an enrollee to act on his or her behalf in any dealings with an MCE or the State. The rules for appointment of representatives set forth in 20 CFR part 404, subpart R apply unless otherwise provided in this subpart.

Managed care entity (MCE) means—

(1) A Medicaid managed care organization (MCO) that has a comprehensive risk contract under section 1903(m) of the Act; or

(2) A primary care case manager.

Managed care organization (MCO) means—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Is organized primarily for the purpose of providing health care services.

(ii) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(iii) Meets the solvency standards of § 438.116.

Prepaid health plan (PHP) means an entity that provides medical services to enrolled recipients under contract with the State agency, and on the basis of prepaid capitation fees, but does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily provided by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, in accordance with State licensure and certification laws and regulations.

Primary care case management means a system under which a primary care case manager contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, one of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means—

(1) Any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to carry out that activity in the State; and

(2) Any entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to deliver those services if licensing or certification is required by State law or regulation.

We also received comments on definitions of "comprehensive risk contract" in § 430.5, which defines a "Comprehensive risk contract" as a contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services: (1) outpatient hospital services; (2) rural health clinic services; (3) FQHC services; (4) other laboratory and X-ray services; (5) nursing facility (NF) services; (6) early and periodic screening, diagnostic, and treatment (EPSDT) services; (7) family planning services; (8) physician services; and (9) home health services. We have moved this definition, along with the following other managed care-related definitions, from part 430 to § 438.2. In addition, we have clarified the definition of health insuring organization so that it does not appear to require that the health insuring organization's (HIO's) providers be capitated.

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Federally qualified HMO means an HMO that HCFA has determined to be a qualified HMO under section 1310(d) of the PHS Act.

Health insuring organization means an entity that, in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a risk contract.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Comments on Definitions

Comment: Several commenters believe that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believe that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to "represent themselves, use legal counsel, a relative, friend or other spokesman." (§ 431.206.) If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (§ 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have deleted the reference to 20 CFR part 404. We have also deleted the reference to "authorized," using only the term "representative" to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads "Representative has the meaning given the term by each State consistent with its laws, regulations, and policies."

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which he or she is acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: One commenter found the definition of PHP to be too vague. Specifically, the commenter was not aware of what was meant by "comprehensive" and that it was confusing to use the words "capitation" and "fee" to describe a capitation payment. The commenter recommended that we not use the word "fee" in conjunction with capitation and that we define "comprehensive."

Another commenter believes the proposed regulations should include a new definition of a prepaid health plan (PHP) to include primary care case managers that are paid on a capitated basis for primary care services only. A commenter recommended that any entity meeting the definition of primary care case manager in section 1905(t) of the Act should be treated the same, whether capitated or paid on a fee-for-service (FFS) basis under State plan payment rates.

Response: Normally, we use the phrase "capitation payment" or "capitation rate" to describe the capitation method of payment rather than use "capitation fee." As such, we agree with the commenter that the word "fee," which is associated with "fee-for-service" payment, does not fit well with the word "capitation." We therefore are revising the definition of PHP by replacing the word "fee" with the word "payment" after "capitation."

With respect to the commenter's request that "comprehensive" be defined, the September 29, 1998 proposed regulations contained a definition of "comprehensive risk contract" that would apply for purposes of the definition of PHP. In the September 29, 1998 proposed rule, it was proposed that this definition be included in § 430.5. Since the commenter apparently did not see this definition, and was not aware that it pertains only to part 438, we are moving the definition of "comprehensive risk contract" from § 430.5 to § 438.2.

We disagree that a primary care case manager paid on a capitation basis should be treated the same as one paid on a fee-for-service basis based on State plan payment rates. The definition of primary care case manager in section 1905(t)(2) of the Act does not preclude payment on a capitation basis. Thus, an entity that meets this definition is subject to the rules and requirements that apply to a primary care case manager, whether the entity is paid on a fee-for-service basis, a risk capitation basis, or some other basis. To the extent that a primary care case manager is paid on a capitation basis for providing less than a comprehensive array of services, it would also meet the definition of a PHP and be subject to the requirements in § 438.8. In this case, the primary care case manager would be both a PHP and a PCCM. When the MCO rules that apply to PHPs are stricter than the rules that apply to all primary care case managers, a primary care case manager paid on a capitation basis would have to follow the MCO rules by virtue of its status as a PHP.

Comment: One commenter noted that the proposed definition of primary care refers to service customarily furnished by various types of physicians but does not mention nurse midwives, nurse practitioners, and physician assistants. The commenter asked us to define primary care to describe the functions of a primary care provider to allow inclusion of those classes of providers who are permitted under State law to practice as primary care providers. A second commenter requested that nurse practitioners and certified nurse midwives be expressly referenced in the definition of primary care.

A few commenters asked us to specifically include Federally qualified health centers (FQHCs) and rural health centers (RHCs) within the definition of primary care case manager, which the commenters appear to believe would be necessary in order for FQHCs and RHCs to have the option of serving as a primary care case manager (and as a result be eligible for automatic reenrollment). One commenter noted that the rule failed to identify obstetricians and gynecologists (Ob-

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Gyns) as primary care case managers and recommended their inclusion in that definition of primary care case manager.

One commenter urged that the definitions of primary care and primary care case manager include licensure or certification imposed by tribal governments in the case of individuals, groups, or entities that deliver health care services on a reservation. This commenter believes that this would be needed in order for some Tribes to implement tribal MCOs or PCCMs. A second commenter also noted that the definition of primary care case manager assumed State licensure and noted that the concept of tribal sovereignty generally precludes State licensing and certification of tribally operated programs. In order to implement an Indian Health Services (IHS) or tribally operated MCE, this commenter asked that language be added exempting tribes and the IHS from State license or certification requirements.

Finally, one commenter requested that the definitions of primary care and primary care case manager be more clear in order to distinguish between a PCCM system and a capitated program. The commenter urged that the language make clear that States have the option of offering a PCCM option as a form of noncapitated managed care. This commenter urged HCFA to require the PCCM option as an element of mandatory managed care at least for people with severe disabilities.

Response: Our definitions of primary care and primary care case manager mirror the statutory language in section 1905(t) of the Act. We believe that the Congress intended to limit the kinds of health care and laboratory services considered to be primary care to those "customarily provided" by the providers listed in the statute (and in the September 29, 1998 proposed rule). Contrary to the apparent belief of the first commenter discussed above, we believe this approach does focus on the "functions" performed, not on who is performing these functions. If the definition had been intended to limit primary care to services actually furnished by the physicians referenced, it would have said services "provided by" these providers, not services that are "customarily provided by" these providers. We thus believe the intent of the definition of primary care is to specify the health care and laboratory services considered to be "primary care." This means that under the proposed rule, the types of practitioners mentioned by the commenters could provide "primary care services" if they are "provided in accordance with State licensure and certification laws and regulations."

The definition of primary care case manager specifies those practitioners who may provide primary care case management services (for example, locating, coordinating and monitoring health care), which may also include the provision of "primary care" if permitted under State law. Nurse practitioners, certified nurse midwives, and physician assistants are included in that definition at State option. Ob-Gyns are already included in the term "physicians" as individuals who the statute specifies may be primary care case managers, and a separate mention is not necessary (particularly since Ob-Gyns are specifically mentioned in the definition of primary care. In addition, the definition of primary care case manager allows for "an entity employing or having other arrangements with physicians to . . ." serve as a primary care case manager. This would include both RHC and FQHCs, which thus similarly do not need to be mentioned by name. This policy is consistent with what we have allowed under the section 1915(b) of the Act waiver authority.

From the comments received, it is clear that there was confusion between the definition for "primary care case manager" and that for "provider." There is also confusion over the term PCCM, which has been used both to identify a managed care system established by the State and type of provider who participates in that system. We are using PCCM to mean "primary care case manager"—a specific term used to describe those providers who qualify to provide primary care case management services. Conversely, the term "provider" is a general term we use in this rule to identify health care professionals who meet the definition; this includes but is not limited to primary care case managers.

The definition of "provider" as published in our September 29, 1998 proposed rule, mirrors the definition of provider published in the June 29, 2000 M+C regulation. However, to further clarify the definition and to be consistent with the definition of "physician" used in section 1861(r)(1) of the Act, we are revising the definition of "provider" (which we are moving to § 400.203 in this final rule) to be "any individual or entity that is engaged in the delivery of health care services in a State and is legally authorized by the State to engage in that activity in the State." We have substituted the words "licensed or certified" with "legally authorized." The revised definition allows States, at their option, to include licensure or certification requirements imposed by Tribal governments. It also provides States the flexibility to determine what State requirements any provider must meet (for example, licensure and certification requirements) in order to provide services under managed care arrangements.

In response to the comments about the provision of primary care by providers certified by Tribes, we believe that a change to the definition of primary care incorporating the above language used in the definition of provider would permit states to allow Tribal-certified providers to furnish primary care as primary care case managers. Accordingly, in response to these comments, in the definition of "primary care," we are changing "in accordance with State licensure and certification laws and regulations" to "to the extent the provision of these services is legally authorized in the State in which they are provided." As in the case of our definition of "provider," we believe that this change is consistent with the Congress' intent that States have the discretion to regulate and authorize these services, while permitting the State flexibility in the approach it uses to do so. We disagree with the commenters that the definition of "primary care case manager" necessarily assumes certification by the State and therefore believe that no changes to this definition are necessary in order for States to permit Tribe-certified providers to serve as primary care case managers.

The primary care and primary care case management definitions do not address the type of payment provided for these services. As stated previously, the definitions related to primary care case manager services generally mirror section 1905(t) of the Act, which does not address payment for these services. These services are usually reimbursed on a fee-for-service (FFS) basis. However, some States do contract with providers or entities on a capitated basis for primary care services. Our definition allows for this practice to continue.

States now have more flexibility to offer Medicaid beneficiaries access to primary care case management services; section 1915(b) of the Act and section 1115 of the Act waiver authority are no longer the only options for States. Section 4702 of the BBA not only provides the definition of primary care case management services in section 1905(t) of the Act (along with definitions of "primary care case manager," "primary care case management contract" and "primary care") and sets forth the contracting

requirements for providing these services, it also allows States to add primary care case management services as an optional State plan service. Moreover, section 4701 of the BBA allows States to enroll specified beneficiaries into a PCCM program under a mandatory managed care program without the need to obtain a waiver authority. The BBA does not, however, require States to have PCCM as an option when implementing mandatory managed care programs. As specified in § 438.52 of the September 29, 1998 proposed rule, the final rule continues to require States to provide a choice of at least two MCOs, PHPs, or PCCMs to beneficiaries required to enroll in a managed care program; but States can choose whether to offer a PCCM program or simply offer a choice of two or more MCOs.

Comment: One commenter believes the definition of "comprehensive risk contract" (now in § 438.2) should include language that makes explicit HCFA's longstanding interpretation that contracts covering specialty care only, such as behavior health contracts, are not comprehensive risk contracts. The commenter suggested that we include this clarification in the definition of comprehensive risk contract. In addition, the commenter suggested that MCO and MCE be defined in § 430.5 because the terms are used several times throughout the Medicaid regulations set forth in subchapter C before they are fully defined in § 438.2.

Response: We do not believe it is necessary to include language expressly reflecting our longstanding position that the provision of only a limited package of inpatient services related to behavioral health problems (or other similarly narrow area) does not constitute the coverage of "inpatient services" as used in the introductory clause in section 1903(m)(2)(A) of the Act, and in the definition of "comprehensive risk contract" that implements this statutory language. Under this interpretation, the reference to "inpatient" services is to coverage of the full range of these services, not a narrow subset. There does not appear to be any confusion regarding this interpretation, and we do not believe that any change in regulations text is justified.

We agree with the commenter that the terms MCO and MCE are used in part 430 before they are defined in § 438.2. Therefore, we are moving all of the relevant managed care definitions from § 430.5 to § 438.2, which will place all managed care definitions in one section. This will also eliminate duplicate definitions (such as PHP) in both sections.

Comment: One commenter believes that "partial" risk arrangements (for example, withhold or bonus arrangements that involve risk without traditional capitation) are not addressed in the definitions of nonrisk contract, PHP, and risk contract. This commenter also found that these arrangements are omitted in the reference in the parenthetical in proposed § 438.50(a) to "whether fee-for-service or capitation" payment will be used. The commenter recommended that to allow for States to adopt partial risk-sharing arrangements, the regulations should specify the regulatory requirements that apply if the State chooses to enter into partial risk arrangements.

Response: To the extent a partial risk arrangement puts an entity at "financial risk for changes in utilization," it would not qualify as a "nonrisk contract" under our definition. It would, however, fall within the definition of "risk contract" since the entity would "assume risk for the costs of services" and could incur losses if the costs exceed payment. In other words, when funds are put at risk, the contract is a risk contract that would be subject to MCO requirements if it were comprehensive. We agree with the commenter, however, that a partial risk contract that is less than comprehensive and does not involve prepaid capitation, arguably would not technically fall within the existing definition of PHP. This could create an unintended loophole. We therefore are revising the definition of PHP to include these payment arrangements by adding the phrase "or on other payment arrangements that do not employ State plan payment rates." This language would continue to exempt entities paid on a fee-for-service basis based on State plan payment rates from the PHP (and thus MCO) requirements, even if they were paid a "case management fee" as a primary care case manager. In this latter situation, there is no financial incentive to deny services.

We also agree with the commenter that the parenthetical in proposed § 438.50(a) (which has been moved to § 438.50(b) as part of a reorganization of that section) excludes partial risk payment arrangements that do not involve capitation. We therefore are adding a "for example" at the beginning of the parenthetical to indicate that these are just examples of what might be specified.

Comment: One commenter suggested that we add the sentence, "An entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract" under the definition of MCO. Other commenters were concerned that the requirement that an MCO is "organized primarily for the purposes of providing health care services" could be read to preclude from participation a legal entity that is not necessarily organized primarily to provide health care, such as a county government.

Another commenter noted that although it appears clear from the discussion of the purpose of the definitions in this section and the provisions of § 438.8 that the definition of an MCO is not intended to include PHPs, it would be clearer if this was explicitly stated. The commenter suggested that we include in our definition of an MCO, a statement that specifies PHPs are not considered MCOs. The commenter also suggested that we add language to the definition of PHP to address the potential for risk arrangements with PHPs other than capitation by adding the phrase "or other risk arrangements" after the words "prepaid capitation fees" because some waivers do not make capitation payments. Another commenter requested that we clarify if MCE includes PCCM programs.

One commenter thought that we interchangeably used the terms MCO and MCE, and used MCE when PCCM was intended, and therefore suggested that we further define the term MCE. The commenter recommended changing MCE to PCCM when appropriate and also revising text to indicate the conditions under which regulations apply to both MCOs and MCEs.

Response: We believe that it would be inaccurate to add the sentence "an entity must be found to meet the definition of an MCO to enter into Medicaid's comprehensive risk contract" because certain statutory exemptions allow for other entities to enter into these contracts. We also believe that § 438.6(a) makes clear the entities with which a State agency may enter into a comprehensive risk contract, and makes clear that this includes an MCO. We agree that a county is not organized "primarily" for the purpose of providing health care services and that counties should be permitted to contract as MCOs if all of the requirements in sections 1903(m) and 1932 of the Act are otherwise satisfied. In our proposed definition of MCO, we retained the requirement that the entity be organized "primarily for the purpose" of providing health care services from our pre-BBA definition of HMO. Since this requirement is not included in the statutory definition of MCO in section 1903(m)(1)(A) of the Act

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and could potentially provide an impediment to the availability of county-sponsored managed care arrangements, we are deleting this requirement in response to this comment.

While we do not agree with the commenter's suggestion that it be specified in the definition of MCO that PHPs are excluded, we agree that it would not be clear from the current definition of MCO that an entity that otherwise meets the definition would be excluded if it does not have a comprehensive risk contract. While the definition of MCE refers to an MCO that has a comprehensive risk contract under section 1903(m) of the Act, the MCO definition itself does not include this restriction. Since the regulations use "MCO requirements" as a shorthand for requirements that apply to comprehensive risk contractors, we agree that it would be a good idea to include this concept in the definition of MCO. Because an entity is required to meet the definition of MCO as a condition for qualifying for a comprehensive risk contract, we are revising the definition of MCO to provide that it is an entity "that has, or is seeking to qualify for, a comprehensive risk contract under this part." With this qualification, it should be clear that a PHP would not be included since a PHP is by definition an entity that "does not have a comprehensive risk contract." With respect to the commenter's suggestion that "or other risk arrangements" be added to the definition of PHP after "prepaid capitation basis," we believe that the commenter's concern has been addressed by the revision we have made in response to the previous comment. The alternative arrangements to capitation suggested by the commenter would be included in the phrase "other payment arrangements that do not employ State plan payment rates." The reason we did not adopt the commenter's specific suggestion of "other risk arrangements" is that this would imply that the reference to "prepaid capitation basis" was exclusively a risk arrangement, when in fact there have been nonrisk PHPs. (In these cases, capitation payments have been subject to a cost-reconciliation process.) Our alternative approach continues to accommodate nonrisk contracts as PHPs.

With respect to comments on the use of the terms MCO, MCE and PCCM, we do not believe that the terms are used interchangeably in the September 29, 1998 proposed rule, but we understand that the application of these terms to various provisions of the regulation has caused confusion. There is a significant difference between an MCO and MCE. An MCE is either an MCO with a risk comprehensive contract or a primary care case manager. The terms MCO and MCE are used in the statute and in the rule to identify when different requirements apply.

However, in the interest of clarity, we are changing the regulations text to indicate when regulations apply to MCOs, PCCMs, or both. We are also deleting the definition of MCE since the term will no longer be necessary as a result of this change.

3. Contract Requirements (Proposed § 438.6)

Proposed § 438.6 set forth rules governing contracts with MCOs, PHPs, or PCCMs. Paragraph (a) of proposed § 438.6 set forth the entities with which a State may enter into a comprehensive risk contract. Paragraph (b) provided that the actuarial basis for capitation payments must be specified in the contract and that the capitation payments could not exceed the upper payment limit in § 447.361. Paragraph (c) contained requirements regarding enrollment, that enrollments be accepted in the order of application up to capacity limits, that enrollment be voluntary unless specified exceptions apply, and that beneficiaries not be discriminated against based on health status. Paragraph (d) provided that MCEs can cover services for enrollees not covered for nonenrolled individuals. Paragraph (e) required that contracts must meet the requirements in § 438.6. Paragraph (f) required that risk contracts provide the State and HHS access to financial records of MCEs. Paragraph (g) required compliance with physician incentive plan requirements in §§ 422.208 and 422.210. Paragraph (h) required compliance with advance directive requirements. Paragraph (i) provided that with certain exceptions, HIOs are subject to MCO requirements. Paragraph (j) set forth the new rules in section 1905(t) (3) of the Act that apply to contracts with primary care case managers.

Computation of Capitation Payments (Proposed §§ 438.6(b), 438.64)

The September 29, 1998 proposed rule proposed that two provisions addressing capitation rates be moved from part 434 to the new part 438 but proposed to retain the existing requirements governing capitation payments, which are incorporated in a new proposed §§ 438.6(b) and 438.64. Proposed § 438.6(b) required that contracts specify the actuarial basis for capitation and that "the capitation payments and any other payments provided for in the contract do not exceed the payment limits set forth in § 447.361." Proposed § 438.64 reflected the requirement in section 1903(m)(2)(A)(iii) of the Act that rates be computed on an "actuarially sound basis."

Comment: A large number of comments from States, provider associations, and advocates objected to the requirement in proposed § 438.6(b)(2) that capitation payments and other payments to the provider cannot exceed the upper payment limit (UPL) set forth at § 447.361. The commenters stated that many States no longer have a fee-for-service base to use in computing the UPL and that it was no longer a valid measure of costs, since it did not recognize or include: (1) additional costs resulting from new regulatory requirements in the September 29, 1998 proposed rule; (2) the costs of required expanded or mandated benefits; (3) overall administrative costs of MCOs; (4) MCO start-up costs; or the decline in MCO profits (in commercial, Medicare, and Medicaid plans). Several commenters indicated that this requirement potentially contradicted the requirement in § 438.64 that rates be computed on an actuarially sound basis since rates that are truly actuarially sound could in some cases exceed the UPL. Commenters recommended that HCFA revise or eliminate the UPL requirement and replace it with new rules on rate setting.

Two commenters stated that there were no good arguments for changing the current UPL provisions.

Response: We agree with the commenters that problems are presented by our decision in the September 29, 1998 proposed rule to retain the current UPL requirement in proposed § 438.6(b)(2). We acknowledge that many States no longer have fee-for-service base year data recent enough to use as a reasonable comparison to the costs of a current capitated managed care system. We therefore are accepting the recommendations of the commenters and are in this final rule deleting § 447.361 and revising § 438.6 by creating a new § 438.6(c), Payments under risk contracts, which (1) does not include a UPL; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disability, ongoing health care needs or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements. While these changes are being included in this final rule in response to comments on the September 29, 1998 proposed rule, because they involve a new approach to regulating capitation payments, we are providing for a 60-day comment period limited to our decision to replace the existing UPL with new § 438.6(c).

In making these changes, we are moving from a review that compares capitation rates in risk contracts to the historical fee-for-service cost of the services under contract for an actuarially equivalent nonenrolled population to a review of the utilization and cost assumptions and methodology used by the State to set the actual capitation rates. We believe that this change will result in a more appropriate review of capitation rates by examining how the rates have been established rather than how they compare to an increasingly difficult to establish fee-for-service equivalent.

This change does not affect the rules governing UPLs for other types of providers or services including the currently applicable provisions in § 447.272, § 447.304, § 447.321 or those in a proposed rule on payments to hospitals, nursing facilities, intermediate care facilities for the mentally retarded, and clinics published on October 10, 2000 (65 FR 60151). Nor will this change affect the UPL for nonrisk contracts in § 447.362, which remains in effect.

While comments are solicited on all aspects of this change, we are specifically requesting comments and suggestions on the provisions in § 438.6(c) and § 438.814 that impose special rules on contracts with incentive arrangements or risk-sharing mechanisms. As set forth above, FFP is only available for risk contracts to the extent that payments are determined on an actuarially sound basis. "Under these provisions, we have determined that where total payments exceed 105 percent of the capitation payments paid under the contract, these payments are no longer actuarially sound. Thus, no FFP would be available for payments resulting from risk corridors or incentive arrangements for amounts that exceed 105 percent of the capitation payments made under the contract. If the risk corridor or incentive arrangement does not apply to all enrollees or services under the contract, the 105 percent limit is based only on that portion of total capitation payments for the enrollees or services covered by the arrangement." States could make payments under these arrangements with their own funds but would be precluded from claiming FFP for these payments.

This limitation protects the Federal government against potentially unlimited exposure under risk corridor or bonus arrangements. This is particularly important since the "cost-effectiveness" requirement in section 1915(b) of the Act and the "budget neutrality" standard imposed under section 1115(a) of the Act demonstrations generally do not contain an outright limit on the Federal share of expenditures under the contract. And, neither of these limits apply to voluntary managed care contracts under section 1915(a) of the Act or contracts for mandatory enrollment under section 1932(a)(1)(A) of the Act using State plan authority.

Without any upper limit on the amount that can be paid in incentive arrangements or risk-sharing mechanisms, the potential exists for inefficiency or inappropriate actions by the contractor to maximize funding, resulting in rates that bear no relationship to those certified by actuaries and which thus are no longer "actuarially sound." We have provided for the limitations in §§ 438.6(c)(5)(ii) and 438.814 as a workable alternative to the current UPL, which meets the following criteria: (1) it provides a clear, consistent rule that can be applied to all risk contracts, regardless of the authority under which the contract operates (waiver or otherwise); (2) it should not discourage the use of any of these arrangements; (3) it explicitly conditions Federal matching funds on the imposition of these limits under any of these arrangements to prevent any potential abuses; and (4) it can be easily administered.

Although not part of this final rule, we also are revising the policies governing cost effectiveness for section 1915(b) of the Act waiver programs. The current regulations at § 431.55, which require waiver programs to be cost-effective and efficient and require States to document this cost-effectiveness of their waiver programs, will remain unchanged. However, HCFA is modifying the process by which States document this cost-effectiveness through re-issuance of State Medicaid Manual provisions and revision of the section 1915(b) of the Act Medicaid waiver applications. The revised waiver cost-effectiveness test will apply to all section 1915(b) of the Act waivers, regardless of the payment system (for example, FFS, capitation) in the State's waiver program.

Comment: Several commenters stated that the current UPL limit does not recognize the cost of providing care to particularly vulnerable populations and that States should be required to use risk-adjusted capitation rates for homeless and other populations with special health care needs. Some of these commenters added that HCFA should encourage States to reimburse MCOs their actual costs for these populations until sufficient data is developed to apply the risk adjustors.

Response: HCFA encourages States to develop capitation rates that are as accurate as possible in predicting the costs of any population enrolled in managed care. To this end, most States already use rates that are risk-adjusted for demographic factors such as age, gender, locality, and adjusted for category of eligibility, all of which will now be required under § 438.6(c)(3)(iii). Only a few States use diagnosis-based risk adjustors, which under § 438.6(c)(3)(iii)(E) of this final rule would be optional. We are not mandating the use of risk adjustment as suggested by the commenter because risk adjustors (both health status and demographic risk adjustors) can only be used when the population falling into any one category is both readily identifiable and large enough to be a statistically valid-sized group. When States have the capability to identify and separate the costs of any individuals with chronic illness, disability, or extensive ongoing health care needs, we would encourage the State to take this into account in its rate-setting methodology. Because the ability to apply these methodologies will vary from State to State, we are not willing to impose this requirement.

However, we are requiring States to utilize risk adjustment, risk sharing, or other mechanisms or assumptions to account for the cost of services for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims when setting the capitation rate. Other identifiable factors, which may have impact on the expected health care costs of an individual, may also be used in setting more accurate capitation rates.

Further, we believe that moving from the UPL requirement to an enhanced documentation of the assumptions and methodology used to develop capitation rates will result in rates that are determined on a more reasonable and predictable basis specific to the population enrolled than the UPL requirement's comparison to fee-for-service costs.

Current regulations provide authority for States to contract with MCOs on a

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nonrisk basis. This type of contract reduces the contractor's risk for changes in enrollee utilization of services under the contract. This provision permits payment to the contractor based on the contractor's costs, subject to the nonrisk upper payment limit in § 447.362 (which is based on FFS costs of the services actually provided, plus an adjustment for administrative costs). However, currently there are very few States with nonrisk contacts. Given our new model of rate review, and the requirement in § 438.6(c)(3)(iv) that "individuals with chronic illness, disability, ongoing health care needs or catastrophic claims" be taken into account, we do not believe it is necessary or appropriate to encourage the greater use of nonrisk contracts as suggested by the commenters.

Comment: Several commenters contended that States' rate-setting processes can be inconsistent, arbitrary, and secretive, and recommended that HCFA require a public process in which States would have to disclose the actuarial information and assumptions in the rate setting process. One commenter wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: We do not believe that requiring a public process in State rate setting would be conducive to more effective rate setting by States. There are currently 19 States that use some form of competitive bidding and 35 States that use a negotiation process to set rates (including some that use a combination of these methods). Imposing a public participation process outside of the requirements for competitive procurement, or in the midst of negotiations between the State and potential contractors, would not be helpful to these processes. We believe that these methods for establishing payment rates differ significantly from FFS under which States establish fee schedules for Medicaid provider payments, such as with institutional payments when a public process is required. Further, we believe that the new rate-setting process set forth at § 438.6(c) will help to make all parties aware of the elements required and assumptions that must be taken into account in establishing capitation rates.

Comment: Several commenters stated that HCFA should define "actuarially sound."

Response: In discussions with actuaries, we have found that there is no universally accepted definition of the term actuarially sound. In the past, we have intended this provision to mean a reflection of past costs and prediction of the future costs of specific services for a specific population based upon concepts of predictability and reasonableness. In § 438.6(c)(1)(i), we have defined the term actuarially sound capitation rates. We have used this term in order to reflect that the emphasis in our review of rates is on the State's assumptions and process used in determining capitation rates, rather than payment amounts. These are defined as rates that are certified by an actuary, developed in accordance with generally accepted actuarial principles and practices, and appropriate for the population and services covered under the contract. The American Academy of Actuaries defines generally accepted actuarial principles and practices as:

* * * those derived from the professional actuarial literature from their common use by actuaries. Actuarial principles and practices are generally accepted when they are consistent with practices described in the actuarial standards of practice adopted by the actuarial Standards Board and to the degrees that they are established by precedent or common usage. (From Section 2, Second Exposure Draft, Proposed Actuarial Standard of Practice, Utilization of Generally Accepted Actuarial Principle and Practices, American Academy of Actuaries.)

The required certification by the State's actuary should include the actuary's determination of the range of soundness for the proposed rates (or specific rate cells). This would be helpful in resolving any disputes that could arise over the soundness of the rates and would supplement the required documentation of the elements and process used to set the capitation rates.

We believe that our definition of actuarially sound capitation rates and new rate setting review requirements provide HCFA's interpretation of actuarial soundness as set forth in section 1903(m)(2)(A)(iii) of the Act.

Comment: One commenter wanted HCFA to apply the actuarial soundness requirement to MCO payments to providers.

Response: We do not have the authority to impose these requirements on rates paid by MCOs to their subcontractors. The only instances in which the statute provides authority to regulate payments by MCOs to subcontractors are the physician incentive plan requirements imposed under section 1903(m)(2)(A)(x) of the Act, and the requirement in section 1903(m)(2)(A)(ix) of the Act that payments by MCOs to FQHCs and RHCs be no less than rates paid to similar subcontractors providing a similar range of services.

Comment: Several commenters stated that HCFA should develop an administrative process for the resolution of rate issues between MCOs and States when potential contractors do not believe that their payment rates are sufficient .

Response: We do not believe it would be appropriate for us to mandate a specific administrative review process for MCO disputes with States over payment rates. It is a State's decision whether to utilize a managed care delivery system in its Medicaid program, and part of that decision may be based upon the rates it believes it can afford to offer prospective MCOs or PHPs. If the rates are not high enough to obtain a sufficient number of contractors, the State must make a decision whether to raise its rates or discontinue its managed care program. HCFA has no authority to require a state to continue or begin a managed care program. We note, however, that under the new procedures in § 438.6(c), HCFA will be reviewing rates for actuarial soundness, so this review provides certain protections to MCOs as to the adequacy of payment rates and should at least in part address the commenters' concerns.

Comment: HCFA should offer technical assistance to States in setting capitation rates.

Response: Section 1903(k) of the Act specifically authorizes us to provide this assistance at no cost to the State, and we have done so in the past. Currently, however, most States have elected to contract with actuarial firms for this assistance.

Comment: One commenter was concerned that language in the September 29, 1998 proposed rule implied that HCFA would no longer review capitation rates and wanted HCFA assurance that it would continue to review capitation rates in contracts.

Response: HCFA will continue to review rates established between states and MCOs or PHPs. In fact, new § 438.6(c) applies these rate-setting requirements to all risk contracts, and we have created a new § 438.6(a) that provides that the HCFA Regional Office must review and approve all MCO and PHP contracts.

Prohibition of Enrollment Discrimination (Proposed § 438.6(c))

Proposed § 438.6(c) (recodified as § 438.6(d) in this final rule) established rules for enrollment and set forth prohibitions against discrimination in the enrollment process. Specifically, proposed § 438.6(c) required that enrollees be accepted in the order in which they applied up to specified capacity limits, provided that with specified exceptions enrollment must be voluntary, and prohibited discrimination based on health status.

Comment: Several commenters noted that the September 29, 1998 proposed rule appropriately prohibits health plans from "cherry picking," which is the concept of discriminating against persons who may have high health care needs. However, they noted that the requirement only applies during open enrollment. The commenters believe that the requirement should not apply only to "official" open enrollment periods, since enrollment can occur at any time during the year as individuals become Medicaid-eligible. The commenters suggested that we revise the September 29, 1998 proposed rule to include the following: "MCE contracts must provide that MCEs will not discriminate on the basis of race, color, or national origin. In addition, the MCE must not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin." This is required under Title VI of the Civil Rights Act and implementing regulations.

Response: We agree with the commenter that there is no reason for limiting the requirement that the MCE accept individuals for enrollment in the order in which they apply only to open enrollment periods. Therefore, we are revising § 438.6(d)(1) to specify that "The MCO, PHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator) up to the limits set under contract."

We also agree that MCOs, PHPs, or PCCMs should not discriminate based on health status, race, color, or national origin and that MCO contracts should contain assurances of compliance with Title VI of the Civil Rights Act and other applicable civil rights and other Federal and State statutes. Thus, we are revising § 438.6(d)(4) to include this provision.

Comment: A commenter noted that the September 29, 1998 proposed rule provides that the contract must prohibit MCEs from discriminating in its enrollment process based on health status or need for health care. The commenter further noted that its State controls the enrollment process and requires the MCO to accept individuals who choose or are assigned the MCO. Thus, the MCO is incapable of discrimination. The commenter suggested that we require that States comply with this requirement without necessarily requiring language in MCO contracts.

Response: Section 438.6(d) implements sections 1903(m)(2)(A)(v) and 1905(t)(3)(D) of the Act, which prohibit discrimination on the basis of health status by an MCO or PCCM, not the State. We believe that this is because the Congress presumed that the State would engage in no such discrimination, since it would have no incentive to do so. Indeed, in the case of an MCO, PHP, or PCCM paid on a risk basis, it would be in the State's financial interests for beneficiaries with higher health care costs to be enrolled. To the extent a State does not permit an MCO to make enrollment decisions, this would ensure compliance with section 1903(m)(2)(A)(v) of the Act and § 438.6(d). We believe that requiring this provision in the contracts is the best approach to ensure that all MCOs, PHPs, and PCCMs consistently comply with this requirement.

Comment: One commenter contended that requiring MCOs, PHPs, and PCCMs to accept individuals eligible for enrollment in the order in which they apply without restriction contradicts the requirement in § 438.50(f)(2) that MCOs, PHPs, and PCCMs seek to preserve the established relationship that an individual has with his or her primary care provider.

Response: We do not believe that the enrollment requirement under § 438.6(d)(1) contradicts the continuity of patient and physician relationships, since it affects only the effective date of enrollments and not the extent to which provider relationships can be maintained once enrollment is effective. We also note that the requirement in § 438.6(d)(1) refers to individuals who "apply" for enrollment, while § 438.50(f)(2) applies in the context of "default" enrollments under a State plan mandatory enrollment program.

Additional Services Under MCO Contracts (Proposed § 438.6(d))

Proposed § 438.6(d) (recodified in this final rule at § 438.6(e)) provided that an MCE is permitted to cover services for enrollees that are not covered under the State plan for beneficiaries not enrolled.

Comment: One commenter noted that the discussion of the purpose of proposed § 438.6(d) in the preamble identifies the provision as applicable to MCO contracts, but the text of the September 29, 1998 proposed rule references MCE and not MCO. The commenter suggested that we change the reference from MCE to MCO. The commenter believes that this change would also have the effect of applying this provision to PHPs, which the commenter thought was appropriate.

Response: The commenter was correct that the text of the preamble to the September 29, 1998 proposed rule identifies this provision as applicable to MCOs and that the text of the section references MCEs. Typically, only an MCO (which by definition is paid on a risk basis) or a primary care case manager paid on a risk basis (which would make it a PHP) would offer additional services not covered under the State plan for nonenrollees. This is because these entities would typically use "savings" (a portion of the risk payment not needed to cover State plan services) to cover the additional services in question. This is why the preamble to the September 29, 1998 proposed rule spoke only of MCOs (which, as the commenter pointed out, would extend to PHPs as well). However, this provision of the regulations is based on the fact that under a voluntary enrollment situation, section 1915(a) of the Act permits contracts with an organization "which has agreed to provide care and services in addition to those offered under the State plan" only to individuals "who elect to obtain such care and services from such organization." Under section 1915(a) of the Act, States are deemed to be in compliance with statewideness and comparability requirements in this situation. There is nothing in section 1915(a) of the Act that limits this result to an MCO (or to MCOs and PHPs) or even requires the organization offering additional services to those who choose to enroll to be paid on a risk basis. In the case of mandatory enrollment under section 1932(a) of the Act, an exemption from Statewideness and comparability requirements permitting additional services for enrollees is similarly provided without regard to whether the entity is an MCO or a primary care case manager. Finally, there is nothing in section 1915(b) or section 1115(a) of the Act that would limit the applicability of the waivers of Statewideness and comparability provided for thereunder to MCOs and PHPs. For these reasons, even though it is unlikely that a nonrisk PHP or PCCM would offer additional services, we are clarifying the reference in what is now § 438.6(e) to apply to MCOs, PHPs, and PCCMs.

Comment: While several commenters recognized that the language in proposed § 438.6(d) exists in the current regulation, they believe that the current regulation has been subject to varied interpretation over the years. The commenters suggested that we clarify whether or not these additional services are included in the base used to determine the upper payment limit (UPL). In other words, if the MCO provides additional services, the commenters believe we should clarify whether or not the State is free to

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increase the capitation rates to reflect the costs of those services, even if the costs did not occur in FFS.

Response: Under the former UPL requirement, the costs of additional services would not have been included in the FFS base in computing the UPL. However, as indicated above, we are eliminating the UPL requirement and substituting a requirement that rates be actuarially sound, certified by an actuary to this effect, and developed in accordance with generally accepted actuarial principles upon the projected cost of services contained in the State plan. Section 438.6(c)(4) requires States to base their capitation rates *only* upon the costs of services covered under the State plan. Thus, even in the absence of the UPL requirement, capitation rates may not reflect the cost of these additional services.

Comment: One commenter wanted us to clarify what additional services could be offered under proposed § 438.6(d) and whether these services would be eligible for FFP.

Response: The additional services that can be offered may be optional services described in section 1905 of the Act or any other medically related services, that are not covered under the State plan. However, as noted in the previous response, the provision of the additional services authorized here is not to be recognized in the capitation rate paid to an MCO or in the FFP available to the State.

Comment: One commenter disagreed with the position that these additional services should not be subject to the statewideness and comparability requirements. This commenter believes that waiving these requirements could potentially lead to discrimination on the basis of health status or disability.

Response: Additional services have been provided by HMOs and PHPs under § 434.20(d) for many years prior to the enactment of the BBA, and we do not believe that this has led to enrollment discrimination. Further, the prohibition on enrollment discrimination in § 438.6(d) requires that MCOs, PHPs, or PCCMs accept individuals in the order in which they apply without restrictions, which will protect enrollees from discrimination on the basis of health status or disability.

Compliance With Contracting Rules (Proposed § 438.6(e))

Proposed § 438.6(e) (recodified in this final rule at § 438.6(f)) required contracts with MCOs and primary care case managers to comply with the requirements in § 438.6.

While we received no comments on this provision, the comment discussed above suggesting that the discrimination provision include language requiring compliance with civil rights laws has prompted us to include a general provision that contracts comply with all applicable State and Federal laws in what is now § 438.6(f). This provision merely recognizes obligations that already exist as a matter of law, and does not impose any new obligations or alter any existing ones. It essentially is a statement that HCFA expects contractors to comply with the law. The revised text now reads as follows:

(f) *Compliance with applicable statutes and contracting rules.* All contracts under this subpart must—

(1) Comply with all applicable State and Federal laws; and

(2) Meet all the requirements of this section.

Inspection and Audit of Records (Proposed § 438.6(f))

Proposed § 438.6(f) (codified in this final rule at § 438.6(g)) required risk contracts to include provisions allowing State and Federal inspection and audit of MCE and MCE subcontractors' financial records. We received no comments on this provision.

Physician Incentive Plan (Proposed § 438.6(g))

Proposed § 438.6(g) (codified in this final rule at § 438.6(h)) required that contracts provide for compliance with the rules governing physician incentive plans that apply to Medicare+Choice organization contracts. These rules require that stop loss protection be provided when a physician incentive plan puts a physician at "substantial financial risk" (defined in the June 29, 2000 Medicare+Choice regulations) for the costs of services he or she does not provide.

Comment: One commenter supported requiring Medicaid MCOs and nonexempt HIOs to comply with Physician Incentive Plan requirements.

Response: The requirement is maintained as set forth in the September 29, 1998 proposed rule.

Advance Directives (Proposed § 438.6(h))

Proposed § 438.6(h) (recodified in this final rule at § 438.6(i)) required that MCOs comply with the advance directive requirements in subpart I of part 489, provide oral and written information on advance directives, and reflect changes in State law within 90 days.

Comment: One commenter supported requiring MCOs and nonexempt HIOs to comply with advance directive requirements. Several commenters noted that the current advance directive requirement in § 434.28 does not include a requirement to provide adult enrollees with oral information on advance directives. They added that this requirement was not included in the BBA and that written information should suffice. They suggested that we revise proposed § 438.6(h)(2) to eliminate the requirement for oral information, which would permit MCOs to respond orally only to answer questions that arise. Another commenter recommended deleting the entire requirement as excessive and unwarranted, except upon request by enrollees. Another commenter noted that MCE Member Handbooks address advance directives but not in the detail now required and will require possible revisions and reissuance by MCEs.

Response: The commenter is correct that §§ 434.28 and 489.100 do not require MCOs to provide adult enrollees with oral information on advance directives policies. Section 434.28 notes that the requirement in § 489.100 includes provisions to *inform* and distribute written information to adult individuals concerning policies on advance directives. However, § 489.102 does not specify that individuals must be *informed* orally but describes the requirement to provide written information. Therefore, we agree with the commenters that oral information is not required, and we have revised the advanced directive requirement now codified at § 438.6(i)(2) to eliminate the requirement to provide oral information. Because section 1903(m)(1)(A) of the Act requires MCOs to provide information on advance directives to enrollees, we do not have the authority to delete the entire requirement. Since the advance directive policies did not change before the September 29, 1998 proposed regulation, we do not believe Member Handbooks would need revisions, unless they did not comply with § 434.28 before the September 29, 1998 proposed regulation.

Comment: Although proposed § 438.6(h)(2) provided that an MCO must include a description of applicable State law and proposed § 438.6(h)(3) specified that the information must reflect changes in the State law as soon as possible but no later than 90 days after the effective date of the change, several commenters believe that it was too administratively burdensome for MCOs to comply with these requirements and recommended that we remove them from the regulation.

Response: This provision is required by section 1903(m)(1)(A) of the Act, which extends the advance directives requirements of section 1902(w) of the Act to MCOs. As a statutory requirement, we do not have the authority to remove this requirement from the regulations.

Nonexempt Health Insuring Organizations (Proposed § 438.6(i))

Proposed § 438.6(i) (recodified in this final rule at § 438.6(j)) clarifies that HIOs that began operating on or after January 1, 1986, and are not exempted by statute, are subject to MCO requirements and may not enter into a comprehensive risk contract if they do not meet the definition of MCO. We received no comments on this provision.

Primary Care Case Management Contracts (Proposed § 438.6(j))

Proposed § 438.6(j) (recodified in this final rule at § 438.6(k)) implemented the requirements in section 1905(t)(3) of the Act that apply to "primary care case management contracts." Specifically, proposed § 438.6(j) required that these contracts (1) provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions; (2) restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation; (3) provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care; (4) prohibit discrimination in enrollment, disenrollment, and reenrollment based on the recipient's health status and need for health care services; and (5) provide that enrollees have the right to terminate enrollment.

Comment: One commenter contended that the primary care case manager contract standards in proposed § 438.6(j) were minimal at best. The commenter asked that patients have rights of access, coverage, information, and disclosure that are as strong as those that apply to MCOs and PHPs.

Another commenter noted the importance of the primary care case manager contract provision to rural beneficiaries because they are more likely to live greater distances from primary care case manager delivery sites. This commenter asked that we define "sufficiently" and "reasonable" as used in proposed § 436.8(j)(2) ("sufficiently near . . . to reach . . . within a reasonable time") and "sufficient" in proposed § 436.8(j)(3) ("sufficient number of physicians or other practitioners"). This commenter asked us to adopt a "lesser of 30 minutes rules" for rural areas with a defined exception for frontier areas approved by HCFA.

Another commenter believes that in the case of direct contracts with primary care providers, our regulations should take into account that these providers may have small group practices and not impose requirements on these providers that are more appropriate for large organizations. The commenter suggested that there should be a way to distinguish the small group provider from the larger group provider and that we should place fewer requirements on primary care case managers. Specifically, this commenter cited requirements such as specific driving or travel distance or 24-hour availability to services as not practicable for small providers and not always important to beneficiaries willing to travel long distances to be with a doctor they trust. The commenter also contended that recipients who have ongoing satisfactory relationships with personal doctors should be allowed to maintain those relationships and that most of the requirements for MCOs are not appropriate for medical group or individual doctors. The commenter believes that there have not been serious problems of quality and access with PCCM programs; and that the management component has proven cost efficient. The commenter is concerned that managed care has already driven out many small health care providers and that HCFA should ensure that further regulation does not drive out more small providers (who are essential to people with disabilities).

Response: As noted above, the contract requirements for primary care case managers in proposed § 438.6(j) largely mirror the language set forth in section 1905(t)(3) of the Act, which was added by section 4702 of the BBA. The BBA is clear in setting forth which contracting requirements should be placed on PCCMs, which should be placed on MCOs, and which apply to all MCOs and PCCMs. As we discussed in the preamble to the September 29, 1998 proposed rule at 63 FR 52026, PCCM contracts must include those requirements set forth in section 1905(t)(3) of the Act as well as any requirements in section 1932 of the Act that apply to MCEs. For example, a PCCM must meet the information requirements set forth in § 438.10 that apply to it. We also have applied access, coverage, and information requirements to primary care case managers when applicable. When the BBA specifies that requirements apply to MCOs, these requirements are not applicable to primary care contracts as long as the services are reimbursed on a fee-for-service basis based on State plan payment rates. (To the extent that a primary care case manager meets the definition of a PHP, however, it would also be subject, by regulation, to specified MCO requirements.)

The requirement in proposed § 438.6(j)(1) that primary care case manager contracts ensure 24-hour availability of information, referral, and treatment for emergency medical conditions simply reflects the requirement in section 1905(t)(3)(A) of the Act, and therefore cannot be revised. We note, however, that providers have flexibility as to how they meet this requirement. For example, providers can have an employee or an answering service or machine that immediately pages an on-call medical professional. This requirement is essential to allowing referrals to be made for nonemergency services, or information to be given about accessing services, or medical problems to be handled during nonoffice hours.

The requirement in proposed § 438.6(j)(2) that beneficiaries be able to access care within a reasonable time using affordable modes of transportation similarly reflects statutory language in section 1905(t)(3)(B) of the Act that cannot be changed. Again, however, States have the flexibility to determine their own standards to allow for differences based on the needs of the beneficiaries, provider availability, and the geographic uniqueness of the State. HCFA anticipates that State agencies will take responsibility for ensuring that these standards are met. One example, as noted in the preamble of the September 29, 1998 proposed rule, is the 30-minute travel time standard. Many States have adopted this standard and apply it to urban areas. Other State agencies have established 10-mile to 30-mile travel distance depending on the area. HCFA encourages States to develop their PCCM programs so that an enrollee residing in the services areas should not have to travel an unreasonable distance beyond what is customary under FFS arrangements. Due to enrollee-specific needs, types of providers needed to meet enrollee needs, availability of public transportation, etc. HCFA is not proposing a set of standards for each PCCM program.

We encourage States to, and States often do, make exceptions for beneficiaries who request to travel further than the time and distance standards set by the State. We also encourage States, to the extent practical,

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to allow beneficiaries who have ongoing successful relationships with providers to maintain those relationships. However, section 1905(t)(3) of the Act does not require this in the case of PCCM contracts.

Section 1905(t)(3) of the Act does not distinguish between small group providers and large group providers and applies its requirements to all primary care case manager contracts. We, therefore, do not have the authority to exempt smaller providers from requirements in section 1905(t)(3) of the Act that are reflected in what is now § 438.6(k), which therefore will remain as written in the September 29, 1998 proposed rule.

4. Provisions That Apply to PHPs (Proposed 438.8)

Proposed § 438.8 provided that specified requirements that apply to MCOs and MCO contracts apply to PHPs and PHP contracts. Specifically, under proposed paragraph (a), the requirements in proposed § 438.6 would apply with the exception of those that pertain to physician incentive plans, advance directives, and HIOs. Proposed paragraphs (b), (c), and (d) incorporated, respectively, the information requirements in proposed § 438.10, the provider discrimination requirement in proposed § 438.12, and the enrollee protections in proposed subpart C of part 438. Proposed paragraph (e) incorporated the quality assurance requirements in proposed subpart E of part 438 to the extent they are applicable to services furnished by the PHP. Proposed paragraph (f) incorporated the requirements in proposed subpart F of part 438 except for proposed § 438.424(b). And proposed paragraph (g) incorporated the enrollment and disenrollment requirements in paragraphs (e) through (h) of proposed § 438.56 and the conflict of interest safeguards in proposed § 438.58.

Physician Incentive/Advance Directives

Comment: Several commenters are concerned that HCFA has not included provisions relating to physician incentive plans and advance directives in its regulations of PHPs. These commenters believe that these two provisions are of vital importance to people with disabilities and chronic illnesses. They believe that to the extent that PHPs perform the same responsibilities as MCOs, they should be subject to the standards comparable to those applied to MCOs.

Some commenters focused on physician incentive plan requirements, agreeing with the above commenters that they should apply when PHPs transfer substantial financial risk to physicians or physician groups. If a State elects to carve out behavioral health, these commenters believe that the same financial arrangement between a PHP and that medical group should be subject to the physician incentive requirements.

The commenters believe that physician incentive plan requirements provide some measure of protection for beneficiaries who might otherwise be under-treated or not treated at all because they have expensive or on-going care needs. They noted that people with chronic and disabling medical or psychiatric disabilities are at high risk for receiving inadequate care because of the high costs often associated with meeting their needs. Moreover, some of the most noted media coverage of treatment cut backs and cut offs has occurred in behavioral health managed care settings when financial incentives are almost always an issue.

These commenters also suggested that enrollees of PHPs should have the same opportunities to execute advance directives prior to the need for this hospitalization, as should enrollees of behavioral health PHPs that cover and provide stabilization and other types of short-term, acute psychiatric interventions in nonhospital settings when psychiatric advance directives might be warranted. Our September 29, 1998 proposed regulations seem to undermine this movement and would likely make acceptance of advance directives by PHPs more difficult. They strongly urged HCFA to make the consumer protections regarding physician incentive plans and advance directives applicable to PHPs.

Another commenter noted that HCFA should give State agencies the discretion to apply advance directives requirements to PHPs. Depending on the nature of the services provided by the PHP, State agencies may believe that it is appropriate for the PHPs to meet the advance directive requirement.

Response: We agree with the commenter that PHPs should provide their enrollees with an opportunity to execute an advance directive to the extent that the PHP performs similar responsibilities as an MCO. So, for example, it may be appropriate for those PHPs that furnish institutional services to provide the opportunity for advance directive. However, there are many PHPs that do not furnish institutional services. Further there are some PHPs that furnish nonclinical services only, such as transportation services. We believe these types of PHPs should not be subject to the advance directive provisions. As a result, we are changing § 438.8(a) to read "(b) The requirement of § 438.6(h) except for—(1) PHPs that contract for nonclinical services, such as transportation services; and (2) when a State believed it is not appropriate for PHPs to meet the advance directive requirement, such as PHPs that only provide dental coverage."

With respect to physician incentive plan requirements, we also agree that these provisions represent significant beneficiary protections that should be extended to enrollees in PHPs that transfer substantial financial risk to physicians or physician groups. We have modified § 438.8(a) to reflect this change.

Comment: One commenter recommended that this section be carefully reviewed to ensure that it is clear about the requirements applicable to PHPs. The commenter apparently believes that requirements only apply to PHPs when the term MCO is used in the sections referenced in paragraphs (a) through (g). In a number of these sections, the commenter concluded from this belief that this would exempt PHPs from provisions that the commenter believes should apply. The commenter also believes that § 438.8 does not include references to sections that the commenter believes should be applicable. For example, § 438.802 is not included, although the commenter believes that paragraphs (a) and (c) should apply. The commenter suggested HCFA re-evaluate the use of this mechanism to identify PHP requirements and consider adding specific references to PHPs in each applicable section.

Response: Section 438.802, which discusses the conditions under which FFP is available to MCOs, is based on section 1903(m) of the Act, which does not apply to PHPs. This provision thus does not provide authority to disallow FFP in payments to PHPs. In order to avoid any confusion as to which provisions apply to PHPs, we have added specific references to PHPs in each applicable section. We are also keeping § 438.8, which identifies most of those provisions that apply to PHPs.

Inapplicability of Sanctions Provisions to PHPs

Comment: One commenter noted that the list of MCO provisions that apply to PHPs omitted the sanctions under subpart I. It is unclear whether this sanction authority applies to PHPs through other regulatory provisions. If not, the commenter recommended that HCFA amend the September 29, 1998 proposed rules to apply the subpart I sanction authority to PHPs.

Response: The proposed PHP regulations are based on the authority under section 1902(a)(4) of the Act to provide for methods of administration that are "found by the Secretary to be necessary for . . . proper and efficient administration." While we believe this provides authority to establish requirements that apply to PHPs, we do not believe that would provide authority to promulgate regulations that would authorize a State to impose civil money penalties or other sanctions that are provided for by the Congress only in the case of MCOs. However, States may cover PHP under their own State sanction laws, and we encourage States to do so whenever they believe it is necessary.

PHPs Regulated as MCOs

Comment: Several commenters were pleased that we, relying on our authority under section 1902(a)(4) of the Act, decided to require by regulation that PHPs comply with regulations implementing many consumer protections which the Congress applied to MCOs in the BBA. One commenter believes that it would be a terrible irony for those with these specialized and significant health care needs to be relegated to having fewer rights than other Medicaid recipients. These commenters believe that PHP enrollees should be entitled to the same protections as MCO enrollees since PHPs perform the same responsibilities as MCOs and have similar financial incentives through risk contracts with States.

Several other commenters, however, believe that the BBA did not give the statutory authority in effect to extend statutory MCO requirements by regulation to PHPs. They were concerned that this would be a strong deterrent for some plans and providers who may want to participate but would see meeting the requirements of BBA as too burdensome. The commenters noted that it may be difficult for behavioral health PHPs and dental health PHPs to meet some of the BBA regulatory requirements. These commenters believed that this would create an undue administrative burden on both the State agency and capitated behavioral health providers. The commenters requested that HCFA carefully consider the administrative costs associated with the application of the MCO requirements to risk-bearing providers that provide limited Medicaid services. Particular areas of concern for PHPs included meeting some of the licensing and certification requirements, information requirements, and State plan and contract requirements. Other commenters noted that the enrollment and disenrollment requirements are simply not suitable for capitated behavioral health providers. They believe that this requirement would result in higher cost and less choice because of the negative impact it will have on subcontractors' participation. One commenter suggested that PHPs should not be covered by provisions of the September 29, 1998 proposed rule.

Response: The BBA and the legislative history of the Medicaid managed care provisions in the BBA are silent on the question of how PHPs are to be treated. The BBA did not change the fact that managed care entities regulated as PHPs are only subject to regulatory requirements that we may publish. We agree with the commenter that the BBA does not itself provide us with authority to regulate PHPs, and we are not relying on the BBA as authority for these regulations. Rather, as noted above, we are relying on our authority under section 1902(a)(4) of the Act to establish requirements found by the Secretary to be "necessary" for "proper and efficient administration." This has been the basis of PHP regulations from the beginning. The existing PHP regulations in part 434 similarly extended to PHPs by regulation requirements in section 1903(m) of the Act that otherwise only applied to comprehensive risk contractors. For example, under § 434.26(a), both PHPs and HMOs were required to limit their Medicare and Medicaid enrollment to 75 percent of total enrollment. It is true that under § 434.26(b)(4), this requirement could be waived for "good cause" in the case of PHPs. Nonetheless, there is longstanding precedent for applying selected requirements in section 1903(m) of the Act by regulation to PHPs. Other longstanding PHP requirements imposed by regulation under the authority in section 1902(a)(4) of the Act include requirements in § 434.27 related to termination of enrollment (for example, a prohibition on termination because of an adverse change in an enrollee's health status), the choice of health professional requirement in § 434.29, requirements in § 434.30 related to emergency medical services, the requirement under § 434.32 that the contract provide for a State-approved grievance procedure, the requirement in § 434.34 that the contract provide for an internal quality assurance system meeting specified standards, and the marketing requirements in § 434.36. We are extending similar requirements in the State responsibilities contained in subpart B of this regulation to PHPs.

All of these requirements were imposed through the same notice and comment rulemaking process being used in this final rule. The only difference between existing requirements and the requirements imposed under this final rule is a matter of degree, not the nature of the requirements in question. We have determined that the BBA contains important beneficiary protections that should be extended by regulation to most PHPs.

It should be noted that not all MCO requirements are being imposed on PHPs and that some PHPs are not required to meet certain specified requirements. For example, as just noted above, we have declined to require that the provisions for sanctions in subpart I be applied to PHPs. Also, some PHPs do not provide the complete set of inpatient hospital services as this term is used in section 1903(m)(2)(A) of the Act, and the exception to the State solvency standards requirement in § 438.116(c)(1) would apply.

Solvency Standards (Proposed § 438.8(d))

Among the beneficiary protections in proposed subpart C that are applied to PHPs under proposed § 438.6(d) are solvency standards in proposed § 438.116. We received several comments on this requirement.

Comment: Several commenters noted that some PHPs would have problems meeting these solvency requirements because not all PHPs, particularly those providing behavioral health services, would fall under one of the exemptions in proposed § 438.116(c). One of the commenters believes it was unclear what a State would have to do to certify a PHP for solvency. The commenter noted that States often use different methodologies than those used for MCOs to determine the solvency standards for PHPs and suggested that States be given more flexibility in this area to set their own PHP solvency standards. Another commenter noted that the solvency requirement is totally inappropriate to PHPs, especially when they serve as subcontractors to an MCO.

Response: Section 438.116(b) requires an MCO, and by operation of § 438.8(d), a PHP, to meet the solvency standards established by the State for private HMOs or to be licensed or certified by the State as a risk-bearing entity. However, § 438.116(c) provides for several possible exceptions to the State solvency standards requirement. If the PHP does not provide the complete set of inpatient hospital services under

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section 1903(m)(2)(A) of the Act, the exception to the State solvency standards requirement in § 438.116(c)(1) would apply. Therefore, the exception in § 438.116(c) would normally apply to behavioral health type PHPs. Even though a PHP may be exempt from the solvency standards in § 438.116(b), it still must meet the basic requirements in § 438.116(a), which requires each PHP to provide assurances satisfactory to the State showing that it has adequate provisions against the risk of insolvency to ensure that its Medicaid enrollees will not be liable for the MCO's debts if it becomes insolvent.

5. Information Requirements (Proposed §§ 438.10 and 438.318)

Proposed § 438.10 set forth requirements that apply to States, MCEs or enrollment brokers concerning the provision of information to enrollees and potential enrollees. Paragraph (a) set forth the basic rule that these entities must comply with applicable requirements. Paragraph (b) set forth requirements relating to language and oral interpretation services. Paragraph (c) set forth requirements regarding the format of materials. Paragraph (d) specified to whom information must be provided and when it must be provided. Paragraph (e) specified the information that must be provided, including information on the amount duration and scope of benefits, procedures for obtaining services, names and locations of providers (and which are accepting new patients), any restrictions on freedom of choice, the extent to which out of network providers can be used and after-hours and emergency coverage are provided, policies on referrals for specialty care, cost sharing, the rights and responsibilities of enrollees, and information on complaints, grievances and fair hearings. Paragraph (f) specifies additional information that must be made available upon request. Paragraph (g) required that services not provided under the contract be identified. Paragraph (h) specified information that primary care case managers are required to provide. And paragraph (i) set forth additional information requirements that apply in the case of a mandatory enrollment program under the authority in section 1932(a)(1)(A) of the Act. Proposed § 438.318 (recodified at § 438.218 in this final rule) required that, as a part of the State's "quality strategy," the requirements in proposed § 438.10 must be satisfied, and that contracts must specify that certain information specified in § 438.318(b)(2) be provided.

Comment: Many commenters remarked that proposed § 438.318, "Enrollee information," is redundant with § 438.10 because both require elements of information that a State, MCE, MCO, or PCCM must provide to enrollees and potential enrollees. Commenters recommended combining these sections with a clear distinction between who must provide information. In addition, several commenters also believed that there should be no distinction between mandatory managed care and nonmandatory managed care with respect to information requirements and that requirements should be applicable to both. Further, commenters believe that the regulation exacerbated a problem that exists to some extent in the statute since some requirements apply to MCOs, some to MCEs, and some to States.

Response: Proposed §§ 438.10 and 438.318 have been combined in response to the commenters' concerns; however, the requirements remain essentially the same, since these requirements reflect statutory requirements set forth in section 1932(a)(5) of the Act. Specifically, as the distinction is made in statute, the requirements distinguish between the information that must be provided by MCOs, PHPs, and primary care case managers. There is a further distinction in the statute for mandatory managed care systems under section 1932 of the Act. In specifying in the proposed regulations who had to provide information, States were afforded the maximum flexibility possible since some States have prohibitions regarding distribution of information by MCOs, while some States require MCOs or enrollment brokers to distribute information. Although the specific requirements are now part of § 438.10, in the quality requirements now codified in subpart D, § 438.218 requires that § 438.10 constitute part of the State's quality strategy.

Comment: A commenter indicated that the term "potential enrollee" needed to be defined because it was unclear if it meant eligible for Medicaid or eligible for enrollment in a managed care plan.

Response: The term "potential enrollee" in this section refers to an individual that has been found eligible for Medicaid and is either required to, or permitted to, join an MCO, PHP, or PCCM. We believe this is clarified with the revised format; therefore, we will not be adding a definition to the regulations text.

Comment: Commenters indicated that the language and format requirements should also apply to member newsletters, health risk appraisal surveys, and health education and preventive care information.

Response: Section 438.10(a)(4) (codified at § 438.10(a)(2) in the September 29, 1998 proposed rule) expressly provides that the provisions of paragraphs (b) (language) and (c) (format) apply to all information furnished to enrollees and potential enrollees, such as enrollment notices, informational, and instructional materials *and* the information specified within the section. HCFA believes that this addresses the commenter's concerns, since the language and format provisions apply to all information furnished to enrollees and potential enrollees, and not just those specified in the § 438.10 itself.

Comment: Many commenters wanted HCFA to require in the regulation that all information and instructional materials (including charts and upon request information) be designated public records and be available to the public.

Response: Assuming that the material the commenters referenced is general information and not specific to an enrollee or potential enrollee, we believe that the information specified in § 438.10 is generally publicly available and therefore may be obtained from the State by following State procedures if the State is in possession of the information. If we are in possession of the information, the information can also be obtained from us under the Freedom of Information Act. We note that States may have procedures to follow for obtaining information.

Comment: A commenter recommended that HCFA encourage States to develop other mediums of notification about managed care options such as public service announcements on radio or TV, posting information on the Internet, and billboards.

Response: While we are not mandating how a State makes individuals aware of their health benefit options, § 438.10 requires that States undertake the activities necessary to fully educate and inform enrollees and potential enrollees about their health care options and how to access benefits.

Comment: Commenters believe that all information provided to enrollees by the State, MCE, or enrollment broker should be developed in consultation with consumers and stakeholder groups.

Response: Although we encourage States to work with consumer and stakeholder groups in the development of material, we do not believe it is necessary to mandate this as part of §§ 438.10 or 438.218. However, many of the elements listed within § 438.10 would be considered marketing material and would therefore have to be reviewed in accordance with the marketing standards at § 438.104, which require consultation with the Medical Care Advisory Committee (MCAC) established under § 431.12 or a similar entity. The MCAC's or similar entity's membership is required by regulation to include consumer membership. Further, under § 438.218, information standards are part of the overall quality strategy at § 438.304, which includes requirements regarding consumer involvement.

Language Requirements (Proposed § 438.10(b)

Comment: Several commenters found the requirement to make information available in the languages that predominate throughout the State to be problematic; however, commenters offered differing opinions on what they wanted to see in the regulation. Many supported our decision not to include a specific percentage threshold for a language to be considered prevalent in a geographic area but remained concerned that the preamble language referenced a 5 percent figure and that HCFA's Medicaid Managed Care Marketing Guidelines include a 10 percent figure. One commenter suggested that it was too costly for MCOs to meet the costs of printing and distributing materials in other languages at the 5 percent threshold. Another commenter believes that the requirements for language and format were overly prescriptive in light of the absence of any evidence that information is not being given to enrollees in an understandable format. Commenters pointed out that these additional administrative costs are funded out of the same dollar that supports the delivery of care.

In contrast, we also heard from many commenters who understood the need for balance between State flexibility and beneficiary protections but believe that HCFA favored State flexibility too much. Commenters stated that only offering guidance in this area was insufficient. They contended that States should be afforded flexibility in developing methods to provide linguistically and culturally competent services but not in determining whether there is a need for these services in a particular State or service area. Commenters requested that the regulation itself include specifics like those discussed in the preamble. Numerous commenters recommended using a prevalent language threshold as a numerical value rather than a percentage. Several commenters recommended that HCFA adopt the standard employed in California, which calls for translation of written material when there are 3,000 Medicaid beneficiaries in an MCO's service area who have limited English proficiency, or 1,000 such Medicaid beneficiaries residing in one zip code, or 1,500 such beneficiaries in two adjacent zip codes. Some commenters noted that even if an individual was not a member of a prevalent language group, he or she had to have access to information.

Response: We believe that the language and format requirements are essential elements for ensuring that enrollees and potential enrollees receive the information necessary to make an informed choice and access benefits. While we believe they are essential elements, we also continues to believe that the best methodology for determining the prevalent language spoken by a population in a geographic area may differ from State to State and therefore we will not be modifying the regulation to mandate a specific methodology. Further, as we are leaving this methodology for States to determine, the 5 percent rate provided in the preamble should be viewed only as an example and not as a standard. The 10 percent figure in the "Medicaid Managed Care Marketing Guidelines," which also contain suggested guidelines and not mandates, may also be acceptable if it meets the needs of the State. We note, however, that a number of commenters believe that a numeric threshold rather than a percentage was more appropriate because of variations in population density. The commenters believe that percentage thresholds would result in empirically low threshold numbers in low density population areas and unacceptably high threshold numbers in high density populations. We find merit in this argument, which we believe further supports our decision to permit the State to determine the best methodology for its situation. We do note the commenters' suggestions as another example for making this determination. We also note that the HHS Office of Civil Rights (OCR) has issued policy guidance on meeting the language needs of recipients of public funds. (See "Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency," 65 FR 52762, August 30, 2000.) This guidance gives further examples and guidance on meeting individuals' language needs. Lastly, we agree with the commenter that oral interpretation services must be available free of charge to each potential enrollee and enrollee even if he or she is not a member of a prevalent language group.

Comment: A commenter noted that the oral interpretation requirements in proposed § 438.10(b) apply to MCEs and interpreted this to mean that it would not apply to PHPs. The commenter apparently interpreted § 438.8 to incorporate only requirements for which MCOs are mentioned by name. Under this interpretation of § 438.8, requirements that apply to MCEs (such as the language requirements in § 438.10(b)) would not be incorporated for PHPs. The commenter believes that the language requirements in § 438.10(b) should apply to PHPs.

Response: As noted above, § 438.8 subjects PHPs and PHP contracts to the requirements in paragraphs (a) through (g) that apply to MCOs and MCO contracts. Therefore, since the requirements in § 438.10 are specified in § 438.8(b), these requirements apply to PHPs.

Comment: In addition to requiring that States develop a methodology for determining the prevalence of beneficiaries needing language assistance, some commenters wanted HCFA to recommend a methodology for States to use in determining the prevalence of disabilities in the enrollee population.

Response: While we understand that it may be useful to know the percentage of individuals that may have a disability, we note that the State and MCOs and PHPs must meet the needs of *all* potential enrollees and enrollees and are specifically required under the Americans with Disabilities Act to accommodate the special needs of disabled individuals. We also note that there is a requirement in § 438.206(d) (codified in § 438.306(d) in the September 29, 1998 proposed rule) that States ensure that MCOs maintain a network that is sufficient to provide adequate access, taking into consideration the anticipated enrollment, with "attention to pregnant women, children, persons with complex and serious medical conditions and persons with special health care needs," as well as "the expected utilization of services, considering enrollee characteristics and health care needs." We therefore do not believe that an additional requirement is warranted; however, the State is free to implement such a requirement.

Comment: A commenter recommended that in addition to making oral interpretation services available, HCFA should mandate States to require professional training of interpreters, appropriate accreditation, and appropriate confidential

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interpretation services. In addition, the commenter recommended the elimination of family members as translators because of confidentiality issues and sufficient reimbursement for translation services, as well as interpretation services. A commenter further indicated that the State should adjust the capitation rate to reflect reimbursement of interpretation services if the MCO is expected to provide the services.

Response: We believe that it is appropriate and necessary to require that interpretation and translation services be available for all potential enrollees and enrollees and have added this requirement to the regulations text. We also believe that the States should be afforded the flexibility to determine how these translation services are provided and paid for (except that beneficiaries cannot be charged for these services). The Office of Civil Rights has issued policy guidance on the training and use of translators, which may be helpful to States in determining how to meet this requirement.

Format Requirements (Proposed § 438.10(c)(2))

Comment: A commenter noted that proposed § 438.10(c)(2) required that informational material take into consideration people with special needs such as the visually impaired or those with limited reading proficiency. The commenter suggested adding language that specifically states that material in alternative formats will be provided to an enrollee *only upon request.*

Response: While we do not expect a State and MCO, PHP, or PCCM to provide information in alternative formats to all potential enrollees and enrollees, regardless of whether or not they have a special need, we do expect the State and MCO, PHP, or PCCM to provide the information when requested and to fully inform potential enrollees and enrollees about the availability of the information. We have modified § 438.10(c) to provide in § 438.10(c)(1)(ii) that information only need be "available" in alternative formats that take into account enrollees with special needs and to make clear in revised § 438.10(c)(2) that enrollees will be informed "on how to obtain information in the appropriate format."

Comment: Several commenters were pleased with language in the preamble to the September 29, 1998 proposed rule discussing what constitutes accessible information for people with disabilities and/or limited reading proficiency but believe that this language should be placed in the regulations text. For example, these commenters favored including references in the regulations to 14-point type, a fourth or fifth grade reading level, and the use of focus groups to test cognitive understanding. One commenter suggested that a failure to do so would be a violation of the Americans With Disabilities Act.

Response: Because there is not one commonly accepted standard for providing formats for beneficiaries with special needs, and in light of variances in enrolled population across States, we believe that a State is in the best position to determine the best formats for information. Allowing States to determine the format for information is consistent with the Americans With Disabilities Act, because States have a requirement under § 438.10(c)(1)(i) to present the information in easily understood language and format, and under § 438.6(c)(1)(ii) to take into consideration the special needs of enrollees. Therefore, States are required to meet the information needs of all enrollees; however, we are allowing the States flexibility in determining how they will meet these needs. Additionally, States are required to comply with the Americans with Disabilities Act without regard to the provisions of this regulation

Comment: A commenter objected that the prescriptive nature of the preamble language requiring information to be written at a fourth or fifth grade level could be problematic when providing information on the amount, duration, and scope of benefits.

Response: We do not agree that the preamble language is too prescriptive. While we have recommended that information be provided at a fourth or fifth grade level, the regulation currently affords the flexibility for States to set their own reading level standards, based on the needs of their population.

Comment: Commenters recommended that the requirement in proposed § 438.10(c)(2) that special needs of the visually impaired be taken into account also be applied to persons with hearing impairments and persons with cognitive impairments.

Response: Section 438.10(c)(1)(ii) of this final rule requires that materials take "into consideration the special needs of those who, *for example,* are visually impaired or who have limited reading proficiency." (Emphasis added.) Thus, this list is not intended to be exhaustive, and the special needs listed are just two examples. Individuals with hearing impairments and cognitive impairments would also be considered individuals with special needs that must be considered in material development. We do not believe that it would be possible to have an exhaustive list of special needs as the enrolled populations and needs of enrollees vary by State. In addition, the individuals with special needs vary depending on the circumstance for providing information. For example, an individual with a hearing impairment would not need custom material for mailings but would for educational presentations. We do expect a State and an MCO, PHP, or PCCM to take into consideration the needs of all potential enrollees and enrollees in their State and MCO, respectively.

Comment: A commenter indicated that communications to homeless persons regarding Medicaid Managed Care benefits must take into account a high level of transience, illiteracy, and cognitive impairment in this group.

Response: As stated above, the requirement to take into consideration special needs of individuals applies to all individuals with special needs including people who are homeless.

Comment: Commenters indicated that the regulation should recognize that effective communication may not only require accessible formats but also requires the need for staff training in the managed care plan, health care provider's office, and the Medicaid agency to effectively interact with persons with disabilities, including hearing impairments and cognitive learning problems. Commenters further indicated that to be effective, face-to-face interactions may be required.

Response: We agree with the commenter that effective communication may require more than printed material and have revised the language at § 438.10(c)(1)(ii) to also require that material is provided in an "appropriate manner' that takes into consideration the special needs of individuals. We have also added a requirement in § 438.10(c)(5) that the State and MCO have mechanisms in place to assist potential enrollees and enrollees with understanding the managed care program and their benefits.

Comment: A commenter believes that the regulations lack the detail needed to assure that States and MCE's understand their obligation to ensure culturally and linguistically appropriate benefits for Medicaid beneficiaries at all levels of the health care delivery system.

Response: We do not agree with the commenter because there are various sections of the regulation that address cultural issues and impose obligations on States to take these issues into account, including the requirements in § 438.10 discussed in this section and requirements in § 438.206 (codified at § 438.306 in the September 29, 1998

proposed rule) discussed below. While we have not provided detailed "specifications" in all cases as to *how* States fulfill these obligations, since we believe States should be provided some flexibility in this area, States will be responsible for accomplishing the commenter's desired results, regardless of what methods they use to achieve them.

We have required that oral interpretation services and translation be provided free of charge to beneficiaries and that information on primary care providers include languages spoken.

Comment: Some commenters advocated that all information should be reviewed and approved by the State if not distributed by the State.

Response: Many of the elements listed in § 438.10 are considered marketing material and must therefore be reviewed in accordance with the marketing standards at § 438.104. Paragraph (b)(2) of § 438.104 specifies that each MCO, PHP, or PCCM contract must provide that the entity does not distribute any marketing materials without first obtaining State approval. Further, those that might not be considered marketing materials, such as appointment notices, etc. still must meet the information standards in § 438.10, including understandability.

When Information Must Be Provided (Proposed § 410(d) and (f)).

Comment: Several commenters sought clarification of when complete benefit information was required to be provided to beneficiaries. One commenter recommended that the "once a year" requirement of § 438.10(d)(2) be changed to "at least once a year" to make it clear that this information need not be provided at a specific anniversary time but rather may be included with other information in the normal course of business during the year.

Response: We agree with the commenter that greater flexibility is needed, and we therefore have provided in a recodified § 438.10(e)(1)(ii) that after the initial provision of information to new enrollees, any significant change in this information must be provided 30 days prior to the effective date of the change. We have also added a requirement in a new § 438.10(f)(4) that all of the information that is "provided" pursuant to new paragraphs (d) and (e) (proposed § 438.10(e)) also be available "upon request" at any time.

Comment: One commenter expressed concern that the proposed requirement for primary care case managers to provide additional information "before" or "during" enrollment is confusing as "before" or "during" can refer to two separate time frames. The commenter recommended that the primary care case manager, or State on behalf of the primary care case manager, be required to provide information "on" enrollment.

Response: We agree with the commenter that further clarification is necessary. The regulation has been modified to reflect the same time frames as those required of MCOs, or the State on behalf of the MCO.

Comment: A commenter believes that in addition to annual notification, there should be notification "as soon as changes occur" in any of the provisions listed in proposed § 438.10(e) (now in §§ 438.10(d)(2) and (e)(2)).

Response: We agree with the commenter that enrollees should be notified if there is a significant change within the program and have modified the regulations in response to this comment. In the new § 438.10(e)(1)(ii), we are requiring that when there is a significant change (as defined by the State) in the information provided under § 438.10(e)(2), a revised version of the information in paragraph (e)(2) must be provided at least 30 days prior to the effective date of the change. We believe the State is best suited to define what is considered to be a significant change.

Comment: Commenters wanted us to further define when the MCO (or the State) must provide information to enrollees. One commenter suggested that the provision be modified to state that the information should be given within "a reasonable time after the MCO receives the notice of the recipient's enrollment *or* the effective date of the enrollment, whichever is later." Another commenter suggested 7 days after enrollment.

Response: The regulation requires that the information be provided within a "reasonable time after it receives, from the State or the enrollment broker, notice of the recipient's enrollment." We believe that the State is in the best position to define this specific time requirement for providing information.

Comment: Commenters indicated that the dissemination of information is very costly. Additionally, commenters believe that the States were in the best position to provide comparative information. The preference of these commenters was that the State agency assume the administrative responsibility for providing information.

Response: We believe we have provided States with significant flexibility, given the detailed statutory requirements in section 1932(a)(5) of the Act. We agree with the commenter that States should assume responsibility, within the constraints of the requirements in section 1932(a)(5) of the Act, and specifically that States should have the flexibility to decide whether they or MCOs provide comparative information.

Comment: A commenter suggested that the regulations should require States to have a mechanism for notifying their enrollees of their right to request and obtain basic information.

Response: Section 438.10(e)(1)(i) requires that States ensure that enrollees are provided the information at least once a year, rather than just be notified as in the proposed rule.

Comment: A commenter recommended that MCOs provide information directly to enrolled adolescents.

Response: While it is probable that adolescents would receive information directly when enrollment is not linked by family unit, in the case of a family unit we believe that sending one copy of information to each household is sufficient and would constitute providing the information to all "enrollees" in that household, provided alternative formats are not necessary for special need reasons. The cost of requiring MCOs to mail directly to multiple family members could be prohibitive. However, this regulation does not prohibit States from imposing this requirement.

Comment: A commenter urged that HCFA ensure that individuals not have to go great lengths to obtain information and that a general request for information should trigger the provision of full information.

Response: We agree with the commenter. Section 438.10(f) includes a requirement that all elements of information be available "upon request." We expect that States and MCOs will not make the process of obtaining information difficult and will provide comprehensive information if any information is requested, since it is in the best interest of all parties that the individuals be as knowledgeable as possible about their health care options, rights, and responsibilities.

Required Information (Proposed § 438.10(e))

Comment: Some commenters argued that proposed §§ 438.10 and 438.318 would impose information requirements upon States or their contracted representatives that go far beyond what is required in statute. Specifically, these commenters pointed out that the statute requires that information on the identity and location of health care providers need only be provided "upon the request" of enrollees or potential enrollees, rather than that it be

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"provided" as specified in proposed § 438.10(e)(3). However, there were also a number of commenters who applauded HCFA for requiring that information be "provided" and suggested that the provision of additional information on the nature of managed care arrangements would also be appropriate.

Response: Section 1932(a)(5) of the Act spells out information that must be available to all enrollees and potential enrollees. The statute, however, only requires that this information be available "upon request." We believe that the information listed is so basic and fundamental to an enrollee's ability to access services and exercise rights that it is "necessary for * * * proper and efficient operation" for this information to be in the hands of all enrollees. For example, an enrollee needs to know about the network of providers in order to access care and about appeal rights to exercise these rights. Therefore, pursuant to our authority under section 1902(a)(4) of the Act to specify what is "necessary for * * * proper and efficient operation," we have required that information such as the names, locations, and telephone numbers of the MCO's network of providers be provided to beneficiaries. We have developed these requirements in keeping with what we believe to be the Congress' general intent that potential enrollees and actual enrollees have this important information. Also, in response to the latter comments that specifically called for information to be given to enrollees on a variety of characteristic features of managed care (for example, prior authorization of services and provider networks), we have added a new type of required information to include "Description of basic features of managed care" and "MCO responsibilities for coordination of enrollee care." We have also required the States and MCOs to have in-place mechanisms to assist potential enrollees and enrollees in understanding the managed care system and their benefits. In the BBA-mandated report to the Congress on safeguards for individuals with special health care needs who are enrolled in Medicaid managed care, we noted the extensive evidence that exists on Medicaid, Medicare, and commercial MCO enrollees that demonstrates their lack of knowledge of the characteristic features of managed care and the implications of their enrollment in an MCO. Similarly, evidence exists that there is widespread confusion about MCO responsibilities for care coordination. The nature of comments received support these additional requirements.

Comment: Commenters believe that the elements of information that the MCO (or State) must provide are often elements that are currently included in the member handbook that is supplied by the MCO or by an enrollment broker. A commenter expressed concern that too much information could be overwhelming, causing people to ignore all of it.

Response: We agree with the commenter that the information that must be provided under the September 29, 1998 proposed regulation generally is already provided to enrollees as a common practice. To the extent this is the case, these existing practices could satisfy the requirements in § 438.10(e) with respect to enrollees. It is not our intent that this information be duplicative of what is currently provided. Section 438.10 allows States to continue their current practice of including information as part of an enrollee handbook or requiring that the MCO or (in the case of potential enrollees) that an enrollment broker provide the information. Therefore, HCFA does not believe that the regulation is duplicative or burdensome. We have modified the regulation to specify in § 438.10(d)(1) that the "State, or its contracted representative" may provide the information in § 438.10(d)(2) to potential enrollees. Because this information is generally currently provided, we also do not believe that the requirements in § 438.10 would result in "information overload."

Comment: Commenters suggested that information on service authorization requirements and provision of transportation to services should be included as elements of the basic information about procedures for obtaining benefits.

Response: Section 438.10(e)(2)(iii) expressly requires that information containing the procedures for obtaining benefits be provided, including any authorization requirements. This should include information on transportation to the extent this is necessary to obtain benefits.

Provider Directories/Provider Information (Proposed § 438.10(e)(3).

Comment: Some commenters believe that information on specialists should only be provided upon request due to the volume of information. These commenters supported this recommendation. They believe that if enrollees are provided with information on specialists, the enrollees may believe that they do not need a referral for speciality care. These commenters believe that this information should only be provided upon request and that it is best provided with the assistance by someone over the phone that has access to timely data. In contrast, we received a number of comments from individuals applauding us for requiring that information on specialists be included in the information, citing that a significant number of Medicaid beneficiaries have special needs and are more reliant on the specialists than the primary care physicians.

Response: Although we acknowledge that including information on specialists adds to the volume of information and further complicates the process of keeping information current, we do believe that a significant number of enrollees rely on this information and therefore continue to believe that, at a minimum, information on provider networks should include information on primary care physicians, specialists, and hospitals, as stated in the preamble to the September 29, 1998 proposed rule. To clarify this point, we have included this preamble reference to specialists in the regulations text at § 438.10(e)(3)(iv).

Comment: A commenter recommended that homeless enrollees receive information about which providers in the network in which they are enrolled have demonstrated competency in meeting their complex health and social needs. Similarly, commenters indicated that information should be available about (1) the ability of providers to treat adolescents and individuals with HIV; (2) the providers' language proficiency; and (3) the accessibility of providers for individuals with disabilities. One commenter suggested that this be required as part of the additional information on education and board certification status of health professionals.

Response: We believe that this type of information should be maintained by the State, MCO, PHP, or PCCM, or enrollment broker (as appropriate) and be available upon request in order to assist individuals when they have a question about a particular service, provider, or location. We have added a requirement in new § 438.10(f)(3) to specify that enrollees, and potential enrollees, are able to obtain any other information on requirements for accessing services or other factors necessary (such as physical accessibility) that may be needed to effectively access benefits.

Comment: Many commenters expressed the view that the requirement to include identification of those network providers who are not accepting new patients is difficult to keep timely and may be out of date by the time it is printed. In contrast, we also received comments from individuals indicating that this information is critical if a beneficiary is expected to make an informed choice.

Response: We acknowledge that this information is time sensitive; however, it is our belief that beneficiaries need this information to make an informed selection. Therefore, we encourage States and their contractors to highlight to potential enrollees and enrollees that it is important to verify through a phone call, or other means, that the information is still current. We also expect that States and their contractors will provide updates to provider directories within a reasonable time frame, although the exact time is left to the State to determine.

Comment: Several commenters strongly recommended that HCFA require, and not simply suggest, that information on ancillary care provider options be provided. Additionally, commenters wanted information provided on Federal or State community health centers, dialysis centers, and mental health and substance abuse treatment centers (in addition to primary care physicians, specialists, and hospitals).

Response: As the enrolled population, and therefore the health needs of the enrollees, varies from State to State, we believe that the State is in the best position to determine what information needs to be included on ancillary care providers (including those listed by the commenters) in order to meet the needs of their respective beneficiaries. We do expect that this information will be available in all cases and that enrollees and potential enrollees will be notified about availability of additional information upon request.

Comment: A commenter recommended that the requirement for "name and location" of network providers be expanded to require the State to provide the name of the clinic or facility, as well as that of the provider, because many patients relate to the clinic and not the provider's name.

Response: While we acknowledge the commenter's point that an individual may be more familiar with a clinic name than a provider name, this is not always the case. We believe that the State or the MCO, PHP, or PCCM is in the best position to know the level of detail regarding site identification that should be included in the information a potential enrollee and enrollee receives.

Comment: A commenter stated that information regarding the education and board certification (and recertification) status of the health care professionals staffing the emergency departments in the enrollee's geographic region should also be provided. They further believe that this additional information should be provided, and not simply made available upon request, because of the need for quick decisions in emergency situations.

Response: Since emergency room physicians are considered health care professionals, *in a situation in which there is a direct contractual relationship* with emergency room physicians, they would be included in the provision at § 438.10(f)(2) that requires information be provided that includes the education and board certification and recertification of health professionals. While it is our belief that some beneficiaries may be interested in receiving these elements, and should be able to obtain them, they are not elements of information that every beneficiary typically uses in selecting a provider. In most cases, in an emergency situation in which time is of the essence, an enrollee would not be "shopping" for the best emergency room doctor but would go to the nearest emergency room. Therefore, while the information must be available "upon request," we have not changed the regulation to require that this information be "provided." Further, we note that if there are not direct contractual relationships with the emergency room physicians, as often is the case, there would be no way for an MCO or State to know this information, and therefore the enrollee or potential enrollee could not obtain the information from the MCO or State.

Comment: A commenter was concerned that HCFA was silent on how frequently the provider directory needs to be updated. The commenter recommended that we convey that the intent is not to mandate that the printed directory be updated more often than periodically, although the commenter expressed that we should expect that current information be available through the MCO and through other sources.

Response: We agree with the commenter's clarification regarding the frequency of printing provider directories, but do not believe that a regulation change is necessary. Specifically, we expect the provider directories to be updated periodically, as defined by the State, but also expect that current information always be available to the enrollee or potential enrollee through the State, MCO, PHP, or PCCM, or State contracted representative.

Comment: Several commenters strongly urged HCFA not to permit the use of "subnetworks" by MCOs. They believe it would be unfair to consumers to join an MCO and then discover that they could not access all providers because they had been assigned to a subnetwork. In addition, commenters recommended that HCFA require that plans clearly indicate if a network listing does not include all clinics and providers located at the facility.

Response: While we are not in a position to dictate permissible contracting entities for MCOs, we do require under § 438.10(e)(2)(iii) that if there are restrictions within a network, the beneficiary be informed of these restrictions as part of the information that they receive.

Information on Benefits

Comment: A commenter recommended that information also should be provided on which populations are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily. Commenters specifically cited the Native American population.

Response: We revised the regulations to include a requirement in § 438.10(d)(2)(i)(B)(vi) that requires State to provide information on which enrollees are excluded from eligibility to enroll, are subject to mandatory enrollment, or may enroll voluntarily.

Comment: Several commenters recommended that information be made available on drug formularies.

Response: As a requirement of § 438.10(e)(2)(i), information must be provided to enrollees on the benefits offered, and the amount, duration, and scope of benefits available under the contract, with "sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including *pharmaceuticals*, and mental health and substance abuse benefits." (Emphasis added.) In addition, there is now a requirement in § 438.10(f)(3) specifying that enrollees and potential enrollees can request other information on requirements for accessing services to which they are entitled under the contract. Therefore, although we support the commenter's goals, we believe that this is sufficiently addressed in the regulation.

Comment: A commenter recommended that this section should clearly define all Federally mandated "benefits" and "services" to which Medicaid enrolles are entitled, including nurse-midwifery services, consistent with section 1905(a)(17) of the Act. The commenter and others recommended the use of both "benefits" and "services" to convey the full range available under the State Plan.

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Response: The terms "benefits" and "services" are synonymous. Section 1932(a)(5) of the Act uses the terms "benefits" in the information section, and therefore "benefits" is the word we have used throughout this section of the regulations. The terminology may be different in other sections if the statute used the word "services" with a different meaning in mind; however, the words are interchangeable.

Comment: A commenter recommended that information be provided on those benefits that are carved out of the program entirely, as well as those that overlap (for example, mental health benefits and prescription coverage).

Response: Information must be provided on all covered and noncovered benefits for each MCO and PHP. While States may determine that this additional information is necessary, it is our belief that it is the duty of the State, MCOs, PHPs, and providers to coordinate programs and not that of the enrollees.

Comment: Several commenters urged that proposed § 438.10(e) be amended to specifically require that the MCO's basic information list include the availability and scope of EPSDT benefits and family planning benefits. Another commenter stated that the information to enrollees should clearly state that the amount, duration, and scope of benefits provided to children under EPSDT are not limited.

Response: Section 438.10(e)(2)(i) requires that information be provided on the benefits offered and the amount, duration, and scope of benefits available under the contract. Section 438.10(e)(xii) requires that information be provided on the benefits that are not available through the contract but are covered as part of the State plan.. Finally, § 438.10(e)(2)(vi) requires that information be provided on the extent to which an enrollee may obtain benefits from out-of-network providers. The preamble specifically cites family planning benefits (when appropriate) as an example. HCFA believes that EPSDT benefits are also benefits that fall within the purview of this requirement. Therefore, sufficient information on EPSDT and family planning benefits will be provided.

Comment: Many commenters believe that while providing information on benefits, as well as those carved out, seemed reasonable, the requirement to include information on the amount, duration, and scope was problematic and too voluminous to provide.

Response: We expect that States and MCOs, PHPs, or PCCMs would use general terms and groupings for benefits that have no limitations; however, additional information would be expected if there was a limitation in a particular service. We believe that individuals need sufficient detail to ensure that they receive the benefits that they are entitled to receive and therefore have not modified the regulation as suggested by the commenters.

Grievance Information (Proposed § 438.10(e)(11)

Comment: Proposed 438.10(e)(10) (recodified at § 438.10(e)(2)(xi)) required that enrollees and potential enrollees be provided information about any appeal rights made available to providers. Commenters suggested that we remove that requirement because it is not directly relevant to enrollees.

Response: This regulation reflects the requirement under section 1932(a)(5)(B)(iii) of the Act, "Grievance and appeal procedures," which refers to information on procedures available to an enrollee *and* a health care provider seeking to challenge or appeal a failure to cover a service.

Primary Care Case Manager Requirements (Proposed § 438.10(h))

Comment: Some commenters contended that primary care case managers generally are provided a minimum case management fee that would not cover the cost of providing the information required under proposed § 438.10(h) (recodified as § 438.10(g)). A commenter suggested that the enrollment broker would be in a better position to provide this information. Another commenter believes that the State should be able to decide who provides the information required under proposed § 438.10(h).

Response: Under § 438.10(g), the State is afforded the flexibility of determining whether the State, contracted representative, or primary care case manager is to provide the information. However, if an enrollee requests information about the grievance procedure from the primary care case manager, he or she should be able to obtain it without having to contact the State. As this information must be available only "upon request," we do not believe that it will be overly burdensome for the primary care case manager to provide the information.

Comment: Some commenters were concerned that a primary care case manager's duty to inform consumers about their grievance rights "upon request" may be perceived as supplanting the obligation of MCOs and States to provide written notice of an adverse decision, regardless of whether it is requested. They supported the requirement that case managers be aware of the procedures for filing a grievance and be required to provide information upon request but wanted a statement included that this did not replace the requirement to provide notification for adverse decisions.

Response: The requirements in § 438.10(g) are information requirements, analogous to the information requirements for MCOs under § 438.10(e)(x), and have no effect on the notice and appeal requirements in subpart F of part 438. We therefore do not believe any revisions to the regulations are warranted in response to this comment.

Comment: Certain commenters were displeased that there was no requirement that MCOs provide information about their quality assurance program to enrollees and potential enrollees in the Medicaid program. They believe the regulation should include, as information provided "upon request," information of the type provided under § 422.111(c)(2), (4) and (5) of the June 29, 2000 Medicare+Choice regulations. Specifically, commenters believe that Medicaid beneficiaries should also have access to the following information that is provided to Medicare+Choice enrollees under those regulations: information on utilization control procures; information on the financial condition of the MCO; and a summary of physician compensation arrangements. They also recommended that States require MCOs to provide treatment protocol information to beneficiaries upon request and provide information on HEDIS indicators; results of plan quality studies; external reviews; compliance audits; and summarized complaint and grievance data.

Response: We agree with the commenters that the cited information would be useful to beneficiaries and have revised § 438.10(f) to require that MCOs provide the same information, upon request, that Medicare+Choice organizations are required to provide under § 422.111(c)(2), (4), and (5). With respect to the additional information requested regarding HEDIS indicators and the results of quality studies and external reviews, the results of external reviews under section 1932(c)(2) of the Act will be made available to enrollees and potential enrollees, as required under section 1932(c)(2)(A)(iv) of the Act. Given the lack of experience in analyzing HEDIS indicators or quality results, we are not requiring the disclosure of this information to enrollees at this time but would consider doing so at a future date after

we have more experience concerning the reliability and usefulness of these data.

Comment: Some commenters supported the requirement in proposed § 438.10(i)(2)(iv) (recodified in this final rule at § 438.10(h)(3)(iv)) that information on disenrollments be provided in the case of mandatory enrollment programs under section 1932(a) of the Act; however, many believe these reports would not be meaningful unless they specified the various types of disenrollment, such as voluntary disenrollments, emergency disenrollments, and involuntary disenrollments that occur, for example, due to the loss of Medicaid eligibility as these latter categories of disenrollments are outside of the MCO's control. In the absence of this level of specificity, commenters stated that the data were not useful and could be misleading.

Response: We recognize that disenrollment rates can mean different things, depending on what is included in the rate. For this reason, § 438.10(h)(3)(iv) refers to disenrollment rates "as defined by the State." At a minimum, by requiring the State to define "disenrollment rates," there will be uniform comparison of disenrollments among MCOs, PHPs, or PCCMs. We encourage States to consider the concerns noted by commenters when defining disenrollment rates.

Comment: Commenters observed that providing comparative information in chart form as required under proposed § 438.10(i)(1)(ii) (recodified at § 438.10(h)(1)(ii)) is relatively new and if done inappropriately could be misleading. These commenters stressed that to be effective, the presentation of comparative information needs to take into account the characteristics of each MCE as compared to others, as well as the relative size of the MCE, which may make sampling too small for validity.

Response: The actual design and format of the comparison chart required under § 438.10(h)(1)(ii) in the case of mandatory enrollment programs under section 1932(a) of the Act is left to the State to design. We suggest that States note the concerns listed.

Comment: A commenter sought clarification on how a comparative chart-like form is to be used for the proposed information if the MCE is a primary care case manager under a PCCM program.

Response: The comparative chart-like format specified in § 438.10(h)(1)(ii) is expressly required under section 1932(a)(5)(C) of the Act in the case of a mandatory enrollment program under section 1932(a)(1) of the Act. Section 1932(a)(5)(C) of the Act expressly refers to comparing "managed care entities [MCEs] that are (or will be) available and information (presented in a comparative, chart-like form) relating to" specified areas. The statute thus requires the use of these comparative charts in the case of MCOs, PHPs, or PCCMs, whether they be MCOs or primary care case managers. We believe that this is possible, though we would not expect information on primary care case managers to necessarily look similar to that used for comparing MCOs. For example, the chart could list only those primary care case managers that were different in regard to benefits covered and cost sharing imposed. Additionally, § 438.10(h)(3)(ii) requires that quality indicators be provided to the extent available.

6. Provider Discrimination (Proposed § 438.12)

Proposed § 438.12 would implement the prohibition on provider discrimination in section 1932(b)(7) of the Act. The intent of these requirements is to ensure that an MCO does not discriminate against providers, with respect to participation, reimbursement, or indemnification, solely on the basis of their licensure or certification. The requirements do not prohibit an MCO from including providers only to the extent necessary to meet their needs. Further, the requirements do not preclude an MCO from establishing different payment rates for different specialties and do not preclude an MCO from establishing measures designed to maintain the quality of services and control costs, consistent with its responsibilities.

Comment: We received several comments requesting that we clarify our September 29, 1998 preamble language in which we indicate that we did not interpret section 1932(b)(7) of the Act to be an "any willing provider" provision. Several commenters specifically recommended that we reference this statement in our final rule, while others recommended that we reiterate this statement in the preamble to the final rule. One commenter suggested that we reconsider this provision so as to require all willing providers to be included in an MCO's network.

Response: As we stated in the preamble to the September 29, 1998 proposed rule, we believe it is clear that section 1932(b)(7) of the Act does not require that MCOs contract with all licensed providers willing to undertake the provision of services to the MCO's enrollees. To the contrary, section 1932(b)(7) of the Act expressly provides that it "shall not be construed" to prohibit an organization from "including providers only to the extent necessary to meet the needs of . . . enrollees." It also makes clear that restrictions based on maintaining quality or controlling costs are permissible. We believe that the requirements contained in this section of the regulation were intended only to ensure that providers are selected in a fair and reasonable manner and not discriminated against solely because of their license or certification. Thus, we indicated in the September 29, 1998 proposed rule, and we reiterate here, that this section does not require MCOs to contract with "any willing provider." We do not believe it is necessary or appropriate to amend the regulations to expressly reflect this fact, since by its own terms, § 438.12 does not require contracting with all willing providers.

Comment: One commenter requested that we clarify how a State will determine compliance with this provider discrimination provision.

Response: We expect each State agency to develop its own mechanism to ensure that MCOs contract with providers in a fair and reasonable manner. Our regulation provides States sufficient flexibility to determine which mechanism works best for them. We plan to work with States to provide additional guidance on this issue in the future.

Comment: One commenter recommended that the final rule include written notice and appeals procedures for providers participating in an MCO. The commenter suggested that the process for a written notice and appeals procedure should be based, in part, on the interim final Medicare+Choice regulation.

Response: While the Medicare+Choice regulations do require, in the last sentence in § 422.205(a), that Medicare+Choice organizations provide written notice to providers or groups of providers stating the reasons why they were not accepted as part of the organization's provider network, there is no provision for a right to "appeal" such a decision. Under §§ 422.202(a) and 422.204(c), providers have appeal rights only once they have been accepted as a member of the Medicare+Choice organization's provider network. We similarly are not providing for any right to an appeal in this final rule, though States are free to do so. We agree with the commenter, however, that it would be helpful in enforcing the anti-discrimination requirement in section 1932(b)(7) of the Act if MCOs were required to provide written notice to providers seeking to contract with them of the reasons why

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the providers were not included in the MCO's network. We therefore have revised § 448.12(a) to include the same written notice requirement that applies to Medicare+Choice organizations under § 422.205(a).

Comment: Several commenters suggested that additional protections be added to the regulation to further ensure nondiscrimination of providers. The commenters recommended that the regulation expressly prohibit nondiscrimination of providers who serve limited English-proficient populations, high-risk populations, and persons with HIV and AIDS. One commenter stressed the importance of culturally competent providers and recommended that we add a provision to require physicians to be added to an MCO's network because of the "value" they would add in terms of cultural competence.

Response: The statutory provision implemented in § 438.12(a)(1) and (b), section 1932(b)(7) of the Act, addresses only discrimination that is based solely on licensure and not the other types of discrimination addressed by the commenters. However, § 438.12(a)(2) incorporates requirements elsewhere in part 438 that we believe, along with other provisions in part 438, address the commenters' concerns. Specifically, § 438.12(a)(2) requires that providers be selected in accordance with the requirements in § 438.214 of subpart D. Section 438.214(c) in turn requires States to ensure that MCOs use provider selection and retention criteria that "do not discriminate against particular providers, including those who serve high risk populations or specialize in conditions that require costly treatment." We believe that this prohibits the types of discrimination referenced by the commenters. In addition, we refer the commenters to § 438.206(e)(4), which requires MCOs to provide services in a culturally competent manner, including at least complying with the language requirements of § 438.10(b).

Comment: One commenter believes that there was a contradiction between proposed § 438.12 and proposed § 438.306 (recodified at § 438.206 in this final rule) and that clarification was needed in order to comply with the requirements of section 1932(b)(7) of the Act, as the commenter interpreted them. Specifically, the commenter referred to the preamble discussion of proposed § 438.306 in which we stated that if more than one type of provider is qualified to furnish a particular item or service, the State agency should ensure that the MCO's access standards define which providers are to be used and ensure that those standards are consistent with State laws.

Response: Section 438.12 speaks to discrimination by MCOs against providers of services solely on the basis of licensure. In contrast, § 438.206 requires States to establish standards to ensure the availability of services by MCOs. Although the preamble to proposed § 438.306 referred to "types"of providers to be used, it specifies that the MCO's standards for inclusion of providers must be consistent with State law. We do not believe that § 438.206 could reasonably be read as inconsistent with § 438.12 (that is, to permit an MCO to discriminate against providers solely based on licensure or certification). Section 1932(b)(7) of the Act makes clear that MCOs may limit the number of providers with which they contract based on need or to control costs. If more than one type of provider can provide a State plan service, and an MCO already contracts with one such type of provider, we believe that it could under section 1932(b)(7) of the Act and § 438.12 decline to contract with the other type of provider based on cost-effectiveness considerations, unless there is a State plan service that only that type of provider can furnish. For example, if the State plan includes "nurse-midwife" services under section 1905(a)(17) of the Act or certified pediatric nurse practitioner/certified family nurse practitioner services under section 1905(a)(21) of the Act, these services can, by definition, only be provided by the type of provider in question.

Comment: One commenter expressed concern regarding a Medicare Operational Policy Letter, indicating that it could be used as a basis for denying chiropractic services to a Medicaid beneficiary.

Response: First, we note that Medicare Operational Policy Letters do not establish Medicaid policy and are not a valid basis for denying services to Medicaid beneficiaries that would otherwise be covered in accordance with a Medicaid State Plan. The Medicare Operational Policy Letter in question also would not have any applicability even by analogy, because of differences between the way chiropractic services are treated under Medicare and Medicaid. Under Medicare, "chiropractor services" are not listed as a specific covered service or benefit. Rather, under section 1832(a)(2)(B) of the Act, beneficiaries with Medicare Part B are entitled to coverage of "medical and other health services," which in turn is defined in section 1861(s) of the Act as including "physicians services." While there thus is a right to coverage of "physician's services," there is no specific coverage category for the services of a chiropractor. Instead, under the definition of physician in section 1861(r) of the Act, a chiropractor can be considered a physician for purposes of being eligible to provide Medicare covered physician services but only to the extent the chiropractor is performing a manual manipulation of the spine to correct a subluxation. This manual manipulation thus can be reimbursed by Medicare as a physicians' service whether it is performed by a chiropractor or any other physician, such as an orthopedist, who performs this manual manipulation.

In Medicaid, in contrast, section 1905(a)(6) of the Act permits States the option of covering medical or remedial care "furnished by licensed practitioners within the scope of their practice as defined by State law." To the extent a State has decided under section 1905(a)(6) of the Act to cover chiropractor services under its State plan, this covered service by definition could only be provided by a chiropractor.

Comment: We received several comments questioning the statutory basis for § 438.12(b)(2), which permits the MCO to pay different amounts for different specialties. Several commenters suggested that a provider performing the same service should be paid the same amount, regardless of the provider's specialty. They recommended that we remove paragraph (b)(2) or revise it to prohibit MCOs from paying lesser amounts for the same service when provided by different types of practitioners. Other commenters stated that paragraph (b)(2) had the practical effect of requiring MCOs to pay all specialists within the same specialty the same amount. These commenters suggested that HCFA clarify this provision, with one commenter recommending that we amend paragraph (b)(2) to not permit the MCO to use different reimbursement amounts for different specialties or for the same specialty.

Response: We disagree that the statute does not allow an MCO from establishing different reimbursement amounts for different specialties. Section 1932(b)(7) of the Act states that an MCO "may establish measures designed to maintain quality and control costs consistent with the responsibilities of the organization." We believe that paying different amounts to individuals with different specialties can clearly be dictated as a "measure[ ] * * * to control costs." This is because we believe that, in order to attract highly qualified providers of all types, and to attract an adequate number of certain categories of specialists, MCOs may need to pay a higher amount than they would need to pay to attract other types of providers. It would not be cost-effective if the MCO was then required to pay this higher amount to other providers who would be willing based on market rates to join the network for a lower amount. Also, as a quality measure, MCOs should be free to pay providers with more training and experience a higher rate of reimbursement for the services they perform. Moreover, we do not want to preclude MCOs from using incentive payments to reward providers for demonstrating quality improvement or from attracting experienced providers to its network.

For the reasons stated above, we agree with commenters that paragraph § 438.12(b)(2) should be clarified to also permit different reimbursement amounts for the same specialty. Accordingly, we have amended the final regulation at § 438.12(b)(2) to state clearly that an MCO may use different reimbursement amounts for different specialties or for the same specialty.

B. State Responsibilities (Subpart B)

Proposed subpart B set forth the State option to implement mandatory managed care through a State plan amendment, as well as State responsibilities in connection with managed care, such as ensuring choice and continuity of care, enforcing conflict of interest standards and limits on payment, monitoring, and education.

1. State Plan Requirements: General Rule (Proposed §§ 438.50 and 438.56(b), (c), and (d))

Proposed §§ 438.50 and 438.56, implemented section 1932(a)(1) and (2) of the Act, which permits mandatory enrollment of Medicaid beneficiaries in MCOs or PCCMs on the basis of a State plan amendment, without a waiver under section 1915(b) or 1115 of the Act. Under these regulations, a State agency can require most Medicaid beneficiaries to enroll in MCOs or PCCMs without being out of compliance with provisions in section 1902 of the Act on statewideness, comparability, or freedom of choice. Paragraph (b) and (c) set forth the requirements for these programs and the assurances that States must provide. Proposed § 438.56(b) identified limitations on populations that could be mandatorily enrolled. Paragraphs (c) and (d) set forth requirements for enrollment priority and default assignment under these programs.

Comment: One commenter requested that we clarify that § 438.50 does not apply to 1915(b) and 1115 waiver programs since States can mandate enrollment in MCOs and PCCMs under theses waiver authorities without amending their State plan.

Response: We agree with the commenter and we have amended the final rule with comment period to expressly provide that programs operating under section 1915(b) or 1115 the waivers are exempt from the requirements of this section.

Comment: A few commenters expressed the concern that the Federal requirements permit certain SPAs to be effective as early as the first day of the quarter in which the SPA was submitted to us and recommended that we eliminate the retroactive approval of these SPAs. Two commenters erroneously believed that the State risk loss of federal money if the SPA is disapproved, apparently confusing this State plan process with the process of approving contracts under section 1903(m) of the Act. These commenters also expressed a concern that beneficiaries may be permanently adversely affected in the event they are harmed during the retroactive period. One commenter remarked that the State could begin enrolling beneficiaries into a mandatory managed care system that does not guarantee access to reproductive health services prior to the submission of the SPA. Another commenter emphasized that the short timeframes in implementing managed care have caused problems for the consumers and providers in the past, and guidelines from us are needed in areas of payment, enrollment, network adequacy and continuity of care, etc.

Response: We do not believe that the rules governing effective dates for SPAs which mandate enrollment in managed care should differ from the rules that apply to any other amendments to a State's plan. By allowing States to implement a SPA effective the first day of the quarter in which they submit the SPA to us for approval, § 438.50 is consistent with the other SPA effective date provisions in §§ 430.20 and 447.26. The retroactive effective date is only applicable in the case of an approvable SPA. During the retroactive period, the increased beneficiary protections such as grievance procedures, quality assurance, and disenrollment are applicable. Also, before the State may actually enroll beneficiaries into MCOs under this authority, all contracts between the State and the MCO must be approvable and in place and all statutory and regulatory requirements must be satisfied.

Comment: Two commenters indicated that the pre-print form is not sufficiently descriptive. They recommended that the form require the States to provide more detail on family planning, prenatal care, labor and delivery and other reproductive health services. In addition, they would like the States to specify the type of entities with which the State will contract in order to assure access to reproductive health services, supplies and procedures.

Response: We are in the early stages of developing this section of the State plan preprint for amendments under § 438.50, and will take these comments into consideration when designing that form. However, some States have already implemented approved programs under § 438.50 utilizing existing guidance issued in a December 17, 1997 letter to all State Medicaid Directors. We believe that the commenter's specific concerns are addressed in § 438.50(b), which requires States to specify the types of entities with which they will contract under a mandatory managed care program, in combination with § 438.206(c), which requires that contracts with the MCO specify the services that the entity is required to provide, and that States make arrangements to cover all Medicaid services available under the State plan, including any that may not be in the MCO contract.

Comment: One commenter stated that while States can assure that contracts between MCOs and themselves meet all requirements of the Act, a commitment that all MCOs and PCCMs will be in compliance at all times is unrealistic. This commenter recommended that the preferable language would be that the State/local district will take appropriate action against an MCO or PCCM whenever it is determined that one of these entities is not in compliance with the contract.

Response: We agree that a State cannot assure in advance that an MCO or PCCM will always be in compliance with all requirements, and that all we can ask is that the State take appropriate action if it is determined that one of these entities is out of compliance. Subpart I below discusses intermediate sanctions and civil money penalties that can be imposed when MCOs or PCCMs are out of compliance, and subpart J discusses the fact that FFP can be denied in contracts with MCOs that are substantially out of compliance. Proposed § 438.50(b)(4), however, refers to the State being in compliance with requirements in this part relating to MCOs and PCCMs.

Comment: We received one comment stating that the current regulations allow

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our Regional Offices (ROs) to approve SPAs based on policy statements and precedents previously approved by the Administrator. Only disapproval of an amendment must come from the Administrator's office. Currently there are no policy statements or precedents from the Administrator's office to provide guidance to ensure uniform decision making by the ROs. This commenter recommended that approval of the managed care plan amendments should be the responsibility of our Administrator with assistance from the Regional Office until comprehensive guidelines have been developed and disseminated to the Regional Office.

Response: Section 430.15(b) gives our delegated authority to approve the State plan and plan amendments. The consults with our Central Office during the review process to ensure that the SPA meets the requirements of all relevant Federal statutes and regulations as stated in § 430.14. All reviewers in our Central and Regional Offices reference the same tools when reviewing a State plan amendment, including State Medicaid Director letters implementing the managed care provisions in the BBA of 1997 provisions. The delegations of authority are clear on the review of State plan amendments, and the collaboration between the our RO and central office is a long established process. Consequently, we are not making any changes in the approval authority for these SPAs.

State Plan Assurances (Proposed § 438.50(b) and (c))

Comment: A number of commenters felt that the regulation should require the States to publicize any plan amendment for mandatory managed care, and to solicit public involvement in all levels of development before the amendment is approved and implemented. Suggested methods for informing and involving the public included:

- Public hearings and comment periods;
- Involving the State Medical Care Advisory Committee in reviewing amendments and contracts.
- Using our website to notify the public of the submission and approval of State plan amendments.
- Publishing a **Federal Register** notice when States first submit an amendment.
- Requiring that the MCO and PCCM contracts, as well as bids, be designated public record and be available to the public.

Response: We agree with the commenters, and we have amended the final rule with comment period at § 438.50(b)(4) to require state plans to specify: "The process the State uses to involve the public in both design and initial implementation of the program, and the methods it uses to ensure ongoing public involvement once the State plan has been implemented." This language is consistent with the public notice requirements of the State Children's Health Insurance Program.

Comment: One commenter recommended that we establish specific procedures to closely monitor, track and evaluate these State plans.

Response: We acknowledge this concern, and assure the commenter that we will continue to monitor, track, and evaluate State plans via review of provider contracts, site visits, and reporting requirements such as for external quality reviews. Amending the state plan to implement a program of mandatory managed care may eliminate the need for a State to apply for waiver renewals every two years, but does not eliminate the State's obligation to guarantee access to services and provide quality care to its beneficiaries, nor does it eliminate necessary monitoring and evaluation of these programs by us.

Comment: One commenter recommended that State plans and contracts with MCOs provide that the choice of primary care providers for children must include pediatricians, and ensure access to pediatric services. The commenter also recommended a pediatric definition of medical necessity. Other recommendations included that the contracts should ensure that information and training is provided to recipients, physicians and other providers, local agencies and human health services agencies regarding various aspects of the managed care programs. This commenter requested that we require States to describe their plans for conducting performance evaluations.

Response: For reasons discussed in more detail in section II. D. below, in a response to comments on proposed § 438.306 (now codified at § 438.206), with some exceptions (such as a women's health specialist), we generally do not believe it is necessary or appropriate to require that MCOs contract with specific categories of providers. However, also as discussed in that section, we are requiring in § 438.206(d) that in establishing an MCO's provider network, it must consider the anticipated enrollment, with "particular attention to * * * children," and "[t]he numbers and types (in terms of training and experience) of providers required to furnish the contracted services." We believe that these requirements address the commenter's concern about participation of pediatricians. With respect to the recommendation for a "pediatric definition of medical necessity," also as discussed below in section II. D, we are requiring in § 438.210(a)(4)(ii)(B) that an MCO's definition of "medical necessity" address the extent to which it is responsible for covering services related to the ability to achieve age-appropriate growth and development, which is obviously "pediatric-related." We have not required a separate definition. We believe that the commenter's suggestion concerning information requirements has been addressed in § 438.10(d) and (e). Finally, with respect to the issue of "performance evaluations," as discussed in section II. D. below, § 438.240(c)(i) requires that MCOs and PHPs measure performance, while § 438.240(c) requires performance improvement projects.

Limitations on enrollment (Proposed § 438.56(b))

Comment: One commenter correctly noted that if a State wished to use the State plan option, yet wished to mandate managed care enrollment for elements of the Medicaid population exempted under that option, the State must still request a waiver to include the exempt populations, thereby negating the benefits of the State plan option. Another commenter complained of the continued administrative time, expense and confusion in the current waiver renewal process. This commenter also expressed the view that if the BBA is designed to allow greater flexibility for State administration, then greater allowance should be given to the State plan option rather than the waiver.

Response: The proposed rule implements section 1932(a), of the Act as enacted by the Congress. While it provides States with an alternative to the 1915(b) of the Act waiver process with respect to individuals not exempted, we acknowledge that the State plan amendment is not applicable to all situations, and that the State will need to submit a 1915(b) of the Act waiver to enroll exempted population into mandatory managed care programs. We have no discretion to change, this however, because the Congress was clear in exempting these populations.

Comment: One commenter noted that nothing in the BBA prohibits States from exempting populations other than those specified in the Act for mandatory enrollment in managed care, and recommended that language be added to the regulations to indicate that the State may exempt other populations. Another commented that the regulation only lists categories of persons who may not be enrolled in managed care under the State plan managed care option. The commenter suggested that this rule should also allow States using the waiver option to exempt categories from mandatory managed care.

Response: We do not agree that it is necessary to add language to the regulation indicating that States may exempt other populations. Section 1932(a)(2), of the Act identifies those populations which *must be* exempted from mandatory enrollment under this provision. States have had and continue to have the discretion to exempt other populations from mandatory enrollment in managed care.

Comment: Several commenters expressed concern that beneficiaries might not be identified or notified of their exemption from mandatory enrollment, and run the risk of being defaulted into MCOs or PCCMs. They recommended that the State provide a mechanism to ensure that exempt populations are not enrolled into MCOs or PCCMs, and that State be required to permit exempt individuals to self-identify.

Response: Section 438.10(d)(2)(B) of the final rule with comment period has been modified to require that potential enrollees be informed of populations which are exempt from mandatory enrollment in any such program. We agree that self-identification would be an effective tool for individuals who fall into an exempt category, but are not identified as such by the State. Once identified, the State would be obligated to exempt such individual from mandatory enrollment, and to disenroll he or she immediately, if they had been enrolled by default.

Comment: We received comments concerning the applicability of the limitations in section 1932(a)(4) of the Act on the right to disenroll without cause to exempted populations. One commenter urged that the "12 months lock-in" provided for under section 1932(a)(4) of the Act should be restricted to individuals whose enrollment in managed care was mandated. Two commenters suggested that the 12 months lock-in should not be allowed for exempted groups unless a State can demonstrate in a waiver that the population's access to services will not be diminished due to enrollment in an MCO or PCCM.

Response: If an exempted individual voluntarily enrolls in an MCO or PCCM, the same lock-in and disenrollment provisions in section 1932(a)(4) of the Act apply, including the ability to disenroll without cause during the first 90 days of enrollment. This is because section 1903(m)(2)(A)(vi) of the Act incorporates section 1932(a)(4) of the Act in the case of MCOs, while section 1905(3)(E) of the Act incorporates section 1932(a)(4) of the Act in the case of PCCMs. With respect to the last recommendation concerning demonstration of access to services, MCOs must meet the requirements for access and availability of services as specified in §§ 438.206 and 438.207 of the final rule with comment period, while a PCCM contract must meet the requirements for access and services under § 438.6(k).

Comment: Some commenters agreed with the exempted groups as outlined in the proposed rule and recommended that we maintain this provision. Specifically, two commenters agreed that foster care children should be exempted as foster care children move frequently and they may need to change providers for geographic reasons. These commenters also noted that if the child has a disability and moves often because of foster care, it may be important to maintain a single provider to prevent frequent disruption of complex care. Another comment indicated that children under 19 years of age who are eligible for SSI and eligible for dental coverage under EPSDT should not be subject to mandatory enrollment in managed care.

Others felt certain populations should not be excluded from managed care programs, with one commenter recommending legislative action to revise the rules to delete all impediments to enabling managed care programs for the broadest possible populations. The commenters cited positive experiences with exempted populations in mandatory managed care programs and felt that the special needs can best be addressed and coordinated through a network of providers. The commenters' experience has shown that Medicaid clients believe the service is better and the more complicated the care, the more there is a need for managed care. Two commenters expressed the concern that by limiting managed care for certain populations, the message conveyed is that managed care does not work for these populations. They continued to say that many States have been very successful in operating managed care for these exempted populations and it has been shown to be a strong factor in assuring access to primary and preventive care and other needed medical services. One commenter stated that they have taken steps to ensure that MCOs identify and serve children with special health care needs appropriately, including the implementation of broad, functional definitions of Disability and Special Health Care Needs. This commenter partnered closely with the advocate community to develop appropriate standards for this population. They felt that we were incorrect to assume that managed care will not work for these populations.

Response: Section 1932(a)(2) of the Act identifies those groups exempted from mandatory enrollment under this provision. We do not have the authority to add groups or delete groups from this list. The statute does not prevent voluntary enrollment if a voluntary contract exists and an individual believes that his or her needs will be best met with an MCO or PCCM. If a State desires to enroll any of these exempted populations into a managed care program, it may do so by offering voluntary enrollment as an alternative to unrestricted fee-for-service, or it may mandate enrollment through section 1915(b) of the Act or 1115 of the Act waiver authority.

Comment: We received many comments requesting that additional populations be exempt from mandatory managed care because of the complexity of the beneficiaries' medical needs. Commenters recommended that the additional exempted groups should include—

Children with HIV, but who have not developed AIDS;
Patients awaiting transplants and organ transplant recipients;
Patients suffering from cancer;
Patients suffering from arthritis, osteoporosis, chronic and debilitating musculoskeletal conditions;
Children and adults with mental retardation;
Patients with severe and persistent mental illness (SPMI), brain disorders;
Adults with disabilities;
Homeless persons; and
People for whom English is not their primary language or people residing in areas where provider awareness of cultural diversity is limited.

Several commenters suggested that the language in § 438.56(b)(3)(v) (redesignated as § 438.50(d)(3)(v)) narrowly defines children with special needs in Title V programs who are exempted from enrollment. These commenters recommended that this section should be amended to cover all children eligible for Title V special needs as defined by the State's Title V agency. Commenters proposed definitions for foster care or "otherwise in an out-of-home placement." A few commenters recommended the adoption of the Maternal and Child Health

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Bureau's definition of children with special health care needs.

A couple of commenters recommended voluntary enrollment for dual eligibles and for adults with disabilities. One commenter recommended that individuals who have significant, chronic disabilities should have the option to voluntarily enroll and not be subject to any State being eligible to obtain such a waiver from HCFA.

Response: As indicated above, in section 1932(a)(2), of the Act the Congress specified the groups that are exempt from mandatory managed care enrollment through the State plan provision. We do not have the statutory authority to exclude any other populations. Because of variations in States regarding the identification of individuals receiving services through a family-oriented, community based, coordinated care system receiving grant funds under Section 501(a)(1)(D) of Title V, of the Act the December 17, 1997 SMD letter offered guidance to States about developing more detailed operational definitions of this group. The State also has the option to define this group in terms of their special health care needs and to develop a process whereby individuals who are not identified through the initial exemption process could request exemption based on special needs as defined in the State plan.

Although we considered using the Maternal and Child Health Bureau's definition of children with special health care needs, we believe that the identification of this specific group by either program participation or accepted State definition more closely reflects the statutory language while being more administratively feasible.

Enrollment by Default (Proposed § 438.56(d)

Proposed section 438.56(d) set forth the requirements relating to default enrollment of beneficiaries in SPA programs who do not make a choice from among the available MCOs or PCCMs. (Note: As indicated above, this section is being moved to § 438.50 in the final rule with comment period because it applies only to SPA programs.) This provision required that the default enrollment process preserve existing relationships between beneficiaries and health care providers, and relationships with providers that have traditionally served Medicaid beneficiaries. If this is not possible, States are required to distribute the beneficiaries equitably among the available MCOs or PCCMs qualified to serve them.

Comment: A number of commenters pointed out that the proposed rule did not address what constituted an acceptable level of default enrollments. The commenters urge us to encourage States to keep the rate of default enrollments as low as possible, and to use the comment/response section of the final rule with comment period to discuss the successful practices of States like New Jersey and Rhode Island to keep default enrollments low. The commenters urged us to require States to collect and report uniform data on default enrollments (some commenters suggested that the data be broken down by geographic area). Most commenters identified 25 percent as the threshold at which further action should be taken, although one commenter suggested that default enrollments be halted in cases where the default rate goes above 10 percent. The commenters had various suggestions as to what should happen in cases where the rate of default enrollments exceeded the threshold—some said default enrollments should be halted, some said we should review the State's processes, and some said the State should develop and implement corrective actions in their outreach and enrollment processes.

Response: Although the BBA did not specify an acceptable level of default enrollments, we agree that this can be an important measure of the extent to which beneficiaries make informed decisions about enrollment. We agree that States should endeavor to keep default rates low, and the enrollment and information provisions of the regulation are designed to help States achieve a high rate of enrollee choice. Default enrollment rates vary widely because States have greatly different levels of experience with managed care, and because of measurement variation. Although we have decided not to mandate a single acceptable level of default enrollments in the final rule with comment period we will continue to monitor default enrollments in Medicaid managed care programs.

Comment: A number of commenters pointed out that the proposed rule did not specify the time allowed for beneficiaries to choose an MCO or PCCM before default enrollment takes place. The commenters suggested a number of minimum timeframes—20, 30, or 60 days. One commenter also suggested that States be required to offer a longer time period for persons with serious and persistent mental illness.

Response: Section 1932(a)(4)(D)(i) of the Act, as established by the BBA, refers to "the enrollment period specified by the State." Therefore, we believe the Congress intended for each State to be able to set its own enrollment period, depending upon its population and its own experience with managed care. To date, States have demonstrated that a wide variety of time periods can be effective, depending upon their own populations and outreach and educational programs. For example, one State with a low default enrollment rate only allows enrollees 10 days to choose a plan. We have decided not to specify a minimum time period in the final rule with comment period.

Comment: We received one comment urging that default enrollments be prohibited. A number of other commenters indicated that some limitations should be placed upon a State's ability to make default enrollments. A number of limitations were suggested. One commenter said default enrollments should be prohibited in cases of persons with disabilities. Another indicated that the enrollment period should be suspended if the beneficiaries had requested information and not received it, or had requested a face-to-face meeting that could not be scheduled during the enrollment period. Also, this commenter said if the recipient or his guardian could not be reached through no fault of their own, there should be no default enrollment. One commenter said States should be required to assign beneficiaries to a PCCM instead of default enrolling them into an MCO.

Response: The Congress spoke clearly on which groups should be exempt from mandatory enrollment in SPA programs, and these groups are similarly not subject to default enrollments pursuant to section 1932(a)(4)(D) of the Act. For those individuals who are not exempt, the statute requires a default enrollment process for MCOs and PCCMs generally, not just primary care case managers: Specifically, section 1932(a)(4)(D) of the Act provides that under a mandatory program under section 1932(a)(1) of the Act, "the State *shall establish* a default enrollment process * * * under which any * * * individual who does not enroll *with a managed care entity* during the enrollment period. * * *" In granting States the discretion to specify the time period for making an enrollment, we believe that the statute gives States the flexibility to provide for extensions of this time period, or other accommodations when warranted by the needs of the population, so long as they are applied in a uniform manner. We recommend that States grant extensions and other accommodations when they consider it to be appropriate.

Comment: One commenter pointed out that many persons with disabilities, who may be subject to mandatory

enrollment, have a representative payee. The commenter recommended that we require States to notify representative payees when default enrollments are made.

Response: We agree with the commenter that there may be situations when it would be appropriate for the State to notify someone other than (or, at State option, in addition to) the enrollee. However, we believe the final rule with comment period should provide for notification of a broader scope of enrollee representatives than representative payees. In response, we have added language to the final rule with comment period adding references to an enrollee or his or her "authorized representative." This would cover situations including, but not limited to, a representative payee situation. (We have added this language to § 438.56.)

Comment: One commenter said the final rule with comment period should address how enrollees are assigned to PCPs once they have been default enrolled in an MCO, and recommended that we require that MCOs consider geographic, cultural, and linguistic accessibility when assigning enrollees to a PCP.

Response: In requiring States to preserve existing provider-recipient relationships in the default enrollment process, the Congress clearly intended there to be as little disruption as possible in the provision of medical care. We encourage States to monitor this process and to require that MCOs, to the extent possible, make PCP assignments that promote recipient access to care. Additionally, we believe that the access requirements for MCOs contained in § 438.206 will assist in this regard. We do not believe, however, that it is necessary to insert an additional regulatory requirement.

Comment: We received a large number of comments on the default enrollment methodology. One commenter expressed general support for the enrollment by default provisions. A handful of commenters indicated that they thought we had placed too many requirements in the default enrollment section. The bulk of the commenters, however, encouraged us to place additional requirements on States in developing their default enrollment procedures. The commenters who disagreed with our proposed regulations believed either that States should not have to take relationships with existing providers into account, or that the default enrollment procedures should not favor traditional providers. Two commenters felt that favoring traditional providers may discourage participation in managed care programs by commercial MCOs. The commenters who want us to place additional requirements on States disagree with the concept of equitable distribution if it means States are not permitted or required to take additional factors into consideration. Commenters suggested that the rule should require States to take the following factors into account when default enrolling beneficiaries: Geographic accessibility, especially for rural residents; cultural and linguistic competency; experience with special needs populations; physical accessibility; and capacity to provide special care and services appropriate to the needs of the individual. Commenters said persons who are homeless, persons with HIV, and individuals with special health care needs or developmental disabilities should only be assigned to MCOs or PCCMs with demonstrated competency serving them. In addition, commenters said that we should not allow States to favor MCOs or PHPs in their default enrollment methodologies just because they are the lowest cost Entity, and that no default enrollments should be made to plans that do not offer the full scope of basic health care services, including family planning services. Commenters said States should be allowed to consider such factors as success rates in completing EPSDT screens, price, quality, and customer satisfaction in their default enrollment methodology.

Response: The statute clearly indicates that States must take existing relationships into account, "or relationships with providers that have traditionally served beneficiaries under this title." Section 1932(a)(4)(D)(ii)(II) of the Act goes on to specify that if maintaining such relationships is not possible, States must arrange for "the equitable distribution of such individuals among *qualified* managed care entities available to enroll such individuals, consistent with the *enrollment capacities* of the entities. (Emphasis added)" We believe that in using the term "qualified," the Congress intended to permit States to consider such factors as experience with special needs populations. Additionally, for rural residents or beneficiaries with needs for special cultural or linguistic competencies, States may consider MCOs or PCCMs that are equipped to serve them as more qualified. Also, the statute does not define the term "enrollment capacity." We believe States have flexibility to determine that cultural and linguistic competency and other similar factors are related to MCOs'or PCCMs' capacity to serve certain individuals, depending upon their needs. We believe the language as proposed gives States sufficient flexibility to consider these factors, therefore, we have not added new requirements to the final rule with comment period.

Comment: Commenters were divided on the subject of whether members of the same family should be default enrolled to the same plan. Four commenters indicated that family members should be default enrolled in the same MCO or PCCM. One commenter in this group said family members "in general" should be enrolled in the same MCO or PCCM; presumably this indicates there may be circumstances in which family members could be enrolled in different MCOs or PCCMs. Four commenters said there may be circumstances in which family members could be better served by different MCOs or PCCMs. Other commenters raised the same question with regard to whether family members could choose to enroll in different MCOs or PCCMs, as opposed to being defaulted into them.

Response: The statute is silent on whether the default enrollment rules should require family members to be enrolled together. Because State enrollment and eligibility systems may not permit family members to be divided up, we do not recommend placing any requirements on this subject in the final rule with comment period. If States have the capacity to allow family members to choose different MCOs, they should be permitted to do so. Likewise, we assume States will want to default enroll families to the same MCO, and we believe they should be permitted to do so as well. This same policy applies to the question of whether States wish to permit individual family members to choose to enroll in different MCOs or PCCMs.

Comment: A number of commenters discussed our definition of existing relationships between enrollees and providers in the context of making default enrollments. Opinion was divided on the extent to which States should be required to consider existing relationships between beneficiaries and providers. The proposed rule defined an existing relationship as "one in which the provider was the main source of Medicaid services for the recipient during the previous year" and goes on to say that States may establish this through fee-for-service or managed care records, or by contacting the recipient. Several commenters specified that this provision would be difficult to operationalize or even "unworkable." One indicated that if the recipient's previous experience with Medicaid was

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in a fee-for-service system where it was difficult to find participating providers, the existing relationship may not have been an ideal one. However, a number of commenters said the language in the proposed rule did not go far enough. The majority of these commenters indicated that we should require States to examine previous records, and that the look-back period should be 3 years instead of 1 year. One commenter also said States should be required to examine payment records pertaining to services from ancillary providers such as DME suppliers and home health agencies as well. Some commenters also said MCOs should be subject to similar requirements in making enrollee assignments to PCPs.

Response: Because section 1932(a)(4)(D)(ii)(I) of the Act refers to considering existing relationships, we do not have statutory authority to exempt States from this requirement. We do, however, have the authority to define how States meet the requirement. We believe that the regulation gives States the flexibility to determine existing relationships in whatever way makes sense in the context of their program. Therefore, we have decided not to include additional requirements in the final rule with comment period.

Comment: We received a large number of comments urging us to present a more comprehensive definition of traditional providers than the one included in the preamble and proposed rule. The text defined a traditional provider as a provider who has "experience in serving the general Medicaid population." Many commenters pointed to what they felt was confusing language in the preamble: "Under § 438.56(d)(4) we would define 'traditional providers' to be any provider who has been the main source of care for a beneficiary within the last year, and has expertise and experience in dealing with the Medicaid population." Commenters felt this definition either unnecessarily confused existing relationships with traditional providers, or indicated that any provider who had been the main source of care for any recipient could be considered a traditional provider. Two commenters said States should be permitted to develop their own definitions of traditional providers. However, most commenters favored a HCFA definition that would be much more specific than the definition included in the proposed rule. Examples of what commenters said that we should include in the definition are: A certain percentage of Medicaid and uninsured utilization (either a set percentage or a percentage at least equal to the statewide mean); a significant number of years spent serving Medicaid patients; DSH hospitals; public hospitals; FQHCs; CHCs; and Health Care for the Homeless projects.

Response: Although default enrollments may be made to MCOs and not necessarily to individual providers, the statutory language refers specifically to providers. Section 1932(a)(4)(D)(ii)(I) of the Act requires that the default enrollment process take into consideration maintaining "relationships with providers that have traditionally served beneficiaries under this Title." Clarification can be found in the BBA Conference Report, which states that the default enrollment process "must provide for enrollment with an MCO that maintains existing provider-individual relationships or *has contracted with providers that have traditionally served Medicaid [beneficiaries]"* (emphasis added). Therefore, we believe the Congress intended for States to favor MCOs and PCCMs that contract with traditional providers in their default enrollment process. However, because the statute does not define traditional provider, we have the flexibility to either write a definition or allow States to develop their own. Because of the volume and variety of comments, we decided to allow States to develop their own definitions that could include, but not be limited to, DSH hospitals, public hospitals, FQHCs, CHCs, and Healthcare for the Homeless projects.

2. Choice of MCOs, PHPs, or PCCMs (Proposed § 438.52)

Proposed § 438.52 implemented the requirement in section 1932(a)(3) that States must permit an individual to choose from at least two MCOs or PCCMs, including the exceptions to this requirement in a case in which a State elects the option under section 1932(a)(3)(B) to offer a single MCO in a "rural area," and the exception in section 1932(a)(3)(C) permitting a State to offer a single HIO in certain counties.

General Rule

Section 438.52(b) of the proposed rule required that States allow beneficiaries to choose from at least two MCOs or PCCMs.

Comment: We received comments expressing general support for the requirement for choice. One commenter, however, said that merely offering choice may not provide sufficient beneficiary protection, and we should consider alternative ways to provide consumers with accountability and responsiveness.

Response: The requirement for choice of MCO or PCCM appears in the statute, and is consistent with our longstanding policy of generally requiring at least two options in a mandatory managed care program. However, choice is only one piece of an overall strategy to ensure that beneficiaries receive quality services. This regulation implements new requirements for quality, access and availability, and beneficiary protection. We believe these requirements address the concern voiced by the commenter.

Comment: We received a number of comments disagreeing with our decision to apply the requirement for choice to PHPs. The commenters indicated that in the case of behavioral health carve-outs and certain long term care programs, it is not appropriate to require choice. Commenters indicated that the requirement for choice in carve-outs increases administrative costs because the State would be required to solicit business from two MCOs which would utilize the same limited set of providers. One commenter believed that in the case of PHPs, States should be allowed to request waiver authority to limit choice to one PHP, so long as that PHP offers beneficiaries a choice of providers. The commenter stated that we should clarify this in the final rule. The commenter also believed that PHPs should be chosen through a competitive process except when the State has decided to utilize a local governmental organization as a sole source provider. One commenter recommended that § 438.8 be amended to state that the provisions of subpart B apply to PHPs.

Response: Under this final rule with comment period, outside the context of a demonstration project or waiver program, we believe it is appropriate to give enrollees a choice of PHPs, along with the right to disenroll that is provided under section 1932(a)(4) to MCO and PCCM enrollees. As in the case of other PHP requirements, we have based this rule on the authority in section 1902(a)(4) of the Act to provide for methods of administration determined to be necessary for proper and efficient operation of the Medicaid program. Regulations based on provisions in section 1902, however, may be waived by the Secretary under section 1915(b) of the Act or as part of a demonstration project under section 1115 of the Act. Nothing in this regulation changes this waiver authority. Thus, we agree with the commenter that States should be allowed to request a waiver to permit a State to limit enrollees to a single PHP if the enrollees have a choice of providers within the PHP. With respect to the comment on competitive procurement, § 434.6(a)(1) requires that in the case of all Medicaid contracts, States comply with competitive procurement requirements in 45 CFR, part 74. Under these requirements, States are required to engage in competitive procurement "to the maximum extent practical." Thus, we agree with the commenter that PHPs should be chosen through a competitive process. We do not agree, however, that the State necessarily should be exempted from this requirement when it contracts with a government entity. While part 74 at one time exempted such cases from competitive procurement requirements, there is no longer such an across the board exemption. HCFA has, however, exercised discretion it has under part 74 on a case-by-case basis to permit government entities to contract as PHPs without a competitive procurement.

Finally, in response to the last comment, in the final rule with comment period, we have amended § 438.8 to specify that all subpart B provisions except § 438.50 apply to PHPs, because we agree with the commenter that the reference should be made more explicit.

Comment: One commenter said we should clarify our preamble language pertaining to PCCMs. This commenter said it appeared that States could satisfy the requirement for choice with a single PCCM. This commenter said that was contrary to the intent of the BBA, and pointed out that the only exception to the requirement to choice is for rural areas and certain HIOs.

Response: The commenter has confused a PCCM, which we clarify in this final rule with comment period refers to a "primary care case manager" as defined in section 1905(t)(2), with a primary care case management "system," under which beneficiaries have the option of enrolling with one of two or more PCCMs. We recognize that our use of two terms in proposed § 438.2 that would fit with the acronym "PCCM" may have caused this confusion. The term "primary care case management" refers to "a system under which a primary care case manager contracts with the State," while the term "Primary care case manager" is defined as the contracting individual or entity. As discussed in section II. A. above, we have clarified in §§ 400.203 and 438.2 of this final rule with comment period that PCCM refers to a primary care case manager. We agree with the commenter that unless the rural area exception in section 1932(a)(3)(B) applies, a State cannot satisfy the choice requirement through the use of a single PCCM. It can, however, do so through a primary care case management *system*, under which a beneficiary has a choice of two or more PCCMs. We have clarified § 438.52(b) to emphasize this distinction.

Comment: We received a comment recommending that the final rule specify that all beneficiaries must have a choice between two MCOs or PCCM providers that are qualified and experienced in HIV/AIDS care.

Response: We agree that for persons with special needs, including those with HIV/AIDS, being able to choose from MCOs or PCCM providers qualified to meet their needs is essential. Section 438.206 of this final rule with comment period requires States to develop standards for access to care, including attention to special needs populations. The section requires all MCOs to assure that they have the adequate capacity and appropriate services to meet the needs of the expected enrollment. This includes being able to serve any special needs populations that could potentially be enrolled in the MCO. We also require MCOs to consider the experience needed by network providers to serve the expected needs of their enrollees. Lastly, we expect States to aggressively monitor such indicators as grievances, appeals, fair hearing requests, and disenrollment requests as indicators that persons with special needs are not being adequately served.

Comment: One commenter recommended that where there is choice between two MCOs, at least one MCO must offer the full scope of services, including family planning services.

Response: Unlike the case of the Medicare program, the Congress chose not to require that MCOs agree to contract to provide particular services. The text for a comprehensive contract in section 1903(m)(2)(A) makes clear that the MCO and the State have the discretion to decide which Medicaid services will be covered under the MCO's contract. Also, in the case of family planning services, under section 1902(a)(23), an MCO is not permitted to restrict an enrollee to using the MCO's network providers for family planning services. This creates an incentive for MCOs to exclude family planning services from their contracts, since they have no control over when and where such services are obtained. Whether for this reason, or for reasons of conscience, some MCOs are likely to not agree to cover family planning services under their contracts.

However, § 438.10(d) and (e) of this final rule with comment period, enrollees and potential enrollees must be informed of "benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided," and in the case of enrollees "the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers." We believe that these provisions ensure that enrollees have information on the availability of, and access to, required family planning services, regardless of whether these services are included in their MCO's contract.

Comment: We received a few comments recommending that each MCO offer each beneficiary a choice between at least two providers who are geographically, culturally, and linguistically accessible.

Response: This final rule with comment period contains requirements addressing geographic, cultural, and linguistic accessibility. Section 438.206, contains a requirement that MCOs maintain a network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) specifically requires that MCOs consider the geographic location of beneficiaries in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs and PCCMs make information available in languages in use in the enrollment area. MCOs, PHPs, and PCCMs are also required to provide translation services under § 438.10.

Definition of Rural Area

For the purpose of applying the exception for "rural areas" in 1932(a)(3)(B) to the choice requirement in section 1932(3)(A), the notice of proposed rulemaking proposed three definitions of a "rural area." The choices included (1) any area outside an "urban area" as defined in § 412.62(f)(1)(ii), the definition found at § 491.5(c), or an alternative State or HCFA definition. After considering all comments, in this final rule with comment period we define a rural area as any area other than an "urban area" as the latter is defined in § 412.62(f)(1)(ii) of the HCFA rules.

Comment: There was no clear consensus among commenters. A few commenters said our proposed provision was overly broad, and recommended that HCFA make clear in the final rule with comment period that the rural exception would be very

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narrowly construed. Others said there should be no State or HCFA definition apart from the two Medicare definitions. One commenter said we should keep the choice of three definitions, but if we are required to choose only one, we should use the definition found at Part 412 of this chapter. Other commenters said they agree with our prohibition against designating an entire State as a rural area, but one commenter said in some cases it may be appropriate to designate an entire State as a rural area. One commenter said we should choose a single definition of rural, but indicated no preference as to which definition we chose.

We also received a number of recommendations of alternative definitions or criteria. One commenter said any area with at least two qualified bidders should not be considered rural. One commenter said we should allow any medically under served area to be considered rural, and one commenter recommended that we use the Office of Management and Budget definition of non-metropolitan counties as a proxy for rural areas. One commenter recommended that we clarify that any area that is part of a Metropolitan Statistical Area could not be considered rural under a State or HCFA definition.

Response: We have considered all of the comments and decided to accept the commenter's suggestion that a single definition be adopted, as well as the suggestion by the commenter that if a single definition is adopted, we adopt the first definition incorporating the definition of "urban area" in part 412.

Exception for Rural Area Residents

Proposed § 438.52(c), outlined the rural exception to the requirement for choice. Under the proposed rule, in a "rural area" as defined in § 438.52(a), a State may limit beneficiaries to one MCO provided the beneficiary—

- Can choose from at least two physicians or two case managers; and
- Can obtain services from any other provider under any of the following circumstances:

(1) The service or type of provider the enrollee needs is not available within the MCO network.

(2) The provider is not part of the network, but has an existing relationship with the enrollee.

(3) The only plan or provider available to the enrollee does not, because of moral or religious objections, provide the services sought by the enrollee.

(4) The State determines that other circumstances warrant out-of-network treatment.

In the final rule with comment period, in response to comments discussed below, § 438.52(b)(2)(ii)(D) also provides that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. Also in response to comments, we have revised the provision permitting a beneficiary to go out of plan to a provider with "an existing relationship with an enrollee" to be limited to cases in which the provider is the "main source of a service."

Comment: We received a few comments on the overall issue of whether a rural exception should exist. One commenter agreed with the rural exception, while other commenters disagreed. One of these commenters said that in cases where there is only one MCO, States should be required to offer higher capitation rates in order to entice more MCOs to join the market. Other commenters said that in rural areas, States should be required to offer a PCCM option if they cannot get two MCOs to bid. One of these commenters also said States should ensure that primary care providers in rural areas should receive high enough capitation rates to cover their costs.

Response: The rural exception is provided by statute as a State option, and we thus have no authority to deny States this option by either requiring a second managed care entity (a PCCM) or mandating that payment be increased enough to attract a second MCO.

Comment: A few commenters said they do not believe HCFA should allow plans that do not offer family planning services to serve as the single MCO in a rural area. One commenter pointed out that if the only plan available does not offer family planning services, and a pregnant enrollee desires a cesarean section and a tubal ligation, the enrollee would be required to have her cesarean section through the MCO and would then have to go out of network for the tubal ligation, thus having a separate surgical procedure that would subject her to undue risk. Other commenters said the final rule with comment period should specify that when rural enrollees go out of plan for a service that is not offered by the MCO, they should also be able to get "related services" out of network. The commenters said this would assist pregnant women who desire a tubal ligation simultaneously with a cesarean section delivery.

Response: As discussed above, the statute allows MCOs to decide which services they choose to agree to cover under their contracts. However, in the case of a single MCO in a rural area, these decisions could affect the health of a Medicaid beneficiary in the manner suggested by the commenter. Thus, as noted above, in response to these comments, we have provided in § 438.52(b)(2)(ii)(D) that enrollees may also go outside the network for services if he or she needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all of the related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Comment: A number of commenters recommended that we add language to § 438.52(b) requiring that rural enrollees have a choice between two physicians or case managers. One commenter said we should require that the two physicians or case managers are "qualified to provide the beneficiary with appropriate and necessary health care services consistent with the beneficiary's initial assessment and treatment plan." One commenter said that in the case of enrollees with HIV, they should have a choice between two PCPs who are qualified and experienced in providing HIV/AIDS care. One commenter said the PCPs should be within 30 minutes or 30 miles from the beneficiary, except in frontier areas. Another commenter said there should also be a requirement for choice between two specialists or the ability to continue existing provider relationships out of network, and the final commenter said if the choice is between two PCCM case managers, they should be affiliated with separate practices if possible. Another commenter said rural beneficiaries in general do not have enough protection. This commenter suggested that we add a new subsection to the final rule with comment period cross-referencing all other exemptions and requirements, such as geographic accessibility, language and cultural competency, etc.

Response: The comments listed above all pertain in some way to accessibility to qualified and experienced providers. As stated above, this regulation contains extensive requirements designed to ensure beneficiary access to services, and these requirements pertain to rural as well as non-rural managed care providers. The relevant requirements can be found in § 438.6 (Contracting requirements), § 438.10 (Information requirements), § 438.110 (Assurance of adequate capacity and services), and § 438.206 (Availability of services). Also, under § 438.52(b)(2) (rural beneficiaries have the ability to continue existing provider relationships under this regulation. In light of the above protections, discussed in detail elsewhere in this preamble, we do not agree that it is necessary to add additional language to § 438.52 in response to these comments.

Comment: One commenter suggested that we delete § 438.52(b)(2), which lists the reasons rural beneficiaries may go out of network. This commenter believes these provisions go beyond our statutory authority and are in some cases redundant because if a certain service is not available within the network, the MCO would be contractually obligated to pay for it anyway.

Response: We disagree with the commenter. Section 1932(a)(3)(B)(ii) of the Act, provides that rural beneficiaries can be limited to one MCO, if the MCO "permits the individual to obtain such assistance from any other provider in appropriate circumstances (as established by the State under regulations from the Secretary)." The Congress clearly intended for rural beneficiaries to access out-of-network services in appropriate circumstances, and clearly granted HCFA the discretion to define those circumstances in regulations. Section 438.52(b)(2) of the final rule with comment period extends these rights in a manner that recognizes both State flexibility and the importance of protecting enrollees.

Comment: We received one comment suggesting that the final rule include an additional reason beneficiaries can access out of network services. This commenter said the State should be required to let beneficiaries go out of network if treatment or services have been reduced or eliminated within a geographic area covered by the MCO.

Response: As discussed in section II. D. below, § 438.206(d)(5) allows beneficiaries to seek out-of-network treatment if the type of service or provider needed is not available within the network. We believe this language responds to the situation outlined by the commenter.

Comment: Another commenter suggested that we add a new subsection to the final rule outlining an additional reason beneficiaries can go out of network. This commenter suggested allowing beneficiaries to go out of network because "The only plan or provider available to the enrollee is not able, because of prior court-ordered (involuntary) receipt of services from that provider, to develop a therapeutic relationship with the enrollee for the provision of mental health services."

Response: We agree that in cases where the only available provider had previously treated the enrollee against his or her will, it would be difficult to establish a therapeutic relationship. We have decided not to add the suggested language to the final rule with comment period, however, because we believe the scenario outlined by the commenter would be covered by the existing language, particularly the section indicating that rural enrollees can go out of network in "other circumstances."

Comment: One commenter stated we should add clarifying language to this section indicating that when rural enrollees go out of network for services under the circumstances outlined in the regulation, they do not incur any additional cost.

Response: Section 438.106, Liability for payment, already covers these circumstances. Section 438.106(c) specifies that MCOs cannot hold Medicaid enrollees liable for "payments for services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO provided the services directly." We believe enrollees in rural exception areas going out of network in the circumstances outlined in this chapter are protected by this provision. Therefore, we do not believe it is necessary to include the suggested language in § 438.52(b)(2). However, if a beneficiary chooses to go out of network for reasons other than those outlined in the rural provisions, the beneficiary would be liable for payment for the service.

Comment: We received a few comments recommending that the provisions allowing beneficiaries to go out of network be rewritten to specifically address the needs of rural enrollees with disabilities who have multiple medical needs. The commenters are concerned that enrollees be able to preserve existing relationships with DME suppliers. In addition, one commenter said enrollees should be able to go out of network if the only provider available does not have experience with the individual's disability, a provider cannot meet the needs of an enrollee (for example, an enrollee needs a home health aide in the morning but the only agency in the network only has aides available mid-day), or the enrollee has had "previous problems" with the provider. In addition, this commenter said the rural exception should make clear that in border areas, the out of network provider can be in a different State if that provider is geographically closer.

Response: Regarding the comment about border areas, the Medicaid program already accommodates crossing State lines in circumstances in which this is consistent with traditional patterns of care. We do not expect that this regulation will disrupt or change this situation. Regarding the other situations mentioned by commenters, as we have stated previously, the ability to go out of network is meant to be interpreted broadly. We expect that in cases in which enrollees with disabilities can make a case that their needs are not well-served by the MCO, they would be allowed to go out of network by the State pursuant to § 438.52(b)(2)(A) or (E). However, we also expect that because of the breadth of these provisions, MCOs serving rural beneficiaries will make strong efforts to have a comprehensive network that meets the needs of all of their enrollees. Rural MCOs, like all other MCOs, are responsible for making sure they have a network adequate to meet the needs of their anticipated enrollment, and this includes individuals with disabilities.

Comment: We received a few comments recommending that the provisions allowing enrollees to go out of network be expanded. Some commenters said all enrollees in all mandatory and voluntary managed care systems should have the same rights to go out of network. One commenter said urban beneficiaries should be able to use FQHC services if they are enrolled in MCOs that do not offer FQHC services.

Response: We believe that where there is a choice between MCOs, it is not necessary to give beneficiaries the same rights to go out of network that exist in rural areas with a single MCO. Regarding the FQHC comment, FQHC services are already a mandatory service under the Medicaid program. FQHC services must be available through a State's managed care program, or be provided as an out-of-network option. We expect beneficiaries who have a choice of MCOs and who wish to use FQHCs to choose their MCO accordingly. In addition, beneficiaries who either choose or are enrolled by default into an MCO that does not include an FQHC have 90 days to disenroll without cause.

Comment: We received a number of comments stating that the provision allowing beneficiaries to go out of network if the service or type of provider desired is not available within the MCO network is too broad. One commenter simply said the provision is

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inappropriate. Other commenters said that this should be permitted only if the MCO does not have other in-network alternatives.

Response: In providing for a rural exception to choice, the Congress clearly intended to protect enrollees by giving them the right to go out of network in appropriate circumstances. We expect States to monitor their managed care programs, particularly in rural areas, to ensure that enrollees have access to appropriate services. We are not revising § 438.52(b)(2) in response to these comments.

Comment: We received a number of comments recommending that we clarify what is meant by not available within the network. The commenters recommended that we define "available" to encompass such factors as geographic accessibility, cultural and linguistic competency, appointment waiting times, and appropriateness of provider (for example, pediatric verses adult specialist). One of the commenters also recommended that we make it clear that when we refer to providers in this provision, we are including safety-net providers and clinics.

Response: We do not agree that it is necessary to amend the regulation. Under this final rule with comment period, rural MCOs must meet many new requirements addressing geographic, cultural, and linguistic accessibility. Section 438.207(b)(2) requires that MCOs maintain network of providers sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees. Section 438.206(d)(1)(v) requires that MCOs consider the geographic location of enrollees in developing their provider networks. Section 438.206(e)(2) requires that MCOs deliver services in a culturally competent manner, and § 438.10 requires that States and MCOs, PHPs, and PCCMs make information available in languages in use in the enrollment area. In the instance of a service for which there is no available provider who meets the above provisions, that service would not be considered available, and under § 438.206(d)(5), the enrollee would be able to obtain the service out-of-network. Regarding the comment about appropriateness of provider, we do expect States and MCOs to consider this when evaluating requests to obtain needed services out-of-network. In evaluating such requests, States may consider such factors as age, medical condition, general medical practice in the area, and overall availability of specific providers. Regarding the clinic and safety-net services, we have decided not to amend the regulation in response to this comment. This provision is meant to address beneficiary choice, and is not meant to single out certain types of providers for guaranteed participation.

Comment: A large number of commenters disagreed with giving rural beneficiaries the right to go out-of-network when they have an existing relationship with a provider who is not in the MCO network. Some commenters recommended that HCFA place a time limit on how long the relationship can be continued, and a few said the final rule should define what is meant by an existing relationship. Other commenters recommended that various limitations be placed on this provision, such as only allowing it when the beneficiary also meets one of the other criteria for going out-of-network; only permitting it when the individual has a chronic or terminal illness; only permitting it when the provider is in the MCO's service area; and permitting it only when a change in the provider relationship will result in an adverse health outcome. In addition, one commenter said it should be left to the MCO's discretion whether the relationship should be continued, and one commenter said the provider should be required to pass the MCO's credentialing process. One commenter said we should clarify that an existing relationship includes the example of a pregnant woman who initiated prenatal care with a provider before enrolling in the MCO.

Response: The requirement for choice in managed care programs is an important right granted to enrollees by the Congress. Where there is no choice, such as in rural areas with one MCO, The Congress intended for beneficiaries to have the protection of going out-of-network in appropriate circumstances, and directed the Secretary to publish regulations to specify the circumstances. However, we agree with the commenters who urged us to clarify what is meant by an existing relationship, and how long the relationship should be continued. Therefore, we amended the regulation to specify that this provision applies when the provider is the main source of a service to an enrollee and that the enrollee may continue to see the provider as long as the provider continues to be the main source of the service. We believe that these provisions cover a pregnant enrollee who, before enrolling in the MCO, had initiated prenatal care with a provider outside the MCO's network, and wished to continue seeing that provider.

Comment: We received a few comments recommending that we add to the scope of the provision allowing rural beneficiaries to go out of plan to a provider with whom they have an existing relationship. Some commenters recommended that the final rule clarify that this exception applies to specialists as well as primary care providers. One commenter said the final rule should specify the scope of services the out-of-network provider may provide. For example, this commenter said an obstetrician caring for a high-risk pregnant woman should be able to order tests without any limitation.

Response: In providing for this exception, and in further clarifying it, we clearly intend for specialists as well as PCPs to be included. We do not believe any further clarification is necessary. Furthermore, we intend for the scope of services provided by the out-of-network provider to be directly related to the beneficiary's overall condition and medical history, and we expect out-of-network providers and the MCO to share information regarding the patient's care for all treatment, because the MCO is ultimately responsible for payment. Again, we do not believe it is necessary to add language allowing providers the right to provide unlimited diagnostic and treatment services.

Comment: We received two comments recommending that the provision allowing rural beneficiaries to go out of network also apply to urban beneficiaries who want to go out of network to use Indian Health Service/Tribal providers/Urban Indian (I/T/U) providers.

Response: We disagree that it is necessary to add the suggested language to the regulation because Indian enrollees, whether in urban or rural areas, already have the right to access I/T/U providers outside of their networks in programs established under section 1915(b) or section 1115 authority, and in voluntary programs. Neither the BBA nor this regulation removes that authority. Additionally, Indians are exempt from mandatory enrollment into an MCO or PCCM under the new section 1932(a) authority, except where the MCO or PCCM is an I/T/U provider.

In responding to this comment, we have noted that Urban Indian health programs were inadvertently omitted from the list of entities into which an Indian eligible could be mandatorily enrolled under section 1932(a). In this Final rule with comment period, we have modified § 438.50(d)(2) to correct this omission.

Comment: One commenter recommended that we increase the State requirements for quality monitoring in areas falling under the rural exception.

Response: This regulation implements strong new quality requirements for Medicaid managed care arrangements. We expect States to aggressively monitor quality in all managed care programs, including those covered by the rural exception. We do not agree with the commenter that the quality requirements for rural programs should be different from the general quality requirements.

3. Enrollment and Disenrollment: Requirements and Limitations (Proposed § 438.56)

Applicability

Section 1932(a)(4) sets forth a number of requirements relating to enrollment and disenrollment in Medicaid managed care programs. Proposed § 438.56(a)(2) specified that most of the enrollment/disenrollment provisions apply to all MCO, PHP, and PCCM contracts, regardless of whether enrollment is mandated under a waiver or section 1932, or is voluntary. The only provisions in this section that apply only to programs under which enrollment is mandated under section 1932(a)(1)(A) are the limitations on enrollment and default enrollment provisions. (In the final rule with comment period, these Section 1932 provisions have been moved to § 438.50.)

Comment: We received a number of comments objecting to the proposed rule's provisions concerning the applicability of enrollment requirements. One commenter contended that the 90-day right to disenroll without cause, the disenrollment for cause provisions, and the appeals provisions should apply only to mandatory managed care programs under section 1932(a)(1)(A) of the Act. A number of other commenters did not believe a 12-month lock-in should be applied in cases of voluntary enrollment. Two comments appear to be based upon misunderstanding because the proposed rule as written already reflected their suggestions. (One comment urged us to apply subsections (e) through (h) of the proposed rule to PHPs, and one comment says subsections (b) through (d) should apply only to section 1932 programs.) The commenters who indicated we applied various provisions too broadly would like HCFA to restrict the applicability of the provisions to mandatory enrollment under section 1932 programs.

Response: The BBA amended section 1903(m)(2)(A) of the Act to require, in a new paragraph (xi), that MCOs and MCO contracts "comply with the applicable requirements of section 1932." The BBA also amended section 1903(m)(2)(A)(vi) to require that contracts with MCOs permit "individuals to terminate * * * enrollment *in accordance with section 1932(a)(4),*" and must provide for "notification in accordance with [that] section." (Emphasis added.) These requirements apply to all MCO contracts, regardless of whether enrollment in the contracts is voluntary, mandated under a waiver, or mandated under section 1932(a) of the Act. The enrollment requirements the proposed rule applies to MCOs all either apply by their own terms to MCOs, or are incorporated as set forth above under section 1903(m)(2)(A)(vi) of the Act.

In the case of primary care case managers, section 1905(t)(3)(F) similarly requires that primary care case manager contracts comply with "applicable provisions of section 1932," while section 1905(t)(3)(F) requires that enrollees be provided the "right to terminate enrollment in accordance with section 1932(a)(4)." Again, this provision is not limited to cases in which the primary care case manager is participating in a mandatory program under section 1932(a).

The only provisions of section 1932 of the Act that not are applicable to all MCO, PHP, and PCCM contracts are those which include the language "In carrying out paragraph (1)(A)," which refers to the statutory authority to establish mandatory managed care programs through the State Plan Amendment process. These are the provisions we have designated as applicable to section 1932(a)(1)(A) programs only. In order to prevent any future confusion regarding which provisions apply only to section 1932(a)(1)(A) programs, we are in this final rule with comment period moving all such provisions to § 438.50.

With respect to the commenters who believed that the 12-month lock in should not apply when enrollment is voluntary, again, this result is dictated by the statute. Under section 1903(m)(2)(A)(vi) of the Act, an enrollee in an MCO has the right to disenroll only to the extent this is provided for in section 1932(a)(4) of the Act, which permits disenrollment without cause only in the first 90 days and annually thereafter. Under section 1915(a) of the Act, where enrollment is voluntary such an arrangement will not be considered to violate the general freedom of choice provision in section 1902(a)(23).

Disenrollment by the Recipient: Timing

Section 438.56(e) of the proposed rule (recodified at § 438.56(c) in the final rule with comment period) set forth the general rules regarding disenrollment rights. These provisions apply to all situations in which States choose to restrict disenrollment. Beneficiaries are permitted to disenroll for cause at any time, without cause during their first 90 days of enrollment, and annually thereafter. In certain circumstances (rural areas with only one MCO, or areas in which the statute permits contracting with only a single county-sponsored HIO), these rules apply to changes between individual physicians or primary care case managers.

Comment: We received one comment suggesting that the proposed rule did not go far enough in setting up a consistent process for disenrollment. The commenter recommended that HCFA include a requirement in the final rule that the disenrollment (and enrollment) process should be consistent across all MCOs, and PCCMs in a State.

Response: We are sensitive to the concern that to the greatest extent possible, a State's program should be consistent in order to avoid confusion and misunderstanding on the part of enrollees. We encourage States to establish uniform procedures in the area of enrollment and disenrollment, and we note that this section sets forth rules regarding the process that must be followed in all Medicaid managed care programs that restrict disenrollment in any way. We believe the proposed regulation provided a great degree of consistency in this process. We also believe the information requirements in § 438.10 and the notice requirements in § 438.56 will alleviate any potential confusion among enrollees. Therefore, we have decided not to change the final rule with comment period in response to this comment.

Comment: Several commenters noted that the proposed rule did not include a provision providing for MCO or PCCM disenrollments of beneficiaries for cause. Commenters recommended that HCFA adopt the language in the Medicare+Choice regulation allowing MCOs and PCCMs to request disenrollment of beneficiaries for uncooperative or disruptive behavior, or for fraudulent behavior.

Response: The previous regulation (at § 434.27) required PHP and HMO contracts to specify the process by which they could request that the State disenroll beneficiaries. It appears that the omission of this provision in § 438.56 was simply an oversight. In response to this comment, we are including a provision in this rule allowing MCOs, PHPs, and PCCMs to request disenrollment of enrollees. Section 438.56(b) of the final rule with comment period requires that MCO, PHP, and PCCM contracts specify the

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reasons for which an MCO, PHP, or PCCM may request disenrollment of an enrollee. This section also prohibits MCOs, PHPs, and PCCMs from requesting disenrollment on the basis of the enrollee's adverse changes in health status, diminished mental capacity, utilization of medical services, or uncooperative or disruptive behavior resulting from an enrollee's special needs. The only exception to this rule is where the beneficiary's continued enrollment in the MCO, PHP, or PCCM seriously impairs the entity's ability to furnish services to either this enrollee or other enrollees in the entity.

Contracts must also specify how the MCO, PHP, or PCCM will assure the State agency that it will not request disenrollment for reasons other than those permitted under the contract. As suggested by the commenter, these changes reflect the provisions contained in the Medicare+Choice regulations.

Comment: We received comments regarding the special circumstances of persons who are homeless, particularly related to their transience and special needs in obtaining information critical in choosing an MCO or PCCM.

Response: We agree that persons who are homeless present a unique situation. Due to the lack of a mailing address and general transience, it is likely that they may not receive information about choice of MCOs or PCCMs or the fact they have been enrolled in an MCO or PCCM until they attempt to receive care. As a protection for this population, we are revising the regulation to include, as a cause for disenrollment, (under paragraph (d)(2) of the section) the fact that a person was homeless (as defined by the State) or a migrant worker at the time of an enrollment by default. This is in addition to all other disenrollment rights offered to all enrollees.

Comment: We received many comments asserting that cause is not adequately defined. Commenters urged HCFA to publish a broad definition of cause. Comments suggesting what would constitute cause included—inadequacy of an MCO's medical personnel in treating HIV; inability to access primary and preventive care; inability to access family planning services; the MCO's failure to offer family planning services; geographic, cultural, and linguistic barriers; an enrollee's PCP has left the MCO; lack of access to pediatric and pediatric subspecialty services; the need for the enrollee to access local Indian health care services that are not available in the MCO; inability to obtain information in an accessible format; and inability to receive services appropriate to the medical condition. In addition, one commenter suggested that States be required to "look behind" HIV-related disenrollment requests to determine whether there are systemic problems in serving individuals with HIV.

Response: We agree that cause should be more specifically defined, and have revised § 438.56(d)(2) to provide examples that will be deemed to constitute cause. These reasons for disenrollment are similar to the grounds for going out of plan where the rural area exception applies. Specifically, under § 438.56(d)(2), an enrollee may disenroll for cause if (1) the enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default, (2) the MCO or PCCM does not, because of moral or religious objections, cover services the enrollee seeks, (3) the enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk, and (4) other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

Further regarding the related services provision, we recognize that enrollees in this situation who are otherwise satisfied in their MCO or PHP may not want to disenroll in order to receive the related services together. We note that § 438.206 specifies that if the network cannot provide the necessary services covered under the contract (including related services) needed by the enrollee, these services must be adequately and timely covered out-of-network for as long as the MCO or PHP is unable to provide them. Under this provision, the enrollee would be able to avoid the need to disenroll from his or her current MCO or PHP but could still receive the related services concurrently.

Comment: One commenter pointed out that while a later section of the proposed rule speaks to the effective date of for-cause disenrollments, it does not address the effective date for without-cause disenrollments. The commenter recommended that there be a required effective date, and that it be no later than the timeframe provided for in the for-cause section, that is the beginning of the second calendar month following the month in which the request for disenrollment was made.

Response: We realize that the heading of § 438.56(f) in the proposed rule, "Procedures for Disenrollment for Cause," suggests that we intended to limit these requirements to disenrollment for cause. However, HCFA did not intend that States be required or encouraged to set up a different process based upon whether or not the disenrollment request is for cause. Therefore, we have retitled the two paragraphs which now contain the same provisions (§ 438.56(d) and (e)) as "Procedures for Disenrollment" and "Time-frame for disenrollment determination"

Comment: We received a number of comments disagreeing with giving enrollees the right to disenroll without cause for 90 days after enrolling in (or being default enrolled into) an MCO, PHP or PCCM. Several commenters believed that the 90-day period was too lengthy, but one commenter stated that "[t]he removal of the right to disenroll at any time troubles us." The commenters opposing the 90-day period did not offer suggestions of a shorter time period. One commenter recommended that there should only be one 90-day period, and not a new opportunity to disenroll without cause every time a recipient enters a new MCO, PHP, or PCCM.

Response: The requirement to allow beneficiaries to disenroll without cause for 90 days appears in section 1932(a)(4), so we do not have authority to remove or alter this right, or the length of the 90 day time period. As for the question of whether there is a new 90-day period with each new MCO, PHP, or PCCM enrollment, the statute refers to enrollment with the MCO or PCCM and not initial enrollment in the managed care program. Therefore, there is no room for interpretation of that provision as just allowing for a single 90-day disenrollment period without regard to whether the beneficiary enrolls in a new MCO or PCCM.

Comment: A number of commenters disagreed with our interpretation that the right to disenroll for 90 days without cause only applies the first time a recipient is enrolled in a particular MCO, PHP, or PCCM. The commenters recommended that the final rule provide for a right to disenroll for 90 days each time a recipient enters an MCO, PHP, or PCCM, even if he or she has been enrolled in that MCO. PHP, or PCCM previously. Commenters indicated that this is justified on the basis that there could have been substantial changes in an MCO, PHP, or PCCM since the recipient's previous enrollment.

Response: The statute does not make clear whether the 90 day period following notice of enrollment with an MCO or PCCM applies only once, when the individual is initially enrolled with the MCO or PCCM, or each time the individual enrolls with an MCO or PCCM, even if he or she has been enrolled in the MCO or PCCM before. We believe that the purpose of the extended 90 day disenrollment period is to allow the beneficiary to become familiar with an MCO or PCCM before deciding whether to remain enrolled. Once a beneficiary has been an enrollee of an MCO or PCCM this rationale no longer applies. While it is true that an MCO, PHP, or PCCM might change in the interim, this is equally true of an MCO, PHP, or PCCM that the enrollee might remain enrolled with. A beneficiary would still have an annual opportunity to disenroll in both cases. We believe that the interpretation the commenter has suggested would create a potential for abuse by providing an incentive for frequent changes in enrollment that could result in multiple 90 day periods for the same MCO, PHP, or PCCM.

Comment: The proposed rule specifies that the 90-day clock for enrollees to disenroll without cause begins upon the actual date of enrollment, and further provides that if notice of enrollment is delayed, the State may extend the 90-day period. All comments we received on this issue urged HCFA to adopt what they consider to be stronger language. The commenters suggested that HCFA provide that the 90-day disenrollment period begins when notice of enrollment is actually received. Furthermore, they contended that States should be required, rather than permitted, to extend the 90-day period in the event that notice to the enrollee is delayed. A couple of commenters also believed that States and MCOs, PHPs, and PCCMs should be required to guarantee that the notice is actually received; and in the case of homeless individuals, that the notice is received prior to the initial assessment by the MCO, PHP, or PCCM.

Response: By providing for the 90-day period to begin when the enrollment takes effect, HCFA was attempting an interpretation of the statute that would offer maximum protection to enrollees. That is because in many States, notice of enrollment may be sent to the recipient up to 60 days before the effective date of the enrollment. However, because there is such a high level of concern that beneficiaries will be harmed in cases when notice of enrollment is mailed after the effective date, we are adding regulation text providing that the 90 day period begins upon the enrollment, or the date the notice is sent, whichever is later. Regarding the request that States and MCOs, PHPs, and PCCMs be required to guarantee that notices are actually received, we do not believe it is appropriate to require such a guarantee when there are certain factors beyond the control of the State or MCO, PHP, or PCCM. However, it is in a State's best interest to make the maximum effort possible to ensure that notices are received, and we encourage States to take measures to ensure this to the best of their ability.

Comment: We received one question about whether States should be able to differentiate between different types of MCOs, PHPs, and PCCMs in the 12-month lock-in provision. The commenter recommended that States be allowed to have different lock-in periods depending upon whether the enrollee was locked into a PCCM or an MCO.

Response: Section 1932(a)(4), which applies to both MCOs and PCCMs, requires that enrollees be allowed to disenroll for cause at any time, and without cause during the initial 90 days, and "at least every 12 months thereafter." As long as no enrollee is locked-in for a period of more than 12 months, there is no prohibition against States implementing different lock-ins for MCOs, PHPs, and PCCMs.

Comment: A number of commenters said they believe the provision for an annual disenrollment opportunity may create confusion. The commenters suggested that States be required to hold an annual open enrollment period.

Response: The statute requires States to permit enrollees to disenroll from an MCO or PCCM for a 90-day period at the beginning of enrollment, and "at least every 12 months thereafter." As long as the State meets the requirement to inform beneficiaries of their right to terminate or change enrollment at least 60 days in advance, the State may structure the annual opportunity in whatever way it sees fit. This may involve holding an annual open enrollment period as the commenters suggested, or individually offering each recipient an opportunity to change enrollment upon his or her enrollment anniversary.

Comment: Section 438.56(e)(2) of the proposed rule (moved to § 438.52(c) in the final rule) provided that in rural areas with only one MCO, States may meet the disenrollment requirements by allowing enrollees to change physicians or case managers within the MCO. A commenter contended that PCCM enrollees in rural areas should be allowed to disenroll and transfer to fee-for-service Medicaid if only a single PCCM is available, since section 1905(t)(3)(E) of the Act requires that a beneficiary have a choice.

Response: Section 1905(t)(3)(E) of the Act requires that primary care case manager contracts permit disenrollment in accordance with section 1932(a)(4) of the Act. As defined in § 438.2, a primary care case manager may be an individual physician or a group of physicians. Therefore, a State arguably would be complying with the requirement in section 1932(a)(4) of the Act if it allows enrollees to change primary care case managers since (to the extent these individual managers are each considered managed care entities.) More importantly, however, we believe that section 1932(a)(3)(B) provides an exception not only to the rule set forth in section 1932(a)(3)(A) of the Act that an enrollee have a choice of more than one MCO, but as an implicit exception to the requirement in section 1932(a)(4)(A) of the Act that a beneficiary be able to disenroll from an MCO. Thus, even if the State has only a single MCO contract in a rural area pursuant to section 1932(a)(3)(B) of the Act, we believe that the requirements in section 1932(a)(4) of the Act would be satisfied by permitting disenrollment from an individual primary care physician. The authority in section 1932(a)(3)(B) of Act to permit the choice of entity requirement in section 1932(a)(3)(A) of the Act to be fulfilled by providing a choice of individual physicians would be meaningless if section 1932(a)(4) of the Act were nonetheless construed to permit an individual to disenroll from an MCO, as opposed to changing individual physicians. Thus, where the conditions in section 1932(a)(3)(B) have been satisfied, the requirement in section 1932(a)(4), as made applicable by section 1905(t)(3)(E), is satisfied by permitting beneficiaries to disenroll from their primary care physician.

Procedures for Disenrollment

Section 438.56(f) of the notice of proposed rulemaking set forth the required procedures for processing disenrollment requests. (We note here that the proposed rule referred to "Procedures for disenrollment for cause," but as noted above, in response to comments, we have renamed the two paragraphs containing material from proposed § 438.56(f) "Procedures for disenrollment" and "Timeframe for Disenrollment Decisions.") In § 438.56(f), we proposed that enrollees be required to submit written requests for disenrollment to the State agency or to the MCO, PHP, or PCCM. MCOs, PHPs, and PCCMs are required to

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submit copies of disenrollment requests to the State agency. Proposed § 438.56(f) provided that while MCOs, PHPs, and PCCMs may approve disenrollment requests, only the State agency may deny such requests.

In cases where the State agency receives the request, under proposed § 438.56(f) it could either approve the request or deny it. Requests for disenrollment had to be processed in time for the disenrollment to take effect no later than the first day of the second month following the month in which the enrollee made the request. Proposed § 438.56(f) further provided that if the State or MCO, PHP, or PCCM does not act within the specified timeframe, the request was considered approved.

Response: This comment is quoting language from proposed § 438.56(e)(1), which is retained in the final rule with comment period in § 438.56(c). This language states that if the State chooses to limit or restrict enrollment, it must permit enrollment without cause in the first 90 days an individual is enrolled in an MCO, PHP, or PCCM, and annually thereafter. This rule would be irrelevant if a State chose not to limit disenrollment at all. To clarify our position in response to the commenter, if a State wishes to permit disenrollment at any time, or more frequently than the minimum disenrollment rights required under § 438.56(c), the same rules on notice and effective date apply as apply when a State "chooses to restrict disenrollment."

Comment: Several comments felt that the final rule should specify that disenrollment requests may be submitted by either the enrollee or his or her representative. In addition, others felt that we should delete the reference to 20 CFR part 404, subpart R in the definition of authorized representative. The commenters believed that these rules, which generally govern representative payees for Social Security programs, have little, if any, relevance to the Medicaid program and that these requirements would limit assistance to beneficiaries in the Medicaid managed care enrollment process. They indicated that current rules recognize that beneficiaries may require assistance in a variety of circumstances and provide that applicants and recipients may obtain that assistance from a variety of sources. For example, commenters pointed out that in formal proceedings such as fair hearings, Medicaid beneficiaries enjoy the right to "represent themselves, use legal counsel, a relative, friend or other spokesman." (42 CFR 431.206). If the applicant is incompetent or incapacitated, anyone acting responsibly for the applicant can make application on the applicant's behalf (42 CFR 435.907). People with disabilities who are incompetent or incapacitated can currently be represented by anyone acting responsibly on their behalf. Commenters indicated that State law is available, and is used to step in when a person cannot make medical decisions on his or her behalf.

Response: We concur with the commenters and have modified § 438.56(d) to add "his or her representative" to enrollee. In addition, we have deleted the reference to 20 CFR Part 404. We have also deleted the reference to "authorized", using only the term representative to allow for a broad range of representatives, consistent with existing policies and practices. The definition, which has been moved to § 430.5, now reads "Representative has the meaning given the term by each State consistent with its laws, regulations, and policies."

We agree with the commenters that the appropriateness of a representative depends on the significance of the activity for which they are acting as representative, so that States should have the flexibility to determine who may represent the beneficiary in various activities. The State may establish various criteria depending upon the situation (for example, disenrollment requests, choice of health plans, receiving notices, filing grievance and appeals (including requests for expedited review, being included as a party to the appeal and the State fair hearing, receiving marketing materials, being provided opportunity to review records, etc.) In determining who may represent beneficiaries, we anticipate that States will provide special consideration for individuals with cognitive impairments, who are unable to appoint their own representatives, but who may be especially vulnerable and require assistance in accessing the protections offered in these regulations.

Comment: A number of commenters disagreed with the requirement that disenrollment requests be submitted in writing, contending that this may present a barrier to some enrollees, and that the process should be as barrier-free as possible.

Response: We agree and are interested in reducing or eliminating barriers wherever possible. Therefore, § 438.56(d) has been amended to specify that disenrollment requests may be written or oral. Further, we note that States cannot impose a requirement that beneficiaries appear in person to request disenrollment.

Comment: We received a number of comments relating to the time allowed for processing disenrollment requests. The only references to a timeframe appeared in the proposed rule at § 438.56(f)(2)(ii) and § 438.56(f)(4)(i). (These sections are redesignated as § 438.56(d)(3)(ii) and § 438.56(e)(1) in the final rule.) Disenrollment requests, if approved, must take effect no later than "the first day of the second month after the enrollee makes the request." (This is re-wording of previous statutory language, formerly found at section 1903(m)(2)(A)(vi) of the Act, which required disenrollment requests to be effective at the "beginning of the first calendar month following a full calendar month after the request is made for such termination." This specific language was removed by BBA and was not replaced with any alternative timeframe.) Commenters urged HCFA to spell out a more specific list of requirements relating to processing of requests. Although not all comments suggested a specific timeframe, most urged an "expedited" process for urgent or emergency situations. Commenters who did specify a timeframe for urgent or emergency situations indicated that requests should be required to be processed within 3 or 5 days. One commenter said disenrollment requests on behalf of children with special health care needs should be processed within 72 hours. It is important to note that the comments addressed "processing" of disenrollment requests, and not the effective dates. It is safe to assume, however, that the commenters would support an expedited effective date as well as expedited processing.

Response: Because of the removal of the effective date requirement in section 1903(m)(2)(A)(vi) of the Act, the statute is silent on how long the disenrollment process should take.

In response to the above comments, we believe that other beneficiary protections within this final rule with comment period, for example § 438.206(d)(5), provide adequate protection and access to necessary medical services covered under the contract out-of-network for as long as the MCO pro PHP is unable to provide them.

Comment: One commenter recommended that HCFA require States to establish an Ombudsman program to intervene in the disenrollment process.

Response: We are sensitive to the need for enrollees to have adequate protection in the enrollment and disenrollment process. This is particularly a concern for those who may have limited experience with managed care systems. We believe we have built numerous protections into

§ 438.56, including a provision for an appeals process when disenrollment requests are denied. In addition, it is important to note that many States use enrollment brokers, who act as independent third parties and assist enrollees in making their choice of managed care organizations. We believe that it is not necessary to require States to establish Ombudsman programs, although we would encourage them to do so.

Comment: One commenter believed the provision describing how MCOs, PHPs, and PCCMs should process disenrollment requests was too prescriptive. The commenter felt we should allow States to individually develop the process for MCO, PHP, and PCCM handling of disenrollment requests. However, other commenters felt this provision was too flexible, and recommended that MCOs, PHPs, and PCCMs not be permitted to process disenrollment requests. These commenters recommended that only the State or an independent third party, such as an enrollment broker, be permitted to handle disenrollment requests.

Response: Disenrollment is an important right granted to beneficiaries by the Congress, especially in an environment in which States can now require a lock-in period of up to 12 months. The consistent process required under this regulation is intended to guarantee that beneficiaries will be able to exercise this right as intended by the Congress. However, the statute is silent on certain aspect of disenrollment, including who should process such requests. Allowing MCOs, PHPs, and PCCMs to process requests is longstanding policy, and is based upon the principle of State flexibility, because States are closest to the situation and should be aware of whether such a policy would be beneficial to enrollees.

Further, we understand the concern that MCOs, PHPs, and PCCMs may have an incentive to discourage beneficiaries from disenrolling, or to disenroll more costly beneficiaries, but we believe adequate safeguards have been built into the process to protect enrollees. For example, MCOs, PHPs, and PCCMs may approve disenrollment requests, but they may not disapprove them. If an MCO, PHP, or PCCM does not take action to approve a request, it must refer the request to the State agency for a decision. States are also required to give enrollees who disagree with disenrollment decisions access to the State fair hearing system. It is important to note, also, that involving the MCO, PHP, or PCCM in the process may benefit enrollees. In many instances, the MCO, PHP, or PCCM may be able to resolve the problem that led the enrollee to request disenrollment, thus meeting the beneficiary's needs while preventing the necessity to disenroll. In addition, we expect that MCOs would track reasons for these requests as part of their quality improvement programs.

In this rule we believe we have taken the interests of beneficiaries and States into account and balanced the need for beneficiary protection with the need for flexibility in program administration. We therefore disagree with the commenters, and have decided not to change this provision in the final rule with comment period.

Comment: A number of commenters asked for clarification of the requirement that MCOs, PHP, and PCCMs to notify the State if they do not take action on a request for disenrollment. Commenters recommended that the final rule be revised to provide that MCOs, PHPs, and PCCMs are required to notify the State when they disapprove requests, as well as when they do not take action. In addition, one commenter proposed that HCFA require the State to aggressively monitor MCO, PHP, and PCCM denials of disenrollment requests. These commenters apparently did not understand that MCOs, PHPs and PCCMs would not be permitted to disapprove disenrollment requests.

Response: We disagreed with the commenters who argued the provision (re-designated as § 438.56(d)(5) in the final rule with comment period) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their programs and beneficiaries. We do agree, however, that there are cases where requiring the use of the internal grievance process may not be appropriate, therefore, we have specified that in cases expedited disenrollment, this provision does not apply.

Comment: Proposed § 438.56(f)(3) provided that States may require beneficiaries to use the internal MCO grievance process before making a determination on a request for disenrollment if a delay would not pose jeopardy to the enrollee's health. Some commenters disagreed with this provision, while another recommended that enrollees be required to use the internal grievance process. Other commenters said enrollees should be allowed to go straight to the State's fair hearing process for disenrollment requests. Still other commenters commented proposed that HCFA clarify that the exception for jeopardy to health should apply in cases in which the harm to an enrollee's health may not become apparent until later. Also, the commenter recommended that we include language indicating that in the case of pregnant women, jeopardy to the health of the fetus also be considered. Another commenter recommended that in the case of children, the delays that would jeopardize development be addressed.

Response: We disagreed with the commenters who argued the provision (redesignated as § 438.56(d)(5) in the final rule) should be deleted. We have decided to retain the provision for two reasons. First, the internal grievance process can eliminate the need to disenroll by resolving the issue that led to the disenrollment request. We consider this to be beneficial from a continuity of care standpoint, as well as a quality standpoint. Secondly, we believe that States should have the flexibility to decide whether the internal grievance process is helpful in the context of disenrollment requests. States are in the best position to make this determination based upon their knowledge of their programs and beneficiaries.

Comment: The proposed rule requires disenrollment requests, if approved, to take effect no later than the first day of the second month following the month in which the enrollee makes the request. A number of commenters were dissatisfied with this provision and said it should be made more specific. One commenter recommended that the timeframes specified in the Subpart F (Grievance System) be applied to the disenrollment process. A number of commenters recommended that the timeframe be made more specific, with a number of recommendations that requests be processed within five days.

Response: As stated elsewhere, the required timeframe for processing disenrollments is meant to be a maximum, not a minimum. However, the regulation is also designed to be workable in all States, and States have very different systems capabilities to accommodate changes in managed care enrollment. As noted above, the timeframes we have adopted were in place for many years under section 1903(m) before the BBA. Because

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capitation payments are made on a monthly basis, most States may want to make disenrollments effective on the first day of a month. However, there is no prohibition against a State adopting a process that calls for timeframes that mirror those contained in Subpart F, as the commenter recommended.

Comment: Proposed § 438.56(f)(4)(ii) provided that if the State agency fails to make a determination on a disenrollment request within the specified timeframe, the request is deemed approved. Commenters recommended that HCFA make clear that the "deemed approved" language applies whether the State or the MCO, PHP, or PCCM is processing the disenrollment request.

Response: We agree that in cases where MCOs, PHPs, and PCCMs are permitted by the State to process disenrollment requests, the same timeframes should apply. Section 438.56(e)(3) of the final rule with comment period makes this clear.

Notice and Appeals

Section 438.56(g) of the proposed rule (§ 438.56(f) in the final rule with comment period) specified that States restricting disenrollment in Medicaid managed care programs must require MCOs and PCCMs to notify beneficiaries of their disenrollment rights at least 60 days before the start of each enrollment period and at least once a year. The paragraph further required that the State establish an appeal process for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

Comment: Some commenters disagreed with our approach of providing for MCOs and PCCMs to provide disenrollment rights notices, while others agreed with this general approach, but said we should impose additional requirements on States. In addition, some commenters believed that the provision is too prescriptive.

The commenters who disagreed with permitting MCOs and PCCMs to provide disenrollment rights notices said the final rule should provide that only the State or an enrollment broker should notify enrollees of their disenrollment rights. In addition, these commenters proposed that States be required to develop a model from which would be translated into all languages in use in the State, and field tested before being used in the Medicaid program.

Commenters who supported additional requirements said the regulation should require such notice to be provided upon initial enrollment, and that we should add language requiring that the notice be understandable to beneficiaries, consistent with the provisions of regulations that apply to the Medicare + Choice program.

The commenters who said the provision was too prescriptive recommended that we mirror the statutory language requiring one annual notice 60 days before the beginning of the enrollment period, and that the final rule should reflect that the enrollee handbook constitutes sufficient notice regarding disenrollment rights. One commenter suggested that we require "adequate notice" at a time specified by the State.

Response: Section 1932(a)(4) requires an annual notice at least 60 days before the beginning of an individual's annual opportunity to disenroll, but does not specify whether the MCO, PHP, PCCM or the State should send the notice. In response to the concerns raised by the commenters, and in recognition of the fact that some States may want to send the notices themselves (or employ an enrollment broker to perform this function), the final rule with comment period (at § 438.56(f)) requires the State to provide that enrollees are given written notice and ensure access to State fair hearing for those dissatisfied with a denial based on lack of good cause. Regarding the model form comment, this seems to be a reasonable approach and it is one we believe many States will employ, but we do not believe it is necessary or prudent to make this a regulatory requirement. Regarding the comment about mirroring the Medicare+Choice regulation, we believe that the statutory requirements provide sufficient protections to beneficiaries in this case. We also believe the information requirements found at § 438.10 provide a great degree to specificity in terms of how States will inform enrollees of their rights and responsibilities.

Comment: One commenter said we should require that the notice of disenrollment rights be sent to a representative payee, if one exists.

Response: The concerns of this commenter have been addressed by our decision to revise the final rule with comment period to provide that notice be provided to an enrollee or his or her representative. We note that a representative payee would not necessarily be authorized by the enrollee, or under State law, to represent the enrollee for purposes other than handling the benefits check. The final rule with comment period provides for notice to the representative.

Comment: Two commenters said that in addition to laying out notification requirements, the final rule should speak to the form used to request disenrollment. One commenter suggested that HCFA develop a model form, while the other suggested that HCFA require States to develop a single form for use throughout their program.

Response: We agree that in many cases, use of a standard form for disenrollments (both annual and for-cause) can aid in program administration. Many States will probably choose this approach, which they are free to do under this final rule with comment period as long as they also permit oral disenrollment requests as required under § 438.56(d). Because we believe that States may have legitimate reasons for choosing other approaches, however, and in light of our decision in response to comments to permit oral disenrollment requests, we have decided not to make this a regulatory requirement.

Comment: We received a number of comments on the requirement for States to establish an appeals process for enrollees who disagree with denials of disenrollment requests. The commenters said that when enrollees disagree with a State denial of a disenrollment request, they should be able to proceed directly to the fair hearings process without going through a separate appeals process.

Response: The cited provision was not intended to require States to establish a process separate from the fair hearing system. As noted above, § 438.56(f)(2) of the final rule with comment period requires that State fair hearings be made available.

Automatic Re-enrollment

Proposed § 438.56(h) reflected the provision in section 1903(m)(2)(H) of the Act specifying that if the State plan so provides, MCO and PCCM contracts must provide for automatic re-enrollment of individuals who are disenrolled only because they lose Medicaid eligibility for a period of two months or less.

Comment: One commenter pointed out that the proposed language did not specify how the enrollment/disenrollment provisions (such as timeframes for changing MCOs and PCCMs) in this rule apply in cases of automatic re-enrollment.

Response: Section 438.56(h) reflects a statutory provision that was enacted in 1990, and is simply being incorporated into regulation. The commenter is correct that the proposed rule did not address how to apply the enrollment/disenrollment provisions to enrollees who have a temporary loss of Medicaid eligibility. We have decided to add clarifying language to the final rule with comment period in § 438.56(c)(2)(iii) indicating that if a temporary loss of eligibility causes a recipient to miss the annual right to disenroll without cause, that right will be given upon re-enrollment. The enrollee would not, however, be entitled to a new 90 day period.

Comment: Two commenters pointed out that the preamble and regulations text of the proposed rule were in conflict regarding the re-enrollment timeframe. (The preamble indicated a window of up to four months.) The commenters indicated their preference for the four-month window. One commenter said they favor State flexibility and indicated they currently use a window of 90 days in their program. Two other commenters suggested a three-month window.

Response: Section 1903(m)(2)(H) provides a re-enrollment window of two months, therefore, the reference to four months in the preamble to the proposed rule was an error. States may use a shorter timeframe, but not a longer one.

4. Conflict of Interest Safeguards (§ 438.58)

Proposed § 438.58 required as a condition for contracting with MCOs that States establish conflict of interest safeguards at least as effective as those specified in section 27 of the Office of Federal Procurement Policy Act.

Comment: One commenter supported the provision as written requiring that there be conflict of interest safeguards on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or default enrollments.

Response: The final rule with comment period makes no change in the proposed language, other than to reflect the applicability of this provision, like other provisions in subpart B, to PHPs (see section 2. above).

Comment: Two commenters suggested that the safeguards be applied to all MCOs, PHPs and PCCMs, not just MCOs.

Response: Section 438.58 implements section 1932(d)(3), which specifies only contracts under section 1903(m) (i.e, contracts with MCOs). For this reason, we referenced only MCOs in proposed § 438.58. However, while the conflict of interest standards in § 438.58 are triggered by MCOs, in the sense that the State cannot enter into MCO contracts unless they are in place, they apply to anyone with responsibilities "relating to" MCOs or to the "default enrollment process specified in § 438.56," which would also include responsibilities for PCCMs. In addition, as discussed in section 2. above, we have made all provisions in subpart B except for § 438.50, applicable to PHPs.

Comment: One commenter agreed that these safeguards regarding conflicts of interest for State and local officials were necessary and welcome; however, it envisioned additional protections for any entity engaged in "determining or providing managed health care to Medicaid-eligible beneficiaries [should] have policy-making bodies that consist of at least 60 percent" of beneficiaries who will be served by the program.

Response: We do not believe that the regulation should be amended. Ensuring 60% Medicaid beneficiary representation on any board involved in determining how managed care will be provided to Medicaid eligibles is not feasible, given resource constraints at the State level. Furthermore, we have no statutory basis for requiring such representation.

5. Limit on Payment to Other Providers (§ 438.60)

Proposed section 438.60 prohibited payment for services which were covered under a contract between an MCO and the State, except for emergency and post-stabilization services in accordance with section 438.114(c) and (d).

Comment: All commenters maintained that the language in § 438.60 is too restrictive: the only exempted service are emergency services and post-stabilization services. Additional "exceptions" proposed were—family planning, school-based services, immunizations by local health agencies, certified nurse midwife services, tribal health provider services, and EPSDT services.

Response: We believe that the commenters have misunderstood this provision and that the exemption for emergency and post stabilization services in the proposed rule may have helped create this confusion. The intent of section 438.60 is to prohibit duplicate payments (once through capitation, once through FFS) for services for which the State had contracted with an MCO to provide. We believe that the exemption for emergency and post stabilization services was incorrect, since the MCO is obligated to cover and pay for these services for its enrollees. Thus, any payment by the State would be a duplicate payment. We are deleting this exemption from the final rule with comment period.

A State has in effect already paid for services that are included in an MCO's contract, and does not have an obligation to pay for them a second time, if a beneficiary obtains the services outside of the MCO's network.

In instances where out-of-network services may be authorized, e.g., the rural exception to the choice requirement, family planning, school-based services, immunizations, CMN or tribal services either the MCO or the state has the financial obligation to pay for the services. The State may pay for the services that were under the contract only if there is an adjustment or reconciliation made to the amounts paid the MCO in its capitation payments. In this situation, the services were not considered ultimately to be covered under the MCO contract. In situations where any of these services are carved out of the contracts (and the capitation rates paid the MCO) this is not an issue. State option to allow beneficiaries to go out-of-network for these services is not hindered by this section.

In addition, this provision precludes States from making additional payments directly to providers for services provided under a contract with an MCO or PHP, except when these payments are required by statute or regulation, such as with DSH or FQHC payments. We have clarified this provision accordingly in the final rule.

Comment: One commenter wanted HCFA to clarify what "service availability" actually means.

Response: For purposes of this provision, "available" would refer to services covered under the contract. A State is held accountable (§ 438.306) for ensuring that all covered services are available and accessible to enrollees—both services under the contract and those State plan services not included in the contract with the MCO.

6. Continued Service to Recipients (§ 438.62)

Proposed § 438.62 required States to arrange for continued services to beneficiaries who were enrolled in an MCO whose contract was terminated or beneficiaries who were disenrolled for any reason other than a loss of Medicaid eligibility.

Comment: We received a series of general comments that, overall, § 438.62 did not address the continuation of an enrollee's ongoing treatment when transitioning to managed care. Specifically, the commenters expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from FFS into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious

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and possibly irreversible consequences on an individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

Response: Section 438.308 addresses continuity and coordination of care requirements on MCOs, and comments on this provision generally are discussed in more detail in section II. D. below, discussing comments on proposed subpart E. We believe, however, that some comments on perceived inadequacies in § 438.308, specifically those expressing concerns about continued access to services as beneficiaries are transitioned from FFS into managed care, could be addressed in part by amending proposed § 438.62. Proposed § 438.62 represented a recodification of a longstanding requirement in part 434, at § 434.59, which required that provision be made for continued services when enrollment in an MCO or a PHP is terminated. This requirement was imposed under our authority in section 1902(a)(4) to specify methods necessary for proper and efficient administration. In response to the above comments, we believe it is appropriate to extend the requirement in § 438.62 (previously in § 434.59) to situations other than the transition out of an MCO or PHP.

We believe that most States already have mechanisms in place to transition enrollees into managed care from fee-for-service and from one MCO to another. However, we acknowledge the commenters' concerns that our proposed regulation does not address an enrollee's potential disruption of services, even for a short period of time, from the period of initial enrollment until the time of assessment by the new primary care physician or specialist in the receiving MCO or PHP.

In response to the large number of comments received on this issue, we are in this final rule with comment period, again under our authority in section 1902(a)(4), expanding the scope of § 438.62. The commenters referred to "managed care" generally, in asking that our regulations address "transitioning from FFS into managed care." We therefore are extending § 438.62 to enrollees in PCCMs, as well as MCOs and PHPs. The language of the proposed version of § 438.62 becomes paragraph (a) in the final rule with comment period, except with reference to MCOs, PHPs, and PCCMs rather than only MCOs, to afford enrollees of PHPs and PCCMs the same protections. The added paragraph (b) requires States to have mechanisms to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service.

We wish to emphasize that we are not mandating any specific mechanism that States must implement, nor are we mandating a specific list of services or equipment that must be covered during the transition period. However, we are requiring that the mechanism apply to at least the following categories of enrollees: (1) Children and adults receiving SSI; (2) children in Title IV–E foster care; (3) recipients aged 65 or older; (4) pregnant women; (5) any other recipient whose care is paid for under State-established, risk-adjusted, high-cost payment categories; and (5) any other category of recipients identified by HCFA. We also specify that the State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. Further, the State must ensure that the enrollee's ongoing health care needs are met during the transition period by establishing procedures to ensure that, at a minimum, the enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers; new providers are able to obtain copies of appropriate records consistent with applicable Federal and State law; and any other necessary procedures are in effect.

Comment: One commenter believes that it is unclear what level of effort by the State is sufficient to comply with the requirement. In an FFS environment, referral services are less comprehensive and "delays" might be defined differently.

Response: We believe that both terms, "without delay" and "delay" represent straightforward guidance and that no further changes are needed.

7. Monitoring Procedures (§ 438.66)

Proposed section 438.66 states that a State must have in place procedures for monitoring MCO practices and procedures with regard to enrollment/termination, implementation of grievance procedures, violations subject to intermediate sanctions (such as failing to provide services for which it has contracted), and violations for the conditions for FFP (such as conditions of FFP for enrollment broker services). As noted above, we have made this and most other provisions applicable to PHPs in response to comments. We therefore in this final rule with comment period have added "to the extent applicable, for PHPs," since not all of these provisions apply to PHPs.

Comment: One commenter noted that with regard to enrollment and termination practices, HCFA did not specify "beneficiaries" or "providers," but assumes we meant beneficiaries only.

Response: This section of the regulation does not implement a BBA requirement, and was incorporated from existing regulations without substantive changes. We did not intend to modify or expand its meaning. That said, we agree that paragraph (a) needs clarification, and in response to this comment, the final rule with comment period specifies that it applies to "recipient enrollment and disenrollment," and adds a paragraph (e) "All other provisions of the contract, as appropriate."

Comment: Another commenter states that the regulation should specify timeframes, and suggests annual monitoring for grievance procedures, and quarterly monitoring for enrollment/termination. This commenter furthermore notes that we have required the latter in some 1915(b) waivers and 1115 demonstrations.

Response: Given our desire to maximize States' flexibility in administering their State plans, we do not specify for each item how often the monitoring must be done, merely that it is a requirement to do so. Our experience with States' monitoring of MCOs in section 1115 demonstrations and in 1915(b) program waivers suggests to us that States implementing these procedures will do so on an annual or quarterly basis—if not more often than that.

Comment: One commenter suggested that HCFA require States to have procedures to monitor specialty referral services.

Response: With respect to the suggestion of monitoring procedures for specialty referral services, we note that 438.10 already requires MCOs to make available information to beneficiaries on how to access services, including those (such as referrals) that may require authorization. If these procedures are not being followed, we believe that the complaints and grievances data (which the State is required under this subsection to monitor) will demonstrate whether the MCO is following its own (State-approved, see § 438.700) procedures. Furthermore, we have clarified with new paragraph (e) what has always been our expectation; namely, that States monitor compliance with all aspects of the contract. Such a requirement implicitly includes the monitoring of special referral services.

Comment: One commenter believed that HCFA should require States to have procedures in place to monitor the degree of enrollment of pediatricians/other providers, the provision and access to services not covered under the contract, and EPSDT services.

Response: We believe that it would be unnecessarily onerous to add requirements regarding monitoring the participation of pediatricians and other providers and EPSDT services. The MCOs have already agreed to provide all medically necessary services in their contract (including EPSDT, if included in a particular contract) and therefore have strong incentives to have adequate provider and specialist network capacity, especially because if it they do not, the State can impose intermediate sanctions or terminate the contract before it would otherwise expire (see § 438.718). Furthermore, it is a contract requirement that MCOs provide for arrangements with, or referrals to, "sufficient numbers of physicians and other practitioners to ensure that services under the contract" are furnished (see § 438.6). Furthermore, again, we have clarified in paragraph (e) that States monitor contract compliance. Such a requirement implicitly includes the monitoring of number of pediatricians and other providers. Moreover, States are required at § 441.56 to meet certain EPSDT targets, whether or not they are contracted services. With regard to "wraparound services," we note that § 438.206(c) makes clear that it is the responsibility of the State to ensure that services not covered by the contract are provided to Medicaid beneficiaries. If such services are not being provided, a State's monitoring of trends in its Fair Hearings process should reveal any problem with respect to access to "wraparound" services.

Comment: One commenter believed that HCFA should require the State to have procedures for monitoring training (of both beneficiaries and providers).

Response: We believe the fact that under § 438.218, the information requirements in § 438.10 are part of the State's quality assurance program provides assurance that the State will have to monitor the training and education of beneficiaries with respect to their enrollment and participation in MCOs or PCCMs. Furthermore we have clarified with (e) what has always been our expectation; namely that States monitor contract compliance. Such a requirement implicitly includes the monitoring of beneficiary education. We believe that with respect to provider training, it is the responsibility of the State to ensure that MCOs, PHPs, or their subcontractors have the requisite training and information for program participation.

Comment: One commenter requests that States be required to monitor samples of all notices sent to the enrollee by the MCO, PHP, or PCCM, and by all subcontractors.

Response: HCFA believes that the requirement at 438.700, which makes a plan's or subcontractor's distribution of materials that are not State-approved subject to sanctions addresses the concern raised by this commenter. Such a requirement implicitly includes the State's monitoring of materials sent to beneficiaries by the MCOs, PHPs or PCCMs. This also would be the subject of monitoring under § 438.66(e).

Comment: We received a number of general comments on the need for greater understanding of persons with special health care needs by MCOs and their providers. Specifically, in the area of coverage and authorization, a commenter contended that the managed care industry has very little knowledge of the needs of persons with disabilities. commenters further argued that the importance of certain services is often overlooked by the managed care industry. Another commenter argued that we should require MCOs to make every effort to provide training and education for their practitioners on the diagnosis of certain conditions such as HIV and AIDS. We also received comments on the need for MCO providers to have appropriate knowledge and skills to treat adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs. One commenter specifically recognized the need for MCO recognition of the unique needs of the homeless population.

Response: Based on comments described here and other general comments requesting additional consumer protections for persons with specific conditions or disabilities, we are persuaded that additional requirements are necessary to ensure appropriate education of all managed care entities and providers on the unique care needs of special needs populations. Accordingly, the final rule with comment period contains a new § 438.68 Education of MCOs, PHPs, and PCCMs. This section requires that the State agency have in effect procedures for educating the MCO, PHP, and PCCM and any subcontracting providers about the clinical and non-clinical service needs of enrollees with special health care needs.

C. Subpart C (Enrollee Protections)

Proposed subpart C set forth a variety of enrollee protections including the following: (1) requiring information on benefits be specified (proposed § 438.100); (2) rights concerning provider communications with enrollees (proposed § 438.102); (3) limits on marketing activities (proposed § 438.104); (4) limits on enrollee liability for payment (proposed § 438.106) and cost-sharing (proposed § 438.108); (4) an obligation for MCOs and PHPs to provide assurances of adequate capacity (proposed § 438.110); (5) rights in connection with emergency and post-stabilization services (proposed § 438.114); and (6) MCO solvency standards (proposed § 438.116).

1. Benefits (§ 438.100)

As proposed, § 438.100 required that Medicaid contracts between States and MCOs specify the benefits the MCO is responsible for providing or making available to Medicaid enrollees. The proposed section also required States to make arrangements for furnishing those State plan services that MCOs were not responsible to provide under the contract, and to give written information to enrollees on how and where they may obtain these additional services. Many commenters were confused by this section because it duplicated provisions in other sections. To eliminate duplication, the requirements in proposed § 438.100 have been incorporated into other sections, notably § 438.10, Information requirements; § 438.206 Availability of services; and § 438.210 Coverage and authorization of services. The requirement in proposed § 438.100(a) that contracts specify the services the entity is required to provide to Medicaid enrollees is now set forth in § 438.210(a)(1). The requirement in proposed § 438.100(b) concerning the State's obligations to services not covered under the contract is now set forth in § 438.206(c), while the requirement to provide information to enrollees and potential enrollees is in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g).

We have moved the requirements relating to enrollee rights from proposed § 438.320 to § 438.100. Throughout the preamble, we have responded to comments according to their numerical sequence in the proposed rule. This section only addresses responses to comments regarding proposed § 438.100 (Benefits). Comments and responses relating to the enrollee rights are now in § 438.100 but were in the proposed § 438.320 are discussed in section II. D.

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below in the discussion of comments on the subpart in which these enrollee rights appeared in the proposed rule. In this final rule with comment period the content of proposed subpart E has been redesignated as subpart D with sections redesignated from the 300 series to the 200 series.

Comment: One commenter believed that we went beyond the authority in the statute by requiring the contract to specify the services the MCO, PHP, or PCCM is required to provide.

Response: We believe that the commenter apparently read the proposed rule to preclude States from incorporating the description of the benefits covered under the contract by referencing a separate document describing the benefits (for example, a provider agreement). However, the proposed rule was not intended to prohibit accepted methods of incorporating substantive contract provisions by cross-referencing separate documents. The reference documents must be sufficiently detailed to make clear to all parties the types and scope of the services for which the MCO is responsible.

Comment: Several commenters urged that we require States to include specific contract language holding MCOs responsible for the early prevention, screening, diagnosis and treatment (EPSDT) of eligible enrollees through the full scope of EPSDT benefits required under States' Medicaid plans. Commenters also expressed the view that States must make arrangements for providing at no cost to enrollees EPSDT services and benefits that are not covered or are not provided by the entities in accordance with the contract.

Response: These issues are addressed in section II. D. below in responses to similar questions raised with respect to § 438.210 Coverage and authorization of services and § 438.206(c) Availability of services.

Comment: Commenters strongly recommended that we clarify that contract language must address MCO, PHP, or PCCM and State agencies' roles for case management when covered services overlap with services that are not the responsibility of the MCO, PHP or PCCM to provide or to make available. Some of the commenters noted that mental health services for chronic conditions are frequently not included under MCO, PHP, or PCCM contracts. Without clear delineation of responsibility between the mental health services provided by the entity and those covered outside the MCO, PHP, or PCCM, enrollees may not receive the services they are entitled to receive under the State plan.

Response: We agree that coordination of care is an important component of managed care and that coordination may be challenging because an MCO may not cover all of the services included in the State plan. To ensure that care is appropriately coordinated, § 438.208(h)(7) of this final rule with comment period requires that each MCO and PHP implement a program to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In section 438.10(d)(2)(i)(C), we also require that the information furnished to potential enrollees include general information about MCO responsibilities for coordination of care.

Comment: One commenter recommended that a mechanism be established to assist enrollees with obtaining the services they are entitled to under the State plan, but that are not covered by the MCO, PHP, or PCCM. Proposed § 438.100 required States to give enrollees written instructions on how to obtain those services, but it did not specify how enrollees would know to contact the State for instructions.

Response: Proposed § 438.100(b) set forth the State's obligation to make services under the States plan available and give enrollees instructions on how to obtain them, but did not specifically address the general provision of information to beneficiaries on this obligation as required under section 1932(a)(5)(D) of the Act, Information on Benefits not Covered. As noted above, in § 438.10(d)(2)(ii)(E), § 438.10(e)(2)(vii), and § 438.10(g) of this final rule with comment period, we address the information requirements relating to availability of services, and specify that this information include information about benefits that are available under the State plan but not covered under the contract, including how and where the enrollee may obtain these benefits, any cost sharing, and how transportation is provided.

Comment: Several commenters urged that MCO, PHP, or PCCM contracts specify the services that the entity is to provide to Medicaid enrollees. For those Medicaid services that are not included in the MCO, PHP, or PCCM contract, the commenters believed that the State should make arrangements for providing those services and give enrollees written instruction on how to obtain them. Another commenter found the meaning of the term "arrangement" in proposed § 438.100(b) unclear.

Response: Proposed § 438.100(a) required that MCO contracts (and § 438.8(d) PHP contracts) specify the services that have to be provided to Medicaid enrollees. In this final rule with comment period, this requirement is in § 438.210(a). In proposed § 438.100(a), we did not require that PCCM contracts specify this information, this was an error, since section 1932(b)(1) of the Act requires that PCCM contracts "specify the benefits the provision (or arrangement) for which the PCCM is responsible." Section 1932(a)(5)(D) of the Act sets forth the obligation to inform enrollees in an entity of services "not made available to the enrollee through the entity," and of "where and how enrollees may access" benefits, applies to "managed care entities," or "MCEs" (a term that includes both MCOs and PCCMs). We therefore are including PCCMs in § 438.210(a)(1) (which contains the requirement that contracts specify covered services that was in proposed § 438.100(a)) and § 438.206(c) (which contains the State obligation formerly in proposed § 438.100(b)).

With respect to the requirement that information be provided on what State plan services are not covered by the contract, and how and where enrollees may obtain services, proposed § 438.10(g) already extended this requirement to PCCMs. This is retained in § 438.10(g) of this final rule with comment period.

Proposed § 438.100(b) provided that States must make "arrangements" for furnishing services not covered under the contract with the MCO. We agree with the last commenter that the term is unclear. Therefore, in § 438.206(c), we provide that if an MCO contract does not cover all of the services under the State plan, the State must make available those services from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided. We interpret the phrase "make available from other sources" to mean that the State must directly pay for the service through a fee-for-service contract or contract with another organization to provide the service.

Comment: One commenter recommended that the representative payee or other responsible person be included in dissemination of information advising enrollees on how and where to access these additional benefits.

Response: We did not adopt the exact language recommended. The information requirements in § 438.10 provide for informing authorized representatives.

2. Enrollee-Provider Communications (§ 438.102)

Medicaid beneficiaries are entitled to receive from their health care providers

the full range of medical advice and counseling that is appropriate for their condition. Section 1932(b)(3) of the Act added by the BBA clarifies and expands on this basic right by precluding an MCO from establishing restrictions that interfere with enrollee-provider communications. In § 438.102 of the proposed rule, we provided a definition of the term "practitioner" and outlined the general rule prohibiting interference with provider-enrollee communications. We also specified that this general rule would not require the MCO to cover, furnish or pay for a particular counseling or referral service if the MCO objects to the provision of that service on moral or religious grounds, and provides information to the State, prospective enrollees, and to current enrollees within 90 days after adopting the policy with respect to any particular service.

Comment: Several commenters found the definition of "practitioner" at § 438.102(a) too restrictive and felt that it needed to be expanded to include professionals as: dental hygienists; marriage, substance abuse, and family counselors; interns; licensed psychiatric technicians; and pharmacists. One commenter pointed out that the proposed definition referred to a limited number of providers and excluded several of those referenced in the statute. Commenters recommended either adding those professions referenced in the statute or specifying that those listed in the regulations served as examples only. Another commenter suggested adding "including, but not limited to" language.

Response: Section 1932(b)(3)(C) of the Act provides an exact list of professions that are covered under this provision. In the proposed rule, we erroneously omitted several classes of professionals that were included in the statute. Therefore, we have revised § 438.102(a) to mirror the list contained in the statute. We have also replaced the term "practitioner" with "health care professional" in order to be consistent with the statute.

Comment: One commenter expressed concern that proposed § 438.102(b) did not require that State contracts with MCO or MCO contracts with providers be made available for public viewing.

Response: In this final rule with comment period, we do not require that contracts be made available to the public because doing so may deter MCOs from bidding on Medicaid contracts and may result in States not getting the best price. However, in § 438.10(f)(5), we have required that States and MCOs make available, upon request, information relating to the type of compensation arrangements that physicians have with MCOs and States.

Comment: Several commenters preferred the language included in the Medicare+Choice regulation implementing statutory authority for protecting provider-enrollee communications that is similar to that in the BBA for Medicaid. The commenters believed that the Medicare+Choice provisions in § 422.206 are more encompassing than those in proposed § 438.102 because they also bar Medicare+Choice organizations from—(1) restricting providers from advocating on the patient's behalf; (2) prohibiting providers from sharing information regarding alternative treatment; and (3) prohibiting providers from discussing the risks, benefits, and consequences of treatment or lack of treatment, and the opportunity for the enrollee to refuse treatment or express preferences for future treatment. The commenters also state that violations are subject to Federal sanctions. Two commenters stressed that providers must be free of all restrictions on communicating with enrollees and be able to provide complete information on all treatment options.

Response: We agree with the commenters who favor the approach taken in the Medicare+Choice regulations and have revised § 438.102(b) to parallel the requirements in § 422.206. We note that since the intermediate sanctions in subpart I apply only to MCOs, the new paragraph referring to sanctions applies only to MCOs.

Comment: Some commenters suggested that we reinforce the fact that a health care professional cannot be prevented from furnishing needed information to patients during the course of routine primary and preventive care visits or other treatment. These commenters expressed concern about language in the preamble to the proposed rule which states that, " an MCO may not limit a provider's ability to counsel or advise an enrollee on treatment options that may be appropriate for the enrollee's condition or disease, unless the terms of § 438.102(c) apply and are satisfied." Specifically, the commenters requested that we remove reference to § 438.102(c).

Response: We agree with the commenters that the preamble language was misleading in implying that § 438.102(c) would permit an MCO to actually prevent a provider from providing counseling. We have revised § 438.102 in this final rule with comment period so that it is clear that § 438.102(c) only relieves an MCO from being required to provide, arrange, or pay for counseling or referrals as the result of the prohibition in § 438.102(b)(1), but does not give the MCO the right to prevent a physician from giving counseling if the physician is willing to forego any payment that may be associated.

Comment: One commenter recommended allowing an enrollee to terminate or change enrollment at any time after they receive notification that an MCO will exercise its right under § 438.102(c) not to provide, reimburse, or provide coverage of a counseling or referral service that is provided as the result of the requirement in § 438.102(b).

Response: We agree with the commenter. Section 438.56(d)(2)(ii) of this final rule with comment period provides that if an MCO does not provide a service because of moral or religious objections (whether pursuant to § 438.102(c), or otherwise) the enrollee may disenroll for cause. It is important to note that regardless of whether the MCO covers a certain service that is included in the State plan, the enrollee will have access to that service. If an MCO contract does not cover all of the services under the State plan (regardless of the reason) the State must make available those services from other sources. In addition, the Medicaid statute guarantees freedom of choice for family planning services so an enrollee may always seek services out-of-network. Therefore, we permit enrollees to disenroll if services are not covered because of moral or religious objections. We emphasize that disenrollment is not necessary in order to access the services.

Comment: Most commenters supported the conscience clause provision at proposed § 438.102(b)(2) which provides that, subject to certain information requirements, an MCO is not required to provide, reimburse for, or provide coverage of a counseling or referral services furnished as the result of the rule in § 438.102(b)(1) if the MCO objects on moral or religious grounds. However, several commenters objected to the policy that MCOs may elect not to provide coverage for some services that are included in the State plan. They stated that if the MCO objects to a Medicaid-covered service on moral or religious grounds, it is their responsibility to arrange for coverage through subcontracts or by providing access to the service out-of-network. Others stated that to allow MCOs to pick and choose what services they will be responsible for runs counter to how

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managed care contracts are designed and bid out. This provision would in these commenters' view complicate bid pricing and evaluation, increase administrative costs to the State (to make separate arrangements for these services and provide notice to beneficiaries), and could be confusing to beneficiaries.

One commenter believed that the proposed rule creates an undue burden for enrollees who are seeking family planning services and disrupts their continuity of care, and that these disruptions could result in lower quality of family planning care for women. Commenters recommend either removing the conscience protection provisions or changing the regulation to allow States to require MCOs that have moral objections to providing certain services to obtain them through subcontracts or out-of-network arrangements.

Response: We do not have the authority to delete the conscience protection provision because it is required by section 1932(b)(3)(B) of the Act. However, this conscience provision alone would not by itself permit an MCO to avoid providing a State plan service that it has contracted to provide. As noted in the preamble to this final rule with comment period, the conscience protection in section 1932(b)(3)(B) of the Act only protects an MCO from being required to pay for something as the result of the rule in section 1932(b)(3)(A) of the Act. Section 1932(b)(3)(B) of the Act begins with the words "*Subparagraph (A) shall not be construed as requiring* a Medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service", if the MCO objects and gives the required notice. This is an exception to the obligations under paragraph (A), not a "blanket" authority to decline to cover services the MCO would otherwise be obligated to provide. As noted in section II. B above, however, unlike a Medicare+Choice organization, that must contract to provide Medicare services, a Medicaid contracting MCO is free to negotiate with the State over which services it will provide. Clearly, section 1932(a)(5)(D) of the Act (requiring that certain arrangements be made with respect to State plan services not furnished through an MCO or PCCM) contemplates an MCO's right to decide which State plan services to agree to include in its contract. An MCO that objects to covering a State plan service would not agree in the contract to provide that service. In such a case, the State is clearly obligated to ensure the availability of the service out of plan. If the MCO did agree to provide a State plan service under its contract, it could not attempt to "change its mind" by relying on the "conscience protection" in section 1932(a)(3)(B) of the Act, since its obligation to provide the State plan service would be pursuant to its contract, not section 1932(a)(3)(A) of the Act. It is important to note that under existing regulations, MCOs may not restrict an enrollee's freedom of choice with respect to family planning services. In other words, enrollees may always seek family planning services out-of-network.

Comment: Commenters expressed concern about how enrollees will receive notice of an MCO change in policy. One commenter recommended linking this requirement with the information requirements in § 438.10(c), which requires plans to use easily understood language and format and take into consideration the special needs of those, for example, are visually impaired or have limited reading proficiency. Others recommended that we explain how an MCO should provide notice to ensure enrollees are adequately informed.

Response: We agree with the commenters that the information furnished to enrollees and potential enrollees under this section should be governed by the same rules as the information furnished under § 438.10. Therefore, we have revised § 438.102(c) to require that the information furnished under this section be "consistent with the provisions of § 438.10."

We believe that it is critical that enrollees and potential enrollees have sufficient information to understand how and where to obtain a service that is not covered by the MCO. This responsibility is shared by the MCO and the State. As discussed in section II. A. above under § 438.10(e)(1)(ii), an MCO or PHP must inform potential enrollees of any "significant" change in the information in § 438.10(e)(2) at least 30 days prior to the change. Section 438.10(e)(2) includes a description of what services the MCO or PHP covers. This advance notice requirement would ordinarily apply to a change in what the MCO or PHP would cover. While section 1932(a)(3)(B) of the Act requires only that notice be provided within 90 days after a decision was made not to cover something under its provisions, and meeting this condition would permit an MCO to qualify for the exception in section 1932(a)(3)(B) of the Act. We believe that the general rule in § 438.10(e)(1)(ii) should continue to apply, and are revising § 438.102(b)(1)(B) to clarify this fact.

Comment: Commenters were concerned that public entities may want to exercise the conscience protection exception at § 438.102(c), which the commenters believe could violate the Constitution (presumably because the first amendment "establishment clause" would prevent a public entity from citing a "religious" objection to covering a service). These commenters recommended that we state that public entities that sponsor or operate MCOs cannot assert moral or religious objections, and thus decline to provide, reimburse for, or provide coverage of any counseling or referral service.

Response: We have not incorporated the commenters suggestion because section 1932(b), (3)(B) of the Act and § 438.102(c) are not limited to an objection on "religious" grounds, but also on "moral" grounds, and there is nothing to preclude a governmental entity from expressing a moral objection. However, there is no basis in the BBA for making a distinction between public and private MCOs in this area.

Comment: One commenter was concerned that subcontractors may not be required to adhere to the provisions of § 438.102 regarding enrollee-provider communications. The commenter suggested that subcontractors should expressly be covered as they were in proposed § 438.310(b)(1), which explicitly sets forth requirements for "the MCO and its subcontractors."

Response: In § 438.6(l) of this final rule with comment period, we state that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 provides that for all 1903(m) contracts, "the State must ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor * * *". We believe that the combination of these two provisions satisfies the commenter's concerns and that additional subcontractor language is not needed in § 438.102.

Comment: One commenter indicated that § 438.102 does not address enforcement mechanisms nor remedies for providers that believe they were penalized or terminated by the plan for providing information to an enrollee. The commenter suggest that we provide these enforcement mechanisms.

Response: If providers believe that an MCO has violated the requirements of section 1932(b)(3)(A) of the Act and § 438.102(b), they should bring this to the attention of the State Medicaid agency, which could then investigate the situation and determine whether to

impose sanctions under § 438.102(e) and § 438.700(d). We believe that this sanction authority provides a sufficient enforcement mechanism.

3. Marketing (§ 438.104)

In accordance with section 1932(d)(2) of the Act, proposed § 438.104 set forth requirements for, and restrictions on, marketing activities by MCO, PHP and PCCMs. (The regulations text referred to "MCEs," includes MCOs and PCCMs and proposed § 438.8(d) made the requirements applicable to PHPs.). Proposed § 438.104 included definitions of "choice counseling", "cold-call marketing", "enrollment activities", "enrollment broker", "marketing materials", and "recipient and potential recipient." The definitions related to enrollment broker functions ("choice counseling," "enrollment activities," and "enrollment broker") were included in error and have in this final rule with comment period been moved to § 438.810, Expenditures for Enrollment Broker Services. We also proposed requirements and prohibitions for MCO, PHP, or PCCM contracts. Specifically, § 438.104(b)(1) proposed that the contract must specify the methods by which the entity assures the State agency that the marketing plans and materials are accurate and do not mislead, confuse, or defraud the recipients or State agency. Section 438.104(b)(2) proposed restrictions on MCO, PHP, or PCCM contracts, which are discussed in detail below. Section § 438.104(c) proposed to require the State to consult with a MCAC or an advisory committee with similar membership in reviewing marketing materials. Comments we received on these issues and our responses follow.

a. General Comments

Comment: Proposed § 438.8(d) provided that the error of subpart C, including § 438.104 applies to PHPs to the same extent that the sections apply to MCOs. Section 438.104 only includes references to managed care entities (MCEs) which appears to mean the section is not applicable to PHPs.

Response: The marketing rules set forth in § 438.104 apply to MCOs, PCCMs and, as specified in § 438.8(d), to PHPs as well. Given the confusion reflected in this comment, throughout this final rule with comment period, we have revised the regulation text to indicate in each requirement whether it applies to PHPs, while also retaining § 438.8.

Comment: One commenter believed that we should establish specific and significant monetary fines for coercive or unethical marketing practices.

Response: Many States have already determined what marketing violations are punishable and have set significant fines or sanctions. In addition, § 438.700 requires States that contract with MCOs to establish intermediate sanctions and includes as reasons for imposing these sanctions: (1) discrimination among enrollees based on health status or need for services; (2) misrepresenting or falsifying information furnished to either the State, enrollees, potential enrollees, health care providers or us; and (3) distributing marketing materials that have not been approved by the State, or that contain false or materially misleading information. States have the flexibility to impose sanctions or restrictions as they find appropriate. In addition, § 438.730 allows us to impose a sanction either based upon a State agency's recommendation, or directly.

Comment: Several commenters urged HCFA to prohibit other types of marketing, and require more strict oversight of MCOs", PHPs", and PCCMs' activities.

Response: Some degree of flexibility is needed if MCOs, PHPs, and PCCMs are to continue offering Medicaid products in a competitive environment. Section 438.104(b)(2)1)(i) requires States to review and approve all marketing materials prior to distribution, and § 438.104(b)(2) requires assurances that marketing materials do not confuse, mislead or defraud. Section 438.104(b)(1)(v) prohibits specific marketing practices, such as door to door, telephone, or other "cold call" marketing. It is not clear what "other types of marketing" would warrant a prohibition. Therefore, we do not believe that additional regulatory requirements are necessary.

Comment: Commenters suggested that we revise the preamble to indicate that the marketing limitations apply to homeless shelters as well as other institutional settings. The commenters believe that it is not appropriate to approach homeless people, and that strong Federal protection is needed.

Response: The general prohibition on "cold call" marketing would prohibit "approaching" homeless people in a shelter (or elsewhere) or other institutionalized individuals. We agree with the commenters, and are stating here that all limitations on marketing apply equally in these settings.

Comment: One commenter indicated that it makes little sense to mandate choice of an MCO when under the proposed regulation, MCOs may not use marketing to effectively differentiate their Medicaid products and compete for greater enrollment.

Response: We do not believe that these marketing rules unfairly restrict an MCO, PHP, or PCCM's ability to compete in the marketplace. We do not prohibit all types of marketing activity. States may permit MCO, PHP, and PCCMs to—(1) participate in health fairs and community presentations; (2) use various forms of "broadcast" advertising; (3) send mailings to potential enrollees; (4) respond to individual requests for information; and (5) engage in other activities as long as they are approved and subject to sufficient oversight. Even where MCOs, PHPs, and PCCMs have similar structures and networks, it is possible for them to offer additional benefits, for example, child care to differentiate one MCO, PHP, or PCCM from another. In addition, MCOs, PHPs and PCCMs can provide results of enrollee satisfaction surveys, report cards, or other types of information on quality of care to potential enrollees.

b. Cold-Call Marketing

Proposed § 438.104(a) defined cold-call marketing as any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll in that particular MCO, PHP, or PCCM. Cold-call marketing includes door-to-door, telephone or other related marketing activities performed by MCOs, PHPs, or PCCMs and their employees (that is, direct marketing) or by agents, affiliated providers, or contractors (that is, indirect marketing). In the preamble to the proposed rule, we noted that cold-call marketing includes activities as a physician or other members of the medical staff, or a salesperson, or other MCO, PHP, or PCCM employee or independent contractor approaching a beneficiary in order to influence a beneficiaries decision to enroll with a particular MCO, PHP, or PCCM. In proposed § 438.104(b)(2)(v), we expressly prohibited MCO, PHP, or PCCMs from directly or indirectly engaging in door-to-door, telephone, or other cold-call marketing activities.

Comment: One commenter felt that the definition of "cold-call marketing" could inadvertently prohibit appropriate marketing activities, for example, direct contact at health fairs and community-based organization offices.

Response: The prohibition on cold-call marketing only applies to "unsolicited" contact by the MCO, PHP, or PCCM. For example, if a beneficiary attends a health fair or similar event, the beneficiary would be seeking information about health care and, therefore, the contact between the MCO,

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PHP, or PCCM and the beneficiary would not be considered "unsolicited." We note, however, that MCO, PHP, or PCCM participation in health fairs and other community activities is considered marketing and, therefore, must have the State's approval.

Comment: Commenters suggested that we return to the statutory language defining cold-call marketing. The commenters' rationale was that because the regulations apply to voluntary as well as mandatory programs, the prohibited activities would preclude viable enrollment numbers.

Another commenter contended that the proposed definition of "direct marketing" went beyond the statutory prohibition of "cold-call" marketing. Another commenter believed that the restriction against providers attempting to influence patients' choice could severely limit opportunities for MCOs, PHPs, and PCCMs to attract members and might unintentionally create an unlevel playing field because this sort of marketing is currently conducted by PSOs, hospital systems, and providers with a particular interest in one health plan.

Response: Section 1932(d)(2)(E) of the Act prohibits direct or indirect door-to-door, telephonic, or other "cold-call" marketing of enrollment. These provisions were added to the Act by section 4707 of the BBA, Protections Against Fraud and Abuse. Our interpretation of the Congress' intent is that the statutory language was meant to minimize the potential for abusive marketing practices in both voluntary and mandatory programs. Specifically, we interpreted the term "direct marketing" to mean marketing by an MCO, PHP or PCCM or its employees; the term "indirect marketing" to mean marketing by an MCO, PHP, or PCCM, or its agents, affiliated providers, or contractors. The terms "door-to-door" and "telephonic" marketing are self-explanatory. We interpreted the term "other cold-call marketing" as other unsolicited contacts. If the Congress intended to prohibit only unsolicited door-to-door or telephone contacts, the "other" forms would not have been included in the prohibition. There are several other types of marketing that are permitted under this regulation. For example, States may permit the use of billboards, newspaper, television, and other media to advertise MCOs, PHPs, MCOs, or PHPs. Mailings are also permitted as long as they are distributed to the MCO's, PHP's, or PCCM's entire service area covered by the contact. States may also provide marketing materials on behalf of MCOs, PHPs, and PCCMs.

Comment: Several commenters, while indicating support for the ban on door-to-door, telephonic and other cold call marketing, expressed concern over the inclusion of physician activities including approaching a beneficiary to influence a decision to enroll with a certain plan. The commenters considered it inappropriate to place any limits on information provided to a beneficiary within the context of a doctor-patient relationship. Another commenter stated that the prohibition on contact by affiliated physicians and medical staff seems to conflict with the need to preserve continuity of care between patients and providers. The commenters observed that, although these providers may have incentives to recruit patients, these incentives must be balanced against the desire of many Medicaid patients to continue seeing providers with whom they have established a relationship.

Response: There is no prohibition against a physician responding to a patient's request for advice in the context of the doctor-patient relationship, or identifying all MCOs, PHPs, or PCCMs with which the physician has a contract. The intent of § 438.104(b)(1)(v) is to prohibit unsolicited marketing activities. Medical advice given as part of a doctor-patient relationship is not considered marketing. Our definition of cold-call marketing as "unsolicited" leaves patients free to seek out the advice of their providers. However, the cold call prohibition would prevent providers or their staff from approaching a patient about choosing an MCO, PHP, or PCCM. Providers are often members of several MCOs, PHPs, and PCCMs and permitting them to approach a member about any particular MCO, PHP, or PCCM could give the appearance of influence by factors not necessarily in the best interests of the patient.

Comment: One commenter called the cold-call provision "overly restrictive" and felt that it presented serious problems for MCOs, PHPs, and PCCMs that use clinic-based community providers. The commenter also felt that the regulation contradicted the proposed default assignment process because States are expected to assign individuals to existing providers and these providers would be restricted from giving information to assist in the process. The commenter recommended that participating physicians be permitted to provide approved informational materials about plans in which they participate to patients in their offices in an unbiased, non-threatening manner, and that the State monitor to ensure compliance.

Response: The default assignment process is considered a State's last resort for matching a non-responding individual with a provider. The fact that an individual is in a physician's office inquiring about what MCOs, PHPs, or PCCMs the provider participates in, indicates that default assignment is not likely to be necessary. However, if the individual does not make a selection, the office visit may facilitate the default assignment process because, under § 438.50(f), the State's default enrollment process must seek to preserve existing provider-beneficiary relationships. In addition, a State may choose to permit providers to display approved materials about all plans in which they participate. The regulation only prohibits unsolicited personal contact by any person or entity representing a particular MCO, PHP, or PCCM.

Comment: A commenter pointed out that safety net providers often perform outreach to uninsured individuals who may be eligible for Medicaid. The commenter believes that the marketing prohibition could discourage providers from promoting Medicaid enrollment. It was suggested that a discussion on the subject of maintaining an existing provider relationship could be interpreted as cold-call marketing. A safety-net provider indicated that they allow their physicians and medical staff to discuss options and provide literature supplied by MCOs, PHP, or PCCMs. They felt that a patient's physician often provides the best assistance and information for making an informed decision.

Response: We encourage outreach to those individuals who may be eligible for Medicaid. However, outreach which relates to establishing Medicaid eligibility should be distinct from marketing, which is considered to have a bias in favor of one MCO, PHP, or PCCM or provider option over another. Medical staff will be assumed to be acting in the best interest of the beneficiary's health when discussing or encouraging a Medicaid application. This activity would not be considered marketing unless it also includes a distinct attempt to encourage selection of a particular MCO, PHP, or PCCM. If, in the course of a discussion, a beneficiary inquires about how to continue seeing a particular provider, there is no prohibition on providing information on the MCOs, PHPs, or PCCMs in which that provider participates. On the other hand, contact with an enrollee or potential enrollee by any other person or entity on behalf of a particular MCO, PHP or PCCM (prior to establishing Medicaid eligibility or selecting an MCO, PHP, or PCCM option) will be considered marketing and will be subject to State and Federal scrutiny.

Comment: A commenter called the restriction on physicians advising their patients "an unnecessary gag rule" and indicated that it would prevent a physician from steering a severe asthmatic to an MCO, PHP, or PCCM that excels in managing asthma care. The commenter also pointed out that the rule would not prevent physicians from "trashing" other MCOs, PHPs, or PCCMs.

Response: A distinction should be made between patient counseling based on a patient's request done by medical staff on the basis of medical factors, and steering, which may be based on inappropriate factors such as administrative or fiscal issues. Providers are free to advise their patients, as specified in § 438.102, and they may respond to questions about the availability of specific services from MCOs, PHPs, or PCCMs with which they are affiliated. States should keep in mind, however, that medical staff providing patient counseling may not necessarily be aware of other factors, such as health conditions of other family members required to join an MCO, PHP, or PHP or of areas in which other MCOS, PHPS, or PCCMs may excel.

We agree with the commenter that negative marketing activities ("trashing") should also be addressed in this regulation, and we have done so through a new definition of "marketing" in § 438.104(a). Under this definition, any communication by an MCO, PHP, or PCCM (or any of its agents or independent contractors) with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to decide to enroll or re-enroll in that particular Medicaid product, or either not to enroll in or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product would be considered marketing and, therefore, would be covered by this regulation. We also have revised the definitions of "marketing materials" and "cold call marketing to incorporate the new marketing definition.

Comment: One commenter contended that the language of the regulation was inconsistent with the language in the preamble because the regulation merely prohibits unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of influencing the individual to enroll. The commenter noted that the preamble describes cold-call marketing as unsolicited contact by an employee, affiliated provider or contractor of the entity. The commenter stated that the language of the regulation was clear and concise and did not require the explanation in the preamble.

Response: In § 438.104(a), we state that any reference to MCO, PHP, or PCCM and entity includes "any of the entity's employees, affiliated providers, agents, or contractors." Therefore, the regulatory language is consistent with the preamble.

Comment: Commenters agreed with the prohibition against providers attempting to influence patients to join a particular MCO, PHP, or PCCM. However, the commenters pointed out that it is difficult for States to detect this type of activity.

Response: As systems have become more sophisticated, new and more effective methods of oversight continue to evolve. The difficulty in detecting certain inappropriate activities does not relieve MCOs, PHPS, and PCCMs or States from the obligation to protect the interests of the beneficiary. Many standard methods of monitoring marketing, such as reviewing grievances and appeals from beneficiaries and providers, tracking enrollment and disenrollment trends, and conducting beneficiary surveys will help detect patterns of aggressive or unfair marketing practices.

Comment: A commenter expressed concern that this provision unduly restricts the ability of MCOs to educate enrollees or potential enrollees about managed care and does not focus on group settings for example, schools, day care centers, and churches, where MCOs could target larger groups of Medicaid enrollees. The commenter asked HCFA to broaden the provision by giving additional examples of State approved activities.

Response: This regulation does not prohibit educational activities on the part of MCOs. However, any contacts other than patient counseling by any MCO, PHP, or PCCM staff or representative would be considered marketing, subject to State oversight. The regulation does not prohibit States from permitting MCOs, PHPs, or PCCMs to market to groups, for example, schools, churches, and day care centers. States are responsible for approving and monitoring these types of presentations and ensuring that beneficiaries attend voluntarily with knowledge that they are attending a marketing presentation.

Comment: Another commenter indicated that the definition of "cold-call marketing" might be too broadly defined and should not apply to public places where MCOs are engaging in marketing practices approved by the State.

Response: States may permit and establish rules for marketing in public places. However, States may not permit uninvited personal solicitations in public places, for example, eligibility offices and supermarkets. Some States allow representatives of available MCOs, PHPs, and PCCMs to be in eligibility offices or other locations on certain days, or on a rotating basis to answer questions and provide information to beneficiaries. In these situations, there should be provisions to monitor contacts to ensure that unbiased information is available about all options and that beneficiaries are not coerced. However, marketing or other MCO, PHP, or PCCM representatives who approach beneficiaries as they enter or exit eligibility offices or other public places, call at residences uninvited, are considered cold-call contacts and are not permitted.

Comment: One commenter expressed concern that the regulation narrows marketing options by restricting the role of MCOs in community-based efforts.

Response: We believe the statute gives States broad authority to determine what marketing activities are permitted with the exception of unsolicited personal contacts by MCOs, PHPs, and PCCMs or their representatives. States are free to use MCOs in community-based efforts. However, those efforts are considered marketing, therefore the materials (for example, activities and presentations) are subject to State review and approval.

Definition of Marketing Materials

In the NPRM, we proposed to define marketing materials as materials that—(1) are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; (2) are used by the MCO, PHP, or PCCM to communicate with individuals who are not its enrollees; and (3) can reasonably be interpreted as intended to influence the individuals to enroll or re-enroll in that particular MCO, PHP, or PCCM.

Comment: Some commenters said that the definition of marketing materials should not include communication intended to serve the needs of existing enrollees and suggested that the regulation be revised to clarify that marketing materials are those materials intended to influence non-enrollees to join a particular MCO, PHP, or PCCM. One commenter thought the definition of marketing materials was incomplete and should be changed to read "can reasonably be interpreted as intended to influence the individual to enroll or re-enroll in that particular MCO, PHP, or

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PCCM." Another commenter indicated that the combination of requirements at proposed § 438.104(a) (definition of marketing materials) and proposed § 438.104(b)(2)(1) (prohibition on the distribution of marketing material without State approval) required States to approve all marketing materials prior to distribution, whether or not they are targeted to Medicaid beneficiaries. It was pointed out that this would be administratively impossible and could raise constitutional issues.

Response: We disagree with the first commenters who favored limiting marketing materials to those directed at individuals who are not enrollees (which was the position taken in the NPRM), and agree with the second commenter who endorsed the language in the definition referring to influencing individuals to "re-enroll." In such a case, the individual already is enrolled and the portion of the definition referring to "individuals not enrolled" conflicts with the language favored by the commenter. We therefore have removed the portion of the definition limiting its applicability so that it is clear that marketing materials include those intended to influence both enrollees and potential enrollees. States retain the authority to interpret the term and are responsible for evaluating whether certain materials satisfy the definition. States may interpret this term broadly and determine that all materials are subject to review, but we assume that many States will determine that routine correspondence (such as appointment reminders) do not fall within the definition of "marketing materials" and therefore are not subject to review.

We have incorporated the new definition of marketing into the definition of "marketing materials."

Comment: Commenters supported our broad definition of marketing materials and our efforts to ensure the accuracy and truthfulness of the materials. However, some commenters felt that an absence of a clear definition of marketing could mean that many activities, for example, hiring community residents to talk about the benefits of belonging to a particular plan or persuading neighbors to join a plan, might not be covered. The commenters indicated that a common usage understanding of the term "materials" would not appear to include a spokesperson or representative. They also stated that it was unclear whether paying neighbors to say nice things about a plan would constitute cold call marketing. They suggested that we include a broad definition of marketing and include examples of marketing, and of false and misleading marketing. One commenter suggested that the following language, "inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether written or oral) that—(1) the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order not to lose benefits; or (2) the MCO, PHP, or PCCM is endorsed by the Federal government, State government or us." Another commenter recommended that we expand the regulation by requiring States to review marketing materials to ensure that MCOs do not imply that all persons are required to enroll in managed care in order to continue receiving Medicaid benefits.

Response: The comments recommending a "definition of marketing" have been addressed by our inclusion of a separate definition of marketing in this final rule with comment period. As noted above, we have defined "marketing" as "any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee that can reasonably be interpreted as intended to influence the recipient to enroll or re-enroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either not to enroll, or to disenroll from another MCO's, PHP's, or PCCM's Medicaid product." We also agree that language suggested by the commenter would be helpful, and provide in § 438.104(b)(2) that inaccurate, false, or misleading statements include, but not limited to any assertion or statement (whether written or oral) that the beneficiary must enroll in the MCO, PHP, or PCCM in order to obtain benefits, not to lose benefits, or that the MCO, PHP, or PCCM, is endorsed by either the Federal government, State government, similar entities or us.

States are required to review and approve all marketing materials under § 438.104(b)(1)(i). We expect this review to include screening for misleading information including any implication that individuals who are not required to enroll will lose their benefits if they do not enroll. In addition, the revised information provision at § 438.10(d)(2)(i)(B) requires that beneficiaries must be informed prior to selection of an MCO about which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

Comment: One commenter believed that the definition of marketing materials was too narrow because it did not address materials developed by State agencies (for example, the Office of Mental Hygiene and the Office of Developmental Disabilities) that participate in informing and encouraging potential enrollees about managed care. The commenter recommended that other parties have the authority to refer materials being used for marketing purposes to the MCAC or similar reviewing body to review and determine if the materials are unbiased.

Response: Section 438.104 addresses marketing materials that are produced by or on behalf of an MCO, PHP, or PCCM. To the extent that a State agency such as those mentioned by the commenter is acting as a PHP (for example, as a provider of behavioral health services under a "carve-out"), any materials it generates would be subject to the requirements in § 438.104. If, however, the agency has no stake in where an individual enrolls, and is essentially acting on behalf of the State Medicaid agency, it is not clear what "bias" the agency would have that would be detected by review. We therefore do not believe that review of such materials pursuant to § 438.104 is necessary or appropriate.

We note that § 438.10 requires that all information for enrollees and potential enrollees meet language and format requirements to facilitate understanding and take into consideration special needs. This applies to information furnished by any State or local agencies. States may choose to require the review of materials other than those subject to review as marketing materials under § 438.104.

Comment: A commenter suggested that we require that marketing material be distributed to the entire geographic area at least 90 days prior to enrollment, and only after the material is approved.

Response: The length of time needed for distribution of marketing materials may vary from State to State depending on factors, for example, Medicaid managed care penetration. Therefore, we do not mandate specific time frames for marketing activity. We encourage States to carefully consider the timing of the distribution of any marketing or other materials to maximize informed choice. The information provision at § 438.10(d)(1)(iii) requires that basic information be provided within a time frame that enables potential enrollees to use the information in choosing among available MCOs. With respect to mandatory managed care programs, we require States to establish standards and time requirements for fully informing and providing sufficient time to make an informed choice.

In response to the last part of the commenter's concerns, the regulation does require that all marketing materials be reviewed and approved by the State prior to distribution. Failure by an MCO, PHP, or PCCM to submit materials for review may result in sanctions by the State in accordance with § 438.700(c).

Comment: Several commenters asked that we clarify requirements related to reproductive health services. The commenters believe that we should require marketing materials to contain clear and prominent information about any reproductive health services not covered by the plan. Commenters recommended that marketing materials specify any Medicaid-covered reproductive health benefits that are not provided by the plan and state that all Medicaid beneficiaries have the right to obtain family planning services and supplies from any Medicaid participating provider. They also recommended that materials clearly indicate which subcontracting entities, for example, hospitals, medical groups, or subnetworks restrict access to reproductive health services.

Response: We agree with the commenters that Medicaid beneficiaries should have clear and complete information on the availability of family planning services. We have not, however, included specific requirements relating to family planning services in this section. In § 438.10, we require that the information furnished to enrollees and potential enrollees specify any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided. We have also revised the information requirements to require that the information furnished to enrollees identify the extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers. We refer the commenters to the comments and responses for proposed § 438.10.

Comment: A commenter asserted that the requirement that the State approve marketing materials prior to distribution would be difficult to implement because of time constraints. The commenter speculated that documents would have to be provided at least 30 days in advance and the State would incur additional administrative burden and costs. The commenter recommended that legislative action be taken to delete this requirement. Another commenter stated that the regulations did not specify that all health plan information and marketing materials must be approved by the State agency. The commenter suggested that we mandate strict requirements for accuracy and disclosure and require State review of all health plan information.

Response: The commenter is correct that legislative action would be required to eliminate the requirement for State review and approval of marketing materials under section 1932(d)(2)(A) of the Act. We note that many States already required prior approval of marketing materials prior to enactment of this requirement in the BBA. One State commented that these provisions posed no problem because its contracts and marketing manual already contained provisions that comply with or exceed these requirements. We believe that State review and approval is extremely important and that any burden should be offset by the additional protections afforded Medicaid beneficiaries. Marketing materials for MCOs contracting with Medicare undergo similar review prior to distribution, so this provision aligns Medicaid more closely with the Medicare rules.

Comment: A commenter suggested that marketing materials be made available in formats other than Braille for the visually impaired. The commenter believes that States and MCOs, PHPs, or PCCMs need flexibility in determining the appropriate formats, such as large print, audiotape or other formats in addition to Braille.

Response: There is no requirement in the regulations that marketing materials be in Braille for the visually impaired. The discussion of § 438.10 in the preamble of the proposed rule stated that all materials take into account specific needs of enrollees and potential enrollees, including furnishing information in alternative formats for the "visually impaired (through other media for example, large print, Braille, or audio tapes) * * *" (63 FR 52029). Section 438.10(c)(2) requires that materials be available in alternative formats that take into consideration, for example, the special needs of those who are visually impaired or have limited reading proficiency. States have the flexibility to decide which formats are most appropriate.

c. Requirements and Prohibitions

Proposed § 438.104(b) provided that MCO, PHP, and PCCM contracts must specify the methods by which the entity assures the State agency that marketing plans and materials are accurate and do not mislead, confuse, or defraud beneficiaries or the State. The proposed rule also stated that MCO, PHP, and PCCM contracts must provide that the entity distribute materials to the entire service area—(1) does not distribute marketing materials without prior approval; (2) complies with the information requirements in § 438.10; (3) does not seek to influence enrollment with the sale of other insurance; and (4) does not engage in cold-call marketing.

Comment: Several commenters believed that the language in proposed § 438.104 was vague, merely repeated the statutory language, and provided little concrete guidance to States or MCOs, PHPs, and PCCMs. Commenters suggested that we establish a detailed review guide with specific criteria developed with input from Medicaid beneficiaries and their advocates and that we review all MCO contracts for their marketing plans.

Response: We currently have marketing guidelines that will be updated to reflect the requirements of this final rule with comment period. In developing these guidelines, we often rely on prior implementation experience, including input from affected parties. We regularly use these types of guidelines, as we review and approve MCO, PHP, and PCCM contracts.

Comment: One commenter argued that it was unnecessary to require that MCO, PHP, and PCCM contracts specify the methods by which they will assure that marketing materials do not mislead or confuse. The commenter stated that the requirement that marketing materials be submitted to the State prior to use would be sufficient to ensure the desired outcome.

Response: We believe that both prior approval and contract review provide important beneficiary protections and both are specifically required by the law. Section 1932(d)(2)(A)(i) of the Act specifically requires prior approval of marketing materials by the State and that the materials do not contain false or misleading information. The requirement that the contract contain such assurances has been in § 434.36 since 1988, based on a provision of the Act which the BBA did not remove. States and MCOs should be used to complying with this provision.

d. Service Area

Proposed § 438.104(b)(2)(ii) required that marketing materials be distributed to the entire service area.

Comment: One commenter applauded this requirement stating that without it health plans might attempt to engage in preferential selection of enrollees by excluding geographic areas where Medicaid beneficiaries have higher costs. The commenter believes that we should expand this requirement to ensure that MCOs, PHPs, and PCCMs do not attempt similar preferential

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practices through other means, for example, refusing to provide marketing materials in certain languages, developing marketing materials that are difficult to understand, or by distributing materials in ways or in places that exclude people with disabilities. The commenter recommended that we state explicitly in regulations that discrimination on any of these bases is not permissible. Another commenter suggested that MCOs', PHPs', and PCCMs' marketing activities not be permitted to "red-line" certain areas of the community or certain groups of people because vulnerable populations, such as those with mental retardation are often targets for marketing "scams."

Response: We believe that the commenters' concerns are addressed in other sections of the regulation. Section 438.10 specifies general requirements that apply to all information furnished to enrollees including requirements relating to language and format. Section 438.6(d)(3) requires that MCO, PHP, and PCCM contracts provide that the MCO, PHP, or PCCM will not, on the basis of health status or need for health services discriminate against individuals eligible to enroll. In addition, MCO, PHP, and PCCM contracts must specify that the MCO, PHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin. In § 438.206(d)(7), we require the State to ensure that an MCO ensure that its providers do not discriminate against Medicaid enrollees. We specifically provided in § 438.100(d) that the State must ensure that each MCO, PHP, and PCCM complies with applicable Federal and State laws, (for example, Title VI of the Civil Rights Act of 1964, The Age Discrimination Act of 1975, The Rehabilitation Act of 1973, and Titles II and III of the Americans with Disabilities Act). We believe that these sections sufficiently protect the beneficiary against the discriminatory practices identified by the commenter, and therefore we have not incorporated any additional changes into § 438.104.

Comment: Several commenters believed that the service area requirement in proposed § 438.104(b)(2)(ii) could impede an MCO's, PHP's, or PCCM's ability to reach targeted populations with unique needs or characteristics within service areas. Commenters provided examples such as mailings to certain zip codes informing members of activities at a hospital in their neighborhood and mailings to specified non-English speaking populations in the service area. One commenter asserted that the proposed policy makes distribution problematic because services must be provided in a culturally competent manner but a marketing plan cannot be varied to target specific populations. In addition, a commenter explained that States often allow new MCOs to begin rolling out a program in certain counties within the service area. The commenter asserted that the proposed rule would prohibit MCOs from mailing to just those portions of the service area in which they are allowed to enroll. Some commenters believed that the proposed requirement was unnecessary, unduly burdensome and costly. One commenter contended that because the proposed definition of marketing materials included billboards and media advertisements, the "service area" requirement was unrealistic. One commenter felt that the provision would also inappropriately prohibit activities such as health fairs if material disseminated during these activities has not been distributed to the entire service area. Another commenter suggested that MCOs, PHPs, and PCCMs be encouraged to distribute materials where they have current capacity to serve more members and should be permitted to conduct local advertising, such as that carried out in collaboration with a particular clinic or group practice where appropriate. Another commenter acknowledged the need to ensure that MCOs, PHPs and PCCMs do not engage in risk pool segmentation, but felt that the regulation needed to be more flexible to accommodate circumstances where MCOs, PHPs, and PCCMs may wish to communicate information about locally available services to those residing in subareas of the overall service area.

One commenter recommended that we require MCOs, PHPs and PCCMs to distribute materials to all eligible enrollees in a specified county or region to avoid confusion to those in a particular sector in which the marketing materials do not apply. Some commenters indicated that MCOs, PHPs, and PCCMs, should have the ability to tailor the form and style of marketing to communicate effectively with demographic subgroups of a service area. Others suggested that the service area-wide distribution requirement apply just to MCO, PHP, and PCCM mailings of marketing materials and that those currently enrolled in the MCO, PHP, or PCCM be excluded from the requirement. One commenter thought it reasonable to require that materials be sent only to those who are eligible or potentially eligible for Medicaid in a given service area.

Response: Section 1932(d)(2)(B) of the Act requires that marketing materials be distributed to the entire service area. The intent of this provision is to prohibit marketing practices that favor certain geographic areas over those thought to produce more costly enrollees. However, the regulation might not allow for diversity and cultural sensitivity. In response to the commenters' concerns, we have revised proposed § 438.104(b)(2)(ii) (redesignated as § 438.104(b)(1)(ii) in this final rule with comment period) to require that each MCO, PHP, and PCCM contract must provide that the entity "distributes the materials to its entire service area as indicated in the contract." The phrase "as indicated in the contract" is intended to provide States and MCOs, PHPs, and PCCMs with some flexibility in designing and implementing marketing plans and in developing marketing materials. We expect that when States review MCO, PHP, PCCM, or marketing and informing practices, they will not only consider accuracy of information, but also factors such as language, reading level, understandability, cultural sensitivity, and diversity. In addition, the State review should ensure that MCOs, PHPs, and PCCMs do not target or avoid populations based on their perceived health status, cost, or for other discriminatory reasons. For example, a State may permit distribution of materials customized for an Hispanic population group as long as the materials are comparable to those distributed to the English speaking population. While the presentation and formats of the information may be varied based on the culture and distinct needs of the population, the information conveyed should be the same in accordance with § 438.10. In the above example, the materials for the Hispanic population group must be distributed to all those Medicaid eligibles or enrollees who require or request Hispanic-related materials. Materials would not need to be distributed to every individual in a given service area, but they would need to be distributed to all known Medicaid eligibles or enrollees in an area. States that use this flexibility to allow selective marketing may permit distribution by zip code, county or other criteria within a service area if the information to be distributed pertains to a local event such as a health fair, a provider, hospital or clinic. However, States must ensure that health fairs are not held in areas only known to have or perceived as having a more desirable population. We have chosen not to limit the distribution requirement only to mailings because broadcast advertising and other marketing activities can also be done selectively. All marketing activities should be conducted in a manner that provides for equitable distribution of materials and without bias toward or against any group.

Comment: Some commenters asked whether marketing materials must be distributed to the entire service area all at once. Because materials may generate significant interest and phone calls to the MCO, PHP, or PCCM, and distributing materials to the entire service area at one time could be overwhelming. The commenters asked that staggered mailings be allowed so that responses to potential member inquiries can be timely. They also wanted flexibility to distribute marketing materials by zip code.

Response: States that permit marketing may oversee incremental distribution of marketing materials as long as the service area wide distribution requirements are observed.

Comment: Some commenters believe that States should ensure that when MCOs, PHPs, and PCCMs distribute marketing materials to the entire service area, the materials are in the languages spoken in that area, and proportional to the number of beneficiaries in the area with limited English proficiency. The commenters asserted that it is critical that the enrollment activities and the enrollment staff be capable of communicating effectively with those who have limited English proficiency and that there be adequate supplies of marketing materials in the appropriate languages. Several commenters contended that the regulation was too vague in this area, and should provide more concrete guidance.

Several comments, although not specifically addressing the service area distribution requirement, emphasized that MCOs, PHPs, and PCCMs (and their enrollment staff and written materials) be tailored to the needs of those with limited English proficiency. They also recommended that materials be appropriately translated throughout the service area. The recommendation was that this be required, and that guidelines be established for appropriate marketing to non-English and limited English-speaking individuals. One commenter observed that there are no cultural and linguistic requirements for marketers in the regulation and suggested that we require assurances of cultural and linguistic competency of marketers.

Response: We agree with the commenters that it is important for potential enrollees and enrollees with limited English proficiency have access to information in the appropriate language. Section 483.10(b) provides specific guidance regarding the language requirements applicable to information furnished to potential enrollees and enrollees. These requirements apply to all information, including marketing material, therefore, we do not believe that further guidance is needed in this section of the regulation.

Comment: One commenter urged that providers who contract with an MCO, PHP, or PCCM be able to market their program and services to other managed care entities inside and outside of their geographic area in order to fill vacancies. The commenter believed that the marketing restrictions might allow MCOs, PHPS, and PCCMs to unreasonably restrict the ability of providers to contract with other entities. The commenter recommended that the marketing restrictions not be applicable to marketing materials developed by a provider who contracts with an MCO, PHP, or PCCM to solicit services and fill vacancies.

Response: The marketing restrictions contained in this regulation apply to MCO, PHP, or PCCM marketing directly or indirectly to Medicaid enrollees and potential enrollees. The provision does not apply to certain providers or facilities marketing their services to MCOs, PHPs, or PCCMs.

Sale of Other Insurance

Proposed § 438.104(b)(2)(iv) required MCO, PHP, and PCCM contracts to assure that the entity does not seek to influence enrollment in conjunction with the sale of any other insurance. We stated in the preamble that we interpreted this provision to mean that MCOs, PHPs, and PCCMs may not entice a potential enrollee to join the MCO, PHP, or PCCM by offering the sale of any other type of insurance as a bonus for enrollment. However, we invited comment on this provision because we did not have any legislative history to consider when developing our interpretation.

Comment: Several commenters believed that language in this section was vague and needed clarification. Others expressed support for our interpretation prohibiting the offering for the sale of any other type of insurance as a bonus for enrollment and felt that the choice of an MCO, PHP, or PCCM must be unaffected by extraneous and conflicting incentives.

Some commenters encouraged us to prohibit other types of bonuses or gifts as inducements to enroll. These commenters noted that in the past, gifts have been offered to induce individuals to sign forms that they did not realize would change how they access their health care. Commenters recommended that, if we allow MCOs, PHPs and PCCMs to offer additional health care benefits for which they are not at risk, we should require minimum time periods during which the benefits must be offered, and require advance notice to members and an opportunity to change MCOs, PHPs, or PCCMs for cause if the benefits are discontinued. For example, commenters stated that some MCOs, PHPs, or PCCMs have offered extra benefits (eyeglasses) to induce enrollment and then discontinued these benefits after the initial enrollment period ended. Commenters indicated that Federal regulation was necessary in order to reduce the adverse impact of practices without entirely discouraging the provision of the extra benefits.

One commenter observed that inducements are generally ineffective, except when plans are essentially indistinguishable to beneficiaries. The commenter suggested that MCOs, PHPs, and PCCMs be encouraged to pursue market differentiation by offering better information about their quality and other attributes.

Response: In the past, we have provided guidance to States concerning incentives to enroll and the marketing of these incentives. However, we do not consider the expansion of the list of prohibited incentives to be within the purview of this regulation. States may permit MCOs, PHPs, and PCCMs to offer nominal incentives, similar to those commonly offered to commercial populations, or may choose to prohibit this practice entirely. States may also choose to set standards governing the offering of additional benefits. MCOs, PHPs, and PCCMs should be aware that practices such as offering additional benefits and the discontinuation of these benefits may, under certain circumstances, be considered deceptive, misleading or fraudulent activity and, therefore, could subject them to penalties. In response to commenters requesting clarification, we have revised the language to include situations where additional insurance is offered even if it is not offered for sale. This would include situations where, for example, an MCO offers a free burial insurance policy as an incentive to join that MCO.

State Agency Review

Proposed § 438.104(c) provided that, in reviewing the marketing materials submitted by MCOs, PHPs, and PCCMs, the State must consult with its MCAC or an advisory committee with similar

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membership. In § 431.12 of our existing rules, we established the requirements for an MCAC. The MCAC must include Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low income populations and with the resources available and required for their care. The MCAC must also include the Director of the Public Welfare Department or the Public Health Department, whichever does not head the Medicaid agency, as well as members of consumer groups including Medicaid beneficiaries and consumer organizations such as labor unions, cooperatives, and consumer-sponsored prepaid group practice plans.

Comment: A commenter requested clarification as to whether, when neither the Director of the Public Welfare Department, nor the Director of the Public Health Department was not the head of the Medicaid agency, if both were required to serve on the MCAC. This commenter also asked if the director(s) could designate a staff member to serve on the MCAC.

Response: We recognize that in some States neither the Director of the Public Welfare Department nor the Director of the Public Health Department is the head of the Medicaid agency. In this case, the State has the flexibility to decide if only one of these departments is represented on the MCAC or both are included. We also believe that, as long as the basic requirements at § 431.12 are satisfied, the specific rules governing the administration of the MCAC are properly left to the State's discretion. For example, States may permit the Director of the Public Health Department or the Public Welfare Department to delegate their representation to other qualified individuals representing their Department.

Comment: Commenters suggested that the composition of the MCAC should be revised to include at least one MCO, PHP, or PCCM that provides services to beneficiaries. One commenter suggested that beneficiaries with disabilities be represented on the MCAC. Another commenter suggested that the MCAC membership and role be clearly stated and public.

Response: The State may always add to the current MCAC composition requirements to include representatives of any affected groups or entities, such as MCOs, PHPs, or PCCMs. We encourage States to have an MCAC membership that is diverse and represents groups served by the State's program, for example, minorities and individuals with special needs. With respect to the final comment, we note that § 431.12 requires that the State plan must "provide for a MCAC meeting the requirements of this section" and that the State plan is a public document. We would encourage States to ensure that the public is clearly and completely informed about the role and membership of the MCAC or any similar committee.

Comment: One commenter felt that HCFA went beyond the requirements of section 1932(d)(2)(A)(ii) of the Act in requiring consultation with a committee with specific composition since the statute refers only to a "MCAC."

Response: We believe that in using the term "MCAC" the Congress intended to refer to the requirements in § 431.12 governing MCACs. We recognize, however, that consultation regarding marketing materials is a new and distinct function, and that the State may wish to designate a separate committee to perform this function rather than require the existing MCAC to assume it. We want to afford States the flexibility to develop a second committee, but we require that any committee charged with this responsibility also comply with the existing MCAC requirements in § 431.12.

Comment: Some commenters believed that it was not appropriate to include Medicaid consumers on a MCAC charged with reviewing proposed marketing materials from competing HMOs.

Response: The requirement for consumer participation in the MCAC has been in the regulations for many years. When the Congress specifically identified a "medical care advisory committee" as a consultant in the review and approval of marketing materials, we believe that they intended to incorporate by reference the current composition requirements of the required advisory body with this name. We continue to believe that consumers are extremely helpful in this advisory capacity because they are the intended audience of marketing materials and can provide important feedback on the review and approval of materials.

Comment: Many commenters contended that the use of a MCAC to review and approve specific pieces of marketing material was impractical, burdensome, unrealistic, and an example of micro-management. Many States' MCACs meet monthly, bi-monthly, or quarterly. Several commenters believe that it would be difficult, if not impossible, to provide the quick turnaround, in some cases ten days or less, necessary for approval of marketing materials. Some States require that marketing materials be submitted sixty days prior to intended use and some commenters believed that adding another level of review would slow down the process. The regulation was also called, by one commenter "unnecessary and bureaucratic" and not in keeping with the guiding principles cited in the preamble.

Many commenters who objected to MCAC review of marketing materials suggested that the MCAC or similar body review generic marketing materials or approve guidelines instead of reviewing each individual MCO's, PHP's, or PCCM's materials. Some commenters stated that the committee could establish review standards and then State or local staff trained in those standards could perform the actual review. They indicated that the committee's role should be consultative and not decision making. Others suggested that marketing materials be reviewed retroactively.

Response: We do not intend to require that the committee itself review and approve marketing materials. Rather, we intend to reflect section 1932(d)(2)(A)(ii) of the Act, which requires the State to consult with the committee during the State's own process of review and approval. The State is not required to obtain the committee's approval or consensus on the materials. The State has tremendous flexibility in determining how to consult with the committee. A State may elect to require the committee to review the actual marketing materials. If so, then in order to expedite the total review time, the State could permit the committee members to conduct their review concurrently with the State's review.

States may also consult with the committee in the development of standardized guidelines or protocols that are intended to facilitate State review. States may consult with the committee to develop suggested language and deem approval of an MCO's, PHP's, or PCCM's materials if that language is used. MCOs, PHPs, and PCCMs could also use some of the suggested language and then identify areas where different language has been used, and States could then limit the review or consultation to that particular portion of the materials. In response to the last comment, we believe that the statutory language ("in the process of reviewing and approving" marketing materials) precludes consulting with the committee retroactively.

Comment: One commenter suggested that the composition requirements of the MCAC could result in a conflict of interest between members and MCOs, PCCMs, and PHPs. Another commenter suggested that the MCAC be held to confidentiality standards.

Response: The MCAC composition requirements have been in the regulations for over twenty years, and have always involved the potential for conflict between providers and beneficiaries who are served by the providers. We do not believe that this regulation raises any new concerns regarding conflicts of interest. Therefore, we are not revising the composition requirements in this final rule with comment period. We would not anticipate that the MCAC or any similar advisory body would have a need to review or have access to individually identifiable information about Medicaid beneficiaries, but if they did, then they would be governed by the same confidentiality standards that apply to the State Medicaid agency (Subpart F, Part 431).

Comment: Many commenters expressed strong support for requiring that marketing materials be reviewed by a committee to ensure that the materials are not false or misleading and to ensure that the information is understandable. One commenter stated that using established MCACs would not provide a level of consumer and advocate involvement sufficient to identify and resolve problems or develop appropriate policies. This commenter recommended that States be required to actively work with consumers on contract development, client protections, quality assurance, and problem resolutions.

Response: We appreciate the commenters' support. This provision, however, is intended to be limited to requiring consultation with a committee that includes consumer representation on the subject of the review and approval of marketing materials. This provision does not speak to the need for consumer participation in the development of the entire managed care system. We do require consumer involvement in other sections of this final regulation; for example, in § 438.202(c) we require the State to provide for the input of beneficiaries and other stake-holders in the development of the quality strategy, which must include making the strategy available for public comment before adopting the quality strategy. We encourage involvement by stakeholders during all phases of managed care implementation.

Comment: Commenters pointed out that neither the nature of the consultation nor its expected outcome was specified in the proposed rule.

Response: The legislative history do not indicates that the Congress intended for the consultation to be of any specific nature or have any specific outcome. Instead, it prescribe a Federal standard. We believe it is more appropriate to permit States to define the specific role of the committee.

Comment: A commenter pointed out that States that have adopted model legislation developed by the National Association of Insurance Commissioners (NAIC) have regulatory processes in place for the review of marketing materials and that MCAC involvement could lead to conflicts between the MCAC and the regulatory body.

Response: The NAIC's "Advertisements of Accident and Sickness Insurance Model Regulation" sets forth minimum criteria to ensure proper and accurate description of products and to protect prospective enrollees. The criteria are similar to the criteria for advertisements of Medicare supplemental insurance. States are free to use all or part of this model to craft their marketing standards and contract language. A State's use of NAIC or similar standards should neither conflict with nor complicate consultation with the MCAC or similar committee because the committee should be following standards adopted by the State.

4. Liability for Payment (§ 438.106)

Proposed § 438.106, consistent with section 1932(b)(6) of the Act, required MCOs to provide that their Medicaid enrollees will not be held liable for—(1) the debts of the MCO in the event of insolvency; (2) services provided to the enrollee for which the State does not pay the MCO or the MCO does not pay the individual or provider that furnishes the services under a contractual, referral, or other arrangement; or (3) payments for services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO provided the services directly.

Comment: We received several comments in response to our request for public guidance on § 438.106(c) that refers to beneficiary liability for payments to a provider "in excess of the amount the enrollee would owe if the MCO provided the services directly". Most commenters agreed with our position that Medicaid managed care enrollees should not be responsible for more than nominal charges for cost sharing. One commenter sought clarification of when the situation described in § 438.106(c) would apply, and another suggested that the amount owed by the Medicaid beneficiary should be any cost sharing required by the contract. Another commenter suggested that the provision may have been intended to address a recent trend in the managed care industry of establishing coverage options that allow enrollees to go out of network for services in exchange for higher premiums or co-pays (that is, "point-of-service" options), as there may have been concern that this type of coverage could be interpreted by MCOs as a non-Medicaid benefit for which they could charge.

Response: As we stated in the preamble to the proposed rule, Medicaid beneficiaries should not "owe" an MCO any payment amounts beyond nominal cost sharing. Section 1916 of the Act specifically prohibits States and plans from imposing additional cost sharing. We agree with the comment that § 438.106(c) would prohibit MCOs from offering a point-of-service option. This paragraph states that an enrollee may not be held liable for payment (for services furnished under a contract, referral, or other arrangement) in excess of the amount that the enrollee would owe if the MCO provided the services directly. In other words the enrollee may only be held liable for nominal cost sharing.

Under this regulation, enrollees may obtain out-of-network services under the following circumstances:

- Enrollees may always obtain family planning services out-of-network, as provided in our current regulations at § 431.51;
- Enrollees who reside in rural areas and are mandatorily enrolled in a single MCO, PHP, or PCCM may obtain out-of-network services as provided in § 438.52(b);
- Enrollees may obtain emergency and post-stabilization services from out-of-network providers as specified in § 438.114;
- Enrollees may obtain services out-of-network if the network is unable to meet an enrollee's medical needs as specified in § 438.206(d)(5).

The protection in § 438.106(c) would apply under all of these circumstances, therefore, the enrollee could not be held liable for costs in excess of the amount that the enrollee would owe if the MCO provided the services directly.

Comment: Several commenters were concerned that § 438.106 could be interpreted to require an MCO to pay its network providers for services that are not covered under the Medicaid State plan or are furnished by its network providers not in accordance with the provider's contract terms with the MCO. They suggested that we add language to clarify that the MCO's obligations are limited to those services that are covered under the contract between the

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State agency and the MCO, as well as to those services covered under the contract between the MCO and the provider.

Response: In this section, we intend to protect beneficiaries against liability for payment of covered services. We agree with commenters that the proposed language could be interpreted as prohibiting enrollee liability for non-covered services or non-emergency or urgently needed services provided out of network, although this is not the intent. We therefore provide in this final rule with comment period at § 438.106(b) and (c) that enrollees cannot be held liable for "covered" services. "Covered" services would include any service that the State covers through its managed care program, whether it is a service that is covered under the contract between the State and the MCO (including additional or alternative services to traditional State plan services), or a service that is carved out of the capitation rate and paid fee for service, as long as the service is obtained appropriately. This provision does not preclude enrollee liability for non-covered services, or for covered services that are obtained inappropriately (for example, services obtained without a referral when one was required) unless, on appeal, it is determined that the services are covered.

Comment: One commenter requested that we add language that incorporates the "hold harmless" concept developed by the NAIC. Specifically, the commenter suggested that we revise the regulations to provide that beneficiaries should be "held harmless" for the cost of covered services except for applicable cost sharing.

Response: We believe that the provisions of § 438.106, as written, sufficiently convey that enrollees may not be held liable for the cost of covered services except for nominal cost sharing. We do not believe it is necessary to add additional language referencing the NAIC's "hold harmless" concept.

Comment: Several commenters suggested that we clarify that beneficiaries should not be held liable for family planning services covered under the Medicaid program, nor should they be held liable for reproductive services that are not provided by the health plan or its subcontracting providers or that are not reasonably accessible within the health plan.

Response: As stated above, we have revised § 438.106 to reflect that enrollees may not be held liable for "covered" services, which include family planning services. Section 431.51(a)(4), (5), and (6) provide that Medicaid beneficiaries enrolled in an MCO, PHP, or PCCM may not be denied freedom of choice for family planning services. This means that even family planning services that an enrollee obtains out of network are "covered" services for which the beneficiary may not be held liable. In addition, § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies. Therefore, we do not believe it is necessary to specifically address family planning services in § 438.106.

5. Cost Sharing (§ 438.108)

Prior to the enactment of the BBA, MCOs were prohibited from imposing cost sharing on enrollees. The BBA eliminated this prohibition, and provided that copayments for services furnished by MCOs may be imposed in the same manner as they are under fee-for-service. In § 438.108 of the NPRM, we proposed that the contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with § 447.50 through § 447.58 of existing regulations.

Comment: One commenter recommended that we specify in § 438.108 that family planning services and supplies are excluded from cost sharing.

Response: This section specifies that any cost sharing imposed for services provided by an MCO must be in accordance with § 447.50 through § 447.58 of our rules. Because § 447.53(b)(5) states that cost sharing cannot be imposed for family planning services and supplies, we do not believe it is necessary to refer to this exclusion again under § 438.108.

Comment: Several commenters believed that it was important that contracts make clear that any cost sharing imposed under the contract must be nominal. Commenters also expressed concern that cost sharing could become a barrier to care, and that cost sharing requirements could be particularly problematic for enrollees who regularly use the health care system. The commenters believe that even nominal copayments, if consistently collected by MCOs, could deter enrollees from obtaining needed care.

Response: The regulation clearly requires that any cost sharing imposed for services delivered either by an MCO or under fee-for-service be nominal. We agree with the commenters that cost sharing may act as a deterrent to obtaining care. Therefore, in § 447.53, we are adding a new paragraph (e) that states: "No provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing." This language closely tracks the statutory language in section 1916(e) of the Act. This provision applies to services furnished either by an MCO or under fee-for-service.

Comment: One commenter suggested that we exclude enrollees receiving home and community-based waiver services from cost sharing.

Response: The BBA did not identify any new groups of enrollees to be excluded from cost sharing. The law only provided that cost sharing for MCO services may be permitted in the same manner as it is permitted under fee-for-service. Enrollees receiving home and community-based waiver services are not excluded under our current fee-for-service program and therefore, we are not excluding them from cost sharing for services furnished by an MCO. We note that States may always elect not to impose cost sharing on all enrollees or on specific groups of enrollees.

Comment: A few commenters stated that cost sharing creates a barrier to American Indian and Alaskan Native (AI/AN) participation in Medicaid programs, because they can access the Indian Health Service (IHS) and tribally-operated programs without paying for services. Further, the commenters noted that IHS and tribal providers are not authorized by the Congress to impose cost sharing for services provided to American Indians. These commenters recommend that we exercise the Federal trust responsibility to provide health care for AI/AN populations by exempting them from any cost sharing in Medicaid programs. Since the Federal government pays 100 percent FMAP for services delivered by tribally operated facilities, the commenters believe there should be a provision explicitly prohibiting States from imposing cost sharing on AI/AN Medicaid beneficiaries.

Response: The Congress has been very specific in section 1916 of the Act in specifying which categories of individuals or services are exempt from cost-sharing, and we believe that it would be inconsistent with Congressional intent to exempt additional groups. We note that under § 447.53(b)(1), all children (including AI/AN children) are exempted from cost sharing.

Comment: One commenter recommended that we eliminate the application of § 447.57 to cost sharing for services furnished by MCOs. The commenter stated that § 447.57 prohibits States from reimbursing providers for unpaid copayments. The State Medicaid plan must specify that the State agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, co-insurance, copayments, or similar charges that the provider has waived or are uncollectible. The commenter expressed concern that this provision inappropriately places the economic burden of unpaid copayments on health care providers, such as community pharmacies. The commenter stated that requiring pharmacies to absorb the cost of unpaid copayments discourages participation by pharmacies in Medicaid MCOs and discourages MCOs from participating in Medicaid.

Response: The BBA allows us to permit copayments under managed care in the same manner as we permit them under fee-for-service. At this time, we are not proposing to revise the rules that apply under fee-for-service to remove the requirement that States not reimburse providers for uncollected payments. Therefore, it will also apply to services furnished by an MCO. We encourage interested parties to work with States in developing their cost sharing policies.

Comment: One commenter felt that MCOs should be required to make cost sharing requirements clear in all cases, and enrollees should be informed of what constitutes "good cause." The commenter recommended that if an MCO advertises that it does not require copayments, then it should be prohibited from charging copayments for two years. The commenter also stated that MCOs should make clear at the time of open enrollment whether they intend to charge copayments during the contract year.

Response: We agree with the commenter that enrollees should have clear information about cost sharing requirements. In § 438.10(d) and (e), we specify that information furnished to potential enrollees and enrollees, respectively, must include information on any cost sharing. MCOs are also required to inform potential enrollees and enrollees of any significant changes in the information that was furnished to them 30 days prior to the effective date of the changes. While the State will determine what qualifies as "significant", we assume that States would find that the introduction of new cost sharing requirements would constitute a significant change.

In addition, in § 438.56(d)(2)(iv), we specify that "good cause" for disenrollment by the enrollee includes poor quality care, lack of access to necessary specialty services covered under the contract, or other reasons satisfactory to the State agency. Under this provision, the State could determine that a change in the MCO's cost-sharing policy constitutes "good cause" for disenrollment.

Comment: One commenter expressed concern about the inappropriate use of hospital emergency rooms. The commenter recommended that we allow and encourage States to charge beneficiaries a $25 copayment per visit for inappropriate use of the emergency room. According to the commenter, MCOs could require that hospitals collect the copayment at the time of the visit and the enrollees would not be denied care because of inability to pay the copayment. If it was determined that a true emergency existed, the copayment would be refunded. The commenter believes that this would serve as an incentive to enrollees to seek care in the appropriate setting, at the appropriate time and would allow the primary care physician to establish a medical relationship with the beneficiary.

Response: Under § 447.53(b)(4), emergency services are exempted from cost sharing. Specifically, copayments may not be imposed on "[s]ervices provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—(1) placing the patient's health in serious jeopardy; (2) serious impairment to bodily functions; or (3) serious dysfunction of any bodily organ or part." We emphasize that as long as the enrollee seeks emergency services that could "reasonably be expected" to have the above effects, a copayment may not be imposed, even if the condition was determined not to be an emergency.

The State may decide to impose a copayment for non-emergency services furnished in an emergency room in cases where the enrollee sought services in an emergency room when the standard under § 447.53(b)(4) was not met. Furthermore, the State may request a waiver of the requirement that cost sharing charges be nominal. Section 431.57 provides that for non-emergency services furnished in a hospital emergency room, the Secretary may grant a waiver to permit a State to impose a copayment of up to double the nominal copayment allowed under § 447.54.

Allowing payment of a copayment up front in a hospital emergency room as the commenter suggested would raise the implication of non-compliance with the standard in § 447.53(b)(4). However, enrollees should be aware that if they seek services in an emergency room when the standard in § 447.53(b)(4) is not met, they may be held liable for cost sharing.

6. Assurances of Adequate Capacity and Services (§ 438.110)

Under the authority of section 1932(b)(5) of the Act, proposed § 438.110 required that an MCO provide the State and the Secretary with adequate assurances that the MCO has the capacity to service the expected enrollment in its service area.

In proposed § 438.110, we interpreted the term "assurances" to require MCOs to submit documentation to both the State and us. While States were given the flexibility to decide the types of documentation to be submitted by MCOs, we specified that the documentation had to address the State's standards for access to care outlined under proposed § 438.306 (redesignated as § 438.206 in this final rule with comment period). In addition, we proposed that MCOs be required to submit documentation to the State and us, along with State certification, at least every two years, and at the time the MCO enters into or renews a contract with the State or when there has been significant change in the MCO's delivery network or enrollee population.

We received many comments on this section from State agencies, professional organizations, and advocates. A number of commenters appeared confused over this section's interface with proposed § 438.306, and argued that we need to be more detailed in both sections of this final rule with comment period. We recognize that the requirements relating to availability of services and assurances of adequate capacity are closely related and therefore, in this final rule with comment period, we have redesignated § 438.110 as § 438.207 so that these requirements may be read and applied together. We will respond to the comments that were received regarding proposed § 438.110 below.

Comment: Several commenters felt that proposed § 438.110, combined with proposed § 438.306, did not recognize the unique needs of homeless persons, women, children, and individuals with disabilities. Commenters believed we should require additional documentation, and establish standards that specifically recognize the needs of these populations.

Many recommendations were offered. With regard to the persons who are homeless, commenters recommended that MCOs and PHPs should create linkages with service providers offering a wide range of culturally appropriate

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medical and social services, including case management. They recommended that the services be available at sites such as soup kitchens, drop-in centers, and shelters where homeless people congregate and are willing to receive care.

A few commenters suggested that we should respond to the needs of children by requiring that primary care pediatricians be available to provide care to children under 19 years of age. In addition, commenters suggested that we require pediatricians to serve as primary care providers, and require that such providers be available 24 hours a day, 7 days a week. Further, the commenters believed that we should require MCOs to include specialists with appropriate pediatric training and expertise, and require that they have arrangements with appropriate tertiary care centers. If an MCO fails to have an adequate number of pediatric providers, including primary and specialty care, the commenter urged that we require that these services be available to enrollees out of network at no additional costs.

Other commenters recommended that proposed § 438.110 be amended to require MCOs to document the availability of women's health specialists. Specifically, one commenter recommended that MCOs that do not contract with hospitals and health entities that provide a full range of reproductive services should be required to demonstrate access to alternative sites, which are medically appropriate and geographically, culturally, and linguistically accessible. In addition, if an MCO cannot demonstrate a full range of reproductive health services, the State should demonstrate to HCFA how individuals will be able to access those benefits without any undue burden.

Commenters also recommended that a provision be added to specifically address the needs of disabled individuals. One commenter recommended that we require MCOs to—(1) identify the populations that will be served, if disabled or unique; and (2) identify specialized professionals, DME, and related supply services that will be available to accommodate each population category. Another commenter suggested that MCOs should be required to document an appropriate range of services and networks, given that various communities may speak different languages. Other commenters suggested that we incorporate stronger requirements that address access to ancillary services, linguistic access, and physical access. Finally, one commenter recommended that we require physicians trained in mental illness to act as primary care providers for persons suffering from mental illness.

Response: The proposed rule was developed to address the needs of all Medicaid populations served under managed care. As we indicated in the preamble to the proposed rule, proposed § 438.110 was to address the procedural requirements for submitting assurances of adequate capacity and services, while proposed § 436.306 was to address the substantive requirements ensuring the availability of services. The intent behind both sections was that States be given flexibility to develop access standards and documentation requirements appropriate for the populations enrolled and specific to the unique circumstances in each State.

Although we therefore do not mandate all of the detailed requirements suggested by commenters, we do require in this final rule with comment period that States, MCOs, and PHPs, maintain an adequate delivery network under § 438.206(d)(1), pay particular attention to pregnant women, children, and persons with special health care needs. We added the last category of enrollees to recognize the special needs of individuals who, for example, disabled or homeless, and who require special attention from the MCO in order to access the health care system.

In addition, in this final rule with comment period, we require the State to identify to the MCO or PHP upon enrollment specific groups at risk of having special health care needs. We also require MCOs and PHPs to make a best effort attempt to identify and comprehensively assess pregnant women, and persons with special health care needs.

We believe that the above provisions ensure that the State, when developing its standards for access to care and when monitoring an MCO's or PHP's capacity and adequacy of services, pays particular attention to managed care enrollees who are vulnerable. Although this final rule with comment period does not include all recommendations offered by the commenters, States are free to consider them.

Comment: One commenter noted that neither States nor MCOs have developed a methodology to measure adequate capacity. The commenter states that while many States have required MCOs to submit a great deal of information with the intent to measure adequate capacity, that information for the most part has not been useful. Further, the commenter expressed concern that MCOs will be required to submit unnecessary data and information, thus wasting considerable resources. This commenter suggested that the most expedient and effective way to measure adequacy and access is to ensure that enrollees know how to contact the managed care plan for information and how to file complaints and grievances. The commenter recommended that States be allowed to use their judgment on these issues under their existing certification processes.

Response: Section 1932(b)(5) of the Act requires MCOs to provide the State and the Secretary with adequate assurances that the MCO has the capacity to serve the expected enrollment of Medicaid beneficiaries in its service area. The Congress specified that these assurances must demonstrate that each MCO has an appropriate range of services, and a sufficient number, mix, and geographic distribution of providers. Based on this statutory mandate, we are imposing detailed requirements on MCOs and States, including a requirement that MCOs submit documentation. We believe that States must have documentation in order to assess capacity and adequacy of services. We have clarified in this final rule with comment period that the documentation required under this section must be submitted by MCOs in a format specified by the State and acceptable to us. We recognize that MCOs may not be able to construct a provider network that anticipates all future needs of enrollees. Therefore, in this section we are requiring that the MCO have policies and practices in place to address unanticipated need for, or limitations in availability within their service area of, certain experienced providers when required by enrollees. We agree with the commenter that enrollees must know how to contact the MCO and know how to file grievances, appeals, and State fair hearings. Section 438.10 requires that this information be furnished to enrollees.

Comment: We received one comment questioning whether we should apply proposed § 438.110 to voluntary MCOs. The commenter believed that the provisions are burdensome for MCOs and PHPs in which enrollment is voluntary, especially when they are added to the proposed access requirements. The commenter recommended that this section be applied only to MCOs and PHPs in which enrollment is mandatory.

Response: Section 1932(b)(5) of the Act does not distinguish between voluntary or mandatory managed care organizations; rather, the statute generally references managed care organizations under section 1903(m) of the Act, which applies to both voluntary and mandatory enrollment MCOs. Section 1903(m)(2)(A)(xi) of the Act requires that all MCOs meet applicable requirements in section 1932 of the Act. We have no discretion to exempt voluntary enrollment MCOs from the requirement in section 1932(b)(5) of the Act. We also do not see any justification for applying a lower standard under section 1932(b)(5) of the Act in the case of MCOs with voluntary enrollment. Under section 1903(m)(2)(A)(vi) of the Act, once an individual enrolls in a "voluntary enrollment" MCO, the enrollee may be "locked in" after the first 90 days for 12 months at a time. It is just as important to ensure adequate capacity in a case, as it is in the case of a "mandatory enrollment" situation.

Comment: We received one comment supporting proposed § 438.110(a), and the grievance and appeals provisions in proposed subpart E. The commenter noted that these provisions are consistent with the broader and more detailed obligations imposed on all health benefit plans in California.

Response: Our intent in the proposed and this final rule with comment period is not to prohibit a State from imposing more stringent standards concerning the adequacy of an MCO's network capacity and services. Our intent is to ensure that States, at a minimum, review MCO network capacity and services, and certify to us that the MCO satisfies the State's requirements for availability of services, as required under § 438.206. We are pleased that our standards are consistent with California's.

Comment: We received many comments suggesting that the documentation described in proposed § 438.110(b) should be sent to the State and not directly to HCFA. Although several commenters favored HCFA becoming more involved in reviewing MCO documentation justifying adequate capacity and services, a large number of commenters recommended that we delete the requirement for direct submission of documentation by MCOs to HCFA.

Specifically, commenters argued that States, and not HCFA, were responsible for entering into and monitoring contracts with MCOs, and ensuring that adequate capacity exists to serve enrollees. Other commenters argued that direct submission of documentation to HCFA would be redundant, unprecedented, and contrary to our stated intent to provide States flexibility wherever possible. A few commenters suggested that the proposed documentation requirements went beyond the statutory provisions in the BBA, which in the commenters' view only require that "assurances" be made to the Secretary.

Commenters also asserted that the proposed rule does not recognize the differences among the 50 states, and questioned what HCFA would do with the information once received, and whether we would be diminishing the management authority of the States. Finally, a number of commenters asked that we consider the administrative burden of this requirement, believing it would constitute unnecessary micro-management on the part of the Federal government.

Response: Based on comments received, we have re-evaluated proposed requirement that assurances be routinely and directly provided to us. This requirement was based on the fact that section 1932(a)(5) of the Act requires that MCOs provide adequate assurances to "the State and the Secretary." We believe, however, that the requirement that the Secretary be provided with adequate assurances can be satisfied by requiring the State to provide assurances to us that it is satisfied that standards are met. In this final rule with comment period, we do not require the MCO to submit documentation directly to us. We agree that documentation should be submitted to the States that are the entities that contract with MCOs, and that it might be redundant for us to regularly receive all of the documentation. In this final rule with comment period, we require only that the State submit to us certification of an MCO's adequate capacity and services in accordance with State-established standards for access to care under § 438.206. We also added a provision that allows us to inspect the documentation submitted by MCOs.

We did not intend to interfere with the State's role in determining whether an MCO has demonstrated adequate capacity and services. We believe that the approach in this final rule with comment period satisfies our statutory requirements by providing us with sufficient flexibility to monitor State's actions and it also satisfies the commenters concerns by restoring the role of the States and reducing administrative burden. With respect to the commenters suggesting that our requirements go beyond the statute's requirement for "assurances," we note that the title of section 1932(b)(5) of the Act is "Demonstration of adequate capacity and services," and that the text requires "adequate" assurances. We believe it is reasonable, in order for the State to be "adequately" assured of an MCO's or PHP's capacity, and in order for the MCO or PHP to "demonstrate" such capacity, to expect documentation in support of the assurances it makes.

Comment: One commenter recommended that we request legislative action to eliminate the requirement in section 1932(b)(5) of the Act that assurances be submitted directly to HCFA. The commenter argued that direct submission by an MCO to HCFA would be unprecedented and redundant.

Response: A legislative change is not necessary in light of our decision to interpret our requirement as satisfied by the provision of assurances to us by States.

Comment: We received a number of comments on proposed § 438.110(b) asking that we provide additional clarification on the format of information to be received from MCOs and States assuring adequate capacity. Commenters questioned whether we would specify the electronic format to be used to submit information and whether we would require States to change current formatting requirements. One commenter reminded us that a change in formatting requirements could result in States and MCOs, PHPs, and PCCMs abandoning software already in use. Another commenter noted that for multi-state health plans, different electronic formatting requirements in each State would have enormous cost implications. This commenter suggested that States submit aggregate health plan information to HCFA.

Response: Because we no longer require direct submission of documentation from MCOs, it is not necessary to prescribe formatting requirements. We are requiring in this final rule with comment period that documentation be submitted in a format specified by the State and acceptable to us. We recognize that different States use different systems for collecting information. Accordingly, we permit a State to tailor the format of the documentation to its own unique system and resource capabilities. In meeting this requirement the State should submit to us its proposed format for approval. As we gain more experience in implementing this provision, we will provide formal guidance on acceptable formats. Although we are no longer requiring the direct submission of documentation from MCOs, we are requiring that States certify to us the MCO's assurances of adequate capacity and services. We wish to emphasize that the State certification must address how the MCO demonstrated compliance with the State's access standards developed under § 438.206.

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Comment: We received a number of comments on proposed § 438.110(b)(1), which requires an MCO to submit documentation demonstrating that it offers an appropriate range of services for the enrollees in the service area, including access to specialty services. Many commenters supported the reference to specialty services. Several commenters noted that for many individuals with disabilities and mental illness, specialty care often amounts to primary care. In contrast, several commenters objected to this provision and argued that the BBA did not address specialty care as part of this requirement. One commenter indicated that there are no national standards to determine specialty care capacity and services.

Many recommendations were offered. A number of commenters recommended that we maintain this requirement in the final rule with comment period, with a few suggesting that we provide technical assistance to States. One commenter suggested that we only require MCOs to demonstrate that they have the capacity to provide specialty services in a timely and accessible manner, and that we require MCOs to disclose what provisions they have made for infrequently used tertiary care services. Another commenter suggested that the State agency obtain proof, as appropriate, that it furnishes health services required by enrollees as promptly as is appropriate and that the services meet the agency's quality standards. Finally, one commenter suggested that we incorporate into the regulation itself the preamble language discussing proposed § 438.306, which suggests that States consider the volume of services furnished to other enrollees, and reminds States to ensure that providers are accessible to those who rely on public transportation.

Response: Although section 1932(b)(5) of the Act refers expressly only to preventive and primary care services, it requires assurances of "capacity to serve the expected enrollment," presumably including those enrollees who need specialty services. While it specifies expressly that these assurances should "includ[e]" assurances with respect to preventive and primary care, this does not mean that assurances about other types of services are not necessary. Indeed, the very clause that references preventive and primary care (section 1932(b)(5)(A)) of the Act also references "an appropriate range of services," which we believe includes specialty services. Section 1932(b)(5)(B) of the Act refers to "a sufficient * * * mix * * * of providers of services," which again in our view refers to having "sufficient" capacity for all types of providers, including specialists. We believe that section 1932(a)(5) of the Act, as we interpret it, provides authority for us to require assurances of specialty services. (We also have relied on our general authority under section 1902(a)(4)) of the Act.

We continue to believe that assurances with regard to specialists are important, and agree with the commenters that support this requirement. MCOs and PHPs must demonstrate access to specialty services based on the access standards established by the State under § 438.206. This reflects our recognition of the growing body of evidence showing that individuals secure positive health outcomes when treated by providers experienced in caring for significant numbers of individuals with a particular health care condition (for example HIV/AIDS). Also, in response to the above comments about the importance of specialty care which can serve as primary care for special populations, in § 438.206(d)(1)(iii), of this final rule with comment period, we have added a parenthetical statement to specify that in establishing the network, consideration of the types of providers needed must take into account the providers' "training and experience".

We emphasize that to demonstrate adequate access to specialty services, MCOs and PHPs need not contract with specialists in instances where a specialist provides infrequently used services or procedures. An MCO or PHP may satisfy this requirement in these types of cases, for example, by having appropriate arrangements with specialists, and allowing enrollees to go to these out-of-network providers to receive medically necessary specialty care. We note that in circumstances where an MCO's or PHP's provider network is unable to meet an enrollee's needs and the enrollee must seek care from an out-of-network provider, the enrollee may not be held liable for any additional expenses. In other words, for those services, enrollee liability must be the same regardless of whether they were received from in-network or out-of-network providers. Section 438.207(b)(4) of this final rule with comment period recognizes limitations in provider networks that may necessitate other arrangements, and provides for such alternative arrangements.

Although we believe examples in the preamble discussion of proposed § 438.306 referenced by the commenter are appropriate for State consideration, we have not incorporated them in this regulation. Given differences that may exist among States, it would be inappropriate to impose national ratio standards for access to specialty care.

Finally, in terms of providing technical assistance, we are always available to provide specific guidance to States upon request. We regularly provide technical assistance in a variety of different forms, including issuing letters to State Medicaid Directors, publishing Medicaid policy manuals, reviewing waiver applications and contracts, performing on-site monitoring reviews, and engaging in regular dialogue directly with State officials.

Comment: We received one comment requesting that we define the term "mix" in proposed § 438.110(b)(2), which stated that the MCO must submit documentation to demonstrate that it "maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area." The commenter argued that the term "mix" is too vague. Further, as used in the context of the proposed regulation, the term could be interpreted to mean ethnic, language, and cultural diversity, or various types of specialties. The commenter recommended that we articulate this term to ensure that rights and protections are not restricted.

Response: The term "mix" is taken directly from the statute and we have retained it in this final rule with comment period. We believe that the term "mix" refers to provider types, for example, as we have just noted above, the appropriate types of specialists. We note, however, that States will be required to review documentation submitted by MCOs to ensure that each MCO has demonstrated adequate capacity and services in accordance with the State's standards for access to care. One of the requirements of the access provisions is that a State ensure that each MCO provides services in a culturally competent manner (§ 438.206(e)(2)).

Comment: We received a number of comments on proposed § 438.110(c), which required MCOs to submit the documentation described in paragraph (b) at least every two years, specifically at the time the MCO enters into or renews a contract with the State, and at the time the State determines that there has been a significant change in the MCO's delivery network or enrollee population. A number of commenters suggested that the two year time frame for assessing adequate capacity and services was insufficient and would not adequately protect enrollees. The commenters recommended that we require an annual assessment of adequate capacity.

A number of other commenters suggested that States should have flexibility in determining when to require an MCO to provide assurances of adequate capacity. They argued that the two year time period specified in the proposed rule was too arbitrary and does not tie to existing contracts or waiver periods. Moreover, they noted that many States and MCOs assess adequate capacity within shorter intervals than the 2-year period proposed in the regulation. Their recommendations included a number of the following options: (1) shortening the time frame to one year; (2) revising the rule to allow for certifications to be submitted with waiver renewals, contract processes, or other administrative processes; and (3) requiring that assurances be sent at a time period agreed upon by HCFA and the State.

One commenter specifically noted that changes in reimbursement, limits on services, and the existence of closed panels affect provider composition. This commenter suggested that we require States to re-assess provider adequacy if changes in reimbursement policy or other factors require a change in network composition. Another commenter believed that if there is no substantial change in the delivery system, there is no need to re-submit information at each renewal. Finally, one commenter questioned how long it would take HCFA to review provider networks before approval can be given of a contract or contract amendment, since there were no time frames offered in the regulation for HCFA's review process.

Response: The time frames specified in proposed § 438.110 were never intended to prohibit a State from assessing adequate capacity at intervals shorter than two years. We proposed that, at a minimum, MCOs must submit the documentation at least every 2 years, and envisioned that States regularly would assess adequate capacity at the time it enters into or renews a contract with an MCO and when the State determines that there has been a significant change in an MCO's delivery network or enrollee population.

In response to commenters concerns, we have revised the provision in this final rule with comment period. We now require the MCO to submit documentation annually. The MCO is still required to submit the documentation at the time it enters into a contract and any time there has been a significant change in the MCO's operation that would affect capacity and services. We also in § 438.207(c)(2) provide examples of what constitutes a significant change in the MCO's operations. Although States are free to include other changes, we believe, at a minimum, significant changes include—(1) a significant MCO service or benefit change; (2) an expansion or reduction of the MCO's geographic service area; (3) the enrollment of a new population in the MCO; and (4) a significant MCO rate change. We also specify that after the State reviews the documentation from the MCO, the State must certify to us that the MCO has complied with the State's requirements for availability of services, as set forth in § 438.206.

Finally, we acknowledge that several commenters were confused over the interface of this rule with the section 1915(b) of the Act, waiver review process. Commenters should be aware that, if there has been a significant period of time between the State's assessment of adequate capacity at the time of a waiver renewal, we may ask the State to update its analysis of adequate capacity and services as part of the waiver review process, and may request documentation of an MCO's capacity at that time.

Comment: Several commenters expressed the view that § 438.110 did not have any enforcement mechanism. Citing problems encountered by American Indians in gaining access to specialists in voluntary Medicaid managed care programs, one commenter suggested that as an enforcement tool, we compare the rates paid for Medicaid beneficiaries by an MCO or PHP to those paid under fee-for-service Medicaid to ensure that a sufficient amount is paid to ensure access and availability. Further, the commenter suggested that we also direct detection and enforcement activity at providers that limit the number of appointments they make available to Medicaid enrollees. Another commenter argued that we did not discuss any consequences to the MCO should it fail to demonstrate adequate capacity and services. This commenter suggested that we address corrective action plans and other appropriate consequences in the regulation. Several other commenters recommended that the regulation explicitly describe HCFA's authority to determine whether States and MCOs or PHPs have adequately demonstrated capacity, and describe HCFA's ability to deny FFP if they have not.

Response: In addition to reviewing managed care contracts, we regularly monitor the operation of Medicaid managed care programs throughout the country. We have a variety of different monitoring tools, such as reviewing State reports and MCO or PHP documentation, interviewing representatives of the State, MCO or PHP, interviewing enrollees, reviewing provider agreements and contracts, and surveying participating providers.

We also have many mechanisms to enforce the provisions of this section. They range from issuing letters and corrective action plans to imposing terms and conditions under waiver programs, to conducting regular on-site monitoring reviews, and to withholding FFP under § 438.802(c) of this final rule with comment period (see section II. H. below). Our goal is to work with States to resolve problems and take action, as appropriate for the particular circumstances.

We note, in response to the commenter's concern regarding access to specialists under managed care, that section 1903(m)(1)(A)(i) of the Act requires an MCO to "make services it provides to individuals eligible for benefits under this title accessible to individuals to the same extent as such services are made accessible to individuals (eligible for Medicaid assistance under the State plan) not enrolled with the organization." Accordingly, under managed care, States must ensure that MCOs provide Medicaid enrollees access to contracted services to the same extent such access is available under fee-for-service. Again, FFP could be disallowed in the case of a failure to comply.

Comment: We received a few comments questioning whether there is an adequate process for input and disclosure with regard to proposed § 438.110. One commenter recommended that we require public disclosure, upon request, of criteria used by an MCO or PHP to select and monitor the performance of health care providers, including those providing specialty services to persons with chronic diseases or disabilities. The commenter further recommended that the final rule with comment period require public disclosure of QISMC and accreditation surveys, arguing that we should require the same disclosure of quality assurance in Medicaid managed care as required under the Medicare+Choice program.

Another commenter recommended that we require States and HCFA to provide public access to documents, provide reasonable notice of pending review, permit public comment, and hold review hearings as appropriate. Finally, several commenters recommended that we require States to obtain input from consumers, consumer advocates, and medical providers, for

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use in setting access standards. They suggested that States may do this through MCAC, proposed rulemaking, or public hearings on proposed State plan amendments.

Response: In § 438.202(c) of this final rule with comment period, we require the State to provide for the input of recipients and other stakeholders in the development of the quality assessment and performance improvement strategy, including making the strategy available for public comment before adopting it in final. We believe that the quality strategy required in § 438.202(c) is the appropriate venue for public input with respect to State requirements governing MCO assurances of adequate capacity and services.

In § 438.207 of this final rule with comment period, we do not impose specific requirements with respect to public disclosure of documentation. We hope that States, consistent with their own laws, will provide enrollees and other stakeholders access to all relevant documentation submitted by MCOs to demonstrate their capacity to deliver contracted services. We note that States and MCOs, PCCMs, and PHPs must comply with the enrollee information requirements in § 438.10.

Comment: A few commenters questioned whether we would consider granting waivers of the requirement under proposed § 438.110 that adequate capacity be assured. One commenter recommended that MCOs be granted waivers from this requirement if they can demonstrate that a good faith effort has been made to solicit providers to participate in the MCO's network. The commenter asserted that there may not be an appropriate mix or geographic distribution of providers in certain areas, and there may be a limited number of specialty providers. The commenter suggested that, if the MCOs can demonstrate that there are not enough Medicaid providers for a particular zip code, they should be permitted to allow enrollees to go out of the service area.

Response: The provisions of § 438.206, Availability of services, allow States flexibility in designing standards for access to care. States should take into consideration locations where certain provider types may not be available. In these cases, States may permit MCOs to make arrangements with other providers outside of an MCO's service area in order to ensure capacity and services adequate to meet the needs of the enrollee population.

As a general rule, § 438.206 requires the MCO to maintain and monitor a network of appropriate providers. We recognize, however, that geographic mail distribution of providers, limitations in the number of certain providers nationally, as well as other factors, may make it difficult for MCOs to always be able to construct a provider network that will be able to address all the health care needs of its enrollees. For example, we acknowledge that the MCO's providers may not always be experienced in providing care to an individual who has a rare condition. Consequently, in § 438.207(b)(4) we require MCOs to have policies and practices to address unanticipated scarcity of providers to meet the health care needs of the enrolled population. Specifically, these policies and procedures should address the following: (1) the unanticipated need for providers with particular types of experience; and (2) the unanticipated limitation of the availability of such providers. In addition, § 438.206(d)(5) provides that if MCO's network is unable to meet an enrollee's needs, the MCO must permit the enrollee to access out-of-network providers.

Comment: One commenter specified that since deeming is allowed under section 1932(c)(2)(B) and (C) of the Act, we should allow States to deem an MCO or PHP as having met the requirements of § 438.110, if the organization has been accredited by a recognized accrediting body or has been Medicare certified.

Response: Section 1932(c)(2)(B) of the Act provides that States have the option of substituting private accreditation for the external quality review (EQR) required under section 1932(c)(2)(A) of the Act when EQR activities would duplicate an accreditation review. Section 1932(c)(2)(C) of the Act provides States the option to forgo EQR under section 1932(c)(2)(A) of the Act when the Medicaid MCO also has a Medicare+Choice contract in effect, and has complied with Medicaid EQR requirements for at least two years. The deeming provisions cited by the commenter only applies to the EQR requirements in section 1932(c)(2)(A)of the Act, and have no applicability to the requirement for assurances of adequate capacity in section 1932(b)(5) of the Act implemented in proposed § 438.110 and § 438.207 of this final rule with comment period. This final rule with comment period requires that assurances of adequate capacity be made at the time of contract approval and annually thereafter. We believe that it is essential that an adequate provider network be in place when beneficiaries are first enrolled in an MCO. The EQR activities are retrospective, that is, they take place after the fact and review for adherence to standards. While we believe that the EQR review is important, it is not an appropriate substitute for an assurance of adequate capacity.

Comment: We received a few comments questioning our proposal to eliminate part 434, subpart E from the regulations; specifically, the requirements under § 434.50(b) and § 434.52. Under § 434.50(b), a State was required to obtain proof from each contractor, of the contractor's ability to provide services under the contract efficiently, effectively, and economically. Under § 434.52, a State agency was required to obtain proof that each contractor furnished the health care services required by the enrolled recipients as promptly as is appropriate, and that the services met the agency's quality standards.

Commenters argued that these sections contain important consumer protections that should be maintained. Further, commenters asserted that the proposed rule no longer requires the State to obtain assurances that the services meet the State's quality standards, and only addresses the theoretical availability of services as opposed to whether the services are provided in a timely fashion.

Response: We believe that it would be confusing and redundant to retain these requirements. In part 438, we incorporate and expand upon the requirements previously set forth in subpart E of part 434. We disagree that the provisions in the proposed and this final rule with comment period no longer require a State to obtain assurances that an MCO's services meet the State's quality standards, and only address the theoretical availability of services. In this final rule with comment period, States must develop a quality assessment and improvement strategy that requires MCOs to meet State standards for access to care and to submit documentation demonstrating adequate capacity and services. In particular, we note that one of the access requirements is that MCOs adhere to the State's standards for timely access to care (§ 438.206(e)(1)).

7. Emergency and Post-Stabilization Services (§ 438.114)

Section 1932(b)(2) of the Act provides that each contract with an MCO or PCCM must require the MCO or PCCM—(1) to provide coverage of emergency services without regard to prior authorization, or the emergency care provider's contractual relationship with the MCO or PCCM; and (2) to comply with guidelines established under section 1852(d)(2) of the Act (with respect to coordination of post-stabilization services) in the same manner as those guidelines apply to Medicare+Choice plans.

In proposed § 438.114, we set forth the rules implementing these emergency and post-stabilization requirements. We proposed definitions of emergency medical condition, emergency services, and post-stabilization services. We proposed to require MCOs to provide specific information regarding emergency and post-stabilization services to enrollees at the time of enrollment and annually thereafter. We also outlined proposed rules for coverage and payment of these services.

We interpreted the term "coverage" to mean that an MCO that pays for hospital services generally must pay for emergency services obtained by Medicaid enrollees. We interpreted coverage in the primary care case management context to mean that the PCCM must allow direct access to emergency services without prior authorization. We applied different meanings to the term "coverage" because while PCCMs are primarily individuals paid on a fee-for-service basis, they receive a State payment to manage an enrollee's care. We determined that while PCCMs, unlike MCOs, are not likely to be involved in a payment dispute involving emergency services, they could be involved in an authorization dispute over whether a self-referral to an emergency room is authorized without prior approval of the PCCM. Accordingly, proposed § 438.114(d)(2) provided that enrollees of PCCM are entitled to the same emergency services coverage without prior authorization as is available to MCO enrollees under section 1932(b)(2) of the Act.

Section 1932(b)(2)(B) of the Act defines emergency services as covered inpatient or outpatient services that are furnished by a provider qualified to furnish services under Medicaid that are needed to evaluate or stabilize an emergency medical condition. Emergency medical condition is defined in section 1932(b)(2)(C) of the Act as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part. While this standard encompasses clinical emergencies, it also clearly requires MCOs to base coverage decisions for emergency services on the severity of the symptoms at the time of presentation and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson. The above definitions were set forth in proposed § 438.114(a). The identical definitions appear in the Medicare+Choice rules at § 422.113(b) and therefore, to avoid duplication, we incorporate those definitions by reference in this final rule with comment period.

Comment: One commenter stated that no protections now exist to require MCOs to cover ambulance services. The commenter cited proposed § 438.100(b), which states that Medicaid contracts with MCOs, PCCMs, or PHPs must either provide for all Medicaid services covered under the State plan or make arrangements to furnish those services. The commenter asserted that ambulance services should be covered in this regulation based on the authority in § 440.170(a), which states that transportation is a Medicaid covered service.

Response: Section 440.170(a) applies to non-emergency transportation, which is an optional Medicaid service that States may choose to provide or not to provide. Ambulance services are not included in the definition of "emergency services," as that definition refers to "inpatient or outpatient services." If a State covers ambulance services under its State plan, and these services are included in an MCO's contract, then the MCO must cover the ambulance services under the same terms they are covered under fee-for-service Medicaid. We recognize that the Medicare program has separate statutory authority to cover ambulance transportation when other transportation may jeopardize an enrollee's health, and that the Medicare+Choice statute thus obligates Medicare+Choice organizations to cover them. We do not, however, have that same statutory authority in the Medicaid program.

Comment: We received a number of comments on the rules governing post-stabilization care. Some commenters objected to requiring pre-approval from MCOs, PHPs, or PCCMs for post-stabilization services. Others opposed requiring an MCO, PHP, or PCCM with a risk contract that covers post-stabilization services to pay for those services without pre-approval if the MCO, PHP, or PCCM does not respond within one hour after receiving the provider's request or cannot be contacted for approval. The commenters believe that the requirement is too burdensome and the time frame is too short for an MCO, PHP, or PCCM to make an informed decision. Others thought the time period was too long for emergency physicians who must keep track of patient condition and be responsible for the stability of the patient. Some commenters believed that our preamble definition of post-stabilization was inconsistent with the definition in the regulation. They noted that the proposed definition in the preamble better described "maintenance care," and that it should not be used in place of the regulation definition.

Response: We acknowledge that the definition of post-stabilization in the preamble differed from that in the proposed regulations text, and that the preamble definition was not consistent with the Medicare+Choice definition that we are required to apply to Medicaid under section 1932(b)(2)(A)(ii) of the Act. We regret any confusion that this may have caused.

Under the Medicare+Choice definition at § 422.113(c)(1), post-stabilization care services means "covered services, related to an emergency medical condition, that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or * * * to improve or resolve the enrollee's condition." The Medicare+Choice rules create a two-step process for post-stabilization care. The first step occurs during the one-hour time frame, while the hospital waits for a response from the MCO. The second step occurs after the first hour. When the MCO receives a call from the treating hospital requesting prior authorization or transfer, the MCO has one hour to make a decision on a course of treatment, and respond to the treating hospital. During that one hour, the MCO is responsible for services related to the emergency medical condition that are necessary to maintain stabilization. Any period of instability that rises to the level of an emergency medical condition that occurs during this time would be covered under provisions at § 422.113(b) related to emergency services.

The rule further establishes that if the MCO fails to respond within the one-hour time frame, or the MCO cannot be reached, the treating physician can proceed with post-stabilization services that are administered not only to ensure stability, but also to improve or resolve the patient's condition. If a nonphysician MCO representative and the treating physician cannot reach an agreement on a course of treatment, the MCO must allow the treating physician to speak with a plan physician and the

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treating physician may proceed with care administered to improve or resolve the patient's condition until a plan physician is reached.

The MCO is financially responsible for post-stabilization services until the MCO and the treating physician execute a plan for safe transfer of responsibility. Safe transfer of responsibility should occur with the needs and the condition of the patient as the primary concern, so that the quality of care the patient receives is not compromised.

Comment: Many commenters recommended that we broaden the definition of emergency services to include coverage of "urgently needed" services. The commenters believe that expanding the definition would allow enrollees more leeway in seeking care in an emergency department for conditions that may benefit from earlier intervention. Some commenters stated that this policy would create a margin of safety for enrollees who may underestimate the severity of their illnesses and delay care if only the prudent layperson standard applies.

Response: The Congress has defined the obligations of an MCO to cover services received outside of an MCO's network. While MCO's are obligated to cover emergency services and post-stabilization services, there is no counterpart under the Medicaid statute for the obligation under section 1852(d)(C)(i) of the Medicare statute to cover "urgently needed services." This latter obligation generally applies only when an individual is out of the Medicare+Choice organization's service area, since it only permits services to be covered when they were not available through the organization's network. Since Congress in the BBA chose to obligate Medicare+Choice organizations to cover "urgently needed services, but chose not to do so in the same law in the case of Medicaid-contracting MCOs' we believe it would be inconsistent with Congressional intent to impose an obligation on MCOs to cover urgently needed services received out of area.

Comment: One commenter noted that some MCOs used a retrospective utilization review process to accept or deny an emergency claim based on a professional assessment of the nature of the emergency. The commenter believes that this violates the prudent layperson standard.

Response: Retrospective utilization review does not necessarily conflict with the prudent layperson standard as long as the MCO (or the State) reviews all documentation, takes into account the enrollee's presenting symptoms and applies the prudent layperson standard in making its determination. If the retrospective review reveals that the enrollee acted in a manner consistent with the prudent layperson standard, the enrollee may not be held liable for any additional costs even if it turned out that the case did not present a clinical "emergency" (that is, even if it turned out that the reasonable belief of a "prudent layperson" was incorrect). Section 438.114(e)(2) of this final rule with comment period expressly states that an enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition and stabilize the patient.

Comment: Many commenters were concerned that requiring MCOs, PHP, and PCCMs to provide a list of emergency settings and any other locations at which MCO, PHP, or PCCM physicians and hospitals provide emergency services covered under contract would imply that enrollees may not use any hospital or other proper setting for emergency care, but rather are limited to using participating hospitals. They suggested that we require that the list be accompanied by a clear statement of the enrollee's right to use any hospital or other setting for emergency care consistent with this section. One commenter requested that we prohibit MCOs from using lists of examples in their instructional materials of when it is inappropriate to use an emergency room because people with certain disabilities may require emergency treatment for some conditions that would not be emergencies for the general population.

Response: We agree with the first comment and have revised § 438.114(b) of this final rule with comment period to include as item (5) of the information that must be provided to enrollees and potential enrollees, the fact that, subject to the requirements of the section, the enrollee has the right to use any hospital or other setting for emergency care.

We believe that it is appropriate for MCOs, as well as States, to educate enrollees as to when they should or should not access emergency care. However, we have deleted the requirement that information provided to enrollees and potential enrollees include appropriate use of emergency services. States and MCOs can best determine how and when to provide this education to enrollees. Further, to monitor the appropriateness of the information provided, we encourage States to establish information requirements and review enrollee emergency information from MCOs before it is released.

Comment: Some commenters suggested that information regarding access to and availability of emergency and post-stabilization services should be available to potential enrollees upon request at any time, and this information should be posted prominently in emergency rooms and in providers' offices.

Response: We agree that potential enrollees should receive information regarding emergency care access. We have revised the introductory text of § 438.114(b) to require that the information be furnished to potential enrollees upon request. We encourage States, MCOs, PHPs, and PCCMs to disseminate information on access to enrollees as broadly as possible. We do not agree that we should require that this information be posted in emergency rooms as this is more appropriately provided by the State or the MCO, PHP, or PCCM.

Comment: Some commenters suggested that the MCO, PHP, or PCCM or State should be required to provide the enrollee with information regarding the education and board certification and recertification status of the health care professionals staffing the emergency departments in the enrollees' geographical region. They noted that under proposed § 438.10(f)(2)(ii), this information is provided only upon request. The commenters explained that in emergencies, the enrollee will not have time to choose which emergency department to use and that unless the enrollees have the information on the education and board certification and recertification status ahead of time, they will not be able to use these markers of quality in an emergency situation.

Response: Under section § 438.10, enrollees may request information from MCOs, PHPs, and PCCMs regarding education and board certification status of its participating health care professionals and hospitals. If enrollees are particularly concerned about these issues, they may request the information immediately upon enrollment so that they have it available before they need emergency services.

Comment: Some commenters believed that the regulations should prohibit MCOs from developing lists of "symptoms" and diagnoses for coverage of emergency services under the "prudent layperson" standard. In these commenters' view, the development of such lists is an attempt to establish plan-specific "prudent layperson" standards in the commenters' view, and could have the effect of vitiating legislative intent. They believe that lists should be expressly prohibited, and that the prudent layperson standard requires review on a case-by-case basis that considers not only the patient's complaint, but also age and medical history. The commenters suggest revising the regulation to prevent the use of lists under the prudent layperson definition. If such lists are permitted, these commenters believe that MCOs should be required to conduct broad scale enrollee education regarding the list of symptoms for coverage of emergency services. One commenter suggested that we add the following language to § 438.114: "What constitutes an emergency medical condition with reference to the definitions in paragraph (a) of this section cannot be limited by lists of diagnoses or symptoms, or by retrospective audits based on such restrictive emergency lists, including refusal by the MCO, PHP, or PCCM, to process any claim which does not contain the primary care provider's authorization number." Another commenter also stated that some MCOs require the primary care provider's authorization number to appear on filed claims in order to receive reimbursement, and that this conflicts with the prudent layperson standard

Response: We believe that the use of authorization codes in the payment approval process may be an effective and efficient way for a State, MCO, or PHP to avoid the need to apply the prudent layperson standard on a case-by-case basis, in that it can be assumed that the primary care physician has already done so. However, the absence of such an authorization cannot be used to deny an emergency room claim. Denials must be based on a case-by-case review applying the "prudent layperson" standard. We agree with the commenter's suggestion that this final rule with comment period should state what constitutes an emergency may not be limited "on the basis of diagnoses or symptoms," and have included a provision in § 438.114(e)(1)(i) of this final rule with comment period. We also agree that the regulations should expressly state that coverage of emergency room services cannot be denied based on the fact that it does not contain the primary care provider's authorization number. This suggestion is reflected in section 438.114(e)(1)(ii) of this final rule with comment period. With respect to the question of "retrospective" audits, we have addressed this above, and believe that this is addressed in the regulations in § 438.114(d)(1)(ii)(A) that makes it clear that coverage cannot be denied because the symptoms turned out not to be a "real" emergency in the sense that health was really at risk in the sense a prudent layperson might reasonably believe it would be. This should not be construed as mandating States, MCOs, or PHPs to pay a claim if the hospital or other provider has not submitted the pertinent documentation within either reasonable, or where applicable, legal time frames.

Comment: One commenter believed that the provisions of proposed § 438.114(f) that requires the attending physician to determine when an enrollee is stable, is an important safeguard to ensure that the person most knowledgeable about the enrollee's current condition will make this determination. Others disagreed, stating that allowing the attending physician to be the sole person to determine when an enrollee is stabilized enough for transfer may undercut the MCO's ability to manage inpatient services and has potential for abuse. These commenters recommended allowing the attending physician's decision to come under retrospective review.

Response: Once an emergency medical condition is acknowledged, the emergency physician is in the best position to decide when stabilization is achieved. As noted above, section 1932(b)(1)(2)(A)(ii) of the Act requires that MCOs and PCCMs follow the "post-stabilization" guidelines established for the Medicare+Choice program under section 1852(d)(2) of the Act. The Medicare+Choice regulations state that the emergency physician decides when a patient is stable, and that this decision is binding on Medicare+Choice organizations. Because Medicare+Choice post-stabilization rules govern Medicaid, we would have no discretion to adopt a different rule for Medicaid even if we agreed with the commenter.

Comment: Commenters expressed concern that MCOs will argue that in some cases, coverage of screening is not covered under the definition of emergency services in proposed § 438.114, even in cases in which a screening is required under the Emergency Medical Treatment and Labor Act (EMTALA). These commenters contended that MCOs frequently refuse coverage, relying on their own definitions of reimbursable emergency services, when these definitions are more narrow than what the hospital is required to cover under EMTALA requirements. This policy places physicians and hospitals in the position of being legally obligated to render treatment for which they will not be paid. Some commenters recommend adding in the emergency services definition that "evaluate or stabilize," includes those services required under EMTALA. One commenter recommended adding "within the meaning of 42 U.S.C. 1395dd" at the end of the emergency services definition at proposed § 438.114(a)(2), and adding preamble language that states that the MCO must "pay for the cost of emergency services obtained by Medicaid enrollees." However, one commenter stated that under such a definition, an emergency condition exists if certain acute symptoms are manifested even though the underlying condition may not be an emergency. The commenter asserted that EMTALA requirements are expansive, and would result in more emergency room services being approved for payment. This commenter believed additional benefits to Medicaid beneficiaries are appropriate, but that unless additional funding is provided, expanding emergency services effectively creates an unfunded mandate for additional services for which an MCO will have to pay.

Response: The definition of emergency services includes the evaluation necessary to stabilize a patient with an emergency medical condition. We believe that all screening (beyond the initial routine procedures for example, checking blood pressure and, temperature) used to determine whether an emergency medical condition actually exists involve medical screens and tests that would have to be covered. We do not agree that MCOs should be required to cover any screening required under EMTALA. The Congress only required MCOs to cover services if the "prudent layperson" standard is satisfied. Under EMTALA, a hospital would have certain screening obligations even in a case in which the prudent layperson standard clearly was not met, but an individual nonetheless presented themself for treatment at an emergency room. Because the Congress limited an MCO's obligation to situations in which the "emergency medical condition" definition containing the prudent layperson standard is met, we would have no authority to require MCOs to pay for services when this definition is not met, even if EMTALA would require the hospital to incur costs. Under this regulation, MCOs may not refuse coverage by relying on their own definition of reimbursable emergency services if the prudent layperson standard is met, regardless of EMTALA.

We are not addressing the issue of additional funding for emergency services in this regulation. We note, however, that under § 438.6(c) all capitation rates paid under risk contracts must be actuarially sound and

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appropriate for the services to be furnished under the contract.

Comment: Some commenters were concerned that States will attempt to obtain a waiver of the emergency services provisions in the BBA under section 1915(b) of the Act or section 1115 of the Act, and require prior authorization for emergency services. They recommend not allowing the emergency services section to be waived through section 1915(b) of the Act or section 1115 of the Act.

Response: We view access to emergency services using the prudent layperson standard as an important enrollee protection and we do not foresee a circumstance under which we would exercise our authority under section 1115 of the Act to permit an MCO to engage in prior authorization. We note that section 1915(b) of the Act only permits waivers of section 1902 provisions, and would not provide authority to permit prior authorization even if we were inclined to do so.

Comment: Some commenters recommended that we establish a central contact point at HCFAs central and regional offices where individuals and entities could direct inquiries regarding State and MCO or PCCM activity with respect to emergency services, establish a process for obtaining a timely remedy for these concerns, and clearly set out penalties that States or HCFA can impose for violations of the regulations and statute.

Response: The appropriate HCFA regional office should be contacted regarding any concerns about application of the emergency services provision of the regulation. In turn, our regional office will contact the central office should they need policy guidance. This is the regular procedure within HCFA and we believe it appropriate to follow it for these issues as well as all others. We note, with respect to penalties, that a failure to comply with the requirements in § 438.114 would constitute a failure to comply with section 1932(b)(2) of the Act, and would be sanctionable under § 438.700(d) of this final rule with comment period.

Comment: One commenter recommended stating in § 438.114 that copayments not permitted under fee-for-service may not be imposed for emergency services under managed care.

Response: Restrictions on copays in managed care are by statute, the same as for fee-for-service. This issue is addressed in the comments on § 438.108, which incorporates the fee-for-service limits on cost-sharing in § 447.50 through § 447.58.

Comment: One commenter believed that the provision of information that describes or explains what constitutes an emergency should be the responsibility of the State and should not be left to the MCO. The commenter recommended allowing States to provide information on what constitutes an emergency service. Others stated that the provision at § 438.114(b) requires States, MCOs, and PHPs to provide information annually, especially on post-stabilization because it is burdensome, unnecessary, and potentially confusing to enrollees. Others suggested removing the annual requirement or making information available upon request of the enrollee.

Response: We have revised § 438.114(b) to require that the information must be furnished by the State or at State option, by the MCO, PHP, or PCCM. We believe that States should be permitted to delegate this dissemination responsibility to MCOs, PHPs, or PCCMs. We do not believe that it is too burdensome to require this information, including post-stabilization requirements to be furnished on an annual basis and therefore, we have retained this requirement. We note that under the Medicare+Choice program, we also require that information regarding emergency services be provided annually.

Comment: One commenter believed that HCFA should include in the regulatory text, rather than just the preamble, a statement that MCOs must pay for the cost of emergency services obtained by Medicaid enrollees. Some commenters felt that the language in proposed § 438.114(e)(1)(i) was confusing, and did not make clear that MCOs must pay for treatment at facilities outside its network. They suggested replacing paragraph (i) with "(i) An enrollee had an emergency medical condition as defined at § 438.114(a)." However, some commenters disagreed, stating that the language clearly articulates the requirement to cover and pay for emergency services that meet the prudent layperson standard."

Response: While we have not changed the policy, we have clarified the requirements in this section by revising paragraph (d) to state that the specified entities must cover and pay for emergency services regardless of whether the entity that furnishes the service has a contract with the MCO, PHP, or PCCM. In addition, we specify that the entities may not deny payment for treatment obtained when either—(1) an enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in the definition of emergency medical condition, or (2) a representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services. This paragraph also outlines the coverage and payment rules that apply to PCCMs not responsible for payment.

Comment: One commenter believed that paragraph (b)(6) concerning preauthorization was confusing. The commenter noted that "prior authorization," "pre-authorization," and "pre-approved" are used synonymously throughout the regulation and that we should choose one word to be consistent. They recommend revising (b)(6) to read, "* * * but payment is required if the MCO does not provide prior authorization within an hour * * *" and choose one word for prior authorization throughout.

Response: We agree with the commenter and have adopted the term "prior authorization" throughout the regulation. In addition, we have revised § 438.114(b) to add to the list of required information the post stabilization rules set forth at § 422.113(c) of the Medicare regulations. Proposed paragraph (c) (coverage and payment for post-stabilization services) has been replaced by a paragraph (f) that provides for coverage and payment "in accordance with § 422.113(c) of this chapter."

Comment: Some commenters urged that the regulation make clear that the attending physician determines the point at which prior authorization must be sought for post-stabilization services. One of the commenters recommended changing "attending physician" to "emergency physician" to clarify who is actually physically present caring for the patient.

Response: We agree with the commenters' point, and in this final rule with comment period at § 438.114(e)(3), we use the term "attending emergency physician" to describe who determines that the patient's condition is stable.

Comment: One commenter suggested replacing "MCE physicians" in proposed § 438.114(b)(4) with "MCO, PHP, or PCCM providers" to accurately reflect the full range of qualified health professionals.

Response: We agree with the commenter and have revised paragraph (b)(4) as suggested (as noted above, we have also replaced references to "MCEs" with references to all entities subject to the rule, in this case, MCOs, PHPs, and PCCMs). In addition, we are changing "practitioner" in proposed § 438.114(f) to "provider" in § 438.114(e)(3) of this final rule with comment period. However, we want to make clear that an emergency physician must provide oversight to those providers who are not physicians.

Comment: Some commenters suggested striking the phrase "with an average knowledge of health and medicine" from the definition of emergency services at § 438.114(a). The commenters believe the phrase is ambiguous and likely to invite legal challenge because what is average in one community or culture may be different in another.

Response: The language referenced by the commenters is in the statute and therefore we have retained it.

Comment: Some commenters question the meaning of proposed § 438.114(c)(4), specifying the circumstances under which the State must pay for post-stabilization services not covered under an MCE (that is, MCO or PCCM) risk contract. The commenters recommend stating, "if post-stabilization services are not covered by an MCO, PHP, or PCCM risk contract, the State must pay for all medically necessary services."

Response: We agree with the commenters that the language in proposed § 438.114(c)(4) was confusing. We have replaced this section with a reference to the post-stabilization requirements in § 422.113(b) of the Medicare+Choice regulations. We note that if the hospital contacts the MCO, PHP, or PCCM for prior approval, and the MCO, PHP, or PCCM determines that it is not at risk for that specific service because it is not obligated to cover the service under its contract, then it should refer the hospital to the appropriate payer. For example, if a hospital contacts an MCO for prior approval for mental health services after the enrollee has been stabilized and the MCO contract does not include mental health services, then the MCO should refer the hospital to either the State or the appropriate PHP.

Comment: Many commenters believed that the prudent layperson standard is not easily adapted to non-medical conditions such as behavioral health which is not generally evaluated based on impairment of bodily function or dysfunction of a bodily organ or part. The commenters felt that individuals with mental health problems should have the same protections as others who may experience a medical emergency. Other commenters stated that the concept of "danger to others" inherent in many definitions of emergent behavioral health conditions is absent and arguably is not easily assessed by a person untrained in the assessment of behavioral health risks. They suggested separately defining urgent conditions as mental health crises that require immediate treatment to avoid hospitalization, and suggested establishing authorization criteria similar to post-stabilization criteria in the proposed rule. One commenter believed that both the "danger to others" and "prudent layperson" standards could be used simultaneously without violating the regulations. Other commenters suggested that the emergency medical condition definition encompasses mental illness as well as physical illness because it states "* * * could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy * * *"

Response: We agree that the emergency medical condition definition using the prudent layperson standard pertains to mental health as well as physical health. We note that this is also the case with EMTALA. We believe that the reference to "placing the health of the individual in serious jeopardy" is sufficient to cover mental health emergencies.

8. Solvency Standards (§ 438.116)

Section 4706 of the BBA added new solvency standards to section 1903(m)(1) of the Act, requiring that an MCO's provision against the risk of insolvency meet the requirements of a new section 1903(m)(1)(C)(i) of the Act unless exceptions in section 1903(m)(1)(C)(ii) of the Act apply. Under section 1903(m)(1)(C)(i) of the Act, the organization must meet "solvency standards established by the State for private health maintenance organizations" or be "licensed or certified by the State as a risk-bearing entity." The exceptions to this new requirement in section 1903(m)(1)(C)(ii) of the Act apply if the MCO—(1) is not responsible for inpatient services; (2) is a public entity; (3) has its solvency guaranteed by the State; or (4) is controlled by FQHCs and meets standards the State applies to FQHCs. Section 4710(b)(4) of the BBA provided that the new solvency standards applied to contracts entered into or renewed on or after October 1, 1998. Proposed § 438.116 essentially reflected these statutory provisions. In addition to the specific comments addressed below, we received many comments indicating general support for the implementation of the new solvency exceptions.

Comment: One commenter expressed concern that proposed § 438.116(c)(5), which would exempt MCOs with contracts entered into on or before October 1998, will lead to the lack of beneficiary protection in the event of insolvency in these plans. The commenter questioned whether this exemption applies to contracts in effect in 1998 as well.

Response: The BBA specified contracts entered into or renewed on or after October 1, 1998, as the effective date of the new solvency requirements. At this time, all contracts are subject to the new requirements. In this final rule with comment period, we have removed paragraphs (c)(5) and (c)(6).

Comment: One commenter asked if all MCOs, PHPs, and PCCMs must be licensed or certified as risk-bearing entities, and if carve-out services provided by PHPs would be considered "public entities," and be exempt from the solvency standards.

Response: This section does not require that all MCOs, PHPs, and PCCMs be licensed or certified as risk bearing entities. First, the solvency requirements in this section are only applicable to MCOs and PHPs, not to PCCMs. While § 438.116(b)(1) provides that subject to certain exceptions, an MCO or PHP must meet the solvency standards established by the State for private HMOs, or be licensed or certified by the State as a risk-bearing entity. The commenter is correct that this requirement does not apply to MCOs that are public entities. With respect to carve-out services provided by a PHP, if the PHP is a public entity, it does not have to meet the private HMO solvency standards or be licensed or certified by the State as a risk bearing entity. However, the PHP would still have to make assurances satisfactory to the State that it has adequate provision against the risk of insolvency.

Comment: One commenter questioned whether in a subcontracting situation, the subcontractor would be subject to the solvency standards. The commenter noted that it is important for all entities serving Medicaid beneficiaries be solvent.

Response: We agree that it is important for all entities serving Medicaid enrollees to be solvent. We believe that the responsibilities of subcontractors and MCOs with respect to their subcontractors are adequately addressed in other sections. We note that § 438.6(l) provides that all subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract. In addition, § 438.230 requires that the State ensure that each MCO oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor. It also requires that each MCO monitors the subcontractor's performance on an ongoing basis and subjects the subcontractor to formal review "according to a periodic

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schedule established by the State, consistent with industry standards or State MCO laws and regulations."

Comment: One commenter noted that under the Medicare+Choice regulations, MCOs are permitted to apply for a Federal waiver (preemption) from State solvency requirements if such requirements are more stringent that the Federal PSO requirements. The commenter suggested that in light of the availability of waivers in Medicare, Medicaid regulations should recognize that some PSOs are not going to meet State solvency requirements, and permit their participation in Medicaid managed care without meeting the State requirements.

Response: We do not have the statutory authority to exempt PSOs from the Medicaid solvency requirements in section 1903(m)(1) of the Act. The waiver authority in the BBA for PSOs that wish to enter into Medicare+Choice contracts BBA applies only to the Medicare program.

Comment: One commenter does not believe that Federally Qualified HMOs should be exempt from solvency requirements.

Response: Federally Qualified HMOs from solvency requirements are subject to detailed solvency requirements under title XIII of the Public Health Service Act and part 417 of this chapter. The commenter is correct, section 1903(m)(1)(A) of the Act provides that "an organization that is a qualified health maintenance organization as defined in section 1310(d) of the Public Health Service Act is deemed to meet the solvency requirements in section 1903(m)(1)(A)(i) and (ii) of the Act." Since this exemption is set forth in the statute, we do not have the authority to change it. This comment has prompted us to recognize that we did not provide for this exemption in proposed, § 438.116, therefore, we have revised this final rule with comment period.

Comment: Several commenters asserted that the basic rule of this section was confusing with respect to the solvency requirements an MCO must meet.

Response: In response to this comment, we have revised § 438.116 to separate the "basic rule" from the "other requirements" that must be met as required under section 1903(m)(1)(C).

Comment: One commenter believed that proposed § 438.116(c)(2) which provides that the State solvency requirements in paragraph (b) do not apply if the MCO is a public entity, would mean that a county consortium would not need to meet the State's financial solvency requirements. The commenter asked if these Federal regulations preempt the State statute.

Response: Section § 438.116(b)(2) in this final rule with comment period (§ 438.116(c)(2) in the proposed rule) does not exempt public entities from all solvency requirements under Federal regulation. Section § 438.116(b)(1) specifies that unless an exception in paragraph (b)(2) applies, an MCO must meet the solvency standards established by the State for private HMOs or be licensed or certified as a risk bearing entity by the State. While paragraph (b)(2) exempts public entities from this requirement, under § 438.116(a), these entities must still make assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency. States retain the flexibility to determine what assurances must be provided.

Comment: Several commenters supported the provision that exempts public entities from solvency standards imposed on private HMOs.

Response: While we acknowledge the support of this comment, we would like to reiterate that public entities are not exempt from all solvency standards. Public entities must still provide assurances satisfactory to the State showing that they have adequate provision against the risk of insolvency in accordance with § 438.116(a).

Comment: One commenter recommended that Federal requirements for capitalization should apply to all managed care organizations. In addition, the commenter suggested Federal and State governments should pre-approve all contracts with managed care organizations whose enrollees are primarily Medicaid insured, and require both Federal and State governments to guarantee provider payments if organizations become insolvent.

Response: We do not have statutory authority to establish Federal requirements for capitalization to guarantee payments to providers, or to require States to do so. However, under § 438.6 (Contract requirements), our Regional Office will review and approve all MCO and PHP contracts, and under § 438.806(b), prior approval by us is required for all MCO contracts with a value in excess of $1,000,000. While there is no Federal requirement that States guarantee provider payments, if, under § 438.116(b)(2)(iv), an MCO has its solvency guaranteed by the State, the State would be liable for all of the MCO's debts, including provider payments, if the MCO became insolvent.

Comment: One commenter noted that proposed § 438.116(c) provided that public entities are not required to meet the standards a State imposes on its private HMOs. The commenter questioned how this policy would affect a State that imposes the same or similar requirements on both private and public HMOs. In addition, the commenter asked if this provision applies to tribal governments.

Response: Even though public entities are not required to meet the solvency standards established by the State for private HMOs, public entities are still required to make adequate assurances satisfactory to the State that they have adequate provision against the risk of insolvency. States still have the flexibility to determine what assurances they consider adequate. Therefore, a State may require that public entities meet requirements that are the same or similar to those it imposes on private HMOs. With respect to tribal governments, if the MCO operates outside of the reservation, State solvency standards apply. But a State does not have jurisdiction to impose solvency standards on an on-reservation tribal MCO as a general operating condition.

Comment: One commenter expressed concern that we intend to accept State solvency standards rather than imposing Federal solvency standards.

Response: We do not have statutory authority to require a Federal solvency standard because the BBA specifically provides for State flexibility in this area.

D. Quality Assessment and Performance Improvement (Proposed Subpart E Recodified as Subpart D)

Background

Section 4705 of the BBA created section 1932(c) of the Act, paragraph (1) which requires State agencies that contract with Medicaid MCOs under section 1903(m) of the Act to develop and implement quality assessment and improvement strategies. Proposed subpart E (recodified as subpart D in this final rule with comment period) implemented section 1932(c)(1 of the Act), and set forth specifications for the quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care through contracts with MCOs and (where applicable) PHPs.

Proposed § 438.302 established standards for State contracts with MCOs and PHPs, and required that each State must have a strategy for continually monitoring and evaluating MCO and PHP compliance with those standards. Proposed § 438.304 set forth minimum elements required in each State's quality improvement strategy. Proposed § 438.306 set forth standards for

availability of services addressing: (1) Beneficiary choice of entities; (2) services not covered by the MCO or PHP; (3) the MCO or PHP delivery network including: assurance of adequate capacity and services; the right to access to a women's health care specialist; credentialing requirements; 24 hour, seven day per week access; and convenient hours of operation; (4) coordination of care including screening and assessment; (5) procedures designed to identify and treat pregnancy and complex and serious medical conditions, and (6) a cultural competency requirement.

Proposed subpart E also contained rules regarding coverage and authorization decisions (proposed § 438.310), provider selection (proposed § 438.314), enrollee information (proposed § 438.318), enrollee rights (proposed § 438.320), confidentiality and accuracy of enrollee records (proposed § 430.324), and enrollment and disenrollment requirements (proposed § 438.326).

Additionally, proposed § 438.328 required an effective grievance system that meets the requirements of subpart F of this part; and proposed § 438.330 provided for oversight and accountability by the MCO or PHP of functions and responsibilities delegated to subcontractors.

Proposed § 438.340 required that MCOs and PHPs have an ongoing quality assessment and performance improvement program for the services it furnishes to enrollees; that the performance improvement programs achieve any minimum performance levels required by the State; and that the MCO or PHP achieves significant and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction. The State also would be required under proposed § 438.336 to ensure that each MCO and PHP uses practice guidelines meeting specified criteria and under proposed § 438.342 to maintain a health information system that collects, analyzes, integrates, and reports data on the achievement of the objectives of this subpart.

1. Scope (Proposed § 438.300)

Proposed § 438.300 set forth the scope of subpart E.

Comment: Several commenters found the provisions in subpart E on Quality Assessment and Performance Improvement to be overly prescriptive. One commenter believed that the lack of flexibility would prevent States from accommodating new approaches and standards in a rapidly changing marketplace. One commenter contended that the provisions do not make allowances for resource limitations of States, while another suggested that the provisions of this part are unnecessary because of our review and approves MCO contracts.

Response: We understand the concern that this rule establishes substantial new requirements for States, MCOs, and PHPs. However, we believe that these provisions are important beneficiary protections, and reflect the intent of the Congress in enacting the quality and beneficiary protections of the BBA. As required by a directive from President Clinton, we also sought to incorporate the provisions of the Consumers Bill of Rights wherever permissible under our legal authority. When drafting the proposed rule, we spoke to States as well as representatives of beneficiaries to inform ourselves as to their views. We then tried to strike an appropriate balance that would reflect the Congressional intent, but also maintain flexibility for States, where possible, and avoid unreasonable burden and costs on MCOs and PHPs. Public comment on the proposed rule provided us an additional opportunity to hear the opinions of stakeholders. In this final rule with comment period we make many of the changes suggested by commenters.

Comment: Several commenters believed that these regulations would discourage or prevent State innovation in designing managed care programs, especially as States would fear the loss of Federal financial participation.

Response: We hope that these regulations will not have the effect of discouraging State innovation in managed care, because we recognize the important contributions made by States who have led the way in the past. We will continue to encourage and support State innovation in the future. However, we believe that a formal approach to quality assessment and improvement is an essential component of all successful health care delivery programs, including managed care programs, and that it is appropriate to incorporate such formal quality approaches into Medicaid managed care programs. We note that the approaches to quality assessment and improvement that are contained in this regulation are consistent with quality measurement and improvement activities currently in use throughout the health care industry

Comment: Several commenters contended that the quality provisions of subpart E are so burdensome to MCOs that this will discourage their participation in Medicaid managed care.

Response: We are concerned that some MCOs have decided to leave the Medicaid market and we have seriously considered the burden these regulations carry as we developed this final rule with comment period. While we have made some changes in recognition of this burden, we must balance this concern with beneficiary concerns raised by numerous commenters. This is especially important because the Medicaid population includes many individuals with special health care needs.

Comment: One commenter stated support for the comprehensive quality assessment framework of the proposed rule.

Response: We believe that the statute intends that State quality strategies be sufficiently broad to ensure a high quality of care for Medicaid managed care enrollees. This is the reason why we proposed a comprehensive strategy, and are retaining it in the final rule with comment period.

Comment: Several commenters discussed the provision of the BBA that requires us to conduct a study of the protections (if any) that may be needed when enrolling individuals with special health care needs into managed care. The commenters believed that we should have begun the study promptly following enactment of the BBA so that the results of the study could be reflected in the final rule with comment period.

Response: The research, analysis, and writing of this BBA-mandated study was underway during the public comment period for the proposed rule. As a result, in analyzing and responding to the comments, we were able to consider the comments in light of the findings and evidence resulting from this study. While we believe that the proposed rule addressed the needs of all Medicaid enrollees, including those with special health care needs, we have made revisions to the proposed rule in response to comments that have been informed by the findings in the BBA special needs study.

Comment: Numerous commenters raised questions about the relationship of the requirements of subpart E to our standards and guidelines for Medicaid and Medicare managed care organizations contained in our Quality Improvement System for Managed Care (QISMC) document. Several commenters interpreted the regulation to incorporate QISMC requirements. One commenter contended it was unrealistic to expect a small State to implement QISMC without allowing for incremental implementation over an extended period of time. Another

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commenter suggested that the regulation should require the use of QISMC, and that QISMC should be modified and strengthened by incorporating ideas contained in our document titled "Key Approaches to the Use of Managed Care Systems for Persons with Special Health Care Needs." Another commenter asserted that not requiring States to use QISMC for Medicaid, when we are using it for Medicare, discriminates against Medicaid beneficiaries. Another commenter asked how future improvements to QISMC will be incorporated into the regulations. Another commenter asked how we will review State strategies when States choose not to use QISMC. One commenter felt that QISMC was inadequate to improve the health care provided to vulnerable populations.

Response: All these comments reflect some confusion about the relationship of this BBA regulation to QISMC. The quality provisions of the BBA regulation and QISMC are similar, but not identical.

In 1996, before the BBA was enacted, we began an initiative that aimed, in part, to—

- Develop a coordinated Medicare and Medicaid quality oversight system that would reduce duplicate or conflicting quality requirements for Medicaid and Medicare managed care and send a uniform message on quality to managed care organizations and beneficiaries; and
- Make the most effective use of existing quality measurement and improvement tools, while allowing sufficient flexibility to incorporate new developments in the rapidly advancing state of quality measurement.

This initiative was QISMC. The most prominent products of the QISMC initiative were standards and guidelines for Medicaid and Medicare-contracting MCOs. For Medicaid, these standards updated and replaced earlier standards sent by us to States as part of the Quality Assurance Reform Initiative (QARI). The QARI standards were provided to States as technical assistance tools for their discretionary use although most States with MCO contracts used them, in part or in whole. QISMC was intended to replicate the success of QARI, in part by disseminating revised standards that reflected advances in private sector accreditation standards, as well as advances in quality measurement and improvement in both the public and private sectors.

After the BBA was passed in 1997, our development of the regulations to implement the quality assessment and improvement provisions of the law was informed by our prior work in developing QISMC. From the QISMC work, we identified those fundamental activities that formed the essence of quality measurement and improvement. These activities and standards were revised as necessary to reflect a level of detail appropriate for regulations and included in our proposed rule. For this reason, many of the regulations implementing the BBA quality provisions reflect QISMC standards. However, while QISMC was developed as a set of standards that address MCOs and PHPs, the legal requirements set forth in this final rule with comment period address States as well as MCOs and PHPs.

QISMC has been offered to States as a tool to use to the extent the State wishes, as long as the State complies with the requirements in this final rule with comment period. While full compliance with QISMC would help satisfy the quality requirements in subpart D that were based in part on QISMC standards, a State may meet the minimum standards in the regulation without requiring the use of QISMC. If a State requires MCOs and PHPs to follow QISMC, this will promote compliance with the regulatory requirements that overlap the QISMC standards. However, compliance with QISMC is not sufficient to meet all the provisions of the regulation because this regulation includes a much broader range of topics than is covered by QISMC. For the foregoing reasons, we will not use QISMC to monitor States, but rather monitor against the regulatory requirements.

Comment: Several commenters questioned the relationship of Medicaid quality provisions and those used by private accrediting organizations for the commercial managed care market. Two commenters suggested that private sector standards be used for Medicaid, either at State direction or through deeming. Another commenter recommended against use of private sector standards because he believes that they are geared to a generally healthy population while the Medicaid population includes populations with special health care needs.

Response: The Medicare+Choice statute, at section 1852(e)(4) of the Act, provides authority for Medicare+Choice organizations that are reviewed by private accreditation bodies to have a broad range of Medicare+Choice requirements "deemed" satisfied based on such private accreditation (if the private accreditation body applies standards at least as stringent as Medicare's). This authority includes the authority to "deem" compliance with QISMC standards, which is mandatory for Medicare+Choice organizations. There is no comparable broad deeming authority provided for MCOs or PHPs under the Medicaid statute. The only Medicaid authority for "deeming" by private accreditation bodies relates to the deeming of external review requirements under section 1932(c)(2)(A) of the Act. This rulemaking does not address these requirements, or provisions for the deeming of these requirements in section 1932(c)(2)(B) and (C) of the Act. These are being addressed in a separate rulemaking, in which a notice of proposed rulemaking was published on December 1, 1999, 64 FR 67223.

Comment: Several commenters questioned the applicability (or non-applicability) of subpart E to entities other than MCOs. One commenter agreed with applying the provisions of this subpart to PHPs. Another commenter suggested that we extend these requirements to all MCEs, including PCCMs. Another commenter suggested that the provisions of subpart E not be applied to capitated PCCMs. Lastly, another commenter suggested that PHPs be excluded from external quality review, because the commenter believed that this imposes an undue burden on States for contracts that are limited in scope.

Response: In section 1932 of the Act, the Congress included provisions that apply to all MCEs (that is, to MCOs and PCCMs), provisions that apply only to MCOs, and provisions that apply only to PCCMs. Since the Congress thus addressed PCCMs in section 1932 of the Act, we believe that where it applied a requirement only to MCOs, this reflects a clear and expressed intent that the requirement not apply to PCCMs. We therefore are not applying the regulations implementing section 1932(c)(1) of the Act to PCCMs. With respect to PHPs, as we have noted above, the Congress was silent, in section 1932 of the Act and its legislative history, concerning what requirements should be applied to these entities. At the time the Congress acted, we had longstanding regulations in place applying selected section 1903(m) of the Act requirements to PHPs. We believe that given that PHPs are paid on a risk basis, the concerns that caused the Congress to impose the quality requirements in section 1932(c)of the Act on MCOs apply with equal force to PHPs, and that the extension of these requirements to PHPs under our authority in section 1902(a)(4) of the Act is appropriate. With respect to the comment on risk-based PCCMs, they are not subject to these requirements by virtue of their status as PCCMs, since as we have just noted, we are not imposing these requirements on PCCMs. Rather, as a risk contractor, they also meet the definition of PHP, and are subject to these requirements by virtue of their status as PHPs. Only PCCMs that fall in both categories would be subject to the requirements in subpart D.

Comment: Several commenters questioned the relationship of the quality provisions to waiver approval requirements. One contended that the relationship is unclear and duplicative. Another questioned if waivers of any of the quality provisions will be approved in light of the proposed rule's preamble language which states that waivers will only be granted if the quality requirements in this regulation are met or exceeded.

Response: We believe that the BBA quality requirements that are addressed in this subpart should apply to managed care provided through MCOs and PHPs regardless of the authority used to establish these programs. Quality is equally important whether the managed care program is established through a waiver granted under section 1115 or 1915(b) of the Act or as a State plan amendment under section 1932(a) of the Act. Therefore, generally, States will be required to follow these provisions as a condition for approval of a waiver, However, the Secretary has the discretion to waive these requirements if quality is addressed in the waiver program in a manner that equals or exceeds the quality requirements contained in this subpart. We believe that to do less would deny beneficiaries important protections and be counter to Congressional intent.

Comment: One commenter believed that the most important quality standard for persons with disabilities is that these individuals be served in the least restrictive setting, and that the standard for outcomes should include the achievement of the highest level of functioning for each individual.

Response: We agree that it is important to serve persons with disabilities in the setting that they desire. We further agree that achievement of the highest level of functioning is a desirable outcome for this population. This is consistent with the provisions of the proposed regulation. However, we are not specifying in the regulation particular performance measures for any of the populations served by the Medicaid program. The strength of each particular performance measure is dependant upon the specifications for calculating the measure. Performance measure specifications typically change over time as information systems, coding, survey instruments and other methods of data collection change over time. For this reason, we do not believe it is appropriate to establish specific performance measures in regulation.

Comment: One commenter noted that the proposed rule only addresses requirements that States and MCOs must meet, and suggested that these requirements will be effective in improving the quality of health care only if they are acted upon by external sources.

Response: Subpart D of this final rule with comment period interprets and implements section 1932(c)(1) of the Act and sets forth required quality standards. We agree that these new provisions must be executed well to have the desired impact of improving the health care provided to Medicaid beneficiaries. In this regard, States play a key role. They establish the provisions of MCO and PHP contracts and are primarily responsible for ensuring that the regulatory requirements are effectively implemented by MCOs and PHPs. We are responsible for overseeing the States' adherence to these rules. To this end we have revised, and will be further revising (based on this final rule with comment period), protocols that HCFA Regional Offices use to monitor State compliance with statutory and regulatory requirements.

Comment: Several commenters questioned the consistency between Medicaid and Medicare quality requirements. One suggested that the Medicaid requirements should be the same as those for Medicare. The other commenter suggested that the Medicaid subpart be reworked because it is not appropriate to apply the Medicare standards to Medicaid due to differences in the populations covered by each program.

Response: As stated in the introduction, the proposed Medicaid rule is consistent with the Medicare+Choice regulations wherever we believe it is appropriate. We believe that quality provisions should be consistent for all of our programs unless the statutory requirements differ, or program or population differences necessitate different standards. In creating this consistency, we carefully considered the needs of both Medicaid and Medicare beneficiaries and, where possible, proposed quality provisions that meet the needs of both. We believe that this approach best meets the needs of our beneficiaries (many of whom are eligible for both programs), and reduces burden on MCOs that contract with both programs. In subpart D, the regulatory requirements are consistent with those that apply to Medicare+Choice organizations. As noted above, however, under Medicare, Medicare+Choice organizations are all required to comply with QISMC, while States have the option of using all or part of QISMC in the case of Medicaid-contracting MCOs and PHPs.

Comment: Several commenters suggested that particular quality measures be incorporated into the regulation. One commenter wanted to ensure use of quality standards for patients with end stage renal disease, including a specific standard identified by the commenter. Another commenter suggested that all States measure quality against objectives contained in "Healthy People 2000 and 2010," publications of the Department of Health and Human Services that outline a comprehensive health promotion and disease prevention agenda for the nation. Another commenter suggested that we establish, for children and adults with disabilities, a distinct set of quality standards (that is, performance levels) to ensure that these persons obtain the quality health care and health-related services necessary for them to lead full lives.

Response: We do not believe that particular quality measures should be specified in the regulation. Performance measures and quality standards change over time and it is important that the most current and useful measures can be quickly adopted. However, in response to these comments we have added a provision at § 438.204(c) that requires States to use performance measures and levels prescribed by us, as part of their State quality strategy. We also have provided in § 438.240(c)(2)(ii)(A) of the final rule with comment period that States must require their contracting MCOs and PHPs to meet these specific performance levels. This allows us to establish performance measures and levels for subsets of the Medicaid population, such as persons with end stage renal disease or other disabilities. We plan to use performance measures and levels that are widely accepted, standardized, and have undergone validity and reliability testing. At the present time, we are not aware of large numbers of such measures specific to persons with disabilities such as end stage renal disease that would meet these requirements. However, we expect measures to be developed over time that will meet these criteria. In the meantime, in response to the comment concerning the disabled population, we have added a new § 438.240(b)(4) to require States to have procedures to identify enrollees with special health care needs and to assess the quality and

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appropriateness of care provided to these individuals. Also in response to this comment, we have in § 438.204(e)(2) required that the number of MCO and PHP enrollees with special health care needs be reported to us. The identification of these individuals and the assessment of their care and services is an essential step in assuring high-quality health care for them. We note that we also provide, in § 438.240(c)(1), for States to specify performance measures for their MCOs and PHPs to support quality improvement.

Comment: Several commenters suggested that we establish quality performance levels for States and MCOs.

Response: We agree with these commenters, and in response to these comments, and as noted above, we have added a new § 438.204(c) that requires that State quality strategies include our-prescribed performance measures and levels that States must require their MCOs and PHPs to meet. We believe that by requiring States to require their MCOs and PHPs to meet a specified level of performance on specific measures, we are carrying out its responsibility to ensure quality in the Medicaid program. We intend to use widely-recognized measures and establish levels through a public process, or based on statutory requirements. We have retained the States' authority to set minimum performance levels for MCOs and PHPs.

Comment: Several commenters suggested that States and MCOs be required to have vision and mission statements.

Response: We do not agree that it is essential for each State and MCO to have a vision and mission statement to support its quality strategy, nor do we believe it would be appropriate for us to mandate such a statement. While this approach can be an effective management tool, we believe that States should have the discretion to decide whether to adopt this approach, as long as they meet the elements for a comprehensive quality strategy set forth in this final rule with comment period.

Comment: Several commenters suggested that State quality strategies be required to address all statutory and regulatory requirements, not only those addressed in subpart E.

Response: We believe that the scope of this subpart is sufficiently broad to include the wide range of areas related to quality. We note that none of the commenters provided any specific examples of additional areas that they believe would be appropriate for inclusion. Therefore, we are not broadening the scope of the State quality strategy beyond the areas covered in the proposed rule.

2. State Responsibilities (Proposed § 438.302)

Proposed § 438.302 set forth the State's responsibilities in implementing its quality strategy. Specifically, § 438.302 required that each State: (1) have a strategy for assessing and improving the quality of services provided by an MCO and PHP; (2) ensure compliance with standards established by the State agency; and (3) conduct regular, periodic reviews to evaluate the effectiveness of its strategy, as often as the State agency determines appropriate, but at least every 3 years.

Comment: We received a large number of comments suggesting that the regulation require States to involve stakeholders in the development of their quality strategies, as is recommended in the preamble to the proposed rule. One commenter suggested that the Medical Care Advisory Committee perform this function. Another commenter suggested that the proposed State quality strategy should be published and comments from the public should be considered before the plan is made final.

Response: As stated in the preamble of the proposed rule, we expect that State agencies will consider the input of stakeholders when developing performance goals that are clear, fair, and achievable. We also believe that it is reasonable and appropriate for States to consider the ideas of stakeholders and other members of the public in the design of their quality strategies. Therefore, in response to this comment, and earlier comments on § 438.110 discussed in section II. C. above, in § 438.202(c) of the final rule with comment period we require States to provide for input of beneficiaries and other stakeholders regarding their quality strategies, and specifically, to make the strategies available to the public before adopting them. We do not specify what process States must use to obtain public input, because we wish to allow States flexibility to structure this process as they find appropriate. For several years, States with section 1115 demonstration projects have been required to have a process for public input. States with 1115 demonstrations may want to use this process for receiving comments on their quality strategy or choose another process.

Comment: Several commenters suggested that we add more specificity to the requirement for a State quality strategy. Most of the commenters suggested that the regulation should require that the strategy be put in writing. Two commenters suggested that standards be established to measure the success of the strategy. One commenter suggested that we incorporate in the regulation the language contained in the preamble that the strategies should be "well considered," "well coordinated," and "overarching." Another commenter suggested that the regulation require State strategies to address all statutory and regulatory standards, identify each component of the strategy, address how the components are coordinated, ensure adequate monitoring and oversight, and be effective.

Response: We agree that the State quality strategies should be in writing, and in response to this comment, we are including this requirement in the final rule with comment period, in § 438.202(b). We believe that this new requirement, along with the requirement at § 438.202(c) that States consider the input of stakeholders in the design of their strategies, the requirement at § 438.202(e) that States conduct periodic reviews of the effectiveness of their strategy, and the requirement in § 438.204(g) that the State strategy include standards at least as stringent as those set forth in subpart D, provide the best mechanisms to ensure that the strategies will (1) be well considered, well coordinated, and overarching; (2) identify each component of the strategy and how components are coordinated; and (3) be effective. Therefore, we have not added the specific requirements suggested by the commenter to the regulation.

Comment: Several commenters considered the proposed maximum three year period between State reviews of the effectiveness of their quality strategies to be too long. The commenters instead suggested an annual review of MCO or PHP compliance with contract requirements. One commenter believed that the three year time period was inconsistent with QISMC requirements, and certification and licensing procedures. Another commenter expressed support of the three year time frame.

Response: The commenters who objected to the three year maximum period between reviews of the State quality strategy appear to have misunderstood the intent of § 438.202(e). Section 438.202(e) does not apply to State review of MCO and PHP compliance with contracts, but to review of the effectiveness of the *State's* quality strategy. State monitoring and review of MCOs and PHPs is addressed, in the context of the State's quality strategy, in § 438.204(b)(2), which requires States to continuously monitor and evaluate MCO and PHP compliance with the standards specified in the subpart. The evaluation of the State's quality strategy under § 438.202(e) is intended to be a broad review of the interrelationship of all the elements that the State is required to include in its quality strategy to determine the effectiveness of this strategy as a whole. We believe it is particularly important for States to step back and review the "big picture" at least every three years because the field of quality review and measurement is rapidly evolving, making it important for States to reassess their approach at regular intervals. Requiring periodic review on a more frequent basis may not provide the State with sufficient time to effectively implement its strategy. For this reason, we are retaining the provision requiring review at least every three years.

Comment: Several commenters suggested that the final regulation require that beneficiaries be provided information about the State quality assurance program and MCO and PHP quality. In particular, the commenters wanted enrollees and potential enrollees to receive information on quality indicators, quality improvement topics, external review results, compliance audits, summarized complaint and grievance data, and disenrollment counts.

Response: We agree that beneficiaries, upon request, should have access to information concerning the State quality strategy and MCO and PHP performance. In § 438.202(b) and (c) of the final rule with comment period we require that the States' quality strategies be in writing and that stakeholders have an opportunity to make suggestions and comment on the strategy. We believe that this requirement will also serve the purpose of ensuring that beneficiaries can obtain information on that strategy. Section 438.10 of the regulation specifies what information must be furnished to enrollees and potential enrollees by the State, the MCO or PHP, and the enrollment broker. For MCOs, PHPs, and as appropriate PCCMs that enroll beneficiaries under a State plan program under section 1932(a) of the Act, this includes quality and performance indicators that can be used to compare plans. In addition, the proposed rule implementing the external quality review (EQR) requirements in section 1932(c)(2)of the Act, published in the **Federal Register** on December 1, 1999 (64 FR 67223), identifies EQR results that it proposes must be made available to enrollees. We believe that these requirements will ensure that enrollees and potential enrollees have access to information that will enable them to compare the performance of MCOs and to make an informed choice.

Comment: One commenter suggested that we add a new paragraph to proposed § 438.302 that would require that State strategies address all covered services, including midwifery services.

Response: We do not believe it is appropriate to specify that all covered services be included, since all covered services may not be included under an MCO or PHP contract. We also believe that the existing regulations already cover all services that are covered under the contract, as § 438.202(a) refers to "managed care services offered" by MCOs and PHPs. This would include any services they offer. Under § 438.206(c) of the final rule with comment period, the State is responsible for making available to the enrollee any Medicaid service not covered under the MCO or PHP contract, and these thus would not be included in an MCO or PHP quality strategy.

Comment: One commenter believed that furnishing quality oral health services requires planning and treatment decisions that are made by the dentist and the patient together.

Response: We agree with the commenter, and believe that the final rule with comment period addresses this issue. Paragraphs (b)(5) and (b)(6) of § 438.100 (previously designated as § 438.320(b)(4) and (5) in the proposed rule) specify the right of enrollees to receive information on available treatment options, and to participate in decisions regarding their health care.

Comment: One commenter asked what criteria we will use to review and evaluate State quality strategies.

Response: Since the requirement that States develop and follow State strategies is new, we have no experience with reviewing and evaluating these strategies. In response to the commenter's concern, however, we have added a new paragraph (f) to § 438.202 requiring States to submit to us a copy of their initial strategies and all significant revisions thereafter. We also in paragraph (f)(2) specify that States must regularly report to us on the implementation and effectiveness of their strategies.

3. Elements of State Quality Strategy (Proposed § 438.304)

Proposed § 438.304 set forth the minimum elements of a State quality strategy, including contract provisions that incorporate the standards specified in this subpart. Specifically, quality strategies would include procedures for assessing the quality and appropriateness of care and services provided, including but not limited to: (1) contract provisions that incorporate the standards specified in this subpart; (2) procedures for assessing the quality and appropriateness of care and services, including, but not limited to continuous monitoring and evaluation of MCO and PHP compliance with the standards; (3) annual, external independent reviews of quality outcomes, and timeliness of, and access to services covered under each MCO and PHP contract; (4) appropriate use of intermediate sanctions that at a minimum, meet the requirements in subpart I; (5) an information system sufficient to support initial and ongoing operation and review of the State's quality strategy; and (6) standards, at least as stringent as those required under proposed §§ 438.306 through 438.342, for access to care, structure and operations, and quality measurement and improvement. In developing a strategy, we communicated our expectations that each State will work with beneficiaries and their advocates, quality experts, managed care organizations, and other stakeholders to develop performance goals that are clear, fair, and achievable.

Comment: As proposed, § 438.304 required States to "continuously monitor" MCO and PHP compliance with the quality standards. Many commenters urged that we revise this requirement. Several commenters suggested that the regulation require an annual audit of each MCO for compliance with the standards; that the requirement include monitoring of grievances and logs of calls to beneficiary "hotlines"; and that a medical records review be required of catastrophic events, random records, and persons with disabilities. Other commenters suggested replacing the continuous monitoring requirement with a more flexible standard related to the MCO's or PHP's contract cycle or to the need for monitoring based on the plan's performance.

Response: We continue to believe that States should be required to continuously monitor and evaluate MCO and PHP compliance with quality standards. States may choose, as part of their quality strategies, to conduct a comprehensive audit of MCOs and/or PHPs on an annual or other basis, but this should not relieve them of the ongoing responsibility to ensure that MCOs and PHPs are meeting the standards at all times. States are in the best position to decide how best to accomplish this activity and may vary their requirements according to their knowledge of particular MCOs and

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PHPs. We believe the requirement in § 438.416(d) requiring MCOs and PHPs to submit to the State summaries of their handling of grievances and appeals is sufficient to address the comments regarding monitoring of grievances. However, we have not required MCOs and PHPs to have a "hotline", therefore, including a monitoring requirement for hotlines would not be appropriate. With respect to medical records, we do not believe that we should specify what records States should review or the frequency with which they should perform review. Rather, we believe that this should be left to States to determine as part of their overall quality strategies. With respect to persons with disabilities, we have added new requirements for monitoring. New § 438.204(b)(1) requires States, as a part of their quality strategies to have procedures to identify, and assess the quality and appropriateness of care furnished to, enrollees with special health care needs.

Comment: One commenter suggested that, as part of the State quality strategy, States should be required to evaluate the effectiveness of services provided to beneficiaries with limited English proficiency. Another commenter suggested that States should collect and analyze data on cultural competency. This commenter further suggested that States conduct demonstration projects related to cultural competency to better understand this new and critical area of quality assessment.

Response: We agree that in order for States' MCOs and PHPs to effectively address cultural competency, they all must have basic information on the cultural characteristics of their Medicaid enrollees. We therefore have revised § 438.204(b)(1) of the final rule with comment period to require States, as a part of their quality strategies, to include procedures to identify the race, the ethnicity, and primary language spoken of each MCO and PHP enrollee and to provide this information to each MCO and PHP at the time of each Medicaid beneficiary's enrollment in the MCO or PHP. Further, § 438.306(e)(4) of the proposed rule has been modified as § 438.206(e)(2) of the final rule with comment period to require the State to ensure that each MCO and PHP provides services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds. This means that, as part of its quality strategy, the State must monitor and evaluate the effectiveness of these provisions. We would welcome State demonstrations or other strategies to develop effective means of evaluating cultural competency in the provision of services.

Comment: Several commenters recommended that we add a State quality strategy element requiring the State to have an information system capable of managing the data that MCOs are required to report under proposed § 438.342. Another commenter stated that the regulation should require compatibility between the MCO's and the State's information systems.

Response: Section 438.204(g) of the final rule with comment period includes, as an element of the State quality strategy, that the State provide for "structure and operations" standards (among other standards) at least as stringent as those of this subpart. Because the health information systems requirement is included in the subpart, it is unnecessary to add this as an element of the State quality strategy. Likewise, the information systems requirements in § 438.242 are sufficient. While this section does not specify that MCO and PHP systems must be compatible with those of the State, we believe that it is in the State's best interest to require this. If a State chooses not to impose this requirement on an MCO or PHP, the State remains responsible for obtaining from the MCO or PHP the information specified in § 438.242 and incorporating into its information system. Some States may choose this option for MCOs or PHPs that need time to acquire a compatible system or to modify an existing system to make it compatible.

Comment: Numerous commenters requested information concerning the EQR element of the State quality strategy. Several commenters felt that requiring States to review quality outcomes, timeliness, and access to care under the EQR would be expensive and excessive; and that therefore, review of all three of these areas should not be required annually. One commenter suggested that States should be allowed to conduct an in-house review. Another commenter believed that well performing MCOs and PHPs should not be required to undergo an annual review. One commenter wanted additional information about how EQR fits into the State quality strategy and QISMC. Another commenter suggested that we should establish criteria for EQR organizations. One commenter suggested that we publish interim standards for EQR that would allow States to access the 75 percent matching rate established by the BBA.

Response: As noted above, on December 1, 1999, we published in the **Federal Register** a proposed rule to implement the BBA provision that requires an annual, external independent review of the quality outcomes and timeliness of, and access to, services covered under each MCO contract. 64 FR 67223. This proposed regulation includes information that will address the comments made concerning § 438.304(c) of the proposed rule. The statute requires that we contract with an independent quality review organization to develop protocols to be used in the reviews. That work is now underway. Until that work is completed, we cannot publish standards to permit States to access the 75 percent matching rate provided by the BBA. We note, however, that States may currently receive a 75 percent Federal match under section 1903(a)(3)(c) of the Act for EQR activities conducted by Peer Review Organizations (PROs) and entities that meet the requirements for contracting as a PRO.

Comment: One commenter suggested that we add the word "items" before "services" in § 438.304(c) of the proposed rule, as it is included in the statute. The commenter also suggested that we include a list of examples of such items, such as durable medical equipment, assistive devices, certain birth control items, and prescriptions.

Response: Ordinarily, we do not use the term "items" in our regulations because the term "services," as used in the regulations, includes covered "items" as well. While only the Medicare regulations expressly specify that "services" includes "items" (42 CFR 400.202), section 1905(a) of the Act uses the term "care and services" to encompass all services or items for which Medicaid payment may be made. References in the regulations to "services" therefore, include covered "items" as well. We are not adding the word "items" before "services" in § 438.204(d) (§ 438.304(c) in the proposed rule).

Comment: One commenter expressed the need to clarify that appeals on coverage and claims are handled through the State fair hearing process, and not through complaints to the EQR.

Response: The commenter is correct that appeals on coverage and claims decisions by enrollees are properly addressed through the internal appeals process of the MCO and PHP and the State fair hearings process. The proposed EQR regulation makes clear that handling enrollee appeals is not an EQR function.

4. Availability of Services (Proposed § 438.306)

Section 1932(c)(1)(A)(i) of the Act, as added by section 4704 of the BBA,

requires each State that contracts with MCOs under section 1903(m) of the Act to develop and implement standards for access to care under its quality assessment and improvement strategy. Section 438.306 of the proposed rule established standards for access to care. Paragraph (a) required that States ensure that all covered services are available and accessible to enrollees. Paragraph (b) specified that if a State agency limits freedom of choice, the State agency must comply with the requirements of proposed § 438.52, which specify the choices that the State agency must make available. Paragraph (c) specified that if an MCO or PHP contract did not cover all services under the State plan, the State agency must arrange for those services to be made available from other sources, and instruct all enrollees on where and how to obtain them, including how transportation is provided. In § 438.306(d) we proposed new requirements for the delivery networks of MCOs and PHPs to ensure that all covered services under a contract are available and accessible to enrollees. These requirements would be imposed on State agencies, which in turn would enforce these requirements on MCOs and PHPs. Specifically, paragraph (d)(1) proposed that the State agency require all MCOs and PHPs to maintain and monitor a network of appropriate providers that is supported by written arrangements and is sufficient to provide adequate access to covered services. In this context, adequate access generally means that all contracted services, other than out-of-area emergency care services, are available within the MCO's or PHP's network. In establishing and maintaining such a network, the proposed rule required that MCOs and PHPs consider (1) anticipated enrollment, with particular attention to pregnant women and children; (2) the expected utilization of services, considering enrollee characteristics and health care needs; (3) the numbers and types of providers required to furnish contract services; (4) the number of network providers who are not accepting new patients; (5) the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.

In § 438.306(d)(2) we proposed that the State be required to ensure that MCOs and PHPs allow women direct access to a woman's health specialist for women's routine and preventive services, and in paragraph (d)(3) we proposed that MCOs and PHPs seeking an expansion of their service area demonstrate that they have sufficient numbers and types of providers to meet the anticipated additional volume and types of services the additional enrollee population may require. Proposed § 438.306(d) also required that: (1) the State agency ensure that each MCO and PHP demonstrate that its providers are credentialed as described in proposed § 438.314, (2) when medically appropriate, each MCO and PHP make services available 24 hours a day, 7 days a week, (3) as part of the State quality strategy, the State must ensure that each MCO and PHP requires its providers to meet the State-established standards for timely access to care and member services, taking into account the urgency of need for services; and (4) that each MCO and PHP establish mechanisms to ensure compliance and monitor continuously for compliance, and take corrective action in cases of non-compliance.

In § 438.306(e) we proposed that each MCO and PHP be required to provide each enrollee with an initial health assessment within 90 days of the effective date of enrollment, and that pregnant women and individuals with complex and serious medical conditions receive this baseline health risk assessment within a shorter period of time. We further proposed that each MCO and PHP have in place State-approved procedures to identify and furnish care to pregnant women and individuals with complex and serious medical conditions; and that appropriate medical procedures be implemented to address and monitor their care, including specifying an adequate number of direct access visits to specialists as required by the treatment plan.

Finally, proposed § 438.306(e)(4) required that the State ensure that each MCO and PHP provide services in a culturally competent manner, including satisfying the language requirements in § 438.10(b).

Comment: We received several comments in support of the proposed rule, but a few commenters suggested that we revise it to include more specific wording. For instance, one commenter recommended that we expand the rule to make clear that access includes receiving services in a timely manner. Another commenter suggested that we change the language to ensure that all covered services are available to each enrollee as medically necessary. Another commenter suggested that the regulation be revised to reflect that both services and "items" were available and accessible to enrollees. This commenter was concerned that the proposed language did not address access to medical equipment, drugs, and other supplies covered by a State Medicaid plan.

Response: Paragraph (a) was intended to convey the broad general intent of the subsequent provisions. Subsequent provisions of the final rule provide more detailed specifications for what access standards must include, including timely access to care and medical necessity. As noted in a previous response, we have not added the word "items" to explicitly address access to "items and services" covered by an MCO or PHP contract because the term "services," as used in the regulations, includes covered "items" as well. While only the Medicare regulations expressly specify that "services" includes "items" (42 CFR 400.202), section 1905(a) of the Act uses the term "care and services" to encompass all services or items for which Medicaid payment may be made. References in the regulations to "services" therefore, include covered "items" as well.

Comment: We received numerous comments in response to proposed § 438.306(c), which requires a State—

- To arrange for State plan services not covered under an MCO or PHP contract to be made available from other sources; and
- To instruct enrollees on where and how to obtain these services, including how transportation is provided.

Most of the commenters supported the inclusion of this provision, indicating that distribution of information on out-of-plan services has been unsatisfactory in the past. However, a few commenters requested clarification of this provision and wondered whether States could delegate this responsibility to MCOs. In contrast, one commenter disagreed that MCOs should have the responsibility to advise enrollees on where and how to obtain services not provided by the MCO.

Response: We recognize that States have discretion to contract with MCOs or PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. Our intention in proposing this provision was to ensure that enrollees in managed care have access to services covered under a State plan but not provided by an MCO or PHP. We believe that the duty to inform enrollees on how to obtain those services rests primarily with the State. However, we agree that a State may delegate this responsibility to an MCO or PHP as part of its contract.

Comment: One commenter believed that we have gone beyond our authority

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in proposing § 438.306(c). The commenter suggested that our use of the words "arrange for services to be made available from other sources" expands the State's responsibility to a greater degree under managed care than under a fee-for-service arrangement. In light of such concerns, the commenter recommended that the clause be deleted, and argued that States should only be responsible for guaranteeing payment for State plan services not covered under an MCO contract.

Response: States continue to have the same responsibility they have always had to ensure that covered benefits are available to eligible beneficiaries in accordance with a Medicaid State plan. In proposing § 438.306(c), it was never our intent to imply that States act as case managers in "arranging for services to be available from other sources." Therefore, we agree that some change to the proposed rule is necessary to clarify the State's responsibility. In the final rule with comment period, § 438.206(c) requires that, if the MCO or PHP does not cover all of the services under the State's plan, the State must make available those services from other sources and provide enrollees with information on where and how to obtain them, including how transportation is provided.

Comment: We received several comments on proposed § 438.306(c) with regard to the provision of transportation. One commenter noted that transportation has been an issue in certain counties within its State. Another commenter noted that transportation is particularly important for adolescents. Several commenters made specific recommendations. For example, one commenter recommended that we clarify how transportation is reasonably provided, and require that it be subject to the availability of public transportation in the region. Other commenters recommended that we make the transportation requirement a separate provision.

Response: Under § 431.53 of our regulations, a State Medicaid agency is required to specify in its State plan that the agency will (1) ensure all necessary transportation for recipients to and from providers, and (2) describe the methods that the agency will use to meet this requirement. Proposed § 438.306(c) was intended to ensure that, under managed care, enrollees still receive necessary transportation services consistent with what is described in the Medicaid State plan. We do not believe any changes are necessary to further require access to transportation services under managed care.

Comment: Several commenters requested that § 438.306(c) specifically refer to services excluded from a contract because of religious beliefs. In addition, commenters requested that we address the knowledge and expertise of providers with respect to the scope of services provided by the MCO.

Response: We believe that the information requirements in §§ 438.10(e)(2)(xii) and 438.102 specifically address the commenters' concerns. Section 438.10(e)(2)(xii) requires that, either the State or the MCE, as appropriate, must furnish enrollees and potential enrollees with information on how to obtain services covered under a State plan. This encompasses information on services not covered under an MCO or PHP contract because of moral or religious objections and information on the education, licensure, and board certification of providers. Section 438.102(c) requires that MCOs or PHPs that elect on moral or religious grounds under § 438.102(b)(3) not to provide, reimburse, or provide coverage of a counseling or referral service that they would otherwise be required to under § 438.102(b)(1), must furnish information about the services it does not cover to the State and to potential enrollees and enrollees at certain times.

Comment: We received several comments suggesting that proposed § 438.306(d)(1), which set forth requirements for establishing, maintaining, and monitoring a network of appropriate providers, imposed an undue administrative burden on States. Commenters objected to the general requirement for the State to ensure that MCOs maintain and monitor a network of appropriate providers "that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract." One commenter believed that documentation referenced in the general requirement was rarely available to the Medicaid agency, much less to MCOs. The commenter viewed the requirement as impractical, and believed that there was potential for large implementation problems. Another commenter suggested that, although it is the duty of the State to monitor MCO contracts, it would be a huge administrative burden to verify that a written agreement exists with each provider.

Response: We do not agree that this requirement is impractical or imposes an undue burden on States. This provision is consistent with § 438.230, which requires written agreements that specify the delegated activities and reporting responsibilities of a subcontractor. We believe that, without written agreements, MCOs and PHPs cannot assure their enrollees sufficient access to network providers. Therefore, States must obtain assurances from and monitor MCOs and PHPs, as appropriate, to verify that such agreements exist.

Comment: Numerous commenters suggested that we revise proposed § 438.306(d)(1) to add a requirement that States and MCOs make available, as part of their network, providers experienced in serving individuals with certain conditions, and providers with specialty training. For example, commenters suggested that we require MCOs to contract with providers experienced in serving individuals with HIV/AIDS, children with special health care needs, individuals with chronic diseases, and individuals with physical and developmental disabilities. One commenter recommended that the final regulation establish minimum standards for a provider's experience in serving persons with chronic diseases and disabilities in managed care plans. Minimum standards suggested by commenters include: (1) current caseload of persons with certain chronic diseases or disabilities, (2) provider training in treating persons with certain diseases or disabilities, (3) extent or duration of experience serving persons with certain chronic diseases or disabilities, and (4) measures of successful outcomes in treating persons with chronic diseases or disabilities.

Response: We agree that States should ensure that MCOs make available, as part of their network or through other arrangements, access to providers experienced in treating conditions such as HIV/AIDS and access to specialty providers for certain chronic conditions. Therefore, in response to this comment, in § 438.206(d)(1)(iii), we have added "training and experience" to the list of attributes MCOs and PHPs must consider when establishing their provider networks. We also have added, in § 438.206(d)(1)(i) "persons with special health care needs" as a category of enrollees to whom States, MCOs ans PHPs should pay particular attention in meeting this requirement.

We do not believe it is appropriate to further specify in regulation the types of specialists that must be included in an MCO's or PHP's provider network, nor do we believe it appropriate to define what constitutes an experienced provider for certain types of conditions. Because the evidence base regarding how to precisely define all types of "experienced providers" is still limited, we believe that States are in a better position to impose specific requirements on MCOs and PHPs,

consistent with their standards for access to care and the population enrolled in managed care. However, also in response to the concerns raised in this comment, we have added a requirement at § 438.206(d)(5) that if the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them. We intend that the inability to provide medically necessary services would extend to a situation in which the enrollee needs related and covered services (for example, a Cesarean section and a tubal ligation) to be performed at the same time; not all related and covered services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk. We further specify at § 438.206(d)(8) that the State must ensure that use of out-of-network-providers incurs no greater cost to the enrollee beyond what he or she would have paid had the services been received from a network provider.

We emphasize that § 438.206 is integrally linked to § 438.207, which requires MCOs and PHPs to give the State assurances of adequate capacity and services to serve the MCO's and PHP's expected Medicaid enrollment, including access to specialty services. In meeting the requirements of the final rule with comment period, each MCO and PHP will have to submit assurances of its capacity to States, and States will have to submit certification to us, annually and at any time there has been a significant change in the MCO's and PHP's network that would affect adequate capacity and services. We reserve the right to inspect documentation submitted by MCOs and PHPs to the State. With these requirements, we believe that appropriate checks are in place to ensure that States are monitoring MCOs and PHPs against the State's standards for access to care.

Comment: We received several comments suggesting that proposed § 438.306(d)(1)(i) should specifically consider other populations with special health care needs in addition to pregnant women and children. Commenters recommended that we revise § 438.306(d)(1)(i) to also consider people with disabilities, adults with special health needs, persons with mental illness, persons with substance abuse problems, persons with developmental disabilities, and persons with functional disabilities or complex problems involving multiple medical and social needs such as HIV/AIDS and homelessness.

Response: We agree and have revised this provision. As noted above, § 438.206(d)(1)(i) of the final rule with comment period requires that each MCO and PHP, in establishing its provider network, take into consideration "persons with special health care needs," as well as pregnant women and children. Also, in response to this comment, § 438.208(b) of the final rule with comment period requires that States implement "mechanisms to identify to the MCO or PHP, upon enrollment" categories of enrollees at risk of having special health care needs, children under age 2, and other enrollees known to be pregnant or have special health care needs.

"Persons with special health care needs" is the terminology used by the Congress at section 4705(c)(2) of the BBA that called for the Secretary to conduct a study of the safeguards needed when such individuals are enrolled in Medicaid managed care. In undertaking this study, we conceptualized individuals with special health care needs as persons who either (1) have functional disabilities (e.g., difficulty bathing, dressing, eating, communicating, or problems with mobility) or (2) live with health or social conditions that place them at risk of developing functional disabilities (for example: mental retardation; serious chronic illnesses such as HIV, schizophrenia, or degenerative neurological disorders; disabilities resulting from many years of chronic illness such as arthritis, emphysema, or diabetes; and certain environmental risk factors such as homelessness or family problems that lead to the need for placement in foster care). From this conceptual framework, our study identified six groups of individuals with special health care needs:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental. As noted above, under new § 438.208(b)(1), States are required to identify enrollees in these categories to their MCO or PHP.

Subsequent to the passage of the BBA, we also began to explore the concept of "persons with complex and serious medical conditions." This category of persons was referenced in the proposed rule because they are a group of individuals addressed in the Consumer Bill of Rights and Responsibilities (CBRR). On August 31, 1999, the Institute of Medicine (IOM) submitted a report to us entitled "Definition of Serious and Complex Medical Conditions." This study was requested in order to provide guidance to Medicare M+C organizations (who do not have a BBA mandate with respect to "persons with special health care needs"). While the IOM recommended that the establishment of an administrative definition for serious and complex medical conditions would be premature at this time, it also described a "serious and complex condition" as: * * * one that is persistent and substantially disabling or life threatening that requires treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member."

In examining the similarities and differences between the concepts of "special health care needs" and "serious and complex medical conditions" as articulated in our work for its Report to the Congress and the IOM, respectively, it is clear that individuals with, "persistent and substantially disabling * * * [conditions] that require treatments and services across a variety of domains of care to ensure the best possible outcomes for each unique patient or member," are included in our conceptual framework of "persons with special health care needs." The only component of the IOM description of persons with serious and complex medical conditions that is not readily apparent as included in our conceptual description of persons with special health care needs are those health conditions that are "life threatening." However, we believe that persons with life threatening conditions can reasonably be considered to have a special health care need. Therefore, the provisions of this final rule with comment period require States to ensure that each MCO and PHP establish and maintain a network of providers that considers the MCO's or PHP's anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also, throughout this final rule with comment period, deleted the language, "individuals with serious and complex health care needs" where used in the proposed rule, and replaced

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it with "persons with special health care needs."

Comment: We received numerous comments that generally supported the requirement in proposed § 438.306(d)(1)(iii) that MCOs consider the numbers and types of providers needed to furnish contracted services. Many commenters recommended that, instead of providing examples in the preamble, we establish in regulation specific enrollee-to-provider ratio standards. While several commenters suggested that we incorporate the examples from the preamble into the regulation itself, other commenters suggested that we apply other enrollee-to-primary care provider ratios ranging from 1200:1 to 2500:1. Some providers believed that primary care assignments should be discontinued when a patient load reaches 3,000. Several believed that enrollee-to-provider ratios should encompass all patients treated by a provider, and not just Medicaid patients. Finally, some commenters also believed that specific ratios for specialists should be established in regulation, such as ratios for pediatric specialists and providers serving persons with HIV/AIDS.

Response: We do not believe it is appropriate to set national standards that specify maximum enrollee-to-provider ratios. We believe that the inclusion of such ratios in regulations would be too prescriptive, and would not be appropriate for all Medicaid managed care programs across the country. The variation in the comments we received attests to this. Because of such variation, we believe that States are in a better position to establish specific standards to ensure that an adequate number of providers is maintained within MCO and PHP networks.

Comment: Some commenters requested that we establish specific standards in the final rule with comment period outlining the types of providers that must be included in an MCO's network. One commenter specifically recommended that the term "provider" be defined when establishing standards for the various disciplines and specialty areas of practice. Other commenters recommended that an MCO be required to include in its network specified types of providers such as nurse-midwives, obstetricians and gynecologists, pediatric specialists, and providers with demonstrated competence in serving enrollees with mental illness, substance abuse problems, developmental disabilities, functional disabilities, and complex problems involving multiple medical and social needs such as homelessness and HIV/AIDS.

Response: We do not believe it appropriate to impose national standards requiring specific numbers and types of providers. States have implemented varying and often unique programs that cover a variety of benefits. Some of these programs serve a broad spectrum of Medicaid enrollees; while others serve a narrower group. One set of standards may not be appropriate in every circumstance. However, we have required at § 438.206(d) that each State must ensure that each MCO and PHP maintain and monitor a network of providers that is sufficient to provide adequate access to all services covered under the contract, and that in constructing this network, each MCO and PHP must consider (among other requirements): (1) the anticipated enrollment, with particular attention to pregnant women, children and persons with special health care needs, and (2) the numbers and types (in terms of training and experience) of providers required to furnish the contracted services.

Comment: We received a number of comments suggesting that we establish in the final rule with comment period a national geographic access standard. Section 438.306(d)(1)(v) of the proposed rule required MCOs and PHPs, when establishing and maintaining their provider networks, to take into account the geographic location of providers and enrollees, considering distance, travel time, the means of transportation ordinarily used by enrollees, and whether the location provided physical access for enrollees with disabilities. Commenters offered a variety of recommendations to supplement this provision. Some commenters suggested that geographic standards be based on travel time and not distance, and others urged that we liberalize geographic access standards to take into account allowable public transportation time. Several commenters recommended that we require a general time of 30 minutes from an enrollee's residence, and others recommended an exception for frontier areas. Further, other commenters suggested varying standards, such as 30 miles or 30 minutes for rural areas, 20 miles or 30 minutes for urban areas, and 45 minutes for specialty care; whereas other commenters suggested a 30 minute or 30 mile standard, with a 60 minute or 60 mile standard for rural areas.

Response: We do not believe it is appropriate to set national geographic access standards in these regulations. We recognize that there are unique circumstances which exist in each State for which a national standard could be inappropriate. This is reflected in the comments received and in the preamble to the proposed rule in which we noted that a provider network should be structured so that an enrollee residing in the service area does not have to travel an unreasonable distance to obtain a covered service, beyond what is customary under a Medicaid fee-for-service arrangement. The preamble to the proposed rule also acknowledged that many Medicaid enrollees may use public transportation. We stated that "in areas where Medicaid managed care enrollees rely heavily on public transportation, the State should ensure that providers are accessible through these means within the same time frames as enrollees who have their own means of transportation." Because of this, we believe that States are in a better position to establish access standards, including geographic access standards, as part of their States' quality assessment and improvement strategy. Our availability of services requirements under § 438.206 of the final rule with comment period allow States sufficient flexibility to develop access standards that are appropriate for their own circumstances, and ensure that States take into consideration important factors such as distance, travel time, and the means of transportation normally used by enrollees.

Comment: We received several comments requesting that we be more specific with respect to our requirement that MCOs and PHPs take into account a location's physical accessibility for enrollees with disabilities. While the commenters generally supported inclusion of this provision, they also believed that we should be more specific in our final rule with comment period. Several commenters believed that we should require States, at a minimum, to ensure that sites are physically accessible and comply with the Americans with Disabilities Act. One commenter suggested that States and MCOs ensure access not only to locations, but also to all aspects of medical treatment. Other commenters stressed that in addition to physical access, it is just as important for populations with special health care needs, such as persons with mental retardation, to have access to knowledgeable and trained staff, to receive understandable information, to be able to communicate with a provider if he or she is hearing impaired, and to have longer appointment times. They recommended that we reflect these adaptations in the final rule with comment period.

Response: We believe that several of the requirements in this final rule with comment period address many of the commenters' concerns. We specifically refer commenters to the following:

- Sections 438.206(d)(1)(i) and (d)(1)(ii) require each MCO and PHP, when establishing their provider networks, to take into consideration their anticipated enrollment, with particular attention to persons with special health care needs, and their expected utilization of services, considering the enrollees' characteristics and health care needs.
- Section 438.206(d)(1)(iii) requires each MCO and PHP to also consider the numbers and types (in terms of training and experience) of providers needed.
- Section 438.206(d)(1)(v) requires MCOs and PHPs to consider distance, travel time, means of transportation ordinarily used by enrollees, and whether the location provides physical access for enrollees with disabilities.
- Section 438.100 requires the State to ensure that MCOs, PHPs, and PCCMs, comply with applicable Federal and State laws that pertain to enrollee rights. The Americans with Disabilities Act is explicitly mentioned as one of these Federal laws. Section 438.100 also requires States to ensure that enrollees receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollees' conditions and ability to understand.
- Section 438.102(b)(2)(ii) requires that steps be taken to ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

All these requirements were designed to ensure that States address issues such as physical access and composition of provider networks. We have not required in this final rule with comment period that populations with special health care needs always have longer appointment times because it is not yet possible to precisely define all individuals with special health care needs, and because all such individuals may not always require longer appointment times.

Comment: We received several comments on proposed § 438.306(d)(2), which requires that female enrollees have direct access to women's health specialists within the network for women's routine and preventive services, notwithstanding that the MCO maintains a primary care provider for each enrollee.

Overall, many commenters supported inclusion of this provision. However, a few commenters requested clarification of regulatory terms. For example, several commenters expressed concern over what they viewed as the ambiguity of the term "women's health specialist." They requested that we expand the definition of that term in the final regulation to include specific provider types, such as nurse-midwives or obstetricians/gynecologists. Others felt that this provision could be construed to include non-licensed practitioners or laypersons.

Response: We do not define "women's health specialist" in this final rule with comment period, because different types of health professionals may, through education and/or clinical experiences, be appropriately thought of by a contracting MCO or PHP or enrollee as a "women's health specialist." However, we intend for the term to refer to licensed health professionals with specific clinical education and training in women's health care, including obstetricians, gynecologists, nurse midwives, and nurse practitioners, consistent with State licensing requirements.

Comment: Several commenters felt that the term "routine and preventive services" in proposed § 438.306(d)(2) should be excluded from this provision, while other commenters felt that we should define the term further. One commenter felt that we should define the term based on existing professional guidelines. Others requested that we define the term to include specific services, such as prenatal care, labor and delivery services, breast exams, mammography, and pap smears.

Response: We agree that some clarification is needed. In § 438.206(d)(2) of the final rule with comment period, an MCO or, as appropriate, a PHP is required to provide female enrollees with direct access to a woman's health specialist within the network for covered care necessary to provide women routine and preventive health care services. This would include initial and follow-up visits for services unique to women such as prenatal care, mammograms, pap smears, and for services to treat genito-urinary conditions such as vaginal and urinary tract infections and sexually transmitted diseases.

Comment: Several commenters requested that we expand proposed § 438.306(d)(2) to clarify whether the requirement applies to both adult females and to minor adolescent females. Other commenters suggested that we add language that would allow direct access to a women's health specialist for pregnant enrollees of any age, but otherwise would set a limit for access to a women's health specialist to age 15 or older.

Response: We used the term "female enrollees" to include minor females. Thus, we believe that if there is a medical need to see a women's health specialist, there should be no impediment based on the age of the enrolled female.

Comment: One commenter believed that proposed § 438.306(d)(2) would conflict with recent insurance legislation in the State which allows MCOs to require a women's health specialist to have a referral arrangement with, but not actual referrals from, an enrollee's primary care physician. Another commenter stated that it is unclear whether a female enrollee would be able to choose any women's health specialist within the network.

Response: We believe that, within MCO and PHP networks, female enrollees must have direct access to a women's health specialist for covered care necessary to provide women's routine and preventative health care services. We believe that this means that each woman should have access to any women's health specialist within the network, unless some network providers are not accepting new enrollees or there are other network restrictions based on the enrollee's choice of primary care provider. (For example, a woman may choose a primary care provider that is part of a subnetwork of providers within an MCO. As long as the woman was informed of the consequences of choosing a primary care provider that is a part of a subnetwork, at the time of her enrollment, she can be restricted to using only those specialists, including women's health specialists that are part of the subnetwork—although provisions for using out-of-network providers would still apply.) This provision was proposed consistent with statutory authority requiring States to develop standards for access to care "in a manner that ensures continuity of care and adequate primary care and specialized services capacity" (section 1932(c)(1)(A)(i) of the Act). Moreover, this provision is consistent with the beneficiary rights in the CBRR.

Comment: We received several comments recommending that proposed § 438.306(d)(2) be applied to all managed care entities, including PCCMs, HIOs, and PHPs. Commenters also suggested that we should apply this provision to individuals in managed care plans with 6-month eligibility.

Response: Section 438.206(d)(2) is based on authority in section 1932(c)(1)(A)(i) of the Act. As noted above, with respect to the quality assurance requirements implementing

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section 1932(c)(1) of the Act generally, the Congress chose to apply this provision only to MCOs, while other provisions in the same section were made applicable to both MCOs and PCCMs (*i.e.*, to "MCEs"). The Congress thus expressed a clear intent that these requirements not apply to PCCMs. With respect to HIOs, if they are required to meet the definition of MCO and comply with section 1903(m) of the Act requirements, these requirements would apply to them. If, however, they have a specific statutory exemption from section 1903(m) of the Act, again, the Congress has spoken directly to the question of whether these requirements should apply, and determined that they should not. We therefore believe it would be inconsistent with clearly expressed Congressional intent to subject PCCMs or section 1903(m) of the Act-exempted HIOs to requirements based on the authority in section 1932(c)(1) of the Act. Also as noted above, however, in the case of PHPs, the Congress was silent as to what standards should apply, and based on our authority under section 1902(a)(4) of the Act, we have applied the requirements in subpart D (including the woman's health requirement in § 438.306(d)(2)) to PHPs, as appropriate. We do not believe that we need to explicitly reference individuals with six-month eligibility because the provision applies to all women regardless of their length of eligibility or enrollment.

Comment: One commenter suggested that § 438.306(d)(2) should not apply to behavioral health organizations, since women's health specialists do not exist in such settings.

Response: We agree with the commenter that this requirement may not apply to PHPs that deliver a limited set of services under a capitated arrangement. PHPs of this type typically include organizations contracted to provide mental health or substance abuse services and organizations that provide dental services. Section 438.8(a) of the final rule with comment period specifies that the quality assessment and performance improvement requirements apply to PHPs "to the extent that they are applicable to the services furnished by the PHP." In the example of a behavioral health organization, access to a women's health specialist for covered care necessary to provide women's routine and preventive health care services would not be applicable.

Comment: Several commenters believed that § 438.306(d)(2), pertaining to women's direct access to a women's health specialist, as proposed, would impede continuity of care. They recommended that this provision be eliminated. Another commenter recommended that we delete the phrase "notwithstanding that the MCO maintains a primary care provider for each enrollee."

Response: As we have stated, we believe that female enrollees must have direct access to a women's health specialist within an MCO's and PHP's network as applicable and PHP's network as applicable. This provision was proposed in order to provide access in a manner that ensures adequate specialized services as required under section 1932(c)(1)(A)(i) of the Act and in order to implement the CORR. To make this purpose and the provision more clear, we have replaced the words "notwithstanding that the MCO maintains a primary care provider for each enrollee" with the sentence, "This [direct access to a women's health specialist] is in addition to the enrollee's designated source of primary care, if that source is not a women's health specialist." This change of wording also emphasizes that a female enrollee's right to directly access a women's health specialist cannot be satisfied, under Medicaid, by simply offering the opportunity to choose a women's health care specialist as a primary care case manager. We believe that in the case of the Medicaid population, direct access for these services is critical, and that the opportunity to choose a primary care case manager who provides these services is not sufficient, since a woman may not wish to see a woman's health specialist for general care.

Comment: We received one comment referencing § 438.306(d)(2) which suggested that OB/GYNs be able to serve as primary care physicians. The commenter expressed concern that women may not receive information about when they are entitled to self-refer to OB/GYNs. The commenter recommended that such information be required.

Response: Our intent in the proposed rule was not to require States and MCOs or PHPs to allow (or preclude States and MCOs or PHPs from allowing) OB/GYNs, or other specialists, to serve as primary care providers. The final rule with comment period, as amended, provides flexibility for States to determine the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the enrollee population being served. Moreover, the information requirements at § 438.10, as amended, are written to ensure that enrollees receive adequate information on procedures for obtaining all benefits, including information on the right of female enrollees to directly access a women's health specialist within the MCO or PHP network for covered care necessary to provide women's routine and preventive health care services.

Comment: We received a comment on the grievances and appeals provisions urging that enrollees faced with an adverse decision have the right to a second opinion, and that this right be mentioned in the adverse action notice. The commenter felt that enrollees should have the right to out-of-network, unbiased, second opinions, and this right should be specified in the regulations.

Response: We agree that enrollees should have access to an unbiased second opinion. We believe that this right extends beyond an adverse action notice to any instance in which the enrollee requests a second opinion. Therefore, we have added requirements in the regulation, both in Enrollee rights (§ 438.100) and in the Availability of services provisions (§ 438.206(d)(3)), with regard to second opinions. Contrary to the commenter's suggestion, we believe that an enrollee can receive an unbiased opinion from another qualified health professional in the network. Accordingly, we have specified that the MCO or PHP must provide for an enrollee to have access to a second opinion from a qualified provider *within the network* or arrange for the enrollee to obtain a second opinion outside of the network if an additional qualified health care professional is not currently available within the network.

Comment: We received many comments on proposed § 438.306(d)(5), which required the State to ensure that, when medically appropriate, the MCO or PHP makes services available 24 hours a day, 7 days a week. The proposed regulations stated that this provision applies, at a minimum, to emergency services and post-stabilization services, and to non-emergency services that are required immediately because of unforseen illness. A majority of the comments requested further clarification of terms and standards. Specifically, several commenters requested that the term "unforseen illness" be clarified or deleted. Many commenters argued that the term is too restrictive, invites legal controversy over its interpretation, and is contrary to managed care's emphasis on prevention, early detection, and treatment. Other commenters urged that we adopt and apply specific standards for urgent care of 24 to 48 hours depending on the day of the week an unforseen illness occurs. One commenter specifically recommended that we add an additional standard of 24 hour, 7 day "crisis services" for beneficiaries with mental illness. Another commenter felt that MCOs should have a mechanism to conduct triage and assessment, but should not have to make available non-emergency, non-urgent care 24 hours a day, 7 days a week. Finally, one commenter stated that the availability of services under this provision should be based on medical necessity and not medical "appropriateness."

Response: Our intent in proposing § 438.306(d)(5) was to ensure that individuals who require home health services or other types of non-hospital based services receive care, when medically necessary, during non-business hours. After further review and consideration of comments received, we have revised the policy so that the final rule with comment period requires MCOs and PHPs to ensure that services are available 24 hours a day, 7 days a week, when medically necessary (§ 438.206(e)(1)(iii)). We believe this change ensures access to care without using potentially ambiguous terms such as "unforseen illness" and "medically appropriate." We further believe that this requirement is consistent with our overall intent as reflected in other provisions in the final rule with comment period, including § 438.114, Emergency and post-stabilization services, and § 438.210, Coverage and authorization of services.

Comment: Several commenters felt that proposed § 438.306(d)(5) was too prescriptive and costly. One commenter believed that the provision was likely to increase the number of providers who refuse to see Medicaid patients, and suggested that normal physician practice standards should be acceptable for all populations. Other commenters recommended that the provision be deleted.

Response: As we have indicated above, we believe this provision is important to ensure that enrollees have access to medically necessary care during traditional, non-business hours.

Comment: We received numerous comments on proposed § 438.306(d)(6), which required MCOs and PHPs to ensure that its providers' hours of operation are convenient to enrollees, and do not discriminate against Medicaid enrollees. One commenter supported the provision, but suggested that we reference populations with special health care needs. Other commenters believed that the term "convenient" in the proposed regulation was too ambiguous and subjective, and that this term required further clarification. One commenter specifically argued that we were imposing a new requirement in Medicaid managed care that we have not imposed in Medicaid fee-for-service. Finally, other commenters suggested that this particular provision, if included in the final rule with comment period, would have widespread implications for the program. They argued that we have exceeded our statutory authority in proposing this provision.

Response: Upon further consideration, and based on comments received, we agree that the term "convenient" needs clarification. As a result, we have moved this requirement to § 438.206(e), because we believe that it more appropriately falls under the "provision of services" paragraph. Under paragraph (e)(1)(ii), the MCO or PHP must ensure that its providers' hours of operation are convenient for the enrollees, as determined by a State-established methodology, and that they are at least comparable to Medicaid fee-for-service.

We believe that the State should establish standards for what is convenient for enrollees in terms of provider hours of operation. Those standards should be at least comparable to Medicaid fee-for-service. Thus, an enrollee who was able to schedule weekend or evening appointments under the Medicaid fee-for-service program should have access to appointments during those hours under Medicaid managed care.

We continue to believe that the State and MCO or PHP must ensure that providers do not discriminate against Medicaid enrollees. Thus, we retain this requirement in § 438.206(d)(7).

Comment: One commenter suggested that we apply proposed § 438.306(d)(6) to MCEs, and not just MCOs.

Response: We proposed § 438.306(d)(6) under the authority of section 1932(c)(1)(A)(i) of the Act. As discussed above in connection with proposed § 438.306(d)(2), the Congress expressed a clear intent that requirements under section 1932(c)(1) of the Act apply to MCOs, but not PCCMs. When the Congress wanted to apply requirements to PCCMs as well as MCOs, it did so by referencing "MCEs," which includes MCOs and PCCMs. We thus believe it would be inconsistent with clearly stated Congressional intent to apply requirements under section 1932(c)(1) of the Act to PCCMs.

Comment: We received numerous comments on proposed § 438.306(e)(1)(i), which required MCOs and their providers to meet State-established standards for access to care and member services, taking into account the urgency of the need for services. Several commenters recommended that we incorporate into the final regulation the suggested standards outlined in the preamble to the proposed rule. The commenters' rationale for incorporating the suggested standards in the final rule with comment period is that the standards reflect existing managed care contracts and there appears to be no reason for State flexibility regarding maximum wait times for care. The same commenters argued that the BBA gives us the authority to establish minimum standards for quality assessment and improvement strategies. Several other commenters noted the importance of establishing standards for in-office waiting times, especially for mental health services.

Commenters offered a number of recommendations that included standards in addition to, or as alternatives to, those presented in the preamble to the proposed rule. Moreover, the recommendations referenced both in-office waiting times and appointment scheduling times. Specifically, the additional standards included referral appointments to specialists within 30 days for routine care, 72 hours for urgent care, and 24 hours for emergency appointments. Other additional standards included routine, prenatal visits within 2 weeks for the first trimester, 1 week for the second trimester, and 3 days for the third trimester. Recommended alternative standards included in-office waiting times of no longer than 45 minutes or 1 hour, and appointment times for routine appointments ranging from 2 weeks to 30 days.

Response: Section 1932(c)(1)(A)(i) of the Act provides that "the State shall develop * * * a quality assessment and improvement strategy," that shall include "[s]tandards for access to care." Under the authority of section 1932(c)(1)(A)(i) of the Act, we have proposed regulations to ensure that States take into consideration certain requirements when developing their standards for access to care. One of these requirements (contained in § 438.306(e)(1)(i) of the proposed rule) is that MCOs and PHPs and their providers meet State-established standards for access to care.

We disagree with commenters who suggest that national standards should be established in the final regulation. First, as just noted, the statute calls for "the State" to "develop" such standards, not us. This suggests that the Congress contemplated that standards

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be State-specific. Secondly, patterns of care delivery typically vary across the country. Because of this, a single national standard may not be appropriate in all localities. Therefore, we only included suggested standards in the preamble to the proposed rule as examples for States to consider. The various additional and alternative suggestions offered by commenters may also be appropriate for States to consider. However, we will not mandate any of them in this final rule with comment period.

Comment: Several commenters suggested that proposed § 438.306(e)(1)(i) was too burdensome, and not consistent with the common practice of wait times for appointments of six to eight weeks. Further, commenters suggested that if more stringent standards are imposed for Medicaid managed care enrollees than commercial enrollees, providers may avoid serving Medicaid members.

Response: We do not agree with commenters who suggest that we are imposing more stringent standards for Medicaid enrollees than commercial enrollees. In this final rule with comment period, we require MCOs and PHPs to meet State-established standards. Further, we require that provider hours of operation be at least comparable to fee-for-service. We included examples in the preamble of the proposed rule for State consideration only. These examples were not mandatory requirements. In fact, we specifically indicated that States should evaluate a number of factors, including common waiting times for comparable services in the community. We believe that this statement reflects our intent that, in designing standards for timely access to care, States consider existing practice patterns.

Comment: We received one comment that we should revise proposed § 438.306(e)(1)(i) to add the word "subcontractors" after providers, to ensure that subcontractors are required to meet State-established standards for timely access to care and member services.

Response: We do not believe that such a change is necessary for the final rule with comment period. Section 438.230 of the final rule with comment period establishes requirements for subcontractual relationships and delegation. It ensures that each MCO and PHP oversees and is held accountable for any functions and responsibilities that it delegates to a subcontractor. In addition, § 438.6(l) requires that all subcontracts meet the contracting requirements that are appropriate to the service or activity delegated under that subcontract. We believe that these provisions are adequate to ensure that subcontractors are held to the same access standards imposed on MCOs and PHPs by the State.

Comment: Several commenters took issue with the examples contained in the preamble for proposed § 438.306(e)(1)(i), which requires States to establish mechanisms to ensure MCO compliance with standards for timely access to care. Several commenters expressed concern that documenting in-office waiting times would be administratively burdensome, would lead to increased costs, and may reduce the willingness of HMOs to participate in Medicaid. One commenter believed that satisfaction surveys would be sufficient to indicate if a problem exists, which can then be explored with audits of individual providers. Another commenter suggested that our preamble discussion on compliance include methods for gaining consumer feedback in addition to mail and telephone surveys.

Response: In the preamble to the proposed rule, we offered a number of mechanisms that States, MCOs and PHPs could use to monitor compliance with timeliness standards, including the use of surveys, analysis of complaints and grievances, provider self-reports, random audits, and test calls. While we cautioned States on the use of general surveys of its enrolled population, we did not discount the use of surveys all together. For example, the Agency for Healthcare Research and Quality's (AHRQ's) Consumer Assessment of Health Plans Study (CAHPS) survey tools are reliable and valid survey instruments that can be used to assess many aspects of health care, including access to quality and timeliness of care. We believe that States should consider all appropriate mechanisms for measuring MCO and PHP performance against State standards, and rely on those mechanisms which are most effective.

5. Proposed § 438.306(e)(2) (Initial Assessment) and (e)(3) (Pregnancy and Complex and Serious Medical Conditions)

Paragraph (e)(2) of proposed § 438.306 required States to ensure that MCOs and PHPs provide initial assessments of each enrollee within 90 days, and within a shorter period of time for pregnant women and enrollees with complex and serious medical conditions. Paragraph (e)(3) of proposed § 438.306 set forth specific requirements for dealing with the two groups and for their treatment plans. We received a great many comments on these proposed provisions which, in the final rule with comment period, are redesignated under § 438.208, and incorporate several additional groups and time frames.

Comment: Many commenters requested clarification on what constitutes an initial assessment as proposed. Several commenters questioned whether a telephone call or questionnaire might suffice. Other commenters suggested that initial assessment should be face-to-face, and should cover both health and social issues. Several commenters suggested that, particularly for enrollees with complex or serious medical conditions, and populations such as the homeless, pregnant women, newborns, and children, assessments should be conducted face-to-face. One commenter specifically recommended that we define initial assessments to include the following services: a comprehensive health and developmental history, a comprehensive unclothed physical exam, laboratory tests including blood level assessments appropriate for age and risk factors, and health education.

Response: We agree that the term "initial assessment" is misleading. While our original intent was that this term be analogous to the term "screening," we are persuaded by comments that certain individuals require a more thorough and timely assessment by an MCO or PHP provider after enrollment. Accordingly, in § 438.208(d) and (e) we are now requiring that the MCO or PHP make a best effort to identify, screen, and comprehensively assess pregnant women, children under the age of 2 years old, and enrollees with special health care needs.

In order to assist MCOs and PHPs in conducting the types of assessments suggested by the commenters, in section 438.208(b) we are requiring States to identify to MCOs and PHPs populations "at risk" of having special health care needs, children under age 2, and other enrollees known by the State to be pregnant or to have special health care needs. The "at risk" populations include: (1) Children and adults receiving SSI benefits; (2) children in title IV–E foster care; (3) enrollees over age 65; (4) enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and (5) any other groups of enrollees identified by us (§ 438.208(b)(1)).

Also in order to address the commenters' concerns about ensuring appropriate assessments, in § 438.208(e) of the final rule with comment period, we require the MCO or PHP to implement mechanisms to ensure the ongoing screening of its enrolled population to identify and comprehensively assess persons who become pregnant or who develop special health needs following enrollment in the MCO or PHP.

We believe that a State and MCO or PHP should have the flexibility to choose the form and substance of the initial screen or screens. Initial screens may take the form of a phone call, mailed questionnaire, home visit or physical examination; however, it must be sufficient to identify individuals with special health care needs. Further, the initial screen should also attempt to collect information on any languages or TTY requirements, and needs for accessible medical facilities and/or transportation services. The comprehensive health assessment, on the other hand, should include a physical examination by an MCO or PHP provider. In fulfilling the screening and assessment requirements, the MCO or PHP must ensure that its providers have the information required for effective and continuous patient care and quality improvement.

Comment: We received many comments with respect to time frames. Commenters varied in their opinions. Several commenters believed that 90 days was too long to wait for an initial assessment (now referred to as "screening" in the final rule with comment period), particularly for enrollees with serious and complex medical conditions. Many other commenters expressed concern over whether an MCO or PHP could perform an initial assessment (screening) on each enrollee within 90 days. These commenters noted the difficulty in contacting an enrollee and ensuring the cooperation of an enrollee in seeing a physician in order to have an assessment (screening) completed. They felt that initial assessments (screening) within 90 days was unrealistic and longer time frames were needed. One commenter suggested that the issue of timing can better be addressed in the contract between the State and the MCO or PHP. The commenter believed that the 90 day requirement should not be a Federal mandate.

Many recommendations were offered. One commenter suggested that a health assessment (screen) need only take place once a year, with an initial assessment (screening) occurring within 180 days if (1) the member has not used the emergency room within the last 90 days, (2) the member is in good health, and (3) the member has reported to the MCO or PHP that it has had a health assessment. Other commenters recommended a shorter time frame of 30 days, and recommended special time standards for specific populations, such as requiring an initial assessment (screening) within 15 to 30 days from enrollment for newborns and young children and within 72 hours for enrollees with HIV. Other commenters suggested more general standards of no more than 60 days to complete initial assessments (screening), to 180 days for adults and 90 days for children. One commenter recommended that MCOs or PHPs only be required to make a good faith effort to contact each new member at least two times to schedule an appointment with his or her primary care provider. Other commenters recommended that we revise the final rule with comment period to require MCOs and PHPs to meet a variation of the following language: (1) Make a good faith effort to conduct an assessment (screening), (2) make available within 90 days of enrollment an initial assessment (screening), (3) inform enrollees of the need for an initial assessment (screening), or (4) make a substantial attempt to provide initial assessments (screenings). One commenter suggested that an assessment for a child under the age of 21 should meet the requirements of the EPSDT guidelines set forth in §§ 441.50 through 441.62.

Response: We agree with many of the comments received. Specifically, we agree with the comment that an MCO or PHP should only be required to make an "effort" to perform a screening or assessment. We agree that, through no fault of its own, an MCO or PHP may not be able to achieve full compliance with the proposed initial assessment (screening) requirement. We therefore have revised the requirement to provide, in § 438.208(d) of the final rule with comment period that MCOs and PHPs must make a "best effort" to perform the screening and assessment required in this section. A "best effort" means that the MCO or PHP should follow-up on unsuccessful attempts to contact an enrollee. With this change, we wish to make clear that the MCO or PHP is not relieved of the obligation to screen all enrollees. Rather, we only wish to acknowledge that an MCO or PHP may not be able to achieve 100 percent compliance with the screening and assessment requirements. We also recognize that some enrollees may be unable to cooperate with the MCO's or PHP's efforts to screen and assess them. In these cases, MCOs and PHPs should document the attempt to screen and (as applicable) assess individual enrollees.

We also agree with the commenters who believed that a 90 day time frame was too long, and specifically with the suggestion of a 30 day time frame in connection with enrollees with special needs. Because of this, we have revised the rule to include different time frames for screening the especially vulnerable groups of pregnant women and persons who either have been identified as having special health care needs, or have been identified by the State under § 438.208(b) as being in categories at risk for having special health care needs. Although we have not identified children under 2 years of age as enrollees "at risk," we recognize the importance of timely screening and assessment of young children and have added them to the groups requiring quicker screening. Specifically, under § 438.208(d), we require MCOs (and PHPs as determined by the State in accord with § 438.208(a)(2)) to make a "best effort" to screen and comprehensively assess pregnant women, children under 2 years of age, and persons determined to have special health care needs in accordance with the following timeframes:

(1) For enrollees identified by the State as at risk of having special care needs, screening within 30 days of receiving the State's identification, and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification through screening.

(2) For enrollees identified by the State as being children under age 2, and for other enrollees who are identified by the State or who identify themselves as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

(3) For all other enrollees, screening within 90 days of enrollment and for those the screening identifies as being pregnant or having special health care needs, comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days after the date of identification.

We believe that these standards are reasonable to ensure that persons requiring special medical attention from MCOs and PHPs receive services as expeditiously as possible. Because we agree with the commenters recommending these shorter time frames that such time frames are necessary to help ensure the health of vulnerable beneficiaries, we are not accepting the comments that suggested

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longer time frames, or abandoning this requirement altogether.

Comment: Several commenters suggested that an initial assessment (now referred to as "screening" in the final rule with comment period) not be required for enrollees who are continuing patients of the MCO or provider, or when a prior assessment (screening) is available to the MCO.

Response: We recognize that in some situations it would be duplicative and unnecessary to require screening of an enrollee. For instance, we would not expect an MCO to screen enrollees for whom current health care information is available, such as enrollees already under the care of providers with the MCO's network, or who maintain the same primary care provider when enrolling in a different MCO. In such a case, the screening required under this rule could be considered to have been performed. To ensure compliance with the revised requirements for enrollee screening, MCOs and PHPs should document in the enrollee's health record why screening is not necessary.

Comment: We received a few comments that the proposed initial assessment (screening) requirements should not apply to PHPs, such as managed behavioral health organizations. The commenters recommended that this provision apply only to managed care organizations that provide primary and preventive care services.

Response: As previously indicated, § 438.8 makes the subpart D rules applicable to PHPs to the extent that they are applicable to the services furnished by the PHP. Some PHPs provide services to the most vulnerable Medicaid enrollees, many of whom are diagnosed with chronic conditions or who are determined to have long-term care needs. Thus, timely screening and assessment of these individuals by PHPs, in relationship to the scope of services provided by the PHP, is necessary to ensure that those requiring special attention receive necessary medical care.

We acknowledge, however, that a State might design a managed care initiative that involves PHPs for which an initial screening by the PHP might be duplicative. For example, a State may utilize a separate "carve-out" program for mental health services in which an enrollee may require referral by the MCO contracted to provide physical health services. In such a case, a State might design its managed care initiative to have the MCO screen for both physical and mental health. The MCO could screen the enrolled population to identify enrollees who likely require mental health services, and could share the results of the screen with the PHP. The PHP, in turn, would conduct a comprehensive health assessment through appropriate health care professionals. States must determine the most effective and efficient strategy for assuring that all Medicaid MCO and PHP enrollees are screened.

While the State is responsible for ensuring that a screening is carried out on all Medicaid managed care enrollees by some combination of the enrollee's MCO and PHP, in response to this comment, we are under § 438.208(a)(2) of this final rule with comment period providing the State with the flexibility to decide how this responsibility will be carried out, and whether PHPs will be required to perform screenings and assessments in cases in which an enrollee is enrolled in both an MCO and a PHP or more than one PHP.

Our decision in response to the comment to permit State flexibility with respect to PHP screening raises issues of coordination between MCOs and PHPs and responsibilities for screening, assessment and treatment planning for Medicaid enrollees who also receive Medicare and are enrolled in a Medicare +Choice plan. The commenter presumably was concerned about possible duplication of efforts in urging that only the single entity furnishing primary care perform screenings. We believe that this concern about duplication can be addressed, while still providing for PHP screening where appropriate, by requiring in a new § 438.208(h)(3), that each MCO or PHP share the results of its screening or assessment of an enrollee (or both, if the MCO or PHP performs both) with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment (or both). To address the issue of Medicaid enrollees also receiving Medicare and enrolled in a Medicare+Choice plan, we have added a new provision at § 438.208(a)(3) requiring the State to determine the extent to which each MCO is to perform initial screening, assessment and treatment planning for such enrollees, consistent with the services the State requires the MCO to provide.

Comment: We received a number of comments on proposed § 438.306(e)(3)(iii) which required the MCO to develop treatment plans that are appropriate for the conditions identified, specify an adequate number of direct access visits to specialists, and are updated periodically by the physician responsible for the overall coordination of the enrollee's health care. Some commenters suggested that MCOs and physicians need to be given the flexibility to evaluate each enrollee's circumstance. Other commenters urged that the regulations require that enrollees participate in treatment planning. Several commenters believed that enrollees with complex and serious medical conditions should be permitted direct access to specialists, even if they are out-of-network providers. Other commenters suggested that this provision be deleted because it can be interpreted to permit unlimited access to specialists. One commenter expressed the view that direct access to specialists is a benefit that has just begun to evolve in commercial plans, and accordingly should not be applied until MCOs and PHPs can further manage a direct access system.

Response: We disagree with commenters who suggest that this provision permits unlimited access to specialists. It was never our intent to guarantee unlimited access. Proposed § 438.306(e)(3)(iii) was drafted to ensure that enrollees with complex and serious medical conditions (now referred to as enrollees with special health care needs) be permitted a sufficient number of direct access visits to specialists as required by the treatment plan. Our overall intent in the final rule with comment period remains the same. We continue to believe that enrollees with special health care needs who are undergoing an approved course of treatment should be able to access specialists within the MCO's or PHP's network without having to obtain numerous authorizations from their primary care providers, and that this is necessary in order to meet the "access to care" standard in section 1932(c)(1)(A)(i) that services be available "in a manner that ensures * * *adequate * * * specialized services capacity." In recognition of varying MCO and PHP practices, the final rule with comment period, requires the treatment plan to specify either an adequate number of direct access visits to specialists or a standing referral to specialists. However, we continue to require that the treatment plan be time-specific, and updated periodically to determine whether continued access to a specialist for a course of treatment is necessary. To avoid confusion, in this final rule with comment period, we also have added a specific requirement that we believe was implicit in the proposed rule. Section 438.206(f)(6) now expressly requires that the treatment plan ensure periodic reassessment for each enrollee as his or her health requires. In addition, in response to the comments

on the need for enrollee participation and that treatment planning consider the needs and preferences of the enrollee, at § 438.206(f)(5) we added a requirement that treatment plans be developed with enrollee participation.

Comment: We received a number of comments urging that we revise proposed § 438.306(e)(3) to further address and consider populations with special health care needs. Many commenters wanted us to further clarify and define the term "complex and serious medical conditions." Specifically, one commenter recommended that we revise the wording of proposed § 438.306(e)(3)(ii) to state: "Timely identifies individuals with complex and serious medical conditions or mental disabilities, assesses those conditions, and identifies appropriate health care services for monitoring, treatment, or rehabilitation." Another commenter recommended that the regulation include a list of conditions that mandate the actions spelled out in proposed § 438.306(e)(3)(ii) and (iii). Although the commenter recognized that it would be impractical to include an exhaustive list, he argued that there are some chronic conditions that should be listed, particularly where continuing attention and monitoring are vital. Some of the populations that commenters recommended include persons with mental disabilities, cancer patients, persons with end stage renal disease, persons awaiting organ transplants, persons with HIV/AIDS, children with special health care needs, and persons with cerebral palsy or other conditions related to the presence of a developmental disability. In contrast to identifying an exhaustive list of conditions, one commenter suggested that we develop a definition for complex and serious medical conditions based on patient requirements for higher levels of resources. This commenter argued that such a definition would require MCOs that enroll persons whose needs exceed normal actuarial physical and mental utilization estimates for a working age population to demonstrate higher capacity both in their networks and with respect to their access standards.

Response: We agree that clarification is needed and, as previously discussed, have revised this provision to require that MCOs and—where applicable—PHPs, screen and comprehensively assess "enrollees with special health care needs," which, as noted above, is how we now refer to individuals with complex and serious medical conditions. As we discussed previously, "persons with special health care needs" is the terminology used by the Congress at section 4705(c)(2) of the BBA. We have conceptualized this term to include:

(1) children with special health care needs;

(2) children in foster care;

(3) individuals with serious and persistent mental illness/substance abuse;

(4) individuals who are homeless;

(5) older adults (individuals 65 years of age and older) with disabilities; and

(6) adults under 65 who are disabled or who have a chronic condition, whether physical or mental.

We note that this listing of individuals with special health care needs is not an operational definition of persons with special health care needs and that health services research is still in the process of developing conceptual models, screening tools and approaches to identifying individuals with special health care needs.

Comment: We received a number of comments suggesting that under proposed § 438.306(e)(2) and (3), we should require continuing coverage of on-going treatment, even if it is out-of-network, until the time of an initial assessment when a primary care physician, in consultation with a specialist, establishes a new care plan. Commenters believed that unless an MCO is given prior information, it will not know if an enrollee is pregnant or has a complex medical condition to provide an assessment prior to 90 days. Other commenters noted that the disruption of services can be particularly harmful for enrollees with complex and serious medical conditions. To facilitate the initial assessment, one commenter recommended that we require the State Medicaid agency to provide the MCO with information on age, eligibility category, and whether a child is in foster care or is in an out-of-home placement.

Response: We believe that most States already have mechanisms in place to transition enrollees with ongoing health care needs to managed care. However, we acknowledge the commenters' concerns that our proposed regulation did not address the potential disruption of services, even for a short period of time, between enrollment and the time of assessment by the new primary care physician/specialist in the receiving MCO or PHP. To address this concern, as discussed in section II. B. above, we have added a new paragraph (b) to proposed § 438.62 to require a State to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM; from one MCO, PHP or PCCM to another; or from an MCO, PHP or PCCM to fee-for-service. We believe this provision, plus the requirements in § 438.208 for (1) State identification of enrollees with special needs or at risk for special needs, and (2) MCO and PHP screening and assessments, respond to commenters' concerns that MCOs have the means to identify, in an expedient fashion, enrollees who require immediate attention, and provide needed services to such enrollees.

Comment: One commenter objected to the fact that proposed § 438.306(e)(3) required an MCO to implement and update a treatment plan. Specifically, the commenter suggested that requiring an MCO to implement a treatment plan for specific enrollees is not appropriate for such an administrative entity, as such plans should be developed and implemented only by a patient's physician or other health care professional.

Response: We agree with the commenter. Section 438.208(g) of the final rule with comment period, requires MCOs and PHPs to use appropriate health care professionals to perform comprehensive health assessments and to develop and implement treatment plans.

Comment: A commenter suggested that proposed § 438.306(e)(3) be revised to require the MCO to timely provide effective EPSDT screens and mandated EPSDT services.

Response: EPSDT screenings are required in current regulations. We believe it would be duplicative to restate those requirements in this final rule with comment period.

Comment: One commenter believed that proposed § 438.306(e)(3)(iii)(C) is unclear, and recommends that the final rule with comment period be changed to read "a treatment plan that specifies an adequate number of direct access visits to specialists as appropriate to the enrollee's condition." Further, the commenter suggests that we add the phrase "or, when required by the condition, the names of specialists to whom the enrollee shall have direct access for the duration of the treatment plan."

Response: We agree that the proposed language was unclear. We have revised the cited provision, which is now redesignated as § 438.208(f), to require MCOs and PHPs to implement a treatment plan that: (1) is appropriate to the enrollee's conditions and needs identified by screening and assessment, and (2) specifies either a standing referral or an adequate number of direct

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access visits to specialists. We expect that the treatment plan will specify the specialist(s) to whom the enrollee has direct access, but do not believe it necessary to require in regulations text that the treatment plan must specify the actual names of specialist to whom the enrollee shall have direct access for the duration of the treatment plan.

Comment: Several commenters expressed concern with proposed § 438.306(e)(3)(iii)(D). Commenters suggested that requiring physicians themselves to update a treatment plan is unrealistic and administratively burdensome. One commenter recommended that the final rule with comment period, be revised to permit the updating of a treatment plan by a specialist instead of a primary care provider.

Response: We agree on the need to allow for situations in which a specialist or other health care professional within an MCO or PHP assumes the responsibility for updating an enrollee's treatment plan. While we believe that a treatment plan should be developed in coordination with an enrollee's primary care provider, we recognize that MCOs or PHPs may permit professionals other than the enrollee's primary care provider to update the enrollee's treatment plan. Accordingly, in the final rule with comment period, § 438.208(g) requires MCOs and PHPs to use "appropriate health care professionals" to develop, implement, and update any required treatment plan.

Comment: We received a number of comments on proposed § 438.306(e)(4), which required that MCOs and PHPs ensure services are provided in a culturally competent manner, including at least meeting the language requirements of § 438.10. Overall, the majority of commenters supported this provision, but many suggested that we clarify the provision in the final rule with comment period. Several commenters requested that we define cultural competency and strengthen the regulation to require that MCOs include in their networks providers that have an understanding of enrollees' customs and traditions.

Commenters offered many recommendations. One commenter suggested specific language: "the MCO ensures that services are provided in a culturally competent manner to all enrollees, by providers with appropriate knowledge and skills to treat enrollees who are members of linguistic or ethnic minorities, and adults and children with special health care needs, including recipients with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs (for example, HIV/AIDS and homelessness)." Several other commenters recommended that we add requirements such as: (1) full attention by the MCO to racial and ethnic minorities, (2) interpreter services, including braille and sign language, (3) an appropriate number of caregivers properly trained in cultural competency, and (4) provider awareness of medical risk related to racial, ethnic, and socioeconomic factors. Finally, other commenters recommended that we: (1) mandate California's standards for cultural competency, (2) limit providers who are culturally aware to 5 percent or 200 in number to combat recruitment or other training burdens, (3) revise the rule to require that MCOs identify enrollees who belong to ethnic minority groups that may have special barriers in accessing care, and make continued efforts to improve accessibility, or (4) mandate that the National Committee for Quality Assurance (NCQA) require MCOs to collect ethnicity data to ensure quality so that appropriate educational, screening, and treatment programs can be developed.

Response: We do not believe it is appropriate to add all of the specificity suggested by the commenters, however we do agree that further strengthening and clarification is needed. As a result, we have added a provision at § 438.204 that requires States, as an element of their State quality strategies, to identify and provide MCOs and PHPs with information, on, the race, ethnicity, and primary language spoken by each Medicaid beneficiary at the time of their enrollment in an MCO or PHP. We will provide technical assistance to States on implementing these requirements. Our final rule with comment period also has been revised at § 438.206(e)(2) to require MCOs and PHPs to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds.

While we decline to add a definition of cultural competency in regulation text because the state of the art with respect to standards for cultural competency is still evolving. States should undertake efforts to further define cultural competency in their contracts and in standards for access to care under their quality assessment and performance improvement strategies. We offer the following statement as one that States may consider using in any definition of cultural competency: "Cultural competency in health care is a set of attitudes, skills, behaviors, and policies that enable organizations and individuals to work effectively in cross-cultural situations. It reflects an understanding of the importance of acquiring and using knowledge of the unique health-related beliefs, attitudes, practices, and communication patterns of beneficiaries and their families to improve services, enhance beneficiary understanding of programs, increase community participation, and eliminate disparities in health status among diverse population groups."

Comment: Several commenters believed that we needed to further clarify proposed § 438.306(e)(4) to ensure appropriate linguistic access. One commenter recommended that the comment period be strengthened to require, at a minimum, that MCOs and PHPs have a means of communicating during medical and administrative encounters.

Response: We agree that some clarification in the final rule with comment period is needed. As noted above, we have provided in § 438.206(e)(2) that MCOs and PHPs must provide services in a culturally competent manner to all enrollees, including those with limited English proficiency, and diverse cultural and ethnic backgrounds. Further, as noted above in section II.A., we require in § 438.10(b) that States and MCOs, PCCMs and PHPs make interperter services available to meet the needs of all enrollees. We believe that § 438.10(b) is sufficient to ensure that enrollees have means of communication during medical and administrative encounters.

5. Continuity and Coordination of Care (Proposed § 438.308)

Proposed § 438.308 set forth a series of requirements to ensure that a State require MCOs and PHPs to maintain continuity and coordination of care for its enrollees. Proposed § 438.308(a) required that MCOs and PHPs have in place written policies that provide each enrollee with an ongoing source of primary care appropriate to the enrollee's needs, as well as, formally designating a practitioner who is responsible for coordinating the enrollee's overall health care.

In proposed § 438.308(b), MCOs and PHPs were required to ensure coordination of services, both internally and with services available from the community.

Proposed § 438.308(c) required MCOs and PHPs and their providers to have the information necessary for effective and continuous patient care and quality improvement, including procedures to ensure that each provider maintains

health records that meet requirements established by the MCO or PHP, taking into account professional standards, and there is appropriate and confidential exchange of information among providers.

Proposed § 438.308(d) required procedures to ensure that providers inform enrollees of specific health conditions that require follow-up, and if appropriate, provide training in self care, and deal with factors that hinder enrollee compliance with prescribed treatment or regimens.

Comment: We received a number of comments urging that proposed § 438.308 address the continuation of an enrollee's ongoing treatment when transitioning to managed care. (Similar comments, discussed above, were also received on proposed § 438.306(e)). Although many commenters commended us for addressing the issue of continuity and coordination of care once a beneficiary has been enrolled in managed care, many also expressed concern that the proposed regulation did not highlight the need for identification and continuation of an enrollee's treatment when transitioning from fee-for-service into managed care or from one managed care organization to another. Several commenters stated that the interruption of treatment for only a short period of time could have serious and possibly irreversible consequences on a individual's health. Other commenters suggested that ongoing treatment without interruption was especially critical for persons suffering from mental illness, substance abuse, and chronic conditions such as HIV/AIDS.

A number of recommendations were offered. Some commenters recommended that we require continued coverage of ongoing treatment until a new care plan is established as a result of an initial assessment in the receiving MCO. Other commenters suggested that we define continuing treatment to include equipment, medical supplies, and prosthetic and orthotic appliances. Several commenters also recommended specific regulatory language that would permit an enrollee to continue to be covered for a course of treatment for a specified transition period. These commenters suggested that State agencies or the MCO or both be required to notify enrollees of the right to have treatment continued. In addition, the forwarding MCO should be required to share all medical files on a transferring enrollee with the receiving MCO.

Response: As noted above in this section, and as discussed more fully in section II. B., in response to the large number of comments on this issue, we have added to § 436.62 a new paragraph (b) that requires States to have a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service into a MCO, PHP or PCCM; from one MCO, PHP or PCCM to another MCO, PHP, or PCCM; or from an MCO, PHP, or PCCM to fee-for-service. We further have specified minimum requirements that the State transition mechanisms must address, and have identified specific population categories that State transition mechanism must cover.

Comment: Several commenters believed that proposed § 438.308 did not adequately address the issue of prior existing relationships. Commenters voiced concerns about the impact on enrollees when existing relationships have to be discontinued as a result of mandatory managed care programs, or as a result of providers leaving the network. These commenters specifically referenced populations with special health care needs and pregnant women as particular populations who would suffer an adverse impact. Some commenters recommended that pregnant women have the option to continue care with their OB/GYN until completion of post-partum care and others recommended that women who have already initiated prenatal care be exempted from the mandatory enrollment requirement. Other commenters focused their recommendations on other populations with special health care needs, with some recommending that we require MCOs to contract with providers currently serving Medicaid beneficiaries, and others requesting that we exempt populations with special health care needs from managed care entirely, particularly children with special health care needs.

Response: In section 1932(a)(2) of the Act, the Congress specifically exempted certain categories of children with special needs and Medicare eligible beneficiaries from mandatory enrollment under section 1932(a)(1) of the Act. Given the level of specificity in the statute, we believe that it would be inconsistent with Congressional intent to exempt additional categories of beneficiaries. With respect to the suggestion that MCOs be required to cover out-of-network services, once again the Congress has specified in detail those circumstances (e.g., post-stabilization services), for which an MCO is required to pay for out-of-network services or those circumstances (e.g., family planning services) for which an MCO cannot limit an enrollee to its network of providers. We do not believe that we would have authority to require MCOs to cover non-emergency services furnished by a provider with whom the MCO has no relationship. However, we understand the commenters' concerns that an existing relationship may be disrupted as a result of a beneficiary enrolling in managed care, and as discussed in the previous comment response, we believe we have addressed this problem in § 438.62(b). We wish to make clear that the requirements in § 438.62(b) are not intended to preempt State laws that require continuation of care outside the network.

Comment: We received numerous comments on proposed §§ 438.308(a)(1) and (a)(2). Several commenters argued that certain individuals with disabilities and other chronic conditions may require a specialist or other qualified and experienced practitioner as their primary care provider. Some commenters recommended that the final regulation explicitly provide for the designation of a specialist as the primary care provider in certain instances, such as for persons with complex and serious medical conditions. One commenter suggested that an MCO be required to refer chronic renal disease patients to a nephrologist for primary care services before a patient develops end stage renal disease. Another commenter suggested that we add language to allow residents, under supervision, to serve in the role of "continuing physician." Finally, one commenter recommended that primary care systems not be allowed as care managers for complex behavioral needs.

Response: We agree that there may be instances where a specialist would be an appropriate choice for a primary care provider, particularly for individuals with special health care needs. However, we decline to impose that degree of specificity in regulation because: (1) the existing evidence base regarding better health outcomes for individuals whose primary care provider is a specialist is limited; and (2) it is not possible at present to specify in this regulation all the decision rules to direct when a given individual must have a specialist as a primary care provider. We believe that States, MCOs, and PHPs have sufficient flexibility under the final rule with comment period to permit specialists or other experienced providers to serve as primary care providers, as appropriate.

We also do not believe that it is appropriate to revise this final rule with comment period, to prohibit primary care systems from acting as care managers for persons with complex

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behavioral needs. Again, States have the flexibility to decide the appropriate specifications to impose on MCOs and PHPs regarding the types of primary care providers, depending on the nature of the managed care program in the State and the population being served.

Comment: One commenter recommended that we revise proposed §§ 438.308(a)(1) and (a)(2) to allow an MCO or enrollee to designate a medical group or provider entity, instead of an individual, for primary care and overall coordination.

Response: We agree that the MCO should have the flexibility to include medical groups and other provider entities as sources of primary care and overall coordination. Our intent in drafting the proposed rule was to ensure that enrollees have an ongoing source of primary care and a designated person or entity responsible for coordinating their health care. Section 438.208(h) in the final rule with comment period, now requires the State to ensure that each MCO and each PHP: (1) provide each enrollee with an ongoing source of primary care appropriate to his or her needs; and (2) have a mechanism to identify the person or entity formally designated as primarily responsible for coordinating the enrollee's health care. While we thus have added flexibility to designate a medical group or entity as the primary care source, we urge MCOs and PHPs to make every effort to promote a relationship between an enrollee and a single primary care provider.

Comment: Several commenters requested that we clarify whether we are proposing a "case-manager" or "point-of-entry" care coordination model in proposed § 438.308(a). One of these commenters stated that under either model, the entity must be intimately familiar with the varied needs of the enrollee, and stressed that appropriate safeguards must be in place to ensure effective coordination among care providers. One commenter specifically recommended that we modify the proposed rule to indicate that, based on the initial assessment under proposed § 438.306(e)(2), the type of care coordination for each enrollee be determined by an analysis of individual need.

Response: Our intent was not to propose a "case-manager," "point-of-entry," or any other particular model of care coordination. Rather, our intent was to ensure that MCOs and PHPs, regardless of the model of care coordination, make every effort to promote a relationship between the enrollee and the primary care provider source. We recognize that some MCOs and PHPs might have systems of care coordination under which a person or entity, other than the enrollee's primary care provider, coordinates services. We believe that our revised language in § 438.208(h) better reflects our intent.

With respect to the specific comment that the type of care coordination for each enrollee be determined by an analysis of individual need, we believe that the comprehensive assessment, treatment plan, and coordination program requirements in § 438.208 sufficiently address this issue.

Comment: A commenter found proposed § 438.308(a)(1) unclear, and thought that it could be interpreted to mean that an MCO must provide each enrollee with a primary care provider, and allow self-referral to a specialist on an as-needed basis. This commenter recommended that we delete this provision because, as the commenter interpreted it, it was unworkable in a managed care environment.

Response: We have clarified our final rule with comment period so that each MCO and each PHP must provide an enrollee with an ongoing source of primary care appropriate to his or her needs, and have a mechanism to identify the person or entity who is formally designated as primarily responsible for coordinating the enrollee's health care. We believe that this language is clear and cannot be interpreted to allow self-referral to a specialist.

Comment: We received several comments supporting the proposed provision in § 438.308(b), which requires an MCO to ensure coordination of services internally and with services available from community organizations and other social programs. Many of these commenters requested that we expand the coordination of services list. In contrast, several other commenters stated that they felt that the proposed regulation was unclear and questioned whether it was practical for an MCO to serve as a gatekeeper for non-medical services. Some commenters questioned our authority in proposing this provision, with a few stating that this provision was a major expansion of State and MCO responsibility. Several of these commenters indicated that this provision would be difficult for States to monitor, and recommended either that we clarify the regulatory language or delete the provision entirely. In addition, one commenter referenced the cost-effectiveness test under 1915(b) of the Act waiver programs, noting that such a test is based on a comparison to historic fee-for-service costs that does not include costs associated with coordinating services with other social programs.

Response: We agree that the extent to which an MCO can coordinate all health and health-related services that are needed by an individual enrollee is variable, and that effective approaches to care coordination has not been well addressed to date by health services research. MCO responsibility for care coordination can range from: (1) coordination of all Medicaid services included in the contract between the MCO and the State; (2) coordination of all Medicaid services regardless of whether they are included in the MCO's contract with the State; and (3) coordination of all health, social, educational, and other services needed to maintain optimal health of an enrollee. Determining the appropriate level of responsibility for the MCO for care coordination is complex. The ability of the MCO to coordinate care is determined, in part, by the authority the MCO has to coordinate care provided by entities not a part of the MCO and by the MCO's available resources. Further, social or community organizations external to the MCO may not desire the MCO to coordinate care out of concern that care will be "medicalized" or that the authority of other agencies for care coordination will be weakened.

Since these are complex issues, we encourage all State Medicaid agencies to work with beneficiaries, MCOs and PHPs and other stakeholders in their State to determine the appropriate responsibilities of MCOs and PHPs in the State for care coordination. We accordingly have, in response to the above comments, deleted the requirement in proposed § 438.308(a)(2) that MCOs and PHPs coordinate services available from community organizations and social programs. We note, however, that an MCO or PHP may still have responsibilities for coordination that exist under fee-for-service Medicaid. Under § 431.615, State Medicaid agencies are required to establish, as part of their State plan, "arrangements" with State health and vocational rehabilitation agencies and Title V grantees. These arrangements must include coordinating plans for health services provided or arranged for recipients. In addition, similar arrangements are required under § 431.620, between a State Medicaid agency and State mental health authority or mental institutions. Section 431.635 also outlines requirements for the coordination of Medicaid with Special Supplemental Food Programs for Women, Infants, and Children (WIC). While these requirements are imposed on States, we believe that States may delegate some of these coordination responsibilities to MCOs and PHPs. To the extent that these responsibilities are delegated, MCOs and PHPs must ensure coordination of health-related services with community and other social groups. This is now a State option, however.

In response to comments, § 438.208(h) of the final rule with comment period, thus requires that: "Each MCO and PHP must implement a coordination program that: (1) Meets the requirements specified by the State; (2) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee; (3) Coordinates the services it furnishes to enrollees with the services the enrollee receives from any other MCOs and PHPs; (4) Ensures that the results of its screen or assessment of an enrollee (or both, if the MCO or PHP performs both) are shared with other entities serving the enrollee, so that those entities need not duplicate the MCO's or PHP's screening or assessment or both; (5) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224; (6) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers; (7) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens; and (8) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242. We are further requiring in § 438.10(d)(2)(i)(C) that the scope of MCO and PHP coordination be disclosed to potential enrollees by adding "MCO and PHP responsibilities for coordination of enrollee care" as an additional type of information that must be provided to potential enrollees.

Comment: Several commenters suggested that proposed § 438.308(b) would not achieve continuity and coordination of services if an MCO contract does not cover all medically necessary services included in a State plan. These commenters believed that an MCO should take responsibility for coordinating all Medicaid services that are not part of its contract. One commenter requested that we clarify whether a State may determine that a State entity, local organization, or community organization is more appropriate to fulfill the coordination role. As an alternative, the commenter recommends that we revise the final rule with comment period to state, "With the permission of the enrollee, or when consistent with the State's confidentiality laws, the MCO must provide that its providers release information concerning the enrollee's medical treatment to community organizations and other social programs when so requested by such organizations or programs."

Response: Consistent with our response to the prior comment, and with our revisions to this section, we do not believe that § 438.208(h) prevents a State Medicaid agency from delegating the responsibility for coordinating health-related services to entities other than the MCO or PHP, such as other State and local organizations. Under the final rule at with comment period, § 438.208(h), States have the discretion to contract with MCOs and PHPs to provide a specific set of services that may not include all services covered under a Medicaid State plan. In a situation where the State has assumed a coordination function or delegated it to an entity other than the MCO or PHP, the MCO or PHP must still coordinate care and services to the extent and manner specified by the State and ensure that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

Comment: We received several comments on proposed § 438.308(c)(2), which would require an appropriate and confidential exchange of information among providers. One commenter indicated that he or she was pleased to see the importance of confidentiality stressed. However, several comments suggested that proposed § 438.308(c)(2) lacked specificity about what information should and should not be shared between primary care and behavioral health providers. Several of these commenters recommended that enrollees be provided informed consent before information is shared. One commenter specifically noted that existing confidentiality requirements, especially those related to substance abuse treatment, severely limit the practitioner's ability to exchange treatment information. Another commenter stated that it is difficult to know what proposed § 438.308(c)(2) means without a definition of the term "confidential." This commenter recommended that we reference applicable State law in the final rule with comment period.

Response: Our intent in drafting this provision was to ensure that MCOs and PHPs and their providers have the information necessary for effective and continuous patient care and quality improvement. In proposed § 438.308(c), we referenced the need for providers to maintain health records consistent with the requirements established by MCOs and PHPs, taking into account professional standards. In proposed § 438.308(c)(2), we also referenced the need for confidential exchange of information among providers. Both of these requirements were included in an effort to reinforce the confidentiality requirements in proposed § 438.324. We did not intend that the proposed rule be interpreted to require informed consent or to supersede relevant State law governing the exchange of information between providers.

We decided to revise the requirement to provide further clarification and to avoid confusion over the interface of this provision with § 438.224. Accordingly, § 438.208(h)(7) of the final rule with comment period, specifies that each MCO and PHP must ensure that its providers have the information necessary for effective and continuous patient care and quality improvement "consistent with the confidentiality and accuracy requirements of § 438.224 and the information requirements of § 438.242". In addition, at § 438.208(h)(4), we require that MCOs and PHPs have coordination programs that ensure that each enrollee's privacy is protected consistent with the requirements of § 438.224. Based on these revisions, we believe that there is no need to define the term "confidential."

Comment: We received several comments in support of proposed § 438.308(d), which would require MCOs and PHPs to have procedures in place to ensure that providers: (1) Inform enrollees of specific conditions that require follow-up and, if appropriate, provide training in self-care, and (2) deal with factors that hinder enrollee compliance with prescribed treatments or regimens. One commenter noted that the proposed rule recognizes the value of disease management programs. Another commenter supported the rule but felt that we should further clarify it to ensure that MCOs take responsibility to educate patients as to when they may go to emergency rooms. Another commenter asked that we recognize that there are limits on self-care requirements due to the nature of an enrollee's disability.

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Other commenters objected to the proposed rule. One commenter opined that self-care cannot be legislated. This commenter believed that by making this a compliance issue, we were exceeding her authority. Another commenter felt that this provision was not practical and would lead to increased administrative costs.

Response: We continue to believe in the value of providing information and training on conditions that may improve with self-care, and encourage MCOs to provide for this. However, we are persuaded by commenters that some of the conceptual language on "specific health conditions that require follow-up" and "if appropriate, provide training in self-care" are unclear and subjective. We note that potentially all health conditions that require a visit to a health care practitioner require some degree of "follow-up." Accordingly, in § 438.208(h)(6) of the final rule with comment period, we only require that MCOs and PHPs have in effect procedures to "address factors (such as lack of transportation) that hinder enrollee adherence to prescribed treatment regimens."

With regard to the comment that MCOs and PHPs should have the responsibility to educate beneficiaries on the proper use of the emergency room, we encourage MCOs and PHPs to undertake this type of education. However, any training effort must be consistent with the emergency services requirements in § 438.114.

6. Coverage and Authorization of Services (Proposed § 438.310)

Proposed § 438.310 set forth requirements to ensure that each contract with an MCO or PHP identify all services offered under the contract and follow written policies and procedures for processing requests for services in a manner that ensures access to these services. Further, the proposed requirements would ensure that utilization management activities are not structured in a manner that is detrimental to enrollees. These standards implement section 1932(b)(1) of the Act, and to the extent appropriate and applicable, are consistent with Medicare+Choice regulations at § 422.112.

In paragraph § 438.310(a) we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO or PHP identifies, defines, and specifies the amount, duration, and scope of all Medicaid benefits that the MCO or PHP must furnish. Furthermore, the contract must specify what constitutes medically necessary services to the extent they are described in the State plan, and provide that the MCO or PHP furnishes the services in accordance with that provision. We believe these requirements are essential, as it is a concern that an MCO's or PHP's authorization procedures, if unduly burdensome, can prevent an enrollee from having access to, or receiving services to which they are entitled under the State plan. In addition to serving as a protection for enrollees, these requirements support the provider's needs and desires to know what is required for authorization determinations.

In § 438.310(b) we proposed to require that, in processing requests for initial or continuing authorization of services, the MCO or PHP and its subcontractors: (1) follow written policies and procedures that reflect current standards of medical practice; (2) specify the information required for authorization decisions; (3) have in effect mechanisms to ensure consistent application of review criteria; (4) consult with the requesting provider when appropriate; and (5) observe time frames specified in paragraph (d) of proposed § 438.310.

In paragraph (c), we proposed that MCO and PHP contracts be required to provide that written notice be provided, within the time frames in paragraph (d), of decisions to "deny, limit, reduce, delay, or terminate" services, including specific reasons for the decision, along with information on the enrollees right to file a grievance or request a State Fair Hearing.

In paragraph (d), we proposed that contracts be required to specify that services will be provided as expeditiously as the enrollee's health condition requires, and within State-established time frames not to exceed 14 days in ordinary cases, and 72 hours if a further delay could "seriously jeopardize the enrollee's life or health or ability to regain maximum function.

In paragraph (e) we required that each MCO and PHP contract must provide that, consistent with § 438.6(g) and § 422.208, compensation to individuals or entities that conduct utilization management activities is not to provide incentives to deny, limit or discontinue medically necessary services.

Comment: Numerous commenters expressed the view that proposed § 438.310(a)(1) would be difficult to implement. These commenters felt that while a general description of categories of core benefits and service limitations seemed reasonable, the requirement to include the amount, duration, and scope of each service in the contract was not reasonable, and would make the contract too extensive to manage; create unintended exclusions; not allow for consideration of patient specific needs; and require frequent contract amendments to keep current. They also urged that States have the flexibility to determine the level of detail to include in contracts, and believed that the requirements in proposed § 438.310 went beyond legislative intent. Commenters recommended that the contract identify, define, and specify each service that must be offered, but that the amount, duration, and scope be defined in a State Plan or other document. In contrast to the commenters who were opposed to the provision, several commenters supported the proposed provision, stating that it was essential that contracts make clear the services that an MCO must offer to ensure that the enrollee receives the services that they are entitled to under the State Plan. Commenters who supported the provision did not distinguish between the requirement to identify the services and the requirement to include the amount, duration, and scope of each service.

Response: The intent behind this provision was to ensure that enrollees receive the services that they are entitled to receive under the State plan, regardless of the MCO or PHP that they elect, with the recognition that some MCOs and PHPs may not directly provide some services, in which case the State must arrange for these services. While we acknowledge the difficulties that were raised concerning implementing this provision as proposed, we also agree with commenters who stated that it was essential that the contract make clear the services an MCO or PHP is to offer. Any limitations in amount, duration and scope are important features of benefit coverage. Failure to address them in a contract creates the potential for confusion between the State and MCO or PHP and thereby the possibility that an enrollee may not have timely access to service to which he or she is entitled. Because of these concerns, the final rule with comment period at § 438.210 still requires that the amount, duration, and scope of services be specified, now on the basis of what is contained in the State Plan. It further requires that the amount, duration, and scope be such as can reasonably be expected to achieve the purposes for which the services are furnished. However, we also note that if an MCO or PHP does not cover a particular service, the State must make arrangements to ensure that enrollees are able to receive all services covered under the State plan.

Comment: One commenter believed that proposed § 438.310(a)(1) gives the impression that States and MCOs may negotiate away existing Federal requirements governing coverage determinations in the Medicaid program. Specifically, the commenter pointed out that existing regulations for fee-for-service at § 440.230 require that services be provided in sufficient amount, duration, and scope "to reasonably achieve its purpose." It further prohibits States from arbitrarily denying or reducing the amount, duration, or scope of such services solely on the basis of diagnosis, type of illness, or condition. Although State agencies may place limits on a service, limitations much be based on appropriate criteria such as "medical necessity" or on utilization control procedures. The commenter was concerned that § 438.310(a)(1) could be read to undermine these requirements by implying discretion to define amount, duration, and scope in contracts in a manner negotiated between the State and MCO or PHP.

Response: We agree with the commenter that the provisions at § 440.230 should also apply to a managed care arrangement, and we accordingly have included them in § 438.210 of the final rule with comment period in response to this comment. In addition, we have clarified that services limited for the purpose of utilization control must still be provided in sufficient amount, duration, and scope to reasonably achieve the purpose for which they are furnished.

Comment: One commenter suggested that benefits and services referenced in § 438.310(a)(1) include all Federally mandated benefits and services, including nurse-midwifery services.

Response: Federal law allows States to "carve-out" specific Medicaid services from contracts with MCOs and PHPs, and offer them on a fee-for-service basis or through a separate managed care contractor. For this reason, proposed § 438.310(a)(1) was not intended to govern what services are to be included in or covered by an MCO or PHP contract, but to require that, for those services that are included in or covered by the contract, that the contract identify, define and specify those services. Therefore, we are not requiring in the final rule with comment period that each MCO and PHP contract include all Federally mandated benefits and services, including nurse-midwifery services.

Comment: Many commenters suggested the regulation mandate a definition of medical necessity for States to use in their managed care contracts, or more specific guidance regarding the definition. Commenters presented a range of reasons for including a standard definition, including the need for consumers and providers to understand the scope and limits of health care benefits, ensuring enrollees are not denied services to which they are entitled, avoiding disputes between States and MCOs or PHPs and providers, eliminating State variances in the definition, curbing future lawsuits, and improving the incentive for managed care plans to compete based on innovative quality improvements, rather than restrictive authorizations.

Several different definitions were suggested by different commenters. Some of the recommendations suggested that the definition reflect maintenance of functioning, prevention of deterioration, optimum participation in community living, consideration of the differences between children and adults (especially age-appropriate services and the developmental, rather than rehabilitative, nature of some services for children), and should specifically address mental health needs.

Other commenters found the provision regarding medical necessity too prescriptive and believed that medical issues should not be resolved through a regulation or contracting process.

Response: We disagree that the provision is too prescriptive. States have existing medical necessity specifications in Medicaid fee-for-service programs and individuals enrolled in managed care are entitled to the same services as all other Medicaid eligible persons in the State. Clear specifications of medical necessity in the contract are critical in determining what a State is paying MCOs and PHPs to provide and, in some cases, what the State is providing outside the managed care setting for all parties in the program. The application of State specifications in individual situations allows for medical judgement.

However, we also do not agree that a definition of medical necessity should be included in the regulations. There currently exists no widely-accepted national definition, and at present States currently are allowed under § 440.230(d) to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures," and have great flexibility in defining that criteria. Therefore, we do not believe it is appropriate to promulgate a national definition at this time. However, we believe that more specific guidance regarding State contract specifications is needed. In particular we believe that medical necessity criteria used by Medicaid MCOs and PHPs should not be more restrictive than the State Medicaid medical necessity criteria used in the State's Medicaid program overall, and that this be evident to all parties, thus decreasing the potential for disputes.

Therefore, we have revised the regulation to require that the specifications of medical necessity in the contract must be no more restrictive than any such specifications in the State Medicaid fee-for-service program, described in State statute, regulations, State plan, or other policy or procedures. This addition of "State statute, regulations or other policy or procedures" provides greater specificity than the sole reference to "State plan." found in the proposed rule. We further agree that the contract should be clear about what the State's specifications are with respect to medical necessity criteria. Therefore, we have added provisions requiring that the contract address the extent to which the MCO or PHP is responsible for covering medically necessary services to: (1) prevent, diagnose, and treat health impairments; (2) enable the enrollee to achieve age-appropriate growth and development; and (3) attain, maintain or regain functional capacity. While we are not mandating that services must be covered to meet these goals, the contract must clearly address the extent of each MCO's and PHP's responsibility to provide such services. This provision will promote greater consistency of medical necessity specifications across MCOs and PHPs within a State. We believe that services to meet mental health needs are understood to be under the purview of these specifications without specific mention.

We believe this revised regulatory provision, in conjunction with other provisions in this regulation, will meet commenters' concerns regarding beneficiary understanding as well. Section 438.10 requires that information regarding the kinds of benefits, and amount, duration and scope of benefits available under the contract must be provided to enrollees or potential enrollees upon request. This provision should improve the understanding of beneficiaries so they are not denied services to which they are entitled. This section also requires the provision of information regarding grievance, appeal and fair hearing procedures to assure that beneficiaries understand their ability to dispute decisions made by MCOs and PHPs.

We anticipate that greater specificity in MCO and PHP contracts will reduce the potential for MCOs and PHPs to

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develop specifications of medical necessity inconsistent with those developed by the State Medicaid agency. However, it must be noted that medical necessity relates to determinations regarding specific care given to a specific patient with specific medical condition under certain circumstances and is thus more focused on individual situations. Some potential for dispute is inherent in such decisions.

Comment: Many commenters indicated that the regulation should recognize the special status of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) provisions, and provide specific reference to them under the medical necessity provision.

Response: This regulation does not affect any of the pre-existing EPSDT regulations. Further, some EPSDT services may be provided by the State outside of the managed care contract. We believe it is redundant and unnecessary to repeat all existing requirements in this regulation, which focuses on managed care programs. For this reason, we have not included any specific reference to EPSDT in the provisions on medical necessity.

Comment: Some commenters found that the proposed regulation gave the impression that the States and MCOs may negotiate away the Federal legal requirements governing coverage determinations in the Medicaid program. Comments suggested that the regulations ensure that States include in managed care contracts a definition of medical necessity consistent with Federal law.

Response: The provision addressing medical necessity in no way affects any other Federal requirements governing coverage determination in the Medicaid program. All parties must adhere to all other Federal statutes and regulations. However, we believe it would be redundant to repeat all such requirements in this regulation.

Comment: Commenters urged that we review and approve definitions of medical necessity before approving managed care contracts.

Response: Section 438.6 of this final rule with comment period requires us to review and approve MCO and PHP contracts. As part of that review, we will assure that regulatory requirements at § 438.210 pertaining to MCO and PHP contract provisions on medical necessity are met. While these provisions are not a definition of medical necessity, they will promote greater shared understanding by MCOs, and PHPs and beneficiaries about how medical necessity is determined.

Comment: One commenter asserted that ongoing monitoring by us is essential to ensure that States or MCOs do not define medical necessity so narrowly that they deprive beneficiaries of services to which they are entitled under Medicaid.

Response: We agree that ongoing monitoring of managed care programs is important. We utilize a variety of mechanisms to monitor State contracts and State Medicaid managed care initiatives. These mechanisms include: data reviews, State and MCO on-site reviews, and input from beneficiaries, advocates and providers. Furthermore, other provisions in this regulation, such as § 438.204(d) (which requires external reviews of the timeliness of and access to services covered under each MCO and PHP contract), provide significant additional information to assist us and States in monitoring.

Comment: One commenter believed that each State operating a Medicaid managed health care plan that includes children should be required to consult with the State agency that is responsible for overseeing the delivery of early childhood intervention services (under Paragraph B and C of Individuals with Disabilities Education Act) to ensure that the plan includes adequate provisions for coordination of health and early intervention services to such youngsters.

Response: We strongly support coordination between appropriate State agencies. In § 438.202, we require States to provide for the input of recipients and other stakeholders in the development of the State strategy for quality assessment and performance improvement. We consider other State agencies such as State Mental Health and Substance Abuse agencies, Title V Maternal and Child Health agencies, and IDEA agencies as stakeholders who should have input into the development of the strategy.

Comment: We received comments urging that there be no gaps in Medicaid services. A major problem, in the view of these commenters, is that States often are unaware of their responsibility to fill gaps left in the case of services not provided through an MCO or PHP.

Response: We agree that all needed Medicaid covered services must be furnished. In the final rule with comment period—

Section 438.210 requires that the contract identify, define, and specify services that the MCO or PHP is required to offer; and

Section 438.206 specifies if an MCO or PHP contract does not cover all of the services in the State plan, the State must make those services available from other sources and give enrollees information on how and where to obtain them, including how transportation is provided.

In determining whether services should be provided in individual cases, fair hearing officers are bound by their interpretation of the State's overall Medicaid program coverage criteria, and must apply these criteria rather than specific coverage criteria in the contract if the hearing officer determines that the contract criteria are inconsistent with State criteria. The State retains overall responsibility for covering all services in accordance with the Medicaid State plan and implementing policies and procedures, regardless of whether some or all of these services may have been contracted to an MCO or PHP.

Comment: Commenters expressed divergent views on the basis for medical necessity determinations, including preferences for evidence-based standards, professional standards, generally accepted standards of medicine, or deference to the recommendation by the treating professional. Some voiced concern that the evidence-based standard for determining which services are medically necessary would limit obligations to services deemed effective based on quantitative or scientific studies. Quantitative evidence of efficacy does not always exist with respect to persons with developmental disabilities or other special populations who have not been involved in studies. On the other hand, some commenters felt the professional standard of review was inappropriate because of disputes among professionals.

Response: Because of the variable evidence base for the efficacy of the multitude of therapeutic interventions possible for any population, and the lack of consensus regarding the best approach to medical necessity determinations (as evidenced by the comments received) we do not mandate a single approach for determining medical necessity. States have great flexibility in establishing this standard, which is applicable in both fee-for-service and managed care.

Comment: Commenters indicated that MCO subcontracts should be required to include the same "medical necessity" definition, as well as EPSDT requirements and access standards, and the clear description of benefits that are contained in contracts between the State and MCOs.

Response: MCOs and PHPs are responsible for assuring that services are provided in accordance with their contract with the State, regardless of any subcontracts in place. MCOs and PHPs may delegate activities, but not responsibility, for contract provisions. Section 438.230(a)(1) requires the State to ensure that each MCO or PHP oversees and is accountable for functions delegated to subcontractors. States must monitor this process on an ongoing basis and insure the development of corrective action plans, where necessary.

Comment: A commenter believed that all coverage decisions made by the MCO should be consistent with current standards of medical practice.

Response: Section 438.210(b)(1) of the final rule with comment period, requires that the MCO or PHP and its subcontractors follow written policies and procedures that reflect current standards of medical practice in processing requests for initial and continuing authorization of services.

Comment: A commenter was concerned that proposed § 438.310(b)(1) could be interpreted to require a written authorization for every authorization decision. The commenter felt that while this may be possible for many courses of treatment, it was not universally possible.

Response: Section 438.210(b)(1) of the final rule with comment period requires MCOs and PHPs to follow written policies and procedures that reflect current standards of medical practice. The provision applies to the authorization process in general, not each determination. The intent is to ensure that actual determinations are consistent and made in accordance with policies and procedures that reflect current standards of medical practice.

Comment: Some commenters noted that a stated intent of the service request processing requirements in proposed § 438.310(b) was to ensure that the authorization process was not unduly burdensome for providers. These commenters believed that this objective would be better achieved by a more general requirement that the MCO's process be reasonable, rather than by asking States and MCOs to establish specific requirements in their contracts. They felt the requirements were too detailed for a contract, and that the level of specificity was not called for under the BBA. Commenters were most opposed to the requirement that each contract specify the information required for authorization decisions. In contrast, one commenter believed that there should be more specificity than we proposed, especially in the area of routine authorization decisions.

Response: The reason for proposed § 438.310(b) was that there is concern that the authorization process itself could be one of the reasons enrollees do not receive services to which they are entitled under the State plan. We want to ensure that the authorization procedure itself does not prevent enrollees from receiving services that they are entitled to receive under the State plan, and that the MCO's or PHP's information requirements do not place undue burden on the provider or the enrollee. To make explicit our intent that the authorization process not be unduly burdensome for providers or enrollees, in response to the above comments, we have expressly stated this in § 438.210(b)(2)(i) of this final rule with comment period.

Comment: One commenter believed that the requirement for consistent application of review criteria should be eliminated because in this commenter's view it would require health plans to establish another complicated audit process. The commenter felt that the inconsistencies that this provision addresses would be picked up by existing audit procedures.

Response: We believe that consistent application of review criteria is essential in assuring beneficiaries' access to care. Therefore, at § 438.210(b)(2) we retain the requirement that MCOs and PHPs have mechanisms in effect to ensure consistent application of review criteria for authorization decisions. Whether a mechanism is acceptable, as well as how a mechanism is defined, is not dictated in the regulations, but left up to the discretion of the State and the MCO or PHP.

Comment: One commenter felt that it was important to establish a structure that would assure that MCOs' authorization procedures are evaluated on a periodic basis, with the input of practice managers.

Response: Since the requirements of § 438.210 are part of MCO and PHP contract requirements for access to care, States are responsible for ensuring compliance with service authorization requirements as part of their overall quality strategy, as set forth in § 438.202 (State Responsibilities) and § 438.204 (Elements of State Quality Strategies). MCOs and PHPs are also required by § 438.240 to have an ongoing quality assessment and performance improvement program that has in effect mechanisms to detect both underutilization and overutilization of services. In light of the above requirements, we do not believe it is additionally necessary to require in this rule that authorization procedures separately be evaluated on a periodic basis with the input of practice managers.

Comment: One commenter recommended that the regulation require that initial coverage decisions that alter the request of the provider in any way be made, and certified, by a licensed medical doctor. The commenter also urged that initial coverage decisions mirror the requirement in the grievance process (proposed § 438.406(d)) that the review of a denial based on medical necessity be conducted by a "provider with appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease."

Response: We agree, in part, with these comments. While we agree that individuals who make initial coverage decisions should be health professionals who have appropriate clinical expertise, we note that relevant expertise may be possessed by health care professionals who are not always physicians. Dentists, psychologists and certified addiction therapists are examples of health professional who are not physicians, but who may have appropriate clinical expertise. Therefore, in response to the above comments, we have provided in § 438.210(b)(3) of the final rule with comment, that any decision to deny or limit a service must be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

Comment: Commenters contended that the requirement in proposed § 438.310(c) that a written notice be sent to the provider for all authorization decisions not fully approved as requested is not current practice for commercial MCO contracts.

Response: We believe that the provider should be notified of all MCO and PHP service authorization decisions that are not fully approved as requested. In § 438.210(c) of the final rule with comment period, we have removed the requirement that this notice be in writing to ease the burden on MCOs and PHPs.

Comment: Numerous commenters had difficulty distinguishing between the requirements at §§ 438.310(c) and (d) pertaining to a notice of adverse action and the time frames for such action, and those in § 438.404 requiring an MCO to give notice of intended action when an MCO intends to deny, limit, reduce, delay or terminate a service or deny payment for a service. There were other comments on these provisions.

Response: We agree that, in the proposed rule, the distinction between proposed §§ 438.310(c) and (d) and proposed § 438.404 was not clear. In the final rule with comment period, § 438.210(c) requires only that the notice of adverse action meet the requirements of § 438.404, and paragraphs (d) and (e) set forth only the

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time frames for standard and for expedited authorization decisions, respectively. For further clarity, we note that the distinction between proposed § 438.310 and § 438.404 is drawn at the point the authorization decision is made. If the decision is authorized outright, there is no link to § 438.404; however, if the decision is made to deny or limit a service, notice must be given in accordance with § 438.404, as these decisions are subject to the grievance and appeal process.

Comment: Some commenters were opposed to proposed § 438.310(d) which specified the time frames for providing services. They did not believe it was reasonable to expect services to be provided within the specified time frames. Several commenters suggested that the time frames be consistent for both the Medicaid and the Medicare programs, since providers participate in both programs.

Response: There was an unintended ambiguity in proposed § 438.310(d). The time frames were intended to apply to authorization of services, not furnishing of services. The final rule with comment period, at § 438.210(d) and (e), makes clear that the time frames are applicable to standard and expedited authorizations. The time frames are necessary to ensure that the appeal time frames can be met when an authorization is not approved. In general, the time frames are consistent with those in Medicare.

Comment: In addition to comments interpreting the time frames in proposed § 438.310(d) to apply to the furnishing, rather than the authorization of services, there were comments that understood § 438.310(d) to apply to authorizations, but found 14 calendar days insufficient for a routine authorization if all of the supporting documentation was not present. The commenters recommended that the 14 days should begin after all of the supporting information is received.

Response: The time frame in proposed § 438.310(d) and § 438.210(d) of this final rule with comment period, allows for an extension of up to an additional 14 days if the enrollee or the provider requests extension, or the MCO or PHP justifies to the State agency that additional information is needed and that the extension is in the enrollee's interest.

Comment: Numerous commenters questioned whether enrollees were adequately protected by the provision in § 438.310(d)(2) requiring authorization to be made no later than 3 working days after receipt of the request for service (with a possible extension of up to 14 additional calendar days) if the ordinary 14 day time frame could seriously jeopardize the enrollees' life or health or ability to regain maximum function. The commenters felt that each case is unique, and that in some cases, immediate authorization is necessary, and in others, 24 hours, etc. A standing minimum of 3 working days, with an extension of 14 days possible, was not acceptable to these commenters. One commenter believed that 14 days was excessive for an ordinary authorization that could be completed in a much shorter time.

Response: We recognize that there may be situations in which 72 hours, or the additional 14 days, would be detrimental to the enrollee's health. Under § 438.210(e) of the final rule with comment period, the time frame for an expedited authorization decision is "as expeditiously as the enrollee's health condition requires" and in the case of a decision that denies or limits services, early enough to permit the MCO or PHP to process an appeal within 72 hours after receipt of the request for service. The time frames are provided as minimum requirements, but we expect States, MCOs and PHPs to consider the enrollee's health concern as the foremost deciding factor.

Comment: A commenter suggested that we revise § 438.310(d) to allow the provider, rather than just the enrollee, to request extensions in service authorization time frames. As justification, the commenter said that the time required for the provider to arrange for the enrollee to request an extension may force an MCO to deny services that would otherwise be approved, if the provider had time to submit additional documentation.

Response: We agree with the commenter, and in the final rule with comment period, have provided that the provider, acting on behalf of the enrollee, as well as the enrollee may request extension for a standard authorization decision, but only the enrollee may request extension for an expedited decision.

Comment: A commenter indicated that in § 438.310(d), as well as others in the subsection, the reference to "physician" should be deleted and "attending provider" should be inserted. The rationale for this recommendation was that the language should more accurately reflect the full range of qualified health professionals.

Response: We agree and have replaced the term "physician" with "provider."

Comment: Two commenters offered their support for the requirement in proposed § 438.310(e) that compensation to utilization review entities not be structured so as to provide incentives to deny, limit, or discontinue medically necessary services.

Response: We have retained this provision as § 438.210(f) of this final rule with comment period.

Comment: Several commenters encouraged us to avoid duplication in the regulation.

Response: We agree, and have attempted to avoid unnecessary duplication in this final rule with comment period. For example, we have eliminated duplication of information requirements that in the NPRM appeared both in proposed § 438.10 and proposed § 438.318.

7. Establishment of Provider Networks (Proposed § 438.314)

Proposed § 438.314 placed requirements on State Medicaid agencies to ensure that contracted MCOs and PHPs have written policies and procedures for the selection and retention of providers. This proposed section required States to ensure that such policies include requirements for initial provider credentialing and recredentialing in accordance with time frames set by the State, but not less frequently than what the State requires for private HMOs.

Comment: Many commenters believed that proposed § 438.314 was too prescriptive. Some commenters interpreted the proposed rule as extending credentialing requirements to providers who perform services under the supervision of physicians, and argued that these requirements generally should only apply to physicians. These commenters expressed the view that requiring credentialing of a broader range of providers adds no value. There were a number of recommended credentialing approaches ranging from adoption of the NCQA credentialing criteria, the American Medical Association's credentialing process, and Medicare policy.

Response: We reexamined the proposed rule in light of these comments and in response to these comments, have made several clarifications to the final rule with comment period. We believe these changes will address most of the commenters' overriding concerns about ambiguity as to who will be subject to credentialing requirements. The final rule with comment period at § 438.214(b) now includes provisions on credentialing that were intended, but not explicit in the proposed rule. Specifically, in § 438.214(b) we now clarify which providers are subject to credentialling and recredentialling requirements, distinguishing in § 438.214(b)(1) requirements that must be met by physicians and other licensed, independent providers from requirements in § 438.214(b)(2) that must be met by other providers. Exceptions to these requirements are described in § 438.214(b)(3). These exceptions apply to providers who are permitted to furnish services only under the direct supervision of a physician or other provider, and for hospital-based health care professionals (such as emergency room physicians, anesthesiologists, and certified registered nurse anesthetists) who provide services only incidental to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

We did not adopt the NCQA standards as suggested by commenters. While our requirements are not identical to the NCQA standards, they have much in common. For example, the exceptions to credentialing outlined above are the same as the exceptions under the NCQA standards. The AMA credentialling process no longer exists.

Comment: One commenter recommended that board certification be dropped as a credentialing criterion.

Response: No change was required in response to this comment, since board certification was not a requirement in the proposed rule, and is not in this final rule with comment period.

Comment: One commenter believed that credentialing criteria should be appropriate to the nature of the services provided.

Response: We believe the credentialing criteria are sufficiently flexible to recognize the characteristics of each MCO and PHP, and the providers within its network.

Comment: One commenter believed that provider selection should be based on objective quality standards.

Response: We believe that the final rule with comment period, as structured, provides for objective quality standards.

Comment: One commenter recommended that we require "economic profiling" to be adjusted to reflect varying practice characteristics.

Response: We cannot respond to this comment because we do not understand what the commenter means by "economic profiling," or what its relationship is to credentialing. The intent of this rule was to ensure that MCOs and PHPs implement a formal selection process and, at a minimum, that the process address provider qualifications, provider discrimination, the exclusion of certain providers and additional requirements States may want to impose.

Comment: One commenter recommended that there be written policies and procedures for selection and retention of physicians.

Response: We agree, and in response to this comment, the final rule with comment period at § 438.214(a) now specifies that States must ensure that MCOs' and PHPs' selection and retention policies and procedures must be in writing.

Comment: One commenter recommended that the final rule with comment period, prohibit MCOs from removing providers from their networks without good cause.

Response: While States would be permitted under § 438.214(e) to adopt such a rule if they believe it would be appropriate based on conditions in the State, we do not believe that such a requirement should be imposed nationally in this final rule with comment period. This is because we believe that it may be reasonable, in some cases, for an MCO or PHP to remove providers from its network without cause. For example, there may be a need for an MCO to reduce the size of its provider network if its enrollment declines, and its payments to providers are based on a certain volume. In addition, evaluating the quality of care of providers may be facilitated by having fewer providers serve greater numbers of enrollees. We wish to note that under § 438.12(a)(1), if an MCO or PHP declines to include a provider in its network, it must give the provider written notice of the reason for this decision.

Comment: A number of commenters believed that there was a need to specifically assure that there be no discrimination against providers who traditionally serve more vulnerable populations, such as those who serve limited English proficient populations, high risk populations, and those requiring high-cost treatments. One commenter suggested that such providers be given priority in network selection and referrals. The same commenter believed that MCO gatekeepers frequently do not have professional credentials, and therefore should not control access to care.

Response: It is not clear why the commenters believe there is a need for assurance that there be no discrimination against providers who traditionally serve vulnerable populations, since proposed § 438.314(b)(3) expressly provided that selection and retention criteria could not "discriminate against * * * those who serve high risk populations." This provision has been retained in the final rule with comment period at § 438.214(c). We believe the commenters' concerns are also addressed in a number of other sections. For example, as discussed above, § 438.10(b) requires that information be available in languages spoken in the service area, and that interpreters be available to meet the needs of all enrollees, and § 438.206(e)(2) requires that MCOs and PHPs provide services in a culturally competent manner. Both of these provisions would encourage the use of providers who "serve limited English proficient populations."

Under § 438.206(d), in establishing a provider network, MCOs and PHPs are required to consider persons with special health care needs and include the numbers and types of providers "in terms of training and experience" required to serve the population. Again, this favors the use of providers with experience with vulnerable populations. Finally, under § 438.50(f)(2), in the case of a default enrollment process under a mandatory program under section 1932(a)(1) of the Act, an attempt must be made to preserve existing provider-beneficiary relationships, and relationships with providers that have traditionally served the Medicaid populations. Again, this favors giving priority to providers serving the vulnerable populations cited by the commenter.

With respect to the concern that gatekeepers do not have necessary professional credentials, § 438.210(b)(3) requires that any denials of an authorization for services be made by "a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease." We believe that all of the foregoing provisions adequately address the commenter's concerns.

Comment: Several commenters were unclear on the meaning of "high-risk populations" as used in proposed § 438.314(b)(3), and sought clearer standards under this provision. Commenters suggested specific examples of high risk patients, including adults and children with special health care needs, such as those with mental illness, substance abuse problems, developmental disabilities, functional disabilities, or complex problems involving multiple medical and social needs like HIV/AIDS, and the homeless. Other commenters felt that the provision governing providers who serve "high-risk" populations should be dropped from the rule as too vague to implement, and questioned the wisdom of employing such standards, which

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they believed would lead to unresolvable disputes.

Response: We disagree with the commenters who believe that we should delete the requirement in proposed § 438.314(b)(3), because we believe that many Medicaid beneficiaries are best served by providers who are experienced in caring for individuals with the health or social conditions that make an enrollee "high risk;" (for example, poverty, homelessness, disrupted family situations). We agree that the specific examples of high risk populations cited by the commenters are examples of high risk populations. We do not believe, however, that we should include regulations text specifically citing such categories, since this may be seen as limiting the scope of this provision. We instead believe that States should be free to interpret "high risk populations" based on their knowledge of the high risk populations in their State.

Comment: One commenter discussed the very valuable role nonprofit social service agencies play in the care delivery system for Medicaid beneficiaries, and expressed the view that these provider agencies would gain more credibility if they were accredited by the Medicaid program. There are now standards for such agencies that are recognized by many States. The commenter recommended that such agencies be accredited, and that they have the option of accreditation from the Council of Accreditation (COA), a body more representative of the social service model, as well as by a medical accrediting body such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or a JCAHO-type accrediting body.

Response: We do not believe it would be appropriate at this time to provide for accreditation of these agencies because (1) accreditation standards and procedures for such entities are in their formative stage, and (2) to the extent these agencies provide specific Medicaid State plan services, they would already be subject to any accreditation requirements applicable to the service in question. We note, however, that there is no Federal prohibition preventing States from adopting such quality standards if they choose.

Comment: One commenter took exception to the requirement at proposed § 438.314(b)(1) that provider selection criterion would be based in part on eligibility for payment under Medicaid. The commenter believed that there would be times when an MCO may wish to provide services through a provider in good standing who is not an eligible provider type under fee-for-service.

Response: We have clarified the final rule with comment period at § 438.214(d) to better reflect our intent to preclude only providers who have been barred from participation in the Medicaid program (for example, providers convicted of fraud). We did not intend to preclude States from allowing MCOs or PHPs to provide services through providers in good standing who do not participate in the traditional part of the Medicaid program (for example, alternative providers or providers who have not otherwise chosen to participate in the Medicaid fee-for-service program).

Comment: A commenter recommended that MCOs not be permitted to have separate panels of providers for Medicaid and for their other lines of business.

Response: Our experience has demonstrated that such a requirement is not practical. We have considered imposing such a requirement in the past, and have determined that it would not be in the best interests of Medicaid beneficiaries to do so. Some of the most successful managed care programs have employed providers with particular experience in treating the Medicaid population. Permitting these providers to exclusively serve Medicaid beneficiaries allows more Medicaid beneficiaries to access these experienced providers. It is also the case that some managed care organizations include physicians in their networks who would not agree to accept Medicaid patients. In such a case, if these MCOs or PHPs were not permitted to limit Medicaid patients to a subset of physicians who agree to treat Medicaid beneficiaries, they would not be available as a Medicaid option. We therefore are not including this requirement.

8. Enrollee Rights (Proposed § 438.320) (Redesignated as § 438.100)

As part of these standards, in proposed § 438.320(a), we required that each contract with an MCO or PHP have written policies with respect to enrollee rights, and the MCO or PHP ensure compliance with Federal and State laws affecting the rights of enrollees, and ensure that its staff and affiliate providers take these rights into account when furnishing services. Under proposed § 438.320(b), States must ensure that each enrollee has a right to: Receive information regarding their health care; have access to health care; be treated with respect and consideration for enrollee dignity and privacy; participate in decision making regarding his or her health care; receive information on available treatment options or alternative courses of care, and have access to his or her medical records. Proposed § 438.310(c) required that States ensure compliance with various civil rights laws.

Comment: Several commenters felt that the rights in proposed § 438.320 should be extended to individuals enrolled in PCCMs, as well as those in MCOs and PHPs.

Response: As discussed above, to the extent requirements in proposed subpart E are grounded in section 1932(c)(1) of the Act, we determined that it would be inconsistent with the Congressional intent to apply them to PCCMs, since the Congress made a conscious decision not to do so even when other provisions in section 1932 of the Act did so apply. We believe that the rights in § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d), however, are supported by our authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration, and the requirement in 1902(a)(19) of the Act that States provide "safeguards as may be necessary to assure that * * * care and services will be provided * * * in the best interests of the recipients." Therefore, in response to this comment, we are revising § 438.100(a)(2), (b)(1), (b)(4), (b)(5), (b)(6), (b)(8), (c), and (d) to make these paragraphs and subparagraphs applicable to PCCMs.

Comment: Several commenters suggested that without proper enforcement, the "rights" that were contained in proposed § 438.320 were just "paper rights."

Response: We agree that to be effective, enrollees" rights must be enforced, and believe that the final regulation with comment period include provision for enforcement. First, under subpart F, discussed in section II. E. below, enrollees have the right to file a grievance with their MCO or PHP if they believe any of their rights have been violated. In addition, (1) § 438.66 mandates that States actively monitor MCOs' and PHPs' operations, (2) § 438.202(d) requires that States ensure compliance by MCOs and PHPs with the quality standards established by the State, and (3) § 438.204(b)(2) requires that State quality strategies include continuous monitoring and evaluation of MCO and PHP compliance with standards. We believe that these provisions do provide for enforcement of enrollee rights.

Comment: Several commenters were concerned that the enrollee rights outlined in proposed § 438.320 contained too much subjective language that could be construed in any way that an MCO chooses.

Response: We believe that the provisions for Enrollee Rights now set forth in § 438.100 are specific enough to ensure specified rights for enrollees of MCOs, PHPs, and PCCMs, while still affording States the flexibility to determine how to guarantee that these rights are upheld.

Comment: Several commenters found the rights outlined in proposed § 438.320 too sparse, and believed that they did not fully implement the recommendations in the Consumer Bill of Rights and Responsibilities (CBRR).

Response: Proposed § 438.320 was intended to articulate a broad set of fundamental enrollee rights, and was not intended to encompass all aspects of the CBRR, which are reflected in detail in numerous provisions throughout virtually every subpart in part 438. For example, important enrollee rights are reflected in the information requirements in § 438.10 in subpart A, the continuity of care requirements in § 438.62 in subpart B, the rights related to provider enrollee-communication and emergency services in §§ 438.102 and 438.114 in subpart C, the right to access to a woman's health care specialist in § 438.206(d)(2) in subpart D, and the grievance and appeal rights throughout subpart F. See our discussion of these and other provisions for further discussion of how this final rule with comment period implements the CBRR.

Comment: One commenter objected to the provision in § 438.320(c) requiring that MCOs and PHPs must "comply with any other Federal and State laws that pertain to enrollee rights," because the commenter believed it was not appropriate for the Federal government to regulate compliance with State laws.

Response: The language in the proposed rule was intended to acknowledge that there are a number of States with their own requirements pertaining to enrollee rights. We do not believe that it is inappropriate to require that the State ensure that the MCOs, PHPs and PCCMs also comply with these regulations. However, we are not expecting States to take over the enforcement of State and Federal laws that are not within their jurisdiction. In order to more narrowly define the Federal and State laws that are being referenced, we have added the term "applicable" to the final regulation.

Comment: One commenter suggested that in addition to providing services in accordance with proposed §§ 438.306 through 438.310, proposed § 438.320(b)(2) should also include the right to "receive all services provided under the State plan."

Response: The requirement that a beneficiary receive all services provided under the State plan is set forth in § 438.206(c), which is incorporated in § 438.100(b)(2), so that this right is included in § 438.100.

Comment: One commenter requested that we explicitly state that enrollees have a right to a second opinion.

Response: We agree, and in response to this comment, have added a reference at § 438.100(b)(3) to the right to a second opinion provided for under § 438.206(d)(3).

Comment: Several commenters offered their support for proposed § 438.320(b)(3) which required that enrollees be treated with respect and due consideration for their dignity and privacy. It was the commenter's belief that populations with special needs have not always been treated in this manner. However, one commenter, while supporting the provision, felt that the standard was not appropriate for a Federal regulation, and would be difficult for States to measure or enforce.

Response: We believe that there are ways to monitor compliance with this provision retrospectively through such means as enrollee surveys, site visits, hot lines, and grievance procedures. In addition, including respect, dignity and privacy as explicit enrollee rights attempts to address this issue proactively. As commenters indicated, we believe this is a fundamental and important enrollee right and, as such, should be included in the regulation.

Comment: Several commenters suggested that we revise the language in proposed § 438.320(b)(4) to state that the information must be presented in a language appropriate to the consumer's condition and ability to understand.

Response: Section 438.100 provides that enrollees receive information in accordance with § 438.10, which requires that all information furnished to enrollees and potential enrollees meet specified language and format requirements. We believe these provisions address the commenter's concern. We therefore do not believe that a revision to the language at § 438.100 is necessary.

Comment: While offering support for the provision that requires information to be provided to enrollees, some commenters suggested that we revise the proposed regulation to require "full and complete" information on "all" available treatment options and "alternatives," including alternatives as to the "site of care." These commenters felt that these revisions are essential in ensuring that enrollees receive information on family planning services that are not covered by the MCO.

Response: We consider the commenters' suggestions already addressed in the regulations. For example, § 438.102(b)(1)(ii) and (iii) give enrollees a right to all "information the enrollee needs in order to decide among all relevant treatment options." and "the risks, benefits and consequences of treatment or non-treatment." With respect to information on family planning services, § 438.10(e)(2)(vi) expressly requires that information be provided on how enrollees may obtain family planning services from out-of-network providers. In the case of services not covered through the MCO or PHP, under § 438.10(e)(2)(xii), information must be provided on how and where the enrollee must obtain the benefits. In the case of benefits not covered on moral or religious grounds, information must be provided on how or where to obtain information about the service.

Comment: Several commenters offered their support for proposed § 438.320(b)(5), requiring that enrollees be permitted to participate in decisions on their health care, but requested that this provision be revised to clarify that enrollees not only have the right to participate in decisions, but that they also had the right to refuse treatment. Additionally, commenters wanted this provision to explicitly state that enrollees had the right to participate in "all" treatment decisions and to make "informed decisions."

Response: We agree with the commenters that it may not be clear that the right to participate in decisions also includes the right to refuse care, although this was our original intent. Consequently, we have revised § 438.100 (b)(6) to expressly include the right to refuse treatment. However, we believe that the suggested changes to include the qualifiers "all" and "informed" are not necessary, as these concepts are already contained in the provision as written.

Comment: A number of commenters believed that enrollee "access" to records was not sufficient, and that they also needed to be able to receive "copies" of their medical records, and all relevant documents, at no cost. They also requested that we revise proposed § 438.320(b)(6) to include the right to correct inaccuracies, and to append the record if there was a disagreement.

Response: We agree with the commenters that enrollees should also have the right to receive copies of medical records, and have addressed the commenters concerns in § 438.224 (Confidentiality and accuracy of

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enrollee records), discussed in section II. D. 8. below. In response to this comment, we have provided in § 438.100(b)(7) for the right to receive a copy of records, and request that they be amended or corrected, and have referenced § 438.224. We have not, however, required that enrollees be able to receive a copy of his or her medical record at no cost, because we believe that providers may incur some costs in responding to numerous requests to photocopy medical records and related documents.

Comment: Some commenters suggested that we provide additional detail on the specific relevant sections of the laws cited in proposed § 438.320(c) and citations for the regulations implementing these provisions.

Response: In response to this comment, we have included additional detail, including citations to implementing regulations in some cases, in § 438.100(d) of the final rule with comment period.

Comment: A commenter recommended that the text of proposed § 438.320(c), and not just the preamble, make clear the point that State Medicaid Agencies are not expected to take over the enforcement of State and Federal laws not within their jurisdiction.

Response: We believe that it is clear from the preamble to the proposed rule and to this final rule with comment period, that we are not expecting States to take over the enforcement activities that are not within their jurisdiction. However, as noted above, in order to more narrowly define the Federal and State laws that are being referenced, we have added "applicable" to the regulation.

Comment: A number of commenters believed that enrollees should be free to exercise their rights without fear from reprisal from the MCO or PHP in which they are enrolled, including the right to refuse services, without the loss of other desired services or disenrollment.

Response: We agree with commenters, and in response to this comment have added language at § 438.100(c) to ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PHP, PCCM, their providers, or the State agency treats the enrollee.

Comment: Commenters requested that we include explicit statements of additional enrollee rights, including the right to: (1) Fully participate in the development of their plan of care and treatment decisions; (2) participate in research or experimentation only with informed, voluntary, written consent; (3) be free from physical, verbal, sexual, or psychological abuse, exploitation, coercion, or neglect; and (4) be treated in a humane environment that affords reasonable protection from harm and ensures privacy.

Response: Section 438.100(b)(6) provides enrollees with the right to participate in decisions regarding their health care, which we believe would include plans of care, treatment decisions, or participation in any research or experimentation. With respect to the right to be free from abuse, exploitation, or neglect, or to be treated in a humane environment that affords protection from harm and ensures privacy, we believe that these rights are inherent in the right under § 438.100(b)(4) to be treated with respect and dignity and the confidentiality rights in § 438.224, discussed in section II.D.9. below. Further, we have revised proposed § 438.306(e)(3)(iii)(now § 438.208(f)(5) to require that treatment plans, developed for individuals who are pregnant or who have special health care needs, are to be developed "with enrollee participation".

Comment: Commenters suggested that we add as a right that beneficiaries have the right to be free from seclusion, physical or chemical restraints, used by staff as a means of coercion, discipline, convenience or retaliation.

Response: We agree that this is a fundamental right, and in response to this comment, have added it to the requirements of § 438.100 in the final rule with comment period.

Comment: Commenters proposed the inclusion in proposed § 438.320 of a number of additional rights in the following areas: information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage.

Response: As discussed previously, § 438.100 was intended to put forth a basic and general fundamental set of rights. More detailed and specific enrollee rights are articulated in greater detail in other sections of the regulation. The suggested changes in the areas of information standards, complaint and grievance procedures, quality assurance, service authorization, choice, disenrollment, emergency services, access and capacity, and benefits and coverage are more fully detailed in the corresponding provisions of the regulations which are dedicated to these respective topic areas. Therefore, the specific suggestions offered by the commenters were considered in the context of these other provisions. For example, the comment that the enrollee has the right to receive timely and adequate advance written notice of any decision to deny, delay, reduce, suspend, or terminate medical services is addressed in §§ 438.210(c) and 438.404.

9. Confidentiality (Proposed § 438.324)

Current regulations at 42 CFR part 431, subpart F govern the safeguarding of beneficiary information at the State level. The regulations in part 431, subpart F, specify for State Medicaid agencies, among other things, the types of information to be safeguarded, when such information may be released, and how such information is to be distributed.

In proposed § 438.324, consistent with the regulations at part 431 subpart F, we proposed that the State ensure, through its contracts with MCOs and PHPs, that each MCO and PHP (1) maintain records and information (in oral, written, or electronic format) in a timely and accurate manner, (2) safeguard the privacy of any information that identifies a particular enrollee by ensuring that original records are released only in accordance with Federal or State law, or court orders or subpoenas; copies of records and information are released only to authorized individuals; and unauthorized individuals do not gain access to, or alter, patient records, (3) protect the confidentiality and privacy of minors, subject to applicable State and Federal laws, (4) ensure that enrollees have timely access to records and information that pertain to them, and (5) abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. The requirements we proposed in this section are consistent with the right to confidentiality of health information supported by the CBRR.

We received numerous comments in response to this section requesting that we include specific guidelines and address substantive issues in more detail. Prior to addressing these comments, we must first clarify our original intent in proposing this section. We included this section in order to ensure that MCOs and PHPs would be held responsible for safeguarding the confidentiality of enrollee information. We did not intend to impose specific guidelines for the use and disclosure of enrollee information. We recognized that there are many different State and Federal laws that specifically address confidentiality and it was not our intent to interfere with these laws. Several States have enacted strong privacy protections that will continue to apply to MCOs and PHPs participating in the Medicaid program. In addition, the Secretary is currently developing a final regulation that will address confidentiality of health information at the Federal level in accordance with section 264 of the Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104–191). In order to remain consistent with existing laws and regulations, as well as the forthcoming HIPAA regulation, we only included general requirements in this section.

Comment: We received two comments on proposed § 438.324(b)(1), which provided that original medical records must be released only in accordance with Federal or State law, or court orders or subpoenas. One commenter recommended that we revise the regulation to require that both the original and copies of patient medical records be released to Medicaid fraud control units and other law enforcement agencies. Another commenter suggested that this provision conflicts with requirements in § 431.306(f). That section requires that when a court issues a subpoena for a case record, the Medicaid agency must inform the court of the applicable statutory provisions, policies, and regulations restricting the disclosure of information. The commenter believed that in light of this existing requirement, the release of information should not be required through the use of subpoena power alone.

Response: The requirement proposed in § 438.324(b)(1) was intended to highlight the importance of ensuring the integrity and availability of original medical records. If an MCO or PHP receives a request for an enrollee's information, we would expect that the MCO or PHP would typically only release a copy of that information. However, as the commenters note, the proposed language could create confusion regarding the requirements for this subset of identifiable health information, and how it differs from the protections afforded to other such information. It was our intent that originals should only be released in accordance with applicable laws. Therefore, in order to more accurately reflect this intent, in § 438.224(c) of the final rule with comment period, we have deleted the specific reference to court orders and subpoenas, and eliminated the provision singling out original records from other health information. We rely on the State, the MCO, and the PHP to make appropriate decisions regarding disclosure of copies versus originals, based on the specific circumstances of each disclosure. Procedures to be followed in response to a subpoena are addressed by the requirement (in the parenthetical in the first line of § 438.224) that MCOs and PHPs must follow subpart F of part 431.

Comment: We received several comments in response to proposed § 438.324(b)(2), which requires that copies of records and information from MCOs be released only to authorized individuals. Several commenters believed that we did not define the term "authorized individual" or "authorized representative" in the proposed rule, and that it was thus unclear who may receive medical records from an MCO or PHP. Other commenters found that this provision did not include necessary language addressing inappropriate disclosures of information within an MCO or PHP. Specific recommendations made by commenters were that the definition of "authorized individual" include family members, guardians, and legally authorized representatives.

Response: We recognize that the use of the term "authorized" in this section has generated some confusion. It was our expectation that the MCO or PHP would establish and follow procedures to specify who would be "authorized" to received confidential enrollee information, and that these procedures would reflect applicable Federal and State law. We recognize that the term could be interpreted in other ways. Therefore, in § 438.224(b) and (c) of the final rule with comment period, we have revised the language to make more explicit our intent as to what would constitute an authorized disclosure, and in doing so, we removed the term "authorized individual."

Comment: Several commenters requested that the proposed rule be strengthened with regard to limiting the flow of identifiable data. Some commenters suggested that we require MCOs and PHPs to use non-identifiable data whenever identifiable data is not needed to complete a task. Some commenters stressed that the final rule with comment period should also include additional safeguards to protect a beneficiary's sensitive health information, so that the disclosure of identifiable data can be used only for activities which MCOs or PHPs and providers need for legitimate purposes. One commenter recommended that an MCO or PHP should be required to define when identifiable data is necessary for a particular activity. In addition, several commenters recommended that we include technical standards in the regulations to address electronic and paper records. Finally, other commenters suggested we include incentives in the regulation for MCOs and PHPs to use non-identifiable data, and include a requirement for MCOs and PHPs to justify the use of identifiable data needed for an activity.

Response: These comments describe many standard procedures that should be in place for protection of health information and ones which MCOs and PHPs will likely put in place to comply with the requirements of this section. However, consistent with the above discussion of our purpose in writing this section of the rule, our intent was not to create specific technical mechanisms (including standards regarding the use of identifiable and non-identifiable data) that MCOs and PHPs must have to safeguard data. As discussed previously, we proposed this section because we believe that MCOs and PHPs should have safeguards in place (including, as appropriate, the ones suggested by the commenters) to ensure that patient-identifying information is used for legitimate purposes. To underscore our intent not to create new technical standards, we have deleted sections of the proposed rule (§ 438.224(d) and (e)) that we believe are already covered by the requirements at Subpart F of part 431 and which may have inadvertently lead readers to believe that we were attempting to create new standards.

Therefore, we have not revised this section to include technical standards for securing electronic and paper records, or to impose specific requirements on MCOs and PHPs as to when they must use non-identifiable data. However, in response to the broad concern expressed by commenters about the different ways patient-identifying information might be used or disclosed to others, we have added a new requirement at § 438.224(e) that requires the State to ensure that each MCO and PHP establish and implement procedures to ensure that enrollees receive, upon request, information pertaining to how MCOs and PHPs use and disclose identifiable information.

Comment: We received several comments in support of proposed § 438.324(c), which requires MCOs and PHPs to have procedures to protect the confidentiality and privacy of minors, subject to applicable Federal and State law. Several commenters indicated that a major obstacle to minors obtaining needed health care is due to concerns about the lack of confidentiality. They suggested that we maintain the proposed regulation and preamble, which they believe is clear in that it refers to services and treatment which minors can obtain without parental consent and what information can be

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released to a parent upon request. They also suggested that family planning, mental health, and substance abuse services be addressed by the MCO's or PHP's procedures.

In contrast, several commenters contended that all information about a minor should be released to parents barring a court order stating otherwise. One commenter focused on the developmentally disabled population, and believed that copies of medical records, treatment options, and confidential information relevant to the receipt of medical services must be communicated to a family member or guardian prior to proceeding with the proposed treatment. Other commenters suggested that the final regulation stress confidentiality of family planning services for adults as well as minors.

Response: Section 438.324, as a whole, was intended to ensure that MCOs and PHPs have procedures to protect the confidentiality of all enrollees. We proposed a specific provision addressing the confidentiality of minors in recognition of the large number of enrollees under age 18. It was not our intent to interfere with Federal and State laws that address the confidentiality of minors. Therefore, in the final rule with comment period, we have removed the reference to minors because we intend the term "enrollee" to encompass all enrollees.

Comment: Several commenters recommended that we revise proposed § 438.324(d) to clarify that, in addition to enrollees, authorized representatives of enrollees must have timely access to records and information. One commenter recommended that we revise this provision to require MCOs to provide enrollees with access to their records within 24 hours (excluding weekends and holidays); and to obtain photocopies. Another commenter pointed out that under their State law, the Medicaid agency is not required to provide timely access to records if the beneficiary is currently under civil or criminal investigation. Another commenter questioned this provision, and suggested that under patient/doctor confidentiality, the patient holds the privilege of confidentiality, not the provider. Further, the commenter contended that patients are the owners of their medical records and always have had the opportunity to review and correct errors. The commenter wondered what role an MCO or PHP should play in enforcing patient rights. Several commenters also suggested that enrollees be able to receive copies of their records. Commenters also recommended that enrollees be able to request amendments or corrections to their records.

Response: We proposed § 438.324(d) to ensure that MCOs and PHPs have orderly procedures to enable an enrollee to access his or her medical records in a timely manner. It was not our intent to interfere with Federal or State laws governing access to medical records or other information. While we have not included specific time lines, exceptions, and rules in this provision, we have, in § 438.224 of the final rule with comment period, clarified the language to more clearly reflect our intent. We have replaced the general term "access" with more specific language in § 438.224(f) that requires the State to ensure that each MCO and PHP has procedures to ensure that the enrollee can request and receive a copy of his or her records and information and that the enrollee may request amendments or corrections.

Comment: Several commenters questioned proposed § 438.324(e), which required MCOs and PHPs to abide by all Federal and State laws regarding confidentiality and disclosure of mental health records, medical records, other health information, and any information about an enrollee. One commenter believed that it was redundant for the Federal government to regulate compliance with State law. Another commenter contended that Federal requirements should preempt State and local confidentiality laws. This commenter suggested that requiring multi-state Medicaid MCOs to adopt different State confidentiality procedures in each State was unduly burdensome, and serves no legitimate purpose. This commenter recommended that confidentiality requirements be uniform and pre-empt State and local confidentiality laws.

Response: It was not our intent to preempt or supersede other Federal or State laws governing confidentiality. Rather, we intended to create a baseline of protections for Medicaid managed care enrollees that is consistent with other applicable laws. We continue to believe that it is important to highlight other applicable laws and to require that States ensure that MCOs and PHPs have procedures that comply with these laws; and therefore, we have retained this requirement. With respect to the commenter urging that Federal requirements be established that would pre-empt State law, we believe that this would be inconsistent with the structure of the Medicaid program, which is a State-run program under which States are granted discretion to establish their own approach. While a national MCO or PHP may have to follow different rules in different States under the Medicaid program, this would be equally true for their commercial lines of business in different States.

Comment: We received several comments supporting proposed § 438.324(e). Several commenters appreciated that we made a distinction between medical records, and the sharing of necessary information between physical health providers and mental health and substance abuse providers. While some commenters recommended that the language be maintained, other commenters recommended that we clarify the regulation to require compliance with Federal rules concerning confidentiality of substance abuse treatment and to emphasize the primacy of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Records.

Response: Under this provision, MCOs and PHPs must abide by all Federal and State laws regarding the confidentiality of health information, including laws pertaining to the confidentiality of substance abuse treatments. We have clarified our final rule with comment period to require that the State must ensure that, for medical records and any other health and enrollment information that identifies a particular enrollee, the MCO or PHP establishes and implements procedures to abide by all Federal and State laws regarding confidentiality and disclosure. We believe that this provision, as stated, includes existing laws that govern confidentiality and disclosure of medical records, mental health records, substance abuse records, and any other identifiable information.

Comment: A commenter expressed concern that § 438.324 does not address how confidentiality policies will affect the use of patient information in research. The commenter stressed that studies of disease, epidemiology, therapy, and health services depend on access to patient records, including records for Medicaid managed care enrollees. The commenter recommended that we address the issue of research in the final rule with comment period so that medical records are available through a process that meets confidentiality concerns but is not unduly burdensome.

Response: The use and disclosure of health information for research is an extremely complicated issue. We do not believe that this regulation is the appropriate vehicle to specify when such uses and disclosures are appropriate and what specific safeguards must be in place to protect that information. We do require the State to ensure that MCOs and PHPs safeguard the confidentiality of any information that identifies a particular enrollee. In addition, we require the State to ensure that MCOs and PHPs have procedures in place that address how the information will be used and disclosed. We would expect that these procedures would specifically address when the MCO or PHP would use enrollee information for research and under what circumstances it would disclose the information to outside researchers. As noted above, the forthcoming HIPAA regulation will address this issue in more detail.

10. Enrollment and Disenrollment (Proposed § 438.326) and Grievance Systems (Proposed § 438.328)

These proposed sections required that a State agency include as part of its quality strategy ensuring compliance with the enrollment requirements in § 438.56, and, consistent with section 1932(c)(1)(A)(ii) of the Act, with the grievance requirements in subpart F. We received no comments on proposed § 438.326, and one comment relating to proposed § 438.328.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications, and other forms of non-coverage to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree with this comment. In § 438.228(b) of the final rule with comment period, we have added a requirement that States must conduct random reviews to ensure that each MCO and PHP and its providers and contractors are notifying enrollees in a timely manner. We have further added at § 438.228(c) a requirement that State must review, upon request of the enrollee, grievances not resolved by an MCO or PHP to the satisfaction of the enrollee.

11. Subcontractual Relationships and Delegation (Proposed § 438.330)

Proposed § 438.330 set forth requirements specifying that the State must ensure that an MCO or PHP entering into a contract with the State oversees and remains entirely accountable for the performance of any activity it delegates to a subcontractor. Under proposed § 438.330, it is the sole responsibility of the MCO or PHP to ensure that the delegated activity or function is performed in accordance with applicable contractual requirements. Specifically, under proposed § 438.330, the MCO or PHP should: (1) Evaluate the ability of the prospective contractor to perform the functions delegated; (2) enter into a written agreement that specifies the delegated activities and reporting requirements of the subcontractor, and provides for revocation of the delegation or imposition of other sanctions if the subcontractor's performance is inadequate; (3) monitor the subcontractor's performance on an ongoing basis, and subject the subcontractor to formal review at least once a year; and (4) if deficiencies or areas for improvement are identified, take corrective action. These provisions are consistent with the CBRR as they relate to consumer choice of provider networks that are adequate to serve the needs of consumers, and in particular, these provisions ensure that States hold MCOs and PHPs accountable for the availability and adequacy of all covered services.

Comment: One commenter recommended requiring certifications to the State that payments under a subcontract are sufficient for the services required. Commenters recommended that all subcontracts should be made available for public inspection, so that they are available to the State, enrollees, and advocates.

Response: While we are not requiring a direct certification to the State, it is the MCO's or PHP's responsibility under § 438.230(b)(1) to evaluate, before delegation occurs, the prospective subcontractor's ability to perform the activities that are to be delegated. This evaluation may include evaluation of the subcontractor's financial stability and financial ability to deliver services. Subsequently, the MCO or PHP is held accountable for any functions it delegates, and therefore, has ultimate responsibility for oversight of the subcontractor. In addition, there is nothing in this provision that would preclude a State from requiring such a certification if it so chooses.

Moreover, we do not review subcontracts and normally do not become involved in the relationship between MCOs and PHPs and their subcontractors, with the exception of physician incentive rule arrangements, which must be disclosed. The law imposes requirements on MCOs, not on their subcontractors. We do not believe that we should be involved because the MCO or PHP (with whom there is a direct relationship) is ultimately responsible that requirements are met. Therefore, we will not in this final rule with comment period require public access to subcontracts. However, public access to subcontracts is subject to State procedures and policies governing their disclosure.

Comment: Several commenters requested clarification on the definition of subcontractor. The commenters questioned whether we intended for this provision to apply to individual providers or solely to organizations. One commenter expressed the view that if an individual physician/provider is considered to be a subcontractor, the requirement for annual recredentialing would be unreasonable. Another commenter suggested that we give States the flexibility to define subcontractor as it applies to these provisions, while other commenters recommended that we define the term so that these provisions would apply solely to organizations.

Response: Any entity, whether an individual or organization, that is not an employee of the organization, but who assumes responsibility on behalf of the MCO or PHP, would be considered to be a subcontractor. While we are not specifically defining subcontractor, we do intend for it to include any non-employee individuals or organizations within the MCO's or PHP's network.

Comment: One commenter believes the requirement that the MCO subject each subcontractor's performance to formal review on an annual basis is unnecessarily prescriptive. The commenter notes that there is considerable overlap between this requirement and the provider credentialing requirements, and that States should have flexibility in this area.

Response: The intent of this provision was not to require recredentialing once a year. Proposed § 438.330 was designed to hold MCOs and PHPs accountable for the availability and adequacy of all covered services delivered through their subcontracts. As a result of this comment, we have revised § 438.230(b)(3) of the final rule with comment period to require that the MCO or PHP monitor the subcontractor's performance on an ongoing basis, and subject it to formal review according to a periodic schedule established by the State, consistent with industry standards or State laws and regulations.

Comment: One commenter expressed the view that the proposed rule did not go far enough in protecting an enrollee's rights when Medicaid services are delegated to subcontractors. The commenter believed that the enrollee has the right to know what to expect of a subcontractor, and that the State should be much more involved in making sure the subcontractor complies with the requirements of the contract and State and Federal law. The commenter recommended that, at a minimum, all subcontracts should be directly monitored by the State with the

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monitoring procedures applicable to the MCO also applied to subcontractors.

Response: Section 438.230(a) of the final rule with comment period requires that the MCO or PHP oversee, and be held accountable for, any functions and responsibilities that it delegates to any subcontractor. Therefore, it is the MCO's or PHP's responsibility to ensure that its subcontractors are in compliance with all applicable laws, including those identified under § 438.100 (Enrollee Rights). It is the sole responsibility of the MCO or PHP to ensure that the delegated function is performed in accordance with applicable contractual requirements. However, there is nothing in this provision that precludes States from monitoring subcontracts if they so choose.

Comment: One commenter recommended that regulatory language be revised so that it is the same as that used in the Medicare+Choice regulations. The commenter believes that this will reduce the regulatory burden on managed care organizations that contract under both programs. The commenter recommends that the Medicaid final rule with comment period require that subcontractors comply with all applicable Medicaid laws, regulations, and our guidance.

Response: For the most part, the requirements contained in the Medicare regulations for subcontractors are reflected in the Medicaid regulatory language. However, in response to this comment, we have added a new provision at § 438.6(l) to require that all subcontracts fulfill the requirements of part 438 that are appropriate to the service or activity delegated under the subcontract.

Comment: One commenter suggested that the final rule with comment period address the obligation of States and MCOs to certain subcontractors, specifically Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs). They recommended that the rule reflect the statutory requirement that MCOs that enter into contracts with FQHCs and RHCs are required to provide payment that is not less than the level and amount of payment which would be made for services from a provider which is not an FQHC or RHC. These commenters also believed that the final rule with comment period should reflect the requirement that States directly compensate FQHCs and RHCs if they receive less compensation than that to which they are entitled. The commenters believe that an FQHC's or RHC's ability to provide high quality services, such as HIV services, in a managed care environment depends upon linkages with MCOs that include adequate compensation.

Response: The rules cited by the commenter are "transitional" in nature, as the payments provided for thereunder are to be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time. Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and we have provided guidance to all States on FQHCs and RHCs, through State Medicaid Director Letters on April 21, 1998, October 23, 1998, and September 27, 2000. We will continue, as necessary, to clarify FQHC and RHC payment policies.

Comment: One commenter expressed the view that subcontractual relationships may not be advantageous between Indian Health Service (IHS) and tribally operated programs and MCOs, if they are only reimbursed at a capped rate that does not give them the ability to recoup the costs of providing services in reservation communities located in rural and isolated locations. However, the commenter believed that some contracts may be desirable in communities where a local relationship with an MCO provider provides a network of support services not available in the Indian health care system. Another commenter cited a Memorandum of Agreement between IHS and HCFA, and Federal legislation, which each provide that IHS is compensated at a special rate, and that tribally operated programs may also choose to be compensated at the IHS rate. Furthermore, services furnished by these entities are entitled to a 100 percent Federal matching rate. The first commenter requested that we require that IHS or tribal providers operating as subcontractors be allowed to bill States or their fiscal intermediaries directly for American Indian Medicaid beneficiaries. The second commenter recommended that IHS, tribal providers, and urban Indian clinics receive payment for services to IHS beneficiaries who are also Medicaid beneficiaries from States or their fiscal intermediaries directly and not be required to bill MCOs, regardless of whether the facility is a subcontractor or providing "off-plan" services.

Response: As also noted in section II. H. below, policies concerning IHS or tribal providers, the rates paid to such providers, or the Federal matching applicable to such providers, are unaffected by, and are outside the scope of, this rulemaking.

12. Practice Guidelines (Proposed § 438.336)

Proposed § 438.336 required that States ensure that each MCO and PHP develop or adopt and disseminate practice guidelines that met standards set forth in proposed § 438.336(a), which required that the guidelines: (1) Be based on reasonable medical evidence or a consensus of health care professionals; (2) consider the needs of MCO and PHP enrollees; (3) be developed in consultation with contracting health care professionals, and (4) be reviewed and updated periodically. MCOs and PHPs were required under proposed § 438.336(b) to disseminate the guidelines to providers and enrollees where appropriate, or when they request them. Proposed § 438.336(c) required that decisions with respect to utilization management, enrollee education, coverage of services, and other areas be consistent with the guidelines.

Comment: Several commenters requested clarification of the regulatory language requiring MCOs and PHPs to "develop" (or adopt) practice guidelines. One commenter assumed that § 438.336 did not require the development of "new" practice guidelines, but only that if practice guidelines currently exist, they should be disseminated according to the language in this section. Another commenter was unclear if the provision required MCOs to adopt guidelines, or required MCOs, if using practice guidelines, to use them in accordance with this section.

Other commenters requested that MCOs be allowed to "develop" their own practice guidelines instead of "utilizing" existing practice guidelines developed by governmental agencies. Some commenters believed that practice guidelines should not be required. These commenters believed a blanket requirement for practice guidelines in all disease management areas is unwise, as not all areas have developed guidelines. Also, the commenters noted that the Medicare+Choice regulations do not mandate the development of guidelines.

Response: We realize that the words "develops" and "development" were misleading in that they appeared to suggest that we were encouraging MCOs and PHPs to develop their own practice guidelines, instead of using those already established by expert panels. We have removed those words from § 438.236 of the final rule with comment period. Since a number of practice guidelines already exist for a variety of clinical areas, we do not specify how many or which practice guidelines MCOs and PHPs must adopt. Rather, each MCO and each PHP will need to establish a process for identifying and reviewing guidelines that are relevant to the health conditions of its enrolled population and implement a process, in conjunction with its providers, for the adoption and implementation within the MCO or PHP. This is consistent with industry standards in the private sector. NCQA's 1999 accreditation standard QI8, "Clinical Practice Guidelines," states, "The MCO is accountable for adopting and disseminating practice guidelines for the provision of acute and chronic care services that are relevant to its enrolled membership."

Comment: Multiple commenters recommended that the final rule with comment period specifically mention or require MCOs to use the following specified Federal Practice Guidelines: (1) Federal "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents," (2) Federal "Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection," and (3) the "USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons with Human Immunodeficiency Virus," and update as appropriate.

Several commenters felt this section should be clearer and more specific to the unique health care needs of children, for example, specifically referencing the American Academy of Pediatrics (AAP) immunization guidelines.

One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities.

Response: Many evidence-based practice guidelines exist that would be beneficial for MCOs and PHPs to adopt as tools for improving the quality of health care provided to enrollees. Because of the growing number of such guidelines, the variation in the strength of the evidence base supporting these guidelines, and the need for ongoing review and updating of guidelines, we are reluctant to single out a subset of practice guidelines as superior to all others and preferentially require adherence to them in this regulation. We do, however, reference the Adult and Pediatric Guidelines for use of Antiretroviral Agents in Treatment of HIV Disease as examples of the type of guidelines that should be adopted. We did not specifically require that the guidelines be adopted due to the reasons stated above. However, we have referenced HIV guidelines in the text of § 438.236(b) as examples of guidelines that could be adopted consistent with this final rule with coment period, to reflect our strong belief that adherence to the HIV guidelines is essential to providing quality HIV care. We would continue to hold this position as long as the guidelines continue to meet the criteria in § 438.236(b). In addition to the guidelines referenced in the regulations text, we also strongly recommend that MCOs and PHPs adopt the following HIV guidelines if they continue to meet the criteria in § 438.336(b): USPHS/IDA Guidelines for Prevention of Opportunistic Infections in Persons Infected with HIV, Public Health Task Force Recommendations for the Use of Antiretroviral Drugs in Pregnant Women Infected with HIV–1 for Maternal Health and Reducing Perinatal HIV–1 Transmission in the United States, and US Public Health Service Recommendations for Human Immunodeficiency Virus Counseling and Voluntary Testing of Pregnant Women. We did not include references to any immunizations schedules, because current law requires State Medicaid agencies to provide all immunizations recommended by the Advisory Committee on Immunization Practices as part of the EPSDT program.

Comment: One commenter expressed the view that practice guidelines should take into consideration the needs of populations with special health care needs. One other commenter believed that a lack of medical evidence cannot be taken as a sign of a lack of efficacy. People with disabilities have limited access to clinical trials, and would suffer if practice guidelines based on clinical proof of efficacy were needed to ensure coverage. One commenter felt that guidelines should not be required to be based on "reasonable medical evidence," because in some specialty areas, including mental health, there is not an established base of published clinical trial outcomes. The commenter also noted Federal case law, that requires the provision of appropriate treatment, even if the treatment is not supported by clinical studies.

Two commenters agreed that MCOs should use practice guidelines that are evidence-based and developed by clinicians with training and expertise in a field, but they believed that some guidelines are not developed in an empirical framework, and if implemented, could jeopardize both children's access to and types of treatments received.

One commenter agreed that practice guidelines can be helpful, but found that the area of mental health has not developed sufficient guidelines for all courses of treatment. The commenter believed that use of guidelines in the area of mental health may result in the denial of treatment as new treatment methods are developed.

Response: Some commenters have interpreted the regulation as requiring practice guidelines to be based on clinical trials, and were concerned about the potential lack of clinical trials including populations with special health care needs. In fact, this regulation does not require the use of practice guidelines for all conditions, or restrict the use of guidelines to those based on clinical trials. Section 438.236(b)(1) of the final rule with comment period requires that the guidelines be based on "reasonable clinical evidence or a consensus of health care professionals in the particular field," which does not necessitate that a clinical trial have been conducted; for example, guidelines for Perinatal Care, developed by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

The commenters are also concerned over the lack of practice guidelines for some conditions, such as mental health, and fear that treatment may be denied. The regulation does not specify the number of practice guidelines that must be adopted, nor does it mandate for which conditions practice guidelines must be developed. The lack of practice guidelines for a particular condition does not provide a basis for an MCO or PHP to fail to treat conditions for which there is no guidance.

Comment: Two commenters suggested that we only permit practice guidelines developed by licensed health care providers in a particular field. Another commenter wanted to give greater weight to the requirements that guidelines based on "reasonable medical evidence or a consensus of health care professionals in the particular field (§ 438.336(a)(1))," and that they "consider the needs of the MCO's enrollees (§ 438.336(a)(2))" than the requirement that they be developed "in consultation with contracting health care professionals (§ 438.336(a)(3))." The commenter believed that guidelines developed in accordance with § 438.336(a)(3) could lead to "garden variety" practice guidelines. One commenter believed that professional specialty organizations have adopted many national standards and practice guidelines that should be used.

Response: Because there is variation in the evidence base that supports all medical interventions, we believe we must be flexible and accept the use of guidelines developed both by clinical evidence or a consensus of health care professionals in the particular field. We

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have replaced the word "reasonable" with the words "valid and reliable" to better describe the type of clinical evidence that should serve as a basis for practice guidelines that MCOs and PHPs are to adopt. The language we have used in the proposed rule and final rule with comment period at § 438.236 is consistent with industry standards.

Comment: One commenter suggested that practice guidelines be based on reasonable "clinical" evidence instead of reasonable "medical" evidence. Two commenters believe that if medical evidence does not exist, it may be due to the rarity of the disease, inadequate research infrastructure, or the fact that people with disabilities do not have as much access to clinical trials.

Response: We agree with the commenters. The term "medical" typically refers to actions and treatments related to physician practices, while "clinical" extends to health care researchers, as well as other health care providers, such as dentists, pharmacists, and nurses. Because of this, in response to this comment, we have substituted "clinical" for "medical" in § 438.236(b)(1). By replacing "medical" with the broader term, "clinical," we are also being more consistent with the following examples. The Institute of Medicine (IOM) discusses practice guidelines in the context of "clinical practice." For example, "Practice guidelines must include statements about when they should be reviewed to determine whether revisions are warranted, given new clinical evidence or professional consensus (or the lack of it)." The IOM also points out that two of the key attributes of practice guidelines include "clinical applicability" and "clinical flexibility."

One source of clinical practice guidelines on a variety of topics and that can help interested parties compare different practice guidelines on the same topic is the Agency for Healthcare Research and Quality's (AHRQ) National Guideline Clearinghouse, available at www.AHRQ.gov.

Comment: One commenter believed that MCOs should be required to report on compliance with scientifically grounded clinical practice guidelines where they exist for persons with disabilities. The same commenter also believed that the regulation should require that the amount, duration, and scope of coverage for covered benefits be reasonably sufficient to achieve the purpose of the service.

Response: We have decided not to require reporting on, or State monitoring of, compliance with the guidelines adopted by each MCO and PHP due to excessive cost and administrative burdens. Instead we have chosen to emphasize the adoption and dissemination of evidence-based and widely accepted practice guidelines by MCOs and PHPs to their providers. We also believe that compliance with those practice guidelines adopted by States and MCOs and PHPs can be monitored through the quality assessment and performance improvement project requirements in § 438.240.

The commenter's second concern about the amount, duration, and scope of coverage for covered benefits was addressed in the response to comments on § 438.310.

Comment: One commenter believed that MCOs need to require their providers to use practice guidelines through a MOA or linkage agreements.

Response: We do not believe it is appropriate for the regulation to specify how MCOs and PHPs are to promote adherence to the guidelines by their contracted providers. We note that the state-of-the-art of information dissemination, technology transfer, and changing provider practice patterns is complex and continues to be the subject of much study.

Comment: One commenter believed that decisions about medical care should be based on medical necessity and medical judgement, and that these may not in individual cases, be consistent with the guidelines. Several commenters stated that practice guidelines are guidelines only, and should not restrict access and should be consistent with individual needs.

Many commenters expressed a concern that no requirement exists requiring individual coverage decisions to conform to government practice and care guidelines, especially in the area of HIV/AIDS treatment.

One commenter expressed a concern regarding how MCOs contracting with Medicaid will apply EPSDT standards and guidelines to children being served, and specifically to children with special health care needs.

Response: Our intent is not to substitute practice guidelines for professional judgement in the care of individuals. Practice guidelines are guidelines, not mandates, and should be applied consistent with the needs of the individual.

Comment: One commenter expressed a concern that MCOs will not reimburse subcontractors for services that are not recognized as medically necessary, or not consistent with nationally recognized practice guidelines.

Response: As noted above, there are many evidence-based practice guidelines that would be helpful to MCOs and PHPs in undertaking efforts to improve the quality of health care provided to enrollees. However, we are not prescribing a uniform set of guidelines that must be used, or specifying that guidelines must be used whenever they are available. Rather, we are requiring that MCOs and PHPs consider relevant guidelines and choose those they find appropriate. Because it is not practical for an MCO or PHP to focus its quality assessment and improvement efforts simultaneously on all areas for which there are practice guidelines, it is not our expectation that MCOs and PHPs will adopt practice guidelines for all areas of treatment.

For those clinical areas for which an MCO or PHP has adopted a clinical practice guideline, if an enrollee requests services that contradict the practice guideline, the MCO or PHP may have grounds for withholding the services or refusing to pay for the service. Similarly, if an MCO or PHP found a requested service not to be medically necessary, the MCO or PHP would have grounds for withholding the service or refusing to pay for the service. However, there are two means of recourse for beneficiaries who believe that they have been inappropriately denied a service based on a practice guideline. First, the enrollee may appeal the denial of services on an individual basis. Second, the enrollee may request that the Medicaid agency review the guideline to see that it meets the regulation requirements that guidelines be evidence-based and up-to-date. We believe this will protect enrollees from the misuse of practice guidelines.

Comment: One commenter believed that guidelines should also be disseminated to enrollee representative, advocates, and the general public. Several commenters agree that enrollees, as well as the public, should have a right to obtain a copy of the practice guidelines.

In contrast, many other commenters voiced concern over the dissemination of guidelines to anyone other than appropriate providers. Some stated that the dissemination of guidelines intrudes on the practice of medicine and exceeds BBA requirements. One commenter believed that the administrative effort and expense would be too high if guidelines were to be disseminated "as appropriate." Two commenters were unclear about the meaning of "as appropriate." One commenter stated that disclosure of practice guidelines to enrollees may present problems around inclusion of proprietary information directly related to the conduct of business between providers and the MCO. Two commenters question the value/usefulness of guidelines being disseminated to individual enrollees, as the information may be too confusing for them to comprehend. Finally, several commenters agree that guidelines should be disseminated to practitioners, but not to enrollees. These commenters believed the provider could give the guidelines to the enrollee as part of a treatment plan.

One commenter feared that the requirement to disseminate guidelines to all providers may result in MCOs collecting or creating guidelines in cases where medical outcomes are uncertain, expert preferences are mixed, or no justification is needed when following a treatment option. Another commenter believed that guidelines should only be disseminated to providers affected by the guidelines.

Response: Concerns over the dissemination of practice guidelines fell into two opposing views. Some commenters believed that guidelines should be available not only to enrollees, but also to enrollee representatives, advocates, and the general public. Other commenters believed that the current dissemination language is too broad, and that it would create a burden on MCOs to have to disseminate guidelines to all providers and all enrollees. Others were simply unclear as to what the words disseminate "as appropriate" entailed. We believe that guidelines should be disseminated to all providers who are likely to deliver the type of care that is the subject of the guideline (e.g. an MCO need not disseminate guidelines on childhood immunizations to its adult specialty surgeons). We also believe that enrollees with particular health concerns; e.g., asthma, may reasonably want to know if an MCO or PHP has adopted any particular guidelines on asthma care (such as those promulgated by the National Institutes of Health), and if so, would want to receive a copy of the guidelines. To clarify this section, and the intentions of the regulatory language regarding dissemination, we are revising the regulation at § 438.236(c)to read as follows: "Each MCO and PHP disseminates the guidelines to all affected providers, and upon request to enrollees and potential enrollees."

13. Quality Assessment and Performance Improvement Program (Proposed § 438.340)

Proposed § 438.340 required each MCO and PHP that contracts with a State Medicaid agency to have an ongoing quality assessment and performance improvement program, and specified the basic elements of such a MCO and PHP program. Under proposed § 438.340(b), MCOs and PHPs were required to: (1) Achieve minimum performance levels on standardized quality measures, using standard measures required by the State; (2) conduct performance improvement projects; and (3) have in effect mechanisms to detect both underutilization and overutilization of services. Proposed § 438.340(c) provides for minimum MCO and PHP performance levels to be established by the State. Proposed § 438.340(d) established criteria for performance improvement projects, requiring, among other things: (1) the State to establish contractual obligations for the number and distribution of projects among specified clinical and non clinical areas; and to specify certain non clinical focus areas to be addressed by performance improvement projects; (2) that each MCO and each PHP assess its performance for each project based on systematic, ongoing collection, and analysis off valid and reliable data on one or more quality indicators; (3) that each MCO's and each PHP's interventions result in improvement that is significant and sustained over time; and (4) that each MCO and each PHP report the status and results of each project to the State agency as requested. Proposed § 438.340(e) required the State to review, at least annually, the impact and effectiveness of each MCO's and each PHP's quality assessment and performance improvement program; and authorized the State agency to require each MCO and each PHP to have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

Comment: Several commenters believed that States could be faced with the loss of FFP when MCOs fail to achieve minimum performance levels, since meeting these levels is a requirement under proposed § 438.340(b)(1), and section 1903(m) of the Act requires that requirements under section 1932 of the Act be met as a condition for FFP. These commenters believed that this would give States an incentive to set performance levels that are low enough to be easily achieved. The commenters felt that the States needed the flexibility to make exceptions for MCOs and providers with high-risk patient caseloads.

Response: We would not expect to deny FFP to any State that establishes a Quality Assessment and Performance Improvement Program that meets the requirements in the regulations, even if an individual MCO or PHP might not achieve required performance levels in a single instance. Therefore, we do not agree that States will establish low minimum performance levels because of fear of loss of FFP. States are responsible for judging MCO and PHP performance in meeting the levels. We intend that the minimum performance levels be set at levels that can realistically be achieved. We require States to consider data and trends in managed care and fee-for-service in setting the levels. This is key to the process of quality improvement that we establish in this regulation.

Comment: One commenter believed that phase-in of full compliance with the imposed standards, and ongoing improvement over time should be allowed.

Response: As stated above, we believe that these regulations allow for flexibility. We believe that all MCOs and PHPs should be responsible for measuring their performance using standard measures set by the State, meet State-established minimum performance levels and conduct performance improvement projects. These are basic elements of a quality improvement program.

Comment: Several commenters were concerned that the proposed rule did not expressly require States to study care across the spectrum of enrolled populations, or to establish minimum quality measures relevant to all enrollees.

Response: For performance improvement projects, the regulation specifies four clinical areas that must be addressed over time. We intend that these areas (that is, prevention and care of acute and chronic conditions, high-volume services, high-risk services, and continuity and coordination of care) to apply to all enrolled populations. We do not specify that States must use measures of performance that address all conditions affecting all enrollees, because the state-of-the-art and limitations on resources do not allow this. However, in response to this comment, and other comments discussed in section II. C. above, we have added a provision at § 438.240(c)(2)(ii)(A) that permits us to specify standardized quality measures to be used by MCOs and PHPs. This provides us with the opportunity to specify measures for subpopulations of Medicaid enrollees and we could use this authority if a State failed to address certain subpopulations of enrollees. In addition, also in response to this and other comments, we have added at § 438.240(b)(4) a requirement that MCOs and PHPs must have in effect mechanisms to assess the quality and

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appropriateness of care furnished to enrollees with special health care needs.

Comment: Several commenters believed that minimum performance levels should not be set below established compliance levels, for example in EPSDT, even if the State/MCOs are well below these standards at present.

Response: While we permit States to set minimum performance levels for their MCOs and PHPs, this authority does not diminish the responsibility of States to meet performance levels established by law, such as conducting EPSDT screening and providing EPSDT services.

Comment: Several commenters believed that the Federal government should develop over time performance measures, and set minimum performance levels, based on an aggregation of data submitted by the MCOs.

Response: We agree with this comment. In the final rule with comment period, in response to this comment and other comments discussed in section II. C. above, we have added a provision (§ 438.204(c)) that requires States to include among their strategies, performance measures and levels prescribed by us. This does not reduce the State's authority to set minimum levels for MCOs and PHPs. We expect that States will pass on to MCOs and PHPs responsibility to meet Federally-established performance levels in order for the States to meet their own targets.

Comment: One commenter read proposed § 438.340(c)(2)(i) to imply that States cannot impose standards on MCOs in addition to those specifically allowed by this regulation. The commenter also believed that proposed § 438.340(c)(6), which allows States to require the MCO to undertake performance projects specific to the MCO, and to participate annually in statewide performance improvement projects, could be read to prevent the State from being able to go further. The commenter suggested deleting §§ 438.340(c)(2)(i) and (c)(6).

Response: Section 438.240(c)(2)(i) of the final rule with comment period permits States to choose how many performance measures and performance measurement projects to require from their MCOs and PHPs. It sets as a minimum requirement that MCOs and PHPs measure, report to the State, and conduct performance improvement projects (PIPs). This regulation does not prohibit a State from imposing standards in addition to those specifically provided for in the regulation. Neither does it prohibit the State from imposing a greater number or diversity of performance improvement projects specific to a given MCO or PHP or on a statewide basis.

Comment: One commenter believed that the level of detail for quality assessment and performance improvement left little flexibility for States to accommodate the special needs of newly formed MCOs that may have limited resources and experience with such activities required during their initial contract period.

Response: States have considerable flexibility in determining how many projects an MCO or PHP must conduct, the areas to be addressed by the projects, the scope of the projects, and the amount of improvement expected. We believe this latitude is sufficient for States to address the circumstances of new MCOs or PHPs and those with fewer resources than others.

Comment: Several commenters were concerned that prospectively determined, quantifiable quality improvement goals could be difficult for MCOs and PHPs to achieve, as they do not control all factors impacting such improvement. They believed that circumstances outside the control of the MCO could make it difficult or impossible to complete a study and collect clean data. These commenters felt that States needed flexibility to accommodate these problems appropriately, without facing sanctions, when noncompliance occurs as a result of factors beyond the control of the MCO.

Response: As stated in the responses to several comments above, we believe these regulations provide States with considerable flexibility to set requirements for their MCOs and PHPs. States also have flexibility in deciding when sanctions should be imposed on MCOs and PHPs. Also, while we agree that some factors that affect quality improvement may be outside of the MCO's or PHP's control, we believe that many factors are within the control of MCOs or PHPs, and that MCOs and PHPs should be held accountable for quality improvement.

Comment: Several commenters believed that we should require States to allow MCOs sufficient time to implement programs and systems. They were concerned about the total administrative burden being imposed by the proposed rule (for example, the requirement that MCOs maintain health information systems that collect, analyze, integrate, and report necessary data).

Response: We do not agree that States should be able to postpone the Quality Assessment and Performance Improvement (QAPI) provisions to give MCOs or PHPs the time to develop programs and systems. MCOs and PHPs now have the responsibility to monitor care, and to do this requires that they have programs and data that can be used to measure their performance.

Comment: One commenter did not believe new requirements on MCOs should be imposed unless specific additional funding covering the costs of such requirements is made available.

Response: In this final rule with comment period we are replacing the upper payment limit on payments to MCOs and PHPs with a different mechanism to contain managed care costs. This new method will allow for additional costs to be considered in setting capitation rates including the costs of complying with QAPI requirements.

Comment: Another commenter wanted us to review existing QI projects that MCOs are conducting as part of HEDIS reporting and NCQA accreditation, so as not to duplicate measures and increase administrative costs.

Response: The relationship in Medicaid is between the State and the MCO or PHP, not between us and the MCO or PHP. In establishing these requirements, nothing in the regulation prohibits States from considering other QI projects their MCOs are conducting, and we would encourage States to do so.

Comment: Several commenters believed that State agencies should consider historical MCO and FFS Medicaid performance data and trends to determine the appropriateness of quality measures. They also believed that performance levels adopted by States should be reasonably attainable. They asked that the following preamble language be inserted into the regulation text, "In establishing minimum performance levels, the State agency should ensure that the targets are achievable, meaningful, and equitable. The State agency must consider historical plan and FFS Medicaid performance data and trends."

Response: Section 438.240(c)(2)(ii)(B) of the final rule with comment period provides that States should "consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State," in setting minimum performance levels. This addresses the issues of achievability and equity.

Comment: Several commenters believed that a predefined percentage, like QISMC's standard of a 10 percent reduction in deficient care, would stifle creative approaches to QI. They also object to the 10 percent standard because it is inconsistent with NCQA's

"meaningful" standard for improvement, based on effort. The same commenters also believed that the 10 percent standard could cause MCO not to pursue QI projects for which a 10 percent reduction was difficult to predict. The commenters would like to see the defined percentages removed from the preamble, and in its place have NCQA's "meaningful" improvement standard inserted.

Response: The 10 percent reduction rule from QISMC is in the preamble as an example only and is not a requirement. However, we believe that the true test of quality improvement is measurable improvement. This requires that a numeric benchmark or percentage improvement goal be in place. Therefore, we do not agree that a standard of "meaningful" improvement is sufficient. The regulation does not require the use of the 10 percent reduction standard. States have the discretion to establish specific numeric, objective improvement levels themselves.

Comments: Many commenters believed that without specific instructions from us, stating that MCOs must identify and monitor care delivered to populations with special health care needs enrolled in an MCO, it is unlikely that results from QAPI will reflect the experiences of these groups. They also believed that HEDIS for Medicaid does not include many measures specific to children or adults with special health care needs. The commenters would like to see specific quality assurance activities and outcome measures, focusing on the various populations with special health care needs, to be developed in conjunction with advocates and experienced providers in these areas.

Response: We agree that populations with special health care needs should not be left out of MCO and PHP quality assessment and performance improvement activities. Section 438.240(d)(2) of the final rule with comment period requires that performance measurement and quality improvement projects address the entire Medicaid enrolled population in an MCO or PHP to whom the measure is relevant. The regulation also requires that all enrolled populations be measured over time. As discussed above, we have added provisions permitting the Secretary to specify annual quality measures and performance improvement project topics for MCOs and PHPs. Through this mechanism, we have the authority to direct States, MCOs, and PHPs to address subgroups of enrollees should the States fail to do so. To make explicit the requirement that populations with special health care be included in MCO and PHP quality assessment and performance improvement activities, we have added a new item at § 438.240(b)(4) requiring that MCOs and PHPs have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We note however that more effective and plentiful quality indicators to measure the quality of care delivered to individuals with special health care needs are still needed.

Comment: One commenter believed that in addition to reporting performance measures, States or medical auditors should also target and access medical records to study overall treatment of specified conditions and adherence with treatment protocols.

Response: We do not agree that we should require States (in addition to using performance measures and quality assessment and performance improvement projects) to separately review medical records to study overall treatment of specific conditions and monitor the use of treatment protocols. While States are free to undertake this activity, we believe that the elements of State quality assessment and performance improvement strategy will be sufficient to monitor health care quality (including adherence to treatment protocols).

Comment: One commenter favored outcomes measured through both process indicators and "quality of life" indicators.

Response: The term performance measure, as we are using it, provides the option for States to use process and outcome measures, including quality of life indicators.

Comment: A commenter recommended a requirement that HEDIS be the standardized tool for QAPI, instead of leaving this up to States.

Response: We believe that the choice of performance measures and measurement tools should be left to the discretion of individual States. Many States now use a number of HEDIS measures; however, we note that HEDIS as a measurement set has limitations and may not serve the complete needs of States or fully address the Medicaid population.

Comment: A commenter believed that the statement, "projects are representative of the entire spectrum of clinical and non-clinical areas," should be qualified so that projects are not required to cover the entire spectrum every year, but should focus on one area each year, as long as the subject varies over time.

Response: The proposed rule did not, and the final rule with comment period does not, require that all areas be addressed each year. States may specify the number of projects its MCOs and PHPs must conduct, and the requirement would be met if the State requires only one project. We have clarified the final rule with comment period to state at § 438.240(d)(3) that States must require each MCO and each PHP or more to initiate one or more performance improvement projects per year.

Comment: One commenter asked if a successful NCQA review would be acceptable in lieu of the required yearly audit, since this would save administrative efforts and expense.

Response: As discussed above in section II. C., while section 1932(c)(2) of the Act provides for external quality review (EQR) requirements to be met based on other accreditations, there is no such authority for the requirements under section 1932(c)(1) of the Act (as is the case with respect to similar requirements under the Medicare+Choice program).

Comment: A commenter was concerned about the fact that many subpopulations served by an MCO were small in number, and believed it may be difficult to produce any meaningful results for quality assurance and performance measurement. The commenter asked if aggregate results of a performance project across several MCOs of a national company would be acceptable.

Response: States are accountable for the quality of care for their Medicaid beneficiaries, and must be permitted to set the requirements for the MCOs and PHPs with which they contract. Therefore, we will not modify the regulation to permit MCOs or PHPs to aggregate data across States.

Comment: Several commenters wanted States to publish performance measurement tools and results of assessments. The commenters were concerned that no requirement exists that requires MCOs to provide information about quality assurance programs to enrollees and potential enrollees in Medicaid.

Response: While we have not provided in this final rule with comment period for the provision of information on MCO or PHP quality measures, this will be provided for in the final EQR regulation, as it is required under section 1932(c)(2)(A)(iv) of the Act.

Comment: Several commenters believed that self-reported quality measures should be subject to external validation by the State, and that State-

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defined measures and performance improvement projects should be required to use audited data.

Response: This type of external review is provided for in section 1932(c)(2) of the Act, which is being implemented in a separate rulemaking.

Comment: Some commenters did not believe that the use of the word benchmark in the preamble discussion of proposed § 438.340(d)(9) was clear. Yet they believed that benchmarking is one of the key terms for QI, and needs to be expanded in the final rule with comment period.

Response: We agree that the term "benchmarks" can have many connotations, and have deleted it from the final rule with comment period.

Comment: A commenter requested that we include a definition of "high-volume" or "high-risk" services. The commenter believed this should be defined to require the review of mental health services, and did not believe that mental health services would be considered high-volume or high-risk without these services being expressly included in the definition.

Response: We have chosen not to define "high-volume" or "high-risk" services, as they differ relative to individual MCOs or PHPs and the populations they serve. For example a PHP behavioral health carve-out would only include mental health services. We believe States are in the best position to define this for their MCOs and PHPs.

Comment: One commenter urged that cultural competence be included as a nonclinical area of performance measurement in the regulation.

Response: We agree that cultural competence is a nonclinical area that may be a topic of a performance improvement project. In response to this comment, in § 438.240(d)(5)(iii) of the final rule with comment period, we have added "cultural competence" as a non-clinical area.

Comment: Several commenters asked that we establish a process for detailed discussions with MCOs to better understand the operational issues associated with implementing the proposed standards of the regulation. Two of the commenters desired discussions with us to define short- and long-term goals for Medicaid managed care quality oversight and to arrive at a focused strategy. For example, they believed that HEDIS was undermined by the ability of States to establish an independent system of quality improvement strategies.

Response: We are working to provide technical assistance tools to the States. In turn, the States will be able to work with MCOs and PHPs, and MCOs and PHPs will have an opportunity to provide public input to the quality strategy in their respective State.

Comment: A commenter believed that more "horizontal" lines of communication regarding performance improvement and measurement needed to occur, in addition to the current "vertical" lines of communication between the States, MCOs, and HCFA. For example, they would like to see communication take place across MCOs and across State agencies.

Response: We agree that communication across organizational components is of considerable value, and this function is currently addressed through membership organizations, such as the American Public Human Services Association (APHSA). These organizations can assist with the exchange and gathering of information through conferences and publications.

14. Health Information Systems (Proposed § 438.342)

Section 1932(c)(1)(iii) of the Act requires States that contract with Medicaid managed care organizations to develop a State quality assessment and improvement strategy that includes procedures for monitoring and evaluating the quality and appropriateness of care and services to enrollees that reflect the full spectrum of the population enrolled under the contract, and that includes requirements for provision of quality assurance data to the State, by MCOs using the data and information set that the Secretary has specified for use under the Medicare+Choice program, or such alternative data as the Secretary approves, in consultation with the State.

In proposed § 438.342, we provided that the State ensure that each MCO and PHP maintain a health information system that collects, analyzes, integrates, and reports data that can achieve the objectives of this part. Under the proposed rule, we specified that the system should provide information on areas including, but not limited to, utilization, grievances, disenrollments and solvency. Furthermore, we proposed that the State ensure through its contracts with MCOs and PHPs that each MCO and PHP be required to: (1) Collect data on enrollee and provider characteristics, as specified by the State, and on services furnished to enrollees; (2) ensure that the data received from providers are accurate and complete by verifying the accuracy and timeliness of reported data, screening the data for completeness, logic and consistency, and by collecting service information in standardized formats to the extent feasible and appropriate; and (3) make available all collected data to the State and HCFA. An MCO or PHP was permitted to use any method or procedure for data collection, so long as it could demonstrate that its system achieves the objectives of this standard.

Comment: Several commenters believed that the regulation should specifically require appropriate acquisition of data by MCOs concerning race, ethnicity, sex, age, disability, and primary language. These commenters believed that without the collection of such data, compliance and enforcement with civil rights laws including Title VI and the ADA would be difficult.

Response: All of the above, with the exception of age and sex, are explicitly addressed in this final rule with comment period. Information on disability will be captured through the initial and ongoing assessment provisions of § 438.208. Primary language spoken is addressed in the language requirement of § 438.10(b). As discussed previously, race and ethnicity are addressed in § 438.204(b)(1)(iii). However, sex and age are fundamental pieces of demographic information that are essential if MCOs and PHPS are to be able to comply with the information system requirements in § 438.242. Age and sex are such routinely collected demographic information, that we do not believe it necessary to expressly mandate their collection in the regulation.

Comment: Several commenters urged that the timing and costs associated with implementing the regulations be evaluated. These commenters suggested that we allow more time to comply with the regulation, because of millennium activities that are utilizing the majority of State and MCO resources. Several other commenters questioned how funding for this activity would occur, as they did not believe they had the resources to meet the requirements.

Response: Given the passage of time since January 1, 2000, "Y2K" activities should no longer be utilizing State systems resources. We will work with States to assist them in implementation of this final rule with comment period. As for the funding for implementing the requirements, new Medicaid State agency system development design and implementation is funded at 90 percent and maintenance to existing systems is matched at 50 percent.

Comment: Several commenters questioned the logic of including solvency information in the same system as enrollee-specific data such as utilization, grievances and disenrollments. These commenters did not believe solvency information should

be included as a mandatory element of a health information system. The commenters believed that a State's current standards for reporting and format should be sufficient.

Response: We agree that this is not the appropriate place to capture solvency information. In response to this comment, we have removed the reference to solvency from § 438.342(a).

Comment: Several commenters found the requirement that MCOs make all collected data available to both the State and HCFA excessive and redundant since the State must also submit data to us. The commenters noted that it is the MCO's business to manage their population and to report required data to the State. Duplicative reporting requirements could increase the administrative expenses of MCOs, and make contracts with State Medicaid programs less attractive to commercial HMOs.

Response: We agree that it is burdensome to request all information to be sent to both the State and to HCFA. In response to this comment we have provided in § 438.242(b)(3) of this final rule with comment period that MCOs and PHPs make all collected data available to the State as required in subpart D, and to us upon request.

Comment: Several commenters recommended that we establish national data collection standards for States to use for the collection of encounter data, EPSDT, and network information. These commenters specified that these standards should be based on current data elements that could be systematically produced by providers, and captured by MCOs and PHPs.

Response: We desire to have consistency of information, and to have national standards in those cases where it makes sense to do so. However, we must also balance that desire with providing States with the necessary flexibility to implement their individual Medicaid programs. We are working on several initiatives to standardize data collection on a national level. The Health Insurance Portability and Accountability Act (HIPAA) requires us to work toward the goals recommended by several of the commenters.

E. Grievance Systems (Subpart F)

Background

Proposed subpart F was based on section 1902(a)(3) of the Act (requires a State plan to provide an opportunity for a fair hearing to any person whose request for assistance is denied or not acted upon promptly), section 1902(a)(4) of the Act (authorizes the Secretary to specify methods of administration that are "necessary" for "proper and efficient administration"), and section 1932(b)(4) of the Act (requires that MCOs have an internal grievance procedure under that a Medicaid enrollee, or a provider on behalf of an enrollee, may challenge the denial of coverage of or payment by the MCO).

In this subpart, we proposed regulations that lay out the required elements of the grievance system required under section 1932(b)(4) of the Act, and how it interfaces with the State fair hearing requirements in section 1902(a)(3) of the Act; describing what constitutes a notice (that is, the first step in the grievance system); addressing complaints and grievances, including timeframes for taking action; the process for actions; how grievances are to be handled; and how enrollees are to be notified of the resolution of grievances. In addition, the proposed rule provided for expedited resolution of grievances and appeals in specific circumstances; addressed the requirement for continuation of benefits; included the requirement that MCOs and PHPs clearly and fully inform enrollees of the entire system so that they are aware of it and how to use it; specified what materials must be provided when notifying an enrollee, and the requirements for those materials; and lay out the requirements relating to record keeping, monitoring, and the consequences of noncompliance.

1. Statutory Basis and Definitions (Proposed § 438.400)

Definitions of terms that would apply for purposes of proposed subpart F are found in § 438.400 of the proposed rule, in that the following terms have the indicated meanings:

Complaint was defined as any oral or written communication made by or on behalf of an enrollee to any employee of either the MCO, PHP, its providers, or to the State, expressing dissatisfaction with any aspect of the MCO's, PHP's, or provider's operations, activities, or behavior, regardless of whether the communication requests any remedial action.

Enrollee was defined for purposes of subpart F, as an enrollee or their authorized representative.

Governing body was defined as the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance was defined as a written communication, submitted by or on behalf of a Medicaid enrollee expressing dissatisfaction with any aspect of the MCO's, PHP's, or providers's operations, activities, or behavior that pertains to the following: (1) The availability, delivery, or quality of health care services, including utilization review decisions that are adverse to the enrollee; (2) payment, treatment, or reimbursement of claims for health care services; or (3) issues unresolved through the complaint process provided for under the proposed rule.

Comment: Some commenters questioned HCFA's statutory authority to promulgate the detailed requirements in proposed subpart F, given the limited amount of text in section 1932(b)(4) of the Act.

Response: As noted above, these rules are based only in part on section 1932(b)(4) of the Act. We believe that those portions of subpart F that address an MCO's internal grievance system constitute a reasonable implementation of authority under section 1932(b)(4) of the Act. This rule is also based on our general authority under section 1902(a)(4) of the Act, and on the State fair hearing requirements in section 1902(a)(3) of the Act, that prior to this final rule with comment period have not been implemented in regulations that apply to managed care enrollees. We believe that the requirements in subpart F of this final rule with comment period are warranted in order to ensure that MCOs have an effective and useful internal grievance process, as required under section 1932(b)(4) of the Act, and in order to ensure that MCO and PHP enrollees have access to the same State fair hearing process that fee-for-service enrollees have under subpart E of part 431. This final rule with comment period applies the general rights in section 1902(a)(3) of the Act to managed care enrollees both in MCOs and PHPs. In the case of PHPs, the requirements in subpart F are based both on section 1902(a)(3)of the Act and, in the case of longstanding PHP regulations, they are generally on our broad authority under section 1902(a)(4) of the Act to specify methods necessary for proper and efficient administration. In the case of MCOs, we are also implementing the requirements in section 1932(a)(4) of the Act, and setting forth what we believe is necessary to adequately meet these requirements as we have interpreted them. The analysis of key court decisions has also guided the development of these final regulations, just as the Supreme Court's *Goldberg* v. *Kelly* decision was incorporated in the State fair hearing regulations under part 431, subpart E to which the MCO and PHP grievance system is linked.

Comment: Some commenters believed that while we took case law into account in proposed subpart F, HCFA did not go far enough to protect

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Medicaid managed care enrollees' rights in the following three areas: (1) Continuation of benefits; (2) direct access to State fair hearings; and (3) time frames for action.

Response: We have carefully considered all comments on these three issues and address each issue below in the context of our discussion of regulation language that pertains to the issue. In general, we recognize that we have a responsibility to protect Medicaid enrollees and ensure their rights. To meet this responsibility, we have established a set of Federal protections that apply to Medicaid enrollees regardless of their State of residence. This will ensure a minimum degree of consistency with the level of protection afforded Medicare beneficiaries. States may choose to add to these protections by exceeding the minimum levels required by this regulation.

In developing these regulations, we relied heavily on the Consumer Bill of Rights and Responsibility (CBRR). We also examined the grievance procedures of many States, and considered all comments on these issues. We have carefully documented, tracked, and analyzed each decision we have made with respect to our consideration of commenters' suggestions in light of the guiding principles in the CBRR.

Comment: We received comments that suggested that we specify a different grievance process for enrollees with addiction or mental health issues or, at a minimum, make specific mention of these concerns in the regulation, and adopt the principles of the Model Managed Care Consumer Protection Act proposed by the President's Commission on Model State Drug Laws. Under this Act, the patient, family, or program must be permitted to appeal directly outside the MCO or PHP. These commenters also suggested that there be a separate office responsible for the addiction and mental health grievance process and to advocate for patients and families.

Response: We do not agree that there should be separate grievance processes, procedural requirements, or offices based on diagnosis-specific or population-specific criteria. The grievance system set forth in this regulation is designed to address the needs of all Medicaid enrollees, including those with special health care needs. PHPs providing mental health or substance abuse services are also subject to these provisions, that we believe adequately protect individuals with these conditions.

Comment: Many commenters strongly recommended that we eliminate the "complaint" category set forth in the proposed rule, while others supported the broad definition of "complaint" as separate from "grievances" subject to a State fair hearing, but recommended changes to better distinguish these categories. The comments advocating the elimination of a separate complaint category are first presented below followed by the comments supporting retention of the two categories but recommending changes related to these categories.

In support of eliminating separate categories, one commenter contended that it has been well documented that Medicare+Choice organizations misidentify what should be appeals under the Medicare+Choice appeals system as "grievances," are not subject to external administrative and judicial review under that system. The commenter believed that HCFA should eliminate the "complaint" level, because the commenter saw it as the equivalent of "grievances" under Medicare+Choice, and in order to avoid confusion and prevent the potential mishandling of appeals. One commenter noted that under the proposed rule, an MCO or PHP could fail to acknowledge an appeal and provide the required notice to enrollees simply because the enrollees failed to "use the magic words" when filing their dispute.

Another commenter believed that because the NPRM does not require that complaints be monitored and tracked as closely as grievances, MCOs and PHPs have an incentive to categorize a dispute as a complaint. The commenter stated that this could benefit the MCO or PHP because complaints would not be reflected in the MCO's or PHP's performance ratings, and MCOs and PHPs should not be given the authority to decide whether an issue is a complaint or grievance.

Another commenter expressed the view that a complaint process does not protect the enrollee and, therefore, should be deleted from the regulation. This commenter believed that MCOs and PHPs would be able to resolve complaints on a more informal basis through the customer service department, while enrollees' rights to a formal appealable grievance would remain.

One commenter noted that many States have a single definition for a "grievance" in order to avoid confusion for MCOs, PHPs and enrollees. The commenter felt that this simplifies reporting and facilitates the resolution of a complaint. One commenter said that all issues should be tracked as grievances whether submitted orally or in writing. Another said that enrollees should be able to address any problem that they have with the MCO, PHP, or a provider without getting trapped or confused by a labeling and tracking process. Several commenters said the documentation of all complaints as well as grievances should be required.

A commenter felt that allowing both an informal complaint and a formal grievance process has led to confusion of enrollees, MCOs and PHPs, as well as to inappropriate transfers and unnecessary delays. This commenter believed that there have been many instances of MCOs and PHPs re-classifying grievances as "complaints" in order to evade review or to slow the dispute resolution process, and that an enrollee's rights may hinge on this classification process.

One commenter believed that enrollees should be given the right to request expedited resolution of complaints and these should be treated in the same manner as grievances were under the proposed rule, for when expedited resolution is requested by the enrollee or the provider.

One commenter noted that under existing fee-for-service regulations, all disputes are dealt with in a uniform manner and all that is required to obtain a hearing is a "clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority." According to this commenter, this [42 CFR 431.201] definition allows for differences in presentation of disputes and does not require beneficiaries to refer to rules and definitions when presenting them. In the commenter's opinion, many beneficiaries do not have the capacity to distinguish between a "complaint" and a "grievance."

Other commenters agreed that there should be distinct categories for complaints and grievances subject to appeal, but suggested changes to how these categories are defined and the provisions applying to each. These comments follow.

One commenter believed that complaints that are not resolved to the beneficiary's satisfaction within 30 days after filing should automatically become appealable grievances.

Another commenter stated that if the complaint process is not eliminated, it should be regulated to the same extent as the grievance process was under the proposed rule. The commenter suggested that the regulation should provide more guidance on how complaints are to be handled. The regulation should also specify who distinguishes a complaint from a grievance and the qualifications of this decision-maker. The distinction between a complaint and grievance, as used in the proposed rule, needed to be clarified with examples, in the commenter's view. Matters do not always squarely fit within one category.

One commenter said that the terms "complaint" and "grievance" should be clarified in the regulation, and that the complaint process would address those communications that were not grievances under the proposed rule. The commenter provided examples of topics that would likely be addressed as complaints in this process for example, waiting times, operating hours, demeanor of health care personnel, and the adequacy of facilities.

A commenter noted that the preamble's characterization of complaints differs from the regulatory definition. The commenter stated that the regulation defines complaints but includes no guidance on how they are to be handled. One commenter noted that the preamble says that complaints include problems involving waiting times and operating hours. However, the commenter noted, if a beneficiary must wait three weeks for an appointment during limited afternoon hours, this clearly is an availability and quality problem which should be defined as an appealable grievance.

One commenter believed that the distinction made in the proposed rule between complaints and grievances was subjective and suggested that the proposed rule's requirement that grievances be in writing would greatly reduce the number of disputes handled through the grievance process, because of the difficulty enrollees may have in filing a written appeal. The commenter further noted that some problems require immediate response, which a telephone communication allows.

One commenter thought that grievances which result from unresolved complaints should apply only to unresolved complaints that are related to service delivery or treatment. This commenter believes that appeals should be available only for "actions" (that is, the denial, reduction, or termination of services), and that frivolous complaints not resolved to the enrollee's satisfaction should not be entitled to a State fair hearing. This commenter was concerned that the proposed regulation opens up the State fair hearing process to virtually any expression of dissatisfaction with the operation of the MCO or PHP.

A final commenter recommended that we use the terms used in the Medicare+Choice regulations to simplify MCO and PHP documentation, and MCO and PHP enrollee education. According to the commenter, consistent use of terms would also make life easier for providers and for enrollees who participate in both the Medicare and Medicaid programs.

Response: We agree with the commenters who were confused by the way the term "grievance" was used in the proposed rule, particularly in light of Medicare+Choice's use of the term "grievance" as a complaint that is not subject to external review or a State fair hearing. Our use of the term "grievance" in the proposed rule was based on the fact that the Congress, in section 1932(b)(4) of the Act, referred to an internal "grievance procedure under that an enrollee could challenge a denial of payment or coverage." The Congress used the term "grievance" to refer to a type of appeal that under the Medicare+Choice program was subject to appeal and was under that program's terminology not a grievance. It was for this reason that we used the term "complaint" to refer to the type of problem labeled a "grievance" in the Medicare+Choice program. In order to adopt an approach more consistent with Medicare's (to avoid confusion for organizations that participate in both programs). In this final rule with comment period, we are deleting the use of the word "complaint," and using the term "grievance" to refer to the same types of enrollee problems. Also, in this final rule with comment period, like in the Medicare+Choice program, we establish two mutually exclusive categories: (1) a "grievance," that is not subject to the State fair hearing process (called a "complaint" in the proposed rule), and (2) an "appeal," that is subject to a State fair hearing (encompassed in the term "grievance" in the proposed rule). Because the Congress employed the term "grievance procedure" in section 1932(c)(4) of the Act, we continue to use the term "grievance system" to refer to the overall grievance and appeal system provided for in subpart F.

Specifically, in response to the above comments, we have in this final rule with comment period: (1) dropped the definition of "complaint;" (2) changed the definition of "grievance" to roughly track the definition of "complaint" used in the proposed rule; and (3) added a new definition of "appeal" to § 438.400 so that grievance and appeal are two mutually exclusive categories. We agree with the commenters favoring the employment of two distinct categories because we believe that certain disagreements between the MCO or PHP and its enrollees should have a higher standard of review, and should be subject to a State fair hearing if the MCO or PHP decision is adverse to the enrollee. The term "appeal" also is used by most States for State fair hearing requests. In this final regulation, the term "appeal" is used to refer to requests for an MCO or PHP hearing, as well as, for a State fair hearing. As just noted, it is also the term used in Medicare and will reduce the burden on MCOs and PHPs for educating providers and dually-eligible enrollees.

To clearly distinguish between a grievance and an appeal, in this final rule with comment period, we have added a definition of "action" as the event that entitles an enrollee to file an appeal and defined a grievance as involving a matter other than an action. An action includes the following: (1) the denial or limited authorization of a requested service; (2) the reduction, suspension, or termination of previously authorized services; (3) the denial of payment, in whole or in part for a service, for a resident of a rural area with only one MCO or PHP; (4) the denial of a Medicaid enrollee's request to exercise their right to obtain services out of network; (5) the failure to either furnish, arrange or provide for payment of services in a timely manner; and (6) the failure of an MCO or PHP to resolve an appeal within the timeframes provided in the regulation. In addition, for a State agency, the denial of a Medicaid enrollee's request to disenroll is an action.

In response to comments that we should set out additional requirements for MCOs and PHPs when they are addressing complaints (now called grievances), we have added several requirements. In this final rule with comment period, we require that MCOs and PHPs ensure correct classification of grievances. We also provide examples of grievance issues in the regulation text (in a parenthetical in the revised definition of grievance). We specify maximum timeframes for MCOs and PHPs to dispose of grievances. We provide in § 438.406(a)(7)(ii) that grievances involving clinical issues and those regarding denials to expedite resolution of appeal be decided by a health care professional with appropriate clinical expertise. We also provide that while grievances are not subject to review at the State fair hearing level, they are subject to further review by the State at the request of the enrollee. We also provide that MCOs and PHPs must work with the State to dispose of grievances if the State considers the MCO or PHP response to be insufficient. In addition, the State must monitor these processes and incorporate that monitoring into its overall quality improvement strategy.

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Overall, we believe that this new approach will streamline the grievance and appeal process, eliminate confusion on the part of enrollees and providers, be more consistent with Medicare, and provide protection for enrollees.

Comment: Some commenters believed that the grievance and appeals provisions should apply to PCCMs, as well as, to MCOs and PHPs.

Response: We do not agree with the commenter's suggestion that the grievance and appeal provisions should apply to PCCMs. PCCMs are often individual physicians or small group practices and can not be expected to have the administrative structure to support a grievance process. Because PCCMs that are not capitated (capitated PCCMs would be subject to subpart F as PHPs) are reimbursed through the fee-for-service system, they are subject to the State fair hearing process described in 42 CFR 431 Subpart E. Moreover, as noted above in section II. D. with respect to the quality requirements in section 1932(c)(1) of the Act, the Congress made a conscious decision in section 1932(b)(4) of the Act to apply the grievance requirements only to MCOs in that section, notwithstanding the fact that other requirements in section 1932 of the Act apply to PCCMs. We believe it would be inconsistent with Congressional intent to apply grievance requirements to PCCMs. In the case of PHPs, the Congress was silent in section 1932 of the Act. We believe that because PHPs are paid on a risk basis like MCOs and have a financial incentive to deny care like MCOs, grievance and appeal protections are as important for PHP enrollees as they are for MCO enrollees.

Comment: One commenter urged that grievances and appeals be classified according to the type of denial (for example, a clinical determination should be subject to appeal). The commenter stated that this differentiation is important because denials of service may have a critical impact on the patient's health, unlike denials of payment and general grievances.

Response: In this final rule with comment period (§ 438.400(b)) the definition of "action" distinguishes what is subject to appeal from what is addressed as a grievance. In addition, we also distinguish between grievances involving quality of care issues and other grievances. Section 438.406(a)(7)(ii) of this final rule with comment period provides that grievances involving a clinical issue or a grievance of a denial of a request for expedited appeal must be decided by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

2. General Requirements (Proposed § 438.402)

Proposed § 438.402 stated the general requirements of the MCO and PHP grievance system, and required MCOs and PHPs to have a grievance system that includes a complaint (now referred to as grievance) process, a grievance (now called appeal) process, and a link to the State's fair hearing system. Proposed § 438.402 required the MCO and PHP to—

- Base its complaint (now grievance) and grievance (now appeal) process on written policies and procedures that, at a minimum, meets the conditions set forth in this subpart.
- Obtain the State's written approval of the grievance (now appeal) policies and procedures before implementing them.
- Provide for its governing body to approve and be responsible for the effective operation of the system;
- Provide for the governing body to review and resolve complaints (now grievances) and grievances (now appeals) unless it delegates this responsibility to a grievance committee.
- Provide through its grievance (now appeal) process clearly explained steps that permit the enrollee to appeal to the MCO, PHP, and to the State.
- Allow the enrollee a reasonable time to file an appeal, include for each step timeframes that take into consideration the enrollee's health condition and provide for expedited resolution of grievances (now appeals) in accordance with § 438.410, not substitute for the State's fair hearing system.
- Permit enrollees to appear before the MCO and PHP personnel responsible for resolving the grievance (now appeal), and provide that, if the grievance (now appeal) resolution decision is wholly or partly adverse to the enrollee, the MCO or PHP submits the decision and all supporting documentation to the State as expeditiously as the enrollee's health condition requires but no later than the following for—

++A standard resolution, no later than 30 days after receipt of the grievance (now appeal) or the expiration of any extension; and

++An expedited resolution, no later than 24 hours after reaching the decision.

Additionally, the State must either permit the enrollee to request a State fair hearing on a grievance (now appeal) at any time, or provide for a State fair hearing following and MCO or PHP adverse decision on the matter that gave rise to the grievance (now appeal).

Comment: Given the provision in proposed § 438.402(a) requiring a link between the grievance system under section 1932(b)(4) of the Act and the State fair hearing system, the right under proposed § 438.402(d) to a fair hearing (either directly, or following an adverse MCO or PHP decision), and language in the preamble to the proposed rule requesting comments on whether fair hearing timeframes should be revised, several commenters were prompted to comment generally on the State fair hearing process. Many of these commenters recommended substantial revisions to HCFA's State fair hearing regulations, and requested that HCFA convene a meeting to discuss proposed changes to those recommendations. The commenters agreed that the State fair hearing process needs to be revised, but there was no consensus on how it should be revised. Several commenters wanted Medicaid to adopt the same standards for the State fair hearing process that were proposed for the MCO and PHP internal grievance process. Other commenters wanted an expedited State fair hearing. Commenters suggested various timeframes which ranged from 24 hours to 15 days. Finally, one commenter wanted HCFA to eliminate extensions for State fair hearings provided for in the Medicaid manual.

Response: We have decided to postpone consideration of major modifications to the State fair hearing regulations generally and to develop an NPRM to propose changes to the State fair hearing rules. At that time we will also review the provisions in the Medicaid Manual related to fair hearings. We will consider using the negotiated rule-making process in developing this NPRM.

In response to these and other comments, however, this final rule with comment period does require, under §§ 438.408(j)(3)(ii) and 431.244(f)(2), expedited State fair hearings when a service has been denied and a delay in receipt of that service could jeopardize the enrollee's health. States must conduct a State fair hearing and issue a final decision on these cases as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receipt of the appeal.

Comment: Several commenters requested modifications to the State fair hearing regulations to allow MCOs and PHPs to become a party to the hearing. The commenters believed that the MCO or PHP should have an opportunity to present its position on the dispute at the hearing. Other commenters noted that several States have not recognized MCOs and PHPs as parties to State fair hearing.

Response: We agree that MCOs and PHPs should be parties to the State fair hearing and in response to this comment, have provided for this in the final rule with comment period at § 438.408(j)(2). As parties to the hearing, we believe it is clear that MCOs and PHPs are subject to the hearing decision. As parties to the hearing it will also be clear that an MCO or PHP can present its position at a State fair hearing which we think is appropriate because the MCO or PHP will be liable for providing and paying for a service if the State fair hearing officer overturns the decision.

Comment: Several commenters noted that some State fair hearing officers do not believe that they have jurisdiction over MCOs and PHPs and believe they lack authority to order MCOs and PHPs to take a particular action. These commenters believed it would be very helpful for the regulations to provide that both the agency and the State fair hearing officer have authority to order the MCO or PHP to provide a required service or perform a corrective action, including reimbursing for services.

Response: We agree with commenters that State fair hearing officers should have jurisdiction over Medicaid MCOs and PHPs. As just noted, we have provided at § 438.408(j)(2) that MCOs and PHPs are parties to a State fair hearing appealing their decisions. With this addition, we think it will be clear that the presiding officer of the proceeding has jurisdiction over a party to the hearing.

Comment: One commenter recommended that an expedited State fair hearing be available to Medicaid beneficiaries who are not enrolled in managed care. The commenter noted that increasingly, fee-for-service arrangements use prior authorization processes, and as in managed care, the care under review may be urgently needed.

Response: While we believe there is merit in the commenter's suggestion from a policy perspective, we are not amending the State fair hearing regulations to provide an expedited hearing in fee-for-service situations, because the proposed regulation addressed Medicaid managed care, not the fee-for-service delivery system. We plan to develop an NPRM to revise the State fair hearing regulations as they pertain to fee-for-service and managed care. When this NPRM is published, the public will be invited to comment on these proposed rules. In this final rule with comment period we revise the State fair hearing regulation only to provide an expedited timeframe for resolution of appeals involving MCO or PHP denials of services in situations that require expedited resolution. This matter was put before the public in our proposed rule.

Comment: Several commenters recommended that HCFA establish more specific standards for the State fair hearing processes, including specific standards regarding the qualifications of hearings officers. Commenters were concerned with State use of hearing officers who lack adequate understanding of clinical issues when a hearing involves a denial based on lack of medical necessity.

Response: We have not addressed this concern in this final rule, comment period. As with judicial review, the presiding officer is usually not medically trained. It is the responsibility of both parties to explain the matter in a way that can be understood by the adjudicator. Parties may retain experts to present technical issues. In addition, as provided in section 431.420, provides that if the hearing officer finds it necessary, they may order an independent medical assessment to be performed at State expense.

Comment: Several commenters recommended that we require States to consult with beneficiaries, advocates, and the State MCAC when developing State grievance requirements.

Response: In § 438.202(c) we require that States provide for the input of beneficiaries and stakeholders in the development of their quality strategies. Grievance and appeal procedures must be addressed as part of State quality strategies. This provides an opportunity for beneficiary and stakeholder input. We are not specifying the mechanisms States must use to receive input. Therefore, States may, but are not required to, consult with their MCAC on grievance requirements.

Comment: Several commenters supported the requirement in proposed § 438.402(b)(3) that the MCO and PHP grievance process must be approved by the MCO's or PHP's governing body. Other commenters were concerned that requiring the governing body to approve and be responsible for the operation of the process was unnecessary and inefficient. They believed that the State should determine whether MCOs and PHPs have appropriate staff to handle the grievance process.

Response: Our intent is to ensure the involvement of individuals with authority to direct corrective action should systemic changes be required. The regulations at § 434.32, that this regulation replaces, required that the MCO ensure the participation of individuals with authority to require corrective action. We retain this requirement in this final rule with comment period. The actual processing of grievances and appeals can be delegated to a grievance committee of less senior employees.

Comment: Several commenters thought that the 90-day period for filing appeals following the notice of action was burdensome to MCOs and PHPs, because MCOs and PHPs need more timely filing by enrollees in order to assess their potential payment liabilities. Another commenter noted that § 431.221 of the current regulation, that is cited in proposed § 438.402(c)(1)(ii) provides that the State must allow for a reasonable time, not to exceed 90 days for beneficiaries to file an appeal. One commenter implied that the proposed rule states that the State must allow a minimum of 90 days for filing of appeals is inconsistent with the current regulation and that application of the proposed rule would result in different standards for managed care and fee-for-service appeals.

Response: Our intent in the NPRM was to mirror the filing timeframes for the State fair hearing, that is, a reasonable amount of time up to 90 days. This is reflected in the parenthetical in proposed § 438.402(c)(1)(ii) stating "as provided under the fair hearing process at proposed § 431.221." Our reference to 90 days was incorrect because it did not reflect the fact that the regulation we intended to incorporate provided for "up to" 90 days. We therefore have revised this final rule with comment period to mirror § 431.221. In addition, we have incorporated in the regulation the longstanding policy at § 2901.3 of the Medicaid Manual that beneficiaries be given a minimum of 20 days to file an appeal. We believe that this policy more specifically defines the requirement in the current regulation that beneficiaries be given "a reasonable amount of time" to file an appeal. We believe that placing this requirement in this final rule with comment period will increase public awareness of this standard.

In the notice of action, MCOs and PHPs must include information on the deadline for filing an appeal. Further, in States that do not require that enrollees appeal first through the MCO or PHP grievance system, the notice of action must also state that the enrollee may appeal directly to the State for a fair hearing.

Comment: We received several comments concerning the manner in

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which grievances and appeals may be filed.

One commenter recommended that an enrollee be permitted to submit a grievance or appeal either orally or in writing. If the decision is made to require that grievances and appeals be submitted in writing, the commenter urged that MCOs and PHPs be required to provide assistance in the process. The commenter believed that requiring Medicaid enrollees to submit grievances and appeals in writing may deprive some beneficiaries of their rights if they are not proficient in English, have little formal education or a low level of literacy, or have disabilities that prevent or make writing difficult.

Another commenter suggested that staff designated to receive and resolve grievances or appeals (proposed § 438.406(a)) be charged with reducing to writing any oral request for official review or remedial action. The commenter felt that the regulations should require MCOs and PHPs to record oral grievance and appeal requests.

One commenter suggested that we clarify whether the enrollee or the MCO or the PHP must put in writing the request for expedited resolution. Another commenter noted that the requirement for written confirmation of an oral request for expedited resolution can be a barrier to an enrollee who has severe and persistent mental illness, and who is in a period of cognitive deficit. This commenter recommended that an oral request should be allowed to suffice in this circumstance.

One commenter stated that we should delete all reference to oral requests because information received orally may be misconstrued. Another commenter stated that the regulation should include language requiring MCOs and PHPs to record oral grievances.

Response: For standard appeals, as is the case for State fair hearing requests, in this final rule with comment period, we are providing in § 438.402(c)(2) that enrollees may start the appeal clock with an oral request but must follow it with a written request. A written appeal best documents the issue being appealed. This requirement cannot be used to limit enrollees' rights. MCOs and PHPs are required in § 438.406(a)(3) to provide reasonable assistance to enrollees who file grievances or appeals, including assistance with the completion of forms. Our requirement should not preclude Medicaid enrollees with legitimate claims from pursuing those claims because of language or physical barriers. In expedited situations, this final rule with comment period provides that the enrollee is not required to place the appeal in writing. In § 438.410(c)(3) we require that MCOs and PHPs record all expedited oral appeals in writing.

Comment: Some commenters interpreted the NPRM to require that all denials of service authorization be automatically transferred to the MCO and PHP grievance system for processing as an appeal. They believed that a requirement would be too burdensome.

Response: We did not intend that all service authorization denials automatically become appeals. Proposed § 438.402(c)(1)(i) provides for the "enrollee to appeal" to the MCO and to the State. Even the expedited appeal process under proposed § 438.410 provided in paragraph (a)(1) apply only when "an enrollee makes the request". In this final rule with comment period, we continue to provide that the enrollee must appeal service authorizations denial.

Comment: We received many and varied comments on proposed § 438.402(c)(4), that required MCOs and PHPs to forward information to the State on appeal decisions that were adverse to the beneficiary (in whole or part).

Several commenters believed that the regulation should not only require the transfer of information to the State, but that this should automatically start the process for a State fair hearing.

Similarly, several commenters thought that HCFA should provide that a denial of a request for expedited appeal be automatically appealed to the State agency for a fair hearing. Several commenters noted that the 90-day limit for completion of the State fair hearing would be difficult to meet unless the State starts the fair hearing process upon receipt of the information from the MCO or PHP. Other commenters felt that this requirement would create an overwhelming amount of paperwork and that States would prefer to receive the information at the time a State fair hearing is requested. Several commenters thought that the 24-hour turnaround timeframe for an MCO or PHP to forward the paperwork for an expedited hearing decision is too short and unrealistic given holidays. Several commenters believed that a complex system would be costly and prone to error. One commenter supported the practice of one State that requires MCOs to report only those grievances that are unresolved after 30 days, noting that the State reviews other grievances as part of the annual MCO audit process. One commenter thought that beneficiaries should have to affirmatively request a State fair hearing and that this is sufficient to guarantee the appeal rights of enrollees. One commenter noted that the States are already able to get this type of information through the audit process.

Response: We have revised the requirement for MCOs and PHPs to automatically forward information to the State on appeal decision adverse to the beneficiary to require this only in the case of decisions that are expedited. For these cases, we believe that it is necessary for the State to receive the file and supporting documentation so that it can begin the State fair hearing process as soon as an appeal is filed. Because we have included a requirement for States to expedite the fair hearing process in these cases and decide the appeal within 72 hours of receiving the request, it is essential that they not lose time by needing to request the appeal file from the MCO or PHP. Also, because of the requirement for an expedited fair hearing, we continue to require that the file be forwarded within 24 hours.

For standard appeals, we have removed the requirement that the file be forwarded automatically. We are persuaded by the comment that this requirement would be burdensome on MCOs, PHPs, and States, and is not necessary to protect beneficiaries. In this final rule with comment period, we require MCOs and PHPs to forward within 72 hours files requested by the State. States will request these files upon receipt of a request for a fair hearing or for a standard appeal.

Comment: Several commenters expressed the view that in proposed § 438.402(c), HCFA has taken an important step by recognizing the need for uniform timeframes across managed care programs, and that setting timeframes recognizes the need for MCOs and PHPs to conclude their reviews promptly. However, these commenters recommended that the final rule with comment period should explicitly provide that MCOs and PHPs must resolve appeals within a timeframe that would allow the State agency to proceed with a State fair hearing, if applicable, and ensure a final decision within 90 days of the initial appeal. The commenter believes that this is needed so that beneficiaries; States, and MCOs and PHPs will clearly understand that the timeframe for final administrative action is not affected by the appeal process at the MCO and PHP level. One commenter expressed the opposite view and requested that the regulations clarify that the time allowed for State fair hearing decisions under 42 CFR 431.244(f) does not begin until a Medicaid beneficiary requests a State fair hearing following the conclusion of the MCO and PHP appeal process. This commenter expressed the opinion that if both the MCO and PHP appeal process and the State fair hearing process are to have sufficient time to meet all the requirements imposed on each of them, then both should not have to be completed in the time allowed for one.

Response: We believe that it is important to maintain a total maximum time period for appeals to be resolved at the MCO and PHP level and by the State at the fair hearing level. However, we recognized that the 90-day timeframe for the completion of both reviews discussed in the preamble of the proposed rule is not workable because the time allowed the MCO or PHP to complete action (30 days with a possible 14 day extension), together with the time allowed by the State for a beneficiary to file a fair hearing request (up to 90 days), may exceed 90 days. Therefore, in this final rule with comment period, we have retained a total of 90 days for consideration of an appeal, but we are providing that this period be interrupted between the time the MCO issues its notice of decision and the beneficiary files for a State fair hearing. We provide that the State has 90 days to complete the State fair hearing process minus the number of days taken by the MCO or PHP to resolve the initial appeal. In addition, in order to ensure that MCO and PHP review does not unduly delay the appeal process, we have provided that if an MCO or PHP does not complete its review within the required timeframes that this becomes an adverse action.

Comment: Several commenters agreed with our statement that the MCO and PHP grievance process is not a substitute for the State fair hearing process.

Response: We agree with the commenter that it is critical that all beneficiaries, including those enrolled in MCOs or PHPs, have access to the State fair hearing process rights provided for under section 1902(a)(3) of the Act.

Comment: Several commenters wanted specific mention of members' right to a second opinion, and would like that right mentioned in adverse action notices. The commenters believed that members should have a right to out-of-plan, unbiased second opinions.

Response: In response to this and other comments, we explicitly provide in § 438.206(d)(3) of this final rule with comment period for the right to a second opinion in the network, or outside the network if an appropriate provider is not available within the network, and this right is referenced in § 438.100(b)(3). We do not provide the right to a second opinion out of network if there is another provider within the network qualified to provide a second opinion. We believe that this is consistent with the concept of holding the MCO or PHP accountable for services to their enrollees. This final rule with comment period provides that enrolles must be informed of the right to a second opinion as part of enrollment information and we therefore, do not believe it is necessary to require that it be included in the notice of action.

Comment: Several commenters supported allowing the State to choose whether to require that enrollees exhaust MCO and PHP grievance procedures prior to appealing to the State for a fair hearing. Other commenters believed that the regulations should not permit States to require the exhaustion of the internal MCO and PHP grievance process prior to permitting access to the State fair hearing process. These commenters felt that requiring the exhaustion of an MCO's and PHP's internal grievance process would inevitably lead to delays, confusion about timing, and a denial to the right to a timely State fair hearing. Commenters also believed that the internal MCO and PHP process was not impartial because the MCO or PHP has a financial interest in the outcome. Finally, one commenter argued that forcing individuals with disabilities to navigate the administrative procedures of the grievance process would be inconsistent with the provisions of the Americans with Disabilities Act (ADA), because in this commenter's view, the ADA prohibits requiring qualified individuals with disabilities to complete administrative processes that cannot be directly linked to the provision of the services offered.

Response: We continue to believe that a State should be permitted to require Medicaid managed care enrollees to exhaust MCO and PHP appeal remedies prior to accessing the State fair hearing process. This not only gives the MCO or PHP an opportunity to reconsider its decision, if the decision is reversed, it reduces the burden on the fair hearing system. We do not understand the commenter's contention that requiring exhaustion in the case of people who have disabilities necessarily would violate the ADA. While we would agree that exhaustion would not be required in the case of a claim under the ADA itself, the exhaustion requirement at issue here involves an appeal of an "action" (for example, a denial of payment or coverage). It is true that the ADA requires that reasonable accommodations be made for people who have disabilities in the conduct of the MCO or PHP level grievance process, and the extent of an obligation is based on the facts and circumstances of the individual case. It is not clear, however, why it would be any more of a burden for an individual who has a disability to file an appeal with their MCO or PHP than it would be to file a request for a State fair hearing. If anything, it might be easier, because the enrollee would have an existing relationship with the MCO or PHP. MCOs and PHPs should be aware of their obligations under the ADA to accommodate people who have disabilities in the grievance process. We do not believe that requiring enrollees who have disabilities to use the same process as other enrollees violates the ADA.

Comment: One commenter questioned HCFA's statutory authority for the requirement that the State fair hearing process be available to review MCO and PHP determinations. This commenter noted that the BBA does not mention the State fair hearing process and infers that the Congress intended that the MCO and PHP appeal process alone address enrollee appeals. Another commenter believed that open access to State fair hearings essentially would negate the grievance procedures within an MCO or PHP.

Several commenters applauded HCFA for providing detailed guidance to MCOs and PHPs on establishing grievance processes. One commenter felt that there also is currently little, if any, link between the MCO and PHP appeal process and the State fair hearing process. Beneficiaries are informed of both options, but are not advised as to whether they must exercise these options in a particular order or whether one "trumps" the other. One commenter believed that allowing the State to choose to provide a fair hearing only after running the course of the MCO's and PHP's grievance system could be the equivalent of denying a fair hearing, which is a beneficiary right. This commenter stated that better mechanisms to coordinate simultaneous participation in both the MCO and PHP and State systems should be devised.

Response: As discussed above, the requirements in subpart F are based only in part on the internal grievance requirements in section 1932(b)(4) of the Act. To the extent these regulations apply to the MCO internal grievance process, they are grounded on section 1932(b)(4) of the Act. To the extent these regulations involve the State fair hearing process, however, including the requirement that MCO and PHP internal grievance processes interface with the

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State fair hearing process, they are based on the fair hearing requirements in section 1902(a)(3) of the Act. The State fair hearing process guarantees all Medicaid beneficiaries an independent hearing. At the time the original fair hearings regulations were promulgated, beneficiaries were not enrolled in managed care arrangements as they are today. Even if the BBA had never been enacted, there would have been a need to promulgate regulations applying the fair hearing rights that all beneficiaries have in the managed care context. We took the opportunity to do so in the proposed rule implementing the grievance requirements in section 1932(b)(4) of the Act. We believe that these regulations are clearly authorized. With respect to the commenter's argument that allowing States to require exhaustion could be "the equivalent" of denying a fair hearing, which is a beneficiary right, this is clearly not the case. As noted above, in cases that exhaustion is required, if the MCO or PHP does not favorably resolve the case by the timeframe provided, the case is automatically forwarded to the State for a fair hearing, and a decision must be made within the same 90-day timeframe that would apply if the fair hearing was requested directly. States should work with MCOs, PHPs, and enrollees to ensure that enrollees understand the linkage between the MCO and PHP grievance processes and the State fair hearing process.

Comment: Several commenters thought that the proposed regulations should preserve beneficiaries' State fair hearing rights, not expand them to include appeals from unresolved complaints, that these commenters saw as a burden on State fair hearing systems. They requested that proposed § 438.402(d) be amended to restrict the right to a State fair hearing to enrollees appealing MCO and PHP decisions denying, reducing, or terminating medical care for an enrollee. Other commenters requested that HCFA confirm that the State fair hearing process applies only to issues that involve claims for services or denials of coverage. These commenters noted that current regulations at § 431.200 provide that the hearing right arises when the "Medicaid agency takes action to suspend, terminate, or reduce services." In the commenter's view, quality or access grievances that do not also involve the denial of services should not be appealed through the State fair hearing process and should be pursued through the MCO's and PHP's internal grievance process or with the External Quality Review Organization with which the State contracts. These commenters also stated that medical treatment decisions made by providers should not be subject to the State fair hearing process.

Response: We agree that the scope of issues subject to the State fair hearing process should not be as broadly defined as in the NPRM. This final rule with comment period specifies that actions, as defined in the regulation, are subject to appeal at the MCO or PHP, and to the State for a fair hearing. This includes a denial of a service, a limitation on receipt of a service, or the reduction, suspension, or termination of a service. We recognize that a provider may deny a requested service for a variety of reasons, including that the provider does not believe the service is medically appropriate for the enrollee. However, because of the financial arrangement that provides a capitated payment to an MCO or PHP for services provided to an enrollee, we believe that the enrollee needs to have recourse through an appeal if a requested service is not provided.

Comment: One commenter contended that the option for the State to require exhaustion at the MCO and PHP level or allow for direct appeal to a State fair hearing could be interpreted to allow an enrollee to file an appeal after the conclusion of the 90-day timeframe for filing.

Response: As discussed above, this final rule with comment period clearly provides that the enrollee has a reasonable time period specified by the State, not less than 20 days and not to exceed 90 days, to file an appeal with the MCO or PHP, or with the State following an unsuccessful appeal to the MCO or PHP, or initially with the State if the State does not provide for exhaustion. If an enrollee does not file an appeal with the MCO, PHP or State, the enrollee would have waived their right to an appeal.

Comment: Several commenters asked for clarification on how Medicare-Medicaid dual eligible enrollees would access the Medicare and Medicaid external hearing processes.

Response: As in the fee-for-service system, dually eligible Medicare-Medicaid beneficiaries have the appeal rights provided for under both programs, to the extent the particular program has paid for the service in question. If a dually-eligible enrollee is enrolled in a Medicare+Choice plan, then the Medicare+Choice appeals process would apply to benefits covered under that program, including otherwise non-Medicare benefits covered under the Medicare+Choice plan. When a dually eligible beneficiary is enrolled in a Medicaid MCO or PHP, and is denied a service covered by Medicare, the beneficiary similarly has Medicare appeal rights, as well as Medicaid rights to the extent that Medicare applies a different standard from Medicaid. In the case of an MCO or PHP denial of a Medicaid service not covered by Medicare, the appeal rights in subpart F apply. In all cases, the notice of action will inform the beneficiary of how to file an appeal.

Comment: Commenters requested that HCFA amend the language in the regulation to say that the MCO and PHP must "have," rather than "provide for," a link to the State fair hearing process.

Response: In this final rule with comment period at § 438.402(a) we define "grievance system" as including the MCO and PHP grievance and appeal processes, and access to the State's fair hearing system. We believe this change clearly establishes the link from the MCO and PHP processes to the State fair hearing process.

Comment: Several commenters asked that HCFA require States to allow providers the right to challenge MCO and PHP decisions on behalf of enrollees.

Response: Séction 1932(b)(4) of the Act expressly requires that MCOs have a grievance procedure in place under that an enrollee "or a provider on behalf of an enrollee" can "challenge the denial of coverage or payment" by an MCO. We agree with the commenters that States are required to allow providers the right to do so, on behalf of an enrollee. In response to this comment, we have added at § 438.402(c)(1) a provision to permit the provider to file a grievance or appeal or request a State fair hearing on behalf of an enrollee with the enrollee's written consent. This condition that the enrollee provide written consent for the provider to act on their behalf reflects policy communicated in a letter to the State Medicaid Directors dated February 20, 1998 that stated, the enrollees' consent is needed if a provider submits an appeal on their behalf. We note that enrollees may be financially liable for the costs of services when provided as a continued benefit during appeal. Therefore, it is important that enrollees understand the possible implications of an appeal and consent to the appeal.

Comment: Commentators urged that HCFA require States to establish a system for administrative appeals that providers could appeal adverse network selections, payments, or other administrative actions that directly affect providers but that only indirectly affect beneficiaries.

Response: The Congress spoke to issues involving MCO relationships with subcontracting providers in provisions: (1) regulating physician incentive arrangements in section 1903(m)(2)(A)(x) of the Act, (2) prohibiting discrimination based on licensure in section 1932(b)(7) of the Act, prohibiting restrictions of provider-enrollee communications in section 1932(b)(3) of the Act, and in section 1932(b)(4) of the Act providing for a provider to file a grievance on behalf of an enrollee. We believe that if the Congress had intended that providers have specific appeal rights under Federal law, these would have been provided for in section 1903(m) or section 1932 of the Act. We believe that this is best left for providers and MCOs or PHPs to negotiate. However, this regulation does not prohibit a State from granting providers the right to challenge MCO and PHP decisions affecting them.

Comment: One commenter suggested that if a decision to deny an item or service is reversed, the MCO or PHP should be required to review all similarly situated beneficiaries and make the item or service available to them as well, regardless of whether the beneficiaries have filed appeals.

Response: We believe that decisions on appeals are so fact-specific that it would not be practical to apply an across the board rule. However, where a State requires MCOs and PHPs to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order. Under § 431.250(d), FFP may be claimed for such expenditures.

3. Notice of Intended Action (Proposed § 438.404)

Under proposed § 438.404, MCOs and PHPs were required to provide enrollees timely written notice of a decision to deny, limit, reduce, delay or terminate a service, within timeframes specified in § 438.310, and in the notice explain the action the MCO or PHP intends to take, the reasons for the action, any laws and rules that support the action, the enrollee's right to file a grievance with the MCO or PHP, the enrollee's right to request a State fair hearing, the circumstances under which expedited grievance review is available and how to request it, how to file grievances (called complaints in proposed § 438.404), appeals (called grievances in proposed § 438.404), and State fair hearing requests; that if an appeal is filed, the enrollee has a right to appear in person before the MCO or PHP personnel assigned to resolve the appeal; the circumstances under which benefits will continue pending resolution, how to contact the designated office described in § 438.406(a), and how to obtain copies of enrollee's complete records.

Comment: We received many comments regarding notice to enrollees. Several commenters believed that a strict application of this principle would be burdensome, especially if applied to the following: (1) Prescription drugs; (2) decisions of primary care physicians (PCPs) made without involvement of the MCO or PHP utilization control unit; (3) MCO and PHP decisions to authorize a limited number of visits; and (4) denials of payment to a specialist when the visit was without a referral by a PCP. One commenter pointed out that denials are typically the result of provider administrative issues involving coding practices, contractual fee schedules, and timely filing. The commenter recommended that the regulation not require that notice be sent to members as a result of provider administrative issues.

One commenter found this provision fairly consistent with current Medicaid fee-for-service requirements, except for the requirement to give notice of a "delay of service." This commenter expressed concern that a notice would be required when a utilization management representative asks for additional information or tests prior to approving a service, as this would confuse the member and create an administrative burden for the MCO or PHP. Several commenters strongly agreed that notice should be provided in all instances when an enrollee's authorization is denied or limited or a service already provided to the enrollee is reduced, terminated, suspended, or delayed.

Several commenters wanted the definition of grievance in the proposed rule (containing grounds for a grievance now included in the definition of "action" in this final rule with comment period) to be expanded to include a determination by the MCO or PHP to deny a service because the MCO or PHP believes that the service is not included in its contract. Similarly, the commenters wanted a State's denial of a service included if the State's reason for denial is because the service is to be provided by the MCO or PHP.

Response: In this final rule with comment period, we define "action," and specify that notice must be sent to enrollees any time an action occurs. We believe that it is an essential enrollee protection that they be sent a notice of all actions, including those that the commenter believes to be burdensome to the MCO and PCP. We define "action" as a denial or limitation of a service authorization request; a reduction, suspension, or termination of a service previously authorized; a denial of payment for a service by an MCO, PHP, or its providers; the failure to furnish, arrange, or provide for payment in a timely manner; or a decision by the State not to grant an enrollee's request to disenroll from the MCO or PHP. In addition, an action includes, for residents of rural areas with only one MCO or PHP, the denial of an enrollee's request to go out of plan. Actions may be taken by the MCO, PHP, or its providers.

The terms "deny or limit" apply when the service requested by the enrollee or provider on behalf of the enrollee is not yet authorized or referred by either the MCO's or PHP's primary care physician, or otherwise authorized by the MCO or PHP in whole or in part. Under this final rule with comment period, a notice of service denial must be sent to the enrollee even if the MCO or PHP believes that its contract does not require that it provide the service. Without this requirement, the enrollee would have no recourse if the MCO or PHP denied the service in error. In this final rule with comment period, we have deleted the reference to a "delay" in service. We provide in § 438.210 that requested services must be approved or denied within 14 days. A request not acted on within this timeframe is considered a denial and a notice of denial must be sent to the enrollee. Extensions to the 14-day time period to act on a service authorization can be requested by the enrollee or by the MCO or PHP when taking additional time is in the best interest of the enrollee. The terms "reduction, suspension, or termination of services or denial of payment" are the same as the traditional fee-for-service definitions of those terms, that is, when a service has been authorized or is being provided and the MCO, PHP, or its provider reduces the number or frequency of the service, stops providing the service prior to the end of the time that was originally authorized, stops providing the service for a period of time, or refuses to pay for a covered or authorized service. The final two criteria in the definition of an action give managed care enrollees a remedy when the State denies a request for disenrollment or the State, MCO or PHP denies the request of an enrollee who is enrolled in a single rural MCO or PHP to go out-of-plan.

Comment: Some commenters contended that MCOs and PHPs do not always know when their providers deny

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services, making it difficult for them to comply with the notice requirements.

Response: MCOs and PHPs must have a system in place to identify these situations, and to ensure that notice is provided. In this final rule with comment period, we allow providers of MCOs and PHPs to provide only general information in the notices they give to enrollees. When this option is chosen, the MCO or PHP must send the enrollee another notice that provides information specific to the enrollee's situation. (See § 438.404(d)(2)). To meet this requirement, MCOs and PHPs will need to have systems in place to find out from their providers when an enrollee has been denied a service or had a service reduced, suspended, or terminated.

Comment: Several commenters believed that Medicaid beneficiaries do not file grievances and appeals very often because of the complex requirements imposed by States, MCOs and PHPs. These commenters further stated that a system established to facilitate resolution of grievances or appeals should ensure that beneficiaries are encouraged to voice their dissatisfaction without fear of reprisal or consequences of any kind.

Response: To ensure beneficiary rights to appeal, in response to this comment, in this final rule with comment period at § 438.404(b), we specify what must be included in the notice of action. This includes information about the right to appeal, how to file an appeal, how to obtain assistance with filing, and that filing an appeal will not negatively affect the way enrollees are treated by MCOs, PHPs, their providers, or the State.

Comment: Several commenters were concerned that enrollees' rights to notice may be violated if HCFA did not prohibit States from delegating responsibility for State fair hearing notices to MCOs and PHPs. They believed that until States, MCOs, and PHPs can better ensure timeliness in processing appeals as well as full constitutional protections, there should be no delegation of the State's responsibility for providing a due process notice to beneficiaries.

Response: We have not accepted this recommendation because we believe that States may find MCO or PHP issuance of State fair hearing notices the most efficient and timely way to get the information about State fair hearing rights to enrollees when an action is taken by the MCO or PHP.

Comment: Several commenters requested that § 438.404 be amended to specifically address situations in which an MCO or PHP intends to deny, limit, reduce, delay, or terminate a service, or deny payment for a service in whole or in part.

Response: The current appeal notice requirements require a notice any time there is an "action", that can include the reduction of services for a Medicaid-eligible individual. Similarly, the notice requirements in this regulation apply when MCOs or PHPs intend to deny, limit, reduce, suspend, or terminate a service, or deny payment for a service in whole or in part. The terms "reduce" and "limit" were included in the notice requirements to cover instances in which already authorized services or requested services, respectively, were decreased or diminished in part.

Comment: Several commenters noted that they do not believe that the expiration of an approved number of visits should be considered a termination. They noted that the enrollee is free to request that the service be continued, but that this request should be treated as a new request for a service. Other commenters expressed the opposite view, and noted that they believe that re-authorization of a service at a lower level than previously received, or a denial of re-authorization is a termination or reduction of the service and should require notice and the continuation of benefits pending appeal. Several commenters requested that the regulation clarify how continuation of benefits applies to prescription medications.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for purposes of notice and continuation of benefits. When a prescription (including refills) runs out and the enrollee requests another prescription, this is a new request not a termination of benefits. In these circumstances, the MCO or PHP would not need to send a notice or continue benefits pending the outcome of an appeal or State fair hearing. If the enrollee requests a re-authorization that the MCO or PHP denies, the MCO or PHP must treat this request as a new request for service authorization and provide notice of the denial or limitation. However, in this situation, if the enrollee appeals the action, benefits would not be continued.

Comment: Several commenters pointed out that HCFA exclusively relies on a written notice to meet the enrollees' needs. They found this policy insufficient, given language, literacy, and disability barriers. Other commenters noted that some States require MCOs and PHPs to send notices by certified mail, and believed that this was very costly, and often unsuccessful in reaching enrollees.

Response: We recognize that Medicaid beneficiaries often face language, literacy, and disability barriers. To address this issue, we have applied the information requirements found at § 438.10, including the language requirements in § 438.410(b) to the notice requirements. We also require that MCOs and PHPs mail notices to an authorized representative designated by the enrollee. We are not requiring States to provide notice in formats other than in writing, except in the case of notices about expedited hearings, that must be provided orally due to time considerations. In this final rule with comment period, we do not prohibit States from setting additional requirements for MCOs and PHPs concerning notices.

Comment: One commenter believed that HCFA has underestimated the true burden associated with MCO and PHP notices.

Response: We address this issue under the Collection of Information Requirements section of this preamble.

Comment: One commenter requested that we adopt the notice timeframes in part 431, subpart E for the situations covered by those sections, and allow States to set other notice timeframes. Several commenters disagreed with the use of a 10-day notice period prior to the date of action. They found that period to be too long because the medical condition of the enrollee may require quicker action. They also suggested that HCFA disregarded the exceptions to the 10-day rule set forth in § 431.213(h). That regulation allows for notice to be sent on the date of the action when a change in the level of medical care is prescribed by the beneficiary's physician. This exception should be interpreted to give MCO's and PHP's the flexibility to give notices, in specified cases, immediately prior to the action being taken.

Response: This final rule with comment period does not change the current regulation at § 431.213 and is consistent. Under § 438.404(c)(1) of this final rule with comment period, timeframes for notices for the reduction, suspension, or termination of previously authorized services are governed by the State fair hearing regulations found in 42 CFR 431 subpart E. While some MCOs and PHPs may find the advance notice requirement inappropriate, there are exceptions to advance notice, that allow notice to be given on the date of the action (see § 431.213). These exceptions would cover situations that a provider believes an immediate change in care is appropriate for the health

condition of the enrollee, for example, the reduction in dosage of a prescription drug.

Comment: We received several comments regarding the elements of a notice. Several commenters suggested that the written notice requirements of proposed § 434.404 be modified to mirror the existing State fair hearing regulations. Other commenters pointed out that HCFA is requiring a great deal of information in the notices required under proposed § 434.404. They suggested deleting some of the requirements. One commenter believed that information on continuation of benefits should be provided if a service is terminated or reduced. Commenters requested that information be provided in the notice about how to contact the MCO or PHP to receive help in filing an appeal. One commenter requested that the rule require MCOs and PHPs to notify the enrollee of their right to expedited review.

Several commenters wanted the content and time line requirements clarified in the notice and a full explanation to be provided of the laws and rules that support the action, rather than a citation to a particular statute or regulation. These commenters requested clarification that the enrollee has a right to obtain other relevant information germane to the resolution of the enrollee's issue. These commenters further requested a clarification that notices must specify the reasons or criteria used in determining that the request was not medically necessary.

Response: We agree that notices given by MCOs and PHPs should, at a minimum, contain the information required by the State fair hearing notices. We have provided for this in this final rule with comment period. However, we have retained the requirements specified in the NPRM concerning the content of the notice, including information about the circumstances under which an enrollee may receive expedited review, and the reason for the action. We believe that requiring the inclusion of the reason for the action will provide the enrollee with information to understand why it occurred, and help the enrollee to decide whether to appeal. We made one change to the NPRM requirements to remove the requirement that the notice specify that the enrollee may appear before the person assigned by the MCO or PHP to resolve the appeal, as we have deleted this requirement for MCOs and PHPs in this final rule with comment period.

In response to the commenter who favored inclusion of information in the notice about continuation of benefits when benefits are being terminated or reduced, we have added a requirement that the notice state that an enrollee may be held liable for payment for services if the enrollee requests continuation of benefits during appeal. This provides the enrollees with a more complete picture of what the continuation of benefits provision means to them. We also agree with the commenter favoring a requirement that the notice contain information on how to obtain assistance from the MCO or PHP in filing an appeal, and have provided for this in § 438.404(b)(8) of this final rule with comment period.

Comment: Several commenters believed that we should require MCOs and PHPs to provide enrollees with copies of their records within 24 hours of the request and, if the member (or authorized representative) is unable to pick up the copies, that they be mailed the next business day.

Response: In § 438.224 we provide that MCOs and PHPs must ensure that enrollees may request and receive a copy of their medical records and information. MCOs and PHPs should allow members to obtain copies of their medical records in a timely manner to allow the enrollee to submit information in support of their appeal. However, we have not accepted the commenter's suggested deadline, as we believe that this would be impractical and create too great a burden for MCOs and PHPs. We believe that States should have the flexibility to decide whether to establish deadlines in this area.

Comment: Several commenters believed that the notice should explain that the enrollee may be represented by counsel or a legal representative during the grievance process and include the address and phone number for free legal assistance. They noted that the right to be represented by counsel is required under the *Goldberg* v. *Kelly* ruling and that this right is given to fee-for-service Medicaid beneficiaries in the State fair hearing process.

Other commenters believed that it is sufficient to provide enrollees information regarding free legal services in a Medicaid brochure or other enrollee notification materials. Another stated that providing this information on a routine basis would be burdensome and that it may not be accurate because assistance is not available in all areas.

Response: In response to these comments at § 438.404(b)(1) of this final rule with comment period, we provide that the notice must inform the enrollee of the right to represent themselves or to use legal counsel, a relative, a friend, or other spokesperson. We do not believe it is necessary to require that the notice itself include information about free legal assistance, and we leave it to States to decide how this information is to be made available to beneficiaries.

Comment: Several commenters urged us to require each State to develop a uniform notice to be used by MCOs and PHPs. They contended that requiring use of a State-developed uniform notice is a simple, common sense way to assure consistency in the grievance and State fair hearing process across MCOs and PHPs, and would best protect the constitutional rights of the beneficiary.

Response: We believe that due process and notice requirements can be observed without requiring each State to develop a uniform notice for MCO and PHP use. States are expected to review MCO and PHP notices to ensure that all required elements, including those listed in § 431.200 et seq., are included. Nothing in our regulations prohibits States from developing a uniform notice for use by their MCOs and PHPs if they choose.

Comment: Several commenters suggested that the notice should explicitly inform the beneficiary that filing an appeal or State fair hearing request would not affect the way the member is treated by the provider, MCO, PHP, or the State.

Response: In response to this comment, we have provided under § 438.404(b)(11) of this final rule with comment period that the notice must inform the enrollee that filing an appeal or requesting a State fair hearing (where an enrollee is permitted to do so directly) will not negatively affect or impact the way the MCO or the PHP and their providers, or the State agency, treat the enrollee.

Comment: Several commenters believed that providing for an in-person hearing before the MCO or PHP would significantly increase the time and expense involved, without substantially improving the quality of the system. They also questioned if this requirement is realistic for appeals that are expedited. Finally, commenters noted that the appearance of disgruntled enrollees before MCO and PHP personnel may pose a security risk to MCO and PHP staff.

Response: We agree that due process does not require an in-person hearing at the MCO and PHP. However, we believe that enrollees should have an opportunity to present evidence and allegations of fact or law related to the issue in dispute, in person as well as in writing. In this final rule with comment period (§ 438.406(b)(4)), we provide enrollees the opportunity to present their cases in person but do not require a formal hearings process. We have also

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removed the requirement that the in-person presentation must be before the decision maker for the MCO or PHP. We do this because of the burden this would place on MCOs and PHPs. Appeals requiring expedited resolution, MCOs and PHPs must notify enrollees of the limited time available for them to appear in person.

4. Handling of Complaints (Grievances) (Proposed § 438.406)

Proposed § 438.406 set forth how grievances or appeals (called complaints and grievances in the proposed rule) must be handled. The general requirement for handling grievances and appeals required MCOs and PHPs to have an adequately staffed office, acknowledge receipt of each grievance and appeal, give enrollees any assistance with completing forms or taking other steps necessary to obtaining resolution at the PHP level, and conduct appeals using impartial individuals who were not involved in any previous level of review. Proposed § 438.406(d) required that in the case of a denial based on lack of medical necessity, the individual must be a physician with appropriate expertise in the field the encompasses the enrollees condition.

Comment: One commenter advocated deleting proposed § 438.406 altogether. Other commenters believed that requirements should be added to those in § 438.406. Among the suggested additions, one commenter wanted the regulation to prohibit MCOs and PHPs from using internal appeal timeframes and procedures to avoid the medical decision process, or to discourage or prevent members from receiving medically necessary care in a timely manner. Another commenter asked that we include a clear explanation of the role of personnel provided by the MCO or PHP to advocate for the enrollee, provide customer service, or assist in resolving grievances. Another suggested that we require MCOs and PHPs to give consumers written notice of a hearing and a description of the hearing procedures, at least fifteen days in advance. One suggested that we require MCOs and PHPs to hold internal hearings at mutually convenient times. Another said we should require MCOs and PHPs to postpone hearings at the request (for just cause) of the enrollee. When enrollees have cause, one commenter wanted us to provide that enrollees need not appear at a hearing and that the hearing be conducted in the same manner regardless of the consumer's presence. Another asked that we forbid all ex parte discussions. One commenter wanted us to require MCO and PHP staff to attempt, whenever possible, to resolve grievances informally pending a decision, but that resolution should not permit the MCO or PHP to consider the grievance "withdrawn" in order to evade State review. Another asked that formal rules of evidence not be used, but rather that enrollees be allowed to submit written information in support of their claims, arrange for a physician or other expert to testify on the enrollee's behalf, and compel the appearance of MCO or PHP staff to answer questions concerning the dispute. Commenters believed that if the MCO or PHP has an attorney present at the hearing, the role of the attorney should be to ensure that a fundamentally State fair hearing takes place and all issues in dispute are adequately addressed. The attorney should not, in these commenters' view, be permitted to argue the MCO or PHP position in the dispute. These commenters believed that consumer representatives should be trained and certified by the State on a periodic basis, that MCOs and PHP should be required to document how they select the consumer representatives on the internal hearing committee, and that this selection process should be approved by the State on a yearly basis.

Response: The proposed rule did not propose to require a formal hearing at the MCO and PHP level. We believe that commenters misconstrued the provision in the proposed regulation concerning the in-person appearance of the enrollee to be a requirement for a formal hearing. This was not our intent. The proposed rule only addressed the presentation of evidence by the enrollee in person to the MCO or PHP. We do not believe a hearing is necessary at the MCO and PHP level and therefore, do not require it in this final rule with comment period. Because we did not propose a hearing and are not providing for a hearing before the MCO or PHP in this final rule with comment period, we are not addressing the comments relating to the nature of a hearing. We believe that the provisions remaining in this section strike an appropriate balance between proscribing sufficient provisions to protect beneficiaries and retaining some flexibility for MCOs and PHPs to design, with State approval, the procedures for their appeal processes.

Comment: One commenter was concerned that proposed § 438.406(b) did not specify a time period within that the MCO or PHP must transmit its acknowledgment of receipt of a grievance or appeal. The commenter believed that an enrollee who files a grievance or appeal needs to know in a timely manner whether the MCO or PHP has received it. Consequently, the commenter suggested that § 438.406(b) indicate that the MCO or PHP must acknowledge receipt within a specified time period, perhaps 24 hours after receiving a grievance or appeal. One commenter believed that the regulation was intended to require the MCO or PHP to acknowledge receipt of grievances or appeals in writing.

Response: We require MCOs and PHPs to acknowledge the receipt of grievances and appeals, but we do not specify that the acknowledgments be in writing, nor do we specify the timeframes in which they must be provided. We believe that requirements would be burdensome for MCOs and PHPs. States, at their option, may consider adding these requirements.

Section 438.416(b) of this final rule with comment period requires that MCOs and PHPs track the date of acknowledgment and report it to the State as part of the annual disclosure report under § 438.416(d). State monitoring should include tracking this activity.

Finally, if the appeal was oral and is not expedited, the acknowledgment must tell the enrollee that although the timeframe for resolution has begun, the appeal must be submitted in writing. The MCO or PHP must assist the enrollee with the written request, if asked.

Comment: Several commenters requested that HCFA modify the language in proposed § 438.406(c) to change the requirement that MCOs and PHPs must provide enrollees "any assistance" to "reasonable assistance" with the completion of forms or other procedural steps in the grievance process. These commenters were concerned that the phrase "taking other steps necessary to obtain resolution of the grievance" may require the MCO or PHP to pay for a second opinion on the disputed service in order to "obtain resolution." Other commenters wanted this provision clarified so that MCOs and PHPs would not be required to pay for attorney representation or other unreasonable assistance.

Other commenters urged that the following be required elements of MCO and PHP assistance to beneficiaries during the grievance process: (1) A toll-free number with adequate interpreter capability including TTY; (2) outreach to beneficiaries with limited English proficiency, in accordance with Title VI of the Civil Rights Act of 1964; (3) an ombudsman program; and (4) a State established consumer assistance program to assist enrollees (especially homeless persons) to navigate the grievance process.

Response: In response to the above comment, we have revised the language to require MCOs and PHPs to provide "any reasonable assistance" for the completion of forms or other procedural steps in the grievance and appeal process. Also in response to the above comments, we have deleted the phrase "to obtain resolution of the complaint or grievance at the MCO level," as we do not intend for this provision to require MCOs and PHPs to do more than assist enrollees during the grievance process.

In response to the above suggestions to specify required elements of assistance, in § 438.406(a)(3) of this final rule with comment period, we require MCOs and PHPs to make interpreter services available to enrollees, as well as, toll-free numbers that have adequate TTY/TTD and interpreter capability. By including these as examples of types of assistance required to meet certain needs, we do not intend that other reasonable assistance need not be given. We believe, for example, that MCOs and PHPs are required by this provision to provide reasonable assistance to meet other needs of enrollees, and assisting enrollees who have low-literacy abilities.

In this section, we do not address outreach to beneficiaries with limited English proficiency, but we note that the information requirements in § 438.10(b) and (c), in the section on Notice of Action (§ 438.404), and in the section on Information about the Grievance System (§ 438.414) require that information and assistance be provided to these enrollees.

The remaining comments relate to State responsibilities. This section addresses MCO and PHP requirements. We have not revised § 438.404 to address these points.

Comment: One commenter urged HCFA to create an affirmative duty of the provider to assist the enrollee in registering an appeal.

Response: We do not agree that the provider should be required to assist the beneficiary in filing a grievance or an appeal. We believe that this is appropriately the responsibility of the MCO and PHP, and we are requiring in this regulation that they provide this assistance. They are free, however, to use their contracting providers to provide this assistance on their behalf.

Comment: Several commenters commended HCFA for specifying that individuals making decisions on appeals must not have been involved previously in the claim, but requested that § 438.406 omit the word "impartial" when referring to individuals employed by a MCO or PHP who serve as decision makers. These commenters believed that MCO and PHP employees involved in appeal decisions can never be impartial.

Response: The requirement is that the MCO and PHP decision makers not have played a role in the original decision. Therefore, the term "impartial" is unnecessary and in response to this comment, we have removed it in § 438.406(a)(7) of this final rule with comment period.

Comment: Several commenters requested that enrollees receive access to hearings presided over by independent panels of clinical peer professionals. One commenter believed that enrollees should be able to seek review by an external panel and receive a de novo determination if the decision denies or limits a covered benefit, denies payment of services deemed not medically necessary or experimental, involves services that exceed a significant threshold, or puts the patient's life or health in jeopardy.

Response: The regulations provide for external review through the State fair hearing process that is available to all beneficiaries as required under section 1902(a)(3) of the Act. These regulations link the internal grievance procedures required under section 1932(b)(4) of the Act with the existing State fair hearing process that implements section 1902(a)(3) of the Act. Under the State fair hearing process, Medicaid beneficiaries are guaranteed due process through an independent hearing meeting the standards set forth in the Supreme Court's *Goldberg* v. *Kelly* decision. While the hearing officer is not required to be a health professional, we would expect medical evidence to be presented by clinicians to support an enrollee's appeal.

While the State fair hearing provides beneficiaries with an independent review of their appeals and is a beneficiary right that cannot be denied, we are aware that some States have established independent panels to review MCO and PHP decisions unfavorable to enrollees, and have made these available to Medicaid managed care enrollees. This regulation does not prohibit use of this review process by Medicaid enrollees. However, any process cannot be substituted for the grievance process and fair hearing process that is required under this final rule with comment period and the regulations at 42 CFR part 431, subpart E. If an enrollee chooses to appeal through the grievance and State fair hearing process, the decisions under this process would be controlling over any inconsistent determination made by another State body.

Comment: We received several comments concerning our decision, stated in the preamble, not to require the establishment of ombudsman programs. One commenter suggested that an enrollment broker may effectively serve as an initial unbiased contact for grievances and appeals and assist beneficiaries through the grievance process or refer them for appropriate assistance from an ombudsman or other outside source. One commenter suggested that States should establish centralized advocacy and customer service programs available to all citizens enrolled in MCOs (not just Medicaid enrollees).

Several commenters requested that ombudsman programs be established and have sign language, interpreters, and TTYs. The commenters stated that the need for an external agency, as an ombudsman program, is well proven and should be required by the regulation.

Commenters noted that the Medicaid population includes individuals with limited education, linguistic and cultural barriers to care, and frequent negative experiences in accessing entitlements and challenging bureaucratic institutions. They stated that enrollees should have designated points of contact to receive counseling on grievances or appeals if managed care is to be successful as a quality health delivery system for the Medicaid program.

Response: We encourage States to establish consumer assistance programs to assist enrollees in navigating the grievance and appeal system. After careful consideration, we have decided not to include a requirement that MCOs, PHPs, or State agencies establish ombudsman programs to assist beneficiaries. We believe that each State agency should establish its own approach to how enrollees obtain assistance during the grievance process, including the State fair hearing process. We require that MCOs and PHPs assist enrollees in completing forms and taking other procedural steps. Other assistance could be provided through a more comprehensive ombudsman program. We encourage States, MCOs, and PHPs to work with the ombudsman programs currently operating through State Medicaid Agencies, Departments on Aging, and Insurance Commissioners. In many instances, States may be able to expand existing State ombudsman programs with few additional resources. As noted in 42 CFR 431.250, FFP is available for transportation costs and other expenses of Medicaid enrollees during the appeals process.

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Comment: One commenter pointed out that the word "contracts" in the first paragraph of the preamble to proposed § 438.406 should be "contacts".

Response: This commenter is correct. However, because this language did not appear in proposed regulations text, and the preamble to this final rule with comment period controls the meaning of the final regulations, no action was required in response to this comment.

Comment: Several commenters suggested that all appeals be filed by enrollees on a form developed by the State. They further suggested that MCOs and PHPs submit these to the State Medicaid agency, and that the Medicaid agency log in the appeals and return them to the MCO and PHP within 72 hours.

Response: We do not agree with this suggestion. We are not requiring use of a State-developed form for filing appeals, as this would require that enrollees obtain these forms, possibly delaying the process, and may be an impediment to enrollees wishing to file appeals. We note that States may wish to develop forms to guide and assist enrollees in filing appeals. However, their use must be at the option of the enrollee. As for filing appeals with the State, we are aware that a similar process is required by the State of Tennessee. We are concerned that the central log-in system used by that State agency would not work well in other States. A log-in procedure would require a well-developed infrastructure that could be costly and burdensome to many States, and that would add another layer (and, even under the commenter's proposal add 72 hours) to the appeals process. Furthermore, we believe that other parts of this rule will result in many of the same benefits noted by advocates of the approach used by Tennessee. For example, under § 438.416, we require that MCOs and PHPs keep a log of grievances and appeals and that its contents be reported to the State. This will provide the State the same information obtained through the commenters' suggested approach. Additionally, State on-site reviews can monitor appeal processes to determine if MCOs and PHPs are meeting required timeframes.

Comment: Several commenters requested that the person investigating the grievance should receive training on the Medicaid statute, regulations, and contractual provisions; on confidentiality and patient protections; and on the grievance process.

Response: We agree that MCOs and PHPs should provide this training to their personnel. States should consider making this a requirement of their MCOs and PHPs. However, we do not think it necessary to require specific MCO and PHP training programs in Federal regulations.

Comment: Several commenters urged that this final rule with comment period require that grievances and appeals involving application of medical standards should be reviewed by an appropriately trained physician.

Response: This final rule with comment period at § 438.406(a)(7)(ii) provides that the individual making a decision must be a health professional; with appropriate clinical expertise in treating the enrollee's condition or disease for—(1) an appeal of a denial that is based on lack of medical necessity, (2) a grievance regarding denial of expedited resolution of an appeal, and (3) a grievance or appeal that involves clinical issues.

Comment: Several commenters pointed out that the NPRM referred to "physicians" when describing individuals with appropriate medical expertise to make decisions on grievances and appeals concerning clinical issues. They noted that other health care professionals, not just physicians, are competent to make decisions and commonly perform these services in the private market. They stated that Medicaid beneficiaries are best served by having service denials reviewed by qualified health care professionals with appropriate expertise.

Response: We agree that health providers, other than physicians, may be appropriate to make decisions when the area of expertise required is other than a physician (for example, a dentist). In § 438.406(a)(7)(ii) of this final rule with comment period we have removed the term "physician" and replaced this with "health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease."

5. Grievance (Appeal): Resolution and Notification (Proposed § 438.408)

Proposed § 438.408 required MCOs and PHPs to investigate each appeal (called grievance in the proposed rule) to base the decision on the record of the case, including any MCO or PHP hearing provided under § 438.402(c)(3), and relevant program laws, regulation and policies; and to resolve each as expeditiously as the enrollee's health condition requires, within State established time-frames, but no later than 30 days after it receives the appeal. The MCO or PHP would be permitted to extend the 30 day timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justifies a need for additional information on how the delay is in the interest of the enrollee. For an appeal that requires an expedited resolution under § 438.10, proposed § 438.408(a)(3) required that it be resolved as expeditiously as the enrollee's health condition requires, within timeframes established by the State, but no later than 72 hours after it receives the appeal. The MCO or PHP again would be permitted to extend the timeframe by up to 14 days if the enrollee requests the extension, or if the MCO or PHP justified a need for additional information or how the delay is in the best interest of the enrollee. Proposed § 438.408 also set forth requirements for notification if the decision is adverse or partially adverse to the enrollee. For a standard resolution the timeframe was no later than 30 days after it received the appeal, and for an expedited resolution, no later than 24 hours after it reaches the decision. The content of the notice must include the name of the MCO or PHP contact, the results of the appeal and the date competed, a summary of the steps taken on behalf of the enrollee to resolve the issue, a clear explanation of the right to a State fair hearing, circumstances under which benefits would continue if a State fair hearing request was filed, and the potential for enrollee liability for services furnished during the pending appeal if an adverse decision is reached.

Comment: One commenter believed that HCFA underestimated the burden associated with the grievance system timeframes.

Response: We address the burden imposed by this provision elsewhere in this preamble, in the section titled Collection of Information Requirements.

Comment: Several commenters believed that extensions to the appeals timeframes benefit the MCOs and PHPs more than the enrollee, and recommended that we eliminate them.

Response: We believe that extensions may be necessary to provide additional time to decide appeals when information necessary to the decision cannot be obtained in time to meet the timeframes, and that extensions may be in the enrollee's interest In expedited cases, however, we agree with the commenter that giving MCOs and PHPs the discretion to extend timeframes may be problematic because this is by definition a case that the enrollee's health is at risk. Therefore, we believe that unless the enrollee actually has determined that an extension is in their interests and requests an extension, there should be no extensions in expedited cases, and we accept the commenters' recommendation that

extensions be eliminated to this extent. In this final rule with comment period, therefore, for appeals that are expedited, only the enrollee may request an extension. This is an added protection for enrollees who are appealing to receive services without which their health may be jeopardized.

Comment: Several commenters strongly favored the adoption of standardized timeframes for Medicaid that conform with those for Medicare.

Response: We have retained the same timeframes for Medicaid that are used for Medicare. Appeals must be resolved as quickly as the enrollee's health condition requires, or no later than 30 days for standard appeals, and 72 hours for expedited appeals. As under the Medicare+Choice program, we permit 14 day extensions for both standard and expedited appeals when requested by the enrollee. In the case of a standard appeal a 14-day extension may also be obtained if the MCO or PHP justifies to the State Medicaid agency that it is in the enrollee's interests. As noted in response to the previous comment, we have eliminated extensions in expedited cases unless requested by the enrollee.

In response to the above comment favoring the adoption of Medicare timeframes, we are extending the extent to which this final rule with comment period follows Medicare timeframes by providing in §§ 438.408(j)(3)(ii) and 431.244(f)(2)(ii) and (iii), for an expedited State fair hearing in cases of expedited appeals. Specifically, we require that the State fair hearing decision be made within 72 hours, that is the same timeframe used for Medicare for expedited appeals to the Center for Health Dispute Resolution (CHDR), the current Medicare contractor for external independent review under Medicare+Choice. The fair hearing process is the Medicaid counterpart of CHDR review, in that in both cases it is the first "independent" and "external" review of a managed care organization's decision.

Comment: Comments on standardized timeframes differed. Some commenters believed that consistent timeframes are especially important in expedited appeals when the enrollee's health condition needs to be taken into consideration. Other commenters supported the adoption of standardized timeframes, but called for them to be shorter. One commenter believed that the timeframes in the proposed rule might violate Constitutional due process because the timeframes outlined do not adequately protect beneficiaries.

Other commenters criticized the standardized timeframes. Several commenters found the timeframes unreasonable, unrealistic, subjective, and too prescriptive and asked for more State flexibility to set timeframes. One commenter wanted the timeframes to begin when all documentation is received from providers. One commenter noted that most States already have expedited timeframes and changing these requirements may be confusing for beneficiaries and may not provide any additional protections to enrollees. One commenter found the extensive and varying timeframes for resolutions confusing and believed that it would be difficult to administer.

Response: We continue to believe that the regulation should establish timeframes for steps in the internal appeal process and that an expedited timeframe is necessary when the use of standard timeframes may jeopardize the enrollee's health. This is an important beneficiary protection and is necessary to ensure that the overall timeframe of 90 days for a decision at the State fair hearing (excluding the time the beneficiary takes to file for a State fair hearing) can be met in all cases. In § 438.408(a) we provide for States to establish timeframes that "may not exceed" the timeframes specified in this final rule with comment period. States may establish shorter timeframes.

Comment: Several commenters believed that mandatory timeframes might be difficult to meet if enrollees fail to submit timely information, or are not available for an in-person presentation to the MCO or PHP. These commenters asked that a limit be placed on the number of days MCOs and PHPs are responsible for providing continued services pending final determination.

Response: We believe that the timeframes included in the regulation will result in timely decisions on appeals. Enrollees must be informed of the timeframes, and provided an opportunity to present evidence and appear in person before an MCO or PHP representative. However, if they do not provide information to support their appeal, the MCO or PHP is responsible for deciding the appeal on the basis of available information within the timeframes set out. Continuation of benefits for already authorized services must continue throughout these periods until the final decision at the MCO, PHP, or State is made, whichever is later. Given the limits on timeframes for decision in this rule, we do not believe that "time limits" are necessary. We note that there are no such limits under fee-for-service Medicaid.

Comment: Several commenters thought that MCOs and PHPs should be required to receive written approval from the State before extending the timeframes.

Response: We are not requiring that MCOs and PHPs receive prior approval from the State for extensions, as we do not believe that this would be practical, given the number of cases and the timeframes involved. However, States are required to monitor MCO and PHP use of extensions and may require that MCOs and PHPs provide justification for any extension.

Comment: Several commenters believed that the enrollee should be forwarded a concurrent copy of the MCO's or PHP's written request given the opportunity to respond to the MCO's or PHP's request for a time extension, and provided a concurrent copy of the State's response. One commenter warned that requiring prior approval would be burdensome.

Response: We agree that enrollees should be informed when an MCO or PHP grants an extension, and in response to this comment have provided for this in § 438.408(d)(2) of this final rule with comment period. The MCO or PHP notice must include the reasons for the delay and inform the enrollee of the right to file a grievance if the enrollee disagrees with the decision to extend the timeframes. We do not believe that this requirement will unduly burden MCOs and PHPs, as we believe that most appeals will be decided within the time period allowed before an extension is needed. We note that our decision to not permit MCOs or PHPs to extend the timeframe for an expedited appeal absent a request by an enrollee is also responsive to the commenters' concerns about an enrollee being informed of extensions and having the opportunity for input.

Comment: One commenter requested that we require the MCO or PHP to give a written justification to the enrollee whenever the MCO or PHP extends the 14-day timeframe, and that a copy be included in the case file. Another commenter noted that the MCO or PHP does not need to obtain prior approval before granting itself an extension, and as currently drafted, the enrollee appears to have no recourse other than to file a grievance with the MCO or PHP, even in situations when the enrollee's life may be jeopardized. They believe that due process and fundamental fairness require MCOs and PHPs to provide notice to the enrollee, and that the enrollee should have the right to object and have the dispute immediately decided by an impartial decision maker. A delay in decision making constitutes a delay in providing the service. and is subject to Constitutional requirements

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and *Goldberg* v. *Kelly* in this commenter's view.

One commenter also requested that physicians (in addition to enrollees) should have a right to request a 14-day extension.

Response: We agree that MCOs and PHPs, upon granting themselves an extension, should notify the enrollee in writing of the extension and of the enrollee's right to file a grievance if the enrollee disagrees with an extension of the timeframes. We do not believe that providers need to be given the right to seek an extension. The provider is associated with the MCO or PHP that can grant itself an extension in a non-expedited case if the standard is met. The MCO or PHP must also provide justification for the extension to the State, if required. We note that the commenter's concern about "situations when the enrollee's life may be jeopardized" by an MCO or PHP-initiated extension has been addressed by our decision to eliminate the opportunity for the MCO or PHP to extend the deadline in expedited cases absent an enrollee request.

Comment: One commenter believed that the timeframes should begin when the appeal initially is made, not when it is submitted in writing.

Response: We agree that timeframes should begin when the enrollee first appeals the action, regardless of whether the appeal is made orally or in writing. When setting the timeframe for resolving appeals in § 438.406(b)(3) of this final rule with comment period, we refer to the date that the MCO or PHP first "receives" an oral or written appeal as the point that the time for resolving the appeal has begun. We note, however, that the enrollee must follow a standard oral appeal for a request with a written request.

Comment: Several commenters recommended that the timeframe for making a decision on a request to authorize a service should be less than the 14 days proposed.

Response: We continue to believe that 14 days is an appropriate outer limit for the time allowed for an MCO or PHP to authorize a service. We have retained the provision of the NPRM that requires this decision to be make more quickly if required by the enrollee's health needs. In addition, in this final rule with comment period, when a determination is made that a case meets the standards for an expedited appeal, the MCO or PHP must decide an appeal of this decision no later than 72 hours after the appeal is filed.

Comment: One commenter agreed with our decision stated in the preamble to the proposed rule not to require MCOs and PHPs to automatically resolve any dispute in the enrollee's favor that the MCO or PHP did not resolve within a defined timeframe. Other commenters supported requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. These commenters reported ongoing problems of MCOs and PHPs denying services for months while multiple requests for information are made.

Several commenters reported that some State laws provide safeguards when decisions on medical care are not made within required timeframes, including deeming the failure to make a timely decision an adverse decision subject to appeal or automatic approval of the service.

Several commenters pointed out that in HCFA's Medicare+Choice regulations, the failure of a Medicare+Choice organization to meet initial determination and reconsideration timeframes is automatically considered an adverse decision and automatically referred to the next level of review.

Response: We are not requiring that appeals be resolved automatically in the favor of the enrollee if not completed within a specific time period. Instead, non-compliance will be considered an adverse decision, and automatically referred to the next level of review (the State fair hearing process). For service authorization requests, an MCO or PHP not completing authorizations within the specified timeframes would be required to send a notice of adverse action explaining the enrollee's appeal rights. As the commenters noted, this is consistent with Medicare's policy for reconsiderations not acted upon within the required timeframes. That is, the Medicare+Choice organization's failure to act is considered an affirmation of its adverse decision and the file must be sent to the independent entity for an independent outside review. This first level of independent review under Medicare+Choice is analogous to fair hearing review under this final rule with comment period.

Comment: One commenter asked that the words "title of staff person" be substituted for "name of staff person" to protect MCO and PHP staff members from possible retaliation by enrollees.

Response: We agree and have changed "name" to "title" in this final rule with comment period.

6. Expedited Resolution of Grievances and Appeals (Proposed § 438.410)

Proposed § 438.410 required that each MCO and PHP establish and maintain an expedited review process for appeals (called grievances in the proposed rules) and set forth requirements for the resolution of expedited grievances and appeals including, responses to oral or written requests if the MCO or PHP determines, or the provider indicates that the time for a standard resolution could seriously jeopardize the enrollees's life, health, or ability to regain maximum function.

Comment: Some commenters applauded our inclusion of an expedited grievance process similar to that under Medicare+Choice and-then-proposed the Department of Labor regulations. Others argued for State flexibility and contended that prescriptive Federal requirements preclude States from taking into account other expedited processes that they have implemented with respect to clinical aspects of appeals, for example, preauthorizations.

Response: We believe that expedited resolution is necessary to ensure that appeals of situations that potentially place an enrollee's health in jeopardy are not delayed. The Consumer Bill of Rights and Responsibilities (CBRR) and beneficiary advocates have both recommended the adoption of expedited procedures. Although States have historically instituted different processes to protect beneficiaries, HCFA believes that standardized expedited appeal processes are needed to protect beneficiaries in a capitated health care delivery system.

Comment: One commenter requested that "retain function" be added to the criteria for expedited grievances and appeals. The commenter stated that retention of less than full function is often the goal for beneficiaries with long-term disabilities who cannot expect to regain full function but should be protected against further loss of function. Other commenters wanted the expedited process to apply when the enrollee has significant pain or side effects, and for children with special health care needs.

Response: In response to this comment, we have revised the language for expedited appeals to include all instances for which the time needed for standard resolution could "seriously jeopardize the enrollee's life or health, or the ability to attain, maintain, or regain maximum function." With this revision, the Medicaid criteria are more inclusive than those for Medicare. We believe that these criteria are sufficient to address situations that the enrollee is in significant pain or is having significant side effects. Finally, we do not agree that children with special health care needs should automatically receive expedited appeals in all cases solely on the basis of being in that category. We believe that the criteria we have established will ensure that expedited appeals will be available when they are needed.

Comment: Several commenters suggested that the regulations allow the beneficiary to obtain an expedited review based on the beneficiaries' own attestation that the standard for expedited review has been met. They believed that MCOs and PHPs should not be given control over the situation because their financial arrangements with physicians may provide an incentive to deny services. One commenter supported the ability of an enrollee to obtain an expedited resolution if the enrollee obtains the support of a physician.

Response: We do not agree that an enrollee's attestation should be sufficient to require an expedited appeal. The enrollee may not be objective in this determination or may not have the knowledge to draw a correct conclusion. It is not clear what would preclude enrollees under this approach from attesting that the standard is met in every case simply to get faster action on all appeals. We are including in this final rule with comment period a provision that if a provider makes the request, or supports the enrollee's request for expedited review, the review must be expedited. We believe this sufficiently protects enrollees.

Comment: Several commenters noted that the rule should prohibit retaliation by the MCO or PHP against physicians who support their patients' requests for expedited appeals.

Response: We intend that providers who advocate on behalf of their patients should be protected against retaliation by MCOs and PHPs in all circumstances. In response to this comment, we expressly prohibit any retaliation in § 438.402(b)(5) of this final rule with comment period.

Comment: One commenter expressed concern regarding the logistics of requiring MCOs and PHPs to give prompt oral notice to an enrollee of any denial of an expedited request. They noted that some Medicaid enrollees may not be accessible by telephone.

Response: We are aware that some Medicaid enrollees may not have telephones. Nevertheless, MCOs and PHPs must make reasonable efforts to notify enrollees orally of decisions not to expedite the appeal and follow up with a written notice within two calendar days. MCOs and PHPs should request information from enrollees about how and where they can be contacted.

Comment: Several commenters recommended that the State Medicaid agency be required to hear all expedited appeals and issue decisions within specified timeframes. One commenter recommended we include a requirement that decisions be made within 24 hours; another suggested two days.

Response: This final rule with comment period requires the State to conduct a fair hearing and make its decision within 72 hours for service authorization denials that meet the criteria for expeditious handling. We have limited this requirement to initial denials of authorization for a service because in the case of a decision to reduce or terminate benefits, benefits continue through the State fair hearing decision. The enrollee's health is protected during the time it takes for the State fair hearing decision to be made. We have chosen to use the same 72-hour standard that applies to MCO or PHP review in expedited cases because we do not believe it would be reasonable to expect the State to complete review of all expedited cases in 24 hours. We also note that this 72-hour timeframe is employed in Model guidelines established by the National Association of Insurance Commissioners (NAIC), in Department of Labor regulations governing Retirement Income Security Act (ERISA) health plans, and at both the Medicare+Choice organization and independent external review levels in the Medicare+Choice program.

Comment: Several commenters pointed out that proposed § 438.410 (c)(2) allowed a physician to request an expedited appeal. They suggested that we broaden this provision to allow other health care professionals to make these requests.

Response: We agree that all health care professionals who provide services to Medicaid beneficiaries should be permitted to request expedited appeals. As discussed above, we have made this change in this final rule with comment period.

7. Information About the Grievance System (Proposed § 438.414)

Proposed § 438.414 required that MCOs and PHPs provide information about the grievance system to enrollees, potential enrollees (as provided by the State), and all providers at the time they enter into a contract with the MCO and PHP. It also specified that the content of the information include a description of the grievance process that is developed or approved by the State, and that it include the following: (1) specification of what constitutes grounds for a complaint (now grievance) grievance (now appeal) or State fair hearing; (2) an explanation of how to file for each; (3) an explanation of the assistance available; (4) toll-free numbers (with TTY and interpreter capability) for enrollees to register grievances and appeals; (5) titles and telephone numbers of persons responsible for the functioning of the grievance process and with authority to require corrective action; (6) assurance that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO or PHP, their providers, or the State agency treat the individual; and (7) information on how to obtain care or services during the grievance or fair hearing processed. Section 438.414 also requires that the MCO or PHP to provide enrollees and potential enrollees with aggregate information regarding the nature of enrollee appeals and their resolution.

Comment: One commenter believed that we underestimated the true burden associated with MCO and PHP grievance information requirements.

Response: We address the issue of burden in the Burden Statement to this final regulation.

Comment: Several commenters requested that we explicitly require notices and information about the grievance system to be written at a fourth grade level, translated into prevalent languages, and accessible to persons with hearing and sight impairment.

One commenter requested us to require MCOs, PHPs, and PCCMs to use at least one of the following reference materials: (1) Fry Readability Index; (2) PROSE: The Readability Analyst; (3) Gunning FOG Index; or (4) McLaughlin SMOG Index.

Response: In this final rule with comment period, we require that notices meet the formatting and language requirements at § 438.10. We believe that it is appropriate that we include a general requirement for material to be written in easily understood language and formatted likewise. We also provide that material must be translated into the prevalent languages in the MCO's or PHP's service area. In the preamble to the proposed rule, we provided examples of standards States can use to determine prevalence. We are not requiring that material be written at a specific grade level because no single level is possible or appropriate for all material.

Comment: One commenter believed that additional State flexibility was necessary regarding how and when information should be distributed to enrollees. Another commenter asked for more clarification about the detail of the information that must go to all enrollees

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and the time that information must be sent. One commenter requested that States develop standard language that MCOs and PHPs be required to use in their member handbooks. Several commenters supported the amount of detail in the regulation regarding information because it ensures that information about beneficiary protections is provided more uniformly to enrollees.

Response: We are not mandating that States require the use of standard language because, we believe that States should be permitted to decide this based on State circumstances. With respect to the timing of the provision of information, § 38.10(d), (e), and (f) set forth requirements as to when information about the grievance system must be provided to enrollees and potential enrollees. With respect to the information on grievances and appeals addressed in § 438.414, for enrollees, § 438.10(e)(1) requires that this information (referenced in § 438.10(e)(2)(x)) be provided within a reasonable time after the MCO or PHP receives notice of enrollment, and once a year thereafter. In the case of potential enrollees, § 438.10(f)(7) requires that the information described in paragraphs (d) and (e) of § 438.10 (including the grievance information described in § 438.10(e)(2)(x)) be provided only upon request. In § 438.414(a)(1) and (3), we require MCOs and PHPs to provide information about the grievance system to enrollees, and to providers and subcontractors (at the time of entering into a contract). In section 438.414(a)(2), we require that the State, a State contractor, or MCOs and PHPs provide this information to potential enrollees. In § 438.404 we require that information about the grievance system be sent to enrollees as part of the notice of action.

Comment: One commenter believed that the State fair hearing process should be explained clearly to enrollees at the time of enrollment, and annually thereafter. Several commenters asked that MCOs and PHPs be required to give enrollees information on the right to be represented by counsel, and the availability of free legal assistance. One commenter requested that beneficiaries be informed of their rights during the grievance process at every stage.

Response: We have revised this regulation to clarify that the beneficiary's State fair hearing rights must be explained, including the fact that enrollees have the right to represent themselves, or be represented by legal counsel, a relative, a friend, or other spokesperson. We do not require MCOs and PHPs to inform beneficiaries about the availability of free legal counsel. This is consistent with the current policy in fee-for-service. In the State Medicaid Manual (SMM 2900.3), we require States to maintain a list of available free legal services and to notify beneficiaries of their right to legal assistance, including free legal assistance. States may, at their option, require MCOs and PHPs to maintain copies of this list and make it available to enrollees.

Comment: Several commenters thought that we should require MCOs and PHPs to provide grievance, appeal, and State fair hearing information to potential enrollees, upon request, and to enrollees upon initial enrollment, and whenever the grievance system is changed by the MCO, PHP, or the State. Several commenters wanted aggregate information on grievances and their resolution to be given to consumers as part of their initial and annual enrollment choice information. Several commenters wanted grievance data to be available to the general public, as well as, to enrollees and potential enrollees. One commenter encouraged us to have consistent requirements for Medicaid and Medicare.

Response: As noted above, we require the State to ensure that information on grievances and appeals is provided to potential enrollees upon request, either by the State or its contractor (for example, an enrollment broker), or by the MCO or PHP. MCOs and PHPs also are required to provide this information to enrollees at the time of enrollment, and annually thereafter. Information will also be provided as part of notices of actions. We believe that this will provide enrollees with the information they need to exercise their rights.

We agree with the commenter that MCOs and PHPs should provide aggregate information on grievances and appeals to enrollees, potential enrollees, and the general public upon request. In response to this comment, § 438.414(d) of this final rule with comment period provides that aggregate information be released to the public upon request.

Comment: One commenter requested that HCFA require that information about the grievance system be provided to subcontractors as well as to contracting providers.

Response: In § 438.414(a)(3) of this final rule with comment period, we specify that this information must be provided to subcontractors as well as to contractors.

8. Recordkeeping and Reporting Requirements (Proposed § 438.416)

Proposed § 438.416 required that MCOs and PHPs comply with specified record keeping requirements, that also had to be done in compliance with confidentiality requirements in § 438.324. Specifically, MCOs and PHPs were required to—

- Maintain a log of all grievances and appeals (called complaints and grievances in the proposed rule).
- Track each appeal until its final resolution.
- Record any disenrollment and the reason for it, even if it occurs before the appeal process is complete.
- Retain the records of grievances and appeals (including their resolution) and disenrollments for three years, and make them accessible to the State or if any litigation, claim negotiation, audit or other action is started before the end of this three year period, the MCO or PHP must retain the records until completion of the action and resolution of the issues, if later than three years.
- Analyze the collected information and prepare and send to the State a summary as often as the State requests, but at least annually—

++ The number and nature of all complaints and grievances.

++ The timeframes within which they were resolved, and the decisions.

++ A listing of all grievances that have not been resolved to the satisfaction of the affected enrollee.

++ The number and nature of grievances for which the MCO or PHP provided expedited resolution, and the decisions.

++ Trends relating to a particular provider or a particular service.

Comment: One commenter believed that HCFA underestimated the true burden associated with MCO and PHP record keeping and reporting requirements.

Response: We address the issue of burden in the section of the preamble titled Collection of Information Requirements.

Comment: Several commenters suggested that the State be allowed to determine the specific data elements to collect on grievances and appeals, and how and when reports are to be submitted to the State. Other commenters supported the inclusion of the elements included in the proposed rule.

Response: We believe that a minimum set of data should be available from all MCOs and PHPs to facilitate monitoring. We have changed this final rule with comment period to remove the requirement in proposed § 438.416(e)(3) that MCOs and PHPs submit a list of all appeals not resolved to the satisfaction of the enrollee. We believe that this requirement is unnecessary now that MCOs and PHPs will be required to forward all appeals not resolved to the satisfaction of the enrollee to the State for a fair hearing. We note that States have the flexibility, at their option, to set record keeping and reporting requirements in addition to these Federal minimums. For example, States may establish a minimum number of categories of grievances and appeals that MCOs and PHPs must report (for example, delays in receiving referrals, delays in access to specialists or services, dissatisfaction with quality of care, and waiting times for appointments).

Comment: Several commenters wanted the regulation to specify that MCOs and PHPs should collect and report information on the number and nature of requests for expedited review.

Response: We agree that we should require that MCOs and PHPs collect and report information on the number of requests for expedited review, and in response to this comment have provided in § 438.416(b) of this final rule with comment period that grievances and appeals must be classified in terms of whether the disposition was standard or expedited. We have retained the requirement in proposed § 438.416(e)(1) (now § 438.416(d)(1)) that information be reported on the "nature of all grievances and appeals," whether expedited or standard.

Comment: Several commenters wanted grievances to be tracked, sorted by type, number and resolution, and reported to the same extent as appeals. They believed that this would be useful in identifying problems with education and outreach.

Response: This final rule with comment period requires that grievances, as well as appeals, be tracked and reported. In response to the comment favoring additional tracking, we have added a requirement to the regulation that MCOs and PHPs must track and report on the time frames for acknowledging to the enrollee the receipt of grievances and appeals.

Comment: Several commenters objected to the requirement in proposed § 438.416(c) that MCOs and PHPs record any disenrollments and the reason for them, because these commenters believed that the State controls the disenrollment process and maintains data regarding disenrollments. Therefore, these commenters believed that States, not MCOs and PHPs, should be required to maintain disenrollment records. One commenter noted that requiring the collection of disenrollment information is good and that it should also be classified

Response: We have removed the requirement for an MCO or PHP to "record any disenrollment and the reason for it" from the proposed provisions at § 438.416 because this was duplicative of the requirement at proposed § 438.342(a) that the State ensure that each MCO and PHP maintain a health information system that collects, integrates and reports data on areas including disenrollments. However, in response to this comment, we recognize that there is a distinction between disenrollments from an MCO or PHP due to loss of Medicaid eligibility and other disenrollments initiated by the enrollee of the MCO or PHP. Given that information regarding disenrollments due to loss of Medicaid eligibility is not typically known by MCOs or PHPs, in response to this comment, we have modified the reference to disenrollment in § 438.242 to refer to "disenrollment for other than loss of Medicaid eligibility."

Comment: One commenter requested that we clarify that the regulation requires MCOs and PHPs to provide the State only with information about grievances and appeals of Medicaid enrollees, not all enrollees.

Response: We believe that the regulation is clear that this information must be supplied only for Medicaid enrollees, as it references grievance and appeal mechanisms that are only available to enrollees.

Comment: We received several comments regarding the annual disclosure of information. One commenter believed that annual disclosure of aggregate data was appropriate, but that reporting trends relating to a particular provider or particular service was not. Commenters urged us not to require such information to be reported. They were very concerned that these reports would have a detrimental effect on existing quality improvement and peer review processes.

Response: We agree that Federal reporting of trends relating to particular providers may not be appropriate, and in response to this comment have deleted this requirement from this final rule with comment period. States, at their option, may develop provider grievance and appeal profiling requirements consistent with State laws.

Comment: Several commenters asked that State Medicaid agencies and ombudsman programs have access to MCO and PHP logs. In addition, commenters urged that the regulation require States to provide members of the public, upon request, with MCO and PHP summaries. Another commenter recommended that HCFA require MCOs and PHPs to identify trends on grievances and appeals for particular enrollee sub-populations. One commenter wanted the regulation to require MCOs and PHPs to computerize their grievance and appeal logs and report to the State on a quarterly rather than annual basis.

Response: States have the authority to require that MCOs and PHPs make available to the State grievance and appeal logs or other MCO and PHP grievance system documents. In the final regulation we are requiring that States must make information on MCO and PHP grievances and appeals available to the public. We do not agree that we should be more prescriptive in the regulation about reporting requirements. States, at their option, may require MCOs and PHPs to provide ombudsman programs access to grievance and appeal logs, to include information about all systemic issues that emerged from grievances and appeals, to report on their response to systemic problems, to report grievance and appeal data on particular subpopulations of enrollees including persons with special needs, to computerize logs, or to report on a more frequent basis. In designing their quality strategies, States should consider what additional information they or others will need to support those strategies.

9. Continuation of Benefits Pending Resolution of a State Fair Hearing Decision (Proposed § 438.420)

Proposed § 438.420 set forth requirements for MCOs and PHPs, in the case of an appeal from the termination or reduction of services currently being provided to continue services upon a timely appeal while the MCO or PHP considers the appeal, and through the end of any State fair hearing. As used in this section, "timely" means filing on or before the time limit specified by the State and communicated in the notice of intended action, or before the effective date of the MCO's or PHP's proposed action, whichever is later. Although the benefit is to be continued during the resolution process, enrollees who lose their appeal at either the plan or State fair hearing levels will be liable for the cost of all appealed services from the later of the effective date of the Notice of Intended Action or the date of the timely filed appeal, through the date of the denial of the appeal.

Comment: Commenters expressed concern that the regulation may be read to permit benefits to be stopped after the appeal to the MCO or PHP, but before the State fair hearing.

Response: We intend for benefits to continue through the enrollee's final appeal at the State fair hearing when requested by the enrollee. Section 438.420(d)(1) of this final rule with

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comment period makes it clear that benefits must continue without interruption, if elected by the enrollee, through the conclusion of the State fair hearing process if the case is not favorably resolved at the MCO or PHP level.

Comment: One commenter thought that requiring continuation of benefits through the State fair hearing decision was inappropriate because the enrollee may be liable for payment for services provided during this period if the appeal is ultimately denied at the State fair hearing.

Response: We provide that enrollees must request to have benefits continue during the appeal process because of their potential financial liability in the event that they are unsuccessful. In § 438.404(b)(7) of this final rule with comment period, we require that the notice of action inform the enrollee of the potential financial liability for services continued during appeal. Likewise, in § 438.408(g)(4)(iii), we require a written notice to the enrollee that the enrollee may request that benefits be continued and of the potential financial liability if the benefits continue.

Comment: We received many comments regarding enrollees' rights to continuation of benefits during the MCO and PHP appeal process. Several commenters thought that the regulations should include a provision to require MCOs and PHPs to continue benefits when the appeal involves services that are being terminated or reduced. Several commenters felt that continuation of benefits pending resolution of an appeal or State fair hearing without financial risk, is one of the most important protections needed for managed care enrollees.

Several commenters were opposed to extending continuation of benefits to the MCO and PHP appeal process. One contended that this requirement would have significant cost implications. Another believed that benefits should be continued only at the point when an enrollee requests an external fair hearing.

One commenter thought that requiring MCOs and PHPs to continue benefits would place them in an untenable position with their providers, compromising their ability to manage care and cost. They expressed concern that this provision may damage managed care programs and believed it unnecessary given the requirement of expedited review of appeals in cases in which a delay could jeopardize health.

One commenter argued that requiring continuation of benefits during an MCO or PHP appeal, as opposed to a State fair hearing, was not consistent with this commenter's interpretation of the statute and case law. It appeared to this commenter that a beneficiary would obtain double benefits in this situation. The commenter requested clarification to explain the duration of continuation of benefits when they are provided during the MCO and PHP appeal process. The same commenter also felt that continuation of benefits would make it difficult for the State to track the case and determine the beneficiary's eligibility for continuation of benefits at the point of the State fair hearing.

Response: Because we allow States to require exhaustion of the MCO and PHP appeal before receiving a State fair hearing, we believe that, in order for the right to continued benefits during a fair hearing to be meaningful, that continuation of benefits must begin with the filing of the appeal and continue until the State fair hearing decision. Continuation of benefits at the MCO and PHP level thus is not a "double" benefit, but part of the same longstanding right to continuation of benefits that has existed for Medicaid beneficiaries when services are reduced or terminated.

As in fee-for-service, under managed care, the right to continuation of benefits is not exercised without financial risk to the beneficiary of payment for services provided should he or she lose the appeal. The enrollee may choose not to request continuation of benefits because of the potential liability. The notice of adverse action must include an explanation of this choice.

While expedited appeals will decrease the amount of time MCOs and PHPs are liable to continue benefits for enrollees with pending appeals, the expedited appeal process does not substitute for the protection provided to Medicaid beneficiaries of the right to continuation of benefits pending the outcome of a State fair hearing decision.

If the benefit is a Medicaid covered service, but not a MCO or PHP covered service, the State, not the MCO or PHP is responsible for providing those services pending the outcome of the State fair hearing.

It is not clear why the last commenter believes that providing continued benefits through the fair hearing level is inconsistent with the statute or case law. We believe that it simply gives MCO and PHP enrollees the same Medicaid fair hearing rights that all other enrollees have under the program. To the extent that we are aware of case law on this issue, courts have supported continuation of benefits in the managed care context.

Comment: One commenter requested that this section should make clear that re-authorization of a service at a lower level than previously received, or a denial of re-authorization, is a termination or reduction of the service requiring the continuation of benefits pending appeal.

Response: We believe that the expiration of an approved number of visits does not constitute a termination for the purposes of notice and continuation of benefits. If an enrollee requests re-authorization for services and the MCO or PHP denies the request or re-authorizes the services at a lower level than requested, the MCO or PHP must treat this request as a new service authorization request and provide notice of the denial or limitation. The MCO or PHP is not obligated to provide continuation of benefits in this circumstance. This policy is consistent with that in fee-for-service.

Comment: One commenter objected to requiring MCOs and PHPs to cover the service pending appeal if the enrollee is no longer eligible for Medicaid and there is no emergency.

Response: The policy for continuation of benefits does not apply when an enrollee loses Medicaid eligibility.

Comment: We received many comments regarding the requirements in proposed § 438.420(b) that a MCO or PHP physician with authority under the MCO or PHP contract must have authorized the enrollee's services in order for them to be continued.

Several commenters believed that benefits should be continued in all cases in which a dispute involves a service covered under the Medicaid State plan. They argued that conditioning continuation of benefits on the benefits having been authorized was inconsistent with constitutional due process requirements. They contended that the rule could lead to an interruption in services when services are prescribed by an out-of-plan emergency room physician or by an out-of-network provider who is treating a Medicaid beneficiary because the MCO or PHP does not have an available provider in the network; the MCO or PHP pays for the service although it is prescribed by an out-of-network provider; a beneficiary is receiving out-of-network family planning services; or an enrollee, while continuously eligible for Medicaid, either changes MCOs or PHPs or joins an MCO or PHP (from fee-for-service or PCCM) during a course of treatment.

Several commenters recommended that the regulation be amended to trigger continued services regardless of whether the provider requests the service. They contended that there is a direct financial conflict of interest between a provider employed by a MCO or PHP (or contracting with a MCO or PHP) and the patient. These commenters also said that MCO and PHP doctors base treatment decisions, in part, on MCO and PHP guidelines and receive bonuses if they meet performance goals that may include utilization criteria.

Response: For continuation of services to apply, the services must have been previously authorized. This final rule with comment period uses the term "authorized provider" rather than "MCO or PHP physician" to address some of the concerns expressed by the commenters. We note, with respect to the example of emergency services cited by the commenters, that in section 1932(b)(2)(A)(ii) of the Act, the Congress has provided MCOs with the right to decide whether to authorize out of network "post-stabilization services" once an emergency medical condition has been stabilized. The Congress contemplated that services would only be covered by Medicaid if authorized by the MCO, or covered under the post-stabilization guidelines in cases in which the MCO does not respond timely to a request for coverage authorization. To the extent the MCO or PHP does not authorize continued services by a non-network provider, it must assume responsibility for the services through a network provider, so there would be no interruption in needed services.

Where services were not covered in the first place because they were not authorized or covered as emergency services or post-stabilization services, there could be no "right" to continuation of coverage, even if the services would be covered under the State plan for a beneficiary not enrolled with an MCO or PHP. We therefore disagree with the commenters who suggested that it violated due process to require MCOs and PHPs to provide continuation of services only when the services in question were authorized in the first place.

However, if services are covered under Medicaid, under this final rule with comment period, benefits must be continued if the beneficiary timely appeals a decision to terminate, reduce or suspend the services, regardless of whether or not the beneficiary is enrolled in a MCO or PHP. We note that this includes instances in which the services were begun by a provider under the fee-for-service system, but a MCO or PHP made a decision to terminate, reduce, or suspend them. These beneficiaries' rights to continued care are addressed under regular fee-for-service rules, and it is the State that is obligated to ensure that these rights are enforced. States should specify in their contracts with MCOs and PHPs whether the MCO, PHP, or the State will assume financial responsibility for these services under these circumstances. We note that § 438.62(b) requires that States have a mechanism in effect to ensure continued access to services when an enrollee with "ongoing" health care needs is transitioned from fee-for-service to managed care.

Benefits must be continued by the MCO or PHP in the following situations, (this assumes that the benefits are included in the MCO or PHP contract): (1) the MCO or PHP pays for services prescribed out-of-plan; (2) services are prescribed by an outside specialist who is treating the enrollee with the MCO's or PHP's knowledge and consent; (3) family planning services are being received from a provider who is not part of the MCO or PHP network, and family planning services are covered under the MCO or PHP contract; and (4) in rural areas, where individuals are, by law, permitted to seek out-of-network services/providers, for example when the service or provider is not available within the MCO or PHP. If the benefit is not included in the MCO or PHP contract, the State must pay to continue the benefits.

Comment: Several commenters requested that we delete the requirement that the beneficiary must request continued benefits. They contended that this requirement was constitutionally defective in that they believed continued benefits, without pre-requisites to obtaining them, to be a cornerstone of due process.

The commenters noted that the existing regulation at 42 CFR 431.230(b) provides for the possibility of recoupment, yet benefits are continued when an appeal is filed timely. The commenters found no reason to change this long-standing rule for beneficiaries who are receiving services through an MCO or PHP.

Response: We do agree with the commenters view that beneficiaries should not be required to specifically request continuation of benefits. We continue to believe that beneficiaries should have to request continuation as they may be held liable for services if the final decision is not in their favor. We have provided that enrollees be notified that they may incur a financial liability if their appeal is unsuccessful. As in the case of the fee-for-service regulations, benefits will only be continued if the enrollee files a timely appeal. This is a "prerequisite" to obtaining them which has been upheld in the courts as consistent with due process.

Comment: Several commenters expressed concern that beneficiaries may request continuances of State fair hearings, and extend the period during which benefits will continue. They recommended that the final regulation specify the grounds on which an enrollee may request a hearing continuance. If a continuance is granted for reasons other than good cause, these commenters believed that the MCO or PHP should not be obligated to continue to provide services during the period of the continuance.

Response: We do not agree that we should specify when a State fair hearing officer may grant a continuance, as we believe that this should be left to the hearing officer's discretion, as is the case under fee-for-service Medicaid. The State Medicaid Manual at 2900 permits the State fair hearing officer to grant one continuance of up to 30 days.

Comment: Several commenters recommended that we establish parameters for the liability of MCOs and PHPs for care provided pending the outcome of the hearing. Commenters wanted to work with HCFA to develop this provision. They stated that MCOs and PHPs should be compensated appropriately if they are required to provide services, and the hearing decision upholds the MCO's or PHP's determination.

Some commenters believed that it would be unrealistic to assume that an MCO or PHP would be able to collect payment for services from an enrollee if the final decision is not in their favor. They noted that Medicaid beneficiaries generally do not have the financial resources to pay, and MCOs and PHPs thus should be able to recoup payment from a provider, with the provider then billing the enrollee. They believed that this process would add to the administrative burden of the MCO or PHP and the provider.

One commenter recommended that MCOs and PHPs should be paid their costs for providing services during the hearing process if the enrollee is unsuccessful at the State fair hearing and the MCO or PHP is unsuccessful in collecting from the enrollee.

Another commenter recommended that MCOs and PHPs be reimbursed on a fee-for-service basis for services provided during the time taken for the appeal and State fair hearing.

One commenter asked that this section be amended to limit the responsibility of enrollees for services provided that are the subject of the appeal, rather than all services provided during this time period.

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Several commenters were concerned that MCOs and PHPs would use the requirement that enrollees be told of their potential liability for payment for services continued to intimidate enrollees from using the grievance process. These commenters noted that, under the fee-for-service system, States seldom try to recover the cost of services from a beneficiaries, but under a managed care system, the MCOs and PHPs are more likely to attempt recovery to avoid financial losses.

Response: States, in their contracts with MCOs and PHPs, have the flexibility to determine what entity is responsible to cover costs of services continued through an appeal. We believe that States are in the best position to decide what entity should pay. They may prefer to take this into account in setting capitation rates for MCOs and PHPs or may prefer to pay for these services directly.

The current requirement in the Medicaid fee-for-service program is that beneficiaries who lose their appeal at the State fair hearing level are liable for the costs of the services continued during the appeal. Enrollees must be told of their potential liability in order for them to make an informed choice about whether or not to accept continued services. Section 438.408(i)(4) of this final rule with comment period thus requires written notice of this potential liability, and the option to refuse continued benefits. Enrollees are not liable for all services provided during this time period, but only for services continued because of their appeals. We have clarified the language on this point in the regulation (§ 438.420 (e)). FFP is available to States for payments for services continued pending a State fair hearing decision. Likewise, if the MCO or PHP is unable to collect from the enrollee after a good faith effort, FFP is available to the State under § 431.250(a) for payments for services continued pending a hearing decision.

10. Effectuation of Reversed Grievance Resolutions (Proposed § 438.421)

Proposed § 438.421(a) provided that if the MCO or PHP decides an appeal (called a grievance in the proposed rule) in favor of the enrollee, the MCO or PHP was required to authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calender days after the date the MCO or PHP receives the request for reconsideration. Furthermore, under proposed § 438.421(b), if the MCO's or PHP's decision on a appeal was reversed under the State fair hearing process, the MCO or PHP must authorize or provide the disputed service as expeditiously as the enrollee's health condition requires within time frames established by the State, but no less than 60 calendar days from the date the MCO or PHP receives notice reversing the MCO's or PHP's decision to deny.

Comment: Several commenters disagreed with the time frames in the proposed rule for providing a service, which depended on whether the beneficiary won the appeal at the MCO or PHP (30 days to provide the service), or at the State fair hearing (60 days to provide the service). Another commenter believed that the time frames should take into consideration the appropriateness of the procedure or treatment for the individual, as there may be cases in which providing the service within 30 days may not be clinically appropriate for the enrollee. The commenter further noted that external factors for example, scheduling and bed availability may affect the time frame for providing treatment. Several commenters supported the elimination of time frames because in the view of these commentators, beneficiaries with successful appeals should not have to wait at all following the decision.

Response: We agree that MCOs and PHPs should remove barriers to receipt of the services and take into account the needs of the individual. Therefore, in response to the above comments, we are eliminating the time frames in proposed § 438.421 (§ 438.424 in this final rule with comment period), and requiring that the services be provided as soon as required to meet the needs of the beneficiary. This is consistent with the State fair hearing policy in 42 CFR 431.246.

Comment: One commenter asked that we hold States, MCOs, and PHPs financially responsible for the cost of services inappropriately withheld if the enrollee obtains them outside the network and their appeal is upheld. The commenter believed that failure to provide for this remedy could encourage States, MCOs, and PHPs to refuse expensive care until after an appeal is resolved.

Response: We agree with these commenters. In response to this comment, we have provided in § 438.424(b) of this final rule with comment period that the State, MCO, or PHP must pay for services denied to an enrollee when the enrollee received the services and later won an appeal of the denial.

11. Monitoring the Grievance System (Proposed § 438.422)

In proposed § 438.422, we required the MCO, PHP, and the State to use the grievance and appeal logs (called complaint and grievance logs in the proposed rule) and annual appeal summary required under § 438.416 for contract compliance and quality monitoring. At a minimum, proposed § 438.422 required that the contract between the State and the MCO or PHP require that logs be reviewed and summarized for trends in grievances and appeals by provider or by service, and the requirement that MCOs and PHPs conduct follow up reviews, report results to the State, and take corrective action when necessary.

Comment: One commenter requested that HCFA either define the term "undesirable trend" or delete the term.

Response: We agree that the term "undesirable trend" is vague. We now require in § 438.426(b) that when the MCO or PHP identifies through trends in the data collected in § 438.416(b) that systemic changes are needed, the MCO or PHP must investigate, report the results to the State, and take corrective action.

Comment: One commenter requested that we mandate that States conduct random reviews of service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner.

Response: We agree that States should monitor service denial notifications to ensure that MCOs and PHPs are notifying members in a timely manner. This should be an integral part of each State's Quality Improvement Strategy and contract compliance monitoring. We believe that States are in the best position to determine the timing for this monitoring.

Comment: Several commenters requested that we modify this section to require States to require MCOs and PHPs to take corrective action if numerous grievances are filed concerning the same issue.

Response: As part of the State's quality strategy, which includes monitoring MCO and PHP grievances and appeals, States are required to take corrective action when needed to remedy problems.

Comment: Several commenters felt that the requirement to identify trends by provider constitutes a serious breach under State law of the peer review processes and legal privileges. They believed that these issues can be monitored appropriately by the States without requiring reports.

Response: We agree that Federal requirements that require MCOs and PHPs to report on undesirable trends relating to providers is not appropriate, and we have revised the rule to delete this requirement. States, at their option, may develop provider grievance and appeal profiling requirements that are consistent with State laws concerning peer review.

12. Consequences of Noncompliance (Proposed § 438.424)

Comment: We received many comments that this section confused readers, particularly with respect to the types of sanctions States could impose on MCOs and PHPs.

Response: We have eliminated this proposed section from this final rule with comment period. This section was intended to emphasize the importance of MCOs' and PHPs' compliance with the provisions of this Subpart. It did not convey any authority or responsibility to the States, MCOs, or PHPs.

F. Certifications and Program Integrity Protections (Subpart H)

Background

We believe it is important for MCOs to develop effective internal controls to fight fraud and abuse and to ensure quality of health care services to Medicaid beneficiaries. Administrative and management procedures, including a compliance plan, address specific areas of concern or potential areas of risk for MCOs. It is in the best interest of MCOs, State agencies, and HCFA to make a commitment to an effective administrative and management arrangement that will significantly aid in the elimination of fraud and abuse.

By requiring certification of the accuracy of data used to determine payments, of information contained in contracts, proposals, and other related documents submitted to State agencies, and of administrative and management procedures designed to prevent fraud and abuse, we are working to promote program integrity, protect Medicaid managed care enrollees, and protect Medicaid government funds.

Subpart H of proposed part 438, Certifications and Program Integrity Provisions, contains safeguards to promote program integrity within Medicaid managed care programs. We have proposed that these rules apply only to MCOs, as they were not made applicable to PHPs under proposed § 438.8.

Proposed § 438.600 sets forth the statutory basis for the requirements in subpart H, which is based on section 1902(a)(4) of the Act. Proposed § 438.600 permits us to find methods of administration that are "necessary for proper and efficient administration" of the plan. The requirements in subpart H are also based on section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to ensure that eligibility will be determined and to provide services in a manner consistent with simplicity of administration and the best interests of recipients.

Proposed § 438.602 requires that when State payments to an MCO are based on data submitted by the MCO, which include enrollment information and encounter data, the MCO must, as a condition for receiving payment, attest to the data's accuracy, completeness, and truthfulness. Proposed § 438.606 requires that an entity seeking an MCO contract have administrative and management arrangements or procedures designed to prevent fraud and abuse, which include reporting to the State, HCFA, or OIG (or both) credible information on violations of laws by the MCO or its subcontractors or enrollees. In the case of enrollee's violations, this proposed requirement only applies if the enrollee's violations pertain to his or her enrollment, or to provision or payment for health services.

Proposed § 438.608 sets forth a separate certification requirement, requiring that MCOs certify the accuracy, completeness, and truthfulness of information in contracts, requests for proposals, and other related documents specified by the State.

Comment: One commenter suggested that the program integrity requirements in subpart H apply to all MCOs/primary care case managers (PCCMs), not just MCOs.

Response: We agree with the commenter that the requirements in subpart H should have applicability beyond MCOs. The commenter suggested that primary care case managers should be subject to these requirements. We agree with this recommendation to the extent the PCCM is paid on a risk basis as the MCOs that were the subject of subpart H. In this case, payments may also be based on encounter data submitted by the entity, and the same types of incentives and potential for fraud and abuse apply. However, in the case of a PCCM paid a fixed monthly case management fee, payments for services furnished to an enrollee are paid under the existing State plan payment process, which is subject to existing fraud and abuse protections that apply generally to providers that bill Medicaid. In order to identify only those PCCMs and other non-MCO entities that are paid on a risk basis, we are revising § 438.8 to require that PHPs comply with the program integrity requirements in subpart H.

Comment: One commenter requested clarification as to whether subpart H applies only to MCOs operated under a State plan option or to both those operated under a State plan option and those operated under a waiver program.

Response: The requirements of subpart H apply to MCOs, whether the MCO or PHP operates under a waiver program, a mandatory managed care program, or a voluntary program.

Comment: Several commenters believe that requiring certification of data as 100 percent accurate and complete is unworkable and not customary. The commenters suggested that this provision does not recognize the impossibility of meeting an absolute standard, that this provision should be changed to correlate with more commonly accepted standard language on certifications and to correlate with the language adopted by the Medicare+Choice program.

Response: We recognize that requiring attestation that data is 100 percent accurate may not be feasible. We believe that it is important to ensure accurate data submissions. Because this information may directly affect the calculation of payment rates, we are amending the regulation to be consistent with the current language being adopted in the Medicare+Choice provisions; that is, we will require that attestations be "based on best knowledge, information, and belief." We have restructured and recodified some of the provisions of proposed subpart H. The revised certification requirement containing the Medicare+Choice language is now in § 438.606(b). These certifications will assist HCFA, State agencies, and OIG in combating fraud and abuse and in investigating and prosecuting suspected cases of fraud as authorized by the False Claims Act.

Comment: One commenter believes that the relationship between the submission of data and Medicaid payments is neither clear nor uniform and that there may be a tenuous connection between the State's reliance on the substance of the data and its payments to the MCO. The commenter also believes that certification of data fails to address incentives for underutilization and permits Medicaid payment for coverage of services that the MCO may not actually be providing. This commenter recommended that the MCO's payments be based upon filing a "claim" for these payments, certifying the data on which payments may be based, and whether the MCO substantially meets its contract requirements.

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Response: Not all States base payments to MCOs on encounter data or on enrollment data submitted by the MCO. In this case, the certification requirement in proposed § 438.604(a) would not apply as it only applies to data when payments are based on the data. If it is not clear that there is a connection between given data and payment, those data may not have to be certified. We believe it is important that data are certified as accurate, at least to the best of the MCO's belief, if payment to that MCO will be based on these data. Submission of data that are complete and accurate will provide the State with information needed to set actuarially sound capitation rates. We disagree with the commenter that underutilization is not addressed at all, as encounter data can be used by States to identify and address underutilization and the potential for payments made for services not furnished. While we do not require States to collect encounter data from MCOs, we believe this is becoming a State requirement. It is unclear how the commenter's first recommendation concerning basing payment on filing a claim and certifying data associated with the claim relates to the commenter's concern for underutilization or how the recommendation differs from the requirements in subpart H. We agree with the commenter that MCOs should be required to certify that services are being provided in substantial compliance with their contracts, since under § 438.802(c) of this final rule (discussed in section II.H of this final rule) FFP is only available in contract payments if the MCO is in substantial compliance with its contract. We have revised §§ 438.604 and 438.606 to provide for this certification.

Comment: Several commenters believe the data should be certified by the Chief Executive Officer (CEO) or the Chief Financial Officer (CFO) whom they believe would have actual knowledge of the accuracy, completeness, and truthfulness of the data and believe that this requirement would force the MCOs to establish procedures and protocols to ensure that the information is correct. These commenters believe that problems arise when the person signing the certification may not have direct information concerning these facts, and that the CEO or CFO should certify the accuracy of the data on a document, a requirement similar to that in the Medicare+Choice program.

Response: We agree with these commenters that an accountable individual such as the CEO or CFO should sign the certification, and we accept the commenters' suggestion that the Medicare+Choice requirement be adopted. Under § 422.502(l) of the Medicare+Choice regulations, certifications must be signed by "the CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer." We have adopted this language in § 438.606(a)(2) of this final rule.

Comment: Several commenters urged that related entities, contractors, or subcontractors that generate these data should be required to certify the accuracy, completeness, and truthfulness of the data.

Response: We agree with these commenters, and we are providing (1) in § 438.602 that an MCO "and its subcontractors" must comply with the certification requirements in subpart H; and (2) in §thnsp;438.606(a)(1) that MCOs must require subcontractors to certify the data they submit to MCOs if the data are used in determining the MCO's payment.

Comment: Another commenter believes that the large majority of data on which payment is based is determined by the State agency and not by the MCO. Regardless of the billing data submitted by the plan, the commenter believes the State determines the payment to the MCO based on information within the State system and the certification of the accuracy of the data should be applied equally to the State agency.

Response: The purpose of the certification requirement with respect to data submitted to the State by the MCO is to ensure that MCOs do not submit false or inaccurate data that might result in inappropriate higher payment amounts. It is a protection for the State and HCFA against being defrauded, or paying an MCO more than the amount to which it should be entitled. The State has no incentive to pay more than the amount dictated by accurate information, and has existing incentives to use accurate data. A major purpose of the certification requirement is to facilitate possible cases under the False Claims Act. States are not subject to the False Claims Act. States are subject to detailed requirements in § 438.6(c) requiring that payments are accurate and appropriate. We do not believe that States should have to certify data. However, if payment is based solely on State data, and an MCO does not submit any data upon which its payment is based an MCO would not have to sign certifications under subpart H.

Comment: One commenter believes that data integrity is critical but was still unclear on certification requirements.

Response: We believe that this final rule clearly spells out which data must be certified (§ 438.604), who must certify the data (§ 438.606(a)), and to which data the certifying individual is attesting (§ 438.606(b)). We believe that the requirements of these regulations are clear. We believe that imposing more detailed requirements than already set forth in this final rule would be overly prescriptive and that States should have flexibility in applying these requirements.

Comment: One commenter believes that the State Medicaid Fraud Control Units (MFCUs) should be added to the list of parties to whom the MCO must submit the reports required in § 438.606.

Response: We did not identify the MFCUs as a recipient of the reports on the violations of law because States are already required under 42 CFR 455.21 to refer to the MFCU all cases of suspected provider fraud, including such materials as records or information kept by the State Medicaid Agency or its contractors, computerized data stored by the Agency, and any information kept by providers to which the State Medicaid Agency is authorized access. States already have established relationships with MFCUs relative to referring cases of suspected fraud and abuse. We believe this requirement is already sufficiently addressed, and we have not revised this aspect of the proposed rule.

Comment: One commenter suggested that administrative and management arrangements or procedures should include specific plans for the method by which the MCO intends to discover and discourage fraud and abuse and that these specific plans should be submitted to the State Medicaid Agency for review and prior approval before execution of any contract. The commenter believes that specific plans would eliminate subjective determinations by each MCO of that which constitutes effective arrangements and management procedures.

Response: We believe that it is appropriate to allow States flexibility in determining their requirements for MCOs in this regard. We also note that States may have laws that govern this authority, and we wish to respect those laws.

Comment: One commenter noted differences between the language in proposed § 438.606 requiring only that MCOs have a process for reporting violations of law and language in §422.501(b)(3)(vi) of the Medicare+Choice interim final rule published on June 28, 1998 requiring that Medicare+Choice organizations have a comprehensive compliance plan

that includes an "adhered-to" process for reporting credible information to HCFA and/or OIG. The commenter recommended that HCFA adopt the Medicare+Choice language in §422.501(b)(3)(vi). The commenter believes consistency between Medicare and Medicaid will reduce the regulatory burden on managed care plans that elect to participate in both programs by eliminating any uncertainty as to what standard of conduct applies. A few commenters raised concerns about the general requirement that MCOs have "administrative and management arrangements or procedures designed to guard against fraud and abuse." Instead of imposing Federal requirements in this area, such as self-reporting, the commenter believes the rule should allow States to take the lead in working with MCOs to combat fraud and abuse in the Medicaid program.

Response: We agree with the first commenter that maintaining consistency with Medicare+Choice will eliminate unnecessary burden on plans and that administrative and management procedures that include a compliance plan will work toward that end. We have included a compliance plan that includes the same elements as those listed in the Medicare+Choice final rule published on June 29, 2000 (65 FR 40170). We disagree with the second commenter that there should be no Federal requirements, but, consistent with the commenter and consistent with the Medicare final rule, which deleted the mandatory self-reporting requirement in§422.501(b)(3)(vi)(H), we have deleted this requirement. The Medicaid MCO requirements and Medicare+Choice requirements are now consistent on this issue.

Comment: A few commenters raised concern over the term "credible" information. One commenter believes the word "credible" should be replaced with the standard contained in § 455.15, specifically that if there is "reason to believe that an incident of fraud or abuse has occurred," MCOs are required to report this to the State. One commenter believes the word "credible" should be eliminated entirely so that MCOs are not penalized for reporting in good faith information that is later found not to be credible.

Response: We have deleted the Federal self-reporting requirement containing the word "credible," so these comments are moot.

G. Sanctions (Subpart I)

Section 1932(e)(1) of the Act requires, as a condition for entering into or renewing contracts under section 1903(m) of the Act, that State agencies establish intermediate sanctions that the State agency may impose on an MCO that commits one of six specified offenses: (1) Failing substantially to provide medically necessary services; (2) imposing premiums or charges in excess of those permitted; (3) discriminating among enrollees based on health status or requirements for health care services; (4) misrepresenting or falsifying information; (5) failing to comply with physician incentive plan requirements; and (6) distributing marketing materials that have not been approved or that contain false or materially misleading information. In the case of violation number 6, the statute imposes sanctions against PCCMs as well as MCOs. Proposed § 438.700 contains the above provisions from section 1932(e)(1)of the Act.

In section 1932(e)(2) of the Act, the Congress provided specific sanction authority under which State agencies may impose civil money penalties in specified amounts for specified violations, take over temporary control of an MCO, suspend enrollment or payment for new enrollees, or authorize enrollees to disenroll without cause. These provisions are reflected in proposed § 438.702(a). Given the extraordinary nature of the sanction of taking over management of an MCO, we proposed in § 438.706 that this sanction be imposed only in the case of "continued egregious behavior," in situations in which there is "substantial risk" to enrollee health, or when the sanction is "necessary to ensure the health of enrollees."

Although these sanctions are referenced in section 1932(e)(1) of the Act as sanctions to be imposed on MCOs and on PCCMs only in the case of marketing violations, section 1932(e)(2)(C) of the Act refers to a "managed care entity," while paragraphs (D) and (E) that follow refer to "the entity" and provide for suspension of enrollment or suspension of payment after the date the Secretary notifies "the entity" of a determination that it has violated "section 1903(m) or * * * section [1932]." While only an MCO could violate section 1903(m) of the Act, a PCCM could violate requirements of section 1932 of the Act that apply to MCOs and PCCMs generally or to PCCMs specifically. In proposed § 438.702(b)(2), we interpret the foregoing language to mean that the sanctions in sections 1932(e)(2)(D) and (E) of the Act are available in the case of a PCCM that violates "any requirement" in section 1932 of the Act. The general intermediate sanction authority in paragraphs (D) and (E) of section 1932(e)(2) of the Act is reflected in § 438.702(b)(1) with respect to MCOs. In light of the foregoing interpretation, paragraphs (b)(4) and (b)(5) of § 438.702 use the term MCO or PCCM rather than MCO only, even though the only "determinations" that apply to PCCMs are terminations under proposed § 438.700(a)(6) (marketing violations) or the general violations of section 1932 of the Act that are addressed in § 438.702(b)(2). Under the codification in the proposed rule, these latter determinations technically are not "determinations under § 438.700," and are not included under paragraphs (b)(4) and (b)(5) of § 438.702. As recodified in this final rule, these determinations are addressed in § 438.700(d).

Section 1932(e)(3) of the Act requires that, for MCOs with chronic violations, the State impose temporary management and allow disenrollment without cause. This provision is implemented in proposed § 438.706(b).

Section 1932(e)(4) of the Act authorizes State agencies to terminate the contract of any MCO or PCCM that fails to meet the requirements in sections 1932, 1903(m), or 1905(t),of the Act. This authority is implemented in proposed § 438.708. Under section 1932(e)(4)(B) of the Act, before terminating a contract, the State is required to provide a hearing. Proposed § 438.710 sets forth this hearing requirement as well as procedures for the hearing. Under section 1932(e)(4)(C) of the Act, enrollees must be notified of their right to disenroll immediately without cause in the case of any enrollee subject to a termination hearing. Proposed § 438.722 reflects this provision.

Section 1932(e)(5) of the Act contains a general requirement that States provide "notice" and "such other due process protections as the State may provide" in the case of sanctions other than terminations, which are governed by section 1932(e)(4)(B) of the Act. Section 1932(e)(5) of the Act also provides that "a State may not provide a managed care entity with a * * * hearing before imposing the sanction" of temporary management. Proposed § 438.710(b) reflects this statutory language.

In proposed § 438.724, we proposed that States be required to notify HCFA whenever they impose or lift a sanction.

The new sanction authority in section 1932(e) of the Act represents the first time that the Congress has granted Medicaid sanction authority directly to State agencies. Under section 1903(m)(5) of the Act, which the Congress has left in place, HCFA has authority to impose sanctions when Medicaid-contracting MCOs commit

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offenses that are essentially the same as those identified in section 1932(e)(1) of the Act. In proposed § 438.730, we retain the existing regulations implementing section 1903(m)(5) of the Act, which is currently codified at § 434.67.

Comment: A few commenters recommended that we add the requirement: "States shall develop criteria to guide them in their determinations of when and how to use specific sanctions individually or in conjunction with each other."

Response: While section 1932(e) of the Act mandates that States establish intermediate sanctions, it grants States flexibility to determine which sanctions to impose and when to impose them, stating that State sanctions "may include" those identified in section 1932(e)(2) of the Act and that the State "may impose" these sanctions. We believe that the Congress intended to give States discretion and flexibility in this area. While we would expect that most States would establish specific criteria to guide their exercise of sanction authority, we believe it should be a State decision whether or to what extent it imposes sanctions. We are not including the suggested Federal criteria requirement.

Comment: One commenter suggested that we provide expressly in subpart I that sanctions be imposed for violations of proposed § 438.100, which require that contracts specify what services are included in the contract and require that States make arrangements for those not covered through the contract. The commenter believes that this would help ensure access to all Federally mandated benefits and services, including nurse-midwifery services.

Response: The Congress intended that States have flexibility in imposing sanctions, requiring only that States have sanctions in place for the specific violations in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act. Our authority under section 1903(m)(5) of the Act is similarly limited. Even under our broad interpretation of paragraphs (D) and (E) of section 1932(e)(2) of the Act, under which States may impose intermediate sanctions for any violation of sections 1903(m) or 1932 of the Act, the sanctions suggested by the commenter would not be provided for since neither of these sections mandate the inclusion of the contract terms required under proposed § 438.100(a) or impose the obligation on States under proposed § 438.100(b). If services that are included in the contract are not provided, sanctions are authorized under § 438.700(a)(1).

Comment: One commenter supported the provisions in subpart I but suggested that misrepresentation to any member of the public should also be cause for sanction.

Response: Sections 438.700(b)(4) and (5) allow States to impose sanctions on MCOs for misrepresenting or falsifying information that they furnish to HCFA, the State, an enrollee, potential enrollee, or health care provider. This provision implements section 1932(e)(1)(A)(iv) of the Act, which specifies these entities. It is not clear how a misrepresentation to a member of the public who is not a provider, enrollee, or potential enrollee would be relevant. We believe that this list covers any individual, government agency, or entity that could be affected by a misrepresentation. States are free to develop, under State law, a policy to require sanctioning for misrepresentation to any member of the general public.

Comment: One commenter had serious concerns about what the commenter perceived to be the absence of adequate Federal, as opposed to State, standards on the rights to be afforded to MCOs to contest sanctions. Although this aspect of the rule reflects section 1932(e)(5) of the Act, which leaves the decision on what due process protections to provide to MCOs to the States, the commenter believes that States should be encouraged to provide MCOs the same procedural protections that HCFA has provided to Medicare+Choice organizations before HCFA imposes sanctions.

The commenter was also concerned about potential conflicts between the intermediate sanctions required under the Act and the provisions of State law. This commenter also applauded the proposed rule allowing MCOs to be sanctioned for not providing medically necessary services to Medicaid enrollees. Regarding discrimination among enrollees on the basis of health status or need for health care services, the commenter recommended that all health insurance policies fulfill the following requirements: (1) no waiting periods for enrollment; (2) no limitation of coverage or reimbursement because of severe chronic or common recurring illnesses; (3) no premium rate increases based on experience only on community rating; and (4) guaranteed renewability and portability.

Response: The statute requires timely written notice, a hearing before terminating an MCO contract, and in the case of other sanctions for "such other due process protections as the State may provide." The commenter recognizes that the Congress has expressly granted States the discretion to determine what procedures to afford to MCOs in the case of intermediate sanctions and civil money penalties. We agree with the commenter that States should be encouraged to consider offering the types of procedures offered to Medicare+Choice organizations under the Medicare regulations. We do not agree that there is a risk of conflict between the intermediate sanctions authority in subpart I and provisions of State law, because these sanctions have to be established only if State law does not cover the specified situations. With regard to the commenter's suggestion concerning discrimination, we believe that the regulations address these issues. In the case of the "waiting period" issue, § 438.6(c)(1) requires that enrollees be accepted in the order in which they apply without restrictions. With respect to the issues of coverage limits or premium increases based on a health condition, § 438.6(c)(1) addresses the provision prohibiting discrimination based on health status or need for health services. Section 438.6(c)(1) also addresses the issue of renewability to the extent that the individual remains Medicaid eligible and the contract remains in place. Since Medicaid only covers people who meet financial eligibility requirements, it is impossible to guarantee renewability. "Portability" of Medicaid benefits is similarly impossible.

Comment: A commenter suggested that subpart I should address the issue of inadvertent balance billing of Medicaid enrollees. There are no guidelines that would enable the State agency or contracting MCOs to differentiate minor technical violations from those that should result in sanctions and fines of several thousand dollars. The regulations should develop criteria to guide this kind of decision making and to protect MCOs from arbitrary State action.

Response: Under section 1932(e) of the Act, imposition of sanctions is almost entirely at a State's discretion, other than termination and temporary management rules. We believe that States are in the best position to develop criteria for when they will impose sanctions for balance billing violations, which could be sanctioned under section 1932(e)(1)(A)(ii) of the Act and § 438.700(b)(2) (codified at § 438.700(a)(2) in the proposed rule) as "charges on enrollees" in "excess of" the charges permitted under title XIX.

Comment: A commenter stated that section 438.700, which specifies the basis on which States may impose intermediate sanctions on an MCO, should include discrimination based on race, ethnicity, or language. This would be in keeping with Title VI of the Civil Rights Act which states that "no person in the United States shall, on ground of race, color or national origin, be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." Several of the commenters stated that the omission of Title VI requirements from the list of sanctionable activities reduces the likelihood that MCOs will comply with cultural competency requirements. It is also very important that the rules strengthen the requirements for both State Medicaid agencies and their managed care plans to collect data regarding the race/ethnicity of the enrollees and the care of patients with limited proficiency and/or low literacy. The commenter recommended amending proposed § 438.700(a)(3) (recodified at § 438.700(b)(3) in this final rule) to read, "Acts to discriminate among enrollees on the basis of their health status, race, color or national origin, or requirements for health care services."

Response: Section 438.700(b)(3) reflects the language in section 1932(e)(1)(A)(iii) of the Act, which addresses only discrimination based on health status. Since § 438.700(b) reflects the specified violations for which the Congress in section 1932(e)(1)(A) of the Act said States must have sanctions, we believe that we do not have authority under section 1932(e) of the Act to add additional grounds. The civil rights law cited by plaintiffs has its own enforcement provisions, which are administered by the HHS Office for Civil Rights. We believe that it is appropriate to inform MCOs of their obligations under this and other civil rights laws and have required under revised § 438.6(d)(4) that contracts expressly reflect these obligations. Also, § 438.100(d) specifies that the State must require MCOs to comply with Title VI of the Civil Rights Act and other civil rights laws. In addition to the Federal enforcement remedies under civil rights laws, States are free to impose sanctions on an MCO that denies services on the basis of race, color, or national origin, or establish their own rules under State law.

Comments: In general, several commenters wanted the regulation to be clear that States have the authority to impose sanctions for violations beyond those that are listed in the regulation. These commenters do not believe that the six violations listed in this section should be seen as exhaustive and that States should not be precluded from establishing and imposing separate State sanctions or from imposing other types of sanctions. These commenters believe that while our intent may have been clear in the preamble, we should set forth our policy with respect to sanctions in the regulations text. Specifically, the commenters stated that it is unclear whether the regulations allow States to broaden the parameters for imposing sanctions on MCOs or limit the States to the basis set forth in the Act and the regulations. States have made progress in developing their own protections and responses to hold MCOs accountable and should not be preempted by Federal law from using them. They stated that we recognized this concept in the preamble of the proposed rule and suggested that we incorporate this concept into the actual regulations text. They believe that the six offenses outlined in the regulation should not be the only offenses that would permit imposition of sanctions. There are numerous offenses that MCOs could commit that could affect both the integrity of the Medicaid program and the quality of care that Medicaid enrollees receive, for example, failure by the plan to submit accurate data or failure to achieve State defined quality improvement standards. The commenters believe that we should not limit a State's ability to enforce its contract and should instead give States the explicit authority to impose sanctions if an MCO performs unsatisfactorily as found during an annual medical review or audit or if an MCO does not provide complete data to a State or Federal regulator. Recommended solutions provided by the commenters included the following:

- Add a paragraph (a)(7) to § 438.700 stating that sanctions can be used for violations of 1903(m) and 1932 of the Act;
- Add a new paragraph (c) to § 438.700 that specifies: "State agencies retain authority to provide for additional sanctions under State law or regulation that address both these specified areas of noncompliance as well as additional areas of noncompliance. Nothing in this regulation prevents State agencies from exercising that authority;"
- Add a new paragraph (a)(7) § 438.700 that allows States to impose sanctions for any breach of contract not mentioned in paragraphs (a)(1) through (a)(6);
- Amend § 438.700(a) to specify that the sanctionable violations include, but are not limited to, the specified violations;
- Add to § 438.700(a), after the word "determination," "based on findings from onsite survey, enrollee, or other complaints, financial audits, or any other means." This language clarifies that the State is authorized to act based on findings it has made, regardless of the source of the original information. Broad authority for the State to sanction on the basis of complaints provides enrollees with assurances that the State can hold the entity accountable for specific acts of noncompliance that enrollees or their advocates bring to the State's attention but that might not be evident on an onsite survey.

Response: We agree with the commenters that the sanctions in subpart I do not prevent States from imposing any other sanction they wish under State law, and that the regulations should clearly state that this is the case. We are adopting the commenter's suggested regulations text in a new paragraph (b) in § 438.702. We also agree that it would be useful to clarify that these sanctions may be imposed based on information obtained through enrollee complaints, audits, onsite surveys, or any other means and have added the commenter's suggested language to § 438.700(a).

We disagree with the commenters' suggestions that the list of sanctions in proposed § 438.700(a) be broadened or that the regulations provide for imposing the full range of possible sanctions in the case of any violation of section 1932 or 1903(m) of the Act. To the extent that a State is relying not on any State law, but solely on the affirmative authority enacted by the Congress in section 1932(e) of the Act, this authority is necessarily limited to that provided by the Congress. While we have broadly interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act to permit suspension of enrollment or payment for any violations of 1903(m) and 1932 of the Act (see § 438.700(d)) and the above discussion of proposed § 438.702(b), section 1932(e) of the Act does not contain authority to impose any of the other sanctions in section 1932(e)(2) of the Act for violations other than those enumerated in section 1932(e)(1)(A)(i) through (v) of the Act.

Comment: One commenter argued that we should amend § 438.700(a) to apply to PCCMs as well as to MCOs. This commenter does not believe there was a compelling argument for applying most sanctions only to MCOs. The commenter argued that PCCMs that fail to provide medically necessary services, misrepresent information provided to HCFA, the State, an enrollee, potential enrollee, or health care provider, or impose excessive premiums or charges on enrollees should be subject to sanctions. Another commenter strongly advised HCFA against drawing a

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distinction between MCOs and PCCMs in granting the States authority to impose sanctions for inappropriate behavior. Other commenters also believe that the final rule should provide additional authority to impose sanctions on all MCOs and PCCMs and specifically suggested that the final rule gives States the authority to—

- Require noncompliant MCOs or PCCMs to submit a corrective action plan;
- Temporarily and permanently withhold capitation payments and shared savings in response to unsatisfactory MCO or PCCM performance during an annual medical review or an audited review;
- Make adjustments in MCO or PCCM payments;
- Mandate payment for medically necessary treatment;
- Recoup the cost of State payment for out-of-plan care from a noncompliant MCO or PCCM; and
- Arrange for the provision of health care services by third parties at the cost and expense of the delinquent MCO or PCCM.

These commenters believe that Medicaid beneficiaries in both delivery systems should receive equal protection under the law and that denying States equal authority for imposing sanctions under both delivery systems is not judicious. Conversely, one commenter found applying sanctions to PCCMs problematic because this would hold these entities to a higher standard. California PCCMs currently are not Knox-Keene licensed. This commenter was concerned that this section of the proposed rule may require PCCMs to become Knox-Keene licensed and/or their contracts may have to be amended to reflect the new higher standard.

Response: To the extent a State is relying solely on the Federal authority provided by the Congress as its authority to impose a sanction, this authority is limited to that which the Congress provided. With respect to the violations enumerated in paragraphs (i) through (v) of section 1932(e)(1)(A) of the Act, all but the marketing violations are limited to MCOs. We have already interpreted paragraphs (D) and (E) of section 1932(e)(2) of the Act broadly to permit the sanctions in those paragraphs to be imposed on PCCMs in the case of any violation of section 1932 of the Act. We do not believe that section 1932(e) of the Act can reasonably be interpreted to provide authority for the types of sanctions suggested by the commenter. Because most PCCMs are paid on a fee-for-service basis, they do not have the same incentives to deny medically necessary services that MCOs do. States may provide for sanctions against PCCMs under their own State sanction laws. With respect to the commenter concerned about applying sanctions to PCCMs, the Congress provided for this in section 1932(e) of the Act, and we do not believe that this application is inappropriate or would subject PCCMs to the Knox-Keene Act.

While States are free to adopt the specific additional enforcement strategies suggested by the commenter in the bullet points above, these strategies cannot be included in regulations implementing section 1932(e) of the Act, since there is no reasonable reading of the provisions of section 1932(e) of the Act that would authorize those remedies.

Comment: One commenter believes that HCFA should specify additional grounds for imposing intermediate sanctions and suggested that the final regulations explicitly state that States may impose sanctions when an MCO fails to comply with the grievance regulations of this part. States would be more likely to impose these intermediate sanctions rather than the options provided for in § 438.424.

Response: The sanction authority provided for by the Congress in section 1932(e) of the Act is limited. Section 1932(e) of the Act sets forth the minimum set of violations that must be subject to sanction and provides Federal authority to impose sanctions for these violations. We cannot expand on this authority by regulation. We have clarified in the preamble, and now in § 438.702(b), that States are free to impose sanctions under State law that go beyond those authorized by the Congress in section 1932(e) of the Act, including sanctions for failing to comply with grievance requirements. To the extent that an MCO violates the grievance requirements or regulations implementing section 1932(b)(4) of the Act, States could impose the limited sanctions provided for under paragraph (D) and (E) of section 1932(e)(2) of the Act and § 438.700(b).

Comment: One commenter believes that we should amend § 438.700(a)(1) to refer expressly to the failure to provide medically necessary "items" as well as services, since this term is included in section 1932(e)(1)(A)(i) of the Act. Alternatively, the commenter suggested that we use the term "benefits" rather than "services," since the commenter believes that the former term would include services and items. For example, prescription drugs and durable medical equipment may not be considered "services."

Response: We do not use the term "items" in our regulations because the term "services" as used in the regulations includes covered "items" as well. While only the Medicare regulations expressly specify that "services" includes " items" (§ 400.202), section 1905(a) of the Act uses the term "care and services" to encompass all services or items for which Medicaid payment may be made. References in the regulations to "services" include covered "items" as well.

Comment: A few commenters were confused regarding our role in the sanction area. These commenters are unclear as to whether HCFA would be making sanction determinations, either at the request of the State or independently. The commenters are opposed to HCFA making sanction determinations without the involvement of the State.

Response: Under § 438.730 of the final rule, previously codified at § 434.67, we may impose sanctions on an MCO based on the recommendation of the State. Under paragraph (e) of § 438.730, we also retain the right to act independently with respect to sanctions. This is consistent with section 1903(m)(5) of the Act, which grants us the authority to impose sanctions against an MCO. This Federal authority was not affected by the new BBA sanction provisions in section 1932(e) of the Act. While we would not expect to impose sanctions without the involvement of the State, we believe that the regulations should reflect the fact that the Congress has authorized us to do so.

Comment: One commenter believes that additional consumer protections were needed with regard to the right to disenroll without cause when sanctions are imposed and that States should be required to educate enrollees on the circumstances that allow them to disenroll automatically. Another commenter requested that HCFA clarify that a State is free to suspend default enrollment, leaving beneficiaries to make an affirmative decision whether to enroll. Several other commenters suggested that HCFA further clarify this provision and give States the option of suspending all enrollment, not just default enrollment. According to the commenters, this clarification would not only provide States with greater flexibility but would also permit greater choice for Medicaid beneficiaries.

Response: Under § 438.702(a)(4) of the final rule, the State may suspend all new enrollment, including default enrollment, as an intermediate sanction. The State is not precluded from establishing other types of intermediate sanctions that are not included in the

regulation. With respect to the suggestion concerning information provided to enrollees, § 438.56(c) requires that information on an enrollee's disenrollment rights be provided annually, including the circumstances under which a beneficiary can disenroll "for cause."

Comment: Several commenters requested clarification that States still have the flexibility to establish civil money penalties beyond those listed in the regulation. One commenter specifically mentioned that the amounts of the civil money penalties seemed high but that they would not be problematic so long as the amounts were not mandatory. Another commenter mentioned that if PCCMs could be sanctioned, there should be a regulatory ceiling on the amount of the penalty.

Response: The amounts specified in this provision only apply to the extent the State is relying upon Federal law, under section 1932(e) of the Act, as its authority to act. States may, under State law, establish additional civil money penalties that may be more severe than those authorized under section 1932(e)(2)(A) of the Act or § 438.704. With respect to PCCMs, to the extent the State is relying on Federal law as its authority for the establishment of sanctions, the civil money penalties under § 438.704 would be maximum amounts. A State is not precluded from developing additional intermediate sanctions against PCCMs or MCOs, as explicitly noted in § 438.702(b).

Comment: One commenter believes that HCFA should provide additional guidance as to how the amount of the civil money penalty elected, in cases in which States have discretion to choose an amount below a specified maximum, should be related to the purported harm. The commenter believes that HCFA should provide some rationale for assessing money penalties and should discuss this section with the commenter to develop this rationale.

Response: Section 1932(e)(2)(A) of the Act establishes a relationship between the amount of the civil money penalty (as described in § 438.704 of the final rule) and the specific violations to which these penalties apply. In clauses (i) and (ii), "maximum" amounts are specified. We believe that by establishing a "maximum" amount for these violations, the Congress intended that States have the discretion to decide what amount to impose below these maximum amounts. We are allowing the States to decide the amount they wish to impose in penalties and to establish criteria for cases when particular amounts at or below the specified maximums will be imposed.

Comment: One commenter expressed confusion regarding the maximum penalty that can be imposed under section 1932(e)(2)(A)(iii) of the Act for imposing premiums or charges in excess of those permitted. Under section 1932(e)(2)(A)(iii) of the Act, for this type of violation, the penalty that can be imposed is double the amount of any excess amount charged to an enrollee with half this amount refunded to the overcharged enrollee or enrollees. The commenter asked whether this would be for the one enrollee who reported a $5 overcharge (that is, one $10 amount) or $10 per each enrollee in the plan. Another commenter suggested that the regulation should be changed to provide that it is the MCO's responsibility, not the State's, to return the amount of the overcharge to affected enrollees and that the authority to collect double the amount of the excess charge provides authority to collect more than the $25,000 limit stated in paragraph (a).

Response: Section 438.704(b)(4) of the final rule specifies that for premiums or charges in excess of the amounts permitted under the Medicaid program, civil money penalties may be imposed at an amount representing double the amount of the excess charges. This would be imposed for each instance of the violation and not necessarily calculated using the total number of enrollees in the plan. If all enrollees were charged the excess amount, this amount would be doubled for all enrollees. Since the State imposes and collects the entire fine, we believe that the State ordinarily would reimburse enrollees by distributing half the amount specified in section 1932(e)(2)(A)(iii) of the Act. We would leave it to the State's discretion, however, whether it wishes to reimburse enrollees through the MCO.

With respect to the commenter's last point about the applicability of the authority to impose $25,000 in penalties in cases of overcharges to enrollees, section 1932(e)(2)(A)(i) of the Act permits a civil money penalty of "not more than" $25,000 for "each determination" under section 1932(a)(1)(A) of the Act, "except as provided in clause (ii), (iii), or (iv)." We believe that this language could reasonably be interpreted in two ways. Under one reading, "except as provided in clause (ii), (iii), or (iv)" would be interpreted to mean that clause (i) has applicability only when the other three clauses do not apply. Under this interpretation, one would look solely to clause (ii), (iii), or (iv) to determine the amount that could be imposed in civil money penalties when those clauses apply. If the amount under section 1932(e)(2)(A)(iii) of the Act was $10,000, only this amount could be imposed in penalties. The commenter has suggested an alternative reading, under which the "except as provided" clause is read as an exception to the $25,000 limit in clause (i). Under this interpretation, civil money penalties of up to $25,000 could be imposed for any determination under section 1932(e)(1)(A) of the Act "except" to the extent that an even higher amount is permitted in the cited clauses. The $25,000 amount would, under this reading, constitute a "floor" authorized penalty with potentially higher "ceilings" under the other clauses. The $100,000 amount provided for under clause (ii) is higher than $25,000 and would constitute an exception to the $25,000 limit. The amount determined under clause (iv) would similarly be higher than $25,000, as long as just two individuals were denied enrollment based on health status (which would result in a penalty of $30,000). Under clause (iii), "double the excess amount charged" also could easily exceed $25,000, and thus also constitute an "exception" to the $25,000 limit in clause (i). We agree with the commenter that this latter interpretation is the best interpretation of the statute, in that a substantial penalty could be imposed for overcharging enrollees, even if the amount of the overcharge is not substantial. We are providing in § 438.704(b)(4) that States may impose civil money penalties of the "higher of" $25,000 or the amount under section 1932(e)(2)(A)(iii) of the Act.

Comment: Several commenters requested that HCFA reconcile the numerous variations between proposed § 438.704 and 42 U.S.C. 1396u2(e)(2)(A). The commenters suggested that the term "either" in proposed § 438.704(a) should be eliminated and replaced with the term "any" and that the words "a failure to act" in proposed § 438.704(a)(1) should be replaced with "an act or failure to act." These changes would make it clear that the State is not being directed to respond to one circumstance at the expense of another and that noncompliance can be applied in both actions and failures to act.

Response: We agree with the commenter's points, and the revised version of § 438.704 does not contain the reference to "failure to act" without "action," or the word "either" as referenced by the commenter.

Comment: Numerous commenters believe that we were too restrictive in our interpretation of the $100,000 cap for some of the civil money penalties

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outlined in the proposed regulation. In the view of these commenters, the MCO should be fined $15,000 for each beneficiary not enrolled as a result of discrimination, plus $100,000. One commenter believes that there should not be a $100,000 cap at all, because in large areas that threshold is quickly met and enforcement could not proceed.

Response: Under section 1932(e)(2)(A)(iv) of the Act, the provision for a $15,000 penalty for each individual denied enrollment under "a practice" described in section 1932(e)(1)(A)(iii) of the Act is "subject to" section 1932(e)(2)(A)(ii) of the Act. Section 1932(e)(2)(A)(ii) of the Act limits the amount of any penalty for "a determination under [section 1932(e)](1)(A) to $100,000." If section 1932(e)(2)(A)(iv) of the Act were intended to permit penalties in excess of $100,000 for a finding of discrimination under section 1932(e)(1)(A)(iii) of the Act, it would have said "in addition to" the amount in clause (ii) of section 1932(e)(2)(A)(ii). Instead, it says that the amount under section 1932(e)(2)(A)(iv) of the Act is "subject to" clause (ii). We believe this can only be read to mean that the total amount under clause (iv) is "subject to" the limit in clause (ii) and cannot exceed $100,000 per determination of a discriminatory practice. If there is more than one finding of a discriminatory "practice described in" section 1932(e)(1)(A)(iii) of the Act, a penalty of up to $100,000 could be imposed for each such finding.

Comment: All of the commenters oppose the required imposition of temporary management in the case of repeated violations. They believe that we should take a flexible approach to this provision, as it is unlikely that States would choose to impose this requirement, and in many instances this requirement would be overly burdensome. Most commenters indicated that States will be more likely to terminate an MCO's contract under these egregious circumstances in which our regulation requires the imposition of temporary management. Commenters stated that, putting aside the practical problems associated with such a remedy, they believe that a plan that is incapable of managing itself would be equally poorly run by temporary management. In the view of these commenters, this plan should have its contract terminated and should not be subject to the imposition of outside management in a probably futile attempt to salvage the operation. Another commenter stated that this provision is of great concern because the State should always have the authority to terminate the MCO's contract if the MCO meets any specified contract termination threshold. Forcing the State to continue a contractual arrangement and payment when the State has determined that termination is the most appropriate course of action strikes this commenter as imprudent. The imposition of temporary management may be very administratively complex if the State MCO licensing agency does not concur with this course of action, particularly when the MCO has lines of non-Medicaid business that would be affected. Requiring the State to work through the complexities of imposing temporary management when this does not appear to be the appropriate response would be very problematic to the State and have potentially negative ramifications for both enrollees and providers. One commenter believes that if it is appropriate for a State government agency to take over the management of a managed care plan, the appropriate agency would be the State Department of Insurance. That agency generally has far more experience in managing troubled insurers and managed care plans. The commenter recommended that HCFA convey these points to State agencies. Another commenter stated that temporary management requires extensive knowledge and should only be used sparingly. The commenter believes that the State should defer to the State insurance commissioner as temporary management should fall under his or her purview. One commenter would favor a change in the regulation to allow temporary management as an option rather than a mandate. Implementing this sanction would place a heavy administrative burden on the State. Although States would have the discretion to impose this sanction on an MCO, it is doubtful this sanction would ever be used. Authorizing the State to take over management of a commercial enterprise seems to go beyond the scope of authority available to the State, while allowing immediate disenrollment of enrollees is quite justified. The commenter also stated that it is not necessary to assume management of the MCO when other sanctions are available, including termination of the MCO's contract. This sanction is overreaching and invades the State's right to determine appropriate sanctions for its plans. Another commenter stated that in the event of continued egregious behavior by an MCO, the State would certainly terminate the contract and reassign enrollees but would not want to be put in the position of managing an MCO. Although this provision is based on statutory language, the commenter urged HCFA to recognize and to minimize the potential conflict with existing State insurance regulations, policies, and processes for monitoring and taking action against financially insecure plans. One commenter recommended that the regulations reflect the decision reached in the preamble, stating that States set the thresholds for egregious actions requiring temporary management and that the contract can be terminated rather than imposing temporary management.

Response: Section 1932(e)(3) of the Act provides that the State shall (regardless of what other sanctions are provided) impose the sanction of temporary management in cases in which an MCO has "repeatedly" violated section 1903(m) of the Act. To the extent that the commenters believe that the requirement in § 438.706(b) is inappropriate, their arguments are properly directed at the Congress, since this regulatory provision merely reflects the statutory requirement in section 1932(e)(3) of the Act and has no independent legal effect. We have no authority to alter or delete this requirement. We agree with some of the sentiments reflected in the above comments and intend to give States the maximum flexibility permitted by statute. The regulations permit the State to terminate a contract at any time and to do so rather than imposing temporary management. States are also free to establish a threshold in their State plan or otherwise that would have to be met before an MCO is considered to have "repeatedly" committed violations of section 1903(m) of the Act for purposes of the mandatory temporary management requirement in section 1932(e)(3) of the Act. Since the circumstances for each population and MCO vary greatly, we believe it is prudent to work with each State to determine a reasonable threshold. All States will have ample ability to terminate a contract, if they choose, rather than imposing the temporary management requirement.

Comment: Two commenters were concerned over the effect imposition of temporary management would have on the MCO's commercial enrollment. Another noted that, based upon the regulatory language, this provision could apply to an MCO that also has Medicare and/or commercial business. These commenters believe that this sanction provision raises serious practical concerns, especially with the lack of any due process protections other than written notice. One commenter recommended adding a new paragraph (c) to § 438.706 that says the State shall develop criteria for who can serve as a temporary manager and shall maintain a list of individuals and entities meeting the criteria who are able and willing to serve in that capacity.

Response: We have no authority to change the requirement in § 438.706(b), since it reflects the statutory requirement in section 1932(e)(3) of the Act. States are free to develop the criteria suggested by the commenter or to maintain the list suggested. Since States are free to terminate a contract before it gets to the stage of a mandatory temporary management, and in keeping with our decision to grant States maximum flexibility in complying with section 1932(e)(3) of the Act, we do not accept the commenter's suggestion that these specific approaches be mandated. We note that for those situations in which temporary management would be mandated under whatever criteria the State develops, MCOs would have had ample warning through other intermediate sanctions and corrective action plans. Since States have the authority to terminate a contract instead of imposing temporary management, termination is more likely to be a State's sanction of choice, with MCOs receiving hearings prior to termination. Except for repeated section 1903(m) of the Act violations, the rest of this section is for use entirely at a State's option. Because we believe that States will be unlikely to exercise temporary management under § 438.706, we believe there should be no effect on an MCO's commercial or Medicare enrollment. In the unlikely event that a State takeover of management were to occur, we would expect States to take measures to limit the scope of their control to the parameters necessary to administer the Medicaid contract.

Comment: One commenter encouraged States to take into consideration the unique needs of children when determining the identification of egregious behavior and threats to enrollees and the number of offenses that would require imposition of temporary management.

Response: We encourage States to take the unique needs of children into consideration when determining when temporary management of an MCO is appropriate. We will take this into consideration when working with States that wish to develop thresholds of section 1903(m) of the Act violations.

Comment: One commenter appreciated being given the clear authority to impose temporary management on an MCO. Another group of commenters supported HCFA's guidance in § 438.706(a) regarding when the voluntary imposition of temporary management is appropriate. Voluntary imposition of temporary management is appropriate when the State finds through onsite survey, enrollee complaints, financial audits, or any other means that there is egregious behavior on the part of the MCO, substantial risk to enrollees' health, or the need to impose the sanctions to ensure the health of the MCO's enrollees.

Response: We appreciate the commenters' support and approval.

Comment: Numerous commenters were concerned over their perception of a lack of an adequate opportunity for MCOs to contest a State decision to impose a sanction. The commenters noted that while § 438.710(b) requires that a hearing be provided before a contract is terminated, § 438.710(a) requires in the case of other sanctions only that written notice be provided of the sanction and of any due process requirements that the State elects to provide. One commenter was concerned about a perceived lack of minimum procedures before the State can impose sanctions such as civil money penalties or suspension of new enrollment or payments. Another commenter had serious concerns about the absence of Federal procedural process requirements before the imposition of sanctions on MCOs. Based on the terms of the proposed rule, the State agency would have discretion to impose civil money penalties suspend new enrollment, and suspend payment without giving the MCO and PCCM an opportunity to present its views before the decision maker. One commenter believes that rather than denying the right to a hearing relative to the imposition of temporary management, as provided in section 1932(e)(5) of the Act, the entire concept should be reconsidered. One commenter suggested that minimum procedural safeguards should be included in these regulations but did not specify what these minimum safeguards should be. Another commenter recommended that HCFA require State agencies to ensure some form of procedural due process to be used prior to imposition of sanctions. Two commenters recommended that, at a minimum, MCOs be granted procedural safeguards that are the same or very similar to the procedural safeguards that HCFA has given Medicare+Choice organizations.

Response: We do not prohibit States from establishing the "due process protections" that they consider appropriate. As noted earlier, section 1932(e)(5) of the Act provides States with the discretion to make this decision, stating that " * * * the State shall provide the entity with notice and such other due process protections *as the State may provide*, * * *" (Emphasis added.) We believe it would be inconsistent with this provision to dictate that specific procedures be employed. We find one area in which our proposed rule goes beyond the requirements of the statute in potentially denying an MCO an opportunity to contest a sanction. Proposed § 438.710(b) of the Act provides that the State could not delay imposition of temporary management "during the time required for due process procedures, and may not provide a hearing before the imposition of temporary management." (Emphasis added.) Section 1932(e)(5) of the Act provides for the State to afford "due process protections," but precludes a State only from providing a "hearing" before imposing temporary management. In response to the above concerns, we have revised what is now § 438.706(c) to eliminate the reference to due process protections and to reflect the statute by prohibiting the State only from providing a hearing before imposing temporary management.

Comment: One commenter believes that when a contractor is terminated, adequate notice needs to be given to beneficiaries. The commenter recommended that we require timely notice to beneficiaries when States terminate an MCO or when an MCO withdraws from the program. This notice should include accurate information on options to enable beneficiaries to make informed choices among other available MCOs and PCCMs.

Response: We agree that Medicaid beneficiaries enrolled in an MCO or PCCM that is being terminated should receive timely notice of the termination with information on the options available to the beneficiary once the termination is effective. While the Congress provided in section 1932(e)(4)(C)(i) of the Act for notice to enrollees of a decision to terminate a contract, this notice is provided only when the State exercises its discretion to permit enrollees to disenroll immediately without cause before the termination hearing is completed. Section 1932(e)(4)(C)(i) of the Act clearly provides that States "may" provide such notice. We agree with the commenter that if a decision to terminate an MCO is upheld, and a termination is about to take effect, beneficiaries should be notified. Under section 1902(a)(19) of the Act, which requires that States provide safeguards necessary to assure that care and

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services are provided in a manner "consistent with * * * the best interests of recipients," we are adding § 438.710(b)(2)(iii) to require that notice of the termination be provided to enrollees of the terminated MCO or PCCM, with information on their options following the effective date of the termination.

Comment: We received one comment that stated that in order to avoid conferring an unintended defense to MCOs that meet the contractual standard for termination of the contract, we should specify that failure of a State to impose intermediate sanctions is no basis for objection or affirmative defense against a contract termination.

Response: States have the authority to terminate an MCO's or PCCM's contract without first having to impose intermediate sanctions, such as civil money penalties. If a State chooses not to impose intermediate sanctions before it terminates an MCO's or PCCM's contract, this action should not be used as an affirmative defense on the part of the MCO or PCCM against contract termination. We do not believe it is necessary or appropriate to make this statement in the regulation text itself.

Comment: Several commenters disagreed with the language in proposed § 438.718(a) that allows a State to terminate an MCO's or PCCM's contract if the MCO or PCCM failed "substantially" to carry out the terms of its contract. These commenters argued that the term substantially does not appear in section 1932(e)(4) of the Act, which is implemented in revised § 438.708, and severely restricts State flexibility in protecting Medicaid beneficiaries and the integrity of the Medicaid program. In the commenters' view, the added burden of proving substantial failure to comply is unnecessary and will add layers of litigation when a State seeks to terminate an MCO or PCCM. These commenters recommended removing the word "substantially."

Other commenters made the same point about our inclusion of the word "substantially" in proposed § 438.708, which implements the obligation in section 1932(e)(3) of the Act to impose temporary management in the case of repeated violations. Although the preamble indicates that we introduced the word "substantially" in order to allow States greater flexibility, there is no indication that the Congress intended for there to be greater flexibility in the application of this statutory requirement. These commenters argued that if the Congress had intended flexibility, it would not have made this provision "mandatory" in the first place, noted that this provision is the only mandatory requirement that sanctions be imposed, and noted that this provision is triggered only in instances in which the MCO repeatedly failed to meet requirements. These commenters found it difficult to understand why we would take what they considered the only mandatory sanction in the statute and attempt to give States greater flexibility.

Response: We agree that the word "substantially" is not used in section 1932(e)(4) or section 1932(e)(3) of the Act, is potentially ambiguous, and could create misunderstanding and enforcement problems. We included this term in proposed §§ 438.718(a) and 438.708 because we did not believe that termination or temporary management would be warranted for violations that are not substantive in nature, such as clerical or non-quality related reporting violations. In response to the above comments, in the final rule, we have changed "substantially" to "substantive" in both § 438.708(a) and § 438.706(b) as codified at § 438.708 in the proposed rule.

Comment: One commenter believes that the 30-to 60-day time frame for the termination hearing was insufficient and imposed an undue administrative burden. Another commenter recommended that the regulation provide notice of the intent to terminate 60 days before the effective date of the termination. The commenter also believes that the final regulation should establish criteria for when termination should be imposed and notice of when a termination decision has been made. A third commenter argued that this proposed requirement would impose a hardship on States because they are required to set the date and time for a hearing that the provider may not wish to have or be willing to attend. One commenter suggested that the termination notification should inform the MCO of its right to request a hearing and the procedures for doing so by phone or by mail. Upon the receipt of a hearing request, the State would be required to schedule the hearing not fewer than 30 or more than 60 days thereafter, unless the State agency and MCO or PCCM agree in writing to a different date.

Response: Because of legitimate concerns from many different parties, and in light of the fact that the Congress chose to provide States with their own discretion to establish due process protections, we are removing the time frames that were in the proposed rule and allowing the State to develop its hearing process and its timing.

Comment: We received several comments requesting that we require the pre-termination hearings be open to the public, since public disclosure is an important step towards ensuring accountability. These commenters stated that the Supreme Court has recognized the public policy value of having program participants most affected by an enforcement decision participate in an enforcement hearing, citing the Supreme Court's decision in O'Bannon v. Town Court Nursing Center, 447 U.S. 773 (1980). One commenter requested that we clarify who may participate in the hearing and the procedural rules that apply to the hearing. Another commenter recommended that States be required to provide potentially affected enrollees with the following: (1) written notice at least 15 days before the date of the pre-termination hearing and (2) information regarding how enrollees may testify at that hearing. Commenters stated that we should require that this notice be (1) written at no higher than a fourth grade level, (2) translated into the prevalent languages spoken by the population in the service area, and (3) accessible to persons with hearing and sight impairments.

Response: We believe that the above suggestions represent good ideas. With respect to the period prior to a decision following a hearing, the Congress has suggested that States should have discretion whether to notify enrollees of the proposed termination. Under section 1932(e)(4)(C) of the Act, the State "may" notify "individuals enrolled with a managed care entity which is the subject of a hearing to terminate the entity's contract with the State of the hearing." We believe it would be inconsistent with Congressional intent to mandate notice at this time. We have required that notice to enrollees be provided if a decision to terminate is upheld in a hearing. Any notice the State sends to enrollees must meet the language and format requirements of § 438.10(b) and (c).

Comment: One commenter stated that sometimes it is necessary for the State to terminate a contract with a PCCM because, the PCCM has left the practice without notifying the State. In that situation, the proposed requirement for notice and hearing before termination would not allow the State to take immediate action and would cause hardship to enrollees whose access to medical care would be greatly hindered.

Response: While a State may not terminate a contract with an MCO or PCCM, unless the State provides a hearing before termination in the situation described by the commenter, the statutory requirement for pre-termination hearing would not apply because the PCCM would have "terminated" the contract. Enrollees would not be adversely affected if the State gives them prompt notice and assists them to enroll in another MCO or PCCM or change to the fee-for-service program.

Comment: Several commenters recommended that we specify that States may inform enrollees of their right to disenroll any time after the State notifies the MCO or PCCM of its intent to terminate. Commenters stated that this section does not make clear at what point in the termination process States are required to notify enrollees. The commenters suggested that we explicitly require MCOs or PCCMs to provide both oral and written notification to enrollees and specify that this may be sent before completion of the hearing process. Steps should be taken to ensure that all people, including individuals with limited English proficiency, limited reading skills, visual impairments, or other disabilities are effectively notified. The final regulation should include adequate safeguards to ensure continuity of care during the time needed for enrollees to select another MCO or PCCM. Other commenters stated that this notification should be mandatory.

Response: Under § 438.722, the State may notify enrollees and authorize them to disenroll without cause at any time after it notifies the MCO or PCCM of its intent to terminate. The notice to enrollees must meet the language and format requirements of § 438.10(b) and (c). Section 438.62 requires the State agency to have a mechanism to ensure continuity of care during the transition from one MCO or PCCM to another or from an MCO or PCCM to fee-for-service. We have not required that notice be oral as well as written.

Comment: The State does not notify HCFA before imposing sanctions or once the sanction has been lifted. Why would HCFA need or want to be notified for each MCO infraction when it never has been in the past and has not needed the information? The commenter recommends that the requirement to notify HCFA of every sanction is not necessary and should be dropped.

Response: We agree that this would be burdensome. It is also unnecessary since we can access this information when needed. This requirement has been removed.

Comment: Many commenters recommended some level of public notification of imposition of sanctions. Some commenters stated that notice of the sanctions should be required to be given to current enrollees, by all enrollment brokers to potential enrollees, and to a newspaper of wide circulation in the area served by the MCO. Public information about the imposition of sanctions will contribute another layer of accountability to the extent members of the public, specifically the Medicaid population, are able to exercise choice among health care providers. Others stated that, although this section is an important provision to assist Federal oversight, enrollees, health care providers, and potential enrollees should also receive timely information concerning the following issues: (1) whether a specific MCO has been sanctioned, (2) the type of sanction, (3) the reason the sanction was imposed, and (4) what steps the enrollee can take to protect himself or herself. The independent enrollment assistant should provide potential enrollees with this information in both oral and written form, and the sanctioned MCO should be required to provide to current enrollees and health care providers in its network timely written information on sanctions. This requirement will ensure public access to critical information on quality of services. The State should also provide this information, upon request, to the general public. These notices should also meet the literacy recommendations discussed previously. Commenters further suggested that we add the following, "prior to enrollment, the enrollment broker (or other entity conducting enrollment) shall provide each eligible recipient with information regarding which MCOs or primary care case managers have been sanctioned, the types of sanctions, and the reasons for the sanctions. In addition, this information will be publicly available, upon request, from the State."

Response: In response to this and the preceding comment, we have revised § 438.724 so that, instead of requiring notice to HCFA, it requires States to publish public notice describing the intermediate sanction imposed, the reasons for the sanction, and the amount of any civil money penalty. We specify that the notice must be published no later than 30 days after imposition of the sanction and must appear as a public announcement in either the newspaper of widest circulation in each city with a population of 50,000 or more within the MCO's service area, or the newspaper of widest circulation in the MCO's service area if there is not, within that area, any city with a population of 50,000 or more.

Comment: Section 438.730 authorizes HCFA to impose sanctions directly on MCOs. Although this provision is authorized by the BBA, some commenters urged HCFA, except in extraordinary circumstances, to defer to States on the appropriateness of sanctions. They stated that such an approach is consistent with the roles performed by States and HCFA under the Medicaid program. The commenters were concerned about HCFA making sanction determinations without the involvement of the State and want clarification that sanctions will not be imposed by HCFA without involvement of the State.

Response: We already had sanctioning authority codified by § 434.67, which has been redesignated as § 438.730. We have no plans to deviate from our traditional role of deferring to States on the monitoring of day-to-day MCO or PCCM operations and their appropriateness. The regulation itself makes clear that our involvement would be based on the State's recommendation.

Comment: Several commenters suggested that HCFA should take a more proactive role in ensuring oversight and monitoring. The early implementation of mandatory Medicaid managed care has been plagued with problems. Neither the State nor HCFA has provided adequate oversight to protect beneficiaries. Managed care has clearly not lived up to its promise of providing quality care at lower costs. There is considerable doubt that it ever will. Unlike their wealthier counterparts, Medicaid beneficiaries cannot simply pay out-of-pocket if their managed care plan does not provide the care they need. Health care consumers across the nation are calling for greater accountability and oversight. This is extremely important to Medicaid beneficiaries. The commentors are deeply concerned that HCFA has placed too much of the oversight and enforcement responsibilities on the State Medicaid agencies. The Congress did not revoke HCFA's statutory authority to sanction MCOs or PCCMs. Although the regulations transfer much of this responsibility to the State, beneficiaries have little assurance that the State will adequately protect them, particularly since State Medicaid agencies do not have a good track record of oversight and enforcement. Reports by the GAO and OIG have called for greater Federal oversight and enforcement. This focus makes even less sense with the BBA changes than it did under preexisting authority. Why would a State interested in enforcing compliance recommend that HCFA impose a sanction that the State itself is authorized to impose? Why would a

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State not interested in enforcing compliance recommend anything at all to HCFA? The proposed rule lacks any assurance that HCFA will act if the State fails to act. When will HCFA perform these functions, if they are not performed by the State? What would trigger HCFA action or will it be entirely at HCFA's discretion? Will HCFA monitor States' actions or failure to act? The commenters believe that this section should be rewritten to eliminate the State as a recommender of action to HCFA and to emphasize HCFA's independent authority to impose sanctions. As with States, the section should direct that sanctions can be imposed based on findings made through onsite surveys, enrollee complaints, financial audits, or any other means. The regulation should state that HCFA will automatically perform the functions articulated in § 438.730 if an MCO performs any of the following activities: (1) Fails to carry out the terms of its contract; (2) fails to substantially provide medically necessary services that it is required to provide; (3) imposes premiums or charges in excess of those permitted by law; (4) discriminates among enrollees on the basis of health status or requirements for health care services; (5) misrepresents information that is furnished to HCFA, the State, an enrollee, a potential enrollee, or managed care plan; (6) does not comply with physician incentive requirements; (7) distributes, either directly or indirectly, information that has not been approved by the State or that contains false or materially misleading information; (8) engages in any behavior that is contrary to any requirements of section 1903(m) or 1932 of the Act and implementing regulations; (9) places enrollee health at substantial risk; or (10) by virtue of its conduct, poses a serious threat to an enrollee's health or safety or both.

Response: We have always had independent authority to sanction MCOs but not the resources to monitor them individually. Our primary tools to influence State activities with its MCOs have been corrective action plans, specific performance actions, and denials of FFP.

Comment: Several commenters were concerned at the absence of guidelines or criteria that would be used by a State agency in determining the amount of sanctions and urge us to include these guidelines and criteria. There must be standards of reasonableness that would apply to ensure that MCOs are not arbitrarily subjected to sanctions that are excessive in comparison with the nature of the offense in question.

Response: We may not impose standards or criteria because the Federal sanctioning authority is completely a State option (other than temporary management) and we do not set criteria for States using State authority. Any extra requirements could have a chilling effect of discouraging the use of the Federal authority. The monetary amounts specified in § 438.704 are limits, giving MCOs protection against excessive fines. The only mandatory due process protections involve termination of the contract and are contained in the statute.

Comment: One commenter recommended deletion of § 438.730. The commenter stated that if the State believes that an MCO should be sanctioned, it is free to impose that sanction without HCFA involvement. The commenter also pointed out that the sanctions that HCFA may impose are the same sanctions available to the State.

Response: This section is a redesignation of § 434.67, which reflects authority granted through section 1903(m)(5) of the Act, part of the Social Security Act before enactment of the BBA. We have no authority to remove these provisions from the regulations.

Comment: Several commenters believe that HCFA should publicly report the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. This information should then be updated regularly. Requiring that this information be made public and updated on a regular basis will help ensure the State's accountability to recipients and the public at large. Since a similar provision under § 434.67 has existed for several years, they would like HCFA to specify in the preamble the number of times States have recommended that HCFA deny payment and the result of each of the recommendations. They are concerned that this provision has not been implemented to the extent necessary to protect beneficiaries. They believe that information on the number of times States have recommended denial of payment is a critical element in determining how active States have been in monitoring compliance and protecting beneficiaries.

Response: We disagree that sanctions should be publicly reported. The existing longstanding sanction provision at § 434.67 does not require us to report to the public the number of recommendations by States for imposition of sanctions or actions resulting from the recommendations. We do not require regular reporting of sanctions that are imposed on MCOs through provisions of this final regulation because we do not want to discourage State use of sanctions. The preamble to this final regulation is not the appropriate place to report on activity related to the existing regulation.

H. Conditions for Federal Financial Participation (Subpart J)

Subpart J of the proposed rule set forth largely recodified versions of the regulations in part 434, subpart F. These regulations contain rules regarding the availability of Federal financial participation (FFP) in MCO contracts.

1. Basic Requirements (§ 438.802)

Proposed § 438.802 was based on the existing § 434.70 and provided that FFP is only available in expenditures under MCO contracts for periods that—(1) the contract is in effect and meets specified requirements; and (2) the MCO, its subcontractors, and the State are in compliance with contract requirements and the requirements in part 438.

Comment: One commenter noted that proposed § 438.802(c) represents a more stringent standard than the long-standing standard in § 434.70(b), arguing that the proposed standard is "much too onerous." The commenter noted that under § 434.70(b), FFP could be withheld if an MCO "substantially fails to carry out the terms of the contract," while under proposed § 438.802(c), FFP is based on the MCO and State being "in compliance" with the requirements of the contract. The commenter argued that States may hesitate to incorporate special quality initiatives into their contracts anticipating that FFP will be withheld if State or plan (or both) are not in complete compliance.

Response: Like proposed § 438.802, § 434.70(a) provided that FFP was available in contract payments "only" for periods that the contract "is in effect" and "[m]eets the requirements of this part," specifically including physician incentive plan requirements. Unlike proposed § 438.802, however, § 434.70(a) is also based on FFP on meeting "appropriate requirements of 45 CFR part 74." Proposed § 438.802 dropped this latter condition. Proposed § 438.802 was less stringent than § 434.70. The commenter is focusing not on the contract's compliance with requirements but on the MCO's compliance with the contract. We agree with the commenter that § 438.802(c) imposes a stricter standard than § 431.70(b) and it was not our intent to put States and plans at higher risk of FFP withholding than they were before. In this final rule with comment period, we have substituted "substantial compliance" for "compliance" in the Basic Requirements section, both in § 438.802(c) and § 438.802(b), regarding compliance with physician incentive plan requirements.

Comment: Several commenters argued that compliance with ADA and Civil Rights Act requirements should be added to § 438.802.

Response: Entities that contract with Medicaid are required to comply with both the ADA and the Civil Rights Act as well as all other applicable law and Federal regulation. As discussed above, in § 438.6 of this final rule with comment period, we have added language requiring that contracts expressly prohibit MCOs from discrimination based on race, color, or national origin and require compliance with all applicable State and Federal laws.

Comment: A commenter argued that there is an inequity in a system that certain States pay extremely high capitation rates for disabled populations (in which FFP is awarded) but do not provide for a comparable level of FFP to cover equivalent populations in other States. This commenter found general reason for concern about which populations different States are covering and the method by which different States are providing that care (fee-for-service versus managed care).

Response: Section 1902 of the Act requires that States provide medical assistance to certain mandatory groups and provide them with a certain specified minimum level of benefits. However, States have considerable latitude in deciding which other groups to cover and what levels of payment to set for their contracting MCOs, within the parameters of actuarial soundness and the rate setting requirements in § 438.6(c). It is the nature of a State run program for benefits to vary from State to State. However, as discussed above in section II. A, § 438.6(c)(1)(i)(B) requires that payment rates be "appropriate for the populations to be covered," and § 438.6(c)(1)(i)(B)(3)(iv) requires that payment and cost assumptions be "appropriate for individuals with special health needs." We believe that these requirements should ensure that payments are sufficient for disabled enrollees when they are enrolled in managed care contracts.

2. Prior Approval (§ 438.806)

Proposed § 438.806 was based on § 434.71 and provided that FFP was not available in expenditures under contracts involving over a specified financial amount ($1 million for 1998, adjusted by the consumer price index for future years) "prior approved" by us.

Comment: Several commenters believe that the $1 million figure for 1998 was too low, and one suggested raising it to a $5 million minimum.

Response: We do not have the authority to raise the threshold amount for required prior approval of contracts, which is stipulated in section 1903(m)(2)(A)(iii) of the Act.

Comment: A commenter suggested that this final rule with comment period clarify (1) that State or county-level purchasers will not be at risk because the State has not obtained the approval required under § 438.806 by the time the contract needs to be implemented and (2) that FFP is available retroactively if approval from the HCFA Regional Office is not secured by the time of the effective date of the contract.

Response: This rule does not change our existing interpretation of the prior approval requirement. For any contract that is implemented without first obtaining approval from the HCFA Regional Office, the State is at risk for FFP in payment for those services should the contract not be approved. The risk facing county-level purchasers is a question of the degree to which a State puts its own counties at risk within the context of State law and regulations. With regard to the related question of FFP retroactive to the effective date of the contract, the revision of § 438.806(b)(1) does not expand the scope of the original regulation. It merely adjusts upward the threshold amount for prior approval, which was $100,000 before the BBA raised the cost.

3. Exclusion of Entities (§ 438.808)

Proposed § 438.808 reflects the limitation on FFP in section 1902(p)(2) of the Act under which FFP in payments to MCOs is based. FFP payments are based on the State excluding from participation as an MCO any entity that could be excluded from Medicare and Medicaid under section 1128(b)(8) of the Act, that has a substantial contractual relationship with an entity described in section 1128(b)(8)(B) of the Act, or employs or contracts with individuals excluded from Medicaid. We received no comments on this section.

4. Expenditures for Enrollment Broker Services (§ 438.810)

Proposed § 438.810 reflects the conditions on FFP for enrollment broker services set forth in section 1903(b)(4) of the Act, which was added by section 4707(b) of the BBA. This section permits FFP in State expenditures for the use of enrollment brokers only if the following conditions are met:

- The broker is independent of any managed care entity or health care provider that furnishes services in the State in which the broker provides enrollment services.
- No person who is the owner, employee, or consultant of the broker or has any contract with the broker—
  - —Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker provides enrollment services;
  - —Has been excluded from participation under title XVIII or XIX of the Act;
  - —Has been debarred by any Federal agency; or
  - —Has been, or is now, subject to civil monetary penalties under the Act.
- The initial contract or memorandum of agreement (MOA) or memorandum of understanding (MOU) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

Comment: Several commenters expressed support for this provision and indicated that it is critical that the broker remain independent and unbiased.

Response: We appreciate the commenters support and agree that this provision is of great help in ensuring that beneficiaries are able to make informed choices.

Comment: One commenter suggested that we allow a "de minimis" exception for certain levels of stock ownership, especially in a publicly traded company. The commenter also suggested that HCFA rules preempt similar State rules to avoid excessive application of these rules.

Response: We believe that any degree of ownership, including any amount of stock in an MCO, PHP, or PCCM or other provider, by enrollment broker owners, staff, or contractors may create the potential for bias. That is why we are not providing for exceptions in § 438.810. Although section 1903(b)(4) of the Act and § 438.810 of the regulations set forth conditions that must be met to receive FFP, States have the prerogative to set rules more stringent than the Federal rules.

Comment: Some commenters believe that § 438.810 should include safeguards to protect Medicaid beneficiaries from false and deceptive advertising. A commenter recommended that, when brokers are used to enroll Medicaid beneficiaries into managed care, States should be required to assure that they have

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accurate data about the Medicaid eligibles and the availability of MCOs, PHPs, or PCCMs and any subcontracting providers.

Response: We agree that it is important for States to provide enrollment staff with accurate information about Medicaid eligibles and about MCOs, PHPs, or PCCMs and their subcontracting providers. Sections 438.10(d) and (e) require that enrollees and potential enrollees be provided with names and locations of current network providers, including identification of those who are not accepting new patients. It also emphasizes that information must be sufficient to allow an informed decision. We believe that this addresses the expressed concerns. States or enrollment brokers must make efforts to provide the most accurate and current information available. State and broker data systems differ in their capabilities, and provider and eligibility information changes daily. We ordinarily address this issue during pre-implementation review and monitoring of mandatory programs.

Comment: One commenter believes that it is not necessary for us to approve initial enrollment broker contracts or memoranda of understanding because statutory limitations are straightforward, FFP is limited, and brokers must be independent. In this commenter's view, contract approval is not necessary to ensure compliance, since the threat of civil money penalties is sufficient.

Another commenter supported our decision to require prior approval of initial enrollment broker contracts but suggested that we provide additional guidance pointing to minimum qualifications of enrollment brokers.

One commenter acknowledged the need for contract review but suggested that we impose a 30 day time limit for review in order to avoid delaying contract implementation. Once this time had elapsed, the contract would be deemed approved.

Response: We have already reviewed some broker contracts and MOAs/MOUs on a voluntary basis. Much of the current review consists of technical assistance and advice about whether contracts contain legally required provisions, as well as assurances of quality and results of noncompliance. We intend to issue contract review guidelines for our staff.

We will not impose a time limit for review of contracts since it is impossible to assess workloads and the amount of time required for review. Once mandatory contract review is implemented, we will assess the length of time required for review and recommend time frames if necessary.

Comment: One commenter believes that fiscal intermediaries for State Medicaid programs face an inherent conflict of interest, because they are paid to process claims for traditional fee-for-service Medicaid programs, and assisting Medicaid beneficiaries to enroll in a managed care entity poses a threat to these agents' primary source of revenue. In this commenter's view, the intermediaries have a strong incentive to maintain the status quo. The commenter recommended that HCFA's rules should prohibit entities from serving as enrollment brokers for States in which they serve as fiscal intermediaries.

Response: We are aware that some fiscal intermediaries have adapted to the managed care environment by performing enrollment broker functions in some States. This is often convenient for States that already have fiscal intermediary contracts in place. Since enrollment brokering has become an additional line of business for some of these agents, we believe that the incentives for bias toward fee-for-service are minimal. In addition, we anticipate that States desiring to use fiscal intermediaries in the role of enrollment brokers would consider any inherent bias during the selection process.

Comment: One commenter asked about the applicability of this provision to a public entity in which eligibility and enrollment functions might occur in one division and other divisions might be responsible for purchasing or providing some Medicaid covered services. The commenter asked whether State "conflict of interest" regulations, if approved by HCFA, would satisfy the intent of this section. The commenter noted that if county government employees conduct enrollment and education, and counties are also directly involved in arranging for or providing Medicaid services directly, FFP would not be payable for the county employee's enrollment services. The commenter suggested that we define "independent" in such a way as to allow a county employee to conduct enrollment activities as long as the county has in place adequate safeguards to protect against conflict of interest. For example, if an employee conducting enrollment is employed under a separate division or department and is not subject to supervision or discipline by a separate division or department that conducts purchasing or operates an MCO, the commenter recommended that this be considered acceptable.

Response: The managed care enrollment function is an administrative function of the State. The State may choose to contract out this function, have it done by the State or local staff, or even allow MCO staff to perform this function. The example of a county eligibility employee performing enrollment activities when the county also provides services would violate § 438.810, thus precluding payment of FFP for the enrollment activities. The Medicaid eligibility function must always be performed by State or local staff. This function cannot be contracted out to other entities. If MCO, PHP, or PCCM enrollment is contracted out to an enrollment broker, defined as an entity or individual that performs choice counseling and/or enrollment activities, the broker may not have any connection to or interest in any entity or health care provider that provides coverage of services in the same State. An enrollment broker might be a public or quasi-public entity with a contract or MOA/MOU with the State or county. In this situation, this entity may not furnish health care services in the State. For example, a State may not contract with or have an MOU with a county health department to do managed care enrollment or choice counseling because the health department provides health services. A community organization that provides health services in the State, for example, an organization providing health care to homeless individuals, may contract or subcontract to perform outreach and education, but not enrollment and choice counseling functions. An MCO, PHP, PCCM, or other health care provider that provides services in a State may not also have an interest of any sort in an organization performing Medicaid enrollment or choice counseling. This restriction is based upon the statutory language contained in section 1903(b)(4) of the Act.

In § 438.810(b)(1) of this final rule with comment period, we have clarified that an enrollment broker would not meet the test for independence if it is an MCO, PHP, PCCM or other health care provider, or owns, or is owned by an MCO, PHP, PCCM, or other health care provider in the State in which the broker operates.

A State's conflict of interest regulations ordinarily address situations in which a State or local officer, employee, or agent has responsibilities related to the awarding of contracts. Conflicts of interest involving Medicaid officials have long been prohibited under sections 1902(a)(4)(C) and (D) of the Act. This language prohibits conflict of interest by current or former State and local officers, employees, or independent contractors responsible for the expenditure of substantial amounts of funds under the State plan. The conflict of interest language in § 438.58 applies to State and local officers and employees and agents of the State who have responsibilities relating to MCO contracts or the default enrollment process. Conversely, it specifically prohibits conflict of interest in any Medicaid managed care contracting activities, including enrollment broker contracting. Section 438.810 specifically addresses situations in which a relationship between a health care provider and an individual or entity responsible for choice counseling or enrollment may be biased by that relationship. While conflict of interest provisions would be expected to be in place in the State, § 438.810 covers an additional situation in which potential conflict of interest might influence a Medicaid recipient's choice of plan.

5. Costs Under Risk and Nonrisk Contracts (§ 438.812)

Proposed § 438.812 was transferred in its entirety from previous §§ 434.74 and 434.75 and was unchanged in the proposed rule. Proposed § 438.812 provides that States receive Federal matching for all costs covered under a risk contract at the "medical assistance" rate, while under a nonrisk contract only the costs of medical services are matched as "medical assistance," and all other costs are matched at the administrative rate.

Comment: One commenter believes that we should provide additional guidance on what constitutes the "furnishing of medical services" as described in § 438.812(b)(1). The distinction between what is administrative and what is a medical service is becoming less clear in this commenter's view.

Response: We do not believe additional clarification in the regulations text is necessary. The costs of medical services are the payments made to providers for furnishing services covered under the contract. In the case of fee-for-service Medicaid, this would be the State plan payment amounts. These costs could either be in the form of payments to providers (fee-for-service, per diem, or capitation) or "salary" in the case of an employee. Administrative costs would include member services, claims processing, coverage decisions, and other activities that would be matched as administrative costs under fee-for-service Medicaid.

Comment: One commenter noted that the proposed rule discussion of § 438.812 did not address the Federal medical assistance percentage (FMAP) that States receive for services provided to American Indians by the Indian Health Service (IHS) and tribally operated programs. The commenter believes that the regulation should specifically address how the special matching rate for eligible IHS services will be applied and the State role in assuring that standards are met.

Response: We agree that the FMAP rate for services provided to Indians by IHS or tribally operated programs applies whether the IHS or tribal facility operates in fee-for-service or managed care. There is no need to change this regulation since, when applicable, this special FMAP rate is the "medical assistance" rate in that case. The regulation differentiating FMAP rates for risk and nonrisk contracts would not prohibit or in any way modify the matching rate that is required for IHS or eligible tribal facilities. Section 438.812 simply recodifies longstanding regulations and does not involve or affect HCFA policy on the application of the FMAP for IHS services in the managed care context.

In response to this and other comments received, we want to reemphasize that tribal and IHS providers are not necessarily required to be licensed by a State as long as they meet the State's or MCO's qualifications. We believe that the definition of provider in § 400.203 will ensure that these providers are not inappropriately excluded from participation in Medicaid managed care programs.

6. Condition for Federal Financial Participation (FFP) in Certain Contract Arrangements (§ 438.814)

As discussed in detail in section II. A of this regulation, this new section reflects the condition for FFP in contracts that contain incentive arrangement or risk corridors. As described in new § 438.6(c)(5) on rate setting for risk contracts, FFP is only available in these contracts to the extent that payments do not exceed 105 percent of the payment rate determined to be actuarially sound.

I. Revisions to Parts 435, 440, and 447; Miscellaneous Comments

In addition to the provisions set forth in the new part 438, and the fair hearing provisions in part 431 discussed in section II. E. above, the proposed rule contained amendments to Parts 435, 440, and 447 which we discuss below. These provisions included amendments to §§ 435.212 and 435.326 to reflect the new terminology adopted by the BBA (for example, "MCO" and "MCE"). We also proposed a new § 440.168 in part 440 to include a description of primary care case management services. Amendments to part 447 not already addressed above include a new § 447.46(f) implementing the timely claims payment requirements in section 1932(f), and a new § 447.60 regulating MCO cost-sharing, which was made permissible under BBA amendments to section 1916 of the Act. In this section, we discuss the comments we received on the above regulations. We received no comments on the revisions to part 435, or on § 447.60. We also in this section address miscellaneous comments that did not relate to a specific section of the proposed regulations.

1. Guaranteed Eligibility

Section 435.212 was amended in the proposed rule to implement section 1902(e)(2) of the Act. This change will permit State agencies, at their option, to provide for a minimum enrollment period of up to six months for individuals enrolled in a PCCM or any MCO. Previously, this option was only available to enrollees of Federally-qualified HMOs.

Comment: One commenter observed that the provision in the proposed rule is inconsistent, authorizing guaranteed eligibility for individuals enrolled in any MCE (MCO or PCCM) in the introductory text of the section, while limiting the authority to MCOs elsewhere.

Response: Using both terms in the proposed rule was an inadvertent error. We have clarified this issue by using the terms MCO and PCCM throughout the final rule, as intended by the BBA.

2. Definition of PCCM Services (Proposed § 440.168)

Section 4702 of the BBA adds PCCM services to the list of optional Medicaid services in Section 1905(a) of the Act. The BBA also added Section 1905(t) to the Act. This new subsection defines PCCM services, identifies who may provide them, and sets forth requirements for contracts between PCCMs and the State agency. This means that in addition to contracting with PCCMs under a section 1915(b) waiver program or section 1115 demonstration project, or under the new authority in section 1932(a)(1) to mandate managed care enrollment, States may now add PCCMs as an optional State plan service. Regardless of the vehicle used, proposed § 438.6(j) set forth the minimum contract requirements States must have with their primary care case managers.

Proposed § 440.168(a) set forth the definition of primary care case management services, for case

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management related services that include "location, coordination, and monitoring of primary health care services," that are provided under a contract between the State and either (1) an individual physician (or, at State option, a physician assistant, nurse practitioner, or certified nurse-midwife), or (2) a group practice or entity that employs or arranges with physicians to furnish services. Proposed § 438.168(b) provided that PCCM services may be offered as a voluntary option or on a mandatory basis under section 1932(a)(1) or a section 1115 or 1915(b) waiver.

Comment: One commenter expressed concerns about any form of required case management.

Response: Current law, through freedom of choice waivers under sections 1915(b) and 1115 of the Act, has for many years permitted States to require that Medicaid beneficiaries obtain their care through PCCM programs. Section 4702 of the BBA provided States additional flexibility by adding PCCM services to the list of optional Medicaid services. This allows States, at their option, to provide quality health care services and to enhance access to Medicaid beneficiaries through an arrangement that has proven to be cost effective to the Medicaid program. In addition, this section sets forth new requirements for contracts between primary care case managers and the State agency that provide important protections for beneficiaries and ensure access to quality health care. We believe that these protections, along with other beneficiary protections provided for in this final rule, adequately address the commenter's concerns.

3. Timeliness of Provider Payments (Proposed § 447.46)

Section 1932(f) of the Act specifies that contracts with MCOs under section 1903(m) must provide that, unless an alternative arrangement is agreed to, payment to health care providers for items and services covered under the contract must be made on a timely basis, consistent with the claims payment procedures described under section 1902(a)(37)(A) of the Act. The procedures under section 1902(a)(37)(A) of the Act require that 90 percent of claims for payment (for which no further written information or substantiation is required in order to make payment) made for services covered under the contract and furnished by health care providers are paid within 30 days of receipt, and that 99 percent of such claims are paid within 90 days of receipt. These requirements were included in proposed § 447.46.

Comment: One commenter objected generally to the requirements in proposed § 447.46, while another argued that the provision for developing a mutually agreed upon alternative payment schedule between an MCO and provider would not resolve the issue of timely payments. This commenter recommended that the timely payment provisions should provide that payments must be made in a manner consistent with State law, or, in the absence of a State requirement, in accordance with requirements in Federal regulation. This commenter did not believe that MCOs should be free to negotiate alternative arrangements. Another commenter contended that delayed payments for both managed care and fee-for-service programs have long been a problem in State Medicaid programs. This commenter felt that physicians, hospitals, and health systems should be paid for the covered services they provide to Medicaid beneficiaries in a timely manner, and that chronic payment delays by Medicaid programs and plans discourage physician and provider participation, are disruptive to the patient-physician relationship, and could adversely affect patient access. This commenter recommended that HCFA adopt a standard that would require payment to health care providers within 14 days for uncontested claims which are filed electronically and within 30 days for paper claims which are uncontested. In addition, the commenter recommended that for capitated payment systems, HCFA should require MCOs to make capitated payment to physicians and providers shortly after the beneficiary's enrollment, and also promulgate a standard time frame for payments by States to physicians and other providers of services under Medicaid fee-for-service programs.

Response: Congress was very specific in section 1932(f) to incorporate the standards set forth in section 1902(a)(37)(A), and provide that parties could also agree to an alternative payment schedule. We do not have the discretion to change the timeframes in section 1902(a)(37)(A), or to eliminate the right to negotiate an alternative schedule, as these are mandated by statute. We note that if an alternative payment schedule is established, it must be stipulated in the contract according to § 447.46(c)(3). The statute does not address the timing of capitation payments, which we believe should be negotiated between the parties.

4. Miscellaneous Preamble Comments

a. Effective Date of the Final Rule

In the proposed rule, we stated our intention to make the final rule effective 60 days following publication. However, those provisions which must be implemented through contracts would be effective for contracts entered into or revised on or after 60 days following the effective date, but no longer than 12 months from the effective date.

Comment: Several commenters asked us to clarify or revise the proposed effective date. In particular, the commenters were concerned that adequate time was not allowed for implementing the many changes proposed in the regulation. One commenter suggested that HCFA give States an additional year from final publication of the regulation to bring contracts into compliance. Another commenter recommended that HCFA consider allowing States at least 120 days to implement the final regulation.

Response: In recognition of the significant changes within this final rule, we have set the implementation date of this final rule to take effect 90 days following publication. Although we believe that it is important to provide BBA protections as soon as possible, we believe that changing the effective date will help to ease the State burden of implementing these provisions. Further, those provisions of the final rule that must be implemented through contracts with MCOs, PHPs, HIOs or enrollment brokers must be reflected in contracts entered into or revised on or after 90 days following the publication date, but no longer than 12 months from the effective date. Because a substantial number of the provisions of the final rule are implemented through contract revisions, the effective date for many provisions will be delayed in many States. Of course, some provisions in this final rule reflect statutory requirements that are already in effect. HCFA has provided State agencies with guidance on implementing these provisions through a series of letters to State Medicaid Directors. These letters appear on the HCFA Home Page and can be accessed at http:www.hcfa.gov.

b. Absence of FQHC and RHC Provisions in the Proposed Rule

Comment: Several commenters requested that HCFA address the new FQHC and RHC reimbursement requirements set forth in section 4712(b) of the BBA. One of the commenters was concerned that unless these provisions were included in the regulation there would be no mechanism to ensure State and MCO compliance. The commenter acknowledged that HCFA had undergone a process to inform State Medicaid Directors of their new obligations under the BBA through a series of letters. However, without this requirement in the regulation, the commenter was concerned that both MCOs and States would disregard the Federal statutory protections intended to preserve FQHCs and RHCs as vital Medicaid providers. Moreover, the commenter argued that regulations have the force of law, whereas States have challenged in the past whether they are legally bound by guidance in letters to State Medicaid Directors. By placing these requirements in its regulations, the commenter believed that HCFA could ensure that States or MCOs that fail to comply with BBA's requirements would be subject to sanctions by HCFA. The remaining commenters questioned HCFA's interpretation of the FQHC/RHC statutory provision and believe that this area should be clarified in regulation and open to public comment.

Response: This rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled "Managed Care." The provisions relating to FQHC/RHC payment are set forth in Chapter 2, "Flexibility in Payment of Providers," and thus arguably are outside the scope of this rulemaking. Even if this rule were the appropriate vehicle for regulations implementing these FQHC/RHC provisions, we do not believe that such regulations would be warranted. The rules in question are "transitional" in nature, as the 100 percent cost payments described will eventually be phased out over the next several years. We do not believe it appropriate to promulgate regulations that will be obsolete in a relatively short period of time.

Moreover, we do not believe regulations are necessary, as the statutory requirements are straightforward and self-implementing, and HCFA has provided guidance to all States, through State Medicaid Director Letters on April 21, 1998 and October 23, 1998, on FQHCs and RHCs. We disagree with the commenter that there is no "enforcement mechanism" for these requirements. The requirements in question, as interpreted by HCFA in State Medicaid Director Letters, are fully enforceable. A State that fails to fulfill its obligations under section 1902(a)(13)(C)(ii) to make required quarterly supplemental payments to FQHCs/RHCs that subcontract with MCOs would be subject to a compliance enforcement action under section 1904. If an MCO fails to comply with section 1903(m)(2)(A)(ix) by paying at least what it pays other providers, HCFA would disallow Federal financial participation (FFP) in payments under the MCO's contract. Thus, the FQHC/RHC requirements in question are self-implementing and fully enforceable. HCFA's interpretations of these requirements are also enforceable, and entitled to deference from courts.

c. General Comments on the Proposed Rule

Comment: Several commenters supported HCFA in its implementation of the BBA, and were pleased to see the proposed rule reflect many of the recommendations from the Consumer's Bill of Rights and Responsibilities (CBRR). These commenters also believed that the proposed rule was a thoughtful implementation of the BBA provisions, which adequately reflected the intent and hope of the Congress and provides functional guidance to States without becoming overly burdensome or demanding. Other commenters believed that the regulation is a positive step toward improving quality for Medicaid beneficiaries in managed care and that the regulation is brief, simple and written at a readable level.

However, several other commenters criticized HCFA for creating regulations that they perceived as overly burdensome that did not allow sufficient State flexibility. These commenters also argued that the proposed regulations went beyond the statutory intent and authority of the BBA, and that the regulations would lead to increased administrative costs for Medicaid MCOs. These commenters believed that HCFA was micro-managing its approach to Medicaid managed care, and the proposed regulations, if finalized, would make it increasingly difficult for State Medicaid agencies to provide access to quality health care through MCOs, since MCOs would not be willing to participate. Another commenter believed that the proposed regulations did not reflect the approach of a purchaser, but the approach of a unilateral regulator particularly with respect to the CBRR and other beneficiary protections.

Response: The regulation was developed to provide States with an appropriate level of flexibility that we believe to be consistent with necessary beneficiary protections. Thus, State flexibility had to be balanced against statutory requirements of the BBA, and a Presidential directive that required Medicaid program compliance to the extent permitted by law, with the recommendations in the CBRR. In response to specific comments regarding the over-prescriptiveness or burden of certain provisions, we have made some changes to promote even greater flexibility, and also added requirements in response to other commenters. Further, the regulation has been designed to provide a framework that allows HCFA and States to continue to incorporate further advances for oversight of managed care, particularly as it pertains to beneficiary protection and quality of care. With respect to HCFA's statutory authority, we summarize each provision of the effected regulations followed by our response.

Comment: In general, a few commenters were concerned that what they believe to be over-prescriptiveness of the regulation would result in MCOs leaving the Medicaid managed care market. These commenters believed that the prescriptive mandates of the regulation would limit and hinder negotiations with MCOs, because of the additional requirements that would have to be met for Medicaid members as opposed to commercial members. As a result, the commenters argued that these requirements would be administratively burdensome for MCOs. In addition, the commenters believed that the financing of these administrative requirements was so inadequate MCOs would be forced out of the Medicaid market due to financial reasons.

Response: We will be reviewing this issue as we are also concerned about the continued viability of MCOs in the Medicaid managed care market. However, we also recognize the importance of quality care and consumer protections for Medicaid beneficiaries enrolled in Medicaid managed care and are unwilling to sacrifice these very necessary protections. In this final rule we have also revised the upper payment limit requirement, which may result in increased levels of funding for MCOs.

d. Beneficiary Protections in FFP

Comment: Commenters expressed concern that the proposed rule did not extend its numerous beneficiary protections to the fee-for-service (FFP) delivery system, and that many of the protections within the regulation have no corollary protections in FFP. The commenters noted that in FFP Medicaid, there were no rights afforded to providers who will coordinate care, nor was there adequate quality assurance activities, information on participating providers, or detailed grievance procedures. The commenters believed that the proposed regulation makes it difficult to make meaningful comparisons between FFP and managed care. Another commenter felt that the proposed rule did not adequately

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recognize that managed care is not the only system that States will be using to provide health services to beneficiaries, as many States will continue to operate a FFP system. The commenter believed that it is the clear intent of Federal legislation that all Medicaid beneficiaries should receive the same protections and advantages without respect to the type of provider that is under contract. Therefore, in the commenters opinion, the regulations that apply to MCOs should also apply to the State Medicaid agencies in their operation of FFP systems.

Response: While HCFA agrees that beneficiary protections are also important for beneficiaries receiving care under fee-for-service arrangements, this rulemaking primarily implements Chapter 1 of Subtitle H of the BBA, titled "Managed Care." These statutory provisions do not apply to FFP Medicaid, and cannot be extended to FFP arrangements in this final rule, since the proposed rule did not indicate that fee-for-service Medicaid provisions were at issue in this rulemaking. However, States do have the flexibility to develop beneficiary protections similar to those presented in this regulation for those still receiving care through fee-for-service.

e. Use of Examples in the Preamble

Comment: Some commenters were concerned over the use of examples in the preamble to the September 29, 1998 Notice of Proposed Rule Making (NPRM) and the potential applicability of these examples in a court of law. These commenters requested that HCFA clarify that the examples in the preamble to the proposed rule would not be standards enforceable by law. They believed that the use of examples could lead to unintended interpretations of the final rule. One commenter suggested that HCFA make a clear statement "that the preamble that accompanied the proposed rule was intended to spark discussion, not provide guidance for further interpretations."

Response: The examples provided in the preamble to the NPRM were intended to be just that, examples. They were included in the preamble discussion to provide options for States when implementing the provisions within the proposed rule. We did not include these examples in the regulation text itself, as they were intended to be illustrative in nature and States always retain the flexibility to deviate from these examples.

f. Consistency with Medicare

Comment: Several commenters disagreed with our guiding principle that, where appropriate, we would promote consistency with the Medicare+Choice program in developing this regulation. One commenter argued that the Medicaid statute is not designed to promote consistency with Medicare. The commenter did not believe that consistency between Medicare and Medicaid is a valid reason to deviate from the principle of State flexibility. The commenter believed that Title XIX provides Federal funds for various State medical assistance programs that are to be administered by States within broad Federal rules, and noted that those Federal rules, as found in Title XIX, contain no general requirement for consistency with Medicare. The commenter further noted that the preamble to the proposed rule also states that "the regulations were written to support State agencies in their role as health care purchasers * * * and * * * to provide State agencies with the tools needed to become better purchasers." The commenter found this to be a "paternalistic" approach, which in the commenter's view was inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules. Portions of the proposed regulations intended to "support" States as health care purchasers, but which do not implement any requirement under Title XIX, should in the commenter's view be issued as guidance or advice to States, not as additional requirements in Federal regulations. Finally, the commenter found the "uniform national application" of "best practices," as defined by HCFA, to be inconsistent with the nature of the Medicaid program as one administered by States within broad Federal rules.

Several other commenters, however, supported the guiding principle of consistency with the Medicare+Choice program, and believed that it would help relieve the administrative burdens imposed on MCOs, because to the extent that the Medicare and Medicaid programs are consistent with each other, administrative efficiencies result. The commenters also felt that establishing uniform industry standards was beneficial not only to MCOs and primary care case managers, but also for consumers receiving services and providers who contract with those MCOs or primary care case managers to deliver health care services. The commenters commended HCFA for recognizing that while it is imperative that there be consistency and uniform application of standards, some areas require a unique approach by States; as a result, the commenters support HCFA's efforts to allow States the flexibility in developing such programs.

Response: It was our intent to create consistency with Medicare+Choice program requirements in order to ensure that the managed care industry would not have to comply with multiple sets of standards. However, where there was a clear need for State flexibility or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from Medicare+Choice policy. We believe that this final rule effectively balances the need for flexibility and consistency, while providing States with the broad tools they need to become more efficient purchasers of health care. As we developed this final rule, we continued to work with our Medicare colleagues to coordinate changes to provisions in this final rule that had counterparts in the Medicare+Choice regulations. While we have promoted uniform national application of knowledge and best practices learned, the Medicaid statue has always given States the flexibility to design their own Medicaid programs.

g. Applicability of BBA Provisions to Waiver Programs

Section 4710(c) of the BBA provides that nothing in the managed care provisions of the BBA (Chapter 1 of subtitle H) shall be construed as affecting the terms and conditions of any waivers granted States under section 1915(b) or 1115 of the Act. The Conference Report on the BBA clarifies that this exemption is intended solely for waivers that are approved or in effect as of August 5, 1997 (the date of enactment). We indicated in the preamble to the proposed rule that we interpreted this exemption to apply to 1915(b) waivers only for the period of time for which a waiver has been approved as of August 5, 1997, at which time the State would be required to comply with the BBA provisions. In the case of waivers under section 1115 demonstration projects approved as of August 5, 1997, the terms and conditions are similarly "grandfathered" under section 4710(c) of the Act only for the period of time for which the waivers were approved as of August 5, 1997. However, unlike section 1915(b) waivers, these demonstration projects are subject to another BBA provision that affects the applicability of BBA managed care provisions. Section 4757 of the BBA added a new section 1115(e), providing for a three year extension of demonstrations if certain conditions are met. If a section 1115 demonstration approved on or before August 5, 1997 is renewed under the terms of section 1115(e), the terms and conditions that applied on the last day approved under the original demonstration remain in effect during the three year extension period. Thus, if terms inconsistent with the BBA managed care provisions were still in effect by virtue of section 4710(c), these terms were extended for three years if there an extension was granted under section 1115(e).

Comment: Many commenters felt that HCFA's interpretation of section 4710(c) as applicable only for periods for which waivers were approved on August 5, 1997 was inconsistent with the commenters' view of the intent of this provision. These commenters felt that States had developed specific provisions of their waivers and demonstrations to address specific issues within the State, doing so in consultation with all appropriate stakeholders, and that to require changes in the programs now would result in confusion for enrollees and providers, disruptions in the delivery system, and increased administrative costs for both the States and health plans.

Response: We disagree with the commenters' view of this provision. Language in the Conference Report on the Balanced Budget Act of 1997 specifically states the intent of Congress as limiting the exemption contained in section 4710(c) to waivers "either approved or in effect" as of the date of enactment. Since section 1915(b) waivers are specifically limited by statute to no more than 2 years and section 1115 demonstration waivers are typically granted for periods of no more than 5 years, the waiver which is "approved" or "in effect" as of the date of enactment expires at some point thereafter. While States may request renewals of section 1915(b) waivers for up to 2 years, these additional waiver periods cannot be seen to have been "approved" or "in effect" on August 5, 1997. This is similarly the case with respect to standard extensions of a section 1115 demonstration approved after August 5, 1997. As explained above, however, in this latter case, a totally separate provision of the BBA created section 1115(e) of the Act, that requires the terms and conditions in effect on the date before a section 1115 demonstration would otherwise expire be extended for three years. Section 1115 demonstrations that do not qualify for an extension under the authority in section 1115(e)(1) do not maintain the same exemption, and would be subject to all BBA provisions in effect at the time of the expiration of the 1115 authority approved as of August 5, 1997 (in the absence of new waiver or matching authority under section 1115(a) exempting a State from BBA requirements).

We have provided some flexibility to States in phasing in BBA requirements by permitting exemptions for any provisions addressed in the State's waiver proposal, statutory waivers, special terms and conditions, operational protocol, or other official State policy or procedures approved by HCFA, rather than limiting the exemption solely to specific "Special Terms and Conditions" negotiated between HCFA and the States. We believe that HCFA has balanced the need to implement important beneficiary protections contained within the BBA with the flexibility that States need to effectively phase-in these requirements in programs designed to meet specific needs within the State.

Comment: Some commenters felt that the terms and conditions agreed to by HCFA and the State should continue to be the applicable rules under which a waiver program is operated.

Response: As indicated above, not only the special terms and conditions, but any other policies, procedures or protocols approved by HCFA will remain in effect for the period the State is entitled to an exemption under this provision. With the exception of section 1115 demonstrations extended under section 1115(e) of the Act, we believe that Congress limited this exemption to the time period of the waiver approved or in effect as of August 5, 1998.

Comment: Several commenters argued that the BBA provisions were intended to apply to managed care programs established under State plan amendments authorized by section 1932(a) of the Act, and should not apply at all to waiver programs.

Response: The BBA provisions on managed care in sections 4701 through 4710 of the BBA that are limited in their application to mandatory managed care under the State plan contain a specific reference to that section of the Act. Both the definition of PCCM services in section 1905(t) (in section 1905(t)(3)(F)), and section 1903(m)(2)(A), in the case of MCOs, require compliance with applicable provisions in section 1932. Thus, when a provision in section 1932 applies to an MCO or MCE, and is not limited to a program under section 1932(a)(1), it applies regardless of the authority under which the managed care program in which they participate operates. Thus, these provisions apply to all types of managed care—voluntary or mandatory, State plan or waiver.

Comment: Some commenters felt that HCFA inappropriately limited this exemption by applying it only to provisions that were "specifically addressed" in approved State documents, rather than to the entire waiver program.

Response: We believe that we have adopted a broad interpretation of the applicability of section 4710(c). Section 4710(c) states that the managed care provisions shall not be construed to affect the "terms and conditions" of waivers. As noted above, this could have been interpreted to apply only to provisions set forth in actual formal "terms and conditions." We have interpreted this to refer to anything addressed in the State's approved waiver materials. In such cases, no determination need be made as to whether the State's policy or procedures meet or exceed the BBA requirement during the duration of the waiver period approved as of August 5, 1997 (or an extension under section 1115(e) in the case of a section 1115 demonstration). We note that the BBA contains provisions such as fraud and abuse protections, some of the quality provisions, a prudent layperson's definition of emergency, and the extension of guaranteed eligibility to PCCMs, which would not usually be addressed in a State's waiver materials. We believe it is important to implement these provisions which can provide beneficiary protections beyond that already provided for in a State's waiver.

Comment: One commenter questioned the impact of this exemption on a State which is phasing-in a waiver on a county-by-county basis, where parts of the State would be exempt from BBA requirements, while other parts of the State would be subject to them.

Response: A State that is phasing-in a waiver which was approved prior to August 5, 1997 maintains exemptions from the BBA for the whole service area of its waiver program as it is implemented, not merely the areas which were implemented prior to that date. The language in the Conference Report provides the exemptions for any waiver which is "approved or in effect."

Comment: One commenter believed that HCFA should provide additional clarification as to how this exemption from BBA provisions applies to section 1115 demonstrations.

Response: HCFA Regional Offices have been working with section 1115 States to identify those areas that need to come into compliance with BBA provisions. These decisions will have to be on a State-by-State basis, determined

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by the specific provisions in effect in each State's waiver program. Once HCFA has determined which BBA provisions apply and which do not apply, the exemptions will remain in place until the current approved period of the waiver expires, or if it is extended under section 1115(e), the end of the three year extension. At this time States will need to come into compliance with all BBA provisions that are currently in effect. The only exception is for a State that receives an extension of its section 1115 authority under section 1115(e)(1) which, as indicated above, requires the same terms and conditions to be in place when the waiver is extended for up to three years.

Comment: One commenter felt that the BBA provisions should be applied immediately to all new and existing waiver programs.

Response: Section 4710(c) provides that nothing in the BBA provisions on managed care "shall be construed as affecting the terms and conditions of any waiver . . . under section 1115 or 1915(b) of the Social Security Act." We believe that this language precluded us from applying these provisions in an inconsistent manner with such waiver terms and conditions.

h. Comments Relating to American Indians and Alaskan Native Populations

Comment: We received several comments that specifically addressed the relationship of the proposed regulation to the American Indian and Alaskan Native (AI/AN) populations. Most of the commenters were concerned that the tribal health care systems would be drastically impacted by the proposed regulation. Because of this impact, one commenter recommended that the Indian Health Service (IHS) and the tribal system be exempted from the proposed regulations, and that we consult with IHS and tribal organizations before including them in the proposed regulations. Another commenter indicated that States should recognize the inherent sovereignty of Indian Tribes and Nations and the special status of health programs for American Indians under Federal law. This commenter recommended that States implementing Federal programs need to develop a consultation policy that ensures tribal participation in developing health care programs. Another commenter stated that the proposed regulation showed concern for consumer protection in general, but gave little attention to the specific needs and circumstances of AI/AN consumers and Indian health providers. In the commenter's opinion, the best way to ensure that this happens is to require States to engage in meaningful tribal consultation. Several other commenters specified that the proposed rule does not mention or discuss the special relationship that exists between the United States and its indigenous peoples, namely American Indians, Alaskan Natives, Aleuts, Eskimos and Native Hawaiians. These commenters believed that it is important to specifically include language that acknowledges this relationship and allows the Federal government to provide services for these groups. This would be done not on the basis of race or ethnicity, but rather upon the Federal government's historical relationship with native peoples and their governments who live in areas which are not portions of States of the United States but who have had affinities to these areas long before these States came to be part of the United States. The commenters also noted the importance of including language in the final rule that recognized the trust responsibilities of the Federal government to indigenous peoples and their respective tribes in developing program standards, including defining cultural competence, enrollment policies and procedures, marketing, access, grievances, quality assurance and sanctions for MCOs providing health services to their peoples and not the States.

Response: While we are aware of, and concerned about, the impact of this final rule on IHS and tribal health systems, we are not exempting them from its application when they operate as Medicaid managed care entities or subcontract with Medicaid managed care entities. First, there is no basis in the statute for such an exemption. We also believe that Medicaid beneficiaries who use such systems are entitled to the protections and safeguards embodied in this rule whether or not they use IHS and tribal systems. We do however understand that IHS and tribal health systems have unique circumstances, and we have consulted with IHS and tribal governments on many issues. These consultations have resulted in some adjustments to the rule. We will continue the consultation process as we interpret and implement this final rule to ensure that we address the concerns of IHS and tribal health systems. We do not believe, however, that this rulemaking is an appropriate vehicle to address the full range of Federal treaty relationships with tribal groups cited, since its scope is limited to the Medicaid managed care provisions in Chapter 1 of Subtitle H of the BBA.

Comment: One commenter strongly suggested that efforts be made by Tribal, Federal and State officials to implement the IHS/HCFA Memorandum of Agreement (MOA). The commenter believed that MOA provisions for 100 percent FMAP for tribally operated facilities should be honored under any State managed care system in the views of this commenter. The commenter believed that States operating Medicaid managed care programs should carve out IHS and tribal programs as Medicaid providers eligible for the "pass-through" reimbursement. Another commenter stated that Indian health facilities should be paid by Medicaid for every visit in which Medicaid covered services are provided to a Medicaid beneficiary. This would apply to the Indian Health Service direct service facilities, tribally operated facilities, and urban Indian clinics, collectively known as the I/T/U. The commenter believed that the I/T/U should be paid by Medicaid at a rate that covers the cost of delivering services, considering that there is little opportunity to shift costs to other third party payers. The commenter further stated that barriers to participation should be eliminated for AI/AN populations for health care programs that receive any Federal funding. Recognizing the limitations in funding, the commenter believed that resources should be used to the maximum extent for direct patient care and prevention activities while keeping administrative functions as efficient as possible.

Response: As discussed above in the discussion of comments on Subpart J section II. H., issues of Federal matching funding levels are outside the scope of the proposed rule or this final rule, which has no effect on matching rates for services furnished by IHS or tribal facilities. We note that the commenter is mistaken in suggesting that the cited MOA requires any particular payment levels to IHS or tribal facilities (and further note that it does not address urban Indian facilities at all). We recognize, however, that IHS and tribal health systems and providers may have unique circumstances in contracting with such programs. We intend to continue to work with IHS and the tribes to minimize barriers to participation in Medicaid managed care programs, and to address the matching rate issues raised by the commenters.

i. Miscellaneous Comments

Comment: One commenter recommended that the final rule address the administration of non-emergency MCO transportation services. The commenter believed (based on recommendations made by HCFA's Transportation Technical Advisory Group) that coordination with transportation agencies and other human service providers increased the efficiency of the transportation system, helped control costs, and can provide better service to Medicaid and non-Medicaid users of the transportation system. The commenter noted that it is in the interest of the community, State, and the health care and transportation industries to develop coordinated networks of transportation. Further, according to the commenter, States should have the ability to operate their non-emergency transportation services with Federal matching funding comparable to the optional medical service match to improve the States' capacity to coordinate transportation services, thereby saving Medicaid related costs while supporting the existing public transportation network.

Response: The issue of non-emergency transportation services is not an issue that is unique to managed care. This regulation only pertains to the Medicaid managed care provisions in the BBA, and thus, non-emergency transportation is beyond the scope of this regulation and the statute it implements.

Comment: One commenter disagreed with the deletion of the requirement that no more than 75 percent of enrollees in risk contracts be eligible for Medicare or Medicaid. Although it is not clear why this would be the case, the commenter apparently believed that this deletion would result in MCOs decreasing the numbers of Medicaid beneficiaries.

Response: First, the 75/25 enrollment requirement is a limit on the percentage of enrollees eligible for Medicaid, and therefore there is no reason to believe it would result in decreased Medicaid enrollment. Any changes that resulted from its elimination would presumably increase Medicaid enrollment. More importantly, this change was made by Congress in the BBA, and we thus had no discretion in this rulemaking to retain it. We note that this requirement was previously used as a rough "proxy" to ensure quality services by requiring that an MCO attract commercial customers. This "proxy" has been replaced in the BBA with more direct quality requirements implemented in this final rule.

Comment: We received one comment urging that the proposed rule deal with the effects on Medicaid of the law prohibiting "public benefits" going to individuals who are not citizens or permanent residents.

Response: This subject is outside the scope of this rulemaking.

Comment: A few commenters suggested that HCFA require State agencies to consult with beneficiaries and the physician community at all stages of the planning and implementation of new managed care initiatives. The commenters believed that physician organizations can offer significant input into the development of professional standards effecting patient care delivery, evaluating the adequacy of provider networks, and assessing quality of care delivered. Further, the commenters believed that we should continuously monitor and evaluate State experiences with physician participation and serve as a clearinghouse of information for States on successful strategies.

Response: We realize that public and physician consultation are important factors in the development of Medicaid managed care initiatives and encourage stakeholder input at all stages of managed care development. However, we are not requiring a specific requirement for stakeholder involvement since States, based on the uniqueness of their Medicaid managed care programs, are in the best position to determine how this involvement should be structured. Each State is required to have a Medical Care Advisory Committee (MCAC) established for the purpose of advising the Medicaid agency about health and medical services. This committee, by regulatory definition, is required to include physicians and beneficiaries. We encourage States to continue to use the MCAC as a mechanism for obtaining input on managed care issues. Likewise, under § 438.302, we are requiring public consultation in development of the State's quality strategy, though we are not specifying the structure of this consultation.

Comment: One commenter expressed concern with the lack of discussion in the preamble and proposed regulation text of requirements or directions to States regarding long term care services and support delivered by MCOs. The commenter believed that this was of particular concern since the elderly and people with disabilities account for the majority of Medicaid spending.

Response: While long-term care services were not explicitly addressed in the regulation, we believe the regulation was written in such a manner to encompass all the types of services delivered under managed care including long-term care. Long-term care issues were considered in discussions during the development of the final regulation.

Comment: Several commenters were concerned with what they believed to be a lack of clarity and specificity in the proposed rule concerning children and children with special health care needs. These commenters believed that the final rule should be more specific on child health requirements separate from adult health requirements, since children have distinct medical and developmental health care needs. The commenters also stated that the proposed rule offered no special protection for children with special health care needs. One commenter stated that when Congress enacted section 1932(a)(2)(A) of the Act, it intended that HCFA develop standards and protections for special needs children above and beyond the managed care standards and protections provided to all beneficiaries. The commenter further indicated that because children with special health care needs are the most vulnerable, it was essential that HCFA provide specific regulations that protects these children in managed care environments.

Response: We agree that children, and particularly children with special health care needs, have unique needs that differ from the adult population. While this final rule establishes a general framework for States to use when developing managed care programs to serve all of its enrolled populations, as discussed in section II. D. above, it also takes into account and implements recommendations set forth in HCFA's report to Congress on special needs beneficiaries required under section 4705(c)(2) of the BBA. We note that section 1932(a)(2)(A) specifically exempts special needs children from being mandatorily enrolled in the State Plan Option for Medicaid managed care. In addition, under 1915(b) waivers HCFA has established new interim criteria that States must meet when establishing programs for children with special health care needs. These criteria require additional reporting and monitoring for children with special health care needs. And finally, the terms and conditions for 1115 waiver programs also contain specific areas that address the needs of these types of children.

Comment: One commenter was concerned about the impact of Medicaid managed care on the nation's dental schools and other hospital-based or allied dental education programs. The commenter urged HCFA to recognize the special role of dental education institutions in serving the Medicaid population and to use the regulations to strengthen the Medicaid program by improving access to dental prevention and treatment services. Finally, this commenter recommended that the proposed regulations be revised to amplify the specific requirements of law related to the access of diagnostic,

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preventive and treatment services for children under Medicaid's EPSDT program. The commenter was specifically concerned about the impact of managed care on the utilization rate for children's dental services.

Response: We recognize the importance of the nation's dental schools and other hospital-based dental education programs in serving the dental needs of the Medicaid population. At this time, we do not believe it is necessary to develop a separate regulation to address access to dental prevention and treatment services. This final rule is designed to address access issues related to all Medicaid managed care services. For example, an MCO that delivers dental services to Medicaid beneficiaries must comply with the access requirements in the regulation. The MCO must ensure that it offers an appropriate range of services and that it maintains a network of providers that is sufficient to meet the needs of its enrollees. Further, according to § 438.206(a), each State must ensure, through its contract with an MCO, that all of the covered services are accessible for all the beneficiaries enrolled with the MCO. We are also optimistic that managed care will facilitate increased utilization in the area of dental services.

Comment: Several commenters recommended that HCFA develop a final rule which ensures that States, MCOs and PCCMs will develop Medicaid managed care programs that protect the rights of enrollees who are homeless, promote their access to an appropriate range of services, and improve the quality of care available to them.

Response: We believe this final rule protects the rights of all beneficiaries, including persons who are homeless. For example, § 438.206 requires that the delivery network meet the needs of the population served and that access to services be guaranteed, while under § 438.100 all beneficiaries must be treated with dignity and respect. We recognize that persons who are homeless face unique difficulties in receiving information needed to make appropriate choices among MCO or PCCM options due to transience, lack of mailing address, and other circumstances. Under § 438.56(d)(2)(i), persons who are homeless, and who have been automatically assigned at their initial enrollment into an MCO or PCCM, may disenroll and re-enroll with a different MCO or PCCM at any time. We believe this will give persons who are homeless the opportunity to learn more about managed care when they need medical services and make the most effective choice of MCOs or PCCMs at that time.

Comment: One commenter recommended that there should be some form of consumer assistance programs to help enrollees navigate the managed care system.

Response: We agree that there must be adequate and appropriate consumer assistance programs available to enable beneficiaries to navigate the managed care system. We also agree that it is a State's responsibility to ensure that consumer assistance is available to its beneficiaries. However, because consumer assistance can be accomplished in many different ways, and should be designed by each State to meet the unique characteristics of its managed care population and program, we are not imposing a Federal requirement for this. Some States already use toll free hotlines for consumer assistance, while others have developed ombudsman programs. We do require that MCOs must give enrollees reasonable assistance they need in completing forms or other procedural steps in the grievance process.

Comment: Several commenters believed that the regulation should clearly respond to the special needs of medically vulnerable beneficiaries with acute, chronic and disabling conditions and contain specific definitions of these diagnoses, as well as clear definitions of "mental illness" and "addictive disorders" so that coverage for these conditions are included under the service plan. One commenter recommended the inclusion within all Medicaid mental health managed care benefit packages of psychosocial rehabilitative services, self-help services and peer supports, and other non-medical services designed to help consumers improve their level of functioning, increase their ability to live independently and cope with ongoing symptoms and side effects of medications. Further, the commenter contended that States should be required to establish the methodology necessary to measure the prevalence of chronic mental illness, acute mental illness, or substance abuse per county, taking into account the predicted health care needs of the population to be enrolled. Another commenter believed that the regulation should incorporate a requirement that each Medicaid managed care behavioral health plan name and provide a full continuum of addiction treatment services in the network including: hospital and non-hospital detoxification, hospital and non-hospital rehabilitation, short and long term rehabilitation, outpatient, partial hospitalization services and treatment for the family. This commenter also recommended that a particular university be given a strong role in review of these provisions, and that this role should be written into regulation.

Response: The regulation was intended to address needs and protections for all Medicaid beneficiaries in managed care. The information requirements at § 438.10 require that the State must, directly, or through the MCO, PHP, or PCCM, provide information on any benefits to which the beneficiary is entitled under the Medicaid program, but that are not covered under the MCO, PHP, or PCCM contract, and specific instructions on where and how to obtain those benefits, including how transportation is provided. Further, we are not identifying specific types of treatment and services in the regulation for one type of service category. Each State has the flexibility to determine the services that will be covered under their own State Medicaid program. This regulation pertains only to the delivery of services, not the benefits provided under the State's Medicaid program. With respect to the last comment on the role of a specified university, we do not believe it would be appropriate to grant an outside private body government oversight authority.

Comment: One commenter suggested that MCO, PHP, and PCCM contracts should specify the services that the entity is responsible to provide, and that the State should be required to make arrangements for providing other State plan services, and give beneficiaries written information on how to obtain them.

Response: As noted above in section II. C., § 438.210(a) requires that contracts specify the services the entity is required to provide, and § 438.206(c) requires that if an MCO contract does not cover all of the services covered under the State plan, the State must make available those services from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided. Further, the information requirements under § 438.10 require that the State must, directly or through the MCO, PHP, or PCCM, provide to Medicaid beneficiaries information on any services to which they may be entitled under the Medicaid program, but that are not covered under the MCO PHP, or PCCM contract and specific instructions on where and how to obtain those services, including how transportation is provided.

Comment: One commenter recommended that a new paragraph should be included (titled "Americans with Disabilities Act") to require that each MCO must ensure that: (1) the physical and mental disabilities of enrollees and potential enrollees are reasonably accommodated, including flexible scheduling, extra assistance and specialized staff training; (2) enrollees with disabilities receive services in the most integrated setting appropriate to their needs, including community based services to enable them to live in community settings instead of institutions or residential treatment facilities; (3) no eligibility criteria, service authorization procedures, utilization review practices or other methods of administration are employed that defeat or substantially impair, with respect to individuals with disabilities, accomplishment of the objectives of the State's medical assistance program; and (4) qualified individuals with disabilities be provided services, benefits and aids that are as effective in affording equal opportunity to obtain the same result, to gain the same benefit or to reach the same level of achievement as that provided to others.

Response: We do not feel it is necessary to add a separate provision as other areas of the regulation respond to this issue. Section 438.100 requires that the State must ensure that each MCO and PHP comply with any and all Federal laws pertaining to enrollee rights, including the Americans with Disabilities Act. Further, § 438.6(f) requires that all contracts must comply with all applicable State and Federal laws and regulations, including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act.

Comment: One commenter was concerned with what will happen to people with mental retardation should an MCO, PHP, or PCCM withdraw from the Medicaid market. The commenter stated that if a Medicaid MCO or PHP leaves the Medicaid market, there must be protections in place to ensure continuing access to medically necessary services for individuals with mental retardation and other disabilities who critically need access to these health and health related services and supports to live in the community.

Response: It is the State's ultimate responsibility to ensure access to Medicaid covered services. In the event that an MCO or PHP withdraws from the Medicaid market, the State must ensure that services are delivered to all Medicaid beneficiaries either through another Medicaid MCO or PHP, or through fee-for-service arrangements.

Comment: One commenter found it disturbing that managed care consumer protections and quality measures for the Medicare population have more "teeth" than those required for Medicaid. The commenter felt that this perceived distinction in the requirements of Medicare managed care and Medicaid managed care continues what the commenter believed to be ongoing discrimination against people who are poor and disabled.

Response: It was our intent to create consistency with the Medicare+Choice requirements to lessen the impact that multiple regulatory and administrative standards exert on the managed care industry. However, where there was a clear need for greater beneficiary protection or where consistency with the Medicare+Choice program was not appropriate for Medicaid managed care, we deviated from the Medicare+Choice policy. We believe that this final rule balances the need for flexibility and consistency, while providing States with the broad tools necessary to become better purchasers of health care. We believe that this final rule contains protections for enrollees that are equal to or exceed those in the Medicare+Choice final rule. This includes sanction and civil money penalty authority similar to that in the Medicare+Choice rule. We thus disagree with the commenter's premise about the Medicare+Choice rule having more "teeth."

Comment: Several commenters urged HCFA to provide special attention to the effect of these regulations on people with disabilities. The commenters believed that the regulations must provide specific protections for special needs populations, such as those with spinal cord injury or dysfunction when enrollment in Medicaid managed care is mandatory. One commenter believed a methodology should be developed which would allow States to inventory disabled populations on a per county basis in order to ensure that adequate numbers of providers, especially specialists, would be available to serve the enrolled special needs population.

Response: The regulation was intended to address the needs and protections for all Medicaid beneficiaries in managed care, including persons with disabilities. The regulation was written in a manner to establish a general framework for States to use when developing managed care programs to serve all of its enrolled populations. We believe the regulation allows greater access to quality health care services delivered through managed care arrangements for persons with disabilities. As noted above in section II. C., § 438.206(d) requires that MCOs and PHPs take into account the anticipated enrollment of persons with special health care needs in establishing their provider network, and must have the appropriate numbers and "types" of providers in terms of training and experience to meet these needs. We believe these provisions directly address the commenters' concerns.

Comment: One commenter suggested that the final regulation make clear that all States are free to adopt more rigorous standards of consumer protections in Medicaid managed care.

Response: The consumer protections in this regulation were not designed to prevent States from developing more rigorous standards. States retain the flexibility to develop more restrictive consumer protection provisions that go beyond those contained in this regulation.

Comment: Several commenters noted that the issue of low physician participation in Medicaid does not appear to have been addressed in the proposed rule, and believed that this has always been a concern under the Medicaid program. Some of the commenters believed that because of inadequate funding and administrative requirements, physicians have minimized their participation in the Medicaid program. These commenters believed that financial incentives may be an appropriate mechanism to entice physician participation. On the other hand, a commenter felt that financial incentives that may prevent the delivery of medically necessary services may be partially controlled by prohibiting any financial incentives. Another commenter recommended that in addition to physician incentive plans that place physicians at substantial financial risk for services they do not provide, having to conduct enrollee surveys, and provide adequate and appropriate stop loss protection, HCFA should also state that financial risk will reside with the plan in instances where a plan decision results in a limit on the services provided. Finally, one commenter felt that there was a need to develop financial incentives for managed care plans to compete on the basis of quality rather than the basis of price. This commenter believed that it is important for Medicaid managed care regulations to establish rewards for MCOs based on quality, not merely cost reductions.

Response: The general issue of relatively low levels of physician participation in the Medicaid program is

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outside the scope of this rulemaking. We note, however, that levels of participation in managed care settings have been higher than under fee-for-service Medicaid, and that a managed care enrollee is ensured access to a primary care provider under this final rule. Thus, to the extent managed care is involved, physician participation is guaranteed under this final rule to the extent necessary to meet access requirements. Specifically, § 438.207 requires that each MCO and PHP must ensure that it maintains a network of providers that is sufficient in number, mix and geographic distribution to meet the needs of the anticipated number of enrollees in the MCO's or PHP's service area. Further, under § 438.214, the State must ensure that each MCO and PHP have a process for formal selection and retention of providers that does not discriminate against those that serve high risk populations or specialize in conditions that require costly treatment. With respect to financial incentives for MCOs and PHPs, these are addressed in § 422.6(c)(5) as part of the discussion of actuarially sound rates. See section II. A. above. Beyond these limits, we believe States should have flexibility in this area. With respect to financial incentives for individual physicians, § 438.6(h) requires that MCO and PHP contracts provide for compliance with the physician incentive plan requirements.

Comment: One commenter wrote to express concerns regarding the quality of care delivered by a particular managed care program. The commenter was concerned about the introduction of managed care for persons with disabilities and persons with chronic conditions. The commenter contended that they were misled by their health plan, and the organization denied and reduced care when not appropriate.

Response: We anticipate that the new consumer protections, quality provisions and grievance system requirements in this final rule will work to alleviate problems in the areas addressed by the commenter.

Comment: One commenter believed that the final rule should maintain an adequate safety net to guarantee the continued viability of Medicaid managed care and to allow for reasonable alternatives. The commenter cautioned States moving towards mandatory managed care that they must avoid the tendency to make the area fit MCOs rather than the MCOs address the area. The commenter felt that "cookie cutter" approaches will not work in large rural States, and it might be difficult to develop health plan networks in rural areas.

Response: We recognize that States are unique and have different needs for their enrolled populations. This final rule was designed to maintain State flexibility as much as possible, so that States can implement managed care programs that meet the needs of their beneficiaries.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The following information collection requirements and associated burdens are subject to the PRA. For purposes of this requirement, we incorporated pertinent managed care data from the 1999 Medicaid enrollment report. As of June, 1999, there were 375 managed care organizations (MCOs) (this includes 2 HIOs that must adhere to the MCO requirements of this regulation), 37 primary care case management systems (PCCMs), 412 managed care entities (MCOs and PCCMs combined), and 129 prepaid health plans (PHPs). There were a total of 24,470,583 beneficiaries enrolled in these plans (some beneficiaries are enrolled in more than one plan) in forty-eight States and the District of Columbia (Wyoming and Alaska do not currently enroll beneficiaries in any type of managed care).

A. Section 438.6 Contract Requirements

1. Section 438.6(c) Payments Under the Contracts

a. Requirement

In summary, § 438.6(c) modifies the rules governing payments to MCOs and PHPs by doing the following: (1) eliminates the upper payment limit (UPL) requirement; (2) requires actuarial certification of capitation rates; (3) specifies data elements that must be included in the methodology used to set capitation rates; (4) requires States to consider the costs for individuals with chronic illness, disablility, ongoing health care needs, or catastrophic claims in developing rates; (5) requires States to provide explanations of risk sharing or incentive methodologies; and (6) imposes special rules, including a limitation on the amount that can be paid under FFP in some of these arrangements.

b. Burden

We believe that the burden of providing additional information to support the actuarial soundness of a State's capitation rates will be offset by the elimination of the UPL requirement. States will no longer be required to extract fee-for-service (FFP) data and manipulate that data by trending and other adjustments in order to establish a FFP equivalent for purposes of comparison to capitation rates.

2. Section 438.6(i)(2) Advance Directives

a. Requirement

This paragraph requires that MCOs and PHPs (States may determine that it is inappropriate to require this of some PHPs) provide adult enrollees with written information on advance directives policies and include a description of applicable State law.

b. Burden

The burden associated with this requirement is the time it takes to furnish the information to enrollees. We assume that this information would be furnished with the rest of the information required by other regulations sections and is therefore subsumed under those requirements.

B. Section 438.8 Provisions That Apply to PHPs

Section 438.8(a) Contract Requirements

a. Requirement

This section imposes most of the contract requirements contained in § 438.6 on PHPs, including advance directives (in most instances) and physician incentive plan requirements.

2. Burden

PHPs have not previously been required to maintain written policies and procedures with respect to advance directives. This requires the PHP to provide written information to enrollees of their rights under this provision and the PHP's policies with respect to the implementation of those rights. We project 8 hours for each of the 129 PHPs to establish this policy and 2 minutes per enrollee for provision of this information, and acceptance of this right to each of approximately 8.1 million individuals enrolled in PHPs. The total time for this would be 271,032 hours.

Under the physician incentive plan provision, PHPs, like MCOs, will be required to provide descriptive information to States and HCFA to determine whether or not there is substantial financial risk in their subcontracts. In addition, enrollees must be surveyed and provided information on the risk arrangements when substantial risk exists.

We are basing our projections of burden upon information published in the **Federal Register** on March 27, 1996 and December 31, 1996 (61 FR 13445 and 61 FR 69049) which contained the original regulatory provisions on physician incentive plans for Medicare and Medicaid HMOs. Based on those assumptions, we believe no more than one third of the approximately 130 PHPs use incentive or risk payment arrangements with their subcontracting providers. Affected PHPs would be required to provide detailed responses to State surveys regarding their payment mechanisms and amounts. At the projected 100 hours per response for approximately 43 PHPs the total burden would be 4300 hours. For those PHPs with substantial financial risk, there are other requirements such as stop loss insurance and beneficiary surveys. We believe there would be minimal additional burden as a result of these requirements (because many already comply with these requirements) and that this would apply to no more than one fourth of those PHPs with risk or incentive payments, or a total of 11. We estimate an additional 10 hours per plan for a total of 110 hours. Altogether, we estimate 4,410 hours of burden through imposition of this requirement on PHPs.

C. Section 438.10 Information Requirements

1. Section 438.10(b), (d), (e), and (f)

a. Requirement

In summary, § 438.10(b), (d) and (e) state that each State, MCO, PHP, and PCCM must furnish information to enrollees and potential enrollees, to meet the requirements of this section. Paragraph (b) requires that the State notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees that oral interpretation and written information are available in languages other than English and how to access those services. The basic information listed in paragraph (d) and (e) of this section must be provided to each enrollee or to any potential enrollee upon request, by the MCO or PHP (unless the State chooses to furnish it directly), within a reasonable time after it receives from the State notice of the beneficiary's enrollment. This information must be provided on an annual basis thereafter, the MCO or PHP must notify enrollees of their right to obtain this information upon request. The information that must be provided includes the following:

Information for potential enrollees

General information must be provided about the basic features of managed care, which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP, and MCO and PHP responsibilities for coordination of enrollee care.

Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area must be provided. This includes information on benefits covered; cost sharing if any; service area; names, locations, and telephone numbers of current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients; and benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.

Information for enrollees

The State must give each enrollee written notice of any change (that the State defines as "significant") in the information specified at least 30 days before the intended effective date of the change and make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

Required information:

- Kinds of benefits, and amount, duration, and scope of benefits available under the contract; enrollee rights as specified in § 438.100.
- Procedures for obtaining benefits, including authorization requirements.
- Names, locations, and telephone numbers of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.
- Any restrictions on the enrollee's freedom of choice among network providers.
- The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.
- The extent to which, and how, after-hours and emergency coverage are provided.
- Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.
- Cost sharing, if any.
- Grievance, appeal, and fair hearing procedures for enrollees, including time-frames, required under § 438.414(b).
- Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.
- Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. The State must furnish information about how and where to obtain the service.
- Information on how to obtain continued services during a transition, as provided in § 438.62.
- The rules for emergency and post-stabilization services, as set forth in § 438.114.
- Additional information that is available upon request, and how to request that information.

At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed above.

In addition, § 438.10(f) requires that information related to the licensure, certification, and accreditation status of MCOs, PHPs, and their providers be

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furnished to each enrollee and each potential enrollee.

b. Burden

We believe the burden placed on States, MCOs, PHPs, and enrollment brokers as a result of this requirement is the time associated with modifying the content of existing information materials, as well as the time associated with distributing the materials to enrollees as specified by the regulation. We estimate that it will initially take 12 hours for each MCO or PHP to modify existing information materials to conform with the requirement above. We further estimate that there are approximately 375 MCOs and 129 PHPs, equating to an initial modification burden of approximately 6,048 hours. After the initial modification, we estimate that it will take MCOs and PHPs approximately 4 hours each to annually update the information materials, equating to an annual total burden of approximately 2,016 hours.

We expect that it will take MCOs, PHPs, or States approximately 5 minutes per enrollee to mail the initial packet, for an estimated 20.2 million enrollees. The total burden associated with this requirement is approximately 1,683,000 hours, approximately 3,340 hours per MCO or PHP, or 34,000 hours per State.

We similarly estimate that it annually will take MCOs, PHPs, or States 5 minutes per enrollee to mail information materials upon request. We estimate that 10 percent of enrollees and potential enrollees will request information annually, equating to approximately 2,020,000 enrollees and potential enrollees. The annual mailing burden associated with this requirement is estimated to be 2,020,000 individuals multiplied by 5 minutes per person, for a total burden of approximately 168,300 hours (approximately 330 hours per MCO or PHP, or 3,400 hours per State).

Finally, we estimate that it will annually take MCOs, PHPs, or States 5 minutes per enrollee to notify enrollees of their right to receive information. Five minutes multiplied by an estimated total enrollee population of 20,200,000 individuals equates to an annual burden of approximately 16,830,000 hours or approximately 3,300 hours per MCE or PHP or 33,400 hours per State.

2. Section 438.10(g)

a. Requirement

Section 438.10(g) requires that each primary care case manager (PCCM) (and PHPs that operate like PCCMs) provide similar types information to potential enrollees including information on provider names and locations, benefits, grievance procedures, and procedures for obtaining services during the appeals process.

b. Burden

The burden associated with this requirement is the amount of time required by States or their contracted representative to mail the required information to potential enrollees. We believe that it will take the 30 States approximately 5 minutes per enrollee to mail this information. We estimate that there are a total of approximately 4,274,000 PCCM enrollees, and that 10 percent of those enrollees will request this information. This equates to an annual burden of 5 minutes multiplied by 427,400 enrollees, or approximately 35,600 hours (approximately 962 hours per primary care case manager).

3. Section 438.10(h)

a. Requirement

In summary, § 438.10(h) states that if a State plan provides for mandatory MCO, PHP, or PCCM enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must provide information in a comparative, chart-like format, to potential enrollees and at least once a year thereafter. The information must include the MCO's, PHP's or PCCM's service area, the benefits covered under the contract, any cost sharing imposed by the MCO, PHP, or PCCM and, to the extent available, quality and performance indicators, including but not limited to disenrollment rates and enrollee satisfaction.

b. Burden

We believe that the additional burden on States (for example those not yet captured in the above provisions) is the length of time associated with creating the comparative chart. We estimate that it will take States approximately 4 hours each to create the comparative chart. We further estimate that approximately 8 States per year will avail themselves of the State Plan Option, for a total annual burden of approximately 32 hours.

D. Section 438.12 Provider Discrimination Prohibited

a. Requirement

This section requires that if an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

b. Burden

The burden associated with this requirement is the time it takes the MCO or PHP to draft and furnish the providers with the requisite notice. We estimate that it will take an hour to draft and furnish any given notice. We estimate that on average each MCO and PHP will need to produce 10 notices per year for a total of 5,040 hours.

E. Section 438.50(b) State Plan Information

a. Requirements

Each State must have a process for the design and initial implementation of the State plan that involves the public and have methods in place to ensure ongoing public involvement once the State plan has been implemented.

b. Burden

The burden associated with this section includes the time associated with developing the process for public involvement, including annual updates. We estimate that it will take 40 hours per State to develop the process for, and involving, the public for a total burden of 1960 hours (48 States and D.C.). We estimate that ensuring ongoing public involvement will take another 20 hours per State annually for a total annual burden of 980 hours.

F. Section 438.56z Disenrollment: Requirements and Limitations

1. Section 438.56(b)

a. Requirement

All MCO, PHP, and PCCM contracts must—

(1) Specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs; and

(3) Specify the methods by which the MCO, PHP, or PCCM ensures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

b. Burden

The burden of submitting this supporting documentation when MCOs, PHPs, or PCCMs request disenrollment of beneficiaries would be two hours per request. We calculate that approximately one-tenth of one percent of enrollees (24,470) would be affected, or 43 per MCO, PHP, or PCCM annually. The total burden would be 48,940 hours, or 87 hours per MCO, PHP, or PCCM.

2. Section 438.56(d)(1)

a. Requirement

In order to disenroll, the beneficiary (or his or her representative) must submit an oral or written request to the State agency (or its agent) or to the MCO, PHP or PCCM where permitted.

b. Burden

We believe that the burden associated with this requirement is the length of time it would take enrollees to submit in writing a disenrollment request, if they choose to use the written format. We estimate that it will take approximately 10 minutes per enrollee to generate a written disenrollment request. We estimate that approximately 5 percent of MCO, PHP, and PCCM enrollees will request that they be disenrolled from an MCO, PHP, or PCCM. Approximately one-fourth of the enrollees will choose a written rather than an oral request. This equates to an annual burden of approximately 10 minutes multiplied by 306,000 affected enrollees (one-fourth of the 1,221,000 enrollees requesting disenrollment), or approximately 51,000 hours.

3. Section 438.56(d)(3)

a. Requirement

When MCOs, PHPs, or PCCMs are processing disenrollment requests and do not act to approve them, they must submit written notice to the State and then the State takes action. When a State is acting on a for-cause disenrollment request, they may request written information from the MCO, PHP, or PCCM to determine the outcome. In addition, if the MCO, PHP, or PCCM approves the disenrollment for cause, it must give the enrollee and the State agency written notice of its determination.

b. Burden

We believe that the burden associated with this requirement is the time taken for MCOs, PHPs, or PCCMs to submit written notice to the State and beneficiaries.

Of the 1,221,000 affected enrollees, we calculate that one-fifth (244,000) will not be approved. If each notice takes 15 minutes to produce, the total burden would be 61,000 hours. Of the 244,000 enrollees not approved, we calculate that three-fourths (183,000) will involve the State requesting information from the MCO, PHP, or PCCM justifying the denial. At one hour per request, the total burden on MCOs, PHPs, or PCCMs would be 183,000 hours.

We estimate that the MCOs, PHPs, and PCCMs will need to produce notices for the remaining four-fifths of enrollees requesting disenrollment (977,000) and the States to approve the request for disenrollment. As this notice will probably be a short form letter, with attachments as necessary, we believe that it will take ten minutes per request to send out the notices, or an annual burden of 163,000 hours.

G. Section 438.102 Enrollee-Provider Communications

a. Requirement

Section 438.102(c) states that the general rule in paragraph (b) of this section does not require the MCOs and PHPs to cover, furnish, or pay for a particular counseling or referral service if the MCO or PHP objects to the provision of that service on moral or religious grounds; and makes written information on these policies available to (1) prospective enrollees, before and during enrollment and, (2) current enrollees, within 90 days after adopting the policy with respect to any particular service.

b. Burden

The above information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

H. Section 438.114 Emergency Services

a. Requirement

Section 438.114(b) states that at the time of enrollment and at least annually thereafter, each MCO, PHP, and State (for PCCMs) must provide, in clear, accurate, and standardized form, information that, at a minimum, describes or explains (1) What constitutes an emergency, with reference to the definitions in paragraph (a) of this section, (2) the appropriate use of emergency services, (3) the process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent, (4) the locations of emergency settings and other locations at which MCO physicians and hospitals provide emergency services and post-stabilization care covered under the contract, and (5) the fact that prior authorization is not required.

a. Burden

The following information collection requirement is subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

I. Section 438.202 State Responsibilities

a. Requirement

Each State contracting with an MCO or PHP must have a strategy for assessing and improving the quality of managed care services offered by the MCO or PHP, document the strategy in writing and make it available for public comment before adopting it in final, and conduct periodic reviews to evaluate the effectiveness of the strategy at least every three years. Each State must also submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, States are required to submit to HCFA regular reports on the implementation and effectiveness of the strategy, consistent with the State's own periodic review of its strategy's effectiveness, but at least every three years.

b. Burden

The burden associated with this section is limited to those States offering managed care through MCOs or PHPs (49) and includes the time associated with developing the proposed strategy, publicizing the proposed strategy, incorporating public comments, submitting an initial copy of the strategy to HCFA prior to its implementation and whenever significant changes are made, and submitting regular reports on the implementation and effectiveness of the strategy at least every three years. We estimate that it will take 40 hours per State to develop the proposed strategy for a total burden of 1960 hours. We estimate that publicizing the proposed strategy will take 2 hours per State for a total burden of 98 hours. We estimate that incorporating public comments for the final strategy will take another 40 hours per State for a total burden of 1960 hours. We estimate it will take one hour per State to submit an initial copy of the strategy to HCFA and whenever significant changes are made for a total of 49 hours. We estimate it will take 40 hours per State to create and submit a report on the implementation and effectiveness of the strategy. We assume that these reports will be submitted at least every three years for a total annual burden of 653 hours.

K. Section 438.204 Elements of State Quality Strategies

a. Requirement

In this final rule we have added a new requirement at § 438.204(b)(1)(iii) that a State identify the race, ethnicity, and primary language spoken by each MCO

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and PHP enrollee and report this information to each MCO and PHP in which each beneficiary enrolls at the time of their enrollment.

b. Burden

We believe that most States currently track race and ethnicity data in their eligibility systems. If States do not, minor changes in their software will be needed. With respect to primary language of enrollees, there will likely be additional programming needed for all States. We estimate that this would require 2 hours of programming for each of the 49 jurisdicitons for a total of 98 hours.

L. Section 438.206 Availability of Services

a. Requirement

Paragraph (c) of this section requires that if an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

b. Burden

The burden associated with this requirement is the time it takes to provide the information. This burden of this requirement is included in the general disclosure requirements in § 438.10.

M. Section 438.207 Assurances of Adequate Capacity and Services

a. Requirement

Section 438.207 requires that each MCO and PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, that it has the capacity to serve the expected enrollment in its service area in accordance with the States' standards for access to care and meets specified requirements.

Section 438.207(c) requires that this documentation be submitted to the State at least annually, and specifically at the time the MCO or PHP enters into a contract with the State and at any time there has been a significant change (as defined both by the State and this regulation) in the MCO's or PHP's operations that would affect adequate capacity and services.

Section 438.207(d) requires the State, after reviewing the MCO's or PHP's documentation, to certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth at § 438.206.

b. Burden

We believe that MCOs and PHPs already collect and provide this information to State agencies as part of their customary and usual business practices and that the only additional burden on MCOs and PHPs is the length of time required for MCOs and PHPs to compile this information in the format specified by the State agency, and the length of time for the MCOs and PHPs to mail the information to the State and the HCFA. We estimate that it will take each MCO and PHP approximately 20 hours to compile the information necessary to meet this requirement, for a total of 20 hours multiplied by 504 MCOs and PHPs, or approximately 10,000 hours. In addition, we estimate that it will take MCOs and PHPs approximately 5 minutes each to mail the materials associated with this burden to the State for an annual burden of approximately 5 minutes multiplied by 502 MCOs and PHPs, or approximately 42 hours.

In this final rule we have added requirements to the types of assurances that MCOs and PHPs must provide (for example assurances that the MCO or PHP has policies and practices to address situations where there are: (1) unanticipated needs for providers with particular types of experience; and (2) unanticipated limitations on the availability of such providers. In addition, we have added new requirements under § 438.206(d) that when establishing and maintaining provider networks, each MCO and PHP must consider the anticipated enrollment with respect to persons with special health care needs and the experience of providers required to furnish contracted services. Documentation to support assurances by each MCO and PHP that they have considered the anticipated enrollment of persons with special health care needs and have recruited or are in the process of recruiting experienced providers is part of the assurances that must be provided to the State. We do not believe that it is customary, or part of the ususal business practice of MCOs and PHPs to collect data that includes totals for projected enrollment of persons with special health care needs and their specialized provider requirements. We estimate that obtaining information on: (1) the numbers and types of persons with special health care needs that could be anticipated to enroll in the MCO or PHP; (2) the types of experienced providers they would require; (3) the experience of the existing providers in the MCO's or PHP's network; and (4) the numbers and types of additional experienced providers needed, would require an estimated 40 hours of work for each of the 504 MCOs and PHPs for a total estimated burden of 20,160 hours.

N. Section 438.240 Quality Assessment and Performance Improvement Program; Performance Improvement Projects

a. Requirement

Section 438.240(c) states that each MCO and PHP must annually measure its performance using standard measures required by the State and report its performance to the State. In this final rule we have added a requirement that the State must include any minimum performance measures and levels specified by HCFA. In addition to using and reporting on measures of its performance, in § 438.240(d)(3) States are to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In § 438.240(d)(10) each MCO and PHP is required to report the status and results of each such project to the State as requested.

B. Burden

This regulation would require States to require each MCO and PHP to annually produce at least two performance measures. Based on discussions with the 17 States with the largest Medicaid managed care enrollments, all 17 States are already doing so. Because the use of performance measures in managed care has become commonplace in commercial, Medicare and Medicaid managed care, we do not believe that this regulatory provision imposes any new burden on MCOs, PHPs, or States.

With respect to the requirements for performance improvement projects in § 438.240(d), we expect that, in any given year, each MCO and PHP will complete two projects, and will have four others underway. We further expect that States will request the status and results of each MCO's and PHP's projects annually. Accordingly, we estimate that it will take each MCO and PHP 5 hours to prepare its report for each project, for an annual total burden of 30 hours per MCO and PHP. In aggregate, this burden equates to 30 hours multiplied by an estimated 504 MCOs and PHPs, or approximately 15,120 hours.

O. Section 438.242 Health Information Systems

a. Requirement

Section 438.242(b)(2) requires the State to require each MCO and PHP to collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees, through an encounter data system or other such methods as may be specified by the State. Section 438.242(b)(3) states that each MCO and PHP must make all collected data available to the State and to HCFA, as required in this subpart, or upon request.

b. Burden

The above information collection requirements are subject to the PRA. However, we believe that the burden associated with these information collection requirements is exempt from the Act in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

P. Section 438.402 General Requirements

a. Requirement

In summary, § 438.402 requires each MCO and PHP to have a grievance system, sets out general requirements for the system, and establishes filing requirements. It provides that grievances and appeals may be filed either orally or in writing, but that oral appeals (except those with respect to expedited service authorization decisions) must be followed by a written request.

b. Burden

We estimate that approximately 1 percent of 20.2 million MCO and PHP enrollees (202,000) annually will file a grievance with their MCO or PHP and that approximately .5 percent (101,000) annually will file an appeal. For these cases, we estimate that the burden on the enrollee filing a grievance or appeal is approximately 20 minutes per case. The total annual burden on enrollees is 101,000 hours.

Q. Section 438.404 Notice of Action

a. Requirement

In summary, § 438.404 states that if an MCO or PHP intends to deny, limit, reduce, or terminate a service; deny payment; deny the request of an enrollee in a rural area with one MCO or PHP to go out of network to obtain a service; or fails to furnish, arrange, provide, or pay for a service in a timely manner, the MCO or PHP must give the enrollee timely written notice and sets forth the requirements of that notice.

b. Burden

We estimate that the burden associated with this requirement is the length of time it would take an MCO or PHP to provide written notice of an intended action. We estimate that it will take MCOs and PHPs 30 seconds per action to make this notification. We estimate that approximately 5 percent (1,010,000) of the approximately 20.2 million MCO and PHP enrollees will receive one notice of intended action per year from their MCO or PHP (2,004 hours per MCO or PHP) for a total burden of approximately 8417 hours.

R. Section 438.406 Handling of Grievances and Appeals

a. Requirement

In summary, § 438.406 states that each MCO and PHP must acknowledge receipt of each grievance and appeal.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

S. Section 438.408 Resolution and Notification: Grievances and Appeals

a. Requirement

In summary, § 438.408 states that for grievances filed in writing or related to quality of care, the MCO or PHP must notify the enrollee in writing of its decision within specified timeframes. The notice must also specify that the enrollee has the right to seek further review by the State and how to seek it. All decisions on appeals must be sent to the enrollee in writing within specified timeframes and, for notice of expedited resolution, the MCO or PHP must also provide oral notice. The decision notice must include the MCO or PHP contact for the appeal, the results of the process and the date it was completed, and a summary of the steps the MCO or PHP has taken on the enrollee's behalf to resolve the issue. For an oral grievance that does not relate to quality of care, the MCO or PHP may provide oral notice unless the enrollee requests that it be written.

This section also provides, for expedited appeals, that MCOs and PHPs must submit delayed and adverse appeal decisions to the State fair hearing office along with all supporting documentation.

b. Burden

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

T. Section 438.410 Expedited Resolution of Grievances

1. Paragraph (c)

a. Requirement

Paragraph (c), Requirements for appeals, requires each MCO and PHP to document all oral requests in writing and maintain the documentation in the case file.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

2. Paragraph (d)

a. Requirement

Section 438.410(d) states that if an MCO denies a request for expedited grievance, it must automatically transfer the request to the standard time frame process and give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter.

b. Burden

The above information collection requirements are not subject to the PRA. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

U. Section 438.414 Information About the Grievance System

a. Requirement

Sections 438.414(a) and (b) state that each MCO and PHP must provide information about the grievance system, as specified in § 438.10 and this subpart to: (1) Enrollees, (2) potential enrollees (as permitted by the State), and (3) all providers and contractors, at the time of subcontracting. The information must explain the grievance system through a State-developed or State-approved description and must include the information set forth in § 438.414 (b)(1) through (6).

In addition, § 438.414(c) states that upon request, the MCO or PHP must provide enrollees and potential enrollees with aggregate information derived from the collected information in § 438.416(e), regarding the nature of enrollee grievances and their resolution.

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(c) Requirements for appeals. Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

b. Burden

These information collection requirements are subject to the PRA. However, we believe the burden associated with these requirements is captured in the general information requirements in § 438.10.

V. Section 438.416 Recordkeeping and Reporting Requirements

a. Requirement

Sections 438.416 (a) and (c) state that each MCO and PHP must maintain a log of all complaints and grievances and their resolution, and retain the records of complaints, grievances (including their resolution) and disenrollments for three years, in a central location, and make them accessible to the State.

In addition, § 438.416(d) states that each MCO and PHP must, at least once a year, send to the State a summary that includes the following information, (1) the number and nature of all grievances and appeals, (2) the time frames within which they were acknowledged and resolved, and (3) the nature of the decisions. This material is available to the public upon request under § 438.10.

b. Burden

We estimate that approximately .5 percent of the approximately 20.2 million MCO and PHP enrollees will file a grievance with their MCO or PHP (200 per MCO or PHP). The recording and tracking burden associated with each grievance is estimated to be 1 minute per request (3.4 hours per MCO or PHP), for a total burden of 1,680 hours (1 minute multiplied by an estimated 101,000 enrollees who would file a grievance).

This section also contains the applicable requirements that MCOs and PHPs must follow to submit the annual summary of complaints and grievances. Every MCO and PHP (approximately 504 organizations) must submit an annual report. We estimate that the burden on the MCO or PHP for collecting information and preparing this summary will be approximately 4 hours per MCO/PHP or approximately 2,016 hours total.

W. Section 438.604 Data That Must Be Certified

a. Requirement

When payments from States to MCOs and PHPs are based on data submitted by the MCO or PHP that include, but are not limited to, enrollment information, encounter data, or other information required by the State, the MCO or PHP must attest to such data's accuracy, completeness, and truthfulness as a condition of receiving such payment. Each MCO and PHP must certify that it is in substantial compliance with its contract. Certification is required, as provided in § 438.606, for all documents specified by the State.

b. Burden

While the requirement for MCOs and PHPs (and their contractors) to attest to the accuracy of enrollment information encounter data or other information required by the State is subject to the PRA, as is the requirement for MCOs and PHPs to certify the accuracy, completeness, and truthfulness of all information provided in contracts, requests for proposals, or other related documents specified by the State, the burden associated with these requirements is captured during the submission of such information. Therefore, we are assigning one token hour of burden for this requirement.

X. Section 438.710 Due Process: Notice of Sanction and Pre-termination Hearing

1. (a) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(a) states that before imposing any of the sanctions specified in this subpart, the State must give the affected MCO or PCCM written notice that explains the basis and nature of the sanction. Section 438.724 also requires all intermediate sanctions to be published in a newspaper in order to notify the public.

b. Burden

The above information collection requirements are not subject to the P.A. They are exempt under 5 CFR 1320.4(a) because they occur as part of an administrative action.

2. (b)(1) Due Process: Notice of Sanction and Pre-Termination Hearing

a. Requirement

Section 438.710(b)(1) states that before terminating an MCO's or PCCM's contract, the State must give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

b. Burden

The above information collection requirement is not subject to the PRA. It is exempt under 5 CFR 1320.4(a) because it occurs as part of an administrative action.

Y. Section 438.722 Disenrollment During Termination Hearing Process

a. Requirement

Section 438.722(a) states that after a State has notified an MCO or PCCM of its intention to terminate the MCO or PCCM's contract, the State may give the MCO's or PCCM's enrollees written notice of the State's intent to terminate the MCO's or PCCM's contract.

b. Burden

States already have the authority to terminate MCO or PCCM contracts according to State law and have been providing written notice to the MCOs or PCCMs. States are now given, at their discretion, the option of notifying the MCO's or PCCM's enrollees of the State's intent to terminate the MCO's or PCCM's contract. While it is not possible to gather an exact figure, we estimate that 12 States may terminate 1 contract per year. We estimate that it will take States 1 hour to prepare the notice to enrollees, for a total burden of 12 hours. In addition, we estimate that it will take States approximately 5 minutes per beneficiary to notify them of the termination, equating to a burden of 5 minutes multiplied by 12 States multiplied by 40,080 beneficiaries per MCO or PCCM, for a burden of approximately 40,080 hours. The total burden of preparing the notice and notifying enrollees is 40,096.

Z. Section 438.810 Expenditures for Enrollment Broker Services

a. Requirement

Section 438.810(c) requires that a State contracting with an enrollment broker must submit the contract or memorandum of agreement (MOA) for services performed by the broker to HCFA for review and approval prior to the effective date of services required by the contract or MOA.

b. Burden

The burden associated with this requirement is the length of time for a State to mail each contract to HCFA for review. We estimate that the burden associated with this requirement is 5 minutes per enrollment broker contract, for a total annual burden of approximately 3 hours per year (5 minutes multiplied by an estimated 35 enrollment broker contracts in the States using brokers).

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, DHES, SSG, Attn: Julie Brown, HCFA–2001–F, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer.

VII. Provisions of the Final Rule

For reasons specified in the preamble, we have made the following changes to the proposed rule:

Part 400—Introduction; Definitions

Section 400.203

We have revised this section to include three new provisions. First, we specify that *PCCM* stands for primary care case manager. Second, we specify that *PCP* stands for primary care physician. Third, we have revised the definition of *provider* to clarify that, for the fee-for service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency and for the managed care program, it means an any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Part 430—Grants to States for Medical Assistance

Section 430.5

We have revised this section by removing the definition of *clinical laboratory*, moving the definition of *authorized representative* to this section from § 438.2, and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from this section to § 438.2. We have revised the definition of *authorized representative* to provide that the term will be defined by each State consistent with its laws, regulations, and policies.

Part 431—State Organization and General Administration

Section 431.200

We have revised paragraph (c) to include a reference to section 1819(f)(3) of the Act.

Section 431.201

We have defined service authorization request to mean a managed care enrollee's request for the provision of a Medicaid-covered service.

Section 431.244

We have revised paragraph (f) regarding time frames for State fair hearings to include a requirement for an expedited hearing for certain service authorization requests. We have redesignated paragraph (g) as (h) and included a new paragraph (g) which permits States to allow a hearing officer to grant an extension of the time frames under certain circumstances.

Part 434—Contracts

Section 435.212

We revised this section to replace "HMO," wherever it appears, with "MCO and PCCM" rather than "MCO."

Section 435.1002

We revised paragraph a to include a reference to § 438.814.

Part 438—Managed Care Provisions

Subpart A—General Provisions

Section 438.2

We have revised this section by moving the definition of *authorized representative* to § 430.5 and moving the definitions of *capitation payment, federally qualified HMO, health insuring organization, nonrisk contract, prepaid health plan,* and *risk contract* from § 430.5 to this section. We have revised the definition of *capitation payment* to clarify that the State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the *payment*, rather than a *fee*. We have clarified the definition of health insuring organization (HIO) so that it does not appear to require that an HIO's subcontractors be capitated. Since we have decided to specify within each regulatory provision, whether it applies to MCOs, PHPs, and/or PCCMs, we no longer use the term managed care entity, and have deleted that definition. We have revised the definition of *nonrisk contract* to clarify that the term refers to a contract under which the contractor is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter. In addition, under a nonrisk contract, the contractor may be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits. Finally, we have clarified the definition of PHP to indicate that PHPs may be reimbursed by any non-state plan methodology, not just capitation.

Section 438.6

We have revised this section to include a new paragraph (a) that provides for regional office review of all MCO and PHP contracts including those that are not subject to the prior approval requirements in § 438.806. We are making significant revisions to paragraph (c). We have extended the rate setting requirements to all risk contracts. We are removing the requirement that rates not exceed the upper payment limit (UPL) set forth in § 447.361 and substituting an expanded requirement for actuarial soundness including certification of capitation rates by an actuary. We specify data elements to be included in the methodology used to set capitation rates and require States to consider the costs for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims in developing rates. We also require States to provide explanations of risk-sharing or incentive methodologies and impose special rules, including a limitation on FFP, in contracts utilizing some of these arrangements. These changes are being made as a Final Rule with a 60-day period for submission of comments.

We have revised paragraph (d) to clarify that the provision applies to MCOs and PHPs, not MCEs. Paragraph (i)(2) is revised to clarify that MCOs and PHPs are not required to provide adult enrollees with oral information on advance directives.

Section 438.8

We have revised paragraph (a) to provide that the requirements for advance directives specified in § 438.6 apply to all PHPs except where the State believes that they are not appropriate, for example, if the PHP contract only covers dental services or non-clinical services such as transportation. We have also expanded the PHP requirements to include compliance with the physician incentive plan rules and all of the State

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responsibility provisions of Subpart B (except for the State plan provisions in § 438.50).

Section 438.10

We have revised this section to include the substantive requirements from § 438.318. We have also made several minor wording and organizational changes that served to clarify the requirements of this section. We have clarified how these rules apply to PHPs, whereby PHPs that have PCCM contracts are subject to the rules governing PCCMs, but all other PHPs are subject to the rules governing MCOs.

In paragraph (c), we have clarified that informational material must be available in alternative formats and in a manner that takes into consideration special needs, such as visual impairment or limited reading proficiency. In addition, paragraph (c) provides that the State and MCE must provide instructions to enrollees and potential enrollees regarding how they may obtain information in an appropriate format.

We have revised paragraph (d) to require the State or its contracted representative to provide information to potential enrollees regarding which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily.

We have included a new provision in paragraph (e)(1)(ii), which requires an MCO to inform enrollees regarding any significant changes in any of the information that was furnished to them. The MCO must furnish the information within 90 days after the effective date of the change. We have included regulatory language in paragraph (e)(2) requiring the information provided to enrollees to include names and locations of current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients. In paragraph (e)(3), we have revised the annual notice requirement to provide that at least once each year, the MCO, the State or its contracted representative must notify enrollees of their right to request and obtain specified information.

In paragraph (g), we have clarified that the time frames for furnishing information are the same for both PCCMs and MCOs.

We have revised paragraph (f) to provide that enrollees and potential enrollees may request and receive information on requirements for accessing services, including factors such as physical accessibility.

Section 438.12

We have revised paragraph (b) to permit different reimbursement amounts for the different specialties or for the same specialty.

Subpart B—State Responsibilities

Section 438.50

We have revised this section by including paragraph (b)(4), which requires the State plan to specify the process that the State uses to involve the public in both the design and the initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented. We have also revised the language in paragraph (a) to clarify that the provisions of this section do not apply to programs that have mandatory managed care enrollment pursuant to a waiver under either section 1115 or section 1915(b) of the Act. We have moved the requirements regarding limitations on enrollment and default enrollment from § 438.56 to this section so that they are only applicable in State plan managed care programs.

Section 438.52

We have revised the definition of "rural" area in paragraph (a) to eliminate the State's option to use definitions other than any area outside an "urban area" as defined in § 412.62(f)(1)(ii). We have revised the exception for rural area residents in paragraph (c) to clarify that an enrollee must be permitted to obtain services from an out of network provider if the provider is the main source of a service to that individual. We also require that, in rural areas, an enrollee must be permitted to obtain services from an out of network provider if he or she needs related services, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

Section 438.56

We have moved the requirements regarding limitations on enrollment and default enrollment from this section to § 438.50. We have revised paragraph (a) to provide that the provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM provider.

We have revised paragraph (b) to require that all MCE contracts must specify the reasons for which the MCO, PHP, or PCCM may request disenrollment of an enrollee. The contracts must also provide that the MCO, PHP, or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs except where the behavior impairs the ability of the MCO, PHP, or PCCM to furnish services to this enrollee or others.

In paragraph (c), we have clarified that an enrollee may request disenrollment without cause in four instances:

- During the 90 days following the date of the recipient's initial enrollment, or the date the State sends the recipient notice of the enrollment, whichever is later.
- At lease once every 12 months thereafter.
- Upon automatic reenrollment, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.
- When the State imposes an intermediate sanction, as specified in § 438.702(a)(3)

We have revised paragraph (d) to permit an enrollee to submit either an oral or a written request for disenrollment. In subparagraph (d)(2), we have significantly revised the provisions relating to "for cause" disenrollment. We identify three circumstances that would constitute cause under the final rule:

- The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP, or PCCM by default.
- The plan does not, because of moral or religious objects, cover the service the enrollee seeks.
- The enrollee needs related services to be performed at the same time, not all related services are available within the network, and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

In subparagraph (d)(iv), we recognize that the enrollee may cite other reasons for requesting disenrollment that could constitute "cause" under the rule, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with an enrollee's special health care needs.

In paragraph (e), we clarify the time frames for disenrollments to provide that regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PHP, or PCCM files a request.

We have revised paragraph (f) to clarify that if a State restricts disenrollment under this section, it must provide that enrollees are furnished a written notice of their disenrollment rights at least 60 days before the start of each enrollment period. In addition, if a State denies a disenrollment request, it must provide notice to the enrollee of their right to file a request for a State Fair Hearing.

Section 438.60

We have deleted an exception for emergency and post stabilization services from this provision, which had been erroneously included in the NPRM, since duplicate payments are prohibited for these services.

Section 438.62

We have added a new paragraph (b) that requires the State agency to have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP, or PCCM, from one MCO, PHP, or PCCM to another, or from an MCO, PHP, or PCCM to fee-for-service. We require that this mechanism apply at least to the following groups:

- Children and adults receiving SSI benefits.
- Children in Title IV–E foster care.
- Recipients aged 65 or older.
- Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.
- Any other category of recipients identified by HCFA.

In addition, we require the State to notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism. We also require the State to ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

- The enrollee has access to services consistent with the State plan and is referred to appropriate health care providers.
- Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records.
- Any other necessary procedures are in effect.

Section 438.64

We have deleted this section which required that capitation payments be computed on an actuarially sound basis, and incorporated it into the new § 438.6(c) provisions.

Section 438.68

We have added this new section which requires the State agency to have in effect procedures for educating MCOs, PHPs, or PCCMs and their providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

Section 438.100

We removed the language relating to benefits and moved the provisions relating to "Enrollee Rights" from § 438.320 to this section. We revised the enrollee rights in paragraph (b) to include the following two rights:

- To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.3206(d)(3).
- To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation, as specified in other Federal regulations on the use of restraints.

In addition, we have revised three of the enrollee rights to provide that the State must ensure that the enrollee has the right—

- To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. We clarify that if the MCO does not cover a service because of moral or religious objections, then the MCO need not furnish information on where and how to obtain the service, but only on where and how to obtain *information* about the service.
- To participate in decisions regarding his or her health care, including the right to refuse treatment.
- To request and receive a copy of his or her medical records and to request that they be amended or corrected, in accordance with § 438.3224.

We have included a new requirement in paragraph (c) that provides that the State must ensure that an enrollee's free exercise of his or her rights does not adversely affect the way the MCO, PCCM, or PHP, the MCO, PCCM, or PHP's providers, or the State agency treat the enrollee. In paragraph (d), we have revised the list of examples of applicable Federal and State laws for which States must ensure MCO, PCCM, or PHP compliance.

Section 438.102

We have replaced the term "practitioner" with "health care professional" and revised the definition to mirror the statutory language. We have reorganized the substantive provisions of the section to clarify the requirements. We revised paragraph (c) to include all of the information requirements that apply if an MCO does not provide a counseling or referral service based on moral or religious objections. We have clarified that, if the MCO does not cover a service under this section, then it is not required to inform enrollees and potential enrollees about how and where to obtain the service, but rather how and where to obtain information about a service. In paragraph (d), we require the State to provide information to enrollees on how and where to obtain a service that the MCO does not cover based on moral or religious objections.

Section 438.104

In paragraph (a) we moved the definitions of *choice counseling*, *enrollment activities*, and *enrollment broker* from this section to § 438.810. We revised the definition of *marketing materials* to mean materials that are produced in any medium, by or on behalf of an MCO, PCCM, or PHP and can reasonably be interpreted as intended to market to enrollees or potential enrollees. We also defined *marketing* to mean any communication from an MCO, PCCM, or PHP, any of its agents or independent contractors, with an enrollee or potential enrollee that can reasonably be interpreted as intended to influence that individual to enroll or reenroll in that particular MCO, PCCM, or PHP's Medicaid product or disenroll from another MCO, PCCM, or PHP's Medicaid product.

In paragraph (b), we have clarified that inaccurate, false, or misleading statements include, but are not limited to, any assertion or statement (whether oral or written) that the beneficiary must enroll in the MCO, PCCM, or PHP in order to obtain benefits or in order to not lose benefits or that the MCO, PCCM, or PHP is endorsed by HCFA, the Federal or the State government, or similar entity. We have also revised two of the provisions in subparagraph (b)(2) in order to clarify that the MCO, PCCM, or PHP contract must provide that the MCO, PCCM, or PHP distributes their marketing materials to its entire service area, as indicated in the contract and that the MCO, PCCM, or PHP does not seek to influence enrollment in conjunction with the sale or offering of any other insurance.

Section 438.108

In § 447.53(e), we now prohibit providers from denying care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

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Section 438.110

We have moved the provisions related to assurances of adequate capacity and services to § 438.207.

Section 438.114

We have removed the definitions of *emergency medical condition, emergency services,* and *post-stabilization services* and included cross references to the definitions of the same terms in the regulations governing the Medicare+Choice program. We have revised paragraph (c) to provide that the following entities are responsible for coverage and payment of emergency services and post-stabilization services:

- The MCO
- The primary care case manager that has a risk contract
- The State, in the case of a primary care case manager that has a fee-for-service contract.

In paragraph (d), we clarify the specific rules governing coverage and payment for emergency services. We revised paragraph (e) to provide for additional rules that govern emergency services. First, the entity responsible for payment may not limit what constitutes an emergency medical condition based on lists of particular diagnoses or symptoms and it may not refuse to process a claim because it does not contain the primary care provider's authorization number. Second, once a qualified provider determines that an enrollee has an emergency medical condition, the enrollee may not be held liable for subsequent screening and treatment needed to diagnose the specific condition, or stabilize the patient. Third, the attending emergency physician or the provider actually treating the enrollee is responsible for determining when the enrollee is sufficiently stabilized, and that determination is binding on the entities responsible for payment.

We have also revised paragraph (f) to require post-stabilization services to be covered and paid for as provided in the regulations governing the Medicare+Choice program (§ 422.113). We explain that, in applying the Medicare+Choice provisions, reference to "M+C" organization" must be read as reference to the entity responsible for Medicaid payment, as specified in paragraph (c) of this section.

Subpart D—Quality Assessment and Performance Improvement

Note: In the proposed rule, this subpart was subpart E, and the sections were numbered as §§ 438.300 to 438.342. In this final rule, this subpart has been relocated as Subpart D and the sections are numbered as §§ 438.200 to 438.242. Sections referenced herein use the §§ 438.200 to 438.242 numbering of the final rule.

Section 438.202 State responsibilities

In paragraph (b) we require each State contracting with an MCO or PHP to document its quality strategy in writing. In paragraph (c) we require each State to provide for the input of recipients and other stakeholders in the development of the quality strategy, including making the strategy available for public comment before adopting it in final. In paragraph (e) we require the State to update the strategy. In paragraph (f) we require each State to submit to HCFA a copy of the initial strategy and a copy of the revised strategy whenever significant changes are made. In addition, we require the State to submit to HCFA regular reports on the implementation and effectiveness of the strategy.

Section 438.204 Elements of State Strategies

We have revised paragraph (b) to require that the State quality strategy must include procedures for identifying enrollees with special health care needs and assessing the quality and appropriateness of care furnished to those enrollees. We included a new paragraph (c) to require the State quality strategy to incorporate performance measures and levels prescribed by HCFA.

Section 438.206 Availability of Services

We have revised paragraph (d) to clarify that the State must ensure that when each MCO and PHP establishes and maintains its network of providers, each MCO and PHP considers the anticipated enrollment, with particular attention to pregnant women, children, and persons with special health care needs. We have also clarified that each MCO and PHP must consider the training and experience of providers when establishing and maintaining its provider network. In subparagraph (d)(3), we have included a new requirement for MCO and PHP networks (consistent with the scope of the PHP's contracted services) to provide for a second opinion from a qualified health care professional within the network or otherwise arrange for the enrollee to obtain one outside the network at no cost to the enrollee if an additional professional is not currently available within the network. In subparagraph (d)(5) we have added a new requirement that the MCO or PHP must permit an enrollee to access out-of-network providers to receive medical services, if the MCO's or PHP's network is unable to provide the necessary medical services, for as long as the MCO or PHP is unable to provide the services. We have added a new requirement at subparagraph (d)(7) requiring an MCO or PHP to ensure that its providers do not discriminate against Medicaid enrollees. At subparagraph (d)(8) we have added a new requirement that requires the MCO or PHP to require out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensure that the cost to the enrollee is no greater than it would be if the services were furnished within the network. We have moved requirements that MCOs and PHPs must ensure that provider hours of operation are convenient for the enrollees from subparagraph (d)(6) to subparagraph (e)(1)(ii), and have added a requirement that convenience be determined by a State-established methodology, and at least comparable to Medicaid fee-for-service. We have also moved the requirement that services must be available 24 hours a day, 7 days a week, when medically necessary from subparagraph (d)(5) to (e)(1)(iii).

We have moved the requirements relating to initial assessment from this section to § 438.208.

Section 438.207 Assurances of Adequate Capacity and Services

We have created this new section which relocates and adds to the requirements regarding assurances of adequate capacity and services previously located at § 438.110. We have revised paragraph (a) to provide that each MCO and PHP must give assurances to the State (in the NPRM the MCO was to also give assurance to HCFA) that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart. In paragraph (b), we have required that each MCO and PHP must submit specific documentation that must be in a format specified by the State and acceptable to the HCFA. In subparagraph (b)(4), we have added requirements that each MCO and PHP must document that it has policies and practices in place to address situations in which there is unanticipated need for providers with particular types of experience or unanticipated limitation of the availability of such providers. We revised paragraph (c) to require the submission of the assurance documentation at least once a year as opposed to every two years as stated in the proposed rule. We also added in paragraph (c) circumstances which we believe constitute a significant change in the MCO's or PHP's operation and which would require the MCO or PHP to resubmit assurances documenting adequate capacity and services. These are: (1) A significant change in the MCO's or PHP's services or benefits; (2) an expansion or reduction of the MCO's or PHP's geographic service area; (3) the enrollment of a new population in the MCO or PHP; and (4) a significant change in the MCO or PHP rates. We also revised paragraph (d) to provide that after the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206. We have added a new paragraph (e) to provide that the State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

Section 438.208 Coordination and Continuity of Care

We have made significant changes to the content and organization of this section. As a part of those changes, we have moved section 438.306(e)(2) and (3) pertaining to initial assessment, and pregnancy and complex and serious medical conditions, to this section. We have clarified that the words "initial assessment" used in the proposed rule are actually two different functions: screening and assessment. We have also replaced the words "persons with serious and complex medical conditions" with the words "persons with special health care needs." In new paragraph (a) we have clarified that the State needs to determine the extent to which requirements pertaining to initial and ongoing screenings and assessments, and primary care are appropriate requirements for PHPs based on the scope of the PHP's services, and the way the State has organized the delivery of managed care services. New paragraph (b) requires the State to implement mechanisms to identify to the MCO and PHP upon enrollment, the following groups:

- Enrollees at risk of having special health care needs, including —
  - ++Children and adults who are receiving SSI benefits;
  - ++Children in Title IV-E foster care;
  - ++Enrollees over the age of 65;
  - ++Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories; and
  - ++Any other category of recipients identified by HCFA
- Other enrollees known to be pregnant or to have special health care needs
- Children under the age of 2

We have revised paragraph (d) to clarify and expand upon MCO and PHP responsibilities for screening and assessment. In subparagraph (d)(1)(i), we require that for enrollees identified by the State as being at risk of having special health care needs, the MCO (and PHP as determined appropriate by the State) must make a best effort attempt to perform a screening within 30 days of receiving the identification from the State. For any enrollee that the screening identifies as being pregnant or having special health care needs, the MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph(d)(2), we require that for enrollees under the age of two or other enrollees known by the State to be pregnant or to have special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (d)(3), we require that for all other enrollees, each MCO (and PHP as determined appropriate by the State) must screen them within 90 days from the date of enrollment. For any enrollee that the screening identifies as being pregnant or having special health care needs, each MCO (and PHP as determined appropriate by the State) must perform a comprehensive assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

We have also added a requirement in subparagraph (e) for MCOs (and PHPs as determined appropriate by the State) to implement mechanisms to identify enrollees who develop special health care needs after enrollment in the MCO or PHP and perform comprehensive assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

In subparagraph (f), we have revised the requirements relating to treatment plans. We require that each MCO and PHP must implement a treatment plan for pregnant women and for enrollees determined to have special health care needs. The treatment plan must —

- Be appropriate to the conditions and needs identified and assessed;
- Be for a specific period of time and periodically updated;
- Specify a standing referral or an adequate number of direct access visits to specialists;
- Ensure adequate coordination of care among providers;
- Be developed with enrollee participation; and
- Ensure periodic reassessment of each enrollee as his or her health requires.

In subparagraph (g), we clarify that MCOs and PHPs must use appropriate health care professionals to perform any comprehensive assessments required by this section and develop and implement any treatment plans required by this section. In paragraph (h) and subparagraph (h)(1), we have revised the requirements relating to primary care and over-all coordination to clarify that the MCO (and PHP as determined appropriate by the State) must have a coordination program that meets State requirements and ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care furnished to the enrollee. In subparagraph (h)(2) we require the MCO or PHP to coordinate the services it furnishes to the enrollee with the services the enrollee receives from any other MCOs or PHPs. In addition, subparagraph (h)(3) requires the MCO's or PHP's coordination program to ensure that the results of its screening and assessment of an enrollee is shared with the other entities serving the enrollee, so that those entities need not duplicate the screening or assessment. Subparagraph (h)(4) requires that in the process of coordinating care, the MCO or PHP ensures that each enrollee's privacy is protected consistent with confidentiality requirements at § 438.224. Subparagraph (h)(5) requires MCOs and PHPs to ensure that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

In subparagraph (h)(6), we require each MCO and PHP to have in effect procedures to address factors that hinder enrollee adherence to prescribed treatments or regimens. In subparagraph (h)(7), we require the MCO to ensure that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality requirements in § 438.224 and the information system requirements of § 438.242.

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Section 438.210 Coverage and Authorization of Services

We have revised paragraph (a) to clarify the contract requirements relating to coverage of services. In subparagraph (a)(1), we require that each contract identify, define and specify each service that the MCO or PHP is required to offer. In subparagraph (a)(2), we require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that are specified in the State plan and can reasonably be expected to achieve the purpose for which the services are furnished. Subparagraph (a)(3) specifies that the MCO or PHP may not arbitrarily deny or reduce the amount, duration, or scope of a required services solely because of the diagnosis, type of illness, or condition and that the MCO or PHP may place appropriate limits on a service on the basis of criteria such as medical necessity or for the purposes of utilization control (provided the services furnished can reasonably be expected to achieve their purpose).

In subparagraph (a)(4), we require the contract to specify what constitutes medically necessary services in a manner that is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State plan, and other State policy and procedures. The contract must specify the extent to which "medically necessary services" includes services to prevent, diagnose, treat, or cure health impairments, enable the enrollee to achieve age-appropriate growth and development, and enable the enrollee to attain, maintain, or regain functional capacity. Subparagraph (a)(5) requires the MCO or PHP to furnish services in accordance with their contract specifications.

We have revised paragraph (b) to specify that with respect to the processing of requests for initial and continuing authorization of services, each contract must not have information requirements that are unnecessary or unduly burdensome for the provider or the enrollee. We have also included a requirement that any decision to deny a service authorization request or to authorize service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in the field of medicine that encompasses the enrollee's condition or disease.

We have revised paragraph (c) to clarify that each contract must provide for the MCO or PHP to notify the requesting provider and give the enrollee written notice of any decision to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. We also clarify that the notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

We have revised the time frames for expedited service authorization decisions. In paragraph (e), we require that under specific circumstances, the contract must provide for the MCO or PHP to make a decision as expeditiously as the enrollee's health condition requires but not later than 72 hours after receipt of the request for service.

Section 438.214 Provider Selection

We have changed the name of this section from "establishment of provider networks" to "provider selection." We have reorganized this section to clarify the requirements that apply to licensed independent providers (for example, physicians) and other providers. In subparagraph (b)(3), we have created an exception that applies to providers who are permitted to furnish services only under the direct supervision of a physician or other provider and hospital-based providers who provide services only incident to hospital services. The latter exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network. In subparagraph (b)(4) we have added requirements that the initial credentialling application be dated and signed and that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information. We have added a new requirement in paragraph (d) that specifies that MCOs and PHPs may not employ or contract with providers excluded from participation in Federal health care programs. In addition, we state in paragraph (e) that each MCO and PHP must comply with any additional requirements established by the State.

Section 438.218 Enrollee Information

We have moved the provisions from this section to § 438.10 and clarified that the information requirements that States must meet under § 438.10 constitute part of the State's quality strategy.

Section 438.320 Enrollee Rights

We have moved the requirements regarding enrollee rights to § 438.100.

Section 438.224 Confidentiality and Accuracy of Enrollee Records

We have changed the name of this section from "confidentiality" to "confidentiality and accuracy of enrollee records." We have also reorganized this section to clarify the requirements that apply to MCOs and PHPs. We clarify that this section applies to medical records and any other health and enrollment information maintained with respect to enrollees. In paragraph (c) we require MCOs and PHPs to establish and implement procedures that specify for what purposes the MCO or PHP uses the information and to which entities outside the MCO or PHP (and for what purposes) it discloses the information. In paragraph (d), we clarify that MCO and PHP procedures must safeguard the confidentiality of any information (in *any* form) that identifies a particular enrollee. We have revised the requirements of paragraph (e) to provide that MCO and PHP procedures must ensure that originals of medical records are released only in accordance with Federal and State law. We have also revised the requirements for access in paragraph (f) to require that, consistent with applicable Federal and State law, MCO and PHP procedures must ensure that each enrollee may request and receive a copy of his or her records and information and added a requirement that the enrollee may request that they be amended or corrected.

Section 438.228 Grievance Systems

We have added to this section two new paragraphs. Paragraph (b) requires that if the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each MCO and PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner. Paragraph (c) requires the State to establish a process to review, upon request by the enrollee, quality of care grievances not resolved by the MCO or PHP to the satisfaction of the enrollee.

Section 438.230 Subcontractual Relationships and Delegations

We have revised subparagraph (b)(3) to require each MCO and PHP to formally review its subcontractors' performances according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations. In the proposed rule this formal review was to be carried out at least once a year. We have included a new requirement in subparagraph (b)(5) that, consistent with the requirements in §§ 438.604 and 438.606 pertaining to submission of certain data by the MCO and PHP that must be certified, each MCO and PHP must require subcontractors to provide certifications with respect to the performance of their duties under the contract and submissions that may be related to State payments.

Section 438.236 Practice Guidelines

We have revised the requirements in paragraph (b) to clarify that each MCO and PHP must adopt (as opposed to develop) practice guidelines. We have further revised the regulation to require that the guidelines—

- Are based, in part, on valid and reliable clinical evidence as opposed to "reasonable medical evidence"; and
- Are reviewed and updated periodically as appropriate.

We include an example of practice guidelines that satisfy the requirements of this section (The Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection).

In paragraph (c), we clarify the dissemination requirements by specifying that each MCO and PHP must disseminate the guidelines to affected providers, and upon request to enrollees and potential enrollees.

Section 438.240 Quality Assessment and Performance Improvement Program

We have added additional provisions and made clarifications to this section. We have added in paragraph (a) a provision that HCFA may specify standardized quality measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs. We have added as subparagraph (b)(4) a provision that the State must require each MCO and PHP to have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs. We have revised subparagraph (c)(1) to clarify that each MCO and PHP must measure its performance annually. We have added in subparagraph (c)(2) a new requirement that the State must, in establishing minimum performance levels for MCOs and PHPs, include any minimum performance levels specified by HCFA.

In subparagraph (d)(2) we clarified that each performance improvement project must represent the entire Medicaid enrolled population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant. In subparagraph (d)(3), we have clarified that the State is to ensure that each MCO and PHP initiates each year one or more performance improvement projects. In subparagraph (d)(4), we have added "cultural competence" as a required non-clinical area for MCO and PHP performance improvement projects.

Section 438.242 Health Information Systems

In paragraph (a) we have deleted the requirement that MCO and PHP health information systems should provide information on MCO or PHP solvency. In paragraph (a) we also have clarified that information on Medicaid enrollee disenrollments pertains to disenrollments for other than loss of Medicaid eligibility.

Subpart F—Grievance System

Section 438.400

We have revised the terms used in this section, using "grievance and appeal" to replace "complaint and grievance". We have added a definition of "action" and of "quality of care grievance". We have also defined what constitutes an action.

Section 438.402

We have revised this section to include filing requirements as well as general requirements. In the general requirements in paragraph (b), we add that grievances and appeals must be accepted from the representative of the enrollee as well as from the enrollee; that the enrollee or his or her representative is to receive required notices and information; that the MCO or PHP must ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal; that at the enrollee's request, the MCO or PHP must refer to the State quality of care grievances not resolved to the satisfaction of the enrollee, and the MCO or PHP must require providers to give notice to enrollees of actions. Under the filing requirements in paragraph (c) we add that a provider may file an appeal on behalf of an enrollee with the enrollee's written consent. We clarify that an enrollee has a reasonable time specified by the State, not to exceed 90 days, to file an appeal after the date of an action. We also provide that a appeal may be filed either orally or in writing but that an oral request for standard resolution of the appeal must be followed by a written request. We specify that notice of action for failure to furnish or arrange for a service or provide payment in a timely manner must be provided whenever the entity has delayed access to the service to the point when there is substantial risk that further delay will adversely affect the enrollee's heart condition.

Section 438.404

We have revised paragraph (a) to provide that the notice of action must be in writing and must meet the language and format requirements of § 438.10. In paragraph (b), we specify what must be contained in the notice of action. In this paragraph we have added that the notice must include information on the circumstances under which the enrollee may be required to pay for the costs of services furnished while the appeal is pending and how the enrolees may decline amortization of benefits; that the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson; and that filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee. In paragraph (c), we refer to § 438.210 for the time frames that apply to mailing the notice. In paragraph (d), we specify certain notice requirements for subcontractors or providers who are not employees to furnish a notice of action. We also moved to § 438.406 the provision on the right of the enrollee to appear before the MCO or PHP in person and removed the provision that the appearance must be before the person assigned to resolve the grievance.

Section 438.406

We have revised paragraph (a) to clarify that each MCO or PHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps, including providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability. We also require the MCO or PHP to ensure that the enrollee's communication is correctly classified as a "grievance" or an "appeal", that each communication is transmitted timely to staff who have the authority to act upon it, and that it is investigated and disposed of or resolved as required. We expanded the provision in the proposed rule concerning the types of appeals that must be decided by a health care professional to include, in addition to denials based on lack of medical necessity, all grievances and appeals that involve clinical issues and grievances regarding a denial to expedite resolution of an appeal. We also clarify that a health care

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professional with appropriate clinical expertise, not only a physician, can serve as the decision maker. In paragraph (b), we have included several additional requirements that apply only to appeals, including that the timeframes for resolution of appeals must take account of the enrollee's health condition, that the enrollee and his or her representative have the opportunity to examine the enrollee's case file, and that the enrollee and his or her representative are parties to the appeal.

Section 438.408

In paragraph (a), we added a basic rule that an MCO or PHP must dispose of grievances and resolve appeals as expeditiously as the enrollee's health condition requires within State-established timeframes not exceeding the timeframes specified in this section. We have included in paragraph (b) the provision in paragraph (a)(4) of the proposed rule regarding the basis for decisions. In paragraph (c) we specify the timeframes for disposing of grievances and resolving appeals. We have added timeframes for disposing of grievances, specifying that grievances of a denial of a request to expedite resolution of an appeal must be disposed of within 72 hours of receipt of the grievance. We also added a provision that all other grievances must be disposed of within 90 days. We continue to provide for a 30-day timeframe for resolving appeals that are not expedited. In paragraph (d) we address extensions of timeframes for decisions. In the final rule we eliminated the authority of the MCO or PHP to grant itself an extension when an appeal is expedited. In the final rule we have added a provision that when an MCO or PHP grants itself an extension of the timeframe for decision of an appeal that is not expedited, the enrollee must be given written notice of the reason for the delay and of the enrollee's right to file a grievance with the decision. We added in the final rule the provision in paragraph (e) that the enrollee must be given written notice of the disposition of all grievances filed in writing and of all quality of care grievances. Oral notices can be provided to enrollees who file oral grievances not related to quality of care, unless the enrollee requests a written notice. In paragraph (f) we have added to the final rule that the notice on disposition of a quality of care grievance must include information that the enrollee has the right to seek further review by the State, and how to request it. In paragraph (h) we have revised the requirement of the proposed regulation that the notice of an appeal resolution must include the name of the MCO or PHP contact and now specify that the title of the contact, not the name, must be included. In paragraph (h) we add a requirement that the MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient. In paragraph (i) of the final rule we specify that expedited appeals not wholly favorable to the enrollee must be submitted to the State. In paragraph (j) we provide that the timeframe for fair hearing decision is 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. The time used by the beneficiary to file for a State fair hearing does not count toward the 90 days. We have added a provision stating that the parties to a State fair hearing are the enrollee and his or er representative, or the representative of the deceased enrollee's estate. Finally, we add that for appeals of service authorization denials that meet the criteria for expedited resolution, the State fair hearing decision must be within 72 hours of receipt of the file.

Section 438.410

In paragraph (a), we retain the requirement from the proposed rule that each MCO and PHP must establish and maintain an expedited review process for grievances and appeals. In paragraph (b), we add to the final rule a requirement for expedited review of certain grievances. In paragraph (c), we describe the requirements that apply to appeals. In the proposed rule we provided for expedited resolution of appeal if non-expedited resolution would jeopardize the enrollee's life or health or the enrollee's ability to regain maximum function. In the final rule we add "attain and maintain" maximum function. In paragraph (d), we specify the steps that the MCO or PHP must take if it denies a request for expedited resolution of an appeal. In the final rule we require that the enrollee be notified of the decision within two calendar days. The proposed rule specified the timeframe as two working days. We also specify in the final rule that if the enroll resubmits the request for expedited resolution with a provider's letter of support, the resolution of the appeal will be expedited.

Section 438.414

In this section on information about the grievance system, in the final rule we differentiate between information that must be available with respect to fair hearings from that with respect to grievances and appeals. We added to the required items information about the right of the enrollee to represent himself or herself or to be represented by legal counsel, a friend or relative, or other spokesperson. We also added that information be provided on the fact that benefits will be continued if requested by an enrollee who files an appeal or requests for fair hearing and that the enrollee may be required to pay the cost of services while an appeal is pending if the final decision is adverse to the enrollee. In the proposed rule we provided that benefits would continue only if requested by the enrollee.

Section 438.416

We have added to the reporting requirements that grievances and appeals be tracked according to whether the disposition and resolution was standard or expedited and that a record must be maintained of when grievances and appeals were acknowledged and provide that . We have deleted the requirement to record disenrollments and that the summary submitted to the State include trends by particular providers or services.

Section 438.420

We have revised the provision that for services to be continued they must have been ordered by the MCO or PHP treating physician or another MCO or PHP physician and that the physician is authorized to order services under the MCO or PHP contract. The new requirement is that the services must have been ordered by an authorized provider. The final rule adds in paragraph (d) specifications for the duration of continued or reinstated benefits.

Section 438.421

We have removed this section and moved the provisions relating to effectuation of reversed appeal resolutions from this section to § 438.424.

Section 438.422

We have removed this section and moved the provisions relating to monitoring of the grievance and appeal system from this section to § 438.426.

Section 438.424

We have removed the 30-calendar day and 60-calendar day time periods for providing services originally denied but authorized through an appeal or fair hearing, respectively. We retain as the sole time determinate that the service must be provided as expeditiously as the enrollee's health condition requires. We also add to the final rule a provision that services denied during appeal that were received and are subsequently

authorized must be paid for by the MCO, PHP, or the State, to State policy and regulations.

Section 438.426

We have added this new section and moved the requirements relating to monitoring of the grievance and appeal system from § 438.422 to this section. We also provide in this section that if the summaries of grievances and appeals reveal a need for changing the system, the MCO or PHP must conduct an in-depth review and take corrective action.

Subpart H—Certifications and Program Integrity Protections

Section 438.602

We have revised the name and content of this section to address the basic rule that as a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO and its subcontractors must comply with the certification and program integrity requirements of this subpart.

Section 438.604

We have added this new section to identify the types of data that must be certified. In paragraph (a), we require that when State payments to the MCO is based on data submitted by the MCO, including, but not limited to, enrollment information, encounter data, and other information required by the State, including data in contracts, proposals and other related documents, the State must require certification of the data as provided in § 438.606. In paragraph (b), we require that the certification must ensure that the MCO is in substantial compliance with the terms of the contract, and must be as provided in § 438.606, regardless of whether or not payment is based on data. In paragraph (c), we provide that certification is required for all documents specified by the State.

Section 438.606

We have revised the name and content of this section to address the source, content and timing of certification. In paragraph (a), we provide that subcontractors must certify data that they submit to the MCO and that the MCO certify the data that it submits to the State. One of the following individuals must certify the MCOs data:

- The MCO's Chief Executive Officer (CEO)
- The MCO's Chief Financial Officer (CFO)
- An individual who has delegated authority to sign for, and who reports directly to, the MCO's CEO or CFO.

In paragraph (b), in the case of data and/or other documents specified by the State, we require that the certification must attest to the accuracy, completeness, and truthfulness of the data/documents, based on best knowledge, information, and belief. In paragraph (b), in the case of certification of contract compliance, we require that the MCO attest based on best knowledge, information, and belief that they are in substantial compliance with their contract. In paragraph (c), we require the MCO to submit the certification concurrently with the certified data. In paragraph (c), we require that the MCO submit the certification of substantial compliance when requesting payment.

Section 438.608

We have revised the name and content of this section to include the program integrity requirements. In paragraph (a), we specify that the general rule is that the MCO must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse. In paragraph (b), we describe the specific requirements that apply to the administrative and management arrangements or procedures, which include:

- Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.
- The designation of a compliance officer and a compliance committee that are accountable to senior management.
- Effective training and education for the compliance officer and the organization's employees.
- Effective lines of communication between the compliance officer and the organization's employees.
- Enforcement of standards through well-publicized disciplinary guidelines.
- Provision of internal monitoring and auditing.
- Provision for prompt response to detected offenses and development of corrective action initiatives relating to the MCO's contract, including specific reporting requirements.

Subpart I—Sanctions

Section 438.700

We have revised paragraph (a) to clarify that States that contract with either MCOs or PHPs must establish intermediate sanctions. We have added a sentence to paragraph (a) specifying that a State's determination may be based on findings from onsite surveys, enrollee or other complaints, financial audits, or any other means. In paragraph (c) we clarify that the intermediate sanctions may be imposed if the State determines that the MCO or PHP distributes directly, or indirectly through any agent or independent contract, marketing materials that have not been approved by the State or that contain false or materially misleading information.

We have moved the requirements that were previously in § 438.702(b) to this section for clarity. In the new paragraph (d) we provide that the intermediate sanctions described in § 438.702(a)(4) and (a)(5) may be imposed if the State determines that an MCO or PHP violates any of the requirements in section 1903(m) of the Act or an MCO or PHP violates any of the requirements of section 1932 of the Act.

Section 438.702

We have revised subparagraph (a)(4) to provide that the State may impose an intermediate sanction that suspends all new enrollment, including default enrollment, after the effective date of the sanction. We have revised subparagraph (a)(5) to provide that the State may suspend payment for recipients enrolled after the effective date of the sanction. We have revised paragraph (b) to specify that State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance.

Section 438.704

We have revised subparagraph (b)(3) to clarify that the penalty is subject to the overall limit of $100,000 under subparagraph (b)(2). We have also revised subparagraph (b)(4) to clarify that the limit on the penalty is greater of double the amount of the excess charge or $25,000.

Section 438.706

We have revised paragraph (a) to clarify that the State may impose the sanction of temporary management under certain circumstances. We also removed a reference to § 434.67. We have moved the requirements that were previously in § 438.708 to paragraph (b) of this section. That paragraph provides that the State must impose the sanction of temporary management if it finds that an MCO or PHP has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. In addition, the State must also grant enrollees the right to terminate enrollment without cause. In

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paragraph (c) we specify that the State may not delay imposition of temporary management to carry out due process procedures and may not provide a hearing before imposing this sanction.

Section 438.708

We have revised the name and content of this section to include the requirements relating to termination of an MCO or PHP contract that were previously in § 438.718. We have moved the requirements relating to mandatory imposition of the sanction of temporary management from this section to § 438.706. We have revised terminology in paragraph (a) from "substantially" to "substantive."

Section 438.710

We have revised the name and content of this section to include the requirements relating pre-termination hearing that were previously in § 438.720. We have revised paragraph (b) by removing the required time frames. Paragraph (b)(2) provides that prior to a pre-termination hearing, the State must give the MCO or PHP written notice of its intent to terminate, the reason for termination, and the time and place of the hearing. In addition, after the hearing, the State must give the MCO or PHP written notice of the decision affirming or reversing the proposed termination and, for an affirming decision, the effective date of termination. We have added a statement at paragraph (b)(2)(iii) that for an affirming decision, the State must give enrollees of the MCO or PHP notice of the termination along with information on their options for receiving care following the effective date of termination.

Section 438.718

We have removed this section and moved the requirements relating to termination of an MCE contract to § 438.708.

Section 438.720

We have removed this section and moved the requirements relating to pre-termination hearing to § 438.710.

Section 438.724

We have revised the name and content of this section to by removing the requirements for providing notice to HCFA of sanctions and by including new requirements for providing public notice of sanctions. In paragraph (a), we provide that the State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty. In paragraph (b), we require the State to publish the notice no later than 30 days after it imposes the sanction. The notice must be a public announcement in either the newspaper of widest circulation in each city within the MCO's or PHP's service area that has a population of 50,000 or more or the newspaper of widest circulation in the MCO's or PHP's service area, if there is no city with a population of 50,000 or more in that area.

Section 438.726

We have added this new section to include the requirement that was previously in § 438.730(g). We require that the State plan must provide for the State to monitor for violation that involve the actions and failures to act specified in this section and to implement the provisions of this section.

Section 438.730

We have revised paragraph (a) to provide that a State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6). Under paragraph (b), we have clarified that if HCFA accepts a State's recommendation, HCFA must convey the determination to the OIG for consideration of possible imposition of civil money penalties under section 1902(m)(5)(A) of the Act and part 1003 of this title. We also explain that, in accordance with the provisions of part 10003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

Section 438.802

We have revised paragraph (b) to provide that FFP is available under an MCO or PHP contract only for periods during which the MCO or PHP and its subcontractors are in substantial compliance with the physician incentive plan requirements and the MCO or PHP and the State are in substantial compliance with the requirements of the MCO or PHP contract and of this part.

Section 438.810

We moved the definitions of *choice counseling, enrollment activities, and enrollment broker* from § 438.104 to paragraph (a) of this section. We have also included a new definition of *enrollment services*, which means choice counseling, enrollment activities, or both. We have revised paragraph (b) to include the conditions that enrollment brokers must meet so that State expenditures for their use qualify for FFP. In subparagraph (b)(1), we require that the broker and its subcontractors are independent of any managed care entity or health care provider in the State in which they provide enrollment services. We clarify that a broker or subcontractor is not considered "independent" if it is, is owned by, or owns any MCO, PHP, PCCM or other health care provider in the State in which it provides enrollment services. In subparagraph (b)(2), we require that the broker and its subcontractors be free from conflict of interest.

Section 438.814

We have added this new section to prohibit FFP for payments in accordance with risk corridors or incentive arrangements to the extent that these arrangements result in payments that exceed 105% of the approved capitation rates, for the services or enrollees covered by the risk corridor or incentive arrangement.

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 447.361

This section, which contained the upper payment limit for risk contracts, has been deleted and replaced by expanded requirements for actuarial soundness of capitation rates in new § 438.6(c).

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

Section 447.361

This section, which contained the upper payment limit for risk contracts, has been deleted and replaced by expanded requirements for actuarial soundness of capitation rates in new § 438.6(c).

Part 447—Payments for Services

Section 447.53

We have revised paragraph (e) to specify that no provider may deny care or services to an individual eligible for the care or services on account of the individual's inability to pay the cost sharing.

VIII. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule meets the criteria of being economically significant because the impact will be over $100 million.

The RFA requires agencies to analyze options for regulatory relief of small entities. This rule implements Medicaid managed care provisions as directed by BBA. The statute does not permit significant alternatives to regulation; however, we have considered ways to reduce burden on small entities.

This final rule with comment period primarily impacts beneficiaries, State Medicaid agencies, enrollment brokers, MCOs, PHPs, and PCCMs. Small entities include small businesses, nonprofit organizations, and other entities that have annual revenues of $5 million or less. Individuals and State governments are not included in this definition. Thus, most of the entities impacted by this regulation do not qualify as small entities. Individual PCCMs and a limited number of small PHPs would be considered small entities for purposes of this regulation.

In publishing this final rule with comment period, we considered regulatory alternatives that would reduce the burden on small entities. Thus, we have decided against imposing additional requirements on PCCMs beyond those specified in the BBA. We also have not applied all MCO requirements to all PHPs. For example, the advance directives requirements do not apply to PHPs that only cover dental or nonclinical services. In addition, PHPs are only required to comply with quality assessment and performance improvement provisions to the extent that they apply services actually provided by the PHP.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

We do not anticipate that the provisions in this final rule with comment period will have a substantial economic impact on most hospitals, including small rural hospitals. The BBA provisions include some new requirements on States, MCOs, and PHPs, but no new direct requirements on individual hospitals. The impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs and PHPs. Furthermore, the impact will also vary according to each hospital's current procedures and level of compliance with existing law and regulation pertaining to Medicaid managed care. For these reasons, this final rule is not expected to have a significant impact on the operations of a substantial number of hospitals.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100 million or more.

B. Summary of the Final Rule

This rule implements the Medicaid provisions as directed by the BBA. The primary objectives of these provisions are to allow for greater flexibility for State agencies to participate in Medicaid managed care programs and provide greater beneficiary protections and quality assurance standards. The regulation addresses pertinent areas of concern between States and MCOs, PHPs, and PCCMs, including enrollment, access to care, provider network adequacy, and grievance and appeal procedures for beneficiaries.

Specific provisions of the regulation include the following:

- Permitting States to require in their State plan that Medicaid beneficiaries be enrolled in managed care.
- Eliminating the requirement that no more than 75 percent of enrollees in an MCO or PHP be Medicaid or Medicare enrollees.
- Specifying a grievance and appeal procedure for MCO and PHP enrollees.
- Providing for the types of information that must be given to enrollees and potential enrollees, including language and format requirements.
- Requiring that MCOs and PHPs document for the States that they have adequate capacity to serve their enrollees and that States certify this to HCFA.
- Specifying quality standards for States and MCOs and PHPs.
- Increasing program integrity protections and requiring certification of data by MCOs and PHPs.
- Increasing the threshold for prior approval of MCO and PHP contracts from $100,000 to $1 million.
- Permitting cost sharing for managed care enrollees under the same circumstances as permitted in fee-for-service.
- Expanding the managed care population for which States can provide 6 months of guaranteed eligibility.
- Revising the rules for setting capitation rates.

It would be extremely difficult to accurately quantify the overall impact of this regulation on States, MCOs, PHPs, and PCCMs because there is enormous variation among States and these entities regarding their current regulatory and contract requirements, as well as organizational structure and capacity. Any generalization would mask important variations in the impact by State or managed care program type. The Lewin Group, under a contract with the Center for Health Care Strategies, recently completed a study to measure the cost impact of the proposed regulation. The study is the best information we currently have available on the potential incremental impact of the proposed regulation. Further, the study does not include an analysis of the proposed regulation in total, as it only focused on four areas within the proposed regulation: individual treatment plans, initial health assessments, quality improvement porgrams and grievance systems/State fair hearings. While the study's focus is on some of the proposed regulation provisions, of which many have changed, we believe that the overall cost conclusions are relevant to this final rule. In addition to examining the four regulatory requirements, they cited the

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need to evaluate the incremental and aggregate effects of the rule; different managed care models (for example, overall enrollment; the Medicare, commercial, and Medicaid mix; geographic location); and State regulatory requirements (for example, State patient rights laws, regulation of noninsurance entities). The Lewin report also points out that many of the BBA provisions were implemented through previous guidance to the States, so the regulatory impact only captures a subset of the actual impact of the totality of BBA requirements.

According to the MCOs included in Lewin's study, many of the proposed provisions are not expected to have large incremental costs. The study mainly focused on the assessment and treatment management components of the regulation, as well as the quality improvement projects. For example, they estimate the incremental cost of an initial assessment (called screening in the final regulation) as ranging from $0.17 to $0.26 per member per month (PMPM), but for an MCO that currently performs an initial assessment, the incremental cost is estimated as $0.03 to $0.06 PMPM. Similarly, the costs of quality improvement projects can vary from $60,000 to $100,000 in the first year (start-up), $80,000 to $100,000 in the second and third years (the intervention and improvement measurement cycle), and $40,000 to $50,000 for the forth and subsequent years (ongoing performance measurement).

In summary, according to the Lewin Study, States and their contracting managed care plans have already implemented many provisions of the BBA. While there are incremental costs associated with the proposed and final regulatory requirements, they will vary widely based on characteristics of individual managed care plans and States. Finally, the BBA requirements are being implemented in an increasingly regulatory environment. Therefore, States, MCOs, and PHPs will likely face additional costs not related to these regulatory requirements. Thus, the incremental impact of these requirements on costs to be incurred would be difficult if not impossible to project.

We believe that the overall impact of this final rule will be beneficial to Medicaid beneficiaries, MCOs, PHPs, States, and HCFA. Many of the BBA Medicaid managed care requirements merely codify in Federal law standards widely in place in State law or in the managed care industry. Some of the BBA provisions represent new requirements for States, MCOs, PHPs, and PCCMs but also provide expanded opportunities for participation in Medicaid managed care.

It is clear that all State agencies will be affected by this Medicaid regulation but in varying degrees. Much of the burden will be on MCOs, PHPs, and PCCMs contracting with States, but this will also vary by existing and continuing relationships between State agencies and MCOs, PHPs, and PCCMs. This regulation is intended to maximize State flexibility and minimize the compliance cost to States, MCOs, and PHPs to the extent possible consistent with the detailed BBA requirements. We believe the final rule will result in improved patient care outcomes and satisfaction over the long term.

Recognizing that a large number of entities, such as hospitals, State agencies, and MCOs will be affected by the implementation of these statutory provisions, and a substantial number of these entities may be required to make changes in their operations, we have prepared the following analysis. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by both the RFA and RIA.

C. State Options to Use Managed Care

1. Managed Care Organizations

Under this provision, a State agency may amend its State plan to require all Medicaid beneficiaries in the State to enroll in either an MCO or PCCM without the need to apply for a waiver of "freedom of choice" requirements under either section 1915(b) or 1115 of the Act. However, waivers would still be required to include certain exempted populations in mandatory managed care programs, notably SSI populations, American Indians, and other groups of children with special needs. Federal review would be limited to a one-time State Plan Amendment (SPA) approval, while States would no longer need to request waiver renewals every 2 years for section 1915(b) of the Act and 5 years for section 1115 of the Act waivers. State agencies may include "exempted" populations as voluntary enrollees in State plan managed care programs to maintain parallel waiver programs. Currently, four States use SPAs to require beneficiary enrollment in capitated managed care organizations. In short, the new State plan option provides State agencies with a new choice of method to require participation in managed care. MCOs, PHPs, and providers would continue to provide care in a manner consistent with current and future standards, regardless of SPAs, and consequently Medicaid beneficiaries would receive the same level of health care in compliance with current and future standards.

Pursuing the SPA option rather than a section 1915(b) or 1115 of the Act waiver may reduce State administrative procedures because it would eliminate the need for States to go through the waiver renewal process. Likewise, we will benefit from a reduced administrative burden if fewer waiver applications and renewals are requested. However, we believe the overall reduction in burden to both States and to us would be small in relation to the overall administrative requirements of the Medicaid program.

2. Primary Care Case Management

Prior to the BBA, many State agencies elected to implement a PCCM system through a freedom of choice waiver under section 1915(b)(1) of the Act. Under the BBA, States may now require beneficiaries to use a PCCM provider under their State plans without the need for a waiver. As of December 2000, five States have chosen this option. Most State agencies, however, have continued to use waiver authority to require enrollment in PCCMs. Therefore, while the BBA provision provides potential for more PCCM programs to come into being, we do not expect expansion of PCCMs to be substantial due to the State plan option. To the extent that the use of PCCMs increases, patients of these providers will benefit from greater continuity of care and patient protections deriving from new and existing standards.

D. Elimination of 75/5 Rule

Prior to the passage of the BBA, nearly all MCOs and PHPs contracting with Medicaid were required to limit combined Medicare and Medicaid participation to 75 percent of their enrollment, and State agencies had to verify enrollment composition as a contract requirement. Elimination of this rule allows MCOs and PHPs to participate without meeting this requirement and eliminates the need for States to monitor enrollment composition in contracting MCOs and PHPs. This will broaden the number of MCOs and PHPs available to States for contracting, leading to more choice for beneficiaries.

With greater flexibility for State and MCO or PHP participation in managed care, providers can serve more Medicaid beneficiaries under managed care programs. Medicaid managed care enrollees will have better access to care and improved satisfaction.

E. Increased Beneficiary Protection—Grievance Procedures

The BBA requires MCOs to establish internal grievance procedures that permit an eligible enrollee, or a provider on behalf of an enrollee, to challenge the denials of coverage of medical assistance or denials of payment. While these requirements were not previously required by statute, we believe, based on recent State surveys, such as the National Academy for State Health Policy survey of 10 States in 1999, and the American Public Human Services Association survey of 13 States in 1997, that they reflect widespread current practice and, therefore, do not impose significant incremental costs on MCOs, PHPs, or State agencies.

F. Provision of Information

In mandatory managed care programs, we have required that beneficiaries be fully informed of the choices available to them in enrolling with MCOs and PHPs. Section 1932(a)(5) of the Act, enacted in section 4701(a)(5) of the BBA, describes the kind of information that must be made available to Medicaid enrollees and potential enrollees. It also requires that this information, and all enrollment notices and instructional materials related to enrollment in MCOs and PHPs, be in a format that can be easily understood by the individuals to which it is directed. We do not believe that these requirements deviate substantially from current practice. Furthermore, there is no way to quantify the degree of burden on State agencies, MCOs, and PHPs for several reasons. We do not have State-specific data on what information States currently provide, or the manner in which they provide it. Variability among States indicates that implementing or continuing enrollee information requirements will represent different degrees of difficulty and expense.

As a requirement under the provision of information section, State agencies opting to implement mandatory managed care programs under the SPA option are required to provide comparative information on MCOs and PCCMs to potential enrollees. Currently only eight States have exercised the option to use an SPA to require beneficiary enrollment in managed care. However, for States that do select this option, we do not believe that providing the comparative data in itself represents a burden, as these are elements of information that most States currently provide. The regulation specifies that the information must be presented in a comparative or chart-like form that facilitates comparison among MCOs, PHPs, and PCCMs. This may be perceived as a burden to States that have previously provided this information in some other manner; however, it is our belief that even in the absence of the regulation, the trend is for States, and many accreditation bodies such as the National Committee for Quality Assurance (NCQA), to use chart-like formats. Consequently, enrollees will benefit from having better information for selecting MCOs, PHPs, and PCCMs. Only a few States have opted for SPAs so far, but it is anticipated that more States will participate over the long term. States that participate in the future will benefit from any comparative tools developed by other States.

G. Demonstration of Adequate Capacity and Services

The BBA requires Medicaid MCOs to provide the State and the Secretary of HHS with assurances of adequate capacity and services, including service coverage within reasonable time frames. States currently require assurances of adequate capacity and services as part of their existing contractual arrangements with MCOs and PHPs. However, certification of adequacy has not been routinely provided to HCFA in the past. Under this rule, each State retains its authority to establish standards for adequate capacity and services within MCO and PHP contracts. This may be perceived as a burden to MCOs and PHPs, and for States which have to date not been required to formally certify that an MCO or PHP meets the State's capacity and service requirements. However, certification to HCFA will ensure an important beneficiary protection while imposing only a minor burden on States to issue a certification to HCFA.

Quantifying the additional burden on States, MCOs, or PHPs as a result of implementing this regulation is not feasible for several reasons. First, HCFA does not have State-specific data on the types of detailed information States currently require of their MCOs and PHPs to assure adequate capacity and services. Second, we do not have State-specific information on the manner in which State agencies collect and evaluate documentation in this area. Rather, each State agency has its own documentation requirements and its own procedures to assure adequate capacity and services. This regulation contemplates that States continue to have that flexibility.

Under this regulation, State agencies will determine and specify both the detail and type of documentation to be submitted by the MCO or PHP to assure adequate capacity and services and the type of certification to be submitted to us. Accordingly, variability among State agencies implementing this regulation represents different degrees of detail and expense. Regardless of the level of additional burden on MCOs, PHPs, State agencies, and us, Medicaid beneficiaries will receive continued protections in access to health care under both State and Federal law.

H. New Quality Standards

The BBA requires that each State agency have an ongoing quality assessment and improvement strategy for its Medicaid managed care contracting program. The strategy, among other things, must include: (1) standards for access to care so that covered services are available within reasonable time frames and in a manner that ensures continuity of care and adequate capacity of primary care and specialized services providers; (2) examination of other aspects of care and service directly related to quality of care, including grievance procedures, marketing, and information standards; (3) procedures for monitoring and evaluating the quality and appropriateness of care and service to enrollees; and (4) regular and periodic examinations of the scope and content of the State's quality strategy.

The provisions of this regulation establish requirements for State quality strategies and requirements for MCOs and PHPs that States are to incorporate as part of their quality strategy. These MCO and PHP requirements address: (1) MCO and PHP structure and operations; (2) Medicaid enrollees' access to care; and (3) MCO and PHP responsibilities for measuring and improving quality. While these new Medicaid requirements are a significant increase in Medicaid regulatory requirements in comparison to the regulatory requirements that existed before the BBA, we believe the increases are appropriate because many of the requirements are either identical to or consistent with quality requirements placed on MCOs and PHPs by private sector purchasers, the Medicare program, State licensing agencies, and private sector accreditation organizations. While these new requirements also will have implications for State Medicaid agencies that will be responsible for monitoring for compliance with the new requirements, we believe that a number of recent statutory, regulatory, and private sector developments will enable State Medicaid agencies to more easily monitor for compliance than in the past at potentially less cost to the State. First, the BBA also included provisions

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addressing how States are to fulfill the statutory requirement for an annual, external quality review (EQR) of each Medicaid-contracting MCO and PHP. (These provisions are addressed in a separate rulemaking). Prior to the BBA, 75 percent Federal financial participation in the cost of these activities was available to States only if the State used a narrowly defined list of entities to perform the quality review. The BBA opened up the possibility for use of a much wider array of entities to perform this function. Further, in HCFA's proposed rule to implement these EQR provisions published on December 1, 1999, we specified that the 75 percent Federal match would also be available to EQR organizations that performed activities necessary for monitoring compliance with these BBA quality requirements for MCOs and PHPs. The BBA also provided that States could exercise an option whereby MCOs that were accredited by a private accrediting organization under certain conditions could be determined to meet certain of the quality requirements specified in this rule, thereby avoiding costs to the State of directly monitoring for compliance with these requirements. In response to this, private accrediting organizations such as the National Committee for Quality Assurance have developed Medicaid accreditation product lines.

In addition, prior to issuance of the proposed rule, we worked closely with State Technical Advisory Groups (TAGs) in developing the managed care quality regulations and standards. Requirements under this regulation build on a variety of initiatives of State Medicaid agencies and HCFA to promote the assessment and improvement of quality in plans contracting with Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with State and Federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system for Medicare and Medicaid that reduces duplicate or conflicting efforts and emphasizes demonstrable and measurable improvement.
- QARI, serving as a foundation to the development of QISMC, highlights the key elements in the Health Care Quality Improvement System (HCQIS), including internal quality assurance programs, State agency monitoring, and Federal oversight. This guidance emphasizes quality standards developed in conjunction with all system participants, such as managed care contractors, State regulators, Medicaid beneficiaries or their representatives, and external review organizations.

Further, we have built on efforts in other sectors in developing these quality requirements in order to capitalize on current activities and trends in the health care industry. For example, many employers and cooperative purchasing groups and some State agencies already require that organizations be accredited by the National Committee on Quality Assurance (NCQA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Accreditation Healthcare Commission (AAHC), or other independent bodies. Many also require that organizations report their performance using Health Plan Employer Data & Information Set (HEDIS), Foundation for Accountability (FACCT), or other measures and conduct enrollee surveys using the Consumer Assessment of Health Plans Study (CAHPS) or other instruments. NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. Also, States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners (NAIC) has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

While we anticipate that many organizations will need to invest in new staff and information systems in order to perform these new quality improvement activities, it is difficult to quantify these financial and operational "investments," as State agencies, MCOs, and PHPs across the country exhibit varying capabilities in meeting these standards. These new quality requirements will present administrative challenges for some State agencies and MCOs; however, PHPs and States have significant latitude in how these requirements will be implemented. Acknowledging that there likely will be some degree of burden on States, MCOs, and PHPs, we also believe that the long-term benefits of greater accountability and improved quality in care delivery will outweigh the costs of implementing and maintaining these processes over time.

I. Administration

1. Certifications and Program Integrity Protections

BBA sections 1902(a)(4) and (19) require that States conduct appropriate processes and methods to ensure the efficient operation of the health plans. This includes mechanisms to not only safeguard against fraud and abuse but also to ensure accurate reporting of data among health plans, States, and HCFA.

Section 438.602 of the regulation addresses the importance of reliable data that are submitted to States and requires MCOs and PHPs to certify the accuracy of these data to the State. These data include enrollment information, encounter data, or other information that is used for payment determination. For the most part, States reimburse MCOs and PHPs on a capitated basis and do not use claims or encounter data as a basis for payment. However, the collection of encounter, provider, and enrollment data will be most useful for States in measuring quality performance and addressing various methodologies of rate-setting and risk adjustment. The Medicaid provision of attesting to the validity of data presents an additional step in the process of data submission. MCOs and PHPs have historically worked closely with States when reporting Medicaid data in order to affirm that the data are accurate and complete. Submitting a certification of validity could take place in a variety of ways and will represent a varying degree of burden for health plans.

Section 438.606 requires MCOs and PHPs to have effective operational capabilities to guard against fraud and abuse. This will result in reporting violations of law by MCOs and PHPs to the State. Providers and health plans have traditionally ensured compliance with Federal and State laws when providing and delivering health care to members. For example, many health plans comply with standards set by the National Association of Insurance Commissioners (NAIC). However, additional resources and procedures will be necessary to have a systematic process for documenting violations and formally notifying the State of these instances.

The requirement for MCOs and PHPs to certify the accuracy and completeness of provider contracts or other documents is consistent with current practices. These demonstrations are evident in NCQA accreditation procedures, Medicaid waiver reviews, and audits that are necessary for compliance with other relevant State and Federal laws. Depending on the MCO or PHP, new processes may be necessary to comply with this standard. This requirement may not necessarily result in new mechanisms or resources for MCOs and PHPs but may create the need for more coordination with additional State Medicaid Agency representatives in the review of provider contracts.

2. Change in Threshold from $100,000 to $1 Million

Before the passage of the BBA, the Secretary's prior approval was required for all HMO contracts involving expenditures in excess of $100,000. Under the BBA, the threshold amount is increased to $1 million. This change in threshold will have minimal impact on plans currently contracting with State agencies for Medicaid managed care. Currently, only one or two plans in the country have annual Medicaid expenditures of under $1 million. Therefore, this new provision will not affect a significant number of plans or States.

J. Permitting Same Copayments in Managed Care as in FFP

Under section 4708(c) of the BBA, States may now allow copayments for services provided by MCOs and PHPs to the same extent that they allow copayments under fee-for-service. Imposition of copayments in commercial markets typically results in lower utilization of medical services, depending on the magnitude of payments required of the enrollee. Thus, we would normally expect State agencies that implement copayments for MCO or PHP enrollees to realize some savings as a result. However, applying copayments in Medicaid populations may cause States, MCOs, and PHPs to incur overhead costs related to administering these fees that more than offset these savings. This is due to several factors including that copayments are significantly lower for Medicaid beneficiaries than typical commercial copayments, that it is difficult to ensure compliance with these payments, and that collection efforts would be necessary for MCOs or PHPs to obtain all fees due to them. Also, if State agencies take advantage of this option, Medicaid managed care enrollees may defer receipt of health care services and find their health conditions deteriorate such that costs of medical treatment may be greater over the long term. As a result of these variables, it is difficult to predict how many States will take advantage of this new option of permitting copayments for MCO or PHP enrollees.

K. Six-Month Guaranteed Eligibility

The legislation has expanded the States' option to guarantee up to 6 months eligibility in two ways. First, it expands the types of MCOs whose members may have guaranteed eligibility, in that it now includes anyone who is enrolled with a Medicaid managed care organization as defined in section 1903(m)(1)(A) of the Act. Second, it expands the option to include those enrolled with a PCCM as defined in section 1905(t) of the Act. These changes are effective October 1, 1997. To the extent that State agencies choose this option, we expect MCOs, PHPs, and PCCMs in those States to support the use of this provision since it affords health plans with assurance of membership for a specified period of time. Likewise, beneficiaries will gain from this coverage expansion, and continuity of care will be enhanced. The table below displays our estimates of the impact of the expanded option for 6 months of guaranteed eligibility under section 4709 of the BBA.

COST OF 6-MONTH GUARANTEED ELIGIBILITY OPTION

[Dollars in millions rounded to the nearest $5 million]

	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Federal	40	55	80	115	165	230
State	30	45	60	905	125	175
Total	70	100	140	205	290	405

The estimates of Federal costs are reflected in the current budget baseline. The estimates assume that half of the current Medicaid population is enrolled in managed care and that this proportion will increase to about two-thirds by 2003. We also assume that 15 percent of managed care enrollees are currently covered by guaranteed eligibility under rules in effect prior to enactment of the BBA and that the effect of the expanded option under section 4709 of the BBA will be to increase this rate to 20 percent initially and to 30 percent by 2003. The guaranteed eligibility provision is assumed to increase average enrollment by 3 percent in populations covered by the option. This assumption is based on computer simulations of enrollment and turnover in the Medicaid program. Per capita costs used for the estimate were taken from the President's FY 1999 budget projections and the costs for children take into account the interaction of this provision with the State option for 12 months of continuous eligibility under section 4731 of the BBA. The distribution between Federal and State costs is based on the average Federal share representing 57 percent of the total costs.

In States electing the 6-month guaranteed eligibility option, Medicaid beneficiaries will have access to increased continuity of care, which should result in better health care management and improved clinical outcomes.

L. Financial Impact of Revised Rules for Setting Capitation Payments

This rule replaces the current upper payment limit (UPL) requirement at § 447.361 with new rate-setting rules incorporating an expanded requirement for actuarial soundness of capitation rates as described in detail in § 438.6(c) below. In general, we do not expect a major budget impact from the use of these new rate setting rules. While the new rate setting rules may provide some States additional flexibility in setting higher capitation rates than what would have been allowed under current rules, we believe that the requirements for actuarial certification of rates, along with budgetary considerations by State policy makers, would serve to limit increases to within reasonable amounts. Moreover, the Secretary would retain the authority to look behind rates that appear questionable and disapprove any that did not comply with the new rate setting requirements.

M. Administrative Costs

This regulation requires States to include certain specifications in their contracts with MCOs, PHPs, and PCCMs and to monitor compliance with those contract provisions. It also requires States to take a proactive role in monitoring the quality of their managed care program. These requirements will add some administrative burden and costs to States. The amount of additional administrative cost will vary by State depending on how inclusive current practice is of the new

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requirements. In addition, for those States not using like requirements at present, we believe that most would be adopting similar requirements on their own in the future absent this regulation.

The regulation will also increase Federal responsibilities for monitoring State performance in managing their managed care programs. However, no new Federal costs are expected as HCFA plans to use existing staff to monitor these new requirements.

N. Conclusion

This BBA managed care regulation will affect HCFA, States, MCOs, PHPs, PCCMs, providers, and beneficiaries in different ways. The initial investments that are needed by State agencies and MCOs, PHPs, and PCCMs will result in improved and more consistent standards for the delivery of health care to Medicaid beneficiaries. Greater consumer safeguards will result from new quality improvement and protection provisions. Consequently, long term savings will derive from more consistent standards across States, MCOs, PHPs, and PCCMs and increased opportunities for provider and beneficiary involvement in improved access, outcomes, and satisfaction.

O. Federalism

Under Executive Order 13132, we are required to adhere to certain criteria regarding Federalism in developing regulations. We have determined that this final regulation will not significantly affect States rights, roles, and responsibilities. The BBA requires States that contract with section 1903(m) of the Act organizations to have certain beneficiary protections in place when mandating managed care enrollment. This final rule implements those BBA provisions in accordance with the Administrative Procedure Act. This rule also eliminates certain requirements viewed by States as impediments to the growth of managed care programs, such as disenrollment without cause at any time and the inability to amend the State plan without a waiver for mandatory managed care enrollment. We apply many of these requirements to prepaid health plans as set forth in our September 29, 1998 proposed rule. We believe this is consistent with the intent of the Congress in enacting the quality and beneficiary protection provisions of the BBA.

We worked closely with States in developing this regulation. We met with State officials and other stakeholders to discuss opportunities and concerns before the end of the comment period. Throughout the development of the regulation, we consulted with State Medicaid agency representatives in order to gain more understanding of potential impacts. At the November 1997 meeting of the Executive Board of the National Association of State Medicaid Directors (NASMD), we discussed the process for providing initial guidance to States about the Medicaid provisions of the BBA. We provided this guidance through issuance of a series of letters to State Medicaid Directors. From October 1997 through April 2000, over 50 of these letters were issued. Much of the policy included in this regulation relating to the State plan option provision was included in these letters. In May 1998, the Executive Committee of NASMD was briefed on the general content of the regulation. More specific State input was obtained through discussions throughout the Spring of 1998 with the Medicaid Technical Advisory Groups (TAGs) on Managed Care and Quality. These groups are comprised of Medicaid agency staff with notable expertise in the subject area and our regional office staff and are staffed by the American Public Human Services Association. The Managed Care TAG devoted much of its agenda for several monthly meetings to BBA issues. The Quality TAG participated in two conference calls exclusively devoted to discussion of BBA quality issues. Through these contacts, HCFA explored with State agencies their preferences regarding policy issues and the feasibility and practicality of implementing policy under consideration. We also invited public comments as part of the rulemaking process and received comments from over 300 individuals and organizations. Most of the commenters had substantial comments that addressed many provisions of the regulation.

We also received hundreds of comments on every subpart of the final rule, including comments for many States and membership organizations representing States. Many of the recommendations made by commenters have been incorporated into this final rule. For recommendations not accepted, a response has been included in this preamble. Moreover, we discussed technical issues with State experts through technical advisory groups to make certain that the final rule could be practically applied.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

For the reasons set forth in the preamble, the Health Care Financing Administration is amending 42 CFR Chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 400.203 [Amended]

2. In § 400.203, the following statements are added, in alphabetical order, and the definition of "provider" is revised to read as set forth below.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, it means any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, it means any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

1. The authority citation for part 430 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In part 430 a new § 430.5 is added, to read as follows:

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan and in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency's capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 431.51, the following changes are made:

a. In paragraph (a) introductory text, "and 1915(a) and (b) of the Act." is revised to read "1915(a) and (b) and 1932(a)(3) of the Act."

b. Paragraphs (a)(4) and (a)(5) are revised and a new paragraph (a)(6) is added, as set forth below.

c. In paragraph (b)(1) introductory text, "and part 438 of this chapter" is added immediately before the comma that follows "this section".

d. In paragraph (b)(2), "an HMO" is revised to read "a Medicaid MCO".

The additions and revisions read as follows:

§ 431.51 Free choice of providers.

(a) *Statutory basis.* * * *

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

* * * * *

3. In § 431.55, a sentence is added at the end of paragraph (c)(1)(i) to read as follows:

§ 431.55 Waiver of other Medicaid requirements.

* * * * *

(c) * * *

(1) * * *

(i) * * * The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

4. Section 431.200 is revised to read as follows:

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for hearing if the State agency takes action to suspend, terminate, or reduce services, or an MCO or PHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the pre-admission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

§ 431.201 [Amended]

5. In § 431.201, the following definition is added in alphabetical order:

* * * * *

Service authorization request means a managed care enrollee's request for the provision of a service.

6. In § 431.220, the introductory text of paragraph (a) is revised, the semicolons after paragraphs (a)(1), (a)(2), and (a)(3) and the "and" after the third semicolon are removed and periods are inserted in their place, and a new paragraph (a)(5) is added, to read as follows:

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

* * * * *

(5) Any MCO or PHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

* * * * *

§ 431.244 [Amended]

7. In § 431.244, paragraph (f) is revised to read as follows:

* * * * *

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee files an MCO or PHP appeal.

(ii) The date the enrollee files a request for State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, from the MCO or PHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(c)(2) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) As expeditiously as the enrollee's health condition requires, but no later than 72 hours after the agency receives, directly from an MCO or PHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in § 438.410(c)(2) of this chapter.

PART 434—CONTRACTS

1. The authority citation for part 434 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 434.1, paragraph (a) is revised to read as follows:

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

* * * * *

§ 434.2 [Amended]

3. In § 434.2, the definitions of "Capitation fee", "Clinical laboratory", "Contractor", "Enrolled recipient", "Federally qualified HMO", "Health insuring organization (HIO)", "Health maintenance organization (HMO)", "Nonrisk", "Prepaid health plan (PHP)", "provisional status HMO", and "risk or underwriting risk" are removed.

§§ 434.6 [Amended]

4. In paragraph (a)(1), "Appendix G" is removed.

§ 434.20 through 434.38 [Removed]

5. Subpart C, consisting of §§ 434.20 through 434.38, is removed and reserved.

§§ 434.42 and 434.44 [Removed]

6. In subpart D, §§ 434.42 and 434.44 are removed.

§§ 434.50 and 434.67 [Removed]

7. Subpart E, consisting of §§ 434.50 through 434.67, is removed and reserved.

8. Section 434.70 is revised to read as follows:

§ 434.70 Conditions for Federal financial participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* HCFA may withhold FFP for any period during which—

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(1) The State fails to meet the State plan requirements of this part; or

(2) Either party substantially fails to carry out the terms of the contract.

§§ 434.71 through 434.75 and 434.80 [Removed]

9. Sections 434.71 through 434.75, and 434.80 are removed.

PART 435—ELIGIBILITY IN THE STATES, THE DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

1. The authority citation for part 435 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 435.212, the following changes are made:

a. Throughout the section, "HMO", wherever it appears, is revised to read "MCO".

b. The section heading and the introductory text are revised to read as follows:

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

* * * * *

3. Section 435.326 is revised to read as follows:

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

§ 435.1002 [Amended]

4. In § 435.1002, in paragraph (a), "§§ 435.1007 and 435.1008" is revised to read §§ 435.1007, 435.1008, and 438.814 of this chapter,"

5. A new part 438 is added to chapter IV to read as follows:

PART 438—MANAGED CARE PROVISIONS

Subpart A—General Provisions

Sec.
438.1 Basis and scope.
438.2 Definitions.
438.6 Contract requirements.
438.8 Provisions that apply to PHPs.
438.10 Information requirements.
438.12 Provider discrimination prohibited.

Subpart B— State Responsibilities

438.50 State Plan requirements.
438.52 Choice of MCOs, PHPs, and PCCMs.
438.56 Disenrollment: Requirements and limitations.
438.58 Conflict of interest safeguards.
438.60 Limit on payment to other providers.
438.62 Continued services to recipients.
438.66 Monitoring procedures.
438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

Subpart C—Enrollee Rights and Protections

438.100 Enrollee rights.
438.102 Provider-enrollee communications.
438.104 Marketing activities.
438.106 Liability for payment.
438.108 Cost sharing.
438.114 Emergency and post-stabilization services.
438.116 Solvency standards.

Subpart D—Quality Assessment and Performance Improvement

438.200 Scope.
438.202 State responsibilities.
438.204 Elements of State quality strategies.

Access Standards

438.206 Availability of services.
438.207 Assurances of adequate capacity and services.
438.208 Coordination and continuity of care.
438.210 Coverage and authorization of services.

Structure and Operation Standards

438.214 Provider selection.
438.218 Enrollee information.
438.224 Confidentiality and accuracy of enrollee records.
438.226 Enrollment and disenrollment.
438.228 Grievance systems.
438.230 Subcontractual relationships and delegation.

Measurement and Improvement Standards

438.236 Practice guidelines.
438.240 Quality assessment and performance improvement program.
438.242 Health information systems.

Subpart E—[Reserved]

Subpart F—Grievance System

438.400 Statutory basis and definitions.
438.402 General requirements.
438.404 Notice of action.
438.406 Handling of grievances and appeals.
438.408 Resolution and notification: Grievances and appeals.
438.410 Expedited resolution of grievances and appeals.
438.414 Information about the grievance system.
438.416 Recordkeeping and reporting requirements.
438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.
438.424 Effectuation of reversed appeal resolutions.
438.426 Monitoring of the grievance system.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

438.600 Statutory basis.
438.602 Basic rule.
438.604 Data that must be certified.
438.606 Source, content, and timing of certification.
438.608 Program integrity requirements.

Subpart I—Sanctions

438.700 Basis for imposition of sanctions.
438.702 Types of intermediate sanctions.
438.704 Amounts of civil money penalties.
438.706 Special rules for temporary management.
438.708 Termination of an MCO or PCCM contract.
438.710 Due process: Notice of sanction and pre-termination hearing.
438.722 Disenrollment during termination hearing process.
438.724 Public notice of sanction.
438.726 State plan requirement.
438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

Subpart J—Conditions for Federal Financial Participation

438.802 Basic requirements.
438.806 Prior approval.
438.808 Exclusion of entities.
438.810 Expenditures for enrollment broker services.
438.812 Costs under risk and nonrisk contracts.
438.814 Limit on payments in excess of capitation rates.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State Medicaid plan. The application of the requirements of this part to PHPs that do not meet the statutory definition of MCO or to a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.
(2) Rural health clinic services.
(3) FQHC services.
(4) Other laboratory and X-ray services.
(5) Nursing facility (NF) services.
(6) Early and periodic screening diagnostic, and treatment (EPSDT) services.
(7) Family planning services.
(8) Physician services.
(9) Home health services.

Federally qualified HMO means an HMO that HCFA has determined to be a qualified HMO under section 1310(d) of the PHS Act.

Health insuring organization (HIO) means an entity that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers; and

(2) Under a risk contract with the State.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is —

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid health plan (PHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates; and

(2) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.
(2) A nurse practitioner.
(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The HCFA Regional Office must review and approve all MCO and PHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with one of the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts.*—(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to

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compensate for distortions in costs, utilization, or the number of eligibles.

(2) *Basic requirements.* (i) All capitation rates paid under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as inflation, MCO or PIP administration (subject to the limits in § 438.6(c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by:

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are based only upon services covered under the State plan and to be provided under the contract to Medicaid-eligible individuals.

(iii) Its projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies (other than risk corridors) must be computed on an actuarially sound basis.

(ii) If risk corridors or incentive arrangements result in payments that exceed the approved capitation rates, the FFP limitation of § 438.814 applies.

(iii) For all incentive arrangements, the contract must provide that the arrangement is —

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Designed to include withholds or other payment penalties if the contractor does not perform the specified activities or does not meet the specified targets;

(D) Made available to both public and private contractors;

(E) Not conditioned on intergovernmental transfer agreements; and

(F) Necessary for the specified activities and targets.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PHPs, and PCCMs must provide as follows:

(1) The MCO, PHP or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PHP or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PHP or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO or PHP contract may cover, for enrollees, services that are in addition to those covered under the State plan.

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable State and Federal laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO and PHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210, references to "M+C organization", "HCFA", and "Medicare beneficiaries" must be read as references to "MCO or PHP", "State agency" and "Medicaid recipients", respectively.

(i) *Advance directives.* (1) All MCO and most PHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures with respect to advance directives. This requirement does not apply to PHP contracts where the State has determined such application would be inappropriate, as described in § 438.8(a)(2).

(2) The MCO or PHP must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(3) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56.

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional in the MCO to the extent possible and appropriate.

§ 438.8 Provisions that apply to PHPs.

The following requirements and options apply to PHPs, PHP contracts, and States with respect to PHPs, to the same extent that they apply to MCOs, MCO contracts, and States with respect to MCOs.

(a) The contract requirements of § 438.6, except for the following:

(1) Requirements that pertain to HIOs.

(2) Requirements for advance directives, if the State believes that they are not appropriate, for example, for a PHP contract that covers only dental services or non-clinical services such as transportation services.

(b) The information requirements in § 438.10.

(c) The provision against provider discrimination in § 438.12.

(d) The State responsibility provisions of subpart B except § 438.50.

(e) The enrollee rights and protection provisions in subpart C of this part.

(f) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PHP.

(g) The grievance system provisions in subpart F of this part.

(h) The certification and program integrity protection provisions set forth in subpart H of this part.

§ 438.10 Information requirements.

(a) *Basic rules.* (1) Each State or its contracted representative, and each MCO, PHP, or PCCM must, in furnishing information to enrollees and potential enrollees, meet the requirements that are applicable to it under this section.

(2) The information required for all potential enrollees must be furnished by the State or its contracted representative or, at State option, by the MCO or PHP.

(3) The information required for all enrollees must be furnished by each MCO or PHP, unless the State chooses to furnish it directly or through its contracted representative.

(4) PHPs must comply with the requirements of this section, as appropriate. PHPs that contract as PCCMs must meet all of the requirements applicable to PCCMs. All other PHPs must meet all of the requirements applicable to MCOs.

(5) The language and format requirements of paragraphs (b) and (c) of this section apply to all information furnished to enrollees and potential enrollees, such as enrollment notices and instructions, as well as the information specified in this section.

(6) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(7) Each MCO and PHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(8) If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act (that is, as a State plan option), the additional requirements of paragraph (h) of this section apply.

(b) *Language.* The State must meet the following requirements:

(1) Establish a methodology for identifying the non-English languages spoken by enrollees and potential enrollees throughout the State.

(2) Provide written information in each non-English language that is necessary for effective communication with a significant number or percentage of enrollees and potential enrollees.

(3) Require each MCO, PHP, and PCCM to make its written information available in the languages that are prevalent in its particular service area.

(4) Make oral interpretation services available and require each MCO, PHP, and PCCM to make those services available free of charge to the recipient to meet the needs of each enrollee and potential enrollee.

(5) Notify enrollees and potential enrollees, and require each MCO, PHP, and PCCM to notify its enrollees and potential enrollees—

(i) That oral interpretation and written information are available in languages other than English; and

(ii) Of how to access those services.

(c) *Format.* (1) The material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) The State must provide instructions to enrollees and potential enrollees and require each MCO, PHP, and PCCM to provide instructions to its enrollees and potential enrollees on how to obtain information in the appropriate format.

(d) *Information for potential enrollees.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must provide the information specified in paragraph (d)(2) of this section as follows:

(i) To each potential enrollee residing in the MCO's or PHP's service area;

(ii) At the time the potential enrollee first becomes eligible for Medicaid, is considering choice of MCOs or PHPs under a voluntary program, or is first required to choose an MCO or PHP under a mandatory enrollment program; and

(iii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs or PHPs.

(2) *Required information.* The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in an MCO or PHP; and

(C) MCO and PHP responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO and PHP serving an area that encompasses the potential enrollee's service area:

(A) Benefits covered;

(B) Cost sharing, if any;

(C) Service area;

(D) Names, locations, telephone numbers of, and non-English language spoken by current network providers, including at a minimum information on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information about how and where to obtain the service, but only about how and where to obtain information about the service. The State must furnish information about where and how to obtain the service.

(e) *Information for enrollees.*—(1) *To whom and when the information must be furnished.* The MCO or PHP must—

(i) Furnish to each of its enrollees the information specified in paragraph (e)(2) of this section within a reasonable time

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after the MCO or PHP receives, from the State or its contracted representative, notice of the recipient's enrollment, and once a year thereafter.

(ii) Give each enrollee written notice of any change (that the State defines as "significant") in the information specified in paragraph (e)(2) of this section, at least 30 days before the intended effective date of the change.

(iii) Make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

(2) *Required information.* The information for enrollees must include the following:

(i) Kinds of benefits, and amount, duration, and scope of benefits available under the contract. There must be sufficient detail to ensure that enrollees understand the benefits to which they are entitled, including pharmaceuticals, and mental health and substance abuse benefits.

(ii) Enrollee rights as specified in § 438.100.

(iii) Procedures for obtaining benefits, including authorization requirements.

(iv) Names, locations, telephone numbers of, and non-English languages spoken by current network providers, including information at least on primary care physicians, specialists, and hospitals, and identification of providers that are not accepting new patients.

(v) Any restrictions on the enrollee's freedom of choice among network providers.

(vi) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

(vii) The extent to which, and how, after-hours and emergency coverage are provided.

(viii) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(ix) Cost sharing, if any.

(x) Grievance, appeal, and fair hearing procedures for enrollees, including timeframes, required under § 438.414(b).

(xi) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

(xii) Any benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO or PHP does not cover because of moral or religious objections, the MCO or PHP need not furnish information on how and where to obtain the service, but only on how and where to obtain information about the service. The State must furnish information about how and where to obtain the service.

(xiii) Information on how to obtain continued services during a transition, as provided in § 438.62.

(xiv) The rules for emergency and post-stabilization services, as set forth in § 438.114.

(xv) Additional information that is available upon request, and how to request that information.

(3) *Annual notice.* At least once a year, the MCO or PHP, or the State or its contracted representative, must notify enrollees of their right to request and obtain the information listed in paragraphs (e)(2) and (f) of this section.

(f) *MCO or PHP information available upon request.* The following information must be furnished to enrollees and potential enrollees upon request, by the MCO or PHP, or by the State or its contracted representative if the State prohibits the MCO or PHP from providing it:

(1) With respect to MCOs and health care facilities, their licensure, certification, and accreditation status.

(2) With respect to health care professionals, information that includes, but is not limited to, education, licensure, and Board certification and recertification.

(3) Other information on requirements for accessing services to which they are entitled under the contract, including factors such as physical accessibility and non-English languages spoken.

(4) A description of the procedures the MCO or PHP uses to control utilization of services and expenditures.

(5) A summary description of the methods of compensation for physicians.

(6) Information on the financial condition of the MCO or PHP, including the most recently audited information.

(7) Any element of information specified in paragraphs (d) and (e) of this section.

(g) *Information on PCCMs and PHPs.*—(1) *To whom and when the information must be furnished.* The State or its contracted representative must furnish information on PCCMs and PHPs to potential enrollees—

(i) When potential enrollees first become eligible for Medicaid or are first required to choose a PCCM or PHP under a mandatory enrollment program; and

(ii) Within a timeframe that enables them to use the information in choosing among available PCCMs or PHPs .

(2) *Required information.*—(i) *General rule.* The information must include the following:

(A) The names of and non-English languages spoken by PCCMs and PHPs and the locations at which they furnish services.

(B) Any restrictions on the enrollee's choice of the listed PCCMs and PHPs.

(C) Except as provided in paragraph (g)(2)(ii) of this section, any benefits that are available under the State plan but not under the PCCM or PHP contract, including how and where the enrollee may obtain those benefits, any cost-sharing, and how transportation is provided.

(ii) *Exception.* For counseling and referral services that are not covered under the PCCM or PHP contract because of moral or religious objections, the PCCM or PHP need not furnish information about how and where to obtain the service but only about how and where to obtain information about the service. The State must furnish the information on how and where to obtain the service.

(3) *Additional information available upon request.* Each PCCM and PHP must, upon request, furnish information on the grievance procedures available to enrollees, including how to obtain benefits during the appeals process.

(h) *Special rules: States with mandatory enrollment.*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under section 1932(a)(1)(A) of the Act, the State or its contracted representative must furnish information on MCOs, PHPs, and PCCMs (as specified in paragraph (h)(3) of this section), either directly or through the MCO, PHP, or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished to all potential enrollees—

(i) At least once a year; and

(ii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (d) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (h)(2) of this section, and includes the following for each contracting MCO, PHP, or PCCM:

(i) The MCO's, PHP's, or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO, PHP, or PCCM.

(iv) To the extent available, quality and performance indicators, including, but not limited to, disenrollment rates as defined by the State, and enrollee satisfaction.

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO or PHP may not discriminate with respect to the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO or PHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals an MCO or PHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO or PHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO or PHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO or PHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State plan requirements.

(a) *General rule.* A State plan that provides for requiring Medicaid recipients to enroll in managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following laws and regulations:

(1) Section 1903(m) of the Act, with respect to MCOs and MCO contracts.

(2) Section 1905(t) of the Act, with respect to PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, with respect to the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, with respect to MCOs and PCCMs.

(5) Part 434 of this chapter, with respect to all contracts.

(6) Section 438.6(c), with respect to payments under any risk contracts, and § 447.362 with respect to payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An "existing provider-recipient relationship" is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have "traditionally served" Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph(b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider is not available within the MCO, PHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient. (This provision applies as long as the provider continues to be the main source of the service).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines

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that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, "rural area"is any area other than an "urban area" as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act;

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PHP, or HIO under paragraph (b)(2) or (b)(3) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.58 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PHP or PCCM.* All MCO, PHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PHP or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PHP or PCCM may not request disenrollment because of a change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except where his or her continued enrollment in the MCO, PHP or PCCM seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PHP or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PHP or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment.* (1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PHP or PCCM, if the State permits MCOs, PHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee was homeless (as defined by the State) or a migrant worker at the time of enrollment and was enrolled in the MCO, PHP or PCCM by default.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PHP or PCCM action on request.* (i) An MCO, PHP or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraphs (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PHP or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PHP or the PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PHP or PCCM files the request.

(2) If the MCO, PHP or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraphs (e)(1) and (e)(2) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs or PHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to MCO or PHP contracts or the default enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO or PHP for services available under the contract between the State and the MCO or PHP, except where such payments are provided for in title XIX of the Act or 42 CFR.

§ 438.62 Continued services to recipients.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PHP or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PHP or PCCM for any reason other than ineligibility for Medicaid.

(b) The State agency must have in effect a mechanism to ensure continued access to services when an enrollee with ongoing health care needs is transitioned from fee-for-service to an MCO, PHP or PCCM, from one MCO, PHP or PCCM to another, or from an MCO, PHP or PCCM to fee-for-service.

(1) The mechanism must apply at least to the following:

(i) Children and adults receiving SSI benefits.

(ii) Children in title IV–E foster care.

(iii) Recipients aged 65 or older.

(iv) Pregnant women.

(v) Any other recipients whose care is paid for under State-established, risk-adjusted, high-cost payment categories.

(vi) Any other category of recipients identified by HCFA.

(2) The State must notify the enrollee that a transition mechanism exists, and provide instructions on how to access the mechanism.

(3) The State must ensure that an enrollee's ongoing health care needs are met during the transition period, by establishing procedures to ensure that, at a minimum—

(i) The enrollee has access to services consistent with the State plan, and is referred to appropriate health care providers;

(ii) Consistent with Federal and State law, new providers are able to obtain copies of appropriate medical records; and

(iii) Any other necessary procedures are in effect.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's or PHP's operations, including, at a minimum, operations related to:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

§ 438.68 Education of MCOs, PHPs, and PCCMs and subcontracting providers.

The State agency must have in effect procedures for educating MCOs, PHPs, PCCMs and any subcontracting providers about the clinical and other needs of enrollees with special health care needs.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and each PHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PHP, or PCCM has the following rights: The right

(i) To receive information in accordance with § 438.10.

(ii) To be treated with respect and with due consideration for his or her dignity and privacy.

(iii) To receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(e).)

(iv) To participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) To be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(3) An enrollee of an MCO or a PHP also has the following rights—The right

(i) To be furnished health care services in accordance with §§ 438.206 through 438.210.

(ii) To obtain a second opinion from an appropriately qualified health care professional in accordance with § 438.206(d)(3).

(iii) To request and receive a copy of his or her medical records, and to request that they be amended or corrected, as specified in § 438.224.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PHP or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PHP, and PCCM complies with any other applicable Federal and State laws (such as: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 484; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and Titles II and III of the Americans with Disabilities Act and other laws regarding privacy and confidentiality).

§ 438.102 Provider-enrollee communications.

(a) *Health care professional defined.* As used in this subpart, "health care professional" means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(b) *General rules.* (1) An MCO or PHP may not prohibit, or otherwise restrict a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, with respect to the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

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(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) MCOs and PHPs must take steps to ensure that health care professionals—

(i) Furnish information about treatment options (including the option of no treatment) in a culturally competent manner; and

(ii) Ensure that enrollees with disabilities have effective communication with all health system participants in making decisions with respect to treatment options.

(3) Subject to the information requirements of paragraph (c) of this section, an MCO or PHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (b)(1) of this section is not required to do so if the MCO or PHP objects to the service on moral or religious grounds.

(c) *Information requirements: MCO and PHP responsibility.* (1) An MCO or PHP that elects the option provided in paragraph (b) (3) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO or PHP to the option provided in paragraph (b)(3) of this section, the overriding rule in § 438.10(e)(1)(ii) requires the MCO or the PHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10(d) and (e), the information that MCOs and PHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (b)(3) of this section, but only how and where to obtain information about the service.

(d) *Information requirements: State responsibility.* For each service excluded by an MCO or PHP under paragraph (b)(2) of this section, the State must furnish information on how and where to obtain the service, as specified in §§ 438.10(e)(2)(xii) and 438.206(c).

(e) *Sanction.* An MCO or PHP that violates the prohibition of paragraph (b)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PHP, or PCCM to an enrollee or potential enrollee, that can reasonably be interpreted as intended to influence the recipient to enroll or reenroll in that particular MCO's, PHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to enrollees or potential enrollees.

MCO, PHP, PCCM, and *entity* include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any other insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that would be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PHP, or PCCM is endorsed by HCFA, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO and PHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's or PHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO or the PHP; or

(2) The State, or the MCO or PHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO or PHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and post-stabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition has the meaning given the term in § 422.113(b) of this chapter.

Emergency services has the meaning given the term in § 422.113(b) of this chapter.

Post-stabilization care services has the meaning given the term in § 422.113(c) of this chapter.

(b) *Information requirements.* To enrollees and potential enrollees upon request, and to enrollees during enrollment and at least annually thereafter, each State (or at State option, each MCO, PHP, and PCCM) must provide, in clear, accurate, and

standardized form, information that describes or explains at least the following:

(1) What constitutes emergency medical condition, emergency services, and post-stabilization services, with reference to the definitions in paragraph (a) of this section.

(2) The fact that prior authorization is not required for emergency services.

(3) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent.

(4) The locations of any emergency settings and other locations at which MCO, PHP, and PCCM providers and hospitals furnish emergency services and post-stabilization services covered under the contract.

(5) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(6) The post-stabilization care services rules set forth at § 422.113(c) of this chapter.

(c) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and post-stabilization care services.

(1) The MCO or PHP.

(2) The PCCM that has a risk contract that covers such services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(d) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (c) of this section—

(i) Must cover and pay for emergency services regardless of whether the entity that furnishes the services has a contract with the MCO, PHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (b)(1)(A), (B), and (C) of the definition of emergency medical condition in § 422.113 of this chapter.

(B) A representative of the MCO, PHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(e) *Additional rules for emergency services.* (1) The entities specified in paragraph (c) of this section—

(i) May not limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) May not refuse to process any claim because it does not contain the primary care provider's authorization number.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (c) of this section as responsible for coverage and payment.

(f) *Coverage and payment: Post-stabilization services.* Post-stabilization care services are covered and paid for in accordance with provisions set forth at § 422.113(c) of this chapter. In applying those provisions, reference to "M+C organization" must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (c) of this section.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO and PHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's or PHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements.*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, a MCO and a PHP must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs and PHPs. It also establishes standards that States, MCOs and PHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PHP must—

(a) Have a strategy for assessing and improving the quality of managed care services offered by all MCOs and PHPs:

(b) Document the strategy in writing.

(c) Provide for the input of recipients and other stake-holders in the development of the strategy, including making the strategy available for public comment before adopting it in final;

(d) Ensure compliance with standards established by the State, consistent with this subpart; and

(e) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy as often as the State considers appropriate, but at least every 3 years.

(f) Submit to HCFA the following:

(1) A copy of the initial strategy, and a copy of the revised strategy, whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy, consistent with paragraph (e), at least every 3 years.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following—

(a) MCO and PHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures for assessing the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PHP contracts. These include, but are not limited to—

(1) Procedures that—

(i) Identify enrollees with special health-care needs; and

(ii) Assess the quality and appropriateness of care furnished to

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enrollees with special health-care needs; and

(iii) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PHP for each Medicaid enrollee at the time of enrollment.

(2) Continuous monitoring and evaluation of MCO and PHP compliance with the standards.

(c) Performance measures and levels prescribed by HCFA consistent with section 1932(c)(1) of the Act.

(d) Arranging for annual, external independent reviews of the quality outcomes and timeliness of, and access to the services covered under each MCO and PHP contract.

(e) Appropriate use of intermediate sanctions that, at a minimum, meet the requirements of Subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

Access Standards

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all covered services are available and accessible to enrollees.

(b) *Choice of entities.* If a State limits freedom of choice, it must comply with the requirements of § 438.52, which specifies the choices that the State must make available.

(c) *Services not covered by an MCO, PHP, or PCCM contract.* If an MCO, PHP, or PCCM contract does not cover all of the services under the State plan, the State must make those services available from other sources and provide to enrollees information on where and how to obtain them, including how transportation is provided.

(d) *Delivery network.* The State must ensure that each MCO, and each PHP consistent with the scope of PHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO and PHP must consider the following:

(i) The anticipated Medicaid enrollment, with particular attention to pregnant women, children, and persons with special health-care needs.

(ii) The expected utilization of services, considering Medicaid enrollee characteristics and health care needs.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee, if an additional qualified professional is not currently available within the network.

(4) When seeking an expansion of its service area, demonstrates that it has sufficient numbers and types (in terms of training, experience, and specialization) of providers to meet the anticipated additional volume and types of services the added Medicaid enrollee population may require.

(5) If the network is unable to provide necessary medical services, covered under the contract, to a particular enrollee, the MCO or PHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO or PHP is unable to provide them.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(7) Ensures that its providers do not discriminate against Medicaid enrollees.

(8) Requires out-of-network providers to coordinate with the MCO or PHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(e) *Furnishing of services.* The State must ensure that each MCO and PHP complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO and each PHP must —

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of need for services;

(ii) Ensure that its network's provider hours of operation are convenient for the enrollees, as determined by a State-established methodology, and at least comparable to Medicaid fee-for-service.

(iii) Make services available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance;

(v) Monitor continuously to determine compliance; and

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO and each PHP ensures that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* Each MCO and each PHP must give assurances to the State that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of assurances.* Each MCO and each PHP must submit documentation to the State, in a format specified by the State and acceptable to HCFA, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of services, including preventive services, primary care services and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(3) Meets the availability of services requirements in § 438.206.

(4) Has in place policies and practices to deal with situations in which there is—

(i) Unanticipated need for providers with particular types of experience; or (ii) Unanticipated limitation of the availability of such providers.

(c) *Timing of documentation.* Each MCO and each PHP must submit the documentation described in paragraph (b) of this section at least once a year, and specifically—

(1) At the time it enters into a contract with the State; and

(2) At any time there has been a significant change (as defined by the State) in the MCO's or PHP's operations that would affect adequate capacity and services, including—

(i) A significant change in the MCO's or PHP's services or benefits;

(ii) An expansion or reduction of the MCO's or PHP's geographic service area;

(iii) The enrollment of a new population in the MCO or PHP; and

(iv) A significant change in the MCO or PHP rates.

(d) *State review and submission to HCFA.* After the State reviews the documentation submitted by the MCO or PHP, the State must certify to HCFA that the MCO or PHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *HCFA's right to inspect documentation.* The State must make available to HCFA, upon request, all documentation collected by the State from the MCO or PHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement.*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure that MCOs and PHPs comply with the requirements of this section.

(2) *PHP exception.* For PHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, whether a particular PHP is required—

(i) To perform the initial and ongoing screenings and assessments specified in paragraphs (d) and (e) of this section; and

(ii) To meet the primary care requirement of paragraph (h)(1) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For an MCO that serves enrollees who are also enrolled in a Medicare+Choice plan and also receive Medicare benefits, the State determines to what extent that MCO must meet the initial screening, assessment, and treatment planning provisions of paragraphs (d), (e), and (f) of this section.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *State responsibility to identify enrollees with special health care needs.* The State must implement mechanisms to identify to the MCO and PHP, upon enrollment, the following groups:

(1) Enrollees at risk of having special health care needs, including—

(i) Children and adults who are receiving SSI benefits;

(ii) Children in Title IV–E foster care;

(iii) Enrollees over the age of 65; and

(iv) Enrollees in relevant, State-established, risk-adjusted, higher-cost payment categories.

(v) Any other category of recipients identified by HCFA.

(2) Children under the age of 2.

(3) Other enrollees known by the State to be pregnant or to have special health care needs.

(c) *Requirements for MCOs and PHPs.* The State must ensure—

(1) That each MCO, and each PHP for which the State determines it is appropriate in accordance with paragraphs (a)(2) and (a)(3) of this section, meets the requirements of paragraphs (d), (e), and (h)(1) of this section; and

(2) That each MCO and each PHP meets the requirements of paragraphs (f), (g), and (h)(2) through (h)(6) of this section.

(d) *Initial screening and assessment.* Each MCO and each PHP must make a best effort attempt to meet the following standards:

(1) For enrollees identified under paragraph (b)(1) of this section,

(i) Performs enrollee screening within 30 days of receiving the identification; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(2) For enrollees identified under paragraphs (b)(2) and (b)(3) of this section, or who identify themselves as being pregnant or having special health care needs, performs a comprehensive health assessment as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(3) For all other enrollees—

(i) Performs screening within 90 days from the date of enrollment; and

(ii) For any enrollee the screening identifies as being pregnant or having special health care needs, performs the comprehensive health assessment as expeditiously as the enrollee's health requires but no later than 30 days from the date of identification.

(e) *On-going screening and assessment.* Each MCO and each PHP must implement mechanisms to—

(1) Identify enrollees who develop special health care needs after they enroll in the MCO or PHP; and

(2) Perform comprehensive health assessments as expeditiously as the enrollee's health requires, but no later than 30 days from the date of identification.

(f) *Treatment plans.* For pregnant women and for enrollees determined to have special health care needs, each MCO and each PHP implements a treatment plan that—

(1) Is appropriate to the conditions and needs identified and assessed under paragraphs (d) and (e) of this section;

(2) Is for a specific period of time and is updated periodically;

(3) Specifies a standing referral or an adequate number of direct access visits to specialists;

(4) Ensures adequate coordination of care among providers;

(5) Is developed with enrollee participation; and

(6) Ensures periodic reassessment of each enrollee as his or her health condition requires.

(g) *Use of health care professionals.* Each MCO and each PHP uses appropriate health care professionals to—

(1) Perform any comprehensive health assessments required by this section; and

(2) Develop, implement, and update any treatment plans required by this section.

(h) *Primary care and coordination program.* Each MCO and each PHP must implement a coordination program that meets State requirements and achieves the following:

(1) Ensures that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinates the services the MCO or PHP furnishes to the enrollee with the services the enrollee receives from any other MCOs and PHPs;

(3) Shares with other MCOs and PHPs serving the enrollee the results of its screenings and assessments of the enrollee so that those activities need not be duplicated.

(4) Ensures that in the process of coordinating care, each enrollee's privacy is protected consistent with the confidentiality requirements in § 438.224.

(5) Ensures that each provider maintains health records that meet professional standards and that there is appropriate and confidential sharing of information among providers.

(6) Has in effect procedures to address factors (such as a lack of transportation) that may hinder enrollee adherence to prescribed treatments or regimens.

(7) Ensures that its providers have the information necessary for effective and continuous patient care and quality improvement, consistent with the confidentiality and accuracy requirements of § 438.224 and the information system requirements of § 438.242.

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§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PHP, or PCCM must identify, define, and specify each service that the MCO, PHP, or PCCM is required to offer, and each contract with an MCO or PHP must meet the following requirements:

(1) Require that the MCO or PHP make available the services it is required to offer at least in the amount, duration, and scope that—

(i) Are specified in the State plan; and

(ii) Are sufficient to reasonably be expected to achieve the purpose for which the services are furnished.

(2) Provide that the MCO or PHP—

(i) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of the diagnosis, type of illness, or condition; and

(ii) May place appropriate limits on a service—

(A) On the basis of criteria such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(1)(ii) of this section.

(3) Specify what constitutes "medically necessary services" in a manner that—

(i) Is no more restrictive than the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO or PHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(4) Provide that the MCO or PHP furnishes the services in accordance with the specifications of paragraph (a)(3) of this section.

(b) *Processing of requests.* With respect to the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO or PHP and its subcontractors have in place, and follow, written policies and procedures that reflect current standards of medical practice;

(2) That the MCO or PHP—

(i) Not have information requirements that are unnecessary, or unduly burdensome for the provider or the enrollee;

(ii) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(iii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollees's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO or PHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO or PHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. The notice must meet the requirements of § 438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for standard authorization decisions.* Each contract must provide for the MCO or PHP to make a standard authorization decision and provide notice—

(1) As expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO or the PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Timeframe for expedited authorization decisions.* (1) For cases in which a provider indicates, or the MCO or PHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, each contract must provide for the MCO or PHP to make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.

(2) The MCO or PHP may extend the 72-hour time period by up to 14 calendar days if the enrollee requests extension.

(f) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(g), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

Structure and Operation Standards

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure that each contracted MCO and PHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(b) *Credentialing and recredentialing requirements.* Each MCO and each PHP must follow a documented credentialing process for providers who have signed contracts or participation agreements with the MCO or the PHP.

(1) *Physicians and other licensed independent providers.* The process for physicians, including members of physician groups, and other licensed independent providers, includes—

(i) Initial credentialing when a physician or other provider enters the MCO or PHP network or a physician enters a physician group; and

(ii) Recredentialing within timeframes set by the State, which may be no less than the State requires for private MCOs.

(2) *Other providers.* The process for other providers must include an initial determination, and redetermination at specified intervals. The redetermination cycles must be the same as Federal or State credentialing cycles. The purpose is to ensure that, at a minimum, the provider—

(i) Is licensed (if required by the State); and

(ii) Has met any other applicable Federal or State requirements.

(3) *Exception.* The requirements of paragraphs (b)(1) and (b)(2) of this section do not apply to either of the following:

(i) Providers who are permitted to furnish services only under the direct supervision of a physician or other provider.

(ii) Hospital-based providers (such as emergency room physicians, anesthesiologists, or certified nurse anesthetists) who provide services only incident to hospital services. This exception does not apply if the provider contracts independently with the MCO or PHP or is promoted by the MCO or PHP as part of the provider network.

(4) *Initial credentialing.* Initial credentialing—

(i) Requires a written, dated and signed application that is updated in writing at recredentialing;

(ii) Requires that applications, updates, and supporting information submitted by the applicant include an attestation of the correctness and completeness of the information; and

(iii) Is based on primary source verification of licensure, disciplinary status, and a site visit as appropriate.

(5) *Recredentialing.* Recredentialing includes updating of information obtained during initial credentialing and an assessment of provider performance indicators obtained through the following:

(i) Quality Assessment and Performance Improvement Programs.

(ii) The utilization management system.

(iii) The grievance system.

(iv) Enrollee satisfaction surveys.

(v) Other MCO or PHP activities specified by the State.

(c) *Nondiscrimination.* MCO and PHP provider selection policies and procedures, consistent with § 438.12, do not discriminate against particular providers that serve high risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs or PHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO and PHP must comply with any additional requirements established by the State.

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality and accuracy of enrollee records.

The State must ensure that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO and PHP establishes and implements procedures to do the following:

(a) Maintain the records and information in a timely and accurate manner.

(b) Abide by all Federal and State laws regarding confidentiality and disclosure.

(c) Specify—

(1) For what purposes the MCO or PHP uses the information; and

(2) To which entities outside the MCO or PHP, and for what purposes, it discloses the information.

(d) Except as provided in applicable Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to him or her and request that they be amended or corrected.

(e) Ensure that each enrollee may request and receive information on how the MCO or PHP uses and discloses information that identifies the enrollee.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO and PHP complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure that each MCO and PHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

(c) The State must establish a process to review, upon request by the enrollee, any quality of care grievance that the MCO or the PHP does not resolve to the enrollee's satisfaction.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure that each MCO and PHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO and PHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO or PHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO or PHP identifies deficiencies or areas for improvement, the MCO and the subcontractor take corrective action.

(5) Consistent with §§ 438.604 and 438.606, each MCO and PHP requires from subcontractors certifications with respect to—

(i) Submissions that may be related to State payments; and

(ii) The performance of their duties under the contract.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure that each MCO and PHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and PHP adopts practice guidelines (for example, The Guidelines for the Use of Antiretroviral Agents in HIV–Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection) that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

(2) Consider the needs of the MCO's or PHP's enrollees;

(3) Are adopted in consultation with contracting health care professionals; and

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO and PHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions with respect to utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) Paragraphs (b) through (d) of this section set forth the basic elements, minimum performance levels, and performance improvement projects required for MCOs and PHPs.

(3) HCFA may specify standardized quality measures, and topics for performance improvement projects to be required by States in their contracts with MCOs and PHPs.

(b) *Basic elements of MCO and PHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PHP comply with the following requirements:

(1) Achieve required minimum performance levels on standardized quality measures, in accordance with paragraph (c) of this section;

(2) Conduct performance improvement projects as described in

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paragraph (d) of this section. These projects must achieve, through ongoing measurements and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical care areas that can be expected to have a favorable effect on health outcomes and enrollee satisfaction; and

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Minimum performance levels.* (1) Each MCO and PHP must meet the following requirements:

(i) Annually measure its performance, using standard measures required by the State, consistent with the requirements of § 438.204(c), and report its performance to the State.

(ii) Achieve all minimum performance levels that the State establishes with respect to the standard measures.

(2) The State—

(i) May specify the standard measures in uniform data collection and reporting instruments; and

(ii) Must, in establishing minimum performance levels for the MCOs and PHPs—

(A) Include any minimum performance measures and levels specified by HCFA;

(B) Consider data and trends for both the MCOs and PHPs and fee-for-service Medicaid in that State; and

(C) Establish the minimum performance levels prospectively, each time a contract is initiated or renewed.

(d) *Performance improvement projects.* (1) Performance improvement projects are MCO and PHP initiatives that focus on clinical and non-clinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each project must represent the entire Medicaid enrollee population to which the measurement specified in paragraph (d)(1)(i) of this section is relevant.

(3) The State must ensure that each MCO and PHP initiates each year one or more projects among the required clinical and non-clinical areas specified in paragraphs (d)(4) and (d)(5) of this section. To ensure that the projects are representative of the entire spectrum of clinical and non-clinical areas associated with MCOs and PHPs, the State must specify the appropriate distribution of projects.

(4) Clinical areas include—

(i) Prevention and care of acute and chronic conditions;

(ii) High-volume services;

(iii) High-risk services; and

(iv) Continuity and coordination of care.

(5) Non-clinical areas include—

(i) Grievances and appeals;

(ii) Access to, and availability of, services; and

(iii) Cultural competence.

(6) In addition to requiring each MCO and PHP to initiate its own performance improvement projects, the State may require that an MCO or PHP—

(i) Conduct particular performance improvement projects on a topic specified by the State; and

(ii) Participate annually in at least one Statewide performance improvement project.

(7) For each project, each MCO and PHP must assess its performance using quality indicators that are—

(i) Objective, clearly and unambiguously defined, and based on current clinical knowledge or health services research; and

(ii) Capable of measuring outcomes such as changes in health status, functional status, and enrollee satisfaction, or valid proxies of these outcomes.

(8) Performance assessment on the selected indicators must be based on systematic ongoing collection and analysis of valid and reliable data.

(9) Each MCO's and PHP's interventions must achieve improvement that is significant and sustained over time.

(10) Each MCO and PHP must report the status and results of each project to the State as requested.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PHP's quality assessment and performance improvement program. The review must include—

(i) The Each MCO's and PHP's performance on the standard measures on which it is required to report; and

(ii) The results of the each MCO's and PHP's performance improvement projects.

(2) The State may require that an MCO or PHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure that each MCO and PHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system should provide information on areas including, but not limited to, utilization, grievances, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or such other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to HCFA, as required in this subpart.

Subpart E [Reserved]

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4)of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

(1) In the case of an MCO or PHP or any of its providers—

(i) The denial or limited authorization of a requested service, including the type or level of service;

(ii) The reduction, suspension, or termination of a previously authorized service;

(iii) The denial, in whole or in part, of payment for a service;

(iv) For a resident of a rural area with only one MCO or PHP, the denial of a Medicaid enrollee's request to exercise his or her right to obtain services outside the network; or

(v) The failure to furnish or arrange for a service or provide payment for a service in a timely manner.

(vi) The failure, of an MCO or PHP, to resolve an appeal within the timeframes provided in § 408(i)(2).

(2) In the case of a State agency, the denial of a Medicaid enrollee's request for disenrollment. An appeal of this type is to the State Fair Hearing Office.

Appeal means a request for review of an action, as "action" is defined in this section.

Governing body means the MCO's or PHP's Board of Directors, or a designated committee of its senior management.

Grievance means an expression of dissatisfaction about any matter other than an action, as "action" is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PHP level and access to the State Fair Hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

Quality of care grievance means a grievance filed because the enrollee believes that any aspect of the care or treatment that he or she received failed to meet accepted standards of health care and caused or could have caused harm to the enrollee.

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PHP must have a system that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *General requirements for the grievance system.* The MCO or PHP must—

(1) Base its grievance and appeal processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subpart;

(2) Obtain the State's written approval of the policies and procedures before implementing them;

(3) Provide for its governing body to approve and be responsible for the effective operation of the system;

(4) Provide for its governing body to review and dispose of grievances and resolve appeals, or make written delegation of this responsibility to a grievance committee;

(5) Ensure that punitive action is neither threatened nor taken against a provider who requests an expedited resolution, or supports an enrollee's grievance or appeal;

(6) Accept grievances and appeals, and requests for expedited disposition or resolution or extension of timeframes from the enrollee, from his or her representative, or from the provider acting on the enrollee's behalf and with the enrollee's written consent.

(7) Provide to the enrollee and to his or her representative the notices and information required under this subpart; and

(8) At the enrollee's request, refer for State review any quality of care grievance resolution with which the enrollee is dissatisfied.

(9) Require providers to give notice in accordance with § 438.404(d).

(c) *Filing requirements.*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may not file a grievance or request a State fair hearing.

(2) *Timing.* (i) For an action as defined in § 438.400 (b)(1)(v), the enrollee or the provider may file an appeal whenever the entity has delayed access to the service to the point where there is a substantial risk that further delay will adversely affect the enrollee's health condition.

(ii) For all other actions, the State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PHP's notice of action.

Within that timeframe—

(A) The enrollee or the provider may file an appeal; and

(B) In a State that does not require exhaustion of MCO and PHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(b) and (c) of this chapter to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) Any laws and rules that require or permit the action.

(4) The enrollee's or the provider's right to file an MCO or PHP appeal.

(5) The enrollee's right to request a State fair hearing.

(6) The enrollee's right to present evidence in person if he or she chooses.

(7) The procedures for exercising the rights specified in this paragraph.

(8) The circumstances under which expedited resolution is available and how to request it.

(9) The enrollees right to have benefits continue pending resolution of the appeal or issuance of a fair hearing decision, if the enrollee or the provider timely files the appeal or the enrollee timely requests a State fair hearing.

(10) The circumstances under which the enrollee may be required to pay the costs of any services furnished while the appeal is pending if the final outcome is an adverse decision.

(11) How the enrollee may request continuation of benefits.

(12) How to contact the MCO or PHP to receive assistance in filing an appeal or requesting a State fair hearing.

(13) How to obtain copies of enrollee records, including records other than medical records.

(14) That the enrollee has the right to represent himself or herself, to use legal counsel, or to use a relative, or friend or other individual as spokesperson.

(15) That filing an appeal or requesting a State fair hearing will not negatively affect or impact the way the MCO and the PHP and their providers, or the State agency, treat the enrollee.

(c) *Timing of notice.* Except as provided in paragraph (d) of this section, the MCO or PHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)

(4) If the MCO or PHP extends the timeframe in accordance with § 438.210(d), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the

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timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(e).

(d) *Special rule for subcontractors and providers who are not employees.* (1) An MCO or PHP may permit its subcontractors and providers who are not employees to give enrollees notice that includes only the information specified in paragraphs (b)(4) through (b)(15) of this section.

(2) If the MCO or PHP elects the option provided in paragraph (d)(1) of this section, and receives an appeal on any action by the subcontractor or provider who is not an employee, the MCO or PHP must, in acknowledging the appeal, include the information required under paragraphs (b)(1) through (b)(3) of this section.

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PHP must meet the following requirements:

(1) Have an adequately staffed office that is designated as the central point for enrollee issues, including grievances and appeals.

(2) Establish an appeals process that meets the requirements of paragraph (b) of this section.

(3) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(4) Ensure that the enrollee's communication is correctly classified as a "grievance" or an "appeal".

(5) Acknowledge receipt of each grievance and appeal.

(6) Ensure that each grievance and appeal—

(i) Is transmitted timely to staff who have authority to act upon it; and

(ii) Is investigated and disposed of or resolved in accordance with § 438.408.

(7) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must consist of clearly explained steps that meet the following requirements:

(1) Include, for each step, timeframes that take account of the enrollee's health condition and provide for expedited resolution in accordance with § 438.410.

(2) Provide that oral inquiries about the opportunity to appeal are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(3) Ensure that the acknowledgment of an oral appeal specifies that, although the time allowed for the MCO or PHP to resolve the appeal has begun, unless the request is for expedited resolution, the MCO or PHP cannot complete the resolution until the enrollee or the provider submits the appeal in writing.

(4) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as well as in writing. (The MCO or PHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(5) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Basis for decision.* The MCO or PHP must base the decision on the record of the case, including all relevant Federal and State statutes, program regulations and policies, and any evidence presented under § 438.406(b)(4), in connection with the filing of the appeal.

(c) *Specific timeframes.*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PHP receives the grievance.

(2) *Expedited disposition of grievances.* For a grievance on a denial of a request to expedite resolution of an appeal, the timeframe is 72 hours after receipt of the grievance.

(3) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the timeframe is 30 days after the MCO or the PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(4) *Expedited resolution of appeals.* For expedited resolution of an appeal, the timeframe for resolution and notice to the enrollee is 72 hours after the MCO or PHP receives the appeal. This timeframe may be extended under paragraph (d) of this section.

(d) *Extension of timeframes.*—(1) *Limits on extension.* (i) For a grievance on denial of a request to expedite resolution of an appeal, the timeframe may not be extended.

(ii) For expedited resolution of an appeal, the MCO or PHP may extend the 72-hour timeframe by up to 14 calendar days only if the enrollee requests extension.

(iii) For standard resolution of an appeal or for a quality of care grievance, the MCO or PHP may extend the 30-day timeframe for up to 14 calendar days if—

(A) The enrollee requests extension; or

(B) The MCO or PHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PHP extends the timeframes, it must—

(i) For any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay and of the enrollee's right to file a grievance if he or she disagrees with the decision to extend the timeframe; and

(ii) For any extension, dispose of the grievance or resolve the appeal no later than the date on which the extension expires.

(e) *Format of notice*—(1) *Grievances.* (i) For all written grievances and all grievances that relate to quality of care, the MCO or PHP must provide a written notice of disposition.

(ii) For an oral grievance that does not relate to quality of care, the MCO may provide oral notice unless the enrollee requests that it be written.

(2) *Appeals.* (i) For all appeals, the MCO or PHP must provide written notice of disposition.

(ii) For notice of expedited resolution, the MCO or PHP must also provide oral notice.

(f) *Content of notice of MCO or PHP grievance disposition.* The written notice must explain the following:

(i) The disposition of the grievance.

(ii) The fact that, if dissatisfied with the disposition of a quality of care grievance, the enrollee has the right to seek further State review, and how to request it.

(g) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The title of the MCO or PHP contact for the appeal.

(2) The results of the resolution process and the date it was completed.

(3) A summary of the steps the MCO or the PHP has taken on the enrollee's behalf in resolving the issue.

(4) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State Fair Hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PHP's action.

(h) *Collaboration on State review of grievances.* The MCO or PHP must work with the State to dispose of the grievance if the State considers that the MCO or PHP response was insufficient.

(i) *Referral of adverse or delayed appeal decisions to the State Fair Hearing Office*—(1) *Basis for submission.* The MCO or PHP must submit to the State Fair Hearing Office the file and all supporting documentation—

(i) For any appeal that was subject to expedited resolution and for which the MCO or PHP—

(A) Reaches a decision that is wholly or partially adverse to the enrollee; or

(B) Fails to reach a decision within the timeframes specified in paragraph (i)(2) of this section.

(ii) For any appeal that was not expedited, at the request of the State.

(2) *Timeframes for decision*—(i) *Standard resolution.* For a standard resolution, the basic timeframe is 30 days from receipt of the appeal, and may be extended for an additional 14 calendar days if the enrollee requests extension or the MCO or PHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(ii) *Expedited resolution.* For an expedited resolution, the basic timeframe is 72 hours from receipt of the appeal and may be extended for up to 14 calendar days, but only if the enrollee requests extension.

(3) *Timeframes for submission.* The timeframes for submission to the State Fair Hearing Office are as follows:

(i) For a standard resolution: 72 hours after the MCO or PHP receives the State's request.

(ii) For an expedited resolution: 24 hours after the MCO or PHP reaches an adverse decision, or the basic or extended timeframe for decision expires.

(j) *Requirements for State fair hearings*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days if—

(i) The State requires exhaustion of the MCO or PHP level appeal procedures, from the date of the MCO's or PHP's notice of resolution; and

(ii) The State does not require exhaustion of the MCO or PHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

(3) *Timeframes for decision.* The State agency must take final administrative action as follows:

(i) Other than as specified in paragraph (j)(3)(ii) of this section, within a period of time not to exceed 90 days minus the number of days taken by the MCO or PHP to resolve the internal appeal. This timeframe begins on the date the State receives the beneficiaries' request for a State Fair Hearing.

(ii) For service authorization appeals that meet the criteria for expedited resolution as set forth in § 438.410, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of a fair hearing request from the enrollee, or the file from the MCO or PHP.

§ 438.410 Expedited resolution of grievances and appeals.

(a) *General rule.* Each MCO and PHP must establish and maintain an expedited review process for grievances and appeals.

(b) *Requirements for grievances.* (1) The MCO or PHP must expedite disposition of grievances that pertain to denial of a request for expedited resolution of an appeal.

(2) The MCO or PHP may expedite disposition of other grievances, consistent with State guidelines.

(c) *Requirements for appeals.* Each MCO and PHP must meet the following requirements with respect to appeals:

(1) Establish a convenient and efficient means for an enrollee or a provider to request expedited resolution of an appeal;

(2) Provide expedited resolution of an appeal in response to an oral or written request if the MCO or PHP determines (with respect to a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(3) Document all oral requests in writing; and

(4) Maintain the documentation in the case file.

(d) *Action following denial of a request for expedited resolution.* If the MCO or PHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution, beginning the 30-day period as of the day it received the request for expedited resolution;

(2) Give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice that includes the following:

(i) Informs the enrollee of the right to—

(A) File a grievance if he or she is dissatisfied with the MCO's or PHP's decision not to expedite resolution of the appeal; or

(B) Resubmit the request with a provider's letter of support.

(ii) Explains that—

(A) If the enrollee files a grievance, the MCO or PHP will process the appeal using the 30-day timeframe for standard resolution; and

(B) If the enrollee resubmits the request with a provider's letter of support, the MCO or PHP will expedite resolution of the appeal.

(iii) Provides instructions about grievance procedures, including timeframes.

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§ 438.414 Information about the grievance system.

(a) *To whom information must be furnished.* (1) Each MCO and PHP must provide the information specified in paragraph (b) of this section to enrollees and to all providers and subcontractors at the time they enter into a contract.

(2) Each MCO or PHP or, at State option, the State or its contracted representative must provide the information specified in paragraph (b) to all potential enrollees.

(b) *Required information.* The information that is provided under paragraph (a) of this section must explain the grievance system through a State-developed or State-approved description, in the format required under § 438.10(c), and must include the following:

(1) With respect to State fair hearing—

(i) The right to hearing;

(ii) The method for obtaining a hearing; and

(iii) The rules that govern representation at the hearing.

(2) The right to file grievances and appeals.

(3) The requirements and timeframes for filing a grievance or appeal.

(4) The availability of assistance in the filing process.

(5) The right to represent himself or herself or to be represented by legal counsel or a relative or friend or other spokesperson.

(6) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(7) The fact that filing a grievance or appeal or requesting a State fair hearing will not adversely affect or impact the way the MCO or the PHP and their providers or the State agency treat the enrollee.

(8) The fact that, when requested by the enrollee

(i) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(ii) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(c) *Language, format, and timing requirements.* The information furnished under this section must meet the language and format requirements of § 438.10(b) and (c), and must be furnished to enrollees and potential enrollees at the times specified in § 438.10(e) through (h).

(d) *Aggregate information.* Upon request, the MCO or PHP must provide to enrollees, potential enrollees, and the general public, aggregate information based on the information required under § 438.416(d).

§ 438.416 Record keeping and reporting requirements.

Each MCO and PHP must comply with the following requirements, and in so doing must also comply with the confidentiality requirements of § 438.224.

(a) *Log.* Maintain a log of all grievances and appeals, showing the date of acknowledgment, the MCO's or PHP's decision, and the date of disposition or resolution.

(b) *Tracking.* Track each grievance and appeal until its final disposition or resolution, and classify them in terms of whether the disposition or resolution was standard or expedited.

(c) *Retention of records.* (1) Retain the record of each grievance and appeal, and its disposition or resolution in a central location, and accessible to the State, for at least 3 years.

(2) If any litigation, claim negotiation, audit, or other activity involving these records is initiated before the end of the 3-year period, retain the record until the later of the following:

(i) The date the activity is completed and any issues arising from it are resolved.

(ii) The end of the 3-year period.

(d) *Reporting.* As often as the State requests, but at least once a year, each MCO and PHP must analyze the records maintained under this paragraph and submit to the State a summary that includes the following information:

(1) The number and nature of all grievances and appeals.

(2) The timeframes within which they were acknowledged and disposed of or resolved.

(3) The nature of the decisions.

§ 438.420 Continuation of benefits while the MCO or PHP appeal and the State Fair Hearing are pending.

(a) *Terminology.* As used in this section, "timely" filing means filing on or before the later of the following:

(1) The expiration of the timeframe specified by the State (in accordance with § 438.404(c)(3)) and communicated in the notice of action.

(2) The intended effective date of the MCO's or PHP's proposed action.

(b) *Continuation of benefits.* The MCO or PHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The period covered by the authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Reinstatement of benefits.* The MCO or PHP must reinstate the enrollee's benefits under any of the circumstances specified in § 431.231 of this chapter.

(d) *Duration of continued or reinstated benefits.* If the MCO or PHP continues or reinstates the enrollee's benefits while the appeal is pending, the following rules apply:

(1) The MCO or PHP must continue the benefits until one of the following occurs:

(i) The enrollee withdraws the appeal.

(ii) The MCO or PHP resolves the appeal in the enrollee's favor.

(iii) The State Fair Hearing Office issues a hearing decision on a request received directly from the enrollee or referred by the MCO or PHP.

(2) If the MCO or PHP appeals the decision or the State fair hearing decision is favorable to the enrollee, the MCO or PHP must restore regular benefits.

(e) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PHP's action, the MCO or PHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO or PHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PHP or the State must pay for those services, in accordance with State policy and regulations.

§ 438.426 Monitoring of the grievance system.

(a) *Basis for monitoring.* The records that the MCOs and PHPs are required to maintain and summarize under § 438.416 provide the basis for monitoring by the MCO or PHP, and by the State.

(b) *Responsibility for corrective action.* If the summaries required under paragraph (d) of § 438.416 reveal a need for changing the system, the MCO or the PHP must conduct an in-depth review, and take corrective action.

Subpart G—[Reserved]

Subpart H—Certifications and Program Integrity Provisions

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4) and 1902(a)(19) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

§ 438.602 Basic rule.

As a condition for contracting and for receiving payment under the Medicaid managed care program, an MCO or PHP and its subcontractors must comply with the certification and program integrity requirements of this section.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to the MCO or PHP are based on data submitted by the MCO or PHP, the State must require certification of the data as provided in § 438.606. The data that must be certified includes, but is not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Certification of substantial compliance with contract.* Regardless of whether payment is based on data, each MCO and PHP must certify that it is in substantial compliance with its contract.

(c) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* With respect to the data specified in § 438.604, the MCO or PHP must require—

(1) That subcontractors certify the data they submit to the MCO or PHP; and

(2) That one of the following certify the data the MCO or PHP submits to the State:

(i) The MCO's or PHP's Chief Executive Officer.

(ii) The MCO's or PHP's Chief Financial Officer.

(iii) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of data.

(2) That the MCO or PHP is in substantial compliance with its contract.

(3) To the accuracy, completeness and truthfulness of documents specified by the State.

(c) *Timing of certification.* The MCO or PHP must submit the certification concurrently with the certified data or, in the case of compliance with the terms of the contract, when requesting payment.

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision of internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PHP's contract.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State's determination may be based on findings from onsite survey, enrollee or other complaints, financial status, or any other source.

(b) An MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to HCFA or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) An MCO or a PCCM distributes directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) An MCO violates any of the requirements in section 1903(m) of the Act and implementing regulations, or an MCO or a PCCM violates any of the requirements of section 1932 of the Act and implementing regulations. (For these violations, only the sanctions specified in § 438.702(a)(4) and (a)(5) may be imposed.)

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management as provided in § 438.706. (The State may not impose this sanction on a PCCM.)

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(3) Granting enrollees the right to terminate enrollment without cause. (The State must notify the affected enrollees of their right to disenroll.)

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until HCFA or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties

(a) *General rule.* The limit on, or specific amount of, a civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to HCFA or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that —

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act;

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* (1) The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3).

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM—

(a) Has failed to carry out the substantive terms of its contract; or

(b) Has failed to meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Before imposing any of the alternative sanctions specified in this subpart, the State must give the affected entity timely written notice that explains—

(1) The basis and nature of the sanction; and

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing.*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pretermination hearing.

(2) *Procedures.* The State must—

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may—

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract; and

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Public notice of sanction.

(a) *Content of notice.* The State must publish a notice that describes the intermediate sanction imposed, explains the reasons for the sanction and specifies the amount of any civil money penalty.

(b) *Publication of notice.* The State must publish the notice—

(1) No later than 30 days after it imposes the sanction; and

(2) As a public announcement in—

(i) The newspaper of widest circulation in each city within the MCO's service area that has a population of 50,000 or more; or

(ii) The newspaper of widest circulation in the MCO's service area, if there is no city with a population of 50,000 or more in that area.

§ 438.726 State plan requirement.

The State plan must provide for the State to monitor for violations that involve the actions and failures to act specified in this section and to implement the provisions of this section.

§ 438.730 Sanction by HCFA: Special rules for MCOs with risk contracts.

(a) *Basis for sanction.* (1) A State agency may recommend that HCFA impose the denial of payment sanction on an MCO with a comprehensive risk contract if the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(2) The State agency's recommendation becomes HCFA's recommendation unless HCFA rejects it within 15 days of receipt.

(b) *Notice of sanction.* If HCFA accepts the recommendation, the State agency and HCFA take the following actions:

(1) The State agency—

(i) Gives the MCO written notice of the proposed sanction;

(ii) Allows the MCO 15 days from date of receipt of the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(iii) May extend the initial 15-day period for an additional 15 days if, before the end of the initial period, the MCO submits a written request that includes a credible explanation of why it needs additional time; and

(iv) May not grant an extension if HCFA determines that the MCO's conduct poses a threat to an enrollee's health or safety.

(2) HCFA conveys the determination to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties in addition to, or in place of, the sanctions that may be imposed under this section.

(c) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation; and

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(2) The State agency decision under paragraph (c)(1) of this section, forwarded to HCFA, becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from date of receipt.

(3) If HCFA reverses or modifies the State agency decision, the agency sends the MCO a copy of HCFA's decision.

(d) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date of the notice of sanction under paragraph (b) of this section.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(ii) If HCFA, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, HCFA may make the sanction effective earlier than the date of HCFA's reconsideration decision under paragraph (c) of this section.

(e) *HCFA's role.* HCFA retains the right to independently perform the functions assigned to the State agency under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the following conditions are met:

(a) The contract—

(1) Meets the requirements of this part; and

(2) Is in effect.

(b) The MCO and its subcontractors are in substantial compliance with the physician incentive plan requirements set forth in §§ 422.208 and 422.210 of this chapter.

(c) The MCO and the State are in substantial compliance with the requirements of the MCO contract and of this part.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of MCO or is one of the entities described in paragraphs (a)(2) through (a)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by HCFA is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from HCFA under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from such contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person; and

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered "independent" if it—

(i) Is an MCO, PHP, PCCM or other health care provider in the State

(ii) Is owned or controlled by an MCO, PHP, PCCM, or other health care provider in the State; or

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(iii) Owns or controls an MCO, PHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(c) *Prior approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by HCFA before the effective date of the contract or MOA.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

§ 438.814 Limit on payments in excess of capitation rates.

FFP is not available for payments pursuant to risk corridors or incentive arrangements that exceed 105 percent of that portion of the aggregate amount approved capitation payments attributable to the enrollees or services covered by the risk corridor or incentive management.

PART 440—SERVICES: GENERAL PROVISIONS

1. The statutory citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In subpart A, a new § 440.168 is added, to read as follows:

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the regular State plan program; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

PART 447—PAYMENTS FOR SERVICES

1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. A new § 447.46 is added, to read as follows:

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* "Claim" and "clean claim" have the meaning given those terms in § 447.45.

(c) *Contract requirements.*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of paragraphs (d)(2), (d)(3) of § 447.45, and abide by the specifications of paragraphs (d)(5) and (d)(6) of that section..

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) Any alternative schedule must be stipulated in the contract.

§ 447.53 [Amended]

3. In § 447.53(b), the following changes are made:

A. In paragraph (b) introductory text, the parenthetical phrase is removed.

B. Paragraph (b)(6) is removed.

4. A new paragraph (e) is added to read as follows:

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

§ 447.58 [Amended]

5. In § 447.58, "Except for HMO services subject to the copayment exclusion in § 447.53(b)(6), if " is removed and "If" is inserted in its place.

6. A new § 447.60 is added to subpart A to read as follows:

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

§ 447.361 [Removed]

Section 447.361 is removed.

(Catalog of Federal Domestic Assistance Program No. 93778, Medical Assistance)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 20, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01–1447 Filed 1–18–01; 8:45 am]

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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 330

RIN 3206–AI28

Federal Employment Priority Consideration Program for Displaced Employees of the District of Columbia Department of Corrections

AGENCY: U.S. Office of Personnel Management.

ACTION: Interim regulations with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing interim regulations to implement provisions of law affecting the priority consideration program for certain displaced employees of the District of Columbia Department of Corrections seeking Federal positions. These regulations also incorporate comments and suggestions received on the interim regulations OPM published on August 4, 1998.

DATES: This interim regulation is effective on January 22, 2001. Written comments will be considered if received no later than March 23, 2001.

ADDRESSES: Send or deliver written comments to: Carol J. Okin, Associate Director for Employment, Office of Personnel Management; Suite 6500, 1900 E Street NW., Washington, DC 20415–9000.

FOR FURTHER INFORMATION CONTACT: Jacqueline Yeatman on (202) 606–0960, FAX (202) 606–2329, TDD (202) 606–0023 or by email at jryeatma@opm.gov.

SUPPLEMENTARY INFORMATION:

Initial Public Law and Regulations

The National Capital Revitalization and Self-Government Improvement Act (part of the Balanced Budget Act of 1997, sec. 11201, Pub. L. 105–33, 111 Stat. 738, enacted August 5, 1997) mandated that the Lorton Correctional Complex be closed by December 31, 2001. Section 11203 of this law gave priority consideration to employees of the District of Columbia (DC) Department of Corrections (DOC) displaced by this closure. The law established two priority consideration programs—one for vacant Bureau of Prisons law enforcement positions (for employees meeting the qualification and suitability requirements for those positions), and another for most other Federal vacancies. The Department of Justice maintains the priority consideration program for displaced Department of Corrections employees interested in Federal Bureau of Prisons law enforcement positions.

On August 4, 1998, OPM issued interim regulations with request for comment to implement the Priority Consideration Program covering most vacancies in Federal agencies. Under the interim regulations, present and former DC DOC employees receiving a reduction in force (RIF) separation notice from the DC Government issued after August 7, 1997, were eligible for priority consideration when applying for certain vacant competitive service positions in Federal Executive Branch agencies (unless they had been appointed to a law enforcement position in the Department of Justice Bureau of Prisons). In order to receive this priority, the DC DOC employee had to apply and be found well-qualified. This priority consideration was similar to the program for Federal employees described in 5 CFR part 330, subpart G—Interagency Career Transition Assistance Plan (ICTAP) for Displaced Employees. The law provided that this program would expire one year after closure of the Lorton correctional complex.

Second Public Law

After we published the interim regulations, President Clinton signed the District of Columbia Courts and Justice Technical Corrections Act of 1998 (Pub. L. 105–274) on October 21, 1998. This law contained several major changes affecting the Priority Consideration Program covering most Federal vacancies. One significant change was elimination of the requirement that DC Corrections employees be "well-qualified" to get priority. The other major change in the law was the establishment of a competitive service appointing authority for DC DOC appointees hired through this program.

As a result of this second statute, agencies *must:* (1) Make all new appointments under this program into the competitive service; and (2) retroactively convert/correct appointments of those already hired into competitive service appointments. Because of these significant statutory changes, we have modified these regulations and are reissuing them in interim form with request for comments. This will allow for timely implementation while giving users the opportunity to submit any concerns or questions they may have about the revised regulations.

Comments Received on Initial Regulations Issued

After OPM published the initial regulations in August, 1998, we received comments from three Federal agencies. Two agencies noted the issue of the order of selection as it applies to this program. The interim regulations stated, in § 330.1103(d), that the priority and order of selection for this program are similar to ICTAP (the order of selection and exceptions to ICTAP appear in § 330.705). The commenting agencies believed the exceptions to this program, and the relationship to ICTAP priority, needed clarification. We have therefore attempted to clarify this issue in § 330.1103 of these regulations. In addition, the current ICTAP regulations, issued on July 27, 1999, include a cross-reference in § 330.705 that specifically mentions the DC DOC program.

Two agencies asked about the relationship between meeting the requirements for a Federal Bureau of Prisons (BOP) law enforcement position and this program. These agencies would prefer that OPM restrict DC DOC employees to priority under only one program at a time. However, the second public law includes a specific provision making DC DOC employees not yet "appointed to a Federal Bureau of Prisons law enforcement position" eligible for this program. A DC DOC employee would meet this definition up until actual appointment to a BOP law enforcement position. Therefore, we have revised § 330.1101 accordingly, and eliminated paragraph (b) of § 330.1103.

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Another agency asked whether an employee receiving a *time-limited* appointment to a BOP law enforcement position would lose the right to priority under this program. We believe that Congress intended to assist displaced DC DOC employees in securing *permanent* employment, either in a BOP law enforcement position or in another Federal position. Therefore, we are modifying § 330.1101 to make a DC DOC employee eligible for selection priority under this program until appointed to a *permanent* BOP law enforcement position. This means that a former DC DOC employee could accept a time-limited law enforcement position with the Bureau of Prisons, while still exercising the right to selection priority under these regulations for other Federal employment.

One agency objected to the fact that employees under this program receive priority for vacancies nationwide, and potentially for more than one year, while priority under ICTAP is limited to a single commuting area and to one year. Several agencies were concerned that they might be required to pay employee relocation costs, even in cases where they lack the resources to do so. The statute for this program, however, is broad, and precludes us from limiting the area of consideration or the length of eligibility. Therefore, we have not changed these provisions in this regulation. However, we did find that some of the references to the program termination date in the initial regulation did not precisely match the language in the law. Therefore, we have modified references to the program termination date in sections 330.1102 and 330.1106 to better reflect the statutory language. Since the current statute requires DC to close the Lorton Correctional Complex by December 31, 2001, we expect this program to expire on December 31, 2002, at the latest.

Two agencies raised additional questions, including: (1) Will OPM impose any additional requirements for agency reports or vacancy announcements? (2) are competitive service vacancies lasting 120 days or less covered by this program? (3) are there any grade-level requirements? (4) are DC DOC employees required to submit a current performance appraisal? (5) if an employee declines a permanent offer under this program, will they lose their eligibility? and (6) does this program require a second review of applicants when they are found ineligible for priority?

OPM considered imposing additional requirements for announcements or agency reporting for this program, but decided against it. The current regulations under section 330.102 require agencies to notify OPM of competitive service vacancies lasting 121 days or more. Therefore, we have added a similar definition of a "vacancy" to these regulations. As for the grade level requirements, differences in the DC Government employment system make it impractical to impose grade level and performance appraisal requirements for applicants under this program. We believe the requirement to be "qualified" will screen out candidates with insufficient experience. We do, however, agree with the commenters that we need to address what happens when a candidate declines a job offer; such a provision already exists under ICTAP. Therefore, we are adding language (mirroring the ICTAP) allowing agencies to terminate their future consideration of a candidate under this program if he/she declines, or fails to respond to, a firm offer. We also agree that it is important to have a second review when an applicant initially fails to meet the program requirements. Therefore, we have added this provision to these regulations.

Other Issues Addressed

While we were developing these regulations, two agencies asked us to address some additional questions: (1) Are DC DOC employees entitled to priority under these regulations for *non-law enforcement* jobs in the Bureau of Prisons? and (2) Is the DC DOC employee required to submit proof of their eligibility for priority like ICTAP candidates? We clarified these issues by: (1) Adding language based on the original law to the definition of vacancy in § 330.1103 to clarify which Bureau of Prisons positions are covered; and (2) adding language to § 330.1104(a)(3) requiring applicants to provide proof of their eligibility under this subpart.

One additional issue surfaced during the development of this regulation. A number of DC DOC managers and supervisors were moved into positions in the newly created Management Supervisory Service (MSS), making them, in effect, at-will employees. As a result, these employees would be separated by non-RIF termination procedures under the Lorton closure. We consulted with DC Government to find the best way to clarify the continuing eligibility of these employees for this priority consideration program, and modified section 330.1104 accordingly.

Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

Pursuant to 5 U.S.C. 553(b)(3)(B), I find that good cause exists for waiving the general notice of proposed rulemaking because it would be contrary to the public interest to delay access to benefits provided by law. Also, pursuant to 5 U.S.C. 553(d)(3), I find that good cause exists to waive the delay in the effective date and make this amendment effective in less than 30 days. The delay in the effective date is being waived to give effect to the benefits extended by the amended provisions at the earliest practicable date.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it pertains only to Federal agencies.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

List of Subjects in 5 CFR Part 330

Armed forces reserves, Government employees.

U.S. Office of Personnel Management.

Janice R. Lachance,

Director.

Accordingly, OPM is amending part 330 of title 5, Code of Federal Regulations, as follows:

PART 330—RECRUITMENT, SELECTION, AND PLACEMENT (GENERAL)

1. The authority citation for part 330 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3301, 3302; E.O. 10577, 3 CFR 1954–58 Comp., p. 218; § 330.102 also issued under 5 U.S.C. 3327; subpart B also issued under 5 U.S.C. 3315 and 8151; § 330.401 also issued under 5 U.S.C. 3310; subpart G also issued under 5 U.S.C. 8337(h) and 8457(b); subpart K also issued under sec. 11203 of Pub. Law 105–33 (111 Stat. 738) and Pub. Law 105–274 (112 Stat. 2424); subpart L also issued under sec. 1232 of Pub. L. 96–70, 93 Stat. 452.

2. Section 330.1101 is revised to read as follows:

§ 330.1101 Purpose.

A displaced employee of the District of Columbia (DC) Department of Corrections (DOC) who is separated from his/her position as a result of the closure of the Lorton Correctional Complex, and who has not been appointed to a permanent Federal Bureau of Prisons law enforcement position, is entitled to priority consideration for other Federal vacancies when he/she applies and is found qualified.

3. Section 330.1102 is revised to read as follows:

§ 330.1102 Duration.

This program terminates 1 year after the closing of the Lorton Correctional Complex.

4. Paragraph (b) of § 330.1103 is removed and paragraphs (c), (d) and (e) are redesignated as paragraphs (b), (c) and (d) and revised to read as follows:

§ 330.1103 Definitions.

* * * * *

(b) *Vacancy* means any competitive service position, including non-law enforcement positions in the Federal Bureau of Prisons, to be filled for a total of 121 days or more, including all extensions, regardless of whether the agency issues a specific vacancy announcement. This program does not apply to law enforcement positions covered by the Federal Bureau of Prisons Priority Consideration Program.

(c) *Priority consideration* means that a displaced DC DOC employee eligible under this subpart who applies for a vacancy and is determined to be qualified, is accorded similar priority and order of selection as an eligible current or former displaced Federal employee under 5 CFR part 330, subpart G—Interagency Career Transition Assistance for Displaced Employees. Actions which are exempt from the requirements of 5 CFR part 330 subpart G will also be exempt from the requirements of this subpart. Agencies must follow the order of selection in § 330.705(a) in filling vacancies in the Federal Government with candidates from outside their own workforce. DC DOC employees are eligible for this priority consideration without regard to any geographical restrictions.

(d) *Qualified* means an eligible employee who:

(1) Possesses the knowledge, skills, and abilities which meet the basic qualification standards and eligibility requirements for the position, including any medical qualifications, suitability, citizenship, minimum educational and experience requirements, and any applicable selective factors;

(2) Is physically qualified, with reasonable accommodation where appropriate, to perform the essential duties of the position;

(3) Meets any special qualifying condition(s) that OPM has approved for the position; and

(4) Is able to satisfactorily perform the duties of the position upon entry.

5. In § 330.1104, paragraphs (a)(1), (a)(2), (a)(3), (a)(4), (b), (c)(2), (c)(4) and (c)(5) are revised, and a new paragraph (c)(6) is added to read as follows:

§ 330.1104 Eligibility.

(a)* * *

(1) Be in receipt of a RIF separation notice, or a similar notice of non-disciplinary termination from the Management Supervisory Service, issued by the DC Department of Corrections in connection with the closure of the Lorton Correctional Complex.

(2) Have not been appointed to a permanent Federal Bureau of Prisons law enforcement position;

(3) Apply for a vacancy within the time frames established by the agency, and include proof of eligibility;

(4) Be found qualified for the specific vacancy.

(b) *Eligibility for priority consideration begins:* on the date the DC DOC employee receives or is issued a specific RIF separation notice, or a similar notice of non-disciplinary termination from the Management Supervisory Service (MSS), issued by the DC DOC due to the closure of the Lorton Correctional Complex.

(c) * * *

(2) When the DC DOC employee is no longer being separated by RIF, or by similar non-disciplinary termination from the Management Supervisory Service, due to the closure of the Lorton Correctional Complex;

* * *

(4) When the DC DOC employee voluntarily separates by resignation or retirement prior to the RIF effective date or the non-disciplinary MSS termination date;

(5) When the DC DOC employee is separated by a non-RIF involuntary separation or disciplinary or other MSS termination not related to the closure of the Lorton correctional complex; or

(6) Eligibility within a specific agency may terminate if the employee:

(i) Declines a permanent appointment offered by the agency (whether competitive or excepted) when the employee applied and was found qualified; or

(ii) Fails to respond within a reasonable period of time to an offer or official inquiry of availability from the agency.

6. Section 330.1105 is revised to read as follows:

§ 330.1105 Selection.

(a) If two or more individuals eligible for priority under subpart G of this part (the Interagency Career Transition Assistance Plan), under subpart K of this part (Federal Employment Priority Consideration for Displaced Employees of the District of Columbia Department of Corrections), and/or under subpart L of this part (Interagency Career Transition Assistance for Displaced Former Panama Canal Zone Employees) apply for a vacancy and are eligible for priority, the agency has the discretion to select any of the individuals.

(b) Agencies will conduct a documented, independent second review whenever an otherwise eligible employee fails to meet the "qualified" requirement. The applicant must be advised in writing of the results of the second review.

7. The heading and paragraphs (a) and (b) of § 330.1106 are revised to read as follows:

§ 330.1106 Appointment.

(a)(1) Selectees under this subpart receive noncompetitive appointments to the competitive service under the authority of Public Law 105–274, enacted October 21, 1998.

(2) Agencies must retroactively and noncompetitively convert or correct any excepted appointments made under section 11203(b) of Public Law 105–33 to competitive service appointments under Public Law 105–274. For employees appointed before October 21, 1998, the conversion will be effective on October 21, 1998. For employees appointed on or after October 21, 1998, agencies must correct the record to reflect competitive service appointment as of the original appointment date.

(b) Eligibility for appointment under this subpart expires 1 year after the closing of the Lorton Correctional Complex.

[FR Doc. 01–1487 Filed 1–19–01; 8:45 am]

BILLING CODE 6325–01–U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 00–110–1]

West Indian Fruit Fly

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are quarantining part of Cameron County, TX, because of the West Indian fruit fly and restricting the interstate movement of regulated articles from the quarantined area. This action is necessary on an emergency basis to prevent the spread of the West Indian fruit fly to noninfested areas of the United States.

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DATES: This interim rule was effective January 12, 2001. We invite you to comment on this docket. We will consider all comments that we receive by March 23, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 00–110–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 00–110–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Spaide, Assistant Director, Invasive Species and Pest Management, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

We are amending the "Domestic Quarantine Notices" in 7 CFR part 301 by adding a new subpart, "West Indian Fruit Fly" (§§ 301.98 through 301.98–10, referred to below as the regulations). The regulations quarantine part of Cameron County, TX, because of the West Indian fruit fly and restrict the interstate movement of regulated articles from the quarantined area.

The West Indian fruit fly, *Anastrepha obliqua* (Macquart), is a very destructive pest of fruits and vegetables, including carambola, grapefruit, guava, limes, mangoes, oranges, passion fruit, peaches, and pears. This pest can cause serious economic losses by lowering the yield and quality of these fruits and vegetables and, in some cases, by damaging seedlings and young plants. Heavy infestations can result in complete loss of these crops.

Recent trapping surveys near Rio Hondo, TX, have established that part of Cameron County is infested with the West Indian fruit fly.

Officials of the Animal and Plant Health Inspection Service (APHIS) and State and county agencies in Texas have begun an intensive survey and eradication program in the infested area. Also, as explained below, Texas has restricted the intrastate movement of certain articles from the infested area to prevent the spread of the West Indian fruit fly within Texas. However, Federal regulations are necessary to restrict the interstate movement of certain articles from the infested area to prevent the spread of the West Indian fruit fly to noninfested areas of the United States. This interim rule establishes those Federal regulations, which are described below.

Section 301.98—Restrictions on Interstate Movement of Regulated Articles

Section 301.98 prohibits the interstate movement of regulated articles from quarantined areas except in accordance with the regulations.

Section 301.98–1—Definitions

Section 301.98–1 contains definitions of the following terms: *Administrator, Animal and Plant Health Inspection Service, certificate, compliance agreement, core area, day degrees, Departmental permit, dripline, infestation, inspector, interstate, limited permit, moved (move, movement), person, Plant Protection and Quarantine, quarantined area, regulated articles, State,* and *West Indian fruit fly.*

Section 301.98–2—Regulated Articles

Certain articles present a significant risk of spreading the West Indian fruit fly if they are moved from quarantined areas without restrictions. We call these articles regulated articles. Paragraphs (a) through (e) of § 301.98–2 list the following as regulated articles:

- The West Indian fruit fly;
- Certain fruits and vegetables (fruits or vegetables that are canned or dried or that are frozen below −17.8 °C (0 °F) are exempted, since the West Indian fruit fly cannot survive such processing);
- Soil within the dripline of plants that produce those fruits or vegetables; and
- Any other product, article, or means of conveyance that an inspector determines to present a risk of spreading the West Indian fruit fly when the inspector notifies the person in possession of the product, article, or means of conveyance that it is subject to the restrictions in the regulations.

The last item listed above, which provides for the designation of "any other product, article, or means of conveyance" as a regulated article, is intended to address the risks presented by, for example, a truck with West Indian fruit fly pupae in the cracks of its floorboards, thus enabling an inspector to designate that truck as a regulated article in order to ensure that any necessary risk-mitigating measures are carried out.

Section 301.98–3—Quarantined Areas

Paragraph (a) of § 301.98–3 provides the criteria for the inclusion of States, or portions of States, in the list of quarantined areas. Under these criteria, any State or portion of a State in which the West Indian fruit fly is found by an inspector, or in which the Administrator has reason to believe that the West Indian fruit fly is present, will be listed as a quarantined area. These criteria also provide that an area will be designated as a quarantined area when the Administrator considers it necessary due to the area's inseparability for quarantine enforcement purposes from localities in which the West Indian fruit fly has been found.

Paragraph (a) of § 301.98–3 also provides that we will designate less than an entire State as a quarantined area only if we determine that the State has adopted and is enforcing restrictions on the intrastate movement of regulated articles that are equivalent to those imposed on the interstate movement of regulated articles and that the designation of less than the entire State as a quarantined area will prevent the interstate spread of the West Indian fruit fly. These determinations would indicate that infestations are confined to the quarantined areas and eliminate the need for designating an entire State as a quarantined area.

The boundary lines that delimit the portion of a State that is designated as a quarantined area are set up approximately 4.5 miles from the locations where West Indian fruit fly has been detected. The 4.5 mile radius distance for regulated areas from the trapping sites for West Indian fruit fly is based upon several factors, including: Previous experience with fruit fly eradication programs, estimated efficacy of trapping grids, available data on natural dispersal, and recommendations from fruit fly experts familiar with the biology and behavior of the West Indian fruit fly. The boundary lines may vary due to factors such as the location of West Indian fruit fly host material, the location of transportation centers such as bus stations and airports, the pattern of persons moving in that State, the number and patterns of distribution of the West Indian fruit fly, and the use of clearly identifiable lines for the boundaries.

We have determined that it is not necessary to designate the entire State of Texas as a quarantined area. The West Indian fruit fly has not been found in any area of the State other than a portion of Cameron County, and Texas has adopted and is enforcing restrictions on the intrastate movement of regulated articles from that area that are substantially the same as those we are imposing on the interstate movement of regulated articles. Therefore, in accordance with the criteria described in the previous paragraph, we have designated part of the Rio Hondo area of Cameron County, TX, as a quarantined area. The boundaries of the quarantined area are described in § 301.98–3(c) in the rule portion of this document.

Paragraph (b) of § 301.98–3 provides that we may temporarily designate any nonquarantined area in a State as a quarantined area when we determine that the nonquarantined area meets the criteria for designation as a quarantined area described in § 301.98–3(a). In such cases, we will give the owner or person in possession of the area a copy of the regulations along with written notice of the area's temporary designation as a quarantined area, after which time the interstate movement of any regulated article from the area will be subject to the regulations. This provision is necessary to prevent the spread of the West Indian fruit fly during the time between the detection of the pest and the time a document quarantining the area can be made effective and published in the **Federal Register**. In the event that an area's designation as a temporary quarantined area is terminated, we will provide written notice of that termination to the owner or person in possession of the area as soon as is practicable.

Section 301.98–4—Conditions Governing the Interstate Movement of Regulated Articles from Quarantined Areas

This section requires most regulated articles moving interstate from quarantined areas to be accompanied by a certificate or a limited permit. APHIS or the U.S. Department of Agriculture (the Department) may move regulated articles interstate without a certificate or limited permit if the articles are moved for experimental or scientific purposes. However, the articles must be moved in accordance with a Departmental permit issued by the Administrator, under conditions specified on the permit to prevent the spread of the West Indian fruit fly.

Except for articles moved by APHIS or the Department, only articles that are moved into the quarantined area from outside the quarantined area and that are accompanied by a waybill that indicates the point of origin may be moved interstate from the quarantined area without a certificate or limited permit. Additionally, the articles must be moved in an enclosed vehicle or be completely enclosed so as to prevent access by West Indian fruit flies. The regulated articles must also be moved through the quarantined area without stopping (except for refueling, rest stops, emergency repairs, and for traffic conditions such as traffic lights and stop signs), and the regulated articles must not be unpacked or unloaded in the quarantined area.

Section 301.98–5—Issuance and Cancellation of Certificates and Limited Permits

Under Federal domestic plant quarantine programs, there is a difference between the use of certificates and limited permits. Certificates are issued for regulated articles when an inspector finds that, because of certain conditions (e.g., the article is free of West Indian fruit fly), there is no pest risk before movement. Regulated articles accompanied by a certificate may be moved interstate without further restrictions. Limited permits are issued for regulated articles when an inspector finds that, because of a possible pest risk, the articles may be safely moved interstate only subject to further restrictions, such as movement to limited areas and movement for limited purposes. Section 301.98–5 explains the conditions for issuing a certificate or limited permit.

Specifically, § 301.98–5(a) provides that a certificate will be issued by an inspector for the movement of a regulated article if the inspector determines that the article: (1) Is free of the West Indian fruit fly; has been treated in the presence of an inspector in accordance with § 301.98–10; or comes from a premises of origin that is free of the West Indian fruit fly; (2) will be moved in compliance with any additional emergency conditions deemed necessary to prevent the spread of the West Indian fruit fly under section 414 of the Plant Protection Act (Title IV, Pub. L. 106–224, 114 Stat. 444, 7 U.S.C. 7714); and (3) is eligible for unrestricted movement under all other Federal domestic plant quarantines and regulations applicable to that article.

We have included a footnote (number 4) that provides an address for securing the addresses and telephone numbers of the local Plant Protection and Quarantine offices at which services of inspectors may be requested. We have also included a footnote (number 5) that explains that the Secretary of Agriculture can, under the Plant Protection Act, take emergency actions to seize, quarantine, treat, destroy, or apply other remedial measures to articles that are, or that he or she has reason to believe are, infested or infected by or contain plant pests.

Paragraph (b) of § 301.98–5 provides for the issuance of a limited permit (in lieu of a certificate) by an inspector for interstate movement of a regulated article if the inspector determines that the article is to be moved to a specified destination for specified handling, utilization or processing, and that the movement will not result in the spread of the West Indian fruit fly.

Paragraph (c) of § 301.98–5 allows any person who has entered into and is operating under a compliance agreement to issue a certificate or limited permit for the interstate movement of a regulated article after an inspector has determined that the article is eligible for a certificate or limited permit under § 301.98–5(a) or (b).

Also, § 301.98–5(d) contains provisions for the withdrawal of a certificate or limited permit by an inspector if the inspector determines that the holder of the certificate or limited permit has not complied with conditions for the use of the document. This section also contains provisions for notifying the holder of the reasons for the withdrawal and for holding a hearing if there is any conflict concerning any material fact in the event that the person wishes to appeal the cancellation.

Section 301.98–6—Compliance Agreements and Cancellation

Section 301.98–6 provides for the issuance and cancellation of compliance agreements. Compliance agreements are provided for the convenience of persons who are involved in interstate shipments of regulated articles from quarantined areas. A compliance agreement will be issued when an inspector has determined that the person requesting the compliance agreement is knowledgeable regarding the requirements of the regulations and the person has agreed to comply with those requirements. This section contains a footnote (number 7) that explains how compliance agreements may be arranged.

Section 301.98–6 also provides that an inspector may cancel the compliance agreement upon finding that a person who has entered into the agreement has failed to comply with any of the provisions of the regulations. The inspector will notify the holder of the compliance agreement of the reasons for

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cancellation and offer an opportunity for a hearing to resolve any conflicts of material fact in the event that the person wishes to appeal the cancellation.

Section 301.98–7—Assembly and Inspection of Regulated Articles

Section 301.98–7 provides that any person (other than a person authorized to issue certificates or limited permits under § 301.98–5(c)) who desires a certificate or limited permit to move regulated articles must request, at least 48 hours before the desired interstate movement, that an inspector issue a certificate or limited permit. The regulated articles must be assembled in a place and manner directed by the inspector.

Section 301.98–8—Attachment and Disposition of Certificates and Limited Permits

Section 301.98–8 requires the certificate or limited permit issued for movement of the regulated article to be attached, during the interstate movement, to the regulated article, or to a container carrying the regulated article, or to the accompanying waybill. Further, the section requires that the carrier must furnish the certificate or limited permit to the consignee listed on the certificate or limited permit upon arrival at the location provided on the certificate or limited permit.

These provisions are necessary for enforcement purposes and to ensure that persons desiring inspection services can obtain them before the intended movement date.

Section 301.98–9—Costs and Charges

Section 301.98–9 explains the APHIS policy that the services of an inspector that are needed to comply with the regulations are provided without cost between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays, to persons requiring those services, but that we will not be responsible for any other costs or charges (such as overtime costs for inspections conducted at times other than between 8 a.m. to 4:30 p.m., Monday through Friday, except holidays).

Section 301.98–10—Treatments

Section 301.98–10 lists treatments that qualify soil and regulated articles for interstate movement with a certificate as provided in § 301.98–5.

Paragraph (a) provides that fruits and vegetables originating inside the quarantined area that are to be moved outside the quarantined area must be treated with an applicable treatment listed in the Plant Protection and Quarantine Treatment Manual, which is incorporated by reference at 7 CFR 300.1, "Materials incorporated by reference."

Paragraph (b) provides that soil within the dripline of plants that are producing or have produced the fruits and vegetables listed in § 301.98–2(a) of this subpart may be treated with diazinon at the rate of 5 pounds active ingredient per acre with sufficient water to wet the soil to a depth of at least ½ inch. Research by the Agricultural Research Service has determined that this diazinon treatment would destroy the West Indian fruit fly in soil.

Paragraph (c) provides that premises that are located within the regulated area but outside the infested core area, and that produce regulated articles, may receive regular treatments with malathion or spinosad bait spray. These treatments must take place at 6-to 10-day intervals, starting a sufficient time before harvest (but not less than 30 days before harvest) to allow for completion of egg and larvae development of the West Indian fruit fly. Determination of the time period must be based on the day degrees model for West Indian fruit fly. Since the length of fruit fly life cycles vary according to the temperature of their environment, the day degrees model is used to project the duration of the life cycle of the fruit fly. Once treatment has begun, it must continue through the harvest period. The malathion bait spray treatment must be applied by aircraft or ground equipment at a rate of 2.4 oz of technical grade malathion and 9.6 oz of protein hydrolysate per acre. Spinosad bait spray must be applied by aircraft or ground equipment at a rate of 0.01 oz of a USDA-approved spinosad formulation and 48 oz of protein hydrolysate per acre. For ground applications of Spinosad, the mixture may be diluted with water to improve coverage. After the treatment cycle is complete, regulated articles produced on the premises will be eligible for interstate movement with a certificate as provided in § 301.98–5.

Emergency Action

This rulemaking is necessary on an emergency basis to prevent the West Indian fruit fly from spreading to noninfested areas of the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule quarantines part of Cameron County, TX, because of the West Indian fruit fly and restricts the interstate movement of regulated articles from the quarantined area. This action is necessary on an emergency basis to prevent the spread of the West Indian fruit fly to noninfested areas of the United States.

Within the regulated area there are approximately 22 small entities that may be affected by this rule. These include 5 fruit sellers and 17 growers. These 22 entities comprise less than 1 percent of the total number of similar entities operating in the State of Texas. Additionally, these small entities sell regulated articles primarily for local intrastate—not interstate—movement, so the effect, if any, of this rule on these entities appears to be minimal.

The effect on those few entities that do move regulated articles interstate from the quarantined area will be minimized by the availability of various treatments that, in most cases, will allow these small entities to move regulated articles interstate with very little additional cost.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for the West Indian Fruit Fly Cooperative Eradication Program. The assessment provides a basis for the conclusion that the implementation of this interim rule will not have a significant impact on human health and the natural environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0170 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503, and (2) Docket No. 00–110–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 00–110–1 and send your comments within 60 days of publication of this rule.

This interim rule quarantines a part of Cameron, TX, because of the West Indian fruit fly and restricts the interstate movement of regulated articles from the quarantined area. Its implementation will require us to engage in certain information collection activities, in that certain articles may not be moved interstate from the quarantined area unless they are accompanied by a certificate or a limited permit. A certificate or limited permit may be issued by an inspector (*i.e.*, an APHIS employee or other person authorized by the APHIS Administrator to enforce the regulations) or by a person who has entered into a written compliance agreement with APHIS. We are soliciting comments from the public concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

Respondents: State and county cooperators (inspectors); and producers, handlers, and movers of regulated fruit and vegetables in Cameron County, TX.

Estimated annual number of respondents: 37.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 37.

Estimated total annual burden on respondents: 37 hours.

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: Title IV, Pub. L. 106–224, 114 Stat. 438, 7 U.S.C. 7701–7772; 7 U.S.C. 166; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293, and Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. Part 301 is amended by adding a new "Subpart—West Indian Fruit Fly," §§ 301.98 through 301.98–10, to read as follows:

Subpart—West Indian Fruit Fly

Sec.

301.98 Restrictions on interstate movement of regulated articles.
301.98–1 Definitions.
301.98–2 Regulated articles.
301.98–3 Quarantined areas.
301.98–4 Conditions governing the interstate movement of regulated articles from quarantined areas.
301.98–5 Issuance and cancellation of certificates and limited permits.
301.98–6 Compliance agreements and cancellation.
301.98–7 Assembly and inspection of regulated articles.
301.98–8 Attachment and disposition of certificates and limited permits.
301.98–9 Costs and charges.
301.98–10 Treatments.

Subpart—West Indian Fruit Fly

§ 301.98 Restrictions on interstate movement of regulated articles.

No person may move interstate from any quarantined area any regulated article except in accordance with this subpart.[1]

§ 301.98–1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture.

[1] Any properly identified inspector is authorized to stop and inspect persons and means of conveyance and to seize, quarantine, treat, apply other remedial measures to, destroy, or otherwise dispose of regulated articles as provided in section 414 of the Plant Protection Act (Title IV, Pub. L. 106–224, 114 Stat. 444, 7 U.S.C. 7714).

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Certificate. A document in which an inspector or person operating under a compliance agreement affirms that a specified regulated article is free of West Indian fruit fly and may be moved interstate to any destination.

Compliance agreement. A written agreement between APHIS and a person engaged in growing, handling, or moving regulated articles, wherein the person agrees to comply with this subpart.

Core area. The 1-square-mile area surrounding each property where West Indian fruit fly has been detected.

Day degrees. A mathematical construct combining average temperature over time that is used to calculate the length of a West Indian fruit fly life cycle. Day degrees are the product of the following formula, with all temperatures measured in °F: (Minimum Daily Temp+ Maximum Daily Temp)/2) − 54°=Day Degrees.

Departmental permit. A document issued by the Administrator in which he or she affirms that interstate movement of the regulated article identified on the document is for scientific or experimental purposes and that the regulated article is eligible for interstate movement in accordance with § 301.98–4(c) of this subpart.

Dripline. The line around the canopy of a plant.

Infestation. The presence of the West Indian fruit fly or the existence of circumstances that makes it reasonable to believe that the West Indian fruit fly is present.

Inspector. Any employee of the APHIS, U.S. Department of Agriculture, or other person authorized by the Administrator to perform the duties required under this subpart.

Interstate. From any State into or through any other State.

Limited permit. A document in which an inspector or person operating under a compliance agreement affirms that the regulated article identified on the document is eligible for interstate movement in accordance with § 301.98–5(b) of this subpart only to a specified destination and only in accordance with specified conditions.

Moved (move, movement). Shipped, offered for shipment, received for transportation, transported, carried, or allowed to be moved, shipped, transported, or carried.

Person. Any association, company, corporation, firm, individual, joint stock company, partnership, society, or other entity.

Plant Protection and Quarantine. Plant Protection and Quarantine, Animal and Plant Health Inspection Service, United States Department of Agriculture.

Quarantined area. Any State, or any portion of a State, listed in § 301.98–3(c) of this subpart or otherwise designated as a quarantined area in accordance with § 301.98–3(b) of this subpart.

Regulated article. Any article listed in § 301.98–2 or otherwise designated as a regulated article in accordance with § 301.98–2(d).

State. The District of Columbia, Puerto Rico, the Northern Mariana Islands, or any State, territory, or possession of the United States.

West Indian fruit fly. The insect known as the West Indian fruit fly, *Anastrepha obliqua* (Macquart), in any stage of development.

§ 301.98–2 Regulated articles.

The following are regulated articles:

(a) West Indian fruit flies.[2]

(b)(1) The following fruits and vegetables:

Barbados cherry (*Malpighia glabra*)
Carambola (*Averrhoa carambola*)
Grapefruit (*Citrus paradisi*)
Granadilla, giant (*Passiflora quadrangularis*)
Guava (*Psidium guajava*)
Guava, strawberry (*Psidium littorale*)
Hog-plum (*Spondias mombin*)
Japanese plum (*Prunus salicina*)
Jew plum (*Spondias cytherea*)
Ketembilla (*Dovyalis hebecarpa*)
Lime, sweet (*Citrus aurantifolia*)
Loquat (*Eriobotrya japonica*)
Malay-apple (*Syzygium malaccense*)
Mango (*Mangifera indica*)
Orange, sour (*Citrus aurantium*)
Orange, sweet (*Citrus sinensis*)
Passion fruit (*Passiflora edulis*)
Peach (*Prunus persica*)
Pear (*Pyrus communis*)
Ramón (*Brosimum alicastrum*)
Red mombin (*Spondias purpurea*)
Rose-apple (*Syzygium jambos*)
Sapodilla (*Manilkara zapota*)
Sapote (*Diospyros* spp.)

(2) Any fruits or vegetables that are canned or dried or frozen below −17.8 °C. (0 °F.) are not regulated articles.

(c) Soil within the dripline of plants that are producing or have produced the fruits or vegetables listed in paragraph (b) of this section.

(d) Any other product, article, or means of conveyance not listed in paragraphs (a) through (c) of this section that an inspector determines presents a risk of spreading the West Indian fruit fly, when the inspector notifies the person in possession of the product, article, or means of conveyance that it is subject to the restrictions of this subpart.

[2] Permit and other requirements for the interstate movement of West Indian fruit flies are contained in part 330 of this chapter.

§ 301.98–3 Quarantined areas.

(a) Except as otherwise provided in paragraph (b) of this section, the Administrator will list as a quarantined area in paragraph (c) of this section each State, or each portion of a State, in which the West Indian fruit fly has been found by an inspector, in which the Administrator has reason to believe that the West Indian fruit fly is present, or that the Administrator considers necessary to quarantine because of its inseparability for quarantine enforcement purposes from localities in which the West Indian fruit fly has been found. Less than an entire State will be designated as a quarantined area only if the Administrator determines that:

(1) The State has adopted and is enforcing restrictions on the intrastate movement of the regulated articles that are substantially the same as those imposed by this subpart on the interstate movement of regulated articles; and

(2) The designation of less than the entire State as a quarantined area will prevent the interstate spread of the West Indian fruit fly.

(b) The Administrator or an inspector may temporarily designate any nonquarantined area in a State as a quarantined area in accordance with paragraph (a) of this section. The Administrator will give a copy of this regulation along with a written notice for the temporary designation to the owner or person in possession of the nonquarantined area. Thereafter, the interstate movement of any regulated article from an area temporarily designated as a quarantined area will be subject to this subpart. As soon as practicable, this area will be added to the list in paragraph (c) of this section or the designation will be terminated by the Administrator or an inspector. The owner or person in possession of an area for which designation is terminated will be given notice of the termination as soon as practicable.

(c) The areas described below are designated as quarantined areas:

Texas

Cameron County. That portion of Cameron County bounded by a line drawn as follows: Beginning at the intersection of FM 106 and Robertson Road; then north on Robertson Road to Fernando Road; then east on Fernando Road to Alexander Road; then north on Alexander Road to Taubert Road; then east on Taubert Road to FM 2925; then north on FM 2925 to Johnson Road; then east on Johnson Road to North Olimeto Road; then east along an imaginary line to FM 1847; then south on FM 1847 to FM 510; then west on FM 510 to Casey Road; then north on Casey Road to Bean Road; then west on Bean Road to FM 345; then north on FM 345 to Glenview Road; then west on Glenview Road to Robertson Road; then north on Robertson Road to the point of beginning.

§ 301.98–4 Conditions governing the interstate movement of regulated articles from quarantined areas.

Any regulated article may be moved interstate from a quarantined area [3] only if moved under the following conditions:

(a) With a certificate or limited permit issued and attached in accordance with §§ 301.98–5 and 301.98–8 of this subpart;

(b) Without a certificate or limited permit if:

(1) The regulated article originated outside the quarantined area and is either moved in an enclosed vehicle or is completely enclosed by a covering adequate to prevent access by West Indian fruit flies (such as canvas, plastic, or other closely woven cloth) while moving through the quarantined area; and

(2) The point of origin of the regulated article is indicated on the waybill, and the enclosed vehicle or the enclosure that contains the regulated article is not opened, unpacked, or unloaded in the quarantined area; and

(3) The regulated article is moved through the quarantined area without stopping except for refueling or for traffic conditions, such as traffic lights or stop signs.

(c) Without a certificate or limited permit if the regulated article is moved:

(1) By the United States Department of Agriculture for experimental or scientific purposes;

(2) Pursuant to a Departmental permit issued by the Administrator for the regulated article;

(3) Under conditions specified on the Departmental permit and found by the Administrator to be adequate to prevent the spread of the West Indian fruit fly; and

(4) With a tag or label bearing the number of the Departmental permit issued for the regulated article attached to the outside of the container of the regulated article or attached to the regulated article itself if not in a container.

(Approved by the Office of Management and Budget under control number 0579–0170)

[3] Requirements under all other applicable Federal domestic plant quarantines and regulations must also be met.

§ 301.98–5 Issuance and cancellation of certificates and limited permits.

(a) A certificate may be issued by an inspector [4] for the interstate movement of a regulated article if the inspector determines that:

(1)(i) The regulated article has been treated under the direction of an inspector in accordance with § 301.98–10 of this subpart; or

(ii) Based on inspection of the premises of origin, the premises are free from the West Indian fruit fly; or

(iii) Based on inspection of the regulated article, the regulated article is free of West Indian fruit flies; and

(2) The regulated article will be moved through the quarantined area in an enclosed vehicle or will be completely enclosed by a covering adequate to prevent access by the West Indian fruit fly; and

(3) The regulated article is to be moved in compliance with any additional emergency conditions the Administrator may impose under section 414 of the Plant Protection Act (Title IV, Pub. L. 106–224, 114 Stat. 444, 7 U.S.C. 7714) [5] to prevent the spread of the West Indian fruit fly; and

(4) The regulated article is eligible for unrestricted movement under all other Federal domestic plant quarantines and regulations applicable to the regulated article.

(b) An inspector [6] will issue a limited permit for the interstate movement of a regulated article if the inspector determines that:

(1) The regulated article is to be moved interstate to a specified destination for specified handling, processing, or utilization (the destination and other conditions to be listed in the limited permit), and this interstate movement will not result in the spread of the West Indian fruit fly because life stages of the West Indian fruit fly will be destroyed by the specified handling, processing, or utilization;

(2) The regulated article is to be moved in compliance with any additional emergency conditions the Administrator may impose under section 414 of the Plant Protection Act (Title IV, Pub. L. 106–224, 114 Stat. 444, 7 U.S.C. 7714) to prevent the spread of the West Indian fruit fly; and

(3) The regulated article is eligible for interstate movement under all other Federal domestic plant quarantines and regulations applicable to the regulated article.

(c) Certificates and limited permits for the interstate movement of regulated articles may be issued by an inspector or person operating under a compliance agreement. A person operating under a compliance agreement may issue a certificate for the interstate movement of a regulated article if an inspector has determined that the regulated article is eligible for a certificate in accordance with paragraph (a) of this section. A person operating under a compliance agreement may issue a limited permit for interstate movement of a regulated article when an inspector has determined that the regulated article is eligible for a limited permit in accordance with paragraph (b) of this section.

(d) Any certificate or limited permit that has been issued may be withdrawn, either orally or in writing, by an inspector if he or she determines that the holder of the certificate or limited permit has not complied with all conditions in this subpart for the use of the certificate or limited permit. If the withdrawal is oral, the withdrawal and the reasons for the withdrawal will be confirmed in writing as promptly as circumstances allow. Any person whose certificate or limited permit has been withdrawn may appeal the decision in writing to the Administrator within 10 days after receiving the written notification of the withdrawal. The appeal must state all of the facts and reasons upon which the person relies to show that the certificate or limited permit was wrongfully withdrawn. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflict as to any material fact. Rules of practice concerning a hearing will be adopted by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0170)

[4] Services of an inspector may be requested by contacting local offices of Plant Protection and Quarantine, which are listed in telephone directors. The addresses and telephone numbers of local offices may also be obtained from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Invasive Species and Pest Management, 4700 River Road Unit 134, Riverdale, MD 20737–1236, or the APHIS web site at http://www.aphis.usda.gov/travel/aqui.html.

[5] Section 414 of the Plant Protectin Act (Title IV, Pub. L. 106–224, 114 Stat. 444, 7 U.S.C. 7714) provides that the Secretary of Agriculture may, under certain conditions, hold, seize, quarantine, treat, apply other remedial measures to destroy or otherwise dispose of any plant, plant pest, plant product, article, or means of conveyance that is moving, or has moved into or through the United States or interstate if the Secretary has reason to believe the article is a plant pest or is infested with a plant pest at the time of movement.

[6] See footnote 4 to § 301.98–5(a).

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§ 301.98–6 Compliance agreements and cancellation.

(a) Any person engaged in growing, handling, or moving regulated articles may enter into a compliance agreement when an inspector determines that the person understands this subpart, agrees to comply with its provisions, and agrees to comply with all the provisions contained in the compliance agreement.[7]

(b) Any compliance agreement may be canceled, either orally or in writing, by an inspector whenever the inspector finds that the person who has entered into the compliance agreement has failed to comply with this subpart. If the cancellation is oral, the cancellation and the reasons for the cancellation will be confirmed in writing as promptly as circumstances allow. Any person whose compliance agreement has been canceled may appeal the decision, in writing, within 10 days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully canceled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflict as to any material fact. Rules of practice concerning a hearing will be adopted by the Administrator.

§ 301.98–7 Assembly and inspection of regulated articles.

(a) Any person (other than a person authorized to issue certificates or limited permits under § 301.98–5(c)) who desires to move a regulated article interstate accompanied by a certificate or limited permit must notify an inspector [8] as far in advance of the desired interstate movement as possible, but no less than 48 hours before the desired interstate movement.

(b) The regulated article must be assembled at the place and in the manner the inspector designates as necessary to comply with this subpart.

§ 301.98–8 Attachment and disposition of certificates and limited permits.

(a) A certificate or limited permit required for the interstate movement of a regulated article must, at all times during the interstate movement, be:

(1) Attached to the outside of the container containing the regulated article; or

(2) Attached to the regulated article itself if not in a container; or

(3) Attached to the consignee's copy of the accompanying waybill. If the certificate or limited permit is attached to the consignee's copy of the waybill, the regulated article must be sufficiently described on the certificate or limited permit and on the waybill to identify the regulated article.

(b) The certificate or limited permit for the interstate movement of a regulated article must be furnished by the carrier to the consignee listed on the certificate or limited permit upon arrival at the location provided on the certificate or limited permit.

(Approved by the Office of Management and Budget under control number 0579–0170)

§ 301.98–9 Costs and charges.

The services of the inspector during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, except holidays) will be furnished without cost. The user will be responsible for all costs and charges arising from inspection and other services provided outside normal business hours.

§ 301.98–10 Treatments.

Treatment schedules listed in the Plant Protection and Quarantine Treatment Manual to destroy the West Indian fruit fly are authorized for use on regulated articles. The Plant Protection and Quarantine Treatment Manual is incorporated by reference. For the full identification of this standard, see § 300.1 of this chapter, "Materials incorporated by reference." The following treatments also may be used for the regulated articles indicated:

(a) *Soil within the dripline of plants that are producing or have produced the fruits and vegetables listed in § 301.98–2(a) of this subpart.* Apply diazinon at the rate of 5 pounds active ingredient per acre to the soil within the dripline with sufficient water to wet the soil to at least a depth of ½ inch.

(b) *Premises.* Fields, groves, or areas that are located within a quarantined area but outside the infested core area and that produce regulated articles may receive regular treatments with either malathion or spinosad bait spray as an alternative to treating fruits and vegetables as provided in the Plant Protection and Quarantine Treatment Manual. These treatments must take place at 6- to 10-day intervals, starting a sufficient time before harvest (but not less than 30 days before harvest) to allow for development of West Indian fruit fly egg and larvae. Determination of the time period must be based on the day degrees model for West Indian fruit fly. Once treatment has begun, it must continue through the harvest period. The malathion bait spray treatment must be applied by aircraft or ground equipment at a rate of 2.4 oz of technical grade malathion and 9.6 oz of protein hydrolysate per acre. The spinosad bait spray treatment must be applied by aircraft or ground equipment at a rate of 0.01 oz of a USDA-approved spinosad formulation and 48 oz of protein hydrolysate per acre. For ground applications, the mixture may be diluted with water to improve coverage.

Done in Washington, DC, this 12th day of January 2001.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–1618 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–34–P

[7] Compliance agreement forms are available without charge from the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Invasive Species and Pest Management, 4700 River Road Unit 134, Riverdale, MD 20737–1236, and from local offices of the Plant Protection and Quarantine, which are listed in telephone directories.

[8] See footnote 4 to § 301.98–5(a).

DEPARTMENT OF JUSTICE

8 CFR Parts 3, 212, and 240

[EOIR No. 127P; AG Order No. 2358–2001]

RIN 1125–AA29

Executive Office for Immigration Review; Section 212(c) Relief for Certain Aliens in Deportation Proceedings Before April 24, 1996

AGENCY: Executive Office for Immigration Review, Justice.

ACTION: Final rule.

SUMMARY: This final rule creates a uniform procedure for applying the law as enacted by the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA). This rule allows certain aliens in deportation proceedings that commenced before April 24, 1996, to apply for relief pursuant to section 212(c) of the Immigration and Nationality Act (INA). In addition, this rule makes several technical amendments to an earlier regulation relating to the streamlining authority of the Board of Immigration Appeals.

EFFECTIVE DATE: This final rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Charles Adkins-Blanch, General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2400, Falls Church, Virginia 22041, telephone (703) 305–0470.

SUPPLEMENTARY INFORMATION:

Why Is the Department Issuing This Final Rule?

Before the comprehensive revision of the INA by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), Pub. L. No. 104–208, Div. C, 110 Stat. 3009, section 212(c) of the INA, provided that aliens who were lawfully admitted for permanent residence, who temporarily proceeded abroad voluntarily and not under an order of deportation, and who were returning to a lawful unrelinquished domicile in the United States of seven consecutive years, could be admitted to the United States in the discretion of the Attorney General. 8 U.S.C. 1182(c) (1994). Although section 212(c) by its terms applied only to aliens in exclusion proceedings (*i.e.*, aliens seeking to enter at the border), it had been construed for many years also to allow aliens who were placed in deportation proceedings in the United States to apply for discretionary relief from deportation. *See Matter of Silva*, 16 I. & N. Dec. 26, 29–30 (BIA 1976); *Gonzalez* v. *INS*, 996 F.2d 804, 806 (6th Cir. 1993); *Ashby* v. *INS*, 961 F.2d 555, 557 & n.2 (5th Cir. 1992); *Tapica-Acuna* v. *INS*, 640 F.2d 223, 225 (9th Cir. 1981); *Francis* v. *INS*, 532 F.2d 268, 273 (2d Cir. 1976).

In the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA), Pub. L. No. 104–132, 110 Stat. 1214, Congress significantly restricted the availability of discretionary relief from deportation under section 212(c). Section 440(d) of AEDPA amended section 212(c) of the INA to provide that section 212(c) "shall not apply to an alien who is deportable by reason of having committed any criminal offense covered by section 241(a)(2)(A)(iii), (B), (C), or (D), or any offense covered by section 241(a)(2)(A)(ii) for which both predicate offenses are, without regard to the date of their commission, otherwise covered by section 241(a)(2)(A)(i)." AEDPA section 440(d), as amended by IIRIRA section 306(d). The effect of section 440(d) of AEDPA was to render ineligible for relief under INA section 212(c) aliens deportable because of convictions for certain criminal offenses, including aggravated felonies, controlled substance offenses, certain firearms offenses, espionage, and multiple crimes of moral turpitude.

AEDPA did not contain a provision expressly stating whether section 440(d) was to be applied to criminal aliens who applied for section 212(c) relief, were placed in deportation proceedings, were convicted, or committed the crimes rendering them deportable before AEDPA was enacted. In *Matter of Soriano*, Interim Decision 3289 (BIA 1996), the Board of Immigration Appeals (Board) held that section 440(d) of AEDPA did not apply to aliens who had applied for section 212(c) relief before AEDPA was enacted, but did apply to all other aliens covered in the provision, including those whose proceedings commenced or whose criminal conduct or conviction occurred before AEDPA was enacted.

At the request of the Immigration and Naturalization Service (INS), the Attorney General vacated the Board's decision in *Soriano* and certified the question to herself. On February 21, 1997, the Attorney General concluded that section 440(d) applied to (and thereby rendered ineligible for section 212(c) relief) all aliens who had committed one of the specified offenses and who had not finally been granted section 212(c) relief before AEDPA was enacted, including those who were already in deportation proceedings or who had already applied for section 212(c) relief at the time of AEDPA's enactment.

How Have the Federal Courts Ruled on the Issue?

Following the Attorney General's decision in *Soriano*, the Board and the Immigration Courts denied applications for relief under section 212(c) filed by aliens who fell within the categories identified in AEDPA section 440(d), regardless of the date of the crime, conviction, deportation proceedings, or application for section 212(c) relief. Numerous aliens challenged their final orders of deportation in both district courts and courts of appeals, arguing that AEDPA section 440(d) should not be applied "retroactively" to their cases, and that the Attorney General had erred in her construction of AEDPA section 440(d) in *Soriano*.

The *Soriano* issue has given rise to widespread litigation in almost every circuit. Only the D.C. Circuit has yet to decide a case on the *Soriano* issue. Eight circuits—the First, Second, Third, Fourth, Sixth, Eighth, Ninth, and Eleventh Circuits—have now disagreed with the Attorney General's holding in *Soriano*. Seven of the eight circuits have held that section 440(d) of AEDPA does not apply to aliens who filed applications for section 212(c) relief before AEDPA was passed. *See Goncalves* v. *Reno*, 144 F.3d 110, 126–33 (1st Cir. 1998), *cert. denied*, 526 U.S. 1004 (1999); *Henderson* v. *INS*, 157 F.3d 106, 128–30 (2d Cir. 1998), *cert. denied sub nom. Reno* v. *Navas*, 526 U.S. 1004 (1999); *Sandoval* v. *Reno*, 166 F.3d 225, 239–42 (3d Cir. 1999); *Tasios* v. *Reno*, 204 F.3d 544, 547–52 (4th Cir. 2000); *Pak* v. *Reno*, 196 F.3d 666, 674–76 (6th Cir. 1999); *Shah* v. *Reno*, 184 F.3d 719, 724 (8th Cir. 1999); *Magana-Pizano* v. *INS*, 200 F.3d 603, 610–11 (9th Cir. 1999; *Mayers* v. *INS*, 175 F.3d 1289, 1301–04 (11th Cir. 1999) *superceded by statute in Richardson* v. *Reno*, 180 F.3d 1311 (11th Cir. 1999).

The First Circuit has gone further and held that AEDPA section 440(d) likewise does not apply to aliens who were placed in deportation proceedings before AEDPA was passed, even if they did not actually request section 212(c) relief until after AEDPA was passed. *See Wallace* v. *Reno*, 194 F.3d 279, 285–88 (1st Cir. 1999). Other circuits have either likewise so held or strongly implied in their reasoning. *See Henderson*, 157 F.3d at 129–31; *Sondoval*, 166 F.3d at 241–42; *Mayers*, 175 F.3d at 1304; *see also Shah*, 184 F. 3d at 724 (adopting reasoning of *Goncalves*, *Henderson*, and *Mayers*).

By contrast, and at the time of the publication of the proposed Soriano rule, the Seventh Circuit held, consistent with the Attorney General's conclusion in *Soriano*, that section 440(d) of AEDPA applies even to aliens who were in deportation proceedings and had applied for section 212(c) relief when AEDPA was enacted. *See Turkhan* v. *Perryman*, 188 F.3d 814, 824–28 (7th Cir. 1999); *see also LaGuerre* v. *Reno*, 164 F.3d 1035, 1040–41 (7th Cir. 1998), *cert. denied*, 120 S. Ct. 1157 (2000). However, the Seventh Circuit has recently held that an alien's due process rights were violated by the retroactive application of section 440(d) of AEDPA where there was significant evidence that the availability of a section 212(c) waiver influenced the alien's decision to plead guilty. *See Jideonwo* v. *INS*, 224 F.3d 692, 699–701 (7th Cir. 2000).

Aliens have also argued that persons who were placed in deportation proceedings *after* AEDPA was enacted, but who committed their crimes and were convicted before that date, should be eligible for section 212(c) relief, and that AEDPA section 440(d) would be impermissibly retroactive if applied to them.

Three circuits—the Third, Fifth and Tenth—have affirmatively held that AEDPA section 440(d) *does* foreclose section 212(c) relief for aliens who were placed in proceedings after AEDPA was enacted, even if their criminal offenses were committed before the enactment of AEDPA. *See DeSousa* v. *Reno*, 190 F.3d 175, 185–87 (3d Cir. 1999); *Requena-Rodriguez* v. *Pasquarell*, 190 F.3d 299, 306–08 (5th Cir. 1999); *Jurado-Gutierrez* v. *Greene*, 190 F.3d 1135, 1147–52 (10th Cir. 1999), *cert. denied sub nom Palangas-Suarez* v. *Greene*, 120 S. Ct. 1539 (2000). The Seventh Circuit has necessarily adopted that position as well. *See Turkhan*, 188 F.3d at 824–28 (holding that section 440(d) bars relief for *all* criminal aliens who had not been

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granted section 212(c) relief at the time AEDPA was enacted, necessarily including all those whose convictions occurred prior to AEDPA but whose deportation proceedings were initiated after enactment of AEDPA).

The Ninth Circuit has concluded that aliens who are deportable based on a qualifying criminal conviction entered prior to AEDPA but after a full trial are properly covered by AEDPA section 440(d) and therefore ineligible for section 212(c) relief. *See Magana-Pizano*, 200 F.3d at 610–11. The Ninth Circuit also held, however, that because of concerns about retroactivity and reliance, it could not exclude the possibility that section 440(d) should not be applied to an alien who pleaded guilty or nolo contendere to his disqualifying criminal offense and who can show that the plea "was entered in reliance on the availability of discretionary waiver under § 212(c)." *Id.* at 613. The Court therefore remanded the case to the district court to determine whether the alien could show such reliance. *See id.* at 609. The First Circuit has issued a similar ruling, holding that section 440(d) does not apply in a case where an alien pleaded guilty to and was convicted of a qualifying offense before AEDPA was enacted but was placed in proceedings afterwards, if the alien could show that he entered his guilty plea in reliance on the state of the law before AEDPA's enactment. *Mattis* v. *Reno*, 212 F.3d 31, 35–40 (1st Cir. 2000). The First Circuit found no evidence of such reliance in that case, however. *See id.* at 39.

Additionally, the Fourth Circuit held that the statute is inapplicable, because of perceived retroactivity concerns, to an alien who pleaded guilty and was convicted before AEDPA was enacted even if his deportation proceedings were commenced after enactment of AEDPA. The court reasoned that the alien had detrimentally relied upon the availability of discretionary relief from deportation when he entered his guilty plea prior to the enactment date. *See Tasios*, 204 F.3d at 550–52.

More recently, the Second Circuit has held that section 440(d) of AEDPA is not applicable in the case of an alien in removal proceedings who entered a guilty plea before April 24, 1996, the effective date of AEDPA. *See St. Cyr* v. *INS*, 229 F.3d 406, 418 (2d Cir. 2000). The Office of the Solicitor General filed a petition for certiorari in *St. Cyr* on November 13, 2000. Additionally, the Ninth Circuit has recently ruled that Congress intended that the repeal of section 212(c) apply to all proceedings commenced after April 1, 1997. However, the Ninth Circuit also remanded this case for a determination whether the alien based his pre-AEDPA guilty plea in reliance upon the availability of section 212(c) relief, in accordance with the court's reasoning in *Magana-Pizano, supra*. *Richards-Diaz* v. *Fasano*, 233 F.3d 1160 (9th Cir. 2000).

Why Is the Attorney General Promulgating a Rule of Uniform Implementation of AEDPA for Aliens Seeking Section 212(c) Relief?

Issues concerning the construction of AEDPA section 440(d) affect a large number of aliens and are of considerable importance to the Department of Justice, including the INS and the Executive Office for Immigration Review (EOIR). Approximately 800 aliens who have been found deportable by the Immigration Court and the Board have filed challenges to *Soriano* in federal district court. In addition, a number of cases in which the application of *Soriano* may be dispositive are still pending before the Immigration Court and the Board.

There is an important public interest in the uniform administration of the immigration laws. The Constitution grants Congress the power to establish "an uniform Rule of Naturalization," U.S. Const. art. I, § 8, cl. 4, and it is generally desirable as well that immigration rules be consistent throughout the country, to minimize distinctions among aliens based solely on geographical factors. There is also an important public interest in the completion of proceedings involving criminal aliens. The Department of Justice therefore sought to have the Supreme Court definitively resolve the *Soriano* issue during the October Term 1998 by petitioning for a writ of certiorari from the First Circuit's decision in *Goncalves* and the Second Circuit's decision in *Henderson*. On March 8, 1999, the Supreme Court denied those certiorari petitions.

In light of the Supreme Court's denial of certiorari in *Goncalves, Henderson/Navas*, and *LaGuerre* in February 2000, the decisions of eight circuits rejecting the decision in *Soriano*, and the large number of aliens who are affected by the issue, the Attorney General has considered whether the government's interest in the uniform administration of the immigration laws, avoiding unnecessary delays in the completion of proceedings involving criminal aliens, and the reasoning of the courts that have rejected her construction of AEDPA section 440(d) in *Soriano*, warrant a change in the Department's application of AEDPA section 440(d). In the interest of the uniform and expeditious administration of the immigration laws, the Attorney General acquiesces on a nationwide basis in those appellate decisions holding that AEDPA section 440(d) is not to be applied in the cases of aliens whose deportation proceedings were commenced before AEDPA was enacted.

In particular, the Attorney General acquiesces in the courts' conclusion, as a matter of statutory construction, that Congress intended that section 440(d) of AEDPA not be applied to deportation proceedings that had been commenced before AEDPA was enacted into law. In reaching that conclusion, the courts generally have applied the first step of the two-step retroactivity analysis set forth by the Supreme Court in *Landgraf* v. *USI Film Products*, 511 U.S. 244 (1994). In the first step of that analysis, the courts inquire whether Congress has specifically addressed the temporal application of a statute. The courts that have rejected *Soriano* have generally relied on two factors to reach the conclusion that Congress specifically addressed the temporal application of AEDPA section 440(d). First, they have observed that Congress expressly made other provisions of AEDPA, such as section 413(f), applicable to pending deportation proceedings, and they have drawn a negative inference from the fact that Congress did not intend section 440(d) to be applied to pending proceedings. Second, examining the legislative history of AEDPA, they have noted that an earlier version of AEDPA in Congress would have applied what became section 440(d) to pending cases, but that provision was deleted by the conference committee. *Magana-Pizano*, 200 F.3d at 611; *Pak*, 196 F.3d at 676; *Shah*, 184 F.3d at 724; *Mayers*, 175 F.3d at 1302–03; *Sandoval*, 166 F.3d at 241; *Henderson*, 157 F.3d at 129–30; *Goncalves*, 144 F.3d at 128–33.

These factors are specific to AEDPA and concern only the first step of the *Landgraf* analysis. They do not concern the question of whether the application of section 440(d) to pending deportation proceedings would be regarded as retroactive under the second step of the *Landgraf* analysis. As to that question, the Attorney General maintains the Department of Justice's longstanding position that questions about an alien's deportability or eligibility for discretionary relief from deportation are matters inherently prospective in nature.

In the absence of contrary circuit precedent, the Attorney General will continue to apply AEDPA section 440(d) in the cases of aliens whose deportation proceedings were commenced after AEDPA was enacted into law, even if the alien committed his crime or was

convicted of the crime before that date. The Attorney General continues to believe that matters affecting deportation and relief from deportation are inherently prospective in nature, and that the presumption against retroactive application of federal statutes does not apply in such circumstances. The Attorney General is currently presenting that position to the U.S. Supreme Court in *INS* v. *St. Cyr*, No. 00–767, a case involving the temporal scope of the repeal of section 212(c) in IIRIRA. Therefore, the Department declines to extend nationwide the decisions of the First, Second, Fourth, and Ninth Circuits holding AEDPA section 440(d) inapplicable to aliens who were placed in proceedings after the date of enactment of AEDPA based on guilty pleas entered before that date. The Department will, however, follow circuit precedent on the temporal scope of AEDPA section 440(d).

The interpretation of AEDPA that would be changed by this rule has, of course, affected many aliens whose deportation proceedings were commenced before enactment of AEDPA but who were unable to obtain section 212(c) relief in those proceedings because of the *Soriano* decision. This rule provides a mechanism for such aliens who now have a final order of deportation to reopen their immigration proceedings if they would have been eligible to apply for section 212(c) relief but for the *Soriano* decision.

The Attorney General has considered the important interest in avoiding delays in deportation proceedings and, on balance, has decided to define the class of aliens eligible for reopening under this rule in categorical terms. For aliens who have a final order of deportation, based on established principles requiring exhaustion of all available administrative remedies, this rule could properly be written to limit relief on reopening only to those aliens who can show that they had affirmatively applied for relief under section 212(c) in their prior immigration proceedings and had appealed an immigration judge's adverse decision to the Board of Immigration Appeals. However, this rule does not require that eligible aliens make a specific factual showing that they previously applied for section 212(c) relief notwithstanding the *Soriano* decision, or appealed an immigration judge's adverse decision to the Board. Instead, this rule is drafted in order to relieve both the government and the alien of the burdens of litigating such factual issues in each case at the motion to reopen stage. In light of the highly unusual circumstances of the *Soriano* litigation, the interest in expeditious enforcement of the immigration laws will be more effectively served by focusing attention on the merits of the claims for discretionary relief from deportation with respect to aliens in the defined class who otherwise would have been eligible to seek section 212(c) relief in their immigration proceedings but for the *Soriano* precedent.

Who Is Eligible To Apply for Section 212(c) Relief?

Under this rule, eligible aliens in pending deportation proceedings may apply for section 212(c) relief if the proceedings were commenced prior to the enactment of AEDPA. This rule also provides a 180-day period for a defined class of aliens who had been adversely affected by the *Soriano* decision to file a motion to reopen in order to apply for section 212(c) relief. This special reopening rule would cover aliens who:

(1) Had deportation proceedings before the Immigration Court commenced before April 24, 1996;

(2) Are subject to a final order of deportation;

(3) Would presently be eligible to apply for section 212(c) relief if proceedings were reopened and section 212(c) as in effect on April 23, 1996, were applied; and

(4) Either,

(i) Applied for and were denied section 212(c) relief by the Board on the basis of the 1997 decision of the Attorney General in *Soriano* (or its rationale), and not any other basis;

(ii) Applied for and were denied section 212(c) relief by the Immigration Court and did not appeal the denial to the Board (or withdrew an appeal), and would have been eligible to apply for section 212(c) relief at the time the deportation became final but for the 1997 decision of the Attorney General in *Soriano* (or its rationale); or

(iii) Did not apply for section 212(c) relief but would have been eligible to apply for such relief at the time the deportation order became final but for the 1997 decision of the Attorney General in *Soriano* (or its rationale).

This rule is not intended to apply to an alien who filed an application for section 212(c) relief that was denied by an immigration judge or the Board for reasons other than *Soriano* or its rationale. For example, an alien whose section 212(c) application was denied on the merits or before the AEDPA statute was enacted is not covered by this rule.

This rule is also not intended to apply to aliens outside the United States or aliens with final orders of deportation who have returned to the United States illegally. Moreover, this rule does not provide a basis for such aliens to seek or secure admission or parole into the United States to file a section 212(c) application.

What Is Required To Be Statutorily Eligible for Section 212(c) Relief?

The alien must be a lawful permanent resident, returning to a lawful, unrelinquished domicile of seven consecutive years, who may be admitted in the discretion of the Attorney General without regard to section 212(a) (other than paragraphs (3) and (9)(C)), who is deportable on a ground that has a corresponding ground of exclusion, and who has not been convicted of one or more aggravated felonies for which he or she has served an aggregate term of imprisonment of at least five years. *See* INA § 212(c), 8 U.S.C. § 1182(c) (1994); *In re Davis*, Interim Decision 3439 (BIA 2000); *Matter of Hernandez-Casillas*, 20 I. & N. Dec. 262 (A.G. 1991).

How Is 7 Years Lawful, Unrelinquished Domicile in the United States Defined in This Rule?

The alien must have lived in the United States as either a lawful permanent resident or a lawful temporary resident pursuant to section 245A or section 210 of the INA for at least seven years, as defined in 8 CFR 212.3(f). For purposes of this rule, an alien begins accruing time as of the date of entry or admission as either a lawful permanent resident or lawful temporary resident and the accrual of time ceases when there is a final administrative order in the alien's case, as defined in 8 CFR 240.52 and 3.1(d)(2). When a motion to reopen is filed pursuant to this rule, the alien must have accrued seven years of lawful unrelinquished domicile as of the date of his or her final administrative order which the alien seeks to reopen.

Is There a Fee for Filing This Application?

If the alien has already filed a section 212(c) application and only needs to update the application, no fee is required. If the alien has not filed a section 212(c) application and has a final administrative order, he or she must file a motion to reopen. If the motion to reopen is granted, he or she must pay the fee required by 8 CFR 103.7(b)(1) for Form I–191 (currently $170). *See* 8 CFR 103.7.

An alien in deportation proceedings who has not filed an application shall submit the Form I–191 to the Immigration Court with the appropriate fee receipt attached.

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If the case is pending before the Board, the alien must file a copy of the application with the motion and if the motion is granted and the case is remanded to the Immigration Court, the alien must then file the application with the appropriate fee. Nothing in this rule changes the requirements and procedures in 8 CFR 3.31(b), 103.7(b)(1), and 240.11(f) for paying the application fee for a section 212(c) application after a motion to reopen is granted if such an application was not previously filed. Fees must be submitted to the local office of the Immigration and Naturalization Service in accordance with 8 CFR 3.31. An applicant who is eligible for section 212(c) relief and is unable to pay the filing fee may request a fee waiver in accordance with 8 CFR 103.7(c).

What Is the Procedure for an Applicant Who Is Currently in Deportation Proceedings Before the Immigration Court or the Board of Immigration Appeals?

Immigration Court. An eligible alien who has a deportation proceeding pending before the Immigration Court should file a section 212(c) application pursuant to this rule, or request a reasonable period of time to submit an application pursuant to this rule. If the alien already has an application on file, he or she may file a supplement to the existing section 212(c) application.

Board of Immigration Appeals. An eligible alien who has a deportation proceeding pending before the Board should file with the Board a motion to remand to the Immigration Court to file a section 212(c) application or to supplement his or her existing section 212(c) application on the basis of his or her eligibility for such relief pursuant to this rule. If the alien appears to be statutorily eligible for relief under this rule, the Board shall remand the case to the Immigration Court for adjudication, unless the Board chooses to exercise its discretionary authority to adjudicate the matter on the merits without a remand.

What If An Applicant Is the Subject of a Final Order of Deportation?

Aliens who have final administrative orders. An alien who is the subject of a final order of deportation who is eligible to apply for section 212(c) relief pursuant to this rule must file a motion to reopen with the Immigration Court or the Board of Immigration Appeals, whichever last held jurisdiction. The front page of the motion and any envelope containing the motion should include the notation "Special 212(c) Motion." The fee for motions to reopen (currently $110) will be waived for aliens eligible for section 212(c) relief pursuant to this rule. The waiver of the fee is only applicable to motions to reopen seeking section 212(c) relief pursuant to this rule. The reopening and remand will be limited to issues concerning the alien's eligibility for relief under section 212(c) and may not address the alien's deportability or any other basis for relief from deportation, unless the Board is also reopening under other applicable provisions of law, in which case the issues may be consolidated for hearing as appropriate and all appropriate motions fees will apply.

If the alien previously filed an application for section 212(c) relief, he or she must file a copy of that application or a copy of a new application and supporting documents with the motion to reopen. If the motion to reopen is granted, an alien who previously filed an application will not be required to pay a new filing fee for the section 212(c) application, Form I–191.

If the alien has not previously filed an application for section 212(c) relief, the alien must submit a copy of his or her completed application and supporting documents with the motion to reopen. If the motion is granted, the alien must then file the application with the appropriate fee.

Cases remanded to the board. If a case has been remanded to the Board by a federal court based on a judicial decision rejecting the Attorney General's decision in *Soriano*, the Board will comply with the order of the district or circuit court.

What Happens if an Applicant Currently Has a Motion to Reopen or Motion to Reconsider Pending Before the Immigration Court or the Board?

Immigration court. If an alien has a pending motion to reopen or reconsider filed with the Immigration Court, other than a motion to reopen to apply for section 212(c) relief, he or she must file a new motion to reopen with the Immigration Court to apply for section 212(c) relief on the basis of his or her eligibility pursuant to this rule.

Board of immigration appeals. If an alien has a pending motion to reopen or reconsider filed with the Board, other than a motion to reopen to apply for section 212(c) relief, the alien must file a new motion to reopen with the Board to apply for section 212(c) relief on the basis of his or her eligibility pursuant to this rule.

New motion to reopen. An alien may file only one motion to reopen for purposes of establishing eligibility under this rule. A new motion to reopen filed pursuant to this rule either before the Immigration Court or the Board, as appropriate, must specify whether the alien has any pending motions before the Immigration Court or the Board. All motions to reopen to apply for section 212(c) relief filed pursuant to this rule are subject to the restrictions specified in this rule. The usual time and number restrictions on motions, as articulated in 8 CFR 3.2 and 3.23, shall apply to all other motions.

Is an Alien With a Final Administrative Order of Deportation Required To File a Motion To Reopen Under This Rule Within the 180 day Period in Order To Seek Section 212(c) Relief?

This rule is intended to provide a single, straightforward process for the defined class of aliens who were adversely affected by *Soriano* to reopen their immigration proceedings based on the interpretive change announced in this rule.

Accordingly, 8 CFR 3.44 is intended to provide the sole process for eligible aliens who have a final administrative order of deportation to reopen their cases on account of the change in the governing law announced in this rule in order to apply for section 212(c) relief. However, the existing reopening rules in 8 CFR 3.2 and 3.23 allow aliens to seek to reopen their cases notwithstanding the time limits on certain other grounds unrelated to a change in the law. As provided in 8 CFR 3.44(h), this rule would not prevent an alien from filing a motion to reopen under the existing rules based on any other basis or exception.

Does the Filing of an Application for Section 212(c) Relief Stay the Execution of a Final Order?

The mere filing of a motion to reopen to apply for section 212(c) relief with the Immigration Court or the Board does not stay the execution of the final order of deportation. To request that execution of the final order be stayed by the Immigration and Naturalization Service, the alien must file an Application for Stay of Removal (Form I–246), following the procedures set forth in 8 CFR 241.6. To request that execution of the final order be stayed by the Immigration Courts or the Board, the alien must comply with the procedures outlined in 8 CFR 3.2(f) and 3.23(b)(v).

What Happens if an Application Is Denied by the Immigration Court?

If the Immigration Court denies the section 212(c) application of an alien in deportation proceedings before the Immigration Court, the decision may be appealed to the Board along with, and under the same procedures as apply to, other issues, if any, properly before the Board on appeal.

What Happens if an Alien Fails To Appear for a Hearing Before the Immigration Court on a Section 212(c) Application?

An alien must appear for all scheduled hearings before an Immigration Court, unless his or her appearance is waived by the Immigration Court. An alien who is in deportation proceedings before the Immigration Court, and who fails to appear for a hearing regarding a section 212(c) application, will be subject to the applicable statutory and regulatory *in absentia* procedures (*i.e.*, section 242B of the Act as it existed prior to amendment by IIRIRA, and applicable regulations).

When Was the Proposed Rule Published and When Were Comments Received?

The Department of Justice (Department) published in the **Federal Register** a proposed rule at 65 FR 44476 on July 18, 2000, which created a uniform procedure for applying the law as enacted by the Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA). The Department requested comments from the public for a period of 30 days, ending on August 17, 2000. In response to requests from the public, and to ensure the public ample opportunity to fully review and comment on the proposed rule, the Department published a notice in the **Federal Register** on October 11, 2000, extending the public comment period to October 11, 2000 (65 FR 60384).

How Many Comments Were Received From Interested Parties During the Comment Period?

In response to the proposed rulemaking, the Department received 169 comments from various organizations, attorneys, and other interested individuals. Each Member of Congress, representative or member of a non-governmental organization (NGO), interested individual, or private attorney was counted separately as a "commenter." Commenters included 10 Members of Congress, one Division of a State Department of Criminal Justice, 91 representatives of a number of NGOs, 11 private attorneys or legal professionals, and 56 interested individuals. Included in that number were eight letters submitted individually by eight separate NGOs. Five NGOs submitted identical form letters. One commentary was jointly submitted by a group of 10 NGOs and four legal professionals not affiliated with any of the NGOs, while another commentary was submitted by a group of 38 NGOs. Finally, identical form letter commentaries were separately submitted by 30 individual members of a single NGO. The Department appreciates the contributions of all individuals and groups who submitted comments.

What Were the Specific Comments and How Is the Department Amending the Rule as a Result?

The issues raised by the commenters generally fell into five categories: (1) Procedural requirements; (2) eligibility; (3) nationwide uniformity; (4) parole; and (5) miscellaneous issues. The number of commenters raising issues pertaining to procedural requirements totaled 151 and those raising eligibility concerns totaled 158. Commenters who raised issues pertaining to parole totaled 123, while only 20 commenters were concerned with uniformity issues. Five commenters addressed miscellaneous issues. Comments in each of these areas are discussed in further detail below.

1. Issues Pertaining to Procedural Requirements

Concerns regarding various procedural requirements were raised by 151 commenters. All but two representatives from NGOs made suggestions concerning procedural issues, and 48 out of 56 interested individuals made similar suggestions.

Comment: One hundred forty-six commenters expressed concern that the proposed rule lacks a mechanism to inform the public of available relief. These commenters suggested that the Department undertake the responsibility to notify each alien who appeared to be potentially eligible to file a motion to reopen, since it would be unlikely that an eligible, unrepresented alien would be aware of the relief available to him or her under the rule. Further, this group of commenters suggested that the Department provide public notice of the relief in appropriate venues and languages reaching the largest number of individuals both in and outside of the United States.

Response: Notification of the availability of section 212(c) relief under this rule will be provided in the same manner and form as notification for other forms of relief. Final rules are always published in the **Federal Register** and are available on the Federal Register website. In addition, the Department will issue a press release announcing the effective date of the final rule and outlining the eligibility requirements. The Department has received, and will likely continue to receive, numerous telephone inquiries regarding the availability of section 212(c) relief pursuant to this rule from interested individuals and has directed them to the **Federal Register** for further updates.

Comment: A group of 10 NGOs suggested that all individuals currently in proceedings should be notified, in person or via certified mail, of their possible eligibility for relief.

Response: Because the regulation includes individuals who are potentially eligible for relief even though they have not yet filed a section 212(c) application, it would be difficult for the Department to identify the class of potentially eligible individuals with any accuracy. Moreover, in view of the administrative burdens involved in such a notification initiative, the Department has concluded that the traditional means of notification through the **Federal Register** is sufficient, particularly in combination with the press release the Department is issuing on this subject.

Comment: These same commenters, speaking as a group, stated that although aliens presently in proceedings before the Immigration Court or the Board are intended to be covered by the proposed rule, the rule itself does not contain language which specifically includes such aliens.

Response: 8 CFR 212.3(g) includes all eligible aliens whose deportation proceedings commenced before April 24, 1996. Nothing in the rule excludes otherwise covered aliens whose proceedings are pending as of the effective date of this final rule.

Comment: The same group of 10 NGOs provided additional suggestions: (1) Eliminating the requirement of a motion to reopen altogether; (2) requiring the Board and the Immigration Courts to reopen *sua sponte* each case in which an individual may be eligible for relief under the rule, and (3) providing notice to the alien of such potential eligibility. An additional 129 commenters endorsed the *sua sponte* reopening of cases. Thirty commenters also suggested that no remand should be required for cases currently pending before the Board. Instead, they suggested that any appeal by the INS deemed without merit by the Board be dismissed and the decision of the Immigration Judge granting the section 212(c) waiver be reinstated.

Response: Pursuant to 8 CFR 3.2 and 3.23, *sua sponte* reopening of any case may occur at the discretion of the Board or an Immigration Judge, but such reopening is not mandated by this rule. The burden of establishing eligibility for section 212(c) relief, as with any other request for relief from deportation, is

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upon the alien, and it is incumbent upon any alien subject to a final order of deportation who wishes to pursue relief in proceedings to do so in a diligent and timely fashion, under the provisions of this rule. The Department cannot, as a practical matter, undertake the enormous burden of examining past cases that resulted in a final order of deportation for possible *sua sponte* reopening. Such a burden would result in inordinate delays in adjudicating cases currently pending before the Board and the Immigration Courts.

With regard to INS appeals of section 212(c) applications that are presently pending before the Board, these cases will be adjudicated in the same manner as any other pending appeal subject to a superseding regulation or change in the law. The Board will continue to exercise its appellate authority to affirm the decision of the Immigration Judge, remand the case for an additional hearing, or adjudicate the appeal by applying the provisions of section 212(c) as promulgated prior to AEDPA.

Comment: One commenter writing on behalf of an NGO suggested that the Department adopt a "streamlined" motion to reopen procedure using a simple, one-page fill-in or check-off form.

Response: In view of the widely varying circumstances in each case, and the traditional requirement that persons seeking to reopen completed proceedings carry a burden of establishing, among other things, prima facie eligibility for relief upon reopening, the Department declines to adopt a "one-size-fits-all" form and will adhere to the normal requirements concerning motions to reopen, except as specifically modified by the rule.

Comment: Twenty-one commenters suggested that aliens filing motions to reopen should not be required to file any legal documents previously submitted to the INS or to the Immigration Court.

Response: In cases where an alien is filing a motion to reopen his or her proceedings based upon alleged eligibility for a form of relief from removal or deportation, the alien has the burden of establishing prima facie eligibility for that form of relief. This rule is not intended to alter that fundamental legal principle. In accordance with 8 CFR 3.23(b)(3), "[a]ny motion to reopen for the purpose of acting upon an application for relief must be accompanied by the appropriate application for relief and all supporting documents." Because the files maintained by the INS often vary from those maintained by the Immigration Courts and the Board, a policy at variance from the regulations would cause aliens to operate on the mistaken assumption that the Immigration Court, the Board, and the INS maintain duplicate files while considering eligibility for relief. In addition, if an alien filed a motion to reopen without attaching supporting documents, but with the expectation that the Immigration Judge or Board would rely on certain documents the alien believes were already in the file in adjudicating that motion, that alien may not necessarily make a prima facie case for relief.

Comment: One hundred thirty-five commenters requested either that the 90-day time limit on motions to reopen be eliminated and that no time limit whatsoever be imposed, or that the time period for filing a motion to reopen be extended from 90 days to 1 year commencing on the date of actual notice to the alien. They noted that it could prove difficult for aliens and their representatives to gather the necessary documentation to support their motions to reopen during the currently allotted 90-day time period.

Response: The Department recognizes the difficulty that aliens and/or their representatives may experience in assembling adequate documentation to establish prima facie eligibility under this rule. The Department also recognizes that in cases where the order of deportation became final many years ago, aliens and/or their representatives might need to request copies of conviction records from Federal or State authorities. The Department recognizes that it may be difficult for many bona fide applicants to become informed of available relief, obtain counsel, gather all necessary documents and file a motion to reopen within the currently allotted 90 days time period. Accordingly, the Department is adopting this suggestion to a limited extent, and is extending the period of time during which motions to reopen may be filed to 180 days commencing on the effective date of this rule. The Department feels that this time period strikes a reasonable balance between the litigative difficulties for aliens filing motions and the administrative need for a finite and workable program.

Comment: Sixty-five percent (65%) of the commenters suggested that an automatic stay of deportation be provided in conjunction with the filing of a motion to reopen under this rule, effective upon filing of the motion.

Response: With very limited exceptions, the prevailing rule in immigration jurisprudence is that the mere filing of an application, motion, or petition does not automatically stay execution of a deportation order. Were it otherwise, individuals subject to a final order of deportation could thwart or delay deportation through meritless filings with the Service, Immigration Court, or Board. The Department will adhere to the traditional approach in this rule. Aliens who believe they are eligible for relief under this rule are free to request a discretionary stay of deportation from the Service, the Immigration Court, or the Board as appropriate.

2. Issues Pertaining to Eligibility

One hundred fifty-four commenters raised concerns regarding the determination of eligibility for relief under the proposed rule.

Comment: One hundred forty-eight commenters felt that using the date of "commencement" of proceedings to determine eligibility for section 212(c) relief was arbitrary, because commencement of proceedings is affected by various extraneous factors. For example, approximately 20 commenters suggested that individuals who had been served with Orders to Show Cause (OSCs) at any time, whether before or after April 24, 1996, should be eligible to apply for relief under the proposed rule, regardless of whether they had already filed a section 212(c) waiver application. An equal number of commenters suggested that aliens who had committed or been convicted of offenses prior to April 24, 1996, be afforded an opportunity to apply for relief under the proposed rule. One commenter suggested that section 212(c) be amended to include post-April 1996 convictions.

Response: The well-established rule in immigration law, as stated in 8 CFR 3.14(a), is that "[j]urisdiction vests, and proceedings before an Immigration Judge commence, when a charging document is filed with the Immigration Court by the Service." Up until the point of filing, the Service can cancel a charging document. *See* 8 CFR 239.2(a). After that point, it must request that the Immigration Court terminate proceedings. *See* 8 CFR 239.2(c). Hence, filing of the charging document with the Immigration Court is the critical event as regards the initiation of deportation proceedings.

Because many other legal determinations depend on whether proceedings have commenced, the need for a bright-line rule as to the time of commencement is clear. The Department will adhere to its well-established regulatory scheme as regards commencement of proceedings, and will not rely on some other event such as the issuance or service of the charging document as determining whether proceedings have begun.

Some circuits have looked to the service of a charging document as the critical event for purposes of "retroactivity" analysis. The Department disagrees with the reasoning of these courts, and declines to adopt it in this rule. In any such circuit, however, the Department will regard AEDPA section 440(d) as inapplicable to aliens whose charging documents were served before AEDPA's enactment if required to do so by circuit precedent. A circuit's adoption of a "retroactivity" analysis based on service of the charging document does not compel the further conclusion that proceedings commence with the service of a charging document. The latter conclusion flatly contradicts well-settled law.

Comment: In adjudicating motions to reopen, one commenter suggested that when determining eligibility for section 212(c) relief in proceedings, only evidence available before April 24, 1996, be considered.

Response: Applications for relief from deportation are considered to be ongoing, and the Board assesses eligibility for relief as of the time of its decision. *See In re Yeung*, Interim Decion 3297 (BIA 1997); *Matter of U-M-*, 20 I. & N. Dec. 327, 332 (BIA 1991), *aff'd sub nom. Urbina-Mauricio* v. *INS*, 989 F.2d 1085 (9th Cir. 1993). To abandon this long-standing view would put the Department in the position of granting permanent U.S. status to persons presently ineligible for such status under applicable statutes. The Department declines to adopt such an approach. It should be noted that this rule often operates to the advantage of the respondent in proceedings, for example, by allowing for consideration of equities gained up until the date of the application.

Comment: Approximately *five* commenters felt that the *Soriano* decision deprived many aliens of a full and fair opportunity to pursue their applications for relief from deportation under section 212(c). These commenters cited examples where aliens were not permitted to file section 212(c) waiver applications because they were found ineligible on statutory grounds and their applications were pretermitted. Two Members of Congress joined in this view, noting that absent section 440(d) of the AEDPA, an alien would have been permitted to litigate issues of statutory eligibility. Additionally, thirty-one percent of commenters felt that affected aliens should be returned to their position prior to the issuance of the *Soriano* decision by the Attorney General. One hundred forty commenters suggested that the language in proposed 8 CFR 3.44(b)(4)(i), which currently states, *inter alia*, that:

> A motion to reopen proceedings to seek section 212(c) relief under this section must establish that the alien: * * * (4) Either—(i) Applied for and was denied section 212(c) relief by the Board on the basis of the 1997 decision of the Attorney General in Matter of Soriano (or its rationale), *and not any other basis* (emphasis added); be changed to read as follows:
>
> A motion to reopen proceedings to seek section 212(c) relief under this section must establish that the alien: * * * (4) Either—(i) Applied for and was denied section 212(c) relief *in whole or in part on the basis of the Attorney General's 1997 decision in Soriano.* (Emphasis added.)

One commenter suggested that the rule contain examples illustrating the meaning of "on the basis of * * * [*Soriano*] and not any other basis."

Response: The purpose of this rule is to provide a uniform interpretation of AEDPA section 440(d) and to provide a remedy for certain aliens subject to a final order based on proceedings commenced before AEDPA's enactment who are eligible presently (*i.e.*, at the time of decision) for section 212(c) relief and would have been eligible to apply at the time of their final orders but for the *Soriano* decision. The "not any other basis" language ensures that persons who were ineligible for or denied relief on some other basis, and thus were not affected by *Soriano*, do not improperly benefit from the rule.

Comment: Presenting the opposite view that the proposed *Soriano* rule should be construed as narrowly as possible, another commenter suggested deleting proposed 8 CFR 3.44(b)(4)(iii) altogether, which permits aliens who did not apply for section 212(c) relief but would have been eligible for such relief "but for" the Attorney General's decision in *Soriano*. This commenter also recommended that the final condition imposed in 3.44(b)(4)(i), which restricts eligibility to those aliens whose section 212(c) applications were denied "on the basis" of *Soriano* "and not any other basis," be added to 3.44(b)(4)(ii). Another commenter agreed with the proposed rule as written, stating that section 212(c) applications denied for reasons other than *Soriano* should be excluded from the coverage of the rule.

Response: As noted in the proposed rule, this final rule is intended to provide a uniform interpretation of section 440(d) of AEDPA and to mitigate disagreements among the circuits regarding the scope of its application. If the Department were to delete 8 CFR section 3.44(b)(4)(iii), relief under this rule would be limited to those aliens who filed applications for 212(c) relief and would leave unresolved those cases where an alien's application for 212(c) relief was pretermitted. Therefore, the Department declines to adopt this suggestion.

Comment: A group of 10 commenters suggested that the word "presently" be deleted in proposed 8 CFR 3.44(b)(3). These commenters stated that, as currently written, the proposed rule would exclude individuals eligible for section 212(c) at the time of an incorrectly pretermitted application, but who "presently" have not had a lawful unrelinquished domicile of seven years in the United States.

Response: The Department chooses to retain the word "presently" in 8 CFR section 3.44(b)(3). As noted above, the rule does require eligibility (but for the *Soriano* decision) for section 212(c) relief at the time of the final deportation order. But the rule requires present eligibility for relief as well, because applications for relief are considered to be ongoing, and the Department's adjudicators assess eligibility for relief at the time of decision. This rule is not intended to change the statutory requirements for eligibility for section 212(c) relief, but is strictly limited to providing a uniform interpretation of the temporal scope of section 440(d) of AEDPA.

3. Issues Pertaining to Nationwide Uniformity

Nineteen commenters stated that the proposed rule is too narrow, and will not achieve the desired goal of nationwide uniformity due to the controlling case law in numerous circuits. These commenters cited the 1st, 4th, and 11th Circuit decisions holding that lawful permanent residents may apply for section 212(c) relief if they were in deportation proceedings before April 1, 1997, and pled guilty to criminal charges in reliance on eligibility for section 212(c) relief. *See, e.g. Mattis*, 212 F.3d at 35–40 (section 212(c) available to aliens in deportation proceedings who pled guilty to a crime in reliance upon availability of section 212(c) relief); *Wallace*, 194 F.3d at 287 (section 212(c) available to aliens in proceedings, deemed to commence when the OSC was served upon the alien, rather than filed with the Immigration Court); *Tasios*, 204 F.3d at 550–52 (section 212(c) available to aliens who pled guilty prior to the enactment of the AEDPA); *Alanis-Bustamante* v. *Reno*, 201 F.3d 1303,

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1308–10 (11th Cir. 2000) (section 212(c) available to aliens in proceedings, deemed to commence when the OSC was served on the alien, rather than filed with the Immigration Court).

Response: By this rule, the Department only agrees to acquiesce on a nationwide basis in the decisions of those circuits that have ruled that Congress did not intend to apply AEDPA section 440(d) to the cases of aliens whose deportation proceedings were commenced before AEDPA was enacted. While uniformity is an important goal, and one of the principal motivations for this rule, there is no requirement that the Department adopt the view of the least restrictive circuit in order to achieve perfect uniformity, and it will not do so. Rather, the Department has adopted what it considers to be the soundest and best supported rule among the various approaches taken by the courts of appeals.

Comment: By contrast, one commenter stated that "[n]one of the Article I constitutional powers to make "uniform laws" have been interpreted to require true or pure uniformity." Further, this commenter stated that at most "geographical uniformity" in a given location, rather than nationwide, is required by the Constitution and that "uniformity among persons" is not required.

Response: As noted above, the Department agrees that perfect uniformity is not required. Nevertheless, uniformity is an important goal, and the present rule is intended to achieve that goal within reasonable limits.

4. Issues Pertaining to Parole

Comment: One hundred twenty-three commenters suggested that lawful permanent residents who complied with their deportation orders and were deported from the United States be granted parole, thus enabling them to pursue motions to reopen and present cases on the merits of their section 212(c) waiver applications. One commenter believed that no filing deadline should be imposed for an alien who is currently outside of the United States and who asserts eligibility for relief under this rule.

One hundred four commenters stated that absent a provision to permit parole of aliens into the United States, such aliens will be summarily denied relief. Citing H.R. 5062, which was introduced in the 106th Congress, Second Session, these commenters indicated that in recently proposed legislation, the House of Representatives established that aliens unjustly removed from the United States should have the opportunity to return to the United States to have their claims considered.

Nonetheless, one commenter expressed support for the language in proposed 8 CFR 3.44(i), which excludes aliens who have departed, aliens who have a final order of removal and illegally returned, and aliens who have not been admitted or paroled into the United States. A group of 10 commenters felt that 3.44(i), in its entirety, should be deleted from the final rule.

Response: The Department's primary purpose in publishing this rule is to alleviate the inter-circuit conflicts regarding the temporal scope of section 440(d) of AEDPA. None of the circuits that have disagreed with the Attorney General's decision in *Soriano* have adopted a general view that aliens who were removed or departed the United States should be permitted to return. The Department has no method of identifying or discerning the location of aliens who departed on account of the *Soriano* decision and the commenters who offered this suggestion have provided none. The government's interest in finality, the considerable administrative burdens involved, and the risk of paroling persons ultimately determined not to be eligible for relief all counsel against providing for the parole of deported criminals back into the United States.

5. Miscellaneous Issues

Five commenters addressed miscellaneous issues. Three commenters expressed their general support for the proposed rule.

Comment: One commenter stated that overall, the proposed rule is not supported by legislative history. That commenter stated that the goal of Congress in amending and ultimately repealing section 212(c) relief was to enhance the ability of the United States to deport criminal aliens.

Response: While the Department acknowledges Congress' general intentions regarding the efficient removal of criminal aliens, it must also note the lack of perfect congressional clarity with regard to the applicability of AEDPA section 440(d) to cases pending at the time of AEDPA's enactment. This lack of clarity has led to costly litigation, sharp disagreements within the circuits, and a consequent lack of uniformity in the law on this question. The present rule seeks to ameliorate this situation by promoting uniformity in the law, within reasonable limitations, throughout the United States.

Comment: One commenter suggested that the policy reasons underlying the proposed rule apply equally to section 212(i) waivers. This commenter stated that the regulations should address and overturn the Board's ruling in *In re Cervantes-Gonzalez*, Interim Decision 3380 (BIA 1999), which addressed section 212(i) of the INA and its requirement that an alien establish extreme hardship to his or her U.S. citizen or permanent resident alien spouse or parent in order to qualify for a waiver of inadmissibility.

Response: The present rule seeks to promote uniformity by adopting a single rule for applying AEDPA section 440(d) nationwide (except where prohibited by the law of the circuit). The policy goals underlying this initiative do not exist with respect to section 212(i), which has not been the subject of similarly sharp or widespread interpretive disagreement within the circuits. The Department will not disturb the existing administrative jurisprudence regarding section 212(i).

What Technical Amendments Are Being Made to the Board of Immigration Appeals Streamlining Regulation?

8 CFR 3.1(d)(1–a) was redesignated as section 3.1(d)(2) in the Board of Immigration Appeals Streamlining final regulation published Monday, October 18, 1999 (64 FR 56135). Additionally, 8 CFR 3.1(d)(2) was redesignated as section 3.1(d)(3). Consequently, those paragraphs in 8 CFR which refer to section 3.1(1–a) or section 3.1(d)(2) are misleading and need to be amended.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), the Attorney General certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule allows certain aliens to apply for INA section 212(c) relief; it has no effect on small entities such as that term is defined in 5 U.S.C. 601(6).

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996. *See* 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

This rule is considered by the Department of Justice to be a "significant regulatory action" under Executive Order 12866, section 3(f). Regulatory planning and Review. Accordingly, this regulation has been submitted to the Office of Management and Budget for review.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Plain Language Instructions

We try to write clearly. If you can suggest how to improve the clarity of these regulations, call or write Charles Adkins-Blanch, General Counsel, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2400, Falls Church, Virginia 22041, telephone (703) 305–0470.

Paperwork Reduction Act

This rule will increase the use of Form I–191 but will not result in a material change in that form, and the INS is adjusting the total burden hours of the form accordingly.

List of Subjects

8 CFR Part 3

Administrative practice and procedure, Immigration, Organization and functions (Government agencies).

8 CFR 212

Administrative practice and procedure, Aliens, Passports and visas, Immigration, Reporting and recordkeeping requirements.

8 CFR 240

Administrative practice and procedure, Immigration.

Accordingly, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 3—EXECUTIVE OFFICE FOR IMMIGRATION REVIEW

1. The authority citation for part 3 continues to read as follows:

Authority: 5 U.S.C. 301; 8 U.S.C. 1101 note; 8 U.S.C. 1103, 1252 note, 1324b, 1362, 28 U.S.C. 509, 510, 1746; sec. 2, Reorg. Plan No. 2 of 1950; 3 CFR, 1949–1953 Comp., p. 1002.

§ 3.1 [Amended]

2. In section 3.1(d)(2)(iii), references to "paragraph (d)(1–a)(i)" are revised to read "paragraph (d)(2)(i)."

§ 3.3 [Amended]

3. In section 3.3(b), the reference to "§ 3.1(d)(1–a)(i)" is revised to read "§ 3.1(d)(2)(i)."

4. Section 3.44 is added to subpart C to read as follows:

§ 3.44 Motion to reopen to apply for section 212(c) relief for certain aliens in deportation proceedings before April 24, 1996.

(a) *Standard for adjudication.* Except as provided in this section, a motion to reopen proceedings to apply for relief under section 212(c) of the Act will be adjudicated under applicable statutes and regulations governing motions to reopen.

(b) *Aliens eligible to reopen proceedings to apply for section 212(c) relief.* A motion to reopen proceedings to seek section 212(c) relief under this section must establish that the alien:

(1) Had deportation proceedings before the Immigration Court commenced before April 24, 1996;

(2) Is subject to a final order of deportation,

(3) Would presently be eligible to apply for section 212(c) as in effect on or before April 23, 1996; and

(4) Either—

(i) Applied for and was denied section 212(c) relief by the Board on the basis of the 1997 decision of the Attorney General in *Matter of Soriano* (or its rationale), and not any other basis;

(ii) Applied for and was denied section 212(c) relief by the Immigration Court, did not appeal the denial to the Board (or withdrew an appeal), and would have been eligible to apply for section 212(c) relief at the time the deportation became final but for the 1997 decision of the Attorney General in *Matter of Soriano* (or its rationale); or

(iii) Did not apply for section 212(c) relief but would have been eligible to apply for such relief at the time the deportation order became final but for the 1997 decision of the Attorney General in *Matter of Soriano* (or its rationale).

(c) *Scope of reopened proceedings.* Proceedings shall be reopened under this section solely for the purpose of adjudicating the application for section 212(c) relief, but if the Immigration Court or the Board reopens on other applicable grounds, all issues encompassed within the reopening proceedings may be considered together, as appropriate.

(d) *Procedure for filing a motion to reopen to apply for section 212(c) relief.* An eligible alien must file either a copy of the original Form I–191 application, and supporting documents, or file a copy of a newly completed Form I–191, plus all supporting documents. An alien who has a pending motion to reopen or reconsider before the Immigration Court or the Board, other than a motion for section 212(c) relief, must file a new motion to reopen to apply for section 212(c) relief pursuant to this section. The new motion to reopen shall specify any other motions currently pending before the Immigration Court or the Board that should be consolidated. The Service shall have 45 days from the date of service of the motion to reopen to respond. In the event the Service does not respond to the motion to reopen, the Service retains the right in the reopened proceedings to contest any and all issues raised. Any motion for section 212(c) relief pending before the Board or the Immigration Courts on January 22, 2001 that would be barred by the time or number limitations on motions shall be deemed to be a motion to reopen filed pursuant to this section.

(e) *Fee and number restriction for motion to reopen waived.* No filing fee is required for a motion to reopen to apply for section 212(c) relief under this section. An eligible alien may file one motion to reopen to apply for section 212(c) relief under this section, even if a motion to reopen was filed previously in his or her case.

(f) *Deadline to file a motion to reopen to apply for section 212(c) relief under this section.* An alien with a final administrative order of deportation must file a motion to reopen by June 23, 2001.

(g) *Jurisdiction over motion to reopen to apply for section 212(c) relief and remand of appeals.*

(1) Notwithstanding any other provisions, any motion to reopen filed pursuant to this section to apply for section 212(c) relief shall be filed with

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the Immigration Court or the Board, whichever last held jurisdiction over the case.

(2) If the Immigration Court has jurisdiction, and grants only the motion to reopen to apply for section 212(c) relief pursuant to this section, it shall adjudicate only the section 212(c) application.

(3) If the Board has jurisdiction and grants only the motion to reopen to apply for section 212(c) relief pursuant to this section, it shall remand the case to the Immigration Court solely for adjudication of the section 212(c) application (Form I–191), unless the Board chooses to exercise its discretionary authority to adjudicate the matter on the merits without a remand.

(h) *Applicability of other exceptions to motions to reopen.* Nothing in this section shall be interpreted to preclude or restrict the applicability of any other exception to the motion to reopen provisions of this part as defined in 8 CFR 3.2(c)(3) and 3.23(b).

(i) *Limitations on eligibility for reopening under this section.* This section does not apply to:

(1) Aliens who have departed the United States;

(2) Aliens with a final order of deportation who have illegally returned to the United States; or

(3) Aliens who have not been admitted or paroled.

PART 212—DOCUMENTARY REQUIREMENTS: NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

5. The authority citation for part 212 continues to read as follows:

Authority: 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1187, 1225, 1226, 1227, 1228, 1252; 8 CFR part 2.

6. Paragraph (g) is added to section 212.3 to read as follows:

§ 212.3 Application for the exercise of discretion under § 212(c).

* * * * *

(g) *Relief for certain aliens who were in deportation proceedings before April 24, 1996.* Section 440(d) of Antiterrorism and Effective Death Penalty Act of 1996 (AEDPA) shall not apply to any applicant for relief under this section whose deportation proceedings were commenced before the Immigration Court before April 24, 1996.

PART 240—PROCEEDINGS TO DETERMINE REMOVABILITY OF ALIENS IN THE UNITED STATES

7. The authority citation for 8 CFR part 240 continues to read as follows:

Authority: 8 U.S.C. 1103, 1182, 1186a, 1224, 1225, 1226, 1227, 1251, 1252 note, 1252a, 1252b, 1362; secs. 202 and 203, Pub. L. 105–100 (111 Stat. 2160, 2193); sec. 902, Pub. L. 105–277 (112 Stat. 2681); 8 CFR part 2.

§ 240.15 [Amended]

8. In § 240.15, the reference to "§ 3.1(d)(1–a)" is revised to read "§ 3.1(d)(2)."

§ 240.21 [Amended]

9. In § 240.21(c), the reference to "§§ 3.1(d)(2) and 3.39" is revised to read "§§ 3.1(d)(3) and 3.39."

§ 240.53 [Amended]

10. In § 240.53(a), the reference to § 3.1(d)(1–a)" is revised to read "§ 3.1(d)(2)."

Dated: January 17, 2001.

Janet Reno,

Attorney General.

[FR Doc. 01–1785 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–CE–75–AD; Amendment 39–12061; AD 2001–01–11]

RIN 2120–AA64

Airworthiness Directives; Rolladen Schneider Flugzeugbau GmbH Models LS 4 and LS 4a Sailplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to certain Rolladen Schneider Flugzeugbau GmbH (Rolladen Schneider) Models LS 4 and LS 4a sailplanes. This AD requires you to inspect the airbrake system for damage and proper rigging, with correction, repair, or replacement, as necessary. This AD also requires you to report any damage found to the Federal Aviation Administration (FAA). This AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for Germany. The actions specified by this AD are intended to detect and correct damage to the airbrake locking bracket caused by asymmetric loads. This condition could result in the pilot's inability to operate the airbrake controls, with consequent loss of sailplane control.

DATES: This AD becomes effective on March 9, 2001.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of March 9, 2001.

ADDRESSES: You may get the service information referenced in this AD from Rolladen-Schneider Flugzeugbau GmbH, Muhlstrasse 10, D–63329 Egelsbach, Germany; phone: ++ 49 6103 204126; facsimile: ++ 49 6103 45526. You may examine this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 99–CE–75–AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Brian Hancock, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4143; facsimile: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

What events have caused this AD? The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, recently notified FAA that an unsafe condition may exist on certain Rolladen Schneider Models LS 4 and LS 4a sailplanes. The LBA reports two occurrences of damaged airbrake locking brackets found on the above-referenced sailplanes. The damage was the result of improper rigging of the airbrake system. The asymmetric load that occurs over time with an improperly rigged airbrake system could result in cracks in the welding region of the airbrake tube and lateral deformation of the airbrake locking bracket.

What are the consequences if the condition is not corrected? Damage to the airbrake locking bracket, if not detected and corrected, could result in the pilot's inability to operate the airbrake controls with consequent loss of sailplane control.

Has FAA taken any action to this point? We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Rolladen Schneider Models LS 4 and LS 4a sailplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on November 9, 2000 (65 FR 67315). The NPRM proposed to require you to inspect the airbrake locking bracket on the rear landing gear box for signs of fatigue (cracks in the paint, paint chips, or cracks in the welding region to the tube) and inspect for proper rigging of the airbrake system; reassemble the airbrake system (if improper rigging is found). If any sign of fatigue is evident, disassemble the airbrake system, obtain a modified airbrake locking bracket from the manufacturer, install this bracket, and accomplish certain adjustments after reassembling the airbrake system; and report any damage found to the FAA.

The FAA is requiring a reporting requirement so we can get an idea of how many sailplanes in the fleet have damaged or incorrectly rigged airbrake systems. We will utilize this information in deciding whether any of the required actions should be repetitive or whether we should initiate additional rulemaking.

Was the public invited to comment? Interested persons were afforded an opportunity to participate in the making of this amendment. No comments were received on the proposed rule or the FAA's determination of the cost to the public.

FAA's Determination

What is FAA's final determination on this issue? After careful review of all available information related to the subject presented above, we have determined that air safety and the public interest require the adoption of the rule as proposed except for minor editorial corrections. We determined that these minor corrections:

—Will not change the meaning of the AD; and

—Will not add any additional burden upon the public than was already proposed.

Cost Impact

How many sailplanes does this AD impact? We estimate that this AD affects 78 sailplanes in the U.S. registry.

What is the cost impact of this AD on owners/operators of the affected sailplanes? We estimate the following costs to accomplish the inspection and any necessary reassembly:

Labor cost	Parts cost	Total cost per sailplane	Total cost on U.S. operators
1 workhour × $60 per hour = $60	Not applicable	$60 per sailplane	$60 × 78 = $4,680.

We estimate the following costs to accomplish any necessary modification that will be required based on the results of the inspection. We have no way of determining the number of sailplanes that may need such modification:

Labor cost	Parts cost	Total cost per sailplane
2 workhours × $60 per hour = $120	The manufacturer will modify the airbrake bracket free of charge.	$120 per sailplane.

Compliance Time of this AD

What is the compliance time of this AD? The compliance time of this AD is within the next 30 calendar days after the effective date of this AD.

Why is the compliance time presented in calendar time instead of hours time-in-service (TIS)? Damage to the airbrake locking brake occurs as a result of sailplane operation. However, the reason the damage occurs is because of incorrect rigging of the airbrake system. We have determined that a calendar time for compliance is necessary because this incorrect rigging is not directly related to sailplane operation. The chance of this situation occurring is the same for a sailplane with 10 hours time-in-service (TIS) as it is for a sailplane with 500 hours TIS. For this reason, the FAA has determined that a compliance based on calendar time will be utilized in this AD in order to assure that the unsafe condition is addressed on all sailplanes in a reasonable time period.

Why is the compliance time of this AD different than the German AD and the service information? The service information specifies the actions required in this AD "prior to further flight" and the German AD mandates these actions "prior to further flight" for sailplanes registered for operation in Germany. The FAA does not have justification for requiring the action prior to further flight. Instead, the FAA has determined that 30 calendar days is a reasonable time period for accomplishing the actions in this AD.

Regulatory Impact

Does this AD impact various entities? The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

Does this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new AD to read as follows:

2001–01–11 Rolladen Schneider Flugzeugbau GMBH:

Amendment 39–12061; Docket No. 99–CE–75–AD.

(a) *What sailplanes are affected by this AD?* This AD affects models LS 4 and LS 4a sailplanes, serial numbers 4000 through 4852, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above sailplanes must comply with this AD.

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(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct damage to the airbrake locking bracket caused by asymmetric loads. This condition could result in the pilot's inability to operate the airbrake controls with consequent loss of sailplane control.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect the airbrake locking bracket on the rear landing gear box for signs of fatigue (cracks in the paint, paint chips, or cracks in the welding region to the tube) and inspect for proper rigging of the airbrake system.	Within the next 30 calendar days after March 9, 2001 (the effective date of this AD).	Inspect for proper rigging in accordance with the procedures contained in the applicable maintenance manual. Inspect the airbrake locking bracket in accordance with the procedures contained in Rolladen Schneider Technical Bulletin No 4042, dated July 2, 1999.
(2) If any sign of fatigue is evident, accomplish the following: (i) Disassemble the airbrake system; (ii) Obtain a modified airbrake locking bracket from the manufacturer (2-day turnaround time) and install this bracket; and (iii) Reassemble the airbrake system and accomplish the adjustments listed in the service bulletin.	Accomplish all actions prior to further flight after the inspection required in paragraph (d)(1) of this AD.	Accomplish the disassembly, installation, assembly, and adjustments in accordance with procedures contained in the applicable maintenance manual and the procedures in Rolladen Schneider Technical Bulletin No. 4042, dated July 2, 1999.
(3) If no signs of fatigue are found but the airbrake system is incorrectly assembled, disassemble the system and reassemble, including accomplishing the adjustments listed in the service bulletin.	Accomplish all actions prior to further flight after the inspection required in paragraph (d)(1) of this AD.	Accomplish in accordance with procedures contained in the applicable maintenance manual and the procedures in Rolladen Schneider Technical Bulletin No. 4042, dated July 2, 1999.
(4) If no signs of fatigue are found and the airbrake system is correctly assembled, then no further action is required by this AD.	AD complied with	AD complied with.
(5) If any discrepancy is found that requires additional work as required by paragraphs (d)(2) and (d)(3) of this AD, then send information describing the discrepancies found and the follow-on work that was necessary to the FAA.	Within 10 days after the inspection required by this AD or within 10 days after March 9, 2001 (the effective date of this AD), whichever occurs later.	Mail the information to: FAA, Small Airplane Directorate (ACE–112), Attention: Docket No. 99–CE–75–AD, 901 Locust, Room 301, Kansas City, Missouri 64106.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each sailplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For sailplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Brian Hancock, Aerospace Engineer, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4143; facsimile: (816) 329–4090.

(g) *What if I need to fly the sailplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your sailplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Rolladen Schneider Technical Bulletin No. 4042, dated July 2, 1999. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You can get copies from Rolladen-Schneider Flugzeugbau GmbH, Muhlstrasse 10, D–63329 Egelsbach, Germany. You can look at copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on March 9, 2001.

Note 2: The subject of this AD is addressed in German AD 1999–270, dated July 22, 1999.

Issued in Kansas City, Missouri, on January 8, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1230 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–391–AD; Amendment 39–12060; AD 2001–01–10]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 747–400, 747–400F, 767–200, and 767–300 Series Airplanes Equipped With Pratt & Whitney Model PW4000 Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to all Boeing Model 747–400, 747–400F, 767–200, and 767–300 series airplanes equipped with Pratt & Whitney Model PW4000 series engines. This action requires revising the Airplane Flight Manual (AFM). This action is necessary to prevent reduced acceleration and climb performance relative to performance data in the AFM, which could result in runway overruns or impact with obstacles or terrain. This action is intended to address the identified unsafe condition.

DATES: Effective February 6, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 6, 2001.

Comments for inclusion in the Rules Docket must be received on or before March 23, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–391–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-iarcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–391–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dennis Kammers, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2956; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: The FAA has received reports that Pratt & Whitney Model PW4000 series engines with certain early-production fan blades (Phase 0/1, FB2B or FB2T) installed on Boeing Model 747–400, 747–400F, 767–200, and 767–300 series airplanes do not produce the amount of thrust indicated in the Airplane Flight Manual (AFM). This thrust shortfall is due to erosion of the fan blade's leading edge. The flight crew has no indication of this shortfall in thrust. This condition results in reduced acceleration and climb performance relative to performance data in the AFM, which, if not corrected, could result in an overrun of the runway or impact with an obstacle or terrain.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Telex M–7200–00–02672, dated November 1, 2000, including two attachments titled, "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 747–400," and "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 767–200/767–300," both dated November 1, 2000. The telex and its attachments contain performance adjustments for the AFM for Model 747–400, 747–400F, 767–200, and 767–300 series airplanes equipped with one or more Pratt & Whitney Model PW4000 series engines with early production fan blades. Inclusion of these performance adjustments in the AFM addresses the unsafe condition associated with the shortfall in thrust caused by the early production fan blades.

Explanation of the Requirements of the Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, this AD is being issued to prevent reduced acceleration and climb performance relative to performance data in the AFM, which could result in runway overruns or impact with obstacles or terrain. This AD requires accomplishment of the actions specified in the telex and attachments described previously, except as discussed below.

Differences Between Telex and This AD

Operators should note that, although the telex states that the airplane manufacturer was advised that the FAA would recommend a compliance time of 45 days after the effective date of the AD for the actions in the telex, paragraph (a) of this AD actually requires revising the AFM within 30 days after the effective date of this AD. In developing an appropriate compliance time for this AD, the FAA considered not only the manufacturer's recommendation, but the degree of urgency associated with addressing the subject unsafe condition, the average utilization of the affected fleet, and the time necessary to revise the AFM. In light of all of these factors, the FAA finds a 30-day compliance time for completing the required actions to be warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

Operators also should note that this AD applies to all Boeing Model 747–400, 747–400F, 767–200, and 767–300 series airplanes equipped with Pratt & Whitney Model PW4000 series engines. For airplanes that have current-production fan blades (Phase 3, FB2C) installed on all engines, the performance adjustments in the attachments to the telex referenced above are not applicable. However, this AD requires revision of the AFM for all airplanes to address the potential for future installation of early production fan blades (Phase 0/1, FB2B or FB2T). Note 1 is included in this AD to clarify this point.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the

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Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–391–AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–01–10 Boeing: Amendment 39–12080. Docket 2000–NM–391–AD.

Applicability: Model 747–400, 747–400F, 767–200, and 767–300 series airplanes equipped with Pratt & Whitney Model PW4000 series engines; certificated in any category.

Note 1: For airplanes that have current-production fan blades (Phase 3, FB2C) installed on all engines, the performance adjustments in the attachments to Boeing Telex M–7200–00–02672, dated November 1, 2000, as referenced in this AD, are not applicable. However, this AD requires revising the Airplane Flight Manual (AFM) for all airplanes to address the potential for future installation of certain early-production fan blades (Phase 0/1, FB2B or FB2T).

Note 2: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced acceleration and climb performance, relative to performance data in the AFM, which could result in runway overruns or impact with obstacles or terrain, accomplish the following:

AFM Revision

(a) Within 30 days after the effective date of this AD, revise the FAA-approved AFM by inserting a copy of this AD with Boeing Telex M–7200–00–02672, dated November 1, 2000, including the performance adjustments in "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 747–400," (for Boeing Model 747–400 and 747–400F series airplanes) or "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 767–200/767–300," (for Boeing Model 767–200 and –300 series airplanes), both dated November 1, 2000, as applicable.

(b) When the information in Boeing Telex M–7200–00–02672 and its attachments have been incorporated into FAA-approved general revisions of the AFM, the general revisions may be incorporated in the AFM, and this AD with the telex and its attachments may be removed from the AFM.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The actions shall be done in accordance with Boeing Telex M–7200–00–02672, including Attachments "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 747–400" and "Performance for Operation of PW4000 Series Engines with FB2B or FB2T Fans Installed[,] 767–200/767–300," dated November 1, 2000, as applicable. (Note: The attachment titles are indicated only on the first page of each attachment; no other page contains this information.) This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(f) This amendment becomes effective on February 6, 2001.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1234 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–SW–63–AD; Amendment 39–12083; AD 2000–25–52]

RIN 2120–AA64

Airworthiness Directives; MD Helicopters, Inc. Model 369A, H, HE, HM, HS, D, E, FF, and 500N Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Emergency Airworthiness Directive (AD) 2000–25–52 which was sent previously to all known U.S. owners and operators of MD Helicopters, Inc. (MDHI) Model 369A, H, HE, HM, HS, D, E, FF, and 500N helicopters. This amendment supersedes an existing emergency AD that requires, before further flight, performing a tap inspection on both the upper and lower surfaces of each main rotor blade (blade). If any voids are detected that exceed specified inspection requirements, the emergency AD also requires replacing the unairworthy blade with an airworthy blade before further flight. This amendment requires the same actions as the emergency AD and corrects the applicability to include the appropriate serial numbers. This amendment is prompted by the discovery of an error in the emergency AD. The actions specified by this AD are intended to prevent failure of a blade and subsequent loss of control of the helicopter.

DATES: Effective February 6, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 6, 2001.

Comments for inclusion in the Rules Docket must be received on or before March 23, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2000–SW–63–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: 9-asw-adcomments@faa.gov.

The service information referenced in this AD may be obtained from Helicopter Technology Company, LLC, 12923 South Spring St., Los Angeles, CA 90061, telephone (310) 523–2750, fax (310) 523–2745. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Marc Belhumeur, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76193–0170, telephone (817) 222–5177, fax (817) 222–5783.

SUPPLEMENTARY INFORMATION: On November 21, 2000, the FAA issued Emergency AD 2000–24–51 that applies to MDHI Model 369A, H, HE, HM, HS, D, E, FF, and 500N helicopters and requires, before further flight, performing a tap inspection on both the upper and lower surfaces of each blade. If any voids are detected that exceed specified inspection requirements, this AD requires replacing the unairworthy blade with an airworthy blade before further flight. That action was prompted by a blade failure due to fatigue cracking that originated at corrosion pits on the spar bonded surfaces, resulting in an accident that destroyed a Hughes Model 369D helicopter. That condition, if not corrected, could result in failure of a blade and subsequent loss of control of the helicopter.

Since the issuance of that AD, the FAA discovered an error in the applicability section. The part numbers are not listed correctly with the appropriate serial numbers and, as a result, the FAA received requests from operators to clarify which blade part numbers are affected since the emergency AD deviates from the applicable service bulletin. The intent of Emergency AD 2000–24–51 was not to deviate from the part numbers and serial numbers listed in the service bulletin. To assure affected blades are correctly identified, the FAA issued superseding Emergency AD 2000–25–52 to correct the applicability. The requirements for accomplishing the intent of the emergency AD remain the same.

The FAA has reviewed Helicopter Technology Company, LLC, Mandatory Service Bulletin No. 2100–2R2, dated November 14, 2000 (SB), which describes procedures for performing a one-time inspection of each blade for skin-to-spar bonding voids before further flight.

Since the unsafe condition described is likely to exist or develop on other MDHI Model 369A, H, HE, HM, HS, D, E, FF, and 500N helicopters of the same type designs, the FAA issued Emergency AD 2000–25–52 to detect a void in the bonding that could result in a crack due to corrosion pits on the blade spar bonded surfaces, failure of a blade, and subsequent loss of control of the helicopter. The AD requires, before further flight, performing a tap inspection on both the upper and lower surfaces of each blade. If any voids are detected that exceed specified inspection requirements, this AD requires replacing the unairworthy blade with an airworthy blade before further flight. The actions must be accomplished in accordance with the SB described previously. The short compliance time involved is required because the previously described critical unsafe condition can adversely affect the structural integrity and controllability of the helicopter. Therefore, the actions listed previously are required before further flight, and this AD must be issued immediately.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on December 5, 2000, to all known U.S. owners and operators of MDHI Model 369A, H, HE, HM, HS, D, E, FF, and 500N helicopters. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13) to make it effective to all persons.

The FAA estimates that 300 helicopters of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per helicopter to accomplish each inspection and 5 work hours per helicopter to replace 1 blade, and that the average labor rate is $60 per work hour. Required parts will cost approximately $10,000 per blade. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $3,630,000, assuming $12,100 per

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helicopter for 10 inspections ($1,800) and one blade replacement ($10,390).

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 2000–SW–63–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

2000–25–52 MD Helicopters, Inc.: Amendment 39–12083. Docket No. 2000–SW–63–AD. Supersedes Emergency AD 2000–24–51, Docket No. 2000–SW–62–AD.

Applicability: Model 369A, H, HE, HM, HS, D, E, FF, and 500N helicopters, with main rotor blade (blade), part number (P/N) 500P2100–BSC (serial number (S/N) with a prefix of "K" and 101 through 562); P/N 500P2100–101 or P/N 500P2100–301 (S/N with a prefix of "A" and 001 through 999 or S/N with a prefix of "B" and 001 through 529); or blade, P/N 500P2300–501 (S/N with a prefix of "T" and 101 through 107), manufactured by Helicopter Technology Company, LLC, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required before further flight, unless accomplished previously.

To detect a void in the bonding that could result in a crack due to corrosion pits on the blade spar bonded surfaces, failure of a blade, and subsequent loss of control of the helicopter, accomplish the following:

(a) Perform a tap inspection on both the upper and lower surfaces of each blade in accordance with the "INSPECTION" paragraph of Helicopter Technology Company, LLC, Mandatory Service Bulletin Notice No. 2100–2R2, dated November 14, 2000 (SB). If any voids on a blade are detected that exceed specified inspection requirements of the SB, replace the unairworthy blade with an airworthy blade before further flight.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Certification Office.

(c) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the requirements of this AD can be accomplished.

(d) The tap inspections shall be accomplished in accordance with the "INSPECTION" paragraph of Helicopter Technology Company, LLC, Mandatory Service Bulletin Notice No. 2100–2R2, dated November 14, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Helicopter Technology Company, LLC, 12923 South Spring St., Los Angeles, CA 90061, telephone (310) 523–2750, fax (310) 523–2745. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on February 6, 2001, to all persons except those persons to whom it was made immediately effective by Emergency AD 2000–25–52, issued December 5, 2000, which contained the requirements of this amendment.

Issued in Fort Worth, Texas, on January 10, 2001.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 01–1586 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–SW–67–AD; Amendment 39–12056; AD 2000–26–06]

RIN 2120–AA64

Airworthiness Directives; Eurocopter Deutschland GMBH Model MBB–BK 117 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD) that applies to Eurocopter Deutschland GMBH (ECD) Model MBB–BK 117 helicopters. That AD currently requires, before further flight, creating a component log card or equivalent record and determining the calendar age and number of flights on each tension-torsion (TT) strap. This amendment establishes a life limit for certain main rotor TT straps. This amendment is prompted by an accident in which a main rotor blade (blade) separated from an ECD Model MBB–BK 117 helicopter due to fatigue failure of a TT strap. The actions specified by this AD are intended to prevent fatigue failure of a TT strap, loss of a blade, and subsequent loss of control of the helicopter.

DATES: Effective February 26, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 26, 2001.

ADDRESSES: The service information referenced in this AD may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Charles Harrison, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5128, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 2000–01–11, Amendment 39–11509 (65 FR 2017, January 13, 2000), which applies to ECD Model MBB–BK 117 helicopters, was published in the **Federal Register** on September 18, 2000 (65 FR 56275). That action proposed establishing a life limit for the TT straps of 120 months since installation on any helicopter or 25,000 flights, whichever occurs first.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 127 helicopters of U.S. registry will be affected by this AD, that it will take approximately 16 work hours per helicopter to accomplish the required actions, and that the average labor rate is $60 per work hour. Required parts will cost approximately $10,400 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $1,442,720.

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–11509 (65 FR 2017, January 13, 2000), and by adding a new airworthiness directive (AD), Amendment 39–12056, to read as follows:

2000–26–06 Eurocopter Deutschland GMBH: Amendment 39–12056. Docket No. 99–SW–67–AD. Supersedes AD 2000–01–11, Amendment 39–11509, Docket No. 99–SW–60–AD.

Applicability: Model MBB–BK 117 A–1, A–3, A–4, B–1, B–2, and C–1 helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue failure of a tension-torsion (TT) strap, loss of a main rotor blade (blade), and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight,

(1) Remove TT straps, P/N 2604067 (Bendix) or J17322–1 (Lord), from service or re-identify them as P/N 117–14110 or 117–14111, respectively, in accordance with the Accomplishment Instructions, paragraph 2.B.1.2., Eurocopter Deutschland GMBH Alert Service Bulletin MBB–BK–117 No. ASB–MBB–BK 117–10–120, Revision 1, dated August 31, 1999 (ASB). TT straps, P/N 2604067 (Bendix) or J17322–1 (Lord), are no longer eligible for installation.

(2) Create a component log card or equivalent record for each TT strap.

(3) Review the history of the helicopter and each TT strap. Determine the age since initial installation on any helicopter (age) and the number of flights on each TT strap. Enter both the age and the number of flights for each TT strap on the component log card or equivalent record. When the number of flights is unknown, multiply the number of hours time-in-service (TIS) by 5 to determine the number of flights.

(4) Remove any TT strap from service if the total hours TIS or number of flights and age cannot be determined.

(b) Before further flight, remove any TT strap, part number (P/N) 117–14110 or 117–

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14111, that has been in service 120 months since initial installation on any helicopter or accumulated 25,000 flights (a flight is a takeoff and a landing). Replace the TT strap with an airworthy TT strap.

(c) This AD revises the Airworthiness Limitations Section of the maintenance manual by establishing a life limit for the TT strap, P/N 117–14110 and 117–14111, of 120 months or 25,000 flights, whichever occurs first.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(e) Special flight permits may be issued in accordance with § 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) The modification shall be done in accordance with the Accomplishment Instructions, paragraph 2.B.1.2., Eurocopter Deutschland GMBH Alert Service Bulletin MBB–BK–117 No. ASB–MBB–BK 117–10–120, Revision 1, dated August 31, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on February 26, 2001.

Note 3: The subject of this AD is addressed in the Luftfahrt Bundesamt (Federal Republic of Germany) AD 1999–284/2, dated September 1, 1999.

Issued in Fort Worth, Texas, on December 15, 2000.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 01–1585 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–03–AD; Amendment 39–12086; AD 2001–02–02]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–8–200, and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Bombardier Model DHC–8–200, and –300 series airplanes. This action requires repetitive inspections to detect chafing or arcing damage to the cable/wire and fuel tube assemblies on the right hand side of each engine, and replacement with new components, if necessary. This action also provides an optional terminating action for the repetitive inspections required by this AD. This action is necessary to prevent chafing of the cable/wire bundles against the fuel line, which could result in arcing and a consequent fire or explosion. This action is intended to address the identified unsafe condition.

DATES: Effective February 6, 2001.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 6, 2001.

Comments for inclusion in the Rules Docket must be received on or before February 21, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–03–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-iarcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2001–NM–03–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in this AD may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: James Delisio, Aerospace Engineer, Airframe and Propulsion Branch, ANE–171, FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7521; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION: Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, recently notified the FAA that an unsafe condition may exist on certain Bombardier Model DHC–8–200 and –300 series airplanes. TCAA advises that a pinhole in the high pressure fuel line was detected. Investigation revealed that the cause of the pinhole was due to arcing from an adjoining wire. The arcing occurred approximately four inches from the fuel-cooled oil cooler. Although the fuel line and wire are separated by two cushion clamps, the cushion clamps can rotate and thereby allow the wire bundle to chafe against the fuel line. Such chafing of the wire bundles could result in arcing and a consequent fire or explosion.

Explanation of Relevant Service Information

Bombardier has issued Alert Service Bulletin A8–73–23, dated November 3, 2000, which describes procedures for repetitive general visual inspections to detect chafing or arcing damage to the cable and the fuel tube assemblies on the right hand side of each engine, and replacement with new components, if necessary. The alert service bulletin also describes procedures for an optional modification that entails, among other things, rerouting the existing wire harness to the opposite side of the oil cooler, and shortening and securing the wire harness, if necessary. That modification eliminates the need for the repetitive inspections. TCAA classified this alert service bulletin as mandatory and issued Canadian airworthiness directive CF–2000–33, dated November 14, 2000, in order to assure the continued airworthiness of these airplanes in Canada.

FAA's Conclusions

These airplane models are manufactured in Canada and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCAA has kept the FAA informed of the situation described above. The FAA has examined the findings of TCAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent chafing of the cable/wire bundles against the fuel line, which could result in arcing and a consequent fire or explosion. This AD requires accomplishment of the repetitive general visual inspections, and replacement, if necessary, in accordance with the inspection and repair procedures specified in the alert service bulletin described previously. This AD also provides an optional terminating action for the repetitive inspections required by this AD.

Interim Action

This is considered to be interim action. The FAA is currently considering superseding this AD to require modification of the cable assembly, which would constitute terminating action for the repetitive inspections required by this AD. However, the planned compliance time for the installation of the modification is sufficiently long so that notice and opportunity for prior public comment will be practicable.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2001–NM–03–AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001–02–02 Bombardier, Inc. (Formerly deHavilland, Inc.): Amendment 39–12086. Docket 2001–NM–03–AD.

Applicability: Model DHC–8–201, –202, –301, –311, and –315 airplanes having serial numbers 100 through 552 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent possible arcing between the electrical wiring and the fuel tube, which could result in a fire or explosion, accomplish the following:

Inspection

(a) Within 50 flight hours or 10 days after the effective date of this AD, whichever

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occurs first: Do a general visual inspection to detect chafing or arcing damage to the cable and the fuel tube assemblies on the right hand side of each engine, per Bombardier Alert Service Bulletin A8–73–23, dated November 3, 2000. Repeat the inspection every 500 flight hours or 3 months, whichever occurs first.

Note 2: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

Repair

(b) If any damage to the fuel tube or cable assembly is detected, before further flight, replace the damaged component per Bombardier Alert Service Bulletin A8–73–23, dated November 3, 2000. Thereafter, repeat the inspection required by paragraph (a) of this AD every 500 flight hours or 3 months, whichever occurs first.

Optional Terminating Action

(c) Accomplishment of the modification instructions described in Bombardier Alert Service Bulletin A8–73–23, dated November 3, 2000, that specifies, among other actions, rerouting the existing wire harness to the opposite side of the oil cooler, constitutes terminating action for the repetitive inspection requirements of this AD.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(f) The actions shall be done in accordance with Bombardier Alert Service Bulletin A8–73–23, dated November 3, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in Canadian airworthiness directive CF–2000–33, dated November 14, 2000.

Effective Date

(g) This amendment becomes effective on February 6, 2001.

Issued in Renton, Washington, on January 12, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1659 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ANM–20]

RIN 2120–AA66

Amend Legal Description of Jet Route J–501

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on November 20, 2000. The legal description of Jet Route 501 (J–501) contained an inadvertent error that included the intersection of the Bethel 258° radial and the Anchorage CTA/FIR boundary. This action corrects that error by removing the reference to the intersection.

EFFECTIVE DATE: 0901 UTC, January 25, 2001.

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION: On November 20, 2000, Airspace Docket No. 00–ANM–20 (65 FR 69664), was published amending the legal description of J–501. This description contained an inadvertent error that included the intersection of the Bethel 258° radial and the Anchorage CTA/FIR boundary. This action corrects that error by removing the reference to the intersection.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the legal description for J–501, as published in the **Federal Register** on November 20, 2000, (65 FR 69664), and incorporated by reference in 14 CFR 71.1, is corrected as follows:

§ 71.1 [Corrected]

On page 69665, correct the legal description of J–501, to read as follows:

Paragraph 2004—Jet Routes

* * * * *

J–501 [Amended]

From San Marcus, CA, via Big Sur, CA; Point Reyes, CA, via Rogue Valley, OR; Hoquiam, WA; INT Hoquiam 354° and Tatoosh, WA, 162° radials; Tatoosh; Tofino, BC, Canada, RBN. From Sandspit, BC, Canada; Biorka Island, AK; Yakutat, AK; Johnstone Point, AK; Anchorage, AK; Sparrevohn, AK; Bethel, AK; excluding the airspace within Canada.

* * * * *

Issued in Washington, DC, on January 10, 2001.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 01–1853 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ANM–14]

Establishment of Class E Airspace, Prineville, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes the Prineville, OR, Class E airspace to accommodate airspace required for the establishment of a new Standard Instrument Approach Procedure (SIAP) to the Prineville Airport, Prineville, OR.

EFFECTIVE DATE: February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Durham, ANM–520.7, Federal Aviation Administration, Docket No. 00–ANM–14, 1601 Lind Avenue SW, Renton, Washington 98055–4056: telephone number: (425) 227–2527.

SUPPLEMENTARY INFORMATION:

History

On October 16, 2000, the FAA proposed to amend Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by establishing Class E airspace at Prineville, OR, in order to accommodate a new Area Navigation (RNAV) SIAP to Runway 10, RNAV RWY 28, and Non-Directional Beacon (NDB) RWY 10 SIAP at Prineville Airport, Prineville, OR (65 FR 200). This amendment provides Class E5 airspace at Prineville, OR, to meet current criteria standards associated with the SIAPs. Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal. No comments were received.

The Rule

This amendment to Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) establishes Class E airspace at Prineville, OR, in order to accommodate a new SIAPs to the Prineville Airport, Prineville, OR. This amendment establishes Class E5 airspace at Prineville, OR, to meet current criteria standards associated with the SIAPs. The FAA establishes Class E airspace where necessary to contain aircraft transitioning between the terminal and en route environments. This rule is designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under Instrument Flight Rules (IFR) at the Prineville Airport and between the terminal and en route transition stages.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700 feet or more above the surface of the earth, are published in Paragraph 6005, of FAA Order 7400.9H dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Prineville, OR [New]

Prineville Airport, OR
(lat. 44°17'13"N., long. 120°54'14"W.)

That airspace extending upward from 700 feet above the surface within a 6.9-mile radius of the airport, and 3.5 miles each side of the 283° bearing from the airport extending to 12.2 miles, and 3 miles each side of the 121° bearing from the airport extending to 7.2 miles; that airspace extending upward from 1,200 feet above the surface within a 9.2-miles radius of the airport clockwise from the 320° bearing to the 190° bearing, then extending to 27.4 miles from the airport in an arc clockwise to the 230° bearing, then extending to 37.5 miles from the airport in an arc clockwise to the 320° bearing, then extending 6.8 miles each side of the 121° bearing from the airport to 34.3 miles; excluding that airspace within Federal Airways; the Redmond, OR Class D and E airspace.

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Issued in Seattle, Washington, on January 8, 2001.

Dan A. Boyle,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 01–1672 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ANM–21]

Modification of Class E Airspace, Astoria, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Astoria, OR, Class E airspace to accommodate airspace required to support military operations at the Oregon Air National Guard (ORANG) Camp Rilea Heliport, Astoria, OR.

EFFECTIVE DATE: February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Durham, ANM–520.7, Federal Aviation Administration, Docket No. 00–ANM–21, 1601 Lind Avenue SW, Renton, Washington 98055–4056: telephone number: (425) 227–2527.

SUPPLEMENTARY INFORMATION:

History

On October 16, 2000, the FAA proposed to amend Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by modifying Class E airspace at Astoria, OR, in order to support military operations at the Oregon Air National Guard (ORANG) Camp Rilea Heliport, Astoria, OR (65 FR 200). this amendment modifies Class E2 airspace at Astoria, OR, to allow less restrictive military air operations to and from Camp Rilea Heliport. Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal. No comments were received.

The Rule

This amendment to Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) modifies Class E airspace at Astoria, OR, in order to allow the ORANG to conduct air operations at Camp Rilea without impacting civil air traffic, and to provide a less restrictive environment for military air operations to and from Camp Rilea Heliport, Astoria, OR. The FAA establishes Class E airspace where necessary to contain aircraft transitioning between the terminal and en route environments. This rule is designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under Instrument Flight Rules (IFR) and Visual Flight Rules (VFR) at the Port of Astoria Airport and Camp Rilea Heliport, and between the terminal and en route transition stages.

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The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas designated as surface area for an airport, are published in Paragraph 6002, of FAA Order 7400.9H dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6002 Class E airspace areas designated as surface area for an airport

* * * * *

ANM OR E2 Astoria, OR [Revised]

Astoria, Port of Astoria Airport, OR
(lat. 46°09′28″N, long. 123°52′44″W)
Astoria VOR/DME
(lat. 46°09′42″N, long. 123°52′50″W)
Karpen NDB
(lat. 46°08′22″n, long. 123°35′14″W)
Astoria ILS Localizer
(lat. 46°09′35″N, long. 123°53′28″W)
Camp Rilea Heliport
(lat. 46°06′59″N, long. 123°55′54″W)

Within a 4-mile radius of the Port of Astoria Airport, and within 1.8 miles each side of the Astoria VOR/DME 268° radial extending from the 4-mile radius to 7 miles west of the VOR/DME, and within 1.8 miles each side of the Astoria ILS localizer east course extending from the 4-mile radius to the Karpen NDB, excluding the airspace within a wedge south of Camp Rilea Heliport, from the 120 bearing clockwise to the 225 bearing of the Camp Rilea Heliport.

* * * * *

Issued in Seattle, Washington, on January 8, 2001.

Dan A. Boyle,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 01–1673 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 00–ANM–16]

Modification of Class E Airspace, Tillamook, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Tillamook, OR, Class E airspace to accommodate airspace required to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Tillamook Airport, Tillamook, OR, and to support a Terminal Arrival Area (TAA) airspace design.

EFFECTIVE DATE: February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Durham, ANM–520.7, Federal Aviation Administration, Docket No. 00–ANM–16, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone number: (425) 227–2527.

SUPPLEMENTARY INFORMATION:

History

On November 13, 2000, the FAA proposed to amend title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by modifying Class E airspace at Tillamook, OR, in order to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Tillamook Airport, Tillamook, OR (65 FR 219). This amendment modifies Class E5 airspace at Tillamook, OR, to provide adequate Class E 700 feet, and 1,200 feet controlled airspace, above the surface of the earth required to contain aircraft executing the RNAV RWY 13 Standard Instrument Approach Procedure (SIAP) with a Terminal Arrival Area (TAA) design to Tillamook Airport. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Tillamook Airport, Tillamook, OR. Interested parties were invited to participate in the rulemaking proceeding by submitting written comments on the proposal. No comments were received.

The Rule

This amendment to Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) revises Class E airspace at Tillamook, OR, in order to accommodate a new SIAP to the Tillamook Airport, Tillamook, OR. This amendment revises Class E5 airspace at Tillamook, OR, to meet current criteria standards associated with the RNAV RWY 13 SIAP. The FAA establishes Class E airspace where necessary to contain aircraft transitioning between the terminal and en route environments. This rule is designed to provide for the safe and efficient use of the navigable airspace and to promote safe flight operations under Instrument Flight Rules (IFR) at the Tillamook Airport and between the terminal and transition stages.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9H dated September 1, 2000, and effective September 11s incorporated by reference in 14 CFR 7.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulator Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565. 3 CFR, 1959–1963 Comp., p. 389.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Tillamook, OR [Revised] (lat. 45°25′07″N., long. 123°48′49″W.)

That airspace extending upward from 700 feet above the surface within the 7.5-mile radius of the Tillamook Airport, and within 2.5 miles each side of the 334° bearing from the airport extending 13.8 miles; and that airspace extending upward from 1,200 feet above the surface within the 30 mile radius of lat. 45°37′05″N., long. 123°56′36″W., extending clockwise from the 246° bearing to the 064° bearing, and within the 30 miles radius of lat. 45°39′57″N., long 123°47′30″W., extending clockwise from the 064° bearing to the 154° bearing of lat. 45°37′05″N., long. 123°56′36″W., and within the 30 miles radius of lat. 45°34′11″N., 124°05′41″W., extending counterclockwise from the 244° bearing to the 154° bearing of lat. 45°37′05″N., long. 123°56′36″ W.; and excluding that airspace that extends more than 12 miles west of the U.S. shoreline; that airspace within Federal airways; the Astoria, OR; the Portland-Hillsboro, OR; and the Portland, OR, Class E airspace areas.

* * * * *

Issued in Seattle, Washington, on January 8, 2001.

Dan A. Boyle,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 01–1855 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Parts 335 and 340

[Doc. #001229368–0368–01]

RIN 0625–AA58

Imports of Certain Worsted Wool Fabric; Implementation of Tariff Rate Quota Established Under Title V of the Trade and Development Act of 2000

AGENCY: Department of Commerce, International Trade Administration.

ACTION: Interim Final Rule; Request for Comments.

SUMMARY: The Department of Commerce is issuing interim regulations implementing Section 501(e) and Section 504(b) of the Trade and Development Act of 2000 ("the Act"). Section 501(e) requires the President to fairly allocate tariff rate quotas on the import of certain worsted wool fabrics, tariff rate quotas which were established by Sections 501(a) and 501(b) of the Act. Section 504(b) authorizes the President to modify the limitations on worsted wool fabric imports under the tariff rate quotas. The President has delegated to the Secretary of Commerce the authority to allocate the quantity of imports under the tariff rate quotas and to determine whether the limitations on the quantity of imports under the tariff rate quotas should be modified.

DATES: This interim final rule is effective January 22, 2001. To be considered, written comments must be received by 5:00 p.m. on March 23, 2001.

ADDRESSES: Comments should be addressed to: Deputy Assistant Secretary for Textiles, Apparel and Consumer Goods Industries, Room 3001, United States Department of Commerce, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4058.

SUPPLEMENTARY INFORMATION:

Background

The Act creates two tariff rate quotas, providing for temporary reductions for three years in the import duties on two categories of worsted wool fabrics suitable for use in making suits, suit-type jackets, or trousers: (1) for worsted wool fabric with average fiber diameters greater than 18.5 microns (new Harmonized Tariff Schedule of the United States (HTS) heading 9902.51.11), the reduction in duty is limited to 2,500,000 square meter equivalents or such other quantity proclaimed by the President; and (2) for worsted wool fabric with average fiber diameters of 18.5 microns or less (new HTS heading 9902.51.12), the reduction is limited to 1,500,000 square meter equivalents or such other quantity proclaimed by the President.

The Act requires that the tariff rate quotas be allocated. More specifically, the President must ensure that the tariff rate quotas are fairly allocated to persons (including firms, corporations, or other legal entities) who cut and sew men's and boys' worsted wool suits, suit-type jackets and trousers in the United States and who apply for an allocation based on the amount of such suits cut and sewn during the prior calendar year.

The Act requires that the President annually consider requests by U.S. manufacturers of certain worsted wool apparel to modify the limitation on the quantity of fabric that may be imported under the tariff rate quotas, and grants the President the authority to proclaim modifications to the limitations. In determining whether to modify the limitations, the President must consider specified U.S. market conditions with respect to worsted wool fabric and worsted wool apparel.

In Presidential Proclamation 7383, of December 1, 2000, the President authorized the Secretary of Commerce: (1) to allocate the imports of worsted wool fabrics under the tariff rate quotas; (2) to annually consider requests from domestic manufacturers of worsted wool apparel to modify the limitation on the quantity of worsted wool fabrics that may be imported under the tariff rate quotas; (3) to determine whether the limitations on the quantity of imports of worsted wool fabrics under the tariff rate quotas should be modified and to recommend to the President that appropriate modifications be made; and (4) to issue regulations to implement relevant provisions of the Act.

The Presidential Proclamation authorizing the Department of Commerce to issue regulations to implement these provisions was issued on December 1, 2000. Pursuant to the Act, the tariff rate quotas entered into force on January 1, 2001. Thus, there is good cause to find that in order to meet

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the statutory implementation date and to ensure that importers receive the benefit of the reduction in tariff rate as soon as possible, the otherwise applicable notice and comment procedures are impracticable and contrary to the public interest under 5 U.S.C. 553(b)(B). Moreover, for the same reason, there is good cause to find that the effective date of this rule should not be delayed until 30 days after its publication under 5 U.S.C. 553(d)(3). While these interim regulations will be effective upon publication, the Department of Commerce hereby solicits comments on these interim regulations and will amend them in final regulations if appropriate. The Department is particularly interested in comments concerning any impact these regulations might have on small or medium sized businesses.

This interim rule contains information collection requirements subject to the Paperwork Reduction Act (PRA). These information collection requirements cannot be implemented until they have received PRA approval from the Office of Management and Budget (OMB); a request for approval on an emergency basis is pending, and when approval is provided, notice will be published in the **Federal Register**. In addition, the collection will be submitted to OMB for permanent approval under the PRA.

Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. The information collected will be used by the Department to allocate the tariff rate quota among U.S. manufacturers and to determine whether the tariff rate quota limitations should be modified. Responses to the collection of information are required for a manufacturer to receive an allocation of the tariff rate quota, to submit a request for a modification, and to comment on such a request. Confidentiality of information will be handled in accordance with §§ 335.3(e) and 340.5(b). Records substantiating information provided in an application to receive an allocation must be retained. It is estimated that the annual public burden for the collection will average: (1) seven hours per application for an allocation of a tariff rate quota; (2) one hour per application for a reallocation; (3) 24 hours per request for a modification of a limitation on the tariff rate quotas; and (4) 24 hours for comments on such a request. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Washington, DC, 20503 (Attention: ITA Desk Officer).

Part 335

Section 501(e) of the Act requires that the worsted wool fabrics imported under the tariff rate quotas be "fairly allocated" to persons "who cut and sew men's and boys' worsted wool suits and suit-like jackets and trousers in the United States and who apply for an allocation based on the amount of such suits cut and sewn during the prior calendar year." As the Joint Explanation of the Committee of Conference ("Conference Report") makes clear, Congress intended the tariff rate quotas to address the duty situation faced by U.S. wool suit manufacturers, in which worsted wool fabric is subject to considerably higher duties than worsted wool suits, a situation compounded by reductions in tariffs on wool suits under free trade agreements with Canada and Mexico.

The Department, promptly upon promulgation of these interim regulations, intends to begin the process of soliciting applications for a license for an allocation of the 2001 tariff rate quotas on worsted wool fabrics. In following years, applications will be solicited on or around August 31, in order to allow companies to be informed of their allocation as early as possible while still allowing an allocation based on previous year production. The Department intends to make its determination regarding the allocation on or about November 1 and to issue licenses no later than December 31 of the year preceding the tariff rate quota year.

Each of the two tariff rate quotas will be allocated based on previous year production utilizing the worsted wool fabric that is the subject of the tariff rate quota. That is, the tariff rate quota on worsted wool fabric with average fiber diameters greater than 18.5 microns (HTS 9902.51.11) will be allocated based on production utilizing this type of worsted wool fabric, while the tariff rate quota on worsted wool fabric with average fiber diameters of 18.5 microns or less (HTS 9902.51.12) will be allocated based on production utilizing this type of worsted wool.

In 2000, in tracking purchases of worsted wool fabric and production of worsted wool apparel, most manufacturers did not maintain records regarding the micron count of the worsted wool fabric. Therefore, it is necessary to provide an alternative method for manufacturers to report 2000 production information in order to fairly allocate the two tariff rate quotas. For purposes of reporting 2000 production, the interim regulations permit manufacturers to estimate the micron count of the worsted wool fabric used in production based on the value of the worsted wool fabric used, as value is the best proxy for micron count. The regulations provide values to be used to report estimated 2000 production if micron count is not available.

For reporting subsequent year production information, applicants will be required to report production based on micron count of the worsted wool fabric, and in order to receive an allocation of the 2002 tariff rate quotas, manufacturers must begin tracking purchases and production utilizing micron count no later than January 1, 2001. In order to utilize micron count for purposes of allocating the 2002 tariff rate quotas, to utilize the most current data possible for all years, and to meet the statutory requirement that the allocation be based on production during the prior calendar year, each tariff rate quota will be allocated based on production during the first six months of the previous calendar year, annualized.

Pursuant to the statutory requirement, allocation will be limited to persons who cut and sew three types of garments during the calendar year of the application: (1) men's and boys' worsted wool suits; (2) men's and boys' worsted wool suit-type jackets; and (3) men's and boys' worsted wool trousers. Only manufacturers of all three types of garments will be eligible for an allocation. Pursuant to the statutory requirement that allocation be based on the men's and boys' worsted wool suits cut and sewn during the prior calendar year, in allocating the tariff rate quotas, only production of men's and boys' worsted wool suits will be considered. To be considered, a worsted wool garment must contain at least 85 percent by weight worsted wool, which is consistent with the definitions of wool fiber and fabric in the Act and the Conference Report.

In order to fairly allocate the tariff rate quotas, manufacturers that utilize imported worsted wool fabric in production will be provided a greater allocation than manufacturers that utilize domestic worsted wool fabric. This will allow the manufacturers that will actually use the imported fabric that is subject to the tariff rate quotas to obtain a relatively greater share of the fabric, as compared to manufacturers that use only domestic fabric. For the purpose of calculating allocations, suit production will be increased by the ratio of imported fabric used to total fabric used in the production of men's and boys' suits. For example, if an applicant uses imported fabric for 30 percent of its worsted wool suits production, that applicant's suit production level will be increased by 30 percent for purposes of calculating the applicant's allocation.

In order to ensure that the tariff rate quotas are fully utilized, a licensee that will not import the full quantity allocated to it is required to surrender the unused allocation to the Department for reallocation. The quantity surrendered will be reallocated to licensees that apply for a reallocation on the same basis as the original allocation. A licensee that does not surrender unused allocation and fails to import at least 95 percent of the quantity allocated will be penalized in the subsequent year by a reduction in its allocation proportionate to the amount unused.

Part 340

Section 504(b) of the Act requires the President to consider, on an annual basis, requests by U.S. manufacturers of certain worsted wool apparel to modify the limit on importation under the tariff rate quotas. As the Act requires the consideration of such requests "on an annual basis," the first petition process, for the modification of the 2001 tariff rate quotas, will take place promptly, and a petition process will take place for each subsequent year the tariff rate quotas are in effect. Each year, the Department will cause to be published in the **Federal Register** a notice soliciting requests by U.S. manufacturers for modification of the limit for the following year. The Department will then cause to be published in the **Federal Register** a notice soliciting comments by any interested person, including U.S. manufacturers of worsted wool fabric, wool yarn, wool top and wool fiber, regarding the requested modification or modifications. In order to allow manufacturers and other interested persons to submit the most current data possible and to allow the Department to make its determination prior to January 1, manufacturers will have 15 days to submit a request and interested persons will have 20 days to submit comments.

Within 30 days of the end of the period for receiving public comments regarding requested modification or modifications, the Department will make a determination whether the limitations should be modified and recommend to the President that appropriate modification be made. The determination and recommendation will be based on the U.S. market conditions, particularly those factors set forth in the Act.

Dated: January 17, 2001.

Norman Y. Mineta,

Secretary, United States Department of Commerce.

List of Subjects

15 CFR Part 335

Imports, Quotas, Reporting and Recordkeeping, Tariffs, Textiles.

15 CFR Part 340

Imports, Quotas, Reporting and Recordkeeping, Tariffs, Textiles.

For the reasons stated in the preamble, 15 CFR Parts 335 and 340 are added to state as follows:

PART 335—IMPORTS OF WORSTED WOOL FABRIC

Sec.

335.1 Purpose.
335.2 Definitions.
335.3 Applications to receive allocation.
335.4 Allocation.
335.5 Licenses.
335.6 Surrender, reallocation and license utilization requirement.
335.7 Modifications of the limitation.

Authority: Title V Pub. L. 106–200, 114 Stat. 299; Presidential Proclamation 7383 (December 1, 2000).

§ 335.1 Purpose.

This part sets forth regulations regarding the issuance and effect of licenses for the allocation of Worsted Wool Fabric under the Tariff Rate Quotas established by Section 501 of the Act.

§ 335.2 Definitions.

For purposes of these regulations and the forms used to implement them:

The Act means the Trade and Development Act of 2000 (Public Law No. 106–200, 114 Stat 251).

The Department means the United States Department of Commerce.

HTS means the Harmonized Tariff Schedule of the United States.

Imports subject to Tariff Rate Quotas are defined by date of presentation as defined in 19 CFR 132.1(d) and 19 CFR 132.11(a).

Licensee means an applicant for an allocation of the Tariff Rate Quotas that receives an allocation and a license.

Production means cutting and sewing garments in the United States.

Tariff Rate Quota or Quotas means the temporary duty reduction provided under Section 501 of the Act for limited quantities of fabrics of worsted wool with average diameters greater than 18.5 micron, certified by the importer as suitable for use in making suits, suit-type jackets, or trousers (HTS heading 9902.51.11), and for limited quantities of fabrics of worsted wool with average diameters of 18.5 microns or less, certified by the importer as suitable for use in making suits, suit-type jackets, or trousers (HTS heading 9902.51.12).

Tariff Rate Quota Year means a calendar year for which the Tariff Rate Quotas are in effect.

Worsted Wool Fabric means fabric containing at least 85 percent by weight worsted wool.

Worsted Wool Suits means men's and boys' worsted wool suits, containing at least 85 percent by weight worsted wool fabric.

Worsted Wool Suit-Type Jackets mean men's and boys' worsted wool suit-type jackets, containing at least 85 percent by weight worsted wool fabric.

Worsted Wool Trousers means men's and boys' worsted wool trousers, containing at least 85 percent by weight worsted wool fabric.

§ 335.3 Applications to receive allocation.

(a) In each year prior to a Tariff Rate Quota Year, the Department will cause to be published a **Federal Register** notice soliciting applications to receive an allocation of the Tariff Rate Quotas.

(b) An application for a Tariff Rate Quota allocation must be received, or postmarked by the U.S. Postal Service, within 30 calendar days after the date of publication of the **Federal Register** notice soliciting applications.

(c) During the calendar year of the date of the application, an applicant must have cut and sewed in the United States all three of the following apparel products: Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers. The applicant may either have cut and sewn these products on its own behalf or had another person cut and sew the products on the applicant's behalf, provided the applicant owned the fabric at the time it was cut and sewn. The application must contain a statement to this effect.

(d) An applicant must provide the following information in the format set forth in the application form provided by the Department:

(1) *Identification.* Applicant's name, address, telephone number, fax number, and federal tax identification number; name of person submitting the application, and title, or capacity in

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which the person is acting for the applicant.

(2) *Production.* Name and address of each plant or location where Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers were cut and sewn by the applicant and the name and address of all plants or locations that cut and sewed such products on behalf of the applicant. Production data, including the following: the quantity and value of the Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers cut and sewn in the United States by applicant, or on behalf of applicant, from fabric owned by applicant. This data must indicate actual production (not estimates) of Worsted Wool Suits, Worsted Wool Suit-Type Jackets and Worsted Wool Trousers containing at least 85 percent worsted wool fabric by weight with an average diameter of 18.5 microns or less. This data must also indicate actual production (not estimates) of Worsted Wool Suits, Worsted Wool Suit-Type Jackets and Worsted Wool Trousers containing at least 85 percent worsted wool fabric by weight with average diameter greater than 18.5 microns. Production data must be provided for the first six months of the year of the application. This data will be annualized for the purpose of making Tariff Rate Quota allocations.

(3) *2000 Production Data.* For applications for the 2001 Tariff Rate Quota Year, if production data is not available by micron count, the following method of estimating micron count will be accepted: To estimate production of Worsted Wool Suits, Worsted Wool Suit-Type Jackets and Worsted Wool Trousers made from worsted wool fabric with average diameter 18.5 microns or less, use a value of $8.50 per square meter (f.o.b. plant) or more for such garments made from domestic fabric and $12.50 per square meter (c.i.f. duty paid landed value) or more for such garments made from imported fabric. To estimate production of such garments made from worsted wool fabric with average diameter greater than 18.5 microns, use a value of less than $8.50 per square meter (f.o.b. plant) for such garments made from domestic fabric and less than $12.50 (c.i.f. duty paid landed value) per square meter for such garments made from imported fabric.

(4) *Worsted Wool Fabric.* Data indicating the quantity and value of the Worsted Wool Fabric used in reported production.

(5) *Certification.* A statement by the applicant (if a natural person), or on behalf of applicant, by an employee, officer or agent, with personal knowledge of the matters set out in the application, certifying that the information contained therein is complete and accurate, signed and sworn before a Notary Public, and acknowledging that false representations to a federal agency may result in criminal penalties under federal law.

(e) *Confidentiality.* Any business confidential information provided pursuant to this section that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law.

(f) *Record Retention:* The applicant shall retain records substantiating the information provided in § 335.3(d)(2), (3), and (4) for a period of 3 years and the records must be made available upon request by an appropriate U.S. government official.

§ 335.4 Allocation.

(a) Each Tariff Rate Quota (HTS 9902.51.11 and HTS 9902.51.12) will be allocated separately. Allocation will be based on an applicant's Worsted Wool Suit production, on a weighted average basis, and the proportion of imported Worsted Wool Fabric consumed in the production of Worsted Wool Suits.

(b) For the purpose of calculating allocations, Worsted Wool Suit production will be increased by the percentage of imported fabric consumed in the production of Worsted Wool Suits to total fabric consumed in this production. For example, if an applicant uses 30 percent imported fabric in the production of Worsted Wool Suits, that applicant's production level will be increased by 30 percent.

(c) The Department will cause to be published in the **Federal Register** its determination to allocate the Tariff Rate Quotas and will notify applicants of their respective allocation as soon as possible. Promptly thereafter, the Department will issue licenses.

§ 335.5 Licenses.

(a) Each Licensee will receive a license, which will include a unique control number. The license is subject to the surrender and reallocation provisions in § 335.6.

(b) A license may be exercised only for fabric entered for consumption, or withdrawn from warehouse for consumption, during the Tariff Rate Quota Year specified in the license. A license will be debited on the basis of date of entry for consumption or withdrawal from warehouse for consumption.

(c) A Licensee may import fabric certified by the importer as suitable for use in making suits, suit-type jackets, or trousers under the appropriate Tariff Rate Quota as specified in the license (*i.e.*, under the Tariff Rate Quota for fabric of worsted wool with average fiber diameters greater than 18.5 micron or the Tariff Rate Quota for fabric of worsted wool with average fiber diameters of 18.5 micron or less) up to the quantity specified in the license subject to the Tariff Rate Quota duty rate. Only a Licensee or an importer authorized by a Licensee will be permitted to import fabric under the Tariff Rate Quotas and to receive the Tariff Rate Quota duty rate.

(d) The term of a license shall be the Tariff Rate Quota Year for which it is issued. Fabric may be entered or withdrawn from warehouse for consumption under a license only during the term of that license. The license cannot be used for fabric entered or withdrawn from warehouse for consumption after December 31 of the year of the term of the license.

(e) The importer of record of fabric entered or withdrawn from warehouse for consumption under a license must be the Licensee or an importer authorized by the Licensee to act on its behalf. If the importer of record is the Licensee, the importer must possess the license at the time of filing the entry summary or warehouse withdrawal for consumption (Customs Form 7501).

(f) A Licensee may only authorize an importer to import fabric under the license on its behalf by making such an authorization in writing or by electronic notice to the importer and providing a copy of such authorization to the Department. A Licensee may only withdraw authorization from an importer by notifying the importer, in writing,or by electronic notice, and providing a copy to the Department.

(g) The written authorization must include the unique number of the license, must specifically cover the type of fabric imported, and must be in the possession of the importer at the time of filing the entry summary or warehouse withdrawal for consumption (Customs Form 7501), or its electronic equivalent, in order for the importer to obtain the applicable Tariff Rate Quota duty rate.

(h) It is the responsibility of the Licensee to safeguard the use of the license issued. The Department and the U.S. Customs Service will not be liable for any unauthorized or improper use of the license.

§ 335.6 Surrender, reallocation and license utilization requirement.

(a) Not later than September 30 of each Tariff Rate Quota Year, a Licensee that will not import the full quantity granted in a license during the Tariff Rate Quota Year shall surrender the allocation that will not be used to the Department for purposes of reallocation through a written or electronic notice to the Department, including the license control number and the amount being surrendered. The surrender shall be final, and shall apply only to that Tariff Rate Quota Year.

(b) For purposes of this section, "unused allocation" means the amount by which the quantity set forth in a license, including any additional amount received pursuant to paragraph (d) of this section, exceeds the quantity entered under the license, excluding any amount surrendered pursuant to paragraph (a) of this section.

(c) The Department will notify Licensees of any amount surrendered and the application period for requests for reallocation. A Licensee that has imported, or intends to import, a quantity of Worsted Wool Fabric exceeding the quantity set forth in its license may apply to receive additional allocation from the amount to be reallocated. The application shall state the maximum amount of additional allocation the applicant will be able to use.

(d) The amount surrendered will be reallocated to Licensees that have applied for reallocation. The entire amount surrendered will be reallocated pro-rata among applicants based on the applicant's share of the annual allocation, but will not exceed the amount set forth in the reallocation application as the maximum amount able to be used.

(e) A Licensee whose unused allocation in a Tariff Rate Quota Year exceeds five percent of the quantity set forth in its license shall be subject to having its allocation reduced in the subsequent Tariff Rate Quota Year. The subsequent Tariff Rate Quota Year allocation will be reduced from the quantity such Licensee would otherwise have received by a quantity equal to 25 percent of its unused allocation from the prior year. A Licensee whose unused allocation in two consecutive Tariff Rate Quota Years exceeds five percent of the quantity set forth in its license shall have its allocation reduced in the subsequent Tariff Rate Quota Year by a quantity equal to 50 percent of its unused allocation from the prior year.

(f) No penalty will be imposed under paragraph (e) of this section if the Licensee demonstrates to the satisfaction of the Department that the unused allocation resulted from breach by a carrier of its contract of carriage, breach by a supplier of its contract to supply the fabric, act of God, or force majeure.

§ 335.7 Modifications of the Limitation.

In the event the limitation on the quantity of imports of Worsted Wool Fabric under the Tariff Rate Quotas is increased, the increase will be allocated on the same basis as the rest of the Tariff Rate Quotas. Licenses will be issued or adjusted accordingly.

PART 340—MODIFICATION OF THE TARIFF RATE QUOTA LIMITATION ON WORSTED WOOL FABRIC IMPORTS

Sec.
340.1 Purpose.
340.2 Definitions.
340.3 Requests for modification.
340.4 Comments regarding requested modification.
340.5 Requests for modification and comments.
340.6 Requests for additional information.
340.7 Determination.

Authority: Pub. L. 106–200, 114 Stat. 299; Presidential Proclamation 7383 (December 1, 2000).

§ 340.1 Purpose.

This part sets forth regulations regarding the procedures for considering requests to modify the limitations on the quantity of imports of fabrics of worsted wool under the Tariff Rate Quotas established by Section 501 of the Act. Section 504 of the Act requires annual consideration of such requests made by U.S. manufacturers of certain apparel products made of Worsted Wool Fabrics and grants the authority to modify the limitations.

§ 340.2 Definitions.

For purposes of these regulations and the forms used to implement them:

The Act means the Trade and Development Act of 2000 (Public Law No. 106–200, 114 Stat 251).

The Department means the United States Department of Commerce.

HTS means the Harmonized Tariff Schedule of the United States.

Imports subject to Tariff Rate Quotas are defined by date of presentation as defined in 19 CFR 132.1(d) and 19 CFR 132.11(a).

Production means cutting and sewing garments in the United States.

Tariff Rate Quota or Quotas means the temporary duty reduction provided under Section 501 of the Act for limited quantities of fabrics of worsted wool with average diameters greater than 18.5 micron, certified by the importer as suitable for use in making suits, suit-type jackets, or trousers (HTS heading 9902.51.11), and for limited quantities of fabrics of worsted wool with average diameters of 18.5 microns or less, certified by the importer as suitable for use in making suits, suit-type jackets, or trousers (HTS heading 9902.51.12).

Tariff Rate Quota Year means a calendar year for which the Tariff Rate Quotas are in effect.

Worsted Wool Fabric means fabric containing at least 85 percent by weight worsted wool.

Worsted Wool Suits means men's and boys' worsted wool suits, containing at least 85 percent by weight worsted wool fabric.

Worsted Wool Suit-Type Jackets mean men's and boys' worsted wool suit-type jackets, containing at least 85 percent by weight worsted wool fabric.

Worsted Wool Trousers means men's and boys' worsted wool trousers, containing at least 85 percent by weight worsted wool fabric.

§ 340.3 Requests for Modification.

(a) On an annual basis, the Department will cause to be published a **Federal Register** notice soliciting requests from U.S. manufacturers of Worsted Wool Suits, Worsted Wool Suit-Type Jackets, and Worsted Wool Trousers to modify the limitations on the quantity of imports of fabrics of worsted wool under the Tariff Rate Quotas. Requests must be received, or postmarked, on a date no later than 15 calendar days after the date of the **Federal Register** notice.

(b) A request shall include:

(1) The name, address, telephone number, fax number, and Internal Revenue Service number of the requester;

(2) The relevant worsted wool apparel product(s) manufactured by the person(s), that is, Worsted Wool Suits, Worsted Wool Suit-Type Jackets, or Worsted Wool Trousers;

(3) The modification requested, including the amount of the modification and the limitation that is the subject of the request (HTS heading 9902.51.11 and/or 9902.51.12); and

(4) A statement of the basis for the request, including all relevant facts and circumstances.

(c) A request should include the following information for each limitation that is the subject of the request, to the extent available:

(1) A list of suppliers from which the requester purchased domestically produced Worsted Wool Fabric during the 12 months preceding the request, the dates of such purchases, the quantity purchased, the quantity of imported Worsted Wool Fabric purchased, the countries of origin of the imported Worsted Wool Fabric purchased, the average price paid per square meter of the domestically

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produced Worsted Wool Fabric purchased, and the average price paid per square meter of the imported Worsted Wool Fabric purchased;

(2) A list of domestic Worsted Wool Fabric producers that declined, on request, to sell Worsted Wool Fabric to the requester during the 12 months preceding the request, indicating the product requested, the date of the order, the price quoted, and the reason for the refusal;

(3) The requester's domestic production and sales for the most recent six month period for which such data is available and the comparable six month period in the previous year, for each of the following products: Worsted Wool Suits, Worsted Wool Suit-Type Jackets, or Worsted Wool Trousers;

(4) Evidence that the requester lost production or sales due to an inadequate supply of domestically-produced Worsted Wool Fabric on a cost competitive basis; and

(5) Other evidence of the inability of domestic producers of Worsted Wool Fabric to supply domestically produced Worsted Wool Fabric to the requester.

§ 340.4 Comments regarding requested modification.

(a) If the Department receives a request or requests from a U.S. manufacturer under § 340.3, the Department will cause to be published in the **Federal Register** a notice summarizing the request or requests and soliciting comments from any interested person, including U.S. manufacturers of Worsted Wool Fabric, wool yarn, wool top and wool fiber, regarding the requested modification. Comments must be received, or postmarked, on a date not later than 20 calendar days after the date of the **Federal Register** notice.

(b) If the person submitting comments is a domestic producer of Worsted Wool Fabric, comments should include, to the extent available, the following information for each limitation with respect to which comments are being made:

(1) A list of domestic manufacturers of Worsted Wool Suits, Suit-Type Jackets, or Trousers for whom orders were filled during the twelve months prior to the submission of the comments, the date of such orders, the total quantity ordered and supplied in square meters of domestically produced Worsted Wool Fabric and of imported Worsted Wool Fabric, and the average price received per square meter of domestically produced Worsted Wool Fabric and of imported Worsted Wool Fabric for such orders.

(2) A list of all requests to purchase Worsted Wool Fabric during the twelve months prior to the submission of the comments that were rejected by the person submitting the comments, indicating the dates of the requests, the quantity requested, the price quoted, and the reasons why the request was rejected;

(3) Data indicating increase and/or decrease in production and sales for the most recent six month period for which data is available and the comparable six month period in the previous year of domestically-produced Worsted Wool Fabrics used in the production of Worsted Wool Suits, Suit-Type Jackets and Trousers.

(4) Evidence of lost sales due to the temporary duty reductions on certain Worsted Wool Fabric under the Tariff Rate Quotas; and

(5) Other evidence of the ability of domestic producers of Worsted Wool Fabric to meet the needs of the manufacturers of Worsted Wool Suits, Suit-Type Jackets and Trousers in terms of quantity, variety, and other relevant factors.

§ 340.5 Requests for modification and comments.

(a) Requests for modification and comments must be accompanied by a statement by the person submitting the request or comments (if a natural person), or an employee, officer or agent of the legal entity submitting the request or comments, with personal knowledge of the matters set forth therein, certifying that the information contained therein is complete and accurate, signed and sworn before a Notary Public, and acknowledging that false representations to a federal agency may result in criminal penalties under federal law.

(b) Any business confidential information provided pursuant to this section that is marked business confidential will be kept confidential and protected from disclosure to the full extent permitted by law. To the extent business confidential information is provided, a non-confidential submission shall also be provided, in which business confidential information is summarized or, if necessary, deleted.

§ 340.6 Requests for additional information.

The Department may request additional information from any manufacturer of Worsted Wool Suits, Suit-Type Jackets and Trousers, or manufacturer of Worsted Wool Fabric, wool yarn and wool top and fiber concerning information relevant to modifying the limitations.

§ 340.7 Determination.

(a) Based on information obtained, including information on market conditions obtained pursuant to the monitoring required under Section 504(a) of the Act, the Department shall consider the following United States market conditions as required by Section 504(b)(2) of the Act:

(1) Increases or decreases in sales of the domestically-produced Worsted Wool Fabrics used in the manufacture of Worsted Wool Suits, Suit-Type Jackets and Trousers;

(2) Increases or decreases in domestic production of such Worsted Wool Fabrics;

(3) Increases or decreases in domestic production and consumption of Worsted Wool Suits, Suit-Type Jackets and Trousers;

(4) The ability of domestic producers of Worsted Wool Fabrics to meet the needs of domestic manufacturers of Worsted Wool Suits, Suit-Type Jackets and Trousers in terms of quantity and the ability to meet market demands for the apparel items;

(5) Evidence that domestic manufacturers of Worsted Wool Fabrics used in the manufacture of Worsted Wool Suits, Suit-Type Jackets and Trousers have lost sales due to the temporary duty reductions on certain fabrics of worsted wool under the Tariff Rate Quota;

(6) Evidence that domestic manufacturers of Worsted Wool Suits, Suit-Type Jackets and Trousers have lost sales due to the inability to purchase adequate supplies of worsted wool fabrics on a cost competitive basis; and

(7) Price per square meter of imports and domestic sales of Worsted Wool Fabrics.

(b) Not later than 30 calendar days after the end of the comment period provided for in § 340.4(a), and on the basis of its consideration of the market conditions set forth in paragraph (a) of this section and other relevant factors, and using the facts available, the Department will determine whether the limitations on the quantity of imports under the Tariff Rate Quotas should be modified and recommend to the President that appropriate modifications be made. Consistent with section 504(b)(3)(B) of the Act, such modification shall not exceed 1,000,000 square meter equivalents for each of the Tariff Rate Quotas.

[FR Doc. 01–1949 Filed 1–18–01; 1:51 pm]
BILLING CODE 3510–25–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 740 and 748

[Docket No. 010112014–1014–01]

RIN 0694–AC41

Implementation of Presidential Announcement of January 10, 2001: Revisions to License Exception CTP; Corrections

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: On January 19, 2001 the Bureau of Export Administration (BXA) published a final rule revising License Exception CTP. This rule corrects inadvertent citation references in the January 19 rule.

DATES: This rule is effective January 19, 2001.

FOR FURTHER INFORMATION CONTACT: Sharron Cook in the Office of Exporter Services, Bureau of Export Administration, at (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This final rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. This regulation involves collections previously approved by the Office of Management and Budget under control numbers 0694–0088, "Multi-Purpose Application," which carries a burden hour estimate of 45 minutes per manual submission and 40 minutes per electronic submission. Miscellaneous and recordkeeping activities account for 12 minutes per submission. Information is also collected under OMB control number 0694–0107, "National Defense Authorization Act," Advance Notifications and Post-Shipment Verification Reports, which carries a burden hour estimate of 15 minutes per report. This rule also involves collections of information under OMB control number 0694–0073, "Export Controls of High Performance Computers" and OMB control number 0694–0093, "Import Certificates and End-User Certificates."

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act requiring notice of proposed rule making, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (see 5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rule making and an opportunity for public comment be given for this rule. Because a notice of proposed rule making and opportunities for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects in 15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Foreign trade, Reporting and record keeping requirements.

Accordingly, parts 740 and 748 of the Export Administration Regulations (15 CFR Parts 730–799) are amended as follows:

1. The authority citation for 15 CFR Part 740 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

2. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; Pub. L. No. 106–508; 50 U.S.C. 1701 *et seq.*; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 3, 2000 (65 FR 48347, August 8, 2000).

PART 740—CORRECTED

3. Part 740 is corrected by revising the phrase "paragraph (d)(2)" to read "paragraphs (d)(5)(i)(A) or (d)(5)(i)(B)" in paragraph 740.7(d)(4).

PART 748—CORRECTED

4. Section 748.10 is corrected by revising the citation reference "§ 740.7(d)(2)" to read "§ 740.7(d)(5)(i)(A) or § 740.7(d)(5)(i)(B)" in paragraph (b)(3)(i).

Dated: January 17, 2001.

Eileen M. Albanese,

Director, Office of Exporter Services, Export Administration.

[FR Doc. 01–1863 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 14, and 16

[Docket No. 98–1042]

Revision of Administrative Practices and Procedures; Meetings and Correspondence; Public Calendars

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations relating to meetings, correspondence, and the agency's public calendar. This action makes FDA's procedures more concise and understandable to the public, minimizes confusion about publicly available information concerning agency meetings, provides for more effective disclosure of such information, and allows the FDA to reallocate resources to areas of more urgent public health need.

DATES: This rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Brian Mayhew, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5211, e-mail: bmayhew@oc.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 17, 1998 (63 FR 69575), FDA issued a proposed rule to modify certain regulations pertaining to the public calendar and public meetings because such regulations are no longer effective in serving their intended purposes.

In that proposed rule, FDA tentatively concluded that the proposed action would make its procedures for public calendars and public meetings more concise and understandable to the public, minimize confusion about publicly available information

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concerning agency meetings, provide for more effective disclosure of such information, and allow FDA to reallocate resources to areas of more urgent public health need.

Interested parties were given until March 2, 1999, to comment on the proposal. Three letters, each containing one or more comments, were received in response to the proposal. Such letters were from a research laboratory, a blood bank association, and a research institute. The blood bank association supported the proposal, while the two other organizations suggested a number of modifications. The comments received and FDA's responses are addressed below.

II. Comments and Agency Response

A. The Prospective Public Calendar

(Comment 1) The proposed regulation would eliminate the prospective public calendar. Three comments addressed the elimination. One comment suggested that FDA evaluate whether the use of the prospective public calendar affects participation in FDA sponsored events before eliminating the prospective public calendar. Another comment noted that the proposed rule included no data to support the agency's tentative conclusion that maintenance of the prospective public calendar is no longer practical, workable, or beneficial to the public.

While the agency has not formally studied the impact of the public calendar on the amount of participation in a public event, FDA notes that it generally does a great deal of outreach through other mechanisms, including the **Federal Register**, the Internet, direct mailings, and other direct communications. In fact, the prospective public calendar may be one of the least effective mechanisms for notifying the public of upcoming public events, given that maintenance of the calendar has been given a lower priority and fewer resources have been expended to ensure that information on the public calendar is accurate and current. FDA has not performed a study regarding the maintenance of the public calendar either. However, the agency believes that it is much more efficient to allocate its limited resources to more effective methods of communication to its stakeholders.

(Comment 2) One comment requested that FDA not abandon any important communication mechanism such as the prospective public calendar that is designed to fulfill its obligation to notify the participants about future events until it fully examines whether some simple improvements to the existing system will fix problems for FDA and the public.

Due to the extremely positive response that the agency receives at its public meetings, public hearings, and other widely-attended events, the agency believes that other mechanisms, such as the Internet and the **Federal Register**, are effectively communicating the relevant information about FDA events. FDA does not believe that simple improvements to the current prospective public calendar will significantly improve its effectiveness.

(Comment 3) One comment asserted that the reasons provided for removing the prospective public calendar (i.e., need for frequent changes to the calendar, difficulty in projecting entries 4 weeks in advance) do not appear sufficient to warrant elimination of the availability of this information from the general public, especially in light of the resources expended on direct mail, the **Federal Register**, and FDA Internet activities.

The agency notes that it is precisely because of the availability of these other mechanisms that it is deleting the prospective public calendar requirements from its regulations. The agency will continue to use these very effective and efficient mechanisms in the future. Resources devoted to these other mechanisms will more adequately ensure that the public receives information regarding FDA meetings than if those same resources were devoted to maintaining the prospective public calendar.

(Comment 4) One comment stressed the importance of the agency providing adequate advance time for its announcements through other mechanisms.

The agency agrees with this comment, and it will strive to ensure that adequate time will be provided to the public when it disseminates information about public events via the Internet, the **Federal Register**, or other mechanisms.

(Comment 5) One comment suggested that with the abandonment of the prospective public calendar, it is extremely important that FDA maintain the timely publication of all meeting summaries because they are important and useful to the public.

FDA agrees with this comment.

(Comment 6) One comment argued that it was unrealistic to expect that the public at large is able to access the same information via the Internet as in the publication it plans to discontinue.

The agency believes that Internet access has become increasingly widespread in recent years. However, even in the event that a person did not have Internet access, other mechanisms, including **Federal Register** notices and direct mail, will provide adequate notification to the public regarding information previously contained in the prospective public calendar.

B. The Retrospective Public Calendar

(Comment 7) Under the proposed regulations, only meetings between certain senior agency officials and persons outside the executive branch of Government would be included on the retrospective public calendar. If a large number of persons is in attendance at a meeting, the name of each person need not be specified in the calendar entry, and if more than one FDA representative is in attendance, only the most senior official would report the meeting. One comment stated that these proposed changes would significantly limit the availability of potentially important information and would significantly restrict the range of input reflecting the various levels within FDA.

As stated in the proposed rule (63 FR 69575), the agency finds that it has become unduly burdensome for assistants, deputies, and representatives of the agency's senior officials to report meetings. FDA anticipates that despite this limitation on the reporting of some meetings, those meetings that are of greatest interest to the public will be reflected on the retrospective public calendar, thereby providing an appropriate level of public access to information.

C. Public Meetings

(Comment 8) Under the proposed regulations, FDA representatives may determine when it is appropriate to create an official transcript, recording, or memorandum of a meeting. One comment stated that, due to these changes in § 10.65(b) through (f) (21 CFR 10.65(b) through (f)), the availability of potentially important information will be denied to the public.

Because of limited resources, the agency finds that the determination of whether memoranda of a given meeting should be prepared should be left to the discretion of the senior agency official attending the meeting, taking into consideration the subject matter of the meeting, the public interest in the issue, and the value of using agency resources to prepare such transcripts, recordings, or memoranda. The agency does not believe that this change will significantly diminish the amount of important information made available to the public. This change will allow resources to be redirected to areas of greater public health need. This change does not preclude a participant from

preparing a summary of the meeting for inclusion into the administrative record, regardless of whether the agency creates an official record.

(Comment 9) Under the proposed regulations, meetings may be public or private at FDA's discretion. One comment requested that FDA exclude any individual representing a company that is the sponsor of an application pending before the agency from the definition of "person outside the Federal government." The reason for this request was that the comment did not want such an individual to have his/her meeting denied in favor of a meeting with a larger audience, raising issues about confidential business information.

The agency will not schedule larger meetings in place of necessary meetings with a sponsor of a product with an application pending before the agency. Instead, this clarification in the regulation is intended to provide the agency with the discretion to combine certain meeting requests of a similar nature. The agency has no intention of denying necessary meetings with sponsors where confidential information may be discussed. The comment misinterpreted the intent of the amendment, and the agency does not, therefore, find it necessary to change the definition of "person outside the Federal Government"

(Comment 10) One comment suggested that FDA should publish the criteria that it uses in making a determination about whether a meeting should be public or private.

The agency believes that this comment suggests a more elaborate process for this determination than the agency contemplated or than the agency believes necessary. While FDA is increasingly striving to make its processes open, transparent, and predictable, the agency is continuing to minimize an unnecessary burden on itself or its constituents. The agency reserves the discretion to make determinations about whether a given meeting is public or private on an informal and largely ad hoc basis. However, to the extent possible, FDA will make every effort to honor meeting requests and make its meetings as open and accessible to the public as practical.

(Comment 11) One comment suggested that the agency clarify that if other publicly available documents, such as hearing transcripts, congressional letters, and hearing testimony were not issued in a timely fashion from other sources, FDA will then issue a memorandum.

The agency declines to commit to issuing of a meeting memorandum whenever other sources do not make other documents available. However, FDA will make every effort to ensure that information about meetings with Congress covered by this rule is available as quickly as possible.

III. Changes From the Proposed Rule

Proposed revised § 10.65(e)(1) and (e)(2) have been modified and redesignated as § 10.65(f) to provide information about the filing of memoranda or summaries in the administrative file.

Proposed revised § 10.65(k) has been deleted because the statutory requirement upon which it was based has been repealed. (Public Law 105–362, title VI, section 601(a)(2)(A), 112 Stat. 3285 (1998).)

In this final rule, the agency is amending § 10.100(b)(3) (21 CFR 10.100(b)(3)) to more accurately reflect the current personnel structure of the agency. A reorganization of the Office of the Commissioner of Food and Drugs (the Commissioner) has changed the organizational structure of that office. This reorganization reduces the number of senior officials who would be covered by § 10.100 (b)(3). Therefore, only the Commissioner, Senior Associate Commissioners, Deputy Commissioners, Associate Commissioner for Regulatory Affairs, Center Directors, and the Chief Counsel will be required to report meetings on the retrospective calendar.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that would not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement would be required.

V. Analysis of Impact

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public L. 104–121)) and the Unfunded Mandates Reform Act of 1995 (Pub. Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

The Regulatory Flexibility Act requires an analysis of regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year. The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. This final rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act. Furthermore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further regulatory flexibility analysis is required.

VI. Paperwork Reduction Act of 1995

This regulation would impose no reporting or recordkeeping requirements that would necessitate Office of Management and Budget clearance.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 10, 14, and 16 are amended to read as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461, 21 U.S.C. 141–149, 321–397, 467f, 679, 821 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.30 [Amended]

2. Section 10.30 *Citizen petition* is amended in paragraph (i)(6) by removing "§ 10.65(h)" and adding in its place "§ 10.65(f)".

§ 10.33 [Amended]

3. Section 10.33 *Administrative reconsideration of action* is amended in paragraph (k)(6) by removing

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"§ 10.65(h)" and adding in its place "§ 10.65(f)".

§ 10.35 [Amended]

4. Section 10.35 *Administrative stay of action* is amended in paragraph (h)(6) by removing "§ 10.65(h)" and adding in its place "§ 10.65(f)".

§ 10.40 [Amended]

5. Section 10.40 *Promulgation of regulations for the efficient enforcement of the law* is amended in paragraph (g)(7) by removing "§ 10.65(h)" and adding in its place "§ 10.65(f)".

6. Section 10.65 is revised to read as follows:

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, in which any interested person may participate.

(1) The Commissioner shall inform the public of the time and place of the meeting and of the matters to be discussed.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(c) Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. FDA will make reasonable efforts to accommodate such requests.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a) of this chapter. Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the agency will attend the meeting. The person requesting the meeting may request, but not require or preclude, the attendance of a specific FDA employee.

(3) A person who wishes to attend a private meeting, but who is not invited to attend either by the person requesting the meeting or by FDA, or who otherwise cannot attend the meeting, may request a separate meeting with FDA to discuss the same matter or an additional matter.

(d) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency. In pursuing this responsibility, the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting that is closed on the basis of gender, race, or religion.

(e) An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the agency determines that such documentation will be useful.

(f) FDA promptly will file in the appropriate administrative file memoranda of meetings prepared by FDA representatives and all correspondence, including any written summary of a meeting from a participant, that relate to a matter pending before the agency.

(g) Representatives of FDA may initiate a meeting or correspondence on any matter concerning the laws administered by the Commissioner. Unless otherwise required by law, meetings may be public or private at FDA's discretion.

(h) A meeting of an advisory committee is subject to the requirements of part 14 of this chapter.

7. Section 10.100 is revised to read follows:

§ 10.100 Public calendar.

(a) *Public calendar.* A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with onsite contractors.

(b) *Calendar entries.* The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

(c) *Affected persons.* The following FDA representatives are subject to the requirements of this section:

(1) Commissioner of Food and Drugs.

(2) Senior Associate Commissioners.

(3) Deputy Commissioners.

(4) Associate Commissioner for Regulatory Affairs.

(5) Center Directors.

(6) Chief Counsel for the Food and Drug Administration.

(d) *Public display.* The public calendar will be placed on public display at the following locations:

(1) Dockets Management Branch.

(2) Office of the Associate Commissioner for Public Affairs.

(3) The FDA home page, to the extent feasible.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

8. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.20 [Amended]

9. Section 14.20 *Notice of hearing before an advisory committee* is amended by removing paragraph (e).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

10. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.60 [Amended]

11. Section 16.60 *Hearing procedure* is amended by removing paragraph (a)(3).

Dated: January 5, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1566 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–2336]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food. This action is in response to a petition filed by Holliday Pigments, Ltd.

DATES: This rule is effective January 22, 2001. Submit written objections and requests for a hearing by February 21, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1999 (64 FR 39146), FDA announced that a food additive petition (FAP 9B4670) had been filed by Holliday Pigments, Ltd., Morley St., Kingston upon Hull, HU8 8DN ENGLAND. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of manganese ammonium pyrophosphate (C.I. Pigment Violet 16) as a colorant for all polymers intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by February 21, 2001. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding an entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

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Substances	Limitations
Manganese Violet (manganese ammonium pyrophosphate; CAS Reg. No. 10101–66–3).	For use at levels not to exceed 2 percent by weight of polymers. The finished articles are to contact food only under conditions of use A through H as described in table 2 of § 176.170(c) of this chapter.

Dated: December 27, 2000.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–1565 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR PART 16

[AAG/A Order No. 212–2001]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Final Rule.

SUMMARY: The Department of Justice is further exempting the United States Marshals Service (USMS) Internal Affairs System, JUSTICE/USM–002, from subsections (e)(1) and (e)(5) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2), (k)(2) and (k)(5). This system is currently exempt from subsections (c)(3) and (4), (d), (e)(2) and (3), (e)(4)(G) and (H), (e)(8), (f) and (g) pursuant to subsections (j)(2) and (k)(5). In addition to records compiled during the course of investigations of allegations of misconduct or criminal violations by USMS personnel, this system also contains records compiled for law enforcement investigations related to actual or potential civil and regulatory violations. The additional exemptions are necessary to avoid interference with such law enforcement investigations and to protect the privacy of third party individuals.

EFFECTIVE DATE: This rule will be effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Mary E. Cahill on (202) 307–1823.

SUPPLEMENTARY INFORMATION: A proposed rule with invitation to comment was published in the **Federal Register** on November 8, 1999 (64 FR 60753). The public was given 30 days in which to comment. No public comments were received.

This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby stated that the order will not have a "significant economic impact on a substantial number of small entities."

List of Subjects in 28 CFR Part 16

Administrative Practice and Procedure, Courts, Freedom of Information Act, Government in the Sunshine Act, and Privacy.

Dated: January 8, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, 28 CFR Part 16 is amended as follows:

1. The authority for Part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717, 9701.

2. 28 CFR 16.101 is amended by revising paragraphs (e), introductory text, (e)(1), (f)(1), and (f)(3); by redesignating paragraphs (f)(7), (f)(8) and (f)(9) as paragraphs (f)(8), (f)(9) and (f)(10) and adding new paragraph (f)(7) as follows:

§ 16.101 Exemption of U.S. Marshals Service (USMS) Systems—limited access, as indicated.

* * * * *

(e) The following system of records is exempt from 5 U.S.C. 552a(c)(3) and (4), (d), (e)(1), (2) and (3), (e)(4)(G) and (H), (e)(5), (e)(8), (f) and (g).

(1) Internal Affairs System (JUSTICE/USM–002)—Limited access. These exemptions apply only to the extent that information in this system is subject to exemption pursuant to 5 U.S.C. 552a(j)(2), (k)(2) or (k)(5). Where compliance would not interfere with or adversely affect the law enforcement process, the USMS may waive the exemptions, either partially or totally.

(f) * * *

(1) From subsections (c)(3) and (d) to the extent that release of the disclosure accounting may impede or interfere with civil or criminal law enforcement efforts, reveal a source who furnished information to the Government in confidence, and/or result in an unwarranted invasion of the personal privacy of collateral record subjects or other third party individuals.

* * * * *

(3) From subsection (e)(1) to the extent that it is necessary to retain all information in order not to impede, compromise, or interfere with civil or criminal law enforcement efforts, e.g., where the significance of the information may not be readily determined and/or where such information may provide leads or assistance to Federal and other law agencies in discharging their law enforcement responsibilities.

(4) * * *

(5) * * *

(6) * * *

(7) From subsection (e)(5) because in the collection of information for law enforcement purposes it is impossible to determine in advance what information is accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance and the accuracy of such information can only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability to collect information for law enforcement purposes and interfere with the preparation of a complete investigative report or otherwise impede effective law enforcement.

* * * * *

[FR Doc. 01–1737 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–04–M

DEPARTMENT OF JUSTICE

28 CFR Part 25

[AG Order No. 2354–2001]; [FBI 105F]

RIN 1110–AA02

National Instant Criminal Background Check System Regulation

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice ("DOJ" or "the Department") is publishing a final rule amending the DOJ regulation implementing the National Instant Criminal Background Check System ("NICS") pursuant to the Brady Handgun Violence Prevention Act ("Brady Act"): to establish a reduced retention period of 90 days for information relating to allowed firearm transfers in the system transaction log of background check transactions ("NICS Audit Log"), to clarify that only the FBI has direct access to the NICS Audit Log, and to clarify that, in furtherance of the purpose of auditing the use and performance of the NICS, the FBI may extract and provide information from the NICS Audit Log to the Bureau of Alcohol, Tobacco and Firearms ("ATF") for use in ATF's inspections of Federal Firearms Licensee ("FFL") records, provided that ATF destroys the NICS Audit Log information about allowed firearm transfers within the applicable retention period (unless discrepancies are found) and maintains a written record certifying the destruction.

EFFECTIVE DATE: March 5, 2001.

FOR FURTHER INFORMATION CONTACT: Fanny Haslebacher, Attorney-Advisor, Federal Bureau of Investigation, Module A–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306–0147, (304) 625–2000.

SUPPLEMENTARY INFORMATION: This document finalizes the rule proposed in the **Federal Register** on March 3, 1999, (64 FR 10262). The FBI accepted comments on the proposed rule from interested parties until June 6, 1999, and slightly over 150 comments were received. With the exception of two technical changes explained below, the proposed rule is adopted as final.

Significant Comments or Changes

The Retention Period

Many of the comments asserted that the FBI was violating the requirements of the Brady Act by keeping information about approved firearm transfers for any period of time in the NICS Audit Log. Commenters stated that, in their view, the Brady Act requires immediate destruction of identifying information about individuals who have been approved for the transfer of a firearm. Commenters also asserted that the retention of information about approved firearm transfers in the NICS Audit Log constituted a firearms registry in violation of section 103(i) of the Brady Act. Some commenters labeled the NICS Audit Log a "back door" registration system or a *de facto* registry and expressed concern that such a "registry" could lead to future gun confiscations.

The Department of Justice received and considered similar comments when promulgating the final NICS regulation that established the current retention period of six months for information in the NICS Audit Log about approved firearm transfers. The discussion accompanying the final rule provided the following explanation of the Department's construction of the Brady Act as it relates to the record destruction requirement and the question of whether the NICS Audit Log constitutes a firearms registry:

> The FBI will not establish a federal firearms registry. The FBI is expressly barred from doing so by section 103(i) of the Brady Act. In order to meet her responsibility to maintain the integrity of Department systems, however, the Attorney General must establish an adequate system of oversight and review. Consequently, the FBI has proposed to retain records of approved transactions in an audit log for a limited period of time solely for the purpose of satisfying the statutory requirement of ensuring the privacy and security of the NICS and the proper operation of the system. Although the Brady Act mandates the destruction of all personally identified information in the NICS associated with approved firearms transactions (other than the identifying number and the date the number was assigned), the statute does not specify a period of time within which records of approvals must be destroyed. The Department attempted to balance various interests involved and comply with both statutory requirements by retaining such records in the NICS Audit Log for a limited, but sufficient, period of time to conduct audits of the NICS.
>
> 63 FR 58304.

The United States Court of Appeals for the District of Columbia Circuit recently held that the Attorney General reasonably interpreted the Brady Act to permit the temporary retention of certain information regarding NICS background checks for purposes of auditing the NICS. The court held that the six-month retention period was reasonable. *National Rifle Ass'n of America, Inc.* v. *Reno*, 216 F.3d 122 (D.C. Cir. 2000), rehearing denied (Oct. 26, 2000).

The temporarily retained information on approved firearm transfers is used only for purposes related to discovering misuse or avoidance of the system or ensuring the proper operation of the system: *e.g.* (1) comparing system records of a transaction with FFL records of the same transaction in order to detect cases where discrepancies in personal identifying information or missing records may reveal either (a) unauthorized NICS checks or (b) the submission of inaccurate information to the NICS for the purpose of avoiding a background check on the person to whom the gun is transferred; (2) reviewing system records in response to allegations of system misuse; (3) performing internal employee audits to monitor employee performance and adherence to established procedures; (4) evaluating system performance, identifying and resolving operational problems, and generating statistical reports; and (5) assisting in the resolution of appeals of NICS denials. Many of these system audits would not be possible with just the NICS Transaction Number and the date on which it was issued.

A number of comments incorrectly interpreted the proposed rule as intending to allow the FBI and/or ATF to regularly conduct continued scrutiny or "audits" of persons who have been approved for purchase of a firearm. It is true that, if during the course of any authorized system activity it is determined that a purchaser who should have been denied was given a proceed or a purchaser who should have been given a proceed was denied, the FBI will attempt to remedy the error. In the case of someone who was approved for a transfer who should have been denied, the NICS will notify the FFL of the error. If the NICS is informed that the firearm was transferred, the NICS will notify ATF. However, other than in conjunction with activities which are linked to discovering misuse or avoidance of the system or ensuring the proper operation of the system, proceed transactions are not subjected to continued scrutiny.

Some comments doubted the ability of the audits to prevent abuses or halt illegal or falsified transfers of firearms. The Department believes that examination of FFL records in conjunction with statistical reports (*i.e.*, the number of approved and disapproved transactions for a particular time period) combined with information in the NICS Audit Log about the background checks may reveal misuse of the system or improper record keeping practices when, for instance, (1) the FFL has requested more background checks than indicated by the number of ATF Firearm Transaction Record Form 4473s ("4473s") on file, (2) the FFL has requested fewer background checks than the number of 4473s on file, or (3) personal information recorded on the 4473s is significantly different from the information provided in the NICS background checks.

One comment suggested that the vast majority of FFLs are honest and would not abuse the system, and that if an FFL were to intentionally submit false information to the system, he or she would not record different information on the 4473 that would allow for the discovery of the discrepancy. While this scenario is possible, it is also possible, for example, that the information

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recorded on the 4473 may in fact be different from the information provided to the system, or that there may be fewer 4473s than NICS checks that have been requested by the FFL. The latter scenarios would reveal possible system misuse. The Department believes that it is essential to retain approval information temporarily to allow for the possibility of discovering such abuses. At a minimum, allowing for the possibility of audits should have a deterrent effect on FFLs who might otherwise consider abusing the system. If approval information were destroyed immediately, the NICS would have to rely completely on the "honor system" without any means to determine whether FFLs or FFL employees submit accurate identifying information about prospective purchasers to the NICS. If approval information were destroyed immediately, there would be no safeguards against the submission of false information to the NICS for the purpose of avoiding Brady background checks or doing unauthorized checks. While most FFLs and their employees are honest and conscientious, even one instance of gun violence that results from an unlawful firearm transfer allowed by uncheckable and undeterred system abuse can have a devastating impact on the lives of individual victims and communities. The Brady Act's purpose is to prevent gun violence resulting from unlawful firearm transfers. The temporary retention of information about allowed firearm transfers is meant to advance this statutory purpose, as well as the statutory obligation to protect the privacy and security of the information of the system.

A number of comments asked how the privacy interests of individuals approved for a firearm transfer have been accounted for in the rule. Those interests have been addressed in the rule first by reducing the retention period for information about allowed transfers to the shortest practicable period of time that will allow audits. The numerous comments received expressing concern about the privacy of individuals purchasing guns is the reason the original proposal of an 18-month retention period was first reduced to six months, and now has been reduced to 90 days, even though a longer retention period would increase the FBI's ability to detect and deter misuse of the system. In fact, the 90-day period has been adopted notwithstanding comments from two law enforcement representatives and the FBI's Criminal Justice Information Services (CJIS) Advisory Policy Board (an advisory committee made up of representatives of various government agencies involved in the criminal justice process which provides advice to the Director of the FBI on the management of criminal justice information systems operated by the FBI's CJIS Division) that recommended increasing the temporary retention of approved transactions from six months to one year.

The privacy interests of individuals approved for a firearm transfer have also been accounted for in the rule by the limitation on direct access to information about allowed transfers. As stated in the amended § 25.9(b)(2) of the regulation, the temporarily retained "[i]nformation in the NICS Audit Log pertaining to allowed transfers may be accessed directly only by the FBI for the purpose of conducting audits of the use and performance of the NICS." Limiting direct access to allowed transfers in the NICS Audit log to the FBI ensures controlled access to the information so that it is used only for the authorized purposes discussed above.

Individual privacy interests are also protected through compliance by the NICS with the Privacy Act of 1974. The Privacy Act regulates the collection, maintenance, use and dissemination of personal information by federal government agencies. A Privacy Act notice has been published for the NICS system (63 FR 65223) (November 25, 1998) which explains the system's purpose, routine uses, and policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system. As stated in the NICS Privacy Act notice, "The NICS regulations are to be read together with the NICS system notice." (63 FR 65224.) Thus, for example, Routine Use "C" provides for further coordination among law enforcement agencies for the purposes of investigating, prosecuting, and/or enforcing violations of criminal or civil law or regulation that may come to light during NICS operations. This portion of the routine use notice, read together with the NICS regulations, makes it clear that only the FBI has direct access to allowed transactions in the NICS Audit Log for purposes of conducting audits of the use and performance of the NICS, and that, if any record is found during this activity that indicates, either on its face or in conjunction with other information, a violation or potential violation of law, that record may be disclosed to the agency responsible for investigating the matter. By limiting direct access to information concerning allowed transfers to the FBI, and by limiting dissemination of information pursuant to published routine uses, the Department believes that it has struck the appropriate balance between protecting the personal privacy of individuals in the system and ensuring the proper and authorized operation of the system.

Several comments expressed concern that the information about allowed firearm transfers in the NICS Audit Log could fall into the hands of thieves who could target the homes of gun owners. The security measures used by the FBI at its computer facilities exceed industry standards to prevent either unauthorized destruction or theft of information. It is extremely unlikely that FBI firearm transaction records could be accessed or obtained by unauthorized individuals or entities.

Finally, one comment observed that if the NICS used technology that sent an encrypted "digital signature" of the information received by the system about prospective firearm purchasers back to the FFL, the goal of having such information available to audit the system could be achieved without any retention of the identifying information about approved purchasers by the FBI. In such a case, the FBI could destroy the information immediately and then simply provide to ATF the "key" that would unlock the encrypted information retained by the FFLs for use when ATF performed its FFL inspections. The Department believes that this approach is not currently feasible since its implementation would require an electronic interface with the system on the part of all FFLs. Although the FBI is working toward providing electronic access to the NICS by FFLs, such access has not yet been established, and, even when available, only FFLs with the appropriate computer equipment will be able to take advantage of the electronic link to NICS. In addition, the Brady Act requires that the system must, at a minimum, provide FFLs with telephone access to the NICS. It would not be easy or reliable to transmit digital signature information to FFLs over the telephone. Thus, while on its face this approach to the record retention and audit issues may have some appeal, there are technical and legal hurdles that do not make it feasible to pursue such an approach at this time. In addition, while such an approach would make record retention by the FBI unnecessary for FFL audits, it would not eliminate the need for some temporary retention of information about approved transfers to accomplish internal audits and to enable system troubleshooting.

Providing NICS Audit Log Information to ATF

Many of the comments dealt with the proposed provision allowing the FBI to share data with ATF for the purpose of comparing background check data received by the FBI with information recorded on the corresponding Form 4473 on file with an FFL. The commenters stated that the Brady Act requires immediate destruction of such records, thus making them unavailable for sharing; they also stated that the keeping and sharing of information about allowed firearms transfers constitutes a firearms registry. For the reasons cited above, the Department does not believe that the Brady Act requires immediate destruction of these records or that the temporary retention of NICS transaction information for the limited purpose of auditing use and performance of the system constitutes a firearms registry.

Several comments also stated that section 103(i)(1) of the Brady Act specifically prohibits transferring these records to ATF. Section 103(i)(1) provides that Federal officials may not "require that any record or portion thereof generated by the system established under [the Brady Act] be recorded at or transferred to a facility owned, managed, or controlled by the United States or any State or political subdivision thereof." The Department believes, however, that section 103(i), which is entitled "Prohibition Relating to Establishment of Registration Systems With Respect to Firearms," is intended only to prevent the establishment of a firearms registry and to prevent the government from requiring third parties outside the government from recording information about firearm transactions at a government facility. See *National Rifle Ass'n* v. *Reno*, 216 F.3d at 131. Therefore, since neither the NICS Audit Log itself nor the proposed provision of information to ATF for use in its inspections of FFLs (together with the proviso that ATF destroy the information about allowed transfers within the 90-day retention period) operates as or otherwise establishes a firearms registry, the sharing of such information with ATF does not violate section 103(i)(1).

Finally, some comments expressed the belief that the transfer of information from the NICS Audit Log to ATF also violates the Firearm Owners' Protection Act (FOPA), as codified in 18 U.S.C. 926(a). Section 926(a) provides, in relevant part, that regulations implementing the Gun Control Act promulgated by the Secretary of the Treasury after enactment of FOPA may not require that records that must be maintained by an FFL be recorded at or transferred to a government facility. Since these regulations are promulgated by the Department of Justice pursuant to the Brady Act, and since the NICS Audit Log information that will be provided to ATF consists of NICS system records, not records of an FFL, section 926(a) does not apply to the regulation adopted here.

Technical and Editorial Changes

When the Retention Period Begins To Run

The Department did not adopt the change we proposed in section 25.9(b)(1) of the NICS regulation to provide that the retention period begins to run on "the day after the NICS check is received," instead of the day the "transfer is allowed." The intention of this proposed change was to provide a uniform date from which to begin the retention period. It was noted by NICS Operations Center staff, however, that beginning the retention period on the day after the NICS check was received would complicate the processing of appeals that result in the reversal of a NICS denial in cases where the reversal occurs more than 90 days after the request for the NICS check was received. Under the NICS appeals process, the system gives the successful appellant a form certifying to the FFL that the system has changed the NICS determination from "denied" to "allowed." When presented with the certificate, the FFL must contact the system to confirm the "allowed" determination. The system would not be able to provide such confirmation unless the record of the "allowed" determination is retained for a reasonable period after the transaction is allowed. For this reason, the provision in § 25.9(b)(1) of the regulation providing that the retention period begins running from the date the transfer is allowed is being left unchanged.

Syntactical Change

A syntactical change was made to clarify the following sentence in the proposed rule: "Information in the NICS Audit Log pertaining to allowed transfers may only be directly accessed by the FBI for the purpose of conducting audits of the use and performance of the NICS." In the final rule, the sentence reads as follows: "Information in the NICS Audit Log pertaining to allowed transfers may be accessed directly only by the FBI for the purpose of conducting audits of the use and performance of the NICS." This change was made to better convey the intended meaning of the proposed language, i.e., that only the FBI has direct access to the NICS Audit Log.

Applicable Administrative Procedures and Executive Orders

Regulatory Flexibility Analysis

The Attorney General, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. While many FFLs are small businesses, they are not subject to any additional burdens by the plan adopted to audit their use of the NICS. In addition, the rule will not have any impact on an FFL's ability to contact the NICS, nor will it result in any delay in receiving responses from the NICS.

Executive Order 12866

The Department of Justice has completed its examination of this final rule in light of Executive Order 12866, section 1(b), Principles of Regulation. The Department of Justice has determined that this rule is a "significant regulatory action" under section 3(f) of Executive Order 12866, and thus it has been reviewed by the Office of Management and Budget (OMB).

Executive Order 13132

This final rule will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Unfunded Mandates Reform Act

This final rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This final rule is not a major rule as defined by the Small Business Regulatory Enforcement Fairness Act of 1996. 5 U.S.C. 804. This rule will not

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result in an annual effect on the economy of $100,000,000 or more, a major increase in costs or prices, or have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act of 1995

The collection of information for NICS previously was approved by OMB and issued OMB control numbers 1110–0026, 1512–0129, and 1512–0130.

List of Subjects in 28 CFR Part 25

Administrative practice and procedure, Business and industry, Computer technology, Courts, Firearms, Law enforcement officers, Penalties, Privacy, Reporting and record keeping requirements, Security measures, Telecommunications.

Accordingly, part 25 of title 28 of the Code of Federal Regulations is amended as follows:

PART 25—DEPARTMENT OF JUSTICE INFORMATION SYSTEMS

1. The authority citation for Part 25 continues to read as follows:

Authority: Pub. L. 103–159, 107 Stat. 1536.

Subpart A—The National Instant Criminal Background Check System

§ 25.9 [Amended]

2. In § 25.9, paragraph (b) is revised to read as follows:

* * * * *

(b) The FBI will maintain an automated NICS Audit Log of all incoming and outgoing transactions that pass through the system.

(1) The NICS Audit Log will record the following information: type of transaction (inquiry or response), line number, time, date of inquiry, header, message key, ORI, and inquiry/response data (including the name and other identifying information about the prospective transferee and the NTN). In cases of allowed transfers, all information in the NICS Audit Log related to the person or the transfer, other than the NTN assigned to the transfer and the date the number was assigned, will be destroyed after not more than 90 days after the transfer is allowed. NICS Audit Log records relating to denials will be retained for 10 years, after which time they will be transferred to a Federal Records Center for storage. The NICS will not be used to establish any system for the registration of firearms, firearm owners, or firearm transactions or dispositions, except with respect to persons prohibited from receiving a firearm by 18 U.S.C. 922 (g) or (n) or by state law.

(2) The NICS Audit Log will be used to analyze system performance, assist users in resolving operational problems, support the appeals process, or support audits of the use of the system. Searches may be conducted on the Audit Log by time frame, i.e., by day or month, or by a particular state or agency. Information in the NICS Audit Log pertaining to allowed transfers may be accessed directly only by the FBI for the purpose of conducting audits of the use and performance of the NICS. Permissible uses include extracting and providing information from the NICS Audit Log to ATF in connection with ATF's inspections of FFL records, provided that ATF destroys the information about allowed transfers within the retention period for such information set forth in paragraph (b)(1) of this section and maintains a written record certifying the destruction. Such information, however, may be retained as long as needed to pursue cases of identified misuse of the system. The NICS, including the NICS Audit Log, may not be used by any Department, agency, officer, or employee of the United States to establish any system for the registration of firearms, firearm owners, or firearm transactions or dispositions. The NICS Audit Log will be monitored and reviewed on a regular basis to detect any possible misuse of the NICS data.

* * * * *

Dated: January 12, 2001.

Janet Reno,

Attorney General.

[FR Doc. 01–1616 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–06–U

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–01–002]

RIN 2115–AE47

Drawbridge Operation Regulations: Hillsborough River

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the operation of the Brorein and Platt Street Drawbridges across the Hillsborough River in Tampa, Florida. This temporary rule allows the Brorein and Platt Street Drawbridges to remain closed to navigation from 10 a.m. to 6 p.m. on Saturday, January 27, 2001. This action is necessary to facilitate the Ye Mystic Krewe of Gasparilla Invasion and Parade.

DATES: This rule is effective from 10 a.m. to 6 p.m. on January 27, 2001.

ADDRESSES: Material received from the public as well as documents indicated in this preamble as being available in the docket are part of docket [CGD07–01–002] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, Florida, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Seventh Coast Guard District, Bridge Section, at (305) 415–6743.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this rule. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM was impracticable because there was not sufficient time remaining after the bridge owner notified us of the need for the bridge to remain closed for the Gasparilla event.

For the same reason, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

The Brorein and Platt Street Drawbridges, miles 0.16 and 0.0 respectively, across the Hillsborough River, have vertical clearances of 15.6 feet at mean high water and a horizontal clearance of 80 feet between fenders. The existing operating regulations in 33 CFR 117.291(a) require the bridge to open on signal after two hours notice.

The City of Tampa Department of Public Works requested that the Brorein and Platt Street Drawbridge operations be temporarily changed to allow the Ye Mystic krewe of Gasparilla Invasion and Parade. This temporary change to the drawbridge operating regulations will allow the drawbridge to remain closed from 10 a.m. to 6 p.m., Saturday, January 27, 2001.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–888–612), we considered whether this rule will have a significant economic effect upon a substantial number of small entities. "Small entities" include small business, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit the Hillsborough River under the Brorein or Platt Street Drawbridges on January 27, 2001.

This temporary rule will not have a significant economic impact on a substantial number of small entities because the regulations will only be in effect for eight hours in an area of limited marine traffic, and the event will be highly publicized.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–221), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or safety that may disproportionately affect children.

Environment

The Coast Guard has considered the environmental impact of this action and has determined under figure 2–1, paragraph 32(e) of Commandant Instruction M16475.1C, that this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From 10 a.m. to 6 p.m. on January 27, 2001, in § 117.291, temporarily suspend paragraph (a) and add a new temporary paragraph (c) to read as follows:

§ 117.291 Hillsborough River.

* * * * *

(c)(1) The draws of the bridges at Platt Street, mile 0.0, and Brorein Street, mile 0.16, need not open to navigation.

(2) The draws of the bridges at Kennedy Boulevard, mile 0.4, Cass Street, mile 0.7, Laurel Street, mile 1.0, West Columbus Drive, mile 2.3, and West Hillsborough Avenue, mile 4.8, shall open on signal if at least two hours notice is given; except that, the draws shall open on signal as soon as possible after a request by a public vessel of the United States, a vessel owned or operated by the State, county or local government and used for public safety purposes, or a vessel in distress.

Dated: January 12, 2001.

T.W. Allen,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 01–1850 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Southeast Alaska; 01–001]

RIN 2115–AA97

Safety Zone; Wrangell Narrows, Petersburg, AK

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone around the barge SWINIMOSH which will be conducting blasting/dredging operations along the navigable waters of Wrangell Narrows Shipping Channel, Petersburg, Alaska. This safety zone will require periodic complete channel closures to all vessel traffic transiting the channel as necessary for the barge SWINIMOSH to conduct operations. This safety zone is needed to protect maritime vessels transiting the area from

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the potential hazards associated with the blasting/dredging operations conducted by the barge SWINIMOSH.

DATES: This rule is effective from 12 a.m., January 15, 2001 until 12 a.m., April 02, 2001.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at U.S. Coast Guard, Marine Safety Office, 2760 Sherwood Lane, Suite 2A, Juneau, Alaska between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (907) 463–2450.

FOR FURTHER INFORMATION CONTACT: Lieutenant Cecil McNutt Jr., Chief Port Operations Department, U.S. Coast Guard Marine Safety Office Juneau, (907) 463–2470.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was not published for this regulation. In keeping with requirements of 5 U.S.C. 553(B), the Coast Guard finds a good cause exists for not publishing a NPRM. Application for the blasting operations was not received by the Marine Safety Office Juneau until December 19, 2000. The operations are scheduled to commence January 15, 2001; thus time to publish a NPRM is inadequate for this regulation. In keeping with requirements of 5 U.S.C. 553 (d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**. Publication of a NPRM and delay of the effective date would be contrary to the public interest because immediate action is necessary to protect the safety of the maritime vessel traffic in the vicinity of the blasting operation.

Background and Purpose

The U.S. Army Corps of Engineers through its contractor Western Marine Construction, Inc. will be conducting blasting/dredging operations on portions of Wrangell Narrows Shipping Channel for the Wrangell Narrows Project (ACOE project number DACW85–00–C–0015). This dredging project is necessary to maintain safe navigation within the Wrangell Narrows Shipping Channel. A 500-yard safety zone around the barge SWINIMOSH along with periodic complete channel closures is needed to protect the safety of the maritime vessel traffic from the potential hazards associated with blasting/dredging operations.

The blasting operations will begin 12 a.m. January 15, 2001, and will last until 12 a.m. April 2, 2001. This safety zone is necessary to protect the maritime public from the potential hazards associated with the blasting/dredging operations.

Regulatory Evaluation

This temporary rule is not a significant regulatory action under section 3(f) of the Executive Order 12866 and does not require an assessment of potential costs and benefits under sections 6(a)(3) of that Order. It has been exempted from review by the Office of Management and Budget under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant impact on a substantial number of small businesses and not-for-profit organizations that are not dominant in their respective fields, and governmental jurisdictions with populations less than 50,000. For the same reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under section 605 (b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with section 213 (a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If your small business or organization is affected by this rule and you have questions concerning its provisions or options for compliance, please contact the office listed in **ADDRESSES** in this preamble.

Collection of Information

This rule contains no information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this temporary final rule under the principles and criteria contained in Executive Order 13132 and has determined that this temporary final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this temporary final rule and concluded that, under figure 2–1, paragraph (34)(g), of Commandant Instruction M16475.1C, this temporary final rule is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under **ADDRESSES**.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) and E.O. 12875, Enhancing the Intergovernmental Partnership, (58 FR 58093; October 28, 1993) govern the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This rule will not impose an unfunded mandate.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary § 165.T17–SEAK–001 is added to read as follows:

§ 165.T17–SEAK–001 Wrangell Narrows Channel, Petersburg, Alaska-Safety Zone.

(a) *Location.* The following area is a temporary safety zone: the waters within a 500 yard radius of the barge SWINIMOSH while engaged in blasting/dredging operations to include periodic complete channel closures in Wrangell Narrows Shipping Channel, Petersburg AK from Point Lockwood Rock, Lighted Marker #1 (LL #22845), 56°34.0′ N, 132°58.1′ W to Rock Point, Lighted Marker #40 (LL #23070), 56°40.3′ N, 132°56.1′ W.

(b) *Effective Dates.* This rule is effective from 12 a.m., January 15, 2001 until 12 a.m., April 02, 2001.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within this safety zone is prohibited except as authorized by the Captain of the Port-Southeast Alaska. The attending tug WALDO will be standing by on channel 16 and 13 for traffic advisory. All approaching vessel traffic must contact the tug WALDO prior to transiting the channel.

Dated: January 3, 2001.

R. C. Lorigan,

Captain, U.S. Coast Guard, Captain of the Port, Southeast Alaska.

[FR Doc. 01–1669 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–00–227]

RIN 2115–AA97

Safety Zone: Coast Guard Activities New York Annual Fireworks Displays

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing 12 permanent safety zones for annual fireworks displays located in the Port of New York/New Jersey. This action is necessary to provide for the safety of life on navigable waters during the events. This action is intended to restrict vessel traffic in a portion of the affected waterways.

DATES: This rule is effective February 21, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–00–227) and are available for inspection or copying at room 204, Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, NY between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4012.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On November 2, 2000, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone: Coast Guard Activities New York Annual Fireworks Displays in the **Federal Register** (65 FR 65814). We received no letters commenting on the proposed rule. No public hearing was requested, and none was held.

Background and Purpose

The Coast Guard is establishing twelve permanent safety zones, in eight separate locations, that will be activated for fireworks displays occurring at the same location and time on an annual basis. The eight locations are north of Bar Beach in Hempstead Harbor; Pier 14, Manhattan, in the East River; Highlands, NJ on Sandy Hook Bay; Kingston, NY on Rondout Creek; Tottenville, Staten Island, in the Arthur Kill; Red Bank, NJ on the Navesink River; the Burlington Bay Breakwater, VT; and Rensselaer, NY on the Hudson River. There are four annual fireworks displays at the location off Pier 14 in the East River and two annual displays at the location in Hempstead Harbor. Establishing permanent safety zones by notice and comment rulemaking gave the public the opportunity to comment on the zones, provided better notice than promulgating temporary rules annually, and decreases the amount of annual paperwork required for these events. The Coast Guard has received no prior notice of any impact caused by the previous events.

The Coast Guard is revising 33 CFR 165.161 by adding six new locations, revising the effective dates for two current locations, and removing three locations from the section because they are now permanent fireworks safety zones regulated by 33 CFR 165.168. The two current locations with revised effective dates are Highlands, NJ, and Kingston, NY. The three locations that are being removed are Glen Cove, NY, Yonkers, NY, and Elizabeth, NJ.

The sizes of these safety zones were determined using National Fire Protection Association and New York City Fire Department standards for 6–12 inch mortars fired from a barge or shore, combined with the Coast Guard's knowledge of tide and current conditions in these areas. The twelve safety zones are:

North Hempstead, NY Fireworks, Hempstead Harbor

The safety zone includes all waters of Hempstead Harbor within a 300-yard radius of the fireworks barge in approximate position 40°49′54″N 073°39′14″W (NAD 1983), about 360 yards north of Bar Beach, Hempstead Harbor. There are two annual fireworks displays in Hempstead Harbor. Aside from being on different days, the safety zone for each display is the same. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Friday before Memorial Day and the Saturday after Labor Day. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday before Memorial Day and the Sunday after Labor Day. The safety zone closes a portion of southern Hempstead Harbor and prevents marine traffic from transiting a portion of this area. Vessel traffic will be able to transit through the northern 6,000 yards of Hempstead Harbor as this location is in the extreme southern end of Hempstead Harbor. It is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

Seaport Memorial Day, Labor Day, New Year's Eve, and the Deepavali Festival Fireworks, East River

The safety zone includes all waters of the East River south of the Brooklyn Bridge and north of a line drawn from the southwest corner of Pier 3, Brooklyn, to the northeast corner of Pier 6, Manhattan. There are four annual fireworks displays in the East River. Aside from being on different days and at different times, the safety zone for each display is the same. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on Memorial Day, Labor Day, and New Year's Eve; and from 6 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first Sunday in October. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the day following Memorial Day, Labor Day, and New Year's Eve; and from 6 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first Monday in October. The safety zone closes a portion of the East River and prevents marine traffic from transiting this area. It is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

Highlands, NJ Fireworks, Sandy Hook Bay

The safety zone includes all waters of Sandy Hook Bay within a 150-yard radius of the fireworks barge in approximate position 40°24′33.8″N 073°59′46.2″W (NAD 1983), about 1,200 yards west of Plum Island. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday before Father's Day. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on Father's Day. The safety zone closes a portion of Sandy Hook Bay and the Shrewsbury

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River, and prevents marine traffic from transiting a portion of this area. It is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

Kingston, NY Fireworks, Rondout Creek

The safety zone includes all waters of Rondout Creek between the Kingston-Port Ewen Bridge (mile 1.1) and the Kingston-US 9 Bridge (mile 1.3). The fireworks are fired from shore at the Kingston Municipal Docks. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday and Sunday before July 4th. The safety zone closes a portion of Rondout Creek and prevents marine traffic from transiting the area. It is needed to protect boaters from the hazards associated with fireworks launched from shore in the area.

Staten Island Fireworks, Arthur Kill

The safety zone in the Arthur Kill includes all waters of the Arthur Kill, Ward Point Bend (West), and the Raritan River Cutoff, within a 300-yard radius of the fireworks barge in approximate position 40°30′18″N 074°15′30″W (NAD 1983), about 300 yards west of Conference House Park, Staten Island. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd and the Saturday before Labor Day. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 4th and 5th, and the Sunday and Monday of Labor Day weekend. The safety zone prevents vessels from transiting a portion of the Arthur Kill, Ward Point Bend (West), and the Raritan River Cutoff, and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Recreational vessels will still be able to transit through the western 50 yards of the 540-yard wide Arthur Kill during the event. Additionally, vessels are not precluded from getting underway, or mooring at, public or private facilities in Perth Amboy, NJ, in the vicinity of this zone.

Red Bank, NJ July 3rd Fireworks, Navesink River

The safety zone northwest of Red Bank includes all waters of the Navesink River within a 360-yard radius of the fireworks barge in approximate position 40°21′20″N 074°04′10″W (NAD 1983), about 360 yards northwest of Red Bank, NJ. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 4th. The safety zone prevents vessels from transiting a portion of the Navesink River and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

Burlington, VT July 3rd Fireworks, Burlington Bay

The safety zone includes all waters of Burlington Bay within a 300-yard radius of the fireworks barge in approximate position 44°28′30.6″N 073°13′31.3″W (NAD 1983), beside the Burlington Bay Breakwater. The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the following two Fridays and Saturdays. The safety zone prevents vessels from transiting a portion of Burlington Bay, and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

Rensselaer, NY Fireworks, Hudson River

The safety zone includes all waters of the Hudson River within a 180-yard radius of the fireworks barge in approximate position 42°38′23″N 073°44′59.1″W (NAD 1983), about 480 yards south of the Dunn Memorial Bridge (mile 145.4). The safety zone is effective annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first and second Saturday in August. If the event is cancelled due to inclement weather, then this safety zone is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first and second Sunday in August. The safety zone prevents vessels from transiting a portion of the Hudson River, and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area.

The effective period for each safety zone is from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.), except for the safety zone off Pier 14 in the East River on the first Sunday in October which is effective from 6 p.m. (e.s.t.) to 1 a.m. (e.s.t.). However, vessels may enter, remain in, or transit through these safety zones during this time frame if authorized by the Captain of the Port New York, or designated Coast Guard patrol personnel on scene, as provided for in 33 CFR 165.23. Generally, blanket permission to enter, remain in, or transit through these safety zones will be given except for the 45-minute period that a Coast Guard patrol vessel is present. These safety zones will not create a significant economic impact on marine traffic due to the following: the minimal time that vessels will be restricted from the zones, and all of the zones are in areas where the Coast Guard expects insignificant adverse impact on all mariners from the zones' activation. All of the displays take place late at night on a national holiday with the exceptions of Highlands, NJ, Rensselaer, NY, and the Deepavali Festival Fireworks. The Coast Guard has promulgated safety zones for fireworks displays at all 8 areas in the past and we have not received notice of any negative comments on these annual displays. Additionally, marine traffic can plan their transits through these areas around the time the safety zones are in effect. The marine community will have advance notice of these events as they are annual events with local community support. The Sandy Hook and Hudson River Pilots Associations will be notified prior to these events. Advance notifications will also be made to the local maritime community by the Local Notice to Mariners. Marine information and facsimile broadcasts may also be made.

This rule is being established to provide for the safety of life on navigable waters during the events, to give the marine community the opportunity to comment on the zones, and to decrease the amount of annual paperwork required for these events.

Discussion of Comments and Changes

The Coast Guard received no letters commenting on the proposed rulemaking. No changes were made to this rulemaking.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

This finding is based on the minimal time that vessels will be restricted from the zones, vessels will be able to transit through these safety zones except for the 45-minute period that a Coast Guard patrol vessel is present, and all of the zones are in areas where the Coast Guard expects insignificant adverse impact on all mariners from the zones' activation. All of the displays take place late at night on a national holiday with the exceptions of Highlands, NJ, Rensselaer, NY, and the Deepavali Festival Fireworks. The Coast Guard has promulgated safety zones for fireworks displays at all 8 areas in the past and we have not received notice of any negative comments on these annual displays. Additionally, marine traffic can plan their transits through these areas around the time the safety zones are in effect. The marine community will have advance notice of these events as they are annual events with local community support. The Sandy Hook and Hudson River Pilots Associations will also be notified prior to these events. Advance notifications will also be made to the local maritime community by the Local Notice to Mariners. Marine information and facsimile broadcasts may also be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit or anchor in a portion of: Hempstead Harbor, the East River, Sandy Hook Bay, Rondout Creek, the Arthur Kill, the Navesink River, Burlington Bay, and the Hudson River during the times these zones are activated.

These safety zones will not have a significant economic impact on a substantial number of small entities for the following reasons: These are all annual events with local community support and vessels will normally be precluded from entering any of the zones for only a 45-minute period on an annual basis. Before the effective period, we will issue maritime advisories widely available to users of the Port of New York/New Jersey by the Local Notice to Mariners. Marine information and facsimile broadcasts may also be made. Additionally, the Coast Guard has not received any negative reports from small entities affected by these displays during these displays in previous years.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. This rule fits paragraph 34(g) as it establishes 12 safety zones. A "Categorical Exclusion Determination" is available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. Revise § 165.161 to read as follows:

§ 165.161 Safety zones: Coast Guard activities New York annual fireworks displays.

(a) *Safety zones.* The following areas are designated safety zones:

(1) *North Hempstead, NY, fireworks, Hempstead Harbor.*

(i) *Location.* All waters of Hempstead Harbor within a 300-yard radius of the fireworks barge in approximate position 40°49′54″ N 073°39′14″ W (NAD 1983), about 360 yards north of Bar Beach, Hempstead Harbor.

(ii) *Effective period.* Paragraph (a)(1)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Friday before Memorial Day, and the Saturday after Labor Day. If the event is cancelled due to inclement weather, then paragraph (a)(1)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday before Memorial Day and the Sunday after Labor Day.

(2) *Seaport Memorial Day fireworks, East River, NY:*

(i) *Location.* All waters of the East River south of the Brooklyn Bridge and north of a line drawn from the southwest corner of Pier 3, Brooklyn, to the northeast corner of Pier 6, Manhattan.

(ii) *Effective period.* Paragraph (a)(2)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on Memorial Day. If the event is cancelled due to inclement weather, then paragraph (a)(2)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the day following Memorial Day.

(3) *Highlands, NJ, fireworks, Sandy Hook Bay:*

(i) *Location.* All waters of Sandy Hook Bay within a 150-yard radius of the

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fireworks barge in approximate position 40°24′33.8″ N 073°59′46.2″ W (NAD 1983), about 1,200 yards west of Plum Island.

(ii) *Effective period.* Paragraph (a)(3)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday before Father's Day. If the event is cancelled due to inclement weather, then paragraph (a)(3)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on Father's Day.

(4) *Kingston, NY, fireworks, Rondout Creek:*

(i) *Location.* All waters of Rondout Creek between the Kingston-Port Ewen Bridge (mile 1.1) and the Kingston-US 9 Bridge (mile 1.3).

(ii) *Effective period.* Paragraph (a)(4)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday and Sunday before July 4th.

(5) *Staten Island July 3rd fireworks, Arthur Kill:*

(i) *Location.* All waters of the Arthur Kill, Ward Point Bend (West), and the Raritan River Cutoff, within a 300-yard radius of the fireworks barge in approximate position 40°30′18″ N 074°15′30″ W (NAD 1983), about 300 yards west of Conference House Park, Staten Island.

(ii) *Effective period.* Paragraph (a)(5)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd. If the event is cancelled due to inclement weather, then paragraph (a)(5)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 4th and July 5th.

(6) *Red Bank, NJ, July 3rd fireworks, Navesink River:*

(i) *Location.* All waters of the Navesink River within a 360-yard radius of the fireworks barge in approximate position 40°21′20″ N 074°04′10″ W (NAD 1983), about 360 yards northwest of Red Bank, NJ.

(ii) *Effective period.* Paragraph (a)(6)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd. If the event is cancelled due to inclement weather, then paragraph (a)(6)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 4th.

(7) *Burlington, VT, July 3rd fireworks, Burlington Bay:*

(i) *Location.* All waters of Burlington Bay within a 300-yard radius of the fireworks barge in approximate position 44°28′30.6″N 073°13′31.3″W (NAD 1983), beside the Burlington Bay Breakwater.

(ii) *Effective period.* Paragraph (a)(7)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on July 3rd. If the event is cancelled due to inclement weather, then paragraph (a)(7)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the following two Fridays and Saturdays.

(8) *Rensselaer, NY, fireworks, Hudson River:*

(i) *Location.* All waters of the Hudson River within a 180-yard radius of the fireworks barge in approximate position 42°38′23″ N 073°44′59.1″ W (NAD 1983), about 480 yards south of the Dunn Memorial Bridge (mile 145.4).

(ii) *Effective period.* Paragraph (a)(8)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first and second Saturday in August. If the event is cancelled due to inclement weather, then paragraph (a)(8)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first and second Sunday in August.

(9) *Staten Island Labor Day fireworks, Arthur Kill:*

(i) *Location.* All waters of the Arthur Kill, Ward Point Bend (West), and the Raritan River Cutoff, within a 300-yard radius of the fireworks barge in approximate position 40°30′18″ N 074°15′30″ W (NAD 1983), about 300 yards west of Conference House Park, Staten Island.

(ii) *Effective period.* Paragraph (a)(9)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Saturday before Labor Day. If the event is cancelled due to inclement weather, then paragraph (a)(9)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the Sunday and Monday of Labor Day Weekend.

(10) *Seaport Labor Day fireworks, East River, NY:*

(i) *Location.* All waters of the East River south of the Brooklyn Bridge and north of a line drawn from the southwest corner of Pier 3, Brooklyn, to the northeast corner of Pier 6, Manhattan.

(ii) *Effective period.* Paragraph (a)(10)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on Labor Day. If the event is cancelled due to inclement weather, then paragraph (a)(10)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the day following Labor Day.

(11) *Deepavali Festival fireworks, East River, NY:*

(i) *Location.* All waters of the East River south of the Brooklyn Bridge and north of a line drawn from the southwest corner of Pier 3, Brooklyn, to the northeast corner of Pier 6, Manhattan.

(ii) *Effective period.* Paragraph (a)(11)(i) of this section is in effect annually from 6 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first Sunday in October. If the event is cancelled due to inclement weather, then paragraph (a)(11)(i) of this section is effective from 6 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the first Monday in October.

(12) *Seaport New Year's Eve fireworks, East River, NY:*

(i) *Location.* All waters of the East River south of the Brooklyn Bridge and north of a line drawn from the southwest corner of Pier 3, Brooklyn, to the northeast corner of Pier 6, Manhattan.

(ii) *Effective period.* Paragraph (a)(12)(i) of this section is in effect annually from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on New Year's Eve. If the event is cancelled due to inclement weather, then paragraph (a)(12)(i) of this section is effective from 8 p.m. (e.s.t.) to 1 a.m. (e.s.t.) on the day following New Year's Eve.

(b) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene-patrol personnel. These personnel comprise commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

Dated: January 10, 2001.

R.E. Bennis,

Rear Admiral, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 01–1667 Filed 1–19–01; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 9

[FRL–6935–6]

OMB Approvals Under the Paperwork Reduction Act; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this technical amendment amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information.

EFFECTIVE DATE: This final rule is effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, (202) 564–8019.

SUPPLEMENTARY INFORMATION: EPA is amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. The amendment updates the table to list those information collection requirements promulgated under the Accidental Release Prevention Requirements; Risk Management Programs Under the Clean Air Act Section 112(r)(7); Distribution of Off-Site Consequence Analysis Information, which appeared in the **Federal Register** on August 4, 2000 (65 FR 48107). The affected regulations are codified at 40 CFR Part 1400. EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR Part 9 of the Agency's regulations. The table lists CFR citations with reporting, recordkeeping, or other information collection requirements, and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR Part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. Due to the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without prior notice and comment.

I. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). This rule also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655 (May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of January 22, 2001. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

Dated: January 12, 2001.

Timothy Fields, Jr.,

Assistant Administrator, Office of Solid Waste and Emergency Response.

For the reasons set out in the preamble, 40 CFR part 9 is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by adding a new heading for Distribution of Off-Site Consequence Analysis Information and entries in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Distribution of Off-Site Consequence Analysis Information	
1400.3	2050–0172
1400.4	2050–0172
1400.6	2050–0172
1400.9	2050–0172
* * * * *	

[FR Doc. 01–1826 Filed 1–19–01; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Part 301–10

[FTR Amendment 95]

RIN 3090–AH36

Federal Travel Regulation; Privately Owned Vehicle Mileage Reimbursement

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Final rule.

SUMMARY: This final rule increases the mileage reimbursement rate for use of a privately owned vehicle (POV) on official travel to reflect current costs of operation as determined in cost studies conducted by the General Services Administration (GSA). The governing regulation is revised to increase the mileage allowance for advantageous use of a privately owned airplane from 88 to 96.5 cents per mile, the cost of operating a privately owned automobile from 32.5 to 34.5 cents per mile, and the cost of operating a privately owned motorcycle from 26.0 to 27.5 cents per mile.

EFFECTIVE DATE: This final rule is effective January 22, 2001.

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FOR FURTHER INFORMATION CONTACT: Devoanna R. Reels, Program Analyst, telephone 202–501–3781.

SUPPLEMENTARY INFORMATION:

A. Background

Pursuant to 5 U.S.C. 5707(b), the Administrator of General Services has the responsibility to establish the privately owned vehicle (POV) mileage reimbursement rates. Separate rates are set for airplanes, automobiles (including trucks), and motorcycles. In order to set these rates, GSA is required to conduct periodic investigations, in consultation with the Secretaries of Defense and Transportation, and representatives of Government employee organizations, of the cost of travel and the operation of POVs to employees while engaged on official business. As required, GSA conducted an investigation of the costs of operating a POV and is reporting the cost per mile determination. The results of the investigation have been reported to Congress and a copy of the report appears as an attachment to this document. GSA's cost studies show the Administrator of General Services has determined the per-mile operating costs of a POV to be 96.5 cents for airplanes, 34.5 cents for automobiles, and 27.5 cents for motorcycles. As provided in 5 U.S.C. 5704(a)(1), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS has announced a new single standard mileage rate for automobiles of 34.5 cents effective January 1, 2001. Additionally, based on updated data reflecting current costs to an agency of operating a Government Furnished Vehicle (GFV), GSA has increased the rate for use of a POV instead of a GFV from 23.5 cents to 28.5 cents per mile.

B. Regulatory Flexibility Act

This final rule is not required to be published in the **Federal Register** for notice and comment; therefore, the Regulatory Flexibility Act does not apply.

C. Executive Order 12866

GSA has determined that this final rule is not a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this final rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget under 44 U.S.C. 501 *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This final rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

List of Subjects in 41 CFR Part 301–10

Government employees, Travel and transportation expenses.

For the reasons set forth in the preamble, 41 CFR part 301–10 is amended to read as follows:

PART 301–10—TRANSPORTATION EXPENSES

1. The authority citation for 41 CFR part 301–10 continues to read as follows:

Authority: 5 U.S.C. 5707; 40 U.S.C. 486(c); 49 U.S.C. 40118.

2. Section 301–10.303 is amended by revising the entries Privately owned airplane, Privately owned automobile, and Privately owned motorcycle in the table to read as follows:

§ 301–10.303 What am I reimbursed when use of a POV is determined by my agency to be advantageous to the Government?

For use of a	Your reimbursement is
Privately owned airplane	[1] 96.5
Privately owned automobile	[1] 34.5
Privately owned motorcycle	[1] 27.5

[1] Cents per mile.

§ 301–10.310 [Amended]

3. Section 301–10.310(a) is amended by removing "23.5" and adding in its place "28.5".

Dated: January 10, 2001.

Thurman M. Davis, Sr.,

Acting Administrator of General Services.

Attachment to Preamble—Report to Congress on the Costs of Operating Privately Owned Vehicles

Subparagraph (b)(1)(A) of section 5707 of title 5, United States Code, requires the Administrator of General Services, in consultation with the Secretaries of Defense and Transportation, and representatives of Government employee organizations, to periodically investigate the cost of travel and the operation of privately owned vehicles (airplanes, automobiles, and motorcycles) to Government employees while on official business, to report the results of the investigations to Congress, and to publish the report in the **Federal Register**. This report is being published to comply with the requirements of the law.

Dated: January 10, 2001.

Thurman M. Davis, Sr.,

Acting Administrator of General Services.

Report to Congress

Subparagraph (b)(1)(A) of section 5707 of title 5, United States Code, requires that the Administrator of General Services, in consultation with the Secretaries of Defense and Transportation, and representatives of Government employee organizations, conduct periodic investigations of the cost of travel and the operation of privately owned vehicles (POVs) (airplanes, automobiles, and motorcycles) to Government employees while on official business and report the results to Congress at least once a year. Subparagraph (b)(2)(B) of section 5707 of title 5, United States Code, further requires that the Administrator of General Services determine the average, actual cost per mile for the use of each type of POV based on the results of the cost investigation. Such figures must be reported to Congress within 5 working days after the cost determination has been made in accordance with 5 U.S.C. 5707(b)(2)(C).

Pursuant to the requirements of subparagraph (b)(1)(A) of section 5707 of Title 5, United States Code, the General Services Administration (GSA), in consultation with the Secretaries of Defense and Transportation, and representatives of Government employee organizations, conducted an investigation of the cost of operating a POV. As provided in 5 U.S.C. 5704(a)(1), the automobile reimbursement rate cannot exceed the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS has announced a new single standard mileage rate for automobiles of 34.5 cents effective January 1, 2000.

As required, GSA is reporting the results of the investigation and the cost per mile determination. Based on cost studies conducted by GSA, I have determined the per-mile operating costs of a POV to be 96.5 cents for airplanes, 34.5 cents for automobiles, and 27.5 cents for motorcycles.

I will issue a regulation to increase the current 88 to 96.5 cents for privately owned airplanes, 32.5 to 34.5 cents for privately owned automobiles, and 26.0 to 27.5 cents for privately owned motorcycles. This report

to Congress on the cost of operating POVs will be published in the Federal Register.

[FR Doc. 01–1466 Filed 1–19–01; 8:45 am]

BILLING CODE 6820–34–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[FCC 00–352]

Waivers, Reductions and Deferrals of Regulatory Fees; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission published in the **Federal Register** of December 18, 2000, a document that was to deny the petition for reconsideration filed by the Cellular Telecommunications Industry Association on August 2, 1999 regarding the Report and Order in the matter of Assessment and Collection of Regulatory Fees for Fiscal Year 1999 and also amend the Commission's rule regarding petitions for reduction of regulatory fees. Inadvertently, the document did not include the paragraph noting the denial of the petition for reconsideration. This document corrects that error.

DATES: Effective January 17, 2001.

FOR FURTHER INFORMATION CONTACT: Carla Conover, Office of General Counsel, (202) 418–7882.

SUPPLEMENTARY INFORMATION: In FR Doc. 00–31946, published in the **Federal Register** of December 18, 2000 (65 FR 78989), the paragraph noting the denial of a petition for reconsideration was not included. This correction includes that paragraph.

1. This supplementary information is a summary of the Commission's Memorandum Opinion and Order on Reconsideration (Order) in MD Docket No. 98–200 (FCC 00–352), adopted September 21, 2000, and released October 10, 2000. The complete text of the Order is available for inspection and copying during normal business hours in the FCC Reference Information Center, Courtyard Level, 445 12th Street, SW., Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Services (ITS, Inc.), CY–B400, 445 12th Street, SW., Washington, DC.

2. In FR Doc. 00–31946, on page 78989, in the first column, in the Summary, insert this sentence at the end of the paragraph: This document also denies the petition for reconsideration filed by the Cellular Telecommunications Industry Association on August 2, 1999 regarding the Report and Order adopted on June 11, 1999 in the matter of Assessment and Collection of Regulatory Fees for Fiscal Year 1999.

3. On page 78989, in the third column, insert the following before the List of Subjects in 47 CFR Part 1: 4. The petition for reconsideration filed by the Cellular Telecommunications Industry Association on August 2, 1999 regarding the Report and Order adopted on June 11, 1999 in the matter of Assessment and Collection of Regulatory Fees for Fiscal Year 1999 is denied.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–1251 Filed 1–19–01; 8:45 am]

BILLING CODE 6712–01–U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 13 and 17

RIN AG44

Response to Public Comments on Amending General Permitting Regulations Relating to Habitat Conservation Plans, Safe Harbor Agreements and Candidate Conservation Agreements With Assurances

AGENCIES: Fish and Wildlife Service, Department of the Interior.

ACTION: Final rule; affirmation.

SUMMARY: On June 17, 1999, the U.S. Fish and Wildlife Service (Service) published a final rule amending parts 13 and 17 of title 50 of the Code of Federal Regulations (CFR). This rule created regulations for the new Safe Harbor and Candidate Conservation Agreements with Assurances policies, and also dictated when the permitting requirements of Habitat Conservation Plan (HCP), Safe Harbor Agreement (SHA) and Candidate Conservation Agreement with Assurances (CCAA) permits, issued under the authority of section 10 of the Endangered Species Act of 1973, as amended (ESA), will vary from the Service's general part 13 permitting requirements. On February 11, 2000, we published a request for additional public comment on seven specific regulatory changes that altered the applicability of 50 CFR part 13 to permits for HCPs, SHAs and CCAAs. Based on our review of the comments, we have decided not to repropose any of the amendments to part 13 or part 17.

DATES: Final rule published on June 17, 1999 remains effective.

ADDRESSES: Chief, Division of Conservation and Classification, or Chief, Division of Consultation, Habitat Conservation Planning and Recovery, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, Virginia 22203 (Telephone 703/358–2171; Facsimile 703/358–1735).

FOR FURTHER INFORMATION CONTACT: Nancy Gloman, Chief, Division of Conservation and Classification, U.S. Fish and Wildlife Service (telephone 703/358–2171, facsimile 703/358–1735), or Renne Lohoefener, Chief, Division of Consultation, Habitat Conservation Planning and Recovery, U.S. Fish and Wildlife Service (telephone 703/358–2171, facsimile 703/358–1735).

SUPPLEMENTARY INFORMATION:

Background

The Service administers a variety of conservation laws that authorize the issuance of certain permits for otherwise prohibited activities. In 1974, we published 50 CFR part 13 to consolidate the administration of various permitting programs. Part 13 established a uniform framework of general administrative conditions and procedures that would govern the application, processing, and issuance of all Service permits. We intended that the general part 13 permitting provisions would apply to the various Federal wildlife and plant programs administered by the Service and that the specific permitting requirements applicable to each of these programs would supplement rather than replace the general part 13 requirements.

Subsequent to the 1974 publication of part 13, we added many wildlife regulatory programs to title 50 of the CFR. For example, we added part 18 in 1974 to implement the Marine Mammal Protection Act, modified and expanded part 17 in 1975 to implement the ESA, and added part 23 in 1977 to implement the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). These parts contained their own specific permitting requirements in addition to the general permitting provisions of part 13.

With respect to most of the programs under the ESA, the combination of part 13's general permitting provisions and part 17's specific permitting provisions have worked well since 1975. However, in three areas of emerging permitting policy under the ESA, the general approach of part 13 has turned out to be

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inappropriately constraining and narrow. These three areas involve the Habitat Conservation Planning, Safe Harbor, and Candidate Conservation Agreements with Assurances programs.

Congress amended section 10(a)(1) of the ESA in 1982 to authorize incidental take permits associated with HCPs. Many HCP permits involve long-term conservation commitments that run with the affected land for the life of the permit or longer. We negotiate such long-term permits recognizing that a succession of owners may purchase or resell the affected property during the term of the permit. The Service does not view this system as a problem, where the requirements of such permits run with the land and successive owners agree to the terms of the HCP. Property owners similarly do not view this arrangement as a problem so long as we can easily transfer incidental take authorization from one property owner to the next.

In other HCP situations, the HCP permittee may be a State or local agency that intends to sub-permit or blanket the incidental take authorization to hundreds if not thousands of its citizens. We do not view this activity as a problem so long as the original agency permittee abides by, and ensures compliance with, the terms of the HCP.

The above HCP scenarios have not been easily reconcilable with certain sections of part 13. For example, 50 CFR sections 13.24 and 13.25 generally impose significant restrictions on right of succession and transferability of permits. While these restrictions are well justified for most wildlife permitting situations, they have imposed inappropriate and unnecessary limitations for HCP permits where the term of the permit may be lengthy and the parties to the HCP have foreseen the desirability of simplifying sub-permitting and permit transference from one property owner to the next, or from a State or local agency to citizens under its jurisdiction.

Similar problems also could have arisen in attempting to apply the general part 13 permitting requirements to permits issued under part 17 to implement SHAs and CCAAs. A major incentive for property owner participation in the Safe Harbor or Candidate Conservation Agreements with Assurances programs is the long-term certainty the programs provide, including the certainty that the take authorization will run with the land if it changes hands and the new owner agrees to be bound by the terms of the original Agreement. Property owners could have viewed the limitations in several sections (*e.g.*, sections 13.24 and 13.25) as impediments to the development of these Agreements.

We promulgated revisions to parts 13 and 17 of the regulations that specify the instances in which the specific permit procedures for HCP, SHA, and CCAA permits will differ from the general part 13 permit procedures. We published a proposed rule on June 12, 1997, (62 FR 32178) to change the regulations at 50 CFR part 17 in order to implement the new SHA and CCAA policies and to revise the way in which the part 13 regulations would apply to the specific HCP, SHA, and CCAA regulations. On June 17, 1999, we issued a final rule (64 FR 32706) that created regulations for the SHA and CCAA policies, and changed the applicability of parts of the general part 13 permit regulations to the HCP, SHA, and CCAA programs. We also published a notice on September 30, 1999, (64 FR 52676) to correct certain errors that appeared in the final regulations. On February 11, 2000, we published a request for additional public comment (65 FR 6916) on the seven specific regulatory changes that altered the applicability of part 13 to the HCP, SHA, and CCAA programs and that were part of the June 17, 1999, final rule. This document responds to the additional public comments we received as a result of the February 11, 2000, notice.

Summary of Comments Received

We received approximately 450 comments from individuals, conservation groups, trade associations, Federal, State and local agencies, businesses, and private organizations in response to our February 11, 2000, request for additional comments on our June 17, 1999, final rule. Because most of these letters included similar comments (more than 350 were form letters received electronically), we grouped the comments according to issues. We further divided these issues into two sets. The issues in the first set deal with the June 17, 1999, final rule as a whole. The issues in the second set pertain to the individual sections of the June 17, 1999, final rule and are organized accordingly. In addition, we received a number of comments, including comments on the February 23, 1998, "No Surprises" final rule (63 FR 8859) itself and on the HCP program in general. These comments are beyond the scope of our request and we are not responding to those comments as part of this process. The following is a summary of the relevant comments and the Service's responses.

General Issues

Issue 1: We received over 300 comments on the public notice process associated with the June 17, 1999, final rule. Most commenters appear to believe that the February 11, 2000, request for additional comments was in fact the first opportunity for the public to comment on the proposal to conform the general permit regulations of part 13 to the HCP program. For example, many of the commenters stated that they viewed it to be "a flagrant subversion of the concept of public notice and comment for the government to make important final rule changes and subsequently, many months later, solicit public comment on them."

Response 1: Although not within the scope of the request for public comments, we believe these comments warrant a response because they indicate a high level of confusion concerning the nature of the February 11, 2000, notice seeking additional public comment. We believe that we have provided the public more than adequate notice to review comment on the June 17, 1999, final rule. The February 11, 2000 request for public comment was the second opportunity, not the first, that the public had to comment on changes to part 13 contained within our June 17, 1999, final rule. We first proposed changes to part 13 in order to conform part 13 with the HCP program in June of 1997.

In the summary section of our June 12, 1997, proposed rule (62 FR 32178), we stated, "in addition, the Service proposes technical amendments to its general regulations (50 CFR part 13) which are applicable to all of its various permitting programs. These proposed revisions would clarify the application of existing general permit conditions to the permitting procedures associated with Habitat Conservation Plans, Safe Harbor Agreements and Candidate Conservation Agreements issued under section 10 of the Act." The background section of the June 12, 1997, proposed rule went into great detail on the basis for proposing changes to part 13 stating, "in most instances, the combination of part 13's general permitting provisions and part 17's specific permitting provisions have worked well since 1975. However, in three areas of emerging permitting policy the 'one size fits all' approach of part 13 is inappropriately constraining and narrow." In the public comments solicited section of the June 12, 1997, proposed rule, we also specifically requested comment on "the proposed regulatory changes to 50 CFR parts 13 and 17." Our June 12, 1997, proposed rule would have dealt with the potential for conflict between parts 13 and 17 by providing in the scope section of the part 13 (50 CFR 13.03) that the specific provisions in the HCP, SHA and CCAA regulations, and associated permits and agreements, would control wherever they were in conflict with the general part 13 permitting regulations. In the June 17, 1999, final rule, we chose to make seven specific changes to parts 13 and 17 that removed the potential for conflict, rather than to change the scope of part 13. We view the final approach as well within the scope of the initial proposal and completely conforming to the public notice requirements of the Administrative Procedure Act.

Specific Issues

In our public notice of February 11, 2000, we sought additional public comment on our specific changes to the permitting regulations found in our June 17, 1999, final rule. The specific issues we received are arranged according to the relevant regulation with a summary of the June 17, 1999, final rule changes. Our responses to the issues raised are as follows:

Section 13.21(b)(4)—Issuance of Permits

We revised the HCP permit issuance criteria in sections 17.22(b)(2) and 17.32(b)(2) to except HCP permits from section 13.21(b)(4) and also included a similar provision in the SHA and CCAA permit regulations (sections 17.22(c)(2) and (d)(2) and 17.32(c)(2) and (d)(2)). Section 13.21(b)(4) generally prevents the Service from issuing a permit for an activity that "potentially threatens a wildlife or plant population." However, the specific issuance criteria for HCP, SHA, and CCAA permits all require a finding that the permit will "* * * not appreciably reduce the likelihood of survival and recovery of the species in the wild." See, for example, 50 CFR 17.22(b)(2)(i)(D).

Issue 2: We received four comments specifically on the applicability of section 13.21(b)(4). One commenter opposed the revision, and three commenters supported it. The comment in opposition to the change believed that it would shift the standard for permit issuance from "survival and recovery" to "continued existence."

Response 2: The old provision under section 13.21(b)(4) was unnecessary and potentially in conflict with the issuance criteria for permits under the HCP, SHA, and CCAA programs. The decision to rely on the permit issuance criteria in section 10 of the ESA instead of on part 13 has not changed our standard for HCP permits. The provision in section 13.21(b)(4) predates the creation of the HCP program by Congress in 1982. Although the standard in section 13.21(b)(4), with its focus on "potential threats to a wildlife population," works well for research permits, it is not well suited to the HCP program which does allow for incidental take in a population if it is minimized and mitigated to the maximum extent practicable. This standard is also arguably inconsistent with the species-focused statutory issuance criteria created by the 1982 amendments to the ESA. Our June 17, 1999, final rule changes to parts 17.22(b)(2), (c)(2), (d)(2) and 17.32(b)(2), (c)(2), and (d)(2) retain the criteria for the issuance of permits associated with an HCP, SHA, or CCAA as, among others, "* * * not appreciably reduce the likelihood of survival and recovery. * * *" Therefore, this standard for these permits did not shift.

Section 13.23(b)—Amendment of Permits

We revised section 13.23(b), which generally reserves to the Service the right to amend permits "for just cause at any time." The revision clarified that the Service's reserved right to amend HCP, SHA, and CCAA permits must be exercised consistently with the assurances provided to permit holders through the permits and regulations.

Issue 3: We received four comments on the change to section 13.23(b). All four commenters supported the change, noting that the old provision was arguably inconsistent with the "No Surprises" final rule.

Response 3: We agree that the revision removes a potential conflict between the general provisions of part 13 and the more specific permit regulations in part 17.

Sections 13.24 and 13.25—Right of Succession by Certain Persons and Transfer of Permits and Scope of Permit Authorization

We revised sections 13.24 and 13.25 in order to expand and streamline the process for permit succession or transfer. We also revised section 13.25(d) to describe the circumstances under which a person is considered to be acting under the direct control of a state or local governmental entity and therefore is entitled to act under the authority of an incidental take permit issued to the state or local governmental entity.

Issue 4: We received six comments on the revisions to sections 13.24 and 13.25. Five of the comments voiced support for the changes, noting that ease of transferability will make the permit more worthwhile to landowners. One comment, on behalf of a number of local governmental entities, raised two issues concerning the revisions to section 13.25(d). This commenter felt that the term "under the jurisdiction" was vague and suggested we use non-limiting examples to indicate that any person whose activities are subject to the customary planning, permitting, and regulatory activities of a local government would be considered a person "under the jurisdiction" of the governmental entity for purposes of section 13.25(d). This commenter also felt that the use of the term "permit" was problematic because local governments sometimes operate in a permitting capacity without actually issuing a permit (*e.g.*, resolutions, "conditions" or "requirements").

Response 4: The old provisions at 13.24 and 13.25 were justified for most wildlife permitting situations, but not for HCPs, SHAs, and CCAAs. These agreements often involve substantial long-term conservation commitments, and we negotiate such agreements recognizing that there may be succession or transfer in land ownership during the term of the permit.

We agree that any person whose activities are subject to the customary planning, permitting, and regulatory activities of a state or local government would be considered a person "under the jurisdiction" of the governmental entity for purposes of section 13.25(d). We also believe that the second qualifying statement that "the permit provides that such persons may carry out the authorized activity" sufficiently narrows the scope of the transfer of take authorization.

We do not believe that the "permit" concept should be broadened to include circumstances in which an individual does not execute some type of document with the Service or a local governmental entity sponsoring an HCP. We structured section 13.25(d) to accommodate situations in which a local government is not regulating an activity through a local permit, but still wants to sponsor a regional HCP permit using a subpermitting process. In those situations the local government must still use some type of written instrument to include individuals within the permit's coverage, in accordance with the implementing agreement for the HCP. We, therefore, do not view the current language in section 13.25(d) as posing the problem raised by the comment.

Issue 5: Another commenter believed that the emphasis in section 13.25(d) on local governments meant that private conservation banks would not be allowed. The commenter recommended that this section be changed to allow

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private entities to pass on the take authorization of a permit to individuals who purchase conservation bank credits.

Response 5: We designed section 13.25(d) to provide a process for local governments to assist with HCP implementation on a regional basis through the exercise of local land use authority. We do not view section 13.25(d) as prohibiting private conservation banks in any way, but we also do not view it as the appropriate regulatory provision to convey take authorization to purchasers of conservation bank credits. The current regulatory framework provides flexibility on how permits should be structured around conservation banks and we believe this issue can be addressed through the development of policy on conservation banking instead of through regulatory revisions.

Issue 6: One commenter objected that the new requirements for permit transfer required more for SHAs than the Safe Harbor policy did. The commenter specifically pointed to the requirement for a "joint submission" by the current and prospective landowner instead of the simpler requirement for a new landowner on their own to simply express an interest in continuing with the SHA.

Response 6: We agree with the commenter that it would be an odd result if it were easier to apply for a SHA than to transfer an existing agreement during the purchase of property. We do not believe that the changes to section 13.25 make it more difficult to transfer an existing permit than to apply for a new one. We also do not believe that the requirement set forth in section 13.25 for a "joint submittal" on the part of the old and new landowners is particularly onerous. The original landowner needs to provide some sort of communication to the Service in order to inform us of that landowner's desire to terminate the agreement. The new landowner would similarly be providing the Service with an indication of whether they seek to continue the SHA of their predecessor or not. We do not believe it will be difficult for the two entities to provide a joint submittal when the intent is to carry on the SHA. We will continue to track this issue as we gain experience with the Safe Harbor program and will consider modifications to the program in the future should the requirement for a "joint submittal" prove troublesome.

Section 13.26—Discontinuance of Permit Activity

In the June 17, 1999, final rule, we added a new subparagraph (7) to sections 17.22(b) and 17.32(b) to make clear that HCP permittees remain responsible for mitigation required under the terms of their permits even after surrendering their permits. The general provision on permit surrender at section 13.26 did not address this issue. The new provisions made it clear that any mitigation owed for take occurring prior to permit surrender would still be required after the permit was surrendered.

Issue 7: We received three comments on the addition of subparagraph (7) to sections 17.22(b) and 17.32(b). Two of the commenters supported the new provision addressing post termination mitigation, finding that it was a reasonable way to address the issue. One commenter did not favor the provision and suggested it was unfair to the permittee to be asked for mitigation after the permit has been surrendered or revoked.

Response 7: We have limited the requirement for post termination mitigation to those situations in which the take has occurred prior to permit surrender, but the mitigation that was agreed to has not been completed. In order to obtain a permit, the HCP must include measures that minimize and mitigate the anticipated impacts and ensure that adequate funding for the plan will be provided. In addition, the HCP must not appreciably reduce the likelihood of survival and recovery of the species to be permitted. With the issuance of the permit the Service makes a finding that the HCP has met the issuance criteria based on the assumption that the implementation of the operating conservation program will offset the proposed impacts. Therefore, we believe it is fair to require the permittee to complete mitigation for take that has already occurred.

Section 13.28a—Permit Revocation

We modified the permit revocation criteria in section 13.28(a) to provide that the section 13.28(a)(5) criterion shall not apply to HCP, SHA, and CCAA permits. We determined that it would be more appropriate to refer instead to the statutory issuance criterion in 16 U.S.C. 1539(a)(2)(B)(iv) that prohibits the issuance of a permit unless the Service finds the permit will not appreciably reduce the likelihood of survival and recovery of the species. We, therefore, included in the HCP regulations a provision (sections 17.22(b)(8) and 17.32(b)(8)) that allows a permit to be revoked if continuing the permitted activity would be inconsistent with 16 U.S.C. 1539(a)(2)(B)(iv) and the inconsistency had not been remedied in a timely fashion. We also included similar provisions for SHA and CCAA permits (sections 17.22(c)(7) and (d)(7), and sections 17.32(c)(7) and (d)(7)).

Issue 8: We received numerous comments on the provisions addressing permit revocation. The comments ranged widely, but generally fell into two categories, one of which is that the agency did not go far enough with the revocation provision and the other is that the agency went too far with the revocation provision. With respect to comments objecting because the revocation provision did not go far enough, many of the commenters stated that they did not see any reason why the old provision in section 13.28(a) should be replaced with a standard they viewed as less protective. These commenters also stated that the revocation provision should have mandatory language like the word "shall" to indicate that revocation is not discretionary. Many commenters questioned why the Service should have to step in at public expense to remedy jeopardy situations before a permit can be revoked. Some questioned what the standard "in a timely fashion" means. One commenter suggested that the revocation provision also contain a reference to adverse modification of critical habitat, while another commenter recommended that the word "jeopardy" be used instead of "appreciable reduction in likelihood of survival and recovery" because the commenter viewed "jeopardy" to be a higher standard.

With respect to comments expressing concern that the Service has gone too far, we received a number of comments stating that the revocation provision undermined the "No Surprises" rule. These commenters strongly opposed any further expansion of the revocation provision and suggested further expansion would be contrary to congressional intent. A number of commenters requested that the Service reaffirm the principles of "No Surprises" and noted that revocation should be "an action of last resort." Another commenter requested that we limit revocation to instances where the permittee is not in compliance with the permit or, at a minimum, add to the revocation provision a statement to indicate that the burden is on the agency to establish that the conditions for revocation exist. Another commenter stated that the revocation provision is not applicable to the Safe Harbor context and that Safe Harbor revocation should be limited to instances where the permittee is not in compliance or has refused efforts to salvage animals or to sell land at fair market value.

Response 8: We believe that it is inappropriate to have a standard for revocation of a permit that is different from the standard for issuing the permit in the first place. When Congress amended the ESA in 1982 to create the HCP permit program, it clearly indicated that the relevant focus would be at the species level. Section 13.28(a)(5) predates the 1982 amendments and focuses only on the wildlife population in the permitted area. We therefore believe that it is appropriate to replace section 13.28(a)(5) with a provision that more accurately reflects the congressional intent behind the 1982 amendments. The new revocation provision established in sections 17.22 and 17.32 is written in a manner that indicates when revocation is not permissible instead of when it is. As a result, the suggestion that the word "may" be changed to "shall" is not practical. In addition, decisions involving permit revocation are fact-intensive and will require the exercise of discretion on the part of the agency. It is therefore questionable whether permit revocation standards can be described as being mandatory versus discretionary.

In the February 23, 1998, "No Surprises" final rule, we provided the rationale for committing the agency to step in and attempt to remedy jeopardy situations in cases where the permittee is in full compliance with the permit and has a properly implemented conservation plan in place. In exchange for assurances, the HCP permittee has agreed to undertake extensive planning and to include contingencies to address changed circumstances. This requirement does not exist in other Federal permitting programs. We believe it is fair, therefore, to commit the agency to step in and address unforeseen circumstances in the very rare circumstance that this will be required.

Because each HCP is so case-specific it is not possible to indicate what remedying the jeopardy situation in "a timely fashion" means in all instances. Whether a response can be deemed timely or not will depend on highly fact-specific issues, including the species involved and the source of the problem.

We do not see the need to add a reference to adverse modification of critical habitat or to use the word "jeopardy" in the revocation provisions. Instead we view it to be preferable to simply reference the statutory permit issuance criterion. Although one commenter viewed the terms "jeopardy" and "appreciable reduction of survival and recovery" to mean two different things, we view the terms to be synonymous, and in fact the agency's definition of "jeopardy" is to "reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild."

As we stated in our notice of February 11, 2000, "the Service is firmly committed, as required by the "No Surprises" final rule, to utilizing its resources to address any such unforeseen circumstances," and we view the revocation provision as available "as a last resort in the narrow and unlikely situation in which an unforeseen circumstance results in likely jeopardy to a species covered by the permit and the Service as not been successful in remedying the situation through other means." (65 FR 6916, 6918). We further view the likelihood of the revocation provision applying in the Safe Harbor context to be extremely remote and likely to occur only in the limited circumstances described by the commenter. Because the revocation provision is based on a biological situation and therefore applies to more situations than those in which the permittee is in non-compliance, we decline to narrow the provision as requested by one commenter. We believe that the current revocation provision is consistent with congressional intent and strikes the right balance between the need for permittee certainty and the need to avoid jeopardy to the species covered by the permit. We also believe that existing regulatory provisions, both in part 13 and the "No Surprises" final rule, adequately detail the agency's burden in permit revocation contexts and that there is, therefore, no need to add the suggested process changes to the revocation provision.

Section 13.50—Acceptance of Liability

We revised section 13.50 to allow more flexibility where the permittee is a State or local governmental entity and has thus taken a leadership role and is assisting in implementation of the permit program. In this limited situation, the governmental permittee would not be liable for activity conducted by sub-permittees under the authority of the permit issued to the governmental entity.

Issue 9: We received one comment in support of the change to section 13.50. The commenter noted that the change to limit the liability of State and local governments that hold master permits would encourage greater regional HCP planning.

Response 9: We agree and believe that the revision to section 13.50 is warranted. In large regional plans, the local jurisdiction largely administers the implementation of the HCP. In doing so, the local jurisdiction extends the incidental take authority of their permit to other non-Federal entities undertaking activities in accordance with the HCP. We believe it is those entities that should be responsible for their actions involving implementation of the HCP and incidental take permit, rather than the governmental entity that holds the master permit.

Sections 17.22(c)(5), (d)(5) and 17.32(c)(5), (d)(5)—Assurances Provided to the Permittee in the Case of Changed or Unforeseen Circumstances

We extended the "No Surprises" assurances that apply to HCP permits to SHA and CCAA permits. We did this by adding a new subparagraph (5) to sections 17.22(c) and (d) and 17.32(c) and (d).

Issue 10: We received two comments supporting the addition of assurances to the SHA and CCAA programs.

Response 10: Many landowners would be willing to manage their lands voluntarily to benefit fish, wildlife, and plants, especially those in decline, provided that they are not subjected to additional regulatory restrictions as a result of their conservation efforts. Therefore, we agree that when a landowner voluntarily implements the provisions of a SHA or CCAA, in accordance with the respective standards of those programs, the landowner should receive assurances that we will not require any additional conservation measures without their consent.

Summary

After careful review of all of the comments received, we have determined that none of the comments revealed problems with the current regulatory framework that would warrant a reproposal of the permit regulation changes. Based on our review of the comments, we believe that the changes to the permit regulations effectively achieve the goal of conforming part 13 to the more recently created permit programs for HCPs, SHAs, and CCAAs and that they strike the proper balance. Accordingly, we have decided not to repropose any of the amendments to part 13 or part 17.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: January 10, 2001.

Jamie R. Clark,

Director, Fish and Wildlife Service.

[FR Doc. 01–1483 Filed 1–19–01; 8:45 am]

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Proposed Rules

Federal Register
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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 319

[Docket No. 93–131–1]

Importation of Mangoes From the Philippines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations governing the importation of fruits and vegetables to allow the importation of mangoes from Guimaras Island in the Republic of the Philippines, subject to inspection and the completion of a prescribed vapor heat treatment. We believe that this action is warranted because there appears to be no significant pest risk associated with the importation of mangoes from Guimaras Island in the Philippines under these circumstances. This action would relieve restrictions on the importation of mangoes from the Philippines without presenting a significant risk of introducing plant pests into the United States.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by March 23, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to:

Docket No. 93–131–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 93–131–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Paul Gadh, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–6799.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR 319.56 through 319.56–8 (referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

Currently, the regulations do not allow the importation of mangoes from the Philippines. However, the Republic of the Philippines Department of Agriculture (RPDA) has requested that the Animal and Plant Health Inspection Service (APHIS) allow mangoes from the Philippine island of Guimaras to be imported into the United States.

Several plant pests, including the mango seed weevil (*Sternochetus mangiferae*) and fruit flies of the genus *Bactrocera* are known to attack mangoes in the Philippines. If introduced into the United States, these pests would present a serious threat to domestic fruit crops. We are proposing to allow mangoes to be imported from Guimaras Island in the Philippines under conditions designed to mitigate the risk of plant pest introduction. The provisions for the importation of mangoes from the Philippines would be set out in a new section, § 319.56–2ii, which is explained below.

Limitation of Origin

As stated in paragraph (a) of the proposed regulations, we would allow only mangoes grown on the island of Guimaras, which is free of the mango seed weevil, to be imported into the United States. The regulations in § 319.56–2(e) contain provisions for the importation of a fruit or vegetable from a definite area or district of the country of origin that has been found free from certain injurious insects that attack the fruit or vegetable, provided that all other injurious insects that attack the fruit or vegetable in the area or district of the country of origin have been eliminated from the fruit or vegetable by treatment or any other procedures that may be prescribed by the Administrator. In the case of the Philippines, ongoing surveys conducted by the RPDA's Bureau of Plant Industry have established that the island of Guimaras is free from infestations of mango seed weevil. Additionally, the Government of the Philippines has adopted and is enforcing requirements that establish Guimaras as a quarantined area for mangoes in order to prevent the mango seed weevil and other injurious insects from being introduced onto the island from other areas of the Philippines or the world. APHIS has determined that those requirements are at least equivalent to those requirements imposed under the regulations to prevent the introduction into the United States and interstate spread of injurious insects. Finally, as required by § 319.56–2(f)(3), the RPDA has submitted to APHIS written detailed procedures for the conduct of surveys and the enforcement of requirements to prevent the introduction of injurious insects onto Guimaras. (Additional information regarding the establishment and maintenance of the mango seed weevil-free status of Guimaras Island may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.)

Treatment and APHIS Inspection

Because the island of Guimaras has not been found to be free of fruit flies of the genus *Bactrocera*, paragraph (b) of the proposed regulations would require that the mangoes be treated in accordance with the Plant Protection and Quarantine (PPQ) Treatment Manual, which is incorporated by reference into the Code of Federal Regulations at 7 CFR 300.1. Specifically, the mangoes would have to be subjected to vapor heat treatment to prevent the introduction of *Bactrocera* spp. fruit flies into the United States. The vapor heat treatment, which would have to be conducted in the Philippines under the supervision of an APHIS inspector, would be conducted as follows:

- Size the fruit before treatment. Place temperature probes in the centers of several fruits.
- Raise the fruit pulp temperature to 46 °C (115 °F) until the fruit reaches that temperature. Hold temperature at 46 °C (115 °F) for 10 minutes.

The vapor heat treatment described above has been determined by the U.S. Department of Agriculture's (USDA's) Agricultural Research Service to be adequate to provide quarantine security against the two fruit fly species of concern, *Bactrocera occipitalis* and *B. philippensis*. As part of this proposed rule, we would update the PPQ Treatment Manual to prescribe the vapor heat treatment described above for mangoes from the Philippines. Mangoes treated in this manner would present an insignificant risk of introducing fruit flies of the genus *Bactrocera* into the United States. Further, pest risk analyses [1] conducted by APHIS have determined that any other injurious insects that might be carried by mangoes from Guimaras would be readily detectable by an inspector. Therefore, paragraph (c) of the proposed regulations would state that the mangoes are also subject to inspection and disinfection at the port of first arrival in the United States, as provided in § 319.56–6 of the regulations.

Box Labeling

In addition to the pest-free area and treatment requirements discussed above, paragraph (d) of the proposed regulations would also require that each box of mangoes imported into the United States from the Philippines be marked in accordance with § 319.56–2(g) of the regulations. Specifically, each box of mangoes would have to be clearly labeled with the following information:

- The name of the orchard or grove of origin, or the name of the grower;
- A statement that the mangoes were produced on the island of Guimaras, Republic of the Philippines; and
- The type and amount of fruit it contains.

Paragraph (g) of § 319.56–2 requires such box labeling for each box of fruit or vegetables that, like the mangoes that are the subject of this proposed rule, are imported into the United States in accordance with § 319.56–2(e)(3) or (e)(4).

[1] Information regarding these analyses may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Phytosanitary Certificate

Paragraph (e) of the proposed regulations would require each shipment of mangoes to be accompanied by a phytosanitary certificate issued by the RPDA that contains additional declarations stating that the mangoes were grown on the island of Guimaras and have been treated for fruit flies of the genus *Bactrocera* in accordance with the PPQ Treatment Manual. The phytosanitary certificate would serve as RPDA's official confirmation that the origin and treatment requirements of the regulations had been met.

Trust Fund Agreement

We are proposing that APHIS' participation in the treatment and inspection activities in the Philippines that would be required for the importation of mangoes be contingent upon the RPDA entering into a trust fund agreement with APHIS. Under paragraph (f) of the proposed regulations, the trust fund agreement would require the RPDA to pay, in advance of each shipping season, all costs that APHIS estimates that it will incur in providing the necessary services in the Philippines during that shipping season. Such costs would include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the inspectors in performing the services.

The trust fund agreement would require the RPDA to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement would further require that the RPDA deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any additional mangoes would be treated or inspected. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the RPDA or held on account until needed, at the RPDA's option.

Department Not Responsible for Damage

Paragraph (g) of the proposed regulations would explain that, although the treatments for mangoes prescribed in the PPQ Treatment Manual are judged from experimental tests to be safe, the USDA is not responsible for any damage that might be sustained by the mangoes as a result of the prescribed treatment.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would amend the regulations governing the importation of fruits and vegetables by allowing, under certain conditions, the importation of mangoes from the Philippines into the United States.

Analysis

Nearly all of the mangoes consumed in the United States are imported, and the quantity of imported mangoes has grown steadily and rapidly in recent years. Over the 5-year period 1995 through 1999, mango imports increased at an annual rate of about 9 percent (table 1). During this same period, the average value of imported mangoes fell from about $0.85 per kg to about $0.65 per kg. These data suggest a high level of market competition among those countries supplying mangoes to the U.S. market.

TABLE 1.—QUANTITY AND VALUE OF U.S. MANGO IMPORTS, 1995–1999

Year	Metric tons	Value (in millions)
1995	141,673	$121.01
1996	171,349	103.81
1997	186,530	119.07
1998	197,587	132.43
1999	218,941	142.99

Source: USDA, National Agricultural Statistics Service.

Mexico is the source of most U.S. mango imports, supplying between 75 percent and 85 percent in each of the 5 years between 1995 and 1999. Other major sources are Brazil, Ecuador, and Peru.

U.S. production of mangoes has primarily been in southern Florida, with a smaller quantity grown in Hawaii and a negligible amount produced in California. According to the 1997 Census of Agriculture, there were 218 mango farms in Florida, 171 in Hawaii, and 2 in California. The total domestic harvest that year was about 2,829 metric tons, of which about 97 percent was produced in Florida and about 3 percent produced in Hawaii. There are no U.S. mango exports.

Florida's mango producers suffered a severe setback in 1992, when Hurricane

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Andrew destroyed many of the trees. According to the Florida Agricultural Statistics Service, bearing acres fell from 2,500 in 1992 to 1,400 in 1993. Yields have also declined sharply, from 160 bushels per acre in 1992 to 71 bushels per acre in 1997, due in part to bloom and disease problems at fruit set. Consequently, the value of Florida's mango production in 1997, $1.45 million, was only one-third of the value of production in 1992, $4.28 million.

The Florida Agricultural Statistics Service has not reported on mango production since 1997, a reflection of the industry's decline. Little of the State's crop now enters the national market to compete with fresh fruit imports. Most of the production is either consumed fresh within Florida or is processed into chutney or other products.

The quantity of mangoes expected to be imported from Guimaras Island is not known. In 1993, about 3,000 metric tons were reportedly produced there. If all of the island's 1993 production were exported to the United States, it would represent an amount similar to what was harvested domestically in 1997 (the most recent year for which U.S. production data are available). However, given the large quantity of mangoes imported from Mexico and other countries, 3,000 metric tons represent only about 1.6 percent of what the U.S. supply was in 1997, and an even smaller proportion of today's supply; between 1997 and 1999, U.S. mango imports increased by more than 17 percent.

The Regulatory Flexibility Act requires that agencies consider the economic effects of their rules on small entities. Whether affected entities may be considered small depends on their annual gross receipts. Annual receipts of $500,000 or less is the small entity criterion set by the Small Business Administration for establishments primarily engaged in "other noncitrus fruit farming" (NAICS code 111339). Most, if not all, mango producers in the United States are small entities.

Conclusion

U.S. mango imports dwarf domestic production. Mango imports during the late 1990's expanded annually by amounts several times greater than the quantity likely to be imported from Guimaras Island. It is reasonable to assume that the growth in U.S. mango imports will continue, with Guimaras Island but one more foreign source. We do not expect that the economic effects of this proposed rule on U.S. entities, large or small, would be significant.

The proposed importation of mangoes from Guimaras Island is not expected to significantly affect U.S. mango producers. The amount imported will be very small compared to current import levels. Moreover, much of Florida's harvest (the source of 97 percent of domestic production in 1997) is consumed within that State or is processed into chutney and other products; these markets are unlikely to be affected by the availability of an additional source of imported fresh mangoes.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule would allow mangoes to be imported into the United States from the Philippines. If this proposed rule is adopted, State and local laws and regulations regarding the importation of fruits and vegetables under this rule would be preempted while the mangoes are in foreign commerce. Mangoes are generally imported for immediate distribution and sale to the consuming public, and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 93–131–1. Please send a copy of your comments to: (1) Docket No.93–131–1, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would amend the regulations governing the importation of fruits and vegetables to provide for the importation into the United States of mangoes grown on Guimaras Island in the Philippines under conditions designed to prevent the introduction into the United States of plant pests. The proposed program for the importation of mangoes from Guimaras Island would require the use of box marking to indicate the origin of the fruit, phytosanitary certificates to confirm that the fruit has been grown and treated in accordance with the conditions set forth in the regulations, and a trust fund agreement between the RPDA and APHIS to cover the Agency's participation in the treatment and inspection activities in the Philippines that would be required for the importation of mangoes.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

Respondents: Philippine plant protection officials; mango producers and packinghouses on Guimaras Island, Philippines.

Estimated annual number of respondents: 20.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 40.

Estimated total annual burden on respondents: 40 hours.

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

7 CFR Part 300

Incorporation by reference, Plant pests and diseases, Quarantine.

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend title 7, chapter III, of the Code of Federal Regulations as follows:

PART 300—INCORPORATION BY REFERENCE

1. The authority citation for part 300 would continue to read as follows:

Authority: Title IV, Pub. L. 106–224, 114 Stat. 438, 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

2. In § 300.1, paragraph (a), the introductory text would be revised to read as follows:

§ 300.1 Materials incorporated by reference.

(a) *Plant Protection and Quarantine Treatment Manual.* The Plant Protection and Quarantine Treatment Manual, which was reprinted November 30, 1992, and includes all revisions through [*date*], has been approved for incorporation by reference in 7 CFR chapter III by the Director of the Office of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

* * * * *

PART 319—FOREIGN QUARANTINE NOTICES

3. The authority citation for part 319 would continue to read as follows:

Authority: Title IV, Pub. L. 106–224, 114 Stat. 438, 7 U.S.C. 7701–7772; 7 U.S.C. 450; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

4. A new § 319.56–2ii would be added to read as follows:

§ 319.56–2ii Administrative instructions: conditions governing the entry of mangoes from the Philippines.

Mangoes (fruit) *(Mangifera indica)* may be imported into the United States from the Philippines only under the following conditions:

(a) *Limitation of origin.* The mangoes must have been grown on the island of Guimaras, which the Administrator has determined meets the criteria set forth in § 319.56–2(e)(4) and § 319.56–2(f) with regard to the mango seed weevil *(Sternochetus mangiferae).*

(b) *Treatment.* The mangoes must be subjected to vapor heat treatment for fruit flies of the genus *Bactrocera* in accordance with the Plant Protection and Quarantine Treatment Manual, which is incorporated by reference at § 300.1 of this chapter. The treatment must be conducted in the Philippines under the supervision of an inspector.

(c) *APHIS inspection.* Mangoes from the Philippines are subject to inspection under the direction of an inspector, either in the Philippines or at the port of first arrival in the United States. Mangoes inspected in the Philippines are subject to reinspection at the port of first arrival in the United States as provided in § 319.56–6.

(d) *Labeling.* Each box of mangoes must be clearly labeled in accordance with § 319.56–2(g).

(e) *Phytosanitary certificate.* Each shipment of mangoes must be accompanied by a phytosanitary certificate issued by the Republic of the Philippines Department of Agriculture that contains additional declarations stating that the mangoes were grown on the island of Guimaras and have been treated for fruit flies of the genus *Bactrocera* in accordance with the Plant Protection and Quarantine Treatment Manual.

(f) *Trust Fund Agreement.* Mangoes that are treated or inspected in the Philippines may be imported into the United States only if the Republic of the Philippines Department of Agriculture (RPDA) has entered into a trust fund agreement with APHIS. That agreement requires the RPDA to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing inspection services in the Philippines during that shipping season. Those costs include administrative expenses and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by APHIS in performing these services. The agreement requires the RPDA to deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the RPDA to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before any more mangoes will be treated or inspected in the Philippines. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the RPDA or held on account until needed, at the RPDA's option.

(g) *Department not responsible for damage.* The treatments for mangoes prescribed in the Plant Protection and Quarantine Treatment Manual are judged from experimental tests to be safe. However, the Department assumes no responsibility for any damage sustained through or in the course of such treatment.

Done in Washington, DC, this 16th day of January 2001.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–1655 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 1

[Docket No. 99–087–2]

Licensing and Inspection Requirements for Dealers of Dogs Intended for Hunting, Breeding, or Security Purposes

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of extension of comment period.

SUMMARY: We are extending the comment period for our proposed rule to amend the Animal Welfare regulations to reflect our policy of regulating wholesale dealers of dogs intended for hunting, breeding, or security purposes. This action will allow interested persons additional time to prepare and submit comments.

DATES: We invite you to comment on Docket No. 99–087–1. We will consider all comments that we receive by April 3, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 99–087–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 99–087–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except

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holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry DePoyster, Senior Veterinary Medical Officer, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 734–7586.

SUPPLEMENTARY INFORMATION:

Background

On December 4, 2000, we published in the **Federal Register** (65 FR 75635–75637, Docket No. 99–087–1) a proposal to amend the Animal Welfare regulations to require that only wholesale dealers of hunting, breeding, and security dogs be licensed and inspected. This change would be reflected in the definition for "dealer" in 9 CFR 1.1. This action would bring our regulations into accord with our policy to regulate wholesale dealers of hunting, breeding, and security dogs.

Comments on the proposed rule were required to be received on or before February 2, 2000. We are extending the comment period on Docket No. 99–087–1 for an additional 60 days. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 16th day of January 2001.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–1654 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. CE164; Notice No. 23–01–01–SC]

Special Conditions: Ayres Corporation, Model LM 200, "Loadmaster" Cargo and Baggage Compartment Fire Protection

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special conditions.

SUMMARY: This action proposes special conditions for the Ayres Corporation, Model LM 200 "Loadmaster" airplane. This airplane will have a novel or unusual design feature(s) associated with all-cargo and combination cargo/passenger (COMBI) interior configurations. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: Comments must be received on or before February 21, 2001.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Regional Counsel, ACE–7, Attention: Rules Docket, Docket No. CE164, 901 Locust, Room 506, Kansas City, Missouri 64106, or delivered in duplicate to the Regional Counsel at the above address. Comments must be marked: CE164. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Les Taylor, Federal Aviation Administration, Aircraft Certification Service, Small Airplane Directorate, ACE–111, 901 Locust, Room 301, Kansas City, Missouri, 816–329–4134, fax 816–329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. The proposals described in this notice may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to CE164." The postcard will be date stamped and returned to the commenter.

Background

On April 16, 1996, Ayres Corporation, P.O. Box 3090, Albany, Georgia 31708–3090, applied for a commuter category, all-cargo type certificate for their new Model LM 200. In May 1997, they reapplied for passenger and COMBI interior configurations. The Model LM 200 airplane is a nine-passenger, twin-engine airplane. The LM 200 will have all-cargo and COMBI versions.

The Model LM 200 all-cargo and COMBI airplanes are considered a novel design and were not considered when those airworthiness standards were promulgated. The FAA has determined that the existing regulations do not provide adequate or appropriate safety standards for cargo and baggage compartment fire protection in these versions of the LM 200. In order to provide a level of safety that is equivalent to that afforded to occupants of the passenger version, additional airworthiness standards, in the form of additional special conditions, are necessary.

Type Certification Basis

Under the provisions of 14 CFR § 21.17, Ayres Corporation must show that the Model LM 200 meets the applicable provisions of 14 CFR part 23 as amended by Amendments 23–1 through 23–53, effective April 30, 1998, and any exemptions, equivalent level of safety findings and special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 23) do not contain adequate or appropriate safety standards for the Ayres Corporation Model LM 200 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model LM 200 must comply with the part 23 fuel vent and exhaust emission requirements of 14 CFR part 34, the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy pursuant to Section 611 of Public Law 92–574, the "Noise Control Act of 1972."

Special conditions, as appropriate, as defined in § 11.19, are issued in accordance with § 11.38, and become part of the type certification basis in accordance with § 21.17(a)(2).

Special conditions are initially applicable to the model for which they

are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The Model LM 200 will incorporate the following novel or unusual design features: an all-cargo and a COMBI interior configuration.

Applicability

As discussed above, these special conditions are applicable to the Ayres Corporation, Model LM 200. Should Ayres Corporation apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

It is FAA's understanding that Ayres Corporation accepts the special conditions in the FAA position as noted in Ayres letter dated February 9, 1999. Compliance will be shown through design, test and analyses by Ayres Corporation.

This action affects only certain novel or unusual design features on one model of airplane. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113 and 44701; 14 CFR 21.16 and 21.17; and 14 CFR 11.28 and 11.49.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for the Ayres Corporation Model LM 200 airplane applicable to the all-cargo and COMBI interior configurations.

In addition to the Part 23 regulations required by the certification basis of the airplane, the following are also required for cargo or baggage compartments:

(a) Flight tests must demonstrate means to exclude hazardous quantities of smoke, flames, or extinguishing agent from any compartment occupied by crew or passengers.

(b) Cargo compartments shall have either fire or smoke detection provisions, or both, unless the compartment location is such that a fire can be easily detected by the pilots while seated at their duty stations. The cargo and baggage fire protection must be in accordance with § 23.855 as well as the following:

1. The detection system must provide a visual indication to the flight crew within one minute after the start of a fire.
2. The system must be capable of detecting a fire at a temperature significantly below that at which the structural integrity of the airplane is substantially decreased.
3. There must be means to allow the crew to check the functioning of each fire detector circuit while in flight.
4. The detection system effectiveness must be shown for all approved operating configurations and conditions.

(c) The flight crew must have means to shut off the ventilating airflow to or within the compartment, from the pilot's station, on an all-cargo configuration.

(d) Passenger and COMBI configurations where the cargo or baggage compartment are not accessible to the flightcrew, must have an approved, built-in fire extinguishing system. The built-in fire extinguishing system shall be controllable from the pilot's station. There must be means to control ventilation and drafts within an inaccessible cargo or baggage compartment so the extinguishing agent can control any fire that may start in the compartment. The built-in fire extinguishing system must be installed so that no extinguishing agent likely to enter the personnel compartments will be hazardous to the occupants. The discharge of the fire extinguishing system must not cause structural damage. The capacity of the extinguishing system must be adequate for any fire likely to occur in the compartment where used. Consideration must be given to the volume of the compartment and the ventilation rate.

(e) In addition to the fire extinguishers required by § 23.851, a hand fire extinguisher must be readily accessible for use in each cargo and baggage compartment that is accessible to crewmembers in flight. Hazardous quantities of smoke, flames or extinguishing agent must not enter any compartment occupied by crew or passengers, when the access to that compartment is used.

(f) Protective breathing equipment must be installed for crewmembers in each crewmember compartment. Protective breathing equipment must:

1. Be designed to protect the flightcrew from smoke, carbon dioxide and other harmful gases at the pilot's station and while combating fires in cargo or baggage compartments.
2. Have masks that cover the eyes, nose and mouth; or masks that cover the nose and mouth plus accessory equipment to cover the eyes.
3. Allow the flightcrew to use the radio equipment and to communicate with each other while at their assigned stations.
4. Not cause any appreciable adverse effect on vision and must allow corrective glasses to be worn.
5. Supply protective oxygen of 15 minutes duration per crewmember at a pressure altitude of 8,000 feet with a respiratory minute volume of 30 liters per minute BTPD (BTPD refers to body temperature conditions (that is 37 °C at ambient pressure, dry)). If a demand oxygen system is used, a supply of 300 liters of free oxygen at 70 °F and 760 mm. Hg. pressure is considered to be adequate to meet the 15-minute-duration requirement at the prescribed altitude and minute volume. If a continuous flow protective breathing system is used (including a mask with a standard rebreather bag), a flow rate of 60 liters per minute at 8,000 feet (45 liters per minute at sea level) and a supply of 600 liters of free oxygen at 70 °F and 760 mm. Hg. pressure is considered to be adequate to meet the 15-minute-duration requirement at the prescribed altitude and minute volume.
6. Be free from hazards in itself, in its method of operation, and in its effect upon other components.
7. Have a means to allow the crew to readily determine, during flight, the quantity of oxygen available in each source of supply.

Issued in Kansas City, Missouri, on January 5, 2001.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1670 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–SW–27–AD]

Airworthiness Directives; Bell Helicopter Textron, Inc. Model 412 Helicopters and Agusta S.p.A. Model AB412 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD) that applies to certain serial-numbered Bell Helicopter Textron, Inc. (Bell) Model 412 helicopters and Agusta S.p.A. (Agusta) Model AB412 helicopters. That AD currently requires a temporary reduction of the never-exceed velocity (Vne) limitation until an inspection of the tail rotor yoke (yoke) assembly for fatigue damage and installation of a redesigned yoke flapping stop are accomplished. Recurring periodic and special inspections to detect occurrences of yoke overload are also required. This AD would require the same actions as the previous AD but would expand the applicability of the AD to all Bell Model 412, 412CF, 412EP, and Agusta Model AB412 helicopters. This proposal is prompted by the determination that the unsafe condition exists on all Bell Model 412 and all Agusta Model AB412 helicopters, regardless of serial number. The actions specified by the proposed AD are intended to prevent static and dynamic overload damage to the yoke that could result in loss of the tail rotor and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before March 23, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 99–SW–27–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: 9-asw-adcomments@faa.gov. Comments may be inspected at the Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed AD may be obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101, telephone (817) 280–3391, fax (817) 280–6466 for the Bell Model 412 helicopters; and Agusta S.p.A., 21017 Cascina Costa di Samarate (VA), Italy, Via Giovanni Agusta 520, telephone 39 (0331) 229111, fax 39 (0331) 229605–222595 for the Agusta Model AB412 helicopters. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Uday Garadi, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5123, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the maksing of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this document may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 99–SW–27–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 99–SW–27–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

On March 16, 1998, the FAA issued AD 98–07–03, Amendment 39–10421, Docket No. 97–SW–58–AD (63 FR 14026, March 24, 1998), applicable to Bell Model 412 helicopters, serial numbers (S/N) 33001 through 33213, 34001 through 34024, 36001 through 36121, 46400 through 46434, and 46437; and Agusta Model AB412 helicopters, S/N prior to and including S/N 25806 and S/N 25901, to require a temporary reduction of the Vne limitation until an inspection of the yoke assembly for fatigue damage and installation of a redesigned yoke flapping stop are accomplished. Recurring periodic and special inspections to detect occurrences of yoke overload are also required. That action was prompted by laboratory tests and engineering analyses which indicated that the yoke assembly is susceptible to fatigue damage due to unforeseen static and dynamic loading of the tail rotor against the original flapping stop. The requirements of that AD are intended to prevent fatigue failure of the yoke that could result in loss of control of the tail rotor and subsequent loss of control of the helicopter. A correction to a technical bulletin date referenced in that AD was issued on July 10, 1998 (63 FR 38742, July 20, 1998).

Since the issuance of AD 98–07–03, the FAA has determined that the unsafe condition exists on all Bell Model 412, 412CF, and 412 EP and Agusta Model AB412 helicopters and that the applicability of AD 98–07–03 should have included all serial numbers of these helicopters. The proposed AD would also correct the unsafe condition, which was listed as fatigue failure and correct the reference to Registro Aeronautico Italiano AD 97–223, which was dated incorrectly in AD 98–07–03.

Since an unsafe condition has been identified that is likely to exist or develop on all Bell Model 412 or Agusta Model AB412 helicopters of the same type designs, the proposed AD would supersede AD 98–07–03. The proposed AD would require a reduction of the Vne limitation until an inspection of the yoke assembly for static and dynamic overload damage and installation of a redesigned yoke flapping stop are accomplished and includes additional periodic and special inspections to detect a yoke overload.

The FAA estimates that 135 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 6.5 work hours per helicopter to install the placard, inspect the yoke assembly, and install the yoke. Required parts would cost approximately $511 per helicopter. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $121,635.

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–10421 (63 FR 14026, March 24, 1998 and 63 FR 38742, July 20, 1998), and by adding a new airworthiness directive (AD), to read as follows:

Bell Helicopter Textron, Inc. and Agusta S.p.A.: Docket No. 99–SW–27–AD. Supersedes AD 98–07–03, Amendment 39–10421, Docket No. 97–SW–58–AD.

Applicability: Bell Helicopter Textron, Inc. Model 412, 412CF, and 412EP helicopters and Agusta S.p.A. Model AB412 helicopters, with tail rotor yoke assembly, part number (P/N) 212–011–702–all dash numbers, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent static and dynamic overload damage to the tail rotor yoke (yoke) that could result in loss of the tail rotor and subsequent loss of control of the helicopter, accomplish the following:

(a) Before further flight, review the historical records of the yoke assembly for any static or dynamic overload damage history, other than normal usage, that could have imposed a bending load on the yoke but did not require replacing the yoke assembly; for example, an incident in which a damaged tail rotor blade was replaced due to a blade strike. If such a history exists, replace the yoke with an airworthy yoke.

(b) Before further flight, unless the requirements of paragraph (c) of this AD have been accomplished previously:

(1) Install a Never Exceed Velocity (Vne) red line at 120 knots indicated airspeed (KIAS) on the pilot and copilot airspeed indicators using red tape or paint and a slippage indicator on the instrument case and glass.

(2) Install a placard made of material that is not easily erased, disfigured, or obscured on the instrument panel in clear view of the pilot and copilot: "Observe temporary Maximum Never Exceed (Vne) airspeed red line (marked at 120 knots indicated airspeed (KIAS)). Vne is 20 KIAS less than the value presented on the airspeed limitation placard for each ambient condition."

(3) Insert the applicable Bell Helicopter Textron (BHT) 412 Temporary Revision, dated August 16, 1996, into the Model 412 Rotorcraft Flight Manual (RFM) or the applicable section of Agusta AB412 Temporary Revision No. 2, dated April 17, 1997, into the Model AB412 RFM.

(c) Within 180 calendar days:

(1) Remove yoke assembly, P/N 212–011–702-all dash numbers, and replace it with an airworthy yoke assembly, P/N 212–011–702-all dash numbers, with zero hours time-in-service (TIS), or an airworthy yoke (regardless of TIS) that has passed a one-time x-ray diffraction inspection in accordance with BHT Alert Service Bulletin (ASB) 412–96–89, Revision A, dated October 17, 1997; BHT ASB 412CF–96–01, dated September 3, 1996; or, Agusta Bolletino Tecnico (Technical Bulletin) No. 412–65, dated April 17, 1997, whichever is applicable.

(2) Install an airworthy tail rotor flapping stop, P/N 212–011–713–103.

(3) After the requirements of paragraphs (c)(1) and (c)(2) of this AD are accomplished, remove the 120 KIAS redline from the pilot and copilot airspeed indicators; remove the Vne airspeed restriction placard; and remove the BHT 412 Temporary Revision, dated August 16, 1996; BHT ASB 412CF–96–01, dated September 3, 1996; or Agusta AB412 Temporary Revision No. 2, as applicable, from the RFM.

(d) After accomplishing the requirements of paragraph (c) of this AD, at intervals not to exceed 25 hours TIS, inspect the yoke assembly and tail rotor flapping stop (stop) in accordance with Part III, Recurring 25-Hour Special Inspection and Conditional Inspection Requirement, of Bell Helicopter Textron ASB 412–96–89, Revision A, dated October 17, 1997; BHT ASB 412CF–96–01, dated September 3, 1996; or Agusta Bolletino Tecnico (Technical Bulletin) No. 412–65, dated April 17, 1997, as applicable. Replace any unairworthy yoke assembly or stop with an airworthy yoke assembly or stop before further flight.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter at airspeeds not to exceed 120 KIAS to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Registro Aeronautico Italiano (Italy) AD 97–223, dated August 1, 1997.

Issued in Fort Worth, Texas, on January 8, 2001.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 01–1587 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–272–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier Model DHC–7 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness

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directive (AD) that is applicable to certain Bombardier Model DHC–7 series airplanes. This proposal would require modification of the pressure hoses to the ground spoiler actuators. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign airworthiness authority. This action is necessary to prevent blockage of pressure hoses to the ground spoiler actuators, leading to uncommanded deployment of the ground spoilers, resulting in reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by February 21, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–272–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–272–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Bombardier, Inc., Bombardier Regional Aircraft Division, 123 Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office (ACO), 10 Fifth Street, Third Floor, Valley Stream, New York.

FOR FURTHER INFORMATION CONTACT: Ezra Sasson, Aerospace Engineer, ANE–172, FAA, New York ACO, 10 Fifth Street, Third Floor, Valley Stream, New York 11581; telephone (516) 256–7250; fax (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–272–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–272–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Transport Canada Civil Aviation (TCCA), which is the airworthiness authority for Canada, notified the FAA that an unsafe condition may exist on certain Bombardier Model DHC–7 series airplanes. TCCA advises that an operator has reported that an uncommanded deployment of all ground spoilers occurred during an engine ground-run and that all attempts by the flight crew to retract the spoilers were unsuccessful. Investigation of the problem identified the cause as a failed piston seal in a pressure hose to the ground spoiler actuators. This condition, if not corrected, could result in the blockage of pressure hoses to the ground spoiler actuators, leading to uncommanded deployment of the ground spoilers, resulting in reduced controllability of the airplane.

Explanation of Relevant Service Information

Bombardier has issued Service Bulletin 7–27–90, dated September 3, 1999, which describes procedures for modification of the pressure hoses to the ground spoiler actuators. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. TCCA classified this service bulletin as mandatory and issued Canadian airworthiness directive CF–99–29, dated November 3, 1999, in order to assure the continued airworthiness of these airplanes in Canada.

FAA's Conclusions

These airplane models are manufactured in Canada and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, TCCA has kept the FAA informed of the situation described above. The FAA has examined the findings of TCCA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

The FAA estimates that 30 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed modification, and that the average labor rate is $60 per work hour. There would be no charge for required parts. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $7,200, or $240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Bombardier, Inc. (Formerly de Havilland, Inc): Docket 2000–NM–272–AD.

Applicability: Model DHC–7 series airplanes, serial numbers 003 through 113 inclusive; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent blockage of pressure hoses to the ground spoiler actuators, leading to uncommanded deployment of the ground spoilers, resulting in reduced controllability of the airplane, accomplish the following:

Modification

(a) Within 12 months after the effective date of this AD: Modify the pressure hoses on each ground spoiler actuator, in accordance with Bombardier Service Bulletin 7–27–90, dated September 3, 1999.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Canadian airworthiness directive CF–99–29, dated November 3, 1999.

Issued in Renton, Washington, on January 11, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1663 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–263–AD]

RIN 2120–AA64

Airworthiness Directives; Construcciones Aeronauticas, S.A. (CASA), Model CN–235 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all CASA Model CN–235 series airplanes. This proposal would require installing a second electrical connector in the electrical Master Central Unit. This action is necessary to prevent the loss of electrical power, other than that provided by the emergency system, in the event of disconnection of the single electrical connector within the electrical Master Central Unit. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by February 21, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–263–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: 9-anm-nprmcomment@faa.gov. Comments sent via fax or the Internet must contain "Docket No. 2000–NM–263–AD" in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Construcciones Aeronauticas, S.A., Getafe, Madrid, Spain. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, ANM–116, FAA, 1601 Lind Avenue, SW., Renton,

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Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (e.g., reasons or data) for each request.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 2000–NM–263–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–263–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direccion General de Aviacion Civil (DGAC), which is the airworthiness authority for Spain, notified the FAA that an unsafe condition may exist on all CASA Model CN–235 series airplanes. The DGAC advises that an incorrect assembly of the electrical connector of the Master Central Unit could lead to a disconnection of the connector. This condition, if not corrected, could result in the loss of electrical power, other than that provided by the emergency system, in the event of disconnection of the single electrical connector within the electrical Master Central Unit.

Explanation of Relevant Service Information

CASA has issued Service Bulletin SB–235–24–14, dated June 27, 2000, which describes procedures for installing a second connector in the Master Central Unit. This second connector would allow the electrical connections to the generator and the battery on each side of the electrical Master Central Unit to be independent. The accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The DGAC classified this service bulletin as mandatory and issued Spanish airworthiness directive 06/00, dated June 27, 2000, in order to assure the continued airworthiness of these airplanes in Spain.

FAA's Conclusions

These airplane models are manufactured in Spain and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

The FAA estimates that 1 airplane of U.S. registry would be affected by this proposed AD, that it would take approximately 8 work hours to accomplish the proposed installation, and that the average labor rate is $60 per work hour. Required parts would cost approximately $877. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $1,357.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Construcciones Aeronauticas, S.A. (CASA): Docket 2000–NM–263–AD.

Applicability: All Model CN–235 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the loss of electrical power, other than that provided by the emergency system, in the event of disconnection of the single electrical connector within the electrical Master Central Unit, accomplish the following:

Installation

(a) Within 6 months after the effective date of this AD: Install a second electrical connector in the Master Central Unit, in accordance with CASA Service Bulletin SB–235–24–14, dated June 27, 2000.

Alternative Methods of Compliance

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Spanish airworthiness directive 06/00, dated June 27, 2000.

Issued in Renton, Washington, on January 12, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1664 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–57–AD]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company 150, 172, 175, 180, 182, 185, 206, 210, and 336 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM); Extension of the comment period.

SUMMARY: This document provides additional time for the public to comment on a proposal to adopt a new airworthiness directive (AD) that would apply to certain Cessna Aircraft Company (Cessna) 150, 172, 175, 180, 182, 185, 206, 210, and 336 series airplanes. The proposed AD would affect those airplanes equipped with 0513166 series plastic control wheels. The proposed AD would require you to repetitively inspect these wheels for cracks, conduct a pull test on these wheels, and replace any control wheels that are cracked or that do not pass the pull test. Replacement of the control wheels would be with ones that are FAA-approved and are not 0513166 series plastic control wheels. The proposed AD is the result of many incidents of control wheels cracking or breaking on the above-referenced airplanes. Comments received on the original notice of proposed rulemaking (NPRM) specify additional time to respond to the proposed action. The actions specified by the proposed AD are intended to detect and correct cracked or defective control wheels, which could result in loss of control of the airplane during takeoff, landing, or ground operations.

DATES: The Federal Aviation Administration (FAA) must receive any comments on this proposed rule by April 4, 2001. This is extended from February 2, 2001.

ADDRESSES: Send three copies of comments to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–57–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. You may read comments at this location between 8 a.m. and 4 p.m., Monday through Friday, except holidays.

You may get the service information referenced in the proposed AD from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517–5800; facsimile: (316) 942–9006. You may read this information at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Eual Conditt, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4128; facsimile: (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

How do I comment on this proposed AD? We invite your comments on the proposed rule. You may send whatever written data, views, or arguments you choose. You need to include the rule's docket number and send your comments in triplicate to the address named under the caption **ADDRESSES**. We will consider all comments received by the closing date named above, before acting on the proposed rule. We may change the proposals contained in this notice because of the comments received.

Are there any specific portions of the proposed AD I should pay attention to? The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of the proposed rule that might call for a need to change the proposed rule. You may look at all comments we receive. We will file a report in the Rules Docket that summarizes each FAA contact with the public that concerns the substantive parts of this proposal.

The FAA is reexamining the writing style we currently use in regulatory documents, in response to the Presidential memorandum of June 1, 1998. That memorandum requires federal agencies to communicate more clearly with the public. We are interested in your comments on the ease of understanding this document, and any other suggestions you might have to improve the clarity of FAA communications that affect you. You can get more information about the Presidential memorandum and the plain language initiative at *http://www.faa.gov/language/*.

How can I be sure FAA receives my comment? If you want us to

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acknowledge the receipt of your comments, you must include a self-addressed, stamped postcard. On the postcard, write "Comments to Docket No. 98–CE–57–AD." We will date stamp and mail the postcard back to you.

Discussion

What events have caused this proposed AD? The FAA has received reports of many incidents of control wheels cracking or breaking on Cessna 150, 172, 175, 180, 182, 185, 206, 210, and 336 series airplanes. The problem control wheels are 0513166 series plastic control wheels.

The cause of this problem is because of temperature variations in the molding process during manufacture of the control wheels and deterioration with age and temperature extremes.

This condition could result in the control wheels breaking while the airplane is in operation. A consequent loss of control of the airplane during takeoff, landing, or ground operations could occur.

We issued an NPRM that proposed to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to certain Cessna Aircraft Company (Cessna) 150, 172, 175, 180, 182, 185, 206, 210, and 336 series airplanes. The NPRM would require you to:

—Repetitively inspect and pull test the 0513166 series control wheels; and

—If necessary, replace any control wheels that fail the inspection or pull test.

What has happened to cause FAA to issue this document? We received comments on the NPRM indicating the need for more time to provide data on the proposed AD. Based on these comments and the interest in the rule expressed by various operators and other interested parties, FAA has decided to extend the comment period on this rule to seek additional data. Therefore, the comment period is extended approximately 60 days and will close April 4, 2001.

We are including additional preamble information and the actual AD for the reader's convenience.

What are the differences between the service bulletin and the proposed AD? The Cessna service letter specifies inspecting and testing the control wheels as soon as possible and positively by the next 100-hour inspection. We propose that you inspect and pull test the control wheels and replace (if necessary) the control wheels within 100 hours time-in-service (TIS) after the effective date of this proposed AD, and then at intervals not to exceed 12 months until the control wheels are replaced.

We believe that these compliance times will give the owners or operators of the affected airplanes enough time to have the proposed actions performed without compromising the safety of the airplanes.

Cost Impact

How many airplanes would this proposed AD impact? We estimate the proposed AD would affect 12,592 airplanes in the U.S. registry.

What would be the cost impact of the proposed AD on owners/operators of the affected airplanes? We estimate the following costs to do the proposed inspection and pull test:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
1 hour at $60 for each hour	No parts are required	1 hour x $60 = $60	12,592 airplanes × $60 for each airplane = $755,520.

We estimate the following costs to do any necessary control wheel replacements that would be required based on the results of the proposed inspection and pull test. We have no way of determining the number of airplanes that may need such control wheel replacement:

Labor cost	Parts cost	Total cost per airplane
1 hour at $60 for each hour	$597 for each control wheel	$60 + $597 = $657.

These figures only consider the cost of the first inspection and test and do not account for repetitive inspections and tests. We do not have any means of finding out the number of repetitive inspections and tests the owner/operator would incur over the life of an affected airplane.

Regulatory Impact

How would this proposed AD impact various entities? The proposed regulations would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have determined that this proposed rule would not have federalism implications under Executive Order 13132.

Does this proposed AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this proposed action (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if put into effect, will not have a significant economic impact, positive or negative, on a large number of small entities under the criteria of the Regulatory Flexibility Act. We have placed a copy of the draft regulatory evaluation prepared for this action in the Rules Docket. You may get a copy of it by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Cessna Aircraft Company: Docket No. 98–CE–57–AD.

(a) *What airplanes are affected by this AD?* This AD affects the following airplanes that are certificated in any category and incorporate at least one 0513166 series plastic control wheel:

Model	Serial Nos.
150	17684 through 17999, 59001 through 59018 and 617.
150A	15059019 through 15059350 and 628.
150B	15059351 through 15059700.
150C	15060088 through 15060772.
172A	46755 through 47746; 622 and 625.
172B	17247747 through 17248734 and 630.
172C	17248735 through 17249544.
172D	17249545 through 17250572.
172E	17259573 through 17250872 and 639.
P172	P17257120 through P17257188.
175A	56239 through 56777 and 619.
175B	17556778 through 17557002.
175C	17557003 through 17557119.
180C	50662 through 50911 and 624.
180D	18050912 through 18051063.
180E	18051064 through 18051183.
180F	18051184 through 18051312.
180G	18051313 through 18051329.
182C	52359 through 53007 and 631.
182D	18253008 through 18253598 and 51623.
182E	18253599 through 18254423.
182F	18254424 through 18255058.
182G	18255059 through 18255113.
185	185–0001 through 185–0237 and 632.
185A	185–0238 through 185–0512.
185B	185–0513 through 185–0653.
185C	185–0654 through 185–0663.
206	206–0001 through 206–0062.
210	57001 through 57575 and 618.
210A	21057576 through 21057840 and 616.
210B	21057841 through 21058085.
210C	21058086 through 21058220.
210D	21058221 through 21058240.
210–5 (205)	205–0001 through 205–0480 and 641.
210–5A (205A)	205–0481 through 205–0520.
336	336–0001 through 336–0195.

Note 1: Serial numbers 616 through 619, 622, 624, 625, 628, 630 through 632, 639, 641, and 51623 are engineering-fabricated prototype airplanes that were used for prototypes and then sold. These airplanes carry unique serial numbers that are not in sequence with other airplane serial numbers.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the above airplanes must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect and correct cracked or defective control wheels, which could result in loss of control of the airplane during takeoff, landing, or ground operations.

(d) *What must I do to address this problem?* To address this problem, you must do the following actions:

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Actions	Compliance times	Procedures
(1) Check your maintenance records to determine whether this AD applies to your airplane by doing the following: (i) Check the maintenance records to determine whether a 0513166 series plastic control wheel is installed. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may check the maintenance records. (ii) If, by checking the maintenance records, the pilot can positively show that no 0513166 series plastic control wheels are installed, then the inspection, testing, and replacement requirements of this AD do not apply. The AD is complied with after you make an entry into the aircraft records that shows compliance with this portion of the AD, in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).	Required within 100 hours time-in-service (TIS) after the effective date of this AD.	No special procedures required to check the maintenance records.
(2) For any affected airplane where at least one 0513166 series plastic control wheel is installed, do the following: (i) Inspect each control wheel for cracks; and (ii) Conduct a pull test on each control wheel	Before further flight after the maintenance records check or within 100 hour TIS after the effective date of this AD, and reinspect afterward at intervals not to exceed 12 months until all control wheels are replaced with FAA-approved control wheels that are not 0513166 series plastic control wheels.	Do this following the instructions of Cessna Service Letter No. 64–8, dated February 14, 1964.
(3) Replace any cracked control wheel or any control wheel that does not pass any pull test, with an FAA-approved control wheel that is not a 0513166 series plastic control wheel.	Do this replacement before further flight after the inspection where the cracked or failed control wheel is found.	Do the replacements following the instructions in the applicable maintenance or service manual.
(4) Do not install, on any affected airplane, a 0513166 series plastic control wheel.	As of the effective date of this AD	Not Applicable.
(5) You may replace all control wheels with wheels that are not part number 0513166, as terminating action for the repetitive inspection and test requirement of this AD.	You may replace all control wheels at any time, except for those control wheels that are cracked or do not pass a pull test. Such wheels must be replaced prior to further flight, as required by paragraph (d)(3) of this AD.	Do the replacements following the instructions in the applicable maintenance or service manual.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Send your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 2: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. You should include in the request an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Eual Conditt, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4128; facsimile: (316) 946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get the service information referenced in the AD from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; or you may examine this document at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on January 11, 2001.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1665 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 00N–1633]

RIN 0910–AB95

Marking Requirements for and Prohibitions on the Reimportation of Imported Food Products That Have Been Refused Admission Into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the food import regulations to require food products which, for safety reasons, are refused entry into the United States to be marked "UNITED STATES REFUSED ENTRY." The proposed rule would also prohibit persons from refusing to affix this mark on refused food, from importing or offering to import a previously refused food, and from altering, removing, tampering with, or concealing a mark. The proposed rule is intended to protect the public health against unsafe imported food products and to facilitate the examination of imported products.

DATES: Submit written comments by April 9, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) authorizes FDA to examine foods, drugs, devices, and cosmetics imported or offered for import into the United States and to refuse admission to products under certain conditions. Imported products are subject to the same statutory and regulatory requirements as domestic products. For example, a domestic food product must not be adulterated or misbranded. Similarly, an imported food that is intended for sale in the United States must not be adulterated or misbranded.

FDA's examination of imports often begins with a review of records to determine whether additional scrutiny is warranted. FDA may, based on its review of the records, permit the goods to proceed, visually examine or take samples of the goods for laboratory analysis, or verify the registration, listing, declarations, and certifications for the product. For food products, visual examinations may be inadequate for detecting suspected microbiological contamination, pesticide residues, and other toxic elements, so FDA may take samples of an imported food product for further examination. If the examination shows that the food product appears to be in compliance with U.S. requirements, FDA releases the shipment to proceed into U.S. commerce. If the food product appears to be not in compliance, the importer has an opportunity to provide evidence or testimony that the food product complies with U.S. requirements or to submit a plan to recondition the food product to bring it into compliance if such reconditioning is possible. If, after the importer has had an opportunity to present its views or if reconditioning failed to bring the food into compliance, the food product is not in compliance, FDA may refuse admission to the food product. If refused products are not reexported within 90 days of refusal, the U.S. Customs Service (Customs Service) will have the products destroyed.

Additionally, under section 304 of the act (21 U.S.C. 334), FDA may initiate seizure and condemnation proceedings against any article of food that is adulterated or misbranded, or which may not be introduced into interstate commerce under section 404 of the act (21 U.S.C. 344). A court may, after seizure and condemnation of an imported article, order the article to be destroyed or permit the article to be reexported (see *United States* v. *Food, 2,998 Cases*, 64 F.3d 984 (5th Cir. 1995)). The Customs Service also has seizure procedures (see 19 U.S.C. 1595a).

In recent years, the demand on FDA's resources for reviewing food imports has increased significantly. For example, in 1985, approximately 950,000 line items of goods were offered for import into the United States. (A line item corresponds to a specific item on an invoice or shipping papers.) By 1998, the number of line items had increased to over 3 million (see statement by William B. Schultz, Deputy Commissioner for Policy, Food and Drug Administration, before the Permanent Subcommittee on Investigations, Senate Committee on Government Affairs, September 24, 1998). FDA's ability to inspect a sufficient proportion of imports has been severely hampered by this increase. Currently, FDA examines or samples less than 2 percent of imported foods for compliance with FDA requirements.

FDA is aware that some unscrupulous importers use various measures to subvert this process in order to introduce unsafe food products into the United States. In April 1998, the General Accounting Office (GAO) issued a report entitled "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable" (GAO/RCED–98–103). The GAO report stated that some importers evade import controls and are able to introduce contaminated, adulterated, or unsafe food into the United States even when FDA refused to admit the food and the Customs Service ordered the food to be reexported or destroyed. In particular, the GAO report noted that FDA does not require that refused foods be marked as "refused entry."

Additionally, in 1998, the Senate Governmental Affairs Committee's Permanent Investigations Subcommittee held hearings on the safety of food imports. The Committee heard testimony about various methods used to avoid food safety inspections and to introduce adulterated food into the United States. These methods included reimporting refused goods through another U.S. port ("port shopping") and substituting trash or other items for adulterated food products for which FDA has refused entry so that the trash and other items, rather than the adulterated food products, were destroyed or reexported (Ref. 2) (statement of "Former Customs Broker"). Placing a clearly identifiable mark on food imports that have been refused admission for safety reasons would help curtail the reintroduction of unsafe food products into the United States.

On July 3, 1999, the President issued a memorandum to the Secretary of Health and Human Services and the Secretary of the Treasury (the Secretaries) on the safety of imported foods. The memorandum identified food safety as a high priority and, among other things, directed the Secretaries to take all actions available to "prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called 'port shopping'), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons...."

II. Description of the Proposed Rule

A. Introduction

FDA is proposing to amend its import regulations to create a new § 1.98 entitled "Marking Requirements for and Prohibitions on the Reimportation of Food Products That Have Been Refused Admission into the United States." The proposal would require importers or consignees to mark food (including animal feed) that FDA refuses to admit, for safety reasons, into the United States. The mark should make it more difficult for imported food products that have been refused admission into the United States to evade import controls and would complement FDA's efforts to monitor food imports more effectively. The proposed rule would also prohibit importers from reimporting refused shipments.

FDA and the Customs Service held two public meetings to discuss imported food safety on February 10, 2000, in Los Angeles, CA, and on February 17, 2000, in Washington, DC. Several comments were made concerning marking refused food imports, and FDA addresses those

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comments as part of this description of the proposed rule.

B. Who Must Affix the Mark?

If you are an importer or consignee of a shipment of imported food that FDA has refused to admit for safety reasons, you would be subject to the rule. (For purposes of this rule, the reference to "safety reasons" means that consuming the imported food could adversely affect a person's health.) Under proposed § 1.98(a), if FDA has refused to admit your imported food into the United States for safety reasons, you must mark the refused food as "UNITED STATES REFUSED ENTRY." An FDA employee or FDA-designated official (such as an FDA-commissioned official) would supervise the marking process.

In contrast, if FDA refused admission of your imported food for other nonsafety reasons, you would not be subject to this rule. For example, if FDA refused to admit your imported food because it was labeled in a foreign language, you would not have to mark the refused food product. If, however, FDA refused to admit your imported food because it contained an unsafe ingredient, you would have to mark the refused product in accordance with the regulation.

C. What Must the Mark Look Like?

Proposed § 1.98(b) would require you to make the mark in capital letters at least 2.5 centimeters (cm) or 1 inch high. The mark would state "UNITED STATES REFUSED ENTRY." The mark's language and format are similar to those used by the U.S. Department of Agriculture on meat and meat food products that have been refused admission into the United States (9 CFR 327.26(c)).

Some comments during a public meeting suggested that the mark include some indication of why the food product was refused entry instead of stating simply that the food was refused entry. FDA has not included this suggestion in the proposed rule because the text of the proposed mark, "UNITED STATES REFUSED ENTRY," is applicable to all products that are refused entry for safety reasons and is similar to a mark used by the U.S. Department of Agriculture. If FDA required the mark to explain the reasons for the refusal, importers and consignees would need multiple marks (to cover the various possible reasons for refusing entry) or would need to use "fill in the blank" marks which could then be illegible (if the reasons are handwritten) or difficult to use (if the reasons are machine-printed). Nevertheless, FDA welcomes additional comment on this point.

Proposed § 1.98(b)(1) would require the mark to be permanent, clear, and conspicuous. This will help ensure that the mark is noticeable. For example, if the mark is affixed to a bill of lading, you could place the mark diagonally across the center of the document and use colored ink. However, the proposal would not specify any particular method of marking. In other words, you can use adhesive labels, ink stamps, or any other marking tool or device so long as the mark is at least 2.5 cm or 1 inch high, uses the correct language, is clear and conspicuous, and is permanently affixed to the refused imported food's container (where possible) and to shipping documents accompanying the imported food before it leaves the port of entry.

Another comment at a public meeting suggested that the mark be in "invisible ink" that FDA would be able to see through the use of some scanning device. Some individuals expressed concern about how a visible mark would affect the refused product's ability to enter a foreign country or return to the exporting country. This proposed rule does not include the use of "invisible ink." One important benefit of the mark is that it is supposed to be clear and conspicuous; this will make it easier for FDA and the Customs Service to detect attempts to bring refused food products back into the United States. If the mark could only be seen by using some unspecified device, FDA and the Customs Service might find it difficult to determine whether the mark was correctly applied, to see the mark on goods that are being reintroduced into the United States in spite of an earlier refusal, or to readily distinguish between foods that should be admitted into the United States from foods that have already been refused entry. FDA invites comment on this point.

FDA also invites comments on whether the rule should use or allow for different size requirements due to the variety of food packages and product sizes and whether the rule should require any particular form of marking.

D. Where Must the Mark Go?

Proposed § 1.98(b)(1) would require you to affix the mark permanently to the packing container holding the refused food and on invoices, bills of lading, and any other documents accompanying the food when it is exported from the United States. The proposal would explain that, for purposes of thois rule, a packing container is any container used to pack one or more immediate containers of the refused food and that an immediate container is any container which holds an imported food for sale to the ultimate consumer. For example, assume that you have a box that holds 24 cans of imported food. the box would be the packing container, and each can would be an immediate container. You would, under the proposal, mark the box rather than mark each can. FDA would not require you to mark every individual retail unit (unless the immediate container also happens to be the packing container, such as a large bag of rice or flour). If the mark cannot be permanently affixed to a packing container (as with bulk agricultural commodities, such as a railcar of wheat, a truckload of potatoes, or a tanker of corn syrup) you would only have to place the mark on documents accompanying the food when it leaves the United States.

Several comments at the public meeting said the mark should go on cargo containers used to transport large amounts of imported food products. Others suggested using seals on cargo containers instead of merely marking the containers. FDA interpreted these comments concerning cargo containers as applying the mark or seal on items such as rail cars, containers to be attached to trucks, and other large, reusable containers. FDA has not included the comments' suggestions in this proposed rule. By proposing to require the mark to be clear, conspicuous, and permanent, FDA intends to make it difficult for a person to "port shop" or to conceal refused food. If the mark were placed on a large, reusable cargo container (such as a tractor trailer or rail car), it would be easy to defeat the rule simply by moving the refused food from the marked cargo container to an unmarked container. For example, if the mark is on a container attached to a truck instead of the packing containers holding the refused food product, the intent behind the rule could be defeated by shifting the refused food product from the marked tractor trailer to an unmarked one. In contrast, if the mark is on the packing containers (such as boxes or wrapped shipping palettes) holding the refused food, it will be more difficult, both in terms of time and cost, to open and repackage the refused food, and thus evade the rule's purpose. FDA invites additional comment on this point.

E. When Must You Affix the Mark?

Proposed § 1.98(b)(2) would require you to affix the mark, under the supervision of an FDA employee or person designated by FDA, before the food is exported. This is to ensure that you place the mark, as required, on the refused food before the food leaves the United States.

F. Enforcement Issues

If this rule is finalized with a prohibition on the reimportation of refused food, reimportation of refused food in violation of this rule would constitute a violation of 19 U.S.C. 1595a which would then permit the Customs Service to seize, forfeit, and destroy the goods after following the appropriate procedures. Thus, proposed § 1.98(c) would prohibit you from: (1) Importing or offering to import any food that has been previously refused admission into the United States and marked as "UNITED STATES REFUSED ENTRY;" and (2) altering, removing, tampering with, or concealing a mark. If you refuse to affix a mark on a refused food import, FDA and the Customs Service might deny permission to re-export the refused food product, order the product to be destroyed, and take other regulatory action against you and the refused food. The Customs Service might also assess civil money penalties under 19 U.S.C. 1592 or 1595a(b) if you alter, remove, tamper with, or conceal a mark.

G. Authority Citation Changes

FDA is also proposing to amend the authority citation for 21 CFR part 1 to include references to sections 704 of the act (21 U.S.C. 374) and 801 of the act and section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). These statutory provisions provide additional legal authority to issue the proposed rule (as explained in section III of this document).

III. Legal Authority

Section 801(a) of the act states that FDA shall refuse to admit imported food into the United States if the imported food has been manufactured, processed, or packed under insanitary conditions, is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or is adulterated or misbranded. Sections 402 and 403 of the act (21 U.S.C. 342 and 343) describe when a food is adulterated and misbranded respectively. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

The proposed rule is within FDA's authority at sections 402, 403, 701, and 801 of the act. Because marking refused goods would permit FDA to more efficiently enforce section 801 of the act, FDA is authorized to impose marking requirements on such food products. The mark would help ensure that food products that fail to meet the conditions for admission into the United States do not enter or reenter interstate commerce.

Section 704 of the act authorizes FDA to conduct inspections for the efficient enforcement of the act. Assuming that the proposed rule is later finalized, FDA may need to conduct inspections to help enforce the rule. Thus, while section 704 of the act does not provide independent authority to mark refused food imports, it is relevant to FDA's enforcement of the rule.

The proposed rule is also authorized by sections 301 of the PHS Act (42 U.S.C. 241) and 361 of the PHS Act. Section 301 of the PHS Act authorizes FDA to "render assistance" to appropriate public health authorities in the conduct of or to promote coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of disease. Section 361 of the PHS Act authorizes FDA to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Marking food products that have been refused entry into the United States would assist foreign public health officials to determine whether to take regulatory action against a particular product. The mark would alert foreign countries that the food product has already been refused admission into the United States. Marking such food products would also help prevent the introduction, transmission, or spread of communicable diseases into the United States by making it more difficult for such rejected food products to enter the United States through a different port or to escape detection.

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(a), 25.30(k), and 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the marking requirements proposed in this document are not subject to review by the Office of Management and Budget (OMB) because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). Rather, the proposed statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 considers a rule to be a "significant regulatory action" if (among other things) it may have an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. For reasons explained later in this section, FDA concludes that the proposed rule, if finalized, would not have a significant economic impact on a substantial

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number of small entities. Therefore, a regulatory flexibility analysis is not required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule because the proposed rule is not expected to result in any 1 year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

B. The Rationale Behind This Proposed Rule

The introduction to this proposed rule explains the reasons, such as "port shopping" and the President's July 3, 1999, memorandum on the safety of imported foods that prompted FDA, in conjunction with the Customs Service, to issue this regulation. FDA refers readers to that discussion if they seek details regarding the reasons for this proposal and the problems concerning the reimportation of previously refused imported food.

C. Regulatory Options Considered

As described earlier, the proposed rule would require importers and consignees whose food products have been refused admission in to the United States for safety reasons to mark such products as "UNITED STATES REFUSED ENTRY." This will make it easier for FDA and the Customs Service to detect attempts to re-introduce previously-refused imported food into the United States.

In drafting this rule, FDA considered and rejected several alternatives. For example, one option would be to order the destruction of all refused food imports. While this would deter "port shopping" and similar illegal practices, this alternative is not feasible because it would require Federal resources to be diverted to supervising or otherwise ensuring that the refused food imports are stored until they can be destroyed and that they are actually destroyed. Additionally, the standard of proof to support the destruction of violative products is greater than the standard of proof for refusing to admit imported products, so ordering the destruction of refused food imports would increase, rather than decrease, the demands on government field resources. This alternative would also be extremely costly to importers since many refused shipments can be exported and legally sold or reconditioned for sale in other countries.

Another alternative would be a "no action" option. This alternative was unacceptable because it would allow illegal practices, such as port shopping, to continue and would result in the reentry of previously refused food imports into the United States. Consumers who ingested those unsafe food imports would, in turn, be subject to foodborne illnesses. Consequently, a "no action" alternative would not further efforts to protect the public health.

Another alternative would be to mark some, but not all, food refused for safety reasons. This alternative would be less costly, but would also be less efficient and less practical. This alternative was unacceptable because it would create an opportunity for some refused food imports to reenter the United States through port shopping (and to harm consumers) and because an unmarked, but previously-refused, food import would be difficult to detect compared to a previously-refused and marked food import. Additionally, marking some, but not all, refused food would inevitably create arguments as to FDA's criteria for deciding which refused foods should or should not be marked and whether a specific food import met that criteria.

For example, if the alternative was to mark refused food depending on its geographic origin (under a theory that some foreign nations regulate exported food more rigorously than others so that the United States could relax its safeguards for foods from those countries), the result would be both inefficient and unfair. To illustrate this point, assume that country A has a food regulatory system while country B has a less demanding regulatory system. If an alternative would mark unsafe food from country B, but not mark a similar, unsafe food from country A, such an alternative would make it possible for unsafe food from country A to be port shopped, thereby defeating the intent of the rule. Marking would then depend on geographic origin rather than the safety of the food itself.

As another example, if the alternative were to mark refused food imports based on their potential risk, such as marking refused foods which, if consumed, would cause death or serious illness in humans, such an approach would be impractical and difficult to apply. To illustrate this point, assume that an imported food product appears to be contaminated because mold is visible on the product. If marking depended on whether the moldy food would cause death or serious illness, arguments would inevitably arise concerning the identification of the mold, its toxicological properties (if any), the methodology or references used to analyze the mold or to determine the seriousness of the health risk associated with the mold, etc.

D. Benefit-Cost Analysis

1. Strategic Action by Importers

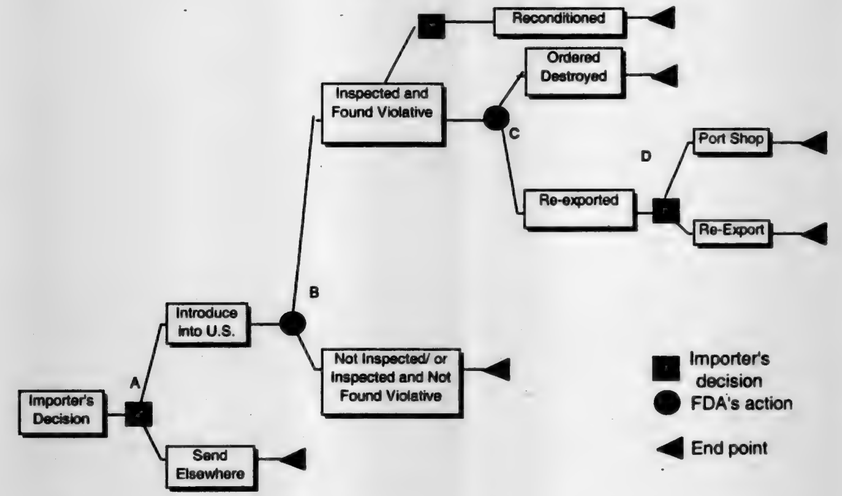
Although the vast majority of importers and consignees comply with the act, some attempt to circumvent Federal law and introduce unsafe food into U.S. commerce through illegal means such as port shopping. For these importers and consignees, measures such as those contained in this proposed rule are necessary to deter illegal conduct.

An importer's or consignee's decision on how to dispose of its cargo is influenced by changes in the expected profits associated with each of its choices. Requiring importers and consignees to mark "UNITED STATES REFUSED ENTRY" on imported food which has been refused admission for safety reasons changes the expected profits associated with the initial decision to attempt to import unsafe food. A mark also affects the expected profits associated with the decision to recondition, re-export, or port shop after a shipment is found violative.

The decision process of an importer of potentially unsafe food can be represented visually by a decision tree (see figure 1). This illustrates how requiring "UNITED STATES REFUSED ENTRY" on refused imports will alter an importer's or consignee's incentives. The same tree shows the possible outcomes and decisions an importer or consignee can make at each stage of the importation process. At point A, an importer or consignee with violative food first decides whether to attempt to import the food into the United States. This decision will be influenced by the price the importer or consignee can get for the food if it is successfully imported, the probability the cargo will be inspected, and the cost to the importer or consignee if the food is inspected and found violative. At point B, whether the cargo is inspected is a function of factors such as the port of entry, FDA's inspection rate, and the type of product. If it is found violative, the importer may choose to recondition the food to correct the violations. At point C, FDA refuses admission of the food. If the food is not destroyed, at point D the importer or consignee may have the option of re-exporting to a foreign country or port shopping.

Illustration 1:

A Dynamic Representation of the Introduction of Food into Commerce in the United States



2. The Rule's Effect on Deterrence

Labeling refused imported foods as"UNITED STATES REFUSED ENTRY" alters the incentive structure that importers and consignees face when deciding whether to introduce their product into United States commerce. In particular, there are four ways that the rule would increase the deterrence value of the FDA inspection system.

a. Port shopping will be reduced. One primary goal of this rule would be to reduce port shopping. Placing a mark on a refused food import will reduce the probability that the refused food import will be re-imported into the United States. The cost of port shopping will increase because resources would have to be expended to repackage a product that has been marked. Thus, port shopping will become relatively less attractive to importers and consignees.

b. Decrease in the value of re-exported items. The value of a product destined for reexport will decrease if it is marked "UNITED STATES REFUSED ENTRY." After the product has been marked, the importer or consignee has two costly choices: (1) Relabel containers or repackage the product into containers that do not bear the mark after the product leaves the United States, or (2) sell the goods abroad with the mark intact. It is likely that such a mark would be viewed less than favorably by food safety inspectors and importers in international markets. Thus, the expected profit from selling goods that are marked would be lower than if the mark did not exist, so this loss is in addition to the loss of value from refusal alone. Either of the importer's or consignee's choices (repackage or sell with the mark intact) would lower the expected profit of reexporting.

c. Reconditioning will become a more favored alternative. The expected profit from reconditioning a refused food import is not likely to change with this rule. Consequently, since the expected profits from port shopping and re-exporting refused food imports are expected to fall, reconditioning the cargo becomes economically more attractive. FDA expects that more importers and consignees will choose to recondition their product.

d. Decrease in the introduction of unsafe food into the United States. As with reconditioning, the expected profit from initially sending a potentially unsafe product to a foreign port is not expected to change significantly with this rule. Therefore, as the expected profit from attempting to import unsafe food into the United States is lowered (because the cost of re-importing and re-exporting unsafe food is increased), the incentive to ship one's product directly to a foreign (non-United States) market is increased. The net result of such a dynamic is that more unsafe food products will either be directly shipped to foreign markets or reconditioned at the point of export.

3. Benefits From The Rule

a. Health benefits. As described earlier, the proposed rule, if finalized, would decrease the number of unsafe imported food products reaching the U.S. consumer. The rule should

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discourage attempts to introduce or reintroduce unsafe imported food into the United States and encourage the reconditioning of imported food that FDA has refused to admit for safety reasons. Consequently, U.S. consumers would benefit through a reduction in the number of foodborne illnesses due to unsafe imported foods. Because FDA cannot quantify the amount of illegal re-importation of refused foods, the agency cannot make a definitive prediction of the value of the reduced illnesses arising from this proposed rule.

Although foods that represent a direct and serious danger to public health are, in most cases, destroyed,[1] refused food eligible for re-exportation may also present a health hazard. Typical reasons for refusal include illegal food or color additives, pesticide contamination, foreign objects, poor sanitation, and unregistered manufacturers or processes not filed. Each of these reasons for refusal may represent a health risk. Illegal food or color additives can cause allergic reactions in sensitive individuals. These allergic reactions can range from mild contact dermatitis to a severe allergy attack. Also, long-term exposure to some illegal color additives has been linked to cancer. Sanitation problems indicate the food was held in unsanitary conditions, which may indicate more serious problems such as contamination with microbial pathogens. Pesticide contamination may represent a long-term cancer risk. A single exposure to a violative pesticide level is very unlikely to result in cancer, but prolonged exposure over years may lead to increased risk. "Process not filed" indicates that FDA has not approved the canning process the manufacturer uses. Without FDA approval, it is not known if the firm is using a canning process that may result in botulism contamination. Although the probability of contamination is low, botulism is a very severe illness that has a high mortality rate.

Table 1 of this document shows some possible illnesses and injuries that can result from unsafe foods and includes their symptoms and an average cost per case. The quality-adjusted life days (QALD) (Ref. 8) column represents the lost utility per day to a consumer from an illness, essentially the loss to the consumer due to symptoms and problems associated with the illness. The QALD's are valued in dollars by multiplying the number of lost days by the value of statistical day, $630 (see 64 FR 36516 at 36523, (July 6, 1999)). This value of a statistical life day is drawn from the economic literature (Ref. 10). The medical cost column is the direct, medical cost of illness, which includes hospitalization and doctor visits. Most illnesses arising from *E. Scherichia coli* O157:H7 or *Salmonella* are self-limiting and short in duration, but some illnesses due to *Salmonella* or *E. coli* O157:H7 can be quite serious. *E. coli* in some cases can result in kidney damage or death. Salmonella can sometimes trigger chronic arthritis and in a very small percentage of cases can result in death.

TABLE 1.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE RULE

Potential Harm	Symptoms	QALD Loss	Dollar Value of Lost QALD's	Medical Costs	Total Cost
Allergens: Contact dermatitis	Reddening, swelling, itching of skin	2.10	$1,325	$125	$1,450
Allergens: Allergic reaction	Difficulty breathing, asthma, rash, possible shock	1.03	$646	$550	$1,196
Objects in food: Simple dental injury	Toothache, headache	0.23	$145	$0	$145
Objects in food: Complex dental injury	Simple, plus infection	3.47	$2,187	$3,540	$5,727
Objects in food: Oral emergency	Sharp pain in mouth, face, neck, bleeding, plus possible metastatic or local infection.	4.27	$2,687	$3,540	$6,227
Objects in food: Tracheo-esophageal obstruction	Choking, difficulty breathing, cyanosis, hypertension	0.48	$304	$0	$304
Objects in food: Esophageal perforation	Pain in chest, bleeding aspiration pneumonia, requires surgery.	13.93	$8,776	$14,160	$22,936
Canning processes: Botulism	Nausea, diplopia, blurred vision, lack of coordination, Can include loss of muscle strength, paralysis, death.	667.94	$420,801	$29,526	$450,327
Filth: Salmonella	Vomiting, nausea, possible arthritis, low probability of death.	24.37	$15,357	$2,289	$17,646
Filth: E. coli	Vomiting, nausea, bloody stools, possible kidney damage, low probability of death.	10.79	$6,797	$4,829	$11,626

[1] Sources: *E. coli* and *Salmonella* costs were taken from "Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products," 963 FR 24254 at 24259-24267, (May 1, 1998).
[2] Objects in food, allergens, and botulism costs were taken from Research Triangle Institute. Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act.

b. Other consumer benefits. While problems such as insects or filth in food may not always represent a direct health threat, they show that the food was not held in sanitary conditions. Moreover, consumers who purchase food expect it to be clean and sanitary. Consumer research shows cleanliness is important to consumers. For example, the Food Marketing Institute found 89 percent of consumers surveyed ranked a clean, neat store as a very important factor in selecting their primary supermarket. If consumers pay a premium believing their food is sanitary and the food is not, this payment represents a social loss. However, FDA cannot quantify this economic loss because FDA does not know what percentage of the price of food is a "cleanliness premium."

4. Costs of the Rule

Costs include both materials and time and would be incurred by both FDA and importers or consignees. The importers and consignees would bear the responsibility for marking; FDA would verify that the mark is affixed to the refused food. It is not clear which method importers and consignees will use to mark refused food imports, so FDA has, for purposes of this analysis, used labeling, an inexpensive and time efficient method, to estimate costs.

a. Materials. Placing labels on all the packages would require the use of a label gun and printed labels. Label guns cost approximately $100, and FDA assumes that three label guns would be needed at each of the 132 ports. Labels reading "UNITED STATES REFUSED ENTRY" would also have to be printed at an approximate cost of $0.025 per label.

b. Time—i. Importer's time. The number of hours spent applying labels is a function of the number of rejected shipments and their size. FDA assumes the average shipment consists of 500 cartons and will take approximately 3 hours to mark. FDA also assumes the importer or consignee will hire labor at the average hourly cost for transportation and moving occupations published by the Bureau of Labor Statistics (BLS), $17.64 (BLS, "Employer Costs for Employee Compensation Summary," 1999). Under these assumptions, it will cost approximately $53 in labor (3 hours x $17.64 per hour) to mark each shipment. It is not clear how many shipments will need to be marked. As a baseline, FDA estimates that 7,338 shipments would be marked. However, FDA expects more importers and consignees will decide to recondition after rejection (percent correctable in table 2 of this document), or will not attempt to import previously refused or unsafe food (expected avoidance in table 2 of this document), due to the higher cost of shipments being rejected. The "static annual cost" is the cost assuming more of the shipments found violative are corrected at the port. The "dynamic annual cost" is the "static annual cost" reduced by the percentage decrease (expected avoidance) we expect in initial importation attempts. Based on FDA's experience, the agency can estimate the number of shipments that can be reconditioned rather than re-exported. The percentage of shipments that can be reconditioned is a function of the reason for refusal. Also, the reduction in the number of attempted imports of violative shipments, "expected avoidance," is a function of the ease of correcting the violation before shipment. Again, FDA bases its estimates on the agency's experience. For example, in fiscal year 1999, FDA refused admission to 2,260 shipments because the manufacturer was not registered or the process was not filed. Approximately 80 percent of these shipments can be corrected before importation or at the port by filing for process approval or by registering the manufacturer. This would reduce the number of shipments that could be marked from 2,260 to 452. The cost of marking these shipments would then be $23,925 in labor costs and $5,651 for labels for importers. It would cost FDA $33,229 to confirm the marks had been made. The sum of these costs is $62,805. However, because FDA expects importers and consignees will be less likely to attempt to import unsafe food initially (expected avoidance), FDA then reduces this cost by 50 percent, which is then $31,402. Added to this cost is a fraction of the cost of the label guns. Label guns are durable goods and so the value of a label gun should not be added to the cost of marking each shipment.

ii. FDA inspector's time. The proposed rule would require FDA to confirm that the importer or consignee marks the refused food import. FDA estimates that this process would require approximately 60 minutes in travel time and 30 minutes to confirm marking per shipment. FDA estimates the value of a FDA inspector's time based on a GS-10, step 5 rate, plus 100 percent in overhead. At this hourly rate, FDA's labor costs for each shipment would be $74.

TABLE 2.—ANNUAL LABELING COST ESTIMATES

	Reason for Refusal				
	Manufacturer Not Registered/Process Not Filed	Illegal Food/Color Additives	Pesticide Contamination	Sanitation	Total Annual Refusals
Estimated refusals	2,260	1,530	873	2,675	7,338
Percent correctable	80%	0%	0%	50%	
Number of refusals to be marked	452	1,530	873	1,337	4,192
FDA Costs.					
FDA hours per refusal	1.5	1.5	1.5	1.5	
FDA hourly rate	$49	$49	$49	$49	
Total FDA cost	$33,229	$112,445	$64,160	$98,297	$308,131
Importer Costs.					
Importer hours per refusal	3	3	3	3	
Importer hourly rate	$17.64	$17.64	$17.64	$17.64	
Label costs	$5,651	$19,123	$10,912	$16,717	
Total importer cost	$29,576	$100,083	$57,106	$87,491	$274,257
Static annual cost	$62,805	$212,528	$121,266	$185,789	$582,388
Expected avoidance	50%	50%	15%	15%	
Dynamic annual cost	$31,402	$106,264	$103,076	$157,921	$398,663

TABLE 3.—FIXED LABELING COSTS

Labeling Guns for Importers	
Number of ports	132
Label guns needed per port of entry	3
Cost per label gun	$100
TOTAL LABEL GUN COSTS = NUMBER OF PARTS X LABEL GUNS NEEDED PER PORT OF ENTRIES X COST PER LABEL GUN	$39,600

TABLE 4.—TOTAL COSTS

Labeling Guns for Importers	
Annual costs	$398,663

[1] Currently FDA is considering a policy that would recommend the destruction of hazardous food imports. Because dangerous foods may be re-exported without this policy there is the potential for these foods to be port shopped. This proposed rule, if finalized, would then also discourage the re-importation of foods that present a direct hazard to the public health, as well as foods representing an indirect threat, and the rule's benefits would be higher.

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TABLE 4.—TOTAL COSTS—Continued

Labeling Guns for Importers	
Other costs	$39,600
TOTAL FIRST-YEAR COSTS	$438,263

c. Diminished value of shipments. Cargo marked "UNITED STATES REFUSED ENTRY" will lose value due to diminished value in foreign ports, in addition to the loss of the U.S. market for the product. The importer or consignee suffers an initial loss of value due to rejection of its cargo, regardless of the mark. However, there is an additional loss of value attributable to the marking that is a cost of this rule. This loss of value is a cost of the rule that is borne directly by the importer or consignee, but may be passed on to consumers in the form of higher food prices. This loss ofvalue is difficult to quantify. How the mark decreases the value of the cargo would be a function of the initial value of the cargo, type of product, reason for refusal, and the reluctance of the new buyer to purchase previously refused merchandise.

5. Summary of Benefits and Costs

The uncertain nature of the number of illnesses prevented and the difficulty in quantifying the benefits to consumer of having clean foods, regardless of the danger, prevents a definitive statement about benefits and costs. Because FDA expects the costs to be approximately $438,263, this sets a threshold value for the benefits. If the benefits due to reduced illness and consumer valuation of clean food exceed $438,263, the rule's benefits will exceed its costs.

E. Initial Regulatory Flexibility Analysis

1. Introduction

FDA has examined the economic implication of these proposed rules as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule would have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

2. Economic Effects on Small Entities

The proposed rule, if finalized, would affect many small entities, primarily food importers or consignees. More than 95 percent (1,690 of 1,725 importers identified through a search in Dialog Classic) of food importers are small (Ref. 3) as defined by the Small Business Administration (establishments with less than 100 employees). These small importers or consignees will face a cost of approximately $75 per unsafe food shipment in time and materials. In addition, the value of their unsafe food shipment will fall. This cost is difficult to quantify, but can be bounded by the cost of repackaging the merchandise. FDA does not expect this cost for any one small importer or consignee to be significant, so the agency concludes that this proposed rule does not place a disproportionate burden on small businesses. Furthermore, this cost is borne only by small businesses that attempt to re-import unsafe, and previously refused, foods.

3. Regulatory Options

Exempting small businesses from the proposed rule would lift the burden on small entities. However, since most entities affected by the rule are small, this would effectively negate the rule's purpose. For reasons already discussed in section VII.C of this document, other regulatory options, such as destroying all refused food imports, taking no action, marking some but not all refused food imports, and marking based on geographic origin, are not feasible in light of the proposed rule's purposes. FDA also notes that the proposal contains options (with respect to the method used to affix the mark) for importers and consignees, and importers and consignees whose shipments are refused admission for safety reasons may decide to re-condition, destroy, or re-export an unsafe food import. Given these options available to small entities, FDA did not consider additional options.

4. Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

FDA is not aware of any relevant Federal rule which may duplicate or conflict with the proposed rule. The exportation of refused food products must also comply with Customs rules for exportation of refused imports at 19 CFR 12.4, 18.25, 18.26, and 158.45. In addition, Customs routinely orders redelivery of refused merchandise under to the conditions contained in the basic importation and entry bond. Therefore, importers of refused food imports must comply with the bond conditions contained in 19 CFR 113.62, as required by 19 CFR 12.3.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by April 9, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bureau of Labor Statistics, Employer Costs for Employee Compensation Summary, http://stats.bls.gov/news.release/ecec.nws.htm (1999).

2. Congressional Hearing, The Safety of Food Imports: Fraud and Deception in the Food Import Process; Hearing Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, September 10, 1998.

3. Dialog Classic. Search of wholesalers who import with SIC codes between 5141 to 5149 that are importers, February 29, 2000.

4. Food and Drug Administration, "Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rules to Ensure the Safety of Juice and Juice Products," (63 FR 24254, May 1, 1998).

5. Food and Drug Administration, "Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels," (64 FR 36516, July 6, 1999).

6. Food Marketing Institute, 1999. Consumer Attitudes and the Supermarket. Research International USA.

7. GAO Report, "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable" (GAO/RCED–98–103).

8. Kaplan, R. M., J. P. Anderson, and T. G. Ganiats, "The Quality of Well-Being Scale: Rationale for a Single Quality of Life Index," edited by Walker, S. R. and Rosser, R. M., *Quality of Life Assessment: Key Issues in the 1990s*; The Netherlands: Kluwer Academic Publishers, 1993.

9. Mauskopf, J.A., Mt French, A. S. Ross, D. M. Maguire, R. W. Leukrith, Jr., and K. D. Fisher, "Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act," Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.

10. Viscusi, W. K., "The Value of Risks to Life and Health." *Journal of Economic Literature*, Volume 31, pp. 1912-1946, December 1993.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 343, 352, 355, 360b, 362, 371, 374, 381; 42 U.S.C. 216, 264.

2. Add section 1.98 to subpart E to read as follows:

§ 1.98 Marking of food imports refused entry into the United States.

(a) If you are an importer or consignee and your imported food has been refused admission into the United States for safety reasons and you want to reexport the food, you must mark the refused food, before you reexport it, with the following mark:

Illustration 2

UNITED STATES REFUSED ENTRY

(b) You must make the mark at least 2.5 cm. or 1 inch high in capital or uppercase letters. The mark must be clear, conspicuous, and permanently affixed. You also must:

(1) Affix the mark to the packing container of the food, if possible, and to an invoice, bill of lading, and any other shipping document accompanying the food when it is exported. For purposes of this rule, a packing container is any contaner used to pack one or more immediate containers of the refused food, and an immediate container is any container which holds an imported food for sale to the ultimate consumer. the term "packing container" excludes trailers, railroad cars and similar transportation-related items, and

(2) Affix the mark, under the supervision of a FDA employee or individual designated by FDA, before the food is exported.

(c) You must not:

(1) Import or offer to import any food that has been previously refused admission into the United States and marked as "UNITED STATES REFUSED ENTRY;" or

(2) Alter, remove, tamper with, or conceal a "UNITED STATES REFUSED ENTRY" mark.

Dated: November 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

January 9, 2001,

Timothy E. Skud,

Acting Deputy Assistant Secretary. Department of the Treasury.

[FR Doc. 01–1607 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 870

RIN 1029–AB95

Abandoned Mine Land (AML) Fee Collection and Coal Production Reporting on the OSM–1 Form

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; reopening and extension of the comment period.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM) are reopening and extending the comment period on a proposal to amend our regulations governing Abandoned Mine Land (AML) reclamation fee reporting to allow for the electronic filing of the information required on the OSM–1 Form.

DATES: *Written comments:* We will accept written comments on the proposed rule until 5 p.m., Eastern time, on February 21, 2001.

ADDRESSES: If you wish to comment, you may submit your comments by any one of the following methods. You may mail or hand-deliver comments to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 101, 1951 Constitution Avenue, NW, Washington, DC 20240. You may also submit comments to OSM via the Internet at: osmrules@osmre.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Spillane, Office of Surface Mining Reclamation and Enforcement, Denver Federal Center, Building 20k, Room B–2005, Denver, Colorado 80225; Telephone 303–236–0330, Ext. 278. E-mail: sspkillan@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background Information
II. How Would the Electronic Submission Process Work?
III. How Do I Submit Comments on the Proposed Rule?

I. Background Information

On February 15, 2000 (65 FR 7706), we published a proposed rule which would revise our regulations to allow a coal operator (or the entity reporting for the operator) the option of filing the OSM–1 Form electronically. Because of the notary requirement in section 402(c) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), the

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proposed rule also required the operator to print out and maintain on file, a properly notarized paper copy of the OSM–1 Form for review by OSM's Fee Compliance auditors. In the proposed rule published on February 15, 2000, section 870.17(b) reads in part as follows: (b) Maintain a properly notarized paper copy of the identical OSM–1 Form for review and approval by OSM's Fee Compliance auditors.

In order to further simplify the process and to make it easier for the operator to store records electronically, we are considering an option which would eliminate the need for the operator to notarize the OSM–1 Form and maintain a paper copy on file. We are considering adopting a final rule which would allow the operator to electronically submit the OSM–1 Form and include a statement made under penalty of perjury that the information contained in the OSM–1 Form is true and correct. The statement would *not* have to be notarized but it would have to be electronically signed, dated, and transmitted to OSM as part of the OSM–1 Form. In the final rule, section 870.17(b) would read as follows: (b) Submit an electronically signed and dated statement made under penalty of perjury that the information contained in the OSM–1 Form is true and correct.

The authority for filing the form without notarization is found in 28 U.S.C. 1746. Section 1746 provides in part:

> Wherever, under any law of the United States or under any rule, regulations, order, or requirement made pursuant to law, any matter is required or permitted to be supported, evidenced, established, or proved by the sworn declaration, verification, certificate, statement, oath, or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than a notary public), such matter may, with like force and effect, be supported, evidenced, established, or proved by the unsworn declaration, certificate, verification, or statement, in writing of such person which is subscribed by him, as true under penalty of perjury and dated, in substantially the following form:
>
> * * * * *
>
> (2) If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)".

The option of using a signed a dated electronic statement made under penalty of perjury in lieu of a notarized statement will facilitate compliance with the requirements of the Government Paperwork Elimination Act (GPEA), Pub. L. 105–277, Title XVII. GPEA requires agencies, by October 21, 2003, to provide for (1) the option of electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper; and (2) the use and acceptance of electronic signatures, when practicable. GPEA specifically states that electronic records and their related electronic signatures are not to be denied legal effect, validity, or enforceability merely because they are in electronic form.

Comments are also requested on whether in addition to the option being proposed today, we should also retain the notary option published in the **Federal Register** on February 15, 2000. If both options are adopted, the final rule would provide the operator with two choices in addition to the existing process: Either sending the OSM–1 Form data electronically while maintaining a properly notarized paper copy of the OSM–1 Form, or sending the OSM–1 Form data electronically with an electronically signed and dated statement made under penalty of perjury.

As previously stated, the electronic submission of the OSM–1 Form would be an option that is available to the operator. Even if a final rule is adopted which allows the submission of the OSM–1 Form electronically, we would continue to accept the quarterly filing of the OSM–1 Form in paper format with the sworn, notarized statement that is currently in use.

Because 28 U.S.C. 1746 already allows the operator to use an unsworn statement made under penalty of perjury in lieu of a sworn, notarized statement, we are considering modifying the paper form to incorporate an appropriate signature block for this provision. The new paper form, if adopted, would allow the operator to submit either the sworn, notarized statement, or an unsworn statement made under penalty of perjury. We believe that this modification would further simplify reporting requirements for operators. Your comments on this matter are also requested.

How Would the Electronic Submission Process Work?

We intend to develop a website where companies will be able to log in an complete the OSM–1 Form on-line. Access to the website will be controlled by ID and password which will be used as the method of electronic signature. When initially accessing the website, companies will be able to down-load encryption software which is free. The data which is encrypted can be read only by the company and OSM and the data submitted by the company cannot be changed by unauthorized persons. A file transfer protocol (FTP) version of the electronic OSM–1 Form will allow companies with a large number of reporting permits to automate their filing process by transferring their data report files directly from their computer to OSM. The FTP process will use a form of electronic signature called a Public Key Infrastructure (PKI). PKI is a system for encrypting, decrypting, signing and verifying the data transferred electronically. With PKI, the company (user) can obtain a free download of the software for a private signing key. With this key, the user creates a digital signature on an electronic file or encrypts the data. OSM, as the recipient of the file, employs the public key to validate the signature made with the private key or decrypts the data. The two keys are mathematically linked and form a unique pair. Only the public key can validate the signature made with the associated private key(s). This process also verifies that the file has not been altered since its encryption. The companies that use FTP will also need a user identification and password to enable them to print their OSM report from the website after their data is transferred.

II. How Do I Submit Comments on the Proposed Rule?

Written Comments: If you submit written or electronic comment on the proposed rule during the 30-day extended comment period, they should be specific, should be confined to issues pertinent to the notice, and should explain the reason for any recommended change(s). Where practical, you should submit three copies of your comments. We may not be able to consider or include in the Administrative Record comments delivered to an address other than those listed above (see **ADDRESSES**).

Electronic Comment: Please submit Internet comments as an ASCII or WordPerfect file avoiding the use of special characters and any form of encryption. Please also include "Attn: RIN 1029–AB95" and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly at 202–208–2847.

Availability of Comments: Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours at the OSM Administrative Record Room (see **ADDRESSES**). Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entity.

Dated: January 16, 2001.

Kathrine L. Henry,

Acting Director, Office of Surface Mining Reclamation and Enforcement.

[FR Doc. 01–1765 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD7–00–123]

RIN 2115–AE47

Drawbridge Operation Regulations: Siesta Drive Drawbridge, Gulf Intracoastal Waterway, Florida

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating regulations of the Siesta Drive drawbridge across the Gulf Intracoastal Waterway, mile 71.6 at Sarasota, Florida. This rule would allow the drawbridge to open only every 20 minutes between the hours of 7 a.m. and 6 p.m., Monday through Friday, except Federal holidays. This action is intended to improve the movement of morning commuter traffic while not unreasonably interfering with the movement of vessel traffic.

DATES: Comments and related material must reach the Coast Guard on or before March 23, 2001.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Room 406, Miami, FL 33131. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD07–00–123] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Room 406, Miami, FL 33131 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Bridge Branch, 909 SE 1st Ave., Miami, FL 33130, telephone number 305–415–6743.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07–00–123], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Bridge Branch, Seventh Coast Guard District, 909 SE 1st Ave., Room 406, Miami, FL 33131, explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Siesta Drive bascule bridge is a two lane narrow undivided urban arterial roadway, which is already severely congested due to insufficient capacity. The proposed rule would extend the existing 20 minute weekday schedule to cover the morning commuter period. The bridge opens less than once per hour during this period so the effect on vessels is not considered unreasonable.

Discussion of Proposed Rule

The proposed rule would allow the bridge to start its scheduled openings at 7 a.m. weekdays instead of the present 11 a.m. to 6 p.m. schedule. This should facilitate the movement of commuter traffic across the drawbridge while not unreasonably interfering with the movement of vessel traffic through the drawspans.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040, February 26, 1979).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The number of openings that occur during the proposed period of additional regulations is less than once per hour and the maximum waiting time would be 20 minutes

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit under the Siesta Key bridge during the hours of 7 a.m. to 11 a.m. on weekdays. This proposed rule would not have a significant economic impact on a substantial number of small entities because the number of openings that occur during the proposed period of additional regulations is less than once per hour and the maximum waiting time would be 20 minutes.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this proposed rule so that

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they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the Bridge Branch, Seventh Coast Guard District.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

We have analyzed this proposed rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that Order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those costs. This proposed rule would not impose an unfunded mandate.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that, under figure 2–1, paragraph (32)(e) of Commandant Instruction M16475.lC, this proposed rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast

Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.287(b–1) is revised to read as follows:

§ 117.287 Gulf Intracoastal Waterway.

* * * * *

(b-1) The draw of the Siesta Key bridge, mile 71.6 at Sarasota, shall open on signal, except that from 7 a.m. to 6 p.m. Monday through Friday, except Federal holidays, the draw need open only on the hour, twenty minutes past the hour, and 40 minutes past the hour. On weekends and federal holidays from 11 am to 6 pm the draw need open only on the hour, 20 minutes past the hour, and 40 minutes past the hour.

* * * * *

Dated: December 27, 2000.

G.W. Sutton,

Captain, U.S. Coast Guard, Commander, Seventh Coast Guard District, Acting.

[FR Doc. 01–1544 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 167

[USCG–1999–4974]

Port Access Routes; Strait of Juan de Fuca and Adjacent Waters

AGENCY: Coast Guard, DOT.

ACTION: Notice of study results.

SUMMARY: The Coast Guard announces the completion of a Port Access Route Study which evaluated the need for modifications to current vessel routing and traffic management measures for the Strait of Juan de Fuca, Haro Strait, Boundary Pass, Rosario Strait, the Strait of Georgia, and adjacent waters. The study was completed in November, 2000. This notice summarizes the study recommendations, which include enhancements to existing vessel routing measures, the addition of new vessel routing measures, and the creation of several new operational procedures.

ADDRESSES: Comments and material received from the public, as well as the actual study and other documents mentioned in this notice, are part of docket USCG–1999–4974 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street, SW., Washington, DC, 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: For further information on this notice, contact Lieutenant Junior Grade Aaron Meadow-Hills, Thirteenth Coast Guard District, telephone 206–220–7215, e-mail ameadows-hills@pacnorwest.uscg.mil; or George Detweiler, Office of Vessel Traffic Management, Coast Guard, telephone 202–267–0416, e-mail gdetweiler@comdt.uscg.mil. For questions on viewing the docket, contact Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202–366–9329.

SUPPLEMENTARY INFORMATION: You may obtain a copy of the Port Access Route Study by contacting either person listed under **FOR FURTHER INFORMATION CONTACT** section. A copy is also available in the public docket at the address listed under the **ADDRESSES** section and electronically on the DMS Web Site at http://dms.dot.gov.

Definitions

The following definitions should help you review this notice:

Area to be avoided (ATBA) means a routing measure comprising an area within defined limits in which either navigation is particularly hazardous or it is exceptionally important to avoid casualties and which should be avoided by all ships, or certain classes of ships.

Cooperative Vessel Traffic Service (CVTS) means the system of vessel traffic management established and jointly operated by the United States and Canada within adjoining waters. In addition, CVTS facilitates traffic movement and anchorages, avoids jurisdictional disputes, and renders assistance in emergencies in adjoining United States and Canadian waters.

Precautionary area means a routing measure comprising an area within defined limits where ships must navigate with particular caution and within which the direction of traffic flow may be recommended.

Recommended route means a route of undefined width, for the convenience of ships in transit, which is often marked by centerline buoys.

Regulated Navigation Area (RNA) is a water area within a defined boundary for which regulations for vessels navigating within the area have been established under 33 CFR part 165.

Traffic lane means an area of defined width in which one-way traffic is established. Natural obstacles, including those forming separation zones, may constitute a boundary.

Traffic Separation Scheme (TSS) means a routing measure aimed at the separation of opposing streams of traffic by appropriate means and by the establishment of traffic lanes.

Background and Purpose

When did the Coast Guard Conduct this Port Access Route Study (PARS)?

We announced the PARS in a notice published in the **Federal Register** on January 20, 1999 (64 FR 3145) and completed the PARS in November, 2000.

What is the study area?

The study area encompasses waters in and around the Strait of Juan de Fuca, approximately between longitudes 126°W and 122°40′W, including Admiralty Inlet, Rosario Strait and adjacent waterways, Haro Strait, Boundary Pass and the Strait of Georgia. The study area also includes both U.S. and Canadian TSS's and an ATBA. Portions of the study area are managed jointly by United States and Canadian Coast Guards pursuant to the CVTS agreement.

Why did the Coast Guard conduct this PARS?

The latest Waterways Analysis and Management System (WAMS) report for the Strait of Juan de Fuca, dated June 1995, identified potential measures to improve navigational safety and traffic management efficiency. In 1997, on behalf of the Coast Guard, the Volpe National Transportation Systems Center conducted a broad assessment of the probabilities and consequences of marine accidents in the Puget Sound-area, including Puget Sound, the Strait of Juan de Fuca, passages around and through the San Juan Islands, and the offshore waters of the Olympic Coast National Marine Sanctuary. This assessment, formally titled "Scoping Risk Assessment: Protection Against Oil Spills in the Marine Waters of Northwest Washington State", also known as the "Puget Sound Additional Hazards Study" or "Volpe Study," recommended several vessel routing measures for further study, including changes to the offshore approaches to the Strait of Juan de Fuca. Implementation of the changes recommended in these documents requires IMO approval. This is contingent on the completion of a port access route study.

How did the Coast Guard conduct this PARS?

First, we announced the start of the study through a Notice of Study published in the **Federal Register** (64 FR 3145, January 20, 1999). Second, we extended the comment period of the Notice of Study and announced that we would conduct a public meeting through a Notice of Meeting; Extension of Comment Period published in the **Federal Register** (64 FR 18651, April 15, 1999). The public meeting was held on May 12, 1999 as announced. Because of the lack of a substantive number of comments to the original notice and our strong desire to engage the public in the study process, we asked for comments on a number of issues and recommendations. These issues and recommendations were presented in a Notice of Preliminary Study Recommendations with Request for Comments. The notice was published in the **Federal Register** on February 23, 2000 (65 FR 8917). During the comment period we and our Canadian counterparts embarked on a vigorous outreach program that presented the recommendations and solicited comments from a variety of waterway users and other potentially affected/interested groups. We offered to meet with them to explain the PARS Study and solicit their input. Over 300 copies of this **Federal Register** notice (65 FR 8917), with chartlets, were distributed by mail and direct handout.

The recommendations of the PARS are based in large part on comments received to the docket, extensive public outreach meetings, and recent studies such as the Puget Sound Additional Hazards Study, and the North Puget Sound Long-Term Oil Spill Risk Management Study. Heavy reliance was also placed on the expert opinions of the U.S. and Canadian VTS operators and managers.

Study Recommendations

The PARS evaluated 13 separate issues resulting in 28 specific final recommendations intended to improve the safety of vessel traffic in the study area. For the purposes of this notice, we condensed the 28 recommendations into the following list. The actual PARS should be consulted for a detailed explanation of each recommendation. The PARS also contains chartlets of the proposed changes/additions to the TSS. It can be accessed as described in the **ADDRESSES** section of this notice. The PARS recommendations include:

- Mandate use of the TSS for certain classes of vessels.
- Expand the applicability of certain provisions of Rule 10 of the International Regulations for Prevention of Collision at Sea, 1972 (72 COLREGS) along with development of a CVTS reporting system for violations of Rule 10.
- Expand the use of VTS radio frequencies to facilitate passing arrangements.
- Expand the geographic boundaries and the applicability of the existing ATBA located in the vicinity of the Olympic Coast Marine Sanctuary. Retain the voluntary nature of the ATBA.
- Reconfigure and extend the TSS seaward at the entrance to the Strait of Juan de Fuca.
- Modify the location, orientation, and dimensions of the existing TSS in the Strait of Juan de Fuca.
- Create a recommended route south of the TSS in the Strait of Juan de Fuca for smaller, slower moving traffic.
- Relocate the Pilot Area and reconfigure the traffic lanes and precautionary area off Port Angeles to improve traffic flow and reduce risks.
- Establish new vessel operating procedures to improve safety in the U.S. waters off Port Angeles, WA, through an RNA or other appropriate method.
- Change the vessel traffic lanes and precautionary area east of Victoria, British Columbia.
- Establish precautionary areas off Discovery Island and around the Victoria Pilot Station; and reconfigure the TSS connecting the two precautionary areas.
- Create a new two-way traffic lane in Haro Strait and Boundary Pass and establish a precautionary area off Turn Point.
- Create new vessel operating procedures to improve safety in the vicinity of Turn Point through the creation of a Turn Point CVTS Special Operating Area and its rules and procedures.
- Expand Precautionary Area "RB" at the south end of Rosario Strait.
- Expand the geographic applicability of the existing Rosario Strait VTS Special Area regulations contained in 33 CFR 161.55 to include Bellingham Channel and other adjacent waters.
- Create a new TSS to link the existing TSS in Georgia Strait, with the exiting TSS north of Rosario Strait and to the east of Succia Island.
- Create new precautionary areas in Georgia Strait off East Point and west of

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Delta Port and the Tsawwassen Ferry Terminal.

• Expand the U.S. VMRS requirements to match those of Canada which include all vessels 20 meters or more in length.

Next Steps

The PARS contains a number of recommendations, which will be implemented in various ways by U.S. and Canadian Authorities. A brief synopsis of how the various proposals will proceed towards implementation follows:

1. Changes to the TSS, ATBA, and adding recommended routes will require approval by the International Maritime Organization (IMO). Any changes to the TSS will be accomplished through the rulemaking process.

2. Changes to the U.S. VTS Regulations, including the designation of a VTS Special Area with associated rules, will be accomplished through the rulemaking process.

3. The designation of an RNA with associated rules will be accomplished through the rulemaking process.

4. Changes to aids to navigation resulting from the above actions will be accomplished through standard established procedures, i.e., notification of proposed changes in the Local Notice to Mariners with an opportunity for comment and notification of the final changes.

5. Revisions to the operating procedures for the CVTS will be developed by the Joint Coordinating Group and published in the CVTS Users Manual.

6. Canadian authorities will follow their own, but similar implementation process.

Conclusion

We appreciate the comments we received concerning the PARS. We will provide ample opportunity for additional comments on any recommended changes to existing routing or operational measures that require codification through notices of proposed rulemakings (NPRM's) published in the **Federal Register**.

Dated: January 16, 2001.

R.C. North,

U.S. Coast Guard, Assistant Commandant for Marine, Safety and Environmental Protection.

[FR Doc. 01–1847 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC86

Special Regulations; Areas of the National Park System; Religious Ceremonial Collection of Golden Eaglets From Wupatki National Monument

AGENCY: National Park Service, Interior.

ACTION: Proposed rule.

SUMMARY: The National Park Service (NPS) has preliminarily determined that under certain circumstances it is appropriate to allow the Hopi Tribe to collect golden eaglets within Wupatki National Monument, a unit of the National Park System, for religious ceremonial purposes. This rule would authorize this activity upon terms and conditions sufficient to protect park resources against impairment, and consistent with the Bald and Golden Eagle Protection Act.

DATES: Written comments will be accepted by mail, fax, or electronic mail through March 23, 2001.

ADDRESSES: Comments should be addressed to: Kym Hall, National Park Service, 1849 C Street, N.W., Room 7413, Washington, DC 20240. Fax: (202) 208–6756. Email: WASO_Regulations@nps.gov.

FOR FURTHER INFORMATION CONTACT: Sam Henderson, Superintendent, Wupatki National Monument, 6400 N. Highway 89, Flagstaff, Arizona 86004. Telephone: (520) 526–1157. Fax: (520) 526–4259. Email: WUPA_superintendent@nps.gov or Dr. Patricia Parker, Chief, American Indian Liaison Office, National Park Service, 1849 C Street, N.W., Room 3410, Washington, DC 20240. Telephone: (202) 208–5475. Fax: (202) 208–0870. Email: Pat_Parker@nps.gov

SUPPLEMENTARY INFORMATION:

Existing Regulations

A subsection of NPS regulations, promulgated in 1983, prohibits "possessing, destroying, injuring, defacing, removing, digging, or disturbing from its natural state" living or dead wildlife or fish, plants, paleontological specimens, or mineral resources, or the parts or products of any of these items, except as otherwise provided. 36 CFR 2.1(a).

Another provision of these regulations authorizes NPS to issue permits allowing the collection of national park system resources for research upon certain conditions. 36 CFR 2.5(b). No such permit may be issued except to:

> an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display when the superintendent determines that the collection is necessary to the stated scientific or resource management goals of the institution or agency and that all applicable Federal and State permits have been acquired, and that the intended use of the specimens and their final disposal is in accordance with applicable law and Federal administrative policies.

In addition, a permit may not be issued if "removal of the specimen would result in damage to other natural or cultural resources, affect adversely environmental or scenic values, or if the specimen is readily available outside of the park area."

Subsection 2.5(c) prohibits issuing a permit to take a specimen that is listed as an endangered or threatened species under state or federal law unless the specimen "cannot be obtained outside of the park area and the primary purpose of the collection is to enhance the protection or management of the species." Subsection 2.5(f) prohibits issuing a research collection permit in park areas where the enabling legislation prohibits the killing of wildlife.

NPS regulations allow a park superintendent to "designate certain fruits, berries, nuts or unoccupied seashells which may be gathered by hand for personal use or consumption" if "the gathering or consumption will not adversely affect park wildlife," or otherwise adversely affect the plant species, or park resources. 36 CFR 2.1(c)(1). Another subsection addresses the ceremonial use of NPS resources, stating that the regulations "shall not be construed as authorizing the taking, use or possession of fish, wildlife or plants for ceremonial or religious purposes, except where specifically authorized by Federal statutory law, treaty rights, or in accordance with § 2.2 [wildlife protection] or § 2.3 [fishing]." 36 CFR § 2.1(d). The preamble to this rulemaking explained that the provision was added in response to comments that had "questioned the applicability" of the regulation in such circumstances, and went on to say:

> The Service recognizes the American Indian Religious Freedom Act directs the exercise of discretion to accommodate Native religious practice consistent with statutory management obligations. The Service intends to provide reasonable access to, and use of, park lands and park resources by Native Americans for religious and traditional activities. However, the National Park Service is limited by law and regulations from authorizing the consumptive use of park resources. (48 FR 30,252 (1983)).

The Need To Revise the Regulations

In 1999, members of the Hopi Tribe requested permission from the NPS to take golden eaglets from Wupatki National Monument for religious purposes. Citing the National Park Service Organic Act and 36 CFR 2.1, 2.2, and 2.5, the NPS denied the Hopi request. The Assistant Secretary for Fish and Wildlife and Parks then withdrew the NPS denial in order to reconsider the issue. Upon advice of the Solicitor, as explained below, the proposal is being made to change the regulation to allow favorable action on the Hopi request.

The practice of eagle gathering is at the heart of the Hopi religious ceremonial cycle and the Hopi culture. The eagle serves as the link between the spiritual world and the physical world of the Hopi, a connection that embodies the very essence of Hopi spirituality and belief. Golden eaglets are gathered from nests soon after birth and are kept and raised to fledglings in Hopi villages. Later, during the Niman Kachina ceremony, the golden eagles are sacrificed and "sent" to their spiritual home. The eagles' feathers are subsequently used in all Hopi religious ceremonies such as the Kachina, Flute, and Snake ceremonies. The cyclical relationship between the eagle and the Hopi is renewed annually through the practice of eaglet gathering, sustaining the connection between the spiritual and physical worlds for the next generation of Hopi.

The importance that the Hopi attach to the ceremonial gathering of eagles is expressed in Article IV of the Tribal Constitution approved by Secretary of the Interior Ickes on December 19, 1936:

> The Tribal Council shall negotiate with the United States Government agencies concerned, and with other tribes and other persons concerned, in order to secure protection of the right of the Hopi Tribe to hunt for eagles in its traditional territories, and to secure adequate protection for its outlying, established shrines.

Only a few of the Hopi clan and religious societies bear the important ceremonial obligation of eagle gathering, and each of these has a traditional area from which it—and no other clan or society that is not related to it—may gather eagles. Hopi clan ownership of traditional eagle nests is well documented in the anthropological literature. "The nests of eagles near village ruins are owned by the descendants of clans which once lived in their neighborhood." Jesse Walter Fewkes, Property Rights in Eagles Among the Hopi, 2 American Anthropologist (n.s.), 690–707, 693 (1900). "The territory around the Hopi villages where eagles may be found is, and has been from time immemorial, divided into portions or allotments, which are controlled by certain clans or families. These territories extend as far as 50 and 60 miles from the villages." H.R. Voth, Notes on the Eagle Cult of the Hopi, collected in H.R. Voth, Brief Miscellaneous Hopi Papers, Field Columbian Museum, Publication 157, 107–109, Anthropological Series 11(2)(1912). Clan ownership of eagle nesting areas corresponds to the early settlement areas and migration routes of the clans before they arrived at their modern villages. The Hopi regard the eagles as embodying the spirits of their ancestors, and the clan areas often contain, or are very close to, Hopi clan ruins.

Anthropologists have described the "famous nest at Wupatki" as an important area for traditional eagle gathering by the Hopi. Florence H. Ellis, The Hopi: Their History and Use of Lands (n.d.) 149–154, collected in Hopi Indians (1974). Wupatki National Monument was set aside by President Coolidge in 1924 under the authority of the Antiquities Act, 16 U.S.C. §§ 431–33. The Proclamation is silent on eagle gathering. It identified the purpose of the monument in language common to the time; that is, to reserve and protect "prehistoric ruins built by the ancestors of a most picturesque tribe of Indians still surviving in the United States, the Hopi or People of Peace." Proc. No. 1721 (43 Stat. 1977).

Legal Considerations

The National Park Organic Act created the NPS and defined its purpose in relevant part as follows:

> The service * * * shall promote and regulate the use of the Federal areas known as national parks, monuments and reservations * * * by such means and measures as conform to the fundamental purpose * * * which purpose is to conserve the scenery and the natural and historic objects and the wildlife therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations. 16 U.S.C. 1.

The 1916 Act further authorizes the Secretary of the Interior to make "such rules and regulations as he may deem necessary or proper for the use and management of" the National Park System, and to "provide in his discretion for the destruction of such animals and of such plant life as may be detrimental to the use of" units of the National Park System. 16 U.S.C. 3.

In 1978, section 1 of the Organic Act was amended to include these provisions:

> Congress declares * * * [that the] National Park System [shall be] preserved and managed for the benefit and inspiration of all the people of the United States * * * [and] directs that the promotion and regulation of the various areas of the National Park System * * * shall be consistent with and founded in the purpose established by Section 1 * * * to the common benefit of all the people of the United States. The authorization of activities shall be construed and the protection, management, and administration of these areas shall be conducted in light of the high public value and integrity of the National Park System and shall not be exercised in derogation of the values and purposes for which these various areas have been established except as may have been or shall be directly and specifically provided by Congress. 16 U.S.C. 1a–1.

With some exceptions, the NPS has generally prohibited consumptive uses of National Park System resources except as specifically authorized by Congress. Applicable regulations generally prohibit hunting of wildlife, and prohibit removal of plants, paleontological, archeological, cultural or mineral resources, but allow recreational fishing and the collection of fruits, nuts, and berries for personal consumption. See 36 CFR 2.1(a); 2.1(c); 2.2 and 2.3.

Constitutional Considerations and Statutes, Court Decisions, and Executive Orders that Address Indian Religious Ceremonial Concerns

The following discussion explains why we believe applicable laws and policies allow the NPS to accommodate the Hopi's religious ceremonial interest in collecting golden eaglets (*Aquila chrysaeots*) at Wupatki National Monument to the extent it will not result in impairment of the resources protected by the National Park Service Organic Act.

Constitutional considerations. The leading judicial guidance on the intersection between management of federal non-Indian lands and Indian religious practices is *Lyng* v. *Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439 (1988). The Supreme Court there made clear that the First Amendment's free exercise clause permits curtailing Indian religious practices on federal lands in appropriate circumstances. See also *U.S.* v. *Hugs*, 109 F.3d 1375 (9th Cir. 1997) (permit requirement of Bald and Golden Eagle Protection Act does not violate free exercise clause when applied to Native

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American religious practices, even though it imposed a substantial burden on the practice of Native American religions in which eagles and eagle parts "play a central role," because it was the least restrictive means of serving the compelling governmental interest of protecting eagles, while permitting access to eagles and eagle parts for religious purposes); Regulation of Hardrock Mining (Solicitor's Opinion M #36999, Dec. 27, 1999) (Constitution does not compel rejection of the proposed mining plan on BLM-managed public land even though it would seriously and irreparably degrade a cultural resource of importance to a nearby Indian Tribe). The Constitution does not, in other words, require the National Park Service to accommodate uses, by Indians or others, of national park system resources for religious ceremonial purposes. The Supreme Court also said in *Lyng*, however, that "the Government's rights to the use of its own land * * * need not and should not discourage it from accommodating [Indian] religious practices * * *" 485 U.S. at 454. See also Solicitor's Opinion M #36999, at 5. Such accommodations may be undertaken in appropriate cases without raising questions under the establishment clause of the First Amendment. See *Bear Lodge Multiple Use Assoc.* v. *Babbitt*, 175 F.3d 814 (10th Cir. 1999), cert. denied, 2000 WL 305849 (March 27, 2000) (upholding Park Service's encouragement of a voluntary month-long "no-climb" period at Devil's Tower National Monument in order to accommodate Indian religious practices); Office of Legal Counsel, Department of Justice, Memorandum to the Secretary of the Interior—Permissible Accommodation of Sacred Sites, September 18, 1996, p. 1 (federal government "has broad latitude to accommodate the use of sacred sites by federally recognized Indian tribes" without violating the establishment clause).

Such accommodations may appropriately provide preferences for Indian tribes and their members. Such preferences have unique and deep roots in American law, and may be upheld when similar practices involving others might not pass muster. See, e.g., *Morton* v. *Mancari*, 417 U.S. 535 (1974) (Bureau of Indian Affairs hiring preference for Indians upheld because policy was based on political relationship between Tribes and Federal Government); *Rupert* v. *Director, U.S. Fish & Wildlife Service*, 857 F. 2d 32 (1st. Cir. 1992) (upholding exemption from criminal prosecution for possession of eagle feathers by members of federally recognized tribes); *Peyote Way Church of God* v. *Thornburgh*, 922 F.2d 1210, 1217 (5th Cir. 1991) (upholding statutory exemption from laws prohibiting peyote possession for Native American Church members, the court noting that the federal-tribal relationship "precludes the degree of separation between church and state ordinarily required by the First Amendment"); *United States* v. *Gibson*, 2000 WL 117987 (11th Cir. Aug. 21, 2000) (limitation of religious use exemption under Bald and Golden Eagle Protection Act to Indians who were members of federally recognized tribes did not violate non-tribal members" constitutional or statutory free exercise rights).

The Religious Freedom Restoration Act (RFRA). RFRA, enacted in 1993, 42 U.S.C. 2000bb *et seq.*, provides that the government may substantially burden a person's exercise of religion only if the exercise is in furtherance of a compelling governmental interest and it is the least restrictive means of furthering that compelling governmental interest.[1] There is a reasonable argument that the NPS regulations prohibiting collection of golden eaglets in Wupatki National Monument may substantially burden the Hopis' exercise of religion, to the extent that collection of these resources may be regarded as a necessary element in the Hopis' religious ceremony. Whether the prohibition could be sustained under RFRA would depend on whether there is a compelling governmental interest at stake, and whether the prohibition is the least restrictive means of furthering it. Since the NPS is charged with the conservation of wildlife under its Organic Act, 16 U.S.C. 1, it is understood that the NPS has a compelling governmental interest in the absolute bar on the take of wildlife for all purposes except scientific research. There is a question however if this prohibition is the least restrictive means to further that interest. The question becomes more difficult given the Hopi religion's necessity of taking a golden eaglet from a specific location of historical and religious importance, in this instance, Wupatki National Monument. Prohibiting this religious exercise may amount to a substantial burden on their religion. Cf. *Callahan* v. *Woods*, 736 F.2d 1269, 1272 (9th Cir. 1984) ("If the compelling state goal can be accomplished despite the exemption of a particular individual, then a regulation which denies an exemption is not the least restrictive means of furthering the state interest.") We do not have to reach these questions here, however, if the NPS has the authority to, and has decided to accommodate, the Hopi Tribe's religious ceremonial collection of golden eaglets at Wupatki National Monument. Plainly the RFRA encourages, and does not prohibit, such accommodation.

The American Indian Religious Freedom Act (AIRFA). This Act, enacted in 1978, declares "the policy of the United States to protect and preserve for American Indians their inherent right of freedom to believe, express and exercise the[ir] traditional religions * * * including but not limited to access to sites, use and possession of sacred objects, and the freedom to worship through ceremonials and traditional rites." 42 U.S.C. 1996. The second section of AIRFA, not codified in the U.S. Code, requires the President to direct the various federal agencies responsible for administering relevant laws to "evaluate their policies and procedures in consultation with native traditional religious leaders in order to determine appropriate changes necessary to protect and preserve Native American religious cultural rights and practices," and directed the President to report to Congress with twelve months of enactment the results of the evaluation. 92 Stat. 469.

The Secretary of the Interior convened a task force of federal agencies, which issued the report called for by Congress. American Indian Religious Freedom Act Report (Federal Agencies Task Force, August 1979). The Task Force discussed, among other things, the problem of restricting the gathering of indigenous natural substances from federal lands for use in Indian religious ceremonies and practices, noting in particular that the "gathering of a specific plant or animal may be forbidden or limited by conservation statutes." *Id.* at 51–53. It recommended that each agency "accommodate Native American religious practices to the fullest extent possible" under existing statutes, and also that agencies "revise existing regulations, policies and practices to provide for separate consideration of any Native American religious concerns * * *. *Id.* at 62–63. The report also recommended that agencies "provide exemptions from restrictions on access to and gathering, use and possession of federal property for Native American religious purposes similar to those provided for scientific purposes." *Id.* at 63.

AIRFA does not create any judicially enforceable rights. *Lyng* v. *Northwest Indian Cemetery Protective Ass'n*, 485 U.S. 439, 455, 471 (1988). Courts have, however, construed AIRFA to require federal agencies to:

> learn about, and to avoid unnecessary interference with, traditional Indian religious practices, [and to] evaluate their policies and procedures in light of the Act's purpose, and ordinarily should consult Indian leaders before approving a project likely to affect religious practices. AIRFA does not, however, declare the protection of Indian religions to be an overriding federal policy, or grant Indian religious practitioners a veto on agency action.

Wilson v. *Block*, 708 F.2d 735, 746 (D.C. Cir. 1983) *cert. denied*, 464 U.S. 956 (1983). Thus AIRFA requires federal agencies to consider, but not necessarily to defer to, Indian religious values. *Id.* at 747. See also *Havasupai Tribe* v. *U.S.*, 752 F. Supp. 1471, 1488 (D. Ariz. 1990), *aff'd* 943 F.2d 32 (9th Cir. 1991), *cert. denied*, 503 U.S. 959 (1992); cf. *Lyng*, *supra*, 485 U.S. at 454.

Executive Orders and other Policy Statements. A 1994 policy statement, and Executive Orders issued in 1996 and 1998, have all promoted government accommodation of Indian religious practices within the limits of agency discretion. President Clinton's "Policy Concerning Distribution of Eagle Feathers for Native American Religious Purposes" (1994) recognizes the important place eagles occupy in many Native American religious and cultural practices and directs executive departments and agencies to "work cooperatively with tribal governments and to reexamine broadly their practices and procedures to seek opportunities to accommodate Native American religious practices to the fullest extent under the law." 59 FR 22,953 (Apr. 29, 1994).

President Clinton's 1996 Executive Order on Sacred Sites directs that federal agencies:

> shall, to the extent practicable, permitted by law, and not clearly inconsistent with essential agency functions, (1) accommodate access to and ceremonial use of Indian sacred sites by Indian religious practitioners and (2) avoid adversely affecting the physical integrity of such sacred sites.

Executive Order 13,007, section 1, 61 FR 26,771 (1996). The Order defines "sacred site" as a "specific, discrete, narrowly delineated location of Federal land" identified by tribal interests as "sacred by virtue of its established religious significance to, or ceremonial use by an Indian religion." *Id.* § 1(b)(iii). While the Order does not reach directly to the collection of plants or wildlife on federal land for Indian religious purposes, it is suggestive of accommodation where possible. The Departmental Manual implementing the Sacred Sites Executive Order requires Interior agencies to establish procedures that accommodate "access to and ceremonial use by religious Indian practitioners of Indian sacred sites" and to "consult with tribal governments and give full consideration to tribal views in its decision making process." 512 DM §§ 3.4(1)(b); 3.7 (1998).

President Clinton's 1998 Executive Order on Consultation and Coordination with Indian Tribal Governments states in pertinent part that "each agency shall, to the extent practicable and permitted by law, consider any application by an Indian tribal government for a waiver of statutory or regulatory requirements." No. 13,084, 63 FR 27655 (May 14, 1998). Recently, President Clinton reaffirmed the United States' commitment to consultation with Indian tribal governments and issued Executive Order 13175 (November 6, 2000) which details the process agencies must follow to ensure meaningful and timely input from tribal officials in the development of regulations or policies that have tribal implications.

None of these executive directives purport to (nor could they) provide legal authority to override existing laws such as those that govern management of the national park system. To the extent permitted by law, however, they direct federal agencies to accommodate uniquely Indian needs.

General discussion and conclusion. In light of the statutes, court decisions, executive orders and other legal considerations discussed above, we believe the NPS has a reasonable legal basis for promulgating a regulation that allows the Hopi Tribe to collect golden eaglets at Wupatki National Monument for religious ceremonial purposes. The collection of golden eaglets from specific geographic areas is an important part of the Hopi religion, and there is an ancestral and historical connection between the Hopi Tribe and Wupatki National Monument. The proposed regulation would allow the NPS to include terms and conditions, including gathering times, take limits, and permit tenure, that are sufficient to protect the park resources against impairment, and would require compliance with the Bald and Golden Eagle Protection Act.

The proposed regulation, and the accompanying environmental assessment, applies only to this narrow situation. It is possible that the NPS will receive requests from other tribes for similar rule changes to address their religious practices. Such requests will be addressed on their merits. Any further rule change must follow notice and comment and other procedures required by applicable law. The current proposal is to deal strictly and exclusively with the Hopi Tribe's proposal to collect golden eaglets at Wupatki National Monument.

Public Participation: If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to the National Park Service, Ranger Activities Division, Suite 7408, 1849 C St. NW., Room 7413, Washington, DC 20240. You may also comment via the Internet to WASO_Regulations@nps.gov. Please submit Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please include "RIN 1024–AC86" in your subject line and your name and return address in the body of your message. Finally, you may hand-deliver comments to Kym Hall, National Park Service, 1849 C St. NW., Room 7413, Washington, DC 20240. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Drafting Information: The principal author of this proposed interpretive rule is John Leshy, Solicitor, Department of the Interior.

Compliance With Other Laws

Regulatory Planning and Review (E.O. 12866)

In accordance with the criteria in Executive Order 12866, OMB has determined the rule not to be significant.

(1) This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

[1] The Supreme Court has held that RRA is unconstitutional as applied to state governments, *City of Boerne* v. *Flores*, 521 U.S. 507, 117 S.Ct. 2157 (1997), but the question here is the impact of RFRA on the federal government.

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(2) This rule does not interfere with actions taken or planned by another agency. The Hopi must obtain a permit from the Fish and Wildlife Service before being allowed to collect golden eaglets. However, this rule does not at all affect the standards, times or necessary elements for obtaining that permit. This rule only addresses the ability of the Hopi to collect golden eaglets from Wupatki National Monument after they have received the necessary permit from FWS.

(3) This rule does not alter the budgetary effects of entitlements, grants, user fees, or monetary loan programs or the rights or obligations of their recipients.

(4) This proposed rule may be controversial because it proposes to allow a new collection of wildlife, but it proposes to do so only in very extremely limited circumstances, for a single or very few specimens of a single species of non-endangered wildlife in a single unit of the National Park System for a very narrowly defined purpose by a single entity, and only then when it is determined by the U.S. Fish & Wildlife Service and the National Park Service to be consistent with the laws protecting wildlife and with the laws preventing impairment of natural resources in the National Park System, respectively.

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*). The economic effects of this rule are local in nature and negligible in scope.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule will have no effect on small or large businesses. It addresses only the Hopi Tribe's religious ceremonial collection of golden eaglets at Wupatki National Monument and involves no small businesses. This rule:

1. Does not have an annual effect on the economy of $100 million or more.

2. Does not represent a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

3. Does not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. The Department has determined that this rule meets the applicable standards provided in section 3(a) and 3(b)(2) of Executive Order 12988.

Takings (E.O. 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. No property acquisition or impacts on private property owners are expected due to the administrative nature of the rule. The rule addresses only Hopi collection of golden eaglets from Wupatki National Monument, and no private property rights are involved or affected.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This regulation will not have a substantial direct effect on the states, or on the distribution of power and responsibilities among the various levels of government. The rule addresses only the collection of golden eaglets from Wupatki National Monument, a unit of the national park system, and such activity does not require state activity.

Civil Justice Reform (E.O. 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. The preamble clearly explains that the rule creates a special exception to 36 CFR 2.1(d) which allows the Hopi to collect golden eaglets from Wupatki National Monument for religious ceremonial purposes subject to conditions sufficient to prevent impairment.

Paperwork Reduction Act

This rule does not require an information collection from 10 or more parties. It does not require submissions under the Paperwork Reduction Act or OMB form 83–I.

National Environmental Policy Act

This rule does not constitute a major federal action significantly affecting the quality of the human environment. A draft Environmental Assessment has been completed. Copies of that assessment may be obtained through one of several methods.

—Internet: http://www.nps.gov/wupa/
—By email: wupa_superintendent@nps.gov
—By mail: Superintendent, Wupatki National Monument, 6400 N. Highway 89, Flagstaff, Arizona 86004.

Public comments regarding the Environmental Assessment may be submitted to Kym Hall, National Park Service, 1849 C Street NW., Room 7413, Washington, DC 20240, by email to WASO_regulations@nps.gov, or by fax at (202) 208–6756. Public comments will be accepted through March 19, 2001.

Government-to-Government Relationship With Tribes

In accordance with the Executive Order 13175 "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249) and 512 DM 2, we have identified potential effects on the Hopi Indian Tribe. The proposed regulation, and the accompanying environmental analysis, applies only to this narrow situation. It is possible that the NPS will receive requests from other tribes for similar rule changes to address their religious practices. Such requests will be addressed on their merits. Any further rule change must follow notice and comment and other procedures required by applicable law. The current proposal is to deal strictly and exclusively with the Hopi Tribe's proposal to collect golden eaglets at Wupatki National Monument. We have consulted with the Hopi Tribe regarding the proposed rule. We will further consider their comments, and the comments of all interested parties, that are received during the comment period.

Clarity of This Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments on how to make this rule easier to understand, including answers to questions such as the following: (1) Are the requirements in the rule clearly stated? (2) Does the rule contain technical language or jargon that interferes with its clarity? (3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Would the rule be easier to understand if it were divided into more (but shorter) sections? (A "section" appears in body type and is preceded by the symbol "§" and a numbered heading; for example, **§ 7.101 Wupatki National Monument** (5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the proposed rule? What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street NW, Washington, DC 20240. You may also email the comments to this address: Exsec@ios.doi.gov.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and recordkeeping requirements.

Accordingly, we propose to amend Part 7 of 36 CFR as set forth below:

PART 7—SPECIAL REGULATIONS; AREAS OF THE NATIONAL PARK SYSTEM

1. The table of contents is amended by adding § 7.101 to read as follows:

Sec.

* * * * *

7.101 Wupatki National Monument.

2. The authority for Part 7 is revised to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q) 462(k). Sec. 7.96 also issued under D.C. Code 8–137 (1981); D.C. Code 40–721 (1981). Sec. 7.101 also issued under 42 U.S.C. 2000bb; 42 U.S.C. 1996; Executive Orders No. 13084, 13007, 13175.

3. Add § 7.101 to read as follows:

§ 7.101 Wupatki National Monument.

(a) *Collection of golden eaglets from Wupatki National Monument by Hopi Tribe.* Upon terms and conditions sufficient to prevent impairment to park resources, and upon a showing that the Tribe has a valid permit to collect golden eaglets under the Bald and Golden Eagle Act, 16 U.S.C. 668–668d, the Superintendent of Wupatki National Monument shall grant a permit to the Hopi Tribe to collect golden eaglets from Wupatki National Monument for religious ceremonial purposes.

(b) [Reserved].

Dated: January 12, 2001.

Kenneth L. Smith,

Assistant Secretary, Fish and Wildlife and Parks.

[FR Doc. 01–1743 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–70–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX–126–3–7474; FRL–6934–3]

Approval and Promulgation of Air Quality State Implementation Plans (SIP); Texas: Motor Vehicle Inspection and Maintenance (I/M) Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: We, the EPA, are proposing full approval of revisions to the Vehicle Inspection and Maintenance (I/M) Program for the Dallas/Fort Worth (DFW), Houston-Galveston Area (HGA) and El Paso (ELP) ozone nonattainment areas adopted by the State of Texas. The revisions replace the two-speed idle test in Dallas and Tarrant Counties with ASM–2, expand the upgraded I/M program to cover the entire DFW nonattainment area plus five additional counties, and implement On-Board Diagnostic (OBD) testing in Dallas, Tarrant, Harris, and El Paso Counties. The I/M SIP revision is part of the DFW Attainment Demonstration.

DATES: Comments must be received on or before February 21, 2001.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations. Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. Texas Natural Resource Conservation Commission, 12100 Park 35 Circle, Austin, Texas 78711–3087. Persons interested in examining these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra G. Rennie, Air Planning Section (6PD–L), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7367.

SUPPLEMENTARY INFORMATION:

What Is the Status of the Current I/M Program in Texas?

A low-enhanced vehicle I/M program called the Texas Motorist Choice (TMC) Program is operating in the Dallas-Fort Worth, Houston, and El Paso ozone nonattainment areas. The program consists of a 2-speed idle test and gas cap test in Dallas, Tarrant, Harris, and El Paso counties, the core counties of the program. In addition, the program has a remote sensing component to identify gross polluters that commute into the core counties from Denton and Collin Counties in the Dallas-Fort Worth area, and from seven surrounding nonattainment counties in the Houston area. An interim conditional approval for this program was proposed on October 3, 1996 (61 FR 51651). An interim final conditional approval was published on July 11, 1997 (62 FR 37138). The conditions were removed from the interim approval on April 23, 1999 (64 FR 19910).

The State submitted an approvable 18-month demonstration on February 8, 1999, as required by the National Highway System Designation Act of 1995 (NHSDA), Public Law 104–59, section 348(c)(1). The program was not fully approved at that time because one provision of the interim approval required that the State provide evidence that the remote sensing program be effective in identifying the shortfall in number of vehicles needed to make up for the lack of a tailpipe testing program in all the nonattainment counties. The State began the remote sensing program in October 1998. Because the State submitted this I/M SIP revision in which it expands geographic coverage, the requirement to cover the shortfall with remote sensing (the final barrier to final full approval) is eliminated when the new I/M tests start in each county in the DFW area.

Why Is the State Submitting This SIP Revision to the I/M Program?

The DFW nonattainment area was bumped up from moderate to serious effective March 23, 1998 (63 FR 8128). An attainment demonstration submitted in March 1999 was found to be incomplete, which started a Federal sanction clock (64 FR 29570, June 2, 1999). This I/M SIP revision was submitted as part of the new DFW attainment demonstration. Modeling has shown that NO_X reductions are essential to reaching attainment in the DFW area. As a result, the Texas Motorist Choice I/M program has been revised to include measurement for NO_X emissions and to provide additional NO_X emission reductions by expanding coverage of the program to all four counties within the nonattainment area (Dallas, Tarrant, Collin and Denton) and selected attainment counties in the DFW Consolidated Metropolitan Statistical Area (CMSA).

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What Did the State Submit?

The I/M SIP revision was submitted under a Governor's letter dated April 25, 2000. The State plans to replace the 2-speed idle test in the DFW area with ASM–2, and expand the testing area to include all four nonattainment counties plus five additional counties contiguous to the nonattainment area (Ellis, Johnson, Kaufman, Parker, and Rockwall). The SIP revision contains a narrative, rules, modeling, and supporting documentation as outlined in the requirements of the Federal I/M rules.

What Is an ASM–2 Test?

Acceleration Simulation Mode, known as ASM, operates the vehicle at a steady load and steady speed on a treadmill-type device called a dynamometer. The test more accurately simulates real world driving conditions than the current two-speed idle test. ASM–2 means that the test is performed in both approved testing modes, *i.e.*, operating the vehicle at 50% load at 15 MPH (ASM5015) and then operating the vehicle at 25% load at 25 MPH (ASM2525). The test measures exhaust concentrations for hydrocarbons, carbon monoxide, and NO_X. Pass/fail standards are based on the chassis model year and engine displacement.

EPA's Analysis of Texas's I/M Program

The EPA reviewed the State's proposal against the requirements contained in the Act and Federal I/M rules (40 CFR part 51, subpart S). The submittal was also reviewed for administrative completeness under criteria contained in Federal rules (40 CFR part 51, appendix V). The submittal was found complete in a letter dated June 23, 2000.

The following analysis addresses how the State intends to fulfill the requirements of the Act and the Federal I/M rules. Only the sections of the rule for which the State has made changes are discussed. All other sections of this I/M SIP submittal remain the same as previously approved on an interim basis.

Legal authority for the State to implement the I/M program continues to be granted by Chapter 382 of the Texas Health and Safety Code, and Transportation Code sections 502 and 548.

Section 51.350 Applicability

EPA's regulations establish the minimum geographic scope for nonattainment I/M programs based on nonattainment classification and area population. As stated previously, the Texas Motorist Choice program currently approved in the SIP does not include tailpipe testing throughout the urbanized nonattainment areas. The vehicle shortfall is covered through a remote sensing program.

Beginning January 1, 2001, On-Board Diagnostic (OBD) testing will be added to the low-enhanced, two-speed idle test currently implemented in Harris, Dallas, Tarrant, and El Paso Counties. The shortfall in vehicle coverage for the HGA nonattainment area will continue to be made up by remote sensing within Harris County to identify gross polluting vehicles commuting in from the seven surrounding nonattainment counties. The shortfall in vehicle coverage for the DFW nonattainment area will continue to be made up by remote sensing within Dallas and Tarrant Counties to identify gross polluting vehicles commuting in from Collin and Denton Counties only until tailpipe testing begins in those counties. In prior actions on the Texas I/M SIP, we said the remote sensing program must prove to be effective in identifying and obtaining repairs on the same number of vehicles that would be brought in if the program covered the entire urbanized area. Otherwise, the Texas I/M core program areas (Harris County, Dallas, and Tarrant Counties) must be expanded to include the entire urbanized area. (See, 61 FR 51659 and 62 FR 37141.) The DFW I/M core area is being expanded to include the entire nonattainment area plus five additional counties in the CMSA. An expansion to the entire nonattainment area is currently being proposed by the State for HGA but is not the subject of this notice.

Beginning May 1, 2002, the State commits to begin vehicle testing in Dallas, Tarrant, Collin and Denton Counties utilizing ASM–2 or a vehicle emissions testing program that meets SIP emissions reduction requirements and is approved by EPA. This will be in addition to OBD testing.

Beginning May 1, 2003, the State will expand the I/M program to include the attainment counties of Ellis, Johnson, Kaufman, Parker, and Rockwall. These additional counties will transition from performing just safety inspections plus gas cap pressure testing to also doing OBD and ASM–2 (or other EPA approved) testing as described above.

The State submittal meets the requirements of § 51.350 of the Federal I/M regulation for approval.

Section 51.351–352 Low Enhanced I/M Performance Standard

The State submitted a modeling demonstration using the EPA computer model MOBILE5a_h and localized parameters showing that the low enhanced performance standard can be met for Volatile Organic Compounds (VOCs) and Nitrogen Oxides (NO_X) in the DFW area with the ASM–2 test proposed by the State. The low enhanced performance standard is established in 40 CFR 51.351(g). The State modeled with a test and repair program that assumes a 100 percent credit for network effectiveness, although the compliance rate is estimated at 95 percent. The State submitted an approvable 18-month demonstration on February 8, 1999, as required by the NHSDA that validated the program credit claimed.

The State submittal meets the performance standard requirement of the Federal I/M regulation for approval.

Section 51.354 Adequate Tools and Resources

Section 382.037(e) and (k), of the Texas Health and Safety Code, authorizes the program to charge an emission inspection fee. The SIP narrative also describes the budget, staffing support, and equipment that will be added to the existing personnel and budget needed to implement the program.

The State submittal meets the adequate tools and resources requirements of the Federal I/M regulations for approval.

Section 51.357 Test Procedures and Standards

Vehicles tested in all area programs are also subject to an antitampering check and a gas cap pressure test. Vehicles that are model year 1996 and newer will receive an OBD check. In the DFW I/M program area, vehicles that are model year 1995 and older will be subject to an ASM–2 loaded mode tailpipe test. The State already committed to implementing OBD testing on all 1996 and newer vehicles beginning January 1, 2001, in a SIP revision that was approved April 23, 1999 (64 FR 19910).

The State submittal meets this requirement for vehicle coverage of the Federal I/M rule.

Section 51.358 Test Equipment

The revised I/M SIP describes the ASM–2 test equipment that will be used in the DFW I/M program area. Specifications are included. OBD testing equipment will meet all Federal requirements contained in 40 CFR 85.2207–2231 and Society of Engineers practices in J2962, J1978, and J1979. The OBD equipment will be tethered to the emissions analyzer which will automatically record the data into a central data collection system.

The State submittal meets the requirement for vehicle coverage of the Federal I/M rule.

Section 51.371 On-Road Testing

Vehicles commuting into Dallas and Tarrant Counties from Denton and Collin Counties will continue to be monitored via remote sensing through April 30, 2002. Starting May 1, 2002, all subject vehicles in Collin and Denton County will receive a tailpipe emissions test, as described in this proposal and the revised SIP.

In addition, the State will comply with the on-road testing requirements by continuing to use remote sensing to evaluate the on-road emissions performance of at least 20,000 vehicles (or 0.5 percent of the fleet) subject to emissions testing in all I/M program areas. All probable high-emitting vehicles which are registered within these counties are identified for compliance follow-up.

The State submittal meets the requirement for on-road testing of the Federal I/M rule.

Section 51.373 Implementation Deadlines

The Texas Motorist Choice Program met the November 15, 1997, start date requirement of the NHSDA. The Texas Motorist Choice Program started in July 1996 in Dallas and Tarrant Counties and in January 1997 in Harris and El Paso Counties. It has been operating continuously since that time.

The revised I/M SIP commits to a schedule for start-up of ASM–2 testing activities and OBD testing. All other aspects of this regulation remain the same as previously approved on an interim basis.

The State submittal meets the compliance with implementation plan submission requirements of the Federal I/M regulations for approval.

Notice of Proposed Rulemaking

Our review of this submittal indicates that the proposed SIP revision meets the minimum requirements of the Act and Federal I/M rules. Based upon the discussion contained in the previous analysis sections and in the Technical Support Document accompanying this notice, we find that the State's submittal represents an acceptable approach to the I/M requirements and meets the requirements for approval.

We propose to grant full approval of the Texas Motorist Choice I/M program in the DFW area. We also propose to approve the I/M SIP revision pertaining to the Houston-Galveston Area and El Paso nonattainment areas.

Nothing in this action should be construed as permitting, allowing, or establishing a precedent for any future request for revision to any State implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. This proposed action merely approves state law as meeting federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). For the same reason, this proposed rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 4, 2001.

Gregg A. Cooke,

Regional Administrator, Region 6.

[FR Doc. 01–1519 Filed 1–19–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 534

[Docket No. NHTSA 2001–8668]

RIN 2127–AG97

Fuel Economy Standards—Rights and Responsibilities of Manufacturers in the Context of Changes in Corporate Relationships

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes a new regulation to define the rights and responsibilities of manufacturers under

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the agency's corporate average fuel economy program in the context of changes in corporate relationships. The proposed regulation addresses the rights and responsibilities of predecessors and successors, as well the rights and responsibilities of manufacturers in other situations where there have been changes in corporate relationships, e.g., changes in control. Among other things, the proposed regulation would address how fuel economy credits are allocated in these types of situations.

DATES: Comments must be received by March 23, 2001.

ADDRESSES: You should mention the docket number of this document in your comments and submit your comments in writing to: Docket Management, Room PL–401, 400 Seventh Street, S.W., Washington, D.C. 20590. Alternatively, you may submit your comments to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on "Help & Information" or "Help/Info" to obtain instructions for filing the document electronically. (This website also enables you to view the materials in the docket for this rulemaking.)

You may call Docket Management at 202–366–9324. You may visit the Docket from 10:00 a.m. to 5:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Edward Glancy, Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590 (202–366–2992).

SUPPLEMENTARY INFORMATION:

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I. Background

A. Statutory Provisions

In December 1975, Congress enacted the Energy Policy and Conservation Act (EPCA) in response to the energy crisis created by the oil embargo of 1973–74 and the level of oil imports, particularly from OPEC sources. Congress included a provision establishing an automotive fuel economy regulatory program. That provision added a new Title V, "Improving Automotive Efficiency," to the Motor Vehicle Information and Cost Saving Act. Congress has made various amendments to the fuel economy provisions since 1975, and the fuel economy provisions are now codified in Chapter 329 of Title 49 of the United States Code.

Under Chapter 329, manufacturers are required to meet average fuel economy standards for passenger automobiles and light trucks. While separate fuel economy standards apply for each model year, manufacturers that fail to achieve the level of a standard within a particular model year do not necessarily violate the statute. Instead, under certain circumstances, a shortfall in one year (or years) can be offset if a manufacturer exceeds the standard in another year (or years). Under the Act, manufacturers earn credits for exceeding average fuel economy standards which may be carried back for three model years or carried forward for three model years.

Chapter 329 defines the term "manufacturer" as "a person engaged in the business of manufacturing automobiles, including a predecessor or successor of the person to the extent provided under regulations prescribed by the Secretary * * *" (The Secretary has delegated responsibility for the automotive fuel economy program to NHTSA. 49 CFR 1.50(f).) To date, we have not issued any regulations concerning predecessors and successors. We have also not issued any regulations concerning the rights and responsibilities of manufacturers in other situations where there have been changes in corporate relationships, *e.g.*, changes in control.

B. Past Positions Taken by NHTSA With Respect to Predecessors and Successors

Under general principles of corporate law, the term "successor" ordinarily refers to a corporation which, through amalgamation, consolidation, or other legal succession, becomes invested with the rights and assumes the burdens of another corporation. See Black's Law Dictionary, West Publishing Co.

The automotive fuel economy program contains provisions which raise special issues related to the rights and burdens of predecessors and successors. Of particular significance are the provisions related to credits.

Because credits may be carried backward three years and forward three years, compliance with a fuel economy standard for a particular model year may actually be determined over as much as a seven-year period. A variety of changes in corporate relationships may occur during such a long period, e.g., mergers, acquisitions, spin-offs, etc., and these provisions raise the issue of how credits and shortfalls should be allocated when such changes occur.

In a 1990 letter to Chrysler, we addressed how fuel economy values should be calculated for Chrysler and AMC during the model year in which Chrysler acquired AMC, model year (MY) 1987. We concluded that all of Chrysler's and AMC's vehicles should be treated as manufactured by the same manufacturer for that model year. In reaching this conclusion we stated the following: [1]

> Fuel economy standards apply to passenger automobiles manufactured by a manufacturer, for a particular model year. See section 502(a)(l). Moreover, average fuel economy is calculated based on the total number of passenger automobiles manufactured in a given model year by a manufacturer. See section 503(a)(l). Under section 503(c), the term "passenger automobiles manufactured by a manufacturer" includes all automobiles manufactured by persons who control, are controlled by, or are under common control with, such manufacturer." Since Chrysler controlled AMC prior to the end of the 1987 model year, and since fuel economy standards apply to particular model years as a whole and not to separate parts of a model year, it is our opinion that all of the vehicles produced by both Chrysler and AMC for model year 1987 shall be treated as if manufactured by the same manufacturer, *i.e.*, placed into one fleet. Otherwise, one or both of the manufacturers would have two separate CAFÉ values, pre-acquisition (or pre-control) and post-acquisition (or post-control), for the same model year.

We also addressed generally the issue of how credits may be applied between predecessors and successors, along with the legal and policy issues associated with applying credits between predecessors and successors. Among other things, we stated the following:

[1] Our 1990 letter referred to the language and section numbers of the Motor Vehicle Information and Cost Savings Act. Those provisions were codified into 49 U.S.C. Chapter 329 by Pub. L. 103–272 (July 5, 1994). Section 1(a) of that law stated that the laws being codified were being done so "without substantive change".

> We will now address generally the issue of how credits may be used where one manufacturer is the successor of another. In discussing the issue, we will refer to the following hypothetical example: A and B are both car manufacturers. After consolidation, A is the only surviving corporation and is invested with the rights and assumes the burdens of B. Thus, A is the "successor" of B.
>
> While this example and subsequent discussion is for passenger automobiles, the relevant requirements concerning the earning and availability of credits are essentially identical for passenger automobile standards and light truck standards. Compare section 502(l)(1)(B) and 49 CFR Part 535, and see 45 FR 83233–36, December 18, 1980. Thus, our analysis for passenger automobile standards is also relevant to light truck standards.
>
> Section 502(l)(1)(B) states:
>
> Whenever the average fuel economy of the passenger automobiles manufactured by a manufacturer in a particular model year exceeds an applicable average fuel economy standard * * *, such manufacturer shall be entitled to a credit calculated under subparagraph (C), which—
>
> (i) shall be available to be taken into account with respect to the average fuel economy of that manufacturer for any of the three consecutive model years immediately prior to the model year in which such manufacturer exceeds such applicable average fuel economy standard, and
>
> (ii) to the extent that such credit is not so taken into account pursuant to clause (i), shall be available to be taken into account with respect to the average fuel economy of that manufacturer for any of the three consecutive model years immediately following the model year in which such manufacturer exceeds such applicable average fuel economy standard.
>
> We note first that credits earned by a particular manufacturer are only "available to be taken into account with respect to the average fuel economy of *that* manufacturer," for any of the three model years before, or after, the model year in which the credits are earned. (Emphasis added.) In the example set forth above, B is no longer a manufacturer under the Cost Savings Act. (Indeed, it is no longer a "person" under section 501(8).) Thus, in the absence of some provision concerning "successors," any unused credits that B had earned prior to the consolidation would expire unused, since the only manufacturer to which they are available no longer exists. However, for some purposes B continues to exist as part of A, its "successor."
>
> Section 501(8)'s definition of "manufacturer" does not provide that the term "manufacturer" necessarily includes any predecessor or successor but instead provides that the term does so "to the extent provided under rules which the Secretary shall prescribe." This provision was added by the Automobile Fuel Efficiency Act of 1980 as a conforming amendment to the section concerning modification of local content requirements to encourage domestic production of fuel efficient automobiles and *not* to the section concerning credits. The legislative history does not provide any indication as to why the provision was added, and, to date, NHTSA's administration of the statutory provisions concerning modification of the local content requirements has not turned up a situation for which such rules would be relevant. Should rules be issued under section 501(8), NHTSA would do so by notice-and-comment rulemaking, taking account of the purposes of that section and the statutory scheme as a whole.
>
> Notwithstanding the absence of rules, we do not believe that Congress intended to require the forfeit of a manufacturer's unused credits in a situation where that manufacturer's substance continues to exist as part of a "successor." Thus, taking account of section 501(8) and the statutory scheme as a whole, we conclude that, in the example set forth above, B can be deemed as continuing to exist as part of A, from the time of succession.
>
> This conclusion does not, however, permit the general integration of A's and B's credits and shortfalls. Under section 502(l)(1)(B), credits earned by a particular manufacturer are only "available to be taken into account with respect to the average fuel economy of *that* manufacturer." Since B's existence as part of A only dates from the time of succession, B is not the same manufacturer as A prior to the time of succession. Thus, any credits earned by B would only be available to offset A's shortfalls for the model years during which B exists as part of A, since it is only at that time that the credits earned by B and applied to A can be considered to be taken into account with respect to the average fuel economy of "that manufacturer." Similarly, the only credits earned by A which would be available to B would be those credits earned during the time when B exists as part of A.
>
> The general integration of A's and B's credits would be inconsistent with the basic structure of section 502(l)(1). Assume, for example, that A and B are separate manufacturers for model years 1 through 6, and A is the successor of B for model year 7. If general integration of credits were permitted, credits earned by B in model year 4 could be applied to A's CAFÉ for model years 1–6, as well as model year 7. However, the structure of section 502(l)(1) does not permit this result. Under paragraph (B)(i), any credits earned by B in model year 4 are available to be carried back with respect to B's CAFÉ for any of model years 1, 2 and 3. To the extent that such credits are not so used, paragraph (B)(ii) makes those credits available to be carried forward with respect to B's CAFÉ for any of model years 5, 6 and 7. In order for credits earned by B in model year 4 to be applied to A's CAFÉ for model years 1–6, B's credits would first have to be carried forward to model year 7 (the model year where A is B's successor) and then be carried back to model years 1–6 (for application to A's CAFÉ), a process which has no statutory basis.
>
> We will now apply the general analysis discussed above to the particular facts cited in Chrysler's letter. Prior to MY 1987, Chrysler and AMC were two separate manufacturers. Chrysler acquired AMC during MY 1987, and became the "successor" to AMC at that time. Under section 502(l)(1)(B), credits earned by a particular manufacturer are only "available to be taken into account with respect to the average fuel economy of that manufacturer." Since AMC's existence as part of Chrysler only dates from MY 1987, AMC was not the same manufacturer as Chrysler prior to MY 1987. Thus, any credits earned by AMC would only be available to Chrysler to offset CAFÉ shortfalls incurred in the model years during which AMC exists as part of Chrysler, *i.e.*, MY 1987 and thereafter, since it is only at that time that the credits earned by AMC and applied to Chrysler can be considered to be taken into account with respect to the average fuel economy of "that manufacturer." Similarly, the only credits earned by Chrysler which would be available to AMC would be those credits earned during the time when AMC exists as part of Chrysler, *i.e.*, credits earned in MY 1987 and thereafter.
>
> The issue of the extent to which Chrysler could use AMC's credits was subsequently raised in the context of an enforcement proceeding brought by NHTSA staff concerning Chrysler's apparent violation of the light truck CAFÉ standard for MY 1984. On January 8, 1992, DOT Chief Administrative Law Judge John J. Mathias issued an Initial Decision and Order (I.D.) in which he stated that he agreed with the substance of NHTSA Complaint Counsel's position but concluded that the Complaint should be dismissed because NHTSA had not prescribed rules pursuant to section 501(8) of the Act (since recodified at 49 U.S.C. 32901(a)(13)(A)) that define the extent to which the term "manufacturer" includes any predecessor or successor of a

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manufacturer of automobiles. *CHRYSLER CORPORATION (NHTSA—Fuel Economy Standards Enforcement)*, U.S. Dep't. of Transportation, Office of Hearings, Washington, D.C., Docket 47414 (January 8, 1992). Later, NHTSA's Administrator set aside the I.D. and issued an order directing that the agency commence a proceeding to prescribe such rules. *In re CHRYSLER CORPORATION; Corporate Average Fuel Economy Enforcement Proceeding*, U.S. Dep't. of Transportation, National Highway Traffic Safety Administration, Docket No. 47414 (March 31, 1992).

II. Proposal

A. Introduction

Our initial purpose in developing this proposal was to define the extent to which predecessors and successors of manufacturers of automobiles should be included within the term "manufacturer." However, during the development of the proposal, we decided to expand that purpose. We recognized that a number of the issues concerning how credits may be used between predecessors and successors also arise in the context of other changes in corporate relationships, *e.g.*, changes in control. While we could handle issues related to changes in control by interpretation of the statute, we believe it would be helpful for both the industry and the agency to have a regulation in place which provides guidance in this area.

In developing this proposal, we have attempted to achieve two key goals. First, we would like the regulation to be as faithful as possible to the purpose of the statute and the overall statutory scheme. Second, we would like the regulation to be as simple as possible, while still providing the necessary guidance for the agency and the industry to use in determining how changes in corporate relationships are to be considered in determining compliance with fuel economy standards.

The purpose of Chapter 329 is, of course, energy conservation. As to the overall statutory scheme, we believe there are several aspects that are relevant to how we should treat changes in corporate relationships.

First, to promote flexibility, Congress decided to allow compliance with fuel economy standards to be determined over a multi-year period. In particular, a manufacturer may offset a shortfall for any given model year by using credits it has earned or will earn in the three prior model year or three succeeding model years.

Second, Congress limited the use of credits to the manufacturer which earned them; credits may not be bought or sold.

Third, average fuel economy is measured, and compliance with fuel economy standards determined, for groups of companies within a control relationship rather than for individual companies.

We believe that each of these aspects of the statutory scheme needs to be reflected in the regulation concerning the rights and responsibilities of manufacturers in the context of changes in corporate relationships.

As to our desire to keep the regulation as simple as possible, we are concerned that an effort to comprehensively address all of the various ways corporate relationships may change over time could get the agency bogged down in defining endless situations that it would probably never have to deal with in practice. At the same time, we believe there is a need for the regulation to provide the necessary guidance for the agency and the industry to use in determining how changes in corporate relationships are to be considered in determining compliance with fuel economy standards. We are proposing a regulation that we believe would accomplish this. A discussion of the proposed regulation follows.

B. The Proposed Regulation

The proposed regulation is relatively short. It begins by setting forth definitions of several key terms, including predecessor, successor and control relationship. It includes a section which specifically addresses several situations concerning predecessors and successors which have either already occurred or might reasonably be expected to occur. Examples, in the form of specific factual situations, are provided for purposes of clarity. It also includes a section which specifically addresses several potential situations regarding changes in control relationships. The details of the proposed regulation are discussed below. We specifically request comments on whether the regulation should specifically address any additional types of changes in corporate relationships, or provide additional examples in the form of factual situations and, if so, how. To the extent that a situation arose that was not directly addressed by the regulation, the agency would make necessary determinations based on interpretation of the statute and the principles reflected in the regulation.

We note that the proposed regulation would adopt the same positions concerning predecessors and successors as we did in our 1990 letter to Chrysler.

1. Definitions

The proposed regulation includes four definitions.

Control relationship. "Control relationship" is defined to mean the relationship that exists between manufacturers that control, are controlled by, or are under common control with, one or more other manufacturers. This definition reflects the provision at 49 U.S.C. 32901(a)(4) which specifies that the automobiles manufactured by a manufacturer include automobiles manufactured by a person that controls, is controlled by, or is under common control with the manufacturer.

Successor. "Successor" is defined to mean "a manufacturer which has become vested with the rights and assumed the burdens of another manufacturer." This definition reflects the ordinary corporate law meaning of the term "successor."

Predecessor. "Predecessor" is defined to mean "a manufacturer whose rights have been vested in and whose burdens have been assumed by another manufacturer." This definition reflects the ordinary corporate law meaning of the term and mirrors the proposed definition for "successor."

Identity. Under the proposed regulation, "identity" is defined to mean "the relationship between a predecessor and a successor during the time in which the successor owns 50 percent or more of the assets, based on valuation, that had belonged to the predecessor." This is the time when we believe it is reasonable to view the predecessor manufacturer as continuing to exist as part of the successor. The proposed limitation with respect to owning 50 percent or more of the assets is to address a possible situation where one company might purchase another, become the successor, but then quickly sell the assets to a third company. As discussed below, we use the concept of identity, in the context of predecessors and successors, as part of specifications to ensure that credits are only used by a manufacturer which can reasonably be considered to have earned them.

2. Predecessors and Successors

The proposed regulation has four specifications which define the extent to which predecessors and successors of manufacturers of automobiles are included within the definition of "manufacturer," for purposes of the automotive fuel economy program. Examples, in the form of specific factual situations, are provided for purposes of clarity.

Specification (a). The first proposed specification provides that "(s)uccessors are responsible for any civil penalties that arise out of fuel economy shortfalls incurred by predecessors." We recognize that this specification could be considered unnecessary in the sense that it simply states what follows directly from corporate law: the assumption of the burdens of a predecessor corporation, as well as the vesting of the rights of that corporation, is an inherent part of being a successor under corporate law. However, we believe that any regulation which specifies the extent to which predecessors and successors of manufacturers of automobiles are included within the definition of "manufacturer," for purposes of the automotive fuel economy program, should make this clear at the outset.

Specification (b). The second specification provides that "(i)f one manufacturer becomes the successor of another manufacturer during a model year, all of the vehicles produced by those manufacturers during the model year are treated as though they were manufactured by the same manufacturer." It also provides that "(a) manufacturer is considered to have become the successor of another manufacturer during a model year if it is the successor on September 30 of the corresponding calendar year and was not the successor for the preceding model year."

As we discussed in our 1990 letter to Chrysler, fuel economy standards apply to passenger automobiles manufactured by a manufacturer, for a particular model year, and average fuel economy is calculated based on the total number of passenger automobiles manufactured in a given model year by a manufacturer. We recently reiterated that view in a January 13, 2000 letter to Volvo Cars of North America. Since fuel economy standards apply to particular model years as a whole and not to separate parts of a model year, we believe that if one manufacturer acquires another during a model year, they should be deemed the same manufacturer, with a single CAFE value, for that model year.

In a 1990 letter to Ford, we concluded that, for purposes of deciding the model year in which one manufacturer acquires another, the "traditional model year," starting approximately October 1, is the appropriate frame of reference. The second sentence in specification (b) reflects this interpretation.

Specification (c). The third proposed specification provides that "(c)redits earned by a predecessor may be used by a successor for those model years in which there is an identity between the predecessor and successor, subject to availability of the credits and the general three-year restriction on carrying credits forward."

As we discussed in our letter to Chrysler, the statute provides that credits are available only to the manufacturer which earned them. Therefore, in the absence of some regulatory provision concerning successors, any unused credits of a predecessor would simply expire unused.

However, we continue to believe that Congress did not intend to require the forfeit of a manufacturer's unused credits in a situation where that manufacturer's substance continues to exist as part of a "successor." We are therefore proposing that credits earned by a predecessor may be used by a successor for those model years in which there is identity between the predecessor and successor.

Credits earned by a predecessor could not, however, be used by a successor for model years in which there was no identity between the predecessor and successor. We believe that, in such a situation, the credits could not reasonably be considered to be used by the manufacturer which had earned them.

The following example helps illustrate how this provision would work in practice:

A purchases B in model year x and becomes the successor of B. A's CAFE in model year x (which includes the combined production of what had been A and B) is less than the applicable CAFE standard for that model year. B had credits at the time of the acquisition because it exceeded the applicable fuel economy standard in the previous model year. The credits of B (the predecessor) could be used by A in model year x, model year x+1 and model year x+2, because there would be an identity between B and A in those model years. However, the credits of B could not be used to offset any shortfall incurred by A in model year x-1 or before, since there was no identity between B and A during those model years.

As indicated above, we believe that the use of B's credits (the predecessor's credits) by A (the successor) for model years x-1 or before (model years before the acquisition) could not reasonably be considered to be use by the manufacturer which had earned them. There was no relationship between A and B model year x-1 and before; they were two completely different manufacturers.

Moreover, as we discussed in our 1990 letter to Chrysler, the statute does not provide for the same credits being carried both forward and backward; *e.g.*, forward to A from before the time it acquired B and then backward to A for the model years prior to the acquisition when A had shortfalls.

Finally, it would be inappropriate to allow A (the successor) to succeed to rights with respect to B's credits that are greater than B had at the time of the acquisition. As of the time of the acquisition, the only right B had with respect to carrying its existing credits backward was the right to apply them to its own fleet; it did not have the right to apply them to the fleets of other manufacturers or to sell them to be applied to such fleets.

Specification (d). The fourth proposed specification provides that "(c)redits earned by a successor during model years in which there is an identity between the successor and predecessor may be used to offset a predecessor's shortfall, subject to availability of the credits and the general three-year restriction on carrying credits backward."

Under the statute, a manufacturer that experiences a shortfall which it cannot offset by using credits it has earned during the past three model years has three additional model years to earn offsetting credits. However, given that the statute provides that credits may only be used by the manufacturer that earned them, there would be no way of offsetting a predecessor's remaining shortfalls in the absence of a regulatory provision.

We do not believe that Congress intended to require the forfeiture of a manufacturer's ability to offset CAFE shortfalls by earning future credits simply because it was acquired by another manufacturer; i.e., in a situation where that manufacturer's substance continues to exist as part of a "successor." We are therefore proposing that credits earned by a successor during model years in which there is an identity between the successor and predecessor may be applied to a predecessor's shortfall.

Specifications (c) and (d), taken together, give the successor all the rights the predecessor had with respect to credits, both as to the use of existing credits *and* the ability to earn future credits to offset existing shortfalls. We are aware that some manufacturers would like the successor to somehow have greater rights than those enjoyed by the predecessor. For example, while AMC's rights to its MY 1984 credits, as

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of the time of its acquisition in MY 1987, were to apply them to its own fleet in MY 1981–1983 and 1985–1986 (since it had no successor in that time period) and to apply them to itself (as part of Chrysler) in MY 1987. Chrysler, as successor to AMC, wanted to be able to apply AMC's 1984 credits to offset shortfalls incurred by its own (Chrysler's) pre-MY 1987 fleet. However, such use of AMC's credits could not reasonably be considered a use by the manufacturer which had earned them and therefore would be inconsistent with the statute.

We also note that permitting such use of credits would discourage energy conservation. For example, to the extent that a successor had been planning to exceed standards in the future to earn credits that could be carried back to cover pre-acquisition shortfalls, permitting the successor to use the predecessor's previously earned credits to cover those shortfalls would remove the incentive to exceed those standards.

3. Manufacturers within Control Relationships

The proposed regulation has eight specifications concerning the rights and responsibilities of manufacturers within control relationships. These specifications are generally based on the same principles we considered in developing the proposed specifications concerning predecessors and successors. A discussion of the eight specifications follows.

Specification (a). The first proposed specification provides that "(i)f a civil penalty arises out of a fuel economy shortfall incurred by a group of manufacturers within a control relationship, each manufacturer within that group is jointly and severally liable for the civil penalty." This specification follows directly from the statutory provisions which provide that average fuel economy is measured, and compliance with fuel economy standards determined, for groups of companies within a control relationship rather than for individual companies. However, we believe that any regulation which specifies the rights and responsibilities of manufacturers within control relationships should make this clear at the outset. As a practical matter, we would initially seek payment of any civil penalties arising from the fuel economy performance of a group of manufacturers within a control relationship from whoever that group designated as being responsible.

Specification (b). The second proposed specification provides that "(a) manufacturer is considered to be within a control relationship for an entire model year if and only if it is within that relationship on September 30 of the calendar year in which the model year ends." This specification corresponds directly to the proposed specification (b) for predecessors and successors, and reflects the same rationale.

Specification (c). The third proposed specification provides that "(t)o the extent that a manufacturer within a control relationship was outside that relationship for a previous model year and not within any other control relationship, credits earned by the manufacturer during such model year may be used by the group of manufacturers within the control relationship for those model years in which the manufacturer is within that relationship, subject to the agreement of the manufacturer, the availability of the credits, and the general three-year restriction on carrying credits forward."

This specification is very similar to the proposed specification (c) for predecessors and successors. If a previously independent manufacturer has been purchased or otherwise brought within a control relationship, its credits do not expire but can continue to be used by it under the same conditions as before. For model years in which it is now part of a group of manufacturers, application of its credits to itself would mean application to the entire group of manufacturers since average fuel economy is measured, and compliance with fuel economy standards determined, for groups of companies within a control relationship rather than for individual companies.

We note that one difference between this proposed specification and the corresponding one we are proposing for predecessors and successors is the statement that use of the credits is subject to the agreement of the manufacturer which earned them. In the case of a predecessor/successor situation, the predecessor no longer exists and the successor has assumed all of its rights and duties. In this situation, however, the previously independent company continues to exist and could have different interests than the group of manufacturers. We therefore believe it is appropriate to make use of the credits subject to the agreement of that company. Similar provisions are included in several of the other proposed specifications for manufacturers within control relationships.

Specification (d). The fourth proposed specification provides that "(t)o the extent that a manufacturer within a control relationship was outside that relationship for a previous model year and not within any other control relationship, shortfalls incurred by the manufacturer for such model year may be offset by credits earned by the group of manufacturers within the control relationship for subsequent model years in which the manufacturer is within the relationship, subject to the agreement of the other manufacturers, the availability of the credits, and the general three-year restriction on carrying credits backward."

This specification is very similar to the proposed specification (d) for predecessors and successors.

Specifications (e) through (h). The final four proposed specifications for manufacturers within control relationships address situations in which a manufacturer which is controlled by another manufacturer is sold or otherwise spun off. We note that, given the general trend toward consolidation in the auto industry, this situation appears less likely to arise than the ones discussed earlier. Nonetheless, we believe that there is sufficient possibility that spin-offs may occur that it is reasonable to address spin-offs in the proposed regulation.

The proposed specifications generally provide that a company which has been spun off may use credits that were earned while it was part of a group of manufacturers, subject to the agreement of the other manufacturer or manufacturers in the group. They also generally provide that credits which the spun-off company earns may be carried back to the group of manufacturers for model years in which it was part of the group, subject to the spun-off company's approval.

We recognize that in situations where a manufacturer which is controlled by another manufacturer is sold to a third manufacturer, there is a possibility that the manufacturers might wish to transfer a greater number of credits than can reasonably be considered to be related to the transaction at issue. The following example illustrates such a possibility:

A, a very large manufacturer with a large credit balance, controls B, a very small manufacturer which only produces vehicles with low fuel economy, by virtue of owning B's stock. A sells B to C, a very large manufacturer with a large credit deficit. C would like to get as many credits as possible in this transaction.

In this situation, we believe it would be reasonable to permit B to take some credits with it. It was part of the group of manufacturers which earned the credits. Moreover, B might be able to argue that it did not improve its fuel economy in the past because it was part of a group of manufacturers that together exceeded the CAFE standard.

However, given that the statute does not permit the selling of credits, we do not believe it would be reasonable to permit B to take with it a greater number of credits than it could use if it had become independent. B has not produced any vehicles which exceed the fuel economy standard, and, if we permitted a large-scale transfer of credits, the sale of B might be nothing more than a disguised transaction to transfer credits. We have therefore included provisions in the proposed specifications to limit the transfer of credits in this and similar types of situations to numbers that can reasonably be considered to be directly related to the sale of the company at issue.

4. Changes in Corporate Relationships Not Directly Addressed by the Proposed Regulation

We believe the proposed regulation addresses the types of changes in corporate relationships that are most likely to occur. Moreover, we are requesting comments on whether the regulation should specifically address any additional types of changes in corporate relationships, or provide additional examples in the form of factual situations and, if so, how. Depending on the comments, we may include provisions in the final rule addressing additional types of changes in corporate relationships and/or additional examples in the form of factual situations. Since we do not believe it would be possible to comprehensively address every conceivable situation that could arise, the proposed regulation includes a provision stating that to the extent that the regulation does not directly address an issue concerning the rights and responsibilities of manufacturers in the context of a change in corporate relationships, the agency will make determinations based on interpretation of the statute and the principles reflected in the regulation.

C. Supplementary Fuel Economy Reports

One of our regulations, 49 CFR Part 537, Automotive Fuel Economy Reports, requires automobile manufacturers to submit to the agency reports concerning their plans to comply with fuel economy standards. While we are not proposing any changes to Part 537, we would note that successors must submit supplementary reports if required by section 537.8 of that regulation.

III. Rulemaking Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. This rulemaking document is not economically significant. It was reviewed by the Office of Management and Budget under E.O. 12866, "Regulatory Planning and Review." The rulemaking action has been determined to be significant under the Department's regulatory policies and procedures, given the public interest in the automotive fuel economy program.

The proposed regulation would not create any new obligations. It would adopt the same positions concerning predecessors and successors as we have previously taken in interpretation letters.

As discussed earlier in this notice, if we did not adopt regulations governing the use of CAFE credits by predecessors and successors, a predecessor's unused credits would simply expire, since the only manufacturer which could use them would no longer exist. Similarly, there would be no way of offsetting a predecessor's remaining CAFE shortfalls in the absence of some provision concerning successors. The successor would thus be required to pay the predecessor's penalties, a responsibility which it assumed with the rest of the predecessor's obligations, but would have no ability to earn future credits to offset the predecessor's shortfalls.

To address this inequity, the proposed rule, like our prior interpretation, would give the successor all the rights the predecessor had with respect to the use of preexisting credits and the ability to earn future credits.

The proposed provisions concerning the rights and responsibilities of manufacturers in other situations where there have been changes in corporate relationships, e.g., changes in control, are essentially a statement of our interpretation of the statute and reflect the same principles as the provisions relating to predecessors and successors.

B. Regulatory Flexibility Act

We have considered the effects of this rulemaking action under the Regulatory Flexibility Act (5 U.S.C. § 601 *et seq.*) I hereby certify that the proposed rule would not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required for this action. As discussed above, the proposed regulation would not create any new obligations but would simply adopt the same positions concerning predecessors and successors as we have previously taken in interpretation letters. Similarly, the proposed provisions concerning the rights and responsibilities of manufacturers in other situations where there have been changes in corporate relationships, e.g., changes in control, are essentially a statement of our interpretation of the statute and reflect the same principles as the provisions relating to predecessors and successors. Moreover, as a practical matter, the acquiring corporations most likely to be affected by this regulation are not small businesses.

C. National Environmental Policy Act

NHTSA has analyzed this proposed amendment for the purposes of the National Environmental Policy Act and determined that it would not have any significant impact on the quality of the human environment.

D. Executive Order 13132 (Federalism)

The agency has analyzed this proposal in accordance with the principles and criteria set forth in Executive Order 13132 and has determined that it does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The proposed rule would have no substantial effects on the States, or on the current Federalism-State relationship, or on the current distribution of power and responsibilities among the various local officials.

E. Unfunded Mandates Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). The proposed rule would not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually.

F. Executive Order 12778 (Civil Justice Reform)

This proposed rule does not have any retroactive effect. However, we would, as a practical matter, consider the regulation in any enforcement action regarding predecessors and successors

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that involved conduct that occurred before the regulation became effective.

As discussed earlier, the proposed regulation would not create any new obligations but would adopt the same positions concerning predecessors and successors as we have previously taken in interpretation letters. If we did not adopt special provisions governing the use of CAFE credits by predecessors and successors, a predecessor's unused credits would simply expire, since the only manufacturer which could use them would no longer exist. Similarly, there would be no way of offsetting a predecessor's remaining CAFE shortfalls in the absence of some provision concerning successors.

The proposed rule, like our prior interpretation, would address this inequity and give the successor all the rights the predecessor had with respect to credits. Thus, to the extent we considered and followed the approach of the proposed rule in any enforcement action regarding predecessors and successors that involved conduct that occurred before the regulation became effective, any effect on the amount of penalties would be beneficial for the manufacturers.

We would similarly consider the regulation in any enforcement action regarding other situations where there have been changes in corporate relationships, e.g., changes in control, that involved conduct that occurred before the regulation became effective. However, the proposed provisions are essentially a statement of our interpretation of the statute.

States are preempted from promulgating laws and regulations contrary to the provisions of this rule. The rule does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

G. Paperwork Reduction Act

This rulemaking action does not include any collections of information.

H. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

I. Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998, require each agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

—Have we organized the material to suit the public's needs?
—Are the requirements in the rule clearly stated?
—Does the rule contain technical language or jargon that is not clear?
—Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
—Would more (but shorter) sections be better?
—Could we improve clarity by adding tables, lists, or diagrams?
—What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this NPRM.

J. Executive Order 13045

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under E.O. 12866, and (2) concerns an environmental, health or safety risk that NHTSA has reason to believe may have a disproportionate effect on children. This regulatory action does not meet either of those criteria.

K. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) requires NHTSA to evaluate and use existing voluntary consensus standards [2] in its regulatory activities unless doing so would be inconsistent with applicable law (e.g., the statutory provisions regarding NHTSA's vehicle safety authority) or otherwise impractical. This requirement is not relevant to this rulemaking action.

IV. Submission of Comments

How do I prepare and submit comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Comments may also be submitted to the docket electronically by logging onto the Dockets Management System website at http://dms.dot.gov. Click on "Help & Information" or "Help/Info" to obtain instructions for filing the document electronically.

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR Part 512.)

Will the agency consider late comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under DATES. To the extent possible, we will also consider comments that Docket Management receives after that date. If Docket Management receives a comment too late for us to consider it in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

[2] Voluntary consensus standards are technical standards developed or adopted by voluntary consensus standards bodies. Technical standards are defined by the NTTAA as "performance-based or design-specific technical specifications and related management systems practices." They pertain to "products and processes, such as size, strength, or technical performance of a product, process or material."

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location.

You may also see the comments on the Internet. To read the comments on the Internet, take the following steps:

(1) Go to the Docket Management System (DMS) Web page of the Department of Transportation (http://dms.dot.gov/).

(2) On that page, click on "search."

(3) On the next page (*http://dms.dot.gov/search/*), type in the four-digit docket number shown at the beginning of this document. Example: If the docket number were "NHTSA–1998–1234," you would type "1234." After typing the docket number, click on "search."

(4) On the next page, which contains docket summary information for the docket you selected, click on the desired comments. You may download the comments.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

List of Subjects in 49 CFR Part 534

Fuel economy, Motor vehicles.

In consideration of the foregoing, we propose to amend chapter V of title 49 of the Code of Federal Regulations by adding a new part 534 to read as follows:

PART 534—RIGHTS AND RESPONSIBILITIES OF MANUFACTURERS IN THE CONTEXT OF CHANGES IN CORPORATE RELATIONSHIPS

Sec.
534.1 Scope.
534.2 Applicability.
534.3 Definitions.
534.4 Predecessors and successors.
534.5 Manufacturers within control relationships.
534.6 Situations not directly addressed by this regulation.

Authority: 49 U.S.C. 32901; delegation of authority at 49 CFR 1.50.

§ 534.1 Scope.

This part defines the rights and responsibilities of manufacturers in the context of changes in corporate relationships for purposes of the automotive fuel economy program established by 49 U.S.C. chapter 329.

§ 534.2 Applicability.

This part applies to manufacturers of passenger automobiles and light trucks.

§ 534.3 Definitions.

(a) *Statutory definitions and terms.* All terms used in 49 U.S.C. chapter 329 are used according to their statutory meaning.

(b) As used in this part—

Control relationship means the relationship that exists between manufacturers that control, are controlled by, or are under common control with, one or more other manufacturers.

Identity means the relationship between a predecessor and a successor during the time in which the successor owns 50 percent or more of the assets, based on valuation, that had belonged to the predecessor.

Predecessor means a manufacturer whose rights have been vested in and whose burdens have been assumed by another manufacturer.

Successor means a manufacturer which has become vested with the rights and assumed the burdens of another manufacturer.

§ 534.4 Predecessors and successors.

For purposes of the automotive fuel economy program, "manufacturer" includes "predecessors" and "successors" to the extent specified in paragraphs (a) through (d) of this section.

(a) Successors are responsible for any civil penalties that arise out of fuel economy shortfalls incurred by predecessors.

Example: A purchases B in model year x and is generally invested with the rights and duties of B. B had a fuel economy shortfall two model years before (model year x-2) for which credits are not available and is subject to civil penalties which have not yet been paid. A is responsible for those civil penalties.

(b) If one manufacturer has become the successor of another manufacturer during a model year, all of the vehicles produced by those manufacturers during the model year are treated as though they were manufactured by the same manufacturer. A manufacturer is considered to have become the successor of another manufacturer during a model year if it is the successor on September 30 of the corresponding calendar year and was not the successor for the preceding model year.

(c) Credits earned by a predecessor may be used by a successor for those model years in which there is an identity between the predecessor and successor, subject to availability of the credits and the general three-year restriction on carrying credits forward.

Example: A purchases B in model year x and becomes the successor of B. A's CAFE in model year x (which includes the combined production of what had been A and B) is less than the applicable CAFE standard for that model year. B had credits at the time of the acquisition because it exceeded the applicable fuel economy standard in the previous model year. The credits of B (the predecessor) could be used by A in model year x, model year x+1 and model year x+2, because there would be an identity between B and A in those model years. However, the credits of B could not be used to offset any shortfall incurred by A in model year x-1 or before, since there was no identity between B and A during those model years.

(d) Credits earned by a successor during model years in which there is an identity between the successor and predecessor may be used to offset a predecessor's shortfall, subject to availability of the credits and the general three-year restriction on carrying credits backward.

Example: A purchases B in model year x and becomes the successor of B. B had a fuel economy shortfall two model years before (model year x-2). Any credits earned by A in model year x and model year x+1 could be applied to B's shortfall, since there is an identity between A and B in model year x and model year x+1. However, credits earned by A in any model year before model year x could not be applied to B's shortfall, since there was no identity between A and B in model year x-1.

§ 534.5 Manufacturers within control relationships.

(a) If a civil penalty arises out of a fuel economy shortfall incurred by a group of manufacturers within a control relationship, each manufacturer within that group is jointly and severally liable for the civil penalty.

(b) A manufacturer is considered to be within a control relationship for an entire model year if and only if it is within that relationship on September 30 of the calendar year in which the model year ends.

(c) To the extent that a manufacturer within a control relationship was outside that relationship for a previous model year and not within any other control relationship, credits earned by the manufacturer during such model year may be used by the group of manufacturers within the control relationship for those model years in which the manufacturer is within that relationship, subject to the agreement of the manufacturer, the availability of the credits, and the general three-year restriction on carrying credits forward.

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(d) To the extent that a manufacturer within a control relationship was outside that relationship for a previous model year and not within any other control relationship, shortfalls incurred by the manufacturer for such model year may be offset by credits earned by the group of manufacturers within the control relationship for subsequent model years in which the manufacturer is within the relationship, subject to the agreement of the other manufacturers, the availability of the credits, and the general three-year restriction on carrying credits backward.

(e) If a manufacturer which is controlled by another manufacturer is sold or otherwise spun off so that it is no longer within that control relationship and is not within any other control relationship, it may use credits that were earned by the group of manufacturers within the control relationship while the manufacturer was within that relationship, subject to the agreement of the other manufacturers, the availability of the credits and the general restriction on carrying credits forward.

(f) If a manufacturer which is controlled by another manufacturer is sold or otherwise spun off so that it is no longer within that control relationship but is within another control relationship, it may use credits that were earned by the group of manufacturers within the former control relationship while the manufacturer was within that relationship, subject to the agreement of the other manufacturers, the availability of the credits, and the general restriction on carrying credits backward, and subject to a demonstration by the manufacturer, and approved by the Administrator, that the credits to be used are no more than the manufacturer could use if it were not within another control relationship.

(g) If a manufacturer which is controlled by another manufacturer is sold or otherwise spun off so that it is no longer within that control relationship, credits earned by that manufacturer may be used by the manufacturer or group of manufacturers previously within the control relationship for model years in which the manufacturer was within that relationship, subject to the agreement of the previously controlled manufacturer, the availability of the credits and the general restriction on carrying credits backward.

(h) If a manufacturer which is controlled by another manufacturer is sold or otherwise spun off so that it is no longer within that control relationship but is within another control relationship, credits earned by manufacturers within the latter control relationship for model years in which the manufacturer is within that relationship may be used by the manufacturer or group of manufacturers within the former control relationship for model years in which the manufacturer was within that relationship, subject to the agreement of the group of manufacturers within the latter control relationship, the availability of the credits, and the general restriction on carrying credits backward, and subject to a demonstration by the manufacturer, and approved by the Administrator, that the credits to be used are no more than the manufacturer would have earned if it were not within another control relationship.

§ 534.6 Situations not directly addressed by this regulation.

To the extent that this regulation does not directly address an issue concerning the rights and responsibilities of manufacturers in the context of a changes in corporate relationships, the agency will make determinations based on interpretation of the statute and the principles reflected in the regulation.

Issued on: January 10, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1524 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 554, 573, and 576

[Docket No. NHTSA 2001–9677; Notice 1]

RIN 2127–AI25

Standards Enforcement and Defect Investigation; Defect and Noncompliance Reports; Record Retention

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Advance Notice of Proposed Rulemaking (ANPRM).

SUMMARY: This document requests comments on ways that the National Highway Traffic Safety Administration (NHTSA) may implement the "early warning reporting requirements" of the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act. The TREAD Act directs NHTSA to publish a rule requiring vehicle and equipment manufacturers to report claims data and other information, whether originating in the United States or in a foreign country, that may assist in identifying defects related to motor vehicle safety in vehicles or equipment in the United States. The Act further authorizes NHTSA to require the reporting of other information. These manufacturers must also report to us all incidents, of which they receive notice, involving fatalities or serious injuries which are alleged or proven to have been caused by a possible defect in their products, whether in the United States or abroad, when the possible defective vehicle or equipment is identical or substantially similar to a vehicle or equipment offered for sale in the United States. We intend to issue a notice of proposed rulemaking (NPRM) later in 2001 to amend our procedural regulations on standards enforcement and defect investigation, reporting requirements, and recordkeeping, on the basis of comments we receive in response to this ANPRM.

DATES: Comment closing date: Comments must be received on or before March 23, 2001.

ADDRESSES: All comments on this notice should refer to the docket and notice number set forth above and be submitted to Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. The docket room hours are from 9:30 a.m. to 5:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For non-legal issues, contact George Person, Office of Defects Investigation, NHTSA (phone: 202–366–5210). For legal issues, contact Taylor Vinson, Office of Chief Counsel, NHTSA (phone: 202–366–5263).

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SUPPLEMENTARY INFORMATION:

I. Background

A. The Firestone ATX and Wilderness Tire Recall

On August 9, 2000, Bridgestone/Firestone, Inc. (Firestone) announced that it would recall certain ATX, ATXII, and Wilderness AT tires that contained a defect related to sudden tread separation (collectively referred to in this notice as "the recalled tires"). On August 16, Firestone filed its formal defect report with NHTSA pursuant to 49 CFR part 573. The recall covered P235/75R15 size tires including all ATX and ATX II tires of that size, and all Wilderness AT tires of that size produced at Firestone's Decatur, Illinois, manufacturing plant. At the time, Firestone estimated that approximately 6.5 million of the 14.4 million tires covered by the recall were still in use throughout the United States.

B. Information and Data in the Possession of NHTSA Before May 2, 2000, Related to Possible Safety Problems With Firestone ATX and Wilderness Tires

Between March 1990 and February 2000, NHTSA's consumer complaint database received approximately 46 complaints about Firestone ATX and Wilderness tires (we received additional limited information in July 1998 from State Farm Insurance Company related to insurance claims allegedly involving Firestone ATX tires). Beginning in February 2000, we began to receive additional complaints following a broadcast by a Houston, Texas, television station of a program on the failure of these tires on Ford Explorer vehicles. In March 2000, NHTSA's Office of Defects Investigation (ODI) opened an initial evaluation (IE) to consider whether to open a defect investigation. On May 2, 2000, we opened such an investigation (Investigation No. PE00–020) after having received an additional 44 reports since February 2000. Most of these complaints involved tires installed on Ford Explorer vehicles. None of the complaints covered tires in use outside the United States. The investigation covered over 47 million ATX and Wilderness tires, of various sizes, made in several plants.

C. Information and Data in the Possession of Firestone and Ford Indicating That the Tires Might Contain a Safety-Related Defect

At about the time of the Texas television program in February 2000, Firestone had recorded 193 personal injury claims, 2,288 property damage claims, and was a defendant in 66 law suits related to the tires covered by the investigation. It had also received a number of requests for financial adjustments from consumers who were unhappy with their tires. NHTSA was not aware of these data until after we opened our investigation because Firestone was not required to provide this information to us in the absence of a specific request, and it did not voluntarily provide it.

Ford Motor Company (Ford) had previously taken several actions overseas to address safety problems related to Wilderness tires on Ford Explorer vehicles. In August 1999, Ford offered to replace the P255/70R16 Firestone Wilderness AT tires installed as original equipment on certain Ford Explorer and Mercury Mountaineer models in use in the Persian Gulf region. Ford stated that this action was taken because the tires "may experience interior tire degradation and tread separation, due to unique Gulf Coast usage patterns and environmental conditions, resulting in a loss of vehicle control." Late in February 2000, Ford made a similar offer for almost identical reasons to owners in Malaysia and Thailand of "certain 1997 Explorers equipped with P235/75R15 Firestone "All Terrain" Brand Tires." A third offer was made, for the same reasons as the other two offers, in May 2000, to owners in Venezuela covering "certain 1996 through 1999 Explorers equipped with P235/75R15 or P255/70R16 Firestone 'All Terrain' brand tires." Firestone was aware of each of these actions. In none of the three instances did Ford or Firestone notify NHTSA of these actions. Although 49 U.S.C. 30166(f) as implemented by 49 CFR 573.8 would have required Ford to notify us of these actions if they had occurred in the United States, there was no requirement for it to do so because they did not occur in the United States.

D. Federal Safety-Related Defect Reporting Requirements Before the TREAD Act

Title 49, United States Code, Chapter 301—Motor Vehicle Safety, is the basic motor vehicle safety statute administered by NHTSA (the "Vehicle Safety Act"). Under 49 U.S.C. 30118(c)(1), a manufacturer of a motor vehicle or replacement equipment must notify NHTSA if the manufacturer "learns the vehicle or equipment contains a defect and decides in good faith that the defect relates to motor vehicle safety." [1] As noted in *United States* v. *General Motors Corp. (X-Cars)*, "a manufacturer incurs its duties to notify [NHTSA] and remedy [the defect] whether it actually determined, or it should have determined, that its vehicles are defective and the defect is safety-related." 656 F. 2d 1555, 1559 n. 5 (D.C. Cir. 1987). The *X-Cars* court held that a "manufacturer cannot evade its statutory obligations that exist when it determines that a defect is safety-related 'by the expedient of declining * * * to reach its own conclusion as to the relationship between a defect in its vehicles and * * * safety.'" *Id.* (quoting *United States* v. *General Motors Corp.*, 574 F. Supp. 1047, 1050 (D. D.C. 1983).

Prior to the TREAD Act, a manufacturer's automatic (*i.e.*, not in response to NHTSA's information requests under which information is required as part of an investigation) reporting obligations under Section 30166 were established by 49 U.S.C. 30166(f), providing copies of communications about defects and noncompliance, as implemented by 49 CFR 573.8, Notices, bulletins, and other communications. Section 30166(f) provides that:

> A manufacturer shall give [NHTSA] a true or representative copy of each communication to the manufacturer's dealers or to owners or purchasers of a motor vehicle or replacement equipment produced by the manufacturer about a defect or noncompliance with a motor vehicle safety standard * * * in a vehicle or equipment that is sold or serviced.

NHTSA issued a regulation thereunder, 49 CFR 573.8, which specifies that:

> Each manufacturer shall furnish to the NHTSA a copy of all notices, bulletins, and other communications (including those transmitted by computer, telefax or other electronic means, and including warranty and policy extension communiques and product improvement bulletins), other than those required to be submitted by Sec. 573.5(c)(9), sent to more than one manufacturer, distributor, dealer, lessor, lessee, or purchaser, regarding any defect in its vehicles or items of equipment (including any failure or malfunction beyond normal deterioration in use, or any failure of performance, or flaw or unintended deviation

[1] Notification is also required if a manufacturer "decides in good faith that the vehicle or equipment does not comply with an applicable motor vehicle safety standard issued under this chapter." Section 30118(c)(2). These standards are the Federal motor vehicle safety standards (FMVSS) appearing at 49 CFR part 571.

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from design specifications), whether or not such defect is safety related. Copies shall be in readable form and shall be submitted monthly, not more than five (5) working days after the end of each month.[2]

However, the statute and regulation did not require manufacturers to provide these documents with respect to actions occurring outside the United States.

E. The TREAD Act (Pub. L. 106–414)

In October 2000, H.R. 5164, the "Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act" was passed by the Congress. It was signed by the President on November 1, 2000, Pub. L. 106–414.

In H. R. Rep. 106–954, accompanying H.R. 5164, Congress noted that NHTSA did not have adequate, timely data about Firestone ATX and Wilderness tires:

> First, it is clear that the data available to NHTSA regarding the problems with the Firestone tires was insufficient. While testimony showed that the agency had received some complaints about the tires, both from consumers and from an automobile insurance company, they did not receive data about Ford's foreign recall actions or the internal company data on claims related to this data. * * * The Committee believes that the provisions of this legislation are an initial step toward correcting these problems. (p. 7)

The TREAD Act seeks to ensure that NHTSA receives appropriate data in a timely fashion, including that related to foreign recall actions and internal company data on claims and lawsuits related to defects. It does so in part by amending 49 U.S.C. 30166 to add a new subsection (m), Early warning reporting requirements. Subsection (m) requires NHTSA to initiate a rulemaking proceeding not later than 120 days after enactment of the TREAD Act to establish early warning reporting requirements for manufacturers of motor vehicles and motor vehicle equipment. NHTSA is further required to issue a final rule not later than June 30, 2002.

Sections 30166(m)(3), (4), and (5) specify requirements for, respectively, the reporting elements of early warning, the handling and utilization of reporting elements, and periodic review and update of the final rule.

The crux of the early warning provisions is Section 30166(m)(3), which states:

> (3) Reporting elements.
>
> (A) Warranty and claims data. As part of the final rule * * * the Secretary [of Transportation] shall require manufacturers of motor vehicles and motor vehicle equipment to report, periodically or upon request by the Secretary, information which is received by the manufacturer derived from foreign and domestic sources to the extent that such information may assist in the identification of defects related to motor vehicle safety in motor vehicles and motor vehicle equipment in the United States and which concerns—
>
> (i) data on claims submitted to the manufacturer for serious injuries (including death) and aggregate statistical data on property damage from alleged defects in a motor vehicle or in motor vehicle equipment; or
>
> (ii) customer satisfaction campaigns, consumer advisories, recalls, or other activity involving the repair or replacement of motor vehicles or items of motor vehicle equipment.
>
> (B) Other data. As part of the final rule * * *, the Secretary may, to the extent that such information may assist in the identification of defects related to motor vehicle safety in motor vehicles and motor vehicle equipment in the United States, require manufacturers of motor vehicles or motor vehicle equipment to report, periodically or upon request of the Secretary, such information as the Secretary may request.
>
> (C) Reporting of possible defects. The manufacturer of a motor vehicle or motor vehicle equipment shall report to the Secretary, in such manner as the Secretary establishes by regulation, all incidents of which the manufacturer receives actual notice which involve fatalities or serious injuries which are alleged or proven to have been caused by a possible defect in such manufacturer's motor vehicle or motor vehicle equipment in the United States, or in a foreign country when the possible defect is in a motor vehicle or motor vehicle equipment that is identical or substantially similar to a motor vehicle or motor vehicle equipment offered for sale in the United States.

The TREAD Act thus provides for NHTSA to require manufacturers of motor vehicles and motor vehicle equipment to provide information related to claims for deaths and serious injuries, property damage, communications to customers, other data, and incidents causing fatalities or serious injuries in which a manufacturer's product was involved, caused by possible defects in vehicles or equipment in the United States, or in identical or substantially similar vehicles or equipment in a foreign country. Information provided under the TREAD Act will enhance the ability of NHTSA to be aware of potential safety-related defects as soon as possible. We also anticipate that the Act will provide an incentive to manufacturers to develop or refine internal systems more attuned to analysis of data and early detection of possible safety problems.

The purpose of this ANPRM is to initiate rulemaking on the early warning reporting requirements and to discuss the ways in which NHTSA may best use this information and data to fulfill the statutory goal.

II. General Definitions

Section 30166(m) uses some terms that were originally defined in the National Traffic and Motor Vehicle Safety Act of 1966 (now codified as 49 U.S.C. Chapter 301—Motor Vehicle Safety) and introduces some new ones that have not been defined. The terms defined in Section 30102 that are relevant to this document are:

1. Motor vehicle—"a vehicle driven or drawn by mechanical power and manufactured primarily for use on the public streets, roads, and highways. * * *"
2. Motor vehicle equipment—"(A) any system, part or component of a motor vehicle as originally manufactured; (B) any similar part or component manufactured or sold for replacement or improvement of a system, part, or component, or as an accessory or addition to a motor vehicle; or (C) any device or an article or apparel * * * that is not a system, part, or component of a motor vehicle and is manufactured, sold, delivered, offered, or intended to be used only to safeguard motor vehicles and highway users against risk of accident, injury, or death."
3. Manufacturer—"a person—(A) manufacturing or assembling motor vehicles or motor vehicle equipment; or (B) importing motor vehicles or motor vehicle equipment for resale."
4. Defect—"includes any defect in performance, construction, a component, or material of a motor vehicle or motor vehicle equipment."
5. Motor vehicle safety—"the performance of a motor vehicle or motor vehicle equipment in a way that protects the public against unreasonable risk of accidents occurring because of the design, construction, or performance of a motor vehicle, and against unreasonable risk of death or injury in an accident, and includes nonoperational safety of a motor vehicle."

The terms in Section 30166(m) that have not been defined by Section 30102 and for which we seek to develop a meaning are "claim," "property damage," "aggregate statistical data," "serious injury," and "substantially similar." We shall discuss these terms and their possible meanings in the course of this document.

III. Who Is Covered by the New Reporting Requirements?

The TREAD Act requires information to be submitted by manufacturers of motor vehicles and motor vehicle equipment. We have identified the following categories of manufacturers of vehicles and equipment.

Motor vehicle manufacturers. Domestic vehicle manufacturers are manufacturers who produce motor vehicles in the United States, including corporations that are subsidiaries of, or otherwise controlled by, manufacturers incorporated in a country outside the United States. Foreign vehicle manufacturers are manufacturers who produce motor vehicles outside the United States, which are shipped to and sold in the United States. A foreign motor vehicle manufacturer may have a subsidiary in the United States. Multinational motor vehicle manufacturers are manufacturers that produce vehicles in one or more foreign countries and the United States. Some have acquired other motor vehicle manufacturers who continue to produce vehicles under their original nameplates. Some, like Ford Motor Company (which has acquired Volvo, Land Rover, Jaguar, Aston Martin, and Pivco of Norway), are headquartered in the U.S. Others, like DaimlerChrysler AG (which acquired Chrysler Corporation), are headquartered in a foreign country.

Many motor vehicles manufactured in the United States are produced by companies which are U.S. subsidiaries of corporations organized under the laws of other countries (*e.g.*, the Dodge Stratus, manufactured by DaimlerChrysler Corporation which is a subsidiary of DaimlerChrysler AG). A number of other vehicles are produced outside the United States by foreign manufacturers and imported by their U.S. subsidiaries (*e.g.*, Mercedes-Benz passenger cars produced in Germany by DaimlerChrysler AG and imported by Mercedes-Benz USA, Inc.). Where multinational manufacturers do business both in the United States and elsewhere, some vehicles certified for sale in the United States may have counterpart models sold outside the United States (*e.g.*, Mercedes-Benz C Class, Toyota's right-hand drive Camry produced in Kentucky for export to Japan, and Toyota's Echo, sold in other countries as the Yaris). While these models may not be exactly identical to the models sold in the United States, they are similar enough such that in many or most cases, it is likely that defects occurring in counterpart models sold outside the United States will also exist in their U.S. model counterparts. Information about such problems in these foreign vehicles is also subject to the early warning requirements to be specified in our regulations. Thus, for example, if Toyota Motors Ltd. of Japan (the foreign parent) has information about a safety problem on the Yaris that caused a serious injury or that led to a recall or similar campaign in Japan or another foreign country, Toyota USA would be required to report it to us, since it could be an indication of possible problems with the Echo, sold in the United States.

The increasing globalization of the automotive industry in the past decade is likely to result, in the coming years, in various efficiencies and benefits from common platforms and common parts. When this occurs, new and more complex issues may arise about the relationship of defects in derivative vehicles, and whether vehicles and equipment are substantially similar to each other.

The TREAD Act specifically requires vehicle and equipment manufacturers to provide information on safety-related incidents and activities occurring outside the United States. Normally, we would expect this information to be provided through a designated entity in the United States (*e.g.*, the importer or a U.S. manufacturing subsidiary). However, the information could be reported directly by the foreign manufacturer or the foreign portion of a multinational corporation.

Registered Importers. "Registered Importers (RI)" import motor vehicles that were not originally manufactured as conforming with the Federal motor vehicle safety standards. These are colloquially known as "gray market" vehicles. RIs bring gray market vehicles into conformity, certify their conformity, and sell them. Currently, 99% of the vehicles imported by RIs have been manufactured for the Canadian market. All have virtually identical counterparts in the United States. Such defects as may exist in these Canadian gray market vehicles are, in general, corrected by the manufacturer of the U.S. counterpart, which also honors warranty claims on these vehicles. The sole manufacturer that does not do so is Honda-Acura. Because RIs are not factory-authorized distributors and dealers, it appears unlikely that they will receive and possess warranty data and other information that would be meaningful under the early warning requirements. We seek comments on whether RIs should be included in the early warning reporting requirements.

Miscellaneous motor vehicle manufacturers. The scope of "manufacturer" also includes manufacturers of incomplete vehicles as defined by 49 CFR part 568, *Vehicles Manufactured in Two or More Stages*, who have contingent defect reporting responsibilities under 49 CFR 573.3(c). Because a person who alters a certified vehicle is required to affix its own certification under certain conditions, in the same manner as the vehicle's original manufacturer, the early warning reporting requirements could be viewed as applicable as well to alterers who certify.

Motor vehicle equipment manufacturers. There is a wide range of equipment manufacturers. We are considering whether periodic reporting by some manufacturers of motor vehicle equipment is necessary to fulfill the intent of the TREAD Act.

With respect to original equipment (see 49 U.S.C. 30102(a)(7)(A), 49 U.S.C. 30102(b)(1)(C)), there are approximately 14,000 individual items of original equipment in a contemporary passenger car. However, many of these items are not supplied directly to the vehicle manufacturer, but are incorporated into components assembled by a person other than the manufacturer of the part. There is a growing trend to packaging individual parts into a single unit, or module. For example, a steering wheel assembly may include an air bag, horn control, turn signal control, wiper control, ignition switch, cruise control, lighting controls, as well as associated wiring. These units are assembled by a supplier, often with components from various manufacturers. In many instances, a defect in a modular component installed as original equipment is far more likely to come to the direct attention of the vehicle manufacturer than the assembler of the component, or the manufacturers of the component's individual parts.

With respect to "replacement/accessory equipment" and "off-vehicle equipment" (see generally 49 U.S.C. 30102(a)(7)(B) and 30102(b)(1)(D)), the number of items cannot be estimated at this time. Some are very important from a safety perspective, such as tires and child seats, while others have less of a safety nexus. Although each manufacturer of each of these items of motor vehicle equipment is within the scope of the early warning reporting requirements, as defined by statute, we are considering whether it would be appropriate to have different requirements applicable to different types of equipment manufacturers.

Tires are motor vehicle equipment. With respect to the recall provisions of the Safety Act, 49 U.S.C. 30118–30121, tires are replacement equipment rather than original equipment (49 CFR 579.4(b)(2)). Therefore, tire manufacturers have the duty to conduct notification and remedy campaigns and to address defective or noncompliant tires, including tires installed on new vehicles. Tire brand name owners are also considered manufacturers (49 U.S.C. 30102(b)(1)(E)) and have the

[2] The notices, bulletins, and other communications required to be submitted by Sec. 573.5(c)(9), which Sec. 573.8 excludes, are those that relate directly to a noncompliance or a safety-related defect that a manufacturer has determined and reported to NHTSA.

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same defect and noncompliance reporting requirements as tire manufacturers under 49 CFR 573.3(d) .

Importers of motor vehicle equipment for resale are also "manufacturers of motor vehicle equipment." A large number of these may not be U.S. subsidiaries of the foreign manufacturer of the product they import (*e.g.*, importers of lighting equipment manufactured in Asia). A defect existing in the equipment they import could relate to safety. These importers could receive warranty or other claims. We see no reason not to apply the early warning reporting requirements to these importers. For example, we tentatively decided that importers of tires that are not affiliated with the actual tire manufacturers should be subject to the same early warning reporting requirements as domestic manufacturers of tires.

In some cases, the importer may be the most likely reporting entity. Although importers may lack engineering expertise, they may be most able to provide information related to returned parts, complaints, claims, and injuries.

Neither the TREAD Act nor its legislative history evidence a Congressional intent to exclude any manufacturer of motor vehicle equipment (or motor vehicles) from the early warning reporting requirements. Nevertheless, we recognize that some items of motor vehicle equipment rarely, if ever, develop a safety-related defect (*e.g.*, exterior and some interior trim, motorcycle rider vests). We recognize that, with respect to such items, only limited reporting may be required. Even though there may not be a safety need to require reporting of a full range of information by such equipment manufacturers, we tentatively believe that a manufacturer of any item of motor vehicle equipment should be required to report to us any claim it receives alleging that a death or serious injury was caused by a defect in its product.

There is a variety of alternative approaches that we might adopt with respect to reporting related to equipment. On one side, we might require reporting of limited kinds of information such as deaths, but not others, such as property damage. On the other side, we might require reporting with regard to only some classes of equipment items. Possible approaches are addressed below.

i. *Reporting initially limited to specific equipment items.* Given the vast number of motor vehicle parts, the questions at present of the types and quantity of data that are pertinent to the early warning reporting requirements, and the data storage and processing systems that may be required within NHTSA, it may be more effective to adopt an incremental approach, and initially to require reports from manufacturers of only a relatively small number of original or replacement equipment items. On the basis of safety-related defects reported in the past five years, we would include tentatively in this category tires, child restraint systems, fuel tanks, air bags and related components, and axle/suspension/brake components on heavy trucks and trailers. We would also include original and replacement equipment manufacturers of seat belt assemblies and air bags and related components such as sensors. Comments are requested on whether we initially should limit our reporting requirements to a subset of equipment manufacturers, and, if so, how that subset should be defined.

ii. *Reporting of equipment items directly covered by the FMVSS.* Initially, or after a period of time in which both industry and NHTSA have had experience with the reporting requirements, these requirements could include or be extended to require all manufacturers of original or replacement equipment that is directly covered by a Federal motor vehicle safety standard (FMVSS) to report on the same basis as vehicle manufacturers as defined by Section 30102(a)(5)(A). This would include, for example, all manufacturers of brake hoses (FMVSS No. 106), lighting equipment (FMVSS No. 108), tires (FMVSS No. 109 and 119), brake fluids (FMVSS No. 116), retreaded tires (FMVSS No. 117), rims for vehicles other than passenger cars (FMVSS No. 120), warning devices (FMVSS No. 125), non-pneumatic temporary spare tires (FMVSS No. 129), glazing (FMVSS No. 205), seat belt assemblies (FMVSS No. 209), child restraint systems (FMVSS No. 213), motorcycle helmets (FMVSS No. 218), rear impact guards (FMVSS No. 223), and compressed natural gas fuel containers (FMVSS No. 304).

iii. *Subsequent extension of reporting requirements to all manufacturers of components that a vehicle manufacturer uses in complying with Federal crash-avoidance and some crash-protection and post-crash standards.* The next tier of equipment manufacturers that might be required to report on the same basis as vehicle manufacturers could be manufacturers of original or replacement equipment which are parts of systems covered by the FMVSS "100" series, the "crash-avoidance" standards. For example, motor vehicles are required to comply with the braking performance standards (FMVSS Nos. 105, 121, 122, and 135), but the individual components of brake systems (other than brake hoses and brake fluid) are not covered by the FMVSS. Thus, we could apply the early warning requirements to the manufacturer of any component in a motor vehicle brake system (*e.g.*, discs, rotors, brake lining), or any other vehicle system that is covered by any of the Federal "crash avoidance" standards (FMVSS Nos. 101–135).

We have had a frequent number of recalls over the past five years because of safety problems with seats, seat backs, and their attachments. Therefore, we could include all components required to comply with FMVSS No. 207, *Seating Systems*. Given the national concern for child safety, we could also add manufacturers of components that a vehicle manufacturer uses to comply with FMVSS No. 225, *Child Restraint Anchorage Systems*.

This approach might also be extended to include components of fuel systems used in vehicles required to comply with FMVSS No. 301, *Fuel System Integrity*, and FMVSS No. 303, *Fuel System Integrity of Compressed Natural Gas Vehicles*, because fuel system parts, hoses, fuel lines, and connectors are frequently the subject of recall campaigns. Finally, it is important to post-crash safety that materials used in the interior of vehicles fully conform to FMVSS No. 302, *Flammability of Interior Materials*. We could apply the reporting requirements to manufacturers who provide interior materials to vehicle manufacturers, even though the vehicle manufacturers have the responsibility to certify compliance with FMVSS No. 302.

iv. *Exclusions.* There seems little safety need to require manufacturers of accessory equipment or articles of apparel (other than motorcycle helmets and jack stands) to report to us unless there is a death or serious injury allegedly involving a defect in their products. However, there may be accessories such as tire inflation pressure gauges or battery cables which, if not properly manufactured, could present a safety defect issue, and whose manufacturers should report.

Given the universe of motor vehicle equipment manufacturers, it may be that some will be excluded from the reporting requirements. For instance, the supplier of a part used in a subassembly, though a manufacturer of motor vehicle equipment by definition, might be excluded if there is a historically low recall rate on that subassembly. On the other hand, if the manufacturer of a relatively insignificant part such as a fastener or bolt becomes aware that it has produced a defective part, that information ought to be reported to us, so that we can decide whether to open a defect investigation with respect to the vehicles in which that part has been used.

Questions to be answered. We seek answers to the following questions relating to who should be covered by the early warning reporting requirements.

A. Which of the manufacturers listed above should be covered by the final rule and why?

B. Are there other entities that should be covered by the reporting requirements and why?

C. Should any of the above manufacturers or other entities be covered by only some reporting requirements and not others?

D. With respect to manufacturers' international feedback mechanisms, to what extent is information provided in the English language? Are there delays in transmitting information such as narrative field reports due to the need to translate it into English? If so, what is the length of delays?

E. What accessories could develop safety-related defects?

IV. What Information and Data Should Be Reported?

Because Section 30166(m) authorizes regulations that will require manufacturers to report to NHTSA information and data which relate to possible defects, the agency anticipates that these regulations will take the form of amendments to 49 CFR part 573, *Defect and Noncompliance Reports*. This could result in renumbering some existing provisions.

The purpose of the early warning reporting requirements is to provide information to NHTSA that will assist in the early detection of possible safety-related defects. We believe that the following information and data are relevant to this purpose:

A. Relevant Information and Data

Warranty claim data. We believe that information about warranty claims can often provide relevant information that indicates the possible existence of a safety defect. "Warranty data" appears in the heading of Section 30166(m)(3)(A) as one type of "reporting element." Thus, although it does not explicitly appear in the text of subparagraphs (i) and (ii) of that paragraph, we believe that warranty information is included within its ambit. In any event, warranty data would be included within the scope of "other data" whose reporting we can require under Section 30166(m)(30(B).

Vehicle manufacturers have complex systems of warranty coverage, which involve codes that are revised from time to time. There are large numbers of warranty claims. We understand that vehicle manufacturers review warranty information for various reasons including cost control, needed product improvement, billing of suppliers, emissions-related reporting, and safety. We have limited familiarity with original equipment manufacturer warranty systems. We do know that vehicle manufacturers have required original equipment manufacturers to provide reimbursement to manufacturers for warranty costs and for various campaigns. We also have some familiarity with warranty systems used by manufacturers of some types of replacement equipment, such as child seats.

The threshold question is what information about warranty claims may assist in the identification of defects related to motor vehicle safety. We are considering listing in the final rule systems, parts, and components that are particularly safety related. We have reviewed safety-related recalls during the 1995–2000 period and have identified the following parts/components as the most frequent subjects of recall campaigns: fuel systems (15% of all campaigns), brakes (13%), and suspensions (11%). We classify recalls related to restraint systems, seats, instrument panels, gauges, etc. as "interior systems;" these have accounted for 14% of the recall campaigns. Beyond this, there are miscellaneous other parts/components each of which comprises less than 10% of all campaigns but which together constitute the remaining 47% of recall campaigns. It seems to us that information on warranty data relating to parts/components that have been the subject of recall campaigns might be significant early warning indicators of possible safety-related defects. We appreciate that over the long run and in the future the current list may be underinclusive because it may not include new technologies. We may amend the final rule at some future time to accommodate new technologies because, historically, defects in newly-developed parts have given rise to a substantial number of safety recalls.

The agency does not want to require the submission of excessive warranty claim information. One mechanism may be to establish cumulative or periodic thresholds below which warranty information would not have to be reported. For example, a manufacturer might not be required to report warranty information on a passenger car component until the warranty claims rate reached x% of production.[3] We might apply a lower threshold if that same component were used on a school bus, *i.e.*, reporting would be required when warranty claims reached only y%. Similarly, there may be specific instances where we would employ much lower thresholds where critical safety components are involved, such as seat belt buckles.

The warranty information that we would find useful is that relating to make, model, model year, and the component or warranty code. The final rule would require each manufacturer to report to us a complete list of relevant warranty codes. However, in order for the agency to effectively use this information, it would be helpful for us to receive it in a standardized manner. Thus, we are considering whether to require some standardization of warranty codings among manufacturers.

Claims and Incidents Involving Serious Injury or Death: Section 30166(m)(3)(A)(i) requires manufacturers to provide information concerning data on claims submitted to a manufacturer for serious injury or death, to the extent that such information may assist in the identification of safety-related defects. Section 30166(m)(3)(C) also requires a manufacturer to report incidents of which it receives actual notice which involve deaths or serious injuries which are alleged or proven to have been caused by a defect, regardless of whether there is a "claim." We believe that to achieve the goals of the TREAD Act, "claim" must be construed broadly. For example, we have tentatively concluded that it includes subrogation claims filed by an insurer against a manufacturer. It also includes lawsuits against a manufacturer, whether or not they are preceded by a separate "claim." Some manufacturers may employ outside law firms to handle claims or lawsuits on a routine basis. Manufacturers would be required to report all covered claims against them whether they are being handled by house counsel or outside counsel.

While we do not have information related to foreign mechanisms paralleling domestic claims, we intend to obtain equivalent information from foreign sources. It is not necessary that

[3] We note that the California Air Resource Board (CARB) has implemented such a system with respect to air-quality-emissions components on vehicles sold or registered in California. We are considering whether a similar system might be effective in the early warning of safety defects.

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the claim relate to a crash; the Vehicle Safety Act is concerned with non-operational safety as well.

We realize that claims and allegations may be presented against a manufacturer using a wide variety of terms. We also understand that claims may allege in various terms personal injury or death from alleged defects in various items. Sometimes the defect may not be clearly alleged. For example, assume that a person asserts that an air bag deployed in a low-speed parking lot fender bender and a vehicle occupant is seriously injured. Should this be viewed as including an implicit allegation that a safety defect contributed to the occupant's injury and constitute a claim?

At the outset, we are considering requiring that manufacturers only provide summary information, as opposed to a copy of the claim itself. We are considering requiring more information for a lawsuit than for a claim that has not become a suit. One approach would be to require a brief description of the alleged defect giving rise to the complaint, including an identification of the component or system at issue. Other identifying information would include: if a vehicle, the make, model, model year and VIN; if a child seat, the make, model, model number and date of manufacture; if other equipment, the date of manufacture, serial number, and a description of the product; and, if a tire, the brand name, model name, and size, the DOT identification number, and the make, model, and VIN of the vehicle on which it was installed. For lawsuits, we are considering also requiring the case name, case number, identification of court or tribunal where the action is pending (whether in the United States or elsewhere).

Claims for deaths. The statute requires manufacturers to provide data on claims "for serious injuries (including death)." Consistent with principles of common law, this would include all deaths that occur within one year of the incident in question.

Claims for serious injuries. The statute does not define "serious injury" nor is there any legislative history as to what Congress meant by this term. Injuries may be characterized in a variety of ways in claims. Some could allege simply that an "injury" has occurred. Others might allege that the injuries are "serious" or "substantial" with no further description. Some could specify a specific injury or injuries from which one might infer that an injury was serious.

We believe that it would be valuable to first identify what we believe is a serious injury and then deal with how to assess whether a claim presents a serious injury. A system of rating the severity of motor vehicle crash-related injuries has been developed which aids in establishing uniform data bases for crash injury statistics. This system is the Abbreviated Injury Scale (AIS), which has been in use in the United States for approximately 30 years. The first AIS was published in 1971 under the auspices of the joint Committee on Injury Scaling, comprised of representatives of the American Medical Association (AMA), American Association for Automotive Medicine (AAAM), and the Society of Automotive Engineers (SAE). Since 1976, the AIS has been accepted and used by crash researchers in many parts of the world. It ranks the severity of injuries numerically from 1 to 7: minor, moderate, serious, severe, critical, maximum, injured unknown severity. The injuries recorded are those that occur to the head (cranium and brain), face, neck, thorax, abdomen and pelvic contents, spine, upper extremity, lower extremity, external/skin, and burn injuries and other trauma. Each body area receives a separate report. One possible approach would be to define a "serious injury" as one with a level of AIS 3 or higher, which is consistent with the AIS scale. The AIS is explained more clearly in the 2000 NASS Injury Coding Manual, edited for us by Veridian Engineering of Buffalo, NY. We have placed a copy of the Manual in the docket.

Claims that are presented to manufacturers often will not have sufficient information to be classified using the AIS criteria. Some may allege only that the complainant was injured, without stating the nature of the injury or its severity. In these events, a manufacturer will not know initially whether the claim reflects a "serious injury." There are a number of potential ways to address this. One is to require manufacturers to review claims as they are received and attempt to determine whether they involve serious injuries and, if there is insufficient information, to require reassessment after additional information is received (e.g., through follow-up communications or pre-trial discovery). Another is to require a manufacturer to report all claims of injury. Manufacturers may prefer this as relieving them of the need to make subjective determinations, even though the statute only requires them to submit data on claims for "serious" injuries.

We note that, notwithstanding this discussion of "serious injury" for purposes of the TREAD Act, motor vehicle safety encompasses all injuries, not just those which are above a specified AIS level. Therefore, even if the final rule limits the submission of injury-related information to that which is AIS 3 or above, this is not to be construed to mean that the agency will not conduct defect investigations or seek safety recalls when the AIS level of the injuries caused by a particular defect is likely to be only AIS 1 or 2.

Claims: property damages. Section 30166(m)(3)(A)(i) also requires manufacturers to provide us with "aggregate statistical data on property damage." This provision appears to have been included to address situations similar to that which occurred with Firestone tires, when that company had extensive data on property damage incidents but did not share it with NHTSA. When a claim is submitted to a manufacturer solely for property damage, the manufacturer would not have to provide us with a copy of the claim or full summary information on each individual claim. Rather, we tentatively would require manufacturers to provide such information in an aggregate form at the end of each reporting period, clearly identifying the specific product, item, and/or components that allegedly cause the damage, and informing us of the number of additional property damage claims that were received since the last reporting period. This would be accompanied with a description of the condition leading to the property damage claims, using terms as they are commonly understood (for example, a manufacturer could not fail to report a fire to us if it characterized it as a "thermal event" in internal documents, in any instance where there is ignition resulting in an alleged flame). As with warranty claims, we could provide that such reports would only need to be submitted if the number of claims about a particular vehicle, equipment item, or component was above a specified threshold. We also could require these reports to include percentages. For example, a manufacturer might be required to report that "15% of the total claims in the aggregate alleged property damage are due to fire."

Field Reports. Manufacturers also receive "field reports" from employees and dealers indicating the possible existence of problems. These are often particularly valuable because they provide insights into problems by persons with considerable vehicle expertise. We expect to require "field reports" under the "other data" provisions of Section 30166(m)(3)(B). The threshold substantive question is what field reports may assist in the identification of defects related to motor vehicle safety. The information management issues include identifying them and managing narrative field information.

Consumer complaints. Manufacturers often receive complaints from consumers where no injury has occurred. For purposes of this rulemaking proceeding, we intend to construe any communication requesting restitution for an injury or property damage as a "claim," and not as a mere "consumer complaint." Some consumer complaints may be related to safety and might help in an early detection of a possible safety-related defect. These may be particularly important after the expiration of warranties. We would appreciate comments on how they should be evaluated to identify those that are related to safety, and how and whether such complaints should be submitted to us under Section 301166(m)(3)(B).

Information on customer satisfaction campaigns, consumer advisories, recalls, or other activity involving the repair or replacement of motor vehicles or items of motor vehicle equipment. Section 30166(m)(3)(A)(ii) requires manufacturers to provide information which concerns "customer satisfaction campaigns, consumer advisories, recalls, or other activity involving the repair or replacement of motor vehicles or items of motor vehicle equipment" (In this case, we will use the term "campaign" to cover all these different types of actions). While the nexus requirement—"to the extent that such information may assist in the identification of defects related to motor vehicle safety"— must be met, Section 30166(m)(3)(A)(ii) applies regardless of whether a manufacturer has decided that a defect exists, whether or not the conditions or circumstances in question relate to motor vehicle safety. The new section is broader than the current regulation, 49 CFR 573.8 (based on Section 30166(f)), which requires a manufacturer to provide copies of communications regarding "any defect" including "any failure or malfunction beyond normal deterioration in use, or any flaw or unintended deviation from design specifications, whether or not such defect is safety related."

In our view, this category of information includes any communication to, or made available to, a dealer, distributor, other manufacturer, or more than one owner, whether in writing or by electronic means, relating to replacement or modification of a component, or modification of the way that a vehicle or equipment item is to be operated.[4] However, in addition to the communication itself, we tentatively plan to require the submission of information regarding the facts and analysis that led to the manufacturer's decision to issue the communication.

It should be relatively straightforward to identify whether a campaign has been conducted. With respect to the issue of whether the subject of a "campaign" may assist in the identification of defects, we do not believe that the description provided in the communication itself should be dispositive. Some communications may be phrased in a way to avoid any suggestion of a possible defect or a safety relationship. Thus, it may be in the interest of safety to err on the side of inclusiveness and to require a manufacturer to provide copies of all communications with its dealers or customers, written or electronic, when certain components or systems are involved. Of course, we are not interested in financial or marketing information provided to dealers or distributors.

We also note that, in lieu of providing notices in hard copies to their dealers, some manufacturers are posting information about "campaigns" and other service information on their internal websites. In order to keep appraised of these "notices," we are considering proposing that manufacturers provide us periodically with a list (and possibly copies) of their electronic postings.

Internal investigations. After receiving field reports, consumer complaints, or other data indicating a potential problem in a vehicle component, manufacturers often initiate internal investigations into the issues which may or may not be concluded with the reporting to NHTSA that a safety-related defect has been determined to exist. In some instances, these investigations may parallel a related NHTSA investigation. We are considering whether to require manufacturers to provide us with information regarding such internal investigations pursuant to Section 30166(m)(3)(B). If we do so, we will need to identify precisely what sort of "investigations" are covered, what information we should require about these investigations, and when we would require the information to be submitted.

Changes to components and service parts. When a manufacturer decides to change a part (either as a running change or as a change to a service part), it could signal that the original was underdesigned or overloaded. An example would be an electrical switch that is made more robust or the inclusion of a new relay to reduce the electrical load to eliminate an overheating condition that could lead to a fire. Thus, we are considering requiring the submission of information regarding such changes. Manufacturer communications about changes in products and service procedures can also indicate potential defects. We are considering requiring manufacturers to provide NHTSA with a dealer password so that we can access their internal websites (This access would be limited so that we could not access financial or marketing information). However, some of these changes may bear little relevance to safety issues. If we require manufacturers to provide information regarding design and service parts changes, we will need to decide whether information about all such changes should be provided or only those relating to specified safety components of a vehicle, and the criteria that should be adopted to ensure that we receive the information mot likely to provide early warning of defects.

Remedy failures. We are also considering whether to require manufacturers to provide us with information regarding instances in which a vehicle or child seat has had to be remedied more than once in the course of a safety recall campaign.

Fuel leaks, fires, and rollovers. We are especially concerned with motor vehicle fuel leaks, fires, and rollovers. We may require manufacturers to provide information on fuel leaks, fires, and rollovers separate from other information.

B. *Vehicles and equipment covered: substantially similar vehicles and equipment in foreign countries.* Pursuant to Section 30166(m)(3)(C), manufacturers must report incidents involving fatalities or serious injuries that are alleged or proven to be caused by a product defect "in a foreign country when the possible defect is in a motor vehicle or motor vehicle equipment that is identical or substantially similar to a motor vehicle or motor vehicle equipment offered for sale in the United States." (This is in addition to the duty to report claims and other information covered by Section 30166(m)(3)(A) that are "derived from foreign and domestic sources.")

We interpret the word "identical" to mean "the same as." As for "substantially similar," we begin with a

[4] We do not plan to require the submission of information involving disputes with individual owners about possible problems with their vehicles.

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recognition that in recent years there has been an increasing amount of commonality among basic platforms, body structure and engines of motor vehicles. If a vehicle is a model that is manufactured in the United States by a domestic manufacturer and certified as conforming to the FMVSS, and the manufacturer produces the same model for sale outside the United States, we would regard the exported model as a "substantially similar" motor vehicle for the life of both models, even if there were minor changes to the vehicles shipped abroad (e.g., if Company A produces a model for export for one model year longer than a certified model, that exported model would nevertheless be "substantially similar" to the certified models of previous model years). If a motor vehicle is manufactured outside the United States and certified for sale in the United States, and the foreign manufacturer produces the same model (i.e., same exterior body shell and family of engines), for sale in other countries, we would also consider that to be a "substantially similar" motor vehicle for the life of both models whether or not there were minor differences. We recognize, however, that there may be issues as to whether differences are "minor," and we seek comments on that subject .

The phrase "substantially similar" also appears in Section 30141(a)(1)(A), added by the Imported Vehicle Safety Compliance Act of 1988. This section provides that a RI may import a motor vehicle not originally manufactured to comply with the FMVSS if the NHTSA Administrator decides that the vehicle is "substantially similar" to a motor vehicle of the same model year that was certified for sale in the United States.[5] Except for vehicles originally manufactured for sale in Canada, virtually all these decisions have been made pursuant to petitions by RIs. A list of eligible vehicles is published as an appendix following 49 CFR part 593, and periodically during the fiscal year as additional decisions are made. While the list contains a number of vehicles that would be "substantially similar" under both Sections 30141 and the early warning reporting requirements of Section 30166(m), it is not exclusive and does not constitute the entire universe of "substantially similar" motor vehicles subject to early warning requirements. (The part 593 list also includes some vehicles that are not "substantially similar" to vehicles certified for sale in the United States, but that are eligible for importation on the alternative statutory basis that they have safety features that comply or are capable of being altered to comply with the FMVSS).

There may be instances in which vehicles may not be identical or substantially similar but may have components that are identical to those used in a vehicle sold in the United States.

The simpler an item of equipment is, the more likely it is to be identical or substantially similar in the United States and in foreign markets. The phrase "substantially similar" applied to motor vehicle equipment raises a question of magnitude given the generic nature of many parts. Most tires can be viewed as substantially similar in a literal sense. One windshield wiper may be viewed as "substantially similar" to another. For instance, a windshield wiper installed on a Mercedes A Class car which is not sold in the United States could be considered substantially similar to a wiper on the Mercedes M Class vehicle which is manufactured and sold in the United States. If DaimlerChrysler AG receives information in Germany indicating a potential safety problem with the A Class wiper blades, how relevant would that be to identifying a possible safety problem with wiper blades on a M Class vehicle? The potential for relevance grows if the wiping systems themselves on the two vehicles are identical or substantially similar, or if they are replaceable by the same part.

C. *Cut off dates.* Although a manufacturer is required to notify NHTSA, owners, and dealers if it or the agency determines that a vehicle contains a safety-related defect, it need not provide a remedy without charge if the determination is made more than 10 years after its first sale. See 49 U.S.C. 30120(g), as amended by Section 4 of the TREAD Act. There may be types of information otherwise covered by this rule that, due to the passage of time or other occurrence, need not be provided for safety purposes. If any commenter believes that there should be exclusions based on time, the commenter should provide a detailed rationale for such a belief.

D. *Questions to be answered.* We seek answers to the following questions on the type of information to be reported.

General Questions

1. Which offices of manufacturers receive, classify, and evaluate warranty and claims data, and other data or information, related to deaths, serious injuries, and property damage involving a manufacturer's products that occur in the United States?

2. In what form is that data received and maintained? If it is maintained electronically, please describe the data base system in which it is kept.

3. Is the information referred to in question 1 otherwise classified (for example, warranty codes, lawsuits)? If so, how? By whom is such information evaluated?

4. Do manufacturers in the United States (defined to include importers of vehicles or equipment for resale), currently receive warranty and claims data, and other data or information, related to deaths, serious injuries, and property damage involving their products that occur outside the United States? If so, in what form are these data received?

5. If a manufacturer in the United States does not receive, maintain, and evaluate such data or information referred to in paragraph 3 above, what entity does (*e.g.*, foreign affiliate, factory-authorized importer, outside counsel, other third-party entity)? Do manufacturers require that entity to make periodic reports to it?

6. In what form is foreign the data or information received (*e.g.*, electronically, e-mail, inter-company memo)? Is it maintained separately or is it combined with data about events occurring in the United States?

7. What is the length of time that manufacturers maintain warranty data and claims data? is this period different for data related to events occurring outside the United States?

8. Are U.S. dealers currently collecting and/or maintaining information relevant to early warning reporting? If so, what is this information, and to what extent is it furnished to the manufacturer?

9. Should there be a cut off date for reporting (*e.g.*, not require it regarding vehicles or equipment that are older than some specified age)? If so, what age or ages?

10. Is there additional information or data beyond that mentioned in this notice that manufacturers should report to NHTSA that would assist in the identification of defects related to motor vehicle safety? For example, assembly plant quality reports, dealer feedback summaries, test fleet summary reports, fleet experience, and rental car company reports.

Questions Relating to Claims

1. What is the appropriate definition of "claim?'

2. What information should be submitted (*e.g.*, just the number of claims by make, model year and component or system, or more information, including summaries and names of complainants)?

3. Should NHTSA only require the submission if claims are about problems with certain components? If so, which ones?

4. Should information about all claims involving serious injuries or deaths be submitted, or should there be some threshold?

Questions Relating to Warranties

1. Should warranty data be reported? If so, are there specific categories which should be included or excluded ?

2. How do manufacturers maintain warranty data? How long is it kept? For what purposes is it kept? How do manufacturers review warranty data to identify possible safety concerns?

3. What thresholds, if any, would be appropriate with respect to specific vehicle components, systems, and equipment items, below which warranty information would not have to be reported to NHTSA? Should there be different thresholds for different components or systems?

4. Should thresholds be based solely on claims rates, or should there be some absolute number of claims that would trigger a reporting requirement?

5. What sorts of warranty information should be reported (*e.g.*, make, model, model year, component)?

6. Are there warranty codes common to the motor vehicle industry? Passenger car industry? Heavy truck industry? Motor home industry? Child seat industry? Etc.?

7. Should we require warranty data to be submitted using standardized codes? If so, what level of standardization would be appropriate?

8. In what form should we require warranty information to be submitted?

Questions Relating to Lawsuits

1. What information should be provided about lawsuits?

2. Should information be provided about each lawsuit involving an alleged defect?

3. If not, what threshold would be appropriate? Should there be different thresholds based on the component or system involved?

Questions Relating to Design Changes

1. Should information about design changes be provided? If so, should all changes be covered or just or only those relating to specified components or systems important to vehicle safety? If so, which components or systems?

2. Should different considerations apply to prospective-only running changes than to changes to service parts?

Questions Relating to Deaths and Serious Injuries

1. What systems for characterizing the seriousness of injuries are used in countries other than the United States? How do they relate to the AIS system?

2. Are the AIS3 "serious" criteria appropriate as indicia of "serious injury"? If not, what criteria are appropriate?

3. How shall it be determined whether a claim pertaining to an injury pertains to a serious injury? What assumptions should be made? If an initial claim does not allege a "serious" injury, should the manufacturer be required to report the claim later if it learns that the injury was serious or alleged to be serious?

4. Would manufacturers find it less burdensome to report to NHTSA all allegations of injury caused by a product defect?

5. How and to which office of a manufacturer are deaths and serious injuries reported? Is the answer different with respect to incidents that occur in foreign countries?

Questions Relating to Property Damage

1. What data should manufacturers include as "aggregate statistical data"?

2. What type of statistical data relating to property damage (including fire and corrosion) do manufacturers maintain? What corporate office is responsible for their maintenance? Is the answer different with respect to incidents and claims in foreign countries?

3. How is this data maintained by manufacturers? How is it used?

4. How should this data be submitted to NHTSA to best provide an early warning of potential safety defects?

Questions on Internal Investigations

1. Should a manufacturer be required to report information on active investigations that it has initiated with respect to potential defects in its vehicles or equipment? How, if at all, should it be determined that these are safety related? What is the extent to which this information should be reported?

2. What is an appropriate definition of an internal investigation that should be reported to NHTSA?

3. Should manufacturers be required to report such investigations as soon as they are commenced? If not, at what point should the investigation be reported to NHTSA?

Questions on Customer Satisfaction Campaigns, Etc.

1. Should "customer satisfaction campaigns," "consumer advisories," "recalls" or "other activities involving the repair of motor vehicles or motor vehicle equipment" be defined in NHTSA's regulation, and, if so, what would be an appropriate definition for each of these terms?

2. How many and what kind of customer satisfaction campaigns, consumer advisories, recalls, or other activity involving repairs have occurred since January 1, 1998, that were not required to be reported to NHTSA under 49 CFR 573.8? Indicate whether these occurred in the United States or foreign countries. Please submit a copy of all communications provided to consumers or dealers with respect to each such campaign, advisory, recall, or other activity.

Questions on Identical and "Substantially Similar" Motor Vehicles and Equipment

1. Is the word "identical" understood internationally, or do we need to define it? If so, how?

2. How should a manufacturer determine if a vehicle sold in a foreign country is "substantially similar" to vehicles sold in the United States? Is it enough that the vehicles share the same platform and/or engine family? If not, why not?

3. How should "substantially similar" motor vehicle equipment be defined? Would the definition be different with respect to individual parts, component parts, assemblies and systems? Other than tires and off-vehicle equipment (such as child seats), should the definition be restricted to replacement equipment for substantially similar motor vehicles?

Questions on Field Reports

1. What is an appropriate definition for "field report'?

2. In the context of field reports for which information is to be provided, should there be a list of systems, parts, and components that are safety related? Should it be the same as the list for warranty claims and other claims?

3. Do manufacturers screen field reports for safety-related information? If so, what are their systems and how do they work?

4. How do manufacturers process and maintain field reports? Is all information entered into computers?

5. What information regarding field reports should be provided NHTSA? Should there be a numerical or rate threshold before field reports must be provided?

[5] The Administrator must also decide that the vehicle is capable of being readily altered to comply with all applicable FMVSS. The authority to decide extends only to motor vehicles and not to motor vehicle equipment.

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V. When should information be reported?

Section 30166(m)(3)(A) and (B) state that the information covered by those paragraphs shall be reported "periodically or upon request" by NHTSA. Section 30166(m)(3)(C) states that the information covered by that paragraph shall be reported "in such manner as [NHTSA] establishes by regulation."

A. *Periodically.* The statute authorizes us to require periodic reporting by manufacturers of information related to the early warning of defects. Some types of information may be more significant than other (*e.g.*, deaths allegedly caused by safety defects) and justify a more frequent period of reporting than other types.

1. *Upon receipt of information*—We are considering proposing that any manufacturer of motor vehicles or motor vehicle equipment report to us within two weeks of its receipt of information alleging or demonstrating that a fatality has occurred due to a defect in one of its products. This would be an episodic report providing certain information when the manufacturer receives it, rather than a report containing information that accumulates within a specific period of time.

2. *Monthly.* Problems arising in certain types of motor vehicles or equipment may require more frequent reporting than others, especially where an accumulation of claims or warranty data has reached whatever threshold for reporting that we eventually set. Defect-related information concerning school buses, emergency vehicles, child restraints, automatic restraint systems, seat belts, and fuel systems seems critical to us. We may require reporting of information in these categories on a monthly basis. This information would be due in our offices on a specified day (*e.g.*, the 15th day) following the end of each calendar month.

We might also require manufacturers of vehicles and equipment to report to us monthly if they learn of an incident in which it was alleged that the vehicle or equipment of the manufacturer caused or contributed to an injury that required the hospitalization of any person for more than observation.

Although the consequences may vary, it is also important for us to be aware promptly of failures of remedies that have been implemented to address safety-related defects and noncompliances, since the components or systems involved have already been determined to create a safety problem. Therefore, reports of such problems might also be required on a monthly basis.

3. *Quarterly.* Reporting other types of safety-related data might be on a quarterly basis. These data might include aggregate statistical data, warranty claims related to other components, and claims/lawsuits alleging fires. These reports would cover the calendar quarters of a year and be submitted by a specified day following the end of the reporting quarter (*i.e.*, a report for information received from January 1 through March 31 would be due sometime in April). This is the same schedule of reporting that we have established under 49 CFR 573.7 for the reporting of information about safety recalls.

B. *Upon NHTSA's request.* The TREAD Act requires all manufacturers to provide information and data relevant to early warning when NHTSA requests. Such a requirement complements NHTSA's pre-TREAD authorities to request safety-related information as part of our investigations.

C. *Questions to be answered.* We seek answers to the following questions relating to when information should be reported. In responding to each of the following questions, please provide specific recommendations, and the rationale for each recommendation.

1. Should reporting frequency vary depending on the type of information (*e.g.*, deaths, injuries, warranty rates, complaints, etc.)? If so, what is an appropriate frequency for each type?

2. Should reporting frequency vary depending on the type of vehicle or equipment (*e.g.*, passenger car, bus, child seats or other equipment)? If so, what is an appropriate frequency for each type?

3. Should reporting frequency vary depending upon the component or system involved (*e.g.*, air bag, child restraint, seat belt assemblies, brakes)? If so, what is an appropriate frequency for each?

4. Should manufacturers of particular equipment, such as off-vehicle and accessory equipment, be required to report data on a periodic basis, or only if they receive certain information such as claims alleging deaths or serious injuries involving their products?

VI. How Should Information Be Reported?

At the present time, we have limited knowledge about early warning information that manufacturers, particularly equipment manufacturers, receive, in what form it is received, and how, if at all, they route, code, maintain, and review the information. We believe that it is likely that the types of information to be reported under Section 30166(m)(3) are kept in a variety of manufacturer computer systems and formats. Some manufacturers probably use different computer systems for different types of information, and some may not be computerized at all. To be able to use this information efficiently, NHTSA will have to maintain it in computer systems that can read and incorporate the information into a standardized set of data fields,. definitions, and codes. We seek comments on the best ways to assure that NHTSA can do this.

In our view, the early warning provisions contemplate that manufacturers must do more than merely provide raw information and data. Section 30166(m)(3) states that the information reportable to NHTSA is "information which is received by the manufacturer derived from foreign and domestic sources." One meaning of "derive" is "to reach or obtain by reasoning; deduce; infer" (Random House Compact Unabridged Dictionary, Second Special Edition (1996), p. 536). The aspects of reasoning, deduction, and inference in the definition of "derive," in our view, authorize a rule that requires a manufacturer to process, organize, and to some degree analyze the raw data and information it has, so that meaningful information is provided. Moreover, it is evident that we may specify the form in which information is reported in order to ensure that it can be efficiently used for its intended purpose of identifying defects related to motor vehicle safety.

NHTSA would expect manufacturers to provide collated and aggregated information by vehicle make, model, model year, and component system, broken down by failure or fault codes. Since it is absolutely essential that NHTSA be able to obtain information in a standardized form, we anticipate identifying relevant codes for reporting purposes.

A possible alternative on which we would appreciate comments would be to have each manufacturer of vehicles or equipment submit a spreadsheet in a specified format with the aggregate number of claims and other information (such as production volumes) by make, model, model year, and component (we would specify which components). The reports would be individually categorized according to the topics discussed above (e.g., injury claims, death claims, lawsuits, incidents). We would then be able to run a computer program to identify spikes or unusual trends in each of these categories.

To assure that manufacturers understand their reporting responsibilities, we are considering developing a matrix of information with the reporting periods specified from left to right across the top (on bi-weekly, monthly, quarterly) and the type of information to be provided listed in a left-hand column from top to bottom. Thus, under "Deaths," we would place "X" in the column whose heading reads "On Receipt." We could develop a separate matrix for each type of manufacturer so that it would know exactly what to submit and when.

Questions to be answered. We seek answers to the following questions relating to the manner in which information should be reported.

1. How would manufacturers prefer to report information to us (e.g., hard copy, electronically)? If both, what would be in hard copy? What would be in electronic format? Which electronic format(s) would be preferable?

2. Should information regarding deaths and serious injuries be submitted in the form in which it is received by the manufacturer, the form in which it is entered into a database by the manufacturer, or in some other way?

The following five questions relate to the possible use of a spreadsheet for reporting aggregate information.

1. What do manufacturers understand the term "aggregate statistical information" to mean?

2. Is aggregate statistical information regarding claims, deaths and injuries likely to be useful in identifying potential safety-related defects? Would it be too general to be useful?

3. Would this type of aggregate statistical information tend to result in a large number of investigations into issues that are not related to potential safety-related defects?

4. Would the submission of supplemental information beyond the aggregate statistical information be necessary or appropriate to provide NHTSA with sufficient information upon which to decide to open an investigation? What types of such information?

5. If NHTSA needs to submit requests for supplemental information, should the requests be made as part of an investigation? If not, why not? If not, how should NHTSA characterize these requests, and should the requests and responses be made available to the public?

VII. How NHTSA Might Handle and Utilize Early Warning Information Reported To It

A. *Specifications for use of information.* Section 30166(m)(4)(A)(i) and (ii) require that our early warning rule specify how the information reported to us will be used. Those paragraphs provide:

(A) [NHTSA's] specifications. In requiring the reporting of any information requested by [NHTSA] under this subsection, [NHTSA] shall specify in the final rule * * * (i) how [early warning] information will be reviewed and utilized to assist in the identification of defects related to motor vehicle safety; [and] (ii) the systems and processes [that NHTSA] will employ or establish to review and utilize such information.

These provisions relate to internal NHTSA matters and are not ordinarily required by the Administrative Procedure Act to be adopted pursuant to notice and comment. Nevertheless, we are seeking public comment on ways to improve our collection, review, and analysis of information and data with the new reporting tools which Congress has given us.

At this point, in the immediate aftermath of the enactment of the TREAD Act, we have only just begun to consider how we might best implement the early warning information and data received, but have formulated no procedures. In part, these procedures will depend upon the form of the rule as we will propose it later this year. They will also depend on the result of the ongoing study of the "standards, criteria, procedures and methods" used by NHTSA in determining whether to open a defect or noncompliance investigation that is being conducted pursuant to Section 15 of the TREAD Act. In the NPRM, we will specifically address the matters covered by subparagraphs (i) and (ii) above, and indicate how we propose to amend 49 CFR part 554, *Standards Enforcement and Defects Investigation* (one purpose of which is to inform the public of the procedures we follow in investigating possible safety-related defects).

Questions to be answered.

1. How should NHTSA review and utilize the information to be submitted under the early warning rule?

2. What system or processes should NHTSA utilize in reviewing this information?

B. *Information in possession of manufacturer.* Section 30166(m)(4)(B), Information in possession of manufacturer, states that our early warning regulations "may not require a manufacturer of a motor vehicle or motor vehicle equipment to maintain or submit records respecting information not in the possession of the manufacturer." There is nothing in the legislative history that amplifies the statutory language. We interpret "possession" as meaning not only information in the actual possession of a manufacturer, but also constructive possession and ultimate control of information, such as information in foreign countries, or information possessed by outside counsel or consultants. We interpret Section 30166(m)(4)(B) as prohibiting us from imposing a requirement that a manufacturer collect data that it does not possess.

A colloquy on the floor of the House does not explain the provision but addressed the need to preserve relevant records:

> Mr. Markey: Concern has been expressed that this provision not become a loophole for unscrupulous manufacturers who might be willing to destroy a record in order to demonstrate that it is no longer in its possession. Would [Mr. Tauzin] agree that it is in [NHTSA's] discretion to require a manufacturer to maintain records that are in fact in the manufacturer's possession and that it would be a violation of such a requirement to destroy such a record?
>
> Mr. Tauzin: The gentleman is again correct.

We regard this as encouraging, if not mandating, us to amend our record keeping regulations in 49 CFR part 576 to assure that records covered by the early warning regulation are kept for an appropriate length of time. We note that part 576 currently applies only to vehicle manufacturers. Consistent with the above colloquy, we intend to expand its applicability to manufacturers of at least certain types of equipment.

Further, we intend to adopt a requirement to assure that manufacturers that are currently collecting information that would be reportable under the early warning requirements do not cease collecting it.

C. Disclosure. Section 30166(m)(4)(C), Disclosure, states that:

> None of the information collected pursuant to the final rule . . . shall be disclosed pursuant to section 30167(b) unless the Secretary determines the disclosure of such information will assist in carrying out sections 30117(b) and 30118 through 30121.

We believe that section 30166(m)(4)(C) will have almost no impact. Historically, requests by the public for information that have submitted to us have been addressed under the Freedom of Information Act (FOIA), 5 U.S.C. 552. Section 30167(b), Defect and noncompliance information, provides for disclosure of information related to a defect or noncompliance that we decide will assist us in carrying out Sections 30117(b), Maintaining purchaser records and procedures; Section 30118, Notification of defects and noncompliance; Section 30119, Notification procedures; Section 30120, Remedies for defects and noncompliance; and Section 30121, Provisional notification and civil

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actions to enforce. Historically, NHTSA has not invoked Section 30167(b) in deciding to release information to the public.

In signing H.R. 5164 on November 1, 2000, the President stated that he was directing us "to implement the information disclosure requirements of the [TREAD] Act in a manner that assures maximum public availability of information." As a practical matter, we do not interpret Section 30166(m)(4)(C) as affecting the current policies and practices applicable to the disclosure of information to the public.

The primary differences between pre-TREAD Act and post-TREAD Act reporting are likely to be in the mechanisms for reporting and amount of information reported. Before the TREAD Act, other than material submitted pursuant to 49 CFR 573.8, information in NHTSA's possession relating to a possible defect that was not the subject of an ongoing investigation was primarily in the form of consumer complaints. Under the TREAD Act, information will also be generated through periodic reports to NHTSA of information that a manufacturer might not otherwise have disclosed unless specifically asked by NHTSA to provide it. However, most of this information is likely to be similar to the types of information that NHTSA regularly obtained during its investigations pursuant to information requests or special orders.

The TREAD Act does not affect the right of a manufacturer to ask for a determination that information it may report to NHTSA is confidential.

D. *Burdensome requirements.*

Section 30166(m)(4)(D), Burdensome requirements, requires that the final rule:

> shall not impose requirements unduly burdensome to a manufacturer or a motor vehicle or motor vehicle equipment, taking into account the manufacturer's cost of complying with such requirements and [NHTSA's] ability to use the information sought in a meaningful manner to assist in the identification of defects related to motor vehicle safety.

On the basis of this ANPRM, manufacturers should have a general idea of the types of data and information that they may be required to submit under a final rule. This should allow them to make a tentative assessment of the burdens that compliance may entail and to provide comments.

Some burdens may be relatively infrequent, such as identifying and reviewing relevant warranty codes. Some burdens may be mostly one-time events, such as programming computer programs. Other burdens may be periodic, such as reporting warranty information, claims, deaths and serious injuries, and lawsuits.

In light of recent developments, some manufacturers may already be refining existing internal procedures, or developing new procedures, intended to provide them with an earlier warning of potential safety problems. To the extent that these procedures are being developed and implemented as part of a corporate policy and the procedures parallel those that are adopted in the final rule, the burden imposed by a final rule would appear to be lessened.

Questions To Be Answered

While we recognize that we have not proposed specific requirements, we would appreciate comments providing us with cost and burden estimates to the extent possible.

1. What are the estimated startup and ongoing costs (including financial as well as manpower costs) of complying with the early warning reporting requirements discussed in this notice? What is the basis for the estimate?

2. How should NHTSA decide whether particular requirements are "unduly" burdensome? Should we balance the burdens against the anticipated benefits of receiving the information in question? If so, how should we perform that balancing?

3. What is the most effective early warning information and least burdensome ways of providing it?

4. Have manufacturers developed or are manufacturers beginning to develop and implement their own early warning reporting procedures in advance of NHTSA's rulemaking? If so, what are these procedures. How do these procedures differ from those discussed in the ANPRM? How are they similar?

VIII. Periodic Review

Under section 30166(m)(5), NHTSA must specify in the final rule "procedures for the periodic review and update of such rule." Once a final rule amending Part 573 is developed and issued, we anticipate that experience will indicate areas where the regulation ought to be amended, to add or delete information required, and to modify our information-gathering procedures. We would then implement rulemaking to make these adjustments. Accordingly, we plan to amend Part 554 to state that we will review our defect information-gathering procedures at least once every four years. It is likely that the initial review will be sooner than that period.

IX. Rulemaking Analyses

Executive Order 12866 and DOT Regulatory Policies and Procedures; Unfunded Mandates Reform Act of 1995. This advance notice was not reviewed under Executive Order 12866 and the Department of Transportation's regulatory policies and procedures. Due to the preliminary nature of this document, NHTSA has identified few specific changes that it might propose to its regulations. Further, it has limited current cost information that might be relevant to any potential changes. Accordingly, NHTSA is unable now to evaluate the economic impacts that this rulemaking might ultimately have. At this time, it does not appear that the rule resulting from this rulemaking will be significant. However, NHTSA will reassess this rulemaking in relation to the Executive Order, the DOT Regulatory Policies and Procedures, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) and other requirements for analyzing rulemaking impacts after using the information received in response to this advance notice to select specific proposed changes. To that end, the agency solicits comments, information, and data useful in assessing the impacts of making changes as specified in Section 3(b) of the TREAD Act as discussed in this document.

Regulatory Flexibility Act. NHTSA has considered the impact of this rulemaking action in relation to the Regulatory Flexibility Act (5 U.S.C. Sec. 601 *et seq.*). Most manufacturers of motor vehicles and motor vehicle equipment are not small entities. We have asked manufacturers of motor vehicles and motor vehicle equipment to specifically comment on the burdens that might be imposed upon them by compliance with Section 3(b) of the TREAD Act. The final rule will not impose new substantive requirements, but will require new reporting. However, the requirements have not been delineated. Accordingly, no regulatory flexibility analysis has been prepared at this time.

Executive Order 13132 (Federalism). Executive Order 13132 on "Federalism" requires us to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of "regulatory policies that have federalism implications." The E.O. defines this phrase to include regulations "that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." A final rule based upon this ANPRM, would regulate the manufacturers of motor vehicles and motor vehicle equipment, would not have substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in E.O. 13132.

Civil Justice Reform. A rule based on this ANPRM would not have a retroactive or preemptive effect, and judicial review of it may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

Paperwork Reduction Act

The final rule will require manufacturers of motor vehicles and motor vehicle equipment to report information and data to NHTSA periodically and upon request. We may also adopt a standardized form for reporting this information, so as to ensure consistency of responses. These provisions are considered to be information collection requirements, as that term is defined by the Office of Management and Budget (OMB) in 5 CFR part 1329. Accordingly, if requirements are proposed, they will be submitted to OMB for its approval, pursuant to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Request for Comments

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments.

Your comments must not be more than 15 pages long (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.

Please submit two copies of your comments, including the attachments, to Docket Management at the beginning of this document, under **ADDRESSES**.

How Can I be Sure That my Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA (NCC–30), at the address given at the beginning of this document under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies from which you have deleted the claimed confidential business information, to Docket Management at the address given at the beginning of this document under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation, 49 CFR Part 512.

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated at the beginning of this notice under **DATES**. Because we must issue a final rule not later than June 30, 2002, and a proposed rule in the interim, we are unlikely to extend the comment closing dates for this notice or for the proposed rule. However, in accordance with our policies, to the extent possible, we will also consider comments that Docket Management receives after the specified comment closing date. If Docket Management receives a comment too late for us to consider in developing the proposed rule, we will consider that comment as an informal suggestion for future rulemaking action.

How Can I Read the Comments Submitted by Other People?

You may read the comments received by Docket Management at the address and times given near the beginning of this document under **ADDRESSES**.

You may also see the comments on the internet. To read the comments on the internet, take the following steps:

(1) Go to the Docket Management System (DMS) Web page of the Department of Transportation (*http://dms.dot.gov/*).

(2) On that page, click on "search."

(3) On the next page (*http://dms.dot.gov/search/*), type in the four-digit docket number shown at the heading of this document. Example: if the docket number were "NHTSA–2001–1234," you would type "1234."

(4) After typing the docket number, click on "search."

(5) The next page contains docket summary information for the docket you selected. Click on the comments you wish to see.

You may download the comments. The comments are imaged documents, in either TIFF or pdf format. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

Authority: Sec. 3(b), Pub. L. 106–414; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 12, 2001.

Kenneth N. Weinstein,

Associate Administrator for Safety Assurance.

[FR Doc. 01–1502 Filed 1–12–01; 3:48 pm]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 010103003-1003-01, I.D. 083000B]

RIN 0648-AN92

List of Fisheries for 2001

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Marine Fisheries Service (NMFS) proposes changes for 2001 to the List of Fisheries (LOF) as required by the Marine Mammal Protection Act (MMPA). The proposed LOF for 2001 reflects new information on interactions between commercial fisheries and marine mammals. Under the MMPA, NMFS must place a commercial fishery on the LOF into one of three categories based upon the level of serious injury and mortality of marine mammals that occurs incidental to that fishery. The categorization of a fishery in the LOF determines whether participants in that fishery are subject to certain provisions of the MMPA, such as registration, observer coverage, and take reduction plan requirements.

DATES: Comments must be received by March 8, 2001.

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ADDRESSES: Send comments to Chief, Marine Mammal Division, Attn: List of Fisheries, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

Comments regarding the burden-hour estimates or any other aspect of the collection of information requirements contained in this proposed rule should be sent to the Chief, Marine Mammal Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910 and to the Office of Information and Regulatory Affairs, OMB, Attention: NOAA Desk Officer, Washington, DC 20503.

Registration information and materials and marine mammal reporting forms may be obtained from the following regional offices:

NMFS, Northeast Region, One Blackburn Drive, Gloucester, MA 01930-2298, Attn: Sandra Arvilla.

NMFS, Southeast Region, 9721 Executive Center Drive North, St. Petersburg, FL 33702, Attn: Teletha Griffin.

NMFS, Southwest Region, Protected Species Management Division, 501 W. Ocean Blvd., Suite 4200, Long Beach, CA 90802-4213, Attn: Don Peterson.

NMFS, Northwest Region, 7600 Sand Point Way NE, Seattle, WA 98115, Attn: Permits Office.

NMFS, Alaska Region, Protected Resources, P.O. Box 22668, 709 West 9th Street, Juneau, AK 99802.

FOR FURTHER INFORMATION CONTACT: Emily Hanson, Office of Protected Resources, 301-713-2322 ext. 101; Kim Thounhurst, Northeast Region, 978-281-9138; Diane Borggaard, Southeast Region, 727-570-5312; Tim Price, Southwest Region, 562-980-4029; Brent Norberg, Northwest Region, 206-526-6733; Michael Payne, Alaska Region, 907-586-7642. Individuals who use a telecommunications device for the deaf may call the Federal Information Relay Service at 1-800-877-8339 between 8 a.m. and 4 p.m. Eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION:

What Is the List of Fisheries?

Under section 118 of the MMPA, NMFS must publish, at least annually, an LOF that places all U.S. commercial fisheries into one of three categories based on the level of incidental serious injury and mortality of marine mammals that occurs in each fishery. The categorization of a fishery in the LOF determines whether participants in that fishery may be required to comply with certain provisions of the MMPA, such as registration, observer coverage, and take reduction plan requirements.

How Does NMFS Determine In Which Category a Fishery is Placed?

The definitions for the fishery classification criteria can be found in the implementing regulations for section 118 of the MMPA (50 CFR part 229). In addition, these definitions are summarized in the preambles to the final rule implementing section 118 (60 FR 45086, August 30, 1995), the final LOF for 1996 (60 FR 67063, December 28, 1995), and the proposed LOF for 1999 (63 FR 42803, August 11, 1998). These criteria are also summarized here.

Fishery Classification Criteria

The fishery classification criteria consist of a two-tiered, stock-specific approach that first addresses the total impact of all fisheries on each marine mammal stock and then addresses the impact of individual fisheries on each stock. This approach is based on consideration of the rate, in numbers of animals per year, of incidental mortalities and serious injuries of marine mammals due to commercial fishing operations relative to the Potential Biological Removal (PBR) level for each marine mammal stock. The PBR level is defined in 50 CFR 229.2 to mean the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population.

Tier 1: If the total annual mortality and serious injury across all fisheries that interact with a stock is less than or equal to 10 percent of the PBR level of this stock, all fisheries interacting with this stock would be placed in Category III. Otherwise, these fisheries are subject to the next tier of analysis to determine their classification.

Tier 2, Category II: Annual mortality and serious injury of a stock in a given fishery is greater than or equal to 50 percent of the PBR level.

Tier 2, Category II: Annual mortality and serious injury of a stock in a given fishery is greater than 1 percent and less than 50 percent of the PBR level.

Tier 2, Category III: Annual mortality and serious injury of a stock in a given fishery is less than or equal to 1 percent of the PBR level.

Tier 1, therefore, considers the cumulative fishery mortality and serious injury for a particular stock, while Tier 2 considers fishery-specific mortality for a particular stock. Additional details regarding how threshold percentages between the categories were determined are provided in the preamble to the final rule implementing section 118 of the MMPA (60 FR 45086, August 30, 1995).

How Do I Find Out if a Specific Fishery is in Category I, II, or III?

This proposed rule includes two tables that list all U.S. commercial fisheries by LOF Category. Table 2 lists all of the fisheries in the Pacific Ocean (including Alaska). Table 3 lists all of the fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean.

How Do I Register?

Owners of vessels or gear engaging in a Category I or II fishery, are required under 50 CFR 229.4 to obtain a marine mammal authorization. You must register through a NMFS Regional Offices (see **ADDRESSES**) unless you participate in a fishery that has an integrated registration program. Upon receipt of a completed registration, NMFS will issue vessel or gear owners a decal to display on their vessels and an authorization certificate that must be in the possession of the operator while fishing. The procedures and fees associated with registration differ between Regions.

For some fisheries, NMFS has integrated the MMPA registration process with existing state and Federal fishery license, registration, or permit systems and related programs. Participants in these fisheries are automatically registered under the MMPA and are not required to pay the $25 registration fee.

Which Fisheries Have Integrated Registration Programs?

The following fisheries have integrated registration programs under the MMPA: All Alaska Category II fisheries; all Washington and Oregon Category II fisheries; and three Atlantic fisheries (the Gulf of Maine, U.S. mid-Atlantic lobster fishery, the Atlantic squid, mackerel, butterfish trawl fishery, and the Northeast sink gillnet fishery). Special procedures and instructions for registration in these integrated fisheries are described in the preamble to the final LOF for 1998 (63 FR 5748, February 4, 1998).

How Do I Renew My Registration Under the MMPA?

The Regional Offices annually send renewal packets to participants in Category I or II fisheries that have previously registered; however, it is your responsibility to ensure that registration or renewal forms are submitted to NMFS at least 30 days in advance of fishing. If you have not received a renewal packet by January 1, or are registering for the first time, request a registration form from the appropriate Regional Office (see **ADDRESSES**).

Am I Required to Submit Reports When I Injure or Kill a Marine Mammal During the Course of Commercial Fishing Operations?

Any vessel owner or operator, or fisher (in the case of non-vessel fisheries), participating in a Category I, II, or III fishery must comply with 50 CFR 229.6 and report all incidental injuries or mortalities of marine mammals that occur during commercial fishing operations to NMFS. "Injury" is defined in 50 CFR 229.2 as a wound or other physical harm. In addition, any animal that ingests fishing gear, or any animal that is released with fishing gear entangling, trailing, or perforating any part of the body is considered injured and must be reported. Instructions on how to submit reports can be found in 50 CFR 229.6.

Am I Required to Take an Observer Aboard My Vessel?

Fishers participating in a Category I or II fishery are required to accommodate an observer onboard your vessel(s) upon request. Observer requirements can be found in 50 CFR 229.7.

Am I Required to Comply With Any Take Reduction Plan Regulations?

Fishers participating in a Category I or II fishery are required to comply with any applicable take reduction plans. NMFS may develop and implement take reduction plans for any Category I or II fishery that interacts with a strategic stock.

Sources of Information Reviewed for the Proposed 2001 LOF

NMFS reviewed the marine mammal incidental serious injury and mortality information presented in the Stock Assessment Reports (SARs) for all observed fisheries to determine whether proposed changes in fishery classification were warranted. NMFS also reviewed other sources of new information, including marine mammal strandings data, observer program data, fisher self-reports, and other information that is not included in the SARs.

NMFS' SARs provide the best available information on both the level of serious injury and mortality of marine mammals that occurs incidental to commercial fisheries and the PBR levels for marine mammal stocks. The information contained in the SARs is reviewed by regional scientific review groups (SRGs) representing Alaska, the Pacific coast (including Hawaii), and the Atlantic coast (including the Gulf of Mexico). The SRGs were created by the MMPA to review the science that goes into the stock assessment reports and advise NMFS on population status and trends, uncertainties in the science, research needs, and other issues.

The proposed LOF for 2001 is based on information provided in the final SARs for 1996 (63 FR 60, January 2, 1998), the final SARs for 1999 (65 FR 12514, March 9, 2000), and the draft SARs for 2000 (65 FR 31520, May 18, 2000). The final SARs for 1999 and draft SARs for 2000 provide new estimates of total serious injury and mortality of marine mammals that occur incidental to some U.S. commercial fisheries and provide new estimates of PBR levels for some marine mammal stocks. If information in the 2000 draft SARs changes as a result of public comments or additional review by the Scientific Review Groups, these updates will be incorporated in the final LOF for 2001.

Changes Resulting From New Draft SARs

Tables 2 and 3 list all U.S. commercial fisheries, the number of participants in each fishery, and the marine mammal stocks and/or species incidentally killed or injured in each fishery. Information in Table 2 was updated to include the following changes in the final 1999 Atlantic and Gulf of Mexico SARs and draft 2000 Atlantic and Gulf of Mexico SARs:

1. The Northern Gulf of Mexico stock of dwarf sperm whales was designated as non-strategic.

2. The Northern Gulf of Mexico stock of pygmy sperm whales was designated as non-strategic.

3. The Western North Atlantic stock of Atlantic spotted dolphin was designated as non-strategic.

4. The Western North Atlantic stock of pantropical spotted dolphin was designated as non-strategic.

5. The Western North Atlantic stock of dwarf sperm whales was designated as non-strategic.

6. The Western North Atlantic stock of long-finned pilot whales is proposed to be designated as strategic.

The 1999 final Pacific SARs included updates to include new information on fishery mortality, fisher self-reporting, and stranding data through 1997, resulting in revisions to 11 stocks, but no changes to the status of any Pacific stocks. The draft 2000 Pacific SARs included a complete set of revised stock assessments for Pacific marine mammal stocks under NMFS jurisdiction, including the following changes in status:

1. The California/Oregon/Washington stock of short-finned pilot whales is proposed to be designated as non-strategic;

2. The Central California stock of harbor porpoise is proposed to be designated as strategic; and

3. The Hawaii stock of false killer whales is proposed to be designated as strategic.

The final 1999 Alaska SARs and draft 2000 Alaska SARs provided updates to the number of participants in each Alaska commercial fishery, and to the list of species and/or stocks incidentally injured or killed in each fishery. When possible, the number of participants in Alaska fisheries provided in Table 3 in the LOF reflects the number of permits fished in 1999. For those fisheries for which this information was not available, the number of permits issued in 1999 or the number of permits fished or issued in prior years were used to represent the number of participants. The new information did not change the status of any of the Alaska stocks.

Proposed Changes to the 2001 LOF

NMFS is proposing specific changes to the LOF that would take effect in 2001. With the exception of the proposed changes, NMFS will retain the fishery classifications as published in the final LOF for 1999 (64 FR 9067, February 24, 1999), and which continued to be effective in 2000 (65 FR 24448, April 26, 2000). NMFS solicits comments on the proposed changes and should be advised of any fishery that is not included in the LOF. As a result of comments or information received after the publication of the proposed 2001 LOF, NMFS may redefine existing fishery definitions, recategorize fisheries, or add and delete fisheries from this list for the final 2001 LOF.

This proposed LOF addresses commercial fisheries only, but NMFS is currently working with the Atlantic States Marine Fisheries Commission and states, partly at the request of the Mid-Atlantic Harbor Porpoise Take Reduction Team, to look for ways to quantify and address recreational fisheries and marine mammal interactions. NMFS solicits comments on distinguishing between the commercial and recreational fishing sectors when analyzing marine mammal strandings that display evidence of fishery interactions.

Table 1 has been added to the LOF to provide a summary of fisheries for which changes are proposed and to identify the type of change. The first column identifies the fishery as listed in the existing List of Fisheries, the middle column shows the proposed change, and the third column lists how the fishery is listed in the proposed 2001 LOF. The category of each fishery is indicated in parenthesis. A more

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detailed discussion of the change made to each fishery follows in the text, organized by the type of change. Updates to the number of participants and to the marine mammal species and stocks incidentally injured and killed are not included in this table. Changes not reflected in Table 1 were either made directly to Tables 2 or 3 or are discussed in the "Other Proposed Changes or Clarifications to the LOF" section.

TABLE 1—SUMMARY OF CHANGES PROPOSED FOR THE 2001 LIST OF FISHERIES

Fishery Listing in the 2000 List of Fisheries	Proposed Change	Fishery Listing in Proposed 2001 List of Fisheries
Commercial Fisheries in the Pacific Ocean		
AK Clam Hand Shovel (III)	Reorganized	AK Clam (III); AK Clam Mechanical/ Hydraulic (III)
AK Octopus/Squid "Other" (III)	Renamed	AK Squid/Pot (III)
AK Southeast Alaska Herring Food/Bait Pound Net (III)	Renamed	AK Southeast Herring Roe/Food/Bait Pound Net (III)
AK Southern Bering Sea, Aleutian Islands, and Western Gulf of Alaska Sablefish Longline/Set Line (federally regulated Waters) (III); AK State Waters Sablefish Longline/Set Line (III); AK Miscellaneous Finfish/Groundfish Longline/Set Line (III).	Reorganized	AK Bering Sea, Aleutian Islands Groundfish Longline/ Set Line (federally Regulated Waters, including miscellaneous finfish and sablefish) (III); AK Gulf of Alaska Groundfish Longline/Set Line (federally regulated waters, including miscellaneous finfish and sablefish) (III); AK State-Managed Waters, Groundfish Longline/Set Line (including sablefish, rockfish, and miscellaneous finfish) (III)
Southeast AK Salmon Drift Gillnet (II)	Renamed	AK Southeast Salmon Drift Gillnet (II)
Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/Set Line (III).	Recategorized	Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/Set Line (II)
N/A	Added	AK Herring Spawn on Kelp Pound Net (III)
N/A	Added	AK Snail Pot (III)
N/A	Added	California Longline (II)
Commercial Fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean		
Atlantic Ocean, Gulf of Mexico Blue Crab Trap/Pot (III)	Reorganized and Recategorized	Atlantic Blue Crab Trap/Pot (II); Gulf of Mexico Blue Crab Trap/Pot (II); Northeast Trap/Pot (II)
Atlantic Ocean, Caribbean, Gulf of Mexico Large Pelagics Drift Gillnet (I).	Removed	N/A
Atlantic Squid, Mackerel, Butterfish Trawl (II)	Recategorized	Atlantic Squid, Mackerel, Butterfish Trawl (I)
Bluefish, Croaker, Flounder Trawl Fishery (III)	Reorganized	Mid-Atlantic Mixed Species Trawl Fishery (III)
Gulf of Maine Small Pelagics Surface Gillnet (II)	Renamed	Northeast Anchored Pelagic Gillnet (II)
Gulf of Maine, Southeast U.S. Atlantic Coastal Shad, Sturgeon Gillnet (III)	Reorganized and Recategorized	Southeast Atlantic Gillnet (II); Northeast Sink Gillnet (I); Northeast Anchored Pelagic Gillnet (II); Northeast Drift Gillnet (II)
Gulf of Maine/U.S. Mid-Atlantic Lobster Trap/Pot (I)	Renamed	Northeast/Mid-Atlantic American Lobster Trap/Pot (I)
Gulf of Maine, U.S. Mid-Atlantic Mixed Species Trap/Pot (III)	Reorganized and Recategorized	Northeast Trap/Pot (II); Mid-Atlantic Mixed Species Trap/Pot (III)
Gulf of Mexico Inshore Gillnet (III) Gulf of Mexico Coastal Gillnet (III); Gulf of Mexico King and Spanish Mackerel Gillnet (III).	Reorganized and Recategorized	Gulf of Mexico Gillnet (II)
Mid-Atlantic Coastal Gillnet (II)	Recategorized	Mid-Atlantic Coastal Gillnet (I)
Mid-Atlantic Haul Seine (II)	Reorganized and Renamed	North Carolina Long Haul Seine (II); Mid-Atlantic Haul/ Beach Seine (II)
U.S. Mid-Atlantic Mixed Species Stop/Seine/Weir (III)	Renamed	U.S. Mid-Atlantic Mixed Species Stop Seine/Weir (except the North Carolina Roe Mullet Stop Net) (III)
Mid-Atlantic, Southeastern U.S. Atlantic, Gulf of Mexico Shrimp Trawl (III).	Renamed	Southeastern U.S. Atlantic, Gulf of Mexico Shrimp/ Trawl Fishery (III)
North Carolina Inshore Gillnet (III)	Recategorized	North Carolina Inshore Gillnet (II)
Southeastern U.S. Atlantic, Caribbean Haul Seine (III); Caribbean Beach Seine (III).	Reorganized and Renamed	Southeastern U.S. Atlantic Haul/Beach Seine (III); Caribbean Haul/Beach Seine (III)
All Southeastern Atlantic Gillnet Fisheries (except for Category II Shark Gillnet); Florida East Coast King and Spanish Mackerel Gillnet (III).	Reorganized and Recategorized	Southeast Atlantic Gillnet (II)
Southeastern U.S. Atlantic, Gulf of Mexico Snapper-Grouper and Other Reef Fish Bottom Longline/Hook-and-Line(III).	Renamed	Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean Snapper-Grouper and Other Reef Fish Bottom Longline/Hook-and-Line(III)
Southeastern U.S. Atlantic, Gulf of Mexico, Caribbean Spiny Lobster Trap/Pot(III).	Reorganized	Florida Spiny Lobster Trap/Pot (III); Caribbean Spiny Lobster Trap/Pot(III)
N/A	Added	Caribbean Gillnet (III)
N/A	Added	Caribbean Mixed Species Trap/Pot (III)
N/A	Added	Gulf of Mexico Haul/Beach Seine (III)
N/A	Added	Gulf of Mexico Mixed Species Trap/Pot (III)
N/A	Added	Gulf of Mexico Mixed Species Trawl (III)
	Added	Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean Cast Net (III)
N/A	Added	Mid-Atlantic Pound Net (II)
N/A	Added	North Carolina Long Haul Seine (II)
N/A	Added	Northeast Drift Gillnet (II)
N/A	Added	Northeast Trap/Pot (II)

TABLE 1—SUMMARY OF CHANGES PROPOSED FOR THE 2001 LIST OF FISHERIES—Continued

Fishery Listing in the 2000 List of Fisheries	Proposed Change	Fishery Listing in Proposed 2001 List of Fisheries
N/A	Added	Southeastern U.S. Atlantic, Gulf of Mexico Golden Crab Trap/Pot (III)
N/A	Added	Southeastern U.S. Atlantic, Gulf of Mexico Stone Crab Trap/Pot (III)

Fisheries Elevated to Category I

Atlantic Squid, Mackerel, Butterfish Trawl Fishery

NMFS proposes to elevate the Atlantic Squid, Mackerel, Butterfish Trawl Fishery to Category I as justified by the following tier analysis. Marine mammal species and stocks incidentally injured and killed by the Atlantic Squid, Mackerel, Butterfish Fishery during the 1996-1998 period include: common dolphin (WNA stock), white-sided dolphin (WNA stock), and *Globicephala, sp.* (includes long-finned and/or short-finned pilot whales)(WNA stock).

Tier 1 Evaluation: The NMFS Sea Sampling program recorded takes of pilot whales (WNA stock), Atlantic white-sided dolphins (WNA stock), and common dolphins (WNA stock) between 1996-1998. According to data presented in the draft 2000 SAR, annual serious injury and mortality across all fisheries for the pilot whale, white-sided dolphin, and common dolphin stocks exceeds 10 percent of the PBR level (78, 184, and 107, respectively). Therefore, this fishery is subject to Tier 2 analysis.

Tier 2 Evaluation: Bycatch analysis for this fishery during the 1996-1998 period is reported in the draft 2000 SAR. The analysis resulted in an estimated average mortality rate for this fishery of 43 pilot whales and 367 common dolphins per year, which is greater than 50 percent of the PBR level for both stocks. Therefore, this fishery is proposed to be elevated to Category I.

Mid-Atlantic Coastal Gillnet Fishery

NMFS proposes to elevate the Mid-Atlantic Coastal Gillnet fishery to Category I based on new observer bycatch information about bottlenose dolphins (WNA coastal stock) presented in the draft 2000 SAR. The geographic boundaries of the Mid-Atlantic Coastal Gillnet Fishery would be maintained. This fishery includes all gillnet fishing that is south of Long Island, landward of the 72°30' W. line, and north of a line extending due east from the North Carolina/South Carolina border. However, the Mid-Atlantic Coastal Gillnet Fishery would not include the Category III inshore gillnet fisheries, which are not changed on the LOF.

Marine mammal species and stocks incidentally injured and killed in the Mid-Atlantic Coastal Gillnet Fishery include: bottlenose dolphin (WNA coastal stock), harbor porpoise (Gulf of Maine/Bay of Fundy stock), harbor seal (WNA stock), harp seal (WNA stock), humpback whale (undetermined North Atlantic stock), minke whale, (WNA stock), *Globicephala, sp.* (includes long-finned and/or short-finned pilot whales) (WNA stock), white-sided dolphin (WNA stock), and common dolphin (WNA stock).

The tier analysis justifying this change follows:

Tier 1 Evaluation: The NMFS Sea Sampling program has documented takes of coastal bottlenose dolphins in the Mid-Atlantic Coastal Gillnet Fishery. Incidental mortality and serious injury of bottlenose dolphin (WNA coastal stock) across all fisheries exceeds 10 percent of the PBR level (25). Therefore, this fishery is subject to Tier 2 analysis.

Tier 2 Evaluation: The draft 2000 SAR reports that the total annual estimated average fishery-related mortality or serious injury to bottlenose dolphin (WNA coastal stock) by mid-Atlantic coastal gillnets during 1994-1998 was 45.8 bottlenose dolphins, which is greater than 50 percent of the PBR level (25) for this stock. Therefore, NMFS proposes to elevate this fishery to Category I.

Fisheries Elevated to Category II

Atlantic Blue Crab Trap/Pot Fishery

NMFS proposes to rename the Atlantic portion of the Category III Atlantic Ocean, Gulf of Mexico Blue Crab Trap/Pot Fishery the Atlantic Blue Crab Trap/Pot Fishery and elevate the fishery to Category II based on a review of fishery interaction data from bottlenose dolphin strandings in the southeastern Atlantic. The geographic range of this fishery would extend from 72°30' W. longitude south from Long Island to Florida's Atlantic coast. The blue crab is distributed along the entire East Coast. However, data suggest that significant fishing effort does not occur north of 72°30' W. longitude. This northern boundary would also encompass most of the distribution of coastal bottlenose dolphins along the East Coast. Any blue crab pot effort north of 72°30' W. longitude would be included in the Northeast Trap/Pot Fishery.

The marine mammal species and stocks incidentally injured and killed include the bottlenose dolphin (WNA coastal stock) and West Indian manatee (FL stock). NMFS is presently evaluating this fishery to determine the number of participants, although historic numbers indicate that there may be at least 16,000 participants in this fishery. NMFS will also consider registration options for this fishery that will minimize the registration burden on fishers. The tier analysis justifying this change follows:

Tier 1 Evaluation: Incidental mortality and serious injury of bottlenose dolphins (WNA coastal stock) across all fisheries is greater than 10 percent of the PBR level (25), therefore this fishery is subject to Tier 2 analysis.

Tier 2 Evaluation: Between 1994 and 1998, 22 bottlenose dolphin carcasses (4.4 dolphins per year on average) recovered by the Stranding Network between North Carolina and Florida's Atlantic coast displayed evidence of possible interaction with a trap/pot fishery (i.e., rope and/or pots attached, or rope marks). Additionally, although not included in the analysis, at least two dolphins were reported to be released alive (condition unknown) from blue crab traps/pots during this time period.

Given that other sources of annual serious injury and mortality estimates (e.g., observer data) related to the Atlantic Blue Crab Trap/Pot Fishery are unavailable, the stranding data (4.4 bottlenose dolphins per year) were used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin (WNA coastal stock) mortality and serious injury from the Atlantic Blue Crab Trap/Pot Fishery is estimated to be between 1 percent and 50 percent of the PBR level (25), warranting placement of this fishery in Category II.

Gulf of Mexico Blue Crab Trap/Pot Fishery

NMFS proposes to rename the Gulf of Mexico portion of the Category III Atlantic Ocean, Gulf of Mexico Blue

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Crab Trap/Pot Fishery to the Gulf of Mexico Blue Crab Trap/Pot Fishery and elevate this fishery to Category II based on a review of fishery interaction data from bottlenose dolphin strandings in the Gulf of Mexico. The marine mammal species and stocks incidentally injured and killed include the bottlenose dolphin (Western, Eastern, and Northern Gulf of Mexico stocks and Gulf of Mexico Bay, Sound, and Estuarine stock), and West Indian manatee (FL stock). There are approximately 4,113 commercial blue crab fishers in the Gulf of Mexico. NMFS will consider registration options for this fishery that will minimize the registration burden on fishers. The tier analysis justifying this change follows:

Tier 1 Evaluation: As noted in the tier analysis for the Gulf of Mexico gillnet fishery, total annual mortality and serious injury of bottlenose dolphin (Gulf of Mexico Bay, Sound, and Estuarine stock) exceeds 10 percent of the PBR level (39.7), and, therefore, the Gulf of Mexico Blue Crab Trap/Pot Fishery is subject to Tier 2 analysis.

Tier 2 Evaluation: Between 1994 and 1998, seven bottlenose dolphin carcasses (1.4 dolphins per year on average) recovered by the Gulf of Mexico stranding network displayed evidence of possible interaction with a trap/pot fishery (i.e., rope and/or pots attached, or rope marks). Additionally, although not included in the analysis, at least 1 dolphin was reported to be released alive (condition unknown) from a blue crab trap/pot in the Gulf of Mexico during this time period.

Because the Gulf of Mexico Blue Trap/Pot Fishery occurs predominantly in inshore waters, NMFS combined the PBR of the tentative Gulf of Mexico Bay, Sound and Estuarine stocks from Florida's Gulf coast to the Mississippi River mouth (39.5).

Given that other sources of annual serious injury and mortality estimates (e.g., observer data) related to the Gulf of Mexico Blue Crab Trap/Pot Fishery are unavailable, the stranding data (0.8 bottlenose dolphins per year) were used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin mortality and serious injury from the Gulf of Mexico Blue Trap/Pot Fishery is estimated to be between 1 percent and 50 percent of the PBR level (39.7) for bottlenose dolphins (Gulf of Mexico Bay, Sound, and Estuarine stock), placing this fishery in Category II.

Gulf of Mexico Gillnet Fishery

NMFS proposes to combine the Gulf of Mexico Inshore Gillnet Fishery, the Gulf of Mexico Coastal Gillnet Fishery, and the Gulf of Mexico King and Spanish Mackerel Gillnet Fishery into a new Gulf of Mexico Gillnet Fishery. The COLREGS line[1] is presently used to divide the Gulf of Mexico Inshore Gillnet Fisheries (i.e., fisheries occurring in bays, sounds, or estuaries) from the Gulf of Mexico Coastal Gillnet Fisheries, but NMFS has learned that similar gillnet fisheries occur both inside and outside of the COLREGS line. Therefore, NMFS proposes to combine these fisheries in the LOF for clarity. The Gulf of Mexico Gillnet Fishery has 734 participants.

Based on analogy with other gillnet fisheries, the Atlantic Scientific Review Group (ASRG) recommendation that NMFS elevate all gillnet fisheries to at least Category II (unless evidence to the contrary is available), a NOAA memo indicating that stranding data substantially underestimate human related mortality levels (August 6, 1999, NOAA Memo from R. Merrick and S. Swartz to D. Wieting), and the actual stranding data presented in the following tier analysis, NMFS is proposing to elevate the Gulf of Mexico Gillnet Fisheries to Category II. The species and stocks incidentally injured and killed include bottlenose dolphin (Gulf of Mexico Western, Northern, and Eastern Coastal Stocks and the Gulf of Mexico Bay, Sound and Estuarine Stock).

Tier 1 Evaluation: The Gulf of Mexico Menhaden Purse Seine Fishery, a Category II fishery, has documented interactions with coastal stocks of bottlenose dolphin, which exceed 10 percent of the combined PBR level (154) for the Western, Northern and Eastern coastal bottlenose dolphin stocks. Therefore the Gulf of Mexico Coastal Gillnet Fishery is subject to Tier 2 analysis.

For the Gulf of Mexico Bay, Sound and Estuarine Stock of bottlenose dolphin (which was not affected by the menhaden purse seine fishery and thus not part of the previous tier analysis), the total annual mortality and serious injury exceeds 10 percent of the PBR level (39.7). Therefore, the Gulf of Mexico Inshore Gillnet Fishery is also subject to Tier 2 analysis and data on this fishery will be combined with the coastal gillnet fishery for the Tier 2 analysis on the Gulf of Mexico gillnet fishery.

Tier 2 Evaluation: Between 1994 and 1998, the stranding network in the Gulf of Mexico recovered 35 bottlenose dolphins that died as a result of fishery interactions. Of these, up to 10 carcasses showed evidence of gillnet interactions (i.e., attached gillnet and net marks): one in the eastern Gulf of Mexico, eight in the northern Gulf of Mexico, and one in the western Gulf of Mexico, for an average of two bottlenose dolphin mortalities recovered by the U.S. stranding network per year with evidence of gillnet interactions.

Conclusive stock structure information on bottlenose dolphins in the Gulf of Mexico is not yet available, so currently NMFS is generally unable to identify from which stock stranded bottlenose dolphin originate. To take this uncertainty into consideration, NMFS combined the PBR levels across the Gulf of Mexico Western (29), Northern (35), and Eastern (90) coastal stocks (total PBR level of 154) and the Gulf of Mexico Bay, Sound and Estuarine stock (39.7) for a total PBR level in the Gulf of Mexico of 193.7.

Given that the Gulf of Mexico Gillnet Fisheries have not been observed to date, the stranding data (two bottlenose dolphins per year) were used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin mortality and serious injury from these fisheries is estimated to be between 1 percent and 50 percent of the PBR level (193.7), placing this fishery in Category II. As noted in the August 6, 1999, NOAA Memo from R. Merrick and S. Swartz to D. Wieting, it is believed that true mortality rates are higher than what stranding data indicate.

Preliminary breakdown by area and stock for bottlenose dolphin found in bays, sounds, and estuaries (i.e., inside the COLREGS line) supports a Category II classification for at least one of the areas/stocks. For example, in the Bay Boudreau and Mississippi Sound (Block B02-05, 29, 31), one dead dolphin was recovered by the southeast U.S. stranding network on average per year with evidence of a gillnet interaction. Annual serious injury and mortality related to the inshore gillnet fishery for this stock is between 1 percent and 50 percent of the PBR level (13).

Most stranded animals used in the analyses with evidence of gillnet interactions occurred in the northern Gulf of Mexico. Net bans in state waters off of Florida and Texas may explain why most stranded animals with evidence of a gillnet interaction occurred in the northern Gulf of Mexico. Gillnet fisheries may occur in Federal waters off of Florida and Texas, but resulting marine mammal mortalities may occur too far offshore to be reflected in the beach strandings.

[1] As defined in 33 CFR part 80, COLREGS demarcation lines delineate those waters upon which mariners shall comply with the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS) and those water upon which mariners shall comply with the Inland Navigation Rules. The waters inside of the lines are Inland Rules waters. The waters outside the lines are COLREGS waters. COLREGS demarcation lines are depicted or noted on nautical charts published by NOAA (Coast Charts 1:80,000 scale) and described in 33 CFR part 80.

Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/ Set Line Fishery

NMFS proposes to elevate the Hawaii Swordfish, Tuna, Billfish, Mahi Mahi, Wahoo, Oceanic Sharks Longline/Set Line Fishery (Hawaii longline fishery) to Category II because of the diversity of marine mammal species that have been documented to interact with the fishery, including false killer whales (Hawaiian stock), Risso's dolphin (Hawaiian stock), bottlenose dolphin (Hawaiian stock), spinner dolphin (Hawaiian stock), and short-finned pilot whales (Hawaiian stock). The draft 2000 Pacific SARs present data about these stocks of marine mammals and calculate a rate of interaction between the Hawaii longline fishery and each stock based on observer data. However, the abundance estimate and PBR for each stock is based on twelve aerial surveys conducted within approximately 25 nautical miles of the main Hawaiian Islands in 1993, 1995, and 1998, and therefore underestimates the abundance and PBR for each stock within the U.S. Exclusive Economic Zone (EEZ) off of Hawaii. NMFS also has records of an interaction between the Hawaii longline fishery and a sperm whale (Hawaiian stock) in 1999 and a humpback whale (Central North Pacific stock) in 1991. Regardless of the limitations of the abundance estimates and PBRs, observer data show that the Hawaii longline fishery has occasional interactions with marine mammals and should therefore be elevated to Category II. In addition, the recategorization of this fishery from Category III to Category II is consistent with the way NMFS has addressed other U.S. pelagic longline fisheries, all of which are Category I or II.

North Carolina Inshore Gillnet Fishery

NMFS proposes to elevate the North Carolina Inshore Gillnet Fishery to Category II. A Geographic Information System (GIS) analysis was performed on fisheries interaction data from bottlenose dolphin strandings in North Carolina to confirm locations as inside (inshore) or outside (coastal) of the COLREGS line currently used to distinguish between North Carolina's inshore and coastal gillnet fisheries. The analysis revealed 12 fishery interaction-related strandings in inshore waters. The tier analysis justifying the elevation follows:

Tier 1 Evaluation: Incidental mortality and serious injury across all fisheries for bottlenose dolphins (WNA coastal stock) is greater than 10 percent of the PBR level (25). This fishery is thus subject to Tier 2 analysis.

Tier 2 Evaluation: Between 1993 and 1997, 12 bottlenose dolphins that died as a result of fishery interactions were recovered from inshore waters in North Carolina. Of these, eight carcasses bore evidence of possible gillnet interaction. Of the carcasses stranding inshore and displaying evidence of gillnet interactions, two were clearly attributable to gillnet interactions (i.e., visible monofilament net marks and/or gear present on the carcass). Counting only these latter two animals, there were 0.4 dead bottlenose dolphins with clear evidence of gillnet interactions recovered from inshore waters by the southeast U.S. stranding network on average per year. Additionally, although not included in the analysis, a live dolphin entangled in a gillnet in inshore waters was disentangled and released in September of 1997.

Given that an annual serious injury and mortality estimate related to the North Carolina Inshore Gillnet Fishery has not been calculated to date, the stranding data (0.4 bottlenose dolphins per year) was used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin (WNA coastal stock) mortality and serious injury from the North Carolina Inshore Gillnet Fishery is estimated to be between 1 percent and 50 percent of the PBR level (25), placing this fishery in Category II.

Other inshore gillnet fisheries in the Mid-Atlantic will be re-evaluated in a future LOF cycle for consistency with the changes proposed this year.

Southeast Atlantic Gillnet Fishery

NMFS proposes to include all southeast Atlantic gillnet fisheries (excluding the separate Category II Southeastern U.S. Atlantic Shark Gillnet Fishery) into one gillnet fishery complex named the Southeast Atlantic Gillnet Fishery for two reasons: (1) New information indicates a more extensive use of stab nets (i.e., sink gillnets) in the fishery for coastal migratory pelagics than was previously known, and (2) the Florida net ban has resulted in the redistribution of effort from state gillnet fisheries (e.g., for pompano, spot, croaker) into Federal waters. The Florida East Coast Pelagics King and Spanish Mackerel Gillnet Fisheries are included in this proposed new fishery. Gillnet fishing for shad in the southeast would also be included in this proposed fishery (see proposal for Gulf of Maine, Southeast U.S. Atlantic Coastal Shad, Sturgeon Gillnet Fishery). There are approximately 640 participants in this fishery: 279 participants gillnetting for various target species in the southeast Atlantic, and 361 participants from the Southeast shad component of the Gulf of Mexico, Southeast, U.S. Atlantic Coastal Shad, Sturgeon Gillnet Fishery. This number includes recreational fishermen who have a South Carolina commercial shad license. Presently, it is not possible to determine the number of recreational versus commercial fishers who have a commercial shad license. NMFS will revise the number of participants to exclude recreational fishermen in a future LOF cycle if the information necessary to do this becomes available.

Based on analogy with other gillnet fisheries, the ASRG recommendation that NMFS elevate all gillnet fisheries to at least Category II (unless evidence to the contrary is available), and a review of stranding records from 1994-1998, NMFS proposes to place this fishery in Category II. The marine mammal species and stock incidentally injured and killed is bottlenose dolphin (WNA coastal stock). The tier analysis justifying this change follows:

Tier 1 Evaluation: Incidental mortality and serious injury across all fisheries for bottlenose dolphin (WNA coastal stock) is greater than 10 percent of the PBR level (25). This fishery is thus subject to Tier 2 analysis.

Tier 2 Evaluation: Between 1994 and 1998, 44 bottlenose dolphins that died as a result of fishery interactions were recovered by stranding network members in South Carolina, Georgia, and the Atlantic coast of Florida. Of these, five carcasses (1 dolphin per year on average) bore evidence of a possible gillnet interaction (attached gillnet and net marks).

Given that an annual serious injury and mortality estimate related to the Southeast Atlantic Gillnet Fishery has not been calculated to date, the stranding data (one bottlenose dolphin per year) was used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin (WNA coastal stock) mortality and serious injury from the Southeast Atlantic Gillnet Fishery is estimated to be between 1 percent and 50 percent of the PBR level (25), placing this fishery in Category II. Fisheries Added to the LOF

Alaska Herring Spawn On Kelp Pound Net Fishery

NMFS proposes to add the Alaska Herring Spawn on Kelp Pound Net Fishery to the LOF as a Category III

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fishery. This fishery would include fisheries of Southeast Alaska and Prince William Sound. These fisheries were previously on the LOF as Category III fisheries, but they had become inactive and were removed in 1993. These fisheries have become active again.

Alaska Snail Pot Fishery

NMFS proposes to add the AK Snail Pot Fishery to the LOF as a Category III fishery. This small fishery targets three species of sea snails in the Bering Sea (typically north and west of the Pribilof Islands), using extremely small pots (less than 18 inches (45.7 cm) across). This is an extremely temporary and opportunistic fishery, typically occurring after the opilio crab fishery. Activity in the fishery is completely market driven, and while there were four permits fished in 1997, in 1998 there were no landings. According to Alaska Department of Fish and Game, it would not be impossible, but extremely unlikely for a marine mammal to get entangled in this gear. The fishery was observed for crab bycatch, and subsequently has been exempted from observer coverage since none was found. All other pot fisheries in AK are currently Category III fisheries.

California Longline Fishery

NMFS proposes to add the California Longline Fishery to the LOF as a Category II fishery. This fishery is directed primarily towards swordfish caught outside of the U.S. EEZ off of California. Longline vessels unloading their catch in California ports are required to fish outside of the U.S. EEZ and have a California state commercial fishing license. Currently, approximately 40 to 50 longline vessels unload in California. Traditionally, many of these vessels landed in Hawaii, but closures around the Hawaiian Islands have moved fishing effort farther east, and as a result some longline vessels now land in California. The California longline fishery is currently not covered by a fishery management plan (FMP), nor is it subject to any requirements to carry observers. However, the Pacific Fishery Management Council is in the process of developing a pelagic FMP that will include the California longline fishery. The FMP is expected to be finalized in 2002.

Preliminary catch data has been compiled for the California longline fishery from skipper logbooks, dated between August 1, 1995 and December 31, 1999. The logbooks do not report any whale or dolphin interactions, but do show interactions with California sea lions and a Hawaiian monk seal. However, because the California longline fishery does not operate in the same area that Hawaiian monk seals occur, NMFS believes the Hawaiian monk seal identification may be incorrect. Regardless, the gear and methods of fishing by the California longline fishery are similar to those of the Hawaiian longline fishery. Therefore, NMFS expects that the California Longline Fishery will occasionally interact with marine mammals. For this reason, this fishery is proposed to be added to the LOF as a Category II fishery. The categorization of this fishery in Category II is consistent with the way NMFS has addressed other U.S. pelagic longline fisheries, all of which are Category I or II.

Caribbean Gillnet Fishery

NMFS proposes to add the Caribbean Gillnet Fishery to the LOF as a Category III fishery. NMFS is currently examining this fishery, and will determine in a future LOF if a Category II designation is more appropriate. The marine mammal species and stocks incidentally injured and killed include dwarf sperm whales (WNA stock) and West Indian manatees (Antillean stock). During the last 10 years, the Caribbean stranding network has recorded a gillnet interaction with a dwarf sperm whale from the Western North Atlantic stock. During the last 20 years, West Indian manatees have interacted with gillnet gear in the Caribbean. There are 991 gillnet (including trammel net) fishers in Puerto Rico. The number of participants in the U.S. Virgin Islands is unknown.

Caribbean Mixed Species Trap/Pot Fishery

Mixed species trap/pot fisheries exist in the Caribbean but were omitted from past LOFs. NMFS proposes to add the Caribbean Mixed Species Trap/Pot Fishery to the LOF as a Category III fishery. There are 501 mixed species trap/pot fishers in Puerto Rico. The number of participants in the U.S. Virgin Islands is unknown. NMFS is presently evaluating this fishery to determine if any species and stocks of marine mammals are incidentally injured and killed.

Gulf of Mexico Haul/Beach Seine Fishery

The Gulf of Mexico Haul/Beach Seine Fishery was omitted from past LOFs. NMFS proposes to add this fishery to the LOF as a Category III fishery. NMFS believes the specific gear configuration used and operational practices employed (i.e short soak times) warrant a Category III designation for this fishery. At present, no marine mammal interactions are documented.

Gulf of Mexico Mixed Species Trap/Pot Fishery

Mixed species trap/pot fisheries exist in the Gulf of Mexico, but were omitted from past LOFs. NMFS proposes to add the Gulf of Mexico Mixed Species Trap/Pot Fishery to the LOF as a Category III fishery. NMFS is evaluating this fishery to determine if any species and stocks of marine mammals are incidentally injured and killed and to determine the number of participants in this fishery.

Gulf of Mexico Mixed Species Trawl Fishery

The Gulf of Mexico Mixed Species Trawl fishery was omitted from previous LOFs. NMFS proposes to add this fishery to the LOF as a Category III fishery. The Gulf of Mexico Mixed Species Trawl Fishery would incorporate trawl fisheries occurring in the southeast region that are not currently in the LOF, which include a periodic cannonball jellyfish trawl fishery on the west coast of Florida, and a mullet trawl fishery in the Gulf of Mexico. NMFS estimates that 20 fishers participate in this fishery.

Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean Cast Net Fishery

NMFS proposes to add the Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean Cast Net Fishery to the LOF as a Category III fishery. The southeast U.S. stranding network reported two manatees (West Indian, FL) entangled in cast nets, although it is unknown whether these nets were recreational or commercial. Until NMFS can further evaluate the gear types as well as the spatial and temporal distribution of the commercial fisheries NMFS cannot confirm manatee interactions with this fishery. NMFS is presently evaluating the number of participants in the commercial sector.

Mid-Atlantic Pound Net Fishery

NMFS proposes to add the Mid-Atlantic Pound Net Fishery to the LOF. Stranding data for 1993-1997 suggest that this fishery has occasional takes of coastal bottlenose dolphins. Stranding network members who have observed dolphin behavior around pound nets report that dolphins play and feed around pound nets and can become entangled in the leader part of the nets. The leader is a net that guides fish into the pound net.

Data from the Chesapeake Bay suggest that the likelihood of bottlenose dolphins entanglement in pound net leads may be affected by the mesh size of the lead net (Bellmund, *et al.*, 1997), but the information is not conclusive. A study conducted by the NMFS Beaufort Lab from 1988 to 1999 observing pound nets to study sea turtles resulted in no observations of bottlenose dolphin entanglements in the small mesh leader fishery (stretch mesh leader/lines ≤8 inches (20.3 cm)).[2] On each observed set, leaders were examined from the water's surface by boat. No bottlenose dolphin entanglements were observed. NMFS requests public comment on the issue of whether different mesh sizes used in pound net leads would result in differential bycatch rates of bottlenose dolphins or any other marine mammal stock.

NMFS proposes to specify the northern boundary of the Mid-Atlantic Pound Net fishery based on bottlenose dolphin distribution and the southern boundary as the North Carolina/South Carolina border. NMFS will revisit this gear type and similar gear types (e.g., staked traps, weirs) in a future LOF. The names "staked traps" and "weirs" are used interchangeably with "pound nets" and are fished as far north as Maine. NMFS has not yet analyzed all data on marine mammal interactions or fishing effort for this fishery complex and are therefore not prepared to propose a comprehensive change at this time.

NMFS proposes to classify the Mid-Atlantic Pound Net Fishery as a Category II fishery. There are 438 participants in the Mid-Atlantic Pound Net Fishery. Marine mammal species and stocks incidentally injured and killed include bottlenose dolphin (WNA coastal stock). The tier analysis justifying this classification follows:

Tier 1 Evaluation: Stranding data for 1993-1997 documents interactions between the Western North Atlantic Coastal stock of bottlenose dolphin and the Mid-Atlantic Pound Net Fishery. According to data presented in the draft 2000 SAR for 1996-1998, annual serious injury and mortality across all fisheries for bottlenose dolphin (WNA coastal stock) exceeds 10 percent of the PBR level (25). Therefore, this fishery is subject to Tier 2 analysis.

Tier 2 Evaluation: Two bottlenose dolphin carcasses were found entangled in the leads of pound nets in Virginia during 1993-1997, for an average of 0.4 bottlenose dolphin strandings per year. A third record of an entangled bottlenose dolphin in Virginia in 1997 may have been applicable to this fishery. This entanglement involved a bottlenose dolphin carcass found near a pound net with twisted line marks consistent with the twine in the nearby pound net lead rather than with monofilament gillnet gear.

Given that other sources of annual serious injury and mortality estimates (e.g., observer data) related to the Mid-Atlantic Pound Net Fishery are not available, the stranding data (0.4 bottlenose dolphins per year) were used as a minimum estimate of annual serious injury and mortality. Therefore, bottlenose dolphin mortality and serious injury from the Mid-Atlantic Pound Net Fishery is estimated to be between 1 percent and 50 percent of the PBR level (25) for the Western North Atlantic Coastal stock of bottlenose dolphins, placing this fishery in Category II.

North Carolina Long Haul Seine Fishery

NMFS proposes to add the North Carolina Long Haul Seine Fishery to Category II and separate this fishery from the Mid-Atlantic Haul/Beach Seine Fishery (see Other Proposed Changes to the List of Fisheries section for a definition of this fishery). According to the North Carolina Division of Marine Fisheries gear description, this fishery is defined as a multi-filament seine pulled by two boats for a distance of up to several miles. Fish are encircled and concentrated by pulling the net around a fixed stake. There are currently 33 participants in the North Carolina Long Haul Seine Fishery.

The marine mammal stranding network has recorded interactions between multi-filament gear types and bottlenose dolphins (WNA coastal stock). For one of these interactions, long haul seines were specifically implicated as the probable source of interaction. In addition, a stranding network representative observed the live release of three bottlenose dolphins from a long haul seine. These observations support the decision to place this fishery in Category II until NMFS has more data with which to support another classification.

Northeast Drift Gillnet Fishery

NMFS proposes to add the Northeast Drift Gillnet Fishery to the LOF as a Category II fishery to ensure that drift gillnet fisheries for species other than large pelagics are included in the LOF. Based on analogy with other gillnet fisheries, the Atlantic SRG recommended that NMFS place gillnet fisheries in Category II (unless evidence to the contrary is available).

Currently there is no listing for this type of gear in the Northeast. For the purposes of the LOF, drift gillnet, or driftnet, gear is gillnet gear that is free-floating on both ends or is free-floating on one end and attached to the vessel on the other end. Driftnet gear is not anchored to the bottom. In addition, fishing with drift gillnet gear of mesh size smaller than those typically used to target large pelagic species has been recorded for several finfish species, and this fishing effort occurring in the Northeast is currently not represented on the LOF.

The proposed Northeast Drift Gillnet Fishery would include all fishing with drift gillnet gear, regardless of target species or depth of the water column. The geographic boundaries for the proposed Northeast Drift Gillnet Fishery would extend from the U.S./Canadian border south to 72°30' W. longitude, and continue south from the south shore of Long Island, New York. The Northeast Drift Gillnet Fishery would not include any sink gillnet fishing occurring in the areas listed as Category III inshore gillnet fisheries.

Northeast Trap/Pot Fishery

NMFS has documented entanglement of whales, pinnipeds, and small cetaceans in fixed gear, although the gear involved in whale entanglements often cannot be attributed to a specific fishery. However, both lobster pot gear and sink gillnet gear have been identified in whale entanglements. Whales primarily become entangled in the vertical components of the gear (e.g., buoy lines), although entanglement also occurs in the horizontal components of the gear (e.g., gillnet panels, lobster pot groundlines). Small cetaceans and pinnipeds become entangled in net panels of fixed gear, and occasionally in buoy lines (small cetaceans) and traps (pinnipeds). The Gulf of Maine/U.S. Mid-Atlantic Lobster Trap/Pot Fishery (proposed to be renamed the Northeast/Mid-Atlantic American Lobster Trap/Pot Fishery) was elevated to Category I in the 1997 LOF because of evidence of incidental take resulting in serious injury and mortality of right whales.

[2] From 1988-1994, 34 pound net trips, with 10-20 sets per trip, were observed in northern and southern Core Sound and southeastern Pamlico Sound. During 1995-1997, pound net trips were observed for over 13 weeks from September to December, ranging from southern Core Sound to eastern Albemarle Sound in 1995, and from southern Core Sound to central Pamlico Sound in 1996 and 1997.

There were 1,084 observed sets in 1995 (10 percent of pound nets set were sampled each week as determined by weekly aerial surveys flown to quantify pound net effort), 1,084 in 1996 (20 percent of pound nets set were sampled each week), and 1,162 in 1997 (11 percent of pound nets set were sampled each week). During 1998 and 1999 approximately 156 pound net observations occurred from June-August in the northern Core Sound each year, with moderate effort during the fall of 1998 and light effort during the fall of 1999.

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Several other fixed gear fisheries in the Northeast use gear components similar to those used in the Lobster and Blue Crab Trap/Pot fisheries and, therefore, may take marine mammals if fishing effort overlaps marine mammal distribution. The majority of records of entanglements in fixed gear cannot be attributed to a specific fishery; therefore, NMFS cannot conclude that entanglement of marine mammals in trap/pot fisheries other than lobster and blue crab trap/pot gear is not occurring.

Trap/pot gear is generally fished either as single pots with one buoy line or as strings of pots with one or more buoy lines. In a time/area used by marine mammals, there may be virtually no difference in the potential for buoy line entanglement between similar gear components in different fisheries. Groundlines, which are known to entangle whales, are used for multi-pot trawls in several trap/pot fisheries. Furthermore, several trap/pot fisheries have developed in the Northeast that are not represented on the current LOF, including the hagfish, red crab, stone crab, and jonah crab fisheries. The hagfish pot fishery sets strings of hagfish barrels in known high-use areas for whales. A finback whale was entangled in hagfish gear in 1997. Entanglements in red crab gear have not been recorded in U.S. waters, but the gear is fished in whale habitat, and entanglements of right and humpback whales in red crab gear have been recorded in Canadian waters in recent years.

These other trap/pot fisheries may occasionally result in serious injury and mortality to marine mammals. Therefore, NMFS proposes to reclassify these fisheries based on analogy with the lobster trap/pot fishery. However, NMFS does not believe that the rate of incidental serious injury/mortality in non-lobster trap/pot fisheries would be at the Category I level, specifically because there are far fewer participants than in the lobster fishery. Therefore, NMFS proposes to reclassify the other trap/pot fisheries as Category II.

NMFS proposes to name this fishery the Northeast Trap/Pot Fishery. The Northeast Trap/Pot Fishery would extend from the U.S./Canadian border down to the 72°30' W. line, and continue south from the south shore of Long Island, New York to a line extending due east from the Virginia/North Carolina border. The other trap/pot fisheries in the Mid-Atlantic will be re-evaluated in a future LOF cycle for consistency with the changes proposed this year.

Southeastern U.S. Atlantic, Gulf of Mexico Golden Crab Trap/Pot Fishery

The Southeastern U.S. Atlantic, Gulf of Mexico Golden Crab Trap/Pot Fishery was omitted from past LOFs. NMFS proposes to add this fishery to the LOF as a category III fishery. NMFS has no documentation of any marine mammal species and stocks incidentally injured and killed in this fishery. The gear rarely uses buoy lines to the surface, and therefore NMFS believes it is unlikely to result in entanglement. There are 10 participants in this fishery.

Southeastern U.S. Atlantic, Gulf of Mexico Stone Crab Trap/Pot Fishery

The Southeastern U.S. Atlantic, Gulf of Mexico Stone Crab Trap/Pot Fishery was omitted from past LOFs. NMFS proposes to add this fishery to the LOF as a category III fishery. The southeast U.S. stranding network has reported one bottlenose dolphin entangled in this fishery in 1998. Marine mammal species and stocks incidentally injured and killed in this fishery include bottlenose dolphin (Eastern Gulf of Mexico coastal stock). There are 4,453 participants in this fishery.

Fisheries Removed from the LOF

Atlantic Ocean, Caribbean, Gulf of Mexico Large Pelagics Drift Gillnet Fishery

NMFS proposes to remove this fishery from the LOF because NMFS regulations now prohibit this as a gear type for the swordfish and tuna component of this fishery. Any drift gillnet fisheries that do occur would be incorporated into the existing and proposed LOF gillnet listings.

Organizational Changes to the LOF

AK Clam Fishery

NMFS proposes to combine the AK Clam Hand Shovel and the AK Clam Mechanical/Hydraulic Fisheries into one AK Clam Fishery. The new fishery designation would include participants in the southeast AK Geoduck Dive Fishery, which are currently considered part of the AK Urchin and Other Fish/Shellfish Fishery. Since each of these fisheries is currently in Category III, NMFS proposes that the new AK Clam Fishery also be in Category III.

AK Southern Bering Sea, Aleutian Islands, and Western Gulf of Alaska Sablefish Longline/Set Line (Federally Regulated Waters)

NMFS proposes to change the names of several AK longline/set line fisheries to make the names of these fisheries in the LOF consistent with the way these fisheries are addressed in the SARs. NMFS proposes to split the AK Southern Bering Sea, Aleutian Islands, and Western Gulf of Alaska Sablefish Longline/Set Line (federally regulated waters) into the AK Bering Sea, Aleutian Islands Groundfish Longline/Set Line (federally regulated waters, including miscellaneous finfish and sablefish), the AK Gulf of Alaska Groundfish Longline/Set Line (federally regulated waters, including miscellaneous finfish and sablefish), and the AK State-Managed Waters, Groundfish Longline/Set Line (including sablefish, rockfish, and miscellaneous finfish) Fisheries. The AK State Waters Sablefish Longline/Set Line and AK Miscellaneous Finfish/Groundfish Longline/Set Line Fisheries would be incorporated appropriately into the three new fisheries. These changes would make the LOF directly comparable with the SARs and observer data for these longline fisheries.

Bluefish, Croaker, Flounder Trawl Fishery

NMFS proposes to combine the Bluefish, Croaker, Flounder Trawl Fishery into the Mid-Atlantic Mixed Species Trawl Fishery. The Bluefish, Croaker, Flounder Trawl Fishery may consist of at least two separate fisheries, and although bluefish, croaker, and flounder are often caught, they may not always be the target species. Therefore, placing this fishery into the broader Mid-Atlantic Mixed Species Trawl Fishery will ensure that this fishing activity is covered by the LOF. The 550 participants currently listed in the Bluefish, Croaker, Flounder Trawl Fishery may already be reflected in the number of participants for the Mid-Atlantic Mixed Species Trawl Fishery. NMFS will evaluate the number of participants in these fisheries and provide an update in future LOFs.

Caribbean Haul/Beach Seine Fishery

NMFS proposes to combine the Caribbean Haul Seine and Caribbean Beach Seine fisheries into one fishery called the Caribbean Haul/Beach Seine Fishery. Marine mammal species and stocks incidentally injured and killed include the West Indian manatee Antillean stock. The Florida stock of West Indian manatee was incorrectly listed as interacting with this fishery in past LOFs.

Gulf of Maine, Southeast U.S. Atlantic Coastal Shad, Sturgeon Gillnet Fishery

Sturgeon is now a prohibited species in both state and Federal waters. Therefore, NMFS proposes to remove this Category III fishery from the LOF to reflect these changes.

Gillnet fishing for shad in the Southeast is included in the proposed Category II Southeast Atlantic Gillnet Fishery. Gillnet fishing for shad in the Northeast is included in the Northeast Sink Gillnet Fishery, the Northeast Anchored Pelagic Gillnet Fishery, and/or the Northeast Drift Gillnet Fishery, depending on the type of gear used. Gillnet fishing for shad in the Mid-Atlantic (i.e., the 73o30' W line to the North Carolina/South Carolina border) is included in the U.S. Mid-Atlantic Coastal Gillnet Fishery (57 FR 20328, May 12, 1992).

Gulf of Maine, U.S. Mid-Atlantic Mixed Species Trap/Pot Fishery

NMFS proposes to separate the Gulf of Maine, U.S. Mid-Atlantic Mixed Species Trap/Pot Fisheries into two separate listings: the Northeast Trap/Pot Fishery and the Mid-Atlantic Mixed Species Trap/Pot Fishery. The marine mammal species and stocks incidentally injured and killed in the Mid-Atlantic Mixed Species Trap/Pot Fishery include the humpback whale (Gulf of Maine stock), minke whale (Canadian east coast stock), and harbor porpoise (Gulf of Maine/Bay of Fundy stock). Additional information on the Northeast Trap/Pot Fishery is described later in this preamble. NMFS is presently evaluating the Mid-Atlantic Mixed Species Trap/Pot Fishery to determine the target species and number of participants. NMFS will evaluate this fishery in a future LOF for consistency with the Northeast Trap/Pot Fishery.

Southeastern U.S. Atlantic, Gulf of Mexico, Caribbean Spiny Lobster Trap/Pot Fishery

NMFS proposes to divide the Southeastern U.S. Atlantic, Gulf of Mexico, Caribbean Spiny Lobster Trap/Pot Fishery into two separate fisheries: the Florida Spiny Lobster Trap/Pot Fishery and the Caribbean Spiny Lobster Trap/Pot Fishery.

Marine mammal species and stocks incidentally injured and killed in the Florida Spiny Lobster Fishery include the West Indian manatee (FL stock) and bottlenose dolphin (WNA coastal stock). This fishery occurs off of Florida in the Southeastern U.S. Atlantic and Gulf of Mexico. NMFS is currently evaluating the number of participants in the Florida spiny lobster fishery.

There are no known marine mammal species and stocks incidentally injured and killed as a result of the Caribbean Spiny Lobster Fishery. There are 197 participants in this fishery in Puerto Rico. The number of participants in the U.S. Virgin Islands is unknown.

Name Changes to Fisheries in the LOF

AK Octopus/Squid Pot Fishery

The LOF previously included a listing for the AK Octopus/Squid "Other" Fishery. Although this fishery originally included several gear types (dive gear, hand pick, mechanical jigging, and pot), only the pot fishery is currently active. As a result, NMFS proposes to change the name to the AK Octopus/Squid Pot Fishery and list this fishery with the other Category III pot fisheries.

AK Southeast Alaska Herring Food/Bait Pound Net Fishery

The name of the AK Southeast Alaska Herring Food/Bait Pound Net Fishery is changed to the AK Southeast Herring Roe/Food/Bait Pound Net Fishery.

Gulf of Maine Small Pelagics Surface Gillnet Fishery

NMFS proposes to change the name of the Category II Gulf of Maine Small Pelagics Surface Gillnet Fishery to the Northeast Anchored Pelagic Gillnet Fishery to include anchored pelagic gillnet effort in other parts of the Northeast and for species other than small pelagics in the LOF. The Northeast Anchored Pelagic Gillnet Fishery would include the use of gillnet gear of any size and for any target species that is anchored and fished in the upper two thirds of the water column. The geographic boundaries for the proposed Northeast Anchored Pelagic Gillnet Fishery would extend from the U.S./Canadian border to 72°30' W. longitude, and continue south from the south shore of Long Island, New York. The Northeast Anchored Pelagic Gillnet Fishery would not include any sink gillnet fishing occurring in the areas listed as Category III inshore gillnet fisheries.

Gulf of Maine/U.S. Mid-Atlantic Lobster Trap/Pot Fishery

NMFS proposes to change the name of this fishery from the Gulf of Maine/U.S. Mid-Atlantic Lobster Trap/Pot Fishery to the Northeast/Mid-Atlantic American Lobster Trap/Pot Fishery to reflect the distinction between the American Lobster Fishery and the Spiny Lobster Fishery. The new name is also intended to clarify that fishing in other areas of the Northeast, for example offshore areas that might not be considered part of the Gulf of Maine, are included in the LOF.

Mid-Atlantic Haul Seine Fishery

The name of the Mid-Atlantic Haul Seine fishery is changed to the Mid-Atlantic Haul/Beach Seine fishery for clarity. This fishery includes seines where one end is secured (e.g., swipe net, long seine) as well as seines that may be secured at both ends and hauled up on the beach.

Mid-Atlantic Mixed Species Stop/Seine/Weir Fishery

The U.S. Mid-Atlantic Mixed Species Stop/Seine/Weir Fishery is changed to the U.S. Mid-Atlantic Mixed Species Stop Seine/Weir Fishery to be consistent with the category title for this fishery.

Mid-Atlantic, Southeastern U.S. Atlantic, Gulf of Mexico Shrimp Trawl Fishery

The Mid-Atlantic component of the Mid-Atlantic, Southeastern U.S. Atlantic, Gulf of Mexico Shrimp Trawl Fishery is removed, and the name changed to the Southeastern U.S. Atlantic, Gulf of Mexico Shrimp Trawl Fishery. The new name reflects that this fishery operates from North Carolina into the Gulf of Mexico.

Southeast AK Salmon Drift Gillnet

The name of the Southeast AK Salmon Drift Gillnet Fishery is changed to the AK Southeast Salmon Drift Gillnet Fishery.

Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean Snapper-Grouper and Other Reef Fish Bottom Longline/Hook-and-Line Fishery

NMFS proposes to revise the name of the Southeastern U.S. Atlantic, Gulf of Mexico Snapper-Grouper and Other Reef Fish Bottom Longline/Hook-and-Line Fishery to include the Caribbean. There are 1,349 bottom longline/hook-and-line fishers in Puerto Rico. The number of participants in the U.S. Virgin Islands is unknown.

Southeastern U.S. Atlantic, Caribbean Haul Seine Fishery

The name of the Southeastern U.S. Atlantic, Caribbean Haul Seine Fishery is changed to the Southeastern U.S. Atlantic Haul/Beach Seine Fishery.

Other Proposed Changes or Clarifications to the LOF

Atlantic Ocean, Caribbean, Gulf of Mexico Large Pelagics Longline Fishery

The estimated number of participants in the Atlantic Ocean, Caribbean, Gulf of Mexico Large Pelagics Longline Fishery is updated to 443. This represents the number of permits issued, not active participants.

Calico Scallops Trawl Fishery

The estimated number of participants in the Calico Scallops Trawl Fishery is updated to 12.

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Category II Haul Seine Fisheries

The name of the Haul Seine Fisheries title is changed to Haul/Beach Seine Fisheries for clarity.

Category III Haul Seine

The name of the Haul Seine Fisheries title under Category III is changed to Haul/Beach Seine Fisheries and the Beach Seine Fisheries title is removed for clarity. The Caribbean Beach Seine Fishery is changed to the Caribbean Haul/Beach Seine Fishery and included in the new category.

Mid-Atlantic Menhaden Purse Seine

The list of marine mammal species and stocks incidentally injured and killed in the Mid-Atlantic Menhaden Purse Seine Fishery is updated to reflect a fisher report of a humpback whale becoming entangled in the purse seine net, which was subsequently released alive.

Northeast Sink Gillnet Fishery

NMFS is not proposing to change the definition or categorization of this fishery, but provides the following explanation for clarification and comparison with fisheries for which changes are proposed. The Northeast Sink Gillnet Fishery is retained in Category I with the current geographic boundaries defining this fishery. The Northeast Sink Gillnet Fishery continues to include all fishing with sink gillnet gear, regardless of target species, from the U.S./Canadian border to 72°30' W. longitude, and continuing south from the south shore of Long Island, New York. To differentiate from other LOF gillnet listings, sink gillnet gear is considered to be anchored gillnet gear fished in the lower third of the water column. The Northeast Sink Gillnet Fishery would not include any sink gillnet fishing occurring in the areas listed as Category III inshore gillnet fisheries.

Southeastern U.S. Atlantic Shark Gillnet Fishery

The list of marine mammal species and stocks incidentally injured and killed in the Southeastern U.S. Atlantic Shark Gillnet Fishery is updated to reflect an Atlantic spotted dolphin that was reported incidentally taken and released alive.

Southeastern U.S. Stranding Data Review

The Southeast Fisheries Science Center is presently conducting a comprehensive review of all stranding records and if there are any changes in these estimates they will be listed in a subsequent LOF. At this time, the estimates of incidental mortality and serious injury presented in this proposed LOF are considered minimum.

References

Bellmund, S.A., Musick, J.A., Klinger, R.C., Byles, R.A., Keinath, J.A., and Barnard, D.E. 1997. Ecology of Sea Turtles in Virginia. Final Report to National Marine Fisheries Service Northeast Region. Contract number NA80FAC-00004. Virginia Institute of Marine Science, Gloucester Point, Virginia.

List of Fisheries

The following two tables list U.S. commercial fisheries according to their assigned categories under section 118 of the MMPA including proposed changes. The estimated number of vessels/participants is expressed in terms of the number of active participants in the fishery, when possible. If this information is not available, the estimated number of vessels or persons licensed for a particular fishery is provided. If no recent information is available on the number of participants in a fishery, the number from the 1996 LOF is used.

The tables also list the marine mammal species and stocks that are incidentally killed or injured in each fishery based on observer data, logbook data, stranding reports, and fishers' reports. This list includes all species or stocks known to incur injury or mortality in a given fishery. However, not all species or stocks identified are necessarily independently responsible for a fishery's categorization. There are a few fisheries that are in Category II that have no recently documented interactions with marine mammals. Justifications for placement of these fisheries are by analogy to other gear types that are known to injure or kill marine mammals, as discussed in the final LOF for 1996 (60 FR 45086, December 28, 1995).

Commercial fisheries in the Pacific Ocean (including Alaska) are included in Table 2; commercial fisheries in the Atlantic Ocean, Gulf of Mexico, and Caribbean are included in Table 3. An asterisk (*) indicates that the stock is a strategic stock; a plus (+) indicates that the stock is listed as threatened or endangered under the Endangered Species Act.

TABLE 2.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE PACIFIC OCEAN

Fishery Description	Estimated no. of vessels/persons	Marine mammal species and stocks incidentally killed/injured
Category I		
GILLNET FISHERIES:		
CA angel shark/halibut and other species large mesh (>3.5in) set gillnet.	58	Harbor porpoise, central CA Common dolphin, short-beaked, CA/OR/WA Common dolphin, long-beaked CA California sea lion, U.S. Harbor seal, CA Northern elephant seal, CA breeding Sea otter, CA
CA/OR thresher shark/swordfish drift gillnet	130	Steller sea lion, Eastern U.S.*+ Sperm whale, CA/OR/WA*+ Dall's porpoise, CA/OR/WA Pacific white sided dolphin, CA/OR/WA Risso's dolphin, CA/OR/WA Bottlenose dolphin, CA/OR/WA offshore Short-beaked common dolphin CA/OR/WA Long-beaked common dolphin CA/OR/WA Northern right whale dolphin, CA/OR/WA Short-finned pilot whale, CA/OR/WA* Baird's beaked whale, CA/OR/WA Mesoplodont beaked whale, CA/OR/WA Cuvier's beaked whale, CA/OR/WA Pygmy sperm whale, CA/OR/WA California sea lion, U.S. Northern elephant seal, CA breeding Humpback whale, CA/OR/WA-Mexico* Minke whale, CA/OR/WA Striped dolphin, CA/OR/WA Killer whale, CA/OR/WA Pacific coast Northern fur seal, San Miguel Island
Category II		
GILLNET FISHERIES:		
AK Bristol Bay salmon drift gillnet	1,903	Steller sea lion, Western U.S.*+ Northern fur seal, Eastern Pacific* Harbor seal, Bering Sea Beluga whale, Bristol Bay Gray whale, Eastern north Pacific Spotted seal, AK Pacific white-sided dolphin, North Pacific
AK Bristol Bay salmon set gillnet	1,014	Harbor seal, Bering Sea Beluga whale, Bristol Bay Gray whale, Eastern North Pacific Northern fur seal, Eastern Pacific* Spotted seal, AK
AK Cook Inlet salmon drift gillnet	576	Steller sea lion, Western U.S.*+ Harbor seal, GOA Harbor porpoise, GOA Dall's porpoise, AK Beluga whale, Cook Inlet*+
AK Cook Inlet salmon set gillnet	745	Steller sea lion, Western U.S.*+ Harbor seal, GOA Harbor porpoise, GOA Dall's porpoise, AK Beluga whale, Cook Inlet*+
AK Kodiak salmon set gillnet	188	Harbor seal, GOA Harbor porpoise, GOA Sea otter, AK
AK Metlakatla/Annette Island salmon drift gillnet	60	None documented
AK Peninsula/Aleutian Islands salmon drift gillnet	164	Northern fur seal, Eastern Pacific* Harbor seal, GOA Harbor porpoise, Bering Sea Dall's porpoise, AK
AK Peninsula/Aleutian Islands salmon set gillnet	116	Steller sea lion, Western U.S.*+ Harbor porpoise, Bering Sea

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TABLE 2.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery Description	Estimated no. of vessels/persons	Marine mammal species and stocks incidentally killed/injured
AK Prince William Sound salmon drift gillnet	541	Steller sea lion, Western U.S.*+ Northern fur seal, Eastern Pacific* Harbor seal, GOA Pacific white-sided dolphin, North Pacific Harbor porpoise, GOA Dall's porpoise, AK Sea Otter, AK
AK Southeast salmon drift gillnet	481	Steller sea lion, Eastern U.S.*+ Harbor seal, Southeast AK Pacific white-sided dolphin, North Pacific Harbor porpoise, Southeast AK Dall's porpoise, AK Humpback whale, central North Pacific*+
AK Yakutat salmon set gillnet	170	Harbor seal, Southeast AK Gray whale, Eastern North Pacific
WA Puget Sound Region salmon drift gillnet (includes all inland waters south of US-Canada border and eastward of the Bonilla-Tatoosh line treaty Indian fishing is excluded).	725	Harbor porpoise, inland WA Dall's porpoise, CA/OR/WA Harbor seal, WA inland
PURSE SEINE FISHERIES:		
AK Southeast salmon purse seine	416	Humpback whale, central North Pacific*+
CA anchovy, mackerel, tuna purse seine	150	Bottlenose dolphin, CA/OR/WA offshore California sea lion, U.S. Harbor seal, CA
CA squid purse seine	65	Short-finned pilot whale, CA/OR/WA*
TRAWL FISHERIES:		
AK miscellaneous finfish pair trawl	2	None documented
LONGLINE FISHERIES:		
California longline	45	California sea lion
HI swordfish, tuna, billfish, mahi mahi, wahoo, oceanic sharks longline/set line.	140	Humpback whale, Central North Pacific*+ False killer whales, HI Risso's dolphin, HI Bottlenose dolphin, HI Spinner dolphin, HI Short-finned pilot whale, HI Sperm whale, HI
OR swordfish floating longline	2	None documented
OR blue shark floating longline	1	None documented
Category III		
GILLNET FISHERIES:		
AK Kuskokwim, Yukon, Norton Sound, Kotzebue salmon gillnet	1,922	Harbor porpoise, Bering Sea
AK miscellaneous finfish set gillnet	3	Steller sea lion, Western U.S.*+
AK Prince William Sound salmon set gillnet	30	Steller sea lion, Western U.S.*+ Harbor seal, GOA
AK roe herring and food/bait herring gillnet	2,034	None documented
CA set and drift gillnet fisheries that use a stretched mesh size of 3.5 in or less.	341	None documented
Hawaii gilinet	115	Bottlenose dolphin, HI Spinner dolphin, HI
WA Grays Harbor salmon drift gillnet (excluding treaty Tribal fishing).	24	Harbor seal, OR/WA coast
WA, OR herring, smelt, shad, sturgeon, bottom fish, mullet, perch, rockfish gillnet.	913	None documented
WA, OR lower Columbia River (includes tributaries) drift gillnet	110	California sea lion, U.S. Harbor seal, OR/WA coast
WA Willapa Bay drift gillnet	82	Harbor seal, OR/WA coast Northern elephant seal, CA breeding
PURSE SEINE, BEACH SEINE, ROUND HAUL AND THROW NET FISHERIES:		
AK Metlakatla salmon purse seine	10	None documented
AK miscellaneous finfish beach seine	1	None documented
AK miscellaneous finfish purse seine	3	None documented
AK octopus/squid purse seine	2	None documented
AK roe herring and food/bait herring beach seine	8	None documented
AK roe herring and food/bait herring purse seine	624	None documented
AK salmon beach seine	34	None documented
AK salmon purse seine (except Southeast Alaska, which is in Category II).	953	Harbor seal, GOA

TABLE 2.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery Description	Estimated no. of vessels/persons	Marine mammal species and stocks incidentally killed/injured
CA herring purse seine	100	Bottlenose dolphin, CA coastal California sea lion, U.S. Harbor seal, CA
CA sardine purse seine	120	None documented
HI opelu/akule net	16	None documented
HI purse seine	18	None documented
HI throw net, cast net	47	None documented
WA (all species) beach seine or drag seine	235	None documented
WA, OR herring, smelt, squid purse seine or lampara	130	None documented
WA salmon purse seine	440	None documented
WA salmon reef net	53	None documented
DIP NET FISHERIES:		
CA squid dip net	115	None documented
WA, OR smelt, herring dip net	119	None documented
MARINE AQUACULTURE FISHERIES:		
CA salmon enhancement rearing pen	>1	None documented
OR salmon ranch	1	None documented
WA, OR salmon net pens	14	California sea lion, U.S. Harbor seal, WA inland waters
TROLL FISHERIES		
AK north Pacific halibut, AK bottom fish, WA, OR, CA albacore, groundfish, bottom fish, CA halibut non-salmonid troll fisheries.	1,530 (330 AK)	None documented
AK salmon troll	2,335	Steller sea lion, Western U.S.*+ Steller sea lion, Eastern U.S.*+
American Samoa tuna troll	<50	None documented
CA/OR/WA salmon troll	4,300	None documented
Commonwealth of the Northern Mariana Islands tuna troll	50	None documented
Guam tuna troll	50	None documented
HI net unclassified	106	None documented
HI trolling, rod and reel	1,795	None documented
LONGLINE/SET LINE FISHERIES:		
HI trolling, rod and reel.		
AK Bering Sea, Aleutian Islands groundfish longline/set line (federally regulated waters, including miscellaneous finfish and sablefish).	115	Northern elephant seal, CA breeding Killer whale, Eastern North Pacific resident Killer whale, transient Steller sea lion, Western U.S.*+ Pacific white-sided dolphin, North Pacific Dall's porpoise, AK Harbor seal, Bering Sea
AK Gulf of Alaska groundfish longline/set line (federally regulated waters, including miscellaneous finfish and sablefish).	867	Steller sea lion, Western U.S.*+ Harbor seal, Southeast AK Northern elephant seal, CA breeding
AK halibut longline/set line (State and Federal waters)	3,079	Steller sea lion, Western U.S.*+
AK octopus/squid longline	7	None documented
AK state-managed waters groundfish longline/setline (including sablefish, rockfish, and miscellaneous finfish).	731	None documented
CA shark/bonito longline/set line	10	None documented
WA, OR, CA groundfish, bottomfish longline/set line	367	None documented
WA, OR North Pacific halibut longline/set line	350	None documented
TRAWL FISHERIES:		
AK Bering Sea and Aleutian Islands Groundfish Trawl	166	Steller sea lion, Western U.S.*+ Northern fur seal, Eastern pacific* Killer whale, Eastern North Pacific resident Killer whale, Eastern North Pacific transient Pacific white sided dolphin, North Pacific Harbor porpoise, Bering Sea Harbor seal, Bering Sea Harbor seal, GOA Bearded seal, AK Ringed seal, AK Spotted seal, AK Dall's porpoise, AK Ribbon seal, AK Northern elephant seal, CA breeding Sea otter, AK Pacific walrus, AK Humpback whale, Central North Pacific*+ Humpback whale, Western North Pacific*+
AK food/bait herring trawl	3	None documented

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TABLE 2.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery Description	Estimated no. of vessels/persons	Marine mammal species and stocks incidentally killed/injured
AK Gulf of Alaska groundfish trawl	198	Steller sea lion, Western U.S.*+ Northern fur seal, Eastern Pacific* Harbor seal, GOA Dall's porpoise, AK Northern elephant seal, CA breeding Fin whale, Northeast Pacific
AK miscellaneous finfish otter or beam trawl	6	None documented
AK shrimp otter trawl and beam trawl (statewide and Cook Inlet)	58	None documented
AK state-managed waters of Cook Inlet, Kachemak Bay, Prince William Sound, Southeast AK groundfish trawlWA, OR, CA groundfish trawl.	2	None documented
WA, OR, CA groundfish trawl	585	Steller sea lion, Western U.S.*+ Northern fur seal, Eastern Pacific* Pacific white-sided dolphin, central North Pacific Dall's porpoise, CA/OR/WA California sea lion, U.S. Harbor seal, OR/WA coast
WA, OR, CA shrimp trawl	300	None documented
POT, RING NET, AND TRAP FISHERIES:		
AK Bering Sea, Gulf of Alaska finfish pot	257	Harbor seal, GOA Harbor seal, Bering Sea Sea otter, AK
AK crustacean pot	1,852	Harbor porpoise, Southeast AK
AK octopus/squid pot	72	None documented
AK snail pot	2	None documented
CA lobster, prawn, shrimp, rock crab, fish pot	608	Sea otter, CA
OR, CA hagfish pot or trap	25	None documented
WA, OR, CA crab pot	1,478	None documented
WA, OR, CA sablefish pot	176	None documented
WA, OR shrimp pot & trap	254	None documented
HI crab trap	22	None documented
HI fish trap	19	None documented
HI lobster trap	15	Hawaiian monk seal*+
HI shrimp trap	5	None documented
HANDLINE AND JIG FISHERIES:		
AK miscellaneous finfish handline and mechanical jig	100	None documented
AK North Pacific halibut handline and mechanical jig	93	None documented
AK octopus/squid handline	2	None documented
American Samoa bottomfish	<50	None documented
Commonwealth of the Northern Mariana Islands bottomfish	<50	None documented
Guam bottomfish	<50	None documented
HI aku boat, pole and line	54	None documented
HI deep sea bottomfish	434	Hawaiian monk seal*+
Hi inshore handline	650	Bottlenose dolphin, HI
HI tuna	144	Rough-toothed dolphin, HI Bottlenose dolphin, HI Hawaiian monk seal*+
WA groundfish, bottomfish jig	679	None documented
HARPOON FISHERIES:		
CA swordfish harpoon	228	None documented
POUND NET/WEIR FISHERIES:		
AK herring spawn on kelp pound net	452	None documented
AK Southeast herring roe/food/bait pound net	3	None documented
WA herring brush weir	1	None documented
BAIT PENS:		
WA/OR/CA bait pens	13	None documented
DREDGE FISHERIES:		
Coastwide scallop dredge	108 (12 AK)	None documented
DIVE, HAND/MECHANICAL COLLECTION FISHERIES:		
AK abalone	1	None documented
AK clam	156	None documented
WA herring spawn on kelp	4	None documented
AK dungeness crab	3	None documented
AK herring spawn on kelp	363	None documented
AK urchin and other fish/shellfish	471	None documented
CA abalone	111	None documented
CA sea urchin	583	None documented
HI coral diving	2	None documented
HI fish pond	10	None documented
HI handpick	135	None documented
HI lobster diving	6	None documented
HI squiding, spear	267	None documented

TABLE 2.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE PACIFIC OCEAN—Continued

Fishery Description	Estimated no. of vessels/persons	Marine mammal species and stocks incidentally killed/injured
WA, CA kelp	4	None documented
WA/OR sea urchin, other clam, octopus, oyster, sea cucumber, scallop, ghost shrimp hand, dive, or mechanical collection.	637	None documented
WA shellfish aquaculture	684	None documented
COMMERCIAL PASSENGER FISHING VESSEL (CHARTER BOAT) FISHERIES:		
AK, WA, OR, CA commercial passenger fishing vessel	>7,000 (1,107 AK)	None documented
HI "other"	114	None documented
LIVE FINFISH/SHELLFISH FISHERIES:		
CA finfish and shellfish live trap/hook-and-line	93	None documented

* Marine mammal stock is strategic or is proposed to be listed as strategic in the draft SARs for 2000.
+ stock is listed as threatened or endangered under the Endangered Species Act (ESA) or as depleted under the MMPA. List of Abbreviations Used in Table 2: AK, Alaska; GOA; CA , California; HI, Hawaii Gulf of Alaska; OR, Oregon, and WA, Washington

TABLE 3.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally injured and killed
Category I		
GILLNET FISHERIES:		
Northeast sink gillnet	341	North Atlantic right whale, WNA*+ Humpback whale, WNA*+ Minke whale, Canadian east coast Killer whale, WNA White-sided dolphin, WNA* Bottlenose dolphin, WNA offshore Harbor porpoise, GME/BF* Harbor seal, WNA Gray seal, WNA Common dolphin, WNA * Fin whale, WNA *+ Spotted dolphin, WNA False killer whale, WNA Harp seal, WNA
U.S. Mid-Atlantic coastal gillnet	>655	Humpback whale, WNA*+ Minke whale, Canadian east coast Bottlenose dolphin, WNA offshore Bottlenose dolphin, WNA coastal*+ Harbor porpoise, GME/BF* Harbor seal, WNA Harp seal, WNA Long-finned pilot whale, WNA* Short-finned pilot whale, WNA* White sided dolphin, WNA Common dolphin, WNA
LONGLINE FISHERIES:		
Atlantic Ocean, Caribbean, Gulf of Mexico large pelagics longline	<200	Humpback whale, WNA*+ Minke whale, Canadian east coast Risso's dolphin, WNA Long-finned pilot whale, WNA* Short-finned pilot whale, WNA* Common dolphin, WNA* Atlantic spotted dolphin, WNA* Pantropical spotted dolphin, WNA* Striped dolphin, WNA Bottlenose dolphin, WNA offshore Bottlenose dolphin, GMX Outer Continental Shelf Bottlenose dolphin, GMX Continental Shelf Edge and Slope Atlantic spotted dolphin, Northern GMX Pantropical spotted dolphin, Northern GMX Risso's dolphin, Northern GMX Harbor porpoise, GME/BF*
TRAP/POT FISHERIES:		

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TABLE 3.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally injured and killed
Northeast/Mid-Atlantic American lobster trap/pot	13,000	North Atlantic right whale, WNA*+ Humpback whale, WNA*+ Fin whale, WNA*+ Minke whale, Canadian east coast Harbor seal, WNA
TRAWL FISHERIES:		
Atlantic squid, mackerel, butterfish trawl	620	Common dolphin, WNA* Risso's dolphin, WNA Long-finned pilot whale, WNA* Short-finned pilot whale, WNA* White-sided dolphin, WNA*
Category II		
GILLNET FISHERIES:		
Gulf of Mexico gillnet	724	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal Bottlenose dolphin, Eastern GMX coastal Bottlenose dolphin, GMX Bay, Sound, and Estuarine*
North Carolina inshore gillnet	94	Bottlenose dolphin, WNA coastal*+
Northeast anchored pelagic gillnet	133	Humpback whale, WNA*+ White-sided dolphin, WNA* Harbor seal, WNA
Northeast drift gillnet	unknown	None documented
Southeast Atlantic gillnet	640	Bottlenose dolphin, WNA coastal
Southeastern U.S. Atlantic shark gillnet	12	Bottlenose dolphin, WNA coastal* North Atlantic right whale, WNA*+ Atlantic spotted dolphin, WNA
TRAWL FISHERIES:		
Atlantic herring midwater trawl (including pair trawl)	17	Harbor seal, WNA
TRAP/POT FISHERIES:		
Atlantic blue crab trap/pot	>16,000	Bottlenose dolphin, WNA coastal* West Indian manatee, FL
Gulf of Mexico blue crab trap/pot	4,113	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal Bottlenose dolphin, Eastern GMX coastal Bottlenose dolphin, GMX Bay, Sound, & Estuarine* West Indian manatee, FL*+
Northeast trap/pot	unknown	Fin whale, WNA
PURSE SEINE FISHERIES:		
Gulf of Mexico menhaden purse seine	50	Bottlenose dolphin, Western GMX coastal Bottlenose dolphin, Northern GMX coastal
HAUL/BEACH SEINE FISHERIES:		
Mid-Atlantic haul/beach seine	25	Bottlenose dolphin, WNA coastal* Harbor porpoise, GME/BF*
North Carolina long haul seine	33	Bottlenose dolphin, WNA coastal*
STOP NET FISHERIES:		
North Carolina roe mullet stop net	13	Bottlenose dolphin, WNA coastal*
POUND NET FISHERIES:		
Mid-Atlantic pound net	438	Bottlenose dolphin, WNA coastal*
Category III		
GILLNET FISHERIES:		
Caribbean gillnet	>991	Dwarf sperm whale, WNA West Indian manatee, Antillean
Chesapeake Bay inshore gillnet	45	Harbor porpoise, GME/BF
Delaware Bay inshore gillnet	60	Humpback whale, WNA*+ Bottlenose dolphin, WNA coastal*+ Harbor porpoise, GME/BF*
Long Island Sound inshore gillnet	20	Humpback whale, WNA*+ Bottlenose dolphin, WNA coastal*+ Harbor porpoise, GME/BF*
Rhode Island, southern Massachusetts (to Monomoy Island), and New York Bight (Raritan and Lower New York Bays) inshore gillnet.	32	Humpback whale, WNA*+ Bottlenose dolphin, WNA coastal*+ Harbor porpoise, GME/BF*
TRAWL FISHERIES:		
Calico scallops trawl	12	None documented
Crab trawl	400	None documented
Georgia, South Carolina, Maryland whelk trawl	25	None documented
Gulf of Maine, Mid-Atlantic sea scallop trawl	215	None documented
Gulf of Maine northern shrimp trawl	320	None documented

TABLE 3.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally injured and killed
Gulf of Mexico butterfish trawl	2	Atlantic spotted dolphin, Eastern GMX Pantropical spotted dolphin, Eastern GMX
Gulf of Mexico mixed species trawl	20	None documented
Mid-Atlantic mixed species trawl	>1,000	None documented
North Atlantic bottom trawl	1,052	Long-finned pilot whale, WNA* Short-finned pilot whale, WNA* Common dolphin, WNA* White-sided dolphin, WNA* Striped dolphin, WNA Bottlenose dolphin, WNA offshore
Southeastern U.S. Atlantic, Gulf of Mexico shrimp trawl	>18,000	Bottlenose dolphin, WNA coastal*+
U.S. Atlantic monkfish trawl	unknown	Common dolphin, WNA*
MARINE AQUACULTURE FISHERIES:		
Finfish aquaculture	48	Harbor seal, WNA
Shellfish aquaculture	unknown	None documented
PURSE SEINE FISHERIES:		
Gulf of Maine Atlantic herring purse seine	30	Harbor porpoise, GME/BF* Harbor seal, WNA Gray seal, WNA
Gulf of Maine menhaden purse seine	50	None documented
Florida west coast sardine purse seine	10	Bottlenose dolphin, Eastern GMX coastal
Mid-Atlantic menhaden purse seine	22	Bottlenose dolphin, WNA coastal*+ Humpback whale, WNA*+
U.S. Atlantic tuna purse seine	unknown	None documented
U.S. Mid-Atlantic hand seine	>250	None documented
LONGLINE/HOOK-AND-LINE FISHERIES:		
Gulf of Maine tub trawl groundfish bottom longline/ hook-and-line	46	Harbor seal, WNA Gray seal, Northwest North Atlantic Humpback whale, WNA
Gulf of Maine, U.S. Mid-Atlantic tuna, shark swordfish hook-and-line/harpoon.	26,223	Humpback whale, WNA
Southeastern U.S. Atlantic, Gulf of Mexico, and Caribbean snapper-grouper and other reef fish bottom longline/hook-and-line.	>5,000	None documented
Southeastern U.S. Atlantic, Gulf of Mexico shark bottom longline/ hook-and-line.	124	None documented
Southeastern U.S. Atlantic, Gulf of Mexico, U.S. Mid-Atlantic pelagic hook-and-line/harpoon.	1,446	None documented
TRAP/POT FISHERIES		
Caribbean mixed species trap/pot	>501	None documented
Caribbean spiny lobster trap/pot	>197	None documented
Florida spiny lobster trap/pot	unknown	West Indian manatee, FL*+ Bottlenose dolphin, WNA coastal*+
Gulf of Mexico mixed species trap/pot	unknown	None documented
Mid-Atlantic mixed species trap/pot	unknown	Humpback whale, Gulf of Maine Minke whale, Canadian east coast Harbor porpoise, GM/BF
Southeastern U.S. Atlantic, Gulf of Mexico golden crab trap/pot	10	None documented
Southeastern U.S. Atlantic, Gulf of Mexico stone crab trap/pot	4,453	Bottlenose dolphin, Eastern Gulf of Mexico coastal
U.S. Mid-Atlantic eel trap/pot	>700	None documented
U.S. Mid-Atlantic and Southeast U.S. Atlantic black sea bass trap/ pot.	30	None documented
STOP SEINE/WEIR/POUND NET FISHERIES:		
Gulf of Maine herring and Atlantic mackerel stop seine/weir	50	North Atlantic right whale, WNA* Humpback whale, WNA*+ Minke whale, Canadian east coast Harbor porpoise, GME/BF* Harbor seal, WNA Gray seal, Northwest North Atlantic
U.S. Mid-Atlantic crab stop seine/weir	2,600	None documented
U.S. Mid-Atlantic mixed species stop seine/weir (except the North Carolina roe mullet stop net).	500	None documented
DREDGE FISHERIES:		
Gulf of Maine mussel	>50	None documented
Gulf of Maine, U.S. Mid-Atlantic sea scallop dredge	233	None documented
U.S. Mid-Atlantic/Gulf of Mexico oyster	7,000	None documented
U.S. Mid-Atlantic offshore surf clam and quahog dredge	100	None documented
HAUL/BEACH SEINE FISHERIES:		
Caribbean haul/beach seine	15	West Indian manatee, Antillean
Gulf of Mexico haul/beach seine	unknown	None documented
Southeastern U.S. Atlantic, haul/beach seine	25	None documented

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TABLE 3.—PROPOSED LIST OF FISHERIES COMMERCIAL FISHERIES IN THE ATLANTIC OCEAN, GULF OF MEXICO, AND CARIBBEAN—Continued

Fishery Description	Estimated # of vessels/persons	Marine mammal species and stocks incidentally injured and killed
DIVE, HAND/MECHANICAL COLLECTION FISHERIES:		
Atlantic Ocean, Gulf of Mexico, Caribbean shellfish dive, hand/mechanical collection.	20,000	None documented
Gulf of Maine urchin dive, hand/mechanical collection	>50	None documented
Gulf of Mexico, Southeast Atlantic, Mid-Atlantic, and Caribbean cast net.	unknown	None documented
COMMERCIAL PASSENGER FISHING VESSEL (CHARTER BOAT) FISHERIES:		
Atlantic Ocean, Gulf of Mexico, Caribbean commercial passenger fishing vessel.	4,000	None documented

* Marine mammal stock is strategic or is proposed to be listed as strategic in the draft SARs for 2000.
+ Stock is listed as threatened or endangered under the ESA or as depleted under the MMPA. List of Abbreviations Used in Table 3 FL - Florida NC - North Carolina GA - Georgia SC - South Carolina GME/BF - Gulf of Maine/Bay of Fundy TX - Texas GMX - Gulf of Mexico WNA - Western North Atlantic

Classification

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed LOF for 2001, if adopted, would not have a significant economic impact on a substantial number of small entities for the following reasons.

Under existing regulations, all fishers participating in Category I or II fisheries, must register, obtain an Authorization Certificate, and pay a fee of $25. The Authorization Certificate authorizes the taking of marine mammals incidental to commercial fishing operations. NMFS has estimated that approximately 22,400 fishing vessels operate in Category I or II fisheries, and, therefore, are required to register. However, the registration for the majority of these fishers has been integrated with existing state or Federal registration programs, and those fishers do not need to register separately under the MMPA. Currently, approximately 3,800 fishers register directly with NMFS under the MMPA authorization program.

This proposed rule would require the registration of approximately 22,219[3] additional fishers. Fisheries that are proposed to be elevated to Category II and whose participants would be required to register with NMFS include the Hawaii Swordfish, Tuna, Billfish, Mahi Mahi Wahoo, Oceanic Sharks, Longline/Set Line Fishery (140 participants), the North Carolina Inshore Gillnet Fishery (94 participants), the Gulf of Mexico Gillnet Fishery (724 participants), the Southeast Atlantic Gillnet Fishery (640 participants), the Atlantic Blue Crab Fishery (>16,000), and the Gulf of Mexico Blue Crab Fishery (4,113 participants). The California Longline Fishery (45 participants), the Mid-Atlantic Pound Net Fishery (438 participants), the Northeast Trap/Pot Fishery (unknown number of participants), the North Carolina Long Haul Seine Fishery (33 participants) and the Northeast Drift Gillnet Fishery (unknown number of participants) are new fisheries that have been proposed to be added to the LOF this year as Category II fisheries.

Participants in fisheries elevated to Category II or added to the LOF may already participate in Category I or II fisheries for which they currently register under the MMPA or participate in Federal or State fisheries with integrated registration programs, and therefore would not be required to register separately under the MMPA or pay the $25 registration fee.

The $25 registration fee, with respect to anticipated revenues, is not considered significant. NMFS will also consider integrating registration requirements with other fisheries to minimize the registration burden on fishers. NMFS would waive the registration fee for fisheries where an integrated registration program can be arranged.

As a result of the certification, a regulatory flexibility analysis was not prepared.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number. This proposed rule does not contain new collection-of-information requirements subject to the Paperwork Reduction Act; however, the proposed addition of fisheries to Category II in the LOF could result in up to 22,219 fishers being subject to an existing collection-of-information requirement. However, NMFS expects that most of these fishers will not be required to do any additional reporting. For example, this number includes 16,000 fishers who have historically participated in the Atlantic Blue Crab Trap/Pot Fishery and 4,113 fishers who have historically participated in the Gulf of Mexico Blue Crab Trap/Pot Fishery. NMFS is currently evaluating the current number of participants in these two fisheries and is planning to integrate registration with existing state or Federal registration programs as soon as possible. Also, many of the fishers may already participate in other Category I or II fisheries or participate in Federal or state fisheries with integrated registration programs and would not be required to register separately under the MMPA.

The collection of information for the registration of fishers under the MMPA has been approved by the OMB under OMB control number 0648-0293 (0.25 burden hours per report for new registrants and 0.15 burden hours for renewals). These estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these reporting burden estimates or any other aspect of the collections of information, including suggestions for reducing burdens to NMFS and OMB (see **ADDRESSES**).

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

An environmental assessment was prepared under the National Environmental Policy Act (NEPA) for regulations to implement section 118 of the MMPA (1995 EA). The 1995 EA concluded that implementation of those regulations would not have a significant impact on the human environment. This proposed rule, if implemented, would not make any significant change in the management of reclassified fisheries, and therefore this proposed rule is not expected to change the analysis or conclusion of the 1995 EA. The classification of fisheries on the LOF is not considered to be a management action. If NMFS takes a management action, for example, through the development of a Take Reduction Plan (TRP), NMFS would prepare an environmental document as required under NEPA specific for that action.

Changes to the proposed LOF for 2001 will not affect species listed as threatened or endangered under the Endangered Species Act (ESA) or their associated critical habitat. The impacts of numerous fisheries have been analyzed in various biological opinions and this proposed rule will not affect the conclusions of those opinions. The classification of fisheries on the LOF is not considered to be a management action that would impact threatened or endangered species. If NMFS takes a management action, for example, through the development of a Take Reduction Plan (TRP), NMFS would conduct consultation under section 7 of the ESA specific for that action.

This proposed rule will have no adverse impacts on marine mammals and may have a positive impact on marine mammals by improving knowledge of marine mammals and the fisheries interacting with marine mammals through information collected from observer programs or take reduction teams.

This proposed rule will not affect the land or water uses or natural resources of the coastal zone, as specified under section 307 of the Coastal Zone Management Act.

The President has directed Federal agencies to use plain language in their communications with the public, including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this rule. Such comments should be sent to the Office of Protected Resources (see **ADDRESSES**).

Dated: January 12, 2001.

William T. Hogarth,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 01–1542 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–22–S

[3]This number includes 16,000 fishers who have historically participated in the Atlantic Blue Crab Fishery. NMFS is currently evaluating the current number of participants and will provide that information in a future LOF cycle.

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Notices

Federal Register
Vol. 66, No. 14
Monday, January 22, 2001

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AFRICAN DEVELOPMENT FOUNDATION

Sunshine Act Meeting

TIME: 10:00 am–4:00 pm.
PLACE: ADF Headquarters.
DATE: Friday, 26 January 2001.
STATUS: Open.

Agenda

10:00 am Chairman's Report
10:30 am–12:00 pm President's Report
12:00 pm Lunch
1:00–2:30 pm President's Report (Continued)
2:30–4:00 pm Executive Session (Closed)
4:00 pm Adjournment

If you have any questions or comments, please direct them to Doris Martin, General Counsel, who can be reached at (202) 673–3916.

Nathaniel Fields,
President.

[FR Doc. 01–1860 Filed 1–17–01; 4:19 pm]
BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Natural Resources Conservation Service

Farmland Protection Program

AGENCY: Commodity Credit Corporation, Natural Resources Conservation Service, Department of Agriculture (USDA).
ACTION: Notice of request for proposals.

SUMMARY: Section 388 of the Federal Agriculture Improvement and Reform Act of 1996 established the Farmland Protection Program (FPP). The Secretary of Agriculture delegated the authority for FPP to the Chief of the Natural Resources Conservation Service (NRCS), who is a vice president of the Commodity Credit Corporation (CCC). The Agricultural Risk Protection Act of 2000 provides $10 million in financial and technical assistance for the purposes described in FPP in fiscal year 2001. The CCC requests proposals from federally recognized Indian tribes, States, units of local government, and non-governmental organizations to cooperate in the acquisition of conservation easements or other interests in prime, unique, or other productive soil that is subject to a pending offer, for the purpose of limiting conversion to nonagricultural uses of that land. An additional $20 million has also been provided for FPP in accordance with the Conference Report on H.R. 4577, Department of Labor, Health, and Human Services, and Education and Related Agencies Appropriations (House of Representatives—December 15, 2000). This amount excludes proposals from non-governmental organizations and is dedicated only to proposals from federally recognized Indian tribes, States, and units of local government. USDA has designated up to $5 million to be provided to State agencies that have a long and effective history of purchasing development rights on farmland.

DATES: Proposals must be received in the NRCS State Office within 45 days of the date of this notice.

ADDRESSES: Written proposals should be sent to the appropriate NRCS State conservationist, Natural Resources Conservation Service, USDA. The telephone numbers and addresses of the NRCS State conservationists are attached in the appendix of this notice.

FOR FURTHER INFORMATION CONTACT: Douglas J. Lawrence, NRCS; phone: (202) 720–1510; fax: (202) 690–6473; or e-mail: doug.lawrence@usda.gov; Subject: 2001 FPP.

SUPPLEMENTARY INFORMATION:

Background

Urban sprawl continues to threaten the Nation's farmland. Social and economic changes over the past three decades have influenced the rate at which land is converted to non-agricultural uses. Population growth, demographic changes, preferences for larger lots, inexpensive fuel costs, expansion of transportation systems, and economic prosperity have contributed to increases in agricultural land conversion rates.

The amount of farmland lost to development is not the only significant concern. Another cause for concern is the quality and pattern of farmland being converted. In most States, prime farmland is being converted at two to four times the rate of other, less-productive agricultural land.

There continues to be an important national interest in the protection of farmland. Once developed, productive farmland with rich topsoil is effectively lost forever, placing future food security for the Nation at risk. Land use devoted to agriculture provides an important contribution to environmental quality, history, and scenic beauty.

Availability of Funding

Effective on the publication date of this notice, the CCC announces the availability, until September 30, 2001, of $30 million for FPP. The CCC, acting through the appropriate NRCS State conservationist, must receive proposals for participation within 45 days of the date of this notice. State, tribal, and local governmental entities may apply for money under funding sources; however, non-governmental organizations are only eligible for the original $10 million provided by the Agricultural Risk Protection Act of 2000.

Selection will be based on the criteria established in this notice. Selected eligible entities may receive no more than 50 percent of the purchase price for each conservation easement, not to exceed the fair market value of the interest to be purchased. Pending offers by an eligible entity must be for the acquisition of an easement for a minimum duration of 30 years.

Definitions

Chief means the Chief of NRCS, USDA.

Eligible entities means federally recognized Indian tribes, States, units of local government, and non-governmental organizations that have pending offers for the acquisition of conservation easements for the purposes of protecting the agricultural use. Non-governmental organizations are only eligible for the $10 million originally authorized by the Agricultural Risk Protection Act of 2000.

Field Office Technical Guide means the official NRCS guidelines, criteria, and standards for planning and applying conservation treatments and conservation management systems. It contains detailed information on the conservation of soil, water, air, plant, and animal resources applicable to the local area for which it is prepared.

Land Evaluation and Site Assessment (LESA) means the Federal land site evaluation system used to rank land, based on soil potential for agriculture, as well as social and economic factors, such as location, access to market, and adjacent land use.

Non-governmental organization, as defined in section 211(a) of the Agricultural Risk Protection Act of 2000, is any organization that:

(1) Is organized for, and at all times since the formation of the organization, has been operated principally for one or more of the conservation purposes specified in clause (i), (ii), or (iii) of section 170(h)(4)(A) of the Internal Revenue Code of 1986;

(2) Is an organization described in section 501(c)(3) of that code that is exempt from taxation under 501(a) of that code;

(3) Is described in section 509(a)(2) of that code; or

(4) Is described in section 509(a)(3) of that code and is controlled by an organization described in section 509(a)(2) of that code.

Prime and unique farmland are defined separately, as follows:

- Prime farmland is land that has the best combination of physical and chemical characteristics for producing food, feed, fiber, forage, oilseed, and other agricultural crops with minimum inputs of fuel, fertilizer, pesticides, and labor, without intolerable soil erosion, as determined by the Secretary.
- Unique farmland is land other than prime farmland that is used for the production of specific high-value food and fiber crops, as determined by the Secretary. It has the special combination of soil quality, location, growing season, and moisture supply needed to economically produce sustained high quality or high yields of specific crops when treated and managed according to acceptable farming methods. Examples of such crops include citrus, tree nuts, olives, cranberries, fruits, and vegetables. Additional information on the definition of prime, unique, or other productive soil can be found in section 1540(c)(1) of the Farmland Protection Policy Act (Public Law 97–98) (7 U.S.C. 4201, *et seq.*).

Purchase price means the fair market value ascertained through standard real property appraisal methods. Fair market value is defined as the price at which a willing seller and a willing buyer will trade.

State conservationist means the NRCS employee authorized to direct and supervise NRCS activities in a State or the Caribbean Area (Puerto Rico and the Virgin Islands).

Overview of the Farmland Protection Program

The CCC will accept proposals submitted to the NRCS State offices from eligible entities, including federally recognized Indian tribes, States, units of local government, and non-governmental organizations that have pending offers for the acquisition of conservation easements for the purposes of protecting the agricultural use of the land. Reference information regarding the FPP can be found in the "Catalog of Federal Domestic Assistance #10.913."

All proposals must be submitted to the appropriate NRCS State conservationist within 45 days of the date of this notice. The NRCS State conservationist may consult with the State Technical Committee (established pursuant to 16 U.S.C. 3861) to evaluate the merits of the proposals.

The NRCS State conservationist will review and evaluate the proposals based on State, local program, tribal, or non-governmental organization eligibility, land eligibility, and the extent to which the proposal will protect prime, unique, or other productive soil. Proposals must provide adequate proof of a pending offer for the subject land. Proposals submitted directly to the NRCS national office will not be accepted and will be returned to the submitting entity.

The NRCS State conservationist will transmit a cover letter with a list of the ranked proposals and properties that meet the criteria established in this notice to the NRCS national office in Washington, DC, where the final selection of proposals will occur. Once selected, eligible entities must work with the appropriate NRCS State conservationist to finalize and sign cooperative agreements, incorporating all necessary FPP terms.

The conveyance document used by the eligible entity must be reviewed and approved by the NRCS national office before being recorded. Since title to the easement is held by an entity other than the United States, the conveyance document must contain a clause that all rights conveyed by the landowner under the document will become vested in the United States should the federally recognized Indian tribe, State, local government entity, or non-governmental organization (*i.e.*, the grantee(s)) abandon or attempt to terminate the conservation easement. As a condition for participation, all land in the easement shall be included in a conservation plan developed and implemented according to the NRCS Field Office Technical Guide.

Organization and Land Eligibility Selection Criteria

To be eligible, a federally recognized Indian tribe, State, unit of local government, or non-governmental organization must have a farmland protection program that purchases agricultural conservation easements for the purpose of protecting prime, unique, or other productive soil by limiting conversion to nonagricultural uses. In addition, applicants must provide information in their proposals demonstrating their ability, both legally and programmatically, to acquire conservation easements for the purpose of limiting conversion to nonagricultural uses.

The following land, if subject to a pending offer by an eligible entity, is eligible for enrollment in the FPP:

(1) Land with prime, unique, or statewide and locally important farmland and

(2) Other incidental land that would not otherwise be eligible, but when considered as part of a pending offer, NRCS determines that inclusion of such land would significantly augment protection of the associated farmland.

Proposal Criteria

Proposals must contain the information set forth below in order to receive consideration:

1. Organization and programs: Eligible entities must describe their farmland protection program and their record of acquiring and holding permanent agricultural land protection easements or other interests. Information provided in the proposal should:

(a) Demonstrate a commitment to long-term conservation of agricultural lands through the use of voluntary easements or other legal devices to protect farmland from conversion to nonagricultural uses;

(b) Demonstrate a capability to acquire, manage, and enforce easements and other interests in land;

(c) Demonstrate the availability of funds equal to at least 50 percent of the projected easement purchase price for the proposed land parcel(s); and

(d) Have pending offer(s). A pending offer is a bid, contract, or option extended to a landowner by an eligible entity to acquire a conservation easement or other interests in land to limit nonagricultural uses of the land before the legal title to these rights has

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been conveyed. The pending offers must be for the primary purpose of protecting topsoil by limiting conversion to nonagricultural uses.

2. To ensure that the maximum efficiency of dollars is obtained, USDA is designating a reserve, not to exceed $5 million, to States that have a long history of purchasing development rights and that have a developed infrastructure for protection of farmland, along with a strong program for State funding of such efforts. To be eligible, State agencies must meet the following criteria, in addition to the criteria set forth above:

(a) Possess both a high public and private investment per capita in the purchase of development rights on working farms over the last 10 years;

(b) Have provided on-going appropriations for the purchase of development rights over the last 10 years;

(c) Have established partnerships with private nonprofit land trusts; and

(d) Are located in States where the average cost of purchasing development rights, for all entities involved, is below $1,000 per acre.

3. Lands to be acquired: The proposal should describe the lands to be acquired with assistance from FPP. Specifically, the proposal should include:

(a) A map showing the proposed protected area(s);

(b) The amount and source of funds currently available for each easement (or other interest) to be acquired;

(c) The criteria used to set the acquisition priorities; and

(d) A detailed description of the land parcel(s), including:

(i) The priority of the offer;

(ii) The name(s) of the landowner(s);

(iii)The address and location map(s) of the parcel(s);

(iv) The size of the parcel in acres;

(v) The acres of the prime, unique, or statewide and locally important soil in the parcels. Farmland that is of statewide or local importance is used for the production of food, feed, fiber, forage, or oilseed crops. The appropriate State or local government agency(s) determines statewide or locally important farmland with concurrence from the Secretary.

(vi) A map showing the location of other protected parcels in relation to the land parcels proposed to be protected;

(vii) Estimated cost of the easement(s): The consideration to be paid to any landowners for the conveyance of any lands or interests in lands shall be no more than the purchase price of the land or interests conveyed, as determined by an appraiser licensed in the State. All parcels nominated for FPP assistance shall be appraised and all appraisals shall conform to the Uniform Appraisal Standards for Federal Land Acquisitions (Interagency Land Acquisition Conference, 1992).

(viii) Type of instrument (*e.g.*, easement deed) used to prevent agricultural land conversion;

(ix) Indication of the accessibility to markets;

(x) Indication of an existing agricultural infrastructure, on- and off-farm, and other support system(s);

(xi) Statement regarding the level of threat from urban development;

(xii) Other factors from an evaluation and assessment system used to set priorities. If the eligible entity used the LESA system or a similar land evaluation system as its tool, include the value(s) (*i.e.* score(s)) for the land parcels slated for acquisition; and

(xiii) Other information that may be relevant.

In submitting proposals, entities should indicate on the cover of the proposal whether they are a nongovernmental organization, local, Tribal or State agency. In the case of a State agency, if the State is applying for funds that are reserved for State agencies with a long history of farmland protection, State agencies must include documentation to support the criteria outlined in section 2 under Proposal Criteria.

NRCS Role

Once the appropriate NRCS State office has assessed organization eligibility and the merits of each proposal, the NRCS State conservationist shall determine whether the farmland is eligible for financial assistance from FPP. NRCS will use the LESA system or a similar land evaluation system to evaluate the land and rank parcels.

Ranking Considerations

NRCS will only consider enrolling eligible land in the program that is of sufficient size and has boundaries that allow for efficient management of the area. The land must have access to markets for its products and an infrastructure appropriate for agricultural production. NRCS will not enroll land in FPP that is owned in fee title by an agency of the United States, or land that is already subject to an easement or deed restriction that limits the conversion of the land to nonagricultural use. NRCS will not enroll otherwise eligible lands if NRCS determines that the protection provided by the FPP would not be effective because of on-site or off-site conditions. For example, a proposal may nominate an agricultural parcel surrounded by a developed area. In addition, NRCS may learn that the local government's long-term plan or zoning regulations earmark the parcel for future development. In light of the parcel's isolation from other farms and the local government's position, expressed in either its land use plan or zoning, NRCS may determine that the use of FPP funds is not appropriate.

NRCS will place a priority on acquiring easements or other interests in lands that provide permanent protection from conversion to nonagricultural use. NRCS will place a higher priority on easements acquired by entities that have extensive experience in managing easements. NRCS will place a higher priority on lands and locations that help create a large tract of protected area for viable agricultural production. NRCS will place a higher priority on lands and locations that link to other Federal, tribal, State, local, or non-governmental organization efforts with complementary farmland protection objectives. NRCS may place a higher priority on lands that provide special social, economic, and environmental benefits to the region. A higher priority may be given to certain geographic regions where the enrollment of particular lands may help achieve national, State, and regional goals and objectives, or enhance existing government or private conservation projects.

Cooperative Agreements

The CCC will use a cooperative agreement with a selected eligible entity as the mechanism for participation in FPP. The cooperative agreement will address, among other things:

(1) The interests in land to be acquired, including the form of the easements to be used and terms and conditions;

(2) The management and enforcement of the rights acquired;

(3) The role of NRCS;

(4) The responsibilities of the easement manager on lands acquired with the assistance of FPP; and

(5) Other requirements deemed necessary by the CCC to protect the interests of the United States.

The cooperative agreement will also include an attachment listing the pending offers accepted in FPP, landowners' names, addresses, location map(s), and other relevant information.

Signed in Washington, DC, on January 16, 2001.

Danny D. Sells,

Deputy Vice President, Commodity Credit Corporation and Associate Chief, Natural Resources Conservation Service.

NRCS State Conservationists

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DEPARTMENT OF AGRICULTURE

Forest Service

Basin Creek Mine Final Water Treatment System proposal, Beaverhead-Deerlodge National Forest, Jefferson County, MT

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement to document the analysis and disclose the environmental impacts of a proposed action to develop a final water treatment system at the inactive Basin Creek Mine. The mine site is located on the Continental Divide about 30 miles southwest of Helena, Montana.

The proposed action would finalize the reclamation of the closed mine by defining a long-term water treatment system to treat effluent coming from the reclaimed leach pad (known as Leach Pad 3) on National Forest System lands. The effluent needs to be treated in perpetuity to ensure that any residual contaminants (cyanide or heavy metals) originating from the reclaimed leach pad do not degrade water quality. The decision to be made is to determine the type of final water treatment system that will be developed.

DATES: Initial comments concerning the scope of the analysis should be received in writing no later than January 31, 2001.

ADDRESSES: The responsible official is Forest Supervisor Janette Kaiser, Beaverhead-Deerlodge National Forest, Dillon, Montana. To facilitate the analysis of public comments, send written comments to District Ranger Terry Sexton, Jefferson Ranger District, 3 Whitetail Road, Whitehall, MT 59759. Comments may be electronically submitted to tsexton@fs.fed.us.

FOR FURTHER INFORMATION CONTACT: Terry Sexton, District Ranger, at the above address, or phone (406) 287–3223 or 1–800–433–9206, or by email to tsexton@fs.fed.us.

SUPPLEMENTARY INFORMATION: The Basin Creek Mine is an inactive open pit heap leach gold mine. The site contains the headwaters of the municipal watersheds for the city of Helena (Monitor Creek) and the town of Basin (Basin Creek). Active mining operations were most recently conducted from 1988 through 1990 on patented land belonging to Pegasus Gold Corporation and National Forest System lands administered by the Beaverhead-Deerlodge National Forest. Final reclamation and closure of the site began in 1994 and is scheduled for completion in the fall of 2001. The State of Montana Department of Environmental Quality will be preparing a separate document to analyze the effects of a proposed action to develop final water treatment systems for two other sources of effluent located on private land at the mine site. Discharges from the water treatment systems will require a National Pollutant Discharge Elimination System (NPDES) permit; a federal permit issued by the Corp of Engineers.

The Forest Service, Environmental Protection Agency, and the State of Montana are cooperating agencies for this proposal.

The project area is located in Township 8N, Range 6W, Sections 25 and 26. The scope of this proposal is limited to developing a final long-term water treatment system for the effluent originating from Leach Pad 3.

Public participation is important to this analysis. Part of the goal of public involvement is to identify additional issues and to refine the general, tentative issues. A scoping notice describing the proposal will be mailed to those who request information on mining activities on the Beaverhead-Deerlodge National Forest. There are no scoping meetings scheduled.

Preliminary issues identified by the Forest Service include effects to water quality, and maintenance and effective life of the water treatment system. The analysis will consider all reasonably foreseeable activities. The interdisciplinary team has not yet identified any preliminary alternatives to the proposed action. Alternatives will be developed based on the key issues identified after scoping.

People may visit with Forest Service officials at any time during the analysis and prior to the decision. Two periods are specifically designated for comments on the analysis: (1) During the scoping process and (2) during the draft EIS period.

During the scoping process, the Forest Service is seeking additional information and comments from individuals or organization who may be interested in or affected by the proposed action, and Federal, State and local agencies. The Forest Service invites written comments and suggestions on this action, particularly in terms of identification of issues and alternative development.

The draft EIS should be available for review in March, 2001. The final EIS is scheduled for completion in May, 2001.

The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. City of Angoon v. Hodel, 803 F.2d 1016, 1022 (9th Cir. 1986) and Wisconsin Heritages, Inc. v. Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important the those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

The responsible official will make the decision on this proposal after considering comments and responses, environmental consequences discussed in the final EIS, applicable laws, regulations, and policies. The decision and reasons for the decision will be documented in a Record of Decision.

Dated: December 18, 2000.

Janette S. Kaiser,

Forest Supervisor.

[FR Doc. 01–1818 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Advisory Committee on Agriculture Statistics

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice of renewal at USDA.

SUMMARY: The U.S. Department of Agriculture (USDA) has renewed the charter for the Advisory Committee for Agriculture Statistics. Effective October 1, 1996, responsibility for the census of agriculture program was transferred to the National Agricultural Statistics Service (NASS) at USDA from the Bureau of the Census, U.S. Department of Commerce. Effective February 2, 1997, NASS also received the transferred program positions and staff from the Bureau of the Census, U.S. Department of Commerce. Responsibility for the Advisory Committee on Agriculture Statistics, which is a discretionary committee, was transferred, along with its allocated slot, to USDA with the census of agriculture program.

The Advisory Committee on Agriculture Statistics has provided input and direction to the census of agriculture program since the committee was first established on July 16, 1962. It has been particularly critical to have the committee as a valuable resource to USDA during the transfer of the census from the U.S. Department of Commerce.

The purpose of the committee is to make recommendations on census of agriculture operations including questionnaire design and content, publicity, publication plans, and data dissemination.

FOR ADDITIONAL INFORMATION OR COMMENTS: Contact R. Ronald Bosecker, Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 1400 Independence Avenue SW., Room 4117 South Building, Washington, DC 20250–2000, (202) 720–2707.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C. appendix), notice is hereby given that the Secretary of Agriculture has renewed the charter for the Advisory Committee on Agriculture Statistics, hereafter referred to as Committee. The purpose of the Committee is to advise the Secretary of Agriculture on the conduct of the periodic censuses and surveys of agriculture, other related surveys, and the types of agricultural information to obtain from respondents. The committee also prepares recommendations regarding the content of agriculture reports, and presents the views and needs for data of major suppliers and users of agriculture statistics.

The Secretary of Agriculture has determined that the work of the Committee is in the public interest and relevant to the duties of USDA. No other advisory committee or agency of USDA is performing the tasks that will be assigned to the Committee.

The Committee, appointed by the Secretary of Agriculture, shall consist of 25 members representing a broad range of disciplines and interests, including, but not limited to, agricultural economists, rural sociologists, farm policy analysts, educators, State agriculture representatives, and agriculture-related business and marketing experts.

Representatives of the Bureau of the Census, U.S. Department of Commerce, and Economic Research Service, USDA, serve as ex-officio members of the Committee.

The committee draws on the experience and expertise of its members to form a collective judgment concerning agriculture data collected and the statistics issued by NASS. This input is vital to keep current with shifting data needs in the rapidly changing agricultural environment and keep NASS informed of emerging developments and issues in the food and fiber sector that can affect agriculture statistics activities.

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Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDA, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Paul W. Fiddick,

Assistant Secretary for Administration.

[FR Doc. 01–1267 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service; Notice of a Finding of No Significant Impact

Hickory Creek Watershed; Coffee, Grundy, Warren Counties; Tennessee

AGENCY: Natural Resources Conservation Service; USDA.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Regulations (40 CFR part 1500); and the Natural Resources Conservation Service Guidelines (7 CFR Part 650); the Natural Resources Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Hickory Creek Watershed; Coffee, Grundy, and Warren Counties; Tennessee.

FOR FURTHER INFORMATION CONTACT: James W. Ford, State Conservationist, Natural Resources Conservation Service, 675 U.S. Courthouse, 801 Broadway, Nashville, Tennessee 37203, telephone number (615) 277–2531.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, James W. Ford, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

Hickory Creek Watershed, Tennessee
Notice of a Finding of No Significant Impact

The project purpose is watershed protection. The planned works of improvement include installation of animal waste management systems and measures to reduce erosion and sedimentation. Federal financial assistance will be provided to accelerate financial and technical assistance for land treatment.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various federal, state, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting James W. Ford.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904, Watershed Protection and Flood Prevention, and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with state and local officials.)

Dated: January 3, 2001.

James W. Ford,

State Conservationist.

[FR Doc. 01–1722 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–16–M

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

Notice of Proposed Changes to Section IV of the Field Office Technical Guide (FOTG) of the Natural Resources Conservation Service in Michigan

AGENCY: Natural Resources Conservation Service (NRCS) in Michigan, US Department of Agriculture.

ACTION: Notice of availability of proposed changes in Michigan NRCS FOTG, Section IV for review and comment.

SUMMARY: It is the intention of NRCS in Michigan to issue revised conservation practice standards in Section IV of the FOTG. The revised standards include:

Herbaceous Wind Barriers (422A)
Riparian Forest Buffer (391)
Cover Crop (340)
Prescribed Grazing (528A)
Wetland Wildlife Habitat Management (644)
Shallow Water Management For Wildlife (646)
Windbreak/Shelterbelt Establishment (380)
Field Border (386)
Early Successional Habitat Development/Management (647)
Stream Crossing and Livestock Access (728)
Agrichemical Containment Facility (702)
Manure Transfer (634)
Closure of Waste Impoundments (360)
Grassed Waterway (412)

DATES: Comments will be received on or before February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Inquire in writing to Kevin Wickey, Assistant State Conservationist for Technology, Natural Resources Conservation Service, 3001 Coolidge Road, Suite 250, E. Lansing, MI 48823. Copies of these standards will be made available upon written request. You may submit electronic requests and comments to *Kevin.Wickey@mi.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Kevin Wickey 517–324–5279.

SUPPLEMENTARY INFORMATION: Section 393 of the Federal Agriculture Improvement and Reform Act of 1996 states that revisions made after enactment of the law, to NRCS state technical guides used to carry out highly erodible land and wetland provisions of the law, shall be made available for public review and comment. For the next 30 days, the NRCS in Michigan will receive comments relative to the proposed changes. Following that period, a determination will be made by the NRCS in Michigan regarding disposition of those comments and a final determination of change will be made.

Dated: December 22, 2000.

Ronald C. Williams,

State Conservationist, E. Lansing, Michigan.

[FR Doc. 01–1838 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–16–P 4

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to and deletions from procurement list.

SUMMARY: The Committee is proposing to add to the Procurement List service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete services previously furnished by such agencies.

Comments must be received on or before: February 19, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Addition

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information. The following service has been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Janitorial/Custodial, Basewide, Little Rock Air Force Base, Arkansas, NPA: Pathfinder Schools, Inc., Jacksonville, Arkansas.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for deletion from the Procurement List.

The following services have been proposed for deletion from the Procurement List:

Services

Grounds Maintenance, Rogue River National Forest, J. Herbert Stone Nursery, 2606 Old Stage Road, Central Point, Oregon.

Support Activities for Forestry (TSI), Crane Division, Naval Surface Warfare Center, Crane, Indiana.

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 01–1646 Filed 1–19–01; 8:45 am]

BILLING CODE 8353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the procurement list.

SUMMARY: This action adds to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities previously furnished by such agencies.

EFFECTIVE DATE: February 19, 2001.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Louis R. Bartalot (703) 603–7740.

SUPPLEMENTARY INFORMATION: On November 13, November 17 and November 24, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (65 FR 67714, 69499 and 70459) of proposed additions to and deletions from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List.

Accordingly, the following commodities and services are hereby added to the Procurement List:

Commodities

Sorbents, Chemical and Oil
4235–01–441–0246
4235–01–441–0248
4235–01–451–8744
4235–01–453–5159
4235–01–456–8571
4235–01–456–8575
4235–01–456–8858
4235–01–456–8862
4235–01–456–9893
4235–01–456–9899
4235–01–457–0005
4235–01–457–0031
4235–01–457–0421
4235–01–457–0431
4235–01–457–0518
4235–01–457–0658
4235–01–457–0663
4235–01–457–0677
4235–01–457–0678

Services

Food Service
Kirtland Air Force Base, New Mexico
Grounds Maintenance
Department of Energy, Nevada Support Facility, 232 Energy Way, North Las Vegas, Nevada
Janitorial/Custodial
Depot Maintenance Industrial Fund, Tinker Air Force Base, Oklahoma

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This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action will not have a severe economic impact on future contractors for the commodities and services.
3. The action will result in authorizing small entities to furnish the commodities and services to the Government.
4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. Accordingly, the following commodities are hereby deleted from the Procurement List:

Commodities

Arming Adapter, Self Adjusting
1325–01–158–8635
1325–01–159–8083
Air Freshener Deodorant, General Purpose
6840–00–932–4692
Envelope, Wallet
7530–00–281–4844
7530–00–281–4846

Louis R. Bartalot,

Deputy Director (Operations).

[FR Doc. 01–1647 Filed 1–19–01; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Public Meeting: With the Community College of the Air Force Board of Visitors To Review and Discuss Academic Policies and Issues Relative to the Operation of the College

AGENCY: Department of the Air Force, DOD.

ACTION: Notice of meeting.

SUMMARY: The Community College of the Air Force (CCAF) Board of Visitors will hold a meeting to review and discuss academic policies and issues relative to the operation of the college. Agenda items include a review of the operations of the CCAF and an update on the activities of the CCAF Policy Council.

Members of the public who wish to make oral or written statements at the meeting should contact First Lieutenant Matthew M. Groleau, Designated Federal Officer for the Board, at the address below no later than 4:00 p.m. on April 1, 2001. Please mail or electronically mail all requests. Telephone requests will not be honored. The request should identify the name of the individual who will make the presentation and an outline of the issues to be addressed. A minimum of 35 copies of the presentation materials must be given to First Lieutenant Matt Groleau no later than 3 days prior to the time of the board meeting for distribution. Visual aids must be submitted to First Lieutenant Matt Groleau on a 3½" computer disk in Microsoft PowerPoint format no later than 4:00 p.m. on April 1, 2001 to allow sufficient time for virus scanning and formatting of the slides.

DATES: The meeting will be held on Wednesday, May 9, 2001 at 1:00 p.m. on the First Floor Conference Room, Community College of the Air Force, 130 West Maxwell Boulevard, Maxwell Air Force Base, Alabama 36112.

FOR FURTHER INFORMATION CONTACT: First Lieutenant Matt Groleau, Community College of the Air Force, 130 West Maxwell Boulevard, Maxwell Air Force Base, Alabama 36112–6613, (334) 953–7322, or through electronic mail at matthew.groleau@maxwell.af.mil.

Janet A. Long,

Air Force Federal Register Liaison Officer.

[FR Doc. 01–1570 Filed 1–19–01; 8:45 am]

BILLING CODE 5001–05–U

DEPARTMENT OF COMMERCE

Census Bureau

The Census 2000 Count Question Resolution Program

ACTION: Proposed collection; comment request.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C.3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 23, 2001.

ADDRESSES: Direct all written comments to Madeleine Clayton, Departmental Forms Clearance Officer, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at mclayton@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information and instructions should be directed to Robert A. Rinaldi, Assistant Division Chief, Decennial Management Division, U.S. Census Bureau, SFC–2, Room 2002, Washington, DC 20233–001. Telephone: 301–457–8226; fax: 301–457–8328; or e-mail: *Count.Question.Resolution@census.gov*

SUPPLEMENTARY INFORMATION:

I. Abstract

This notice provides information concerning the Census 2000 Count Question Resolution (CQR) program that will be implemented to respond to challenges to the Census 2000 housing unit counts and group quarters counts received from local and tribal governmental entities in the U.S. and Puerto Rico. This program will become effective on June 30, 2001, and will end on September 30, 2003.

After the release of Census 2000 Public Law 94–171 redistricting data containing population counts and the Demographic Profiles and Summary File 1 (SF1) that contain the number of housing units and group quarters population counts, some governmental entities may want to challenge these official Census 2000 counts.

Challenges to the overseas counts of persons in the military and Federal civilian personnel stationed overseas and their dependents living with them will not be accepted. These overseas counts are obtained using administrative records and will be used solely for reapportioning seats in the U.S. House of Representatives and do not provide the substate geographic information required for the CQR program.

No additional data will be collected as part of the CQR program. We will only use those data that have already been collected. The Census Bureau will respond to all questions and will notify all affected governmental entities of any corrections to their official counts as a result of CQR. All challenges should be sent to the Census Bureau's headquarters. (The specific mailing address and a glossary of terms are provided in the Exhibit at the end of this notice's Method of Collection section.)

Background

The Census Bureau implemented the Local Update of Census Addresses (LUCA) program for Census 2000. Participating local and tribal governments were given the opportunity to review and update the Census Bureau's address list before it was used for the actual census enumeration. In cases where the local or tribal government and the Census Bureau could not agree on the housing unit address list, the governmental unit could use an appeal process administered by the Census Address List Appeals Office. The Census Bureau also used the LUCA Special Places program to involve local and tribal governments in helping to identify special places, such as college dormitories, nursing homes and other types of group living arrangements.

In addition to LUCA, governmental units with city-style address areas had another opportunity to update the Census 2000 address list for the New Construction program. We also conducted the Boundary and Validation program, in which we provided local officials with maps that showed boundaries of their jurisdiction and asked them to make corrections, if necessary.

The Census Bureau had a comprehensive program to improve the quality of the housing unit counts. A number of extensive operations afforded other opportunities for additions, corrections, and deletions of census addresses and corrections of population counts. Between May and August 2000, the Coverage Edit Follow-up operation resolved population count discrepancies and obtained additional information on households with more than six persons. The Coverage Improvement Follow-up (CIFU) operation (June–August 2000) enumerated housing units that were inaccurately classified as vacant or nonexistent in an earlier census operation. It also enumerated added housing units discovered in an earlier census operation; housing units added through the LUCA 98 and 99 appeals process; new addresses from periodic postal updates; blank or missing mail return forms; and addresses provided in the New Construction update by local and tribal governments.

During July and August 2000, the Residual Nonresponse Follow-up operation completed questionnaires for housing units where identification numbers existed for forms that were checked out of the Local Census Office, were not included in CIFU, and did not have census data captured. The Field Verification operation (July–August 2000) verified specific addresses that did not match the Decennial Master Address File. Another operation, Population Unknown Supplementary (July–August 2000), was conducted to determine the number of people in housing units that the Nonresponse Follow-up operation (April–June 2000) had identified as occupied, but the number of occupants were unknown.

Data collection for Census 2000 ended in the Local Census Offices on or before August 30, 2000. This schedule was needed to allow the Census Bureau time to produce the state level apportionment counts by December 31, 2000, as required by law.

The Census Bureau also conducted the Accuracy and Coverage Evaluation operation that includes a coverage measurement survey that is expected to determine and correct for the number of people and housing units missed or erroneously included in Census 2000. This survey, a nationwide sample survey of about 314,000 housing units, was conducted by the Census Bureau independently of Census 2000. All enumeration activities, as well as person interviewing follow-up, were completed by late November 2000.

Although many local and tribal governments participated in the LUCA and New Construction programs and the Census Bureau conducted an extensive quality improvement program, the Census Bureau still expects to receive challenges after it releases the official Census 2000 housing unit and group quarters population counts contained in the Demographic Profiles, which are scheduled for release between June and September 2001. The CQR start date of June 30, 2001, also is coordinated with the release of the Summary File 1 (SF1) on a state-by-state basis between June and September 2001. The SF1 will contain block-level data on the number of housing units. It also will show group quarters population counts by blocks.

The Bureau of the Census (Census Bureau) must be contacted directly by officials of local and tribal governments in order to initiate the challenge process. However, the Census Bureau also will accept challenges from county clerks, city planners, local planning board representatives, and state legislative representatives with redistricting functions within each state and state equivalents who are acting on the behalf of a local or tribal jurisdiction.

Types of Corrections That Will Be Considered for the Census 2000 CQR Program

Corrections for three types of challenges will be made as a result of the Census 2000 CQR program. (For acceptable documentation to initiate such challenges, refer to the Method of Collection section, "Criteria for Acceptable Documentation Necessary to Initiate the Census 2000 CQR Process.")

(1) *Boundary corrections*—Census 2000 respects the proper alignment of the jurisdictional boundaries of functioning governmental units as legally in effect on January 1, 2000. The Census Bureau needs to ensure that the geographic assignment information provided does not, in fact, reflect boundary changes made after January 1, 2000. Problems, such as the inaccurate reporting of jurisdictional boundaries and the inaccurate recording of such boundaries by the Census Bureau, will be addressed by the CQR program. The boundaries of other geographic and statistical areas, such as census designated places, census tracts, voting districts, school districts, and the like are not in the scope of the Census 2000 CQR program.

(2) *Geocoding corrections*—placement of living quarters and associated population within the correct boundaries, census blocks, and the like. Even if the CQR process does not result in a change to the total count for a local or tribal jurisdiction, we will send a letter to the local or tribal government official when the Census Bureau moves group quarters or housing units to different blocks within the jurisdiction.

(3) *Coverage corrections*—specific living quarters and persons residing therein that were identified during the Census 2000 process but erroneously included or excluded due to processing errors; these corrections could be additions or deletions.

Changes That Result in Corrections

The corrected CQR counts that are issued are based on the housing unit and population counts as of April 1, 2000. The new official census counts may be used by the governmental entities for all programs requiring official Census 2000 data. The Census Bureau will not make corrections to the data concerning the characteristics of the population and housing inventory. The corrected counts will be reflected in the Census Bureau's decennial file modified for use in making postcensal estimates that will be released on a flow basis beginning in December 2002. An inventory of corrections also will be available on the *American FactFinder*

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Internet Data Access System (errata) and updated periodically. The base files for the census will remain unrevised so that none of the standard Census 2000 data products will reflect the corrections.

Challenges That Do Not Result in Corrections

When a local or tribal government provides evidence that the Census Bureau missed housing units or group quarters that existed on April 1, 2000, but the CQR research and Census 2000 records show that all of the Census Bureau's boundary information, geocoding, and processing were correctly implemented, the Census Bureau will respond by sending a letter to the official or his/her representative stating that the Census Bureau will maintain the documentation for consideration in the context of address list updating activities over the decade.

Internal Census Bureau Review

Changes to the boundaries or counts for a jurisdiction also may result from Census Bureau initiated research and review of census files. The Census Bureau reviews Census 2000 data by checking for data reasonableness, internal and intra-product consistency, and consistency with historical and external data sources. This review process begins with an analysis by Census Bureau staff, the Federal-State Cooperative Program for Population Estimates and others. These reviewers identify, address, and/or explain issues or problems related to coverage, content, processing, and geocoding. Unresolved potential problems will be forwarded to the CQR staff for additional analysis. Changes made as result of this internal review and/or research will be incorporated into the CQR process and documented in the same way that changes based on jurisdictional CQR challenges will be documented. In cases where changes to the housing unit and/or population counts are made, new official counts will be issued to the affected jurisdictions.

II. Method of Collection

Criteria for Acceptable Documentation Necessary To Initiate the Census 2000 CQR Process

The Census Bureau will require documentation before committing resources to investigate concerns raised by local and tribal officials or their representatives about boundary and geographic assignment errors or the accuracy of the census housing unit or group quarters population counts. In general, when submitting a challenge, governmental entities must:

- Specify whether the challenge disputes the location of a governmental unit boundary or the number of housing units and/or group quarters population counts in one or more tabulation blocks.
- For boundary disputes, indicate on a map the location of the governmental unit boundary in dispute; that is, it must be shown where the Census Bureau incorrectly depicts the boundary and show the correct boundary legally in effect as of January 1, 2000. (For types of maps that can be used, refer to the section "Types of Acceptable Paper Maps.")
- For housing unit challenges, identify the specific Census 2000 tabulation block that is being contested and a list of the addresses of all housing units in that block on April 1, 2000. (See the section "Challenge Criteria: Housing Unit Count.")
- For group quarters (see Census Bureau group quarters definition listed under "Definition of Key Terms") challenges, provide the name of the group quarters and evidence, e.g., a listing of patients residing in the XYZ Nursing Home as of April 1, 2000, that supports the number of persons residing there on April 1, 2000, as necessary, and show the specific Census 2000 tabulation block in which the group quarters population is being contested.
- Provide electronic or paper versions of documentation to support the challenge.

Boundary Challenge Criteria

All governmental unit boundary challenges must be based on boundaries that were legally in effect on January 1, 2000. The Census Bureau will compare the maps and appropriate supporting documentation submitted by the challenging entity with the information used by the Census Bureau to depict the boundaries for Census 2000.

Maps submitted by local and tribal governments must show the correct location of the boundary and the portion of the boundary that the Census Bureau depicted incorrectly, including the Census 2000 tabulation block numbers associated with the boundary. The local or tribal government also should provide the Census Bureau with a list of addresses in affected tabulation blocks, indicating their location in relationship to the boundary requiring correction.

For boundary changes affected by legal actions not recorded by the Census Bureau, local or tribal governments must submit the effective date and the ordinance number or law that effectuated the change in boundaries, provide evidence that the state certifying official has approved the boundary change, and provide a statement that the boundary is not under litigation. The change also must be certified by a local official. Regardless of whether the Census Bureau changes boundaries or does not change boundaries as a result of the CQR evidence and the Census Bureau's research, the Census Bureau will notify the complainant and any affected adjacent governmental entity(es) of the results.

Types of Acceptable Paper Maps

- Paper Census 2000 Public Law 94–171 County Block Maps—These maps will accompany the Redistricting Data Summary Files.
- Paper Census 2000 Redistricting Block Maps for Washington, DC.
- Paper Census 2000 Redistricting Municipio Block Maps for Puerto Rico—These maps will accompany the Puerto Rico Redistricting Data File.
- Paper Census 2000 Block Maps—These maps will be provided to local and tribal jurisdictions and will show tabulation block numbers. They are a companion map for the Demographic Profiles that will contain information on population totals, including group quarters and selected population and housing characteristics.
- Paper Maps based on the 2000 TIGER/Line® File—These maps are generated by local or tribal governments based on information from the Census Bureau's 2000 TIGER/Line® files using commercial geographic information systems.
- Other Paper Maps Showing Census Bureau 2000 Tabulation Block Numbers and Boundaries—These maps should show geographic boundaries as of January 1, 2000, that identify census tabulation blocks, census tracts, legal and statistical entities and state boundaries; maps depicting data collection blocks cannot be used. In general, maps should be comparable to Census 2000 maps.

Challenge Criteria

Housing Unit Count

Supporting evidence that specifically reflects the validity of any address list source must reflect residential addresses that existed as viable living quarters on April 1, 2000. Challenges to housing unit counts must specify the tabulation block(s) for which the counts are being challenged.

SF1 can be used to obtain tabulation block housing unit counts. Complainants must provide a complete address list for all units that should be included in each contested block. (Refer to the section "Types of Address Lists.")

Local or tribal officials must certify that the addresses on their lists existed and could be lived in on April 1, 2000. See Census Bureau "housing unit" definition listed under "Definitions of Key Terms."

Group Quarters Population Count

Supporting evidence that specifically reflects the validity of any address list source should be dated no later than April 1, 2000. Challenges to group quarters population counts must specify the tabulation block(s) for which the counts are being challenged. A group quarters is defined as a place where people live or stay other than the usual house, apartment, or mobile home. Two general types of group quarters are recognized: institutional (for example, nursing homes, mental hospitals or wards, hospital or wards for chronically ill patients, hospices, and prison wards) and noninstitutional (for example, college or university dormitories, military barracks, group homes, shelters, missions, and flophouses). Group quarters may have housing units on the premises for staff and/or guests.

SF1 can be used to obtain tabulation block group quarters population counts. Complainants must provide a complete address list (refer to the section "Types of Address Lists") for all group quarters units that should be included in each contested block. (For the definition of group quarters, see the section "Definitions of Key Terms.")

The local or tribal official should certify that the addresses on their lists existed and could be lived in on April 1, 2000.

Types of Address Lists

- City-Style Address Lists—Must contain city-style addresses (house number, street name, post office name, state, and ZIP Code) organized by Census 2000 tabulation block within census tract. Housing unit identifiers in multi-unit buildings (such as apartment numbers) must be included, if applicable.
- Non-City-Style Address Lists—Non-city-style addresses must be keyed to the local or tribal government's map-spotted maps, that is, maps that show the exact location of the housing unit. The list should be focused on the specific area and/ or addresses where the problem exists. All housing units in the disputed block must be map spotted and a description of the housing unit and location must be supplied. The following is an example of a map-spotted address and housing unit description: Map Spot 4567–01, Derby Road, 2-story house on left with red brick chimney, 6 houses from the intersection of Highways 12 and 19, Anytown, Georgia 10020.

Group Quarters Information

Provide the name, address, and telephone number for the administrative office of the facility (special place and group quarters) as of April 1, 2000. In addition, provide the census tract and tabulation block number for the location of the group quarters.

Statistical Corrections

The data produced by the Census Bureau may be corrected by applying statistical techniques to the data files. Challenges to the Census Bureau will be investigated based on the data without the statistical correction.

Census Bureau Actions

The Census Bureau will investigate challenges to determine whether information about the existence of a housing unit or occupied group quarters on April 1, 2000, was identified but does not appear in the final census files due to an error in processing the information. The Census Bureau will not collect new information.

Definitions of Key Terms

American FactFinder—The generalized electronic system for access and dissemination of much of Census Bureau data. The system is available through the Internet and offers prepackaged data products and the ability to build custom products. The system serves as the vehicle for accessing and disseminating data from Census 2000 (as well as the 1997 Economic Censuses and the American Community Survey).

Census Block—A geographic area bounded on all sides by visible or nonvisible features shown on census maps. A block is the smallest geographic entity for which the Census Bureau collects and tabulates decennial census information. See also block boundary, block number, collection block, statistical entity, and tabulation block.

Census Tract—Small, relatively permanent statistical subdivisions of counties delineated by local committees of census data users in accordance with Census Bureau guidelines for the purpose of collecting and presenting decennial census data. These neighborhoods contain between 1,000 and 8,000 people, typically approximately 1,700 housing units and 4,000 people.

Census Designated Place—A geographically defined statistical entity delineated for each decennial census according to Census Bureau guidelines comprising a densely settled concentration of population that is not incorporated or established by law but is locally recognized and identified by a name.

County—A type of governmental unit that is the primary legal subdivision of every state except Alaska and Louisiana (which have boroughs and parishes, respectively).

Demographic Profile—A one-page table containing data at the place level that shows information on total population, sex, age, race, Hispanic or Latino origin, household relationship, group quarters population, household type, housing occupancy, and housing tenure.

Group quarters—A place where people live or stay other than the usual house, apartment, or mobile home. The Census Bureau recognizes two general types of group quarters: institutional (for example, nursing homes, mental hospitals or wards, hospital or wards for chronically ill patients, hospices, and prison wards) and noninstitutional (for example, college or university dormitories, military barracks, group homes, shelters, missions, and flophouses). Special places may have housing units on the premises for staff or guests.

Housing unit—A house, an apartment, a mobile home or trailer, a group of rooms, or a single room that is occupied as a separate living quarters, or, if vacant, is intended for occupancy as a separate living quarters. A housing unit is defined as a living quarters that is closed to the elements and has all exterior windows and doors installed and final usable floors in place. For vacant units, the criteria of separateness and direct access are applied to the intended occupants, whenever possible. If that information cannot be obtained, the criteria are applied to the previous occupants.

Local Census Office—A temporary Census Bureau office established for Census 2000 data collection purposes. These offices managed address listing field work, conducted local recruiting, and created a local presence. They were called "district office" in previous censuses.

Municipio—A primary legal subdivision of Puerto Rico (synonymous to a county).

Overseas counts—Counts of military and Federal civilian personnel stationed overseas and their dependents living with them.

Postcensal Estimates—Population estimates for the years following the last published decennial census. Existing data series, such as births, deaths, Federal tax returns, medicare enrollment, and immigration and housing unit information are used to update the decennial census counts

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during the estimating process. These estimates are used in Federal funding allocations, monitoring recent demographic trends, and benchmarking may federally funded survey totals.

Public Law 94–171—The Federal law amending Section 141 of Title 13 directing the Secretary of Commerce (who delegates that responsibility to the Director of the Census Bureau) to provide selected decennial census data tabulations to the states by April 1 of the year following the census. These tabulations are used by the states to redefine the areas included in each Congressional District and the areas used for state and local elections, a process called redistricting.

Special Place—A place containing one or more group quarters, including hotels and campgrounds. A special place also may include housing units occupied by staff or guests.

Summary File 1—A data file that presents counts and basic cross-tabulations of information collected from all people and housing units. This information includes age, sex, race, Hispanic or Latino origin, household relationship, and whether the residence is owned or rented. Data will be available down to the block level for many tabulations, but limited to the census tract level in cases where there are concerns with disclosure. Summaries also will be included for other geographic areas, such as ZIP Code Tabulation Areas and Congressional Districts.

Exhibit—Additional Information

This section provides additional information on how the Census 2000 CQR program will operate.

1. Where Should a Governmental Unit Submit a Challenge for the Census 2000 CQR program?

Governmental units challenging the completeness or accuracy of the Census 2000 counts should submit their challenge in writing to: Count Question Resolution Program, Room 2002, SFC—2, Decennial Management Division, U.S. Census Bureau, Washington, DC 20233–0001.

2. Will the Census Bureau Make Corrections to the Census Counts Based on Information Submitted by Governmental Units?

The Census Bureau will make corrections if research indicates they are warranted. Our experience has shown that many of the questions received from the local or tribal officials do not reflect errors in census counts. Questions may result from an incorrect or incomplete understanding of the procedures used to take the census. In other instances, questions about census counts reflect a local or tribal official's reliance on different enumeration concepts, definitions, geographic assignments, and/or the currency of the information in comparison to the census. The Census Bureau's determination of whether a correction is necessary will be based on the quality and completeness of the information provided by local and tribal governmental unit representatives and the results of the Census Bureau's review of the census records.

3. Will the Census Bureau Incorporate Corrections From the CQR Process Into the Apportionment or Redistricting Data or Subsequent Data Products?

The Census Bureau will not change the apportionment counts to reflect corrections resulting from the CQR process. The apportionment counts were delivered to the President on December 28, 2000.

The Census Bureau will begin delivery of the counts required for redistricting purposes in March 2001 and will complete this delivery by the statutory deadline of April 1, 2001. The Census Bureau will not incorporate CQR corrections into the redistricting data and subsequent data products for Census 2000. This process will allow the Census Bureau to maintain consistency between data products while maintaining the schedule for timely release of the data. However, the Census Bureau will issue a revised official Census 2000 population and housing unit counts for the affected governmental entity(es), maintain a list of CQR corrected areas on the *American Factfinder*, and will incorporate any corrections into its Postcensal Estimates program beginning in December 2002.

III. Data

OMB Number: Not available.

Form Number: None.

Type of Review: Regular collection.

Affected Public: Local governmental jurisdictions in the United States and Puerto Rico.

Estimated Number of Respondents: Approximately 3,000 annually.

Estimated Time Per Response: 5.2 hours (based on an average challenge of 40 housing units).

Estimated Total Annual Burden Hours: 15,600 hours.

Estimated Total Annual Cost: $244,440.00.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, USC, Section 141.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 12, 2001.

Madeleine Clayton,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–1564 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; Randy Reyes

In the Matter of: Randy Reyes, currently incarcerated at: Wachenhut FCI, USM #05425–089, P.O. Box 17001, 1500 Cadet Road, Taft, California 93268; and with an address at: 5250 Colodny Drive, #3, Agoura Hills, California 91301–2656.

Order Denying Export Privileges

On January 14, 2000, Randy Reyes (Reyes) was convicted in the United States District Court for the Eastern District of Wisconsin of violating Section 38 of the Arms Export Control Act (22 U.S.A. 2778 (1990 & Supp. 2000)) (the AECA) and the International Emergency Economic Powers Act (50 U.S.C.A. 1701–1706 (1991 & Supp. 2000)) (IEEPA). Specifically, Reyes was convicted of knowingly and willfully exporting and attempting to export from the United States aircraft component parts which were designated as defense articles on the United States Munitions List without having first obtained from the Department of State a license or written authorization, and of knowingly and willfully exporting and attempting to export from the United States to Iran through Geneva, Switzerland, aircraft component parts.

Section 11(h) of the Export Administration Act of 1979, as amended (currently codified at 50 U.S.C.A. app 2401–2420 (1991 & Supp. 2000 and Pub. L. No. 106–508, November 13, 2000)) (the Act) [1] provides that, at the discretion of the Secretary of Commerce,[2] no person convicted of violating the AECA or the IEEPA, or certain other provisions of the United States Code, shall be eligible to apply for or use any export license issued pursuant to, or provided by, the Act or the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (2000), as amended (65 FR 14862, March 20, 2000)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any license issued pursuant to the Act in which such a person had any interest at the time of conviction may be revoked.

Pursuant to sections 766.25 and 750.8(a) of the Regulations, upon notification that a person has been convicted of violating the AECA or the IEEPA, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that person's export privileges for a period of up to 10 years from the date of conviction and shall determine whether to revoke any license previously issued to such a person.

Having received notice of Reyes's conviction for violating the AECA and the IEEPA, and after providing notice and an opportunity for Reyes to make a written submission to the Bureau of Export Administration before issuing an Order denying his export privileges, as provided in section 766.25 of the Regulations, I, following consultations with the Director, Office of Export Enforcement, have decided to deny Reyes's export privileges for a period of 10 years from the date of his conviction. The 10-year period ends on January 14, 2010. I have also decided to revoke all licenses issued pursuant to the Act in which Reyes had an interest at the time of his conviction.

Accordingly, it is hereby Ordered:

I. Until January 14, 2010, Randy Reyes, currently incarcerated at: Wachenhut FCI USM # 05425–089, P.O. Box 17001, 1500 Cadet Road, Taft, California 93268, and with an address at: 5250 Colodny Drive, #3, Agoura Hills, California 91301–2656, may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States, that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

II. No person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin, that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

III. After notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to Reyes by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

IV. This Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

V. This Order is effective immediately and shall remain in effect until January 14, 2010.

VI. In accordance with Part 756 of the Regulations, Reyes may file an appeal from this Order with the Under Secretary for Export Administration. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

VII. A copy of this Order shall be delivered to Reyes. This Order shall be published in the **Federal Register**

Dated: January 5, 2001.

Eileen M. Albanese,

Director, Office of Exporter Services.

[FR Doc. 01–1620 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–DT–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Action Affecting Export Privileges; Peter Rigolli, Also Known as Pietro Rigolli, Ian Falcon, G. Tedaldi, Rafael Heredia, and Farid H. Talab

In the Matter of: Peter Rigolli, also known as Pietro Rigolli, Ian Falcon, G. Tedaldi, Rafael Heredia, and Farid H. Talab, currently incarcerated at: Inmate #044–22082, FCI Otisville, P.O. Box 600, Otisville, New York 10963; and with an address at: 118 Northview, Dollar Des, Ormeaux, Quebec, Canada H9B3J6.

Order Denying Export Privileges

On March 27, 2000, Peter Rigolli, also known as Pietro Rigolli, Ian Falcon, G.

[1] During the time of the Act's lapse, (August 20, 1994 through November 12, 2000) the President, through Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), which had been extended by successive Presidential Notices, the most recent being that of August 3, 2000 (65 FR 48347, August 8, 2000), continued the Regulations in effect under the IEEPA.

[2] Pursuant to appropriate delegations of authority that are reflected in the Regulations, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by section 11(h) of the Act.

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Tedaldi, Rafael Heredia, and Farid H. Talab (hereinafter referred to as Rigolli), was convicted in the United States District Court for the District of Connecticut of violating the International Emergency Economic Powers Act (50 U.S.C.A. 1701–1706 (1991 & Supp. 2000)) (IEEPA) and the Export Administration Act of 1979, as amended (currently codified at 50 U.S.C.A. app. 2401–2420 (1991 & Supp. 2000 and Pub. L. No. 106–508, November 13, 2000)) (the Act).[1] Specifically, Rigolli was convicted of knowingly and willfully exporting and causing to be exported from the United States to Canada and Switzerland, and then re-exported to Iran, aircraft parts without having first obtained a validated export license, and of knowingly and willfully making false, fictitious, and fraudulent statements and representations to effect the export of aircraft engine parts by representing that the ultimate destination for those parts was the country of Singapore, which statement he knew to be untrue.

Section 11(h) of the Act provides that, at the discretion of the Secretary of Commerce,[2] no person convicted of violating the IEEPA or the Act, or certain other provisions of the United States Code, shall be eligible to apply for or use any export license issued pursuant to, or provided by, the Act or the Export Administration Regulations (currently codified at 15 CFR Parts 730–774 (2000), as amended (65 FR 14862, March 20, 2000)) (the Regulations), for a period of up to 10 years from the date of the conviction. In addition, any license issued pursuant to the Act in which such a person had any interest at the time of conviction may be revoked.

Pursuant to sections 766.25 and 750.8(a) of the Regulations, upon notification that a person has been convicted of violating the IEEPA or the Act, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, shall determine whether to deny that person's export privileges for a period of up to 10 years from the date of conviction and shall also determine whether to revoke any license previously issued to such a person.

Having received notice of Rigolli's conviction for violating the IEEPA and the Act, and after providing notice and an opportunity for Rigolli to make a written submission to the Bureau of Export Administration before issuing an Order denying his export privileges, as provided in section 766.25 of the Regulations, I, following consultations with the Director, Office of Export Enforcement, have decided to deny Rigolli's export privileges for a period of 10 years from the date of his conviction. The 10-year period ends on March 27, 2010. I have also decided to revoke all licenses issued pursuant to the Act in which Rigolli had an interest at the time of his conviction.

Accordingly, it is hereby *Ordered:*

I. Until March 27, 2010, Peter Rigolli, also known as Pietro Rigolli, Ian Falcon, G. Tedaldi, Rafael Heredia, and Farid H. Talab, currently incarcerated at: Inmate #044–22082, FCI Otisville, P.O. Box 600, Otisville, New York 10963; and with an address at: 118 Northview, Dollar Des, Ormeaux, Quebec, Canada H9B3J6, may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States, that is subject to the Regulations, or in any other activity subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefiting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

II. No person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the denied person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the denied person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the denied person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the denied person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the denied person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the denied person, or service any item, of whatever origin, that is owned, possessed or controlled by the denied person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

III. After notice and opportunity for comment as provided in Section 766.23 of the Regulations, any person, firm, corporation, or business organization related to Rigolli by affiliation, ownership, control, or position of responsibility in the conduct of trade or related services may also be subject to the provisions of this Order.

IV. This Order does not prohibit any export, reexport, or other transaction subject to the Regulations where the only items involved that are subject to the Regulations are the foreign-produced direct product of U.S.-origin technology.

V. This Order is effective immediately and shall remain in effect until March 27, 2010.

VI. In accordance with Part 756 of the Regulations, Rigolli may file an appeal from this Order with the Under Secretary for Export Administration. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

VII. A copy of this Order shall be delivered to Rigolli. This Order shall be published in the **Federal Register**.

Dated: January 5, 2001.

Eileen M. Albanese,

Director, Office of Exporter Services.

[FR Doc. 01–1619 Filed 1–19–01; 8:45am]

BILLING CODE 3510–DT–M

[1] During the time of the Act's lapse, (August 20, 1994 through November 12, 2000) the President, through Executive Order 12924 (3 CFR, 1994 Comp. 917 (1995)), which had been extended by successive Presidential Notices, the most recent being that of August 3, 2000 (65 FR 48347, August 8, 2000), continued the Regulations in effect under the IEEPA.

[2] Pursuant to appropriate delegations of authority that are reflected in the Regulations, the Director, Office of Exporter Services, in consultation with the Director, Office of Export Enforcement, exercises the authority granted to the Secretary by section 11(h) of the Act.

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 71–2000]

Foreign-Trade Zone 50, Long Beach, California, Proposed Foreign-Trade Subzone, ARCO Products Company (Oil Refinery Complex), Long Beach, California, Area; Correction

The **Federal Register** notice (65 FR 82320, 12/28/00) describing the application submitted to the Foreign-Trade Zones Board (the Board) by the Board of Harbor Commissioners of the City of Long Beach, grantee of FTZ 50, requesting special-purpose subzone status for the oil refinery complex of Atlantic Richfield Company (ARCO), in the Long Beach, California, area, is corrected as follows: in paragraph 2, the description of Sites 5, 6, and 7 should be as follows:

"*Site 5* (5 tanks, 1.1 million barrel capacity, 15 acres)";
"*Site 6* (13 tanks, 3.6 million barrel capacity, 75 acres)";
"*Site 7* (20 tanks, 1.1 million barrel capacity, 20 acres)".

Dated: January 11, 2001.

Dennis Puccinelli,

Executive Secretary.

[FR Doc. 01–1685 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1138]

Grant of Authority for Subzone Status Alliant Aerospace Composite Structures Company (Space Launch Vehicle Composite Structures) Iuka, Mississippi

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board (the Board) to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Vicksburg-Jackson Foreign Trade Zone, Inc., grantee of Foreign-Trade Zone 158, has made application for authority to establish special-purpose subzone status at the space launch vehicle composite structure manufacturing facility of Alliant Aerospace Composite Structures Company (Inc.), located in Iuka, Mississippi (FTZ Docket 25–2000, filed 6–2–00);

Whereas, notice inviting public comment was given in the **Federal Register** (65 FR 36887, 6–12–00); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, therefore, the Board hereby grants authority for subzone status at the space launch vehicle composite structure manufacturing facility of Alliant Aerospace Composite Structures Company (Inc.), located in Iuka, Mississippi (Subzone 158C), at the location described in the application, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 5th day of January 2001.

Troy H. Cribb,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 01–1683 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1136]

Grant of Authority for Subzone Status; Sunoco, Inc. (Oil Refinery Complex), Toledo, Ohio

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Toledo-Lucas County Port Authority, grantee of Foreign-Trade Zone 8, has made application to the Board for authority to establish special-purpose subzones status at the oil refinery complex of Sunoco, Inc., located in Toledo, Ohio (FTZ Docket 17–2000, filed 5/3/00);

Whereas, notice inviting pubic comment was given in the **Federal Register** (65 FR 31141, 5/16/00); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now, therefore, the Board hereby grants authority for subzone status at the oil refinery complex of Sunoco, Inc., located in Toledo, Ohio (Subzone 8H), at the locations described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR 146.41, 146.42) products consumed as fuel for the petrochemical complex shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR 146.42) may be elected on inputs covered under HTSUS Subheadings #2710.00.05–#2710.00.10, #2710.00.25, and #2710.00.4510 which are used in the production of:

—Petrochemical feedstocks (examiner's report, Appendix "C");
—Products for export; and,
—Products eligible for entry under HTSUS #9808.00.30 and #9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 5th day of January 2001.

Troy H. Cribb,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

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Appendix C

STANDARD APPENDIX FOR OIL REFINERY SUBZONES[1] PETROCHEMICAL FEEDSTOCKS/REFINERY BY-PRODUCTS—NPF STATUS

	HTSUS No.	Duty rate
Benzene	2707.10.00	Free.
Toluene	2707.20.00	Free.
Xylenes	2707.30.00	Free.
Naphthalene	2707.40.00	Free.
Other Aromatic Hydrocarbon Mixtures	2707.50.00	Free.
Carbon Black Oil	2707.99.50	Free.
	2803.00.00	Free.
Distillates/Fuel Oils	2710.00.05	5.25¢/bbl.
	2710.00.10	10.5¢/bbl.
Kerosene	2710.00.20	10.5¢/bbl.
Naphthas (except motor fuel & blendstocks)	2710.00.25	10.5¢/bbl.
Mixtures of Hydrocarbons, not elsewhere specified	2710.00.45	10.5¢/bbl.
Liquified Natural Gas	2711.11.00	Free.
Propane	2711.12.00	Free.
Butanes	2711.13.00	Free.
Ethylene, Propylene, Butylene, Butadiene	2711.14.00	Free.
Ethane, other Liquified Petroleum Gases	2711.19.00	Free.
Natural Gas, gaseous	2711.21.00	Free.
Gaseous Propane, Butane, other Petroleum Gases	2711.29.00	Free.
Paraffin Waxes & Petroleum Jelly	2712.10.00–2712.90.20	Free.
Petroleum Coke and Asphalt	2713.11.00–2713.90.00	Free.
	2714.10.00–2715.00.00	Free.
Sulfur	2802.00.00	Free.
	2503.00.00	Free.
Sulfuric Acid	2807.00.00	Free.
Acyclic Hydrocarbons:		
Saturated		
Ethane and Butane	2901.10.10	Free.
n-Pentane and Isopentane	2901.10.30	Free.
Other	2901.10.40	Free.
Unsaturated		
Ethylene, Propylene, Butylene	2901.21.00–2901.23.00	Free.
Buta-1-3-diene	2901.24.10	Free.
Dicyclopentadiene	2902.19.0010	Free.
Cyclic Hydrocarbons:		
Benzene, Toluene and Xylenes	2902.20.00–2902.44.00	Free.
Cumene	2902.70.00	Free.
Pseudocumene	2902.90.10	Free.

[1] This is a comprehensive list of finished products that may be produced with NPF inputs at the subzones designated in Appendix A (Fed. Reg. Notice of 9/2/99, 64 FR 48140) based on previous FTZ Board authorizations for oil refineries.

[FR Doc. 01–1681 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1137]

Grant of Authority for Subzone Status; Conoco, Inc., (Oil Refinery Complex), Ponca City, Oklahoma

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Port Authority of the Greater Oklahoma City Area, grantee of Foreign-Trade Zone 106, has made application to the Board for authority to establish special-purpose subzone status at the oil refinery complex of Conoco, Inc., located in Ponca City, Oklahoma (FTZ Docket 18–2000, filed 5/3/00);

Whereas notice inviting public comment was given in the **Federal Register** (65 FR 31141, 5/16/00); and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now therefore, the Board hereby grants authority for subzone status at the oil refinery complex of Conoco, Inc., located in Ponca City, Oklahoma (Subzone 160E), at the locations described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR §§ 146.41, 146.42) products consumed as fuel for the petrochemical complex shall be subject to the applicable duty rate.

2. Privileged for foreign status (19 CFR § 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR § 146.42) may be elected on inputs covered under HTSUS Subheadings #2710.00.05—#2710.00.10 #2710.00.25, and #2710.00.4510 which are used in the production of:

—Petrochemical feedstocks (examiner's report, Appendix "C")
—Products for export; and,
—Products eligible for entry under HTSUS #9808.00.30 and #9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 5th day of January 2001.

Troy H. Cribb,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

STANDARD APPENDIX FOR OIL REFINERY SUBZONES [1] PETROCHEMICAL FEEDSTOCKS/REFINERY BY-PRODUCTS NPF STATUS

	HTSUS No.	Duty rate
Benzene	2707.10.00	Free.
Toluene	2707.20.00	Free.
Xylenes	2707.30.00	Free.
Napthalene	2707.40.00	Free.
Other Aromatic Hydrocarbon Mixtures	2707.50.00	Free.
Carbon Black Oil	2707.99.50	Free.
	2803.00.00	Free.
Distillates/Fuel Oils	2710.00.05	5.25¢/bbl.
	2710.00.10	10.5¢/bbl.
Kerosene	2710.00.20	10.5¢/bbl.
Naphthas (except motor fuel & blendstocks)	2710.00.25	10.5¢/bbl.
Mixtures of Hydrocarbons, not elsewhere specified	2710.00.45	10.5¢/bbl.
Liquified Natural Gas	2711.11.00	Free.
Propane	2711.12.00	Free.
Butanes	2711.13.00	Free.
Ethylene, Propylene, Butylene, Butadiene	2711.14.00	Free.
Ethane, other Liquified Petroleum Gases	2711.19.00	Free.
Natural Gas, gaseous	2711.21.000	Free.
Gaseous Propane, Butane, other Petroleum Gases	2711.29.00	Free.
Paraffin Waxes & Petroleum Jelly	2712.10.00–2712.90.20	Free.
Petroleum Coke and Asphalt	2713.11.00–2713.90.00	Free.
	2714.10.00–2715.00.00	Free.
Sulfur	2802.00.00	Free.
	2503.00.00	Free.
Sulfuric Acid	2807.00.00	Free.
Acyclic Hydrocarbons:		
Saturated:		
Ethane and Butane	2901.10.10	Free.
n-Pentane and Isopentane	2901.10.30	Free.
Other	2901.10.40	Free.
Unsaturated:		
Ethylene, Propylene, Butylene	2901.21.00–2901.23.00	Free.
Buta-1-3-diene	2901.24.10	Free.
Dicyclopentadiene	2902.19.0010	Free.
Cyclic Hydrocarbons:		
Benzene, Toluene and Xylenes	2902.20.00–2902.44.00	Free.
Cumene	2902.70.00	Free.
Pseudocumene	2902.90.10	Free.

[1] This is a comprehensive list of finished products that may be produced with NPF inputs at the subzones designated in Appendix A (Fed. Reg. Notice of 9/2/99, 64 FR 48140) based on previous FTZ Board authorizations for oil refineries.

[FR Doc. 01–1682 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1140]

Grant of Authority for Subzone Status; Tesoro Northwest Company (Oil Refinery), Anacortes, WA

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR Part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, an application from the Port of Tacoma, grantee of FTZ 86, for authority to establish special-purpose subzone status at the oil refinery complex of Tesoro Northwest Company in Anacortes, Washington, was filed by the Board on March 15, 2000, and notice inviting public comment was given in the **Federal Register** (FTZ Docket 10–2000, 65 FR 15305, 3/22/00); and,

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Whereas, the Board adopts the findings and recommendations on the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations would be satisfied, and that approval of the application would be in the public interest if approval is subject to the conditions listed below;

Now, Therefore, the Board hereby authorizes the establishment of a subzone (Subzone 86D) at the oil refinery complex of Tesoro Northwest Company, in Anacortes, Washington, at the location described in the application, subject to the FTZ Act and the Board's regulations, including § 400.28, and subject to the following conditions:

1. Foreign status (19 CFR §§ 146.41, 146.42) products consumed as fuel for the refinery shall be subject to the applicable duty rate.

2. Privileged foreign status (19 CFR § 146.41) shall be elected on all foreign merchandise admitted to the subzone, except that non-privileged foreign (NPF) status (19 CFR § 146.42) may be elected on refinery inputs covered under HTSUS Subheadings #2709.1000–#2710.00.1050, #2710.00.2500 and #2710.00.4510 which are used in the production of:

—Petrochemical feedstocks and refinery by-products (examiners report, Appendix "C");

—Products for export; and

—Products eligible for entry under HTSUS #9808.00.30 and #9808.00.40 (U.S. Government purchases).

Signed at Washington, DC, this 8th day of January 2001.

Troy H. Cribb,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Appendix C

STANDARD APPENDIX FOR OIL REFINERY SUBZONES [1] PETROCHEMICAL FEEDSTOCKS/REFINERY BY-PRODUCTS—NPF STATUS

	HTSUS No.	Duty rate
Benzene	2707.10.00	Free.
Toluene	2707.20.00	Free.
Xylenes	2707.30.00	Free.
Naphthalene	2707.40.00	Free.
Other Aromatic Hydrocarbon Mixtures	2707.50.00	Free.
Carbon Black Oil	2707.99.50	Free.
	2803.00.00	Free.
Distillates/Fuel Oils	2710.00.05	5.25¢/bbl.
	2710.00.10	10.5¢/bbl.
Kerosene	2710.00.20	10.5¢/bbl.
Naphthas (except motor fuel & blendstocks)	2710.00.25	10.5¢/bbl.
Mixtures of Hydrocarbons, not elsewhere specified	2710.00.45	10.5¢/bbl.
Liquified Natural Gas	2711.11.00	Free.
Propane	2711.12.00	Free.
Butanes	2711.13.00	Free.
Ethylene, Propylene, Butylene, Butadiene	2711.14.00	Free.
Ethane, other Liquefied Petroleum Gases	2711.19.00	Free.
Natural Gas, gaseous	2711.21.000	Free.
Gaseous Propane, Butane, other Petroleum Gases	2711.29.00	Free.
Paraffin Waxes & Petroleum Jelly	2712.10.00–2712.90.20	Free.
Petroleum Coke and Asphalt	2713.11.00–2713.90.00	Free.
	2714.10.00–2715.00.00	
Sulfur	2802.00.00	Free.
	2503.00.00	Free.
Sulfuric Acid	2807.00.00	Free.
Acyclic Hydrocarbons:		
Saturated Ethane and Butane	2901.10.10	Free.
Unsaturated Ethylene, Propylene, Butylene	2901.21.00–2901.23.00	Free.
Buta-1-3-diene	2901.24.10	Free.
Dicyclopentadene	2902.19.0010	Free.
Cyclic Hydrocarbons: Benzene, Toluene and Xylenes	2902.20.00–2902.44.00	Free.
Cumene	2902.70.00	Free.
Pseudocumene	2902.90.10	Free.

[1] This is a comprehensive list of finished products that may be produced with NPF inputs at the subzones designated in Appendix A (Fed. Reg. Notice of 9/2/99, 64 FR 48140) based on previous FTZ Board authorizations for oil refineries.

[FR Doc. 01–1684 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–DS–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–605]

Frozen Concentrated Orange Juice from Brazil; Preliminary Results of Antidumping Duty Administrative Review; Time Limits

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Extension of Time Limits of Preliminary Results of 1999–2000 Administrative Review.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Irina Itkin, Office of AD/CVD Enforcement, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC, 20230; telephone (202) 482–0656.

Postponement of Preliminary Results of Administrative Review

The Department issued the initiation of the thirteenth administrative review of the antidumping duty order on frozen concentrated orange juice from Brazil on June 30, 2000 (65 FR 41942 (July 7, 2000)). The current deadline for the preliminary results in this review is January 30, 2001. In accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h)(2), the Department finds that the preliminary results cannot be issued within the original time frame due to the extraordinarily complicated nature of certain cost issues in this review.

Because it is not practicable to complete the administrative review within the time limits mandated by the Uruguay Round Agreements Act (245 days from the last day of the anniversary month for preliminary results), pursuant to section 751(a)(3)(A) of the Act, and 19 CFR 351.213(h)(2), the Department is extending the time limit for completion of the preliminary results of the administrative review until May 30, 2001.

This extension is in accordance with section 751(a)(3)(A) of the Act.

Dated: January 16, 2001.

Richard W. Moreland,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 01–1842 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee (ETTAC)

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

Date: February 8, 2001.

Time: 9:00 a.m. to 3:30 p.m.

Place: Room 3407, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUMMARY: The Environmental Technologies Trade Advisory Committee will hold a plenary meeting on February 8, 2001, in Room 3407 of the U.S. Department of Commerce.

During the morning, the ETTAC will hear reports on cross-cutting trade and environment issues including those at issue in the U.S.-Jordan, and U.S. Singapore free trade agreements negotiations and the Free Trade Agreement of the Americas. The ETTAC will also hear a report from its Government Resources Subcommittee and review past initiatives. In the afternoon, the ETTAC will conduct a strategic planning session.

The ETTAC is mandated by Public Law 103–392). It was created to advise on the environmental trade policies and programs of the U.S. Government and to help it to focus its resources on increasing the exports of the U.S. environmental industry. The ETTAC operates as an advisory committee to the Secretary of Commerce and the interagency Environmental Trade Working Group (ETWG) of the Trade Promotion Coordinating Committee (TPCC). The ETTAC was originally chartered in May of 1994. It was most recently rechartered until May 30, 2002. The ETTAC was created on May 31, 1994, to advise the U.S. government on policies and programs to expand U.S. exports of environmental products and services.

For further information phone Jane Siegel, Office of Technologies Industries, (ETI), U.S. Department of Commerce at (202) 482–5225. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to ETI.

Dated: January 12, 2001.

Carlos F. Montoulieu,

Deputy Assistant Secretary.

[FR Doc. 01–1602 Filed 1–19–01; 8:45 am]
BILLING CODE 3510–DR–U

DEPARTMENT OF COMMERCE

International Trade Administration

North American Free-Trade Agreement, Article 1904; NAFTA Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On December 28, 2000, Dofasco filed a First Request for Panel Review with the United States Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free Trade Agreement. Panel review was requested of the final results of the full sunset review of antidumping duty orders made by the United States International Trade Commission, respecting Certain Corrosion-Resistant Steel Flat Products from Canada and the continuation of antidumping duty order by the U.S. Department of Commerce based on the International Trade Commission's determination. These determinations were published in the **Federal Register**, (65 FR 75301) on December 1, 2000 and (65 FR 78469) on December 15, 2000. The NAFTA Secretariat has assigned Case Number USA–CDA–00–1904–11 to this request.

FOR FURTHER INFORMATION CONTACT: Caratina L. Alston, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established *Rules of Procedure for Article 1904 Binational Panel Reviews* ("Rules"). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

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A first Request for Panel Review was filed with the United States Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on December 28, 2000, requesting panel review of the final determination described above.

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is January 29, 2001);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is February 12, 2001); and

(c) The panel review shall be limited to the allegations of error of fact or law, including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: January 8, 2001.

Caratina L. Alston,

United States Secretary, NAFTA Secretariat.

[FR Doc. 01–1819 Filed 1–19–01; 8:45 am]

BILLING CODE 3510–GT–U

DEPARTMENT OF COMMERCE

[I.D. 011701A]

Submission for OMB Review; Comment Request

The Department of Commerce has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Fisheries Certificate of Origin.

Form Number(s): NOAA Form 370.

OMB Approval Number: 0648-0335.

Type of Request: Regular submission.

Burden Hours: 1,033.

Number of Respondents: 350.

Average Hours Per Response: 20 minutes for a processor response, 5 minutes for a Captain's statement.

Needs and Uses: Information required by International Dolphin Conservation Program Act (IDCPA), amendments to the Marine Mammal Protection Act (MMPA), is needed to document the dolphin safe status of tuna import shipments and domestic deliveries of tuna by U.S.-flag purse seine fishing vessels; verify that import shipments of fish were not harvested by large-scale, high seas driftnets; and verify that tuna was not harvested by an embargoed nation or one that is otherwise prohibited from exporting tuna to the United States. Forms are submitted by importers, processors, and/or purse seine vessel operators.

Affected Public: Business and other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395-3897.

Copies of the above information collection proposal can be obtained by calling or writing Madeleine Clayton, Departmental Forms Clearance Officer, (202) 482-3129, Department of Commerce, Room 6086, 14th and Constitution Avenue, NW, Washington, DC 20230 (or via the Internet at MClayton@doc.gov).

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, Washington, DC 20503.

Dated: January 12, 2001

Madeleine Clayton,

Departmental Forms Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 01–1845 Filed 1–19–01; 8:45am]

BILLING CODE 3510–22–S

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 2501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden; it includes the actual data collection instruments [if any].

DATES: Comments must be submitted on or before February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Christopher W. Cummings, Division of Trading and Markets, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581 and refer to OMB Control No. 3038–0039.

SUPPLEMENTARY INFORMATION:

Title: Procedural Requirements for Requests for Interpretative, No-Action, and Exemptive Letters (OMB Control No. 3038–0049). This is a request for extension of a currently approved information collection.

Abstract: Commission Rule 140.99 requires persons submitting requests for exemptive, no-action, and interpretative letters to provide specific written information, certified as to completeness and accuracy, and to update that information to reflect material changes. The proposed rule was promulgated pursuant to the Commission's rulemaking authority contained in section 8a(5) of the Commodity Exchange Act, 7 U.S.C. 12a(5) (1994).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the CFTC's regulations were published on December 30, 1981. See 46 FR 63035 (Dec. 30, 1981). The **Federal Register** notice with a 60-day comment period soliciting comments on this collection of information was published on December 12, 2000 (65 FR 77595).

Burden Statement: The respondent burden for this collection is estimated to average 7 hours per response. These estimates include the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: 280.

Estimated Number of Respondents: 280.

Estimated Total Annual Burden on Respondents: 1,957 hours.

Frequency of Collection: On occasion.

Send comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, to the addresses listed below. Please refer to OMB Control No. 3038–0049 in any correspondence.

Christopher W. Cummings, Division of Trading and Markets, U.S. Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581, and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for CFTC, 725 17th Street, Washington, DC 20503.

Dated: January 16, 2001.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 01–1766 Filed 1–19–01; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Establishment of the Panel To Review the V–22 Program

ACTION: Notice of establishment.

SUMMARY: The Panel to Review the V–22 Program is being established in consonance with the public interest and in accordance with the provisions of Pub. L. 92–463, the "Federal Advisory Committee Act," Title 5 U.S.C., Appendix 2. Due to the urgent business tasked to this Panel by the Secretary of Defense, this notice is being published less than 15 days before the Panel's establishment.

This Panel will conduct an independent, high-level review of the V–22 program to include safety of the aircraft and recommend any proposed changes or corrective actions, and report the results of the Secretary of Defense.

The Panel will consist of four members with expertise, knowledge, and the experience necessary in matters related to the V–22 review.

FOR FURTHER INFORMATION: Contact Gary Gray, OUSD (Acquisition, Technology, and Logistics), 703–697–0638.

Dated: January 12, 2001.

L.M. Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1716 Filed 1–19–01; 8:45 am]

BILLING CODE 5000–10–m

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the President's Information Technology Advisory Committee (formerly the Presidential Advisory Committee on High Performance Computing and Communications, Information Technology, and the Next Generation Internet)

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for the next meeting of the President's Information Technology Advisory Committee. The meeting will be open to the public. Notice of this meeting is required under the Federal Advisory Committee Act, (Pub. L. 92–463).

DATES: February 7 and 8, 2001.

ADDRESSES: NSF Board Room (Room 1235), National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

Proposed Schedule and Agenda: The President's Information Technology Advisory Committee (PITAC) will meet in open session from approximately 3:00–5:00 p.m. on February 7 and 8:00 a.m.—2 p.m. on February 8, 2001.

This meeting will include: (1) Updates and reports from the PITAC's panels on: learning, digital libraries; healthcare; the digital divide; and international issues; (2) a discussion of PITAC's newly formed panels, especially national security and individual security; (3) a discussion on information technology and the Federal government; and (4) additional topics, as appropriate.

FOR FURTHER INFORMATION: The National Coordination Office for Information Technology Research and Development (formerly The National Coordination Office for Computing, Information, and Communications) provides information about this Committee on its web site at: http://www.itrd.gov; it can also be reached at (703) 292–4873. Public seating for this meeting is limited, and is available on a first-come, first-served basis.

Dated: January 12, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1719 Filed 1–19–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

ACTION: Cancellation of Advisory Committee Meeting.

SUMMARY: The Defense Science Board (DSB) Task Force on Systems Technology for the Future U.S. Strategic Posture meeting scheduled for December 14–15, 2000, was not held.

Dated: January 12, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1717 Filed 1–19–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

AGENCY: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board (DSB) Task Force on Options for Acquisition of the Advance Targeting Pod and Advanced Technology FLIR Pod (ATP/ATFLIR) Will meet in closed session on January 17–18, 2001, and January 26, 2001, at Strategic Analysis Inc., 3601 Wilson Boulevard, Arlington, VA.

The mission of the DBS is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At these meetings, the Task Force will review and evaluate the Department's options for acquisition of third generation Forward Looking Infrared (FLIR) targeting pods for the Air Force and the Navy. They will also consider the state of technical maturity of all the concepts and pods available, as will as the realism of the schedules and costs in view of other service flight program software, aircraft integration, and service specific requirements.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. II), it has been determined that these Defense Science Board meetings, concern matters listed in 5 U.S.C. § 552b(c) (1), and that accordingly these meetings will be closed to the public.

Due to critical mission requirements and the short timeframe to accomplish this review, there is insufficient time to provide timely notice required by Section 10(a)(2) of the Federal Advisory Committee Act and Subsection 101–6.1015(b) of the GSA Final Rule on Federal Advisory Committee Management, 41 CFR Part 101–6, which further requires publication at least 15 calendar days prior to the first meeting of the Task Force on January 14–18, 2001.

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Dated: January 12, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer Department of Defense.

[FR Doc. 01–1715 Filed 1–19–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board

ACTION: Meeting date change of advisory committee meeting.

SUMMARY: The Defense Science Board (DSB) Task Force on Systems Technology for the Future U.S. Strategic Posture closed meeting scheduled for February 14–15, 2001, has been changed to February 13–14, 2001. The meeting will be held at Strategic Analysis Inc., 3601 Wilson Boulevard, Suite 600, Arlington, VA.

Dated: January 12, 2001.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 01–1718 Filed 1–19–01; 8:45 am]

BILLING CODE 5001–10–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Report

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Ocean Research Advisory Panel (ORAP) report, "Strategic Vision for Achieving Sustainable Marine Resources Within the US EEZ," is available for public inspection.

DATES: Summary comments are desired by Tuesday, January 16, 2001, however the report will continue to be available for public review until June 30, 2001.

ADDRESSES: The report is available for review at and comments should be submitted to the National Oceanographic Partnership Program (NOPP) Program Office, 1755 Massachusetts Avenue, NW, Suite 800, Washington, DC 20036. See **SUPPLEMENTARY INFORMATION** section for electronic access and filing addresses.

FOR FURTHER INFORMATION CONTACT: Dr. Steven E. Ramberg, Office of Naval Research, 800 North Quincy Street, Arlington, VA 22217–5660, telephone number (703) 696–4358.

SUPPLEMENTARY INFORMATION: This report was prepared in response to request by the National Ocean Research Leadership Council to prepare a strategic vision for a U.S. research program to study marine biological resources within the 200-nautical mile U.S. exclusive economic zone (EEZ) together with the means to make these resources economically and ecologically sustainable by 2010. The report is available for review on the NOPP website at http://www.nopp.org. Comments on the report may be submitted by electronic mail (e-mail) to nopp@brook.edu. This notice of report availability is provided in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2).

Dated: January 5, 2001.

J. L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 01–1621 Filed 1–19–01; 8:45 am]

BILLING CODE 3810–FF–U

DEPARTMENT OF EDUCATION

Fund for the Improvement of Education (FIE) Program

AGENCY: Office of Educational Research and Improvement, Department of Education.

ACTION: Notice of proposed priority.

SUMMARY: The Assistant Secretary for Educational Research and Improvement proposes a priority under the Fund for the Improvement of Education (FIE) for a grant competition for Community Coaches. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2001 and later years.

DATES: We must receive your comments on or before February 21, 2001.

ADDRESSES: Address all comments about this proposed priority to Pat O'Connell Ross, U.S. Department of Education, 555 New Jersey Avenue, NW., room 602D, Washington, DC 20202–5530. If you prefer to send your comments through the Internet, use the following address: comments@ed.gov.

You must include the term Community Coaches in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Pat O'Connell Ross. Telephone: (202) 219–2169 or via Internet: patricia_ross@ed.gov.

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT.**

SUPPLEMENTARY INFORMATION:

Invitation to Comment

We invite you to submit comments regarding this proposed priority.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from this proposed priority. Please let us know of any further opportunities we should take to reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed priority in room 600, 555 New Jersey Avenue, NW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate aid, such as a reader or print magnifier, to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed priority. If you want to schedule an appointment for this type of aid, you may call (202) 205–8113 or (202) 260–9895. If you use a TDD, you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

General Information

OERI administers the Fund for the Improvement of Education under section 10101, Part A of Title X of the Elementary and Secondary Education Act of 1965, as amended. The purpose of the Fund for the Improvement of Education (FIE) is to support nationally significant programs to improve the quality of education, assist all students to meet challenging State content standards, and contribute to the achievement of the National Education Goals.

The Assistant Secretary is authorized, under section 10101, to support nationally significant programs and projects to improve the quality of education, and may carry out programs and projects through grants to State and local educational agencies, institutions of higher education, and other public and private agencies, organizations, and institutions. These activities may include activities to promote and evaluate counseling and mentoring for students, including intergenerational mentoring.

The Assistant Secretary believes that community coaches, who can help young people in learning through community service and who can serve to link the school with the business sector and the community, have the potential for providing high-quality, cost-effective mentoring for elementary and secondary students that can lead to improved personal, civic, and academic skills. The Assistant Secretary is interested in funding pilot projects that can serve as models for schools across the nation. These projects should support and evaluate the effectiveness of strategies that—

- Help young people gain concrete leadership skills by designing and implementing their own community-building projects;
- Help teachers and other school personnel identify and use the resources of their surrounding community to engage children in community service connected to their academic learning; and
- Engage students in hands-on learning and help them develop personal, civic, and academic skills through structured service projects that meet community needs.

Projects could include partnerships between schools and hospitals, nursing homes, community recreation centers, and human service agencies of all types. The community coaches could be AmeriCorp members, teachers, guidance counselors, or other members of the community.

Discussion of Priority

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing or funding additional priorities, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this proposed priority, we invite applications through a notice in the **Federal Register**. When inviting applications we designate the priority as absolute, competitive preference, or invitational. The effect of each type of priority follows:

Absolute priority: Under an absolute priority we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority we give competitive preference to an application by either (1) awarding additional points, depending on how well or the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the priority a competitive or absolute preference over other applications (34 CFR 75.105(c)(1)).

Priority

Pilot Projects—Community Coaches for Elementary and Secondary Students

Projects that propose to develop and evaluate pilot programs that use community coaches in schools to help elementary or secondary or both students engage in structured service-learning projects that meet community needs. A "community coach" is a caring adult who offers guidance and support to young people and is committed to strengthening student community service. "Service learning" engages students in hands-on learning and helps them develop personal, civic, and academic skills through structured service projects that meet community needs.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Electronic Access to This Document

You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites:

http://ocfo.ed.gov/fedreg.htm
http://www.ed.gov/news.html

To use PDF, you must have Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at (888) 293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo.gov/nara/index.html

Program Authority: 20 U.S.C.8001.

(Catalog of Federal Domestic Assistance Number 84.215 Fund for the Improvement of Education Program)

Dated: January 16, 2001.

C. Kent McGuire,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 01–1761 Filed 1–17–01; 11:06 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA No. 84.335]

Child Care Access Means Parents In School Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2001

Purpose of Program: The Child Care Access Means Parents In School (CCAMPIS) Program supports the participation of low-income parents in postsecondary education through the provision of campus-based childcare services.

Eligible Applicants: Institutions of higher education that have a total amount of all Federal Pell Grant funds awarded to students enrolled at the institution of higher education for the preceding fiscal year that equals or exceeds $350,000.

Deadline for Transmittal of Applications: April 24, 2001.

Deadline for Intergovernmental Review: June 25, 2001.

Applications Available: February 23, 2001.

Available Funds: $20,000,000.

Estimated Range of Awards: $10,000–$300,000. An institution will be eligible for a maximum grant award equal to one (1) percent of its Federal Pell Grant disbursement with no grant being less than $10,000.

Estimated Average Size of Awards: $100,000.

Estimated Number of Awards: 150–200.

Project Period: 48 months.

Note: The Department is not bound by any estimates in this notice.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 85, 86, 97, 98 and 99.

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In preparing applications, applicants should pay particular attention to the requirements in section 427 of the General Education Provisions Act (GEPA), as detailed later in this notice. Applicants must address the requirements in section 427 in order to receive funding under this competition. Section 427 requires each applicant to describe the steps it proposes to take for addressing one or more barriers (i.e., gender, race, national origin, color, disability, or age) that can impede equitable access to, or participation in, the program. A restatement of compliance with civil rights requirements is not sufficient to meet the requirements in section 427 of GEPA. Because there are no program-specific regulations for the Child Care Access Means Parents In School Program, applicants are encouraged to read the authorizing statute in section 419N of the Higher Education Act of 1965, as amended (HEA).

Priority:

Competitive Priority: Under 34 CFR 75.105(c)(2)(i) and 20 U.S.C. 1070e(d) the Secretary gives preference to applications that meet the following competitive priority. The Secretary awards up to 10 points to an application that meets this competitive priority. These points are in addition to any points the application earns under the selection criteria:

Projects that leverage significant local or institutional resources, including in-kind contributions to support the activities, and use a sliding fee scale for childcare services provided by a facility assisted under this grant in order to support a high number of low-income parents pursuing postsecondary education at the institution.

Selection Criteria: In evaluating an application for a new grant under this competition, the Secretary uses selection criteria under 34 CFR 75.209 and 75.210 of EDGAR. The Secretary informs applicants in the application package of the selection criteria and factors, if any, to be used for this competition and of the maximum weight assigned to each criterion.

Page Limit: The application narrative (Part C of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We suggest you limit Part C to the equivalent of no more than 50 pages using the following standards:

- A "page" is 8.5" x 11" on one side only, with 1" margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, references, and captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12-point or larger or no smaller than 10 pitch (characters per inch).

The page limit does not apply to the cover sheet, the budget section, including the narrative budget justification, the assurances and certifications, the three-page abstract, the resumes, or the letters of support. However, you must include all of the application narrative in Part C.

Application Procedures:

Note: Some of the procedures in these instructions for transmitting applications differ from those in the Education Department General Administrative Regulations (EDGAR) (34 CFR 75.102). Under the Administrative Procedure Act (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments make procedural changes only and do not establish new substantive policy. Therefore, under 5 U.S.C. 553(b)(A), the Secretary has determined that proposed rulemaking is not required.

Pilot Project for Electronic Submission of Applications: The U.S. Department of Education is expanding its pilot project of electronic submission of applications to include certain formula grant programs, as well as additional discretionary grant competitions. The Child Care Access Means Parents In School (CCAMPIS) Program, CFDA No, 84.335, is one of the programs included in the pilot project. If you are an applicant under the CCAMPIS Program, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e=APPLICATION, formerly e-GAPS) portion of the Grant Administration and Payment System (GAPS). We request your participation in this pilot project. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in this e-APPLICATION pilot, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value or penalty because you submit a grant application in electronic or paper format.
- You can submit all documents electronically, including the Application for Federal Education Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Fax a signed copy of the Application for Federal Assistance (ED 424) after following these steps:

(1) Print ED 424 from the e-APPLICATION system.

(2) Make sure that the institution's authorizing representative signs this form.

(3) Before faxing this form, submit your electronic application via the e-APPLICATION system. You will receive an automatic acknowledgement, which will include a PR/Award number (an identifying number unique to your application).

(4) Place the PR/Award number in the upper right hand corner of the ED 424.

(5) Fax the ED 424 to the Application Control Center within three working days of submitting your electronic application. We will indicate a fax number in e-APPLICATION at the time of your submission.

We may request that you give us original signatures on all other forms at a later date.

You may access the electronic grant application for the CCAMPIS Program at: *http://e-grants.ed.gov*

We have included additional information about the e-APPLICATION pilot project (see Parity Guidelines between Paper and Electronic Applications) in the application package.

For Applications Contact: Education Publications Center (EDPUBS), P.O. Box 1398, Jessup, Maryland 20794–1398. Telephone (toll free) 1–877–433–7827. Fax: (301) 470–1244. If you use a telecommunications device for the deaf (TDD) you may call toll free 1–877–576–7734. You may also contact EDPUBS at its web site: *http://www.ed.gov/pubs/edpubs.html*. Or you may contact EDPUBS at its e-mail address: *edpubs@net.ed.gov*.

If you request an application from EDPUBS, be sure to identify this competition as follows: CFDA number 84.335.

For Application or Information Contact: Karen W. Johnson, U.S. Department of Education, 1990 K Street, NW, Suite 7018, Washington, DC 20006. Telephone: (202) 502–7525. Fax: CCAMPIS Program (202) 502–7864. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact person listed in the preceding paragraph. Individuals with disabilities may obtain a copy of the application package in an alternative format, also, by contacting that person. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

Electronic Access to This Document: You may view this document, as well as all other Department of Education documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at either of the following sites: *http://ocfo.ed.gov/fedreg.htm* and http://www.ed.gov/news.html. To use PDF, you must have the Adobe Acrobat Reader, which is available free at either of the previous sites. If you have questions about using the PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.access.gpo.gov/nara/index.html*.

Program Authority: 20 U.S.C. 1070e.

Dated: January 16, 2001.

Lee A. Fritschler,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 01–1680 Filed 1–19–01; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Notice of Availability of Funds and Request for Applications To Support Medical Surveillance for Former Department of Energy Workers at the Pantex Plant in Amarillo, Texas

AGENCY: Office of Environment, Safety and Health, DOE.

ACTION: Notice of availability of funds and request for applications.

SUMMARY: The Department of Energy (DOE) Office of Environment, Safety and Health (EH) announces the availability of funds to evaluate former workers whose employment at the Pantex Plant in Amarillo, Texas, may have placed their long-term health at significant risk. This Notice of Availability of Funds and Request for Applications to Support Medical Surveillance for Former DOE Workers at the Pantex Plant does not affect cooperative agreements awarded pursuant to similar **Federal Register** announcements published on March 1, 1996, and March 25, 1997.

DATES: Applications submitted in response to this announcement must be received by March 30, 2001.

ADDRESSES: U.S. Department of Energy, Office of Health Studies, EH–6/270CC, 19901 Germantown Road, Germantown, Maryland 20874–1290.

FOR FURTHER INFORMATION CONTACT: Requests for further information may be directed to Ms. Kathleen Taimi, Office of Health Studies (EH–6), telephone: (301) 903–0262. Applications may be submitted to Ms. Taimi at the address listed above. (For application forms, please contact Ms. Sue Anderson, Office of Health Studies, telephone: (301) 903–7030.)

SUPPLEMENTARY INFORMATION:

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I. Purpose
II. Project Description
III. DOE's Policy on Protection of Human Subjects Reviews
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V. Application Format
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I. Purpose

Section 3162 of the National Defense Authorization Act for Fiscal Year 1993 (Pub. Law 102–484) directs the Secretary of Energy, in consultation with the Secretary of Health and Human Services, to develop a program of medical evaluation for current and former DOE workers at significant risk for health problems due to exposures to hazardous or radioactive substances during employment. On March 1, 1996, the first "Notice of Availability of Funds and Request for Applications to Support Medical Surveillance for Former DOE Workers" was published in the **Federal Register** (61 FR 8047). In September 1996, the DOE Former Workers Program was implemented with the award of six cooperative agreements to begin projects at the following DOE sites: Hanford Site, Nevada Test Site, Rocky Flats Environmental Technology Site, Portsmouth Gaseous Diffusion Plant, Paducah Gaseous Diffusion Plant, and the Oak Ridge Reservation. At five of the sites, the project teams are focusing on a selected group or groups of former workers (e.g., production workers or construction workers). At the Rocky Flats Site, the project team has evaluated medical surveillance needs among all former workers.

On March 25, 1997, the second **Federal Register** Notice (62 FR 14123) announced the availability of additional funds for several new projects. In particular, DOE was interested in funding medical surveillance for former workers at major DOE sites not included in the first six projects. In September and December 1997, four new cooperative agreements were awarded to begin one project each at the Los Alamos National Laboratory and the Idaho Engineering and Environmental Laboratory, and two projects at the Savannah River Site. Currently, all ten projects in the DOE Former Workers Program are screening groups of former workers who are potentially at significant risk for health problems due to work-related exposures.

This third Notice announces the availability of funds for one new project to be funded through a cooperative agreement. DOE is interested in applications for a new project at the Pantex Plant in Amarillo, Texas. Former workers at this major DOE site are not included in any of the ongoing medical surveillance projects. DOE will accept applications only for a project at the Pantex Plant.

Experience with all of these projects will help DOE to evaluate needs and options for a long term medical surveillance program for former workers and to determine how such a program may be implemented and effectively integrated with other ongoing DOE activities.

II. Project Description

DOE intends to award one new cooperative agreement with specific goals identical to the goals of the ongoing projects. The goals of the DOE Former Workers Program projects are to:

- Identify groups of workers at significant risk for occupational diseases;
- Notify members of these risk groups; and
- Offer these workers medical screening that can lead to medical interventions.

The cooperative agreement will begin with a needs assessment, and continue with medical screening, if determined by DOE to be warranted. The needs assessment should provide the basis for identifying the group or groups of former Pantex workers who are potentially at significant risk for health problems due to work-related exposures. It is recommended that no group or groups of former workers be initially excluded from evaluation during the needs assessment. Applications that select only certain worker groups for evaluation, while excluding other former Pantex workers from the needs assessment process, must provide site-specific information that fully justifies such initial targeting.

Pursuant to this Notice, DOE intends to award one cooperative agreement

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awarded in the amount of approximately $400,000 to conduct a needs assessment and to prepare a detailed plan for medical screening. This is expected to take 8–10 months. The medical screening, if warranted, will be funded through annual continuation awards under the same cooperative agreement for up to 3 more years. The estimated annual funding expected to be available for medical screening is $790,000.

Needs Assessment

The awardee shall conduct a needs assessment that will include a review of existing site-specific information and other means to identify the most significant radiation and non-radiation exposures to former Pantex workers. During the needs assessment, the awardee shall conduct the following tasks:

1. Identify existing information relevant to exposure and health outcomes among former workers;
2. Utilize this information to identify or develop viable methods for contacting these former workers;
3. Provide an initial determination of the most significant worker hazards, problems and concerns at the Pantex Plant;
4. Identify approaches for conducting the project in partnership with unions, site management, operating contractors, community representatives, and State and local health officials; and
5. Attend semiannual DOE-coordinated meetings of investigators to share information on ongoing Former Worker Program projects.

The awardee shall prepare a draft needs assessment report that will document the need for medical surveillance of former Pantex workers and describe the targeted cohort(s) for which further evaluation and medical screening is recommended. The draft report also will: (1) Define the size of the former workers target population; (2) document the specific chemical, physical and/or radiological hazards and the degree of potential exposure (duration and magnitude); and (3) characterize the nature and extent of the health impacts that are anticipated.

In addition, based upon the findings of the needs assessment, the awardee shall develop a detailed proposed plan and budget for medical screening of the targeted worker cohort(s). The proposed medical screening plan should include the specific tasks described below.

The awardee shall submit the draft needs assessment and the proposed plan and budget for medical screening to DOE within 10 months from the award date. DOE will evaluate the draft needs assessment report and proposed plan and budget for medical screening. The draft needs assessment report will be finalized following review and comment by DOE. If warranted, DOE will approve and support the medical screening plan and budget through annual continuation awards.

Medical Screening

The awardee shall conduct the following specific tasks to implement the approved medical screening plan:

1. Identify and locate those former workers who, based on the results of the needs assessment, are at significant risk of adverse health effects;
2. Ascertain the health concerns of former workers identified in task 1 related to their past DOE employment;
3. Communicate risk information to former workers regarding the nature of their health risk and discuss the actions that could be taken;
4. Provide medical screening to targeted former worker populations based on exposure history and the availability of acceptable screening tests;
5. Assist in the coordination of referrals, diagnostic workup, and follow-up treatment, including the coordination with state and federal workers' compensation programs and other existing insurance and benefits programs;
6. Ensure dialogue with local parties concerned with the project;
7. Evaluate former workers' satisfaction with the project; and
8. Attend semiannual DOE-coordinated meetings to share information with other Former Worker Program projects.

III. DOE's Policy on Protection of Human Subjects Reviews

DOE has codified the Federal Policy for the Protection of Human Subjects in 10 CFR part 745. As defined in this regulation, human subjects research may include a broad range of studies. DOE has determined that former worker medical surveillance projects fall under the broad definition of human subjects research, and, accordingly, each project requires Institutional Review Board (IRB) review and approval. The IRB review and approval process will ensure adequate protection of workers' privacy and confidentiality during project activities such as the review and collection of identifiable private information and the handling of personal medical records.

It is the DOE's policy that any DOE-funded project involving DOE workers at a specific site must be reviewed and approved by that DOE site's IRB. The DOE site IRB review takes place following award of the new cooperative agreement, and annually thereafter. Since the Pantex Plant yet does not have an IRB established, the DOE Human Subjects Manager will designate another DOE site's IRB for the review and approval of this project. In addition, applicants may have to comply with their own institution's requirements regarding review of human subjects research. Documentation of all required IRB approvals must be submitted to DOE prior to implementation of any project activities that involve collection of personally identified data or contact with individual workers.

IV. Applications

This Notice of Availability is issued pursuant to DOE regulations contained in 10 CFR part 602: "Epidemiology and Other Health Studies Financial Assistance Program," as published in the **Federal Register** on January 31, 1995 (60 FR 5841). The Catalog of Federal Domestic Assistance number for 10 CFR part 602 is 81.108, and its solicitation control number is EOHSFAP 10 CFR part 602. 10 CFR part 602 contains the specific requirements for applications, evaluation, and selection criteria. Only those applications following these specific criteria and forms will be considered. Application forms may be obtained as noted above.

V. Application Format

The application shall contain two sections, technical scope of work and budget proposal. The technical scope of work shall be no more than fifty (50) pages in length; resumes of proposed key personnel should be submitted as an appendix to the technical scope of work and will not be counted against the page limit. Budget proposals have no page limit. Because the scope of medical screening will be dependent on the results of the needs assessment, the technical description of the proposed medical screening may be less specific than that for the needs assessment, but must clearly demonstrate a capability to conduct the medical screening. It is left to the applicant to determine how best to structure the application. However, the following information shall be included:

1. Applications shall include a detailed project description that discusses all of the specific tasks to be performed under the proposed project. At a minimum, the tasks listed above, in Section II, Project Description, must be described in detail for the needs assessment, and more generally for medical screening. The project description must include clear statements of what is not known and what is uncertain, as well as statements of what is known. The project description must describe how independent, external peer review of the project will be conducted. The project description must demonstrate that the applicant has the ability to integrate its work with the activities of any other organizations at the Pantex Plant, as appropriate.

2. Applications must demonstrate the competency of project personnel and the adequacy of resources. Applications must demonstrate that the applicant is perceived as neutral and credible, and is capable of conducting scientifically valid and responsible medical surveillance projects. Applications must demonstrate that the applicant has the experience and capability to plan, organize, manage, and facilitate worker and union participation in planning and execution. Applications must also demonstrate that the applicant has the experience and ability to effectively communicate complicated scientific information on potential risks and uncertainties to workers, local and national stakeholders, concerned citizens, and decision makers at all levels. Applications must demonstrate that the applicant presently has or is capable of obtaining staff with the training, expertise, and experience needed to conduct a scientifically complex needs assessment and medical screening program. Applications must identify the technical and scientific staff that will conduct the project and detail their professional experience, as well as their level of project involvement. Applications must demonstrate that the applicant has the capability for both financial and scientific management, and a demonstrated skill in planning and scheduling a project of comparable magnitude to that proposed under this Notice.

3. The budget proposal for the needs assessment must include a summary breakdown of all costs, and provide a detailed breakdown of costs on a task-by-task basis for each task contained in the project description. Costs for the medical screening tasks may be more general estimates since the initial award will support the preparation of a more detailed plan for the medical screening. For planning purposes, as noted above in Section II, Project Description, it is expected that annual funding in the amount of $790,000 will be available for medical screening for up to 3 years. Any expectation concerning cost sharing must be clearly stated. Cost sharing is encouraged, but it will not be considered in the selection process.

4. Budget proposals shall include an estimate of the costs for any project support work by DOE site contractors not routinely provided by DOE (see section VII, DOE's Role). Costs for DOE contractor work such as copying, filming, scanning, and/or abstracting site data, including charges associated with any needed computer programming of data, should be included in the proposed budgets for the needs assessment and the medical screening.

VI. Application Evaluation and Selection

Applications will be subjected to formal merit review (peer review) and will be evaluated against the following criteria listed in descending order of importance and codified at 10 CFR 602.9(d):

1. Scientific and technical merit of the proposed research;
2. Appropriateness of the proposed method or approach;
3. Competency of research personnel and adequacy of proposed resources; and
4. Reasonableness and appropriateness of the proposed budget.

Applications will be peer reviewed by evaluators apart from DOE employees and contractors as described in the Office of Environment, Safety and Health's Merit Review System (57 FR 55524, November 25, 1992) and at 10 CFR 602.9(c). Submission of an application constitutes agreement that this is acceptable to the applicant. DOE is under no obligation to pay for any costs associated with preparation or submission of an application, whether or not an award is made.

DOE reserves the right to fund, in whole or in part, one or none of the applications submitted in response to this solicitation.

VII. DOE's Role

In order for DOE to utilize a cooperative agreement for this project, there must be substantial involvement between DOE and the awardee. DOE established the specific tasks for this project and will conduct the selection and award process, which will include evaluations by persons outside the Federal Government. DOE will provide programmatic direction, policy guidance and oversight through continuous consultation and interaction with project investigators. DOE will evaluate the results of the needs assessment and, if warranted, will fund medical screening at the Pantex Plant. As outlined in DOE's "Access Handbook, Conducting Health Studies at Department of Energy Sites," DOE will facilitate access to the Pantex Plant, as appropriate, and help familiarize investigators with the facility and historical operations. DOE will facilitate access to exposure records, including the identification and retrieval of records relating to DOE activities, and declassification of records, as needed. DOE will establish requirements for data collection and reporting. DOE will coordinate the semiannual Former Worker Program meetings. DOE may establish an independent advisory group that will provide advice to DOE and to project investigators. Finally, DOE will monitor and evaluate the results of the project, including the worker participants' level of satisfaction. In addition to helping former workers at the Pantex Plant, information gained from this project will contribute to DOE's ongoing efforts to improve health and safety programs for current workers.

VIII. Applicants

Applicants for this cooperative agreement could include domestic nonprofit and for profit organizations, universities, medical centers, research institutions, other public and private organizations, including State and local governments, labor unions and other employee representative groups, and small, minority and/or women-owned businesses. Consortiums of interested organizations are strongly encouraged to apply. The awardees will work cooperatively with former workers, DOE site officials, DOE operating contractors, labor organizations, health officials, and designated community representatives.

Issued in Washington, DC, on January 11, 2001.

Paul J. Seligman,

Deputy Assistant Secretary for Health Studies.

[FR Doc. 01–1603 Filed 1–19–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Science; Office of Science Financial Assistance Program Notice 01–11: Scientific Discovery through Advanced Computing in High Energy and Nuclear Physics Research

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice inviting research grant applications.

SUMMARY: The Office of High Energy and Nuclear Physics (HENP) of the Office of Science (SC), U.S. Department of Energy (DOE), hereby announces its interest in receiving grant applications for the Department's Scientific Discovery

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through Advanced Computing Program (SciDAC). The goal of this program is to enable the use of terascale computers to dramatically extend our exploration of the fundamental processes of nature as well as to advance our ability to predict the behavior of a broad range of complex natural and engineered systems. This goal is to be achieved through the creation of scientific simulation codes that achieve high performance on a single node, scale to hundreds of nodes and thousands of processors, and have the potential to adapt over time and to be ported to future generations of high performance computers. Projects should address a problem of national scientific or engineering significance clearly related to the mission of DOE. They are expected to have high visibility and to present a long-term vision of how their work will fundamentally impact scientific discovery in specific areas of High Energy Physics or Nuclear Physics research.

The full text of Program Notice 01–11 is available via the Internet at the following web site address: *http://www.science.doe.gov/production/grants/grants.html*.

DATES: Preapplications referencing this program notice must be received by 4:30 P.M. EST, February 7, 2001. A response encouraging or discouraging the submission of a formal application will be communicated by E-mail within 14 days.

Formal applications submitted in response to this notice must be received no later than 4:30 P.M., March 15, 2001, to be accepted for merit review and consideration for award in Fiscal Year 2001.

ADDRESSES: Preapplications referencing Program Notice 01–11 should be forwarded to: U.S. Department of Energy, Office of Science, Office of High Energy and Nuclear Physics, SC–20, 19901 Germantown Road, Germantown, Maryland 20874–1290, ATTN: Peter Rosen. Preapplications can also be submitted via E-mail at the following E-mail address: peter.rosen@science.doe.gov.

Formal applications referencing Program Notice 01–11 should be forwarded to: U.S. Department of Energy, Office of Science, Grants and Contracts Division, SC–64, 19901 Germantown Road, Germantown, Maryland 20874–1290, ATTN: Program Notice 01–11. The above address must be used when submitting applications by U.S. Postal Service Express Mail, any commercial mail delivery service, or when hand-carried by the applicant. An original and seven copies of the application must be submitted.

FOR FURTHER INFORMATION CONTACT: Dr. S. Peter Rosen, Office of High Energy and Nuclear Physics, SC–20, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290, E-mail: peter.rosen@science.doe.gov.

SUPPLEMENTARY INFORMATION:

Background: Scientific Discovery Through Advanced Computing

Advanced scientific computing will be a key contributor to scientific research in the 21st Century. Within the Office of Science (SC), scientific computing programs and facilities are already essential to progress in many areas of research critical to the nation. Major scientific challenges exist in all SC research programs that can best be addressed through advances in scientific supercomputing, *e.g.*, designing materials with selected properties, elucidating the structure and function of proteins, understanding and controlling plasma turbulence, and designing new particle accelerators. To help ensure its missions are met, SC is bringing together advanced scientific computing and scientific research in an integrated program entitled "Scientific Discovery through Advanced Computing."

The Opportunity and the Challenge

Extraordinary advances in computing technology in the past decade have set the stage for a major advance in scientific computing. Within the next five to ten years, computers 1,000 times faster than today's computers will become available. These advances herald a new era in scientific computing. Using such computers, it will be possible to dramatically extend our exploration of the fundamental processes of nature (*e.g.*, the structure of matter from the most elementary particles to the building blocks of life) as well as advance our ability to predict the behavior of a broad range of complex natural and engineered systems (*e.g.*, the earth's climate or an automobile engine).

To exploit this opportunity, these computing advances must be translated into corresponding increases in the performance of the scientific codes used to model physical, chemical, and biological systems. This is a daunting problem. Current advances in computing technology are being driven by market forces in the commercial sector, not by scientific computing. Harnessing commercial computing technology for scientific research poses problems unlike those encountered in previous supercomputers, in magnitude as well as in kind. As noted in the 1998 report [1] from the NSF/DOE "National Workshop on Advanced Scientific Computing" and the 1999 report [2] from the President's Information Technology Advisory Committee, this problem will only be solved by increased investments in computer software—in research and development of scientific simulation codes as well as on the mathematical and computing systems software that underlie these codes.

Investment Plan of the Office of Science

To meet the challenge posed by the new generation of terascale computers, SC will fund a set of coordinated investments as outlined in its long-range plan for scientific computing, Scientific Discovery through Advanced Computing,[3] submitted to Congress on March 30, 2000. First, it will create a Scientific Computing Software Infrastructure that bridges the gap between the advanced computing technologies being developed by the computer industry and the scientific research programs sponsored by the Office of Science. Specifically, the SC effort proposes to:

- Create a new generation of Scientific Simulation Codes that take full advantage of the extraordinary computing capabilities of terascale computers.
- Create the Mathematical and Computing Systems Software to enable the Scientific Simulation Codes to effectively and efficiently use terascale computers.
- Create a Collaboratory Software Environment to enable geographically separated scientists to effectively work together as a team and to facilitate remote access to both facilities and data.

These activities are supported by a Scientific Computing Hardware Infrastructure that will be tailored to meet the needs of SC's research programs. The Hardware Infrastructure is robust, to provide the stable computing resources needed by the scientific applications; agile, to respond to innovative advances in computer technology that impact scientific computing; and flexible, to allow the most appropriate and economical resources to be used to solve each class of problems. Specifically, the SC proposes to support:

- A Flagship Computing Facility, the National Energy Research Scientific Computing Center (NERSC), to provide the robust, high-end computing resources needed by a broad range of scientific research programs.
- Topical Computing Facilities to provide computing resources tailored for specific scientific applications and to serve as the focal point for an application community as it strives to optimize its use of terascale computers.
- Experimental Computing Facilities to assess the promise of new computing technologies being developed by the computer industry for scientific applications.

Both sets of investments will create exciting opportunities for teams of researchers from laboratories and universities to create new revolutionary computing capabilities for scientific discovery.

The Benefits

The Scientific Computing Software Infrastructure, along with the upgrades to the hardware infrastructure, will enable laboratory and university researchers to solve the most challenging scientific problems faced by the Office of Science at a level of accuracy and detail never before achieved. These developments will have significant benefits to all of the government agencies that rely on high-performance scientific computing to achieve their mission goals as well as to the U.S. high-performance computing industry.

Background: Scientific Simulation in High Energy Physics and Nuclear Physics Research

The Office of High Energy and Nuclear Physics supports a program of research into the fundamental nature of matter and energy. In carrying out this mission it:

- Builds and operates large, world class charged-particle accelerator facilities for the nation and for the international scientific research community;
- Builds detectors and instruments, for accelerator and non-accelerator based experiments, designed to answer fundamental questions about the nature of matter and energy; and
- Carries out a program of scientific research based on experimental data, theoretical studies, and scientific simulation.

This solicitation is focused on proposals to accelerate progress through the use of scientific simulation codes.

Computational modeling and simulation are among the most significant developments in the practice of scientific inquiry in the 20th century. The coming advances in computing performance, if they can be realized for scientific problems, herald a new era in scientific computing. If computers capable of 100 teraflops or more become available in the next few years, it will be possible to dramatically extend our exploration of the fundamental processes of nature. It will also be possible to predict the behavior of a broad range of complex systems, such as charged-particle accelerator components, and eventually entire accelerators.

However, it is clear that the development of scientific codes that are capable of utilizing terascale computers efficiently and are adaptable, portable and re-usable is a massive undertaking that could take as long as 8–10 years to achieve its most ambitious scientific goals. This may require efforts of hundreds of person-years of work.

It is also apparent that the most appropriate, cost-effective computing resources for scientific simulations vary significantly from application to application. Therefore, much work is needed to understand the optimal configuration of computing hardware for each task and to design operating environments best able to foster significant scientific discoveries.

This solicitation is for proposals that articulate the long-term vision and potential for scientific progress through simulation, whilst laying out a concrete step-wise program of work and scientific research for the next 3 to 5 years.

The scope and complexity of the proposed projects will require close collaboration among researchers from computational and theoretical physics, computer science, and applied mathematics disciplines. Accordingly, this solicitation calls for the creation of scientific simulation teams, or collaborations, as the organizational basis for a successful application. A scientific simulation team is a multi-institutional, multi-disciplinary group of people who will:

- Create scientific simulation codes that take full advantage of terascale computers,
- Work closely with other SciDAC teams and centers to ensure that the best available mathematical algorithms and computer science methods are employed, and
- Manage the work of the team in a way that will foster good communication and decision making (see section on Collaboration and Coordination below).

Partnerships among universities, national laboratories, and industry are encouraged. Applications are being sought in the broad topical areas listed below.

Accelerator Science and Simulation

The successful development of large accelerator facilities involves enormous investments in theory, experiment and simulation. Optimizing the performance of current accelerators and the design of future accelerators will require unprecedented precision in accelerator component design and beam dynamics and control. Applicants should explain how the proposed program of work will facilitate important design decisions, increase safety and reliability, optimize performance and reduce the cost of accelerators.

The development of a comprehensive, coherent terascale simulation environment for the U.S. particle accelerator community will involve development of new computational models and codes, mathematical models, program frameworks and visualization techniques. The scientific software, while making good use of existing codes for (a) calculations for the design of complex electromagnetic components and systems and (b) beam dynamics calculations for predicting beam halo, must provide high performance on terascale computers and be capable of scaling to 100 teraflops or more. New codes will need to be developed for problems, such as electromagnetic modeling of lossy structures and wakefields, parallel static computation for electric and magnetic component design, and parallel modeling of intense beams in injectors, linear and circular machines. Models need to be developed to include a range of physical phenomena such as collisions, synchrotron radiation, and surface emissions. In order to simulate accelerator components and entire accelerators, the scientific simulation codes will need to work together to carry out simulations of complex systems involving tight coupling of beam dynamics and electromagnetics.

Collaborative work with Fusion Energy Scientists may also be useful since there are some common problems related to modeling electromagnetic fields and beam dynamics.

Theoretical Research

In the past few years, several areas of theoretical research have demonstrated

[1] This workshop was sponsored by the National Science Foundation and the Department of Energy and hosted by the National Academy of Sciences on July 30–31, 1998. Copies of the report may be obtained from: http://www.er.doe.gov/production/octr/mics/index.html

[2] Copies of the PITAC report may be obtained from http://www.ccic.gov/ac/report/.

[3] Copies of the SC computing plan, Scientific Discovery through Advanced Computing, can be downloaded from the SC web site at: http://www.sc.doe.gov/production/octr/index.html.

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the potential to further scientific knowledge by efficiently using scientific simulation codes on terascale computers to:

• Provide a major quantitative tool for simulations of quantum chromodynamics (QCD) on a lattice, which will:

(a) Provide crucial information in support of the experimental programs in high energy and nuclear physics.

(b) Make accurate determinations of a number of fundamental quantities, such as the coupling constant that determines the strength of quark-gluon interactions, and the underlying masses of the quarks.

(c) Explore the limitations, if any, of the "Standard Model" of particle interactions.

(d) Explore how quarks and gluons provide the binding and spin of the nucleon.

• Develop theoretical models of complex systems under extreme conditions, such as:

(a) Exploration of complex theoretical models of supernovae and comparison of the predictions with experimental results.

(b) Study of the behavior of supersymmetric and other quantum field theories.

Particular areas of interest include, but are not limited to:

Quantum Chromodynamics (QCD)

The development of a coherent terascale simulation environment for the study of QCD that will permit evolution of scientific codes to take advantage of 100 teraflop computers is a challenging problem. It demands a coordinated effort to provide the computer software infrastructure, the detailed scientific codes and algorithms, together with effective ways of using computing hardware now and in the future.

Simulations of Complex Nuclear Structure, Such as Found in Core-Collapse Supernovae

The development of a comprehensive model that brings together nuclear physics, particle physics, fluid dynamics, radiation transport, and general relativity is an equally challenging problem. Data from next-generation neutrino detectors, gravitational wave observatories, ground and space-based observatories, new radioactive beam facilities, and other experimental facilities will provide opportunities to evaluate and refine the many underlying physical models in the simulation.

Testbeds and Collaboratory Software Environments

Collaboratories link geographically dispersed researchers, data and tools, via high performance networks, to enable remote access to facilities, access to large datasets and shared environments. They enable geographically separated scientists to effectively work together as a team and facilitate remote access to both computing facilities and data.

As the size and complexity of high energy and nuclear physics experiments has increased so have the number and geographical dispersion of the researchers and the amount of data that must be collected, simulated and analyzed. Thus future experiments critically depend on the existence of such distributed hardware and software environments for their success. The scientific simulation applications that are the focus of this solicitation will also consist of geographically dispersed researchers, and will require high performance networks, to enable remote access to computing facilities, and multi-terabyte datasets.

Proposals for testbeds and collaborations across organizations that include network researchers, middleware developers and high energy and nuclear physicists are encouraged. However, they should be submitted in response to Notice 01–06 of the Office of Advanced Scientific Computing Research (ASCR). Copies should also be submitted to the Office of High Energy and Nuclear Physics, and joint funding can be considered.

Collaboration and Coordination

It is expected that all applications submitted in response to this notice will be for scientific simulation teams involving more than one institution. Applications from different institutions, directed at a common research activity, must include a common technical description of the overall research project. Each participating institution must have a qualified principal investigator, who is responsible for the part of the effort at that institution, and separate face pages and budget pages for each institution. The distinct scope of work proposed for each institution must be clearly specified. Any work proposed in computer science or applied mathematics should also be described separately. Applicants should include cost sharing whenever feasible. Synergistic collaborations with researchers in federal laboratories and Federally Funded Research and Development Centers (FFRDCs), including the DOE National Laboratories are encouraged, although funds will not be provided to these organizations under this particular Notice. Further information on preparation of collaborative proposals is available in the Application Guide for the Office of Science Financial Assistance Program that is available via the Internet at: *http://www.science.doe.gov/production/grants/Colab.html*.

Preapplications

Potential applicants are strongly encouraged, but not required, to submit a brief preapplication consisting of two or three pages of narrative describing the research objectives, technical approaches and management plan. Each preapplication should include a cover sheet with the title of the project, project principal investigator, institutions involved, and their principal investigators and senior personnel. The name, telephone number, and e-mail address of each principal investigator should also be provided. In addition, brief, one-page curriculum vitae should be submitted for the principal investigators and other senior personnel involved. Preapplications will be evaluated to assess their programmatic relevance, and a response will be provided to the principal investigator within 14 days of receipt. However, notification of a successful preapplication is not an indication that an award will be made in response to a formal application.

Program Funding

Up to $2,500,000 of Fiscal Year 2001 funding will be available for grant awards in FY 2001. Additional funding for each proposed project may be available through the Office of Advanced Scientific Computing Research for closely related research in computer science and/or applied mathematics. Applications may request support for up to three years, with out-year support contingent on the availability of funds and satisfactory progress. To support multi-disciplinary, multi-institutional efforts, funding levels of up to $1.0 million per project may be requested, under this notice, for the first year of the project. Requests for increased funding levels in future years will be entertained subject to availability of funds, progress of the funded activity, and programmatic needs.

As required by the SC Grant Application Guide, applicants must submit their budgets using the Budget Page (DOE Form 4620.1) with one Budget Page for each year of requested funding. The requested funding for the proposed work in computer science and applied mathematics should be included with the other project costs on the Budget Page. However, applicants are also requested to list the proposed computer science and applied mathematics costs separately in an appendix, as the Office of Advanced Scientific Computing Research may support this part of the work (up to 20–25% of the total project cost). The Office of High Energy and Nuclear Physics expects to fund three or four successful projects, depending on the size of the awards.

Evaluation Criteria

Applications will be subjected to scientific merit review (peer review) and will be evaluated against the following criteria listed in descending order of importance as codified in 10 CFR 605.10(d) (www.science.doe.gov/production/grants/605index.html):

1. Scientific and/or technical merit of the project,
2. Appropriateness of the proposed method or approach,
3. Competency of the applicant's personnel and adequacy of the proposed resources,
4. Reasonableness and appropriateness of the proposed budget.

The evaluation of applications under item 1, Scientific and Technical Merit, will pay particular attention to:

(a) the potential of the proposed project to achieve a major advance in high energy and/or nuclear physics;

(b) the potential of the proposed project to advance the state-of-the-art in computational modeling and simulation in areas pertinent to high energy and nuclear physics research;

(c) the need for extraordinary computing resources to address problems of critical scientific importance to the high energy physics or nuclear physics program and the demonstrated abilities of the applicants to exploit terascale computers;

(d) knowledge of and coupling to previous efforts in scientific simulation;

(e) the extent to which the project incorporates broad community (industry/academia/other federal programs) interaction;

(f) the extent to which the results of the project are likely to be extensible to other program or discipline areas; and

(g) the importance of the proposed project to the mission of the Office of High Energy and Nuclear Physics and its impact on overall DOE goals.

The evaluation under item 2, Appropriateness of the Proposed Method or Approach, will also consider the following elements related to appropriateness of the proposed Scientific Computing Hardware Infrastructure to be used and of the quality of planning:

(a) Viability of the plan with respect to the scale and nature of current and future Computing Hardware Infrastructure needed;

(b) clarity of the plan in detailing areas of work to be addressed by discipline scientists, computational scientists, applied mathematicians, computer scientists and computer programmers;

(c) quality of the plan for effective collaboration among participants;

(d) quality of the plan for ensuring communication with other advanced computation and simulation efforts;

(e) viability of the plan for deploying the software and for assuring long-term maintenance, support, and re-use of the scientific codes and software infrastructure developed;

(f) viability of the plan for verifying and validating the models developed, including verification using experiment results; and

(g) quality and clarity of the proposed work schedule and project deliverables.

The evaluation will include program policy factors such as the relevance of the proposed research to the terms of the announcement and the agency's programmatic needs.

Note, that external peer reviewers are selected with regard to both their scientific expertise and the absence of conflict-of-interest issues. Non-federal reviewers may be used, and submission of an application constitutes agreement that this is acceptable to the investigator(s) and the submitting institution.

General information about development and submission of applications, eligibility, limitations, evaluations and selection processes, and other policies and procedures may be found in the Application Guide for the Office of Science (SC) Financial Assistance Program and in 10 CFR part 605. Electronic access to SC's Financial Assistance Guide and required forms is made available via the Internet using the following Web site address: *http://www.science.doe.gov/production/grants/grants.html*.

In addition, for this notice, project descriptions must be 25 pages or less, including tables and figures, but excluding attachments. The application must also contain an abstract or project summary, letters of intent from all non-funded collaborators, and short curriculum vitae of all senior personnel. On the SC grant Face Page (DOE Form 4650.2), in block 15, also provide the Principal Investigator's phone number, FAX number, and E-mail address.

The Catalog of Federal Domestic Assistance Number for this program is 81.049, and the solicitation control number is ERFAP 10 CFR Part 605.

Issued in Washington DC on January 10, 2001.

John Rodney Clark,

Associate Director of Science for Resource Management.

[FR Doc. 01–1782 Filed 1–19–01; 8:45 am]

BILLING CODE 6450–01–U

DEPARTMENT OF ENERGY

Office of Science; Basic Energy Sciences Advisory Committee Renewal

Pursuant to Section 14(a)(2)(A) of the Federal Advisory Committee Act and in accordance with title 41 of the Code of Federal Regulations, Section 101–6.1015, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Basic Energy Sciences Advisory Committee has been renewed for a two-year period beginning in January 2001. The Committee will provide advice to the Director, Office of Science, on the basic energy sciences program.

The Secretary has determined that the renewal of the Basic Energy Sciences Advisory Committee is essential to the conduct of the Department's business and in the public interest in connection with performance of duties imposed upon the Department of Energy by law. The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, the Department of Energy Organization Act (Public Law 99–91), and rules and regulations issued in implementation of those Acts.

Further information regarding this advisory committee can be obtained from Rachel Samuel at (202) 586–3279.

Issued in Washington, DC, on January 16, 2001.

James N. Solit,

Advisory Committee Management Officer.

[FR Doc. 01–1692 Filed 1–19–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Fernald

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Fernald. The Federal

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Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Monday, February 5, 2001 6:00 p.m.–8:30 p.m.

ADDRESSES: Fernald Environmental Management Project Site, Services Building Conference Room, 7400 Willey Road, Hamilton, OH 45219.

FOR FURTHER INFORMATION CONTACT: Lois Yasutis, Phoenix Environmental, 6186 Old Franconia Road, Alexandria, VA 22310, at (703) 971–0030 or e-mail; *lyasutis@theperspectivesgroup.com.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda:

6:00 p.m. Call to Order
6:00–6:15 p.m. Chair's Remarks and Announcements
6:15–8:15 p.m. Presentation and Discussion of Rebaselining Scenarios
8:15–8:30 p.m. Public Comment
8:30 p.m Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Board chair either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact the Board chair at the address or telephone number listed below. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer, Gary Stegner, Public Affairs Office, Ohio Field Office, U.S. Department of Energy, is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC, 20585 between 9:00 a.m. and 4:00 p.m., Monday–Friday, except Federal holidays. Minutes will also be available by writing to the Fernald Citizens' Advisory Board, c/o Phoenix Environmental Corporation, MS–76, Post Office Box 538704, Cincinnati, OH 43253–8704, or by calling the Advisory Board at (513) 648–6478.

Issued at Washington, DC on January 1, 2001.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 01–1694 Filed 1–19–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Science; High Energy Physics Advisory Panel Renewal

AGENCY: Department of Energy.

ACTION: Notice of renewal.

SUMMARY: Pursuant to Section 14(a)(2)(A) of the Federal Advisory Committee Act, App. 2, and section 101–6.1015(a)(1), title 41, Code of Federal Regulations and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the High Energy Physics Advisory Panel has been renewed for a two-year period, and joint ownership has been instituted for the Department of Energy and National Science Foundation (NSF) beginning in January 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Rachel M. Samuel at (202) 586–3279.

SUPPLEMENTARY INFORMATION: The Panel will provide advice to the Director of the Office of Science (DOE), and the Assistant Director, Mathematical & Physical Sciences Directorate (NSE), on long-range planning and priorities in the national high-energy physics program. The Secretary of Energy and Director of the National Science Foundation have determined that renewal of the Panel is essential to conduct business of the Department of Energy and the National Science Foundation and is in the public interest in connection with the performance of duties imposed by law upon the Department of Energy and the National Science Foundation. The Panel will continue to operate in accordance with the provisions of the Federal Advisory Committee Act (Pub. L. No. 92–463), the General Services Administration Final Rule on Federal Advisory Committee Management, and other directives and instructions issued in implementation of those acts.

Issued in Washington DC on January 16, 2001.

James N. Solit,

Advisory Committee Management Officer.

[FR Doc. 01–1693 Filed 1–19–01; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–691–000]

Duke Energy Hinds, LLC; Notice of Issuance of Order

Duke Energy Hinds, LLC (Duke Hinds) submitted for filing a rate schedule under which Duke Hinds will engage in wholesale electric power and energy transactions at market-based rates. Duke Hinds also requested waiver of various Commission regulations. In particular, Duke Hinds requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Duke Hinds.

On January 9, 2001, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Duke Hinds should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Duke Hinds is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security or another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Duke Hinds's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 8, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.* (call 202–208–2222 for assistance).

David P. Boerger,

Secretary.

[FR Doc. 01–1580 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–65–000]

Eastern Shore Natural Gas Company; Notice of Application

January 16, 2001.

Take notice that on January 11, 2001, Eastern Shore Natural Gas Company (Eastern Shore), Post Office Box 1769, Dover, Delaware 19903–1769, filed in Docket No. CP01–59–000 an application pursuant to Section 7(c) of the Natural Gas Act for authorization to construct and operate additional pipeline and compression facilities in Maryland and Pennsylvania to expand its system by providing added transportation capacity, all as more fully set forth in the application on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us/online/htm* (call 202–208–2222 for assistance).

Eastern Shore proposes to construct and operate 6 miles of 16-inch pipeline looping on its existing system in Maryland and Pennsylvania to install 3,330 horsepower of additional capacity at the existing Daleville Compressor Station on Eastern Shore's system in Chester County, Pennsylvania, and to install delivery point facilities in Chester County, Pennsylvania. It is stated that the proposed construction would enable Eastern Shore to provide 19,800 dt equivalent of additional daily firm service capacity on its system. Eastern Shore estimates the total cost of the proposed facilities at $12,478,745. It is requested that a certificate be issued allowing construction to be completed by November 1, 2001.

Eastern Shore asserts that the facilities would provide system-wide benefits without requiring a rate increase for existing customers. Therefore, Eastern Shore requests a determination that the cost of the project be given rolled-in rate treatment. Eastern Shore convened an open season for the additional capacity and secured 10-year firm contracts with PECO Energy Company, Connectiv Power Delivery, and Delaware Division of Chesapeake Utilities Corporation for the additional capacity.

Any questions regarding the application should be directed to Stephen C. Thompson, President, Eastern Shore Natural Gas Company, 417 Bank Lane, Dover, Delaware 19904, (302) 734–6710.

Any person desiring to be heard or to make any protest with reference to said application should on or before February 6, 2001, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Comments and protests may be filed electronically in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's website at http://ferc.fed.us/efi/doorbell.htm.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Eastern Shore to appear or be requested at the hearing.

David P. Boergers,

Secretary.

[FR Doc. 01–1754 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–574–000]

Hunlock Creek Energy Ventures; Notice of Issuance of Order

January 12, 2001.

Hunlock Creek Energy Ventures (Hunlock) submitted for filing a rate schedule under which Hunlock will engage in wholesale electric power and energy transactions at market-based rates. Hunlock also requested waiver of various Commission regulations. In particular, Hunlock requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Hunlock.

On January 9, 2001, pursuant to delegated authority, the director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Hunlock should file a motion to intervene or protest with the

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Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Hunlock is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Hunlock's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 8, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1582 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–480–000 and ER01–480–001]

Mobile Energy, LLC; Notice of Issuance of Order

January 12, 2001.

Mobile Energy, LLC (Mobile) submitted for filing a rate schedule under which Mobile will engage in wholesale electric power and energy transactions at market-based rates. Mobile also requested waiver of various Commission regulations. In particular, Mobile requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Mobile.

On January 10, 2001, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Mobile should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Mobile is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Mobile's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is February 9, 2001.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1581 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–52–000]

Raton Gas Transmission Company; Notice of Filing

January 12, 2001.

Take notice that on December 18, 2000, pursuant to Section 7(c) of the Natural Gas Act, 15 U.S.C. 717f(c), and Part 157 of the Federal Energy Regulatory Commission's (Commission) Regulations, Raton Gas Transmission Company (Raton) filed an abbreviated application for an amendment to its certificate of public convenience and necessity.

Raton requests that the Commission amend Raton's present certificate, and authorize Raton to transport natural gas on behalf of Zia Natural Gas Company, Raton Natural Gas Company and the City of Las Vegas, New Mexico.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.211 or 385.214 of the Commission's Rules and Regulations. All such motions or protests must be filed on or before February 2, 2001. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

David P. Boergers,

Secretary.

[FR Doc. 01–1579 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EC01–35, et al.]

Riverside Canal Power Company, et al.; Electric Rate and Corporate Regulation Filings

January 12, 2001.

Take notice that the following filings have been made with the Commission:

1. Riverside Canal Power Company

[Docket No. EC01–35–000]

Take notice that on January 10, 2001, Riverside Canal Power Company (Riverside) tendered for filing, pursuant to section 203 of the Federal Power Act, supplemental information for its application for authority to lease certain jurisdictional facilities to Southern California Edison Company for the periods of August 15, 2000 to October 30, 2000 and from June 1, 2001 through October 31, 2001.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

2. Enron North America Corp., Brownsville Power I, L.L.C., Caledonia Power I, L.L.C., and Cinergy Capital & Trading, Inc.

[Docket No. EC01–53–000]

Take notice that on January 10, 2001, Enron North America Corp. (ENA), on behalf of two wholly-owned subsidiaries, (Brownsville Power I, L.L.C. (Brownsville) and Caledonia Power I, L.L.C. (Caledonia)), and Cinergy Capital & Trading, Inc. (CCT) tendered for filing an application requesting all necessary authorizations under section 203 of the Federal Power Act for ENA to sell, and for CCT to purchase, securities evidencing one hundred percent (100%) ownership interests in Brownsville and Caledonia.

Comment date: January 31, 2001, in accordance with Standard Paragraph E at the end of this notice.

3. Citizens Utilities Company

[Docket Nos. ER95–1586–007; EL96–17–000; OA96–184–000]

Take notice that on January 3, 2001, in compliance with the Commission's letter order of November 13, 1997 approving the September 12, 1997 Settlement Agreement in the above-referenced proceedings, Citizens Communications Company (CCC), formerly known as Citizens Utilities Company, filed its Second Refunds Compliance Report.

A copy of this filing was served on the service list in the above-referenced dockets. In addition, a copy is available for inspection at the offices of CCC's Vermont Electric Division during regular business hours.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

4. Citizens Utilities Company

[Docket Nos. ER95–1586–008; EL96–17–003; OA96–184–005]

Take notice that on January 3, 2001, in compliance with the terms of the September 12, 1997 Settlement Agreement in the above-referenced proceedings, as amended, Citizens Communications Company (CCC), formerly known as Citizens Utilities Company, filed certain tariff and rate schedule sheets with respect to its Vermont Electric Division's open access transmission tariff (CCC's FERC Electric Tariff Original Volume No. 2), and Rate Schedule FERC No. 28. To comply with the terms of the Settlement Agreement, CCC requests an effective date of January 3, 2001 for these tariff and rate schedule sheets.

A copy of this filing was served on the service list in the above-referenced proceedings. In addition, a copy is available for inspection at the offices of CCC's Vermont Electric Division during regular business hours.

Comment date: January 24, 2001, in accordance with Standard Paragraph E at the end of this notice.

5. Citizens Utilities Company

[Docket Nos. ER95–1586–009; EL96–17–000; OA96–184–000]

Take notice that on January 5, 2001, Citizens Communications Company (CCC), formerly known as Citizens Utilities Company, filed a supplement to the Second Refunds Compliance Report, which CCC filed with the Commission on January 3, 2001.

A copy of this filing was served on the service list in the above-referenced proceedings. In addition, a copy is available for inspection at the offices of CCC's Vermont Electric Division during regular business hours.

Comment date: January 26, 2001, in accordance with Standard Paragraph E at the end of this notice.

6. Entergy Services, Inc.

[Docket No. ER01–475–001]

Take notice that on January 8, 2000, Entergy Services, Inc. (Entergy), on behalf of Entergy Mississippi, Inc., tendered for filing in this docket a supplement to its November 17, 2000 filing of the First Revised Interconnection Agreement with Southaven Power LLC. Entergy states that the filing consists of a revised blackline version of the First Revised Interconnection Agreement that reflects the changes to the agreement resulting from that filing.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

7. Williams Energy Marketing & Trading Company

[Docket No. ER01–911–000]

Take notice that on January 8, 2001, Williams Energy Marketing & Trading Company (Williams EM&T) tendered for filing pursuant to Section 205 of the Federal Power Act (FPA), 16 U.S.C. 824d (1994), and part 35 of the Commission's Regulations, 18 CFR part 35, revised pages to the Reliability Must-Run Service Agreements (RMR Agreements) between Williams EM&T and the California Independent System Operator Corporation (ISO) for certain RMR units located at the Alamitos, Huntington Beach, and Redondo Beach Generating Stations.

The purpose of the filing is to update Williams EM&T's existing RMR Agreements to reflect an extension of two of the three existing RMR Agreements, a change in units under those agreements, and certain annual updates to Schedules A, B, C, D, F and J of the RMR Agreements.

Williams EM&T requests waiver of the prior notice requirements of Section 35.3 of the Commission's regulations, 18 CFR 35.3, to permit its revised RMR Agreements to become effective as of January 1, 2001.

Copies of the filing were served upon the ISO and Southern California Edison Company.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

8. Central Maine Power Company

[Docket No. ER01–912–000]

Take notice that on January 8, 2001, Central Maine Power Company (CMP) submitted for filing a "Transmission and Distribution Separation Filing," in order to separate CMP's overall transmission and distribution requirement into its components. The Maine Public Utility Commission has approved this transmission and distribution split pursuant to Order No. 888's seven-factor test.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

9. Entergy Services, Inc.

[Docket No. ER01–913–000]

Take notice that on January 8, 2001, Entergy Services, Inc., on behalf of Entergy Arkansas, Inc., Entergy Gulf States, Inc., Entergy Louisiana, Inc., Entergy Mississippi, Inc., and Entergy New Orleans, Inc., (collectively, the Entergy Operating Companies) tendered for filing a Non-Firm Point-To-Point Transmission Service Agreement and a Short-Term Firm Point-To-Point Transmission Service Agreement both between Entergy Services, Inc., as agent for the Entergy Operating Companies, and Transmission Management Services, L.L.C.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

10. Commonwealth Edison Company

[Docket No. ER01–914–000]

Take notice that on January 8, 2001, Commonwealth Edison Company (ComEd) submitted for filing an executed Dynamic Scheduling Agreement (Agreement) with its

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Wholesale Merchant Function Division (WMD) under ComEd's Open Access Transmission Tariff (OATT). The Agreement provides the necessary arrangements for Dynamic Scheduling under a Service Agreement for 35 MW of point-to-point transmission service from ComEd to AEP to service a load connected to the AEP system for the period January 1, 2001 to December 31, 2001.

ComEd requests an effective date of January 1, 2001.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

11. CPN Pleasant Hill, LLC and CPN Pleasant Hill Operating, LLC

[Docket No. ER01–915–000]

Take notice that on January 8, 2001, CPN Pleasant Hill, LLC (CPN), and CPN Pleasant Hill Operating LLC (CPN Operating) tendered for filing proposed market-based rate schedules and under which CPN and CPN Operating will make wholesale sales of electric energy, capacity, and ancillary services at market-based rates. In addition, CPN Operating submits for filing under section 205 of the Federal Power Act two power sales agreements.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

12. Arizona Public Service Company

[Docket No. ER01–916–000]

Notice of Filing: Take notice that on January 9, 2001, Arizona Public Service Company (APS) tendered for filing Service Agreements to provide Long-Term Firm Point-to-Point Transmission Service to Public Service Company of New Mexico, Wholesale Power Marketing under APS" Open Access Transmission Tariff.

A copy of this filing has been served Public Service Company of New Mexico, Wholesale Power Marketing, and the Arizona Corporation Commission.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

13. Arizona Public Service Company

[Docket No. ER01–917–000]

Take notice that on January 9, 2001, Arizona Public Service Company (APS) tendered for filing a Generator Interconnection Facilities Construction Agreement that sets forth an arrangement under which APS will construct, own, and operate interconnection facilities for Panda Gila River, L.P. The interconnection facilities are necessary to deliver power from Panda's proposed generating facility.

A copy of this filing has been served on the Arizona Corporation Commission and Panda Gila River, L.P.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

14. Arizona Public Service Company and Arizona Electric Power Cooperative, Inc.

[Docket No. ER01–918–000]

Take notice that January 9, 2001, Arizona Public Service Company (APS) and Arizona Electric Power Cooperative, Inc. filed a Notice of Cancellation of APS–FPC Rate Schedule No. 62.

Copies of the filing have been sent to AEPCO and the Arizona Corporation Commission.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

15. Engage Energy America, LLC.

[Docket No. ER01–919–000]

Take notice that on January 9, 2001, Engage Energy America LLC. submitted a Notice of Succession pursuant to 18 CFR 35.16 and 131.51 of the Commission's regulations. Engage Energy America Corp (WGSI Delaware) has changed its name to Engage Energy America LLC. and effective December 29, 2000, succeeded to Engage Energy America Corp."s First Revised Rate Schedule FERC No. 1, Market-Based Rate Schedule filed in Docket No. ER01–251–000, which was effective October 27, 2000.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

16. Northern Indiana Public Service Company

[Docket No. ER01–920–000]

Take notice that on January 9, 2001, Northern Indiana Public Service Company tendered for filing an executed Standard Transmission Service Agreement for Non-Firm Point-to-Point Transmission Service between Northern Indiana Public Service Company and Engage Energy America Corporation (EEAC).

Under the Transmission Service Agreement, Northern Indiana Public Service Company will provide Point-to-Point Transmission Service to EEAC pursuant to the Transmission Service Tariff filed by Northern Indiana Public Service Company in Docket No. OA96–47–000 and allowed to become effective by the Commission.

Northern Indiana Public Service Company has requested that the Service Agreement be allowed to become effective as of January 10, 2001.

Copies of this filing have been sent to Engage Energy America Corporation, the Indiana Utility Regulatory Commission, and the Indiana Office of Utility Consumer Counselor.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

17. Commonwealth Edison Company

[Docket No. ER01–921–000]

Take notice that on January 9, 2001, Commonwealth Edison Company (ComEd) tendered for filing a MBR Sales Agreement with NewEnergy Midwest, LLC as a customer under ComEd's FERC Electric Market Based-Rate Schedule for power sales.

ComEd requests an effective date of December 20, 2000 for the agreement and accordingly seeks waiver of the Commission's notice requirements.

Copies of the filing were served on NewEnergy Midwest, LLC.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

18. Westcoast Power Marketing Inc.

[Docket No. ER01–922–000]

Take notice that on January 9, 2001, Westcoast Power Marketing Inc. (Westcoast Power), Canada Trust Tower, 1100, 421–7th Avenue, SW. Calgary, Alberta, Canada T2P 4K9 filed in Docket No. ER95–378 pursuant to 18 CFR 35.13 and 131.53 of the Federal Energy Regulatory Commission's Rules and Regulations, a Notice of Cancellation to become effective January 10, 2001.

Westcoast Power states that it has never entered into any wholesale electric power or energy transactions, and has never utilized its Electric Rate Schedule FERC No. 1.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

19. Southern California Edison Company

[Docket No. ER01–923–000]

Take notice, that on January 9, 2001, Southern California Edison Company (SCE) tendered for filing the SCE–CDWR Cherry Valley, Crafton Hills and Greenspot Pumping Stations Interconnection Facilities Agreement (Agreement) between SCE and the State of California Department of Water Resources (CDWR).

Copies of this filing were served upon the Public Utilities Commission of the State of California and the State of California Department of Water Resources.

Comment date: January 30, 2001, in accordance with Standard Paragraph E at the end of this notice.

20. Florida Keys Electric Cooperative Association, Inc.

[Docket No. ES01–15–000]

Take notice that on January 5, 2001, Florida Keys Electric Cooperative Association, Inc. (Florida Keys) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to issue short-term promissory notes in an amount not to exceed $8.7 million.

Florida Keys also requests a waiver of the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

Comment date: February 2, 2001, in accordance with Standard Paragraph E at the end of this notice.

21. Ogden Martin Systems of Fairfax, Inc.

[Docket No. ES01–16–000]

Take notice that on January 8, 2001, Ogden Martin Systems of Fairfax, Inc. submitted an application pursuant to section 204 of the Federal Power Act seeking a blanket authorization to issue securities and debt.

Comment date: January 29, 2001, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the Comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of these filings are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at http://www.ferc.fed.us/ online/rims.htm (call 202–208–2222 for assistance).

David P. Boergers,

Secretary.

[FR Doc. 01–1781 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL00–95–000, EL00–95–002, EL00–95–003, EL00–98–000, EL00–98–002, EL00–98–003, EL00–107–000, EL00–97–000, EL00–104–000, EL01–1–000, EL01–27–000 and EL01–10–000]

San Diego Gas & Electric Company, v. Sellers of Energy and Ancillary Services into Markets Operated by the California Independent System Operator and the California Power Exchange, Respondents; Investigation of Practices of the California Independent System Operator and the California Power Exchange; Public Meeting in San Diego, California; Reliant Energy Power Generation, Inc., Dynegy Power Marketing, Inc., and Southern Energy California, L.L.C., Complainants, v. California Independent System Operator Corporation, Respondent; California Electricity Oversight Board, Complainant, v. All Sellers of Energy and Ancillary Services into the Energy and Ancillary Services Markets Operated by the California Independent System Operator and the California Power Exchange, Respondents; California Municipal Utilities Association, Complainant, v. all Jurisdictional Sellers of Energy and Ancillary Services into Markets Operated by the California Independent System Operator and the California Power Exchange, Respondents; Californians for Renewable Energy, Inc. (CARE), Complainant, v. Independent Energy Producers, Inc., and All Sellers of Energy and Ancillary Services into Markets Operated by the California Independent System Operator and the California Power Exchange; All Scheduling Coordinators Acting on Behalf of the Above Sellers; California Independent System Operator Corporation; and California Power Exchange Corporation, Respondent; Puget Sound Energy, Inc., Complainant v. All Jurisdictional Sellers of Energy and/or Capacity at Wholesale into Electric Energy and/or Capacity Markets in the Pacific Northwest, Including Parties to the Western Systems Powers Pool Agreement, Respondents; Notice of Organization Of Technical Conference

January 16, 2001.

This notice announces the organization of the previously noticed technical conference, to be held on January 23, on the development of market monitoring procedures for the markets involving the California Independent System Operator.

The conference will begin with a discussion of the principles that should govern market monitoring and an identification of the issues that need to be resolved to develop a market monitoring plan. Following this discussion examples of market monitoring procedures will be considered. This will be an informal, off-the-record conference in its format. The California Independent System Operator staff is expected to present an example of a market monitoring plan for discussion. The California Power Exchange also is expected to propose principles to be used in developing a market monitoring plan and may also present an example of a plan. These proposals will be made available for review in advance on the conference of the Internet websites of these entities (*www.caiso.com* and *www.calpx.com*). Any party who would like to propose principles to govern the development of a market monitoring plan or an example of a plan is invited to do so but should make the proposal available to the parties in advance of the conference.

The conference will begin at 9:30 a.m. at 888 First Street, NE., Washington DC in the Commission room, Room 2C. Any questions concerning the conference should be directed to Scott Miller at (202) 208–2171 or Andra Wolfman at (202) 208–2097.

David B. Boergers,

Secretary.

[FR Doc. 01–1755 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. RP00–477–000, RP01–18–000 and RP01–81–000]

Tennessee Gas Pipeline Company; Notice of Change of Location of Technical Conference

January 16, 2001.

Take notice that the technical conference scheduled for Tuesday, January 23, 2001, at 10:00 am, in the above-captioned proceedings will be held at the Holiday Inn On the Hill, 415 New Jersey Avenue, NW., Washington, DC 20001.

All interested persons and Staff are permitted to attend.

David P. Boergers,

Secretary.

[FR Doc. 01–1753 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act; Notice

The Following Notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: January 24, 2001, 10 a.m.

PLACE: Room 2C, 888 First Street, NE. Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

Note. Items Listed on the Agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: David P. Boergers, Secretary Telephone (202) 208–0400, for a recording listing items Stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Reference and Information Center.

758th—Meeting January 24, 2001 Regular meeting (10 a.m.)

Consent Agenda—Markets, Tariffs and Rates—Electric

CAE–1.
Docket# ER01–513, 000, Sithe Edgar LLC, Sithe New Boston LLC, Sithe Framingham LLC, Sithe West Medway LLC, Sithe Wyman LLC, Sithe Mystic LLC, AG-Energy, L.P., Power City Partners, L.P., Seneca Power Partners, L.P., Sterling Power Partners, L.P., Sithe Power Marketing, L.P and Sithe Power Marketing, INC.
CAE–2.
Docket# ER01–592, 000, Western Resources, Inc.
Other#s ER01–615, 000 ,Public Service Company of New Mexico
CAE–3.
Docket# ER01–123, 000, Illinois Power Company
CAE–4.
Docket# ER01–563, 000, Conectiv Energy Supply, Inc. and Delmarva Power & Light Company
Other#s ER00–1770, 002, Delmarva Power & Light Company, Conectiv Delmarva Generation, Inc., Atlantic City Electric Company, Conectiv Atlantic Generation, LLC and Conectiv Energy Supply, Inc.
ER00–3322, 002, Delmarva Power & Light Company, Conectiv Delmarva Generation, Inc., Atlantic City Electric Company, Conectiv Atlantic Generation, LLC and Conectiv Energy Supply, Inc.
CAE–5.
Docket# EC01–13, 000, Bangor Hydro-Electric Company and Emera Incorporated
CAE–6.
Docket# ER97–3463, 001, Pennsylvania-New Jersey-Maryland Interconnection
CAE–7.
Docket# ER99–2028, 001, PJM Interconnection, L.L.C.
CAE–8.
Docket# ER99–3144, 003, Alliance Companies, American Electric Power Service Corporation on Behalf of: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, Consumers Energy Company, the Detroit Edison Company, First Energy Corporation on Behalf of: the Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company, the Toledo Edison Company and Virginia Electric and Power Company
Other# EC99–80, 003, Alliance Companies, American Electric Power Service Corporation on behalf of: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, Consumers Energy Company, the Detroit Edison Company, First Energy Corporation on behalf of: the Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company, the Toledo Edison Company and Virginia Electric and Power Company
EC99–80, 004, Alliance Companies, American Electric Power Service Corporation on behalf of: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, Consumers Energy Company, the Detroit Edison Company, First Energy Corporation on behalf of: the Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company, the Toledo Edison Company and Virginia Electric and Power Company
EC99–80, 005, Alliance Companies, American Electric Power Service Corporation on behalf of: Appalachian Power Company, Columbus Southern Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, Consumers Energy Company, Detroit Edison Company, First Energy Corporation on behalf of: the Cleveland Electric Illuminating Company, Ohio Edison Company, Pennsylvania Power Company, the Toledo Edison Company and Virginia Electric and Power Company
EC00–103, 000, Consumers Energy Company
ER00–2869, 000, Consumers Energy Company
CAE–9.
Docket# EC00–49, 002, Consolidated Edison, Inc. and Northeast Utilities
CAE–10.
Docket# ER01–66, 001, Pacific Gas and Electric Company
CAE–11.
Omitted
CAE–12.
Docket# ER01–103, 000, Firstenergy Services, Inc.
Other#s ER01–103, 001, Firstenergy Services, Inc.
CAE–13.
Docket# EL01–13, 000, Duke Energy Corporation, Carolina Power & Light Company, South Carolina Electric & Gas Company and Gridsouth Transco, LLC
CAE–14.
Docket# EL00–116, 000, Alliance for Municipal Power
CAE–15.
Docket# ER93–150, 017, Boston Edison Company
Other#s EL93–10, 010, Boston Edison Company
CAE–16.
Docket# EC00–137, 000, Connecticut Light and Power Company, Western Massachusetts Electric Company, United Illuminating Company, Central Maine Power Company, Fitchburg Gas and Electric Light Company, New England Power Company, Public Service Company of New Hampshire, Dominion Resources, Inc., and Dominion Nuclear Connecticut, Inc.
CAE–17.
Docket# ER00–1439, 002, Automated Power Exchange, Inc.
Other#s ER00–1439, 001, Automated Power Exchange, Inc.

Consent Agenda—Markets, Tariffs and Rates—Gas

CAG–1.
Omitted
CAG–2.
Omitted
CAG–3.
Docket# RP01–196, 000, Venice Gathering System, L.L.C.
CAG–4.
Docket# RP01–177, 000, Cove Point LNG Limited Partnership
CAG–5.
Docket# RP01–205, 000, Southern Natural Gas Company
CAG–6.
Docket# RP96–383, 016, Dominion Transmission, Inc.
CAG–7.
Docket# PR00–12, 000, Louisiana Intrastate Gas Company, L.L.C.
CAG–8.
Docket# RP96–383, 017, Dominion Transmission, Inc.
CAG–9.
Docket# RP00–627, 001, Northern Natural Gas Company
CAG–10.
Docket# RP97–71, 021, Transcontinental Gas Pipe Line Corporation
Other#s RP97–71, 020, Transcontinental Gas Pipe Line Corporation
CAG–11.
Docket# RP96–272, 025, Northern Natural Gas Company
Other#s RP96–272, 021, Northern Natural Gas Company
CAG–12.
Docket# MG01–4, 000, El Paso Natural Gas Company
CAG–13.
Docket# MG00–10, 000, Northwest Pipeline Corporation
CAG–14.
Docket# MG00–1, 002, Clear Creek Storage Company, L.L.C.
CAG–15.
Docket# MG00–11, 000, Kern River Gas Transmission Company
CAG–16.
Docket# RP01–189, 000, Northern Nevada Industrial Gas Users v. Northwest Pipeline Corporation
CAG–17.
Omitted
CAG–18.
Omitted

Consent Agenda—Energy Projects—Hydro

CAH–1.
Docket# P–2069, 004, Arizona Public Service Company
CAH–2.
Docket# P–4632, 027, Clifton Power Corporation
CAH–3.
Omitted

Consent Agenda—Energy Projects—Certificates

CAC–1.
Docket# CP97–168, 005, Alliance Pipeline L. P.
CAC–2.
Docket# CP00–374, 000, Kinder Morgan Interstate Gas Transmission LLC
Other#s CP00–375, 000, K N Energy, a Division of Kinder Morgan, Inc.
CAC–3.
Omitted
CAC–4.
Omitted
CAC–5.
Docket# RP00–220, 001, Town of Neligh, Nebraska v. Kinder Morgan Interstate Gas Transmision, L.L.C. And K N Energy, a Division of Kinder Morgan, Inc.
Other#s RP00–220, 000, Town of Neligh, Nebraska v. Kinder Morgan Interstate Gas Transmision, L.L.C. And KN Energy, a Division of Kinder Morgan, Inc.
CAC–6.
Omitted
CAC–7.
Docket# CP99–241, 002, ANR Pipeline Company
CAC–8.
Docket# CP01–57, 000, Suncor Development Company
CAC–9.
Docket# CP00–166, 000, Williams Gas Pipelines Central, Inc.

Energy Projects—Hydro Agenda

H–1.
Reserved

Energy Projects—Certificates Agenda

C–1.
Reserved

Markets, Tariffs and Rates—Electric Agenda

E–1.
Reserved

Markets, Tariffs and Rates—Gas Agenda

G–1.
Reserved

David P. Boergers,
Secretary.
[FR Doc. 01–1961 Filed 1–18–01; 11:01 am]
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DEPARTMENT OF ENERGY

[Docket No. RM98–1–000]

Regulations Governing Off-the-Record Communications; Public Notice

January 12, 2001.

This constitutes notice, in accordance with 18 CFR 385.2201(h), of the receipt of exempt and prohibited off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive an exempt or a prohibited off-the-record communication relevant to the merits of a contested on-the-record proceeding, to deliver a copy of the communication, if written, or a summary of the substance of any oral communication, to the Secretary.

Prohibited communications will be included in a public, non-decisional file associated with, but not part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such requests only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication should serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications will be included in the decisional record of the proceeding, unless the communications was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(v).

The following is a list of exempt and prohibited off-the-record communications received in the Office of the Secretary within the preceding 14 days. The documents may be viewed on the Internet at *http://www.ferc.fed/online/us/rims.htm* (call 202–208–2222 for assistance).

Exempt

1. EL00–62–013, 01–03–01, The Honorable Jack Reed.
2. EL00–95–000, 12–27–00, G. Richard Judd.
3. EL00–95–000, 01–05–01, Frank J. De Smidt.
4. EL00–95–000, 01–05–01, Gary L. Vyne.
5. EL00–95–000, 01–05–01, Sidney L. Stevens.
6. EL00–95–000, 01–05–01, Frank J. De Smidt.
7. EL00–95–000, 01–05–01, Curt Johnson.
8. EL00–95–000, 01–05–01, Gary Vyne.
9. RT01–75–000, 01–10–01, Russell L. Morris.
10. EL00–62–013, 01–10–01, The Honorable, Edward J. Markey, John Joseph Moakley, Barney Frank, Edward M. Kennedy, John Kerry, William D. Delahunt, John W. Olver, Michael E. Capuano, Richard E. Neal, James P.

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McGovern, Martin T. Meehan, John F. Tierney.

David P. Boergers,

Secretary.

[FR Doc. 01–1578 Filed 1–19–01; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6934–7]

Gulf of Mexico Program—Management Committee Meeting

AGENCY: U.S. Environmental Protection Agency (US EPA).

ACTION: Notice of meeting.

SUMMARY: Under the Federal Advisory Act, Public Law 92463, EPA gives notice of a meeting of the Gulf of Mexico Program (GMP) Management Committee (MC).

DATES: The MC meeting will be held on Tuesday, February 13, 2001 from 1:00 to 5:00 p.m. and on Wednesday, February 14, 2001 from 8:30 to 11:30 a.m.

ADDRESSES: The meeting will be held at the Hampton Inn, Two Via DeLuna, Pensacola Beach, Florida, 32561, (850)932–6800.

FOR FURTHER INFORMATION CONTACT: Gloria D. Car, Designated Federal Officer, Gulf of Mexico Program Office, Building 1103, Room 202, Stennis Space Center, MS 39529–6000 at (228) 688–2421.

SUPPLEMENTARY INFORMATION: Proposed agenda items will include: Federal Program and Budget Summary, Review Draft GMP Policy Review Board Recommendations for 2001, FY 2001 Workplan Overview and Implementation Status, Review Annual Report to National Aquatic Nuisance Species Task Force, Coastal America Update, Overview of Memorandum of Understanding developed by USGS/NOAA/EPA , Update on Mexico/United States Governors' Accord.

The meeting is open to the public.

Dated: January 11, 2001.

Gloria D. Car,

Designated Federal Officer.

[FR Doc. 01–1650 Filed 1–19–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6935–1]

Request for Nominations to the National Advisory Council for Environmental Policy and Technology, Standing Committee on Sectors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for nominations.

SUMMARY: The Environmental Protection Agency (EPA) is inviting nominations for membership on its National Advisory Council for Environmental Policy and Technology (NACEPT), Standing Committee on Sectors. The Agency is seeking qualified senior level decision makers from diverse stakeholder groups throughout the U.S. to be considered for appointments. Nominations will be accepted until close of business on February 15, 2001, and need to include a resume or short biography describing the qualifications of the nominee and the nominee's current mailing address, e-mail address and daytime telephone number.

ADDRESSES: Submit nominations to Ms. Kathleen Bailey, Designated Federal Officer, EPA, Office of the Administrator, Office of Policy, Economics and Innovation, Office of Business and Community Innovation, Sector Strategies Division, Mail Code 1808, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also e-mail nominations to *bailey.kathleen@epa.gov*.

SUPPLEMENTARY INFORMATION: NACEPT is a federal advisory committee under the Federal Advisory Committee Act, PL 92463. NACEPT consists of a representative cross-section of EPA's partners and principle constituents who provide advice and recommendations to the Administrator and other EPA officials on a broad range of domestic and international environmental policy issues.

The Standing Committee on Sectors, a subcommittee of NACEPT, has existed for two years and provides a federal advisory forum from which the Agency can continue to receive valuable multi-stakeholder advise and recommendations on the use of industry sector-based approaches to environmental protection. The Standing Committee on Sectors and NACEPT recently endorsed the EPA Sector Program Plan 2001–2005, and provided EPA's Administrator with six additional recommendations to foster implementation of the Plan. The vision statement in the Plan is: "EPA Leadership Enables Environmental Excellence by U.S. Industries—Over the next five years, better understanding and cooperation among industry, government, and citizen stakeholders will help large numbers of facilities in a variety of industrial sectors make continuous improvement toward environmental excellence. Stakeholder-supported environmental strategies for industry sectors will bring marked reductions in pollution, waste, environmental and human health impacts, and regulatory burden." The Sector Program Plan 2001–2005, and other relevant information is available on EPA's web site *www.epa.gov/sectors*.

We are accepting nominations for approximately 15–18 members. Criteria for selection will include the following:

—Representatives from workgroups of the Standing Committee on Sectors which have continuing projects, i.e. printing, petroleum, and metal finishing.
—Representatives from a broad range of EPA stakeholder groups which have an interest and experience in dealing with sector issues, e.g. business/industry, state/local/tribal governments, national and local environmental, environmental justice, and labor groups.
—Senior level representatives with decision-making authority for their organization.
—Representatives with experience working collaboratively with stakeholder groups in addition to their own.

Nominations will be accepted until close of business on February 15, 2001, and need to include a resume or short biography describing the qualifications of the nominee and the nominee's current mailing address, e-mail address, and daytime phone number. Nominees invited to participate will receive an invitation from EPA's Deputy Administrator.

For further information, please contact Ms. Kathleen Bailey, Designated Federal Officer, EPA, Office of the Administrator, Office of Policy, Economics and Innovation, Office of Business and Community Innovation, Sector Strategies Division, Mail Code 1808, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Phone: 202/260–3413; e-mail *bailey.kathleen@epa.gov*.

Kathleen Bailey,

Designated Federal Officer, NACEPT Standing Committee on Sectors.

[FR Doc. 01–1828 Filed 1–19–01; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6935–7]

Notice of Proposed NPDES General Permit for Discharges From the Coastal Subcategory of the Oil and Gas Extraction Point Source Category in Texas (TXG330000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of draft NPDES general permit.

SUMMARY: EPA Region 6 is proposing to reissue General NPDES Permit No. TXG330000 regulating discharges from oil and gas wells in the Coastal Subcategory of the Oil and Gas Extraction Point Source Category in Texas. Most of the requirements in this proposed permit are the same as in the previous permit having an effective date of October 21, 1993 and expiration date of October 21, 1998. The main differences between the previous permit and this proposed permit are: discharges from New Sources are authorized by this permit, there are changes in the requirements for treated waste water from drilling fluids/cuttings and dewatering effluent, and changes in the requirements for well treatment, completion and workover fluids. These permit requirement changes are the result of incorporating additional or more stringent requirements contained in effluent limitations guidelines for the Coastal Subcategory contained in 40 CFR part 435, subpart D.

Additionally, EPA Region 6 is proposing to reissue NPDES General Permit TXG290000, regulating produced water and produced sand discharges to coastal water in Texas, and combine that permit with NPDES General Permit TXG330000. Permit No. TXG330000 previously regulated all discharges from wells in the Coastal Subcategory of the Oil and Gas Extraction Point Source Category, except for produced water and produced sand. Combining these two permits will, thereby, allow regulation of all discharges from Coastal Subcategory wells in one permit. General Permit TXG290000 also regulated the discharge of produced water from wells in the Stripper and Offshore Subcategories which discharged into coastal waters of Texas. Regulation of that produced water will also be incorporated into General Permit TXG330000.

DATES: Comments on this proposed permit must be submitted by March 23, 2001.

ADDRESSES: Comments on this proposed permit should be sent to the Regional Administrator, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Smith, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7191. Copies of the complete fact sheet and proposed permit may be obtained from Ms. Smith. The fact sheet and proposed permit can also be found on the Internet at http://www.epa.gov/earth1r6/6wq/6wq.htm. In addition, the current administrative record on the proposal is available for examination at the Region's Dallas offices during normal working hours after providing Ms. Smith 24 hours advanced notice.

SUPPLEMENTARY INFORMATION:

Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Operators of oil and gas wells in the Coastal Subcategory of the Oil and Gas Extraction Point Source Category.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your (facility, company, business, organization, etc.) is regulated by this action, you should carefully examine the applicability criteria in part I, section A.1 of this permit. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Section 301(a) of the Clean Water Act (CWA or the Act), 33 U.S.C. 1311(a), makes it unlawful to discharge pollutants to waters of the United States in the absence of authorizing permits. CWA section 402, 33 U.S.C. 1342, authorizes EPA to issue National Discharge Elimination System (NPDES) permits allowing discharges on condition they will meet certain requirements, including CWA sections 301, 304, and 401 (33 U.S.C. 1331, 1314 and 1341). Those statutory provisions require that NPDES permits include effluent limitations requiring that authorized discharges: (1) Meet standards reflecting levels of technological capability, (2) comply with EPA-approved state water quality standards and (3) comply with other state requirements adopted under authority retained by states under CWA 510, 33 U.S.C. 1370.

Two types of technology-based effluent limitations must be included in the permit proposed here. With regard to conventional pollutants, *i.e.*, pH, BOD, oil and grease, TSS and fecal coliform, CWA section 301(b)(1)(E) requires effluent limitations based on "best conventional pollution control technology" (BCT). With regard to nonconventional and toxic pollutants, CWA section 301(b)(2)(A), (C), and (D) require effluent limitations based on "best available pollution control technology economically achievable" (BAT), a standard which generally represents the best performing existing technology in an industrial category or subcategory. BAT and BCT effluent limitations may never be less stringent than corresponding effluent limitations based on best practicable control technology (BPT), a standard applicable to similar discharges prior to March 31, 1989 under CWA 301(b)(1)(A).

National guidelines establishing BCT, BAT and New Source Performance Standards have been promulgated for discharges from facilities in the Coastal Subcategory of the Oil and Gas Extraction Point Source Category. The final rule for these guidelines was published in the **Federal Register** at 61 FR 66086 on December 16, 1996. These guidelines can also be found at 40 CFR part 435, subpart D. The current proposal is to reissue NPDES General Permit TXG330000 which was issued in the **Federal Register** at 58 FR 49126 with an effective date of October 21, 1993, and an expiration date of October 21, 1998. Additionally, NPDES General Permit TXG290000, regulating produced water and produced sand discharges to coastal waters in Texas, will be reissued and combined with NPDES General Permit TXG330000. General Permit TXG290000 had an effective date of February 8, 1995 and an expiration date of February 7, 2000. Since these expired permits were issued before the BCT and BAT guidelines were promulgated, BCT and BAT requirements were based on

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best professional judgement. The current proposed permit incorporates the BCT, BAT and New Source Performance Standards from 40 CFR part 435, subpart D.

Changes From the Expiring Permit

Although the 40 CFR part 435, subpart D, requirements are mostly the same as those in the expiring permits which were derived using best professional judgement, requirements for several waste streams are more stringent. The proposed permit, therefore, incorporates those more stringent guidelines limits. Specifically, the discharge of well treatment, completion and workover fluids is now prohibited. In addition, the discharge of dewatering effluent from reserve pits which received drilling fluids and/or drill cuttings after January 15, 1997, is prohibited. Since the guidelines do not address reserve pits which did not receive drilling fluids and/or drill cuttings after January 15, 1997, the limits in the previous permit apply, with one exception. In the previous permit, the No Free Oil limit was to be measured by a visual sheen test with the option of using the static sheen test. Since the guidelines require the use of the static sheen test for all No Free Oil limits except for deck drainage, the No Free Oil requirement for the reserve pit dewatering effluent discharges and the formation test fluid discharges has been changed to use of the static sheen test only. The proposed permit also authorizes discharges from new source facilities, whereas, the expiring permit does not.

Summary of Proposed Permit Limitations

A. Drilling fluids—No Discharge.
B. Drill cuttings—No Discharge.
C. Produced water—No Discharge.
Exception: Facilities in the Stripper Subcategory located east of the 98th meridian whose produced water comes from the Carrizo/Wilcox, Reklaw or Bartosh formations in Texas and whose produced water does not exceed 3000 mg/l Total Dissolved Solids shall meet the following limits: 25 mg/l monthly average and 35 mg/l daily maximum for oil and grease.
D. Produced sand—No discharge.
E. Dewatering effluent—No Discharge.
Exception: Dewatering effluent from reserve pits which have not received drilling fluids and/or drill cuttings since January 15, 1997, shall meet the following limits:

Free oil—No Discharge as determined by the static sheen test
Oil and grease—15 mg/l daily maximum
TSS—50 mg/l daily maximum
TDS—3000 mg/l daily maximum, except for discharges to tidally influenced watercourses if the TDS of the treated reserve pit effluent does not exceed the TDS concentration of the receiving water at the point of discharge at the time of discharge.
COD—200 mg/l daily maximum
pH–6.0–9.0 Std. Units
Chlorides—500 mg/l daily maximum (discharges to inland areas) and 1000 mg/l daily maximum (discharges to tidally influenced water courses). Chloride concentration may exceed 1000 mg/l in tidally influenced watercourses (downstream of the upper limit of saltwater intrusion) if the chloride concentration of the treated reserve pit effluent does not exceed the chloride concentration of the receiving water at the point of discharge at the time of discharge.
Hazardous metals—The discharge must not contain concentrations of the substances classified as "hazardous metals" in excess of the levels allowed by TAC 319.21)

F. Deck drainage—No discharge of free oil as determined by the presence of a film or sheen upon or a discoloration of the surface of the receiving water (visual sheen).

G. Formation test fluids—No Discharge except to bays and estuaries where no chloride standards have been established.

Where discharges are allowed:

Free oil—No Discharge as determined by the static sheen test.
pH–6.0–9.0 Std. Units

H. Well treatment, completion and workover fluids—No Discharge.

I. Sanitary waste—

No floating solids
BOD5–45 mg/l daily maximum
TSS–45 mg/l daily maximum
Fecal coliform—200/100 ml daily maximum

J. Domestic waste—No Discharge of floating solids or garbage or foam.

K. Miscellaneous discharges: Desalinization unit discharge; blowout preventer fluid;uncontaminated ballast and bilge water; mud, cuttings and cement at the sea floor; boiler blowdown; excess cement slurry; diatomaceous earth filter media; uncontaminated water—Discharge of free oil is prohibited as determined by a visual sheen on the surface of the receiving water. Discharge is authorized only at times when visual sheen observation is possible. Discharge may occur at any time if the operator uses the static sheen method for detecting free oil.

Other Legal Requirements

A. State Certification

Under section 401(a)(1) of the Act, EPA may not issue an NPDES permit until the State in which the discharge will originate grants or waives certification to ensure compliance with appropriate requirements of the Act and State law. Section 301(b)(1)(C) of the Act requires that NPDES permits contain conditions that ensure compliance with applicable state water quality standards or limitations. The proposed permit contains limitations intended to ensure compliance with state water quality standards and has been determined by EPA Region 6 to be consistent with the Texas water quality standards and the corresponding implementation plan. The Region has solicited certification from the Railroad Commission of Texas.

B. National Environmental Policy Act

EPA's regulations at 40 CFR part 6, subpart F, which implement the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C 4331, *et seq.*, provide the procedures for carrying out the NEPA environmental review process for the issuance of new source NPDES permits. The purpose of this review process is to determine if any significant environmental impacts are anticipated by issuance of NPDES permits authorizing discharges from new sources. In order to make this determination, EPA has prepared an environmental assessment in accordance with 40 CFR 6.604. Based on this environmental assessment document, EPA has determined that there will be no significant impact as the result of issuing today's proposed permit adding coverage of discharges from new sources. EPA is, therefore, proposing to issue a Finding of No Significant Impact in accordance with 40 CFR part 6 procedures concerning adding new source coverage to this general permit.

C. Endangered Species Act

When EPA issued the previous Permit TXG330000, effective October 21, 1993, covering existing sources, but not New Sources, the United States Fish and Wildlife Service concurred with EPA's finding that the permit was unlikely to adversely affect any threatened or endangered species or its critical habitat. When EPA issued Permit TXG290000, effective February 8, 1995, the Service also concurred with EPA's finding that the permit was unlikely to adversely affect any threatened or endangered species or its critical habitat. As discussed previously in this Fact Sheet, the proposed permit requirements are the same as, and in some instances more stringent than, those in the previous permit. Furthermore, the proposed limits are sufficiently stringent to assure state water quality standards will be met. The effluent limitations established in these permits ensure protection of aquatic life and maintenance of the receiving water as an aquatic habitat. The Region, therefore, finds that adding New Source coverage to the permit is also unlikely to adversely affect any threatened or endangered species or its critical habitat. EPA is seeking written concurrence from the United States Fish and Wildlife Service and the National Marine Fisheries Service on this determination.

D. Magnuson-Stevens Fishery Conservation and Management Act

The 1996 amendments to the Magnuson-Stevens Fishery Conservation and Management Act set forth a new mandate to identify and protect important marine and anadromous fisheries habitats. The purpose of addressing habitat in this act is to further the goal of maintaining sustainable fisheries. Guidance and procedures for implementing these amendments are contained in National Marine Fisheries Service regulations (50 CFR 600.805–600.930). These regulations specify that any Federal agency that authorizes or proposes to authorize an activity which would adversely affect an Essential Fish Habitat is subject to the consultation provisions of the Manguson-Stevens Act. The Texas Coastal Subcategory areas covered by this general permit include Essential Fish Habitat designated under the Magnuson-Stevens Act.

Based on the prohibitions and limitations and other requirements contained in this proposed general permit, as well as the Essential Fish Habitat Assessment prepared for this permit reissuance, the Region finds that adoption of the proposed permit is unlikely to adversely affect Essential Fish Habitat. EPA is seeking written concurrence from the National Marine Fisheries Service on this determination.

E. Coastal Zone Management Act

The Coastal Zone Management Act and its implementing regulations (15 CFR part 930) require that any Federally licensed or permitted activity affecting the coastal zone of a state with an approved Coastal Zone management Program be consistent with that Program. EPA has concluded, based on the conditions, limitations and prohibitions of this permit that the discharges associated with this proposed permit are consistent with the Texas Coastal Management Program goals and policies. EPA has requested a consistency determination from the Texas Coastal Coordination Council.

F. Historic Preservation Act

Facilities which adversely affect properties listed or eligible for listing in the National Register of Historical Places are not authorized to discharge under this permit.

G. Economic Impact (Executive Order 12866)

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. EPA has determined that this general permit is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to formal OMB review prior to proposal.

H. Paperwork Reduction Act

The information collection required by this permit has been approved by OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, in submission made for the NPDES permit program and assigned OMB control numbers 2040–0086 (NPDES permit application) and 2040–0004 (discharge monitoring reports).

I. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires that EPA prepare a regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. As discussed below, the permit being proposed to be reissued is not a "rule" subject to the Regulatory Flexibility Act. EPA prepared a regulatory flexibility analysis, however, on the promulgation of the Coastal Subcategory guidelines on which many of the permit's effluent limitations are based. That analysis shows that compliance with the permit requirements will not result in a significant impact on dischargers, including small businesses, covered by these permits. EPA Region 6 therefore concludes that the permits proposed today will not have a significant impact on a substantial number of small entities.

J. Unfunded Mandates Reform Act

Section 201 of the Unfunded Mandates Reform Act (UMRA), Public Law 104–4, generally requires Federal agencies to assess the effects of their "regulatory actions" on State, local, and tribal governments and the private sector. UMRA uses the term "regulatory actions" to refer to regulations. (See, e.g., UMRA section 201, "Each agency shall * * * assess the effects of Federal regulatory actions * * * (other than to the extent that such regulations incorporate requirements specifically set forth in law)" (emphasis added)). UMRA section 102 defines "regulation" by reference to section 658 of Title 2 of the U.S. Code, which in turn defines "regulation" and "rule" by reference to section 601(2) of the Regulatory Flexibility Act (RFA). That section of the RFA defines "rule" as "any rule for which the agency publishes a notice of proposed rulemaking pursuant to section 553(b) of the Administrative Procedure Act (APA), or any other law * * *"

NPDES general permits are not "rules" under the APA and thus not subject to the APA requirement to publish a notice of proposed rulemaking. NPDES general permits are also not subject to such a requirement under the Clean Water Act (CWA). While EPA publishes a notice to solicit public comment on draft general permits, it does so pursuant to the CWA section 402(a) requirement to provide "an opportunity for a hearing." Thus, NPDES general permits are not "rules" for RFA or UMRA purposes.

EPA thinks it is unlikely that this proposed permit issuance would contain a Federal requirement that might result in expenditures of $100 million or more for State, local and tribal governments, in the aggregate, or the private sector in any one year. The Agency also believes that the proposed permit issuance would not significantly nor uniquely affect small governments. For UMRA purposes, "small

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governments" is defined by reference to the definition of "small governmental jurisdiction" under the RFA. (See UMRA section 102(1), referencing 2 U.S.C. 658, which references section 601(5) of the RFA.) "Small governmental jurisdiction" means governments of cities, counties, towns, etc., with a population of less than 50,000, unless the agency establishes an alternative definition. The proposed permit issuance also would not uniquely affect small governments because compliance with the proposed permit conditions affects small governments in the same manner as any other entities seeking coverage under the permit.

Dated: January 8, 2001.

Sam Becker,

Acting Director, Water Quality Protection Division, Region 6.

[FR Doc. 01–1829 Filed 1–19–01; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

January 12, 2001.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before March 23, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commissions, Room 1 A–804, 445 Twelfth Street, SW., Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–0286.

Title: Section 80.302 Notice of discontinuance, reduction, or impairment of service involving a distress watch.

Form No.: N/A.

Type of Review: Extension of existing collection.

Respondents: Business or other for-profit, individuals or households, non-profit institutions, state and local governments.

Number of Respondents: 160.

Estimated Time Per Response: 1 hour.

Total Annual Burden: 160 hours.

Total Annual Cost: 0.

Needs and Uses: The reporting requirement contained in Section 80.145 is necessary to ensure that the U.S. Coast Guard is timely notified when a coast station, which is responsible for maintaining a listening watch on a designated marine distress and safety frequency, discontinues, reduces or impairs its communications services. This notification allows the Coast Guard to seek an alternate means of providing radio coverage to protect the safety of life and property at sea or object to the planned diminution of service. The information is used by the U.S. Coast Guard district office nearest to the coast station. Once the Coast Guard is aware that such a situation exists, it is able to inform the maritime community that radio coverage has or will be affected and/or seek to provide coverage of the safety watch via alternate means. When appropriate the Coast Guard may file a petition to deny an application.

OMB Number: 3060–0361.

Title: Section 80.29 Change during license term.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households; Business or other for-profit; Not-for-Profit Institutions; State, Local or Tribal Government.

Number of Respondents: 250.

Estimated Time Per Response: 1 hour

Total Annual Burden: 250 hours total annual burden.

Needs and Uses: The information is used by the FCC to update the coast and ship station license files and data base concerning current name and address of licensees. Information concerning changes in the names of vessels is also used to update the ITU List of Ship Stations.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–1756 Filed 1–19–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

January 12, 2001.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before March 23, 2001. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commissions, 445 12th Street, SW., Room 1–A804, Washington, DC 20554 or via the Internet to lesmith@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collections contact Les Smith at (202) 418–0217 or via the Internet at lesmith@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval No.: 3060–0634.

Title: Section 73.691 Visual Modulation Monitoring.

Form No.: n/a.

Type of Review: Extension of currently approved collection.

Respondents: Businesses or other for-profit, not-for-profit institutions.

Number of Respondents: 20 (2 notifications per respondent); 6 letters.

Estimated Hours Per Response: 1.0 hours.

Frequency of Response: on occasion.

Cost to Respondents: $0.

Estimated Total Annual Burden: 46.

Needs and Uses: Section 73.691(b) requires TV stations to enter into the station log the date and time of the initial technical problems that make it impossible to operate a TV station in accordance with the timing and carrier level tolerance requirements. If this operation at variance is expected to exceed 10 consecutive days, a notification must be sent to the FCC. The licensee must also notify the FCC upon restoration of normal operations. If causes beyond the control of the licensee prevent restoration of normal operations within 30 days, a written request must be made to the FCC. The data is used by FCC staff to maintain accurate and complete technical information about a station's operation. In the event that a complaint is received from the public regarding a station's operation, this information is necessary to provide an accurate response.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 01–1757 Filed 1–19–01; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 5, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Frank D. Neese, Indianapolis, Indiana; to retain voting shares of First Community Bancshares, Inc., Bargersville, Indiana, and thereby indirectly retain voting shares of First Community Bank and Trust, Bargersville, Indiana.

Board of Governors of the Federal Reserve System, January 16, 2001.

Robert deV. Frierson

Associate Secretary of the Board.

[FR Doc. 01–1656 Filed 1–19–01; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Interagency Committee for Medical Records (ICMR); Printed Construction Cancellation of Medical Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: Because of low usage only the cut sheet version of the following Standard Form is cancelled: SF 519A, Medical Record—Radiologic Consultation Request/Report (NSN 7540–00–634–4161).

The 3-part set of the form (NSN 7540–00–634–4162) is still current and available from the Federal Supply Service.

DATES: Effective January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: January 5, 2001.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 01–1832 Filed 1–19–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Office of Public Health and Science; Request for Applications for the National Community Centers of Excellence in Women's Health (CCOE) Program

AGENCY: Office of the Secretary, Office of Public Health and Science, Office on Women's Health.

Authority: This program is authorized by 42 U.S.C. 300u–2(a)(1), 300u–3, and 300u–6(e).

Purpose: To provide recognition and funding to community-based programs that unite promising approaches in women's health through the integration of the following *six components:* (1) Comprehensive health service delivery, (2) training for lay and professional health providers, (3) community-based research, (4) public education and outreach, (5) leadership development for women as health care consumers and providers, and (6) technical assistance to ensure the replication of promising models and strategies that coordinate and integrate women's health activities at the community level and improve health outcomes for underserved women. The National Community Centers of Excellence in Women's Health (CCOE) program is not for the development of new programs or to fund direct service but rather to integrate, coordinate, and strengthen linkages between activities/programs that are already underway in the community in order to reduce fragmentation in women's health services and activities.

The proposed CCOE program must address women's health from a women-centered, women-friendly, women-relevant, holistic, multi-disciplinary, cultural and community-based perspective. Information and services provided must be at the educational level and within the language and cultural context that are most appropriate for the individuals for whom the information and services are intended. Women's health issues are defined in the context of women's lives, including their multiple social roles and the importance of relationships with other people to their lives. This definition of women's health encompasses both mental and physical health (including oral health) and spans the life course.

The CCOE program will be supported through the cooperative agreement mechanism, to allow a collaborative relationship between the CCOEs and the

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Department of Health and Human Services (DHHS) offices. The DHHS funding offices include the Office on Women's Health (OWH), the Office of Minority and Women's Health in the Bureau of Primary Health Care of the Health Resources and Services Administration, and the Office of Minority Health. These offices will provide the technical assistance and oversight necessary for the implementation, conduct, and assessment of program activities.

Specifically, the Federal Government will:

1. Participate in at least two annual meetings with the CCOE Center Directors in the Washington, DC area.
2. Participate in the development of a comprehensive national CCOE "how-to manual."
3. Review and approve the CCOEs" local evaluations.
4. Participate in a national evaluation of the CCOE programs using guidance/measurements provided by the OWH.
5. Review and concur with project modifications.
6. Review the design of CCOE home pages.
7. Site visit CCOE facilities annually.
8. Review all quarterly and final progress reports.

The DHHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010. Emphasis will be placed on aligning CCOE activities and programs with the Healthy People 2010: Goal 2—eliminating health disparities due to age, gender, race/ethnicity, education, income, disability, living in rural localities, or sexual orientation. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 web site: *http://www.health.gov/healthypeople*. The reference document entitled "Healthy People 2010: Understanding and Improving Health" is available for $9.00. Another reference is the Healthy People 2000 Review—1998–99. One free copy may be obtained from the National Center for Health Statistics (NCHS), 6525 Belcrest Road, Room 1064, Hyattsville, MD 20782 or telephone (301) 458–4636 [DHHS Publication No. (PHS) 99–1256]. This document may also be downloaded from the NCHS web site: http://www.cdc.gov/nchs.

Program Goals

The goals of the CCOE program are to:

1. Reduce the fragmentation of services and access barriers that women encounter using a framework that coordinates and integrates comprehensive health services with research, training, education, and leadership activities in the community to advance women's health.
2. Create healthier communities with a more integrated and coordinated women's health delivery system targeted to underserved women.
3. Empower underserved women as health care consumers and decision-makers.
4. Increase the women's health knowledge base using community-based research that involves the community in identifying research areas that address the health needs, and respond to, issues of concern to underserved women.
5. Increase the number of health professionals trained to work with underserved communities and increase their leadership and advocacy skills.
6. Increase the number of young women who pursue health careers and also increase the leadership skills and opportunities for women in the community.
7. Spread the successes, through technical assistance, of model women's health program strategies and new innovations to communities across the country that may be interested in replicating the model.
8. Eliminate health disparities for women who are underserved due to age, gender, race/ethnicity, education, income, disability, living in rural localities, or sexual orientation.

Background

The concept for the CCOE program is based on the National Centers of Excellence in Women's Health (CoE) program. The CoEs have been functioning in academic health centers since 1996. The unique feature of the CoE program has been the way it has brought together the disparate set of women's health activities that take place in academic health centers: linking together women's health research, medical education, clinical services, community outreach, and leadership development for women in academic medicine to create a more dynamic and informed system of care. The primary role of the CoEs has been to unite women's health activities and programs, promote multi-disciplinary and cross-departmental collaborations, and institutionalize a more integrative approach to women's health in academic health centers. The success of the CoE model has been rooted in this integrative approach.

The intent of the National Community Centers of Excellence in Women's Health (CCOE) program is to integrate, coordinate, and strengthen linkages between programs/activities that are already underway in the community to reduce fragmentation in women's health services and activities. Like the CoE program, the CCOE program must use an integrative approach that focuses on linking existing activities, rather than creating new ones, using the community-based organization as the nucleus for operationalizing the new model. The technical assistance component will enable the lessons learned from this unique model to be replicated in other communities around the country.

As noted in Healthy People 2010, which outlines the health goals for our Nation, most successful community health initiatives involve multiple disciplines and interventions, linking community strengths and resources so that the whole is indeed greater than the sum of its parts. The CCOE program will link community resources that address women's health activities and disciplines to increase awareness/knowledge and to advance women's health efforts more efficiently.

Eligible Applicants

The CCOE applicants must be a public or private nonprofit community-based hospital, community health center, or community-based organization serving underserved women. Community health centers funded under Section 330 of the Public Health Service Act are encouraged to apply. All applicants receiving Section 330 funding must identify themselves as recipients of these funds in the Background section of the application and by checking the appropriate response on the OWH Project Profile form. Community entities/organizations that have alliances, partnerships, networks with, or have other affiliations with an academic health center are also eligible to apply for a CCOE grant as long as the community entity/organization has a leading management role in the activity and maintains control of all funding. Academic health centers and state and county health departments are not eligible for funds under this announcement.

To ensure a wide geographic distribution of the Center of Excellence in Women's Health model, applications will be accepted from organizations in all of the American States and Territories except those that already have a National Center of Excellence in Women's Health (CoE) program or a National Community Center of Excellence in Women's Health (CCOE) program. Thus, applications will not be accepted from programs in the following states: AZ, CA, IL, IN, LA, MA, MI, MO, NC, NY, PA, PR, WA, and WI. Preference will be given to DHHS regions that do not have a CCOE or a CoE program and to programs proposed to be implemented in medically underserved areas, enterprise communities, and empowerment zones.

Deadline

To be considered for review, applications must be received by May 1, 2001. Applications will be considered as meeting the deadline if they are: (1) Received on or before the deadline date or (2) postmarked on or before the deadline date and received in time for orderly processing. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks will not be accepted as proof of timely mailing. Applications submitted by facsimile transmission (FAX) or any other electronic format will not be accepted. Applications that do not meet the deadline will be considered late and will be returned to the applicant unread.

Addresses/Contacts

Applications must be prepared using Form PHS 5161–1 (Revised June 1999). Questions regarding programmatic information and/or requests for technical assistance in the preparation of grant applications should be directed in writing to Ms. Barbara James, CCOE Program Director, Division of Program Management, Office on Women's Health, Parklawn Building, Room 16A–55, 5600 Fishers Lane, Rockville, MD 20857, e-mail: bjames1@osophs.dhhs.gov.

Technical assistance on budget and business aspects of the application may be obtained from Ms. Karen Campbell, Acting Grants Management Officer, Division of Management Operations, Office of Minority Health, Office of Public Health and Science, Rockville, MD 20852, telephone: (301) 594–0758.

Completed applications also should be submitted to: Ms. Karen Campbell, Acting Grants Management Officer, Division of Management Operations, Office of Minority Health, Office of Public Health and Science, Rockwall II Building, Room 1000, 5515 Security Lane, Rockville, MD 20852.

Availability of Funds

The Office on Women's Health anticipates making between 3 to 5 new awards in FY 2001. Awards of up to $150,000 total costs (direct and indirect) for a 12-month period will be made to up to 5 competing applicants. However, the actual number of awards made will depend upon the amount of funds available for the CCOE program.

Period of Support

The start date for the cooperative agreement will be September 30, 2001. Support may be requested for a total project period not to exceed 5 years. Noncompeting continuation awards of up to $150,000 (total cost) per year will be made subject to satisfactory performance and the availability of funds.

Use of Grant Funds

Project Requirements

A CCOE program must: (1) Develop and/or strengthen a framework to bring together a comprehensive array of services for women; (2) develop promising strategies to train a cadre of health care providers capable of addressing issues at the community level that impact underserved women's health needs; (3) develop strategies to prevent and/or reduce illness or injuries that appear controllable through individual knowledge and behavior; (4) conduct community-based research in women's health; (5) enhance public education and outreach activities in women's health with an emphasis on prevention and/or reduction of illness or injuries that appear controllable through increased knowledge that leads to a modification of behavior; (6) promote leadership/career development for women in the health professions and women/girls in the community; (7) demonstrate an ability to foster the transfer of lessons learned to other communities interested in improvements in women's health; (8) evaluate their program; and (9) participate in a national evaluation of the CCOE program. A CCOE program may develop outreach and education materials, training programs, and leadership development activities/materials. Award recipients must also, with input from community representatives, put into place and track a set of measurable objectives for improving health outcomes and decreasing health disparities for underserved women in the community. In addition, the CCOE program must contribute to the development of a comprehensive national CCOE "how-to manual" by submitting, as part of their annual report, a section on steps taken to implement each component of the CCOE program, a discussion of the effectiveness of the implementation strategy(ies) and how measured, and the impact of the program on the targeted community/population. A draft manual will be developed and made available to other organizations interested in establishing a CCOE program. The OWH plans to publish a final "how-to manual" near the end of the third cycle of funding for the CCOE program.

At a minimum, each CCOE clinical care center must be a physically-identifiable space, within the CCGE facility(s), for the delivery of comprehensive health care for women only. The CCOE clinical care center must have permanent signage and initially, at least 50 percent of the facility's space and 50 percent of the operational hours must be devoted to women-friendly, women-centered, women-relevant care delivered from a multidiscliplinary, holistic, and culturally and linguistically appropriate perspective. The CCOE clinical care center must also have a schedule and procedures for identifying and counting the women served by the CCOE and for tracking the cost of services provided to women who receive care through the CCOE program.

Use of Funds

A majority of the funds from the CCOE award must be used to support staff and efforts aimed at coordinating and integrating the major components of the CCOE program. The Center Director, or the person responsible for the day-to-day management of the CCOE program, must devote at least a 50 percent level of effort to the program. Additionally, 25 percent of the funds must target efforts to foster the transfer of lessons learned/successful strategies from the CCOE program (technical assistance). These may include either process-based lessons (*i.e.*, How to bring multiple community partners together) or outcomes-based lessons (*i.e.*, How to increase diabetes screening and control through improved outreach, education, and treatment). The CCOEs must foster the replication of promising models from their sites through activities such as showcasing them at meetings and workshops; providing direct technical assistance to other communities; participating in the development of national replication guides/materials; and providing technical assistance to health professionals, directly or through their professional organizations, interested in working with underserved women in the community. Applicants must provide a plan for how they will provide technical assistance in the first year. They will be expected to identify at least one sustained interaction with another community, beginning no later than 6 months after receipt of the CCOE award, and provide materials for the development of a manual that describes how to link, coordinate, and partner within the community to form the CCOE infrastructure.

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Funds may be used for personnel, consultants, supplies (including screening, education, and outreach supplies), and grant related travel. Items costing less than $5,000 are considered to be supplies. Funds may not be used for construction, building alterations, equipment, medical treatment, or renovations. All budget requests must be justified fully in terms of the proposed CCOE goals and objectives and include a computational explanation of how costs were determined.

The CCOE Center Directors will meet twice a year in the Washington metropolitan area. The CCOE's budget should include a request for funds to pay for the travel, lodging, and meals for the first Center Directors' meeting of each year. The first meeting is usually held between mid-October and mid-December. The OWH will pay the travel and other expenses associated with the second annual CCOE meeting.

Criteria for Evaluating Applications

Review of Applications

Applications will be screened upon receipt. Those that are judged to be incomplete, arrive after the deadline, or from states that already have a CCOE or a CoE program will be returned without review or comment. Accepted applications will be reviewed for technical merit in accordance with DHHS policies. Applications will be evaluated by a technical review panel composed of experts in the fields of program management, community service delivery, community outreach, health education, community-based research, and community leadership development. Consideration for award will be given to applicants that best demonstrate progress and/or plausible strategies for eliminating health disparities through the integration of services, community-based research, education, training, leadership/career development, and technical assistance to other communities. Applicants are advised to pay close attention to the specific program guidelines and general instructions in the application kit and to the definitions provided.

Application Requirements

Each applicant for a cooperative agreement grant funded under this CCOE announcement must, at a minimum:

1. Present a plan to integrate all six components of the CCOE program by the end of the first year of funding, although only four components have to be in place at the time the application is submitted. The challenge of the CCOE model is to stretch the "medical health care model" and "think out of the box" about ways to improve the health status of underserved women. Applicant are encouraged to be creative in suggesting ways to increase integration among the CCOE components.

2. Develop a CCOE advisory board or ensure that their already established advisory board is included in the decision-making process for CCOE program development, identification of community-based research questions, and formulation of CCOE policies. Applicants should also ensure that the advisory board includes representative(s) from their community partners.

3. Be a sustainable organization with an established network of partners capable of providing coordinated and integrated women's health services in the targeted community. The network of partner organizations must have the capability to coordinate and provide comprehensive, seamless health services for women and empower them with community-based women's health research information that addresses issues of particular concern to the women, teaching/training opportunities in women's health, leadership opportunities for community women in health, and community outreach/education activities in women's health to improve the health status of women in the community. The applicant will need to define the components of comprehensive care, demonstrate that they are culturally, linguistically, and gender appropriate, and show that they have a clear and sustainable framework for providing those services.

4. Have an established clinical care center/facility, an operating public educational/outreach program, and a community identified as the recipient of technical assistance at the time the application is submitted. A time line and plans for phasing in the remaining CCOE components by the end of Year 1 must be described in detail in the application.

5. Demonstrate the ways in which the organization and the care that are coordinated through its partners are women-focused, women-friendly, women-relevant, and sensitive to the importance of patient/provider communication/relationships for medically underserved women of all ages. The care that is coordinated through this organization must be focused on health promotion, disease prevention, and treatment.

6. Detail/specify the roles and resources/services that each partner organization brings to the program, the duration and terms of agreement as confirmed by a signed agreement between the applicant organization and each partner, and describe how the partner organizations will operate within the CCOE structure. The partnership agreement(s) must name the individual who will work with the CCOE program, describe their function, and state their qualifications. The documents, specific to each organization (form letters are not acceptable), must be signed by individuals with the authority to represent the organization (e.g., president, chief executive officer, executive director) and submitted as part of the grant application.

7. Describe in detail plans for the local evaluation of the CCOE program and when and how information obtained from the evaluation will be used to enhance the CCOE program. The applicant most also indicate their willingness to participate in a national evaluation of the CCOE program to be conducted under the leadership of the OWH.

8. Describe in detail the planned community-based research and the research methodology/procedure. Applicants may: (a) Propose original patient-oriented research; (b) enter into a formal agreement with institutions conducting population-based research to facilitate women's entry into clinical trial(s)/patient-oriented research; (c) participate in the national evaluation of the CCOE program (required of all awardees); (d) link with organizations conducting community-based research; and/or (e) propose other creative research projects. To satisfy the community-based research component of the CCOE program, all applicants must undertake at least two of the research activities listed above, in addition to the required participation in the national CCOE evaluation.

Application Review Criteria

The technical review of applications will consider the following factors:

Factor 1: Implementation Plan—45%

This section must discuss:

1. Appropriateness of the existing community resources and linkages established to deliver coordinated women's services to meet the requirements of the CCOE program.

2. Appropriateness of proposed approach, component integration, and specific activities described to address each element of the National Community Center of Excellence in Women's Health program including: (a) Comprehensive women's health services, (b) outreach and education, (c) training for professional and lay health care workers serving underserved women, (d) community-based research that involves the community in substantive roles/ways, (e) leadership/career development for women providers, and women/girls in the community across the life span, and (f) technical assistance-the ability to train others in lessons learned and replication of successful strategies. Although all components of the CCOE do not have to be in place/operational at the time the application is submitted, the applicant must discuss/describe the resources available to support each component, time lines and plans for phasing in each component, and the relationship of each component to the overall goals and objectives of the CCOE program.

3. Soundness of evaluation objectives for measuring program effectiveness and changes in health outcomes.

4. Willingness to participate in the national CCOE evaluation.

5. Willingness to contribute to the development of a comprehensive national CCOE "how-to manual."

Factor 2: Management Plan—15%

Applicant organization's capability to manage the project as determined by the qualifications of the proposed staff or requirements for "to be hired" staff, proposed staff level of effort, management experience of the lead agency and the experience, resources and role of each partner organization as it relates to the needs and programs/activities of the CCOE program, diversity of the CCOE staff as it relates to and reflects the community and populations served, and integration of the advisory board into the CCOE activities.

Factor 3: Evaluation Plan—10%

A clear statement of program goal(s) and thoroughness, feasibility and appropriateness of the local CCOE evaluation design, data collection plan, analysis of results, and procedures to determine if program goals are met. A clear statement of willingness to be involved actively in the national CCOE evaluation.

Factor 4: Technical Assistance—10%

Plans for the provision of technical assistance and the potential for replication of the CCOE model in similar populations and communities. The plan must include justification for the community selected and a detailed discussion of how the applicant will sustain interaction with the community. Technical assistance to the selected community must begin no later than 6 months after receipt of the CCOE award.

Factor 5: Objectives—10%

Merit of the objectives outlined by the applicant to address the CCOE program discussed in the program goals section in a way relevant to the targeted community needs and available resources. Objectives must be measurable and attainable within a stated time frame.

Factor 6: Background—10%

Adequacy of demonstrated knowledge of systems of health care for underserved women at the local level; demonstrated need within the proposed local community and target population of underserved women; demonstrated support and established linkages in place to operate a fully functional CCOE program; demonstrated access to medically underserved women; and documented past efforts/activities outcome with underserved women.

Award Criteria

Funding decisions will be made by the Office on Women's Health, and will take into consideration the recommendations and ratings of the review panel, program needs, geographic location, stated preferences, and the recommendations of DHHS Regional staff. A pre-site visit, conducted by DHHS regional staff, will be scheduled prior to the award of a grant with all applicants with scores in the funding range. The purpose of the visit will be to assess the applicants readiness to implement a CCOE program.

Organization of Application

Applicants are required to submit an original ink-signed and dated application and 15 photocopies. All pages must be numbered clearly and sequentially beginning with the Project Profile. The application must be typed double-spaced on one side of plain 8½" × 11" white paper, using at least a 12 point font, and contain 1" margins all around.

The Project Summary and Project Narrative must not exceed a total of *25* double-spaced pages, excluding the appendices. The original and each copy must be stapled and/or otherwise securely bound. The application should be organized in accordance with the format presented in the Program Guidelines. An outline for the minimum information to be included in the "Project Narrative" section is presented below.

I. Background
   A. Local CCOE purpose(s) and goals
   B. Section 330 funding
   C. Local CCOE program objectives
      1. Tied to program goal(s)
      2. Measurable with time frame
      3. Elements identified in Factor 5: Objectives
   D. CCOE organization charts that include partners and a discussion of the resource being contributed to the CCOE, partners, personnel and their expertise and how their involvement will help achieve the CCOE program goals

II. Implementation Plan (Approach to the establishment of the CCOE program)
   1. Components in place and plans with a timetable for phasing in the other CCOE components
   2. Partnerships and referral system/follow up
   3. Community-based research
   4. National CCOE "how-to manual"
   5. Elements identified in Factor 1: Implementation Plan

III. Management Plan
   A. Key project staff
   B. To-be-hired staff and their qualifications
   C. Staff responsibilities
   D. Management experience of the lead agency and partners as related to their role in the CCOE program
   E. Advisory board
   F. Elements identified in Factor 2: Management Plan

IV. Local CCOE Evaluation Plan
   A. Purpose
   B. Design/methodology
   C. Use of results to enhance programs
   D. Elements identified in Factor 3: Evaluation Plan

V. Technical Assistance/Replication Strategy
   A. Identification of Technical Assistance community
   B. Reason for selection of Technical Assistance community
   C. Technical Assistance plans/strategies/time line
   D. Plans for sustaining Technical Assistance
   E. Elements identified in Factor 4: Technical Assistance

Appendices
   A. Progress Report Outline
   B. Memorandums of Agreement/Understanding/Partnership Letters
   C. Required Forms (Assurance of Compliance Form, etc.)
   D. Other Attachments

Definitions

For the purposes of this cooperative agreement program, the following definitions are provided:

Clinical Care Center: At a minimum, each CCOE clinical care center must be a physically-identifiable space, within the CCOE facility(s), for the delivery of comprehensive health care for women only. The CCOE clinical care center must have permanent signage and initially, at least 50 percent of the facility's space and 50 percent of the operational hours must be devoted to women-friendly, women-centered, women-relevant care delivered from a multidisciplinary, holistic, and culturally and linguistically appropriate perspective. The CCOE clinical care

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center must also have a schedule and procedures for identifying and counting the women served by the CCOE and for tracking the cost of services provided to women who receive care through the CCOE program.

Community-based: The locus of control and decision-making powers are located at the community level, representing the service area of the community or a significant segment of the community.

Community-based organization: Public and private, nonprofit organizations that are representative of communities or significant segments of communities.

Community-based research: Community members work with researchers to help determine research issues, shape the research process/objectives, and bring research results back to the community. Community members' participation maximizes the potential for exchange in knowledge and implementation of research findings. The shared goal is to maintain scientific integrity in the research methods, while also incorporating the skills, knowledge, and strengths of the participants/beneficiaries of the research. There is an emphasis on ensuring that research results are translated into practice and communicated back to the community.

Community health center: A community-based organization that provides comprehensive primary care and preventive services to medically underserved populations. This includes but is not limited to programs reimbursed through the Federally Qualified Health Centers mechanism, Migrant Health Centers, Primary Care Public Housing Health Centers, Healthcare for the Homeless Centers, and other community-based health centers.

Comprehensive women's health services: Services including, but going beyond traditional reproductive health services to address the health needs of underserved women in the context of their lives, including a recognition of the importance of relationships in women's lives, and the fact that women play the role of health providers and decision-makers for the family. Services include basic primary care services; acute, chronic, and preventive services; mental and dental health services; patient education and counseling; promotion of healthy behaviors (like nutrition, smoking cessation, substance abuse services, and physical activity); and enabling services. Ancillary services are also provided such as laboratory tests, X-ray, environmental, social referral, and pharmacy services.

Coordinated care: The formal linkages, case management services, partnering arrangements, and patient advocate support that enable better coordination of women's health resources and help underserved women to navigate systems to obtain the comprehensive health services they need. Community-based organizations are expected to coordinate with State and local health departments, nonprofit organizations, academic institutions, or other local organizations in the community as appropriate.

Culturally competent: Information and services provided at the educational level and in the language and cultural context that are most appropriate for the individuals for whom the information and services are intended.

Cultural perspective: Recognizes that culture, language, and country of origin have an important and significant impact on the health perceptions and health behaviors that produce a variety of health outcomes.

Enabling services: Services that help women access health care, such as transportation, translation, child care, and case management.

Healthy People 2010: A set of national health objectives that outlines the prevention agenda for the Nation. Healthy People 2010 identifies the most significant preventable threats to health and establishes national goals for the next ten years. Individuals, groups, and organizations are encouraged to integrate Healthy People 2010 into current programs, special events, publications, and meetings. Businesses can use the framework, for example, to guide worksite health promotion activities as well as community-based initiatives. Schools, colleges, and civic and faith-based organizations can undertake activities to further the health of all members of their community. Health care providers can encourage their patients to pursue healthier lifestyles and to participate in community-based programs. By selecting from among the national objectives, individuals and organizations can build an agenda for community health improvement and can monitor results over time.

Holistic: Looking at women's health from the perspective of the whole person and not as a group of different body parts. It includes mental as well as physical health.

Integrated: In the CCOE context, the bringing together of the numerous spheres of activity (6 CCOE components) that touch women's health, including clinical services, research, health training, public health outreach and education, leadership development for women, and technical assistance. The goal of this approach is to unite the strengths of each of these areas, and create a more informed, less fragmented, and efficient system of women's health for underserved women that can be replicated in other populations and communities.

Lifespan: Recognizes that women have different health and psycho-social needs as they encounter transitions across their lives and that the positive and negative effects of health and health behaviors are cumulative across a woman's life.

Multi-disciplinary: An approach that is based on the recognition that women's health crosses many disciplines, and that women's health issues need to be addressed across multiple disciplines, such as adolescent health, geriatrics, cardiology, mental health, reproductive health, nutrition, dermatology, endocrinology, immunology, rheumatology, dental health, etc.

Social Role: Recognizes that women routinely perform multiple, overlapping social roles that require continuous multi-tasking.

Sustainability: An organization's or program's staying power: The capacity to maintain both the financial resources and the partnerships/linkages needed to provide the services demanded by the CCOE program. It also involves the ability to survive change, incorporate needed changes, and seize opportunities provided by a changing environment.

Underserved Women: In the context of the CCOE model, women who encounter barriers to health care that result from any combination of the following characteristics: Poverty, ethnicity and culture, mental or physical state, housing status, geographic location, language, sexual orientation, age, and lack of health insurance/under-insured.

Women-centered/women-focused: Addressing the needs and concerns of women (women-relevant) in an environment that is welcoming to women, fosters a commitment to women, treats women with dignity, and empowers women through respect and education. The emphasis is on working with women, not for women. Women clients are considered active partners in their own health and wellness.

Reporting and Other Requirements

General Reporting Requirements

In addition to those listed above, a successful applicant will submit an annual progress report that includes a summary of the local CCOE evaluation and a discussion of steps taken to implement each component of the CCOE program and the impact of the program on the targeted community/population, an annual Financial Status Report, a final Progress Report, a final Financial Status Report, and a technical assistance documentation report in the format established by the Office on Women's Health, in accordance with provisions of the general regulations which apply under "Monitoring and Reporting Program Performance," 45 CFR Part 74, Subpart J and Part 92.

Additionally, a successful applicant will submit quarterly progress reports. An original and two copies of the quarterly progress report must be submitted by January 1, April 1, July 1, and October 1. The last quarterly report will serve as the annual progress report and will describe all project activities for the entire year. The annual progress report is submitted by October 1 of each year, with the exception of the last year of the award when the report will be due by September 30.

Provision of Smoke-free Workplace and Nonuse of Tobacco Products by Recipients of PHS Grants

DHHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children.

Public Health System Reporting Requirements

This program is subject to the Public Health Systems Reporting Requirements. Under these requirements, a community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprized on proposed health services grant applications submitted by community-based non-governmental organizations within their jurisdictions.

Community-based, non-governmental applicants are required to submit, no later than the Federal due date for receipt of the application, the following information to the head of the appropriate state and local health agencies in the area(s) to be impacted: (a) A copy of the face page of the application (SF 424), (b) a summary of the project (PHSIS), not to exceed one page, which provides: (1) A description of the population to be served, (2) a summary of the services to be provided, and (3) a description of the coordination planned with the appropriate state or local health agencies. Copies of the letters forwarding the PHSIS to these authorities must be contained in the application materials submitted to the Office on Women's Health.

State Reviews

This program is subject to the requirements of Executive Order 12372 which allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. The application kit to be made available under this notice will contain a listing of States which have chosen to set up a review system and will include a State Single Point of Contact (SPOC) in the State for review. Applicants (other than federally recognized Indian tribes) should contact their SPOCs as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC in each affected State. The due date for State process recommendations is 60 days after the application deadline. The Office on Women's Health does not guarantee that it will accommodate or explain its responses to State process recommendations received after that date. (See "Intergovernmental Review of Federal Programs," Executive Order 12372, and 45 CFR Part 100 for a description of the review process and requirements.)

OMB Catalog of Federal Domestic Assistance

The OMB Catalog of Federal Domestic Assistance Number is 93.290.

Dated: January 16, 2001.

David Satcher,

Assistant Secretary for Health and Surgeon General.

[FR Doc. 01–1807 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–17–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of the Health

Part N, national Institutes of health, of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and human Services (40 FR 22859, May 27, 1975, as amended most recently and 65 FR 20477, April 2000, and redesignated from Part HN as Part N at 60 FR 56606, November 9, 1995) is amendment as set forth below to reflect the establishment of the Center on Minority Health and Health Disparities (NCMHD), National Institutes of Health. the Public health Service Act (42 U.S.C. 281 *et seq.*) as amended by P.L. 106–525, the Minority Health and Health Disparities research and Education Act of 2000, provides the authorities of the center and abolishes the Office of research on Minority Health (ORMH) within the Office of the Director, NIH. The functions and resources of the ORMH are transferred to the newly established NCMHD.

Section N–B, Organization and Functions, is amended as follows: (1) After the heading National Center for Complementary and Alternative Medicine (ND, formerly HND), insert the following:

National Center on Minority Health and Health Disparities (NE, formerly HNE), (1) Advises the NIH director and Institute and Center ((C) directors on the development of NIH-wide policy issues related to minority health disparities research, research on other health disparities, and related research training and serves as principal liaison with other agencies of the PHS, DHHS, and Federal Government; (2) develops, in consultation with the NIH Director, IC directors, and the advisory council, a comprehensive strategic plan that identifies and establishes objectives, priorities, budgets, and policy statement governing the conduct and support of all NIH minority health disparities research, research on other health disparities, and related research training activities; (3) evaluates NIH minority health disparities research programs and other health disparities research programs that are carried out by the ICs; (4) administers funds for the support of minority health disparities research and other health disparities research, through grant-making and through leveraging the programs of the ICs; (5) provides staff support to the NCMHD Advisory Council and tans-NIH coordination Committee for minority health disparities research and other health disparities research at NIH; (6) develops and maintains a Health Disparities Information (HDI) data base on intramural and extramural activities of relevance to the Center's mission and prepares special or recurring reports as needed; (7) develops culturally appropriate strategies to assure that the public is informed about various diseases and conditions that affect racial and ethnic minorities and other "health disparity populations" and issues and related NIH research activities and advances; (8) informs the scientific and medical communities and other

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Government agencies of NIH health disparities activities and involves them in efforts to expand and encourage minority health disparities research, research on other disparities, and related research training program; (9) promotes the growth and quality of minority health disparities research and research on other health disparities through improved resource allocation at the NIH, expanded collaboration among the NIH ICs and among academic institutions, improving the research infrastructure at minority serving institutions, and through the development of innovative programs such as a Centers of Excellence Program, a research endowment program, an extramural loan repayment program, and programs promoting Federal, State and local cooperation; (10) provides leadership in expanding the pool of experienced investigators in the areas of minority health disparities research and research on other health disparities; and (11) in consultation with the NIH Director, implements Title I of the Minority Health and Health Disparities Research and Education Act of 2000, as it relates to the NCMHD.

Office of the Director (NE1, formerly HNE1), (1) Plans, directs, coordinates, and evaluates the activities and programs of the NCMHD; (2) coordinates with the NIH Institutes and Centers and other Federal agencies on programs of relevance to the mission of the Center; (3) advises the NIH Director, the NIH Institutes and Centers, and others on matters relating to minority health disparities research, research on other health disparities, and related research training, including efforts to increase the participation of minority groups and subjects of clinical research; (4) plans and supervises the implementation and evaluation of administrative and management services and support to the programs and activities of the NCMHD; (5) directs and supervises the formulation, presentation, and execution of the Center's budget; (6) informs the scientific and medical communities and other Government agencies of NIH activities relevant to minority health disparities research and research on other health disparities and involves them in efforts to expand and encourage research and training programs in these areas.

Office of Finance and Administration (NE12, formerly HNE12). (1) Provides, secures, and negotiates regarding the resources and services needed for the operations of the Center, including the Office of the Director; (2) manages the Center's operational budget and performs a variety of management analysis functions; (3) assists in planning and formulating the Center's research budget and executes the budget; (4) implements a comprehensive program of personnel management services for the Center, within the authority delegated by the NIH Director; (5) provides leadership in the Center in the areas of computer information technology and in the use of computers as communication tools to include assisting in the development and monitoring of databases, in particular the Health Disparities Information (HDI) System, and monitors the development of the Center's website.

Office of Extramural Activities (NE13, formerly HNE13). (1) Provides staff support to the NCHMD Advisory Council, the congressionally authorized group that advises, assists, consults with, and make recommendations to the Center Director, and provides the second level of peer review of grant applications; (2) provides oversight for and/or coordinates scientific review activities with the staff of NCMHD programs and with the Center for Scientific Review, NIH and/or with offices of review within relevant NIH Institutes and Centers, as required; (3) provides policy direction and coordination for planning and executing initial scientific and technical reviews of applications for grants and contracts conducted within the Center, as required; (4) coordinates the identification and selection of qualified experts to serve on review committees and assists with the review of grant applications and contract proposals, as required; (5) serves as an information and coordination center for all grant applications and contract proposals pending review by the unit; (6) supervises the scientific review administrators for the initial scientific review of grant proposals reviewed within NCHMD; (7) maintains uniform policies and procedures governing technical review of grant applications and contract proposals within NCHMD; (8) provides administrative and technical support in the development, execution, and monitoring of grant and contract programs, as required; (9) provides oversight and direction for the grants management functions of the NCHMD; and (10) maintains liaison with grants and contracts management staffs in other Institutes and Centers, with central OD/NIH offices, grantees, and contractors.

Office of Communications and Public Liaison (NE14, formerly HNE14). (1) Disseminates information on scientific and policy developments related to the mission of the Center; (2) plans and implements a comprehensive information and communications program; (3) coordinates with the NIH Institutes and Centers on minority health disparities research and research on other health disparities for the purposes of serving as a clearinghouse and focal point for disseminating information on the goals and advances in these programs; (4) maintains liaison with the NIH Office of Communications and Public Liaison; (5) provides oversight for the maintenance of the Center's website; and (6) provides leadership and coordinates with the Division of Scientific Planning and Analysis on issues related to trans-NIH conferences and/or other conferences and workshops of relevance to the mission of the Center.

Office of Research Training and Capacity Building (NE15, formerly HNE15). (1) Provides leadership in implementing the trans-NIH strategic plan to improve the effectiveness of all NIH programs aimed at increasing minority participation in biomedical research; (2) develops and implements outreach and science education initiatives aimed at increasing the participating of underrepresented minorities in biomedical research; (3) develops and implements initiatives aimed at building health disparity research capacity at minority institutions, minority-serving institutions, and at designated centers of excellence; (4) develops and implements an extramural loan repayment program with a focus on expanding the cadre of clinical investigators engaged in minority health disparities research and research on other health disparities; and (5) creates innovative initiatives aimed at increasing underrepresented minority investigators' access to NIH funding opportunities.

Division of Research (NE2, formerly HNE2). (1) Advises the Center Director on matters relating to minority health disparities research and research on other health disparities, including enhancing the participation of underrepresented minorities in research; (2) advises the Center Director during the consultative process of establishing NIH-wide goals for minority health disparities research, research on other health disparities, research and training, and on the development of the trans-NIH health disparities strategic plan; (3) provides leadership in implementing the trans-NIH health disparities strategic plan to improve the effectiveness of all NIH programs aimed at increasing NIH-supported research on diseases and conditions that disproportionately affect racial and ethnic minorities and other "health disparity groups,"; and (4) creates initiatives to enhance inclusion as well as targeted minority health disparities research and research on other health disparities.

Division of Community-Based Research and Outreach (NE3, formerly HNE3). (1) Develops and implements partnering initiatives to promote cooperation among Federal agencies, State, local, tribal, and regional public health agencies, and private entities in minority health disparities research and research on other health disparities as required by the Minority Health and Health Disparities Research and Education Act of 2000; (2) develops and implements a community-based research program for the National Institutes of Health with a focus on disease prevention, implementation of health messages in relevant racial and ethnic minority and disadvantaged communities, and elucidating barriers to effective health care, etc; and (3) coordinates with appropriate DHHS organizations and other Federal entities on programs of relevance to the mission of the Center.

Division of Scientific Planning and Policy Analysis (NE4, formerly HNE4). (1) Advises the Center Director regarding the analysis and evaluation of Center-supported programs, as requested; (2) represents the Center Director, as requested, on the trans-NIH Coordinating Committee during the consultative process of identifying annual trans-NIH priorities in regard to minority health disparities research, research training and capacity building, and research on other health disparities, including the allocation of resources in support of identified priorities; (3) provides program support for trans-NIH conferences and/or other conferences and workshops of relevance to the mission of the Center; (4) develops major policy and program recommendations, as requested by the Director, NIH, based on an evaluation of the status of support and accomplishments of NCMHD-supported programs; (5) conducts the Center's legislative liaison activities; and (6) serves as the clearinghouse and focal point for interpreting the goals and results of Center-supported research programs and projects for disseminating information to Congress and the Executive Branch.

Office of Scientific and Strategic Planning (NE42, formerly HNE42). (1) Coordinates, as requested, with the Center's Director on the development of a trans-NIH health disparities strategic plan; (2) assists and advises the Director in preparation for Congressional testimony and hearings and in the development of justifications for resource appropriations; (3) develops annual reports reflecting the status of trans-NIH implementation of initiatives, including executive orders, related to minority health disparities research and research on other health disparities, including those designed to enhance research and training capacity at minority and minority-serving institutions; and (4) conducts the Center's Freedom of Information and Privacy Act activities.

Office of Program Analysis and Data Management (NE43, formerly HNE43). (1) Coordinates, as required, with the Office of Scientific Planning, NCMHD, on the development of annual reports reflecting the status of trans-NIH implementation of initiatives, including executive orders, related to minority health disparities research and research on other health disparities, including those designed to enhance research and training capacity at minority and minority-serving institutions; (2) represents the Center, as requested, in the development, implementation, and monitoring of a trans-NIH coding system for identifying "targeted" and "inclusion" research and training initiatives as it relates to "health disparity populations" as well as identifying infrastructure and capacity building awards made to minority and minority-serving institutions; (3) collects and maintains data on trans-NIH programs and activities aimed at reducing and/or eliminating health disparities; (4) provides oversight for the development of the Health Disparities Information (HDI) System, a database for identifying and tracking all NIH-supported minority health disparities research, research on other health disparities, research training, and construction projects data; (5) acquires data and performs analyses for use in NCMHD planning and development; and (6) coordinates the presentation of the Center's plans and reports.

Delegations of Authority Statement: All delegations and redelegations of authority to offices and employees of NIH that were in effect immediately prior to the effective date of this reorganization and are consistent with this reorganization shall continue in effect, pending further redelegation.

Dated: January 16, 2001.

Donna E. Shalala,

Secretary, Department of Health and Human Services.

[FR Doc. 01–1808 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30DAY–15–01]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7090. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

Proposed Project

A Survey of Pediatricians' Attitudes and Practices about Promoting Communication between Parents and Their Children about Sexuality and Sexual Risk—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC). CDC proposes to assess pediatricians' attitudes, beliefs, and practices regarding promotion of parent-child communication about sexuality and sexual risk, and barriers to offering sexual health counseling to parents. The survey will assess which services are currently offered by physicians (e.g., discussions, pamphlets, videos, referrals to educational programs); when and to whom physicians offer services; the barriers that prevent physicians from offering services; and the types of services pediatricians believe are feasible to offer. Results of this survey will be used to develop effective programs to help pediatricians facilitate communication between parents and children about sexuality and STD/HIV prevention. Increasing parent-adolescent communication about sexuality and STD/HIV is important because many adolescents are having unprotected sex at an early age, and although parent-adolescent communication has been found to be associated with lower sexual risk behavior among adolescents, many parents are not talking to their adolescents. Thus, strategies are needed to inform parents about the benefits of communication as a way to enhance their child's sexual health. Consistent with recommendations from the American Medical Association and the

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American Academy of Pediatrics, physicians can play an important role in educating parents about ways to promote their child's sexual health. The total annual burden for this project is 300 hours.

Respondents	Number of respondents	Number of responses	Average hour burden per response
Pediatricians	900	1	20/60

Dated: January 16, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1763 Filed 1–19–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1283]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by February 21, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling Regulations—21 CFR Parts 101, 102, 104, and 105 (OMB Control No. 0910–0381)—Extension

FDA regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. FDA's food labeling regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and of sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the act and the FPLA.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.9(g)(9) also provides for the submission to FDA of requests for alternative approaches to nutrition labeling. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling.

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(b) provides the reference amount that is used for determining the serving sizes for baking powder, baking soda, and pectin. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show FDA detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC. Section 101.12(h) provides for the submission of petitions to FDA to request changes in the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares the level of a nutrient in the food with the level of the same nutrient in another "reference" food, the claim must also disclose the identity of the reference food, the amount of the nutrient in each food, and the percentage or fractional amount by which the amount of the nutrient in the labeled food differs from the amount of the nutrient in the reference food. It also requires that when this comparison is based on an average of served foods, this information must be provided to consumers or regulatory officials upon request. Section 101.13(q)(5) requires that restaurants document and provide to appropriate regulatory officials, upon request, the basis for any nutrient content claims they have made for the foods they sell.

Section 101.14 provides for the disclosure of nutrition information in accordance with § 101.9 and, under some circumstances, certain other information as a condition for making a health claim for a food product. Section 101.15 provides that, if the label of a food product contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in both the foreign language and in English. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives in food products. Section 101.22(i)(4) sets forth reporting and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavor. Section 101.30 specifies the conditions under which a beverage that purports to contain any fruit or vegetable juice must declare the percentage of juice present in the beverage and the manner in which the declaration is to be made.

Section 101.36 requires that nutrition information be provided for dietary supplements offered for sale, unless an exemption in § 101.36(h) applies. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to FDA of requests for alternative approaches to nutrition labeling. Also, § 101.36(h)(2) cross-references the provisions in § 101.9(j)(18) for the submission of small business exemption notices.

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruits, vegetables, and fish at the point of purchase, and § 101.45 contains guidelines for providing such information. Also, § 101.45(c) provides for the submission of nutrient data bases and proposed nutrition labeling values for raw fruit, vegetables, and fish to FDA for review and approval.

Sections 101.54, 101.56, 101.60, 101.61, and 101.62 specify information that must be disclosed as a condition for making particular nutrient content claims. Section 101.67 cross-references requirements in other regulations for ingredient declaration (§ 101.4) and disclosure of information concerning performance characteristics (§ 101.13(d)). Section 101.69 provides for the submission of a petition requesting that FDA authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that FDA authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure of the amount of soluble fiber per serving in the nutrition labeling of a food bearing a health claim about the relationship between soluble fiber and a reduced risk of coronary heart disease. Section 101.79(c)(2)(iv) requires the disclosure of the amount of folate per serving in the nutrition labeling of a food bearing a health claim about the relationship between folate and a reduced risk of neural tube defects.

Section 101.100(d) provides that any agreement that forms the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the act be in writing and that a copy of the agreement be made available to FDA upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions.

Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form and prescribes conditions under which a food whose label does not accurately reflect the actual quantity of contents may be sold, with appropriate disclosures, to an institution operated by Federal, State, or local government. Section 101.108 provides for the submission to FDA of a written proposal requesting a temporary exemption from certain requirements of §§ 101.9 and 105.66 for the purpose of conducting food labeling experiments with FDA's authorization.

Regulations in part 102 define the information that must be included as part of the statement of identity for particular foods and prescribe related labeling requirements for some of these foods. For example, § 102.22 requires that the name of a protein hydrolysate shall include the identity of the food source from which the protein was derived.

Part 104, which pertains to nutritional quality guidelines for foods, cross-references several labeling provisions in part 101 but contains no separate information collection requirements.

Part 105 contains special labeling requirements for hypoallergenic foods, infant foods, and certain foods represented as useful in reducing or maintaining body weight.

The disclosure and other information collection requirements in the above regulations are placed primarily upon manufacturers, packers, and distributors of food products. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants.

The purpose of the food labeling requirements is to allow consumers to be knowledgeable about the foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to FDA provide the basis for the agency to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable FDA to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the act or the FPLA.

In the **Federal Register** of October 10, 2000 (65 FR 60195), the agency requested comments on the proposed collection of information. The agency received several comments, none of which were relevant to the PRA.

FDA estimates the burden of this collection of information as follows:

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TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Sections and Parts	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours	Total Capital, Operating, and Maintenance Costs
101.3 and 101.22, and 102 and 104	17,000	1.03	17,500	0.5	8,750	0
101.4, 101.22, and 101.100, and 102, 104, and 105	17,000	1.03	17,500	1	17,500	0
101.5	17,000	1.03	17,500	0.25	4,375	0
101.9, 101.13(n), 101.14(d)(3), and 101.62, and 104	17,000	1.03	17,500	4	70,000	$1,000,000
101.9(g)(9) and 101.36(f)(2)	12	1	12	4	48	0
101.9(j)(18) and 101.36(h)(2)	10,000	1	10,000	8	80,000	0
101.10	265,000	1.5	397,500	0.25	99,375	0
101.12(b)	29	2.3	66	1	66	$39,600
101.12(e)	25	1	25	1	25	0
101.12(g)	5,000	1	5,000	1	5,000	0
101.12(h)	5	1	5	80	400	$400,000
101.13(d)(1) and 101.67	200	1	200	1	200	0
101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62	2,500	1	2,500	1	2,500	0
101.13(q)(5)	265,000	1.5	397,500	0.75	298,125	0
101.14(d)[2]	265,000	1.5	397,500	0.75	298,125	0
101.15	160	10	1,600	8	12,800	0
101.22(i)(4)	25	1	25	1	25	0
101.30 and 102.33	1,500	3.3	5,000	1	5,000	0
101.36	300	40	12,000	4	48,000	$15,000,000
101.42 and 101.45	72,270	1	72,270	0.50	36,135	0
101.45(c)	5	4	20	4	80	0
101.69	3	1	3	25	75	0
101.70	3	1	3	80	240	$400,000
101.77(c)(2)(ii)(D)	1,000	1	1,000	0.25	250	0
101.79(c)(2)(iv)	100	1	100	0.25	25	0
101.100[2]	1,000	1	1,000	1	1,000	0
101.105 and 101.100(h)	17,000	1.03	17,500	0.5	8,750	0
101.108	0	0	0	40	0	0
Total					998,869[1]	$16,800,000

[1]Due to a clerical error, the total that appeared in table 1 in the **Federal Register** of Tuesday, October 10, 2000 (65 FR 60195), was incorrect. Table 1 of this document contains the correct estimates.
[2]Sections 101.14(d)(2) and 101.100(d) were incorrectly cited in table 1 in the **Federal Register** of Tuesday, October 10, 2000 (65 FR 60195). Table 1 of this document contains the correct citations.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeepers	Total Annual Records	Hours per Record	Total Hours	Total Capital, Operating, and Maintenance Costs
101.12(e)	25	1	25	1	25	0

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeepers	Total Annual Records	Hours per Record	Total Hours	Total Capital, Operating, and Maintenance Costs
101.13(q)(5)	265,000	1.5	397,500	0.75	298,125	0
101.14(d)(2)	265,000	1.5	397,500	0.75	298,125	0
101.22(i)(4)	25	1	25	1	25	0
101.100(d)(2)	1,000	1	1,000	1	1,000	0
101.105(l)	100	1	100	1	100	0
Total					597,400	0

These estimates are based on the document entitled "Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations," which is the agency's most recent comprehensive review of food labeling costs that published in the **Federal Register** of January 6, 1993 (58 FR 2927); agency communications with industry; and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: January 12, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–1567 Filed 1–19–01; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1571]

Enrofloxacin for Poultry; Opportunity for Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Veterinary Medicine (CVM), is revising a notice of opportunity for hearing (NOOH) that published in the **Federal Register** on October 31, 2000 (65 FR 64954). After publishing the NOOH, CVM determined that some estimates of numbers of human campylobacteriosis cases and fluoroquinolone-resistant *Campylobacter* cases provided by a risk assessment used as a reference in the NOOH were incorrect. CVM has revised the risk assessment and is revising the estimates that were provided in the NOOH. This notice also extends the deadline for the sponsor to submit data and analysis upon which a request for a hearing relies. Other interested persons may submit comments on the NOOH before the deadline.

DATES: Submit all written data and analysis upon which a request for a hearing relies and other written comments by February 21, 2001.

ADDRESSES: Data and analysis and other comments are to be identified with Docket No. 00N–1571 and must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The revised risk assessment entitled "The Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, Revised: January 5, 2001" (hereafter referred to as Ref. 2a) is available electronically at http://www.fda.gov/cvm/antimicrobial/antimicrobial.html and in this docket.

FOR FURTHER INFORMATION CONTACT: Linda Tollefson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–2950.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2000 (65 FR 64954), CVM published an NOOH proposing withdrawal of the approval of a new animal drug application (NADA) for the use of the fluoroquinolone enrofloxacin in poultry. The NOOH included estimates that were taken from Ref. 2 of the October 31, 2000, NOOH, the risk assessment entitled "Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, October 18, 2000." After publication of the NOOH, CVM determined that two of the cell references in the risk assessment were mislabeled and as a result, the model outputs were incorrect. CVM has revised the risk assessment to correct the cell references. Because CVM needed to make these corrections to the risk assessment, it has also incorporated the final FoodNet data for 1999 into the risk assessment and has made other related changes. CVM is revising the NOOH to reflect the changes in the risk assessment and to add the revised risk assessment Ref. 2a to the list of references in the NOOH. CVM does not believe that these revisions in any way alter the underlying basis of the NOOH.

The following section describes the location and revisions to the October 31, 2000, NOOH.

II. Revisions

Based on the revisions to the risk assessment, CVM is revising the estimates in the October 31, 2000, NOOH for the mean estimate of cases of campylobacteriosis; the mean estimate of the domestically-acquired

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fluoroquinolone-resistant *Campylobacter* cases in humans attributable to consumption of chicken; and the mean estimate of the number of people who were infected with fluoroquinolone-resistant *Campylobacter* from consuming or handling chicken and who subsequently received a fluoroquinolone as therapy for their illness. CVM is also adding the revised risk assessment to the References section of the NOOH.

Table 1 provides the location and actual revisions of items in the NOOH.

TABLE 1.—REVISIONS TO THE OCTOBER 31, 2000, NOOH

Location	Sentence as published	Correction
64955, 2d column, beginning on the 9th line from bottom of page	The risk assessment determined * * * a mean estimate of 11,477 persons (5th and 95th percentiles: 6,412 and 18,978) * * *"	"The risk assessment determined * * * a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) * * *"
64962, 1st column, beginning on the 8th line	"Using the data on human *Campylobacter* * * * calculated a mean estimate of 1.7 million cases of campylobacteriosis (5th and 95th percentiles: 1.1 million and 2.7 million) for 1999 (Ref. 2)."	"Using the data on human *Campylobacter* * * * calculated a mean estimate of 1.4 million cases of campylobacteriosis (5th and 95th percentiles: 0.9 million and 2.1 million) for 1999 (Ref. 2a)."
64962, 1st column, 1st full paragraph, beginning on the 7th line from the bottom of the paragraph	"For 1999, the mean estimate of * * * is 190,421 (5th and 95th percentiles: 103,471 and 318,321) (Ref. 2)."	"For 1999, the mean estimate of * * * is 153,580 (5th and 95th percentiles: 83,990 and 258,047) (Ref. 2a)."
64962, 1st column, 2d full paragraph, beginning on the 7th line	"For 1999, the estimated * * * 11,477 (5th and 95th percentiles: 6,412 and 18,978) (Ref. 2)."	"For 1999, the estimated * * * a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) (Ref. 2a)."
64962, 2d column, 1st full paragraph, beginning on the 13th line from the bottom of the paragraph	"The risk assessment determined in 1999 a mean estimate of 11, 477 people (5th and 95th percentiles: 6,412 and 18,978) * * *"	"The risk assessment determined in 1999 a mean estimate of 9,261 people (5th and 95th percentiles: 5,227 and 15,326) * * *"
64963, 2d column under IX. References, between Refs. 2 and 3		Insert the following reference between Refs. 2 and 3: "2a. The Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, Revised: January 5, 2001."

Dated: January 16, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–1866 Filed 1–18–01; 11:03 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1685]

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, a New General Test Procedure, and Revisions to a Policy; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, a proposed new general test procedure, and proposed changes to a policy in the fourth edition. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients and to a policy, as well as new monographs and a new general test procedure, are being prepared by The National Academies, Institute of Medicine (IOM), Committee on Food Chemicals Codex (the committee). This material is expected to be included in the next publication of the Food Chemicals Codex (the third supplement to the fourth edition), scheduled for public release in the summer of 2001.

DATES: Submit written comments by March 8, 2001. (The committee advises that comments received after this date may not be considered for the third supplement to the fourth edition. Comments received too late for consideration for the third supplement will be considered for later supplements or for a new edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO–3042, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the proposed new Food Chemicals Codex specification monographs, proposed changes to certain monographs, the proposed new general test procedure, and the proposed changes to a policy may be obtained upon written request from the IOM (address above) or may be examined at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs, general test procedure, or policy desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ricardo Molins, Project Director/FO–3042, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or

Paul M. Kuznesof, Division of Product Manufacture and Use (HFS–246), Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

SUPPLEMENTARY INFORMATION: By contract with the IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.

In the **Federal Register** of August 8, 2000 (65 FR 48521), FDA announced that the committee was considering revised monographs, new and revised general test procedures, and revised test solutions for inclusion in the third supplement to the fourth edition of the Food Chemicals Codex. FDA is now announcing that the committee is soliciting comments and information on proposed new Food Chemicals Codex specification monographs, additional proposed changes to certain monographs, a proposed new general test procedure, and proposed changes to a policy. These new and revised monographs, new general test procedure, and revised policy are also expected to be published in the third supplement to the fourth edition of the Food Chemicals Codex. Copies of the proposed items may be obtained upon written request from IOM at the address listed above or through the Internet at http://www.iom.edu/fnb/fcc.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new and revised monographs, new general test procedure, or revised policy into FDA regulations without ample opportunity for public comment. If FDA decides to propose the adoption of new monographs and changes that have received final approval of the committee, it will announce its intention and provide an opportunity for public comment in the **Federal Register**.

The committee invites comments and suggestions by all interested parties on specifications to be included in the 14 proposed new monographs, proposed revisions of 24 current monographs, proposed new general test procedure, and proposed revisions to a policy listed below:

I. Proposed New Monographs

Flavor Chemicals
Acetaldehyde Diethyl Acetal
2-Acetyl Thiazole
Allyl Phenoxy Acetate
Allyl Propionate
Borneol
Butyl 2-Methyl Butyrate
2-sec-Butyl Cyclohexanone
Diphenyl Ether
d-Fenchone
Fenchyl Alcohol
Furfuryl Alcohol
2-Furyl Methyl Ketone
Salatrim
Soy Protein Concentrate

II. Current Monographs to Which the Committee Proposes to Make Revisions

Ammonium Phosphate, Monobasic (fluoride test corrected)
Carmine (description and assay test revised)
Enzyme Preparations (classifications and reactions added for α-Acetolactatedecarboxylase; Aminopeptidase, Leucine; and Lysozyme)
Flavor Chemicals
Cinnamic Acid (solubility in alcohol revised)
d-Dihydrocarvone (solubility in alcohol revised)
2-Heptanone (specific gravity revised)
Hexyl Isovalerate (solubility in alcohol revised)
Isoamyl Benzoate (solubility in alcohol revised)
Nerolidol (assay revised)
(Z)-6-Nonen-1-ol (refractive index revised)
alpha-Pinene (angular rotation revised)
2-Undecenol (specific gravity revised)
Potassium Phosphate, Monobasic (fluoride test corrected)
Potassium Phosphate, Tribasic (fluoride test corrected)
Potassium Pyrophosphate (fluoride test corrected)
Potassium Tripolyphosphate (fluoride test corrected)
Sodium Acid Pyrophosphate (fluoride test corrected)
Sodium Metaphosphate, Insoluble (fluoride test corrected)
Sodium Phosphate, Dibasic (fluoride test corrected)
Sodium Phosphate, Monobasic (fluoride test corrected)
Sodium Polyphosphate, Glassy (fluoride test corrected)
Sodium Potassium Tripolyphosphate (fluoride test corrected)
Sodium Trimetaphosphate (fluoride test corrected)
Sodium Tripolyphosphate (fluoride test corrected)

III. Proposed New General Test Procedure

Lipase (Microbial) Activity for Medium- and Long-Chain Fatty Acids (new enzyme assay)

IV. Proposed Revised Policy

Heavy Metals Limits Policy (reference to heavy metals as lead removed, additional revisions)

V. Comments and Electronic Access

Interested persons may, on or before March 8, 2001, submit to the Committee on Food Chemicals Codex written comments regarding the monographs, general test procedure, and proposed revision of the policy identified in this notice. Timely submission will ensure that comments are considered for the third supplement to the fourth edition of the Food Chemicals Codex. Comments received after this date may not be considered for the third supplement, but will be considered for subsequent supplements or for a new edition of the Food Chemicals Codex. Those wishing to make comments are encouraged to submit supporting data and documentation with their comments. Two copies of any comments regarding the monographs, general test procedure, or policy listed in this notice are to be submitted to the Committee on Food Chemicals Codex (address above). Comments and supporting data or documentation are to be identified with the docket number found in brackets in the heading of this document and each submission should include the statement that it is in response to this **Federal Register** notice. The committee staff will forward a copy of each comment to the Dockets Management Branch (address above). Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies may also be obtained through the Internet at http://www.iom.edu/fnb/fcc.

Dated: January 10, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–1713 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 5, 2001, from 8 a.m. to 6 p.m.

Location: Gaithersburg Marriott Washingtonian Center Salons F and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

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Contact Person: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 171, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and make recommendations on a premarket submission for a distal protection device used in the treatment of saphenous vein graft disease. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for distal protection devices used in diseased saphenous vein grafts.

Procedure: On February 5, 2001, from 8 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 26, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m., and a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee near the end of the panel deliberations on February 5, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 26, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 5, 2001, from 3 p.m. to 6 p.m., the meeting will be closed to the public to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)) regarding pending and future circulatory system device submissions. In addition, the committee will discuss and review trade secret and/or confidential commercial information presented by a sponsor.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 12, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–1712 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0001]

Regulatory Procedures Manual; Chapter 9: Import Operations/Action, Subchapter: Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new subchapter of the Regulatory Procedures Manual. The new subchapter is entitled "Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food." This subchapter has been provided to FDA's field offices to provide procedures for communication with the U.S. Customs Service (U.S. Customs) regarding assessment of civil monetary penalties involving imported foods. The subchapter is located in FDA's Regulatory Procedures Manual.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the subchapter entitled "Communication Concerning Assessment of Civil Monetary Penalties by U.S. Customs Service in Cases Involving Imported Food" to Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the subchapter.

Submit written comments on the subchapter to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

On July 3, 1999, the President announced an initiative to ensure the safety of imported food by directing the Secretary of Health and Human Services (DHHS) and the Secretary of Treasury to develop new operational procedures to protect the public health. The initiative is geared to optimize the statutory authorities and resources available to FDA, DHHS and U.S. Customs, Department of Treasury to protect consumers from unsafe imported foods. The President directed the agencies to target unscrupulous importers who violate the import laws and work to subvert the system by introducing unsafe foods into U.S. markets. Six specific objectives were emphasized in the directive.

On December 11, 1999, the President announced the plan developed by FDA and U.S. Customs in response to the directive of July 3, 1999. One element of the plan was to enhance enforcement by having U.S. Customs assess civil monetary penalties in cooperation with FDA. The subchapter now being announced is setting out the procedures for accomplishing this objective.

The subchapter does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs, or the public. The subchapter is being distributed in accordance with FDA's policy for Level 2 guidance documents as set out in the agency's good guidance practices regulation, published in the **Federal Register** of September 19, 2000 (65 FR 56468).

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this subchapter. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies of the subchapter at http://www.fda.gov/ora.

Dated: January 12, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–1699 Filed 1–17–01; 11:07 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0002]

Regulatory Procedures Manual; Chapter 9: Import Operations/Action, Subchapter: Secured Storage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new subchapter of the Regulatory Procedures Manual. The new subchapter is entitled "Secured Storage." This subchapter has been provided to FDA's field offices to provide operational procedures for identifying those importers who should be referred to the U.S. Customs Service (U.S. Customs) so that U.S. Customs can require those importers to place their imported foods into secured storage under the control of U.S. Customs pending a decision by FDA of their admissibility. The subchapter is located in Chapter 9 of FDA's Regulatory Procedures Manual.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the subchapter entitled "Secured Storage" to Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the subchapter to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the subchapter.

FOR FURTHER INFORMATION CONTACT: Joseph L. McCallion, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

On July 3, 1999, the President announced an initiative to ensure the safety of imported food by directing the Secretary of the Department of Health and Human Services (DHHS) and the Secretary of the Treasury to develop new operational procedures to protect the public health. The initiative is geared to optimize the statutory authorities and resources available to the FDA, DHHS, and the U.S. Customs, Department of the Treasury, to protect consumers from unsafe imported foods. The President directed the agencies to target unscrupulous importers who violate the import laws and work to subvert the system by introducing unsafe foods into U.S. markets. Six specific objectives were emphasized in the directive.

On December 11, 1999, the President announced the plan developed by FDA and U.S. Customs in response to the directive of July 3, 1999. One element of the plan was to prevent distribution of imported unsafe food by requiring importers with a history of illegal distribution, misrepresentation, or substitution to hold future shipments in secure storage facilities until specifically released by FDA. The subchapter now being made available is setting out the procedures for accomplishing this objective.

The subchapter does not create or confer any rights, privileges, or benefits for, or on, any person and does not operate to bind FDA, U.S. Customs, or the public. The subchapter is being distributed in accordance the FDA's policy for Level 2 guidance documents as set out in the agency's good guidance practices, published in the **Federal Register** of September 19, 2000 (65 FR 56468).

II. Comments

Interested persons may, at any time, submit written comments to the Dockets Management Branch (address above) regarding this new subchapter. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the subchapter and any received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain a copy of this subchapter at http://www.fda.gov/ora.

Dated: January 12, 2001.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–1700 Filed 1–17–01; 11:07 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0025]

Guidance for Industry on FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "FDA Recommendations for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues." Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn using recombinant deoxyribonucleic acid (DNA) techniques to make the corn more resistant to certain types of insects. StarLink™ corn is lawful only for use in animal feed, not human food. However, some Cry9C-containing corn was commingled with yellow corn intended for human use. This document outlines the approach that FDA recommends to manufacturers of corn products for human food use for sampling and testing yellow corn (and milled yellow corn in certain situations) in order to minimize the production of human food products with corn containing the Cry9C protein.

DATES: Submit written comments concerning this guidance to the Dockets Management Branch (address below) by March 23, 2001. After March 23, 2001, submit written comments to the contact person (address below).

ADDRESSES: Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to Lauren M. Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321. Send one self-adhesive address label to assist that office in processing your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and comments received by March 23, 2001, are available for public

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examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lauren M. Posnick, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321, FAX 202–205–4422, e-mail: lposnick@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing guidance for industry on sampling and testing for the presence of Cry9C protein residues in yellow corn (and milled yellow corn in certain situations) intended for human food use. Cry9C is a pesticidal protein that was introduced into the StarLink™ variety of yellow corn to make the corn more resistant to certain types of insects. The Environmental Protection Agency (EPA) authorized StarLink™ corn only for use in animal feed, not human food. EPA has not authorized the use of StarLink™ corn in human food because there is an unresolved question about the allergenic potential of the Cry9C protein.

Although restricted to animal food use, some StarLink™ corn was commingled with yellow corn intended for human use. In addition, in certain limited cases, the Cry9C protein has also been detected in corn seeds of a non-StarLink™ variety of corn or in corn from such seeds. Aventis S.A., the developer of StarLink™, in cooperation with the U.S. Department of Agriculture, has been buying back harvested StarLink™ corn from the year 2000 crop to prevent its introduction into the human food supply. Because some Cry9C-containing corn may have been missed in the buy-back program and because some StarLink™ corn from the 1999 crop may still be in some grain elevators, FDA is urging corn dry-milling and masa operations to screen yellow corn (and milled yellow corn in certain situations) to minimize the production of human food products with corn containing the Cry9C protein. Because corn containing the Cry9C pesticide is adulterated if intended for human food use (21 U.S.C. 342(a)(2)(B)), manufacturers who detect Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.

The guidance document contains FDA's recommendations to dry milling and masa operations for sampling and testing yellow corn shipments; the guidance recommends appropriate tests, representative sampling procedures, appropriate analytical procedures, and appropriate personnel training. FDA believes these recommendations will help manufacturers to identify those lots of corn that contain the StarLink™ variety commingled with other yellow corn and avoid the use of such corn in human food products.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking on sampling and testing yellow corn for residues of the Cry9C protein. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. To the extent that use of this guidance helps millers and food manufacturers avoid the production of human food containing Cry9C residues, the guidance will help prevent human exposure to a potential food allergen and will otherwise help prevent adulteration of the food supply. Due to the urgent need to convey the sampling and testing recommendations to members of the food industry to help prevent the further introduction of Cry9C-containing corn into the human food supply, FDA conveyed the substance of this guidance to affected millers and food manufacturers in a letter dated December 27, 2000 (Ref. 1). Similarly, FDA is making this guidance document effective immediately because public participation prior to its implementation is not appropriate in these circumstances (21 CFR 10.115(g)(2); 65 FR 56478). However, in its letter of December 27, 2000, FDA recognized that some dry milling and masa operations may have inventories of stored grain or meal that have not been tested or have not been tested as described in the guidance document. Consistent with that advice, the agency is recommending that manufacturers that choose to follow this sampling guidance phase it in over a period of no more than 30 days dating from December 27, 2000.

Although the guidance document announced in this notice is being implemented immediately, FDA is requesting comments on the guidance. FDA will review all comments received, revise the guidance in response to the comments as appropriate, and publish a notice of availability of the revised guidance, if it is revised.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this immediately-in-effect guidance by March 23, 2001. After March 23, 2001, submit written comments regarding this guidance to the contact person (address above). FDA will consider such comments when determining whether to revise the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and comments received by March 23, 2001, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at www.cfsan.fda.gov.

III. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday

1. Letter and recommendations, dated December 27, 2000.

2. "Sampling and testing plan, scientific basis," January, 2000.

Dated: January 12, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–1609 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10027]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Request: New collection; Title of Information Collection: Ambulance Attachment Form; Form Number: HCFA–10027 (OMB approval #: 0938–NEW); Use: This form is used by ambulance suppliers in Missouri to report information needed to process their claims; it is an attachment to the HCFA form 1491, which is used to submit ambulance claims; Frequency: On occasion; Affected Public: Business or other for-profit, Not-for-profit institutions, State, local, or tribal gov; Number of Respondents: Total Annual Responses: 5,000; Total Annual Hours Requested: 167 hours.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, HCFA–10027; Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 10, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1724 Filed 1–19–01; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–304 and 304a]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement (Medicaid Drug Rebate Program—Labelers); *Form No.:* HCFA–304 and 304a (OMB# 0938–0676); *Use:* Section 1927 of the Social Security Act requires drug labelers to enter into and have in effect a rebate agreement with HCFA for States to receive funding for drugs dispensed to Medicaid recipients; *Frequency:* Quarterly; *Affected Public:* Business or other for-profit; *Number of Respondents:* 561; *Total Annual Responses:* 3,744; *Total Annual Hours:* 139,560. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 10, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1723 Filed 1–19–01; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0232]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Integrity Program Organizational Conflict of Interest Disclosure Certificate and Supporting Regulations at 42 CFR 421.300–421.318; *Form No.:* HCFA–R–0232 (OMB# 0938–0723); *Use:* HCFA needs this information to assess whether contractors who perform, or who seek to perform, Medicare Integrity Program functions, such as medical review, fraud review or cost audits, have organizational conflicts of interest and whether any conflicts have been resolved. The entities providing the information are organizations that have been awarded, or seek award of, a Medicare Integrity Program contract; *Frequency:* On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 10; *Total*

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Annual Responses: 10; *Total Annual Hours:* 2,400. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Wendy Taylor, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 10, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–1725 Filed 1–19–01; 8:45 am]

BILLING CODE 4120–03–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2089–CN]

RIN 0938–AK33

State Children's Health Insurance Program; Final Allotments to States, the District of Columbia, and U.S. Territories and Commonwealths for Fiscal Year 2001; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice; correction.

SUMMARY: This notice corrects the final allotments for Fiscal Year 2001 that appeared in the notice concerning the State Children's Health Insurance Program (SCHIP) published in the **Federal Register** on January 3, 2001.

EFFECTIVE DATE: This correction is effective January 3, 2001.

FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019.

SUPPLEMENTARY INFORMATION: On January 3, 2001, we published a final notice in the **Federal Register** (66 FR 376) that set forth the final allotments of Federal funding available to each State, the District of Columbia, and each U.S. Territory and Commonwealth for fiscal year (FY) 2001 under title XXI of the Social Security Act (the Act). There was an error in the computation of the FY 2001 allotments due to the fact that one of the formulas used in determining the allotments was incorrect. More specifically, the FY 1999 proportions were inadvertently applied twice in the calculation of the formula; the FY 1999 and FY 2000 proportions should have been applied instead. The term "proportion" is defined in section 2104(b)(4)(D)(I) of the Act and refers to a State's share of the total amount available for allotment for any given year. This document corrects the error made in the final notice.

Correction of Errors

In FR Doc. 01–69, published on January 3, 2001 (66 FR 376) make the following correction: On *page 379*, replace the text within the table entitled "Table of State Children's Health Insurance Program Final Allotments for FY 2001". The column descriptions and keys from the January 3, 2001 document are included to assist the reader.

Table of State Children's Health Insurance Program Final Allotments for FY 2001

Key to Table

Column/Description

Column A = Name of State, District of Columbia, U.S. Commonwealth or Territory.

Column B = Number of Children. The Number of Children for each State (provided in thousands) was determined and provided by the Bureau of the Census based on the arithmetic average of the number of low-income children and low-income uninsured children, and is based on the three most recent March supplements to the CPS of the Bureau of the Census officially available before the beginning of the calendar year in which the fiscal year begins. The FY 2001 allotments were based on the 1997, 1998, and 1999 March supplements to the CPS. These data represent the number of people in each State under 19 years of age whose family income is at or below 200 percent of the poverty threshold appropriate for that family, and who are reported to be not covered by health insurance. The Number of Children for each State was developed by the Bureau of the Census based on the standard methodology used to determine official poverty status and uninsured status in their annual March CPS on these topics.

For FY 2001, the Number of Children is equal to the sum of 50 percent of the number of low-income uninsured children in the State and 50 percent of the number of low-income children in the State.

Column C = State Cost Factor. The State Cost Factor for a State is equal to the sum of: 0.15, and 0.85 multiplied by the ratio of the annual average wages in the health industry per employee for the State to the annual wages per employee in the health industry for the 50 States and the District of Columbia. The State Cost Factor for each State was calculated based on such final wage data for each State as reported, determined, and officially available to HCFA by the BLS in the Department of Labor for each of the most recent 3 years before the beginning of the calendar year in which the fiscal year begins. The FY 2001 allotments were based on final BLS wage data for 1995, 1996, and 1997.

Column D = Product. The Product for each State was calculated by multiplying the Number of Children in Column B by the State Cost Factor in Column C. The sum of the Products for all 50 States and the District of Columbia is below the Products for each State in Column D. The Product for each State and the sum of the Products for all States provides the basis for allotment to States and the District of Columbia.

Column E = Proportion of Total. This is the calculated percentage share for each State of the total allotment available to the 50 States and the District of Columbia. The Percent Share of Total is calculated as the ratio of the Product for each State in Column D to the sum of the products for all 50 States and the District of Columbia below the Products for each State in Column D. In FR Doc. 01–69, published on January 3, 2001, this column was incorrectly calculated and resulted in errors in columns F and G.

Column F = Adjusted Proportion of Total. This is the calculated percentage share for each State of the total allotment available after the application of the floors and ceilings and after any further reconciliation needed to ensure that the sum of the State proportions is equal to one. The three floors specified in the amended statute are: (1) A floor of $2 million divided by the total of the amount available; (2) an annual floor of 90 percent of (that is, 10 percent below) the preceding fiscal year's allotment proportion; and (3) a cumulative floor of 70 percent of (that is, 30 percent below) the FY 1999 allotment proportion. There is also a cumulative ceiling of 145 percent of (that is, 45 percent above) the FY 1999 allotment proportion.

Column G = Allotment. This is the SCHIP allotment for each State, Commonwealth, or Territory for the fiscal year. For each of the 50 States and the District of Columbia, this is determined as the Adjusted Proportion of Total in Column F for the State multiplied by the total amount available for allotment for the 50 States and the District of Columbia for the fiscal year.

For each of the U.S. Territories and Commonwealths, the allotment is determined as the Proportion of Total in Column E multiplied by the total amount available for allotment to the U.S. Territories and Commonwealths. For the U.S. Territories and Commonwealths, the Proportion of Total in Column E is specified in section 2104(c) of the Act. The total amount is then allotted to the U.S. Territories and Commonwealths according to the percentages specified in section 2104 of the Act. There is no adjustment made to the allotments of the U.S. Territories and Commonwealths as they are not subject to the application of the floors and ceiling. As a result, Column F in the table, the Adjusted Proportion of Total, is empty for the U.S. Territories and Commonwealths.

CORRECTED SCHIP ALLOTMENTS FOR FEDERAL FISCAL YEAR 2001 [1]

A State	B Number of children (00)	C State cost factor	D Product	E Proportion of total [4]	F Adjusted proportion of total [4] (percent)	G Allotment [2]
Alabama	302	0.9659	291.71	1.52	1.65	$69,311,033
Alaska	41	1.0392	42.61	0.22	0.21	8,987,100
Arizona	542	1.0514	569.88	2.96	2.96	124,519,004
Arkansas	277	0.8931	246.94	1.28	1.28	53,957,231
California	2,905	1.1108	3,226.23	16.77	16.77	704,930,926
Colorado	204	1.0017	204.34	1.06	1.06	44,648,559
Connecticut	162	1.1165	180.31	0.94	0.94	39,398,021
Delaware	51	1.0889	54.99	0.29	0.25	10,505,758
District of Columbia	42	1.2960	53.78	0.28	0.28	11,751,544
Florida	978	1.0305	1,007.86	5.24	5.24	220,217,905
Georgia	621	0.9953	618.09	3.21	3.21	135,053,332
Hawaii	74	1.1690	85.92	0.45	0.28	11,669,166
Idaho	110	0.8893	97.83	0.51	0.49	20,715,109
Illinois	787	0.9966	783.85	4.07	3.80	159,838,759
Indiana	298	0.9234	274.71	1.43	1.43	60,023,791
Iowa	178	0.8469	150.76	0.78	0.78	32,940,215
Kansas	154	0.8719	134.27	0.70	0.70	29,337,719
Kentucky	276	0.9276	256.02	1.33	1.33	55,939,972
Louisiana	396	0.8876	351.06	1.82	1.95	82,017,657
Maine	68	0.9049	61.53	0.32	0.32	13,444,691
Maryland	225	1.0460	235.34	1.22	1.22	51,422,315
Massachusetts	292	1.0495	305.92	1.59	1.33	55,879,946
Michigan	573	1.0074	576.71	3.00	2.84	119,473,472
Minnesota	255	0.9824	250.02	1.30	0.88	37,042,610
Mississippi	289	0.8882	256.24	1.33	1.33	55,987,988
Missouri	326	0.9204	299.59	1.56	1.56	65,460,375
Montana	83	0.8415	69.42	0.36	0.36	15,169,315
Nebraska	102	0.8563	87.34	0.45	0.45	19,084,374
Nevada	120	1.1954	143.45	0.75	0.75	31,344,200
New Hampshire	58	0.9826	56.99	0.30	0.28	11,932,994
New Jersey	403	1.1237	452.28	2.35	2.35	98,823,044
New Mexico	219	0.9225	201.56	1.05	1.21	50,766,995
New York	1,360	1.0841	1,473.80	7.66	7.66	322,025,819
North Carolina	501	0.9899	495.95	2.58	2.47	103,718,942
North Dakota	48	0.8697	41.31	0.21	0.16	6,575,656
Ohio	675	0.9650	650.87	3.38	3.38	142,214,540
Oklahoma	262	0.8523	222.88	1.16	1.64	69,088,406
Oregon	228	1.0063	229.45	1.19	1.19	50,134,100
Pennsylvania	638	0.9969	636.01	3.31	3.31	138,968,854
Rhode Island	44	0.9785	42.57	0.22	0.22	9,300,803
South Carolina	294	1.0055	295.61	1.54	1.54	64,591,234
South Dakota	43	0.8703	37.42	0.19	0.19	8,177,039
Tennessee	446	0.9991	445.11	2.31	2.05	86,296,823
Texas	2,028	0.9277	1,880.82	9.77	10.76	452,531,213
Utah	153	0.9059	138.14	0.72	0.72	30,184,401
Vermont	29	0.8696	25.22	0.13	0.11	4,611,995
Virginia	350	0.9885	345.50	1.80	1.80	75,491,290
Washington	314	0.9467	296.78	1.54	1.45	60,869,643
West Virginia	108	0.8961	96.77	0.50	0.50	21,144,989
Wisconsin	241	0.9438	226.99	1.18	1.18	49,597,970
Wyoming	38	0.8779	32.92	0.17	0.17	7,193,664
Total states only			19,241.72	100.00	100.00	4,204,312,500
Allotments for commonwealths and territories [3]						
Puerto Rico				91.60		41,116,950
Guam				3.50		1,571,083
Virgin Islands				2.60		1,167,075

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CORRECTED SCHIP ALLOTMENTS FOR FEDERAL FISCAL YEAR 2001 [1]—Continued

A State	B Number of children (00)	C State cost factor	D Product	E Proportion of total [4]	F Adjusted proportion of total [4] (percent)	G Allotment [2]
American Samoa				1.20		538,650
N. Mariana Islands				1.10		493,763
Total commonwealths and territories only				100.00		44,887,500
Total states and commonwealths and territories						4,249,200,000

(1) Corrects chart that was originally published in the **Federal Register** on January 3, 2001 on pages 379-380.
(2) Total amount available for allotment to the 50 States and the District of Columbia is $4,204,312,500; determined as the fiscal year appropriation ($4,275,000,000) reduced by the total amount available for allotment to the Commonwealths and Territories under section 2104(c) of the Act ($10,687,500) and amounts for Special Diabetes Grants ($60,000,000) under sections 4921 and 4922 of the Balanced Budget Act of 1997 (BBA 1997) (Public Law 105–33).
(3) Total amount available for allotment to the Commonwealths and Territories is $10,687,500 (determined as .25 percent of $4,275,000,000, the fiscal year appropriation) plus $34,200,000 as specified in section 2104(c)(4)(B) of the Act.
(4) Percent share of total amount available for allotment to the Commonwealths and Territories is as specified in section 2104(c) of the Act.

(Authority: Section 1102 of the Social Security Act, 42 U.S.C. 1302)
(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: January 12, 2001.

Brian P. Burns,

Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 01–1690 Filed 1–19–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Uniform Data System (OMB No. 0915–0193)—Revision

This is to request a revision of approval of the Uniform Data System (UDS), which contains the annual reporting requirements for the cluster of primary care grantees funded by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA). The UDS includes reporting requirements for grantees of the following primary care programs: Community Health Centers, Migrant Health Centers, Health Care for the Homeless, Outreach and Primary Health Services for Homeless Children and Public Housing Primary Care. Authorizing Legislation is found in Public Law 104–299, Health Center Consolidation Act of 1996, enacting Section 330 of the Public Health Service Act.

The Bureau of Primary Health Care collects data on its programs to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments. To meet these objectives, BPHC requires a core set of information collected annually that is appropriate for monitoring and evaluating performance and reporting on annual trends. The UDS includes two components: the Universal Report, completed by all grantees, provides data on services, staffing, and financing; and the Grant Report, completed by grantees funded under the Homeless or Public Housing Program as well as one of the other programs, provides data on characteristics of users whose services fall within the scope of the Homeless or Public Housing Program grant. Grantees are also asked to provide information on the charges, collections, bad debt write off and contractual disallowances by payor sources (Medicaid, Medicare, self pay and private insurance). In addition, grantees need to include categories to some of the lists (*e.g.*, services, ICD codes, CPT codes) and annotating the forms to indicate which lines are subtotals and the lines to which they sum.

Estimates of annualized reporting burden are as follows:

Type of report	Number of respondents	Hours per response	Total burden hours
Universal Report	712	24	17,088
Grant Report	96	16	1,536
Total	712		18,624

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 12, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1611 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Grantee Data Reporting System for the Rural Health Outreach Grant Program (RHOGP): New

The Rural Health Outreach Grant Program (RHOGP) is one of the major grant programs managed and funded by the Office of Rural Health Policy, Health Resources and Services Administration. The overall objectives of the program are to expand access to, coordinate, restrain the cost of, and improve the quality of essential health care services, including preventive and emergency services, through the development of integrated health care delivery systems or networks in rural areas and regions. While each project has different objectives and activities, all grantee projects involve the use of Networks of three or more organizations working together to improve health care in their communities. Projects may be carried out by networks of the same providers (*e.g.*, all hospitals) or more diversified networks.

The proposed data collection instruments are intended to strengthen the Office of Rural Health Policy's (ORHP) Outreach Grant Program's existing grantee evaluation process and grantee data collection. This information collection activity will provide ORHP with an increased capacity for monitoring and evaluation and will permit the efficient review of the grant projects in relation to HRSA's strategic objectives.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Grantee Reporting Form	53	1	8	424
Year 1 Progress Report	140	1	8	1120
Year 2 Progress Report	140	1	8	1120
Final Report	53	1	12	636
Total	193			3300

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 11, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1613 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Scholarship Program for Students of Exceptional Financial Need (EFN) and Program of Financial Assistance for Disadvantaged Health Professions Students (FADHPS): Regulatory Requirements (OMB No. 0915–0028)—Reinstatement, With Change

The EFN Scholarship Program, authorized by section 736 of the Public Health Service (PHS) Act, and the FADHPS Program, authorized by section 740(a)(2)(F) of the PHS Act, provides financial assistance to schools of allopathic and osteopathic medicine and dentistry for awarding tuition scholarships to health professions students who are of exceptional financial need. To be eligible for support under the FADHPS Program, a student must also be from a

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disadvantaged background. In return for this support, students of allopathic and osteopathic medicine must agree to complete residency training in primary care in 4 years, and practice in primary care for 5 years after completing residency training.

The program regulations contain recordkeeping requirements designed to ensure that schools maintain adequate records for the government to monitor program activity and that funds are spent as intended. The estimate of burden for the regulatory requirements of this clearance are as follows:

Form	Number of respondents	Responses per respondents	Total responses	Minutes per response	Total burden hours
EFN/FADHPS	80	1	80	10	14

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 12, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1612 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of February 2001.

Name: National Advisory Council on the National Health Service Corps.

Date and Time: February 1, 2001; 6:00 p.m.–9:00 p.m.; February 2, 2001; 8:30 a.m.–4:30 p.m.; February 3, 2001; 9:00 a.m. to 5:00 p.m.; February 4, 2001; 8:30 a.m.–10:30 a.m.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852. Phone: (301) 468–1100.

The meeting is open to the public.

Agenda: The Council will focus its agenda on strategic and operational plans for the current fiscal year.

For further information, call Ms. Eve Morrow, Division of National Health Service Corps, at (301) 594–4144.

Agenda items and times are subject to change as priorities dictate.

Dated: January 12, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1610 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of February 2001.

The National Advisory Committee on Rural Health will convene its thirty-seventh meeting at the time and place specified below:

Name: National Advisory Committee on Rural Health.

Date and Time: February 4, 2001; 2:00 p.m.–4:45 p.m.; February 5, 2001; 8:30 a.m.–4:45 p.m.; and February 6, 2001; 8:30 a.m.–4:15 a.m.

Place: Washington Court Hotel, 525 New Jersey Avenue, NW., Washington, DC 20001, Phone: (202) 628–2100.

The meeting is open to the public.

Purpose: The National Advisory Committee on Rural Health provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health care services in rural areas.

Agenda: Sunday, February 4, at 2:00 p.m. the chairperson, Senator Nancy Kassebaum Baker will open the meeting and welcome the committee members. The new director of the Office of Rural Health Policy (ORHP) will give an update on office activities. The first plenary session will be a presentation on the Medicare Reform Report. The day will close at 4:45 PM.

Monday morning at 8:30 a.m., there will be presentations on federally qualified health centers and rural health clinics. After lunch, there will be a presentation on what the States are doing about the uninsured. The day will close at 4:45 PM.

Tuesday morning at 8:30 am, the Committee will discuss report recommendations. There will be a presentation on rural public health, and an update on Health Care Financing Administration (HCFA) activities. After lunch, additional presentations and discussion on the uninsured. At the end of the day the Committee will discuss future activities and next meeting. The meeting will be adjourned at 4:15 PM.

Anyone requiring information regarding the Committee should contact Marcia K. Brand, Ph.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Sandi Lyles or Lilly Smetana, Office of Rural Health Policy, (301) 443–0835. The National Advisory Committee meeting agenda will be posted on ORHP's website, www.ruralhealth.hrsa.gov.

Dated: January 16, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1714 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General; Program Exclusions: December 2000

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of December 2000, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject city, state	Effective date
Program-Related Convictions	
Ashkaryan, Gevork North Hollywood, CA	01/18/2001
Barksdale, Evelyn R Gillispie, IL	01/18/2001
Blum, Eduardo Miami, FL	01/18/2001
Brock, Danny Leslee Cottageville, SC	01/18/2001
Carbone, Francisco Weston, CT	01/18/2001
Carsillo, Richard Asheville, NC	01/18/2001
Downtown Dental Center, PA Paterson, NJ	01/18/2001
Foreman, Lenetta Grant Tahlequah, OK	01/18/2001
Gallardo, Omar Matamoras, PA	01/18/2001
Goodman, Harold F Quincy, MA	01/18/2001
Gordon, Howard Boca Raton, FL	01/18/2001
Hamlin, Donald R Burnside, KY	01/18/2001
Isola, Joseph C Norwell, MA	01/18/2001
Jackson, Robert Jerry Mt. Juliet, TN	01/18/2001
Khandwala, Nitin Livingston, NJ	01/18/2001
Kinloch-Linder, Henri Renee Walterboro, SC	01/18/2001
Lathan, Janice Macon, MS	01/18/2001
Limon, Josephine Apodaca Glendale, AZ	01/18/2001
Mack, Demetrius L Milwaukee, WI	01/18/2001
Madruga, Jorge Corona, NY	01/18/2001
Neufeld, Elliot Lance Columbus, OH	01/18/2001
Nguyen, Doi Thanh San Diego, CA	01/18/2001
O'Donnell, Carol Syracuse, NY	01/18/2001
Orthopedic Surgery of S. Shore Quincy, MA	01/18/2001
Pierce, Ben Houston, TX	01/18/2001
Ramos-Santiago, Nelson DeJesus Pensacola, FL	01/18/2001
Rodriguez, Pedro J Charlotte, NC	01/18/2001
Sailors, Betty Smith Lexington, KY	01/18/2001
Streetman, Donald Ernest Statesboro, GA	01/18/2001
Way, Latoshia E Cottageville, SC	01/18/2001
Welber, Agneta Brooklyn, NY	01/18/2001
Zwiebel, Kenneth Laurel Hollow, NY	01/18/2001
Felony Controlled Substance Conviction	
Draper, Byrant	01/18/2001
Maxwell AFB, AL	
Hogg, Amber Donee Heber Springs, AR	01/18/2001
Jenkins, Kimberly Kay Huntington BCH, CA	01/18/2001
Kennedy, John Henry Chattanooga, TN	01/18/2001
Story, Diana L Lenoir, NC	01/18/2001
Thomasson, Dustin Wade Enid, OK	01/18/2001
Walker, Pamela Demetria Marianna, FL	01/18/2001
Patient Abuse/Neglect Convictions	
Anderson, Robert Jr Hattiesburg, MS	01/18/2001
Bridges, Daniel Picayune, MS	01/18/2001
Brown, Derek Milton San Antonio, TX	01/18/2001
Brown, Carl E Rutland, VT	01/18/2001
Burrus, Shantina Marie Hopkinsville, KY	01/18/2001
Carroll, Christopher A Wesson, MS	01/18/2001
Gurwell, Kenneth Warren Susanville, CA	01/18/2001
Harvey, Raysha Kenee Long Beach, MS	01/18/2001
Hutton, Shirley Ann Columbia, MS	01/18/2001
Lambriola, Vincent P Cedar Grove, NJ	01/18/2001
Lera, Thomas Alfred Jr Galveston, TX	01/18/2001
McGregor, Clinton E Baltimore, MD	01/18/2001
Mize, Erick Wayne Stringtown, OK	01/18/2001
Moore, Kimberly E Trenton, TN	01/18/2001
Moret, Israel Bridgewater, MA	01/18/2001
Morris, Christel Rozell Tacoma, WA	01/18/2001
Potter, Rose M Columbus, OH	01/18/2001
Sledge, Katrina E Macon, MS	01/18/2001
Tanner, Karen S Columbus, OH	01/18/2001
Wallace, Arthur Cleveland Elmira, NY	01/18/2001
Williams, Roger L Belleville, IL	01/18/2001
Wrinkles, Jeffrey W. Plains, MO	01/18/2001
Controlled Substance Convictions	
Chaiet, Melvin Beltsville, MD	01/18/2001
Muhar, Ivy Mae St. Petersburg, FL	01/18/2001
License Revocation/Suspension/ Surrendered	
Abney, Dennis Burlingame, CA	01/18/2001
Allen, Joy Holley	01/18/2001
Mabelvale, AR	
Ashmore, Patricia Todd Clifton Hgts, PA	01/18/2001
Atkinson, Deborah Jean Lewisville, TX	01/18/2001
Ball, Louis Albert S. Lake Tahoe, CA	01/18/2001
Barber, Bradley James Potsdam, NY	01/18/2001
Barnes, Deborah D Newport News, VA	01/18/2001
Baumgartner, Debra L Thompson, CT	01/18/2001
Bellin, Eugene LLoyd Bronx, NY	01/18/2001
Berkness, Carrie Lee St. Francis, MN	01/18/2001
Bernhard, Kathleen Mary Port Jervis, NY	01/18/2001
Berry, Cathy Diane Gamble Hanceville, AL	01/18/2001
Bickerstaff, Delton Lee Jr Selma, AL	01/18/2001
Biljan, Sheila Marie Inver Grove Hgts, MN	01/18/2001
Braid, Byron Saul Chadds Ford, PA	01/18/2001
Brooker, Debra Marie Framingham, MA	01/18/2001
Brubaker, Susan Lynne San Anselmo, CA	01/18/2001
Bustamante, Eduardo Munoz Amherst, MA	01/18/2001
Byram, James Ray Florence, AL	01/18/2001
Camarata, Anthony Rochester, NY	01/18/2001
Campagnone, Paul J Colchester, VT	01/18/2001
Campos-Deltoro, Carolyn Anne Salem, AR	01/18/2001
Cannon, Kathy M Northridge, CA	01/18/2001
Carron, William Clark Seattle, WA	01/18/2001
Carter-Oberstone, Becky Durley	01/18/2001
Fallbrook, CA	
Chadd, Stephen Mark Corpus Christi, TX	01/18/2001
Chance, Charlene Kim Elgin, MN	01/18/2001
Chin, Ed Ming New York, NY	01/18/2001
Chirhart, Cynthia Ann Temple, TX	01/18/2001
Chizmar, Elizabeth A Springfield, VT	01/18/2001
Ciani, John Thomas Schenectady, NY	01/18/2001
Ciaren, Paul R Orwell Township, OH	01/18/2001
Clausen, Winifred Elra Santa Rosa, CA	01/18/2001
D'Ascoli, Bartholomew R Montague, NJ	01/18/2001
Davidson, Kenneth Ronald Reseda, CA	01/18/2001
Davis, Mario M Pittsburgh, PA	01/18/2001
Dhaliwal, Rimplejit Singh Bakersfield, CA	01/18/2001
Dodd, Elizabeth P	01/18/2001

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Subject city, state	Effective date
Kalamazoo, MI	
Dougherty, Bruce Elliott ..... Middletown, CT	01/18/2001
Dyer, Marcella C ..... Springfield, VA	01/18/2001
English, Robert Livingston III ... Santa Rosa, CA	01/18/2001
Farquhar, Nancy Ann ..... Hoover, AL	01/18/2001
Faybik, Michelle Leigh H ..... New Kensington, PA	01/18/2001
Ford, Bonnie Lee ..... Bovey, MN	01/18/2001
Foster, Lynn Kay ..... Martinez, CA	01/18/2001
Freeland, Frances J ..... Meriden, CT	01/18/2001
Freeman, Janet Sue ..... Edgewater, FL	01/18/2001
Gamber, Elizabeth A ..... Lake Havasu City, AZ	01/18/2001
Gordon, Teri L ..... Wyandotte, MI	01/18/2001
Grant, Richard Leslie ..... Wasilla, AK	01/18/2001
Gunkel, George Frederick ..... San Francisco, CA	01/18/2001
Hancock, Julie Delynn ..... Stephenville, TX	01/18/2001
Harper, Patricia E ..... Newark, TX	01/18/2001
Hickman, Clara Charlene ..... Piedmont, AL	01/18/2001
Hill, Patricia S ..... West Monroe, NY	01/18/2001
Hoagland, William Russell ..... Boling Green, FL	01/18/2001
Hudson, Leigh Ann ..... New Castle, DE	01/18/2001
Irvine, Gerald Lenard ..... Montgomery, AL	01/18/2001
Jones, Mary Dee ..... Greensburg, LA	01/18/2001
Kelley, Ira John ..... Conneautville, PA	01/18/2001
Kooker, Robert Allen ..... Loomis, CA	01/18/2001
Lake, Alan Shanley ..... Anaheim, CA	01/18/2001
Lambe, Michael J ..... New Britain, CT	01/18/2001
Lambert, Sheryl Yanick ..... Chicago, IL	01/18/2001
Lansford, Cynthia Leah ..... Birmingham, AL	01/18/2001
Large, James Matthew ..... Finleyville, PA	01/18/2001
Licerio, Lulex Guerrero ..... Orangeburg, NY	01/18/2001
Lopp, Roddie M ..... Louisburg, NC	01/18/2001
Lucker, Edward ..... Pleasant Valley, NY	01/18/2001
Lynch, Francis R ..... N. Haven, CT	01/18/2001
Marsh, John R ..... San Andreas, CA	01/18/2001
Martinez, Maria Anita ..... Fresno, CA	01/18/2001
Mather, William H ..... Douglasville, GA	01/18/2001
Matthews, Pamela ..... Chicago, IL	01/18/2001
McAllister, Charles H ..... Hialeah, FL	01/18/2001
McClellan-Dunson, Ionia ..... Freeport, IL	01/18/2001
McCulloch, Rhonda Kay ..... Hokes Bluff, AL	01/18/2001
McCurry, Tamiko ..... Chicago, IL	01/18/2001
McDonald, Keith William ..... Secaucus, NJ	01/18/2001
McElroy, Sheronne Renee ..... Chicago, IL	01/18/2001
Meads, Linda ..... Los Altos, CA	01/18/2001
Medina, Benjamin ..... Chicago, IL	01/18/2001
Melchor, Eduardo L ..... Barrington, IL	01/18/2001
Melton, Walter ..... Sprott, AL	01/18/2001
Mendelsohn, Deborah Miriam .. Waverly, PA	01/18/2001
Mendo-Cruz, Patricia ..... Whittier, CA	01/18/2001
Michalowski, Andrew Peter ..... Berwyn, IL	01/18/2001
Midzenski, Malinda A ..... Baltimore, MD	01/18/2001
Millburn, Joanne M ..... Philadelphia, PA	01/18/2001
Miller, Nival Rizk ..... Tuscaloosa, AL	01/18/2001
Mitchell, Brian ..... Chicago, IL	01/18/2001
Monteee, Romeo ..... Coral Springs, FL	01/18/2001
Moody, Beth Ann ..... Conroe, TX	01/18/2001
Moore, Samantha Claire ..... Rainbow City, AL	01/18/2001
Moy, Jenny ..... Chicago, IL	01/18/2001
Mullins, Phyllis ..... Gulfport, MS	01/18/2001
Murphy, Gregory Allen ..... Bolingbrook, IL	01/18/2001
Murphy, Madison Dee ..... Idaho Falls, ID	01/18/2001
Nelson, Mae Ellen ..... Lubbock, TX	01/18/2001
Nelson, Janice Louise ..... Chicago, IL	01/18/2001
Newkirk, Garry Lee ..... Pacifica, CA	01/18/2001
Nicolai, Anne ..... Davison, MI	01/18/2001
Nkatu, Nsiele M ..... Los Angeles, CA	01/18/2001
Norris, Stephanie Ann ..... Cambridge, IL	01/18/2001
O'Brien, Patricia A ..... Washington, PA	01/18/2001
O'Connor, Michael W ..... Chicago, IL	01/18/2001
O'Dell, Bruce La Von ..... Mesa, AZ	01/18/2001
O'Shea, Frank M ..... Ellicott City, MD	01/18/2001
Palmer, Donna Kay Mitchell ..... Picayune, MS	01/18/2001
Pascucci, Nicholas James ..... Woodhaven, NY	01/18/2001
Peirce, Mary Elizabeth Chandle ..... Daphne, AL	01/18/2001
Perkerson, Ralph Benton Jr ..... Jacksonville, FL	01/18/2001
Petersen, David K ..... Boise, ID	01/18/2001
Preston, Anne Shannon ..... Vestavia, AL	01/18/2001
Preston, Colleen Marie ..... Elk River, MN	01/18/2001
Ransom, Robert Stephens ..... Irvine, CA	01/18/2001
Ream, Monica Irwin ..... Elfred, PA	01/18/2001
Roberson, Traci S ..... Detroit, MI	01/18/2001
Roberts, Rammie ..... Oklahoma City, OK	01/18/2001
Roberts, John ..... Los Angeles, CA	01/18/2001
Ruffolo, Pasquale R ..... Hamden, CT	01/18/2001
Salter, Clifford James ..... St. Petersburg, FL	01/18/2001
Santa-Teresa, Bienvendio ..... Irvine, KY	01/18/2001
Savedra, Phyllis ..... Long Beach, CA	01/18/2001
Self, Jo Anna ..... Bessemer, AL	01/18/2001
Sen, Devashish ..... Newton, MA	01/18/2001
Shelton, Margaret Ann ..... Capitola, CA	01/18/2001
Smith, Randolph Lee ..... Pomona, CA	01/18/2001
Street, Brenda Hardin ..... Hot Springs, AR	01/18/2001
Swanson, Andrew Norman ..... Napa, CA	01/18/2001
Wagner, Marie W ..... Dallas, TX	01/18/2001
White, Clinton Ray ..... Clute, TX	01/18/2001
Winmill, Diana Renee ..... Blackfoot, ID	01/18/2001
Yarbrough, Ardry Lance ..... Atoka, OK	01/18/2001
Young, Patricia Anketell ..... Sherman Oaks, CA	01/18/2001
Federal State Exclusion/Suspension	
Angulo, Ismael ..... Chicago, IL	01/18/2001
Bungcayao, Isabelo Calacal ..... Oak Brook, IL	01/18/2001
Jairath, Ravindra Kumar ..... Chicago, IL	01/18/2001
Kilani, Reda ..... Naperville, IL	01/18/2001
Quach, Minh ..... Chicago, IL	01/18/2001
Tabe, Henry Brendan Ebot ..... Oak Park, IL	01/18/2001
Trung Tin Gift & Pharmacy ..... Chicago, IL	01/18/2001
Fraud/Kickbacks	
Eaglin, Gerardette ..... Marietta, GA	10/17/2000
Entities Owned/Controlled by Convicted	
Agma, Drug, Inc	01/18/2001

Subject city, state	Effective date
East Meadow, NY	
Appalachian Medical Supply .... Asheville, NC	01/18/2001
Burnside Pharmacy ..... Burnside, KY	01/18/2001
Genesee Hearing Svcs, LLP .... Buffalo, NY	01/18/2001
Home Infusion Mgmt. Svc ..... Congers, NY	01/18/2001
Medical Repair Center, Inc ..... La Mesa, CA	01/18/2001
Willowbrook Medical Treatment Wayne, NJ	01/18/2001
Default on Heal Loan	
Ardalan, Mehrmaz ..... West Hills, CA	01/18/2001
Booher-Fulton, Janette L ..... S. San Francisco, CA	01/18/2001
Bunce, Christine T ..... Oakland, CA	01/18/2001
Caldwell, Larry Von ..... Gretna, LA	01/18/2001
Dominics, Beth Anne ..... Los Angeles, CA	01/18/2001
Dowell, Alfonzo N Jr ..... Oklahoma City, OK	01/18/2001
Farrell, Robert J ..... San Diego, CA	12/13/2000
Funcia, Ana T ..... Miami, FL	01/18/2001
Gieschen, John M ..... Santa Cruz, CA	01/18/2001
Gillies, Douglas K ..... Roswell, NM	01/18/2001
Grant, Terry E ..... Freeport, NY	01/18/2001
Imani, Ibn A ..... Tallahassee, Fl	11/21/2000
Jakubczak, Arthur F ..... Perth Amboy, NJ	01/18/2001
Jefferson, Michael Kenneth ..... Woodland Hills, CA	01/18/2001
Jimerson, Ruthie M ..... Youngstown, OH	11/27/2000
Jubert, Angela K ..... Anderson, IN	11/27/2000
McGinn, Thomas D ..... Milford, UT	01/18/2001
Mendes, Antonio C ..... Canton, MA	01/18/2001
Negron, Candido ..... Philadelphia, PA	01/18/2001
Omohundro, William A ..... S. Pittsburg, Tn	01/18/2001
Pinnace, Jeanette L ..... Ridley Park, PA	11/28/2000
Polee, George ..... Nashville, TN	11/28/2000
Rey, Jorge E ..... Chino, CA	01/18/2001
Rocha, Mark W ..... Riverside, CA	11/29/2000
Smith-Chapin, June D ..... Auburn Hills, MI	01/18/2001
Soto, Mario J ..... Fresno, CA	01/18/2001
Summers, Shawn J ..... Los Angeles, CA	01/18/2001
Taylor, Berlan L ..... Alicia, AR	01/18/2001
Yagow, John T ..... Watertown, WI	01/18/2001

Dated: January 8, 2001.

Calvin Anderson, Jr.,

Director, Health Care Administrative Sanctions, Office of Inspector General.

[FR Doc. 01–1622 Filed 1–19–01; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESS: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Ribonuclease H1—A Protein Expressed in Escherichia coli From a Cloned Human RNase H1 cDNA

Robert J. Crouch, Susana Cerritelli, Sergey Gaidamakov, and Hirofumi Yamada (NICHD)

DHHS Reference No. E–047–01/0

Licensing Contact: Sally Hu; 301/496–7056 ext. 265; e-mail: hus@od.nih.gov.

Available for licensing through a Materials License Agreement (no patent or patent application) are samples of purified human RNase H1 protein, expressed in E. coli from human RNase H1 cDNA. This protein is important for cellular functions such as DNA synthesis and repair. This protein also is related by sequence, structure and enzymatic mechanism to the RNase H of retroviruses such as HIV. Since the cellular and viral proteins have similar properties, it would be useful to screen for potential drugs that have little or only modest effects on the cellular protein while inhibiting the HIV enzyme. Thus, the availability of both the retroviral and human RNases H1 makes drug screening and anti-sense therapy possible to perform.

Methods for the Identification of Textual and Physical Structured Query Fragments for the Analysis of Textual and Biopolymer Information

Robert J. Boissy (NIEHS)

DHHS Reference No. E–270–99/0 filed 15 Nov 2000

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention comprises algorithms implemented in software for "structured combinatorial queries" that may be used for analyses of relatedness and information content in any textual information, and especially in biological sequences. The invention also includes experimental methods for isolating and comparing DNA fragments ("Structured Query Fragments" or SQFs) obtained using site-specific cleavage effectors acting on substrate DNA that is asymmetrically end-immobilized on a solid support. A small, structured array of such cleavage effectors may be used in a combinatorial fashion to generate progressively expanding sets of asymmetrically end-immobilized, double-stranded DNA. This ultimately yields extremely large numbers of SQFs, which typically have lengths in the range of 100–700 nucleotides (and are termed ranged SQFs). Thus, each SQF is defined by a method (a specific combinatorial pathway required to isolate it) and one or more properties (typically its length). These attributes yield sufficient information to identify and assign ranged SQFs to specific locations in known sequences automatically using the software disclosed in the invention. The invention shows how millions of individual ranged SQFs distributed throughout the human genome may be unambiguously identified at nucleotide resolution using a fragment analysis instrument. Accordingly, the invention provides a computational method that is flexible and efficient at comparing large amounts of textual information (typically biological sequence data), and a unique laboratory strategy that emulates the computational method and provides a highly scalable approach for physical analyses of polynucleotides. This laboratory strategy allows for the analysis and isolation of large numbers

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of specific SQFs of interest, without the use of cloning techniques or polynucleotide amplification protocols that require locus-specific primers.

Probe Using Diffuse-Reflectance Spectroscopy

Amir H. Gandjbakhche (NICHD), David W. Hattery (NICHD), James L. Mulshine (NCI), Paul D. Smith (ORS), Ernie Hawk (NCI), Victor Chernomordik (NICHD)

DHHS Reference No. E–309–00/0 filed 06 Oct 2000

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention uses an oblique angle reflectance spectroscopy method to non-invasively quantify the thickness of the oral epithelium as a means for quantifying inflammation at sites in the oral cavity. In this technique, a toothbrush-sized probe is used to direct photon sources at two or more oblique angles and measure the scattered spectra to determine the thickness of the epithelial layer. Analysis of the spectra provides the location of the stroma/epithelium interface. The invention has applications in the assessment of drugs used in the treatment of Leukoplakia, which is characterized by a thickening of the oral epithelium as the underlying stroma remains unchanged. The invention provides a non-invasive technique for determining the efficacy of drugs used to treat the lesion, and promises to replace the need for uncomfortable punch biopsies.

Modified HCV Peptide Vaccine

Jay A. Berzofsky (NCI), Pablo Sarobe (NCI), CD Pendleton (NCI), Stephen M. Feinstone (FDA)

DHHS Reference Nos. E–192–98/0 filed 21 Aug 1998 and E–192–98/1 filed 17 Aug 1999

Licensing Contact: Carol Salata; 301/496–7735 ext. 232; e-mail: salatac@od.nih.gov.

Hepatitis C virus (HCV) is a single stranded RNA virus responsible for the majority of non-A non-B hepatitis. Hepatitis C virus (HCV) has a worldwide distribution and is a major cause of liver cirrhosis and hepatocellular carcinoma in the U.S., Europe, and Japan. For this reason, development of a vaccine against hepatitis C is of great importance.

The present invention provides immunogenic peptides of HCV core protein which elicit an enhanced immune response, methods for making these peptides, and methods for using these peptides for a variety of therapeutic, diagnostic, and prognostic applications, including a vaccine. More specifically, the present invention provides an isolated peptide, an isolated HCV core polypeptide, a fragment of an HCV core polypeptide and nucleic acids which encode the peptides and polypeptides of this invention. The invention provides a modified HCV core peptide that is more immunogenic than the corresponding natural core peptide for eliciting human cytotoxic T lymphocytes.

Dated: January 8, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 01–1643 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Novel Technologies for Noninvasive Detection, Diagnosis, and Treatment of Cancer.

Date: February 23, 2001.

Time: 8 am to 5 pm.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute, 6130 Executive Boulevard, Conference Room J, Rockville, MD 20852.

Contact Person: Lalita D. Palekar, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8066, Bethesda, MD 20892–7405, (301) 496–7575.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1629 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovative Cancer Complementary and Alternative Medicine Initiative in Cancer Centers.

Date: February 19–21, 2001.

Time: 7:00 pm to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Gerald G. Lovinger, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8070, Rockville, MD 20892–7405, 301/496–7987.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1628 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: February 20–22, 2001.

Time: 9:00 AM to 12:00PM.

Agenda: To review and evaluate grant applications.

Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: Harvey P. Stein, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8137, Bethesda, MD 20892, (301) 496–7841.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1630 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center Institute Special Emphasis Panel, Spore Review Genitourinary and Prostate Cancer.

Date: February 15–16, 2001.

Time: 8:00 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Brian E. Wojcik, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8019, Bethesda, MD 20892, 301/402–2785.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institute of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1631 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Determining the Carcinogenic Significance of Heterocyclic Amines.

Date: February 9, 2001.

Time: 11:00 AM to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Grants Review Branch, Division of Extramural Activities, 6116 Executive Boulevard, Room 8127, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael B. Small, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8040, Bethesda, MD 20892, 301/402–0996.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1632 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: January 29, 2001.

Time: 12:30 pm to 2:30 pm.

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Agenda: To get updates from the working groups and to discuss the advocates section of the April 2001 DCLG meeting.

Place: National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Elaine Lee, Acting Executive Secretary, Office of Liaison Activities, National Institute of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594–3194.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1633 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Human Factors in Breast Cancer Detection and Diagnosis.

Date: February 8–10, 2001.

Time: 7:30 PM to 12 PM.

Agenda: To review and evaluate grant applications.

Place: Wyndham Garden Brookfield, 18155 W. Bluemound Rd., Brookfield, WI 53045.

Contact Person: William D. Merritt, Scientific Review Administrator, Grants Review Branch, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8034, MSC 8328, Bethesda, MD 20892–8328, 301–496–9767.

This notice is being published less than 15 days prior to the meeting the due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1634 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Orientation and Review: Demonstration & Education Research Grants.

Date: February 22, 2001.

Time: 1:15 PM to 4:45 PM.

Agenda: To review and evaluate grant applications.

Place: Washington National Airport Hilton, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Louise P. Corman, Scientific Review Administrator, Review Branch, Room 7180, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1635 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Adhesion Molecules in Transfusion Biology.

Date: January 30, 2001.

Time: 11 AM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Columbia Sheraton, 10207 Wincopin Circle, Columbia, MD 21044.

Contact Person: Jeffrey H. Hurst, Health Scientist Administrator, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301–435–0303.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1636 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institutes; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Biobehavioral Bases of CHD Risk and Management.

Date: February 22, 2001.

Time: 9 AM to 12:30 PM.

Agenda: To review and evaluate grant applications.

Place: Washington National Airport Hilton, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Louise P. Corman, Review Branch, NIH, NHLBI, Rockledge Building II, 6701 Rockledge Drive, Suite 7180, Bethesda, MD 20892–7924, (301) 435–0270.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Disease Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1637 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel.

Date: February 2, 2001.

Time: 8 AM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Joyce A. Hunter, Review Branch, Room 7194, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20872.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 11, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1642 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Environmental Health Sciences Special Emphasis Panel, January 16, 2001, 1 p.m. to January 16, 2001, 3 p.m., NIEHS, 79 T. Alexander Drive, Building 4401, Conference Room 3446, Research Triangle Park, NC 27709 which was published in the **Federal Register** on November 28, 2000, FR 229:70928.

The telephone conference call meeting will be held on March 19, 2001, from 1 p.m. to 3 p.m. at the same location, instead of January 16, 2000, as previously advertised. The meeting is closed to the public.

Dated: January 4, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1627 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Social Isolation, Loneliness, Health and the Aging Process.

Date: January 25, 2001.

Time: 12 PM to 3 PM.

Agenda: To review and evaluate grant applications.

Place: 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Health Scientific Administrator, Office of Scientific Review, National Institute on Aging the Bethesda Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (301) 496–9666.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel FTD: Genes, Images and Emotions.

Date: January 30–31, 2001.

Time: 7 PM to 5 PM.

Agenda: To review and evaluate grant applications.

Place: Radisson Miyako, 1625 Post Street, San Francisco, CA 94115.

Contact Person: Louise L. Hsu, Scientific Review Administrator, the Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–9666.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel, Effects of

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Stress, the hypothalamic pituitary-adrenal axis and health in aging.

Date: February 1, 2001.

Time: 1 PM to 3:30 PM.

Agenda: To review and evaluate grant applications.

Place: 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call)

Contact Person: Arthur D. Schaerdel, the Bethesda Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–9666.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1639 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–5(C3)B.

Date: January 29, 2001.

Time: 3 PM to 5 PM.

Agenda: To review and evaluate contract proposals.

Place: 6707 Democracy Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Francisco O. Calvo, Acting Chief, Review Branch, DEA, NIDDK, Room 655, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8897.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–1(C2).

Date: February 8, 2001.

Time: 2 PM to 4 PM.

Agenda: To review and evaluate contract proposals.

Place: 6707 Democracy Blvd., 2 Democracy Plaza, RM 653, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Carolyn Miles, Scientific Review Administrator, Review Branch, DEA, NIDDK, Room 641, 6707 Democracy Boulevard, National Institutes of Health, Bethesda, MD 20892, (301) 594–8897.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1640 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 12–13, 2001.

Open: February 12, 2001, 8:30 AM to 5 PM.

Agenda: Discussion of Program Policies and Issues. Agenda: http://www.niehs.nih.gov/dert/c-agenda.htm.

Place: National Institutes of Health, Natcher Building, Conference Room D, 45 Center Drive, Bethesda, MD 20892.

Open: February 13, 2001, 8:45 AM to 9:15 AM.

Agenda: Report of the Director, DERT.

Place: National Institutes of Health, Natcher Building, Conference Room D, 45 Center Drive, Bethesda, MD 20892.

Closed: February 13, 2001, 9:15 AM to adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Conference Room D, 45 Canter Drive, Bethesda, MD 20892.

Contact Person: Anne P. Sassaman, Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233, Research Triangle Park, NC 27709, 919/541–7723.

(Catalogue of Federal Domestic Assistance Program Nos. 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences, National Institutes of Health, HHS)

Dated: January 12, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1641 Filed 1–19–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Obligated Service for Mental Health Traineeships: Regulations (42 CFR Part 62a) and Forms—(Extension; OMB No. 0930–0074)—SAMHSA's Center for Mental Health Services (CMHS) awards grants to institutions for training instruction and traineeships in mental health and related disciplines. Graduate student recipients of these clinical traineeships must perform service, as determined by the Secretary to be appropriate in terms of the individual's training and experience, for a length of time equal to the period of support. The clinical trainees are required to submit SAMHSA Form SMA 111, a payback agreement, SAMHSA Form 111–1, which ensures agency receipt of a termination notice prior to the end of support, and the SAMHSA Form SMA 111–2, which is an annual report on employment status and any changes in name and/or address, to SAMHSA. The annual burden estimate is provided below.

42 CFR Section	No. of respondents	No. of responses/respondent	Hours per response	Total burden hours
64a.104(a–b),(c)(1)—Termination Notice and Exit Interview (Form SMA 111)	100	1	.25	25
64a.104(c)(2,3)—Payback Agreement and Entrance Interview (Form SMA 111–1)	100	1	.25	25
64a.105(b)(2)Annual Payback Activities Certification (Form SMA 111–2	700	1	.18	126
Total burden	900			176

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Stuart Shapiro, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 12, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–1593 Filed 1–19–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of a Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council in February 2001.

The SAMHSA National Advisory Council meeting will be open and will include a summary and discussion on the implementation of SAMHSA's reauthorization legislation, discussions on SAMHSA's 2001 and 2002 budget, on appropriations and transition issues, on homeless funding issues and options, on SAMHSA's relationships with its Constituency Organizations and a report on the evaluation of SAMHSA's peer review process. In addition, there will be a discussion on ways in which SAMHSA can expand communication with the National Institute of Mental Health, the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and their National Advisory Councils. Finally, there will be a discussion on the SAMHSA Council and its eight workgroups.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

Substantive program information, a summary of the meeting, and a roster of Council members may be obtained from the contact whose name and telephone number is listed below.

Committee Name: SAMHSA National Advisory Council.

Date/Time: Thursday, February 8, 2001, 9:00 a.m. to 4:50 p.m. (Open); Friday, February 9, 2001, 8:30 a.m. to 12:00 p.m. (Open).

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Contact: Toian Vaughn, Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 17–89, Rockville, MD 20857, Telephone: (301) 443–7016; FAX: (301) 443–1587 and e-mail: TVaughn@samhsa.gov.

Dated: January 10, 2001.

Toian Vaughn,

Committee Management Officer, SAMHSA.

[FR Doc. 01–1268 Filed 1–19–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–08]

Submission for OMB Review: Multifamily Housing Rehabilitation Loan Program for Capital Repairs

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice of proposed information collection requirement.

SUMMARY: The Department of Housing and Urban Development (HUD) is publishing a Housing Notice which enables qualified owners to submit applications, subject to HUD review, for a loan to address the rehabilitation and repair needs of aging multifamily properties. To determine whether a project is qualified to receive funding, HUD will be collecting information from those applicants that wish to participate. The proposed information collection requirement has been submitted to the Office of Management and Budget (OMB) for review as required by the Paperwork Reduction Act.

DATES: Submit comments on or before: January 29, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–2374 (This is not a toll-free number) or e-mail to Wayne_Eddins@HUD.gov. Copies of the available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review as required by the Paperwork Reduction Act (44 USC Chapter 35). HUD has requested OMB approval by April 29, 2000.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless collection displays a valid control number.

This notice contains the following information:

(1) The title for the collection of information;

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(2) A summary of the collection of information;

(3) A brief description of the need for the information and proposed use of the information;

(4) A description of the likely respondents, including the estimated number of likely respondents, and proposed frequency of response to the collection of information;

(5) An estimate of the total annual reporting and recordkeeping burden that will result from the collection of information;

Title: Multifamily Housing Rehabilitation Loan Program for Capital Repairs

OMB Control Number: 2502–

Type of submission: Owners of eligible projects (applicants) will be required to submit to HUD information to show that the project meets the basic eligibility criteria, that rehabilitation is necessary to address the physical needs that exist at the property, and that they do not have the financial resources available to address these needs. These requirements will enable eligible applicants to take advantage of a loan that will enable them to resolve the physical deficiencies at the property.

The information includes (a) an application cover letter and description of the proposed use of funds; (b) a worksheet that demonstrates the calculation of the loan amount; (c) an updated Comprehensive Needs Assessment (CNA) including HUD Forms 96001, 96002, and 96003; (d) the project's REAC physical and financial assessment scores; and (e) for profit-motivated owners, evidence of their minimum contribution towards the total cost of the rehabilitation.

Need and use of the information: The information will be used in order to demonstrate the need for assistance in order to correct the physical deficiencies of the property. The Department will review the information to determine whether the basic eligibility criteria is met, if a loan is needed for rehabilitation of the project, and that the project income is not sufficient to support the rehabilitation. Form Number(s): HUD Forms 96001, 96002, 96003.

Respondents: Multifamily property owners, primarily nonprofit entities.

Reporting Burden:

Number of respondents	×	Frequency of response	×	Hours per response	=	Total burden hours
400		1		4–24		1600–9600

Contact: Eileen Hearty, HUD (202–708–2866, ext. 2641), Joseph Lackey, OMB, (202) 395–7316.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: January 16, 2001.

Wayne Eddins,

Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1840 Filed 1–19–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–07]

Notice of Submission of Proposed Information Collection to OMB; Contract Administration—Public and Indian Housing

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 21, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0039) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Contract Administration—Public and Indian Housing.

OMB Approval Number: 2577–0039.

Form Numbers: HUD–5372, HUD–5100.

Description of the Need for the Information and its Proposed Use: Public Housing Agencies (PHA) and Indian Housing Authorities (IHA) must maintain certain records or submit certain documents to HUD in conjunction with the award of oversight of construction contracts for development of new low-income housing developments or modernization of existing developments.

Respondents: State, Local or Tribal Government.

Frequent of Submission: On occasion.

Reporting Burden:

	Number of respondents	×	Frequency of response	×	Hours per response	=	Burden hours
Application	2,199		5.27		1.25		14, 506

Total Estimated Burden Hours: 14,506.

Status: Reinstatement, without change.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 12, 2001.

Wayne Eddins,

Departmental Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 01–1841 Filed 1–19–01; 8:45 am]

BILLING CODE 4210–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4632–N–02]

Notice of Funding Availability Fair Share Allocation of Incremental Voucher Funding Fiscal Year 2001; Amendment and Deadline Extension

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Fund Availability (NOFA); Amendment to MTCS Threshold.

SUMMARY: On December 13, 2000, HUD published its Notice of Funding Availability for Fair Share Allocation of Incremental Voucher Funding for Fiscal Year 2001 ("Fair Share NOFA"). This notice amends the December 13, 2000 Fair Share NOFA to revise the Multifamily Tenant Characteristics System (MTCS) threshold to include MTCS reporting information ending December 2000, and to extend the application deadline.

DATES: Applications are due on February 20, 2001. Applicants that already submitted applications, need not resubmit a new application, and need not amend their applications. Applicants that already submitted applications, however, may submit new or amended applications if they so choose.

Additional Information

Background—December 13, 2001 NOFA

If you are interested in applying for funding under the Fair Share NOFA, and did not apply earlier, please review the entire Fair Share NOFA, published on December 13, 2000 (65 FR 78040). Except for the amendment made by this document, and the extension of the application deadline, all other provisions of the Fair Share NOFA are unchanged and remain applicable.

The December 13, 2000 Fair Share NOFA will provide you with detailed information regarding the submission of an application, Section 8 program requirements, the application selection process to be used by HUD in selecting applications for funding, and other valuable information relative to a PHA's application submission and participation in the program covered by this NOFA.

Amendments to December 13, 2000 Fair Share NOFA

Amendment #1. Section VI(F) of the December 13, 2000 Fair Share NOFA (at 65 FR 78045, third column) is amended to read as follows:

(F) *Multifamily Tenant Characteristics System (MTCS) Reporting Certification.* In order to be eligible to submit an application under this Fair Share NOFA, the PHA must have a minimum reporting rate of not less than 85 percent for housing choice voucher and certificate resident records to HUD's MTCS (see 24 CFR Part 908 and Notices PIH 98–30, 99–2 and 2000–13) for the period ending December 1999, and must submit a certification with its application certifying to having met this requirement.

In the event a PHA received less than an 85 percent rate of reporting under MTCS for this period, the PHA will still be considered to have passed the threshold if: (1) subsequently achieved a minimum reporting rate of not less than 85 percent for housing choice voucher and certificate resident records to HUD's MTCS; or (2) the PHA has requested forbearance from HUD under the applicable procedures in Notice PIH 2000–13 for the semi-annual assessment period ending December 2000, contingent upon HUD approval of the forbearance request. In the latter instance, the PHA must submit a certification with its application indicating that it has either achieved such a minimum reporting rate as of the December 2000 reporting period, or that it has submitted a forbearance request to HUD for the semi-annual assessment period ending December 2000, and acknowledges that the forbearance request must be approved by HUD in order for the PHA to pass the Fair Share NOFA's MTCS threshold requirement.

Amendment #2. Section VII(B)(2)(i) of the December 13, 2000 Fair Share NOFA (at 65 FR 78046, third column) is amended to read as follows:

(i) The applicant has failed to achieve a minimum 85 percent submission rate for housing choice voucher and certificate resident records to HUD's Multifamily Tenant Characteristics System (MTCS), as set forth in 24 CFR part 908 and Notices PIH 98–30, 99–2 and 2000–13, for the periods ending December 1999 and December 2000, and has failed to receive approval for forbearance from HUD for the period ending December 2000.

Dated: January 17, 2001.

Gloria Cousar,

Acting General Deputy, Assistant Secretary for Public and Indian Housing.

[FR Doc. 01–1800 Filed 1–17–01; 3:40 pm]

BILLING CODE 4210–33–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4463–N–06]

Mortgage and Loan Insurance Programs Under the National Housing Act—Debenture Interest Rates

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, (HUD).

ACTION: Notice of Change in Debenture Interest Rates.

SUMMARY: This notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Commissioner under the provisions of the National Housing Act (the "Act"). The interest rate for debentures issued under Section 221(g)(4) of the Act during the 6-month period beginning January 1, 2001 is 7⅛ percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the 6-month period beginning January 1, 2001, is 6 percent.

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FOR FURTHER INFORMATION CONTACT: James B. Mitchell, Department of Housing and Urban Development, 451 7th Street, SW., Room 6164, Washington, DC 20410. Telephone (202) 708–3944, extension 2612, or TDD (202) 708–4594 for hearing- or speech-impaired callers. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: Section 2224 of the National Housing Act (24 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to Section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at 24 CFR 203.405, 203.479, 207.259(e)(6), and 220.830. Each of these regulatory provisions states that the applicable rates of interest will be published twice each year as a notice in the **Federal Register**.

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the annual interest rate determined by the Secretary of the Treasury pursuant to a statutory formula based on the average yield of all outstanding marketable Treasury obligations of maturities of 15 or more years.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of Section 224, that the statutory maximum interest rate for the period beginning January 1, 2001, is 6 percent and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 6 percent for the 6-month period beginning January 1, 2001. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to Section 221(g)(4)) with an insurance commitment or endorsement date (as applicable) within the first 6 months of 2001.

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1980:

Effective interest rate	on or after	prior to
9½	Jan. 1, 1980	July 1, 1980
9⅞	July 1, 1980	Jan. 1, 1981
11¾	Jan. 1, 1981	July 1, 1981
12⅞	July 1, 1981	Jan. 1, 1982
12¾	Jan. 1, 1982	July 1, 1983
10¼	Jan. 1, 1983	July 1, 1983
10⅜	July 1, 1983	Jan. 1, 1984
11½	Jan. 1, 1984	July 1, 1984
13⅜	July 1, 1984	Jan. 1, 1985
11⅝	Jan. 1, 1985	July 1, 1985
11⅛	July 1, 1985	Jan. 1, 1986
10¼	Jan. 1, 1986	July 1, 1986
8¼	Jan. 1, 1986	July 1, 1987
8	Jan. 1, 1987	July 1, 1987
9	July 1, 1987	Jan. 1, 1988
9⅛	Jan. 1, 1988	July 1, 1988
9⅜	July 1, 1988	Jan. 1, 1989
9¼	Jan. 1, 1989	July 1, 1989
9	July 1, 1989	Jan. 1, 1990
8⅛	Jan. 1, 1990	July 1, 1990
9	July 1, 1990	Jan. 1, 1991
8¾	Jan. 1, 1991	July 1, 1991
8½	July 1, 1991	Jan. 1, 1992
8	Jan. 1, 1992	July 1, 1992
8	July 1, 1992	Jan. 1, 1993
7¾	Jan. 1, 1993	July 1, 1993
7	July 1, 1993	Jan. 1, 1994
6⅞	Jan. 1, 1994	July 1, 1994
7¾	July 1, 1994	Jan. 1, 1995
8⅜	Jan. 1, 1995	July 1, 1995
7¼	July 1, 1995	Jan. 1, 1996
6½	Jan. 1, 1996	July 1, 1996
7¼	July 1, 1996	Jan. 1, 1997
6¾	Jan. 1, 1997	July 1, 1997
7⅛	July 1, 1997	Jan. 1, 1998
6⅜	Jan. 1, 1998	July 1, 1998
6⅛	July 1, 1998	Jan. 1, 1999
5½	Jan. 1, 1999	July 1, 1999
6⅛	July 1, 1999	Jan. 1, 2000
6½	Jan. 1, 2000	July 1, 2000
6½	July 1, 2000	Jan. 1, 2001
6	Jan. 1, 2001	July 1, 2001

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the "going Federal rate" of interest in effect at the time the debentures are issued. The term "going Federal rate" is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a statutory formula based on the average yield on all outstanding marketable Treasury obligations of 8- to 12-year maturities, for the 6-month periods of January through June and July through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to Section 221(g)(4) during the 6-month period beginning January 1, 2001, is 7⅛ percent.

HUD expects to publish its next notice of change in debenture interest rates in June 2001.

The subject matter of this notice falls within the categorical exemption from HUD's environmental clearance procedures set forth in 24 CFR 50.20(1). For that reason, no environmental finding has been prepared for this notice.

(Sections 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 1715*l*, 1715o; Section 7(d), Department of HUD Act, 42 U.S.C. 3535(d)).

Dated: January 12, 2001.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 01–1707 Filed 1–19–01; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. FR–4572–D–16]

Office of the Secretary—Housing-Federal Housing Commissioner; Delegation and Redelegation of Authority Under Section 203(d)(6) of the Federal Property and Administrative Services Act of 1949

AGENCY: Office of the Secretary, Office of Housing, HUD.

ACTION: Notice of delegation and redelegation of authority to recommend to the General Services Administration disposal of surplus real property, including buildings, fixtures and equipment situated thereon and to take all steps necessary, including fixing the sale or lease value, to sell or lease such property for the purpose of self-help housing, in accordance with Section 203(k)(6) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484(k)(6)) (FPASA).

SUMMARY: In this Notice, the Secretary delegates to the Assistant Secretary for Housing-Federal Housing Commissioner, who retains and redelegates this authority to the Director, Office of Single Family Assets Management, the authority under Section 203(d)(6) of FPASA to recommend to the General Services Administration disposal of surplus real property, including buildings, fixtures and equipment situated thereon and to take all steps necessary, including fixing the sale or lease value, to sell or lease such property of self-help housing.

EFFECTIVE DATE: January 12, 2001.

FOR FURTHER INFORMATION CONTACT: Director, Office of Single Family assets Management, Room 9162, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone: (202) 708–1672. This is not a toll-free number. This number may be accessed via TTY by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Pub. Law 105–50 (Oct. 6, 1997) amended the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484) by adding section 203(k)(6), which authorizes the Secretary of HUD, in consultation with the Administrator of the General Services Administration, to dispose of surplus federal property to states, their political subdivisions or instrumentalities, and nonprofits for the purpose of providing self-help housing to low income individuals. These responsibilities are being delegated by the Secretary to the Assistant Secretary for Housing-Federal Housing Commissioner, who further redelegates them to the Director, Office of Single Family Assets Management.

Accordingly, the Secretary delegates, and the Assistant Secretary for Housing-Federal Housing Commissioner redelegates, authority as follows:

Section A. Authority Delegated and Redelegated

1. The authority of the Secretary under Section 203(k)(6) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484) to recommend surplus federal real property to the Administrator of the General Services Administration as needed for providing housing or housing assistance for low-income persons and to take all steps reasonably necessary to sell and lease surplus federal property for that purpose, including fixing sale or lease value, is hereby delegated to the Assistant Secretary for Housing-Federal Housing Commissioner, who retains this authority and redelegates it to the Director, Office of Single Family Assets Management.

Authority: Section 203(k)(6) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484(k)).

Dated: January 12, 2001.

Saul N. Ramirez, Jr.,

Deputy Secretary of Housing and Urban Development.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner, Department of Housing and Urban Development.

[FR Doc. 01–1706 Filed 1–19–01; 8:45 am]

BILLING CODE 4210–32–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4643–N–01]

Sections 202 and 811 Capital Advance Programs: Revised Development Cost Limits

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice announces changes to the development cost limits for the Sections 202 and 811 Capital Advance Programs. The development cost limits were established in 1989 for the Section 811 group homes and in Fiscal Year (FY) 1999 were increased by 20 percent. Also in FY 1999 the cost limits for elderly projects and independent living projects for persons with disabilities were replaced with the Section 221(d)(3) per unit limits authorized by Congress in 1992.

Even with last year's increase in the development cost limits, a number of nonprofit owners still need additional sources of funding to construct their projects. In an attempt to alleviate this problem, the base development limits from 1989 and 1992 respectively have been adjusted to 2000 using the Federal Reserve Bank of Minneapolis' Consumer Price Index (CPI) calculator which may be found on the internet at http://minneapolisfed.org/economy/calc/cpihome.html.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Willie Spearmon, Director, Office of Housing Assistance and Grant Administration, Department of Housing and Urban Development, 451 7th St. SW, Washington, DC 20410, 202–708–3000. (This is not a toll-free number.) For hearing and speech-impaired persons, this number may be accessed via TTY by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 202 (12 U.S.C. 1701q), Supportive Housing for the Elderly, of the National Housing Act of 1959, requires the Secretary to periodically establish development cost limitations by market area for various types and sizes of supportive housing for the elderly by publishing a notice in the **Federal Register**. The statute also requires that the Secretary adjust the cost limitation not less than once annually to reflect changes in the general level of construction, reconstruction or rehabilitation costs.

Section 811 (42 U.S.C. 8013), Supportive Housing for Persons with Disabilities, of the Cranston-Gonzales National Affordable Housing Act contains similar language.

HUD has determined the best way to comply with this requirement is to adjust the base limits annually by changes in the CPI. We found the CPI not only easy to use but meeting Congressional intention.

Therefore, the total development cost of the property or project attributable to dwelling use, adjusted by locality as described below, (less the incremental development cost and the capitalized operating costs associated with any excess amenities and design features the borrower must pay for) may not exceed:

(1) For the elderly.

For non-elevator structures:

$41,238 per family unit without a bedroom;

$47,548 per family unit with one bedroom;

$57,344 per family unit with two bedrooms.

For elevator structures:

$43,398 per family unit without a bedroom;

$49,748 per family unit with one bedroom;

$60,493 per family unit with two bedrooms.

(2) For persons with disabilities.

(a) For independent living projects and dwelling units in multifamily developments, condominium and cooperative housing.

For non-elevator structures:

$41,238 per family unit without a bedroom;

$47,548 per family unit with one bedroom;

$57,344 per family unit with two bedrooms;

$73,400 per family unit with three bedrooms;

$81,770 per family unit with four or more bedrooms.

For elevator structures:

$43,398 per family unit without a bedroom;

$49,748 per family unit with one bedroom;

$60,493 per family unit with two bedrooms;

$78,257 per family unit with three bedrooms;

$85,902 per family unit with four or more bedrooms.

(b) For group homes only.

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TYPE OF DISABILITY

No. of residents	Physical and/or developmental	Chronic mental illness
2	$166,022	$160,262
3	178,533	172,340
4	191,045	183,069
5	203,556	193,798
6	216,054	204,527
7	221,547	209,653
8	227,040	214,778
9	236,972	223,212
10	248,013	232,616
11	256,835	240,065
12	266,766	248,498
13	277,308	257,140
14	287,836	265,782
15	298,365	274,409

These cost limits reflect those costs reasonable and necessary to develop a project of modest design that complies with HUD minimum property standards; the accessibility requirements of § 891.120(b); and the project design and cost standards of § 891.120 and § 891.210.

Increased development cost limits.

(1) HUD may increase the development cost limits by up to 140 percent in any geographic area where the cost levels require, and may increase the development cost limits by up to 160 percent on a project-by-project basis. This increase may include covering additional costs to make dwelling units accessible through rehabilitation.

(2) If HUD finds that high construction costs in Alaska, Guam, the Virgin Islands, or Hawaii make it infeasible to construct dwellings, without the sacrifice of sound standards of construction, design, and livability, within the development cost limits provided above, the amount of the capital advances may be increased to compensate for such costs. The increase may not exceed the limits established above (including any high cost area adjustment) by more than 50 percent.

HUD expects to publish its next notice of change in the development cost limits in October 2001.

Dated: January 12, 2001.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 01–1839 Filed 1–19–01; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection Renewal Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: The U.S. Fish and Wildlife Service has submitted the collection of information from applicants who wish to obtain a permit to conduct activities under a number of wildlife conservation laws, treaties and regulations. A copy of the information collection requirement is included in this notice. If you wish to obtain copies of the proposed information collection requirement, related forms, and explanatory material, contact the Collection Clearance Officer at the address listed below.

DATES: OMB has up to 60 days to approve or disapprove information collection but may respond after 30 days. Therefore, to ensure maximum consideration you must submit comments on or before February 21, 2001.

ADDRESSES: Send your comments and suggestions on specific requirements to the Office of Management and Budget, Attention: Department of the Interior Desk Officer, 725 17th Street, NW, Washington, DC 20503, and to Rebecca Mullin, Collection Clearance Officer, U.S. Fish and Wildlife Service, MS–222–ARLSQ; 4401 N. Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related forms, contact Rebecca A. Mullin, Collection Clearance Officer at 703–358–2287, or electronically to *rmullin@fws.gov*.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and record keeping activities [see 5 CFR 1320.8(d)]. The U.S. Fish and Wildlife Service (We) has submitted a request to OMB to renew its approval of the collection of information for the Service's license/permit application form number 3–200–19 through 3–200–25 and 3–200–27 through 3–200–53. We are requesting a 3-year term of approval for this information collection activity.

A previous 60-day notice on this information collection requirement was published in the July 6, 2000 (65 FR 41716) **Federal Register** inviting public comment. No comments on the previous notice were received. This notice provides an additional 30 days in which to comment on the following information.

We invite comments concerning this renewal on: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the collection of information; (3) ways to enhance the quality, utility and clarity of the information to be collected; and, (4) ways to minimize the burden of the collection of information on those who are to respond. The information collections in this program are part of a system of record covered by the Privacy Act [5 U.S.C. 552 (a)].

Federal agencies may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number. The OMB control number for this collection is 1018–0093.

The information collection requirements in this submission implement the regulatory requirements of the Endangered Species Act (16 U.S.C. 1539), the Convention on International Trade in Endangered Species of Wild Flora and Fauna (TIAS 8249), the Migratory Bird Treaty Act (15 U.S.C. 704), the Lacey Act (18 U.S.C. 42–44), the Bald and Golden Eagle Protection Act (16 U.S.C. 1361–1407), and Wild Bird Conservation Act (16 U.S.C. 4901–4916), and are contained in Service regulations in Chapter I, Subchapter B of Title 50 Code of Federal Regulations (CFR), Parts 15, 16, 17 and 23. Common permit applications and record keeping requirements have been consolidated in 50 CFR 13, and unique requirements of the various statutes in the applicable Part.

OMB Control Number: 1018–0093.

Service Form Numbers: 3–200–19 through 3–200–25 and 3–200–27 through 3–200–53

Frequency of Collection: On Occasion.

Description of Respondents: Individuals, biomedical companies, circuses, zoological parks, botanical gardens, nurseries, museums, universities, scientists, antique dealers, exotic pet industry, hunters, taxidermists, commercial importers/exporters of wildlife and plants, freight forwarders/brokers, local, State, tribal and Federal governments.

Total Annual Burden Hours: 4500.

Total Annual Responses: 5959.

Total Annual Non-Hour Cost Burden: $149,000.

Dated: January 16, 2001.

Mark Phillips,

Service Information Collection Officer.

[FR Doc. 01–1705 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Policy Regarding Capture and Removal of Southern Sea Otters in a Designated Management Zone

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Statement of policy.

SUMMARY: This notice advises the public that we, the U.S. Fish and Wildlife Service (Service), have determined that we will not capture and remove southern sea otters from the southern California sea otter management zone pending completion of our ongoing reevaluation of the southern sea otter translocation program including the preparation of a supplemental environmental impact statement (EIS) and release of a final evaluation of the translocation program.

On July 19, 2000, we finalized a biological opinion in accordance with section 7(a)(2) of the Endangered Species Act of 1973, as amended (ESA), evaluating containment of southern sea otters, including the capture and removal of otters from a designated management zone. That biological opinion is based on substantial new information on the population status, behavior, and ecology of the southern sea otter, and concludes that continued containment of southern sea otters will likely jeopardize the continued existence of the southern sea otter. On July 27, 2000 (65 FR 46172), we published a notice of intent to prepare a supplemental EIS on the southern sea otter translocation plan.

We have determined, based on our recent biological opinion, that containment of southern sea otters, at present, is not consistent with the requirement under the Act to avoid jeopardy to the species. We are in the process of reevaluating the translocation program and expect to complete a supplemental EIS and finalize our evaluation of the translocation program, including evaluation of the failure criteria developed for the program, by December 2002. We have provided and will continue to provide for public participation during that process. Upon completion of these documents, we will determine whether the southern sea otter translocation plan needs to be modified (including under what circumstances containment of southern sea otters can resume) or terminated to make it consistent with the survival and recovery needs of the species.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Sanders, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, California, 93003–7726, (telephone: 805/644–1766; facsimile: 805/644–3958).

SUPPLEMENTARY INFORMATION:

Background

On January 14, 1977 (42 FR 2968), we listed the southern sea otter (*Enhydra lutris nereis*) as a threatened species under the ESA on the basis of its small population size, greatly reduced range, and the potential risk from oil spills. We established a recovery team for the species in 1980 and approved a recovery plan on February 3, 1982. In the recovery plan, we identified the translocation of southern sea otters to a remote location in order to establish a second colony of otters as an effective and reasonable recovery action, although we acknowledged that a translocated southern sea otter population could impact shellfish fisheries that had developed in areas formerly occupied by southern sea otters. Goals cited in the recovery plan included: minimizing risk from potential oil spills; establishing at least one additional breeding colony outside the then-current southern sea otter range; and compiling and evaluating information on historical distribution and abundance, available but unoccupied habitat, and potential fishery conflicts.

The purpose of the translocation program was to establish southern sea otters in one or more areas outside the otters' then-current range to minimize the possibility of a single natural or human-caused catastrophe, such as an oil spill, adversely affecting a significant portion of the population. Ultimately, it was anticipated that translocation would result in a larger population size and a more continuous distribution of animals throughout the southern sea otter's former historical range. We viewed translocation as important to achieve recovery and to identify the optimum sustainable population (OSP) level for the southern sea otter as required under the Marine Mammal Protection Act (MMPA).

Translocation of a listed species to establish experimental populations is specifically authorized under section 10(j) of the ESA. However, the southern sea otter is protected under both the ESA and the MMPA, and the MMPA contains no similar translocation provisions. For southern sea otters, this dilemma was resolved by the passage of Public Law (P.L.) 99–625 (Fish and Wildlife Programs: Improvement; Section 1. Translocation of California Sea Otters) on November 7, 1986, which specifically authorized development of a translocation plan for southern sea otters administered in cooperation with the affected State.

If the Secretary of the Interior chose to develop a translocation plan under P.L. 99–625, the plan was to include: the number, age, and sex of sea otters proposed to be relocated; the manner in which sea otters were to be captured, translocated, released, monitored, and protected; specification of a zone into which the experimental population would be introduced (translocation zone); specification of a zone surrounding the translocation zone that did not include range of the parent population or adjacent range necessary for the recovery of the species (management zone); measures, including an adequate funding mechanism, to isolate and contain the experimental population; and a description of the relationship of the implementation of the plan to the status of the species under the ESA and determinations under section 7 of the ESA. The purposes of the management zone were to facilitate the management of southern sea otters and containment of the experimental population within the translocation zone and to prevent, to the maximum extent feasible, conflicts between the experimental population and other fishery resources within the management zone. Any sea otter found within the management zone was to be treated as a member of the experimental population. The Service was required to use all feasible non-lethal means to capture sea otters in the management zone and return them to the translocation zone or to the range of the parent population.

On March 6, 1987, we completed an intra-Service biological opinion that evaluated translocation of southern sea otters to San Nicolas Island, our preferred translocation site. That biological opinion analyzed effects on the parent population caused by removal of southern sea otters from the population for translocation and the effects on the species of containment (removal) of otters from the management zone. The proposed translocation plan was found to be a well-designed recovery action that maximized the

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opportunity for success while minimizing negative impacts on the parent population. We concluded that the southern sea otter translocation plan would not likely jeopardize the continued existence of the species.

In May 1987, we finalized an EIS which analyzed the impacts of establishing a program to translocate southern sea otters from their then-current range along the central coast of California to areas of northern California, southern Oregon, or San Nicolas Island off the coast of southern California. San Nicolas Island was identified as our preferred alternative. A detailed translocation plan meeting the requirements of Pub. L. 99–625 was included as an appendix to the final EIS.

Regulations to implement Pub L. 99–625 were finalized August 11, 1987 and are found at 50 CFR 17.84(d). They provide details of the translocation plan, including criteria for determining whether the translocation program would be considered a failure. Waters surrounding San Nicolas Island were designated as the translocation zone, and all waters south of Point Conception, California, with the exception of waters surrounding San Nicolas Island, were designated as the management zone.

On August 19, 1987, as part of our cooperative actions with the State of California, we signed a Memorandum of Understanding with the California Department of Fish and Game (CDFG) providing for cooperative research and management efforts to promote recovery of the southern sea otter population in California. The agreement also included provisions to minimize conflicts between southern sea otters, existing shellfish fisheries, and other users of marine resources through containment of sea otters that might enter the management zone.

We implemented the translocation plan and began moving groups of southern sea otters from the coast of central California to San Nicolas Island starting on August 24, 1987. In December 1987, in coordination with the CDFG, we began capturing and moving sea otters that entered the designated management zone in an effort to minimize conflicts between sea otters and fisheries within the management zone and to facilitate the management of sea otters at San Nicolas Island.

We released 140 southern sea otters at San Nicolas Island between August 1987 and March 1990. As of March 1991, approximately 14 sea otters (10 percent) were thought to remain at the island. Some sea otters died as a result of translocation; many swam back to the parent population, some moved into the management zone; and the fate of more than half the sea otters taken to San Nicolas is unknown. In 1991, we stopped translocating sea otters to San Nicolas Island, due to low retention and survival. However, we continued monitoring the sea otters remaining in the translocation zone. Sea otter surveys at San Nicolas Island are now conducted by the Biological Resources Division of the U.S. Geological Survey on a bimonthly basis.

Sea otters were captured and removed from the management zone until February 1993. At that time, two sea otters that had been recently captured in the management zone were found dead shortly after their release in the range of the parent population. A total of four sea otters were known or suspected to have died within 2 weeks of being moved from the management zone. We suspended all sea otter capture activities in the management zone to evaluate sea otter capture and transport methods. Results of the evaluation were inconclusive, but we remained concerned that capture and transport of sea otters found in the management zone could result in the death of some animals. Between December 1987 and February 1993, 24 sea otters were captured and removed from the management zone and returned to the parent range. Of these, 2 sea otters were captured twice in the management zone after being moved to the northern end of the parent range, suggesting that capture and relocation were ineffective. We discontinued containment efforts after 1993 in response, in part, to our concerns about the unexpected mortalities of otters experienced during or shortly following their removal from the management zone. We also recognized that techniques at the time, which proved to be less effective than originally predicted and were labor intensive, were not a feasible means of containing otters. In 1997, CDFG announced that they also would no longer be able to assist with sea otter captures in the management zone.

A group of approximately 100 southern sea otters moved from the parent range into the northern end of the management zone in 1998. At the same time, range-wide counts of the southern sea otter population indicated a decline of approximately 10 percent since 1995. Given the decline in the southern sea otter population, we asked the Southern Sea Otter Recovery Team, a team of biologists with special expertise in sea otter ecology, for a recommendation regarding the capture and removal of sea otters in the management zone. The recovery team recommended that we not move sea otters from the management zone to the parent population because moving large groups of sea otters and releasing them within the parent range would be disruptive to the social structure of the parent population.

In August 1998, we held two public meetings to provide information on the status of the translocation program, identify actions we intended to initiate, and solicit general comments and recommendations. At these meetings, we announced that we would reinitiate consultation under section 7 of the ESA for the containment program and begin the process of evaluating failure criteria established for the translocation plan. The technical consultant group for the Southern Sea Otter Recovery Team, composed of representatives from the fishery and environmental communities as well as State and Federal agencies, was also expanded to assist with evaluating the translocation program. We provided updates on the translocation program and status of the southern sea otter population to the California Coastal Commission, Marine Mammal Commission, and California Fish and Game Commission in 1998 and 1999.

In March 1999, we distributed our draft evaluation of the translocation program to interested parties. The draft document included the recommendation that we declare the translocation program a failure because fewer than 25 sea otters remained in the translocation zone and reasons for the translocated otters' emigration or mortality could not be identified and/or remedied. We received substantive comments from agencies and the public following release of the draft for review.

We prepared a draft biological opinion evaluating southern sea otter containment and distributed it to interested parties for comment on March 19, 1999. We completed a final opinion on July 19, 2000. Our reinitiation of consultation was prompted by the receipt of substantial new information on the population status, behavior, and ecology of the southern sea otter that revealed effects of containment that were not previously considered. Specifically, the biological opinion noted that in 1998 and 1999 southern sea otters moved into the management zone in much greater numbers than had occurred in prior years; analysis of carcasses indicated that southern sea otters were being exposed to environmental contaminants and diseases which could be affecting the health of the population; range-wide counts of southern sea otters found

numbers were declining; recent information, in particular the implications of the effects of the Exxon Valdez oil spill, indicated that sea otters at San Nicolas Island would not be isolated from the potential effects of a single large oil spill; and the capture and release of large groups of sea otters was likely to result in substantial adverse effects on the parent population. The Service concluded that reversal of the southern sea otter population decline and expansion of the southern sea otter's population distribution are essential to its survival and recovery. The Service further concluded that continuation of the containment program, while restricting the southern sea otter to the area north of Point Conception, will likely exacerbate recent sea otter population declines and increase vulnerability to a catastrophic oil spill or other man-made or natural stochastic events, and, therefore, likely jeopardize the continued existence of the species.

On February 8, 2000, a draft revised recovery plan for the southern sea otter was released for public review and comment (65 FR 6221). Based on the observed decline in abundance and shift in distribution of the southern sea otter population, the recovery team recommended in the draft revised recovery plan that it would be in the best interest of the southern sea otter to declare the experimental translocation of southern sea otters to San Nicolas Island a failure and discontinue maintenance of the management zone. The recovery team's recommendation will be fully evaluated through our ongoing NEPA process on the translocation action.

Current Status

In 4 of the past 5 years, population counts have shown a decline in southern sea otters. Survey data collected in spring 2000 were encouraging, with the number of southern sea otters counted approaching the highest recorded count for the population. However, more survey data are needed to determine whether the spring 2000 count was an anomaly or the beginning of a positive trend in southern sea otter population growth. In spite of more than 140 sea otters having been translocated and evidence of reproduction, the population of sea otters at San Nicolas Island currently comprises only approximately 20 adults.

To date, the southern sea otter translocation program has not met the primary goal of establishing a viable population of southern sea otters at San Nicolas Island. In the translocation plan we determined that a self-sustaining colony size of 150 southern sea otters would be necessary to consider the population at San Nicolas Island viable. Based on trends since the translocation program began and current circumstances, the best scientific information indicates that a population of this size may not be attainable.

On July 27, 2000 (65 FR 46172), we published in the **Federal Register** a notice of intent to prepare a supplemental EIS on the southern sea otter translocation program. The need for a supplemental EIS is based on changed circumstances and new information since the original EIS on translocation of southern sea otters was prepared in 1987. Public scoping meetings were held on August 15 and 17, 2000, with the purpose of soliciting information to be used in defining the overall scope of the supplemental EIS, identifying significant issues to be addressed, and identifying alternatives to be considered. The technical consultants to the Southern Sea Otter Recovery Team met to discuss the supplemental EIS on September 26, 2000. We expect a draft supplemental EIS to be completed and released for public comment by September 2001 and a final document to be completed approximately a year later. The draft evaluation of the translocation program released in March 1999 will be finalized following further opportunity for public participation in the decision-making process and completion of the EIS.

Public Law 99–625 and the ESA

Section 7 of the ESA mandates that no Federal agency—including the U.S. Fish and Wildlife Service—may take any action that is likely to jeopardize the continued existence of a listed species. The translocation plan we developed in 1987 pursuant to the discretionary authority vested in the Secretary of the Interior was a Federal action for which consultation was required. Therefore, prior to implementing the translocation program, we conducted an internal consultation under section 7. That internal consultation resulted in a biological opinion dated March 6, 1987, in which we concluded that implementation of the translocation plan as proposed was not likely to jeopardize the southern sea otter. Specifically we concluded that implementing zonal management of sea otters by establishing a translocation zone surrounding San Nicolas Island to which otters would be moved, establishing a surrounding "otter free" management zone south of Point Conception from which otters would be removed, demarcating the southward limit of the parent range at Point Conception to allow for range expansion by the parent population, removal and translocation of up to 250 sea otters from the parent population to San Nicolas Island, and containment of otters by non-lethal means and their return to the parent population or San Nicolas Island would not likely jeopardize the continued existence of the species. Had we concluded in our 1987 biological opinion that implementation of the translocation plan, or any of its components, would result in jeopardy to the sea otter, the program could not have legally proceeded as implementation would have violated the ESA.

Our implementing regulations at 50 CFR 402.16(b) require any Federal agency to reinitiate consultation if new information reveals that an action may affect a listed species in a manner or to an extent not previously considered. Significant new information that has come to light since inception of the translocation plan has included evidence of: (1) Recent annual declines in the parent population; (2) exposure of otters to contaminants; (3) movement of significant numbers of otters from the parent range into the management zone; (4) potential effects of a single, large oil spill on the entire sea otter population, including San Nicolas Island; and (5) substantial adverse impacts to the parent population likely to result from reintroduction of large numbers of contained otters. Pursuant to our section 7 responsibilities, we reinitiated consultation in 1999 on the containment component of the translocation plan to consider the significant new information about the potential effects of containment on the parent population of southern sea otters. In our July 2000 biological opinion we concluded that containment of sea otters from the management zone and reintroduction back into the parent population would likely jeopardize the continued existence of the species. In light of the determination from our July 2000 biological opinion, we may not proceed with containment until the factors that may cause jeopardy to the southern sea otter are addressed.

Our determination is consistent with both the structure and intent of Pub. L. 99–625. The statute as written recognizes the applicability of the ESA generally—and section 7 in particular—to the translocation plan throughout its various subsections (*e.g.*, sections 1(b)(6), 1(c), 1(d), 1(e), and 1(f)). Further, the intent of Pub. L. 99–625 was to allow the Secretary to implement what was then identified as a critical recovery action under the 1982 recovery plan ,

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and any implementation contrary to this recovery goal would contradict the purpose of the statute. Indeed, we have determined that containment under the present circumstances could lead to extinction of the species. Finally, apart from the specific references to section 7 throughout Pub. L. 99–625, the statute's discretionary grant of authority to the Secretary to develop and implement a translocation plan in the first instance brings the Secretary's affirmative decision to develop—and to continue to implement—the plan squarely within the universe of federal actions to which section 7 of the ESA applies. Having concluded under section 7 that implementation of the containment component of the plan would likely jeopardize the sea otters' continued existence, we may not proceed with that aspect of the translocation plan.

Without the legal protection afforded by section 7, actions undertaken by the Service, an authorized State agency, or an authorized agent of either the Service or such agency to effect containment are not insulated from liability under section 9 of the ESA and implementing regulations, which prohibit take of listed species unless otherwise authorized or exempt. Section 1(f) of Pub. L. 99–625 declares that no act by the Service or authorized State agency personnel to effect the translocation or management of a sea otter under the translocation plan may be treated as a violation of the ESA or the Marine Mammal Protection Act. However, the protective shield provided by this section no longer applies where the Service has determined that a component of the underlying plan itself—containment—is likely to jeopardize the continued existence of the sea otter. Under the present circumstances, any act by Service or authorized State agency personnel to remove otters from the management zone and relocate them to the parent population that results in take of an otter in either the management zone or the parent population would be in violation of section 9 of the ESA and subject to appropriate enforcement action.

Service's Position

Our mission is to work with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people. The southern sea otter is threatened with extinction. The southern sea otter translocation plan was developed to help this species recover by establishing an experimental population. We have yet to establish an experimental population, the southern sea otter continues to be threatened with extinction, and we have concluded that implementing the containment provisions of the southern sea otter translocation plan under the current circumstances will likely jeopardize the continued existence of the species.

We are preparing a supplemental EIS to evaluate new information regarding the translocation program and the status of the sea otter and to consider whether modifications to the southern sea otter translocation program as presently structured, or termination of the program, would be appropriate. We will also finalize our evaluation of the translocation program, including analysis of the failure criteria established for the program. Containment of southern sea otters under the current circumstances would violate our duty under the Endangered Species Act to avoid any action that would likely jeopardize the continued existence of the species. Therefore, we will not capture and remove sea otters from the management zone until we complete our reevaluation of the translocation program unless, during this interim period, new information or changed circumstances indicate that containment no longer poses likely jeopardy to the species. We will continue to solicit public input and comments regarding the translocation plan as part of our NEPA review and any rulemaking process.

Dated: January 16, 2001.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 01–1799 Filed 1–17–01; 3:23 pm]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

[AZ–070–01–1232–EA, SRP–070–01–07/08]

Bureau of Land Management

AGENCY: Bureau of Land Management, Interior.

ACTION: Temporary Closure of Selected Public Lands in La Paz County, Arizona, during the operation of the 2001 Whiplash Parker 400K/200K (kilometer) Desert Races.

SUMMARY: The Lake Havasu Field Office Manager announces the temporary closure of selected public lands under its administration in La Paz County, Arizona. This action is being taken to help ensure public safety and prevent unnecessary environmental degradation during the official permitted running of the 2001 Whiplash Parker 400K/200K Desert Races.

DATES: February 2, 2001, through February 4, 2001.

SUPPLEMENTARY REGULATIONS: Specific restrictions and closure periods are as follows:

Designated Course

1. The portion of the race course comprised of BLM lands, roads and ways located two miles either side of:
   (a) Shea Road from the eastern boundary of the Colorado River Indian Tribes Reservation to the junction with Swansea Road, and two miles either side of Swansea Road from its junction with Shea Road to the eastern bank of the Central Arizona Project Canal.
   (b) Swansea Road from its junction with Shea Road to the Four Corners intersection. The unpaved road from Midway north to Mineral Wash, and then west to the CAP Canal is closed to public use from 6:00 a.m. Friday, February 2, 2001 to 6:00 p.m. Sunday, February 4, 2001.
2. The entire designated race course is closed to all vehicles except authorized and emergency vehicles.
3. Vehicle parking or stopping in areas affected by the closure is prohibited except in the designated spectator areas. Emergency parking for brief periods of time is permitted on roads open for public use.
4. Spectator viewing on public land is limited to the designated spectator areas located south and north of Shea Road, as signed, approximately eight miles east of Parker, Arizona.
5. The following regulations will be in effect for the duration of the closure. Unless otherwise authorized, no person shall:
   a. Camp in any area outside of the designated spectator areas.
   b. Enter any portion of the race course or any wash located within the race course, including all portions of Osborne Wash.
   c. Spectate or otherwise be located outside of the designated spectator or pit areas.
   d. Possess or use fireworks.
   e. Operate any vehicle, other than registered event vehicles, which is not legally registered for street and highway operation, including operation of such a vehicle in any area affected by this closure.
   f. Park any vehicle in violation of posted restrictions, or in such a manner as to obstruct or impede normal or emergency traffic movement or the parking of other vehicles, create a safety hazard, or endanger any person, property or feature.
   g. Take any vehicle through, around or beyond a restrictive sign, recognizable barricade, fence or traffic control barrier.
   h. Fail to keep their campsite/viewing area free of trash and litter during the period of occupancy or fail to remove all personal equipment, trash, and litter upon departure.

Signs and maps directing the public to the designated spectator areas will be provided by the Bureau of Land Management and/or the event sponsor. The above restrictions do not apply to emergency vehicles and vehicles owned by the United States, the State of Arizona or La Paz County. Vehicles under permit for operation by event participants must follow the race permit stipulations. Authority for closure of public lands is found in 43 CFR 8340, Subpart 8341; 43 CFR 8360, Subpart 8364.1, and 43 CFR 8372. Persons who violate this closure order are subject to arrest and, upon conviction, may be fined not more than $100,000 and/or imprisoned for not more than 12 months.

FOR FURTHER INFORMATION CONTACT: Bryan Pittman, District Law Enforcement Ranger, or Myron McCoy, Outdoor Recreation Planner, Bureau of Land Management Lake Havasu Field Office, 2610 Sweetwater Avenue, Lake Havasu City, Arizona 86406, (520) 505–1200.

Dated: January 10, 2001.

Donald Ellsworth,

Field Manager, Lake Havasu Field Office.

[FR Doc. 01–1605 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–074–1220–PA–241A]

Notice of Proposed Closure of Certain Lands to Off-Highway Vehicle Use to Implement the Medicine Lodge Resource Management Plan, and Big Desert Management Framework Plan, Upper Snake River District, Idaho

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The Idaho Falls Field Office, Bureau of Land Management (BLM), proposes to close or seasonally restrict certain public lands in the Upper Snake River District, Idaho, to use by motor vehicles, including off-highway vehicles, snowmobiles and other snow machines under BLM's off-highway vehicle regulations. The notice affects lands covered by two land use plans and several activity level plans. The Medicine Lodge Resource Management Plan and the Big Desert Management Framework Plan described certain lands as "Closed to Off Highway Vehicles," and classified others as "Semi-Primitive Non-Motorized." The purpose of these proposed closures is to manage the specified lands to protect watershed, wildlife, and scenic values from damage caused by off-highway vehicle use, and to prevent undue and unnecessary disturbance to big game populations migrating to crucial winter range habitat.

DATES: You must submit your comments to BLM at the appropriate address below on or before February 21, 2001. BLM will not necessarily consider any comments received after that date in making its decisions on the final order.

ADDRESSES: Anyone wishing to make comments may submit them in person or by mail to the Field Manager, BLM Idaho Falls Field Office, 1405 Hollipark Drive, Idaho Falls, ID 83401–2100.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedure

Your comments on the proposed closure order should be specific, should be confined to issues pertinent to the proposed closure order, and should explain the reason for any recommended change. Where possible, your comments should refer to the specific section or paragraph of the proposal or to the specific tract of land that you are addressing. BLM may not necessarily consider or include in the Administrative Record for the final closure order comments that BLM receives after the close of the comment period or comments delivered to an address other than those listed above.

BLM will make your comments, including your name and address, available for public review at the Idaho Falls Field Office during regular business hours (7:45 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays). Under certain conditions, BLM may keep your personal information confidential. You must prominently state your request for confidentiality at the beginning of your comment. BLM will consider withholding your name, street address, and other identifying information on a case-by-case basis to the extent allowed by law. BLM will make available to the public all submissions from organizations and businesses and from individuals identifying themselves as representatives or officials of organizations or businesses.

II. Background

The authority for these closures is 43 CFR 8342.2(c), which directs BLM to "* * * take action by marking and other appropriate measures to identify designated areas and trails so that the public will be aware of locations and limitations applicable thereto. The authorized officer shall make appropriate informational material, including maps, available for public review."

The proposed closures implement the Medicine Lodge Resource Management Plan (RMP), the Big Desert Management Framework Plan (MFP) and associated activity level plans include the Sands Habitat Management Plan, Tex Creek Wildlife Management Area Plan, and the Snake River Activity/Operations Plan, and will remain in effect permanently with the publication of the final notice. This notice identifies by legal land description the precise areas that are closed to implement the plans.

There are several closure areas identified in the Medicine Lodge RMP. This notice only deals with the Tex Creek/Willow Creek, Big Bend Ridge, and Stinking Springs areas as well as river bottoms along the South Fork of the Snake River. The Big Desert MFP has identified a critical wildlife area along the main stem of the Snake River below Idaho Falls, Idaho.

The Tex Creek and Willow Creek areas are crucial wildlife areas lying east of Idaho Falls, Idaho. A majority of the lands are included in the Tex Creek Wildlife Management Area and are cooperatively managed with Idaho Dept. of Fish & Game and Bureau of Reclamation lands.

The closure affecting the Big Bend Ridge area implements the Sands Habitat Management Plan. An objective of this plan is to minimize the degree of harassment of elk due to human activity within the habitat management plan boundaries from November 15 to April 15 of the next year annually. Within the overall area, a seasonal "No Human Entry" closure is already in effect from January 1 through April 30 of each year throughout the majority of the wintering big game range. This closure notice would cover the transition area or migration route to the winter range and protect the habitat from OHV use. The established designated routes across public land along Fourth of July Creek, Saddorous Hill, and Hidden Reservoir/Jackson Mill roads will remain open.

Areas along the South Fork of the Snake River includes the Stinking Springs area and critical floodplain river bottom lands. The Snake River Activity/Operations Plan restricted OHV use to a

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few existing roads and trails such as the Stinking Springs Trail. The river bottom lands are experiencing increases in new OHV trails. BLM considers these lands sensitive riparian habitat areas. Therefore, BLM needs to restrict OHV use on these lands.

Under the authority and for the reasons stated in the Background section, the Idaho Falls Field Office, Bureau of Land Management, issues the following closure notice.

Closure of Certain Public Lands in the Upper Snake River District to Motor Vehicle Use

Tex Creek/Willow Creek Area

Effective (30 days after the date of publication of final closure order in the **Federal Register**), Bureau of Land Management (BLM)—administered public lands located in the Tex Creek/Willow Creek area, described below, that are designated as "Closed to Off Highway Vehicles (OHV)" or "Semi Primitive Non-motorized" in the Medicine Lodge Resource Management Plan are closed to motor vehicle use, including off highway vehicles (OHV) and snow machines. The only exceptions to this closure are administrative use of vehicles by the Bureau of Land Management and use by BLM permittees, including State and local government agencies. The area is bounded generally by the Bone Road on the west, Caribou National Forest on the east, the Bonneville and Bingham County lines on the south, and Ririe Reservoir to the north, and is located within the Tex Creek Wildlife Management Area. The legal description of the lands is as follows:

Boise Meridian, Idaho

T. 1 N., R. 40 E.,
Sec. 1, W½ SE¼;
Sec. 4, S½ SE¼;
Sec. 5, Lots 3 and 4, S½ NW¼, SW¼ NE¼, W½ SE¼, SE¼ SE¼, SW¼;
Sec. 7, E½ SE¼, NW¼ SE¼;
Sec. 8, W½ SW¼, N½ NE¼, NE¼ NW¼;
Sec. 9, S½ NE¼, S½ NW¼;
Sec. 10, NW¼, NW¼ NE¼;
Sec. 12, E½ NE¼;
Sec. 17, W½, W½ SE¼, SW¼ NE¼;
Sec. 18, E½ E½;
Sec. 19, N½ NE¼;
Sec. 20, NW¼;
Sec. 21, SE¼ SW¼;
Sec. 28, N½ NW¼, SE¼ NW¼, E½ SW¼, SW¼ SW¼, W½ SE¼, SE¼ SE¼;
Sec. 29, N½ N½;
Sec. 32, Lots 1 and 2, N½ SE¼, S½ NE¼, NE/14 NE¼;
Sec. 33, Lots 1–4, NW¼ NE¼, NE¼ NW¼, W½ NW¼, N½ SW¼, N½ SE¼;
Sec. 34, SW¼ SW¼.
T. 1 N., R. 41 E.,
Sec. 7, Lots 2 and 3, SW¼ SE¼, SE¼ SW¼;
Sec. 14, SW¼, S½ NW¼, NE¼ NW¼, SW¼ SE¼;
Sec. 15, SE¼, N½ SW¼, SE¼ NE¼, NW¼ NE¾;
Sec. 17, NW¼ NW¼;
Sec. 21, NE¼;
Sec. 23, W½, S½ NE¼, NW¼ NE¼;
Sec. 26, N½ SW¾, SW¼ NW¼;
Sec. 27, S½ NE¼, N½ SW¼, SE¼ NW¼.
T. 2 N., R. 40 E.,
Sec. 23, N½ SW¼, SW¼ SW¼, SE¼ NE¼, NE¼ NE¼;
Sec. 24, S½ NW¼, NE¼ SW¼, SE¼ SE¼;
Sec. 25, E½ SW¼, W½ SE¼.
T. 2 N., R. 41 E.,
Sec. 35, SE¼ NW¼.
T. 1 S., R. 40 E.,
Sec. 2, SW¼, S½ SE¼;
Sec. 3, Lot 1, E½ SE¼;
Sec. 10, E½ NE¼, NE¼ SE¼;
Sec. 11, E½, NW¼, N½ SE¼, SE¼ SW¼;
Sec. 12, SW¼, S½ NW¼, S½ SE¼;
Sec. 13, E½, E½ W½;
Sec. 24, NE¼, N½ SE¼, SW¼ SE¼;
Sec. 25, W½ NE¼.
T. 1 S., R. 41 E.,
Sec. 7, Lots 3 and 4;
Sec. 18, Lots 1–4;
Sec. 19, Lots 1–4, SE¼, E½ SW¼, S½ NE¼, SE¼ NW¾;
Sec. 20, SW¼, W½ SE¼, SW¼ NW¼;
Sec. 30, E½E½.
T. 1 S., R. 42 E.,
Sec. 18, NE¼, SE¼ NW¼, N½ SE¼, SE¼ SE¼.

Stinking Springs

Effective (30 days after the date of publication of final closure order in the **Federal Register**), Bureau of Land Management (BLM)-administered public lands located in the Stinking Springs area north of the South Fork of the Snake River near Heise, Idaho, described below, are closed to motor vehicle use, including off-highway vehicles (OHV) and snow machines. The only exceptions to this closure are administrative use of vehicles by the Bureau of Land Management and use by BLM permittees, including State and local government agencies. The Stinking Springs Trail shall remain open to all modes of travel from 4/15 to 11/15 of each year. Snow machines and full size passenger vehicles are prohibited year round. The area is bounded generally by the South Fork of the Snake River on the south and west, the Kelly Canyon Road and Targhee National Forest on the north and east. The legal description of the lands is as follows:

Boise Meridian, Idaho

T. 4 N., R. 41 E.,
Sec. 32, SE¼, SE¼ NE¼, and lands east of the Kelly Canyon Road in the NE¼ NE¼, NW¾ NE¼, SW¼ NE¼, NE¼ SW¼;
Sec. 33, All.
T. 3 N., R. 41 E.,
Sec. 2, SW¼;
Sec. 3, All;
Sec. 4, SE¼, SE¼ SW¼, NE¼ SW¼, NW¼ SW¼;
Sec. 5, NW¼ NE¼;
Sec. 8, Lots 6 and 8;
Sec. 9, Lots 2 and 3, NE¼, NW¼, SE¼, NE¼ SW¾;
Sec. 10, NW¾, SW¼, NE¼ NE¼, NW¼ NE¼, SW¼ NE¼;
Sec. 11, Lot 2, N½ NW¼;
Sec. 15, Lots 7 and 8, NW¼ NW¼;
Sec. 16, Lots 5 and 6.

Big Bend Ridge

Effective (30 days after the date of publication of final closure order in the **Federal Register**), BLM-administered public lands located in the Rattlesnake-Box Canyon, July Creek and Blue Creek areas, described below, are closed to motor vehicle use, including off-highway vehicles (OHV) and snow machines from October 1 to December 31 of each year, except on designated roads. The only exceptions to this closure are administrative use of vehicles by the Bureau of Land Management and use by BLM permittees, including State and local government agencies. The area is bounded by the Targhee National Forest on the east and north, Ashton Reservoir on the south, and the Sand Creek road on the west. The legal description of the lands is as follows:

Boise Meridian, Idaho

T. 9 N., R. 42 E.,
Sec. 1, Lot 4, SW¼ NW¼, W½ SW¼;
Sec. 2, All;
Sec. 3, All;
Sec. 4, All;
Sec. 5, Lots 1, 2, and 4, S½ NE¼, SE¼, SW¼ NW¼;
Sec. 6, Lot 1, SE¼ NE¼;
Sec. 8, NE¼, E½ SE¼;
Sec. 9, All;
Sec. 10, W½, SE¼, N½ NE¼, SW¼ NE¼;
Sec. 11, NW¼ NW¼, NW¼ NE¼;
Sec. 12, NE¾ NW¼;
Sec. 15, NW¼, NW¼ SE¼, W½ NE¼, NE¼ NE¼;
Sec. 17, SE¼, E½ NE¼, S½ SW¼;
Sec. 18, SE¼ SE¼;
Sec. 20, N½ N½;
Sec. 21, N½ N½, SE¼ NW¼, SW¼ NE¼.
T. 10 N., R. 42 E.,
Sec. 30, Lot 5;
Sec. 31, Lots 1–8, NE¼ SE¼.
T. 10 N., R. 41 E.,
Sec. 1, Lots 1–3, S½ N½, S½;
Sec. 2, SE¼;
Sec. 8, SE¼ SE¼;
Sec. 11, NE¼ NW¼, N½ NE¼;
Sec. 12, NW¼ NW¼, SW¼ SE¼, E½ E½;
Sec. 13, NE¼, NE¼ SE¼, NW¼ NW¼, SE¼ SW¼.
T. 11 N., R. 41 E.,
Sec. 29, S½ SW¼;
Sec. 32, NW¼.

South Fork of the Snake and Main Snake Rivers

Effective (30 days after the date of publication of final closure order in the **Federal Register**), BLM-administered public lands located in the South Fork of the Snake and Main Snake River corridors, described below, designated as Closed to Off-Highway Vehicles (OHV) in the Snake River Activity/Operations Plan, and Big Desert MFP are closed to motor vehicle use, including off-highway vehicles (OHV) and snow machines. The only exceptions to this closure are administrative use of vehicles by the Bureau of Land Management and use by BLM permittees, including State and local government agencies. The areas are bounded generally by the South Fork Snake and Main Snake Rivers. The legal description of the lands is as follows:

Dry Canyon: Those portions of the following described lands lying east and west of the South Fork Snake River.

Boise Meridian, Idaho

T. 2 N., R. 43 E.,
Sec. 5, Lots 1–4;
Sec. 6, Lots 1–3, Lots 8–13, E½ SW¼, and those portions of BLM lying within Lots 5–7;
Sec. 7, Lots 2, 3, and 6, and those portions of BLM lying within Lot 4.

Warm Springs: Those portions of the following described lands lying east of the South Fork Snake River.

Boise Meridian, Idaho

T. 3 N., R. 42 E.,
Sec. 12, Lots 3–6, 10 and 11;
Sec. 13, Lots 10 and 11.

Mud Creek Bar: Those portions of the following described lands lying east of the South Fork Snake River.

Boise Meridian, Idaho

T. 3 N., R. 42 E.,
Sec. 4, Lots 9 and 10;
Sec. 5, Lots 15 and 16;
Sec. 9, Lot 11.

Wolf Flat: Those portions of the following described lands lying north of the South Fork Snake River.

Boise Meridian, Idaho

T. 3 N., R. 41 E.,
Sec. 10, Lots 1 and 2;
Sec. 11, Lots 3 and 4;
Sec. 15, Lot 6.

Kelly Island: Those portions of the following described lands lying east and north of the South Fork Snake River and west and south of the South Fork county road (USFS road 206).

Boise Meridian, Idaho

T. 3 N., R. 41 E.,
Sec. 5, Lots 13 and 14.
T. 4 N., R. 41 E.,
Sec. 31, Lots 13 and 14;
Sec. 32, Lot 3.

Kelly Canyon: Those portions of the following described lands lying north and west of the Kelly Canyon Road.

Boise Meridian, Idaho

T. 4 N., R. 41 E.,
Sec. 29, Lot 5, SE¼, E½ SW¼, SW¼ SW¼, SW¼ NE¼, S½ NW¼;
Sec. 32, NW¼, NE¼ SW¼, N½ NE¼, SW¼ NE¼.

Cress Creek Trail: Those portions of the following described lands lying north and east of the South Fork Snake River.

Boise Meridian, Idaho

T. 4 N., 40 E.,
Sec. 23, Lots 6 and 11, SE¼ SE¼, W½ SE¼, NE¼ SW¼;
Sec. 26, Lots 8 and 9.

Twin Bridges: Those portions of the following described lands lying east of the south bridge and up the South Fork Snake River.

Boise Meridian, Idaho

T. 4 N., 40 E.,
Sec. 21, Lots 5–13.

Lorenzo Bridge: Those portions of the following described lands lying east of the South Fork Snake River.

Boise Meridian, Idaho

T. 5 N., R. 39 E.,
Sec 28, Lots 18–21, excluding the boat ramp access area.

Menan Bridge: Those portions of the following described lands lying South of the Snake River and east of the Menan Bridge.

Boise Meridian, Idaho

T. 5 N., R. 38 E.,
Sec 22, Lots 15, 16, 19, and 20.

Kellers Island: Those portions of the following described lands lying west of the Snake River.

Boise Meridian, Idaho

T. 5 N., R. 38 E.,
Sec 7, Lot 13;
Sec. 18, Lots 16 and 17.

Deer Parks: Those portions of the following described lands lying south of the Butte Market Lake Canal and north of the Snake River.

Boise Meridian, Idaho

T. 5 N., R. 37 E.,
Sec 12, Lots 9–12;
Sec. 13, Lots 9 and 10;
Sec. 14, Lots 9–12.

Ducks Unlimited Tract C: Those portions of the following described lands lying east of the Snake River.

Boise Meridian, Idaho

T. 4 N., R. 37 E.,
Sec 10, Lots 7, 15–17.

Firth River Bottom: Those portions of the following described lands lying west of the Snake River and east of the Peoples Canal.

Boise Meridian, Idaho

T. 1 South, R. 36 E.,
Sec 26, Lots 9–11, and 17.

Firth River Bottom: Those portions of the following described lands lying east of the Snake River and east of the Peoples Canal.

Boise Meridian, Idaho

T. 1 South, R. 36 E.,
Sec 27, Lot 6;
Sec. 34, Lots 8 and 15.

FOR FURTHER INFORMATION CONTACT: Jeff Gardetto, Wildlife Management Biologist, (208) 524–7545.

Dated: January 8, 2001.

Joe Kraayenbrink,

Idaho Falls Field Manager.

[FR Doc. 01–1727 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–GG–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–6332–AA; HAG01–0074]

Notice of Availability of the Heligate Recreation Area Management Plan/Draft Environmental Impact Statement (DEIS) for the 27 mile section of the Rogue River from the mouth of the Applegate River to Grave Creek

AGENCY: Bureau of Land Management, Medford District Office, Grants Pass Resource Area.

SUMMARY: In accordance with Section 202 of the National Environmental Policy Act of 1969 and Section 202 of the Federal Land Policy and Management Act of 1976, a Recreation Area Management Plan and DEIS have been completed for a portion of the Medford District. The DEIS describes and analyzes future options for managing the 27 mile section of the Rogue River (from the mouth of the Applegate River to Grave Creek) in southern Josephine County, Oregon.

The need for action is based on BLM visitor use reports that show major increases in water-based visitor use activities, on a recreation use study, and on a scoping effort which identified visitor use conflicts. The purpose of the action is to ensure recreational use levels are in alignment with the purposes of the Wild and Scenic Rivers Act of October 2, 1968.

All of the recommend planning issues share one topic: The growth of different

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types of recreation use on the river, and how much recreation use can and should the river support. The identified issues are motorized boating, non-motorized float boating, non-mortorized boat angling, user fees, camping, trails, day-use areas, public access and visitor services.

The DEIS analyzes five alternatives ranging from fewer watercraft and less visitor use to maximum watercraft and visitor use. Open houses will be held on January 18, 2001, from 7 p.m. to 10 p.m. at the City of Grants Pass Council Chambers, 101 NW A. Street in Grants Pass, and on January 24, 2001, from 7 p.m. to 10 p.m. at the Medford District Office, 3040 Biddle Road, in Medford.

DATES: Comments will be accepted until February 24, 2001. Informal meetings may be scheduled before the comment period closes.

ADDRESSES: Comments should be addressed to Cori Cooper, Planning Team Leader, Grants Pass Resource Area, Bureau of Land Management, Medford District Office, 3040 Biddle Road, Medford, Oregon 97504. Individual copies of the DEIS may be obtained by contacting the Planning Team Leader.

Comments, including names and addresses, will be available for public review. Individual respondents may request confidentiality. If you wish to withhold your name and/or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law.

Dated: January 9, 2000.

Abbie Jossie,

Field Manager, Grants Pass Resource Area.

[FR Doc. 01–1726 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–924–1430–HN–003E; MTM 84984, MTM 86124]

Public Notice—Jurisdiction Transfer as Required by the Crow Boundary Settlement Act of 1994; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice correction.

SUMMARY: This notice corrects the total acreage figure published in the **Federal Register**, 65 FR 59011, dated October 3, 2000, for the transfer of exclusive jurisdiction and administration of the surface estate from the Bureau of Land Management to the United States of America, Bureau of Indian Affairs, in trust for the Crow Indian Tribe.

On page 59011, column 3, the aggregate 12,465.32 acres is corrected to read "The areas described aggregate 12,431.59 acres in Big Horn and Yellowstone Counties, Montana." This correction does not alter the effective date of the original notice.

FOR FURTHER INFORMATION CONTACT: Russell Sorensen, BLM Dillon Field Office, 1005 Selway Drive, Dillon, Montana 59725–9431, 406–683–8036.

Dated: January 8, 2001.

Thomas P. Lonnie,

Deputy State Director, Division of Resources.

[FR Doc. 01–1730 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–SS–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WO–260–01–1060–00–24 1A]

Wild Horse and Burro Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Announcement of meeting.

SUMMARY: The Bureau of Land Management (BLM) announces that the Wild Horse and Burro Advisory Board will conduct a meeting on matters pertaining to management and protection of wild, free-roaming horses and burros on the Nation's public lands.

DATES: The advisory board will meet Tuesday, February 20, 2001 from 8:00 a.m. to 5:00 p.m. local time, and on Wednesday, February 21, 2001, from 8:00 a.m. to 12 noon local time. Submit written comments pertaining to the Advisory Board meeting no later than close of business February 28, 2001.

ADDRESSES: The Advisory Board will meet at the Bureau of Land Management's National Training Center at 9829 N. 31st Avenue, Phoenix, Arizona, in the Oregon Room.

Send written comments pertaining to the Advisory Board meeting to: Bureau of Land Management, National Wild Horse and Burro Program, WO–260, Attention: Ramona Delorme, 1340 Financial Boulevard, Reno, Nevada, 89502–7147.

FOR FURTHER INFORMATION CONTACT: Janet Nordin, Wild Horse and Burro Public Outreach Specialist, (775) 861–6583. Individuals who use a telecommunications device for the deaf (TDD) may reach Ms. Nordin at any time by calling the Federal Information Relay Service at 1–800–877–8339.

Electronic Access and Filing Address. Speakers may transmit comments electronically via the Internet to: *Janet_Nordin@blm.gov*. Please include the identifier "WH&B" in the subject of your message and your name and address in the body of your message.

SUPPLEMENTARY INFORMATION:

I. Public Meeting

Under the authority of 43 CFR part 1784, the Wild Horse and Burro Advisory Board advises the Secretary of the Interior, the Director of the BLM, the Secretary of Agriculture, and the Chief, Forest Service, on matters pertaining to management and protection of wild, free-roaming horses and burros on the Nation's public lands. The tentative agenda for the meeting is:

Tuesday, February 20, 2001

Introduction
Approval of September Board Minutes
Research
Marketing Study
Subcommittee Feedback
Wild Horse and Burro Strategy Update
Public Comment
Adjourn

Wednesday, February 21, 2001

Reports
Emerging issues
Close Out/Recommendations
Adjourn

The meeting site is accessible to individuals with disabilities. An individual with a disability needing an auxiliary aid or service to participate in the meeting, such as interpreting service, assistive listening device, or materials in an alternate format, must notify the person listed under **FOR FURTHER INFORMATION CONTACT** two weeks before the scheduled meeting date. Although the BLM will attempt to meet a request received after that date, the requested auxiliary aid or service may not be available because of insufficient time to arrange it.

The Federal advisory committee management regulations [41 CFR 101–6.1015(b)], require BLM to publish in the **Federal Register** notice of a meeting 15 days prior to the meeting date.

II. Public Comment Procedures

Members of the public may make oral statements to the Advisory Board on February 20, 2001 at the appropriate point in the agenda. This opportunity is anticipated to occur at 4:00 p.m. local time. Persons wishing to make statements should register with the BLM by noon on February 20, 2001, at the meeting location. Depending on the number of speakers, the Advisory Board may limit the length of presentations. At previous meetings, presentations have been limited to three minutes in length. Speakers should address the specific wild horse and burro-related topics listed on the agenda. Speakers must submit a written copy of their statement to the address listed in the **ADDRESSES** section or bring a written copy to the meeting.

Participation in the Advisory Board meeting is not a prerequisite for submission of written comments. The BLM invites written comments from all interested parties. Your written comments should be specific and explain the reason for any recommendation. The BLM appreciates any and all comments, but those most useful and likely to influence decisions on management and protection of wild horses and burros are those that are either supported by quantitative information or studies or those that include citations to and analysis of applicable laws and regulations. Except for comments provided in electronic format, speakers should submit two copies of their written comments where feasible. The BLM will not necessarily consider comments received after the time indicated under the **DATES** section or at locations other than that listed in the **ADDRESSES** section.

In the event there is a request under the Freedom of Information Act (FOIA) for a copy of your comments, the BLM will make them available in their entirety, including your name and address (or your e-mail address if you file electronically). However, if you do not want the BLM to release your name and address (or e-mail address) in response to a FOIA request, you must state this prominently at the beginning of your comment. The BLM will honor your request to the extent allowed by law. The BLM will release all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, in their entirety, including names and addresses (or e-mail addresses).

Dated: January 11, 2001.

Henri R. Bisson,

Assistant Director, Renewable Resources and Planning.

[FR Doc. 01–1679 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–930–1430–ET; COC–28578]

Public Land Order No. 7478; Opening of Public Land Under Section 24 of the Federal Power Act; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order opens, subject to the provisions of section 24 of the Federal Power Act, 40 acres of public land withdrawn by a Secretarial order which established Bureau of Land Management Power Site Reserve No. 105. This action will allow for disposal of the land and retain the power rights to the United States. The land has been and will remain open to mineral leasing and, under the provisions of the Mining Claims Rights Restoration Act of 1955, to mining.

EFFECTIVE DATE: April 23, 2001.

FOR FURTHER INFORMATION CONTACT: Doris E. Chelius, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215–7093, 303–239–3706.

By virtue of the authority vested in the Secretary of the Interior by the Act of June 10, 1920, section 24, as amended, 16 U.S.C. 818 (1994), and pursuant to the determination of the Federal Energy Regulatory Commission in DVCO–532, it is ordered as follows:

1. At 9 a.m. on April 24, 2001, the following described public land withdrawn by the Secretarial Order dated January 14, 1910, which established Power Site Reserve No.105, will be opened to disposal subject to the provisions of section 24 of the Federal Power Act as specified by the Federal Energy Regulatory Commission determination DVCO–532, and subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law:

Sixth Principal Meridian
T. 7 S., R. 70 W., sec. 20, SW¼ SE¼.

The area described contains 40 acres in Jefferson County.

2. The State of Colorado has a preference right for public highway rights-of-way or material sites for a period of 90 days from the date of publication of this order and any location, entry, selection, or subsequent patent shall be subject to any rights granted the State as provided by the Act of June 10, 1920, Section 24, as amended, 16 U.S.C. 818 (1994).

Dated: December 22, 2000.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 01–1571 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MTM 88993]

Public Land Order No. 7480; Withdrawal of National Forest System Lands in the Rocky Mountain Front; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order withdraws approximately 405,000 acres of National Forest System lands from location and entry under the United States mining laws for a period of 20 years to preserve the traditional cultural uses by Native Americans, threatened and endangered species, and the outstanding scenic values and roadless character.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: David Whittekiend, Lewis and Clark National Forest, 1101 15th Street North, Great Falls, Montana 59403–0869, 406–791–7700.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Subject to valid existing rights, the National Forest System lands within the following described areas are hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2 (1994)) to preserve the outstanding values of the Rocky Mountain Front:

Principal Meridian, Montana

(PB identifies Protracted Blocks)

T. 16 N., R. 6 W.,
Secs. 30 and 31.
T. 15 N., R. 7 W.,
Secs. 2 and 6.
T. 16 N., R. 7 W., unsurveyed
T. 17 N., R. 7 W., partly unsurveyed
T. 16 N., R. 8 W., unsurveyed
PB 37, PBs 43 to 47, inclusive, Secs. 12, 13, 14, 23, 26, 27, and 28, excluding wilderness;
PB 48 and Secs. 24 and 25;
T. 17 N., R. 8 W., partly unsurveyed
PBs 37 and 39, and Secs. 2, 11, 12, 13, and 25;
PBs 38, 40, and 41, and Secs. 3, 10, 14, 15, 22, 35 and 36, excluding wilderness.
T. 18 N., R. 8 W., unsurveyed

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PBs 37 to 50, inclusive, Secs. 7 to 10, inclusive, and Secs. 14, 15, 16, 23, 26 and 35;
Secs. 17, 18, 20, 21, 22, 27, and 34, excluding wilderness.
T. 18 N., R. 9 W.,
PB 37;
PB 38 and Secs. 3, 11, 12, and 13, excluding wilderness.
T. 19 N., R. 9 W.,
Secs. 25 and 36;
PBs 37 to 44, inclusive, Secs. 4 to 11, inclusive, Secs. 14, 15, 16, 22, 23, and 27, unsurveyed;
Secs. 17, 18, 20, 21, 28, 33, and 34, unsurveyed, excluding wilderness.
T. 20 N., R. 9 W., partly unsurveyed
T. 21 N., R. 9 W., partly unsurveyed
T. 22 N., R. 9 W., unsurveyed
PBs 37 to 52, inclusive, Secs. 2 to 5, inclusive, Secs. 8 to 11, inclusive, Secs. 14 to 18, inclusive, Secs. 20 to 23, inclusive, and Secs. 26 to 29, inclusive;
Secs. 6 and 7, excluding wilderness.
T. 23 N., R. 9 W., unsurveyed
PBs 37 to 42, inclusive, Secs. 2, 3, 10, 11, 14, 15, 21, 22, 23, 26, 27, 28, 33, 34, and 35;
Secs. 4, 5, 8, and 9, Secs. 16 to 20, inclusive, and Secs. 29 to 32, inclusive, excluding wilderness.
T. 24 N., R. 9 W., unsurveyed
PBs 37 to 42, inclusive, Secs. 2 to 11, inclusive, Secs. 14 to 17, inclusive, and Secs. 21, 22, 23, 26, 27, 34 and 35;
Secs. 18, 19, 20, 28, 29, 30, and 33, excluding wilderness.
T. 25 N., T. 9 W., unsurveyed
T. 26 N., R. 9 W., unsurveyed
PBs 37, 38, and 39, PBs 44 to 48, inclusive, Secs. 11, 14, 23, 26, 33, 34, and 35;
PBs 40 and 41, Secs. 10, 15, and 22, Secs. 27 to 32, inclusive, excluding wilderness.
T. 27 N., R. 9 W.,
Secs. 9, 16, 21, 22, 23, 26, 27, 34 and 35;
Secs. 28 and 33, excluding wilderness.
T. 19 N., R. 10 W.,
Secs. 1, 2, 12, and 13, excluding wilderness.
T. 20 N., R. 10 W., unsurveyed
Secs. 1 to 5, inclusive, Secs. 8 to 17, inclusive, Secs. 21 to 28, inclusive, and Sec. 36;
Secs. 6, 7, 18, 19, 20, and 29, Secs. 32 to 35, inclusive, excluding wilderness.
T. 21 N., R. 10 W., unsurveyed
PBs 37 and 38, Secs. 12 and 13, Secs. 24 to 28, inclusive, and Secs. 33 to 36, inclusive;
PB 39, Secs. 11, 14, and 15, Secs. 20 to 23, inclusive, and Secs. 29 to 32, inclusive, excluding wilderness.
T. 22 N., R. 10 W., partly unsurveyed
PBs 37, 38, 40, and 41, Secs. 1, 2, 11, 14, and 35, excluding wilderness;
PB 39 and Secs. 12, 13, 25, 26, and 36;
T. 24 N., R. 10 W., unsurveyed
Secs. 1, 12, and 13, excluding wilderness.
T. 25 N., R. 10 W., unsurveyed
Secs. 1, 2, 3, 11, 12, and 13;
Sec. 4, excluding wilderness and Flathead National Forest System lands;
Secs. 9, 10, 14, 15, 23, 24, 25, and 36, excluding wilderness.
T. 26 N., R. 10 W.,
Secs. 25 and 26, excluding wilderness;
Secs. 27, 28, and 33, excluding wilderness and Flathead National Forest System lands;
Secs. 34, 35, and 36.
T. 28 N., R. 10 W.,
PBs 38, 39, and 40, and Secs. 6, 7, and 18, unsurveyed;
PB 41, and Secs. 19 and 30, excluding wilderness, unsurveyed.
T. 29 N., R. 10 W.,
PBs 37, 38, and 39, and Secs. 30 and 31, unsurveyed.
T. 20 N., R. 11 W., unsurveyed
Secs. 12 and 13, excluding wilderness.
T. 27 N., R. 11 W., unsurveyed
Secs. 3, 4, and 5, excluding wilderness.
T. 28 N., R. 11 W.,
Secs. 1 to 24, inclusive, and Sec. 28;
Secs. 25, 26, and 27, and Secs. 29 to 34, inclusive, excluding wilderness.
T. 29 N., R. 11 W.,
PBs 37 to 44, inclusive, Secs. 5 to 9, inclusive, Secs. 15 to 23, inclusive, and Secs. 25 to 36, inclusive, unsurveyed.
T. 30 N., R. 11 W.,
PBs 37, 38, and 39, unsurveyed.
T. 28 N., R. 12 W., unsurveyed
Secs. 1 to 18, inclusive, and Secs. 22 to 26, inclusive;
Secs. 19, 20, 21, 27, 28, and 34, excluding wilderness and Flathead National Forest System lands;
Secs. 35 and 36, excluding wilderness.
T. 29 N., R. 12 W., unsurveyed
Secs. 1 to 30, inclusive, and Secs. 32 to 36, inclusive; Sec. 31, excluding Flathead National Forest System lands.
T. 30 N., R. 12 W.,
PBs 37 to 46, inclusive; Tract 47, PBs 48, 49, and 50, sec. 7, Secs. 17 to 21, inclusive, and Secs. 26 to 36, inclusive.
T. 31 N., R. 12 W.,
Sec. 31, excluding Blackfeet Indian Reservation.
T. 28 N., R. 13 W.,
Secs. 1 and 2, Secs. 11 to 14, inclusive, and Sec. 23, excluding Flathead National Forest System lands;
Sec. 24, excluding wilderness and Flathead National Forest System lands.
T. 29 N., R. 13 W.,
Secs. 1 to 4, inclusive, and Secs. 10 to 14, inclusive;
Secs. 5, 6, 8, 9, 15, and 16, Secs. 22 to 25, inclusive, and sec. 36, excluding Flathead National Forest System lands.
T. 30 N., R. 13 W., unsurveyed
PBs 37, 38, 40, and 40A, PBs 43 to 51, inclusive, PBs 54, 55, 56, and 59, PBs 61 to 66, inclusive, PB 68, Secs. 23 to 27, inclusive, and Secs. 32 to 36, inclusive, and all unpatented tracts;
PB 71, excluding Flathead National Forest System lands.
T. 31 N., R. 13 W.,
PBs 42, 46, 48, 49, and 50, unsurveyed.
The areas described contain approximately 405,000 acres in Lewis and Clark, Teton, Pondera, and Glacier Counties.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: January 16, 2001.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 01–1816 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–062–01–1220–AA]

Notice of Camping and Wood Cutting and Gathering Restrictions, Moab Field Office

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Notice of camping and wood cutting and gathering restrictions—Moab Field Office, Utah.

SUMMARY: This notice, applicable to specified public lands administered by the BLM Moab Field Office, limits camping to developed campgrounds and designated sites, allows BLM to limit the size of designated camping areas, and requires the use of portable toilets at these designated sites where toilets are not provided. The notice also prohibits wood cutting and gathering, including Christmas tree cutting, for these intensively used areas and the Sand Flats Recreation Area. These actions are implemented on an interim basis to protect natural resources pending revision of the Resource Management Plan (RMP) for the area administered by the Moab Field Office.

DATES: This notice is effective January 22, 2001, and shall remain in effect until modified or the RMP is amended.

FOR FURTHER INFORMATION CONTACT: Russell von Koch, Resource Advisor, BLM Moab Field Office, 82 East Dogwood Avenue, Moab, Utah 84532 or telephone 435–259–2100.

SUPPLEMENTARY INFORMATION: Frequent use of public lands near Moab, Utah for camping at undeveloped sites and associated wood cutting and gathering is damaging soils, vegetation, and scenic values at local destination areas and along popular trails and roads. The following actions are necessary to limit impacts to natural resource values and maintain the quality of recreation opportunities.

Camping Restrictions Along Highway and Road Corridors

Camping with vehicles on BLM administered public land within one-half mile of the following highways and roads is limited to developed campgrounds and designated sites on a year-round basis to protect scenic values, reduce damage to soils and vegetation, and provide for public safety:

(1) Utah Highway 313;

(2) The Island in the Sky entrance road between Utah Highway 313 and Canyonlands National Park;

(3) The Gemini Bridges route (primarily Grand Co. No. 118) and the spur route from it into "The Bride Canyon;"

(4) The Kane Creek Canyon Rim route from U.S. Highway 191 to where it crosses the eastern boundary of section 20, T. 27 S., R. 22 E. exclusive of the state and private land west of Blue Hill; and

(5) Lands within Long Canyon north of the Colorado Riverway Recreation Area and south of the State land at the head of the canyon within one-half mile of the Long Canyon Road (Grand Co. No. 135).

Other Camping Restrictions

Camping with vehicles on BLM administered public lands is also limited for the above reasons to developed campgrounds and designated sites on a year-round basis in the following areas:

(1) The lands along both sides of U.S. 191 bounded by Arches National Park on the east, private lands in Moab Valley on the south, the Potash Rail Spur on the west, and private and State land near the lower Gemini Bridges Trailhead on the north;

(2) Lands located between the road to Nefertiti Rapid (Grand Co. No. 154) and the shoreline of the Green River along the east side of the river from the public land boundary near Swaseys Take-out upstream to the upper end of the Nefertiti Rapid parking area;

(3) Lands including the Pace Hill, Castle Rock, Ida Gulch, Professor Valley, Mary Jane Canyon, and the upper Onion Creek areas that are south of the Colorado Riverway Recreation Area as established in 1992, below the rims of Adobe and Fisher Mesas, and west of the private land in Fisher Valley;

(4) Lands along the Potash Trail (Grand Co. No. 134, the road between the western end of Utah Highway 279 and Canyonlands National Park) that are east of Canyonlands National Park; south of Dead Horse Point State Park, and other state and private lands, north of the Colorado River, and west of the Colorado Riverway Recreation Area as established in 1992, excluding riverside campsites accessible by water craft from the Colorado River; and

(5) Lands within the Mill Creek Canyon Planning Area.

Backpack type camping within the Mill Creek Planning Area is allowed at sites one-quarter mile or farther from designated roads and greater than 100 feet from Mill Creek and from archaeological sites. All camping continues to be prohibited in the Powerdam and Flat Pass areas under a previously published notice.

For all of the above locations, at developed campgrounds and designated sites where camping is authorized, camping and vehicle travel may be limited to posted site boundaries and parking areas.

Possession and use of portable toilets for solid human body waste is required for overnight use at all designated campsites in the areas described above, except at sites where constructed toilets are provided. Disposal of portable toilet waste off public land is required.

Wood Cutting and Gathering Restrictions

Wood cutting and gathering, including Christmas tree cutting, on BLM administered public land, within all of the areas described above under Camping Restrictions, is prohibited at all times to protect scenic values and vegetation. In addition, wood cutting and gathering, including Christmas tree cutting, is prohibited within the Sand Flats Recreation Area.

Exceptions

Camping and wood cutting and gathering restrictions do not apply to activities permitted by the BLM (including traditional and historic uses by Native Americans); BLM official uses; or military, fire, emergency, or law enforcement actions.

Implementation

Maps showing these and all current Moab Field Office camping and wood cutting and gathering restrictions are available for public review at the Moab Field Office. These restrictions are also shown on a map on the Moab Field Office's website at *http://www.blm.gov/utah/moab*. BLM will provide public land users with information about these camping and wood cutting and gathering restrictions using brochures, signs, and bulletin boards with maps at major entry areas. Enforcement actions will be taken as necessary.

Authority: Pub. L. 94–579, 43 CFR 8364.1.

Dated: January 12, 2001.

Sally Wisely,

State Director.

[FR Doc. 01–1594 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–DQ–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–062–01–1220–AA]

Notice of Travel Restrictions

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Notice of Travel Restrictions, Moab Field Office, Utah.

SUMMARY: This notice places restrictions on travel by off-road vehicles (ORV's) and mountain bikes on specific public land administered by the BLM Moab Field Office. These actions are necessary to halt ongoing impacts and prevent future degradation of resource values. They are being implemented on an interim basis to protect resource values and public safety, pending revision of the Resource Management Plan (RMP) for the area administered by the BLM Moab Field Office. This notice also affirms and describes previous travel restrictions that remain in effect.

DATES: This notice is effective January 22, 2001, and shall remain in effect until modified or the RMP is amended.

FOR FURTHER INFORMATION CONTACT: Russell von Koch, Resource Advisor, BLM Moab Field Office, 82 East Dogwood Avenue, Moab, Utah 84532 or telephone 435–259–2100.

SUPPLEMENTARY INFORMATION: In 1985, the Grand Resource Area RMP left the majority of the public land currently administered by the Moab Field Office as "Open to Off-road Vehicle Use." Since publication of the plan, specific public land areas administered by the Moab Field Office have become destinations for travel by off-road vehicles users and mountain bikers. Cross-country travel off established roads and trails by motorized vehicles and mountain bikes is causing damage to scenic, cultural, soil, vegetation, and wildlife habitat resources in the high use areas identified below and, in some cases, is causing or threatens to cause considerable adverse effects to those resource values. Short-cutting, making parallel routes, detouring around challenging segments, and widening routes threaten the integrity of existing routes, reduce their value for commercial recreation and special events, and make them less attractive for recreation use. The proliferation of multiple routes off long established roads and trails also contributes to confusion among users as to their location on the ground and has led to more frequent search and rescue activity.

On several historic, interpretive, or recreational single-track trails, certain

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uses are incompatible with the protection of significant resource values or involve safety or management concerns. Specific actions are necessary to manage these routes.

New Travel Restrictions, Moab Travel Management Area (MTMA)

Travel by ORV's and mountain bikes, on public land in five areas administered by the Moab Field Office, is now limited to existing roads and trails, except where more restrictive designations apply as described below under Existing Designations. Cross-country travel in these five areas, collectively referred to as the Moab Travel Management Area (MTMA), is prohibited, except for travel by mountain bike and two-wheel motorcycle on established slickrock riding areas (Bartlett Wash slickrock area, Tusher Canyon slickrock area, and slickrock areas along the Monitor and Merrimac and Lower Monitor and Merrimac trails), where such use does not further disturb vegetation or soils. To protect public safety and enhance user experience, BLM will provide maps of, and sign and mark recommended routes.

Under this action, approximately 245,642 acres currently designated as Open to ORV travel will be managed as ORV and mountain bike Travel Limited to Existing Roads and Trails. This change involves 25 percent of the land currently Open to ORV use and 13 percent of the total public land within the Moab Field Office. The intent of these year-round ORV designation changes is to protect natural resource and scenic values from the adverse effects of cross-country travel, maintain the integrity of established travel routes, and provide for public safety until the RMP is revised.

MTMA 1 (approximately 15,031 acres, in 3 parcels) is northwest of Moab along the boundary of Arches National Park. It includes all public land south of Township 22 S, west of Arches National Park, east of U.S. Highway 191 and north of the private land at the mouth of Moab Canyon.

MTMA 2 (approximately 189,939 acres) is northwest of Moab. It includes all public land west of U.S. Highway 191; south of the Canyonlands Field Airport, the Mancos shale land already limited to existing roads and trails, the Levi Well Road, and the Tenmile Point Road; east of the public land already limited to existing roads and trails along the east side of the Green River rims, and north of the northern boundary of Canyonlands National Park, the block of State and Private land around Dead Horse Point State Park and Potash, and the land north of Utah Highway 279. Land inside this boundary (in South Sevenmile Canyon and the Colorado Riverway), where ORV travel is already limited to designated roads and trails remains so designated.

MTMA 3 (approximately 28,266 acres) is west and south of Moab. It includes all public land west of U.S. Highway 191; north of the southern rim of Kane Creek Canyon and the land on Hatch Point already designated as limited to existing roads; and east and south of the Colorado River. Land in the Behind the Rocks Wilderness Study Area (WSA), which is closed to ORV use (subject to valid existing rights), and within the Colorado Riverway, where ORV use is limited to designated roads and trails, remains so designated.

MTMA 4 (approximately 6,558 acres) is northeast of Moab along the Entrada Bluffs Road. It includes an area bounded on the south by a one-half mile wide corridor along County Road 105 (Entrada Bluffs Road) and on the north by land already limited to existing roads and trails along the Dolores River.

MTMA 5 (approximately 5,848 acres) is northeast of Moab along the Utah/Colorado border. The area, which includes May Flat, is approximately 8 miles long and 2 miles wide. It is bordered by areas where ORV travel is currently limited to existing roads and trails on the north and west; private land to the southwest; the Colorado River on the south, and the Colorado-Utah state line near Rabbit Valley on the east.

Interpretive Trails Closed to Motorized and Mountain Bike Travel

The Sauropod Dinosaur Trackway Interpretive Trail, and the Mill Canyon Dinosaur Interpretive Trail are closed to motorized travel and mountain bike use to prevent resource damage to paleontological resources, scenic values, vegetation, and soils.

Single-Track Trails Closed to Motorized Travel

The following single-track trails are closed to motorized travel to prevent further damage to scenic values, soils, and vegetation along these narrow trails and to provide for public safety: (1) The entire Portal Trail from Jaycee Park to the top of Poison Spider Mesa; (2) the Hunter Canyon Rim Trail from the drill hole at the end of the Hunter Canyon Rim ORV route to the Kane Creek Road; (3) the Hidden Valley Trail from its trailhead in Spanish Valley to the boundary of the Behind the Rocks WSA.

Implementation

Maps showing all current Moab Field Office ORV designations are available for public review at the Moab Field Office. The designations are also shown on a map on the Moab Field Office's website at *http://www.blm.gov/utah/moab*. BLM will provide public land users with information about travel restrictions using brochures, signs, and bulletin boards with maps at major entry areas. It will protect key areas from further cross-country travel using signs and simple barriers as appropriate. Enforcement actions will be taken as necessary. BLM will provide maps of, and mark and sign recommended routes.

Future Planning

These travel restrictions are an interim measure to protect resource values and route integrity by prohibiting cross-country use and use on the specific single-track trails identified above until the RMP is revised. Revision of the RMP will address long term travel management across a range of management options.

Existing Designations

Except for those formerly Open areas where travel is now Limited to Existing Roads and Trails, this notice does not change the ORV designations made through the RMP or previously published **Federal Register** travel notices covering the public land administered by the Moab Field Office. These designations are affirmed and described below. The travel designation map on the Moab Field Office website shows all applicable travel designations.

Closed Areas

The Behind the Rocks Wilderness Study Area, Negro Bill Canyon, and the east side of Westwater Canyon are closed to ORV use subject to valid existing rights. The Windwhistle and Hatch Point Campgrounds, the Canyonlands, Needles, and Anticline Overlooks, and the Onion Creek sensitive plant site are closed to ORV use off developed roads. The Black Ridge Wilderness Area is also closed to ORV and mechanized travel by act of Congress through the Colorado Canyons National Conservation Area and Black Ridge Canyons Wilderness Act of 2000.

Limited to Designated Roads and Trails Areas

ORV Travel in the Mill Creek and East Mill Creek areas and the Colorado Riverway is limited to designated routes. ORV and mountain bike travel in the Sand Flats Recreation Area, the Kens Lake area, the Sevenmile Canyon area, and the NW ¼ of Section 24 and the SW ¼ of Section 13, T. 25 S., R. 20 E. S.L.M. in the Little Canyon area is limited to designated routes.

Limited to Existing Roads and Trails Areas

The 1985 RMP designated the Mancos shale areas in the Cisco and Green River desert areas; the Colorado, Green, and Dolores river corridors; portions of the Canyon Rims Recreation Area, and the area between Dead Horse Point State Park and the Colorado River as limited to existing roads and trails.

Exceptions

The travel restrictions in this notice do not apply to wheelchairs, water craft, military, fire, emergency, or law enforcement vehicles used for emergency purposes, vehicles expressly permitted by the BLM, or BLM vehicles required for official use, and are subject to valid existing rights.

Authority: Pub. L. 94–579, E. O. 11644, E. O. 11989, 43 CFR 8341.2, 43 CFR 8364.1

Dated: January 12, 2001.

Sally Wisely,

State Director.

[FR Doc. 01–1595 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–DQ–U

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–6320–AA; HAG01–0071]

Prohibition of Certain Activities on the Medford District in and Around the Woodrat Mountain hang Gliding Site, Jackson County, Oregon

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Prohibition on Certain Activities on Public Lands in Jackson County, Oregon.

SUMMARY: Hang gliding is temporarily prohibited on the Medford District, Jackson County, Oregon, from January 4, 2001 to November 1, 2001, during periods of helicopter logging, or upon cancellation of this notice. This prohibition is being made in the interest of public safety while the Poor Bishop timber sale is taking place in the Woodrat Mountain area.

The following public lands are affected: T. 38 S., R. 3 W, Sections 23, 25, 26; *Williamette Meridian, Jackson County, Oregon.*

FOR FURTHER INFORMATION CONTACT: Steven Armitage, Forest Manager, at (541) 618–2333.

Authority: 43 CFR 8364.

Penalty: Any person failing to comply with this prohibition may be subject to imprisonment for not more than 12 months, or a fine in accordance with the applicable provisions of 18 U.S.C. 3571, or both.

Dated: January 4, 2001.

Rich Drehobl,

Field Office manager, Ashland Field Office.

[FR Doc. 01–1729 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–110–6320–NW; HAG01–0063]

Notice of Temporary Restriction on Public Lands; Jackson, County, Oregon

AGENCY: Bureau of Land Management, Medford District, Ashland Field Office, Oregon.

ACTION: A temporary restriction of the use of paint ball equipment on public lands administered by the Bureau of Land Management (BLM), Ashland Field Office, Medford District, Oregon.

SUMMARY: The BLM is temporarily restricting the use of paint ball equipment on certain public lands in Jackson County.

DATES: This restriction will take effect upon the published date of this notice. The closure will continue until rescinded by BLM, to allow time for natural restoration to be completed.

FOR FURTHER INFORMATION CONTACT: Field Office Manager, Ashland Field Office, Medford District, 3040 Biddle Road, Medford, Oregon 97504, telephone (541) 618–2310.

Discussion of the Rules: The public lands affected by this closure are all lands administered by the BLM in NE¼SW¼, section 23 of Township 37 South, Range 1 East, Willamette Meridian, Jackson County, Oregon. This area is located on the west side of Antelope Creek, within the riparian reserve zone. Antelope Creek is an anadromous fish stream and is managed in accordance with the Aquatic Conservation Strategy of the Northwest Forest Plan. This area has been used for unregulated paint ball activity, unauthorized cutting of vegetation, trampling of riparian vegetation and crossing of the stream by off-road vehicles. This use is causing soil erosion into streams, loss of vegetation and disturbance to anadromous fish populations. In addition, vehicles are being used for transporting household and commercial trash that is being illegally dumped, causing further degradation of the soil and water conditions. In order to protect the natural resources, and follow the guidance of the Northwest Forest Plan, paint ball and off-road activity must stop.

Closure and restriction signs will be posted at main entry points. Maps of the closure area may be obtained from the Medford District Office.

Prohibited Act: Under 43 CFR 8364.1, the Bureau of Land Management will enforce the following rule within the Antelope Creek closure and restriction area:

a. You must not use paint ball equipment.

b. You must not engage in paint ball activity.

c. You must not drive off established roads.

Exemptions: Persons who are exempt from these rules include any federal, state or local officer or employee in the scope of their duties, members of any organized rescue or fire-fighting force in performance of an official duty, and any person authorized in writing by the Bureau of Land Management.

Penalties: The authority for this closure is found under section 303(a) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1733(a)) and 43 CFR 8360.0–7. Any person who violates this closure may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Dated: January 2, 2001.

Rich Drehobl,

Field Office Manager, Ashland Field Office.

[FR Doc. 01–1728 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–092–1610–00]

Notice of Availability

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM), Glasgow Field Station, announces the availability of a proposed Resource Management Plan (RMP) Amendment and Environmental Assessment (EA). The proposed plan amendment/EA addresses two potential ACECs in the Glasgow Field Station,

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Valley County, Montana. The proposed plan is to designate a Bitter Creek Area of Critical Environmental Concern (ACEC) and a Mountain Plover ACEC.

DATES: The proposed plan amendment may be protested. The 30-day protest period will commence with the date of publication of this notice. Protests must be submitted on or before February 21, 2001.

ADDRESSES: Written protests must be sent to: Director, Bureau of Land Management, Attention: Ms Brenda Williams, Protests Coordinator, WO–210/LS–1075, Department of the Interior, Washington, DC 20240. The overnight mail address is: Director, Bureau of Land Management, Attention: Ms Brenda Williams, Protests Coordinator (WO–210), 1620 L Street, NW., Rm. 1075, Washington, DC 20036 [Phone: 202/452–5510].

FOR FURTHER INFORMATION CONTACT: John Fahlgren, Assistant Field Manager, BLM, Glasgow Field Station, RR1–4775, Glasgow, MT 59230. 406–228–3750.

SUPPLEMENTARY INFORMATION: This proposed plan amendment/EA addresses special management for two ACECs; Bitter Creek and Mountain Plover. The public land being considered is located in Valley County, Montana. This plan would amend the Judith-Valley-Phillips RMP. The Bitter Creek Wilderness Study Area (WSA) (59,660 acres) was found to meet the criteria as a potential ACEC due to the scenic diversity and variety of vegetation types and wildlife habitat. The proposed plan is to designate a Bitter Creek ACEC. If Congress released Bitter Creek from WSA status, a plan for management of the ACEC would be initiated within two years. Until an ACEC management plan is completed for Bitter Creek, management would be the same as the revised edition of the Interim Management Policy for Lands Under Wilderness Review (1998). The Mountain Plover area (24,730 acres) provides natural habitat for the mountain plover, a prairie bird. It is an area of native plover habitat which is not associated with black-tailed prairie dogs. The proposed plan is to designate a Mountain Plover ACEC. Management prescriptions limiting surface disturbing activities would apply within the ACEC to protect the mountain plover during the nesting period from April 1 to July 31. These management prescriptions include a seasonal restriction on oil and gas activities, mitigating measures considered in Plan of Operations, seasonal stipulation on right-of-way grants, and off-highway vehicle travel seasonally limited to designated roads and trails.

The BLM's resource management planning process includes an opportunity for administrative review via a plan protest to the BLM's Director. Any person who participated in the planning process and has an interest which is or may be adversely affected by the approval of an amendment to an RMP may protest such approval. Careful adherence to the following guidelines will assist in preparing a protest that will assure the greatest consideration to your point of view. Only those persons or organizations who participated in the planning process may protest. A protesting party may raise only those issues which were commented on during the planning process. New issues may be raised at any time but should be directed to the appropriate BLM field office for consideration in plan implementation, as potential plan amendments, or as otherwise appropriate. The protest period extends for 30 days. There is no provision for any extension of time. To be considered "timely," your protest must be postmarked no later than the last day of the protest period. Also, although not a requirement, we suggest that you send your protest by certified mail, return receipt requested. In order to be considered complete, your protest must contain, at a minimum, the following information:

(1) The name, mailing address, telephone number and interest of the person filing the protest.

(2) A statement of the issue or issues being protested.

(3) A statement of the part or parts of the amendment being protested. To the extent possible, this should be done by reference to specific pages, paragraphs, sections, tables, maps, etc. included in the proposed amendment.

(4) A copy of all documents addressing the issue or issues submitted during the planning process by the protesting party or an indication of the discussion date of the issue(s) for the record.

(5) A concise statement explaining why the proposed decision is believed to be incorrect. This is a critical part of your protest. Take care to document all relevant facts. As much as possible, reference or cite the planning documents, environmental analysis documents, available planning records (*i.e.*, meeting minutes or summaries, correspondence, etc.). A protest which merely expresses disagreement with the proposed decision, without any data will not provide us with the benefit of your information and insight. In this case, the Director's review will be based on the existing analysis and supporting data.

At the end of the 30-day protest period, the BLM may issue a Decision Record, approving implementation of any portions of the proposed plan amendment not under protest. Approval will be withheld on any portion of the plan under protest until the protest has been resolved.

(**Authority:** Sec. 202, Pub. L. 94–579, 90 Stat. 2747 (43 U.S.C. 1712))

Dated: January 8, 2001.

John Fahlgren,

Assistant Field Manager, Bureau of Land Management.

[FR Doc. 01–1624 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–957–00–1420–BJ: GP01–0069]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Oregon State Office, Portland, Oregon, thirty (30) calendar days from the date of this publication.

Willamette Meridian

Oregon

T. 22 S., R. 8 W., accepted November 3, 2000
T. 19 S., R. 1 W., accepted November 13, 2000
T. 29 S., R. 10 W., accepted November 22, 2000
T. 31 S., R. 5 W., accepted December 18, 2000

Washington

T. 23 N., R. 10 W., accepted November 6, 2000

If protests against a survey, as shown on any of the above plat(s), are received prior to the date of official filing, the filing will be stayed pending consideration of the protest(s). A plat will not be officially filed until the day after all protests have been dismissed and become final or appeals from the dismissal affirmed.

The plat(s) will be placed in the open files of the Oregon State Office, Bureau of Land Management, 1515 SW. 5th Avenue, Portland, Oregon 97201, and will be available to the public as a matter of information only. Copies of the plat(s) may be obtained from the above office upon required payment. A person or party who wishes to protest against a survey must file with the State Director, Bureau of Land Management, Portland, Oregon, a notice that they wish to protest prior to the proposed official filing date given above. A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within thirty (30) days after the proposed official filing date.

The above-listed plats represent dependent resurveys, survey, and subdivision.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, (1515 SW. 5th Avenue) P.O. Box 2965, Portland, Oregon 97208.

Dated: January 3, 2001.

Robert D. DeViney, Jr.,

Branch of Realty and Record Services.

[FR Doc. 01–1572 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NMNM 103446]

Public Land Order No. 7479; Withdrawal of National Forest System Land for Guadalupe Cave Resource Protection Area; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 27,299.50 acres of National Forest System land from mining and mineral leasing, for 20 years to protect the Guadalupe Cave Resource Protection Area.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Jeanette Espinosa, BLM New Mexico State Office, P.O. Box 27115, Santa Fe, New Mexico 87502–0115, 505–438–7597.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Subject to valid existing rights, the following described National Forest System land is hereby withdrawn from location and entry under the United States mining laws (30 U.S.C. Ch. 2 (1994)), and from leasing under the mineral leasing laws (30 U.S.C. 181 *et seq.* and 30 U.S.C. 351 *et seq.* (1994)), to protect the Guadalupe Cave Resource Protection Area.:

New Mexico Principal Meridian

Lincoln National Forest

T. 25 S., R. 21 E.,
Sec. 36, lot 4, S½SW¼, and SW¼SE¼.
T. 26 S., R. 21 E.,
Sec. 1;
Sec. 2, E½;
Sec. 10, SE¼SE¼;
Sec. 11, E½ and SW¼;
Secs. 12, 13, and 14;
Sec. 15, E½, S½ NW¼, and SW¼;
Sec. 16, S½SE¼;
Sec. 20, SE¼;
Secs. 21 to 28, inclusive;
Sec. 29, E½;
Sec. 32, lots 1 and 2, and N½ NE¼;
Sec. 33, lots 1 to 4, inclusive, and N½N½;
Sec. 34, lots 1 to 4, inclusive, and N½N½;
Sec. 35, lots 1 to 4 inclusive, and N½N½;
Sec. 36, lots 1 to 4, inclusive, and N½N½.
T. 25 S., R. 22 E.,
Sec. 13, S½;
Sec. 14, S½;
Sec. 15, S½ and NW¼;
Sec. 16, S½ and NE¼;
Sec. 20, SE¼SW¼ and SE¼; secs. 21 to 29, inclusive;
Sec. 31, E½, E½W½, and SW¼SW¼;
Sec. 32, 33, and 34.
T. 26 S., R. 22 E., secs. 3, 4, and 5;
Sec. 6, lots 1 to 4, inclusive, E½, and E½W½;
Sec. 7, lots 1 to 4, inclusive, E½, and E½W½; secs. 8, 9, 10, 15, 16, and 17;
Sec. 18, lots 1 to 4, inclusive, E½, and E½W½.

The area described contains approximately 27,299.50 acres in Eddy County.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: January 16, 2001.

Sylvia V. Baca,

Assistant Secretary of the Interior.

[FR Doc. 01–1817 Filed 1–19–01; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–1430–ET; OR–56288]

Notice of Proposed Withdrawal; Oregon

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Secretary of Interior proposes to withdraw approximately 151,970 acres of Federal lands, to protect the nationally significant ecological and biological values of the Siskiyou Wild Rivers area. Subject to valid existing rights, this notice segregates the Federal lands described below for up to 2 years from location and entry under the mining laws. The lands have been and will remain open to the public land laws and mineral leasing laws unless closed by other segregations of record.

FOR FURTHER INFORMATION CONTACT: Mike Barnes, Oregon State Office, Bureau of Land Management, 503–952–6155.

ADDRESSES: State Director, Oregon State Office, Bureau of Land Management, P.O. Box 2965, Portland, Oregon 97208–2965.

SUPPLEMENTARY INFORMATION: The purpose of the proposed withdrawal is to protect the nationally significant ecological and biological diversity of the Siskiyou Wild Rivers area while it is determined whether special management designation for the area is warranted and to assess the views of the public on such a designation. The Siskiyou Wild Rivers area also contains outstanding scenic and recreation values and special status plant and animal species and their habitats. The proposal, if finalized, would withdraw, subject to valid existing rights, the following described Federal lands and, if acquired by the United States, any non-Federal lands within the area, from location and entry under the mining laws. The Federal lands have been and will remain open to the public land laws and the mineral leasing laws, subject to other segregations of record:

1. The Federal lands proposed for withdrawal are described as:

Willamette Meridian

T. 37 S., R. 6 W.,
sec. 31, W½.
T. 38 S., R. 6 W.,
sec. 30, S½;
sec. 31.
T. 39 S., R. 6 W.,
sec. 5, E½;
secs. 6 and 8.
T. 33 S., R. 7 W.,
secs. 18, 19, 30, and 31.
T. 34 S., R. 7 W.,
secs. 6, 7, 18, 19, 30, and 31.
T. 35 S., R. 7 W.,
secs. 3 to 10, inclusive, and secs. 15, 17, 18 and 19;
sec. 20, W½.
T. 39 S., R. 7 W.,
sec. 1, E½;
sec. 2.
T. 32 S., R. 8 W.,
sec. 31.
T. 33 S., R. 8 W.,
secs. 5 to 36, inclusive.
Tps. 34 and 35 S., R. 8 W., inclusive.
T. 38 S., R. 8 W.,
secs. 9, 15, 21, and 28.
T. 39 S., R. 8 W.,
sec. 31.
T. 40 S., R. 8 W.,
secs. 7, 10, 15, and secs. 17 to 20 inclusive;

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sec. 22, N½;
sec. 33, S½ NE¼ and S½;
sec. 34.
T. 32 S., R. 9 W.,
sec. 8, S½;
secs. 3 to 35, inclusive.
Tps. 33, 34, and 35 S., R. 9 W., inclusive.
T. 41 S., R. 9 W.,
sec. 9.
Tps. 32, 33 and 34 S., R. 10 W., inclusive.
T. 32 S., R. 11 W., inclusive.

The areas described aggregate approximately 151,970 acres, more or less, in Curry, Coos, Josephine, and Douglas Counties.

2. For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the State Director at the address indicated above.

3. Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard with respect to the proposed withdrawal must submit a written request to the State Director at the address indicated above within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set fourth in 43 CFR 2300. For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary land uses which may be permitted during the segregative period include licenses, permits, rights-of-way, and disposal of vegetative resources other than under the mining law.

Dated: January 16, 2001.

Ray Brady,

Manager, Lands and Realty Group.

[FR Doc. 01–1703 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–958–1430–ET; OR–56289]

Notice of Proposed Withdrawal; Oregon and California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture, Forest Service, filed an application to withdraw approximately 1,093,953 acres of National Forest System lands from location and entry under the mining laws to protect the nationally significant ecologic and biologic diversity of the Siskiyou Wild Rivers area which also contain outstanding scenic and recreation values, and special status plant and animal species and their habitats. The lands remain open to such uses as may be made of National Forest System lands.

DATES: Written comments should be received on or before April 23, 2001.

ADDRESSES: Written comments should be sent to the Office of the Chief, Forest Service, U.S. Department of Agriculture, 201 14th Street, SW. at Independence Ave., SW., Washington, DC 20250.

SUPPLEMENTARY INFORMATION: The purpose of the proposed withdrawal is to protect the nationally significant ecologic and biologic diversity of the Siskiyou Wild Rivers area which also contain outstanding scenic and recreation values, and special status plant and animal species and their habitats while it is determined whether special management designation for the area is warranted and to assess the views of the public on such a designation. The proposal, if finalized, would withdraw the following described National Forest System lands from location and entry under the mining laws. The lands will remain open to such uses as may be made of National Forest System lands subject to valid existing rights:

1. The National Forest System lands proposed for withdrawal are described as:

Willamette Meridian

T. 31 S., R.'s 10 and 11 W.;
T. 32 S., R.'s 10 to 14 W., inclusive;
T. 33 S., R.'s 10 to 14 W., inclusive;
T. 34 S., R.'s 9 to 13 W., inclusive;
T. 35 S., R.'s 8 to 13 W., inclusive;
T. 36 S., R.'s 7 to 13 W., inclusive;
T. 37 S., R.'s 8 to 13 W., inclusive;
T. 38 S., R.'s 8 to 13 W., inclusive;
T. 39 S., R.'s 5, 6, 9, 10, 11, and 12 W., inclusive;
T. 40 S., R's 5, 6, 7, 9, 10, 11, and 12 W., inclusive;
T. 41 S., R.'s 5 to 12 W., inclusive.

Humbolt Meridian, California

T. 47 N., R.'s 3 to 6 E., inclusive;
T. 48 N., R.'s 4 to 6 E., inclusive.

The area described contains 1,093,953 acres in Oregon and California.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Chief of the Forest at the address indicated above.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard with respect to the proposed withdrawal must submit a written request to the Forest Chief at the address indicated above within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set fourth in 43 CFR 2300. For a period of 2 years from the date of publication of this notice in the **Federal Register**, the land will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary land uses which may be permitted during the segregative period include licenses, permits, rights-of-way, and disposal of vegetative resources other than under the mining law.

Dated: January 12, 2001.

Nina Rose Hatfield,

Acting Director, Bureau of Land Management.

[FR Doc. 01–1697 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Notice of Availability of a Final General Management Plan Amendment/ Environmental Impact Statement for Dry Tortugas National Park, Monroe County, FL

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of a Final General Management Plan Amendment/ Environmental Impact Statement for Dry Tortugas National Park, Monroe County, Florida.

SUMMARY: The National Park Service has prepared a Final General Management Plan Amendment/Environmental Impact Statement (GMPA/EIS) that evaluates long-term management alternatives for Dry Tortugas National Park. Consistent with the park's purpose, significance, and mission goals, five alternatives were evaluated for guiding the management of the park over the next 15 to 20 years. The alternatives incorporate various zoning applications and other management provisions to ensure resource protection and quality visitor experience conditions. The environmental consequences anticipated from implementation of the various alternatives are addressed in the document. Impact topics include natural and cultural resources, visitor experience, socioeconomic environment, and park operations/ facilities.

DATES: The document will be available for review for 30 days from the publication of a notice by the Environmental Protection Agency in the **Federal Register**. After the 30-day review period, a Record of Decision will be signed that will document NPS approval of the final Dry Tortugas GMPA/EIS, and identify the selected alternative for implementation.

ADDRESSES: The final Dry Tortugas GMPA/EIS will be mailed to agencies, organizations, and individuals on the park's mailing list. Public reading copies of the document will also be available for review at the following locations:

- Everglades National Park—Headquarters, 40001 State Road 9336, Homestead, FL
- Offices of the Florida Keys National Marine Sanctuary: 216 Ann Street, Key West, FL, 5550 Overseas Highway, Marathon, FL, 95200 Overseas Highway, Key Largo, FL
- Miami-Dade Public Library Branches: 700 N. Homestead Blvd., Homestead, FL, 101 West Flagler St., Miami, FL, 10750 SW 211th St., Miami, FL
- Monroe County Public Library Branches: 700 Fleming St., Key West, FL, 3251 Overseas Highway, Marathon, FL, Mile Marker 81.5, Islamorada, FL, Mile Marker 100, Key Largo, FL
- Collier County Public Library, 650 Central Avenue, Naples, FL
- St. Petersburg Public Library, 3745 9th Ave. North, St. Petersburg, FL

In addition, the document will be posted on the Dry Tortugas National Park Webpage (*www.nps.gov/drto/planning*). A limited number of printed copies will be available from the Superintendent on request.

FOR FURTHER INFORMATION CONTACT: Maureen Finnerty, Superintendent, Everglades and Dry Tortugas National Parks, 40001 State Road 9336, Homestead, FL 33034–6733.

SUPPLEMENTARY INFORMATION: The following management alternatives were evaluated in the GMPA/EIS:

Alternative A—As the no-action alternative, this alternative represents a continuation of current management policies and operations. The park would attempt to accommodate increasing visitor use while protecting resources to the extent allowable under current policy and legal requirements.

Alternative B—Under this alternative, visitors would be free to travel throughout much of the park and have a variety of recreational experiences. However, the park would more closely manage the types and levels of acceptable visitor use to provide greater protection of park resources and to ensure quality visitor experiences. Greater emphasis would be placed on measures to monitor resource conditions and to implement appropriate protection/remedial actions as necessary.

Alternative C (proposed action)—In addition to the provisions of Alternative B, this alternative calls for the application of a research natural area zone (covering about one half of the park) in which no fishing would be allowed, the implementation of a visitor permitting system, and increased reliance on commercial service providers to direct and structure visitor use. These measures would be anticipated to further enhance resource protection and visitor experience objectives.

Alternative D—Provisions of this alternative are similar to those of Alternative C, with the further restrictions that only commercial tour operators providing public tours would be allowed in the research natural area zone. Private boaters would be required to obtain a permit to boat or engage in other park-allowed activities outside of the research natural area zone. As under Alternative C, the research natural area zone would cover approximately half of the park, although its spatial configuration would be different. Visitor experiences would be highly structured, but diverse opportunities for recreational activities would remain available.

Alternative E—This alternative places primary emphasis on resource protection and conservation with the majority of the park zoned a research natural area. Visitation would be strictly managed throughout most of the park to reduce or avoid impacts on the fragile resource base.

Planning for the Dry Tortugas GMPA/EIS was coordinated with concurrent planning for the Florida Keys National Marine Sanctuary, administered by the National Oceanic and Atmospheric Administration. The latter plan proposes a no-take ecological reserve within the remote westernmost portion of the marine sanctuary.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. If you wish for us to withhold your name and/ or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: January 9, 2001.

W. Thomas Brown,

Regional Director, Southeast Regional Office, National Park Service.

[FR Doc. 01–1576 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–10–M

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Record of Decision for Final Environmental Impact Statement and Bison Management Plan for the State of Montana and Yellowstone National Park

The U.S. Department of the Interior's National Park Service and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service and Forest Service have signed a Record of Decision (December 20, 2000) on a Joint Management Plan for bison in Yellowstone National Park and Montana.

The Plan is designed to preserve the largest wild, free-ranging population of bison in the United States while minimizing the risk of brucellosis disease transmission (between bison and cattle) to protect the economic interest and viability of the livestock industry in the State of Montana.

While the Joint Management Plan is not intended to be a brucellosis eradication plan, it employs many tools to manage and reduce the potential risk of brucellosis transmission from bison to cattle. Limited numbers of bison will

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be allowed on public lands outside the park during winter when cattle are not present. Bison will not be allowed to intermingle with cattle and will be hazed back into the park when the weather typically moderates in the spring (mid-April on the north side and mid-May on the west side). The agencies will capture or remove bison still remaining outside the park that cannot be hazed. Any possible risk to cattle will be further minimized before cattle are allowed to return to public lands by waiting a sufficient amount of time to ensure that the bacteria which causes the disease is no longer alive outside the park.

The agencies will further manage the risk of transmission of brucellosis to cattle by limiting the number of bison outside the park in the north (Reese Creek) and west (West Yellowstone) management areas through intensive monitoring and hazing, and when necessary, capture, test, and slaughter of seropositive bison. Management activity will be increased as bison move toward the edges of management zones outside the park. The plan also provides that the agencies will maintain a spring bison population of up to 3,000 animals. The agencies also agree to increase implementation of non-lethal management measures should severe winter conditions result in a large management removal or natural winter die off.

In an effort to further reduce the risk of transmission and protect cattle, the agencies will require vaccination if 100% of all vaccination-eligible cattle in north and west management zones are not vaccinated within one year. APHIS will pay for all direct vaccination costs. Allowing untested bison outside the park in the north and west boundary management zones will begin after the agencies have had experience with seronegative bison in certain areas outside the park during winter and when the National Park Service initiates vaccination of bison with a safe and effective vaccine utilizing a safe remote delivery system inside the park.

With the implementation of this plan, the federal agencies and the State of Montana recognize that bison are an essential component of the greater Yellowstone ecosystem and that the cooperation of several agencies is needed to fully manage the herd to reduce the risk of transmission of brucellosis from bison to cattle and maintain a wild, free-ranging population of Yellowstone bison.

The Joint Management Plan, included in the Record of Decision, is a slightly altered version of the existing plan presented in the federal agencies' final Environmental Impact Statement (FEIS). The State of Montana incorporated and adopted the federal agencies' FEIS into its own FEIS for bison management and has recently signed their Record of Decision, which implements the same Joint Management Plan as the federal agencies.

A copy of the Record of Decision on Bison Management for Yellowstone National Park and the State of Montana can be obtained via the internet by visiting the National Park Service web site at *http://www.nps.gov/planning* or by calling (307) 344–2159.

Jack Neckels,

Acting Director, Intermountain Region.

[FR Doc. 01–1574 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Acadia National Park Bar, Harbor, ME; Acadia National Park Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770, 5 U.S.C. App. 1, Sec. 10), that the Acadia National Park Advisory Commission will hold a meeting on Monday, February 5, 2001.

The Commission was established pursuant to Public Law 99–420, Sec. 103. The purpose of the commission is to consult with the Secretary of the Interior, or his designee, on matters relating to the management and development of the park, including but not limited to the acquisition of lands and interests in lands (including conservation easements on islands) and termination of rights of use and occupancy.

The meeting will convene at park Headquarters, McFarland Hill, Bar Harbor, Maine, at 1:00 PM to consider the following agenda:

1. Review and approval of minutes from the meeting held September 11, 2000.
2. Committee reports
   Land Conservation
   Park Use
   Science
   Nomination
3. Old business
4. Chairman's report
5. Superintendent's report
6. Public comments
7. Proposed agenda for next Commission meeting on Monday, June 4, 2001.

The meeting is open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meeting.

Further information concerning this meeting may be obtained from the Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, tel: (207) 288–3338.

Dated: January 9, 2001.

Len Bobinchock,

Acting Superintendent, Acadia National Park.

[FR Doc. 01–1575 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Park System Advisory Board; Meeting

AGENCY: National Park Service, Interior.

ACTION: Notice of meeting.

Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix (1994), that the National Park System Advisory Board will meet January 24–26, 2001, in the Board Room of the American Geophysical Union Building, 2000 Florida Avenue, NW., Washington, DC.

The Board will convene from 9:00 a.m., until 5:00 p.m., on January 24 and 25. On January 26, the Board will convene at 9:00 a.m., and adjourn at 12:00 noon. The Board will consider procedural matters relative to completing its study of the future of the National Park Service and the National Park System. During the morning session on January 24, the Board will be addressed by leaders of national organizations having interest in National Park Service matters.

The Board may be addressed at various times by officials of the National Park Service and the Department of the Interior; and other miscellaneous topics and reports may be covered. The order of the agenda may be changed, if necessary, to accommodate travel schedules or for other reasons.

The Board meeting will be open to the public. Space and facilities to accommodate the public are limited and attendees will be accommodated on a first-come basis. Anyone may file with the Board a written statement concerning matters to be discussed. The Board may also permit attendees to address the Board, but may restrict the length of the presentations, as necessary to allow the Board to complete its agenda within the allotted time.

Anyone who wishes further information concerning the meeting, or who wishes to submit a written statement, may contact Mr. Loran Fraser, Office of Policy, National Park Service, 1849 C Street, NW., Washington, DC 20240 (telephone 202–208–7456).

Draft minutes of the meeting will be available for public inspection about 12 weeks after the meeting, in room 2414, Main Interior Building, 1849 C Street, NW., Washington, DC.

Dated: January 11, 2001.

Denis P. Galvin,

Acting Director, National Park Service.

[FR Doc. 01–1658 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–70–U

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 13, 2001. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, 1849 C St., NW, NC400, Washington, DC 20240. Written comments should be submitted by February 6, 2001.

Carol D. Shull,

Keeper of the National Register.

ARKANSAS

Van Buren County
Patterson, Walter, Filling Station, (Arkansas Highway History and Architecture MPS) AR 65, bet. Griggs and Court Sts., Clinton, 01000074

CALIFORNIA

Los Angeles County
Nuetra Office Building, 2379 Glendale Building, Los Angeles, 01000075

Orange County
Fullerton First Methodist Episcopal Church, 117-N. Pomona Ave., Fullerton, 01000076

Sacramento County
Galarneaux, Mary Haley, House, 922–924 T. St., Sacramento, 01000077

FLORIDA

Palm Beach County
College Park Historic District, Roughly bounded by Maryland Dr., N. Federal Hwy., 19th Ave. N., and N. Dixie Hwy., Lake Worth, 01000078

GEORGIA

Fulton County
Westinghouse Electric Company Building, 426 Marietta St., NW, Atlanta, 01000080

Habersham County
Loudermilk Boarding House, 271 Foreacre St., Cornelia, 01000079

ILLINOIS

Clay County
Meyer, Pearl and Bess, House, 233 E. 2nd St., Flora, 01000084

Cook County
Chicago and North Western Railroad Depot, 6088 North Northwest Hwy., Chicago, 01000081
Olympia Fields Country Club,2800 Country Club Dr., Olympia Fields, 01000082

Du Page County
Immanuel Evangelical Church, 302 S. Grant St., Hinsdale, 01000085

Richland County
Hopkinson, Ambrose, House, 122 W. Elm St., Olney, 01000083

MASSACHUSETTS

Middlesex County
Bell Rock Memorial Park, Bounded by Main, Wigglesworth, Meridan, and Ellis Sts., Malden, 01000086

Plymouth County
Bridgewater Iron Works, Vic. of High St., Bridgewater, 01000087

Suffolk County
Brighton Center Historic District, Academy Hill R., Chestnut Hill Ave., Dighton, Elko, Henshaw, Leicester, Market, Washington, and Winship Sts., Boston, 01000088
Chelsea Garden Cemetery, Shawmut St., Chelsea, 01000089

SOUTH DAKOTA

Butte County
Lincoln School, (Schools in South Dakota MPS) 706 Jackson, Belle Fourche, 01000098

Clay County
Gunderson House, 24 S. Harvard, Vermillion, 01000092

Codington County
Fowler, C.E. and Bertha, House, 316 SE First Ave., Watertown, 01000096

Day County
Roslyn Auditorium, (Federal Relief Construction in South Dakota MPS) 510 Main, Roslyn, 01000097

Hughes County
Rowe House, 1118 E. Capitol, Pierre, 01000095

Lincoln County
Kennedy, C.B., Mansion, 903 N. Dakota St., Canton, 01000093

Meade County
Minneapolis Brewing Company Beer Warehouse, SD 212, Faith, 01000100

Moody County
South Dakota Dept. of Trans. Br. No. 51–124–136, (Historic Bridges in South Dakota MPS) Second St. over the Big Sioux R., Egan, 01000090

Pennington County
Swander Bakery Building, 301 12th St., Rapid City, 01000099

Union County
United Brethren Church, 31141 476th Ave., West Akron, 01000091

Yankton County
Burns House, 816 Pine St., Yankton, 01000094

TENNESSEE

Humphreys County
Fort Hill and Butterfield, Archibald D., House, (Archeological Resources of the American Civil War in Tennessee MPS) 201 Fort Hill Dr., Waverly, 01000101

TEXAS

Bee County
Bee County Courthouse, 105 W. Corpus Christi St., Beeville, 01000105

Dallas County
Turtle Creek Pump Station, 3630 Harry Hines Blvd., Dallas, 01000103

Fort Bend County
Moore, John M. and Lottie D., House, 406 S. Fifth St., Richmond, 01000104

Tarrant County
Marine Commercial Historic District, Roughly defined by N. Main St., bet. N. Side Dr. and N. 14th St., Fort Worth, 01000102

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WISCONSIN

Crawford County
Tainter Cave, (Wisconsin Indian Rock Art Sites MPS) Address Restricted, Clayton, 01000106

Manitowoc County
Saint Luke's Church Complex, 1800–1816 Jefferson St., Two Rivers, 01000107

A request for REMOVAL for procedural error has been made for the following resource:

MISSOURI

Clay County
Clardy Heights Historic District (Liberty, Clay County, Missouri MPS AD) 716, 734, and 758 W. Liberty Dr. Liberty, 00001609

A request for removal has been made for the following resource:

WASHINGTON

Kittitas County
Kinkade, J.W., Farmstead Off US 7B Ellensburg vicinity, 82004257

[FR Doc. 01–1742 Filed 1–19–01; 8:45 am]

BILLING CODE 4310–70–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–445]

Certain Plasma Display Panels and Products Containing Same; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. § 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on December 21, 2000, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, on behalf of the Board of Trustees of the University of Illinois, of Urbana, Illinois, and Competitive Technologies, Inc., of Fairfield, Connecticut. Supplements to the complaint were filed on December 28, 2000 and January 3, 2001. The complaint, as supplemented, alleges violations of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain plasma display panels and products containing same by reason of infringement of claims 22–26, 28–33, 36, and 38–41 of U.S. Letters Patent 5,081,400 and claims 10–11 of U.S. Letters Patent 4,866,349. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint and supplements, except for any confidential information contained therein, are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may be obtained by accessing its internet server (http://www.usitc.gov).

FOR FURTHER INFORMATION CONTACT: Steven A. Glazer, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–205–2577.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR § 210.10 (2000).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on January 16, 2001, Ordered That—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain plasma display panels or products containing same by reason of infringement of claims 22–26, 28–33, 36, or 38–41 of U.S. Letters Patent 5,081,400 or claims 10–11 of U.S. Letters Patent 4,866,349, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are—The Board of Trustees of the University of Illinois, 352 Henry Administration Building, 506 South Wright Street, Urbana, Illinois 61801; and Competitive Technologies, Inc., 1960 Bronson Road, Fairfield, Connecticut 06430.

(b) The respondents are the following companies alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Fujitsu Limited, 6–1, Marunouchi 1–chome, Chiyoda-Ku, Tokyo 100–8211, Japan; Fujitsu General Limited, 1116, Svenaga, Takatsu-ku, Kawasaki, 213 Japan; Fujitsu General America Corp., 353 Route 46 West, Fairfield, New Jersey 07004; and Fujitsu Microelectronics, Inc., 3545 N. First Street, San Jose, California 95134.

(c) Steven A. Glazer, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401–K, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, the Honorable Debra Morriss is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR § 210.13. Pursuant to 19 CFR §§ 201.16(d) and 210.13(a) of the Commission's Rules, such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting a response to the complaint will not be granted unless good cause therefor is shown.

Failure of any respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against such respondent.

Issued: January 16, 2001.
By order of the Commission.

Donna R. Koehnke,
Secretary.

[FR Doc. 01–1784 Filed 1–19–01; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Partial Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on January 8, 2001, a proposed Partial Consent Decree in *United States* v. *American Scrap Company, et al.*, Civil Action No. 1:99–CV–2047, was lodged with the United States District Court for the Middle District of Pennsylvania.

In this action, the United States seeks the reimbursement of response costs in connection with the Jack's Creek/Sitkin Smelting Superfund Site in Mifflin County, Pennsylvania ("the Site"), pursuant to the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 9601 *et seq.* The Partial Consent Decree resolves the United States' claims against Konica Graphic Imaging, Inc. ("Konica") for response costs incurred as a result of the release or threatened release of hazardous substances at the Site. Konica will pay the United States $60,127.90. The Partial Consent Decree will not resolve the United States' claims against the remaining defendants in the litigation.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Partial Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Washington, DC 20044, and should refer to *United States* v. *American Scrap Company, et al.*, D.J. Ref. 90–11–2–911/1.

The Partial Consent Decree may be examined at the Office of the United States Attorney, Middle District of Pennsylvania, Federal Building, 228 Walnut Street, Suite 220, Harrisburg, PA 17108, or at the Region III Office of the Environmental Protection Agency, 1650 Arch Street, Philadelphia, Pennsylvania 19103. A copy of the Partial Consent Decree may also be obtained by mail by requesting a copy from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $4.25 (17 pages at 25 cents per page reproduction cost) payable to the Consent Decree Library.

Walker Smith,
Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–1734 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Partial Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

Under CERCLA Section 122(d)(2), 42 U.S.C. 9622(d)(2), and 28 CFR 50.7, notice is hereby given that on January 5, 2001, a proposed Consent Decree (the "Decree") in *United States* v. *Philip Katz, et al.*, Civil Action No. JFM 01–63 was lodged with the United States District Court for the District of Maryland.

In this action the United States seeks reimbursement of response costs in connection with the Cherry Pit Drum Superfund Site in Anne Arundel, Howard, and Charles County, Maryland (the "Site"). The Decree resolves the United States' claims under CERCLA Section 107(a) against Philip Katz, Arthur C. Isenhart, Authorized Trailer Services, Inc., Bernard A. Bailey, Southern Maryland Trailer Rental, Inc., Glen E. Shepke, and A–1 Storage Trailer, Inc. for response costs incurred as a result of the release or threatened release of hazardous substances at the Site. These parties will pay the United States $126,000. The Decree also resolves the United States' claims for civil penalties under CERCLA Section 104(e) against Bernard A. Bailey.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Philip Katz, et al.*, D.J. Ref. 90–11–3–06765.

The Decree may be examined at the Office of the United States Attorney, District of Maryland, 101 West Lombard Street, Baltimore MD 21201, and at U.S. EPA Region III Office of Regional Counsel, 1650 Arch Street, Philadelphia, PA 19103. A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $6.00 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Walker B. Smith,
Principal Deputy Chief, Environmental Enforcement Section, Environmental and Natural Resources Division.

[FR Doc. 01–1760 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy, 28 CFR § 50.7, notice is hereby given that a consent decree in United States v. Lightman, *et al.*, Civil No. 92–4710 (D.N.J.), was lodged on January 8, 2001 with the United States District Court for the District of New jersey.

The proposed consent decree embodies an agreement with Jerome Lightman and Lightman Drum Company, pursuant to Section 107 of CERCLA, 42 U.S.C. § 9607, to pay approximately $550,000 in settlement of claims for EPA's past and future response costs at three Superfund sites, the D'Imperio Property Superfund Site in Hamilton Township, New Jersey, the Ewan Superfund Site in Shamong Township, New Jersey, and the Duane Marine Superfund Site in Perth Amboy, New Jersey.

The monies paid by the settling defendants under the consent decree will be used to reimburse past costs incurred at the three sites. The consent decree provides the settling defendants with releases for civil liability for EPA's past and future CERCLA response costs at the three sites.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, U.S. Department of Justice, P.O. Box 7611, Washington, DC 20044–7611, and should refer to United States v. Lightman, *et al.*, DOJ Ref. No. 90–11–3–942A.

The proposed consent decree may be examined at the Office of the United States Attorney, Post Office Bldg., 4th Floor, 4th and Market Streets, Camden, NJ 08101, and at the Region II Office of the Environmental Protection Agency, Region II Records Center, 290 Broadway, 17th Floor, New York, NY 10007–1866. A copy of the proposed consent decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $5.75 (25 cents per page

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reproduction costs), payable to the Consent Decree Library.

Bruce Gelber,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–1733 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Water Act

Consistent with Departmental policy, 28 CFR 50.7 and 38 FR 19029, notice is hereby given that on January 8, 2001, a proposed Consent Decree in *United States* v. *Hitchiner Manufacturing Company, Inc.*, Civil Action No. 01–11–JD was lodged with the United States District Court for the District of New Hampshire. The proposed Consent Decree will resolve the United States' claims under Section 309 of the Clean Water Act ("CWA"), 33. U.S.C. 1319, on behalf of the U.S. Environmental Protection Agency ("EPA") against the defendant relating to the Beacon Street Facility and the Redington Street Facility, both located in Littleton, New Hampshire, and the Milford Facility, located in Milford, New Hampshire. The Complaint alleges that the defendant is liable under Section 309 of the Clean Water Act ("CWA"), 33 U.S.C. 1319.

Pursuant to the Consent Decree, the defendant agrees to pay to the United States a civil penalty of $525,000 and to perform injunctive relief. Further, the defendant agrees to: comply with the federal pretreatment standards for the Metal Finishing Point Source Category set forth at 40 CFR 433.17; comply with the General Pretreatment Regulations for Existing and New Sources of Pollution set forth at 40 CFR part 403, at its Beacon Street and Redington Street Facilities; begin monitoring all process wastewater discharged to the Town of Littleton's publicly owned treatment works from its Beacon Street and Redington Street Facilities; submit monthly reports on the samplying and analysis; and implement the individual Storm Water Pollution Prevention Plans, which were developed for each facility.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed consent decree. Any comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, DC 20044–7611, and should refer to *United States* v. *Hitchiner Manufacturing Company, Inc.*, Civil Action No. 01–11–JD, D.J. Ref. 90–5–1–1–06922.

The proposed consent decree may be examined at the Office of the United States Attorney, District of New Hampshire, U.S. Department of Justice, 55 Pleasant Street, Room 352, Concord, New Hampshire, 03301–3904, and at U.S. EPA New England (Region 1), One Congress Street, Suite 1100, Boston, Massachusetts, 02114–2023. A copy of the proposed consent decree may be obtained by mail from the Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611. In requesting a copy, please enclose a check (there is a 25 cent per page reproduction cost) in the amount of $6.75 payable to the Consent Decree Library.

Bruce Gelber,

Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–1732 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Resource Conservation and Recovery Act and Under the Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on January 8, 2000, a proposed consent decree in *United States* v. *Rhode Island Technical Plating, Inc.*, Civil Action No. 01–007L was lodged with the United States District Court for the District of Rhode Island.

In this action the United States sought injunctive relief and assessment of civil penalties in connection with the electroplating and metal finishing facility owned by Rhode Island Technical Plating ("RITP"), in Cranston, Rhode Island. The Complaint alleges that the defendant is liable under sections 3008(a) and 3008(g) of the Resource Conservation and Recovery Act ("RCRA") and under Section 113(b) of the Clean Air Act. Pursuant to the decree, defendant will perform a RCRA facility investigation and take appropriate steps to bring its facility into compliance with applicable law. Defendant will also pay to the United States, a civil penalty of $20,000. This settlement is based, in part, on the Defendant's limited financial ability to pay.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* versus *Rhode Island Technical Plating, Inc.*, Civil Action No. 01–007L, D.J. Ref. 90–7–1–06063.

The proposed consent decree may be examined at the Office of the United States Attorney, District of Rhode Island, 150 South Main Street, Providence, Rhode Island, 02906, and at U.S. EPA New England (Region 1), One Congress Street, Suite 1100, Boston, Massachusetts, 02114–2023. A copy of the proposed consent decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $12.00 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Bruce S. Gelber,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 01–1731 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 213–2001]

Privacy Act of 1974; System of Records

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is hereby given that the Department of Justice proposes to modify a system of records maintained by the Immigration and Naturalization Service (INS), specifically:

Security Access Control System (SACS), JUSTICE/INS–014, last published May 10, 1990 (55 FR 19674).

The system of records is being modified: (1) To add additional sites where the system is located, (2) add a new category of individual covered by the system, (3) to add four routine use disclosures, (4) expand the safeguards, (5) revise the System Manager section to include all Security Directors within the INS and (6) correct the Retention and Disposal section. Other minor changes and edits have also been made to the sections on Record Access Procedures and Contesting Record Procedures of the notice.

In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment on the modified system. The Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to conclude its review of the system. Therefore, please submit any comment by (30 days from the publication date of this notice). The public, OMB, and the Congress are invited to submit any comments to Mary Cahill, Management Analyst, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 1400, National Place Building).

In accordance with 5 U.S.C. 552a, the Department has provided a report to OMB and the Congress.

Dated: January 8, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

JUSTICE/INS–014

SYSTEM NAME:

Security Access Control System (SACS).

SYSTEM LOCATION:

Headquarters, Regional and District offices, Administrative Centers, and other Immigration and Naturalization Service (INS) file control offices as detailed in JUSTICE/INS–999, last published in the **Federal Register** on April 13, 1999 (64 FR 18052).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

INS employees and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

SACS is an automated system which contains: employee name, badge number, social security number, physical descriptions, photographs, date, time and location of entry into and departure from INS buildings and office suites.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 12356, 5 U.S.C. 552a(e)(10), Public Law Number 90–620, as amended (44 U.S.C. Chapters 21 and 23), 5 U.S.C. 301, and 40 U.S.C. 486(c), as implemented by 41 CFR 101–20.3 and 41 CFR 101–20.103. The Executive Order and statutes address the security of records maintained by Federal agencies, Public Buildings, Property and Works to include Conduct on Federal Property and Physical Protection and Building Security.

PURPOSE(S):

The purpose of the system is to improve the security of Federal records and property, and the safety of INS employees, by instituting a more effective means by which to detect unauthorized entry into the INS buildings. Access passes (i.e., card key) must be inserted into an electronic card reader which will record identifying data and will automatically unlock the entrance door if the pass is active and authorized.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

A. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

B. To a Member of Congress or staff acting on the Member's behalf when the Member or staff requests the information on behalf of and at the request of the individual who is the subject of the record.

C. To the General Services Administration and the National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To contractors who have been hired to perform Immigration and Naturalization Service functions to the extent necessary to enable them to perform their assigned duties.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on magnetic media within the server and on data cartridges used as back-ups.

RETRIEVABILITY:

Records are retrieved by last name, social security number or numerically by access pass number.

SAFEGUARDS:

The databases is maintained in a locked room with access limited to the Security staff and INS management and supervisory officials. System users must sign on with INS assigned and approved user identification and password.

RETENTION AND DISPOSAL:

Data recorded on magnetic media within the server will be retained for a period of three years, at which time the information will be deleted. Information on data cartridges will be retained briefly until the date is erased by recording new data. Key accountability files (*i.e.*, files that relate to the accountability of issued card keys) are retained and disposed of in accordance with General Records Schedule 18, items 16 and 18.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Security and Security Officers at each INS office maintaining a database as noted in System Locations.

NOTIFICATION PROCEDURE:

Address inquiries to the system manager identified above.

RECORD ACCESS PROCEDURES:

Requests for access to records in this system shall be in writing, and should be addressed to the appropriate INS FOIS/PA Officer where the records are located or if unknown to the FOIS/PA Officer at 425 I Street, NW, Second Floor, Union Labor Life Building, Washington, DC 20536. Such requests may be submitted either by mail or in person. Clearly mark the envelop "Privacy Act Request." The requester shall include a description of the general subject matter and provide his or here full name, date and place of birth, verification of identifying (in accordance with 8 CFR 103.21 (b)) and any other identifying information which may be of assistance in locating the record. The requester shall also provide a return address for transmitting the records to be released.

CONTESTING RECORD PROCEDURES:

A determination as to the granting or denial of a request shall be made at the time a request is received. An individual who desires to request amendment of records maintained in the system should direct his or her request to the appropriate FOIS/PA Officer at the INS office where the record is maintained or (if unknown) to the INS FOIA/PA Officer at 425 I Street, NW, Second Floor, Union Labor Life Building, Washington, DC. 20536. The request should state clearly and concisely the information being contested, the reasons for contesting it and the proposed amendment to the information.

RECORD SOURCE CATEGORIES:

INS employees.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–1738 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 214–2001]

Privacy Act of 1974; System of Records

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the

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Immigration and Naturalization Service (INS), Department of Justice, proposes to modify the following system of records previously published July 31, 2000 (65 FR 46738):

Deportable Alien Control System (DACS), JUSTICE/INS–012

INS proposes to add two new routine use disclosures, identified as routine use (K) and (L). The purpose of routine use (K) is to allow legal service providers to call an INS detention facility in advance of a visit to the site, to determine whether a certain individual is detained. The release of the information is discretionary and will only pertain to whether or not the individual concerned is currently detained at that facility. Routine use (L) allows contractors working on behalf of INS to have access to necessary information to assist in this program.

In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment on the new routine use disclosures. The Office of Management and Budget (OMB), which has oversight responsibilities under the Act, requires a 40-day period in which to conclude its review of the system. Therefore, please submit any comments by February 21, 2001. The public, OMB, and the Congress are invited to send written comments to Mary Cahill, Management Analyst, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 1400, National Place Building).

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and the Congress on the proposed modification.

Dated: January 8, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

JUSTICE/INS–012

SYSTEM NAME:

Deportable Alien Control System (DACS).

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND PURPOSE OF SUCH USES:

Relevant information contained in this system of records may be disclosed as follows:

* * * * * *

K. To legal service providers who are authorized to represent individuals in removal proceedings with the United States Immigration and Naturalization Service, to assist individuals in INS custody acquire legal representation.

L. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government, when necessary to accomplish an agency function related to this system of records.

* * * * *

[FR Doc. 01–1739 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 215–2001]

Privacy Act of 1974; System of Records

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is hereby given that the Department of Justice proposes to establish a new system of records to be maintained by the Immigration and Naturalization Service (INS).

The Image Storage and Retrieval System, JUSTICE/INS–005, is a new system of records for which no public notice consistent with the provisions of 5 U.S.C. 552a(e)(4) and (11) has been published.

In accordance with 5 U.S.C. 552a(e)(4) and (11), the public is given a 30-day period in which to comment on routine use disclosures. The Office of Management and Budget (OMB), which has oversight responsibility under the Act, requires a 40-day period in which to conclude its review of the system. Therefore, please submit any comments by February 21, 2001. The public, OMB and the Congress are invited to submit any comments to Mary Cahill, Management Analyst, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 1400, National Place Building).

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and the Congress.

Dated: January 8, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

JUSTICE/INS–005

SYSTEM NAME:

INS Image Storage and Retrieval System (ISRS).

SYSTEM LOCATIONS:

Headquarters, Regional Offices, Administrative Centers, Service Centers, District Offices, Ports of Entry, and file control offices of the Immigration and Naturalization Service in the United States as detailed in JUSTICE/INS–999, last published, April 13, 1999 (64 FR 18052). Other offices having access to the system are: The Law Enforcement Support Center, 188 Harvest Lane, Williston, Vermont 05495; the Central States Command Center, 10 West Jackson Boulevard, Chicago, Illinois 60604; and the Forensic Document Laboratory, 8000 Westpark Drive, Suite 325, McLean, Virginia 22101–3105.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons lawfully admitted for permanent residency; Asylees and Parolees lawfully admitted for employment authorization (although, Asylees and Parolees are not initially covered under the Privacy Act, these individuals often change their status to lawful permanent residents and at that time will be covered by the Privacy Act); Commuters and other persons authorized for frequent border crossing; Naturalized United States Citizens.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of formatted data base records of personal biographical data including: Name, date of birth, mother's first name, father's first name, and country of birth; and biometric information (*i.e.*, fingerprints, digital images of facial picture, and signatures).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

8 U.S.C. 1103, 1321, and 1360.

PURPOSE(S):

This system of records is used: To verify controlled INS documents issued to individuals covered by the system; to assist the INS with its responsibility to detect and reduce fraudulent entry to the United States; and to detect and reduce the proliferation of fraudulent INS documents.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Relevant information contained in this system of records may be disclosed as follows:

A. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

B. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of and at the request of the individual who is the subject of the record.

C. To the General Services Administration and National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To the appropriate agency/organization/task force, regardless of whether it is Federal, State, local, foreign, or tribal, charged with the enforcement (*e.g.*, investigation and prosecution) of a law (criminal or civil), regulation, or treaty, of any record contained in this system of records which indicates either on its face, or in conjunction with other information, a violation or potential violation of that law, regulation, or treaty.

E. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government, when necessary to accomplish an agency function related to this system of records.

F. Pursuant to subsection (b)(3) of the Privacy Act, the Department of Justice may disclose relevant and necessary information to a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

INS Image Storage and Retrieval System (ISRS) information is stored on magnetic media (internal image server disk drives).

RETRIEVABILITY:

Individual records are indexed and retrievable by name, alien registration number (A-number), and application receipt number. In cases where an individual record can not be retrieved by one of these key indexes, combinations of multiple data elements may be used (*e.g.* name, date of birth, and country of birth) if necessary, to assist in the identification and retrieval of a unique record.

SAFEGUARDS:

Most INS offices are located in buildings under security guard, with access limited to INS and other Federal Government employees and authorized visitors. All records are stored in spaces which are locked outside of normal office hours at the Department of Justice Data Center. The automated equipment is physically accessible only by authorized Department of Justice personnel. Electronic access to the automated system is controlled by restricted password for use at remote terminals in secured areas.

RETENTION AND DISPOSAL:

Image Storage and Retrieval System data records are retained in the system for a period of 75 years and them destroyed.

SYSTEM MANAGER AND ADDRESS:

Associate Commissioner, Immigration Resources Management, Immigration and Naturalization Service, 800 I Street, NW., Room 700, Washington, DC 20536.

NOTIFICATION PROCEDURES:

Inquiries should be addressed to the system manager at the INS office where the record is maintained or (if unknown) to the FOIA/PA Officer, INS, 425 I Street NW., Second Floor, Union Labor Life Building, Washington, DC 20536.

RECORD ACCESS PROCEDURE:

Requests for access to records in this system shall be in writing and should be addressed to the System Manager noted above or to the appropriate FOIA/PA Officer as indicated in System Locations. Requests sent directly to the System Manager should be submitted by mail. Requests to the FOIA/PA Officer may be submitted by mail. Requests to the FOIA/PA Officer may be submitted either by mail or in person. If a request for access is made by mail, the envelope and letter shall be clearly marked Privacy Access Request. Include a description of the general subject matter and if known, the related file number. To identify a record, the requester should provide his or her full name, date and place of birth, verification of identity in accordance with 8 CFR 103.21(b) or provide a statement under penalty of perjury, alien number, the date and place of entry into or departure from the United States and any other identifying information which may be of assistance in locating the record. The requester shall also provide a return address for transmitting the records to be released.

CONTESTING RECORD PROCEDURES:

An individual desiring to request amendments of records maintained in this system should direct his or her request to the System Manager or to the appropriate FOIA/PA Officer noted in System Locations. The request should state the information being contested, the reason(s) for contesting it, and the proposed amendment thereof. Persons filing such requests should mark the envelope with the following legend Privacy Act Amendment Request.

RECORD SOURCE CATEGORIES:

Basic information contained in this INS data repository is supplied by aliens wishing to seek entry to the United States and/or those already in the United States seeking benefits from the Immigration and Naturalization Service. External entities including Department of State overseas consular offices and United States embassies and the Department of Labor may also provide data on individuals seeking entry into the United States.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–1740 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 216–2001]

Privacy Act of 1974; System of Records

Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), notice is hereby given that the Department of Justice proposes to establish a new system of records to be maintained by the Immigration and Naturalization Service (INS).

The I–551 Renewal Program Temporary Sticker Issuance I–90 Manifest System (SIIMS), JUSTICE/INS–033, is a new system of records for which no public notice consistent with the provisions of 5 U.S.C. 552a(e)(4) and (11) has been published.

In accordance with 5 U.S.C. 552a(e) and (11), the public is given a 30-day period in which to comment on proposed routine use disclosures. The Office of Management and Budget (OMB), which has oversight responsibilities under the Act, requires a 40-day period in which to conclude its review of the proposal. OMB, the Congress, and the public, are invited to send written comments to Mary Cahill, Management Analyst, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 1400, National Place Building).

In accordance with 5 U.S.C. 552a, the Department has provided a report to OMB and the Congress.

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Dated: January 8, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

JUSTICE/INS–033

SYSTEM NAME:

I—551 Renewal Program Temporary Sticker Issuance I–90 Manifest System (SIIMS).

SYSTEM LOCATION:

Immigration and Naturalization Service (INS) Headquarters, Service Centers, District Offices, sub-offices, and Ports of Entry, as detailed in JUSTICE/INS–999, published April 13, 1999 (64 FR 18052).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are: covered by provisions of the Immigration and Nationality Act of the United States; have been lawfully admitted permanent residents for at least ten years; and are in possession of an expiring or expired Form I–551 (Permanent Resident Card, previously known as the Alien Registration Card), and have properly filed a Form I–90 (Application to Replace Alien Registration Card), with appropriate fee, for renewal of this expiring/expired I–551, at the District or sub-office.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records from this system are in automated and paper form. The records identify the sticker number applied to the back of the I–551 after an I–90 application and fee has been accepted. The system also includes the alien number and name of the applicant; the type and amount of fee remittance accepted; the location where the application was accepted; the date of the application; and the identification of the individual issuing the sticker.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

8 U.S.C. Sections 1103, 1154, 1304, 1305, and 1360.

PURPOSE(S):

The system enables INS to track the issuance of the stickers, and provides for accountability and control of specific sticker issuance. In some instances, field inquiries of the system also will enable INS to determine if a particular sticker was properly issued and/or is a legitimate issuance.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Relevant information contained in this system of records may be disclosed as follows:

A. To Federal, State, tribal, and local government law enforcement and regulatory agencies, foreign governments, and individuals and organizations during the course of investigation in the processing of a matter, or a proceeding within the purview of the immigration and nationality laws, to elicit information required by INS to carry out its functions and statutory mandates.

B. To a Federal, State, tribal, local or foreign government agency or organization, or international organization, lawfully engaged in collecting law enforcement intelligence information, whether civil or criminal, and/or charged with investigating, prosecuting, enforcing or implementing civil and/or criminal laws, related rules, regulations or orders, to enable these entities to carry out their law enforcement responsibilities, including the collection of law enforcement intelligence.

C. To either a party or the tribunal in a proceeding before a court or other adjudicative body before which INS or the Department of Justice (DOJ) is authorized to appear when any of the following is a party to litigation or has an interest in litigation and such records are determined by INS, or DOJ, to be relevant to the litigation: (1) The DOJ, or any DOJ component, or any subdivision thereof; (2) any DOJ employee in his or her official capacity; (3) any DOJ employee in his or her individual capacity where the DOJ has agreed to represent the employee or has authorized a private attorney to represent him or her; and (4) the United States, where the INS or the DOJ determines that the litigation is likely to affect it or any of its subdivisions.

D. To a Federal, State, local or foreign government agency in response to its request, in connection with the hiring or retention by such agency of an employee, the issuance of a security clearance, the reporting of an investigation of such an employee, the letting of a contract, or the issuance of a license, grant, loan or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

E. To a Federal, State, local, tribal, or foreign government agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a decision of INS concerning the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant or other benefit.

F. To the news media and the public pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

G. To a Member of Congress or staff acting on the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

H. To the General Services Administration and the National Archives and Records Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

I. To an attorney or representative acting on behalf an individual covered by this system of records in connection with any proceeding before the INS or the Executive Office for Immigration Review.

J. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government, when necessary to accomplish an agency function related to this system of records.

K. Pursuant to subsection (b)(3) of the Privacy Act, the Department of Justice may disclose relevant and necessary information to a former employee of the Department for purposes of: responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility.

POLICIES AND PRACTICES OF STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM STORAGE:

Information will be stored on magnetic disks and/or tape in INS Headquarters. Paper records will be stored in INS offices, file drawers, and/or filing cabinets.

RETRIEVABILITY:

Information will be retrievable by sticker number. Other specific information reports may be generated for quality control and verification purposes. The reports can be retrieved by date, location, issuing agent, and/or alien number.

SAFEGUARDS:

Most INS offices are located in buildings under security guard, with access limited to INS and other Federal Government employees and authorized visitors. All records are stored in spaces which are locked during non-duty office hours. Many records are stored in cabinets or machines which are also locked during non-duty office hours. Access to automated records is controlled by passwords and name identifications.

RETENTION AND DISPOSAL:

The sticker issuance data in the electronic tracking system is maintained for three years and then destroyed. The sticker issuance in manifest form is downloaded from the electronic system and maintained in case of inquiries. It is maintained for three years and then destroyed. The Form I–90 applications are mailed to the Service Centers where they are placed in application receipt files, maintained for ten years, and then destroyed. If a Form I–90 application is denied, it is placed in the alien file. NOTE: Alien files and the Central Index System (CIS) contain all relevant information pertaining to the permanent resident status of the applicant and are maintained for 75 years.

SYSTEM MANAGER AND ADDRESS:

Associate Commissioner, Field Services Operation, Immigration Services Division, Immigration and Naturalization Service, 801 I Street NW, Room 900, Washington, DC 20536.

NOTIFICATION PROCEDURE:

Any inquiries regarding specific sticker issuance information contained in this system should be addressed in writing to the System Manager listed above or to the Freedom of Information Act/Privacy Act (FOIA/PA) officer where the record is located (See System Location).

RECORD ACCESS PROCEDURE:

Requests for access to a record from this system shall be in writing. Clearly mark the envelope and letter "Privacy Act Request." The requester shall provide his or her full name, the sticker issuance number, the general nature of the inquiry, and if possible the date that the application was filed at the INS office and the location of the INS office where the application was accepted. The requester also shall provide date and place of birth, verification of identity [in accordance with 8 CFR 103.21(b) or a sworn statement under penalty of perjury], his or her notarized signature, and any other information that may assist in identifying and locating the record. The requester also should provide a return address for transmitting the record(s) to be released.

CONTESTING RECORDS PROCEDURE:

Direct all requests to contest or amend information to the System Manager or FOIA/PA officer as indicated above. State clearly and concisely the information being contested, the reason for contesting it, and the proposed amendment thereof. Clearly mark the envelope "Privacy Act Amendment Request." The record must be identified in the same manner as described for making a request for record access (see above). To facilitate the expeditious handling of the amendment request, include a copy of the response received to the Privacy Act Request.

RECORD SOURCE CATEGORIES:

Information contained in this system of records is obtained from the applicant during the issuance of an I–551 extension after an applicant has filed an I–90 to renew and expiring/expired I–551 in his or her possession.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 01–1741 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Agency Information Collection Activities; Proposed Collection; Comments Requested

ACTION: Notice of Information Collection Under Review; Existing Collection in use without an OMB control number; National Sex Offender Registry.

The Department of Justice, Federal Bureau of Investigation, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995. OMB approval has been requested by January 24, 2001. The proposed information collection is published to obtain comments from the public and affected agencies. If granted, the emergency approval is only valid for 180 days. Comments should be directed to OMB, Office of Information Regulation Affairs, Attention: Department of Justice Desk Officer (202) 395–6466, Washington, DC 20530.

During the first 60 days of this same review period, a regular review of this information collection is also being undertaken. All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Beth Saymon, Acting Unit Chief, Review, Analysis, and Development Unit, Program Development Section, Criminal Justice Information Services Division, Federal Bureau of Investigation, 1000 Custer Hollow Road, Clarksburg, WV 26306.

We request written comments and suggestions from the public and affected agencies concerning the proposed collection of information. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this collection:

(1) Type of information collection: Existing Collection in use without an OMB control number.

(2) *Title of Form/Collection:* National Sex Offender Registry

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Federal Bureau of Investigation.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary—50 States, 5 territories, the District of Columbia, and registered sex offenders who moved to another state. The National Sex Offender Registry data is collected from the 50 states, 5 territories, and the District of Columbia. In addition registered sex offender must notify the FBI when they move to another state. The state must notify the Federal Bureau of Investigation if they cannot

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verify the address or locate a person required to register with the states registration program. The registry was established by the FBI in accordance with Federal law (42 U.S.C. 14072) in order to track the whereabouts and movements of persons who have been convicted of a criminal offense against a victim who is a minor; persons who have been convicted of a sexually violent offense; and persons who are sexually violent predators.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Number of respondents: 56 government entities and 8,400 registered sex offenders annually. The estimated time for the average respondent to respond: 2 minutes per transaction, average 250,000 total transaction per year.

(6) *An estimate of the total of public burden (in hours) associated with the collection:* Approximately 8,333 total annual burden hours [250,000×2=500,000 minutes/60 minutes.]

If additional information is required contact: Robert B. Briggs, Department Clearance Office, United States Department of Justice, Information Management and Security Staff Justice Management Division, Suite 1220, National Place, 1331 Pennsylvania Avenue NW, Washington, DC 20530.

Dated: January 16, 2001.

Robert B. Briggs,

Department Clearance Officer, United States Department of Justice.

[FR Doc. 01–1846 Filed 1–19–01; 8:45 am]

BILLING CODE 4401–02–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 218–2001]

Privacy Act of 1974; System of Records

AGENCY: Federal Bureau of Investigation, DOJ.

ACTION: Notice.

SUMMARY: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), and Office of Management and Budget (OMB) Circular No. A–130, notice is hereby given that the Department of Justice, Federal Bureau of Investigation (FBI), is amending the following system of records which was originally published in the **Federal Register** on November 25, 1998 (63 FR 65223), and was amended on December 14, 2000 (65 FR 78190):

The National Instant Criminal Background Check System (NICS) JUSTICE/FBI–018.

Opportunity for Comment: The Privacy Act (5 U.S.C. 552a(e)(4) and (11)) requires that the public be given 30 days in which to comment on any new or amended uses of information in a system of records. In addition, in accordance with Privacy Act requirements (5 U.S.C. 552a(r)), the Department of Justice has provided a report on these modifications to OMB and the Congress. OMB, which has oversight responsibilities under the Act, requires that OMB and the Congress be given 40 days in which to review major changes to Privacy Act systems. Therefore, the public, OMB, and the Congress are invited to submit written comments on this modification.

Address Comments or Requests for Further Information to: Mary E. Cahill, Management Analyst, Management and Planning Staff, Justice Management Division, Department of Justice, 1400 National Place Building, Washington, DC 20530.

EFFECTIVE DATE: These proposed changes will be effective March 5, 2001 unless comments are received that result in a contrary determination.

SUPPLEMENTARY INFORMATION: The Department is modifying the system of records to include one new routine use. This new routine use provides for disclosure of information in the NICS Audit Log to the Bureau of Alcohol, Tobacco, and Firearms (ATF) in connection with ATF's inspections of Federal Firearms Licensee records. The notice is also being modified to reflect that information about allowed transfers will only be retained in the NICS Audit Log for 90 days, unless such information is needed to pursue identified cases of misuse. Revisions to 28 CFR part 25 which underlie these changes are being implemented in the Rules section of today's **Federal Register**.

The notice is also being revised to clarify that system limitations on retaining information only apply to allowed transactions.

Accordingly, the system of records is modified as provided below.

Dated: January 12, 2001.

Stephen R. Colgate,

Assistant Attorney General for Administration.

Justice/FBI–018

SYSTEM NAME

National Instant Criminal Background Check System (NICS).

ACTION

The system notice published in the **Federal Register** on November 25, 1998 (63 FR 65223), and amended on December 14, 2000 (65 FR 78190), is further amended as follows:

1. In the section titled "Categories of Individuals Covered by the System," subsection L is amended by changing the fourth and fifth sentences so that the subsection now reads as follows:

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM

* * * * *

L. Has applied for the transfer of a firearm or for a firearms-related permit or license and has had his or her name forwarded to the NICS as part of a request for a NICS background check. (Identifying information about this category of individuals is maintained for system administration and security purposes in the "NICS Audit Log," a system transaction log described below under the headings "CATEGORIES OF RECORDS IN THE SYSTEM" and "RETENTION AND DISPOSAL." Identifying information may also be maintained in appeals files for those individuals who have requested the reason for a denial or delay from the FBI, or from a law enforcement agency serving as a POC, and/or challenged the accuracy or validity of a disqualifying record or otherwise inquired about a NICS transaction. In cases of allowed transfers, all information in the NICS Audit Log related to the person or the transfer, other than the NICS Transaction Number (a unique number assigned to each valid background request inquiry) assigned to the transfer and the date the number was assigned, will be destroyed after not more than 90 days after the transfer is allowed, provided that such information may be retained for a longer period if necessary to pursue identified cases of misuse of the system. In such cases, the system will not contain any details about the type of firearm which is the subject of the proposed transfer (other than the fact that it is a handgun or long gun) or whether a sale or transfer of a firearm has actually taken place.)

2. The section titled "Routine Uses of Records Maintained in the System, Including Categories of Users and the Purposes of Such Uses" is amended by adding a new subparagraph ("J") at the end to read as follows:

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES

* * * * *

J. Information in the NICS Audit Log (including records of approved and denied transfers) may be disclosed to the Bureau of Alcohol, Tobacco, and Firearms (ATF) in connection with ATF's inspections of Federal Firearms Licensee records.

3. In the section titled "Retention and Disposal" the second paragraph is amended to read as follows:

RETENTION AND DISPOSAL

* * * * *

The FBI will maintain an audit Log of all NICS transactions. Firearms transaction approvals will be maintained for 90 days (except that such information may be retained for a longer period if necessary to pursue identified cases of misuse of the system). The NICS Transaction Number (the unique number assigned to the NICS transaction) and the date on which it was assigned will be maintained indefinitely. Information related to firearms transfer denials will be retained for 10 years and then disposed of as directed by the National Archives and Record Administration.

* * * * *

[FR Doc. 01–1612 Filed 1–19–01; 8:45 am]

BILLING CODE 4410–02–M

DEPARTMENT OF LABOR

Office of the Secretary

Office of Small Business Programs Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c) (2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Small Business Programs (OSBP) is soliciting comments concerning the proposed new collection of the Small Business Programs Information Management System. A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before March 23, 2001.

ADDRESSES: Send comments to Elaine B. Murrell, Small Business Advisor, U.S. Department of Labor, Office of Small Business Programs, Room C–2318, 200 Constitution Avenue, NW., Washington, DC 20210; E-Mail: *murrell-elaine@dol.gov*; Telephone: 202–693–6467 (this is not a toll free number); Fax: 202–693–6485.

FOR FURTHER INFORMATION CONTACT: Elaine B. Murrell, telephone: 202–693–6467.

SUPPLEMENTARY INFORMATION:

I. Background

Federal agencies are required to promote procurement opportunities for small, small disadvantaged, and 8(a) businesses by the Small Business Act, as amended, (Public Law 95–507, Sections 8 and 15) and Pub. L. 100–656 (Sections 502 and 503). The Federal Acquisition Streamlining Act of 1994 (Pub. L. 103–355) mandates similar efforts for small women-owned businesses. Public Law 106–50 created the program for service-disabled veteran-owned small businesses. Public Law 105–135 established the HubZone program. The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) requires Federal agencies to make available to small businesses compliance guides and assistance on the implementation of regulations and directives of enforcement laws they administer. Executive Orders 12876, 12900, and 13021 direct Federal agencies to implement programs, respectively, regarding Historically Black Colleges and Universities, Educational Excellence for Hispanic Americans, and Tribal Colleges and Universities that are administered by the respective White House Initiative offices (in the U.S. Department of Education). Executive Order 13125 directs Federal agencies to ensure that Asian Americans and Pacific Islanders are afforded opportunity to fully participate in Federal Programs. Further, Executive Order 13170 requires that Departments take a number of actions to increase outreach and maximize participation of small disadvantaged businesses in their procurements. Executive Order 13157 strengthens the executive branch's commitment to increased opportunities for women-owned small businesses. Accordingly, the Small Business Programs Information Management System is needed to gather, document, and manage identifying information for four Office of Small Business Programs constituency groups: Small Businesses; Trade Associations; Minority Colleges and Universities; and Tribal Governments. Via this system, the constituent groups will have the opportunity to voluntarily provide to OSBP information about their organizations. The information will be used by OSBP and DOL agencies to maximize communication with the respective constituency groups regarding relevant OSBP and DOL programs, initiatives, and procurement opportunities; to track and solicit feedback on customer service to group members; and to facilitate registration of group members for OSBP-sponsored activities.

II. Review Focus

The Office of Small Business Programs is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

III. Current Actions

There are no current actions.

Type of Review: New Collection.

Agency: Office of Small Business Programs.

Title: Small Business Program Information Management System.

OMB Number: 1290–0NEW.

Agency Number: OSBP 1.

Affected Public: Business or other for-profit; Not-for-profit institutions; State, Local, or Tribal Governments.

Total Respondents: 4,000.

Total Responses: 6,000.

Frequency: On Occasion.

Average Time Per Response: 7 minutes.

Estimated Total Burden Hours: 700 hours.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

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Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they also will become a matter of public record.

Signed at Washington, DC, this 16th day of January, 2001.

June M. Robinson,

Director, Office of Small Business Programs.

[FR Doc. 01–1615 Filed 1–19–01; 8:45 am]

BILLING CODE 4510–23–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Investment Act, Section 171(d), Demonstration Program: Incumbent/Dislocated Worker Skill Shortage II Demonstration Program; Notice of Changes to Solicitation for Grant Applications (SGA)

On October 31, 2000, the Department of Labor (DOL) announced in the **Federal Register** (65 FR 64991–65007; FR Doc. 00–27930) a solicitation for grant applications (SGA) for the Incumbent/Dislocated Worker Skill Shortage II Demonstration Program (Reference: SGA/DFA 00–113). Proposals for this SGA were to be submitted by 4:00 p.m. Eastern Time on Tuesday, January 16, 2001.

Included among the requirements for activities under this demonstration program was the use of the lower living standard income level (LLSIL) as a wage standard for certain jobs to be filled by demonstration participants who were successful training completers. The relevant portion of the SGA at Part II, Section D., Wages noted:

> Proposals must provide assurance that all participating firms which employ successful training completers have committed to pay wages to these completers * * * at a level at least equal to meeting the lower living standard income level as defined in Section 101(24) of WIA.

As a result of several inquiries regarding the LLSIL and in further consideration of this matter, the Department wishes to both clarify its intent and to change this requirement as originally announced. Because the LLSIL is adjusted for several factors, some inquirers have suggested that use of this standard in connection with its adjustments for family size could violate current equal pay protection standards. The Department wishes to note that violation of equal pay protection standards is not the intended use of the LLSIL in this SGA and regrets any misunderstanding in this matter.

Effective this date, Part II, Section D., Wages of the referenced SGA is replaced as follows:

> Proposals must provide assurance that all participating firms which employ successful training completers have committed to pay wages to these completers at the wage level set by any collective bargaining agreement which covers positions to be filled by the project participants, or, if no such agreement exists, at a level at least equal to meeting the lower living standard income level as defined in Section 101(24) of WIA for a family of four.

As the above change indicates, the LLSIL, when used, is to be applied in the amounts applicable to a family of four. By standardizing the application of the LLSIL to this family size for this demonstration, a uniform wage level will be applicable for all persons regardless of their respective family sizes. All other adjustments to the LLSIL (regional, metropolitan, urban and rural differences) will continue to be applicable as provided in Section 101(24) of WIA.

(Information on the current LLSIL's may be found at: www.wdsc.org/llsil/ or in the **Federal Register** (65 FR 30630–30636; FR Doc. 00–11978))

To allow additional time for applicants to consider this notice, the Department hereby reopens and extends the deadline for receipt of proposals for this SGA until 4:00 p.m. Eastern Time on Wednesday, February 21, 2001. In addition, applicants who submitted proposals by the original deadline of January 16, 2001 are invited to amend their proposals accordingly by this new deadline.

Other than indicated herein, the requirements established by the above referenced October 31, 2000 SGA (SGA/DFA 00–113) remain in force.

Signed at Washington, DC, this sixteenth day of January 2001.

Laura A. Cesario,

Grant Officer, Division of Federal Assistance.

[FR Doc. 01–1696 Filed 1–17–01; 11:06 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment and Training Administration

Senior Community Service Employment Program; Notice of Town Hall Meeting on the 2000 Amendments to the Older Americans Act

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of Town Hall Meeting.

SUMMARY: Notice is given of the first in a series of Town Hall Meetings that the Department of Labor intends to convene to assist in the identification of issues to be addressed in the implementation of changes to the Senior Community Service Employment Program (SCSEP) occasioned by the Older Americans Act Amendments of 2000, and to obtain the benefit of various practitioners' concerns and experiences in the operation of the SCSEP. Town Hall Meetings will be held in various locations throughout the country, in order to facilitate the participation of all interested individuals.

DATES: The first Town Hall Meeting will be held on Monday, January 22, 2001, from 7:00 p.m. to 9:00 p.m. The date, location and time for subsequent Town Hall Meetings will be announced in advance in the **Federal Register**.

ADDRESSES: The first Town Hall Meeting will be held at the Westin Peachtree Plaza Hotel at 210 Peachtree Street, NW., Atlanta, Georgia, in conjunction with the National Older Worker Conference sponsored by the National Association of State Units on Aging.

FOR FURTHER INFORMATION CONTACT: Mr. Erich W. ("Ric") Larisch, Chief, Division of Older Worker Programs, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N4644, Washington, DC 20210, Telephone: (202) 693–3742 (voice) TTY (202) 693–2871 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The purpose of the Town Hall Meetings is to provide each interested individual with an opportunity to comment on the Department of Labor's approach to the implementation of changes to the SCSEP occasioned by the revisions to title V of the Older Americans Act Amendments of 2000 (OAA) (Pub. L. 106–501) (dated November 13, 2000). Each attendee is welcome to offer comments on a variety of subjects, including: (1) Issues and concerns that should be addressed in regulations; (2) issues and concerns that should be addressed in policy guidance; (3) suggestions and comments on the overall implementation plan, such as consultation strategies; (4) specific suggestions on the approach that should be taken in implementing any or all of the new title V provisions; and (5) suggestions on revisions that should be made to the existing title V regulations which were published in the **Federal Register** on Wednesday, May 17, 1995 (20 CFR part 641).

PUBLIC PARTICIPATION:

All interested individuals are invited to attend this Town Hall Meeting.

Persons wishing to make statements or presentations at the Town Hall Meetings should limit oral statements to 5 minutes, but extended written statements may be submitted for the record. Written statements may also be submitted without presenting oral statements. Individuals may submit written comments to the Employment and Training Administration, Division of Older Worker Programs, 200 Constitution Avenue, NW., Room N4644, Washington. DC 20210, Attention: Mr. Erich W. ("Ric") Larisch.

Minutes of all Town Hall Meetings and summaries of other documents will be available to the public on the SCSEP website http://www.wdsc.org/owprog. Any written comments on the minutes should be directed to Mr. Erich W. ("Ric") Larisch, as shown above.

Individuals with disabilities who are planning to attend the Atlanta Town Hall Meeting should contact Ms. Theresa Lambert of the National Association of State Units on Aging at (202) 898–2578, (this is not a toll-free number) if special accommodations are needed.

Signed at Washington DC, this 17 day of January, 2001.

Raymond L. Bramucci,

Assistant Secretary of Labor.

[FR Doc. 01–1801 Filed 1–19–01; 8:45 am]

BILLING CODE 4510–30–U

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–10571, et al.]

Proposed Exemptions; Keystone Brokerage, Inc. (Keystone)

AGENCY: Pension and Welfare Benefits Administration, Labor

ACTION: Notice of proposed exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Proposed Exemption, within 45 days from the date of publication of this Federal Register Notice. Comments and requests for a hearing should state: (1) The name, address, and telephone number of the person making the comment or request, and (2) the nature of the person's interest in the exemption and the manner in which the person would be adversely affected by the exemption. A request for a hearing must also state the issues to be addressed and include a general description of the evidence to be presented at the hearing.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, Room N–5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Attention: Application No. _____, stated in each Notice of Proposed Exemption. The applications for exemption and the comments received will be available for public inspection in the Public Documents Room of the Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N–5638, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of proposed exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of proposed exemption are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Keystone Brokerage, Inc. (Keystone), et al. Located in Williamsport, PA

[Application No. D–10571]

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, August 10, 1990).[1]

Section I. Covered Transactions

If the exemption is granted, the sanctions resulting from the application of section 4975 of the Code, by reason of 4975(c)(1)(A) through (D) of the Code shall not apply, effective October 3, 1997 through June 30, 2000, to the purchase or redemption of shares, by a self-directed individual retirement account (the IRA), of investment portfolios (the Portfolios) of certain mutual funds that were affiliated with Keystone (the Affiliated Funds) or in other mutual funds that were unaffiliated with Keystone (the Third Party Funds),[2] in connection with the IRA's participation in the KeyPremier Nautilus Series Program, or its successor, the Nautilus Series Program, (together, the Investment Advisory Program).

In addition, the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(E) and (F) of the Code, shall not apply, effective October 3, 1997 through June 30, 2000, to (1) the provision, by Keystone, of asset allocation and related services to an independent fiduciary of an IRA (the Independent Fiduciary), which resulted in the selection of Portfolios in the Investment Advisory Program by the Independent Fiduciary for the investment of IRA assets; and (2) the receipt of fees by Martindale Andres & Co., Inc. (Martindale) and Governor Group Advisors, Inc. (GGA), affiliates of Keystone, in connection with provision of investment advisory or sub-advisory services to the Fund Portfolios.

This proposed exemption is subject to the conditions set forth below in Section II.

[1] This proposed exemption applies to IRAs described in section 408(a) of the Code. Pursuant to 29 CFR 2510.3–2(d), the IRAs are not "employee benefit plans" covered under Title I of the Act. However, the IRAs are subject to jurisdiction pursuant to section 4975 of the Code.

[2] The Affiliated Funds and the Third Party Funds are collectively referred to herein as the Funds.

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Section II. General Conditions

(a) The participation by an IRA in the Investment Advisory Program was approved by an Independent Fiduciary.

(b) As to each IRA, the total fees that were paid to Keystone and its affiliates constituted no more than reasonable compensation for the services provided.

(c) With the exception of distribution-related fees paid to Keystone pursuant to Rule 12b–1 (the Rule 12b–1 fees) of the Investment Company Act of 1940 (the Investment Company Act) which were offset, no IRA paid a fee or commission by reason of the acquisition or redemption of the shares of the Funds.

(d) The terms of each purchase or redemption of shares in the Funds remained at least as favorable to an investing IRA as those obtainable in an arm's length transaction with an unrelated party.

(e) Keystone provided written documentation to each IRA's Independent Fiduciary of its recommendations or evaluations regarding the Fund Portfolios as well as the design and parameters with respect to an asset allocation model (the Asset Allocation Model), based upon objective criteria that were uniformly applied.

(f) Any recommendation or evaluation made by Keystone to an Independent Fiduciary was implemented only at the express direction of such Independent Fiduciary.

(g) The quarterly fee paid by an IRA to Keystone and its affiliates for asset allocation and related services rendered to such IRA under the Investment Advisory Program (the Outside Fee) was offset by—

(1) All gross investment management fees (the Advisory Fees) that were paid by the Affiliated Funds to Keystone, including any sub-advisory fees that were paid by the Affiliated Funds to third party sub-advisers;

(2) All administrative fees (the Administrative Fees) that were paid to GGA and BISYS Fund Services Limited Partnership (BISYS), an unrelated party; and

(3) All Rule 12b–1 Fees that were paid by the Third Party Funds to Keystone or its current and former affiliates with respect to an Investment Advisory Account (the Account), such that the sum of the offset and the net Outside Fee always equaled the aggregate Outside Fee, thereby making the selection of Affiliated Funds or Third Party Funds revenue-neutral.

(h) With respect to its participation in the Investment Advisory Program, prior to purchasing shares in the Portfolios of the Affiliated Funds and the Third Party Funds—

(1) Each Independent Fiduciary received the following written or oral disclosures from Keystone:

(A) A brochure describing the Investment Advisory Program; an Investment Advisory Program Account Agreement (the Account Agreement); a description of the Asset Allocation Models; and a reference guide/disclosure statement providing details about the Investment Advisory Program, the fees charged thereunder, the procedures for establishing, making additions to and withdrawing from the Accounts, and other related information;

(B) A risk tolerance and goal analysis questionnaire (the Questionnaire) or a written report of responses given by the Independent Fiduciary in a personal interview (the Interview) with a Keystone representative (the Interview Report);

(C) Copies of applicable prospectuses (the Prospectuses) for the Fund Portfolios discussing the investment objectives of the Portfolios; the policies employed to achieve the objectives of the Portfolios; the corporate affiliation existing between Keystone and its affiliates; the compensation paid to such entities; disclosures relating to rebalancing and reallocating Asset Allocation Models; and information explaining the risks attendant to investing in Portfolios for the Affiliated Funds and the Third Party Funds;

(D) Upon written or oral request to Keystone, a Statement of Additional Information supplementing the applicable Prospectus, which described the types of securities and other instruments in which the Portfolios could invest and the investment policies and strategies that the Portfolios could utilize, including a description of the risks;

(E) A copy of the Account Agreement between the IRA and Keystone relating to the IRA's participation in the Investment Advisory Program;

(F) A written recommendation of a specific Asset Allocation Model, together with a copy of the Questionnaire and response or the Interview Report;

(G) Upon written request to Keystone, a copy of any investment advisory agreement or sub-advisory agreement between Keystone and the Affiliated Funds; and

(H) Written disclosures of Keystone's affiliation or non-affiliation with the parties who act as sponsors, distributors, administrators, investment advisers and sub-advisers, custodians and transfer agents of the Portfolios.

(2) If accepted as an investor in the Investment Advisory Program, the Independent Fiduciary was required to acknowledge in writing to Keystone prior to purchasing shares of the Fund, that such Independent Fiduciary had received copies of the documents described in paragraph (h)(1) of this Section II and represent to Keystone that such individual was—

(A) Independent of Keystone and its affiliates;

(B) Knowledgeable with respect to the IRA in administrative matters and funding matters related thereto; and

(C) Able to make an informed decision concerning participation in the Investment Advisory Program.

(i) Subsequent to its participation in the Investment Advisory Program, each Independent Fiduciary received the following written or oral disclosures from Keystone with respect to ongoing participation:

(1) Written confirmations of each purchase or redemption transaction involving shares of an Affiliated Fund or a Third Party Fund Portfolio (including transactions resulting from the realignment of assets caused by a change in the Asset Allocation Model's investment mix and from periodic rebalancing of Account assets);

(2) Telephone quotations of such Independent Fiduciary's IRA Account balance;

(3) A periodic, but not less frequently than quarterly, Statement of Account specifying the net asset value of the IRA's assets in such Account, a summary of purchase, sale and exchange activity and dividends received or reinvested, a summary of cumulative realized gains and/or losses, and a statement of fees paid to Keystone and its affiliates;

(4) Semiannual and annual reports that included financial statements for the Portfolios;

(5) A quarterly report pertaining to the applicable Asset Allocation Model describing the Asset Allocation Model's performance during the preceding quarter; market conditions and economic outlook; and, if applicable, prospective changes in Portfolio allocations for the Asset Allocation Model and the reasons therefor;

(6) At least annually, a written or oral inquiry from Keystone to ascertain whether the information provided on the Questionnaire or in the Interview Report was still accurate or required updating; and

(7) At least annually during the first calendar quarter of each year after March 24, 1999, or at other times specified in Section II(l), a termination form (the Termination Form), meeting the requirements of Section II(k) and (l) below.

(j) If authorized in writing by the Independent Fiduciary, the IRA was automatically rebalanced on a quarterly basis by Keystone (using the net asset values of the affected Funds as of the close of business on a pre-established date) to the Asset Allocation Model previously prescribed by the Independent Fiduciary, if one or more Fund allocations deviated from the Asset Allocation Model prescribed by the Independent Fiduciary because—

(1) At least one transaction required to rebalance the IRA among the Funds involved a purchase or redemption of securities valued at $250 or more; and

(2) The net asset value of the Fund affected was more than 5 percent of the IRA's investment in such Fund.

(k) Keystone was authorized to provide written notice to the Independent Fiduciary, at least 30 days prior to the implementation of any of the following changes:

(1) A change in the asset mix outside the current Asset Allocation Model;

(2) The division of a class of assets (the Asset Class);

(3) The replacement of a Third Party Fund with an Affiliated Fund, or an Affiliated Fund with a Third Party Fund; and

(4) An increase in the Outside Fee.

(l) The written notice described above in Section II(k) was required to—

(1) State that the Independent Fiduciary could terminate the IRA's participation in the Investment Advisory Program at will and without penalty, upon receipt by Keystone of written notice from the Independent Fiduciary; and

(2) Explain that any of the proposed changes noted in paragraphs (k)(1)–(4) of Section II would go into effect if the Independent Fiduciary did not elect to withdraw by the effective date.

(3) For changes occurring after March 24, 1999, the notice was to be accompanied by a Termination Form containing instructions identical to those set forth above in paragraphs (l)(1)–(2) of this Section II.

(m) Keystone was not authorized to replace an Affiliated Fund with a Third Party Fund Portfolio or vice versa, nor was Keystone authorized to make an additional Third Party Fund Portfolio available for investment under the Investment Advisory Program.

(n) Keystone will maintain, for a period of six years, the records necessary to enable the persons described in paragraph (o) of this Section II to determine whether the conditions of this exemption have been met, except that—

(1) A prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Keystone and/or its affiliates, the records are lost or destroyed prior to the end of the six year period; and

(2) No party in interest, other than Keystone, shall be subject to the taxes imposed by section 4975(a) and 4975(b) of the Code if the records are not maintained or are not available for examination as required by paragraph (o) of this Section II below.

(o)(1) Except as provided in section (o)(2) of this paragraph, the records referred to in paragraph (o) of this Section II are unconditionally available at their customary location during normal business hours by—

(A) Any duly authorized employee or representative of the Department, the Internal Revenue Service or the Securities and Exchange Commission;

(B) Any Independent Fiduciary of a participating IRA or any duly authorized representative of such Independent Fiduciary; and

(C) Any participant or beneficiary of any participating IRA or any duly authorized representative of such participant or beneficiary.

(2) None of the persons described above in paragraphs (o)(1)(B) and (o)(1)(C) of this paragraph (o) are authorized to examine the trade secrets of Keystone or commercial or financial information which is privileged or confidential.

Section III. Definitions

For purposes of this proposed exemption:

(a) The term "Keystone" means Keystone Brokerage, Inc. and any affiliate of Keystone, as defined in paragraph (b) of this Section III.

(b) An "affiliate" of Keystone includes—

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with Keystone; (For purposes of this subparagraph, the term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.)

(2) Any individual who is an officer, director or partner in Keystone or a person described in subparagraph (b)(1); and

(3) Any corporation or partnership of which Keystone or an affiliate or a person described in subparagraphs (b)(1) or (b)(2) of this Section III, is a 10 percent or more partner or owner.

(c) The term "officer" means a president, any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), or any other officer performing a policy-making function for the entity.

(d) The term "IRA" includes a self-directed individual retirement account which is described in section 408(a) of the Code and which is not an "employee benefit plan" covered under Title I of the Act. The term "IRA" does not include any IRAs that were sponsored or maintained by Keystone or its affiliates for their own employees nor does it include any IRAs that were held by employees of Keystone or its affiliates in their individual capacities.

(e) The term "Independent Fiduciary" means an individual who was covered under a self-directed IRA which invested in shares of the Funds.

(f) The term "Asset Class" means an asset class under a classification system used by Morningstar, Inc. (Morningstar) or Lipper, Inc. (Lipper). For purposes of this exemption, two Funds were not in the same Asset Class if they were classified differently under either the Morningstar or Lipper classification systems. Thus, for example, if two Funds were treated in separate Asset Classes under the Morningstar system, they would be treated as being in separate Asset Classes even if the Funds were in the same Asset Class (or were not classified at all) under the Lipper system.

(g) The term "Affiliated Fund" means a portfolio of an investment company registered under the Investment Company Act for which Keystone or an affiliate acted as the investment adviser and may have also acted as the sub-adviser, co-administrator or custodian.

(h) The term "Third Party Fund" means a portfolio of an investment company that is registered under the Investment Company Act for which neither Keystone nor any affiliate acted as an investment adviser, sub-adviser, co-administrator or custodian.

(i) The "Advisory Fees" refer to the investment advisory fees that were paid by the Affiliated Funds to Keystone and its affiliates.

(j) The "Administrative Fees" refer to the co-administration fees that were paid by the Affiliated Funds to GGA and BISYS.

(k) The "Rule 12b–1 Fees" were paid to Keystone and its affiliates by the Third Party Funds in connection with certain distribution-related services (*e.g.*, advertising) that were made pursuant to a written plan of distribution.

EFFECTIVE DATE:

If granted, this proposed exemption will be effective from October 3, 1997 until June 30, 2000.

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Summary of Facts and Representations

Description of the Parties

1. The parties to the transactions are described as follows:

(a) *Keystone Financial, Inc. (KFI)* is a bank and financial services holding company headquartered in Harrisburg, Pennsylvania. KFI provides a full range of banking and non-banking services to persons and entities in Pennsylvania, Maryland, West Virginia, Virginia, New York, Ohio and Delaware.

(b) *Keystone* is a second-tier subsidiary of KFI. Keystone provided services to the IRAs under the Investment Advisory Program described herein and served as a broker-dealer for trades under such Program.

(c) *Key Trust Company (KeyTrust)* of Horsham, Pennsylvania, is a subsidiary of KFI. KeyTrust served as custodian for those IRAs utilizing the Investment Advisory Program.

(d) *Martindale* of West Conshocken, Pennsylvania, is a subsidiary of KFI. Martindale served as the sub-adviser to the Affiliated Funds and prior to February 1, 1999, it served as the investment adviser to such Funds.

(e) *BISYS* of Columbus, Ohio, is a registered broker-dealer. As noted above, BISYS is not affiliated with Keystone, KFI, KeyTrust or Martindale. BISYS, through its affiliated clearing broker, Corelink Financial, Inc. (Corelink), acted as the clearing broker with respect to purchases and sales of Fund shares by the IRAs participating in the Investment Advisory Program. In addition, BISYS performed various administrative, accounting, and recordkeeping functions on behalf of Keystone. In this capacity, BISYS, through Corelink, held Fund shares on behalf of IRAs participating in the Investment Advisory Program and served as sub-custodian for IRAs utilizing the Program under a custodial services agreement with KeyTrust. Further, BISYS served as distributor, Fund accountant, transfer agent, and administrator or co-administrator for the Affiliated Funds.[3]

(f) *GGA*, a wholly-owned subsidiary of KFI, served as the investment adviser to the Affiliated Funds. In addition, GGA and BISYS served as co-administrators for the Affiliated Funds.

(g) *The IRAs* participating in the Investment Advisory Program included self-directed IRAs which are described in section 408(a) of the Code and which are not "employee benefit plans" covered under Title I of the Act. All IRA holders were outside clients of Keystone and its affiliates rather than employees of these entities. The IRAs did not include any IRAs sponsored by Keystone and/or its affiliates nor did they include IRAs held by employees of Keystone and/or its affiliates in their individual capacities.

Description of the Funds

2. The Affiliated Funds participating in the Investment Advisory Program consisted of a group of Fund Portfolios referred to as "Governor Funds." Originally, the Affiliated Funds included the following Fund Portfolios of "The Sessions Group": the KeyPremier Prime Money Market Fund, the KeyPremier Intermediate Term Income Fund, the KeyPremier Established Growth Fund and the KeyPremier Aggressive Growth Fund.

The Sessions Group was an open-end management investment company registered under the Investment Company Act of 1940 (the Investment Company Act), for which Martindale served as the investment adviser. The Sessions Group was also an Ohio business trust that offered shares in 19 separate series. Each series of shares constituted a different Portfolio, only 4 of which were offered to investors under the Investment Advisory Program. The Sessions Group was designed to provide a convenient means of investing in separate Portfolios that were professionally managed by Martindale. Shares in The Sessions Group were offered to trust customers of KeyTrust, other banking subsidiaries of Keystone, and the general public. Although some Portfolios required investors to pay load charges, all Fund Portfolios were offered to IRA investors at no load.

3. Pursuant to an advisory agreement, Martindale served as the investment adviser to the Affiliated Funds comprising The Sessions Group from October 3, 1997 until February 1, 1999. Martindale's investment advisory agreement had been approved by the Board of Trustees (the Trustees) for an initial period of up to two years and was required to be re-approved thereafter by the Trustees or the Portfolios' shareholders, at least annually.

Subject to the supervision and direction of the Trustees, Martindale managed the investment and reinvestment of the assets of each Portfolio of The Sessions Group and provided investment guidance and policy direction in connection with the objectives and policies of each such Portfolio. Although each Affiliated Fund Portfolio paid Martindale an Advisory Fee for services rendered, Martindale agreed to waive a portion of such fee. The waiver continued throughout Martindale's tenure as investment adviser.

The Advisory Fees were computed daily and paid monthly at an annual rate based on a percentage of the value of the Portfolio's average daily net assets. Depending upon the Affiliated Fund Portfolio managed, the annualized Advisory Fees that were payable to Martindale are shown in the following table. The left-hand column of the table reflects the Advisory Fees that would have been paid to Martindale had the waiver been lifted while the right-hand column of the table shows the Advisory Fees that were actually paid to Martindale during the waiver.

Portfolio	Before waiver (percent)	After waiver (percent)
KeyPremier Prime Money Market Fund	0.40	0.20
KeyPremier Intermediate Term Income Fund	0.60	0.30
KeyPremier Established Growth Fund	0.75	0.40
KeyPremier Aggressive Growth Fund	1.00	0.50

4. Effective February 1, 1999, The Sessions Group was reorganized into "Governor Funds," a Delaware business trust which then comprised the Affiliated Funds. Like The Sessions Group, Governor Funds constituted an open-end management investment company registered under the Investment Company Act where shares were offered to IRA investors, at no load. These Affiliated Funds were advised by GGA and consisted of the following 12 Portfolios: the Prime Money Market Fund, the U.S. Treasury Obligations Money Market Fund, the Established Growth Fund, the Aggressive Growth Fund, the Emerging Growth Fund, the International Equity Fund, the Intermediate Term Income Fund, the Limited Duration Government Securities Fund, the Pennsylvania Municipal Bond Fund, the Lifestyle Conservative Growth Fund, the Lifestyle Moderate Growth Fund, and the Lifestyle Growth Fund.

Under the Investment Company Act, Governor Funds, as the successor Affiliated Funds, continued the business of The Sessions Group. In this regard, amounts formerly invested in The Sessions Group were reinvested in the corresponding Affiliated Fund Portfolios of Governor Funds.

5. As investment adviser to the Affiliated Funds, GGA also waived a portion of its Advisory Fees. The waiver remained in effect for the duration of the Investment Advisory Program. The following table shows the Advisory Fees that were payable to GGA. Such fees are expressed as a percentage of each Portfolio's net assets. The left-hand column of the table shows the Advisory Fees that would have been paid to GGA had the waiver been lifted while the right-hand column of the table shows the Advisory Fees that were actually paid to GGA during the waiver.

Portfolio	Before waiver (percent)	After waiver (percent)
Prime Money Market Fund	0.40	0.20
U.S. Treasury Obligations Money Market Fund	0.40	0.20
Established Growth Fund	0.75	0.60
Aggressive Growth Fund	1.00	0.70
Emerging Growth Fund	1.25	0.50
International Equity Fund	1.25	0.40
Intermediate Term Income Fund	0.60	0.30
Limited Duration Government Securities Fund	0.60	0.30
Pennsylvania Municipal Bond Fund	0.60	0.30
Lifestyle Conservative Growth Fund	0.25	0.15
Lifestyle Moderate Growth Fund	0.25	0.15
Lifestyle Growth Fund	0.25	0.15

Martindale served as sub-adviser to each of the Affiliated Funds, except the International Equity Fund. For sub-advisory services rendered, Martindale was paid an annualized sub-advisory fee by the Affiliated Funds, as a percentage of each Portfolio's net assets. Martindale's sub-advisory fees, which were paid out of GGA's Advisory Fees, are presented as follows:

Portfolio	Sub-advisory fee (percent)
Prime Money Market Fund	0.10
U.S. Treasury Obligations Money Market Fund	0.20
Established Growth Fund	0.40
Aggressive Growth Fund	0.50
Emerging Growth Fund	0.50
International Equity Fund	0.40
Intermediate Term Income Fund	0.30
Limited Duration Government Securities Fund	0.30
Pennsylvania Municipal Bond Fund	0.30
Lifestyle Conservative Growth Fund	0.05
Lifestyle Moderate Growth Fund	0.05
Lifestyle Growth Fund	0.05

In addition, GGA and BISYS served as co-administrators for the Affiliated Funds. The maximum annualized fee payable to each entity under their Management and Co-Administration Agreement was 0.15 percent of the average daily net assets of the Prime Money Market Fund, the Pennsylvania Municipal Bond Fund, the Established Growth Fund, the Intermediate Term Income Fund, the Aggressive Growth Fund, the U.S. Treasury Obligations Money Market Fund, the Limited Duration Government Securities Fund, the Emerging Growth Fund and the International Equity Fund. Because GGA and BISYS waived a portion of their Administrative Fees, the aggregate annualized fee paid to each co-administrator was reduced to 0.115 percent.

6. Overall responsibility for management and supervision of the Affiliated Funds was vested in five Trustees, three of whom were unrelated to Keystone and its affiliates. The Trustees approved all significant agreements involving the Affiliated Funds and the persons and companies that furnished services to such Funds. A Trustee could be removed by either (a) a two-thirds vote of the Trustees or (b) by a vote of shareholders owning at least two-thirds of the outstanding shares of all series of the Affiliated Funds. If a Trustee was an officer or a director of Keystone, a sub-adviser, Martindale, GGA, or BISYS, it was precluded from receiving compensation from The Affiliated Funds.

Each Affiliated Fund Portfolio was required to bear its own expenses. These expenses included all fees and other costs not specifically waived and/or borne by the Affiliated Funds' service providers.

7. The Third Party Funds were open-end, diversified investment companies registered under the Investment Company Act whose sponsors, administrators, distributors, investment advisers, and sub-advisers were not affiliated with Keystone or its affiliates. The Third Party Funds were made available by Keystone to the IRAs, at no load, in the event the Affiliated Funds failed to offer a Portfolio in a particular Asset Class.

IRA investors participating in the Investment Advisory Program were offered two Third Party Funds. These Funds were The Putnam Fund for Growth and Income and The T. Rowe Price International Stock Fund.

For distribution-related services that were rendered to the Third Party Funds, Keystone and its affiliates received Rule 12b–1 Fees that were paid by the respective Third Party Funds to their distributors. The Rule 12b–1 Fees were in the form of trailing commissions and did not exceed 0.25 percent of the assets invested in each Third Party Fund Portfolio.

Description of the Investment Advisory Program/Request for Exemptive Relief

8. The Investment Advisory Program was an asset allocation program that was offered by Keystone to IRA participants between October 3, 1997 and June 30, 2000. Formerly known as the "KeyPremier Nautilus Series Program" but later referred to as the "Nautilus Program," the Investment Advisory Program was designed to provide small- and medium-sized investors with access to the type of investment advice typically available only to larger investors. The Investment Advisory Program offered IRA investors the following features: (a) A unified Account statement covering all investments; (b) automatic allocation of assets and contributions; (c) a single asset allocation fee; and (d) no sales charges on purchases, redemptions, or transfers between investments. The minimum investment required for an Independent Fiduciary to establish an Account under the Investment Advisory Program was $25,000.

Effective June 30, 2000, Keystone discontinued the Investment Advisory Program. Currently, it is providing asset allocation services under a separate program which does not involve investment in any Affiliated Funds or Third Party Funds from which it will receive fees. However, for the interim period between October 3, 1997 and June 30, 2000, Keystone and the other parties to the transactions have requested an administrative exemption from the Department in order to provide retroactive relief for any prohibited transactions that may have arisen during the operation of the Investment Advisory Program.

If granted, the proposed exemption would be effective from October 3, 1997 until June 30, 2000. The proposed exemption would permit the purchase

[3] As discussed herein, Funds shares were sold to the IRAs at no load. Thus, the participating IRAs did not compensate Corelink, or for that matter, BISYS. Keystone represents that it does not know whether BISYS compensated Corelink for services rendered nor is it certain why BISYS executed trades through Corelink rather than performing this service directly.

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or redemption, by an IRA, of shares of certain Affiliated Fund and the Third Party Fund Portfolios, in connection with the IRA's participation in the Investment Advisory Program. In addition, the proposed exemption would permit Keystone's provision of asset allocation and related services to an IRA's Independent Fiduciary, which resulted in such Independent Fiduciary's selection of Portfolios in the Investment Advisory Program for the investment of IRA assets, and the receipt of fees by Keystone and/or its affiliates.

Keystone believes that because it and Key Trust would be considered disqualified persons with respect to the IRAs participating in the Investment Advisory Program, the decision by an Independent Fiduciary to participate in such Program would be statutorily exempt under section 4975(d)(2) of the Code. However, Keystone notes that there is uncertainty regarding the availability of section 4975(d)(2) of the Code where the asset allocation recommendations provided to an Independent Fiduciary of an IRA under the Investment Advisory Program may cause such entities to be considered fiduciaries with respect to the IRAs. Therefore, Keystone has requested retroactive exemptive relief from the Department for the transactions described above.

Operation of the Investment Advisory Program

9. Before opening an Account in the Investment Advisory Program, Keystone provided each Independent Fiduciary with the following information: (a) A brochure describing the Investment Advisory Program; (b) an Account Agreement; (c) a description of the available Asset Allocation Models; and (d) a reference guide/disclosure document providing detailed information outlining the mechanics of the Investment Advisory Program, the fees charged under such Program, the procedures for establishing Accounts and making withdrawals and additions, and other related information. If an Independent Fiduciary wished to open an Account with Keystone, such Independent Fiduciary would complete an Account Agreement and answer a series of questions regarding investment objectives and risk tolerance. Answers to these questions were communicated to an investment adviser representative for Keystone (the Keystone Representative) either through a personal Interview, or by obtaining and completing a Questionnaire (which was in paper or electronic form).

Once completed, the Questionnaire was presented to the Keystone Representative. If answers were given through an Interview, the Keystone Representative would prepare a written report of the answers (*i.e.*, the Interview Report). Then, a copy of the Interview Report would be given to the Independent Fiduciary. The responses provided by the Independent Fiduciary during the Interview or on the Questionnaire were scored by the Keystone Representative to determine which of several Asset Allocation Models were the most appropriate, given the financial goals, objectives and risk tolerances previously identified by the Independent Fiduciary in the Interview or Questionnaire.

10. The Asset Allocation Models were designed to satisfy a variety of risk tolerances, investment horizons, and tax planning concerns. There were six Asset Allocation Models available to the IRAs under the Investment Advisory Program. Each Asset Allocation Model consisted of an asset distribution among the Asset Classes.

The Asset Allocation Models were developed and maintained by an investment committee (the Allocation Committee) consisting of investment professionals of the Asset Management Division of KFI.

In constructing the Asset Allocation Models, the Allocation Committee utilized Encorr Software which had been developed by Ibbotson Associates, an unrelated party, to determine the optimal allocations for various risk/return tolerances among five general Asset Classes based on historical risk and return. The Allocation Committee then divided one of these Asset Classes (*e.g.*, Large Cap) into two asset sub-classes (*e.g.*, Large Cap and Large Cap Growth) on the basis of historical risk and return data as shown below in Table I.

TABLE I.—SAMPLE ASSET ALLOCATION MODEL

Asset class	Fund type	Portfolio	Percentage
Money Market	Affiliated	Prime Money Market Fund	6
Fixed Income	Affiliated	Intermediate Term Income Fund	76
Large Cap Growth	Affiliated	Established Growth Fund	8
Large Cap Value	Third Party	Putnam Fund for Growth and Income	10
Total			100

11. The Allocation Committee could make adjustments to the Asset Allocation Models to take into consideration the investment goals and risk tolerances represented by such Models, and to account for changes in the economy and market conditions. These adjustments could include changing the investment mix of the Asset Allocation Models by modifying the proportion of assets invested in each Asset Class. In no event could Keystone change the asset mix of an Asset Allocation Model without first notifying the Independent Fiduciary in writing of the proposed change and giving such Independent Fiduciary at least 30 days within which to elect not to have the change made. However, if the Independent Fiduciary did not elect otherwise, Keystone was authorized to make the change.

12. The Retail Investment Product Committee of KFI (the Review Committee) was responsible for selecting the Portfolios used to satisfy the asset allocations specified by the Allocation Committee for each Asset Allocation Model. The Review Committee was composed of KFI officers with substantial portfolio management, investment and regulatory compliance experience. These officers also served on the Allocation Committee.

The Review Committee selected Portfolios of the Affiliated Funds for investment to the extent that the Affiliated Funds offered a Portfolio in a particular Asset Class. If no Affiliated Fund offered the requisite Portfolio, the Review Committee selected Portfolios of the Third Party Funds for investment. Any changes in the Portfolios on the part of Keystone in order to satisfy investment in a particular Asset Class were only made after Keystone had provided written notice to all affected Independent Fiduciaries. In addition, these changes would only be implemented if the Independent Fiduciaries did not elect otherwise within 30 days of such notification.

13. Based on the results generated from the Interview or Questionnaire, a Keystone Representative recommended to the Independent Fiduciary an Asset Allocation Model, together with the corresponding initial investment mix of Portfolios that comprise the Asset Allocation Model. The asset allocation services provided by the Keystone Representative were of an advisory nature and were not binding upon the Independent Fiduciary. No action was taken on the initial recommendation unless and until the Independent Fiduciary accepted and approved, in writing, the Asset Allocation Model and corresponding investment mix recommended by the Keystone Representative. The Independent Fiduciary could add or withdraw IRA assets to or from the Account at any time (subject to any applicable minimum redemption and purchase requirement). Further, the Independent Fiduciary could also choose a different Asset Allocation Model by submitting a new Questionnaire or by means of a new Interview if the investment needs and goals of the Independent Fiduciary had changed.

Rebalancing of IRA Accounts

14. Keystone invested the Account in the Affiliated Funds and/or Third Party Funds that the Allocation Committee had previously chosen to satisfy the allocation called for by the Asset Allocation Model.[4] However, it was anticipated that over time, disproportionate earnings as between asset types would cause an Account's investment mix to drift out of balance with the Asset Allocation Model originally chosen by the Independent Fiduciary. For example, if the chosen Asset Allocation Model called for 50 percent of an Account's assets to be invested in the Fixed Income Class through the Intermediate Term Income Fund, and 50 percent in cash through the Prime Money Market Fund, and if the Intermediate Term Income Fund performed better than the Money Market Fund during a particular period of time, more than 50 percent of the Account's assets would be invested in the Fixed Income Class by the end of the period.

To correct this imbalance, Keystone would periodically move assets among the chosen investments by buying and selling shares of selected Portfolios from appropriate distributors on the second to the last business day of each calendar quarter. For purposes of rebalancing, Keystone used the net asset values of the affected Funds as of the close of business for the preceding trading day.[5] Keystone had no discretion as to the timing or amount of the rebalancing.

In the case of the foregoing example, Keystone would sell shares of the Intermediate Term Income Fund and invest the proceeds in the Prime Money Market Fund so that the Account would again be 50 percent invested in Fixed Income Securities and 50 percent in cash. Rebalancing would be conducted on a quarterly basis and confined to bringing the Account into balance with the Asset Allocation Model chosen by the Independent Fiduciary. Moreover, rebalancing would only occur if the percentage of assets invested in a particular Portfolio varied from the Asset Allocation Model by more than a predetermined threshold set forth in the Account Agreement.[6] As stated above, Keystone used the net asset values of the Affiliated Funds as of the close of business on the preceding trading day.

Reallocation of IRA Accounts

15. Keystone represents that from time to time, it was authorized to make changes to the asset mix of the Asset Allocation Models, as well as to the mix and identity of Affiliated Fund and/or Third Party Fund Portfolios that satisfied the Asset Allocation Models. However, Keystone states that it never utilized the reallocation method during the time period the Investment Advisory Program was in effect. Had Keystone decided to implement the reallocation mechanism, it would have been required to inform each affected Independent Fiduciary in advance and in writing of the proposed change. In addition, Keystone would have been required to provide each Independent Fiduciary with the opportunity to elect not to permit such change.[7] If the Independent Fiduciary took no action, Keystone would have been authorized to realign each Account on a quarterly basis to make the Account's investment mix match the new investment mix of the Asset Allocation Model selected by the Independent Fiduciary.

Disclosures

16. Aside from the Questionnaire and Interview Report described above, in order for an IRA to participate in the Investment Advisory Program, Keystone provided an Independent Fiduciary with the following materials and oral disclosures:

- A brochure describing the Investment Advisory Program; an Account Agreement; a description of the Asset Allocation Models; and a reference guide/disclosure statement providing details about the Investment Advisory Program, the fees charged thereunder, the procedures for establishing, making additions to and withdrawing from Accounts, and other related information.
- Copies of applicable Prospectuses for the Portfolios discussing the investment objectives of the Portfolios, the policies employed to achieve these objectives, and the corporate affiliation existing between Keystone and its affiliates, the compensation paid to such entities, disclosures relating to rebalancing and reallocating Asset Allocation Models (even though the reallocation service was never implemented), and information explaining the risks attendant to investing in the Portfolios.
- Upon written or oral request to Keystone, a Statement of Additional Information supplementing the Prospectuses, which described the type of securities and other instruments in which the Portfolios may invest and the investment policies and strategies that the Portfolios may utilize, including a description of the risks.
- A copy of the Account Agreement between the IRA and Keystone relating to the IRA's participation in the Investment Advisory Program.
- A written recommendation of a specific Asset Allocation Model, together with a copy of the Questionnaire and response, or the Interview Report.

If accepted as an investor in the Investment Advisory Program, the Independent Fiduciary was required to

[4] The Independent Fiduciary could specifically instruct Keystone not to invest in a specific Portfolio, in which case any IRA assets invested in that Portfolio would be reinvested within five business days in another Portfolio selected by Keystone and specifically approved by the Independent Fiduciary. A fee was charged for each such special instruction.

[5] Neither Keystone nor any of its affiliates received a commission from such purchases and sales.

[6] In other words, an Account would be rebalanced if the transactions requiring rebalancing had a "material effect" on the allocation. To have a material effect on an allocation of an Account, at least one transaction required to rebalance the Account had to be greater than $250 and at least one transaction had to change the value of the Fund Portfolio by more than 5 percent (*i.e.*, the percentage of an IRA's assets invested in a Portfolio compared to the percentage called for in the Asset Allocation Model selected for the IRA). However, Keystone reserved the right to rebalance an Account even if the required minimums were not satisfied.

For example, if under the Asset Allocation Model, 35 percent of an IRA's assets were invested in the Established Growth Fund, then rebalancing would occur if the percentage actually invested in the Established Growth Fund increased above 40 percent or decreased below 30 percent (but only if the dollar amount of the rebalancing transaction would exceed $250).

[7] For reallocations occurring after March 24, 2000, Keystone would have been required to include a Termination Form with the notice. See Representation 21. However, as stated above, Keystone never implemented the reallocation mechanism even though this change was communicated to IRA investors in the Termination Form.

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acknowledge in writing to Keystone, prior to investing through such Program, that such Independent Fiduciary had received copies of the aforementioned documents. In addition, the Independent Fiduciary was required to represent to Keystone that such individual was (a) independent of Keystone and its affiliates; (b) knowledgeable with respect to the IRA in administrative matters and funding matters related thereto; and (c) able to make an informed decision concerning participation in the Investment Advisory Program.

17. In addition, on an ongoing basis, Keystone was required to provide each Independent Fiduciary with the following oral or written disclosures:

- Written confirmations of each purchase and redemption of shares of a Portfolio (including transactions resulting from the realignment of assets caused by a change in the Asset Allocation Model's investment mix and from periodic rebalancing of Account assets).
- Telephone quotations of Account balances.
- A periodic, but not less frequently than quarterly, Statement of Account specifying the net asset value of the IRA's assets invested in such Account, a summary of purchase, sale and exchange activity and dividends received or reinvested, a summary of cumulative realized gains or losses, and a statement of the fees paid to Keystone and its affiliates.
- Semiannual and annual reports that included financial statements for the Portfolios.
- A quarterly report pertaining to the applicable Asset Allocation Model describing such Asset Allocation Model's performance during the preceding quarter, market conditions and economic outlook and, if applicable, prospective changes in Portfolio allocations for the Asset Allocation Model, and the reasons therefor.
- At least annually, a written or oral inquiry from Keystone to ascertain whether the information provided in the Questionnaire or Interview Report was still accurate, and to determine whether such information should be updated.
- At least annually, a Termination Form.

Fee Structure

18. As to each investing IRA, the total fees paid to Keystone and its affiliates constituted not more than reasonable compensation for the services provided within the meaning of section 4975(d)(2) of the Code. Keystone charged each participating IRA an annual investment fee (the Outside Fee) at rates set forth in the Account Agreement. For example, if the average daily value of the Account—

- Exceeded $149,999, the Outside Fee charged was 1.30 percent; or
- Was less than $150,000, the Outside Fee charged was 1.55 percent.

The Outside Fee was computed quarterly on the average daily value of the assets in an IRA's Account during the quarter and was deducted directly from the Account (or paid directly by the Independent Fiduciary), also on a quarterly basis.

Although Keystone was authorized to increase the Outside Fee periodically, it never implemented this change. Assuming the Outside Fee had been increased, Keystone would have been required to notify the Independent Fiduciaries of all IRAs participating in the Investment Advisory Program, in writing, at least 30 days prior to the effective date of a such fee increase. The Independent Fiduciary would have been permitted to withdraw from the Investment Advisory Program at will and without penalty, and the fee increase would only have gone into effect if the Independent Fiduciary did not elect to withdraw by the effective date.

As stated above, each investing IRA did not pay any sales loads on the purchase of Portfolio shares through the Investment Advisory Program. The Accounts were invested only in Portfolios which charged no front- end or back-end sales charges or for which the sales charges had been waived.

As discussed in Representation 3, Martindale received Advisory Fees from the Affiliated Funds. These annualized fees were paid at the Fund Portfolio-level and were based on a percentage of the assets held by such Portfolio, of between 0.20 percent and 0.50 percent. Similarly, GGA received annualized Advisory Fees of between 0.15 percent and 0.70 percent and Martindale received sub-advisory fees ranging from 0.05 percent to 0.50 percent.

In addition to the Advisory Fees, GGA and BISYS received Administrative Fees from the Affiliated Funds of 0.115 percent.

Further, Keystone and its affiliates received Rule 12b–1 Fees from certain Third Party Fund distributors with respect to IRA assets invested in the Third Party Funds through the Investment Advisory Program. The Rule 12b–1 Fees were in the form of trailing commissions of up to 0.25 percent per annum of the net asset value of each Third Party Fund.

Besides the aforementioned fees, each Portfolio incurred certain expenses. These expenses included charges for legal and accounting services, printing costs, registration fees, regulatory compliance costs, costs associated with maintaining the Fund's legal existence, and shareholder communication costs.

19. Keystone represents that with respect to each Account, it offset, quarterly, against the Outside Fee it received, (a) all Advisory Fees (including sub-advisory fees that were paid to third party sub-advisers), (b) all Administrative Fees GGA and BISYS received from the Affiliated Funds, and (c) all Rule 12b–1 Fees that were paid to Keystone and its affiliates by the respective Third Party Funds. Thus, the sum of the offset and the net Outside Fee would always equal the aggregate Outside Fee and the selection of Affiliated Funds or Third Party Funds would always be revenue-neutral. Moreover, Keystone believed this method of offsetting of all Fund-level fees would eliminate any conflicts of interest resulting from the investment of an Account's assets in certain Fund Portfolios that generated higher overall fees for Keystone and its affiliates.

At the end of each quarter, Keystone calculated the percentage of gross revenues that it and its affiliates earned during the quarter in the form of Advisory Fees (from the Affiliated Funds) or Rule 12b–1 Fees (from the Third Party Funds). These figures were calculated as a percentage of the average daily net value of assets in each Portfolio. The weighted average of such revenues (the Offset Percentage) were then calculated for each Asset Allocation Model as shown below in TABLE II. This yielded the amount of the Advisory Fees and Rule 12b–1 Fees that were earned by Keystone and its affiliates. Such fees were expressed as a percentage of the average daily net value of Account assets. Because the Outside Fee was also calculated as a percentage of the average daily net value of Account assets, Keystone reduced the Outside Fee for the quarter for each IRA by subtracting from the Outside Fee, the Offset Percentage for the Asset Allocation Model in which the IRA's assets had been invested during the quarter. Only after the Offset Percentage had been subtracted would Keystone deduct the Outside Fee from the IRA's Account.

TABLE II.—EXAMPLE OF OUTSIDE FEE OFFSET BASED ON AN ACCOUNT WITH AN AVERAGE DAILY VALUE OF $150,000 OR MORE

[All percentages annualized]

Fund type	Asset class	Total revenues (percentage)		Percentage of assets allocated to fund		Weighted fee percentage
Affiliated Fund	Fixed Income	0.60	×	35.00	....	21.00
Affiliated Fund	Money Market	0.40	×	30.00	....	12.00
Third Party Fund	International Equity	0.20	×	35.00	....	7.00
Total			....	100	....	40.00
Outside Fee:			....	1.30	....	
Weighted Average of Keystone Revenues (40 + 100):			....	0.40	....	
Net Account Fee (Annual) Would be Calculated Quarterly.			....	0.90	....	

20. Like the Affiliated Funds, the Third Party Funds also incurred expenses for shareholder services, custody, the costs of regulatory compliance, legal fees, and shareholder communication costs, as well as the management and service fees imposed by investment advisers and service providers unaffiliated with Keystone or its affiliates. As for both the Affiliated and the Third Party Funds, these Fund-level expenses were not offset against Keystone's Outside Fee.

Termination Form

21. An Independent Fiduciary had the ability to withdraw from the Investment Advisory Program at any time, provided such fiduciary gave proper notice to Keystone. In addition, Keystone was authorized to provide 30 days' advance written notice to the Independent Fiduciary if it wished to change the asset mix of an Account outside of an Asset Allocation Model, divide an Asset Class, replace a Third Party Fund with an Affiliated Fund or vice versa, or increase its Outside Fee. The written notice was required to (a) state that the Independent Fiduciary could terminate the IRA's participation in the Investment Advisory Program at will and without penalty, upon receipt by Keystone of written notice from the Independent Fiduciary; and (b) explain that any of the changes noted above would go into effect if the Independent Fiduciary did not elect to withdraw by the effective date.

However, under either circumstance, there was no formalized structure in place whereby Keystone could inform an Independent Fiduciary of his or her right to withdraw from the Investment Advisory Program on a more frequent basis or to document the Independent Fiduciary's withdrawal decision. Therefore, on March 24, 1999, Keystone began distributing the Termination Form to each Independent Fiduciary participating in the Investment Advisory Program. Although distribution of such form would be required thereafter, at least annually (*i.e.*, during the first calendar quarter of each year), it was considered mandatory in all cases where Keystone wished to make the changes noted above.

The Termination Form was to be accompanied by instructions on its use. The instructions, which contained information similar to the contents of Keystone's formerly-disseminated notice, provided that (a) the authorization was terminable at any time and without penalty, either by completing and returning the Termination Form or by sending other written notice to Keystone; and (b) no purchases and sales under the Account Agreement would be executed after the next business day following Keystone's receipt of the Termination Form or other written withdrawal notice. Assuming Keystone proposed to modify an asset mix or raise its Outside Fee, the Termination Form would also have stated that the change would only go into effect if the Independent Fiduciary did not elect to withdraw by the effective date.

Keystone represents that it never replaced an Affiliated Fund with a Third Party Fund Portfolio or vice versa, nor did it otherwise make an additional Third Party Fund Portfolio available for investment under the Investment Advisory Program, change an asset mix outside of an Asset Allocation Model or increase its Outside Fee. Therefore, there were no special circumstances to warrant an earlier distribution of such form. Moreover, because of the contemplated termination of the Investment Advisory Program on June 30, 2000, Keystone made no further annual distribution of the Termination Form to Independent Fiduciaries.

22. It is represented that the transactions satisfied the statutory criteria for an exemption under section 4975(c)(2) of the Code because:

(a) The investment of an IRA's assets under the Investment Advisory Program was made by a fiduciary that was independent of Keystone and its affiliates and such Independent Fiduciary maintained complete discretion with respect to the IRA's continued participation in the Investment Advisory Program.

(b) No IRA paid a fee or commission by reason of the acquisition or redemption of shares of Fund Portfolios.

(c) As to each IRA, the total fees that were paid to Keystone and its affiliates constituted no more than reasonable compensation for the services provided.

(d) Prior to investing under the Investment Advisory Program, each Independent Fiduciary received offering materials and disclosures from Keystone which set forth all material facts concerning the purpose, fee structure, rebate arrangement, operation, rebalancing, risks and participation in such Program.

(e) Keystone provided written documentation to an Independent Fiduciary of its recommendations based upon objective criteria that were uniformly applied.

(f) The quarterly Outside Fee that was paid by an IRA to Keystone for asset allocation and related services rendered to such IRA under the Investment Advisory Program was offset by—(1) all gross Advisory Fees received by Keystone and/or its affiliates from the Affiliated Funds, including sub-advisory fees that are paid to third party sub-advisers; (2) all Administrative Fees received by GGA and BISYS from the Affiliated Funds; and (3) all Rule 12b-1 Fees that were paid by the Third Party Funds to Keystone and/or its affiliates, such that the sum of the Outside Fee

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and the Offset Fees equaled the total Outside Fee, and the selection of Affiliated or Third Party Fund Portfolios was revenue-neutral.

(g) Although Keystone had discretion to make unilateral Model Adjustments to an IRA's Asset Allocation Model, it was bound by the financial goals and risk tolerances that the Model represented and it was limited in the degree of change that it could make to an Asset Allocation Model's investment mix.

(h) In rebalancing an IRA investor's Account, neither Keystone nor its affiliates exercised discretionary management or control over the IRA.

(i) Although the Independent Fiduciary could withdraw from the Investment Advisory Program at any time, any authorizations made by such IRA investors with respect to increases in the Outside Fee, Model Adjustments that were outside of an Asset Allocation Model, the addition or substitution of a Fund, would be terminable at will and without penalty to the IRA, upon receipt by Keystone of a Termination Form from such IRA investor which would advise the Independent Fiduciary (1) of his or her right to withdraw from the Investment Advisory Program and (2) that absent affirmative approval, the change would be effective as of a given date.

(j) Each Independent Fiduciary received disclosures from Keystone regarding the participation of the IRA in the Investment Advisory Program.

(k) All dealings between an IRA, the Funds and Keystone remained on a basis which was at least as favorable to the IRA as such dealings are with other shareholders of the Funds holding the same classes of shares as the IRA.

Notice to Interested Persons

Keystone will provide notice of the proposed exemption to Independent Fiduciaries of IRAs formerly investing in the Investment Advisory Program within 30 days of the publication of the notice of pendency in the **Federal Register**. Such notice will be provided by first-class mail and will include a copy of the notice of proposed exemption, as published in the **Federal Register**, as well as a supplemental statement, as required pursuant to 29 CFR 2570.43(b)(2). The supplemental statement will inform interested persons of their right to comment on and/or to request a hearing with respect to the pending exemption. Therefore, comments and requests for a hearing must be received by the Department no later than 60 days from the date of the publication of this notice of proposed exemption in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone (202) 219–8881. (This is not a toll-free number.)

Reagent Chemical & Research, Inc. Employees Profit Sharing Plan and Trust (the Plan) Located in Middlesex, New Jersey

[Application No. D–10793]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale of a certain residential lot (the Property) by the Plan to Mr. Brian Skeuse and Mrs. Jan Skeuse (the Skeuses), parties in interest with respect to the Plan; provided that the following conditions are satisfied:

(a) the sale is a one-time cash transaction;

(b) the Plan receives the greater of either: (i) $105,000; or (ii) the current fair market value for Property established at the time of the sale by an independent qualified appraiser; and

(c) the Plan pays no commissions or other expenses associated with the sale.

Summary of Facts and Representations

1. The Plan was adopted on December 12, 1962. The Plan is a defined contribution plan with approximately 309 participants. As of July 22, 1999, the Plan had approximately $30,438,854 in total assets. Reagent Chemical & Research, Inc. (RCR) is the sponsor of the Plan. RCR is a subchapter "S" corporation organized under the laws of State of Delaware. RCR is in the business of manufacture, distribution and sale of specialty chemicals. The Plan's current trustees are John T. Skeuse, brother of Brian Skeuse, and Stephen T. Finney, brother-in-law of Brian Skeuse.

2. On November 3, 1980, the Plan purchased approximately 34.58 acres of land (the Land) from Joe and Wenona Russo, unrelated third parties, for $225,000.[8] The Property is a 2.5 acre parcel of the Land. Therefore, the applicant represents that the cost of the Property to the Plan, based on the per acre price paid for the Land, was $16,304.35. The Property is adjacent to the Skeuses' personal family residence. It is represented that the decision to purchase the Property as a investment for the Plan was made by Robert Dallas and Thomas Skeuse, Sr., who were the Plan's trustees at the time of the transaction.[9]

The Property is held in the Plan's aggregate portfolio and has not been allocated to any participant's account in the Plan. At the time of the Plan's purchase in 1980, the Property represented less than 1% of the Plan's total assets. The applicant represents that as of November 27, 2000, the Property continued to represent less than 1% of the total value of the Plan's assets.

3. The applicant represents that the Property has not been used or leased by anyone, including the parties in interest described herein, since it was acquired by the Plan. Thus, the applicant states that the Property has not been an income-producing asset and has been held for possible appreciation.

The Plan has paid for taxes, insurance and maintenance on the Property since the acquisition (the Holding Costs). Specifically, the Plan has paid a total of approximately $34,870 in property taxes for the Property during this period. Further, the Plan has paid approximately $4,500 for the design and approval of a residential septic tank system for the Property. The applicant estimates that the insurance costs incurred by the Plan for the Property during the period from 1980 until 1999 were approximately $1,000. The applicant states that the Holding Costs for the Property have been approximately $40,370. Therefore, the total cost for the Property (*i.e*, the acquisition price of $16,304, plus the Holding Costs of approximately $40,370) was approximately $56,674 as of December 2000.

[8] The Plan sold approximately 10 acres of the Land in 1987 to Brian Skeuse, a party in interest, pursuant to the terms and conditions of Prohibited Transaction Exemption (PTE) 87–17, 52 FR 2630 (January 23, 1987). The Department is providing no opinion herein as to whether the conditions of PTE 87–17 were met.

[9] The Department is not providing any opinion in this proposed exemption as to whether the acquisition and holding of the Land, including the Property, by the Plan violated any of the provisions of Part 4 of Title I of the Act.

However, the Department notes that an investigation regarding the subject investments made by the Plan and related transactions has been conducted by the Department's Regional Office in New York. In this regard, the proposed exemption, if granted, will enable the Plan to be made "whole" with regard to the total costs to the Plan for the Property and will allow the Plan to reinvest the proceeds of the proposed sale in other assets which may yield greater returns.

4. The Property is located on 30 Old Hill Road, Raritan Township, Hunterdon County, New Jersey. The Property was appraised on May 11, 1999, as having a fair market value of $95,000 (the Appraisal). The Appraisal was prepared by George A. Copeland, Jr., MAI (Mr. Copeland), who is an independent, qualified real estate appraiser in the State of New Jersey. Mr. Copeland is with Copeland Appraisal Associates, Inc., located at 971 U.S. Route 202 in Somerville, New Jersey. Mr. Copeland states that consideration was given in the Appraisal to three approaches to value, *i.e.*, the cost approach, sales comparison approach, and income approach. However, Mr. Copeland relied on the sales comparison approach to determine the fair market value of the Property.

Mr. Copeland also submitted several updates to the Appraisal of the Property. The first update is dated March 23, 2000 (Update I). Update I states that the fair market value of the Property was $100,000 as of March 23, 2000.

The second update to the Appraisal of the Property is dated November 20, 2000 (Update II). Update II states that the fair market value of the Property was $105,000, as of November 20, 2000.

Finally, the applicant also submitted a supplement to the Update II dated December 22, 2000 (the Supplement). Because the Property is adjacent to the Skeuses' personal family residence, Mr. Copeland considered whether a sale of the Property by the Plan to the Skeuses would merit a premium above the fair market value for the Property. However, in the Supplement, Mr. Copeland states that the Property would not merit a premium above its fair market value in any sale to an adjacent property owner.

5. The applicant now proposes that the Skeuses purchase the Property from the Plan in a one-time cash transaction. The applicant represents that the proposed transaction would be in the best interest and protective of the Plan. The Plan will pay no commissions or other expenses associated with the sale. The Skeuses will pay the Plan the greater of either: (a) $105,000; or (b) the current fair market value of the Property, as established by a qualified independent appraiser at the time of the transaction. In this regard, Mr. Copeland or another independent qualified appraiser will update the Appraisal to determine the current fair market value for the Property at the time of the proposed sale. The sale of the Property will enable the Plan to sell an illiquid non-income producing asset and reinvest the sale proceeds in assets that may yield higher returns.

6. In summary, the applicant represents that the transaction will satisfy the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because:

(a) The proposed sale will be a one-time cash transaction;

(b) the Plan will receive the greater of either: (i) $105,000; or (ii) the current fair market value for the Property, as established at the time of the sale by an independent qualified appraiser;

(c) the Plan will pay no fees, commissions or other expenses associated with the sale; and

(d) the sale will enable the Plan to divest itself of a non-income producing asset and acquire investments which may yield higher returns.

Notice to Interested Persons

The applicant represents that notice of the proposed exemption (the Notice) will be distributed to interested persons, by first class mail, or by posting in RCR's facilities, within thirty (30) days of the date the Notice is published in the **Federal Register**. Such interested persons will include all participants in the Plan, all fiduciaries of the Plan, and any officer or director of RCR. The distribution to interested persons shall include a copy of the Notice, as published in the **Federal Register**, and a supplemental statement, as required pursuant to 29 CFR 2570.43(b)(2), which shall inform such persons of their right to comment and/or request a hearing with respect to the Notice.

Comments and requests for a public hearing with respect to the Notice are due sixty (60) days following the publication of the Notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ekaterina A. Uzlyan of the Department at (202) 219–8883. (This is not a toll-free number.)

Ibbotson Associates, Inc. (Ibbotson) Located in Chicago, Illinois

[Exemption Application No.: D–10897]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 2570, Subpart B (55 FR 32836, 32847, August 10, 1990). If the exemption is granted, the restrictions of sections 406(a) and 406(b) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (F) of the Code, shall not apply to the provision of asset allocation services (the Service) by Ibbotson to Plan participants and the receipt of fees by Ibbotson from Service Providers in connection with the provision of such asset allocation services, provided that the following conditions are met.

I. General Conditions

A. The retention of Ibbotson to provide the Service will be expressly authorized in writing by an independent fiduciary of each Plan.

B. Ibbotson shall provide the independent fiduciary of each Plan with the following, in writing:

(1) Prior to authorization, a complete description of the Service and disclosures of all fees and expenses associated with the Service.

(2) Any other reasonably available information regarding the Service that the independent fiduciary requests.

(3) A contract for the provision of the Service which defines the relationship between Ibbotson, the Service Providers and the Plan sponsor, and the obligations thereunder. Such contract shall be accompanied by a termination form with instructions on the use of the form. The termination form must expressly state that a Plan may terminate its participation in the Service without penalty at any time. However, a Plan which terminates its participation in the Service before the expiration of the contract will pay its pro-rata share of the fees that it would otherwise owe for the Service under the contract and, if applicable, any direct costs actually incurred by Ibbotson which would have been recovered from the Plan but for the termination of the contract, including any direct setup expenses not previously recovered. Thereafter, the termination form shall be provided no less than annually.

(4) At least 45-days prior to the implementation of any material change to the Service or increase in fees or expenses charged for the Service, notification of the change and an explanation of the nature and the amount of the change in the Service or increase in fees or expenses.

(5) A copy of the proposed and final exemption, if granted, as published in the **Federal Register**.

(6) An annual report of Plan activity which summarizes the performance of the asset allocation categories provided to the Plan and provides a breakdown of all fees and expenses paid to Ibbotson in connection with the provision of the Service to the Plan for the year. Such report shall be provided no more than 45 days after the period to which it relates. Upon the independent fiduciary's or Plan sponsor's request,

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such report may be provided more frequently.

C. Ibbotson will provide each Plan participant with the following:

(1) Written notice that the Service is available and provided by Ibbotson, an entity independent of the Service Provider and the Plan sponsor.

(2) Prior to using the Service, full written disclosures that will include information about Ibbotson and a description of the Service.

(3) Access to Ibbotson's web site or paper-based communications which will clearly indicate that the Plan participant is receiving the Service from Ibbotson, and that Ibbotson is independent of the Service Provider.

(4) A tolerance questionnaire which must be completed prior to utilization of the Service.

(5) An investment advisory service agreement under which the Plan participant will acknowledge his or her understanding that the Service is provided by Ibbotson and not the Service Provider. This agreement must be completed prior to utilization of the Service.

D. Any investment advice given to a Plan participant by Ibbotson under the Service will be based solely on the responses provided by the Plan participant through the Service's interactive computer program or through a paper or telephone interview and will be based on the application of an objective methodology developed by Ibbotson.

E. Any investment advice given to a Plan participant will be implemented only at the express direction of the Plan participant.

F. The total fees paid to Ibbotson and a Service Provider, in connection with the provision of the Service, by each Plan does not exceed "reasonable compensation" within the meaning of section 408(b)(2) of the Act.

G. The only fees which are payable to Ibbotson in connection with the provision of the Service include, subject to negotiation, one or more of the following:

(1) An annual flat fee based on a fixed dollar amount per Plan participant for the Service. This fee may be paid by the Plan, Plan sponsor, Plan participant or the Service Provider.

(2) A technology licensing fee payable by the Service Provider in the first year that the Service is provided to a Plan. The fee will be a fixed dollar amount based on the number of Plan participants and beneficiaries contained on the Service Provider's record-keeping system. Each time the number of Plan participants and beneficiaries on the Service Provider's record-keeping system increases by at least 10%, an additional fixed dollar amount based on the increase in Plan participants and beneficiaries will be assessed and charged to the Service Provider for the new Plan participants and beneficiaries (the Revised Technology Fee).

(3) For subsequent years, Ibbotson will charge the Service Provider an annual technology maintenance fee equal to up to 20% of the technology licensing fee charged to the Service Provider in the first year plus up to 20% of the Revised Technology Fee.

(4) Ibbotson will charge the Plan or Plan sponsor an Internet customization fee where a Plan sponsor contracts directly with Ibbotson for the provision of the Service. This flat fee will be based on the time spent by Ibbotson personnel on its customization of the Service for the particular Plan.

(5) For those Plan sponsors electing to receive a Plan analysis report, an annual flat fee based on a fixed dollar amount per Plan investment analysis report. This fee will be paid by the Plan sponsor or Service Provider.

H. No portion of any fee or other consideration payable by the Plan or the Plan sponsor to Ibbotson in connection with the Service will be received or shared with a Service Provider.

I. Neither the fees charged nor the compensation received by Ibbotson will be affected by the investment selections or the decisions made by the Plan participants and beneficiaries regarding investments of the assets in their accounts.

J. Each Service Provider shall represent to Ibbotson that it will not impose any additional fees and/or charges (relating to the investment products made available to Plans) on Plans who contract for the Service unless such fees and charges are imposed on the Service Provider's similarly situated clients who do not contract for the Service.

K. Ibbotson will maintain insurance coverage from an insurer with a rating in one of the three highest generic categories by at least one nationally recognized statistical rating service, in the amount of at least $5 million for the payment of any liabilities that may arise with respect to the Service by reason of a breach of fiduciary duty described in section 404 of the Act or a violation of the prohibitions of section 406 of the Act or section 4975 of the Code. Such insurance coverage will be provided under a "claims made" policy. In the event that Ibbotson changes insurers or ceases to provide the Service, Ibbotson will maintain "trail coverage" with respect claims made during the period in which the policy was in effect for a period of three years following such a change or cessation of the Service.

L. No Service Provider shall at any time own any interest, by vote or value in Ibbotson, and neither Ibbotson nor any affiliate shall own any interest, by vote or value, in a Service Provider.

M. The annual revenues derived by Ibbotson from any one Service Provider shall not constitute more than 5% of the annual revenues of Ibbotson.

N. Ibbotson will maintain for a period of six years, the records necessary to enable the persons described in paragraph (O) of this section to determine whether the conditions of the exemption are met, including records of the recommendations made to Plan participants and beneficiaries and their investment choices, except that—

1. A prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Ibbotson, the records are lost or destroyed prior to the end of the six year period.

2. No party in interest, other than Ibbotson shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or the taxes imposed by section 4975(a) and (b) of the Code if records are not maintained or not available for examination as required by this paragraph and paragraph O(1) below.

O. (1) Except as provided in subparagraph (2) of this paragraph and notwithstanding any provisions of subsections (a)(2) and (b) of Section 504 of the Act, the records referred to paragraph (N) of this section are unconditionally available at their customary location for examination during normal business hours by—

(a) Any duly authorized employee or representative of the Department of Labor, the Internal Revenue Service, or the Securities and Exchange Commission,

(b) Any fiduciary of a participating Plan or any duly authorized representative of such fiduciary,

(c) Any contributing employer to any participating Plan or any duly authorized representative of such employer, or an employee organization whose members are participants and beneficiaries of a participating Plan; or

(d) Any Plan participant or beneficiary of any participating Plan or any duly authorized representative of such Plan participant or beneficiary.

(2) None of the persons described in paragraph (1)(b)–(d) of this paragraph (O) shall be authorized to examine trade secrets of Ibbotson, or commercial or financial information which is privileged or confidential.

III. Definitions

A. The term "Service" means the asset allocation service provided by Ibbotson to Plans which is accessed through computer software and other written communications in order to provide personalized recommendations to Plan participants regarding the allocation of their investments among the options offered under their Plan.

B. The term "Service Provider" means an entity that has been in the financial services business for at least three years, and during such period, has not been convicted of a felony offense involving abuse or misuse of such entity's employee benefit plan position or employment, or any felony arising out of the conduct of the business of a broker, dealer, investment adviser, bank, insurance company or fiduciary. Such entity is also described in one of the following categories:

1. A bank, savings and loan association, insurance company or registered investment adviser which meets the definition of a "qualified professional asset manager" (QPAM) set forth in section V(a) of Prohibited Transaction Exemption 84–14 (49 Fed. Reg. 9494 (Mar. 13, 1984)), as corrected at 50 Fed. Reg. 41430 (Oct. 10, 1985) and in addition, has, as of the last day of its most recent fiscal year, total client assets under management and control in an amount not less than $250 million; or

2. A broker dealer registered under the Securities Exchange Act of 1934, which has, as of the last day of its most recent fiscal year, $1 million in shareholders' or partners' equity, and total client assets under management and control in an amount not less than $250 million.

C. The term "independent fiduciary" means a Plan fiduciary which is independent of Ibbotson and its affiliates and independent of the Service Provider and its affiliates.

D. The term "affiliate" includes:

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, relative of, or partner in any such person; and

(3) Any corporation or partnership, of which such person is an officer, director or partner.

E. The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

F. The term "Plan" means an employee benefit pension plan as defined in section 3(2) of the Act.

Summary of Facts and Representations

1. Ibbotson, founded by Professor Roger Ibbotson in 1976, provides products and services to help investment professionals make asset allocation decisions for their clients. Ibbotson's mission is to help its clients gather, manage and retain assets. Its clients include financial planners, brokers, brokerage firms, mutual fund companies, institutional and small money managers, pension funds, 401(k) providers, banks and private bankers and insurance companies. In its application, Ibbotson states that Professor Ibbotson's study, Stocks, Bonds, Bills and Inflation, has become an indispensable annual reference tool for investment and financial professionals.

2. The Applicant represents that the Service will be beneficial to Plan participants because it will provide Plan participants with guidance involving analytical techniques and financial concepts that typically result in a more focused and well thought out program for Plan investments. The Applicant further states that the Service, thereby, allows Plan participants to more fully exercise their rights to self-direct their investments. The Service integrates retirement planning and fund allocation recommendations, including current Plan savings, other retirement savings, personal retirement income goals and tolerance for risk, time horizon to retirement and the fund choices specifically available in a participant's Plan. According to Ibbotson, these factors can be the most crucial in developing an effective individual retirement plan.

The Applicant further indicates that the individual guidance which is provided by the Service is not typically available due to the hesitancy of Plan sponsors and Service Providers to provide such advice out of concern for potential liability, and the high cost of obtaining this type of advice on an individual basis. Ibbotson believes that the advice provided by the Service is similar to that used by professional investment managers for the allocation of assets in a defined benefit plan.

3. Before a Plan's independent fiduciary may authorize the Plan's participation in the Service, Ibbotson must provide the independent fiduciary with a complete description of the Service, written disclosures of all fees and expenses associated with the Service, and a written contract for the provision of the Service which defines the relationship between Ibbotson, the Service Provider and the Plan sponsor and the obligations thereunder.[10] Such contract will be renewable annually and will include: (a) A provision under which the Plan shall have 45 days notice prior to implementation of any material change to the Service or any fee or expense increases in connection with the provision of the Service by Ibbotson; and (b) a provision which states that a Plan may terminate its participation in the Service at any time without penalty. However, a Plan which terminates its participation in the Service before the expiration of the contract will be responsible for the payment of its pro-rata share of the fees owed under the contract as of the date of termination, and, if applicable, any direct costs actually incurred by Ibbotson which would have been recovered by Ibbotson but for the termination of the contract, including any direct setup expenses not previously recovered. In addition, Ibbotson shall provide the independent fiduciary with a copy of the proposed and the final exemption, if granted, as published in the **Federal Register**.

4. Ibbotson will provide the Service either directly to Plan participants through an agreement with the Plan sponsor or through an agreement with the Service Providers sponsoring the investment vehicles offered to Plan participants. In situations where Ibbotson contracts directly with the Plan Sponsor, Ibbotson will customize the Service for each Plan.[11] The fees

[10] In this regard, the Department notes that the fiduciary responsibility provisions of the Act apply to the decision of a Plan's independent fiduciary to authorize the Plan's participation in the Service. Section 404 of the Act requires, among other things, that a fiduciary of a plan must act prudently, solely in the interest of the plan's participants and beneficiaries, and for the exclusive purpose of providing benefits to participants and beneficiaries. Accordingly, the Plan's independent fiduciary must act prudently when deciding to participate in the Service, and in considering the fees associated with the Service. The Department expects that the Plan's independent fiduciary, prior to authorizing the Plan's participation in the Service, will understand fully the operation of the Service, and the compensation paid thereunder, following disclosure by Ibbotson of all relevant information pertaining to the Service.

[11] The provision of investment advisory services to plans would be exempt from the prohibitions of section 406(a) of ERISA if the conditions of section 408(b)(2) are met. Section 2550.408b–2(a) of the Department's regulations provides that section 408(b)(2) of the Act exempts from the prohibitions of section 406(a), payment by a Plan to a party in interest, including a fiduciary for * * * any service (or combination of services) if (1) such service is necessary for the establishment or operation of the Plan; (2) such * * * service is furnished under a contract or arrangement which is reasonable; and (3) no more than reasonable compensation is paid for such * * * service. The regulation also provides that section 408(b)(2) does not contain an exemption from acts described in a section 406(b) even if such act occurs in connection with a provision of services that is exempt under section

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charged for the Service will be based on a flat fee per participant. In many instances, Ibbotson will need to coordinate with the Plan's record-keeper or another Service Provider in offering the Service to a Plan's participants. Such entities will be independent of Ibbotson. All fees for the Service will be paid by the Plan sponsor or the Plan to Ibbotson, and the Service Providers will not receive any portion of such fees or other consideration from Ibbotson.

In the second situation, Ibbotson will provide the Service to Plan participants pursuant to a contract that the Plan sponsor enters into with a Service Provider. In these instances, the fees for the Service will still be based on a flat dollar amount per Plan participant, but will be paid to Ibbotson by the Service Provider, the Plan or Plan participant. In addition, Ibbotson will enter into a written agreement with the Plan sponsor defining the relationship between the Plan sponsor, Ibbotson and the Service Provider.

5. The Applicant states that, once a Plan fiduciary has authorized its Plan's participation in the Service, Plan participants will receive written notice that the Service is available and provided by Ibbotson, an entity which is independent of the Service Provider. Each Plan participant will receive an investment advisory service agreement under which each participant will acknowledge his or her understanding that the Service is provided by Ibbotson and not the Service Provider. In addition, Plan participants will receive full disclosures about Ibbotson and the Service.

Access to the Service will be provided to Plan participants through the Internet, or by written materials. A Plan participant will answer a questionnaire which consists of multiple questions that are designed to evaluate a Plan participant's anticipated time horizon to retirement, savings rate and other personal financial factors. After the interview is completed, the Plan participant will receive recommendations with respect to his or her savings rate, retirement age and asset allocation[12] and the percentage of assets that the Plan participant should allocate to each option.

If a Plan participant elects to receive his/her advice through the Internet, the Plan participant will first access a website provided by the Service Provider or the Plan sponsor. There will be an electronic link from the Plan sponsor's or Service Provider's website to Ibbotson's website where the questionnaire and investment advice is housed. The Applicant represents that Ibbotson will always retain sole control over the content of the Service and the advice contained therein. Ibbotson will regularly monitor the contents of the Service and the advice contained therein to ensure that it remains the product of the objective methodology developed by Ibbotson. Ibbotson states that it will be apparent to the Plan participant that Ibbotson is the sole-provider of such advice.

For those Plan participants using the Internet, the completed questionnaire is scored by computer. For those Plan participants who select to receive his/her advice in paper form, Ibbotson will mail the Service materials to Plan sponsors or Plan participants after the Plan sponsor has decided to hire Ibbotson. The Plan participants will mail their written responses back to Ibbotson. Ibbotson will, in turn, score the questionnaire and send its recommendations, etc., directly back to the Plan participant. The Plan participant, will, if she or he chooses to implement the recommendations, then mail or telephone the instructions to the Service Provider (or other designated agent for receiving such investment instructions.) All recommendations will be generated by Ibbotson's proprietary forecasting engine based on an analysis of Plan participant's responses to the questionnaire and an analysis of the investment options offered under the relevant Plan, including any employer stock fund.[13] Based on the score, the Plan participant is categorized into one of several investment recommendations.[14]

Each recommendation contains a description of the investor profile associated with such recommendation that a Plan participant can review to see if he or she feels that he or she has been correctly classified. The Service will also allow Plan participants to experiment with different risk/return scenarios to better understand what impact the recommended allocation will likely have on his/her retirement.

6. The Applicant states that the advice provided to Plan participants will be based on the application of an objective methodology developed by Ibbotson. The investment recommendations generated by the Service are standardized. Such recommendations are generated through an automated process that is then applied to each Plan and Plan participant advised by Ibbotson. The advice provided to a Plan participant through the Service may only be implemented if it is expressly authorized in writing by the Plan participant. The Service will inform Plan participants periodically of the need to review their situation. Plan participants are advised that the investment advice is valid for one year and it is advisable to repeat the questionnaire process periodically and if there are significant life events (such as the birth of a child or an increase in salary.)

7. The Applicant represents that its role in performing the Service on behalf of a Plan, includes gathering information about the investment options offered in a particular Plan, and developing a recommended portfolio for each investor type. First, each Plan's investment option style is analyzed. Then, seven (or more) Plan-specific asset allocation recommendations (from lower to higher risk) are generated by using proprietary Ibbotson software. Finally, the allocations are electronically transferred to a web site "server" (computer system) where one of the asset allocations is recommended to a Plan participant, based on his/her inputs.

Ibbotson constructs portfolios with different risk and return characteristics using the investment options available under the Plan. These portfolios form the foundation of the advice which is provided to a Plan participant. This methodology can be broken into five steps.

Step 1: Selection of asset classes. Before creating specific portfolios for each investment option, Ibbotson believes that it is first necessary to construct strategic asset-class level portfolios. These strategic portfolios reflect the underlying asset allocations that Ibbotson would like to achieve using the specific investment options available under the Plan. Asset classes used to create the strategic portfolios may include: Large, mid and small cap stocks, international stocks, emerging stocks, long, intermediate and short term government bonds, high-yield bonds, municipal bonds, cash, and company stock. The asset classes used depend on the number and types of investment options available in the 401(k) plan. Ibbotson requires that the investment options in a plan provide exposure to at least small and large stocks, cash, and bonds for advice to be given. If the exposure to each of these asset classes is not available, Ibbotson will not provide advice services.

Step 2: Develop expected returns. Ibbotson uses historical relationships and current yields on government bonds to generate expected returns. This approach separates the expected return of each asset class into three components. The first two components are a real risk-free rate of return and an estimate of future inflation. It is Ibbotson's belief that the current yield on a long-term, zero coupon government bond is the best estimate of these two components. The third component is the difference between the historical return on any asset class and the historical return on long-term, zero coupon government bonds. This difference represents the incremental return over the risk free rate investors have earned from taking on the risk of investing in an asset class. The sum of these components is the expected return Ibbotson uses in the mean-variance optimization process. Standard deviations and correlations for the asset classes are calculated using historical data.

Step 3: Build model portfolios. Ibbotson employs the standard mean-variance analysis from Modern Portfolio Theory to evaluate and determine its strategic, asset-level portfolio recommendations. However, rather than taking portfolios directly off of the efficient frontier defined by the estimates created in Step 2, Ibbotson chooses portfolios that are very close to the efficient frontier under many different economic and investment performance scenarios. Ibbotson believes that choosing portfolios this way ensures that the strategic portfolio characteristics will be relatively stable over time and will avoid drastic asset class shifts. Ibbotson deems that it is essential to build portfolios that have these stable properties to minimize the need for the Plan participant to make frequent changes to his or her portfolio.

Step 4: Select funds. Once asset-level model portfolios are developed, they are implemented using the investment options available under the plan. Since at any time most funds are investing in securities from several asset classes, Ibbotson employs a statistical method to determine what asset classes a fund's investment approach is exposing the Plan participant to. Using the asset exposures from this technique, Ibbotson combines the funds so that the total asset class exposure of the funds in the portfolio equals the desired strategic portfolio weights. Since consistency of asset exposure in funds through time is so important, investment options that have little or no history must provide sufficient additional information to base reasonable expectations on. A mutual fund's manager tenure and fees and expenses are also evaluated as part of this process.

Step 5: Monitor and re-balance. The portfolio choices must be reviewed regularly and rebalanced. Portfolio rebalancing is the process of moving a fund's asset class exposures toward its strategic target. This process seeks to reduce the relative performance risk associated with moving the asset class exposures away from what was intended in the strategic asset allocation. There are a variety of conditions that could cause a rebalancing of a portfolio. Market movements, fund asset exposure changes, removal and replacement of mutual funds can trigger rebalancing.

As part of this ongoing process, the funds are evaluated quarterly and the strategic asset allocations are updated once a year. A set of criteria, including absolute and relative performance, is used to evaluate the funds used in the advice portfolios. Funds that do not meet the criteria will be placed on a watch list. The placement of a fund on the watch list does not mean that the fund will be replaced, it is a trigger to begin further due diligence on the fund.

To be removed from the watch list, certain pre-established qualitative and quantitative measures must be met. After a fund has been placed on the watch list and further due diligence has determined that the fund no longer meets the objectives of one or more of the portfolios, Ibbotson will advise the plan sponsor to consider a suitable replacement. Any new fund entering the program will be studied and analyzed using the same methodology for initial fund selection outlined above.

8. Ibbotson next describes the steps involved in providing individualized advice to Plan participants. The steps start with forecasting many possible expected investment returns scenarios and the collecting of the Plan participant's individual needs and risks. These are then combined with the relevant tax and plan rules to show the Plan participant the risk of his or her current investment path and to calculate advice to optimize the 401(k) plan portfolio. Rather than using a questionnaire to approximate the risk tolerance level of the Plan participant, Ibbotson uses a simulation-based forecasting approach designed to show a Plan participant the risks of various investment decisions personalized to his or her individual circumstances. The advice generated recommends a portfolio risk level, a savings rate and a retirement age appropriate to that Plan participant's retirement income goals.

Step 1: Generate return and inflation data. Ibbotson's first step in this process is to generate hundreds of sets of asset return and inflation data covering the next 40 years. This data is randomly calculated using historical data and the relationships it has exhibited through time. This forecasting software uses this data to model the many possible wealth and income paths a Plan participant might face. By generating a variety of possible future wealth patterns, the Plan participant gets a better picture of not just the average path his or her wealth might take but also of shortfalls that are possible.

Holdings of individual stocks are modeled but company stock is modeled as a separate asset class included along with all of the asset classes in the system. If a Plan participant is required or chooses to hold company stock then that will be included in the solution; however, company stock is factored into the solution with the same return as the appropriate capitalization group asset class with twice the standard deviation.

All of this simulation data is updated annually along with the strategic asset allocation portfolios.

Step 2: Gather data from plan participant and record keeper. Ibbotson's forecasting process enables the Plan participant to input data to take into account all of the Plan participant's needs and assets (college funding, new house, etc.) and assets (taxable and nontaxable) before selecting the appropriate portfolio. Ibbotson believes that this approach yields a more appropriate overall portfolio/savings match with the Plan participant's needs. To the extent input is provided by the Plan participant, the Ibbotson process takes into account items such as savings, current balances, investment makeup, and projected cash in-flows and out-flows for both Plan participant and his or her spouse.

Step 3: Calculate current situation. The Plan participant will be shown two separate scenarios through the Ibbotson

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406(b)(2). Section 2550.408b–2(e)(1) further provides that a fiduciary does not engage in an act described in section 406(b)(1) of the Act if the fiduciary does not use any of the authority, control or responsibility which makes such person a fiduciary to cause the Plan to pay additional fees for a service furnished by such fiduciary or to pay a fee for a service furnished by a person in which the fiduciary has an interest which may affect the exercise of such fiduciary's best judgment as a fiduciary. In general, whether a violation of section 406(b) occurs during the operation of an investment advisory program is an inherently factual matter. *See* Advisory Opinion 84–04 (January 4, 1984).

[12] The recommendation will describe and identify the specific investment options available through the participant's Plan and in which options the Plan participant should invest.

[13] The Service will not, however, make any recommendations will respect to investments in employer stock. Instead the Service will treat the participant-designated level of employer stock holdings as an investment in the particular asset class in which the stock falls (*i.e.*, large capitalized equity) with two times the volatility of that class and develop an overall recommendation with this assumption.

[14] These recommendation involve lower to high risk portfolios.

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advice application. The first calculates what chance the Plan participant might have of making his or her retirement goals if he or she continues with the current portfolio risk level and savings rate as entered in Step 2. The second recommends an advice solution and is described in Step 4.

To calculate what chances the Plan participant has of making the retirement goals if no change to the portfolio or savings rate is made, the software uses the simulation data to calculate the wealth that might be accumulated under hundreds of possible future scenarios. These calculations take into account Social Security payments, taxes, and all of the other savings and withdrawals the Plan participant has entered as well as the various investment return and inflation scenarios. Some of these future wealth and income levels will be good, some will be average and some will be inadequate relative to the Plan participant's individual retirement goals. The results of all of these calculations are summarized into a few probability statistics that are communicated to the Plan participant.

Step 4: Calculate advice. Ibbotson states that its advice methodology provides the Plan participant with a recommendation that includes the portfolio risk level, savings rate and retirement age. Since in the 401(k) plan world, the advice can only be given on that portfolio alone, the Ibbotson methodology takes all of the Plan participant's total holdings into account (taxable and tax deferred) and proposes a 401(k) portfolio that gets the Plan participant's total holdings as close to optimal as possible.

Ibbotson believes that this presents the Plan participant with a more balanced solution for achieving his or her goals with the flexibility to change the parameters if he or she sees fit. Starting with a better balanced portfolio means that Plan participants just looking for an answer will get a sound answer more quickly and Plan participants that want to experiment with different levels of risk, savings rate, and or retirement age will start from a more solid position.

Step 5: Present results. The advice process has many steps. However, the user only sees the results of Steps 4 and 5. The typical statistics that will be shown include the most likely income level that the Plan participant might have along with the least likely possibilities. These statistics for the scenario where no changes are made and for those where the Plan participant implements the advice will be displayed side by side so the Plan participant can easily see the differences. When compared to the level of income the Plan participant would like in retirement, this process shows the Plan participant just how much risk is being taken and just how likely the Plan participant is of hitting his or her goals. Ibbotson believes there is no better way to show a Plan participant in terms that can be understood of the risk and reward of the decisions he or she makes. Ibbotson also presents a short-term risk measure to assist in understanding volatility on the way to retirement and its impact on long-term goals. A Plan participant can further individualize the solution if he or she wants to take more risk, cannot save as much as recommended, or wants to change his or her retirement age.

Once finalized, the Plan participant can then implement his or her decision. Although the solution is a "snapshot" based on the then-inputted data, the system will inform the Plan participant periodically of the need to review his or her situation. It will also be stated that his revisiting is most important if there have been any changes in the Plan participant's assumptions such as a promotion or the birth of a child. Under any circumstances, a Plan participant will be cautioned to review his or her situation once a year to update any changes to the information upon which the advice was based and to adjust their 401(k) portfolio, if needed.

9. Ibbotson represents that it will maintain insurance coverage in the amount of at least $5 million for the payment of any liabilities that may arise by reason of a breach of fiduciary duty described in section 404 of the Act or a violation of the prohibited transaction provisions of section 406 of the Act or section 4975 of the Code. This insurance coverage will be available to provide financial support to Ibbotson in the event a breach of fiduciary duty claim is brought against Ibbotson, and it is determined that Ibbotson has incurred liabilities by reason of such breach. The insurance shall be provided pursuant to a "claims made" policy which covers claims made during the policy period. In the event that Ibbotson changes insurers or ceases to provide the Service, Ibbotson will maintain "tail coverage" with respect to claims made for a period of up to three years after such change.[15]

10. The Applicant represents that potential Service Providers will include banks and trust companies, mutual fund companies, brokerage firms and insurance companies. They will be required to meet minimum standards prior to participating in the provision of the Service. To qualify as a Service Provider, the entity must either be: (a) A commercial bank or trust company, savings and loan association, insurance company, or registered investment adviser which meets the definition of a "qualified professional asset manager" (QPAM) set forth in Part V(a) of Prohibited Transaction Exemption 84–14; and have total client assets under management and control in an amount no less than $250 million, or (b) a broker-dealer regulated under the Securities Exchange Act of 1934 and which had, as of the last day of its most recent fiscal year, $1 million in shareholders' and partners' equity, or total client assets under management and control in an amount no less than $250 million.

In addition, the Applicant will require that each candidate meet minimum standards to ensure: (1) The availability of multiple investment options across a number of asset classes, (2) adequate service capabilities and service performance standards, with an ongoing adherence to those standards, (3) the absence of dependence solely upon bundled products[16] for defined contribution Plans, and (4) the Service Provider must in Ibbotson's view, have a high level of professionalism and accountability.

Further, the entity must have adequate capitalization; have been in the financial services business for three years and not been convicted of a felony offense involving abuse or misuse of such entity's employee benefit plan position or employment, or any felony arising out of the conduct of the business of a broker, dealer, investment adviser, bank, insurance company or fiduciary.

11. In providing the Service, depending on the specific circumstances surrounding a particular Plan and the outcome of negotiations between Ibbotson and the Plan sponsor or Service Provider, the fees that Ibbotson will charge will include some or all of the following fees. A technology licensing fee will be charged to the Service Provider. This fee is a one-time fee charged in the first year the Service is provided to a Plan based on the number of Plan participants contained on a Service Provider's record-keeping system. For subsequent years, Ibbotson will charge to the Service Provider a flat per Plan participant fee for each occurrence of at least 10% growth in Plan participants on its record-keeping system (the Revised Technology Fee). In the second year of operation with a Service Provider, Ibbotson will charge a Service Provider a technology maintenance fee equaling up to 20% of the first year's technology licensing fee plus up to 20% of the Revised Technology Fee.

When a Plan sponsor contracts with Ibbotson to customize the Service to its particular Plan, Ibbotson will charge an Internet customization fee to the Plan or the Plan sponsor. This fee is based on the time spent by Ibbotson personnel in its customization of the Service to a particular Plan. In addition, Ibbotson will charge a flat annual per Plan participant advice fee which may be paid by the Plan, Plan sponsor, the Plan participants or the Service Provider.

Finally, Ibbotson will also offer a Plan investment analysis report to Plan sponsors. This report is separate from the investment analysis advice provided to Plan participants and is optional. Ibbotson will analyze the Plan and its investment options. For those Plan sponsors who elect to receive a Plan investment analysis by Ibbotson, Ibbotson will also charge a Plan investment analysis fee based on a flat dollar amount per year. This fee may be paid by the Plan sponsor or the Service Provider.

12. In summary, it is represented that the proposed transaction will satisfy the statutory criteria for an exemption under section 408(a) of the Act because:

(a) The participation in the Service will be expressly authorized in writing by an independent fiduciary.

(b) Ibbotson shall provide the independent fiduciary of each Plan with written disclosure describing the Service and all fees and expenses associated with the Service, a written contract for the provision of the Service, a copy of the proposed and final exemption, and summary of annual Plan activity and expense reports.

(c) Ibbotson will furnish the Plan participants with the following: notice that the Service is provided by Ibbotson, an entity that is independent from the Service Provider and the Plan sponsor; and full disclosure about the Service and Ibbotson; and a risk tolerance questionnaire.

(d) Any investment advice given to Plan participants will be based on the Plan participants' responses to the questionnaire and any investment advice provided only will be implemented at the express direction of the Plan participant.

(e) The total fees paid to Ibbotson and a Service Provider by each Plan participant participating in the Service does not exceed reasonable compensation within the meaning of section 408(b)(2) of the Act.

(f) No portion of any fee or other consideration paid to Ibbotson or in connection with the Service will be shared or received by a Service Provider.

(g) Neither the fees charged nor the compensation received by Ibbotson will be affected by the investment selections of Plan participants.

(h) Participation in the Service will not cause the Plan to pay any additional fees or commissions with respect to acquisitions or dispositions of investments offered under the Plan.

(i) No Service Provider shall own any interest in Ibbotson.

(j) Neither Ibbotson nor any affiliate shall own an interest in a Service Provider.

(k) The annual revenues derived by Ibbotson from any one Service Provider shall not be more than 5% of its annual revenues.

(l) Ibbotson will maintain fiduciary liability insurance in the amount of at least $5 million.

Notice to Interested Persons

The Applicant represents that because potentially interested Plan participants and beneficiaries cannot be identified at this time, the only practical means of notifying such Plan participants and beneficiaries of this proposed exemption is by publication in the **Federal Register**. Therefore, comments and requests for a hearing must be received by the Department not later than February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Allison Padams Lavigne , US Department of Labor, (202)219–8971. (This is not a toll free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries, and protective of the rights of participants and beneficiaries of the plan;

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction; and

(4) The proposed exemptions, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 10th day of January, 2001.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits, Administration, U.S. Department of Labor.

[FR Doc. 01–1197 Filed 1–19–01; 8:45 am]

BILLING CODE 4510–29–P

[15] The Department notes that the condition requiring the maintenance of $5 million of insurance coverage will not foreclose future consideration by the Department of another mechanism designed to assure some degree of financial accountability in the event of breaches of fiduciary duty described in section 404 or violations of the prohibited transaction provisions.

[16] Bundled products provide employers with a package of services including record-keeping, legal, administrative, trust, educational, investment, etc., with respect to the establishment and maintenance of plans by employers.

LEGAL SERVICES CORPORATION

Sunshine Act Meeting of the Board of Directors

TIME AND DATE: The Board of Directors of the Legal Services Corporation will meet on January 27, 2001. The meeting will begin at 10 a.m. and continue until conclusion of the Board's agenda.

LOCATION: Embassy Suites Hotel, 300 Tallapoosa Street, Montgomery, AL.

STATUS OF MEETING: Open, except that a portion of the meeting may be closed pursuant to a vote of the Board of Directors to hold an executive session. At the closed session, the Corporation's General Counsel will report to the Board on litigation to which the Corporation is

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or may become a party, and the Board may act on the matters reported. The closing is authorized by the relevant provisions of the Government in the Sunshine Act [5 U.S.C. 552b(c) (10)] and the corresponding provisions of the Legal Services Corporation's implementing regulation [45 CFR § 1622.5(h)]. A copy of the General Counsel's Certification that the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Open Session

1. Approval of agenda.
2. Approval of the minutes of the Board's meeting of November 11, 2000.
3. Approval of the minutes of the Executive Session of the Board's meeting of November 11, 2000.
4. Approval of minutes of the Board's telephonic meeting of November 28, 2000.
5. Scheduled Public Speakers.
6. Chairman's Report.
7. Members' Report.
8. Inspector General's Report.
9. President's Report.
10. Consider and act on the report of the Board's Committee on Provision for the Delivery of Legal Services.
11. Consider and act on the report of the Board's Operations and Regulations Committee.
12. Consider and act on the report of the Board's Finance Committee.
13. Consider and act on the Board's 2000 Annual Performance Reviews Committee's report on the annual evaluation of the Corporation's President.
14. Consider and act on possible dissolution of the Board's 2000 Annual Performance Reviews Committee.
15. Consider and act on adjustment of the President's salary in light of the increase in Level V of the Executive Schedule specified in 5 U.S.C. § 5316.
16. Presentation by John McKay and Tom McWeeney on Strategic Planning performance measures, including the development of performance indicators/performance measurement instruments and the testing of these instruments in the "real world."
17. Consider and act on the request by the President of LSC for an exception to the Performance/Incentive Awards Policy adopted by the Board on November 20, 1999, so as to allow the making of a cash award—in this instance, The President's Award—to a corporate officer.
18. Election of Board Chair.
19. Election of Vice-Chair.
20. Consider and act on Board committee appointments.
21. Consider and act on proposed changes to the currently scheduled June 2001, September 2001, and November 2001 Board meetings.
22. Consider and act on the Board's meeting schedule, including designation of locations, for calendar year 2002.

Closed Session

23. Briefing [1] by the Inspector General on the activities of the Office of Inspector General.
24. Consider and act on the Office of Legal Affairs' report on potential and pending litigation involving LSC.

Open Session

25. Consider and act on other business.
26. Public Comment.

CONTACT PERSON FOR INFORMATION: Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336–8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S–S Cushing, at (202) 336–8800.

January 18, 2001.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 01–2003 Filed 1–18–01; 2:50 pm]

BILLING CODE 7050–01–P

[1] Any portion of the closed session consisting solely of staff briefings does not fall within the Sunshine Act's definition of the term "meeting" and, therefore, the requirements of the Sunshine Act do not apply to any such portion of the closed session. 5 U.S.C. 552(b)(a)(2) and (b). See also 45 CFR 1622.2 & 1622.3.

4. Review and adoption of FY '01 operating budget for the Corporation.
5. Review of expenses through November 30, 2000.
6. Consider and act on other business.
7. Public comment.

CONTACT PERSON FOR INFORMATION: Victor M. Fortuno, Vice President for Legal Affairs, General Counsel, & Corporate Secretary, at (202) 336–8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S–S Cushing, at (202) 336–8800.

Dated: January 18, 2001.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel, & Corporate Secretary.

[FR Doc. 01–2004 Filed 1–18–01; 2:50 pm]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting of the Board of Directors Operations & Regulations Committee

TIME AND DATE: The Operations and Regulations Committee of the Legal Services Corporation Board of Directors will meet on January 26, 2001. The meeting will begin at 1:00 p.m. and continue until the Committee concludes its agenda.

LOCATION: Embassy Suites Hotel, 300 Tallapoosa Street, Montgomery, AL.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of November 10, 2000.
3. Consider and act on the Property Acquisition and Management Manual.
4. Consider and act on the Interim Report of the Regulations Review Task Force.
5. Consider and act on other business.
6. Public comment.

CONTACT PERSON FOR INFORMATION: Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336–8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S-S Cushing, at (202) 336–8800.

LEGAL SERVICES CORPORATION

Sunshine Act Meeting; Sunshine Act Meeting of the Board of Directors Finance Committee.

TIME AND DATE: The Finance Committee of the Legal Services Corporation Board of Directors will meet on January 26, 2001. The meeting will begin at 3:15 p.m. and continue until the Committee concludes its agenda.

LOCATION: Embassy Suites Hotel, 300 Tallapoosa Street, Montgomery, AL.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Consider and act on staff recommendation to change LSC's pension provider.
3. Office of the Inspector General's presentation of the Corporation's FY '00 annual audit.

Dated: January 18, 2001.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 01–2005 Filed 1–18–01; 2:50 pm]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting; Sunshine Act Meeting of the Board of Directors Ad Hoc Committee on Performance Reviews of the President

TIME AND DATE: The Ad Hoc Committee on Performance Reviews of the President of the Legal Services Corporation's Board of Directors will meet on January 26, 2001. The meeting will begin at 4:30 p.m. and continue until conclusion of the committee's agenda.

LOCATION: Embassy Suites Hotel, 300 Tallapoosa Street, Montgomery, AL.

STATUS OF MEETING: Except for approval of the committee's agenda and any miscellaneous business that may come before the committee, the meeting will be closed to the public. The closing is authorized by the relevant provisions of the Government in the Sunshine Act [5 U.S.C. 552b(c)(2) & (6)] and the corresponding provisions of the Legal Services Corporation's implementing regulation [45 CFR § 1622.5(a) & (e)]. A copy of the General Counsel's Certification that the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

OPEN SESSION:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of November 10, 2000.

CLOSED SESSION:

3. Consider and act on recommendation to the Board of Directors on the annual evaluation of the President for FY 2000.

OPEN SESSION:

4. Consider and act on other business.
5. Public comment

CONTACT PERSON FOR INFORMATION: Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Corporate Secretary, at (202) 336–8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S-S Cushing at (202) 336–8800.

Dated: January 18, 2001.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 01–2006 Filed 1–18–01; 2:50 pm]

BILLING CODE 7050–01–P

LEGAL SERVICES CORPORATION

Sunshine Act Meeting; Sunshine Act Meeting of the Board of Directors Committee on Provision for the Delivery of Legal Services

TIME AND DATE: The Committee on Provision for the Delivery of Legal Services of the Legal Services Corporation Board of Directors will meet on January 26, 2001. The meeting will begin at 9:00 a.m. and continue until the Committee concludes its agenda

LOCATION: Embassy Suites Hotel, 300 Tallapoosa Street, Montgomery, AL.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of agenda.
2. Approval of the minutes of the Committee's meeting of November 10, 2000.
3. Panel presentation by Willie Abrams (LSC Program Counsel) and representatives of Legal Services Corporation of Alabama, Legal Services of North-Central Alabama, and Legal Services of Metro Birmingham on the problems and challenges programs face in serving rural southern clients.
4. Panel presentation on Building a State Justice Community in Alabama by Joseph Dailing (Executive Director of Prairie State Legal Services in Illinois and a state planning consultant with LSC), Robert Gross (LSC Senior Program Counsel for State Planning), and representatives of the LSC-funded Alabama programs—Legal Services Corporation of Alabama, Legal Services of North-Central Alabama, and Legal Services of Metro Birmingham.
5. Update on State Planning by Randi Youells and Robert Gross.
6. Update by Randi Youells on recent activities, including Results Project, Performance Measures, CSR Self-Inspection, Technology Initiative Grants, Competition and Grants Management, the Client-Centered Conference, the Leadership and Diversity Project, and the Gender Task Force.
7. Consider and act on other business.
8. Public comment.

CONTACT PERSON FOR INFORMATION: Victor M. Fortuno, Vice President for Legal Affairs, General Counsel & Secretary of the Corporation, at (202) 336–8800.

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Elizabeth S-S Cushing, at (202) 336–8800.

Dated: January 18, 2001.

Victor M. Fortuno,

Vice President for Legal Affairs, General Counsel & Corporate Secretary.

[FR Doc. 01–2007 Filed 1–18–01; 2:50 pm]

BILLING CODE 7050–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–017]

Information Collection: Submission for OMB Review, Comment Request

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of Agency Report Forms Under OMB Review.

SUMMARY: The National Aeronautics and Space Administration has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Comments on this proposal should be received on or before February 21, 2001.

ADDRESSES: All comments should be addressed to Mr. Brian Dunbar, Code PM, National Aeronautics and Space Administration, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Ms. Carmela Simonson, Office of the Chief Information Officer, (202) 358–1223.

Reports: None.

Title: Voluntary Response Survey of NASA Internet Customers.

OMB Number: 2700–.

Type of review: New.

Need and Uses: NASA is seeking input from Internet users that they will use to redesign the NASA Home Page, the NASA-wide Search Engine and other Internet offerings so that the NASA Web is more customer-focused and provides users with the information they are seeking more quickly.

Affected Public: Individuals or households.

Number of Respondents: 100.

Responses Per Respondent: 4.

Annual Responses: 400.

Hours Per Request: 15 min.

Annual Burden Hours: 100.

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Frequency of Report: Quarterly.

David B. Nelson,

Deputy Chief Information Officer, Office of the Administrator.

[FR Doc. 01–1777 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–007]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Rob Padilla, Patent Counsel, Ames Research Center, Mail Code 202A–3, Moffett Field, CA 94035; Tel. (650) 604–5104; Fax (650) 604–7486.

NASA Case No. ARC–14231–2: Body Sensing System;

NASA Case No. ARC–14231–3: Multimodality Instrument for Tissue Characterization;

NASA Case No. ARC–14254–1: Waterproofing of Low Density Aerogels;

NASA Case No. ARC–14418–1: En Route Spacing System and Method;

NASA Case No. ARC–14494–1: Characterization of Bioelectric Potentials.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1767 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–008]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: John Kusmiss, Patent Counsel, NASA Management Office-JPL, 4800 Oak Grove Drive, Mail Stop 180–801, Pasadena, Ca 91109; Tel. (818) 354–7770.

NASA Case No. NPO–19442–2: Composite Material Switches;

NASA Case No. NPO–20837–1: Evolutionary Technique for Automated Synthesis of Electronic Circuits;

NASA Case No. DRC–098–096: Helicopter Tail Boom with Venting for Alleviation and Control of Tail Aerodynamic Boom Loads and Methods Thereof;

NASA Case No. DRC–099–016: Wind Advisory System.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1768 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–009)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Michael Gomet, Patent Attorney, Goddard Space Flight Center, Mail Code 750.2, Greenbelt, MD 20771; 301–286–6521.

NASA Case No. GSC–13913–1: Sol-Gel Processing to Form Doped Sol-Gel Monoliths Inside Hollow Core Optical Fiber and Sol-Gel Core Fiber Devices Made Thereby;

NASA Case No. GSC–13988–1: Combination Radial and Thrust Magnetic Bearings; NASA Case No. GSC–14240–1: Methods and Systems for Collecting Data from Multiple Fields of View;

NASA Case No. GSC–14302–1: Three Dimensional Empirical Mode Decomposition Analysis Apparatus and Method.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1769 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 01–010]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Kent N. Stone, Patent Counsel, Glenn Research Center at Lewis Field, Mail Code 500–118, Cleveland, Ohio 44135; Tel. (216) 433–8855; Fax (216) 433–6790.

NASA Case No. LEW–16685–2: Shape Memory Alloy Actuator;

NASA Case No. LEW–16056–3: Procedure for Making a Hollow Cathode Assembly;

NASA Case No. LEW–16684–1: Thermal Barrier Braided Rope Seal;

NASA Case No. LEW–16685–2: Actuator Control Using Shape Memory Alloys, Microsystems and Optically Controlled Switches;

NASA Case No. LEW–16690–1: An Assembly for Moving a Robotic Device along Selected Axes;

NASA Case No. LEW–16790–1: Exoskeletal Engine;

NASA Case No. LEW–16871–1: Method and Apparatus for Removal of Biologically Active Contaminants from the Surfaces of Surgical Implants and Other Biomedical Components and Materials;

NASA Case No. LEW–16999–1: Thermocouple Boundary Layer Rake;

NASA Case No. LEW–17022–1: Etch-Stop Fuse for Precision Thickness and Depth Control;

NASA Case No. LEW–17041–1: Method of Improving the Plating Process Employing Directed High Intensity Acoustic Beams.

Dated: January 11, 2001.

Edward A. Frankle,

General, Counsel.

[FR Doc. 01–1770 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–011)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Edward Fein, Patent Counsel, Johnson Space Center, Mail Code HA, Houston, Texas 77058–3696; Tel. (281) 483–4871; Fax (281) 244–8452.

NASA Case No. MSC–22616–3: Preservation of Liquid Biological Samples;

NASA Case No. MSC–22633–1: Growth Stimulation of Biological Cells and Tissue by Electromagnetic Fields and Uses Thereof;

NASA Case No. MSC–22936–2: Microencapsulated Bioactive Agents and Method of Making;

NASA Case No. MSC–23049–2: Method of Constructing a Microwave Antenna;

NASA Case No. MSC–23049–3: Method for Selective Thermal Ablation;

NASA Case No. MSC–23049–4: Computer Program for Microwave Antenna.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1771 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–012)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Linda Blackburn, Patent Counsel, NASA Langley Research Center, Mail Code 212, Hampton, VA, 23681–2199; Tel. (757) 864–9260; Fax (757) 864–9190.

NASA Case No. LAR–15449–2: Method to Prepare Processable Polyimides with Reactive Endgroups Using 1, 3-Bix (3-Aminophenoxyl) Benzene (Continuing App of –1);

NASA Case No. LAR–15470–1–CU: Dry Process for Manufacturing Hybridized Boron Fiber-Carbon Fiber Thermoplastic Composite Materials;

NASA Case No. LAR–15543–2: Phenylethynyl Containing Reactive Additives (Divisional of LAR–15543–1);

NASA Case No. LAR–15642–1: High Pressure, High Frequency Fluid Valve;

NASA Case No. LAR–15712–1–CU: Catalytic Oxidation Sensor for Hydrocarbons and Volatile Organic Compounds;

NASA Case No. LAR–15817–1: Method and Apparatus for Encouraging Physiological Self-Regulation Through Modulation of an Operator's Control Input to a Video Game;

NASA Case No. LAR–15851–1–CU: Process for Coating Substrates with Catalyst Materials;

NASA Case No. LAR–15852–1: Dry Process for Manufacturing Hybridized Boron Fiber/Carbon Fiber Thermoplastic Composite Materials from a Solution Coated Precursor;

NASA Case No. LAR–15926–1: Reference Sample Technique to Measure Material Nonlinearity;

NASA Case No. LAR–15954–1: Single Laser Sweep Full S-Parameter Characterization of Fiber Bragg Gratings;

NASA Case No. LAR–15960–1: Polymer-Polymer Bilayer Actuator;

NASA Case No. LAR–15962–1–CU: Poly (Aryl Ether Ketones) Bearing Alkylated Side Chains;

NASA Case No. LAR–16005–1: High Precision Solid State Wavelength Monitor;

NASA Case No. LAR–16038–1: Electrostrictive Graft Elastomers;

NASA Case No. LAR–16039–1: Non-Uniform Thickness Electroactive Device;

NASA Case No. LAR–16219–1: Membrane Position Control;

NASA Case No. LAR–16220–1: Membrane Tension Control.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1772 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–013)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: James McGroary, Patent Counsel, Marshall Space Flight Center, Code LS01, Huntsville, AL 35812; Tel. (256) 544–0013; Fax (256) 544–0258.

NASA Case No. MFS–26378–1: Plasma Spray Capacitance and Capaciflector Sensor Probes;

NASA Case No. MFS–31138–2–DIV: Method of Making a Rocket Engine Thrust Chamber Assembly;

NASA Case No. MFS–31148–2–DIV: Fabrication Process for Combustion Chamber/Nozzle Assembly;

NASA Case No. MFS–31175–2–CIP: Gasket Assembly for Sealing Mating Surfaces;

NASA Case No. MFS–31229–1: Method and Apparatus for Applying Readable Identification Symbols to Substrates;

NASA Case No. MFS–31289–2: Method and System for Reducing Plasma Loss in a Magnetic Mirror Fusion Reactor;

NASA Case No. MFS–31294–2–CIP: Aluminum Alloy and Articles Cast Therefrom;

NASA Case No. MFS–31294–5–CIP: Aluminum-Silicon Alloy Having Improved Properties at Elevated Temperatures and Articles Cast Therefrom;

NASA Case No. MFS–31294–6–CIP: Aluminum-Silicon Alloy Having Improved Properties at Elevated Temperatures and Process for Producing Cast Articles Therefrom;

NASA Case No. MFS–31379–2–DIV: Method of Making a Composite Tank;

NASA Case No. MFS–31432–1: Panoramic Detection System for Generating a 360-Degree Image;

NASA Case No. MFS–31455–1: Process for a High Efficiency Class D

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Microwave Power Amplifier Operating in the S-Band;

NASA Case No. MFS–31475–1: Panoramic Refracting Optic (PRO);

NASA Case No. MFS–31524–1: SADL: Simulation Architecture Description Language.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1773 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–014)]

Government-Owned Inventions, Available for Licensing

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability of inventions for licensing.

SUMMARY: The inventions listed below are assigned to the National Aeronautics and Space Administration, have been filed in the United States Patent and Trademark Office, and are available for licensing.

DATES: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Diana Cox, Patent Counsel, Kennedy Space Center, Mail Code: CC–A, Kennedy Space Center, FL, 32899; Tel. (321) 867–7214; Fax (321) 867–1817.

NASA Case No. KSC–12052: Communications Interface for Wireless Communications Headset;

NASA Case No. KSC–12056: Air Pollution Control Method and Apparatus for Removal of Nitrogen Oxides from Stationary Combustion Sources;

NASA Case No. KSC–12144: Architectural Assessment Tool—Enhanced (AATe);

NASA Case No. SSC–00120–1: Seal Ring Installation Tool.

Dated: January 11, 2001.

Edward A. Frankle,

General Counsel.

[FR Doc. 01–1774 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–016)]

NASA Advisory Council (NAC), Aero-Space Technology Advisory Committee (ASTAC); Propulsion Systems Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces a NASA Advisory Council, Aero-Space Technology Advisory Committee, Propulsion Systems Subcommittee meeting.

DATES: Thursday, February 15, 2001, 8 a.m. to 5 p.m. and Friday, February 16, 2001, 8 a.m. to 4 p.m.

ADDRESSES: National Aeronautics and Space Administration, John H. Glenn Research Center at Lewis Field, Administration Building, Room 215, 21000 Brookpark Road, Cleveland, OH 44135.

FOR FURTHER INFORMATION CONTACT: Dr. Arun K. Sehra, National Aeronautics and Space Administration, John H. Glenn Research Center at Lewis Field, 21000 Brookpark Road, Cleveland, OH 44135, 216/433–3397.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Aerospace Programmatic Overview

—NASA GRC Aeropropulsion Overview

—Ultra-Efficient Engine Technology Review

—Propulsion Systems Base R&T Prog. Review

—GPRA Milestones Review

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Dated: January 16, 2001.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–1776 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (01–015)]

NASA Advisory Council (NAC), Task Force on International Space Station Operational Readiness; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting change.

Federal Register Citation of Previous Announcement: 65 FR 243, Notice Number 00–143, December 18, 2000.

Previously Announced Date and Address of Meeting: Wednesday, January 31, 2001, 12 p.m.–1 p.m. Eastern Standard Time; NASA Headquarters, 300 E Street, SW, Room 7W31, Washington, DC 20546.

Changes in the Meeting: Date changes to Wednesday, February 7, 2001; Time remains 12 p.m.–1 p.m. Eastern Standard Time; NASA Headquarters, 300 E Street, SW, Room 7W31, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Mr. Philip Cleary, Code IH, National Aeronautics and Space Administration, Washington, DC 20546–0001, 202/358–4461.

SUPPLEMENTARY INFORMATION: This meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—To assess the operational readiness of the International Space Station to support the new crew and the American and Russian flight team's preparedness to accomplish the Expedition Two mission.

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitors register.

Dated: January 16, 2001.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 01–1775 Filed 1–19–01; 8:45 am]

BILLING CODE 7510–01–U

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–8]

Calvert Cliffs Nuclear Power Plant; Notice of Docketing of the Materials License SNM–2505 Amendment Application for the Calvert Cliffs Independent Spent Fuel Storage Installation

By letter dated November 16, 2000, Calvert Cliffs Nuclear Power Plant (CCNPP) submitted an application to the Nuclear Regulatory Commission (NRC or the Commission) in accordance with 10 CFR Part 72 requesting an amendment of the Calvert Cliffs independent spent fuel storage installation (ISFSI) license (SNM–2505) for the ISFSI located in Calvert County, Maryland. CCNPP is seeking Commission approval to amend the materials license to reflect changes to License Conditions 9, 12, and 16. Changes to Conditions 9 and 12 involve eliminating references to certain documents. Changes to Condition 16 involve elimination of the helium leak test for the double-closure seal welds located at the bottom of the dry shielded canisters.

This application was docketed under 10 CFR part 72; the ISFSI Docket No. is 72–8 and will remain the same for this action. The amendment of an ISFSI license is subject to the Commission's approval.

The Commission may issue either a notice of hearing or a notice of proposed action and opportunity for hearing in accordance with 10 CFR 72.46(b)(1) or, if a determination is made that the amendment does not present a genuine issue as to whether public health and safety will be significantly affected, take immediate action on the amendment in accordance with 10 CFR 72.46(b)(2) and provide notice of the action taken and an opportunity for interested persons to request a hearing on whether the action should be rescinded or modified.

For further details with respect to this application, see the application dated November 16, 2000, which is available for public inspection at the Commission's Public Document Room, One White Flint North Building, 11555 Rockville Pike, Rockville, MD, or from the publically available records component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at *http://www.nrc.gov/nrc/adams/index.html* (the Public Electronic Reading Room).

Dated at Rockville, Maryland, this 5th day of January 2001.

For the U.S. Nuclear Regulatory Commission.

E. William Brach,

Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 01–1597 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NOTICE REGULATORY COMMISSION

[Docket No. 70–3098]

Notice of Opportunities for Hearings Related to Licensing the Mixed Oxide Fuel Fabrication Facility

Within the next several months, the U.S. Nuclear Regulatory Commission (NRC) expects to receive an application from Duke Cogema Stone & Webster (DCS) to construct and operate a mixed oxide (MOX) fuel fabrication facility to be located at the U.S. Department of Energy's Savannah River Site. The regulations in 10 CFR part 70 for a plutonium fuel fabrication plant contemplate two approvals—approval for construction (10 CFR 70.23(a)(7), (b)) and approval for operation (10 CFR 70.23(a)(8)). The regulations in 10 CFR part 70 do not, however, mandate a particular approval or hearing process. The appropriate approval and hearing process—one stage or two stage—will depend largely on the nature, level of detail and degree of completeness of the application. This notice is intended to inform the public of the staff's planned approach for possible hearing issues related to the MOX fuel fabrication facility.

Although the regulations do not require the applicant to submit a comprehensive and complete application covering both construction and operation before the Commission can approve commencement of construction, an applicant has the option of submitting a complete license application addressing both construction and operation at the outset. We understand, however, that DCS will be submitting an initial application (including the environmental report) focusing on siting matters and the design bases of the principal structures, systems, and components, leaving the balance of the information, including detailed design and safety evaluation issues and operating issues, to be addressed in a second submittal. In this case, a two-stage approval and hearing process is appropriate. NRC will be providing an opportunity for a hearing in connection with each of the two required approvals (approval for construction and approval for operation). Any NRC adjudicatory proceedings regarding the MOX facility would be subject to the procedural requirements of 10 CFR part 2, Subpart L.

The first hearing would encompass issues related to the construction approval, and would likely be limited to whether applicable NRC requirements have been met regarding the general design bases for the principal structures, systems, and components, the quality assurance program, and environmental issues. The second hearing would encompass all other issues related to the issuance of a 10 CFR part 70 license. Such issues would include whether operation of the MOX facility, as constructed, will adequately protect health, minimize danger to life or property, and control special nuclear material.

FOR FURTHER INFORMATION CONTACT: Timothy C. Johnson, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415–7299.

Dated at Rockville, Maryland, this 11th day of January 2001.

For the Nuclear Regulatory Commission.

Eric J. Leeds,

Chief, Special Projects Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 01–1598 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–354]

PSEG Nuclear LLC; Notice of Consideration of Issuance of Amendment To Facility Operating License No. NPF–57 Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–57 issued to PSEG Nuclear LLC (the licensee) for operation of the Hope Creek Generating Station, located in Salem County, New Jersey.

The proposed amendment would revise the Technical Specifications (TS) to change the acceptance values for Core Spray subsystem flow contained in TS 4.5.1.b.1 from the current value of 6350 gallons per minute (gpm) to 6150 gpm.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended

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(the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change specifies revised surveillance values for the Core Spray System and does not alter any system or modify any operating procedures. The Core Spray pumps will remain able to perform their required safety related function in order to provide cooling to the reactor core. The revised surveillance value will not increase the consequences of accidents previously evaluated in the SAR [Safety Analysis Report].

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change specifies revised surveillance requirements of the core spray system and makes no changes to the physical plant or operating procedures. No new accident scenarios, failure mechanisms or limiting single failures are created as a result of the proposed change in the core spray system surveillance value. The change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change specifies surveillance requirements for the core spray system. Analyses have determined that for operation at the new surveillance limit, fuel cladding oxidation and hydrogen generation remain within previously analyzed limits. There will not be a significant increase in peak cladding temperature resulting from this change and that the limits specified in 10CFR50.46 continue to be met.

10CFR50.46 (b)(1) Peak cladding temperature. The calculated maximum fuel element cladding temperature shall not exceed 2200° F.

(2) Maximum cladding oxidation. The calculated total oxidation of the cladding shall nowhere exceed 0.17 times the total cladding thickness before oxidation.

(3) Maximum hydrogen generation. The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam shall not exceed 0.01 times the hypothetical amount that would be generated if all of the metal in the cladding cylinders surrounding the fuel, excluding the cladding surrounding the plenum volume, were to react.

The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or a change in the methods governing plant operation. Thus, the proposed change, which revises the surveillance limit for the core spray system, does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 21, 2001, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov). If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Mr. Jeffrie J. Keenan, Esquire, PSEG Nuclear—N21, P.O. Box 236, Hancocks Bridge, NJ 08038, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated January 8, 2001, which is available for public inspection at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this 16th day of January, 2001.

For the Nuclear Regulatory Commission.

Richard B. Ennis,

Project Manager, Section 2, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–1779 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271]

Vermont Yankee Nuclear Power Corporation; Notice of Withdrawal of Application for Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has granted a request by Vermont Yankee Nuclear Power Corporation (VYNPC, the licensee) to withdraw its December 21, 1999, as supplemented on September 12 and 19, 2000, application for an amendment to Facility Operating License No. DPR–28, for the Vermont Yankee Nuclear Power Station, located in Windham County, Vermont.

The proposed amendment would have revised the Technical Specifications (TS) to change the control rod block requirements consistent with the BWR/4 Standard Technical Specifications.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment on January 26, 2000 (65 FR 4291). However, by letter dated December 26, 2000, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated December 21, 1999, as supplemented on September 12 and 19, 2000, and the licensee's letter dated December 26, 2000, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (*http://www.nrc.gov*).

Dated at Rockville, Maryland, this 12th day of January 2001.

For the Nuclear Regulatory Commission.

Robert M. Pulsifer,

Project Manager, Section 2, Project Directorate I, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 01–1601 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–29]

Yankee Atomic Electric Company; Notice of Withdrawal of Application for Amendment to the Possession Only License

The U.S. Nuclear Regulatory Commission (the Commission) has granted the request of Yankee Atomic Electric Company (the licensee) to withdraw its March 17, 1999, application for proposed amendment to the Possession Only License No. DPR–3 for the Yankee Nuclear Power Station, located in Rowe, Massachusetts.

The proposed amendment would have revised the Yankee Nuclear Power Station's Defueled Technical Specifications by transferring the administrative requirements to the Yankee Decommissioning Quality Assurance Program.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on April 7, 1999 (64 FR 17032). However, by letter dated

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April 23, 1999, the licensee withdrew the proposed change.

For further details with respect to this action, see the application for amendment dated March 17, 1999, and the licensee's letter dated April 23, 1999, which withdrew the application for license amendment. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and accessible electronically through the ADAMS Public Electronic Reading Room link at the NRC Web site (http://www.nrc.gov).

Dated at Rockville, Maryland, this 12th day of January 2001.

For the Nuclear Regulatory Commission.

Phillip M. Ray,

Project Manager, Project Directorate IV & Decommissioning Division of Licensing Project Management Office of Nuclear Reactor Regulation.

[FR Doc. 01–1778 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licensees

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of availability of final NUREG.

SUMMARY: The NRC is announcing the availability of the final NUREG–1556, Volume 18, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Service Provider Licenses," dated November 2000.

The NRC is using Business Process Redesign techniques to redesign its materials licensing process, as described in NUREG–1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign." A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. This final NUREG report is the eighteenth guidance document developed to support an improved materials licensing process.

This guidance is intended for use by applicants, licensees, and the NRC staff, and will also be available to Agreement States. This document combines and updates the guidance found in the following draft regulatory guides: "Guide for the Application for a License for the Use of Radioactive Materials for Calibrating Radiation Survey and Monitoring Instruments," "Guide for the Application for the Use of Radioactive Materials in Leak-Testing Services," and "Guide for the Applications for the Use of Radioactive Materials in Servicing Preregistered Gauges, Measuring Devices, and Sealed Sources Used in Such Devices." Additionally, NRC staff included information contained in the corresponding Standard Review Plans for these three draft regulatory guides. This final report takes a more risk-informed, performance-based approach to licensing service providers, and reduces the information (amount and level of detail) needed to support an application for these activities. This final document may be used for preparing or reviewing service provider licenses.

A free single copy of final NUREG–1556, Volume 18, may be requested by writing to the U.S. Nuclear Regulatory Commission, ATTN: Mrs. Carrie Brown, Mail Stop TWFN 9–C–24, Washington, DC 20555–0001. Alternatively, submit requests through the Internet by addressing electronic mail to cxb@nrc.gov. A copy of final NUREG–1556, Volume 18, is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555–0001.

FOR FURTHER INFORMATION CONTACT: Mrs. Carrie Brown, TWFN 9–F–24, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–8092; electronic mail address: cxb@nrc.gov.

Electronic Access

Final NUREG–1556, Volume 18, is available electronically by visiting the NRC's Home Page (http://www.nrc.gov/nrc/nucmat.html).

Dated at Rockville, Maryland, this 9th day of January, 2001.

For the Nuclear Regulatory Commission,

Patricia K. Holahan,

Chief, Rulemaking and Guidance Branch Division of Industrial and Medical Nuclear Safety, NMSS.

[FR Doc. 01–1599 Filed 1–19–01; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Consolidated Guidance About Materials Licenses: Guidance for Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance for NRC Licensees Proposing To Work in Agreement State Jurisdiction (Reciprocity)

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of availability of final NUREG.

SUMMARY: The NRC is announcing the availability of the final NUREG–1556, Volume 19, "Consolidated Guidance About Materials Licenses: Guidance For Agreement State Licensees About NRC Form 241 "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters' and Guidance For NRC Licensees Proposing to Work in Agreement State Jurisdiction (Reciprocity)," dated December 2000.

The NRC is using Business Process Redesign techniques to redesign its materials licensing process, as described in NUREG–1539, "Methodology and Findings of the NRC's Materials Licensing Process Redesign." A critical element of the new process is consolidating and updating numerous guidance documents into a NUREG-series of reports. This final NUREG report is the nineteenth guidance document developed to support an improved materials licensing process.

This guidance is intended for use by Agreement State licensees, NRC licensees, NRC staff, and will also be available to Agreement States. This document also provides contact organization guidance to NRC licensees who wish to work in Agreement States.

This document combines and updates the guidance for applicants and licensees previously found in NRC Inspection Manual Chapter 1220, "Processing of 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters,' and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20"; NRC Information Notice No. 90–15: "Reciprocity: Notification Of Agreement State Radiation Control Directors Before Beginning Work In Agreement States"; All Agreement States Letter 96–022, Policy and Guidance Directives (P&GD) 83–19 "Jurisdiction at Reactor Facilities" and 84–17 "Jurisdiction 10 CFR parts 30, 40 and 70 Licenses at Reactor Facilities." In addition, this final report contains pertinent information found in Technical Assistance Requests and Information notices, as listed in Appendix F of the NUREG.

A free single copy of final NUREG–1556, Volume 19, may be requested by writing to the U.S. Nuclear Regulatory Commission, ATTN: Mrs. Carrie Brown, Mail Stop TWFN 9–C24, Washington, DC. 20555–0001. Alternatively, submit requests through the Internet by addressing electronic mail to cxb@nrc.gov. A copy of the final NUREG–1556, Volume 19, is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. 20555–0001.

FOR FURTHER INFORMATION CONTACT: Mrs. Carrie Brown, TWFN 9–F–C24, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC. 20555, telephone (301) 415–8092; electronic mail address: cxb@nrc.gov.

Electronic Access

Final NUREG–1556, Volume 19, is available electronically by visiting the NRC's Home Page (http://www.nrc.gov/nrc/nucmat.html).

Dated at Rockville, Maryland, this 9th day of January, 2001.

For the Nuclear Regulatory Commission.

Patricia K. Holahan,

Chief, Rulemaking and Guidance Branch, Division of Industrial and Medical Nuclear Safety, NMSS.

[FR Doc. 01–1600 Filed 1–19–01; 8:45 am]

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OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives notice of positions placed or revoked under Schedules placed under Schedule C in the excepted service, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Pam Shivery, Director, Washington Service Center, Employment Service (202) 606–1015.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management published its last monthly notice updating appointing authorities established or revoked under the Excepted Service provisions of 5 CFR 213 December 7, 2000 (65 FR 76675). Individual authorities established or revoked under Schedule C between November 1, 2000, and November 30, 2000, appear in the listing below. Future notices will be published on the fourth Tuesday of each month, or as soon as possible thereafter. A consolidated listing of all authorities as of June 30 will also be published.

Schedule C

The following Schedule C authorities were established during November 2000:

Commission on Civil Rights

Special Assistant to the Commissioner. Effective November 22, 2000.

Department of Agriculture

Confidential Assistant to the Administrator, Rural Housing Service. Effective November 2, 2000.

Confidential Assistant to the Administrator, Rural Housing Service. Effective November 3, 2000.

Confidential Assistant to the Administrator, Rural Business-Cooperative. Effective November 9, 2000.

Department of Defense

Staff Specialist to the Deputy Assistant Secretary of Defense for Asian and Pacific Affairs. Effective November 2, 2000.

Department of Education

Confidential Assistant to the Deputy Secretary. Effective November 2, 2000.

Confidential Assistant to the Assistant Secretary, Office of Elementary and Secondary Education. Effective November 6, 2000.

Department of Energy

Special Assistant to the Administrator for National Nuclear Security Administration. Effective November 16, 2000.

Department of Housing and Urban Development

Secretary's Representative to the Deputy Secretary. Effective November 17, 2000.

Special Assistant to the Director, Office of Executive Scheduling. Effective November 30, 2000.

Department of the Interior

Special Assistant to the Director of External Affairs. Effective November 9, 2000.

Department of State

Program Officer to the Assistant Secretary, Office of International Visitors, Bureau of Educational and Cultural Affairs. Effective November 15, 2000.

Department of Transportation

Special Assistant to the Administrator, Federal Highway Administration. Effective November 2, 2000.

Special Assistant to the Director, Office of Public Affairs. Effective November 2, 2000.

Deputy Director of Public Affairs to the Assistant to the Secretary and Director of Public Affairs. Effective November 2, 2000.

Intergovernmental Liaison Officer to the Director, Office of Intergovernmental Affairs. Effective November 6, 2000.

Small Business Administration

Special Assistant to the Deputy Chief of Staff. Effective November 22, 2000.

Scheduler to the Deputy Administrator. Effective November 22, 2000.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1954–1958 Comp.; P.218.

Office of Personnel Management.

Janice R. Lachance,

Director.

[FR Doc. 01–1747 Filed 1–19–01; 8:45 am]

BILLING CODE 6325–01–U

SECURITIES AND EXCHANGE COMMISSION

[Rule 17a–12; SEC File No. 270–442; OMB Control No. 3235–0498]

Submission for OMB Review; Comment Request

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

- Rule 17a–12, Reporting Requirements for OTC Derivatives Dealers

Rule 17a–12 under the Securities Exchange Act of 1934 requires OTC derivatives dealers to file quarterly Financial and Operational Combined Uniformed Single Reports (FOCUS) on Form X–17A–5IIB,[1] the basic document for reporting the financial and operational condition of OTC

[1] Form X–17a–5 [17 C.F.R. 249.617].

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derivatives dealers. Rule 17a–12 also requires that OTC derivatives dealers annually file audited financial statements. The reports required under Rule 17a–12 provide the Commission with information used to monitor the operations of OTC derivatives dealers and to enforce their compliance with the Commission's rules. These reports also enable the Commission to review the business activities of OTC derivatives dealers and to anticipate, where possible, how these dealers may be affected by significant economic events.

The staff estimates that that the average amount of time necessary to prepare and file the information required by Rule 17a–12 is 180 hours per OTC derivatives dealer annually, where the OTC derivatives dealer spends an average of twenty hours preparing each of four quarterly reports, and an additional 100 hours on the annual audit. One entity is presently registered as an OTC derivatives dealer, however the staff estimates that between five and nine additional OTC derivatives dealers may become registered within the next three years. Thus the total burden is estimated to be 1,080 hours annually for six OTC derivatives dealers.[2]

The staff believes that financial reporting specialists will prepare the FOCUS IIB Reports and supporting Schedules, compliance personnel may review the reports to assure compliance with applicable rules, and accountants will prepare the audited annual reports. The staff estimates that the hourly salary of a financial reporting specialist is $72.40 per hour,[3] the hourly salary of a compliance manager is $82.50 per hour,[4] and the hourly salary of a compliance manager is $51.60 per hour.[5] Based upon these numbers, the total cost of compliance for six respondents is $65,950.00 per year.[6]

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

General comments regarding the estimated burden hours should be directed to the following persons: (i) Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, New Executive Office Building, Washington, DC 20503; and (ii) Michael E. Bartell, Associate Executive Director, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW, Washington, DC 20549. Comments must be submitted to OMB within thirty days of this notice.

Dated: January 9, 2001.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1748 Filed 1–19–01; 8:45 am]

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[2] Or 1,800 hours annually for ten OTC derivatives dealers.

[3] Per Securities Industry Association (SIA) Management and Professional Earnings, Table 011 (Financial Reporting Manager) + 35% overhead (based on end-of-year 1998 figures).

[4] SIA Management and Professional Earnings, Table 051 (Compliance Manager) + 35% overhead (based on end-of-year 1998 figures.)

[5] SIA Management and Professional Earnings, Table 003 (Senior Accountant) + 35% overhead (based on end-of-year 1998 figures).

[6] ((19 hours × $72.40 × 4 filings per year) + (1 hour × $82.50 per hour × 4 filings per year) + (100 hours × $51.60 × 1 filing per year) × six OTC derivatives dealers. The total cost for ten respondents would be $109,924.00 per year.

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–24826; 813–212]

BankBoston Co-Investment Partners (1999) L.P. and FleetBoston Financial Corporation; Notice of Application

January 11, 2001.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 ("Act") granting an exemption from all provisions of the Act, except section 9, section 17 (other than certain provisions of paragraphs (a), (d), (e), (f), (g), and (j)), section 30 (other than certain provisions of paragraphs (a), (b), (e), and (h)), sections 36 through 53, and the rules and regulations under the Act.

SUMMARY OF APPLICATION: Applicants request an order to exempt certain partnerships and other entities formed for the benefit of key employees of FleetBoston Financial Corporation and its affiliates from certain provisions of the Act. Each partnership or other entity will be an employees' securities company within the meaning of section 2(a)(13) of the Act.

APPLICANTS: BankBoston Co-Investment Partners (1999) L.P. ("Initial Partnership") and FleetBoston Financial Corporation, on behalf of other partnerships or other investment vehicles which have been or may in the future be formed or through which a Partnership (as defined below) may invest ("Other Partnerships," and together with the Initial Partnership, "Partnerships").

FILING DATES: The application was filed on August 18, 1999, and amended on January 11, 2001.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 5, 2001, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549–0609. Applicants: BankBoston Co-Investment Partners (1999) L.P., 175 Federal Street, Boston, MA 02110; FleetBoston Financial Corporation, 100 Federal Street, Boston, MA 02110.

FOR FURTHER INFORMATION CONTACT: Christine Y. Greenlees, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549–0102 (tel. 202–942–8090).

Applicants' Representations

1. FleetBoston Financial Corporation is a diversified financial services company organized under the laws of the State of Rhode Island. FleetBoston Financial Corporation and its affiliates (as defined in rule 12b–2 under the Securities Exchange Act of 1934 (the "Exchange Act"), other than Third Party Funds (as defined below), are referred to in this notice collectively as "FleetBoston."

2. The Initial Partnership is a limited partnership organized under the laws of the State of Delaware. FleetBoston formed the Initial Partnership to provide investment opportunities to certain of its key employees.

3. FleetBoston may organize Other Partnerships in the future. Each Partnership will be a limited partnership or limited liability company formed as an "employees' securities company" within the meaning of section 2(a)(13) of the Act, and will operate as a closed-end, non-diversified, management investment company.[1] The Partnerships will be established primarily for the benefit of highly compensated employees of FleetBoston as part of a program designed to create capital building opportunities that are competitive with those at other investment banking firms and to facilitate the recruitment of high caliber professionals. Participation in a Partnership will be voluntary.

4. Each Partnership will have a general partner ("General Partner") that is an affiliate that controls, is controlled by or is under common control with FleetBoston Financial Corporation. The General Partner or another FleetBoston entity will act as the investment adviser to a Partnership and will be: (a) Registered as an investment adviser under the Investment Advisers Act of 1940 (the "Advisers Act"), (b) exempt from the registration requirements of the Advisers Act by virtue of section 203(b)(3) of the Advisers Act, or (c) excluded from the definition of investment adviser under the Advisers Act because it is a bank or a bank holding company. BBI Management Co. LLC, a Delaware limited liability company, the members of which will be affiliates that control, are controlled by or are under common control with FleetBoston Financial Corporation, will act as the General Partner of the Initial Partnership. BBI Management Co. LLC is exempt from registration under the Advisers Act.

5. The General Partner will manage, operate, and control each of the Partnerships. However, the General Partner may exercise its authority through its board of managers or directors, including a committee of FleetBoston employees.[2] The General Partner will delegate management responsibility only to entities that control, are controlled by, or are under common control with FleetBoston.

6. Interests in the Partnerships ("Interests") will be offered without registration in reliance on section 4(2) of the Securities Act of 1933 (the "Securities Act"), or Regulation D under the Securities Act, and will be sold only to "Eligible Employees," as defined below. Prior to offering Interests to an Eligible Employee, the General Partner must reasonably believe that the Eligible Employee will be a sophisticated investor capable of understanding and evaluating the risks of participating in the Partnership without the benefit of regulatory safeguards. An Eligible Employee is an individual who is a current or former employee, officer, director, or "Consultant"[3] of FleetBoston and: (a) Meets the standards of an "accredited investor," as defined in rule 501(a)(5) or (6) of Regulation D under the Securities Act (an "Accredited Investor"), or (b) is one of a maximum of 35 individuals who is not an Accredited Investor but who meets certain salary and other requirements ("Other Investors").

7. Each Other Investor will be an Eligible Employee who: (a) Is a "knowledgeable employee," as defined in rule 3c–5 under the Act, of such Partnership (with the Partnership treated as though it were a "Covered Company" for purposes of the rule), or (b) has a graduate degree in business, law, or accounting, has a minimum of five years of consulting, investment banking, or similar business experience, and has had reportable income from all sources of at least $125,000 in each of the two most recent years, and has a reasonable expectation of income from all sources of at least $150,000 in each year in which the Other Investor will be committed to make investments in a Partnership. In addition, an Other Investor qualifying under (b) above will not be permitted to invest in any year more than 10% of his or her income from all sources for the immediately preceding year in the aggregate in the Partnership and in all other Partnerships in which he or she has previously invested.

8. In the discretion of FleetBoston and at the request of an Eligible Employee, an Eligible Employee may assign Interests to an Eligible Family Member or a Qualified Entity, both as defined below (each a "Qualified Participant"). a Qualified Participant that purchases an Interest from a Partner[4] must be an accredited investor under rule 501(a) of Regulation D. An "Eligible Family Member" is a parent, sibling, spouse, child, or grandchild of an Eligible Employee. A "Qualified Entity" is: (a) A trust of which the trustee, grantor, and/or beneficiary is an Eligible Employee, (b) a partnership, corporation, or other entity controlled by an Eligible Employee,[5] or (c) a trust or other entity established solely for the benefit of Eligible Family Members of an Eligible Employee.

9. The terms of a Partnership will be fully disclosed to each Eligible Employee in a partnership agreement (the "Limited Partnership Agreement"), which will be furnished at the time the Eligible Employee is invited to participate in the Partnership. Each Partnership will send audited financial statements to each Partner as soon as practicable after the end of its fiscal year. In addition, each person who was a Limited Partner[6] of such Partnership at any time during the fiscal year then ended will receive a report setting forth such tax information as will be necessary for the preparation by the Limited Partner of his, her or its federal and state income tax returns.

10. Interests in a Partnership will be non-transferable except with the prior written consent of the General Partner. No person or entity will be admitted into a Partnership as a Partner unless the person or entity is an Eligible Employee, a Qualified Participant, or a FleetBoston entity. Interests in the Partnerships will be sold without a sales load.

11. An Eligible Employee's Interest in a Partnership may be subject to repurchase or cancellation if: (a) The Eligible Employee's relationship with FleetBoston is terminated for cause, or (b) the Eligible Employee's employment with FleetBoston ends for any reason. Upon repurchase or cancellation, the General Partner will pay to the Eligible Employee at least the lesser of: (a) The amount paid by the Eligible Employee to acquire the Interest (less prior distributions, plus a specified rate of return, as determined by the General Partner), or (b) the fair market value of the Interest as determined in good faith at the time of repurchase or cancellation by the General Partner. The terms of any repurchase or cancellation will apply equally to any Qualified Participant of an Eligible Employee.

[1] A Partnership may implement its investment program by investing through another Partnership.

[2] References in this notice to the "directors of the General Partner" shall include such board of managers or directors, including a committee of FleetBoston employees.

[3] A "Consultant" is a person or entity who FleetBoston has engaged on retainer to provide services and professional expertise on an ongoing basis as a regular consultant or as a business or legal adviser to FleetBoston and who shares a community of interest with FleetBoston and FleetBoston's employees.

[4] "Partner" means any partner of a Partnership, including the General Partner unless otherwise specified.

[5] The inclusion of partnerships, corporations, or other entities controlled by an Eligible Employee in the definition of "Qualified Entities" is intended to enable Eligible Employees to make investments in the Partnerships through personal investment vehicles for the purpose of personal and family investment and estate planning objectives. Eligible Employees will exercise investment discretion or control over these investment vehicles, thereby creating a close nexus between FleetBoston and these investment vehicles. In the case of a partnership, corporation, or other entity controlled by a Consultant entity, individual participants will be limited to senior level employees, members, or partners of the Consultant who will be required to qualify as an "accredited investor" under 501(a)(6) of Regulation D and who will have access to the General Partner and/or FleetBoston.

[6] "Limited Partner" means any limited partner of a Partnership within the meaning of the Delaware Limited Partnership Act.

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12. Subject to the terms of the applicable Partnership Agreement, a Partnership will be permitted to enter into transactions involving: (a) A FleetBoston entity, (b) a portfolio company, (c) any Partner or person or entity affiliated with a Partner, (d) an investment fund or separate account that is organized for the benefit of investors who are not affiliated with FleetBoston and over which a FleetBoston entity will exercise investment discretion ("Third Party Fund"), or (e) any partner or other investor of a Third Party Fund that is not affiliated with FleetBoston (a "Third Party Investor"). These transactions may include a Partnership's purchase or sale of an investment or an interest from or to any FleetBoston entity or Third Party Fund, acting as principal. Prior to entering into these transactions, the General Partner must determine that the terms are fair to the Partners.

13. A Partnership will not invest more than 15% of its assets in securities issued by registered investment companies (with the exception of temporary investments in money market funds). A partnership will not acquire any security issued by a registered investment company if, immediately after the acquisition, the Partnership will own more than 3% of the outstanding voting stock of the registered investment company.

14. A FleetBoston entity (including the General Partner) acting as agency or broker may receive placement fees, advisory fees, or other compensation from a Partnership in connection with a Partnership's purchase or sale of securities, provided the placement fees, advisory fees, or other compensation are "usual and customary." Fees or other compensation will be deemed "usual and customary" only if: (a) The Partnership is purchasing or selling securities with other unaffiliated third parties, including Third Party Funds, (b) the fees or compensation being charged to the Partnership are also being charged to the unaffiliated third parties, including Third Party Funds, and (c) the amount of securities being purchased or sold by the Partnership does not exceed 50% of the total amount of securities being purchased or sold by the Partnership and the unaffiliated third parties, including Third Party Funds. A FleetBoston entity (including the General Partner) also may be compensated for services to entities in which the Partnerships invest and to entities that are competitors of these entities, and may otherwise engage in normal business activities that conflict with the interests of the Partnerships.

15. A Partnership may pay the General Partner an annual management fee, a flat administrative fee or a "carried interest."[7] The administrative fee will serve to reimburse the General Partner for its costs of managing the Partnership, and will include expenses incurred by a FleetBoston entity for services actually rendered to the Partnership without any additional markup.

16. The General Partner or another FleetBoston entity may make loans to a Partnership. Any such loans will bear interest at a rate no less favorable to a Partnership than the rate that could be obtained on an arm's length basis. Any such indebtedness of a Partnership will be non-recourse to the Partners other than the General Partner.

Applicants' Legal Analysis

1. Section 6(b) of the Act provides, in part, that the SEC will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the SEC will consider, in determining the provisions of the Act from which the company should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company, in relevant part, as any investment company all of whose securities are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) provides that, in connection with any order exempting an investment company from any provision of section 7, certain provisions of the Act, as specified by the SEC, will be applicable to the company and other persons dealing with the company as though the company were registered under the Act. Applicants request an order under sections 6(b) and 6(e) of the Act exempting the Partnerships from all provisions of the Act, except section 9, section 17 (other than certain provisions of paragraphs (a), (d), (e), (f), (g), and (j)), section 30 (other than certain provisions of paragraphs (a), (b), (e), and (h)), sections 36 though 53, and the rules and regulations under the Act.

3. Section 17(a) generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the company. Applicants request an exemption from section 17(a) to permit: (a) A FleetBoston entity or a Third Party Fund (or any affiliated person, as defined in the Act, of any FleetBoston entity or Third Party Fund), acting as principal, to engage in any transaction directly or indirectly with any Partnership or any company controlled by the Partnership; (b) any Partnership to invest in or engage in any transaction with any FleetBoston entity (or any affiliated person, as defined in the Act, of the FleetBoston entity), acting as principal, (i) in which the Partnership, any company controlled by the Partnership, or any FleetBoston entity or Third Party Fund has invested or will invest, or (ii) with which the Partnership, any company controlled by the Partnership, or any FleetBoston entity or Third Party Fund is or will become otherwise affiliated; and (c) any Third Party Investor, acting as principal, to engage in any transaction directly or indirectly with a Partnership or any company controlled by the Partnership.

4. Applicants state that an exemption from section 17(a) is consistent with the protection of investors and is necessary to promote the purpose of the Partnerships. Applicants state that the Participants[8] in each Partnership will be fully informed of the extent of the Partnership's dealings with FleetBoston. Applicants also state that, as professionals employed in the banking and financial services businesses, Participants will be able to understand and evaluate the attendant risks. Applicants assert that the community of interest among the Participants and FleetBoston will provide the best protection against any risk of abuse.

[7] A "carried interest" is an allocation to the General Partner based on the net gains of an investment program. A General Partner that is registered as an investment adviser under the Advisers Act may charge a carried interest only if permitted by rule 205–3 under the Advisers Act. Any carried interest paid to a General Partner that is not registered under the Advisers Act will be structured to comply with section 205(b)(3) of the Advisers Act as if a Partnership were a business development company as defined in the Advisers Act.

[8] "Participant" means any Partner other than the General Partner.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person or principal underwriter of a registered investment company, or any affiliated person of an affiliated person or principal underwriter, acting as principal, from participating in any joint arrangement with the company unless authorized by the SEC. Applicants request exemptive relief to permit affiliated persons of each Partnership, or affiliated persons of any of these persons, to participate in, or effect any transaction in connection with, any joint enterprise or other joint arrangement or profit-sharing plan in which the Partnership or a company controlled by the Partnership is a participant.

6. Applicants submit that it is likely that suitable investments will be brought to the attention of a Partnership because of its affiliation with FleetBoston or FleetBoston's large capital resources, and its experience in structuring complex transactions. Applicants also submit that the types of investment opportunities considered by a Partnership often require each investor to make funds available in an amount that may be substantially greater than what a Partnership may make available on its own. Applicants contend that, as a result, the only way in which a Partnership may be able to participate in these opportunities may be to co-invest with other persons, including its affiliates. Applicants note that each Partnership will be primarily organized for the benefit of employee Participants as an incentive for them to remain with FleetBoston and for the generation and maintenance of goodwill. Applicnts believe that, if co-investments with FleetBoston are prohibited, the appeal of the Partnerships would be significantly diminished. Applicants assert that Eligible Employees wish to participate in co-investment opportunities because they believe that (a) the resources of FleetBoston enable it to analyze investment opportunities to an extent that individual employees would not be able to duplicate, (b) investments made by FleetBoston will not be generally available to investors even of the financial status of the Eligible Employees, and (c) Eligible Employees will be able to pool their investment resources, thus achieving greater diversification of their individual investment portfolios.

7. Applicants assert that the flexibility to structure co-investments and joint investments will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent. Applicants state that the concern that permitting co-investments by FleetBoston and a Partnership might lead to less advantageous treatment of the Partnership should be mitigated by the fact that FleetBoston will be acutely concerned with its relationship with the investors in the Partnership, and the fact that senior officers and directors of FleetBoston entities will be investing in the Partnership. In addition, applicants assert that strict compliance with section 17(d) would cause the Partnership to forego investment opportunities simply because a Participant or other affiliated person of the Partnership (or any affiliate of the affiliated person) made a similar investment.

8. Co-investments with Third Party Funds, or by a FleetBoston entity pursuant to a contractual obligation to a Third Party Fund, will not be subject to condition 3 below. Applicants note that it is common for a Third Party Fund to require that FleetBoston invest its own capital in Third Party Fund investments, and that FleetBoston investments be subject to substantially the same terms as those applicable to the Third Party Fund. Applicants believe it is important that the interests of the Third Party Fund take priority over the interests of the Partnerships, and that the Third Party Fund not be burdened or otherwise affected by activities of the Partnerships. In addition, applicants assert that the relationship of a Partnership to a Third Party Fund is fundamentally different from a Partnership's relationship to FleetBoston. Applicants contend that the focus of, and the rationale for, the protections contained in the requested relief are to protect the Partnerships from any overreaching by FleetBoston in the employer/employee context, whereas the same concerns are not present with respect to the Partnerships vis-á-vis a Third Party Fund.

9. Section 17(e) of the Act and rule 17e–1 under the Act limit the compensation an affiliated person may receive when acting as agent or broker for a registered investment company. Applicants request an exemption from section 17(e) to permit a FleetBoston entity (including the General Partner) that acts as an agent or broker to receive placement fees, advisory fees, or other compensation from a Partnership in connection with the purchase or sale by the Partnership of securities, provided that the fees or other compensation are deemed "usual and customary." Applicants state that for the purposes of the application, fees or other compensation that are charged or received by a FleetBoston entity will be deemed "usual and customary" only if: (a) The Partnership is purchasing or selling securities with other unaffiliated third parties, including Third Party Funds, (b) the fees or compensation being charged to the Partnership are also being charged to the unaffiliated third parties, including Third Party Funds, and (c) the amount of securities being purchased or sold by the Partnership does not exceed 50% of the total amount of securities being purchased or sold by the Partnership and the unaffiliated third parties, including Third Party Funds. Applicants assert that, because FleetBoston does not wish it to appear as if it is favoring the Partnerships, compliance with section 17(e) would prevent a Partnership from participating in transaction where the Partnership is being charged lower fees than unaffiliated third parties. Applicants assert that the fees or other compensation paid by a Partnership to a FleetBoston entity will be the same as those negotiated at arm's length with unaffiliated third parties.

10. Rule 17e–1(b) requires that a majority of directors who are not "interested persons" (as defined in section 2(a)(19) of the Act) take actions and make approvals regarding commissions, fees, or other remuneration. Applicants request an exemption from rule 17e–1(b) to the extent necessary to permit each partnership to comply with the rule without having a majority of the directors of the General Partner who are not interested persons take actions and make determinations as set forth in the rule. Applicants state that because all the directors of the General Partner will be affiliated persons, without the relief requested, a Partnership could not comply with rule 17e–1(b). Applicants state that each Partnership will comply with rule 17e–1(b) by having a majority of the board of directors of the General Partner take actions and make approvals as are set forth in rule 17e–1. Applicants state that each Partnership will comply with all other requirements of rule 17e–1 for the transactions described above in the discussion of section 17(e).

11. Section 17(f) provides that the securities and similar investments of a registered management investment company must be placed in the custody of a bank, a member of a national securities exchange, or the company itself in accordance with SEC rules. Rule 17f–2 under the Act specifies the requirements that must be satisfied for a registered management investment company to act as a custodian of its own investments. Applicants request an exemption from section 17(f) of the Act and rule 17f–2 under the Act to permit the following exceptions from the requirements of rule 17f–2: (a) A

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Partnership's investments may be kept in the locked files of a FleetBoston entity; (b) for purposes of paragraph (d) of the rule, (i) employees of FleetBoston will be deemed to be employees of the Partnerships, (ii) officers or managers of the General Partner of a Partnership will be deemed to be officers of the Partnership, and (iii) the General Partner of a Partnership or its board of directors will be deemed to be the board of directors of the Partnership; and (c) in place of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two employees of FleetBoston. Applicants expect that many of the Partnerships' investments will be evidenced only by partnership agreements, participation agreements, or similar documents, rather than by negotiable certificates that could be misappropriated. Applicants assert that these instruments are most suitably kept in the files of a FleetBoston entity, where they can be referred to as necessary.

12. Section 17(g) of the Act and rule 17g–1 under the Act generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g–1 requires that a majority of directors who are not interested persons take certain actions and give certain approvals relating to fidelity bonding. Applicants request exemptive relief to permit the General Partner's board of directors, who may be deemed interested persons, to take actions and make determinations as set forth in the rule. Applicants state that, because all directors of the General Partner will be affiliated persons, a Partnership could not comply with rule 17g–1 without the requested relief. Specifically, each Partnership will comply with rule 17g–1 by having a majority of the Partnership's directors take actions and make determinations as are set forth in rule 17g–1. Applicants also state that each Partnership will comply with all other requirements of rule 17g–1.

13. Section 17(j) of the Act and paragraph (b) of rule 17j–1 under the Act make it unlawful for certain enumerated persons to engage in fraudulent or deceptive practices in connection with the purchase or sale of a security held or to be acquired by a registered investment company. Rule 17j–1 also requires that every registered investment company adopt a written code of ethics and that every access person of a registered investment company report personal securities transactions. Applicants request an exemption from the provisions of rule 17j–1, except for the anti-fraud provisions of paragraph (b), because they are unnecessarily burdensome as applied to the Partnerships.

14. Applicants request an exemption from the requirements in sections 30(a), 30(b), and 30(e), and the rules under those sections, that registered investment companies prepare and file with the SEC and mail to their shareholders certain periodic reports and financial statements. Applicants contend that the forms prescribed by the SEC for periodic reports have little relevance to the Partnerships and would entail administrative and legal costs that outweigh any benefit to the Partners. Applicants request exemptive relief to the extent necessary to permit each Partnership to report annually to its Participants. Applicants also request an exemption from section 30(h) to the extent necessary to exempt the General Partner of each Partnership, members of the General Partner, or any board of managers or directors or committee of FleetBoston employees to whom the General Partner may delegate its functions, and any other persons who may be deemed to be members of an advisory board of a Partnership, from filing Forms 3, 4, and 5 under section 16(a) of the Exchange Act with respect to their ownership of Interests in the Partnership. Applicants assert that, because there will be no trading market and the transfers of Interests will be severely restricted, these filings are unnecessary for the protection of investors and burdensome to those required to make them.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each proposed transaction otherwise prohibited by section 17(a) or section 17(d) of the Act and rule 17d–1 under the Act to which a Partnership is a party (the "Section 17 Transactions") will be effected only if the General Partner determines that: (a) The terms of the transaction, including the consideration to be paid or received, are fair and reasonable to the Partners of such Partnership and do not involve overreaching of such Partnership or its Partners on the part of any person concerned; and (b) the transaction is consistent with the interests of the Partners of such Partnership, such Partnership's organizational documents, and such Partnership's reports to its Partners. In addition, the General Partner of each Partnership will record and preserve a description of the Section 17 Transactions, the General Partner's findings, the information or materials upon which the findings are based, and the basis therefor. All records relating to an investment program will be maintained until the termination of the investment program and for at least two years thereafter, and will be subject to examination by the Commission and its staff.[9]

2. In connection with the Section 17 Transactions, the General Partner of each Partnership will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for such Partnership, or any affiliated person of such a person, promoter, or principle underwriter.

3. The General Partner of each Partnership will not invest the funds of such Partnership in any investment in which a "Co-Investor" (as defined below) has acquired or proposes to acquire the same class of securities of the same issuer, and where the investment transaction involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which such Partnership and the Co-Investor are participants, unless any such Co-Investor, prior to disposing of all or part of its investment: (a) Gives such General Partner sufficient, but not less than one day's, notice of its intent to dispose of its investment, and (b) refrains from disposing of its investment unless such Partnership has the opportunity to dispose of such Partnership's investment prior to or concurrently with, on the same terms as, and pro rata with, the Co-Investor. The term "Co-Investor" with respect to any Partnership means any person who is: (a) An "affiliated person" (as such term is defined in the act) of such Partnership (other than a Third Party Fund); (b) FleetBoston; (c) an officer or director of FleetBoston; or (d) an entity (other than a Third Party Fund) in which the General Partner acts as a general partner or has a similar capacity to control the sale or disposition of the entity's securities. The restrictions contained in this condition shall not be deemed to limit or prevent the disposition of an investment by a Co-Investor: (a) To its direct or indirect wholly-owned subsidiary, to any company (a "parent") of which such Co-Investor is a direct or indirect wholly-owned subsidiary, or to a direct or indirect wholly-owned subsidiary of its parent; (b) to immediate family members of such Co-Investor or a trust or other investment vehicle established for any such family member; (c) when the investment is comprised of securities that are listed on any exchange registered as a national securities exchange under section 6 of the Exchange Act; (d) when the investment is comprised of securities that are national market system securities pursuant to section 11A(a)(2) of the Exchange Act and rule 11Aa2–1 thereunder; or (e) when the investment is comprised of securities that are listed on or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system for securities.

[9] Each Partnership will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

4. Each Partnership and the General Partner will maintain and preserve, for the life of such Partnership and for at least two years thereafter, such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements that are to be provided to the Participants in such Partnership, and each annual report of such Partnership required to be sent to such Partnerships, and agree that all such records will be subject to examination by the Commission and its staff.[10]

5. The General Partner of each Partnership will send to each Participant in such Partnership who had an interest in any capital account of such Partnership, at any time during the fiscal year then ended, Partnership financial statements audited by such Partnership's independent accountants. At the end of each fiscal year, the General Partner will make a valuation or have a valuation made of all of the assets of the Partnership as of such fiscal year end in a manner consistent with customary practice with respect to the valuation of assets of the kind held by the Partnership. In addition, as soon as practicable after the end of each fiscal year of each Partnership, the General Partner of such Partnership will send a report to each person who was a Participant in such Partnership at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Participant of his, her, or its federal and state income tax returns, and a report of the investment activities of the Partnership during that fiscal year.

6. In any case where purchases or sales are made by a Partnership from or to an entity affiliated with such Partnership by reason of a 5% or more investment in the entity by a FleetBoston employee, officer, or director, such individual will not participate in such Partnership's determination of whether or not to effect such purchase or sale.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1651 Filed 1–19–01; 8:45am]

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[10] Each Partnership will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–27337]

Filings Under the Public Utility Holding Company Act of 1935, as amended ("Act")

January 12, 2001.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendment(s) is/are available for public inspection through the Commission's Branch of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 6, 2001, to the Secretary, Securities and Exchange Commission, Washington, DC 20549–0609, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of facts or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After February 6, 2001, the application(s) and/or declaration, as filed or as amended, may be granted and/or permitted to become effective.

Ameren Corporation Fuels and Services Company (70–9775)

Ameren Energy Fuels and Services Company ("Ameren Fuels"), 1901 Chouteau Avenue, St. Louis, Missouri 63103, an indirect wholly owned nonutility subsidiary of Ameren Corporation, a registered holding company, has filed a declaration under sections 12(b) and 13(b) of the Act and rules 54, 90, and 91 under the Act.

Ameren owns all of the issued and outstanding common stock of Union Electric Company ("Union Electric") and Central Illinois Public Service Company ("DIPS"), each of which is an electric and gas utility company. Together, Union Electric and CIPS provide retail and wholesale electric and retail natural gas services to customers in Missouri and Illinois. Ameren Services Company ("Ameren Services"), a subsidiary service company of Ameren, currently provides various administrative and management services to Union Electric and CIPS and other companies in the Ameren system.

Ameren's direct nonutility subsidiaries include Ameren Energy Resources Company (Ameren Resources), and intermediate subsidiary that holds the securities of other exempt and authorized nonutility companies. Ameren Resources indirectly owns all of the issued and outstanding common stock of Ameren Energy Generating Company ("Ameren GenCo"), an "exempt wholesale generator" ("EWG"). Ameren GenCo was formed to acquire all of the generating assets of CIPS, which occurred in May 2000. Ameren Resources also holds all of the common stock of Ameren Fuels, which was formed to engage in fuels-related businesses that are permitted by rule 58.

Ameren Fuels is requesting authorization to provide fuel procurement and natural gas supply services to (including acting as agent for) Union Electric and CIPS. The services, which are similar to those that Ameren Services currently provides to Union Electric and CIPS, would be performed "at cots" in accordance with Section 13(b) and Rules 90 and 91 of the Act. Ameren Fuels proposes to provide these services pursuant to the terms of a Fuel and Natural Gas Services Agreement ("Agreement"), which was filed as an exhibit to this application-declaration. The Agreement will be filed with the Missouri and Illinois public utilities commissions.

Entergy Corporation (70–9749)

Entergy Corporation ("Entergy"), 639 Loyola Avenue, New Orleans, Louisiana 70113, a registered holding company,

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has filed an application-declaration under sections 6(a)(1) and (2), 7, 9(a), 10, 12(b), 12(c) and 12(e) of the Act and rules 45, 46, 53, 62 and 65.

Entergy proposes to implement an external financing program to fund its system operations by issuing and selling debt and equity securities directly or through newly organized financing subsidiaries and entering into related transactions, through June 30, 2006 ("Authorization Period"). In summary, Entergy proposes to, directly or indirectly, issue and sell common, preferred and trust preferred stock, various forms of preferred or equity-linked securities and unsecured long-term debt ("Long-Term Debt") in an aggregate amount not exceeding $2 billion ("Capital Limitation"). Additionally, Entergy proposes to issue and sell additional short-term debt in the form of notes to banks ("Notes") or commercial paper ("Paper") that in the aggregate, including existing authority to issue Notes, will not exceed an outstanding principal amount of $1.5 billion ("Short-Term Debt").[1] Entergy requests authority to solicit proxies from its common shareholders to amend its articles of incorporation to provide for the issuance of preferred stock. Entergy further proposes to acquire the equity securities of one or more special-purpose subsidiaries organized to issue trust preferred stock, preferred and equity linked securities and Long-Term Debt ("Financing Subsidiaries") and to provide guarantees for any securities issued by the Financing Subsidiaries. Finally, Entergy proposes to enter into hedging transactions regarding the existing debt ("Interest Rate hedges") or the anticipated debt ("Anticipatory hedges") authorized to be issued by itself or any of its subsidiaries.

Entergy may issue common stock, options, warrants or other stock purchase rights exercisable for common stock, under negotiated or competitively bid underwriting agreements or through private placements.[2] Entergy may also issue common stock or options, warrants or other stock purchase rights exercisable for common stock in public or privately negotiated transactions as consideration for the equity securities or assets of other companies, provided that the Commission has authorized the acquisition of the equity securities or assets or the transaction is exempt under the Act. All common stock sales will be at rates or prices and under conditions negotiated or based on, or otherwise determined by, competitive capital markets.

Entergy may issue, in one or more series, preferred stock directly and trust preferred stock and trust preferred and equity linked securities directly or indirectly through Financing Subsidiaries. The securities will be redeemed no later than 50 years after their issuance. The dividend rate for any series of preferred stock or other preferred or equity-linked securities will not exceed at the time of issuance the greater of: (1) 700 basis points over the yield to maturity of a U.S. Treasury security having a remaining term comparable to the term of that series, if issued at a fixed rate, or 700 basis points over the London Interbank Offered Rate ("LIBOR") for the relevant interest rate period, if issued at a floating rate; and (2) a rate that is consistent with similar securities of comparable credit quality and maturities issued by other companies. The preferred stock or other preferred or equity-linked securities may be convertible or exchangeable into shares of Entergy common stock.

Entergy states that its Long-Term Debt may be issued, directly or indirectly through Financing Subsidiaries, in one or more series and may be convertible into any other securities of Entergy. The Long-Term Debt will mature in no more than 50 years from the date of issuance. The maturity dates, interest rates, redemption and sinking fund provisions and conversion features of its Long-Term Debt and any associated fees and expenses will be established by negotiation or competitive bidding. The interest rate on Long-Term Debt will not exceed at the time of issuance of any particular series the greater of: (1) 600 basis points over U.S. Treasury securities having a remaining term comparable to the term of that series, if issued at a fixed rate, or 600 basis points over LIBOR for the relevant interest rate period, if issued at a floating rate; and (2) a gross spread over U.S. Treasury securities that is consistent with similar securities of comparable credit quality and maturities issued by other companies.

Entergy proposes to issue and sell from time to time Short-Term Debt in the form of Notes and/or Paper or engage in short-term financing arrangements available to borrowers with comparable credit ratings. Notes will be issued under one or more existing or new bank credit agreements that will provide credit commitments that will not in the aggregate exceed $1.5 billion. Notes will mature not more than three years from the date of issuance. Paper will be sold at the dealer's discount rate *per annum* on the day of issuance for commercial paper of comparable quality and maturities. In connection with the sale of Paper, Entergy may incur repayment obligations related to letters of credit obtained from one or more banks in support of its Paper obligations. The effective cost of money on Short-Term Debt will not exceed 500 basis points over LIBOR for the relevant interest rate period.

Entergy states that Interest Rate Hedges will only be entered into with counterparties whose senior debt ratings, or whose parent companies' senior debt ratings, as published by Standard and Poor's Ratings Group, are equal to or greater than BBB, or equivalent rating from Moody's Investors' Service or Fitch Investor Service ("Approved Parties"). Interest Rate Hedges will involve the use of financial instruments and derivatives commonly used in today's capital markets, such as interest rate swaps, options, caps, collars, floors, and structured notes or transactions involving the purchase or sale, including short sales, of U.S. Treasury obligations.

The transactions will be for fixed periods and stated notional amounts. In no case will the notional principal amount of any interest rate swap exceed that of the underlying debt instrument and related interest rate exposure. Entergy will not engage in speculative transactions. Fees, commissions and other amounts payable to the counterparty in connection with an Interest Rate Hedge will not exceed those generally obtainable in competitive markets for parties of comparable credit quality.

Entergy asserts that Anticipatory Hedges will only be entered into with Approved Parties to fix and/or limit the interest rate risk associated with any new issuance through: (1) A forward sale of exchange-traded U.S. Treasury futures contracts, U.S. Treasury obligations and/or a forward swap (each a "Forward Sale"); (2) the purchase of put options on U.S. Treasury obligations ("Put Options Purchase"); (3) a Put Options Purchase in combination with the sale of call options on U.S. Treasury obligations ("Zero Cost Collar"); (4) transactions involving the purchase or sale, including short sales, of U.S. Treasury obligations; or (5) some combination of a Forward Sale, Put Options Purchase, Zero Cost Collar and/or other derivative or cash transactions, including, but not limited to structured notes, options, caps and collars, appropriate for the Anticipatory Hedges.

Entergy represents that each Interest Rate Hedge and Anticipatory Hedge will qualify for hedge accounting treatment under generally accepted accounting principles. Entergy will comply with the then existing financial disclosure requirements of the Financial Accounting Standards Board associated with hedging transactions.

Entergy states that the Financing Subsidiaries will be organized for the specific purpose of financing the system's authorized and exempt investment activities. It proposes to use the proceeds from the sale of trust preferred stock, preferred or equity-linked securities and Long-Term Debt to pay dividends, including dividends out of capital, to Entergy, to make loans to Entergy and to otherwise transfer the financing proceeds to, or as directed by, Entergy.[3] Entergy also proposes to guarantee, provide support for or enter into expense agreements in respect to the obligations of any Financing Subsidiary. The amount of any Long-Term Debt or preferred securities issued by any Financing Subsidiary will be counted against the Capital Limitation, to the extent that Entergy guarantees those securities.

[1] By order dated February 26, 1997 (HCAR No. 26674), ("February 1997 Order"), Entergy was authorized to issue and sell notes to banks in an outstanding principal amount of up to $500 million, through December 31, 2002.

[2] By prior Commission order dated December 15, 2000 (HCAR No. 27300), Entergy was authorized to issue and sell up to 30 million shares of its common stock, through June 30, 2006, under its Dividend Reinvestment and Stock Purchase Plan ("Order"). Entergy proposes that the authority to sell common stock requested in this matter be in addition to the authority granted in the Order.

Entergy Louisiana, Inc. (70–7580)

Entergy Louisiana, Inc. ("Entergy Louisiana"), 639 Loyola Avenue, New Orleans, Louisiana 70113, a public-utility subsidiary company of Entergy Corporation, a registered holding company, has filed a post-effective amendment to its application under sections 9(a) and 10 of the Act and rule 54 under the Act.

By prior Commission orders dated February 2, 1989, January 24, 1991, January 24, 1996, and October 15, 1999 (HCAR Nos. 24810, 25246, 26460, and 27087, respectively) ("Prior Orders"), Entergy Louisiana was authorized to enter into and amend a Fuel Lease dated January 31, 1989 ("Lease"), with River Fuel Company # 2, Inc. ("River Fuel"), under which Entergy Louisiana leases nuclear fuel required for use at its Waterford 3 nuclear generating unit ("Waterford 3"). Under the terms of the Lease, River Fuel makes payments to suppliers, processors, and manufacturers necessary to provide nuclear fuel for Waterford 3, or Entergy Louisiana makes these payments and receives reimbursement from River Fuel. Entergy Louisiana is required to make rental payments in amounts necessary for River Fuel to meet its debt service requirements and other expenses.

In accordance with the terms of the Prior Orders, Entergy Louisiana consented to allow River Fuel to finance the acquisition of nuclear fuel through: (a) Revolving credit borrowings and/or the issuance of commercial paper pursuant to an Amended and Restated Credit Agreement, dated November 19, 1999 (the "1999 Credit Agreement"), with the Bank of New York, as agent, and various other lenders; and (b) the issuance and sale of intermediate term secured notes to institutional investors. The commercial paper issued under the 1999 Credit Agreement is supported by irrevocable direct-pay letters of credit issued by the lenders. The Prior Orders further provide that River Fuel's combined obligations under its credit facility and its outstanding intermediate term secured notes may at no time exceed $160 million.

In accordance with the Prior Orders, River Fuel is currently authorized to pay interest under the 1999 Credit Agreement: (a) In the case of base rate borrowings, at a maximum rate equal to the higher of (i) the prime rate in effect on the date of the borrowings, and (ii) the sum of 1% per annum and the Federal Funds Rate in effect on the date of the borrowings, and (ii) the sum of 1% per annum and the Federal Funds Rate in effect on the date of the borrowings; and (b) in the case of borrowings based on the London Interbank Offered Rate ("LIBOR"), a maximum rate of interest equal to 2% per annum above LIBOR.

Also, in accordance with the Prior Orders River Fuel is currently authorized to pay the following fees under the 1999 Credit Agreement: (1) A maximum letter of credit fee of 1% per annum on the average aggregate face amount of commercial paper outstanding during each quarter that Entergy Louisiana's senior debt is investment grade, and 1⅞ per annum on the average aggregate face amount of commercial paper outstanding during each quarter that Entergy Louisiana's senior debt is not investment grade; (2) a maximum commitment fee of ¼ of 1% per annum on the difference between the maximum commitment under the 1999 Credit Agreement and the average daily amount of commercial paper and revolving credit loans outstanding under the 1999 Credit Agreement during each quarter, and (3) a maximum administrative fee of $10,000 per annum.

The Lease prohibits River Fuel from amending the 1999 Credit Agreement or entering into any successor credit agreement without Entergy Louisiana's consent. Due to changes in the credit markets that have occurred since the execution of the 1999 Credit Agreement Entergy Louisiana now proposes to consent to the execution by River Fuel of a new credit agreement and any successor credit agreements.

Specifically, Energy Louisiana proposes to consent to the execution by River Fuel of a new credit agreement, and any successor credit agreements, with loans bearing interest at rates not in excess of those rates generally obtainable at the time for loans having the same or reasonably similar maturities, obtained by companies of the same or reasonably comparable credit quality and having reasonably similar terms, conditions, and features.

Further, Entergy Louisiana proposes to consent to the payment by River Fuel of: (1) A maximum letter of credit of 5% per annum on the average aggregate face amount of commercial paper outstanding during each quarter, with the specific amount of such fee to be determined based upon Entergy Louisiana's senior debt rating; (2) a maximum commitment fee of 2% per annum on the difference between the maximum commitment under the new credit agreement and the average daily amount of commercial paper and revolving credit loans outstanding under the agreement during each quarter; (3) a maximum administrative fee of $50,000 per annum; and (4) maximum one-time closing fees of $1,500,000, consisting of up-front fees, arrangement fees, administrative agency fees and such other closing fees as are customary in connection with similar credit agreements.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1652 Filed 1–19–01; 8:45 am]

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[3] *See* Southern Company, Holding Co. Act Release No. 27134 (February 9, 2000).

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43840; File No. SR–BSE–00–19]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change and Amendment No. 1 of Proposed Rule Change by the Boston Stock Exchange, Inc. Relating to Its Fee Schedule

January 12, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2000, as amended on December 21, 2000,[3] the Boston Stock Exchange, Inc. ("BSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange seeks to amend its Floor Operations Fee Schedule to include a $1,000 monthly Electronic Trading Permits ("ETP") fee charged to members for each trader trading pursuant to an ETP from a remote location.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See December 20, 2000 letter from John A. Boese, Assistant Vice President, Rule Development and Market Structure, BSE, to Madge Hamilton, Division of Market Regulation, Commission (Amendment No. 1). Amendment No. 1 is reflected in this release.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Floor Operations Fee Schedule to include a $1,000 per month ETP fee. This fee will be charged to all members on a per trader basis (*i.e.*, member firms will be billed $1,000 per month per trader holding an ETP). The $1,000 monthly fee is based on the Exchange's analysis of the additional costs that are necessary to operate the BSE's BEACON system from a remote location including, but not limited to, reengineering the design of the Exchange's network, several up-front and ongoing software reprogramming and enhancement efforts, initial and ongoing telecommunication costs, maintenance of equipment at remote locations, hiring and training additional "help desk" personnel specifically for the remote locations, travel costs incurred as a result of ongoing training, system upgrades and regulatory oversight of remote locations, and the creation and updating of training manuals and documentation for remote locations.[4]

2. Statutory Basis

The basis for the proposed rule change is Section 6(b)(4) of the Act,[5] in that the proposed rule change is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its member other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

[4] The Exchange understands that its proposal regarding the Electronic Fee Permits (SR–BSE–00–13) to which the fee proposed herein applies is pending before the Commission. Accordingly, the fees will not go into effect until such time as the Electronic Fee Permit rule change proposal is approved, and the permits are issued. (The Commission notes that, on December 22, 2000, the Commission issued an approval order for the EFPs, SR–BSE–00–13. See Securities Exchange Act Release No. 43766 (December 22, 2000), 66 FR 822 (January 4, 2001).

[5] 15 U.S.C. 78f(b)(4).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change will become effective upon filing of Amendment No. 1 pursuant to Section 19(b)(3) of the Act[6] and subparagraph (e) of the Rule 19b-4.[7] At any time within 60 days of the filing of such amended proposed rule change, the Commission may summarily abrogate such rule change if appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to file number in the caption above and should be submitted by February 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[8]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1805 Filed 1–19–01; 8:45 am]

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[6] 15 U.S.C. 78s(b)(3).

[7] 17 CFR 240.19b–4(e).

[8] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43839; File No. SR–CBOE–00–61]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. To Change the Capitalization Transfer Fee Applicable to Designated Primary Market-Makers

January 12, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 22, 2000, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. On December 4, 2000, the Exchange submitted Amendment No. 1 to the proposed rule change.[3] On December 13, 2000, the Exchange submitted Amendment No. 2 to the proposed rule change.[4] On January 10, 2001, the Exchange submitted Amendment No. 3 to the proposed rule change.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposed to amend its rules regarding application of the fee for changes in ownership of Designated Primary Market Makers ("DPMs"). Below is the complete text of the proposed rule change. Proposed new text is in *italics*. Proposed deletions are in [brackets].

* * * * *

Chapter VIII—Market-Makers, Trading Crowds and Designated Primary Market-Makers

* * * * *

Transfer of DPM Appointments

Rule 8.89. (a)–(e) No change.

(f) The approval or failure to approve a proposed transfer of a DPM appointment, *and the application of the transfer fee under Interpretation .02 of this Rule to a transfer, are* [is] subject to direct review by the Board of Directors upon receipt by the Secretary of the Exchange, within ten (10) days of the time the *Board is notified of the* decision [of the MTS Committee is announced], of (i) a written request for such review made by *a person aggrieved by the decision*, specifying why the *aggrieved person* believes the decision of the Committee should be reversed or modified [(in the case of a failure to approve an application as submitted)] or (ii) a request for review made by at least five Directors of the Exchange (in any case). *For purposes of this Rule, a person must be aggrieved as described in Chapter XIX of the Exchange's rules.*

* * * Interpretations and Policies:

.01 No change.

.02 [Any DPM that is allocated, after June 29, 1999, one or more option classes traded on the Exchange prior to that date shall be subject to a transfer fee in the event of a change in the capitalization of the DPM during the five year period following the allocation of the first such option class to the DPM. For purposes of this transfer fee, a change in the capitalization of a DPM shall be deemed to include any sale, transfer, or assignment of any ownership interest in the DPM or any change in the DPM's capital structure, voting authority, or distribution of profits or losses. This transfer fee shall be equal to the larger of (i) (the applicable percentage set forth below) × (the actual dollar value of the change in capitalization of the DPM as determined by the Exchange) × (the percentage of the DPM's Market-Maker trading volume in its capacity as a DPM in the previous 12 months attributable to option classes allocated to the DPM after June 29, 1999 that were traded on the Exchange prior to that date) and (ii) (the applicable percentage set forth below) × (the current level of overall DPM profitability per contract as determined by the Exchange based on DPM financial reporting) × (the DPM's Market-Maker trading volume in the previous 12 months in option classes allocated to the DPM after June 29, 1999 that were traded on the Exchange prior to that date) × (2) × (the percentage change in the DPM's capitalization as determined by the Exchange). The applicable percentage to be used in the formulas above to determine the transfer fee to be assessed to a DPM shall be 50% in the first year of the five year period during which the DPM is subject to this transfer fee, 40% in the second year, 30% in the third year, 20% in the fourth year, and 10% in the fifth year.]

(a) Certain transfers of interest in DPM appointments that occur after October 20, 2000 shall be subject to a DPM transfer fee. The intent of the Rule is to apply a transfer fee in those instances where one or more principals in the DPM exit or significantly reduce their participation in the DPM operation. The intent of the Rule is not to assess the transfer fee to any transaction that enables a DPM to add new capital, to replace a capital partner, to merge with an existing DPM (where all pre-existing partners continue their participation in the new DPM), or that makes small changes in the ownership or profit sharing arrangement of the DPM. The MTS Committee shall determine, based on the intent of this Rule, whether the transfer fee is applicable to specific transactions.

(c) Factors to be considered in determining whether a transfer of an interest in a DPM appointment is subject to the transfer fee under this Interpretation .02 may include, but are not limited to, any one or more of the following:

*i. Is new capital being contributed to the DPM by the new principal(s)?**

ii. Are the original principals maintaining their level of capital contributions to the DPM or withdrawing capital?** If the original principals are retaining a profit allocation but are not maintaining their level of capital contributions to the DPM, have the original principals incurred financial losses with respect to their investment in the DPM?*

iii. How is the profit allocation structure changing?

*iv. What are the profit percentages allocated to the original principals in relation to the profit percentages allocated to the new principals? Are the profit percentages allocated to the new principals greater than the profit percentages allocated to the original principals?** If yes, does the difference reflect a difference in capital contributed?**

v. What are the profit percentages allocated to the principals who are active in the management of the DPM in relation to the profit percentages

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] In Amendment No. 1, the CBOE re-designated the filing as a submission pursuant to Section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2), rather than Section 19(b)(3)(A) of the Act, 15 U.S.C. 78s(b)(3)(A). *See* letter from Steve Youhn, Attorney, CBOE, to Deborah Flynn, Senior Special Counsel, Division of Market Regulation ("Division"), SEC, dated December 1, 2000 ("Amendment No. 1").

[4] In Amendment No. 2, the CBOE confirmed that its recusal standards would apply to the procedures of the Modified Trading System ("MTS") Committee described herein, and clarified certain portions of the text and description of the proposed rule change. *See* letter from Steve Youhn, Attorney, CBOE, to Deborah Flynn, Senior Special Counsel, Division, SEC dated December 8, 2000 ("Amendment No. 2").

[5] In Amendment No. 3, the CBOE amended the text of the proposed rule change to specify the formula for determining the amount of any fee imposed, and made further clarifications to the text and description of the proposed rule change. *See* letter from Steve Youhn, Attorney, CBOE, to Deborah Flynn, Senior Special Counsel, Division, SEC, dated December 28, 2000 ("Amendment No. 3").

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allocated to those principals that are primarily investors in the DPM? Are the profit percentages allocated to principals who are active in management greater than the profit percentages allocated to principals who are primarily investors? Has the profit allocation split between these two categories of principals changed significantly?***

*vi. Is the purpose of a change in profit percentages to compensate a DPM employee?**

vii. What is the level of consideration that is being received by the original principals?

*viii. Has management of the DPM changed significantly?***

*ix. Will the original principals who were active in the management of the DPM continue in that role?**

An asterisk (*) next to a factor indicates that a positive response to the question posed would be a factor in favor of not imposing the transfer fee. A double asterisk (**) next to a factor indicates that a positive response to the question posed would be a factor in favor of imposing the transfer fee.

(c) The amount of the transfer fee applicable to a specific transaction shall be equal to (the total value of the consideration, as determined by the MTS Committee, to be paid to the original DPM principals prior to June 30, 2004) × (the percentage of the DPM's Market-Maker trading volume in its capacity as a DPM in the previous 12 months attributable to option classes allocated to the DPM after June 29, 1999 that were traded on the Exchange prior to that date) × (the applicable percentage set forth below.) The fee rate percentage to be applied above is: 40% during the time period until June 29, 2001; 30% during the time period from June 30, 2001 to June 29, 2002; 20% during the time period from June 30, 2002 to June 29, 2003; and 10% during the time period from June 30, 2003 to June 29, 2004. The transfer fee expires on June 30, 2004. If the transfer of interest occurs over a period of years, the fee rate percentage applied will be consistent with the year in which the transfer occurs. As an example, if the transfer of a DPM is to occur equally over three years commencing in November 2000, then the fee rate percentage applied would be 40% for the first portion of the transfer, 30% for the second portion of the transfer, and 20% for the last portion of the transfer.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In 1999, CBOE instituted a floor-wide DPM system and awarded the appointment of options classes to DPMs at no cost in exchange for a long-term commitment to the Exchange and a fee on subsequent changes of ownership ("transfer fee"). Currently, the transfer fee, contained in Interpretation and Policy .02 to CBOE Rule 8.89, is imposed on DPMs that undergo changes in their capitalizations during a determined five-year period.[6]

As originally proposed, the Exchange detailed three primary purposes for the transfer fee. First, it was designed to provide those who own DPMs with a significant incentive to capitalize sufficiently the DPM. Second, because the Exchange believes that the allocation of existing options classes to DPMs bestows upon them a valuable right for which they paid no consideration, the Exchange believed it would be inequitable for those DPMs to sell those rights shortly thereafter by transferring all or a portion of their interest in the DPM organization to other parties. Thus, the transfer fee was established to discourage these types of transactions, or if they were to occur, to require a significant portion of the value of the transaction to be paid to the Exchange. Finally, the transfer fee was intended to assure that DPMs maintained a long-term commitment to the Exchange.

The Exchange believes that the DPM transfer fee, as structured, is not accomplishing these primary objectives and that it may be, in fact, having an unintended effect on the ability of CBOE to attract and retain well-capitalized DPMs. Specifically, the Exchange notes that the potential application of the transfer fee may be suppressing a number of proposed transactions that could strengthen the financial resources of DPMs.[7] As originally proposed, the Exchange stated that it would consider changes to the DPM transfer fee if subsequent experience indicated that such changes were necessary and appropriate.[8] In this respect, the Exchange notes that the Exchange's MTS Committee, the Lessors Advisory Committee, and the Floor Directors Committee have evaluated the DPM transfer fee and determined to modify the transfer fee so that it accomplishes its original primary objectives.

The proposed changes are intended to permit a DPM to add new capital, to make small changes in ownership or profit sharing, to replace a capital partner, or to merge with other DPMs (where all pre-existing partners continue their participation in the new DPM), all without triggering the transfer fee. Consistent with the intent of the rule, a transfer fee would continue to be assessed in cases where one or more principals of a DPM exit[s] or significantly reduce[s] their participation in the DPM operation.

To accomplish these changes, the Exchange proposes to amend Interpretation .02 to CBOE Rule 8.89 to modify the instances in which the fee would be assessed. Specifically, the Interpretation would be modified to allow the MTS Committee to analyze each proposed transaction to determine whether the transfer fee should be applied. Factors to be considered in making such a determination may include, but would not be limited to, one or more of the following:

i. Is new capital being contributed to the DPM by the new principal(s)?*

ii. Are the original principals maintaining their level of capital contributions to the DPM* or withdrawing capital**? If the original principals are retaining a profit allocation but are not maintaining their level of capital contributions to the DPM, have the original principals incurred financial losses with respect to their investment in the DPM?

iii. How is the profit allocation structure changing?

iv. What are the profit percentages allocated to the original principals in relation to the profit percentages allocated to the new principals? Are the profit percentages allocated to the new principals greater than the profit percentages allocated to the original principals?** If yes, does the difference reflect a difference in capital contributed?*

v. What are the profit percentages allocated to the principals who are active in the management of the DPM in relation to the profit percentages allocated to those principals that are primarily investors in the DPM? Are the profit percentages allocated to principals who are active in management greater than the profit percentages allocated to principals who are primarily investors?* Has the profit allocation split between these two categories of principals changed significantly?**

vi. Is the purpose of a change in profit percentages to compensate a DPM employee?*

vii. What is the level of consideration that is being received by the original principals?

viii. Has management of the DPM changed significantly?**

ix. Will the original principals who were active in the management of the DPM continue in that role?*

An asterisk (*) next to a factor listed above indicates that a positive response to the question posed would be a factor in favor of not imposing the transfer fee. A double asterisk (**) next to a factor indicates that a positive response to the question posed would be a factor in favor of imposing the transfer fee.

If after its review the MTS Committee determines that the proposed transaction should be subject to the transfer fee, the MTS Committee shall impose the fee. The Exchange proposes to replace the existing formulas for determining the amount of the transfer fee with a new formula contained in Interpretation .02(c) to Rule 8.89. The amount of the transfer fee applicable to a specific transaction would be equal to: (the total value of the consideration, as determined by the MTS Committee, to be paid to the original DPM principals prior to June 30, 2004)×(the percentage of the DPM's Market-Maker trading volume in its capacity as a DPM in the previous 12 months attributable to option classes allocated to the DPM after June 29, 1999 that were traded on the Exchange prior to that date)×(the applicable percentage set forth below.) The fee rate percentage to be applied above is: 40% during the time period until June 29, 2001; 30% during the time period from June 30, 2001 to June 29, 2002; 20% during the time period from June 30, 2002 to June 29, 2003; and 10% during the time period from June 30, 2003 to June 29, 2004.[9] The transfer fee would expire on June 30, 2004.

The Exchange also proposes to amend section (f) to Rule 8.89 to create a review process relating to the application of the transfer fee. Accordingly, this provision allows a person aggrieved by the decision to appeal the MTS Committee's decision to assess the transfer fee, as well as its determination as to the amount of the fee, to the Board of Directors of the Exchange. Additionally, the proposed rule would allow the Board of Directors to call MTS Committee decisions relating to the assessment of the fee for review on the Board's own motion upon the request of five or more directors.

Finally, CBOE proposes to make the effective date of this proposal retroactive to October 20, 2000. If this proposal is not granted retroactive status, the current transfer fee structure will have been applicable to only one transaction. By making the effective date October 20, 2000, the Exchange proposes to avoid assessing a fee to a transaction that, had it occurred one month later, would not have been subject to the fee. Thus, the Exchange does not believe that the interests of fairness are served by assessing a fee to a transaction that occurred during this interim period, a period in which the Exchange already had begun discussions to amend the transfer fee structure.

The Exchange believes that the proposed changes advance the primary objectives of the DPM transfer fee, as identified above. First, the Exchange believes that the proposed changes will facilitate a DPM's ability to maintain sufficient capital to operate as a DPM by allowing it to enter into transactions that enhance its financial operating structure without automatically subjecting it to the DPM transfer fee. As the amount of the business transacted on the Exchange continues to grow, so will a DPM's capital needs. The proposed changes recognizes this and allow DPMs to respond accordingly without being subject to the transfer fee.

Second, that Exchange believes that the proposed changes also continue to ensure that a DPM maintains its long-term commitment to the Exchange. The Exchange believes that by enhancing its capital structure, a DPM is making a long-term commitment to the Exchange that it intends to operate in that capacity for an extended period. For this reason, the Exchange believes it would be counter-productive to assess a fee on those types of transactions.

Third, the Exchange believes the proposed amendments should prevent the "quick sale" of a DPM interest for a profit. The Exchange believes that the proposal advances this objective because it allows DPMs to enhance their capital structures without paying a transfer fee, provided that one or more principals do not exit or significantly reduce their participation in the DPM operation. If, however, the original principals do exit the business or significantly reduce their participation, they will be assessed a fee consistent with the intent of the rule. Accordingly, the proposal should continue to result in the levying of a transfer fee when a DPM tries to profit from the "quick sale" of its interest.

Finally, the Exchange notes that the full membership has had an opportunity to review the proposed changes. In this regard, on November 1, 2000, the Chairmen of the Floor Directors, MTS Appointments, and Lessors Advisory Committees distributed to the membership an Information Circular that discussed the changes and requested comment. To date, the Exchange has received no written comments in opposition to the amendment of the rule.[10] The

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[6] *See* Securities Exchange Act Release No. 43186 (August 21, 2000), 65 FR 51880 (August 25, 2000) (Approval of File No. SR–CBOE–99–37) (approving current transfer fee scheme). The transfer fee generally is equivalent to an applicable percentage of the larger of: (i) (the applicable percentage set forth below) × (the actual dollar value of the change in capitalization of the DPM as determined by the Exchange) × (the percentage of the DPM's market maker trading volume in its capacity as a DPM in the previous 12 months attributable to option classes allocated to the DPM after June 29, 1999 that there traded on the Exchange prior to that date) and (ii) (the applicable percentage set forth below) × (the current level of overall DPM profitability per contract as determined by the Exchange based on DPM financial reporting) × (the DPM's market maker trading volume in the previous 12 months in option classes allocated to the DPM after June 29, 1999 that were traded on the Exchange prior to that date) × (2) × (the percentage change in the DPM's capitalization as determined by the Exchange). The applicable percentage to be used in the formulas above to determine the transfer fee to be assessed to a DPM shall be 50% in the first year of the five year period during which the DPM is subject to this transfer fee, 40% in the second year, 30% in the third year, 20% in the fourth year, and 10 percent in the fifth year.

[7] In this respect, the Exchange notes that the other options exchanges allow specialist assignments to be sold or transferred without the imposition of a fee, leaving CBOE at a competitive disadvantage. For example, on competing exchanges, specialists may take on new partners willing to make capital contributions, they may become part of larger market making organizations, or they may merge with other specialist units to combine their resources. All of these actions, which would trigger application of CBOE's DPM transfer fee, occur on other exchanges without those competing specialist units paying any transfer fee.

[8] *See* Securities Exchange Act Release No. 41872 (September 13, 1999), 64 FR 51158 (September 21, 1999) (Notice of Filing of SR–CBOE–99–37).

[9] If the transfer of ownership occurs over a period of years, the fee rate percentage applied will be consistent with the year in which the transfer occurs. As an example, if the transfer of a DPM is to occur equally over three years commencing in November 2000, then the fee rate percentage applied would be 40% for the first portion of the transfer, 30% for the second portion of the transfer, and 20% for the last portion of the transfer.

[10] The Exchange notes that the Chairman of the Floor Directors Committee received one comment via telephone regarding the proposed amendment.

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Committees have discussed this issue in great detail and believe that the proposed changes will be beneficial to the operation of the Exchange.[11]

2. Basis

For these reasons, the Exchange believes the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and further the objectives of Section 6(b)(5)[13] in particular, because it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

On November 1, 2000, the Chairmen of the Floor Directors, MTS Appointments, and Lessors Committees distributed to the membership an Information Circular that discussed the prescribed changes and requested comment. To date, the Exchange has received no written comments in opposition to the amendment of the rule. The Exchange notes that the Chairman of the Floor Directors Committee received, via telephone, the views of one commenter who supported abolishing the transfer fee altogether.[14] The Exchange believes the proposed amendments will enable it to achieve the original intent of the transfer fee, thereby negating the need to abolish the fee altogether. The Exchange also received a copy of a letter sent to the Commission from another commenter. This commenter opposed allowing the proposed changes to become effective on filing, and urged that they be subject to public comment and review.[15] In Amendment No. 1 to the proposed rule change, the Exchange re-designated the filing as a submission pursuant to Section 19(b)(2) of the Act.[16]

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to File No. SR–CBOE–00–61 and should be submitted by February 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Jonathan G. Katz,

Secretary.

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This commenter supported abolishing the transfer fee altogether. The Exchange also received a copy of a letter sent to the Commission by another commenter. This commenter opposed the filing of the proposed rule change under Section 19(b)(3)(A) of the Act, 15 U.S.C. 78s(b)(3)(A), which would have rendered it effective on filing. The commenter believed that the proposed rule change should be subject to public comment and review pursuant to Section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2). *See* letter from Lawrence J. Blum to Jonathan G. Katz, Secretary, SEC, dated November 24, 2000. The filing was subsequently re-filed under Section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2). *See* Amendment No. 1, *supra* note 3.

[11] The Exchange believes the proposed changes will address the potential shortcomings of the current DPM transfer fee. However, the Exchange will continue to evaluate the fee and make changes to it in the future if such changes are deemed necessary. Any such changes would be submitted to the Commission pursuant to Section 19(b) of the Act (15 U.S.C. 78s(b)).

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 10.

[15] *See supra* note 10.

[16] 15 U.S.C. 78s(b)(2).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43835; File No. SR–CHX–00–31]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Stock Exchange, Incorporated Relating to Preopening Orders

January 11, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2000, the Chicago Stock Exchange, Incorporated ("Exchange" or "CHX") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items, I, II, and III below, which Items have been prepared by the CHX. On December 20, 2000, the Phlx filed Amendment No. 1 to the proposed rule change.[3] The Commission is published this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the CHX rule governing preopening orders in Nasdaq/NM securities to explicitly define "preopening orders" in Nasdaq/NM securities, and to explicitly provide for a single price opening at or better than the NBBO at the first unlocked, uncrossed market.

Below is the text of the proposed rule change. Proposed new language is in *italics* and proposed deletions are in brackets.

* * * * *

Chicago Stock Exchange Rules

Article XX, Rule 37(a)

* * * * *

4. Preopenings. Preopening orders in Dual Trading System issues must be accepted and filled at the primary market opening trade price. In trading halt situations occurring in the primary market, orders will be executed based upon the reopening price. Preopening orders in NASDAQ/NM securities must be accepted and filled [at the Exchange opening trade price] *on a single price opening at or better than the NBBO at the first unlocked, uncrossed market.* In trading halt situations, order will be executed based on the Exchange reopening price. For purposes of this rule, (*a*) pre-opening orders in Dual Trading System Issues are orders that are received before a primary market opens a subject security based on a print or based on a quote *and (b) preopening orders in NASDAQ/NM securities are orders received at or prior to 8:25 a.m. (Central Time) on the date of the opening.*

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CHX included statements concerning the purpose of and basis for the proposed rule change and discussed any concerns it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CHX has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis of, the Proposed Rule Change

1. Purpose

The Exchange proposed to amend the CHX rule governing preopening orders in Nasdaq/NM securities to provide for additional clarity regarding the types of orders eligible for treatment as preopening orders and to price at which such orders will be filled. Because Article XX, Rule 37(a)(4) of the Exchange's rules does not explicitly define what constitutes a preopening order in the case of Nasdaq/NM securities, there has been some confusion as to which orders are eligible for treatment as preopening orders, and consequently, some unintended execution guarantees. The proposed rule change will expressly provide that for an order to be considered a preopening order, an order must be received at or prior to 8:25 a.m. (Central Time) of the date of the opening.

The Exchange also proposed to provide additional clarity regarding the price at which each preopening order will be filled. Currently, the rule provides that preopening orders for Nasdaq/NM securities must be filled "at the Exchange opening trade price." The Exchange believes that it is in the best interest of its order-sending firms and their customers to provide for greater specificity as to the parameters governing the fill price for preopening orders. Accordingly, the proposed rule change provides that each preopening order must be filled "on a single price opening at or better than the NBBO at the first unlocked, uncrossed market."

2. Statutory Basis

The proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder, that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b).[4] In particular, the proposed rule is consistent with Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[5]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–00–31 and should be submitted by February 12, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Jonathan G. Katz,

Secretary.

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[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43841; File No. SR–CTA–01–01]

Consolidated Tape Association; Notice of Filing Seventh Charges Amendment to the Second Restatement of the CTA Plan

January 12, 2001.

Pursuant to Rule 11Aa3–2[1] of the Securities Exchange Act of 1934 ("Act"), notice is hereby given that on January 9, 2001, the Consolidated Tape Association Plan ("CTA Plan") participants ("Participants")[2] filed with

[1] 17 CFR 240.11Aa3–2.

[2] Each participant of the Plan executed the amendments. The Participants include the American Stock Exchange, LLC, Boston Stock

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the Securities and Exchange Commission ("Commission" or "SEC") an amendment to the Second Restatement of the CTA Plan. In the amendment, the Participants propose to modify the Network B ticker charges.

The Participants submitted this notice of proposed amendment to the CTA Plan, which is an effective national system plan,[3] pursuant to Rule 11Aa3–2(c)(1).[4] The Commission is publishing this notice to solicit comments from interested persons on the amendment.

I. Description and Purpose of the Amendments

A. Rule 11Aa3–2[5]

Currently, CTA Network B charges $21.50 per month for the first ticker at each customer location and $13.60 for any additional tickers at that location. This tiered pricing structure is proving difficult for market data vendors to administer in the new vendor billing environment that was recently implemented by CTA Network B.[6]

To address this problem, CTA Network B is proposing to eliminate the "First Ticker" premium charge. Thus, there would be a single monthly ticker charge of $13.60 for each customer at each location. The change would result is a cost savings for all Network B ticker subscribers and will make it easier for vendors to charge for the data.

* * * * *

The filing of the amendment is in fulfillment of the national market system objectives regarding the dissemination of market information as anticipated by Sections 11A(a)(1)(C),[7] 11A(a)(1)(D),[8] and 11A(a)(3)(B)[9] of the Act.

B. Governing or Constituent Documents

Not applicable.

C. Implementation of Amendment

The Participants have manifested their approval of the proposed amendment to the CTA rate schedule by executing the amendment. The rate change would become effective on the first day of the month that follows the month in which the Commission approves the proposed plan amendment.

D. Development and Implementation Phases

See Item I(C).

E. Analysis of Impact on Competition

The Participants believe that the proposed amendment does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Participants do not believe that the proposed plan amendment introduces terms that are unreasonably discriminatory for the purposes of Section 11A(c)(1)(D)[10] of the Act.

F. Written Understanding or Agreements Relating to Interpretation of, or Participation in, Plan

Not applicable.

G. Approval by Sponsors in Accordance With Plan

In accordance with Section XII(b)(iii) of the CTA Plan, each Participant has approved the fee reduction.

H. Description of Operation of Facility Contemplated by the Proposed Amendment

Not applicable.

I. Terms and Conditions of Access

See Item I(A).

J. Method of Determination and Imposition, and Amount of, Fees and Charges

See Item I(A) and the text of the amendment.

K. Method and Frequency of Processor Evaluation

Not applicable.

L. Dispute Resolution

Not applicable.

II. Rule 11Aa3–1[11]

A. Reporting Requirements

Not applicable.

B. Manner of Collecting, Processing, Sequencing, Making Available and Disseminating Last Sale Information

Not applicable.

C. Manner of Consolidation

Not applicable.

D. Standards and Methods Ensuring Promptness, Accuracy and Completeness of Transaction Reports

Not applicable.

E. Rules and Procedures Addressed to Fraudulent or Manipulative Dissemination

Not applicable.

F. Terms of Access to Transaction Reports

See Item I(A).

G. Identification of Marketplace of Execution

Not applicable.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposal between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CTA. All submissions should refer to File No. SR–CTA–01–01 and should be submitted by February 12, 2001.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[12]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1804 Filed 1–19–01; 8:45 am]

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Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., Cincinnati Stock Exchange, Inc., National Association of Securities Dealers, Inc., New York Stock Exchange, Inc., and Philadelphia Stock Exchange, Inc.

[3] The CTA Plan has been designated as an effective transaction reporting plan pursuant to Rule 11Aa3–1(b). 17 CFR 240.11Aa3–1(b).

[4] 17 CFR 240.11Aa3–2(c)(1).

[5] 17 CFR 240.11Aa3–2.

[6] *See* Securities Exchange Act Release No. 42444 (February 18, 2000), 65 FR 11101 (March 1, 2000).

[7] 15 U.S.C. 78k–1(a)(1)(C).

[8] 15 U.S.C. 78k–1(a)(1)(D).

[9] 15 U.S.C. 78k–1(a)(3)(B).

[10] 15 U.S.C. 78k–1(c)(1)(D).

[11] 17 CFR 240.11 Aa3–1.

[12] 17 CFR 200.30–3(a)(27).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43834; File No. SR–NYSE–00–58]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to an Interpretation with Respect to Rule 342 ("Offices—Approval, Supervision, and Control")

January 10, 2001.

Pursuant to Section 19(b)(1) of the Securities and Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 15, 2000, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of interpretations with respect to the meaning administration of existing NYSE Rule 342 ("Offices—Approval, Supervision, and Control") with respect to the supervision of, and the experience requirements for, registered representatives working in small or residence branch offices. The text of the proposed rule change is available from the Office of the Secretary, the NYSE or the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend interpretations concerning the meaning and administration of NYSE Rule 342 with respect to the supervision of, and the experience requirements for, registered representatives working in small or residence branch offices of Exchange member organizations. Interpretation will be published as an Interpretation Memorandum for inclusion in the Exchange's *Interpretation Handbook*.

NYSE Rule 342 requires that each office, department and business activity be under the supervision and control of the member organization establishing it and of the personnel delegated such authority and responsibility. Additionally, the structure and administration of Exchange rules mandate that all member organization employees, including registered representatives, be fully subject to the direct and ongoing supervision, control and discipline of their member organization employers. Further, Exchange Rule 342(c) requires that a member or member organization obtain the Exchange's prior written consent for each office established.

NYSE Rule 342.11 and Current Interpretations. NYSE Rule 342.11 provides that a registered representative ("RR") may operate out of his or her residence, with Exchange approval, and that if the residence is advertised (through, *e.g.*, business cards or stationery), then the residence constitutes a branch office of the member organization employer. Further, and notwithstanding the above, Interpretation/01 to Rule 342.11 in the NYSE Interpretation Handbook states that if an RR regularly operates from his home during business hours (even on a part-time basis), the member organization employer must register the home as a branch office (a "residence office"). Interpretation/03 to Rule 342.11 currently provides that an RR who will be working from his or her residence must have a minimum of six-months securities experience prior to being approved in a residence office.

Proposed Amendment to Interpretation/03 to Rule 342.11. The six-months securities industry experience requirement for RRs in residence offices has come to be viewed as unnecessary and restrictive in that member organizations are prohibited from permitting the RR from working for two additional months *beyond* the prescribed four-month training period of NYSE Rule 345. This six-month experience requirement has particularly affected member organizations structured with multiple one-person offices.

The additional training period for inexperience RRs was appropriate when the interpretation was implemented in the 1970s because of the remote physical location of supervisors. However now, with member organizations increasingly employing advanced technology and electronic communications in the supervision and review of RR activities, supervision can be readily performed without being dependent on close physical proximity of the manager to the RR.

Under the proposed amended Interpretation, the six-month experience requirement will be eliminated, thereby allowing the RR who operates from a residence or one-person office to begin working upon completion of the prescribed four-month training period, provided that the member organization develops and implements special supervisory procedures for heightened supervision for the two month period immediately following completion of prescribed training. The special supervision will include procedures such as:

- Daily review of all customer account activity;
- Daily review of all correspondence including prior approval of all outgoing correspondence;
- Review of all incoming and outgoing electronic communications, *e.g.*, internet use and electronic mail; and
- On-site inspection by the branch office manager (or qualified designee) responsible for supervision of the residence office in the two months following the prescribed training period.

Member organizations will be required to inform RRs operating from a residence or small one-person office of the special supervision, and to maintain records evidencing the implementation and conduct of the special supervision.

The amended interpretation will allow these RRs to begin working immediately after completing the prescribed four-month training period (like all other RRs), while also helping to ensure that, through special supervision, member organizations have appropriate supervision and control of RRs operating from a residence and their customer accounts. Moreover, while the special supervision is required for a limited time, there is the *ongoing* responsibility of the member organizations, beyond the two-month special supervision period, to have

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appropriate policies and procedures in place for the supervision and control of all sales and operational activities of each branch office and of all registered employees and the customer accounts they service.

Proposed Amendments to Interpretations /01,/02, and a New Interpretation /04 to NYSE Rule 342.15. Generally, each location where member organization employees are engaged in activities on behalf on a member organization must be registered as a branch office (excluding locations on the Exchange Floor where member organizations conduct Floor Business).

A "small" office is a branch with three or less registered representatives, one of whom is designated as "RR-in-charge" (this designation is required only if there is more than one registered representative in the small office). A small office may engage in sales activities but may not conduct operational functions, such as cashiering (receipt and disbursement of funds and securities).

Interpretation /02 to NYSE Rule 342.15 currently requires small offices to be under the close supervision and control of the member organization's main office or to be supervised by a manager of another office within short travel distance. Such manager may be responsible for only two small offices.

The proposed amendments to the Interpretation will require that small offices be controlled and supervised by *either* the main office *or* another designated branch office having a qualified (*i.e.*, Series 9 and 10 exam-qualified) Branch Office Manager on the premises. Further, such supervisory arrangements must be made part of the member organization's written plan of supervision. Adoption of the interpretation will eliminate the current provision under Interpretation /01 to NYSE rule 342.15 that a manager may be responsible for only two small offices that are in close geographical proximity. Given modern electronic surveillance and monitoring techniques, this limitation regarding number of offices and geographical location is no longer necessary. New Interpretation /04 to NYSE Rule 342.15 provides that RRs operating from small, one-person branch offices must be subject to the same special supervision prescribed in Interpretation /03 to NYSE Rule 342.11 for residence offices.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b)(5)[3] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, in that it will enhance the process for member organization supervision and control of small and residence branch offices, while also permitting registered representatives to engage in activities upon completion of a prescribed training period.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement in Comments on the Proposed Rule Change Received From Members, Participants or Other

The Exchange has neither solicited nor received any written comments with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve the proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–NYSE–00–58 and should be submitted by February 12, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1750 Filed 1–19–01; 8:45 am]

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[3] 15 U.S.C. 78f(b)(5).

[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43838; File No. SR–NYSE–00–55]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change and Amendment No. 1 by the New York Stock Exchange, Inc. To Permit Firm Delivery of the Regulatory Element of the Continuing Education Program

January 12, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 7, 2000, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. On December 21, 2000, the NYSE amended the proposal.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons, and to grant accelerated approval to the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposal consists of interpretations with respect to the meaning and administration of NYSE Rule 345A ("Continuing Education for Registered Persons"), to permit firm delivery of the Regulatory Element of the Continuing Education Program. Currently, this computer-based training is administered to registered persons by an outside vendor at its locations. The text of the proposed rule change is below. Proposed new language is in italics. Proposed deletions are in brackets.

Rule 345A Continuing Education for Registered Persons

(a) Regulatory Element

/01 Registration Date

Registered persons are required to participate in the Regulatory Element [on three occasions] *on the occurrence of their second registration anniversary date and every three years thereafter,* based on their initial registration anniversary date. Initial registration means the first date that the person became registered with the NYSE, NASD or another self-regulatory organization, regardless of subsequent registrations, provided that the person has remained continuously registered since that initial date.

A person's initial registration date is the date that the registration was originally approved rather than the date the person passed a qualification examination. This includes registered persons who have received waivers from specific examination requirements.

/02 Application

The requirements of the Regulatory Element apply to all persons registered or required to be registered under Exchange rules, even if such persons are not required to be qualified by taking and passing an examination e.g., certain allied members and securities lending representatives.

/03 Firm Delivery of Regulatory Element

Members and member organizations will be permitted to administer the Regulatory Element continuing education program to their registered persons by instituting a firm program acceptable to the Exchange.

The following procedures are required:

A. Senior Officer or Partner In-Charge

- *The firm has designated a senior officer or partner to be responsible for the firm's delivery of the Regulatory Element continuing education program.*

B. Site Requirements.

- *The location of all delivery sites will be under the control of the firm.*
- *Delivery of Regulatory Element continuing education will take place in an environment conducive to training. (Examples: a training facility, conference room or other area dedicated to this purpose would be appropriate. Inappropriate locations would include a personal office or any location that is not or cannot be secured from traffic and interruptions).*
- *Where multiple delivery terminals are placed in a room, adequate separation between terminals will be maintained.*

C. Technology Requirements

- *The communication links and firm delivery computer hardware must comply with standards defined by the Exchange or its designated vendor.*

D. Supervision

- *The firm's Written Supervisory Procedures must contain the procedures implemented to comply with the requirements of its delivery of Regulatory Element continuing education.*
- *The firm's Written Supervisory Procedures must identify the senior officer or partner designated pursuant to 03/A and contain a list of individuals authorized by the firm to serve as proctors.*
- *Firm locations for delivery of Regulatory Element continuing education will be specifically listed in the firm's Written Supervisory Procedures.*

E. Proctors

- *All sessions will be proctored by an authorized person during the entire Regulatory Element continuing education session. Proctors must be present in the session room or must be able to view the person(s) sitting for Regulatory Element continuing education through a window or by video monitor.*
- *The individual responsible for proctoring at each administration will sign a certification that required procedures have been followed, that no material from Regulatory Element continuing education has been reproduced, and that no candidate received any assistance to complete the session. Such certification may be a part of the sign-in log required under F. Administration.*
- *Individuals serving as proctors must be persons registered with an SRO and supervised by the designated senior officer/partner for purposes of firm delivery of the Regulatory Element continuing education.*
- *Proctors will check and verify the identification of all individuals taking Regulatory Element continuing education.*

F. Administration

- *All appointments will be scheduled in advance using the procedures and software specified by the Exchange, its agent or designated vendor to communicate with the PROCTOR system and CRD.*
- *The firm/proctor will conduct each session in accordance with the administrative and appointment scheduling procedures required by the Exchange or its designated vendor.*
- *A sign-in log will be maintained at the delivery facility. Logs will contain the date of each session, the name and social security number of the individual taking the session, that required identification was checked, the sign-in time, the sign-out time and the name of the individual proctoring the session. Such logs are required to be retained pursuant to SEA Rule 17a–4.*
- *No material will be permitted to be utilized for the session nor may any session-related material be removed.*
- *Delivery sites will be made available for inspection by the SROs.*

Before commencing firm delivery of Regulatory Element continuing education, members and member organizations are required to file with their Designated Examining Authority ("DEA"), a letter of attestation (as specified below) signed by a senior officer or partner attesting to the establishment of required procedures addressing senior officer/partner in-charge, supervision, site, technology, proctors and administrative requirements.

The letter of attestation shall read substantially as follows:

(Name of member or member organization) has established procedures for delivering Regulatory Element continuing education on its premises. I have determined that these procedures are reasonably designed to comply with SRO requirements pertaining to firm delivery of Regulatory Element continuing education including that such procedures have been implemented to comply with senior officer/partner in-charge, supervision, site, technology, proctors and administrative requirements.

_____

Signature

_____

Printed Name

_____

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* December 20, 2000 letter from James E. Buck, Senior Vice President and Secretary, NYSE, to Nancy Sanow, Assistant Director, Division of Market Regulation ("Division"), SEC ("Amendment No. 1"). In Amendment No. 1, the NYSE requested accelerated approval of the proposed rule change, and made minor, non-substantive corrections to Exhibit A to the proposed rule change.

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Title (Must be signed by a Senior Officer/ Partner of the firm.)

Date

G. Annual Representation

Each member and member organization will be required to represent to the Exchange, annually, that they have continued to maintain, and reasonably believe that they have complied with, all required procedures outlined in sections A through F of this interpretation for the previous year. Such attestation must be signed by a senior officer or partner.

H. Definition of Senior Officer or Partner

For purposes of interpretation /03, a "senior officer or partner" means the chief executive officer or managing partner or either (A) any other officer or partner who is a member of the member organization's executive or management committee or its equivalent committee or group or (B) if the member organization has no such committee or group, any officer or partner having senior executive or management responsibility who reports directly to the chief executive officer or managing partner. If, in the case of a member organization, its chief executive officer or managing partner does not sign the attestation, a copy of the attestation shall be provided to the chief executive officer or managing partner.

[/03] */04 Registration Lapses*

A person whose registration lapsed for less than two years and who seeks to be reregistered will be required to participate in the Regulatory Element to cover [the] any occasion[s] that [were] was missed during the period in which the person was unregistered, based on such person's initial registration date. [For example, a person whose registration lapses four and a half years after initial registration and thereafter wants to reactivate the registration six years after the initial registration date, must satisfy the fifth-year anniversary Regulatory Element before they may function under the new registration.]

If any such person has been unregistered for more than two years, then such person would be a new registrant and required to satisfy appropriate qualifying examination requirements and satisfy the requirements of the Regulatory Element *based on the new initial registration anniversary* [beginning a new 10-year cycle (*e.g.*, 2, 5 and 10 year anniversaries of reregistration)].

[/04] *05 CRD Notification*

Members and member organizations will be notified by the Central Registration Depository ("CRD") concerning those registered persons in the CRD system whose registration anniversary dates trigger participation in the Regulatory Element computer-based training.

Even though notification will be provided by CRD as a courtesy, the final responsibility to ensure timely participation in and completion of the Regulatory Element as required is that of members and member organizations, and registered personnel themselves.

Members and member organizations and personnel who receive such notices from the CRD but would otherwise be exempt from the requirements of the Regulatory Element because their business is limited solely to the transaction of business on the Floor with members or registered broker-dealers must contact the Exchange's Qualifications and Registrations Department to confirm that they are (by definition) exempt from the Regulatory Element. *However, any such persons who do not conduct public business on the Floor, but maintain a registration (e.g. Series #7 or 7A) that would enable them to conduct a public business, must satisfy the Regulatory Element requirements in order for their registration to remain active.*

[Members and member organizations whose registered personnel are *not* on the CRD system and therefore will not receive CRD notification, are responsible for tracking the registration anniversary dates and contacting the Exchange's Qualifications and Registration Department to make appointments for computer-based training sessions for such persons.]

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to permit firm delivery of the Regulatory Element of the Continuing Education Program.

Background

The Continuing Education Program is designed to keep industry participants up to date on products, services and rules, and is composed of a Regulatory Element and a Firm Element. The Regulatory Element is computer-based training that covers ethical, sales practice, and regulatory matters, and requires that each registered person complete this training on the occurrence of their second registration anniversary date and every three years thereafter. A registered person who fails to complete the training will be deemed inactive, and may not conduct or be compensated for activities requiring registration. The Firm Element requires member and member organizations to provide to registered employees having direct contact with customers ongoing training that is specifically tailored to their business.

Proposed Amended Interpretation of Rule 345A

At the recommendation of the Securities Industry/Regulatory Council on Continuing Education,[4] the Exchange proposes to adopt interpretations of NYSE Rule 345A to permit members and member organizations to administer the Regulatory Element of the Continuing Education Program to their registered persons by instituting firm programs acceptable to the Exchange. Currently, the Regulatory Element is administered only at vendor locations.

Under the proposal, before beginning firm delivery of the Regulatory Element, members and member organizations are required to develop stipulated procedures relating to the delivery of the program and to file with their Designated Examining Authority ("DEA") a letter of attestation signed by a senior officer or partner attesting to the establishment of those required procedures. The stipulated procedures and letter of attestation must address the designation of a senior officer/partner in charge, supervision, delivery site, technology, proctors and administrative requirements. In addition, members and member organizations will be required to file with the Exchange annually an attestation that they have continued to maintain and reasonably believe that they have adhered to all required procedures for the previous year.

In-house delivery of the Regulatory Element will, for the practical purposes of tracking participation by registered category representatives and the aggregate performance by firm and registration category, adhere to the same standards as if it was administered at vendor locations.

Additional amendments to the Interpretation of NYSE rule 345A reflect previous changes to the Rule that require registered persons to complete the Regulatory Element on the occurrence of their second registration anniversary date and every three years thereafter (see Interpretation paragraphs /01 and /04).[5]

Further, paragraph /05 will be amended to delete the provision addressing members and member organizations whose personnel are not included in the CRD system. After November 13, 2000, all member organization personnel will be included in the CRD database and will be tracked for continuing education training purposes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange in general, and in particular, with the requirements of Section 6(b)(5).[6] Section 6(b)(5) requires, among other things, that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and national market system, and in general, to protect investors and the public interest.

The NYSE believes the proposed rule change is also consistent with Section 6(c)(3)(B) of the Act.[7] Under Section 6(c)(3)(B), it is the Exchange's responsibility to prescribe standards for training, experience and competence for persons associated with Exchange members and member organizations. The Exchange has proposed this rule change to establish an additional mechanism for the administration of the Regulatory Element of the Continuing Education Program, which will enable registered persons to satisfy their continuing education obligations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to file number SR–NYSE–00–55 and should be submitted by February 12, 2001.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission has reviewed carefully the NYSE's proposed rule change and Amendment No. 1, and finds, for the reasons set forth below, the proposal is consistent with the requirements of Section 6 of the Act[8] and the rules and regulations thereunder applicable to a national securities exchange.[9] Specifically, the Commission finds the proposal is consistent with Section 6(b)(5) of the Act[10] because it should facilitate compliance with the Regulatory Element of the Continuing Education Program. Under this proposal, firms will be able to deliver the Regulatory Element to their employees in-house. The Commission is satisfied that the proposal provides reasonable safeguards to uphold the integrity of the program, consistent with the requirements specified by the Securities Industry/Regulatory Council.

The Commission also finds the proposal is consistent with Section 6(c)(3)(B) of the Act,[11] because the proposal provides an additional mechanism for the administration of the Regulatory Element of the Continuing Education Program, which should make it easier for registered persons to satisfy their continuing education obligations.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. The Commission notes that the proposed is very similar to SR–NASD–00–64, which the Commission approved after the proposal was published for a full 21-day notice and comment period.[12] Approving this proposal will allow NYSE firms to take advantage of the in-house delivery option, which NASD member firms are

[4] The Securities Industry/Regulatory Council on Continuing Education is comprised of representatives from broker/dealers and SROs whose duties include recommending and helping to develop specific content and questions for the Regulatory Element, as well as minimum core curricula for the Firm Element. The Council has developed a model under which firms may deliver the computer-based training in-house.

[5] The NYSE modified continuing education requirements for registered persons in 1998. *See* Securities Exchange Act Release No. 39712 (March 3, 1998), 63 FR 11939 (March 11, 1998) (Order approving proposed rule changes by the Chicago Board Options Exchange, Municipal Securities Rulemaking Board, National Association of Securities Dealers, Inc., and NYSE). At that time, however, the NYSE did not modify the corresponding Interpretation to NYSE Rule 345A to reflect the changes made to the Rule. The instant proposal now conforms the Interpretation to the requirements of NYSE Rule 345A. Telephone conversation between Donald Van Weezel, Managing Director, Regulatory Affairs, NYSE, and Katherine England, Assistant Director, Division, SEC, and Joseph Morra, Special Counsel, Division, SEC, January 11, 2001.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78f(c)(3)(B).

[8] 15 U.S.C. 78f.

[9] In approving the proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78f(c)(3)(B).

[12] *See* Securities Exchange Act Release No. 43701 (December 11, 2000), 65 FR 79143 (December 18, 2000) (Order approving in-firm delivery of the Regulatory Element of the Continuing Education Requirements). The NASD proposal received one comment letter in support of the proposal, and none in opposition. The only substantive difference between the NASD in-firm delivery rules and the NYSE proposal is the NYSE requires an annual representation that each member and member organization has continued to maintain and comply with all required procedures regarding firm delivery of the Regulatory Element for the previous year. The NASD rules require a one-time attestation. Conversation between Mary Ann Furlong, NYSE, and Joseph P. Morra, Special Counsel, Division, SEC, December 12, 2000.

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already able to do. Additionally, approval of this proposal will conform the Interpretation to Rule 345A to the requirements of NYSE Rule 345A, which Rule was amended in 1998. The Commission finds, therefore, that granting accelerated approval of the proposed rule change, as amended, is appropriate and consistent with the Act.

It is therefore ordered, pursuant to Section 19(b)(2) of Act,[13] that the proposed rule change (SR–NYSE–00–55), as amended, is hereby approved on an accelerated basis.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[14]

Johnathan G. Katz,

Secretary.

[FR Doc. 01–1803 Filed 1–19–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43837; File No. SR–OCC–00–12]

Self-Regulatory Organizations; The Options Clearing Corporation; Order Granting Accelerated Approval of a Proposed Rule Change Relating to the Creation of a Program to Relieve Strains on Clearing Members' Liquidity in Connection With Exercise Settlements

January 12, 2001.

On November 27, 2000, The Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") and on January 8, 2001 amended, a proposed rule change (File No. SR–OCC–00–12) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] Notice of the proposal was published in the **Federal Register** on December 28, 2000.[2] No comment letters were received. For the reasons discussed below, the Commission is granting accelerated approval of the proposed rule change.

Description

1. Background

Under the Third Amended and Restated Options Exercise Settlement Agreement (the "Accord") dated February 16, 1995, between OCC and the National Securities Clearing Corporation ("NSCC"), OCC and NSCC each guarantee that if the other sustains a loss on liquidation of a common member[3] with pending settlement activity at NSCC resulting from option exercises and assignments, it will make a payment to the other in an amount (which may be zero) determined by a formula set forth in the Accord.[4]

Under the Accord, NSCC has until 6:00 a.m. Central Time on the day after an option exercise settlement date (E+4) to notify OCC that it has ceased to act or may cease to act for a common member. If NSCC fails to give such notice by that time, OCC is released from its guarantee obligation with respect to transactions for which E+3 was the settlement date. Because OCC is not released from its guarantee obligation until the morning of E+4, it must continue to hold margin on assignments settling on E+3 until E+4. This means that assets that a clearing member has deposited with OCC as margin for pending assignments cannot be used to settle or to finance settlement of those assignments. Instead, the clearing member must find other sources of financing, which can strain some clearing members' liquidity in months with heavy exercise and assignment activity.

2. The Rule Change

In an effort to reduce the strains on liquidity resulting from the after-the-fact release of margin on pending assignments, OCC, in conjunction with NSCC and The Depository Trust Company ("DTC"), has worked out a program to allow OCC clearing members to withdraw equity securities[5] deposited with OCC as margin and to pledge them to DTC participant lenders as collateral for loans. The proceeds of such loans will be disbursed by the lender directly to OCC and used to discharge settlement obligations of the clearing member at NSCC that were guaranteed by OCC. OCC's liability exposure to NSCC under the Accord will be correspondingly reduced as will OCC's need to continue to hold margin until E+4.

The program will work as follows:

- On the morning of E+3, a clearing member will learn from OCC the amount of the loan that it may collateralize with securities held by OCC as margin. That amount will be no less than the value assigned by OCC to such securities for margin purposes[6] and will be no more than the lesser of (i) the margin requirement for the account from which the securities were to be withdrawn[7] and (ii) the amount of OCC's guarantee exposure to NSCC (assuming that the clearing member's NSCC positions liquidated to a deficit).[8]
- The clearing member will then contact its lender and arrange for the loan. When the terms of the loan are agreed upon, the clearing member will use a new Participant Terminal System screen developed by DTC to confirm both to the lender and to OCC the amount of the loan and the quantity and description of the securities to be withdrawn from OCC and pledged to the lender as collateral. The lender and OCC will use that information to validate the loan request.
- When both the lender and OCC approve the loan, DTC will transfer the securities from a "pledged to OCC" field in the clearing member's DTC account to a special OCC account at DTC. From that account, the securities will be pledged to the lender against receipt of the loan proceeds. The proceeds will thus be paid directly to OCC without passing through the hands of the clearing member.
- Upon receipt in the special OCC account, the loan proceeds will automatically be paid over to NSCC for the benefit of the clearing member resulting in a corresponding reduction in OCC's guarantee exposure to NSCC under the Accord.
- At the end of the day, DTC will automatically transfer the securities from a "pledged to lender" field in the special OCC account to a "pledged to lender" field in the clearing member's DTC account, leaving the clearing member in the same position as if it had been able to pledge the securities to the lender without OCC's intermediation.

Upon allowing securities to be withdrawn and pledged under the program, OCC will reduce its margin requirement in the account from which the securities were withdrawn by an amount equal to the value assigned to the securities for margin purposes. The account will, however, be required to be fully margined the next morning.

Initially, clearing members will be permitted to withdraw and pledge securities held by OCC as margin only on settlement dates for exercises of expiring equity options. OCC may at a future date decide to make the program available on other exercise settlement dates as well.

3. Timing

Historically, the heaviest volume of option expirations and hence exercises occurs in January. In January 2000, 26,099,346 option contracts expired, accounting for 41.9% of total open interest. Open interest as of November 21, 2000, included 26,378,070 contracts expiring in January 2001 (43.2% of total open interest). OCC believes that it is important to have the new program in place in time for the January 2001 expiration to help relieve potential strains on liquidity resulting from the large volume of exercise activity expected to occur at that time.

II. Discussion

Section 17A(b)(3)(F)[9] of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible. For the reasons set forth below, the Commission believes that OCC's proposed rule change is consistent with OCC's obligations under the Act.

The central purpose of the rule change is to allow a clearing member to use assets that it has deposited with OCC as margin for pending assignments to settle and to finance settlement of those assignments. The rule change should relieve clearing members from the responsibility of finding other sources of financing that could strain some clearing members' liquidity in months with heavy exercise and assignment activity. The Commission believes that OCC's program by which clearing members will withdraw and pledge securities that are deposited with OCC as margin and by which OCC in return will receive loans from DTC participant lenders is a safe and acceptable method by which clearing members' will finance their settlement obligations at NSCC. Accordingly, the Commission finds that OCC's program satisfies OCC's obligations to assure the safeguarding of securities and funds which are in the custody or control of OCC or for which it is responsible.

OCC has requested that the Commission find good cause for approving the proposed rule change prior to the thirty day after publication of the notice of filing. The Commission finds good cause for approving the proposed rule change prior to the thirty day after publication of the notice of filing because accelerated approval will permit OCC to implement its program before the January 2001 expiration.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular Section 17A of the Act and the rules and regulations thereunder.

It Is Therefore Ordered, pursuant to section 19(b)(2) of the Act, that the proposed rule change (File No. SR–OCC–00–12) be and hereby is approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[10]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1653 Filed 1–19–01; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43836; File No. SR–PCX–00–33]

Self-Regulatory Organizations; Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change by the Pacific Exchange, Inc. Relating to Use of Telephones on the Options Trading Floor

January 11, 2001.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 1,2000, the Pacific Exchange, Inc. ("PCX" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PCX proposes to amend and codify its policy governing the use of member-owned or Exchange-owned telephones on the trading floor with respect to communications at option trading posts. The text of the proposed rule change is available at the PCX and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

According to the PCX, the purpose of the proposed rule change is to expand the existing PCX policy governing the use of telephones at option trading posts to allow the receipt of orders over outside telephone lines at option trading posts. The proposed rule would generally allow for the receipt of orders directly at the post over outside telephone lines only when the order(s) is placed during *outgoing* telephone calls. Registered Exchange Market Makers, however, may transmit orders directly to the trading post.

Under the proposed rule change, the use of telephones at the option posts must comply with the requirements and conditions set forth in proposed Rule 6.2(h)(3). This proposed rule would provide that: (A) only those quotations that have been publicly disseminated pursuant to PCX Rule 6.73 may be provided over telephones at the post; (B) orders transmitted by registered Exchange Market Makers may be entered directly to the trading posts; all other orders may be entered directly to

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[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 43755, (December 20, 2000), 65 FR 82431.

[3] The Accord also covers situations where an OCC clearing member that is not an NSCC member settles option exercises and assignments through an NSCC member.

[4] For a description of the Accord's formula, refer to Securities Exchange Act Release No. 37731 (September 26, 1996), 61 FR 51731.

[5] OCC plans to allow the use of Government securities as well once the necessary systems are developed. At December 31, 1999, OCC's margin deposits included over $36 billion in equities compared to $9 billion in Governments.

[6] For example, if the clearing member had equity securities with a market value of $10 million on deposit in an account with OCC as margin (which OCC would value at $7 million for margin purposes), the amount of the loan collateralized by those securities would have to be not less than $7 million. If the loan amount were, for example, $6 million OCC would be exchanging $7 million worth of margin for a reduction of only $6 million in its guarantee exposure to NSCC.

[7] If, in the preceding example, the margin requirement in the relevant account were only $6 million, the loan would be limited to that amount, and OCC would only release equity securities with a market value of $8.57 million ($6 million in margin value). The remaining $1.43 million of securities would be excess margin, which the clearing member would be free to withdraw and pledge separately.

[8] If, in the preceding examples, OCC's guarantee exposure to NSCC were only $5 million, the loan would be limited to that amount, and OCC would only release equity securities with a value of $7.15 million ($5 million in margin value). If the loan amount were in excess of $5 million, OCC would be releasing margin worth more than $5 million for a reduction of only $5 million in its guarantee exposure.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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the trading posts only during outgoing telephone calls that are initiated at the option posts; and (C) the Exchange may provide for the taping of any telephone line into the trading posts or may require Members to provide for the tape recording of a dedicated line at the posts at any time. Members and their clerks using the telephone consent to the Exchange tape recording any telephone or line. In addition, in proposed Rule 6.2(h)(5)(A), the PCX proposes to remove the current prohibition against Floor Brokers' use of cellular or cordless phones to make calls to persons located off the trading floor. Under the proposed revision, Floor Brokers will have the same ability to use cellular and cordless phones that PCX Market Makers and Lead Market Makers now have, except that Floor Brokers can accept orders only in outgoing calls initiated at the option post.

The Exchange believes that this proposed expansion of the Exchange's telephone policy at option posts is consistent with the recommendation of the Options Floor Trading Committee (OFTC), which oversees trading at the option posts. According to PCX, easing the current policy would enable the Exchange to provide more efficient access to its trading crowds and customers, increase the speed of the transmittal of orders and the execution of trades, and satisfy customers in an increasingly competitive environment.[3]

The Exchange intends to police compliance with the conditions applicable to the use of telephones at the option trading posts through oversight by and review of complaints from Exchange members at the trading post, as well as observations of Floor Officials and Exchange staff. Further, the Exchange represents that any individual member or associated person receiving orders over outside telephone lines must be properly qualified under Exchange rules.

The Exchange further indicates that the OFTC will be responsible for implementing this policy in conformity with Exchange rules and the Act. The OFTC will approve access, approve the phone technology, and decide any other issues relating to this policy.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with and furthers the objectives of Section 6(b)(5)[4] of the Act in that it is designed to improve communications to and from the Exchange's trading floor in a manner that promotes just and equitable principles of trade, prevents fraudulent and manipulative acts and practices, and maintains fair and orderly markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All submissions should refer to File No. SR–PCX–00–33 and should be submitted by February 12, 2000.

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

The Commission has reviewed the PCX's proposed rule change and finds, for the reasons set forth below, that the proposal is consistent with the requirements of Section 6 of the Act[5] and the rules and regulations thereunder applicable to a national securities exchange. Specifically, the Commission believes the proposal is consistent with Sections 6(b)(5) and 6(b)(8) of the Act.[6] Section 6(b)(5) requires, among other things, that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to facilitate transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system, and, in general, to protect investors and the public interest.[7] Section 6(b)(5) also requires that those rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Section 6(b)(8) of the Act requires that the rules of an exchange not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Commission finds that the proposed rule, which would expand the PCX's policy regarding the use of telephones on its options trading floor by permitting the receipt of off-floor orders over outside telephone lines directly at the equity trading posts during outgoing telephone calls, is consistent with Section 6(b)(5)[8] of the Act in that it is designed to improve communication to and from the Exchange's trading floor in a manner that is consistent with Section 6(b)(5)'s objectives of promotion of just and equitable principles of trade, prevention of fraudulent and manipulative acts and practices, and maintenance of fair and orderly markets. The Commission believes that it is reasonable for PCX to permit PCX Market Makers to send orders to the trading floor via incoming calls, a policy which allows these market makers to transmit their orders more efficiently at those times when they are required to be off the floor. In the Commission's view, it is also reasonable for the Exchange to now allow orders from any other source to go directly to the post as long as those orders are placed in outgoing calls only.

The Commission further finds that the proposed rule change modifies the PCX's communication system in a way that provides for equitable access to the Exchange floor among members, broker-dealers, non-broker-dealers, and public customers alike.[9] Accordingly, the Commission finds that the proposal is consistent with the requirement of Section 6(b)(8)[10] that the proposed rule change not impose a burden on competition that is not necessary or appropriate in furtherance of the Act's purpose.

The Exchange has indicated that it intends to police compliance with the conditions applicable to the use of telephones at the equity trading posts through complaints from Exchange members at the post, as well as observations of Floor Officials and Exchange staff. The Exchange has further indicated that the OFTC will be responsible for implementing this policy in conformity with Exchange Rules and the Act, including approving access and the phone technology, and will decide any other issues relating to this policy.[11] The Commission finds that these proposed means of surveillance are consistent with prevention of fraudulent and manipulative acts and practices, as required by Section 6(b)(5).

For these reasons, the Commission finds good cause for approving the proposed rule change (SR–PCX–00–33) prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. The Commission notes that PCX's proposal is virtually identical to a proposed rule change by CBOE (SR–CBOE–00–04) that was recently approved by the Commission.[12]

The Commission believes that proper surveillance is an essential component of any policy governing telephone access to an exchange's trading floor. Especially important in this case is ensuring that the PCX's surveillance efforts prevent individuals who are not properly qualified to take public orders for securities (*i.e.*, non-Series 7 registered Exchange employees) from interacting with the public. The Commission finds that the safeguards proposed above by the PCX are consistent with the prevention of fraudulent and manipulative acts and practices, as required under Section 6(b)(5).

IT IS THEREFORE ORDERED, pursuant to Section 19(b)(2) of the Act,[13] that the proposed rule change (SR–PCX–00–33) is hereby approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Jonathan G. Katz,

Secretary.

[FR Doc. 01–1802 Filed 1–19–01; 8:45 am]

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[3] *See* Securities Exchange Act Release No. 43194 (August 22, 2000), 65 FR 52457 (SR–CBOE–00–04).

[4] 15 U.S.C. 78f(b)(5).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5) and (b)(8).

[7] In approving this rule, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[8] 15 U.S.C. 78f(b)(5).

[9] The PCX represents, and the Commission notes, that Floor Brokers at the PCX can only receive orders from other broker-dealer member firms, unless they have registered their individual memberships with a member organization approved to transact business with the public, in which case these Floor Brokers would have to be Series 7 qualified, among other requirements. *See* PCX Rule 6.43. Telephone conversation among Michael Pierson, Director, Regulatory Policy, PCX, Cindy Sink, Senior Attorney, PCX, and Geoffrey Pemble, Attorney, Division of Market Regulation, SEC (December 1, 2000).

[10] 15 U.S.C. 78f(b)(8).

[11] Under this proposal, PCX Floor Brokers now will be able to receive telephone orders via personal or Exchange-owned cellular or cordless telephones (pursuant to proposed Rule 6.2(h)(5)(A)). The PCX represents, and the Commission notes, that surveillance of such telephone usage will be accomplished through the record-maintenance requirements in PCX Rule 6.2(h)(9), which would require members to maintain cellular or cordless phone records for at least one year and give the Exchange the authority to inspect such records. Telephone conversation between Cindy Sink, Senior Attorney, PCX, and Geoffrey Pemble, Attorney, Division of Market Regulation, SEC (November 30, 2000).

[12] *See* Securities Exchange Act Release No. 43493 (October 30, 2000).

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Notice Inviting Applications for Funding Under the Business-to-Business Learning, Investment, Networking and Collaboration (BusinessLINC) Program

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Invitation for Applications for Awards for FY 2001.

SUMMARY: The Administrator of the U.S. Small Business Administration (SBA) invites applications for awards for fiscal year 2001 under a grant competition supported by § 102 of Public Law No. 106–554, BusinessLINC Grants and Cooperative Agreements ("BusinessLINC"). The statute authorizes the Administrator to enter into cooperative agreements with qualified coalitions of public and private entities to promote the growth of small businesses by matching large concerns with small concerns and creating business-to-business partnering and mentoring relationships. These BusinessLINC cooperative agreements would provide funding to qualified coalitions to: (1) Expand business-to-business relationships between large and small businesses, and (2) provide businesses with online information and a database of companies that are interested in mentor-protégé programs or community-based, statewide, or local business development programs. Coalitions may consist of public entities, private entities, or a combination of public and private entities. To qualify, the coalition must provide an amount, either in-kind or in cash, equal to the grant amount.

Subject to funding availability, SBA intends to award up to $7.0 million in appropriated funds under this notice and expects to issue up to 50 awards. SBA reserves the right to fund, in whole or in part, any, all or none of the applications submitted in response to this notice. Award amounts may vary, depending upon availability of funds (and performance for option years); however, award amounts will be at least $25,000 and no single awardee may receive more than $250,000 in a single fiscal year.

The selection criteria to be used for this competition will be provided in the application package.

DATES: The closing date for applications is March 20, 2001, 4 p.m., Eastern Standard Time (EST).

ADDRESSES: To obtain a copy of the complete application package, call Mina Bookhard at (202) 205–7080, or see the BusinessLINC Program Announcement under the "Go To New Stuff" icon on SBA's website at www.sba.gov.

FOR APPLICATIONS AND FURTHER INFORMATION: Questions concerning the technical aspects of this notice should be directed to Rick Mayronne at (202) 205–7736. Questions about budget or funding matters should be directed to Mina Bookhard at (202) 205–7080.

Program Authority: 15 U.S.C. § 637(n).

Dated: January 12, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1709 Filed 1–19–01; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

SBA Minority Contractors Finance Pilot Loan Program

AGENCY: Small Business Administration.

ACTION: Notice of pilot program "SBA Minority Contractors Finance Pilot Loan Program"

SUMMARY: The Small Business Administration (SBA) is establishing a pilot program in which certain lenders will be permitted to use their own documentation forms to expeditiously approve loan amounts up to $250,000 for small business contractors and subcontractors in Rhode Island using the Section 7(a) loan program. The program will offer a technical assistance component provided by a Small Business Development Center (SBDC) and additional guaranty support from non-SBA sources for a lower risk exposure that is attractive to lenders and other modifications to SBA's normal lending practices and procedures. This program will be called the SBA Minority Contractors Finance Pilot Loan Program. The purpose for this 18-month pilot program is to address the

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difficulties that small business contractors and subcontractors generally experience with access to capital and bonding. This loan pilot program is a key part of an initiative that will first operate in Rhode Island and, may be expanded to other areas of the country.

EFFECTIVE DATE: This pilot will be effective on January 22, 2001 and will remain in effect for 18 months.

FOR FURTHER INFORMATION CONTACT: Mark Hayward, District Director, U.S. Small Business Administration—Rhode Island District Office, 380 Westminster Mall, 5th floor, Providence, RI 02903, (401) 528–4540; FAX: (401) 528–4539.

SUPPLEMENTARY INFORMATION: The Small Business Administration is establishing a streamlined, user friendly loan pilot program designed to help contractors and subcontractors more readily obtain financing and bonding.

SBA found that small business contractors and sub-contractors historically have not received the procurement, management, technical, and financial assistance necessary to maintain their viability. A Rhode Island advisory panel comprised of local lenders, contractors, bonding agents, and state agencies examined the problem and determined that lending to contractors and subcontractors was specialized financing and that the local lending community was disinclined to provide the same level of underwriting and post approval oversight on loans of $250,000 or less as they were for larger contract loans. Moreover, the interest of the taxpayers whose funds support the SBA guaranty had to be protected.

The principal barriers were seen as (i) too much risk and (ii) excessive cost of monitoring. SBA concluded that if borrowers received specialized technical assistance and the contribution of additional guaranty support from sources outside SBA, financing might be more forthcoming from local lenders.

To that end, the Agency has authorized the acceptance of a supplemental guaranty on a portion (up to 90 percent) of the unguaranteed percentage of SBA 7(a) loans, that will be offered by a lending entity of the Rhode Island Economic Development Corporation. The lending entity will contribute as much as $250,000 to assist minority business enterprises.

The specialized technical assistance component will include the utilization of a SBDC to provide the loan packaging assistance that would help the contractors and sub-contractors prepare their commercial loan applications. Non-SBA funds will support the hiring of an experienced team of contracting professionals with the proper knowledge, skills, and abilities to assist the 15–30 client contractors expected to participate in the pilot in bidding, managing, and completing their projects for 18 months. These professionals will be selected by an Executive Committee consisting of SBA staff, local lenders, contractors, bonding agents, and state agencies in a private/state/federal partnership. The Executive Committee also will provide guidance and oversight of the program. The non-SBA funding and resource partners are private foundations, state agencies, banks, and corporations who are committed to producing positive results. Finally, as part of the technical assistance, an Advisory Board is being formed consisting of prime contractors and state agencies to assure deal flow and expertise.

This pilot program emphasizes collaboration and partnerships with Federal, state and local agencies, as well as private sector partners. The pilot program is scheduled to last 18 months; beginning January 22, 2001. Prior to the termination date, SBA will evaluate the program to determine if it should be continued as is, expanded, or ended.

Program authority: 15 U.S.C. 636(a)(25)(b) or Section 7(a)(25)(b) of the Small Business Act.

Dated: January 11, 2001.

Charles D. Tansey,

Associate Deputy Administrator for Capital Access.

[FR Doc. 01–1787 Filed 1–19–01; 8:45 am]

BILLING CODE 8025–01–U

SOCIAL SECURITY ADMINISTRATION

The Ticket to Work and Work Incentives Advisory Panel Meeting

AGENCY: Social Security Administration (SSA).

ACTION: Notice of teleconference and meeting.

DATES: Teleconference: January 23, 2001, 1:30–3:30 p.m.

Meeting

February 6, 2001, 8:30 a.m.–5 p.m.
February 7, 2001, 8:30 a.m.–5 p.m.
February 8, 2001, 9:00 a.m.–5 p.m.

ADDRESSES:

Teleconference

Social Security Administration, International Trade Center, 500 E St. SW, 8th Floor, Theatre Room, Washington, DC 20254.

Meeting

Bethesda Hyatt, One Bethesda Metro Center, Bethesda, MD, 20814; Phone 301–657–1234; Fax, 301–657–6453. The hotel is located two doors down from the Bethesda Metro Station on the Red line.

SUPPLEMENTARY INFORMATION: Type of meeting: These meetings are open to the public. Interested parties are invited to attend the meetings. The public is invited to participate by coming to the addresses listed above or calling into the teleconference. The public is also invited to submit comments in writing at any time on or before February 8, 2001.

Purpose: In accordance with section 10(a)(2) of the Federal Advisory Committee Act, the Social Security Administration (SSA) announces meetings of the Ticket to Work and Work Incentives Improvement Act (TWWIIA) Advisory Panel (the Panel). Section 101(f) of Public Law 106–170 establishes the Panel to advise the Commissioner of SSA, the President, and the Congress on issues related to work incentives programs, planning and assistance for individuals with disabilities as provided under section 101(f)(2)(A) of the TWWIIA. The Panel is also to advise the Commissioner on matters specified in section 101(f)(2)(B) of that Act, including certain issues related to the Ticket to Work and Self-Sufficiency Program established under section 101(a) of that Act.

The Panel will meet by teleconference commencing Tuesday, January 23, 2001 at 1:30 p.m. to 3:30 p.m. The Panel will use the teleconference to conduct full Panel deliberations on the implementation of the TWWIIA. Public testimony will not be taken.

Agenda (Teleconference): The Panel will deliberate on the implementation of TWWIIA. The public is invited to participate by coming in to the address listed above or calling in to the scheduled teleconference to listen. No public testimony will be taken.

The Panel will meet in person commencing Tuesday, February 6, 2001 at 8:30 a.m. to 5 p.m., Wednesday, February 7, 2001 at 8:30 a.m. to 5 p.m., and Thursday, February 8, 2001 at 9:00 a.m. to 5 p.m. The Panel will use the meeting to receive public testimony, hear presentations on the implementation of TWWIIA, conduct full Panel deliberations, receive briefings and conduct business.

Agenda (Meeting): Public testimony will be heard in person on Tuesday, February 6, 2001 and Wednesday, February 7, 2001 from 8:30 to 9:30. Individuals interested in providing testimony in person should contact the Panel staff as outlined below to schedule time slots. Members of the public must schedule a timeslot in order to comment.

Each presenter will be called on by the Chair in the order in which they are scheduled to testify and is limited to a maximum five-minute verbal presentation. Full written testimony on TWWIIA Implementation, no longer than 5 pages, may be submitted in person or by mail, fax or email on an on-going basis to the Panel for consideration.

In the event that the public comments do not take up the scheduled time period for each day, the Panel will use that time to deliberate and conduct other Panel business. Since seating and teleconference ports may be limited, persons interested in providing testimony at the in person meeting or in attending these meetings should contact the Panel staff by E-mailing Kristen M. Breland, at *'kristen.m.breland@ssa.gov'* or calling (410) 966–7225.

The full agendas for the meetings follow this announcement. The agendas are posted on the Internet at *http://www.ssa.gov/work/Resources/Toolkit/* or can be received in advance electronically or by fax upon request. Seating may be limited so persons interested in attending this meeting should contact the Panel staff by e-mail or telephone.

Contact Information: Anyone requiring information regarding the Panel should contact the TWWIIA Panel staff. Records are being kept of all Panel proceedings and will be available for public inspection by appointment at the Panel office. Anyone requiring information regarding the Panel should contact the Panel staff by:

- Mail addressed to Social Security Administration, Ticket to Work and Work Incentives Advisory Panel Staff, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore MD, 21235.
- Telephone contact with Kristen Breland at (410) 966–7225.
- Fax at (410) 965–9063.
- E-mail to *TWWIIAPanel@ssa.gov.*

Dated: January 17, 2001.

Deborah M. Morrison,

Designated Federal Officer.

Ticket to Work and Work Incentives Advisory Panel—Public Teleconference Meeting

Social Security Administration, 8th Floor Theatre Room, 500 E Street, SW, Washington, DC 20254

Agenda

Tuesday, January 23, 2001

1:30 PM
Meeting Convened by Designated Federal Officer, Deborah Morrison; Sarah Wiggins Mitchell, Chair, Presiding
1:30–3:15 PM
Deliberations on the Implementation of the Ticket to Work and Work Incentives Improvement Act
3:15–3:30 PM
Administrative Issues
3:30 PM
Adjournment

Ticket to Work and Work Incentives Advisory Panel—Public Meeting

Bethesda Hyatt, One Bethesda Metro Center, Bethesda, MD 20814, Phone: (301) 657–1234; Fax (301) 657–6453. The hotel is located two doors down from the Bethesda Metro Station on the Red line.

Agenda

February 6, 7 and 8, 2001

Tuesday, February 6, 2001, Day 1

8:30 AM
Meeting Called to Order by Deborah Morrison, Designated Federal Officer; Welcome and Introductions—Sarah Mitchell, Chair, Presiding
8:30 to 9:30 AM
Public Testimony Comment Period on TWWIIA Implementation
9:30 to 10:30 AM
Presentations from SSA officials
10:30 to 10:45 AM
Break
10:45 to 11:45 AM
Presentations from Congressional Committee Staff
11:45 AM to 1:15 PM
Lunch (On Your Own)
1:15 PM
Meeting Reconvenes, Sarah Mitchell, Presiding
1:15 to 3:00 PM
Panel Deliberations on TWWIIA Implementation
3:00 to 3:30 PM
Break
3:00 to 5:00 PM
Panel Deliberations on TWWIIA Implementation
5:00 PM
Adjournment

Please note: If time allotted for public comment exceeds the time required, the Panel will use the time to deliberate on TWWIIA implementation.

Wednesday, February 7, 2001, Day 2

8:30 to 9:30 AM
Public Testimony Comment Period on TWWIIA Implementation
9:30 to 11:45 AM
Panel Deliberations on TWWIIA Implementation
11:45 AM to 1:15 PM
Lunch (On Your Own)
1:15 PM
Meeting Reconvenes Sarah Mitchell, Presiding
1:15 to 3:30 PM
Panel Deliberations on TWWIIA Implementation
3:30 to 3:45 PM
Break
3:45 to 5:00 PM
Panel Deliberations on TWWIIA Implementation
5:00 PM
Adjournment

Please note: If time allotted for public comment exceeds the time required, the Panel will use the time to deliberate on TWWIIA implementation.

Thursday, February 8, 2001, Day 3

9:00 to 11:45AM
Panel Deliberations on TWWIIA Implementation
11:45 AM to 1:15 PM
Lunch (On Your Own)
1:15 PM
Meeting Reconvenes Sarah Mitchell, Presiding
1:15 to 3:30 PM
Panel Deliberations on TWWIIA Implementation
3:30 to 3:45 PM
Break
3:45 to 5:00 PM
Business Meeting
5:00 PM
Adjournment by Designated Federal Officer

[FR Doc. 01–1952 Filed 1–19–01; 8:45 am]

BILLING CODE 4191–02–U

DEPARTMENT OF STATE

[Public Notice No. 3553]

Bureau of Oceans, International Environmental and Scientific Affairs; Public Meeting To Discuss Recently Completed Negotiations on an International Agreement Through the United Nations Environment Program (UNEP) on Persistent Organic Pollutants (POPs)

SUMMARY: The United States Government, through an interagency working group chaired by the U.S. Department of State, participated in the successful fifth negotiating session on a global agreement to address the release of certain POPs. The Department of State will host a public meeting for interested parties, including

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environmental non-governmental organizations and industry representatives on Tuesday, January 30, 2001, from 10:00 a.m. to 11:00 a.m. in Room 1408 of the U.S. Department of State, 2201 C Street NW, Washington, DC. To arrange for their entrance into the building, attendees should provide to Eunice Mourning of the Office of Environmental Policy, U.S. Department of State (tel. 202–647–9266, fax 202–647–5947) their name, organization, date of birth and Social Security number by noon on Monday, January 29, 2000. Attendees should enter the C Street entrance and bring picture identification with them. For further information, please contact Dr. Marie Ricciardone, U.S. Department of State, Office of Environmental Policy (OES/ENV), Room 4325, 2201 C Street NW, Washington DC 20520, phone 202–736–4660, fax 202–647–5947, e-mail RicciardoneMD@state.gov.

SUPPLEMENTARY INFORMATION:

The UNEP POPs Negotiations

The POPs treaty is the first global treaty to address in a comprehensive manner the risks to human health and the environment of POPs chemicals. The treaty will in the first instance deal with twelve substances: aldrin, endrin, hexachlorobenzene, toxaphene, chlordane, dieldrin, heptachlor, mirex, DDT, PCBs, dioxins and furans. These substances fall into three categories: pesticides, industrial chemicals, and unintended by-products of combustion and industrial processes.

The global agreement is an ambitious undertaking, since it encompasses a broad range of measures to address POPs of transboundary concern. These range from controls on production and use for commercial chemicals, restrictions on POPs wastes, and controls on by-products that come from combustion and industrial processes. For many countries, this will be the first time that manufacture and use of these substances have been restricted, and the effects are likely to be far-reaching.

Since the U.S. and other developed countries have already taken actions on these chemicals, a major goal for the agreement is broad participation by developing countries and, consequently, meaningful reductions in the amount of pollutants that are released into the environment. A critical part of the agreement is the technical and financial assistance mechanisms to help developing countries effectively implement their obligations.

Timetable and Point of Contact

The public meeting will be held on Tuesday, January 20, 2001 from 10 a.m. to 11 a.m. in Room 1408 of the U.S. Department of State. Some members of the interagency working group who participated in the negotiation will provide an overview of the fifth session. The U.S. Department of State is issuing this notice to help ensure that interested and potentially affected parties are aware of and knowledgeable about the conclusion of these negotiations, and have an opportunity to offer comments. Those organizations or individuals which cannot attend the meeting, but wish to either submit a written comment or to remain informed, should provide Eunice Mourning of the Office of Environmental Policy, U.S. Department of State (phone 202–647–9266; fax 202–647–5947) with their statement and/or their name, organization, address, telephone and fax numbers, and their e-mail address.

Dated: January 16, 2001.

Daniel T. Fantozzi,

Director, Office of Environmental Policy, U.S. Department of State.

[FR Doc. 01–1834 Filed 1–19–01; 8:45 am]

BILLING CODE 4710–08–P

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Tennessee Valley Authority (Meeting No. 1526).

TIME AND DATE: 9 a.m. (EST), January 24, 2001.

PLACE: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennessee.

STATUS: Open.

AGENDA: Approval of minutes of meeting held on November 15, 2000.

NEW BUSINESS:

C—Energy

C1. Revision of TVA Policy and Principles on the Environment.

C2. TVA Business Practice entitled "The Sale or Use of Coal Combustion By-Products and Related Services."

C3. Supplement to Contract No. 95P6F–133445 with Day & Zimmermann NPS, Inc., for modification and supplemental maintenance work at TVA's western region fossil facilities.

C4. Contract with KVB-Enertec for selective catalytic reduction flue gas analyzer systems at Allen, Bull Run, Colbert, Cumberland, Kingston, Paradise, and Widows Creek Fossil Plants.

C5. Supplement to Contract No. 00PPW–264807 with Foster Wheeler Energy Corporation for the design and supply of superheater and reheater elements for Widows Creek Fossil Plant Unit 7 and other TVA Fossil Plants.

E—Real Property Transactions

E1. Grant of a permanent easement to the City of Decatur, Alabama, for a sewerline and wastewater treatment plant affecting approximately 2.2 acres of land on Wheeler Reservoir in Morgan County, Alabama, Tract No. XTWR–113SP.

E2. Deed modification affecting approximately 9.3 acres of former TVA land located at Nitrate Plant No. 1 in Colbert County, Alabama, Tract No. XNPT–32, to allow the City of Sheffield to lease the property for the production of movies and for film-making education.

F—Other

F1. Designation of Maureen H. Dunn as Secretary and Clifford L. Beach, Jr., and James E. Norris as Assistant Secretaries of TVA.

F2. Approval to file condemnation cases to acquire the right to remove and dispose of trees that could endanger transmission lines and the temporary right to enter upon land to survey, appraise, and preform title investigations for an easement and right-of-way. The affected transmission lines are Kentucky Dam-Nashville Tap to Ashland City in Cheatham County, Tennessee, and Hanceville-Bremen in Cullman County, Alabama.

Information Items

1. Approval of an Amendment to the Trust Agreement between the Board of Directors of the TVA Retirement System and Fidelity Management Trust Company.

2. Approval of WRH Partners II as a new investment manager for the TVA Retirement System and approval of the Investment Management Agreement between the TVA Retirement System and the new investment manager.

3. Appointment of Karl Dudley, General Manager, Pickwick Electric Cooperative, as a member of Regional Resource Stewardship Council.

4. Approval of the modification of Contract No. P98P01–203507 with Thunder Basin Coal Company, LLC, for coal supply to Allen, Gallatin, Paradise, Johnsonville, Colbert, and Shawnee Fossil Plants.

5. Approval to file a condemnation case to acquire a right-of-way easement for the Weaver-Young Cane transmission line in Union County, Georgia.

6. Approval of a deed modification, at the request of the Tennessee Wildlife Resources Agency, affecting approximately 6.1 acres of land on Fort Loudoun Reservoir in Blount County, Tennessee, Tract No. XTFL–13.

7. Approval of recommendations resulting from the 65th Annual Wage Conference 2000—Construction Project Agreement (Hourly) Wage Rates.

8. Approval of recommendations resulting from the 65th Annual Wage Conference, 2000—Wage Rates of Annual Trades and Labor Employees and Teamsters.

9. Approval of negotiated revisions to General Agreement and related Memorandums of Understanding covering Annual Trades and Labor Employees.

For more information: Please call TVA Public Relations at (865) 632–6000, Knoxville, Tennessee. Information is also available at TVA's Washington Office (202) 898–2999. People who plan to attend the meeting and have special needs should call (865) 632–6000.

Dated: January 17, 2001.

Charles L. Young,

Assistant General Counsel, and Assistant Secretary.

[FR Doc. 01–1993 Filed 1–18–01; 12:52 am]

BILLING CODE 8120–08–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST–2001–8696]

DOT Guidance to Recipients on Special Language Services to Limited English Proficient (LEP) Beneficiaries

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: The United States Department of Transportation is publishing policy guidance on Title VI's prohibition against national origin discrimination as it affects limited English proficient persons.

DATES: This guidance is effective immediately. Comments must be submitted on or before March 23, 2001. DOT will review all comments and will determine what modifications to the policy guidance, if any, are necessary

ADDRESSES: Interested persons should submit written comments to Marc Brenman, Senior Policy Advisor, Office of Civil Rights, Department of Transportation, 400 7th St. SW., Washington, DC 20590, or marc.brenman@ost.dot.gov; comments may also be submitted by facsimile at 202–366–9371.

FOR FURTHER INFORMATION CONTACT: Marc Brenman, Office of Civil Rights, 400 7th St. SW., Washington, DC 20590. Telephone 202–366–1119; e-mail marc.brenman@ost.dot.gov; or David Tochen, Office of the General Counsel, 400 7th St. SW., Washington, DC 20590, 202–366–9153, e-mail david.tochen@ost.dot.gov. Arrangements to receive the policy in an alternative format may be made by contacting the named individuals.

SUPPLEMENTARY INFORMATION: Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, *et seq.* and its implementing regulations provide that no person shall be subjected to discrimination on the basis of race, color, or national origin under any program or activity that receives federal financial assistance.

The purpose of this policy guidance is to clarify the responsibilities of recipients of federal financial assistance from the U.S. Department of Transportation (DOT) ("recipients"), and assist them in fulfilling their responsibilities to limited English proficient (LEP) persons, pursuant to Title VI of the Civil Rights Act of 1964 and implementing regulations. The policy guidance reiterates DOT's longstanding position that in order to avoid discrimination against LEP persons on the grounds of national origin, recipients must take reasonable steps to ensure that such persons have meaningful access to the programs, services, and information those recipients provide, free of charge.

The policy guidance includes an appendix. Appendix A summarizes DOT's Title VI regulations, as they apply to LEP persons.

Dated: January 16, 2001.

Ronald A. Stroman,

Director, Departmental Office of Civil Rights, Department of Transportation.

DOT Guidance to Recipients on Special Language Services to Limited English Proficient (LEP) Beneficiaries

I. Background

On August 11, 2000, President Clinton signed Executive Order 13166, entitled "Improving Access to Services for Persons with Limited English Proficiency." 65 FR 50121 (September 16, 2000). On the same day, the Assistant Attorney General for Civil Rights issued a Policy Guidance Document titled "Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency" (hereinafter referred to as "DOJ LEP Guidance"), reprinted at 65 FR 50123 (September 16, 2000).

Executive Order 13166 requires Federal departments and agencies extending financial assistance to develop and make available guidance on how recipients should, consistent with the DOJ LEP Guidance and Title VI of the Civil Rights Act of 1964, as amended, assess and address the needs of otherwise eligible limited English proficient persons seeking access to the programs and activities of recipients of federal financial assistance. The DOJ LEP Guidance, in turn, provides general guidance on how recipients can ensure compliance with their Title VI obligation to "take reasonable steps to ensure 'meaningful' access to the information and services they provide." DOJ LEP Guidance, 65 FR at 50124. The DOJ LEP Guidance goes on to provide,

> [w]hat constitutes reasonable steps to ensure meaningful access will be contingent on a number of factors. Among the factors to be considered are the number or proportion of LEP persons in the eligible service population; the frequency with which LEP individuals come in contact with the program, the importance of the service provided by the program, and the resources available to the recipient.

Id. The DOJ LEP Guidance explains that the identification of "reasonable steps" to provide oral and written services in languages other than English is to be determined on a case-by-case basis through a balancing of all four factors.

The failure to assure that people who are not proficient in English can effectively participate in, and have meaningful access to, a Department of Transportation (DOT) financial assistance recipient's programs and activities may constitute national origin discrimination prohibited by Title VI and implementing regulations. Supreme Court precedent, and longstanding congressional provisions and federal agency regulations have repeatedly instructed that a nexus exists between language and national origin. As used throughout this Guidance, "DOT" is intended to include all the Department's operating administrations, components, and Secretarial offices.

This LEP Guidance addresses the key elements that DOT encourages its recipients to consider to ensure meaningful access to programs and activities by all people regardless of race or national origin. The purpose of the Guidance is to assist recipients in complying with their Title VI responsibilities to ensure that access to their programs or activities, normally provided in English, are accessible to LEP persons. The Guidance is consistent with the requirements of Executive Order 13166 and with the DOJ LEP Guidance.

During the development of this Guidance, DOT has ensured that stakeholders, such as LEP persons, their

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representative organizations, recipients, and other appropriate individuals and entities have had an adequate opportunity to provide input. Additional input is welcome.

Large numbers of minorities in the United States are linguistically isolated. According to the 1990 U.S. Census, 31.8 million persons or 13% of the total U.S. population (ages 5 and above) speak a language other than English at home. Almost 2 million people do not speak English at all and 4.8 million people do not speak English well. The 1990 U.S. Census also found that various minority populations and subgroups are linguistically isolated: Approximately 4 million Hispanics; approximately 1.6 million Asians and Pacific Islanders; approximately 282,000 Blacks; and approximately 77,000 Native Americans and Alaska Natives. Of those who speak Spanish in the United States, 97% are Hispanic. Research indicates that the correlation between language and national origin is also very high. As of 1989, 72.5% of Chinese Americans speak a language other than English at home. Comparable figures for other Asian Pacific Islander groups exist for Cambodians (81.9%), Vietnamese (80.7%), Laotians (77.4%), Thai (72.5%), Koreans (69.7%), Filipinos (59.9%), Indians (55.3%), and Japanese (40.5%).

School districts in many parts of the country are experiencing a substantial increase in the enrollment of national-origin-minority students who cannot speak, read, or write English well enough to participate meaningfully in educational programs without appropriate support services. There are approximately 3.5 million LEP students in the United States. The number of LEP students enrolled in public and nonpublic schools in the United States continues to increase each year. Between 1990 and 1997, the number of LEP students has risen by 57%. Most LEP students have parents whose skills in English are less than that of the students. The reported number of LEP students in K–12 public schools comprises 8% of the total public school enrollment in the United States. All states enroll LEP students. The states with the largest reported number of LEP students are California (1,381,383), Texas (513,634), and Florida (288,603). The states with the largest reported percentage of LEP students are Alaska (26%), New Mexico (24%), and California (22%). Since many public transportation providers also transport students to and from school, these figures are important.

In regard to one state alone, Pennsylvania ranks tenth among all states in the numbers of foreign-born persons who reside within its borders. Many of these individuals come to the United States with limited English skills, and are at varying stages of learning the English language. In all, more than seven percent of Pennsylvania's residents speak a primary language other than English. It is estimated that Philadelphia alone is home to approximately 30,000 Vietnamese, 25,000 ethnic Chinese, 10,000 Cambodians, and 7,000 Laotians. According to the 1990 Census, approximately 54% of persons in Pennsylvania whose home language is an Asian language do not speak English very well.

Many welfare recipients wrestle with poor job skills, health problems, and lack of transportation, in addition to language barriers. Besides the social, cultural and linguistic barriers, which affect the delivery of adequate transportation services, there are other factors that contribute to the poor social service status of LEP persons. These factors include the following:

- Inadequate number of health care providers and other health care professionals skilled in culturally competent and linguistically appropriate delivery of services.
- Scarcity of trained interpreters at the community level.
- Deficiency of knowledge about appropriate mechanisms to address language barriers in transportation settings.
- Absence of effective partnerships between major mainstream provider organizations and LEP minority communities.
- Low economic status.
- Lack of insurance.
- Organizational barriers.

One recipient reported to DOT as follows, regarding the barriers people who are LEP face in transportation:

> Language barriers prohibit people who are LEP from obtaining services and information relating to transportation services and programs. Because people who are LEP are not able to read instructions or correspondence written in English and may not understand verbal information, they often are not aware of regulatory requirements and legal implications of the services they seek. People who are LEP also do not have the ability to read variable message signs which alert them to dangerous driving conditions. When people who are LEP receive Orders or other legal documents, they often do not understand the contents of the correspondence and its implication to their daily lives. People who are LEP may not be able to take advantage of the transit system, which could affect their job and social opportunities. When their home or business property is acquired by the State DOT, they may not be aware of or understand the benefits to which they are entitled. When individuals do not understand or read English, they are hampered in seeking employment opportunities.

It is essential that transportation providers, professionals, and other DOT recipients become informed about their diverse clientele from a linguistic, cultural and social perspective. These individuals should become culturally competent so they can encourage vulnerable LEP minority populations to access and receive appropriate transportation services with more knowledge and confidence.

Advantages to Recipients Other Than Providing Beneficiary Access to Special Language (Spillover Benefits)

Helping Prevent Complaints: DOT receives complaints from beneficiaries alleging that insufficient information has been provided by recipients to beneficiaries in the primary or home language of the beneficiaries. For example, in the current (as of the date of this guidance) Title VI administrative complaint, West Harlem Environmental Action v. New York Metropolitan Transportation Authority and New York City Transit, the complainants seek as a part of their requested relief, "Translating all notices about impending depot and bus parking lot developments into Spanish." Providing such services before complaints are filed may help forestall such complaints and create better relations with beneficiary groups.

Economic Benefits: Translations of public transportation service documents may assist tourists and help establish localities as thoughtful and appropriate sites for global trade and investment.

II. Definitions

Limited-English-Proficient Persons: Individuals with a primary or home language other than English who must, due to limited fluency in English, communicate in that primary or home language if the individuals are to have an equal opportunity to participate effectively in or benefit from any aid, service or benefit provided by the transportation provider or other DOT recipient.

Linguistically Isolated: This term is defined in the Census as the percentage of the persons in households in which no one over the age of 14 speaks English well, and is used as a direct measure of those persons with a severe language barrier, as distinct from those of foreign origin who speak English well. Those who are linguistically isolated may also be unable to benefit from transportation services and the services of other DOT recipients, and therefore should receive attention from recipients as a high priority.

Federal financial assistance: The term Federal financial assistance to which Title VI applies includes but is not limited to grants and loans of Federal funds, grants or donations of Federal property, details of Federal personnel, or any agreement, arrangement or other contract which has as one of its purposes the provision of assistance.

Qualified interpreter: Qualified interpreter means an interpreter who is able to interpret effectively, accurately, and impartially, either for individuals with disabilities or for individuals with limited English skills. The interpreter should be able to interpret both receptively and expressively, using any necessary specialized vocabulary.

Non-English language relay service: A telecommunications relay service that allows persons with hearing or speech disabilities who use languages other than English to communicate with voice telephone users in a shared language other than English, through a communications assistant who is fluent in that language.

III. Legal Background

Title VI of the Civil Rights Act of 1964 and its implementing regulations prohibit recipients of federal financial assistance from discriminating on the basis of race, color, or national origin. In certain circumstances, failure to provide meaningful access to LEP persons is national origin discrimination. Most of the statements in this Guidance pertain to services provided by a recipient, rather than employment by the recipient. However, employment discrimination is covered by Title VI if the federal financial assistance is provided for the purpose of employment or if employment discrimination results in discrimination against program beneficiaries.

In order to avoid discrimination against LEP persons on the grounds of national origin, Title VI and the DOT Title VI regulations require recipients to take reasonable steps to ensure that LEP persons receive the language assistance necessary to afford them meaningful access to their programs and activities. A useful test of compliance with this guidance is to ask the question, "If we do not provide the service in question in a language a beneficiary understands, will the beneficiary still receive essentially the same benefit or service that we provide to others who are fluent in English?"

As discussed below, the framework for compliance with Title VI in this area is a flexible one, and DOT recognizes that a "one-size-fits-all" approach is not satisfactory. For instance, some recipients may have different Title VI LEP concerns in communities affected by their programs and activities, and may have different amounts of resources available. DOT also recognizes that some recipients are already addressing Title VI LEP concerns through existing programs and activities. We have tried to include examples of these efforts under Section IX, entitled "Promising Practices/Best Practices." More examples are welcome.

Many recipients of Federal financial assistance recognize that the failure to provide language assistance to LEP persons may deny them vital access to programs or activities. The failure to remove language barriers can be attributed to many reasons ranging from ignorance of the fact that some members of the community are unable to communicate in English to intentional discrimination on the basis of national origin. While there is not always a direct relationship between an individual's language and national origin, language often serves as an identifier of national origin. As the Supreme Court observed in *Hernandez* v. *New York*,

> [l]anguage elicits a response from others, * * * ranging from admiration and respect, to distance and alienation, to ridicule and scorn. Reactions of the latter type all too often result from or initiate racial hostility * * * It may well be, for certain ethnic groups and in some communities, that proficiency in a particular language, like skin color, should be treated as a surrogate for race under an equal protection analysis.

500 U.S. 352, 371 (1991). The significant discriminatory effects that result from the failure to provide language assistance to LEP persons, places the treatment of LEP individuals comfortably within the ambit of Title VI and DOT's implementing regulations.

In *Lau* v. *Nichols*, 414 U.S. 563 (1974), the Supreme Court recognized that, pursuant to Title VI, recipients of Federal financial assistance have an affirmative responsibility to provide LEP persons with a meaningful opportunity to participate in publicly funded programs. Lau involved a group of students of Chinese origin who did not speak English to whom the recipient provided the same services—an education provided solely in English—that it provided students who did speak English. The Court held that, under these circumstances, the school district's practice violated the Title VI prohibition against discrimination on the basis of national origin. The Court observed that "[i]t seems obvious that the Chinese-speaking minority receive fewer benefits than the English-speaking majority from respondents' school system which denies them a meaningful opportunity to participate in the educational program—all earmarks of the discrimination banned by" the Title VI regulations. Courts have applied the doctrine enunciated in Lau both inside and outside of the educational context. It has been considered in contexts as varied as what languages drivers' license tests must be given in, to whether material relating to unemployment benefits must be provided in a language other than English.

Most recently, and in a transportation context, the Eleventh Circuit in *Sandoval* v. *Hagan*, 197 F. 3rd 484 (11th Cir. 1999) *petition for certiorari granted, Alexander* v. *Sandoval*, 121 S.Ct. 28 (Sept. 26, 2000) (No. 99–1908) held that the State of Alabama's policy of administering a driver's license examination only in English was a facially neutral practice that had a disproportionate adverse effect on the basis of national origin, in violation of Title VI. The Court specifically noted the nexus between language policies and potential discrimination based on national origin. That is, in *Sandoval*, the vast majority of individuals who were adversely affected by Alabama's English-only driver's license examination policy were of foreign descent. It is interesting to note that the State produced *no* evidence at trial that non-English speakers pose greater highway safety risks than English speakers.

The Title VI regulations prohibit both intentional discrimination and policies and practices that appear neutral but have a discriminatory effect. Thus, a recipient's policies or practices regarding the provision of benefits and services to LEP persons need not be intentional to be discriminatory, but may constitute a violation of Title VI if they have a disproportionate adverse effect on LEP persons' ability to access programs and services. Accordingly, it is useful for recipients to examine their policies and practices to determine whether they adversely affect LEP persons disproportionately. This LEP Guidance provides a legal framework to assist recipients in conducting such assessments.

Title VI prohibits discrimination in any program or activity that receives Federal financial assistance. What constitutes a program or activity covered by Title VI was clarified by Congress when the Civil Rights Restoration Act of 1987 (CRRA) was enacted. The CRRA provides that, in most cases, when a recipient receives Federal financial assistance for a

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particular program or activity, all operations of the recipient are covered by Title VI, not just the part of the program that uses the Federal assistance. Thus, all parts of the recipient's operations would be covered by Title VI, even if the Federal assistance is used only by one part.

The Department of Justice is the principal federal agency for coordinating Title VI requirements. The obligation on the part of recipients to address the language needs of beneficiaries has been a long-standing part of its Title VI coordination policies. See 28 CFR 42.405(d)(1) (1976). Moreover, other federal agencies have adopted Title VI enforcement policies that the denial of benefits to non-English speakers may result in a disparate impact based on national origin in violation of Title VI. For example, inability to drive a car adversely affects individuals in the form of lost economic opportunities, social services, and other quality of life pursuits.

State or local "English-Only" laws

State and local laws may provide additional obligations to serve LEP individuals, but such laws cannot compel recipients of federal financial assistance to violate Title VI. For instance, given our constitutional structure, state or local "English-only" laws do not relieve an entity that receives federal funding from its responsibilities under federal anti-discrimination laws. State and local entities with "English-only" laws are certainly not required to accept federal funding—but if they do, they have to comply with Title VI and its implementing regulations, including their prohibition against national origin discrimination by recipients of federal assistance. Failing to make federally assisted programs and activities accessible to individuals who are LEP will, in certain circumstances, violate Title VI.

In *Sandoval* v. *Hagan*, the Court of Appeals for the Eleventh Circuit found that Alabama's "English-Only policy" had a significant disparate impact on foreign-born individuals, and imposed significant adversity on individuals by excluding otherwise qualified drivers from obtaining licenses. It enjoined the continued use of the "English-Only policy" and ordered Alabama to submit a plan for compliance. People with licenses can get to work in places not served by public transportation and earn better wages. The inability to drive also may stand in the way of satisfying other important needs, such as the need to get emergency medical attention, particularly in rural areas not served by public transportation. Additionally, driver's licenses are the most common form of identification in this country; without one, it is difficult to take part in the life of the community—opening a bank account, cashing a check, getting a library card, etc. For these many reasons, the inability of LEP persons to obtain driver's licenses presents serious problems.

IV. Ensuring Meaningful Access to LEP Persons

Title VI and its regulations require recipients to take reasonable steps to ensure "meaningful" access to DOT recipients' programs and activities. The key to providing meaningful access to LEP persons is to ensure that recipients and LEP beneficiaries can communicate effectively and act appropriately based on that communication. Thus, DOT recipients should take reasonable steps to ensure that LEP persons are given adequate information, are able to understand that information, and are able to participate effectively in recipient programs or activities, where appropriate. As the demographics of the United States continue to change and the proportion of LEP communities and populations continue to grow, a recipient's challenge (as well as DOT's challenge) will be to develop linguistically appropriate and effective methods of communication with LEP persons within the usual, tight resource constraints.

A. Assessment of Meaningful Access

DOT's main focus when evaluating a Title VI complaint based on allegations of national origin discrimination against LEP persons will be whether a recipient has taken reasonable steps to eliminate barriers to meaningful communication with LEP individuals and to provide necessary services equivalent to those provided to people who are fully English proficient. What "reasonable steps" should be taken will depend upon a number of factors. These factors include the following:

- The number and proportion of LEP persons potentially served by the recipient's programs or activities, and the variety of languages spoken in the recipient's service area:

The recipient should consider the number or proportion of people who will be excluded from participation in programs or activities without efforts to remove language barriers. Programs and activities that affect a few or even one LEP person are subject to the Title VI obligation to take reasonable steps to provide meaningful opportunities to obtain services. Nevertheless, the steps that are reasonable for a recipient whose programs or activities affect one LEP person a year may be different than those expected from a recipient whose program or activity affects many LEP persons on a regular basis. However, DOT encourages even those recipients whose programs or activities affect very few LEP persons on an infrequent basis to consider reasonable steps for involvement of LEP persons and to plan for situations in which LEP persons will be affected under the program or activity in question. This plan need not be intricate; it may be as simple as having certain public notices translated into a language other than English, providing an interpreter under certain conditions, or making available technological solutions such as a telephone language line.

- The frequency with which LEP individuals are affected by the program or activity:

The frequency with which LEP persons are affected by the programs or activities is also important. DOT encourages recipients to take into account the frequency with which the recipient's program or activity may affect LEP persons in its service area and to have the flexibility to tailor its actions to those needs. For example, if the recipient knows that there is a large LEP community that exists and that community is often impacted by the recipient's programs and activities, it may want to regularly translate notices of public hearings and post them in areas where LEP individuals will see them. DOT encourages recipients to use communication methods likely to reach the affected community (e.g., insert information with utility bills, place public service announcements on local radio shows, place notices on bulletin boards in grocery stores, houses of worship, community newspapers and community centers). In the notices, you can provide the option of translation services at public hearings if individuals contact you by a certain date. This way, if no one responds you do not expend valuable resources when no actual need for translation services exists.

Notices and information that are generally available to the public should be made available to substantial LEP populations. For example, weather and road condition telephone lines and websites should be available in translation. In areas with severe weather, such notices will probably rise to the level of safety issues, and therefore require the higher level of service described elsewhere in this guidance.

- The importance of the effect of the recipient's program or activity on LEP persons, bearing in mind that transportation is considered an essential service to participation in modern society:

The importance of the effects of the recipient's program or activity on LEP persons has a direct bearing on the reasonableness of steps taken to ensure meaningful participation. DOT encourages you to take more vigorous steps where the denial or delay of access may have more crucial implications than in situations that are not as crucial to one's day-to-day activities. For example, the obligations of federally-assisted health, emergency, hazardous materials, and safety efforts differ from those of a Federally-assisted program where safety or health is not at stake. DOT encourages you to consider the importance of the participation in the program or activity to individuals both immediately and in the long-term, as well as synergistic effects. In a study done in 1995, all Emergency Medical Services (EMS) personnel who participated referred to language as a principal challenge in effectively working with Hispanic community members. In addition, many recently arrived Hispanics are not accustomed to using the telephone to access emergency medical services. Such circumstances justify greater efforts by recipients to educate LEP individuals, as discussed elsewhere in this Guidance. In addition, inability to access public transportation may adversely effect ability to obtain health care, education, and jobs.

- The resources available to the recipient, and whether the recipient has budgeted for provision of special language services:

Resources of a recipient may be a factor in determining the level and kind of language services it should provide. Larger recipients with more resources will have more language service responsibilities than smaller recipients with few resources. DOT will use a reasonableness standard in evaluating whether a recipient's efforts are sufficient. Where excessive cost is proffered by a recipient as a reason for not undertaking necessary special language services, DOT will evaluate the situation on a case-by-case basis. DOT's evaluation will include a consideration of the totality of the recipient's circumstances, including the size of the budget of the largest organizational entity which supervises the work of the program, project or activity that directly receives DOT financial assistance. For example, for a unit of a state department of transportation, the budget of the entire state DOT will be used as a point of reference. Other considerations will include those listed elsewhere in this Guidance, such as the size of the LEP population needing services, the degree to which such populations have been historically excluded from services, the availability of less costly alternative service modalities, whether the costs can be amortized over time or are a one-time expense, whether services can be phased in to avoid excessive cost in any one year, the possibility of alternate sources of funds to pay for the necessary services, whether the services are required in response to complaints or law suits, and how long the recipient has been on notice that the special language services should be provided. Note that Title VI has been in existence since 1964, and that recipients have been on notice that discrimination on the basis of national origin has been prohibited since then.

- The level of services provided to fully English proficient people;

- Whether LEP persons are being excluded from services, or being provided a lower level of services:

Only under rare circumstances could this exclusion be justified, and the burden of proving the need for the exclusion would be very high. Example 1: The recipient provides no services to a neighborhood where LEP people live, while providing services to a neighborhood where fully English proficient people live. Example 2: Several years ago, a job access program funded by DOT's Federal Transit Administration stated in its brochures that eligible applicants must "speak English." Note that the prohibition on exclusion due to national origin would also apply to situations where a recipient excluded a beneficiary from bringing an interpreter to a meeting, test, or other formal situation with the recipient. Although DOT discourages reliance by recipients on beneficiary-supplied interpreters, if the beneficiary desires to use one, and the recipient does not supply an interpreter, the recipient should permit his/her use. DOT recognizes that issues of security of testing are sometimes thought to arise when an non-recipient-supplied interpreter translates for a beneficiary. These issues are the responsibility of the recipient. If security is felt to be a potential problem by a recipient, the recipient bears the burden of supplying the interpreter.

- Whether the recipient has adequate justification for restrictions, if any, on special language services or speaking languages other than English:

Such justifications would be accepted only in rare circumstances. Assertions of safety justifications would generally not be accepted unless accompanied by statistical and/or scientific causality studies and evidence showing a positive correlation between limited English proficiency and crash and death/injury rates at rates substantially higher than would be expected due to chance.

There is no one-size fits all solution for Title VI compliance with respect to LEP persons. When investigating a Title VI complaint, DOT will assess language assistance allegations on a case-by-case basis, and will afford considerable flexibility to recipients to determine precisely how to fulfill this obligation. DOT will focus on the end result—whether recipients have taken the necessary steps to ensure that LEP persons have meaningful access to participate in their programs and activities, and whether those services are being provided so that LEP persons have an equal opportunity to benefit from recipients' services.

V. Compliance and Enforcement

The recommendations outlined in this Guidance are not intended to be exhaustive. Recipients should establish and implement policies and procedures for providing language assistance sufficient to fulfill their Title VI responsibilities and provide LEP persons with meaningful access to services. DOT enforces Title VI as it applies to recipients' responsibilities to LEP persons through the procedures provided for in DOT's Title VI regulations (49 CFR Part 21, see Appendix A), and in appropriate DOT operating administration regulations. These procedures include complaint investigations, compliance reviews, alternative dispute resolution, efforts to secure voluntary compliance and technical assistance.

DOT's Title VI regulations provide that the agency will investigate whenever it receives a complaint, report or other information that alleges or indicates possible noncompliance with Title VI. If the investigation results in a finding of compliance, DOT will inform the recipient and the complainant in writing of this determination, including the basis for the determination. If the investigation results in a finding of noncompliance, DOT must inform the recipient of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance, and must attempt to secure voluntary compliance through informal means. If the matter cannot be resolved informally, DOT must secure compliance through (a) the termination of Federal assistance after the recipient has been given an opportunity for an administrative hearing, (b) referral to DOJ for injunctive relief or other

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enforcement proceedings, or (c) any other means authorized by law.

As the Title VI regulations set forth in the Appendix indicate, DOT has a legal obligation to seek voluntary compliance in resolving cases and cannot seek the termination of funds until it has engaged in voluntary compliance efforts and has determined that compliance cannot be secured voluntarily. During these efforts to secure voluntary compliance, DOT consults with and assists recipients entities in exploring cost effective ways of coming into compliance, by sharing information on potential community resources, by increasing awareness of emerging technologies, by sharing information on how other recipients entities have addressed the language needs of diverse populations, and by proposing reasonable timetables for achieving compliance.

Whenever possible, DOT provides recipients with technical assistance upon request and an opportunity to come into voluntary compliance with Title VI prior to initiating formal enforcement proceedings. In determining a recipient's compliance with Title VI, the Departmental Office of Civil Rights' (DOCR) primary concern is to ensure that the recipient's policies and procedures allow LEP persons to overcome language differences that result in barriers and have a meaningful opportunity to participate in and access programs, services and benefits to the same extent as fully English proficient persons. A recipients's appropriate use of the methods and options discussed in this policy guidance will be viewed by DOCR as evidence of a recipient's willingness to comply voluntarily with its Title VI obligations.

Further, when reviewing any claim of discrimination, DOT considers the severity of the adverse impact on LEP persons, the egregiousness or pervasiveness of any adverse action taken by a recipient, and whether the recipient has shown an intent to discriminate.

Assurance Forms

When organizations apply for DOT financial assistance, they submit an assurance with their applications that they will comply with the requirements of DOT's regulations implementing Title VI with respect to their programs and activities. When they receive DOT financial assistance, they accept the obligation to comply with DOT's Title VI implementing regulations. These assurances should be understood to include provision of services to national origin minority persons who are limited English proficient.

VI. Framework for Language Assistance

DOT has determined that effective language assistance programs usually address each of the elements described below. The failure to incorporate or implement one or more of these elements does not necessarily indicate noncompliance with Title VI. When investigating Title VI complaints, DOT will review the totality of the circumstances to determine whether LEP persons have had meaningful access to participate effectively in a recipient's programs and activities.

1. Needs Assessment

A recipient should conduct a thorough assessment of the language needs of the population and communities affected by the recipient.

The first key to ensuring meaningful access to LEP persons is to assess the language needs of the affected population and communities served, through application of the analysis described elsewhere in this Guidance. Ways to assess language needs include identifying the non-English languages used in communities affected by the recipient, estimating how many people speak each language, where they live, and how well they are currently accessing services provided to those who are fully English proficient. After identifying LEP communities, DOT encourages recipients to consider any barriers to communication with these communities. It is possible that, in certain instances, the results of the assessment may indicate that, although LEP communities are affected by the programs and activities, there are no barriers to communication with these communities, because they are bilingual, for instance, or do not need or want translation services.

An approach may be developed to identify geographic areas where LEP communities live using existing resources such as census data, data from local organizations and community groups, faith-based groups that provide services in languages other than English, immigrant aid organizations, state refugee coordinators, non-English media outlets, and school district LEP statistics. The latter are particularly valuable, since all school districts are required to maintain data on LEP students and provide necessary special language services. It is important to collaborate with community groups and other appropriate stakeholders to develop the criteria for identifying geographic areas. Once the areas are identified, the recipient can work with the affected communities and stakeholders to determine their language assistance needs. The recipient may also choose to identify actual or potential populations within a particular service area or area of responsibility.

Specifically, DOT encourages recipients to identify linguistically isolated populations or job sites in which LEP persons represent a significant proportion of the workforce (*e.g.*, manual labor, hotel cleaning, food preparation, auto supplies, etc.) Transportation entities in particular should be aware of the potential difficulties LEP people may have in public transportation from home to work, health facilities, schools, shopping, faith-based facilities, day-care, and leisure activities. New immigrants to the United States from non-English speaking countries may be especially in need of special language services. Note that Title VI of the Civil Rights Act of 1964 covers "people in the United States." Thus, recipients may generally not refuse to provide services to non-citizens, regardless of immigration status.

Identifying the points of contact in the program or activity where language assistance is likely to be needed, identifying the resources that will be needed to provide effective language assistance, identifying the location and availability of these resources, and identifying the arrangements that should be made to access these resources in a timely manner are important factors to ensure effective provision of services.

2. Written Language Assistance Plan

Recipients should develop and implement written language assistance plans that will ensure meaningful opportunities for LEP persons to access their programs and activities and effectively participate in them.

A recipient can help ensure effective communication with LEP persons by developing and implementing a comprehensive, written language assistance plan. Such a plan should include policies and procedures for identifying and assessing the language needs of LEP persons, and provide for a range of written and oral language assistance options, periodic training of staff, actual provision of services, and monitoring of the program. DOT encourages recipients to consider the transportation needs of the LEP community affected by the recipient's programs and activities while developing this plan. The factor analysis set forth in this Guidance should be the starting point for identifying areas in which language services are needed.

DOT encourages recipients to consider one or more of the following

ideas as they develop language assistance plans:

- Assigning primary responsibility for development and implementation of the plan to an appropriate manager or supervisor.
- Preparing a written summary of results from the needs assessment (discussed above).
- Identifying actions already being taken and existing tools that can be used to provide meaningful access to LEP individuals, and how well they work.
- Creating an inventory of existing materials that have been translated into other languages to assist LEP individuals.
- Regularly updating the inventory of translated materials.
- Drafting a plan that is specific and detailed, yet flexible enough to respond to existing or potential needs over an appropriate time period (*i.e.*, five years).
- Ensuring that translation arrangements have quality control (*i.e.*, mechanisms are in place to ensure that the translation accurately and appropriately conveys the substance of what is contained in the written materials).
- Distributing the names of organizational contacts who will respond to inquiries and requests regarding access to programs and activities by LEP individuals, in appropriate media and publications.
- Addressing the appropriate mix of written and oral language assistance to ensure effective communication with the LEP population.

A plan should generally include:

- Who is responsible for each step.
- When each step is expected to be completed. (Generally speaking, the more vital the service, the sooner it should be provided.)
- What standards and criteria are to be applied to measure the effectiveness of each step.
- What resources will be devoted to each step.
- How the recipient will document implementation of each step.

3. Staff Training

Recipients should ensure that staff understand the recipient's language assistance policy and are capable of carrying it out.

The success of recipients' LEP/Title VI activities will depend on the staff's knowledge, credibility, and actions. DOT encourages recipients to disseminate the recipient's policy to all employees likely to have contact with LEP persons and to periodically train employees. Effective training, which includes cultural and community relations sensitization, is one way to ensure that there is not a gap between your policies and procedures and the actual practices of employees who interact with LEP persons. Effective training ensures that employees are knowledgeable and aware of LEP policies and procedures, can work effectively with in-person and telephone interpreters, and understand the dynamics of interpretation between beneficiaries, providers and interpreters. It is important that this training be part of the orientation for new employees and all employees in beneficiary contact positions should be properly trained. Given the high turnover rate among some types of employees, a recipient may find it useful to maintain a training registry that records the names and dates of employees' training.

4. Provision of Special Language Assistance

Recipients must actually provide necessary services to LEP persons.

Most important to any LEP plan is to actually provide the necessary services. Actual provision of services includes notification of the availability of services. A vital part of an effective compliance program includes having effective methods for notifying LEP persons regarding their right to language assistance and the availability of such assistance free of charge. These methods include but are not limited to:

- Use of language identification cards that allow LEP beneficiaries to identify their language needs to staff and for staff to identify the language needs of applicants and clients. To be effective, the cards (*e.g.*, "I speak cards") should invite the LEP person to identify the language he/she speaks. This identification can be recorded in the LEP person's file, if the recipient keeps such files on beneficiaries.
- Posting and maintaining signs in regularly encountered non-English languages in waiting rooms, reception areas and other initial points of entry. In order to be effective, these signs should inform applicants and beneficiaries of their right to free language assistance services and invite them to identify themselves as persons needing such services.
- Translation of application forms and instructional, informational and other written materials into appropriate non-English languages by competent translators. For LEP persons whose language does not exist in written form, assistance should be provided from an interpreter to explain the contents of the document. LEP persons may need assistance, for example, however, in filling out forms such as those for transit half-fare benefits or paratransit eligibility under the Americans with Disabilities Act.
- Uniform procedures for timely and effective telephone communication between staff and LEP persons. This should include instructions for English-speaking employees to obtain assistance from interpreters or bilingual staff when receiving calls from or initiating calls to LEP persons, and
- Inclusion of statements about the services available and the right to free language assistance services, in appropriate non-English languages, in brochures, booklets, outreach and recruitment information and other materials that are routinely disseminated to the public.

5. Monitoring

Recipients should conduct regular oversight of their language assistance programs to ensure that LEP persons can meaningfully access their programs and activities. It is also important that recipients regularly monitor their language assistance programs by assessing the following:

- Current LEP demographics of the population that is affected by the recipient's programs and activities.
- Current communication needs of LEP communities.
- Whether the recipient's plan is adequately supported so that it has a realistic chance of success.
- Whether existing assistance is meeting the needs of LEP persons.
- Whether recipient staff are knowledgeable about policies and procedures and how to implement them.
- Whether sources of, and arrangements for, assistance are still current and viable.
- Whether the plan is periodically evaluated and revised, as necessary. Note that recipients are required to modify their plans and programs of service if they prove to be unsuccessful after a legitimate trial.
- Number and type of grievances and complaints received by the recipient or against the recipient by DOJ or DOT, alleging lack of provision of services due to limited English proficiency.

One way to evaluate the language assistance program is to seek and obtain feedback from the communities served. DOT believes that compliance with the Title VI language assistance obligation is most likely met when a recipient continuously monitors its program and makes modifications where necessary, including meeting public participation requirements under other initiatives such as environmental justice.

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VII. Ways of Providing Language Services

Once the recipient has determined that language services are needed, there are three main ways of providing those services: oral interpretation; written translation; and alternate, non-verbal methods. The following provides information on these three methods.

A. Oral Language Interpretation

In designing an effective language assistance program, a recipient develops procedures for obtaining and providing trained and competent interpreters and other oral language assistance services, in a timely manner, by taking some or all of the following steps:

- Hiring bilingual staff who are trained and competent in the skill of interpreting.
- Hiring staff interpreters who are trained and competent in the skill of interpreting.
- Contracting with an outside interpreter service for trained and competent interpreters.
- Arranging formally for the services of voluntary community interpreters who are trained and competent in the skill of interpreting.
- Arranging/contracting for the use of a telephone language interpreter service.

Bilingual Staff—Hiring bilingual staff for beneficiary contact positions facilitates participation by LEP persons. However, where there are a variety of LEP language groups in a recipient's service area, this option may be insufficient to meet the needs of all LEP applicants and clients. Where this option is insufficient to meet these needs, the recipient should provide additional and timely language assistance. Bilingual staff should be trained and should demonstrate competence as interpreters.

Staff Interpreters—Paid staff interpreters are especially appropriate where there is a frequent and/or regular need for interpreting services. These persons should be competent and readily available.

Contract Interpreters—The use of contract interpreters may be an option for recipients that have an infrequent need for interpreting services, have less common LEP language groups in their service areas, or need to supplement their in-house capabilities on an as needed basis. Such contract interpreters should be readily available and competent.

Community Volunteers—Use of community volunteers may provide recipients with a cost-effective method for providing interpreter services. However, experience has shown that to use community volunteers effectively, recipients should ensure that formal arrangements for interpreting services are made with community organizations so that these organizations are not subjected to *ad hoc* requests for assistance. In addition, recipients should ensure that these volunteers are competent as interpreters and understand their obligation to maintain client confidentiality. Additional language assistance should be provided where competent volunteers are not readily available during all hours of service.

Telephone Interpreter Lines—A telephone interpreter service line may be a useful option as a supplemental system, or may be useful when a recipient encounters a language that it cannot otherwise accommodate. Such a service often offers interpreting assistance in many different languages and usually can provide the service in quick response to a request. However, recipients should be aware that such services may not always have readily available interpreters who are familiar with the terminology peculiar to the particular program or service. It is important that a recipient not offer this as the only language assistance option except where other language assistance options are unavailable (*e.g.*, in a rural area visited by a LEP beneficiary who speaks a language that is not usually encountered in the area).

B. Translation of Written Materials

An effective language assistance program ensures that written materials that are routinely provided in English to applicants, clients and the public are available in regularly encountered languages other than English. It is particularly important to ensure that vital documents, such as applications, consent forms, letters containing important information regarding participation in a program (such as a cover letter outlining conditions of participation in a paratransit program), notices pertaining to the reduction, denial or termination of services or benefits or that require a response from beneficiaries, notices advising LEP persons of the availability of free language assistance, and other outreach materials be translated into the non-English language of each regularly encountered LEP group eligible to be served or likely to be directly affected by the recipient's program. Materials with a "gatekeeper" function, such as those concerning the necessity for insurance and licensure, should be translated. Notices for the public should be published in the primary non-English language media serving the recipient's service area. However, note the emphasis elsewhere in this document on exploring non-verbal/non-language-based approaches to communication. Warning signs should be posted in the languages spoken by people likely to encounter the signs.

Services such as public safety, police, and law enforcement that might result in the diminution of personal freedom, in fines and penalties, in loss of driving privileges, or in "points" on driving records, are subject to a high burden on the recipient that provides such services, in terms of timeliness and quality of translation of key documents. Many DOT recipients are engaged in such services—such as state departments of public safety, state motor vehicle departments, transit and railroad police, and airport security. More complete guidance for such special language services by law enforcement personnel is available through the Department of Justice.

It is important to ensure that written materials routinely provided by a recipient in English also are provided in regularly encountered languages other than English. It is particularly important to ensure that vital documents are translated into the non-English language of each regularly encountered LEP group eligible to be served or likely to be affected by the recipient's program or activity. A document will be considered vital if it contains information that is critical for obtaining federal services and/or benefits, or is required by law. Vital documents include, for example: applications; consent and complaint forms; notices of rights and disciplinary action; notices advising LEP persons of the availability of free language assistance; and written tests that do not assess English language competency, but rather competency for a particular license, job, or skill for which English competency is not required; and letters or notices that require a response from the beneficiary or client. For instance, if a complaint form is necessary in order to file a claim with an agency, that complaint form would be vital. Non-vital information includes documents that are not critical to access such benefits and services.

Vital documents should be translated when a significant number or percentage of the population eligible to be served, or likely to be directly affected by the program/activity, needs services or information in a language other than English to communicate effectively. For many larger documents, translation of vital information contained within the document will suffice and the documents need not be translated in their entirety.

It may sometimes be difficult to draw a distinction between vital and non-vital documents, particularly when considering outreach or other documents designed to raise awareness of rights or services. Though meaningful access to a program requires an awareness of the program's existence, DOT recognizes that it would be impossible, from a practical and cost-based perspective, to translate every piece of outreach material into every language. Title VI does not require this of recipients. Nevertheless, because in some circumstances lack of awareness of the existence of a particular program may effectively deny LEP individuals meaningful access, it is important to continually survey/assess the needs of eligible service populations to determine whether certain critical outreach materials should be translated into other languages.

DOT's National Highway Traffic Safety Administration (NHTSA) has found that direct translation of safety pamphlets and brochures that have been developed in English into a non-English language often results in an inferior or inappropriate product due to the many dialects and linguistic styles of foreign languages and because the materials were not designed to originally focus on a particular dialect-speaking audience. A better approach is to develop the materials in the language and dialect in which they are intended to be used. Also, involving the target community in review of the final brochure or product can eliminate inappropriate word choice and increase the effectiveness of the messages. Community group involvement can also provide a ready means of distribution of the materials

C. Use of Alternative Communication Methods and Devices:

To alleviate the concerns of recipients, and to reduce cost, DOT encourages recipients to explore use of methods and devices that do not use language. For example, use of pictograms, symbol signs, standard symbolic signs (SMS's), diagrams, color-coded warnings, illustrations, graphics, and pictures can be considered. A major example of the use of such methods in transportation infrastructure is the laminated plastic safety information cards in the seat back pouches on commercial airliners. These cards communicate a great deal of important safety information using very few words in any language. Schematic maps can similarly quickly communicate large amounts of information without words. Standard symbols such as are used on international roads and at the Olympics can be used. Use of such non-verbal methods will also help alleviate problems of communication for those who are illiterate or partially literate, those who are too young to read, and those with hearing impairments. Use of symbol signs may help elderly drivers as well, since signing in highway work areas raises sign legibility issues for older drivers. It may be noted that there is overlap between older drivers and those who are more likely to be LEP in some subpopulations, such as the Navajo. Symbol signs and pictograms also benefit globalization of trade and travel.

Example 1. "Transportation engineers world-wide are moving toward the use of symbol signs in place of word signs because they are easier for people to comprehend in a shorter amount of time. Easily recognized symbols also accommodate people who cannot read English." (Irvine, California, Traffic Research and Control Center (ITRAC))

Example 2. "Universal design considerations also offer the potential to benefit persons with a cognitive disability. For example, standardized symbols, pictures, and color coding offer benefits to persons with a cognitive disability. If written information is provided, the messages should be short and clear. Repetition of symbols and information also helps reduce the difficulty of remembering information." (Transport Canada, "Technologies for travelers with sensory or cognitive disabilities (TP 13247E)")

A Federal Highway Administration (FHWA) study reached these conclusions about symbol signs:

Minimize symbol complexity by using very few details.

Maximize the distance between symbol sign elements.

Use representational rather than abstract symbols.

Use solid rather than outline figures for designs.

Standardize the design of arrowheads, human figures, and vehicles. Retain maximum contrast between the symbol and the sign background.

Use of pictograms in dynamic signs can be considered. These are in use in Europe. Regulatory speed limit messages are presented using a number in a red circle, which is analogous to the European static speed limit sign. Other symbol messages presented to drivers in dynamic message signs include congestion, snow, and diversion (detour) directions. Research is underway to develop additional symbols for inclusion in the European standards for traffic control devices. Two specific conditions for which symbols are being explored are "fog" and "accident."

Example: NHTSA, 49 CFR Parts 571 and 575, Consumer Information Regulations: Utility Vehicle Label; Final Rule, Federal Register, March 9, 1999 (Volume 64, Number 45) "The rule requires the label's header to have an alert symbol (a triangle containing an exclamation point) followed by the statement "WARNING: Higher Rollover Risk" in black text on a yellow background. The following three statements must appear below the header in the center of the label: "Avoid Abrupt Maneuvers and Excessive Speed," "Always Buckle Up," and "See Owner's Manual For Further Information." The rule specifies that the label must contain two pictograms: one showing a tilting utility vehicle on the left of the label, and the other showing a seated vehicle occupant with a secured three-point belt system on the right. The pictograms and the statement must be in black on a white background." The label was revised from 77 words to 19 words and two pictograms. Permission was granted to companies to produce the label with both the required English words and a translation into other languages. Labels have been produced with French and Spanish translations.

There are opportunities for higher technology approaches, such as use of multimedia pictograms, holograms, photographs, looped videotapes, embedded picture instructions to represent destinations and instructions, information kiosks with multiple languages, courtesy telephones at stations linked to a central number with translators, and voice recognition.

VIII. Application of this Guidance for DOT Recipients

Grievance or Complaint Procedures

Generally, a recipient should maintain a written and publicly known grievance or complaint procedure available to members of the public, so that LEP persons can bring alleged problems with lack of services to the recipient's attention for resolution. DOT encourages recipients to resolve such problems at the lowest level possible and encourages use of alternate dispute resolution. Grievance and complaint procedures should be prompt and equitable while obeying generally accepted elements of due process. However, they need not be overly formal. Existing grievance or complaint procedures can be used if they are modified as necessary to clarify their availability for use with LEP disputes and are made available in languages used in the community service area.

LEP Community Outreach and Education

It may be useful for the recipient to have an established, formal linkage between a minority community-based organization and a transportation provider or infrastructure entity. The linkage can be confirmed by a signed agreement between the applicant and linkage organizations which specifies in

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detail the roles and resources that each entity will bring to the project, and states the duration and terms of the linkage. The document can be signed by an individual with the authority to represent the community-based organization (*e.g.*, president, chief executive officer, executive director).

Comprehensive outreach includes the following:

- Use of ethnic media, such as radio, television, newspapers, magazines and websites.
- Use of faith-based organizations, such as temples, mosques and churches.
- Work with community-based organizations at the local (city or county) level that provide social services, health care, classes, etc. to target LEP communities.
- Outreach to schools with substantial enrollments of LEP children.
- Ensure that translated materials provide referrals to telephone numbers or websites that are linguistically accessible (*i.e.*, a flyer in Vietnamese should refer the caller to a hotline with Vietnamese-speaking workers).
- Nontraditional channels, such as day care centers and Headstart programs.
- Forming community groups led by a trained lay educator (a promotore or promotora) to enable adults to discuss issues and learn from each other.

The content of community outreach is important. For example, DOT has been told by a coalition of Southeast Asian-American advocacy groups that many people in their communities lack basic information about transportation services. The information needs include safety and security information, such as what may not be carried on airplanes and questions that will be asked at the ticket counter. Knowledge about public participation opportunities in transportation planning is needed. This area should especially be addressed by metropolitan planning organizations (MPOs).

DOT encourages partnerships among federal recipients and other human services organizations. How these can work is shown in the following example. "Expand existing loan programs that assist welfare recipients in purchasing cars and increase accessibility to public transportation. Counties should expand existing programs or create new programs that lend money to welfare recipients and other low-income families to purchase cars. Counties should also explore savings accounts that enable recipients to save for purchasing their own cars, without jeopardizing their financial eligibility for welfare cash aid. ERA also recommends that counties partner with transportation agencies to translate transportation information and resources into other languages." (Equal Rights Advocates [ERA's] Immigrant Women and Welfare study)

Transportation Planning

Recipients' transportation plans should identify how the needs of LEP persons will be met where a significant number of such persons can be reasonably expected to need transportation services.

Numerical Thresholds

DOT has determined that it will not specify numerical or percentage thresholds for LEP populations that need to be served by recipients. Generally, the larger the number or percent of LEP beneficiaries within a recipient's service area who speak a particular primary or home language, the more thorough, intensive, and speedy the special language services should be. The extent of the service area will in part determine the number or percent of the covered population. For example, the service area of state departments of transportation will generally be considered to be the entire state. The service area of a metropolitan planning organization will be the geographic area for which the MPO provides surface transportation planning services. International airports serve a very broad geographical area, and may be presented with special problems in dealing with a large number of languages. Such difficulties will be taken into consideration by DOT, but it is expected that such transportation providers will know a great deal of demographic information about their users. Similar reasoning applies to national networks like AMTRAK. Note that the population includes those who may potentially be served by the recipient, rather than just those who are presently being served. This is to reach those who are not presently receiving adequate or equitable services from the recipient, but might receive such services if the recipient were to provide special language services to them. DOT recommends that recipients become aware of the changing demographics of their service areas, especially in terms of increasing numbers and percents of languages used, so that recipients can prepare for future service needs.

Emergency Services

DOT funds a number of first responder, emergency, public safety, and hazardous materials services. Because of the safety and health aspects of these services, the need for special language services delivered without noticeable delay by recipients are heightened. Workers in these areas render vitally important services whose very nature requires quick action to protect public safety and health; quick assessment of a situation, often based on input from community members on the spot; the establishment of a close relationship with the client or patient that is based on empathy, confidence and mutual trust; and direction to affected people that must be carried out with specificity to be effective. Such relationships depend heavily on the free flow of communication between professional and client. This essential exchange of information is difficult when the two parties involved speak different languages; it may be impeded further by the presence of an unqualified third person who attempts to serve as an interpreter.

Some safety, emergency, and hazardous materials service providers have sought to bridge the language gap by encouraging LEP clients to provide their own interpreters as an alternative to the agency's hiring of qualified bilingual employees or interpreters. Persons of limited English proficiency must sometimes rely on their minor children to interpret for them during safety incidents. Alternatively, these beneficiaries/clients may be required to call upon neighbors or even strangers they encounter at the site of the incident to act as interpreters or translators.

These practices have severe drawbacks and may violate Title VI of the Civil Rights Act of 1964. In each case, the impediments to effective communication and adequate service are formidable. The beneficiary's untrained "interpreter" is often unable to understand the concepts or official terminology he or she is being asked to interpret or translate. Even if the interpreter possesses the necessary language and comprehension skills, his or her mere presence may obstruct the flow of emergency information to the provider.

When these types of circumstances are encountered, the level and quality of safety and emergency services available to LEP persons stand in stark conflict to Title VI's promise of equal access to federally assisted programs and activities. Services denied, delayed or provided under adverse circumstances have serious and sometimes life threatening consequences for a LEP person and may constitute discrimination on the basis of national origin, in violation of Title VI. Accommodation of these language differences through the provision of effective language assistance will promote compliance with Title VI.

Signage

Signage along highways presents a very difficult LEP topic, due to the large number of signs, the cost of changing them, and limitations on space on the sign. Nevertheless, at least one state department of transportation has reported that some LEP persons may not have the ability to read variable message signs that alert them to dangerous driving conditions. Due to the life-saving potential, and subject to technical and scientific study as to its viability regarding message length and time, DOT recommends that recipients explore the possibility of either using pictorial or symbol messages or translating messages into frequently encountered languages on variable message signs that report dangerous driving conditions.

Regarding multilingual signage, a county long range transportation plan has noted, "Intermodal multilingual referrals and advertising of customer services should be developed. This can include visual, auditive, and print information on how to use the various modes. Appropriate multilingual signage for modes (*e.g.*, bus stops, mode shares, etc.) could be developed and implemented with international symbol signs. Buses could include next stop digital displays inside the bus and/or tone auditory cues for the visually impaired." (Bernalillo County, New Mexico, Long Range Transportation Plan, 1993) As discussed elsewhere in this Guidance, non-verbal methods can be considered, such as reducing the amount of text (*e.g.* "Glover Park," "Massachusetts Avenue," "Addison Road", etc.) and replacing it with numbers, letters, or colors (*e.g.* D2, L6, Blue Line).

Literacy

Recipients should be sensitive to literacy levels of LEP consumers and clients. Some immigrants and refugees come from pre-literate societies and are not literate in their native language, let alone English, or are not literate for other reasons. However, note that literacy is not covered by Title VI. It makes good sense to consider literacy issues when covering LEP issues, because in some cases, the solutions are the same. See the discussion above about using symbol signs, pictograms, and illustrations. Other solutions include the following:

- Contract and work with community-based organizations to review translated materials for appropriateness of language.
- Use focus groups to test messages and language appropriateness, especially if documents are being translated for the first time.
- Be aware that written translations may not be effective for some communities but that there are alternative mechanisms such as the use of audio or video tapes to provide information.

How does low literacy, non-literacy, use of non-written languages, blindness and deafness among LEP populations affect the responsibilities of recipients? Effective communication in any language requires an understanding of the literacy levels of the eligible populations. Where a LEP person has a limited understanding of important matters or cannot read, access to the program is complicated by factors not directly related to language. Under these circumstances, a recipient should provide transportation and related services information to the same extent that it would provide such information to English-speakers. Similarly, a recipient should assist LEP individuals who cannot read in understanding written materials as it would non-literate English-speakers. A non-written language precludes the translation of documents, but does not affect the responsibility of the recipient to communicate the vital information contained in the document or to provide notice of the availability of oral translation according to the size of that language group.

Special Language Services Should be Locally Focused

Language issues are sometimes local issues, due to matters of usage, dialect, and local preference. Recipient programs of special language services should be designed carefully to accommodate local usage and should be field tested with different local language populations to make appropriate corrections to ensure effective communication. Materials in both English and the primary or home language are generally preferred by non-English speaking groups, but use of English only may sometimes be more appropriate, especially if preferred by the community being served. To account for differences in literacy levels and to make materials more attractive, interesting and likely to be used, the use of photographs and illustrations is recommended. The keys are effectiveness, usability, and transmission of information.

Charging for Special Language Services

Recipients should not impose a charge or a fee for special language services to LEP persons.

Separation for Purposes of Provision of Special Language Services

There may be times when it is most efficient for the recipient to provide special language services separately to people who speak a particular non-English language. However, the program design should not separate these beneficiaries beyond the extent necessary to achieve the goals of the recipient's program of services. Methods that do not segregate should be used whenever possible.

Puerto Rico

Much of Puerto Rico's official business is conducted in Spanish. Therefore, recipients located in Puerto Rico or doing business there should, wherever possible, translate documents into Spanish.

Low-Frequency and Unusual or Unexpected Languages

When an individual with limited English skills—who does not speak a language spoken by a "significant number or proportion of the population"—seeks services or information from the recipient, the recipient should then make reasonable efforts to meet the particularized needs of that individual. Such efforts may include, but are not limited to, using a telephone language line, locating and temporarily employing a qualified interpreter who can communicate in the appropriate language. As technology advances, various options for complying with the requirements of this section, such as computerized and/or on-line translation services, are becoming increasingly available to recipients, and the cost of these options is decreasing.

An Asian-Pacific Islander health care advocacy group commented in this way on how transportation can present a barrier to health care for those who speak an unusual language for their location: "Removal of barriers such as transportation: It is important to ensure that there are systems established to address barriers such as transportation and portability in order to ensure that geographic location does not prevent patients from accessing care. [Medical Care Organizations] need to ensure that coverage for enabling transportation is included in the benefits package. Medicaid enrollees often need to access services in other counties. This is particularly important for patients in rural communities, for migrants and for limited English speaking populations. Limited English speaking persons may need to travel a great distance to see a provider who speaks their language." ("Making Managed Care Work for Asian

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& Pacific Islanders: An Action Agenda for APIA Communities," Dong Suh, MPP, Policy Analyst, (415) 954–9966, (415) 954–9999 (fax) or e-mail: dsuh@apiahf.org.)

Surveys

Customer and service surveys by recipients and their contractors, including ones conducted by telephone, should include the ability to obtain information from LEP households and individuals. Given the large number and percent of LEP individuals in the U.S., a general survey would not be regarded as complete without the participation of people who are LEP. For example, NHTSA's semi-annual Motor Vehicle Occupant Safety Survey identified areas of seat belt and car seat safety where people of Hispanic origin differ from the non-Hispanic population. In the 1998 survey, 44% of Hispanic respondents strongly or somewhat agreed with the statement "I would feel self-conscious around my friends if I wore a seat belt and they did not," as opposed to just 15% of non-Hispanics. This information was used to tailor public information and education to the needs and attitudes of the targeted audience.

IX. Promising Practices/Best Practices

The following examples are provided as illustrations of the responses of some recipients to the need to provide services to LEP persons. Although interesting and useful, their listing here does not constitute endorsement by DOT, which will evaluate recipients' situations on a case-by-case basis using the factors described elsewhere in this Guidance.

Language Banks—In several parts of the country, both urban and rural, community organizations and providers have created community language banks that train, hire and dispatch competent interpreters to participating organizations, reducing the need to have on-staff interpreters for low demand languages. These language banks are frequently nonprofit and charge reasonable rates. This approach is particularly appropriate where there is a scarcity of language services or where there is a large variety of language needs.

Language Support Office—A state social services agency has established an "Office for Language Interpreter Services and Translation." This office tests and certifies all in-house and contract interpreters, provides agency-wide support for translation of forms, client mailings, publications and other written materials into non-English languages, and monitors the policies of the agency and its vendors that affect LEP persons.

Multicultural Delivery Project—Another county agency has established a "Multicultural Delivery Project" that is designed to help immigrants and other LEP persons find someone who speaks their language and who can help them navigate the county health and social service systems. The project uses community outreach workers to work with LEP clients and can be used by employees in solving cultural and language issues. A multicultural advisory committee helps to keep the county in touch with community needs.

Use of Technology—Some recipients use their Internet and/or intranet capabilities to store translated documents online. These documents can be retrieved as needed.

Telephone Information Lines and Hotlines—Recipients have established telephone information lines in languages spoken by frequently encountered language groups to instruct callers, in the non-English languages, on how to leave a recorded message that will be answered by someone who speaks the caller's language. For example, NHTSA's Auto Safety hotline has four representatives who speak Spanish and are available during normal hotline business hours (8 a.m.–10 p.m. Eastern Time). The evening hours permit people from the West Coast (where a significant number of LEP persons reside) to call after work. The automated voice response system has an option for instructions in Spanish. Calls from Spanish-speaking customers are placed in a Spanish-speaking cue which has priority for those four operators who speak Spanish.

Signage and Other Outreach—Other recipients have provided information about services, benefits, eligibility requirements, and the availability of free language assistance, in appropriate languages by (a) posting signs and placards with this information in public places such as grocery stores, bus shelters and subway stations; (b) putting notices in newspapers, and on radio and television stations that serve LEP groups; (c) placing flyers and signs in the offices of community-based organizations that serve large populations of LEP persons; (d) establishing information lines in appropriate languages; and (e) using posters with appropriate languages designed to reach potential beneficiaries.

DOT's Research and Special Programs Administration (RSPA), at 49 CFR 192.616 and 195.440, requires "Each [pipeline] operator [to] establish a continuing educational program to enable customers, the public, appropriate government organizations, and persons engaged in excavation related activities to recognize a gas pipeline emergency for the purpose of reporting it to the operator or the appropriate public officials. The program and the media used should be as comprehensive as necessary to reach all areas in which the operator transports gas. The program must be conducted in English and in other languages commonly understood by a significant number and concentration of the non-English speaking population in the operator's area." We recommend such an approach to recipients to meet their individual service provision needs.

The Governor's Highway Safety Office in New Jersey coordinates several programs for the Hispanic community. In Essex County, a bilingual counselor provides community education on safety issues.

Proyecto AASUL (Assistance with Alcohol and Sobriety Uniting Latinas/Ayuda con Alcohol y Sobriedad Uniendo Latinas), funded by the California Department of Transportation, was developed to educate Hispanic women in Southern California about alcohol abuse and related problems. Information and services included a brochure listing alcohol-related service providers with Spanish speaking staff and a fotonovela focusing on the problems of alcoholism in a family setting. A fotonovela is an extensively illustrated booklet that tells a human-interest story.

The El Protector program has been implemented in Del Rio, Texas. The Del Rio Police Department has developed radio spots in Spanish, about traffic safety issues such as putting people in the back of pickup trucks, loading and unloading school buses, drinking and driving, and pedestrian safety.

EMS staff in Los Angeles reported that their system is equipped to receive calls in 86 languages, although Spanish is the most frequent language used by 911 callers who do not speak English.

The Michigan DOT has produced a Title VI poster and brochure in English and Spanish. It?s public hearings officer speaks English and Spanish. One Michigan metropolitan planning organization (MPO) translated its I–496 community involvement materials into Spanish.

The New Jersey Department of Motor Vehicles (DMV) has administered drivers license tests in more than 14 languages for at least 10 years, including French, Greek, Korean, Portuguese, and Turkish. Other states conduct such tests in other languages. For example, Oregon DOT is in the process of having its tests

translated into Japanese and Vietnamese. USDOT recommends that state agencies share such information, to avoid the necessity of each doing every translation.

The New Mexico State Highway and Transportation Department has, with FHWA support, provided Spanish language translations of its Right-of-Way Acquisition and Relocation Brochures. The State also employs bilingual right-of-way agents capable of discussing project impacts in Spanish.

Oregon's DMV website provides online access to English and Spanish versions of its Driver Manual. It has also contracted with a local government to provide additional classes to Hispanic drivers on "rules of the road" after they gain their driver's licenses. The State of Oregon is developing a report on multilingual services provided by State agencies. The final document will be used by State agencies to enhance their existing programs, including expanding communication efforts to serve and protect all Oregonians. On the NHTSA web site, the Traffic Safety Materials Catalog page has an option to permit a search for materials for an Asian-American or Hispanic audience. This search will result in several publications that are available in Spanish or Chinese.

In Puerto Rico, LEP needs have been addressed by providing all government services, programs and activities in Spanish.

Tennessee DOT recipients in a geographical area where there is a significant (above 5%) population that usually speak a language other than English, must translate and post notices and other correspondence advising persons that their right to participate in any programs or activities receiving federal funding cannot be denied on the basis of nation origin.

Texas DOT has in the past provided forms in Spanish to assist LEP persons in filling out forms to request certified copies of vehicle titles. TxDOT also utilizes bilingual employees in its permit office to provide instruction and assistance to Hispanic truck drivers when providing permits to route overweight trucks through Texas. In the On the Job Training Supportive Services Program, Spanish language television has been used to get the information of the opportunities in the construction industry to people who have difficulty reading English.

Virginia DOT became aware that several Disadvantaged Business Enterprise (DBE) firms were about to be removed from construction projects in Northern Virginia because projects required certified concrete inspectors, and the DBE firms were having trouble complying because the concrete inspection test was only offered in English. VDOT used supportive services funding to have the training manual and test material translated into Spanish, and provided tutoring for the DBE firms. The Virginia State Police (VSP) maintain a written list of interpreters available statewide to troopers through the Red Cross Language Bank, as well as universities and local police departments. The VSP carry cards with Miranda rights set forth in several different languages.

The Colorado State Patrol has produced safety brochures in Spanish for farmer and ranchers. It has also printed brochures in Spanish pertaining to regulatory requirements for trucking firms.

In 1996, the Alabama Department of Transportation (ALDOT) was faced with the relocation of 14 Spanish-speaking families who were living in a trailer park in north Alabama. The State determined that most of the residents met the length of occupancy requirements for rental relocation housing payments. Through a right-of-way consultant who was under contract with ALDOT, an interpreter was hired from the University of Alabama—Birmingham to assist the relocation agent in explaining Uniform Relocation Act entitlements to the heads of families. The interpreter was on call throughout the relocation process to accompany the relocation agent whenever it was necessary to contact the displacees. The families were successfully relocated to Department of Social Services replacement housing. Several families moved into surplus Federal Emergency Management Agency mobile homes that were made available through a private buyer who gave the displacees the option of renting or entering into a purchase agreement.

Minnesota DOT (MnDOT) authored a manual entitled "Public Involvement Procedures For Planning and Project Development" that details Mn/DOT requirements to provide access to all residents of Minnesota under environmental justice standards. The manual takes a proactive approach to public involvement. It includes such things as publishing notices in non-English newspapers, printing notices in appropriate languages and providing translators at public meetings. Mn/DOT's Office of EEO Contract Management provides a Spanish language version of a brochure entitled "Mn/DOT Construction Contracts: Labor Provisions for Contractor Employees" to construction employees during reviews and upon request to Contractors for employee distribution. This pamphlet provides general guidelines to labor laws and Mn/DOT contract labor provisions. Mn/DOT's Office of EEO Contract Management is on call to provide Spanish language translation at Mn/DOT's Information Desk. In addition, telephone numbers are provided to persons who wish to speak directly to Spanish-speaking EEO Office employees.

Mn/DOT's Office of EEO Contract Management provides Spanish language translations in both written communications and oral interviews for labor investigations. In addition, the EEO Office provided written materials in Spanish for explanation of processes and procedures for such investigations.

Wisconsin DOT created a Motorist Study Manual Easy reader (3rd grade level, translated by the Janesville Literacy Council) version in English. It is creating one in Spanish and is considering Hmong. There are regular versions (6th grade level) in English, Spanish and Hmong. There is a Motorcycle Study Manual in English and Spanish, and a CDL (Commercial Drivers License) Study Manual in English and Spanish. Knowledge and Highway Sign Tests are provided in 13 languages besides English. Some languages have been available since the late 1970s. Bids are being prepared to update the bank of questions in non-English languages based on demand. Knowledge and Highway Sign Tests are provided via various audio means ranging from cassette tapes in English and Spanish to allowing bilingual translators to verbally present the questions in non-English languages based on demand. A pilot to evaluate automated knowledge test systems is underway at three DMV Service Centers. The pilot includes tests in English, Spanish, and on audiotape. These automated knowledge test systems allow testing in many languages. The Division of State Patrol is using a compact disk with commonly used phrases and sayings in languages other than English that is printable to a paper card, which then contains the phrase in an appropriate language for the LEP person who is interacting with the officer. The officer points to the appropriate column on the card. WIDOT also keeps a roster of employees who speak, read, or write non-English languages.

In Indiana, 15 Commercial Drivers License branches offer the CDL knowledge test orally, in a true/false format.

The Zuni Entrepreneurial Enterprises Inc. (ZEE) Public Transportation Program was designed to develop, implement, and maintain a

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transportation system that provides needed linkages for Native Americans and other traditionally unserved/underserved persons in the service area to access needed vocational training and employment opportunities in order to enhance both the quality of life and the attainment and perpetuation of meaningful employment. The trip purposes served by the Zuni JOBLINKS project included education, employment, and job training. ZEE provided transportation of students to the University of New Mexico at Gallup, transportation of employees to their existing jobs in Gallup, as well as transportation for individuals requiring vocational rehabilitation and job training within the Pueblo of Zuni. The Project Director also took a number of steps to market the JOBLINKS service. He coordinated the broadcast of a radio spot on a local radio station in English and Zuni.

Seattle's Sound Transit's Link Light Rail to the Rainier Valley in south Seattle is an example of best practices. Demographically, the Rainier Valley is home to a high percentage of immigrant, refugee, low income, and disadvantaged Seattle residents. In addition to providing direct service benefits, Sound Transit has also provided the community with information they need to access the service in the appropriate languages. This has taken the form of translated brochures, outreach staff skilled in interpretation, and multi-language phone lines. etc.

The Washington, DC area's Metro transit system (WMATA) publishes pocket guides to the system in French, Spanish, German, and Japanese.

The following example, although it is focused on people who are deaf, is applicable to people who are LEP. Portland's Tri-Met transit system had a growing concern that access needs of people who are deaf or hard-of-hearing have not been fully addressed, due to more immediate ADA priorities such as putting lifts on buses and implementing paratransit plans. They contacted the Oregon Deaf Resources Center (ODRC) to discuss problems and issues and examine how to make public transportation more accessible to this segment of the disability community. One of the first things Tri-Met learned was that the main barrier in fixed-route travel for people who are deaf is difficulty in getting bus drivers to understand questions and provide information. In fact, people in Portland's deaf community reported that they seldom receive accurate, informative communication from transit drivers. The idea developed was to produce a set of pictograms that illustrate situations that typically arise during fixed-route travel, particularly those that are difficult to verbally communicate to people who are deaf or hard of hearing. The pictograms would be laminated and attached to the bus close to the driver to be readily available when needed. As with many improvements in accessibility, it is expected that enhanced communication capability will not only benefit people with hearing impairments, but will also improve communication with other passengers with disabilities, such as those who have cognitive impairments. Tri-Met submitted a proposal to Project ACTION and received funding to develop a standardized picture language for communicating various situations that can occur during fixed-route travel. Suggestions for the type of information to be included in the pictograms were solicited by from deaf communities across the country. The project also includes developing a transit personnel training video, created and produced by people who are deaf, to educate transit drivers about deaf culture. Another project product is an information booklet that illustrates the pictograms and hand signals.

In 1980 when Souris Basin Transportation in North Dakota first started, the illiteracy rate was high among the senior population in their area of operation. To help them identify the bus on which they were riding, SBT started using visual logos on the sides of the vehicles. They have now found that the illiteracy rate has dropped among the seniors, but the LEP population has grown. Therefore, SBT kept the logos on the vehicles. SBT has also added volunteers who speak languages other than English, such as Spanish, German, Norwegian, Swedish and French. These volunteers are only a phone call away from the drivers or staff that need help. Most of the volunteers are at the Minot State University Language Department.

Florida conducts CDL tests in any language needed, and provides interpreters if needed. Out of service warnings for trucks are issued in Spanish and English.

The Iowa Department of Transportation provides a Spanish version of the CDL knowledge test, using a touch screen computer. In addition, they have worked with Refugee Services of Des Moines, and with a local community college in educating Bosnian refugees to take the Commercial Motor Vehicle driving course. DOT especially recommends the idea of working with local community colleges to educate the LEP community in transportation matters.

Sample Notice of Availability of Materials and Services

"**FOR FURTHER INFORMATION CONTACT:** For hearing impaired individuals or non-English speaking attendees wishing to arrange for a sign language or foreign language interpreter, please call or fax [name] of [organization] at Phone: xxx–yyy–zzzz or Fax: xxx–yyy–zzzz."

If there is a known and substantial LEP population which may be served by the program discussed in the notice, the notice should be in the appropriate non-English language.

Resources

U.S. Department of Justice, General LEP Guidance, August 2000.

U.S. Department of Health and Human Services, Limited English Proficiency Guidance.

U.S. Department of Health and Human Services, "Cultural Competence."

Environmental Protection Agency, "Draft Translation and Interpretation Protocol for Promoting Access to EPA Programs, Services, and Information by Persons With Limited English Proficiency."

Glossary of Transportation Terms, English-Spanish, 1994, Federal Highway Administration.

North American Emergency Response Guidebook (NAERG96), published jointly by the U.S. Department of Transportation, Transport Canada (TC), and the Secretariat of Communications and Transportation of Mexico, in English, French and Spanish.

National Directory of Asian Pacific American Organizations, 1999–2000, Organization of Chinese Americans, available through Philip Morris Management Corporation, 120 Park Av., NY, NY 10017.

Southeast Asian American Mutual Assistance Association Directory, 2000, Southeast Asia Resource Action Center, 1628 16th St., NW., Washington, DC 20009, 202–667–4690, www.searac.org.

Red Cross Language Bank.

"Highway Safety Needs of U.S. Hispanic Communities: Issues and Strategies," NHTSA, September 1995, DOT HS 808 373.

Since 1995, individual border States Division Offices of the Department's Federal Motor Carrier Safety Administration (formerly the FHWA Office of Motor Carriers) have translated a number of documents into Spanish to be used to educate Mexican carriers and drivers operating in the commercial zones. These subjects covered include meaning of out-of-service orders, minimum requirements to operate in the U.S., one page pamphlet that explains the U.S. certification program, one page bulletins on various Federal Motor Carrier Safety Regulations, how to obtain an U.S. DOT vehicle identification number, and state specific safety regulations. The following brochures/guidance have been translated into Spanish and are currently distributed at the border or are being reviewed for possible distribution at the U.S. Southern border:

- FMCSRs—Drivers Guide to the FMCSRs (JJ Keller Publication).
- Drug and Alcohol Regulations (JJ Keller Publication).
- HM Basic Awareness Training Course (CD FMCSA Publication).
- MX Program Pamphlet (FMCSA Publication) [Currently Distributed]
- Road User Guide for North America (FHWA Publication) [Currently Distributed in English, Spanish, and French]
- Awake At the Wheel (FMCSA Publication) [Currently Distributed]

Materials developed for international use, such as those developed by FMCSA's ITS/CVO Technology Division for use with border partners Canada and Mexico. These include its pocket brochure in English, Spanish, and French. It is also developing Spanish video scripts.

The Canadian Council of Motor Vehicle Administrators is developing a trilingual chart for conducting roadside commercial vehicle inspection.

"La Seguridad de los Materiales Peligrosos," (The Safety of Dangerous Materials), RSPA, DOT.

The International Pictograms Standard, 414 SE Grand Avenue, Portland, Oregon 97214 USA, (503) 234–1400. "Making conneXions for the Transit Customer," Breaking down illiteracy and other barriers to transit travel. A multi-media computer software program to help people with barriers to literacy become independent transit riders. The software program includes photos, video and voice narration to help clients learn how to best use public transit. Clients use the program at their learning level and pace, on their own, or with the help of a facilitator.

Data Sources

- Census
- Public Schools
- Community-based organizations
- Advocacy and special interest groups
- Indian tribes
- Immigrant aid organizations
- Welfare to Work organizations
- Job Access service providers
- State Migrant Coordinators
- State Refugee Coordinators
- Local refugee services organizations
- National, regional, and local ethnic advocacy organizations
- Unions that represent farmworkers, service workers, and entry level jobholders
- Legal services organizations
- Staff of elected officials in areas with substantial national origin minority communities
- National Environmental Policy Act (NEPA) related demographic studies
- Hispanic Data Handbook
- National Clearinghouse for Bilingual Education
- Center for Applied Linguistics, www.cal.org
- Hispanic Ministry of Catholic Dioceses, Catholic Social Services, Episcopal Bishop's Fund, Hebrew Immigrant Aid Society, and other faith-based entities that serve LEP people
- Language, Demographics and Population Studies Departments at local universities
- Commercial marketing data
- Minority marketing firms

Appendix A to DOT Guidance

DOT's Title VI regulation (49 CFR Part 21) states the following, in part:

§ 21.5 Discrimination prohibited.

(a) General. No person in the United States shall, on the grounds of race, color, or national origin be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under, any program to which this part applies.

(b) Specific discriminatory actions prohibited:

(1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on the grounds of race, color, or national origin.

(i) Deny a person any service, financial aid, or other benefit provided under the program;

(ii) Provide any service, financial aid, or other benefit to a person which is different, or is provided in a different manner, from that provided to others under the program;

(iii) Subject a person to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;

(iv) Restrict a person in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;

(vi) Deny a person an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program; or

(vii) Deny a person the opportunity to participate as a member of a planning, advisory, or similar body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the class of person to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of persons to be afforded an opportunity to participate in any such program; may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting persons to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals of a particular race, color, or national origin.

(5) The enumeration of specific forms of prohibited discrimination in this paragraph does not limit the generality of the prohibition in paragraph (a) of this section.

(7) This part does not prohibit the consideration of race, color, or national origin if the purpose and effect are to remove or overcome the consequences of practices or impediments which have restricted the availability of, or participation in, the program or activity receiving Federal financial assistance, on the grounds of race, color, or national origin.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD17–01–001]

Annual Certification of Cook Inlet Regional Citizen's Advisory Council (CIRCAC)

AGENCY: Coast Guard, DOT.

ACTION: Notice of Recertification.

SUMMARY: Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis, an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Cook Inlet, Alaska. This certification allows the advisory group to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the statute. The purpose of this notice is to inform the public that the Coast Guard has recertified the alternative voluntary advisory group for Cook Inlet, Alaska.

DATES: The effective period of this certification is from September 1, 2000 to August 31, 2001.

FOR FURTHER INFORMATION CONTACT: For general information regarding the CIRCAC or viewing material submitted to the docket, contact LT Ryan Murphy, Seventeenth Coast Guard District, Marine Safety Division, (907) 463–2817.

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SUPPLEMENTERY INFORMATION: As part of the Oil Pollution Act of 1990. Congress passed the Oil Pollution Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990, (the Act), Section 5002, to foster the long-term partnership among industry, government, and local communities in overseeing compliance with the environmental concerns in the operation of terminal facilities and crude-oil tankers. Subsection 5002(o) permits an alternative voluntary advisory group to represent the communities and interests in the vicinity of the terminal facilities in Cook Inlet (CI), in lieu of a council of the type specified in subsection 5002(d), if certain conditions are met..

The Act requires that the group enter into a contract to ensure annual funding, and that it receive annual certification by the President to the effect that it fosters the general goals and purposes of the Act, and is broadly representative of the communities and interests in the vicinity of the terminal facilities and Cook Inlet. Accordingly, in 1991, the President granted certification to the Cook Inlet Regional Citizen's Advisory Council (CIRCAC). The authority to certify alternative advisory groups was subsequently delegated to the Commandant of the Coast Guard and redelegated to the Commander, Seventeenth Coast Guard District.

On October 18, 2000, (65 FR 62407) the Coast Guard announced the availability of the application for recertification that it received from the CIRCAC and requested comments. Eight comments were received.

Discussion of Comments

Of the 8 comments received, all were supportive of recertification and noted the positive efforts, good communication, and broad representation of Cook Inlet communities as CIRCAC carries out its responsibilities as intended by the Act.

Upon review of the comments received regarding the CIRCAC's performance during the past year and the information provided by the RCAC in their annual report and recertification package the Coast Guard finds the CIRCAC meets the criteria established under the Oil Pollution Act, and that recertification in accordance with the Act is appropriate.

Recertification: By letter dated January 2, 2001, the Commander, Seventeenth Coast Guard certified that the CIRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on August 31, 2001.

Dated: January 2, 2001.

T.J. Barrett,

U. S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 01–1849 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

[USCG–2001–8680]

Coast Guard Advisory to Recreational Boaters on Carbon Monoxide Hazard Caused by Generator Exhaust

AGENCY: Coast Guard, DOT.

ACTION: Consumer advisory notice.

SUMMARY: The Coast Guard advises owners and operators of boats to turn off gasoline-powered generators with transom exhaust ports when the swim platform on the stern is in use. The Coast Guard further advises that swimmers should not enter the cavity of a boat designed with a generator emitting exhaust into the cavity between the swim platform and the transom of the vessel. The Coast Guard is concerned about the serious health risk from carbon monoxide poisoning and seeks to prevent loss of life and personal injury.

FOR FURTHER INFORMATION CONTACT: Philip Cappel, Chief, Recreational Boating Product Assurance Division, Commandant (G–OPB–3), 2100 Second Street SW., Washington, DC 20593, telephone (202) 267–0988, e-mail *pcappel@comdt.uscg.mil*. Documents mentioned in this notice as being available in the docket, are part of docket USCG–2001–8680 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov*.

SUPPLEMENTARY INFORMATION: The Coast Guard was made aware of the deadly combination of generator exhaust and swim platforms through a September 2000 National Institute for Occupational Safety and Health (NIOSH) study of houseboat carbon monoxide deaths on Lake Powell in Arizona. The study showed that the particular design of the stern swim platform on certain models of houseboats created a cavity between the hull of the vessel and the swim platform where the gasoline-powered generator exhaust port is located. When the generator is running the carbon monoxide buildup in this cavity, as well as the swim platform and rear deck space, is so high that it creates an imminent danger of death for anyone who enters the cavity even for a very short period of time. The common practice of keeping generators running to power air conditioning, entertainment centers, and electronic suites while moored or anchored has exacerbated the problem.

The Coast Guard has conducted a preliminary investigation into the problem and has issued a letter to all known houseboat manufacturers informing them of this hazard and soliciting their plans for reducing the danger.

The problem may not be confined to houseboats, however, since any boat with the generator exhaust located in the transom and a swim platform could present the same lethal hazard. The Coast Guard is expanding its investigation of this problem to include all types of boats.

Previous carbon monoxide warnings and educational materials have concentrated on the hazards created by the exhaust of the main propulsion engines while underway. Although these dangers still exist, the Coast Guard will develop new educational materials to emphasize the additional hazards of using a gasoline-powered generator, especially while not underway.

The Coast Guard warns all boaters that this is an extremely dangerous matter that could result in serious injury or death and advises all boat owners to heed this warning.

Dated: January 12, 2001.

John W. Whitehouse,

Captain, U.S. Coast Guard, Acting Assistant Commandant for Operations.

[FR Doc. 01–1666 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–15–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping for Air Traffic Procedural Changes Associated With the New York/New Jersey/Philadelphia Metropolitan Airspace Redesign Project

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of intent to prepare an environmental impact statement and conduct scoping meetings.

SUMMARY: The Federal Aviation Administration (FAA), Eastern Region, is issuing this notice to advise the public, pursuant to the National Environmental Policy Act of 1969, as amended, (NEPA) 42 U.S.C. 4332(2)(C) that the FAA intends to prepare an Environmental Impact Statement (EIS) for the proposed New York/New Jersey/Philadelphia Metropolitan Airspace Redesign Project. This Notice of Intent is published as required by the President's Council on Environmental Quality (CEQ) Regulations implementing the provisions of NEPA, 40 CFR parts 1500–1508. The EIS will assess the potential environmental impacts resulting from proposed modifications to air traffic routings in the metropolitan New York and Philadelphia areas. Airports in this are include Newark International Airport, John F. Kennedy International Airport, La Guardia Airport, and the Philadelphia International Airport, as well as several regional (commuter) and general aviation use airports. The redesign project will examine the airspace surrounding area airports up to and including the high altitude enroute structure. The study area includes the State of New Jersey, and parts of New York, Connecticut, Pennsylvania and Delaware. All reasonable alternatives will be considered including a no-charge alternative/option. In order to ensure that all significant issues pertaining to the proposed action are identified, public participation, through public scoping meetings, will be held.

FOR FURTHER INFORMATION CONTACT: Ms. Moira Keane, Environmental Specialist, Federal Aviation Administration, Eastern Region Air Traffic Division, Airspace Branch, AEA–522.1, 1 Aviation Plaza, Jamaica, New York 11434–4809 (718) 553–4530.

SUPPLEMENTARY INFORMATION: The New York/New Jersey/Philadelphia Metropolitan Airspace Redesign Project encompasses a large geographic area, including the State of New Jersey, and parts of New York, Connecticut, Pennsylvania and Delaware. The airports in the study area are: Newark International Airport, John F. Kennedy International Airport, La Guardia Airport and Philadelphia International Airport as well as several regional (commuter) and general aviation use airports.

In response to the enormous flow of air traffic in the study area, the FAA is examining alternative ways to modify air traffic routes and procedures to reduce delays and pilot/controller workloads, while enhancing safety. The airspace redesign team is using sophisticated modeling tools to develop viable air traffic control (ATC) alternatives to current operations. The FAA will examine methods that will take advantage of new and emerging ATC technologies, improved performance characteristics of modern aircraft, as well as improvements in navigation capabilities. The proposed project may include, but will not necessarily be limited to the following alternatives: modification of existing procedures; identification of new conceptual alternative(s), and examination of an ocean routing alternative. The project is not associated with any airport development projects nor construction of any physical facilities.

As part of the airspace redesign effort, a FAA environmental team will provide detailed analyses that will be used to evaluate the potential environmental impacts in the study area. During scoping , and upon publication of a draft EIS and a final EIS, the FAA will be contacting and coordinating with federal, state, and local agencies, as well as the public, to obtain comments and suggestions regarding the EIS for the proposed project. The EIS will assess impacts and reasonable alternatives, including the "no change" alternative, pursuant to NEPA, FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts, DOT Order 5610.1C, Procedures for Considering Environmental Impacts, and the President's Council on Environmental Quality (CEQ) Regulations implementing the provisions of NEPA, 40 CFR Parts 1500–1508.

Public Scoping Process: The FAA will utilize the scoping process as outlined in the Council on Environmental Quality (CEQ) Regulations and guidelines to facilitate public involvement early in the redesign process. Concerned individuals and agencies will be invited to express their views either in writing, by letter or by providing oral comments at a scoping meeting. The purposes of the scoping process and scoping meetings are: (1) To provide a description of the proposed action, (2) to provide an early and open process to determine the scope of issues to be addressed and to identify potentially significant issues or impacts related to the proposed action that should be analyzed in the EIS, (3) to identify other coordination and any permit requirements associated with the proposed action and (4) to identify and eliminate from detailed study those issues that are not significant or those that have been adequately addressed during a prior environmental review process.

The FAA will schedule a series of public scoping meetings. Each meeting will be held from 7 p.m. to 9 p.m. at specific sites located throughout the study area. Each of the meetings will begin with an overview of the project (7 p.m.–7:30 p.m.) and will be followed by an informal open house period (7:30 p.m.–8:30 p.m.). The open house portion of each public scoping meeting will include redesign displays and graphics and will provide an opportunity for one-on-one interaction between the representatives of the FAA and the general public. Following the open house part of the meeting, a Question and Answer session will be provided (8:30 p.m.–9 p.m.). Comments will be received via court reporter or written comment forms throughout the duration of the meeting.

In accordance with NEPA coordination requirements, the FAA will schedule three meetings that will be dedicated primarily to federal, state and local agency staff. These meetings will be scheduled from 1 to 3 p.m. at the Manhattan, NY, Philadelphia, PA and Trenton, NJ meeting locations. Although these meetings will be held primarily for the benefit of federal, state, and local agency staff, they will also be open to the public. The scoping period begins with this announcement. To ensure that all issues are identified, the FAA is requesting comments and suggestions on the project scope from all interested federal, state, and local agencies and other interested parties. In furtherance of this effort, the FAA has established an Internet Website that can be accessed at: http://www.faa.gov/region/aea/atsoeaaa/framedoc.htm. Additional information about the New York/New Jersey/Philadelphia Metropolitan Airspace Redesign Project, including the scoping meeting schedule and meeting locations can be found at this Internet site. Additionally, the FAA will be maintaining the following toll free number for general information: 1–866–EISLine (1–866–347–5463):

The FAA will accept written scoping comments through June 29, 2001. Such comments should be directed to the following address: New York/New Jersey/Philadelphia Metropolitan Airspace Redesign Project, c/o Mr. Mike Merrill, PRC Inc., 12005 Sunrise Valley Dr., Reston, VA 20191–3423. EMAIL: *merrill_michael@prc.com*.

Issued in Jamaica, New York on January 5, 2001.

F.D. Hatfield,

Manager, Air Traffic Division.

[FR Doc. 01–1859 Filed 1–19–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–04]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 12, 2001.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule docket (AGC–200), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–200), Room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029 Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to §§ 11.85 and 11.91.

Issued in Washington, DC, on January 16, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 30173.
Petitioner: Raytheon Aircraft Co.
Section of the 14 CFR Affected: 14 CFR § 25.785(b) and 25.562(c)(3), (c)(5), and (c)(6).
Description of Relief Sought: To allow exemption from the injury criteria aspects of dynamic testing for multiplace side-facing seats to be installed on the Raytheon Hawker Horizon Model 40000.

[FR Doc. 01–1676 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–05]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 12, 2001.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to http://dms.dot.gov. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR §§ 11.85 and 11.91.

Issued in Washington, DC, on January 16, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: FAA–2000–8165.
Petitioner: The Jet Center, Garret Aviation Services.
Section of 14 CFR Affected: 14 CFR § 25.813(e).
Description of Relief Sought: To permit The Jet Center, Garret Aviation Services, to install doors in petitions between passenger compartments on Bombardier Model BD–700–1A10 airplanes used for corporate transportation.

Dispositions of Petitions

Docket No.: FAA–2000–8176.
Petitioner: VARIG S.A.
Section of 14 CFR Affected: 14 CFR § 145.47(b).
Description of Relief Sought/Disposition: To permit VARIG to use the calibration standards of the Instituto Nacional de Metrologia, Normalização e Qualidade Industrial (INMETRO) in lieu of the calibration standards of the U.S. National Institute of Standards and Technology (NIST) to test its inspection and test equipment.
Grant, 11/30/00, Exemption No. 6552B

Docket No.: FAA–2000–8179.
Petitioner: Fairchild Aircraft Incorporated.
Section of 14 CFR Affected: 14 CFR § 91.531(a)(3).
Description of Relief Sought/Disposition: To permit Fairchild to conduct production and experimental test flights in SA227–CC and SA227–DC

Metro 23 airplanes without a pilot designated as second in command (SIC).
Grant, 11/28/00, Exemption No. 5367F

Docket No.: FAA–2000–8180.
Petitioner: Regional Airline Association.
Section of 14 CFR Affected: 14 CFR § 61.3(a) and (c).
Description of Relief Sought/Disposition: To permit the establishment of special procedures that enable an operator to issue to its flight crewmembers, on a temporary basis, confirmation of any required crewmember certificate based on information contained in the operator's approved record system for RAA member carriers and similarly situated 14 CFR part 135 air carriers.
Grant, 11/28/00, Exemption No. 5560C

Docket No.: FAA–2000–8215.
Petitioner: ProJet International Express, Inc.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit PIE to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed in the aircraft.
Grant, 12/05/00, Exemption No. 7391

Petition for Exemption

Docket No.: FAA–2000–8165.
Petitioner: The Jet Center, Garret Aviation Services.
Regulations Affected: 25.813(e).
Description of Petition: To exempt The Jet Center, Garret Aviation Services, from the requirements of 14 CFR 25.813(e) to permit installation of doors in partitions between passenger compartments on Bombardier Model BD–700–1A10 airplanes used for corporate transportation.

[FR Doc. 01–1677 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2001–06]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 12, 2001.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to http://dms.dot.gov. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR §§ 11.85 and 11.91.

Issued in Washington, DC, on January 16, 2001.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: FAA–2000–8188.
Petitioner: Direct Air, LLC.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit Direct Air to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed in the aircraft.
Grant, 12/08/2000, Exemption No. 7399

Docket No.: FAA–2000–8433.
Petitioner: New Air Helicopters.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit NAH to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
Grant, 12/08/2000, Exemption No. 6884A

Docket No.: FAA–2000–8429.
Petitioner: North Star Air Cargo, Inc.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit North Star to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
Grant, 12/08/2000, Exemption No. 6878A

Docket No.: FAA–2000–8432.
Petitioner: Air Vegas, Inc.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit Air Vegas to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
Grant, 12/08/2000, Exemption No. 6588B

Docket No.: FAA–2000–8049.
Petitioner: CareFlite.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit CareFlite to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
Grant, 12/08/2000, Exemption No. 6877A

Docket No.: FAA–2000–8147.
Petitioner: Flight Line Aviation, Inc.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(2).
Description of Relief Sought/Disposition: To permit FLA to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
Grant, 12/08/2000, Exemption No. 6874A

Docket No.: FAA–2000–8000.
Petitioner: Delta Air Lines, Inc.
Section of 14 CFR Affected: 14 CFR § 135.143(c)(1)(ii).
Description of Relief Sought/Disposition: To permit Delta to substitute a qualified and authorized

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check airman for an FAA inspector when an inspector is not available to accomplish the required observation during the scheduled operating experience flight legs of a qualifying pilot in command (PIC) who is completing initial or upgrade training.

Grant, 12/08/2000, Exemption No. 7376A

Docket No.: FAA–2000–8016.
Petitioner: Adams, Jerry L., et al.
Section of 14 CFR Affected: 14 CFR § 121.383(c).
Description of Relief Sought/ Disposition: To permit those individuals to act as pilots in operations conducted under part 121 after reaching their 60th birthdays. Please note that the FAA has assigned a new docket number to this project (FAA–2000–8016; previously Docket No. 30040).

Denial, 12/13/2000, Exemption No. 7405

[FR Doc. 01–1678 Filed 1–19–01; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Field Approval Process

AGENCY: Federal Aviation Administration (FAA) DOT.
ACTION: Notice of meeting.

SUMMARY: The Federal Aviation Administration (FAA) is issuing this notice to advise the public of a meeting to discuss public concerns with the FAA Field Approval Process.

DATES: The meeting will be held on February 23, 2001, 9 A.M. to 4 P.M. Arrangement for presentations must be made by February 16, 2001.

ADDRESSES: The meeting will be held at the FAA 3rd Floor Auditorium, 800 Independence Ave, SW, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Wayne Fry, Federal Aviation Administration, AFS–300, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 493–5228 fax (202) 267–5115.

SUPPLEMENTARY INFORMATION: The meeting will be held on February 23, 2000, from 9 A.M. to 4 P.M., at the FAA 3rd floor Auditorium, Washington, DC. The agenda will include: Field Approval Process Improvement.

Attendance is open to the interested public, but will be limited to the space available. The public must make arrangements by February 16, 2001, to present oral statements at the meeting. To make arrangements to present oral statements, please contact the person listed under the head for **FOR FURTHER INFORMATION CONTACT**. If you are in need of assistance or require a reasonable accommodation for the meeting please contact the person listed under the heading for **FOR FURTHER INFORMATION CONTACT**. In addition, sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT**.

Issued in Washington, DC, on January 17, 2001.

L. Nicholas Lacey,
Director, Flight Standards Service.
[FR Doc. 01–1857 Filed 1–19–01; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent to Rule on Application 01–04–C–00–EUG To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Mahlon Sweet Field, Submitted by the City of Eugene, Mahlon Sweet Field, Eugene, Oregon

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use PFC revenue at Mahlon Sweet Field under the provisions of 49 U.S.C. 40117 and part 158 of the Federal Aviation Regulations (14 CFR 158).

DATES: Comments must be received on or before February 21, 2001.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Mr. J. Wade Bryant, Manager; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250, Renton, Washington 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Robert Noble, Acting Airport Manager, at the following address: 28855 Lockheed Drive; Eugene, Oregon 97402.

Air Carriers and foreign air carriers may submit copies of written comments previously provided to Mahlon Sweet Field, under section 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Suzanne Lee-Pang, (425) 227–2654, Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW, Suite 250, Renton, Washington 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application 01–04–C–00–EUG to impose and use PFC revenue at Mahlon Sweet Field, under the provisions of 49 U.S.C. 40117 and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

On January 11, 2001, the FAA determined that the application to impose and use the revenue from a PFC submitted by City of Eugene, Mahlon Sweet Field, Eugene, Oregon, was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 28, 2001.

The following is a brief overview of the application.

Level of the proposed PFC: $4.50.
Proposed charge effective date: June 1, 2001.
Proposed charge expiration date: June 1, 2003.
Total requested for use approval: 3,255,267.
Brief description of proposed project: Runway 3/21 Safety Area Improvements; Taxiway Extension and Ramp Construction; Terminal Improvements; B Gate South Ramp Reconstruction; Ramp Pavement Rehabilitation; Land Acquisition; Jet Bridge.

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Operations by Air Taxi/Commercial Operators utilizing aircraft having a maximum seating capacity of less than twenty passengers when enplaning revenue passengers in a limited, irregular/ nonscheduled, or special service manner. Also exempted are operations by Air Taxi/Commercial Operators, without regard to seating capacity, for revenue passengers transported for student instruction, non-stop sightseeing flights that begin and end at the airport and are conducted within a 25 mile radius of the same airport, fire fighting charters, ferry or training flights, air ambulance/medivac flights and aerial photography or survey flights.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports Office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue SW., Suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Mahlon Sweet Field.

Issued in Renton, Washington on January 11, 2001.

David A. Field,
Manager, Planning, Programming and Capacity Branch, Northwest Mountain Region.
[FR Doc. 01–1674 Filed 1–19–01; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

TSO–C77b, Gas Turbine Auxiliary Power Units

AGENCY: Federal Aviation Administration, DOT.
ACTION: Notice of availability of technical standard order.

SUMMARY: This notice announces the availability of Technical Standard Order (TSO) C77b. This TSO prescribes the minimum performance standards that gas turbine auxiliary power units (APUs), commonly used in commercial aircraft, must meet in order to be identified with the TSO marking.

EFFECTIVE DATE: January 22, 2001.

FOR FURTHER INFORMATION CONTACT: Mr. Mark A. Rumizen, Engine and Propeller Standards Staff, ANE–110, Engine and Propeller Directorate, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803–5299, telephone (781) 238–7113, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Background

The standards of this TSO will apply to all APUs used for any new application submitted after the effective date of this TSO. APUs currently approved under TSO–C77 or TSO–C77a authorization may continue to be manufactured under the provisions of their original approval. However, under § 21.611(b) of the Federal Aviation Regulations, any major design change to an APU previously approved under TSO–C77 or TSO–C77a would require a new authorization under this TSO. The general layout of this document complies with the updated TSO format.

How To Obtain Copies

A copy of the TSO–C77b may be obtained via Internet (http:/ www.faa.gov/avr/air/air100/ 100home.htm) or by request from the office listed under **FOR FURTHER INFORMATION CONTACT.**

Issued in Burlington, Massachusetts on December 20, 2000.

David A. Downey,
Assistant Manager, Engine and Propeller Directorate Aircraft Certification Service.
[FR Doc. 01–1858 Filed 1–19–01; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Guidance on Longitudinal Telecommunications Installations on Limited Access Highway Right-of-Way

AGENCY: Federal Highway Administration (FHWA), DOT.
ACTION: Notice.

SUMMARY: This document publishes guidance on the installation of telecommunications on limited access highway right-of-way. This guidance was distributed to the FHWA Resource Centers and Division offices on December 22, 2000. These materials are the result of consultations with the Federal Communications Commission with regard to the potential impact of the Telecommunications Act of 1996 on such installations.

FOR FURTHER INFORMATION CONTACT: Mr. William S. Jones, Intelligent Transportation Systems (ITS) Joint Program Office, (202) 366–4651 or Ms. Beverly Russell, Office of the Chief Counsel, (202) 366–1355; Federal Highway Administration, 400 Seventh Street, SW., Washington, DC. 20590–0001. Office hours are from 7:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the **Federal Register**'s home page at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara*. In addition this document is available on the ITS web sit at: *http://www.its.dot.gov*.

Background

Guidance published in this **Federal Register** notice is provided for information purposes. Specific questions on any of the material published in this notice should be directed to the appropriate contact person named in the caption, **FOR FURTHER INFORMATION CONTACT.**

Authority: 23 U.S.C. 315; 49 CFR 1.48.

Issued on: January 11, 2001.

Kenneth R. Wykle,
Federal Highway Administrator.

The text of the FHWA guidance memorandum dated December 22, 2000 follows:

Information: Guidance on Longitudinal Telecommunications Installations on Limited Access Highway Right-of-Way

Anthony R. Kane, Executive Director, HOIT–1.

Directors of Field Services

Resource Center Managers

Division Administrators

A number of States have altered their utility accommodations policies to allow longitudinal access to their limited access highway Right-of-Way (ROW) for telecommunications installations; usually fiber optic cable. Several of these installations to date have been public-private partnerships with the telecommunications industry generally referred to as "Shared Resource" agreements. In December 1999, the Federal Communications Commission (FCC) issued an opinion in the Minnesota Department of Transportation (DOT) case involving such a partnership that defined the FCC's interpretation of the Telecommunications Act of 1996 (TCA) and its application to the Minnesota agreement, which has potentially broad implications for transportation agencies.

As a result of the FCC's opinion, the Federal Highway Administration (FHWA) engaged in a discussion with the FCC to clarify how these partnerships and other similar telecommunications installations should be conducted to avoid conflict with the TCA and be consistent with FHWA's requirements for highway safety and ROW management. These discussions have culminated in an approach that considers both the requirements of the transportation industry and its concern for highway safety, and the FCC's concern with the implementation of the TCA. This approach is documented in two letters. A letter from the FHWA Administrator to the FCC defines the elements of the guidance pertaining to access to freeway ROW, and a letter to the FHWA Administrator from the Chief of the Common Carrier Bureau of the FCC defines the competitive elements of the

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guidance based upon the access restrictions defined by the FHWA.

This is only guidance to assist States in the execution of Shared Resource agreements. Agreements can deviate from these guidelines and still be in conformance with the TCA. However, this guidance is intended to clarify some of the important requirements of the TCA with regard to competition in the telecommunications industry.

Background

Over the past decade, a number of States have implemented Shared Resource agreements with private telecommunications companies. "Shared Resource" is a term identifying public-private arrangements involving the sharing of the public resource of roadway ROW and the private resource of telecommunications expertise and capacity.[1] Most commonly, private telecommunications providers are granted access to limited access highway ROW for their own telecommunications infrastructure (principally fiber optics conduits and cable) in exchange for providing telecommunications infrastructure to public agencies.

Shared Resource agreements can be a beneficial, cost-effective means for State DOT's to obtain the telecommunications infrastructure necessary for Intelligent Transportation Systems (ITS). For example, telecommunications capacity is essential for the integration of both equipment and data components required for State and metropolitan traffic operations systems. Such systems may include traffic control devices (*e.g.* traffic signals), closed circuit television, radar detectors, pavement sensors, etc.

The United States Department of Transportation (U.S. DOT) and the FHWA are responsible for highway safety (23 U.S.C. 401), the management of ROW on the interstate system (23 U.S.C. 109(1) and 111(a)), and implementation of the national ITS program. The FHWA's implementing regulations for utility accommodation are applicable to shared resource agreements and other telecommunications installations. 23 CFR part 645, subpart B. The regulations, in part, require that States accommodate utilities in a manner which does not impair the highway or adversely affect highway traffic safety. 23 CFR 645.211(a). The regulations explicitly require that States examine the effect of utility installation on "safety, aesthetic quality, and the cost or difficulty of highway and utility construction and maintenance." 23 CFR 645.211(b). Though, pursuant to regulations, ROW management responsibilities have largely been devolved to the States, implementation of these responsibilities must remain consistent with FHWA regulations, not only those at 23 CFR part 645, but also those at 23 CFR part 710 governing the interstate ROW.

The FHWA also recognized that the Telecommunications Act of 1996, Pub. L. No. 104–104, 110 Stat. 56 (1996) (codified as amended in scattered sections of title 47 of the United States Code (U.S.C.)), had the potential to impact the installation of telecommunications on freeways. Specifically, the Act prohibits State and local governments from implementing any statute, regulation, or legal requirements which have the effect of prohibiting any entity from providing telecommunications service. 47 U.S.C. 253 (a). However, the section containing this prohibition has two exemptions. First, the prohibition does not affect the ability of the States to impose, on a competitively neutral basis, requirements necessary to preserve and advance universal telecommunications service, protect public safety and welfare, ensure quality of telecommunications service, and safeguard the rights of consumers. 47 U.S.C. 253 (b). Second, the prohibition also does not affect "the authority of a State or local government to manage the public ROW or to require fair and reasonable compensation from telecommunication providers, on a competitively neutral and nondiscriminatory basis, for use of public right-of-way on a nondiscriminatory basis, if the compensation required is publicly disclosed by such government." 47 U.S.C. 253 (c).

In October 1996, the FHWA issued guidelines on the anticipated effects of the TCA on utility accommodations.[2] In these guidelines, the FHWA recommended that the State highway departments desiring to allow one or more telecommunications companies on interstate ROW make their intentions publicly known and give all telecommunications companies the opportunity to compete.

Guidance on Access to Freeway Right-of-Way

State transportation departments are obviously very knowledgeable about FHWA regulations on safety, utility accommodations, and ROW management. However, the FCC's decision on the Minnesota Shared Resource agreement created concerns and uncertainties, notably with regard to dealing with the competitive effects of such agreements on the telecommunications industry and their relationship to the management of ROW and public safety. To alleviate this concern, the U.S. DOT has worked closely with the FCC to develop guidance for States that wish to engage in shared resource and other telecommunications projects.

When States allow telecommunications companies onto the freeway ROW, they are potentially invoking the TCA. The objective of the TCA is to foster competition in the industry. Thus, the TCA contains significant measures to allow new potential competitors an opportunity to compete with the large incumbent "Baby Bells" that have dominated the industry for nearly 100 years. These new competitive measures of the TCA should be considered by States when they choose to allow telecommunications companies onto their freeway rights-of-way.

This guidance identifies points for negotiating, reaching/implementing Shared Resource agreements and other telecommunications installations that involve entering limited access highways (freeways) for the safe installation of fiber optic facilities. In addition, this guidance provides potential criteria for implementing these agreements in a manner that the FCC Common Carrier Bureau has already indicated would be acceptable and likely to maintain a competitively neutral environment in the telecommunications industry in accordance with the TCA.

It should be noted that the telecommunications competitive environment varies across the country. Thus, the circumstances concerning what is fair and equitable can vary from region to region. Therefore, it is reasonably foreseeable that States will develop agreements for telecommunications longitudinal access to freeway ROW that differ from the suggested guidelines, and that those agreements would still be in compliance with the TCA requirements for competitive neutrality in the contractual actions of States.

While these guidelines will not prevent a State's actions from being challenged, the U.S. DOT and the FCC Common Carrier Bureau agree that these guidelines will help States satisfy their obligation under the applicable laws and provide a reasonable level of assurance that a State's actions will not be preempted.

The attachment, "Background Discussion on Guidance: Telecommunications Installations, Limited Access Highway Right-of-Way," (available at: *www.its.dot.gov*) presents a detailed discussion of the FCC's ruling on the Minnesota case, and the rationale for these guidelines which have been developed in cooperation with the FCC.

If a State chooses to allow longitudinal access for fiber optic facilities installation on its freeway ROW pursuant to its Utility Accommodations Policy, it is recommended that the following guidelines apply to that installation.[3] Other provisions factoring in regional characteristics should be considered in agreements with the contractor that specifies details as to how particular issues necessary to protect the public safety are being handled on a project by project basis (*e.g.* topographical and other obstructions encountered, special working conditions and limitations, etc.).

1. In these guidelines, it is understood that the State retains the right and responsibility to manage its freeway ROW. Reasonable, nondiscriminatory time, place, and manner restrictions, including but not limited to traditional permitting conditions, may be placed on the design, installation, operation, and maintenance of fiber optic facilities.

2. All construction should be done in that portion of the ROW that is located furthest from the traveled roadway to the degree feasible, and should be accomplished in accordance with the Manual on Uniform Traffic Control Devices, per 23 CFR part 655.603.

3. If all construction vehicles, equipment, and personnel can be located outside the clear zone on the freeway, as defined in the AASHTO Roadside Design Guide and adopted by FHWA in Federal Aid Policy Guide, Par. 16(a)(3) NS 23 CFR part 625, except for ingress and egress, the State may use the freeway ROW for fiber optic facilities installation as frequently as reasonably necessary to satisfy the requirements of the State, and the needs of the telecommunications providers.[4] A State may limit construction so that there is no more than one installation project underway at any given time on any major segment of the freeway.

4. If construction vehicles, equipment, and personnel cannot be located out of the freeway clear zone, then the State may restrict fiber optic facilities installation to only one time on that area of the freeway where construction would occur within the clear zone. No further installation needs to be allowed on that segment until such time as required by the end of the useful life of the fiber optic facilities, or if the existing capacity is exhausted or existing conduit is full. Existing fiber and conduit capacity will be deemed exhausted whenever the State and the contractor mutually determine that a bona-fide request for dark fiber, conduit space, or a bona-fide request for any other transmission facilities or service cannot be granted. Additional installation at this time will be subject to reasonable nondiscriminatory State requirements, *e.g.*, per #1 above.

5. A State may restrict the location of all the above ground equipment to the edge, or off of the ROW to allow access to that equipment for maintenance from service roads or other non-freeway access if feasible, as determined by the State. Such restrictions should be nondiscriminatory.

Guidance on Competitive Issues

To assist States in meeting the intent of the TCA with regard to maintaining a competitively neutral position in the process of developing and implementing a Shared Resource or other telecommunications installations project, the FCC Common Carrier Bureau suggests the following principles in the development of these projects. These principles should be considered whenever a State decides to limit further installations of fiber optic facilities on its ROW, whether in or out of the clear zone.

1. The contractor should be selected through an open, fair, nondiscriminatory, competitive process.

2. Having selected a contractor, other interested third-party telecommunications companies should be allowed the opportunity to have their fiber optic facilities installed in conjunction with any installation of fiber optic facilities by the contractor. The State may make the contractor the sole party responsible for all installation work done at such times, and require that other third party telecommunications companies contract with that contractor for installation of their fiber optic facilities when their facilities are installed in conjunction with those of the contractor. In such cases, the contractor's charges, terms and conditions for installation should be fair, reasonable, and nondiscriminatory and may include a reasonable profit. The State should give potentially interested third parties reasonable notice of the anticipated or planned opening of the right-of-way. The notice period should reflect the time reasonably required by third parties to develop business plans and obtain financing. Notice can be accomplished through publication and dissemination of a construction schedule for the project. Such publication and dissemination should be reasonably calculated to provide potentially interested third parties with actual notice of the schedule.

3. The contractor should install spare fiber and empty conduit, adequate to accommodate reasonably anticipated future demand, whenever fiber optic facilities cannot be installed outside the clear zone. Each section of fiber/conduit within the clear zone should have connection points (manhole or cabinets) at each end outside the clear zone where third parties can access the conduit or interconnect with facilities in the conduit at their option. All rates, terms and conditions for interconnection and/or use of space in the conduit should be fair, reasonable, and nondiscriminatory and may include a reasonable profit.

4. The contractor should be required to sell fiber on an "Irrevocable Right of Use" (IRU)[5] basis at rates and subject to terms and conditions that are just, reasonable, and nondiscriminatory. The contractor's charges for such facilities may include a reasonable profit.

[1] United States Department of Transportation, Shared Resources: "Sharing Right-of-Way or Telecommunications," Final Report, Publication No. FHWA–PO–96–0015 (April 15, 1996). This document is available online at the web site: *http://www.itsdocs.fhwa.dot.gov* as item no. 1863, 90 pages.

[2] Memorandum from Gerald L. Eller, Director, FHWA's Office of Engineering to Regional Federal Highway Administrators on the Effects of the Telecommunications Act on Utility Accommodation, October 25, 1996.

[3] Pursuant to 23 C.F.R. 645.211, states are required to submit utility accommodations plans for approval.

[4] There is no intention for this guidance to cause States to determine the exact location of the clear zone in any particular area. In most instances, whether a contractor can locate the construction outside the clear zone should be discernable for most portions of the freeway by inspection of a State's existing data on its ROW. The theoretical width of the clear zone, as defined in the roadside Design Guide, can vary substantially depending on the topography of the land involved. Therefore, occasional instances of construction within the clear zone for short distances because of topographical features of the terrain or other factors, can be treated as if the construction were taking place outside the clear zone at the discretion of the State. In such cases the competitive safeguards defined in 3 below should not be necessary.

[5] The commission has defined an IRU interest in a communication facility as "a form of acquired capital in which the holder possesses an exclusive and irrevocable right to use the facility and to include its capital contribution in its rate base, but not the right to control the facility or, depending on the particular IRU contract, any right to salvage". Reevaluation of the Depreciated-Original-Cost Standard in Setting Prices For Conveyances of Capital Interests in Overseas Communication Facilities Between or Among U.S. Carriers, CC Docket No. 87–45, Report and Order, 7 FCC Rcd 4561 at 4564, n.1 (1992).

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5. The contractor should be required to offer facilities and services for resale at rates and subject to terms and conditions that are just, reasonable, and nondiscriminatory and may include a reasonable profit.

6. The agreement with the contractor should require that the contractor comply with the terms defined above, and give third parties the right to challenge the contractor's compliance with the appropriate elements of these terms dealing with third party access before an independent entity which does not benefit directly from the arrangement with the contractor. The independent entity should have the authority to order the contractor to comply with these terms. A State public utilities commission, or independent arbitrator, might serve in this capacity. In this regard, prompt resolution of such issues can be critically important to the development of competition.

7. It is substantially preferable that the contractor be a wholesaler of telecommunication in order to minimize competitive concerns, as opposed to being a retail telecommunications service and facilities provider either directly or through an affiliated entity. This reduces the potential for anti-competitive pricing that could violate section 253 of the TCA. However, if the contractor does provide retail telecommunications service directly or through an affiliated entity, all rates, terms and conditions for its retail service should be fair, reasonable, and nondiscriminatory.

(The provision of retail service by a contractor creates the potential for a "price squeeze" with the contractor overcharging competitors, and its retail arm, for wholesale services and facilities, while competing vigorously on price for retail services. Thus, if the contractor provides retail services, the contractor's charges for services and facilities used by potential retail competitors may require careful scrutiny to avoid potential violations of the TCA.)

Conclusion

These guidelines shall not be used as evidence of any alleged or asserted legal rights with regard to access to freeway ROW, but are being provided to assist States in developing their agreements for telecommunications installations on freeway ROW, particularly dealing with the nondiscriminatory, pro-competitive requirements of the TCA.

The information provided in this discussion of longitudinal access to freeway ROW and the impact of the TCA is provided for guidance purposes only. Local conditions in the telecommunications competitive environment may well dictate other approaches to satisfying the competitive neutrality provisions of the TCA. There is no "right answer" that will serve every situation. However, the points discussed above provide some insight into the thinking of the FCC Common Carrier Bureau on these issues, and can be used to assist States in formulating their approach to the subject of longitudinal access to freeway ROW for telecommunications.

The FHWA anticipates revising these guidelines periodically as information is obtained on the practicality and reasonableness of these recommendations.

Any questions on the guidelines should be addressed to William S. Jones, Intelligent Transportation System Joint Program Office, telephone number (202) 366–2128, Washington, DC 20590, e-mail: *WilliamS.Jones@fhwa.dot.gov*.

[FR Doc. 01–1644 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2001–8611]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collections of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under new procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before March 23, 2001.

ADDRESSES: Comments must refer to the docket and notice numbers cited at the beginning of this notice and be submitted to Docket Management, Room PL–401, 400 Seventh St. SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided, by referencing its OMB Clearance Number. It is requested, but not required, that 1 original plus 2 copies of the comments be provided. The Docket Section is open on weekdays from 10:00 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of the request for collection of information may be obtained at no charge from Dr. William J.J. Liu, NHTSA, 400 Seventh Street, SW., Room 5313, Washington, DC 20590.

Dr. Liu's telephone number is (202) 366–4923. Please identify the relevant collection of information by referring to its OMB Clearance Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

49 CFR 571.218, Motorcycle Helmets

Type of Request—Reinstatement of clearance.

OMB Clearance Number—2127–0518.

Form Number—This collection of information uses no standard forms.

Requested Expiration Date of Approval—Three years from date of approval.

Summary of the Collection of Information—NHTSA has issued Federal Motor Vehicles Safety Standard No. 218, Motorcycle Helmets, which establishes minimum performance requirements for helmets designed for use by motorcyclists and other motor vehicle users. Standard No. 218 requires that each helmet shall be labeled permanently and legibly (S5.6), in a manner such that the label(s) can be read easily without removing padding or any other permanent part.

Description of the Need for the Information and Proposed Use of the information—NHTSA requires labeling information to ensure that helmet owners have important safety information. The information currently provided on the helmet from the labels includes that manufacturer's name or identification, model, size, month and year of manufacture, shell and liner construction of the helmet. The owners will also receive important information on caring for the helmet from the labels. Finally, the DOT symbol signifies the manufacturer's certification that the helmet meets all the requirements in the standard. Labeling is necessary for NHTSA to identify the helmet, particularly, if the helmet failed the compliance tests.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—NHTSA estimates that 32 manufacturers of motorcycle helmets offer their products for sale in the United States. The frequency of response to the collection of information depends on the number of helmets that each manufacturer sells.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information—Currently, 32 manufacturers produce, on the average, a total of approximately 1,600,000 motorcycle helmets a year. NHTSA estimates that the total annual information collection burden on all manufactures is 5,333 hours. NHTSA estimates that "annualized costs on all manufacturers is $640,000."

Authority: 44 U.S.C. 3506(c); delegation of authority at 49 CFR 1.50.

Issued: January 17, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1852 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA 2000–8591; Notice 1]

Bridgestone/Firestone, Inc., Receipt of Application for Decision of Inconsequential Noncompliance

Bridgestone/Firestone, Inc., has determined that approximately 33,000 P235/75R15 Widetrack Wintertrax tires produced in the Sao Paulo, Brazil plant and 1,400 P235/75R15 Lemans A/T tires produced in the Decatur, Illinois plant do not meet the labeling requirements mandated by Federal Motor Vehicle Safety Standard (FMVSS) No. 109, "New Pneumatic Tires."

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Bridgestone/Firestone has petitioned for a determination that the noncompliance is inconsequential to motor vehicle safety and has filed an appropriate report pursuant to 49 CFR part 573, "Defect and Noncompliance Reports."

This notice of receipt of an application is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the application.

The noncompliance with Section 4.2.1(c) relates to maximum load rating for a particular tire size. The Sao Paulo plant produced 33,000 P235/75R15 Widetrack Wintertrax tires from April 2000 through October 2000. The affected tires had the maximum load mismarked. The actual marking was: Max Load 650 Kg (1433 lbs.) @ 300 Kpa (44 psi). The correct marking should have been: Max Load 920 Kg (2029 lbs.) @ 300 Kpa (44 psi).

The affected P235/75R15 Widetrack Wintertrax tires meet all requirements of FMVSS No. 109 except the markings pertaining to maximum load rating.

The noncompliance with Section 4.3.4(a) relates to the maximum inflation pressure of the tire. The Decatur plant produced 1,400 P235/75R15 Lemans A/T tires during DOT weeks 36, 37 and 38 of the year 2000. The affected tires had the inflation pressure (English units only) mismarked on the sidewall opposite the DOT serial number. The actual marking was: Max Load 990 Kg (2183 lbs.) @ 340 Kpa (41 psi). The correct marking should have been: Max Load 990 Kg (2183 lbs.) @ 340 Kpa (50 psi). Bridgestone/Firestone states that this was a single mold issue and the markings in that mold have been corrected.

The affected P235/75R15 Lemans A/T tires meet all requirements of FMVSS No. 109. They have the correct inflation in metric units, and the recommended operation inflation pressure is defined by the placard on the vehicle door or within the owner manual.

Bridgestone/Firestone, Inc., submits that the noncompliance is inconsequential as it relates to motor vehicle safety.

Interested persons are invited to submit written data, views, and arguments on the application described above. Comments should refer to the docket number and be submitted to: U.S. Department of Transportation, Docket Management, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. It is requested that two copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date, will also be filed and will be considered to the extent possible. When the application is granted or denied, the notice will be published in the **Federal Register** pursuant to the authority indicated below. Comment closing date: (February 21, 2001).

(49 U.S.C. 301118, 301120; delegations of authority at 49 CFR 1.50 and 501.8)

Issued on: January 17, 2001.

Stephen R. Kratzke,

Associate Administrator for Safety Performance Standards.

[FR Doc. 01–1851 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2000–8133; Notice 2]

Panoz Auto Development Company; Grant of Application for Temporary Exemption From Federal Motor Vehicle Safety Standard No. 208

This notice grants the application by Panoz Auto Development Company of Hoschton, Georgia, for a temporary exemption from paragraph S4.1.4 of Federal Motor Vehicle Safety Standard No. 208 *Occupant Crash Protection*. The basis of the application is that compliance will cause substantial economic hardship to a manufacturer that has tried to comply with the standard in good faith.

Notice of receipt of the application was published on October 25, 2000, and an opportunity afforded for comment (65 FR 63913).

Panoz received NHTSA Exemption No. 93–5 from S4.1.4 of Standard No.

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208, an exemption for two years which was initially scheduled to expire August 1, 1995 (58 FR 43007). It applied for, and received, two two-year renewals of this exemption (61 FR 2866; 63 FR 16856), the last of which expired March 1, 2000. Panoz now seeks a new exemption from S4.1.4 on hardship grounds, that would expire March 31, 2003. This exemption would apply to the Panoz Roadster but not to the company's other product, the Panoz Esperante, which, during the term of the last exemption, has been designed to comply with S4.1.4.

Panoz's original exemption was granted pursuant to the representation that its Roadster would be equipped with a Ford-supplied driver and passenger airbag system, and would comply with Standard No. 208 by April 5, 1995, after estimated expenditures of $472,000. As of the time of its application, April 1993, the company had expended 750 man hours and $15,000 on the project.

According to its 1995 application for renewal,

> Panoz has continued the process of researching and developing the installation of a driver and passenger side airbag system on the Roadster since the original exemption petition was submitted to NHTSA on April 5, 1993. To date, an estimated 1680 man-hours and approximately $50,400 have been spent on this project.

At that time, Panoz used a 5.0L Ford Mustang GT engine and five speed manual transmission in its car. Because "the 1995 model year and associated emission components were revised by Ford," this caused

> a delay in the implementation of the airbag system on the Roadster due to further research and development time requirements and expenditure of additional monies to evaluate the effects of these changes on the airbag adaptation program.

Shortly before filing its application for first renewal in 1995, Panoz learned that Ford was replacing the 5.0L engine and emission control system on the 1996 Mustang and other passenger cars with a modular 4.6L engine and associated emission components. The 1995 system did not meet 1996 On-Board Diagnostic emission control requirements, and Panoz was faced with using the 1996 engine and emission control system as a substitute. The majority of the money and man hours at that time had been spent on adapting an airbag system to the 5.0L engine car, and the applicant had to concentrate on adapting it to a 4.6L engine car. Panoz listed eight types of modifications and testing necessary for compliance that would cost it $337,000 if compliance were required at the end of a one-year period. It asked for and received a two-year renewal of its exemption.

However, between 1995 and 1997, Panoz found integration of the 4.6L engine into its existing chassis more difficult than anticipated, primarily because the 4.6L was 10 inches wider than the engine it replaced. This required a total redesign of the chassis, requiring expenditure of "a significant amount of resources." Simultaneously, Panoz designed the vehicle to allow for the integration of the Ford Mustang driver-side and passenger-side airbag systems. Panoz described these steps in some detail and estimates that between May 1995 and August 1997 it spent 2200 man-hours and $66,000 on these efforts. In the same time period, it spent $47,000 in static and dynamic crash testing of a 4.6L car related to airbag system development. Panoz concluded by describing the additional modifications and testing required to adapt the Ford system to its car. These costs totaled $358,000. In 1997, the company argued that a two-year renewal of its exemption would provide time to generate sufficient income (approximately $15,000 a month through sales of vehicles and private funding) to fund the modifications and testing. After August 1997, Panoz spent an additional 1779 man hours and $87,375 in airbag development for the Roadster, a large portion of which was to adapt the 1997–98 Ford Mustang mechanical system. In September 1998, NHTSA issued its Notice of Proposed Rulemaking (NPRM) on advanced airbags which would have required Panoz to begin the phase-in of the new system as of September 1, 2002. Panoz decided that the mechanical airbag system it was developing could not comply with the proposed advanced system. It also lacked the resources to develop two systems simultaneously, so it turned its development efforts towards the advanced system, which will be in its new model, Esperante. In November 1999, NHTSA issued a Supplemental NPRM under which implementation of the advanced airbag rule would be delayed for small manufacturers until September 1, 2005 (subsequently adopted in the final rule of May 2000). This resulted in Panoz's resumption of efforts to adapt the Ford Mustang airbag system to its Roadster. However, with its 1999 models, Ford had replaced the mechanical airbag system with an electronic one, "which dictated that Panoz would have to conduct further crash testing in order to properly calibrate the [Restraint Control Module] for application on the AIV Roadster." Panoz intends to have the electronic system adapted by the end of the exemption it has requested. The foregoing is a summary of Panoz's compliance efforts which are set forth in detail in its application.

In sum, Panoz has been exempted from compliance with the airbag requirements for all passenger cars that it manufactured between August 1, 1993, and March 1, 2000, approximately 6½ years. These, however, total only 178 units.

At the time of its original petition, Panoz's cumulative net losses since incorporation in 1989 were $1,265,176. It lost an additional $249,478 in 1993, $169,713 in 1994, $721,282 in 1995, and $1,349,241 in 1996. Its losses continued in 1997, 1998, and 1999, respectively $3,253,111, $4,264,689, and $2,996,903. Thus, Panoz's losses for the years that the exemption was in effect, 1993–99, total $13,004,417.

The applicant reiterated its original arguments that an exemption would be in the public interest and consistent with the objectives of traffic safety. Specifically, The Roadster is built in the United States and uses 100 percent U.S. components, bought from Ford and approximately 95 other companies ("at least 250 employees" of which "remain involved in the Panoz project"). Panoz provides employment for 47 full time and three part time employees. The company now has 33 U.S. dealers. The Roadster is said to provide the public with a classic alternative to current production vehicles. It is the only vehicle that incorporates "molded aluminum body panels for the entire car," a process which continues to be evaluated by other manufacturers and which "results in the reduction of overall vehicle weight, improved fuel efficiency, shortened tooling lead times, and increased body strength." With the exception of S4.1.4 of Standard No. 208, the Roadster meets all other Federal motor vehicle safety standards.

No comments were received on the application.

In spite of its previous exemptions, Panoz has accumulated more than $13,000,000 in net losses during the exemption periods, over half of that occurring in 1998 and 1999 when its latest extension was in effect. After NHTSA had granted the previous extension on April 6, 1998 (63 FR 16856), the agency issued its advanced airbag NPRM, in September 1998, and Panoz turned its limited resources towards an attempt to develop an advanced airbag system in compliance with the proposal, and anticipated that it would have to comply as of September 1, 2002. Fourteen months later, in November 1999, NHTSA issued a supplemental NPRM under which compliance would be deferred until September 1, 2005 for small manufacturers such as Panoz. At this point, Panoz resumed its efforts to modify the Ford mechanical airbag system only to find that Ford had changed to an electronic system with its 1999 models. Panoz could not adopt the system without additional crash testing, and it now anticipates that it will be in compliance at the end of the two-year extension it has requested. Although this is the fourth time that Panoz has applied to NHTSA for an exemption from the automatic restraint requirements of Standard No. 208, the statute imposes no limit on the number of times that a manufacturer may apply, and a further exemption may be granted upon appropriate findings of hardship and good faith efforts to comply.

We have concurred before with Panoz's arguments that an exemption would be in the public interest and consistent with the objectives of motor vehicle safety. The Roadster is built in the United States and 100% of its components are bought from Ford and from other domestic suppliers. With the exception of Standard No. 208, the Roadster is said to meet all other applicable Federal motor vehicle safety standards.

In consideration of the foregoing, we hereby find that Panoz has met its burden of persuasion that, to require compliance with S4.1.4. of Federal Motor Vehicle Safety Standard No. 208 would cause substantial economic hardship to a manufacturer that has tried in good faith to comply with the standard. We further find that a temporary exemption is in the public interest and consistent with the objectives of motor vehicle safety. Accordingly, Panoz Auto Development Company is hereby granted NHTSA Temporary Exemption No. EX2001–1 from S4.1.4 of 49 CFR 571.208 Motor Vehicle Safety Standard No. 208 Occupant Crash Protection. This exemption applies only to the Panoz Roadster and will expire on January 1, 2003.

(49 U.S.C. 30113; delegations of authority at 49 CFR 1.50. and 501.8)

Issued on January 11, 2001.

Rosalyn G. Millman,

Deputy Administrator.

[FR Doc. 01–1691 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2001–8681]

Federal Motor Vehicle Safety Standards; Occupant Crash Protection; Review: Fatality Reduction by Safety Belts; Evaluation Report

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Request for comments on technical report.

SUMMARY: This notice announces NHTSA's publication of a Technical Report reviewing and evaluating its existing Safety Standard 208, Occupant Crash Protection. The report's title is Fatality Reduction by Safety Belts for Front-Seat Occupants of Cars and Light Trucks: Updated and Expanded Estimates Based on 1986–99 FARS Data.

DATES: Comments must be received no later than May 22, 2001.

ADDRESSES:

Report: You may obtain a copy of the report free of charge by sending a self-addressed mailing label to Publications Ordering and Distribution Services (NAD–51), National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590. A summary of the report is available on the Internet for viewing on line at *www.nhtsa.dot.gov/cars/rules/regrev/evaluate/809199.html.* The full report is available on the Internet in PDF format at *www.nhtsa.dot.gov/cars/rules/regrev/evaluate/pdf/809199.pdf.*

Comments: All comments should refer to the Docket number of this notice (NHTSA–2001–8681). You may submit your comments in writing to: U.S. Department of Transportation Docket Management, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590. You may also submit your comments electronically by logging onto the Dockets Management System website at *http://dms.dot.gov.* Click on "Help & Information" or "Help/Info" to obtain instructions for filing the document electronically.

You may call Docket Management at 202–366–9324 and visit the Docket from 10:00 a.m. to 5:00 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Charles J. Kahane, Chief, Evaluation Division, NPP–22, Plans and Policy, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW, Washington, DC 20590. Telephone: 202–366–2560. FAX: 202–366–2559. E-mail: *ckahane@nhtsa.dot.gov.*

For information about NHTSA's evaluations of the effectiveness of existing regulations and programs: Visit the NHTSA web site at *http://www.nhtsa.dot.gov* and click "Regulations & Standards" underneath "Car Safety" on the home page; then click "Regulatory Evaluation" on the "Regulations & Standards" page.

SUPPLEMENTARY INFORMATION: NHTSA estimated in 1984 that manual 3-point safety belts reduce the fatality risk of front-seat occupants of passenger cars by 45 percent relative to the unrestrained occupant. This critically important safety technology should be re-evaluated periodically to see if effectiveness estimates are still current and accurate. However, after 1985, the prime analysis technique for Fatality Analysis Reporting System (FARS) data, double-pair comparison, began producing inflated, unreliable results. The technical report develops an empirical tool to adjust double-pair comparison analyses of 1986–99 FARS data. It validates the adjustments by comparing the belt use of fatally injured people in certain types of crashes to belt use observed on the road in State and national surveys. These methods reconfirm the agency's earlier estimates of fatality reduction by manual 3-point belts: 45 percent in passenger cars and 60 percent in light trucks. Furthermore, they open the abundant 1986–99 FARS data to additional analyses, permitting point-estimation of belt effectiveness by crash type, occupant age and gender, belt type, vehicle type, etc.

How Can I Influence NHTSA's Thinking on This Evaluation?

NHTSA welcomes public review of the technical report and invites reviewers to submit comments about the data and the statistical methods used in the analyses. NHTSA will submit to the Docket a response to the comments and, if appropriate, additional analyses that supplement or revise the technical report.

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the Docket number of this document (NHTSA–2001–8681) in your comments.

Your primary comments must not be more than 15 pages long (49 CFR 553.21). However, you may attach additional documents to your primary comments. There is no limit on the length of the attachments.

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Please send two paper copies of your comments to Docket Management or submit them electronically. The mailing address is U.S. Department of Transportation Docket Management, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590. If you submit your comments electronically, log onto the Dockets Management System website at *http://dms.dot.gov* and click on "Help & Information" or "Help/Info" to obtain instructions.

We also request, but do not require you to send a copy to Charles J. Kahane, Chief, Evaluation Division, NPP–22, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW, Washington, DC 20590 (alternatively, FAX to 202–366–2559 or e-mail to *ckahane@nhtsa.dot.gov*). He can check if your comments have been received at the Docket and he can expedite their review by NHTSA.

How Can I Be Sure That My Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How Do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, send three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NCC–01, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street, SW, Washington, DC 20590. Include a cover letter supplying the information specified in our confidential business information regulation (49 CFR Part 512).

In addition, send two copies from which you have deleted the claimed confidential business information to Docket Management, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590, or submit them electronically.

Will the Agency Consider Late Comments?

In our response, we will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

How Can I Read the Comments Submitted by Other People?

You may read the comments by visiting Docket Management in person at Room PL–401, 400 Seventh Street, SW, Washington, DC from 10:00 a.m. to 5:00 p.m., Monday through Friday.

You may also see the comments on the Internet by taking the following steps:

a. Go to the Docket Management System (DMS) Web page of the Department of Transportation (*http://dms.dot.gov*).

b. On that page, click on "search."

c. On the next page (*(http://dms.dot.gov/search/)* type in the four-digit Docket number shown at the beginning of this Notice (6545). Click on "search."

d. On the next page, which contains Docket summary information for the Docket you selected, click on the desired comments. You may also download the comments.

Authority: 49 U.S.C. 30111, 30168; delegation of authority at 49 CFR 1.50 and 501.8.

William H. Walsh,

Associate Administrator for Plans and Policy.

[FR Doc. 01–1702 Filed 1–19–01; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance

AGENCY: Department of the Treasury ("Treasury").

ACTION: Notice of Department of the Treasury Financial Assistance Subject to Title IX of the Education Amendments of 1972, as amended.

SUMMARY: In accordance with Subpart F of the final common rule for the enforcement of Title IX of the Education Amendments of 1972, as amended ("Title IX"), this notice lists federal financial assistance administered by the U.S. Department of the Treasury that is covered by Title IX. Title IX prohibits recipients of federal financial assistance from discriminating on the basis of sex in education programs or activities. Subpart F of the Title IX common rule requires each federal agency that awards federal financial assistance to publish in the **Federal Register** a notice of the federal financial assistance covered by the Title IX regulations within sixty (60) days after the effective date of the final common rule. The final common rule for the enforcement of Title IX was published in the **Federal Register** by twenty-one (21) federal agencies, including Treasury, on August 30, 2000 (65 FR 52858–52895). Treasury's portion of the final common rule will be codified at 31 CFR Part 28.

SUPPLEMENTARY INFORMATION: Title IX prohibits recipients of federal financial assistance from discriminating on the basis of sex in educational programs or activities. Specifically, the statute states that "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance," with specific exceptions for various entities, programs, and activities. 20 U.S.C. 1681(a). Title IX and the Title IX common rule prohibit discrimination on the basis of sex in the operation of, and the provision or denial of benefits by, education programs or activities conducted not only by educational institutions but by other entities as well, including, for example, law enforcement agencies, departments of corrections, and for profit and nonprofit organizations.

List of Federal Financial Assistance Administered by the Department of the Treasury to Which Title IX Applies

Note: All recipients of federal financial assistance from Treasury are subject to Title IX, but Title IX's anti-discrimination prohibitions are limited to the educational components of the recipient's program or activity, if any.

Failure to list a type of federal assistance below shall not mean, if Title IX is otherwise applicable, that a program or activity is not covered by Title IX.

1. Assistance provided by the Office of the Partnership in Education linking the various Treasury bureaus' educational and community outreach efforts, including: support activities for career academies and Adopt-A-School programs; identifying external and community resources in support of partnership objectives; Computers for Learning, the donation of surplus computer equipment, technology training and support to local schools; Professional Development Series, the workplace readiness training for high school internships; Achieves Initiative, to motivate students to attend and stay in school and to provide financial skills training; and coordination of volunteer efforts involving technology, mentoring and tutoring support for partnership schools. (National and Community Service Act of 1990, 42 U.S.C. 12501; 104 Stat. 3127—Public Law 101–610; and Executive Order 12999 and Executive Order 12820.)

2. Assistance provided by the Federal Law Enforcement Training Center, the Customs Service and the Secret Service in the form of training for state, local, and Federal law enforcement officers. (Omnibus Consolidated Appropriations Act of 1997, 110 Stat. 3009—Public Law 104–208.)

3. Assistance provided by the Community Development Financial Institution Fund in the form of capital to institutions serving distressed communities and low-income individuals. (Riegle Community Development and Regulatory Improvement Act of 1994, Public Law 103–325.)

4. Assistance provided by the Community Adjustment and Investment Program in the form of financial resources for loans or loan guarantees to create or retain private sector jobs in U.S. communities with significant job losses due to changes in trade patterns as a result of the North America Free Trade Agreement. (The North American Free Trade Agreement Implementation Act, 107 Stat. 2057—Public Law 103–182.)

5. Assistance provided by the Customs Service in the form of sharing seized items with other Federal, state, and local law enforcement agencies. (The Department of Treasury Forfeiture Fund, 31 U.S.C. 9703(a)(1)(G).)

6. Assistance provided by the Customs Service in the form of funding for overtime work to state and local agencies assisting Customs in law enforcement activities. (The Department of Treasury Forfeiture Fund, 31 U.S.C. 9703(a)(1)(I).)

7. Assistance provided by the Internal Revenue Service under the Low-Income Taxpayer Clinic (LITC) Program in the form of matching grants for qualifying organizations that provide legal assistance to low-income taxpayers in controversies with the IRS and/or inform Limited English Proficient (LEP) individuals of their tax rights and responsibilities. (IRS Restructuring and Reform Act of 1998, Public Law 105–206.)

8. Assistance provided by the Internal Revenue Service in the form of grants to non-profit organizations that operate Tax Counseling for the Elderly (TCE) programs, which train volunteers to provide free tax help to individuals 60 years of age and over and reimburse volunteers for mileage and other expenses incurred as part of the program. (Section 163 of the Revenue Act of 1978, 92 Stat. 2810—Public law 95–600.)

9. Assistance provided by the Bureau of Alcohol, Tobacco, and Firearms in the form of youth crime prevention focused on gang resistance open to all elementary, middle or junior high schools (Violent Crime Reduction Act, Public Law 103–322, section 32401.)

In addition to the above, further information on Treasury federal financial assistance can be found by consulting the Catalog of Federal Domestic Assistance (CFDA) at *http://www.cfda.gov*. If using the Internet site, please select "Search the Catalog," select "Browse the Catalog—By Agency," and then click on "The Department of Treasury." Catalog information is also available by calling, toll free, 1–800–699–8331 or by writing to: Federal Domestic Assistance Catalog Staff (MVS), General Services Administration, Reporters Building, Room 101, 300 7th Street, SW., Washington, DC 20407.

The following is a list of other federal financial assistance administered by Treasury as derived from the CFDA. For further information on any of these types of federal financial assistance, please consult the CFDA. Abbreviations following each type of federal financial assistance indicate which Treasury Department component administers the relevant federal financial assistance, and are as follows: IRS—Internal Revenue Service; DO—Departmental Offices; ATF—Bureau of Alcohol, Tobacco, and Firearms; USSS—United States Secret Service.

Taxpayer Service—(IRS)
Exchange of Federal Tax Information With State Tax Agencies—(IRS)
Bank Enterprise Award Program—(DO)
ATF Training Assistance—(ATF)
Secret Service Training Activities—(USSS)

Authority: 20 U.S.C. 1681–1688; 65 FR 52881, to be codified at 31 CFR Part 28.

Dated: January 11, 2001.

Lisa G. Ross,

Assistant Secretary for Management and Chief Financial Officer.

[FR Doc. 01–1596 Filed 1–19–01; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Notice of Firearms Manufactured or Imported.

DATES: Written comments should be received on or before March 23, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Art Resnick, Chief, National Firearms Act Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8330.

SUPPLEMENTARY INFORMATION:

Title: Notice of Firearms Manufactured or Imported.

OMB Number: 1512–0025.

Form Number: ATF F 2 (5320.2).

Abstract: ATF F (5320.2) is used by a federally qualified firearms manufacturer or importer to report firearms manufactured or imported and to have these firearms registered in the National Firearms Registration and Transfer Record as proof of the lawful existence of the firearm.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 590.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 5,900.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

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Dated: January 11, 2001.
William T. Earle,
Assistant Director (Management) CFO.
[FR Doc. 01–1809 Filed 1–19–01; 8:45 am]
BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Application for Certification/Exemption of Label/Bottle Approval Under the Federal Alcohol Administration Act.

DATES: Written comments should be received on or before March 23, 2001 to be assured of consideration.

ADDRESS: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Lynne Gittes, Alcohol, Labeling and Formulation Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8140.

SUPPLEMENTARY INFORMATION:

Title: Application for Certification/ Exemption of Label/Bottle Approval Under the Federal Alcohol Administration Act.

OMB Number: 1512–0092.

Form Number: ATF F 5100.31.

Abstract: ATF administers the Federal Alcohol Administration Act and its implementing regulations. The law and regulations provide, in part, standards and guidelines for the labeling of alcohol beverages. Under the law and regulations, U.S. bottlers and importers cannot bottle or import alcohol beverages without a certificate of label approval. To obtain approval, U.S. bottlers and importers must complete ATF F 5100.31.

Current Actions: ATF F 5100.31 has been revised. Minor changes were made to the front of the form. The wording of items 7, 16 and 17 were slightly modified for clarification purposes. The back of the form was completely changed. Following plain language guidelines, the instructions for completing the form and conditions of approval were reformatted. The conditions under which approved labels may be modified without submission of a new application for certificate of label approval were changed. The single-most significant revision of the form is the allowance to add, delete or change any nonmandatory label information without submission of a new application for certificate of label approval. There is an increase in burden hours due to an increase in respondents. The recordkeeping requirement for this information collection is 3 years.

Type of Review: Extension with changes.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 9,047.

Estimated Time Per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 37,016.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 11, 2001.
William T. Earle,
Assistant Director (Management) CFO.
[FR Doc. 01–1810 Filed 1–19–01; 8:45 am]
BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Application For Registration For Tax-Free Transactions Under 26 U.S.C. 4221 (Firearms and Ammunition).

DATES: Written comments should be received on or before March 23, 2001, to be assured of consideration.

ADDRESSES: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Rich Mascolo, Chief, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Title: Application For Registration For Tax-Free Transactions Under 26 U.S.C. 4221 (Firearms and Ammunition).

OMB Number: 1512–0508.

Form Number: ATF F 5300.28.

Recordkeeping Requirement ID Number: ATF REC 5300/28.

Abstract: The information requested on ATF F 5300.28 is necessary for ATF to determine if persons (applicants) should be granted the privilege of purchasing or selling firearms and ammunition tax-free. There is no record retention requirement for the applicant.

Current Actions: There are no changes to this information collection and it is being submitted for extension purposes only.

Type of Review: Extension.

Affected Public: Business or other for-profit, State or local governments.

Estimated Number of Respondents: 125.

Estimated Time Per Respondent: 3 hours.

Estimated Total Annual Burden Hours: 375.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 11, 2001.
William T. Earle,
Assistant Director (Management) CFO.
[FR Doc. 01–1811 Filed 1–19–01; 8:45 am]
BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the Bureau of Alcohol, Tobacco and Firearms within the Department of the Treasury is soliciting comments concerning the Special Agent Medical Preplacement.

DATES: Written comments should be received on or before March 23, 2001 to be assured of consideration.

ADDRESS: Direct all written comments to Bureau of Alcohol, Tobacco and Firearms, Linda Barnes, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Joyce H. Keene, Recruitment and Hiring Branch, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8930.

SUPPLEMENTARY INFORMATION:

Title: Special Agent Medical Preplacement.

Form Number: ATF F 2300.10.

Abstract: Medical standards are part of the qualification standards for positions in the Federal Government. In general, there must be a direct relationship between the medical standard or physical requirement and the actual duties of the position being filled. Failure to meet an established medical standard of physical requirement means that the individual is not qualified for the position. The information obtained from ATF F 2300.10 will be initially used to make a recommendation on either hiring or not hiring an applicant.

Current Actions: This is a new information collection.

Type of Review: New.

Affected Public: Individuals or households.

Estimated Number of Respondents: 300.

Estimated Time Per Respondent: 45 minutes.

Estimated Total Annual Burden Hours: 225.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: January 11, 2001.
William T. Earle,
Assistant Director (Management) CFO.
[FR Doc. 01–1812 Filed 1–19–01; 8:45 am]
BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of Citizen Advocacy Panel, Brooklyn District

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: An open meeting of the Brooklyn District Citizen Advocacy Panel will be held in Brooklyn, New York.

DATES: The meeting will be held Friday, February 9, 2001.

FOR FURTHER INFORMATION CONTACT: Eileen Cain at 1–888–912–1227 or 718–488–3555.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an operational meeting of the Citizen Advocacy Panel will be held Friday, February 9, 2001 6 p.m. to 9:20 p.m. at the Internal Revenue Service Brooklyn Building located at 625 Fulton Street, Brooklyn, NY 11201. For more information or to confirm attendance, notification of intent to attend the meeting must be made with Eileen Cain. Mrs. Cain can be reached at 1–888–912–1227 or 718–488–3555. The public is invited to make oral comments from 8:30 p.m. to 9:20 p.m. on Friday, February 9, 2001.

Individual comments will be limited to 5 minutes. If you would like to have the CAP consider a written statement, please call 1–888–912–1227 or 718–488–3555, or write Eileen Cain, CAP Office, P.O. Box R, Brooklyn, NY, 11201. The Agenda will include the following: various IRS issues.

Note: Last minute changes to the agenda are possible and could prevent effective advance notice.

Dated: January 10, 2001.
John J. Mannion,
Director, Program Planning and Quality.
[FR Doc. 01–1560 Filed 1–19–01; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

[AC–1: OTS Nos. H–3697 and 14379]

BUCS Financial Corp., Owings Mills, Maryland; Approval of Conversion Application

Notice is hereby given that on January 12, 2001, the Director, Examination Policy, Office of Thrift Supervision, or

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his designee, acting pursuant to delegated authority, approved the application of BUCS Federal Bank, Owings Mills, Maryland, convert to the stock form of organization. Copies of the application are available for inspection at the Dissemination Branch, Office of Thrift Supervision, 1700 G Street, NW, Washington, DC 20552, and the Southeast Regional Office, Office of Thrift Supervision, 1475 Peachtree Street, NE., Atlanta, GA 30309.

Dated: January 12, 2001.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Corporate Secretary.

[FR Doc. 01–1577 Filed 1–19–01; 8:45 am]

BILLING CODE 6720–01–M

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; System of Records

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of Amendment to VA System of Records—Voluntary Service Records—VA.

SUMMARY: The Privacy Act of 1974 requires that all agencies publish in the **Federal Register** notice of the existence of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is amending the system of records entitled "Voluntary Service Records—VA" (57VA125) as set forth in the **Federal Register** at 42 FR 6032 dated 02–01–77. The number of the system is changed from 57VA125 to 57VA10C2 to maintain consistency of numbering with the Office code for the VA Voluntary Service (VAVS). VA is amending the system by including a purpose, by adding a new routine use, and by revising the paragraphs for System Location and Policies and Practices for Storing, Retrieving, Retaining, and Disposing of Records in the System, including Storage, Retrievability and Safeguards. VA is republishing the system notice in its entirety.

DATES: Comments on the amendment of this system of records must be received no later than February 21, 2001. If no public comments are received, the new system will become effective February 21, 2001.

ADDRESSES: Written comments concerning the proposed new system of records may be submitted to the Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Comments will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Veterans Health Administration (VHA) Privacy Act Officer, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (727) 320–1839.

SUPPLEMENTARY INFORMATION: VAVS has been an integral part of the VA system since 1946 and operates the largest Volunteer Program in the Federal government supplementing staff and resources in all areas of patient care and support. Its mission is to provide a structured Volunteer Program under the management of VA compensated employees in cooperation with community resources to serve America's veterans and their families with dignity and compassion. VAVS volunteers assist veteran patients by augmenting staff in such settings as hospital wards, nursing homes, community-based volunteer programs, end-of-life care programs, foster care, and veterans outreach centers. VAVS volunteers and their organizations annually contribute millions of dollars in gifts, donations, and time. Volunteers are a priceless asset to these veterans and VA. Electronic and paper records are maintained in Voluntary Service to include master records of Regularly Scheduled (RS) Volunteers, documents of participation of Occasional Volunteers, signed "Waiver of Claims to Remuneration Agreement," parental or guardian consent forms for student volunteers, etc. Voluntary Service administrative and general correspondence files will be maintained in accordance with Records Control Schedule (RCS) 10–1. Voluntary Service has determined as a matter of policy to record hours and visits of all volunteers each month. These paper and electronic records and information may be used for tracking the number of RS Volunteers, Occasional Volunteers, and student volunteers; to produce statistical and managerial reports on the number of hours and visits of all volunteers each month; and to present volunteers with appreciation awards for service. The processing of this data is accomplished by utilizing the Veterans Health Information Systems and Technology Architecture (VISTA).

Routine use 1 has been replaced by three routine use disclosure statements that more accurately reflect disclosing relevant information to agencies charged with enforcing the law conducting investigations. All of the routine use disclosure statements were renumbered. Two routine use disclosures have been added to assist in the administration of the VAVS program. Relevant information may be disclosed to the Department of Justice and United States Attorneys in defense or prosecution of litigation involving the United States, and to Federal agencies upon their request in connection with review of administrative tort claims filed under the Federal Tort Claims Act, 28 U.S.C. 2672. If one of the volunteer drivers is in an accident while driving a Disabled American Veterans vehicle, and there is litigation concerning the accident, VA must be able to provide relevant information. This information may include what assignment the volunteer has and whether or not the volunteer was listed as having worked on the day or days in question. A similar situation would apply if any volunteer were injured while volunteering at VA. Relevant information may be disclosed to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement. VA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. VA must be able to give a contractor whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor from using or disclosing the information for any purpose other than that described in the contract.

The Austin Automation Center (AAC) is designated as the corporate database for this program. Data transmission between the AAC and VA health care facilities is accomplished using the Department's wide area network. All transmissions include header information that is used for validation purposes. In addition, consistency checks in the software are used to validate the transmission, and electronic acknowledgment messages are returned to the sending application. Strict control measures are enforced to ensure that access to, and disclosure from, all records are limited to Voluntary Service employees whose official duties warrant access to files. The automated electronic record system recognizes authorized users by keyboard entry of a series of unique passwords. Employees are required to sign a user access agreement acknowledging their knowledge of confidentiality requirements, and all employees receive annual training on information security. Working spaces and record storage areas in Voluntary Service are locked during non-business hours.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (61 FR 6428), February 20, 1996.

Approved: January 5, 2001.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

57VA10C2

SYSTEM NAME:

Voluntary Service Records—VA.

SYSTEM LOCATION:

Paper and electronic records are maintained at each of the VA health care facilities. Only electronic records are maintained at the Austin Automation Center (AAC), Austin, Texas. Active records are retained at the facility where the individual has volunteered to assist the administrative and professional personnel and at the AAC. Basic information for all inactive records is retained at the facility where the volunteer worked.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All volunteers, regularly-scheduled and occasional, including non-affiliated and members of voluntary service organizations; and welfare, service, veterans, fraternal, religious, civic, industrial, labor, and social groups or clubs which voluntarily offer the services of their organizations and/or individuals to assist with the provision of care to patients, either directly or indirectly, through VA Voluntary Service under Title 38, United States Code, section 513.

CATEGORIES OF RECORDS IN THE SYSTEM:

Administrative records containing personal information about the individual making application to become a volunteer in a VA health care facility, VA regional office, or VA cemetery. These minimum records include the volunteer's name, address, social security number, date of birth, telephone number, next-of-kin information, assignments worked, hours and years of service and last award received. Information relating to the individual membership in service organizations, qualifications, restrictions and preferences of duty and availability to schedule time of service. Medical and training records pertaining to the volunteer's service will also be maintained for all active volunteers at the facility where the volunteer works.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38, United States Code, section 513.

PURPOSE(S):

The records and information are used for tracking the number of Regularly Scheduled (RS) Volunteers, Occasional Volunteers, and student volunteers; to produce statistical and managerial reports on the number of hours and visits of all volunteers each month; and to present volunteers with certificates of appreciation for service.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Any information in this system, except the name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal, State, local or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

2. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to a Federal agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto, in response to its official request.

3. The name and address of a veteran, which is relevant to a suspected violation or reasonably imminent violation of law concerning public health or safety, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, may be disclosed to any foreign, State or local governmental agency or instrumentality charged under applicable law with the protection of the public health or safety if a qualified representative of such organization, agency or instrumentality has made a written request that such name and address be provided for a purpose authorized by law.

4. Volunteer records may be used to confirm volunteer service, duty schedule, and assignments to service organizations, Bureau of Unemployment, insurance firms, office of personnel of the individual's full-time employment; to assist in the development of VA history of the volunteer and his/her assignments; and to confirm voluntary hours for on-the-job accidents, and for recognition awards.

5. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

6. Disclosure may be made to the National Archives and Records Service, General Services Administration, in records management inspections conducted under authority of Title 44 United States Code.

7. Relevant information may be disclosed to the Department of Justice and United States Attorneys in defense or prosecution of litigation involving the United States, and to Federal agencies upon their request in connection with review of administrative tort claims filed under the Federal Tort Claims Act, 28 U.S.C. 2672.

8. Relevant information may be disclosed to individuals, organizations, private or public agencies, etc., with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor or subcontractor to perform the services of the contract or agreement. VA occasionally contracts out certain of its functions when this would contribute to effective and efficient operations.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Magnetic tapes of all active volunteers are maintained at the AAC in Austin, Texas. The AAC only maintains data on active volunteers. Paper documents for all active volunteers are maintained at the individual VA facilities where the volunteer has donated time. Computer files containing such basic information as the volunteer's name, address, social security number, date of birth, telephone number, next-of-kin information, assignments worked, hours and years of service and last award received are retained for all volunteers, either active or inactive, at the VA

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facility where the individual currently volunteers or has volunteered.

RETRIEVABILITY:

All volunteer records are retrieved by name, social security number (SSN) or pseudo SSN.

SAFEGUARDS:

Physical Security:

1. Access to VA working space areas and the AAC is restricted to VA employees on a "need to know" basis. Generally, VA file areas and computer rooms are locked after normal duty hours and are protected from outside access by the Federal Protective Service.

2. Strict control measures are enforced to ensure that access to and disclosure from all records including electronic files stored in the Volunteer Management System in VistA are limited to VAVS employees whose official duties warrant access to those files. The system recognizes authorized employees by a series of individually unique passwords/codes and the employees are limited to only that information in the file which is needed in the performance of their official duties.

3. Any sensitive information that may be downloaded or printed to hard copy format is provided the same level of security as the electronic records. All paper documents and informal notations containing sensitive data are shredded prior to disposal.

4. All new VAVS employees receive initial information security training, and refresher training is provided to all employees on an annual basis.

5. Access to the AAC is generally restricted to Center employees, custodial personnel, Federal Protective Service and other security personnel. Access to computer rooms is restricted to authorized operational personnel through electronic locking devices. All other persons gaining access to computer rooms are escorted. Information stored in the computer may be accessed by authorized VA employees at remote locations including VA health care facilities, Information Systems Centers, VA Central Office, and Veterans Integrated Service Networks. Access is controlled by individually unique passwords/codes which must be changed periodically by the employee.

RETENTION AND DISPOSAL:

The paper and electronic records will be maintained and disposed of in accordance with the records disposition authority approved by the National Archives and Records Administration (NARA).

SYSTEM MANAGER(S) AND ADDRESSE(S):

Official responsible for policies and procedures: Director, Voluntary Service Office (10C2), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420.

Official maintaining the system: National Automated Information Systems Coordinator, VA Medical Center, 2907 Pleasant Valley Blvd., Altoona, Pennsylvania 16602–4377.

NOTIFICATION PROCEDURE:

Individuals seeking information concerning the existence and content of their service records must submit a written request or apply in person to the VA health care facility where their voluntary service was accomplished. All inquiries must reasonably identify, to the VA facility, the portion of the volunteer's service record they want information about and the approximate dates of service, in order to receive that information. Inquiries should include the volunteer's name, social security number or pseudo SSN, organization represented, date of birth, and last address while serving as a volunteer to VA.

RECORDS ACCESS PROCEDURES:

Volunteers, dependents, survivors or duly authorized representatives seeking information regarding access to and contesting of VAVS records may contact the Voluntary Service office at the VA health care facility where the individual was a volunteer worker.

CONTESTING RECORD PROCEDURES:

(*See* Record Access Procedures above.)

RECORD SOURCE CATEGORIES:

Information in this system of records may be provided by the volunteer, the family of youth volunteers, civic and service organizations, and the VA health care facility.

[FR Doc. 01–1561 Filed 1–19–01; 8:45 am]
BILLING CODE 8320–01–P

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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LIST OF PUBLIC LAWS

Note: The List of Public Laws for the 106th Congress, Second Session has been completed and will resume when bills are enacted into public law during the next session of Congress.

A cumulative List of Public Laws was published in Part II of the **Federal Register** on January 16, 2001.

Public Laws Electronic Notification Service (PENS)

Note: PENS will resume service when bills are enacted into law during the next session of Congress.

This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.

CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

A checklist of current CFR volumes comprising a complete CFR set, also appears in the latest issue of the LSA (List of CFR Sections Affected), which is revised monthly.

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1, 2 (2 Reserved)	(869-038-00001-3)	6.50	Apr. 1, 2000
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Title	Stock Number	Price	Revision Date
600-End	(869-038-00202-7)	37.00	Oct. 1, 1999
CFR Index and Findings Aids	(869-042-00047-1)	53.00	Jan. 1, 2000
Complete 1999 CFR set		951.00	1999
Microfiche CFR Edition:			
Subscription (mailed as issued)		290.00	1999
Individual copies		1.00	1999
Complete set (one-time mailing)		247.00	1997
Complete set (one-time mailing)		264.00	1996

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1-189 contains a note only for Parts 1-39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1-39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1-100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 1999, through January 1, 2000. The CFR volume issued as of January 1, 1999 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 1999, through April 1, 2000. The CFR volume issued as of April 1, 1999 should be retained.

[6] No amendments to this volume were promulgated during the period July 1, 1999, through July 1, 2000. The CFR volume issued as of July 1, 1999 should be retained..

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Part II

Department of Energy

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

Energy Conservation Programs for Consumer Products; Test Procedures for Central Air Conditioners and Heat Pumps; Proposed Rule

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DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket No. EE–RM/TP–97–440]

RIN 1904–AA46

Energy Conservation Program for Consumer Products: Test Procedures for Central Air Conditioners and Heat Pumps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Proposed rule and public hearing.

SUMMARY: The Department of Energy (DOE) is proposing changes to its regulations on test procedures for central air conditioners and heat pumps. Today's revision of the test procedure is not expected to alter the minimum energy conservation standards currently in effect. The revised test procedure is up-to-date, more complete and better organized than the current version. It should yield more accurate measurements of the energy efficiency of central air conditioners and heat pumps.

DATES: Comments must be received on or before March 23, 2001. DOE is requesting a signed original, a computer disk (WordPerfect 8) and 10 copies of the written comments. The Department will also accept e-mailed comments but you must send a signed original. Oral views, data, and arguments may be presented at the public workshop (hearing) in Washington, DC, beginning at 9 a.m. on February 7, 2001.

The Department must receive requests to speak at the workshop and a copy of your statements no later than 4 p.m., January 9, 2001, and we request that you provide a computer diskette (WordPerfect 8) of each statement at that time. The DOE panel will read the statements in advance of the hearing and requests that speakers limit oral presentations to a summary. Attendees will have an opportunity to ask questions.

ADDRESSES: Please submit written comments, and requests to speak at the public hearing to: Brenda Edwards-Jones, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Hearings and Dockets, Test Procedures for Central Air Conditioners Including Heat Pumps, Docket No. EE-RM–97–440, EE–41, Room 1J–018, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585–0121. You may send email to: *brenda.edwards-jones@ee.doe.gov*. The hearing will be at the U.S. Department of Energy, Forrestal Building, Room 1E–245, 1000 Independence Avenue, SW., Washington, DC. You can find more information concerning public participation in this rulemaking proceeding in section VI, "Public Comment," of this notice.

You may read copies of the transcript of the public hearing and public comments at the Department of Energy Freedom of Information Reading Room, U.S. Department of Energy, Forrestal Building, Room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–3142, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Michael G. Raymond, U.S. Department of Energy, Energy Efficiency and Renewable Energy, Mail Station EE–41, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585–0121, (202) 586–9611

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Mail Station GC–72, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20585–0103, (202) 586–9526

SUPPLEMENTARY INFORMATION: The proposed rule incorporates, by reference, seven test procedures published by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (ASHRAE), as follows:

- Standard 23–1993, "Methods of Testing for Rating Positive Displacement Refrigerant Compressors and Condensing Units."
- Standard 37–1988, "Methods of Testing for Rating Unitary Air-Conditioning and Heat Pump Equipment."
- Standard 41.1–1986 (Reaffirmed 1991), "Standard Method for Temperature Measurement."
- Standard 41.2–1987 (Reaffirmed 1992), "Standard Method for Laboratory Airflow Measurement."
- Standard 41.6–1994, "Standard Method for Measurement of Moist Air Properties."
- Standard 41.9–1988, "A Standard Calorimeter Test Method for Flow Measurement of a Volatile Refrigerant."
- Standard 116–1995, "Methods of Testing for Rating for Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps."

One test procedure of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers/Air Moving and Conditioning Association, Inc. (ASHRAE/AMCA) is incorporated by reference:

- Standard 51–1999, "Laboratory Methods of Testing Fans for Rating."

One test procedure of the Air-Conditioning and Refrigeration Institute (ARI) is incorporated by reference:

- Standard 210/240–1994, "Unitary Air-Conditioning and Air-Source Heat Pump Equipment."

You can view copies of these standards at the Department of Energy's Freedom of Information Reading Room at the address stated above. You can also obtain copies of the ASHRAE, ASHRAE/AMCA and ARI Standards from the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., 1971 Tullie Circle, NE, Atlanta, GA 30329, http://www.ashrae.org; and the Air-Conditioning and Refrigeration Institute, 4301 North Fairfax Drive, Suite 425, Arlington, VA 22203, http://www.ari.org, respectively.

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I. Summary of Proposed Rule

Today's proposed rule concerns the testing aspect for central air-conditioners and central air-conditioning heat pumps. The Department develops these procedures for manufacturers to test products to measure energy efficiency, energy use, or estimated annual operating cost of a product. It will interest manufacturers, but consumers of air conditioners will see no changes due to this revision, which brings the test procedure up-to-date, and makes it more complete and better organized. Nearly all the technical content is preserved and the use of U.S. customary (i.e., inch-pound) units is maintained. Air conditioners and heat pumps that presently meet the NAECA energy conservation standards will still meet these standards when rated using the revised test procedure.

II. Introduction

A. Authority

The Energy Policy and Conservation Act requires the Department of Energy to establish the Energy Conservation Program for Consumer Products. This program sets test procedures, energy consumption and efficiency labeling, and energy conservation standards for many household, consumer products.[1] The Act requires DOE to determine to what extent a proposed test procedure would change the energy efficiency or energy use of a product from the current test procedure. If we determine that a new test procedure would change the efficiency or use of a covered product, we will amend the standard. To determine the new energy conservation standard, we measure the energy efficiency or energy use of a representative sample of covered products that minimally comply with the existing standard. The average efficiency of these representative samples, tested using the amended test procedure, constitutes the amended standard. EPCA, Section 323(e)(2).

B. Background

1. Short and Long-Term Plans

This proposed DOE test procedure is the first step of a planned two-step revision process. The immediate goal is to promulgate a revised test procedure that is up-to-date, more complete and better organized. Nearly all the technical content is preserved and the use of U.S. customary (*i.e.*, inch-pound) units is maintained. One especially important goal of this first step is to have air conditioners and heat pumps that presently meet the NAECA energy conservation standards to still meet these standards when rated using the revised test procedure.

The second step in the planned revision process is to convert the DOE test procedure to using Systeme Internationale (SI) units while maximizing compatibility with pertinent standards of the International Organization for Standardization (ISO). The goal of this second step is a DOE metric test procedure which will also meet the requirements specified by ISO for determining capacities, EER(s) for a "moderate" climate, and COP's. For example, DOE plans to directly reference selected ISO indoor and outdoor test conditions. However, the DOE test procedure will impose additional requirements, not found in the ISO test standards, that allow determination of the seasonal performance factors SEER and HSPF. Presently, the pertinent ISO standards are either under revision or are being newly developed so we can not yet fully determine the extent of compatibility between the DOE and ISO testing and rating procedures. DOE, via NIST personnel, is participating in the development of the ISO test standards in an effort to minimize the differences. A proposed DOE metric test procedure will be available for industry review several months after the revision of ISO standards (5151 and 13253 or, possibly a combined standard) is completed.

This two-step test procedure revision will not delay the concurrent revision of the NAECA energy conservation standards, nor will standards revision be delayed because of the planned conversion of the test procedure to SI units. Until a DOE metric test procedure has been promulgated, you will make predictions of seasonal performance using the I–P version of the DOE test procedure, *i.e.*, this revision. This revised test procedure modifies tests for certain configurations, but is not expected to impact the performance measurements. In the coming years, when a DOE metric test procedure is progressing through the rulemaking process, DOE and stakeholders will review the best time line for implementing the metric test procedure and instituting compatible NAECA energy conservation standards. As far as possible, the metric test procedure will retain the current energy efficiency descriptors, SEER and HSPF.

2. Background for Today's Proposed Rulemaking

The first DOE test procedure covering central air conditioners and heat pumps was published in the **Federal Register** on December 27, 1979, and became effective January 17, 1980. 44 FR 76700. The test procedure was modified once, in March 1988. 53 FR 8304 (March 14, 1988). Revisions made in 1988 included expanding coverage to variable-speed air conditioners and heat pumps, addressing split-type non-ducted units, and modifying the method used for crediting heat pumps that provide a demand defrost capability.

Five waivers to the DOE test procedure covering central air conditioners and heat pumps have been granted since the 1988 final rulemaking. Waivers have been granted to two different brands of non-defrost heat pumps, to two brands of combined heat pump-water heating appliances, and for a line of burner-assisted heat pumps. Non-defrost heat pumps do not contain a defrost controller and are designed to shut the compressor off under operating

[1] Public Law 94–163, as amended by the National Energy Conservation Policy Act, Public Law 95–619, the National Appliance Energy Conservation Act of 1987, Public Law 100–12, the National Appliance Energy Conservation Amendments of 1988, Public Law 100–357, and the Energy Policy Act of 1992, Public Law 102–486, Part B of Title III of Energy Policy and Conservation Act, as amended, is referred to in this proposed rule as "EPCA" or the "Act." Part B of Title III is codified at 42 U.S.C. 6291–6309.

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conditions where frost accumulation on the outdoor coil is likely. Combined appliances use an extra condensing coil to permit the unit to provide domestic water heating in addition to space conditioning. Burner-assisted heat pumps use a gas-fired burner in the outdoor coil while using electricity to power the refrigerant compressor.

In revising this test procedure, we considered whether actions could be taken to eliminate the continued need for any of the granted waivers. Today's proposed rule covers testing and calculation of HSPF for non-defrost, all-electric heat pumps, eliminating the first two of the five waivers discussed in the preceding paragraph. As the market for dual fuel heat pumps, including burner assisted heat pumps, and combined heat pump-water heating appliances grows, we will pursue the development of separate test procedures for these devices, which will eliminate the remaining three waivers.

We completed the first draft of this revised test procedure for central air conditioners and heat pumps in June 1996. The draft test procedure addressed equipment features presently not covered and improved upon the completeness and readability of the document. The June 1996 draft test procedure was distributed to members of the HVAC industry and academia for comment on the proposed changes.

Several parties provided comments on the June 1996 draft test procedures. We determined that more input on several issues would be beneficial, and DOE held a workshop on September 25, 1997. The workshop focused on five areas of concern. The first area was the identification of commercially-available equipment that is not adequately addressed in the existing test procedure. Examples include non-defrost heat pumps, heat pumps that incorporate a heat comfort controller, multi-split non-ducted heat pumps, two-capacity heat pumps that are sized to meet the space cooling load while operating at low capacity, small duct systems, and single-speed heat pumps having a variable-speed indoor fan that is modulated based on outdoor temperature. The second issue was the appropriate way to conduct steady-state and cyclic testing on units having a variable-speed, constant-air-volume-rate indoor blower. The third area of concern dealt with appropriate adjustments in order to credit a demand defrost capability and to account for the effect of barometric pressure. A group of items that pertained to specifics on lab testing procedures composed the fourth topic of discussion. Examples included how to best test packaged units having leakage, whether to limit manufacturer-specified special lab set-up requirements, recommended static pressure tap manifolding, and electrical energy measurement requirements. The fifth issue concerned the development of new defaults for the cyclic degradation coefficients, as an alternative to having to conduct tests to determine the coefficients.

A transcript of the discussions at the September 25 workshop is available for review in the DOE Freedom of Information Reading Room. The section below summarizes comments received throughout the revision process. During the workshop, several items were introduced but left unresolved. In many of these cases, ARI industry members indicated that they would offer more input and, where possible, a consensus response in the months following the workshop.

At the invitation of ARI, NIST participated in a meeting and teleconferences hosted by the ARI Unitary Small Equipment Engineering Committee in September and October of 1997 and February of 1998. For the meetings/teleconferences that followed the September 25, 1997 Workshop, discussions on DOE test procedure issues focused mainly on eleven issues, namely: (1) Small duct systems, (2) non-defrost systems, (3) multiple split heat pumps, (4) variable-speed, constant CFM blowers, (5) heat pumps that incorporate a heat comfort controller, (6) two capacity heat pumps that are sized to meet the design cooling load while operating at low speed, (7) definition for a demand defrost system, (8) effects of barometric pressure, (9) testing of packaged systems with internal leaks, (10) special laboratory setups, and (11) new default values for the cyclic degradation coefficients, C_D (the measure of performance degradation from cycling losses). Written comments were received dated 24 November 1997 from ARI (ARI, No. 6) that addressed these particular areas. ARI formed a task group to provide additional input on three items: #4, #6, and #9. ARI also hoped to provide data and a strawman approach for addressing item #11. These last four items were discussed during a February 1998 teleconference but ARI provided no consensus by the end of February, the cutoff date imposed by DOE.

The 24 November 1997 written comments from ARI are included among the overall comment summary provided below. With regard to unresolved issues associated with ARI items #4, #6, and #9, we implemented changes based on the information gathered to date. Today's rulemaking proposes no changes for the C_D defaults that may be used instead of conducting extra tests. DOE is willing to investigate and consider new C_D defaults based on the hardware features of the air conditioner or heat pump. ARI and its members have thus far provided no test data nor made any recommendations concerning the hardware features (*e.g.*, type of expansion device, with or without a time delay relay on the indoor fan, type of compressor, off-cycle power consumption, refrigerant charge quantity, rated capacity, etc.) that should be included in a statistical analysis to identify the primary factors and the associated correlations.

A draft of this proposed test procedure was posted to the Office of Codes and Standards web site in October 1998. This document was revised during the summer of 1999 to comply with the President's Memorandum of June 1, 1998, "Plain Language in Government Writing." Thereafter, some sections of the proposed test procedure were reorganized and amended in response to comments received during the DOE internal review process.

In the proposed central air conditioner and heat pump standards rule (65 FR 59590, October 5, 2000), the Department discussed issues associated with mandating thermostatic expansion valves, or TXVs, to help maintain equipment performance under improper charge or airflow. In the standards final rule, we decided not to adopt a TXV requirement, but considered pursuing modifications to this test procedure to encourage the use of TXVs. Such modifications will not be part of this rulemaking, but will be considered in a separate process. Related issues that may be discussed in the separate process include the alternate rating method for mixed systems. The alternate rating method is not a part of this revision, which concerns only appendix M to subpart B of 10 CFR part 430. The alternate rating method is discussed in 10 CFR § 430.24(m). In the last revision of this test procedure in 1988, the adoption of a standard rating procedure for untested combinations of split systems was proposed, but the Department decided not to include a standard rating procedure in the test procedure rule. Instead, the Department requested the National Bureau of Standards to develop a rating method available to any manufacturer to use in rating untested combinations. Manufacturers may use this method or any other after obtaining the Department's approval. It may again be time to discuss a standard mixed system rating method included in the test procedure. These issues will be discussed in a workshop to be held in the spring of 2001.

III. Discussion of Comments

Following the September 1997 workshop, we received comments from the ARI Unitary Small Equipment Engineering Committee and individual ARI members, Proctor Engineering Group, and from the Florida Solar Energy Center. We grouped these comments into the following categories corresponding to sections of the test procedure: General, Definitions, Testing Conditions, and Testing Procedures. (ARI, No. 6, PEG, No. 3, FSEC, No. 7)

A. General

1. Non-ducted Split System Air Conditioners and Heat Pumps

Non-ducted units may use one or more indoor coils. When two or more indoor coils are used, they may operate in response to a single or multiple room thermostats. Standards of the International Organization for Standardization (ISO) differentiate non-ducted units as single or multiple room thermostat systems. We refer to equipment having one or more indoor coils all controlled by a single indoor thermostat as mini-split systems. We refer to equipment that uses two or more indoor thermostats to regulate the operation of two or more indoor coils as multi-split systems.

The current DOE test procedure does not differentiate between mini-split and multi-split systems. Both are tested and seasonal calculations are based on all indoor coils operating simultaneously. The zoning capability of multi-split units, though not operating some indoor coils, is not credited.

As part of its 1992 waiver petition, EnviroMaster International (EMI) sought "to test its three and four zone MC/MH series systems in the manner prescribed in the DOE test for two zone systems." 57 FR 53736 (November 12, 1992). The modification noted in the Decision and Order was to change the wording of Section 3.1.7 to the following:

> "Subsystems of multizone split-type ductless systems shall be tested as a single system. The system energy efficiency shall be based on the sum of the measured capacities of all of the zones in the system divided by the total input power used by the subsystems compressors, outdoor fans, indoor air handlers, and any additional power used by the system."

ARI commented on this issue: "Our members do not believe any change is necessary to the test procedures to address multiple split heat pumps. We are unaware of any unfair treatment of this product in the industry by the current test methods." (ARI, No. 6 at 1).

We propose no changes in today's test procedure. The option of testing each zone separately is possible. Such extra testing should provide a more complete description of the unit's capabilities. However, the benefits would have to be weighed against the considerable increase in the testing burden. The Department recommends tabling this issue until a multi-split manufacturer deems that a different and, most likely, more burdensome test approach is needed.

2. Small-duct, High-velocity Systems

Unico originally requested that DOE add a new class (or subclass) of central air conditioners and heat pumps that covered small-duct, high-velocity (SDHV) systems. Unico recommended changes to the test procedure that were coupled with DOE issuing separate NAECA standards for SDHV systems. The main test procedure changes were to impose higher minimum external static pressures and lower maximum air volume rates requirements on SDHV systems. Unico also provided a proposed definition for SDHV systems. (Unico, No. 5 at 2).

Unico noted how small duct systems differ from more conventional systems: external static is typically 1.5 inches of water, air volume rate is usually one-half of a conventional system, duct outlets into the room are typically two inches in diameter, and air velocity entering the room is in the 800 to 2000 feet per minute range. "We feel this product is different enough that it * * * should be considered for a different class. We have different classes for room air conditioners; we have different classes for packaged terminal units and ductless systems versus ducted systems." (Unico, No. 2HH at 42). ARI commented: "ARI believes that no changes to the existing test procedure are necessary for these products. They are currently tested and rated in accordance with the existing procedure. Furthermore, ARI does not believe a different product class or category should be created for small-duct systems, since that would allow for a potentially separate efficiency standard. They should be held to the same minimum efficiency standards as conventional systems. There is concern that a separate product class could open a loophole in the regulations. Other products might be specifically designed to meet the criteria of the new class, with the only intention being that they would be subjected to a less stringent efficiency standard, while still used in applications for typical equipment." (ARI, No. 6 at 1).

Unico later submitted an alternative proposal to DOE. In its alternative proposal, Unico plans to exercise the option of testing its line of SDHV-units as coil-only units. In the Unico product line, the blower assembly is sold separately from the indoor coil assembly. The only change in the test procedure needed to implement this alternative approach is to relax the maximum pressure drop allowed when testing coil-only units. Presently, the test procedure states that the pressure drop across the indoor coil assembly must not exceed 0.30 inches of water. Unico requested that the limit be increased, preferably to 0.50 inches of water.

Today's proposed test procedure sets a higher pressure drop limit of 0.5 inches of water when testing coil-only units that meet the definition of a small-duct, high-velocity system. The proposed definition is given in section 1.46. We welcome comments on this action. Possible points for consideration include whether the action is acceptable as proposed or if incorporated in combination with a different default fan power and heat adjustment.

3. Non-defrost (Limited-range) Heat Pumps

We granted the first of two waivers for non-defrost heat pumps to Airlex in 1988. 53 FR 52216 (December 27, 1988). The waiver called for testing at 47 °F and 62 °F in lieu of testing at 35 °F and 17 °F. HSPF was calculated. Airlex, to the knowledge of DOE, has since gone out of business. We granted the second waiver to EMI in November 1992. 57 FR 53736 (November 12, 1992). Unlike Airlex, EMI did not seek to report HSPF and so did not offer proposed modifications to the DOE test procedure. We required that EMI state in its printed materials on its non-defrost products that "no HSPF value has been measured since the heat pump cannot be operated at temperatures below 35 °F."

At this time, non-defrost heat pumps appear to be limited to non-ducted, multi-zone, multi-split heat pumps having multiple refrigeration systems where one refrigeration system may be heating while another is cooling. In such systems, having one refrigeration system conduct a defrost while the other refrigeration system(s) is cooling is apparently quite difficult (see below EMI comment). No opposition was voiced at the workshop to a DOE proposal to cover non-defrost heat pumps in the test procedure. We also

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received the following comments at the workshop:

In response to the question on why EMI can not make its non-ducted, multi-refrigeration system, multi-split heat pumps defrost, EMI stated "we have put preliminary designs together, but we've never been able to successfully control the defrost cycle while operating all the circuits." (EMI, No. 2HH at 23). Trane spoke against the option of creating a new class and a new NAECA HSPF energy standard for non-defrost heat pumps. (Trane, No. 2HH at 24). An ARI representative said that presently a multi-zone multi-split would be tested with all refrigeration systems operating in the same mode. (ARI, No. 2HH at 23). In written comments received following the workshop, ARI stated: "For the same rationale as with small duct systems, ARI does not believe a separate product class or category is needed for non-defrost heat pumps. We also recommend no change in the current test procedure to accommodate non-defrost systems. As discussed above, they should be held to the same minimum efficiency standards as conventional systems." (ARI, No. 6 at 1).

Since the workshop, DOE received information on non-ducted, multi-refrigeration system, multi-split heat pumps made by two manufacturers other than EMI. Both of these competing multi-split products provide a defrost capability. The key differentiating feature is that these units do not provide the option of simultaneous heating and cooling like the EMI product. EMI apparently values this simultaneous cooling/heating capability more than a defrost capability while these other two manufacturers do without the simultaneous mode feature in return for being able to defrost. To date, we have found no product that provides both the simultaneous heating/cooling feature and a reverse defrost cycle capability.

From a test procedure standpoint, several options are available. One option, in line with ARI's comment, is to make no applicable changes to the test procedure and allow the existing EMI (and Airlex) waivers to remain. This option defers the issue until we receive another waiver request for a non-defrost heat pump. A second option is to make additions to the test procedure so that the HSPF of any type of non-defrost heat pump could be evaluated. A third option is to exclude heat pumps that are designed to simultaneously heat and cool "whether they can defrost or not" from the scope of the test procedure. The rationale for exclusion would be that such units generally compete with commercial applications where packaged terminal heat pumps and air conditioners are used and so should be tested and rated in a manner comparable to the approach used for packaged terminal equipment (*i.e.*, heating performance descriptor becomes COP at 47 °F and the equipment has no HSPF rating). For this third option, the test procedure could either be changed to cover all other non-defrost heat pumps (even though DOE knows of only the EMI simultaneously heat and cool, non-defrost heat pump) or no changes could be made, again deferring until we receive another waiver petition.

DOE requests comment on the above three and any other options for handling non-defrost heat pumps. To provide an understanding of the test procedure changes required to cover non-defrost heat pumps, we include in today's proposed test procedure (see Sections 3.6.1.1 and 4.2.1.1) the steps required to test and rate most conceivable types of single-speed, non-defrost heat pumps.

4. Heat Pumps That Incorporate a Heat Comfort Controller

Heat comfort controllers modulate the operation of the resistive elements of a heat pump to minimize temperature swings of the heated supply air when operating below the heat pump's balance point. Frequently, they seek to maintain a minimum delivery temperature when operating above the balance point. This latter application can cause the system to use more electrical energy than the heat pump alone would use to meet the building load.

At the 25 September 1997 DOE workshop, the issue was discussed at some length. The workshop members noted that the item can be both an OEM product that is an integral part of the as-shipped heat pump or it can be a field added accessory that is provided by the heat pump manufacturer or, more commonly, by a third party supplier. Also, assuming that the test procedure was modified to cover heat pumps with a heat comfort controller, no workshop invitee spoke in favor of new and separate NAECA standards for such products. The following points were also made at the workshop:

ARI stated if the manufacturer incorporates a heat comfort controller as an OEM feature, it should be covered by the test procedure. (ARI, No. 2HH at 31). Trane stated if the test procedure is modified to cover heat comfort controllers, the rating should be based on operating the controller at its maximum delivery temperature. (Trane, No. 2HH at 60). Proctor Engineering commented: "Units designed to operate with strip heat above the balance temperature should not receive any special consideration in the test process or the [NAECA] Standard. Allowing special consideration will open the door to lower efficiencies in the field where installation errors already result in excessive strip heat use." (PEG, No. 3 at 3). ARI commented: "We request DOE to develop a rating procedure for heat pumps that incorporate the use of electric resistance heat above the balance point. The procedure should be based on the highest indoor air delivery/supply temperature setting that the control system allows, so that the most conservative rating will be derived. Any heat pump that uses this feature, and still meets the minimum HSPF standard should be permitted. However, the existing ICC Model Energy Code prohibits such systems, because there is no rating method for them." (ARI, No. 6 at 2).

Today's proposed test procedure covers heat comfort controllers as applied to most types of single-speed heat pumps. With the heat comfort controller disabled, conduct all the same heating mode tests. Following the normally conducted heating mode test at 47 °F outdoor temperature, conduct an extra abbreviated test with the controller enabled to determine the air delivery temperature when the controller is set to its maximum setting (see Section 3.1.9). We describe proposed steps for calculating the HSPF of a single-speed heat pump having a heat comfort controller in Section 4.2.1.2.

5. Other Commercially-available Equipment that Should Be Covered in the Test Procedure

One focus of the 25 September 1997 DOE workshop was to identify commercially-available equipment that is not covered by the DOE test procedure. For the majority of equipment discussed at the workshop, we provide separate discussions elsewhere in this summary. Equipment types that were discussed and thought not to be a commercial product included: (1) Triple-capacity heat pumps and (2) units that use a two-capacity (two-stage) compressor and a variable-speed indoor fan that is modulated at each fixed stage of compressor operation.

B. Definitions

1. Revise Definition 1.20 "Demand-defrost Control System"

ARI commented: "We recommend that DOE expand the current ARI Standard 210/240 definition of a demand defrost system to include sampling intervals of a minimum of 10 minutes and not to have the definition pertain to time adaptive systems." (ARI, No. 6 at 2)

DOE's goal is to improve upon the existing definition provided in ARI Standard 210/240–94, Section A1.11, and in particular, to stop allowance of the (maximum) 3 percent HSPF credit to units that truly do not offer a demand defrost capability. We provide a proposed definition for a "demand-defrost control system" that seeks to be consistent with ARI's comment as Definition 1.20.

C. Testing Conditions

1. Section 2.2.4. Wet-bulb Temperature Requirements for Air Entering the Indoor and Outdoor Coils

ARI commented: "In order to provide better repeatability when testing packaged systems, which may be susceptible to internal air leakage, ARI believes it may be necessary to specify an outdoor dew point temperature when units are located in the outdoor chamber (ambient). A task group has been formed to investigate this issue and we will provide our recommendations to DOE as soon as they are available." (ARI, No. 6 at 2).

DOE's understanding of the impact of a leak that could result in optimistic results is as follows:

(1) Leak of outdoor air to a location upstream of the indoor coil but downstream of the test facility inlet wet bulb temperature (dew point, relative humidity) sensor. If the outdoor dew point is lower than the indoor dew point, the measured latent capacity will be higher than the true latent capacity, while the measured sensible capacity will be lower than the actual sensible capacity. The effect on total capacity will depend on dry bulb temperature of the outdoor air (82 °F or 95 °F) and the depression of the outdoor dew point relative to the indoor dew point.

(2) Leak of outdoor air to a location downstream of the indoor coil. Results are the same as (1) except that the depression of the outdoor dew point would have to be greater to overcome the negative effect on sensible capacity. The measured air volume rate on the indoor side would be higher than the actual rate at the coil and would thus increase the perceived sensible and latent capacity.

DOE's understanding of the other factors that are related to this issue are as follows. First, psychometric rooms have difficulty achieving and maintaining outdoor wet bulb temperatures in the mid 70's °F and higher during the A and B Tests. If the internal leakage is significant, obtaining a 6 percent energy balance would be difficult to achieve. Although potentially frustrating for a third party tester, the lack of an energy balance should provide impetus for the manufacturer to reduce the leakage. You can avoid the difficulty in maintaining the outdoor wet bulb temperature during the C and D dry coil tests by meeting the requirements of achieving a dry indoor coil, and by using the equation for determining sensible cooling capacity, as opposed to total cooling capacity.

In an effort to avoid potential cases where the leakage causes an optimistic result while still providing an energy balance of 6 percent or less, DOE recommends operating at an outdoor dew point temperature that is the same as the indoor dew point temperature during wet-coil tests where the unit does not reject condensate to the outdoor coil. DOE proposes a test tolerance of ±3.0 °F in the agreement of the average outdoor dew point temperature with the average indoor dew point temperature. In nominal terms, the target outdoor wet bulb temperatures will be 71.7 °F and 67.7 °F for the A and B Tests, respectively.

During heating mode tests, leaks could cause problems if the Outdoor Air Enthalpy Method is used to provide a secondary check of capacity. The proposed test procedure includes a recommendation for regulating the indoor side wet bulb temperature in an effort to minimize the difference between the indoor and outdoor-side dew point temperatures.

2. Section 2.2.5. Additional Refrigerant Charging Requirements

ARI stated: "We believe the test procedure, as currently written, reasonably addresses the issue of special laboratory setups when conducting tests, as prescribed in manufacturer's installation instructions. Therefore, we do not recommend any change with respect to this issue." (ARI, No. 6 at 3).

Presently, any installation step is acceptable so long as it is specified in the manufacturer's installation instructions, including remarks that only apply if conducting laboratory testing. As discussed at the 25 September 1997 DOE workshop, the difficult issue is where to draw the line. Some special setups are justified and/or required when lab testing. DOE is only excluding special lab set-ups for refrigerant charging. With assistance from ARI and third-party laboratories, DOE will monitor test setup requirements to determine if manufacturers are specifying installation instructions inconsistent with the majority of lab installations or otherwise contrary to field practices. Furthermore, DOE is seeking assistance in establishing installation guidelines for items such as pre-washing of coils (*e.g.*, what cleaning agent to use, basic steps that specify the extent of the cleaning), run-in times on compressors, conditions where components (*e.g.*, crankcase heaters) are or are not electrically connected, exclusion of lab-only (or 25 feet only) lineset specifications, etc. These guidelines will be incorporated into future revisions of the test procedure to assist in obtaining consistency in the testing.

In today's proposed test procedure, the title of Section 2.2.5 changes from "Exclusion of special setup requirements if stated in the manufacturer published installation manual" to "Additional refrigerant charging requirements." The section is included for two reasons. The first is to disallow the specification of two refrigerant charging criteria, one that applies for lab testing and one that applies for a field installation. The fact that a lab setting provides better quality control is not sufficient for permitting lab testing using a different charging criteria. The second reason for today's Section 2.2.5 is to avoid discrepancies and delays when third party testing is conducted. The third party testing facility should not have to consult with the manufacturer as to how the unit is to be charged. In the case of a certification failure, the issue of whether the testing facility charged the unit correctly should only be based on whether the manufacturer's charging criteria, as specified in the unit's installation instructions, were followed.

D. Testing Procedures

1. Section 3.1.4. Indoor Air Volume Rates for a Variable-Speed, Constant CFM Blower

ARI stated: "ARI is aware of the need to consider more explicit procedures for testing units with variable speed blowers. Therefore, we have organized a task group to develop a prescribed test method for testing units with variable speed blowers, and we will pass our recommendations on to DOE as soon as they are available." (ARI, No. 6 at 1)

Today's proposed test procedure contains several changes from the existing test procedure to address testing of units having a variable-speed, constant CFM blower. For all tests, the exhaust fan of the air flow measuring apparatus is regulated to obtain an external static pressure that is as close to, while not being less than, the minimum external static pressure specified in the test procedure (see 3.1.4.1.1(b), 3.1.4.4.1, 3.1.4.4.2 and 3.1.4.4.3(b)). (The air flow measuring apparatus, by comparison, is not regulated to obtain the specified air volume rate, as is done when testing units having other than a constant-air-

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volume-rate indoor fan.) For some units, one or more tests may have to be conducted at an external static pressure that is higher than the required minimum value because of instability problems encountered when trying to reduce the external static pressure to the specified minimum. In such cases, steps are outlined for correcting the test results if the difference between the as-tested and the specified minimum external static pressure is 0.03 inches of water or more. An example of the proposed correction method is provided in the last paragraph of Sections 3.3 and 3.7. For systems that operate at multiple air volume rates, the fan laws are used to approximate the target external static pressure for tests conducted at other than the air volume rate used during the A_2 and/or $H1_2$ test.

The proposed test procedure includes a check of the agreement between the lab-measured and manufacturer-certified air volume rates. Today's proposed test procedure calls for the two values to agree within 8 percent (see 3.1.4.1.1(b), 3.1.4.2, 3.1.4.4.2, and 3.1.4.4.3(b)). This percentage is proposed based on manufacturer's comments on the variability of the variable-speed motors relative to estimates of the impact on rated performance caused by an 8 percent deviation. Using the heat pump computer modeling program HPSIM, DOE finds that an 8 percent deviation in SCFM is expected to have a negligible impact on both capacity and EER at the B Test condition while still keeping the maximum impact on capacity at the A Test condition in the 2 percent range. DOE asks that manufacturers provide feedback on the proposed 8 percent tolerance as well as findings from lab testing and computer modeling on the impact on capacity and EER of airflow changes in the 5 to 10 percent range.

Cyclic tests on units having a constant CFM blower may be conducted with or without the indoor fan enabled. If the cyclic test is conducted with the blower disabled, steps for correcting for the power draw of the blower are specified (see 3.5 and 3.5.1).

2. Section 3.1.4.1. Cooling Air Volume Rate

This issue is of interest to the ISO working group that is revising its air conditioner and heat pump test standards. The adoption of a maximum air flow limit has thus far been opposed by the majority of the ISO working group member countries. The following comments were made at the DOE workshop. A Trane representative noted that the 37.5 SCFM per 1000 Btu/h (450 SCFM per ton) maximum air flow requirement is long-standing and is of value because it (1) sets a de facto maximum sensible heat ratio and (2) keeps the air flow in a range that avoids water being blown off the wetted evaporator. (Trane, No. 2HH at 193). A representative of York International suggested reevaluating the basis for the 37.5 SCFM per 1000 Btu/h maximum while considering both full load and part load capacity conditions. (York, No. 2HH at 197).

For today's proposed revision, no change is made in the maximum air volume rate limit. DOE sees such a limit as providing a hedge against promoting efficiency gain at the expense of compromised latent capacity, especially for coil-only units. The limit also helps in having the A and B Tests conducted with a fully wetted coil that, in turn, makes the capacity fluctuations less and the collection of 30 minutes of steady-state data more readily obtainable. DOE encourages and would participate in investigations on whether this limit should be other than its present value of 37.5 SCFM per 1000 Btu/h, or whether an alternative mechanism, such as a limit on sensible heat ratio, should be considered.

Discussion of this issue is timely because no such maximum air volume limit is presently included in ISO Standards 13253 and 5151 for ducted and non-ducted air conditioners and heat pumps. A U.S. proposal to adopt the metric-equivalent of the 37.5 SCFM per 1000 Btu/h limit was voted down by the ISO working group that is presently revising ISO Standards 5151 and 13253. The vast majority of other member countries on the working group perceive air volume rate as a design parameter that should not be impacted by a rating standard. The ISO standards provide capacity test conditions that correspond to a hot, dry climate where latent capacity is not a concern. ISO also provides capacity test conditions for a cool climate. ISO working group members from countries that will rate at this cool climate condition argue that high air volume rates are needed in order to assure that the air delivery temperature is not objectionably cool. Finally, with the exception of the U.S., most countries represented on the ISO working group are predominantly concerned with non-ducted products and calorimeter testing where indoor air volume rate is not typically measured.

The goal when converting the DOE test procedure to a metric format is to make it ISO compatible. Most ducted units sold in the U.S. today are rated at an air volume rate that is less than the 37.5 SCFM per 1000 Btu/h upper limit. This fact suggests that maximum efficiency is achieved at air volume rates lower than 37.5 SCFM per 1000 Btu/h. Thus, having a upper limit may not be important enough to warrant a deviation from ISO. Either way, now is the time to discuss this issue since the revision of the ISO Standard 13253 is still underway. However, it seems unlikely that ISO will adopt an upper limit on air volume rate.

3. Section 3.1.4.1.1. External Static Pressure

Proctor Engineering Group recommended the following changes to make the test specification conform better to measurements of installed systems. When testing units having an indoor fan, "the minimum static pressure should be revised to:

- 0.50 inches of water column for all systems, or
- The maximum allowable external static pressure specified by the manufacturer, whichever is less."

When rating fanless units, "the default Btu/hr (watt draw of the indoor fan motor) should be revised to 2000 Btu/hr per 1000 cfm (586 Watts per 1000 cfm)." For comparison, the external static pressure and fan heat/power defaults presently used in the existing DOE test procedure are 0.1, 0.15, and 0.2 inches of water, with the assigned value being a function of the unit's rated capacity. The presently referenced fan heat/power default adjustment is 1250 Btu/h per 1000 SCFM (365 Watts per 1000 SCFM). Proctor Engineering Group supported its proposed changes by providing results from field measurements on 28 new systems in new construction in Phoenix, Arizona. (PEG, No. 3 at 3).

The Florida Solar Energy Center sent a report on field monitoring work which indicated that "the standard assumption of an external static pressure of 0.2 inches of water column (IWC) for the air handler fan was far lower than the typical values encountered in the field. The average we measured in 14 evaluated installations was 0.54 IWC (range was 0.27 to 0.91 IWC)." The commenter goes on to state his strong belief that "the ARI test condition should be modified to 0.5 IWC to better reflect the actual performance that will be achieved by the air conditioners operating under realistic conditions. Because of this change, the watt draw of the fan motor (and heat released into the supply air stream) should also be revised to reflect the increase in fan power from this change." (FSEC, No. 7 at 1)

Because of concern that such changes would impact the SEER and HSPF of units that have ratings at or near the NAECA minimum standard levels, DOE does not plan to change the static pressure requirements in this revision of the test procedure. Instead, DOE will continue dialogue with the working group that is revising ISO Standard 13253. When the revision of ISO 13253 is completed, DOE will determine the suitability of incorporating part or all of this test procedure in the DOE metric test procedure. ISO Standard 13253 is presently under revision with the present draft containing the following requirements for the minimum external static requirements. (The Inch-Pound equivalent values are not part of the proposed 13253 table but are included here to aid the reader.)

Minimum static pressures

Standard capacity ratings (kW) [kBtu/h]	Minimum external static pressure (Pa) [inches of H_2O]
0 to <8 [0 to <27.3]	25 [0.10]
8 to <12 [27.3 to <41.0]	37 [0.15]
12 to <20 [41.0 to <68.3]	50 [0.20]
20 to <30 [68.3 to <102.4]	62 [0.25]
30 to <45 [102.4 to <153.6]	75 [0.30]
45 to <82 [153.6 to <279.9]	100 [0.40]
82 to <117 [279.9 to <399.3]	125 [0.50]
117 to <147 [399.3 to <501.7]	150 [0.60]
[Above 147 Above 501.7]	175 [0.70]

The numbers up to 20 kW are consistent with the values presently cited in the existing and in this proposed revision of the DOE test procedure.

As for fanless units, the draft revision of ISO 13253 contains a thermodynamically-based equation (volume flow rate x total pressure drop divided by fan static efficiency x fan motor efficiency) to estimate default fan heat/power adjustments. Total pressure drop is taken as the sum of the following:

(1) The lab-measured pressure drop across the indoor, fanless unit

(2) The applicable minimum external static pressure listed in the above table

(3) An estimate for the pressure drop across a typical blower cabinet (=50 Pa).

The minimum external static pressure requirements thus impact both the rating for fanless and blower coil units. For residential size equipment, ISO Standard 13253R uses the following empirical fits to determine the fan static (*SEr*) and fan motor efficiencies (*MEr*).

$$SEr = 0.1881 * Ln(P_r + P_c + 50) - 0.4700$$
$$MEr = 0.060 * Ln[Q * (P_r + P_c + 50) / SEr] + 0.123$$

Where Q is the measured air volume rate of standard air (m^3/s), P_r is the minimum external static pressure (Pa), and P_c is the internal static pressure drop of the indoor coil cabinet assembly measured during the cooling capacity test (Pa).

Any proposal to raise the minimum external static pressure requirements and possibly tweak the ISO approach for estimating fan heat/power adjustments will first have to be agreed upon by the U.S. delegates on the ISO working group. If the proposal is endorsed by the U.S. delegation, then the delegation must submit the proposed change for the consideration of the full working group. NIST, as a member of the U.S. delegation, has raised the issue for discussion among the U.S. delegation. At this point, the U.S. delegation does not have plans for recommending changes to ISO 13253 in this area.

4. Sections 3.2.3 and 3.6.3. Testing a Two-capacity Compressor System

ARI stated: "ARI agrees with DOE that the test procedure should be modified to accommodate more appropriate testing of multiple capacity heat pumps that are sized to meet the cooling load at fan speeds lower than the maximum. We have established a task group to investigate this issue, and will provide our recommendations to DOE as soon as they are available." (ARI, No. 6 at 2).

The proposed test procedure covers two-capacity heat pumps that are designed to operate exclusively at low capacity in meeting the space cooling load while using both low and high capacities when space heating. SEER of the unit is evaluated in the same way as specified for a single-speed air conditioner. HSPF is evaluated using the same algorithm as specified for a "normal" two-capacity heat pump except that the building loads for the heating temperature bins are based on the heat pump's heating capacity when tested at *low capacity* and 47 °F outdoor dry bulb temperature. Previously, the building loads were tied to the heat pump's heating capacity at 47 °F and *high* compressor capacity. The change will drive the balance point of the heat pump down. The issue on this particular subject is whether the heat pump must have a lockout feature to prevent cooling at high capacity or is it sufficient that the rating is applicable so long as the heat pump is sized to operate at low capacity at design cooling conditions? The advantages of the lockout would be to (better) assure that high compressor capacity would not be used when cooling and a particular unit would only have one unique NAECA-required SEER and HSPF rating. Without the lockout feature, the unit would have two SEER and HSPF ratings. A lockout feature is required in accordance with today's proposed test procedure but DOE welcomes further discussion on this issue.

5. Section 3.3. Capacity Adjustments for Barometric Effects

ARI commented: "ARI is aware that barometric pressure can have an affect on test results. However, we believe DOE should allow ASHRAE to finish its analysis of this issue before making changes to the test procedure. The test procedure should be revised to reference ASHRAE Standard 37–1988, with the exception of the section that pertains to corrections made to capacities based on measured barometric pressures, since it is known this section contains an error and is being revised." (ARI, No. 6 at 2).

Today's proposed test procedure reflects the recommendation made by ARI.

6. Sections 3.5.3 and 3.8.1. Cyclic Degradation Coefficients

In the existing DOE test procedure, the default values provided for cooling and heating cyclic degradation coefficients, C_D and C_D, are both 0.25. On the cooling side, the two optional tests are conducted on the majority of units because the experimentally-determined C_D is lower than 0.25. NIST, DOE and ARI members have discussed developing new defaults. The goal is to obtain more representative defaults resulting in less C_D testing

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while still crediting features that enhance cyclic performance. The manufacturers and ARI, as part of their certification program, have experimentally determined the C_D of many units. DOE believes the available data could be used to evaluate a set of new defaults that depend on the hardware components of the air conditioner or heat pump. The compiling of the data, however, is a formidable and thus far uncompleted task.

ARI originally commented: "ARI endorses the concept of providing alternate degradation coefficients (C_D) for systems using specific components known to reduce the typical 0.25 default value. This could significantly reduce test burden by decreasing the need for the cumbersome cyclic test. ARI will continue to work with NIST on this effort, and provide whatever data our members authorize, to help determine appropriate alternatives." (ARI, No. 6 at 3). More recently, ARI members have reconsidered the merits of seeking new C_D defaults. A final decision from ARI is pending.

DOE encourages ARI to provide data and recommendations needed to begin the investigation into better C_D defaults. If better C_D defaults are identified, DOE will initiate steps to implement defaults that are lower than the existing values of 0.25. Such lower defaults could only positively impact the SEER and HSPF of a unit and so would not require adjustments to the existing NAECA energy conservation standards. Defaults that are higher than the existing 0.25 values, which could only negatively impact SEER and HSPF, would most likely become effective the same time as new NAECA energy conservation standards. We will not delay efforts to move today's proposed rulemaking into a final rulemaking by the pursuit of better C_D defaults. If we identify better defaults in sufficient time before the issue of the final rule, so we can obtain public comments on the proposed C_D values, then we will incorporate the better defaults into the final rulemaking. If better defaults are identified after the final rulemaking, DOE will initiate a new rulemaking process where changes and comments are limited to the issue of new C_D defaults.

E. Calculations of Seasonal Performance Descriptors

1. Sections 4.1.4 and 4.2.4. Variable-speed Bin Calculations

In the existing DOE air conditioner and heat pump test procedure, a quadratic fit is used to approximate the change in EER and COP as a function of the outdoor bin temperature. Prior to the 25 September 1997 DOE workshop, consideration had been given to using an alternative fit, a linear over linear rational function of the form $Y=(A_0+A_1 \cdot X)/(1+B_1 \cdot X)$. The rationale function was considered because it maintains a monotonic shape in all cases whereas a quadratic fit can have an inflection point between the points that it is fitting. For the purposes of interpolating the EER or COP of a variable-speed, all-electric heat pump or air conditioner, both fits are expected to give comparable results because the points being fitted have historically been close to linear. For the one variable-speed heat pump considered by NIST, for example, the two fits resulted in SEER and HSPF changes of 0.06% and 0.14%, respectively.

At the 25 September 1997 DOE workshop, the issue was discussed. Trane spoke against adopting the rational function on the basis that no practical problems had arisen with using the quadratic fit over the approximately 15 years that it has been used. (Trane, No. 2HH at 149–150).

Today's proposed test procedure maintains the use of the quadratic fit.

IV. Summary of Proposed Modifications to the DOE Air Conditioner and Heat Pump Test Procedure

In addition to the modifications cited in Section III, the proposed test procedure also incorporates the following changes.

A. Update and Add References for ASHRAE and ARI Standards

The existing test procedure references ASHRAE Standards 37–78 and 41.1 (no year) and ARI Standards 210–79, 240–77, and 320–76. The proposed revised version references ARI Standard 210/240–94 and ASHRAE Standards 23–93, 37–88, 41.1–86 (RA 91), 41.2–87 (RA 92), 41.6–94, 41.9–88, 51–99, and 116–95.

B. Air Volume Rates

ARI Standard 240–77 was previously referenced. Now, rather than referencing ARI Standard 210/240–94, we have added sections within this proposed test procedure. The main reason for no longer referencing ARI Standard 210/240 is that it does not cover variable-speed, constant CFM blowers and does not directly address two-capacity and variable-speed systems. It is preferable to have the overall issue of air volume rates covered in one place rather than in two. The main objective is to agree on air flow rate specifications. If ARI Standard 210/240 is revised to cover these systems, DOE may again reference the ARI Standard.

ASHRAE Standard 37–78 (or 37–88) is no longer referenced for the equation calculating the air volume rate of standard air. The factor $1+W_n$ is missing from the denominator of the equation given in Standard 37–88. This change has been adopted by the committee working to revise Standard 37.

Today's proposed test procedure adopts the approach used in the ISO Standard 5151 of conducting each test at zero external static pressure when testing a non-ducted unit.

C. Cyclic Testing

Industry practice and the method described in ASHRAE Standard 116 was adopted. Section 5.1 of the current Appendix M implies that the air volume rate is to be measured during cyclic tests. Standard test laboratory practice is to try to obtain the same velocity pressure or nozzle static pressure drop that was obtained during the comparable steady-state test. The air volume rate used in the cyclic test calculations is assumed to be the same air volume rate measured during the comparable steady-state test. This change is reflected in this proposed test procedure.

Concerning split-type non-ducted (ductless) systems, Section 4.1.1.5 of Appendix M states that "The integration time for capacity and power shall be from compressor cut-on time to indoor fan cutoff time." The indoor fan is operated for 3 minutes prior to compressor cut-on and for 3 minutes after compressor cutoff during the final OFF/ON interval. This proposed test procedure adopts industry practice and integrates power from compressor OFF to compressor OFF and subtracts the electrical energy associated with operating the indoor fan during the initial 3-minute fan-only period. Space cooling capacity is integrated from compressor ON to indoor fan OFF. As with the present test procedure, fan energy for the three minutes after compressor cutoff is added to the integrated cooling capacity.

The present test procedure does not contain specific information regarding the air dampers: where to install them, how well they should seal, and how quickly they should respond. Much of this information is given in Appendix B of ARI Standard 210/240–94. Needed information is incorporated within the text of the proposed test procedure rather than making specific references to each pertinent section of Appendix B of the ARI Standard.

For dry coil tests, the proposed test procedure adopts ARI Standard 210/240–94 Appendix B language with regard to the requirement that the drain pan be plugged and that the pan should be completely dry.

This notice of proposed rulemaking clarifies that the requirement of making electrical energy measurements using an instrument having an accuracy of ±0.5 percent of reading applies during both the ON and OFF intervals of cyclic tests.

Existing Section 4.1.3.1, which reads "The indoor and outdoor average dry-bulb temperature for the cyclic dry coil test D shall both be within 1.0 °F of the indoor and outdoor average dry bulb temperature for the steady-state dry coil test C, respectively," has been removed from the proposed test procedure. This requirement is automatically met given the 0.5 °F test condition tolerance associated with each test.

For units having a variable-speed indoor fan, the manufacturer will have the option of conducting the cyclic tests with the indoor fan enabled or disabled, the latter being the default option if an attempt at testing with the fan enabled is unsuccessful. Specifically, if testing with the indoor fan operating and it automatically reverses, shuts down, or operates at an uncharacteristically high external static pressure, then a pull-thru method, where the fan is disabled, must be used. Although allowing the option of testing with the fan disabled is needed because of the potential fighting between the unit's fan and the exhaust fan of the air flow measuring apparatus, DOE seeks data from cyclic tests where the fan operates versus tests where the fan is disabled and the pull-thru method is used.

Although a unit having a variable-speed indoor fan may be designed to ramp its fan speed when cycling on and/or off, a step response in air volume rate is nonetheless required during cyclic tests. The work associated with moving the additional air during the ramp periods is performed by the exhaust fan of the air flow measuring apparatus. The step response begins at the initiation of ramp up and ends at the termination of ramp down. The rationale for imposing the step change is mainly due to the difficulty in obtaining the ramp response and then making an accurate measurement of the space conditioning delivered. Systems having indoor fans that ramp are expected to have low cyclic degradation coefficients (C_D) regardless of whether the ramp feature is used, thus the absolute improvement in C_D is expected to be minor. Still, the proposed method of testing will benefit these units. DOE has only been able to obtain data from one unit where two different ramp profiles were compared to the results from imposing step responses in air flow. In one case C_D went from 0.05 ("truth": ramp) to 0.02 (approximation: step change) while in the second case the values were 0.025 and 0.00. DOE seeks additional data showing the difference between the ramp and step responses during cyclic tests.

D. Fanless (Coil-only) Units

Section 4.1 of the existing Appendix M calls for corrections to capacity and power based on CFM. Section 4.2 of existing Appendix M calls for corrections to capacity and power based on SCFM. ITS uses SCFM in all cases. Thus, the proposed test procedure adopts the practice of only specifying the corrections in terms of SCFM.

The proposed test procedure also adopts the ARI Standard 210/240–94 Appendix B requirement that a specific enclosure be constructed (1 inch ductboard) when testing a coil only unit that does not employ an enclosure.

E. Frost Accumulation Test

The proposed test procedure adopts the ASHRAE Standard 116–95 and ARI 210/240–94 convention of specifying the outdoor wet bulb temperature (33 °F) in place of the presently specified dew point temperature (30 °F).

F. Test Tolerance Tables

The current Appendix M contains tables covering all tests except steady-state cooling mode tests, for which Table III in ASHRAE Standard 37–78 is referenced. Table III of ASHRAE Standard 37–78 has been added to the proposed test procedure since all the other tables are included in Appendix M.

The test tolerance tables have been improved. For example, although a test condition tolerance for external resistance to air flow is provided in the current test procedure, it is not applicable for ducted units. Such a test condition tolerance is, however, now applicable to non-ducted units. Also, a test condition tolerance has been added for electrical supply voltage (previously, only a test operating tolerance was specified). Because ASHRAE Standard 37–78 does not cover cooling mode dry coil tests, a test condition tolerance on the indoor inlet wet bulb temperature is not applicable. Test tolerances given on the outdoor outlet dry and wet bulb temperatures are now noted as only being applicable when the Outdoor Air Enthalpy Method is used to provide the secondary capacity measurement.

For the Frost Accumulation Test, the intervals considered to be heating versus defrosting have been modified slightly. Specifically, in the existing test procedure in Section 4.2.3.3, the first 5 minutes after a defrost termination was included in the defrost interval. In the proposed test procedure, the time interval has been increased to 10 minutes. Also, in making the test condition conversion of 30° F dew point to 33° F wet bulb, the test operating tolerance and test condition tolerance convert to wet bulb temperature tolerances of 0.6° F and 0.3° F, respectively. This 0.6° F test operating tolerance on outdoor wet bulb temperature is more stringent than the value allowed for the steady-state tests. The 0.3° F test condition tolerance is the same as required for steady-state tests. Given that these tolerances should be less stringent that those required of a steady-state test, the proposed test procedure adopts the values given in ASHRAE Standard 37: 1.5° F and 0.5° F.

G. Pretest Intervals

Statements given in the DOE proposed test procedure regarding operation prior to recording data have been modified. These changes are as follows.

1. Wet Coil Tests

Existing: "The test room reconditioning apparatus and the equipment under test shall be operated until equilibrium conditions are attained" (Section 4.1.1.1).

Proposed: "For the pretest interval, operate the test room reconditioning apparatus and the unit to be tested until maintaining equilibrium conditions for at least 30 minutes at the specified Section 3.2 test conditions" (Section 3.3).

2. Dry Coil Steady-State Test

Existing: "The test room reconditioning apparatus and the equipment under test shall be operated until equilibrium conditions are attained, but not for less than one hour before data for test C are recorded" (Section 4.1.1.2).

Proposed: Same as proposed for Section 3.3 wet coil tests with the additional requirement to "* * * operate the unit at least one hour after achieving dry coil conditions" (Section 3.4).

3. Dry Coil Cyclic Test

Existing: "* * * test unit shall be manually cycled 'off' and 'on' * * * until steadily repeating ambient conditions are again achieved in both the indoor and outdoor test chambers, but for not less than two complete 'off/on' cycles" (Section 4.1.1.2).

Proposed: "After completing a minimum of two complete compressor

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OFF/ON cycles, determine the overall cooling delivered and total electrical energy consumption during any subsequent data collection interval where the test tolerances given in Table 8 are satisfied" (Section 3.5).

4. Maximum and High Temperature Heating Mode Tests

Existing: "The test room apparatus and test units must be operated for at least one hour with at least one-half hour at equilibrium and at the specified test conditions prior to starting the test" (Section 4.2.1.1).

Proposed: "For the pretest interval, operate the test room reconditioning apparatus and the heat pump until equilibrium conditions are maintained for at least 30 minutes at the specified Section 3.6 test conditions" (Section 3.7).

5. Heating Mode Cyclic Test

Existing: "* * * and be cycled 'on' and 'off' as specified in 3.2.1.2 until steadily repeating ambient conditions are achieved for both the indoor and outdoor test chambers, but for not less than two complete 'off'/'on' cycles" (Section 4.2.1.2).

Proposed: Same as for the dry coil cooling mode cyclic test (see above).

6. Frost Accumulation Test

Existing: "The test room reconditioning equipment and the unit under test shall be operated for at least one-half hour prior to the start of a 'preliminary' test period" (Section 4.2.1.3).

Proposed: "Operate the test room reconditioning apparatus and the heat pump for at least 30 minutes at the specified Section 3.6 test conditions before starting the 'preliminary' test period" (Section 3.9).

7. Low Temperature Test

Existing: "The test room reconditioning equipment shall first be operated in a steady-state manner for at least one-half hour at equilibrium and at the specified test conditions. The unit shall then undergo a defrost, either automatic or manually induced" (Section 4.2.1.4).

Proposed: Same as for the Maximum and High Temperature Heating mode tests (see above) with the following additions. "After satisfying the Section 3.7 requirements for the pretest interval, but before you begin collecting data to determine $\dot{Q}_h^k(17)$ and $\dot{E}_h^k(17)$, conduct a defrost cycle. This defrost cycle may be manually or automatically initiated. (Section 3.10).

H. Multi-Capacity Systems

1. Two-Capacity Heat Pumps that Lock Out Low Capacity at Higher Outdoor Temperatures.

The existing test procedure covers two-capacity units that operate exclusively at high capacity when the building load exceeds the unit's low capacity. The Department is unaware of any two-capacity units that implement such a control strategy and so coverage of them is excluded from today's proposed test procedure. However, coverage was added to address units that lock out low capacity operation at low (heating) or high (cooling) outdoor temperatures. For this new case, a step was added which reverts to a single capacity calculation. The proposed test procedure uses the C_D determined based on cycling at low capacity (or the 0.25 default) in all cases. The Department welcomes comments on any control strategy used by two-capacity units that are not adequately covered in today's proposed test procedure.

2. Systems Having a Single-Speed Compressor and a Variable-Speed Indoor Fan Where Fan Speed or Air Volume Rate Depends on Outdoor Temperature.

The proposed test procedure requires two extra steady-state tests for the cooling mode (see Table 4) and two extra steady-state tests for the heating mode (see Table 10). An extra Frost Accumulation test is optional.

3. Specification of the Air Volume Rate for Tests at Low Capacity

In the existing test procedure, the air volume rate to be used when testing a two capacity system while operating at low capacity is not explicitly addressed. The proposed test procedure requires the use of the fan laws, as is now done for variable-speed systems, to determine the air volume rate when testing a unit having an indoor fan. For fanless units, the air volume rate used when conducting tests at low capacity (i.e., the Minimum Air Volume Rate) is the higher of

(1) The rate specified by the manufacturer; or

(2) 75 percent of the air volume rate used for the high capacity tests.

DOE believes that a lower limit is needed given the finite capabilities of the typical multi-speed furnace blower that is used in field installations. The 75 percent minimum is based on very limited data collected by NIST. The subject has been discussed by industry members at such forums as ASHRAE meetings but no formal consensus has yet been reached for the specified percentage. Data and comments are requested, especially with regard to the specified value of the lower limit.

I. Triple-split Systems

The DOE test procedure refers to ASHRAE Standard 37 on the issue of equipment installation and test set up procedures. ASHRAE Standard 37, in turn, states that you must use the calorimeter air-enthalpy method arrangement when testing units where the compressor is in the indoor section and separately ventilated. For this arrangement, an enclosure must be built around the equipment under test within the indoor chamber. The present requirement is burdensome and DOE knows of no one who uses it when testing triple-splits. Furthermore, the heat loss from the indoor compressor section should be reflected in an adjusted output capacity and not by a raised entering air temperature. The amount of heat dissipated to the ambient by the indoor compressor section of such units is usually minimized as a result of the enclosure of the third section being insulated (mainly in an effort to reduce the operating noise). Based on limited information gained to date, the amount of heat lost from the indoor compressor section is on the order of 2 percent or less of the unit's space conditioning capacity.

The proposed test procedure instructs that triple-split systems are not to be tested using the calorimeter air-enthalpy method arrangement (see note in Section 2.6). At this juncture, no algorithm or method for assigning/determining the heat loss from the indoor compressor section is included. If triple-split systems become more popular and if information becomes available indicating the heat loss from the indoor compressor section exceeds 2 percent of the total, air-side capacity, then DOE will revisit the option of having a capacity adjustment.

J. Time-Adaptive Defrost Control Systems

When conducting a Frost Accumulation test on a heat pump having a time-adaptive defrost control system, repeatable frosting and defrosting intervals typically require (if obtainable at all) an excessive number of cycles. Until a better alternative is identified, defrosts initiated during the "preliminary" test and the "official" test will be manually induced. The manufacturer will be required to provide information as to how long the unit would optimally frost before initiating a defrost. The manufacturer will have to provide information on how to induce a defrost cycle at the appropriate elapsed time. The controls of the unit, however, will still control the duration of the defrost cycle, once initiated.

K. Test Unit Installation

For the most part, equipment installation requirements will continue to be performed according to the manufacturer's installation instructions. However, the proposed test procedure adopts the lab and field practice of insulating the low pressure line(s) of a split system. Also, Section 2.2.5 restricts the use of special refrigerant charging criteria for lab testing.

L. Test Apparatus and Measurement/Sampling Frequency

1. Inlet Plenum for Blower Coils

In the current DOE test procedure, no inlet plenum is required when testing blower coil units. The proposed test procedure recommends that an inlet plenum be installed if space permits. (Lab ceiling height on vertical installation is a limitation.) The test procedure recommends using an inlet plenum that is constructed according to the design specified for fanless units. See Section 2.4.2.

2. Manifolded Static Pressure Taps

The triple-T configuration was found in 1976 to be the preferred method for manifolding static pressure taps ("The design of piezometer rings" by K. A. Blake, Journal of Fluid Mechanics, Vol. 78, part 2, pp. 415–428). The triple-T configuration and the more widely used complete ring, four-to-one manifolding configuration are presently part of the draft revision of ASHRAE Standard 37. This revised test procedure recommends use of either of these two manifolding methods, which are shown in Figure 1. The broken ring, four-to-one manifolding configuration may be used but is not recommended.

3. Temperature Measurement Intervals

The proposed test procedure specifies that dry-bulb temperature measurements are to be measured at the intervals specified in ASHRAE Standard 41.1–86 (RA91). Wet bulb temperature, dew point temperature, or relative humidity are to be measured at the minimum sampling interval specified in Definition 1.14.

4. Temperature Measurement Accuracies

The proposed test procedure defers entirely to ASHRAE Standard 41.1–86 (RA 91) for accuracy and precision requirements.

5. Grid of Individual Temperature Sensors Within the Indoor-Side Outlet Plenum

The proposed test procedure adopts the ARI Standard 210/240–94 Appendix B requirements that a temperature spread of 1.5 °F or less be obtained, and that the outlet temperature grid be composed of a minimum of 9 sensors (while recommending 16). Also, the proposed test procedure recommends redundant sensors to determine the change in dry bulb temperature across the indoor coil.

6. Duct Loss Correction

The proposed test procedure adds a correction for the heat transfer between the test room and an outlet duct sandwiched between the coil and the outlet temperature grid. This correction is already an industry practice.

7. Water vapor measurements using a dew-point hygrometer, a relative humidity meter, or any other alternative instrument

Today's test procedure explicitly permits alternatives to using wet bulb temperature sensors. To ease instrumentation selection, required instrument accuracies are provided for dew point hygrometers and relative humidity meters.

8. Voltmeter Accuracy

The required accuracy of voltage measurements has been changed from ±2% to ±1%.

9. Electrical Power Measurement

Adjustable-speed-driven motors, as used in a variable-speed compressor, distort the input current and, to a lesser degree, voltage waveforms. Published literature [1–7] supports avoiding the use of induction type meters for measuring such non-sinusoidal power and instead recommends using a meter that is capable of sampling up to the 50th harmonic. This point is included in Section 2.8 of today's test procedure as a recommendation when testing a heat pump or air conditioner having a variable-speed compressor. (In terms of a meter sampling frequency, a 50th harmonic requirement corresponds to a minimum sampling frequency between 3 and 30 kHz, depending upon which technical recommendation you wish to cite.)

The majority of the technical references listed below report the performance of specific meters with specific waveforms, some of which should be representative of those found in presently-marketed residential-size air conditioners and heat pumps. In addition to induction watthour meters, a disconcerting result reported in the noted references is that the use of a non-induction meter that can measure up to the 50th harmonic does not insure an accurate measurement but only improves your chances.

References:

1. P.S. Filipski and R. Arseneau, "Behavior of Wattmeters and Watthour Meters Under Distorted Waveform Conditions," IEEE tutorial course, Nonsinusoidal Situations: Effects on the Performance of Meters and Definitions of Power, IEEE, Piscataway, NJ, pp. 13–22, 1990.
2. A. Domijan, Jr., E. Embriz-Santander, A.J. Gilani, G. Lamer, C. Stiles, and C.W. Williams, Jr., "Watthour Meter Accuracy Under Controlled Unbalanced Harmonic Voltage and Current Conditions," IEEE Transactions Power Delivery, Vol. II, No. 1, pp. 64–78, Jan. 1996.
3. A. Domijan, D. Czarkowski, A. Abu-aisheh, and E. Embriz-Santander, "Measurements of Electrical Power Inputs to Variable Speed Motors and Their Solid State Power Converters—Phase II," ASHRAE Research Project 770, Final Report, November 30, 1995.
4. D. Czarkowski and A. Domijan, Jr., "Performance of Electrical Power Meters and Analyzers in Adjustable-Speed Drive Applications," American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Transactions 1997, Vol. 103, Part 1.
5. A.J. Baldwin, N.G. Planer, D.E. Nordell, N. Hohan, "Evaluation of Electrical Interference to the Induction Watthour Meter," EPRI EL–2315, Research Project 1738, Final Report, April 1982.
6. Institute of Electrical and Electronics Engineers (IEEE), Inc., "IEEE Standard 519–1992, IEEE Recommended Practices and Requirements for Harmonic Control in Electrical Power Systems," New York, New York.
7. A. Domijan, and E. Embriz-Santander, "Measurements of Electrical Power Inputs to Variable Speed Motors and Their Solid State Power Converters," American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Transactions 1993, Vol. 99, Part I, pp. 241–258.

M. Different Compressor Speeds and Indoor Fan Capacities Between Cooling and Heating

In the existing test procedure, variable-speed systems that operate at higher speeds when heating than when cooling are covered. In today's proposed revision (as noted above in III.D.4) this allowance has been extrapolated to coverage of two-capacity heat pumps that only operate at low capacity during the cooling season while using both low and high capacities when heating. And, in taking a generic approach, today's test procedure covers any case where the heat pump uses different fan speeds or air volume rates for cooling versus when heating. (See Section 3.1.4.4.2)

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N. Secondary Test Requirements.

When using the Outdoor Air Enthalpy test method, a preliminary test is conducted to compensate, if necessary, for any performance impact caused by the outdoor air-side test apparatus. In accordance with the existing test procedure, a preliminary test is conducted prior to all steady-state tests (i.e., those tests where a secondary measurement of capacity is required). In today's revision, relaxing this requirement is proposed. Section 3.11.1 indicates that the number of preliminary tests can be reduced in most cases to one (for air conditioners or heating-only heat pumps) or two (for heat pumps): one for the first cooling mode steady-state test and one for the first heating mode steady-state test.

O. HSPF Calculations

The last paragraph of Sections 5.2.1 and 5.2.2 of the existing test procedure are not similarly placed in the proposed test procedure. The paragraph in question reads "Once the maximum and minimum HSPF and operating cost values have been obtained for each region, the HSPF and operating cost shall be determined for each standardized design heating requirement (see section 6.2.6) between the maximum and minimum design heating requirements by means of interpolation." The issue of how many HSPF calculations are required has been, and will remain, an item that is covered elsewhere: In 10 CFR part 430, subpart B, § 430.23(m)(3)(ii). In the proposed test procedure, this section along with a short restatement of its contents are included in the Definition (1.27) for HSPF. Because of the relative ease of automating the calculation process, and the nonlinearity of the HSPF versus design heating requirement relationship, no reference is made to obtaining HSPF or operating cost via interpolation.

V. Procedural Requirements

A. Review Under the National Environmental Policy Act of 1969

In this notice, the Department proposes amendments to the test procedures for central air conditioners and heat pumps. We have reviewed the proposed rule under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 et seq., the regulations of the Council on Environmental Quality, 40 CFR parts 1500–1508, DOE regulations for compliance with NEPA, 10 CFR part 1021, and the Secretarial Policy on the National Environmental Policy Act (June 1994). The Department has determined that this rulemaking is covered under the Categorical Exclusion found at paragraph A.6 of appendix A to subpart D, 10 CFR part 1021, which applies to rulemakings that are strictly procedural. This proposed rule is a procedural rulemaking and its implementation will not affect the quality or distribution of energy usage and therefore will not result in any environmental impacts. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

B. Regulatory Review

Today's regulatory proposal has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs in the Office of Management and Budget.

C. Regulatory Flexibility Review

The proposed rule has been reviewed under the Regulatory Flexibility Act, (42 U.S.C. 601–612), which requires preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small businesses and other small entities. The proposed rule affects manufacturers of central air conditioners and heat pumps. The test procedures would not have a significant economic impact, but rather, would provide common testing methods. This revision of the test procedure will not require a significant investment for new testing equipment. DOE accordingly certifies that the proposed rule would not, if promulgated, have a significant economic impact on a substantial number of small entities and that preparation of a regulatory flexibility analysis is not required.

D. "Takings" Assessment Review

DOE has determined pursuant to Executive Order 12630 (52 FR 8859, March 18, 1988) that this proposed regulation, if adopted, would not result in any takings which might require compensation under the Fifth Amendment to the United States Constitution.

E. Federalism Review

Executive Order 13132 (64 FR 43255, August 10, 1999) requires agencies to develop an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have "federalism implications." Policies that have federalism implications are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined today's rule and determined that it does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by the Executive Order.

F. Paperwork Reduction Act Review

This proposed rule contains no new collections of information under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

G. Review Under Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act") requires that the Department prepare an impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. The impact statement must include: (i) Identification of the Federal law under which the rule is promulgated; (ii) a qualitative and quantitative assessment of anticipated costs and benefits of the Federal mandate and an analysis of the extent to which such costs to state, local, and tribal governments may be paid with Federal financial assistance; (iii) if feasible, estimates of the future compliance costs and of any disproportionate budgetary effects the mandate has on particular regions, communities, non-Federal units of government, or sectors of the economy; (iv) if feasible, estimates of the effect on the national economy; and (v) a description of the Department's prior consultation with elected representatives of state, local, and tribal governments and a summary and evaluation of the comments and concerns presented.

The Department has determined that the action proposed today does not include a Federal mandate that may result in estimated costs of $100 million or more to state, local or to tribal governments in the aggregate or to the private sector. Therefore, the requirements of sections 203 and 204 of the Unfunded Mandates Act do not apply to this action.

H. Review Under Executive Order 12988, "Civil Justice Reform"

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by Section 3(a), section 3(b) of the Executive Order specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provide a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of the Executive Order requires Executive agencies to review regulations in light of applicable standards section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE reviewed today's proposed rulemaking under the standards of section 3 of the Executive Order and determined that, to the extent permitted by law, it meets the requirements of those standards.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Today's proposal would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, we have concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Plain Language Review

The President's Memorandum on "Plain Language in Government Writing," 63 FR 31885 (June 10, 1998) directs each federal agency to write all published rulemaking documents in plain language. The Memorandum includes general guidance on what constitutes "plain language." Plain language requirements will vary from one document to another, depending on the intended audience, but all plain language documents should be logically organized and clearly written.

We have tried to make this proposed rule easy to understand. We are also requesting suggestions on how to improve its readability further.

VI. Public Comment Procedures

A. Written Comment Procedures

The Department invites interested persons to participate in the proposed rulemaking by submitting data, comments, or information with respect to the proposed issues set forth in today's proposed rule to Ms. Brenda Edwards-Jones, at the address indicated at the beginning of this notice. We will consider all submittals received by the date specified at the beginning of this notice in developing the final rule.

According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit one complete copy of the document and ten (10) copies, if possible, from which the information believed to be confidential has been deleted. The Department of Energy will make its own determination with regard to the confidential status of the information and treat it according to its determination.

Factors of interest to the Department when evaluating requests to treat as confidential information that has been submitted include: (1) A description of the items; (2) an indication as to whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) an indication as to when such information might lose its confidential character due to the passage of time; and (7) why disclosure of the information would be contrary to the public interest.

B. Issues for Public Comment

The Department of Energy is interested in receiving comments and data concerning these test procedures. Also, the Department welcomes comments on improvements or alternatives to these approaches. In particular, DOE is interested in gathering comments on the following:

1. Non-defrost (limited-range) heat pumps

Which of the three options described in Section III.A.3 should be invoked?

2. Testing units having a constant-air-volume-rate indoor fan

Are the proposed changes described in Section III.D.1 acceptable? In particular, does the proposed 8 percent tolerance on indoor air volume rate provide a fair balance between assuring repeatable results while not being too restrictive given the variation in blower motor performance?

3. Cyclic testing of units having a variable-speed indoor fan (that may or may not provide a constant air volume rate)

For units that ramp the indoor fan speed when cycling on and/or off, data are sought of the type referenced in the last paragraph of Section IV.C (i.e., data that quantifies the effect on C_D from using a ramped air volume rate versus forcing the air volume rate to have a step profile). Also, as described in the second-to-last paragraph of Section IV.C, data from cyclic tests conducted with the indoor fan enabled and disabled are sought.

4. Two-capacity heat pumps that are designed to meet the seasonal cooling load while operating at low capacity

As discussed in the last paragraph of Section III.D.4, should the heat pump be required to have controls that lock out high capacity operation when cooling?

5. Lower limit on the air volume rate used when testing a fanless, two-capacity unit at low compressor capacity

As discussed in Section IV.H.3, data and comments are requested regarding the assigned limit for the air volume rate when testing a fanless, two-capacity unit at low compressor capacity.

Related to this issue is whether the manufacturer should be required to supply, with the unit, the hardware needed to allow the use of two fan speeds on the furnace blower that the unit would be used with in the field. Conceivably, if such hardware was not provided, the test procedure could call for using the same air volume rate for all

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tests, regardless of whether the compressor is operating at high or low capacity. On the other extreme, do any manufacturers provide hardware that allows a multi-speed furnace blower to operate as a variable-speed blower? Or, are there safeguards that will result in all or the vast majority of fanless, two-capacity units to be applied with furnaces having variable-speed blowers? If so, then the lower limit noted in the previous paragraph may not be applicable.

6. Fan defaults for fanless (i.e., coil-only) two-capacity units

In the existing test procedure, the fan heat/power default that is applied when rating fanless units is 1250 Btu/h per 1000 SCFM (365 watts per 1000 SCFM). When testing two-capacity fanless units, this adjustment is applied when evaluating space conditioning capacities and electrical power usages for both high and low compressor capacity operation. Do blower curves for multi-speed indoor fans support the use of the same default for both low and high capacity?

7. Differentiation among two-capacity air conditioners and heat pumps

Is there a need to differentiate between two-capacity units that can transition between high and low compressor capacities on-the-fly versus units that must shut off the compressor for some finite time interval when transitioning? Both the existing test procedure and today's proposed revision do not offer a means for providing such differentiation. To begin to do so would require information on how EER and COP are affected as they change from the value associated with steady operation at one compressor capacity until steady operation is obtained at the other compressor capacity following the transition. DOE seeks comments and data that would help to determine whether the test procedure needs to account for low/high compressor transitioning performance.

8. Testing single-packaged units

Today's proposed test procedure includes new test requirements when testing certain types of single-packaged units. The proposed additions are summarized in III.C.1. As presently proposed, the changes are limited to cooling mode tests where all or part of the indoor section is located in the outdoor test room and to heating mode tests where all or part of the outdoor section is located in the indoor test room. Comments are sought on the general proposal and on whether the approaches should be invoked when testing all packaged units.

9. Multi-capacity units

Are there any multi-capacity units that operate at less than maximum speed or high capacity at the lowest outdoor temperatures (prior to cycling off the compressor, if applicable)? Possibly such a strategy is needed to insure component reliability. Such a contingency is not covered in the existing or proposed test procedure.

10. Cyclic degradation coefficients

Comments are sought on the proposed actions discussed above in Section III.D.6 for working towards new C_D defaults.

11. NAECA energy conservation standards

Changes introduced in today's proposed test procedure are not expected to cause a minimally-compliant unit to now become non-compliant. If a particular proposed change is found to negatively affect minimally compliant units, then DOE would like to know.

12. Small-duct, high-velocity systems

Comments are sought on the proposed actions discussed in Section III.A.2.

C. Public Workshop

1. Procedures for Submitting Requests to Speak

You will find the time and place of the public workshop listed at the beginning of this notice of proposed rulemaking. The Department invites any person who has an interest in today's notice of proposed rulemaking, or who is a representative of a group or class of persons that has an interest in these proposed issues, to make a request for an opportunity to make an oral presentation. If you would like to attend the public workshop, please notify Ms. Brenda Edwards-Jones at (202) 586–2945. You may hand deliver requests to speak to the address indicated at the beginning of this notice between the hours of 8:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays, or send them by mail or e-mail to brenda.edwards-jones@ee.doe.gov.

The person making the request should state why he or she, either individually or as a representative of a group or class of persons, is an appropriate spokesperson, briefly describe the nature of the interest in the rulemaking, and provide a telephone number for contact.

The Department requests each person wishing to speak to submit an advance copy of his or her statement at least 10 days prior to the date of this workshop as indicated at the beginning of this notice. The Department, at its discretion, may permit any person wishing to speak who cannot meet this requirement to participate if that person has made alternative arrangements with the Office of Building Research and Standards in advance. The letter making a request to give an oral presentation must ask for such alternative arrangements.

2. Conduct of Workshop

The workshop (hearing) will be conducted in an informal, conference style. The Department may use a professional facilitator to facilitate discussion, and a court reporter will be present to record the transcript of the meeting. We will present summaries of comments received before the workshop, allow time for presentations by workshop participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Following the workshop, we will provide an additional comment period, during which interested parties will have an opportunity to comment on the proceedings at the workshop, as well as on any aspect of the rulemaking proceeding.

The Department will arrange for a transcript of the workshop and will make the entire record of this rulemaking, including the transcript, available for inspection in the Department's Freedom of Information Reading Room. Any person may purchase a copy of the transcript from the transcribing reporter.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Energy conservation, Household appliances, Incorporation by reference.

Issued in Washington, DC., on December 19, 2000.

Dan W. Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, part 430 of Chapter II of Title 10, Code of Federal Regulations is proposed to be amended as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

1. The authority citation for Part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

2. Section 430.22 is amended:

a. By adding paragraphs (b)(5)3. through (b)(5)10.;

b. by adding paragraph (b)(7).

The additions specified above read as follows:

§ 430.22 Reference Sources.

* * * * *

(b) * * *

(5) * * *

3. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 23–1993, "Methods of Testing for Rating Positive Displacement Refrigerant Compressors and Condensing Units."

4. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 37–1988, "Methods of Testing for Rating Unitary Air-Conditioning and Heat Pump Equipment."

5. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 41.1–1986 (Reaffirmed 1991), "Standard Method for Temperature Measurement."

6. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 41.2–1987 (Reaffirmed 1992), "Standard Method for Laboratory Airflow Measurement."

7. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 41.6–1994, "Method for Measurement of Moist Air Properties."

8. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 41.9–1988, "A Standard Calorimeter Test Method for Flow Measurement of a Volatile Refrigerant."

9. American Society of Heating, Refrigerating, and Air-Conditioning Engineers/Air Moving and Conditioning Association, Inc. Standard 51–1999, "Laboratory Methods of Testing Fans for Rating."

10. American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 116–1995, "Methods of Testing for Rating for Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps."

* * * * *

(7) Air-Conditioning and Refrigeration Institute (ARI), 4301 North Fairfax Drive, Suite 425, Arlington, Virginia 22203, (703) 524–8800, ARI Standard 210/240–1994, "Unitary Air-Conditioning and Air-Source Heat Pump Equipment."

* * * * *

3. Appendix M to Subpart B is revised to read as follows:

Appendix M to Subpart B—Uniform Test Method for Measuring the Energy Consumption of Central Air Conditioners and Heat Pumps

1. Definitions

2. Testing Conditions

2.1 Test room requirements
2.2 Test unit installation requirements.
2.2.1 Defrost control settings
2.2.2 Special requirements for units having a multiple-speed outdoor fan.
2.2.3 Special requirements for multi-split air conditioners and heat pumps, and systems composed of multiple mini-split units (outdoor units located side-by-side) that would normally operate using two or more indoor thermostats.
2.2.4 Wet-bulb temperature requirements for the air entering the indoor and outdoor coils.
2.2.4.1 Cooling mode tests.
2.2.4.2 Heating mode tests.
2.2.5 Additional refrigerant charging requirements
2.3 Indoor air volume rates.
2.3.1 Cooling tests.
2.3.2 Heating tests.
2.4 Indoor coil inlet and outlet duct connections.
2.4.1 Outlet plenum for the indoor coil.
2.4.2 Inlet plenum for the indoor unit
2.5 Indoor coil air property measurements and air damper box applications
2.5.1 Test set-up on the inlet side of the indoor coil: for cases where the inlet damper box is installed
2.5.1.1 If the Section 2.4.2 inlet plenum is installed.
2.5.1.2 If the Section 2.4.2 inlet plenum is not installed
2.5.2 Test set-up on the inlet side of the indoor unit: for cases where no inlet damper box is installed.
2.5.3 Indoor coil static pressure difference measurement
2.5.4 Test set-up on the outlet side of the indoor coil.
2.5.4.1 Outlet air damper box placement and requirements
2.5.4.2 Additional recommendations
2.5.5 Dry bulb temperature measurement
2.5.6 Water vapor content measurement
2.5.7 Air damper box performance requirements
2.6 Airflow measuring apparatus
2.7 Electrical voltage supply
2.8 Electrical power and energy measurements
2.9 Time measurements.
2.10 Test apparatus for the secondary space conditioning capacity measurement
2.10.1 Outdoor Air Enthalpy Method
2.10.2 Compressor Calibration Method
2.10.3 Refrigerant Enthalpy Method.
2.11 Measurement of test room ambient conditions
2.12 Measurement of indoor fan speed
2.13 Measurement of barometric pressure

3. Testing Procedures

3.1 General Requirements
3.1.1 Primary and secondary test methods.
3.1.2 Manufacturer-provided equipment overrides.
3.1.3 Airflow through the outdoor coil.
3.1.4 Airflow through the indoor coil.
3.1.4.1 Cooling Certified Air Volume Rate.
3.1.4.1.1 Cooling Certified Air Volume Rate for Ducted Units.
3.1.4.1.2 Cooling Certified Air Volume Rate for Non-ducted Units.
3.1.4.2 Cooling Minimum Air Volume Rate.
3.1.4.3 Cooling Intermediate Air Volume Rate.
3.1.4.4 Heating Certified Air Volume Rate
3.1.4.4.1 Ducted heat pumps where the Heating and Cooling Certified Air Volume Rates are the same.
3.1.4.4.2 Ducted heat pumps where the Heating and Cooling Certified Air Volume Rates are different due to indoor fan operation.
3.1.4.4.3 Ducted heating-only heat pumps.
3.1.4.4.4 Non-ducted heat pumps, including non-ducted heating-only heat pumps.
3.1.4.5 Heating Minimum Air Volume Rate.
3.1.4.6 Heating Intermediate Air Volume Rate.
3.1.4.7 Heating Nominal Air Volume Rate.
3.1.5 Indoor test room requirement when the air surrounding the indoor unit is not supplied from the same source as the air entering the indoor unit.
3.1.6 Air volume rate calculations.
3.1.7 Test sequence.
3.1.8 Requirement for the air temperature distribution leaving the indoor coil.
3.1.9 Control of auxiliary resistive heating elements.
3.2 Cooling mode tests for different types of air conditioners and heat pumps.
3.2.1 Tests for a unit having a single-speed compressor that is tested with a fixed-speed indoor fan installed, with a constant-air-volume-rate indoor fan installed, or with no indoor fan installed.
3.2.2 Tests for a unit having a single-speed compressor and a variable-speed variable-air-volume-rate indoor fan installed.
3.2.2.1 Indoor fan capacity modulation that correlates with the outdoor dry bulb temperature.
3.2.2.2 Indoor fan capacity modulation based on adjusting the sensible to total (S/T) cooling capacity ratio.
3.2.3 Tests for a unit having a two-capacity compressor.
3.2.4 Tests for a unit having a variable-speed compressor.
3.3 Test procedures for steady-state wet coil cooling mode tests
3.4 Test procedures for the optional steady-state dry coil cooling mode tests
3.5 Test procedures for the optional cyclic dry coil cooling mode tests (the D, D_1, and I_1 Tests)
3.5.1 Procedures when testing ducted systems.
3.5.2 Procedures when testing non-ducted systems
3.5.3 Cooling mode cyclic degradation coefficient calculation.
3.6 Heating mode tests for different types of heat pumps, including heating-only heat pumps.
3.6.1 Tests for a heat pump having a single-speed compressor that is tested with a fixed speed indoor fan installed, with a constant-air-volume-rate indoor fan installed, or with no indoor fan installed.
3.6.1.1 Non-defrost heat pump.
3.6.1.2 Heat pump having a heat comfort controller.

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3.6.2 Tests for a heat pump having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor fan: capacity modulation correlates with outdoor dry bulb temperature.
3.6.3 Tests for a heat pump having a two-capacity compressor
3.6.4 Tests for a heat pump having a variable-speed compressor.
3.7 Test procedures for steady-state Maximum Temperature and High Temperature heating mode tests (the H0, $H0_1$, H1, $H1_2$, $H1_1$, and $H1_N$ Tests).
3.8 Test procedures for the optional cyclic heating mode tests (the $H0C_1$, H1C, and $H1C_1$ Tests).
3.8.1 Heating mode cyclic degradation coefficient calculation.
3.9 Test procedures for Frost Accumulation heating mode tests
3.9.1 Average space heating capacity and electrical power calculations
3.9.2 Demand defrost credit
3.10 Test procedures for steady-state Low Temperature heating mode tests
3.11 Additional requirements for the secondary test methods
3.11.1 If using the Outdoor Air Enthalpy Method as the secondary test method
3.11.1.1 If a preliminary test precedes the official test
3.11.1.2 If a preliminary test does not precede the official test
3.11.1.3 Official test
3.11.2 If using the Compressor Calibration Method as the secondary test method
3.11.3 If using the Refrigerant Enthalpy Method as the secondary test method
3.12 Rounding of space conditioning capacities for reporting purposes.

4. Calculations of Seasonal Performance Descriptors

4.1 Seasonal Energy Efficiency Ratio (SEER) Calculations
4.1.1 SEER calculations for an air conditioner or heat pump having a single-speed compressor that was tested with a fixed-speed indoor fan installed, a constant-air-volume-rate indoor fan installed, or with no indoor fan installed
4.1.2 SEER calculations for an air conditioner or heat pump having a single-speed compressor and a variable-speed variable-air-volume-rate indoor fan
4.1.2.1 Units covered by Section 2.1.2.2.1 where indoor fan capacity modulation correlates with the outdoor dry bulb temperature
4.1.2.2 Units covered by Section 2.1.2.2.2 where indoor fan capacity modulation is used to adjust the sensible to total cooling capacity ratio
4.1.3 SEER calculations for an air conditioner or heat pump having a two-capacity compressor.
4.1.3.1 Steady-state space cooling capacity at low compressor capacity is greater than or equal to the building cooling load at temperature T_j
4.1.3.2 Unit alternates between high (k=2) and low (k=1) compressor capacity to satisfy the building cooling load at temperature T_j
4.1.3.3 Unit only operates at high (k=2) compressor capacity at temperature T_j and its capacity is greater than the building cooling load
4.1.3.4 Unit must operate continuously at high (k=2) compressor capacity at temperature T_j
4.1.4 SEER calculations for an air conditioner or heat pump having a variable-speed compressor
4.1.4.1 Steady-state space cooling capacity when operating at minimum compressor speed is greater than or equal to the building cooling load at temperature T_j
4.1.4.2 Unit operates at an intermediate compressor speed (k=i) in order to match the building cooling load at temperature T_j
4.1.4.3 Unit must operate continuously at maximum (k=2) compressor speed at temperature T_j
4.2 Heating Seasonal Performance Factor (HSPF) Calculations
4.2.1 Additional steps for calculating the HSPF of a heat pump having a single-speed compressor that was tested with a fixed-speed indoor fan installed, a constant-air-volume-rate indoor fan installed, or with no indoor fan installed
4.2.1.1 Space heating capacity and the electrical power consumption calculations for a non-defrost heat pump
4.2.1.2 Space heating capacity and the electrical power consumption calculations for a heat pump having a heat comfort controller
4.2.2 Additional steps for calculating the HSPF of a heat pump having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor fan.
4.2.3 Additional steps for calculating the HSPF of a heat pump having a two-capacity compressor.
4.2.3.1 Steady-state space heating capacity when operating at low compressor capacity is greater than or equal to the building heating load at temperature T_j
4.2.3.2 Heat pump alternates between high (k=2) and low (k=1) compressor capacity to satisfy the building heating load at a temperature T_j
4.2.3.3 Heat pump only operates at high (k=2) compressor capacity at temperature T_j and its capacity is greater than the building heating load
4.2.3.4 Heat pump must operate continuously at high (k=2) compressor capacity at temperature T_j
4.2.4 Additional steps for calculating the HSPF of a heat pump having a variable-speed compressor.
4.2.4.1 Steady-state space heating capacity when operating at minimum compressor speed is greater than or equal to the building heating load at temperature T_j
4.2.4.2 Heat pump operates at an intermediate compressor speed (k=i) in order to match the building heating load at a temperature T_j
4.2.4.3 Heat pump must operate continuously at maximum (k=2) compressor speed at temperature T_j
4.3 Calculations
4.3.1 Calculation of actual regional annual performance factors (APF_A) for a particular location and for each standardized design heating requirement
4.3.2 Calculation of representative regional annual performance factors (APF_R) for each generalized climatic region and for each standardized design heating requirement
4.4 Rounding of SEER , HSPF, and APF for reporting purposes

1. Definitions

1.1 *Annual performance factor* means the total heating and cooling done by a heat pump in a particular region in one year divided by the total electric energy used in one year. Section 430.23(m)(3)(iii) of the Code of Federal Regulations states the calculation requirements for this rating descriptor.

1.2 *ARI* means Air-Conditioning and Refrigeration Institute.

1.3 *ARI Standard 210/240–94* means the test standard "Unitary Air-Conditioning and Air-Source Heat Pump Equipment" published in 1994 by ARI.

1.4 *ASHRAE* means the American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc.

1.5 *ASHRAE Standard 23–93* means the test standard "Methods of Testing for Rating Positive Displacement Refrigerant Compressors and Condensing Units" published in 1993 by ASHRAE.

1.6 *ASHRAE Standard 37–88* means the test standard "Methods of Testing for Rating Unitary Air-Conditioning and Heat Pump Equipment" published in 1988 by ASHRAE.

1.7 *ASHRAE Standard 41.1–86 (RA 91)* means the test standard "Standard Method for Temperature Measurement" published in 1986 and reaffirmed in 1991 by ASHRAE.

1.8 *ASHRAE Standard 41.2–87 (RA 92)* means the test standard "Standard Method for Laboratory Airflow Measurement" published in 1987 and reaffirmed in 1992 by ASHRAE.

1.9 *ASHRAE Standard 41.9–88* means the test standard "A Standard Calorimeter Test Method for Flow Measurement of a Volatile Refrigerant" published in 1988 by ASHRAE.

1.10 *ASHRAE Standard 51–99* means the test standard "Laboratory Methods of Testing Fans for Rating" published in 1999 by ASHRAE and the Air Movement and Control Association, Inc.

1.11 *ASHRAE Standard 116–95* means the test standard "Methods of Testing for Rating for Seasonal Efficiency of Unitary Air Conditioners and Heat Pumps" published in 1995 by ASHRAE.

1.12 *CFR* means Code of Federal Regulations.

1.13 *Constant-air-volume-rate indoor fan* means a fan that varies its operating speed to provide a fixed air volume rate from a ducted system.

1.14 *Continuously recorded*, when referring to a dry bulb measurement, means that the specified temperature must be sampled at regular intervals that are equal to or less than the maximum intervals specified in Section 4.3 part "a" of ASHRAE Standard 41.1–86 (RA 91). If such dry bulb temperatures are used only for test room control, sample at regular intervals that are equal to or less than the maximum intervals specified in Section 4.3 part "b" of the same ASHRAE Standard. Regarding wet bulb temperature, dew point temperature, or relative humidity measurements, continuously recorded means that the measurements must be made at regular intervals that are equal to or less than 1 minute.

1.15 *Cooling load factor (CLF)* means the ratio having as its numerator the total cooling delivered during a cyclic operating interval consisting of one ON period and one OFF period. The denominator is the total cooling that would be delivered, given the same ambient conditions, had the unit operated continuously at its steady-state space cooling capacity for the same total time (ON + OFF) interval.

1.16 *Coefficient of Performance (COP)* means the ratio of the average rate of space heating delivered to the average rate of electrical energy consumed by the heat pump. These rate quantities must be determined from a single test or, if derived via interpolation, must be tied to a single set of operating conditions. COP is a dimensionless quantity. When determined for a ducted unit tested without an indoor fan installed, COP must include the Section 3.7, 3.8, and 3.9.1 default values for the heat output and power input of a fan motor.

1.17 *Cyclic Test* means a test where the unit's compressor is cycled on and off for specific time intervals. A cyclic test provides half the information needed to calculate a degradation coefficient.

1.18 *Damper box* means a short section of duct having an air damper that meets the performance requirements of Section 2.5.7.

1.19 *Degradation coefficient (C_D)* means a parameter used in calculating the part load factor. The degradation coefficient for cooling is denoted by C^c_D. The degradation coefficient for heating is denoted by C^h_D.

1.20 *Demand-defrost control system* means a system that defrosts the heat pump outdoor coil only when measuring a predetermined degradation of performance. The heat pump's controls monitor one or more parameters that always vary with the amount of frost accumulated on the outdoor coil (e.g., coil to air differential temperature, coil differential air pressure, outdoor fan power or current, optical sensors, etc.) at least once for every ten minutes of compressor ON-time when space heating. One acceptable alternative to the criterion given in the prior sentence is a feedback system that measures the length of the defrost period and adjusts defrost frequency accordingly.[1] In all cases, when the frost parameter(s) reaches a predetermined value, the system initiates a defrost. In a demand-defrost control system, defrosts are terminated based on monitoring a parameter(s) that indicates that frost has been eliminated from the coil.

A demand defrost control system, which otherwise meets the above requirements, may allow time-initiated defrosts if, and only if, such defrosts occur after 6 hours of compressor operating time.

1.21 *Design heating requirement (DHR)* predicts the space heating load of a residence when subjected to outdoor design conditions. Estimates for the minimum and maximum DHR are provided for six generalized U.S. climatic regions in Section 4.2.

1.22 *Dry-coil tests* are cooling mode tests where the wet-bulb temperature of the air supplied to the indoor coil is maintained low enough that no condensate forms on this coil.

1.23 *Ducted system* means an air conditioner or heat pump that is designed to be permanently-installed equipment and delivers conditioned air to the indoor space through a duct(s). The air conditioner or heat pump may be either a split system or a single-packaged unit.

1.24 *Energy efficiency ratio (EER)* means the ratio of the average rate of space cooling delivered to the average rate of electrical energy consumed by the air conditioner or heat pump. These rate quantities must be determined from a single test or, if derived via interpolation, must be tied to a single set of operating conditions. EER is expressed in units of

$$\frac{\text{Btu / h}}{\text{W}}.$$

When determined for a ducted unit tested without an indoor fan installed, EER must include the Section 3.3 and 3.5.1 default values for the heat output and power input of a fan motor.

1.25 *Heating load factor (HLF)* means the ratio having as it numerator the total heating delivered during a cyclic operating interval consisting of one ON period and one OFF period. The denominator is the total heating that would be delivered, given the same ambient conditions, if the unit operated continuously at its steady-state space heating capacity for the same total time (ON + OFF) interval.

1.26 *Heat pump having a heat comfort controller* means equipment that regulates the operation of the electric resistance elements to assure that the air temperature leaving the indoor section does not fall below a specified temperature. This specified temperature is usually field adjustable. A method for testing and rating heat pumps having a heat comfort controller is presently limited to heat pumps that meet the equipment criteria of Section 3.6.1.

1.27 *Heating seasonal performance factor (HSPF)* means the total space heating required during the space heating season, expressed in Btu's, divided by the total electrical energy consumed by the heat pump system during the same season, expressed in watt-hours. For all heat pumps, HSPF accounts for the heating delivered and the energy consumed by auxiliary resistive elements when operating below the balance point. This condition occurs when the building load exceeds the space heating capacity of the heat pump condenser. For heat pumps with heat comfort controllers (see Definition 1.26), in addition, HSPF also accounts for resistive heating contributed when operating above the balance point as a result of maintaining a minimum supply temperature. Unless an approved alternative rating method is used, as set forth in 10 CFR part 430, subpart B, § 430.24(m), HSPF must be calculated according to this appendix. Repeat the calculations for each of the six generalized U.S. climatic regions listed in this appendix. For each region, evaluate an HSPF for each standardized design heating requirement that applies. (See 10 CFR part 430 subpart B, § 430.23(m)(3)(ii).) The HSPF used to evaluate compliance with the Energy Conservation Standards (see 10 CFR part 430, subpart C, § 430.32(c)) is based on Region IV, the minimum standardized design heating requirement, and the sampling plan stated in 10 CFR part 430, subpart B, § 430.24(m).

1.28 *Mini-split air conditioners and heat pumps* means non-ducted systems that have a single outdoor section and one or more indoor sections. The indoor sections cycle on and off in unison in response to a single indoor thermostat.

1.29 *Multiple-split air conditioners and heat pumps* means non-ducted systems that have two or more indoor sections. The indoor sections operate independently and can be used to space condition multiple zones in response to multiple indoor thermostats.

1.30 *Non-defrost heat pumps* means equipment that is incapable of defrosting the outdoor coil. The equipment ceases to operate the refrigeration system at outdoor temperatures that are conducive to frost accumulation. A method for testing and rating non-defrost heat pumps is presently limited to heat pumps that meet the equipment criteria of Section 3.6.1.

1.31 *Non-ducted system* means an air conditioner or heat pump that is designed to be permanently-installed equipment and directly heats or cools air within the conditioned space using one or more indoor coils that are mounted on room walls and/or ceilings. The unit may be of a modular design that allows for combining multiple outdoor coils and compressors to create one overall system. Non-ducted systems covered by this test procedure are all split systems.

1.32 *Part-load factor (PLF)* means the ratio of the cyclic energy efficiency ratio (coefficient of performance) to the steady-state energy efficiency ratio (coefficient of performance). Evaluate both energy efficiency ratios (coefficients of performance) based on operation at the same ambient conditions.

1.33 *Seasonal energy efficiency ratio (SEER)* means the total heat removed from the conditioned space during the annual space cooling season, expressed in Btu's, divided by the total electrical energy consumed by the air conditioner or heat pump during the same season, expressed in watt-hours. Unless using an approved alternative rating method, as set forth in 10 CFR part 430, subpart B, § 430.24(m), SEER must be calculated according to Section 4.1 of this appendix. [See 10 CFR part 430, subpart B, 430.23(m)(3)(i).] This Section 4.1 SEER and the sampling plan stated in 10 CFR subpart B, 430.24(m) are used to evaluate compliance with the Energy Conservation Standards. (See 10 CFR part 430, subpart C, § 430.32(c).)

1.34 *Single-packaged unit* means any central air conditioner or heat pump that has all major assemblies enclosed in one cabinet.

[1] Systems that vary defrost intervals according to outdoor dry-bulb temperature are not demand defrost systems.

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1.35 *Split system* means any air conditioner or heat pump that has one or more of the major assemblies separated from the others.

1.36 *Standard Air* means dry air at 70 °F and 14.696 psia. Under these conditions, dry air has a mass density of 0.075 lb/ft.^{3}

1.37 *Steady-state test* means a test where the test conditions are regulated to remain as constant as possible while the unit operates continuously in the same mode.

1.38 *Temperature bin* means the 5 °F increments that are used to partition the outdoor dry-bulb temperature ranges of the cooling (≥ 65 °F) and heating (< 65 °F) seasons.

1.39 *Test condition tolerance* means the maximum permissible difference between the average value of the measured test parameter and the specified test condition.

1.40 *Test operating tolerance* means the maximum permissible range that a measurement may vary over the specified test interval. The difference between the maximum and minimum sampled values must be less than or equal to the specified test operating tolerance.

1.41 *Time adaptive defrost control system* is a demand-defrost control system (see Definition 1.20) that measures the length of the prior defrost period(s) and uses that information to automatically determine when to initiate the next defrost cycle.

1.42 *Time-temperature defrost control systems* initiate or evaluate initiating a defrost cycle only when a predetermined cumulative compressor ON-time is obtained. This predetermined ON-time is generally a fixed value (*e.g.*, 30, 45, 90 minutes) although it may vary based on the measured outdoor dry-bulb temperature. The ON-time counter accumulates if controller measurements (*e.g.*, outdoor temperature, evaporator temperature) indicate that frost formation conditions are present, and it is reset/remains at zero at all other times. In one application of the control scheme, a defrost is initiated whenever the counter time equals the predetermined ON-time. The counter is reset when the defrost cycle is completed. In a second application of the control scheme, one or more parameters are measured (*e.g.*, air and/or refrigerant temperatures) at the predetermined, cumulative, compressor ON-time. A defrost is initiated only if the measured parameter(s) falls within a predetermined range. The ON-time counter is reset regardless of whether a defrost is initiated. If systems of this second type use cumulative ON-time intervals of 10 minutes or less, then the heat pump may qualify as having a demand defrost control system (see Definition 1.20).

1.43 *Triple-split system* means an air conditioner or heat pump that is composed of three separate components: An outdoor fan coil section, an indoor fan coil section, and an indoor compressor section.

1.44 *Two-capacity (or two-stage) compressor* means an air conditioner or heat pump that has one of the following:

(1) A two-speed compressor,

(2) Two compressors where only one compressor over operates at a time,

(3) Two compressors where one compressor (Compressor #1) operates at low loads and both compressors (Compressors #1 and #2) operate at high loads but Compressor #2 never operates alone, and

(4) A compressor that is capable of cylinder or scroll unloading.

For such systems, *low capacity* means:

(1) Operating at low compressor speed,

(2) Operating the lower capacity compressor,

(3) Operating Compressor #1, and

(4) Operating with the compressor unloaded (*e.g.*, operating one piston of a two-piston reciprocating compressor, using a fixed fractional volume of the full scroll, etc.).

High capacity means:

(1) Operating at high compressor speed,

(2) Operating the higher capacity compressor,

(3) Operating Compressors #1 and #2, and

(4) Operating with the compressor loaded (*e.g.*, operating both pistons of a two-piston reciprocating compressor, using the full volume of the scroll).

1.45 *Wet-coil test* means a test conducted at test conditions that typically cause water vapor to condense on the test unit evaporator coil.

1.46 *Small-duct system* means equipment that contains a blower and indoor coil combination that produces at least 1.5 inches of external static across the indoor unit when operated at the certified air volume rate. When applied in the field, small-duct systems use branch ducts having less than 6.0 square inches of free area.

1.47 *ASHRAE Standard 41.6–94* means the test standard "Method for Measurement of Moist Air Properties" published in 1994 by ASHRAE.

2. Testing Conditions

a. This test procedure covers split-type and single-packaged ducted units and split-type non-ducted units. Except for units having a variable-speed compressor, ducted units tested without an indoor fan installed are covered.

b. Only a subset of the sections listed in this test procedure apply when testing and rating a particular unit. Tables 1–A through 1–C show which sections of the test procedure apply to each type of equipment. In each table, look at all four of the Roman—numeral categories to see what test sections apply to your equipment.

1. The first category, Rows I–1 through I–4 of the Tables, pertains to the compressor and indoor fan features of the equipment. After identifying the correct "I" row, find the table cells in the same row that list the type of equipment being tested: Air conditioner (AC), heat pump (HP), or heating-only heat pump (HH). Use the test section(s) listed above each noted table cell for testing and rating the unit.

2. The second category, Rows II–1 and II–2, pertains to the presence or absence of ducts. Row II–1 shows the test procedure sections that apply to ducted systems, and Row II–2 shows those that apply to non-ducted systems.

3. The third category is for special features that may be present in the equipment. When testing units that have one or more of the four (special) equipment features described by the Table footnote for Category III, use Row III to find test sections that apply.

4. The fourth category is for the secondary test method to be used. If you know the secondary method for determining the unit's cooling and/or heating capacity, use Row IV to find the appropriate test sections. Otherwise, include all of the test sections referenced by Row IV cell entries—*i.e.*, sections 2.10 to 2.10.3 and 3.11 to 3.11.3—among those sections consulted for testing and rating information.

c. Obtain a complete listing of all pertinent test sections by recording those sections identified from the four categories above.

d. The user should note that, for many sections, only part of a section applies to the unit being tested. In a few cases, the entire section may not apply. For example, Sections 3.4 to 3.5.3 (which describe optional dry coil tests), are not relevant if the allowed default value for the cooling mode cyclic degradation coefficient is used rather than determining it from testing.

Example for Using Tables 1–A to 1–C.

Equipment Description:

A ducted air conditioner having a single-speed compressor, a fixed-speed indoor fan, and a multi-speed outdoor fan.

Secondary Test Method: Refrigerant Enthalpy Method

Step 1. Determine which of four listed Row "I" options applies ==> Row I–2

Table 1–A: "AC" in Row I–2 is found in the columns for sections 1.1 to 1.47, 2.1 to 2.2, 2.2.4 to 2.2.4.1, 2.2.5, 2.3 to 2.3.1, 2.4 to 2.4.1, 2.5, 2.5.2 to 2.10, and 2.11 to 2.13.

Table 1–B: "AC" is listed in Row I–2 for sections 3 to 3.1.4, 3.1.5 to 3.1.8, 3.2.1, 3.3 to 3.5, 3.5.3, 3.11 and 3.12.

Table 1–C: "AC" is listed in Row I–2 for sections 4.1.1 and 4.4.

Step 2. Equipment is ducted ==> Row II–1

Table 1–A: "AC" is listed in Row II–1 for sections 2.4.2 and 2.5.1 to 2.5.1.2.

Table 1–B: "AC" is listed in Row II–1 for sections 3.1.4.1 to 3.1.4.1.1 and 3.5.1.

Table 1–C: no "AC" listings in Row II–1.

Step 3. Equipment Special Features include multi-speed outdoor fan ==> Row III, M

Table 1–A: "M" is listed in Row III for section 2.2.2

Tables 1–B and 1–C: no "M" listings in Row III.

Step 4. Secondary Test Method is Refrigerant Enthalpy Method ==> Row IV, R

Table 1–A: "R" is listed in Row IV for section 2.10.3

Table 1–B: "R" is listed in Row IV for section 3.11.3

Table 1–C: no "R" listings in Row IV.

Step 5. Cumulative listing of applicable test procedure sections

1.1 to 1.47, 2.1 to 2.2, 2.2.2, 2.2.4 to 2.4.1, 2.2.5, 2.3 to 2.3.1, 2.4 to 2.4.1, 2.4.2, 2.5, 2.5.1 to 2.5.1.2, 2.5.2 to 2.10, 2.10.3, 2.11 to 2.13, 3. to 3.1.4, 3.1.4.1 to 3.1.4.1.1, 3.1.5 to 3.1.8, 3.2.1, 3.3 to 3.5, 3.5.1, 3.5.3, 3.11, 3.11.3, 3.12, 4.1.1, and 4.4.

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Table 1A. Selection of Test Procedure Sections: Section 2 (Testing Conditions)

Key Equipment Features and Secondary Test Method \ Sections From the Test Procedure	1.1 to 1.47	2.1 to 2.2	2.2.1	2.2.2	2.2.3	2.2.4 to 2.2.4.1	2.2.4.2	2.2.5	2.3 to 2.3.1	2.3.2	2.4 to 2.4.1	2.4.2	2.5	2.5.1 to 2.5.1.2	2.5.2 to 2.10	2.10.1	2.10.2	2.10.3	2.11 to 2.13
I-1. Single-speed Compressor; Variable-Speed Variable Air Volume Indoor Fan	AC HP HH	AC HP HH	HP HH			AC HP	HP HH	AC HP HH	AC HP	HP HH	AC HP HH		AC HP HH		AC HP HH				AC HP HH
I-2. Single-speed Compressor Except as Covered by "I-1"	AC HP HH	AC HP HH	HP HH			AC HP	HP HH	AC HP HH	AC HP	HP HH	AC HP HH		AC HP HH		AC HP HH				AC HP HH
I-3. Two-capacity Compressor	AC HP HH	AC HP HH	HP HH			AC HP	HP HH	AC HP HH	AC HP	HP HH	AC HP HH		AC HP HH		AC HP HH				AC HP HH
I-4. Variable-speed Compressor	AC HP HH	AC HP HH	HP HH			AC HP	HP HH	AC HP HH	AC HP	HP HH	AC HP HH		AC HP HH		AC HP HH				AC HP HH
II-1. Ducted												AC HP HH		AC HP HH					
II-2. Non-Ducted																			
III. Special Features				M	G														
IV. Secondary Test Method																O	C	R	

Legend for Table Entries:
Categories I and II: AC= applies for an Air Conditioner that meets the corresponding Column 1 "Key Equipment . . ." criterion
HP = applies for a Heat Pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
HH = applies for a Heating-only Heat pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
Category III: G = ganged mini-splits or multi-splits;
H = heat pump with a heat comfort controller;
M = units with a multi-speed outdoor fan;
N = non-defrost heat pump
Category IV: O = Outdoor Air Enthalpy Method; C = Compressor Calibration Method; R = Refrigerant Enthalpy Method

Table 1B. Selection of Test Procedure Sections: Section 3 (Testing Procedures)

Key Equipment Features and Secondary Test Method \ Sections From the Test Procedure	3. to 3.1.4	3.1.4.1 to 3.1.4.1.1	3.1.4.1.2	3.1.4.2	3.1.4.3	3.1.4.4 to 3.1.4.4.2	3.1.4.4.3	3.1.4.4.4	3.1.4.5	3.1.4.6 to 3.1.4.7	3.1.5 to 3.1.8	3.1.9	3.2.1	3.2.2 to 3.2.2.2	3.2.3	3.2.4	3.3 to 3.5	3.5.1	3.5.2	3.5.3	3.6.1	3.6.1.1
I-1. Single-speed Compressor; Variable-speed, Variable Air Volume Indoor Fan	AC HP HH			AC HP					HP HH		AC HP HH	HP HH		AC HP			AC HP			AC HP		
I-2. Single-speed Compressor Except as Covered by "I-1"	AC HP HH										AC HP HH	HP HH	AC HP				AC HP			AC HP	HP HH	
I-3. Two-capacity Compressor	AC HP HH			AC HP					HP HH		AC HP HH	HP HH			AC HP		AC HP			AC HP		
I-4. Variable-speed Compressor	AC HP HH			AC HP	AC HP				HP HH	HP HH	AC HP HH	HP HH				AC HP	AC HP			AC HP		
II-1. Ducted		AC HP				HP	HH											AC HP				
II-2. Non-Ducted			AC HP					HP HH											AC HP			
III. Special Features																						N
IV. Secondary Test Method																						

Legend for Table Entries:
Categories I and II: AC = applies for an Air Conditioner that meets the corresponding Column 1 "Key Equipment . . ." criterion
HP = applies for a Heat Pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
HH = applies for a Heating-only Heat pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
Category III: G = ganged mini-splits or multi-splits;
H = heat pump with a heat comfort controller;
M = units with a multi-speed outdoor fan;
N = non-defrost heat pump
Category IV: O = Outdoor Air Enthalpy Method; C = Compressor Calibration Method; R = Refrigerant Enthalpy Method

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Table 1B. Selection of Test Procedure Sections: Section 3 (Testing Procedures) (continued)																
Key Equipment Features and Secondary Test Method / Sections From the Test Procedure	3.6.1.2	3.6.2	3.6.3	3.6.4	3.7 to 3.8.1	3.9 to 3.10	3.11	3.11.1 to 3.11.1.3	3.11.2	3.11.3	3.12					
I-1. Single-speed Compressor; Variable-speed, Variable Air Volume Indoor Fan		HP HH			HP HH	HP† HH†	AC HP HH				AC HP HH					
I-2. Single-speed Compressor Except as Covered by "I-1"					HP HH	HP† HH†	AC HP HH				AC HP HH					
I-3. Two-capacity Compressor			HP HH		HP HH	HP† HH†	AC HP HH				AC HP HH					
I-4. Variable-speed Compressor				HP HH	HP HH	HP† HH†	AC HP HH				AC HP HH					
II-1. Ducted																
II-2. Non-Ducted																
III. Special Features	H															
IV. Secondary Test Method										O	C	R				

Legend for Table Entries:
Categories I and II: AC = applies for an Air Conditioner that meets the corresponding Column 1 "Key Equipment . . ." criterion
HP = applies for a Heat Pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
HH = applies for a Heating-only Heat pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
Category III: G = ganged mini-splits or multi-splits;
H = heat pump with a heat comfort controller;
M = units with a multi-speed outdoor fan;
N = non-defrost heat pump
Category IV: O = Outdoor Air Enthalpy Method; C = Compressor Calibration Method; R = Refrigerant Enthalpy Method
† Does not apply to non-defrost heat pumps

Table 1C. Selection of Test Procedure Sections: Section 4 (Calculations of Seasonal Performance Descriptors)																
Key Equipment Features and Secondary Test Method / Sections From the Test Procedure	4 to 4.1	4.1.1	4.1.2 to 4.1.2.2	4.1.3 to 4.1.3.4	4.1.4 to 4.1.4.3	4.2	4.2.1	4.2.1.1	4.2.1.2	4.2.2	4.2.3 to 4.2.3.4	4.2.4 to 4.2.4.3	4.3 to 4.3.2	4.4		
I-1. Single-speed Compressor; Variable Air Volume Indoor Fan	AC HP		AC HP			HP HH	-			HP HH			HP	AC HP HH		
I-2. Single-speed Compressor Except as Covered by "I-1"		AC HP				HP HH	HP HH						HP	AC HP HH		
I-3. Two-capacity Compressor	AC HP			AC HP		HP HH					HP HH		HP	AC HP HH		
I-4. Variable-speed Compressor	AC HP				AC HP	HP HH						HP HH	HP	AC HP HH		
II-1. Ducted																
II-2. Non-Ducted																
III. Special Features									H							
IV. Secondary Test Method								N								

Legend for Table Entries:
Categories I and II: AC = applies for an Air Conditioner that meets the corresponding Column 1 "Key Equipment . . ." criterion
HP = applies for a Heat Pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
HH = applies for a Heating-only Heat pump that meets the corresponding Column 1 "Key Equipment . . ." criterion
Category III: G = ganged mini-splits or multi-splits;
H = heat pump with a heat comfort controller;
M = units with a multi-speed outdoor fan;
N = non-defrost heat pump

Inside these test rooms, use artificial loads during cyclic tests and frost accumulation tests, if needed, to produce stabilized room air temperatures. For one room, DOE recommends using an electric resistance heater(s) having a heating capacity that is

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approximately equal to the heating capacity of the test unit's condenser. For the second room, DOE recommends using a heater(s) having a capacity that is close to the sensible cooling capacity of the test unit's evaporator. Cycle the heater located in the same room as the test unit evaporator coil ON and OFF when the test unit cycles ON and OFF. Cycle the heater located in the same room as the test unit condensing coil ON and OFF when the test unit cycles OFF and ON.

2.2 *Test unit installation requirements.* a. Install the unit according to Section 8.6 of ASHRAE Standard 37–88. With respect to interconnecting tubing used when testing split systems, however, follow the requirements given in Section 5.1.3.5 of ARI Standard 210/240–94. When testing triple-split systems (see Definition 1.43), use the tubing length specified in Section 5.1.3.5 of ARI Standard 210/240–94 to connect the outdoor coil, indoor compressor section, and indoor coil while still meeting the requirement of exposing 10 feet of the tubing to outside conditions. When testing non-ducted systems having multiple indoor coils, connect each indoor fan-coil to the outdoor unit using: a. 25 feet of tubing, or b. tubing furnished by the manufacturer, whichever is longer. If they are needed to make a secondary measurement of capacity, install refrigerant pressure measuring instruments as described in Section 8.6.5 of ASHRAE Standard 37–88. Refer to Section 2.10 of this Appendix to learn which secondary methods require refrigerant pressure measurements. At a minimum, insulate the low pressure line(s) of a split system with foam insulation having an inside diameter that matches the refrigerant tubing and a nominal thickness of ½ inch.

b. For units designed for both horizontal and vertical installation or for both up-flow and down-flow vertical installations, the manufacturer must specify the orientation used for testing. Conduct testing with the following installed:

(1) The most restrictive filter(s),

(2) Supplementary heating coils, and

(3) Other equipment specified as part of the unit, including all hardware used by a heat comfort controller if so equipped (see Definition 1.26).

c. Testing a ducted unit without having an indoor air filter installed is permissible as long as the minimum external static pressure requirement is adjusted as Table 2, note 3 states (see Section 3.1.4). Except as noted in Section 3.1.9, prevent the indoor air supplementary heating coils from operating during all tests. For coil only indoor units that are supplied without an enclosure, create an enclosure using 1 inch fiberglass ductboard having a nominal density of 6 pounds per cubic foot. Or alternatively, use some other insulating material having a thermal resistance ("R" value) between 4 and 6 hr·ft²·°F/Btu. For units where the coil is housed within an enclosure or cabinet, no extra insulating or sealing is allowed.

2.2.1 *Defrost control settings.* Set heat pump defrost controls at the normal settings which most typify those encountered in generalized climatic region IV. (Refer to Figure 2 and Table 17 of Section 4.2 for information on region IV.) For heat pumps that use a time-adaptive defrost control system (see Definition 1.41), the manufacturer must specify the frosting interval to be used during Frost Accumulation tests and provide the procedure for manually initiating the defrost at the specified time. To ease testing of any unit, the manufacturer should provide information and any necessary hardware to manually initiate a defrost cycle.

2.2.2 *Special requirements for units having a multiple-speed outdoor fan.* Configure the multiple-speed outdoor fan according to the manufacturer's specifications, and thereafter, leave it unchanged for all tests. The controls of the unit must regulate the operation of the outdoor fan during all lab tests except dry coil cooling mode tests. For dry coil cooling mode tests, the outdoor fan must operate at the same speed as used during the required wet coil test conducted at the same outdoor test conditions.

2.2.3 *Special requirements for multi-split air conditioners and heat pumps, and systems composed of multiple mini-split units (outdoor units located side-by-side) that would normally operate using two or more indoor thermostats.* During the steady-state tests, shunt all thermostats to make all indoor fan-coil units operating simultaneously. To ease the testing burden of cyclic tests, consider creating a single control circuit that allows simultaneous cycling of all compressor systems. In this test procedure, references to a single indoor fan, outdoor fan, and compressor means all indoor fans, all outdoor fans, and all compressor systems.

2.2.4 *Wet-bulb temperature requirements for the air entering the indoor and outdoor coils.*

2.2.4.1 *Cooling mode tests.* For wet-coil cooling mode tests, regulate the water vapor content of the air entering the indoor unit to the applicable wet-bulb temperature listed in Tables 3 to 6. As noted in these same tables, achieve a wet-bulb temperature during dry-coil cooling mode tests that results in no condensate forming on the indoor coil. Controlling the water vapor content of the air entering the outdoor side of the unit is not required for cooling mode tests except when testing:

(1) Units that reject condensate to the outdoor coil during wet coil tests. Tables 3–6 list the applicable wet-bulb temperatures.

(2) Single-packaged units where all or part of the indoor section is located in the outdoor test room. The average dew point temperature of the air entering the outdoor coil during wet coil tests must be within ±3.0 °F of the average dew point temperature of the air entering the indoor coil over the 30-minute data collection interval described in Section 3.3. For dry coil tests on such units, you may need to limit the moisture content of the air entering the outdoor side of the unit to meet the requirements of Section 3.4.

2.2.4.2 *Heating mode tests.* For heating mode tests, regulate the water vapor content of the air entering the outdoor unit to the applicable wet-bulb temperature listed in Tables 9 to 12. The wet-bulb temperature entering the indoor side of the heat pump must not exceed 60 °F. Additionally, if you use the Outdoor Air Enthalpy test method while testing a single-packaged heat pump where all or part of the outdoor section is located in the indoor test room, adjust the wet-bulb temperature for the air entering the indoor side to yield an indoor-side dew point temperature that is as close as reasonably possible to the dew point temperature of the outdoor-side entering air.

2.2.5 *Additional refrigerant charging requirements.* Charging according to the "manufacturer's instructions," as stated in Section 8.6 of ASHRAE Standard 37–88, means the manufacturer's installation instructions that come packaged with the unit. For third party testing, for example, do not consult the manufacturer about how to charge the unit. If a unit requires charging but the installation instructions do not specify a charging procedure, then evacuate the unit and add the nameplate refrigerant charge. Where the manufacturer's installation instructions contain two sets of refrigerant charging criteria, one for field installations and one for lab testing, use the field installation criteria.

2.3 *Indoor air volume rates.* If a unit's controls allow for overspeeding the indoor fan (usually on a temporary basis), take the necessary steps to prevent overspeeding during all tests.

2.3.1 *Cooling tests.* a. Set indoor fan control options (e.g., fan motor pin settings, fan motor speed) according to the published installation instructions that are provided with the equipment while meeting the airflow requirements that are specified in paragraph b. of this section.

b. Express the Cooling Certified Air Volume Rate, the Cooling Minimum Air Volume Rate, and the Cooling Intermediate Air Volume Rate in terms of standard air.

2.3.2 *Heating tests.* a. If needed, set the indoor fan control options (e.g., fan motor pin settings, fan motor speed) according to the published installation instructions that are provided with the equipment. Do this set-up while meeting all applicable airflow requirements that are specified in paragraph b. of this section.

b. Express the Heating Certified Air Volume Rate, the Heating Minimum Air Volume Rate, the Heating Intermediate Air Volume Rate, and the Heating Nominal Air Volume Rate in terms of standard air.

2.4 *Indoor coil inlet and outlet duct connections.* Insulate and/or construct the outlet plenum described in Section 2.4.1 and, if installed, the inlet plenum described in Section 2.4.2 with thermal insulation having a nominal overall resistance (R-value) of at least 19 hr·ft²·°F/Btu.

2.4.1 *Outlet plenum for the indoor coil.* Attach a plenum to the outlet of the indoor coil. (Note: For some packaged systems, the indoor coil may be located in the outdoor test room.) For non-ducted systems having multiple indoor coils, attach a plenum to each indoor coil outlet. Add a static pressure tap to each face of the (each) outlet plenum, if rectangular, or at four evenly distributed locations along the circumference of an oval or round plenum. Create a manifold that connects the four static pressure taps. Figure 1 provides recommended options for the manifold configuration. See Figures 7 and 8 of ASHRAE Standard 37–88 for the cross-sectional dimensions and minimum length of the (each) plenum and the locations for adding the static pressure taps for units tested with and without an indoor fan installed. For a non-ducted system having multiple indoor coils, have all outlet plenums discharge air into a single common duct. At the plane where each plenum enters the common duct, install an adjustable airflow damper and use it to equalize the static pressure in each plenum.

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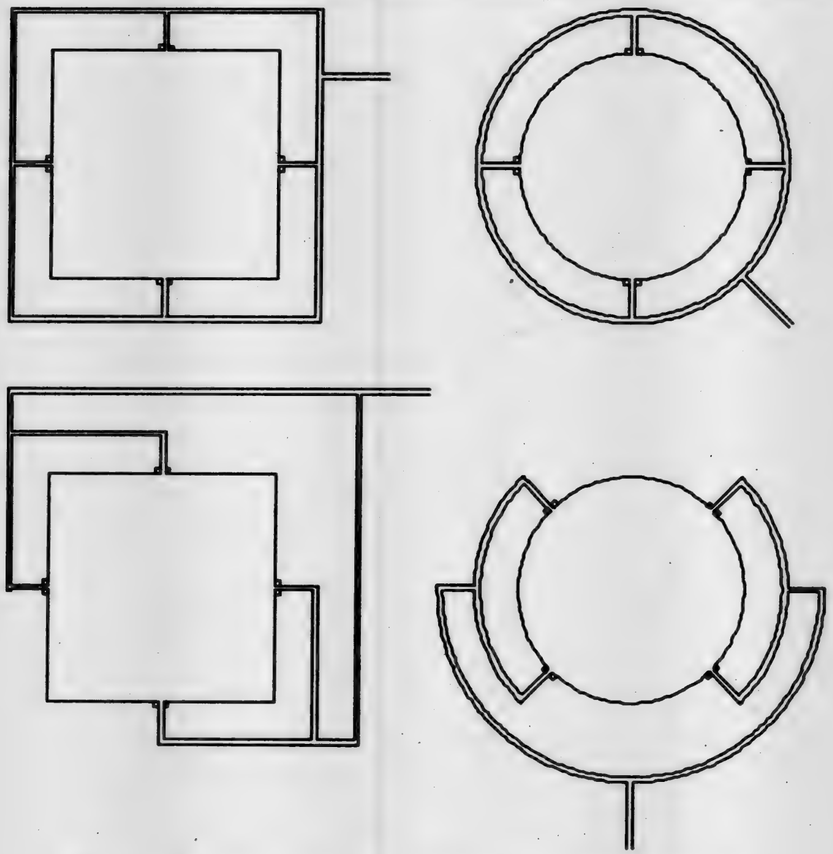


Figure 1. Recommended configuration for manifolding static pressure taps.

2.4.2 *Inlet plenum for the indoor unit.* Install an inlet plenum when testing a coil-only indoor unit or a packaged system where the indoor coil is located in the outdoor test room. Add static pressure taps at the center of each face of this plenum, if rectangular, or at four evenly distributed locations along the circumference of an oval or round plenum. Make a manifold that connects the four static pressure taps. See Figure 8 of ASHRAE Standard 37–88 for cross-sectional dimensions, the minimum length of the inlet plenum, and the locations of the static pressure taps. When testing a ducted unit having an indoor fan (and the indoor coil is in the indoor test room), DOE recommends installing an inlet plenum if sufficient space exists within the test room. If using an inlet plenum, add four static pressure taps and a manifold that connects them together. DOE recommends constructing the inlet plenum and locating the static pressure taps as shown in Figure 8 of ASHRAE Standard 37–88. Never use an inlet plenum when testing a non-ducted system.

2.5 *Indoor coil air property measurements and air damper box applications.* a. Measure the dry-bulb temperature and water vapor content of the air entering and leaving the indoor coil. If needed, use an air sampling device to divert air to a sensor(s) that measures the water vapor content of the air. See Figure 2 of ASHRAE Standard 41.1–86 (RA 91) for guidance on-constructing an air sampling device. The sampling device may also divert air to a remotely located sensor(s) that measures dry bulb temperature. You may use the air sampling device and the remotely located temperature sensor(s) to determine the entering air dry bulb temperature during any test. You may use the air sampling device and the remotely located leaving air dry bulb temperature sensor(s) for all tests except:

(1) Cyclic tests, and

(2) Frost Accumulation tests.

b. An acceptable alternative in all cases, including the two special cases noted above, is to install a grid of dry bulb temperature sensors within the outlet and inlet ducts. Use a temperature grid to get the average dry bulb temperature at one location, leaving or entering, or when two grids are applied as a thermopile, to directly obtain the temperature difference. A grid of temperature sensors (which may also be used for determining average leaving air dry bulb temperature) is required to measure the temperature distribution within a cross-section of the leaving airstream.

c. Use an inlet and outlet air damper box when testing ducted systems if conducting one or both of the cyclic tests listed in Sections 3.2 and 3.6 . Otherwise, DOE recommends installing an outlet air damper box when testing heat pumps, both ducted and non-ducted, that cycle off the indoor fan during defrost cycles. Never use an inlet damper box when testing a non-ducted system.

2.5.1 *Test set-up on the inlet side of the indoor coil: for cases where the inlet damper box is installed.* a: Install the inlet side damper box as specified in Section 2.5.1.1 or 2.5.1.2, whichever applies. Insulate or construct the ductwork between the point where the air damper is installed and where the connection is made to the following:

(1) The inlet plenum (Section 2.5.1.1 units); or

(2) To the indoor unit (Section 2.5.1.2 units) with thermal insulation that has a nominal overall resistance (R-value) of at least 19 hr·ft²·°F/Btu.

b. Locate the grid of entering air dry-bulb temperature sensors, if used, at the inlet of the damper box. Locate the air sampling device, or the sensor used to measure the water vapor content of the inlet air, at a location immediately upstream of the damper box inlet.

2.5.1.1 *If the Section 2.4.2 inlet plenum is installed.* Install the inlet damper box upstream of the inlet plenum. The cross-sectional flow area of the damper box must be equal to or greater than the flow area of the inlet plenum. If needed, use an adaptor plate or a transition duct section to connect the damper box with the inlet plenum.

2.5.1.2 *If the Section 2.4.2 inlet plenum is not installed.* Install the damper box immediately upstream of the air inlet of the indoor unit. The cross-sectional dimensions of the damper box must be equal to or greater than the dimensions of the indoor unit inlet. If needed, use an adaptor plate or a short transition duct section to connect the damper box with the unit's air inlet. Add static pressure taps at the center of each face of the damper box, if rectangular, or at four evenly distributed locations along the circumference, if oval or round. Locate the pressure taps between the inlet damper and the inlet of the indoor unit. Make a manifold that connects the four static pressure taps.

2.5.2 *Test set-up on the inlet side of the indoor unit: for cases where no inlet damper box is installed.* If using the Section 2.4.2 inlet plenum and a grid of dry bulb temperature sensors, mount the grid at a location upstream of the static pressure taps described in Section 2.4.2, preferably at the entrance plane of the inlet plenum. If you do not use the Section 2.4.2 inlet plenum, but you are using a grid of dry bulb temperature sensors, locate the grid approximately 6 inches from the inlet of the indoor coil. Or, in the case of non-ducted units having multiple indoor coils, locate a grid approximately 6 inches from the inlet of each indoor coil. Position an air sampling device, or the sensor used to measure the water vapor content of the inlet air, immediately upstream of the (each) entering air dry-bulb temperature sensor grid. If you are not using a grid of sensors, position the entering air sampling device (or the sensor used to measure the water vapor content of the inlet air) as if the grid were present.

2.5.3 *Indoor coil static pressure difference measurement.* Section 6.4.4.1 of ASHRAE Standard 37–88 describes the recommended method for fabricating static pressure taps. Also refer to Figure 2A of ASHRAE Standard 51–99. Use a differential pressure measuring instrument that is accurate to within ±0.01 inches of water and has a resolution of at least 0.01 inches of water to measure the static pressure difference between the indoor coil air inlet and outlet. Connect one side of the differential pressure instrument to the manifolded pressure taps installed in the outlet plenum. Connect the other side of the instrument to the manifolded pressure taps located in either the inlet plenum or incorporated within the air damper box. If you are not using an inlet plenum or inlet damper box, leave the inlet side of the differential pressure instrument open to the surrounding atmosphere. For non-ducted systems that are tested with multiple outlet plenums, measure the static pressure within each outlet plenum relative to the surrounding atmosphere.

2.5.4 *Test set-up on the outlet side of the indoor coil.* a: Install an interconnecting duct between the outlet plenum described in Section 2.4.1 and the airflow measuring apparatus described below in Section 2.6. The cross-sectional flow area of the interconnecting duct must be equal to or greater than the flow area of the outlet plenum or the common duct used when testing non-ducted units having multiple indoor coils. If needed, use adaptor plates or transition duct sections to allow the connections. DOE recommends taping joints within the interconnecting duct (and the outlet plenum). Construct or insulate the entire flow section with thermal insulation having a nominal overall resistance (R-value) of at least 19 hr·ft²·°F/Btu.

b. Install a grid(s) of dry-bulb temperature sensors inside the interconnecting duct. Also, install an air sampling device, or the sensor(s) used to measure the water vapor content of the outlet air, inside the interconnecting duct. Locate the dry-bulb temperature grid(s) upstream of the air sampling device [or the in-duct sensor(s) used to measure the water vapor content of the outlet air]. Air that circulates through an air sampling device and passed a remote water-vapor-content sensor(s) must be returned to the interconnecting duct at a point:

(1) Downstream of the air sampling device,

(2) Upstream of the outlet air damper box, if installed, and

(3) Upstream of the Section 2.6 airflow measuring apparatus.

2.5.4.1 *Outlet air damper box placement and requirements.* If using an outlet air damper box (see Section 2.5), install it within the interconnecting duct at a location downstream of the location where air from the sampling device is reintroduced or downstream of the in-duct sensor that measures water vapor content of the outlet air. The leakage rate from the combination of the outlet plenum, the closed damper, and the duct section that connects these two components must not exceed 20 cubic feet per minute when a negative pressure of 1 inch of water column is maintained at the plenum's inlet.

2.5.4.2 *Additional recommendations.* DOE recommends installing a mixing device(s) upstream of the outlet air, dry-bulb temperature grid (but downstream of the outlet plenum static pressure taps). Also, consider using a perforated screen located between the mixing device and the dry-bulb temperature grid. DOE recommends using a screen having a maximum open area of 40 percent. One or both items should help to

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meet the maximum outlet air temperature distribution specified in Section 3.1.8. Mixing devices are described in Sections 6.3—6.5 of ASHRAE Standard 41.1–86 (RA 91) and Section 5.2.2 of ASHRAE Standard 41.2–87 (RA 92).

2.5.5 *Dry bulb temperature measurement.* a. Measure dry bulb temperatures as specified in Sections 4, 5, 6.1–6.10, 9, 10, and 11 of ASHRAE Standard 41.1–86 (RA 91). The transient testing requirements cited in Section 4.3 of ASHRAE Standard 41.1–86 (RA 91) apply if conducting a cyclic or Frost Accumulation test.

b. Distribute the sensors of a dry-bulb temperature grid over the entire flow area. DOE recommends using 16 temperature sensors within each temperature grid. The required minimum is 9 sensors per grid. DOE recommends installing redundant inlet and outlet dry bulb temperature sensors and particularly a thermopile. If using thermocouples, DOE recommends the following:

(1) Use 24 gauge wire,

(2) Remove approximately 1 inch of insulation from each lead when preparing to make a junction, and

(3) Use no more than two bonded turns per junction.

2.5.6 *Water vapor content measurement.* Determine water vapor content by measuring dry-bulb temperature combined with the air wet-bulb temperature, dew point temperature, or relative humidity. If used, construct and apply wet-bulb temperature sensors as specified in Sections 4, 5, 6, 9, 10, and 11 of ASHRAE Standard 41.1–86 (RA 91). As specified in ASHRAE Standard 41.1, the temperature sensor (wick removed) must be accurate to within ±0.2 °F. If used, apply dew point hygrometers as specified in Sections 5 and 8 of ASHRAE Standard 41.6–94. The dew point hygrometers must be accurate to within ±0.4 °F when operated at conditions that result in the evaluation of dew points above 35 °F. If used, a relative humidity meter must be accurate to within ±0.7% RH. Other means to determine the psychrometric state of air may be used as long as the measurement accuracy is equivalent or better than the accuracy achieved from using a wet-bulb temperature sensor that meets the above specifications.

2.5.7 *Air damper box performance requirements.* If used (see Section 2.5), the air damper box(es) must be capable of being completely opened or completely closed within 10 seconds for each action.

2.6 *Airflow measuring apparatus.* a. Fabricate and operate an Air Flow Measuring Apparatus as specified in Section 6.6 of ASHRAE Standard 116–95. Refer to Figure 12 of ASHRAE Standard 51–99 or Figure 14 of ASHRAE Standard 41.2–87 (RA 92) for guidance on placing the static pressure taps and positioning the diffusion baffle (settling means) relative to the chamber inlet.

b. Connect the airflow measuring apparatus to the interconnecting duct section described in Section 2.5.4. See Sections 6.1.1, 6.1.2, and 6.1.4, and Figures 1, 2, and 4 of ASHRAE Standard 37–88, and Figures B1, B2, and B4 of ARI Standard 210/240–94 for illustrative examples of how the test apparatus may be applied within a complete laboratory set-up. Instead of following one of these examples, you may use an alternative set-up to handle the air leaving the airflow measuring apparatus and to supply properly conditioned air to the test unit's inlet. The alternative set-up, however, must not interfere with the prescribed means for measuring airflow rate, inlet and outlet air temperatures, inlet and outlet water vapor contents, and external static pressures, nor create abnormal conditions surrounding the test unit. (Note: do not use an enclosure as described in Section 6.1.3 of ASHRAE Standard 37–88 when testing triple-split units.)

2.7 *Electrical voltage supply.* Perform all tests at the voltage specified in Section 5.1.3.2 of ARI Standard 210/240–94 for "Standard Rating Tests." Measure the supply voltage at the terminals on the test unit using a volt meter that provides a reading that is accurate to within ±1.0 percent of the measured quantity.

2.8 *Electrical power and energy measurements.* a. Use an integrating power (watt-hour) measuring system to determine the electrical energy or average electrical power supplied to all components of the air conditioner or heat pump (including auxiliary components such as controls, transformers, crankcase heater, integral condensate pump on non-ducted indoor units, etc.). The watt-hour measuring system must give readings that are accurate to within ±0.5 percent. For cyclic tests, this accuracy is required during both the ON and OFF cycles. Use either two different scales on the same watt-hour meter or two separate watt-hour meters. Activate the scale or meter having the lower power rating within 15 seconds after beginning an OFF cycle. Activate the scale or meter having the higher power rating active within 15 seconds prior to beginning an ON cycle. For ducted units tested with a fan installed, the ON cycle lasts from compressor ON to indoor fan OFF. For ducted units tested without an indoor fan installed, the ON cycle lasts from compressor ON to compressor OFF. For non-ducted units, the ON cycle lasts from indoor fan ON to indoor fan OFF. When testing air conditioners and heat pumps having a variable-speed compressor, avoid using an induction watt/watt-hour meter. Instead, consider using a watt-hour measuring system that is capable of measuring up to the 50th harmonic.

b. When performing Section 3.5 and/or 3.8 cyclic tests on non-ducted units, provide instrumentation to determine the average electrical power consumption of the indoor fan motor to within ±1.0 percent. If required according to Sections 3.3, 3.4, 3.7, 3.9.1, and/or 3.10, this same instrumentation requirement applies when testing air conditioners and heat pumps having a variable-speed constant-air-volume-rate indoor fan or a variable-speed, variable-air-volume-rate indoor fan.

2.9 *Time measurements.* Make elapsed time measurements using an instrument that yields readings accurate to within ±0.2 percent.

2.10 *Test apparatus for the secondary space conditioning capacity measurement.* For all tests, use the Indoor Air Enthalpy Method to measure the unit's capacity. This method uses the test set-up specified in Sections 2.4 to 2.6. For all steady-state tests, in addition, conduct a second, independent measurement of capacity. For split systems, use one of the following secondary measurement methods: Outdoor Air Enthalpy Method, Compressor Calibration Method, or Refrigerant Enthalpy Method. Use either the Outdoor Air Enthalpy Method or the Compressor Calibration Method as the secondary measurement when testing a single packaged unit.

2.10.1 *Outdoor Air Enthalpy Method.* a. To make a secondary measurement of indoor space conditioning capacity using the Outdoor Air Enthalpy Method, do the following:

(1) Measure the electrical power consumption of the test unit,

(2) Measure the air-side capacity at the outdoor coil, and

(3) Apply a heat balance on the refrigerant cycle.

b. The test apparatus required for the Outdoor Air Enthalpy Method is a subset of the apparatus used for the Indoor Air Enthalpy Method. Required apparatus includes the following:

(1) An outlet plenum containing static pressure taps (Sections 2.4, 2.4.1, and 2.5.3),

(2) An airflow measuring apparatus (Section 2.6),

(3) A duct section that connects these two components and itself contains the instrumentation for measuring the dry-bulb temperature and water vapor content of the air leaving the outdoor coil (Sections 2.5.4, 2.5.5, and 2.5.6), and

(4) On the inlet side, a sampling device and optional temperature grid (Sections 2.5 and 2.5.2).

c. During the preliminary tests described in Sections 3.11.1 and 3.11.1.1, measure the evaporator and condenser temperatures or pressures. On both the outdoor coil and the indoor coil, solder a thermocouple onto a return bend located at or near the midpoint of each coil or at points not affected by vapor superheat or liquid subcooling. Alternatively, if the test unit is not sensitive to the refrigerant charge, connect pressure gages to the access valves or to ports created from tapping into the suction and discharge lines. Use this alternative approach when testing a unit charged with a zeotropic refrigerant having a temperature glide in excess of 1°F at the specified test conditions.

2.10.2 *Compressor Calibration Method.* Measure refrigerant pressures and temperatures to determine the evaporator superheat and the enthalpy of the refrigerant that enters and exits the indoor coil. Determine refrigerant flow rate or, when the superheat of the refrigerant leaving the evaporator is less that 5 °F, total capacity from separate calibration tests conducted under identical operating conditions. Install instrumentation; measure refrigerant properties; adjust the refrigerant charge according to Section 7.4.2 of ASHRAE Standard 37–88. Use refrigerant temperature and pressure measuring instruments that meet the specifications given in Sections 5.1.1 and 5.2 of ASHRAE Standard 37–88.

2.10.3 *Refrigerant Enthalpy Method.* For this method, calculate space conditioning capacity by determining the refrigerant enthalpy change for the indoor coil and directly measuring the refrigerant flow rate. Refer to Section 7.6.2 of ASHRAE Standard 37–88 for the requirements for using the method, the additional instrumentation requirements, and information on placing the flow meter and a sight glass. Use refrigerant temperature, pressure, and flow measuring instruments that meet the specifications given in Sections 5.1.1, 5.2, and 5.5.1 of ASHRAE Standard 37–88.

2.11 *Measurement of test room ambient conditions.* a. If using a test set-up where air is ducted directly from the conditioning apparatus to the indoor coil inlet (see Figure 2, Loop Air-Enthalpy Test Method Arrangement, of ASHRAE Standard 37–88), add instrumentation to permit measurement of the indoor test room dry-bulb temperature.

b. If you are not using the Outdoor Air Enthalpy Method, add instrumentation to measure the dry-bulb temperature and the water vapor content of the air entering the outdoor coil. DOE recommends measuring water vapor content by using an air sampling device to divert air to a remotely located sensor(s). If used, construct and apply the air sampling device as per Section 6 of ASHRAE Standard 41.1–86 (RA 91). You may use the air sampling device to also divert air to a sensor that measures outdoor-side entering dry bulb temperature. However, DOE recommends positioning dry bulb temperature sensors around the exterior of the entire outdoor coil and using them to determine an average entering dry bulb temperature. In such cases, use individually monitored sensors to identify any significant temperature distribution. Take steps (e.g., add or re-position a lab circulating fan), as needed, to minimize the magnitude of the temperature distribution. Position any fan in the outdoor test room while trying to keep air velocities in the vicinity of the test unit below 500 feet per minute.

c. Measure dry bulb temperatures as specified in Sections 4, 5, 6.1–6.10, 9, 10, and 11 of ASHRAE Standard 41.1–86 (RA 91). Measure water vapor content as stated above in Section 2.5.6.

2.12 *Measurement of indoor fan speed.* When required, measure fan speed using a revolution counter, tachometer, or stroboscope that gives readings accurate to within ±1.0 percent.

2.13 *Measurement of barometric pressure.* Determine the average barometric pressure during each test. Use an instrument that meets the requirements specified in Section 5.2 of ASHRAE Standard 37–88.

3. Testing Procedures

3.1 *General Requirements.* If during the testing process you make an equipment set-up adjustment that would alter the performance of the unit when conducting an already completed test, then repeat all tests affected by the adjustment. For cyclic tests, instead of maintaining an air volume rate, maintain the airflow nozzle(s)' static pressure difference or velocity pressure during an ON period at the same pressure difference or velocity pressure as measured during the steady-state test conducted at the same test conditions.

3.1.1 Primary and secondary test methods. For all tests, use the Indoor Air Enthalpy Method test apparatus to determine the test unit's space conditioning capacity. The procedure and data collected, however, differ slightly depending upon whether the test is a steady-state test, a cyclic test, or a Frost Accumulation test. The following sections described these differences. For all steady-state tests (i.e., the A, A_2, A_1, B, B_2, B_1, C, C_1, E_V, F_1, G_1, H0, $H0_1$, H1, $H1_2$, $H1_1$, $H1_N$, H3, $H3_2$, and $H3_1$ Tests), in addition, use one of the acceptable secondary methods specified in Section 2.10 to determine indoor space conditioning capacity. Calculate this secondary check of capacity according to Section 3.11. The two capacity measurements must agree to within 6 percent to constitute a valid test. For this capacity comparison, use the Indoor Air Enthalpy Method capacity that is calculated in Section 7.3 of ASHRAE Standard 37–88 (and do not make the after-test fan heat adjustments described in Sections 3.3, 3.4, 3.7, and 3.10 of this Appendix). However, include the appropriate Section 3.3 to 3.5 and 3.7 to 3.10 fan heat adjustments within the Indoor Air Enthalpy Method capacities used for the Section 4 seasonal calculations.

3.1.2 *Manufacturer-provided equipment overrides.* Where needed, the manufacturer must provide a means for overriding the controls of the test unit so that the compressor(s) operates at the specified speed or capacity and the indoor fan operates at the specified speed or delivers the specified air volume rate.

3.1.3 *Airflow through the outdoor coil.* For all tests, meet the requirements given in Section 5.1.3.4 of ARI Standard 210/240–94 when obtaining the airflow through the outdoor coil.

3.1.4 *Airflow through the indoor coil.*

3.1.4.1 *Cooling Certified Air Volume Rate.*

3.1.4.1.1 Cooling Certified Air Volume Rate for Ducted Units. The manufacturer must specify the Cooling Certified Air Volume Rate. Use this value as long as the following two requirements are satisfied. First, when conducting the A or A_2 Test (exclusively), the measured air volume rate, when divided by the measured indoor air-side total cooling capacity, must not exceed 37.5 cubic feet per minute of standard air (SCFM) per 1000 Btu/h. If this ratio is exceeded, reduce the air volume rate until this ratio is equaled. Use this reduced air volume rate for all tests that call for using the Cooling Certified Air Volume Rate. The second requirement is as follows:

a. For ducted units that are tested with a fixed-speed, multi-speed, or variable-speed variable-air-volume-rate indoor fan installed. For the A or A_2 Test (exclusively), the measured external static pressure must be equal to or greater than the applicable minimum external static pressure cited in Table 2. If the Table 2 minimum is not equaled or exceeded, incrementally change the set-up of the indoor fan (e.g., fan motor pin settings, fan motor speed) until the Table 2 requirement is met while maintaining the same air volume rate. If the indoor fan set-up changes cannot provide the minimum external static, then reduce the air volume rate until the correct Table 2 minimum is equaled. For the last scenario, use the reduced air volume rate for all tests that require the Cooling Certified Air Volume Rate.

b. For ducted units that are tested with a constant-air-volume-rate indoor fan installed. For all tests that specify the Cooling Certified Air Volume Rate, obtain an external static pressure as close to (but not less than) the applicable Table 2 value that does not cause instability or an automatic shutdown of the indoor blower. For the A or A_2 Test (exclusively); the average air volume rate from the 30-minute data collection interval (see Section 3.3) and the manufacturer-provided Cooling Certified Air Volume Rate must differ by 8 percent or less.

c. For ducted units that are tested without an indoor fan installed. For the A or A_2 Test, (exclusively), the pressure drop across the indoor coil assembly must not exceed a specified maximum. The maximum value is 0.30 inches of water for all units except small-duct, high-velocity systems (see 1.46) for which the limit is 0.50 inches of water. If the maximum value is exceeded, reduce the air volume rate until the measured pressure drop equals the specified maximum. Use this reduced air volume rate for all tests that require the Cooling Certified Air Volume Rate.

TABLE 2.—MINIMUM EXTERNAL STATIC PRESSURE FOR DUCTED SYSTEMS TESTED WITH AN INDOOR FAN INSTALLED

Rated cooling [1] or heating [2] capacity (Btu/h)	Minimum external resistance [3] (inches of water)
Up Thru 28,800	0.10
29,000 to 42,500	0.15
43,000 and Above	0.20

[1] For air conditioners and heat pumps, the value cited by the manufacturer in published literature for the unit's capacity when operated at the A or A_2 Test conditions.

[2] For heating-only heat pumps, the value the manufacturer cites in published literature for the unit's capacity when operated at the H1 or $H1_2$ Test conditions.

[3] For ducted units tested without an air filter installed, increase the applicable tabular value by 0.08 inches of water.

3.1.4.1.2 Cooling Certified Air Volume Rate for Non-ducted Units. For non-ducted units, the Cooling Certified Air Volume Rate is the air volume rate that results during each test when the unit is operated at an external static pressure of zero inches of water.

3.1.4.2 Cooling Minimum Air Volume Rate. a. For ducted units that regulate the speed (as opposed to the CFM) of the indoor fan,

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$$\text{Cooling Minimum Air Vol. Rate} = \text{Cooling Certified Air Vol. Rate} \cdot \frac{\text{Cooling Minimum Fan Speed}}{\text{A}_2\text{ Test Fan Speed}},$$

where "Cooling Minimum Fan Speed" corresponds to the fan speed used when operating at low compressor capacity (two-capacity system), the fan speed used when operating at the minimum compressor speed (variable-speed system), or the lowest fan speed used when cooling (single-speed compressor and a variable-speed variable-air-volume-rate indoor fan). For such systems, obtain the Cooling Minimum Air Volume Rate regardless of the external static pressure.

b. For ducted units that regulate the air volume rate provided by the indoor fan, the manufacturer must specify the Cooling Minimum Air Volume Rate. For such systems, conduct all tests that specify the Cooling Minimum Air Volume Rate—the A_1, B_1, C_1, F_1, and G_1 Tests—at an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than,

$$\text{A}_1, \text{B}_1, \text{C}_1, \text{F}_1, \text{\& G}_1\text{ Test } \Delta P_{st} = \Delta P_{st,A_2} \cdot \left[\frac{\text{Cooling Minimum Air Volume Rate}}{\text{Cooling Certified Air Volume Rate}}\right]^2,$$

where $\Delta P_{st, A2}$ is the applicable Table 2 minimum external static pressure that was targeted during the A_2 (and B_2) Test. Only for the first test, the average measured air volume rate and the manufacturer-specified Cooling Minimum Air Volume Rate must differ by 8 percent or less.

c. For ducted two-capacity units that are tested without an indoor fan installed, the Cooling Minimum Air Volume Rate is the higher of the rate specified by the manufacturer or 75 percent of the Cooling Certified Air Volume Rate. During the laboratory tests on a coil-only (fanless) unit, obtain this Cooling Minimum Air Volume Rate regardless of the pressure drop across the indoor coil assembly.

d. For non-ducted units, the Cooling Minimum Air Volume Rate is the air volume rate that results during each test when the unit operates at an external static pressure of zero inches of water and at the indoor fan setting used at low compressor capacity (two-capacity system) or minimum compressor speed (variable-speed system). For units having a single-speed compressor and a variable-speed variable-air-volume-rate indoor fan, use the lowest fan setting allowed for cooling.

3.1.4.3 Cooling Intermediate Air Volume Rate. a. For ducted units that regulate the speed of the indoor fan,

$$\text{Cooling Intermediate Air Volume Rate} = \text{Cooling Certified Air Volume Rate} \cdot \frac{\text{E}_V\text{ Test Fan Speed}}{\text{A}_2\text{ Test Fan Speed}}.$$

b. For such units, obtain the Cooling Intermediate Air Volume Rate regardless of the external static pressure.

c. For ducted units that regulate the air volume rate provided by the indoor fan, the manufacturer must specify the Cooling Intermediate Air Volume Rate. For such systems, conduct the E_V Test at an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than,

$$\text{E}_V\text{ Test } \Delta P_{st} = \Delta P_{st,A_2} \cdot \left[\frac{\text{Cooling Intermediate Air Volume Rate}}{\text{Cooling Certified Air Volume Rate}}\right]^2,$$

where $\Delta P_{st, A2}$ is the applicable Table 2 minimum external static pressure that was targeted during the A_2 (and B_2) Test.

d. For non-ducted units, the Cooling Intermediate Air Volume Rate is the air volume rate that results when the unit operates at an external static pressure of zero inches of water and at the fan speed selected by the controls of the unit for the E_V Test conditions.

3.1.4.4 Heating Certified Air Volume Rate.

3.1.4.4.1 Ducted heat pumps where the Heating and Cooling Certified Air Volume Rates are the same.

$$\text{Heating Certified Air Volume Rate} = \text{Cooling Certified Air Volume Rate} \cdot \frac{\text{H1 or H1}_2\text{ Test Fan Speed}}{\text{A or A}_2\text{ Test Fan Speed}}.$$

b. For such heat pumps, obtain the Heating Certified Air Volume Rate without regard to the external static pressure.

c. For ducted heat pumps that regulate the air volume rate delivered by the indoor fan, the manufacturer must specify the Heating Certified Air Volume Rate. For such heat pumps, conduct all tests that specify the Heating Certified Air Volume Rate at an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than,

$$\text{Heating Certified } \Delta P_{st} = \text{Cooling Certified } \Delta P_{st} \cdot \left[\frac{\text{Heating Certified Air Volume Rate}}{\text{Cooling Certified Air Volume Rate}}\right]^2,$$

where the Cooling Certified ΔP_{st} is the applicable Table 2 minimum external static pressure that was specified for the A or A_2 Test. For the first test that uses the Heating Certified Air Volume Rate, the average measured air volume rate and the manufacturer-specified Heating Certified Air Volume Rate, both expressed in SCFM, must differ by 8 percent or less.

d. When testing ducted, two-capacity heat pumps that lock out high capacity operation when cooling, use the appropriate approach of the above two cases for units that are tested with an indoor fan installed. For coil-only (fanless) heat pumps that lock out high capacity cooling, the Heating Certified Air Volume Rate is the lesser of the rate specified by the manufacturer or 133 percent of the Cooling Certified Air Volume Rate. For this latter case, obtain the Heating Certified Air Volume Rate regardless of the pressure drop across the indoor coil assembly.

3.1.4.4.3 *Ducted heating-only heat pumps.* This section applies when testing ducted two-capacity heat pumps that lock out high capacity operation when cooling. The manufacturer must specify the Heating Certified Air Volume Rate. Use this value when the following two requirements are satisfied. First, when conducting the H1 or $H1_2$ Test (exclusively), the measured air volume rate, when divided by the measured indoor air-side total heating capacity, must not exceed 37.5 cubic feet per minute of standard air (SCFM) per 1000 Btu/h. If this ratio is exceeded, reduce the air volume rate until this ratio is equaled. Use this reduced air volume rate for all tests of heating-only heat pumps that call for the Heating Certified Air Volume Rate. The second requirement is as follows:

a. *For heating-only heat pumps that are tested with a fixed-speed, multi-speed, or variable-speed variable-air-volume-rate indoor fan installed.* For the H1 or $H1_2$ Test (exclusively), the measured external static pressure must be equal to or greater than the Table 2 minimum external static pressure that applies given the heating-only heat pump's rated heating capacity. If the Table 2 minimum is not equaled or exceeded, incrementally change the set-up of the indoor fan until the Table 2 requirement is met while maintaining the same air volume rate. If the indoor fan set-up changes cannot provide the necessary external static, then reduce the air volume rate until the correct Table 2 minimum is equaled. For the last scenario, use the reduced air volume rate for all tests that require the Heating Certified Air Volume Rate.

b. *For ducted heating-only heat pumps having a constant-air-volume-rate indoor fan.* For all tests that specify the Heating Certified Air Volume Rate, obtain an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than, the applicable Table 2 minimum. For the H1 or $H1_2$ Test (exclusively), the average air volume rate from the 30-minute data collection interval (see Section 3.7) and the manufacturer-provided Heating Certified Air Volume Rate must differ by 8 percent or less.

c. *For ducted heating-only heat pumps that are tested without an indoor fan installed.* For the H1 or $H1_2$ Test, (exclusively), the pressure drop across the indoor coil assembly must not exceed a specified maximum. The maximum value is 0.30 inches of water for all units except small-duct, high-velocity systems (see 1.46) for which the limit is 0.50 inches of water. If the maximum value is exceeded, reduce the air volume rate until the measured pressure drop equals the specified maximum. Use this reduced air volume rate for all tests that require the Heating Certified Air Volume Rate.

3.1.4.4.4 *Non-ducted heat pumps, including non-ducted heating-only heat pumps.* For non-ducted heat pumps, the Heating Certified Air Volume Rate is the air volume rate that results during each test when the unit operates at an external static pressure of zero inches of water.

3.1.4.5 *Heating Minimum Air Volume Rate.* a. For ducted heat pumps that regulate the speed (as opposed to the CFM) of the indoor fan,

$$\text{Heating Minimum Air Volume Rate} = \text{Heating Certified Air Volume Rate} \cdot \frac{\text{Heating Minimum Fan Speed}}{\text{H1}_2\text{ Test Fan Speed}},$$

where "Heating Minimum Fan Speed" corresponds to the fan speed used when operating at low compressor capacity (two-capacity system), the lowest fan speed used at any time when operating at the minimum compressor speed (variable-speed system), or the lowest fan speed used when heating (single-speed compressor and a variable-speed variable-air-volume-rate indoor fan). For such heat pumps, obtain the Heating Minimum Air Volume Rate without regard to the external static pressure.

b. For ducted heat pumps that regulate the air volume rate delivered by the indoor fan, the manufacturer must specify the Heating Minimum Air Volume Rate. For such heat pumps, conduct all tests that specify the Heating Minimum Air Volume Rate—the $H0_1$, $H1_1$, $H2_1$, and $H3_1$, at an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than,

$$\text{H0}_1, \text{H1}_1, \text{H2}_1, \text{\& H3}_1\text{ Test } \Delta P_{st} = \Delta P_{st,H1_2} \cdot \left[\frac{\text{Htg Minimum Air Vol. Rate}}{\text{Htg Certified Air Vol. Rate}}\right]^2,$$

where is $\Delta P_{st,H1_2}$ is the minimum external static pressure that was targeted during the $H1_2$ Test. Only for the first test, the average measured air volume rate and the manufacturer-specified Heating Minimum Air Volume Rate must differ by 8 percent or less.

c. When testing ducted, two-capacity heat pumps that lock out high capacity operation when cooling, use the appropriate approach of the above two cases for units that are tested with a indoor fan installed.

d. For ducted two-capacity heat pumps that are tested without an indoor fan installed, use the Cooling Minimum Air Volume Rate as the Heating Minimum Air Volume Rate. For ducted two-capacity heat pumps that are tested without an indoor fan installed, and that lock out high capacity operation when cooling, use the Cooling Certified Air Volume Rate as the Heating Minimum Air Volume Rate. For ducted two-capacity heating-only heat pumps that are tested without an indoor fan installed, the Heating Minimum Air Volume Rate is the higher of the rate specified by the manufacturer or 75 percent of the Heating Certified Air Volume Rate. During the laboratory tests on a coil-only (fanless) unit, obtain the Heating Minimum Air Volume Rate without regard to the pressure drop across the indoor coil assembly.

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e. For non-ducted heat pumps, the Heating Minimum Air Volume Rate is the air volume rate that results during each test when the unit operates at an external static pressure of zero inches of water and at the indoor fan setting used at low compressor capacity (two-capacity system) or minimum compressor speed (variable-speed system). For units having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor fan, use the lowest fan setting allowed for heating.

3.1.4.6 *Heating Intermediate Air Volume Rate.* a. For ducted heat pumps that regulate the speed of the indoor fan,

$$\text{Heating Intermediate Air Volume Rate} = \text{Heating Certified Air Volume Rate} \cdot \frac{\text{H2}_\text{V}\text{ Test Fan Speed}}{\text{H1}_2\text{ Test Fan Speed}}.$$

b. For such heat pumps, obtain the Heating Intermediate Air Volume Rate without regard to the external static pressure.

c. For ducted heat pumps that regulate the air volume rate delivered by the indoor fan, the manufacturer must specify the Heating Intermediate Air Volume Rate. For such heat pumps, conduct the $H2_V$ Test at an external static pressure that does not cause instability or an automatic shutdown of the indoor blower while being as close to, but not less than,

$$\text{H2}_\text{V}\text{ Test }\Delta P_{st} = \Delta P_{st,H1_2} \cdot \left[\frac{\text{Heating Intermediate Air Volume Rate}}{\text{Heating Certified Air Volume Rate}}\right]^2,$$

where $\Delta P_{st,H1_2}$ is the minimum external static pressure that was specified for the $H1_2$ Test.

d. For non-ducted heat pumps, the Heating Intermediate Air Volume Rate is the air volume rate that results when the heat pump operates at an external static pressure of zero inches of water and at the fan speed selected by the controls of the unit for the $H2_V$ Test conditions.

3.1.4.7 *Heating Nominal Air Volume Rate.* Except for the noted changes, determine the Heating Nominal Air Volume Rate using the approach described in Section 3.1.4.6. Required changes include substituting "$H1_N$ Test" for "$H2_V$ Test" within the first Section 3.1.4.6 equation, substituting "$H1_N$ Test ΔP_{st}" for "$H2_V$ Test ΔP_{st}" in the second Section 3.1.4.6 equation, substituting "$H1_N$ Test" for each "$H2_V$ Test", and substituting "Heating Nominal Air Volume Rate" for each "Heating Intermediate Air Volume Rate."

3.1.5 *Indoor test room requirement when the air surrounding the indoor unit is not supplied from the same source as the air entering the indoor unit.* If using a test set-up where air is ducted directly from the air reconditioning apparatus to the indoor coil inlet (see Figure 2, Loop Air-Enthalpy Test Method Arrangement, of ASHRAE Standard 37–88), maintain the dry bulb temperature within the test room within ±5.0 °F of the applicable Sections 3.2 and 3.6 dry bulb temperature test condition for the air entering the indoor unit.

3.1.6 *Air volume rate calculations.* For all steady-state tests and for Frost Accumulation ($H2, H2_1, H2_2, H2_V$) Tests, calculate the air volume rate through the indoor coil as specified in Sections 7.8.3.1 and 7.8.3.2 of ASHRAE Standard 37–88. When using the Outdoor Air Enthalpy Method, follow Sections 7.8.3.1 and 7.8.3.2 to calculate the air volume rate through the outdoor coil. To express air volume rates in terms of standard air, use:

$$\bar{V}_s = \frac{\bar{V}_{mx}}{0.075\frac{lbm_{da}}{ft^3} \cdot v'_n \cdot [1+W_n]} = \frac{\bar{V}_{mx}}{0.075\frac{lbm_{da}}{ft^3} \cdot v_n} \qquad (3\text{-}1)$$

where,

$\bar{V}_s$ =

air volume rate of standard (dry) air, $(ft^3/min)_{da}$

$\bar{V}_{mx}$ =

air volume rate of the air-water vapor mixture, $(ft^3/min)_{mx}$

v'_n =

specific volume of air-water vapor mixture at the nozzle, ft^3 per lbm of the air-water vapor mixture

W_n= humidity ratio at the nozzle, lbm of water vapor per lbm of dry air

0.075= the density associated with standard (dry) air

V_n= specific volume of the dry air portion of the mixture evaluated at the dry-bulb temperature, vapor content, and barometric pressure existing at the nozzle, ft^3 per lbm of dry air.

3.1.7 Test sequence. When testing a ducted unit (except if a heating-only heat pump), conduct the A or A_2 Test first to establish or verify the Cooling Certified Air Volume Rate. For ducted heat pumps where the Heating and Cooling Certified Air Volume Rates are different, make the first heating mode test one that requires the Heating Certified Air Volume Rate. For ducted heating-only heat pumps, conduct the H1 or $H1_2$ Test first to establish or verify the Heating Certified Air Volume Rate. When conducting an optional cyclic test, always conduct it immediately after the steady-state test that requires the same test conditions. For variable-speed systems, the first test using the Cooling Minimum Air Volume Rate should precede the EV Test if you expect to adjust the indoor fan control options when preparing for the first Minimum Air Volume Rate test. Under the same circumstances, the first test using the Heating Minimum Air Volume Rate should precede the $H2_V$ Test. The test laboratory makes all other decisions on the test sequence.

3.1.8 Requirement for the air temperature distribution leaving the indoor coil. For at least the first cooling mode test and the first heating mode test, monitor the temperature distribution of the air leaving the indoor coil using the grid of individual sensors described in Sections 2.5 and 2.5.4. For the 30-minute data collection interval used to determine capacity, the maximum spread among the outlet dry bulb temperatures from any data sampling must be 1.5 °F or less. Install the mixing devices described in Section 2.5.4.2 to minimize the temperature spread.

3.1.9 Control of auxiliary resistive heating elements. Except as noted, disable heat pump resistance elements used for heating indoor air at all times, including during defrost cycles and if they are normally regulated by a heat comfort controller. For heat pumps equipped with a heat comfort controller, enable the heat pump resistance elements only during the below-described, short test that follows the H1 or, if conducted, the H1C Test. Set the heat comfort controller to provide the maximum supply air temperature. With the heat pump operating and while maintaining the Heating Certified Air Volume Rate, measure the temperature of the air leaving the indoor-side beginning 5 minutes after activating the heat comfort controller. Sample the outlet dry-bulb temperature at regular intervals that span 5 minutes or less. Collect data for 10 minutes, obtaining at least 3 samples. Calculate the average outlet temperature over the 10-minute interval, T_{CC}.

3.2 Cooling mode tests for different types of air conditioners and heat pumps.

3.2.1 Tests for a unit having a single-speed compressor that is tested with a fixed-speed indoor fan installed, with a constant-air-volume-rate indoor fan installed, or with no indoor fan installed. Conduct two steady-state wet coil tests, the A and B Tests. Use the two optional dry-coil tests, the steady-state C Test and the cyclic D Test, to determine the cooling mode cyclic degradation coefficient, C^c_D. If the two optional tests are not conducted, assign C^c_D the default value of 0.25. Table 3 specifies test conditions for these four tests.

TABLE 3.—COOLING MODE TEST CONDITIONS FOR UNITS HAVING A SINGLE-SPEED COMPRESSOR AND A FIXED-SPEED INDOOR FAN, A CONSTANT AIR VOLUME RATE INDOOR FAN, OR NO INDOOR FAN

Test Description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Cooling Air Volume Rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb	
A Test—required (steady, wet coil)	80	67	95	[1] 75	Cooling Certified [2]
B Test—required (steady, wet coil)	80	67	82	[1] 65	Cooling Certified [2]
C Test—optional (steady, dry coil)	80	[3]	82	–	Cooling Certified [2]
D Test—optional (cyclic, dry coil)	80	[3]	82	–	[4]

[1] The specified test condition only applies if the unit rejects condensate to the outdoor coil.
[2] Defined in Section 3.1.4.1.
[3] The entering air must have a low enough moisture content so no condensate forms on the indoor coil. DOE recommends using an indoor air wet-bulb temperature of 57 °F or less.
[4] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the C Test.

3.2.2 Tests for a unit having a single-speed compressor and a variable-speed variable-air-volume-rate indoor fan installed.

3.2.2.1 Indoor fan capacity modulation that correlates with the outdoor dry bulb temperature. Conduct four steady-state wet coil tests: The A_2, A_1, B_2, and B_1 Tests. Use the two optional dry-coil tests, the steady-state C_1 Test and the cyclic D_1 Test, to determine the cooling mode cyclic degradation coefficient, C^c_D. If the two optional tests are not conducted, assign C^c_D the default value of 0.25. Table 4 specifies test conditions for these six tests.

3.2.2.2 Indoor fan capacity modulation based on adjusting the sensible to total (S/T) cooling capacity ratio. The testing requirements are the same as specified in Section 3.2.1 and Table 3. Use a Cooling Certified Air Volume Rate that represents a normal residential installation. If performed, conduct the steady-state C Test and the cyclic D Test with the unit operating in the same S/T capacity control mode as used for the B Test.

TABLE 4.—COOLING MODE TEST CONDITIONS FOR UNITS HAVING A SINGLE-SPEED COMPRESSOR AND A VARIABLE AIR VOLUME RATE INDOOR FAN THAT IS CONTROLLED AS SPECIFIED IN 3.2.2.1

Test description	Air entering indoor unit temperature (°F)		Air entering outdoor unit temperature (°F)		Cooling air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb	
A_2 Test—required (steady, wet coil)	80	67	95	([1]) 75	Cooling Certified [2].
A_1 Test—required (steady, wet coil)	80	67	95	([1]) 75	Cooling Minimum [3].
B_2 Test—required (steady, wet coil)	80	67	82	([1]) 65	Cooling Certified [2].
B_1 Test—required (steady, wet coil)	80	67	82	([1]) 65	Cooling Minimum [3].
C_1 Test [4]—optional (steady, dry coil)	80	([4])	82	.....	Cooling Minimum [3].
D_1 Test [4]—optional (cyclic, dry coil)	80	([4])	82	.....	([5]).

[1] The specified test condition only applies if the unit rejects condensate to the outdoor coil.
[2] Defined in Section 3.1.4.1.
[3] Defined in Section 3.1.4.2.
[4] The entering air must have a low enough moisture content so no condensate forms on the indoor coil. DOE recommends using an indoor air wet-bulb temperature of 57 °F or less.
[5] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the C_1 Test.

3.2.3 *Tests for a unit having a two-capacity compressor.* a. (See Definition 1.44.) Conduct four steady-state wet coil tests: The A_2, A_1, B_2, and B_1 Tests. Use the two optional dry-coil tests, the steady-state C_1 Test and the cyclic D_1 Test, to determine the cooling mode cyclic degradation coefficient, C^c_D. If the two optional tests are not conducted, assign C^c_D the default value of 0.25. Table 5 specifies test conditions for these six tests.

b. For units having a variable speed indoor fan that is modulated to adjust the sensible to total (S/T) cooling capacity ratio, use Cooling Certified and Cooling Minimum Air Volume Rates that represent a normal residential installation. Additionally, if conducting the optional dry-coil tests, operate the unit in the same S/T capacity control mode as used for the B_1 Test.

c. Two-capacity units that operate exclusively, via a lockout feature, at low compressor capacity when space cooling must be tested as a single speed system (see Section 3.2.1 and Table 3). If a two-capacity

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unit locks out low capacity operation at outdoor temperatures that are less than 95 °F, conduct the A_1 Test using the outdoor temperature conditions listed for the F_1 Test in Table 6 rather than using the outdoor temperature conditions listed in Table 5 for the A_1 Test.

TABLE 5.—COOLING MODE TEST CONDITIONS FOR UNITS HAVING A TWO-CAPACITY COMPRESSOR

Test description	Air entering indoor unit temperature (°F)		Air entering outdoor unit temperature (°F)		Compressor capacity	Cooling air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
A_2 Test—required (steady, wet coil)	80	67	95	[1]75	High	Cooling Certified[2].
A_1 Test—required (steady, wet coil)	80	67	95	[1]75	Low	Cooling Minimum[3].
B_2 Test—required (steady, wet coil)	80	67	82	[1]65	High	Cooling Certified[2].
B_1 Test—required (steady, wet coil)	80	67	82	[1]65	Low	Cooling Minimum[3].
C_1 Test[4]—optional (steady, dry coil)	80	[4]	82		Low	Cooling Minimum[3].
D_1 Test[4]—optional (cyclic, dry coil)	[4]80	82		Low	[5].	

[1] The specified test condition only applies if the unit rejects condensate to the outdoor coil.
[2] Defined in Section 3.1.4.1.
[3] Defined in Section 3.1.4.2.
[4] The entering air must have a low enough moisture content so no condensate forms on the indoor coil. DOE recommends using an indoor air wet-bulb temperature of 57 °F or less.
[5] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the C_1 Test.

3.2.4 Tests for a unit having a variable-speed compressor. a. Conduct five steady-state wet coil tests: the A_2, E_V, B_2, B_1, and F_1 Tests. Use the two optional dry-coil tests, the steady-state G_1 Test and the cyclic I_1 Test, to determine the cooling mode cyclic degradation coefficient, C_D^c. If the two optional tests are not conducted, assign C_D^c the default value of 0.25. Table 6 specifies test conditions for these seven tests. Determine the intermediate compressor speed cited in Table 6 using:

$$\text{Intermediate speed} = \text{Minimum speed} + \frac{\text{Maximum speed} - \text{Minimum speed}}{3}$$

where a tolerance of plus 5 percent or the next higher inverter frequency step from that calculated is allowed.

b. For units that modulate the indoor fan speed to adjust the sensible to total (S/T) cooling capacity ratio, use Cooling Certified, Cooling Intermediate, and Cooling Minimum Air Volume Rates that represent a normal residential installation. Additionally, if conducting the optional dry-coil tests, operate the unit in the same S/T capacity control mode as used for the F_1 Test.

TABLE 6.—COOLING MODE TEST CONDITIONS FOR UNITS HAVING A VARIABLE-SPEED COMPRESSOR

Test description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Compressor speed	Cooling air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
A^2 Test—required (steady, wet coil)	80	67	95	[1]75	Maximum	Cooling Certified[2]
B_2 Test—required (steady, wet coil)	80	67	82	[1]65	Maximum	Cooling Certified[2]
E_V Test—required (steady, wet coil)	80	67	87	[1]69	Intermediate	Cooling Intermediate[3]
B_1 Test—required (steady, wet coil)	80	67	82	[1]65	Minimum	Cooling Minimum[4]
F_1 Test—required (steady, wet coil)	80	67	67	[1]53.5	Minimum	Cooling Minimum[4]
G_1 Test[5]—optional (steady, dry coil)	80	(5)	67		Minimum	Cooling Minimum[4]
I_1 Test[5]—optional (cyclic, dry coil)	80	[5]	67		Minimum	[6]

[1] The specified test condition only applies if the unit rejects condensate to the outdoor coil.
[2] Defined in Section 3.1.4.1.
[3] Defined in Section 3.1.4.3.
[4] Defined in Section 3.1.4.2.
[5] The entering air must have a low enough moisture content so no condensate forms on the indoor coil. DOE recommends using an indoor air wet bulb temperature of 57 °F or less.
[6] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the G_1 Test.

3.3 *Test procedures for steady-state wet coil cooling mode tests* (the *A*, A_2, A_1, *B*, B_2, B_1, E_V, and F_1 Tests). a. For the pretest interval, operate the test room reconditioning apparatus and the unit to be tested until maintaining equilibrium conditions for at least 30 minutes at the specified Section 3.2 test conditions. Use the exhaust fan of the airflow measuring apparatus and, if installed, the indoor fan of the test unit to obtain and then maintain the indoor air volume rate and/or external static pressure specified for the particular test. Continuously record (see Definition 1.14):

(1) The dry-bulb temperature of the air entering the indoor coil,

(2) The water vapor content of the air entering the indoor coil,

(3) The dry-bulb temperature of the air entering the outdoor coil, and

(4) For the Section 2.2.4 cases where its control is required, the water vapor content of the air entering the outdoor coil.

b. Refer to Section 3.11 for additional requirements that depend on the selected secondary test method. After satisfying the pretest equilibrium requirements, make the measurements specified in Table 5 of ASHRAE Standard 37–88 for the Indoor Air Enthalpy method and the user-selected secondary method. Except for external static pressure, make the Table 5 measurements at equal intervals that span 10 minutes or less. Measure external static pressure every 5 minutes or less. Continue data sampling until you obtain a 30-minute period (*e.g.*, four consecutive 10-minute samples) where the test tolerances specified in Table 7 are satisfied. For those continuously recorded parameters, use the entire data set from the 30-minute interval to evaluate Table 7 compliance. Determine the average electrical power consumption of the air conditioner or heat pump over the same 30-minute interval.

c. Calculate indoor-side total cooling capacity as specified in Section 7.3.3.1 of ASHRAE Standard 37–88. Do not adjust the parameters used in calculating capacity for the permitted variations in test conditions. Evaluate air enthalpies based on the measured barometric pressure. Assign the average total space cooling capacity and electrical power consumption over the 30-minute data collection interval to the variables $\dot{Q}_c^k(T)$ and $\dot{E}_c^k(T)$, respectively. For these two variables, replace the "*T*" with the nominal outdoor temperature at which the test was conducted. The superscript *k* is used only when testing multi-capacity units. Use the superscript $k=2$ to denote a test with the unit operating at high capacity or maximum speed, $k=1$ to denote low capacity or minimum speed, and $k=v$ to denote the intermediate speed. For units tested without an indoor fan installed, decrease $\dot{Q}_c^k(T)$ by

$$\frac{1250\ \text{Btu/h}}{1000\ \text{scfm}} \cdot \bar{V}_s,$$

and increase $\dot{E}_c^k(T)$ by,

$$\frac{365\ \text{W}}{1000\ \text{scfm}} \cdot \bar{V}_s,$$

Where

$\bar{V}_s$

is the average measured indoor air volume rate expressed in units of cubic feet per minute of standard air (SCFM).

TABLE 7.—TEST OPERATING AND TEST CONDITION TOLERANCES FOR SECTION 3.3 STEADY-STATE WET COIL COOLING MODE TESTS AND SECTION 3.4 DRY COIL COOLING MODE TESTS

	Test operating tolerance [1]	Test Condition Tolerance [2]
Indoor dry-bulb, °F:		
Entering temperature	2.0	0.5
Leaving temperature	2.0	
Indoor wet-bulb, °F:		
Entering temperature	1.0	[3]0.3
Leaving temperature	[3]1.0	
Outdoor dry-bulb, °F:		
Entering temperature	2.0	0.5
Leaving temperature	[4]2.0	
Outdoor wet-bulb, °F:		
Entering temperature	1.0	[5]0.3
Leaving temperature	[4]1.0	
External resistance to airflow, inches of water	0.05	[6]0.02
Electrical voltage, % of rdg.	2.0	1.5
Nozzle pressure drop, % of rdg.	2.0	

[1] See Definition 1.40.
[2] See Definition 1.39.
[3] Only applies during wet coil tests; does not apply during steady-state, dry coil cooling mode tests.
[4] Only applies when using the Outdoor Air Enthalpy Method.
[5] Only applies during wet coil cooling mode tests where the unit rejects condensate to the outdoor coil.
[6] Only applies when testing non-ducted units.

d. For air conditioners and heat pumps having a constant-air-volume-rate indoor fan, the five additional steps listed below are required if the average of the measured external static pressures exceeds the applicable Section 3.1.4 minimum (or target) external static pressure (ΔP_{min}) by 0.03 inches of water or more.

1. Measure the average power consumption of the indoor fan motor ($\dot{E}_{fan,1}$) and record the corresponding external static pressure (ΔP_1) during or immediately following the 30-minute interval used for determining capacity.

2. After completing the 30-minute interval and while maintaining the same test conditions, adjust the exhaust fan of the airflow measuring apparatus until the external static pressure increases to approximately $\Delta P_1 + (\Delta P_1 - \Delta P_{min})$.

3. After re-establishing steady readings of the fan motor power and external static pressure, determine average values for the indoor fan power ($\dot{E}_{fan,2}$) and the external static pressure (ΔP_2) by making measurements over a 5-minute interval.

4. Approximate the average power consumption of the indoor fan motor at ΔP_{min} using linear extrapolation:

$$\dot{E}_{fan,min} = \frac{\dot{E}_{fan,2} - \dot{E}_{fan,1}}{\Delta P_2 - \Delta P_1}(\Delta P_{min} - \Delta P_1) + \dot{E}_{fan,1}.$$

5. Increase the total space cooling capacity, $\dot{Q}_c^k(T)$, by the quantity $(\dot{E}_{fan,1} - \dot{E}_{fan,min})$, when expressed on a Btu/h basis. Decrease the total electrical power, $\dot{E}_c^k(T)$, by the same fan power difference, now expressed in watts.

3.4 Test procedures for the optional steady-state dry coil cooling mode tests (the C, C_1, and G1 Tests). a. Except for the modifications noted in this section, conduct the steady-state dry coil cooling mode tests as specified in Section 3.3 for wet coil tests. Prior to recording data during the steady-state dry coil test, operate the unit at least one hour after achieving dry coil conditions. Drain the drain pan and plug the drain opening. Thereafter, the drain pan should remain completely dry.

b. Denote the resulting total space cooling capacity and electrical power derived from

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the test as $\dot{Q}^{c}_{ss,dry}(T)$ and $\dot{E}_{ss,dry}(T)$. In preparing for the Section 3.5 cyclic test, record the average indoor-side air volume rate, $\bar{V}$, specific heat $C_{p,a}$ of the air, (expressed on dry air basis), specific volume of the air at the nozzle(s), v_n, humidity ratio at the nozzle(s), W_n, and either pressure difference or velocity pressure for the flow nozzle(s). For units having a variable-speed indoor fan (that provides either a constant or variable air volume rate) that will or may be tested during the cyclic dry coil cooling mode test with the indoor fan turned off (see Section 3.5), include the electrical power used by the indoor fan motor among the recorded parameters from the 30-minute test.

3.5 Test procedures for the optional cyclic dry coil cooling mode tests (the D, D_1, and I_1 Tests). a. After completing the steady-state dry-coil test, remove the Outdoor Air Enthalpy method test apparatus, if connected, and begin manual OFF/ON cycling of the unit's compressor. The test set-up should otherwise be identical to the set-up used during the steady-state dry coil test. When testing heat pumps, leave the switchover valve during the compressor OFF cycles in the same position as used for the compressor ON cycles, unless automatically changed by the controls of the unit. For units having a variable-speed indoor fan, the manufacturer has the option of electing at the outset whether to conduct the cyclic test with the indoor fan enabled or disabled. Always revert to testing with the indoor fan disabled if cyclic testing with the fan enabled is unsuccessful.

b. For units having a single-speed or two-capacity compressor, cycle the compressor OFF for 24 minutes and then ON for 6 minutes ($\Delta\tau_{cyc,dry}$ = 0.5 hours). For units having a variable-speed compressor, cycle the compressor OFF for 48 minutes and then ON for 12 minutes ($\Delta\tau_{cyc,dry}$ = 1.0 hours). Repeat the OFF/ON compressor cycling pattern until you complete the test. Allow the controls of the unit to regulate cycling of the outdoor fan.

c. Sections 3.5.1 and 3.5.2 specify airflow requirements through the indoor coil of ducted and non-ducted systems, respectively. In all cases, use the exhaust fan of the airflow measuring apparatus (covered under Section 2.6) along with the indoor fan of the unit, if installed and operating, to approximate a step response in the indoor coil airflow. Regulate the exhaust fan to quickly obtain and then maintain the flow nozzle(s) static pressure difference or velocity pressure at the same value as was measured during the steady-state dry coil test. The pressure difference or velocity pressure should be within 2 percent of the value from the steady-state dry coil test within 15 seconds after airflow initiation. For units having a variable-speed indoor fan that ramps when cycling on and/or off, use the exhaust fan of the airflow measuring apparatus to impose a step response that begins at the initiation of ramp up and ends at the termination of ramp down.

d. For units having a variable-speed indoor fan, conduct the cyclic dry coil test using a pull-thru approach if any of the following occur when testing with the fan operating:

(1) The test unit automatically cycles off,

(2) Its blower motor reverses, or

(3) The unit operates for more than 30 seconds at a external static pressure that is 0.1 inches of water or more higher than the value measured during the prior steady-state test.

e. For the pull-thru approach, disable the indoor fan and use the exhaust fan of the airflow measuring apparatus to generate the specified flow nozzle(s) static pressure difference or velocity pressure. If the exhaust fan cannot deliver the required pressure difference because of resistance created by the unpowered blower, temporarily remove the blower. After completing a minimum of two complete compressor OFF/ON cycles, determine the overall cooling delivered and total electrical energy consumption during any subsequent data collection interval where the test tolerances given in Table 8 are satisfied. DOE recommends obtaining repeatable results for two or more data collection intervals before terminating the test. If available, use electric resistance heaters (see Section 2.1) to minimize the variation in the inlet air temperature. With regard to the Table 8 parameters, continuously record the dry-bulb temperature of the air entering the indoor and outdoor coils during periods when air flows through the respective coils. Sample the water vapor content of the indoor coil inlet air at least every 2 minutes during periods when air flows through the coil. Record external static pressure and the air volume rate indicator (either nozzle pressure difference or velocity pressure) at least every minute during the interval that air flows through the indoor coil. (These regular measurements of the airflow rate indicator are in addition to the required measurement at 15 seconds after flow initiation.) Sample the electrical voltage at least every 2 minutes beginning 30 seconds after compressor start-up. Continue until the compressor, the outdoor fan, and the indoor fan (if it is installed and operating) cycle off.

f. For ducted units, continuously record the dry-bulb temperature of the air entering (as noted above) and leaving the indoor coil. Or if using a thermopile, continuously record the difference between these two temperatures during the interval that air flows through the indoor coil. For non-ducted units, make the same dry-bulb temperature measurements beginning when the compressor cycles on and ending when indoor coil airflow ceases.

Integrate the electrical power over complete cycles of length $\Delta\tau_{cyc,dry}$. For ducted units tested with an indoor fan installed and operating, integrate electrical power from indoor fan OFF to indoor fan OFF. For all other ducted units and for non-ducted units, integrate electrical power from compressor OFF to compressor OFF. (Some cyclic tests will use the same data collection intervals to determine the electrical energy and the total space cooling. For other units, you will terminate data collection used to determine the electrical energy before you terminate data collection used to determine total space cooling.]

TABLE 8.—TEST OPERATING AND TEST CONDITION TOLERANCES FOR CYCLIC DRY COIL COOLING MODE TESTS

	Test operating tolerance [1]	Test condition tolerance [2]
Indoor entering dry-bulb temperature [3], °F	2.0	0.5
Indoor entering wet-bulb temperature, °F	.....	([4])
Outdoor entering dry-bulb temperature [3], °F	2.0	0.5
External resistance to airflow [3], inches of water	0.05	
Airflow nozzle pressure difference or velocity pressure [3], % of reading	2.0	[5]2.0
Electrical voltage ([6]), % of rdg.	2.0	1.5

[1] See Definition 1.40.
[2] See Definition 1.39.
[3] Applies during the interval that air flows through the indoor (outdoor) coil except for the first 30 seconds after flow initiation. For units having a variable-speed indoor fan that ramps, the tolerances listed for the external resistance to airflow apply from 30 seconds after achieving full speed until ramp down begins.
[4] Shall at no time exceed a wet-bulb temperature that results in condensate forming on the indoor coil.
[5] The test condition shall be the average nozzle pressure difference or velocity pressure measured during the steady-state dry coil test.
[6] Applies during the interval when at least one of the following—the compressor, the outdoor fan, or, if applicable, the indoor fan—are operating except for the first 30 seconds after compressor start-up.

g. If the Table 8 tolerances are satisfied over the complete cycle, record the measured electrical energy consumption as $e_{cyc,dry}$ and express it in units of watt-hours. Calculate the total space cooling delivered, $q_{cyc,dry}$, in units of Btu using,

$$q_{cyc,\,dry} = \frac{60 \cdot \bar{V} \cdot C_{p,a} \cdot \Gamma}{\left[v'_n \cdot (1 + W_n)\right]} = \frac{60 \cdot \bar{V} \cdot C_{p,a} \cdot \Gamma}{v_n} \qquad (3.5-1)$$

where $\dot{V}$, $C_{p,a}$, v_n' (or v_n), and W_n are the values recorded during the Section 3.4 dry coil steady-state test and,

$$\Gamma = \int_{\tau_1}^{\tau_2} \left[T_{a1}(\tau) - T_{a2}(\tau)\right] d\tau, \text{ hr} \cdot {}^{\circ}\text{F}.$$

$T_{a1}(\tau)$ = dry bulb temperature of the air entering the indoor coil at time τ, °F.
$T_{a2}(\tau)$ = dry bulb temperature of the air leaving the indoor coil at time τ, °F.
τ_1 = for ducted units, the elapsed time when airflow is initiated through the indoor coil; for non-ducted units, the elapsed time when the compressor is cycled on, hr.
τ_2 = the elapsed time when indoor coil airflow ceases, hr.

3.5.1 *Procedures when testing ducted systems.* The automatic controls that are normally installed with the test unit must govern the OFF/ON cycling of the air moving equipment on the indoor side (exhaust fan of the airflow measuring apparatus and, if installed, the indoor fan of the test unit). For example, for ducted units tested without an indoor fan installed but rated based on using a fan time delay relay, control the indoor coil airflow according to the rated ON and/or OFF delays provided by the relay. For ducted units having a variable-speed indoor fan that has been disabled (and possibly removed),

$$\frac{365\ \text{W}}{1000\ \text{scfm}} \cdot \bar{V}_s \cdot \left[\tau_2 - \tau_1\right], \qquad (3.5-2)$$

and decrease $q_{cyc,dry}$ by,

$$\frac{1250\ \text{Btu/h}}{1000\ \text{scfm}} \cdot \bar{V}_s \cdot \left[\tau_2 - \tau_1\right]. \qquad (3.5-3)$$

where

$\bar{V}_s$

is the average indoor air volume rate from the Section 3.4 dry coil steady-state test and is expressed in units of cubic feet per minute of standard air (SCFM). For units having a variable-speed indoor fan that is disabled during the cyclic test, increase $e_{cyc,dry}$ and decrease $q_{cyc,dry}$ based on:

a. The product of $[\tau_2 - \tau_1]$ and the indoor fan power measured during or following the dry coil steady-state test or,

b. The following algorithm if the indoor fan ramps its speed when cycling.

1. Measure the electrical power consumed by the variable-speed indoor fan at a minimum of three operating conditions: at the speed/air volume rate/external static pressure that was measured during the steady-state test, at operating conditions associated with the midpoint of the ramp-up interval, and at conditions associated with the midpoint of the ramp-down interval. For these measurements, the tolerances on the airflow volume or the external static pressure are the same as required for the Section 3.4 steady-state test.

2. For each case, determine the fan power from measurements made over a minimum of 5 minutes.

3. Approximate the electrical energy consumption of the indoor fan if it had operated during the cyclic test using all three power measurements. Assume a linear profile during the ramp intervals. The manufacturer must provide the durations of the ramp-up and ramp-down intervals. If a manufacturer-supplied ramp interval exceeds 45 seconds, use a 45-second ramp interval nonetheless when estimating the fan energy. The manufacturer is allowed to choose option a, and forego the extra testing burden of option b, even if the unit ramps indoor fan speed when cycling.

3.5.2 *Procedures when testing non-ducted systems.* Do not use air dampers when conducting cyclic tests on non-ducted units. Until the last OFF/ON compressor cycle, airflow through the indoor coil must cycle off and on in unison with the compressor. For the last OFF/ON compressor cycle—the one used to determine $e_{cyc,dry}$ and $q_{cyc,dry}$—use the exhaust fan of the airflow measuring apparatus and the indoor fan of the test unit to have indoor airflow start 3 minutes prior to compressor cut-on and end three minutes after compressor cutoff. Subtract the electrical energy used by the indoor fan during the 3 minutes prior to compressor cut-on from the integrated electrical energy, $e_{cyc,dry}$. Add the electrical energy used by the indoor fan during the 3 minutes after compressor cutoff to the integrated cooling capacity, $q_{cyc,dry}$. For the case where the non-ducted unit uses a variable-speed indoor fan which is disabled during the cyclic test, correct $e_{cyc,dry}$ and $q_{cyc,dry}$ using the same approach as prescribed in Section 3.5.1 for ducted units having a disabled variable-speed indoor fan.

3.5.3 *Cooling mode cyclic degradation coefficient calculation.* Use two optional dry-coil tests to determine the cooling mode cyclic degradation coefficient, C_D^c. If the two optional tests are not conducted, assign C_D^c the default value of 0.25. Evaluate C_D^c using the above results and those from the Section 3.4 dry coil steady-state test.0

$$C_D^c = \frac{1 - \frac{EER_{cyc,\,dry}}{EER_{ss,\,dry}}}{1 - CLF}$$

where,

$$EER_{cyc,\,dry} = \frac{q_{cyc,dry}}{e_{cyc,dry}},$$

the average energy efficiency ratio during the cyclic dry coil cooling mode test, Btu/W-h

$$EER_{ss,\,dry} = \frac{\dot{Q}_{ss,\,dry}}{\dot{E}_{ss,\,dry}},$$

the average energy efficiency ratio during the steady-state dry coil cooling mode test, Btu/W-h

$$CLF = \frac{q_{cyc,\,dry}}{\dot{Q}_{ss,\,cyc} \cdot \Delta\tau_{cyc,\,dry}},$$

the cooling load factor, dimensionless.

Round the calculated value for C_D^c to the nearest 0.01. If C_D^c is negative, then set it equal to zero.

3.6 *Heating mode tests for different types of heat pumps, including heating-only heat pumps.*

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3.6.1 Tests for a heat pump having a single-speed compressor that is tested with a fixed speed indoor fan installed, with a constant-air-volume-rate indoor fan installed, or with no indoor fan installed. Conduct three tests: the High Temperature (*H1*) Test, the Frost Accumulation (*H2*) Test, and the Low Temperature (*H3*) Test. Conduct the optional High Temperature Cyclic (*H1C*) Test to determine the heating mode cyclic degradation coefficient, C_D^h. If this optional test is not conducted, assign C_D^h the default value of 0.25. Test conditions for these four tests are specified in Table 9.

TABLE 9.—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A SINGLE-SPEED COMPRESSOR AND A FIXED-SPEED INDOOR FAN, A CONSTANT AIR VOLUME RATE INDOOR FAN, OR NO INDOOR FAN

Test description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb	
H1 Test (required, steady)	70	60 (max)	47	43	Heating certified [1]
H1C Test (optional, cyclic)	70	60 (max)	47	43	[2]
H2 Test (required)	70	60 (max)	35	33	Heating certified [1]
H3 Test (required, steady)	70	60 (max)	17	15	Heating certified [1]

[1] Defined in Section 3.1.4.4.
[2] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the *H1* Test.

3.6.1.1 Non-defrost heat pump. For non-defrost heat pumps (see Definition 1.30) that cease compressor operation at outdoor dry-bulb temperatures less than 37 °F, do not conduct the *H2* and *H3* Tests. Instead, conduct a Maximum Temperature (*H0*) Test using the Table 9 Heating Certified Air Volume Rate and the indoor and outdoor coil air inlet conditions specified for the $H0_I$ Test in Table 11.

3.6.1.2 Heat pump having a heat comfort controller. Test any heat pump that has a heat comfort controller (see Definition 1.26) according to Section 3.6.1 and Table 9 with the heat comfort controller disabled. Additionally, conduct the abbreviated test described in Section 3.1.9 with the heat comfort controller active to determine the system's maximum supply air temperature.

3.6.2 Tests for a heat pump having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor fan: capacity modulation correlates with outdoor dry bulb temperature. Conduct five tests: two High Temperature Tests ($H1_2$ and $H1_I$), one Frost Accumulation Test ($H2_2$), and two Low Temperature Tests ($H3_2$ and $H3_I$). Conducting one Frost Accumulation Test ($H2_I$), is optional. Conduct the optional High Temperature Cyclic ($H1C_I$) Test to determine the heating mode cyclic degradation coefficient, C_D^h If this optional test is not conducted, assign C_D^h the default value of 0.25. Table 10 specifies test conditions for these seven tests. If you do not conduct the optional $H2_I$ Test, use the following equations to approximate the capacity and electrical power of the heat pump at the $H2_I$ test conditions:

$$\dot{Q}_h^{k=1}(35) = QR_h^{k=2}(35) \cdot \left\{\dot{Q}_h^{k=1}(17) + 0.6 \cdot \left[\dot{Q}_h^{k=1}(47) - \dot{Q}_h^{k=1}(17)\right]\right\}$$

$$\dot{E}_h^{k=1}(35) = PR_h^{k=2}(35) \cdot \left\{\dot{E}_h^{k=1}(17) + 0.6 \cdot \left[\dot{E}_h^{k=1}(47) - \dot{E}_h^{k=1}(17)\right]\right\}$$

where,

$$QR_h^{k=2}(35) = \frac{\dot{Q}_h^{k=2}(35)}{\dot{Q}_h^{k=2}(17) + 0.6 \cdot \left[\dot{Q}_h^{k=2}(47) - \dot{Q}_h^{k=2}(17)\right]}$$

$$PR_h^{k=2}(35) = \frac{\dot{E}_h^{k=2}(35)}{\dot{E}_h^{k=2}(17) + 0.6 \cdot \left[\dot{E}_h^{k=2}(47) - \dot{E}_h^{k=2}(17)\right]}$$

The quantities $\dot{Q}_h^{k=2}(47)$, $\dot{E}_h^{k=2}(47)$, $\dot{Q}_h^{k=1}(47)$, and $\dot{E}_h^{k=1}(47)$ are determined from the $H1_2$ and $H1_I$ Tests and evaluated as specified in Section 3.7; the quantities $\dot{Q}_h^{k=2}(35)$ and $\dot{E}_h^{k=2}(35)$ are determined from the $H2_2$ Test and evaluated as specified in Section 3.9; and the quantities $\dot{Q}_h^{k=2}(17)$, $\dot{E}_h^{k=2}(17)$, $\dot{Q}_h^{k=1}(17)$, and $\dot{E}_h^{k=1}(17)$ are determined from the $H3_2$ and $H3_I$ Tests and evaluated as specified in Section 3.10.

TABLE 10.—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A SINGLE-SPEED COMPRESSOR AND A VARIABLE AIR VOLUME RATE INDOOR FAN

Test description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb	
$H1_2$ Test (required, steady)	70	60 (max)	47	43	Heating certified [1]
$H1_I$ Test (required, steady)	70	60 (max)	47	43	Heating minimum [2]
$H1C_I$ Test (optional, cyclic)	70	60 (max)	47	43	[3]
$H2_2$ Test (required)	70	60 (max)	35	33	Heating certified [1]
$H2_I$ Test (optional)	70	60 (max)	35	33	Heating minimum [2]
$H3_2$ Test (required, steady)	70	60 (max)	17	15	Heating certified [1]
$H3_I$ Test (required, steady)	70	60 (max)	17	15	Heating minimum [2]

[1] Defined in Section 3.1.4.4.
[2] Defined in Section 3.1.4.5.
[3] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the $H1_I$ Test.

3.6.3 Tests for a heat pump having a two-capacity compressor (see Definition 1.44).

a. Conduct one Maximum Temperature Test ($H0_I$), two High Temperature Tests ($H1_2$ and $H1_I$), one Frost Accumulation Test ($H2_2$), and one Low Temperature Test ($H3_2$). Conduct an additional Frost Accumulation Test ($H2_I$) and Low Temperature Test ($H3_I$) if both of the following conditions exist:

1. You need to know the heat pump's capacity and electrical power at low compressor capacity for outdoor temperatures of 37 °F and less to complete the Section 4.2.3 seasonal performance calculations, and

2. The heat pump's controls allow low capacity operation at outdoor temperatures of 37 °F and less.

b. Conduct the optional Maximum Temperature Cyclic Test ($H0C_I$) to determine the heating mode cyclic degradation coefficient, C_D^h. If this optional test is not conducted, assign C_D^h the default value of 0.25. Table 11 specifies test conditions for these eight tests.

TABLE 11.—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A TWO-CAPACITY COMPRESSOR

Test description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Compressor capacity	Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
$H0_I$ Test (required, steady)	70	60(max)	62	56.5	Low	Heating minimum [1]
$H0C_I$ Test (optional, cyclic)	70	60(max)	62	56.5	Low	[2]
$H1_2$ Test (required, steady)	70	60(max)	47	43	High	Heating certified [3]
$H1_I$ Test (required, steady)	70	60(max)	47	43	Low	Heating minimum [2]
$H2_2$ Test (required)	70	60(max)	35	33	High	Heating certified [3]
$H2_I$ Test [4] (required)	70	60(max)	35	33	High	Heating minimum [1]
$H3_2$ Test (required, steady)	70	60(max)	17	15	High	Heating certified [3]
$H3_I$ Test [4] (required, steady)	70	60(max)	17	15	Low	Heating minimum [1]

[1] Defined in Section 3.1.4.5.
[2] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the *H01* Test.
[3] Defined in Section 3.1.4.4.
[4] Required only if the heat pump's performance when operating at low compressor capacity and outdoor temperatures less than 37 °F is needed to complete the Section 4.2.3 *HSPF* calculations.

3.6.4 Tests for a heat pump having a variable-speed compressor. Conduct one Maximum Temperature Test ($H0_1$), two High Temperature Tests ($H1_2$ and $H1_1$), one Frost Accumulation Test ($H2_V$), and one Low Temperature Test ($H3_2$). Conducting one or both of the following tests is optional: an additional High Temperature Test ($H1_N$) and an additional Frost Accumulation Test ($H2_2$). Conduct the optional Maximum Temperature Cyclic ($H0C_1$) Test to determine the heating mode cyclic degradation coefficient, C_D^h. If this optional test is not conducted, assign C_D^h the default value of 0.25. Table 12 specifies test conditions for these eight tests. Determine the intermediate compressor speed cited in Table 12 using the heating mode maximum and minimum compressors speeds and:

$$\text{Intermediate speed} = \text{Minimum speed} + \frac{\text{Maximum speed} - \text{Minimum speed}}{3}$$

where a tolerance of plus 5 percent or the next higher inverter frequency step from that calculated is allowed. If you do not conduct the $H2_2$ Test, use the following equations to approximate the capacity and electrical power at the $H2_2$ test conditions:

$$\dot{Q}_h^{k=2}(35) = 0.90 \cdot \left\{\dot{Q}_h^{k=2}(17) + 0.6 \cdot \left[\dot{Q}_h^{k=2}(47) - \dot{Q}_h^{k=2}(17)\right]\right\}$$

$$\dot{E}_h^{k=2}(35) = 0.985 \cdot \left\{\dot{E}_h^{k=2}(17) + 0.6 \cdot \left[\dot{E}_h^{k=2}(47) - \dot{E}_h^{k=2}(17)\right]\right\}.$$

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Determine the quantities $\dot{Q}_h^{k=2}(47)$ and $\dot{E}_h^{k=2}(47)$ from the $H1_2$ Test and evaluate them according to Section 3.7. Determine the quantities $\dot{Q}_h^{k=2}(17)$ and $\dot{E}_h^{k=2}(17)$ from the $H3_2$ Test and evaluate them according to Section 3.10. For heat pumps where the heating mode maximum compressor speed exceeds its cooling mode maximum compressor speed, conduct the $H1_N$ Test if the manufacturer requests it. If you conduct the $H1_N$ Test, operate the heat pump's compressor at the same speed as used for the cooling mode A_2 Test. Refer to the last sentence of Section 4.2 to see how the results of the $H1_N$ Test may be used in calculating the heating seasonal performance factor.

TABLE 12.—HEATING MODE TEST CONDITIONS FOR UNITS HAVING A VARIABLE-SPEED COMPRESSOR

Test description	Air entering indoor unit Temperature (°F)		Air entering outdoor unit Temperature (°F)		Compressor speed	Heating air volume rate
	Dry bulb	Wet bulb	Dry bulb	Wet bulb		
$H0_1$ Test (required, steady)	70	60(max)	62	56.5	Minimum	Heating minimum [1]
$H0C_1$ Test (optional, cyclic)	70	60(max)	62	56.5	Minimum	[2]
$H1_2$ Test (required, steady)	70	60(max)	47	43	Maximum	Heating certified [3]
$H1_1$ Test (required, steady)	70	60(max)	47	43	Minimum	Heating minimum [2]
$H1_N$ Test (optional, steady)	70	60(max)	47	43	Cooling Mode Maximum.	Heating nominal [4]
$H2_2$ Test (optional)	70	60(max)	35	33	Maximum	Heating certified [3]
$H2_V$ Test (required)	70	60(max)	35	33	Intermediate	Heating intermediate [5]
$H3_2$ Test (required, steady)	70	60(max)	17	15	Maximum	Heating certified [3]

[1] Defined in Section 3.1.4.5.
[2] Maintain the airflow nozzle(s) static pressure difference or velocity pressure during the ON period at the same pressure difference or velocity pressure as measured during the H01 Test.
[3] Defined in Section 3.1.4.4.
[4] Defined in Section 3.1.4.7.
[5] Defined in Section 3.1.4.6.

3.7 *Test procedures for steady-state Maximum Temperature and High Temperature heating mode tests* (the *H0*, $H0_1$, *H1*, $H1_2$, $H1_1$, and $H1_N$ Tests). a. For the pretest interval, operate the test room reconditioning apparatus and the heat pump until equilibrium conditions are maintained for at least 30 minutes at the specified Section 3.6 test conditions. Use the exhaust fan of the airflow measuring apparatus and, if installed, the indoor fan of the heat pump to obtain and then maintain the indoor air volume rate and/or the external static pressure specified for the particular test. Continuously record the dry-bulb temperature of the air entering the indoor coil, and the dry-bulb temperature and water vapor content of the air entering the outdoor coil. Refer to Section 3.11 for additional requirements that depend on the selected secondary test method. After satisfying the pretest equilibrium requirements, make the measurements specified in Table 5 of ASHRAE Standard 37–88 for the Indoor Air Enthalpy method and the user-selected secondary method. Except for external static pressure, make the Table 5 measurements at equal intervals that span 10 minutes or less. Measure external static pressure every 5 minutes or less. Continue data sampling until you obtain a 30-minute period (e.g., four consecutive 10-minute samples) where the test tolerances specified in Table 13 are satisfied. For those continuously recorded parameters, use the entire data set for the 30-minute interval when evaluating Table 13 compliance. Determine the average electrical power consumption of the heat pump over the same 30-minute interval.

TABLE 13.—TEST OPERATING AND TEST CONDITION TOLERANCES FOR SECTION 3.7 AND SECTION 3.10 STEADY-STATE HEATING MODE TESTS.

	Test operating tolerance [1]	Test condition tolerance [2]
Indoor dry-bulb, °F:		
Entering temperature	2.0	0.5
Leaving temperature	2.0	
Indoor wet-bulb, °F:		
Entering temperature	1.0	
Leaving temperature	1.0	
Outdoor dry-bulb, °F:		
Entering temperature	2.0	0.5
Leaving temperature	[3] 2.0	
Outdoor wet-bulb, °F:		
Entering temperature	1.0	0.3
Leaving temperature	[3] 1.0	
External resistance to airflow, inches of water	0.05	[4] 0.02
Electrical voltage, % of rdg	2.0	1.5
Nozzle pressure drop, % of rdg	2.0	

[1] See Definition 1.40.
[2] See Definition 1.39.
[3] Only applies when the Outdoor Air Enthalpy Method is used.
[4] Only applies when testing non-ducted units.

Calculate indoor-side total heating capacity as specified in Section 7.3.4.1 of ASHRAE Standard 37–88. Do not adjust the parameters used in calculating capacity for the permitted variations in test conditions. Assign the average space heating capacity and electrical power over the 30-minute data collection interval to the variables and $\dot{Q}_h^k(T)$ and $\dot{E}_h^k(T)$, respectively. The "T" and superscripted "k" are the same as described in Section 3.3. Additionally, for the heating mode, use the superscript k=N to denote results from the optional $H1_N$ Test, if conducted.

b. For heat pumps tested without an indoor fan installed, increase $\dot{Q}_h^k(T)$ by

$$\frac{1250\ \text{Btu/h}}{1000\ \text{scfm}} \cdot \overline{\dot{V}}_s,$$

and increase $\dot{E}_h^k(T)$ by,

$$\frac{365\ \text{W}}{1000\ \text{scfm}} \cdot \overline{\dot{V}}_s,$$

where

$\overline{\dot{V}}_s$

is the average measured indoor air volume rate expressed in units of cubic feet per minute of standard air (SCFM). During the 30-minute data collection interval of a High Temperature Test, pay attention to preventing a defrost cycle. Prior to this time, allow the heat pump to perform a defrost cycle if automatically initiated by its own controls. As in all cases, wait for the heat pump's defrost controls to automatically terminate the defrost cycle. Heat pumps that undergo a defrost should operate in the heating mode for at least 10 minutes after defrost termination prior to beginning the 30-minute data collection interval. For some heat pumps, frost may accumulate on the outdoor coil during a High Temperature test. If the indoor coil leaving air temperature or the difference between the leaving and entering air temperatures decreases by more than 1.5 °F over the 30-minute data collection interval, then do not use the collected data to determine capacity. Instead, initiate a defrost cycle. Begin collecting data no sooner than 10 minutes after defrost termination. Collect 30 minutes of new data during which the Table 13 test tolerances are satisfied. In this case, use only the results from the second 30-minute data collection interval to evaluate $\dot{Q}_h^k(47)$ and $\dot{E}_h^k(47)$.

If conducting the optional cyclic heating mode test, which is described in Section 3.8, record the average indoor-side air volume rate,

$\overline{\dot{V}}_s$,

specific heat of the air $C_{p,a}$ (expressed on dry air basis), specific volume of the air at the nozzle(s), v_n (or v_{n_s}), humidity ratio at the nozzle(s), W_n, and either pressure difference or velocity pressure for the flow nozzle(s). If either or both of the below criteria apply, determine the average, steady-state, electrical power consumption of the indoor fan motor ($\dot{E}_{fan,1}$).

a. the Section 3.8 cyclic test will be conducted and the heat pump has a variable-speed indoor fan that is expected to be disabled during the cyclic test, or

b. the heat pump has a (variable-speed) constant-air volume-rate indoor fan and during the steady-state test the average external static pressure (ΔP_1) exceeds the applicable Section 3.1.4.4 minimum (or targeted) external static pressure (ΔP_{min}) by 0.03 inches of water or more. Determine $\dot{E}_{fan,1}$ by making measurements during the 30-minute data collection interval, or immediately following the test and prior to changing the test conditions. When the above "b" criteria applies, conduct the following four steps after determining $\dot{E}_{fan,1}$ (which corresponds to ΔP_1).

1. While maintaining the same test conditions, adjust the exhaust fan of the airflow measuring apparatus until the external static pressure increases to approximately $\Delta P_1 + (\Delta P_1 - \Delta P_{min})$.

2. After re-establishing steady readings for fan motor power and external static pressure, determine average values for the indoor fan power ($\dot{E}_{fan,2}$) and the external static pressure (ΔP_2) by making measurements over a 5-minute interval.

3. Approximate the average power consumption of the indoor fan motor if the 30-minute test had been conducted at ΔP_{min} using linear extrapolation:

$$\dot{E}_{fan,min} = \frac{\dot{E}_{fan,2} - \dot{E}_{fan,1}}{\Delta P_2 - \Delta P_1}(\Delta P_{min} - \Delta P_1) + \dot{E}_{fan,1}.$$

4. Decrease the total space heating capacity, $\dot{Q}_h^k(T)$, by the quantity $(\dot{E})_{fan,1} - \dot{E}_{fan,min}$, when expressed on a Btu/h basis. Decrease the total electrical power, $\dot{E})_h^k(T)$, by the same fan power difference, now expressed in watts.

3.8 *Test procedures for the optional cyclic heating mode tests* (the $H0C_1$, $H1C$, and $H1C_1$ Tests). a. Except as noted below, conduct the cyclic heating mode test as specified in Section 3.5. As adapted to the heating mode, replace Section 3.5 references to "the steady-state dry coil test" with "the heating mode steady-state test conducted at the same test conditions as the cyclic heating mode test." Use the test tolerances in Table 14 rather than Table 8. Record the outdoor coil entering wet-bulb temperature according to the requirements given in Section 3.5 for the outdoor coil entering dry-bulb temperature. Drop the subscript "*dry*" used in variables cited in Section 3.5 when referring to quantities from the cyclic heating mode test. Determine the total space heating delivered during the cyclic heating test, q_{cyc}, as specified in Section 3.5 except for making the following changes.

(1) When evaluating Equation 3.5–1, use the values of,

$\overline{\dot{V}}_s$,

$C_{p,a}v_n$ (or v_{n_s}), and W_n that were recorded during the Section 3.7 steady-state test conducted at the same test conditions.

(2) Calculate γ using,

$$\Gamma = \int_{\tau_1}^{\tau_2} \left[T_{a1}(\tau) - T_{a2}(\tau)\right] \delta\tau,\ \text{hr} \cdot {}^\circ\text{F}.$$

b. For ducted heat pumps tested without an indoor fan installed (excluding the special case where a variable-speed fan is temporarily removed), increase q_{cyc} by the amount calculated using Equation 3.5–3. Additionally, increase e_{cyc} by the amount calculated using Equation 3.5–2. In making these calculations, use the average indoor air volume rate

$(\overline{\dot{V}}_s)$

determined from the Section 3.7 steady-state heating mode test conducted at the same test conditions.

c. For non-ducted heat pumps, subtract the electrical energy used by the indoor fan during the 3 minutes after compressor cutoff from the non-ducted heat pump's integrated heating capacity, q_{cyc}.

d. For single-speed heat pumps that defrosted before completing the Section 3.7 *H1* (or $H1_1$) steady-state test, DOE recommends initiating a defrost cycle before cycling the heat pump OFF and ON according to Section 3.5. Do not restrict air movement through the indoor coil if the heat pump cycles off its indoor fan during the defrost cycle. If conducting a defrost cycle, operate the single-speed heat pump for at least 10 minutes after defrost termination. After that, begin cycling the heat pump immediately or delay until you have re-established the specified test conditions. Pay attention to preventing defrosts after beginning the cycling process. However, if a defrost is automatically or manually initiated once the OFF/ON cycling begins, switch to operating the heat pump continuously until 10 minutes after defrost termination. After that, resume the OFF/ON cycling while conducting a minimum of two complete compressor OFF/ON cycles before determining q_{cyc} and e_{cyc}.

3.8.1 Heating mode cyclic degradation coefficient calculation. Use the results from the optional cyclic test and the required steady-state test that was conducted at the same test conditions to determine the heating mode cyclic degradation coefficient, C_D^h. If the optional test is not conducted, assign C_D^h the default value of 0.25.

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$$C_D^h = \frac{1 - \frac{COP_{cyc}}{COP_{ss}(T_{cyc})}}{1 - HLF}$$

where,

$$COP_{cyc} = \frac{q_{cyc}}{3.413\frac{Btu}{W \cdot h} \cdot e_{cyc}},$$

the average coefficient of performance during the cyclic heating mode test, dimensionless.

$$COP_{ss}(T_{cyc}) = \frac{\dot{Q}_h^k(T_{cyc})}{3.413\frac{Btu/h}{W} \cdot \dot{E}_h^k(T_{cyc})},$$

the average coefficient of performance during the steady-state heating mode test conducted at the same test conditions *i.e.*, same outdoor dry bulb temperature, T_{cyc}, and speed/capacity, *k*, if applicable—as specified for the cyclic heating mode test, dimensionless.

$$HLF = \frac{q_{cyc}}{\dot{Q}_h^k(T_{cyc}) \cdot \Delta\tau_{cyc}}, \text{ the}$$

the heating load factor, dimensionless.

T_{cyc} = the nominal outdoor temperature at which the cyclic heating mode test is conducted, 62 or 47 °F.

$\Delta\tau_{cyc}$ = the duration of the OFF/ON intervals; 0.5 hours when testing a heat pump having a single-speed or two-capacity compressor and 1.0 hour when testing a heat pump having a variable-speed compressor.

Round the calculated value for C_D^h to the nearest 0.01. If C_D^h is negative, then set it equal to zero.

TABLE 14.—TEST OPERATING AND TEST CONDITION TOLERANCES FOR CYCLIC HEATING MODE TESTS

	Test operating tolerance [1]	Test condition tolerance [2]
Indoor entering dry-bulb temperature [3], °F	2.0 [3]	0.5
Indoor entering wet-bulb temperature [3], °F	1.0	
Outdoor entering dry-bulb temperature [3], °F	2.0	0.5
Outdoor entering wet-bulb temperature [3], °F	2.0	1.0
External resistance to air-flow [3], inches of water	0.05	
Airflow nozzle pressure difference or velocity pressure [3], % of reading	2.0	2.0 [4]
Electrical voltage [5], % of rdg	2.0	1.5

[1] See Definition 1.40.
[2] See Definition 1.39.
[3] Applies during the interval that air flows through the indoor (outdoor) coil except for the first 30 seconds after flow initiation. For units having a variable-speed indoor fan that ramps, the tolerances listed for the external resistance to airflow shall apply from 30 seconds after achieving full speed until ramp down begins.
[4] The test condition shall be the average nozzle pressure difference or velocity pressure measured during the steady-state test conducted at the same test conditions.
[5] Applies during the interval that at least one of the following—the compressor, the outdoor fan, or, if applicable, the indoor fan—are operating, except for the first 30 seconds after compressor start-up.

3.9 Test procedures for Frost Accumulation heating mode tests (the *H2*, *H2*$_2$, *H2*$_{VF}$ and *H2*$_f$ Tests). a. Confirm that the defrost controls of the heat pump are set as specified in Section 2.2.1. Operate the test room reconditioning apparatus and the heat pump for at least 30 minutes at the specified Section 3.6 test conditions before starting the "preliminary" test period. The preliminary test period must immediately precede the "official" test period, which is the heating and defrost interval over which data are collected for evaluating average space heating capacity and average electrical power consumption.

b. For heat pumps containing defrost controls which are likely to cause defrosts at intervals less than one hour, the preliminary test period starts at the termination of an automatic defrost cycle and ends at the termination of the next occurring automatic defrost cycle. For heat pumps containing defrost controls which are likely to cause defrosts at intervals exceeding one hour, the preliminary test period must consist of a heating interval lasting at least one hour followed by a defrost cycle that is either manually or automatically initiated. In all cases, the heat pump's own controls must govern when a defrost cycle terminates.

c. The official test period begins when the preliminary test period ends, at defrost termination. The official test period ends at the termination of the next occurring automatic defrost cycle. When testing a heat pump that uses a time-adaptive defrost control system (see Definition 1.41), however, manually initiate the defrost cycle that ends the official test period at the instant indicated by instructions provided by the manufacturer. If the heat pump has not undergone a defrost after 12 hours, immediately conclude the test and use the results from the full 12-hour period to calculate the average space heating capacity and average electrical power consumption. For heat pumps that turn the indoor fan off during the defrost cycle, take steps to cease forced airflow through the indoor coil and block the outlet duct whenever the heat pump's controls cycle off the indoor fan. You should use the outlet damper box described in Section 2.5.4.1, if installed, to affect the blocked outlet duct.

d. Defrost termination occurs when the controls of the heat pump actuate the first change in converting from defrost operation to normal heating operation. Defrost initiation occurs when the controls of the heat pump first alter its normal heating operation in order to eliminate possible accumulations of frost on the outdoor coil.

e. To constitute a valid Frost Accumulation test, you must satisfy the test tolerances specified in Table 15 during both the preliminary and official test periods. As noted in Table 15, test operating tolerances are specified for two sub-intervals: When heating, except for the first 10 minutes after the termination of a defrost cycle (Sub-interval H) and when defrosting, plus these same first 10 minutes after defrost termination (Sub-interval D). Evaluate compliance with Table 15 test condition tolerances and the majority of the test operating tolerances using the averages from measurements recorded only during Sub-interval H. Continuously record the dry bulb temperature of the air entering the indoor coil, and the dry bulb temperature and water vapor content of the air entering the outdoor coil. Sample the remaining parameters listed in Table 15 at equal intervals that span 10 minutes or less.

f. For the official test period, collect and use the following data to calculate average space heating capacity and electrical power. During heating and defrosting intervals when the controls of the heat pump (act to) have the indoor fan on, continuously record the dry-bulb temperature of the air entering (as noted above) and leaving the indoor coil. If using a thermopile, continuously record the difference between the leaving and entering dry-bulb temperatures during the interval(s) that air flows through the indoor coil. For heat pumps tested without an indoor fan installed, determine the corresponding cumulative time (in hours) of indoor coil airflow, $\Delta\tau_{fr}$. Sample measurements used in calculating the air volume rate (refer to Sections 7.8.3.1 and 7.8.3.2 of ASHRAE Standard 37–88) at equal intervals that span 10 minutes or less. Record the electrical energy consumed, expressed in watt-hours, from defrost termination to defrost termination, $e^h_{DEF}(35)$, as well as the corresponding elapsed time in hours, $\Delta\tau_{FR}$.

TABLE 15.—TEST OPERATING AND TEST CONDITION TOLERANCES FOR FROST ACCUMULATION HEATING MODE TESTS

	Test Operating Tolerance [1]		Test Condition Tolerance [2] Sub-interval H [3]
	Sub-interval H [3]	Sub-interval D [4]	
Indoor entering dry-bulb temperature, °F	2.0	[5] 4.0	0.5
Indoor entering wet-bulb temperature, °F	1.0		
Outdoor entering dry-bulb temperature, °F	2.0	10.0	1.0
Outdoor entering wet-bulb temperature, °F	1.5		0.5
External resistance to airflow, inches of water	0.05		[6] 0.02
Electrical voltage, % of rdg	2.0		1.5

[1] See Definition 1.40.
[2] See Definition 1.39.
[3] Applies when the heat pump is in the heating mode, except for the first 10 minutes after termination of a defrost cycle.
[4] Applies during a defrost cycle and during the first 10 minutes after the termination of a defrost cycle when the heat pump is operating in the heating mode.
[5] For heat pumps that turn off the indoor fan during the defrost cycle, the noted tolerance only applies during the 10 minute interval that follows defrost termination.
[6] Only applies when testing non-ducted heat pumps.

3.9.1 Average space heating capacity and electrical power calculations. Evaluate average space heating capacity, $\dot{Q}_h^k(35)$, when expressed in units of Btu per hour, using:

$$\dot{Q}_h^k(35) = \frac{60 \cdot \overline{\dot{V}} \cdot C_{p,a} \cdot \Gamma}{\Delta\tau_{FR}\left[v'_n \cdot (1 + W_n)\right]} = \frac{60 \cdot \overline{\dot{V}} \cdot C_{p,a} \cdot \Gamma}{\Delta\tau_{FR} \cdot v_n}$$

where,

$\overline{\dot{V}}$ =

the average indoor air volume rate measured during Sub-interval H, cfm.

$C_{p,a} = 0.24 + 0.444 \cdot W_n$, the constant pressure specific heat of the air-water vapor mixture that flows through the indoor coil and is expressed on a dry air basis, Btu / lbm_{da} · °F.

V_n = specific volume of the air-water vapor mixture at the nozzle, ft^3 / lbm_{mx}.

W_n = humidity ratio of the air-water vapor mixture at the nozzle, lbm of water vapor per lbm of dry air.

$\Delta\tau_{FR} = \tau_2 - \tau_1$, the elapsed time from defrost termination to defrost termination, hr.

$$\Gamma = \int_{\tau_1}^{\tau_2} \left[T_{a2}(\tau) - T_{a1}(\tau)\right] d\tau, \text{ hr} \cdot \text{°F}.$$

$T_{a1}(\tau)$= dry bulb temperature of the air entering the indoor coil at elapsed time τ, °F; only recorded when indoor coil airflow occurs; assigned the value of zero during periods (if any) where the indoor fan cycles off.

$T_{a2}(\tau)$= dry bulb temperature of the air leaving the indoor coil at elapsed time τ, °F; only recorded when indoor coil airflow occurs; assigned the value of zero during periods (if any) where the indoor fan cycles off.

τ_1 = the elapsed time when the defrost termination occurs that begins the official test period, hr.

τ_2 = the elapsed time when the next automatically occurring defrost termination occurs, thus ending the official test period, hr

V_n = specific volume of the dry air portion of the mixture evaluated at the dry-bulb temperature, vapor content, and barometric pressure existing at the nozzle, ft^3 per lbm of dry air.

Evaluate average electrical power, $\dot{E}^k_h(35)$, when expressed in units of watts, using:

$$\dot{E}\frac{k}{h}(35) = \frac{e_{def}(35)}{\Delta\tau_{FR}}.$$

For heat pumps tested without an indoor fan installed, increase $\dot{Q}^k_h(35)$ by,

$$\frac{1250\ Btu/h}{1000\,scfm} \cdot \overline{\dot{V}}_s \cdot \frac{\Delta\tau_a}{\Delta\tau_{FR}},$$

and increase $\dot{E}^k_h(35)$ by,

$$\frac{365\ W}{1000\,scfm} \cdot \overline{\dot{V}}_s \cdot \frac{\Delta\tau_a}{\Delta\tau_{FR}},$$

where $\dot{V}_s$ is the average indoor air volume rate measured during the Frost Accumulation heating mode test and is expressed in units of cubic feet per minute of standard air (SCFM). For heat pumps having a constant-air-volume-rate indoor fan, the five additional steps listed below are required if the average of the measured external static pressures exceeds the Section 3.1.4.4 minimum (or targeted) external static pressure (ΔP_{min}) by 0.03 inches of water or more.

1. Measure the average power consumption of the indoor fan motor ($\dot{E}_{fan,1}$) and record the corresponding external static pressure (ΔP_1) during or immediately following the 30-minute interval used for determining capacity.

2. After the 30-minute interval is completed and while maintaining the same test conditions, adjust the exhaust fan of the airflow measuring apparatus until the external static pressure increases to approximately $\Delta P_1 + (\Delta P_1 - \Delta P_{min})$.

3. After re-establishing steady readings for the fan motor power and external static pressure, determine average values for the indoor fan power ($\dot{E}_{fan,2}$) and the external static pressure (ΔP_2) by making measurements over a 5-minute interval.

4. Approximate the average power consumption of the indoor fan motor had the 30-minute tests been conducted at ΔP_{min} using linear extrapolation:

$$\dot{E}_{fan,min} = \frac{\dot{E}_{fan,2} - \dot{E}_{fan,1}}{\Delta P_2 - \Delta P_1}(\Delta P_{min} - \Delta P_1) + \dot{E}_{fan,1}.$$

5. Increase the total heating capacity, $\dot{Q}^k_h(35)$, by the quantity $[(\dot{E}_{fan,1} - \dot{E}_{fan,min}) \cdot (\Delta\tau_a / \Delta\tau_{a\,FR})]$, when expressed on a Btu/h basis. Decrease the total electrical power, $\dot{E}^k_h(35)$, by the same quantity, now expressed in watts.

3.9.2 *Demand defrost credit.* Assign the demand defrost credit, F_{def}, that is used in Section 4.2 to the value of 1 in all cases

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except for heat pumps having a demand-defrost control system (Definition 1.20). For such qualifying heat pumps, evaluate F_{def} using,

$$F_{def} = 1 + 0.03 \cdot \left[1 - \frac{\Delta\tau_{def} - 1.5}{\Delta\tau_{max} - 1.5}\right],$$

where,

$\Delta\tau_{def}$ = the time between defrost terminations (in hours) or 1.5, whichever is greater.

$\Delta\tau_{max}$ = maximum time between defrosts as allowed by the controls (in hours) or 12, whichever is less.

For two-capacity heat pumps and for Section 3.6.2 units, evaluate the above equation using the $\Delta\tau_{def}$ that applies based on the Frost Accumulation Test conducted at high capacity and/or at the Heating Certified Air Volume Rate. For variable-speed heat pumps, evaluate $\Delta\tau_{def}$ based on the required Frost Accumulation Test conducted at the intermediate compressor speed.

3.10 *Test procedures for steady-state Low Temperature heating mode tests* (the *H3*, $H3_2$, and $H3_1$ Tests). Except for the modifications noted in this section, conduct the Low Temperature heating mode test using the same approach as specified in Section 3.7 for the Maximum and High Temperature tests. After satisfying the Section 3.7 requirements for the pretest interval but before you begin collecting data to determine $\dot{Q}_h^k(17)$ and $\dot{E}_h^k(17)$, conduct a defrost cycle. This defrost cycle may be manually or automatically initiated. The defrost sequence must be terminated by the action of the heat pump's defrost controls. Begin the 30-minute data collection interval described in Section 3.7, from which $\dot{Q}_h^k(17)$ and $\dot{E}_h^k(17)$ are determined, no sooner than 10 minutes after defrost termination. Defrosts should be prevented over the 30-minute data collection interval.

3.11 *Additional requirements for the secondary test methods.* Prior to evaluating if the energy balance specified in Section 3.1.1 is obtained, you should make an adjustment to account for the energy loss within the air duct that connects the indoor coil and the location where the outlet dry-bulb temperature is measured. If using the Outdoor Air Enthalpy Method, you should make an adjustment to account for the energy loss within the air duct that connects the outdoor coil and the location where the outlet temperature is measured. In all cases, apply the correction to the indoor space conditioning capacity that is determined using the secondary test method.

3.11.1 *If using the Outdoor Air Enthalpy Method as the secondary test method.* During the "official" test, the outdoor air-side test apparatus described in Section 2.10.1 is connected to the outdoor unit. To help compensate for any effect that the addition of this test apparatus may have on the unit's performance, conduct a "preliminary" test where the outdoor air-side test apparatus is disconnected. Conduct a preliminary test prior to the first Section 3.2 steady-state cooling mode test and prior to the first Section 3.6 steady-state heating mode test. No other preliminary tests are required so long as the unit operates the outdoor fan during all cooling mode steady-state tests at the same speed and all heating mode steady-state tests at the same speed. If using more than one outdoor fan speed for the cooling mode steady-state tests, however, conduct a preliminary test prior to each cooling mode test where a different fan speed is first used. This same requirement applies for the heating mode tests.

3.11.1.1 *If a preliminary test precedes the official test.* The test conditions for the preliminary test are the same as specified for the official test. Connect the indoor air-side test apparatus to the indoor coil; disconnect the outdoor air-side test apparatus. Allow the test room reconditioning apparatus and the unit being tested to operate for at least one hour. After attaining equilibrium conditions, measure the following quantities at equal intervals that span 10 minutes or less:

1. The Section 2.10.1 evaporator and condenser temperatures or pressures

2. Parameters required according to the Indoor Air Enthalpy Method.

Continue these measurements until a 30-minute period (e.g., four consecutive 10-minute samples) is obtained where the Table 7 or Table 13, whichever applies, test tolerances are satisfied. After collecting 30 minutes of steady-state data, reconnect the outdoor air-side test apparatus to the unit. Adjust the exhaust fan of the outdoor airflow measuring apparatus until averages for the evaporator and condenser temperatures, or the saturated temperatures corresponding to the measured pressures, agree within ±0.5 °F of the averages achieved when the outdoor air-side test apparatus was disconnected. Calculate the averages for the reconnected case using five or more consecutive readings taken at one minute intervals. Make these consecutive readings after re-establishing equilibrium conditions and before initiating the official test.

3.11.1.2 *If a preliminary test does not precede the official test.* Connect the outdoor-side test apparatus to the unit. Adjust the exhaust fan of the outdoor airflow measuring apparatus to achieve the same external static pressure as measured during the prior preliminary test conducted with the unit operating in the same cooling or heating mode at the same outdoor fan speed.

3.11.1.3 *Official test.* a. Continue (preliminary test was conducted) or begin (no preliminary test) the official test by making measurements for both the Indoor and Outdoor Air Enthalpy Methods at equal intervals that span 10 minutes or less. Discontinue these measurement only after obtaining a 30-minute period where the specified test condition and test operating tolerances are satisfied. To constitute a valid official test,

(1) Achieve the energy balance specified in Section 3.1.1 and,

(2) For cases where you conduct a preliminary test, the capacities determined using the Indoor Air Enthalpy Method from the official and preliminary test periods must agree within 2.0 percent.

b. For space cooling tests, calculate capacity from the outdoor air enthalpy measurements as specified in Section 7.3.3.2 of ASHRAE Standard 37–88. Calculate heating capacity based on outdoor air enthalpy measurements as specified in Section 7.3.4.2 of the same ASHRAE Standard. You may adjust outdoor side capacities according to Section 7.3.3.3 of ASHRAE Standard 37–88 to account for line losses when testing split systems. Do not correct the average electrical power measurement as described in Section 8.5.3 of ASHRAE Standard 37–88.

3.11.2 *If using the Compressor Calibration Method as the secondary test method.* a. Conduct separate calibration tests using a calorimeter to determine the refrigerant flow rate. Or for cases where the superheat of the refrigerant leaving the evaporator is less than 5 °F, use the calorimeter to measure total capacity rather than refrigerant flow rate. Conduct these calibration tests at the same test conditions as specified for the tests in this Appendix. Operate the unit for at least one hour or until obtaining equilibrium conditions before collecting data that will be used in determining the average refrigerant flow rate or total capacity. Sample the data at equal intervals that span 10 minutes or less. Determine average flow rate or average capacity from data sampled over a 30-minute period where the Table 7 (cooling) or the Table 13 (heating) tolerances are satisfied. Otherwise, conduct the calibration tests according to ASHRAE Standard 23–93, ASHRAE Standard 41.9–88, and Section 7.5 of ASHRAE Standard 37–88.

b. Calculate space cooling and space heating capacities using the compressor calibration method measurements as specified in Sections 7.5.7 and 7.5.8, respectively, of ASHRAE Standard 37–88.

3.11.3 *If using the Refrigerant Enthalpy Method as the secondary test method.* Conduct this secondary method according to Section 7.6 of ASHRAE Standard 37–88. Calculate space cooling and space heating capacities using the refrigerant enthalpy method measurements as specified in Sections 7.6.4 and 7.6.5, respectively, of the same ASHRAE Standard.

3.12 *Rounding of space conditioning capacities for reporting purposes.* When reporting rated capacities, round them off as follows.

1. For capacities less than 20,000 Btu/h, round to the nearest 100 Btu/h.

2. For capacities between 20,000 and 37,999 Btu/h, round to the nearest 200 Btu/h.

3. For capacities between 38,000 and 64,999 Btu/h, round to the nearest 500 Btu/h.

For the capacities used to perform the Section 4 calculations, however, round only to the nearest integer.

4. Calculations of Seasonal Performance Descriptors

4.1 *Seasonal Energy Efficiency Ratio (SEER) Calculations.* For equipment covered under Sections 4.1.2, 4.1.3, and 4.1.4, evaluate the seasonal energy efficiency ratio,

$$SEER = \frac{\sum_{j=1}^{8} q_c(T_j)}{\sum_{j=1}^{8} e_c(T_j)} = \frac{\sum_{j=1}^{8} \frac{q_c(T_j)}{N}}{\sum_{j=1}^{8} \frac{e_c(T_j)}{N}}$$

where,

$$\frac{q_c(T_j)}{N} =$$

the ratio of the total space cooling provided during periods of the space cooling season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the cooling season (N), Btu/h.

$$\frac{e_c(T_j)}{N} =$$

the electrical energy consumed by the test unit during periods of the space cooling season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the cooling season (N), W.

T_j = the outdoor bin temperature, °F. Outdoor temperatures are grouped or "binned." Use bins of 5 °F with the 8 cooling season bin temperatures being 67, 72, 77, 82, 87, 92, 97, and 102 °F.

j = the bin number. For cooling season calculations, j ranges from 1 to 8.

Additionally, for Sections 4.1.2, 4.1.3, and 4.1.4, use a building cooling load, $BL(T_j)$. When referenced, evaluate $BL(T_j)$ for cooling using,

$$BL(T_j) = \frac{(T_j - 65)}{95 - 65} \cdot \frac{\dot{Q}_c^{k=2}(95)}{1.1} \qquad (4.1\text{-}2)$$

where,

$\dot{Q}_c^{k=2}(95)$ = the space cooling capacity determined from the A_2 Test and calculated as specified in Section 3.3, Btu/h.

1.1 = sizing factor, dimensionless.

The temperatures 95 °F and 65 °F in the building load equation represent the selected outdoor design temperature and the zero-load base temperature, respectively.

4.1.1 *SEER calculations for an air conditioner or heat pump having a single-speed compressor that was tested with a fixed-speed indoor fan installed, a constant-air-volume-rate indoor fan installed, or with no indoor fan installed.* a. Evaluate the seasonal energy efficiency ratio, expressed in units of Btu/watt-hour, using:

$$SEER = PLF(0.5) \cdot EER_B$$

where,

$$EER_B = \frac{\dot{Q}_c(82)}{\dot{E}_c(82)},$$

the energy efficiency ratio determined from the B Test described in Sections 3.2.1, 3.1.4.1, and 3.3, Btu/h per watt.

$PLF(0.5) = 1 - 0.5 \cdot C_D^c$, the part-load performance factor evaluated at a cooling load factor of 0.5, dimensionless.

b. Refer to Section 3.3 regarding the definition and calculation of $\dot{Q}_c(82)$ and $\dot{E}_c(82)$. If the optional tests described in Section 3.2.1 are not conducted, set the cooling mode cyclic degradation coefficient, C_D^c, to the default value specified in Section 3.5.3. If these optional tests are conducted, set C_d^c to the lower of:

1. The value calculated as per Section 3.5.3 or

2. The Section 3.5.3 default value of 0.25.

$$\frac{q_c(T_j)}{N} = X(T_j) \cdot \dot{Q}_c(T_j) \cdot \frac{n_j}{N} \qquad (4.1.2\text{-}1)$$

where

$$X(T_j) = \begin{Bmatrix} BL(T_j)/\dot{Q}_c(T_j) \\ \text{or} \\ 1 \end{Bmatrix};$$

the cooling mode load factor for temperature bin j, dimensionless.

$\dot{Q}_c(T_j)$ = the space cooling capacity of the test unit when operating at outdoor temperature, T_j, Btu/h.

$$\frac{n_j}{N} =$$

fractional bin hours for the cooling season: the ratio of the number of hours during the cooling season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the cooling season, dimensionless.

a. For the space cooling season, assign

$$\frac{n_j}{N}$$

as specified in Table 16. Use Equation 4.1–2 to calculate the building load, $BL(T_j)$. Evaluate $\dot{Q}_c(T_j)$ using,

4.1.2 *SEER calculations for an air conditioner or heat pump having a single-speed compressor and a variable-speed variable-air-volume-rate indoor fan.*

4.1.2.1 *Units covered by Section 3.2.2.1 where indoor fan capacity modulation correlates with the outdoor dry bulb temperature.* The manufacturer must provide information on how the indoor air volume rate or the indoor fan speed varies over the outdoor temperature range of 67 °F to 102 °F.

Calculate *SEER* using Equation 5.4-1. Evaluate the quantity

$$\frac{q_c(T_j)}{N}$$

in Equation 4.1-1 using,

$$\dot{Q}_c(T_j) = \dot{Q}_c^{k=1}(T_j) + \frac{\dot{Q}_c^{k=2}(T_j) - \dot{Q}_c^{k=1}(T_j)}{FP_c^{k=2} - FP_c^{k=1}} \cdot \left[FP_c(T_j) - FP_c^{k=1}\right] \qquad (4.1.2\text{-}2)$$

where,

$$\dot{Q}_c^{k=1}(T_j) = \dot{Q}_c^{k=1}(82) + \frac{\dot{Q}_c^{k=1}(95) - \dot{Q}_c^{k=1}(82)}{95 - 82} \cdot (T_j - 82),$$

the space cooling capacity of the test unit at outdoor temperature T_j if operated at the Cooling Minimum Air Volume Rate, Btu/h.

$$\dot{Q}_c^{k=2}(T_j) = \dot{Q}_c^{k=2}(82) + \frac{\dot{Q}_c^{k=2}(95) - \dot{Q}_c^{k=2}(82)}{95-82} \cdot (T_j - 82),$$

the space cooling capacity of the test unit at outdoor temperature T_j if operated at the Cooling Certified Air Volume Rate, Btu/h.

b. For units where indoor fan speed is the primary control variable, $FP_c^{k=1}$ denotes the fan speed used during the required A_1 and B_1 Tests (see Section 3.2.2.1), $FP_c^{k=2}$ denotes the fan speed used during the required A_2 and B_2 Tests, and $FP_c(T_j)$ denotes the fan speed used by the unit when the outdoor temperature equals T_j. For units where indoor air volume rate is the primary control variable, the three FP_c's are similarly defined only now being expressed in terms of air volume rates rather than fan speeds. Refer to Sections 3.2.2.1, 3.1.4 to 3.1.4.2, and 3.3 regarding the definitions and calculations of $\dot{Q}_c^{k=1}(82)$, $\dot{Q}_c^{k=1}(95)$, $\dot{Q}_c^{k=2}(82)$, and $\dot{Q}_c^{k=2}(95)$.

Calculate

$$\frac{e_c(T_j)}{N}$$

in Equation 4.1 using,

$$\frac{e_c(T_j)}{N} = \frac{X(T_j) \cdot \dot{E}_c(T_j)}{PLF_j} \cdot \frac{n_j}{N} \qquad (4.1.2\text{-}3)$$

where,

$PLF_j = 1 - C_D{}^c \cdot [1 - X(T_j)]$, the part load factor, dimensionless.

$\dot{E}_c(T_j)$ = the electrical power consumption of the test unit when operating at outdoor temperature T_j, W.

The quantities $X(T_j)$ and n_j/N are the same quantities as used in Equation 4.1.2–1. If the optional tests described in Section 3.2.2.1 and Table 4 are not conducted, set the cooling mode cyclic degradation coefficient, $C_D{}^c$, to the default value specified in Section 3.5.3. If these optional tests are conducted, set $C_D{}^c$ to the lower of

a. The value calculated as per Section 3.5.3 or

b. The Section 3.5.3 default value of 0.25.

Evaluate $\dot{E}(T_j)$ using,

$$\dot{E}_c(T_j) = \dot{E}_c^{k=1}(T_j) + \frac{\dot{E}_c^{k=2}(T_j) - \dot{E}_c^{k=2}(T_j)}{FP_c^{k=2} - FP_c^{k=1}} \cdot \left[FP_c(T_j) - FP_c^{k=1}\right] \qquad (4.1.2\text{-}4)$$

where,

$$\dot{E}_c^{k=1}(T_j) = \dot{E}_c^{k=1}(82) + \frac{\dot{E}_c^{k=1}(95) - \dot{E}_c^{k=1}(82)}{95-82} \cdot (T_j - 82),$$

the electrical power consumption of the test unit at outdoor temperature T_j if operated at the Cooling Minimum Air Volume Rate, W.

$$\dot{E}_c^{k=2}(T_j) = \dot{E}_c^{k=2}(82) + \frac{\dot{E}_c^{k=2}(95) - \dot{E}_c^{k=2}(82)}{95-82} \cdot (T_j - 82),$$

the electrical power consumption of the test unit at outdoor temperature T_j if operated at the Cooling Certified Air Volume Rate, W.

The parameters $FP_c^{k=1}$, $FP_c^{k=2}$, and $FP_c(T_j)$ are the same quantities that are used when evaluating Equation 4.1.2–2. Refer to Sections 3.2.2.1, 3.1.4 to 3.1.4.2, and 3.3 regarding the definitions and calculations of $\dot{E}_c^{k=1}(82)$, $\dot{E}_c^{k=1}(95)$, $\dot{E}_c^{k=2}(82)$, and $\dot{E}_c^{k=2}(95)$.

TABLE 16.—DISTRIBUTION OF FRACTIONAL HOURS WITHIN COOLING SEASON TEMPERATURE BINS

Bin number, j	Bin temperature range °F	Representative temperature for bin °F	Fraction of total temperature bin hours, n_j/N
1	65–69	67	0.214
2	70–74	72	0.231
3	75–79	77	0.216
4	80–84	82	0.161
5	85–89	87	0.104
6	90–94	92	0.052
7	95–99	97	0.018
8	100–104	102	0.004

4.1.2.2 *Units covered by Section 3.2.2.2 where indoor fan capacity modulation is used to adjust the sensible to total cooling capacity ratio.* Calculate SEER as specified in Section 4.1.1.

4.1.3 *SEER calculations for an air conditioner or heat pump having a two-capacity compressor.* Calculate *SEER* using Equation 4.1–1. Evaluate the space cooling capacity, $\dot{Q}_c^{k=1}(T_j)$, and electrical power consumption, $\dot{E}_c^{k=1}(T_j)$, of the test unit when operating at low compressor capacity and outdoor temperature T_j using,

$$\dot{Q}_c^{k=1}(T_j) = \dot{Q}_c^{k=1}(82) + \frac{\dot{Q}_c^{k=1}(95) - \dot{Q}_c^{k=1}(82)}{95-82} \cdot (T_j - 82) \qquad (4.1.3\text{-}1)$$

$$\dot{E}_c^{k=1}(T_j) = \dot{E}_c^{k=1}(82) + \frac{\dot{E}_c^{k=1}(95) - \dot{E}_c^{k=1}(82)}{95-82} \cdot (T_j - 82) \qquad (4.1.3\text{-}2)$$

where $\dot{Q}_c^{k=1}(95)$ and $\dot{E}_c^{k=1}(95)$ are determined from the A_1 Test, $\dot{Q}_c^{k=1}(82)$ and $\dot{E}_c^{k=1}(82)$ are determined from the B_1 Test, and all are calculated as specified in Section 3.3. For two-capacity units that lock out low capacity operation at outdoor temperatures less than 95 °F (but greater than 82 °F), use Equations 4.1.4–1 and 4.1.4–2 rather than Equations 4.1.3–1 and 4.1.3.2 for estimating performance at low compressor capacity.

Evaluate the space cooling capacity, $\dot{Q}_c^{k=2}(T_j)$, and electrical power consumption, $\dot{E}_c^{k=2}(T_j)$, of the test unit when operating at high compressor capacity and outdoor temperature T_j using,

$$\dot{Q}_c^{k=2}(T_j) = \dot{Q}_c^{k=2}(82) + \frac{\dot{Q}_c^{k=2}(95) - \dot{Q}_c^{k=2}(82)}{95-82} \cdot (T_j - 82) \qquad (4.1.3\text{-}3)$$

$$\dot{E}_c^{k=2}(T_j) = \dot{E}_c^{k=2}(82) + \frac{\dot{E}_c^{k=2}(95) - \dot{E}_c^{k=2}(82)}{95-82} \cdot (T_j - 82) \qquad (4.1.3\text{-}4)$$

where $\dot{Q}_c^{k=2}(95)$ and $\dot{E}_c^{k=2}(95)$ are determined from the A_2 Test, $\dot{Q}_c^{k=2}(82)$ and $\dot{E}_c^{k=2}(82)$ are determined from the B_2 Test, and all are calculated as specified in Section 3.3.

The calculation of Equation 4.1–1 quantities

$$\frac{q_c(T_j)}{N} \text{ and } \frac{e_c(T_j)}{N}$$

differs depending on whether the test unit would operate at low capacity (Section 4.1.3.1), cycle between low and high capacity (Section 4.1.3.2), or operate at high capacity (Sections 4.1.3.3 and 4.1.3.4) in responding to the building load. For units that lock out low capacity operation at higher outdoor temperatures, the manufacturer must supply information regarding this temperature so that the appropriate equations are used. Use

$$\frac{q_c(T_j)}{N} = X^{k=1}(T_j) \cdot \dot{Q}_c^{k=1}(T_j) \cdot \frac{n_j}{N}$$

$$\frac{e_c(T_j)}{N} = \frac{X^{k=1}(T_j) \cdot \dot{E}_c^{k=1}(T_j)}{PLF_j} \cdot \frac{n_j}{N}$$

Equation 4.1–2 to calculate the building load, $BL(T_j)$, for each temperature bin.

4.1.3.1 *Steady-state space cooling capacity at low compressor capacity is greater than or equal to the building cooling load at temperature T_j.* $\dot{Q}_c^{k=1}(T_j) \geq BL(T_j)$.

where,

$X^{k=1}(T_j)$ = the cooling mode low capacity load factor for temperature bin j, dimensionless.

$PLF_j = 1 - C_D{}^c \cdot [1 - X^{k=1}(T_j)]$, the part load factor, dimensionless.

$$\frac{n_j}{N} =$$

fractional bin hours for the cooling season; the ratio of the number of hours

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during the cooling season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the cooling season, dimensionless.

$$\frac{n_j}{N},$$

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. Use Equations 4.1.3–1 and 4.1.3–2, respectively, to evaluate $\dot{Q}_c^{k=1}(T_j)$ and $\dot{E}_c^{k=1}(T_j)$. Use Equations 4.1.3–3 and 4.1.3–4, respectively, to evaluate $\dot{Q}_c^{k=2}(T_j)$ and $\dot{E}_c^{k=2}(T_j)$.

4.1.3.3 *Unit only operates at high (k=2) compressor capacity at temperature T_j and its capacity is greater than the building cooling load, $BL(T_j) < \dot{Q}_c^{k=2}(T_j)$.* This Section applies to units that lock out low compressor capacity operation at higher outdoor temperatures.

$$\frac{q_c(T_j)}{N} = \left[X^{k=1}(T_j)\cdot \dot{Q}_c^{k=1}(T_j) + X^{k=2}(T_j)\cdot \dot{Q}_c^{k=2}(T_j)\right]\cdot \frac{n_j}{N}$$

$$\frac{e_c(T_j)}{N} = \left[X^{k=1}(T_j)\cdot \dot{E}_c^{k=1}(T_j) + X^{k=2}(T_j)\cdot \dot{E}_c^{k=2}(T_j)\right]\cdot \frac{n_j}{N}$$

where,

$X^{k=1}(T_j)=$

$$\frac{\dot{Q}_c^{k=2}(T_j) - BL(T_j)}{\dot{Q}_c^{k=2}(T_j) - \dot{Q}_c^{k=1}(T_j)},$$

the cooling mode, low capacity load factor for temperature bin j, dimensionless.

$- X^{k=2}(T_j)=1 - X^{k=1}(T_j)$, the cooling mode, high capacity load factor for temperature bin j, dimensionless.

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. Use Equations 4.1.3–1 and 4.1.3–2, respectively, to evaluate $\dot{Q}_c^{k=1}(T_j)$ and $\dot{E}_c^{k=1}(T_j)$. Use Equations 4.1.3–3 and 4.1.3–4, respectively, to evaluate $\dot{Q}_c^{k=2}(T_j)$ and $\dot{E}_c^{k=2}(T_j)$. If the optional tests described in Section 3.2.3 and Table 5 are not conducted, set the cooling mode cyclic degradation coefficient, $C_D{}^c$, to the default value specified in Section 3.5.3. If these optional tests are conducted, set $C_D{}^c$ to the lower of:

a. The value calculated according to Section 3.5.3 or

b. The Section 3.5.3 default value of 0.25.

4.1.3.2 *Unit alternates between high (k=2) and low (k=1) compressor capacity to satisfy the building cooling load at temperature* T_j, $\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=2}(T_j)$.

$$\frac{e_c(T_j)}{N} = \frac{X^{k=2}(T_j)\cdot \dot{E}_c^{k=2}(T_j)}{PLF_j}\cdot \frac{n_j}{N}$$

$$\frac{q_c(T_j)}{N} = X^{k=2}(T_j)\cdot \dot{Q}_c^{k=2}(T_j)\cdot \frac{n_j}{N}$$

where,

$X^{k=2}(T_j)= BL(T_j) / \dot{Q}_c^{k=2}(T_j)$, the cooling mode high capacity load factor for temperature bin j, dimensionless.

$PLF_j = 1 - C_D{}^c \cdot [1 - X^{k=2}(T_j)]$, the part load factor, dimensionless.

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. Use Equations 4.1.3–3 and 4.1.3–4, respectively, to evaluate $\dot{Q}_c^{k=2}(T_j)$ and $\dot{E}_c^{k=2}(T_j)$. When evaluating the above equation for part load factor at high capacity, use the same value of $C_D{}^c$ as used in the Section 4.1.3.1 calculations.

4.1.3.4 *Unit must operate continuously at high (k=2) compressor capacity at temperature T_j $BL(T_j) \geq \dot{Q}_c^{k=2}(T_j)$.*

$$\frac{q_c(T_j)}{N} = \dot{Q}_c^{k=2}(T_j)\cdot \frac{n_j}{N}$$

$$\frac{e_c(T_j)}{N} = \dot{E}_c^{k=2}(T_j)\cdot \frac{n_j}{N}.$$

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. Use Equations 4.1.3–3 and 4.1.3–4, respectively, to evaluate $\dot{Q}_c^{k=2}(T_j)$ and $\dot{E}_c^{k=2}(T_j)$.

4.1.4 *SEER calculations for an air conditioner or heat pump having a variable-speed compressor.* Calculate *SEER* using Equation 4.1–1. Evaluate the space cooling capacity, $\dot{Q}_c^{k=1}(T_j)$, and electrical power consumption, $\dot{E}_c^{k=1}(T_j)$, of the test unit when operating at minimum compressor speed and outdoor temperature T_j, use,

$$\dot{Q}_c^{k=1}(T_j) = \dot{Q}_c^{k=1}(67) + \frac{\dot{Q}_c^{k=1}(82) - \dot{Q}_c^{k=1}(67)}{82-67}\cdot (T_j - 67) \qquad (4.1.4\text{-}1)$$

$$\dot{E}_c^{k=1}(T_j) = \dot{E}_c^{k=1}(67) + \frac{\dot{E}_c^{k=1}(82) - \dot{E}_c^{k=1}(67)}{82-67}\cdot (T_j - 67) \qquad (4.1.4\text{-}2)$$

where $\dot{Q}_c^{k=1}(82)$ and $\dot{E}_c^{k=1}(82)$ are determined from the B_1 Test, $\dot{Q}_c^{k=1}(67)$ and $\dot{E}_c^{k=1}(67)$ are determined from the F_1 Test, and all four quantities are calculated as specified in Section 3.3. Evaluate the space cooling capacity, $\dot{Q}_c^{k=2}(T_j)$, and electrical power consumption, $\dot{E}_c^{k=2}(T_j)$, of the test unit when operating at maximum compressor speed and outdoor temperature T_j. Use Equations 4.1.3–3 and 4.1.3–4, respectively, where $\dot{Q}_c^{k=2}(95)$ and $\dot{E}_c^{k=2}(95)$ are determined from the A_2 Test, $\dot{Q}_c^{k=2}(82)$ and $\dot{E}_c^{k=2}(82)$ are determined from the B_2 Test, and all four quantities are calculated as specified in Section 3.3.

Calculate the space cooling capacity, $\dot{Q}_c^{k=v}(T_j)$, and electrical power consumption, $\dot{E}_c^{k=v}(T_j)$, of the test unit when operating at outdoor temperature T_j and the intermediate compressor speed used during the Section 3.2.4 (and Table 6) E_V Test using,

$$\dot{Q}_c^{k=v}(T_j) = \dot{Q}_c^{k=v}(87) + M_Q\cdot (T_j - 87) \qquad (4.1.4\text{-}3)$$

$$\dot{E}_c^{k=v}(T_j) = \dot{E}_c^{k=v}(87) + M_E\cdot (T_j - 87) \qquad (4.1.4\text{-}4)$$

where $\dot{Q}_c^{k=v}(87)$ and $\dot{E}_c^{k=v}(87)$ are determined from the E_V Test and calculated as specified in Section 3.3. Approximate the slopes of the $k=v$ intermediate speed cooling capacity and electrical power input curves, M_Q and M_E, as follows:

$$M_Q = \left[\frac{\dot{Q}_c^{k=1}(82) - \dot{Q}_c^{k=1}(67)}{82-67}\cdot (1 - N_Q)\right] + \left[N_Q\cdot \frac{\dot{Q}_c^{k=2}(95) - \dot{Q}_c^{k=2}(82)}{95-82}\right]$$

$$M_E = \left[\frac{\dot{E}_c^{k=1}(82) - \dot{E}_c^{k=1}(67)}{82-67}\cdot (1 - N_E)\right] + \left[N_E\cdot \frac{\dot{E}_c^{k=2}(95) - \dot{E}_c^{k=2}(82)}{95-82}\right]$$

where,

$$N_Q = \frac{\dot{Q}_c^{k=v}(87) - \dot{Q}_c^{k=1}(87)}{\dot{Q}_c^{k=2}(87) - \dot{Q}_c^{k=1}(87)}, \text{ and}$$

$$N_E = \frac{\dot{E}_c^{k=v}(87) - \dot{E}_c^{k=1}(87)}{\dot{E}_c^{k=2}(87) - \dot{E}_c^{k=1}(87)}.$$

Calculating Equation 4.1–1 quantities

$$\frac{q_c(T_j)}{N} \text{ and } \frac{e_c(T_j)}{N}$$

differs depending upon whether the test unit would operate at minimum speed (Section 4.1.4.1), operate at an intermediate speed (Section 4.1.4.2), or operate at maximum speed (Section 4.1.4.3) in responding to the building load. Use Equation 4.1–2 to calculate the building load, $BL(T_j)$, for each temperature bin.

4.1.4.1 Steady-state space cooling capacity when operating at minimum compressor speed is greater than or equal to the building cooling load at temperature T_j, $\dot{Q}_c^{k=1}(T_j) \geq BL(T_j)$.

$$\frac{q_c(T_j)}{N} = X^{k=1}(T_j)\cdot \dot{Q}_c^{k=1}(T_j)\cdot \frac{n_j}{N}$$

$$\frac{e_c(T_j)}{N} = \frac{X^{k=1}(T_j)\cdot \dot{E}_c^{k=1}(T_j)}{PLF_j}\cdot \frac{n_j}{N}$$

where,

$X^{k=1}(T_j) = BL(T_j) / \dot{Q}_c^{k=1}(T_j)$, the cooling mode minimum speed load factor for temperature bin j, dimensionless.

$PLF_j = 1 - C_D\cdot [1 - X^{k=1}(T_j)]$, the part load factor, dimensionless.

$$\frac{n_j}{N} =$$

fractional bin hours for the cooling season; the ratio of the number of hours during the cooling season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the cooling season, dimensionless.

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. Use Equations 4.1.4–1 and 4.1.4–2, respectively, to evaluate $\dot{Q}_c^{k=1}(T_j)$ and $\dot{E}_c^{k=1}(T_j)$. If the optional tests described in Section 3.2.4 and Table 6 are not conducted, set the cooling mode cyclic degradation coefficient, $C_D{}^c$, to the default value specified in Section 3.5.3. If these optional tests are conducted, set $C_D{}^c$ to the lower of:

a. The value calculated according to Section 3.5.3 or

b. The Section 3.5.3 default value of 0.25.

4.1.4.2 Unit operates at an intermediate compressor speed (k=i) in order to match the building cooling load at temperature T_j, $\dot{Q}_c^{k=1}(T_j) < BL(T_j) < \dot{Q}_c^{k=1}(T_j)$.

$$\frac{q_c(T_j)}{N} = \dot{Q}_c^{k=i}(T_j)\cdot \frac{n_j}{N}$$

$$\frac{e_c(T_j)}{N} = \dot{E}_c^{k=i}(T_j)\cdot \frac{n_j}{N}$$

where,

$\dot{Q}_c^{k=1}(T_j) = BL(T_j)$, the space cooling capacity delivered by the unit in matching the building load at temperature T_j, Btu/h. The matching occurs with the unit operating at compressor speed $k = i$.

$\dot{E}_c^{k=1}(T_j) =$

$$\frac{\dot{Q}_c^{k=i}(T_j)}{EER^{k=i}(T_j)},$$

the electrical power input required by the test unit when operating at a compressor speed of $k = i$ and temperature T_j, W.

$EER^{k=i}(T_j)$ = the steady-state energy efficiency ratio of the test unit when operating at a compressor speed of $k = i$ and temperature T_j, Btu/h per W.

Obtain the fractional bin hours for the cooling season,

$$\frac{n_j}{N},$$

from Table 16. For each temperature bin where the unit operates at an intermediate compressor speed, determine the energy efficiency ratio $EER^{k=i}(T_j)$ using,

$$EER^{k=i}(T_j) = A + B\cdot T_j + C\cdot T_j^2.$$

For each unit, determine the coefficients A, B, and C by conducting the following calculations once:

$$D = \frac{T_2^2 - T_1^2}{T_v^2 - T_1^2}$$

$$C = \frac{EER^{k=1}(T_1) - EER^{k=2}(T_2) - B\cdot (T_1 - T_2)}{A = EER^{k=2}(T_2) - T_1^2 - T_2^2 - C\cdot T_2^2}$$

$$B = \frac{EER^{k=1}(T_1) - EER^{k=2}(T_2) - D\cdot \left[EER^{k=1}(T_1) - EER^{k=v}(T_v)\right]}{T_1 - T_2 - D\cdot (T_1 - T_v)}$$

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where,

T_1 = the outdoor temperature at which the unit, when operating at minimum compressor speed, provides a space cooling capacity that is equal to the building load [$\dot{Q}_c^{k=1}(T_1) = BL(T_1)$], °F. Determine T_1 by equating Equations 4.1.4–1 and 4.1–2 and solving for outdoor temperature.

T_v = the outdoor temperature at which the unit, when operating at the intermediate compressor speed used during the Section 3.2.4 E_V Test, provides a space cooling capacity that is equal to the building load [$\dot{Q}_c^{k=v}(T_v) = BL(T_v)$], °F. Determine T_v by equating Equations 4.1.4–3 and 4.1–2 and solving for outdoor temperature.

T_2 = the outdoor temperature at which the unit, when operating at maximum compressor speed, provides a space cooling capacity that is equal to the building load [$\dot{Q}_c^{k=2}(T_2) = BL(T_v)$], °F. Determine T_2 by equating Equations 4.1.3–3 and 4.1–2 and solving for outdoor temperature.

$$EER^{k=1}(T_1) = \frac{\dot{Q}_c^{k=1}(T_1)\ \left[\text{Eqn. 4.1.4-1, substituting } T_1 \text{ for } T_j\right]}{\dot{E}_c^{k=1}(T_1)\ \left[\text{Eqn. 4.1.4-2, substituting } T_1 \text{ for } T_j\right]}, \text{ Btu/h per W.}$$

$$EER^{k=v}(T_v) = \frac{\dot{Q}_c^{k=v}(T_v)\ \left[\text{Eqn. 4.1.4-3, substituting } T_v \text{ for } T_j\right]}{\dot{E}_c^{k=v}(T_v)\ \left[\text{Eqn. 4.1.4-4, substituting } T_v \text{ for } T_j\right]}, \text{ Btu/h per W.}$$

$$EER^{k=2}(T_2) = \frac{\dot{Q}_c^{k=2}(T_2)\ \left[\text{Eqn. 4.1.3-3, substituting } T_2 \text{ for } T_j\right]}{\dot{E}_c^{k=2}(T_2)\ \left[\text{Eqn. 4.1.3-4, substituting } T_2 \text{ for } T_j\right]}, \text{ Btu/h per W.}$$

4.1.4.3 Unit must operate continuously at maximum ($k=2$) compressor speed at temperature T_j, $BL(T_j) \geq \dot{Q}_c^{k=2}(T_j)$. Evaluate the Equation 4.1–1 quantities

$$\frac{q_c(T_j)}{N} \text{ and } \frac{e_c(T_j)}{N}$$

as specified in Section 4.1.3.4 with the understanding that $\dot{Q}_c^{k=2}(T_j)$ and $\dot{E}_c^{k=2}(T_j)$ correspond to maximum compressor speed operation and are derived from the results of the tests specified in Section 3.2.4.

4.2 Heating Seasonal Performance Factor (HSPF) Calculations. Six generalized climatic regions are depicted in Figure 2 and otherwise defined in Table 17. For each of these regions and for each applicable standardized design heating requirement, evaluate the heating seasonal performance factor using,

$$HSPF = \frac{\sum_j^J n_j \cdot BL(T_j)}{\sum_j^J e_h(T_j) + \sum_j^J RH(T_j)} \cdot F_{def} = \frac{\sum_j^J \left[\frac{n_j}{N} \cdot BL(T_j)\right]}{\sum_j^J \frac{e_h(T_j)}{N} + \sum_j^J \frac{RH(T_j)}{N}} \cdot F_{def} \qquad (4.2\text{-}1)$$

where,

$\frac{e_h(T_j)}{N}$ =

the ratio of the electrical energy consumed by the heat pump during periods of the space heating season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the heating season (N), W.

$\frac{RH(T_j)}{N}$ =

the ratio of the electrical energy used for resistive space heating during periods when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the heating season (N), W. Except as noted in Section 4.2.1.2, resistive space heating is modeled as being used to meet that portion of the building load that the heat pump does not meet because of insufficient capacity or because the heat pump automatically turns off at the lowest outdoor temperatures.

T_j = the outdoor bin temperature, °F. Outdoor temperatures are "binned" such that calculations are only performed based one temperature within the bin. Bins of 5 °F are used.

$\frac{n_j}{N}$ =

fractional bin hours for the heating season; the ratio of the number of hours during the heating season when the outdoor temperature fell within the range represented by bin temperature T_j to the total number of hours in the heating season, dimensionless. Obtain

$\frac{n_j}{N}$

values from Table 17.

j = the bin number, dimensionless.

J = for each generalized climatic region, the total number of temperature bins, dimensionless. Referring to Table 17, J is the highest bin number (j) having a nonzero entry for the fractional bin hours for the generalized climatic region of interest.

F_{def} = the demand defrost credit described in Section 3.9.2, dimensionless.

$BL(T_j)$ = the building space conditioning load corresponding to an outdoor temperature of Tj for a given generalized climatic region and design heating requirement, Btu/h.

TABLE 17.—GENERALIZED CLIMATIC REGION INFORMATION

Region Number		I	II	III	IV	V	VI
Heating Load Hours, HLH		750	1250	1750	2250	2750	*2750
Outdoor Design Temperature, T_{od}		37	27	17	5	−10	30
j	T_j(°F)	Fractional Bin Hours, n_j/N					
1	62	.291	.215	.153	.132	.106	.113
2	57	.239	.189	.142	.111	.092	.206
3	52	.194	.163	.138	.103	.086	.215
4	47	.129	.143	.137	.093	.076	.204
5	42	.081	.112	.135	.100	.078	.141
6	37	.041	.088	.118	.109	.087	.076
7	32	.019	.056	.092	.126	.102	.034
8	27	.005	.024	.047	.087	.094	.008
9	22	.001	.008	.021	.055	.074	.003
10	17	0	.002	.009	.036	.055	0
11	12	0	0	.005	.026	.047	0
12	7	0	0	.002	.013	.038	0
13	2	0	0	.001	.006	.029	0
14	−3	0	0	0	.002	.018	0
15	−8	0	0	0	.001	.010	0
16	−130	0	0	0	.005	0	0
17	−18	0	0	0	0	.002	0
18	−23	0	0	0	0	.001	0

*Pacific Coast Region.

Evaluate the building heating load using,

$$BL(T_j) = \frac{(65 - T_j)}{65 - T_{OD}} \cdot C \cdot DHR \quad 4.2\text{-}2$$

where,

T_{OD} = the outdoor design temperature, °F. An outdoor design temperature is specified for each generalized climatic region in Table 17.

C = 0.77, a correction factor which tends to improve the agreement between calculated and measured building loads, dimensionless.

DHR = the design heating requirement (see Definition 1.21), Btu/h.

Calculate the minimum and maximum design heating requirements for each generalized climatic region as follows:

$$DHR_{min} = \begin{cases} \dot{Q}_h^k(47) \cdot \left[\frac{65 - T_{OD}}{60}\right], & \text{for Regions I, II, III, IV, \& VI} \\ \dot{Q}_h^k(47), & \text{for Region V} \end{cases} \Bigg\} \text{Rounded to the nearest standardized DHR given in Table 18.}$$

and

$$DHR_{max} = \begin{cases} 2 \cdot \dot{Q}_h^k(47) \cdot \left[\frac{65 - T_{OD}}{60}\right], & \text{for Regions I, II, III, IV, \& VI} \\ 2 \cdot 2 \cdot \dot{Q}_h^k(47), & \text{for Region V} \end{cases} \Bigg\} \text{Rounded to the nearest standardized DHR given in Table 18.}$$

where $\dot{Q}_h^k(47)$ is expressed in units of Btu/h and otherwise defined as follows.

1. For a single-speed heat pump tested as per Section 3.6.1, $\dot{Q}_h^k(47) = \dot{Q}_h^k(47)$, the space heating capacity determined from the $H1$ Test.

2. For a variable-speed heat pump, a Section 3.6.2 single-speed heat pump, or a two-capacity heat pump not covered by item 3, $\dot{Q}_h^k(47) = \dot{Q}_h^{k=2}(47)$, the space heating capacity determined from the $H1_N$ Test.

3. For two-capacity heat pumps that are designed to operate exclusively, via an equipment lockout feature, at low compressor capacity when space cooling while using both high and low capacities when space heating, $\dot{Q}_h^k(47) = \dot{Q}_h^k(47)$, the space heating capacity determined from the $H1_n$ Test.

If the optional $H1_N$ Test is conducted on a variable-speed heat pump, the manufacturer has the option of defining $\dot{Q}_h^k(47)$ as specified above in item 2 or as $\dot{Q}_h^k(47) = \dot{Q}_h^{k=N}(47)$, the space heating capacity determined from the $H1_N$ Test.

TABLE 18.—STANDARDIZED DESIGN HEATING REQUIREMENTS (BTU/H)

5,000	25,000	50,000	90,000
10,000	30,000	60,000	100,000
15,000	35,000	70,000	110,000
20,000	40,000	80,000	130,000

4.2.1 Additional steps for calculating the HSPF of a heat pump having a single-speed compressor that was tested with a fixed-speed indoor fan installed, a constant-air-volume-rate indoor fan installed, or with no indoor fan installed.

$$\frac{e_h(T_j)}{N} = \frac{X(T_j)\cdot \dot{E}_h(T_j)\cdot \delta(T_j)}{PLF_j}\cdot\frac{n_j}{N} \qquad (4.2.1\text{-}1)$$

$$\frac{RH(T_j)}{N} = \frac{BL(T_j) - \left[X(T_j)\cdot \dot{Q}_h(T_j)\cdot \delta(T_j)\right]}{3.413\frac{Btu/h}{W}}\cdot\frac{n_j}{N} \qquad (4.2.1\text{-}2)$$

where,

$$X(T_j) = \begin{Bmatrix} BL(T_j)/\dot{Q}_h(T_j) \\ \text{or} \\ 1 \end{Bmatrix}$$

whichever is less; the heating mode load factor for temperature bin$_j$, dimensionless.

$\dot{Q}_h(T_j)$ = the space hearing capacity of the heat pump when operating at outdoor temperature T_j, Btu/h.

$\dot{E}_h(T_j)$ = the electrical power consumption of the heat pump when operating at outdoor temperature T_j, W.

$\delta(T_j)$ = the heat pump low temperature cut-out factor, dimensionless.

$PFL_j = 1 - C_{D>}{}^h \cdot [1 - X(T_j)]$, the part load factor, dimensionless.

Use Equation 4.2–2 to determine $BL(T_j)$. Obtain fractional bin hours for the heating season, n_j/N, from Table 17. If the optional *H1C* Test described in Section 3.6.1 is not conducted, set the heating mode cyclic degradation coefficient, $C_D{}^h$, to the default value specified in Section 3.8.1. If this optional test is conducted, set $C_D{}^h$ to the lower of:

a. The value calculated according to Section 3.8.1 or

b. The Section 3.8.1 default value of 0.25.

Determine the low temperature cut-out factor using,

$$\delta(T_j) = \begin{cases} 0, \text{ if } T_j \le T_{off} \text{ or } \dfrac{\dot{Q}_h(T_j)}{3.413\cdot \dot{E}_h(T_j)} < 1 \\ 1/2, \text{ if } T_{off} < T_j \le T_{on} \text{ and } \dfrac{\dot{Q}_h(T_j)}{3.413\cdot \dot{E}_h(T_j)} \ge 1 \\ 1, \text{ if } T_j > T_{on} \text{ and } \dfrac{\dot{Q}_h(T_j)}{3.413\cdot \dot{E}_h(T_j)} \ge 1 \end{cases} \qquad (4.2.1\text{-}3)$$

where,

T_{off} = the outdoor temperature when the compressor is automatically shut off, °F. (If no such temperature exists, T_j is always greater than T_{off} and T_{on}).

T_{on} = the outdoor temperature when the compressor is automatically turned back on, if applicable, following an automatic shut-off, °F.

For non-defrost heat pumps covered under Section 3.6.1.1, determine its space heating capacity, $\dot{Q}_h(T_j)$, and the electrical power consumption, $\dot{E}_h(T_j)$, as specified in Section 4.2.1.1. For heat pumps having a heat comfort controller that are covered under Section 3.6.1.2, determine $\dot{Q}_h(T_j)$ and $\dot{E}_h(T_j)$ as specified in Section 4.2.1.2. For all other heat pumps covered under Section 4.2.1 (and Section 3.6.1), calculate $\dot{Q}_h(T_j)$ and $\dot{E}_h(T_j)$ using,

$$\dot{Q}_h(T_j) = \begin{cases} \dot{Q}_h(17) + \dfrac{\left[\dot{Q}_h(47) - \dot{Q}_h(17)\right]\cdot(T_j - 17)}{47 - 17}, & \text{if } T_j \ge 45\ ^\circ\text{F or } T_j \le 17\ ^\circ\text{F} \\ \dot{Q}_h(17) + \dfrac{\left[\dot{Q}_h(35) - \dot{Q}_h(17)\right]\cdot(T_j - 17)}{35 - 17}, & \text{if } T_j \ge 17\ ^\circ\text{F} < T_j < 45\ ^\circ\text{F} \end{cases} \qquad (4.2.1\text{-}4)$$

$$\dot{E}_h(T_j) = \begin{cases} \dot{E}_h(17) + \dfrac{\left[\dot{E}_h(47) - \dot{E}_h(17)\right]\cdot(T_j - 17)}{47 - 17}, & \text{if } T_j \ge 45^\circ\text{F or } T_j \le 17^\circ\text{F} \\ \dot{E}_h(17) + \dfrac{\left[\dot{E}_h(35) - \dot{E}_h(17)\right]\cdot(T_j - 17)}{35 - 17}, & \text{if } 17^\circ\text{F} < T_j < 45^\circ\text{F} \end{cases} \qquad (4.2.1\text{-}5)$$

where

$\dot{Q}_h(47)$ and $\dot{E}_h(47)$ are determined from the *H1* Test and calculated and as specified in Section 3.7; $\dot{Q}_h(35)$ and $\dot{E}_h(35)$ are determined from the *H2* Test and calculated as specified in Section 3.9.1; and $\dot{Q}_h(17)$ and $\dot{E}_h(17)$ are determined from the *H3* Test and calculated as specified in Section 3.10.

4.2.1.1 *Space heating capacity and the electrical power consumption calculations for a non-defrost heat pump.* Calculate the space heating capacity, $\dot{Q}_h(T_j)$, and the electrical power consumption, $\dot{E}_h(T_j)$, for a non-defrost heat pump covered under Section 3.6.1.1 using,

$$\dot{Q}_h(T_j) = \dot{Q}_h(47) + \left[\dot{Q}_h(62) - \dot{Q}_h(47)\right]\cdot\frac{(T_j - 47)}{62 - 47}$$

$$\dot{E}_h(T_j) = \dot{E}_h(47) + \left[\dot{E}_h(62) - \dot{E}_h(47)\right]\cdot\frac{(T_j - 47)}{62 - 47}$$

where

$\dot{Q}_h(62)$ and $\dot{E}_h(62)$ are determined from the *H0* Test, $\dot{Q}_h(47)$ and $\dot{E}_h(47)$ are determined from the H1 Test, and all four quantities are calculated as specified in Section 3.7. The low temperature cut-out factor, (T_j), must be greater than or equal to 37 °F, in accordance with Section 3.6.1.1.

4.2.1.2 *Space heating capacity and the electrical power consumption calculations for a heat pump having a heat comfort controller.* Calculate the space heating capacity and electrical power of the heat pump without the heat comfort controller being active as specified in Section 4.2.1 (Equations 4.2.1–4 and 4.2.1–5) for each outdoor bin temperature, T_j, that is listed in Table 17. Denote these capacities and electrical powers by using the subscript "hp" instead of "h." Calculate the mass flow rate (expressed in pounds-mass of dry air per hour) and the specific heat of the indoor air (expressed in Btu/lbm$_{da}$ · °F) from the results of the *H1* Test using:

$$\dot{m}_{da} = \bar{\dot{V}}_s \cdot 0.075\frac{lbm_{da}}{ft^3}\cdot\frac{60\ min}{hr} = \frac{\bar{\dot{V}}_{mx}}{v'_n\cdot[1 + W_n]}\cdot\frac{60\ min}{hr} = \frac{\dot{V}_{mx}}{v_n}\cdot\frac{60\ min}{hr}$$

$$C_{p,da} = 0.24 + 0.444\cdot W_n$$

where,

$\bar{\dot{V}}_s$, $\bar{\dot{V}}_{mx}$, v'_n(or v_n), and W_n

are defined following Equation 3–1. For each outdoor bin temperature listed in Table 17, calculate the nominal temperature of the air leaving the heat pump condenser coil using,

$$T_o(T_j) = 70\ ^\circ\text{F} + \frac{\dot{Q}_{hp}(T_j)}{\dot{m}_{da}\cdot C_{p,da}}$$

For outdoor bin temperatures where $T_o(T_j)$ is equal to or greater than T_{CC}, the maximum supply temperature determined according to Section 3.1.9, determine $\dot{Q}_h(T_j)$ and $\dot{E}_h(T_j)$ as specified in Section 4.2.1 [i.e., $\dot{Q}_h(T_j) = \dot{Q}_{hp}(T_j)$ and $\dot{E}_h(T_j) = E_{hp}(T_j)$].

For outdoor bin temperatures where $T_o(T_j) < T_{CC}$, $\dot{Q}_h(Tj) = \dot{Q}_{hp}(T_j) + \dot{Q}_{CC}(T_j)$

$$\dot{E}_h(T_j) = \dot{E}_{hp}(T_j) + \dot{E}_{CC}(T_j)$$

where,

$$\dot{Q}_{CC}(T_j) = \dot{m}_{da}\cdot C_{p,da}\cdot\left[T_{CC} - T_o(T_j)\right]$$

$$\dot{E}_{CC}(T_j) = \frac{\dot{Q}_{CC}(T_j)}{3.413\frac{Btu}{W\cdot h}}$$

Calculate the *HSPF* of a heat pump having a heat comfort controller as specified in Section 4.2.1 with the exception of using the space heating capacity and electrical power given above [$\dot{Q}_h(T_j)$ and $\dot{E}_h(T_j)$] for the calculations at each outdoor bin temperature.

4.2.2 *Additional steps for calculating the HSPF of a heat pump having a single-speed compressor and a variable-speed, variable-air-volume-rate indoor fan.* The manufacturer must provide information about how the indoor air volume rate or the indoor fan speed varies over the outdoor temperature range of 65 °F to –23 °F. Calculate the quantities

$$\frac{e_h(T_j)}{N} \text{ and } \frac{RH_h(T_j)}{N}$$

in Equation 4.2–1 as specified in Section 4.2.1 with the exception of replacing references to the H1C Test and Section 3.6.1 with the *H1C$_1$* Test and Section 3.6.2. In addition, evaluate the space heating capacity and electrical power consumption of the heat pump [$\dot{Q}_h(T_j)$ and $\dot{E}_h(T_j)$] using,

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$$\dot{Q}_h(T_j) = \dot{Q}_h^{k=1}(T_j) + \frac{\dot{Q}_h^{k=2}(T_j) - \dot{Q}_h^{k=1}(T_j)}{FP_h^{k=2} - FP_h^{k=1}} \cdot \left[FP_h(T_j) - FP_h^{k=1}\right]$$

$$\dot{E}_h(T_j) = \dot{E}_h^{k=1}(T_j) + \frac{\dot{E}_h^{k=2}(T_j) - \dot{E}_h^{k=1}(T_j)}{FP_h^{k=2} - FP_h^{k=1}} \cdot \left[FP_h(T_j) - FP_h^{k=1}\right]$$

where the space heating capacity and electrical power consumption at both low capacity (k=1) and high capacity (k=2) at outdoor temperature T_j are determined using,

$$\dot{Q}_h^k(T_j) = \begin{cases} \dot{Q}_h^k(17) + \dfrac{\left[\dot{Q}_h^k(47) - \dot{Q}_h^k(17)\right] \cdot (T_j - 17)}{47 - 17}, & \text{if } T_j \geq 45\ ^\circ\text{F or } T_j \leq 17\ ^\circ\text{F} \\ \dot{Q}_h^k(17) + \dfrac{\left[\dot{Q}_h^k(35) - \dot{Q}_h^k(17)\right] \cdot (T_j - 17)}{35 - 17}, & \text{if } 17\ ^\circ\text{F} < T_j < 45\ ^\circ\text{F} \end{cases} \quad (4.2.2\text{-}1)$$

$$\dot{E}_h^k(T_j) = \begin{cases} \dot{E}_h^k(17) + \dfrac{\left[\dot{E}_h^k(47) - \dot{E}_h^k(17)\right] \cdot (T_j - 17)}{47 - 17}, & \text{if } T_j \geq 45\ ^\circ\text{F or } T_j \leq 17\ ^\circ\text{F} \\ \dot{E}_h^k(17) + \dfrac{\left[\dot{E}_h^k(35) - \dot{E}_h^k(17)\right] \cdot (T_j - 17)}{35 - 17}, & \text{if } 17\ ^\circ\text{F} < T_j < 45\ ^\circ\text{F} \end{cases} \quad (4.2.2\text{-}2)$$

For units where indoor fan speed is the primary control variable, $FP_h^{k=1}$ denotes the fan speed used during the required $H1_1$ and $H3_1$ Tests (see Table 10), $FP_h^{k=2}$ denotes the fan speed used during the required $H1_2$, $H2_2$, and $H3_2$ Tests, and $FP_h(T_j)$ denotes the fan speed used by the unit when the outdoor temperature equals T_j. For units where indoor air volume rate is the primary control variable, the three FP_h's are similarly defined only now being expressed in terms of air volume rates rather than fan speeds. Determine $\dot{Q}_h^{k=1}$ (47) and $\dot{E}_h^{k=1}$ (47) from the $H1_1$ Test, and $\dot{Q}_h^{k=2}$ (47) and $\dot{E}_h^{k=2}$ (47) from the $H1_2$ Test. Calculate all four quantities as specified in Section 3.7. Determine $\dot{Q}_h^{k=1}$ (35) and $\dot{E}_h^{k=1}$ (35) as specified in Section 3.6.2; determine $\dot{Q}_h^{k=2}$ (35) and $\dot{E}_h^{k=2}$ (35) from the $H2_2$ Test and the calculation specified in Section 3.9. Determine $\dot{Q}_h^{k=1}$ (17) and $\dot{E}_h^{k=1}$ (17) from the $H3_1$ Test, and $\dot{Q}_h^{k=2}$ (17) and $\dot{E}_h^{k=2}$ (17) from the $H3_2$ Test. Calculate all four quantities as specified in Section 3.10.

4.2.3 *Additional steps for calculating the HSPF of a heat pump having a two-capacity compressor.* The calculation of the Equation 4.2–1 quantities

$$\frac{e_h(T_j)}{N}$$

and

$$\frac{RH_c(T_j)}{N}$$

differs depending upon whether the heat pump would operate at low capacity (Section 4.2.3.1), cycle between low and high capacity (Section 4.2.3.2), or operate at high capacity (Sections 4.2.3.3 and 4.2.3.4) in responding to the building load. For heat pumps that lock out high and/or low capacity operation at low outdoor temperatures, the manufacturer must supply information regarding the cutoff temperature(s) so that you can select the appropriate equations.

a. Evaluate the space heating capacity and electrical power consumption of the heat pump when operating at low compressor capacity and outdoor temperature T_j using,

$$\dot{Q}_h^{k=1}(T_j) = \begin{cases} \dot{Q}_h^{k=1}(47) + \dfrac{\left[\dot{Q}_h^{k=1}(62) - \dot{Q}_h^{k=1}(47)\right] \cdot (T_j - 47)}{62 - 47}, & \text{if } T_j \geq 40\ ^\circ\text{F} \\ \dot{Q}_h^{k=1}(17) + \dfrac{\left[\dot{Q}_h^{k=1}(35) - \dot{Q}_h^{k=1}(17)\right] \cdot (T_j - 17)}{35 - 17}, & \text{if } 17\ ^\circ\text{F} \leq T_j \leq 40\ ^\circ\text{F} \\ \dot{Q}_h^{k=1}(17) + \dfrac{\left[\dot{Q}_h^{k=1}(47) - \dot{Q}_h^{k=1}(17)\right] \cdot (T_j - 17)}{47 - 17}, & \text{if } T_j < 17\ ^\circ\text{F} \end{cases}$$

$$\dot{E}_h^{k=1}(T_j) = \begin{cases} \dot{E}_h^{k=1}(47) + \dfrac{\left[\dot{E}_h^{k=1}(62) - \dot{E}_h^{k=1}(47)\right] \cdot (T_j - 47)}{62 - 47}, & \text{if } T_j \geq 40\ ^\circ\text{F} \\ \dot{E}_h^{k=1}(17) + \dfrac{\left[\dot{E}_h^{k=1}(35) - \dot{E}_h^{k=1}(17)\right] \cdot (T_j - 17)}{35 - 17}, & \text{if } 17\ ^\circ\text{F} \leq T_j < 40\ ^\circ\text{F} \\ \dot{E}_h^{k=1}(17) + \dfrac{\left[\dot{E}_h^{k=1}(47) - \dot{E}_h^{k=1}(17)\right] \cdot (T_j - 17)}{47 - 17}, & \text{if } T_j < 17\ ^\circ\text{F} \end{cases}$$

b. Evaluate the space heating capacity and electrical power consumption [$\dot{Q}_h^{k=2}(T_j)$ and $\dot{E}_h^{k=2}(T_j)$] of the heat pump when operating at high compressor capacity and outdoor temperature T_j by solving Equations 4.2.2–1 and 4.2.2–2, respectively, for k=2. Determine $\dot{Q}_h^{k=1}$ (62) and $\dot{E}_h^{k=1}$ (62) from the $H0_1$ Test, $\dot{Q}_h^{k=1}$ (47) and $\dot{E}_h^{k=1}$ (47) from the $H1_1$ Test, and $\dot{Q}_h^{k=2}$ (47) and $\dot{E}_h^{k=2}$ (47) from the $H1_2$ Test. Calculate all six quantities as specified in Section 3.7. Determine $\dot{Q}_h^{k=2}$ (35) and $\dot{Q}_h^{k=2}$ (35) from the $H2_2$ Test and, if required as described in Section 3.6.3, determine $\dot{Q}_h^{k=1}$ (35) and $\dot{E}_h^{k=1}$ (35) from the $H2_1$ Test. Calculate the required 35 °F quantities as specified in Section 3.9. Determine $\dot{Q}_h^{k=2}$ (17) and $\dot{E}_h^{k=2}$ (17) and from the $H3_2$ Test and, if required as described in Section 3.6.3, determine $\dot{Q}_h^{k=1}$ (17) and $\dot{E}_h^{k=1}$ (17) from the $H3_1$ Test. Calculate the required 17 °F quantities as specified in Section 3.10.

4.2.3.1 Steady-state space heating capacity when operating at low compressor capacity is greater than or equal to the building heating load at temperature T_j, $\dot{Q}_h^{k=1}(T_j) \geq BL(T_j)$.

$$\frac{e_h(T_j)}{N} = \frac{X^{k=1}(T_j) \cdot \dot{E}_h^{k=1}(T_j) \cdot \delta'(T_j)}{PLF_j} \cdot \frac{n_j}{N} \quad (4.2.3\text{-}1)$$

$$\frac{RH(T_j)}{N} = \frac{BL(T_j) \cdot \left[1 - \delta'(T_j)\right]}{3.413 \dfrac{Btu/h}{W}} \cdot \frac{n_j}{N} \quad (4.2.3\text{-}2)$$

where,

$X^{k=1} = BL(T_j)/\dot{Q}_h^{k=1}(T_j)$, the heating mode low capacity load factor for temperature bin j, dimensionless.

$PLF_j = 1 - C_D^h \cdot [1 - X^{k=1}(T_j)]$, the part load factor, dimensionless.

$\delta'(T_j$ = the low temperature cutoff factor, dimensionless.

If the optional $H0C_1$ Test described in Section 3.6.3 is not conducted, set the heating mode cyclic degradation coefficient, C_D^h, to the default value specified in Section 3.8.1. If this optional test is conducted, set C_D^h to the lower of:

a. The value calculated according to Section 3.8.1 or

b. The Section 3.8.1 default value of 0.25.

Determine the low temperature cut-out factor using,

$$\delta'(T_j) = \begin{cases} 0, & \text{if } T_j \leq T_{off} \\ 1/2, & \text{if } T_{off} < T_j \leq T_{on} \\ 1, & \text{if } T_j > T_{on} \end{cases} \quad (4.2.3\text{-}3)$$

where t_{off} and T_{on} are defined in Section 4.2.1. Use the calculations given in Section 4.2.3.3, and not the above, if:

(1) the heat pump locks out low capacity operation at low outdoor temperatures and

(2) T_j is below this lockout threshold temperature.

4.2.3.2 Heat pump alternates between high (k=2) and low (k=1) compressor capacity to satisfy the building heating load at a temperature T_j, $\dot{Q}_h^{k=1}(T_j) < BL(T_j) < \dot{Q}_h^{k=2}(T_j)$.

Calculate $\dfrac{RH(T_j)}{N}$ using Equation 4.2.3-2. Evaluate $\dfrac{e_h(T_j)}{N}$ using,

$$\frac{e_h(T_j)}{N} = \left[X^{k=1}(T_j) \cdot \dot{E}_h^{k=1}(T_j) + X^{k=2}(T_j) \cdot \dot{E}_h^{k=2}(T_j)\right] \cdot \delta'(T_j) \cdot \frac{n_j}{N}$$

where,

$$X^{k=1}(T_j) = \frac{\dot{Q}_h^{k=2}(T_j) - BL(T_j)}{\dot{Q}_h^{k=2}(T_j) - \dot{Q}_h^{k=1}(T_j)}$$

$X^{k=2}(T_j)$ $1 - X^{k=1}(T_j)$, the heating mode, high capacity load factor for temperature bin j, dimensionless.

Determine the low temperature cut-out factor, $\delta(T)$, using Equation 4.2.3–3.

4.2.3.3 Heat pump only operates at high (k=2) compressor capacity at temperature Tj and its capacity is greater than the building heating load, $BL(T_j) < \dot{Q}_h^{k=2}(T_j)$. This Section applies to units that lock out low compressor capacity operation at low outdoor temperatures. Calculate

$$\frac{RH(T_j)}{N}$$

using Equation 4.2.3–2. Evaluate

$$\frac{e_h(T_j)}{N}$$

using,

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$$\frac{e_h(T_j)}{N} = \frac{X^{k=2}(T_j)\cdot \dot{E}_h^{k=2}(T_j)\cdot \delta'(T_j)}{PLF_j}\cdot\frac{n_j}{N}$$

where,

$X^{k=2}(T_j) = BL(T_j) / \dot{Q}_h^{k=2}(T_j)$.

$PLF_j = 1 - C_D{}^h \cdot [1 - X^{k=2}(T_j)]$.

When evaluating the above equation for part load factor at high capacity, use the same value of $C_D{}^h$ as used in the Section 4.2.3.1 calculations. Determine the low temperature cut-out factor, $\delta(T)$, using Equation 4.2.3–3.

4.2.3.4 *Heat pump must operate continuously at high* (k=2) *compressor capacity at temperature T_j, $BL(T_j)$.*

$$\frac{e_h(T_j)}{N} = \dot{E}_h^{k=2}(T_j)\cdot\delta''(T_j)\cdot\frac{n_j}{N}$$

$$\frac{RH(T_j)}{N} = \frac{BL(T_j) - \left[\dot{Q}_h^{k=2}(T_j)\cdot\delta''(T_j)\right]}{3.413\frac{Btu/h}{W}}\cdot\frac{n_j}{N}$$

where,

$$\delta''(T_j) = \begin{cases} 0, \text{ if } T_j \le T_{off} \text{ or } \dfrac{\dot{Q}_h^{k=2}(T_j)}{3.413\cdot\dot{E}_h^{k=2}(T_j)} < 1 \\ 1/2, \text{ if } T_{off} < T_j \le T_{on} \text{ and } \dfrac{\dot{Q}_h^{k=2}(T_j)}{3.413\cdot\dot{E}_h^{k=2}(T_j)} \ge 1 \\ 1, \text{ if } T_j > T_{on} \text{ and } \dfrac{\dot{Q}_h^{k=2}(T_j)}{3.413\cdot\dot{E}_h^{k=2}(T_j)} \ge 1 \end{cases}$$

4.2.4 Additional steps for calculating the HSPF of a heat pump having a variable-speed compressor. Calculate HSPF using Equation 4.2–1. Evaluate the space heating capacity, $\dot{Q}_h^{k=1}(T_j)$, and electrical power consumption, $\dot{E}_h^{k=1}(T_j)$, of the heat pump when operating at minimum compressor speed and outdoor temperature T_j using,

$$\dot{Q}_h^{k=1}(T_j) = \dot{Q}_h^{k=1}(47) + \frac{\dot{Q}_h^{k=1}(62) - \dot{Q}_h^{k=1}(47)}{62-47}\cdot(T_j - 47) \quad (4.2.4\text{-}1)$$

$$\dot{E}_h^{k=1}(T_j) = \dot{E}_h^{k=1}(47) + \frac{\dot{E}_h^{k=1}(62) - \dot{E}_h^{k=1}(47)}{62-47}\cdot(T_j - 47) \quad (4.2.4\text{-}2)$$

where $\dot{Q}_h^{k=1}(62)$ and $\dot{E}_h^{k=1}(62)$ are determined from the *H0*$_1$ Test, $\dot{Q}_h^{k=1}(47)$ and $\dot{E}_h^{k=1}(47)$ are determined from the *H1*$_1$ Test, and all four quantities are calculated as specified in Section 3.7. Evaluate the space heating capacity, $\dot{Q}_h^{k=2}(T_j)$, and electrical power consumption, $\dot{E}_h^{k=2}(T_j)$, of the heat pump when operating at maximum compressor speed and outdoor temperature T_j by solving Equations 4.2.2–1 and 4.2.2–2, respectively, for k=2. Determine the Equation 4.2.2–1 quantities $\dot{Q}_h^{k=2}(47)$ and $\dot{E}_h^{k=2}(47)$ from the *H1*$_2$ Test and the calculations specified in Section 3.7. Determine $\dot{Q}_h^{k=2}(35)$ and $\dot{E}_h^{k=2}(35)$ from the *H2*$_2$ Test and the calculations specified in Section 3.9 or, if the *H2*$_2$ Test is not conducted, by conducting the calculations specified in Section 3.6.4.

Determine $\dot{Q}_h^{k=2}(17)$ and $\dot{E}_h^{k=2}(17)$ from the *H3*$_2$ Test and the calculations specified in Section 3.10. Calculate the space heating capacity, $\dot{Q}_h^{k=i}(T_j)$, and electrical power consumption, $\dot{E}_h^{k=i}(T_j)$, of the heat pump when operating at outdoor temperature T_j and the intermediate compressor speed used during the Section 3.6.4 *H2*$_V$ Test using,

$$\dot{Q}_h^{k=v}(T_j) = \dot{Q}_h^{k=v}(35) + M_Q\cdot(T_j - 35) \quad (4.2.4\text{-}3)$$

$$\dot{E}_h^{k=v}(T_j) = \dot{E}_h^{k=v}(35) + M_E\cdot(T_j - 35) \quad (4.2.4\text{-}4)$$

where $\dot{Q}_h^{k=v}(35)$ and $\dot{E}_h^{k=v}(35)$ are determined from the *H2*$_V$ Test and calculated as specified in Section 3.9. Approximate the slopes of the *k=v* intermediate speed heating capacity and electrical power input curves, M_Q and M_E, as follows:

$$M_Q = \left[\frac{\dot{Q}_h^{k=1}(62) - \dot{Q}_h^{k=1}(47)}{62-47}\cdot(1 - N_Q)\right] + \left[N_Q\cdot\frac{\dot{Q}_h^{k=2}(35) - \dot{Q}_h^{k=2}(17)}{35-17}\right]$$

$$M_E = \left[\frac{\dot{E}_h^{k=1}(62) - \dot{E}_h^{k=1}(47)}{62-47}\cdot(1 - N_E)\right] + \left[N_E\cdot\frac{\dot{E}_h^{k=2}(35) - \dot{E}_h^{k=2}(17)}{35-17}\right]$$

where,

$$N_Q = \frac{\dot{Q}_h^{k=V}(35) - \dot{Q}_h^{k=1}(35)}{\dot{Q}_h^{k=2}(35) - \dot{Q}_h^{k=1}(35)}, \text{ and}$$

$$N_E = \frac{\dot{E}_h^{k=V}(35) - \dot{E}_h^{k=1}(35)}{\dot{E}_h^{k=2}(35) - \dot{E}_h^{k=1}(35)}.$$

Use Equations 4.2.4–1 and 4.2.4–2, respectively, to calculate $\dot{Q}_h^{k=1}(35)$ and $\dot{E}_h^{k=1}(35)$.

The calculation of Equation 4.2–1 quantities

$$\frac{e_h(T_j)}{N} \text{ and } \frac{RH(T_j)}{N}$$

differs depending upon whether the heat pump would operate at minimum speed (Section 4.2.4.1), operate at an intermediate speed (Section 4.2.4.2), or operate at maximum speed (Section 4.2.4.3) in responding to the building load.

4.2.4.1 Steady-state space heating capacity when operating at minimum compressor speed is greater than or equal to the building heating load at temperature T_j, $\dot{Q}_h^{k=1}(T_j) \ge BL(T_j)$. Evaluate the Equation 4.2–1 quantities

$$\frac{e_h(T_j)}{N} \text{ and } \frac{RH(T_j)}{N}$$

as specified in Section 4.2.3.1. Except now use Equations 4.2.4–1 and 4.2.4–2 to evaluate $\dot{Q}_h^{k=1}(T_j)$ and $\dot{E}_h^{k=1}(T_j)$, respectively, and replace Section 4.2.3.1 references to "low capacity" and Section 3.6.3 with "minimum speed" and Section 3.6.4. Also, the last sentence of Section 4.2.3.1 does not apply.

4.2.4.2 Heat pump operates at an intermediate compressor speed (k=i) in order to match the building heating load at a temperature T_j, $\dot{Q}_h^{k=1}(T_j) < BL(T_j) < \dot{Q}_h^{k=2}(T_j)$. Calculate

$$\frac{RH(T_j)}{N}$$

using Equation 4.2.3–2 while evaluating

$$\frac{e_h(T_j)}{N}$$

using,

$$\frac{e_h(T_j)}{N} = \dot{E}_h^{k=i}(T_j)\cdot\delta'(T_j)\cdot\frac{n_j}{N}$$

where,

$$\dot{E}_h^{k=i}(T_j) = \frac{\dot{Q}_h^{k=i}(T_j)}{3.413\frac{Btu/h}{W}\cdot COP_h^{k=i}(T_j)}$$

and $\delta(T_j)$ is evaluated using Equation 4.2.3–3 while,

$\dot{Q}_h^{k=i}(T_j) = BL(T_j)$, the space heating capacity delivered by the unit in matching the building load at temperature T_j, Btu/h. The matching occurs with the heat pump operating at compressor speed *k=i*.

$COP_h^{k=i}(T_j)$ = the steady-state coefficient of performance of the heat pump when operating at compressor speed *k=i* and temperature T_j, dimensionless.

For each temperature bin where the heat pump operates at an intermediate compressor speed, determine $COP_h^{k=i}(T_j)$ using,

$$COP_h^{k=i}(T_j) = A + B\cdot T_j + C\cdot T_j^2.$$

For each heat pump, determine the coefficients A, B, and C by conducting the following calculations once:

$$D = \frac{T_3^2 - T_4^3}{T_{vh}^2 - T_4^2}$$

$$B = \frac{COP^{k=2}(T_4) - COP^{k=1}(T_3) - D\cdot\left[COP^{k=2}(T_4) - COP^{k=v}(T_{vh})\right]}{T_4 - T_3 - D\cdot(T_4 - T_{vh})}$$

$$C = \frac{COP^{k=2}(T_4) - COP^{k=1}(T_3) - B\cdot(T_4 - T_3)}{T_4^2 - T_3^2}$$

$$A = COP^{k=2}(T_4) - B\cdot T_4 - C\cdot T_4^2.$$

where,

T_3 = the outdoor temperature at which the heat pump, when operating at minimum compressor speed, provides a space heating capacity that is equal to the building load $[\dot{Q}_h^{k=1}(T_3) = BL(T_3)]$, °F. Determine T_3 by equating Equations 4.2.4–1 and 4.2–2 and solving for outdoor temperature.

T_{vh} = the outdoor temperature at which the heat pump, when operating at the intermediate compressor speed used during the Section 3.6.4 H2$_V$ Test, provides a space heating capacity that is equal to the building load $[\dot{Q}_h^{k=v}(T_{vh}) = BL(T_{vh})]$, °F. Determine T_{vh} by equating Equations 4.2.4–3 and 4.2–2 and solving for outdoor temperature.

T_4 = the outdoor temperature at which the heat pump, when operating at maximum compressor speed, provides a space heating capacity that is equal to the building load $[\dot{Q}_h^{k=2}(T_4) = BL(T_4)]$, °F. Determine T_4 by equating Equations by 4.2.2–1 (*k=2*) and 4.2–2 and solving for outdoor temperature.

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$$COP^{k=1}(T_3) = \frac{\dot{Q}_h^{k=1}(T_3)}{3.413\frac{Btu/h}{W}\cdot \dot{E}_h^{k=1}(T_3)} \quad \begin{bmatrix}\text{Eqn. 4.2.4-1, substituting } T_3 \text{ for } T_j\end{bmatrix}$$

$$\begin{bmatrix}\text{Eqn. 4.2.4-2, substituting } T_3 \text{ for } T_j\end{bmatrix}$$

$$COP^{k=v}(T_{vh}) = \frac{\dot{Q}_h^{k=v}(T_{vh})}{3.413\frac{Btu/h}{W}\cdot \dot{E}_h^{k=v}(T_{vh})} \quad \begin{bmatrix}\text{Eqn. 4.2.4-3, substituting } T_{vh} \text{ for } T_j\end{bmatrix}$$

$$\begin{bmatrix}\text{Eqn. 4.2.4-4, substituting } T_{vh} \text{ for } T_j\end{bmatrix}$$

$$COP^{k=2}(T_4) = \frac{\dot{Q}_h^{k=2}(T_4)}{3.413\frac{Btu/h}{W}\cdot \dot{E}_h^{k=2}(T_4)} \quad \begin{bmatrix}\text{Eqn. 4.2.2-1, substituting } T_4 \text{ for } T_j\end{bmatrix}$$

$$\begin{bmatrix}\text{Eqn. 4.2.2-2, substituting } T_4 \text{ for } T_j\end{bmatrix}.$$

4.2.4.3 *Heat pump must operate continuously at maximum (k=2) compressor speed at temperature T_j, $BL(T_j) \geq \dot{Q}_h^{k=2}(T_j)$.* Evaluate the Equation 4.2–1 quantities

$$\frac{e_h(T_j)}{N} \text{ and } \frac{RH(T_j)}{N}$$

as specified in Section 4.2.3.4 with the understanding that $\dot{Q}_h^{k=2}(T_j)$ and $\dot{E}_h^{k=2}(T_j)$ correspond to maximum compressor speed operation and are derived from the results of the specified Section 3.6.4 tests.

4.3 *Calculations of the Actual and Representative Regional Annual Performance Factors for Heat Pumps.*

4.3.1 *Calculation of actual regional annual performance factors (APF_A) for a particular location and for each standardized design heating requirement.*

$$APF_A = \frac{CLH_A \cdot \dot{Q}_c^k(95) + HLH_A \cdot DHR \cdot C}{\frac{CLH_A \cdot \dot{Q}_c^k(95)}{SEER} + \frac{HLH_A \cdot DHR \cdot C}{HSPF}}$$

where,

CLH_A = the actual cooling hours for a particular location as determined using the map given in Figure 3, hr.

$\dot{Q}_c^k(95)$= the space cooling capacity of the unit as determined from the A or A_2 Test, whichever applies, Btu/h.

HLH_A = the actual heating hours for a particular location as determined using the map given in Figure 2, hr.

DHR = the design heating requirement used in determining the HSPF; refer to Section 4.2 and Definition 1.21, Btu/h.

C = defined in Section 4.2 following Equation 4.2–2, dimensionless.

SEER = the seasonal energy efficiency ratio calculated as specified in Section 4.1, Btu/W·h.

HSPF = the heating seasonal performance factor calculated as specified in Section 4.2 for the generalized climatic region that includes the particular location of interest (see Figure 2), Btu/W·h; the *HSPF* should preferably correspond to the actual design heating requirement (*DHR*) if known. But it may correspond to one of the standardized design heating requirements referenced in Section 4.2.

4.3.2 *Calculation of representative regional annual performance factors APF_R) for each generalized climatic region and for each standardized design heating requirement*

$$APF_R = \frac{CLH_R \cdot \dot{Q}_c^k(95) + HLH_R \cdot DHR \cdot C}{\frac{CLH_R \cdot \dot{Q}_c^k(95)}{SEER} + \frac{HLH_R \cdot DHR \cdot C}{HSPF}}$$

where,

CLH_R = the representative cooling hours for each generalized climatic region, Table 19, hr.

HLH_R = the representative heating hours for each generalized climatic region, Table 19, hr.

HSPF = the heating seasonal performance factor calculated as specified in Section 4.2 for each generalized climatic region and for each standardized design heating requirement within each region, Btu/W·h.

The *SEER*, $\dot{Q}_c^k(95)$, *DHR*, and *C* are the same quantities as defined in Section 4.3.1. Figure 2 shows the generalized climatic regions. Table 18 lists standardized design heating requirements.

TABLE 19.—REPRESENTATIVE COOLING AND HEATING LOAD HOURS FOR EACH GENERALIZED CLIMATIC REGION

Region	CLH_R	HLH_R
I	2400	750
II	1800	1250
III	1200	1750
IV	800	2250
V	400	2750
VI	200	2750

4.4 *Rounding of SEER, HSPF, and APF for reporting purposes.* After calculating *SEER* according to Section 4.1, round it off as specified in subpart b, § 430.23(m)(3)(i) of the Code of Federal Regulations. Round Section 4.2 *HSPF* values and Section 4.3 *APF* values as per paragraphs (ii) and (iii), respectively, of Subpart B, § 430.23(m)(3) of the Code of Federal Regulations.

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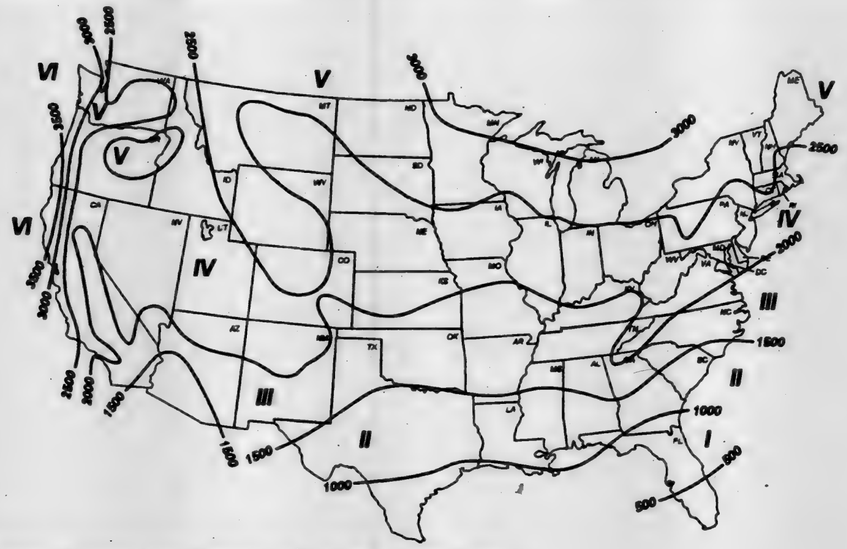


Figure 2 Heating Load Hours (HLH_A) for the United States

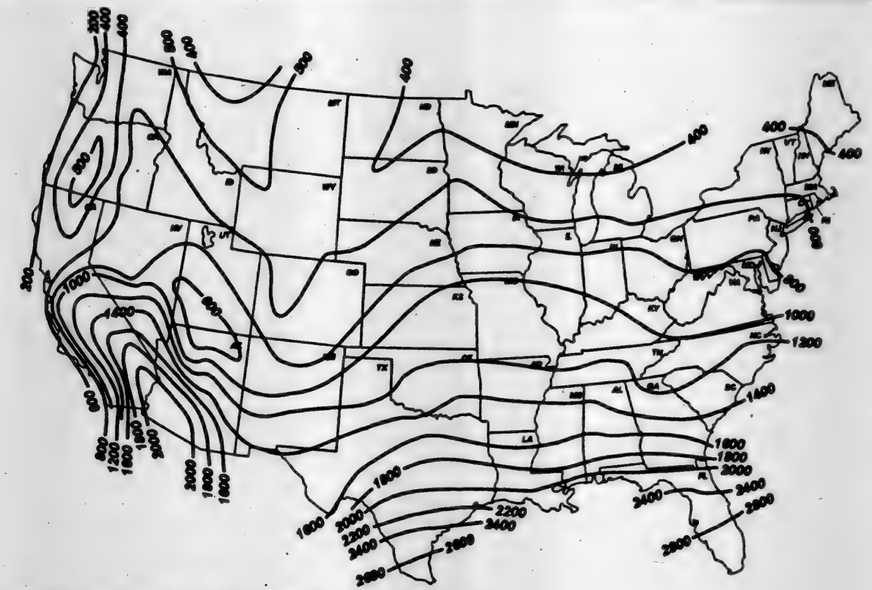


Figure 3 Cooling Load Hours (CLH_A) for the United States

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Part III

Department of Education

Office of Special Education and Rehabilitative Services; Grant Applications Under Part D, Subpart 2 of the Individuals With Disabilities Education Act; Notice

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DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services; Grant Applications Under Part D, Subpart 2 of the Individuals With Disabilities Education Act

AGENCY: Department of Education.

ACTION: Notice inviting applications for new awards for fiscal year (FY) 2001.

SUMMARY: This notice provides closing dates and other information regarding the transmittal of applications for FY 2001 competitions under three programs authorized by the Individuals with Disabilities Education Act (IDEA), as amended. The three programs are: (1) Special Education—Research and Innovation to Improve Services and Results for Children with Disabilities (five priorities); (2) Special Education—Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities (two priorities); and (3) Special Education—Technology and Media Services for Individuals with Disabilities (five priorities).

Goals 2000: Educate America Act

The Goals 2000: Education America Act (Goals 2000) focuses the Nation's education reform efforts on the eight National Education Goals and provides a framework for meeting them. Goals 2000 promotes new partnerships to strengthen schools and expands the Department's capacities for helping communities to exchange ideas and obtain information needed to achieve the goals.

These priorities would address the National Education Goals by helping to improve results for children with disabilities.

Waiver of Rulemaking

It is generally our practice to offer interested parties the opportunity to comment on proposed priorities. However, section 661(e)(2) of IDEA makes the Administrative Procedure Act (5 U.S.C. 553) inapplicable to the priorities in this notice.

General Requirements: (a) The projects funded under this notice must make positive efforts to employ and advance in employment qualified individuals with disabilities in project activities (see Section 606 of IDEA).

(b) Applicants and grant recipients funded under this notice must involve individuals with disabilities or parents of individuals with disabilities in planning, implementing, and evaluating the projects (see Section 661(f)(1)(A) of IDEA).

(c) The projects funded under these priorities must budget for a two-day Project Directors' meeting in Washington, D.C. during each year of the project.

(d) In a single application, an applicant must address only one absolute priority in this notice.

(e) Part III of each application submitted under a priority in this notice, the application narrative, is where an applicant addresses the selection criteria that are used by reviewers in evaluating the application. You must limit Part III to the equivalent of no more than the number of pages listed in the table at the end of this notice for each applicable priority, using the following standards:

- A "page" is 8.5" x 11" (on one side only) with one-inch margins (top, bottom, and sides).
- Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, and captions, as well as all text in charts, tables, figures, and graphs.
- If using a proportional computer font, use no smaller than a 12-point font, and an average character density no greater than 18 characters per inch. If using a nonproportional font or a typewriter, do not use more than 12 characters per inch.

The page limit does not apply to Part I—the cover sheet; Part II—the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the bibliography or references, or the letters of support. However, you must include all of the application narrative in Part III.

We will reject without consideration or evaluation any application if—

- You apply these standards and exceed the page limit; or
- You apply other standards and exceed the equivalent of the page limit.

Reasonable Accommodation: We will consider, and may fund, requests for additional funding above the maximum amounts indicated for each priority or focus as an addendum to an application to reflect the costs of reasonable accommodations necessary to allow individuals with disabilities to be employed on the project as personnel on project activities.

Pilot Project for Electronic Submission of Applications

The U.S. Department of Education is expanding its pilot project of electronic submission of applications to include certain formula grant programs, as well as additional discretionary grant competitions. The three programs in this announcement are included in the pilot project. If you are an applicant for a grant under any of the three programs, you may submit your application to us in either electronic or paper format.

The pilot project involves the use of the Electronic Grant Application System (e-APPLICATION, formerly e-GAPS) portion of the Grant Administration and Payment System (GAPS). We request your participation in this pilot project. We shall continue to evaluate its success and solicit suggestions for improvement.

If you participate in this e-APPLICATION pilot, please note the following:

- Your participation is voluntary.
- You will not receive any additional point value or penalty because you submit a grant application in electronic or paper format.
- You can submit all documents electronically, including the Application for Federal Assistance (ED 424), Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.
- Fax a signed copy of the Application for Federal Assistance (ED 424) after following these steps:

1. Print ED 424 from the e-APPLICATION system.
2. Make sure that the institution's Authorizing Representative signs this form.
3. Before faxing this form, submit your electronic application via the e-APPLICATION system. You will receive an automatic acknowledgment, which will include a PR/Award number (an identifying number unique to your application).
4. Place the PR/Award number in the upper right hand corner of ED 424.
5. Fax ED 424 to the Application Control Center within three working days of submitting your electronic application. We will indicate a fax number in e-APPLICATION at the time of your submission.

- We may request that you give us original signatures on all other forms at a later date.

You may access the electronic grant application for the program at: http://e-grants.ed.gov

We have included additional information about the e-APPLICATION pilot project (see Parity Guidelines between Paper and Electronic Applications) in the application package.

Research and Innovation To Improve Services and Results for Children With Disabilities [CFDA 84.324]

Purpose of Program: To produce, and advance the use of, knowledge to: (a) Improve services provided under IDEA, including the practices of professionals and others involved in providing those services to children with disabilities; and (b) improve educational and early intervention results for infants, toddlers, and children with disabilities.

Eligible Applicants: Under Absolute Priorities 1, 2, 3, and 5, and under focus area 2 of Absolute Priority 4, eligible applicants are State and local educational agencies, institutions of higher education (IHEs); other public agencies, private nonprofit organizations, outlying areas, freely associated States, and Indian tribes or tribal organizations. Under Absolute Priority 4, eligible applicants for focus areas 1 and 3 are limited to local educational agencies (LEAs), or consortia of LEAs with either IHEs or private nonprofit organizations.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 81, 82, 85, 86, 97, 98, and 99; (b) The selection criteria for the priorities under this program are drawn from the EDGAR general selection criteria menu. The specific selection criteria for each priority are included in the funding application packet for the applicable competition.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Grants are required to collaborate with other research institutes, centers, and studies and evaluations, supported by the Department throughout the course of the project.

Priority: Under 34 CFR 75.105(c)(3), we consider only applications that meet one of the following priorities:

Absolute Priority 1—Directed Research Projects (84.324D)

This priority provides support for projects that advance and improve the knowledge base and improve the practice of professionals, parents, and others providing early intervention, special education, and related services. This includes professionals who work with children with disabilities in regular education environments and natural environments. Under this priority, projects must support innovation, development, exchange of information, and use of advancements in knowledge and practice. If the project maintains a web site, it must include relevant information and documents in an accessible form. Projects must (1) use rigorous quantitative or qualitative research and evaluation methods and (2) communicate appropriately with target audiences.

Focus 1—Inclusion of Students With Disabilities in Large-Scale Assessment and Accountability Programs

Recent laws and policies at Federal and State levels require the participation of students with disabilities in large-scale assessment and accountability programs to help ensure that students with disabilities achieve to high standards and have the fullest possible range of educational opportunities. Progress has been made in solving the technical, logistical, and policy obstacles to achieving this participation. However, continued progress is needed, particularly related to young children and children with low incidence disabilities taking regular assessments with or without accommodations.

Focus Area 1 supports projects that pursue systematic programs of applied research to either or both of the following: (a) Determine how State and local education agencies can best achieve the meaningful participation of students with disabilities in large-scale assessment and accountability programs; or (b) study the effects of State and local efforts to achieve this participation.

We intend to make approximately 3 awards in Focus Area 1 of which two of these awards would focus on young children through the age 9 in regular assessments or students with low-incidence disabilities in regular assessments, or both.

Low incidence disabilities include a visual or hearing impairment or simultaneous visual and hearing impairments, a significant cognitive impairment, or any impairment for which a small number of personnel with highly specialized skills and knowledge are needed in order for children with that impairment to receive a free appropriate public education.

Focus 2—Instructional Interventions and Results for Children With Disabilities

The successful implementation of the IDEA Amendments of 1997 requires a strong emphasis on supports for children with disabilities to help them access the general education curricula. Research is needed to describe, test, and validate instructional practices that have the potential for generating positive results for children with disabilities as they strive to meet State and local standards and performance goals set for all students. The research must focus on children in preschool, elementary, middle, or high school.

Projects supported under Focus 2 must investigate one or more issues related to providing instruction in the general education curriculum for children with disabilities. These issues may include, but are not limited to:

(a) The relationship of instructional interventions to results in core subjects such as, language arts, mathematics, science, social studies, foreign language;

(b) Contextual variables that influence access to the general education curriculum for students with disabilities. Contextual variables include, for example, classroom design, relative role of regular educators and special educators, groupings, or management strategies; curricular design, delivery, or materials; and family and staff interaction;

(c) Instructional and curricular accommodations to ensure that students with disabilities have access to the general education curriculum; and

(d) The relationship of inclusive preschool practices and child-family transition practices to child development, readiness skills, and preparation for participation in the primary grades.

We intend to fund a total of nine (9) awards in Focus 2 and to fund:

- At least three (3) projects that address innovative instructional interventions and strategies in core subjects required for high school graduation (e.g., algebra or foreign language); and,
- At least three (3) projects that describe, test, and validate instructional practices that enhance appropriate access to and participation and progress in the general education curriculum for children with cognitive disabilities.

Focus 3—Gender and Special Education

The purpose of this focus area is to explore the influences of gender on special education referral, placement, and service provision for students with disabilities.

Males and females comprise equal proportions of the school-aged population; however, males account for approximately two-thirds of all students served in special education. In many cases, it is not clear if females are underidentified for special education, if males are overidentified, or if real differences exist in the prevalence of disability between males and females. The research to date has primarily addressed commonalities of students rather than differences based on gender.

Some additional facts regarding gender and disabilities include:

(a) Females with disabilities have more significant disabilities than their male peers at the time of referral;

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(b) Females with disabilities have lower IQ scores than their male counterparts at the time of referral; and

(c) Post school outcomes for females with disabilities are significantly worse than their male peers with disabilities.

Little is known, however, about the different characteristics, treatment and experiences of males and females with disabilities. These differences are likely to be caused by a combination of factors.

Under this focus, a research project must pursue a systematic program of research that focuses on one or more issues related to gender and special education. The issues may include, but are not limited to:

(a) The differences that may exist in the prevalence of disabilities based on gender, and, if so, why those differences exist;

(b) The reasons for different outcomes and opportunities, (*e.g.*, employment, parenting, vocational education programs) for students with disabilities based on gender; and

(c) The factors that contribute to disproportionate representation of males and females in special education including (1) students' environmental, social, and learning experiences, and cultural and linguistic characteristics; (2) student or teacher behaviors and interactions; (3) teacher expectations and attitudes.

We intend to fund 3 awards in Focus 3.

Focus 4—Research To Improve Literacy Results for Children Who Are Unresponsive to Effective Classroom or Schoolwide Programs in Grades K–3

Recent reading research has focused on developing and validating strategies and interventions to ensure that children acquire literacy in regular education classroom settings by using effective classroom reading programs. These programs may include explicit and intensive instruction within or outside the classroom in small groups and, in the most difficult cases, with individualized one-on-one tutoring. The hope has been that all children would succeed in these circumstances; however, there are a small number of children who do not benefit at all from these interventions and who are at the highest risk for academic and social failure.

Effective learning and teaching strategies must also be found for these children. These strategies need to be based on the learning characteristics and needs of a child as well as reasonable expectations for the child. Projects supported under Focus 4 must—

(a) Identify the criteria used to decide that a child is unresponsive to interventions that are effective for most students;

(b) Identify and describe characteristics related to (1) the environmental, social, cultural, and English language learning factors each child may have experienced, and (2) the learning characteristics related to the literacy of each child who is unresponsive to reading programs to which a majority of children respond. Learning characteristics may include, but are not limited to, specific deficits in phonological awareness, inattentiveness and distractibility, motivation, language development, developmental delay, and IQ;

(c) Design processes for making decisions about how to target instruction that will be effective given the identified learning characteristics of the child;

(d) Document the progress of individual children toward meeting intervention goals, the fidelity of implementation of interventions, the qualifications of persons who make decisions and who implement interventions, the length and intensity of interventions, and the settings where the interventions take place; and

(e) Evaluate the expectations that were made for each child.

We intend to fund 3 awards in Focus 4.

Focus 5—Research To Improve Reading Comprehension Results for Children With Disabilities

In recent years, research has advanced our understanding of how skilled readers comprehend and how instructional strategies support children with learning disabilities to comprehend text. Comprehension is not merely a text-based process where meaning resides in the text and the role of the reader is to discover the meaning. To develop successful comprehension skills, many children with learning disabilities need an explicit instructional program that: (a) Teaches them how to access prior knowledge through strategies such as semantic mapping, think aloud sheets, *etc.*; (b) motivates and supports persistence on task, including expressions of a student's own thoughts when reading and writing, questioning the expert or inquiring, or using technology or grouping practices; and (c) teaches them cognitive and metacognitive strategies for reading with understanding, including how to monitor one's own progress through self-regulation, summarizing, generating questions, mnemonics, or imagery.

Under Focus 5, a project must pursue a systematic program of applied research that focuses on one or more issues related to improving reading comprehension results of children with learning disabilities related to reading. These issues include, but are not limited to:

(a) The types of effective comprehension instruction for children with learning disabilities in grades K–2, 3–5, and 6–8 inclusive;

(b) The components of particularly effective programs for children with learning disabilities, *e.g.*, the basal materials, supplemental or adapted materials, instructional strategies used by teachers, and how families may support the instructional program;

(c) The types of effective questioning strategies used by teachers, peers, and parents to encourage and develop comprehension skills; and

(d) The kinds of individualized instruction, grouping practices, instructional strategies, and curricula that improve comprehension and problem solving.

We intend to make approximately 3 awards in Focus 5.

Focus 6—Alternative Schools and Programs

Many school districts and States have worked to establish or renew a focus on alternative schools and programs for children who are at-risk of suspension and expulsion from school. While specific definitions of alternative schools and programs vary considerably, they are typically designed to address the needs of students who are at risk of educational failure related to poor academic performance, inconsistent teacher training, truancy, disruptive behavior, suspension, expulsion, or other similar risk factors, and whose needs cannot be well met in a regular or traditional school setting. OSEP is supporting a new fast response survey through the National Center for Educational Statistics that by summer 2001 will provide information from districts on alternative schools and programs. However, research on the universe of alternative schools and programs in operation is much needed. Further, while a number of U.S. Department of Education demonstration projects are developing effective alternative programs to reduce school suspensions and expulsions (see, http://www.ed.gov/offices/OESE/SDFS/altst_200.html), research on the delivery of specific services to, and outcomes for, students with disabilities in alternative schools and programs has been limited.

Projects supported under Focus 6 must investigate one or more of the following issues relating to alternative schools and programs serving students with disabilities:

(a) The variety among alternative schools and programs in terms of definition, type, number of students with and without disabilities served, organizational or governance structures used, and other demographic characteristics.

(b) The referral and identification process and procedures used to place students with disabilities in alternative schools and programs.

(c) Exit procedures, timelimits, and procedures for transition and return to previous school or other settings.

(d) Special education services available and delivered, and outcomes achieved.

(e) The extent to which alternative schools and programs are used as IDEA-required interim alternative educational settings and the distinguishing characteristics of those settings.

(f) Coordination of special services in alternative schools and programs.

Projects must involve a directed in-depth examination of a few selected alternative schools or programs or larger-scale broader surveys of many schools or programs.

We intend to make approximately 3 awards in Focus 6.

Focus 7—Research on Early Childhood Mental Health

The elements of early intervention practice that support the social and emotional development of young children with or at risk of disabilities, are as important as those that support linguistic and cognitive development. An expanding knowledge base in early childhood mental health documents the contribution of emotional, regulatory, and social development, environmental factors, and early relationships to later school success and to the prevention of emotional disturbance. Additional research is needed to document effective practices for identifying and addressing the affective and behavioral problems of young children with or at risk of disabilities. Research may include family support practices that foster social-emotional development and resilience. Applications under this focus area must target the mental health of infants and toddlers (0–2 years old), or preschoolers (3–5 years old) or both (0–5 years old) who are receiving services under either the Part C or Part B programs of IDEA.

All applications submitted under this focus area must describe steps they will take to assure that findings from their research are disseminated to research and training centers (RTC's) funded by the Office of Special Education and Rehabilitative Services, including the two children's mental health RTC's funded by the National Institute on Disability and Rehabilitation Research (NIDRR) and the RTC on the Development of Infants, Toddlers, and Preschoolers with or at Risk of Disabilities.

We intend to make approximately 3 awards in Focus 7. At least one award will be made to a project that addresses the social and emotional development of young children with cognitive disabilities.

Competitive Preference

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period for all Focus Areas: Up to 36 months for all focus areas.

Maximum Award for all Focus Areas: The maximum award amount is $180,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. This maximum award applies to any application for any Focus area. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits for all Focus Areas: The maximum page limit for this priority is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 2—Research and Training Center on the Development of Infants, Toddlers, and Preschool Children With or at Risk of Disabilities (84.324K)

If developmental delays are not addressed by appropriately trained personnel during the early years, a range of learning and behavioral problems may be more likely to occur later in school. Alternatively, early identification and effective interventions—in social, emotional, behavioral, communication, and preliteracy domains—can prevent or reduce the impact of specific disabilities. This priority would establish a research and training center (RTC) to translate the knowledge base on young children's early relationships, emotional, self regulatory, and social development, and environmental factors into effective strategies that establish a foundation for school success. The RTC will demonstrate and evaluate these strategies and implement effective training and dissemination efforts targeted on improving early childhood services and strengthening the capacity of families to support the healthy development of their children.

The RTC will serve as a center of national excellence for service providers, young children with or at risk of disabilities, family members, and other caregivers. The RTC supported under this priority must:

(1) Conduct coordinated and advanced programs of applied research to produce and disseminate knowledge to improve interventions and service delivery systems associated with the healthy mental development of infants, toddlers, and preschool children with or at risk of developmental disabilities, including research on the use of and state of practice in inclusive settings. These children should include those who are from communities representing rural, low income, urban, limited English proficiency, immigrant, and migrant populations.

(2) Provide training, including graduate, preservice, and inservice training, to help improve the skills of personnel serving young children with or at risk of disabilities and their families and caregivers.

(3) Disseminate information through conferences, workshops, public education programs, inservice training programs, and other activities;

(4) Collaborate with other RTC's supported by the Department, including the RTC's on children's mental health supported by the National Institute on Disability and Rehabilitation Research (NIDRR); and

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(5) Utilize modern communication technologies, including the Internet, to expand the impact of its dissemination approaches.

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, D.C. Projects must budget for the travel associated with this review;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The degree to which the project's design and methodology demonstrate the potential for advancing significant new knowledge.

Competitive Preference: Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $500,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 3—Research Institute on Early Literacy for Infants, Toddlers, and Young Children With Visual Impairments (84.324Q)

Current research documents the link between the development of preliteracy and early literacy skills for infants, toddlers, and young children and subsequent reading and academic success. The development of preliteracy and early literacy skills for infants, toddlers, and young children with visual impairments including blindness poses additional challenges for families and professionals. Many of the current practices and intervention strategies which promote the development of preliteracy and early literacy skills, including braille literacy, have not been empirically validated with this population, but were developed for use with infants, toddlers, and young children without visual impairments.

Priority: This priority supports a research institute to identify, validate, and disseminate the best and most promising practices for developing preliteracy and early literacy skills for infants, toddlers, and young children, birth through to entry into first grade, who have visual impairments, including blindness.

A project funded under this priority must—

(a) Review and synthesize the research base and examine the current and most promising practice paradigms in the following areas:

(1) Assessment of the needs of infants, toddlers, and young children with visual impairments, including blindness, as those needs relate to the development of preliteracy and early literacy skills;

(2) Determination of how new or innovative intervention strategies to promote preliteracy and early literacy skills used for other infants, toddlers, and young children, could be applied for use with infants, toddlers, and young children who have visual impairments, including blindness;

(3) Integration of intervention strategies in communication and other developmental domains with preliteracy and early literacy intervention methods for infants, toddlers, and preschoolers with visual impairments, including blindness;

(4) Access to and use of new and developing technologies for use with infants, toddlers, and young children with visual impairments, including blindness, for the development of preliteracy and early literacy skills.

(b) In consultation with the Office of Special Education Programs (OSEP), design and conduct a strategic program of research that addresses knowledge gaps by:

(1) Designing a rigorous research program whose conceptual framework builds upon recent and current research, identifies the gaps in knowledge, and provides a basis for the strategies and procedures to be studied;

(2) Collecting, analyzing, and reporting a variety of data, such as (i) information on the service settings, the service providers, and the infants, toddlers, and young children with visual impairments, including blindness and their families; (ii) outcome measures for the infants, toddlers, and young children and their families who are the focus of the intervention strategies and procedures; and (iii) implementation data from the service providers, administrators, agencies, families, and others involved in the research;

(3) Conducting the research using a variety of methodologies designed to comprehensively examine the impact of the interventions on preliteracy and early literacy skill development in the target population;

(4) Conducting the program of research in settings that ensure that the research findings and products impact preliteracy and early literacy development for all infants, toddlers, and young children with visual impairments, including children with blindness, and those children with visual impairments and secondary disabilities, and including those who are from communities representing rural, low income, urban, limited English proficiency, immigrant, and migrant populations; and

(5) Collaborating with other research institutes, centers, and studies and evaluations supported by the Department.

(c) Design, implement, and evaluate a dissemination approach that links research to practice and promotes the use of current knowledge and ongoing research findings. This approach must:

(1) Develop linkages with OSEP technical assistance providers to communicate research findings and distribute products; and

(2) Prepare the research findings and products from the project in formats that are useful for specific audiences, including early intervention researchers; general and special education researchers; local, State, and national policymakers; education practitioners and early interventionists; and families of infants, toddlers, and young children with visual impairments, including blindness.

(d) Provide training and research opportunities for a limited number of graduate students whose graduate studies are in the area of education for infants, toddlers, and young children with visual impairments, including blindness.

(e) Meet with the OSEP project officer in the first three months of the project to review the program of research, implementation, and dissemination approaches.

(f) In addition to the annual two-day Project Directors' meeting in Washington, D.C. listed in the "General Requirements" section of this notice, budget for another annual two-day trip to Washington, D.C. to collaborate with the OSEP project officer by sharing information and discussing design, implementation, and dissemination issues.

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, D.C. Projects must budget for the travel associated with this review;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The degree to which the project's design and methodology demonstrate the potential for advancing significant new knowledge.

Competitive Preference

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, within this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $500,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 4—Model Demonstration Projects for Children With Disabilities (84.324T)

This priority supports model demonstration projects that develop, implement, evaluate, and disseminate new or improved approaches for providing early intervention, special education and related services to infants, toddlers, and children with disabilities, ages birth through 21. Projects supported under this priority are expected to be major contributors of models or components of models for service providers and for outreach projects funded under IDEA.

Requirements for All Demonstration Projects

A model demonstration project must—

(a) Use rigorous quantitative or qualitative evaluation methods and data;

(b) Evaluate the model by using multiple measures of results to determine the effectiveness of the model and its components or strategies;

(c) Produce detailed procedures and materials that would enable others to replicate the model; and

(d) Communicate with appropriate audiences through means such as special education technical assistance providers and disseminators, refereed journal publications and other publications, conference presentations, or a web site.

If the project maintains a web site, it must include relevant information and documents in an accessible form.

Federal financial participation for a project funded under this priority will not exceed 90 percent of the total annual costs of the project (see section 661(f)(2)(A) of IDEA).

In addition to the annual two-day Project Directors' meeting in Washington, D.C. mentioned in the General Requirements section of this notice, projects must budget for another annual meeting in Washington, D.C. to collaborate with the Federal project officer and the other projects funded under this priority, to share information and discuss model development, evaluation, and project implementation issues.

Under this absolute priority, we will fund projects only in the focus areas listed below.

Focus 1—Model Demonstration Projects To Support Whole-School Reforms of Services for Children With Disabilities

The reauthorization of IDEA in 1997 (Public Law 105–17) encouraged "incentives for whole-school approaches and pre-referral intervention to reduce the need to label children as disabled in order to address their learning needs" (section 601(c)(5)(F)) and authorized: (a) IDEA support for schoolwide programs under Title I of the Elementary and Secondary Education Act of 1965 (section 613(a)(2)(D)); (b) Services and aids that also benefit nondisabled children (section 613(a)(4)(A)); (c) Integrated and coordinated service systems (section 613(a)(4)(B) and 613(f)); and (d) School-based improvement plans (section 613(g)).

This focus supports model projects that demonstrate how promising and proven research-based practices and strategies can be used to develop whole-school approaches that benefit all students, including all students with disabilities, and fully implement all other requirements of the law. Applicants must demonstrate how they will improve results for both students with disabilities and other students.

Specifically, applicants must describe activities to ensure that all students with disabilities have access to and succeed in the general curriculum; can participate in extracurricular activities, if available at the school; receive positive behavioral interventions, supports, and services when appropriate; and are included in State and local assessments.

Flexibility and innovation are encouraged in the design of the models, but every model must involve regular and special education staff in early identification, intervention, and prevention services; provide for parent participation; and make available a continuum of services, aids, and supports to meet the needs of students with disabilities in the least restrictive environment. It is expected that models funded under this priority will build upon other models, strategies, and practices including those supported under IDEA national activities.

Eligible applicants are invited to apply for these grants to foster whole-school projects at (a) Primary and

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elementary school, (b) middle and junior high school, or (c) high school levels. Regardless of who the project applicant is, a partnership between the LEA and an IHE or a private nonprofit organization must be demonstrated and maintained throughout the duration of the project. Applicants are required to collaborate with existing OSEP technical assistance centers and evaluation efforts throughout the course of the project.

Applicants must specify at least one school building, at each grade range addressed in the project, that will participate in the model demonstration project throughout the duration of the grant. Further, the LEA or consortium of an LEA and an IHE or a private nonprofit organization must agree to share evaluation data (with protections for anonymity of subjects) on student achievement and project effectiveness with OSEP-sponsored activities, which will synthesize research and evaluation information across the grantees. In addition projects must ensure and demonstrate how they will monitor and document challenges and progress throughout the project.

Projects funded under this priority must schedule one trip, annually to Washington, D.C. (as specified in the "General Requirements" section of this notice), one trip, annually to Washington, D.C. (as specified in the "Requirements for All Demonstration Projects" section of this notice), and an additional meeting to take place by the end of the first month of the project.

We intend to make approximately 15 awards under this priority. Each of the three grade ranges will be represented in the awards with at least three awards at each level.

Maximum Award: Projects will be funded for up to 48 months. The maximum award amount is $150,000 (exclusive of any matching funds) during each of the first two 12-month funding periods, and $75,000 (exclusive of any matching funds) during each of the two remaining 12-month funding periods. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this focus area is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Focus 2—Strengthening Childcare Infrastructures for Infants, Toddlers, and Preschoolers With Disabilities From Underserved Families and Communities

This focus supports model projects that demonstrate new or innovative childcare models that address the developmental needs of infants, toddlers, and preschoolers with disabilities. In addition to identifying and supporting underserved children with disabilities and their families, projects must address the special and individualized intervention needs of young children without resulting in the removal of children from inclusive settings and typical experiences. To maximize sustainability of change, projects must incorporate multiple formal and informal service delivery systems that have evolved in a community over the years, when identifying and addressing challenges that contribute to uneven service provision.

Challenges addressed under this focus area may include, but are not limited to, one or more of the following:

(a) The lack of available mental health services for children under age 6;

(b) Adverse environmental home or community conditions;

(c) Cultural differences between service providers and families;

(d) Differences between what child care programs offer and what families of young children with disabilities or at-risk for disabilities need or want;

(e) Children living with mentally ill family members;

(f) Children with complex medical concerns; and

(g) Children in families dealing with the stresses of poverty, substance abuse, or violence.

Measurements of model effectiveness should assess multiple influences longitudinally when reporting impact of community, family, and individual intervention variables on child development. Child competence measures should include observational measures of a child's underlying processing and executive functioning over time vis-a-vis the interventions received. In addition to measuring multi-level impact, models should examine whether the interventions can be implemented as planned, whether the participants for whom the program is designed actually participated, and how much the program costs.

Projects funded under this focus must schedule one trip, annually to Washington, D.C. (as specified in the "General Requirements" section of this notice), one trip, annually to Washington, D.C. (as specified in the "Requirements for All Demonstration Projects" section of this notice), and an additional meeting to take place at the beginning of year one, to identify collaborations across sites that can result in increased sample sizes, and planned variations of critical variables, interventions, and outcomes.

We intend to make approximately 3 awards under this focus area.

Maximum Award: The maximum award amount is $180,000 (exclusive of any matching funds) per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this focus is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Focus 3—Agency Participation in Transition

This focus area supports model projects that demonstrate new or improved approaches to participation and successful interagency collaboration in transition planning.

Projects must:

(a) Involve collaboration between multiple systems, such as education, vocational rehabilitation, workforce development, employer organizations, community networks, health, youth and adult service agencies, and other relevant agencies.

(b) Improve transitions between systems and eliminate service disruptions, including waiting lists for students exiting school; and

(c) Demonstrate that student Individualized Education Programs (IEP's) are based on students' interests, preferences, and needs and include, as appropriate, a statement of interagency responsibilities and any needed linkages. The linkages must include, as appropriate, postschool environments such as postsecondary schools, employment, adult service programs, and local One-Stop Career Centers created under the Workforce Investment Act.

Projects funded under this focus must schedule one trip, annually to Washington, D.C. (as specified in the "General Requirements" section of this notice), one trip, annually to Washington, D.C. (as specified in the "Requirements for All Demonstration Projects" section of this notice), and an additional meeting to take place by the end of the first month of the project.

We intend to make approximately 3 awards under this focus area.

Maximum Award: The maximum award amount is $180,000 (exclusive of any matching funds) per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this focus is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Competitive Preference for All Focus Areas

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period for All Focus Areas: Up to 48 months.

Absolute Priority 5—Improving Postschool Outcomes: Identifying and Promoting What Works (84.324W)

With the passage of the Education of the Handicapped Act Amendments of 1983, a Federal initiative was begun to assist high school youth with disabilities in achieving their goals for adult life, including postsecondary education, continuing education, competitive employment, and independent living. This process, known as secondary transition, has continued to be defined and developed in legislation, research, and practice. To a large extent, it has been the impetus for the shift in special education from an emphasis on process to one of achieving better results for children with disabilities. The Office of Special Education Programs (OSEP) has funded approximately 500 secondary transition projects since 1984 to develop, refine and validate effective practices and programs.

Priority: The purpose of this priority is to improve results for secondary-aged youth with disabilities by at a minimum, synthesizing, analyzing, and disseminating information in each of three areas:

—Improving academic results;
—Secondary transition practice; and
—Dropout prevention and intervention, including factors associated with early school exit for students with disabilities.

The project must—

(a) Synthesize the professional literature on each area. In conducting its syntheses, the project must:

(1) Develop a conceptual framework around which research questions will be posed and the synthesis conducted. Develop these research questions with input from potential consumers of the synthesis to enhance the usability and validity of the findings. Consumers include technical assistance providers, policymakers, educators, other relevant practitioners, individuals with disabilities, and parents;

(2) Identify and implement rigorous social science methods for synthesizing the professional knowledge base (including but not limited to, integrative reviews (Cooper, 1982), best-evidence synthesis (Slavin, 1989), meta-analysis (Glass, 1977), multi-vocal approach (Ogawa & Malen, 1991), and National Institute of Mental Health consensus development program (Huberman, 1977);

(3) Implement procedures for locating and organizing the extant literature and ensure that these procedures address and guard against potential threats to the integrity of each synthesis, including the generalization of findings;

(4) Establish criteria and procedures for judging the appropriateness of each synthesis;

(5) Meet with OSEP to review the project's methodological approach for conducting the synthesis prior to initiating the synthesis;

(6) Analyze and interpret the professional knowledge base, including identification of general trends in the literature, points of consensus and conflicts among findings, and areas of evidence where the literature base is lacking. The interpretation of the literature base must address the contributions of the findings for improving policy, academic supports, transition practices, and dropout prevention and intervention;

(7) Submit a draft report of the synthesis in each of the three focus areas, and based on review by OSEP staff, potential consumers, revise and submit a final report to OSEP and the Secondary Education and Transition Technical Assistance Center (SETAC) for dissemination to the field.

(b) Conduct an analysis of each of the three areas to identify effective approaches and practices derived from model demonstration projects (including, but not limited to, projects funded by OSEP, the Rehabilitation Services Administration (RSA), the National Institute on Disability and Rehabilitation Research (NIDRR), the Office of Postsecondary Education (OPE), the Office of Education Research and Improvement (OERI), and the Office of Vocational and Adult Education (OVAE).

In conducting its analyses, the project must:

(1) Identify the relevant projects for each analysis. Describe and implement procedures for locating and organizing relevant information on the individual projects, including sampling techniques, if appropriate;

(2) Articulate a research-based conceptual framework to guide the selection of variables to be examined within and across projects, including demographics, target population, purpose, activities, outcomes, and barriers. Pose research questions around which the analysis will be conducted. Develop these questions with input from potential consumers of the information to enhance the usability and validity of the research findings. Consumers include technical assistance providers, policymakers, researchers, educators, other relevant practitioners, individuals with disabilities, and parents;

(3) Meet with OSEP and the OSERS transition work group to review the project's research questions and methodological approach for conducting the analysis prior to initiation;

(4) Analyze and interpret the findings of the analysis, including similarities and differences among project goals, activities, staffing and costs; points of consensus and conflict among the findings or outcomes of the demonstrations; and the characteristics of model programs that hold significant promise for the field based on outcome data. In addition, the analysis must link to the synthesis on this topic and provide for the future policy formulation, practice implementation, and research priorities; and

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(5) Submit a draft report of the analysis in each of the focus areas, and based on reviews by OSEP staff and potential consumers, revise, and submit a final report to OSEP and SETAC for dissemination and publication to inform policy and practice.

(c) Disseminate results of the project by collaborating with SETAC.

In addition to the annual two-day Project Directors' meeting in Washington, D.C. listed in the "General Requirements" section of this notice, projects must budget for another meeting each year in Washington, D.C. with OSEP to share information and discuss project implementation issues.

Competitive Preferences

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 36 months.

Maximum Award: The maximum award amount is $600,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limit: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Special Education—Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities [CFDA 84.326]

Purpose of Program: The purpose of this program is to provide technical assistance and information, through such mechanisms as institutes, Regional Resource Centers, clearinghouses, and programs that support States and local entities in building capacity, to improve early intervention, educational, and transitional services and results for children with disabilities and their families, and address systemic-change goals and priorities.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, 86, 97, 98, and 99; (b) The selection criteria for the priorities under this program are drawn from the EDGAR general selection criteria menu. The specific selection criteria for each priority are included in the funding application packet for the applicable competition.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Eligible Applicants: State and local educational agencies, institutions of higher education, other public agencies, private nonprofit organizations, outlying areas, freely associated States, Indian tribes or tribal organizations, and for-profit organizations.

Priority: Under section 685 of IDEA and 34 CFR 75.105(c)(3) we consider only applications that meet the following priorities:

Absolute Priority 1—National Clearinghouse on Postsecondary Education (84.326H)

Priority: This priority will support a National Clearinghouse on Postsecondary Education for Individuals with Disabilities. The Clearinghouse must—

(a) Collect and disseminate information on the following:

(1) Legislation affecting individuals with disabilities entering and participating in education and training programs after high school;

(2) Policies, procedures, support services (including assistive technology and adaptations), and other resources available or recommended to facilitate the postsecondary education of individuals with disabilities;

(3) Available resources and support services in postsecondary settings that include, or can be adapted to include individuals with disabilities; and

(4) Sources of financial aid for the postsecondary education and training of individuals with disabilities.

(b) Develop and disseminate a set of materials designed specifically to help prepare students with disabilities for transition to postsecondary education. Audiences for these materials should include vocational rehabilitation counselors, secondary guidance counselors, transition specialists, general and special education teachers, secondary career center and school-to-work staff, staff from Federally funded transition and postsecondary projects, such as, GEAR-UP, 21st Century Schools and TRIO, and students with disabilities and their families.

(c) Identify areas, in addition to those specified in paragraphs (a) and (b), in which information is needed and provide information in those areas;

(d) Develop a coordinated network of professionals, appropriate organizations, secondary and postsecondary education associations, institutions of higher education, mass media, other clearinghouses, and governmental agencies at the Federal, State, and local levels for purposes of disseminating information, promoting awareness of issues related to the postsecondary education of individuals with disabilities, and referring individuals who request information to appropriate resources;

(e) Respond to requests for information from individuals with disabilities, their parents, and professionals in secondary and postsecondary settings, education, vocational rehabilitation, and others who work with such individuals, so that persons may make informed decisions about postsecondary education and training. All information requests should be solicited and responses disseminated through multiple vehicles, accessible to individuals with disabilities. Such vehicles must include a toll free telephone number, a World Wide Web site, and electronic and regular mail. Technologies, such as CD–ROM and listservs should also be considered for information dissemination. Word Wide Web-based delivery of information must be maintained and updated on a regular basis.

(f) Link with other Federally supported technical assistance projects concerned with the transition of students with disabilities from secondary to postsecondary settings, in collecting, developing, and disseminating information. These should include projects funded by the U.S. Department of Education, Office of Special Education and Rehabilitative Services such as the Parent Training and Information Centers (PTIs); the Centers for Independent Living (CILs); the Regional Resource Centers (RRCs); the National Center on Educational Outcomes; the IDEA Partnership Projects; the National Center for Secondary Education and Transition Technical Assistance Center (NCSET); the National Center on the Study of Postsecondary Education Supports (NCSPES); all of the Demonstration Projects to Ensure Students With Disabilities Receive a Quality Higher Education, funded through the U.S. Department of Education's Office of Postsecondary Education; Historically Black Colleges and Universities (HBCUs); and other minority institutions.

(g) Make information products available in accessible formats, and as appropriate, foreign languages.

(h) Work with the American Council on Education (ACE) to ensure the successful transition of materials and resources from the HEATH Resource Center to the newly funded postsecondary clearinghouse.

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, D.C. Projects must budget for the travel associated with this review;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The degree to which the project's design and methodology demonstrate the potential for advancing significant new knowledge.

Competitive Preference

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $500,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 2—National Technical Assistance Project for Infants, Toddlers, and Children Who Are Deaf-Blind (84.326T)

Background

IDEA includes provisions designed to help ensure that each child with a disability is provided a high-quality individual program of services to meet their developmental and educational needs. For children who are deaf and blind to receive such services, intensive technical assistance must be afforded State and local educational agencies to appropriately address the special needs of these children. In addition, given the low-incidence nature of this population, many early intervention programs or educational agencies lack personnel with the training or experience to serve children who are deaf-blind. For these reasons, the following priority supports a project of national scope that provides specialized technical assistance regarding the provision of early intervention, special education, related services, and transitional services to children who are deaf-blind and their families.

Priority: This priority supports one national project that provides technical assistance, training, and information to State deaf-blind projects, families, model demonstration projects, and other agencies and organizations that are responsible for the provision of early intervention, special education, related services, and transitional services for infants, toddlers, and children who are deaf-blind.

The project must:

(a) Identify specific project goals, objectives, and activities in providing an array of services to State projects, families, model demonstration projects, other agencies and organizations that are responsible for providing services to children who are deaf-blind.

(b) Assist State projects and agencies to facilitate local, regional, or State systemic change initiatives that include children who are deaf-blind.

(c) Assist State projects and agencies to increase the States' capacities to improve early intervention, special education, related services, and transitional services to improve outcomes for children who are deaf-blind and their families.

(d) Provide technical assistance, training, and information that focus on the implementation of research-based, effective practices that will result in improved capacity of States and LEAs in providing appropriate assessment, planning, placement, and services.

(e) Provide technical assistance, training, and information that focus on the implementation of IDEA specific to children who are deaf-blind and their families.

(f) Implement and maintain an assessment of the needs of individual States and the overall needs of States to determine the array, type, and intensity of technical assistance to be provided.

(g) Facilitate activities and enhance relationships that build the capacity of deaf-blind children and their families for advocacy, empowerment, and increased knowledge.

(h) Evaluate project goals, objectives, and activities to determine the effectiveness of project strategies and the overall impact of technical assistance.

(i) Collaborate with other Federal technical assistance projects and State agencies that provide early intervention, special education, related services, and transitional services through programs such as Developmental Disabilities, Vocational Rehabilitation, Centers for Independent Living, and Parent Training and Information Centers in the provision of technical assistance, training, and information sharing.

(j) Develop and disseminate materials and products to supplement technical assistance and training. These materials and products must be made available through an accessible Internet web site.

(k) Assist personnel training programs to work collaboratively to impact a greater number of teachers and paraprofessionals so that they can more effectively provide services to children who are deaf-blind.

(l) Gather, maintain, and analyze demographic information on children who are deaf-blind for the purpose of developing project priorities based on

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data documenting the needs of these children.

(m) Assist OSEP in conducting the annual Project Directors' Meeting and other Federal initiatives.

(n) Develop and implement strategies to promote coordination among State and local agencies and organizations and children who are deaf-blind and their families specific to, but not limited to, the following:

(1) Early identification, assessment, placement and service provision;

(2) Alternate assessment as well as appropriate modifications and accommodations;

(3) Participation in the general curriculum and inclusion in natural environments;

(4) Access to appropriate and necessary assistive technology, including augmentative and alternative communication systems;

(5) Family-educator partnerships;

(6) Transition services including appropriate and timely assessment, planning, vocational training, interagency collaboration, and job placement and support;

(7) Consumer self-determination and self-advocacy; and

(8) Designing appropriate evaluation strategies for children who are deaf-blind.

(o) Establish and maintain an advisory committee to assist in promoting project activities. The committee must include at least one individual with deaf-blindness, one parent of a child with deaf-blindness, one representative of a State educational agency, and at least three professionals with training and experience in serving children with deaf-blindness, and other individuals representing appropriate agencies.

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition —

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, DC Projects must budget for the travel associated with this review;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The degree to which the project promotes best practices designed to demonstrate the potential for advancing significant new knowledge in the area of services to children who are deaf-blind.

Competitive Preference:

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $1,700,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Technology and Media Services for Individuals With Disabilities (CFDA 84.327)

Purpose of Program: The purpose of this program is to promote the development, demonstration, and utilization of technology and to support educational media activities designed to be of educational value to children with disabilities. This program also provides support for some captioning, video description, and cultural activities.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, 86, 97, 98, and 99; (b) The selection criteria for the priorities under this program are drawn from the EDGAR general selection criteria menu. The specific selection criteria for each priority are included in the funding application packet for the applicable competition.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Eligible Applicants: State and local educational agencies; institutions of higher education; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

Priority: Under section 687 of IDEA and 34 CFR 75.105(c)(3), we consider only applications that meet the following priority:

Absolute Priority 1—Video Description (84.327C)

Background

This priority supports cooperative agreements to provide video description for national broadcast, satellite, and cable television programs. The purpose of this activity will be to describe television programs and videos in order to make television programming and videos accessible to children and adults who are blind or have low vision. The intent of this priority is to allow children who are blind or have low vision to engage in age appropriate activities that include the watching of television. Only educational, news, and informational television and videos may be described after September 30, 2001.

Priority: To be considered for funding under this priority, a project must —

(a) Include criteria that take into account the preference of consumers for particular topics of interest, the diversity of programs or videos available, and the contribution of these programs or videos to the general educational, social, and cultural experiences of individuals with visual disabilities;

(b) Identify and support a diverse consumer advisory group including parents and educators, that would meet at least annually;

(c) Identify the total number of hours and cost for each program to be described;

(d) Identify for each program or video to be described, the source and amount of any private or other public support, if any;

(e) Demonstrate the willingness of program providers to permit video description and distribution of their program or video; and

(f) Evaluate the effectiveness of the methods and technologies used in providing this service and the impact on intended populations.

Video descriptions produced under these awards must be provided on request to owners or rights holders of programming, and may be reformatted or otherwise adapted by them for future airings or other distributions.

Competitive Preference:

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 36 months.

Maximum Award: The maximum award amount is $350,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 2—Accessible Educational TV (84.327E)

Background

This priority supports cooperative agreements to provide for the description and captioning of widely available, noncommercial, educational, and instructional programming that is suitable for use in the classroom and shown on broadcast, satellite, or basic cable television networks. Captioning provides a visual representation of the audio portion of the programming while video description provides a narrative of what takes place visually on the screen. This will allow children with disabilities in the areas of vision or hearing to engage in age appropriate activities that includes the watching of television. Only educational, news, and informational television and videos may be captioned or described after September 30, 2001.

Priority: To be considered for funding under this competition, a project must —

(a) Include criteria that takes into account the preference of educators, students, and parents for particular educational and instructional programs, the diversity of this type of programming available, and the contribution of this type of programming to the general educational experience of students who have disabilities in the areas of vision or hearing;

(b) Identify and support a diverse consumer advisory group, including parents and educators, that would meet at least annually;

(c) Identify the extent to which the programming is widely available;

(d) Identify the extent to which this commercial-free programming may be taped for later classroom use;

(e) Identify the total number of program hours to be made accessible and the cost per hour for captioning and description;

(f) Identify for each program to be made accessible, the source of any private or other public support, and the projected dollar amount of that support, if any;

(g) Demonstrate the willingness of program providers or owners of programs to permit and facilitate the quality captioning and description of their programs;

(h) Provide assurances from program providers or owners of programs stating the extent to which programs made accessible under this project will air, and will continue to air, without the need for reformatting or additional description;

(i) Evaluate the effectiveness of the methods and technologies used in providing this service and the impact on intended populations; and

(j) Conduct nationwide outreach activities that target the potential audience for this type of programming. To accomplish this objective, the applicant must employ multiple dissemination mechanisms and approaches, such as a user-friendly web site that incorporates hotlinks to other web sites such as the National Clearinghouse in order to further promote and inform the target audiences about the service. This web site must be fully accessible and customized to attract individuals from culturally and economically diverse backgrounds and individuals with disabilities, across varying age levels and professional experiences.

Captions and video descriptions produced under these awards must be provided on request to owners or rights holders of programming, and may be reformatted or otherwise adapted by them for future airings or other distributions.

Competitive Preferences

Within this absolute priority, we will award the following competitive preference, under 34 CFR 75.105(c)(2)(i): An additional 10 points to an applicant that proposes to include in the range of programs to be described and captioned at least 52 hours a year of programming originally broadcast in Spanish.

In addition, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 20 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 120 points.

Project Period: Up to 36 months.

Maximum Award: The maximum award amount is $225,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 3—Open-Captioned Educational Media: Video Selection, Captioning, and Distribution (84.327N)

Background

This priority supports one cooperative agreement for the selection, acquisition, open-captioning, and distribution of media on a nonprofit free loan-basis, for use by students who are deaf or hard of hearing, parents of deaf or hard of

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hearing persons, individuals directly involved in activities promoting the advancement of individuals who are deaf or hard of hearing, and other individuals with disabilities in the United States. This priority would ensure that students and other individuals who are deaf or hard of hearing, as well as other individuals with disabilities, might benefit from the same media used to enrich the educational experiences of students and other individuals who do not have disabilities.

Priority: To be considered for funding under this priority, the project must:

(a) Develop strategies and procedures to be used in determining curricular needs of students who are deaf or hard of hearing in all types of school settings for captioned media;

(b) Obtain media from producers and distributors for screening, evaluation, and captioning. Select from titles submitted by evaluators those that closely match the curricular needs identified under paragraph (a) of this priority, taking into account the media most commonly used in school districts across the nation for students.

(c) Make arrangements with respective producers and distributors to purchase, caption, and distribute selected media, including distribution in alternate formats. Captioned masters must be made available to producers and distributors in an effort to promote the use of captioned media.

(d) For selected media purchased, have captions prepared by captioning agencies that meet guidelines for captioned media take into account the age and reading levels of the likely target audience.

(e) Establish guidelines to ensure even and maximum participation of captioning service providers in providing captions.

(f) Develop and implement quality control guidelines and procedures for checking media after it has been captioned, and procedures for training captioning agencies that express the desire to caption for the program.

(g) Prepare up to 300 copies of each title purchased for distribution through the distribution system. Twenty five percent of the annual acquisition also must be captioned in Spanish so those Latino students who are deaf or hard of hearing can have access to media.

(h) For selected videos to be used in classrooms, select and train writers to prepare lesson guides.

(i) Develop strategies and procedures to be implemented in operating a distribution system, consisting of local and regional depositories for distribution of captioned educational media, and one central general interest and one central educational distribution center. Local and regional depositories may include State schools, public or private school systems, public libraries, colleges or universities, or other distribution points. The system must be computerized and allow electronic ordering, booking, and shipping of materials, including interdepository circulation of free loan captioned media. Explore and utilize alternate delivery methods (i.e., via CD Rom, Internet, or Satellite) of captioned media.

(j) Describe and establish computerized registration procedures, accessible via the Internet, that will be used to register eligible users, schedule captioned media retrieval, and track and record consumer feedback and usage information.

(k) Prepare, update, and distribute copies of a catalog listing all captioned media available under this project, including copies of lesson guides, as they become available. Both lesson guides and catalogs must be made available online.

(l) In years 2 and 4 of the award, convene a meeting of local and regional depository managers, librarians, and audiovisual and other personnel from State educational agencies for the purpose of training and planning. The year two meeting will be held at the project site and the year four meeting will be held in the Washington, D.C. Metropolitan area. Regional meetings of depository managers shall be held in years 1 and 3 of the project and shall coincide with meetings scheduled under paragraph (m). All dates should be coordinated with the Project Officer.

(m) Establish an advisory group of 7 members, which shall meet annually, consisting of video producers and distributors, captioning service providers, consumers of captioned media, parents of students with hearing impairments, public and private school administrators and educational personnel, and members from minority communities. This advisory group shall develop an evaluation program for incorporating the reactions and suggestions of users into the selection and captioning process, provide input regarding the impact on program activities and services, review effectiveness of the system and make recommendations to ensure maximum effectiveness. The Project Officer must approve committee membership. Format, agenda and dates of advisory group meetings shall require prior approval by the Project Officer. A set of recommendations for program enhancements recommended by the advisory group shall be forwarded to the Department annually.

(n) Develop and maintain a comprehensive database containing information related to the availability of open and closed captioned media, information regarding the captioned media loan service, and captioning service providers and procedures for applying for free loan services. In addition, the project shall maintain a clearinghouse of information on the subject of captioning for use by consumers, agencies, corporations, businesses, and schools. All information should be accessible via the Internet.

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, D.C. Projects must budget for the travel associated with this review; and

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

Competitive Preference

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $3,350,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 80 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 4—Closed Captioned Daytime Television Programs (84.327S)

This priority supports cooperative agreements to continue and expand the variety of daytime television programming available nationally to individuals who are deaf or hard of hearing through captioning. Captioning provides a visual representation of the audio portion of television programming and enables children, young adults, and adults who are deaf or hard of hearing to engage in age-appropriate behavior with their nondisabled peers by participating in shared educational, social, and cultural experiences which include the watching of television. Federal funds may not be used to fund more than 65 percent of captioning costs in Year One of the project, no more than 60 percent of the captioning costs in year two, and no more than 55 percent in year three. For the purpose of this activity, program hours, or the costs of captioning associated with those programs, that are funded by promotional billboards shall not be considered as an in-kind cost, or a private sector match, for those Federal funds. Only educational, news, and informational television and videos may be captioned after September 30, 2001.

Priority: To be considered for funding under this priority, a project must—

(a) Include procedures and criteria for selecting programs for captioning that take into account the preference of consumers from diverse communities for particular daytime programs;

(b) Provide a backup system that will ensure quality captioning service;

(c) Identify and support a consumer advisory group, which would meet at least annually;

(d) Identify the total number of hours and the captioning cost per program hour for each of the programs captioned;

(e) Identify for each program to be captioned, the source, and amount of any private or other public support;

(f) Demonstrate the willingness of major national commercial broadcast or basic cable networks to permit and facilitate the quality captioning of their programs; and

(g) Implement procedures for monitoring the extent to which full and accurate captioning is provided and use this information to make refinements in captioning operations.

Captions produced under these awards must be provided on request to owners or rights holders of programming, including networks or syndicators and may be reformatted or otherwise adapted by them for future airings or other distributions.

Competitive Preferences

Within this absolute priority, we will award the following competitive preference, under 34 CFR 75.105(c)(2)(i): An additional 10 points to an applicant that proposes to include in the range of programs to be described and captioned at least 52 hours a year of programming originally broadcast in Spanish.

In addition, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 20 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 120 points.

Project Period: Up to 36 months.

Maximum Award: The maximum award amount is $200,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 50 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

Absolute Priority 5—Research Institute on the Use of Technology In Early Intervention (84.327X)

Background

Technology has shown great potential in supporting the growth and development of children. This is particularly true with infants and toddlers with disabilities. The years from birth to three represent a pivotal stage in a child's life. During this period, young children make important gains in mobility, communication, social awareness, and cognitive understanding. It is also a period of time in which children's development is intrinsically tied to interaction with those who care for them. Technology has the potential to empower families and caregivers to provide the type of environment in which infants and toddlers with disabilities can reach their maximum potential for growth and learning.

The IDEA lists assistive technology devices and services as early intervention services that could be provided to meet the developmental needs of each child and the needs of their families relating to enhancing the child's development. These services are selected in collaboration with the parents and provided in conformity with an individualized family service plan (IFSP) (34 CFR 303.12(a)).

Section 602(1) of IDEA defines an assistive technology (AT) device as "any item, piece of equipment, or product system, whether acquired commercially off the shelf, modified, or customized, that is used to increase, maintain, or improve functional capabilities of a child with a disability." According to Section 602(2), an assistive technology service means, "any service that directly assists a child with a disability in the selection, acquisition, or use of an assistive technology device * * *" The law lists such services as evaluation, purchasing, selection, coordination with other interventions, and training for the child and family, as well as training or technical assistance for professionals.

Even though technology appears to hold great benefits for infants and toddlers with disabilities, the knowledge base on this topic is limited. Evidence of the use and effectiveness of assistive technology for this population is for the most part anecdotal and practitioner-oriented. Comprehensive research on the subject is scarce.

There is little argument that technology devices can help infants and toddlers with disabilities interact with their environment. Some useful AT devices could be off-the-shelf commercial items or materials that have been modified or adapted according to the specific needs of the child. Examples include head pointers, picture boards with symbols or pictures, and pull toys. More complex technologies may involve computers or electronics that often are specially ordered and fitted. Examples are electronic scooters,

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drawing software, or a musical mat. Whatever device or application is chosen, it is important, that when considering the use of technology with young children, the professional involved goes beyond merely matching tools to the child's abilities and disabilities. The decision also should reflect the family's goals and be another tool in helping young children to grow and develop within the context of the family.

Priority: This priority is for a research institute to study the use of technology to enhance the development of infants and toddlers with disabilities ages birth to three years.

The Institute must:

(a) Select a range of settings within States reflecting diverse demographics;

(b) Use methodologies such as interviews, case studies, focus groups, reviews of records, observations, and policy analyses;

(c) Consider what factors enhance or impede decisionmaking, planning, acquisition, maintenance, and training in the use of technology;

(d) Answer, at a minimum, the following research questions:

(1) Prevalence: What percentage of infants and toddlers with disabilities use technology as part of their IFSP? What functions are these devices and services intended to perform for the individual child?

(2) Policy and Resources: What policies or guidelines and processes are in place to help the IFSP team make decisions about the use of technology? What resources are in place to finance the provision of technology? What mechanisms are in place to ensure leveraging of resources among appropriate agencies? How do early intervention programs acquire technology? How is the technology managed and maintained?

(3) Individualized decisionmaking: How are the child's needs for the technology evaluated? How does the IFSP team determine when a technology device or service is appropriate? How is the appropriate technology selected, designed, or adapted to the individual child?

(4) Training and Support: What training and technical assistance is available for service providers, caregivers, families, and other appropriate individuals regarding technology? Are structures in place to promote collaboration among appropriate agencies and service providers?

(e) Design and implement a dissemination approach that promotes the use of current knowledge and ongoing research findings. In support of this approach, the Institute must:

(1) Develop links with appropriate Department of Education technical assistance providers to communicate research findings and distribute products;

(2) Develop a web site to link participating early intervention programs and to provide up-to-date information on findings;

(3) Prepare the research findings in formats that are useful for specific audiences, such as families, service providers, administrators, and policy makers;

(4) Meet with the OSEP project officer and appropriate OSEP staff within the first three months of the project to review the strategic work plan and the approach to dissemination;

(f) Fund at least three graduate students per year as research assistants who have concentrations in early childhood development, early intervention issues, and technology; and

(g) Budget for trips to Washington, DC (one trip during the first year of the project to meet and collaborate with U.S. Department of Education officials; one trip annually, as specified in the "General Requirements" section of this notice, to attend the two-day OSEP Research Project Directors' Conference; and one trip annually to attend the three-day Early Childhood Combined Conference).

In deciding whether to continue this project for the fourth and fifth years, we will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of experts selected by the Secretary, which review will be conducted during the last half of the project's second year in Washington, DC. Projects must budget for the travel associated with this review;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The degree to which the project's design and methodology demonstrate the potential for advancing significant new knowledge.

Competitive Preference

Within this absolute priority, we will give the following competitive preference under section 606 of IDEA and 34 CFR 75.105(c)(2)(i), to applications that are otherwise eligible for funding under this priority:

Up to ten (10) points based on the effectiveness of the applicant's strategies for employing and advancing in employment qualified individuals with disabilities in project activities as required under paragraph (a) of the "General Requirements" section of this notice. In determining the effectiveness of those strategies, we may consider the applicant's past success in pursuit of this goal.

Therefore, for purposes of this competitive preference, applicants can be awarded up to a total of 10 points in addition to those awarded under the published selection criteria for this priority. That is, an applicant meeting this competitive preference could earn a maximum total of 110 points.

Project Period: Up to 60 months.

Maximum Award: The maximum award amount is $500,000 per year. Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. Requests for funding reasonable accommodations are not included in this limitation.

Page Limits: The maximum page limit for this priority is 70 double-spaced pages.

Note: Applications must meet the required page limit standards that are described in the "General Requirements" section of this notice.

For Applications Contact: Education Publications Center (ED Pubs), P.O. Box 1398, Jessup, Maryland 20794–1398. Telephone (toll free): 1–877–4ED–Pubs (1–877–433–7827). FAX: 301–470–1244. Individuals who use a telecommunications device for the deaf (TDD) may call (toll free) 1–877–576–7734.

You may also contact Ed Pubs via its Web site (http://www.ed.gov/pubs/edpubs.html) or its E-mail address (edpubs@inet.ed.gov).

For Further Information Contact: Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue, SW., room 3317, Switzer Building, Washington, DC 20202–2550. Telephone: (202) 260–9182.

If you use a TDD you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the contact persons listed in the preceding paragraph.

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting the Department as listed above. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

Intergovernmental Review

All programs in this notice (except for the Research and Innovation to Improve Services and Results for Children with Disabilities Program) are subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, we intend this document to provide early notification of the Department's specific plans and actions for those programs.

INDIVIDUALS WITH DISABILITIES EDUCATION ACT APPLICATION NOTICE FOR FISCAL YEAR 2001

CFDA No. and name	Applications available	Application deadline date	Deadline for intergovernmental review	Maximum award (per year)*	Project period	Page limit**	Estimated number of awards
84.324D Directed Research Projects.	01/19/01	03/02/01		$180,000	Up to 36 mos	50	27
84.324K Research and Training Center on the Development of Infants, Toddlers, and Preschool Children with or At Risk of Disabilities.	01/19/01	03/09/01		500,000	Up to 60 mos	70	1
84.324Q Research Institute on Early Literacy for Infants, Toddlers, and Young Children with Visual Impairments.	01/19/01	03/09/01		500,000	Up to 60 mos	70	1
84.324T Model Demonstration Projects for Children with Disabilities.	01/19/01	03/16/01			Up to 48 mos	50	21
Focus Area 1: First two 12-month funding periods.				150,000			
Focus Area 1: Final two 12-month funding periods.				75,000			
Focus Areas 2 and 3				180,000			
84.324W Improving Post School Outcomes: Identifying and Promoting What Works.	01/19/01	03/09/01		600,000	Up to 36 mos	70	1
84.326H National Clearinghouse on Postsecondary Education.	01/19/01	03/09/01	05/08/01	500,000	Up to 60 mos	70	1
84.326T National Technical Assistance Project for Infants, Toddlers, and Children Who Are Deaf-Blind.	01/19/01	03/09/01	05/08/01	1,700,000	Up to 60 mos	70	1
84.327C Video Description	01/19/01	03/09/01	05/08/01	350,000	Up to 36 mos	50	2
84.327E Accessible Education TV.	01/19/01	03/16/01	05/15/01	225,000	Up to 36 mos	50	5
84.327N Open-Captioned Educational Media: Selection, Captioning and Distribution.	01/19/01	03/09/01	05/08/01	3,350,000	Up to 60 mos	80	1
84.327S Closed Captioned Daytime Television Programs.	01/19/01	3/23/01	05/23/01	200,000	Up to 36 mos	50	5
84.327X Research Institute on Technology for Early Intervention.	01/19/01	03/30/01	05/30/01	500,000	Up to 60 mos	70	1

*Consistent with EDGAR 34 CFR 75.104(b), we will reject any application that proposes a project funding level for any year that exceeds the stated maximum award amount for that year. We will consider, and may fund, requests for additional funding as an addendum to an application to reflect the costs of reasonable accommodations necessary to allow individuals with disabilities to be employed on the project as personnel on project activities.

**Applicants must limit the Application Narrative, Part III of the Application, to the page limits noted above. Please refer to the "Page Limit" requirements included under each priority description and the page limit standards described in the "General Requirements" section. We will reject and will not consider an application that does not adhere to this requirement.

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Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: http://www.access.gpo/nara/index.html

Program Authority: 20 U.S.C. 1405, 1461, 1472, 1474, and 1487.

Dated: January 10, 2001.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 01–1241 Filed 1–19–01; 8:45 am]

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Federal Register

Monday,
January 22, 2001

Part IV

Environmental Protection Agency

40 CFR Parts 9 and 435

Effluent Limitations Guidelines and New Source Performance Standards for the Oil and Gas Extraction Point Source Category; OMB Approval Under the Paperwork Reduction Act: Technical Amendment; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 435

[FRL–6929–8]

RIN 2040–AD14

Effluent Limitations Guidelines and New Source Performance Standards for the Oil and Gas Extraction Point Source Category; OMB Approval Under the Paperwork Reduction Act: Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule; technical amendment.

SUMMARY: EPA is publishing final regulations establishing technology-based effluent limitations guidelines and standards for the discharge of synthetic-based drilling fluids (SBFs) and other non-aqueous drilling fluids from oil and gas drilling operations into waters of the United States. Oil and gas extraction facilities generate cuttings wastes from drilling operations. This regulation applies to existing and new sources that perform oil and natural gas extraction drilling in certain offshore and coastal waters. The final rule allows a controlled discharge of SBF-cuttings anywhere offshore of Alaska and offshore of the rest of the United States beyond three miles from shore. This regulation prohibits discharge of such fluids in coastal Cook Inlet, Alaska, unless certain findings are made by the permit authority. The final rule prohibits the discharge of SBFs not associated with drill cuttings into all waters of the United States.

Compliance with this rule is estimated to reduce the annual discharge of cuttings by 118 million pounds per year for new and existing sources. This rule will also lead to a decrease of 2,927 tons of air emissions and 200,817 barrels of oil equivalent (BOE) per year for new and existing sources. EPA estimates that the rule will result in annual savings of $48.9 million and no adverse economic impacts to the industry as a whole. EPA also incorporated Best Management Practices (BMPs) into the final rule to provide industry with additional flexibility in meeting today's final rule. In compliance with the Paperwork Reduction Act (PRA), this action also makes a technical amendment to the table in part 9 that lists the Office of Management and Budget (OMB) control numbers issued under the PRA for today's final rule. EPA is amending part 9 to include the OMB control number for the information collection requirements associated with the BMPs promulgated in today's final rule.

DATES: This regulation shall become effective February 21, 2001. For judicial review purposes, this final rule is promulgated as of 1 p.m. Eastern Time on February 5, 2001, as provided in 40 CFR 23.2. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Office of Federal Register as of February 21, 2001.

ADDRESSES: The public record is available for review in the EPA Water Docket, East Tower Basement, Room EB–57, 401 M St. SW., Washington, DC 20460. The public record for this rule has been established under docket number W–98–26, and includes supporting documentation, but does not include any information claimed as Confidential Business Information (CBI). The record is available for inspection from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. For access to docket materials, please call (202) 260–3027 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: For additional technical information contact Mr. Carey A. Johnston at (202) 260–7186 or send E-mail to: johnston.carey@epa.gov. For additional economic information contact Mr. James Covington at (202) 260–5132 or send E-mail to: covington.james@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities

Entities potentially regulated by this action include:

Category	Examples of regulated entities
Industry	Facilities engaged in the drilling of wells in the oil and gas industry in areas defined as "coastal" or "offshore" and discharging in geographic areas where drilling wastes are allowed for discharge (anywhere offshore of Alaska and offshore of the rest of the United States beyond three miles from shore, and the coastal waters of Cook Inlet, Alaska). Includes certain facilities covered under Standard Industrial Classification code 13 and North American Industrial Classification System codes 211111 and 213111.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in 40 CFR part 435 (*see* §§ 435.10 and 435.40). If you have questions regarding the applicability of this action to a particular entity, consult the person listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Compliance Dates

Deadlines for compliance with Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), and Best Available Technology Economically Achievable (BAT) are established in National Pollutant Discharge Elimination System (NPDES) permits. A new source must comply with New Source Performance Standards (NSPS) on the date the new source commences discharging.

Technical Amendments to Part 9

EPA is amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. The amendment updates the table to list those information collection requirements promulgated under today's final rule. The affected regulations are codified at 40 CFR part 9. EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists CFR citations with reporting, recordkeeping, or other information collection requirements, and the current OMB control numbers. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. Due to the technical nature of the table, EPA finds that further notice and comment is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), to amend this table without prior notice and comment. As a result of today's technical amendment pertaining to BMPs, EPA is now authorized under the Paperwork Reduction Act to conduct or sponsor the information collection requirements in 40 CFR 435.13, 435.15, 435.43, and 435.45.

Supporting Documentation

The rules promulgated today are supported by several major documents:

1. "Economic Analysis of Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category" (EPA–821–B–00–012). Hereafter referred to as the SBF Economic Analysis, this document presents the analysis of compliance costs and/or savings; facility closures; and changes in rate of return. In addition, impacts on employment and affected communities, foreign trade, specific demographic groups, and new sources also are considered.

2. "Development Document for Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category" (EPA–821–B–00–013). Hereafter referred to as the SBF Development Document, the document presents EPA's technical conclusions concerning the promulgated rules. This document describes, among other things, the data collection activities, the wastewater treatment technology options, effluent characterization, effluent reduction of the wastewater treatment technology options, estimate of costs to the industry, and estimate of effects on non-water quality environmental impacts.

3. "Environmental Assessment of Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category" (EPA–821–B–00–014). Hereafter referred to as the SBF Environmental Assessment, the document presents the analysis of water quality impacts for each regulatory option. EPA describes the environmental characteristics of SBF drilling wastes, types of anticipated impacts, and pollutant modeling results for water column concentrations, pore water concentrations, and human health effects via consumption of affected seafood.

4. "Statistical Analyses Supporting Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category" (EPA–821–B–00–015). Hereafter referred to as the SBF Statistical Support Document, this document presents analyses of retention on cuttings of SBF. EPA describes the performance characteristics of cuttings treatment technologies and calculates summary statistics for use as numerical limits.

How To Obtain Supporting Documents

All documents are available from the National Service Center for Environmental Publications, PO Box 42419, Cincinnati, OH 45242–2419, (800) 490–9198. The supporting technical documentation (*e.g.*, SBF Development Document) and previous technical documentation and Federal Register notices can also be obtained on the Internet, located at WWW.EPA.GOV/OST/GUIDE. This website also links to an electronic version of today's final rule.

Overview

This preamble includes a description of the legal authority for these final regulations; a summary of the final regulations; background information on the industry and its processes; a description of the technical and economic methodologies and data used by EPA to develop these regulations; and a summary of EPA responses to major comments received on the Proposal (February 3, 1999; 64 FR 5488) and Notice of Data Availability (April 21, 2000; 65 FR 21548). The definitions, acronyms, and abbreviations used in this preamble are defined in Appendix A.

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Appendix A: Definitions, Acronyms, and Abbreviations Used in This Preamble

I. Legal Authority

EPA is promulgating these regulations under the authority of sections 301, 304, 306, 307, 308, 402, and 501 of the Clean Water Act, 33 U.S.C. 1311; 1314, 1316, 1317, 1318, 1342 and 1361. The technical amendment to part 9 is promulgated under the authority of 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

II. Background

A. Clean Water Act

Congress adopted the Clean Water Act (CWA) to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Section 101(a), 33 U.S.C. 1251(a)). To achieve this goal, the CWA prohibits the discharge of pollutants into navigable waters except in compliance with the statute. The Clean Water Act confronts the problem of water pollution on a number of different fronts. Its primary reliance, however, is on establishing restrictions on the types and amounts of pollutants discharged from various industrial, commercial, and public sources of wastewater.

Direct dischargers must comply with effluent limitations in National Pollutant Discharge Elimination System ("NPDES") permits; indirect dischargers must comply with pretreatment standards. These limitations and standards are established by regulation for categories of industrial dischargers and are based on the degree of control that can be achieved using various levels of pollution control technology.

1. Best Practicable Control Technology Currently Available (BPT)—Section 304(b)(1) of the CWA

Section 304(b)(1)(A) of the CWA requires EPA to identify effluent reductions attainable through the application of, "best practicable control technology currently available for classes and categories of point sources." Generally, EPA determines BPT effluent levels based upon the average of the best existing performances by plants of various sizes, ages, and unit processes within each industrial category or subcategory. In industrial categories where present practices are uniformly inadequate, however, EPA may determine that BPT requires higher levels of control than any currently in place if the technology to achieve those levels can be practicably applied (*see* A Legislative History of the Federal Water Pollution Control Act Amendments of 1972, U.S. Senate Committee of Public Works, Serial No. 93–1, January 1973, p. 1468).

In addition, CWA Section 304(b)(1)(B) requires a cost assessment for BPT limitations. In determining the BPT limits, EPA must consider the total cost of treatment technologies in relation to the effluent reduction benefits achieved. This inquiry does not limit EPA's broad discretion to adopt BPT limitations that are achievable with available technology unless the required additional reductions are "wholly out of proportion to the costs of achieving such marginal level of reduction." (*see* Legislative History, op. cit. p. 170). Moreover, the inquiry does not require the Agency to quantify benefits in monetary terms (*e.g.*, American Iron and Steel Institute v. EPA, 526 F. 2d 1027 (3rd Cir., 1975)).

In balancing costs against the benefits of effluent reduction, EPA considers the volume and nature of expected discharges after application of BPT, the general environmental effects of pollutants, and the cost and economic impacts of the required level of pollution control. In developing guidelines, the Act does not require consideration of water quality problems attributable to particular point sources, or water quality improvements in particular bodies of water.

2. Best Available Technology Economically Achievable (BAT)—Section 304(b)(2) of the CWA

The CWA establishes BAT as a principal means of controlling the discharge of toxic and non-conventional pollutants. In general, BAT effluent limitations guidelines represent the best existing economically achievable performance of direct discharging plants in the industrial subcategory or category. The factors considered in assessing BAT include the cost of achieving BAT effluent reductions, the age of equipment and facilities involved, the processes employed, engineering aspects of the control technology, potential process changes, non-water quality environmental impacts (including energy requirements), and such factors as the Administrator deems appropriate. The Agency retains considerable discretion in assigning the weight to be accorded to these factors. An additional statutory factor considered in setting BAT is economic achievability. Generally, the achievability is determined on the basis of the total cost to the industrial subcategory and the overall effect of the rule on the industry's financial health. BAT limitations may be based upon effluent reductions attainable through changes in a facility's processes and operations. As with BPT, where existing performance is uniformly inadequate, BAT may be based upon technology transferred from a different subcategory within an industry or from another industrial category. BAT may be based upon process changes or internal controls, even when these technologies are not common industry practice.

3. Best Conventional Pollutant Control Technology (BCT)—Section 304(b)(4) of the CWA

The 1977 amendments to the CWA required EPA to identify effluent reduction levels for conventional pollutants associated with BCT technology for discharges from existing industrial point sources. BCT is not an additional limitation, but replaces Best Available Technology (BAT) for control of conventional pollutants. In addition to other factors specified in section 304(b)(4)(B), the CWA requires that EPA establish BCT limitations after consideration of a two part "cost-reasonableness" test. EPA explained its methodology for the development of BCT limitations in July 1986 (51 FR 24974).

Section 304(a)(4) designates the following as conventional pollutants: biochemical oxygen demand (BOD_5), total suspended solids (TSS), fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as an additional conventional pollutant on July 30, 1979 (44 FR 44501).

4. New Source Performance Standards (NSPS)—Section 306 of the CWA

NSPS reflect effluent reductions that are achievable based on the best available demonstrated control technology. New facilities have the opportunity to install the best and most efficient production processes and wastewater treatment technologies. As a result, NSPS should represent the greatest degree of effluent reduction attainable through the application of the best available demonstrated control technology for all pollutants (*i.e.*, conventional, non-conventional, and priority pollutants). In establishing NSPS, EPA is directed to take into consideration the cost of achieving the effluent reduction and any non-water quality environmental impacts and energy requirements.

5. Pretreatment Standards for Existing Sources (PSES)—Section 307(b) of the CWA

PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTWs). The CWA authorizes EPA to establish pretreatment standards for pollutants that pass through POTWs or interfere with treatment processes or sludge disposal methods at POTWs. Pretreatment standards are technology-based and analogous to BAT effluent limitations guidelines.

The General Pretreatment Regulations, which set forth the framework for implementing categorical pretreatment standards, are found at 40 CFR part 403. Those regulations contain a definition of pass through that addresses localized rather than national instances of pass through and establish pretreatment standards that apply to all non-domestic dischargers. See 52 FR 1586, January 14, 1987.

6. Pretreatment Standards for New Sources (PSNS)—Section 307(b) of the CWA

Like PSES, PSNS are designed to prevent the discharges of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. PSNS are to be issued at the same time as NSPS. New indirect dischargers have the opportunity to incorporate into their plants the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating NSPS.

7. Best Management Practices (BMPs)

Sections 304(e), 308(a), 402(a), and 501(a) of the CWA authorize the Administrator to prescribe BMPs as part of effluent limitations guidelines and standards or as part of a permit. EPA's BMP regulations are found at 40 CFR 122.44(k). Section 304(e) of the CWA authorizes EPA to include BMPs in effluent limitations guidelines for certain toxic or hazardous pollutants for the purpose of controlling "plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage." Section 402(a)(1) and NPDES regulations (40 CFR 122.44(k)) also provide for best management practices to control or abate the discharge of pollutants when numeric limitations and standards are infeasible. In addition, section 402(a)(2), read in concert with section 501(a), authorizes EPA to prescribe as wide a range of permit conditions as the Administrator deems appropriate in order to ensure compliance with applicable effluent limitations and standards and such other requirements as the Administrator deems appropriate.

8. CWA Section 304(m) Requirements

Section 304(m) of the CWA, added by the Water Quality Act of 1987, requires EPA to establish schedules for: (1) Reviewing and revising existing effluent limitations guidelines and standards; and (2) promulgating new effluent guidelines. On January 2, 1990, EPA published an Effluent Guidelines Plan (55 FR 80), in which schedules were established for developing new and revised effluent guidelines for several industry categories, including the oil and gas extraction industry. Natural Resources Defense Council, Inc., challenged the Effluent Guidelines Plan in a suit filed in the U.S. District Court for the District of Columbia, (*NRDC et al.* v. *Browner*, Civ. No. 89–2980). On January 31, 1992, the Court entered a consent decree (the "304(m) Decree"), which establishes schedules for, among other things, EPA's proposal and promulgation of effluent guidelines for a number of point source categories. The most recent Effluent Guidelines Plan was published in the **Federal Register** on August 31, 2000 (65 FR 53008). This plan requires, among other things, that EPA take final action regarding the Synthetic-Based Drilling Fluids Guidelines by December 2000.

B. Pollution Prevention Act

The Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13101 *et seq.*, Public Law 101–508, November 5, 1990) "declares it to be the national policy of the United States that pollution should be prevented or reduced whenever feasible; pollution that cannot be prevented should be recycled in an environmentally safe manner, whenever feasible; pollution that cannot be prevented or recycled should be treated in an environmentally safe manner whenever feasible; and disposal or release into the environment should be employed only as a last resort * * *" (Sec. 6602; 42 U.S.C. 13101 (b)). In short, preventing pollution before it is created is preferable to trying to manage, treat or dispose of it after it is created. The PPA directs the Agency to, among other things, "review regulations of the Agency prior and subsequent to their proposal to determine their effect on source reduction" (Sec. 6604; 42 U.S.C. 13103(b)(2)). EPA reviewed this effluent guideline for its incorporation of pollution prevention.

According to the PPA, source reduction reduces the generation and release of hazardous substances, pollutants, wastes, contaminants, or residuals at the source, usually within a process. The term source reduction "include(s) equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training or inventory control. The term "source reduction" does not include any practice which alters the physical, chemical, or biological characteristics or the volume of a hazardous substance, pollutant, or contaminant through a process or activity which itself is not integral to or necessary for the production of a product or the providing of a service." 42 U.S.C. 13102(5). In effect, source reduction means reducing the amount of a pollutant that enters a waste stream or that is otherwise released into the environment prior to out-of-process recycling, treatment, or disposal.

In these final regulations, EPA supports pollution prevention technology by encouraging the appropriate use of synthetic-based drilling fluids (SBFs) based on the use of base fluid materials in place of traditional: (1) Water-based drilling fluids (WBFs); and (2) oil-based drilling fluids (OBFs) consisting of diesel oil/or and mineral oil. The appropriate use of SBFs in place of WBFs will generally lead to more efficient and faster drilling and a per well reduction in non-water quality environmental impacts (including energy requirements) and discharged pollutants. Use of SBFs may also lead to a reduced demand for new drilling rigs and platforms and development well drilling though the use directional and extended reach drilling. Discharges from SBF-drilling operations have lower aqueous and

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sediment toxicities, lower bioaccumulation potentials, and faster biodegradation rates as compared to OBFs. In addition, polynuclear aromatic hydrocarbons (PAHs), including those which are priority pollutants, which are constituents in OBFs are not present in SBFs.

EPA considered a "zero discharge" requirement (*i.e.*, BAT/NSPS Option 3) for SBF-cuttings wastes and determined that under this requirement most operators would decrease the use of SBFs in favor of OBFs and WBFs due to lower OBF and WBF drilling fluid unit costs. EPA concluded that a zero discharge requirement for SBF-cuttings and the subsequent increased use of OBFs and WBFs would result in: (1) Unacceptable non-water quality environmental impacts (NWQIs); and (2) more pollutant loadings to the ocean due to operators switching from SBFs to less efficient WBFs.

The appropriate use of SBF in place of OBF will generally shorten the length of the drilling project and eliminate the need to barge to shore or re-inject OBF-waste cuttings, thereby reducing NWQI such as fuel use, air emissions, and land disposal of OBFs. The controlled discharge option also eliminates the risk of OBF and OBF-cuttings spills and cross-media contamination at land disposal operations. Operators would be increasing the toxicity of their drilling fluids and wastes by using OBFs in place of SBFs. As stated in April 2000 (65 FR 21557), EPA used SBF and OBF spill data in the final rule as a factor in supporting a controlled discharge option. U.S. Department of Interior, Minerals Management Service (MMS) spill data show that riser disconnects in deep water drilling can release approximately 2,400 barrels of neat SBF and these incidences occur in deep water on average two to three times per year due to riser failure (Docket No. W–98–26, Record No. IV.B.a.3). Riser disconnects in the deep water are a particular concern due to: (1) Increased riser tensioning; (2) deep water technical requirements (*e.g.*, riser verticality, increased use of top drive systems, multiple flex joints in riser, placement of well heads and upper casing sections in soft sea beds); and (3) deep water ocean environments (*e.g.*, uncharted eddy and loop currents) (Docket No. W–98–26, Record No. IV.B.a.4; Record No. IV.B.a.5). Use of WBFs in place of SBFs would also lead to: (1) An increase in NWQIs due to the increased length of the drilling project; and (2) a per well increase pollutants discharged due to poorer technical performance of WBFs. For these primary reasons, EPA rejected the zero discharge option.

In addition, the technology controls in the final regulation are based on a more efficient solids control technology to increase recycling of SBF in the drilling operation. Increased SBF recycling reduces the quantity of SBF required for drilling operations and the quantity of SBF discharged with drill cuttings. A discussion of this pollution prevention technology is contained in Section V.A of this preamble and in the SBF Development Document.

C. Profile of Industry

1. Well Drilling Process Description

The SBF Development Document presents a thorough description of the industry including drilling practices, solids control systems, and waste disposal operations. The following summary is excerpted from that technical document.

Drilling occurs in two phases: exploration and development. Exploration activities are those operations involving the drilling of wells to locate hydrocarbon bearing formations and to determine the size and production potential of hydrocarbon reserves. Development activities involve the drilling of production wells once a hydrocarbon reserve has been discovered and delineated.

Drilling for oil and gas is generally performed by rotary drilling methods which use a circularly rotating drill bit that grinds through the earth's crust as it descends. Drilling fluids are pumped down through the drill bit via a pipe that is connected to the bit, and serve to cool and lubricate the bit during drilling. The rock chips that are generated as the bit drills through the earth are termed "drill cuttings" or simply "cuttings." The drilling fluid also serves to transport the drill cuttings back up to the surface through the space between the drill pipe and the well wall (this space is termed the annulus), in addition to controlling downhole pressure and stabilizing the well bore.

As drilling progresses, large pipes called "casing" are inserted into the well to line the well wall. Drilling continues until the hydrocarbon bearing formations are encountered. In areas where drilling fluids and drill cuttings are allowed to be discharged under the current regulations, well depths range from approximately 4,000 to 12,000 feet deep, and it takes approximately 20 to 60 days to complete drilling.

On the surface, the drilling fluid and drill cuttings undergo an extensive separation process to remove fluid from the cuttings. The fluid is then recycled into the system, and the cuttings become a waste product. The drill cuttings retain a certain amount of the drilling fluid that are discharged or disposed with the cuttings. Drill cuttings are discharged by the shale shakers and other solids separation equipment (*e.g.*, decanting centrifuges, mud cleaners, cuttings dryers). Drill cuttings are also cleaned out of the mud pits and from the solid separation equipment during displacement of the drilling fluid system (*i.e.*, accumulated solids). Intermittently during drilling, and at the end of the drilling process, drilling fluids may become wastes if they can no longer be reused or recycled.

In the relatively new area of ultra-deep water drilling (*i.e.*, water depths greater than 3,000 feet), new drilling methods are evolving which can significantly improve drilling efficiencies and thereby reduce NWQIs (*e.g.*, fuel, steel casing consumption, air emissions) and the per well amount of pollutants discharged. Subsea drilling fluid boosting, referred to as "dual gradient drilling," is one such new drilling technology. Dual gradient drilling is similar to traditional rotary drilling methods as previously described with the exception that the drilling fluid is energized or boosted by use of a pump at or near the seafloor. By boosting the drilling fluid, the adverse effect on the wellbore caused by the drilling fluid pressure from the seafloor to the surface is eliminated, thereby allowing wells to be drilled with as much as a 50% reduction in the number of casing strings generally required to line the well wall. As a result of the reduced number of casing strings, dual gradient wells can be drilled almost one-third faster and with smaller hole sizes than conventional deep water drilling. Smaller hole sizes and faster drilling translate into fewer pollutants being discharged to the ocean and fewer NWQI. Dual gradient drilling technology can also potentially eliminate or reduce the amount of whole drilling fluid released to the environment during an inadvertent riser disconnect. Finally, dual gradient drilling technology can greatly reduce the potential release of drilling fluid when drilling through shallow sand intervals (*e.g.*, shallow water flow) (Docket No. W–98–26, Record No. IV.B.a.6).

Some dual gradient drilling systems require the separation of the largest cuttings (*e.g.*, larger than approximately ¼ inch) at the seafloor since these cuttings may interfere with the rotatory action of subsea pumps (*e.g.*, electrical submersible pumps). The larger cuttings are routed at the seafloor to a venturi action pump (with no moving parts), mixed with seawater, and pumped to a cuttings discharge hose at the seafloor within a 300 foot radius of the well site. The hose is perforated on the last 50 ft of its length to maximize the spread of cuttings. The action of pumping cuttings with seawater can be expected to have some cleaning and dispersion effect. A remotely operated vehicle (ROV) can also be used to reposition the subsea discharge hose to maximize cuttings dispersal. Representative samples of drill cuttings discharged at the seafloor can be transported to the surface by a ROV for purposes of monitoring. The drilling fluid, which is boosted at the seafloor and transports most of the drill cuttings (*e.g.*, 95–98% of total cuttings generated) back to the surface, is processed as described in the general rotary drilling methods described above in this section.

A commercial potential determination is made at the completion of rotary drilling (*i.e.*, once the target oil or natural gas formations have been reached). The well is then made ready for production by a process termed "completion." Completion involves cleaning the well to remove drilling fluids and debris, perforating the casing that lines the producing formation, inserting production tubing to transport the hydrocarbon fluids to the surface, and installing the surface wellhead. The well is then ready for production (*i.e.*, actual extraction of hydrocarbons).

2. Location and Activity

This rule establishes effluent limitations guidelines and standards that control discharges of SBF and SBF-cuttings throughout the Offshore subcategory beyond three miles from shore, except for Offshore Alaska where no three mile restriction applies. This rule prohibits discharge of SBF and SBF-cuttings in Upper (Coastal Subcategory) Cook Inlet, Alaska, unless operators meet criteria demonstrating that they are unable to: (1) Box and store their cuttings on-site for zero discharge cuttings transfer operations (*i.e.*, haul to shore for land disposal or re-injection at another rig or platform); or (2) re-inject their SBF-cuttings on-site. When Coastal Cook Inlet, AK, operators demonstrate to the NPDES controlling authority that they are unable to achieve zero discharge of their SBF-cuttings, they may discharge their SBF-cuttings under the same controls as exist for SBF-cuttings discharges in Offshore waters. Criteria for establishing when operators cannot achieve zero discharge are established in the final regulation. SBF-cuttings discharged in Offshore Cook Inlet, Alaska, are controlled in the same manner as other SBF-cuttings in other Offshore waters. This rule does not amend the requirements for zero discharge of drilling fluids and drill cuttings where they have already been prohibited from discharge.

Drilling is currently active in three regions: (1) The offshore waters beyond three miles from shore in the Gulf of Mexico (GOM); (2) offshore waters beyond three miles from shore in California; and (3) Cook Inlet, Alaska. Most drilling activity occurs in the GOM, where 1,302 wells were drilled in 1997, compared to 28 wells drilled in California and 7 wells drilled in Cook Inlet. In the GOM, over the last few years, there has been high growth in the number of wells drilled in deep water (*e.g.*, water depths greater than 1,000 feet). For example, in 1995, 84 wells were drilled in deep water, comprising 8.6% of all GOM wells drilled that year. By 1997, that number increased to 173 deep water wells drilled and comprised over 13% of all GOM wells drilled. Most recent 1999 data show that this trend is continuing as over 15% of all GOM wells drilled were in deep water. The increased activity in deep water increases the usefulness of SBFs. Operators drilling in deep water cite the following factors for selecting SBFs over WBFs and OBFs: (1) Potential for riser disconnect (*i.e.*, inadvertent releases of drilling fluid) in floating drill ships, which favors SBF over OBF; (2) higher daily drilling cost which more easily justifies use of more expensive SBFs over WBFs; and (3) greater distance to barge drilling wastes that may not be discharged (*i.e.*, OBFs, WBFs that fail the SPP Toxicity Test as currently required by EPA in Appendix 2 to Subpart A of 40 CFR part 435).

3. Drilling Wastestreams

Drilling fluids and drill cuttings are a major source of waste from exploratory and development well drilling operations. This final regulation establishes limitations for both the drilling fluid and the drill cuttings wastestream when SBFs are used. All other wastestreams and drilling fluids (*e.g.*, WBFs, OBFs) already have limitations; those limitations are outside the scope of this rule. The characteristics of both drilling fluids and drill cuttings wastestreams are summarized in Section V.A of this preamble. A more detailed discussion of the origins and characteristics of these wastes is also included in the SBF Development Document.

D. Proposed Rule

On February 3, 1999 (64 FR 5488), EPA published proposed effluent limitations guidelines for the discharge of SBF drilling fluids and drill cuttings into waters of the United States by existing and new facilities in the oil and gas extraction point source category.

EPA received comments on many aspects of the proposal. The majority of comments related to: (1) The proposed analytical test methods for stock and discharge limitations; (2) equipment used to set BAT and NSPS cuttings retention limitations; (3) Best Management Practices (BMPs) and their use to control small volume spills and releases of SBF; (4) the proposal's engineering and economic modeling parameters; and (5) procedural and definition issues. EPA evaluated all of these issues based on additional information collected by EPA or received during the comment period. EPA then discussed the results of these evaluations in a Notice of Data Availability which is discussed below.

E. Notice of Data Availability

On April 21, 2000 (65 FR 21548), EPA published a Notice of Data Availability (NODA) to present a summary of new data received in comments on the proposed rule or collected by EPA following publication of the proposal. In the April 2000 NODA, EPA discussed the major issues and presented several revised modeling and alternative approaches to address these issues. EPA solicited comment on the data collected since proposal and on the revised modeling and alternative approaches to manage SBF discharges.

III. Summary of Data and Information Received in Response to the Notice of Data Availability

The April 2000 NODA summarized the data and information received by EPA in response to the February 1999 proposal and information received before the April 2000 NODA. This section describes the data received by EPA in response to the April 2000 NODA.

A. Pollutant Loading and Numeric Limit Analyses

1. SBF Retention on Cuttings

SBF retention on cuttings (ROC) data quantify the amount of SBF retained on cuttings (mass of SBF/mass of wet cuttings, expressed as a percentage). Lower ROC values indicate less SBF retained on cuttings. EPA uses ROC data, along with other engineering factors (*e.g.*, installation requirements, fluid rheology) to evaluate the

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performance of various solids control technologies.

In response to the February 1999 proposal, industry submitted data for SBF ROC from 36 wells. EPA determined that 16 files were complete and accurate, and these data were presented in the April 2000 NODA. EPA rejected six files due to incomplete reporting. EPA received 14 files too late for inclusion in the April 2000 NODA analyses.

In response to the April 2000 NODA, EPA received and evaluated ROC data from an additional 79 SBF wells: the 14 received after the February 1999 proposal comment period; 27 additional sets received during the April 2000 NODA comment period; and 38 received after the April 2000 NODA comment period. EPA determined that data from 49 of these 79 wells were complete for inclusion in the final rule analyses. Therefore, EPA used data from 65 wells to determine the ROC performance of the various solids control technologies. The collection, engineering review, and extraction of data from these files are described in the SBF Development Document.

EPA revised the average ROC values of various solids control technologies based on the final ROC data. These revised average ROC values were combined to yield the average ROC value for the following three SBF-cuttings technology options: (1) BAT/NSPS Option 1 is based on the use of shale shakes, cuttings dryer, fines removal unit, and discharges from the cuttings dryer and fines removal unit and has a long-term average ROC value of 4.03%; (2) BAT/NSPS Option 2 is based on the use of shale shakes, cuttings dryer, and fines removal unit, and one discharge from the cuttings dryer, and has a long-term average ROC value of 3.82%; and (3) BAT/NSPS Option 3 is based on the use of shale shakes, cuttings boxes, barges, and zero discharge land disposal and offshore re-injection and has a long-term average ROC value of 10.2%. In addition, using the ROC data, EPA developed a BAT limitation and standard controlling the base fluid retained on cuttings for drilling fluids with the environmental performance of esters (*e.g.*, biodegradation, sediment toxicity). EPA developed this option to provide operators an incentive to use ester-based SBFs and has a long-term average ROC value of 4.8%. EPA used the ROC data to establish a BAT limitation and a NSPS on base fluid retained on cuttings. The base fluid retained on cuttings limitation and standard both incorporate the variability of solids control efficiencies and are higher than the long term average.

2. Days to Drill

EPA uses the number of days to drill the SBF interval, for all four model wells, as an input parameter in the NWQI and cost analysis. EPA extracted relevant data from each of the 65 wells identified above to estimate the number of days to drill each of the four model well SBF intervals (Docket No. W–98–26, Record No. IV.B.a.7). The revised numbers of days required to drill the SBF model wells are based on a revised average rate of SBF-cuttings generation (*i.e.*, 108.7 bbls wet cuttings/day). The revised numbers of days required to drill the SBF model wells are: (1) 5.2 days for shallow-water development wells (SWD); (2) 10.9 days for shallow-water exploratory wells (SWE); (3) 7.9 days for deep-water development wells (DWD); and (4) 17.5 days for deep-water exploratory wells (DWE).

3. Well Count Projections Over Next Five Years

EPA revised well count projections for Offshore GOM, Offshore California, and Cook Inlet, AK, based on information submitted by industry (Docket No. W–98–26, Record No. IV.B.a.9; Record No. IV.B.a.10; Record No. IV.B.a.11). The revised annual well counts are 1,047 shallow water wells and 138 deep water wells in Offshore GOM; 7 shallow water wells and no deep water wells in Offshore California; and 6 shallow water wells and no deep water wells in Cook Inlet, AK. These revised well counts are not significantly different from the well counts used in the February 1999 proposal and April 2000 NODA (*i.e.*, *see* SBF Proposal Development Document (EPA–821–B–98–021), Table IV–2: 1,022 shallow water wells and 139 deep water wells across the GOM, Offshore California, and Cook Inlet, AK).

Industry only provided the well counts in terms of shallow water versus deep water wells. EPA further divided the revised well counts into development and exploratory well category counts for estimating pollutant loadings, compliance costs, and NWQIs. EPA performed this allocation using prior well count data from the April 2000 NODA. EPA derived percentages of development versus exploratory wells for both shallow water well types and deep water well types. EPA then applied these percentages to the revised aggregated shallow water and deep water well counts provided by industry. EPA also collected additional washout rates for WBF and SBF drilling.

EPA also revised well count projections to reflect enhanced directional drilling capabilities when using SBF. EPA received information that SBF directional drilling can reduce the number of wells required to drill a development well project. Specifically, industry stated that SBF development drilling can generally reduce the drilled footage required for full development of a typical reservoir by one-third as compared with WBF drilling (Docket No. W–98–26, Record No. IV.B.a.9). EPA has included this consideration by reducing the footage drilled by one-third for WBF development wells projected to convert from WBF to SBF under the two controlled discharge options.

4. Current and Projected OBF, WBF, and SBF Use Ratios

For the February 1999 proposal and April 2000 NODA, EPA estimated that 80% of the average annual GOM wells are drilled using WBF exclusively; 10% are drilled with SBF; and 10% are drilled with OBF. EPA also included in well counts estimates of operators converting from OBF to SBF or SBF to OBF under each of the SBF-cuttings controlled discharge options.

For the final rule, EPA revised the relative frequency of use between WBF, OBF, and SBF under the two discharge options and the zero discharge option based on data submitted by industry (Docket No. W–98–26, Record No. IV.B.a.9; Record No. IV.B.a.10; Record No. IV.B.a.11). Industry supplied this information to EPA in several formats. EPA used the most reliable information (*e.g.*, the actual well count data for WBF, OBF, and SBF wells over a period of three years) to estimate drilling fluid use under each of the SBF-cuttings control options (*see* SBF Development Document).

EPA believes that some operators would switch from WBFs to SBFs for certain wells due to the increased efficiency of SBF drilling. While no good industry average statistics exist, it is generally considered that SBFs reduce overall drilling time by 50% (*e.g.*, if a well took 60 days to drill with WBF, the same well should be able to be drilled with SBF in 30 days) (Docket No. W–98–26, Record No. IV.B.a.9; Record No. IV.B.a.10; Record No. IV.B.a.11). Reducing drilling time generally reduces drilling costs. However, not all drilling operators will switch from WBFs to SBF due to a variety of other factors, (*e.g.*, WBFs are less expensive (per barrel) than SBFs, potential for lost circulation downhole).

Additionally, EPA believes that under the SBF-cuttings zero discharge option, not all operators would switch from SBFs to OBFs but that some operators would switch to WBFs. Some drilling operations require the technical performance of non-aqueous drilling fluids and operators must select either an OBF or SBF. Therefore, for these drilling operations, operators would select OBFs in place of SBF under the SBF-cuttings zero discharge option as OBFs are less expensive (per barrel) than SBFs. However, some drilling operations could use either WBFs or oleaginous drilling fluids such as OBFs, enhanced mineral oil based drilling fluids, or SBFs. Depending on a variety of site specific factors (*e.g.*, formation characteristics, directional drilling requirements, torque and drag requirements), operators may select WBFs in lieu of SBFs or OBFs under the SBF-cuttings zero discharge option.

5. Waste Volumes and Characteristics

EPA collected additional data to identify the volumes and characteristics of WBF discharges. This additional data more adequately describes the total amount of pollutants loadings and NWQI under each of the three SBF-cuttings management options. For example, under the SBF zero discharge option (BAT/NSPS Option 3) operators would more likely choose WBF and OBF over SBF due primarily to the relatively higher unit cost of SBF.

Different pollutant loadings and NWQI are expected for WBF as compared with either OBF or SBF wells based on differences in washout and length of drilling time. EPA anticipates a reduction in cuttings waste volume when comparing SBF-drilling to WBF-drilling based on greater hole washout (*i.e.*, enlargement) in WBF drilling. Industry estimated that WBF washout percentages vary between 25% and 75%, with 45% being an acceptable average and confirmed EPA's SBF and OBF washout percentage of 7.5% as appropriate (Docket No. W–98–26, Record No. IV.B.a.9).

For the final rule, EPA also estimated that the barite used in SBF drilling is nearly pure barium sulfate (*i.e.*, $BaSO_4$) and, by gravimetric analysis, calculated the weight percentage of barium in barite as 58.8%.

B. Compliance Costs Analyses

1. Equipment Installation and Downtime

For the April 2000 NODA, projected compliance costs for all options included equipment installation and downtime for each SBF well drilled. After further review of ROC data wells (*see* Section III.A), EPA modified this parameter in the final analyses to reflect current practice of drilling multiple wells per year for any one equipment installation (Docket No. W–98–26, Record No. IV.B.a.9). EPA reviewed the ROC well data for the frequency of multiple wells on specified structures. EPA used the resulting well-per-structure analysis to adjust projected annual SBF compliance costs by including the consideration of drilling more than one SBF well per equipment installation per year. EPA estimated that 2.2 development wells per structure and 1.6 exploratory wells per structure are current industry practice, based on industry-submitted data (*see* SBF Development Document).

EPA received information on the ability of operators to install cuttings dryers (*e.g.*, vertical or horizontal centrifuges, squeeze press mud recovery units, High-G linear shakers) on existing GOM rigs (Docket No. W–98–26, Record No. IV.B.b.33). While some industry sources filed timely comments alleging that some rigs could not accommodate additional solids control equipment, in late comments, industry provided data concerning the number of GOM rigs in operation which are not capable of having a cuttings dryer system installed due to either rig space and/or rig design without prohibitive costs or rig modifications.

EPA also received information on a new cuttings containment, handling, and transfer equipment system. The new system is designed to eliminate the need to use cuttings boxes to handle cuttings. EPA received information from one operator that recently field tested the cuttings transfer system on one 12¼ inch well section in the North Sea. The operator contained 100% of the cuttings on a rig (Alba) with limited deck space. Cuttings were handled in bulk below deck and pumped directly onto a waiting vessel for eventual land disposal. The operator estimated that use of the new cuttings transfer system eliminated hundreds of crane lifts and manual handling issues and thereby improved worker safety.

2. Current Drilling Fluid Costs

In response to the April 2000 NODA, EPA revised unit costs of WBF, OBF, and SBF. Based on industry data, EPA used the WBF unit cost of $45 per barrel for the final rule. The February 1999 Proposal and April 2000 NODA used OBF and SBF unit costs of $75 and $200 per barrel of drilling fluid, respectively. Industry data indicates a range of OBF unit costs from $70–$90 per barrel and EPA used the OBF unit cost of $79 per barrel for the final rule. EPA estimates that SBF unit costs will remain between $160 to $300 per barrel of drilling fluid over the next few years. EPA used an SBF unit cost of $221 per barrel of drilling fluid for the final rule based on the most frequently used SBF in the offshore market.

3. Cost Savings of SBF Use as Compared With WBF Use

EPA revised its compliance costs to include the following factors: (1) The cost savings associated with increased rate of penetration when using SBF as compared to WBF; and (2) the cost of lost WBFs that are discharged while drilling. EPA also examined, but did not include in its final compliance cost impacts, the costs associated with projected failures of a fraction of WBF wells to meet sheen or toxicity limitations, including costs of meeting zero discharge from these wells. EPA used this data to examine compliance costs impacts if operators switch from SBF to WBF drilling, or vice versa.

EPA requested data from industry on rate of penetration (ROP) for WBF operations as compared to SBF operations. Industry stated that ROP values of 300 feet per hour for SBF (and OBF) operations and 150 feet per hour for WBF are reasonable averages. However, using these values over an entire well was not recommended "due to the large number of variables" (Docket No. W–98–26, Record No. IV.B.a.9). Industry's information further states that a generally-accepted estimate is that "SBFs reduce overall drilling time by 50%" (Docket No. W–98–26, Record No. IV.B.a.9).

4. Construction Cost Index

EPA used the Construction Cost Index (CCI) from the Engineering News and Record (*see* http://www.enr.com/cost/costcci.asp) to reflect costs in 1999 dollars rather than 1998 dollars as was used for the April 2000 NODA. EPA used a CCI factor of 1.108 to reflect 1999 dollars and a base year of 1995.

C. Economic Impacts Analyses

For the final rule, EPA obtained and used MMS data on drilling through 1999 to identify any new firms operating in the offshore GOM and determine which firms were involved in deep water drilling operations. EPA identified 17 additional firms newly drilling in the GOM, of which 2 were identified as drilling in deep water. Of the new firms, 7 were identified as or assumed to be (for lack of data) small entities. One of these seven small firms was identified as a small entity drilling in deep water. This latter firm drilled two wells in the deep water in 1999.

EPA collected 1999 financial information on number of employees,

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assets, equity, revenues, net income, return on assets, return on equity, and profit margin for the publicly held, newly identified firms. EPA also updated financial information for the publicly held firms identified in February 1999 proposal SBF Economic Analysis (EPA–821–B–98–020).

EPA also collected information on 13 GOM onshore sites where offshore oil and gas drilling waste is handled or disposed. This information consists of precise geographical location, amount of waste handled annually, and site capacity. This information was provided to EPA Region 6 for use in its environmental justice (EJ) computer model to screen for sites (*i.e.*, Tier 1 analysis) where disposal of additional drilling wastes under a zero discharge option might have environmental justice implications. EPA Tier 1 analyses identified that five of the thirteen onshore facilities warranted additional review.

D. Water Quality Impact and Human Health Analyses

In response to April 2000 NODA comments and information, EPA revised the water quality and human health analyses for the final rule based on: (1) Information on seabed surveys; (2) revised fish consumption rates; (3) information on Alaska state water quality standards; and (4) revised ROC data which affect EPA modeling of water quality, sediment quality, and human health impacts.

1. Seabed Surveys

EPA received public comments regarding the impact of SBF discharges on the benthic environment. Several seabed surveys were submitted to EPA together with the public comments. Information from two comments contained specific seabed survey data on sediment SBF concentrations after discharge of SBF cuttings. EPA included additional data from six wells in the calculation of mean SBF sediment concentration (at 100 meters from the modeled discharge) used in the water quality analysis. The mean SBF sediment concentration changed from 14,741 mg/kg as published in the April 2000 NODA to 9,718 mg/kg for modeled Gulf of Mexico wells and from 8,655 mg/kg to 13,052 mg/kg for wells modeled in Offshore California and Cook Inlet, Alaska.

EPA also received information on the on-going joint Industry/MMS GOM seabed survey. The Industry/MMS workgroup completed the first two cruises of the four cruise study in time for EPA's consideration for this final rule. Cruise 1 was a physical survey of 10 GOM shelf locations, with the objective of detection and delineation of cuttings piles using physical techniques. Cruise 2 was to scout and screen the final 5 shelf and 3 deep water GOM wells chosen for the definitive study where SBF were used. The SBF-cuttings discharges included either internal olefins or LAO/ester blends. Both cruises did not detect any large mounds of cuttings under any of the rigs or platforms. Remotely operated vehicles (ROV) using video cameras and side-scanning sonar were used to conduct the physical investigations on the seabed. Video investigations only detected small cuttings clumps (<6") around the base of some of the facilities and 1" thick cuttings accumulations on facility horizontal cross members. Outside of a 50–100' radius from the facility, no visible cuttings accumulations (large or small) were detected at any of the facility survey sites.

Finally, EPA received a report prepared for the MMS which provided a review of the scientific literature and seabed surveys to determine the environmental impacts of SBFs (Docket No. W–98–26, Record No. IV.F.1). The literature report confirms EPA's position that benthic communities will recover as SBF concentrations in sediments decrease and sediment oxygen concentrations increase. The report also confirms EPA's position that within three to five years of cessation of SBF-cuttings discharges, concentrations of SBFs in sediments will have fallen to low enough levels and oxygen concentrations will have increased enough throughout the previously affected area that complete recovery will be possible.

2. Fish Consumption Rates

EPA revised the fish consumption rates for use in environmental assessment analyses. The consumption rates vary depending on the fish habitat location (*i.e.*, freshwater, estuarine, and marine). EPA used the marine only fish consumption rate for the finfish consumption health risk analysis for the Gulf of Mexico and Offshore California. EPA used the estuarine/marine consumption rate for the Cook Inlet, Alaska analysis. EPA used the estuarine/marine consumption rate for all regions in the shrimp consumption health risk analysis.

EPA also conducted an investigation into the environmental factors affecting Native subsistence foods in Cook Inlet. EPA has incorporated relevant information from this investigation into the SBF Environmental Assessment.

3. State Water Quality Standards

EPA evaluated the potential decrease of water quality from the regulatory discharge options and compared the pollutant concentrations to recommended Federal water quality criteria. For discharges occurring in Cook Inlet, Alaska, EPA also compared the receiving water quality to Alaska state water quality standards. EPA used the updated Alaska state standards for the water quality analysis for Cook Inlet, Alaska.

E. Non-Water Quality Environmental Impact Analyses

EPA received additional data affecting the NWQI analyses in response to the April 2000 NODA. These data include additional information on retention on cuttings and information regarding offshore injection and onshore disposal practices for each of the three geographical areas: Gulf of Mexico, Offshore California, and Cook Inlet, Alaska.

EPA revised the average SBF retention on cuttings for the discharge options based on additional ROC data. Revisions in ROC data affect the volume of SBF-cuttings generated. Consequently, EPA revised the amount of SBF-cuttings that will need to be treated under the two SBF-cuttings controlled discharge options (*e.g.*, BAT/NSPS Options 1 and 2). EPA also revised: (1) The amount of SBF-fines that will need to be re-injected on-site or hauled to shore for disposal under one of the SBF-cuttings controlled discharge option (*e.g.*, BAT/NSPS Option 2); and (2) the amount of SBF-fines and SBF-cuttings re-injected on-site or hauled to shore for disposal under the zero discharge option (BAT/NSPS Option 3).

EPA received additional SBF well interval data which was used to re-calculate the number of days to drill the model SBF wells (*see* Section III.B.). For the NWQI analyses, the number of days to drill the model wells serves as the basis for estimating the length of time equipment will be used to either treat the cuttings before discharge or the hauling requirements under the zero discharge option. The EPA NWQI models estimate that air emissions and fuel use rates increase when the time required to complete a model well also increases.

EPA obtained information regarding the current practice of zero discharge disposal for each of three geographic areas, Gulf of Mexico, Offshore California, and Cook Inlet, Alaska (*see* Section IV.D). Current practice indicates that most of the waste generated in the Gulf of Mexico and Offshore California and brought to shore is injected onshore, whereas all of the waste currently generated in Cook Inlet is injected offshore at the drilling site or at a near-by Class II Underground Injection Control (UIC) disposal well. EPA also received from an on-shore injection facility specific equipment information, including the cuttings injection rate and cuttings grinding and injection equipment power requirements and fuel rates (Docket No. W–98–26, Record No. IV.D.2).

Industry provided EPA with information regarding SBF use (*see* Section III.A). One operator (Unocal) stated that it is starting to use SBF to drill the entire well and not just intervals in which WBFs present problems because drilling time can be significantly reduced. EPA incorporated this information into the NWQI analyses by estimating the reduction of impacts when using SBFs instead of WBFs. EPA also received during the April 2000 NODA comment period information related to the average increase in drilling time (1.5 days) in order to comply with zero discharge (Docket No. W–98–26, Record No. IV.A.a.3).

F. Compliance Analytical Methods

EPA completed additional studies in response to the April 2000 NODA to support the development of analytical methods for determining sediment toxicity, biodegradation, and oil retention on cuttings. For sediment toxicity and biodegradation, EPA focused specifically on optimizing test conditions (*e.g.*, test duration, sediment composition), discriminatory power, reproducibility, reliability, and practicality. EPA's sediment toxicity study provided toxicity data for both pure base fluids and standard mud formulations of these base fluids. EPA's biodegradation study evaluated the degradation of pure base fluids as determined by the solid phase test. For oil retention on cuttings, EPA conducted studies to verify and document the sensitivity of the retort test method.

During this same time period, industry sponsored Synthetic Based Muds Research Consortium (SBMRC) conducted parallel studies on the same three parameters (*i.e.*, sediment toxicity, biodegradation, and base fluid retention on cuttings). For sediment toxicity, industry provided extensive data comparing a 4-day versus a 10-day test duration, natural versus synthetic sediments, as well as toxicity data on both pure base fluids and mud formulations of these base fluids. For biodegradation, industry submitted results from the closed bottle and respirometry tests for biodegradation in addition to the solid phase test. For oil retention on cuttings, Industry and EPA conducted rig-based method detection limit studies.

IV. Summary of Revisions Based on Notice of Data Availability Comments

A summary of significant revisions to the analyses made by EPA in response to the February 1999 proposal is provided in the April 2000 NODA (*see* 65 FR 21549, Sections III and IV). This section describes the revisions to the analyses since publication of the April 2000 NODA.

A. Pollutant Loading Analyses

1. Loadings for Water-Based Drilling Fluids and Cuttings

For the final rule, EPA included the pollutant reductions (or increases) of the technology options based on operators switching from OBFs or WBFs to SBFs (or vice versa) and used data contained in the Offshore Development Document (EPA–821–R–93–003). Waste volume and/or pollutant loading data, on use of OBFs and WBFs presented in the Offshore Development Document, were expressed on a "per bbl," "per well," or a "per day" basis. Data from the Offshore rule record included: (1) WBF composition; (2) waste volumes for WBFs, OBFs, and associated cuttings; (3) the frequency of mineral oil use in WBF operations; and (4) the expected permit limitation failure rates (primarily for toxicity) on mineral oil fluids resulting in the requirement to haul or inject these wastes). These data then were applied to the current, revised well count projections and/or projected waste volumes to estimate discharge option loadings and the amount of OBFs, WBFs, and associated cuttings that require zero discharge under existing regulations (*e.g.*, OBFs containing diesel oil, WBFs that fail the SPP Toxicity Test). The Offshore Development Document provided information relevant to the inclusion of WBFs in the final analyses including: (1) Frequency of WBFs that failed permit limitations (Tables XI–10 and XI–7); (2) the composition of WBFs (Tables XI–3 and XI–6); (3) mineral oil composition (Table XI–5); and (4) the composition of cuttings from WBF (Section XI.3.4).

Industry-wide, regional, and total loadings were calculated for the loadings analyses for this final rule from the revised well counts provided by industry (Docket No. W–98–26, Record No. IV.B.a.9; Record No. IV.B.a.10; Record No. IV.B.a.11) combined with composition and estimated discharge volumes for WBFs (Offshore Development Document, Table XI–2).

In the final loadings analyses, EPA also corrected an error in the loading model used for the April 2000 NODA analyses. The error related to how EPA estimated the volume of fines from the fines removal unit captured and not discharged under BAT/NSPS Option 2. The volume of fines is based on many factors including the hole size, washout, and the percentage of the total wet cuttings produced from the solids control system that are fines. EPA incorrectly used the volume of dry cuttings per model well in the April 2000 NODA loading model to estimate the volume of fines generated from the BAT/NSPS Option 2 solids control system. The final loadings model correctly uses the volume of wet cuttings per model well to estimate the volume of fines generated from the BAT/NSPS Option 2 solids control system. The correction of the error had the effect of increasing the amount of fines captured for zero discharge under BAT/NSPS Option 2.

2. Drilling Fluid and Cuttings Composition and Density

The density of drilling wastes hauled in California was revised from 704 to 716 pounds per barrel to reflect the current density derived from the weight and volume data in the revised loadings model. This results in a change in the unit cost to haul waste in California to $12.53 and $5.89 per barrel for disposal and handling costs, respectively.

3. Days to Drill

EPA revised the number of drilling days based on data submitted in response to the April 2000 NODA for each of the four model well types. The number of drilling days input parameter affects NWQI and compliance costs (*e.g.*, equipment rental costs).

4. Directional Drilling

EPA also received additional data concerning the performance of SBF versus WBF for directional drilling operations (Docket No. W–98–26, Record No. IV.B.a.9). EPA used this information, the reduced number of wells and total footage of SBF-drilled development wells, to estimate pollutant loading reductions resulting from WBF to SBF conversions. For each of the two SBF-cuttings controlled discharge options (*i.e.*, BAT/NSPS Option 1 and 2), this revision reduced the annual sum total of discharged WBF and WBF-cuttings.

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B. Compliance Cost Analysis

1. Costs of WBF

As stated above, EPA modified the cost analysis for the final rule to include WBF cost factors. The WBF cost factors that EPA considered include: (1) The cost of discharged WBFs and WBF associated with cuttings discharged onsite; (2) the projected occurrence of mineral oil spots and/or lubrication and the projected failure rate of these mineral oil-amended fluids to meet permit limitations on toxicity and subsequent requirement to re-inject these materials down hole or haul them for onshore disposal; and (3) the rig costs associated with increases or decreases of drilling time related to WBF-to-SBF or SBF-to-WBF conversions over the projected interval of SBF use.

The volumes of discharged WBF and associated cuttings were estimated on a per well basis from data contained in the Offshore Development Document (EPA–821–R–93–003) for Gulf of Mexico, California, and Cook Inlet, AK wells. A weighted average discharge volume for each region, based on volumes projected for shallow wells and deep wells and the projected number of wells for each, was derived to estimate the volume of fluids and cuttings discharged onsite, per well, from WBF operations. (Note: In the Offshore Development Document "shallow" and "deep" refer to well depth, and are not the same as "shallow" water and "deep" water wells which refer to water depth in this final rule.) The volume of adhering WBF on discharged cuttings, as contained in the Offshore Development Document, was estimated at 5% of the total cuttings volume. The costs for these discharged WBFs were then calculated from a per barrel estimate of average WBF cost. These per well costs were then applied to the well count data in this final rule to derive aggregate regional and total costs. Also, to assess lost fluid costs over the projected SBF drilling interval, for the zero discharge option, the average discharge volumes per well were recalculated as average discharge volumes per day, based on the assumed number of days (*i.e.*, 20 days) used in the Offshore Development Document for drilling WBF wells.

The projected incidences of WBF with mineral oil spots, mineral oil lubrication, or both mineral oil spot and lubrication were based on the Offshore Development Document estimates of the percentages of projected wells in each region, projected shallow water versus deep water wells, and the projected incidence of spotting and lubrication. These percentages were then applied to current well count data for this final rule. EPA used the Offshore Development Document rates of failure (*i.e.*, exceeding permit toxicity limitations) to project the current number of wells that would require onsite injection or onshore disposal of mineral oil-amended WBF, and their disposal volumes were calculated from per well volume estimates for WBF wells.

The effect of WBF-to-SBF conversion (anticipated under the discharge options) and SBF-to-WBF conversion (anticipated under the zero discharge option) were derived from the estimated duration (in days) of the SBF-drilled interval. The projected number of drilling days was increased by a factor of 2 for each WBF model well to derive the projected number of drilling days that would be required if WBFs were used in place of SBFs. The incremental drilling time was used to estimate compliance costs (*e.g.*, increased rig costs) associated with SBF-to-WBF conversions.

2. Equipment Installation and Downtime

In the April 2000 NODA, EPA estimated that each SBF well incurred cuttings dryer installation and downtime costs. EPA revised the number of SBF wells drilled per cuttings dryer equipment installation per year based on industry-supplied ROC data (*see* Section III.B.1). EPA concluded that operators are drilling multiple wells per year with the same cuttings dryer equipment installation. Consequently, EPA reduced the number of cuttings dryer equipment installations required to drill the annual number of SBF wells. For development wells, the average number of SBF wells drilled per cuttings dryer equipment installation per year is 2.2. For exploration wells, the average number of SBF wells drilled per cuttings dryer equipment installation per year is 1.6. EPA incorporated these factors into the compliance costs estimates and these factors reduced the overall cuttings dryer equipment installation and downtime costs for the industry.

3. Proportion of Hauled Versus Injected Wastes

EPA estimated in the April 2000 NODA that 80% of drilling operations in the GOM, Offshore California, and Cook Inlet, Alaska, haul waste onshore with the remaining 20% re-injecting these wastes onsite. EPA used these proportions to weight the average cost of complying with zero discharge (*i.e.*, BAT/NSPS Option 3). EPA revised these proportions based on additional information received in response to the April 2000 NODA (*see* Section IV.E below) and updated the compliance cost and NWQI models.

4. OBF and WBF Conversion to SBF

EPA revised its compliance cost model to incorporate the effect of operators switching from one type of drilling fluid to another under each of the three SBF-cuttings technology options (*see* Section III.A.4). Generally, as compared with WBF and OBFs, SBFs led to a reduction in days required to drill a model well which leads to a decrease in drilling costs. Additionally, EPA revised the development drilling footage estimate due to additional information on the improved directional drilling capabilities of SBF over WBF.

C. Economic Impacts Analyses

In response to the April 2000 NODA, EPA identified that two projects used for economic modeling have shut in. Consequently, EPA removed these two projects from the economic analysis. A total of 18 projects remain for the economic modeling of existing projects and 13 remain for the economic modeling of new projects.

EPA added an environmental justice (EJ) analysis which investigates the potential for impacts on minorities and socioeconomically disadvantaged groups under the zero discharge option. EPA performed a Tier 1 screening analysis, which combines geographic location and U.S. Census Bureau data to determine the number of persons living within 1 mile and 50 miles of drilling waste handling and disposal sites, their race, and their socioeconomic status. A computer program developed by EPA Region 6 was used to rank and characterize sites on the basis of whether the populations near the site contain higher proportions of minority and socioeconomically disadvantaged persons than the state as a whole. Based on scores derived for the 13 GOM onshore drilling waste handling and disposal sites, EPA identified five facilities that could be potentially associated with disproportionate impacts on minorities or socioeconomically disadvantaged groups. EPA presents the results of the EJ analysis in Section IX.

D. Water Quality Impact and Human Health Analyses

EPA received comments regarding the heavy metal leach factors used in the water quality impact analyses but did not receive any specific data that could be used in the analyses (Docket No. W–98–26, Record No. IV.A.a.2). EPA therefore did not change these factors. However, EPA reevaluated the modeling used in the proposal that metals for which there were no factors found in the literature were completely insoluble in the receiving water (*i.e.*, the leach factor would be zero). EPA estimated that these heavy metals would not be less soluble than iron which has the lowest leach percentage factor. Thus, the iron leach factor was transferred to the following metals for which a zero leach factor was previously used: aluminum, antimony, beryllium, selenium, silver, thallium, tin, and titanium.

E. Non-Water Quality Environmental Impact Analyses

As mentioned in Section III.E, EPA received additional information regarding waste disposal practices in each of the three geographic areas (*e.g.*, GOM, Offshore California, Cook Inlet, Alaska). As a result of this information, EPA revised the modeling for the fraction of waste either injected at the drill site, injected on-shore or land disposed (*see* SBF Development Document). Though the percentage of waste injected onsite versus hauled to shore (20% vs. 80%) in the GOM remains unchanged, the method of onshore disposal has been revised for the final rule. In the GOM, 80% of the waste hauled to shore is injected onshore and only 20% is landfarmed.

EPA estimates that all SBF wastes from Californian deep water exploratory wells are sent onshore (*i.e.*, 100% onshore disposal vs. 0% on-site injection). For all other wells (*i.e.*, shallow water development and exploratory and deep water development), EPA estimates that most of the offshore waste is disposed through offshore on-site cuttings re-injection (*i.e.*, 20% onshore disposal vs. 80% on-site injection) based on the fact that most of these wells are being drilled from fixed facilities. EPA estimates that most California offshore wastes sent onshore are disposed via onshore formation injection (*i.e.*, 20% of offshore wastes sent onshore disposed via landfarming vs. 80% of offshore wastes sent onshore disposed via onshore injection) based on the number of California land disposal operations.

At proposal, based on the record for the 1996 Coastal rule, EPA determined that onsite injection was not feasible throughout Cook Inlet, Alaska (*see* Coastal Development Document, EPA–821–R–96–023, Section 5.10.3). More recently, however, EPA identified in the April 2000 NODA (65 FR 21558) that the SBF rule record now demonstrates that many Cook Inlet operators in Coastal waters are using cuttings re-injection (*see* Docket No. W–98–26: Record No. III.B.a.11, Record No. III.B.a.23, Record No. III.B.a.53). EPA contacted Cook Inlet operators (*e.g.*, Phillips, Unocal, Marathon Oil) and the State regulatory agency, Alaska Oil and Gas Conservation Commission (AOGCC), for more information on the most recent re-injection practices of Coastal and Offshore Cook Inlet operators (65 FR 21558). AOGCC regulations provide Cook Inlet operators the opportunity to permit and operate Class II disposal wells and annular disposal activities. Information provided to EPA indicate that Cook Inlet operators in Coastal waters are availing themselves of on-site cuttings injection and are receiving AOGCC permits for this activity. Generally, Cook Inlet operators in Coastal waters agree that on-site injection is available for most operations.

AOGCC also agreed that there should be enough formation re-injection disposal capacity for the small number of wells (< 5–10 wells per year) being drilled in Cook Inlet Coastal waters. AOGCC stated, however, that case-specific limitations should be considered when evaluating disposal options. For instance, Unocal has experienced difficulty establishing formation injection in several wells that were initially considered for annular disposal. In addition, Cook Inlet operators have the burden of proving to AOGCC's satisfaction that the waste will be confined to the formation disposal interval. Approval of annular disposal includes a review of cementing and leak-off test records. In some instances the operator may also have to run a cement bond log. When an older well is converted for use as a disposal well, some of this information may not exist. In cases where there is insufficient information, disposal is not allowed. Annular disposal is also limited to the facility on which the waste is generated. Although Class II disposal regulations don't restrict waste transport, it has generally been the practice of the various fields' owners not to accept any waste generated by other operators. In addition, AOGCC stated that a zero discharge requirement poses serious technical hurdles with respect to the handling of drilling waste for exploration drilling with mobile rigs. Normally, there is neither capacity for storage or room for processing equipment on exploratory drilling rigs. Therefore, to be conservative for the NWQI analysis, EPA estimates that all of the cuttings from the Coastal Cook Inlet operations (*i.e.*, shallow water wells) are re-injected (*i.e.*, 0% onshore disposal vs. 100% on-site injection) based on the ability of industry to dispose of oil-based cuttings via on-site formation injection after gaining State regulatory approval.

In order to assess the SBF NWQIs relative to the total impacts from drilling operations, EPA included estimates of the daily drilling rig impacts to the NWQIs from SBF-related activities. The additional impacts consist of fuel use and air emissions resulting from the various drilling rig pumps and motors as well as impacts of a daily helicopter trip for transporting personnel and/or supplies. Impacts were assessed for the number of days that an SBF interval is drilled versus the number of days well intervals are drilled using WBFs and OBFs and for the number of wells drilled using each of the drilling fluids.

F. Numerical Limits for Retention of SBF Base Fluid on SBF-Cuttings

A series of potential numerical limits for retention of SBF base fluid on SBF-cuttings were developed based in part on combinations of data selection criteria suggested in comments on the April 2000 NODA. These data selection criteria include: (1) Existing record of retention calculations (*i.e.*, "back-up" retort sheet information for quality assurance/quality control purposes); and (2) foreign or domestic location of well drilling activity (*e.g.*, North Sea, Canada). Numerical limits promulgated in today's final rule were based on data with existing records of retention calculations, and they included data from well drilling activities in foreign countries. The inclusion of data from foreign countries is intended to include data representing drilling with cuttings dryers at a wider range of geological formations than just the ones for which data was received from current operations.

V. Development and Selection of Effluent Limitations Guidelines and Standards

A. Waste Generation and Characterization

Drill cuttings are produced continuously at the bottom of the hole at a rate dependent on a variety of factors including: (1) The advancement of the drill bit; (2) the size and design of drill bit used (*e.g.*, polycrystalline diamond compact (PDC)); and (3) the drilling fluid type used. Drill cuttings are carried to the surface by the drilling fluid, where the cuttings are separated from the drilling fluid by the solids control system. The drilling fluid is then

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sent back to the active mud system (*e.g.*, mud pumps, down hole, trip tanks, etc.), provided it still has characteristics to meet technical requirements. Drilling fluids cool and lubricate the drill bit, stabilize the walls of the borehole, transport cuttings, and maintain equilibrium between the borehole and the formation pressures. Various sizes of drill cuttings are separated by the solids separations equipment, and it is necessary to remove the fines (*i.e.*, small sized cuttings or "low gravity solids") as well as the large cuttings from the drilling fluid to maintain the required rheological properties.

Increased recovery from the cuttings is more problematic for WBF than for SBF because the WBF water-wets the cuttings which encourages the cuttings to disperse and spoil the drilling fluid properties. Therefore, compared to WBF, more aggressive methods of recovering SBF from the cuttings wastestream are practical.

SBFs, used or unused, are a valuable commodity and not a waste. It is industry practice to continuously reuse the SBF while drilling a well interval, and at the end of the well, to ship the remaining SBF back to shore for refurbishment and reuse. One of the main incentives for operators to attempt to recover as much SBF as possible during drilling is the relatively high unit cost of SBF, approximately $160 to $300 per barrel, as compared to OBFs ($70 to 90 per barrel) and WBFs ($45 per barrel) (Docket No. W–98–26, Record No. IV.B.a.13). Operators involved in the first 1998 GOM field demonstrations of cuttings dryers (*i.e.*, advanced solids control technology) were attempting to obtain further reductions in drilling costs, beyond that obtained by shortening the overall drilling time for the well, by recovering more SBF. SBFs are relatively easy to separate from the drill cuttings because the drill cuttings do not disperse or hydrate in the drilling fluid to the same extent as compared to WBFs. Reducing cuttings hydration is particularly important in certain formations (*e.g.*, shale formations in GOM). With WBF, due to dispersion of the drill cuttings, drilling fluid components often need to be added to maintain the required drilling fluid properties. These additions are often in excess of what the drilling system can accommodate. The excess "dilution volume" of WBF is a resultant waste. This dilution volume waste does not occur with SBF. For these reasons, SBF is only discharged as a contaminant of the drill cuttings wastestream. It is not discharged on purpose as neat drilling fluid (*i.e.*, drilling fluid not associated with cuttings).

Current practice is that the top well section is normally drilled with a WBF. As the well becomes deeper, the performance requirements of the drilling fluid increase, and the operator may, at some point, decide that the drilling fluid system should be changed to either a traditional OBF, based on diesel oil or mineral oil, or an SBF. The system, including the drill string and the solids separation equipment, must be changed entirely from the WBF to the SBF (or OBF) system, and the two do not function as a blended system. The entire system is either: (1) A water dispersible (aqueous) drilling fluid such as a WBF; or (2) an oleaginous drilling fluid such as OBFs, enhanced mineral oil based drilling fluids, or SBFs. The decision to change the system from a WBF water dispersible system to an oleaginous drilling fluid depends on many factors including:

I. The operational considerations (*e.g.*, rig type, risk of riser disconnects, rig equipment, and distance from support facilities);

II. The relative drilling performance of one type fluid compared to another (*e.g.*, rate of penetration, well angle, hole size/casing program options, compatible drilling bit, and horizontal deviation);

III. The presence of geologic conditions that favor a particular fluid type or performance characteristic (*e.g.*, formation stability/sensitivity, formation pore pressure vs. fracture gradient, and potential for gas hydrate formation);

IV. Drilling fluid cost (*i.e.*, base cost plus daily operating cost);

V. drilling operation cost (*i.e.*, rig cost plus logistic and operation support); and

VI. Drilling waste disposal cost.

Industry has commented that while the right combination of factors that favor the use of SBF can occur in any area, they most frequently occur with "deep water" operations (*i.e.*, greater than or equal to 1,000 feet of water). This is due to the fact that these operations are higher cost and can therefore better justify the higher initial cost of SBF use. Industry has also commented that SBF may be increasingly used in shallow water wells due to the ability of SBF to increase average rates of penetration and shorten average times to complete drilling operations (Docket No. W–98–26, Record No. IV.A.a.3).

The volume of cuttings generated while drilling the SBF or OBF intervals of a well depends on the type of well (development or production) and the water depth (shallow or deep). EPA developed OBF and SBF model well characteristics from information provided by the American Petroleum Institute (API). API provided well size date for four types of wells currently drilling the GOM: development and exploratory wells in both deep water (*i.e.*, greater than or equal to 1,000 feet of water) and shallow water (*i.e.*, less than 1,000 feet of water). These model wells are referred to as: (1) Shallow-water development (SWD); (2) shallow-water exploratory (SWE); (3) deep-water development (DWD); and (4) deep-water exploratory (DWE). For the four model wells, EPA determined that the volumes of cuttings generated by these SBF or OBF well intervals are (in barrels): 565 for SWD; 1,184 for SWE; 855 for DWD; and 1,901 for DWE. These volumes represent only the rock, sand, and other formation solids drilled from the hole, and do not include drilling fluid that adheres to these formation cuttings. These values also include the additional formation cuttings volume of 7.5% washout. Washout is caving in or sloughing off of the well bore. Washout, therefore, increases hole volume and increases the amount of cuttings generated when drilling a well. The washout percentage EPA used in its analyses (*i.e.*, 7.5%) is based on the rule of thumb reported by industry representatives of 5 to 10% washout when drilling with SBF or OBF.

Drilling fluid returning from the well is laden with drill cuttings. The drill cuttings range in size from large particles which are on the order of a centimeter or more in size to small particles (*i.e.*, fines or "low gravity solids") which are fractions of a millimeter in size. Standard or current practice solids control systems employ primary and secondary shale shakers in series with a "fines removal unit" (*e.g.*, decanting centrifuge or mud cleaner). The drilling fluid and drill cuttings from the well are first passed through primary shale shakers. These shakers remove the largest cuttings which are approximately 1 to 5 millimeters in size. The drilling fluid recovered from the primary shakers is then passed over secondary shale shakers to remove smaller drill cuttings. Finally, a portion or all of the drilling fluid recovered from the primary and secondary shakers may be passed through the fines removal unit to remove fines from the drilling fluid. It is important to remove fines from the drilling fluid in order to maintain the desired rheological properties of the active drilling fluid system (*e.g.*, viscosity, density). Thus, the cuttings wastestream normally consists of discharged cuttings from the primary and secondary shale shakers and fines from the fines removal unit.

Operators using improved solids control technology process the cuttings discarded from the primary and secondary shale shakers through a "cuttings dryer" (*e.g.*, vertical or horizontal centrifuge, squeeze press mud recovery unit, High-G linear shaker). The cuttings from the cuttings dryer are discharged and the recovered SBF is sent to the fines removal unit. The advantage of the cuttings dryer is that more SBF is recovered for re-use and less SBF is discharged into the ocean. This, consequently, will reduce the pollutant loadings to the ocean and the potential of the waste to cause anoxia (lack of oxygen) in the receiving sediment.

As discussed in the April 2000 NODA (65 FR 21569), solids control equipment generally breaks larger particles into smaller particles. An undesirable increase in drilling fluid weight and viscosity can occur when drill solids degrade into fines and ultra-fines. Ultra-fines are generally classified as being less than 5 microns (10^{-6} meters) in length and solids control equipment generally cannot remove these ultra-fines. An unacceptable high fines content (*i.e.*, generally > 5% of total drilling fluid weight) may consequently lead to drilling problems (*e.g.*, undesirable rheological properties, stuck pipe). Therefore, it is possible that the increased recovery of SBF from cuttings for re-use in the active mud system, often achieved through use of the cuttings dryer in solids control systems, may lead to a build-up in fines for certain formation characteristics (*e.g.*, high reactivity of formation cuttings, limited loss of drilling fluid into the formation). In the April 2000 NODA, EPA solicited comments regarding whether EPA's proposed numeric cuttings retention value might cause operators (where there are unfavorable formation characteristics) to: (1) Dilute the fines in the active mud system through the addition of "fresh" SBF; and/or (2) capture a portion of the fines in a container and send the fines to shore for disposal.

Comments from API/NOIA identified only one instance in which the use of a cuttings dryer in combination with a fines removal unit in the United States may have lead to an increase in "fines build-up" and a loss of circulation event (Docket No. W–98–26, Record No. IV.A.a.13). Further communication with additional industry stakeholders identified that this well (Shell, Green Canyon 69, OCS–G–13159#3) was the first application of the cuttings dryer type (horizontal centrifuge cuttings dryer) in the GOM and inexperience with this type of technology may have contributed to the build-up of fines causing well problems. However, other commentors stated that fines build-up was not an issue for the well in question (Docket No. W–98–26, Record No. IV.A.b.1). Moreover, further industry comments revealed that the properties of formations are often the main culprit of loss circulation and that the same rig (Marianas) had a loss of circulation at another nearby well in the same formation when a cuttings dryer was not being used (Docket No. W–98–26, Record No. IV.A.b.1). Therefore, based on the record, which includes over three dozen successful cuttings dryer deployments, EPA concludes that fines build up is not an issue of concern when operators properly operate and maintain cuttings dryers and fines removal equipment.

Drill cuttings are typically discharged continuously as they are separated from the drilling fluid in the solids separation equipment. The drill cuttings will also carry a residual amount of adhered drilling fluid. Therefore, the two parameters that make up the bulk of the pollutant loadings are TSS and what is measured by the API Retort Method (Appendix 7) as Total Oil. TSS is comprised of two components: the drill cuttings themselves and the solids in the adhered drilling fluid. The drill cuttings are primarily small bits of stone, clay, shale, and sand. The source of the solids in the drilling fluid is primarily the barite weighting agent, and clays (*e.g.*, amine clays) which are added for filtration control and to modify the rheological properties. Benthic smothering and/or sediment grain size alteration resulting in potential damage to invertebrate populations and alterations in benthic community structure is a concern with uncontrolled SBF drilling discharges due to the quantity and characteristics of associated TSS discharges. In general, large cuttings particles with a high percentage of adhering SBF (*e.g.*, >12% (wt. SBF)/(wt. wet cuttings)) tend to conglomerate and quickly settle out to the benthic environment quickly near the well site.

Additionally, environmental impacts can be caused by toxic, conventional, and non-conventional pollutants adhering to the solids. The adhered SBF drilling fluid is mainly composed, on a volumetric basis, of the synthetic material (*i.e.*, "base fluid"). Formation oil can also contaminate SBF-cuttings and contribute priority, conventional, and non-conventional pollutants. The oleaginous material (*i.e.*, SBF base fluid and formation oil) may be toxic and it may contain priority pollutants such as polynuclear aromatic hydrocarbons (PAHs). Depending on bottom currents, temperature, and rate of biodegradation this oleaginous material may cause hypoxia (*i.e.*, reduction in dissolved oxygen concentrations) or anoxia (*i.e.*, absence of dissolved oxygen) in the immediate sediment. Oleaginous materials which biodegrade quickly will reduce dissolved oxygen concentrations more rapidly than more slowly degrading oleaginous materials. EPA, however, thinks that fast biodegradation is environmentally preferable to slower biodegradation despite the increased risk of temporary hypoxia which accompanies fast biodegradation. EPA's position is supported by published seabed surveys which show that benthic re-colonization by infaunal individuals after the discharge of SBF-cuttings or OBF-cuttings can be correlated with the disappearance of the base fluid in the sediment. Large persistent cuttings piles may provide a source of environmental contamination for many years (Docket No. W–98–26, Record No. IV.F.2). Moreover, benthic re-colonization rates do not seem to be correlated with the severity of any hypoxic or anoxic effects that may result while the SBF base fluid is degrading or dispersing. Numerous studies show that SBF base fluids that biodegrade faster lead to a more rapid recovery of the pre-discharge benthic community.

As a component of the drilling fluid, the barite weighting agent is also discharged as a contaminant of the drill cuttings. Barite is a mineral principally composed of barium sulfate ($BaSO_4$), and it is known to generally have trace contaminants of several toxic heavy metals such as mercury, cadmium, arsenic, chromium, copper, lead, nickel, and zinc. SBF also contain non-conventional pollutants found in other drilling fluid components (*e.g.*, emulsifiers, oil wetting agents, filtration control agents, and viscosifiers).

As previously stated in the April 2000 NODA (65 FR 21560), EPA learned that SBF is controlled with zero discharge practices at the drill floor, in the form of vacuums and sumps to retrieve spilled fluid. EPA also learned that approximately 75 barrels of fine solids and barite, which have an approximate SBF content of 25%, can accumulate in the dead spaces of the mud pit, sand trap, and other equipment in the drilling fluid circulation system. Current practice is to either wash these solids out with water for overboard discharge, or to retain the waste solids for disposal. Several hundred barrels (approximately 200 to 400 barrels) of water are used to wash out the mud pits. Industry representatives also indicated to EPA that those oil and gas extraction

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operations that discharge wash water and accumulated solids first recover free SBF.

B. Selection of Pollutant Parameters

1. Stock Limitations and Standards for Base Fluids

a. *General.* In the final rule, where SBF-cuttings may be discharged, except for Cook Inlet, Alaska, EPA is establishing BAT limitations and NSPS that require the synthetic materials which form the base fluid of the SBFs to meet limitations and standards on PAH content, sediment toxicity, and biodegradation. If these stock limitations are not met the technology basis for meeting these limitations and standards is: (1) Product substitution; or (2) zero discharge based on land disposal or cuttings re-injection. The regulated toxic, conventional, and non-conventional pollutant parameters are identified below. A large range of synthetic, oleaginous, and water miscible materials are available for use as base fluids. These stock limitations on the base fluid are intended to encourage product substitution reflecting best available technology and best available demonstrated technology wherein only those synthetic materials and other base fluids which minimize potential loadings and toxicity may be discharged. Additionally, EPA is retaining BPT and BCT requirements for SBFs and SBF-cuttings as no discharge of free oil as determined by the static sheen text (Appendix 1 of subpart A of 40 CFR Part 435).

As stated below in Section V.F, EPA is today promulgating BPT, BCT, BAT, and NSPS for SBFs and SBF-cuttings for Coastal Cook Inlet, Alaska as zero discharge except when Coastal Cook Inlet, Alaska, operators are unable to dispose of their SBF-cuttings using any of the following disposal options: (1) On-site re-injection (annular disposal or Class II UIC); (2) re-injection using a nearby Coastal or Offshore Class II UIC disposal well; or (3) onshore disposal using a nearby Class II UIC disposal well or land application. If an operator is able to make these showings, then the operator would be subject to the same requirements for SBF-cuttings that apply elsewhere. The regulated toxic, conventional, and non-conventional pollutant parameters are identified below.

b. *PAH Content.* EPA is regulating the PAH content of base fluids because PAHs are comprised of toxic priority pollutants. SBF base fluids typically do not contain PAHs, whereas the traditional OBF base fluids of diesel and mineral oil typically contain 5 to 10% PAH and 0.35% PAH respectively. The PAHs typically found in diesel and mineral oil include: (1) the toxic priority pollutants fluorene, naphthalene, phenanthrene, and others; and (2) non-conventional pollutants such as alkylated benzenes and biphenyls. Therefore, the PAH BAT limitation and NSPS are components of this final regulation to help discriminate between acceptable and non-acceptable base fluids.

c. *Sediment Toxicity.* EPA is also regulating the sediment toxicity in base fluids as a non-conventional pollutant parameter and as an indicator for toxic pollutants and non-conventional pollutants in base fluids (*e.g.*, enhanced mineral oils, internal olefins, linear alpha olefins, poly alpha olefins, paraffinic oils, C_{12}–C_{14} vegetable esters of 2-hexanol and palm kernel oil, "low viscosity" C_8 esters, and other oleaginous materials). It has been shown, during EPA's development of the Offshore Guidelines, that establishing limits on toxicity encourages the use of less toxic drilling fluids and additives. Many of the SBF base fluids have been shown to have lower toxicity than OBF base fluids, but among SBFs some are more toxic than others. Today's final discharge option (*i.e.*, BAT/NSPS Option 2) includes a base fluid sediment toxicity stock limitation, as measured by the 10-day sediment toxicity test (ASTM E1367–92) using a natural sediment or formulated sediment and *Leptocheirus plumulosus* as the test organism.

d. *Biodegradation.* EPA is also regulating the biodegradation in base fluids as an indicator of the extent, in level and duration, of the toxic effect of toxic pollutants and non-conventional pollutants present in the base fluids (*e.g.*, enhanced mineral oils, internal olefins, linear alpha olefins, poly alpha olefins, paraffinic oils, C_{12}–C_{14} vegetable esters of 2-hexanol and palm kernel oil, "low viscosity" C_8 esters, and other oleaginous materials). Based on results from seabed surveys at sites where various base fluids have been discharged with drill cuttings, EPA believes that the results from the three biodegradation tests used during the rulemaking (*i.e.*, solid phase test, anaerobic closed bottle biodegradation test, respirometry biodegradation test) are indicative of the relative rates of biodegradation in the marine environment. In addition, EPA thinks the biodegradation parameter correlates strongly with the rate of recovery of the seabed where OBF- and SBF-cuttings have been discharged. The various base fluids vary widely in biodegradation rates, as measured by the three biodegradation methods. However, the relative ranking of the base fluids remain relatively similar across all three biodegradation tests.

As originally proposed in February 1999 (64 FR 5504) and re-stated in the April 2000 NODA (65 FR 21550), EPA is today promulgating a BAT limitation and NSPS to control the minimum amount of biodegradation of base fluid. Today's final discharge option (*i.e.*, BAT/NSPS Option 2) includes a base fluid biodegradation stock limitation, as measured by the marine anaerobic closed bottle biodegradation test (*i.e.*, ISO 11734).

e. *Bioaccumulation.* EPA also considered establishing a BAT limitation and NSPS that would limit the base fluid bioaccumulation potential. The regulated parameters would be the non-conventional and toxic priority pollutants that bioaccumulate. EPA reviewed the current literature to identify the bioaccumulation potential of various base fluids. EPA determined that SBFs are not expected to significantly bioaccumulate because of their extremely low water solubility and consequent low bioavailability. Their propensity to biodegrade makes them further unlikely to significantly bioaccumulate in marine organisms.

EPA identified that hydrophobic chemicals (*e.g.*, ester base fluids) that have a log K_{ow} less than about 3 to 3.5 may bioaccumulate rapidly but not to high concentrations in tissues of marine organisms, particularly if they are readily biodegradable into non-toxic metabolites (Docket No. W–98–26, Record No. IV.F.1). (**Note:** The octanol/water partition coefficient (K_{ow}) is used as a surrogate for estimating lipid/water partitioning). Moreover, hydrophobic chemicals (*e.g.*, C_{16}–C_{18} internal olefins, various poly alpha olefins, and C_{18} n-paraffins) with a log K_{ow} greater than about 6.5 to 7 do not bioaccumulate effectively from the water, because their solubility in both the water and lipid phases is very low (Docket No. W–98–26, Record No. IV.F.1). Finally, the degradation by-products of SBF base fluids (*e.g.*, alcohols) are likely to be more polar (*i.e.*, more miscible with water) than the parent substances. The higher water solubility will result in these degradation by-products partitioning into the water column and being diluted to toxicologically insignificant concentrations.

2. Discharge Limitations

a. *Free Oil.* Under BPT and BCT limitations for SBF-cuttings, EPA retains the prohibition on the discharge of free oil as determined by the static sheen test (*see* Appendix 1 of subpart A of 40 CFR part 435). Under this prohibition, drill cuttings may not be discharged when the associated drilling fluid would fail the static sheen test. The prohibition on the discharge of free oil is intended to minimize the formation of sheens on the surface of the receiving water. The regulated parameter of the no free oil limitation would be the conventional pollutant oil and grease which separates from the SBF and causes a sheen on the surface of the receiving water.

The free oil discharge prohibition does not control the discharge of oil and grease and crude oil contamination in SBFs as it would in WBFs. With WBFs, oils which may be present (*e.g.*, diesel oil, mineral oil, formation oil, or other oleaginous materials) are present as the discontinuous phase. As such these oils are free to rise to the surface of the receiving water where they may appear as a film or sheen upon or discoloration of the surface. By contrast, the oleaginous matrices of SBFs do not disperse in water. In addition they are weighted with barite, which causes them to sink as a mass without releasing either the oleaginous materials which comprise the SBF or any contaminant formation oil. Thus, the test would not identify these pollutants. However, a portion of the SBF may rise to the surface to cause a sheen. The components that rise to the surface fall under the general category of oil and grease and are considered conventional pollutants. Therefore, the purpose of the no free oil limitation of today's final regulation is to control the discharge of conventional pollutants which separate from the SBF and cause a sheen on the surface of the receiving water. The limitation is not intended to control formation oil contamination nor the total quantity of conventional pollutants discharged.

b. *Formation Oil Contamination.* As originally proposed in February 1999 (64 FR 5505) and re-stated in the April 2000 NODA (65 FR 21552), EPA is today promulgating a BAT limitation and NSPS of zero discharge to control formation oil contamination on SBF-cuttings. EPA is also today promulgating a screening method (Reverse Phase Extraction (RPE) method presented in Appendix 6 to subpart A of part 435) and a compliance assurance method (Gas Chromatograph/Mass Spectrometer (GC/MS) method presented in Appendix 5 to subpart A of part 435).

Formation oil is an "indicator" pollutant for the many toxic and priority pollutant pollutants present in formation (crude) oil (*e.g.*, aromatic and polynuclear aromatic hydrocarbons). These pollutants include benzene, toluene, ethylbenzene, naphthalene, phenanthrene, and phenol. EPA is requiring that formation oil contamination be measured at two points. First, EPA is requiring that operators verify and document that a SBF is free of formation oil contamination before initial use of the SBF through use of the GC/MS compliance assurance method (Appendix 5 to subpart A of 40 CFR part 435). Second, EPA is requiring that operators use the RPE method (Appendix 6 to subpart A of 40 CFR part 435) for the SBF recovered by the solids control equipment to detect formation oil contamination. The RPE method is a fluorescence test and is appropriately "weighted" to better detect crude oils. These crude oils contain more toxic aromatic and PAH pollutants and show brighter fluorescence (*i.e.*, noncompliance) in the RPE method at lower levels of crude oil contamination. Since the RPE method is a relative brightness test, operators may also use the GC/MS compliance assurance method when the results from the RPE method are in doubt by either the operator or the enforcement authority. Results from the GC/MS compliance assurance method will supersede those of the RPE method.

c. *Retention of Drilling Fluid on Cuttings.* EPA is today promulgating a BAT limitation and NSPS to control the retention of drilling fluid on drill cuttings. The BAT limitation and NSPS are presented as the percentage of base fluid on wet cuttings (*i.e.*, mass base fluid (g)/mass wet cuttings (g)), averaged over the entire well sections drilled with SBF. The limitation and standard controls the quantity of drilling fluid discharged with the drill cuttings. Both toxic pollutants and non-conventional pollutants would be controlled by this limitation. Several pollutants are present in the barite weighting agent, including the toxic metal pollutants arsenic, chromium, copper, lead, mercury, nickel, and zinc, and the non-conventional metal pollutants aluminum and tin. A complete SBF formulation also includes non-conventional pollutants found in the SBF base fluids (*e.g.*, enhanced mineral oils, internal olefins, linear alpha olefins, poly alpha olefins, paraffinic oils, C_{12}–C_{14} vegetable esters of 2-hexanol and palm kernel oil, "low viscosity" C_8 esters, and other oleaginous materials) and in other drilling fluid components (*e.g.*, emulsifiers, oil wetting agents, filtration control agents, and viscosifiers). These pollutants would not be controlled by the sediment toxicity stock limitations. In response to the February 1999 proposal (64 FR 5501), EPA received comments that these non-conventional pollutants include fatty acids (Docket No. W–98–26, Record No. III.A.a.7). EPA also received further information that the non-conventional pollutants in these drilling fluid components include amine clays, amine lignites, and dimer/trimer fatty acids (Docket No. W–98–26, Record No. III.B.b.1).

This limitation would also control the toxic effect of the drilling fluid and the persistence or biodegradation of the base fluid. Specifically, as stated in the April 2000 NODA (65 FR 21553), lowering the percentage of residual drilling fluid retained on cuttings increases the recovery rate of the seabed receiving the cuttings (Docket No. W–98–26, Record No. I.D.b.30 and 31; Record No. III.B.a.15). Limiting the amount of SBF content in discharged cuttings controls: (1) The amount of toxic and non-conventional pollutants in SBF which are discharged to the ocean; (2) the biodegradation rate of discharged SBF; and (3) the potential for SBF-cuttings to develop cuttings piles and mats which are deleterious to the benthic environment.

As originally proposed in February 1999 (64 FR 5547) and re-stated in the April 2000 NODA (65 FR 21552), EPA is today promulgating a retort and sampling compliance method for the cuttings retention BAT limitation and NSPS (*see* Appendix 7 to subpart A of 40 CFR part 435; API Recommended Practice 13B–2).

d. *Sediment Toxicity.* EPA is also regulating the sediment toxicity in SBF discharged with cuttings as a non-conventional pollutant parameter and as an indicator for toxic pollutants in SBFs. As originally proposed in February 1999 (64 FR 5491) and re-stated in April 2000 (65 FR 21557), EPA is today promulgating a BAT limitation and NSPS to control the maximum sediment toxicity of the SBF discharged with cuttings at the point of discharge. The sediment toxicity of the SBF-cuttings at the point of discharge is measured by the modified sediment toxicity test (ASTM E1367–92) using a natural sediment or formulated sediment and *Leptocheirus plumulosus* as the test organism.

EPA finds that the sediment toxicity test at the point of discharge is practical as an indicator of the sediment toxicity of the drilling fluid at the point of discharge. The sediment toxicity test applied at the point of discharge will control non-conventional pollutants found in some drilling fluid components (*e.g.*, emulsifiers, oil wetting agents, filtration control agents,

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and viscosifiers) which are added to the base fluid in order to build a complete SBF package. Other possible toxic pollutants in drilling fluids may include mercury, cadmium, arsenic, chromium, copper, lead, nickel, and zinc, and formation oil contaminants. As previously stated, establishing discharge limits on toxicity encourages the use of less toxic drilling fluids and additives. The modifications to the 10-day sediment toxicity test include shortening the test to 96-hours. Shortening the test will allow operators to continue drilling operations while the sediment toxicity test is being conducted on the discharged drilling fluid. Moreover, discriminatory power is substantially reduced for the 10-day test on drilling fluid as compared to the 96-hour test (*i.e.*, the 10-day test is of lower practical use in determining whether a SBF is substantially different from OBFs). Finally, operators discharging WBFs are already complying with a biological test at the point of discharge, the 96-hour SPP toxicity test, which tests whole WBF aquatic toxicity using the test organism *Mysidopsis bahia*.

3. Maintenance of Current Requirements

Today's rule does not modify the existing BAT and NSPS limitations on the stock barite of 1 mg/kg mercury and 3 mg/kg cadmium. These limitations control the levels of toxic pollutant metals because cleaner barite that meets the mercury and cadmium limits is also likely to have reduced concentrations of other metals. Evaluation of the relationship between cadmium and mercury and the trace metals in barite shows a correlation between the concentration of mercury with the concentration of arsenic, chromium, copper, lead, molybdenum, sodium, tin, titanium and zinc (*see* Section VI, Offshore Development Document, EPA–821–R–93–003).

Today's rule does not modify the existing BAT and NSPS limitations prohibiting the discharge of drilling wastes containing diesel oil in any amount. Diesel oil is considered an "indicator" for the control of specific toxic pollutants. These pollutants include benzene, toluene, ethylbenzene, naphthalene, phenanthrene, and phenol. Diesel oil may contain from 3 to 10% by volume PAHs, which constitute the more toxic pollutants in petroleum products.

Today's rule does not modify the existing BAT limitation and NSPS for controlling the maximum aqueous phase toxicity of SBF-cuttings at point of discharge using the suspended particulate phase (SPP) test (*see* Appendix 2 of subpart A of Part 435). The BAT limitation and NSPS for controlling aqueous toxicity of discharged SBF-cuttings is retained as the minimum 96-hour LC_{50} of the SPP shall be 3% by volume. EPA is interested in controlling the toxicity of drilling fluids in the sediment and the water column and is requiring both a sediment toxicity test and an aqueous phase toxicity test to assess overall toxicity of the drilling fluid at the point of discharge. EPA finds that the SPP test at the point of discharge is practical as a measurement of the aquatic toxicity of the drilling fluid at the point of discharge. The discharge SPP test will control non-conventional pollutants found in drilling fluid components (*e.g.*, emulsifiers, oil wetting agents, filtration control agents, and viscosifiers) which are added to the base fluid in order to build a complete SBF package. Moreover, operators discharging WBFs are already complying with the SPP toxicity test on discharged WBFs.

C. Regulatory Options Considered and Selected for Drilling Fluid Not Associated With Drill Cuttings

In the February 1999 proposal, EPA proposed BPT, BCT, BAT, and NSPS as zero discharge for SBFs not associated with drill cuttings. In the April 2000 NODA, EPA published two options for the final rule for the BAT limitation and NSPS for controlling SBFs not associated with SBF drill cuttings: (1) Zero discharge; or (2) allowing operators to choose either zero discharge or an alternative set of BMPs with an accompanying compliance method. Industry supported the second option stating that the first option (zero discharge) would result in the costly and potentially dangerous collection, shipping, and disposal of large quantities of rig site wash water containing only a small quantity of SBF (Docket No. W–98–26, Record No. IV.A.a.13). Industry also stated that BMPs would be extremely effective at reducing the quantity of non-cuttings related SBF and would focus operators' attention on reducing these discharges.

EPA is today promulgating BPT, BCT, BAT, and NSPS of zero discharge for SBFs not associated with drill cuttings. This wastestream consists of neat SBFs that are intended for use in the downhole drilling operations (*e.g.*, drill bit lubrication and cooling, hole stability). This wastestream is transferred from supply boats to the drilling rig and can be released during these transfer operations. This wastestream is often spilled on the drill deck but contained through grated troughs, vacuums, or squeegee systems. This wastestream is also held in numerous tanks during all phases of the drilling operation (*e.g.*, trip tanks, storage tanks). EPA received information that rare occurrences of improper SBF transfer procedures (*e.g.*, no bunkering procedures in place for rig loading manifolds) and improper operation of active mud system equipment (*e.g.*, no lock-out, tag-out procedures in place for mud pit dump valves) has the potential for the discharge of tens to hundreds of barrels of neat SBF, or SBF not associated with cuttings, if containment is not practiced (Docket No. W–98–26, Record No. IV.A.a.26, QTECH LTD Reports for Ocean America and Discoverer 534).

Current practice for control of SBF not associated with drill cuttings is zero discharge (*e.g.*, drill deck containment, bunkering procedures), primarily due to the value of SBFs recovered and reused. Therefore, zero discharge for SBF not associated with drill cuttings is technologically available and economically achievable. Moreover, these controls generally allow the re-use of SBF in the drilling operation and has no unacceptable NWQIs.

EPA has also decided that solids accumulated at the end of the well ("accumulated solids") and wash water used to clean out accumulated solids or on the drill floor are associated with drill cuttings and are therefore not controlled by the zero discharge requirement for SBFs not associated with drill cuttings (*see* Section V.F.2.b).

D. BPT Technology Options Considered and Selected for Drilling Fluid Associated With Drill Cuttings

EPA is today promulgating BPT effluent limitations for the cuttings contaminated with SBFs ("SBF-cuttings"). The BPT effluent limitations promulgated today for SBF-cuttings would control free oil as a conventional pollutant. The BPT limitation is no free oil as measured by the static sheen test, performed on SBF separated from the cuttings in U.S. Offshore waters and Coastal Cook Inlet, Alaska.

In setting the no free oil limitation in U.S. Offshore waters and Coastal Cook Inlet, Alaska, EPA considered the sheen characteristics of currently available SBFs. Since this requirement is currently met by dischargers in the GOM, EPA anticipates no additional costs to the industry to comply with this limitation. Therefore, EPA believes that this limitation represents the appropriate level of control for SBFs associated with drill cuttings.

E. BCT Technology Options Considered and Selected for Drilling Fluid Associated With Drill Cuttings

In July 1986, EPA promulgated a methodology for establishing BCT effluent limitations. EPA evaluates the reasonableness of BCT candidate technologies—those that are technologically feasible—by applying a two part cost test: (1) A POTW test; and (2) an industry cost-effectiveness test.

EPA first calculates the cost per pound of conventional pollutant removed by industrial dischargers in upgrading from BPT to a BCT candidate technology and then compares this cost to the cost per pound of conventional pollutants removed in upgrading POTWs from secondary treatment. The upgrade cost to industry must be less than the POTW benchmark of $0.25 per pound (in 1976 dollars). In the industry cost-effectiveness test, the ratio of the incremental BPT to BCT cost divided by the BPT cost for the industry must be less than 1.29 (i.e., the cost increase must be less than 29%).

The BCT effluent limitations promulgated today would control free oil as a conventional pollutant. EPA is today promulgating a BCT effluent limitation for SBF-cuttings of no free oil equivalent to the BPT limitation for SBF-cuttings of no free oil as determined by the static sheen test in U.S. Offshore waters and Coastal Cook Inlet, Alaska.

In developing BCT limits for the U.S. Offshore waters and Coastal Cook Inlet, Alaska, EPA considered whether there are technologies (including drilling fluid formulations) that achieve greater removals of conventional pollutants than promulgated for BPT, and whether those technologies are cost-reasonable according to the BCT Cost Test. EPA identified no technologies that can achieve greater removals of conventional pollutants as compared with the U.S. Offshore waters and Coastal Cook Inlet BPT requirements that are also cost-reasonable under the BCT Cost Test. Accordingly EPA is today promulgating BCT effluent limitations for SBF-cuttings equal to the promulgated BPT effluent limitations for SBF-cuttings in U.S. Offshore waters and Coastal Cook Inlet, Alaska.

F. BAT Technology Options Considered and Selected for Drilling Fluid Associated With Drill Cuttings

EPA is promulgating stock limitations and discharge limitations in a two part approach to control SBF-cuttings discharges under BAT. The first part is based on product substitution through use of stock limitations (*e.g.*, sediment toxicity, biodegradation, PAH content, metals content) and discharge limitations (*e.g.*, diesel oil prohibition, formation oil prohibition, sediment toxicity, aqueous toxicity). The second part is the control of the quantity of SBF discharged with SBF-cuttings. As previously stated in the April 2000 NODA, EPA finds that the second part is particularly important because limiting the amount of SBF content in discharged cuttings controls: (1) The amount of SBF discharged to the ocean; (2) the biodegradation rate of discharged SBF; and (3) the potential for SBF-cuttings to develop cuttings piles and mats which are detrimental to the benthic environment.

EPA is also today retaining the existing BAT limitations on: (1) The stock barite of 1 mg/kg mercury and 3 mg/kg cadmium; (2) the maximum aqueous toxicity of discharged SBF-cuttings as the minimum 96-hour LC_{50} of the Suspended Particulate Phase toxicity test (SPP) shall be 3% by volume; and (3) prohibiting the discharge of drilling wastes containing diesel oil in any amount. These limitations control the levels of toxic metal and aromatic pollutants respectively. EPA at this time thinks that all of these components are essential for appropriate control of SBF-cuttings discharges.

The BAT effluent limitations promulgated today for SBF-cuttings would control a variety of toxic and non-conventional pollutants in the stock base fluids by controlling their PAH content, sediment toxicity, and biodegradation. The BAT effluent limitations promulgated today for SBF-cuttings would also control a variety of toxic and non-conventional pollutants at the point of discharge by controlling formation oil contamination, sediment toxicity, and the quantity of SBF discharged. The BAT stock and discharge limitations are described below.

The BAT level of control in the U.S. Offshore waters has been developed taking into consideration among other things: (1) The availability, cost, and environmental performance of SBF base fluids in terms of PAH content, sediment toxicity, and biodegradation rate; (2) the availability, cost, and environmental performance of SBFs retained on the cuttings discharge in terms of sediment toxicity and biodegradation rate; (3) the frequency of formation oil contamination at the various control levels for the discharges; (4) the availability, cost, and environmental performance of equipment and methods to recover SBF from the drill cuttings being discharged; and (5) the NWQIs of each option. By environmental performance, EPA means both a reduction in the quantity of pollutants discharged to the ocean and a reduction in their environmental effects in terms of sediment toxicity, aquatic toxicity, and biodegradation rate. Issues related to the technical availability and economic achievability of today's promulgated BAT limitations are discussed below by regulated parameter. The NWQIs of each selected option is discussed in Section VIII below. EPA also considered NWQIs in selecting the controlled discharge option for SBF-cuttings (*i.e.*, BAT/NSPS Option 2) (*see* Section VIII).

EPA and industry sediment toxicity and biodegradation laboratory studies show that both vegetable esters and low viscosity esters have better environmental performance than all other SBF base fluids. EPA, however, rejected the option of basing BAT sediment toxicity and biodegradation stock limitations and NSPS solely on vegetable esters and low viscosity esters because the record does not indicate that these fluids can be used in drilling situations throughout the offshore subcategory nor could EPA predict the conditions and circumstances where these fluids would be able to be used (*see* Section V.F.1.a). EPA is sufficiently satisfied, however, that both esters provide better environmental performance (*e.g.*, sediment toxicity, biodegradation). Consequently, EPA is promulgating an alternative higher retention on cuttings (ROC) BAT discharge limitation to encourage the use of esters. The higher ROC discharge limitation for SBFs complying with the stock limitations based on esters is derived from data representing four cuttings dryer technologies (*e.g.*, vertical centrifuge, horizontal centrifuge, squeeze press mud recovery unit, and High-G linear shaker). The lower ROC BAT discharge limitation for the SBFs complying with the C_{16}–C_{18} internal olefin stock limitations is based on data from the two top performing cuttings dryer technologies (*e.g.*, vertical centrifuge and horizontal centrifuge). EPA data demonstrates that operators properly using these cuttings dryer technologies (*e.g.*, vertical centrifuge, horizontal centrifuge, squeeze press, High-G linear shaker) will be able to comply with the final higher ROC numerical limitation for ester-based SBFs. EPA believes that this balancing of the importance of retention values with environmental performance as reflected by sediment toxicity and biodegradation rates is justified because of the greater ability of esters to

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biodegrade and of their lower sediment toxicity.

Therefore, EPA balanced the environmental performance of the base fluid (in terms of sediment toxicity and biodegradation) with the environmental performance of cuttings associated with drilling fluids (in terms of the retention on cuttings limit) to determine the appropriate best available technology. EPA determined that the improved toxicity and biodegradation of the ester based fluids justified increased flexibility in the ROC limitation as long as the limitation reflected the use of cuttings dryers technologies.

EPA, however, did not base the higher ROC BAT discharge limitation for esters on current shale shaker technology because this does not represent the best available technology (or best available demonstrated technology). EPA does not believe that the improved environmental performance of esters justifies the huge difference in pollutant loadings between existing shale shaker technology and newer cuttings dryer technology. Because the effluent limitations and standards promulgated in this rule account for variability, the effluent limitation and standards are higher than the long term average upon which the technology is based. Here, the LTA for the esters ROC limitation of 9.4% is 4.8%; while the LTA for the IOs ROC limitation of 6.9% is 3.82%. By contrast, the LTA for existing shale shaker technology is 10.2%. This difference translates to 118 million pounds per year of pollutants being discharged using the existing and new model well counts for the selected BAT option (*i.e.*, BAT/NSPS Option 2) (*see* SBF Development Document). Further, as previously stated in the April 2000 NODA (65 FR 21553), field results show that: (1) Cuttings are dispersed during transit to the seabed and no cuttings piles are formed when SBF concentrations on cuttings are held below 5%; and (2) cuttings discharged from cuttings dryers (with SBF retention values under 5%) in combination with a sea water flush, hydrate very quickly and disperse like water-based cuttings. Thus, while EPA is willing to provide additional flexibility to dischargers of ester-based fluids, EPA believes that the appropriate technology basis that reflects BAT is cuttings dryers technology.

EPA determined that zero discharge for BAT was technically feasible and economically achievable because prior to the use of SBFs, the industry was able to operate using only the traditional OBFs (based on diesel oil and mineral oil), which are prohibited from discharge. EPA concluded that a zero discharge BAT limitation for SBF-cuttings would decrease the use of SBFs in favor of OBFs and WBFs. This is because a zero discharge BAT limitation for SBF-cuttings would create an incentive for operators to use the least expensive drilling fluids (*i.e.*, OBFs, WBFs) in order to minimize overall compliance costs.

EPA rejected the BAT zero discharge option for SBF-cuttings wastes because it would result in unacceptable increases in NWQIs. Therefore, EPA rejected the zero discharge option for SBF-cuttings wastes in U.S. waters in the Offshore subcategory of 40 CFR part 435 ("U.S. Offshore waters"). As previously stated in Section II.B, use of OBFs in place of SBFs would lead to an increase in NWQIs including the toxicity of the drilling waste. Use of WBFs in place of SBFs would generally lead to a per well increase in pollutants discharged, an increase in NWQIs, and an increase in aquatic toxicity. WBF drilling operations lead to per well increases in pollutants discharged because WBFs generate six times more washout (*e.g.*, sloughing) of the well wall than SBFs. Also, WBF drilling operations lead to increases in NWQIs because WBF drilling operations generally take longer than SBF drilling operations which lead to more air emissions and fuel usage from drilling rigs and equipment. Aquatic toxicity generally increases when drilling fluid manufacturers add supplements (*e.g.*, glycols, shale inhibitors) to WBFs for the purpose of making WBFs have technical capabilities (*e.g.*, lubricity, shale suppression) similar to SBFs. EPA estimates that, under the zero discharge option, some operators would switch to WBF compositions with more non aqueous drilling fluid properties (*e.g.*, lubricity, shale suppression), and that these WBFs would exhibit greater aquatic toxicity.

EPA's analyses show that under the SBF-cuttings zero discharge option as compared to current practice, for U.S. Offshore waters existing sources, there would be an increase of 35 million pounds of cuttings annually shipped to shore for disposal in non-hazardous oilfield waste (NOW) sites and an increase of 166 million pounds of cuttings annually injected. In addition, under the SBF-cuttings zero discharge option, operators would use the more toxic OBFs. The zero discharge option for SBF-cuttings would lead to an increase in annual fuel usage of 358,664 BOE and an increase in annual air emissions of 5,602 tons. Finally, the SBF-cuttings zero discharge option in the U.S. Offshore waters would lead to an increase of 51 million pounds of WBF cuttings being discharged to U.S. Offshore waters. This pollutant loading increase is a result of GOM operators switching from efficient SBF drilling to less efficient WBF drilling.

EPA's analysis shows that the impacts of adequately controlled SBF discharges to the water column and benthic environment are of limited scope and duration. By contrast, the landfilling of OBF-cuttings is of a longer term duration and associated pollutants may affect ambient air, soil, and groundwater quality. EPA and DOE documented at least five CERCLA (or "Superfund") sites in Louisiana and California contaminated with oilfield wastes and more than a dozen other sites subject to Federal or State cleanup actions.

Nonetheless, while SBF-cuttings discharge with adequate controls is preferred over zero discharge in U.S. Offshore waters, SBF-cuttings discharge with inadequate controls is not preferred over zero discharge. EPA believes that to allow discharge of SBF-cuttings in U.S. Offshore waters, there must be appropriate controls to ensure that EPA's discharge limitations reflect the "best available technology" or other appropriate level of technology. EPA has worked with industry to address the appropriate determination of PAH content, sediment toxicity, biodegradation, quantity of SBF discharged, and formation oil contamination that are technically available, economically achievable, and have acceptable NWQIs. The final BAT limitations are a result of this effort and are discussed below.

EPA is today promulgating BAT of zero discharge for SBF-cuttings for Coastal Cook Inlet, Alaska except when Coastal Cook Inlet, Alaska, operators are unable to dispose of their SBF-cuttings using any of the following disposal options: (1) On-site re-injection (annular disposal or Class II UIC); (2) re-injection using a nearby Coastal or Offshore Class II UIC disposal well; or (3) onshore disposal using a nearby Class II UIC disposal well or land application. Coastal Cook Inlet, Alaska, operators are required to demonstrate to the NPDES permit controlling authority that none of the above three disposal options are technically feasible in order to qualify for the alternate BAT limitation. Coastal Cook Inlet, Alaska, operators that qualify for the alternate BAT limitation are allowed to discharge SBF-cuttings at the same level of BAT control as operators in Offshore waters. The NPDES permit controlling authority will use the procedure given in Appendix 1 to subpart D of 40 CFR part 435 to establish whether or not a Coastal Cook Inlet, Alaska, operator qualifies for the SBF-cuttings zero discharge exemption. As stated in Appendix 1 to subpart D of 40 CFR part 435, the following factors are considered in the determination of whether or not Coastal Cook Inlet, Alaska, operators qualify for the SBF-cuttings zero discharge exemption: (1) Inability to establish formation injection in wells that were initially considered for annular or dedicated disposal; (2) inability to prove to UIC controlling authority that the waste will be confined to the formation disposal interval; (3) inability to transport drilling waste to an offshore Class II UIC disposal well or an onshore disposal site; and (4) whether or not there is no available land disposal facilities (*e.g.*, onshore re-injection, land disposal).

EPA finds that this option is technically available and economically achievable. Operators are currently barred from discharging OBFs, SBFs, and enhanced mineral oil based drilling fluids under the Cook Inlet NPDES general permit (64 FR 11889). As previously discussed in Section IV.E, EPA identified that many Cook Inlet operators in Coastal waters are using cuttings re-injection to comply with zero discharge disposal requirements for OBFs and OBF-cuttings. EPA contacted Cook Inlet operators (*e.g.*, Phillips, Unocal, Marathon Oil) and the State regulatory agency, AOGCC, for more information on the most recent re-injection practices of Coastal and Offshore Cook Inlet operators. AOGCC stated that there should be enough formation re-injection disposal capacity for the small number of non-aqueous drilling fluid wells (<5–10 wells per year) being drilled in Cook Inlet Coastal waters. Therefore, since Coastal Cook Inlet operators are already complying with zero discharge of OBF- and SBF-cuttings, this option is economically achievable as there are no incremental compliance costs.

AOGCC stated, however, that case specific limitations should be considered when evaluating disposal options (*see* Section IV.E). Cook Inlet, Alaska, operators may experience the following difficulties in attempting to comply with a zero discharge requirement for SBFs: (1) Inability to establish formation injection in wells that were initially considered for annular or dedicated Class II UIC disposal; (2) inability to prove to AOGCC's satisfaction that the waste will be confined to the formation disposal interval; and (3) inability to transport drilling waste to an offshore Class II UIC disposal well or an onshore disposal site. EPA believes that while these problems are currently not presented by drilling in Cook Inlet, they could be a problem in the future. Further, EPA believes this to be a greater problem in Cook Inlet where climate, tides, and its distance from commercial disposal sites make transportation to shore less feasible than in other offshore waters near the continental U.S. If EPA did not provide for some exceptions within the guideline itself, and these problems presented themselves beyond the time frame for requesting a Fundamentally Different Factors variance (under section 301(n)(2) of the CWA, 180 days) this would render zero discharge not achievable. Therefore, EPA believes it is reasonable to provide for some flexibility to the current practice of zero discharge in Cook Inlet.

EPA further finds the NWQIs of this option for Cook Inlet to be acceptable. As previously stated, few non-aqueous drilling fluid wells are drilled in Coastal Cook Inlet, Alaska (<5–10 wells per year). EPA finds that the small number of wells drilled per year (even if all of them are drilled using SBF) leads to very small increases in NWQIs. Tables 6 though 10 describe the annual air emissions and fuel usage for the three geographic regions including Cook Inlet, Alaska. In particular, a zero discharge requirement for SBFs and SBF-cuttings in Cook Inlet, Alaska, would lead to an annual increase of 94 tons of air emissions and 6,067 BOE fuel used for existing sources. EPA does not anticipate and new sources in Cook Inlet, Alaska. Consequently, EPA finds that the overall small increases in NWQIs from the zero discharge option, as compared to either of the two SBF-cuttings discharge options, in Coastal Cook Inlet, Alaska, are acceptable. The two SBF-cuttings discharge options show little change in NWQIs as compared to baseline (*see* Tables 6 though 9).

1. Stock Base Fluid Technical Availability and Economic Achievability

a. Introduction. As SBFs have developed over the past few years, the industry has come to use mainly a limited number of primary base fluids. These include the internal olefins, linear alpha olefins, poly alpha olefins, paraffinic oils, C_{12}–C_{14} vegetable esters of 2-hexanol and palm kernel oil, and "low viscosity" C_8 esters. These fluids represent virtually all the SBFs currently used in oil and gas extraction industry. EPA collected data on performance, environmental impact, and costs for these SBFs to develop the effluent limitations for today's final rule. The following definitions are used in this preamble to describe various SBFs: (1) Internal olefin (IO) refers to a series of isomeric forms of C_{16} and C_{18} alkenes; (2) linear alpha olefin (LAO) refers to a series of isomeric forms of C_{14} and C_{16} monoenes; (3) poly alpha olefin (PAO) refers to a mix mainly comprised of a hydrogenated decene dimer $C_{20}H_{62}$ (95%), with lesser amounts of $C_{30}H_{62}$ (4.8%) and $C_{10}H_{22}$ (0.2%); (4) vegetable ester refers to a monoester of 2-ethylhexanol and saturated fatty acids with chain lengths in the range C_8–C_{16}; and (5) "low viscosity" ester refers to an ester of natural or synthetic C_8 fatty acids and alcohols. EPA also has data on other SBF base fluids, such as enhanced mineral oil, paraffinic oils (*i.e.*, saturated hydrocarbons or "alkanes"), and the traditional OBF base fluids: mineral oil and diesel oil.

The stock base fluid limitations in today's rule are based on the technology of product substitution. The promulgated limitations are technically available because they are based on currently available base fluids that can be used in the wide variety of drilling situations in U.S. offshore waters. EPA anticipates that the base fluids meeting all requirements would include vegetable esters, low viscosity esters, and internal olefins. In addition, based on current information, EPA believes that the stock base fluid controls on PAH content, sediment toxicity, and biodegradation rate being promulgated today are sufficient to only allow the discharge of only those base fluids (*e.g.*, esters, internal olefins) with lower bioaccumulation potentials (*i.e.*, log K_{ow} <3 to 3.5 and log K_{ow}> 6.5 to 7). Therefore, EPA found it was unnecessary to promulgate a separate limitation for bioaccumulation.

As previously stated in April 2000 (65 FR 21554), EPA considered basing the sediment toxicity and biodegradation stock limitations and standards solely on vegetable esters (*i.e.*, original esters) instead of the proposed C_{16}–C_{18} IO. EPA also considered subcategorizing the final rule to determine when vegetable esters are not practical and when C_{16}–C_{18} IOs could be used instead. EPA considered these options due to the potential for better environmental performance of vegetable ester-based drilling fluids. EPA and industry analytical testing show that esters have better sediment toxicity and biodegradation performance.

EPA rejected the option of basing sediment toxicity and biodegradation stock limitations and standards on vegetable esters due to several technical limitations. These technical limitations of vegetable esters preclude their use in all areas of the GOM, Offshore California, and Cook Inlet, Alaska. Vegetable ester technical limitations

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include: (1) High viscosity compared with other IO SBFs at all temperatures, with an increasing difference as temperature decreases, leading to lower rates of penetration in wells and greater probability of losses due to higher equivalent circulating densities; (2) high gel strength in risers that develops when a vegetable ester-based SBF is not circulated; (3) a high temperature stability limit ranging from about 225 °F to perhaps 320 °F—the exact value depends on the detailed chemistry of the vegetable ester (*i.e.*, the acid, the alcohol) and the drilling fluid chemistry; (4) reduction of the thermal stability limit through hydrolysis when vegetable esters are in contact with highly basic materials (*e.g.*, lime, green cement) at elevated temperatures; and (5) less tolerance of the muds to contamination by seawater, cement, and drill solids than is observed for IO–SBFs (Docket No. W–98–26: Record No. IV.A.a.3, Attachment A2—"Limitations of Esters'; Record No. IV.A.a.13, Attachments Ester-51, 52, 53, 54, 56).

EPA also rejected the option of subcategorizing the use of esters to define drilling conditions when only esters could be allowed for a controlled discharge. EPA could not establish a "bright line" rationale to define the situation where only esters should be the benchmark fluid (*i.e.*, only esters would be allowed for a controlled discharge). EPA considered many of the engineering factors used for selection of a drilling fluid (*e.g.*, rig size and equipment; formation characteristics; water depth and environment; lubricity, rheological, and thixotropic requirements) and determined that this type of sub-categorization was not possible. EPA, however, is encouraging the use of esters by promulgating a higher ROC limitation and standard when esters are used.

EPA also considered basing sediment toxicity and biodegradation stock limitations and standards on low viscosity esters. Comments to the April 2000 NODA state that laboratory analyses, which were designed to simulate GOM conditions to which a fluid may be exposed, indicate that low viscosity esters have the following technical properties: (1) Similar or better viscosity than C_{16}–C_{18} IOs; (2) can be used to formulate stable low viscosity ester-based SBFs up to 300 °F; (3) can be used to formulate low viscosity ester-based SBFs to 16.0+ lbs/gal mud weight; (4) can reduce oil/water ratios to 70/30, thus reducing volumes of base fluid discharged; (5) high tolerance to drilled solids; (6) flat gels make it easier to break circulation, minimizing initial circulation pressures and subsequent risk of fracture; (7) high tolerance to seawater contamination; and (8) rheological properties can be adjusted by use of additives to suit specific conditions (Docket No. W–98–26, Record No. IV.A.a.7). EPA also received information on one well section drilled with low viscosity esters. Some of the results from this low viscosity ester well section were compared to the results from another well section in the same location where C_{16}–C_{18} IOs were used. These results show that the low viscosity ester had: (1) Comparable or better equivalent circulating densities (*i.e.*, acceptable fluid properties); and (2) faster ROP through better hole cleaning and higher lubricity (*i.e.*, fewer days required to drill to total depth which lead to less NWQI and overall drilling costs). The low viscosity esters are relatively new base fluids and have only recently been available to the market. Despite the results from the laboratory analyses and one well section, EPA does not believe that this is enough information to make the determination that low viscosity esters can be used in all or nearly all drilling conditions in the offshore U.S. waters (*e.g.*, differing formations, water depths, and temperatures). Therefore, EPA rejected the option of basing sediment toxicity and biodegradation stock limitations and standards on low viscosity esters. EPA is sufficiently satisfied, however, that low viscosity esters and vegetable esters provide better environmental performance (*e.g.*, sediment toxicity, biodegradation). Consequently, EPA is promulgating higher retention on cuttings discharge limitations where esters are used to encourage operators to use esters when possible.

b. PAH Content Technical Availability. Today's promulgated limitation of PAH content for U.S. Offshore waters is a weight ratio defined as the weight of PAH (as phenanthrene) per weight of the stock base fluid sample. The PAH weight ratio is 0.001%, or 10 parts per million (ppm). This limitation is based on the availability of base fluids that are free of PAHs and the detection of the PAHs by EPA Method 1654A, "PAH Content of Oil by High Performance Liquid Chromatography with a UV Detector." Method 1654A was published in Methods for the Determination of Diesel, Mineral and Crude Oils in Offshore Oil and Gas Industry Discharges (EPA–821–R–92–008, incorporated by reference and available from National Technical Information Service at (703) 605–6000). As originally proposed in February 1999 (64 FR 5503), EPA is promulgating the use of the EPA Method 1654A for compliance with this PAH content BAT limitation.

EPA's promulgated PAH content limitation is technically available. Producers of several SBF base fluids have reported to EPA that their base fluids are free of PAHs. The base fluids which suppliers have reported are free of PAHs include IOs, LAOs, vegetable esters, low viscosity esters, certain enhanced mineral oils, synthetic paraffins, certain non-synthetic paraffins, and others. The use of these fluids can accommodate the broad varieties of drilling situations faced by industry in offshore U.S. waters (*see* SBF Development Document, Chapter IV). Compliance with the stock BAT limitation and NSPS on PAH content will be achieved by product substitution.

c. Sediment Toxicity Technical Availability. EPA is today promulgating a sediment toxicity stock base fluid limitation that would only allow the discharge of SBF-cuttings using SBF base fluids as toxic or less toxic, but not more toxic, than C_{16}–C_{18} IOs. Alternatively, this limitation could be expressed in terms of a "sediment toxicity ratio" which is defined as 10-day LC_{50} of C_{16}–C_{18} internal olefins divided by the 10-day LC_{50} of stock base fluid being tested. EPA is promulgating a sediment toxicity ratio of less than 1.0. Compliance with this limitation is determined by the 10-day *Leptocheirus plumulosus* sediment toxicity test (*i.e.*, ASTM E1367–92: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests With Marine and Estuarine Amphipods' (incorporated by reference and available from ASTM, 100 Bar Harbor Drive, West Conshohocken, PA 19428), supplemented with the preparation procedure specified in Appendix 3 of Subpart A of 40 CFR part 435). As originally proposed in February 1999 (64 FR 5503) and re-stated in April 2000 (65 FR 21549), EPA is promulgating the use of the ASTM E1367–92 method for compliance with this sediment toxicity BAT limitation.

Since the February 1999 proposal, EPA and other researchers conducted numerous 10-day *L. plumulosus* sediment toxicity tests on various SBF base fluids with natural and formulated sediments. Nearly all the SBF base fluids have lower sediment toxicity than diesel and mineral oil. Some SBF base fluids, however, show greater sediment toxicity than other SBF base fluids (*see* 65 FR 21550; Docket No. W–98–26, Record No. IV.A.a.13). The base fluids meeting this limitation include vegetable esters, low viscosity esters, internal olefins, and some PAOs (*see* 65 FR 21550; Docket No. W–98–26, Record No. IV.A.a.13).

EPA finds this limit to be technically available and economically achievable through product substitution because information in the rulemaking record supports the findings that vegetable esters, low viscosity esters, and internal olefins have performance characteristics enabling them to be used in the wide variety of drilling situations in offshore U.S. waters and meet today's promulgated limit.

EPA selected the C_{16}–C_{18} IO, which is the most popular drilling fluid in the GOM, as the basis for the sediment toxicity rate ratio limitation instead of the vegetable ester or low viscosity ester for several reasons: (1) EPA does not believe that vegetable esters can be used in all drilling situations; and (2) EPA does not have sufficient field testing information that low viscosity esters can be used in all drilling situations (*see* Section V.F.1.a). In addition, because of the uncertainty about ester performance, operators may not be encouraged to switch from OBFs or WBFs to SBF when properly installed and maintained. Specifically, vendor supplied data associated with these cuttings dryer deployments suggest that the overall cuttings dryer downtime (*i.e.*, time when cuttings dryer equipment is not operable) is approximately 1 to 2% (Docket No. W–98–26, Record No. IV.A.a.6). EPA finds this small downtime percentage as acceptable.

EPA discussed how it revised the BAT/NSPS-level solids control equipment configuration used in its analyses in the April 2000 NODA (65 FR 21559). EPA also discussed a range of management options regarding the BAT limitation for SBF retention on SBF-cuttings: (1) Two discharges from the BAT/NSPS-level solids control equipment configuration (*i.e.*, one discharge from the cuttings dryer and another discharge from the fines removal unit); (2) one discharge from the BAT/NSPS-level solids control equipment configuration (*i.e.*, one discharge from the cuttings dryer with the fines from the fines removal unit captured for zero discharge); and (3) zero discharge of SBF-cuttings. These three options are labeled as BAT/NSPS Option 1, BAT/NSPS Option 2, and BAT/NSPS Option 3, respectively. EPA estimates that 97% and 3% of the total cuttings are generated by cuttings dryer and fines removal unit, respectively.

EPA developed two numerical well averaged ROC limitations (*i.e.*, one for SBFs with the stock base fluid performance similar to esters and another for SBFs with the stock base fluid performance similar to C_{16}–C_{18} internal olefins) and based both of these ROC limitations on the technology of only one discharge from the cuttings dryer with the fines from the fines removal unit captured for zero discharge (*i.e.*, BAT/NSPS Option 2). The numerical well averaged ROC maximum limitation for SBFs (*i.e.*, 9.4%) with the environmental characteristics of esters is based on a combination of data from horizontal centrifuge, vertical centrifuge, squeeze press, and High–G linear shaker cuttings dryer technologies. The numerical well averaged ROC maximum limitation for SBFs (*i.e.*, 6.9%) with the environmental characteristics of C_{16}–C_{18} internal olefins is based on a combination of data from horizontal and vertical centrifuge cuttings dryer technologies. EPA estimates that operators, generally installing new equipment where none has been used in the past, will be able to choose from among the better technologies, designs, operating procedures, and maintenance procedures that EPA has considered to be among the best available technologies. EPA data demonstrates that operators properly using these cuttings dryer technologies will be able to comply with these final ROC numerical limitations. Data submitted to EPA show that operators using the vertical centrifuge and horizontal centrifuge are capable of achieving the lower ROC limitation (*i.e.*, 6.9%). Data submitted to EPA also show that operators using the vertical centrifuge, horizontal centrifuge, squeeze press, and High-G linear shaker are capable of achieving the higher ROC limitation (*i.e.*, 9.4%). More details on the observed performance of the individual technologies and details of calculation for the numerical limits are presented in the SBF Statistical Support Document and SBF Development Document.

EPA developed the two ROC limitations because EPA used a two part approach to control SBF-cuttings discharges. The first part is the control of which SBF are allowed for discharge through use of stock limitations (*e.g.*, sediment toxicity, biodegradation, PAH content, metals content) and discharge limitations (*e.g.*, diesel oil prohibition, formation oil prohibition, sediment toxicity, aqueous toxicity). The second part is the control of the quantity of SBF discharged with SBF-cuttings. As previously stated, EPA and industry sediment toxicity and biodegradation laboratory studies show that both vegetable esters and low viscosity esters have better environmental performance than all other SBF base fluids. However, because the technical availability of product substitution with esters was not demonstrated across the offshore subcategory, EPA rejected the option of basing sediment toxicity and biodegradation stock limitations and standards on vegetable esters and low viscosity esters (*see* V.F.1.a). EPA is sufficiently satisfied, however, that both esters provide better environmental performance (*e.g.*, sediment toxicity, biodegradation). Consequently, EPA is promulgating a higher retention on cuttings discharge limitation to encourage operators to use esters when possible. EPA estimates that a higher retention on cuttings discharge limitation for esters is equivalent to the same level of control as a lower retention on cuttings discharge limitation for all other SBFs that have poorer sediment toxicity and biodegradation performances.

In response to the April 2000 NODA, EPA received comments from an ester-based SBF manufacturer that EPA should create an incentive for operators to use ester-based SBFs by basing the ROC limitation for ester-based SBFs on baseline solids control equipment (*e.g.*, primary and secondary shale shakers, fines removal unit) (Docket No. W–98–26, Record No. IV.A.a.7). In late comments, this same commentor claimed that a ROC limitation based on any cuttings dryer technology would not provide any incentive for the use of ester-based SBFs (Docket No. W–98–26, Record No. IV.A.a.38). Further, they argued that the superior laboratory performance of these ester base fluids in terms of sediment toxicity and biodegradation justifies allowing them to be discharged with a ROC limitation based on baseline solids control equipment. EPA estimates that a ROC BAT limitation based on the baseline solids control equipment is above 15.3%.

While EPA is willing to expand the technology basis to allow the use of less effective cuttings dryers for ester-based SBFs (*e.g.*, squeeze press, High-G linear shakes), EPA is unwilling to entirely abandon the use of cuttings dryers for ester-based SBF drilling operations. EPA is unwilling to set a higher ROC limitation for SBFs with the environmental performance of ester-based SBFs based on baseline solids control technology because the environmental improvement resulting from the use of improved solids control technology (*i.e.*, cuttings dryers) outweighs the incremental ester laboratory sediment toxicity and biodegradation performance over internal olefins. Cuttings dryers promote pollution prevention through increased re-use of drilling fluids and prevent

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significant amounts of pollutants from being discharged to the ocean.

EPA provides for variability from the long term average (LTA) of performance data from the candidate treatment technology or technologies. The LTA performance of the baseline solids control technology is 10.2%, as compared to the LTA of 4.8% based on data from all four cutting dryer technologies. This difference translates to 118 million pounds per year of pollutants being discharged using the existing and new model well counts for the selected BAT option (*i.e.*, BAT/NSPS Option 2) (*see* SBF Development Document). Further, as previously stated in the April 2000 NODA (65 FR 21553), field results show that: (1) Cuttings are dispersed during transit to the seabed and no cuttings piles are formed when SBF concentrations on cuttings are held below 5%; and (2) cuttings discharged from cuttings dryers (with SBF retention values under 5%) in combination with a sea water flush, hydrate very quickly and disperse like water-based cuttings. Thus, while EPA is willing to provide additional flexibility to dischargers of ester-based fluids, EPA believes that the appropriate technology basis that reflects BAT is cuttings dryers technology. In balancing the environmental effects of these additional ester-based SBFs discharges controlled with the use of baseline solids control technology against the environmental effects of lower internal olefin-based SBFs discharges controlled with the use of cuttings dryers, EPA has concluded that the improvement in solids control technology leading to lower values of ROC is a more significant factor than laboratory data for ester base fluids showing lower sediment toxicity and higher biodegradation.

EPA is also not convinced that the difference in ROC limitations provides no incentive to use ester-based SBFs, as the ester-based SBF manufacturer argues. EPA believes that the difference between 6.9% and 9.4% could provide an incentive for operators to use ester-based SBFs. As operators have increasingly installed cuttings dryers in the GOM (over three dozen successful deployments in the last two years), and as any SBF discharger installs new technology to comply with the lower ROC limitation (*i.e.*, 6.9%), operators may find that it is worthwhile to purchase ester-based SBFs in order to be able to operate with even a greater margin of flexibility under a limit of 9.4% as compared to 6.9%.

As this rule is performance based, EPA is not prohibiting the discharge of SBF-cuttings from the fines removal unit in order to comply with the base fluid retained on cuttings discharge BAT limitation. Operators are only required to show that the volume weighted average of all their SBF-cuttings discharges is below the discharge BAT limitation. EPA expects that most operators will be able to discharge cuttings from the cuttings dryer and fines removal unit and comply with this discharge BAT limitation. If, for example, the average retention of SBF on SBF-cuttings from a cuttings dryer is 6.00%, the average retention of SBF on SBF-cuttings from a fines removal unit is 12.00%, and the fines are observed to comprise 3% of the total cuttings discharged, then the well average is 6.18% (*i.e.*, (0.97) (6.00%) + (0.03)(12.00%) = 6.18%). If the well average for SBF retention from the cuttings dryer exceeds the discharge limit then in order to comply with this discharge BAT limitation all cuttings must be re-injected on-site or hauled to shore for land disposal. EPA finds that if this is the case, the limit is technologically available because operators have transported OBFs to shore since 1986 and have transported WBFs that do not meet the existing effluent limitations and standards since 1993.

EPA finds that both ROC limitations (*i.e.*, 6.9%, 9.4%) are technically available to the industry because they are based on product substitution and a statistical analysis of ROC performance from drilling conditions throughout offshore waters. The BAT limitations for controlling the amount of SBF discharged with SBF-cuttings are calculated such that nearly all well averages for retention are expected to meet these values using the selected technologies without any additional attention to design, operation, or maintenance. EPA data demonstrates that operators properly using these cuttings dryer technologies will be able to comply with these final ROC numerical limitations because: (1) These limits allow for variation in formation characteristics that may not exist in the United States; (2) operators, generally installing new equipment where none has been used in the past, will be able to choose from among the better technologies, designs, operating procedures, and maintenance procedures that EPA considers to be among the best available technologies; and (3) operators may elect to use SBFs with the stock base fluid performance of esters and horizontal or vertical centrifuge cuttings dryers to achieve a ROC well average well below the 9.4% ROC limitation.

Data used in the calculation of the numerical limits exclude retention results submitted without backup calculations (*i.e.*, without raw retort data) and include data from drilling operations in foreign waters (*e.g.*, Canada). EPA excluded ROC data without raw retort data (*e.g.*, masses and volumes of cuttings samples and recovered liquids taken during the retort method by the field technician) due to concerns over data quality (*e.g.*, no independent method to check data quality). EPA included ROC data from Canadian drilling operations to incorporate the variability of cuttings dryer performance in harder and less permeable formations that generally lead to higher ROC values. EPA estimates that the major factors leading to higher ROC values for all solids control equipment include: (1) Slower rates of penetration; (2) formations that are harder and less permeable; and (3) selection of certain drill bits. The Canadian ROC data come from formations that are generally much harder and less permeable than what is observed in the GOM. These harder formations generally lead to slower rates of penetration. The less permeable Canadian formations lead to fewer downhole losses of SBF. Downhole losses require the addition of fresh SBF to maintain volume requirements for the active mud system. These additions of fresh SBF to the active mud system help control the potential of build-up of fines. In addition, operators often use PDC drill bits in order to grind through the hard Canadian formations. This grinding action leads to smaller cuttings than is what is observed in the GOM. The smaller cuttings have more surface area for SBF than larger cuttings and generally have higher ROC values. Consequently, EPA's use of Canadian data in its analyses incorporate sufficient variability to model the formations in GOM, Offshore California, Cook Inlet, Alaska, and other offshore U.S waters where EPA does not have ROC data.

EPA finds that both well-average discharge BAT ROC limitations (*e.g.*, 6.9%, 9.4%) for base fluid on wet cuttings are economically achievable. According to EPA's analysis, in addition to reducing the discharge of SBFs associated with the cuttings, EPA estimates that this control will result in a net savings of $46.9 million ($1999) dollars per year. This savings results, in part, because the value of the SBF recovered is greater than the cost of installation of the improved solids control technology.

EPA concluded that a zero discharge requirement for SBF-cuttings from existing sources and the subsequent increase use of OBFs and WBFs would result in: (1) Unacceptable NWQIs; and (2) more pollutant loadings to the ocean due to operators switching from SBFs to less efficient WBFs (*see* Sections II.B and V.F). For these reasons, EPA rejected the BAT zero discharge option for SBF-cuttings from existing sources.

EPA also requested comments in the April 2000 NODA (65 FR 21570) on the issue of rig compatibility with the installation of cuttings dryers (*e.g.*, vertical or horizontal centrifuges, squeeze press mud recovery units, High-G linear shakers). EPA received general information on the problems and issues related to cuttings dryer installations from API/NOIA stating that not all rigs are capable of installing cuttings dryers (Docket No. W–98–26, Record No. IV.A.a.13). In late comments, some industry commentors asserted that 48 of the 223 GOM drilling rigs are not capable of having a cuttings dryer system installed due to either rig space and/or rig design without prohibitive costs or rig modifications (Docket No. W–98–26, Record No. IV.B.b.33). Upon a further, more extensive review of GOM rigs, these same commentors asserted that 30 of 234 GOM drilling rigs are not capable of having a cuttings dryer system installed due to either rig space and/or rig design without prohibitive costs or rig modifications (Docket No. W–98–26, Record No. IV.B.b.34). EPA also received late comments from one operator, Unocal, stating that 36 of 122 Unocal wells drilled between late 1997 and mid-2000 were drilled with rigs that do not have 40 foot × 40 foot space available which they assert is necessary for a cuttings dryer installation (Docket No. W–98–26, Record No. IV.B.b.31). The API/NOIA rig survey and the Unocal rig survey identified most of the same rigs as unable to install cuttings dryers. However, two rigs (*i.e.*, Parker 22, Nabors 802) identified in the Unocal rig survey as having no space for a cuttings dryer installation were identified in the API/NOIA rig survey as each having a previous cuttings dryer installation. Unocal requested in late comments that EPA subcategorize certain rigs from being subject to the retention limit or that these rigs be able to discharge SBFs using performance that reflects current shale shaker technology (Docket No. W–98–26, Record No. IV.A.a.36).

Based on the record, EPA finds that current space limitations for cuttings dryers do not require a 40 foot × 40 foot space. Specifically, EPA has in the record information gathered during EPA's October 1999 site visit and information supplied by API/NOIA, MMS, and equipment vendors. EPA received information from a drilling fluid manufacturer and cuttings dryer equipment vendor, M-I Drilling Fluids, stating that they are not aware of any GOM rig not capable of installing a cuttings dryer (Docket No. W–98–26, Record No. IV.B.b.32). Another cuttings dryer equipment vendor, JB Equipment, asserted that there are at most only a few rigs that pose questionable installation problems and that they have yet to survey a rig that they could not install a cuttings dryer (Docket No. W–98–26, Record No. IV.B.b.48). JB Equipment also stated that inexperience with cuttings dryer installations may inhibit the ability of operators or rig owners to properly judge whether a cuttings dryer can be installed. JB Equipment cited an example where the operator concluded that a cuttings dryer could not be installed on a rig (Nabors 803) while JB Equipment surveying efforts identified the cuttings dryer installation for the same rig as one of the simplest installations JB Equipment performs. MMS also concluded that rigs do not need a 40 foot × 40 foot space to install a cuttings dryer and that, with the exception of a few jackup and platform rigs, there should not be any significant issues related to installing cuttings dryers on OCS drilling rigs (Docket No. W–98–26, Record No. IV.B.a.28). API/NOIA estimated that 150 square feet are required for a cuttings dryer installation in order to meet the ROC BAT limitation and NSPS (Docket No. W–98–26, Record No. IV.A.a.13). EPA also estimates that the minimum height clearance for a typical cuttings dryer installation is 6 feet (*see* SBF Development Document). The API/NOIA estimate is based on the installation of a horizontal centrifuge cuttings dryer (*i.e.*, MUD–6). The Unocal estimate is based on the vertical centrifuge cuttings dryer and is also characterized by other industry representatives and MMS as too high (Docket No. W–98–26, Record No. IV.B.b.34; Record No. IV.B.a.28). EPA's estimate of a typical vertical centrifuge installation is 15 feet × 15 feet (*i.e.*, 225 square feet) with a minimum height clearance of 11 feet (*see* SBF Development Document). EPA based the ROC BAT limitation and NSPS (*e.g.*, 6.9%) on the use of both these cuttings dryers for SBFs with the stock limitations of C_{16}–C_{18} IOs. Based on comments from operators, equipment vendors, and MMS, EPA believes that most of these shallow water rigs have the requisite 150–225 square feet available to install a cuttings dryer (*see* SBF Development Document). Therefore, EPA finds that operators are not required to have a 1,600 square foot space for a cuttings dryer installation in order to meet the ROC BAT limitation and NSPS. Proper spacing and placement of cuttings dryers in the solids control equipment system should prevent installation problems.

Because of the large discrepancy between EPA's record information and the space requirements asserted by the commenter (1,600 square feet versus EPA's 225 square feet + 11 feet in height for the vertical centrifuge or 150 square feet + 6 feet in height for the horizontal centrifuge—MUD–6), EPA does not necessarily believe that there are as many wells that cannot install cuttings dryers as the commentor (Unocal) claims. Further, based on scant detail supporting these assertions, and their lateness in the process, EPA has no basis upon which to assess them or verify them.

Moreover, EPA does not believe that it has enough information to reasonably subcategorize these facilities, nor did it have time to provide public notice of how it would define such a subcategory, given the court-ordered deadline for this rule. EPA does not believe that basing a subcategory by specifying a space requirement alone (*e.g.* operators that do not have a certain amount of deck space available on, below or adjacent to the deck would not be subject to this requirement) would be sufficient to prevent operators from configuring their other equipment in a manner that would enable them to fit into the subcategory. Such an exception might also lead to operators to make other assertions justifying that they should be included (*e.g.*, that while they have a certain amount of space available, safety reasons prevent placement of the technology on the rig). Without a solution to these issues, EPA is concerned that such a subcategorization would potentially be too broad and be unworkable.

For these reasons, EPA believes that the appropriate way to handle these concerns is through the fundamentally different factors (FDF) variance process. This process, provided for under CWA section 301(n), would allow operators to submit supporting data and information to EPA and would give the public the opportunity to comment on that data to determine whether an FDF is truly warranted for that drilling facility. EPA has authority over owners and operators, who are both dischargers, but the NPDES regulations require the operator to apply for the NPDES permit: "When a facility or activity is owned by one person but is operated by another person, it is the operator's duty to obtain

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a permit," (*see* 40 CFR 122.21(b)). Thus, mobile drill rig "operators" as dischargers can apply for FDFs (*see* 40 CFR 125.32; 122.21(b)).

EPA notes that the ROC limitations and standards do not preclude the use of SBFs if an operator cannot meet them if the operator can meet zero discharge through re-injection or shipment to shore. Historically, dischargers have used water-based fluids in shallow water wells and this may also be an option. EPA considers controlled WBF discharges preferable to uncontrolled SBF discharges. EPA examined the NWQIs associated with these zero discharge operations as acceptable (*see* SBF Development Document). The NWQIs of zero discharge for the shallow water wells are much smaller that those associated for the entire region covered by this rule. Further, while a SBF-cuttings discharge option with adequate controls is preferred over the zero discharge option for SBF-cuttings in U.S. Offshore waters, a SBF-cuttings discharge option with inadequate controls is not preferred over zero discharge. The retention limit is a very important control because it controls: (1) The amount of SBF discharged to the ocean; (2) the biodegradation rate of discharged SBF; and (3) the potential for SBF-cuttings to develop cuttings piles and mats which are detrimental to the benthic environment. In short, EPA does not view existing shale shaker technology (or performance of other technology equivalent to shale shaker technology) to constitute the appropriate level of control under BAT or BADT (NSPS).

EPA has also decided that solids accumulated at the end of the well ("accumulated solids") and wash water used to clean out accumulated solids or on the drill floor are associated with drill cuttings and are therefore not controlled by the zero discharge requirement for SBFs not associated with drill cuttings (*see* Section V.C). EPA has decided to control accumulated solids and wash water under the discharge requirements for cuttings associated with SBFs. The amount of SBF base fluid discharged with discharged accumulated solids will be estimated using procedures in Appendix 7 to subpart A of 40 CFR part 435 and incorporated into the base fluid retained on cuttings numeric limitation or standard. The source of the pollutants in the accumulated solids and associated wash water are drill cuttings and drilling fluid solids (*e.g.*, barite). The drill cuttings and drilling fluid solids can be prevented from discharge with SBF-cuttings due to equipment design (*e.g.*, sand traps, sumps) or improper maintenance of the equipment (*e.g.*, failing to ensure the proper agitation of mud pits). EPA agrees with commentors that the discharge of SBF associated with accumulated solids in the SBF active mud system and the associated wash water is normally a one-time operation performed at the completion of the SBF well (*e.g.*, cleaning out mud pits and solids control equipment).

The quantity of SBF typically discharged with accumulated solids and wash water is relatively small. The SBF fraction in the 75 barrels of accumulated solids is approximately 25% and generally only very small quantities of SBF are contained in the 200 to 400 barrels of associated equipment wash water. Current practice is to retain accumulated solids for zero discharge or recover free oil from accumulated solids prior to discharge. Since current practice is to recover free oil and discharge accumulated solids, the controlled discharge option for SBF-cuttings represents current practice and is economically achievable. Moreover, recovering free oil from accumulated solids prior to discharge has no unacceptable NWQIs. EPA defines accumulated solids and wash water as associated with drill cuttings. Therefore, operators will control these SBF-cuttings wastes using the SBF stock limitations and cuttings discharge limitations. As compliance with EPA's SBF stock limitations and cuttings discharge limitations does not require the processing of all SBF-cuttings wastes through the solids control technologies (*e.g.*, shale shakers, cuttings dryers, fines removal units), operators may or may not elect to process accumulated solids or wash water through the solids control technologies.

EPA is also promulgating a set of BMPs for operators to use that demonstrates compliance with the numeric ROC limitation and therefore reduces the retort monitoring otherwise required to determine compliance with the numeric ROC limitation. This option combines the set of BMPs that represent current practice with BMPs that are associated with the use of improved solids control technology. This option is technologically available and economically achievable for the same reasons that apply to compliance with the ROC numerical limitations. Examples of BMPs that represent current practices are, for example, use of mud guns, proper mixing procedure, elimination of settling places for accumulated solids. Examples of BMPs associated with the use of the new solids control technology are, for example, operating cuttings dryers in accordance with the manufacturer's specifications and maintaining a certain mass flux. If operators elect to use this BMP option, they will be required to demonstrate compliance through limited retort monitoring of cuttings and additional BMP paperwork. Paperwork requirements are detailed in Appendix 7 of subpart A of 40 CFR part 435. Paperwork cost and burden estimates are detailed in Section IX.D of the preamble.

d. *Sediment Toxicity of SBF Discharged with Cuttings.* As originally proposed in February 1999 (64 FR 5491) and re-stated in April 2000 (65 FR 21557), EPA is today promulgating a BAT limitation to control the maximum sediment toxicity of the SBF discharged with cuttings. This BAT limitation controls the sediment toxicity of the SBF discharged with cuttings as a non-conventional pollutant parameter and as an indicator for other pollutants in the SBF discharged with cuttings. Some of the toxic, priority, and non-conventional pollutants in the SBF discharged with cuttings may include: (1) The base fluids such as enhanced mineral oils, internal olefins, linear alpha olefins, poly alpha olefins, paraffinic oils, C_{12}–C_{14} vegetable esters of 2-hexanol and palm kernel oil, "low viscosity" C_8 esters, and other oleaginous materials; (2) barite which is known to generally have trace contaminants of several toxic heavy metals such as mercury, cadmium, arsenic, chromium, copper, lead, nickel, and zinc; (3) formation oil which contains toxic and priority pollutants such as benzene, toluene, ethylbenzene, naphthalene, phenanthrene, and phenol; and (4) additives such as emulsifiers, oil wetting agents, filtration control agents, and viscosifiers.

The sediment toxicity of the SBF discharged with cuttings is measured by the modified sediment toxicity test (*i.e.*, ASTM E1367–92: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests With Marine and Estuarine Amphipods" (incorporated by reference and available from ASTM, 100 Bar Harbor Drive, West Conshohocken, PA 19428), supplemented with the preparation procedure specified in Appendix 3 of subpart A of 40 CFR part 435) using a natural sediment or formulated sediment, 96-hour testing period, and *Leptocheirus plumulosus* as the test organism. EPA is today promulgating a sediment toxicity limitation for the SBF discharged with cuttings at the point of discharge that would only allow the discharge of SBF-cuttings using SBFs as toxic or less toxic, but not more toxic, than C_{16}–C_{18} IOs SBFs. Alternatively, this limitation could be expressed in terms of a "SBF sediment toxicity ratio" which is defined as 96-hour LC_{50} of C_{16}–C_{18} internal olefins SBF divided by the 96-hour LC_{50} of the SBF being discharged with cuttings at the point of discharge. EPA is promulgating a SBF sediment toxicity ratio of less than 1.0.

EPA finds that the sediment toxicity test at the point of discharge is practical as an indicator of the sediment toxicity of the drilling fluid at the point of discharge. As previously stated, establishing discharge limits on toxicity encourages the use of less toxic drilling fluids and additives. The modifications to the sediment toxicity test include shortening the test to 96-hours. Shortening the test will allow operators to continue drilling operations while the sediment toxicity test is being conducted on the discharged drilling fluid. Moreover, discriminatory power is substantially reduced for the 10-day test on drilling fluid as compared to the 96-hour test (*i.e.*, the 10-day test is of lower practical use in determining whether a SBF is substantially different from OBFs). Finally, operators discharging WBFs are already complying with a biological test at the point of discharge, the 96-hour SPP toxicity test, which tests whole WBF aquatic toxicity using the test organism *Mysidopsis bahia*.

The promulgated sediment toxicity limitation would be achievable through product substitution. EPA anticipates that the base fluids meeting the sediment toxicity limitation would include vegetable esters, low viscosity esters, and internal olefins. The reference C_{16}–C_{18} IOs SBF will be formulated to meet the specifications in Table 1 and also contained in Appendix 8 of subpart A of 40 CFR part 435. The sediment toxicity discharge limitation is technically and economically achievable because it is based on currently available base fluids that can be used and are used across the wide variety of drilling situations found in U.S. offshore waters. EPA estimates minimal monitoring costs associated with this limitation. Additionally, the sediment toxicity discharge limitation will not lead to an increase of NWQIs.

TABLE 1.—PROPERTIES FOR REFERENCE C_{16}–C_{18} IOS SBF USED IN DISCHARGE SEDIMENT TOXICITY TESTING

Mud weight of SBF discharged with cuttings (pounds per gallon)	Reference C_{16}–C_{18} IOs SBF (pounds per gallon)	Reference C_{16}–C_{18} ISOs SBF synthetic to water ratio (%)
8.5–11	9.0	75/25
11–14	11.5	80/20
> 14	14.5	85/15
Plastic Viscosity (PV), centipoise (cP)		12–30
Yield Point (YP), pounds/100 sq. ft.		10–20
10-second gel, pounds/100 sq. ft.		8–15
10-minute gel, pounds/100 sq. ft.		12–30
Electrical stability, V		> 300

G. NSPS Technology Options Considered and Selected for Drilling Fluid Associated with Drill Cuttings

The general approach followed by EPA for developing NSPS options was to evaluate the best demonstrated SBFs and processes for control of priority toxic, non-conventional, and conventional pollutants. Specifically, EPA evaluated the technologies used as the basis for BPT, BCT and BAT. The Agency considered these options as a starting point when developing NSPS options because the technologies used to control pollutants at existing facilities are fully applicable to new facilities.

EPA has not identified any more stringent treatment technology option which it considered to represent NSPS level of control applicable to the SBF-cuttings wastestream. Further, EPA has made a finding of no barrier to entry based upon the establishment of this level of control for new sources. Therefore, EPA is promulgating that NSPS be established equivalent to BPT and BAT for conventional, priority, and non-conventional pollutants. EPA concluded that NSPS are technologically and economically achievable for the same reasons that BAT is available and BPT is practical. EPA also concluded that NWQIs are reduced under the selected NSPS for new wells due to the increased efficiency of SBF drilling.

EPA concluded that a zero discharge requirement for SBF-cuttings from new sources and the subsequent increased use of OBFs and WBFs would result in: (1) unacceptable NWQIs; and (2) more pollutant loadings to the ocean due to operators switching from SBFs to less efficient WBFs (*see* Sections II.B and V.F).

For the same reasons that the BAT limitations promulgated in today's rule are technologically and economically achievable, the promulgated NSPS are also technologically and economically achievable. EPA's analyses show that under the SBF zero discharge option for all areas as compared to current practice as a basis for new source standards there would be an increase of 3.4 million pounds of cuttings annually shipped to shore for disposal in NOW sites and an increase of 10.2 million pounds of cuttings annually injected. This zero discharge option would lead to an increase in annual fuel use of 18,067 BOE and an increase in annual air emissions of 528 tons. Finally, the SBF zero discharge option for the GOM would lead to an increase of 7.5 million pounds of WBF-cuttings being discharged to U.S. Offshore waters. This pollutant loading increase is a result of operators in U.S. Offshore waters (in the GOM) switching from efficient SBF drilling to less efficient WBF drilling. EPA found these levels of NWQIs unacceptable and rejected the NSPS zero discharge option for SBF-cuttings from new sources, except in Coastal Cook Inlet, Alaska.

H. PSES and PSNS Technology Options

EPA is not establishing pretreatment standards for the facilities covered by this rule. Based on information in the record, EPA has not identified any existing offshore or Cook Inlet coastal oil and gas extraction facilities that discharge SBF and SBF-cuttings to publicly owned treatment works (POTWs), nor are any new facilities projected to direct these wastes in such manner.

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I. Best Management Practices (BMPs) to Demonstrate Compliance with Numeric BAT Limitations and NSPS for Drilling Fluid Associated with Drill Cuttings

Sections 304(e), 308(a), 402(a), and 501(a) of the CWA authorize the Administrator to prescribe BMPs as part of effluent limitations guidelines and standards or as part of a permit (*see* Section II.A.7). The BMP alternatives to numeric limitations and standards in this final rule are directed, among other things, at preventing or otherwise controlling leaks, spills, and discharges of toxic and hazardous pollutants in SBF cuttings wastes (*see* 65 FR 21569 for a list of the toxic and hazardous pollutants controlled by these BMPs).

As discussed in the April 2000 NODA (65 FR 21568), EPA considered three options for the final rule for the BAT limitation and NSPS controlling SBF retained on discharged cuttings: (1) A single numeric discharge limitation with an accompanying compliance test method; (2) allowing operators to choose either a single numeric discharge limitation with an accompanying compliance test method, or as an alternative, a set of BMPs that employs limited cuttings monitoring; or (3) allowing operators to choose either a single numeric discharge limitation with an accompanying compliance test method or an alternative set of BMPs that employ no cuttings monitoring. Under the third BMP option for SBF-cuttings (*i.e.*, cuttings discharged and not monitored), EPA also considered whether to require as part of the BMP option, the use of a cuttings dryer as representative of BAT/NSPS or to make the use of a cuttings dryer optional.

EPA selects the second BMP option (*i.e.*, allowing operators to choose either a single numeric discharge limitation with an accompanying compliance test method, or as an alternative, a set of BMPs that employs limited cuttings monitoring) in the final rule. EPA selects this option as it provides for a reasonable level of flexibility and is based on quantifiable performance measures. EPA analyses show that cuttings monitoring for the first third of the SBF footage drilled for a SBF well interval is a reliable indicator of the remaining two-thirds of the SBF-interval (*see* SBF Statistical Support Document; Docket No. W–98–26, Record No. III.B.a.16; Record No. III.B.b.15). Procedures for demonstrating compliance with the selected BMP option are given in Appendix 7 to subpart A of part 435.

For the final rule, EPA did not have enough data from across a wide variety of drilling conditions (*e.g.*, formation, water depth, rig size) to demonstrate that BMPs without cuttings monitoring are equivalent to a numeric ROC limitation or standard. EPA is also concerned that a set of BMPs without cuttings monitoring is not as objective to enforce. This is because with a numeric limitation or with the selected BMP option with reduced cuttings monitoring, operators will need to keep records demonstrating compliance with the numeric limitation. By contrast, under a BMP option with no numeric limit, there is no objective performance measure. This presents a particular problem offshore, where real-time inspections are not as practical as on land based industries. Therefore, EPA rejected the third BMP option and cuttings dryer sub-option for SBF-cuttings (*i.e.*, allowing operators to choose either a single numeric discharge limitation with an accompanying compliance test method or an alternative set of BMPs that employ no cuttings monitoring). EPA concluded that BMP option one and BMP option two demonstrate the same level of compliance with the well averaged ROC limitation and standard (*see* SBF Statistical Support Document). Therefore, EPA selected BMP option two over BMP option one to provide operators with greater flexibility to demonstrate compliance with the well averaged ROC limitation and standard.

The BMP option promulgated in this final rule includes information collection requirements that are intended to control the discharges of SBF in place of numeric effluent limitations and standards. These information collection requirements include, for example: (1) Training personnel; (2) analyzing spills that occur; (3) identifying equipment items that might need to be maintained, upgraded, or repaired; (4) identifying procedures for waste minimization; (4) performing monitoring (including the operation of monitoring systems) to establish equivalence with a numeric cuttings retention limitation and to detect leaks, spills, and intentional diversion; and (5) generally to periodically evaluate the effectiveness of the BMP alternatives.

BMP option two also requires operators to develop and, when appropriate, amend plans specifying how operators will implement BMP option two, and to certify to the permitting authority that they have done so in accordance with good engineering practices and the requirements of the final regulation. The purpose of those provisions is, respectively, to facilitate the implementation of BMP option two on a site-specific basis and to help the regulating authorities to ensure compliance without requiring the submission of actual BMP Plans. Finally, the recordkeeping provisions are intended to facilitate training, to signal the need for different or more vigorously implemented BMP alternatives, and to facilitate compliance assessment. Details on burden and cost estimates associated with these additional paperwork requirements are discussed in Section IX.D.

VI. Costs and Pollutant Reductions for Final Regulation

A. Compliance Costs

EPA has analyzed the compliance costs and incremental compliance costs or savings beyond current industry practices and requirements, as well as pollutant loadings and incremental loadings or reductions. EPA has performed these analyses for the Gulf of Mexico, offshore California, and coastal Cook Inlet, Alaska, for baseline (current) costs and three control option costs. (Compliance costs were not developed for other offshore regions in Alaska where oil and gas production activity exists because discharges of drill cuttings is not expected to occur in these areas.) The three technology-based options considered are: (1) BAT/NSPS Option 1 (controlled discharge option with discharges from the cuttings dryer and fines removal unit); (2) BAT/NSPS Option 2 (controlled discharge option with discharges from the cuttings dryer but not the fines removal unit); and (3) BAT/NSPS Option 3 (Zero Discharge Option). Compliance costs/savings and pollutant increases/reductions are based on: (1) Projected annual drilling activity in the three geographic regions; (2) model well volumes and waste characteristics; and (3) technology and monitoring costs.

The compliance cost analysis begins with the development of defined populations of wells on a regional and well-type basis, develops per-well estimates from an analysis of line-item costs, and then aggregates costs into total regional and well-type costs by applying per well costs to appropriate populations of wells. EPA estimates baseline compliance costs for current industry waste management practices and for compliance with each regulatory option. EPA then calculated incremental compliance costs, which reflect the difference between compliance costs for a regulatory option and baseline compliance costs and the net compliance costs or savings which incorporate the costs along with savings realized by recovering drilling fluids and more efficient drilling. Tables 2 and 3, for existing and new sources respectively, list the total annual baseline costs, compliance costs, incremental compliance costs, cost savings, and net incremental compliance costs, calculated for each geographic area and regulatory option.

1. Large Volume Discharges

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Table 2: Summary Annual Cost/Savings, Existing Sources (1999$/year)

Technology Basis	Cost (savings) in 1999$/year			
	Gulf of Mexico [wells/year]	Offshore California [wells/year]	Cook Inlet, Alaska [wells/year]	Total [wells/year]
Baseline/Current Practice Technology Costs:				
Discharge with 10.2% retention of SBF on cuttings	29,437,863 [201]	0 [0]	0 [0]	29,437,863 [201]
Zero Discharge via land disposal or onsite injection				
Current OBF-drilled wells	10,034,296 [67]	413,282 [2]	516,602 [2]	10,964,179 [71]
Current WBF-drilled wells	-- [857]	-- [5]	-- [4]	-- [866]
Total Baseline Costs per Area	**39,472,159** [1,125]	**413,282** [7]	**516,602** [6]	**40,402,042** [1,138]
WBF-Related Cost Savings:				Total per Technology:
BAT/NSPS 1: ROP-related rig cost savings	(33,280,000)	0	0	
Discharged WBF cost savings	(15,552,540)	0	0	**(48,832,540)**
BAT/NSPS 2: ROP-related rig cost savings	(33,280,000)	0	0	
Discharged WBF cost savings	(15,552,540)	0	0	**(48,832,540)**
BAT/NSPS 3: Zero Discharge				**0**
Technology Option Costs:				
BAT/NSPS 1: Discharge of SBF cuttings and fines	35,569,256 [264]	0 [0]	266,864 [1]	35,836,120 [265]
Zero Discharge via land disposal or onsite injection				
Projected OBF-drilled wells	5,992,961 [40]	413,282 [2]	349,706 [1]	6,755,969 [43]
Projected WBF-drilled wells	-- [803]	-- [5]	-- [4]	-- [812]
Total BAT/NSPS Option 1	**41,562,237** [1,107]	**413,282** [7]	**616,570** [6]	**42,592,088** [1,120]
BAT/NSPS 2: Discharge SBF cuttings/zero discharge fines	35,749,388 [264]	0 [0]	266,864 [1]	36,016,252 [265]
Zero Discharge via land disposal or onsite injection				
Projected OBF-drilled wells	5,992,981 [40]	413,282 [2]	349,706 [1]	6,755,969 [43]
Projected WBF-drilled wells	-- [803]	-- [5]	-- [4]	-- [812]
Total BAT/NSPS Option 2	**41,742,369** [1,107]	**413,282** [7]	**616,570** [6]	**42,772,221** [1,120]
BAT/NSPS Option 3: Zero Discharge of SBF	5,318,258 [11]	0 [0]	0 [0]	5,318,258 [12]
Zero Discharge via land disposal or onsite injection				
Projected OBF-drilled wells	62,886,162 [237]	413,282 [2]	516,602 [2]	63,816,045 [241]
Projected WBF-drilled wells	-- [877]	-- [5]	-- [4]	-- [886]
Total BAT/NSPS Option 3	**68,204,419** [1,125]	**413,282** [7]	**516,602** [6]	**69,134,303** [1,138]

Technology Basis	Cost (savings) in 1999$/year			
	Gulf of Mexico [wells/year]	Offshore California [wells/year]	Cook Inlet, Alaska [wells/year]	Total [wells/year]
Incremental Compliance Costs (total annual):				
BAT/NSPS 1: Discharge of SBF cuttings and fines	2,090,078	0	99,968	**2,190,046**
BAT/NSPS 2: Discharge SBF cuttings; zero discharge fines	2,270,210	0	99,968	**2,370,178**
BAT/NSPS 3: Zero Discharge	28,732,260	0	0	**28,732,260**
NET Incremental Annual Compliance Costs (Savings):				
BAT/NSPS 1: Discharge SBF cuttings and fines	(46,742,462)	0	99,968	**(46,642,494)**
BAT/NSPS 2: Discharge SBF cuttings/zero discharge fines	(46,562,330)	0	99,968	**(46,462,362)**
BAT/NSPS 3: Zero Discharge	28,732,260	0	0	**28,732,260**

Table 3: Summary Annual Cost/Savings, New Sources (1999$/year)

Technology Basis	Cost (savings) in 1999$/year
	Gulf of Mexico [wells/year-wpy]
Baseline/Current Practice Technology Costs:	
Discharge with 10.2% retention of SBF on cuttings	2,152,540 [20 wpy]
Zero Discharge via land disposal or onsite injection	
Current OBF-drilled wells	221,430 [2 wpy]
Current WBF-drilled wells	-- [38 wpy]
Total Baseline Costs	**2,373,970** [60 wpy]
WBF-Related Cost Savings:	
BAT/NSPS 1: ROP-related rig cost savings	(1,440,000)
Discharged WBF cost savings	(683,505)
Total WBF-Related Cost Savings	**(2,123,505)**
BAT/NSPS 2: ROP-related rig cost savings	(1,440,000)
Discharged WBF cost savings	(683,505)
Total WBF-Related Cost Savings	**(2,123,505)**
BAT/NSPS 3: Zero Discharge	**0**

Technology Basis	Cost (savings) in 1999$/year
	Gulf of Mexico [wells/year-wpy]
Technology Option Costs:	
BAT/NSPS 1: Discharge of SBF cuttings and fines	1,902,672 [24 wpy]
Zero Discharge via land disposal or onsite injection	
Projected OBF-drilled wells	110,715 [1 wpy]
Projected WBF-drilled wells	-- [35 wpy]
Total BAT/NSPS Option 1	**2,013,387** [60 wpy]
BAT/NSPS 2: Discharge SBF cuttings/zero discharge fines	1,906,776 [24 wpy]
Zero Discharge via land disposal or onsite injection	
Projected OBF-drilled wells	110,715 [1 wpy]
Projected WBF-drilled wells	-- [35 wpy]
Total BAT/NSPS Option 2	**2,017,491** [60 wpy]
BAT/NSPS 3: Zero Discharge of SBF	710,889 [3 wpy]
Zero Discharge via land disposal or onsite injection	
Projected OBF-drilled wells	2,039,092 [15 wpy]
Projected WBF-drilled wells	-- [42 wpy]
Total BAT/NSPS Option 3	**2,749,981** [60 wpy]
Incremental Compliance Costs (total annual):	
BAT/NSPS 1: Discharge of SBF cuttings and fines	**(360,583)**
BAT/NSPS 2: Discharge SBF cuttings; zero discharge fines	**(356,479)**
BAT/NSPS 3: Zero Discharge	**376,011**
NET Incremental Annual Compliance Costs (Savings):	
BAT/NSPS 1: Discharge SBF cuttings and fines	**(2,484,088)**
BAT/NSPS 2: Discharge SBF cuttings/zero discharge fines	**(2,479,984)**
BAT/NSPS 3: Zero Discharge	**376,011**

2. Small Volume Discharges

As previously stated, EPA learned that SBF is controlled with zero discharge at the drill floor, in the form of vacuums and sumps to retrieve spilled fluid and associated wash water. EPA also learned that approximately 75 barrels of fine solids and barite, which have an approximate SBF content of 25%, can accumulate in the dead spaces of the mud pit, sand trap, and other equipment in the drilling fluid circulation system. Current practice is to either wash these solids out with water for overboard discharge, or to retain the waste solids for disposal. Several hundred barrels (approximately 200 to 400 barrels) of water are used to wash out the mud pits. Industry representatives also indicated to EPA that those oil and gas extraction operations that discharge wash water and accumulated solids first recover free SBF.

No additional costs were considered for controlling the minor spills of SBF (*e.g.*, < 5 gallons spilled during each drill string connection or disconnection) at the drill floor as: (1) Zero discharge practices for recovering SBF at the drill floor during drilling are the current practice; and (2) current practice is also to recover free SBF from the wash water used at the drill floor. Additionally, since current practice is to first recover free SBF from accumulated solids and discharge the accumulated solids with wash water, no additional costs were considered for controlling these discharges.

EPA did not select zero discharge for management of these accumulated solids and associated wash water. EPA is defining these wastes as being associated with SBF-cuttings and subject to the same requirements as other SBF discharges associated with SBF-cuttings. In particular, the final rule requires operators to first recover free oil from any accumulated solids or associated wash water prior to discharging the accumulated solids and associated wash water. These practices are related to the current BPT limitations (*i.e.*, no discharge of free oil) and current industry practice using solids control equipment in order to comply with the no free oil (sheen test) and SPP toxicity requirements. Accordingly, the requirement to recover free oil from accumulated solids and associated wash water prior to discharge is technologically and economically achievable with no additional NWQIs. Retort monitoring will also be performed on the accumulated solids and the retort monitoring results will be incorporated into the overall well-average SBF retained on cuttings value as described in Appendix 7 of Subpart A of 40 CFR 435.

B. Pollutant Reductions

The methodology for estimating pollutant loadings and incremental pollutant loadings (reductions) effectively parallels that of the compliance cost analysis. The pollutant loadings analysis uses data from EPA and industry sources that quantify the pollutant characteristics of drilling fluids and cuttings waste streams (typically in, or converted to, a per barrel basis). Waste volumes for the four model well types (DWD, DWE, SWD, SWE) are coupled with these per barrel pollutant quantities to obtain per well estimates of pollutant loadings. These per well estimates are then coupled with the same well count data as used in the cost analysis to derive well type and aggregate regional pollutant loadings for the baseline and all options. Similar to the cost analysis, incremental loadings (or removals) are obtained by difference between the estimated loadings of each option less baseline loadings, at both the BAT and NSPS level of control. This methodology is presented in more detail in the SBF Development Document.

The loadings and non-water quality impacts of wastes subject to zero discharge limitations by this rule are important factors in its development. Zero discharge wastes have two fates: they are injected into sub-seabed formations onsite or they are transported to shore for disposal via land farming or injection. The allocation of zero discharge wastes between onsite injection versus onshore disposal follow the same well type and regional assumptions as were used for the cost analysis. Zero discharge loadings (removals) are determined identically to discharge loadings; they are presented in detail in the Development Document and are summarized below.

Table 4 presents a summary of industry-wide results, by region, for BAT baseline loadings, both discharge options, and the zero discharge option, as well as their incremental loadings (removals). Table 5 presents this information for new sources.

The BCT cost test evaluates the reasonableness of BCT candidate technologies as measured from BPT level compliance costs and pollutant reductions. The proposed BCT level of regulatory control is equivalent to the BPT level of control for both the discharge options and the zero discharge option. If there is no incremental difference between BPT and BCT, there is no cost to BCT and thus the option passes both BCT cost tests.

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Table 4: Summary Annual SBF Pollutant Loadings, Existing Sources (lbs/year)

Technology Basis	SBF Pollutant Loadings (reductions) in pounds/year [wells/year-wpy]			
	Gulf of Mexico	Offshore California	Cook Inlet, Alaska	Total
Baseline/Current Practice Technology Loadings:				
Discharge with LTA of 10.2% SBF ROC	237,890,828 [201 wpy]	NA	NA	237,890,828 [201 wpy]
Discharge of WBF and cuttings	2,093,084,293 [857 wpy]	9,617,040 [5 wpy]	8,407,772 [4 wpy]	2,111,109,104 [866 wpy]
Discharge of OBF	0 [67 wpy]	0 [2 wpy]	0 [2 wpy]	0 [71 wpy]
Total Baseline Loadings per Area	2,330,975,121 [1,125 wpy]	9,617,040 [7 wpy]	8,407,772 [6 wpy]	2,348,999,932 [1,138 wpy]
Technology Option Loadings:				
BAT/NSPS Option 1				
Discharge with LTA of 4.03% SBF ROC	259,628,314 [264 wpy]	0 [0 wpy]	552,796 [1 wpy]	260,181,110 [265 wpy]
Discharge of WBF and cuttings	1,963,501,883 [803 wpy]	9,617,040 [5 wpy]	8,407,772 [4 wpy]	1,981,526,694 [812 wpy]
Discharge of OBF	0 [40 wpy]	0 [2 wpy]	0 [1 wpy]	0 [43 wpy]
Total BAT/NSPS Option 1 Loadings per Area	2,223,130,197 [1,107 wpy]	9,617,040 [7 wpy]	8,960,568 [6 wpy]	2,241,707,804 [1,120 wpy]
BAT/NSPS Option 2				
Discharge with LTA of 3.82% SBF ROC	252,066,749 [264 wpy]	0 [0 wpy]	536,696 [1 wpy]	252,603,445 [265 wpy]
Discharge of WBF and cuttings	1,963,501,883 [803 wpy]	9,617,040 [5 wpy]	8,407,772 [4 wpy]	1,981,526,804 [812 wpy]
Discharge of OBF	0 [40 wpy]	0 [2 wpy]	0 [1 wpy]	0 [43 wpy]
Total BAT/NSPS Option 2 Loadings per Area	2,215,568,632 [1,107 wpy]	9,617,040 [7 wpy]	8,944,468 [6 wpy]	2,234,130,139 [1,120 wpy]
BAT/NSPS Option 3 - Zero Discharge				
Discharge of SBF on cuttings	0 [11 wpy]	0 [0 wpy]	0 [1 wpy]	0 [12 wpy]
Discharge of WBF and cuttings	2,144,121,984 [877 wpy]	9,617,040 [5 wpy]	8,407,772 [4 wpy]	2,162,146,796 [886 wpy]
Discharge of OBF	0 [237 wpy]	0 [2 wpy]	0 [1 wpy]	0 [240 wpy]
Total BAT/NSPS Option 3 Loadings per Area	2,144,121,984 [1,125 wpy]	9,617,040 [7 wpy]	8,407,772 [6 wpy]	2,162,146,796 [1,138 wpy]
Incremental Technology Option Loadings (Reductions):				
BAT/NSPS Option 1				(107,292,128)
BAT/NSPS Option 2				(114,869,793)
BAT/NSPS Option 3- Zero Discharge				(186,853,137)

Note: The following terms are used in this table: long-term average (LTA) and retention on cuttings (ROC)

TABLE 5.—SUMMARY ANNUAL SBF POLLUTANT LOADINGS, NEW SOURCES

[In pounds/year]

Technology basis	SBF pollutant loadings (reductions)—Gulf of Mexico
Baseline/Current Practice Technology Loadings:	
Discharge with LTA of 10.2% SBF ROC	17,405,127
Discharge of WBF and cuttings	92,903,606
Discharge of OBF	0
Total Baseline Loadings	110,308,733
Technology Option Loadings:	
BAT/NSPS Option 1.	
Discharge with LTA of 4.03% SBF ROC	20,241,106
Discharge of WBF and cuttings	87,462,923
Discharge of OBF	0
Total NSPS 1 Loadings	107,704,029
BAT/NSPS Option 2.	
Discharge with LTA of 3.82% SBF ROC	19,722,488
Discharge of WBF and cuttings	87,462,923
Discharge of OBF	0
Total NSPS 2 Loadings	107,185,411
BAT/NSPS Option 3—Zero Discharge.	
Discharge of SBF	0
Discharge of WBF and cuttings	100,387,607
Discharge of OBF	0
Total NSPS 3 Loadings	100,387,607
Incremental Technology Option Loadings (Reductions):	
BAT/NSPS Option 1: Discharge with 4.03% retention of SBF on cuttings	(2,604,704)
BAT/NSPS Option 2: Discharge with 3.82% retention of SBF on cuttings	(3,123,322)
BAT/NSPS Option 3: Zero Discharge of SBF-wastes via land disposal or onsite injection	(9,921,126)

NOTE: EPA estimates the following GOM WBF/OBF/SBF new sources: Baseline—38/2/20; BAT/NSPS Option 1 & 2—35/1/24; and BAT/NSPS Option 3—42/15/3. EPA estimates no new sources for Offshore California or Cook Inlet, AK.

NOTE: The following terms are used in this table: long-term average (LTA) and retention on cuttings (ROC).

VII. Economic Impacts of Final Regulation

EPA evaluated the economic effects of the options considered for today's regulation. The methodology and results are presented in detail in the SBF Economic Analysis (EPA–821–B–00–012). The following discussion presents a summary of that analysis and its conclusions. Small business impacts are summarized below and in Section IX.B. Environmental justice issues are summarized in Section IV.C.

A. Impacts Analysis

EPA examined the potential impacts of the rule several ways: effects on drilling well costs, changes to financial performance of drilling facilities and production, impacts on small firms, and secondary impacts. The economic methodology used to examine potential impacts on drilling well costs, firms, and secondary impacts is the same as that used for the February 1999 proposal (*see* 64 FR 5521–5527; February 1999 proposal Economic Analysis (EPA–821–B–98–020)).

In response to comments and new data, EPA developed a series of economic models for existing and new deep water projects in the Gulf of Mexico similar to those used for the Offshore and Coastal rules (*see* 58 FR 12454–12512 and 61 FR 66086–66130). This additional analysis is discussed in the April 2000 NODA (65 FR 21558). The models focus on the deep water Gulf because it is the region with the highest level of current drilling with and future interest in drilling with SBFs. The economic models are based on a cash flow approach. Revenues are based on an assumed price of oil, current and projected production of oil and gas, well production decline rates, and royalty rates. Operating costs are based on an assumed cost per BOE produced. The models are based on data from MMS and industry (*see* Summary of Data to be Used In Economic Modeling for more details on the methodology, data, and parameters on which the models are based and how the models were constructed (Docket No. W–98–26, Section III.G of the Rulemaking Record)) and SBF Economic Analysis, Appendix A. EPA received no comments on this NODA with respect to the economic methodology or the data.

The costs and revenues are compared yearly and the project is assumed to run for 30 years or to shut in when operating costs exceed revenues. That is, the economic models have differing lifetimes according to project characteristics and each model may have a shortened lifetime as a result of incremental costs. The model then calculates the lifetime of the project, total production, and the net present value of the operation (net income of the operation over the life of the project in terms of today's dollars), which includes the net operating earnings, taxes, expenditures on drilling, other capital expenditures, etc. A positive net present value means that the project is a good investment. In these cases, the return is greater than the discount rate,

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which represents the opportunity cost of capital. If the net present value is negative, it means that money would have been better invested elsewhere. For existing projects, the model uses current operations; all expenditures in prior years, such as exploration, delineation, and infrastructure development costs are considered sunk costs and are not addressed. For new projects, the model uses data and parameters about timing of the various phases of exploration, delineation and development, along with cost estimates about costs incurred during these phases to compute a full lifetime financial model of these projects.

Each model is run twice—with and without the change due to pollution control. The models support changes in both directions—*i.e.*, costs or savings. If a model shows the net present value of a project to be positive in the baseline, but would have a negative net present value under any of the regulatory options, some or all of the wells would not be drilled. This difference between baseline and postcompliance would generate production impacts.

The likely outcome of today's rule is an overall savings associated with the ability to discharge SBF cuttings (*see* Section VI.A). The cost model (which provides the input to the economic models) projects that the savings exceed any incremental costs of compliance in the aggregate. EPA does not expect the alternate higher ROC limitation and standard for drilling fluids with the stock base fluid performance of esters to affect costs. EPA expects that operators will likely use ester-based SBFs for the increased flexibility and not for any economic benefits. The results of the economic models indicate no adverse impacts on drilling well costs (exploratory or developmental), project lifetime, or production for both BAT and NSPS projects. There are no adverse impacts on firms, employment, trade, or inflation.

B. Small Business Analysis

Although today's rule will not have a significant economic impact on a substantial number of small entities (*see* Section VII.A), EPA assessed the impacts of the rule on small businesses. The small business analysis is described more fully in Chapter 6 of the SBF Economic Analysis.

The small business definitions and the methodology were outlined in the April 2000 NODA and the February 1999 Proposal Economic Analysis and have not changed. Briefly, EPA relied on the Small Business Administration's size standards to determine whether a firm is a small business. If EPA could not find employment or revenue data to confirm a firm's size, it was classified as "potentially" small. EPA identified 40 small and potentially small firms. As noted in the previous paragraph, today's rule results in cost savings, and EPA projects no adverse impacts on small businesses.

VIII. Water Quality and Non-Water Quality Environmental Impacts of Final Regulation

A. Overview of Water Quality and Non-Water Quality Environmental Impacts

EPA conducted various analyses to assess the impact of the final regulation on water quality, sediment quality, and human health. In general, EPA has found that no adverse impacts are expected from controlled discharges of SBFs.

B. Water Quality Modeling

In order to assess the impacts of potential SBF discharges to the receiving waters, EPA conducted pore water, water column, and sediment guidelines analyses. EPA calculated pollutant concentrations for both the water column and pore water and compared them to the respective EPA recommended marine water quality criteria or to applicable state standards to determine the nature and magnitude of any projected water quality exceedances. Details of the analyses and results are presented in the final SBF Environmental Assessment.

EPA included the discharge of WBFs in the engineering analyses (*see* Section II.A). Environmental impacts such as water column, pore water, fish tissue and human health risk analyses were not estimated for the discharge of WBFs versus the use and discharge of SBF cuttings. However, industry has provided information that drilling is significantly more efficient using SBFs rather than WBFs because hole volumes with SBFs are approximately 1.8 times smaller. Therefore, the pollutant loadings of appropriately controlled SBF discharge are less than pollutant loadings associated with controlled WBF discharge.

1. Water Column Water Quality Analyses

There are no water quality criteria exceedances in the water column for any of the regulatory options being considered including the ROC option based on data from all four cuttings dryer technologies for drilling fluids with the sediment toxicity and biodegradation characteristics of ester-based SBFs which results in a slightly higher LTA. Also, no Alaska state water quality standards are exceeded under the discharge options in Cook Inlet, Alaska.

2. Pore Water Quality Analyses

As described above in Section III.D.1, the addition of several seabed survey data changed the estimated SBF sediment concentration at 100 meters (328 feet) as used in the pore water quality analyses. The revised analyses estimate that baseline (or BPT) pore water pollutant concentrations at 100 meters from the discharge exceed recommended water quality criteria for the heavy metal, chromium, for two model well types, shallow water exploratory and deep water exploratory. There are no pore water exceedances of any of the Alaska state water quality standards for potential Cook Inlet, Alaska discharges. Also, there are no pore water exceedances under the controlled SBF discharges (*i.e.*, BAT/NSPS Options 1 and 2) including the ROC option based on data from all four cuttings dryer technologies for drilling fluids with the sediment toxicity and biodegradation characteristics of ester-based SBFs which results in a slightly higher LTA.

3. Sediment Guidelines Analyses

The EPA proposed sediment guidelines for the protection of benthic organisms assesses potential benthic impacts of certain metals. The revised analyses, based on revised pore water concentrations, result in 2 exceedances only under the baseline (or BPT) conditions. There are no sediment guidelines exceedances under controlled SBF discharge conditions (*i.e.*, BAT/NSPS Options 1 and 2) including the ROC option based on data from all four cuttings dryer technologies for drilling fluids with the sediment toxicity and biodegradation characteristics of ester-based SBFs which results in a slightly higher LTA.

C. Human Health Effects Modeling

The human health risk analyses were revised to incorporate changes to the fish consumption rates (*see* Section III.D.b). The revised analyses show no risk to human health.

D. Seabed Surveys

EPA reviewed the seabed surveys submitted during public comment to the April 2000 NODA. As previously stated, EPA used data from two surveys drilling six wells with SBFs in the environmental assessment analyses. Additionally, EPA also received information on the on-going joint Industry/MMS GOM seabed survey. The Industry/MMS workgroup has completed the first two cruises of the four cruise study (*see* Section III.D.1). Outside of a 50–100' radius from the drilling facility, no visible cuttings accumulations (large or small) were detected at any of the drilling facility survey sites.

E. Energy Impacts

As described in Sections III.E and IV.E, EPA included additional data and revised several parameters in estimating energy impacts of the final SBF rule. EPA estimated the amount of fuel required, expressed as barrels of oil equivalents per year (BOE/yr), to operate the equipment associated with each of the regulatory options as well as the fuel consumed by daily rig operations. EPA also estimated the current energy requirements of WBF discharge in order to determine the relative decrease in impacts of SBF versus WBF use. EPA does not expect the alternate higher ROC limitation and standard for drilling fluids with the stock base fluid performance of esters to affect energy impacts because equipment used under the ester option (*e.g.*, shale shakers, cuttings dryer, fines removal unit) has the same or similar energy requirements. The results of the energy impact analysis are presented in Tables 6 and 7 for existing and new sources, respectively.

TABLE 6.—INCREMENTAL SUMMARY ANNUAL ENERGY IMPACTS, EXISTING SOURCES

Technology basis	Energy impacts: Reductions (Increases)[a] fuel use (BOE/yr)			
	Gulf of Mexico	Offshore California	Cook Inlet, AK	Total
BAT/NSPS Option 1: Discharge with LTA of 4.03% SBF ROC	202,146	0	19	202,165
BAT/NSPS Option 2: Discharge with LTA of 3.82% SBF ROC	195,124	0	0	195,124
BAT/NSPS Option 3: Zero Discharge of SBF-wastes via land disposal or onsite injection	(346,459)	(6,138)	(6,067)	(358,664)

[a] Annual fuel usage reductions or increases are incremental to baseline/current practice (*i.e.*, discharge of SBF-cuttings at 10.2% ROC in the GOM and zero discharge in Offshore California and Cook Inlet, AK).

Note: BOE = Barrels of Oil Equivalent.
Note: The following terms are used in this table: long-term average (LTA) and retention on cuttings (ROC).

TABLE 7.—INCREMENTAL SUMMARY ANNUAL ENERGY IMPACTS, NEW SOURCES

Technology basis	Energy impacts: Reductions (increases)[a] fuel use (BOE/yr)
BAT/NSPS Option 1: Discharge with LTA of 4.03% SBF ROC	6330
BAT/NSPS Option 2: Discharge with LTA of 3.82% SBF ROC	5693
BAT/NSPS Option 3: Zero Discharge of SBF-wastes via land disposal or onsite injection	(18,067)

[a] Annual fuel usage reductions or increases are incremental to baseline/current practice (*i.e.*, discharge of SBF-currings at 10.2% ROC in the GOM).

Note: BOE = Barrels of Oil Equivalent.
Note: The following terms are used in this table: long-term average (LTA) and retention on cuttings (ROC).
Note: EPA estimates no new sources for Offshore California or Cook Inlet, AK.

F. Air Emission Impacts

EPA calculated the air emissions, expressed as short tons per year, resulting from activities associated with each of the regulatory options. Air emissions are a function of the: (1) Type of fuel burned (*e.g.*, natural gas or diesel); and (2) amount of fuel consumed as determined from the length of equipment operation and the fuel consumption rate. The methodology and modeling parameters parallel that of the energy impact analysis as the amount of fuel consumed is the basis for the air emissions analysis. Therefore, the air emissions analysis includes the estimate of emissions of daily rig operations and an estimate of WBF drilling operation air emissions. EPA does not expect the alternate higher ROC limitation and standard for drilling fluids with the stock base fluid performance of esters to affect air emissions because equipment used under the ester option (*e.g.*, shale shakers, cuttings dryer, fines removal unit) has the same or similar air emissions. The results of the air emission analysis are presented in Tables 8 and 9 for existing and new sources, respectively.

TABLE 8.—INCREMENTAL SUMMARY ANNUAL AIR EMISSIONS, EXISTING SOURCES

Technology basis	Annual Air Emission Reductions (Increases)[a] (tons/yr)			
	Gulf of Mexico	Offshore California	Cook Inlet, AK	Total
BAT/NSPS Option 1: Discharge with LTA of 4.03% SBF ROC	3,172	0	0	3,172
BAT/NSPS Option 2: Discharge with LTA of 3.82% SBF ROC	3,074	0	(1)	3,073
BAT/NSPS Option 3: Zero Discharge of SBF-wastes via land disposal or onsite injection	(5,414)	(94)	(94)	(5,602)

[a] Annual air emissions reductions or increases are incremental to baseline/current practice (i.e., discharge of SBF-cuttings at 10.2% ROC in the GOM and zero discharge in Offshore California and Cook Inlet, AK).

Note: 1 ton = 2000 lbs.
Note: The following terms are used in this table: long-term average (LTA) and retention cuttings (ROC).

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TABLE 9.—INCREMENTAL SUMMARY AIR EMISSIONS, NEW SOURCES—GULF OF MEXICO

Technology basis	Annual air emissions reduction (increases) [a] (tons/yr)
BAT/NSPS Option 1: Discharge with LTA of 4.03% SBF ROC	(136)
BAT/NSPS Option 2: Discharge with LTA of 3.82% SBF ROC	(145)
BAT/NSPS Option 3: Zero Discharge of SBF-wastes via land disposal or onsite injection	(528)

[a] Annual air emissions reductions or increases are incremental to baseline/current practice (i.e., discharge of SBF-cuttings at 10.2% ROC in the GOM).

Note: 1 ton = 2000 lbs.
Note: The following terms are used in this table: long-term average (LTA) and retention on cuttings (ROC).
Note: EPA estimates no new sources for Offshore California or Cook Inlet, AK.

G. Air Emissions Monetized Human Health Benefits

EPA estimated emissions associated with each of the regulatory options as part of the NWQI analyses. The pollutants considered in the NWQI analyses are nitrogen oxides (NO_X), volatile organic carbon (VOC), particulate matter (PM), sulfur dioxide (SO_2), and carbon monoxide (CO). Of these pollutants, EPA monetized the human health benefits or impacts associated with VOC, PM, and SO_2 emissions using the methodology presented in the Environmental Assessment of the Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry (EPA–821–B–98–008). Each of these pollutants have human health impacts and reducing these emissions can reduce these impacts.

Several VOCs exhibit carcinogenic and systemic effects and VOCs, in general, are precursors to ground-level ozone, which negatively affects human health and the environment. PM impacts include aggravation of respiratory and cardiovascular disease and altered respiratory tract defense mechanisms. SO_2 impacts include nasal irritation and breathing difficulties in humans and acid deposition in aquatic and terrestrial ecosystems.

The unit values (in 1990 dollars) are $489 to $2,212 per megagram (Mg) of VOC; $10,823 per Mg of PM; and $3,516 to $4,194 per Mg of SO_2. Using the Engineering News Record Construction Cost Index (*see* www.enr.com/cost/costcci.asp) these conversion factors are scaled up using the ratio of 6060:4732 (1999$:1990$). EPA does not expect the alternate higher ROC limitation and standard for drilling fluids with the stock base fluid performance of esters to affect monetized benefits because equipment used under the ester option (*e.g.*, shale shakers, cuttings dryer, fines removal unit) has the same or similar air emissions. Following is a summary of the monetized benefits for each of the regulatory options for both existing and new sources.

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Table 10: Summary of Monetized Human Health Benefits or Impacts Associated with VOC, PM, and SO_2 Emissions, Existing Sources (1999$/yr)

	Criteria Air Pollutant		
	VOC	PM	SO_2
Baseline/Current Practice Air Emissions, Mg/yr:			
Discharge with 10.2% retention of SBF on cuttings	23,635	3,460	3,006
Zero Discharge (current OBF wells only)	847	126	109
Total Baseline Air Emissions, Mg/yr	24,482	3,586	3,115
Compliance Air Emissions, Mg/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	21,960	3,222	2,799
(2) Discharge with 3.82% retention of SBF on cuttings	21,980	3,226	2,803
(3) Zero Discharge [a]	24,919	3,654	3,175
Incremental Compliance Emission Reductions (Increases), Mg/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	2,522	364	316
(2) Discharge with 3.82% retention of SBF on cuttings	2,502	360	312
(3) Zero Discharge [a]	(437)	(68)	(59)
Unit Value of Poll. Reductions, 1990$/Mg: [b]	489 to 2,212	10,823	3,516 to 4,194
Unit Value of Poll. Reductions, 1999$/Mg: [c]	626 to 2,833	13,860	4,503 to 5,371
Incremental Compliance Benefits (Costs), 1998$/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	1,579,429 to 7,144,576	5,049,778	1,423,174 to 1,697,608
(2) Discharge with 3.82% retention of SBF on cuttings	1,566,817 to 7,087,524	4,991,937	1,406,834 to 1,678,118
(3) Zero Discharge [a]	(273,777) to (1,238,434)	(948,091)	(267,560) to (319,154)

[a] via land disposal or on-site offshore injection
[b] conversion factors from *Environmental Assessment of the Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry* (EPA-821-B-98-008)
[c] scaled from 1990$ using the Engineering News Record Construction Cost Index

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Table 11: Summary of Monetized Human Health Benefits or Impacts Associated with VOC, PM, and SO_2 Emissions, New Sources (1999$/yr)

	Criteria Air Pollutant		
	VOC	PM	SO_2
Baseline/Current Industry Practice Air Emissions, Mg/yr:			
Discharge with 10.2% retention of SBF on cuttings	589	86	75
Compliance Air Emissions, Mg/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	813	119	104
(2) Discharge with 3.82% retention of SBF on cuttings	913	134	117
(3) Zero Discharge [a]	998	146	127
Incremental Compliance Emission Reductions (Increases), Mg/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	(224)	(33)	(29)
(2) Discharge with 3.82% retention of SBF on cuttings	(323)	(48)	(41)
(3) Zero Discharge [a]	(409)	(60)	(52)
Unit Value of Poll. Reductions, 1990$/Mg: [b]	489 to 2,212	10,823	3,516 to 4,194
Unit Value of Poll. Reductions, 1999$/Mg: [c]	626 to 2,833	13,860	4,503 to 5,371
Incremental Compliance Benefits (Costs), 1998$/yr:			
(1) Discharge with 4.03% retention of SBF on cuttings	(140,269) to (634,508)	(453,927)	(128,265) to (152,999)
(2) Discharge with 3.82% retention of SBF on cuttings	(202,421) to (915,655)	(658,885)	(186,271) to (222,190)
(3) Zero Discharge [a]	(256,052) to (1,158,253)	(831,151)	(234,472) to (279,686)

[a] via land disposal or on-site offshore injection

[b] conversion factors from *Environmental Assessment of the Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry* (EPA-821-B-98-008)

[c] scaled from 1990$ using the Engineering News Record Construction Cost Index

H. Solid Waste Impacts

EPA calculated the amount of waste cuttings that would be land disposed, injected onshore, and/or injected onsite in each regulatory scenario, and determined that there would be a considerable reduction in the amount of drill cuttings land disposed and injected with the implementation of a controlled discharge option for SBF-cuttings.

EPA's analyses show that under the SBF-cuttings zero discharge option as compared to current practice, for U.S. Offshore waters existing sources, there would be an annual increase of 35 million pounds of cuttings shipped to shore for disposal in non-hazardous oilfield waste (NOW) sites and an increase of 166 million pounds of cuttings injected. In addition, under the SBF-cuttings zero discharge option, operators would use the more toxic OBFs. The zero discharge option for SBF-cuttings would lead to an increase in annual fuel usage of 358,664 BOE and an increase in annual air emissions of 5,602 tons. Finally, the SBF-cuttings zero discharge option in the U.S. Offshore waters would lead to an increase of 51 million pounds of WBF cuttings being discharged to U.S. Offshore waters. This pollutant loading increase is a result of GOM operators switching from efficient SBF drilling to less efficient WBF drilling.

Additionally, EPA's analyses show that under the SBF-cuttings zero discharge option as compared to current practice, for GOM new sources, there would be an annual increase of 3.4 million pounds of drill cuttings shipped to shore for disposal in NOW sites and an increase of 10.2 million pounds of drill cuttings injected. These zero discharge options for SBF-cuttings would lead to an increase in annual fuel use of 18,067 BOE and an increase in annual air emissions of 528 tons. Finally, the SBF-cuttings zero discharge option in the GOM would lead to an increase of 7.5 million pounds of WBF-cuttings being discharged to U.S. Offshore waters. Again, this pollutant loading increase is a result of GOM operators switching from efficient SBF drilling to less efficient WBF drilling.

I. Other Factors

EPA also considered the impact of the effluent limitations guidelines and standards on safety. EPA has identified two safety issues related to drilling fluids: (1) Deleterious vapors generated by organic materials in drilling fluids; and (2) waste hauling activities that increase the risk of injury to workers.

1. Vapors Generated by Organic Materials in Drilling Fluids

One of the key concerns in exploration and production projects is the exposure of wellsite personnel to vapors generated by organic materials in drilling fluids (Docket No. W–98–26, Record No. III.D.12). Areas on the drilling location with the highest exposure potentials are sites near solids control and open pits. These areas are often enclosed in rooms and ventilated to prevent unhealthy levels of vapors from accumulating. If the total volume of organic vapors can be reduced then any potential health effects will also be reduced regardless of the nature of the vapors.

Generally speaking the aromatic fraction of the vapors is the most toxic to the mammalian system. The high volatility and absorbability through the lungs combined with their high lipid solubility serve to increase their toxicity. OBFs have a high aromatic content and vapors generated from using these drilling fluids include aromatics (*e.g.*, alkybenzenes, naphthalenes, and alkyl-naphthalenes), alkanes (*e.g.*, C_7–C_{18} straight chained and branched), and alkenes. Some minerals oils also generate vapors that contain the same types of chemical compounds, but generally at lower concentrations, as those found in the diesel vapors (*e.g.*, aromatics, alkanes, cyclic alkanes, and alkenes). Because SBF are manufactured from compounds with specifically defined compositions, the subsequent compound can exclude toxic aromatics. Consequently, toxic aromatics can be excluded from the vapors generated by using SBFs.

In general, SBFs (*e.g.*, esters, LAOs, PAOs, IOs) generate much lower concentrations of vapors than do OBFs (Docket No. W–98–26, Record No. III.D.12). Moreover, the vapors generated by these SBFs are less toxic than traditional OBFs because they do not contain aromatics.

2. Waste Hauling Activities

Industry has commented in previous effluent guidelines, such as the Coastal Subcategory Oil and Gas Extraction and Development ELG, that a zero discharge requirement would increase the risk of injury to workers due to increased waste hauling activities. These activities include vessel trips to and from the drilling facility to haul waste, transfer of waste from the drilling facility onto a service vessel, and transfer in port onto a barge or dock.

EPA has identified and reviewed additional data sources to determine the likelihood that imposition of a zero discharge limitation on cuttings contaminated with SBF could increase risk of injury due to additional waste hauling demands. The sources of safety data are the U.S. Coast Guard (USCG), the Minerals Management Service (MMS), the American Petroleum Institute (API), and the Offshore Marine Service Association (OMSA). The following is a summary of the findings from this review.

The data indicate that there are reported incidents that are associated with the collection, hauling, and onshore disposal of wastes from offshore. However, the data do not distinguish whether any of these incidents can be attributed to specific waste management activities.

Most offshore incidents are due to human error or equipment failure. The rate at which these incidents occur will not be changed significantly by increased waste management activities. However, if the number of man hours and/or equipment hours are increased, there will be more reportable incidents given an unchanged incident rate. These potential increases may be offset by reduced incident rates through increased training or equipment maintenance and inspection; but these changes cannot be predicted. One indication that training and maintenance can reduce incident rates is a 1998 API report entitled "1997 Summary of U.S. Occupational Injuries, Illnesses, and Fatalities in the Petroleum Industry," which established that injury incident rates have been decreasing over the last 14 years. If this decrease continues, there should be no increase in the number of safety incidents due to a requirement to haul SBF-contaminated cuttings to shore for disposal. The details of this analysis are available in a technical support document in the rule record for today's final rule.

IX. Regulatory Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action." As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public record.

B. Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 USC 601 et. seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rule requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business with fewer than 500 employees for oil and gas production operators and less than $5 million per year in revenues for oil and gas services providers (*i.e.*, the definitions from SBA's size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impact of today's final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Today's rule affects small businesses only; there are no impacts on small governmental jurisdictions or small organizations.

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In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities. Since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives "which minimizes any significant economic impact of the proposed rule on small entities." 5 U.S.C. Sections 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

EPA projects that today's rule will result in operational savings and will have no adverse economic impacts. These conclusions apply to all firms, both large and small. EPA estimates that between five and 40 small businesses (between five and 40% of all firms) are covered by today's rule. If the small businesses are using SBF and continue to do so, or if they switch to SBF, they need to comply with today's effluent limitations. EPA estimates that the operational savings associated with an allowable SBF-cuttings discharge will result in an economic advantage, contrasted to other SBF-cuttings regulatory scenarios. EPA selected the controlled discharge option which will allow operators to use of SBF in place of OBF and WBFs. Using SBFs in place of OBFs will generally shorten the length of the drilling project and eliminate the need to barge to shore or re-inject OBF-waste cuttings, thereby reducing costs and NWQI such as fuel use, air emissions, and land disposal of OBFs. Use of SBFs in place of WBFs would also lead to: (1) a decrease in costs and NWQIs due to the decreased length of the drilling project; and (2) a per well decrease of pollutants discharged due to improved technical performance of SBFs. EPA estimates that the rule will result in annual savings of $48.9 million and no adverse economic impacts to the industry as a whole. Further, after considerable study, EPA's record indicates that there will be no significant economic impacts to any small entity subject to the rule. The SBF Economic Analysis describes these results in more detail. We have therefore conducted that today's final rule will relieve regulatory burden for all small entities.

C. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective February 21, 2001.

D. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2040–0230.

The information collection requirements are related to the optional use of Best Management Practices (BMPs) in order to reduce SBF-cuttings monitoring. Operators that elect to not use the BMP alternative are not subject to the information collection requirements in today's final rule. BMPs are inherently pollution prevention practices. BMPs may include the universe of pollution prevention encompassing production modifications, operational changes, material substitution, materials and water conservation, and other such measures. BMPs include methods to prevent toxic and hazardous pollutants from reaching receiving waters. Because BMPs are most effective when organized into a comprehensive facility BMP Plan, EPA is requiring operators to complete a BMP Plan when they select the BMP alternative.

The BMP alternative requires operators to develop and, when appropriate, amend plans specifying how operators will implement the specified BMP alternative, and to certify to the permitting authority that they have done so in accordance with good engineering practices and the requirements of the regulation. The purpose of those provisions is, respectively, to facilitate the implementation of BMP alternative on a site-specific basis and to help the regulating authorities to ensure compliance without requiring the submission of actual BMP Plans. Finally, the recordkeeping provisions are intended to facilitate training, to signal the need for different or more vigorously implemented BMPs, and to facilitate compliance assessment.

The information collection requirements in the final rule include, for example: (1) Training personnel; (2) analyzing spills that occur; (3) identifying equipment items that might need to be maintained, upgraded, or repaired; (4) identifying procedures for waste minimization; (5) performing monitoring (including the operation of monitoring systems) to establish equivalence with a numeric cuttings retention limitation and to detect leaks, spills, and intentional diversion; and (6) generally to periodically evaluate the effectiveness of the BMP alternatives.

EPA does not expect that any confidential business information or trade secrets will be required from oil and gas extraction operators as part of this ICR. If information submitted in conjunction with this ICR were to contain confidential business information, the respondent has the authority to request that the information be treated as confidential business information. All data so designated will be handled by EPA pursuant to 40 CFR part 2. This information will be maintained according to procedures outlined in EPA's Security Manual Part III, Chapter 9, dated August 9, 1976. Pursuant to section 308(b) of the CWA, effluent data may not be treated as confidential.

EPA estimated the burden and costs to the regulated community (approximately 67 SBF well drilling facilities annually) and EPA, the NPDES permit control authority, for data collection and record keeping associated with implementation of the BMP alternative. EPA estimates the public reporting burden for the selected BMP option as 787 hours per respondent per year (*i.e.*, (16,750 initial hours/3 years + 47,168 annual hours/year)/67 SBF well operators). EPA also estimated the annual burden for EPA Regions, the NPDES permit controlling authorities, to review BMPs and ensure compliance. EPA estimates that essentially all of the SBF discharges will occur in Federal offshore waters or in Cook Inlet, Alaska, where EPA Region X retains NPDES permit controlling authority. The EPA Regional burden for reviewing BMP Plans is estimated at 380 hours per year (*i.e.*, (536 initial hours/3 years + 201 annual hours/year)).

EPA estimates the public reporting costs as $24,058 per respondent per year (*i.e.*, ($1,235,313 initial costs/3 years + $1,200,138 annual costs/year)/67 SBF well operators). The EPA Regional costs for reviewing BMP Plans is estimated at approximately $12,149 per year (*i.e.*, ($17,152 initial costs/3 years + $6,432 annual costs/year)).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. EPA is amending the table in 40 CFR part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

E. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA projects that the effect of the rule will be a operational savings. EPA has estimated this savings at $48.9 million (1999$, post-tax). Thus, today's rule is not subject to the requirements of Sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. EPA projects that no small governments will be affected by this rule as small governments are not engaged in oil and gas extraction operations in offshore and coastal waters or in issuing NPDES permits for oil and gas extraction operations in offshore and coastal waters. Thus, today's rule is not subject to the requirements of section 203 of the UMRA.

F. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084 EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments nor does it impose substantial direct compliance costs on them. EPA has determined that currently, no communities of Indian tribal governments are affected by this rule as Indian tribal governments are not engaged in oil and gas extraction operations in offshore and coastal waters or in issuing NPDES permits for oil and gas extraction operations in offshore and coastal waters. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule establishes effluent limitations and standards imposing requirements that apply to oil and gas extraction operations in offshore and coastal waters. EPA has determined that there are no oil and gas extraction operations in offshore and coastal waters that are owned and operated by State or local governments. Therefore, this rule will not impose any requirements on State or local governments. Further, the rule will not affect State governments' authority to implement CWA and UIC permitting programs. In fact, the final rule may reduce administrative costs on States that have authorized NPDES programs because although these States must incorporate the new limitations and

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standards in new and revised NPDES permits, they no longer will need to make Best Professional Judgement (BPJ) determinations regarding the appropriate level of technology control. We recognize that there may be a small administrative cost to the State of Alaska to assist EPA Region 10 in determining whether Coastal Cook Inlet, Alaska, operators qualify for the SBF-cuttings zero discharge exemption (*see* Section V.F). Thus, Executive Order 13132 does not apply to this rule.

H. National Technology Transfer and Advancement Act

As noted in the proposed rule (64 FR 5528), section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995, Pub L. 104–113 section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This rule involves technical standards. The rule requires dischargers to measure for two metals, PAH content (as phenanthrene), sediment toxicity, aqueous toxicity, biodegradation rate, formation oil content, and base fluid retained on cuttings. EPA performed a search to identify potentially applicable voluntary consensus standards that could be used to measure the parameters in today's rule. EPA did locate several voluntary consensus standards that required modification for inclusion in the final rule. EPA considered public comments on the proposed rule and worked with stakeholders, including the industry sponsored Synthetic Based Muds Research Consortium (SBMRC), to modify or develop new standards for various parameters (*i.e.*, sediment toxicity, biodegradation rate, PAH content (as phenanthrene), formation oil content, base fluid retained on cuttings). EPA has decided to use modified versions of the following voluntary consensus standards: (1) EPA Method 1654A; (2) ASTM E–1367–92; (3) ISO 11734:1995; and (4) API Recommended Practice 13B–2. As indicated by industry comments on the February 1999 proposal and April 2000 NODA, industry stakeholders support the use of these modified voluntary consensus standards (*see* Docket No. W–98–26, Record No. IV.A.a.13).

I. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This final rule is not subject to E.O. 13045 because it is not "economically significant" as defined under Executive Order 12866, and because the rule does not concern an environmental health or safety risk that may have a disproportionate effect on children.

J. Executive Order 13158: Marine Protected Areas

Executive Order 13158 (65 FR 34909, May 31, 2000) requires EPA to "expeditiously propose new science-based regulations, as necessary, to ensure appropriate levels of protection for the marine environment." EPA may take action to enhance or expand protection of existing marine protected areas and to establish or recommend, as appropriate, new marine protected areas. The purpose of the executive order is to protect the significant natural and cultural resources within the marine environment, which means "those areas of coastal and ocean waters, the Great Lakes and their connecting waters, and submerged lands thereunder, over which the United States exercises jurisdiction, consistent with international law."

EPA believes that this final rule is consistent with the objectives of the Executive Order to protect the ocean environment. By encouraging the use of appropriately controlled SBFs in the place of more toxic OBFs, the ocean will be protected from the effects of spills of OBFs and from the effects of disposal of OBFs onshore. By encouraging the use of appropriately controlled SBFs over WBFs, there will much less drilling waste generated and discharged to the ocean per well and the drilling waste discharged will be far less toxic and will biodegrade at a much faster rate than those of traditional drilling fluids.

X. Regulatory Implementation

Upon promulgation of these regulations, the effluent limitations for the appropriate subcategory must be applied in all Federal and State NPDES permits issued to affected direct dischargers in the oil and gas extraction industry. This section discusses the relationship of upset and bypass provisions, variances and modifications, and monitoring requirements.

A. Implementation of Limitations and Standards

Upon the promulgation of these regulations, all new and reissued Federal and State NPDES permits issued to direct dischargers in the oil and gas extraction industry must include the effluent limitations for the appropriate subcategory. Permit writers should be aware that EPA has now finalized revisions to 40 CFR 122.44(a) which could be particularly relevant to the development of NPDES permits for the oil and gas extraction point source category (*see* 65 FR 30989, May 15, 2000). As finalized, the revision would require that permits have limitations for all applicable guidelines-listed pollutants but allows for the waiver of sampling requirements for guideline-listed pollutants on a case-by-case basis if the discharger can certify that the pollutant is not present in the discharge or present in only background levels from intake water with no increase due to the activities of the dischargers. New sources and new dischargers are not eligible for this waiver for their first permit term, and monitoring can be re-established through a minor modification if the discharger expands or changes its process. Further, the permittee must notify the permit writer of any modifications that have taken place over the course of the permit term and, if necessary, monitoring can be reestablished through a minor modification.

B. Upset and Bypass Provisions

A "bypass" is an intentional diversion of waste streams from any portion of a treatment facility. An "upset" is an exceptional incident in which there is unintentional and temporary noncompliance with technology-based permit effluent limitations because of factors beyond the reasonable control of the permittee. EPA's regulations concerning bypasses and upsets are set forth at 40 CFR 122.41(m) and (n), and 40 CFR 403.16 (upset) and 403.17 (bypass). The reader is also referred to the Offshore Guidelines (58 FR 12501) for a discussion on upset and bypass provisions.

C. Variances and Modifications

The CWA requires application of the effluent limitations and standards established pursuant to section 301, 304, 306, or the pretreatment standards of section 307 to all direct and indirect dischargers. However, section 301(n) provides for the modification of these national requirements in a limited number of circumstances. Moreover, the Agency has established administrative mechanisms to provide an opportunity for relief from the application of national effluent limitations guidelines and pretreatment standards for categories of existing sources for priority, conventional and non-conventional pollutants (*e.g.*, fundamentally different factor variances, removal credits).

The Fundamentally Different Factors (FDF) variances considers those facility specific factors which a permittee may consider to be uniquely different from those considered in the formulation of an effluent limitations guidelines as to make the limitation inapplicable. An FDF variance must be based only on information submitted to EPA during the rulemaking establishing the effluent limitations guidelines from which the variance is being requested, or on information the applicant did not have a reasonable opportunity to submit during the rulemaking process for these effluent limitations guidelines. FDF variance requests must be received by the permitting authority within 180 days of publication of the final rule. The specific regulations covering the requirements for the administration of FDF variances are found at 40 CFR 122.21(m)(1), and 40 CFR part 125, subpart D.

D. Relationship of Effluent Limitations to NPDES Permits and Monitoring Requirements

Effluent limitations act as a primary mechanism to control the discharges of pollutants to waters of the United States. These limitations are applied to individual facilities through NPDES permits issued by EPA or authorized States under section 402 of the Act.

The Agency has developed the limitations for this regulation to cover the discharge of pollutants for this industrial category. In specific cases, the NPDES permitting authority may elect to establish technology-based permit limits for pollutants not covered by this regulation. In addition, if State water quality standards or other provisions of State or Federal Law require limits on pollutants not covered by this regulation (or require more stringent limits on covered pollutants), the permitting authority must apply those limitations.

Working in conjunction with the effluent limitations are the monitoring conditions set out in a NPDES permit. An integral part of the monitoring conditions is the point at which a facility must monitor to demonstrate compliance. The point at which a sample is collected can have a dramatic effect on the monitoring results for that facility. Therefore, it may be necessary to require internal monitoring points in order to ensure compliance. Authority to address internal waste streams is provided in 40 CFR 122.44(i)(1)(iii) and 122.45(h). Permit writers may establish additional internal monitoring points to the extent consistent with EPA's regulations.

An important component of the monitoring requirements established by the permitting authority is the frequency at which monitoring is required. In costing the various technology options for the oil and gas extraction industry, EPA assumed yearly SBF stock limitations monitoring for mercury, cadmium, PAH (as phenanthrene), sediment toxicity, and biodegradation rates and daily or monthly monitoring for diesel oil contamination, formation oil contamination, base fluid retained on cuttings, aqueous toxicity, and sediment toxicity. These monitoring frequencies may be lower than those generally imposed by some permitting authorities, but EPA believes these reduced frequencies are appropriate due to the relative costs of monitoring when compared to the estimated costs of complying with the promulgated limitations.

E. Analytical Methods

Section 304(h) of the Clean Water Act directs EPA to promulgate guidelines establishing test procedures for the analysis of pollutants. These test procedures (methods) are used to determine the presence and concentration of pollutants in wastewater, and are used for compliance monitoring and for filing applications for the NPDES program under 40 CFR 122.21, 122.41, 122.44 and 123.25, and for the implementation of the pretreatment standards under 40 CFR 403.10 and 403.12. To date, EPA has promulgated methods for conventional pollutants, toxic pollutants, and for some non-conventional pollutants. The five conventional pollutants are defined at 40 CFR 401.16. Table I–B at 40 CFR part 136 lists the analytical methods approved for these pollutants. The 65 toxic metals and organic pollutants and classes of pollutants are defined at 40 CFR 401.15. From the list of 65 classes of toxic pollutants EPA identified a list of 126 "Priority Pollutants." This list of Priority Pollutants is shown, for example, at 40 CFR part 423, Appendix A. The list includes non-pesticide organic pollutants, metal pollutants, cyanide, asbestos, and pesticide pollutants.

Currently approved methods for metals and cyanide are included in the table of approved inorganic test procedures at 40 CFR 136.3, Table I–B. Table I–C at 40 CFR 136.3 lists approved methods for measurement of non-pesticide organic pollutants, and Table I–D lists approved methods for the toxic pesticide pollutants and for other pesticide pollutants. Dischargers must use the test methods promulgated at 40 CFR 136.3 or incorporated by reference in the tables, when available, to monitor pollutant discharges from the oil and gas industry, unless specified otherwise in part 435 or by the permitting authority.

As part this rule, EPA is promulgating the use of analytical methods for determining additional parameters that are specific to characterizing SBFs and other drilling fluids which do not disperse in water. These additional stock base fluid parameters include PAH content (as phenanthrene), sediment toxicity, and biodegradation rate. Additional discharge limitations include prohibition of diesel oil discharge, formation (crude) oil contamination, aqueous phase toxicity, sediment toxicity, and quantity of drilling fluid discharged with cuttings.

EPA worked with stakeholders to identify methods for determining these parameters. For PAH content (as phenanthrene), EPA is promulgating the use of EPA Method 1654A. For biodegradation rate, EPA is promulgating the use of the anaerobic closed bottle biodegradation test (*i.e.*, ISO 11734:1995) as modified for the marine environment (*i.e.*, Appendix 4 of subpart A of 40 CFR part 435). For base fluid sediment toxicity, EPA is promulgating the use of the American Society for Testing and Material (ASTM) Method E–1367–92 supplemented with sediment preparation procedures (*i.e.*, Appendix 3 of subpart A of 40 CFR part 435). For drilling fluid sediment toxicity, EPA is promulgating the use of ASTM Method E–1367–92 supplemented with sediment preparation procedures (*i.e.*, Appendix 3 of subpart A of 40 CFR part 435) and reference drilling fluid preparation procedures (*i.e.*, Appendix 8 of subpart

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A of 40 CFR part 435). For aqueous toxicity, EPA is promulgating the use of the Suspended Particulate Phase (SPP) toxicity test (Appendix 2 of subpart A of 40 CFR part 435). For formation (crude) oil contamination in drilling fluid, EPA is promulgating the use of two methods: a reverse phase extraction fluorescence test (RPE) and a gas chromatography/mass spectrometry (GC/MS) test. The RPE test (*i.e.*, Appendix 6 of subpart A of 40 CFR part 435) is a screening method that provides a quick and inexpensive determination of oil contamination for use on offshore well drilling sites, while the GC/MS test (*i.e.*, Appendix 5 of subpart A of 40 CFR part 435) provides: (1) A definitive identification and quantification of oil contamination for baseline analysis; and (2) confirmatory results for the RPE when the RPE results need confirmation. For determining the quantity of drilling fluid discharged with cuttings, EPA is promulgating the use of the American Petroleum Institute (API) Retort Method (Recommended Practice 13B–2) with sampling procedures (*i.e.*, Appendix 7 of subpart A of 40 CFR part 435). For determining when Coastal Cook Inlet, Alaska, operators qualify for an exemption from the Coastal requirement of zero discharge for SBF-cuttings, EPA is promulgating the use of the procedure outlined in Appendix 1 of subpart D of 40 CFR part 435.

EPA Method 1654A, ASTM E–1367–92, and ISO 11734:1995 are incorporated by reference into 40 CFR part 435 because they are published methods that are widely available to the public. Modifications to the anaerobic closed bottle biodegradation test (*i.e.*, ISO 11734:1995) are provided in Appendix 4 of subpart A of 40 part 435. The SPP toxicity test is given in Appendix 2 of subpart A of 40 part 435. Supplemental sediment preparation procedures for ASTM E–1367–92 are provided in Appendix 3 of subpart A of 40 CFR part 435. Reference drilling fluid preparation procedures for ASTM E–1367–92 are provided in Appendix 8 of subpart A of 40 CFR part 435. The text of the GC/MS test, RPE test, and the API retort method are provided in Appendices 5–7 of subpart A of 40 CFR part 435. The procedure for determining when Coastal Cook Inlet operators qualify for an exemption from the Coastal requirement of zero discharge for SBF-cuttings is provided in Appendix 1 of subpart D of 40 CFR part 435.

Appendix A to the Preamble—Abbreviations, Acronyms, and Other Terms Used in This Preamble

Act—Clean Water Act
Agency—U.S. Environmental Protection Agency
AOGCC—Alaska Oil and Gas Conservation Commission
API—American Petroleum Institute
ANL—Argonne National Laboratory (DOE)
ASTM—American Society of Testing and Materials
BADCT—The best available demonstrated control technology, for new sources under section 306 of the Clean Water Act.
BAT—The best available technology economically achievable, under section 304(b)(2)(B) of the Clean Water Act.
bbl—barrel, 42 U.S. gallons
BCT—Best conventional pollutant control technology under section 304(b)(4)(B).
BMP—Best management practices under section 304(e) of the Clean Water Act.
BOD—Biochemical oxygen demand.
BOE—Barrels of oil equivalent
BPJ—Best Professional Judgement
BPT—Best practicable control technology currently available, under section 304(b)(1) of the Clean Water Act.
CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act
CFR—U.S. Code of Federal Regulations
Clean Water Act—Federal Water Pollution Control Act Amendments of 1972 as amended (33 U.S.C. 1251 *et seq*)
Conventional pollutants—Constituents of wastewater as determined by section 304(a)(4) of the Act, including, but no limited to, pollutants classified as biochemical oxygen demanding, suspended solids, oil and grease, fecal coliform, and pH
Direct discharger—A facility which discharges or may discharge pollutants to waters of the United States
D&B—Dun & Bradstreet
DOE—U.S. Department of Energy
DWD—Deep-water development model well
DWE—Deep-water exploratory model well
EMO—Enhanced Mineral Oil Drilling Fluid
EPA—U.S. Environmental Protection Agency
FR—Federal Register
GC—Gas Chromatography
GC/FID—Gas Chromatography with Flame Ionization Detection
GC/MS—Gas Chromatography with Mass Spectroscopy Detection
GOM—Gulf of Mexico
Indirect discharger—A facility that introduces wastewater into a publicly owned treatment works.
IRFA—Initial Regulatory Flexibility Analysis
LC_{50} (or LC50)—The concentration of a test material that is lethal to 50% of the test organisms in a bioassay
mg/l—milligrams per liter
MMS—U.S. Department of Interior, Minerals Management Service
NAF—Non-Aqueous Drilling Fluid (includes OBFs, EMOs, and SBFs)
Non-conventional pollutants—Pollutants that have not been designated as either conventional pollutants or priority pollutants
NODA—Notice of Data Availability (65 FR 21548; April 21, 2000)
NOIA—National Ocean Industries Association
NOW—Nonhazardous Oilfield Waste
NPDES—National Pollutant Discharge Elimination System
NRDC—Natural Resources Defense Council, Inc.
NSPS—New source performance standards under section 306 of the Clean Water Act
NTTAA—National Technology Transfer and Advancement Act
NWQI—Non-Water Quality Environmental Impacts
OBF—Oil-Based Drilling Fluid
OCS—Outer Continental Shelf
OMB—Office of Management and Budget
PAH—Polynuclear Aromatic Hydrocarbon
PDC—Polycrystalline Diamond Compact (drill bit)
POTW—Publicly Owned Treatment Works
ppm—parts per million
PPA—Pollution Prevention Act of 1990
Priority pollutants—The 65 pollutants and classes of pollutants declared toxic under section 307(a) of the Clean Water Act
PSES—Pretreatment standards for existing sources of indirect discharges, under section 307(b) of the Act
PSNS—Pretreatment standards for new sources of indirect discharges, under sections 307(b) and (c) of the Act
RFA—Regulatory Flexibility Act
ROC—Retention on Cuttings
RPE—Reverse Phase Extraction
SBA—U.S. Small Business Administration
SBF—Synthetic Based Drilling Fluid
SBF Development Document—Development Document for Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category (EPA–821–B–00–013)
SBF Economic Analysis—Economic Analysis of Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category (EPA–821–B–00–012)
SBF Environmental Assessment—Environmental Assessment of Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category (EPA–821–B–00–014)
SBF Statistical Support Document—Statistical Analyses Supporting Final Effluent Limitations Guidelines and Standards for Synthetic-Based Drilling Fluids and other Non-Aqueous Drilling Fluids in the Oil and Gas Extraction Point Source Category (EPA–821–B–00–015)
SBMRC—Synthetic Based Muds Research Consortium
SBREFA—Small Business Regulatory Enforcement Fairness Act
SIC—Standard Industrial Classification
SPP—Suspended Particulate Phase toxicity test (Appendix 2 to Subpart A of 40 CFR 435)
SWD—Shallow-water development model well
SWE—Shallow-water exploratory model well
TSS—Total Suspended Solids
UMRA—Unfunded Mandates Reform Act
UIC—Underground Injection Control programs of the Safe Drinking Water Act of 1974 as amended
U.S.C.—United States Code
WBF—Water-Based Drilling Fluid

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 435

Environmental protection, Non-aqueous drilling fluids, Oil and gas extraction, Pollution prevention, Synthetic based drilling fluids, Waste treatment and disposal, Water non-dispersible drilling fluids, Water pollution control.

Dated: December 28, 2000.

Carol M. Browner,

Administrator.

For the reasons set forth in this preamble, 40 CFR parts 9 and 435 are amended as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. In § 9.1 the table is amended by adding entries in numerical order under a new heading titled "Oil and Gas Extraction Point Source Category" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Oil and Gas Extraction Point Source Category:	
435.13	2040–0230
435.15	2040–0230
435.43	2040–0230
435.45	2040–0230
* * * * *	

PART 435—OIL AND GAS EXTRACTION POINT SOURCE CATEGORY

1. The authority citation for Part 435 is revised to read as follows:

Authority: 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342 and 1361.

Subpart A—Offshore Subcategory

2. Section 435.11 is amended by revising paragraphs (b) through (cc) and by adding paragraphs (dd) through (tt) to read as follows:

§ 435.11 Special definitions.

* * * * *

(b) *Average of daily values for 30 consecutive days* means the average of the daily values obtained during any 30 consecutive day period.

(c) *Base fluid* means the continuous phase or suspending medium of a drilling fluid formulation.

(d) *Base fluid retained on cuttings* as applied to BAT effluent limitations and NSPS refers to the American Petroleum Institute Recommended Practice 13B–2 supplemented with the specifications, sampling methods, and averaging method for retention values provided in Appendix 7 of Subpart A of this part.

(e) *Biodegradation rate* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings refers to the ISO 11734:1995 method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" supplemented with modifications in Appendix 4 of 40 CFR part 435, subpart A. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

(f) *Daily values* as applied to produced water effluent limitations and NSPS means the daily measurements used to assess compliance with the maximum for any one day.

(g) *Deck drainage* means any waste resulting from deck washings, spillage, rainwater, and runoff from gutters and drains including drip pans and work areas within facilities subject to this Subpart.

(h) *Development facility* means any fixed or mobile structure subject to this subpart that is engaged in the drilling of productive wells.

(i) *Diesel oil* refers to the grade of distillate fuel oil, as specified in the American Society for Testing and Materials Standard Specification for Diesel Fuel Oils D975–91, that is typically used as the continuous phase in conventional oil-based drilling fluids. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

(j) *Domestic waste* means materials discharged from sinks, showers, laundries, safety showers, eye-wash stations, hand-wash stations, fish cleaning stations, and galleys located within facilities subject to this Subpart.

(k) *Drill cuttings* means the particles generated by drilling into subsurface geologic formations and carried out from the wellbore with the drilling fluid. Examples of drill cuttings include small pieces of rock varying in size and texture from fine silt to gravel. Drill cuttings are generally generated from solids control equipment and settle out and accumulate in quiescent areas in the solids control equipment or other equipment processing drilling fluid (*i.e.*, accumulated solids).

(l) *Wet drill cuttings* means the unaltered drill cuttings and adhering drilling fluid and formation oil carried out from the wellbore with the drilling fluid.

(2) *Dry drill cuttings* means the residue remaining in the retort vessel after completing the retort procedure specified in appendix 7 of subpart A of this part.

(l) *Drilling fluid* means the circulating fluid (mud) used in the rotary drilling of wells to clean and condition the hole and to counterbalance formation pressure. Classes of drilling fluids are:

(1) *Water-based drilling fluid* means the continuous phase and suspending

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medium for solids is a water-miscible fluid, regardless of the presence of oil.

(2) *Non-aqueous drilling fluid* means the continuous phase and suspending medium for solids is a water-immiscible fluid, such as oleaginous materials (*e.g.*, mineral oil, enhanced mineral oil, paraffinic oil, C_{16}–C_{18} internal olefins, and C_6–C_{16} fatty acid/2-ethylhexyl esters).

(i) *Oil-based* means the continuous phase of the drilling fluid consists of diesel oil, mineral oil, or some other oil, but contains no synthetic material or enhanced mineral oil.

(ii) *Enhanced mineral oil-based* means the continuous phase of the drilling fluid is enhanced mineral oil.

(iii) *Synthetic-based* means the continuous phase of the drilling fluid is a synthetic material or a combination of synthetic materials.

(m) *Enhanced mineral oil* as applied to enhanced mineral oil-based drilling fluid means a petroleum distillate which has been highly purified and is distinguished from diesel oil and conventional mineral oil in having a lower polycyclic aromatic hydrocarbon (PAH) content. Typically, conventional mineral oils have a PAH content on the order of 0.35 weight percent expressed as phenanthrene, whereas enhanced mineral oils typically have a PAH content of 0.001 or lower weight percent PAH expressed as phenanthrene.

(n) *Exploratory facility* means any fixed or mobile structure subject to this Subpart that is engaged in the drilling of wells to determine the nature of potential hydrocarbon reservoirs.

(o) *Formation oil* means the oil from a producing formation which is detected in the drilling fluid, as determined by the GC/MS compliance assurance method specified in appendix 5 of subpart A of this part when the drilling fluid is analyzed before being shipped offshore, and as determined by the RPE method specified in appendix 6 of subpart A of this part when the drilling fluid is analyzed at the offshore point of discharge. Detection of formation oil by the RPE method may be confirmed by the GC/MS compliance assurance method, and the results of the GC/MS compliance assurance method shall supercede those of the RPE method.

(p) *M9IM* means those offshore facilities continuously manned by nine (9) or fewer persons or only intermittently manned by any number of persons.

(q) *M10* means those offshore facilities continuously manned by ten (10) or more persons.

(r) *Maximum* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings means the maximum concentration allowed as measured in any single sample of the barite for determination of cadmium and mercury content.

(s) *Maximum for any one day* as applied to BPT, BCT and BAT effluent limitations and NSPS for oil and grease in produced water means the maximum concentration allowed as measured by the average of four grab samples collected over a 24-hour period that are analyzed separately. Alternatively, for BAT and NSPS the maximum concentration allowed may be determined on the basis of physical composition of the four grab samples prior to a single analysis.

(t) *Maximum weighted mass ratio averaged over all NAF well sections* for BAT effluent limitations and NSPS for base fluid retained on cuttings means the weighted average base fluid retention for all NAF well sections as determined by the API Recommended Practice 13B–2, using the methods and averaging calculations presented in Appendix 7 of subpart A of this part.

(u) *Method 1654A* refers to Method 1654, Revision A, entitled "PAH Content of Oil by HPLC/UV," December 1992, which is published in *Methods for the Determination of Diesel, Mineral, and Crude Oils in Offshore Oil and Gas Industry Discharges*, EPA–821–R–92–008. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Technical Information Service, Springfield, VA 22161, 703–605–6000. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

(v) *Minimum* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings means the minimum 96-hour LC_{50} value allowed as measured in any single sample of the discharged waste stream. *Minimum* as applied to BPT and BCT effluent limitations and NSPS for sanitary wastes means the minimum concentration value allowed as measured in any single sample of the discharged waste stream.

(w)(1) *New source* means any facility or activity of this subcategory that meets the definition of "new source" under 40 CFR 122.2 and meets the criteria for determination of new sources under 40 CFR 122.29(b) applied consistently with all of the following definitions:

(i) *Water area* as used in "site" in 40 CFR 122.29 and 122.2 means the water area and water body floor beneath any exploratory, development, or production facility where such facility is conducting its exploratory, development or production activities.

(ii) *Significant site preparation work* as used in 40 CFR 122.29 means the process of surveying, clearing or preparing an area of the water body floor for the purpose of constructing or placing a development or production facility on or over the site.

(2) "New Source" does not include facilities covered by an existing NPDES permit immediately prior to the effective date of these guidelines pending EPA issuance of a new source NPDES permit.

(x) *No discharge of free oil* means that waste streams may not be discharged that contain free oil as evidenced by the monitoring method specified for that particular stream, *e.g.*, deck drainage or miscellaneous discharges cannot be discharged when they would cause a film or sheen upon or discoloration of the surface of the receiving water; drilling fluids or cuttings may not be discharged when they fail the static sheen test defined in Appendix 1 of subpart A of this part.

(y) Parameters that are regulated in this Subpart and listed with approved methods of analysis in Table 1B at 40 CFR 136.3 are defined as follows:

(1) *Cadmium* means total cadmium.

(2) *Chlorine* means total residual chlorine.

(3) *Mercury* means total mercury.

(4) *Oil and Grease* means total recoverable oil and grease.

(z) *PAH (as phenanthrene)* means polynuclear aromatic hydrocarbons reported as phenanthrene.

(aa) *Produced sand* means the slurried particles used in hydraulic fracturing, the accumulated formation sands and scales particles generated during production. Produced sand also includes desander discharge from the produced water waste stream, and blowdown of the water phase from the produced water treating system.

(bb) *Produced water* means the water (brine) brought up from the hydrocarbon-bearing strata during the extraction of oil and gas, and can include formation water, injection water, and any chemicals added downhole or during the oil/water separation process.

(cc) *Production facility* means any fixed or mobile structure subject to this Subpart that is either engaged in well completion or used for active recovery of hydrocarbons from producing formations.

(dd) *Sanitary waste* means the human body waste discharged from toilets and urinals located within facilities subject to this Subpart.

(ee) *Sediment toxicity* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings refers to the ASTM E 1367–92 method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, with Leptocheirus plumulosus as the test organism and sediment preparation procedures specified in Appendix 3 of 40 CFR part 435, subpart A. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

(ff) *Solids control equipment* means shale shakers, centrifuges, mud cleaners, and other equipment used to separate drill cuttings and/or stock barite solids from drilling fluid recovered from the wellbore.

(gg) *SPP toxicity* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings refers to the bioassay test procedure presented in Appendix 2 of subpart A of this part.

(hh) *Static sheen test* means the standard test procedure that has been developed for this industrial subcategory for the purpose of demonstrating compliance with the requirement of no discharge of free oil. The methodology for performing the static sheen test is presented in Appendix 1 of subpart A of this part.

(ii) *Stock barite* means the barite that was used to formulate a drilling fluid.

(jj) *Stock base fluid* means the base fluid that was used to formulate a drilling fluid.

(kk) *Synthetic material* as applied to synthetic-based drilling fluid means material produced by the reaction of specific purified chemical feedstock, as opposed to the traditional base fluids such as diesel and mineral oil which are derived from crude oil solely through physical separation processes. Physical separation processes include fractionation and distillation and/or minor chemical reactions such as cracking and hydro processing. Since they are synthesized by the reaction of purified compounds, synthetic materials suitable for use in drilling fluids are typically free of polycyclic aromatic hydrocarbons (PAH's) but are sometimes found to contain levels of PAH up to 0.001 weight percent PAH expressed as phenanthrene. Internal olefins and vegetable esters are two examples of synthetic materials suitable for use by the oil and gas extraction industry in formulating drilling fluids. Internal olefins are synthesized from the isomerization of purified straight-chain (linear) hydrocarbons such as C_{16}–C_{18} linear alpha olefins. C_{16}–C_{18} linear alpha olefins are unsaturated hydrocarbons with the carbon to carbon double bond in the terminal position. Internal olefins are typically formed from heating linear alpha olefins with a catalyst. The feed material for synthetic linear alpha olefins is typically purified ethylene. Vegetable esters are synthesized from the acid-catalyzed esterification of vegetable fatty acids with various alcohols. EPA listed these two branches of synthetic fluid base materials to provide examples, and EPA does not mean to exclude other synthetic materials that are either in current use or may be used in the future. A synthetic-based drilling fluid may include a combination of synthetic materials.

(ll) *Well completion fluids* means salt solutions, weighted brines, polymers, and various additives used to prevent damage to the well bore during operations which prepare the drilled well for hydrocarbon production.

(mm) *Well treatment fluids* means any fluid used to restore or improve productivity by chemically or physically altering hydrocarbon-bearing strata after a well has been drilled.

(nn) *Workover fluids* means salt solutions, weighted brines, polymers, or other specialty additives used in a producing well to allow for maintenance, repair or abandonment procedures.

(oo) *4-day LC_{50}* as applied to the sediment toxicity BAT effluent limitations and NSPS means the concentration (milligrams/kilogram dry sediment) of the drilling fluid in sediment that is lethal to 50 percent of the Leptocheirus plumulosus test organisms exposed to that concentration of the drilling fluids after four days of constant exposure.

(pp) *10-day LC_{50}* as applied to the sediment toxicity BAT effluent limitations and NSPS means the concentration (milligrams/kilogram dry sediment) of the base fluid in sediment that is lethal to 50 percent of the Leptocheirus plumulosus test organisms exposed to that concentration of the base fluids after ten days of constant exposure.

(qq) *96-hour LC_{50}* means the concentration (parts per million) or percent of the suspended particulate phase (SPP) from a sample that is lethal to 50 percent of the test organisms exposed to that concentration of the SPP after 96 hours of constant exposure.

(rr) *C_{16}–C_{18} internal olefin* means a 65/35 blend, proportioned by mass, of hexadecene and octadecene, respectively. Hexadecene is an unsaturated hydrocarbon with a carbon chain length of 16, an internal double carbon bond, and is represented by the Chemical Abstracts Service (CAS) No. 26952–14–7. Octadecene is an unsaturated hydrocarbon with a carbon chain length of 18, an internal double carbon bond, and is represented by the Chemical Abstracts Service (CAS) No. 27070–58–2. (Properties available from the Chemical Abstracts Service, 2540 Olentangy River Road, PO Box 3012, Columbus, OH, 43210).

(ss) *C_{16}–C_{18} internal olefin drilling fluid* means a C_{16}–C_{18} internal olefin drilling fluid formulated as specified in Appendix 8 of subpart A of this part.

(tt) *C_{12}–C_{14} ester* and *C_8 ester* means the fatty acid/2-ethylhexyl esters with carbon chain lengths ranging from 8 to 16 and represented by the Chemical Abstracts Service (CAS) No. 135800–37–2. (Properties available from the Chemical Abstracts Service, 2540 Olentangy River Road, PO Box 3012, Columbus, OH, 43210)

3. In § 435.12 the table is amended by removing the entries "Drilling muds" and "Drill cuttings" and by adding new entries (after "Deck drainage") for "Water based" and "Non-aqueous" to read as follows:

§ 435.12 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

* * * * *

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BPT EFFLUENT LIMITATIONS—OIL AND GREASE

[In milligrams per liter]

Pollutant parameter waste source	Maximum for any 1 day	Average of values for 30 consecutive days shall not exceed	Residual chlorine minimum for any 1 day
Water-based:			
Drilling fluids	(1)	(1)	NA
Drill Cuttings	(1)	(1)	NA
Non-aqueous:			
Drilling fluids	No discharge	No discharge	NA
Drill Cuttings	(1)	(1)	NA

[1] No discharge of free oil.

* * * * *

4. In § 435.13 the table is amended by revising entry (B) under "Drilling fluids and drill cuttings" and by revising footnote 2 and adding footnotes 5–11 to read as follows:

§ 435.13 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

* * * * *

BAT EFFLUENT LIMITATIONS

Waste source	Pollutant parameter	BAT effluent limitation
Drilling fluids and drill cuttings:		
(B) For facilities located beyond 3 miles from shore:		
Water-based drilling fluids and associated drill cuttings.	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test[2] shall be 3% by volume.
	Free oil	No discharge.[3]
	Diesel oil	No discharge.
	Mercury	1 mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
Non-aqueous drilling fluids (NAFs).		No discharge.
Drill cuttings associated with non-aqueous drilling fluids:		
Stock Limitations (C_{16}–C_{18} internal olefin).	Mercury	1 mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
	Polynuclear Aromatic Hydrocarbons (PAH).	PAH mass ratio[5] shall not exceed $1x10^{-3}$.
	Sediment toxicity	Base fluid sediment toxicity ratio[6] shall not exceed 1.0.
	Biodegradation rate	Biodegradation rate ratio[7] shall not exceed 1.0.
Discharge Limitations	Diesel oil	No discharge.
	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test[2] shall be 3% by volume.
	Sediment toxicity	Drilling fluid sediment toxicity ratio[8] shall not exceed 1.0.
	Formation Oil	No discharge.[9]
	Base fluid retained on cuttings	For NAFs that meet the stock limitations (C_{16}–C_{18} internal olefin) in this table, the maximum weighted mass ratio averaged over all NAF well sections shall be 6.9 g-NAF base fluid/100 g-wet drill cuttings.[10] For NAFs that meet the C_{12}–C_{14} ester or C_8 ester stock limitations in footnote 11 of this table, the maximum weighted mass ratio averaged over all NAF well sections shall be 9.4 g-NAF base fluid/100 g-wet drill cuttings.

BAT EFFLUENT LIMITATIONS—Continued

Waste source	Pollutant parameter	BAT effluent limitation

[2] As determined by the suspended particulate phase (SPP) toxicity test (Appendix 2 of subpart A of this part).

[3] As determined by the static sheen test (Appendix 1 of subpart A of this part).

[5] PAH mass ratio = Mass (g) of PAH (as phenanthrene)/Mass (g) of stock base fluid as determined by EPA Method 1654, Revision A, (specified at § 435.11(u)) entitled "PAH Content of Oil by HPLC/UV," December 1992, which is published in *Methods for the Determination of Diesel, Mineral, and Crude Oils in Offshore Oil and Gas Industry Discharges*, EPA–821–R–92–008. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Technical Information Service, Springfield, VA 22161, 703–605–6000. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[6] Base fluid sediment toxicity ratio = 10-day LC_{50} of C_{16}–C_{18} internal olefin/10-day LC_{50} of stock base fluid as determined by ASTM E 1367–92 [specified at § 435.11(ee)] method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[7] Biodegradation rate ratio = Cumulative gas production (ml) of C_{16}–C_{18} internal olefin/Cumulative gas production (ml) of stock base fluid, both at 275 days as determined by ISO 11734:1995 [specified at § 435.11(e)] method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" as modified for the marine environment (Appendix 4 of subpart A of this part). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[8] Drilling fluid sediment toxicity ratio = 4-day LC_{50} of C_{16}–C_{18} internal olefin drilling fluid/4-day LC_{50} of drilling fluid removed from drill cuttings at the solids control equipment as determined by ASTM E 1367–92 (specified at § 435.11(ee)) method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[9] As determined before drilling fluids are shipped offshore by the GC/MS compliance assurance method (Appendix 5 of subpart A of this part), and as determined prior to discharge by the RPE method (Appendix 6 of subpart A of this part) applied to drilling fluid removed from drill cuttings. If the operator wishes to confirm the results of the RPE method (Appendix 6 of subpart A of this part), the operator may use the GC/MS compliance assurance method (Appendix 5 of subpart A of this part). Results from the GC/MS compliance assurance method (Appendix 5 of subpart A of this part) shall supercede the results of the RPE method (Appendix 6 of subpart A of this part).

[10] Maximum permissible retention of non-aqueous drilling fluid (NAF) base fluid on wet drill cuttings averaged over drilling intervals using NAFs as determined by the API retort method (Appendix 7 of subpart A of this part). This limitation is applicable for NAF base fluids that meet the base fluid sediment toxicity ratio (Footnote 6), biodegradation rate ratio (Footnote 7), PAH, mercury, and cadmium stock limitations (C_{16}–C_{18} internal olefin) defined above in this table.

[11] Maximum permissible retention of non-aqueous drilling fluid (NAF) base fluid on wet drill cuttings average over drilling intervals using NAFs as determined by the API retort method (Appendix 7 of subpart A of this part). This limitation is applicable for NAF base fluids that meet the ester base fluid sediment toxicity ratio and ester biodegradation rate ratio stock limitations defined as: (a) ester base fluid sediment toxicity ratio = 10-day LC_{50} of C_{12}–C_{14} ester or C_8 ester /10-day LC_{50} of stock base fluid as determined by ASTM E 1367–92 (specified at § 435.11(ee)) method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460. (b) ester biodegradation rate ratio = Cumulative gas production (ml) of C_{12}–C_{14} ester or C_8 ester/Cumulative gas production (ml) of stock base fluid, both at 275 days as determined by ISO 11734:1995 (specified at § 435.11(e)) method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" as modified for the marine environment (Appendix 4 of subpart A of this part). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460. (c) PAH mass ratio (Footnote 5), mercury, and cadmium stock limitations (C_{16}–C_{18} internal olefin) defined above in this table.

5. In § 435.14 the table is amended by revising entry (B) under "Drilling fluids and drill cuttings" to read as follows:

§ 435.14 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

* * * * *

BCT EFFLUENT LIMITATIONS

Waste source	Pollutant parameter	BCT effluent limitation
Drilling fluids and drill cuttings:		

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BCT EFFLUENT LIMITATIONS—Continued

Waste source	Pollutant parameter	BCT effluent limitation
• • • • • • •		
(B) For facilities located beyond 3 miles from shore:		
Water-based drilling fluids and associated drill cuttings	Free Oil	No discharge.[2]
Non-aqueous drilling fluids		No discharge.
Drill cuttings associated with non-aqueous drilling fluids	Free Oil	No discharge.[2]
• • • • • • •		

[2] As determined by the static sheen test (Appendix 1 of Subpart A of this part).

6. In § 435.15 the table is amended by revising entry (B) under "Drilling fluids and drill cuttings" and by revising footnote 2 and adding footnotes 5–11 to read as follows:

§ 435.15 Standards of performance for new sources (NSPS).

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

Waste source	Pollutant parameter	NSPS
• •	• • • • • •	
Drilling fluids and drill cuttings:		
• •	• • • • • •	
(B) For facilities located beyond 3 miles from shore:		
Water-based drilling fluids and associated drill cuttings.	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test[2] shall be 3% by volume.
	Free oil	No discharge.[3]
	Diesel oil	No charge.
	Mercury	1mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
Non-aqueous drilling fluids		No charge.
Drill cuttings associated with non-aqueous drilling fluids:		
Stock Limitations (C_{16}–C_{18} internal olefin.	Mercury	1mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
	Polynuclear Aromatic Hydrocarbons (PAH).	PAH mass ratio[5] shall not exceed 1×10^{-5}
	Sediment toxicity	Base fluid sediment toxicity ratio[6] shall not exceed 1.0.
	Biodegradation rate	Biodegradation rate ratio[7] shall not exceed 1.0.
Discharge Limitations	Diesel oil	No discharge.
	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test[2] shall be 3% by volume.
	Sediment toxicity	Drilling fluid sediment toxicity ratio[8] shall not exceed 1.0.
	Formation Oil	No discharge.[9]
	Base fluid retained on cuttings	For NAFs that meet the stock limitations (C_{16}–C_{18} internal olefin) in this table, the maximum weighted mass ratio averaged over all NAF well sections shall be 6.9 g–NAF base fluid/100 g-wet drill cuttings.[10] For NAFs that meet the C_{12}–C_{14} ester or C_8 ester stock limitations in footnote 11 of this table, the maximum weighted mass ratio averaged over all NAF well sections shall be 9.4 g–NAF base fluid/100 g-wet drill cuttings.
• •	• • • • • •	

[2] As determined by the suspended particulate phase (SPP) toxicity test (Appendix 2 of subpart A of this part).

[3] As determined by the static sheen test (appendix 1 of subpart A of this part).

[5] PAH mass ratio = Mass (g) of PAH (as phenanthrene)/Mass (g) of stock base fluid as determined by EPA Method 1654, Revision A, (specified at § 435.11(u)) entitled "PAH Content of Oil by HPLC/UV," December 1992, which is published in *Methods for the Determination of Diesel, Mineral, and Crude Oils in Offshore Oil and Gas Industry Discharges*, EPA–821–R–92–008. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Technical Information Service, Springfield, VA 22161, 703–605–6000. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[6] Base fluid sediment toxicity ratio = 10-day LC_{50} of C_{16}–C_{18} internal olefin/10-day LC_{50} of stock base fluid as determined by ASTM E 1367–92 (specified at § 435.11(ee)) method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[7] Biodegradation rate ratio = Cumulative gas production (ml) of C_{16}–C_{18} internal olefin/Cumulative gas production (ml) of stock base fluid, both at 275 days as determined by ISO 11734:1995 (specified at § 435.11(e)) method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" as modified for the marine environment (Appendix 4 of subpart A of this part). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[8] Drilling fluid sediment toxicity ratio = 4-day LC_{50} of C_{16}–C_{18} internal olefin drilling fluid/4-day LC_{50} of drilling fluid removed from drill cuttings at the solids control equipment as determined by ASTM E 1367–92 (specified at § 435.11(ee)) method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

[9] As determined before drilling fluids are shipped offshore by the GC/MS compliance assurance method (Appendix 5 of subpart A of this part), and as determined prior to discharge by the RPE method (Appendix 6 of subpart A of this part) applied to drilling fluid removed from drill cuttings. If the operator wishes to confirm the results of the RPE method (Appendix 6 of subpart A of this part), the operator may use the GC/MS compliance assurance method (Appendix 5 of subpart A of this part). Results from the GC/MS compliance assurance method (Appendix 5 of subpart A of this part) shall supercede the results of the RPE method (Appendix 6 of subpart A of this part).

[10] Maximum permissible retention of non-aqueous drilling fluid (NAF) base fluid on wet drill cuttings averaged over drilling intervals using NAFs as determined by the API retort method (Appendix 7 of subpart A of this part). This limitation is applicable for NAF base fluids that meet the base fluid sediment toxicity ratio (Footnote 6), biodegradation rate ratio (Footnote 7), PAH, mercury, and cadmium stock limitations (C_{16}–C_{18} internal olefin) defined above in this table.

[11] Maximum permissible retention of non-aqueous drilling fluid (NAF) base fluid on wet drill cuttings average over drilling intervals using NAFs as determined by the API retort method (Appendix 7 of subpart A of this part). This limitation is applicable for NAF base fluids that meet the ester base fluid sediment toxicity ratio and ester biodegradation rate ratio stock limitations defined as: (a) Ester base fluid sediment toxicity ratio = 10-day LC_{50} of C_{12}–C_{14} ester or C_8 ester /10-day LC_{50} of stock base fluid as determined by ASTM E 1367–92 [specified at § 435.11(ee)] method: "Standard Guide for Conducting 10-day Static Sediment Toxicity Tests with Marine and Estuarine Amphipods," 1992, after preparing the sediment according to the method specified in Appendix 3 of subpart A of this part. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA, 19428. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460; (b) Ester biodegradation rate ratio = Cumulative gas production (ml) of C_{12}–C_{14} ester or C_8 ester/Cumulative gas production (ml) of stock base fluid, both at 275 days as determined by ISO 11734:1995 (specified at § 435.11(e)) method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" as modified for the marine environment (Appendix 4 of subpart A of this part). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460; and (c) PAH mass ratio (Footnote 5), mercury, and cadmium stock limitations (C_{16}–C_{18} internal olefin) defined above in this table.

7. Subpart A of this part is amended by adding Appendices 3 through 8 as follows:

Appendix 3 to Subpart A of Part 435—Procedure for Mixing Base Fluids with Sediments

This procedure describes a method for amending uncontaminated and nontoxic (control) sediments with the base fluids that are used to formulate synthetic-based drilling fluids and other non-aqueous drilling fluids. Initially, control sediments shall be press-sieved through a 2000 micron mesh sieve to remove large debris. Then press-sieve the sediment through a 500 micron sieve to remove indigenous organisms that may prey on the test species or otherwise confound test results. Homogenize control sediment to limit the effects of settling that may have occurred during storage. Sediments should be homogenized before density determinations and addition of base fluid to control sediment. Because base fluids are strongly hydrophobic and do not readily mix with sediment, care must be taken to ensure base fluids are thoroughly homogenized within the sediment. All concentrations are weight-to-weight (mg of base fluid to kg of dry control sediment). Sediment and base fluid mixing shall be accomplished by using the following method.

1. Determine the wet to dry ratio for the control sediment by weighing approximately 10 g subsamples of the screened and homogenized wet sediment into tared aluminum weigh pans. Dry sediment at 105 °C for 18–24 h. Remove sediment and cool in a desiccator until a constant weight is achieved. Re-weigh the samples to determine the dry weight. Determine the wet/dry ratio by dividing the net wet weight by the net dry weight:

[Wet Sediment Weight (g)]/[Dry Sediment Weight (g)] = Wet to Dry Ratio [1]

2. Determine the density (g/mL) of the wet control or dilution sediment. This shall be used to determine total volume of wet sediment needed for the various test treatments.

[Mean Wet Sediment Weight (g)]/[Mean Wet Sediment Volume (mL)] = Wet Sediment Density (g/mL) [2]

3. To determine the amount of base fluid needed to obtain a test concentration of 500 mg base fluid per kg dry sediment use the following formulas:

Determine the amount of wet sediment required:

[Wet Sediment Density (g/mL)] × [Volume of Sediment Required per Concentration (mL)] = Weight Wet Sediment Required per Conc. (g) [3]

Determine the amount of dry sediment in kilograms (kg) required for each concentration:

{[Wet Sediment per Concentration (g)]/[Mean Wet to Dry Ratio]} × (1kg/1000g) = Dry Weight Sediment (kg) [4]

Finally, determine the amount of base fluid required to spike the control sediment at each concentration:

[Conc. Desired (mg/kg)] × [Dry Weight Sediment (kg)] = Base Fluid Required (mg) [5]

For spiking test substances other than pure base fluids (*e.g.*, whole mud formulations), determine the spike amount as follows:

[Conc. Desired (mL/kg)] × [Dry Weight Sediment (kg)] × [Test Substance Density (g/mL)] = Test Substance Required (g) [6]

4. For primary mixing, place appropriate amounts of weighed base fluid into stainless mixing bowls, tare the vessel weight, then add sediment and mix with a high-shear dispersing impeller for 9 minutes. The concentration of base fluid in sediment from this mix, rather than the nominal concentration, shall be used in calculating LC_{50} values.

5. Tests for homogeneity of base fluid in sediment are to be performed during the procedure development phase. Because of

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difficulty of homogeneously mixing base fluid with sediment, it is important to demonstrate that the base fluid is evenly mixed with sediment. The sediment shall be analyzed for total petroleum hydrocarbons (TPH) using EPA Methods 3550A and 8015M, with samples taken both prior to and after distribution to replicate test containers. Base-fluid content is measured as TPH. After mixing the sediment, a minimum of three replicate sediment samples shall be taken prior to distribution into test containers. After the test sediment is distributed to test containers, an additional three sediment samples shall be taken from three test containers to ensure proper distribution of base fluid within test containers. Base-fluid content results shall be reported within 48 hours of mixing. The coefficient of variation (CV) for the replicate samples must be less than 20%. If base-fluid content results are not within the 20% CV limit, the test sediment shall be remixed. Tests shall not begin until the CV is determined to be below the maximum limit of 20%. During the test, a minimum of three replicate containers shall be sampled to determine base-fluid content during each sampling period.

6. Mix enough sediment in this way to allow for its use in the preparation of all test concentrations and as a negative control. When commencing the sediment toxicity test, range-finding tests may be required to determine the concentrations that produce a toxic effect if these data are otherwise unavailable. The definitive test shall bracket the LC_{50}, which is the desired endpoint. The results for the base fluids shall be reported in mg of base fluid per kg of dry sediment.

References

American Society for Testing and Materials (ASTM). 1996. Standard Guide for Collection, Storage, Characterization, and Manipulation of Sediments for Toxicological Testing. ASTM E 1391–94. Annual Book of ASTM Standards, Volume 11.05, pp. 805–825.

Ditsworth, G.R., D.W. Schults and J.K.P. Jones. 1990. Preparation of benthic substrates for sediment toxicity testing, Environ. Toxicol. Chem. 9:1523–1529.

Suedel, B.C., J.H. Rodgers, Jr. and P.A. Clifford. 1993. Bioavailability of fluoranthene in freshwater sediment toxicity tests. Environ. Toxicol. Chem. 12:155–165.

U.S. EPA. 1994. Methods for Assessing the Toxicity of Sediment-associated Contaminants with Estuarine and Marine Amphipods. EPA/600/R–94/025. Office of Research and Development, Washington, DC.

Appendix 4 to Subpart A of Part 435—Determination of Biodegradation of Synthetic Base Fluids in a Marine Closed Bottle Test System: Summary of Modifications to ISO 11734:1995

The six modifications specified in this Appendix shall apply to the determination of the biodegradability of synthetic base fluids as measured by ISO 11734:1995. These modifications make the test more applicable to a marine environment and are listed below:

1. The laboratory shall use sea water in place of freshwater media.

1.1 The sea water may be either natural or synthetic. The allowable salinity range is 20–30 ppt.

1.2 To reduce the shock to the microorganisms in the sediment, the salinity of the sediment's porewater shall be between 20–30 ppt.

2. The laboratory shall use natural marine or estuarine sediments in place of digested sludge as an inoculum. The VS of the sediments must be no less than 2%.

2.1 Sediment should be used for testing as soon as possible after field collection. If required, the laboratory can store the sediment for a maximum period of two months prior to use. The test sediment shall be stored in the dark at 4°C.

2.2 The laboratory shall use the sediment mixing procedure specified in Appendix 3 to Subpart A of part 435 to spike the test sediment with base fluids. The final concentration will be 2000 mg carbon/Kg dry weight sediment. No less than 25 g dry weight of the spiked sediment shall be used per 125 ml serum bottle. The volume of sediment and seawater in the bottle shall be 75 ml.

3. The temperature of incubation shall be 20±1°C.

4. The pH is maintained at the level of natural sea water, not at 7.0 as referenced in ISO 11734:1995.

5. The optional use of a trace metals solution as specified in method ISO 11734:1995 shall not be used as part of these test modifications.

6. The laboratory shall conduct the test for 275 days. The laboratory may seek approval of alternate test durations under the approval procedures specified at 40 CFR 136.4 and 136.5. Any modification of this method, beyond those expressly permitted, shall be considered a major modification subject to application and approval of alternate test procedures under 40 CFR 136.4 and 136.5.

Appendix 5 to Subpart A of Part 435—Determination of Crude Oil Contamination in Non-Aqueous Drilling Fluids by Gas Chromatography/Mass Spectrometry (GC/MS)

1.0 Scope and Application

1.1 This method determines crude (formation) oil contamination, or other petroleum oil contamination, in non-aqueous drilling fluids (NAFs) by comparing the gas chromatography/mass spectrometry (GC/MS) fingerprint scan and extracted ion scans of the test sample to that of an uncontaminated sample.

1.2 This method can be used for monitoring oil contamination of NAFs or monitoring oil contamination of the base fluid used in the NAF formulations.

1.3 Any modification of this method beyond those expressly permitted shall be considered as a major modification subject to application and approval of alternative test procedures under 40 CFR 136.4 and 136.5.

1.4 The gas chromatography/mass spectrometry portions of this method are restricted to use by, or under the supervision of analysts experienced in the use of GC/MS and in the interpretation of gas chromatograms and extracted ion scans. Each laboratory that uses this method must generate acceptable results using the procedures described in Sections 7, 9.2, and 12 of this appendix.

2.0 Summary of Method

2.1 Analysis of NAF for crude oil contamination is a step-wise process. The analyst first performs a qualitative assessment of the presence or absence of crude oil in the sample. If crude oil is detected during this qualitative assessment, the analyst must perform a quantitative analysis of the crude oil concentration.

2.2 A sample of NAF is centrifuged to obtain a solids free supernate.

2.3 The test sample is prepared by removing an aliquot of the solids free supernate, spiking it with internal standard, and analyzing it using GC/MS techniques. The components are separated by the gas chromatograph and detected by the mass spectrometer.

2.4 Qualitative identification of crude oil contamination is performed by comparing the Total Ion Chromatograph (TIC) scans and Extracted Ion Profile (EIP) scans of test sample to that of uncontaminated base fluids, and examining the profiles for chromatographic signatures diagnostic of oil contamination.

2.5 The presence or absence of crude oil contamination observed in the full scan profiles and selected extracted ion profiles determines further sample quantitation and reporting requirements.

2.6 If crude oil is detected in the qualitative analysis, quantitative analysis must be performed by calibrating the GC/MS using a designated NAF spiked with known concentrations of a designated oil.

2.7 Quality is assured through reproducible calibration and testing of GC/MS system and through analysis of quality control samples.

3.0 Definitions

3.1 A NAF is one in which the continuous— phase is a water immiscible fluid such as an oleaginous material (e.g., mineral oil, enhance mineral oil, paraffinic oil, or synthetic material such as olefins and vegetable esters).

3.2 TIC—Total Ion Chromatograph.

3.3 EIP—Extracted Ion Profile.

3.4 TCB—1,3,5-trichlorobenzene is used as the internal standard in this method.

3.5 SPTM—System Performance Test Mix standards are used to establish retention times and monitor detection levels.

4.0 Interferences and Limitations

4.1 Solvents, reagents, glassware, and other sample processing hardware may yield artifacts and/or elevated baselines causing misinterpretation of chromatograms.

4.2 All Materials used in the analysis shall be demonstrated to be free from interferences by running method blanks. Specific selection of reagents and purification of solvents by distillation in all-glass systems may be required.

4.3 Glassware shall be cleaned by rinsing with solvent and baking at 400 °C for a minimum of 1 hour.

4.4 Interferences may vary from source to source, depending on the diversity of the samples being tested.

4.5 Variations in and additions of base fluids and/or drilling fluid additives (emulsifiers, dispersants, fluid loss control agents, etc.) might also cause interferences and misinterpretation of chromatograms.

4.6 Difference in light crude oils, medium crude oils, and heavy crude oils will result in different responses and thus different interpretation of scans and calculated percentages.

5.0 Safety

5.1 The toxicity or carcinogenicity of each reagent used in this method has not been precisely determined; however each chemical shall be treated as a potential health hazard. Exposure to these chemicals should be reduced to the lowest possible level.

5.2 Unknown samples may contain high concentration of volatile toxic compounds. Sample containers should be opened in a hood and handled with gloves to prevent exposure. In addition, all sample preparation should be conducted in a fume hood to limit the potential exposure to harmful contaminates.

5.3 This method does not address all safety issues associated with its use. The laboratory is responsible for maintaining a safe work environment and a current awareness file of OSHA regulations regarding the safe handling of the chemicals specified in this method. A reference file of material safety data sheets (MSDSs) shall be available to all personnel involved in these analyses. Additional references to laboratory safety can be found in References 16.1 through 16.3.

5.4 NAF base fluids may cause skin irritation, protective gloves are recommended while handling these samples.

6.0 Apparatus and Materials

Note: Brand names, suppliers, and part numbers are for illustrative purposes only. No endorsement is implied. Equivalent performance may be achieved using apparatus and materials other than those specified here, but demonstration of equivalent performance meeting the requirements of this method is the responsibility of the laboratory.

6.1 Equipment for glassware cleaning.

6.1.1 Laboratory sink with overhead fume hood.

6.1.2 Kiln—Capable of reaching 450 °C within 2 hours and holding 450 °C within ±10 °C, with temperature controller and safety switch (Cress Manufacturing Co., Santa Fe Springs, CA B31H or X31TS or equivalent).

6.2 Equipment for sample preparation.

6.2.1 Laboratory fume hood.

6.2.2 Analytical balance—Capable of weighing 0.1 mg.

6.2.3 Glassware.

6.2.3.1 Disposable pipettes—Pasteur, 150 mm long by 5 mm ID (Fisher Scientific 13–678–6A, or equivalent) baked at 400 °C for a minimum of 1 hour.

6.2.3.2 Glass volumetric pipettes or gas tight syringes—1.0-mL ± 1% and 0.5-mL ± 1%.

6.2.3.3 Volumetric flasks—Glass, class A, 10-mL, 50-mL and 100-mL.

6.2.3.4—Sample vials—Glass, 1- to 3-mL (baked at 400 °C for a minimum of 1 hour) with PTFE-lined screw or crimp cap.

6.2.3.5 Centrifuge and centrifuge tubes—Centrifuge capable of 10,000 rpm, or better, (International Equipment Co., IEC Centra MP4 or equivalent) and 50-mL centrifuge tubes (Nalgene, Ultratube, Thin Wall 25×89 mm, #3410–2539).

6.3 Gas Chromatograph/Mass Spectrometer (GC/MS):

6.3.1 Gas Chromatograph—An analytical system complete with a temperature-programmable gas chromatograph suitable for split/splitless injection and all required accessories, including syringes, analytical columns, and gases.

6.3.1.1 Column—30 m (or 60 m) × 0.32 mm ID (or 0.25 mm ID) 1μm film thickness (or 0.25μm film thickness) silicone-coated fused-silica capillary column (J&W Scientific DB–5 or equivalent).

6.3.2 Mass Spectrometer—Capable of scanning from 35 to 500 amu every 1 sec or less, using 70 volts (nominal) electron energy in the electron impact ionization mode (Hewlett Packard 5970MS or comparable).

6.3.3 GC/MS interface—the interface is a capillary-direct interface from the GC to the MS.

6.3.4—Data system—A computer system must be interfaced to the mass spectrometer. The system must allow the continuous acquisition and storage on machine-readable media of all mass spectra obtained throughout the duration of the chromatographic program. The computer must have software that can search any GC/MS data file for ions of a specific mass and that can plot such ion abundance versus retention time or scan number. This type of plot is defined as an Extracted Ion Current Profile (EIP). Software must also be available that allows integrating the abundance in any total ion chromatogram (TIC) or EIP between specified retention time or scan-number limits. It is advisable that the most recent version of the EPA/NIST Mass Spectral Library be available.

7.0 Reagents and Standards

7.1 Methylene chloride—Pesticide grade or equivalent. Use when necessary for sample dilution.

7.2 Standards—Prepare from pure individual standard materials or purchase as certified solutions. If compound purity is 96% or greater, the weight may be used without correction to compute the concentration of the standard.

7.2.1 Crude Oil Reference—Obtain a sample of a crude oil with a known API gravity. This oil shall be used in the calibration procedures.

7.2.2 Synthetic Base Fluid—Obtain a sample of clean internal olefin (IO) Lab drilling fluid (as sent from the supplier—has not been circulated downhole). This drilling fluid shall be used in the calibration procedures.

7.2.3 Internal standard—Prepare a 0.01 g/mL solution of 1,3,5-trichlorobenzene (TCB). Dissolve 1.0 g of TCB in methylene chloride and dilute to volume in a 100-mL volumetric flask. Stopper, vortex, and transfer the solution to a 150-mL bottle with PTFE-lined cap. Label appropriately, and store at –5 °C to 20 °C. Mark the level of the meniscus on the bottle to detect solvent loss.

7.2.4 GC/MS system performance test mix (SPTM) standards—The SPTM standards shall contain octane, decane, dodecane, tetradecane, tetradecene, toluene, ethylbenzene, 1,2,4-trimethylbenzene, 1-methylnaphthalene and 1,3-dimethylnaphthalene. These compounds can be purchased individually or obtained as a mixture (i.e. Supelco, Catalog No. 4–7300). Prepare a high concentration of the SPTM standard at 62.5 mg/mL in methylene chloride. Prepare a medium concentration SPTM standard at 1.25 mg/mL by transferring 1.0 mL of the 62.5 mg/mL solution into a 50 mL volumetric flask and diluting to the mark with methylene chloride. Finally, prepare a low concentration SPTM standard at 0.125 mg/mL by transferring 1.0 mL of the 1.25 mg/mL solution into a 10-mL volumetric flask and diluting to the mark with methylene chloride.

7.2.5 Crude oil/drilling fluid calibration standards—Prepare a 4-point crude oil/drilling fluid calibration at concentrations of 0% (no spike—clean drilling fluid), 0.5%, 1.0%, and 2.0% by weight according to the procedures outlined in this appendix using the Reference Crude Oil:

7.2.5.1 Label 4 jars with the following identification: Jar 1—0%Ref-IOLab, Jar 2—0.5%Ref-IOLab, Jar 3—1%Ref-IOLab, and Jar 4—2%Ref-IOLab.

7.2.5.2 Weigh 4, 50-g aliquots of well mixed IO Lab drilling fluid into each of the 4 jars.

7.2.5.3 Add Reference Oil at 0.5%, 1.0%, and 2.0% by weight to jars 2, 3, and 4 respectively. Jar 1 shall not be spiked with Reference Oil in order to retain a "0%" oil concentration.

7.2.5.4 Thoroughly mix the contents of each of the 4 jars, using clean glass stirring rods.

7.2.5.5 Transfer (weigh) a 30-g aliquot from Jar 1 to a labeled centrifuge tube. Centrifuge the aliquot for a minimum of 15 min at approximately 15,000 rpm, in order to obtain a solids free supernate. Weigh 0.5 g of the supernate directly into a tared and appropriately labeled GC straight vial. Spike the 0.5-g supernate with 500 μL of the 0.01g/mL 1,3,5-trichlorobenzene internal standard solution (*see* Section 7.2.3 of this appendix), cap with a Teflon lined crimp cap, and vortex for ca. 10 sec.

7.2.5.6 Repeat step 7.2.5.5 except use an aliquot from Jar 2.

7.2.5.7 Repeat step 7.2.5.5 except use an aliquot from Jar 3.

7.2.5.8 Repeat step 7.2.5.5 except use an aliquot from Jar 4.

7.2.5.9 These 4 crude/oil drilling fluid calibration standards are now used for qualitative and quantitative GC/MS analysis.

7.2.6 Precision and recovery standard (mid level crude oil/drilling fluid calibration standard)—Prepare a mid point crude oil/drilling fluid calibration using IO Lab drilling fluid and Reference Oil at a concentration of 1.0% by weight. Prepare this standard according to the procedures outlined in Section 7.2.5.1 through 7.2.5.5 of this appendix, with the exception that only "Jar

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3" needs to be prepared. Remove and spike with internal standard, as many 0.5-g aliquots as needed to complete the GC/MS analysis (*see* Section 11.6 of this appendix—bracketing authentic samples every 12 hours with precision and recovery standard) and the initial demonstration exercise described in Section 9.2 of this appendix.

7.2.7 Stability of standards

7.2.7.1 When not used, standards shall be stored in the dark, at −5 to −20 °C in screw-capped vials with PTFE-lined lids. Place a mark on the vial at the level of the solution so that solvent loss by evaporation can be detected. Bring the vial to room temperature prior to use.

7.2.7.2 Solutions used for quantitative purposes shall be analyzed within 48 hours of preparation and on a monthly basis thereafter for signs of degradation. A standard shall remain acceptable if the peak area remains within ±15% of the area obtained in the initial analysis of the standard.

8.0 Sample Collection Preservation and Storage

8.1 Collect NAF and base fluid samples in 100- to 200-mL glass bottles with PTFE- or aluminum foil lined caps.

8.2 Samples collected in the field shall be stored refrigerated until time of preparation.

8.3 Sample and extract holding times for this method have not yet been established. However, based on initial experience with the method, samples should be analyzed within seven to ten days of collection and extracts should be analyzed within seven days of preparation.

8.4 After completion of GC/MS analysis, extracts shall be refrigerated at 4 °C until further notification of sample disposal.

9.0 Quality Control

9.1 Each laboratory that uses this method is required to operate a formal quality assurance program (Reference 16.4). The minimum requirements of this program shall consist of an initial demonstration of laboratory capability, and ongoing analysis of standards, and blanks as a test of continued performance, analyses of spiked samples to assess accuracy and analysis of duplicates to assess precision. Laboratory performance shall be compared to established performance criteria to determine if the results of analyses meet the performance characteristics of the method.

9.1.1 The analyst shall make an initial demonstration of the ability to generate acceptable accuracy and precision with this method. This ability shall be established as described in Section 9.2 of this appendix.

9.1.2 The analyst is permitted to modify this method to improve separations or lower the cost of measurements, provided all performance requirements are met. Each time a modification is made to the method, the analyst is required to repeat the calibration (Section 10.4 of this appendix) and to repeat the initial demonstration procedure described in Section 9.2 of this appendix.

9.1.3 Analyses of blanks are required to demonstrate freedom from contamination. The procedures and criteria for analysis of a blank are described in Section 9.3 of this appendix.

9.1.4 Analysis of a matrix spike sample is required to demonstrate method accuracy. The procedure and QC criteria for spiking are described in Section 9.4 of this appendix.

9.1.5 Analysis of a duplicate field sample is required to demonstrate method precision. The procedure and QC criteria for duplicates are described in Section 9.5 of this appendix.

9.1.6 Analysis of a sample of the clean NAF(s) (as sent from the supplier—i.e., has not been circulated downhole) used in the drilling operations is required.

9.1.7 The laboratory shall, on an ongoing basis, demonstrate through calibration verification and the analysis of the precision and recovery standard (Section 7.2.6 of this appendix) that the analysis system is in control. These procedures are described in Section 11.6 of this appendix.

9.1.8 The laboratory shall maintain records to define the quality of data that is generated.

9.2 Initial precision and accuracy—The initial precision and recovery test shall be performed using the precision and recovery standard (1% by weight Reference Oil in IO Lab drilling fluid). The laboratory shall generate acceptable precision and recovery by performing the following operations.

9.2.1 Prepare four separate aliquots of the precision and recovery standard using the procedure outlined in Section 7.2.6 of this appendix. Analyze these aliquots using the procedures outlined in Section 11 of this appendix.

9.2.2 Using the results of the set of four analyses, compute the average recovery (X) in weight percent and the standard deviation of the recovery(s) for each sample.

9.2.3 If s and X meet the acceptance criteria of 80% to 110%, system performance is acceptable and analysis of samples may begin. If, however, s exceeds the precision limit or X falls outside the range for accuracy, system performance is unacceptable. In this event, review this method, correct the problem, and repeat the test.

9.2.4 Accuracy and precision—The average percent recovery (P) and the standard deviation of the percent recovery (Sp) Express the accuracy assessment as a percent recovery interval from $P-2S_p$ to $P+2S_p$. For example, if P=90% and S_p=10% for four analyses of crude oil in NAF, the accuracy interval is expressed as 70% to 110%. Update the accuracy assessment on a regular basis.

9.3 Blanks—Rinse glassware and centrifuge tubes used in the method with 30 mL of methylene chloride, remove a 0.5-g aliquot of the solvent, spike it with the 500 µL of the internal standard solution (Section 7.2.3 of this appendix) and analyze a 1-µL aliquot of the blank sample using the procedure in Section 11 of this appendix. Compute results per Section 12 of this appendix.

9.4 Matrix spike sample—Prepare a matrix spike sample according to procedure outlined in Section 7.2.6 of this appendix. Analyze the sample and calculate the concentration (% oil) in the drilling fluid and % recovery of oil from the spiked drilling fluid using the methods described in Sections 11 and 12 of this appendix.

9.5 Duplicates—A duplicate field sample shall be prepared according to procedures outlined in Section 7.3 of this appendix and analyzed according to Section 11 of this appendix. The relative percent difference (RPD) of the calculated concentrations shall be less than 15%.

9.5.1 Analyze each of the duplicates per the procedure in Section 11 of this appendix and compute the results per Section 12 of this appendix.

9.5.2 Calculate the relative percent difference (RPD) between the two results per the following equation:

$$RPD = [D_1 - D_2]/[(D_1 + D_2)/2] \times 100 \quad [1]$$

where:

D_1 = Concentration of crude oil in the sample; and

D_2 = Concentration of crude oil in the duplicate sample.

9.5.3 If the RPD criteria are not met, the analytical system shall be judged to be out of control, and the problem must be immediately identified and corrected, and the sample batch re-analyzed.

9.6 Prepare the clean NAF sample according to procedures outlined in Section 7.3 of this appendix. Ultimately the oil-equivalent concentration from the TIC or EIP signal measured in the clean NAF sample shall be subtracted from the corresponding authentic field samples in order to calculate the true contaminant concentration (% oil) in the field samples (*see* Section 12 of this appendix).

9.7 The specifications contained in this method can be met if the apparatus used is calibrated properly, and maintained in a calibrated state. The standards used for initial precision and recovery (Section 9.2 of this appendix) and ongoing precision and recovery (Section 11.6 of this appendix) shall be identical, so that the most precise results will be obtained. The GC/MS instrument will provide the most reproducible results if dedicated to the setting and conditions required for the analyses given in this method.

9.8 Depending on specific program requirements, field replicates and field spikes of crude oil into samples may be required when this method is used to assess the precision and accuracy of the sampling and sample transporting techniques.

10.0 Calibration

10.1 Establish gas chromatographic/mass spectrometer operating conditions given in Table 1 of this appendix. Perform the GC/MS system hardware-tune as outlined by the manufacture. The gas chromatograph shall be calibrated using the internal standard technique.

Note: Because each GC is slightly different, it may be necessary to adjust the operating conditions (carrier gas flow rate and column temperature and temperature program) slightly until the retention times in Table 2 of this appendix are met.

TABLE 1.—GAS CHROMATOGRAPH/MASS SPECTROMETER (GC/MS) OPERATION CONDITIONS

Parameter	Setting
Injection pot	280 °C

TABLE 1.—GAS CHROMATOGRAPH/MASS SPECTROMETER (GC/MS) OPERATION CONDITIONS—Continued

Parameter	Setting
Transfer line	280 °C
Detector	280 °C
Initial Temperature	50 °C
Initial Time	5 minutes
Ramp	50 to 300 °C @ 5 °C per minute
Final Temperature	300 °C
Final Hold	20 minutes or until all peaks have eluted
Carrier Gas	Helium
Flow rate	As required for standard operation
Split ratio	As required to meet performance criteria (~1:100)
Mass range	35 to 600 amu

TABLE 2.—APPROXIMATE RETENTION TIME FOR COMPOUNDS

Compound	Approximate retention time (minutes)
Toluene	5.6
Octane, n−C_8	7.2
Ethylbenzene	10.3
1,2,4-Trimethylbenzene	16.0
Decane, −C_{10}	16.1
TCB (internal Standard)	21.3
Dodecane, −C_{12}	22.9
1-Methylnaphthalene	26.7
1-Tetradecene	28.4
Tetradecane, −C_{14}	28.7
1,3-Dimethylnaphthalene	29.7

10.2 Internal standard calibration procedure—1,3,5-trichlorobenzene (TCB) has been shown to be free of interferences from diesel and crude oils and is a suitable internal standard.

10.3 The system performance test mix standards prepared in Section 7.2.4 of this appendix shall be used to establish retention times and establish qualitative detection limits.

10.3.1 Spike a 500-mL aliquot of the 1.25 mg/mL SPTM standard with 500 µL of the TCB internal standard solution.

10.3.2 Inject 1.0 µL of this spiked SPTM standard onto the GC/MS in order to demonstrate proper retention times. For the GC/MS used in the development of this method, the ten compounds in the mixture had typical retention times shown in Table 2 of this appendix. Extracted ion scans for m/z 91 and 105 showed a maximum abundance of 400,000.

10.3.3 Spike a 500-mL aliquot of the 0.125 mg/mL SPTM standard with 500 µL of the TCB internal standard solution.

10.3.4 Inject 1.0 µL of this spiked SPTM standard onto the GC/MS to monitor detectable levels. For the GC/MS used in the development of this test, all ten compounds showed a minimum peak height of three times signal to noise. Extracted ion scans for m/z 91 and 105 showed a maximum abundance of 40,000.

10.4 GC/MS crude oil/drilling fluid calibration—There are two methods of quantification: Total Area Integration (C_8–C_{13}) and EIP Area Integration using m/z's 91 and 105. The Total Area Integration method should be used as the primary technique for quantifying crude oil in NAFs. The EIP Area Integration method should be used as a confirmatory technique for NAFs. However, the EIP Area Integration method shall be used as the primary method for quantifying oil in enhanced mineral oil (EMO) based drilling fluid. Inject 1.0 µL of each of the four crude oil/drilling fluid calibration standards prepared in Section 7.2.5 of this appendix into the GC/MS. The internal standard should elute approximately 21–22 minutes after injection. For the GC/MS used in the development of this method, the internal standard peak was (35 to 40)% of full scale at an abundance of about 3.5e+07.

10.4.1 Total Area Integration Method—For each of the four calibration standards obtain the following: Using a straight baseline integration technique, obtain the total ion chromatogram (TIC) area from C_8 to C_{13}. Obtain the TIC area of the internal standard (TCB). Subtract the TCB area from the C_8–C_{13} area to obtain the true C_8–C_{13} area. Using the C_8–C_{13} and TCB areas, and known internal standard concentration, generate a linear regression calibration using the internal standard method. The r^2 value for the linear regression curve shall be greater than or equal to 0.998. Some synthetic fluids might have peaks that elute in the window and would interfere with the analysis. In this case the integration window can be shifted to other areas of scan where there are no interfering peaks from the synthetic base fluid.

10.4.2 EIP Area Integration—For each of the four calibration standards generate Extracted Ion Profiles (EIPs) for m/z 91 and 105. Using straight baseline integration techniques, obtain the following EIP areas:

10.4.2.1 For m/z 91 integrate the area under the curve from approximately 9 minutes to 21–22 minutes, just prior to but not including the internal standard.

10.4.2.2 For m/z 105 integrate the area under the curve from approximately 10.5 minutes to 26.5 minutes.

10.4.2.3 Obtain the internal standard area from the TCB in each of the four calibration standards, using m/z 180.

10.4.2.4 Using the EIP areas for TCB, m/z 91 and m/z105, and the known concentration of internal standard, generate linear regression calibration curves for the target ions 91 and 105 using the internal standard method. The r^2 value for each of the EIP linear regression curves shall be greater than or equal to 0.998.

10.4.2.5 Some base fluids might produce a background level that would show up on the extracted ion profiles, but there should not be any real peaks (signal to noise ratio of 1:3) from the clean base fluids.

11.0 Procedure

11.1 Sample Preparation—

11.1.1 Mix the authentic field sample (drilling fluid) well. Transfer (weigh) a 30-g aliquot of the sample to a labeled centrifuge tube.

11.1.2 Centrifuge the aliquot for a minimum of 15 min at approximately 15,000 rpm, in order to obtain a solids free supernate.

11.1.3 Weigh 0.5 g of the supernate directly into a tared and appropriately labeled GC straight vial.

11.1.4 Spike the 0.5-g supernate with 500 µL of the 0.01g/mL 1,3,5-trichlorobenzene internal standard solution (*see* Section 7.2.3 of this appendix), cap with a Teflon lined crimp cap, and vortex for ca. 10 sec.

11.1.5 The sample is ready for GC/MS analysis.

11.2 Gas Chromatography.

Table 1 of this appendix summarizes the recommended operating conditions for the GC/MS. Retention times for the n-alkanes obtained under these conditions are given in Table 2 of this appendix. Other columns, chromatographic conditions, or detectors may be used if initial precision and accuracy requirements (Section 9.2 of this appendix) are met. The system shall be calibrated according to the procedures outlined in Section 10 of this appendix, and verified every 12 hours according to Section 11.6 of this appendix.

11.2.1 Samples shall be prepared (extracted) in a batch of no more than 20 samples. The batch shall consist of 20 authentic samples, 1 blank (Section 9.3 of this appendix), 1 matrix spike sample (9.4), and 1 duplicate field sample (9.5), and a prepared sample of the corresponding clean NAF used in the drilling process.

11.2.2 An analytical sequence shall be analyzed on the GC/MS where the 3 SPTM standards (Section 7.2.4 of this appendix) containing internal standard are analyzed first, followed by analysis of the four GC/MS crude oil/drilling fluid calibration standards (Section 7.2.5 of this appendix), analysis of the blank, matrix spike sample, the duplicate sample, the clean NAF sample, followed by the authentic samples.

11.2.3 Samples requiring dilution due to excessive signal shall be diluted using methylene chloride.

11.2.4 Inject 1.0 µL of the test sample or standard into the GC, using the conditions in Table 1 of this appendix.

11.2.5 Begin data collection and the temperature program at the time of injection.

11.2.6 Obtain a TIC and EIP fingerprint scans of the sample (Table 3 of this appendix).

11.2.7 If the area of the C_8 to C_{13} peaks exceeds the calibration range of the system, dilute a fresh aliquot of the test sample weighing 0.50-g and re-analyze.

11.2.8 Determine the C_8 to C_{13} TIC area, the TCB internal standard area, and the areas for the m/z 91 and 105 EIPs. These shall be used in the calculation of oil concentration in the samples (see Section 12 of this appendix).

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TABLE 3.—RECOMMENDED ION MASS NUMBERS

Selected ion mass numbers	Corresponding aromatic compounds	Typical rentention time (minutes)
91	Methylbenzene	6.0
	Ethylbenzene	10.3
	1,4-Dimethylbenzene	10.9
	1,3-Dimethylbenzene	10.9
	1,2-Dimethylbenzene	11.9
105	1,3,5-Trimethylbenzene	15.1
	1,2,4-Trimethylbenzene	16.0
	1,2,3-Trimethylbenzene	17.4
156	2,6-Dimethylnaphthalene	28.9
	1,2-Dimethylnaphthalene	29.4
	1,3-Dimethylnaphthalene	29.7

11.2.9 Observe the presence of peaks in the EIPs that would confirm the presence of any target aromatic compounds. Using the EIP areas and EIP linear regression calibrations compare the abundance of the aromatic peaks, and if appropriate, determine approximate crude oil contamination in the sample for each of the target ions.

11.3 Qualitative Identification—See Section 17 of this appendix for schematic flowchart.

11.3.1 Qualitative identification shall be accomplished by comparison of the TIC and EIP area data from an authentic sample to the TIC and EIP area data from the calibration standards (Section 12.4 of this appendix). Crude oil shall be identified by the presence of C_{10} to C_{13} n-alkanes and corresponding target aromatics.

11.3.2 Using the calibration data, establish the identity of the C_8 to C_{13} peaks in the chromatogram of the sample. Using the calibration data, establish the identity of any target aromatics present on the extracted ion scans.

11.3.3 Crude oil is not present in a detectable amount in the sample if there are no target aromatics seen on the extracted ion scans. The experience of the analyst shall weigh heavily in the determination of the presence of peaks at a signal-to-noise ratio of 3 or greater.

11.3.4 If the chromatogram shows n-alkanes from C_8 to C_{13} and target aromatics to be present, contamination by crude oil or diesel shall be suspected and quantitative analysis shall be determined. If there are no n-alkanes present that are not seen on the blank, and no target aromatics are seen, the sample can be considered to be free of contamination.

11.4 Quantitative Identification—

11.4.1 Determine the area of the peaks from C_8 to C_{13} as outlined in the calibration section (10.4.1 of this appendix). If the area of the peaks for the sample is greater than that for the clean NAF (base fluid) use the crude oil/drilling fluid calibration TIC linear regression curve to determine approximate crude oil contamination.

11.4.2 Using the EIPs outlined in Section 10.4.2 of this appendix, determine the presence of any target aromatics. Using the integration techniques outlined in Section 10.4.2 of this appendix, obtain the EIP areas for m/z 91 and 105. Use the crude oil/drilling fluid calibration EIP linear regression curves to determine approximate crude oil contamination.

11.5 Complex Samples—

11.5.1 The most common interferences in the determination of crude oil can be from mineral oil, diesel oil, and proprietary additives in drilling fluids.

11.5.2 Mineral oil can typically be identified by its lower target aromatic content, and narrow range of strong peaks.

11.5.3 Diesel oil can typically be identified by low amounts of n-alkanes from C_7 to C_9, and the absence of n-alkanes greater than C_{25}.

11.5.4 Crude oils can usually be distinguished by the presence of high aromatics, increased intensities of C_8 to C_{13} peaks, and/ or the presence of higher hydrocarbons of C_{25} and greater (which may be difficult to see in some synthetic fluids at low contamination levels).

11.5.4.1 Oil condensates from gas wells are low in molecular weight and will normally produce strong chromatographic peaks in the C_8–C_{13} range. If a sample of the gas condensate crude oil from the formation is available, the oil can be distinguished from other potential sources of contamination by using it to prepare a calibration standard.

11.5.4.2 Asphaltene crude oils with API gravity 20 may not produce chromatographic peaks strong enough to show contamination at levels of the calibration. Extracted ion peaks should be easier to see than increased intensities for the C_8 to C_{13} peaks. If a sample of asphaltene crude from the formation is available, a calibration standard shall be prepared.

11.6 System and Laboratory Performance—

11.6.1 At the beginning of each 8-hour shift during which analyses are performed, GC crude oil/drilling fluid calibration and system performance test mixes shall be verified. For these tests, analysis of the medium-level calibration standard (1-% Reference Oil in IO Lab drilling fluid, and 1.25 mg/mL SPTM with internal standard) shall be used to verify all performance criteria. Adjustments and/or re-calibration (per Section 10 of this appendix) shall be performed until all performance criteria are met. Only after all performance criteria are met may samples and blanks be analyzed.

11.6.2 Inject 1.0 µL of the medium-level GC/MS crude oil/drilling fluid calibration standard into the GC instrument according to the procedures in Section 11.2 of this appendix. Verify that the linear regression curves for both TIC area and EIP areas are still valid using this continuing calibration standard.

11.6.3 After this analysis is complete, inject 1.0 µL of the 1.25 mg/mL SPTM (containing internal standard) into the GC instrument and verify the proper retention times are met (*see* Table 2 of this appendix).

11.6.4 Retention times—Retention time of the internal standard. The absolute retention time of the TCB internal standard shall be within the range 21.0 ± 0.5 minutes. Relative retention times of the n-alkanes: The retention times of the n-alkanes relative to the TCB internal standard shall be similar to those given in Table 2 of this appendix.

12.0 Calculations

The concentration of oil in NAFs drilling fluids shall be computed relative to peak areas between C_8 and C_{13} (using the Total Area Integration method) or total peak areas from extracted ion profiles (using the Extracted Ion Profile Method). In either case, there is a measurable amount of peak area, even in clean drilling fluid samples, due to spurious peaks and electrometer "noise" that contributes to the total signal measured using either of the quantification methods. In this procedure, a correction for this signal is applied, using the blank or clean sample correction technique described in American Society for Testing Materials (ASTM) Method D–3328–90, Comparison of Waterborne Oil by Gas Chromatography. In this method, the "oil equivalents" measured in a blank sample by total area gas chromatography are subtracted from that determined for a field sample to arrive at the most accurate measure of oil residue in the authentic sample.

12.1 Total Area Integration Method

12.1.1 Using C_8 to C_{13} TIC area, the TCB area in the clean NAF sample and the TIC linear regression curve, compute the oil equivalent concentration of the C_8 to C_{13} retention time range in the clean NAF.

Note: The actual TIC area of the C_8 to C_{13} is equal to the C_8 to C_{13} area minus the area of the TCB.

12.1.2 Using the corresponding information for the authentic sample, compute the oil equivalent concentration of the C_8 to C_{13} retention time range in the authentic sample.

12.1.3 Calculate the concentration (% oil) of oil in the sample by subtracting the oil equivalent concentration (% oil) found in the clean NAF from the oil equivalent concentration (% oil) found in the authentic sample.

12.2 EIP Area Integration Method

12.2.1 Using either m/z 91 or 105 EIP areas, the TCB area in the clean NAF sample, and the appropriate EIP linear regression curve, compute the oil equivalent concentration of the in the clean NAF.

12.2.2 Using the corresponding information for the authentic sample, compute its oil equivalent concentration.

12.2.3 Calculate the concentration (% oil) of oil in the sample by subtracting the oil equivalent concentration (% oil) found in the clean NAF from the oil equivalent concentration (% oil) found in the authentic sample.

13.0 Method Performance

13.1 Specification in this method are adopted from EPA Method 1663, Differentiation of Diesel and Crude Oil by GC/FID (Reference 16.5).

13.2 Single laboratory method performance using an Internal Olefin (IO) drilling fluid fortified at 0.5% oil using a 35 API gravity oil was:

Precision and accuracy 94±4%
Accuracy interval—86.3% to 102%
Relative percent difference in duplicate analysis—6.2%

14.0 Pollution Prevention

14.1 The solvent used in this method poses little threat to the environment when recycled and managed properly.

15.0 Waste Management

15.1 It is the laboratory's responsibility to comply with all federal, state, and local regulations governing waste management, particularly the hazardous waste identification rules and land disposal restriction, and to protect the air, water, and land by minimizing and controlling all releases from fume hoods and bench operations. Compliance with all sewage discharge permits and regulations is also required.

15.2 All authentic samples (drilling fluids) failing the RPE (fluorescence) test (indicated by the presence of fluorescence) shall be retained and classified as contaminated samples. Treatment and ultimate fate of these samples is not outlined in this SOP.

15.3 For further information on waste management, consult "The Waste Management Manual for Laboratory Personnel", and "Less is Better: Laboratory Chemical Management for Waste Reduction", both available from the American Chemical Society's Department of Government Relations and Science Policy, 1155 16th Street NW, Washington, DC 20036.

16.0 References

16.1 Carcinogens—"Working With Carcinogens." Department of Health, Education, and Welfare, Public Health Service, Centers for Disease Control (available through National Technical Information Systems, 5285 Port Royal Road, Springfield, VA 22161, document no. PB–277256): August 1977.

16.2 "OSHA Safety and Health Standards, General Industry [29 CFR 1910], Revised." Occupational Safety and Health Administration, OSHA 2206. Washington, DC: January 1976.

16.3 "Handbook of Analytical Quality Control in Water and Wastewater Laboratories." USEPA, EMSSL–CI, EPA–600/4–79–019. Cincinnati, OH: March 1979.

16.4 "Method 1663, Differentiation of Diesel and Crude Oil by GC/FID, Methods for the Determination of Diesel, Mineral, and Crude Oils in Offshore Oil and Gas Industry Discharges, EPA 821–R–92–008, Office of Water Engineering and Analysis Division, Washington, DC: December 1992.

Appendix 6 to Subpart A of Part 435—Reverse Phase Extraction (RPE) Method for Detection of Oil Contamination in Non-Aqueous Drilling Fluids (NAF)

1.0 Scope and Application

1.1 This method is used for determination of crude or formation oil, or other petroleum oil contamination, in non-aqueous drilling fluids (NAFs).

1.2 This method is intended as a positive/negative test to determine a presence of crude oil in NAF prior to discharging drill cuttings from offshore production platforms.

1.3 This method is for use in the Environmental Protection Agency's (EPA's) survey and monitoring programs under the Clean Water Act, including monitoring of compliance with the Gulf of Mexico NPDES General Permit for monitoring of oil contamination in drilling fluids.

1.4 This method has been designed to show positive contamination for 5% of representative crude oils at a concentration of 0.1% in drilling fluid (vol/vol), 50% of representative crude oils at a concentration of 0.5%, and 95% of representative crude oils at a concentration of 1%.

1.5 Any modification of this method, beyond those expressly permitted, shall be considered a major modification subject to application and approval of alternate test procedures under 40 CFR Parts 136.4 and 136.5.

1.6 Each laboratory that uses this method must demonstrate the ability to generate acceptable results using the procedure in Section 9.2 of this appendix.

2.0 Summary of Method

2.1 An aliquot of drilling fluid is extracted using isopropyl alcohol.

2.2 The mixture is allowed to settle and then filtered to separate out residual solids.

2.3 An aliquot of the filtered extract is charged onto a reverse phase extraction (RPE) cartridge.

2.4 The cartridge is eluted with isopropyl alcohol.

2.5 Crude oil contaminates are retained on the cartridge and their presence (or absence) is detected based on observed fluorescence using a black light.

3.0 Definitions

3.1 A NAF is one in which the continuous phase is a water immiscible fluid such as an oleaginous material (e.g., mineral oil, enhance mineral oil, paraffinic oil, or synthetic material such as olefins and vegetable esters).

4.0 Interferences

4.1 Solvents, reagents, glassware, and other sample-processing hardware may yield artifacts that affect results. Specific selection of reagents and purification of solvents may be required.

4.2 All materials used in the analysis shall be demonstrated to be free from interferences under the conditions of analysis by running laboratory reagent blanks as described in Section 9.5 of this appendix.

5.0 Safety

5.1 The toxicity or carcinogenicity of each reagent used in this method has not been precisely determined; however, each chemical shall be treated as a potential health hazard. Exposure to these chemicals should be reduced to the lowest possible level. Material Safety Data Sheets (MSDSs) shall be available for all reagents.

5.2 Isopropyl alcohol is flammable and should be used in a well-ventilated area.

5.3 Unknown samples may contain high concentration of volatile toxic compounds. Sample containers should be opened in a hood and handled with gloves to prevent exposure. In addition, all sample preparation should be conducted in a well-ventilated area to limit the potential exposure to harmful contaminants. Drilling fluid samples should be handled with the same precautions used in the drilling fluid handling areas of the drilling rig.

5.4 This method does not address all safety issues associated with its use. The laboratory is responsible for maintaining a safe work environment and a current awareness file of OSHA regulations regarding the safe handling of the chemicals specified in this method. A reference file of material safety data sheets (MSDSs) shall be available to all personnel involved in these analyses. Additional information on laboratory safety can be found in References 16.1–16.2.

6.0 Equipment and Supplies

Note: Brand names, suppliers, and part numbers are for illustrative purposes only. No endorsement is implied. Equivalent performance may be achieved using apparatus and materials other than those specified here, but demonstration of equivalent performance that meets the requirements of this method is the responsibility of the laboratory.

6.1 Sampling equipment.

6.1.1 Sample collection bottles/jars—New, pre-cleaned bottles/jars, lot-certified to be free of artifacts. Glass preferable, plastic acceptable, wide mouth approximately 1–L, with Teflon-lined screw cap.

6.2 Equipment for glassware cleaning.

6.2.1 Laboratory sink.

6.2.2 Oven—Capable of maintaining a temperature within ±5°C in the range of 100–250 °C.

6.3 Equipment for sample extraction.

6.3.1 Vials—Glass, 25 mL and 4 mL, with Teflon-lined screw caps, baked at 200–250 °C for 1–h minimum prior to use.

6.3.2 Gas-tight syringes—Glass, various sizes, 0.5 mL to 2.5 mL (if spiking of drilling fluids with oils is to occur).

6.3.3 Auto pipetters—various sizes, 0.1 mL, 0.5 mL, 1 to 5 mL delivery, and 10 mL

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delivery, with appropriate size disposable pipette tips, calibrated to within ±0.5%.

6.3.4 Glass stirring rod.

6.3.5 Vortex mixer.

6.3.6 Disposable syringes—Plastic, 5 mL.

6.3.7 Teflon syringe filter, 25-mm, 0.45µm pore size—Acrodisc® CR Teflon (or equivalent).

6.3.8 Reverse Phase Extraction C_{18} Cartridge—Waters Sep-Pak®Plus, C_{18} Cartridge, 360 mg of sorbent (or equivalent).

6.3.9 SPE vacuum manifold—Supelco Brand, 12 unit (or equivalent). Used as support for cartridge/syringe assembly only. Vacuum apparatus not required.

6.4 Equipment for fluorescence detection.

6.4.1 Black light—UV Lamp, Model UVG 11, Mineral Light Lamp, Shortwave 254 nm, or Longwave 365 nm, 15 volts, 60 Hz, 0.16 amps (or equivalent).

6.4.2 Black box—cartridge viewing area. A commercially available ultraviolet viewing cabinet with viewing lamp, or alternatively, a cardboard box or equivalent, approximately 14"x7.5"x7.5" in size and painted flat black inside. Lamp positioned in fitted and sealed slot in center on top of box. Sample cartridges sit in a tray, ca. 6" from lamp. Cardboard flaps cut on top panel and side of front panel for sample viewing and sample cartridge introduction, respectively.

6.4.3 Viewing platform for cartridges. Simple support (hand made vial tray—black in color) for cartridges so that they do not move during the fluorescence testing.

7.0 Reagents and Standards

7.1 Isopropyl alcohol—99% purity.

7.2 NAF—Appropriate NAF as sent from the supplier (has not been circulated downhole). Use the clean NAF corresponding to the NAF being used in the current drilling operation.

7.3 Standard crude oil—NIST SRM 1582 petroleum crude oil.

8.0 Sample Collection, Preservation, and Storage

8.1 Collect approximately one liter of representative sample (NAF, which has been circulated downhole) in a glass bottle or jar. Cover with a Teflon lined cap. To allow for a potential need to re-analyze and/or re-process the sample, it is recommended that a second sample aliquot be collected.

8.2 Label the sample appropriately.

8.3 All samples must be refrigerated at 0–4 °C from the time of collection until extraction (40 CFR Part 136, Table II).

8.4 All samples must be analyzed within 28 days of the date and time of collection (40 CFR Part 136, Table II).

9.0 Quality Control

9.1 Each laboratory that uses this method is required to operate a formal quality assurance program (Reference 16.3). The minimum requirements of this program consist of an initial demonstration of laboratory capability, and ongoing analyses of blanks and spiked duplicates to assess accuracy and precision and to demonstrate continued performance. Each field sample is analyzed in duplicate to demonstrate representativeness.

9.1.1 The analyst shall make an initial demonstration of the ability to generate acceptable accuracy and precision with this method. This ability is established as described in Section 9.2 of this appendix.

9.1.2 Preparation and analysis of a set of spiked duplicate samples to document accuracy and precision. The procedure for the preparation and analysis of these samples is described in Section 9.4 of this appendix.

9.1.3 Analyses of laboratory reagent blanks are required to demonstrate freedom from contamination. The procedure and criteria for preparation and analysis of a reagent blank are described in Section 9.5 of this appendix.

9.1.4 The laboratory shall maintain records to define the quality of the data that is generated.

9.1.5 Accompanying QC for the determination of oil in NAF is required per analytical batch. An analytical batch is a set of samples extracted at the same time, to a maximum of 10 samples. Each analytical batch of 10 or fewer samples must be accompanied by a laboratory reagent blank (Section 9.5 of this appendix), corresponding NAF reference blanks (Section 9.6 of this appendix), a set of spiked duplicate samples blank (Section 9.4 of this appendix), and duplicate analysis of each field sample. If greater than 10 samples are to be extracted at one time, the samples must be separated into analytical batches of 10 or fewer samples.

9.2 Initial demonstration of laboratory capability. To demonstrate the capability to perform the test, the analyst shall analyze two representative unused drilling fluids (e.g., internal olefin-based drilling fluid, vegetable ester-based drilling fluid), each prepared separately containing 0.1%, 1%, and 2% or a representative oil. Each drilling fluid/concentration combination shall be analyzed 10 times, and successful demonstration will yield the following average results for the data set:

0.1% oil—Detected in <20% of samples
1% oil—Detected in >75% of samples
2% oil—Detected in <90% of samples

9.3 Sample duplicates.

9.3.1 The laboratory shall prepare and analyze (Section 11.2 and 11.4 of this appendix) each authentic sample in duplicate, from a given sampling site or, if for compliance monitoring, from a given discharge.

9.3.2 The duplicate samples must be compared versus the prepared corresponding NAF blank.

9.3.3 Prepare and analyze the duplicate samples according to procedures outlined in Section 11 of this appendix.

9.3.4 The results of the duplicate analyses are acceptable if each of the results give the same response (fluorescence or no fluorescence). If the results are different, sample non-homogenicity issues may be a concern. Prepare the samples again, ensuring a well-mixed sample prior to extraction. Analyze the samples once again.

9.3.5 If different results are obtained for the duplicate a second time, the analytical system is judged to be out of control and the problem shall be identified and corrected, and the samples re-analyzed.

9.4 Spiked duplicates—Laboratory prepared spiked duplicates are analyzed to demonstrate acceptable accuracy and precision.

9.4.1 Preparation and analysis of a set of spiked duplicate samples with each set of no more than 10 field samples is required to demonstrate method accuracy and precision and to monitor matrix interferences (interferences caused by the sample matrix). A field NAF sample expected to contain less than 0.5% crude oil (and documented to not fluoresce as part of the sample batch analysis) shall be spiked with 1% (by volume) of suitable reference crude oil and analyzed as field samples, as described in Section 11 of this appendix. If no low-level drilling fluid is available, then the unused NAF can be used as the drilling fluid sample.

9.5 Laboratory reagent blanks—Laboratory reagent blanks are analyzed to demonstrate freedom from contamination.

9.5.1 A reagent blank is prepared by passing 4 mL of the isopropyl alcohol through a Teflon syringe filter and collecting the filtrate in a 4-mL glass vial. A Sep Pak® C_{18} cartridge is then preconditioned with 3 mL of isopropyl alcohol. A 0.5-mL aliquot of the filtered isopropyl alcohol is added to the syringe barrel along with 3.0 mL of isopropyl alcohol. The solvent is passed through the preconditioned Sep Pak® cartridge. An additional 2-mL of isopropyl alcohol is eluted through the cartridge. The cartridge is now considered the "reagent blank" cartridge and is ready for viewing (analysis). Check the reagent blank cartridge under the black light for fluorescence. If the isopropyl alcohol and filter are clean, no fluorescence will be observed.

9.5.2 If fluorescence is detected in the reagent blank cartridge, analysis of the samples is halted until the source of contamination is eliminated and a prepared reagent blank shows no fluorescence under a black light. All samples shall be associated with an uncontaminated method blank before the results may be reported for regulatory compliance purposes.

9.6 NAF reference blanks—NAF reference blanks are prepared from the NAFs sent from the supplier (NAF that has not been circulated downhole) and used as the reference when viewing the fluorescence of the test samples.

9.6.1 A NAF reference blank is prepared identically to the authentic samples. Place a 0.1 mL aliquot of the "clean" NAF into a 25-mL glass vial. Add 10 mL of isopropyl alcohol to the vial. Cap the vial. Vortex the vial for approximately 10 sec. Allow the solids to settle for approximately 15 minutes. Using a 5-mL syringe, draw up 4 mL of the extract and filter it through a PTFE syringe filter, collecting the filtrate in a 4-mL glass vial. Precondition a Sep Pak® C_{18} cartridge with 3 mL of isopropyl alcohol. Add a 0.5-mL aliquot of the filtered extract to the syringe barrel along with 3.0 mL of isopropyl alcohol. Pass the extract and solvent through the preconditioned Sep Pak® cartridge. Pass an additional 2-mL of isopropyl alcohol through the cartridge. The cartridge is now considered the NAF blank cartridge and is ready for viewing (analysis). This cartridge is used as the reference cartridge for determining the absence or presence of fluorescence in all authentic drilling fluid samples that originate from the same NAF. That is, the specific NAF reference blank cartridge is put under the black light along with a prepared cartridge of an authentic sample originating from the same NAF material. The fluorescence or absence of fluorescence in the authentic sample cartridge is determined relative to the NAF reference cartridge.

9.6.2 Positive control solution, equivalent to 1% crude oil contaminated mud extract, is prepared by dissolving 87 mg of standard crude oil into 10.00 mL of methylene chloride. Then mix 40 µL of this solution into 10.00 mL of IPA. Transfer 0.5 mL of this solution into a preconditioned C18 cartridge, followed by 2 ml of IPA.

10.0 Calibration and Standardization

10.1 Calibration and standardization methods are not employed for this procedure.

11.0 Procedure

This method is a screening-level test. Precise and accurate results can be obtained only by strict adherence to all details.

11.1 Preparation of the analytical batch.

11.1.1 Bring the analytical batch of samples to room temperature.

11.1.2 Using a large glass stirring rod, mix the authentic sample thoroughly.

11.1.3 Using a large glass stirring rod, mix the clean NAF (sent from the supplier) thoroughly.

11.2 Extraction.

11.2.1 Using an automatic positive displacement pipetter and a disposable pipette tip transfer 0.1-mL of the authentic sample into a 25-mL vial.

11.2.2 Using an automatic pipetter and a disposable pipette tip dispense a 10-mL aliquot of solvent grade isopropyl alcohol (IPA) into the 25 mL vial.

11.2.3 Cap the vial and vortex the vial for ca. 10–15 seconds.

11.2.4 Let the sample extract stand for approximately 5 minutes, allowing the solids to separate.

11.2.5 Using a 5-mL disposable plastic syringe remove 4 mL of the extract from the 25-mL vial.

11.2.6 Filter 4 mL of extract through a Teflon syringe filter (25-mm diameter, 0.45 µm pore size), collecting the filtrate in a labeled 4-mL vial.

11.2.7 Dispose of the PFTE syringe filter.

11.2.8 Using a black permanent marker, label a Sep Pak® C_{18} cartridge with the sample identification.

11.2.9 Place the labeled Sep Pak® C_{18} cartridge onto the head of a SPE vacuum manifold.

11.2.10 Using a 5-mL disposable plastic syringe, draw up exactly 3-mL (air free) of isopropyl alcohol.

11.2.11 Attach the syringe tip to the top of the C_{18} cartridge.

11.2.12 Condition the C_{18} cartridge with the 3-mL of isopropyl alcohol by depressing the plunger slowly.

Note: Depress the plunger just to the point when no liquid remains in the syringe barrel. Do not force air through the cartridge. Collect the eluate in a waste vial.

11.2.13 Remove the syringe temporarily from the top of the cartridge, then remove the plunger, and finally reattach the syringe barrel to the top of the C_{18} cartridge.

11.2.14 Using automatic pipetters and disposable pipette tips, transfer 0.5 mL of the filtered extract into the syringe barrel, followed by a 3.0-mL transfer of isopropyl alcohol to the syringe barrel.

11.2.15 Insert the plunger and slowly depress it to pass only the extract and solvent through the preconditioned C_{18} cartridge.

Note: Depress the plunger just to the point when no liquid remains in the syringe barrel. Do not force air through the cartridge. Collect the eluate in a waste vial.

11.2.16 Remove the syringe temporarily from the top of the cartridge, then remove the plunger, and finally reattach the syringe barrel to the top of the C_{18} cartridge.

11.2.17 Using an automatic pipetter and disposable pipette tip, transfer 2.0 mL of isopropyl alcohol to the syringe barrel.

11.2.18 Insert the plunger and slowly depress it to pass the solvent through the C_{18} cartridge.

Note: Depress the plunger just to the point when no liquid remains in the syringe barrel. Do not force air through the cartridge. Collect the eluate in a waste vial.

11.2.19 Remove the syringe and labeled C_{18} cartridge from the top of the SPE vacuum manifold.

11.2.20 Prepare a reagent blank according to the procedures outlined in Section 9.5 of this appendix.

11.2.21 Prepare the necessary NAF reference blanks for each type of NAF encountered in the field samples according to the procedures outlined in Section 9.6 of this appendix.

11.2.22 Prepare the positive control (1% crude oil equivalent) according to Section 9.6.2 of this appendix.

11.3 Reagent blank fluorescence testing.

11.3.1 Place the reagent blank cartridge in a black box, under a black light.

11.3.2 Determine the presence or absence of fluorescence for the reagent blank cartridge. If fluorescence is detected in the blank, analysis of the samples is halted until the source of contamination is eliminated and a prepared reagent blank shows no fluorescence under a black light. All samples must be associated with an uncontaminated method blank before the results may be reported for regulatory compliance purposes.

11.4 Sample fluorescence testing.

11.4.1 Place the respective NAF reference blank (Section 9.6 of this appendix) onto the tray inside the black box.

11.4.2 Place the authentic field sample cartridge (derived from the same NAF as the NAF reference blank) onto the tray, adjacent and to the right of the NAF reference blank.

11.4.3 Turn on the black light.

11.4.4 Compare the fluorescence of the sample cartridge with that of the negative control cartridge (NAF blank, Section 9.6.1 of this appendix) and positive control cartridge (1% crude oil equivalent, Section 9.6.2 of this appendix).

11.4.5 If the fluorescence of the sample cartridge is equal to or brighter than the positive control cartridge (1% crude oil equivalent, Section 9.6.2 of this appendix), the sample is considered contaminated. Otherwise, the sample is clean.

12.0 Data Analysis and Calculations

Specific data analysis techniques and calculations are not performed in this SOP.

13.0 Method Performance

This method was validated through a single laboratory study, conducted with rigorous statistical experimental design and interpretation (Reference 16.4).

14.0 Pollution Prevention

14.1 The solvent used in this method poses little threat to the environment when recycled and managed properly.

15.0 Waste Management

15.1 It is the laboratory's responsibility to comply with all Federal, State, and local regulations governing waste management, particularly the hazardous waste identification rules and land disposal restriction, and to protect the air, water, and land by minimizing and controlling all releases from bench operations. Compliance with all sewage discharge permits and regulations is also required.

15.2 All authentic samples (drilling fluids) failing the fluorescence test (indicated by the presence of fluorescence) shall be retained and classified as contaminated samples. Treatment and ultimate fate of these samples is not outlined in this SOP.

15.3 For further information on waste management, consult "The Waste Management Manual for Laboratory Personnel," and "Less is Better: Laboratory Chemical Management for Waste Reduction," both available from the American Chemical Society's Department of Government Relations and Science Policy, 1155 16th Street, NW, Washington, DC 20036.

16.0 References

16.1 "Carcinogen—Working with Carcinogens," Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health, Publication No. 77–206, August 1977.

16.2 "OSHA Safety and Health Standards, General Industry," (29 CFR 1910), Occupational Safety and Health Administration, OSHA 2206 (Revised, January 1976).

16.3 "Handbook of Analytical Quality Control in Water and Wastewater Laboratories," USEPA, EMSL-Ci, Cincinnati, OH 45268, EPA–600/4–79–019, March 1979.

16.4 Report of the Laboratory Evaluation of Static Sheen Test Replacements—Reverse Phase Extraction (RPE) Method for Detecting Oil Contamination in Synthetic Based Mud (SBM). October 1998. Available from API, 1220 L Street, NW, Washington, DC 20005–4070, 202–682–8000.

Appendix 7 to Subpart A of Part 435—API Recommended Practice 13B–2

1. Description

a. This procedure is specifically intended to measure the amount of non-aqueous drilling fluid (NAF) base fluid from cuttings generated during a drilling operation. This procedure is a retort test which measures all oily material (NAF base fluid) and water released from a cuttings sample when heated

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in a calibrated and properly operating "Retort" instrument.

b. In this retort test a known mass of cuttings is heated in the retort chamber to vaporize the liquids associated with the sample. The NAF base fluid and water vapors are then condensed, collected, and measured in a precision graduated receiver.

Note: Obtaining a representative sample requires special attention to the details of sample handling (e.g., location, method, frequency). See Addendum A and B for minimum requirements for collecting representative samples. Additional sampling procedures in a given area may be specified by the NPDES permit controlling authority.

2. Equipment

a. Retort instrument—The recommended retort instrument has a 50-cm³ volume with an external heating jacket.

Retort Specifications:

1. Retort assembly—retort body, cup and lid.

(a) Material: 303 stainless steel or equivalent.

(b) Volume: Retort cup with lid.

Cup Volume: 50-cm³.

Precision: ±0.25-cm³.

2. Condenser—capable of cooling the oil and water vapors below their liquification temperature.

3. Heating jacket—nominal 350 watts.

4. Temperature control—capable of limiting temperature of retort to at least 930 °F (500 °C) and enough to boil off all NAFs.

b. Liquid receiver (10-cm³, 20-cm³)—the 10-cm³ and 20-cm³ receivers are specially designed cylindrical glassware with rounded bottom to facilitate cleaning and funnel-shaped top to catch falling drops. For compliance monitoring under the NPDES program, the analyst shall use the 10-cm³ liquid receiver with 0.1 ml graduations to achieve greater accuracy.

1. Receiver specifications:

Total volume: 10-cm³, 20-cm³.

Precision (0 to 100%): ±0.05 cm³, ±0.05 cm³.

Outside diameter: 10-mm, 13-mm.

Wall thickness: 1.5±0.1mm, 1.2±0.1mm.

Frequency of graduation marks (0 to 100%): 0.10-cm³, 0.10-cm³.

Calibration: To contain "TC" @ 20°C.

Scale: cm³, cm³

2. Material—Pyrex® or equivalent glass.

c. Toploading balance—capable of weighing 2000 g and precision of at least 0.1 g. Unless motion is a problem, the analyst shall use an electronic balance. Where motion is a problem, the analyst may use a triple beam balance.

d. Fine steel wool (No. 000)—for packing retort body.

e. Thread sealant lubricant: high temperature lubricant, e.g. Never-Seez® or equivalent.

f. Pipe cleaners—to clean condenser and retort stem.

g. Brush—to clean receivers.

h. Retort spatula—to clean retort cup.

i. Corkscrew—to remove spent steel wool.

3. Procedure

a. Clean and dry the retort assembly and condenser.

b. Pack the retort body with steel wool.

c. Apply lubricant/sealant to threads of retort cup and retort stem.

d. Weigh and record the total mass of the retort cup, lid, and retort body with steel wool. This is mass (A), grams.

e. Collect a representative cuttings sample (*see* **Note** in Section 1 of this appendix).

f. Partially fill the retort cup with cuttings and place the lid on the cup.

g. Screw the retort cup (with lid) onto the retort body, weigh and record the total mass. This is mass (B), grams.

h. Attach the condenser. Place the retort assembly into the heating jacket.

i. Weigh and record the mass of the clean and dry liquid receiver. This is mass (C), grams. Place the receiver below condenser outlet.

j. Turn on the retort. Allow it to run a minimum of 1 hour.

Note: If solids boil over into receiver, the test shall be rerun. Pack the retort body with a greater amount of steel wool and repeat the test.

k. Remove the liquid receiver. Allow it to cool. Record the volume of water recovered. This is (V), cm³.

Note: If an emulsion interface is present between the oil and water phases, heating the interface may break the emulsion. As a suggestion, remove the retort assembly from the heating jacket by grasping the condenser. Carefully heat the receiver along the emulsion band by gently touching the receiver for short intervals with the hot retort assembly. Avoid boiling the liquids. After the emulsion interface is broken, allow the liquid receiver to cool. Read the water volume at the lowest point of the meniscus.

l. Weigh and record the mass of the receiver and its liquid contents (oil plus water). This is mass (D), grams.

m. Turn off the retort. Remove the retort assembly and condenser from the heating jacket and allow them to cool. Remove the condenser.

n. Weigh and record the mass of the cooled retort assembly without the condenser. This is mass (E), grams.

o. Clean the retort assembly and condenser.

4. Calculations

a. Calculate the mass of oil (NAF base fluid) from the cuttings as follows:

1. Mass of the wet cuttings sample (M_w) equals the mass of the retort assembly with the wet cuttings sample (B) minus the mass of the empty retort assembly (A).

$$M_w = B - A \quad [1]$$

2. Mass of the dry retorted cuttings (M_D) equals the mass of the cooled retort assembly (E) minus the mass of the empty retort assembly (A).

$$M_D = E - A \quad [2]$$

3. Mass of the NAF base fluid (M_{BF}) equals the mass of the liquid receiver with its contents (D) minus the sum of the mass of the dry receiver (C) and the mass of the water (V).

$$M_{BF} = D - (C + V) \quad [3]$$

Note: Assuming the density of water is 1 g/cm³, the volume of water is equivalent to the mass of the water.

b. Mass balance requirement:

The sum of M_D, M_{BF}, and V shall be within 5% of the mass of the wet sample.

$$(M_D + M_{BF} + V)/M_w = 0.95 \text{ to } 1.05 \quad [4]$$

The procedure shall be repeated if this requirement is not met.

c. Reporting oil from cuttings:

1. Assume that all oil recovered is NAF base fluid.

2. The mass percent NAF base fluid retained on the cuttings ($\%BF_i$) for the sampled discharge "i" is equal to 100 times the mass of the NAF base fluid (M_{BF}) divided by the mass of the wet cuttings sample (M_w).

$$\%BF_i = (M_{BF}/M_w) \times 100 \quad [5]$$

Operators discharging small volume NAF-cuttings discharges which do not occur during a NAF-cuttings discharge sampling interval (i.e., displaced interfaces, accumulated solids in sand traps, pit clean-out solids, or centrifuge discharges while cutting mud weight) shall either: (a) Measure the mass percent NAF base fluid retained on the cuttings ($\%BF_{SVD}$) for each small volume NAF-cuttings discharges; or (b) use a default value of 25% NAF base fluid retained on the cuttings.

3. The mass percent NAF base fluid retained on the cuttings is determined for all cuttings wastestreams and includes fines discharges and any accumulated solids discharged [*see* Section 4.c.6 of this appendix for procedures on measuring or estimating the mass percent NAF base fluid retained on the cuttings (%BF) for dual gradient drilling seafloor discharges performed to ensure proper operation of subsea pumps].

4. A mass NAF-cuttings discharge fraction (X, unitless) is calculated for all NAF-cuttings, fines, or accumulated solids discharges every time a set of retorts is performed (*see* Section 4.c.6 of this appendix for procedures on measuring or estimating the mass NAF-cuttings discharge fraction (X) for dual gradient drilling seafloor discharges performed to ensure proper operation of subsea pumps). The mass NAF-cuttings discharge fraction (X) combines the mass of NAF-cuttings, fines, or accumulated solids discharged from a particular discharge over a set period of time with the total mass of NAF-cuttings, fines, or accumulated solids discharged into the ocean during the same period of time (*see* Addendum A and B of this appendix). The mass NAF-cuttings discharge fraction (X) for each discharge is calculated by direct measurement as:

$$X_i = (F_i)/(G) \quad [6]$$

where:

X_i = Mass NAF-cuttings discharge fraction for NAF-cuttings, fines, or accumulated solids discharge "i", (unitless)

F_i = Mass of NAF-cuttings discharged from NAF-cuttings, fines, or accumulated solids discharge "i" over a specified period of time (*see* Addendum A and B of this appendix), (kg)

G = Mass of all NAF-cuttings discharges into the ocean during the same period of time as used to calculate F_i, (kg)

If an operator has more than one point of NAF-cuttings discharge, the mass faction (X_i) must be determined by: (a) Direct measurement (*see* Equation 6 of this Appendix); (b) using the following default values of 0.85 and 0.15 for the cuttings dryer (e.g., horizontal centrifuge, vertical centrifuge, squeeze press, High-G linear shakers) and fines removal unit (e.g., decanting centrifuges, mud cleaners), respectively, when the operator is only discharging from the cuttings dryer and the fines removal unit; or (c) using direct measurement of "F_i" (*see* Equation 6 of this Appendix) for fines and accumulated solids, using Equation 6A of this Appendix to calculate "G_{EST}" for use as "G" in Equation 6 of this Appendix, and calculating the mass (kg) of NAF-cuttings discharged from the cuttings dryer (F_i) as the difference between the mass of "G_{EST}" calculated in Equation 6A of this appendix (kg) and the sum of all fines and accumulated solids mass directly measured (kg) (*see* Equation 6 of this Appendix).

G_{EST} = Estimated mass of all NAF-cuttings discharges into the ocean during the same period of time as used to calculate F_i (*see* Equation 6 of this Appendix), (kg) [6A]

where:

G_{EST} = Hole Volume (bbl) × (396.9 kg/bbl) × (1 + Z/100)

Z = The base fluid retained on cuttings limitation or standard (%) which apply to the NAF being discharge (*see* §§ 435.13. and 435.15).

Hole Volume (bbl) = [Cross-Section Area of NAF interval (in²)] × Average Rate of Penetration (feet/hr) × period of time (min) used to calculate F_i (*see* Equation 6 of this Appendix) × (1 hr/60 min) × (1 bbl/5.61 ft³) × (1 ft/12 in)²

Cross-Section Area of NAF interval (in²) = (3.14 × [Bit Diameter (in)]²)/4

Bit Diameter (in) = Diameter of drilling bit for the NAF interval producing drilling cuttings during the same period of time as used to calculate F_i (*see* Equation 6 of this Appendix)

Average Rate of Penetration (feet/hr) = Arithmetic average of rate of penetration into the formation during the same period of time as used to calculate F_i (*see* Equation 6 of this Appendix)

Note: Operators with one NAF-cuttings discharge may set the mass NAF-cuttings discharge fraction (X_i) equal to 1.0.

5. Each NAF-cuttings, fines, or accumulated solids discharge has an associated mass percent NAF base fluid retained on cuttings value (%BF) and mass NAF-cuttings discharge fraction (X) each time a set of retorts is performed. A single total mass percent NAF base fluid retained on cuttings value ($\%BF_T$) is calculated every time a set of retorts is performed. The single total mass percent NAF base fluid retained on cuttings value ($\%BF_T$) is calculated as:

$$\%BF_{T,j} = \Sigma(X_i) \times (\%BF_i) \quad [7]$$

where:

$\%BF_{T,j}$ = Total mass percent NAF base fluid retained on cuttings value for retort set "j" (unitless as percentage, %)

X_i = Mass NAF-cuttings discharge fraction for NAF-cuttings, fines, or accumulated solids discharge "i", (unitless)

$\%BF_i$ = Mass percent NAF base fluid retained on the cuttings for NAF-cuttings, fines, or accumulated solids discharge "i", (unitless as percentage, %)

Note: $\Sigma X_i = 1$.

Operators with one NAF-cuttings discharge may set $\%BF_{T,j}$ equal to $\%BF_i$.

6. Operators performing dual gradient drilling operations may require seafloor discharges of large cuttings (>¼") to ensure the proper operation of subsea pumps (e.g., electrical submersible pumps). Operators performing dual gradient drilling operations which lead to seafloor discharges of large cuttings for the proper operation of subsea pumps shall either: (a) Measure the mass percent NAF base fluid retained on cuttings value (%BF) and mass NAF-cuttings discharge fraction (X) for seafloor discharges each time a set of retorts is performed; (b) use the following set of default values, (%BF=14%; X=0.15); or (c) use a combination of (a) and (b) (e.g., use a default value for %BF and measure X).

Additionally, operators performing dual gradient drilling operations which lead to seafloor discharges of large cuttings for the proper operation of subsea pumps shall also perform the following tasks:

(a) Use side scan sonar or shallow seismic to determine the presence of high density chemosynthetic communities. Chemosynthetic communities are assemblages of tube worms, clams, mussels, and bacterial mats that occur at natural hydrocarbon seeps or vents, generally in water depths of 500 meters or deeper. Seafloor discharges of large cuttings for the proper operation of subsea pumps shall not be permitted within 1000 feet of a high density chemosynthetic community.

(b) Seafloor discharges of large cuttings for the proper operation of subsea pumps shall be visually monitored and documented by a Remotely Operated Vehicle (ROV) within the tether limit (approximately 300 feet). The visual monitoring shall be conducted prior to each time the discharge point is relocated (cuttings discharge hose) and conducted along the same direction as the discharge hose position. Near-seabed currents shall be obtained at the time of the visual monitoring.

(c) Seafloor discharges of large cuttings for the proper operation of subsea pumps shall be directed within a 150 foot radius of the wellbore.

7. The weighted mass ratio averaged over all NAF well sections ($\%BF_{well}$) is the compliance value that is compared with the "maximum weighted mass ratio averaged over all NAF well sections" BAT discharge limitations (*see* the table in § 435.13 and footnote 5 of the table in § 435.43) or the "maximum weighted mass ratio averaged over all NAF well sections" NSPS discharge limitations (*see* the table in § 435.15 and footnote 5 of the table in § 435.45). The weighted mass ratio averaged over all NAF well sections ($\%BF_{well}$) is calculated as the arithmetic average of all total mass percent NAF base fluid retained on cuttings values ($\%BF_T$) and is given by the following expression:

$$\%BF_{well} = [j=1 \text{ to } j=n\ \Sigma\ (\%BF_{T,j})]/n \quad [8]$$

where:

$\%BF_{well}$ = Weighted mass ratio averaged over all NAF well sections (unitless as percentage, %)

$\%BF_{T,j}$ = Total mass percent NAF base fluid retained on cuttings value for retort set "j" (unitless as percentage, %)

n = Total number of retort sets performed over all NAF well sections (unitless)

Small volume NAF-cuttings discharges which do not occur during a NAF-cuttings discharge sampling interval (i.e., displaced interfaces, accumulated solids in sand traps, pit clean-out solids, or centrifuge discharges while cutting mud weight) shall be mass averaged with the arithmetic average of all total mass percent NAF base fluid retained on cuttings values (see Equation 8 of this Appendix). An additional sampling interval shall be added to the calculation of the weighted mass ratio averaged over all NAF well sections ($\%BF_{well}$). The mass fraction of the small volume NAF-cuttings discharges (X_{SVD}) will be determined by dividing the mass of the small volume NAF-cuttings discharges (F_{SVD}) by the total mass of NAF-cuttings discharges for the well drilling operation ($G_{WELL} + F_{SVD}$).

$$X_{SVD} = F_{SVD} / (G_{WELL} + F_{SVD}) \quad [9]$$

where:

X_{SVD} = mass fraction of the small volume NAF-cuttings discharges (unitless)

F_{SVD} = mass of the small volume NAF-cuttings discharges (kg)

G_{WELL} = mass of total NAF-cuttings from the well (kg)

The mass of small volume NAF-cuttings discharges (F_{SVD}) shall be determined by multiplying the density of the small volume NAF-cuttings discharges (ρ_{svd}) times the volume of the small volume NAF-cuttings discharges (V_{SVD}).

$$F_{SVD} = \rho_{svd} \times V_{SVD} \quad [10]$$

where:

F_{SVD} = mass of small volume NAF-cuttings discharges (kg)

ρ_{svd} = density of the small volume NAF-cuttings discharges (kg/bbl)

V_{SVD} = volume of the small volume NAF-cuttings discharges (bbl)

The density of the small volume NAF-cuttings discharges shall be measured. The volume of small volume discharges (V_{SVD}) shall be either: (a) Be measured or (b) use default values of 10 bbl of SBF for each interface loss and 75 bbl of SBM for pit cleanout per well.

The total mass of NAF-cuttings discharges for the well (G_{WELL}) shall be either: (a) Measured; or (b) calculated by multiplying 1.0 plus the arithmetic average of all total mass percent NAF base fluid retained on cuttings values [see Equation 8 of this Appendix] times the total hole volume (V_{WELL}) for all NAF well sections times a default value for the density the formation of 2.5 g/cm³ (396.9 kg/bbl).

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$$G_{WELL} = \left(1 + \left(\left[i = 1 \text{ to } j = n \sum \left(\%BF_{Tj}\right)\right]/n\right)\right) \times V_{WELL}(bbl) \times 396.9 \text{ (kg/bbl)} \quad [11]$$

where:

G_{WELL} = total mass of NAF-cuttings discharges for the well (kg)
$[j = 1 \text{ to } j = n\ \Sigma 2(\%BF_{Tj})]/n$ = see Equation 8 of this Appendix (unitless as a percentage)
V_{WELL} = total hole volume (V_{WELL}) for all NAF well sections (bbl)

The total hole volume of NAF well sections (V_{WELL}) will be calculated as:

$$V_{WELL}\text{ (barrels)} = \sum \frac{\text{Bit diameter (in)}^2}{1029} \times \text{change in measured depth (ft)} \quad [12]$$

For wells where small volume discharges associated with cuttings are made, $\%BF_{WELL}$ becomes:

$$\%BF_{WELL} = \left((1 - X_{SVD}) \times \left[i = 1 \text{ to } j = n \sum \left(\%BF_{Tj}\right)\right]/n\right) + X_{SVD} \times \%BF_{SVD} \quad [13]$$

Note: See Addendum A and B to determine the sampling frequency to determine the total number of retort sets required for all NAF well sections.

8. The total number of retort sets (n) is increased by 1 for each sampling interval (*see* Section 2.4, Addendum A of this appendix) when all NAF cuttings, fines, or accumulated solids for that sampling interval are retained for no discharge. A zero discharge interval shall be at least 500 feet up to a maximum of three per day. This action has the effect of setting the total mass percent NAF base fluid retained on cuttings value ($\%BF_T$) at zero for that NAF sampling interval when all NAF cuttings, fines, or accumulated solids are retained for no discharge.

9. Operators that elect to use the Best Management Practices (BMPs) for NAF-cuttings shall use the procedures outlined in Addendum B.

Addendum A to Appendix 7 to Subpart A of Part 435—Sampling of Cuttings Discharge Streams for use with API Recommended Practice 13B–2

1.0 Sampling Locations

1.1 Each NAF-cuttings waste stream that discharges into the ocean shall be sampled and analyzed as detailed in Appendix 7. NAF-cuttings discharges to the ocean may include discharges from primary shakers, secondary shakers, cuttings dryer, fines removal unit, accumulated solids, and any other cuttings separation device whose NAF-cuttings waste is discharged to the ocean. NAF-cuttings wastestreams not directly discharged to the ocean (*e.g.*, NAF-cuttings generated from shake shakers and sent to a cuttings dryer for additional processing) do not require sampling and analysis.

1.2 The collected samples shall be representative of each NAF-cuttings discharge. Operators shall conduct sampling to avoid the serious consequences of error (*i.e.*, bias or inaccuracy). Operators shall collect NAF-cuttings samples near the point of origin and before the solids and liquid fractions of the stream have a chance to separate from one another. For example, operators shall collect shale shaker NAF-cuttings samples at the point where NAF-cuttings are coming off the shale shaker and not from a holding container downstream where separation of larger particles from the liquid can take place.

1.3 Operators shall provide a simple schematic diagram of the solids control system and sample locations to the NPDES permit controlling authority.

2.0 Type of Sample and Sampling Frequency

2.1 Each NAF-cuttings, fines, or accumulated solids discharge has an associated mass percent NAF base fluid retained on cuttings value (%BF) and mass NAF-cuttings discharge fraction (X) for each sampling interval (*see* Section 2.4 of this addendum). Operators shall collect a single discrete NAF-cuttings sample for each NAF-cuttings waste stream discharged to the ocean during every sampling interval.

2.2 Operators shall use measured depth in feet from the Kelly bushing when samples are collected.

2.3 The NAF-cuttings samples collected for the mass fraction analysis (*see* Equation 6, Appendix 7 of Subpart A of this part) shall also be used for the retort analysis (*see* Equations 1–5, Appendix 7 of Subpart A of this part).

2.4 Operators shall collect and analyze at least one set of NAF-cuttings samples per day while discharging. Operators engaged in fast drilling (*i.e.*, greater than 500 linear NAF feet advancement of drill bit per day) shall collect and analyze one set of NAF-cuttings samples per 500 linear NAF feet of footage drilled. Operators are not required to collect and analyze more than three sets of NAF-cuttings samples per day (*i.e.*, three sampling intervals). Operators performing zero discharge of all NAF-cuttings (*i.e.*, all NAF cuttings, fines, or accumulated solids retained for no discharge) shall use the following periods to count sampling intervals: (1) One sampling interval per day when drilling is less than 500 linear NAF feet advancement of drill bit per day; and (2) one sampling interval per 500 linear NAF feet of footage drilled with a maximum of three sampling intervals per day.

2.5 The operator shall measure the individual masses (F_i, kg) and sum total mass (G, kg) (*see* Equation 6, Appendix 7 of subpart A of this part) over a representative period of time (*e.g.*, <10 minutes) during steady-state conditions for each sampling interval (*see* Section 2.4 of this addendum). The operator shall ensure that all NAF-cuttings are capture for mass analysis during the same sampling time period (*e.g.*, <10 minutes) at approximately the same time (*i.e.*, all individual mass samples collected within one hour of each other).

2.6 Operators using Best Management Practices (BMPs) to control NAF-cuttings discharges shall follow the procedures in Addendum B to Appendix 7 of subpart A of 40 CFR 435.

3.0 Sample Size and Handling

3.1 The volume of each sample depends on the volumetric flow rate (cm^3/s) of the NAF-cuttings stream and the sampling time period (*e.g.*, <10 minutes). Consequently, different solids control equipment units producing different NAF-cuttings waste streams at different volumetric flow rates will produce different size samples for the same period of time. Operators shall use appropriately sized sample containers for each NAF-cuttings waste stream to ensure no NAF-cuttings are spilled during sample collection. Operators shall use the same time period (*e.g.*, <10 minutes) to collect NAF-cuttings samples from each NAF-cuttings waste stream. Each NAF-cuttings sample size shall be at least one gallon. Operators shall clearly mark each container to identify each NAF-cuttings sample.

3.2 Operators shall not decant, heat, wash, or towel the NAF-cuttings to remove NAF base fluid before mass and retort analysis.

3.3 Operators shall first calculate the mass of each NAF-cuttings sample and perform the mass ratio analysis (*see* Equation 6, Appendix 7 of subpart A of this part). Operators with only one NAF-cuttings discharge may skip this step (*see* Section 4.c.4, Appendix 7 of subpart A of this part).

3.4 Operators shall homogenize (*e.g.*, stirring, shaking) each NAF-cuttings sample prior to placing a sub-sample into the retort cup. The bottom of the NAF-cuttings sample container shall be examined to be sure that solids are not sticking to it.

3.5 Operators shall then calculate the NAF base fluid retained on cuttings using the retort procedure (*see* Equations 1–5, Appendix 7 of subpart A of this part). Operators shall start the retort analyses no more than two hours after collecting the first individual mass sample for the sampling interval .

3.6 Operators shall not discharge any sample before successfully completing the mass and retort analyses [i.e., mass balance requirements (*see* Section 4.b, Appendix 7 of subpart A of this part) are satisfied]. Operators shall immediately re-run the retort analyses if the mass balance requirements (*see* Equation 4, Appendix 7 of subpart A of this part) are not within a tolerance of 5% (*see* Section 4.b, Equation 4, Appendix 7 of subpart A of this part).

4.0 Calculations

4.1 Operators shall calculate a set of mass percent NAF base fluid retained on cuttings values (%BF) and mass NAF-cuttings discharge fractions (X) for each NAF-cuttings waste stream (*see* Section 1.1 of this addendum) for each sampling interval (*see* Section 2.4 of this addendum) using the procedures outlined in Appendix 7 of subpart A of this part.

4.2 Operators shall tabulate the following data for each individual NAF-cuttings sample: (1) Date and time of NAF-cuttings sample collection; (2) time period of NAF-cuttings sample collection (*see* Section 3.1 of this addendum); (3) mass and volume of each NAF-cuttings sample; (4) measured depth (feet) at NAF-cuttings sample collection (*see* Section 2.2 of this addendum); (5) respective linear feet of hole drilled represented by the NAF-cuttings sample (feet); and (6) the drill bit diameter (inches) used to generate the NAF-cuttings sample cuttings.

4.3 Operators shall calculate a single total mass percent NAF base fluid retained on cuttings value ($\%BF_T$) for each sampling interval (*see* Section 2.4 of this addendum) using the procedures outlined in Appendix 7 of Subpart A of this part.

4.4 Operators shall tabulate the following data for each total mass percent NAF base fluid retained on cuttings value ($\%BF_T$) for each NAF-cuttings sampling interval: (1) Date and starting and stopping times of NAF-cuttings sample collection and retort analyses; (2) measured depth of well (feet) at start of NAF-cuttings sample collection (*see* Section 2.2 of this addendum); (3) respective linear feet of hole drilled represented by the NAF-cuttings sample (feet); (4) the drill bit diameter (inches) used to generate the NAF-cuttings sample cuttings; and (5) annotation when zero discharge of NAF-cuttings is performed.

4.5 Operators shall calculate the weighted mass ratio averaged over all NAF well sections ($\%BF_{well}$) using the procedures outlined in Appendix 7 of Subpart A of this part.

4.6 Operators shall tabulate the following data for each weighted mass ratio averaged over all NAF well sections ($\%BF_{well}$) for each NAF well: (1) Starting and stopping dates of NAF well sections; (2) measured depth (feet) of all NAF well sections; (3) total number of sampling intervals (*see* Section 2.4 and Section 2.6 of this addendum); (4) number of sampling intervals tabulated during any zero discharge operations; (5) total volume of zero discharged NAF-cuttings over entire NAF well sections; and (6) identification of whether BMPs were employed (*see* Addendum B of Appendix 7 of subpart A of this part).

Addendum B to Appendix 7 to Subpart A of Part 435— Best Management Practices (BMPs) for use with API Recommended Practice 13B–2

1.0 Overview of BMPs

1.1 Best Management Practices (BMPs) are inherently pollution prevention practices. BMPs may include the universe of pollution prevention encompassing production modifications, operational changes, material substitution, materials and water conservation, and other such measures. BMPs include methods to prevent toxic and hazardous pollutants from reaching receiving waters. Because BMPs are most effective when organized into a comprehensive facility BMP Plan, operators shall develop a BMP in accordance with the requirements in this addendum.

1.2 The BMP requirements contained in this appendix were compiled from several Regional permits, an EPA guidance document (i.e., Guidance Document for Developing Best Management Practices (BMP)" (EPA 833–B–93–004, U.S. EPA, 1993)), and draft industry BMPs. These common elements represent the appropriate mix of broad directions needed to complete a BMP Plan along with specific tasks common to all drilling operations.

1.3 Operators are not required to use BMPs if all NAF-cuttings discharges are monitored in accordance with Appendix 7 of Subpart A of this part.

2.0 BMP Plan Purpose and Objectives

2.1 Operators shall design the BMP Plan to prevent or minimize the generation and the potential for the discharge of NAF from the facility to the waters of the United States through normal operations and ancillary activities. The operator shall establish specific objectives for the control of NAF by conducting the following evaluations.

2.2 The operator shall identify and document each NAF well that uses BMPs before starting drilling operations and the anticipated total feet to be drilled with NAF for that particular well.

2.3 Each facility component or system controlled through use of BMPs shall be examined for its NAF-waste minimization opportunities and its potential for causing a discharge of NAF to waters of the United States due to equipment failure, improper operation, natural phenomena (e.g., rain, snowfall).

2.4 For each NAF wastestream controlled through BMPs where experience indicates a reasonable potential for equipment failure (e.g., a tank overflow or leakage), natural condition (e.g., precipitation), or other circumstances to result in NAF reaching surface waters, the BMP Plan shall include a prediction of the total quantity of NAF which could be discharged from the facility as a result of each condition or circumstance.

3.0 BMP Plan Requirements

3.1 The BMP Plan may reflect requirements within the pollution prevention requirements required by the Minerals Management Service (*see* 30 CFR 250.300) or other Federal or State requirements and incorporate any part of such plans into the BMP Plan by reference.

3.2 The operator shall certify that its BMP Plan is complete, on-site, and available upon request to EPA or the NPDES Permit controlling authority. This certification shall identify the NPDES permit number and be signed by an authorized representative of the operator. This certification shall be kept with the BMP Plan. For new or modified NPDES permits, the certification shall be made no later than the effective date of the new or modified permit. For existing NPDES permits, the certification shall be made within one year of permit issuance.

3.3 The BMP Plan shall:

3.3.1 Be documented in narrative form, and shall include any necessary plot plans, drawings or maps, and shall be developed in accordance with good engineering practices. At a minimum, the BMP Plan shall contain the planning, development and implementation, and evaluation/reevaluation components. Examples of these components are contained in "Guidance Document for Developing Best Management Practices (BMP)" (EPA 833–B–93–004, U.S. EPA, 1993).

3.3.2 Include the following provisions concerning BMP Plan review.

3.3.2.1 Be reviewed by permittee's drilling engineer and offshore installation manager (OIM) to ensure compliance with the BMP Plan purpose and objectives set forth in Section 2.0.

3.3.2.2 Include a statement that the review has been completed and that the BMP Plan fulfills the BMP Plan purpose and objectives set forth in Section 2.0. This statement shall have dated signatures from the permittee's drilling engineer and offshore installation manager and any other individuals responsible for development and implementation of the BMP Plan.

3.4 Address each component or system capable of generating or causing a release of significant amounts of NAF and identify specific preventative or remedial measures to be implemented.

4.0 BMP Plan Documentation

4.1 The operator shall maintain a copy of the BMP Plan and related documentation (e.g., training certifications, summary of the monitoring results, records of NAF-equipment spills, repairs, and maintenance) at the facility and shall make the BMP Plan and related documentation available to EPA or the NPDES Permit controlling authority upon request.

5.0 BMP Plan Modification

5.1 For those NAF wastestreams controlled through BMPs, the operator shall amend the BMP Plan whenever there is a change in the facility or in the operation of the facility which materially increases the generation of those NAF-wastes or their release or potential release to the receiving waters.

5.2 At a minimum the BMP Plan shall be reviewed once every five years and amended within three months if warranted. Any such changes to the BMP Plan shall be consistent with the objectives and specific requirements listed in this addendum. All changes in the BMP Plan shall be reviewed by the permittee's drilling engineer and offshore installation manager.

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5.3 At any time, if the BMP Plan proves to be ineffective in achieving the general objective of preventing and minimizing the generation of NAF-wastes and their release and potential release to the receiving waters and/or the specific requirements in this addendum, the permit and/or the BMP Plan shall be subject to modification to incorporate revised BMP requirements.

6.0 Specific Pollution Prevention Requirements for NAF Discharges Associated with Cuttings

6.1 The following specific pollution prevention activities are required in a BMP Plan when operators elect to control NAF discharges associated with cuttings by a set of BMPs.

6.2 Establishing programs for identifying, documenting, and repairing malfunctioning NAF equipment, tracking NAF equipment repairs, and training personnel to report and evaluate malfunctioning NAF equipment.

6.3 Establishing operating and maintenance procedures for each component in the solids control system in a manner consistent with the manufacturer's design criteria.

6.4 Using the most applicable spacers, flushes, pills, and displacement techniques in order to minimize contamination of drilling fluids when changing from water-based drilling fluids to NAF and vice versa.

6.5 A daily retort analysis shall be performed (in accordance with Appendix 7 to subpart A of Part 435) during the first 0.33 X feet drilled with NAF where X is the anticipated total feet to be drilled with NAF for that particular well. The retort analyses shall be documented in the well retort log. The operators shall use the calculation procedures detailed in Appendix 7 to subpart A of part 435 (*see* Equations 1 through 8) to determine the arithmetic average ($\%BF_{weal}$) of the retort analyses taken during the first 0.33 X feet drilled with NAF.

6.5.1 When the arithmetic average ($\%BF_{weal}$) of the retort analyses taken during the first 0.33 X feet drilled with NAF is less than or equal to the base fluid retained on cuttings limitation or standard (*see* §§ 435.13 and 435.15), retort monitoring of cuttings may cease for that particular well. The same BMPs and drilling fluid used during the first 0.33 X feet shall be used for all remaining NAF sections for that particular well.

6.5.2 When the arithmetic average ($\%BF_{weal}$) of the retort analyses taken during the first 0.33 X feet drilled with NAF is greater the base fluid retained on cuttings limitation or standard (*see* §§ 435.13 and 435.15), retort monitoring shall continue for the following (second) 0.33 X feet drilled with NAF where X is the anticipated total feet to be drilled with NAF for that particular well. The retort analyses for the first and second 0.33 X feet shall be documented in the well retort log.

6.5.2.1 When the arithmetic average ($\%BF_{weal}$) of the retort analyses taken during the first 0.66 X feet (i.e., retort analyses taken from first and second 0.33 X feet) drilled with NAF is less than or equal to the base fluid retained on cuttings limitation or standard (*see* §§ 435.13 and 435.15), retort monitoring of cuttings may cease for that particular well. The same BMPs and drilling fluid used during the first 0.66 X feet shall be used for all remaining NAF sections for that particular well.

6.5.2.2 When the arithmetic average ($\%BF_{weal}$) of the retort analyses taken during the first 0.66 X feet (i.e., retort analyses taken from first and second 0.33 X feet) drilled with NAF is greater than the base fluid retained on cuttings limitation or standard (*see* §§ 435.13 and 435.15), retort monitoring shall continue for all remaining NAF sections for that particular well. The retort analyses for all NAF sections shall be documented in the well retort log.

6.5.3 When the arithmetic average ($\%BF_{weal}$) of the retort analyses taken over all NAF sections for the entire well is greater that the base fluid retained on cuttings limitation or standard (*see* §§ 435.13 and 435.15), the operator is in violation of the base fluid retained on cuttings limitation or standard and shall submit notification of these monitoring values in accordance with NPDES permit requirements. Additionally, the operator shall, as part of the BMP Plan, initiate a reevaluation and modification to the BMP Plan in conjunction with equipment vendors and/or industry specialists.

6.5.4 The operator shall include retort monitoring data and dates of retort-monitored and non-retort-monitored NAF-cuttings discharges managed by BMPs in their NPDES permit reports.

6.6 Establishing mud pit and equipment cleaning methods in such a way as to minimize the potential for building-up drill cuttings (including accumulated solids) in the active mud system and solids control equipment system. These cleaning methods shall include but are not limited to the following procedures.

6.6.1 Ensuring proper operation and efficiency of mud pit agitation equipment.

6.6.2 Using mud gun lines during mixing operations to provide agitation in dead spaces.

6.6.3 Pumping drilling fluids off of drill cuttings (including accumulated solids) for use, recycle, or disposal before using wash water to dislodge solids.

Appendix 8 to Subpart A of Part 435—Reference C_{16}–C_{18} Internal Olefin Drilling Fluid Formulation

The reference C_{16}–C_{18} internal olefin drilling fluid used to determine the drilling fluid sediment toxicity ratio and compliance with the BAT sediment toxicity discharge limitation (*see* § 435.13) and NSPS (*see* § 435.15) shall be formulated to meet the specifications in Table 1 of this appendix.

Drilling fluid sediment toxicity ratio = 4-day LC_{50} of C_{16}–C_{18} internal olefin drilling fluid/4-day LC_{50} of drilling fluid removed from cuttings at the solids control equipment as determined by ASTM E1367–92 [incorporated by reference and specified at § 435.11(ee)] and supplemented with the sediment preparation procedure (Appendix 3 of subpart A of this part).

TABLE 1.—PROPERTIES FOR REFERENCE C_{16}–C_{18} IOs SBF USED IN DISCHARGE SEDIMENT TOXICITY TESTING

Mud weight of SBF discharged with cuttings (pounds per gallon)	Reference C_{16}–C_{18} IOs SBF (pounds per gallon)	Reference C_{16}–C_{18} IOs SBF synthetic to water ratio (%)
8.5–11	9.0	75/25
11–14	11.5	80/20
>14	14.5	85/15
Plastic Viscosity (PV), centipoise (cP)	12–30	
Yield Point (YP), pounds/100 sq. ft	10–20	
10-second gel, pounds/100 sq. ft	8–15	
10-minute gel, pounds/100 sq. ft	12–30	
Electrical stability, V	>300	

Subpart D—Coastal Subcategory

8. Section 435.41 is amended by revising paragraphs (b) through (ff) and by adding paragraphs (gg) through (ii) to read as follows:

§ 435.41 Special definitions.

* * * * *

(b) *Average of daily values for 30 consecutive days* means the average of the daily values obtained during any 30 consecutive day period.

(c) *Base fluid* means the continuous phase or suspending medium of a drilling fluid formulation.

(d) *Base fluid retained on cuttings* as applied to BAT effluent limitations and NSPS refers to the American Petroleum Institute Recommended Practice 13B–2

supplemented with the specifications, sampling methods, and averaging method for retention values provided in Appendix 7 of subpart A of this part.

(e) *Biodegradation rate* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings refers to the ISO 11734:1995 method: "Water quality—Evaluation of the 'ultimate' anaerobic biodegradability of organic compounds in digested sludge—Method by measurement of the biogas production (1995 edition)" (Available from the American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036) supplemented with modifications in Appendix 4 of subpart A of this part.

(f) *Cook Inlet* refers to coastal locations north of the line between Cape Douglas on the West and Port Chatham on the east.

(g) *Daily values* as applied to produced water effluent limitations and NSPS means the daily measurements used to assess compliance with the maximum for any one day.

(h) *Deck drainage* means any waste resulting from deck washings, spillage, rainwater, and runoff from gutters and drains including drip pans and work areas within facilities subject to this Subpart.

(i) *Development facility* means any fixed or mobile structure subject to this Subpart that is engaged in the drilling of productive wells.

(j) *Dewatering effluent* means wastewater from drilling fluids and drill cuttings dewatering activities (including but not limited to reserve pits or other tanks or vessels, and chemical or mechanical treatment occurring during the drilling solids separation/recycle/disposal process).

(k) *Diesel oil* refers to the grade of distillate fuel oil, as specified in the American Society for Testing and Materials Standard Specification for Diesel Fuel Oils D975–91, that is typically used as the continuous phase in conventional oil-based drilling fluids. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103. Copies may be inspected at the Office of the **Federal Register**, 800 North Capitol Street, NW., Suite 700, Washington, DC. A copy may also be inspected at EPA's Water Docket, 401 M Street SW., Washington, DC 20460.

(l) *Domestic waste* means the materials discharged from sinks, showers, laundries, safety showers, eye-wash stations, hand-wash stations, fish cleaning stations, and galleys located within facilities subject to this Subpart.

(m) *Drill cuttings* means the particles generated by drilling into subsurface geologic formations and carried out from the wellbore with the drilling fluid. Examples of drill cuttings include small pieces of rock varying in size and texture from fine silt to gravel. Drill cuttings are generally generated from solids control equipment and settle out and accumulate in quiescent areas in the solids control equipment or other equipment processing drilling fluid (i.e., accumulated solids).

(1) *Wet drill cuttings* means the unaltered drill cuttings and adhering drilling fluid and formation oil carried out from the wellbore with the drilling fluid.

(2) *Dry drill cuttings* means the residue remaining in the retort vessel after completing the retort procedure specified in Appendix 7 of subpart A of this part.

(n) *Drilling fluid* means the circulating fluid (mud) used in the rotary drilling of wells to clean and condition the hole and to counterbalance formation pressure. Classes of drilling fluids are:

(1) *Water-based drilling fluid* means the continuous phase and suspending medium for solids is a water-miscible fluid, regardless of the presence of oil.

(2) *Non-aqueous drilling fluid* means the continuous phase and suspending medium for solids is a water-immiscible fluid, such as oleaginous materials (e.g., mineral oil, enhanced mineral oil, paraffinic oil, C_{16}–C_{18} internal olefins, and C_8–C_{16} fatty acid/2-ethylhexyl esters).

(i) *Oil-based* means the continuous phase of the drilling fluid consists of diesel oil, mineral oil, or some other oil, but contains no synthetic material or enhanced mineral oil.

(ii) *Enhanced mineral oil-based* means the continuous phase of the drilling fluid is enhanced mineral oil.

(iii) *Synthetic-based* means the continuous phase of the drilling fluid is a synthetic material or a combination of synthetic materials.

(o) *Enhanced mineral oil* as applied to enhanced mineral oil-based drilling fluid means a petroleum distillate which has been highly purified and is distinguished from diesel oil and conventional mineral oil in having a lower polycyclic aromatic hydrocarbon (PAH) content. Typically, conventional mineral oils have a PAH content on the order of 0.35 weight percent expressed as phenanthrene, whereas enhanced mineral oils typically have a PAH content of 0.001 or lower weight percent PAH expressed as phenanthrene.

(p) *Exploratory facility* means any fixed or mobile structure subject to this Subpart that is engaged in the drilling of wells to determine the nature of potential hydrocarbon reservoirs.

(q) *Formation oil* means the oil from a producing formation which is detected in the drilling fluid, as determined by the GC/MS compliance assurance method specified in Appendix 5 of subpart A of this part when the drilling fluid is analyzed before being shipped offshore, and as determined by the RPE method specified in Appendix 6 of subpart A of this part when the drilling fluid is analyzed at the offshore point of discharge. Detection of formation oil by the RPE method may be confirmed by the GC/MS compliance assurance method, and the results of the GC/MS compliance assurance method shall supercede those of the RPE method.

(r) *Garbage* means all kinds of victual, domestic, and operational waste, excluding fresh fish and parts thereof, generated during the normal operation of coastal oil and gas facility and liable to be disposed of continuously or periodically, except dishwater, graywater, and those substances that are defined or listed in other Annexes to MARPOL 73/78. A copy of MARPOL may be inspected at EPA's Water Docket; 401 M Street SW., Washington DC 20460.

(s) *M9IM* means those offshore facilities continuously manned by nine (9) or fewer persons or only intermittently manned by any number of persons.

(t) *M10* means those offshore facilities continuously manned by ten (10) or more persons.

(u) *Maximum* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings means the maximum concentration allowed as measured in any single sample of the barite for determination of cadmium and mercury content.

(v) *Maximum for any one day* as applied to BPT, BCT and BAT effluent limitations and NSPS for oil and grease in produced water means the maximum concentration allowed as measured by the average of four grab samples collected over a 24-hour period that are analyzed separately. Alternatively, for BAT and NSPS the maximum concentration allowed may be determined on the basis of physical composition of the four grab samples prior to a single analysis.

(w) *Minimum* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings means the minimum 96-hour LC_{50} value allowed as measured in any single sample of the discharged waste stream.

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Minimum as applied to BPT and BCT effluent limitations and NSPS for sanitary wastes means the minimum concentration value allowed as measured in any single sample of the discharged waste stream.

(x)(1) *New source* means any facility or activity of this subcategory that meets the definition of "new source" under 40 CFR 122.2 and meets the criteria for determination of new sources under 40 CFR 122.29(b) applied consistently with all of the following definitions:

(i) *Water area* as used in "site" in 40 CFR 122.29 and 122.2 means the water area and water body floor beneath any exploratory, development, or production facility where such facility is conducting its exploratory, development or production activities.

(ii) *Significant site preparation work* as used in 40 CFR 122.29 means the process of surveying, clearing or preparing an area of the water body floor for the purpose of constructing or placing a development or production facility on or over the site.

(2) "New Source" does not include facilities covered by an existing NPDES permit immediately prior to the effective date of these guidelines pending EPA issuance of a new source NPDES permit.

(y) *No discharge of free oil* means that waste streams may not be discharged that contain free oil as evidenced by the monitoring method specified for that particular stream, e.g., deck drainage or miscellaneous discharges cannot be discharged when they would cause a film or sheen upon or discoloration of the surface of the receiving water; drilling fluids or cuttings may not be discharged when they fail the static sheen test defined in Appendix 1 of subpart A of this part.

(z) Parameters that are regulated in this subpart and listed with approved methods of analysis in Table 1B at 40 CFR 136.3 are defined as follows:

(1) *Cadmium* means total cadmium.

(2) *Chlorine* means total residual chlorine.

(3) *Mercury* means total mercury.

(4) *Oil and Grease* means total recoverable oil and grease.

(aa) *Produced sand* means the slurried particles used in hydraulic fracturing, the accumulated formation sands and scales particles generated during production. Produced sand also includes desander discharge from the produced water waste stream, and blowdown of the water phase from the produced water treating system.

(bb) *Produced water* means the water (brine) brought up from the hydrocarbon-bearing strata during the extraction of oil and gas, and can include formation water, injection water, and any chemicals added downhole or during the oil/water separation process.

(cc) *Production facility* means any fixed or mobile structure subject to this subpart that is either engaged in well completion or used for active recovery of hydrocarbons from producing formations. It includes facilities that are engaged in hydrocarbon fluids separation even if located separately from wellheads.

(dd) *Sanitary waste* means the human body waste discharged from toilets and urinals located within facilities subject to this subpart.

(ee) *SPP toxicity* as applied to BAT effluent limitations and NSPS for drilling fluids and drill cuttings refers to the bioassay test procedure presented in Appendix 2 of subpart A of this part.

(ff) *Static sheen test* means the standard test procedure that has been developed for this industrial subcategory for the purpose of demonstrating compliance with the requirement of no discharge of free oil. The methodology for performing the static sheen test is presented in Appendix 1 of subpart A of this part.

(gg) *Stock barite* means the barite that was used to formulate a drilling fluid.

(hh) *Synthetic material* as applied to synthetic-based drilling fluid means material produced by the reaction of specific purified chemical feedstock, as opposed to the traditional base fluids such as diesel and mineral oil which are derived from crude oil solely through physical separation processes. Physical separation processes include fractionation and distillation and/or minor chemical reactions such as cracking and hydro processing. Since they are synthesized by the reaction of purified compounds, synthetic materials suitable for use in drilling fluids are typically free of polycyclic aromatic hydrocarbons (PAH's) but are sometimes found to contain levels of PAH up to 0.001 weight percent PAH expressed as phenanthrene. Internal olefins and vegetable esters are two examples of synthetic materials suitable for use by the oil and gas extraction industry in formulating drilling fluids. Internal olefins are synthesized from the isomerization of purified straight-chain (linear) hydrocarbons such as C_{16}–C_{18} linear alpha olefins. C_{16}–C_{18} linear alpha olefins are unsaturated hydrocarbons with the carbon to carbon double bond in the terminal position. Internal olefins are typically formed from heating linear alpha olefins with a catalyst. The feed material for synthetic linear alpha olefins is typically purified ethylene. Vegetable esters are synthesized from the acid-catalyzed esterification of vegetable fatty acids with various alcohols. EPA listed these two branches of synthetic fluid base materials to provide examples, and EPA does not mean to exclude other synthetic materials that are either in current use or may be used in the future. A synthetic-based drilling fluid may include a combination of synthetic materials.

(ii) *Well completion fluids* means salt solutions, weighted brines, polymers, and various additives used to prevent damage to the well bore during operations which prepare the drilled well for hydrocarbon production.

(jj) *Well treatment fluids* means any fluid used to restore or improve productivity by chemically or physically altering hydrocarbon-bearing strata after a well has been drilled.

(kk) *Workover fluids* means salt solutions, weighted brines, polymers, or other specialty additives used in a producing well to allow for maintenance, repair or abandonment procedures.

(ll) *96-hour LC_{50}* means the concentration (parts per million) or percent of the suspended particulate phase (SPP) from a sample that is lethal to 50 percent of the test organisms exposed to that concentration of the SPP after 96 hours of constant exposure.

9. In § 435.42 the table is amended by removing the entries "Drilling fluids" and "Drill cuttings" and by adding new entries (after "Deck drainage") for "Water based" and "Non-aqueous" to read as follows:

§ 435.42 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

* * * * *

BPT EFFLUENT LIMITATIONS—OIL AND GREASE

[In milligrams per liter]

Pollutant parameter waste source	Maximum for any 1 day	Average of values for 30 consecutive days shall not exceed	Residual chlorine minimum for any 1 day
* * * * * * *			
Water-based:			
Drilling fluids	(1)	(1)	NA
Drill Cuttings	(1)	(1)	NA
Non-aqueous:			
Drilling fluids	No discharge	No discharge	NA
Drill Cuttings	(1)	(1)	NA
* * * * * * *			

[1] No discharge of free oil.

* * * * *

10. In § 435.43 the table is amended by revising entry (B) under "Drilling fluids, drill cuttings, and dewatering effluent" and by revising footnote 4 and adding footnote 5 to read as follows:

§ 435.43 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

* * * * *

BAT EFFLUENT LIMITATIONS

Waste source	Pollutant parameter	BAT effluent limitation
* * * * * * *		
Drilling fluids, Drill cuttings, and Dewatering effluent: [1]		
* * * * * * *		
(B) Cook Inlet:		
Water-based drilling fluids, drill cuttings, and dewatering effluent.	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test[4] shall be 3% by volume.
	Free oil	No discharge.[2]
	Diesel oil	No discharge.
	Mercury	1 mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
Non-aqueous drilling fluids and dewatering effluent.		No discharge.
Drill cuttings associated with non-aqueous drilling fluids.		No discharge.[5]
* * * * * * *		

[1] BAT limitations for dewatering effluent are applicable prospectively. BAT limitations in this rule are not applicable to discharges of dewatering effluent from reserve pits which as of the effective date of this rule no longer receive drilling fluids and drill cuttings. Limitations on such discharges shall be determined by the NPDES permit issuing authority.

[2] As determined by the static sheen test (*see* Appendix 1 of Subpart A of this part).

* * * * * * *

[4] As determined by the suspended particulate phase (SPP) toxicity test (*see* Appendix 2 of Subpart A of this part).

[5] When Cook Inlet operators cannot comply with this no discharge requirement due to technical limitations (*see* Appendix 1 of Subpart D of this part), Cook Inlet operators shall meet the same stock limitations (C_{16}-C_{18} internal olefin) and discharge limitations for drill cuttings associated with non-aqueous drilling fluids for operators in Offshore waters (*see* § 435.13) in order to discharge drill cuttings associated with non-aqueous drilling fluids.

11. In § 435.44 the table is amended by revising the entry for "Cook Inlet" under the entry for "Drilling fluids and drill cuttings and dewatering effluent" to read as follows:

§ 435.44 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT).

* * * * *

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BCT EFFLUENT LIMITATIONS

Waste source	Pollutant parameter	BCT effluent limitation
* * *	* * *	*
Drilling fluids, Drill cuttings, and Dewatering effluent: [1]		
* * *	* * *	*
Cook Inlet:		
Water-based drilling fluids, drill cuttings, and dewatering effluent.	Free Oil	No discharge.[2]
Non-aqueous drilling fluids and dewatering effluent		No discharge.
Drill cuttings associated with non-aqueous drilling fluids	Free Oil	No discharge.[2]

[1] BCT limitations for dewatering effluent are applicable prospectively. BCT limitations in this rule are not applicable to discharges of dewatering effluent from reserve pits which as of the effective date of this rule no longer receive drilling fluids and drill cuttings. Limitations on such discharges shall be determined by the NPDES permit issuing authority.
[2] As determined by the static sheen test (*see* Appendix 1 of Subpart A of this part).

* * * * *

12. In § 435.45 the table is amended by revising entry (B) under "Drilling fluids, drill cuttings, and dewatering effluent" and by revising footnote 4 and adding footnote 5 to read as follows:

§ 435.45 Standards of performance for new sources (NSPS).

* * * * *

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

Waste Source	Pollutant parameter	NSPS
* * *	* * *	*
Drilling fluids, Drill cuttings, and Dewatering effluent: [1]		
* * *	* * *	*
(B) Cook Inlet:		
Water-based drilling fluids, drill cuttings, and dewatering effluent.	SPP Toxicity	Minimum 96-hour LC_{50} of the SPP Toxicity Test [4] shall be 3% by volume.
	Free oil	No discharge.[2]
	Diesel oil	No discharge.
	Mercury	1 mg/kg dry weight maximum in the stock barite.
	Cadmium	3 mg/kg dry weight maximum in the stock barite.
Non-aqueous drilling fluids and dewatering effluent.		No discharge.
Drill cuttings associated with non-aqueous drilling fluids.		No discharge.[5]
* * *	* * *	*

[1] NSPS for dewatering effluent are applicable prospectively. NSPS in this rule are not applicable to discharges of dewatering effluent from reserve pits which as of the effective date of this rule no longer receive drilling fluids and drill cuttings. Limitations on such discharges shall be determined by the NPDES permit issuing authority.
[2] As determined by the static sheen test (*see* Appendix 1 of subpart A of this part).
[4] As determined by the suspended particulate phase (SPP) toxicity test (*see* Appendix 2 of subpart A of this part).
[5] When Cook Inlet operators cannot comply with this no discharge requirement due to technical limitations (*see* Appendix 1 of subpart D of this part), Cook Inlet operators shall meet the same stock limitations (C_{16}–C_{18} internal olefin) and discharge limitations for drill cuttings associated with non-aqueous drilling fluids for operators in Offshore waters (*see* § 435.15) in order to discharge drill cuttings associated with non-aqueous drilling fluids.

13. Subpart D is amended by adding Appendix 1 as follows:

Appendix 1 to Subpart D of Part 435—Procedure for Determining When Coastal Cook Inlet Operators Qualify for an Exemption from the Zero Discharge Requirement for EMO-Cuttings and SBF-Cuttings in Coastal Cook Inlet, Alaska

1.0 Scope and Application

This appendix is to be used to determine whether a Cook Inlet, Alaska, operator in Coastal waters (Coastal Cook Inlet operator) qualifies for the exemption to the zero discharge requirement established by 40 CFR 435.43 and 435.45 for drill cuttings associated with the following non-aqueous drilling fluids: enhanced mineral oil based drilling fluids (EMO-cuttings) and synthetic-based drilling fluids (SBF-cuttings). Coastal Cook Inlet operators are prohibited from discharging oil-based drilling fluids. This appendix is intended to define those situations under which technical limitations preclude Coastal Cook Inlet operators from complying with the zero discharge requirement for EMO-cuttings and SBF-cuttings. Coastal Cook Inlet operators that qualify for this exemption may be authorized to discharge EMO-cuttings and SBF-cuttings subject to the limitations applicable to operators in Offshore waters (*see* subpart A of this part).

2.0 Method

2.1 Any Coastal Cook Inlet operator must achieve the zero discharge limit for EMO-cuttings and SBF-cuttings unless it successfully demonstrates that technical limitations prevent it from being able to dispose of its EMO-cuttings or SBF-cuttings through on-site annular disposal, injection into a Class II underground injection control (UIC) well, or onshore land application.

2.2 To successfully demonstrate that technical limitations prevent it from being able to dispose of its EMO-cuttings or SBF-cuttings through on-site annular disposal, a Coastal Cook Inlet operator must show that it has been unable to establish formation injection in nearby wells that were initially considered for annular or dedicated disposal of EMO-cuttings or SBF-cuttings or prove to the satisfaction of the Alaska Oil and Gas Conservation Commission (AOGCC) that the EMO-cuttings or SBF-cuttings will be confined to the formation disposal interval. This demonstration must include:

a. Documentation, including engineering analysis, that shows (1) an inability to establish formation injection (e.g., formation is too tight), (2) an inability to confine EMO-cuttings or SBF-cuttings in disposal formation (e.g., no confining zone or adequate barrier to confine wastes in formation), or (3) the occurrence of high risk emergency (e.g., mechanical failure of well, loss of ability to inject that risks loss of well which would cause significant economic harm or create a substantial risk to safety); and

b. A risk analysis of alternative disposal options, including environmental assessment, human health and safety, and economic impact, that shows discharge as the lowest risk option.

2.3 To successfully demonstrate that technical limitations prevent it from being able to dispose of its EMO-cuttings or SBF-cuttings through injection into a Class II UIC well, a Coastal Cook Inlet operator must show that it has been unable to establish injection into a Class II UIC well or prove to the satisfaction of the Alaska Oil and Gas Conservation Commission (AOGCC) that the EMO-cuttings or SBF-cuttings will be confined to the formation disposal interval. This demonstration must include:

a. Documentation, including engineering analysis, that shows the inability to confine EMO-cuttings or SBF-cuttings in a Class II UIC well (e.g., no confining zone or adequate barrier to confine wastes in formation);

b. Documentation demonstrating that no Class II UIC well is accessible (e.g., operator does not own, competitor will not allow injection); and

c. A risk analysis of alternative disposal option, including environmental assessment, human health and safety, and economic impact, that shows discharge as the lowest risk option.

2.4 To successfully demonstrate that technical limitations prevent it from being able to dispose of its EMO-cuttings or SBF-cuttings through land application, a Coastal Cook Inlet operator must show that it has been unable to handle drilling waste or dispose of EMO-cuttings or SBF-cuttings at an appropriate land disposal site. This demonstration must include:

a. Documentation of site restrictions that preclude land application (e.g., no land disposal sites available);

b. Documentation of the platform's lack of capacity for adequate storage of EMO-cuttings or SBF-cuttings (e.g., limited storage or room for cuttings transfer); or

c. Documentation of inability to transfer EMO-cuttings or SBF-cuttings from platform to land for disposal (e.g., extremely low tides, high wave action).

3.0 Procedure

3.1 Except as described in Section 3.2 of this appendix, a Coastal Cook Inlet operator believing that it qualifies for the exemption to the zero discharge requirement for EMO-cuttings or SBF-cuttings must apply for and obtain an individual NPDES permit prior to discharging EMO-cuttings or SBF-cuttings to waters of the United States.

3.2 Discharges occurring as the result a high risk emergency (e.g., mechanical failure of well, loss of ability to inject that risks loss of well which would cause significant economic harm or safety) may be authorized by a general NPDES permit provided that:

a. The Coastal Cook Inlet operator satisfactorily demonstrates to EPA Region 10 the fulfillment of the other exemption requirements described in Section 2.0 of this appendix, or

b. The general permit allows for high risk emergency discharges and provides Reporting Requirements to EPA Region 10 immediately upon commencing discharge.

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January 22, 2001

Part V

Environmental Protection Agency

40 CFR Part 63
National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6923–8]

RIN 2060–AH61

National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: On April 22, 1994 and June 6, 1994, the EPA issued the "National Emission Standards for Hazardous Air Pollutants for Source Categories: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry and Other Processes Subject to the Negotiated Regulation for Equipment Leaks." This rule is commonly known as the Hazardous Organic National Emission Standards for Hazardous Air Pollutants (NESHAP) or the HON. On January 20, 2000, the EPA proposed amendments to the definition of the term "process vent" and to add procedures for identifying "process vents" in order to ensure consistent interpretation of the term. The EPA also proposed revisions to several provisions of the rule to reflect the terminology used in the revised definition of process vent. These changes were proposed to reduce the burden associated with developing operating permits for facilities subject to the rule. The January 20, 2000 document also proposed to add provisions to allow off-site control of process vent emissions and to add provisions for establishing a new compliance date under certain circumstances. In that action, EPA also proposed to add an alternative procedure for use in determining compliance with wastewater treatment requirements. Today's action takes final action on those proposed amendments.

These amendments to the rule will not change the basic control requirements of the rule or the level of health protection it provides. The rule requires new and existing major sources to control emissions of hazardous air pollutants to the level reflecting application of the maximum achievable control technology.

EFFECTIVE DATE: January 22, 2001.

ADDRESSES: Docket No. A–90–19 contains the supporting information for the original NESHAP and this action. You may inspect this docket and copy materials between 8:00 a.m. and 5:30 p.m., Monday through Friday. The EPA's Air and Radiation Docket and Information Center is located at Waterside Mall, Room M–1500, first floor, 401 M Street, SW, Washington, DC 20460. The telephone number for the Air Docket and Information Center is (202) 260–7548 or (202) 260–7549. You may have to pay a reasonable fee for copying materials.

FOR FURTHER INFORMATION CONTACT: For general questions, contact Dr. Janet Meyer, Coatings and Consumer Products Group, at (919) 541–5254 (meyer.jan@epa.gov). For technical questions on appendix C and wastewater provisions, contact Elaine Manning, Waste and Chemical Processes Group, telephone number (919) 541–5499 (manning.elaine@epa.gov). The mailing address for the contacts is Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: *Docket.* The docket is an organized file of the information considered by the EPA in the development of this rulemaking. The docket is a dynamic file, because material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket, except for certain interagency documents, will serve as the record for judicial review. (See the Clean Air Act (CAA), section 307(d)(7)(A).)

Judicial Review. Under Section 307(b)(1) of the CAA, judicial review of this final action is available only on the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by March 23, 2001. Under Section 307(b)(2) of the CAA, the requirements established by these final rule amendments may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of this rule amendment will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the rule amendments will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at http://www.epa.gov/ttn/oarpg. The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated Entities. The regulated category and entities affected by this action include:

Category	Examples of regulated entities
Industry	Synthetic organic chemical manufacturing industry (SOCMI) units, e.g., producers of benzene, toluene, or any other chemical listed in table 1 of 40 CFR part 63, subpart F.

This table is not intended to be exhaustive but, rather, provides a guide for readers regarding entities likely to be interested in the revisions to the regulation affected by this action. This action is expected to be of interest to owners and operators subject to this rule who have process vents that may be affected by these rule amendments and to those owners or operators who are sending vent streams (gas streams) to another facility for disposal. This action may also be of interest to owners and operators subject to this rule, or another rule in part 63, who plan to use biological treatment to comply with control requirements for wastewater streams. Entities potentially regulated by the HON are those which produce as primary intended products any of the chemicals listed in table 1 of 40 CFR part 63, subpart F, and are located at facilities that are major sources as defined in section 112 of the CAA. Potentially regulated entities generally are companies that manufacture industrial organic chemicals and cyclic organic crude and intermediates. To determine whether your facility is regulated by this action, you should carefully examine all of the applicability criteria in 40 CFR 63.100. If you have questions regarding the applicability of this action to a particular entity, consult Dr. Janet Meyer (see FOR FURTHER INFORMATION CONTACT).

Outline. The information presented in the preamble is organized as follows:

I. Background on the Rule
II. Public Comment on the January 20, 2000 Proposal
III. Summary of Major Comments and Changes to the Proposed Amendments to the Rule
A. Definition of Process Vent and Associated Changes
B. Appendix C to Part 63
C. Miscellaneous Corrections and Clarifications to the Rule
IV. Technical Corrections
V. Administrative Requirements
A. Executive Order 12866, Regulatory Planning and Review
B. Executive Order 13132, Federalism
C. Executive Order 13084, Consultation and Coordination with Indian Tribal Governments
D. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks
E. Unfunded Mandates Reform Act of 1995
F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, *et seq.*
G. Paperwork Reduction Act
H. National Technology Transfer and Advancement Act
I. Congressional Review Act

I. Background on the Rule

On April 22, 1994 (59 FR 19402), and June 6, 1994 (59 FR 29196), EPA published in the **Federal Register** the NESHAP for the synthetic organic chemical manufacturing industry (SOCMI) and for several other processes subject to the equipment leaks portion of the rule. This rule was promulgated as subparts F, G, H, and I in 40 CFR part 63 and are commonly referred to as the hazardous organic NESHAP, or the HON. We have published several amendments to clarify various aspects of the rule since their promulgation. See the following **Federal Register** documents for more information: September 20, 1994 (59 FR 48175); October 24, 1994 (59 FR 53359); October 28, 1994 (59 FR 54131); January 27, 1995 (60 FR 5321); April 10, 1995 (60 FR 18020); April 10, 1995 (60 FR 18026); December 12, 1995 (60 FR 63624); February 29, 1996 (61 FR 7716); June 20, 1996 (61 FR 31435); August 26, 1996 (61 FR 43698); December 5, 1996 (61 FR 64571); January 17, 1997 (62 FR 2721); August 22, 1997 (62 FR 44608); and December 9, 1998 (63 FR 67787).

In June 1994, the Chemical Manufacturers Association (CMA) and Dow Chemical Company (Dow) filed petitions for review of the promulgated rule in the U.S. Court of Appeals for the District of Columbia Circuit, *Chemical Manufacturers Association* v. *EPA*, 94–1463 and 94–1464 (D.C. Cir.) and *Dow Chemical Company* v. *EPA*, 94–1465 (D.C. Cir.). The petitioners raised over 75 technical issues on the rule's structure and applicability. The petitioners raised issues regarding details of the technical requirements, drafting clarity, and structural errors in the drafting of certain sections of the rule. On August 26, 1996, we proposed clarifying and correcting amendments to subparts F, G, H, and I of part 63 to address the issues raised by CMA and Dow on the April 1994 rule. On December 5, 1996 and January 17, 1997, we took final action on the amendments proposed on August 26, 1996. On August 22, 1997, we proposed corrections to the definition of "enhanced biological treatment systems or enhanced biological treatment process" and conforming edits to appendix C of part 63 to reflect these changes to the definition. On December 9, 1998, we took final action on the amendments proposed on August 22, 1997. On January 20, 2000, we proposed revisions to the definition of process vent as well as miscellaneous corrections and clarifying amendments.

II. Public Comment on the January 20, 2000 Proposal

Five comment letters were received on the January 20, 2000 **Federal Register** proposed amendments to the rule. Comment letters were received from consultants, industry representatives, and one trade association. In general, the comment letters were supportive of the proposed changes, however some of the comment letters included suggested editorial revisions to address drafting clarity concerns or correct errors in cross referencing other sections in the rule. We considered these suggestions and, where appropriate, made changes to the proposed amendments. The significant issues raised and the changes to the proposed amendments are summarized in this preamble. A memorandum containing EPA's response to all comments can be found in Docket A–90–19. The responses to comments may also be obtained from the Internet through the Technology Transfer Network (TTN) at http://www.epa.gov/ttn/oarpg.

III. Summary of Major Comments and Changes to the Proposed Amendments to the Rule

A. Definition of Process Vent and Associated Changes Process Vent Definition

One commenter expressed support for the proposed changes to the definition of process vent, but also expressed a concern that the proposed amendments do not adequately address a unique situation that exists at the commenter's facility. Specifically, one of the commenter's HON-covered facilities has a gas stream that passes through a recovery device and has been characterized as a Group 2 process vent (i.e., a vent stream that is not subject to control requirements). This gas stream is part of an approved emissions average, and the commenter has installed a control device to create credits by controlling this gas stream to offset debits created elsewhere in the chemical manufacturing process unit. The commenter also has another gas stream that is a Group 1 process vent (i.e., subject to control requirements) that is combined with the Group 2 process vent after the last recovery device for the Group 2 process vent stream and prior to the entry into the control device. The commenter is concerned that the proposed definition for "process vent" could be read to deem the two physically separate gas streams as a single "process vent." This occurs because the determination of the location of the "process vent" for the Group 2 gas stream would presumably be "the point of entry into [the] control device." The commenter thought that this would be inconsistent with §§ 63.115(a) and 63.150(g)(2), and with EPA's general intent that the characteristics of these gas streams be determined after the last recovery device and prior to the entrance to a control device. The commenter submitted recommended revisions to the proposed definition for process vents and to § 63.107(a) to address their situation.

The EPA thoroughly considered the points raised by the commenter and concluded that the commenter's suggested language for the definition of process vent and for § 63.107(a) would not be compatible with the intent of the January 20, 2000 proposed amendments. The commenter's suggested changes to the proposed amendments would alter the intended effect by requiring the identification of gas streams upstream of the discharge point and requiring identification of the last recovery device and of any streams combined after the recovery device. That identification would significantly increase the information that must be submitted as part of the operating permit application.

As part of the consideration of this comment, we reexamined the interaction between the proposed changes to the definition of process vent and the emissions averaging provisions in the rule. We agree with the commenter that there can be situations where the proposed definition of process vent is incompatible with § 63.150(g)(2)(i). Specifically, the language in § 63.150(g)(2)(i) reflects an assumption that there are no combinations of gas streams after the final recovery device and before any control device. Further, it was also

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assumed that the gas stream is associated with a specific unit operation or process unit (§ 63.150(g)(2)(ii)(B)). For these reasons, we concluded that for the purposes of emissions averaging, it would be appropriate to retain the designation of a process vent and its characteristics as specified in § 63.150(g)(2)(i). Specifically, it was decided that § 63.150(g)(2)(i) should indicate that the process vent stream characteristics shall be determined before the gas stream is combined with other gas streams following the last recovery device. It was also decided that it was necessary to make other edits to § 63.150 to ensure that there is no confusion with the definition of process vent and the directions in § 63.115 for determining the total resource effectiveness (TRE) of the vent stream. Thus, conforming edits were also made to § 63.150(a) and § 63.150(m)(1)(i) and (2)(i) to ensure that the location of the process vent as used in emissions averaging was determined as specified in § 63.150(g)(2)(i). We are also correcting an error in the drafting of § 63.150(g)(2)(iii)(B)(*2*) to replace references to "product recovery devices" with references to "recovery devices." This change was made to make § 63.150(g)(2)(iii)(B)(*2*) consistent with § 63.115(a) and other provisions for determining the characteristics of a vent stream.

Section 63.107(h)(9). One commenter requested that EPA clarify the meaning of the term "process analyzer." The commenter interprets this provision as covering all gas streams exiting a process analyzer, whether the gas stream represents a sample from within the process (i.e., prior to any recovery and control devices) or a sample after the gas stream has exited a recovery device but prior to entry into a control device (if any).

In the proposed language in § 63.107(h)(9), we used the term of art "process analyzer" to refer to instruments that are used in the field as opposed to instruments that are used in a laboratory setting. The use of this term of art was not intended to make a distinction between analyzers used to monitor the composition of a gas stream prior to the last recovery device or following the last recovery device. We did not intend to limit this exemption to analyzers used within the process and to exclude analyzers used on gas streams after discharge from the process. Consequently, in the final amendments we have revised the wording of the proposed § 63.107(h)(9) to refer to "a gas stream exiting an analyzer."

Section 63.110(a). One commenter disagreed with the proposed revision to § 63.110(a). The commenter thought that the proposed change to use the conjunction "and/or" was not as clear as the current version of the rule which uses only the conjunction "and." According to the commenter, the latter is not only correct, it's clearer. The commenter recommended that "and/or" be replaced with "and."

The purpose of this amendment to § 63.110(a) is to add in-process equipment subject to § 63.149 to the list of emission points subject to the provisions in 40 CFR part 63, subpart G. The EPA agrees with the commenter and has revised this text as suggested by the commenter.

B. Appendix C to Part 63

In the January 20, 2000 **Federal Register**, we proposed to amend appendix C to 40 CFR part 63 to add a concentration measurement procedure for determining the fraction biodegraded (f_{bio}) in biological treatment units that are not thoroughly mixed, and thus, have multiple zones of mixing. In the proposed amendments, we specified that you would identify zones with substantially uniform characteristics and would measure representative organic compound concentrations in each zone as well as the inlet and outlet of the biological treatment unit. We received one comment requesting that we clarify that it is acceptable in some circumstances to interpolate compound concentrations for one or more zones when using this new procedure. The commenter noted that if a basin is considered as several zones and one of the interior zones is not readily accessible for sampling, the concentration could be estimated by interpolation of the concentration data for the remaining zones. The commenter noted that this approach is consistent with the instructions provided in the "Technical Support Document for the Evaluation of Aerobic Biological Treatment Units with Multiple Mixing Zones."

We agree that under some circumstances it can be acceptable to allow interpolation of compound concentrations in some zones. Specifically, in units with well-characterized concentration measurements obtained in an initial evaluation of the unit, it may be possible to demonstrate that there is a good correlation of the component concentrations with the locations in the multiple-zone unit. With a good correlation, it may be possible to accurately predict the concentrations in selected zones without actually testing each selected zone. This correlation method may be used for units that have many zones (greater than five) or where one of the interior zones is not readily accessible for sampling. In the final amendments to section III.E for appendix C to 40 CFR part 63, we have added a paragraph to explain those situations where it is acceptable to determine the concentration in the zone by interpolation.

C. Miscellaneous Corrections and Clarifications to the Rule

Two commenters suggested changes to the proposed amendments to correct citations, minor drafting errors, and some minor clarifications of the text. We considered these suggestions and, where appropriate, have made changes to the rule. The sections and the associated changes are:

- Section 63.113(e)—We are revising the sentence to refer to TRE index value in all cases. The proposed language referred to "TRE index" instead of "TRE index value" in the reference to § 63.115.
- Section 63.113(i)(2)—We are correcting the cross reference to § 63.103(c) from § 63.10(b) in the last sentence of this paragraph.
- Section 63.115(f)(1)—We are clarifying that the owner or operator may determine the characteristics of a HON stream, or combination of HON streams, at a representative point as near as practical to, but before, the point at which it is combined with one or more non-HON streams. The change from the proposed amendments is to clarify that the combination may be for one or more non-HON streams.
- Section 63.115(f)(2)—We are correcting a punctuation error in the proposed language.
- Section 63.138(i)(2)(iii)—We are correcting a grammatical error in the last sentence of this paragraph.
- Section 63.147(b)(8) introductory text—We are removing the phrase "in the Notice of Compliance Status Report" which was inadvertently included in the proposed amendment to this paragraph.
- Table 12 to subpart G, item 3—We are revising this item to clarify that it applies to treatment processes other than those listed in items 1 and 2 of table 12 in addition to alternative monitoring parameters listed in item 2.
- Table 20 to subpart G—We are clarifying that the control devices subject to § 63.139 are being used to comply with the requirements in §§ 63.133–63.138. This is a more precise statement of the applicability of table 20 to subpart G than the proposed language.

IV. Technical Corrections

The following amendments are minor technical corrections that were not part of the January 20, 2000 **Federal Register** proposed amendments. These changes are being made as part of today's action as a matter of efficiency in rulemaking. Furthermore, these changes are noncontroversial and do not substantively change the requirements of the rule. By promulgating these technical corrections directly as a final rule, EPA is foregoing an opportunity for public comment on a notice of proposed rulemaking. Section 553(b) of title 5 U.S.C. and section 307(b) of the CAA permit an agency to forego notice and comment when "the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." The EPA finds that notice and comment regarding these minor technical corrections are unnecessary due to their noncontroversial nature, and because they do not substantively change the requirements of the HON. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b) for a determination that the issuance of a notice of proposed rulemaking is unnecessary.

The corrections are:

- Section 63.118(f)(5)—We are correcting the reference to § 63.118(a)(2)(v) to read § 63.118(a)(2). The need to correct this reference was overlooked when we redrafted § 63.118(a) in the January 17, 1997 **Federal Register** amendments.
- Section 63.128(h)(1)(ii)—The citation should say "minimum residence time" instead of "maximum residence time" to be consistent with related combustion device provisions in §§ 63.120(d)(1)(i)(B), 63.139(c)(1)(iii), and 63.172(c) which all use "minimum" residence time. We are correcting this text to be consistent with the other combustion device provisions in subpart G of 40 CFR part 63.
- Section 63.130(d)(5)—We are correcting the reference to § 63.130(a)(2)(v) to read § 63.130(a)(2)(i). The need to correct this reference was overlooked when we redrafted § 63.130 in the January 17, 1997 **Federal Register** amendments.
- Section 63.140(c)—We are correcting the reference to § 63.147(c)(7) to § 63.147(b)(7).
- Section 63.146(b)(9) introductory text and paragraph (b)(9)(iii)—Removing references to § 63.138(d) and (h)(3) in § 63.146(b)(9) introductory text because these treatment options do not require a design evaluation or performance test to demonstrate compliance with the removal requirements. We are deleting § 63.146(b)(9)(iii), and the reference to it in § 63.146(b)(9) introductory text, since it is no longer needed with the above correction to § 63.146(b)(9) introductory text.
- Section 63.146(d)—In order for § 63.146(d) to be consistent with the April 26, 1999 **Federal Register** corrections, we are correcting § 63.146(d) introductory text to add references to paragraph (d), (f), or (g) of § 63.138 and to add references to the monitoring requirements specified in § 63.143(c) and (d).
- Table 12 to subpart G—We are adding the option of monitoring column operating temperature as an alternative to monitoring wastewater feed temperature. Either parameter provides information necessary to evaluate column operating conditions. This change is consistent with parameters specified in § 63.138(d). Without this change, owners or operators using steam strippers who wish to monitor column operating temperature would have to request approval of the alternative monitoring parameters. This was not our intent.
- Table 17 to subpart G, note (f)—As published on January 17, 1997, this footnote should read: "Parameter(s) to be monitored or measured in accordance with Table 12 and § 63.143 of this subpart. " Presently, the note (f) reads "Parameter(s) to be monitored or measured in accordance with Table 12 in § 63.143 of this subpart."

V. Administrative Requirements

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether a regulatory action is "significant" and, therefore, subject to review by the Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof, or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is not a "significant regulatory action" within the meaning of the Executive Order because none of the listed criteria apply to this action. These changes to the HON are primarily technical and administrative and do not raise novel legal or policy issues. These changes are not expected to impose significant new costs. This action will not have an annual effect on the economy of $100 million or other adverse economic impacts, will not create any inconsistencies with other actions by other agencies, will not alter any budgetary impacts, or raise any novel legal or policy issues. Therefore, this action is considered "not significant" and OMB review is not required.

B. Executive Order 13132, Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to OMB, in a separately identified section of the preamble to the

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rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns, and the Agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the Agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

These amendments to the final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's amendments would not impose any enforceable duties on these entities. This action amends the definition of "process vent" and makes other technical and administrative changes to the rule. Thus, the requirements of section 6 of the Executive Order do not apply to these amendments to the final rule.

C. Executive Order 13084, Consultation and Coordination with Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's amendments to the rule would not significantly or uniquely affect the communities of Indian tribal governments. The action amends the definition of "process vent" and makes other technical and administrative changes to the rule. No tribal governments own or operate chemical manufacturing process units that are subject to this rule. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this final amendment to the rule.

D. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it is based on technology performance and not on health or safety risks.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, or tribal governments, in aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that today's action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, or tribal governments in the aggregate, or to the private sector in any 1 year. Thus, today's action is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that today's action contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, today's action is not subject to the requirements of section 203 of the UMRA.

F. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601, et seq.

The RFA generally requires the EPA to give special consideration to the effect of Federal regulations on small entities and to consider regulatory options that might mitigate any such impacts. The EPA is required to prepare a regulatory flexibility analysis and coordinate with small entity stakeholders if the Agency determines that a rule will have a significant economic impact on a substantial number of small entities.

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with these amendments to the rule. The EPA has also determined that these amendments will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small government jurisdictions. Today's amendments are primarily technical and administrative and are not expected to impose significant new costs. The EPA does not anticipate that the changes to the rule will create any significant additional burden for any of the regulated entities.

G. Paperwork Reduction Act

The OMB has approved the information collection requirements contained in the rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, and has assigned OMB control number 2060–0282. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1414.03) and a copy may be obtained from Sandy Farmer by mail at the Collection Strategies Division (2822), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, by email at farmer.sandy@epa.gov, or by calling (202) 260–2740.

Today's amendments to the rule should have a very minor effect on the information collection burden estimates made previously. Based on discussions with industry representatives, EPA believes that this action would result an insignificant increase in the estimated information collection burden. Any increase would be the burden associated with identification of and submittal of compliance documentation for previously unreported process vents subject to this rule. The EPA considers these changes to the rule to represent a clarification of the definition of process vent and the reporting requirements for process vents. Thus, EPA considers that if there is any increase in the burden associated with the rule, this increase would be small and well within the uncertainty of the analysis. Consequently, the ICR has not been revised for these amendments to the rule.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

H. National Technology Transfer and Advancement Act

As noted in the proposed rule, Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104–113, section 12(d) (15 U.S.C. 272 note) directs all Federal agencies to use voluntary consensus standards (VCS) in its regulatory activities instead of government-unique standards unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (*e.g.*, material specifications, test methods, sampling and analytical procedures, business practices, etc.) that are developed or adopted by VCS bodies. The NTTAA requires Federal agencies like the EPA to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable VCS.

This action includes amendments to appendix C to add another procedure for determining fraction biodegraded. Therefore, we conducted a search to identify potentially applicable VCS for this case. However, we identified no such standards, and none were brought to our attention in comments. Therefore, EPA has decided to add the proposed additional procedure to appendix C of 40 CFR part 63.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the SBREFA, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective January 22, 2001.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: December 22, 2000.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart F—National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry

2. Section 63.100 is amended by revising paragraph (e) introductory text, by revising paragraph (j)(4), and by adding paragraph (q) to read as follows:

§ 63.100 Applicability and designation of source.

* * * * *

(e) The source to which this subpart applies is the collection of all chemical manufacturing process units and the associated equipment at a major source that meet the criteria specified in paragraphs (b)(1) through (3) of this section. The source includes the process vents; storage vessels; transfer racks; waste management units; maintenance wastewater; heat exchange systems; equipment identified in § 63.149; and pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, surge control vessels, and bottoms receivers that are associated with that collection of chemical manufacturing process units. The source also includes equipment required by, or utilized as a method of compliance with, subparts F, G, or H of this part which may include control devices and recovery devices.

* * * * *

(j) * * *

(4) Batch process vents within a chemical manufacturing process unit.

* * * * *

(q) If the owner or operator of a process vent, or of a gas stream transferred subject to § 63.113(i), is unable to comply with the provisions of §§ 63.113 through 63.118 by the applicable compliance date specified in paragraph (k),(l), or (m) of this section

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for the reasons stated in paragraph (q)(1),(3), or (5) of this section, the owner or operator shall comply with the applicable provisions in §§ 63.113 through 63.118 as expeditiously as practicable, but in no event later than the date approved by the Administrator pursuant to paragraph (q)(2), (4), or (6) of this section, respectively. For requests under paragraph (q)(1) or (3) of this section, the date approved by the Administrator may be earlier than, and shall not be later than, the later of January 22, 2004 or 3 years after the transferee's refusal to accept the stream for disposal. For requests submitted under paragraph (q)(5) of this section, the date approved by the Administrator may be earlier than, and shall not be later than, 3 years after the date of publication of the amendments to this subpart or to subpart G of this part which created the need for an extension of the compliance.

(1) If the owner or operator has been sending a gas stream for disposal as described in § 63.113(i) prior to January 22, 2001, and the transferee does not submit a written certification as described in § 63.113(i)(2) and ceases to accept the gas stream for disposal, the owner or operator shall comply with paragraph (q)(2) of this section.

(2)(i) An owner or operator directed to comply with paragraph (q)(2) of this section shall submit to the Administrator for approval a compliance schedule, along with a justification for the schedule.

(ii) The compliance schedule and justification shall be submitted no later than 90 days after the transferee ceases to accept the gas stream for disposal.

(iii) The Administrator shall approve the compliance schedule or request changes within 120 days of receipt of the compliance schedule and justification.

(3) If the owner or operator has been sending the gas stream for disposal as described in § 63.113(i) to a transferee who had submitted a written certification as described in § 63.113(i)(2), and the transferee revokes its written certification, the owner or operator shall comply with paragraph (q)(4) of this section. During the period between the date when the owner or operator receives notice of revocation of the transferee's written certification and the compliance date established under paragraph (q)(4) of this section, the owner or operator shall implement, to the extent reasonably available, measures to prevent or minimize excess emissions to the extent practical. For purposes of this paragraph (q)(3), the term "excess emissions" means emissions in excess of those that would have occurred if the transferee had continued managing the gas stream in compliance with the requirements in §§ 63.113 through 63.118. The measures to be taken shall be identified in the applicable startup, shutdown, and malfunction plan. If the measures that can be reasonably taken will change over time, so that a more effective measure which could not reasonably be taken initially would be reasonable at a later date, the Administrator may require the more effective measure by a specified date (in addition to or instead of any other measures taken sooner or later than that date) as a condition of approval of the compliance schedule.

(4)(i) An owner or operator directed to comply with this paragraph (q)(4) shall submit to the Administrator for approval the documents specified in paragraphs (q)(4)(i)(A) through (E) of this section no later than 90 days after the owner or operator receives notice of revocation of the transferee's written certification.

(A) A request for determination of a compliance date.

(B) A justification for the request for determination of a compliance date.

(C) A compliance schedule.

(D) A justification for the compliance schedule.

(E) A description of the measures that will be taken to minimize excess emissions until the new compliance date, and the date when each measure will first be implemented. The owner or operator shall describe how, and to what extent, each measure will minimize excess emissions, and shall justify any period of time when measures are not in place.

(ii) The Administrator shall approve or disapprove the request for determination of a compliance date and the compliance schedule, or request changes, within 120 days after receipt of the documents specified in paragraphs (q)(4)(i)(A) through (E) of this section. Upon approving the request for determination and compliance schedule, the Administrator shall specify a reasonable compliance date consistent with the introductory text in paragraph (q) of this section.

(5) If the owner's or operator's inability to meet otherwise applicable compliance deadlines is due to amendments of this subpart or of subpart G of this part published on or after January 22, 2001 and neither condition specified in paragraph (q)(1) or (3) of this section is applicable, the owner or operator shall comply with paragraph (q)(6) of this section.

(6)(i) An owner or operator directed to comply with this paragraph (6)(i) shall submit to the Administrator for approval, a request for determination of a compliance date, a compliance schedule, a justification for the determination of a compliance date, and a justification for the compliance schedule.

(ii) The documents required to be submitted under paragraph (q)(6)(i) of this section shall be submitted no later than 120 days after publication of the amendments of this subpart or of subpart G of this part which necessitate the request for an extension.

(iii) The Administrator shall approve or disapprove the request for a determination of a compliance date, or request changes, within 120 days after receipt of the request for determination of a compliance date, the compliance schedule, and the two justifications. If the request for determination of a compliance date is disapproved, the compliance schedule is disapproved and the owner or operator shall comply by the applicable date specified in paragraph (k),(l), or (m) of this section. If the request for the determination of a compliance date is approved, the Administrator shall specify, at the time of approval, a reasonable compliance date consistent with the introductory text in paragraph (q) of this section.

3. Section 63.101 is amended by adding in alphabetical order the definition of "Batch process vent" and by revising the definition of "Process vent" to read as follows:

§ 63.101 Definitions.

* * * * *

Batch process vent means gaseous venting to the atmosphere from a batch operation.

* * * * *

Process vent means the point of discharge to the atmosphere (or the point of entry into a control device, if any) of a gas stream if the gas stream has the characteristics specified in § 63.107(b) through (h), or meets the criteria specified in § 63.107(i). For purposes of §§ 63.113 through 63.118, all references to the characteristics of a process vent (e.g., flow rate, total HAP concentration, or TRE index value) shall mean the characteristics of the gas stream.

* * * * *

4. Subpart F is amended by adding a new § 63.107 to read as follows:

§ 63.107 Identification of process vents subject to this subpart.

(a) The owner or operator shall use the criteria specified in this § 63.107 to determine whether there are any process vents associated with an air oxidation reactor, distillation unit, or reactor that is in a source subject to this subpart. A process vent is the point of discharge to the atmosphere (or the point of entry into a control device, if any) of a gas stream if the gas stream has the characteristics specified in paragraphs (b) through (h) of this section, or meets the criteria specified in paragraph (i) of this section.

(b) Some, or all, of the gas stream originates as a continuous flow from an air oxidation reactor, distillation unit, or reactor during operation of the chemical manufacturing process unit.

(c) The discharge to the atmosphere (with or without passing through a control device) meets at least one of the conditions specified in paragraphs (c)(1) through (3) of this section.

(1) Is directly from an air oxidation reactor, distillation unit, or reactor; or

(2) Is from an air oxidation reactor, distillation unit, or reactor after passing solely (*i.e.*, without passing through any other unit operation for a process purpose) through one or more recovery devices within the chemical manufacturing process unit; or

(3) Is from a device recovering only mechanical energy from a gas stream that comes either directly from an air oxidation reactor, distillation unit, or reactor, or from an air oxidation reactor, distillation unit, or reactor after passing solely (*i.e.*, without passing through any other unit operation for a process purpose) through one or more recovery devices within the chemical manufacturing process unit.

(d) The gas stream contains greater than 0.005 weight percent total organic HAP at the point of discharge to the atmosphere (or at the point of entry into a control device, if any).

(e) The air oxidation reactor, distillation unit, or reactor is part of a chemical manufacturing process unit that meets the criteria of § 63.100(b).

(f) The gas stream is in the gas phase from the point of origin at the air oxidation reactor, distillation unit, or reactor to the point of discharge to the atmosphere (or to the point of entry into a control device, if any).

(g) The gas stream is discharged to the atmosphere either on-site, off-site, or both.

(h) The gas stream is not any of the items identified in paragraphs (h)(1) through (9) of this section.

(1) A relief valve discharge.

(2) A leak from equipment subject to subpart H of this part.

(3) A gas stream going to a fuel gas system as defined in § 63.101.

(4) A gas stream exiting a control device used to comply with § 63.113.

(5) A gas stream transferred to other processes (on-site or off-site) for reaction or other use in another process (*i.e.*, for chemical value as a product, isolated intermediate, byproduct, or coproduct, or for heat value).

(6) A gas stream transferred for fuel value (*i.e.*, net positive heating value), use, reuse, or for sale for fuel value, use, or reuse.

(7) A storage vessel vent or transfer operation vent subject to § 63.119 or § 63.126.

(8) A vent from a waste management unit subject to §§ 63.132 through 63.137.

(9) A gas stream exiting an analyzer.

(i) The gas stream would meet the characteristics specified in paragraphs (b) through (g) of this section, but, for purposes of avoiding applicability, has been deliberately interrupted, temporarily liquefied, routed through any item of equipment for no process purpose, or disposed of in a flare that does not meet the criteria in § 63.11(b), or an incinerator that does not reduce emissions of organic HAP by 98 percent or to a concentration of 20 parts per million by volume, whichever is less stringent.

Subpart G—National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater

5. Section 63.110 is amended by revising paragraph (a) to read as follows:

§ 63.110 Applicability.

(a) This subpart applies to all process vents, storage vessels, transfer racks, wastewater streams, and in-process equipment subject to § 63.149 within a source subject to subpart F of this part.

* * * * *

6. Section 63.111 is amended by:

a. Adding in alphabetical order the definition of "Point of transfer";

b. Revising the definition of "Group 1 process vent";

c. Revising the definition of "Group 2 process vent"; and

d. Revising the definition of "Vent stream."

The additions and revisions read as follows:

§ 63.111 Definitions.

* * * * *

Group 1 process vent means a process vent for which the vent stream flow rate is greater than or equal to 0.005 standard cubic meter per minute, the total organic HAP concentration is greater than or equal to 50 parts per million by volume, and the total resource effectiveness index value, calculated according to § 63.115, is less than or equal to 1.0.

Group 2 process vent means a process vent for which the vent stream flow rate is less than 0.005 standard cubic meter per minute, the total organic HAP concentration is less than 50 parts per million by volume or the total resource effectiveness index value, calculated according to § 63.115, is greater than 1.0.

* * * * *

Point of transfer means:

(1) If the transfer is to an off-site location for control, the point where the conveyance crosses the property line; or

(2) If the transfer is to an on-site location not owned or operated by the owner or operator of the source, the point where the conveyance enters the operation or equipment of the transferee.

* * * * *

Vent stream, as used in the process vent provisions, means the gas stream flowing through the process vent.

* * * * *

7. Section 63.113 is amended by:

a. Revising paragraph (a) introductory text and revising the second sentence in paragraph (a)(3);

b. Revising paragraph (c) introductory text and paragraph (c)(1) introductory text;

c. Revising paragraph (e);

d. Revising paragraph (g); and

e. Adding paragraph (i).

The revisions and additions read as follows:

§ 63.113 Process vent provisions—reference control technology.

(a) The owner or operator of a Group 1 process vent as defined in this subpart shall comply with the requirements of paragraph (a)(1), (2), or (3) of this section. The owner or operator who transfers a gas stream that has the characteristics specified in § 63.107 (b) through (h) or meets the criteria specified in § 63.107(i) to an off-site location or an on-site location not owned or operated by the owner or operator of the source for disposal shall comply with the requirements of paragraph (i) of this section.

* * * * *

(3) * * * If the TRE index value is greater than 1.0, the process vent shall comply with the provisions for a Group 2 process vent specified in either paragraph (d) or (e) of this section, whichever is applicable.

* * * * *

(c) Halogenated vent streams from Group 1 process vents that are combusted shall be controlled according to paragraph (c)(1) or (2) of this section.

(1) If a combustion device is used to comply with paragraph (a)(2) of this

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section for a halogenated vent stream, then the gas stream exiting the combustion device shall be conveyed to a halogen reduction device, such as a scrubber, before it is discharged to the atmosphere.

* * * * *

(e) The owner or operator of a Group 2 process vent with a TRE index value greater than 4.0 shall maintain a TRE index value greater than 4.0, comply with the provisions for calculation of a TRE index value in § 63.115 and the reporting and recordkeeping provisions in §§ 63.117(b) and 63.118(c) and (h), and is not subject to monitoring or any other provisions of §§ 63.114 through 63.118.

* * * * *

(g) The owner or operator of a Group 2 process vent with a total organic HAP concentration less than 50 parts per million by volume shall maintain a total organic HAP concentration less than 50 parts per million by volume; comply with the Group determination procedures in § 63.115(a), (c), and (e); the reporting and recordkeeping requirements in §§ 63.117(d) and 63.118(e) and (j); and is not subject to monitoring or any other provisions of §§ 63.114 through 63.118.

* * * * *

(i) *Off-site control or on-site control not owned or operated by the source.* This paragraph (i) applies to gas streams that have the characteristics specified in § 63.107(b) through (h) or meet the criteria specified in § 63.107(i); that are transferred for disposal to an on-site control device (or other compliance equipment) not owned or operated by the owner or operator of the source generating the gas stream, or to an off-site control device or other compliance equipment; and that have the characteristics (e.g., flow rate, total organic HAP concentration, or TRE index value) of a Group 1 process vent, determined at the point of transfer.

(1) The owner or operator transferring the gas stream shall:

(i) Comply with the provisions specified in § 63.114(d) for each gas stream prior to transfer.

(ii) Notify the transferee that the gas stream contains organic hazardous air pollutants that are to be treated in accordance with the provisions of this subpart. The notice shall be submitted to the transferee initially and whenever there is a change in the required control.

(2) The owner or operator may not transfer the gas stream unless the transferee has submitted to the EPA a written certification that the transferee will manage and treat any gas stream transferred under this paragraph (i) and received from a source subject to the requirements of this subpart in accordance with the requirements of either §§ 63.113 through 63.118, or § 63.102(b), or subpart D of this part if alternative emission limitations have been granted the transferor in accordance with those provisions. The certifying entity may revoke the written certification by sending a written statement to EPA and the owner or operator giving at least 90 days notice that the certifying entity is rescinding acceptance of responsibility for compliance with the regulatory provisions listed in this paragraph (i). Upon expiration of the notice period, the owner or operator may not transfer the gas stream to the transferee. Records retained by the transferee shall be retained in accordance with § 63.103(c).

(3) By providing this written certification to EPA, the certifying entity accepts responsibility for compliance with the regulatory provisions listed in paragraph (i)(2) of this section with respect to any transfer covered by the written certification. Failure to abide by any of those provisions with respect to such transfers may result in enforcement action by EPA against the certifying entity in accordance with the enforcement provisions applicable to violations of these provisions by owners or operators of sources.

(4) Written certifications and revocation statements to EPA from the transferees of such gas streams shall be signed by a responsible official of the certifying entity, provide the name and address of the certifying entity, and be sent to the appropriate EPA Regional Office at the addresses listed in § 63.13. Such written certifications are not transferable by the transferee.

8. Section 63.114 is amended by revising paragraph (a)(3), revising paragraph (a)(4)(ii), and revising paragraph (d) to read as follows:

§ 63.114 Process vent provisions—monitoring requirements.

(a) * * *

(3) Where a boiler or process heater of less than 44 megawatts design heat input capacity is used, the following monitoring equipment is required: a temperature monitoring device in the firebox equipped with a continuous recorder. This requirement does not apply to gas streams that are introduced with primary fuel or are used as the primary fuel.

(4) * * *

(ii) A flow meter equipped with a continuous recorder shall be located at the scrubber influent for liquid flow. Gas flow rate shall be determined using one of the procedures specified in paragraphs (a)(4)(ii)(A) through (C) of this section.

(A) The owner or operator may determine gas flow rate using the design blower capacity, with appropriate adjustments for pressure drop.

(B) If the scrubber is subject to rules in 40 CFR parts 264 through 266 that have required a determination of the liquid to gas (L/G) ratio prior to the applicable compliance date for this subpart specified in § 63.100(k), the owner or operator may determine gas flow rate by the method that had been utilized to comply with those rules. A determination that was conducted prior to the compliance date for this subpart may be utilized to comply with this subpart if it is still representative.

(C) The owner or operator may prepare and implement a gas flow rate determination plan that documents an appropriate method which will be used to determine the gas flow rate. The plan shall require determination of gas flow rate by a method which will at least provide a value for either a representative or the highest gas flow rate anticipated in the scrubber during representative operating conditions other than startups, shutdowns, or malfunctions. The plan shall include a description of the methodology to be followed and an explanation of how the selected methodology will reliably determine the gas flow rate, and a description of the records that will be maintained to document the determination of gas flow rate. The owner or operator shall maintain the plan as specified in § 63.103(c).

* * * * * *

(d) The owner or operator of a process vent shall comply with paragraph (d)(1) or (2) of this section for any bypass line between the origin of the gas stream (i.e., at an air oxidation reactor, distillation unit, or reactor as identified in § 63.107(b)) and the point where the gas stream reaches the process vent, as described in § 63.107, that could divert the gas stream directly to the atmosphere. Equipment such as low leg drains, high point bleeds, analyzer vents, open-ended valves or lines, and pressure relief valves needed for safety purposes are not subject to this paragraph (d).

(1) Properly install, maintain, and operate a flow indicator that takes a reading at least once every 15 minutes. Records shall be generated as specified in § 63.118(a)(3). The flow indicator shall be installed at the entrance to any bypass line that could divert the gas stream to the atmosphere; or

(2) Secure the bypass line valve in the non-diverting position with a car-seal or a lock-and-key type configuration. A visual inspection of the seal or closure mechanism shall be performed at least once every month to ensure that the valve is maintained in the non-diverting position and the gas stream is not diverted through the bypass line.

* * * * *

9. Section 63.115 is amended by:

a. Revising paragraph (a) introductory text;

b. Revising paragraph (b) introductory text;

c. Revising paragraph (c) introductory text and paragraphs (c)(4)(i) and (ii);

d. Revising paragraph (d)(1) introductory text and paragraph (d)(1)(iii)(D)(*4*);

e. Revising paragraph (d)(2) introductory text, paragraphs (d)(2)(i) and (ii) introductory text, and paragraph (d)(2)(ii)(C); and

f. Adding paragraph (f).

The revisions and additions read as follows:

§ 63.115 Process vent provisions—methods and procedures for process vent group determination.

(a) For purposes of determining vent stream flow rate, total organic HAP or total organic carbon concentration or TRE index value, as specified under paragraph (b), (c), or (d) of this section, the sampling site shall be after the last recovery device (if any recovery devices are present) but prior to the inlet of any control device that is present and prior to release to the atmosphere.

* * * * *

(b) To demonstrate that a vent stream flow rate is less than 0.005 standard cubic meter per minute in accordance with the Group 2 process vent definition of this subpart, the owner or operator shall measure flow rate by the following procedures:

* * * * *

(c) Each owner or operator seeking to demonstrate that a vent stream has an organic HAP concentration below 50 parts per million by volume in accordance with the Group 2 process vent definition of this subpart shall measure either total organic HAP or TOC concentration using the following procedures:

* * * * *

(*4*) * * *

(i) Method 25A of 40 CFR part 60, appendix A, shall be used only if a single organic HAP compound is greater than 50 percent of total organic HAP, by volume, in the vent stream.

(ii) The vent stream composition may be determined by either process knowledge, test data collected using an appropriate EPA method, or a method or data validated according to the protocol in Method 301 of appendix A of this part. Examples of information that could constitute process knowledge include calculations based on material balances, process stoichiometry, or previous test results provided the results are still relevant to the current vent stream conditions.

* * * * *

(d) * * *

(1) Engineering assessment may be used to determine vent stream flow rate, net heating value, TOC emission rate, and total organic HAP emission rate for the representative operating condition expected to yield the lowest TRE index value.

* * * * *

(iii) * * *

(D) * * *

(*4*) Estimation of maximum expected net heating value based on the vent stream concentration of each organic compound or, alternatively, as if all TOC in the vent stream were the compound with the highest heating value.

* * * * *

(2) Except as provided in paragraph (d)(1) of this section, vent stream flow rate, net heating value, TOC emission rate, and total organic HAP emission rate shall be measured and calculated according to the procedures in paragraphs (d)(2)(i) through (v) of this section and used as input to the TRE index value calculation in paragraph (d)(3) of this section.

(i) The vent stream volumetric flow rate (Q_s), in standard cubic meters per minute at 20 degrees Celcius, shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. If the vent stream tested passes through a final steam jet ejector and is not condensed, the vent stream volumetric flow shall be corrected to 2.3 percent moisture.

(ii) The molar composition of the vent stream, which is used to calculate net heating value, shall be determined using the following methods:

* * * * *

(C) Method 4 of 40 CFR part 60, appendix A, to measure the moisture content of the vent stream.

* * * * *

(f) Notwithstanding any other provisions of this subpart, in any case where a process vent includes one or more gas streams that are not from a source subject to this subpart (hereafter called "non-HON streams" for purposes of this paragraph), and one or more gas streams that meet the criteria in § 63.107(b) through (h) or the criteria in § 63.107(i) (hereafter called "HON streams" for purposes of this paragraph), the owner or operator may elect to comply with paragraphs (f)(1) through (3) of this section.

(1) The owner or operator may determine the characteristics (flow rate, total organic HAP concentration, and TRE index value) for each HON stream, or combination of HON streams, at a representative point as near as practical to, but before, the point at which it is combined with one or more non-HON streams.

(2) If one or more of the HON streams, or combinations of HON streams, has the characteristics (determined at the location specified in paragraph (f)(1) of this section) associated with a Group 1 process vent, the combined vent stream is a Group 1 process vent. Except as specified in paragraph (f)(3) of this section, if none of the HON streams, or combinations of HON streams, when determined at the location specified in paragraph (f)(1) of this section, has the characteristics associated with a Group 1 process vent, the combined vent stream is a Group 2 process vent regardless of the TRE index value determined at the location specified in § 63.115(a). If the combined vent stream is a Group 2 process vent as determined by the previous sentence, but one or more of the HON streams, or combinations of HON streams, has a TRE index value greater than 1 but less than or equal to 4, the combined vent stream is a process vent with a TRE index value greater than 1 but less than or equal to 4. In this case, the owner or operator shall monitor the combined vent stream as required by § 63.114(b).

(3) Paragraphs (f)(1) and (2) of this section are not intended to apply instead of any other subpart of this part. If another subpart of this part applies to one or more of the non-HON streams contributing to the combined vent stream, that subpart may impose emission control requirements such as, but not limited to, requiring the combined vent stream to be classified and controlled as a Group 1 process vent.

10. Section 63.116 is amended by:

a. Revising paragraph (a);

b. Revising paragraph (b)(2);

c. Revising paragraph (c)(1)(i)(B) and paragraph (c)(4)(iv); and

d. Revising paragraph (d) introductory text.

The revisions read as follows:

§ 63.116 Process vent provisions—performance test methods and procedures to determine compliance.

(a) When a flare is used to comply with § 63.113(a)(1), the owner or operator shall comply with paragraphs

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(a)(1) through (3) of this section. The owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration.

(1) Conduct a visible emission test using the techniques specified in § 63.11(b)(4).

(2) Determine the net heating value of the gas being combusted using the techniques specified in § 63.11(b)(6).

(3) Determine the exit velocity using the techniques specified in either § 63.11(b)(7)(i) (and § 63.11(b)(7)(iii), where applicable) or § 63.11(b)(8), as appropriate.

(b) * * *

(2) A boiler or process heater into which the gas stream is introduced with the primary fuel or is used as the primary fuel.

* * * * *

(c) * * *

(1) * * *

(i) * * *

(B) If a vent stream is introduced with the combustion air or as a secondary fuel into a boiler or process heater with a design capacity less than 44 megawatts, selection of the location of the inlet sampling sites shall ensure the measurement of total organic HAP or TOC (minus methane and ethane) concentrations in all vent streams and primary and secondary fuels introduced into the boiler or process heater.

* * * * *

(4) * * *

(iv) If the vent stream entering a boiler or process heater with a design capacity less than 44 megawatts is introduced with the combustion air or as a secondary fuel, the weight-percent reduction of total organic HAP or TOC (minus methane and ethane) across the device shall be determined by comparing the TOC (minus methane and ethane) or total organic HAP in all combusted vent streams and primary and secondary fuels with the TOC (minus methane and ethane) or total organic HAP exiting the combustion device, respectively.

(d) An owner or operator using a combustion device followed by a scrubber or other halogen reduction device to control halogenated vent streams in compliance with § 63.113(c)(1) shall conduct a performance test to determine compliance with the control efficiency or emission limits for hydrogen halides and halogens.

* * * * *

11. Section 63.117 is amended by:

a. Revising paragraph (a) introductory text;

b. Revising paragraph (a)(4)(iv);

c. Revising paragraph (a)(6) introductory text; and

d. Revising paragraph (a)(8).

The revisions read as follows:

§ 63.117 Process vents provisions—reporting and recordkeeping requirements for group and TRE determinations and performance tests.

(a) Each owner or operator subject to the control provisions for Group 1 process vents in § 63.113(a) or the provisions for Group 2 process vents with a TRE index value greater than 1.0 but less than or equal to 4.0 in § 63.113(d) shall:

* * * * *

(4) * * *

(iv) For a boiler or process heater with a design heat input capacity of less than 44 megawatts and where the vent stream is introduced with combustion air or used as a secondary fuel and is not mixed with the primary fuel, the percent reduction of organic HAP or TOC, or the concentration of organic HAP or TOC (parts per million by volume, by compound) determined as specified in § 63.116(c) at the outlet of the combustion device on a dry basis corrected to 3 percent oxygen.

* * * * *

(6) Record and report the following when using a scrubber following a combustion device to control a halogenated vent stream:

* * * * *

(8) Record and report the halogen concentration in the vent stream determined according to the procedures specified in § 63.115(d)(2)(v).

* * * * *

12. Section 63.118 is amended by:

a. Revising paragraph (a)(3);

b. Revising paragraph (e)(1);

c. Revising paragraph (f)(3); and

d. In paragraph (f)(5), revising the reference to "paragraph (a)(2)(v) of this section" to read "paragraph (a)(2) of this section."

The revisions read as follows:

§ 63.118 Process vent provisions—periodic reporting and recordkeeping requirements.

(a) * * *

(3) Hourly records of whether the flow indicator specified under § 63.114(d)(1) was operating and whether a diversion was detected at any time during the hour, as well as records of the times and durations of all periods when the gas stream is diverted to the atmosphere or the monitor is not operating.

* * * * *

(e) * * *

(1) Any process changes as defined in § 63.115(e) that increase the organic HAP concentration of the vent stream,

* * * * *

(f) * * *

(3) Reports of the times and durations of all periods recorded under paragraph (a)(3) of this section when the gas stream is diverted to the atmosphere through a bypass line.

* * * * *

13. Section 63.128 is amended by revising paragraph (b) and paragraph (h)(1)(ii) to read as follows:

§ 63.128 Transfer operations provisions—test methods and procedures.

* * * * *

(b) When a flare is used to comply with § 63.126(b)(2), the owner or operator shall comply with paragraphs (b)(1) through (3) of this section. The owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration.

(1) Conduct a visible emission test using the techniques specified in § 63.11(b)(4). The observation period shall be as specified in paragraph (b)(1)(i) or (ii) of this section instead of the 2-hour period specified in § 63.11(b)(4).

(i) If the loading cycle is less than 2 hours, then the observation period for that run shall be for the entire loading cycle.

(ii) If additional loading cycles are initiated within the 2-hour period, then visible emission observations shall be conducted for the additional cycles.

(2) Determine the net heating value of the gas being combusted, using the techniques specified in § 63.11(b)(6).

(3) Determine the exit velocity using the techniques specified in either § 63.11(b)(7)(i) (and § 63.11(b)(7)(iii), where applicable) or § 63.11(b)(8), as appropriate.

* * * * *

(h) * * *

(1) * * *

(ii) If an enclosed combustion device with a minimum residence time of 0.5 seconds and a minimum temperature of 760 degrees Celsius is used to meet the 98-percent emission reduction requirement, documentation that those conditions exist is sufficient to meet the requirements of paragraph (h)(1) of this section.

* * * * *

§ 63.130 [Amended]

14. Section 63.130 is amended by revising the reference in paragraph (d)(5) from "paragraph (a)(2)(v) of this section" to read "paragraph (a)(2)(i) of this section."

15. Section 63.132 is amended by revising paragraphs (a)(3) and (b)(4) to read as follows:

§ 63.132 Process wastewater provisions—general.

(a) * * *

(3) *Requirements for Group 2 wastewater streams.* For wastewater streams that are Group 2 for table 9 compounds, comply with the applicable recordkeeping and reporting requirements specified in §§ 63.146(b)(1) and 63.147(b)(8).

(b) * * *

(4) *Requirements for Group 2 wastewater streams.* For wastewater streams that are Group 2 for both table 8 and table 9 compounds, comply with the applicable recordkeeping and reporting requirements specified in §§ 63.146(b)(1) and 63.147(b)(8).

* * * * *

16. Section 63.138 is amended by:

a. Revising paragraph (i) introductory text;

b. Adding a sentence to the end of paragraph (i)(1) introductory text;

c. Amending the last sentence in paragraph (i)(2) introductory text by revising the reference to "(i)(2)(iv) of this section" to read "(i)(3) of this section";

d. Adding a sentence to the end of paragraph (i)(2)(i) introductory text;

e. Revising paragraph (i)(2)(iii); and

f. Redesignating paragraph (i)(2)(iv) as paragraph (i)(3).

The revisions and additions read as follows:

§ 63.138 Process wastewater provisions—performance standards for treatment processes managing Group 1 wastewater streams and/or residuals removed from Group 1 wastewater streams.

* * * * *

(i) *One megagram total source mass flow rate option.* A wastewater stream is exempt from the requirements of paragraphs (b) and (c) of this section if the owner or operator elects to comply with either paragraph (i)(1) or (2) of this section, and complies with paragraph (i)(3) of this section.

(1) * * * The owner or operator who meets the requirements of this paragraph (i)(1) is exempt from the requirements of §§ 63.133 through 63.137.

* * * * *

(2) * * *

(i) * * * When determining the total source mass flow rate for the purposes of paragraph (i)(2)(i)(B) of this section, the concentration and flow rate shall be determined at the location specified in paragraph (i)(2)(i)(B) of this section and not at the location specified in § 63.144(b) and (c).

* * * * *

(iii) The owner or operator of each waste management unit that receives, manages, or treats a partially treated wastewater stream prior to or during treatment shall comply with the requirements of §§ 63.133 through 63.137, as applicable. For a partially treated wastewater stream that is stored, conveyed, treated, or managed in a waste management unit meeting the requirements of §§ 63.133 through 63.137, the owner or operator shall follow the procedures in paragraph (i)(2)(i)(B) of this section to calculate mass flow rate. A wastewater stream, either untreated or partially treated, where the mass flow rate has been calculated following the procedures in paragraph (i)(2)(i)(A) of this section, is exempt from the requirements of §§ 63.133 through 63.137.

* * * * *

§ 63.140 [Amended]

17. Section 63.140 is amended by revising the reference to "§ 63.147(c)(7)" in the last sentence of paragraph (c) to read "§ 63.147(b)(7)."

18. Section 63.145 is amended by revising paragraph (j) to read as follows:

§ 63.145 Process wastewater provisions—test methods and procedures to determine compliance.

* * * * *

(j) When a flare is used to comply with § 63.139(c), the owner or operator shall comply with paragraphs (j)(1) through (3) of this section. The owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration.

(1) Conduct a visible emission test using the techniques specified in § 63.11(b)(4).

(2) Determine the net heating value of the gas being combusted using the techniques specified in § 63.11(b)(6).

(3) Determine the exit velocity using the techniques specified in either § 63.11(b)(7)(i) (and § 63.11(b)(7)(iii), where applicable) or § 63.11(b)(8), as appropriate.

* * * * *

19. Section 63.146 is amended by:

a. Adding paragraph (b)(1);

b. Revising paragraph (b)(9) introductory text;

c. Removing paragraph (b)(9)(iii); and

d. Revising paragraph (d) introductory text.

The additions and revisions read as follows:

§ 63.146 Process wastewater provisions—reporting.

* * * * *

(b) * * *

(1) *Requirements for Group 2 wastewater streams.* This paragraph does not apply to Group 2 wastewater streams that are used to comply with § 63.138(g). For Group 2 wastewater streams, the owner or operator shall include the information specified in paragraphs (b)(1)(i) through (iv) of this section in the Notification of Compliance Status Report. This information may be submitted in any form. Table 15 of this subpart is an example.

(i) Process unit identification and description of the process unit.

(ii) Stream identification code.

(iii) For existing sources, concentration of table 9 compound(s) in parts per million, by weight. For new sources, concentration of table 8 and/or table 9 compound(s) in parts per million, by weight. Include documentation of the methodology used to determine concentration.

(iv) Flow rate in liter per minute.

* * * * *

(9) For each waste management unit or treatment process used to comply with § 63.138(b)(1), (c)(1), (e), (f), or (g), the owner or operator shall submit the information specified in either paragraph (b)(9)(i) or (ii) of this section.

* * * * *

(d) Except as provided in paragraph (f) of this section, for each treatment process used to comply with § 63.138(b)(1), (c)(1), (d), (e) , (f), or (g), the owner or operator shall submit as part of the next Periodic Report required by § 63.152(c) the information specified in paragraphs (d)(1), (2), and (3) of this section for the monitoring required by § 63.143(b), (c), and (d).

* * * * *

20. Section 63.147 is amended by:

a. Revising paragraph (b) introductory text;

b. Adding paragraph (b)(8);

c. Revising paragraph (d) introductory text and paragraph (d)(2); and

d. Adding paragraph (d)(3).

The revisions and additions read as follows:

§ 63.147 Process wastewater provisions—recordkeeping.

* * * * *

(b) The owner or operator shall keep in a readily accessible location the records specified in paragraphs (b)(1) through (8) of the section.

* * * * *

(8) *Requirements for Group 2 wastewater streams.* This paragraph

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(b)(8) does not apply to Group 2 wastewater streams that are used to comply with § 63.138(g). For all other Group 2 wastewater streams, the owner or operator shall keep in a readily accessible location the records specified in paragraphs (b)(8)(i) through (iv) of this section.

(i) Process unit identification and description of the process unit.

(ii) Stream identification code.

(iii) For existing sources, concentration of table 9 compound(s) in parts per million, by weight. For new sources, concentration of table 8 and/or table 9 compound(s) in parts per million, by weight. Include documentation of the methodology used to determine concentration.

(iv) Flow rate in liter per minute.

* * * * *

(d) The owner or operator shall keep records of the daily average value of each continuously monitored parameter for each operating day as specified in § 63.152(f), except as provided in paragraphs (d)(1) through (3) of this section.

* * * * *

(2) *Regenerative carbon adsorbers.* For regenerative carbon adsorbers, the owner or operator shall keep the records specified in paragraphs (d)(2)(i) and (ii) of this section instead of daily averages.

(i) Records of the total regeneration stream mass flow for each carbon bed regeneration cycle.

(ii) Records of the temperature of the carbon bed after each regeneration cycle.

(3) *Non-regenerative carbon adsorbers.* For non-regenerative carbon adsorbers using organic monitoring equipment, the owner or operator shall keep the records specified in paragraph (d)(3)(i) of this section instead of daily averages. For non-regenerative carbon adsorbers replacing the carbon adsorption system with fresh carbon at a regular predetermined time interval that is less than the carbon replacement interval that is determined by the maximum design flow rate and organic concentration in the gas stream vented to the carbon adsorption system, the owner or operator shall keep the records specified in paragraph (d)(3)(ii) of this section instead of daily averages.

(i)(A) Record of how the monitoring frequency, as specified in table 13 of this subpart, was determined.

(B) Records of when organic compound concentration of adsorber exhaust was monitored.

(C) Records of when the carbon was replaced.

(ii)(A) Record of how the carbon replacement interval, as specified in table 13 of this subpart, was determined.

(B) Records of when the carbon was replaced.

* * * * *

21. Section 63.150 is amended by:

a. Amending paragraph (a) by adding a sentence to the end of the paragraph;

b. Revising paragraph (g)(2) introductory text and paragraph (g)(2)(i);

c. Revising paragraph (g)(2)(iii)(B)(*2*);

d. Revising paragraph (m)(1)(i); and

e. Revising paragraph (m)(2)(i).

The revisions and additions read as follows:

§ 63.150 Emissions averaging provisions.

* * * * *

(a) * * * Notwithstanding the definition of process vent in § 63.101 and the sampling site designation in § 63.115(a), for purposes of this section the location of a process vent shall be defined, and the characteristics of its gas stream shall be determined, consistent with paragraph (g)(2)(i) of this section.

* * * * *

(g) * * *

(2) Emissions from process vents shall be calculated according to paragraphs (g)(2)(i) through (iii) of this section.

(i) The location of a process vent shall be defined, and the characteristics of its gas stream shall be determined at a point that meets the conditions in either paragraph (g)(2)(i)(A) or (B) of this section and the conditions in paragraphs (g)(2)(i)(C) through (E) of this section.

(A) The point is after the final recovery device (if any recovery devices are present).

(B) If a gas stream included in an emissions average is combined with one or more other gas streams after a final recovery device (if any recovery devices are present), then for each gas stream, the point is at a representative point after any final recovery device and as near as feasible to, but before, the point of combination of the gas streams.

(C) The point is before any control device (for process vents, recovery devices shall not be considered control devices).

(D) The point is before discharge to the atmosphere.

(E) The measurement site for determination of the characteristics of the gas stream was selected using Method 1 or 1A of 40 CFR part 60, appendix A.

* * * * *

(iii) * * *

(B) * * *

(*2*) For determining debits from Group 1 process vents, recovery devices shall not be considered control devices and cannot be assigned a percent reduction in calculating $EPV_{iACTUAL}$. The sampling site for measurement of uncontrolled emissions is after the final recovery device. However, as provided in § 63.113(a)(3), a Group 1 process vent may add sufficient recovery to raise the TRE index value above 1.0, thereby becoming a Group 2 process vent.

* * * * *

(m) * * *

(1) * * *

(i) Determine, consistent with paragraph (g)(2)(i) of this section, whether the process vent is Group 1 or Group 2 according to the procedures in § 63.115.

* * * * *

(2) * * *

(i) Determine, consistent with paragraph (g)(2)(i) of this section, the flow rate, organic HAP concentration, and TRE index value using the methods specified in § 63.115;

* * * * *

22. Section 63.151 is amended by revising paragraph (b)(1)(iii) and by revising paragraph (e)(1) to read as follows:

§ 63.151 Initial notification.

* * * * *

(b) * * *

(1) * * *

(iii) An identification of the kinds of emission points within the source that are subject to this subpart;

* * * * *

(e) * * *

(1) A list designating each emission point complying with §§ 63.113 through 63.149 and whether each emission point is Group 1 or Group 2, as defined in § 63.111. For each process vent within the source, provide the information listed in paragraphs (e)(1)(i) through (iv) of this section.

(i) The chemical manufacturing process unit(s) that is the origin of all or part of the vent stream that exits the process vent.

(ii) The type(s) of unit operations (*i.e.*, an air oxidation reactor, distillation unit, or reactor) that creates the vent stream that exits the process vent.

(iii) For a Group 2 process vent, the last recovery device, if any.

(iv) For a Group 1 process vent, the control device, or other equipment used for compliance.

* * * * *

23. Section 63.152 is amended by adding a new paragraph (b)(6), revising paragraph (c)(4)(iv), and adding a new paragraph (d)(4) to read as follows:

§ 63.152 General reporting and continuous records.

* * * * *

(b) * * *

(6) An owner or operator complying with § 63.113(i) shall include in the Notification of Compliance Status, or where applicable, a supplement to the Notification of Compliance Status, the name and location of the transferee, and the identification of the Group 1 process vent.

* * * * *

(c) * * *

(4) * * *

(iv) For gas streams sent for disposal pursuant to § 63.113(i) or for process wastewater streams sent for treatment pursuant to § 63.132(g), reports of changes in the identity of the transferee.

* * * * *

(d) * * *

(4) If an owner or operator transfers for disposal a gas stream that has the characteristics specified in § 63.107(b) through (h) or meets the criteria specified in § 63.107(i) to an off-site location or an on-site location not owned or operated by the owner or operator of the source and the vent stream was not included in the information submitted with the Notification of Compliance Status or a previous periodic report, the owner or operator shall submit a supplemental report. The supplemental report shall be submitted no later than July 23, 2001 or with the next periodic report, whichever is later. The report shall provide the information listed in paragraphs (d)(4)(i) through (iv) of this section.

(i) The chemical manufacturing process unit(s) that is the origin of all or part of the vent stream that exits the process vent.

(ii) The type(s) of unit operations (*i.e.*, an air oxidation reactor, distillation unit, or reactor) that creates the vent stream that exits the process vent.

(iii) For a Group 2 process vent, the last recovery device, if any.

(iv) For a Group 1 process vent, the identity of the transferee.

* * * * *

Appendix to Subpart G—[Amended]

24. The appendix to subpart G is amended by:

a. Revising table 12;

b. Revising footnote f to table 17; and

c. Revising table 20.

The revisions read as follows:

Appendix to Subpart G—Tables and Figures

* * * * *

TABLE 12.—MONITORING REQUIREMENTS FOR TREATMENT PROCESSES

To comply with	Parameters to be monitored	Frequency	Methods
1. Required mass removal of Table 8 and/or Table 9 compound(s) from wastewater treated in a properly operated biological treatment unit, § 63.138(f), and § 63.138(g).	Appropriate parameters as specified in § 63.143(c) and approved by permitting authority.	Appropriate frequency as specified in § 63.143 and approved by permitting authority.	Appropriate methods as specified in § 63.143 and as approved by permitting authority.
2. Steam stripper	(i) Steam flow rate; and	Continuously	Integrating steam flow monitoring device equipped with a continuous recorder.
	(ii) Wastewater feed mass flow rate; and	Continuously	Liquid flow meter installed at stripper influent and equipped with a continuous recorder.
	(iii) Wastewater feed temperature; or (iv) Column operating temperature.	Continuously	(A) Liquid temperature monitoring device installed at stripper influent and equipped with a continuous or recorder; or (B) Liquid temperature monitoring device installed in the column top tray liquid phase (*i.e.*, at the downcomer) and equipped with a continuous recorder.
3. Other treatment processes or alternative monitoring parameters to those listed in item 2 of this table.	Other parameters may be monitored upon approval from the Administrator with the requirements specified in § 63.151(f).		

TABLE 17.—INFORMATION FOR TREATMENT PROCESSES TO BE SUBMITTED WITH NOTIFICATION OF COMPLIANCE STATUS[a, b]

•	•	•	•	•	•	•

[f] Parameter(s) to be monitored or measured in accordance with Table 12 and § 63.143.

* * * * *

TABLE 20.—WASTEWATER—PERIODIC REPORTING REQUIREMENTS FOR CONTROL DEVICES SUBJECT TO § 63.139 USED TO COMPLY WITH §§ 63.13 THROUGH 63.139

Control device	Reporting requirements
(1) Thermal Incinerator	Report all daily average[a] temperatures that are outside the range established in the NCS[b] or operating permit and all operating days when insufficient monitoring data are collected[c].

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TABLE 20.—WASTEWATER—PERIODIC REPORTING REQUIREMENTS FOR CONTROL DEVICES SUBJECT TO § 63.139 USED TO COMPLY WITH §§ 63.13 THROUGH 63.139—Continued

Control device	Reporting requirements
(2) Catalytic Incinerator	(i) Report all daily average[a] upstream temperatures that are outside the range established in the NCS[b] or operating permit. (ii) Report all daily average[a] temperature differences across the catalyst bed that are outside the range established in the NCS[b] or operating permit. (iii) Report all operating days when insufficient monitoring data are collected[c].
(3) Boiler or Process Heater with a design heat input capacity less than 44 megawatts and vent stream is not mixed with the primary fuel.	Report all daily average[a] firebox temperatures that are outside the range established in the NCS[b] or operating permit and all operating days when insufficient monitoring data are collected[c].
(4) Flare	Report the duration of all periods when all pilot flames are absent.
(5) Condenser	Report all daily average[a] exit temperatures that are outside the range established in the NCS[b] or operating permit and all operating days when insufficient monitoring data are collected[c].
(6) Carbon Adsorber (Regenerative)	(i) Report all carbon bed regeneration cycles when the total regeneration stream mass or volumetric flow is outside the range established in the NCS[b] or operating permit. (ii) Report all carbon bed regeneration cycles during which the temperature of the carbon bed after regeneration is outside the range established in the NCS[b] or operating permit. (iii) Report all operating days when insufficient monitoring data are collected[c].
(7) Carbon Adsorber (Non-Regenerative)	(i) Report all operating days when inspections not done according to the schedule developed as specified in table 13 of this subpart. (ii) Report all operating days when carbon has not been replaced at the frequency specified in table 13 of this subpart.
(8) All Control Devices	(i) Report the times and durations of all periods when the vent stream is diverted through a by-pass line or the monitor is not operating, or (ii) Report all monthly inspections that show the valves are moved to the diverting position or the seal has been changed.

[a] The daily average is the average of all values recorded during the operating day, as specified in § 63.147(d).
[b] NCS = Notification of Compliance Status described in § 63.152.
[c] The periodic reports shall include the duration of periods when monitoring data are not collected for each excursion as defined in § 63.152(c)(2)(ii)(A).

* * * * *

Subpart H—National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks

25. Section 63.180 is amended by revising paragraph (e) to read as follows:

§ 63.180 Test methods and procedures.

* * * * *

(e) When a flare is used to comply with § 63.172(d), the owner or operator shall comply with paragraphs (e)(1) through (3) of this section. The owner or operator is not required to conduct a performance test to determine percent emission reduction or outlet organic HAP or TOC concentration.

(1) Conduct a visible emission test using the techniques specified in § 63.11(b)(4).

(2) Determine the net heating value of the gas being combusted using the techniques specified in § 63.11(b)(6).

(3) Determine the exit velocity using the techniques specified in either § 63.11(b)(7)(i) (and § 63.11(b)(7)(iii), where applicable) or § 63.11(b)(8), as appropriate.

* * * * *

Appendix C—[Amended]

26. Appendix C to part 63 is amended by:

a. Revising the third paragraph in section I;

b. Revising the introductory text in section III;

c. Revising Eqn App. C–4 in section III.D.1 and the paragraph preceding it;

d. Revising Eqn App. C–6 in section III.D.2 and the paragraph preceding it;

e. Adding section III.E;

f. Adding references 7 and 8 to the References section;

g. Revising Figure 1; and

h. Adding Form XIII.

The additions and revisions read as follows:

Appendix C to Part 63

Determination of the Fraction Biodegraded (f_{bio}) in a Biological Treatment Unit

I. Purpose

* * * * *

Unless otherwise specified, the procedures presented in this appendix are designed to be applied to thoroughly mixed treatment units. A thoroughly mixed treatment unit is a unit that is designed and operated to approach or achieve uniform biomass distribution and organic compound concentration throughout the aeration unit by quickly dispersing the recycled biomass and the wastewater entering the unit. Detailed discussion on how to determine if a biological treatment unit is thoroughly mixed can be found in reference 7. Systems that are not thoroughly mixed treatment units should be subdivided into a series of zones that have uniform characteristics within each zone. The number of zones required to characterize a biological treatment system will depend on the design and operation of the treatment system. Detailed discussion on how to determine the number of zones in a biological treatment unit and examples of determination of f_{bio} can be found in reference 8. Each zone should then be modeled as a separate unit. The amount of air emissions and biodegradation from the modeling of these separate zones can then be added to reflect the entire system.

* * * * *

III. Procedures for Determination of f_{bio}

The first step in the analysis to determine if a biological treatment unit may be used without being covered and vented through a closed-vent system to an air pollution control device is to determine the compound-specific f_{bio}. The following procedures may be used to determine f_{bio}:

(1) The EPA Test Method 304A or 304B (appendix A, part 63)—Method for the Determination of Biodegradation Rates of Organic Compounds,

(2) Performance data with and without biodegradation,

(3) Inlet and outlet concentration measurements,

(4) Batch tests,

(5) Multiple zone concentration measurements.

All procedures must be executed so that the resulting f_{bio} is based on the collection system and waste management units being in compliance with the rule. If the collection system and waste management units meet the suppression requirements at the time of the test, any of the procedures may be chosen. If the collection system and waste management units are not in compliance at the time of the performance test, then only Method 304A, B, or the batch test shall be chosen. If Method 304A, B, or the batch test is used, any anticipated changes to the influent of the full-scale biological treatment unit that will occur after the facility has enclosed the collection system must be represented in the influent feed to the benchtop bioreactor unit, or test unit.

Select one or more appropriate procedures from the five listed above based on the availability of site specific data and the type of mixing that occurs in the unit (thoroughly mixed or multiple mixing zone). If the facility does not have site-specific data on the removal efficiency of its biological treatment unit, then Procedure 1 or Procedure 4 may be used. Procedure 1 allows the use of a benchtop bioreactor to determine the first-order biodegradation rate constant. An owner or operator may elect to assume the first order biodegradation rate constant is zero for any regulated compound(s) present in the wastewater. Procedure 4 explains two types of batch tests which may be used to estimate the first order biodegradation rate constant. An owner or operator may elect to assume the first order biodegradation rate constant is zero for any regulated compound(s) present in the wastewater. Procedure 3 would be used if the facility has, or measures to determine, data on the inlet and outlet individual organic compound concentration for the biological treatment unit. Procedure 3 may only be used on a thoroughly mixed treatment unit. Procedure 5 is the concentration measurement test that can be used for units with multiple mixing zones. Procedure 2 is used if a facility has or obtains performance data on a biotreatment unit prior to and after addition of the microbial mass. An example where Procedure 2 could be used is an activated sludge unit where measurements have been taken on inlet and exit concentration of organic compounds in the wastewater prior to seeding with the microbial mass and startup of the unit. The flow chart in figure 1 outlines the steps to use for each of the procedures.

* * * * *

D. Batch Tests (Procedure 4)

* * * * *

1. * * *

Equation App. C–3 can be integrated to obtain the following equation:

$$-t = \frac{VK_s}{A}\ln\left(\frac{s}{s_0}\right) + \frac{Q_m X V^2}{AB}\ln\left(\frac{A+Bs}{A+Bs_0}\right) \quad \text{(Eqn App. C-4)}$$

Where:

$A = GK_{eq}K_s + Q_mVX$

$B = GK_{eq}$

S_o = test compound concentration at t=0

* * * * * * *

2. * * *

Equation App. C–5 can be solved analytically to give:

$$t = \frac{-\left(V_g K_{eq} + V_l\right)}{V_l Q_m X}\left[\left(s - s_0\right) + K_s \ln\left(\frac{s}{s_0}\right)\right] \quad \text{(Eqn App. C-6)}$$

* * * * *

E. Multiple Zone Concentration Measurements (Procedure 5)

Procedure 5 is the concentration measurement method that can be used to determine the f_{bio} for units that are not thoroughly mixed and thus have multiple zones of mixing. As with the other procedures, proper determination of f_{bio} must be made on a system as it would exist under the rule. For purposes of this calculation, the biological unit must be divided [1] into zones with uniform characteristics within each zone. The number of zones that is used depends on the complexity of the unit. Reference 8, "Technical Support Document for the Evaluation of Aerobic Biological Treatment Units with Multiple Mixing Zones," is a source for further information concerning how to determine the number of zones that should be used for evaluating your unit. The following information on the biological unit must be available to use this procedure: basic unit variables such as inlet and recycle wastewater flow rates, type of agitation, and operating conditions; measured representative organic compound concentrations in each zone and the inlet and outlet; and estimated mass transfer coefficients for each zone.

Reference 8 "Technical Support Document for the Evaluation of Aerobic Biological Treatment Units with Multiple Mixing Zones," is a source for further information concerning how to interpolate the biorates for multiple zones. In units with well-characterized concentration measurements obtained in an initial evaluation of the unit, it may be possible to demonstrate that there is a good correlation of the component concentrations with the locations in the multiple-zone unit. With this good correlation, it may be possible to accurately predict the concentrations in selected zones without actually testing each selected zone. This correlation method may be used for units that have many zones (greater than 5) or where one of the interior zones is not readily accessible for sampling. To use this correlation method of estimating zone concentrations, it is necessary to measure the concentrations in the inlet unit, the exit unit, and sufficient interior units to obtain a correlation of component concentrations with the locations. You cannot use this correlation method of estimating selected zone concentrations if monitoring of each zone is required, or if the accuracy and precision of the correlation is inferior to actual individual sampling error. The accuracy and precision of the correlation may be improved by increasing the number of locations tested. Because the correlation is based on many samples, it should provide an accurate representation of a stable operating system.

The estimated mass transfer coefficient for each compound in each zone is obtained from Form II using the characteristics of each zone. A computer model may be used. If the Water7 model or the most recent update to this model is used, then use Form II–A to calculate KL. The TOXCHEM or BASTE model may also be used to calculate KL for the biological treatment unit, with the stipulations listed in Procedure 304B. Compound concentration measurements for each zone are used in Form XIII to calculate the f_{bio}. A copy of Form XIII is completed for each of the compounds of concern treated in the biological unit.

* * * * *

References

* * * * *

7. Technical Support Document for Evaluation of Thoroughly Mixed Biological Treatment Units. November 1998.

8. Technical Support Document for the Evaluation of Aerobic Biological Treatment Units with Multiple Mixing Zones. July 1999.

* * * * *

[1] This is a mathematical division of the actual unit; not addition of physical barriers.

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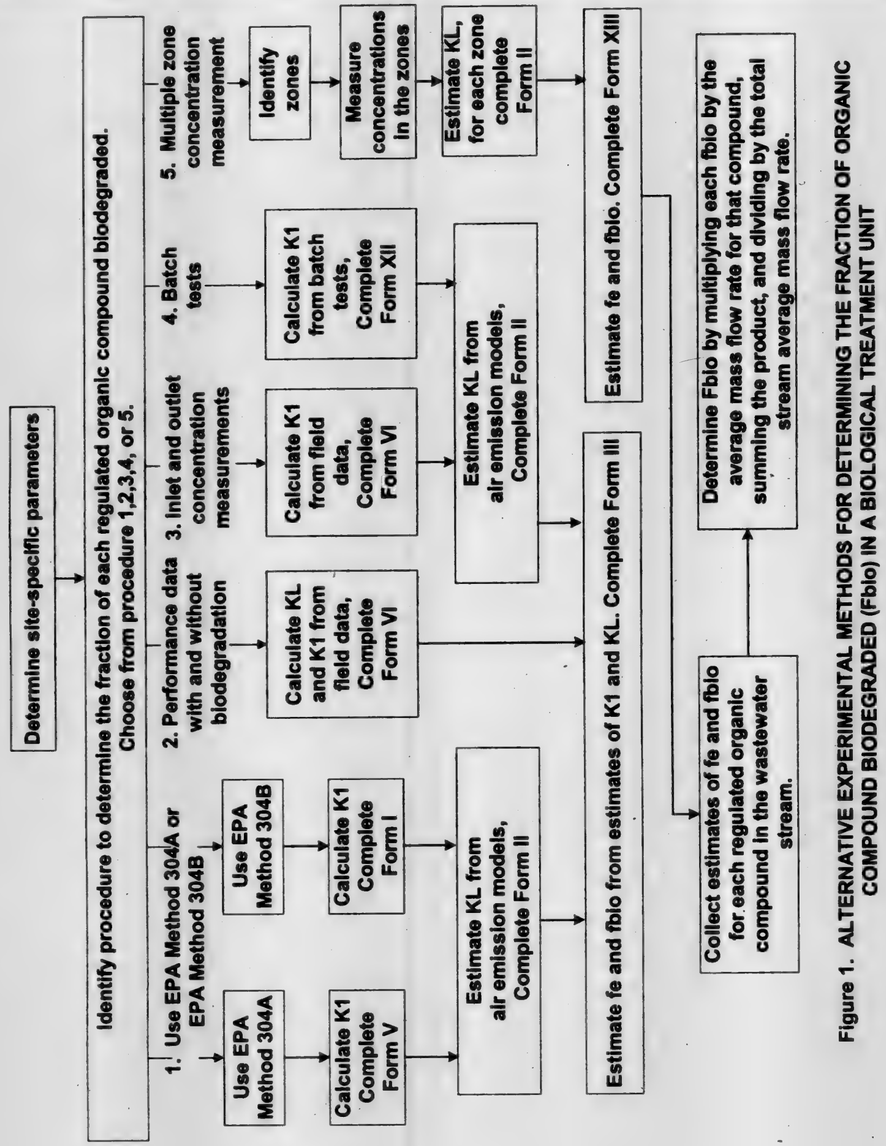


Figure 1. ALTERNATIVE EXPERIMENTAL METHODS FOR DETERMINING THE FRACTION OF ORGANIC COMPOUND BIODEGRADED (Fbio) IN A BIOLOGICAL TREATMENT UNIT

FORM XIII. DATA FORM FOR THE ESTIMATION OF MULTIPLE ZONE BIODEGRADATION FROM UNIT CONCENTRATIONS

NAME OF THE FACILITY for site specific biorate determination		
COMPOUND for site specific biorate determination		
Number of zones in the biological treatment unit	1	
VOLUME of full-scale system (cubic meters)	2	
Average DEPTH of the full-scale system (meters)	3	
FLOW RATE of wastewater treated in the unit (m3/s)	4	
Recycle flow of wastewater added to the unit, if any (m3/s)	5	
Concentration in the wastewater treated in the unit (mg/L)	6	
Concentration in the recycle flow, if any (mg/L)	7	
Concentration in the effluent (mg/L).	8	
TOTAL INLET FLOW (m3/s) line 4 plus the number on line 5	9	
TOTAL RESIDENCE TIME (s) line 2 divided by line 9.	10	
TOTAL AREA OF IMPOUNDMENT (m2) line 2 divided by line 3	11	

Zone number	Concentration for zone, Ci (mg/L)	Area of the zone, A (m2)	Estimate of KL in the zone (m/s) from Form II	AIR STRIPPING KL A Ci (g/s)
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
TOTALS sum for each zone.	12			13

Removal by air stripping (g/s). Line 13.	14	
Loading in effluent (g/s). Line 8 times line 9.	15	
Total loading (g/s). (Line 5 * line 7) + (line 4* line 6).	16	
Removal by biodegradation (g/s) Line 16 minus (line 14 + line 15).	17	
Fraction biodegraded: Divide line 17 by line 16..	18	
Fraction air emissions: Divide line 14 by line 16.	19	
Fraction remaining in unit effluent: Divide line 15 by line 16.	20	

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Research and Special Programs Administration

49 CFR Parts 171, 172, 173, 177 and 178
Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-Organisms; Proposed Rule

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, 177, and 178

[Docket No. RSPA–98–3971 (HM–226)]

RIN 2137–AD13

Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-Organisms

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: RSPA is proposing to revise transportation requirements for infectious substances, including regulated medical waste, by adopting defining criteria and packaging requirements for infectious substances and genetically modified micro-organisms that are consistent with international standards; revising the current broad exceptions for diagnostic specimens and biological products; and authorizing bulk packaging options for regulated medical waste consistent with requirements in international standards and DOT exemptions. These proposals are intended to assure an acceptable level of safety for the transportation of infectious substances and to facilitate domestic and international transportation.

DATES: *Comments.* Submit comments by April 23, 2001. To the extent possible, we will consider comments received after this date in making our decision on a final rule.

ADDRESSES: Submit comments to the Dockets Management System, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001. Comments should identify Docket Number RSPA–98–3971 (HM–226) and be submitted in two copies. If you wish to receive confirmation of receipt of your written comments, include a self-addressed, stamped postcard. You may also submit comments by e-mail by accessing the Dockets Management System web site at "http://dms.dot.gov/" and following the instructions for submitting a document electronically.

The Dockets Management System is located on the Plaza level of the Nassif Building at the Department of Transportation at the above address. You can review public dockets there between the hours of 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. You can also review comments on-line at the DOT Dockets Management System web site at "http://dms.dot.gov/."

FOR FURTHER INFORMATION CONTACT: Eileen Edmonson or Susan Gorsky (202) 366–8553, Office of Hazardous Materials Standards, Research and Special Programs Administration.

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I. Background

On September 2, 1998, the Research and Special Programs Administration (RSPA, we) published an advance notice of proposed rulemaking (ANPRM) on revisions to the current requirements in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180) applicable to the transportation of infectious substances, Division 6.2, including regulated medical waste (63 FR 46844). We asked a variety of questions concerning classification criteria, hazard communication, and packaging requirements for infectious substances consistent with international standards; revisions to the current exceptions in the HMR for diagnostic specimens and biological products; and additional packaging requirements for regulated medical waste (RMW).

In addition, we conducted an electronic public meeting on the Internet from September 14–16, 1998, to facilitate public comment on the issues discussed in the ANPRM. For the Internet meeting, we posted the questions listed in the ANPRM and additional questions to encourage commenters to provide specific quantitative information relative to the transportation of infectious substances.

We received 89 comments in response to the ANPRM and the Internet meeting. Several commenters submitted more than one response. Most comments came from industry associations, colleges and universities, laboratories, and medical waste transporters. Comments were also submitted by state veterinary laboratories, state departments of agriculture, health insurance companies, a blood supplier, equipment suppliers, private citizens, a fire department, a union, and the U.S. Department of Agriculture.

II. Need for New Regulations

Many commenters question the need for increased regulation of infectious substances. They cite their experience with transporting these materials to support their view that there is little or no safety risk associated with such transportation and, thus, no justification for the changes proposed in the ANPRM. Commenters further assert that the proposed packaging and hazard communication requirements will impose significant transportation costs that are not justified by the safety risks involved with shipping infectious substances.

We do not agree that there is little risk associated with the transportation of infectious substances. RSPA's Hazardous Materials Information System (HMIS) includes reports of carriers discovering leaking, unlabeled packages containing blood and other potentially infectious material and of packages containing infectious materials being damaged in handling and releasing their contents. The Centers for Disease Control receives about 400 reports each year from carriers who detect leakage or other damage to packages of infectious substances. Releases of infectious substances in transportation present the possibility of exposure for transportation workers and the general public and can result in costly shipping delays and clean-up efforts.

Further, as a result of a provision in the accident reporting requirements in the HMR and the wording of the INFECTIOUS SUBSTANCE label, many releases of infectious substances are reported to CDC rather than to RSPA. Although the HMR require incident information reported to CDC also to be reported to RSPA in a written incident report, carriers do not routinely do so. This has resulted in under-reporting of these incidents in RSPA's HMIS data base.

Over the last several years, individuals and companies commenting on infectious substances rulemakings or on their own initiative have reported information concerning infectious substance releases. These reports include blood pouring from roll-offs and freight containers transporting regulated medical waste (RMW), the disposal of HIV-contaminated blood in municipal waste cans, overturned vehicles that have released diagnostic specimens on highways, ruptured packages containing diagnostic specimens being transported by aircraft, releases of treatment-resistant diseases from inadequate packaging, and used sharps that puncture inner packagings.

Because of these reports and our own findings, we believe that the current regulatory requirements applicable to transportation of Division 6.2 materials should be strengthened. Accordingly, in this NPRM, we are proposing the following changes to the HMR:

- Adoption of new classification criteria for infectious substances based on defining criteria developed by the World Health Organization and consistent with standards contained in the United Nations Recommendations on the Transport of Dangerous Goods and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- Revision of current packaging requirements for Division 6.2 materials for consistency with international performance standards.
- Elimination of the current exception from requirements in the HMR for diagnostic specimens to impose certain packaging and hazard communication requirements. Diagnostic specimens transported in dedicated motor vehicles by private or contract carriers would continue to be excepted from most requirements in the HMR.
- Modification of the current exception from requirements in the HMR for biological products, limiting the exception to biological products licensed for use under current regulations of the Food and Drug Administration or U.S. Department of Agriculture.
- New transportation requirements for the transportation of genetically modified micro-organisms consistent with international requirements.
- New bulk packaging options for the transportation of RMW, based on current exemption provisions.
- New hazard communication requirements for shipments of Division 6.2 materials.

III. Summary of Proposals in NPRM

A. Classification Criteria for Infectious Substances

In the ANPRM, we indicated that we are considering revising the classification criteria for infectious substances consistent with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations) and the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). In particular, we said we are considering adopting the risk groups and defining criteria developed by the World Health Organization (WHO) for Division 6.2 materials.

Commenters who support international harmonization of the classification criteria for infectious substances note that the proposal in the ANPRM would facilitate shipment of infectious substances in international commerce and by aircraft. Commenters opposed to the proposal are concerned about the possible misinterpretation and misapplication of the WHO risk group criteria. These commenters believe that the WHO risk group definitions are poorly worded and subject to broad interpretation and, as a result, assigning materials to risk group categories may be difficult or impossible.

As we stated in the ANPRM, the hazards posed by Division 6.2 materials vary greatly depending on the pathogenicity of the organism, the mode and relative ease of transmission, and other factors (63 FR 46845). It should be noted that determining if a material is infectious has always included subjective analysis in the absence of actual testing. Classifying these materials based on the level of risk and applying transportation requirements commensurate with that risk should ensure an adequate level of safety without imposing an undue burden on the regulated community. International harmonization of transportation standards also facilitates foreign trade and helps U.S. companies compete in the global economy. Most passenger and cargo air carriers currently require shipments of Division 6.2 materials to conform to the international standards.

Thus, in this NPRM, we are proposing to define Division 6.2 materials using the WHO risk group criteria. The proposal would require Division 6.2 materials to be assigned to risk groups based on the degree to which they cause injury through disease, with Risk Group 1 presenting the lowest risk and Risk Group 4 presenting the highest risk. Assignment to a risk group would be based on the known medical history of the patient or animal, endemic local conditions, symptoms of the patient or animal, or professional judgement concerning the individual circumstances of the patient or animal. Division 6.2 materials assigned to Risk Group 1 would be excepted from requirements in the HMR.

Commenters to the ANPRM are concerned that updated lists indicating risk group assignments for specific pathogens are difficult to obtain. We are aware of several organizations that maintain such lists. The American Biological Safety Association (ABSA) lists bacteria, fungi, viruses, and parasites according to their assigned risk groups. These lists can be found on-line at the ABSA web site (*http://www.absa.org/*). In addition, the ABSA web site includes links to risk group listings from Canada (in Health Canada's Laboratory Biosafety Guidelines at *http://www.hc-sc.gc.ca/hpb/lcdc/biosafty/docs/index.html)* and to Belguim's Biosafety Server (*http://biosafety.ihe.be/)*, which includes information on European regulation of infectious substances. The ABSA web site also includes information on the regulation of infectious substances in Australia, Brazil, Japan, and New Zealand at *http://biosafety.ihe.be/Menu/BiosWorld.html*. We plan to work with WHO and CDC to assure that updated guidance for determining the risk groups for specific materials is easily available.

B. Packaging Requirements for Infectious Substances

The HMR currently require an infectious substance to be packaged in a triple packaging that includes a water-tight primary receptacle, a water-tight secondary packaging, and an outer packaging. The primary receptacle or secondary packaging must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 95kPa (0.95 bar, 14 psi) and temperatures in the range of − 40 °C to +55 °C (− 40 °F to +131 °F). The triple packaging must be capable of passing the performance tests specified in § 178.609.

In this NPRM, we propose to incorporate several changes to the packaging requirements and performance tests to make them

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consistent with the UN Recommendations and ICAO Technical Instructions. For example, we propose to require manufacturers to mark packagings represented as conforming to the specifications for infectious substances packagings in the HMR consistent with UN marking requirements. In addition, we propose to require manufacturers to retain packaging design qualification records and to retest packagings every 24 months. Further, we propose to replace the current requirement for a water immersion test with a water-spray test that simulates exposure to rainfall, as required by the ICAO Technical Instructions. Similarly, we propose to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions to allow variations in the primary receptacles within the secondary packaging without further testing of the completed package if an equivalent level of performance is maintained.

C. Exceptions for Domestic Shipments of Infectious Substances

In the September 1998 ANPRM, we noted that we are considering several exceptions from HMR requirements for domestic shipments of infectious substances by motor carrier. For example, the HMR include exceptions from most requirements of the HMR for hazardous materials transported as materials of trade. Materials of trade include hazardous materials carried by private motor carriers engaged in a principal business other than transportation, such as lawn care, plumbing, welding, and door-to-door sale of consumer goods. The materials of trade exception limits the maximum gross weight of materials of trade that may be carried on a motor vehicle and includes minimum packaging and hazard communication requirements.

In the ANPRM, we invited comments on expanding the materials of trade exception to permit certain biological products, diagnostic specimens, and RMW to be transported by private carriage as materials of trade. Commenters opposed to a materials of trade exception for infectious substances assert that such an exception would not provide an adequate level of safety for transporting infectious materials. Commenters who support a materials of trade exception note that it would reduce potential transportation costs, particularly if we remove the current exceptions in the HMR for diagnostic specimens and biological products.

In this NPRM, we are proposing to expand the materials of trade exceptions currently permitted under § 173.6 of the HMR to include certain biological products, diagnostic specimens, and RMW, including cultures and stocks. As proposed, this exception does not apply to materials known to contain or suspected of containing infectious substances in Risk Group 4.

The proposed exception specifies that the material must be contained in combination packagings consisting of one or more inner packagings inside an outer packaging. The capacity of each inner packaging may not exceed 0.5 kg (1.1 pound) or 0.5 L (17 ounces), and the capacity of the outer packaging may not exceed 4 kg (8.8 pounds) or 4 L (1 gallon). The proposed exception also permits combination packagings consisting of a single inner packaging with a capacity that does not exceed 16 kg (35.2 pounds) or 16 L (4.2 gallons) contained inside a single outer packaging. For RMW in combination packagings, each inner packaging may not exceed 4 kg (8.8 pounds) or 4 L (1 gallon) and the outer packaging may not exceed 16 kg (35.2 pounds) or 16 L (4.2 gallons). Under this proposal, infectious substances transported as materials of trade are subject to the general packaging, hazard communication, and motor vehicle operator notification requirements currently specified in § 173.6. The proposed materials of trade exception would apply to entities such as home health care providers and diagnostic laboratories that transport smaller amounts of infectious substances. We believe that the increased knowledge of the personnel handling these materials, most of whom are trained in the requirements of the Occupational Safety and Health Administration's (OSHA) Universal Precaution regulations for handling potentially contaminated material, will substantially reduce the risks associated with their transportation. In addition, the exception imposes minimum packaging requirements, at minimal cost, for materials currently excepted from the HMR.

D. Diagnostic Specimens

In the ANPRM, we proposed removing the existing broad exception from the HMR for diagnostic specimens and creating a regulatory system based on the WHO risk group definitions that requires diagnostic specimens to be packaged, described, and transported in a manner consistent with their level of risk. We proposed retaining the broad exception from the HMR for diagnostic specimens assigned to Risk Group 1 only. Further, we proposed exceptions to distinguish between a diagnostic specimen known or suspected to contain an infectious substance and one sent for routine testing.

The majority of comments we received in response to the ANPRM address the proposed regulations for diagnostic specimens. Most commenters oppose increased regulation for diagnostic specimens, suggesting that the proposed regulations are not justified by the safety record and will be difficult and costly to implement. Commenters further state that the proposed regulations could result in shipment delays, making early detection and treatment of disease difficult. Commenters note that shippers of diagnostic specimens may have little or no knowledge of what pathogens a given specimen may contain, making application of the WHO risk groups to such materials difficult, at best. Finally, commenters state that the proposed regulations could significantly increase health care costs.

Commenters who support regulation of diagnostic specimens note that releases of these materials do occur in transportation. These commenters generally support removal of the current exception from the HMR for diagnostic specimens to ensure packaging quality and to protect transportation workers and the general public from the risk of exposure to potentially infectious materials.

We agree with commenters that diagnostic specimens should be subject to regulation under the HMR. Our HMIS data base includes reports of packages containing these materials that were damaged in transportation, resulting in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. However, we also agree with commenters that the regulatory requirements proposed in the ANRPM could increase transportation costs for shipment of these materials.

Accordingly, in this NPRM, we are proposing regulations applicable to the transportation of diagnostic specimens that are consistent with proposed amendments to the UN Recommendations. We propose a new entry in the Hazardous Materials Table—"Diagnostic Specimen." There is no UN number, hazard warning label, or packing group assignment.

Under this proposal, diagnostic specimens meeting the definition of a Risk Group 4 material are classed and transported as Division 6.2 materials, UN 2814 or UN 2900. All other diagnostic specimens must be packaged in primary receptacles packed inside secondary packaging to preclude breakage, punctures, or leakage, and, for liquids, with sufficient absorbent material to absorb the entire contents of the primary receptacle. The secondary packaging must be secured in outer packagings with suitable cushioning material. For liquids transported by aircraft, either the primary receptacle or the secondary packaging must be capable of withstanding an internal pressure producing a pressure differential of at least 95kPa (0.95 bar, 14 psi). The completed package must be capable of passing a drop test from a height of at least 1.2 meters (3.9 feet). The package must be marked with the words "Diagnostic Specimens." Diagnostic specimens shipped in conformance with these proposed provisions are excepted from other requirements in the HMR, except that diagnostic specimens transported on board aircraft are subject to the incident reporting requirements in §§ 171.15 and 171.16. Under this proposal, offerors and transporters of diagnostic specimens must be informed of the diagnostic specimen packaging requirements.

In addition to the materials of trade exception discussed above, we are also proposing a complete exception from the HMR for diagnostic specimens transported by private or contract motor carriers. Based on comments received in response to the ANPRM, it is our understanding that most diagnostic specimens are shipped from collection sites (e.g., physicians' offices, nursing homes, clinics, etc.) to testing laboratories by private or contract couriers in dedicated vehicles. The couriers are familiar with the materials they transport and trained in the application of the OSHA Universal Precautions for handling materials that may contain infectious substances. Our proposal would require couriers to be informed about the materials they are transporting. This proposed exception will enable the transportation of diagnostic specimens quickly, efficiently, and safely to testing laboratories.

It should be noted that waste diagnostic specimens—that is, diagnostic specimens that meet the proposed definition for RMW in this NPRM—could not be transported under the exceptions proposed in this NPRM for the transportation of diagnostic specimens. Waste diagnostic specimens would lose their identity as diagnostic specimens for purposes of the HMR and would have to be transported in accordance with the HMR requirements applicable to RMW.

Taken together, we believe that these proposals for the transportation of diagnostic specimens are cost-effective, practical, and easy to understand and implement. Most important, these proposals will assure an adequate level of safety.

E. Biological Products

Commenters to the ANPRM generally support its proposals concerning transportation of biological products. Under current provisions, biological products are excepted from the HMR provided they meet Food and Drug Administration (FDA) or U.S. Department of Agriculture (USDA) regulations governing the transfer of biological products. In this NPRM, we propose to limit this exception to biological products that meet the definition of a Risk Group 1 material or are licensed for use under current FDA or USDA regulations. We propose to require unlicensed biological products meeting the definition of a Risk Group 2, 3, or 4 infectious substance to be classed as infectious substances, Division 6.2, and packaged in specification packagings authorized for the transportation of infectious substances.

In addition, we are proposing to add a special provision in § 172.102, consistent with ICAO Technical Instruction Special Provision A81, to except blood and blood products from current quantity limits for shipments by air when the materials are packaged in primary receptacles that do not exceed 500 ml (17 ounces) and contained in outer packagings not exceeding 4 L (1 gallon).

We also propose to except from all HMR requirements blood collected for blood transfusions, blood collected for the preparation of blood products, blood products intended for transplant, and tissues and organs intended for transplant.

It should be noted that waste biological products—that is, biological products that meet the proposed definition for RMW in this NPRM—may not be transported under the exceptions proposed in this NPRM for the transportation of biological products. Waste biological products lose their identity as biological products for purposes of the HMR and, if they contain infectious substances, must be transported in accordance with the HMR requirements applicable to RMW.

F. Genetically Modified Micro-Organisms

The UN Recommendations and the ICAO Technical Instructions treat any genetically modified micro-organism that meets the definition of a Division 6.2 material as an infectious substance. In addition, these international standards class a genetically modified micro-organism that does not meet the definition of a Division 6.2 material, but is capable of altering plants, animals, or microbiological substances in a way not normally the result of natural reproduction, as a Class 9 material. The UN Recommendations also contain a provision that excludes from regulation genetically modified micro-organisms that are authorized and licensed for use by the government of origin, transit, and destination.

In the ANPRM, we invited comment on whether the HMR should incorporate the international transportation standards for genetically modified micro-organisms. Commenters who addressed this issue are concerned that the proposed regulations could interfere with food and animal production. We appreciate their concerns, but we believe that the potential for environmental and property damage as a result of the release of genetically modified micro-organisms in transportation justifies their regulation as Class 9 materials.

Accordingly, in this NPRM, we propose to add "Genetically modified micro-organism" to the Hazardous Materials Table as a Class 9 material. Under this proposal, these materials must be packaged in conformance with the requirements for packaging infectious substances, except that the packagings need not be marked or tested in accordance with Part 178 requirements.

The NPRM proposes two exceptions applicable to the transportation of genetically modified micro-organisms. First, we propose to except genetically modified micro-organisms from all requirements in the HMR if a federal government agency authorizes their final distribution and use. Second, we propose to except genetically modified micro-organisms from HMR requirements when transported in a non-passenger-carrying transport vehicle operated by a private or contract motor carrier. The materials must be packaged to conform to the provisions described above, and the package must be marked with the proper shipping name "Genetically modified micro-organism." Further, our proposal requires couriers to be informed about the materials they are transporting.

G. Regulated Medical Waste

Commenters generally support the proposals outlined in the ANPRM to permit transportation of RMW in non-specification bulk packagings. Currently, bulk packagings for the transportation of RMW are only authorized under the terms of 29 exemptions. For the most part, these

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packagings have demonstrated that they provide an acceptable level of safety in transportation.

To ensure consistency with international regulations and to provide the broadest selection of authorized bulk packagings, we are also proposing to allow the use of "Large Packagings," which are intermediate bulk packagings containing one or more inner packagings consistent with the requirements of the UN Recommendations. A definition for these packagings was proposed in an NPRM issued under Docket HM–215D, published October 23, 2000 (65 FR 63294) and in the International Maritime Dangerous Goods Code and ICAO's Technical Instructions. As proposed under HM–215D, a Large Packaging consists of an outer packaging containing articles or inner packagings and designed for mechanical handling. A Large Packaging has a capacity greater than 400 kg (882 lbs.) or 450 liters (119 gallons), but does not exceed 3 cubic meters in volume.

Accordingly, in this NPRM we propose to authorize Large Packagings and certain non-specification bulk containers for use as outer packagings for the transportation of RMW. Plastic film bags meeting performance and test requirements for impact and tear resistance are authorized as inner packagings for solid RMW. Inner packagings for liquid RMW must be rigid, leak resistant, puncture resistant, break resistant, impervious to moisture, and sealed to prevent leakage.

In addition to the above, we propose to revise the quantity limitations applicable to shipments of RMW on aircraft. Currently, such shipments are forbidden. We propose to revise the quantity limitations for non-bulk shipments of RMW on board aircraft to read "No limit" for consistency with the ICAO Technical Instructions applicable to quantity limitations for RMW on airplanes. We propose to continue to prohibit bulk shipments of RMW on board aircraft.

H. Used Health Care Products

One commenter suggests that the HMR include an exception for used health care products. The commenter states that used health care products potentially contaminated with infectious substances, such as wound care and sanitary products, surgical equipment, diagnostic and blood testing products, and contraceptives used by consumers, medical professionals, and pharmaceutical providers are routinely returned to manufacturers. Used health care products may be returned for assessment of clinical trials, new product development, customer complaints, product investigations for government compliance, service and repair, and competitor trade-ins.

The infectious status of many of these returned used health care products may not be known. An individual consumer may be unaware that he has an infectious disease or may be reluctant to reveal this information, or a patient may be infectious, but not symptomatic. In addition, patient confidentiality requirements prohibit health care providers from communicating a patient's infectious status to others.

Further, in the case of potentially contaminated used health care products, it is the inanimate product that is being shipped, not the infectious agent. While used health care products may be contaminated with human blood or other body fluids or tissues, these substances usually are dried on the health care product. Special conditions necessary to promote or sustain biological integrity are not available prior to or during shipment. If infectious agents are present on used health care products, they are, in the words of the commenter, "unwanted hitchhikers" and are subject to hostile conditions that may inactivate pathogens over time or, at least, do not support their amplification.

The commenter suggests that neither the HMR nor international standards clearly address the shipment of potentially contaminated used health care products. We agree. Thus, in this NPRM we are proposing to except used health care products being returned to the manufacturer from the requirements of the HMR provided the products are shipped in a triple packaging that conforms to certain manufacturing and marking requirements. Under this proposal, the primary and secondary containers must be marked with the OSHA BIOHAZARD symbol and must be constructed of metal or plastic in a manner that assures that they remain intact during transportation. Under this NPRM, offerors and transporters of used health care products potentially contaminated with an infectious substance must be informed about the used health care product packaging requirements.

I. Hazard Communication

In the ANPRM, we stated that we are considering several options with respect to the marking or placarding of bulk packagings and transport vehicles containing infectious substances, including RMW. Some commenters support a requirement for Division 6.2 placards on each vehicle or bulk packaging that contains any quantity of a Risk Group 4 infectious substance because of the extreme risks to emergency responders and the general public associated with the possible release of such material. These commenters also generally support a requirement for placards on all bulk shipments of infectious substances. Commenters who oppose placarding for shipments of infectious substances suggest that such a requirement is unnecessary, noting that there are significant differences in the potential harm that could result from a transportation incident involving infectious substances as compared to one involving flammable, toxic, or explosive materials.

We agree with commenters that communication of a Risk Group 4 hazard to transportation workers and emergency response personnel is important. However, we are concerned that placarding transport vehicles containing Risk Group 4 infectious substances could compromise the security of the shipments. Further, shipments of Risk Group 4 infectious substances are strictly controlled by CDC regulation. Thus, we are not proposing a placarding requirement in this NPRM.

However, we believe bulk packagings and transport vehicles containing RMW should be marked to communicate to emergency response personnel the nature of the material being transported. We are aware that a number of states and local governments have promulgated marking regulations applicable to the transportation of RMW. Many of these state and local regulations include a requirement for vehicles containing shipments of RMW to be identified with a marking similar to the BIOHAZARD symbol prescribed by OSHA regulations for containers of potentially infectious material. State, local, and tribal governments should be aware that the preemption provisions of Federal hazardous materials transportation law (federal hazmat law; 49 U.S.C. 5101 *et seq.*) generally preclude non-federal governments from imposing requirements applicable to hazardous materials transportation if such requirements are not consistent with the HMR. 49 U.S.C. 5125. Thus, in the absence of a waiver of preemption by the Secretary, where state or local requirements conflict with or are inconsistent with the HMR requirements, the HMR control.

Federal hazmat law codifies the "dual compliance" and "obstacle" criteria for preemption of non-federal regulations. As set forth in 49 U.S.C. 5125(a), these criteria provide that, in the absence of a waiver of preemption by the Secretary under 49 U.S.C. 5125(e) or unless it is authorized by another federal law, a requirement of a state, political subdivision of a state, or Indian tribe is explicitly preempted if:

(1) complying with a requirement of the state, political subdivision or Indian tribe and a requirement of Federal hazardous materials transportation law or a regulation issued under the law is not possible; or

(2) the requirement of the state, political subdivision, or Indian tribe, as applied or enforced, is an obstacle to accomplishing and carrying out Federal hazardous materials transportation law or a regulation prescribed under the law.

Federal hazmat law also includes additional preemption provisions on certain "covered subject" areas. The covered subject areas are:

(a) The designation, description, and classification of hazardous material.

(b) The packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(c) The preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(d) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(e) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container represented, marked, certified, or sold as qualified for use in transporting hazardous material. 49 U.S.C. 5125(b).

Marking is a covered subject for purposes of preemption. Thus, unless authorized by another federal law or a waiver of preemption from the Secretary of Transportation, a non-federal marking requirement is preempted when it is not "substantively the same" as federal hazmat law or a regulation issued under it. 49 U.S.C. 5125(b)(1).

In the interest of uniformity, we believe it is essential that state, local, and tribal marking requirements be consistent from jurisdiction to jurisdiction. Thus, in this NPRM, we propose to require bulk packagings containing RMW to be marked with the appropriate UN identification number. We are also proposing to require bulk packagings of RMW to be identified with a BIOHAZARD marking that conforms to OSHA specifications for the BIOHAZARD marking in 29 CFR 1910.1030(g)(1)(i).

In this NPRM, we are also proposing to revise the INFECTIOUS SUBSTANCE label to reflect the new toll-free number to report infectious substances incidents to the CDC. That toll-free number is 1–800–232–0124.

J. Petitions for Rulemaking

The ANPRM requested comments on a petition for rulemaking (P–1350) submitted by the Medical Waste Institute (MWI) requesting relief for transportation of waste cultures and stocks that meet the definition for Division 6.2 materials. Specifically, MWI requests that we revise the HMR to allow contract and private motor carriers to transport discarded cultures and stocks of infectious substances in non-specification packagings if the carriers use dedicated vehicles. Currently, under § 173.134(b)(3), the HMR allow this type of transportation for RMW that does not contain a culture or stock of an infectious substance.

In support of its petition, MWI states that the current packagings required in the HMR for discarded cultures and stocks are not justified because they are expensive and lack a safety record that proves their actual public health and safety benefits. With its petition, MWI includes HMIS and state incident data on infectious substances for the period 1989 through March 1997.

Experience under exemption DOT–E 11588 has demonstrated that Packing Group II packagings transported by a private or contract carrier in dedicated vehicles provide an acceptable level of protection for waste cultures and stocks of infectious substances. Private and contract carriers that transport these materials have an increased level of knowledge about these materials. Moreover, the use of dedicated vehicles limits public exposure and assures that packages are handled by experienced personnel. We also have found that the general packaging requirements in §§ 173.24 and 173.24a, coupled with OSHA's packaging requirements in 29 CFR 1910.1030 for bloodborne pathogens, are adequate for less virulent types of infectious substances. Therefore, in this NPRM, we are proposing to revise § 173.134(b) to permit transportation of waste cultures and stocks of Risk Group 2 or 3 infectious substances in non-specification packagings when transported by private or contract carriers in dedicated vehicles.

IV. Section-by-Section Review

Part 171

Section 171.7

We propose to revise the table of material incorporated by reference to add two new references to test methods developed by the American Society for Testing and Materials. These tests would be required for plastic inner packagings used to transport RMW inside Large Packagings and non-specification bulk packagings.

Section 171.8

We propose to add definitions for "biological product," "cultures and stocks," "diagnostic specimen," "genetically modified micro-organism," "risk group," "sharps," and "toxin." These definitions would refer readers to the definitions in Part 173 of the HMR.

Section 171.14

We propose to allow a two-year transition period for Division 6.2 labels revised as proposed in this NPRM.

Section 171.15

We propose to remove the term "etiologic agents" from paragraphs (a)(3) and (b) and replace it with "infectious substances." In addition, in paragraph (b) we propose to add wording to emphasize that a written report of an incident involving infectious substances must be submitted to RSPA.

Part 172

Section 172.101

For the entry "Regulated medical waste," we propose to remove the letter "D" in column (1). In column (7), we propose to remove the reference to Special Provision A14 and to revise columns (9A) and (9B) to replace "Forbidden" with "No Limit" for quantity limitations on board aircraft. These proposed changes harmonize requirements in the HMR with those in the ICAO Technical Instructions and facilitate the transportation of RMW in non-bulk packagings by aircraft. In addition, column 8C is revised to replace "none" with 197, to indicate that bulk packagings authorized for the transportation of RMW can be found in § 173.197 of the HMR. Finally, we propose to revise Special Provision A13 to prohibit the transportation of bulk packagings of RMW by aircraft.

For the entries "Infectious substances, affecting animals only" and "Infectious substances, affecting humans," we propose to add new special provisions in column (7). Special Provision A81 provides relief from quantity limits for the transport of blood or blood products that contain infectious substances when in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4L (1 gallon) and packaged in accordance with § 173.196. Special Provision A82 provides relief from UN standard packaging for transporting body parts, whole organs, and whole bodies.

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We propose to add a new entry, "Genetically modified micro-organism," to the Table as a Class 9 material consistent with entries in the UN Recommendations, ICAO Technical Instructions, and International Maritime Dangerous Goods Code.

In addition, we propose to add a new entry, "Diagnostic specimen", to the Table as a Division 6.2 material. There is no UN number, hazard warning label, or packing group assignment.

We also propose to add two new entries for "Toxins, liquid, extracted from living sources, n.o.s., UN 3172" and "Toxins, solid, extracted from living sources, n.o.s., UN 3172." For both entries, a "G" in column (1) indicates that the shipping description on shipping papers must include the technical names for the materials. Both entries indicate that the materials are Division 6.1 materials, UN 3172, PG I, II, or III. We propose to add Special Provision 141 to state that toxins that contain infectious substances or are contained in infectious substances must be classed as Division 6.2 materials and assigned to UN 2814 or UN 2900, as appropriate.

Section 172.102

We propose to revise this section by removing Special Provision A14, revising Special Provision A13, and adding Special Provisions 141, A81, and A82, as detailed above.

Section 172.323

We propose to add this section to require bulk packagings containing RMW to be marked with a BIOHAZARD marking conforming to OSHA regulations at 29 CFR 1910.1030.

Section 172.432

We propose to revise the INFECTIOUS SUBSTANCE label to incorporate the new toll-free telephone number (1–800–232–0124) for reporting incidents to the CDC.

Part 173

Section 173.6

We propose to add a materials of trade exception for diagnostic specimens, biological products, and RMW, other than Risk Group 4 materials. The proposed exception includes packaging requirements and quantity limitations.

Section 173.28

We propose to require Division 6.2 packagings to be decontaminated prior to reuse.

Section 173.134

In paragraph (a), we propose to revise the definitions and classification criteria for "infectious substance," "biological product," "diagnostic specimen," and "regulated medical waste" and to add definitions for "cultures and stocks," "risk group," "sharps," and "toxin."

We propose to revise the definition of "infectious substance" for consistency with international standards and to require materials meeting the definition of an infectious substance to be assigned to risk groups based on the degree to which they cause injury through disease. Infectious substances assigned to Risk Group 1 are not subject to regulation under the HMR.

We propose to revise the definition of "biological product" to require biological products known to contain or suspected to contain a pathogen in Risk Groups 2, 3, or 4 to be classed as Division 6.2 materials, unless otherwise excepted.

We propose to define "cultures and stocks" to mean a material that is prepared and maintained for growth and storage and that contains a Risk Group 2, 3, or 4 infectious substance.

We propose to revise the definition of "diagnostic specimen" to require a diagnostic specimen known to contain or suspected to contain a Risk Group 4 pathogen to be classed as a Division 6.2 material. This determination is based on the known medical history and condition of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning the individual circumstances of the patient or animal.

We propose to revise the definition for "regulated medical waste" to indicate that regulated medical waste is a waste or reusable material that contains or is suspected to contain a Risk Group 2 or 3 infectious substance. As proposed in this NPRM, regulated medical waste containing a Risk Group 4 infectious substance must be classed and transported as a Division 6.2 material, UN 2900 or UN 2814.

We propose to define "risk group" to mean a ranking of a micro-organism's ability to cause injury through disease. Risk group assignment criteria include the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of effective preventive agents and treatments.

We propose to define "sharps" to mean any object that may be contaminated with an infectious substance that is also able to cut or penetrate the skin or packaging material. The term includes needles, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

We propose to define "toxin" to mean a Division 6.1 material secreted from a plant, animal, or bacterial source. The proposed definition notes that toxins that contain an infectious substance or are contained in an infectious substance must be classed as Division 6.2 materials.

In paragraph (b), we propose to list exceptions from the HMR requirements applicable to Division 6.2 materials. Proposed exceptions include:

1. Biological products licensed/approved for public dissemination by FDA or USDA;
2. Blood collected for transfusions or the preparation of blood products, and blood products, tissues, and organs intended for transplant;
3. Diagnostic specimens or biological products transported by private or contract motor carriers in dedicated motor vehicles;
4. Material treated so that it no longer contains an infectious substance;
5. Sanitary waste and sewage;
6. Sewage sludge and compost;
7. Animal waste generated in animal husbandry or food production;
8. Corpses and anatomical parts intended for interment, cremation, or research; and
9. Forensic material transported on behalf of the federal government or a state, local government, or tribal government agency.

We also propose to modify the exception for medical waste generated from households to indicate that such medical waste must be transported in accordance with applicable state, local, or tribal government requirements.

In addition, we propose to revise the exception for laundry or medical equipment conforming to OSHA regulations in 29 CFR 1910.1030 to clarify that this exception applies to medical equipment intended for reuse and equipment used for testing. The revised definition further clarifies that the exception does not apply to medical equipment transported for disposal.

In paragraph (c), we propose to modify the exception for RMW transported by contract or private carriers to include waste cultures and stocks that contain Risk Group 2 or 3 infectious substances.

Finally, we propose to add paragraph (d) to clarify that if an item listed in paragraphs (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of the HMR.

Section 173.140

We propose to add new paragraphs (c) and (d) to provide defining criteria and exceptions for genetically modified micro-organisms that do not meet the definition of a Division 6.2 material, but that have the potential to alter animals, plants, or the environment. These materials are assigned to the Class 9 hazard class. Genetically modified micro-organisms that meet the criteria for a Division 6.2 material must be classed as infectious substances. We propose to except genetically modified micro-organisms from HMR requirements if a federal government agency authorizes their final distribution and use. We also propose to except genetically modified micro-organisms from HMR requirements when transported in a non-passenger-carrying transport vehicle operated by a private or contract motor carrier.

Section 173.196

We propose to revise this section for clarity and consistency with the UN Recommendations and ICAO Technical Instructions. These revisions include packaging and overpack marking requirements to ensure the integrity of the packagings during air transport, including circumstances where the refrigerant is dissipated or lost. A new paragraph (d) is added to prescribe non-specification packaging provisions for body parts.

Section 173.197

We propose to revise this section to authorize certain bulk packagings for the transportation of RMW. Paragraph (a) proposes general requirements for both non-bulk and bulk packagings. Proposed paragraph (b) requires non-bulk packagings to conform to the requirements of part 178 at the Packing Group II performance level. Proposed paragraphs (c) and (d) authorize Large Packagings and non-specification bulk containers for the transportation of RMW. These proposed packaging provisions are based on the terms of 29 current exemptions and our own initiative. Proposed paragraph (c) sets forth conditions governing the use of Large Packagings. Proposed paragraph (d) sets forth the conditions governing the use of non-specification wheeled carts and bulk outer packagings. Proposed paragraph (e) specifies the inner packagings authorized for use with bulk outer packagings.

Section 173.199

We propose to add a new § 173.199 to address packaging requirements for diagnostic specimens and used health care products. Diagnostic specimens meeting the definition of a Risk Group 4 material must be classed and transported as infectious substances, UN 2814 or UN 2900. Generally, we propose to permit all other diagnostic specimens to be shipped in triple packagings that are capable of passing a 1.2 meter (3.9 feet) drop test.

We propose to require liquid diagnostic specimens to be packaged in leakproof primary receptacles with a volumetric capacity of not more than 500 ml (17 ounces). For shipments by aircraft, the primary receptacle or secondary packaging must be able to withstand without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi). The secondary packaging must be leakproof and impervious to moisture. The volumetric capacity of the outer packaging may not exceed 4 L (1 gallon).

We propose to require solid diagnostic specimens to be packaged in a siftproof primary receptacle with a capacity of not more than 500 g (1.1 pounds). The secondary packaging must be leakproof. The capacity of the outer packaging may not exceed 4 kg (8.8 pounds).

We propose to permit shipment of used health care products being returned to the manufacturer in triple packagings, in which the primary and secondary containers must be constructed of plastic or metal and must be marked with the OSHA BIOHAZARD symbol. A used health care product that can cut or penetrate skin or packaging material must be transported in a puncture-resistant primary container.

Under this proposal, diagnostic specimens and used health care products shipped in accordance with these provisions are not subject to any other requirements in the HMR, except for minimal training requirements and, for diagnostic specimens, incident reporting for shipments offered for transportation or transported by aircraft.

Section 173.200

We propose to add a new § 173.200 to address packaging requirements for genetically modified micro-organisms. We propose to require genetically modified micro-organisms to be packaged in conformance with § 173.196, except that the packagings need not be marked in accordance with § 178.503 nor tested in accordance with § 178.609. Alternatively, we propose to permit genetically modified micro-organisms to be transported in packagings that meet the specifications in §§ 173.203 or 173.213 at the Packing Group III performance level.

Part 177

Section 177.834

We propose to revise paragraphs (a) and (g) to indicate that packages containing Division 6.2 materials must be properly secured in a transport vehicle.

Section 177.843

We propose to add a new paragraph (d) to require a transport vehicle to be decontaminated prior to reuse if a Division 6.2 material is released from its packaging inside the vehicle.

Part 178

Section 178.503

We propose to add a new paragraph (f) to incorporate package markings for infectious substances packagings consistent with those in the ICAO Technical Instructions and the UN Recommendations.

Section 178.601

We propose to add a sentence to paragraph (c)(1) of this section to include the tests for infectious substance packaging in the definition of design qualification testing. As a result of this proposed change, manufacturers of infectious substances packagings are required to retain design qualification records in accordance with § 178.601(c)(l). In addition, we propose to add a sentence to paragraph (c)(2) to indicate that, for infectious substances packagings, periodic retesting is the performance of tests specified in § 178.609 at the frequency specified in § 178.601(e). Finally, we propose to add a sentence to paragraph (e) to require packagings used to transport infectious substances to pass periodic retests.

Section 178.609

We propose to revise the section heading to remove the wording "(etiologic agents)." We propose to revise paragraph (c) to permit the use of expanded plastics for inner packagings and require the packaging tests to be determined by the most fragile inner packaging. Paragraphs (d)(1)(i), (d)(1)(iii), and (d)(1)(iv) are revised for clarity. We propose to revise paragraph (e) to replace the current water immersion test with a water spray test that simulates exposure to rainfall consistent with the ICAO Technical Instructions. Paragraphs (h)(1) and (h)(2) are revised to clearly indicate that,

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during the penetration test, penetration of the primary receptacle is not acceptable. Current paragraph (i) is deleted. We propose to add new paragraph (i) to incorporate the selective testing provisions in the UN Recommendations and ICAO Technical Instructions. These provisions allow variations in the primary receptacles within the secondary packaging without further testing of the completed packaging if an equivalent level of performance is maintained.

V. Regulations of Other Agencies

In addition to RSPA, several federal agencies have responsibility for regulating infectious substances and genetically modified micro-organisms.

A. Centers for Disease Control and Prevention

The Department of Health and Human Services is authorized to promulgate regulations to prevent the introduction, transmission, and spread of communicable diseases in the United States. CDC has been delegated authority to regulate the interstate shipment of infectious substances. The current CDC regulations are codified at 42 CFR Part 72. The regulations provide requirements for minimum packaging and labeling for diagnostic specimens and biological products, and include a list of select agents for which special labeling and tracking is required.

On October 28, 1999, CDC published an NPRM, proposing to clarify and expand existing requirements for proper packaging and handling of infectious substances (64 FR 58022). The NPRM includes proposals to ensure that all biological materials known or suspected to contain an infectious substance are packaged to minimize the potential for leakage during transit. The proposed regulations are intended to harmonize CDC regulations with those of other federal agencies and with international standards.

B. Occupational Safety and Health Administration

The Department of Labor's Occupational Safety and Health Administration (OSHA) is authorized to assure safe and healthy workplaces by the Occupational Safety and Health Act of 1970 (OSH Act). OSHA regulations governing occupational exposure to bloodborne pathogens in human blood and body fluids, unfixed tissues, organs, cell cultures, and other fluids from humans or animals are codified at 29 CFR Part 1910.1030. The regulations require persons who handle bloodborne pathogens to utilize Universal Precautions as a means of infection control. The Universal Precautions require human blood and body fluids to be treated as if known to be infectious. Among other requirements, the regulations require specimens of blood or other potentially infectious materials to be placed in containers that prevent leakage during collection, handling, processing, storage, or transport. The regulations also require containers of potentially infectious material to be labeled with a BIOHAZARD label.

C. Food and Drug Administration

The Food and Drug Administration (FDA) regulates, licenses, and approves biological and related products to ensure their purity, potency, safety, and efficacy. FDA regulates vaccines, blood derivatives, allergenic extracts, blood components, whole blood, tissues, monoclonal antibodies, biotech derived products, somatic cell and gene therapies, in vitro diagnostics, and medical devices. FDA's regulations are codified at 21 CFR Parts 1–1299.

D. U.S. Department of Agriculture

The U.S. Department of Agriculture's (USDA) Center for Veterinary Biologics assures that pure, safe, potent, and effective veterinary biological products are available for the diagnosis, prevention, and treatment of animal diseases. The program assures that biological products are free of disease-producing agents, develops appropriate standards and procedures for product release, issues licenses and permits, monitors and inspects products and facilities, and controls field tests and the release of veterinary biological products. USDA regulations for veterinary biological products are codified at 9 CFR parts 101–124.

Several USDA agencies regulate and monitor the use of biotechnology for agriculture. The Animal and Plant Health Inspection Service regulates the movement, importation, and field testing of Genetically Engineered Organisms (GEOs) through permitting and notification procedures. The Food Safety Inspection Service has responsibility for the safe use of engineered domestic livestock, poultry, and products derived from them. The Agricultural Research Service conducts in-house research on GEOs. The Cooperative State Research, Education, and Extension Service administers the biotechnology risk assessment program as well as research programs in gene mapping, sequencing and biotechnology applications. USDA regulations applicable to GEOs are at 7 CFR part 340.

E. Actions to Assure Regulatory Consistency

A number of commenters to the ANPRM urged us to work with other federal agencies to assure that regulations applicable to the transportation of infectious substances are compatible. We agree that persons who offer for transportation or transport infectious substances or genetically modified micro-organisms should not be forced to comply with several sets of inconsistent or conflicting regulations imposed by different federal regulatory agencies. We met with CDC to discuss its 1999 NPRM and potential areas of conflict with the HMR and international standards. In addition, we provided CDC, USDA, FDA, and OSHA with copies of our NPRM in advance of publication in the **Federal Register** for their information and comment, and asked specifically for potential areas of conflict between their regulations and the proposals in this NPRM. None of these agencies identified any potentially conflicting regulatory requirements in their informal responses to our request. We encourage commenters to address this issue as well.

VI. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is not a significant regulatory action under Executive Order 12866 and, therefore, was not reviewed by the Office of Management and Budget. This proposed rule is not a significant regulatory action under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034). A preliminary regulatory evaluation that considers various regulatory alternatives is available for review in the public docket.

The costs of these proposed regulations identified in the regulatory evaluation are attributed to the regulation of shipments of diagnostic specimens that include a Risk Group 2, 3 or 4 pathogen. Our tentative estimate of costs is slightly more than $2 million per year.

Because of a lack of reliable information concerning deaths, injuries, property damage, and other costs attributable to incidents involving the release of an infectious substance, we are unable to quantify potential savings that may result from these proposed rules, if adopted as final. Affected parties and other concerned persons are requested to provide comments on costs and/or potential benefits.

Benefits resulting from implementation of the NPRM proposals include the following:

1. *International harmonization:* Harmonization of requirements in the HMR with standards specified in the UN Recommendations, ICAO Technical Instructions, IMDG Code, and TDG will remove current inconsistencies among the regulations, thereby facilitating efficient transportation of infectious substances across national borders. More importantly, harmonized regulations reduce the potential for misunderstanding and confusion and, thus, enhance safety.

2. *Conversion of exemptions to regulations of general applicability:* Conversion of 29 exemptions applicable to the bulk transportation of RMW to regulations of general applicability will result in a slight cost savings to the 29 exemptions holders and 65 parties-to-the-exemption holders. In addition, the industry will be able to take advantage of the added flexibility provided by the increased number of packaging options for transporting RMW.

3. *Modification of current exceptions for diagnostic specimens and biological products:* We believe that potentially infectious diagnostic specimens and biological products should not be transported without regard to packaging and with no communication of hazard to those who may come into contact with them. The HMIS data base and anecdotal information indicate that packages of these currently excepted materials are sometimes damaged during transportation, resulting in delays and possible risk to cargo handlers, flight crews, emergency responders, and the general public. The proposed requirements in the NPRM for more stringent packaging for these materials combined with the proposed exceptions for transportation of these materials as materials of trade or by private or contract carriers in dedicated vehicles will assure swift and efficient transportation while reducing the risks to transportation workers and the general public. Enhancements to packaging would also reduce the risk of exposure for laboratory workers opening and handling packages at the point of receipt. The minimal level of regulation proposed for these materials would enhance overall safety while imposing insignificant costs on the regulated industry.

4. *New requirements for genetically modified micro-organisms:* We believe that genetically modified micro-organisms that have not been approved for distribution should not be transported without regard to packaging and communication of hazard. Thus, we are proposing new packaging and hazard communication requirements for these currently unregulated materials. The proposal to incorporate into the HMR international standards applicable to genetically modified micro-organisms will enhance transportation safety and reduce potential adverse environmental impacts while imposing minimal requirements on the regulated industry.

Although we cannot assign definitive dollar amounts to these potential benefits, we believe that, taken together, the proposals are the least costly alternatives available for ensuring an acceptable level of transportation safety and that the potential benefits to society more than offset the potential costs associated with this proposed rule.

B. Executive Order 13132

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). This proposed rule would preempt state, local, and Indian tribe requirements but does not propose any regulation that has substantial direct effects on the states, the relationship between the national government and the states, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazardous materials transportation law, 49 U.S.C. 5101–5127, contains an express preemption provision (49 U.S.C. 5125(b)) that preempts state, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This proposed rule addresses covered subject items 1–5 above and would preempt state, local, and Indian tribe requirements not meeting the "substantively the same" standard. This proposed rule is necessary to assure an acceptable level of safety for the transportation of infectious substances and facilitate international transportation of these materials.

Federal hazardous materials transportation law provides at section 5125(b)(2) that, if DOT issues a regulation concerning any of the covered subjects, DOT must determine and publish in the **Federal Register** the effective date of federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. We propose that the effective date of federal preemption be one year from publication of a final rule in the **Federal Register**.

C. Executive Order 13084

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 ("Consultation and Coordination with Indian Tribal Governments"). Because this proposed rule does not significantly or uniquely affect the communities of the Indian tribal governments and does not impose substantial direct compliance costs, the funding and consultation requirements of Executive Order 13084 do not apply.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. Based on the assessment in the preliminary regulatory evaluation, I hereby certify that while the proposed rule would apply to a substantial number of small entities, there would not be a significant economic impact on those small businesses. This certification is based upon a consideration that the identified costs are randomly distributed to the more than 441,000 establishments (offices and clinics of doctors of medicine, dentists, doctors of osteopathy, chiropractors, optometrists, podiatrists, and health practitioners; nursing and personal care facilities; hospitals; and medical and dental laboratories) that comprise Standard Industrial Classification (SIC) Major Group 80 (Health Services). The slightly more than $2 million in annual costs attributed to this proposed rule is a mere fraction of the $300 billion in receipts reported by the health services industry. We believe none of those costs will be disproportionately borne by any of the identified groups of small businesses. If your business or organization is a small entity and if adoption of some or all of the proposed

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provisions could have a significant economic impact on your operations, please submit a comment to explain how and to what extent your business or organization could be affected.

E. Paperwork Reduction Act

RSPA has current information collection approvals under OMB No. 2137–0039, Hazardous Materials Incident Reports, which expires March 31, 2002, with 33,811 burden hours and $811,221.66 annual costs; and OMB No. 2137–0557, Approvals for Hazardous Materials, which expires August 31, 2003, with 180,302 burden hours and $413,737.40 annual costs. We believe that this proposed rule may result in an increase in annual burden hours and costs. If these proposals are finalized, the current approvals would be required to be revised and resubmitted to OMB for extension and re-approval.

Section 1320.8(d), Title 5, Code of Federal Regulations requires RSPA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies information collections that we may submit to OMB for extension and re-approval based on the requirements in this proposed rule. We have revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on changes in this proposed rule since the information collection was last approved. We estimate that the total information collection and recordkeeping burden as proposed in this rule would be revised as follows:

OMB No.: 2137–0039.
Total Annual Responses: 22,900.
Total Annual Burden Hours: 34,441.
Total Annual Burden Cost: $825,621.66.

OMB No.: 2137–0557.
Number of Respondents: 3,523.
Total Annual Responses: 3,875.
Total Annual Burden Hours: 18,405.
Total Annual Burden Cost: $415,237.40.

We specifically request comments on the information collection and recordkeeping burdens associated with developing, implementing, and maintaining these requirements for approval under this proposed rule.

Requests for a copy of the information collection should be directed to Deborah Boothe, Office of Hazardous Materials Standards (DHM–10), Research and Special Programs Administration, Room 8102, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone (202) 366–8553.

Written comments should be addressed to the Dockets Unit as identified in the **ADDRESSES** section of this rulemaking. Comments should be received prior to the close of the comment period identified in the **DATES** section of this rulemaking. Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it displays a valid OMB control number. If these proposed requirements are adopted in a final rule, RSPA will submit the revised information collection and recordkeeping requirements to the Office of Management and Budget for approval.

F. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

G. Unfunded Mandates Reform Act

This NPRM imposes no mandates and thus does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995.

H. Environmental Assessment

We find that there are no significant environmental impacts associated with this proposed rule. An environmental assessment has been placed in the public docket for this rulemaking.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 177

Hazardous materials transportation, Motor carriers, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 178

Hazardous materials transportation, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, we propose to amend 49 CFR parts 171, 172, 173, 177, and 178 as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR part 1.

2. In § 171.7, in the table in paragraph (a)(3), two new entries would be added in alphanumeric sequence under the American Society for Testing and Materials, to read as follows:

§ 171.7 Reference material.

(a) * * *

(3) *Table of material incorporated by reference.* * * *

Source and name of material	49 CFR reference
* * * * * * *	
American Society for Testing and Materials	
* * * * * * *	
ASTM D 1709–97 Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method, 1997 Edition	173.197
* * * * * * *	
ASTM D 1922–94A Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method, 1994 edition	173.197
* * * * * * *	

* * * * *

3. Section 171.8 would be amended by adding the following definitions in alphabetical order to read as follows:

§ 171.8 Definition and abbreviations.

* * * * *

Biological product. See § 173.134 of this subchapter.

* * * * *

Cultures and stocks. See § 173.134 of this subchapter.

* * * * *

Diagnostic specimen. See § 173.134 of this subchapter.

* * * * *

Genetically modified micro-organism. See § 173.140 of this subchapter.

* * * * *

Risk group. See § 173.134 of this subchapter.

* * * * *

Sharps. See § 173.134 of this subchapter.

* * * * *

Toxin. See § 173.134 of this subchapter.

* * * * *

4. Section 171.14 would be amended by adding paragraph (f) to read as follows:

§ 171.14 Transitional provisions for implementing certain requirements.

* * * * *

(f) Division 6.2 labels that conform to specifications in § 172.432 of this subchapter in effect on October 1, 2000, may be used until [two years from the effective date of final rule].

§ 171.15 [Amended]

5. In § 171.15, the following changes would be made:

a. Paragraph (a)(3) would be amended by removing the term "(etiologic agents)".

b. Paragraph (b) introductory text would be amended by removing the term "etiologic agents" and in its place adding the term "infectious substances".

c. Paragraph (b) introductory text would be amended by adding the wording "; however, a written report is still required as stated in paragraph (c) of this section" immediately after the number "202–267–2675".

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

6. The authority citation for part 172 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

7. In § 172.101, the following proper shipping names would be added, in alphabetical order, or revised in the Hazardous Materials Table to read as follows:

§ 172.101 Purpose and use of hazardous materials table.

* * * * *

§ 172.101.—HAZARDOUS MATERIALS TABLE

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or division	Identification Numbers	PG	Label codes	Special provisions	(8) Packaging (§ 173.* * *)			(9) Quantity limitations		(10) Vessel stowage	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only	Location	Other
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)	(10A)	(10B)
	[ADD]												
	Diagnostic specimen.	6.2				A82	134	199	None	4L or 4kg	4L or 4kg	A	40
	* * * * * * *												
	Genetically modified micro-organisms.	9	UN3245		9		140	200	None	No Limit	No Limit	A	40
	* * * * * * *												
G	Toxins, liquid, extracted from living sources n.o.s.	6.1	UN3172	I	6.1	141		201	243	1 L	30 L	B	40
				II				202	243	5 L	60 L	B	40
				III			153	203	241	60 L	220 L	A	40
G	Toxins, solid, extracted from living sources n.o.s.	6.1	UN3172	I	6.1	141		211	243	5 kg	50 kg	B	
				II				212	243	25 kg	100kg	B	
				III			153	213	241	100 kg	200kg	A	
	* * * * * * *												
	[REVISE]												
G	Infectious substances, affecting animals *only*.	6.2	UN2900		6.2	A81, A82	134	196	None	50 ml or 50 g	4L or 4kg	B	40
G	Infectious substances, affecting humans.	6.2	UN2814		6.2	A81, A82	134	196	None	50 ml or 50 g	4L or 4kg	B	40
	* * * * * * *												
	Regulated medical waste.	6.2	UN3291	II	6.2	A13	134, 197	197	197	No Limit	No Limit	A	40
	* * * * * * *												

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8. In § 172.102, in paragraph (c)(1), Special provision 141 would be added, and in paragraph (c)(2), Special Provision A13 would be revised, Special provision A14 would be removed, and Special Provisions A81 and A82 would be added in alphanumeric order to read as follows:

§ 172.102 Special provisions.

* * * * *

(c) * * *

(1) * * *

Code/Special Provisions

* * * * *

141 A toxin from a plant, animal or bacterial source that contains an infectious substance, or a toxin that is contained in an infectious substance, must be classed as Division 6.2 and assigned to UN 2814 or UN 2900, as appropriate.

(2) * * *

Code/Special Provisions

* * * * *

A13 Bulk packagings are not authorized for transportation by aircraft.

* * * * *

A81 The quantity limits in columns (9A) and (9B) do not apply to blood or blood products known to contain or suspected of containing an infectious substance when transported in primary receptacles not exceeding 500 ml (17 ounces) and in outer packagings not exceeding 4 L (1 gallon) and packaged in accordance with § 173.196 of this subchapter. A82 The quantity limits in columns (9A) and (9B) do not apply to human or animal body parts, whole organs or whole bodies known to contain or suspected of containing an infectious substance.

* * * * *

9. A new § 172.323 would be added to read as follows:

§ 172.323 Infectious substances.

(a) In addition to any identification number required by this subpart, a bulk packaging containing a regulated medical waste, as defined in § 173.134(a)(5) of this subchapter, must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i)—

(1) On two opposing sides or two ends other than the bottom if the packaging has a capacity of less than 3,785 L (1,000 gallons). The BIOHAZARD marking must measure at least 273 mm (10.8 inches) on each side and must be visible from the direction it faces.

(2) On each end and each side if the packaging has a capacity of 3,785 L (1,000 gallons) or more. The BIOHAZARD marking must measure at least 273 mm (10.8 inches) on each side and must be visible from the direction it faces.

(b) For a bulk packaging contained in or on a transport vehicle or freight container, if the BIOHAZARD marking on the bulk packaging is not visible, the transport vehicle or freight container must be marked as required by paragraph (a) of this section on each side and each end.

10. In § 172.432, the illustration in paragraph (a) would be revised to read as follows:

§ 172.432 INFECTIOUS SUBSTANCE label.

(a) * * *

* * * * *

BILLING CODE 4910-60-P



* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

11. The authority citation for part 173 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127, 44701; 49 CFR 1.45, 1.53.

12. In § 173.6, paragraph (a)(1) introductory text would be revised, paragraph (a)(4) would be redesignated as paragraph (a)(5), and a new paragraph (a)(4) would be added to read as follows:

§ 173.6 Materials of trade exceptions.

* * * * *

(a) * * *

(1) A Class 3, 8, 9, Division 4.1, 5.1, 5.2, 6.1, 6.2, or ORM–D material contained in a packaging having a gross mass or capacity not over—

* * * * *

(4)(i) A Division 6.2 material, other than a Risk Group 4 material, that is a diagnostic specimen, biological product or regulated medical waste. The material must be contained in a combination packaging consisting of—

(A) One or more inner packagings where the gross mass or capacity of each inner packaging does not exceed 0.5 kg (1.1 pound), or 0.5 L (17 ounces), and an outer packaging having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon); or

(B) A single inner packaging with a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons) in a single outer packaging.

(ii) Regulated medical waste may be packaged in a combination packaging consisting of inner packagings having a gross mass or capacity not exceeding 4 kg (8.8 pounds) or 4 L (1 gallon), and an outer packaging having a gross mass or capacity not exceeding 16 kg (35.2 pounds) or 16 L (4.2 gallons).

Packagings intended to contain sharps must be resistant to puncture and leak resistant.

* * * * *

13. Section 173.28 would be amended by adding paragraph (f) to read as follows:

§ 173.28 Reuse, reconditioning and remanufacture of packagings.

* * * * *

(f) A Division 6.2 packaging that is to be reused must be decontaminated prior to reuse by any means that is effective for neutralizing the infectious substance the packaging previously contained. A secondary packaging or outer packaging that conforms to the requirements of § 173.196 or § 173.199 need not be decontaminated prior to reuse if no leakage from the primary receptacle has occurred.

14. Section 173.134 would be revised to read as follows:

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§ 173.134 Class 6, Division 6.2—Definitions and exceptions.

(a) *Definitions and classification criteria.* For the purpose of this subchapter, the following definitions and classification criteria apply:

(1) *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen that has the potential to cause disease when exposure to it occurs. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro-organisms (hybrid or mutant) that cause infectious disease in humans or animals. A Division 6.2 material must be assigned to a risk group in accordance with this paragraph (a). Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgement concerning individual circumstances of the source patient or animal.

(2) *Biological product* means:

(i) A Division 6.2 material that is derived from a living organism that includes, but is not limited to, materials manufactured and distributed in accordance with one of the following provisions:

(A) 9 CFR part 102 (Licenses for Biological Products);

(B) 9 CFR part 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing);

(C) 9 CFR part 104 (Permits for Biological Products);

(D) 21 CFR part 312 (Investigational New Drug Application); or

(E) 21 CFR parts 600 to 680 (Biologics).

(ii) A *biological product* is used for prevention, treatment, or diagnosis of disease in humans or animals, or for developmental, experimental, or investigational purposes related to these uses. This term includes a finished product such as a vaccine or an unfinished product intended for further processing into a finished product; however, it does not include a diagnostic specimen. Biological products known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate, unless otherwise excepted.

(3) *Cultures and stocks* means a material that is prepared and maintained for growth and storage and that contains a Risk Group 2, 3 or 4 infectious substance.

(4) *Diagnostic specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A *diagnostic specimen* is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 micro-organism, in which case it must be assigned to UN 2814 or UN 2900, as appropriate.

(5) *Regulated medical waste* means a waste or reusable material that contains or is suspected of containing an infectious substance in Risk Group 2 or 3 and is generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment or immunization of human beings or animals; or the production or testing of biological products. *Regulated medical waste* containing an infectious substance in Risk Group 4 must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate.

(6) *Risk group* means a ranking of a micro-organism's ability to cause injury through disease. A *risk group* is defined by criteria developed by the World Health Organization (WHO) based on the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a *risk group* and a packing group. The criteria for each *risk group* according to the level of risk are as follows:

RISK GROUP TABLE

Risk group	Pathogen	Risk to individuals	Risk to the community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.	HIGH	HIGH
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	HIGH	LOW
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	MODERATE	LOW
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	NONE OR VERY LOW	NONE OR VERY LOW

(7) *Sharps* means any object that may be contaminated with a pathogen that is also capable of cutting or penetrating skin or a packaging material. The term includes needles, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.

(8) *Toxin* means a Division 6.1 material secreted from a plant, animal, or bacterial source. A *toxin* that contains an infectious substance or a *toxin* that is contained in an infectious substance must be classed as Division 6.2 and described under UN 2814 or UN 2900, as appropriate.

(b) *Exceptions.* The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(1) Biological products that are known to contain or suspected of containing a pathogen in Risk Group 1, or that do not contain a pathogen.

(2) Biological products that have successfully completed all applicable federal approval or licensing requirements, such as those required by the Food and Drug Administration of the Department of Health and Human Services or the U.S. Department of Agriculture.

(3) Blood that has been collected for the purpose of blood transfusion or for the preparation of blood products, and blood products, tissues, or organs intended for use in transplant operations.

(4) A diagnostic specimen or biological product when transported by a private or contract carrier in a motor vehicle used exclusively to transport diagnostic specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure/contamination to the diagnostic specimen. If a diagnostic specimen or biological product meets the definition of regulated medical waste in paragraph (a)(5) of this section, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste.

(5) Laundry or medical equipment that conforms to the regulations of the Occupational Safety and Health Administration of the Department of Labor in 29 CFR 1910.1030. This exception includes medical equipment that is intended for use, cleaning, or refurbishment, such as reusable surgical equipment, or equipment used for testing where the components within which the equipment is contained essentially function as packaging. This exception does not apply to medical equipment that is being transported for disposal.

(6) A material, including waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so that it no longer meets the definition of an infectious substance.

(7) A living person.

(8) Any waste or recyclable material, other than regulated medical waste, including—

(i) Garbage and trash derived from hotels, motels, and households, including but not limited to single and multiple residences;

(ii) Sanitary waste or sewage;

(iii) Sewage sludge or compost;

(iv) Animal waste generated in animal husbandry or food production; or

(v) Medical waste generated from households and transported in accordance with applicable state, local, or tribal requirements.

(9) Corpses, remains, and anatomical parts that are intended for interment, cremation, or medical research at a college, hospital, or laboratory.

(10) Forensic material that is transported on behalf of a U.S. Government, state, local or Indian tribal government agency. The material must be shipped in a packaging conforming to the provisions of § 173.24.

(c) *Exceptions for regulated medical waste.* The following provisions apply to the transportation of regulated medical waste:

(1) A regulated medical waste that is transported by a private or contract carrier is excepted from—

(i) The requirement for an "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking in accordance with 29 CFR 1910.1030; and

(ii) For other than a waste culture or stock of an infectious substance, the specific packaging requirements of this section if packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030.

(2) A waste culture or stock of a Risk Group 2 or 3 infectious substance may be offered for transportation and transported as a regulated medical waste when it is packaged in a rigid non-bulk packaging conforming to the general packaging requirements of §§ 173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030 and transported by a private or contract carrier using a vehicle dedicated to the transportation of regulated medical waste.

(d) If an item listed in paragraph (b) or (c) of this section meets the definition of another hazard class or if it is a hazardous substance, hazardous waste, or marine pollutant, it must be offered for transportation and transported in accordance with applicable requirements of this subchapter.

15. Section 173.140 would be amended by removing "; or" at the end of paragraph (a) and adding a period in its place and by adding paragraphs (c) and (d) to read as follows:

§ 173.140 Class 9-Definitions.

* * * * *

(c) *Genetically modified micro-organism.* A genetically modified micro-organism is a micro-organism that has been purposely altered through genetic engineering in a way that does not occur naturally.

(1) A Class 9 genetically modified micro-organism does not meet the definition of a Division 6.2 material, but has the potential to alter animals, plants or microbiological substances in a way not normally the result of natural reproduction.

(2) A genetically modified micro-organism that also meets the definition for a Division 6.2 material must be classed as a Division 6.2 material.

(3) A live animal that contains, or is contaminated with, a genetically modified micro-organism, including a genetically modified micro-organism that also meets the definition of a Division 6.2 material, must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(4) A genetically modified micro-organism known or suspected to be dangerous to the environment may not be transported by air unless approved by the Associate Administrator for Hazardous Materials Safety.

(d) *Exceptions for genetically modified micro-organisms.* (1) A genetically modified micro-organism that is authorized by a U.S. Government agency for final distribution and use is not subject to requirements of this subchapter.

(2) A genetically modified micro-organism is excepted from all other requirements of this subchapter when transported in a non-passenger carrying transport vehicle operated by a private or contract motor carrier. The material must be packaged in accordance with the provisions in § 173.203 or § 173.213 at the Packing Group III performance level, and marked with the proper shipping name "Genetically modified micro-organism". Each person who offers or transports a genetically modified micro-organism under the provisions of this paragraph (d) must be informed of the requirements of this paragraph (d).

16. Section 173.196 would be revised to read as follows:

§ 173.196 Infectious substances.

(a) *Division 6.2 packaging.* A Division 6.2 packaging must meet the test standards of § 178.609 of this subchapter and must be marked in conformance with § 178.503(f) of this subchapter. Division 6.2 packaging is a triple packaging that consists of the following components:

(1) A watertight primary receptacle.

(2) A watertight secondary packaging. If multiple primary receptacles are placed in a single secondary packaging, they must be wrapped individually to prevent contact between them.

(3) An outer packaging of adequate strength for its capacity, mass and intended use. The outer packaging must

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measure at least 100 mm (3.9 inches) at its smallest overall external dimension.

(4) For a liquid infectious substance, an absorbent material placed between the primary receptacle and the secondary packaging. The absorbent material must be sufficient to absorb the entire contents of all primary receptacles.

(5) An itemized list of contents enclosed between the secondary packaging and the outer packaging.

(6) The primary receptacle or secondary packaging used for infectious substances must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) and temperatures in the range of −40 °C to +55 °C (−40 °F to +131 °F).

(b) *Additional requirements for packaging infectious substances.* Infectious substances must be packaged according to the following requirements depending on the physical state and other characteristics of the material:

(1) *Infectious lyophilized substances.* Primary receptacles must be flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.

(2) *Liquid or solid infectious substances*—(i) *Infectious substances shipped at ambient temperatures or higher.* Authorized primary receptacles are those of glass, metal, or plastic. Positive means of ensuring a leakproof seal, such as heat seal, skirted stopper, or metal crimp seal, must be provided. If screw caps are used, they must be secured by positive means, such as with adhesive tape.

(ii) *Infectious substances shipped refrigerated or frozen (ice, pre-frozen packs, dry ice).* Ice or dry ice must be placed outside the secondary packagings or in an overpack with one or more complete packages marked in accordance with § 178.503 of this subchapter. Interior supports must be provided to secure the secondary packagings in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging must be leakproof. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas and otherwise meet the provisions in § 173.217. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were lost.

(iii) *Infectious substances shipped in liquid nitrogen.* Primary receptacles capable of withstanding very low temperatures must be used. Secondary packaging must withstand very low temperatures and in most cases will need to be fitted over individual primary receptacles. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the liquid nitrogen as well as the temperatures and pressures of air transport to which they could be subjected if refrigeration were to be lost. Refrigerated liquid nitrogen packagings must be metal vacuum insulated vessels or flasks (also called "dry shippers") vented to the atmosphere to prevent any increase in pressure within the packaging. The use of safety relief valves, check valves, frangible discs, or similar devices in the vent lines is prohibited. Fill and discharge openings must be protected against the entry of foreign materials that might cause an increase in the internal pressure. The package orientation markings specified in § 172.312(b) of this subchapter must be marked on the packaging. The packaging must be designed to prevent the release of any refrigerated liquid nitrogen irrespective of the packaging orientation.

(c) Live animals may not be used to transport infectious substances unless such substances cannot be sent by any other means. An animal that contains or is contaminated with an infectious substance must be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety.

(d) Body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows:

(1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or

(2) In packaging that meets the requirements of § 173.197(a).

17. Section 173.197 would be revised to read as follows:

§ 173.197 Regulated medical waste.

(a) *General provisions.* Non-bulk and bulk packagings used for the transportation of regulated medical waste must be rigid containers that meet the provisions of subpart B of this part. The packaging must be puncture-resistant for sharps and sharps with residual fluid as demonstrated by conducting the performance tests in part 178, subpart M, of this subchapter on packagings containing materials representative of the sharps and fluids (such as sterile sharps) that are intended to be transported in the packagings.

(b) *Non-bulk packagings.* Except as otherwise provided in this subchapter, non-bulk packagings for regulated medical waste must conform to the requirements of part 178 of this subchapter at the Packing Group II performance level.

(c) *Large packagings.* Large Packagings constructed, tested, and marked in accordance with the requirements of the UN Recommendations and conforming to other requirements of this paragraph (c) may be used for the transportation of regulated medical waste, provided that the inner packagings conform to the requirements of paragraph (e) of this section. Each Large Packaging must be capable of meeting the vibration test specified in § 178.819 of this subchapter. Each Large Packaging is subject to the periodic design requalification requirements for intermediate bulk containers in § 178.801(e) of this subchapter and to the proof of compliance requirements of § 178.801(j) and record retention requirements of § 178.801(l) of this subchapter. Inner packagings used for liquids must be rigid.

(1) *Authorized packagings.* The following Large Packagings are authorized for the transportation of liquid or solid regulated medical waste:

(i) Metal: 50A, 50B, or 50N.

(ii) Rigid plastic: 50H.

(2) *Additional requirements.* Each Large Packaging used to transport liquid regulated medical waste must contain absorbent material in sufficient quantity and appropriate location to absorb the entire amount of liquid present in the event of an unintentional release of contents. Each Large Packaging intended for the transportation of sharps containers must be puncture resistant and capable of retaining liquids and must meet the performance tests specified for intermediate bulk containers intended for the transportation of liquids in subpart O of part 178 of this subchapter.

(d) *Non-specification bulk packaging.* A wheeled cart (CART) or bulk outer packaging (BOP) is authorized as an outer packaging for the transportation of regulated medical waste in accordance with the provisions of this paragraph (d).

(1) *General requirements.* The following requirements apply to the transportation of regulated medical waste in CARTs or BOPs:

(i) Each CART or BOP must have non-bulk inner packagings that conform to paragraph (e) of this section.

(ii) Each CART or BOP must have interior surfaces that are smooth, non-porous, and free of cracks, crevices, and other defects that could damage inner packagings or impede decontamination operations.

(iii) Except as otherwise provided in this paragraph (d), each CART or BOP must be used exclusively for the transportation of regulated medical waste. Prior to reuse, each CART or BOP must be decontaminated by any means that is effective for neutralizing the infectious substance the packaging previously contained.

(iv) Untreated cultures and stocks of infectious substances that contain Risk Group 4 materials may not be transported in a CART or BOP.

(v) Division 6.1 toxic waste or Class 7 radioactive waste, with the exception of materials that are chemotherapeutic waste, may not be transported in a CART or BOP.

(vi) Division 6.1 or Class 7 chemotherapeutic waste; untreated stocks and cultures of infectious substances that contain Risk Group 2 or 3 pathogenic organisms; unabsorbed liquids; and sharps containers may be transported in a CART or BOP only if packaged in rigid non-bulk packagings that conform to paragraph (a) of this section.

(2) *Wheeled cart (CART).* A CART is authorized as an outer packaging for the transportation of regulated medical waste if it conforms to the following requirements:

(i) Each CART must consist of a solid, one-piece body, mounted on a minimum of four (4) fixed wheels, with a nominal volume that does not exceed 1,655 liters (437 gallons).

(ii) Each CART must be constructed of metal, rigid plastic, or fiberglass with a hinged and gasketed lid that, when closed, prevents leakage during transport.

(iii) Each CART must be capable of meeting the requirements of § 178.603 (drop test), as specified for solids at the Packing Group II performance level.

(iv) Inner packagings must be placed into a CART and restrained in such a manner as to minimize the risk of breakage.

(3) *Bulk outer packaging (BOP).* A BOP is authorized as an outer packaging for regulated medical waste if it conforms to the following requirements:

(i) Each BOP must be constructed of metal or fiberglass and have a capacity of at least 3.5 cubic meters (123.6 cubic feet) and not more than 45 cubic meters (1,590 cubic feet).

(ii) Each BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top that prevents the intrusion of water (e.g., rain or snow).

(iii) Each opening in a BOP must be fitted with a closure that prevents the intrusion of water or the release of any liquid during all loading, unloading, and transportation operations.

(iv) In the upright position, each BOP must be leakproof and able to contain a liquid quantity of at least 300 liters (79.2 gallons) with closures open.

(v) Inner packagings must be placed in a BOP in such a manner as to minimize the risk of breakage. Rigid inner packagings may not be placed in the same BOP with plastic film bag inner packagings unless separated from each other by rigid barriers or dividers that prevent damage to the packagings caused by load shifting during normal conditions of transportation.

(vi) Division 6.1 or Class 7 chemotherapeutic waste, untreated cultures and stocks of infectious substances that contain Risk Group 2 or 3 pathogenic organisms, unabsorbed liquids, and sharps may be transported in a BOP only if separated and secured as provided by paragraph (d)(3)(v) of this section.

(e) *Inner packagings authorized for Large Packagings, CARTs, and BOPs.* Inner packagings must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, CART, or BOP originates at a single location and is delivered to a single location.

(1) *Solids.* A plastic film bag is authorized as an inner packaging for solid regulated medical waste transported in a CART, Large Packaging, or BOP. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent material to absorb and retain all liquid during transportation.

(i) The film bag may not exceed a volume of 175 L (46 gallons). The film bag must be marked and certified by its manufacturer as having passed the tests prescribed for tear resistance in ASTM D 1709–97, *Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method,* 1997 Edition, and for impact resistance in ASTM D 1922–94A, *Standard Test Method for Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method,* 1994 edition. The film bag must meet an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.

(ii) The plastic film bag must be closed with a minimum of entrapped air to prevent leakage in transportation. The bag must be capable of being held in an inverted position with the closed end at the bottom for a period of 5 minutes without leakage.

(iii) When used as an inner packaging for CARTs or BOPs, a plastic film bag may not weigh more than 10 kg (22 lbs.) when filled.

(2) *Liquids.* Liquid regulated medical waste that is transported in a Large Packaging, CART, or BOP must be packaged in a rigid inner packaging that conforms to the requirements of paragraph (a) of this section. Liquid materials are not authorized for transportation in inner packagings larger than 19 L (5 gallons).

(3) *Sharps.* Sharps that are transported in a Large Packaging, CART, or BOP must be packaged in a puncture-resistant inner packaging (sharps container). Each inner packaging may not exceed 38 L (10 gallons) in volume.

18. A new § 173.199 would be added to read as follows:

§ 173.199 Diagnostic specimens and used health care products.

(a) *Diagnostic specimens.* Diagnostic specimens are excepted from other requirements of this subchapter when offered for transportation or transported in accordance with this section. Diagnostic specimens offered for transportation or transported by aircraft under the provisions of this section are subject to the incident reporting requirements in §§ 171.15 and 171.16 of this subchapter. A diagnostic specimen that meets the definition of a hazard class other than Division 6.2 must be offered for transportation or transported in accordance with applicable requirements of this subchapter.

(1) Diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, a secondary packaging, and an outer packaging.

(2) Primary receptacles must be packed in secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured, or leak their contents into the secondary packaging.

(3) Secondary packagings must be secured in outer packagings with suitable cushioning material such that any leakage of the contents will not impair the protective properties of the cushioning material or the outer packaging.

(4) The completed package must be capable of successfully passing the drop test in § 178.603 of this subchapter at a drop height of at least 1.2 meters (3.9 feet). Each package must be clearly and durably marked with the words "Diagnostic Specimen."

(b) *Liquid diagnostic specimens.* Liquid diagnostic specimens must be packaged in conformance with the following provisions:

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(1) The primary receptacle must be leakproof with a volumetric capacity of not more than 500 ml (16.9 ounces).

(2) Absorbent material must be placed between the primary receptacle and secondary packaging. If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them. The absorbent material must be of sufficient quantity to absorb the entire contents of the primary receptacles.

(3) The secondary packaging must be leakproof.

(4) For shipments by aircraft, the primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi).

(5) The outer packaging may not exceed 4 L (1 gallon) capacity.

(c) *Solid diagnostic specimens.* Solid diagnostic specimens must be packaged in a triple packaging, consisting of a primary receptacle, secondary packaging, and outer packaging, that conforms to the following provisions:

(1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds).

(2) If several fragile primary receptacles are placed in a single secondary packaging, they must be individually wrapped or separated so as to prevent contact between them.

(3) The secondary packaging must be siftproof.

(4) The outer packaging may not exceed 4 kg (8.8 pounds) capacity.

(d) *Used health care products.* Used health care products are medical, diagnostic, or research devices and equipment, and personal care products used by consumers, medical professionals, or pharmaceutical providers that may be contaminated with an infectious substance but do not meet the definition of a diagnostic specimen, biological product, or regulated medical waste. Used health care products being returned to the manufacturer are excepted from the requirements of this subchapter when offered for transportation or transported in accordance with this section. For purposes of this section, a health care product is used when it has been removed from its original inner packaging. Used health care products contaminated with or suspected of contamination with a Risk Group 4 infectious substance may not be transported under the provisions of this section.

(1) Each used health care product must be drained of free liquid to the extent practicable and placed in a watertight metal or plastic primary container. The primary container must be designed and constructed in such a manner as to assure that it remains intact under conditions normally incident to transportation. Each primary container used to transport a used health care product that is capable of cutting or penetrating skin or packaging material must be capable of retaining the product without puncture of the packaging under normal conditions of transport. Each primary container must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i).

(2) Each primary container must be placed inside a watertight metal or plastic secondary container. The secondary container must be designed and constructed in such a manner as to assure that it remains intact under conditions normally incident to transportation. The secondary container must be marked with a BIOHAZARD marking that conforms to 29 CFR 1910.1030(g)(1)(i).

(3) The secondary container must be placed inside an outer packaging with sufficient cushioning material to prevent movement between the secondary container and the outer packaging. An itemized list of the contents of the primary container and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outside packaging.

(e) *Training.* Each person who offers or transports a diagnostic specimen or used health care product under the provisions of this section must be informed of the requirements of this section.

19. A new § 173.200 would be added to read as follows:

§ 173.200 Genetically modified micro-organisms.

A genetically modified micro-organism must be packaged as follows:

(a) In accordance with the provisions in § 173.203 or § 173.213 for liquids or solids, respectively, at the Packing Group III performance level; or

(b) In accordance with the provisions of § 173.196(a), except that the completed package is not subject to the test requirements in § 178.609 of this subchapter.

PART 177—CARRIAGE BY PUBLIC HIGHWAY

20. The authority citation for part 177 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

21. In § 177.834, paragraphs (a) and (g) would be revised to read as follows:

§ 177.834 General requirements.

(a) *Packages secured in a vehicle.* Any tank, barrel, drum, cylinder, or other packaging not permanently attached to a motor vehicle that contains any Class 2 (gases), Class 3 (flammable liquid), Division 6.1 (poisonous), Division 6.2 (infectious substance), Class 7 (radioactive), or Class 8 (corrosive) material must be secured against movement within the vehicle on which it is being transported, under conditions normally incident to transportation.

* * * * *

(g) *Prevent relative motion between containers.* Containers of Class 1 (explosive), Class 2 (gases), Class 3 (flammable liquid), Class 4 (flammable solid), Class 5 (oxidizing), Division 6.1 (poisonous), Division 6.2 (infectious substance), or Class 8 (corrosive) materials must be so braced as to prevent motion thereof relative to the vehicle while in transit. Containers having valves or other fittings must be so loaded that there will be the minimum likelihood of damage thereto during transportation.

* * * * *

22. In § 177.843, new paragraph (d) would be added to read as follows:

§ 177.843 Contamination of vehicles.

* * * * *

(d) Each transport vehicle used to transport Division 6.2 materials must be decontaminated prior to reuse if a Division 6.2 material is released from its packaging during transportation. Decontamination may be by any means that is effective for neutralizing the material released.

PART 178—SPECIFICATIONS FOR PACKAGINGS

23. The authority citation for part 178 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

24. In § 178.503, paragraph (f) would be added to read as follows:

§ 178.503 Marking of packagings.

* * * * *

(f) A manufacturer must mark every UN specification package that is represented as manufactured to meet the requirements of § 178.609 for packaging of infectious substances with the marks specified in this section. The markings must be durable, legible, and must be readily visible, as specified in § 178.3(a). An infectious substance packaging that

successfully passes the tests conforming to the UN standard must be marked as follows:

(1) The United Nations symbol as illustrated in paragraph (e) of this section.

(2) The code designating the type of packaging and material of construction according to the identification codes for packagings specified in § 178.502.

(3) The text "CLASS 6.2".

(4) The last two digits of the year of manufacture of the packaging.

(5) The country authorizing the allocation of the mark. The letters "USA" indicate that the packaging is manufactured and marked in the United States in compliance with the provisions of this subchapter.

(6) The name and address or symbol of the manufacturer or the approval agency certifying compliance with subparts L and M of this part. Symbols, if used, must be registered with the Associate Administrator for Hazardous Materials Safety.

(7) For packagings meeting the requirements of § 178.609(i)(3), the letter "U" must be inserted immediately following the marking designating the type of packaging and material required in paragraph (f)(2) of this section.

25. In § 178.601, paragraphs (c)(1), (c)(2), and (e) would be revised to read as follows:

§ 178.601 General requirements.

* * * * *

(c) * * *

(1) *Design qualification testing* is the performance of the tests prescribed in § 178.603, § 178.604, § 178.605, § 178.606, § 178.607, § 178.608, or § 178.609, as applicable, for each new or different packaging, at the start of production of that packaging.

(2) *Periodic retesting* is the performance of the drop, leakproofness, hydrostatic pressure, and stacking tests, as applicable, as prescribed in § 178.603, § 178.604, § 178.605, or § 178.606, respectively, at the frequency specified in paragraph (e) of this section. For infectious substances packagings that are required to meet the requirements of § 178.609, periodic retesting is the performance of the tests specified in § 178.609 at the frequency specified in paragraph (e) of this section.

* * * * *

(e) *Periodic retesting.* The packaging manufacturer must achieve successful test results for the periodic retesting at intervals established by the manufacturer of sufficient frequency to ensure that each packaging produced by the manufacturer is capable of passing the design qualification tests. Changes in retest frequency are subject to the approval of the Associate Administrator for Hazardous Materials Safety. For single or composite packagings, the periodic retests must be conducted at least once every 12 months. For combination packagings, the periodic retests must be conducted at least once every 24 months. For infectious substances packagings, the periodic retests must be conducted at least once every 24 months.

* * * * *

26. In § 178.609, the section heading, paragraph (c) preceding the table, the introductory text of paragraph (d)(1), paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (e), (h)(1), (h)(2), and (i) would be revised to read as follows:

§ 178.609 Test requirements for packagings for infectious substances.

* * * * *

(c) Packagings prepared as for transport must be subjected to the tests in Table I of this paragraph (c), which, for test purposes, categorize packagings according to their material characteristics. For outer packagings, the headings in Table I relate to fiberboard or similar materials whose performance may be rapidly affected by moisture; plastics, which may embrittle at low temperature; and other materials, such as metal, for which performance is not significantly affected by moisture or temperature. Where a primary receptacle and a secondary packaging of an inner packaging are made of different materials, the material of the primary receptacle determines the appropriate test. In instances where a primary receptacle is made of more than one material, the material most likely to be damaged determines the appropriate test.

* * * * *

(d) * * *

(1) Where the samples are in the shape of a box, five must be dropped in sequence:

(i) Flat on the base;

(ii) * * *

(iii) Flat on the longest side;

(iv) Flat on the shortest side; and * * *

* * *

(e) The samples must be subjected to a water spray that simulates exposure to rainfall of approximately 50 mm (2 inches) per hour for at least one hour. They must then be subjected to the test described in paragraph (d) of this section.

* * * * *

(h) * * *

(1) Samples must be placed on a level, hard surface. A cylindrical steel rod with a mass of at least 7 kg (15 pounds), a diameter not exceeding 38 mm (1.5 inches), and, at the impact end edges, a radius not exceeding 6 mm (0.2 inches), must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the impact end of the sample's impact surface. One sample must be placed on its base. A second sample must be placed in an orientation perpendicular to that used for the first. In each instance, the steel rod must be aimed to impact the primary receptacle(s). There must be no leakage from the primary receptacle(s) following each impact.

(2) Samples must be dropped onto the end of a cylindrical steel rod. The rod must be set vertically in a level, hard surface. It must have a diameter of 38 mm (1.5 inches) and a radius not exceeding 6 mm (0.2 inches) at the edges of the upper end. The rod must protrude from the surface a distance at least equal to that between the primary receptacle(s) and the outer surface of the outer packaging with a minimum of 200 mm (7.9 inches). One sample must be dropped in a vertical free fall from a height of 1 m (3 feet), measured from the top of the steel rod. A second sample must be dropped from the same height in an orientation perpendicular to that used for the first. In each instance, the packaging must be oriented so that the steel rod will impact the primary receptacle(s). There must be no leakage from the primary receptacle(s) following each impact.

(i) *Variations.* The following variations in the primary receptacles placed within the secondary packaging are allowed without additional testing of the completed package. An equivalent level of performance must be maintained.

(1) *Variation 1.* Primary receptacles of equivalent or smaller size as compared to the tested primary receptacles may be used provided they meet all of the following conditions:

(i) The primary receptacles are of similar design to the tested primary receptacle (*e.g.*, shape: round, rectangular, etc.).

(ii) The material of construction of the primary receptacle (glass, plastics, metal, etc.) offers resistance to impact and a stacking force equal to or greater than that of the originally tested primary receptacle.

(iii) The primary receptacles have the same or smaller openings and the closure is of similar design (*e.g.*, screw cap, friction lid, etc.).

(iv) Sufficient additional cushioning material is used to fill void spaces and to prevent significant movement of the primary receptacles.

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(v) Primary receptacles are oriented within the intermediate packaging in the same manner as in the tested package.

(2) *Variation 2.* A lesser number of the tested primary receptacles, or of the alternative types of primary receptacles identified in paragraph (i)(1) of this section, may be used provided sufficient cushioning is added to fill the void space(s) and to prevent significant movement of the primary receptacles.

(3) *Variation 3.* Primary receptacles of any type may be placed within a secondary packaging and shipped without testing in the outer packaging provided all of the following conditions are met:

(i) The secondary and outer packaging combination must be successfully tested in accordance with paragraphs (a) through (h) of this section with fragile (*e.g.*, glass) inner receptacles.

(ii) The total combined gross weight of inner receptacles may not exceed one-half the gross weight of inner receptacles used for the drop test in paragraph (d) of this section.

(iii) The thickness of cushioning material between inner receptacles and between inner receptacles and the outside of the secondary packaging may not be reduced below the corresponding thicknesses in the originally tested packaging. If a single inner receptacle was used in the original test, the thickness of cushioning between the inner receptacles must be no less than the thickness of cushioning between the outside of the secondary packaging and the inner receptacle in the original test. When either fewer or smaller inner receptacles are used (as compared to the inner receptacles used in the drop test), sufficient additional cushioning material must be used to fill the void.

(iv) The outer packaging must pass the stacking test in § 178.606 while empty. The total weight of identical packages must be based on the combined mass of inner receptacles used in the drop test in paragraph (d) of this section.

(v) For inner receptacles containing liquids, an adequate quantity of absorbent material must be present to absorb the entire liquid contents of the inner receptacles.

(vi) If the outer packaging is intended to contain inner receptacles for liquids and is not leakproof, or is intended to contain inner receptacles for solids and is not sift proof, a means of containing any liquid or solid contents in the event of leakage must be provided. This can be a leakproof liner, plastic bag, or other equally effective means of containment.

(vii) In addition, the marking required in § 178.503(f) of this subchapter must be followed by the letter "U".

Issued in Washington, D.C., on December 27, 2000, under authority delegated in 49 CFR part 106.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration.

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Part VII

Department of Housing and Urban Development

24 CFR Part 15

Revision of Freedom of Information Act Regulations; Final Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 15

[Docket No. FR–4292–F–02]

RIN 2501–AC51

Revision of Freedom of Information Act Regulations

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule.

SUMMARY: This final rule amends HUD's Freedom of Information Act (FOIA) regulations in their entirety. It implements the statutory requirements of the Electronic Freedom of Information Act (EFOIA) and makes various streamlining and organizational changes to improve the clarity of the regulatory text. Additionally, this rule incorporates a plain language approach to regulatory drafting by adopting a written style that promotes responsive, accessible and understandable written communication. This rule follows the publication of a July 10, 2000 proposed rule and takes into consideration the public comments received on the proposed rule.

DATES: *Effective Date:* February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Marylea W. Byrd, Assistant General Counsel, FOIA Division, Office of the General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500, Room 10248; telephone (202) 708–3866 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

HUD's regulations at 24 CFR part 15 contain the policies and procedures governing public access to HUD records under the Freedom of Information Act (FOIA) (5 U.S.C. 552). Subject to certain statutory exceptions, the FOIA gives persons the right to request and receive a wide range of information from any Federal agency. Congress has amended the FOIA several times since its enactment in 1982. The most recent amendment occurred in 1996 with the enactment of the Electronic Freedom of Information Act (EFOIA) (Public Law 104–231, approved October 2, 1996).

Pursuant to 5 U.S.C. 552(a)(3)(B), EFOIA requires that readily reproducible records be made available in the format requested, including an electronic format, where applicable. EFOIA also requires that agencies make certain information available over "electronic reading rooms" on the Internet (5 U.S.C. 552(a)(2)(E)). Additionally, EFOIA modifies the deadlines and procedures for processing FOIA requests to provide faster processing for some requests and to assist agencies in reducing backlogs and delays. For example, EFOIA permits agencies to implement multitrack FOIA processing systems based on the estimated amount of work or time (or both) involved in processing individual FOIA requests (5 U.S.C. 552(a)(6)(D)).

On July 10, 2000 (65 FR 42578), HUD published a proposed rule implementing the statutory directives contained in the EFOIA. In addition to EFOIA-related changes, HUD proposed to revise 24 CFR part 15 in its entirety to improve the clarity of its FOIA requirements and procedures. These proposed changes included the consolidation of HUD's FOIA regulations into a single subpart of 24 CFR part 15 (currently, the FOIA regulations are located in seven separate subparts) and the clarification of procedures for requesting HUD records under FOIA.

Since it is important that the requirements governing public access to HUD's records be clear and readily understandable, HUD also proposed to rewrite its FOIA requirements using plain language. The preamble to the July 10, 2000 proposed rule provides additional details regarding the proposed amendments to 24 CFR part 15.

II. Significant Differences Between this Final Rule and the July 10, 2000 Proposed Rule

This final rule makes effective the policies and procedures contained in the July 10, 2000 proposed rule and takes into consideration the public comments received on the proposed rule. The major changes made by this final rule in response to public comment are described below. The rationales for these changes are discussed in greater detail in Section III. of this preamble.

(1) *Incorporation of statutory exemptions to FOIA requirements (§ 15.3).* HUD has added a new § 15.3, which contains the nine statutory exemptions to FOIA disclosure authorized under 5 U.S.C. 552(b)(1).

(2) *Clarification of records that are available at HUD's electronic reading room (§ 15.102 (b)).* HUD has modified this paragraph to clarify that, pursuant to EFOIA, only those documents created after November 1, 1996 are maintained on HUD's electronic reading room.

(3) *Address of HUD's electronic reading room (§ 15.103(c)).* HUD has given a more detailed URL for its Internet web site in order to facilitate easier access to the Department's FOIA electronic reading room.

(4) *Estimate of time for HUD to respond under unusual circumstances (§ 15.104(c)).* HUD has clarified that it will provide an estimate of the time needed to respond to a FOIA request in cases where unusual circumstances enable the Department to extend the period for providing a response.

(5) *Determination of effective date for multitrack assignment when a FOIA request is received by the wrong HUD office (§ 15.105 (a)).* HUD has clarified that FOIA requests received by the wrong HUD office will be assigned within their respective tracks according to either the date on which the request was received by the appropriate office or the end of the ten working day period in which the request should have been forwarded to the proper office.

(6) *Assignment of FOIA requests for expedited processing (§ 15.105(b)).* HUD has clarified that a FOIA request may be assigned for expedited processing at the Department's discretion in absence of compelling need pursuant to 5 U.S.C. 552(a)(6)(E)(i).

(7) *FOIA requests misdirected to HUD (§ 15.107).* HUD has clarified that FOIA requests misdirected to HUD are subject to the requirements of 15.104(a).

(8) *FOIA fee schedule (§ 15.110(c)).* HUD has added a section to the FOIA fee schedule to provide that duplication on electronic format such as CD ROM's and diskette will be charged at actual cost.

(9) *Location of FOIA reading rooms (Appendix A).* This final rule codifies the appendix contained in the July 10, 2000 proposed rule. This appendix provides the addresses of FOIA Reading Rooms located in HUD field offices throughout the country and will assist the public in accessing the reading rooms.

III. Discussion of the Public Comments Received on the July 10, 2000 Proposed Rule

The public comment period on the July 10, 2000 proposed rule closed on September 8, 2000. By close of business on this date, HUD had received 3 public comments. Comments were submitted by a housing authority; a joint comment was submitted by a public interest group and an information clearinghouse; and another joint comment was submitted by various legal aid groups. This section of the preamble presents a summary of the significant issues raised by the public comments on the July 10, 2000 proposed rule and HUD's responses to these comments.

Comment: The final rule should retain FOIA statutory exemptions. The July 10, 2000 proposed rule would have removed regulatory language restating the FOIA statutory exemptions. Two commenters recommended that the final rule retain this language. Additionally, one of the commenters suggested that the exemptions, themselves, be rewritten in plain language.

HUD Response. HUD agrees that, for the convenience of readers, the FOIA statutory exemptions listed at 5 U.S.C. 552(b)(1) should be included in the final rule. Accordingly, this rule states the statutory exemptions in a new § 15.3. HUD will not, however, adopt the suggestion that the statutory exemptions be rewritten in plain language since to do so could unintentionally change their legal meaning or application. Thus, the regulatory exemptions language at § 15.3 continues to track the statutory exemptions set forth in FOIA.

Comment: The rule should clarify those records that are available through HUD's web site. One commenter suggested that HUD's proposed rule implied that all hard copy records in its reading rooms are also available through HUD's web site and that a clarification is needed to distinguish which records are available only in the reading room.

HUD Response. HUD agrees that a clarification is needed to reflect EFOIA's requirement that records created on or after a certain date be made available on the Department's website. Accordingly, HUD has revised § 15.102 to make clear that hard copy records are available in HUD's designated reading rooms and records created on or after November 1, 1996 are also available on HUD's website pursuant to the requirements of FOIA at 5 U.S.C. 552(a)(2)(E).

Comment: The rule does not adequately explain the reasons HUD may grant itself an extension of time to respond due to a FOIA request because of unusual circumstances or provide a date by which a response is expected. One commenter wrote that the proposed rule at § 15.104(c) was imprecise because it did not state that HUD would provide the requester with the date on which a response is expected nor with an explanation of the reasons for the delay.

HUD Response. The proposed rule at § 15.104(c) clearly stated the three "unusual circumstances" that constitute grounds under which HUD may grant itself an extension of time in which to respond to a request. This final rule adopts these provisions of the proposed rule. HUD has, however, modified § 15.104(c) to clarify that a specific estimate of time necessary to respond to the request must be provided to the requester.

Comment: The standards regarding multitrack processing are too vague. One commenter wrote that HUD's descriptions of the factors it would use to determine whether to place a request in its "simple" or "complex" track is too vague to permit requesters to know whether a given request would qualify for the fastest track.

HUD response. HUD disagrees with the commenter. This final rule adopts the language of proposed § 15.105(a) establishing the factors that HUD will consider in determining whether to assign a FOIA request to the "simple" or "complex" track. These include an overall assessment of the time and work associated with obtaining the documents requested with specific consideration given to (1) whether the request involves the processing of voluminous documents and (2) whether the request involves responsive documents from three or more organizational units. It is impracticable under any set of standards to determine with certainty the proper classification of a FOIA request until HUD has actually had the opportunity to evaluate the request. Persons submitting a request for documents should therefore, to the best of their ability at the time of submission, categorize their request in light of these factors.

Comment: HUD should establish a third track for processing FOIA requests involving electronic information, particularly those requests involving voluminous documents maintained in an electronic format. One commenter wrote that FOIA requests would be more likely to be assigned to the complex track if the request involved voluminous documents—even in cases where they are maintained in electronic format. Therefore, HUD should establish a third track for the processing of requests for electronically maintained information.

HUD response. A FOIA request will not automatically be assigned to the complex track merely because it involves voluminous records. Similarly, a FOIA request for information existing in electronic format does not necessarily qualify it on its face for assignment to the simple track. Whether a particular request involving voluminous documents maintained in electronic format is assigned to the simple or complex track will be determined according to the same standards applicable to all FOIA requests. For example, pursuant to the EFOIA amendments, reprogramming may be necessary in regard to the search and retrieval of electronic records. Such efforts, depending on their extent and complexity, may necessitate assigning a particular request to the complex track even though the information is maintained in an electronic format.

HUD disagrees that a third processing track for requests involving electronically maintained records should be implemented. The Department's proposed two-tiered processing approach provides the best avenue for delineating between different levels of FOIA requests and further change would not promote the efficient processing of these requests.

Comment: Where requests for classified records are referred to another agency, the processing date should be set as the date the request is received by HUD. One commenter suggested that the proposed rule at § 15.107 be amended to provide that referrals be processed according to the date HUD received the request and that the requester be given notice of the referral.

HUD response. HUD has revised § 15.107 to make clear that the requirements of § 15.104(a) regarding referral of a misdirected request to the appropriate office also apply to § 15.107. The Department will not, however, assert jurisdiction over another agency's processing procedures by mandating that the date HUD receives the misdirected request constitutes the date on which the request is processed by the agency to which it is ultimately referred.

This comment raised an issue concerning how the Department will handle, for processing purposes, the assignment of FOIA requests that have been directed to the wrong office within HUD. Therefore, HUD has revised § 15.105(a) to clarify that where a request has been misdirected within the Department, the date for assigning the request for processing will be the earlier of the date on which (1) the appropriate office received the request or (2) the end of the 10 working day period in which the request should have been referred to the appropriate office under § 15.104(a).

Comment: The rule does not address duplication charges for electronic media based records. HUD received a comment that the FOIA fee schedule did not take into account charges for reproduced electronically based media, such as CD ROMs and diskettes.

HUD response. HUD has revised proposed § 15.110(c) to add a provision specifying that the amount charged for reproduction of electronically based media such as CD ROMs and diskettes will be actual cost.

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Comment: HUD should increase the information accessible on its website. One commenter suggested that HUD should continue to build on its existing information systems and provided examples of additional information that HUD should make available on its website.

HUD response. While this comment does not involve any suggestions for revisions of the Department's proposed FOIA regulation, per se, HUD is continuing to improve upon and expand customer access to information on the Department's website.

Comment: The Internet reference to HUD's reading room is not sufficiently specific. One commenter wrote that the reference to HUD's general website address in § 15.102 is not specific enough to enable the public to readily locate indices and frequently requested materials which the EFOIA requires be maintained online.

HUD response. HUD agrees that a citation in the regulation to HUD's specific web address containing the Department's reading room FOIA bookshelf is preferable. HUD has therefore revised § 15.102(b) to reflect the Department's web address for the online FOIA bookshelf contained in the Department's reading room.

Comment: HUD should insert hypertext links as a part of indices. One commenter suggested that the value of on-line indices would be enhanced if the indices included hypertext links to information and if they also included detailed explanations of the specific HUD office to which requests for various kinds of information should be directed.

HUD response. While this comment does not involve a suggestion for revision of HUD's proposed FOIA regulation, HUD will keep in mind the comment pertaining to the on-line treatment of indices.

Comment: HUD should adopt an expanded definition for "located" in the context of electronic records. One commenter proposed that HUD adopt a definition for "located," which would specify that electronic records should be considered "located" at particular HUD offices if the records are electronically accessible by personnel at those offices, regardless of where the machines on which the records are stored may be located.

HUD response. HUD has determined that a definition for "located" which would define an electronic record as located anywhere that it can be accessed within the agency would be confusing. While electronic records within the agency can be accessed from more than one particular office, HUD still considers it important that the particular office that has jurisdiction of those records be held accountable for their accuracy and maintenance. Therefore, for purposes of the FOIA, HUD declines to broaden the concept that electronic records are "located" anywhere other than within the particular office which has responsibility for those records.

Comment: HUD should provide an exact date for providing records in response to FOIA requests. One commenter advised that HUD should provide an exact date by which information will actually be provided after HUD approves a FOIA request and that records should be provided no later than twenty business days after HUD issues its response.

HUD response. In the majority of FOIA requests, HUD's response either provides the requested records, provides appropriate exemptions for withholding the records, or both. In other instances, usually at the suggestion of the FOIA requester, the Department will offer the requester the opportunity to inspect the documents, as opposed to providing copies. In some instances, HUD will provide status letters which outline the Department's existing backlog and notifies the requester of their place in HUD's first-in, first-served queue of pending requests. In these instances, it is not practical to provide an exact date in which HUD will respond to the request.

Comment: HUD should broaden the definition of compelling need for the purpose of granting expedited processing to additional types of FOIA requests. One commenter proposed that HUD expand the statutory bases of "compelling need," contained in § 15.105(b), to include circumstances involving expiring Section 8 subsidy contracts. The commenter also suggested that the regulation be revised to reflect that HUD is not limited to the statutory bases of compelling need in order to grant expedited processing.

HUD response. The statutory definition of compelling need limits such a finding to circumstances evidencing an imminent threat to life or safety or, in the case of a person primarily engaged in the dissemination of information, a need to inform the public about actual or alleged federal government activity. HUD may, however, assign FOIA requests for expedited processing where appropriate despite the absence of compelling need. Accordingly, HUD has revised the rule to reflect this discretion pursuant to 5 U.S.C. 552(a)(6)(E)(i).

Comment: HUD should withhold information only if there is a need in the public interest to withhold it. One commenter proposed that HUD reintroduce a provision from its present regulation at § 15.21 that the Department would only withhold a requested record if it came within one of FOIA exemptions and there is a need in the public interest to withhold it.

HUD response. HUD follows the FOIA policy guidance set forth by President Clinton and Attorney General Reno in their October 1993 statements and has determined not to promulgate any criteria in its regulations concerning disclosure of information which might be at variance with those statements. While both statements enunciated standards for the treatment and disclosure of records under the FOIA, neither statement contained an explicit requirement that records not be withheld unless, in addition to applicability of FOIA's exemptions, there "is a need in the public interest to withhold [the records]." HUD has therefore determined that the revised rule better conforms with the policy statements of the President and the Attorney General.

Comment: HUD should specifically allow disclosure of certain housing project financial information pursuant to the Multifamily Assisted Housing Reform and Affordability Act of 1997 (MAHRA). One commenter proposed that § 15.109(a) be revised to allow release of information from profit and loss statements of housing projects to HUD residents, tenant organizations, and their representatives in the context of multifamily operations and restructuring activities, citing the Multifamily Assisted Housing Reform and Affordability Act of 1997 (Title V of the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, approved October 27, 1997) (MAHRA).

HUD response. Section 514(f) of MAHRA requires HUD to establish procedures to provide an opportunity for tenants of projects, residents of the neighborhood, the local government, and other affected parties to participate effectively and on a timely basis in restructuring activities of multifamily housing projects. To this end, HUD is working on a proposed rule implementing the statutory directives of MAHRA which will include procedures under which certain information will be made available to tenants and other groups pursuant to MAHRA. Accordingly, HUD has determined that the proposed MAHRA rule is the proper vehicle for dealing with the types of information to be released under MAHRA and the procedures for making that information available.

Comment: HUD should waive fees for certain low income individuals and constituent groups. One commenter proposed that HUD waive fees for certain requesters, including low-income HUD residents and homeowners, tenant organizations, advocates representing low-income residents, homeowners or tenant organizations and HUD funded technical assistance grantees. In the alternative, the commenter suggested that these requesters be included in the existing category for news media and educational and scientific research.

HUD response. HUD's determination of whether a request for a fee waiver or reduction is warranted is governed by whether disclosure of the information is in the public interest because it is (1) likely to contribute significantly to public understanding of the operations or activities of the government and (2) is not primarily in the commercial interest of the requester. In making this determination, HUD follows fee waiver guidance issued by the Department of Justice. HUD does not believe it prudent to provide blanket fee waivers to any particular individuals or groups. Instead, any requester who requests a fee waiver or reduction should justify in light of statutory and regulatory provisions why they qualify for such a waiver or reduction.

Additionally, the FOIA prescribes certain categories of fee requesters and the types of fees which can be assessed to these requesters. The individuals and groups mentioned by the commenter ordinarily would not qualify for a waived or reduced fee assessment as news media or educational and scientific research requesters.

IV. Findings and Certifications

Environmental Impact

This rule is categorically excluded from environmental review under the National Environmental Policy Act (42 U.S.C. 4321). The revision of the FOIA-related provisions of 24 CFR part 15 falls within the exclusion provided by 24 CFR 50.19(c)(1), in that it does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this rule before publication and in so doing certifies that this rule will not have a significant economic impact on a substantial number of small entities because the rule is procedural. Accordingly, the rule would not have any impact on the substantive rights or duties of small entities requesting HUD records under the Freedom of Information Act. Furthermore, the fees charged under this rule are limited by FOIA to direct costs of searching for, reviewing, and duplicating the records processed for requesters and are not economically significant.

Executive Order 13132, Federalism

Executive Order 13132 (entitled "Federalism") prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial direct compliance costs on State and local governments and is not required by statute, or the rule preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on State and local governments or preempt State law within the meaning of the Executive Order.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 24 CFR Part 15

Classified information, Courts, Freedom of information, Government employees, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, HUD amends 24 CFR part 15 as follows:

PART 15—PUBLIC ACCESS TO HUD RECORDS UNDER THE FREEDOM OF INFORMATION ACT AND TESTIMONY AND PRODUCTION OF INFORMATION BY HUD EMPLOYEES

1. Revise the heading of part 15 to read as set forth above.

2. The authority citation for part 15 is revised to read as follows:

Authority: 42 U.S.C. 3535(d).

Subpart A also issued under 5 U.S.C. 552. Section 15.107 also issued under E.O. 12958, 60 FR 19825, 3 CFR Comp., p. 333. Subparts C and D also issued under 5 U.S.C. 301.

3. Revise subpart A to read as follows:

Subpart A—Purpose and Policy

Sec.
§ 15.1 What is the purpose of this part?
§ 15.2 What definitions apply to this part?
§ 15.3 What exemptions are authorized by 5 U.S.C. 552?

§ 15.1 What is the purpose of this part?

(a) *Subpart B of this part.* Subpart B of this part describes the procedures by which HUD makes documents available under the Freedom of Information Act (FOIA) (5 U.S.C. 552). Subpart A of this part applies to all HUD organizational units; however, applicability of subpart A to the Office of the Inspector General is subject to parts 2002 and 2004 of the title.

(b) *Subpart C of this part.* Subpart C of this part describes the procedures HUD follows in responding to subpoenas or demands of courts and other agencies to produce or disclose documents.

(c) *Subpart D of this part.* Subpart D of this part describes the procedures HUD follows concerning the testimony of its employees in legal proceedings.

(d) *Inapplicability of subparts B and C to Office of Inspector General.* Subparts B and C of this part do not apply to employees in the Office of the Inspector General. The procedures that apply to employees in the Office of the Inspector General are described in part 2004 of this title.

§ 15.2 What definitions apply to this part?

The following definitions apply to this part.

(a) *Terms defined in part 5 of this title.* The terms *HUD, Secretary,* and *Organizational unit* are defined in part 5 of this title.

(b) Other terms used in this part. As used in this part:

Business information means commercial or financial information provided to HUD by a submitter that arguably is protected from disclosure under Exemption 4 (42 U.S.C. 552(b)(4)) of FOIA.

Duplication means the process of making a copy of a document necessary to respond to a FOIA request. Such copies can take the form of paper copy, microfilm, audio-visual materials, or machine readable documentation (*e.g.*, magnetic tape or disk), among others.

Educational institution means:

(1) A preschool;

(2) A public or private elementary or secondary school;

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(3) An institution of graduate higher education;

(4) An institution of undergraduate higher education;

(5) An institution of professional education; or

(6) An institution of vocational education, that primarily (or solely) operates a program or programs of scholarly research.

Employee of the Department means a current or former officer or employee of the United States appointed by or subject to the supervision of the Secretary, but does not include an officer or employee covered by part 2004 of this title.

FOIA means the Freedom of Information Act (5 U.S.C. 552).

Legal proceeding includes any proceeding before a court of law or other authority, i.e., administrative board or commission, hearing officer, arbitrator or other body conducting a quasi-judicial or legislative proceeding.

Legal proceeding among private litigants means any legal proceeding in which the United States is not a party.

Legal proceeding in which the United States is a party means any legal proceeding including as a named party the United States, the Department of Housing and Urban Development, or any other Federal executive or administrative agency or department, or any official thereof in his official capacity.

News means information that is about current events or that would be of current interest to the public.

Person means person as defined in 5 U.S.C. 551(2). It includes corporations and organizations as well as individuals.

Review means the process of examining a document located in response to a request to determine whether any portion of it may be withheld, excising portions to be withheld, and otherwise preparing the document for release. Review time includes time HUD spends considering any formal objection to disclosure made by a submitter under § 15.108. Review does not include time spent resolving general legal or policy issues regarding the application of exemptions.

Search includes all time spent looking manually or by automated means for material that is responsive to a request, including page-by-page or line-by-line identification of material within documents.

Submitter means any person or entity who provides business information, directly or indirectly, to HUD. The term includes, but is not limited to, corporations, State governments, and foreign governments.

§ 15.3 What exemptions are authorized by 5 U.S.C. 552?

(a) The classes of records authorized to be exempted from disclosure by 5 U.S.C. 552 are those which concern matters that are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive order;

(2) Related solely to the internal personnel rules and practices of the Department;

(3) Specifically exempted from disclosure by statute;

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the Department;

(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a state, local or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual;

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of the Department in connection with its responsibility for the regulation or supervision of financial institutions; or

(9) Geological and geophysical information and data, including maps, concerning wells.

(b) Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this section.

4. Revise subpart B to read as follows:

Subpart B—FOIA Disclosure of Information

Sec.

15.101 What is HUD's overall policy concerning disclosing identifiable records?
15.102 Where and when may I inspect and copy records that FOIA requires HUD to make regularly available to the public?
15.103 How can I get other records from HUD?
15.104 What are the time periods for HUD to respond to my request for records?
15.105 How will HUD process my request?
15.106 How will HUD respond to my request?
15.107 How does HUD handle requests that involve classified records?
15.108 What are HUD's policies concerning designating confidential commercial or financial information under Exemption 4 of the FOIA and responding to requests for business information?
15.109 How will HUD respond to a request for information from Form HUD–92410 (Statement of Profit and Loss)?
15.110 What fees will HUD charge?
15.111 How do I appeal a denial of my request for records or a fee determination?
15.112 How will HUD respond to my appeal?

§ 15.101 What is HUD's overall policy concerning disclosing identifiable records?

HUD will fully and responsibly disclose its identifiable records and information consistent with competing public interests concerning the national security, personal privacy, agency deliberative process, and obligations of confidentiality as are recognized by FOIA. HUD will make a record available in the form or format requested, if the record is readily reproducible in that format.

§ 15.102 Where and when may I inspect and copy records that FOIA requires HUD to make regularly available to the public?

(a) You may inspect and copy hardcopy records, including indices of the records, that section 552(a)(2) of FOIA requires HUD make available to the public at HUD's reading rooms. HUD has reading rooms in Headquarters in Washington, DC and in each of the Secretary's Representative's offices. These reading rooms are open during the business hours for the HUD office in which they are located.

(b) For records created on or after November 1, 1996, this information is also available to you through HUD's Internet web site at http://www.hud.gov/ogc/bshelf2a.html.

§ 15.103 How can I get other records from HUD?

(a) *Generally.* You may submit a written request for copies of records in person or by mail.

(b) *Records located in a HUD field office.* If you are submitting a request for records located in a HUD field office, you should deliver or mail your request to the FOIA Liaison in the appropriate HUD Field Office.

(c) *Records located in HUD headquarters.* If you are submitting a request for records located in HUD Headquarters, you should deliver or mail your request to the FOIA Division, Office of the General Counsel. You may also use the FOIA electronic request form on HUD's Internet web site at http://www.hud.gov/ogc/foiafree.html.

(d) *What should I include in my FOIA request?* In your FOIA request you should:

(1) Clearly state that you are making a FOIA request. Although Federal agencies are required to process all requests for documents as Freedom of Information Act requests, whether or not specifically designated as FOIA requests, failure to clearly state that you are making a FOIA request could unduly delay the initial handling of your correspondence through HUD's FOIA processing;

(2) Reasonably describe the records you seek. Include information that you may know about the documents you are requesting;

(3) Indicate the form or format in which you would like the record made available;

(4) State your agreement to pay the fee. You may specify a dollar amount above which you want HUD to consult with you before you will agree to pay the fee;

(5) Indicate the fee category that you believe applies to you (see § 15.110);

(6) If you are making a request on behalf of another person for information about that person, include a document signed by that person authorizing you to request the information on his or her behalf; and

(7) If you are requesting expedited processing, your request should set out the facts you believe show that there is a compelling need (see § 15.104(d)) to expedite processing of your request.

§ 15.104 What are the time periods for HUD to respond to my request for records?

(a) *What time limits generally apply?* If you have met the fee requirements of § 15.110, HUD, in general, will respond within 20 working days after the correct office receives your request. If you have sent your request to the wrong office, that office will send it to the correct office within 10 working days and will send you an acknowledgment letter.

(b) *What time limits apply to requests made on behalf of another person?* The time limits described in paragraph (a) of this section also apply to requests you make on behalf of another person for information about that person. However, the time limits will not commence to run until HUD's receipt of the document signed by that person authorizing you to request information on his or her behalf. If you make your request on behalf of another person without including such signed authorization, HUD will inform you of the authorization needed.

(c) *What time limits apply in unusual circumstances?* If you have requested an especially large number of records, the records are not located in the office handling the request, or HUD needs to consult with another government office, HUD will notify you that extra time is required and provide an estimate of that time. If the extra time needed is more than 10 working days beyond the general time limit set out in paragraph (a) of this section, HUD will offer you any opportunity to limit the scope of your request so that HUD may process it within the extra 10 working day period.

(d) *What time limits apply to my request for expedited processing?* If you requested expedited processing, HUD will notify you within 10 working days after it receives your request whether it will grant expediting processing.

§ 15.105 How will HUD process my request?

(a) *Multitracking.* (1) HUD places each request in one of two tracks. HUD places requests in its simple or complex track based on the amount of work and time involved in processing the request. Factors HUD will consider in assigning a request in the simple or complex track will include whether the request involves the processing of voluminous documents and/or whether the request involves responsive documents from three or more organizational units. Within each track, HUD processes requests in the order in which they are received.

(2) For requests that have been sent to the wrong office, HUD will assign the request within each track using the earlier of either:

(i) The date on which the request was referred to the appropriate office; or,

(ii) The end of the 10 working day period in which the request should have been referred to the appropriate office under § 15.104(a).

(b) Expedited processing. HUD may take your request or appeal out of normal order if HUD determines that you have a compelling need for the records or in other cases as determined by the agency. If HUD grants your request for expedited processing, HUD will give your request priority and will process it as soon as practicable. HUD will consider a compelling need to exist if:

(1) Your failure to obtain the requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual or a threatened loss of substantial due process rights; or,

(2) You are primarily engaged in disseminating information and there is an urgency to inform the public concerning actual or alleged Federal Government activity.

§ 15.106 How will HUD respond to my request?

(a) *Who will respond to my request?* (1) The FOIA Division of the Office of General Counsel in HUD Headquarters and the FOIA liaisons in each HUD Field Office are authorized to release copies of any HUD records unless disclosure is clearly not appropriate under FOIA.

(2) The FOIA Division in HUD Headquarters and the FOIA liaisons in each HUD Field Office may deny a request for a record in accordance with the provisions of FOIA and this part.

(b) *What type of a response will I receive?* Within the time limit described in § 15.103, HUD will either:

(1) Agree to give you all the records you requested;

(2) Advise you that HUD will not give you some or all of the records you requested. Any denial or partial denial of a requested record must be concurred in by the FOIA Division in Headquarters, by counsel in the Field Offices, or by counsel in HUD's Departmental Enforcement Center Satellite Offices. In this case, HUD will:

(i) Explain why it has decided not to comply fully with your request, citing specific exemptions where applicable;

(ii) Describe the records denied or, if there are fewer than 21 records denied, list them specifically;

(iii) Estimate the volume of the records denied unless doing so would harm a protected interest; and

(iv) Explain how to appeal that decision, and provide the name and

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address of the HUD official to whom you should submit your appeal.

(3) Tell you that HUD's estimate of the fee is more than you have agreed to pay and ask to confer within 10 days to see if you can reformulate your request so that HUD can meet your request at a fee that is acceptable to you; or

(4) Tell you that you will not receive a response until you have either paid your fee or committed to the amount of fee you will pay, as applicable, and will provide you 10 days to pay, or commit to pay, the fee.

(5) If you requested expedited processing, advise you whether your request is granted or denied and, if your request is denied, advise you of your right to appeal.

(c) *What action may HUD take if I fail to respond?* If you fail to respond within a period specified in this subpart, HUD may consider your request for records withdrawn and may terminate processing of your request.

§ 15.107 How does HUD handle requests that involve classified records?

If your request involves the release of documents that are classified under Executive Order 12958, HUD will refer your request and the pertinent documents to the originating agency for processing according to the requirements of § 15.104(a). HUD may refuse to confirm or deny the existence of the requested information if the originating agency determines that the fact of its existence is itself classified.

§ 15.108 What are HUD's policies concerning designating confidential commercial or financial information under Exemption 4 of the FOIA and responding to requests for business information?

(a) *HUD's general policy concerning business information which may be considered as confidential commercial or financial information.* Except as provided in this section or otherwise required by law, HUD officers and employees may not disclose business information which is considered as confidential commercial or financial information to anyone other than to HUD officers or employees who are properly entitled to the information to perform their official duties.

(b) *How does a submitter make a claim that business information is confidential commercial or financial information?* (1) If you are a submitter, you may request confidential treatment of business information at the time the information is submitted to HUD or within a reasonable time after it is submitted.

(2) To obtain a designation of confidentiality, you must:

(i) Support your request with an authorized statement or a certification giving the facts and the legal justification for your request and stating that the information has not been made public; and

(ii) Clearly designate the information that you consider confidential.

(3) Your designation of confidentiality will expire 10 years after the date the information was submitted to HUD, unless you have provided a reasonable explanation for a later expiration date.

(c) *How will HUD respond to a request for business information?* If the information requested has been designated in good faith by the submitter as information to be protected under 5 U.S.C. 552(b)(4) ("Exemption 4") or if HUD has reason to believe that the information may be protected by Exemption 4, HUD shall:

(1) Unless an exception in paragraph (c)(2) of this section applies, promptly notify the submitter about the request or the administrative appeal and give the submitter 10 working days to submit a written objection to disclosure. HUD will describe the requested business information or will provide copies of all or a portion of the records;

(2) If any of the following circumstances apply, HUD will not notify the submitter:

(i) HUD determines that the information should not be disclosed;

(ii) The information has been published lawfully or has been made available officially to the public;

(3) A law other than FOIA requires HUD to disclose the information;

(4) A HUD regulation requires HUD to disclose the information. The regulation must:

(i) Have been adopted pursuant to notice and public comment; and

(ii) Specify narrow classes of records submitted to HUD that are to be released under the FOIA.

(d) *Notice to requester.* At the same time HUD notifies the submitter, HUD will also notify the requester that the request is subject to the provisions of this section and that the submitter is being afforded an opportunity to object to disclosure of the information.

(e) *Opportunity to object to disclosure.* If the submitter timely objects to disclosure, HUD will consider the submitter's objections, but will not be bound by them. HUD generally will not consider conclusory statements that particular information would be useful to competitors or would impair sales, or other similar statements, sufficient to justify confidential treatment. Information provided by a submitter or its designee may itself be subject to disclosure under the FOIA.

(f) *Notice of intent to disclose.* If after considering the submitter's objections, HUD decides to disclose business information over the objection of a submitter, HUD will send a written notice of intent to disclose to both the submitter and the requester. HUD will send these notices at least 10 working days before the specified disclosure date. The notices will include:

(1) A statement of the reasons why HUD rejected the submitter's disclosure objections;

(2) A description of the business information to be disclosed; and

(3) A disclosure date.

(g) *What other policies apply to a submitter?*

(1) *HUD notice of FOIA lawsuit.* HUD will promptly notify the submitter of any suit to compel HUD to disclose business information.

(2) *Determination of confidentiality.* HUD will not determine the validity of any request for confidentiality until HUD receives a request for disclosure of the information.

(3) *Current mailing address for the submitter.* Each submitter must give HUD a mailing address for receipt of any notices under this section, and must notify HUD of any change of address.

§ 15.109 How will HUD respond to a request for information from Form HUD–92410 (Statement of Profit and Loss)?

(a) *To whom will HUD disclose the information?* HUD will release information from Form HUD–92410 (or a HUD approved substitute form that the mortgagor may have submitted) only to eligible potential purchasers and only during the period specified by HUD for the mortgage sale.

(b) *Under what conditions will HUD release such information?* HUD will release the information only if all of the following three conditions are met:

(1) The information concerns a project that is subject to a HUD-held mortgage which HUD is selling under the authority of sections 207 (k) and (l) of the National Housing Act (12 U.S.C. 1713 (k) and (l)) or section 7(i)(3) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(i)(3)).

(2) The eligible potential purchasers have agreed to:

(i) Keep the information confidential;

(ii) Disclose the information only to potential investors in the mortgage and only for the period specified by HUD for the mortgage sale and to notify those potential purchasers of their obligations under this section;

(iii) Use the information only to evaluate the mortgage in connection with the mortgage sale; and

(iv) To follow disclosure procedures for that sale that have been established by the Secretary.

(3) The potential investors in the mortgage have agreed to keep the information confidential and to use the information only to evaluate the mortgage in connection with their investment decision.

(c) *To whom may potential investors disclose such information?* Potential investors in the mortgage may disclose the information to other entities only if the disclosure is:

(1) Necessary for the investor's evaluation of the mortgage;

(2) Made in accordance with disclosure procedures for the specific sale that have been established by HUD; and

(3) Limited to the period specified by HUD for the mortgage sale.

(d) *What sanctions are available for improper disclosure of such information?* An eligible potential purchaser or a potential investor (who has received the information from a potential purchaser and has been notified by that entity of its obligations under paragraph (b) of this section), who discloses information from Form HUD–92410 in violation of this section, may be subject to sanctions under part 24 of this title.

§ 15.110 What fees will HUD charge?

(a) *How will HUD determine your fee?* HUD will determine your fee based on which category of requester you are in and on the other provisions of this section. With your request, you should submit information to help HUD determine the proper category. If HUD cannot tell from your request, or if HUD has reason to doubt the use to which the records will be put, HUD will ask you to provide additional information before assigning the request to a specific category.

(b) *What are the categories of requesters?* (1) *Commercial use requester.* You are a commercial use requester if you request information for a use or purpose that furthers your commercial, trade, or profit interests or those interests of the person on whose behalf you have made the request. In determining whether your request properly belongs in this category, HUD determines the use to which you will put the documents requested.

(2) *Educational requester.* You are an educational requester if your request is on behalf of an educational institution and you do not seek the records for a commercial use, but to further scholarly research.

(3) *Non-commercial scientific requester.* You are a non-commercial scientific requester if you are not a commercial use requester and your request is on behalf of an organization that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry.

(4) *Representative of the news media requester.* (i) You are a representative of the news media requester if you actively gather news for an entity that is primarily organized and operated to publish or broadcast news to the public.

(ii) Examples of news media entities include television or radio stations broadcasting to the public at large, and publishers of periodicals (but only in those instances when they can qualify as disseminators of news) who make their products available for purchase or subscription by the general public.

(iii) Freelance journalists may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though not actually employed by it. A publication contract would be the clearest proof, but HUD may also look to the past publication record of a requester in making this determination.

(iv) If you are a representative of the news media requester, HUD will not consider you to be a commercial use requester.

(5) *Other requester.* You are considered an "other" requester if you do not fall within the categories of requesters described in this paragraph (b).

(c) *FOIA Fee Schedule.* The following table sets out the Fee Schedule that HUD uses to determine your fee. The rates for professional and clerical search and review includes the salary of the employee performing the work. The duplication cost includes the cost of operating duplicating machinery. The computer run time includes the cost of operating a central processing unit for that portion of the operating time attributable to searching for responsive records, as well as the costs of operator/programmer salary apportionable to the search. HUD's fee schedule does not include overhead expenses such as costs of space and heating or lighting the facility in which the records are stored.

FOIA FEE SCHEDULE

Activity	Rate	Commercial use requester	News media, educational research, or scientific research requester	Other requester
(1) Professional search	$37.00 per hour	Applies	Does not apply	Applies. No charge for first two hours of cumulative search time.
(2) Professional review	$37.00 per hour	Applies	Does not apply	Does not apply.
(3) Clerical search	$16.35 per hour	Applies	Does not apply	Applies. No charge for first two hours of cumulative search time.
(4) Clerical review	$16.35 per hour	Applies	Does not apply	Does not apply.
(5) Programming services	$35.00 per hour	Applies	Does not apply	Applies.
(6) Computer run time (includes only mainframe search time not printing).	The direct cost of conducting the search.	Applies	Does not apply	Applies.
(7) Duplication costs	$0.15 per page	Applies	Applies. No charge for first 100 pages.	Applies. No charge for first 100 pages.
(8) Duplication costs—tape, CD ROM or diskette.	Actual Cost	Applies	Applies	Applies.

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(d) *How does HUD assess review charges?* HUD will assess review charges only for the first time it analyzes the applicability of a specific exemption to a particular record or portion of a record. HUD will not charge for its review at the administrative appeal level of an exemption already applied. If HUD has withheld in full a record or portions of a record under an exemption which is subsequently determined not to apply, HUD will assess charges for its review to determine the applicability of other exemptions not previously considered.

(e) *How does HUD handle multiple requests?* If you, or others acting with you, make multiple requests at or about the same time for the purpose of dividing one request into a series of requests for the purpose of evading the assessment of fees, HUD will aggregate your requests for records. In no case will HUD give you more than the first two hours of search time, or more than the first 100 pages of duplication without charge.

(f) *Unsuccessful searches.* If HUD's search for records is unsuccessful, HUD will still bill you for the search.

(g) *No charge for costs under $25.* HUD will not charge you a fee if the total amount calculated under this section is less than $25.00.

(h) *Reducing fees in the public interest.* If HUD determines that disclosure of the information you seek is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and that you are not seeking the information for your own commercial interests, HUD may waive or reduce the fee.

(i) *When do I pay the fee?* HUD will bill you when it responds to your request. You must pay within thirty-one calendar days. If the fee is more than $250.00 or you have a history of failing to pay FOIA fees in a timely manner, HUD will ask you to remit the estimated amount and any past due charges before sending you the records.

(j) *What happens if I do not pay the fees?* (1) If you do not pay by the thirty-first day after the billing date, HUD will charge interest at the maximum rate allowed under 31 U.S.C. 3717.

(2) If you do not pay the amount due within ninety calendar days of the due date, HUD may notify consumer credit reporting agencies of your delinquency.

(3) If you owe fees for previous FOIA responses, HUD will not respond to further requests unless you pay the amount due.

(k) *Contract services.* HUD will contract with private sector sources to locate, reproduce and disseminate records in response to FOIA requests when that is the most efficient method. When doing so HUD will charge the cost to the requester that the private sector source has charged HUD for performing these tasks. In some instances, these costs may be higher than the charges HUD would ordinarily charge if the processing tasks had been done by the agency itself. In no case will HUD contract out responsibilities which the FOIA provides that HUD alone may discharge, such as determining the applicability of an exemption, or determining whether to waive or reduce fees. HUD will ensure that, when documents that would be responsive to a request are maintained for distribution by agencies operating statutory-based fee schedule programs such as the National Technical Information Service, HUD will inform requesters of the steps necessary to obtain records from those sources. Information provided routinely in the normal course of business will be provided at no charge.

§ 15.111 How do I appeal a denial of my request for records or a fee determination?

(a) *To what address do I submit my appeals?* You must submit your appeal, in writing, to the address specified in HUD's notice responding to your FOIA request (see § 15.106(a)(2)(iv)). If you send your appeal to the wrong HUD office, that office will forward it to the correct office. That office will also notify you that it has so forwarded your appeal and advise you that, for processing purposes, the time of receipt will be when the appropriate office receives your appeal.

(b) *How much time do I have to submit an appeal?* Your written appeal must be postmarked within 30 calendar days of the date of the HUD determination from which you are appealing. If your appeal is transmitted by other than the United States Postal Service (i.e., facsimile, messenger or delivery service) it must be received in the appropriate office by close of business on the 30th calendar day after the date of the HUD determination.

(c) *What information must I provide if I am appealing a denial of request for information?* If you are appealing a denial of your request for information, the appeal must contain the following information:

(1) A copy of your original request;

(2) A copy of the written denial of your request; and

(3) Your statement of the facts and legal arguments supporting disclosure.

(d) *What information must I provide if I am appealing a fee determination?* If you are appealing a fee determination, including a denial of your request for HUD to waive the fee, the appeal must contain the following information:

(1) The address of the office which made the fee determination from which you are appealing;

(2) The fee that office charged;

(3) The fee, if any, you believe should have been charged;

(4) The reasons you believe that your fee should be lower than the fee which the Agency charged or should have been waived; and

(5) A copy of the initial fee determination and copies of any correspondence concerning the fee.

(e) *What information must I provide if I am appealing a denial of expedited processing?* If you are appealing a denial of your request for expedited processing, your appeal must contain the following information:

(1) A copy of your original request;

(2) A copy of the written denial of your request; and

(3) Your statement of the facts and legal arguments supporting expedited processing.

§ 15.112 How will HUD respond to my appeal?

(a) *How much time does HUD have to decide my appeal?* HUD will decide your appeal of a denial of expedited processing within 10 working days after its receipt. For any other type of appeal, HUD will decide your appeal within 20 working days after its receipt. HUD may have an additional 10 working days if unusual circumstances require.

(b) *What action will HUD take if it grants my appeal?*

(1) *Appeal of a denial of request for information.* If you are appealing a decision to deny your request for records, HUD will either:

(i) Give you the records you requested or advise you that the records will be provided by the originating office;

(ii) Give you some of the records you requested while declining to give you other records you requested, tell you why HUD has concluded that the documents were exempt from disclosure under FOIA, and tell you how to obtain judicial review of HUD's decision; or

(iii) Decline to give you the records you requested, tell you why HUD has concluded that the records were exempt from disclosure under FOIA, and tell you how to obtain judicial review of HUD's decision.

(2) *Appeal of a fee determination.* If you are appealing a fee determination, HUD will either:

(i) Waive the fee or charge the fee that you have requested;

(ii) Modify the original fee charged, and explain why it has determined that the modified fee is appropriate; or

(iii) Advise you that the original fee charged was appropriate, and explain why it has determined that the fee is appropriate.

(3) *Appeal of a denial of expedited processing.* If you are appealing a denial of your request for expedited processing, HUD will either:

(i) Agree to expedited processing of your request; or

(ii) Advise you that the decision to deny expedited processing has been affirmed, and tell you how to obtain judicial review of HUD's decision.

Subparts C, D, E, F, G, and J [Removed]

5. Remove subparts C, D, E, F, G, and J.

6. Redesignate subpart H, consisting of §§ 15.71 through 15.74, as subpart C, consisting of §§ 15.201 through 15.204, to read as follows:

Subpart C—Production in Response to Subpoenas or Demands of Courts or Other Authorities

Sec.
15.201 Purpose and scope.
15.202 Production or disclosure prohibited unless approved by the Secretary.
15.203 Procedure in the event of a demand for production or disclosure.
15.204 Procedure in the event of an adverse ruling.

7. In newly designated § 15.201, the undesignated paragraph is redesignated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 15.201 Purpose and scope.

* * * * *

(b) The term "legal proceeding" has the meaning given in § 15.301(b).

§ 15.203 [Amended]

8. In newly designated § 15.203(a), revise the reference to "§ 15.71" to read "§ 15.201".

§ 15.204 [Amended]

9. In newly designated § 15.204, revise the reference to "§ 15.73(b)" to read "§ 15.203(b)".

§§ 15.81 through 15.85 [Redesignated as §§ 15.301 through §§ 15.305]

10. Redesignate subpart I, consisting of §§ 15.81 through 15.85, as subpart D, consisting of §§ 15.301 through 15.305, to read as follows:

Subpart D—Testimony of Employees in Legal Proceedings

Sec.
15.301 Purpose.
15.302 Testimony in proceedings in which the United States is a party.
15.303 Legal proceedings among private litigants; general rule.
15.304 Legal proceedings among private litigants; subpoenas.
15.305 Legal proceedings among private litigants; expert or opinion testimony.

§ 15.304 [Amended]

11. In newly designated § 15.304, revise the reference to "§§ 15.71–15.74" to read "§§ 15.201 through 15.204".

12. Add appendix A to part 15 to read as follows:

Appendix A to Part 15

HUD FOIA Reading Rooms

The Department maintains a reading room in Headquarters, 451 Seventh Street, SW., Washington, DC 20410 and in each of its Secretary's Representative's Offices as follows:

New England, Boston Office—Room 375, Thomas P. O'Neill, Jr. Federal Building, 10 Causeway Street, Boston, Massachusetts 02222–1092. The New England Office oversees jurisdiction for HUD Offices located in Maine, New Hampshire, Vermont, Massachusetts, Connecticut, and Rhode Island.

New York/New Jersey, New York Office—26 Federal Plaza, New York, New York 10278–0068. The New York/New Jersey Office oversees jurisdiction for HUD Offices located in New York and New Jersey.

Mid Atlantic, Philadelphia Office—Liberty Square Building, 105 South 7th Street, Philadelphia, Pennsylvania 19106–3392. The Mid Atlantic Office oversees jurisdiction for HUD Offices located in Pennsylvania, Delaware, Maryland, Virginia, and West Virginia.

Southeast/Caribbean, Atlanta Office—Five Points Plaza Building, 40 Marietta St., Atlanta, Georgia 30303. The Southeast/Caribbean Office oversees jurisdiction for HUD Offices located in Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Florida, and Puerto Rico.

Midwest, Chicago Office—Ralph Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, Illinois 60604–3507. The Midwest Office oversees jurisdiction for HUD Offices located in Illinois, Indiana, Ohio, Michigan, Wisconsin, and Minnesota.

Southwest, Fort Worth Office—Burnett Plaza Building, 801 Cherry Street, Fort Worth, Texas 76102. The Southwest Office oversees jurisdiction for HUD Offices located in Oklahoma, Texas, Arkansas, Louisiana, and New Mexico.

Great Plains, Kansas City Office—Room 200, Gateway Tower II, 400 State Avenue, Kansas City, Kansas 66101–2406. The Great Plains Office oversees jurisdiction for HUD Offices located in Missouri, Iowa, Kansas, and Nebraska.

Rocky Mountain, Denver Office—633 17th Street, Denver, Colorado 80202–3607. The Rocky Mountain Office oversees jurisdiction for HUD Offices located in Colorado, Utah, Wyoming, North Dakota, South Dakota, and Montana.

Pacific/Hawaii, San Francisco Office—Philip Burton Federal Building & U.S. Courthouse, 450 Golden Gate Avenue, PO Box 36003, San Francisco, California 94102–3448. The Pacific/Hawaii Office oversees jurisdiction for HUD Offices located in California, Nevada, Arizona, and Hawaii.

Northwest/Alaska, Seattle Office—Suite 200, Seattle Federal Office Building, 909 First Avenue, Seattle, Washington 98104–1000. The Northwest/Alaska Office oversees jurisdiction for HUD Offices located in Alaska, Washington, Oregon, and Idaho.

Dated: January 9, 2001.

Andrew Cuomo,

Secretary.

[FR Doc. 01–1397 Filed 1–19–01; 8:45 am]

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Part VIII

Environmental Protection Agency

40 CFR Parts 9, 141, and 142
National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[WH–FRL–6934–9]

RIN 2040–AB75

National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (10 µg/L). This regulation will apply to non-transient non-community water systems, which are not presently subject to standards on arsenic in drinking water, and to community water systems.

In addition, EPA is publishing clarifications for monitoring and demonstration of compliance for new systems or sources of drinking water. The Agency is also clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic contaminants. Finally, EPA is recognizing the State-specified time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with drinking water regulations. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

DATES: This rule is effective March 23, 2001, except for the amendments to §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) which are effective January 22, 2004.

The compliance date for requirements related to the clarification for monitoring and compliance under §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) is January 22, 2004. The compliance date for requirements related to the revised arsenic standard under §§ 141.23(i)(4), 141.23(k)(3), 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) is January 23, 2006. For purposes of judicial review, this rule is promulgated as of January 22, 2001.

ADDRESSES: Copies of the public comments received, EPA responses, and all other supporting documents are available for review at the U.S. EPA Water Docket (4101), East Tower B–57, 401 M Street, SW, Washington DC 20460. For an appointment to review the docket, call 202–260–3027 between 9 a.m. and 3:30 p.m. and refer to Docket W–99–16.

FOR FURTHER INFORMATION CONTACT: The Safe Drinking Water Hotline, phone: (800) 426–4791, or (703) 285–1093, e-mail: hotline.sdwa@epa.gov for general information about, and copies of, this document and the proposed rule. For technical inquiries, contact: Jeff Kempic, (202) 260–9567, e-mail: kempic.jeffrey@epa.gov for treatment and costs, and Dr. John B. Bennett, (202) 260–0446, e-mail: bennett.johnb@epa.gov for benefits.

SUPPLEMENTARY INFORMATION:

Regulated Entities

A public water system (PWS), as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or "other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year." A public water system is either a community water system (CWS) or a non-community water system (NCWS). A community water system, as defined in § 141.2, is "a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents." The definition in § 141.2 for a non-transient non-community water system (NTNCWS) is "a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year." EPA has an inventory totaling over 54,000 community water systems and approximately 20,000 non-transient non-community water systems nationwide. Entities potentially regulated by this action are community water systems and non-transient non-community water systems. The following table provides examples of the regulated entities under this rule.

TABLE OF REGULATED ENTITIES

Category	Examples of regulated entities
Industry	Privately owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water.
State, Tribal, and Local Government	State, Tribal, or local government-owned/operated water supply systems using ground water, surface water, or mixed ground and surface water.
Federal Government	Federally owned/operated community water supply systems using ground water, surface water, or mixed ground water and surface water.

The table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in §§ 141.11 and 141.62 of the rule. If you have any questions regarding the applicability of this action to a particular entity, consult the general information contact listed in the section listing contacts for further information.

Abbreviations used in this rule

<—less than
≤—less than or equal to
>—greater than
≥—greater than or equal to
±—plus or minus
§—section
σ—σ, Greek letter, in statistics represents standard deviation
µg—Microgram, one-millionth of a gram (3.5×10^{-8} of an ounce)
µg/L—micrograms per liter
AA—Activated alumina
AIC—Akaike Information Criterion
ACWA—Association of California Water Agencies
AMWA—Association of Metropolitan Water Agencies
APHA—American Public Health Association

ARARs—Applicable or relevant and appropriate requirements
As (III)—Trivalent arsenic. Common inorganic form in water is arsenite
As (V)—Pentavalent arsenic. Common inorganic form in water is arsenate
ASDWA— Association of State Drinking Water Administrators
AsH_3—Arsine
ASTM—American Society for Testing and Materials
ATSDR—Agency for Toxic Substances and Disease Registry, U.S. Department of Health & Human Services
AWWA—American Water Works Association
AWWARF—American Water Works Association Research Foundation
BAT—Best available technology
BV—Bed volume
CCR—Consumer Confidence Report
CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act administered by EPA for hazardous substances
C/F—Modified coagulation/filtration
CFR—Code of Federal Regulations
CSFII—Continuing Survey of Food Intakes by Individuals
CWA—Clean Water Act administered by EPA for surface waters of the U.S.
CWS—Community water system
CWSS—Community Water System Survey
DMA—Dimethyl arsinic acid, cacodylic acid, $(CH_3)_2HAsO_2$
DNA—Deoxyribonucleic acid
DWSRF—Drinking Water State Revolving Fund
EA—Economic analysis
EDR—Electrodialysis reversal
EEAC—Environmental Economics Advisory Committee
e.g.—*exempli gratia*, Latin for "for example"
EPA—U.S. Environmental Protection Agency
et al.—*et alia*, Latin for "and others"
FACA—Federal Advisory Committee Act
FR—Federal Register
FRFA—Final Regulatory Flexibility Analysis
FSIS—Federalism Summary Impact Statement
GDP—Gross Domestic Product
GFAA—Graphite furnace atomic absorption
GHAA—Gaseous hydride atomic absorption
GI—Gastrointestinal
GW—Ground water
GWR—Ground Water Rule
HRRCA—Health Risk Reduction and Cost Analysis
ICP–AES—Inductively coupled plasma-atomic emission spectroscopy
ICP–MS—Inductively coupled plasma mass spectroscopy
ICR—Information collection request
i.e.—*id est*, Latin for "that is"
IOCs—Inorganic contaminants
ISCV—Intra-system coefficient of variation
IX—Ion exchange
L—Liter, also referred to as lower case "l" in older citations
LD_{50}—The dose of a chemical taken by mouth or absorbed by the skin which is expected to cause death in 50% of the test animals
LS—Modified lime softening
LT1/FBR—Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Recycling Rule
MCL—Maximum contaminant level
MCLG—Maximum contaminant level goal
MDL—Method detection limit
mg—Milligrams, one-thousandth of a gram, 1 milligram=1,000 micrograms
mg/kg—Milligrams arsenic per kilogram body weight or soil weight
mg/L—Milligrams per liter
MHI—Mean household income
MMA—Monomethyl arsenic, arsonic acid, $CH_3H_2ASO_3$
NAOS—National Arsenic Occurrence Survey
NAS—National Academy of Sciences
NAWQA—National Ambient Water Quality Assessment, USGS
NCI—National Cancer Institute
NCWS—Non-community water system
NDWAC—National Drinking Water Advisory Council for EPA
NIRS—National Inorganic and Radionuclide Survey done by EPA
NODA—Notice of Data Availability
NOMS—National Organic Monitoring Survey done by EPA
NPDES—National Pollutant Discharge Elimination System for CWA
NPDWR—National primary drinking water regulation
NR—Not reported
NRC—National Research Council, the operating arm of NAS
NTNCWS—Non-transient non-community water system
NTTAA—National Technology Transfer and Advancement Act
NWIS—National Water Information System of USGS
OGWDW—Office of Ground Water and Drinking Water in EPA
OMB—Office of Management and Budget
PE—Performance evaluation, studies to certify laboratories for EPA drinking water testing
pH—Negative log of hydrogen ion concentration
PNR—Public Notification Rule
POE—Point-of-entry treatment devices
POTWs—Publicly owned treatment works, treat wastewater
POU—Point-of-use treatment devices
ppb—Parts per billion
ppm—Parts per million
PQL—Practical quantitation level
PRA—Paperwork Reduction Act
psi—Pounds per square inch
PT—Performance testing
PUC—Public utilities commission
PWS—Public water systems
QALYs—Quality adjusted life years
RCRA—Resource Conservation and Recovery Act
REF—Relative exposure factors
RFA—Regulatory Flexibility Act
RIA—Regulatory Impact Analysis
RO—Reverse osmosis
RUS—Rural Utilities Service
RWS—Rural Water Survey
SAB—Science Advisory Board
SBAR—Small Business Advocacy Review
SBREFA—Small Business Regulatory Enforcement Fairness Act
SD—Standard deviation
SDWA—Safe Drinking Water Act
SDWIS—Safe Drinking Water Information System
SEER—Surveillance, Epidemiology, and End Results
SM—Standard Method for Examination of Water and Wastewater
SMF—Standardized monitoring framework
SMRs—Standardized mortality ratios
SO4—Sulfate
SOCs—Synthetic organic contaminants
STP–GFAA—Stabilized temperature platform graphite furnace atomic absorption
SW—Surface water
TBLLs—Technically based local limits
TC—Toxicity Characteristic, RCRA hazardous waste
TCLP—Toxicity Characteristic Leaching Procedure, tests for hazardous waste
TDS—Total dissolved solids
TMF—Technical, managerial, financial capacity
TOC—Total organic carbon
UMRA—Unfunded Mandates Reform Act
URTH—Unreasonable risk to health
U.S.—United States
USDA—US Department of Agriculture
USGS—US Geological Survey
UV—Ultraviolet
VOCs—Volatile organic contaminants
VSL—Value of statistical life
VSLY—Value of statistical life year
WHO—World Health Organization
WS—Water supply
WTP—Willingness-to-pay

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I. Background and Summary of the Final Rule

A. What Did EPA Propose?

On June 22, 2000, the **Federal Register** published EPA's proposed arsenic regulation for community water systems and non-transient non-community water systems (65 FR 38888; EPA, 2000i). EPA proposed a health-based, non-enforceable goal, or Maximum Contaminant Level Goal (MCLG), of zero micrograms per liter (µg/L) and a Maximum Contaminant Level (MCL) of 5 µg/L. The Agency also requested comment on alternate MCL levels of 3 µg/L, 10 µg/L, and 20 µg/L. (In the proposed rule EPA expressed arsenic concentration in milligrams per liter (mg/L) or parts per million, which matches the units of the former and current standard for arsenic. Except as noted, the Agency will refer to arsenic concentration in micrograms per liter (µg/L) in this preamble.)

EPA based the June 2000 proposal on extensive analysis including a careful consideration of the following issues: a nonzero MCLG; occurrence of arsenic in public water systems; our approach for estimating national occurrence and co-occurrence; acceptance limits used to establish the practical quantitation level (PQL); rounding of measured values for compliance purposes; extending compliance by two years for systems serving under 10,000 people in order to add capital improvements; dates for reporting changes in the consumer confidence reports and public notification; appropriateness of the national affordability criteria; affordable technologies for small systems; implementation issues for point-of-use (POU) and point-of-entry (POE) treatments; appropriateness of non-hazardous residual costing; our overall analysis of costs; adjusting benefits estimates (*e.g.*, for factors such as latency); our approach for considering uncertainties that affected risk; use of the authority to set an MCL at a level other than the feasible MCL; expression of the MCL as total arsenic; approaches to regulation of NTNCWSs; State program revisions; selenium levels as an attenuation factor in arsenic toxicity; impacts on small entities; use of consensus analytical methods; methods to address environmental justice concerns; and comments on use of plain

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language. We asked commenters to submit data and comments on these issues, as well as any other issues raised in the proposal.

The proposal reflected several types of technical evaluations, including analytical methods performance and laboratory capacity; the likelihood of different size water systems choosing treatment technologies based on source water characteristics; and the national occurrence of arsenic in drinking water supplies. Furthermore, the Agency assessed the quantifiable and nonquantifiable costs and health risk reduction benefits likely to occur at the treatment levels considered, and the effects of arsenic on sensitive subpopulations.

The proposed MCL was consistent with the Agency's use of the new benefit/cost provisions of the Safe Drinking Water Act (SDWA), as amended in 1996 (see section II. of this preamble for additional information about this provision). EPA proposed 3 µg/L as the feasible MCL, after considering treatment costs and efficiency under field conditions as well as considering the appropriate analytical methods. Because EPA determined that the benefits of regulating arsenic at the feasible level would not justify the costs, the Agency proposed an MCL of 5 µg/L, while requesting comment on MCL options of 3 µg/L (the feasible level), 10 µg/L, and 20 µg/L.

We based our estimates of large system compliance costs primarily on costs for coagulation/filtration and lime softening, although we consider several other technologies to be appropriate as best available technology (BAT) technologies. (See Table I.F–1.) For small-system (systems serving 10,000 people and less) compliance costs, we considered the costs for ion exchange, activated alumina, reverse osmosis, and nanofiltration. EPA proposed extending the effective date to five years after the final rule issuance for small community water systems and maintaining the effective date at three years after promulgation for all other community water systems. EPA proposed that States applying to adopt the revised arsenic MCL may use their most recently approved monitoring and waiver plans or note in their primacy application any revisions to those plans. EPA proposed that NTNCWSs monitor for arsenic and report exceedances of the MCL.

The Agency also clarified the procedure used for determining compliance after exceedances for inorganic, volatile organic, and synthetic organic contaminants in §§ 141.23(i)(2), 141.24(f)(15)(ii), and 141.24(h)(11)(ii), respectively. Finally, EPA proposed that new systems and systems using a new source of water be required to demonstrate compliance with the MCLs using State-specified time frames. The clarified new source and new system compliance regulations require that States establish initial sampling frequencies and compliance periods for inorganic, volatile organic, and synthetic organic contaminants in §§ 141.23(c)(9), 141.24(f)(22), and 141.24(h)(20), respectively.

B. Overview of the Notice of Data Availability (NODA)

In the proposed rule, EPA quantified the risk reduction and benefits of avoiding bladder cancer and noted that a peer-reviewed quantification of lung cancer risk from arsenic exposure would probably be available in time to consider for the final rule (65 FR 38888 at 38899; EPA, 2000i). Relying upon a discussion in the National Research Council (NRC) report (NRC, 1999, pg. 8) about the qualitative risks of lung cancer (65 FR 38888 at 38944; 2000i), EPA provided a "What-If" estimate of lung cancer benefits (65 FR 38888 at 38946, 2000i) in the proposed rule. On October 20, 2000, the **Federal Register** published EPA's Notice of Data Availability (NODA) containing a revised risk analysis for bladder cancer and new risk information concerning lung cancer (65 FR 63027; EPA, 2000m), and identified a correction to Table 4 on October 27, 2000 (65 FR 64479; EPA, 2000n). The NODA also provided information concerning the availability of cost curves used to develop the costs published in the proposal.

EPA used new risk information for lung and bladder cancer from a peer-reviewed article written by Morales *et al.* (2000). In the NODA, EPA explained that the authors used several alternative statistical models to estimate cancer risk. EPA explained its reasons for selecting "Model 1" with no comparison population for further analysis. We used daily water consumption (EPA, 2000c) reported by gender, region, age, economic status, race, and separately for pregnant women, lactating women, and women in childbearing years combined with weight data to derive exposure factors for the U.S. We used these exposure factors, our occurrence estimate (EPA 2000g) of populations exposed to arsenic at different concentrations, and the risk distributions from the Morales *et al.* (2000) paper in Monte Carlo simulations to estimate the upper bound of risks faced by the U.S. population. The NODA compared the bladder cancer risks derived for the proposal against the bladder cancer risks derived from the Morales *et al.* (2000) study. EPA also derived lung cancer risks using the same approach and the risk model contained in the Morales *et al.* (2000) study.

EPA also used the newly calculated risks to estimate a lower bound risk in the U.S. This calculation took into account the amount of additional arsenic people in Taiwan were likely to have ingested from water used in food preparation. EPA showed the effects on risks for the U.S. population at both the mean and 90th percentile levels for various arsenic levels in drinking water. Based on the revised risk assessment, we updated our assessment of the relative risk of lung cancer as compared to bladder cancer. The NODA indicated that instead of being 2 to 5 times as many fatal lung cancer cases as bladder cancer cases (as was cited in NRC's Executive Summary, NRC, 1999, pg. 8 as a qualitative estimate), the combined risk of excess lung and bladder cancer were thought to be only about twice that of bladder cancer risk. EPA noted that, while the new risks were higher than the bladder cancer risk in the proposal, the monetized benefits of lung cancer would fall within the lung cancer benefits range estimated using the "What-If" analysis (*e.g.*, $19.6 million—$224 million yearly for an MCL of 10 µg/L) in the proposal (65 FR 38888 at 38959; EPA, 2000m).

In the NODA, EPA also explained that the docket for the proposed rule had the November 1999 version (EPA, 1999o) of "Technologies and Costs for the Removal of Arsenic from Drinking Water" rather than the April 1999 version of the document that was the primary source for the treatment technology cost equations used to generate the national cost estimate. The national cost estimate was presented in the "Proposed Arsenic in Drinking Water Rule Regulatory Impact Analysis" (EPA, 2000h). The NODA therefore announced the availability of the "Technologies and Costs for the Removal of Arsenic from Drinking Water," dated April 1999 (EPA,1999b). The NODA also noted that commenters interested in reproducing the waste disposal curves should consult the "Small Water System Byproducts Treatment and Disposal Cost Document" (EPA, 1993a) and "Water System Byproducts Treatment and Disposal Document (EPA, 1993b)." In addition to placing these documents in the docket, the NODA also specified that an electronic copy of the treatment technology and waste disposal equations used in the development of the RIA could be found in the docket.

EPA made the April 1999 version of the document, "Technologies and Costs for the Removal of Arsenic from Drinking Water" (EPA,1999b) available on its arsenic webpage.

The cost methodology and cost estimates were clearly stated and explained in the proposal for public review and consideration. Through a technical oversight, we incorrectly attributed the source for the cost curves to the November version of the document placed in the docket (EPA, 1999o). As a result, people could not replicate the precise analysis we did, should a commenter desire to do so. More specifically, although the inputs, assumptions, and model methodology were clearly explained, we incorrectly cited the sources of an intermediate step of deriving specific cost curves from those assumptions. Based upon the proposal's detailed discussion of inputs, assumptions and associated methodology, EPA believes the public was fully able to review, understand, and comment on the Agency's estimate of potential impacts. EPA discusses the cost curves further in section III.E.1 of this preamble.

C. Does This Regulation Apply to My Water System?

The final regulation on arsenic in drinking water promulgated today applies to all CWSs and NTNCWSs. The regulation not only establishes an MCLG and MCL for arsenic, but also lists feasible technologies and affordable technologies for small systems that can be used to comply with the MCL. However, systems are not required to use the listed technologies in order to meet the MCL.

D. What are the Final Drinking Water Regulatory Standards for Arsenic (Maximum Contaminant Level Goals and Maximum Contaminant Levels)?

In today's rule, the MCLG is 0 µg/L, and the enforceable MCL is 0.01 mg/L, which is the same as 10 micrograms per liter (µg/L) or 10 parts per billion (ppb). EPA based the MCL on total arsenic, because drinking water contains almost entirely inorganic forms, and the analytical methods for total arsenic are readily available and capable of being performed by certified laboratories at an affordable cost.

E. Will There be a Health Advisory?

A health advisory for arsenic is not part of today's rulemaking. EPA will be considering whether or not to issue a health advisory after evaluating the recommendations of the Science Advisory Board (SAB) (EPA, 2000q). The purpose of an advisory would be to provide useful information to water providers between issuance and implementation of this rule.

F. What are the Best Available Technologies For Removing Arsenic From Drinking Water?

Section 1412(b)(4)(E) of the Safe Drinking Water Act states that each National Primary Drinking Water Regulation (NPDWR) which establishes an MCL shall list the technology, treatment techniques, and other means that the Administrator finds to be feasible for purposes of meeting the MCL. Technologies are judged to be a best available technology (BAT) when the following criteria are satisfactorily met:

(1) The capability of a high removal efficiency;

(2) A history of full-scale operation;

(3) General geographic applicability;

(4) Reasonable cost based on large and metropolitan water systems;

(5) Reasonable service life;

(6) Compatibility with other water treatment processes; and

(7) The ability to bring all of the water in a system into compliance.

EPA identified BATs in this section using the listed criteria. Their removal efficiencies and a brief discussion of the major issues surrounding the usage of each technology are also given in this section. More details about the treatment technologies and costs can be found in "Technologies and Costs for the Removal of Arsenic From Drinking Water" (EPA, 2000t).

1. BAT technologies

EPA reviewed several technologies as BAT candidates for arsenic removal, e.g., ion exchange, activated alumina, reverse osmosis, nanofiltration, electrodialysis reversal, coagulation assisted microfiltration, modified coagulation/filtration, modified lime softening, greensand filtration, conventional iron and manganese removal, and several emerging technologies. The Agency determined that, of the technologies capable of removing arsenic from source water, only the technologies in Table I.F–1 fulfill the requirements of SDWA for BAT determinations for arsenic. The maximum percent of arsenic removal that can be reasonably obtained from these technologies is also shown in the table. These removal efficiencies are for arsenic (V) removal.

TABLE I.F–1.— BEST AVAILABLE TECHNOLOGIES AND REMOVAL RATES

Treatment Technology	Maximum Percent Removal [1]
Ion Exchange (sulfate ≤ 50 mg/L)	95
Activated Alumina	95
Reverse Osmosis	>95
Modified Coagulation/Filtration	95
Modified Lime Softening (pH > 10.5)	90
Electrodialysis Reversal	85
Oxidation/Filtration (20:1 iron:arsenic)	80

[1] The percent removal figures are for arsenic (V) removal. Pre-oxidation may be required.

2. Preoxidation

In water, the most common valence states of arsenic are As (V), or arsenate, and As (III), or arsenite. As (V) is more prevalent in aerobic surface waters and As (III) is more likely to occur in anaerobic ground waters. In the pH range of 4 to 10, As (V) species ($H_2AsO_4^{-}$ and $HAsO_4^{2-}$) are negatively charged, and the predominant As (III) compound (H_3AsO_3) is neutral in charge. Removal efficiencies for As (V) are much better than removal of As (III) by any of the technologies evaluated because the arsenate species carry a negative charge and arsenite is neutral under these pH conditions. To increase the removal efficiency when As (III) is present, pre-oxidation to the As (V) species is necessary.

As (III) may be converted through pre-oxidation to As (V) using one of several oxidants. Data on oxidants indicate that chlorine, potassium permanganate, and ozone are effective in oxidizing As (III) to As (V). Pre-oxidation with chlorine may create undesirable concentrations of disinfection byproducts and membrane fouling of subsequent treatments such as reverse osmosis. EPA has completed research on the chemical oxidants for As (III) conversion, and is presently investigating ultraviolet light disinfection technology (UV) and solid oxidizing media. For POU and POE devices, central chlorination may be required for oxidation of As (III).

3. Factors affecting listing technologies

Ion Exchange (IX) can effectively remove arsenic using anion exchange resins. It is recommended as a BAT primarily for sites with low sulfate because sulfate is preferred over arsenic. Sulfate will compete for binding sites resulting in shorter run lengths. Due to much shorter run lengths than activated alumina, anion exchange must be

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regenerated because it is not cost effective to dispose of the resin after one use. Column bed regeneration frequency is a key factor in the cost of the process and affects the volume of waste produced by the process. The proposed rule preamble noted that anion exchange may be practical up to approximately 120 mg/L of sulfate (Clifford, 1994). The upper-bound sulfate concentration for the final rule is 50 mg/L. The selection of this upper bound is based on several factors, including cost and the ability to dispose of the brine stream.

The proposed rule listed three mechanisms to dispose of the brine stream used for regeneration. The options were: sanitary sewer, evaporation pond, and chemical precipitation. Many comments on the proposed rule were based on the assumption that the waste streams generated would be considered hazardous waste. Waste streams containing less than 0.5% solids are evaluated against the toxicity characteristic directly to determine if the waste is hazardous. Arsenic in the regeneration brine will likely exceed 5 mg/L for most systems with arsenic above 10 µg/L and sulfate below 50 mg/L. Since the brine stream would likely be considered hazardous, EPA eliminated the evaporation pond and the chemical precipitation options from the decision tree as options for disposal of anion exchange wastes. The Agency retained discharge to a sanitary sewer because domestic sewage and any mixture of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works (POTW) for treatment is excluded from consideration as solid waste (40 CFR 261.4). Domestic sewage means untreated sanitary wastes that pass through a sewage system. Discharges meeting the previously stated criteria are excluded from regulation as hazardous waste. However, these assumptions were reviewed to substantially reduce projections of brine wastes going to POTWs from those that were used in support of the proposed rule.

Discharge to a sanitary sewer can be limited by technically based local limits (TBLLs) for arsenic or total dissolved solids. Since anion exchange is regenerated more frequently than activated alumina, the total dissolved solids increase can be significant. Many comments indicated that significant increases in total dissolved solids would be unacceptable, especially in the Southwest where water resources are scarce. Salt is used for regeneration of anion exchange resins. The upper bound of 50 mg/L sulfate for anion exchange is based on projected increases of total dissolved solids using the quantity of salt needed for regeneration and the frequency of regeneration (based on sulfate). The sulfate upper bound for the final rule is significantly lower than the upper bound from the proposed rule. Due to the potential for an increase in total dissolved solids, anion exchange would be favored in areas other than the Southwest where the volume of brine is very small relative to the total volume of wastewater being treated at the POTW. Systems that need to treat only a few entry points or can blend a significant portion of the water to meet the MCL may produce a smaller brine stream to allow the brine to be discharged to a POTW. Water systems should check with the POTW to ensure that the brine stream will be accepted before selecting this option.

Activated Alumina (AA) is an effective arsenic removal technology; however, the capacity of activated alumina to remove arsenic is very pH sensitive. High removals can be achieved over a broad range of pH, but shorter run lengths will be observed at higher pH. Activated alumina can be operated in one of two ways. The activated alumina can either be disposed of or regenerated after the media is exhausted. Under the regeneration option, strong acids and bases are used to remove arsenic from the media so that it can be used again to remove arsenic. Because arsenic is strongly adsorbed to the media, only about 50–70% of the adsorbed arsenic is removed. The brine stream produced by the regeneration process then requires disposal. The proposed rule listed discharge to a sanitary sewer as the disposal mechanism for the brines. Many comments on the proposed rule noted that TBLLs for arsenic or total dissolved solids might restrict discharge of brine streams to the sanitary sewer. Since activated alumina run lengths (i.e., number of bed volumes (BV) per run) are much longer than anion exchange, the arsenic concentrations in the brine stream would likely be much higher. Regeneration of activated alumina media is not recommended for larger systems because: (1) Disposal of the brine may be difficult, (2) the regeneration process is incomplete which reduces subsequent run lengths, and (3) for most systems it will be cheaper to replace the media rather than regenerate it. The option of replacing the spent media with new media is called disposable activated alumina.

The disposable activated alumina option can be operated both at the optimal pH of 6 and at higher natural water pH values. It is expected that larger systems would adjust pH to take advantage of the longer run lengths. EPA developed several disposable activated alumina options for the final rule. Two options were based on operating the process at the natural pH of the water (no pH adjustment). These options are intended primarily for smaller systems, although larger systems may also be able to operate at the natural pH if it is low enough to get sufficiently long run lengths. Two options where the pH was adjusted to pH 6 were also examined. The longer run length is based on using sulfuric acid to lower the pH. However, sulfate can compete for adsorption sites with arsenic. It was recommended that hydrochloric acid be used to obtain a longer run length (Clifford et al., 1998). When pH is adjusted to pH 6, post-treatment corrosion control will be necessary.

In our analysis, we assumed that spent media could be safely disposed of in a non-hazardous landfill. The preamble to the proposed rule described results from testing of activated alumina media used to remove arsenic in drinking water systems with arsenic above 50 µg/L. The results from the Toxicity Characteristic Leaching Procedure (TCLP) on these samples was typically less that 50 µg/L. The current toxicity characteristic (TC) regulatory level for designating arsenic as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) is 5 mg/L (5000 µg/L) and is listed in 40 CFR 261.24(a). The TC regulatory level is one hundred times higher than the results from the activated alumina samples.

Reverse Osmosis (RO) can provide removal efficiencies of greater than 95% when operating pressure is ideal. Water rejection (on the order of 20–25%) may be an issue in water-scarce regions and may prompt systems employing RO to seek greater levels of water recovery. Water recovery is the volume of drinking water produced by the process divided by the influent stream (product water/influent stream). Increased water recovery is often more expensive, since it can involve recycling of water through treatment units to allow more efficient separation of solids from water. This can also produce more concentrated solid wastes. However, the waste stream will generally not be as concentrated as anion exchange brines, so it should be easier to dispose of. Based on the cost of the process, it is unlikely that reverse osmosis would be installed solely for arsenic removal. Blending a treated portion with an untreated portion and

still meeting the MCL would make reverse osmosis more cost effective. If blending is not an option, post-treatment corrosion control would be necessary. Since a large portion of the water is wasted, water quantity could be an issue, especially in the Western U.S. It should be noted that while reverse osmosis is listed as a BAT, it was not used to develop national costs because other options are more cost effective and have much smaller waste streams.

Modified Coagulation/Filtration (C/F) is an effective treatment process for removal of As (V) according to laboratory, pilot-plant, and full-scale tests. The type of coagulant and dosage used affects the efficiency of the process. Below a pH of approximately 7, removals with alum or ferric sulfate/chloride are similar. Above a pH of 7, removals with alum decrease dramatically (at a pH of 7.8, alum removal efficiency is about 40%). Other coagulants are also less effective than ferric sulfate/chloride. Systems may need to lower pH or add more coagulant to achieve higher removals.

Modified Lime Softening (LS), operated within the optimum pH range of greater than 10.5 is likely to provide a high percentage of As removal. Systems operating lime softening at lower pH will need to increase the pH to achieve higher removals of arsenic.

Coagulation/Filtration and Lime Softening are unlikely to be installed solely for arsenic removal. Systems considering installation of one of these technologies should design the process to operate in the optimal pH range if high removal efficiencies are needed for compliance.

Electrodialysis Reversal (EDR) can produce effluent water quality comparable to reverse osmosis. EDR systems are fully automated, require little operator attention, and do not require chemical addition. EDR systems, however, are typically more expensive than nanofiltration and reverse osmosis systems. These systems are often used in treating brackish water to make it suitable for drinking. This technology has also been applied in the industry for wastewater recovery and typically operates at a recovery of 70 to 80%. Since a large portion of the water is wasted, water quantity could be an issue, especially in the Western U.S. It should be noted that while electrodialysis reversal is listed as a BAT, it was not used to develop national costs because other options are more cost effective and have much smaller waste streams.

Oxidation/Filtration (including greensand filtration) has an advantage in that there is not as much competition with other ions. Arsenic is co-precipitated with the iron during iron removal. Sufficient iron needs to be present to achieve high arsenic removals. One study recommended a 20:1 iron to arsenic ratio (Subramanian et al., 1997). Removals of approximately 80% were achieved when iron to arsenic ratio was 20:1. When the iron to arsenic ratio was lower (7:1), removals decreased below 50%. The presence of iron in the source water is critical for arsenic removal. If the source water does not contain iron, oxidizing and filtering the water will not remove arsenic. When the arsenic is present as As(III), sufficient contact time needs to be provided to convert the As(III) to As(V) for removal by the oxidation/filtration process. An additional pre-oxidation step is not required for this process as long as there is sufficient contact time. In developing national cost estimates, EPA assumed that systems would opt for this type of technology only if more than 300 µg/L of iron was present. The Agency assumed a removal percentage of 50% when estimating national costs because the 20:1 ratio could not be verified due to limitations in the co-occurrence database. However, EPA assumed a removal percentage of 80% as part of a sensitivity analysis. At proposal EPA indicated that oxidation filtration was not being listed as BAT because it has a low removal efficiency, which might not be appropriate for an MCL of 5. However, the Agency also noted that this technology may be appropriate for systems that do not require high arsenic removal and had high iron in their source water. Because this is an inexpensive technology that is particularly effective for high-iron, low-arsenic waters, EPA is listing oxidation/filtration as a BAT with a footnote that the iron-to-arsenic ratio must be at least 20:1. Systems with greater than 300 µg/L of iron will also see benefits in the aesthetic quality of the water as the iron can be reduced below the secondary standard. EPA's inclusion of oxidation/filtration as a BAT in today's final rule is based upon further evaluation of all available information and studies as well as on public comments.

4. Other technologies evaluated, but not designated as BAT

Coagulation Assisted Microfiltration. The coagulation process described previously can be linked with microfiltration to remove arsenic. The microfiltration step essentially takes the place of a conventional gravity filter. The University of Houston recently completed pilot studies at Albuquerque, New Mexico on iron coagulation followed by a direct microfiltration system. The results of this study indicated that iron coagulation followed by microfiltration is capable of removing arsenic (V) from water to yield concentrations that are consistently below 2 µg/L. Critical operating parameters are iron dose, mixing energy, detention time, and pH (Clifford, 1997). Coagulation and microfiltration as separate processes have both been installed full scale, but the combined coagulation/microfiltration process does not have a full-scale operation history. Since a full-scale operation history is one of the requirements to list a technology as a BAT, it is not presently being listed as one. It could be designated as such in the future if the technology meets that requirement. EPA used this option in developing the national cost estimate because we believe coagulation/microfiltration is an appropriate technology that will be used by certain water systems to comply with this rule, even though it is not currently listed as BAT for the reasons mentioned.

Granular ferric hydroxide is a technology that may combine very long run length without the need to adjust pH. The technology has been demonstrated for arsenic removal full scale in England (Simms et al., 2000). A pilot-scale study for activated alumina was also conducted on that water and showed run lengths much longer than observed in pilot-scale studies in the United States. Due to the lack of published data showing performance for a range of water qualities, granular ferric hydroxide was not designated a BAT. In addition, there is little published information on the cost of the media, so it is difficult to evaluate cost. Granular ferric hydroxide is being investigated in several ongoing studies and may be an effective technology for removing arsenic. Systems may wish to investigate it and other adsorption technologies such as modified activated alumina and other iron-based media. Many of these other new adsorptive media are also being investigated in several ongoing studies.

5. Waste disposal

Waste disposal will be an important issue for both large and small drinking water plants. Costs for waste disposal have been added to the costs of the treatment technologies (in addition to any pre-oxidation and corrosion control costs), and form part of the treatment trains that are listed in Tables I.G–1, I.G–5, and I.G–6.

The preamble to the proposed rule summarized toxicity characteristic leaching procedure (TCLP) data on residuals from different arsenic removal

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technologies. The arsenic concentrations in TCLP extracts from alum coagulation, activated alumina, lime softening, iron/manganese removal, and coagulation-microfiltration residuals were below 0.05 mg/L, which is two orders of magnitude lower than the current TC regulatory level. The TCLP data for iron coagulation were mixed—the residuals from an arsenic removal plant were below 0.05 mg/L, but the residuals from another iron coagulation plant were above 1 mg/L. However, this is still below the TC regulatory level of 5 mg/L. Based on these data, EPA does not believe that drinking water treatment plant residuals would be classified as hazardous waste. The TCLP data also indicate that most residuals could meet a much lower TC regulatory level. Options where the brine stream could be hazardous were eliminated from the final decision tree. For the purposes of the national cost estimate, it was assumed that solid residuals would be disposed of at nonhazardous landfills.

G. Treatment Trains Considered For Small Systems

1. Can my water system use point-of-use (POU), point-of-entry (POE), or bottled water to comply with this regulation?

Section 1412(b)(4)(E)(ii) of SDWA, as amended in 1996, requires EPA to issue a list of technologies that achieve compliance with MCLs established under the Act that are affordable and applicable to typical small drinking water systems. These small public water systems categories are: (1) population of more than 25 but less than or equal to 500; (2) population of more than 500, but less than or equal to 3,300; and (3) population of more than 3,300, but less than or equal to 10,000. Owners and operators may choose any technology or technique that best suits their conditions, as long as the MCL is met.

The technologies examined for BAT determinations were also evaluated as small system compliance technologies. Several other alternatives that are solely small system options were also evaluated as compliance technologies. Central treatment is not the only option available to small systems. One of the provisions included in the SDWA Amendments of 1996 allows the use of POU and POE devices as compliance technologies for small systems. SDWA stipulates that POU/POE treatment systems:

> shall be owned, controlled and maintained by the public water system or by a person under contract with the public water system to ensure proper operation and maintenance and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems (§ 1412(b)(4)(E)).

Whole-house, or POE treatment, is necessary when exposure to the contaminant by modes other than consumption is a concern; this is not the case with arsenic. Single faucet, or POU treatment, is preferred when treated water is needed only for drinking and cooking purposes. POU devices are especially applicable for systems that have a large flow and only a minor part of that flow directed for potable use such as at many NTNCWSs. POE/POU options include reverse osmosis, activated alumina, and ion exchange processes. POU systems are easily installed and can be easily operated and maintained. In addition, these systems generally offer lower capital costs and may reduce engineering, legal, and other fees associated with centralized treatment options. However, there will be higher administrative costs associated with POU and POE options. For POU options, the trade-off is lower treatment cost since only 1% of the water is treated, but higher administrative and monitoring costs occur. Centrally managed POU options, even with the higher monitoring and administrative costs, are less expensive than central treatment for populations up to 150 to 250 people depending upon the technology and number of households.

Using POU/POE devices introduces some new issues. Adopting a POU/POE treatment system in a small community requires more record-keeping to monitor individual devices than does central treatment. POU/POE systems may require special regulations regarding customer responsibilities as well as water utility responsibilities. The water system or person under contract to the system is responsible for maintaining the devices in customers' homes. This responsibility cannot be delegated to the customer. Use of POU/POE systems does not reduce the need for a well-maintained water distribution system. Increased monitoring may be necessary to ensure that the treatment units are operating properly. Monitoring POU/POE systems is also more complex because compliance samples need to be taken after each POU or POE unit rather than at the entry point to the distribution system to be reflective of treatment.

EPA examined three technologies as POU and POE devices for the proposed rule. EPA assumed that systems would more likely choose to use POU activated alumina (AA) or reverse osmosis (RO), and POE AA in the proposed rule. POU and POE ion exchange (IX) and POE RO were considered, but not included as compliance technologies in the proposed rule. Activated alumina and ion exchange units face a breakthrough issue. If the activated alumina is not replaced on time, there is a potential for significantly reduced arsenic removal. However, if the anion exchange resin is not replaced or regenerated on time, the previously removed arsenic can be driven off the resin by sulfate. Tap water arsenic concentrations can be higher than the source water. This is called chromatographic peaking. Due to the potential for chromatographic peaking and run lengths that would typically be less than six months, anion exchange was not listed as a compliance technology in the proposed rule. POE ion exchange also may present problems with total dissolved solids since the resin would need to be regenerated. Since all sites within the system would need treatment, the total dissolved solids increase from a centrally managed POE ion exchange system would be similar to that from a central treatment ion exchange system. EPA did not list POE RO units as compliance technologies because it could create corrosion control problems. In addition, water recovery would be no higher than central treatment, so water quantity issues associated with central treatment reverse osmosis would be applicable to POE RO.

The proposed rule included POE AA as a small system compliance technology. Arsenic removal by AA is very sensitive to the pH. The finished water pH will typically be higher than the optimal pH of 6 to meet the corrosion control requirements of the lead and copper rule. A finished water pH for many systems would be in the range of pH 7 to pH 8. Using data on activated alumina run length and pH, it was determined that viable run lengths were likely only when the finished water pH was at or below pH 7.5 (Kempic, 2000). Even in this pH range, the media may need to be replaced more frequently than once a year, which would make the option very expensive especially compared to the POU AA option. The run length data used for this analysis were from a site with very little competing ions (Simms and Azizian, 1997). Studies at other sites with higher levels of competing ions have much lower run lengths (Clifford et al., 1998). Based on the limited finished water pH range where POE AA might be effective and the fact that the POU media needs replacing much less frequently due to lower water demand, POE AA has not been listed as a compliance technology in the final rule. POE devices utilizing media that are less sensitive to pH adjustment may be listed as compliance technologies in the future once data on their performance are generated.

The effect of pH was also examined on POU AA. Under the POU AA option, the volume of water requiring treatment is much smaller. The unit will be installed at the kitchen tap and only the water being used for cooking and consumption is being treated for arsenic removal. Since the ratio of the daily volume of water being treated to the size of the unit is much smaller, POU units can be operated for longer periods of time before the media needs to be replaced. The replacement frequency assumed for the costs is every six months. Viable run lengths for the POU option were greater than one year up to pH 8 (Kempic, 2000). This analysis assumed a large daily usage volume of 24 liters per day. The average consumption per person per day is just over 1 liter. Even if competing ions reduced the run length significantly, systems with tap water at or below pH 8 should meet the MCL of 10 µg/L using a six-month replacement frequency for the media. POU AA is a compliance technology when the tap water pH is at or below pH 8.

POU RO was listed as a compliance technology in the proposed rule and it is being listed as a compliance technology in the final rule as well. Several comments indicated that water rejection would be an issue with POU devices. Since only about 1% of the total water used in the household is being treated, POU RO is unlikely to create water quantity problems. If the water rejection rate was 10:1, this would only increase the total household water demand by about 10 percent. Where availability of additional water is limited, systems may want to consider other alternatives to meet the MCL.

In order to be consistent with 1996 SDWA Amendments, EPA issued a **Federal Register** notice on June 11, 1998 (EPA, 1998f) that deleted the prohibition on the use of POU devices as compliance technologies. This prohibition was in 40 CFR 141.101. This section now states that public water systems shall not use bottled water to achieve compliance with an MCL. Bottled water may be used on a temporary basis to avoid unreasonable risk to health. Therefore, bottled water cannot be used as a compliance technology for the arsenic rule.

Likely treatment trains are shown in Table I.G–1. These trains represent a wide variety of solutions, including BATs, that small systems may consider when complying with the proposed arsenic MCL. Not all solutions may be viable for a given system. For example, only those systems with coagulation/filtration in place will be able to modify their existing treatment system. The treatment trains include BATs, waste disposal, and when necessary, pre-oxidation and corrosion control. While systems could install lime softening at pH > 10.5 or optimized coagulation/filtration solely for arsenic removal, EPA does not view this as a likely option. Reverse osmosis and electrodialysis reversal are also not included in this table because other options are more cost effective for arsenic removal and do not reject a large volume of water like these two technologies. RO and EDR may be cost-effective options if removal of other contaminants is needed and water quantity is not a concern.

TABLE I.G–1.— TREATMENT TECHNOLOGY TRAINS FOR CONSIDERATION BY SMALL SYSTEMS IN COMPLYING WITH FINAL RULE INCLUDING BATS

Train #	Treatment Technology Trains for Consideration by Small Systems
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/L.
5	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add mechanical dewatering/non-hazardous landfill waste disposal.
6	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add non-mechanical dewatering/non-hazardous landfill waste disposal.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤ pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 8.0)

Pre-oxidation costs are given as a separate component because they will be incurred only by some systems. In estimating national costs, it was assumed that only systems without pre-oxidation in place would need to add the necessary equipment. It is expected that no surface water systems will need to install pre-oxidation for arsenic removal and that fewer than 50% of the ground water systems may need to install pre-oxidation for arsenic removal. Ground water systems without pre-oxidation should ascertain if pre-oxidation is necessary by determining if the arsenic is present as As (III) or As (V). Ground water systems with predominantly As (V) will probably not need pre-oxidation to meet the MCL.

2. What are the affordable treatment technologies for small systems?

The 13 treatment trains listed in Table I.G–1 were compared against the national-level affordability criteria to determine the affordable treatment trains. The Agency's national-level affordability criteria were published in the August 6, 1998 **Federal Register** (EPA, 1998h). In this notice, EPA discussed the procedure for affordable

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treatment technology determinations for the contaminants regulated before 1996.

The preamble to the proposed arsenic rule described the derivation of the national-level affordability criteria (65 FR 38888 at 38926; EPA, 2000i). A very brief summary follows: First an "affordability threshold" (*i.e.*, the total annual household water bill that would be considered affordable) was calculated. The total annual water bill includes costs associated with water treatment, water distribution, and operation of the water system. In developing the threshold of 2.5% median household income, EPA considered the percentage of median household income spent by an average household on comparable goods and services and on cost comparisons with other risk reduction activities for drinking water such as households purchasing bottled water or a home treatment device. The complete rationale for EPA's selection of 2.5% as the affordability threshold is described in "Variance Technology Findings for Contaminants Regulated Before 1996" (EPA, 1998l).

The Variance Technology Findings document also describes the derivation of the baselines for median household income, annual water bills, and annual household consumption. Data from the Community Water System Survey (CWSS) were used to derive the annual water bills and annual water consumption values for each of the three small system size categories. The Community Water System Survey data on zip codes were used with the 1990 Census data on median household income to develop the median household income values for each of the three small-system size categories. The median household-income values used for the affordable technology determinations are not based on the national median income. The value for each size category is a national median income for communities served by small water systems within that range. Table I.G–2 presents the baseline values for each of the three small-system size categories. Annual water bills and median household income are based on 1995 estimates.

TABLE I.G–2.—BASELINE VALUES FOR SMALL SYSTEMS CATEGORIES

System size category (population served)	Annual household consumption (1000 gallons/yr)	Annual water bills ($/yr)	Median household income ($)
25–500	72	$211	$30,785
501–3,300	74	184	27,058
3,300–10,000	77	181	27,641

For each size category, the threshold value was determined by multiplying the median household income by 2.5%. The annual household water bills were subtracted from this value to obtain the available expenditure margin. Projected treatment costs will be compared against the available expenditure margin to determine if there are affordable compliance technologies for each size category. The available expenditure margin for the three size categories is presented in Table I.G–3.

TABLE I.G–3.—AVAILABLE EXPENDITURE MARGIN FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (population served)	Available expenditure margin ($/household/year)
25–500	559
501–3,300	492
3,301–10,000	510

The size categories specified in SDWA for affordable technology determinations are different than the size categories typically used by EPA in the Economic Analysis. A weighted average procedure was used to derive design and average flows for the 25–500 category using design and average flows from the 25–100 and 101–500 categories. A similar approach was used to derive design and average flows from the 501–1000 and 1001–3300 categories for the 501–3300 category. The Variance Technology Findings document (EPA, 1998l) describes this procedure in more detail. Table I.G–4 lists the design and average flows for the three size categories.

TABLE I.G–4.— DESIGN AND AVERAGE DAILY FLOWS USED FOR AFFORDABLE TECHNOLOGY DETERMINATIONS

System size category (population served)	Design flow (mgd)	Average flow (mgd)
25–500	0.058	0.015
501–3,300	0.50	0.17
3,301–10,000	1.8	0.70

Capital and operating and maintenance costs were derived for each treatment train using the flows listed previously and the cost equations in the Technology and Cost Document. Several conservative assumptions were made to derive the costs. The influent arsenic concentration was assumed to be 50 µg/L, which was the MCL for arsenic prior to this rule. The treatment target was 8 µg/L, which is 80% of the MCL. Thus, little blending could be performed to reduce costs. Capital costs were amortized using the 7% interest rate preferred by OMB for benefit-cost analyses of government programs and regulations rather than a 3% interest rate.

The annual system treatment cost in dollars per year was converted into a rate increase using the average daily flow. The annual water consumption values listed in Table I.G–2 were multiplied by 1.15 to account for water lost due to leaks. Since the water lost to leaks is not billed, the water bills for the actual water used were adjusted to cover this lost water by increasing the household consumption. The rate increase in dollars per thousand gallons used was multiplied by the adjusted annual consumption to determine the annual cost increase for the household for each treatment train. Several comments on affordability presented household cost increases that were

derived by dividing the annual system cost by the number of households. That is an inappropriate method because residential customers would not only be paying for the water that they use, but also all the water used by non-residential customers of the system..

Of the 13 treatment trains in Table I.G–1, the ones identified in Table I.G–5 are deemed to be affordable for systems serving 25–500 people as the annual household cost was below the available expenditure margin. The two trains using coagulation-assisted microfiltration are not affordable for this size category. All 13 treatment trains are deemed to be affordable for systems serving 501–3,300 and 3,301–10,000 people and are presented in Table I.G–6. Centralized compliance treatment technologies include ion exchange, activated alumina, modified coagulation/filtration, modified lime softening, and oxidation/filtration (e.g. greensand filtration) for source waters high in iron. In addition, POU and POE devices are also compliance technology options for the smaller systems.

TABLE I.G–5.— AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATION 25–500

Train No.	Treatment Technology Trains
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/l.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 6.0)

TABLE I.G–6.— AFFORDABLE COMPLIANCE TECHNOLOGY TRAINS FOR SMALL SYSTEMS WITH POPULATIONS 501–3,300 AND 3,301 TO 10,000

Train No.	Treatment Technology Trains
1	Add pre-oxidation [if not in-place] and modify in-place Lime Softening (pH > 10.5) and modify corrosion control.
2	Add pre-oxidation [if not in-place] and modify in-place Coagulation/Filtration and modify corrosion control.
3	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level ≤ 20 mg/L.
4	Add pre-oxidation [if not in-place] and add Anion Exchange and add POTW waste disposal. Sulfate level: 20 mg/L < sulfate ≤ 50 mg/l.
5	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add mechanical dewatering/non-hazardous landfill waste disposal.
6	Add pre-oxidation [if not in-place] and add Coagulation Assisted Microfiltration with corrosion control and add non-mechanical dewatering/non-hazardous landfill waste disposal.
7	Add Oxidation/Filtration (Greensand) (20:1 iron: arsenic) and add POTW for backwash stream.
8	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 7 ≤pH < pH 8.
9	Add pre-oxidation [if not in-place] and add Activated Alumina and add non-hazardous landfill (for spent media) waste disposal. pH 8 ≤ pH ≤ pH 8.3.
10	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 23,100 BV.
11	Add pre-oxidation [if not in-place] and add Activated Alumina with pH adjustment (to pH 6) and corrosion control and add non-hazardous landfill (for spent media) waste disposal. Run length = 15,400 BV.
12	Add pre-oxidation [if not in-place] and add POU Reverse Osmosis.
13	Add pre-oxidation [if not in-place] and add POU Activated Alumina. (Finished water pH ≤ pH 8.0)

3. Can My Water System Get a Small System Variance From an MCL Under Today's Rule?

Section 1415(e)(1) of SDWA allows States to grant variances to small water systems (i.e., systems having 10,000 customers or less) in lieu of complying with an MCL if EPA determines that there are no nationally affordable compliance technologies for that system size/water quality combination. The system must then install an EPA-listed variance treatment technology (section 1412(b)(15)) that makes progress toward the MCL, if not necessarily reaching it. EPA has determined that affordable technologies exist for all three system size categories and has therefore not identified a variance technology for any system size or source water quality combination. Small system variances are not available for the final arsenic MCL.

H. Can My System Get a General Variance or Exemption From the MCL Under Today's Rule?

General variances may be granted in accordance with section 1415(a)(1)(A) of SDWA and EPA's regulations. General variances are available to public water systems that have installed or agree to install the BAT but, due to source water quality, are or will be unable to comply with the national primary drinking water standard. The general variance

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provisions of SDWA are narrowly focused on addressing those rare circumstances where some unusual characteristic of the source water available to a system will result in less effective performance of the BAT. Exemptions may be granted in accordance with section 1416(a) of SDWA and EPA's regulations. Exemptions are designed to provide a system facing compelling circumstances, such as economic hardship, additional time to come into compliance.

Under section 1415(a)(1)(A) of the SDWA, a State that has primary enforcement responsibility (primacy), or EPA as the primacy agency, may grant variances from MCLs to those public water systems of any size that cannot comply with the MCLs because of characteristics of the water sources. The primacy agency may grant general variances to a system on condition that the system install the best available technology, treatment techniques, or other means, and provided that alternative sources of water are not reasonably available to the system. At the time this type of variance is granted, the State must prescribe a schedule for compliance with its terms and may require the system to implement additional control measures. Furthermore, before EPA or the State may grant a general variance, it must find that the variance will not result in an unreasonable risk to health (URTH) to the public served by the public water system.

Under section 1413(a)(4), States that choose to issue general variances must do so under conditions, and in a manner, that are no less stringent than section 1415. Of course, a State may adopt standards that are more stringent than the EPA's standards. EPA specifies BATs for general variance purposes. EPA may identify as BAT different treatments under section 1415 for variances other than the BAT under section 1412 for MCLs. The BAT findings for section 1415 may vary depending on a number of factors, including the number of persons served by the public water system, physical conditions related to engineering feasibility, and the costs of compliance with MCLs. In this final rule, EPA is not specifying different BAT for variances under section 1415(a).

Under section 1416(a), EPA or a State may exempt a public water system from any requirements related to an MCL or treatment technique of an NPDWR if it finds that: (1) Due to compelling factors (which may include a variety of "compelling" factors, including economic factors such as qualification of the PWS as serving a disadvantaged community), the PWS is unable to comply with the requirement or implement measure to develop an alternative source of water supply; (2) the exemption will not result in an URTH; (3) the PWS was in operation on the effective date of the NPWDR, or for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to the new system; and (4) management or restructuring changes (or both) cannot reasonably result in compliance with the Act or improve the quality of drinking water.

If EPA or the State grants an exemption to a public water system, it must at the same time prescribe a schedule for compliance (including increments of progress or measures to develop an alternative source of water supply) and implementation of appropriate control measures that the State requires the system to meet while the exemption is in effect. Under section 1416(b)(2)(A), the schedule prescribed shall require compliance as expeditiously as practicable (to be determined by the State), but no later than 3 years after the compliance date for the regulations established pursuant to section 1412(b)(10). For public water systems serving 3,300 people or less and needing financial assistance for the necessary improvements, EPA or the State may renew an exemption for one or more additional two-year periods, but not to exceed a total of six years, if the system establishes that it is taking all practicable steps to meet certain requirements specified in the statute. Thus, the maximum possible duration of a small systems exemption is nine years beyond the 5-year compliance schedule specified in today's rule.

A public water system shall not be granted an exemption unless it can establish that either: (1) The system cannot meet the standard without capital improvements that cannot be completed prior to the date established pursuant to section 1412(b)(10); (2) in the case of a system that needs financial assistance for the necessary implementation, the system has entered into an agreement to obtain financial assistance pursuant to section 1452 or any other Federal or State program; or (3) the system has entered into an enforceable agreement to become part of a regional public water system.

EPA believes that exemptions will be an important tool to help States address the number of systems needing financial assistance to achieve compliance with the arsenic rule (and other rules) with the available supply of financial assistance. About 2,300 CWSs and about 1,100 NTNCWSs will need to install treatment to achieve compliance with today's final rule. CWSs and not-for-profit NTNCWSs are eligible for assistance from the Drinking Water State Revolving Fund (DWSRF). Between its inception in Federal Fiscal Year 1997 and June 2000, the DWSRF program has provided assistance to about 1,100 systems. Given the many competing demands being placed on financial assistance programs, the ability to extend the period of time available for a system to receive financial assistance will provide important flexibility for States and systems. Exemptions provide an opportunity to extend the period of time during which a system can achieve compliance, thus providing needy systems with additional time to qualify for financial assistance. Under today's action, all systems have 5 years to achieve compliance. Exemptions for an additional 3 years can be made available to qualified systems. For those qualified systems serving 3,300 persons or less, up to 3 additional 2-year extensions to the exemption are possible, for a total exemption duration of 9 years. When added to the 5 years provided for compliance by the rule, this allows up to 14 years for small systems serving up to 3,300 people to achieve compliance.

EPA will issue guidance in the near future on considerations involved in granting exemptions under the arsenic rule, including making findings of no URTH where exemptions are offered.

I. What Analytical Methods are Approved for Compliance Monitoring of Arsenic and What are the Performance Testing Criteria for Laboratory Certification?

1. Approved Analytical Methods

Today's rule lists four analytical technologies that are approved for compliance determinations of arsenic at the MCL of 0.01 mg/L (see Table I.I–1). As noted in the June 22, 2000 proposed rule (65 FR 38888, EPA, 2000i), the methods listed in Table I.I–1 are the same analytical technologies that were approved for arsenic when the MCL was 0.05 mg/L, with the exception of the methods that use Inductively Coupled Plasma Atomic Emission Spectroscopy (ICP–AES) measurement technology. EPA is withdrawing two ICP–AES methods (EPA Method 200.7 and SM 3120B) because their detection limits (0.008 mg/L and 0.050 mg/L respectively) are too high to reliably determine compliance with an MCL of 0.01 mg/L. In the June 2000 proposed rule, EPA noted that the ICP–AES methods were rarely used to obtain laboratory certification when analyzing low level challenge samples for arsenic. Therefore, we believe withdrawal of the availability of the ICP–AES methods for compliance determinations of arsenic in drinking water will not affect laboratory capacity. EPA did not receive any adverse comment on the proposal to withdraw approval of these two methods, and today's final rule amends the CFR to effect this withdrawal.

TABLE I.I–1.—APPROVED ANALYTICAL METHODS (40 CFR 141.23) FOR ARSENIC AT THE MCL OF 0.01 MG/L

Methodology	Reference method
Inductively Coupled Plasma Mass Spectroscopy (ICP–MS)	200.8 (EPA)
Stabilized Temperature Platform Graphite Furnace Atomic Absorption (STP–GFAA)	200.9 (EPA)
Graphite Furnace Atomic Absorption (GFAA)	3113B (SM) D–2972–93C (ASTM)
Gaseous Hydride Atomic Absorption (GHAA)	3114B (SM) D–2972–93B (ASTM)

2. Performance Testing Criteria for Laboratory Certification

For purposes of drinking water laboratory certification, the Agency specifies pass/fail (acceptance) limits for a successful analysis of the required annual challenge sample, i.e., a performance evaluation (PE) or performance testing (PT) sample. These acceptance limits have been historically derived using one of two different approaches:

(a) Variable acceptance limits uniquely derived for each PE study from a regression analysis of the performance of all laboratories that participate in that PE-study, or

(b) Fixed acceptance limits derived from a regression analysis of the laboratory PE sample analysis results in several PE studies.

Variable acceptance limits are analogous to "grading on a curve" which means that the pass/fail limit can vary from PE study to study depending on the quality and experience of the laboratories participating in the study. These limits are specified in the CFR as plus or minus two sigma (2) where sigma is the standard deviation of the analytical results reported in the PE study. EPA specifies variable acceptance limits when a method or measurement technology is new enough that an insufficient number of experienced laboratories have participated in the PE studies or when only a few PE studies have been conducted.

EPA prefers the fixed acceptance limits approach because it is the better indicator of laboratory performance averaged over time and several different concentrations of the target analyte. Fixed limits also provide the same pass/fail benchmark in each PE study. As discussed in the proposed rule, EPA has a large base of PE-study data from which to derive a practical quantitation limit (PQL) and a fixed PE-study acceptance limit for arsenic. Thus, as proposed in the June 2000 rule, today's final rule amends § 141.23(k)(3)(ii) to specify an acceptance limit of ±30% in PE (now known as PT) samples spiked with arsenic at the PQL of 0.003 mg/L or greater. For a brief discussion of the derivation of the PQL for arsenic, see section III.B.1, What is the feasible level?

J. How Will I Know if My System Meets the Arsenic Standard?

This section summarizes changes to the arsenic monitoring and compliance determination requirements. The Agency is also changing the methods used by a system to determine if it is in violation of an MCL for all of the regulated inorganic contaminants (IOCs), synthetic organic contaminants (SOCs), and volatile organic contaminants (VOCs). See section I.J.3. for more information regarding violation determinations.

1. Sampling Points and Grandfathering of Monitoring Data

In today's rule, the Agency is moving the requirements associated with arsenic into § 141.23(c) making it consistent with the requirements for IOCs regulated under the standardized monitoring framework. All CWS and NTNCWSs must monitor for arsenic at each entry point to the distribution system. In some cases, § 142.11(1) allows States to establish regulations that "vary from comparable regulations set forth in part 141 of this chapter, and demonstrate that any different State regulation is at least as stringent as the comparable regulation contained in part 141." Using this authority, States may allow systems to collect samples at an alternative location (e.g., the first point of drinking water consumption in the distribution system) if the State justifies in its primacy program that the alternative location is equally or more protective. States could implement the change in sampling location once the primacy package is approved.

The MCL compliance elements of the rule become effective in 2006. Some ground water systems will collect samples to comply with the sampling requirements for all regulated IOCs (including arsenic) in 2005 in accordance with the State monitoring plan. This sampling event will satisfy the monitoring requirements for the 2005–2007 compliance period, but the revised arsenic MCL will not become effective until 2006. Ground water systems may use grandfathered data collected after January 1, 2005 to satisfy the sampling requirements for the 2005–2007 compliance period. The grandfathered data must report results from analytical methods approved for use by this final rule (e.g., the method detection limit must be substantially less than the revised MCL of 10 µg/L). Data collected using unacceptably high detection levels (e.g. using ICP–AES technology) will not be eligible for grandfathering. If the grandfathered data are used to comply with the 2005–2007 compliance period and the analytical result is greater than 10 µg/L, that system will be in violation of the revised MCL on the effective date of the rule. If systems do not use grandfathered data, then surface water systems must collect a sample by December 31, 2006 and ground water systems must collect a sample by December 31, 2007 to demonstrate compliance with the revised MCL.

2. Compositing of Samples

Compositing of samples is allowed under the standardized monitoring framework. The States that allow compositing of samples use the methodology in the Phase II/V regulations as specified in § 141.23(a)(4). In today's rule, CWSs and NTNCWSs will still be allowed to composite samples; however, if arsenic is detected above one-fifth of the revised MCL (2 µg/L), then a follow-up sample must be taken within 14 days at each sampling point included in the composite as described in § 141.23(a)(4). Compliance determinations must be based on the follow up sample result. Water systems may composite samples (temporally and spatially) until a

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contaminant (arsenic or any other contaminant regulated in the Phase II/V regulations) is detected. Once a contaminant has been detected in a composited sample at concentrations greater than one-fifth of the MCL, the system(s) must discontinue the practice of compositing samples for all future monitoring.

3. Calculation of Violations

In today's rule, the Agency is clarifying the compliance determination section for the IOCs (including arsenic), the SOCs, and the VOCs in §§ 141.23(i), 141.24(f)(15), and 141.24(h)(11), respectively.

Systems will determine compliance based on the analytical result(s) obtained at each sampling point. If any sampling point is in violation of an MCL, the system is in violation. For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. Systems monitoring annually or less frequently whose sample result exceeds the MCL for any inorganic contaminant in § 141.23(c), or whose sample results exceeds the trigger level for any organic contaminant listed in § 141.24(f) or § 141.24(h), must revert to quarterly sampling for that contaminant the next quarter. Systems are only required to conduct quarterly monitoring at the entry point to the distribution system at which the sample was collected and for the specific contaminant that triggered the system into the increased monitoring frequency. Systems triggered into increased monitoring will not be considered in violation of the MCL until they have completed one year of quarterly sampling. If any sample result will cause the running annual average to exceed the MCL at any sampling point (i.e., the analytical result is greater than four times the MCL), the system is out of compliance with the MCL immediately. Systems may not monitor more frequently than specified by the State to determine compliance unless they have applied to and obtained approval from the State. If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running annual average of the samples collected. If a sample result is less than the method detection limit, zero will be used to calculate the annual average. States have the discretion to delete results of obvious sampling or analytic errors.

States still have the flexibility to require confirmation samples for positive or negative results. States may require more than one confirmation sample to determine the average exposure over a 3-month period. Confirmation samples must be averaged with the original analytical result to calculate an average over the 3-month period. The 3-month average must be used as one of the quarterly concentrations for determining the running annual average. The running annual average must be used for compliance determinations.

The rule requires that monitoring be conducted at all entry points to the distribution system. However, the State has discretion to require monitoring and determine compliance based on a case-by-case analysis of individual drinking water systems. The Agency cannot address all of the possible outcomes that may occur at a particular water system; therefore, EPA encourages drinking water systems to inform State regulators of their individual circumstances. Some systems have implemented elaborate plans including targeted, increased monitoring that is more representative of the average annual contaminant concentration to which individuals are being exposed (some States use a time-weighted or flow-weighted averaging approach to determine compliance).

Some States require that systems collect samples from wells that only operate for one month out of the year regardless of whether they are operating during scheduled sampling times. The State may determine compliance based on several factors including, but not limited to, the quantity of water supplied by a source, the duration of service of the source, and contaminant concentration.

4. Monitoring and Compliance Schedule

Systems must begin complying with the clarified monitoring and compliance determination provisions of today's rule effective January 22, 2004 for inorganic, volatile organic, and synthetic organic contaminants. These requirements clarify that for §§ 141.23(i)(2), 141.24(f)(15)(ii), and 141.24(h)(11)(ii) compliance will be determined based on the running annual average of the initial MCL exceedance and any subsequent State-required confirmation samples. In addition, the clarifications address calculation of compliance when a system fails to collect the required number of samples. Compliance (determined by the average concentration) will be based on the total number of samples collected. Some systems have purposely not collected the required number of quarterly samples and only incurred monitoring and reporting violations for the uncollected samples. Any systems that avoid required sampling will calculate MCL violations by dividing the summed samples by the actual number of samples taken. This clarification did not change §§ 141.23(i)(1) and 141.24(h)(11)(i) which allow systems to use zero for all non-detects when calculating MCL violations. In addition, if any one sample would cause the annual average to be exceeded, the system is out of compliance immediately.

Also in today's rule, the Agency is moving the arsenic monitoring and compliance requirements from §§ 141.23(l) to (q) to the standardized monitoring framework in § 141.23 for other IOCs. States may grant systems nine-year monitoring waivers using the conditions in § 141.23(c) for arsenic. The criteria for developing a State waiver program were published in the Phase II/V rules, and as noted in section IV.B. of this rule, the Agency is not modifying the waiver criteria in today's rulemaking. However, the revised arsenic rule is not effective until January 23, 2006 (see section I.M. for a more detailed discussion regarding the effective date of the rule.). States and utilities supported moving arsenic into the standardized monitoring framework.

To use compliance data after the effective date of the 10 µg/L MCL, systems must use an approved method with a method detection limit substantially less than the revised arsenic MCL of 10 µg/L. This means that after December 31, 2006 and December 31, 2007 all surface water systems and groundwater systems, respectively, may not use analytical methods using the ICP–AES technology, because the detection limits for these methods are 8 µg/L or higher. This restriction means that two ICP–AES methods that were approved when the MCL was 50 µg/L may not be used for compliance determinations at the revised MCL of 10 µg/L. The two methods are EPA Method 200.7 and SM 3120B. Prior to 2005, systems may have compliance samples analyzed with these less sensitive methods. However, EPA advises systems to have compliance samples analyzed and reported at the laboratory minimum detection limit.

If sampling demonstrates that arsenic exceeds the MCL, a CWS will be triggered into quarterly monitoring for that sampling point "in the next quarter after the violation occurred." The State may allow the system to return to the routine monitoring frequency when the State determines that the system is reliably and consistently below the MCL. However, the State cannot make a determination that the system is reliably and consistently below the MCL until a minimum of two consecutive ground water, or four consecutive surface water samples, have been collected (§ 141.23(c)(8)).

The Agency is not promulgating a reduced monitoring approach similar to the revised radionuclides final rule published on December 7, 2000 (65 FR 76708; EPA, 2000p). As noted above, all systems have to collect IOC samples once a year or once every three years, depending on the source water, unless they have a waiver. The Agency believes that very few States issue waivers for IOCs because the analysis is relatively inexpensive and most IOCs are naturally occurring elements that may be found in concentrations above the method detection limit. Therefore, the majority of systems must collect routine samples for the regulated IOCs; and most of the methods used for analysis of these contaminants will measure arsenic as well as antimony, beryllium, cadmium, chromium, copper, and nickel.

K. What do I Need to tell My Customers?

1. Consumer Confidence Reports

a. General requirements. In 1998, EPA promulgated the Consumer Confidence Report Rule (CCR) (codified at 40 CFR part 141, subpart O), a final rule requiring community water systems to issue annual water quality reports to their customers (63 FR 44512; EPA, 1998i). The reports are due each year by July 1, and provide a snapshot of water quality over the preceding calendar year. The reports include information on levels of detected contaminants and if the system has violated an MCL or a treatment technique, must also include information on the potential health effects of contaminants from appendix A to subpart O. When they have such violations, systems must also include in their report an explanation of the violation and remedial measures taken to address it. The arsenic health effects language is currently required when arsenic levels exceed 25 µg/L, one-half the existing MCL of 50 µg/L, required under § 141.154(b).

EPA is today retaining the health effects language for arsenic issued with the final CCR Rule and updating appendix A to subpart O to include the MCL and MCLG as revised in this rule, together with special arsenic-specific reporting requirements.

In addition to the standard reporting of arsenic detects and arsenic MCL violations, EPA is today finalizing a requirement (proposed at § 141.154(b); finalized at § 141.154(f)) that CWSs that detect arsenic between the revised and existing MCL (i.e., above 10 µg/L and up to and including 50 µg/L) prior to the effective date for compliance with the revised MCL, include the CCR Rule health effects language in their reports. This action is required even though, technically, the systems are not in violation of the regulations. This requirement will be effective for the five years after promulgation, when systems are not yet required to comply with the revised MCL. Then, beginning January 23, 2006, systems out of compliance must report violations of the revised arsenic MCL under § 141.153(d)(6) to the public.

Based on stakeholder and commenter input, the Agency decided in the final CCR Rule that it would use authority granted in SDWA section 1414(c)(4)(B)(vi) to require inclusion of health effects language for arsenic exceedances before the compliance date. That section allows the Administrator to require inclusion of health effects language for "not more than three regulated contaminants" other than those found to violate an MCL. The Agency used this authority for total trihalomethanes in the Stage 1 Disinfectants and Disinfection Byproducts Rule (63 FR 69390). The Agency is now using this same authority for arsenic, because it believes that it is important to provide customers with the most current understanding of the risk presented by this contaminant as soon as possible after establishing a new standard. This provision provides systems the flexibility to put this health effects information into context and to explain to customers that the system is complying with existing standards.

EPA modified the language it proposed on June 22, 2000 to reflect the MCL promulgated today and to clarify what language a system must include in its report. Systems subject to § 141.154(f) must begin including the arsenic health effects language in the report due by July 1, 2002.

b. Special informational statement. In addition, in the CCR Rule, the Agency decided to require that CCRs include additional information about certain contaminants, one of which was arsenic. As explained in the preamble to the CCR Rule (63 FR 44512 at 44514; EPA, 1998i), because of commenters' concerns about the adequacy of the current MCL, EPA decided that systems that detect arsenic between 25 µg/L and the current MCL must include some information regarding the arsenic standard (§ 141.154(b)). This informational statement is different from the health effects language required for an MCL violation. EPA noted in the CCR rule and in the arsenic proposal that the informational statement requirement would be deleted upon promulgation of a revised MCL.

In view of the fact that EPA is today finalizing an MCL somewhat higher than the technologically feasible MCL, and that some commenters expressed concern about the risk that a higher-than-feasible MCL might present to certain consumers, EPA is today retaining and revising an existing § 141.154(b) requirement that systems which find arsenic below the MCL must provide additional information to their customers. EPA believes that consumers should be aware of the uncertainties surrounding the risks presented even by very low levels of arsenic. While EPA addressed many of the sources of uncertainty in its risk analysis of arsenic in support of the final rule, several sources of uncertainty remain. Chief among these is the mode of action (i.e., the shape of the dose-response curve). EPA continues to research the effects of arsenic (according to an arsenic research plan required by the 1996 SDWA Amendments and submitted to Congress) and should have a better understanding of these effects as the relevant research is completed. EPA believes that this uncertainty adequately justifies retaining the existing requirement to provide consumers with information about low levels of arsenic.

The existing § 141.154(b) requirement is today updated in two ways. First, the arsenic level that triggers the additional information is reset from 25 µg/L (half the existing MCL) to 5 µg/L (half the revised MCL). In the preamble to the CCR Rule, we explained that "[many] commenters agreed that half the MCL would be an appropriate threshold for requiring additional risk-related information." EPA continues to believe that half the MCL is an appropriate trigger for special information about certain contaminants. Beginning with the report due by July 1, 2002, CWSs that find arsenic above 5 µg/L and up to and including 10 µg/L must include § 141.154(b) special health information about arsenic in their consumer confidence reports.

Second, the suggested text of the special information is updated. Rather than stating that "EPA is reviewing the drinking water standard for arsenic . . .," the statement announces clearly that the consumer's water meets EPA's new standard while also noting the cost-benefit trade-off involved in setting that standard. The suggested text further notes that there are uncertainties (described in section III.F of this notice) surrounding the risks of low levels of arsenic. Systems retain the flexibility, as defined in the existing requirement, to

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adjust this language in consultation with the Primacy Agency.

2. Public Notification

On May 4, 2000, EPA issued the final Public Notification Rule (PNR) to revise the minimum requirements that public water systems must meet for public notification of violations of EPA's drinking water standards (65 FR 25982; EPA, 2000e). Water systems must begin to comply with the revised PNR regulations on October 31, 2000 (if they are in jurisdictions where the program is directly implemented by EPA) or on the date a primacy State adopts the new requirements (not to exceed May 6, 2002). EPA's drinking water regulation on arsenic affects public notification requirements and amends the PNR as part of its rulemaking.

Today's final rule will require CWSs and NTNCWSs to provide a Tier 2 public notice for arsenic MCL violations and to provide a Tier 3 public notice for violations of the monitoring and testing procedure requirements. The new arsenic MCL will become effective January 23, 2006. CWSs and NTNCWSs must provide public notification to consumers for any violations after the effective date of the revised arsenic MCL. The PNR requires owners and operators of public water systems to give notice to persons they serve for all violations when they are operating under a variance or exemption (or violate conditions of the variance or exemption).

L. What Financial Assistance is Available for Complying With This Rule?

There are two major sources of Federal financial assistance available for water systems: the Drinking Water State Revolving Fund (DWSRF) and the Water and Waste Disposal Loan and Grant Program of the Rural Utilities Service (RUS) of the U. S. Department of Agriculture.

The 1996 SDWA Amendments authorized (*i.e.*, approved spending) $9.6 billion for the DWSRF program. To date, Congress has appropriated (*i.e.*, provided) $4.2 billion, which includes $825 million for the program in Fiscal Year 2001. By the end of September 2000, States had been awarded $3.2 billion in capitalization grants and, from that, had provided more than $2.8 billion in assistance to eligible drinking water systems. The Federal capitalization grant, together with State matching funds, is currently making available about $1 billion per year. States have considerable discretion in designing their DWSRF program, and have the option of offering special assistance to systems that the State considers to be disadvantaged. Special assistance may include principal forgiveness, a negative interest rate, an interest rate lower than that charged to non-disadvantaged systems, and extended repayment periods of up to 30 years. Federal law allows DWSRF assistance to be provided to water systems of both public ownership and private ownership, although some States are unable or choose not to provide assistance to privately owned systems.

EPA recognizes that public water systems and States face a significant challenge in implementing new requirements that are needed to ensure the continued provision of safe drinking water. While the DWSRF program is proving to be a significant source of funding, it cannot be viewed as the only source of funding. It will take a concerted effort on the part of Federal, State and local governments, private business, and utilities to address the significant infrastructure needs identified by public water systems. In order to ensure that the DWSRF program is used to focus attention on the highest priority needs, all States must give priority to those drinking water infrastructure improvement projects that will have the greatest public health benefit or ensure compliance with SDWA. State DWSRF programs are currently making loans available to the highest ranked projects on their lists and are also using a portion of the grants to support other important drinking water program activities.

The RUS program is focused on providing a safe, reliable water supply and wastewater treatment to residents of rural America. The program offers a combination of low interest loans and grants to systems serving rural areas and cities and towns of up to 10,000 persons and which are publicly owned (including Native American systems) or operated as not-for-profit corporations. In recent years the RUS program has typically offered assistance totaling about $1.3 billion per year, about 60% of which is directed to drinking water projects. Thus, about $780 million per year is available for rural drinking water systems from this program. Together with the approximately $1 billion per year being made available through the DWSRF, this results in a total of about $1.78 billion per year of Federal financial assistance available for drinking water.

Other Federal financial assistance programs exist that may help systems with SDWA compliance related expenditures. However, these other programs are not generally as large or focused on drinking water as are the DWSRF and RUS programs. EPA's Environmental Financial Advisory Board has developed a "Guidebook of Financial Tools" (EPA, 1999c), which offers a comprehensive summary of public and private programs and mechanisms for paying for drinking water and other environmental systems. The handbook is available through EPA's web site at: *http://www.epa.gov/efinpage/guidbk98/index.htm.*

The Federal financial assistance programs described previously clearly face numerous, competing demands on their resources. EPA's 1995 Drinking Water Infrastructure Needs Survey (EPA, 1997a) identified a total 20-year need for all systems of $138.4 billion. The single largest category of need (accounting for over half of the total need) is installation and rehabilitation of transmission and distribution systems. Treatment needs constitute the second largest category of need, accounting for over ¼ of total needs. Storage and source rehabilitation and development constitute the remaining major categories of needs. Thus, systems seeking financial assistance for installation of arsenic treatment are competing for resources with systems seeking assistance for compliance with other rules and with systems seeking resources for basic infrastructure repair and replacement. In seeking to meet these numerous and competing needs, the Agency recognizes the importance of priority setting for financial assistance programs. Systems having the financial capability to secure funding through the capital markets should do so, leaving the Federal financial assistance programs to assist the truly needy systems. Since the demand for assistance will likely outstrip the supply of assistance, States may wish to consider exemptions, which will provide additional time for systems to secure financial assistance.

M. What is the Effective Date and Compliance Date for the Rule?

In the proposed rule, EPA made a finding that all small systems (*i.e.*, systems serving 10,000 people or less) would be granted a 2-year capital improvement extension which extends the MCL effective date for purposes of compliance with the new MCL to January 23, 2006. EPA proposed the 2-year capital improvement extension for small systems because of the time required for systems to plan, finance, design and construct new treatment systems.

Large systems were not provided this additional time because of the greater resources these systems have to perform capital improvements in a timely manner. However, upon consideration of information submitted by commenters, EPA has determined that large systems will also require an additional 2 years to complete the capital improvements necessary to comply with the arsenic MCL. While large systems (*i.e.*, systems serving more than 10,000 people) do have greater resources to implement capital improvements, (*e.g.*, engineering and construction management staff to manage the projects), these systems generally also have more entry points to the distribution system that will require treatment.

A number of treatment technologies are listed as BAT for the proposed rule: ion exchange, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening and electrodialysis reversal. There are also several emerging technologies for arsenic removal, such as nanofiltration and granular ferric hydroxide. To ensure cost effective compliance with the arsenic MCL, systems will need to evaluate their treatment technology options as a first step. This planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Systems choosing to conduct pilot testing may take a year or more to contract with vendors and to perform pilot testing.

Once the planning step is completed systems must design and construct the treatment systems. Design and permitting of the treatment systems can take an additional year, and construction of the treatment system can take another year. Because systems will also need time to: obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, it is likely that most large systems will need additional time beyond the three-year effective date for compliance with the new MCL that EPA proposed.

Based upon these considerations, EPA determined, in accordance with section 1412(b)(10) of SDWA, that the compliance date for the new arsenic MCL, regardless of system size, will be 5 years from the date of promulgation of the standard. See section I.H. for more information regarding variance and exemptions.

N. How Were Stakeholders Involved in the Development of This Rule?

EPA met extensively with a broad range of groups during the development of the arsenic proposal, both at EPA-sponsored meetings and at other organizations' meetings. The **Federal Register** published notices about EPA's arsenic meetings, and we made conference call lines available for those who chose not to attend in person. In addition, EPA notified people about regulatory actions via the three **Federal Register** notices (proposal, notice of data availability, and correction notice), by mail and e-mail. Over 600 people asked to be on the mailing list during the regulatory development period.

EPA held arsenic stakeholders meetings September 11–12, 1997 in Washington, DC; February 25, 1998 in San Antonio, Texas; May 5, 1998 in Monterey, California; June 2–3, 1999 in Washington, DC; and August 9, 2000 in Reno, Nevada. For each of these meetings we invited representatives of States, tribal groups, associations, utilities and environmental groups. The docket for the proposed rule (W–99–16) contains the meeting discussion papers, agendas, participants lists, presentation materials, and executive meeting summaries. All the meeting materials, except the presentations and attendance list, are also available on EPA's arsenic in drinking water web page, *www.epa.gov/safewater/arsenic.html.*

EPA also presented sessions on drinking water regulations (including arsenic) at the National Indian Health Board Annual Conference in Anchorage, Alaska in September 1998. The Inter-tribal Council of Arizona hosted a consultation for EPA with Tribes February 24–25, 1999 in Las Vegas, NV at which an overview of the proposed arsenic regulation was presented. EPA also conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council May 18–20, 1999 in Eureka, California. The Council distributed materials and gathered comments on EPA's drinking water regulations from all recognized Tribal governments.

In addition to the general stakeholder meetings, EPA also had targeted meetings with States' representatives. In May 1999, State regulatory representatives from California, Nevada, Michigan, Illinois, Texas, Indiana, New Mexico, and Louisiana joined EPA in a discussion on the development of the cost of compliance decision tree. In August 1999, State regulatory representatives from Illinois, Indiana, New Mexico, and Texas joined EPA workgroup members in a discussion of the NRC study use, review of the occurrence work, treatment technology update, and regulatory changes. The interaction from these meetings with State colleagues improved the regulatory language and the preamble.

In May 2000, EPA presented a summary of the rule to the National Governors' Association. In May 2000, EPA held a dialogue in Washington, DC with State officials and the associations that represent elected officials. Presentations on arsenic and other drinking water rules under development were given to representatives of the National Association of Towns and Townships, National Governors' Association, National Association of Counties, National League of Cities, Association of State Drinking Water Administrators, Environmental Council of the States, Florida Department of Environmental Protection, Drinking Water Section, Association of State and Territorial Health Officials, and the International City/County Management. The purpose of the dialogue was to consult on the expected compliance and implementation costs of these rules for State, county, and local governments and gain a better understanding of the views of representatives of State, county, and local governments and their elected officials. The meeting materials are in the docket for the proposed rule.

In addition to the various special meetings and discussions mentioned previously, EPA representatives delivered arsenic regulatory development presentations at a variety of meetings held by other organizations. These included the American Water Works Association (AWWA) Inorganic Contaminants Meetings in February, 1998 in San Antonio, TX and in February, 2000 in Albuquerque, NM; meetings of the Association of State Drinking Water Administrators (ASDWA) in February and October 1998, March and October 1999, and in October 2000; meetings of the Association of Metropolitan Water Agencies (AMWA) in January and March 1998; and a meeting of the Association of California Water Agencies in March 1998. EPA also gave several technical presentations and regulatory updates at the AWWA annual meetings as well as at the AWWA Water Quality and Technology Conferences in 1998, 1999, and 2000. EPA participated in the Society of Toxicology arsenic workshop in Philadelphia, PA in March 2000. Finally, EPA co-sponsored and participated in the four International Conferences on Arsenic Exposure and Health Effects in July 1993, June 1995, July 1998, and June 2000.

After the proposal was published in the **Federal Register**, EPA notified all persons on its electronic mailing list for the arsenic rule of its availability and sent information. The Regulatory Impact Analysis went on the arsenic web page a week after the proposal publication. Similarly, EPA also notified the individuals and organizations on this

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mailing list about the NODA and the correction notice.

II. Statutory Authority

Section 1401 of SDWA requires a "primary drinking water regulation" to specify a MCL if it is economically and technically feasible to measure the contaminant and to include testing procedures to insure compliance with the MCL and proper operation and maintenance. An NPDWR that establishes an MCL also lists the technologies that are feasible to meet the MCL, but systems are not required to use the listed technologies (section 1412(b)(3)(E)(i)). As a result of the 1996 amendments to SDWA, when issuing a NPDWR, EPA must also list affordable technologies that achieve compliance with the MCL or treatment technique for three categories of small systems: those serving 10,000 to 3301 persons, 3300 to 501 persons, and 500 to 25 persons. EPA can list modular (packaged) and POE and POU treatment units for the three small system sizes, as long as the units are maintained by the public water system or its contractors. Home units must contain mechanical warnings to notify customers of problems (section 1412(b)(4)(E)(ii)).

In section 1412(b)(12)(A) of SDWA, as amended August 6, 1996, Congress directed EPA to propose a national primary drinking water regulation for arsenic by January 1, 2000 and issue the final regulation by January 1, 2001. At the same time, Congress directed EPA to develop a research plan by February 2, 1997 to reduce the uncertainty in assessing health risks from low levels of arsenic and conduct the research in consultation with the NAS, other Federal agencies, and interested public and private entities. The amendments allowed EPA to enter into cooperative agreements for research. On October 27, 2000, Public Law 106–377, the bill which included Fiscal Year 2001 appropriations for EPA, amended the statutory deadline to direct EPA to promulgate a final arsenic standard by no later than June 22, 2001.

Section 1412(a)(3) requires EPA to propose an MCLG simultaneously with the NPDWR. The MCLG is defined in section 1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Section 1412(b)(4)(B) specifies that each NPDWR will specify an MCL as close to the MCLG as is feasible, with two exceptions added in the 1996 amendments. First, the Administrator may establish an MCL at a level other than the feasible level if the treatment to meet the feasible MCL would increase the risk from other contaminants or the technology would interfere with the treatment of other contaminants (section 1412(b)(5)). Second, if benefits at the feasible level would not justify the costs, EPA may propose and promulgate an MCL "that maximizes health risk reduction benefits at a cost that is justified by the benefits" (section 1412(b)(6)).

When proposing an MCL, EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative maximum contaminant level considered (section 1412(b)(3)(C)(i)). This includes the quantifiable and nonquantifiable benefits from reductions in health risk, including those from removing co-occurring contaminants (not counting benefits resulting from compliance with other proposed or final regulations), costs of compliance (not counting costs resulting from other regulations), any increased health risks (including those from co-occurring contaminants) that may result from compliance, incremental costs and benefits of each alternative MCL considered, and the effects on sensitive subpopulations (e.g., infants, children, pregnant women, elderly, seriously ill, or other groups at greater risk). EPA must analyze the quality and extent of the information, the uncertainties in the analysis, and the degree and nature of the risk. As required by the statute, EPA issued a HRRCA for arsenic (EPA, 2000i) as section XIII of the June 22, 2000 arsenic proposal (65 FR 38888 at 38957).

The 1996 amendments also require EPA to base its action on the best available, peer-reviewed science and supporting studies and to present health effects information to the public in an understandable fashion. To meet this obligation, EPA must specify, among other things,

> peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data (section1412(b)(3)(B)(v)).

Section 1413(a)(1) allows EPA to grant States primary enforcement responsibility (primacy) for NPDWRs when EPA has determined that the State has adopted regulations that are no less stringent than EPA's. States must adopt comparable regulations within two years of EPA's promulgation of the final rule, unless a two-year extension is granted. State primacy also requires, among other things, adequate enforcement (including monitoring and inspections) and reporting. EPA must approve or deny State applications within 90 days of submission (section 1413(b)(2)). In some cases, a State submitting revisions to adopt an NPDWR has primacy enforcement authority for the new regulation while EPA action on the revision is pending (section 1413(c)). Section 1451(a) allows EPA to grant primacy enforcement responsibility to Federally recognized Indian Tribes, providing grant and contract assistance, using the procedures applied to States.

III. Rationales for Regulatory Decisions

A. What Is the MCLG?

The proposed rule suggested that an MCLG of zero be established for arsenic in view of the fact that we are currently unable to specify a safe threshold level due to uncertainty about the mode of action for arsenic. Today's rule establishes a final MCLG for arsenic of zero. After full consideration of public comments, EPA continues to believe that the most scientifically valid approach, given the lack of critical data, is to use the linear approach to assessing the mode of action. This approach results in an MCLG of zero. In the proposal and the NODA, EPA noted that the available data point to several potential carcinogenic modes of action for arsenic (EPA also requested additional data on the mode of action). However, which mode(s) of action is operative is unknown. For this reason, while the Agency recognizes that the dose-response relationship may be sublinear, the data do not provide any basis upon which EPA could reasonably construct this relationship. Thus, EPA has no basis upon which to depart from its assumption of linearity. The NRC report noted that available data that could help determine the shape of the dose-response curve are inconclusive and do not meet EPA's stated criteria for departure from the default assumption of linearity (NRC, 1999). See section III.D.1 for a thorough discussion of the dose-response assessment.

Because the postulated mode of action for arsenic cannot specifically be described and the key events are unknown, the Agency lacks sufficient available, peer-reviewed information to estimate quantitatively a non-linear mode of action. The Agency has thus decided not to depart from the assumption of linearity in selecting an MCLG of zero.

B. What Is the Feasible Level?

1. Analytical Measurement Feasibility

In the development of a drinking water regulation, EPA derives a practical quantitation limit (PQL) to estimate or evaluate the minimum,

reliable quantitation level (concentration) that most laboratories can be expected to meet during day-to-day operations. The PQL accounts for the limits of current measurement technologies and the laboratories that use the methods written around these analytical technologies. The PQL was defined in a November 13, 1985 rule (50 FR 46906, EPA, 1985b) as "the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory operating conditions." A PQL is determined either through use of interlaboratory studies or, in absence of sufficient studies, through the use of a multiplier of 5 to 10 times the method detection limit (MDL). Interlaboratory data are obtained from water supply (WS) studies that are conducted by EPA to certify drinking water laboratories. The WS studies require a candidate laboratory to measure the concentration of the target analyte within specified limits (e.g., ±30%) of the amount spiked into a PE (now called PT) challenge sample. Using graphical or linear regression analysis of the WS data, the Agency sets a PQL at a concentration where at least 75% of experienced laboratories (generally EPA and State laboratories) could perform within this acceptable limit for accuracy, e.g., ±30%.

As discussed in the June 22, 2000 proposed rule for arsenic, the Agency determined that the PQL (i.e., the feasible level of measurement) for arsenic in drinking water is 0.003 mg/L with an acceptance limit of ±30%. The derivation of the PQL for arsenic is consistent with the process used to determine PQLs for other metal contaminants regulated under SDWA and takes into consideration the recommendations from EPA's SAB (EPA, 1995). Using acceptance limits of ±30% and linear regression analysis of six recent WS studies, EPA derived a PQL of 0.00258 mg/L for arsenic, which was rounded to 0.003 mg/L at the ±30%. While the PQL represents a relatively stringent target for laboratory performance, based on the WS data used to derive the PQL for arsenic, the Agency believes most laboratories (using appropriate quality assurance and quality control procedures) can achieve this level on a routine basis.

2. Treatment Feasibility

EPA has determined that 3 µg/L is technologically feasible for large systems based on peer-reviewed treatment information. EPA has listed seven BATs for arsenic in the final rule. They are: ion exchange when sulfate ≤50 mg/L, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening at pH >10.5, electrodialysis reversal, and oxidation/filtration when the iron to arsenic ratio is at least 20:1. Bench, pilot and full-scale data were examined to determine the capabilities of the treatment processes. The treatment performance data are summarized in "Technologies and Costs for the Removal of Arsenic from Drinking Water" (EPA, 2000t).

C. How Did EPA Revise its National Occurrence Estimates?

1. Summary of Occurrence Data and Methodology

Our data and methodology for estimating arsenic occurrence are substantially the same as in the proposed rule (65 FR 38888 at 38903; EPA, 2000i). The data and methodology are described in detail in (EPA, 2000r). Following is a summary of our method. All of the elements of this summary are the same as in the proposed rule, except where noted.

Our occurrence database consists of arsenic compliance monitoring samples of finished drinking water, submitted voluntarily by drinking water agencies in 25 States. The 25 States are distributed throughout the U.S., with at least one located in each of the seven geographic regions that we used in our analysis (65 FR 38888 at 38906; EPA, 2000i; EPA, 2000r). In some States we used data only from a subset of years in which detection limits were lowest. For each PWS in our database, we estimated the mean arsenic concentration over time in finished water, by first "filling in" non-detected concentrations, using one of two statistical methods (EPA, 2000r), then averaging the detected and filled-in observations from that system. Next, we collected the system mean estimates into State distributions, then merged the State distributions into regional and then national distributions. In combining the regional distributions into a national distribution, we weighted each region by the total number of systems in the region, not just the number of systems in the States in our database. This procedure has the same effect as assigning the regional distributions to the 25 States for which we have no observations in our database.

In addition to the distributions of system means, we estimated nationwide intra-system coefficients of variation (ISCV). For a given water system, the ISCV quantifies the variation of mean arsenic levels at the system's entry points to the distribution system (i.e., sampling points of individual wells and treatment points) around the overall system mean. We estimated a separate ISCV for each ground water (gw) CWS, surface water (sw) CWS, and, unlike in the proposed rule, ground water NTNCWS. Each of these ISCVs is assumed to be constant throughout the U.S.

2. Corrections and Additions to the Data

Some public commenters asked whether our data might have errors in the classification of water samples as treated or untreated. If that were the case, then including untreated samples in our database could cause us to overestimate occurrence in finished water. In order to determine whether and to what extent these problems exist, we solicited additional data sets from drinking water agencies in six States (Alabama, California, Illinois, New Mexico, North Carolina, and Texas) from whom we already had data in our draft data set. All six States responded to our request by submitting additional data, including additional identifiers of untreated observations, as well as some new observations not contained in our draft data base. In California, once the newly identified untreated observations were removed from the data set, the number of surface water observations decreased from 2,488 in the draft data set to 1,280 in the final data set. For ground water, on the other hand, the number of samples in California increased from 5,622 to 9,494. The increase resulted in part from the additional data, and in part because we changed our methodology, as we describe below, to include samples from both treated and untreated ground water in our ground water estimates. Changes in the other five States were of smaller size.

We also updated our data set from Utah. The latest data from Utah include more observations and covers the years 1980 to 1999. The total number of observations from Utah in our data set increased from 2,447 to 4,684.

Table III.C–1 compares the number of observations, systems, and States in our database, by system type and source water type, in the proposed and final rules. Note that our complete database is larger than shown in Table III.C–1, but in some States we excluded data from some years in which analytical detection limits were highest. Table III.C–1 counts only the data from the years that we used to estimate occurrence.

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TABLE III.C–1.—SUMMARY OF OCCURRENCE DATABASES FOR THE PROPOSED AND FINAL RULES

System type	Source water	Proposed rule			Final rule		
		# of observations	# of systems	# of States	# of observations	# of systems	# of States
CWS	GW	44,502	15,640	25	53,307	15,931	25
CWS	SW	15,892	2,360	25	16,212	2,228	25
NTNCWS	GW	*6,420	*4,662	*18	7,045	4,382	17
NTNCWS	SW	*420	*150	*14	*409	*118	*15
All	All	67,234	22,812	25	76,973	22,659	25

*Data not used in estimating occurrence.

We also updated our baseline inventory of the public water systems in the U.S. and the populations they serve, by type of system, type of source water, and State. We use this inventory to estimate the numbers of systems and people affected by different MCL options, by multiplying the number of people or systems in a given category by the estimated fraction of systems in that category with mean arsenic greater than the levels of interest. In the proposed rule, the occurrence and regulatory impact analyses used different sets of baseline estimates: occurrence took baseline estimates from EPA's 4th quarter 1997 Safe Drinking Water Information System (SDWIS) database, while the proposal's regulatory impact analysis (RIA) used 4th quarter 1998 SDWIS. The result, as some public commenters pointed out, was that the proposed rule contained two inconsistent sets of estimates of the numbers of people and systems affected by different MCL options (65 FR 38888; EPA, 2000i, Table V–3; EPA, 2000h, Exhibit 4–11). The two estimates of total numbers of systems affected at various MCLs differed by up to 27%. We corrected this inconsistency by adopting, with one modification, the baseline inventory in EPA's Drinking Water Baseline Handbook (EPA, 2000b) throughout this preamble and all supporting documents for the final rule. The inventory in the Baseline Handbook is taken from EPA's 4th quarter 1998 SDWIS database, or the same that was used in the proposed RIA. The only modification we made to the inventory was in Alaska where the Baseline Handbook lists zero NTNCWS and zero population served by NTNCWS. Following public comment from the Alaska Department of Environmental Conservation, we corrected the inventory of NTNCWS in Alaska. The Baseline Handbook and corrected Alaska inventories are shown in Table III.C–2.

TABLE III.C–2.—ALASKA PWS INVENTORIES: BASELINE HANDBOOK AND CORRECTED

System type	Source water	Baseline handbook		Corrected	
		No. of systems	Population served	No. of systems	Population served
CWS	GW	508	227,874	344	175,367
CWS	SW	160	317,155	121	260,792
NTNCWS	GW	0	0	161	51,909
NTNCWS	SW	0	0	35	56,013
All	All	668	545,029	661	544,081

The revised estimates of numbers of systems affected at different arsenic concentrations are shown in Table III.C–6. Since the proposed and final Economic Analysis use the same set of baseline estimates (except for the small correction in Alaska), changes in Table III.C–6 compared to the proposed RIA (EPA, 2000h, Exhibit 4–11) are due to changes in the occurrence estimates in Table III.C–3, which follows. Changes in Table III.C–6 compared to the proposed occurrence analysis (65 FR 38888; EPA, 2000i, Table V–3) are due to changes in occurrence estimates and also correction of the baseline.

3. Changes to the Methodology

In September 1999, EPA sponsored a peer review of our occurrence data and methodology by three independent experts in geochemistry and statistics. In response to that review and public comments, we have made minor revisions to our methodology for estimating occurrence in two ways since the proposed rule.

First, we now estimate the occurrence distribution for ground water NTNCWSs separately from CWSs. In the proposed rule, we used the CWSs distribution as a surrogate for NTNCWSs, for both ground and surface water systems. We now estimate occurrence in ground water NTNCWSs separately, using the same method as for CWSs, as described previously. For ground water NTNCWSs we have data from 17 States, compared to 25 States for CWSs, so there are on average fewer States with data in each region. Moreover we have no data about NTNCWSs from any States in the Southeast region (Alabama, Florida, Georgia, Mississippi, and Tennessee). We therefore used the occurrence distribution for ground water CWSs as a surrogate for ground water NTNCWSs in the Southeast. The revised occurrence estimates for ground water NTNCWSs are shown in Table III.C–3.

We still do not estimate a separate occurrence distribution for surface water NTNCWSs. For surface water NTNCWSs, we did not believe that the 118 systems for which data were provided for NTNCWSs formed as strong a basis for estimating occurrence as the much larger CWS surface water data base, especially in the concentration range of interest. In addition, there is less reason to believe that surface water NTNCWSs will differ from surface water CWSs. We thus believe the surface water CWS estimates provide the soundest basis for estimating impacts given the types of data available.

Second, we have improved our method for estimating intra-system

variability. In the proposed rule, we estimated the ISCV by measuring the total amount of variability of arsenic concentrations around the system mean within each system. The problem with that approach is that it fails to distinguish between-source variability (variability of sampling-point means around the system mean) from within-source variability (variability of observations at each sampling point around the sampling-point mean). Within-source variability includes variations in concentrations through time at a source, and analytical variability caused by imprecision of the analytical methods used to measure arsenic in water samples. The ISCV is intended to describe only between-source variability within a system. Following the recommendations of the peer review, we corrected our model of intra-system variation to include separate terms for between-source and within-source variability. As a result, our estimates of the ISCVs decreased, since we separate out the within-source variability. The revised ISCV estimates are shown in Table III.C–7.

A third change to our methodology is that, for ground water systems, we now include observations on both treated and untreated ground water in our analysis. With the exception of iron removal technologies, most treatment in ground water systems has little effect on arsenic, so one might expect arsenic concentrations to be similar in treated and untreated samples. This turns out to be the case in our data: estimates that included untreated samples were either slightly higher or lower than estimates with only treated samples. We therefore decided to include both treated and untreated samples in our ground water occurrence estimates. For surface water estimates, we still use only samples from treated water.

4. Revised Occurrence Results

Table III.C–3 shows our revised estimates of the national distribution of arsenic occurrence, by system type and source water type. The distributions are stated in terms of "exceedance probabilities," that is, the fraction of systems with mean arsenic equal to or greater than the given concentration, in finished water. The "weighted point estimate" is the combination of State distributions into a national distribution, as described previously. We consider the weighted point estimate to be our best estimate. The "lognormal fit" is the result of fitting a lognormal distribution to the weighted point estimates. The lognormal fit is an approximation to the weighted point estimate, which we use in our cost and benefit analyses (sections III.E and III.F). The lognormal approximation simplifies the simulation studies that we use to derive costs and benefits, by allowing each distribution to be summarized in terms of only two parameters. Table III.C–4 lists the parameters of the fitted lognormal distributions,

TABLE III.C–3.—NATIONAL OCCURRENCE EXCEEDANCE PROBABILITY ESTIMATES

	Percent of systems with mean finished arsenic exceeding concentrations (μg/L) of:				
	3	5	10	20	50
Ground Water CWS					
Weighted point estimate	19.9	12.1	5.3	2.0	0.43
95% confidence interval [1]	[19.3,21.9]	[11.7,13.0]	[5.2,5.9]	[1.9,2.3]	[0.38,0.52]
Lognormal fit	19.7	12.0	5.3	2.0	0.43
Surface Water CWS					
Weighted point estimate	5.6	3.0	0.80	0.32	0.10
95% confidence interval [1]	[4.8,20.6]	[1.8,9.7]	[0.52,1.6]	[0.13,0.82]	[0.02,0.59]
Lognormal fit	5.6	3.0	1.1	0.37	0.067
Ground Water NTNCWS					
Weighted point estimate	24.2	15.6	5.3	2.1	0.47
95% confidence interval [1]					
Lognormal fit	23.4	14.2	6.1	2.2	0.42

[1] Brackets indicate confidence intervals which were computed for the proposed rule and have not been updated. No confidence intervals were computed for NTNCWS.

TABLE III.C–4.—PARAMETERS OF LOGNORMAL DISTRIBUTIONS FITTED TO NATIONAL OCCURRENCE DISTRIBUTIONS

System type	Source water	Log-mean [1]	Log-SD [2]
CWS	GW	−0.25	1.58
CWS	SW	−1.68	1.74
NTNCWS	GW	0.03	1.47

[1] Log-mean = mean of natural logarithm of arsenic concentrations (μg/L).
[2] Log-SD = standard deviation of natural logarithm of arsenic concentrations (μg/L).

Table III.C–3 lists separate distribution estimates for ground and surface water CWS and for ground water NTNCWSs. As we said previously, we believe surface water CWSs provide a more sound basis for estimation.

For CWSs, the estimates in Table III.C–3 have changed only slightly since the proposed rule. For ground water CWSs, the largest change is an increase at 10 μg/L from 5.3% exceedance to 5.4%. For surface water CWSs, the largest change is a decrease at 3 μg/L from 6.0% in the proposed rule to 5.6% in Table III.C–3. This decrease is as expected, since, as we explained previously, our revised database excludes some observations on untreated water that were included in the draft database. Our surface water

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occurrence estimates did increase slightly at 5 µg/L, however, as Table III.C–8 shows.

For ground water NTNCWSs, our estimated exceedance probabilities increased from 19.9% to 24.2% at 3 µg/L, and from 12.1% to 15.6% at 5 µg/L. The estimates at higher concentrations changed by at most 0.1% point. The estimates changed because we now estimate a separate distribution for ground water NTNCWSs, as we described previously.

The confidence intervals listed in Table III.C–3 were computed for the proposed rule, using a computationally intensive resampling procedure, as described in (EPA, 2000r). Since our data set and point estimates have changed only minimally for the final rule, we did not recompute the confidence intervals.

Table III.C–5 shows occurrence distributions in seven geographic regions presented in the proposal and developed by Frey and Edwards (1997). (The States and names of these geographic regions in Table III.C–5 are based directly on the authors' designations.) As in the proposed rule, we find concentrations to be generally highest in the West, and generally lowest in the Southeast and Mid-Atlantic. In regions where analytical reporting limits in our database were mostly higher than 3 µg/L or 5 µg/L, we did not attempt to estimate occurrence at the lowest concentrations. These cases are indicated by dashes in Table III.C–5. In some regions, we were able to estimate occurrence in fewer States at the lowest concentrations, and this sometimes led to inconsistencies in our estimates. For example, for New England surface water CWSs, we estimated occurrence at 3 µg/L using only Maine, and at 5 µg/L using Maine, New Hampshire, and New Jersey. The introduction of more States at higher concentrations led to inconsistent estimates of 6.2% and 11.7% of New England surface water CWSs with arsenic exceeding 3 µg/L and 5 µg/L, respectively. We did not try to resolve these inconsistencies at the regional level, but note that the national occurrence distributions, listed in Table III.C–3, are consistent.

TABLE III.C–5.—REGIONAL OCCURRENCE EXCEEDANCE PROBABILITY ESTIMATES

	Percent of systems with mean finished arsenic exceeding concentrations (µg/L) of:			
	3	5	10	20
Ground Water CWS				
Mid-Atlantic	(2)	[1]0.4	0.7	0.0
Midwest	21.2	13.8	6.2	2.4
New England	21.7	20.8	7.0	2.9
North Central	21.3	13.1	6.0	2.4
South Central	18.6	9.7	3.6	1.1
Southeast	0.9	0.4	0.1	0.0
West	31.5	25.2	12.5	5.0
Surface Water CWS				
Mid-Atlantic	(2)	0.1	0.0	0.0
Midwest	3.0	1.6	0.7	0.3
New England	[1]6.2	11.7	1.0	0.4
North Central	9.1	3.2	0.6	0.1
South Central	3.8	0.9	0.2	0.1
Southeast	0.2	0.1	0.0	0.0
West	12.7	8.2	3.4	1.4
Ground Water NTNCWS				
Mid-Atlantic	(2)	(2)	1.4	0.5
Midwest	26.2	17.1	8.2	3.3
New England	(2)	(2)	2.1	0.6
North Central	29.8	22.8	15.0	9.3
South Central	24.0	14.4	5.9	1.9
Southeast	0.9	0.4	0.1	0.0
West	34.3	21.9	10.5	4.2

[1] Estimate is inconsistent with estimate at the next higher concentration. See text for explanation.
[2] Means not enough data to form an estimate. See text for explanation.

Table III.C–6 shows our estimates of the numbers of systems with mean finished arsenic concentrations in various ranges, by system type and size. As in the proposed rule, we find no evidence of any consistent difference in mean arsenic among systems of different sizes. We conclude that the occurrence distributions shown in Table III.C–3 apply to all categories of system size. In Table III.C–6, therefore, the estimated numbers of systems are computed by multiplying the baseline inventory of all systems of the given size and type, by the corresponding probability of falling within the given range, computed from Table III.C–3 and shown in the "% of systems" rows. The estimates for surface water NTNCWSs were computed by applying the occurrence distribution for surface water CWSs to the baseline inventory of surface water NTNCWSs.

TABLE III.C–6.—STATISTICAL ESTIMATES OF NUMBERS OF SYSTEMS WITH AVERAGE FINISHED ARSENIC CONCENTRATIONS IN VARIOUS RANGES

System size (population served)	Number of systems with mean arsenic concentration (µg/L) in the range of:			
	>3 to 5	>5 to 10	>10 to 20	>20
Ground Water CWS				
25 to 500	2,272	1,980	961	584
501 to 3,300	811	706	343	208
3,301 to 10,000	192	167	81	49
10,001 to 50,000	95	83	40	24
>50,000	15	13	6	4
All	3,384	2,949	1,432	870
% of systems	7.8%	6.8%	3.3%	2.0%
Surface Water CWS				
25 to 500	76	68	14	10
501 to 3,300	92	81	17	12
3,301 to 10,000	47	41	9	6
10,001 to 50,000	41	36	8	5
>50,000	15	13	3	2
All	270	239	51	34
% of systems	2.5%	2.2%	0.5%	0.3%
Ground Water NTNCWS				
25 to 500	1,440	1,713	545	348
501 to 3,300	230	274	87	56
3,301 to 10,000	5	6	2	1
10,001 to 50,000	1	1	0	0
>50,000	0	0	0	0
All	1,677	1,995	635	405
% of systems	8.6%	10.3%	3.3%	2.1%
Surface Water NTNCWS				
25 to 500	14	13	3	2
501 to 3,300	5	4	1	1
3,301 to 10,000	1	1	0	0
10,001 to 50,000	0	0	0	0
>50,000	0	0	0	0
All	20	17	4	2
% of systems	2.5%	2.2%	0.5%	0.3%

Numbers do not add up to totals in some cases due to rounding.

Our proposed and final estimates of intra-system coefficients of variation are shown in Table III.C–7. The revised estimates are lower, since, as we described previously, we now better separate out within-source (time and analytical) variability from the variability of source means within a system. The ISCV estimate for ground water NTNCWSs also has changed because we now estimate it separately from that of ground water CWSs.

TABLE III.C–7.—ESTIMATED INTRA-SYSTEM COEFFICIENTS OF VARIATION (ISCV)

System type	Source water	Proposed rule	Final rule	
		ISCV (percent)	ISCV (percent)	95% confidence interval
CWS	GW	62.9	37.1	[33.1,40.8]
CWS	SW	68.4	52.6	[31.4,69.6]
NTNCWS	GW	62.9	25.2	[9.6,34.7]

Table III.C–8 compares our proposed and final national occurrence estimates to estimates from three other studies: the National Arsenic Occurrence Survey (NAOS) (Frey and Edwards, 1997), National Inorganics and Radionuclides Survey (NIRS) (Wade Miller Associates, 1992), and U.S. Geological Survey (USGS) (USGS, 2000). All of the studies in Table III.C–8 evaluated drinking water except for USGS, which evaluated ambient ground water, some of which came from non-drinking water sources. Wade Miller used surface water estimates from the 1978 Community Water System Survey, which we consider now to be out of date, so those estimates are not shown. Note that Frey and Edwards (1997) found significantly different occurrence distributions for small and large systems, so the NAOS

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estimates are reported separately for small and large systems. The NAOS included samples from all 50 States, but it was a much smaller study (468 samples, compared to about 77,000 in our database), and it analyzed unfinished water samples. Frey and Edwards (1997) applied estimated efficiencies for the treatments known to be in place at the sampling locations; to predict the concentrations in finished water.

TABLE III.C–8.—COMPARISON OF NATIONAL ARSENIC OCCURRENCE ESTIMATES

Study	Type of water	System types	Population served	% of systems with mean arsenic exceeding concentrations (µg/L) of:				
				2	3	5	10	20
Ground Water Systems								
EPA-proposed	raw + finished	CWS	all	27.2	19.9	12.1	5.4	2.1
EPA-final	raw + finished	CWS	all	27.3	19.9	12.1	5.3	2.0
NAOS-small	finished [1]	PWS	≤10,000	23.5	NR	12.7	5.1	NR
NAOS-large	finished [1]	PWS	>10,000	28.8	NR	15.4	6.7	NR
NIRS	finished	CWS	all	17.4	11.9	6.9	2.9	1.1
USGS	raw	PWS	all	25.0	NR	13.6	7.6	3.1
Surface Water Systems								
EPA-proposed	finished	CWS	all	9.9	6.0	2.9	0.8	0.3
EPA-final	finished	CWS	all	9.8	5.6	3.0	0.8	0.3
NAOS-small	finished [1]	PWS	≤10,000	6.2	NR	1.8	0.0	NR
NAOS-large	finished [1]	PWS	>10,000	7.5	NR	1.3	0.6	NR

NR = not reported.
[1] Predicted from raw water, using estimated efficiency of treatment in place.

Table III.C–8 shows that our proposed and final occurrence estimates are only slightly different, with the possible exception of surface water occurrence estimates at 3 µg/L, where our estimate decreased from 6.0% to 5.6% exceedance for the final rule. The difference is explained by the identification and exclusion of samples of untreated water from our database for the final rule, as we described previously. For ground water, our estimates fall within the range reported in the other three studies. For surface water, our estimates are somewhat higher than those of the NAOS.

D. How Did EPA Revise its Risk Analysis?

1. Health Risk Analysis

a. Toxic forms of arsenic. Humans are exposed to many forms of arsenic that have different toxicities. For example, the metallic form of arsenic (0 valence) is not absorbed from the stomach and intestines and does not exert adverse effects. On the other hand, a volatile compound such as arsine (AsH_3) is toxic, but is not present in water or food. Moreover, the primary organic forms (arsenobetaine and arsenocholine) found in fish and shellfish seem to have little or no toxicity (Sabbioni *et al.*, 1991). Arsenobetaine quickly passes out of the body in urine without being metabolized to other compounds (Vahter, 1994). Little is known about the various arsenic species in vegetables, grains, and oils (NRC, 1999). Arsenite (+3) and arsenate (+5) are the most prevalent toxic forms of inorganic arsenic found in drinking water. In general, the inorganic forms of arsenic have been considered to be more toxic than the organic forms. In toxicity tests, the inorganic forms were reported to be more toxic than the organic forms (NAS, 1977) and the trivalent form was more toxic than the pentavalent one (Szinicz and Forth, 1988).

In animals and humans, inorganic pentavalent arsenic is converted to trivalent arsenic that is methylated (*i.e.*, chemically bonded to a methyl group, which is a carbon atom linked to three hydrogen atoms) to monomethyl arsenic (MMA) and dimethyl arsinic acid (DMA), which are organic arsenicals. The primary route of excretion for these four forms of arsenic is in the urine. The organic arsenicals MMA and DMA were once thought to be much less toxic than inorganic arsenicals. Many studies reported organic arsenicals to be less reactive in tissues, to kill less cells, and to be more easily excreted in urine (NRC, 1999). However, recent work has shown that the assumption that organic forms that arise during the metabolism of inorganic arsenic are less toxic than inorganic forms may not be correct (Aposhian *et al.*, 2000; Petrick *et al.*, 2000). One reason for this was that earlier toxicity tests were conducted using pentavalent MMA and DMA because it was believed that trivalent MMA(III) and DMA(III) were too transient to be found in urine. Recently, MMA(III) was isolated in human urine (Aposhian *et al.*, 2000). Tests have demonstrated that MMA(III) is more toxic to hepatocytes (*i.e.*, liver cells) that inorganic trivalent arsenic (Petrick *et al.*, 2000; Styblo *et al.*, 2000). These reports indicate that the metabolism of inorganic arsenic is not necessarily a detoxification process. As yet, it is not known which form of arsenic participates in the key events within cells that disrupt cell growth control and initiate or influence tumor formation. The SAB noted that "[i]t is not possible to consider contributions of different forms of arsenic to the overall response based on the data that are available today" (EPA, 2000q).

b. Effects of acute toxicity. Inorganic arsenic can exert toxic effects after acute (short-term) or chronic (long-term) exposure. From human acute poisoning incidents, the LD_{50} of arsenic has been estimated to range from 1 to 4 mg arsenic per kilogram (kg) of body weight (Vallee *et al.*, 1960, Winship, 1984). This dose would correspond to a lethal dose range of 70 to 280 mg for 50% of adults weighing 70 kg. At nonlethal, but high acute doses, inorganic arsenic can cause gastroenterological effects, shock, neuritis (continuous pain) and vascular effects in humans (Buchanan, 1962). Such incidents usually occur after accidental exposures. However, sometimes high dose acute exposures may be self-administered. For example, inorganic arsenic is a component of some herbal medicines and adverse effects have been reported after use. In one report of 74 cases (Tay and Seah, 1975), the primary signs were skin lesions (92%), neurological (*i.e.*, nerve) involvement (51%), and gastroenterological, hematological (*i.e.*, blood) and renal (*i.e.*, kidney) effects (19 to 23%). Although acute or short-term exposures to high doses of inorganic arsenic can cause adverse effects, such exposures do not occur from U.S. public water supplies in compliance with the current MCL of 50 µg/L. EPA's drinking water regulation addresses the long-term, chronic effects of exposure to low concentrations of inorganic arsenic in drinking water.

c. Non-cancer effects associated with arsenic. A large number of adverse noncarcinogenic effects has been reported in humans after exposure to drinking water highly contaminated with inorganic arsenic. The earliest and most prominent changes are in the skin, *e.g.*, hyperpigmentation and keratoses (calus-like growths). Other effects that have been reported include alterations in gastrointestinal, cardiovascular, hematological (*e.g.*, anemia), pulmonary, neurological, immunological and reproductive/developmental function (ATSDR, 1998).

The most common symptoms of inorganic arsenic exposure appear on the skin and occur after 5–15 years of exposure equivalent to 700 µg/day for a 70 kg adult, or within 6 months to 3 years at exposures equivalent to 2,800 µg/day for a 70 kg adult (NRC, 1999, pg. 131). They include alterations in pigmentation and the development of keratoses that are localized primarily on the palms of the hands, the soles of the feet, and the torso. The presence of hyperpigmentation and keratoses on parts of the body not exposed to the sun is characteristic of arsenic exposure (Yeh, 1973; Tseng, 1977). The same alterations have been reported in patients treated with Fowler's solution (1% potassium arsenite; Cuzick *et al.*, 1982), used for asthma, psoriasis, rheumatic fever, leukemia, fever, pain, and as a tonic (WHO, 1981; NRC, 1999).

Chronic exposure to inorganic arsenic is often associated with alterations in gastrointestinal(GI) function. For example, noncirrhotic hypertension is a relatively specific, but not commonly found manifestation in inorganic arsenic-exposed individuals and may not become a clinical observation until the patient demonstrates GI bleeding (Morris *et al.*, 1974; Nevens *et al.*, 1990). Physical examination may reveal spleen and liver enlargement, and histopathological examination of tissue specimens may demonstrate periportal fibrosis (Morris *et al.*, 1974; Nevens *et al.*, 1990; Guha Mazumder *et al.*, 1997). There have been a few reports of cirrhosis after inorganic arsenic exposure, but the authors of these studies did not determine the subjects' alcohol consumption (NRC, 1999).

Development of peripheral vascular disease (hardening of the arteries to the arms and legs, that can cause pain, numbness, tingling, infection, gangrene, and clots) after inorganic arsenic exposure has also been reported. In Taiwan, blackfoot disease (BFD), a severe peripheral vascular insufficiency which may result in gangrene of the feet and other extremities) has been the most severe manifestation of this effect. Tseng (1977) reported over 1,000 cases of BFD in the arsenic study areas of Taiwan. Less severe cases of peripheral vascular disease have been described in Chile (Zaldivar *et al.*, 1974) and Mexico (Cebrian, 1987). In a Utah study, increased standardized mortality ratios (SMRs) for hypertensive heart disease were noted in both males and females after exposure to inorganic arsenic-contaminated drinking water (Lewis *et al.*, 1999). These reports link exposure to inorganic arsenic effects on the cardiovascular system. Although deaths due to hypertensive heart disease were roughly twice as high as expected in both sexes, increases in death did not relate to increases in dose, calculated as the years of exposure times the median arsenic concentration. The Utah data indicate that heart disease should be considered in the evaluation of potential benefits of U.S. regulation. Vascular effects have also been reported as an effect of arsenic exposure in another study in the U.S. (Engel *et al.*, 1994), in Taiwan (Wu *et al.*, 1989) and in Chile (Borgono *et al.*, 1977). The overall evidence indicating an association of various vascular diseases with arsenic exposure supports consideration of this endpoint in evaluation of potential noncancer health benefits of arsenic exposure reduction.

Studies in Taiwan (Lai *et al.*, 1994) and Bangladesh (Rahman *et al.*, 1998) found an increased risk of diabetes among people consuming arsenic-contaminated water. Two Swedish studies found an increased risk of mortality from diabetes among those occupationally exposed to arsenic (Rahman and Axelson, 1995; Rahman *et al.*, 1998).

Although peripheral neuropathy (numbness, muscle weakness, tremors; ATSDR, 1998) may be present after exposure to short-term, high doses of inorganic arsenic (Buchanan, 1962; Tay and Seah, 1975), there are no studies that definitely document this effect after exposure to levels of less than <50 µg/L of inorganic arsenic in drinking water. Hindmarsh et al. (1977) and Southwick et al. (1983) have reported limited evidence of peripheral neuropathy in Canada and the U.S., respectively, but it was not reported in studies from Taiwan, Argentina or Chile (Hotta, 1989, as cited by NRC 1999).

There have been a few, scattered reports in the literature that inorganic arsenic can affect reproduction and development in humans (Borzysonyi *et al.*, 1992; Desi *et al.*, 1992; Tabacova *et al.*, 1994; Hopenhayn-Rich *et al.*, 2000). After reviewing the available literature on arsenic and reproductive effects, the NRC (1999) wrote that "nothing conclusive can be stated from these studies." Regarding the Hopenhayn-Rich study, the majority of the SAB panel (EPA, 2000q) concluded that while:

> it is generally reasonable to consider that children are generally at greater risk for a toxic response to any agent in water because of their greater drinking water consumption (on a unit-body weight basis), [the SAB does not] believe that this study demonstrates such a heightened sensitivity or susceptibility to arsenic.

The EPA agrees with this conclusion.

d. Cancers associated with arsenic. Inorganic arsenic is a multi-site human carcinogen by the drinking water route. Asian, Mexican and South American populations with exposures to arsenic in drinking water generally at or above hundreds of micrograms per liter are reported to have increased risks of skin, bladder, and lung cancer. The current evidence also suggests that the risks of liver and kidney cancer may be increased following exposures to inorganic forms of arsenic. The weight of evidence for ingested arsenic as a causal factor of carcinogenicity is much greater now than a decade ago, and the types of cancer occurring as a result of ingesting inorganic arsenic have even greater health implications for U.S. and other populations than the occurrence of skin cancer alone. (Until the late 1980s skin cancer had been the cancer classically associated with arsenic in drinking water.) Epidemiologic studies (human studies) provide direct data on arsenic risks from drinking water at exposure levels much closer to those of regulatory concern than environmental risk assessments based on animal toxicity studies.

Skin Cancer. Early reports linking inorganic arsenic contamination of drinking water to skin cancer came from Argentina (Neubauer, 1947, reviewing studies published as early as 1925) and Poland (Tseng *et al.*, 1968). However, the first studies that observed dose-dependent effects of arsenic associated with skin cancer came from Taiwan (Tseng *et al.*, 1968; Tseng, 1977). These studies focused EPA's attention on the health effects of ingested arsenic.

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Physicians administered physical examinations to the study group of over 40,000 residents from 37 villages, as well as to a reference group of 7500 residents reported to be exposed to a median level of 0 to 0.017 mg/L arsenic (reference group). The study population was divided into three groups based on exposure to inorganic arsenic (0 to 0.29, 0.30 to 0.59 and ≥0.60 mg of inorganic arsenic per liter (mg/L) measured at the village level. A dose- and age-related increase of arsenic-induced skin cancer among the villagers was noted. No skin cancers were observed in the low arsenic reference areas. In both the EPA 1988 report on skin cancer and the 1999 NRC report, it was noted that grouping individuals into broad exposure groups (rather than grouping into village exposures) limited the usefulness of these studies for quantitative dose-response estimation. However, these Tseng reports and other corroborating studies such as those by Albores *et al.* (1979) and Cebrian *et al.* (1983) on drinking water exposure and exposures to inorganic arsenic in medicines (Cuzick *et al.*, 1982) and in pesticides (Roth, 1956) led the EPA, using skin cancer as the endpoint, to classify inorganic arsenic as a human carcinogen (Group A) by the oral route (EPA, 1984).

Internal cancers. Exposure to inorganic arsenic in drinking water has also been associated with the development of internal cancers. Chen *et al.* (1985) used SMRs to evaluate the association between ingested arsenic and cancer risk in Taiwan. (SMRs, ratios of observed to expected deaths from specific causes, are standardized to adjust for differences in the age distributions of the exposed and reference populations). The authors found statistically significant increased risks of mortality for bladder, kidney, lung, liver and colon cancers. A subsequent mortality study in the same area of Taiwan found significant dose-response relationships for deaths from bladder, kidney, skin, and lung cancers in both sexes and from liver and prostrate cancer for males. They also found increases in peripheral and cardiovascular diseases but not in cerebrovascular accidents (Wu *et al.*, 1989). There are several corroborating reports of the increased risk of cancers of internal organs from ingested arsenic including two from South American countries. In Argentina, significantly increased risks of death from bladder, lung and kidney cancer were reported (Hopenhayn-Rich *et al.*, 1996; 1998). In a population of approximately 400,000 in northern Chile, Smith *et al.* (1998) found significantly increased risks of bladder and lung cancer mortality.

There have only been a few studies of inorganic arsenic exposure via drinking water in the U.S., and most have not considered cancer as an endpoint. The best U.S. study currently available is that of Lewis *et al.* (1999) who conducted a mortality study of a population in Utah whose drinking water contained relatively low concentrations of arsenic. EPA scientists conducted an epidemiological study of 4,058 Mormons exposed to arsenic in drinking water in seven communities in Millard County, Utah (Lewis *et al.*, 1999). The 151 samples from their public and private drinking water sources had arsenic concentrations ranging from 4 to 620 µg/L with seven median (mid-point in range) community exposure concentrations of 14 to 166 µg/L. Observed causes of death in the study group (numbering 2,203) were compared to those expected from the same causes based upon death rates for the general white male and female population of Utah. While the study population males had a significantly higher risk of prostate cancer mortality, females had no significant excess risk of cancer mortality at any site. Millard County subjects had higher mortality from kidney cancer, but this was not statistically significant. Both males and females in the study group had less risk of bladder, digestive system and lung cancer mortality than the general Utah population. The Mormon females had lower death rates from breast and female genital cancers than the State rate. These decreased death rates were not statistically significant.

Tsai *et al.* (1999) estimated SMRs for 23 cancer and non-cancer causes of death in women and 27 causes of death in men in an area of Taiwan with elevated arsenic exposures. The SMRs in this study are an expression of the ratio between deaths that were observed in an area with elevated arsenic levels and those that were expected to occur, compared to both the mortality of populations in nearby areas without elevated arsenic levels and to the national population. Drinking water (250–1,140 µg/L) and soil (5.3–11.2 mg/kg) in the Tsai *et al.* (1999) population study had high arsenic content. However, the study gives an indication of the types of health effects that may be associated with arsenic exposure via drinking water. The study reports a high mortality rate (SMR > 3) for both sexes from bladder, kidney, skin, lung, and nasal cavity cancers and for vascular disease. Females also had high mortalities for laryngeal cancer.

The SMRs calculated by Tsai *et al.* (1999) used the single cause of death noted on the death certificates. Many chronic diseases, including some cancers, are not generally fatal. Consequently, the impact indicated by the SMR in this study may underestimate the total impact of these diseases. The causes of death reported in this study are consistent with what is known about the adverse effects of arsenic. Tsai *et al.* (1999) identified "bronchitis, liver cirrhosis, nephropathy, intestinal cancer, rectal cancer, laryngeal cancer, and cerebrovascular disease" as possibly "related to chronic arsenic exposure via drinking water," which had not been reported before. In addition, people in the study area were observed to have nasal cavity and larynx cancers not caused by occupational exposure to inhaled arsenic.

A small cohort study in Japan of persons exposed to arsenic in drinking water provides evidence of the association of cancer and arsenic among persons exposed for 5 years to 1000 µg/L or more and followed for 33 years after cessation of exposure. The strongest association was for lung and bladder cancer, similar to results in studies in Taiwan and South America (Tsuda *et al.*, 1995).

Kurttio *et al.* (1999) conducted a case-cohort design study of 61 bladder and 49 kidney cancer cases and 275 controls to evaluate the risk of these diseases with respect to arsenic drinking water concentrations. In this study the median exposure was 0.1 µg/L, the maximum reported was 64 µg/L, and 1% of the exposure was greater than 10 µg/L. The authors reported that very low concentrations of arsenic in drinking water were significantly associated with bladder cancer when exposure occurred two to nine years prior to diagnosis. Arsenic exposure occurring greater than 10 years prior to diagnosis was not associated with bladder cancer risk. This raises a question about the significance of the finding about exposures two to nine years since one would expect earlier exposure to have had an effect given the Tsuda *et al.* (1995) study summarized previously.

The two internal cancers consistently seen and best characterized in epidemiologic studies are those of lung and bladder. EPA considers the studies summarized before as confirmation of its long-standing view that arsenic is a known human carcinogen. This rule relies on assessment of lung and bladder cancers for its quantitative risk estimates in support of the MCL. EPA recognizes that other internal cancers as well as skin cancer are important.

Nonetheless, some issues with other cancer endpoints led to their being considered qualitatively rather than quantitatively. EPA has considered skin and liver cancer qualitatively for the following reasons: (1) The skin cancer endpoint is difficult to analyze because, in the U.S., it is considered curable; and (2) the liver cancer endpoint is likely to have been influenced in Taiwan by the prevalence there of viral hepatitis which is a factor in liver cancer.

How does arsenic cause cancer? EPA sponsored an "Expert Panel on Arsenic Carcinogenicity: Review and Workshop" in May 1997 (EPA, 1997e). The panel evaluated existing data to comment on arsenic's carcinogenic mode of action and the effect on dose-response extrapolations. The panel noted that arsenic compounds have not formed deoxyribonucleic acid (DNA) adducts (*i.e.*, bound to DNA) nor caused point mutations. Thus, indications are that the mode of action does not involve direct reaction with DNA. Trivalent inorganic forms inhibit enzymes, but arsenite and arsenate do not affect DNA replication. The panel discussed several modes of action, concluding that arsenic indirectly affects DNA, inducing chromosomal changes. The panel thought that arsenic-induced chromosomal abnormalities could possibly come from errors in DNA repair and replication that affect gene expression; that arsenic may increase DNA hypermethylation and oxidative stress; that arsenic may affect cell proliferation (cell death appears to be nonlinear); and that arsenic may act as a co-carcinogen. Arsenite causes cell transformation but not mutation of cells in culture. It also induces gene amplification (multiple copies of DNA sequences) in a way that suggests interference with DNA repair or cell control instead of direct DNA damage.

In terms of implications for the risk assessment, the panel noted that risk per unit dose estimates from human studies can be biased either way (*i.e.*, reduced animal fats in the diet would underestimate risk). For the Taiwanese study, the "* * * biases associated with the use of average doses and with the attribution of all increased risk to arsenic would both lead to an overestimation of risk (EPA, 1997e, page 31)." While health effects are most likely observed in people getting high doses, the effects are assigned to the average dose of the exposure group. Thus, risk per unit dose estimated from the average doses would lead to an overestimation of risk (EPA, 1997e, page 31). On the other hand, basing risk estimates on one or two tumor sites may underestimate risk as compared to summing risks for all related health endpoints.

There is much research underway about the mode of action for arsenic. In order to understand the shape of the dose-response relationship in the range of exposure typical of the U.S., that is significantly below the range of observation of epidemiologic studies, one needs to identify which one or more of the possible modes of action is operative. If this can be elucidated, it will become possible to study and quantify the key events within cells that influence cell growth control and how they may quantitatively relate to eventual tumor incidence. Until then the shape of the dose-response relationship and whether there is any threshold cannot be known.

f. What is the quantitative relationship between exposure and cancer effects that may be projected for exposures in the U.S.? The Agency chose to make its quantitative estimates of risk based on the Chen *et al.* (1988; 1992) and Wu *et al.* (1989) Taiwan studies. This choice was endorsed by the NRC and EPA's SAB (EPA, 2000q; NRC, 1999). The database from Taiwan has the following advantages: mortality data were drawn from a cancer registry; arsenic well water concentrations were measured for each of the 42 villages; there was a large, relatively stable study population that had life-time exposures to arsenic; there are limited measured data for the food intake of arsenic in this population; age- and dose-dependent responses with respect to arsenic in the drinking water were demonstrated; the collection of pathology data was unusually thorough; and the populations were quite homogeneous in terms of lifestyle.

EPA recognizes that there are problems with the Taiwan study that introduce uncertainties to the risk analysis such as: the use of median exposure data at the village level; the low income and relatively poor diet of the Taiwanese study population (high levels of carbohydrates, low levels of protein, selenium and other essential nutrients); and high exposure to arsenic via food and cooking water. These are discussed more thoroughly in the following paragraphs. The available studies from Taiwan are ecological studies and have exposure uncertainties that are recognized. Ecological studies are problematic as bases for quantitative risk assessment. Errors in assigning persons to exposures are difficult to avoid. Moreover, all confounding factors that may have contributed to risk may not be adequately accounted for. These uncertainties have to be remembered since they lead to uncertainty in the quantitative dose-response relationship estimated in the observed range of data and in any extrapolation to estimate the potential risk at exposures significantly below the observed range. There is not a way to take all confounding factors into account quantitatively. (see section III.F.)

Notwithstanding these concerns, the Taiwan epidemiological studies provide the basis for assessing potential risk from lower concentrations of inorganic arsenic in drinking water, without having to adjust for cross-species toxicity interpretation. Ordinarily, the characteristics of human carcinogens can be explored and experimentally defined in test animals. Dose-response can be measured, and animal studies may identify internal transport, metabolism, elimination, and subcellular events that explain the carcinogenic process. Arsenic presents unique problems for quantitative risk assessment because there is no test animal species in which to study its carcinogenicity. While such studies have been undertaken, it appears that test animals do not respond to inorganic arsenic exposure in a way that makes them useful as a model for human cancer assessment. Their metabolism of inorganic arsenic is also quantitatively different than humans.

There are issues with the extrapolation of the dose-response from the observed range of exposure in Taiwan to estimate Taiwan cancer risk below the observed data range and application of the same risk estimate to U.S. populations. The following issues have been addressed:

- The Taiwan population ingested more arsenic in food and via cooking with contaminated water than is typical for the U.S. population. This is because the staples of the Taiwan diet were rice and sweet potatoes. Rice and sweet potatoes are high in arsenic and both staples absorb water upon cooking. EPA did a sensitivity analysis of the effect of exposure to arsenic through water used in preparing food in Taiwan. EPA also analyzed the effect of exposure to arsenic through food.
- The Taiwan data on exposure were uncertain because the association of individuals with contaminated wells was made by grouping persons in a village and assuming they had a lifetime of exposure to the median of the concentration of arsenic measured in the wells serving that village. Wells within each village had varying arsenic levels so that people using certain wells had much higher exposures than others in the same village. Not all wells serving all villages were measured. However, all villagers were assigned a single median

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concentration for exposure. In addition, moves made from village to village were not accounted for. When villages with only one arsenic measurement were removed from the data set (on the theory that the exposure data were too uncertain), or when village means instead of medians were used for the exposure estimates, there was no statistically significant change in the estimated point of departure, using Model 1 of Morales et al. (2000).

• The Taiwan population was a rural population that was not well nourished, having deficits of selenium, possibly methionine or choline (methyl donors), zinc and other essential nutrients. This malnourishment is not typical of the U.S. population, although some U.S. populations may have one or another of the same deficits. The Taiwanese population may also have some genetic differences from the general U.S. population. These issues cannot be quantitatively accounted for. However, deficits in selenium in the diet, in particular, are a known risk factor for cancer and indicate possible overestimation of risk when the Taiwan data are applied. EPA has qualitatively taken this into account. (See section III.F.)

• The Utah study (Lewis et al., 1999) did not find any excess bladder or lung cancer risk after exposure to arsenic at concentrations of 14 to 166 µg/L. An important feature of the study is that it estimated excess risk by comparing cancer rates among the study population, in Millard County, Utah to background rates in all of Utah. But the cancer rates observed among the study population, even those who consumed the highest levels of arsenic, were lower, in many cases significantly lower, than in all of Utah. This is evidence that there are important differences between the study and comparison populations besides their consumption of arsenic. One such difference is that Millard County is mostly rural, while Utah as a whole contains some large urban populations. Another difference is that the subjects of the Utah study were all members of the Church of Jesus Christ of Latter Day Saints, who for religious reasons have relatively low rates of tobacco and alcohol use. For these reasons, the Agency believes that the comparison of the study population to all of Utah is not appropriate for estimating excess risks. An alternative method of analysis is to compare cancer rates only among people within the study population who had high and low exposures. The Agency performed such an analysis on the Utah data, using the statistical technique of Cox proportional hazard regression (US EPA, 2000x; Cox and Oakes, 1984). The results showed no detectable increased risk of lung or bladder cancers due to arsenic, even among subjects exposed to more than 100 µg/L on average. On the other hand, the excess risk could also not be distinguished statistically from the levels predicted by model 1 of Morales et al. (2000). What these results show is that the Utah study is not powerful enough to estimate excess risks with enough precision to be useful for the Agency's arsenic risk analysis. Furthermore, the SAB noted that "(a)lthough the data provided in published results of the Lewis, et al., 1999 study imply that there was no excess bladder or lung cancer in this population, the data are not in a form that allows dose-response to be assessed dependably" (EPA, 2000q). The indications of Lewis et al. study have been taken into account in the judgments of the impact of scientific uncertainties on the final MCL.

g. Is it appropriate to assume linearity for the dose-response assessment for arsenic at low doses given that arsenic is not directly reactive with DNA? Independent scientific panels (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) who have considered the Taiwan study have raised the caution that using the Taiwan study to estimate U.S. risk at lower levels may result in an overly conservative estimation of U.S. risk. The independent panels have each said that below the observed range of the high level of contamination in Taiwan the shape of the dose-response relationship may prove to be sublinear when there is adequate data to characterize the mode of action. If so, an assumption that the effects seen per dose increment remain the same from high to low levels of dose may overstate the U.S. risk. In evaluating the benefits of alternative MCLs, EPA weighed both the qualitative and quantitative uncertainties about risk magnitude (see section III.F.)

The use of a linear procedure to extrapolate from a higher, observed data range to a lower range beyond observation is a science policy approach that has been in use by Federal agencies for four decades. Its basis is both science and policy. The policy objectives are to avoid underestimating risk in order to protect public health and be consistent and clear across risk assessments. The science components include its applicability to generally available data sets (animal tests and human studies) and its basis in the fact that cancer is a consequence of genetic changes coupled with the assumption that direct reaction with DNA is a basic mode of action for chemicals causing important genetic changes (Cogliano et al., eds., 1999).

The linear approach is intended to identify a level of risk that is an upper limit on what the risk might be. There are two biological situations in which the linear approach can be a particularly uncertain estimate of risk. One is when the metabolism and toxicokinetics of the agent being assessed cause a nonlinear relationship between the dose of the active form and the dose of the applied form of the agent. If this is not quantitatively dealt with in the dose part of the dose-response estimation, the linear extrapolation will have added uncertainties. In the case of arsenic, it is known that metabolism and toxicokinetics are complex, but the active form(s) is not known. The resulting complexities of estimating dose cannot, therefore, be accounted for in dose-response modeling.

The other situation is when the mode of action of the agent is indirect; that is, when there is not a one-to-one reaction between the active form of the agent and DNA, but, instead, the active form affects other cell components or processes that, in turn, causes genetic change. In such cases, the rates of these secondary processes are limiting, not the dose of the active form. With few exceptions, the rates of these secondary processes are thought not to be a linear function of applied dose. In the case of arsenic, it is known that arsenic does cause genetic changes in short-term tests, but these are indirect genetic changes (not one-to-one reactions between arsenic and DNA).

If there are both complex toxicokinetics and secondary effects, the upper-limit risk estimate from the linear approach provides may be overly conservative. However, there simply are not sufficient data to quantify the effect of these two features of arsenic on risk. While some commenters assert that the Agency can simply use models that have sublinear structures to address the issue of secondary nature of effects, the Agency does not agree. There are no data on the effects of arsenic that may be precursors to cancer. Without such biological data, the exercise of blindly applying models has no anchor, in EPA's judgment. Such modeled extrapolations could take numerous shapes and there is no way to decide how shallow or steep the curve would be or where on the dose gradient the zero risk level might be, given the hundreds of possibilities. There are also certain modes of action that do not involve DNA reactivity, but are thought to be linear in dose response, such as effects on growth-control signals within cells. Since we do not know what the mode of action of arsenic is, we cannot in fact rule out linearity. Therefore, in accordance with the 1986 cancer guidelines, and subsequent guidance discussed later, the Agency cannot reasonably use anything other than a linear mode of action to estimate the upper bound of risk associated with arsenic exposure. Nevertheless, the uncertainties about both of these facets (the toxicokinetics and secondary effects) of risk estimation have been taken into account qualitatively in the Agency's final decision as a perspective on the linear dose-response estimation (see section III.F.).

The Agency considered mode-of-action information as a basis for departing from the assumption of linearity and in the process, developed a framework for judging the adequacy of mode of action data (EPA, 1996a). This framework has been reviewed and supported by the SAB (EPA, 1997f; EPA, 1999g). The framework was applied to the assessment of chloroform (EPA, 2000d).

In order to decide whether a particular mode of action is operative for an agent, the database on mode of action must be rich and able to both describe the sequence of key events in the putative mode of action and demonstrate it experimentally. The elements of the framework analysis include:

• Summary description of postulated mode of action (the postulated sequence of cellular/physiological events leading to cancer must be described.)

• Identification of key events (the specific events that are key to carcinogenesis must described in order to be experimentally examined.)

• Strength, consistency, specificity of association (the experimental observation of the key events and their relationship to tumor development must be described.)

• Dose-response relationship (the dose-response relationship between the key events and tumor incidence must be described and evaluated.)

• Temporal relationship (the key events must be shown to precede tumor development.)

• Biological plausibility and coherence (the postulated mode of action and the data must be in accord with general, accepted scientific evidence about the causes of cancer.)

• Other modes of action (alternative modes of action that are suggested must be examined and their contribution, if any, described.)

• Conclusion (an overall conclusion is made as to whether the postulated mode of action is accurate given the results of evaluation of the evidence under the previous elements.)

• Human relevance, including subpopulations (if the evidence of mode of action of carcinogenicity is from animal studies, its human relevance is examined.)

In the case of chloroform, there was sufficient information to describe key events and undertake mode of action analysis. In the case of arsenic, the postulated mode of action cannot be specifically described, the key events are unknown, and no analysis of the remaining elements of the mode of action framework can be made. Several possible influences of arsenic on the carcinogenic process have been postulated, but there are insufficient experimental data either to show that any one of the possible modes is the influence actually at work or to test the dimensions of its influence as the framework requires.

For chloroform there are extensive data on metabolism that identify the likely active metabolite. The key events—cell toxicity followed by sustained cell proliferation and eventually tumor effects—have been extensively studied in many experiments. The key events have been empirically demonstrated to precede and consistently be associated with tumor effects. In sum, a very large number of studies have satisfied the requirements of the framework analysis. By contrast, the arsenic database fails to even be able to satisfy the first element of the framework; the key events are unknown. While there are a number of possible modes of action implied by existing data, none of them has been sufficiently studied to be analyzed under the Agency's framework. For this reason the comparison of the "best available, peer reviewed data" for arsenic and chloroform shows quite different results. There are not sufficient data on arsenic to describe a mode of action as there were for chloroform. This was also the conclusion of the SAB review of arsenic (EPA, 2000q).

Overall, the NRC and SAB reports agreed that the best available science provides no alternative to use of a linear dose-response process for arsenic because a specific mode (or modes) of action has not been identified. Unlike chloroform, the Agency lacks sufficient available, peer-reviewed information on arsenic to estimate quantitatively a non-linear mode of action. The Agency thus has decided not to depart from the assumption of linearity in selecting an MCLG of zero.

2. Risk factors/bases for upper- and lower-bound analyses

EPA calculated upper- and lower-bound risk estimates for the U.S. population exposed to arsenic concentrations. The approach for this analysis included five components. First, we developed relative exposure factor distributions, which incorporate data from the recent EPA water consumption study with age, sex, and weight data. Second, the Agency calculated the arsenic occurrence distributions for the population exposed to arsenic levels above 3 µg/L. Third, we chose risk distributions for bladder and lung cancer for the analysis from Morales et al. (2000). Fourth, EPA developed estimates of the projected bladder and lung cancer risks faced by exposed populations using Monte-Carlo simulations, bringing together the relative exposure factor, occurrence, and risk distributions. These simulations resulted in upper bound estimates of the risks faced by U.S. populations exposed to arsenic concentrations at or above 3 µg/L in their drinking water. Finally, EPA made adjustments to the lower-bound risk estimates to reflect exposure to arsenic in cooking water and in food in Taiwan. A more detailed description of the risk methodology is provided in Appendix B of the Economic Analysis (EPA, 2000o).

a. Water consumption. EPA recently updated its estimates of per capita daily average water consumption (EPA, 2000c). The estimates used data from the combined 1994, 1995, and 1996 Continuing Survey of Food Intakes by Individuals (CSFII), conducted by the U.S. Department of Agriculture (USDA). The CSFII is a complex, multi-stage area probability sample of the entire U.S. and is conducted to survey the food and beverage intake of the U.S. Per capita water consumption estimates are reported by source. Sources include community tap water, bottled water, and water from other sources, including water from household wells and rain cisterns, and household and public springs. For each source, the mean and percentiles of the distribution of average daily per capita consumption are reported. The estimates are based on an average of 2 days of reported consumption by survey respondents. The estimated mean daily average per capita consumption of "community tap water" by individuals in the U.S. population is 1 liter/person/day. For "total water", which includes bottled water, the estimated mean daily average per capita consumption is 1.2 liters per/person/day. These estimates of water consumption are based on a sample of 15,303 individuals in the 50 States and the District of Columbia. The sample was selected to represent the entire

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population of the U.S. based on 1990 census data.

The estimated 90th percentile of the empirical distribution of daily average per capita consumption of community tap water for the U.S. population is 2.1 liters/person/day; the corresponding number for the 90th percentile of daily average per capita consumption of total water is 2.3 liters/person/day. In other words, current consumption data indicate that 90% of the U.S. population consumes approximately 2 liters/person/day, or less.

Water consumption estimates for selected subpopulations in the U.S. are described in the CSFII, including per capita water consumption by source for gender, region, age categories, economic status, race, and residential status and separately for pregnant women, lactating women, and women in childbearing years. The water consumption estimates by age and sex were used in the computation of the relative exposure factors discussed later.

b. Relative Exposure Factors. Lifetime male and female relative exposure factors (REFs) for each of the broad age categories used in the water consumption study were calculated, where the life-long REFs indicate the sensitivity of exposure to an individual relative to the sensitivity of exposure of an "average" person weighing 70 kilograms and consuming 2 liters of water per day, a "high end" water consumption estimate according to the EPA water consumption study referred to previously (EPA, 2000c). In these calculations, EPA combined the water consumption data with data on population weight from the 1994 Statistical Abstract of the U.S. Distributions for both community tap water and total water consumption were used because the community tap water estimates may underestimate actual tap water consumption. The weight data included a mean and a distribution of weight for male and females on a year-to-year basis. The means and standard deviations of the life-long REFs derived from this analysis are shown in Table III.D–1.

TABLE III.D–1.—LIFE-LONG RELATIVE EXPOSURE FACTORS

	Community water consumption data	Total water consumption data
Male	Mean = 0.60 s.d. = 0.61	Mean = 0.73 s.d. = 0.62
Female	Mean = 0.64 s.d. = 0.6	Mean = 0.79 s.d. = 0.61

c. Arsenic occurrence. EPA recently updated its estimates of arsenic occurrence, and calculated separate occurrence distributions for arsenic found in ground water and surface water systems. These occurrence distributions were calculated for systems with arsenic concentrations of 3 µg/L or above. Arsenic occurrence estimates are described in more detail in section III.C.

d. Risk distributions. In its 1999 report, "Arsenic in Drinking Water," the NRC analyzed bladder cancer risks using data from Taiwan. In addition, NRC examined evidence from human epidemiological studies in Chile and Argentina, and concluded that risks of bladder and lung cancer had comparable risks to those "in Taiwan at comparable levels of exposure" (NRC, 1999). The NRC also examined the implications of applying different statistical analyses to the newly available Taiwanese data for the purpose of characterizing bladder cancer risk. While the NRC's work did not constitute a formal risk analysis, they did examine many statistical issues (*e.g.*, measurement errors, age-specific probabilities, body weight, water consumption rate, comparison populations, mortality rates, choice of model) and provided a starting point for additional EPA analyses. The report noted that "poor nutrition, low selenium concentrations in Taiwan, genetic and cultural characteristics, and arsenic intake from food" were not accounted for in their analysis (NRC, 1999, pg. 295). In the June 22, 2000 proposed rule, EPA calculated bladder cancer risks and benefits using the bladder cancer risk analysis from the NRC report (NRC, 1999). We also estimated lung cancer benefits in a "What If" analysis based on the statement in the 1999 NRC report that "some studies have shown that excess lung cancer deaths attributed to arsenic are 2–5 fold greater than the excess bladder cancer deaths" (NRC, 1999).

In July, 2000, a peer reviewed article by Morales *et al.* (2000) was published, which presented additional analyses of bladder cancer risks as well as estimates of lung and liver cancer risks for the same Taiwanese population analyzed in the NRC report. EPA summarized and analyzed the new information from the Morales *et al.* (2000) article in a NODA published on October 20, 2000 (65 FR 63027; EPA, 2000m). Although the data used were the same as used by the NRC to analyze bladder cancer risk in their 1999 publication, Morales *et al.* (2000) considered more dose-response models and evaluated how well they fit the Taiwanese data for both bladder cancer risk and lung cancer risk. Ten risk models were presented in Morales *et al.* (2000) used with and without one of two comparison populations. After consultation with the primary authors (Morales and Ryan), EPA chose Model 1 with no comparison population for further analysis.

EPA believes that the models in Morales *et al.* (2000) without a comparison population are more reliable than those with a comparison population. Models with no comparison population estimate the arsenic dose-response curve only from the study population. Models with a comparison population include mortality data from a similar population (in this case either all of Taiwan or part of southwestern Taiwan) with low arsenic exposure. Most of the models with comparison populations resulted in dose-response curves that were supralinear (higher than a linear dose response) at low doses. The curves were "forced down" near zero dose because the comparison population consists of a large number of people with low risk and low exposure. EPA believes, based on discussions with the authors of Morales *et al.* (2000), that models with a comparison population are less reliable, for two reasons. First, there is no basis in data on arsenic's carcinogenic mode of action to support a supralinear curve as being biologically plausible. To the contrary, the conclusion of the NRC panel (NRC, 1999) was that the mode of action data led one to expect dose responses that would be either linear or less than linear at low dose. However, the NRC indicated that available data are inconclusive and " * * * do not meet EPA's 1996 stated criteria for departure from the default assumption of linearity." (NRC, 1999)

Second, models that include comparison populations assume that the study and comparison populations are the same in all important respects except for arsenic exposure. Yet Morales *et al.* (2000) agree that "[t]here is reason to believe that the urban Taiwanese population is not a comparable population for the poor rural population used in this study." Moreover, because of the large amount of data in the comparison populations, the model results are sensitive to assumptions about this group. Evidence that supports these arguments are that the risks in the comparison groups are substantially lower than in similarly exposed members of the study group and the shape of the estimated dose-response changes sharply as a result. For these reasons, EPA believes that the models without comparison populations are more reliable than those with them. Of the models that did not include a comparison population, EPA believes that Model 1 best fits the data, based on the Akaike Information Criterion (AIC), a standard criterion of model fit, applied to Poisson models. In Model 1, the relative risk of mortality at any time is assumed to increase exponentially with a linear function of dose and a quadratic function of age.

Morales *et al.* (2000) reported that two other models without comparison populations also fit the Taiwan data well: Model 2, another Poisson model with a nonparametric instead of quadratic age effect, and a multi-stage Weibull (MSW) model. Under Model 2, the points of departure for male and female bladder and lung cancer are from 1% to 11% lower than under Model 1, but within the 95% confidence bounds from Model 1. Model 2 therefore implies essentially the same bladder and lung cancer risks as Model 1. Under the MSW model, compared to Model 1, points of departure are 45% to 60% higher for bladder cancer and for female lung cancer, and 38% lower for male lung cancer. EPA did not consider the MSW model for further analysis, because this model is more sensitive to the omission of individual villages (Morales *et al.*, 2000) and to the grouping of responses by village (NRC, 1999), as occurs in the Taiwanese data. However, if the MSW model were correct, it would imply a 14% lower combined risk of lung and bladder cancers than Model 1, among males and females combined.

Considering all of these results, the Agency decided that the more exhaustive statistical analysis of the data provided by Morales *et al.* (2000), as analyzed by EPA, would be the basis for the new risk calculations for the final rule (with further consideration of additional risk analyses) and other pertinent information. The Agency views the results of the alternative models described above as an additional uncertainty which was considered in the decision concerning the selection of the final MCL (see section III.F. of today's preamble).

e. Estimated risk reductions. Estimated risk reductions for bladder and lung cancer at various MCL levels were developed using Monte-Carlo simulations. Monte-Carlo analysis is a technique for analyzing problems where there are a large number of combinations of input values which makes it impossible to calculate every possible result. A random number generator is used to select input values from pre-defined distributions. For each set of random numbers, a single scenario's result is calculated. As the simulation runs, the model is recalculated for each new scenario that continues until a stopping criteria is reached. These simulations combined the distributions of relative exposure factors (REFs), occurrence at or above 3 µg/L, and risks of bladder and lung cancer taken from the Morales *et al.* (2000) article. The simulations resulted in upper-bound estimates of the actual risks faced by populations exposed to arsenic concentrations at or above 3 µg/L in their drinking water.

f. Lower-bound analyses. Two adjustments were made to the risk distributions resulting from the simulations described previously, reflecting uncertainty about the actual arsenic exposure in the Taiwan study area. First, the Agency made an adjustment to the lower bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. The Taiwanese staple foods were dried sweet potatoes and rice (Wu *et al.*, 1989). Both the 1988 EPA "Special Report on Ingested Inorganic Arsenic" report (EPA,1988) and the 1999 NRC report assumed that an average Taiwanese male weighed 55 kg and drank 3.5 liters of water daily, and that an average Taiwanese female weighed 50 kg and drank 2 liters of water daily. Using these assumptions, along with an assumption that Taiwanese men and women ate one cup of dry rice and two pounds of sweet potatoes a day, the Agency re-estimated risks for bladder and lung cancer, using one additional liter water consumption for food preparation (*i.e.*, the water absorbed by hydration during cooking). This adjustment was discussed and used in the October 20, 2000 NODA (65 FR 63027; EPA, 2000m).

Second, an adjustment was made to the lower-bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. The food consumed daily in Taiwan contains about 50 µg of arsenic, versus about 10 µg in the U.S. (NRC, 1999, pp. 50–51). Thus the total consumption of inorganic arsenic (from food preparation and drinking water) is considered, per kilogram of body weight, in the process of these adjustments. To carry them out, the relative contribution of arsenic in the drinking water that was consumed as drinking water, on a µg arsenic per kilogram body weight per day (µg/kg/day) basis, was compared to the total amount of arsenic consumed in drinking water, drinking water used for cooking, and in food, on a µg/kg/day basis.

Other factors contributing to lower bound uncertainty include the possibility of a sub-linear dose-response curve below the point of departure. The NRC noted "Of the several modes of action that are considered most plausible, a sub-linear dose response curve in the low-dose range is predicted, although linearity cannot be ruled out." (NRC, 1999). The recent Utah study (Lewis *et al.*, 1999), described in section V.G.1(b), provides some evidence that the shape of the dose-response curve may well be sub-linear at low doses. Because sufficient mode of action data were not available, an adjustment was not made to the risk estimates to reflect the possibility of a sub-linear dose-response curve. Additional factors contributing to uncertainty include the use of village well data rather than individual exposure data, deficiencies in the Taiwanese diet relative to the U.S. diet (selenium, choline, etc.), and the baseline health status in the Taiwanese study area relative to U.S. populations. The Agency did not make adjustments to the risk estimates to reflect these uncertainties because applicable peer-reviewed, quantitative studies on which to base such adjustments were not available.

Estimated risk levels for bladder and lung cancer combined at various MCL levels are shown in Tables III.D–2(a-c). The risk estimates without adjustments for exposure uncertainty through cooking water and food are shown Table III.D–2 (a). These estimates incorporate occurrence data, water consumption data, and male and female risk estimates. Lower bounds show estimates using community water consumption data; upper bounds show estimates using total water consumption data. Table III.D–2 (b) shows estimated risk

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levels for bladder and lung cancer combined at various MCL levels with adjustments for exposure uncertainty through cooking water and food. These estimates incorporate occurrence data, water consumption data, and male risk estimates, with lower bounds reflecting community water consumption data and upper bounds reflecting total water consumption data. There are no adjustments for other factors which contribute to uncertainty, such as the use of village well data as opposed to individual exposure data. Tablet III.D–2 (c) is a combination of Table III.D–2(a) and Table III.D–2 (b), with the lower bounds taken from Table III.D–3 (b), and the upper bounds taken from Table III.D–2 (a). Thus Table III.D–2(c) reflects the range of estimates before and after the exposure uncertainty adjustments for cooking water and for food, along with the incorporation of water consumption data, occurrence data, and cancer risk estimates. These estimates were used to estimate the range of potential cases avoided at the various MCL levels.

The lower-bound risk estimates in Tables III.D–2(a-c) reflect the following:

—The community (tap) water consumption from the EPA water consumption study (EPA, 2000c)

—The occurrence distributions of arsenic in U.S. ground and surface water systems

—Male risk estimates from Morales *et al.* (2000)

—Arsenic exposure from cooking water in Taiwan

—Arsenic exposure from food in Taiwan

The upper-bound risk estimates in Tables III.D–2(a-c) reflect the following:

—The total water consumption estimates from the EPA water consumption study (EPA, 2000c)

—The occurrence distributions of arsenic in U.S. ground and surface water systems

—Male and female risk estimates from Morales *et al.* (2000)

TABLE III.D–2(a).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT [1,2]

[without adjustment for arsenic in food and cooking water]

MCL (μg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.93–1.25 \times 10^{-4}$	$1.95–2.42 \times 10^{-4}$
5	$1.63–2.02 \times 10^{-4}$	$3.47–3.9 \times 10^{-4}$
10	$2.41–2.99 \times 10^{-4}$	$5.23–6.09 \times 10^{-4}$
20	$3.07–3.85 \times 10^{-4}$	$6.58–8.37 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.
[2] The estimated risks are male and female risks combined.

TABLE III.D–2(B).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT 1,2

[without adjustment for arsenic in food and cooking water]

MCL (μg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.11–0.13 \times 10^{-4}$	$0.22–0.26 \times 10^{-4}$
5	$0.27–0.32 \times 10^{-4}$	$0.55–0.62 \times 10^{-4}$
10	$0.63–0.76 \times 10^{-4}$	$1.32–1.54 \times 10^{-4}$
20	$1.1–1.35 \times 10^{-4}$	$2.47–2.89 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.
[2] The estimated risks are for males.

TABLE III.D–2(c).—CANCER RISKS FOR U.S. POPULATIONS EXPOSED AT OR ABOVE MCL OPTIONS, AFTER TREATMENT [1,2]

[lower bound with food and cooking water adjustment, upper bound withough food and cooking water adjustment]

MCL (μg/L)	Mean exposed population risk	90th percentile exposed population risk
3	$0.11–1.25 \times 10^{-4}$	$0.22–2.42 \times 10^{-4}$
5	$0.27–2.02 \times 10^{-4}$	$0.55–3.9 \times 10^{-4}$
10	$0.63–2.99 \times 10^{-4}$	$1.32–6.09 \times 10^{-4}$
20	$1.1–3.85 \times 10^{-4}$	$2.47–8.37 \times 10^{-4}$

[1] Actual risks could be lower, given the various uncertainties discussed, or higher, as these estimates assume that the probability of illness from arsenic exposure in the U.S. is equal to the probability of death from arsenic exposure among the arsenic study group.

g. Cases avoided. The lower and upper bound risk estimates from Table III.D–2(c) were applied to the exposed population to generate cases avoided for CWSs serving less than a million customers. Because the actual arsenic occurrence was known for the very large systems (those serving over a million customers), their system-specific arsenic occurrence distributions could be directly computed. The system-specific arsenic distributions allowed direct calculation of avoided cancer cases. The process, described in detail in the Economic Analysis (EPA, 2000o), utilizes the same risk estimates from Morales et al. (2000) that were used in deriving the number of cases avoided in smaller CWSs. Cases avoided for NTNCWSs were also computed separately, utilizing factors developed to account for the intermittent nature of the exposure. These factors are described in the Economic Analysis.

An upper-bound adjustment was made to the number of bladder cancer cases avoided to reflect a possible lower mortality rate in Taiwan than was assumed in the risk assessment process described earlier. We also made this adjustment in the June 22, 2000 proposal. In the Taiwan study area, information on arsenic-related bladder and lung cancer deaths was reported. In order to use these data to determine the probability of contracting bladder and lung cancer as a result of exposure to arsenic, a probability of mortality, given the onset of arsenic-induced bladder and lung cancer among the Taiwanese study population, must be assumed. The study area in Taiwan is a section where arsenic concentrations in the water are very high by comparison to those in the U.S., and an area of low incomes and poor diets, where the availability and quality of medical care is not of high quality, by U.S. standards. In its estimate of bladder cancer risk, the Agency assumed that within the Taiwanese study area, the probability of contracting bladder cancer was relatively close to the probability of dying from bladder cancer (i.e., that the bladder cancer incidence rate was equal to the bladder cancer mortality rate).

We do not have data on the rates of survival for bladder cancer in the Taiwanese villages in the study at the time of data collection. We do know that the relative survival rates for bladder cancer in developing countries overall ranged from 23.5% to 66.1% in 1982–1992 (WHO, 1998). We also have some information on annual bladder cancer mortality and incidence for the general population of Taiwan in 1996. The age-adjusted annual incidence rates of bladder cancer for males and females, respectively, were 7.36 and 3.09 per 100,000, with corresponding annual mortality rates of 3.21 and 1.44 per 100,000 (correspondence from Chen to Herman Gibb, January 3, 2000). Assuming that the proportion of males and females in the population is equal, these numbers imply that the mortality rate for bladder cancer in the general population of Taiwan, at present, is 45%. Since survival rates have most likely improved over the years since the original Taiwanese study, this number represents a lower bound on the survival rate for the original area under study (*i.e.*, one would not expect a higher rate of survival in that area at that time). This has implications for the bladder cancer risk estimates from the Taiwan data. If there were any persons with bladder cancer who recovered and died from some other cause, then our estimate underestimated risk; that is, there were more cancer cases than cancer deaths. Based on the previous discussion, we think bladder cancer incidence could be no more than two-fold bladder cancer mortality; and that an 80% mortality rate would be plausible. Thus, we have adjusted the upper bound of cases avoided, which is used in the benefits analysis, to reflect a possible mortality rate for bladder cancer of 80 percent. Because lung cancer mortality rates are quite high, about 88% in the U.S. (EPA, 1998n), the assumption was made that all lung cancers in the Taiwan study area resulted in fatalities.

The total number of bladder and lung cases avoided at each MCL is shown in Table III.D–3. These cases avoided include CWSs and NTNCWSs cases. The number of bladder and lung cancer cases avoided ranges from 57.2 to 138.3 at an MCL of 3 μg/L, 51.1 to 100.2 at an MCL of 5 μg/L, 37.4 to 55.7 at an MCL of 10 μg/L, and 19.0 to 19.8 at an MCL of 20 μg/L. The cases avoided were divided into premature fatality and morbidity (*i.e.*, illness) cases based on U.S. mortality rates. In the U.S. approximately one out of four individuals who is diagnosed with bladder cancer actually dies from bladder cancer. The mortality rate for the U.S. is taken from a cost of illness study recently completed by EPA (EPA, 1999j). For those diagnosed with bladder cancer at the average age of diagnosis (70 years), the probability for dying of that disease during each year post-diagnosis was summed over a 20-year period to obtain the value of 26 percent. Mortality rates for U.S. bladder cancer patients have decreased overall by 24% from 1973 to 1996. For lung cancer, mortality rates are much higher. The comparable mortality rate for lung cancer in the U.S. is 88% (EPA, 1998n).

TABLE III.D–3.—ANNUAL TOTAL (BLADDER AND LUNG) CANCER CASES AVOIDED FROM REDUCING ARSENIC IN CWSS AND NTNCWS

Arsenic level (μg/L)	Reduced mortality cases[1]	Reduced morbidity cases[1]	Total cancer cases avoided
3	32.6–74.1	24.6–64.2	57.2–138.3
5	29.1–53.7	22.0–46.5	51.1–100.2
10	21.3–29.8	16.1–25.9	37.4–55.7
20	10.2–11.3	8.5–8.8	19.0–19.8

[1] Based on U.S. mortality rates given in the text.

3. Sensitive Subpopulations

The 1996 SDWA amendments include specific provisions in section 1412(b)(3)(C)(i)(V) that require EPA to assess the effects of a contaminant not just on the general population but on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. The NRC subcommittee noted that there is a marked variation in susceptibility to arsenic-induced toxic effects that may be influenced by factors such as genetic polymorphisms (especially in metabolism), life stage at which exposures occur, sex, nutritional status, and concurrent exposures to other agents or environmental factors. The NRC report concluded that there is insufficient scientific information to permit separate cancer risk estimates for potential subpopulations such as pregnant women, lactating women, and children and that factors that influence sensitivity to or expression of arsenic-associated cancer and noncancer effects need to be better characterized. EPA agrees with the NRC that there is not enough information to make risk conclusions on any specific subpopulations.

4. Risk Window

EPA has historically considered 10^{-4} to 10^{-6} as a target risk range protective of public health in its drinking water program. However, the risk-range

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represents a policy goal for EPA, and is not a statutory factor in setting an MCL. Note that the procedure EPA uses to estimate such risks provides an upper-bound estimate. In the case of arsenic, EPA performed a benefit-cost analysis as required by the statute. This analysis is discussed in more detail in section III.F.

E. What Are the Costs and Benefits at 3, 5, 10, and 20 µg/L?

In accordance with section 1412 (b)(3)(C) of SDWA, EPA must analyze the costs and benefits of a proposed NPDWR. To comply with this provision, EPA included the complete analysis in the proposed rule. Also, in accordance with Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the arsenic rule in an Economic Analysis in conjunction with publishing the final rule. EPA has prepared an Economic Analysis to comply with the requirements of this Order. This section provides a summary of the information from the Arsenic Economic Analysis (EPA, 2000o).

1. Summary of Cost Analysis

National cost estimates of compliance with the arsenic rule were derived from estimates of utility treatment costs, monitoring and reporting costs, and start-up costs for both CWS and NTNCWSs. Utility treatment costs were derived using occurrence data, treatment train unit costs, and decision trees. The occurrence data provide a measure of the number of systems that would need to install treatment in each size category. The treatment train unit cost estimates provide a measure of how much a technology will cost to install. Decision trees vary by system size and are used as a prediction of the treatment technology trains facilities would likely install to comply with options considered for the revised arsenic standard. Detailed descriptions of the methodologies used in determining the costs of this rule are found in the "Technologies and Cost for Removal of Arsenic in Drinking Water" document (EPA, 2000t) and also the "Arsenic Economic Analysis" (EPA, 2000o), both of which are in the docket for this final rulemaking.

a. Total national costs. Under the MCL of 10 µg/L, the Agency estimates that total national costs to CWSs are $172.3 million (1999 dollars) annually at a 3% discount rate. This total national cost includes annual treatment costs ($169.6 million), annual monitoring and administrative costs ($1.8 million), and annual State costs ($0.9 million). Assuming a 7% discount rate, total national costs to CWSs are estimated at $196.6 million annually.

Total national costs to NTNCWSs are estimated at $8.1 million annually at a 3% discount rate. This includes annual treatment costs ($7.0 million), annual monitoring and administrative costs ($0.9 million), and annual State costs ($0.1 million). Total national costs to NTNCWSs, assuming a 7% discount rate, are estimated at $9.1 million annually.

Table III.E–1 shows the total national cost breakdown for the arsenic MCL and also for three other arsenic levels considered in the proposed rule. Expected system costs include treatment costs, monitoring costs, and administrative costs of compliance. State costs include monitoring and administrative costs of implementation. As expected, aggregate arsenic compliance costs increase with decreasing arsenic MCL levels as more systems are affected.

TABLE III.E–1.—TOTAL ANNUAL NATIONAL SYSTEM AND STATE COMPLIANCE COSTS

[$ millions, 1999]

Discount rate	CWS		NTNCWS		Total	
	3 percent	7 percent	3 percent	7 percent	3 percent	7 percent
MCL = 3 µg/L						
System Costs	$868.1	$759.5	$28.2	$31.0	$896.3	$790.4
Treatment	665.9	756.5	27.2	29.6	693.1	786.0
Monitoring/Administrative	2.2	3.0	1.0	1.4	3.2	4.4
State Costs	1.4	1.6	0.1	0.2	1.5	1.7
Total[1]	669.4	761.0	28.3	31.1	697.8	792.1
MCL = 5 µg/L						
System Costs	396.4	451.1	17.3	18.9	413.5	470.2
Treatment	394.4	448.3	16.3	17.6	410.6	466.1
Monitoring/Administrative	2.0	2.8	1.0	1.3	2.9	4.1
State Costs	1.1	1.3	0.1	0.2	1.2	1.4
Total[1]	397.5	452.5	17.3	19.1	414.8	471.7
Final MCL = 10 µg/L						
System Costs	171.4	195.5	7.9	8.9	179.4	204.4
Treatment	169.6	193.0	7.0	7.6	176.7	200.6
Monitoring/Administrative	1.8	2.5	0.9	1.3	2.7	3.8
State Costs	0.9	1.0	0.1	0.2	1.0	1.2
Total[1]	172.3	196.6	8.1	9.1	180.4	205.6
MCL = 20 µg/L						
System Costs	62.4	71.4	3.5	4.1	65.9	75.5
Treatment	60.7	69.0	2.6	2.8	63.3	71.8
Monitoring/Administrative	1.7	2.4	0.9	1.3	2.6	3.7

TABLE III.E–1.—TOTAL ANNUAL NATIONAL SYSTEM AND STATE COMPLIANCE COSTS—Continued

[$ millions, 1999]

Discount rate	CWS		NTNCWS		Total	
	3 percent	7 percent	3 percent	7 percent	3 percent	7 percent
State Costs	0.7	0.8	0.1	0.2	0.9	1.0
Total[1]	63.2	72.3	3.6	4.2	66.8	76.5

[1] Total may not match detail due to rounding.

b. Household costs. Table III.E–2 shows mean annual costs per household for those households that are served by systems that may need to treat under today's rule. As discussed in Table III.C–6 of today's preamble and Table 8–2 of the Economic Analysis, of the approximately 74,000 systems that are covered by today's rule, EPA estimates that only about 3,433 of these systems will require treatment. Table III.E–2 refers only to the households served by systems expected to need treatment. The average household cost increase resulting from today's rule is $31.85. However, due to economies of scale, costs per household are higher in the smaller size categories, and lower in the larger size categories. For today's rule (10 µg/L), costs are expected to be $326.82 per household for systems serving <100 people, and $162.50 per household for systems serving 101–500 people. Costs per households in systems larger than those are substantially lower: From $70.72 to $0.86 per household. As shown in Table III.E–2, the costs per household do not vary dramatically across MCL options although Table III.E–1 shows that total national costs are significantly different. This divergence is attributable to the total number of households affected by each MCL level and not the cost of treatment. For example, approximately eleven million households would be affected by an MCL of 3 µg/L compared to approximately three million affected by the today's final rule MCL of 10 µg/L. In addition, the household costs change relatively little among MCL options because while each progressively lower MCL option brings in a larger number of systems subject to the rule, the majority of those systems generally need only minimal removal of arsenic. This fact offsets, to an extent, the increased costs as a result of more systems covered at lower MCL options. A more detailed discussion of household costs can be found in Chapter 6 of the "Arsenic Economic Analysis" document (EPA, 2000o).

TABLE III.E–2.—MEAN ANNUAL COSTS PER HOUSEHOLD

[in 1999 dollars][1]

System size	3 µg/L	5 µg/L	10 µg/L	20 µg/L
<100	$317.00	$318.26	$326.82	$351.15
101–500	166.91	164.02	162.50	166.72
501–1,000	74.81	73.11	70.72	68.24
1,001–3,300	63.76	61.94	58.24	54.36
3,301–10,000	42.84	40.18	37.71	34.63
10,001–50,000	38.40	36.07	32.37	29.05
50,001–100,000	31.63	29.45	24.81	22.63
100,001–1,000,000	25.29	23.34	20.52	19.26
>1,000,000	7.41	2.79	0.86	0.15
All categories	41.34	36.95	31.85	23.95

[1] Only households served by those systems expected to install treatment.

2. Summary of Benefits Analysis

Arsenic ingestion has been linked to a multitude of health effects, both cancerous and non-cancerous. These health effects include cancer of the bladder, lungs, skin, kidney, nasal passages, liver, and prostate. Arsenic ingestion has also been attributed to cardiovascular, pulmonary, immunological, and neurological, endocrine effects. A complete list of the arsenic-related health effects reported in humans is discussed in section III. D of this preamble. Current research on arsenic exposure has only been able to provide enough information to conduct a quantitative assessment of bladder and lung cancers. The other health effects and possible non-health benefits remain unquantified in this analysis but are discussed qualitatively. It is important to note that if the Agency were able to quantify additional arsenic-related health effects and non-health effects, the quantified benefits estimates may be significantly higher than the estimates presented in this analysis. In addition, the SDWA amendments of 1996 require that EPA fully consider both quantifiable and non-quantifiable benefits that result from drinking water regulations and has done this for today's arsenic rule.

a. Primary analysis. Quantifiable benefits. Although arsenic in drinking water has been associated with numerous health effects (see section III.D), the quantified benefits that result from today's rule are associated only with reductions in arsenic-related bladder and lung cancers. A complete discussion of risk assessment methodology and assumptions can be found in Chapter 5 of the "Arsenic Economic Analysis" document (EPA, 2000o).

The quantified benefits for today's rule for both CWSs and NTNCWSs range from $140 million to $198 million and consider both lower- and upper-bound risk levels. Specifically, the benefits to the CWSs are approximately $138.2 million to $193.2 million and $1.4 million to $4.5 million for NTNCWSs. Table III.E–3 shows the complete range of quantified benefits for the other MCL levels considered by the Agency. Section III.D.2. of this preamble explains the derivation of the upper- and lower-bound estimates

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In order to monetize the benefit from the bladder and lung cancers cases avoided, the Agency used two different values. First, a value of statistical life (VSL) estimate was applied to those cancer cases that result in a mortality. EPA assumed a 26% mortality rate for bladder cancer and an 88% mortality rate for lung cancer (EPA, 1999j; EPA, 1998n). The current VSL value used by the Agency is $6.1 million, in 1999 dollars. This value of $6.1 million does not reflect any adjustments to account for national real income growth that occurred subsequent to the completion of the wage-risk studies on which EPA's VSL estimate is derived. Were the Agency to adjust the VSL to account for this growth in real income, the VSL would be approximately $6.77 million (assuming a 1.0 income elasticity).

Second, a willingness-to-pay value (WTP) is used to monetize the cancer cases that do not result in a mortality. The WTP value for avoiding a non-fatal cancer is not currently available; therefore, the Agency used a WTP estimate to reduce a case of chronic bronchitis as a proxy. The use of this value may understate the true benefit if the WTP to avoid a nonfatal cancer is greater than the WTP to avoid a case of chronic bronchitis. The mean value of this WTP estimate is $607,000 (in 1999 dollars). A complete discussion of the VSL and WTP values and how they are calculated can be found in Chapter 5 for the "Arsenic Economic Analysis" document (EPA, 2000o).

—Non-quantifiable benefits. There are a number of important non-quantified benefits that EPA considered in its analysis. Chief among these are certain health impacts known to be caused by arsenic, though, while they may be substantial, the extent to which these impacts occur at levels below 50 μg/L is unknown. These additional health effects include cancers, other than bladder and lung cancers, as well as non-cancer health effects. In addition, EPA has identified non-health benefits that may result from today's rule, which are discussed next.

EPA was not able to quantify many of the health effects potentially associated with arsenic due to data limitations. These health effects include other cancers such as skin and prostate cancer and non-cancer endpoints such as cardiovascular, pulmonary, and neurological impacts. These health effects and the relevant studies linking these health effects to arsenic in drinking water are discussed in section III.D. of today's rule. For example, a number of epidemiologic studies conducted in several countries (*e.g.*, Taiwan, Japan, England, Hungary, Mexico, Chile, and Argentina) report an association between arsenic in drinking water and skin cancer in exposed populations. Studies conducted in the U.S. have not demonstrated an association between inorganic arsenic in drinking water and skin cancer. However, these studies may not have included enough people in their design to detect these types of effects.

Other potential benefits not quantified or monetized in today's rule include reduced uncertainty about becoming ill from consumption of arsenic in drinking water and the ability for some treatment technologies to eliminate multiple contaminants. The reduced uncertainty concept depends on several factors including consumer's degree of risk aversion, their perceptions about the drinking water quality (degree to which they will be affected by the regulatory action), and the expected probability and severity of human heath effects associated with arsenic contamination of drinking water. Another non-quantified benefit is the effect on those systems that install treatment technologies that can address multiple contaminants. For example, membrane systems, such as reverse osmosis, can be used for arsenic removal but can also remove many other contaminants that EPA is in the process of regulating or considering regulating. Therefore, by installing a reverse osmosis system, a system may not have to make any additional changes to comply with these future regulations.

TABLE III.E–3.—ESTIMATED BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER

[$ millions 1999]

Arsenic level (μg/L)	Total quantified health benefits [1]	Potential non-quantified health benefits includes reductions in:
3	$213.8–$490.9	• Skin Cancer. • Kidney Cancer. • Cancer of the Nasal Passages. • Liver Cancer. • Prostate Cancer. • Cardiovascular Effects. • Pulmonary Effects. • Immunological Effects. • Neurological Effects. • Endocrine Effects.
5	$191.1–$355.6	
10	$139.6–$197.7	
20	$66.2–$75.3	

[1] Benefits from reduction in bladder and lung cancer. The range represents both a lower and upper bound risk as discussed in section III. D. of this preamble.

b. Sensitivity analysis on benefits valuation. For the final rulemaking analysis, some commenters have argued that the Agency should consider an assumed time lag or latency period in its benefits calculations. The term "latency" can be used in different ways, depending on the context. For example, health scientists tend to define latency as the period beginning with the initial exposure to the carcinogen and ending when the cancer is initially manifested (or diagnosed), while others consider latency as the period between manifestation of the cancer and death. Latency, in this case, refers to the difference between the time of initial exposure to environmental carcinogens and the actual mortality. Use of such an approach might reduce significantly the present value of health risk reduction benefits estimates.

In the proposed arsenic rule, the Agency included qualitative language on the latency issue, including descriptions of other adjustments which may influence the estimate of economic benefits associated with avoided cancer fatalities. The Agency also agreed to ask the SAB to conduct a review of the benefits' transfer issues and possible adjustment factors associated with economic valuation of mortality risks. A summary of the SAB's recommendations is shown in the following section.

c. SAB recommendations. EPA brought this issue before the Environmental Economics Advisory Committee (EEAC) of EPA's SAB in a meeting held on February 25, 2000 in Washington, DC. The SAB submitted a final report on its findings and recommendations to EPA on July 27, 2000. The Panel's report made a number of recommendations on the adjustment factors and benefit-cost analysis in general. A copy of the final SAB report (EPA, 2000j) is in the record for this rulemaking.

The SAB Panel noted that benefit-cost analysis, as described in the Agency's Guidelines for Preparing Economic Analysis (EPA, 2000k), is not the only analytical tool nor is efficiency the only appropriate criterion for social decision making. The SAB Panel also stated that it is important to carry out such analyses in an unbiased manner with as much precision as possible. In its report, the SAB recommended that the Agency continue to use a wage-risk-based VSL as its primary estimate; any appropriate adjustments that are made for timing (*e.g.*, latency) and income growth should be part of the Agency's main analysis while any other proposed adjustments should be accounted for in sensitivity analyses to show how results would change if the VSL were adjusted for some of the major differences in the characteristics of the risk and of the affected populations. The SAB recommended including only adjustments for latency and income growth in the main analysis because it did not believe any of the other proposed adjustments were adequately supported in the literature at the present time. Specifically, the SAB report recommended that (1) Health benefits brought about by current policy initiatives (*i.e.*, after a latency period) should be discounted to present value using the same rate that is used to discount other future benefits and costs in the primary analysis; and any other proposed adjustments should be accounted for in a sensitivity analysis including adjustments to the VSL for a "cancer premium," voluntariness and controllability, altruism, risk aversion, and ages of the affected population. No adjustment should be made to the VSL to reflect health status of persons whose cancer risks are reduced. (2) Estimates of VSLs accruing in future years should be adjusted in the primary analysis to reflect anticipated income growth, using a range of income elasticities.

After considering the SAB's recommendations, EPA has developed a sensitivity analysis of the latency structure and associated benefits for the arsenic rule, as described in the next section and in the Economic Analysis for the final rule. This analysis consists of health risk reduction benefits that reflect adjustments for discounting, incorporation of a range of latency period assumptions, adjustments for growth in income, and incorporation of other factors such as voluntariness and controllability. Although the SAB recommended accounting for latency in a primary benefits analysis, the Agency believes that, in the absence of any sound scientific evidence on the duration of particular latency periods for arsenic related cancers, discounted benefits estimates for arsenic are more appropriately accounted for in a sensitivity analysis. Sensitivity analyses are generally reserved for examining the effects of accounting for highly uncertain factors, such as the estimation of latency periods, on health risk reduction benefits estimates.

Defining a latency period is highly uncertain because the length of the latency period is often poorly understood by health scientists. In some cases, information on the progression of a cancer is based on animal studies, and extrapolation to humans is complex and uncertain. Even when human studies are available, the dose considered may differ significantly from the dose generally associated with drinking water contaminants (*e.g.*, involve a high level of exposure over a short time period, rather than a long term, low level of exposure). The magnitude of the dose, may in turn, affect the resulting latency period. Information on latency may be unavailable in many cases or, if available, may be highly uncertain and vary significantly across individuals. The Agency recognizes, however, that despite significant uncertainty in the latency period associated with arsenic exposure through drinking water, it is unlikely that all cancer reduction benefits would be realized immediately upon exposure reduction. To the extent that there are delays due to latency in the realization of these benefits, monetized cancer reduction benefits would be discounted; although, as discussed above, this may be offset by other adjustments.

d. Analytical approach. For the latency sensitivity analysis, the health benefits have been broken into separate treatments of morbidity and mortality. The mortality component of the total benefits is examined in this analysis because a cancer latency period (*i.e.*, the time period between initial exposure to environmental carcinogens and the actual fatality) impacts arsenic-related fatalities to a greater extent than arsenic-related morbidity. For purposes of this analysis, the Agency examined the impacts of various latency period assumptions, adjustments for income growth, and incorporation of other adjustments such as a voluntariness and controllability, on bladder and lung cancer fatalities associated with arsenic in drinking water (EPA, 2000k).

Because the latency period for arsenic related bladder and lung cancers is unknown, EPA has assumed a range of latency periods from 5 to 20 years. While both lung and bladder cancer have relatively long, average latencies, the lower end of the latency period is substantially less. As can be seen by inspection of the Surveillance, Epidemiology, and End Results (SEER) data of the National Cancer Institute, significant incidence of both cancers occurs in individuals in the 15–19 year old age groups (NCI, 2000). This strongly indicates a short latency period for whatever the cause of the cancer may have been.

Moreover, the mode of action for arsenic is suspected to be one that operates at a late stage of the cancer process that may advance the expression of cancers initiated by other causes (sometimes referred to as "promoting out" the cancerous effect). Therapeutic treatment with the drug cyclophosphamide, which causes cell toxicity, has been seen to induce bladder cancer in as little as 7 months to 15 years in affected patients. This was of course a high dose treatment, but the example serves to illustrate the ability of an agent to advance the development of cancer.

For these reasons, we believe latency periods of 5, 10, and 20 years serve as reasonable approximations, in the absence of definitive data on arsenic-induced cancers, of the latency periods for the sensitivity analysis.

Table III.E–4 shows the sensitivity of the primary analysis VSL estimate ($6.1 million, 1999 dollars) to changes in latency period assumptions and also with the incorporation of an adjustment to reflect changes in WTP based on real income growth and other adjustment factors. As is shown in Table III.E–4, the adjusted VSL is greater than the primary VSL ($6.77 million versus $6.1 million) at an income elasticity of 1.0, with adjustments for income growth only. Assuming a 3% discount rate, the lowest adjusted VSL value ($3.44 million) is yielded over a 20-year latency period that includes discounting and income growth only (income elasticity = 0.22). Assuming a 7% discount rate, the highest adjusted VSL is also $6.77 million (adjusted for income growth only (income elasticity = 1.0)). The lowest adjusted VSL is $1.61 million (discounted over 20 years).

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TABLE III.E–4.— SENSITIVITY OF THE PRIMARY VSL ESTIMATE TO CHANGES IN LATENCY PERIOD ASSUMPTIONS, INCOME GROWTH, AND OTHER ADJUSTMENTS

[$ millions, 1999]

Adjustment factor	Latency period (Years)		
	5	10	20
3% Discount Rate			
Primary Analysis (No VSL Adjustment)	6.1	6.1	6.1
Adjusted for Income Growth: [1]			
elasticity = 0.22	6.22	6.22	6.22
elasticity = 1.0	6.77	6.77	6.77
Adjusted for Income Growth [1] and Discounting:			
elasticity = 0.22	5.37	4.63	3.44
elasticity = 1.0	5.84	5.04	3.75
Adjusted for Income Growth,[1] Discounting, and 7% Increase for Voluntariness and Controllability:			
elasticity = 0.22	5.74	4.95	3.69
elasticity = 1.0	6.25	5.39	4.01
Break-Even for Other Characteristics (as a percentage of the primary VSL estimate):			
elasticity = 0.22	6 percent	19 percent	40 percent
elasticity = 1.0	−2 percent	12 percent	34 percent
7% Discount Rate			
Primary Analysis (No VSL Adjustment)	6.1	6.1	6.1
Adjusted for Income Growth: [1]			
elasticity = 0.22	6.22	6.22	6.22
elasticity = 1.0	6.77	6.77	6.77
Adjusted for Income Growth [1] and Discounting:			
elasticity = 0.22	4.44	3.16	1.61
elasticity = 1.0	4.83	3.44	1.75
Adjusted for Income Growth, [1] Discounting, and 7% Increase for Voluntariness and Controllability:			
elasticity = 0.22	4.75	3.38	1.72
elasticity = 1.0	5.17	3.68	1.87
Break-Even for Other Characteristics (as a percentage of the primary VSL estimate):			
elasticity = 0.22	22 percent	45 percent	72 percent
elasticity = 1.0	15 percent	40 percent	69 percent

[1] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999.

The first row of both the 3% and 7% discount rate panels in Table III.E–4 shows the VSL used in the primary analysis. Because this value has not been adjusted for discounting over an assumed and unknown latency period, this value does not deviate from the original $6.1 million used in the primary benefits analysis. The second and third rows of both the 3 and 7 percent panels show the adjustments to the primary VSL to account for changes in WTP for fatal risk reductions associated with real income growth from 1990 to 1999. As real income grows, the WTP to avoid fatal risks is also expected to increase at a rate corresponding to the income elasticity of demand, as discussed below. This income growth, from the years 1990 to 1999, accounts for the differences in incomes of the VSL study population versus the population affected by the arsenic rule. This does not include any income adjustments over a latency period because of methodological issues that have not yet been resolved. However, pending the resolution of these issues, EPA may include an adjustment for income growth over a latency period in future analyses, as recommended by the SAB.

The fourth and fifth rows of both the 3% and 7% panels illustrates the impacts of adjusting the primary VSL for discounting and WTP changes based on real income growth over a range of assumed latency periods. As is shown in Table III.E–4, this value decreases from $5.84 million assuming a five-year latency period to $3.75 million assuming a 20-year latency period (at a 3% discount rate and income elasticity of 1.0). At a 7% discount rate, this value decreases from $4.83 million to $1.75 million.

The sixth and seventh rows of the 3% and 7% panels illustrate the effects of incorporating a 7% increase for voluntariness and controllability. The 7% adjustment is based on a study by Cropper and Subramanian (1999) that indicates individuals may place a slightly higher Willingness to Pay (WTP) on risks where exposure is neither voluntary nor controllable by the individual.

In adjusting for WTP changes based on real income growth, EPA used a range of income elasticities from the economics literature. Income elasticity is the % change in demand for a good (in this case, WTP for fatal risk reductions) for every 1% change in income. For example, an income elasticity of 1.0 implies that a 10 percent higher income level results in a 10% higher WTP for fatal risk reductions. In a recent study (EPA, 2000l), EPA reviewed the literature related to the income elasticity of demand for the prevention of fatal health impacts. Based on data from cross-sectional studies of wage premiums, a range of elasticity estimates for serious health impacts was developed, ranging from a lower-end estimate of 0.22 to an upper-end estimate of 1.0.

There are several other characteristics that differ between the VSL estimates used in the primary analysis and an ideal estimate specific to the case of cancer risks from arsenic. These might include a cancer premium, differences in risk aversion, altruism, age of the individual affected, and a morbidity component of the VSL mortality estimate. Very little empirical information is available on the impact that these characteristics have on VSL estimates so they are not accounted for directly in this sensitivity analysis. A more complete discussion of the other characteristics identified by economists as having a potential impact on willingness to pay to reduce mortality risks can be found in chapter seven of the Agency's "Guidelines for Preparing Economic Analyses" (EPA 2000k), which is available in the docket for this final rulemaking.

However, it is possible to use a different type of analysis to address the question: what would the impact on VSL of these additional characteristics need to be to produce the $6.1 million VSL used in the primary benefits analysis? (See primary benefits analysis in section III.E.2.a of today's rule.) The last two rows of the 3% and 7% panels of Table III.E–4 attempt to answer this question in percentage terms. For example, at a 3% discount rate over a 10-year latency period, income elasticity of 1.0, and a 7% adjustment for controllability and voluntariness, a factor of 12% (as shown in the bottom row of the 3% panel of Table III.E–4) indicates that if accounting for these characteristics would increase VSL by more than 12% then the primary analysis will tend to understate the value of risk reductions. If accounting for these characteristics would not increase VSL by at least 12%, then the primary analysis may overstate benefits (a negative % indicates that the primary analysis understates benefits unless the combined impact of these additional characteristics actually reduces VSL estimates).

Some researchers believe that the value of some of these characteristics will substantially add to the unadjusted VSL (one study suggests that a cancer premium alone may be worth an additional 100% of primary VSL value (Revesz, 1999)). Some researchers also believe that some of these characteristics have a negative effect on VSL, suggesting that some of these factors offset one another. Until we know more about these various factors we cannot explicitly make adjustments to existing VSL estimates. The SAB noted in its report that these characteristics require more empirical research prior to incorporation into the Agency's primary benefits analysis, but could be explored as part of a sensitivity analysis.

e. Results. Table III.E–5 illustrates the impacts of changes in VSL adjustment factor assumptions on the estimated benefits for the range of fatal bladder and lung cancer cases avoided in the final arsenic rule, assuming a 3% discount rate. The results of this analysis at a 7% discount rate are given in Table III.E–6. These results were calculated by applying the adjusted VSL from Table III.E–4 to the lower- and upper-bound estimates of fatal bladder and lung cancer cases avoided as shown in Table III.E–3 in section III.D.2 of today's rule. For purposes of this sensitivity analysis, EPA presented combined bladder and lung cancer cases avoided in Tables III.E–5 and III.E–6. Health risk reduction benefits attributable to reduced arsenic levels in both CWSs and NTNCWSs are presented in these tables as well.

It is important to note that the monetized benefits estimates shown in this section reflect quantifiable benefits only. As shown in section III.E.2.a, there may be a number of nonquantifiable benefits associated with regulating arsenic in drinking water. Were EPA able to quantify some of the currently nonquantifiable health effects and other benefits associated with arsenic regulation, monetized benefits estimates would be higher than what is shown in the table. A more complete discussion of how risks from arsenic in drinking water and the corresponding health benefits were calculated is provided in the "Arsenic Economic Analysis" (EPA, 2000o), which is available in the docket for this final rulemaking.

TABLE III.E–5.—SENSITIVITY OF COMBINED ANNUAL BLADDER AND LUNG CANCER MORTALITY BENEFITS ESTIMATES TO CHANGES IN VSL ADJUSTMENT FACTOR ASSUMPTIONS

[$ millions, 1999, 3% discount rate] [1]

Arsenic Level (μg/L)	3	5	10	20
5-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth[2] and Discounting:				
E = 0.22	175–398	156–288	114–160	55–61
E = 1.0	190–433	170–314	124–174	60–66
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	187–425	167–308	122–171	59–65
E = 1.0	204–463	182–336	133–186	64–71
10-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth,[2] and Discounting:				
E = 0.22	151–343	135–249	99–138	47–52
E = 1.0	164–373	147–271	107–150	51–57
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	161–367	144–266	105–148	50–56
E = 1.0	176–399	157–289	115–161	55–61

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TABLE III.E–5.—SENSITIVITY OF COMBINED ANNUAL BLADDER AND LUNG CANCER MORTALITY BENEFITS ESTIMATES TO CHANGES IN VSL ADJUSTMENT FACTOR ASSUMPTIONS—Continued

[$ millions, 1999, 3% discount rate] [1]

Arsenic Level (µg/L)	3	5	10	20
20-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	176–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	112–255	100–185	73–103	35–39
E = 1.0	122–278	109–201	80–112	38–42
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	120–273	107–198	79–110	38–42
E = 1.0	131–297	117–215	85–119	41–45

[1] The lower- and upper-bound benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.
[2] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999. E = income elasticity.

TABLE III.E–6.—SENSITIVITY OF COMBINED ANNUAL BLADDER AND LUNG CANCER MORTALITY BENEFITS ESTIMATES TO CHANGES IN VSL ADJUSTMENT FACTOR ASSUMPTIONS

[$ millions, 1999, 7% discount rate] [1]

Arsenic Level (µg/L)	3	5	10	20
5-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth,[2] and Discounting:				
E = 0.22	145–329	129–238	95–132	45–50
E = 1.0	157–358	141–259	103–144	50–55
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	155–352	138–255	102–142	49–54
E = 1.0	168–383	150–278	110–154	53–58
10-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	103–234	92–170	67–94	32–36
E = 1.0	112–255	100–185	73–103	35–39
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	110–251	98–182	72–101	35–38
E = 1.0	120–273	107–198	78–110	38–42
20-Year Latency Period Assumption				
Primary Analysis (No VSL Adjustment)	199–452	178–328	130–182	62–69
Adjusted for Income Growth: [2]				
E = 0.22	203–461	181–334	133–186	63–70
E = 1.0	221–502	197–364	144–202	69–77
Adjusted for Income Growth [2] and Discounting:				
E = 0.22	53–119	47–86	34–48	16–18
E = 1.0	57–130	51–94	37–52	18–20
Adjusted for Income Growth,[2] Discounting, and 7% Increase for Voluntariness and Controllability:				
E = 0.22	56–127	50–92	37–51	18–20
E = 1.0	61–139	54–100	40–56	19–21

[1] The lower- and upper-bound benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.
[2] This adjustment reflects the change in WTP based on real income growth from 1990 to 1999. E = income elasticity.

As shown in Tables III.E–5 and III.E–6, the highest range of adjusted benefits estimates at the 10 µg/L MCL ($144–$202 million) are yielded when benefits are adjusted for changes in WTP based on real income growth only with an income elasticity of 1.0. The lowest adjusted benefits estimates at the 10 µg/L MCL ($73–$103 million at 3%, $34–$48 million at 7%) are yielded under the assumption of a 20-year latency period that includes adjustments for discounting and WTP changes based on real income growth (income elasticity = 0.22). These results indicate the high degree of sensitivity of benefits estimates to different assumptions of a latency period, discount rate, and income elasticity and also the inclusion of adjustments for income growth and voluntariness and controllability.

3. Comparison of Costs and Benefits

This section presents a comparison of quantifiable total national costs and benefits for each of the arsenic regulatory options considered. Three separate analyses are considered, including a direct comparison of aggregate national costs and benefits, a summary of benefit-cost ratios and net benefits, and the results of a cost-effectiveness analysis of each regulatory option.

a. Total national costs and benefits. Table III.E–7 shows the annual costs and benefits associated with the 10 µg/L MCL and also with three other arsenic levels considered in the proposed rule. Both costs and benefits increase as arsenic levels decrease. Costs increase over decreasing arsenic levels because of the increasing number of systems that must treat to lower arsenic levels. Benefits estimates increase as arsenic levels decrease due to the greater number of both fatal and non-fatal cancer cases avoided at lower arsenic levels. Additionally, other potential non-quantifiable health benefits are summarized in Table III.E–7.

TABLE III.E–7 ESTIMATED ANNUAL COSTS AND BENEFITS FROM REDUCING ARSENIC IN DRINKING WATER

[1999, $ millions]

Arsenic level (µg/L)	Total national costs to CWSs and NTNCSs [1]	Total bladder cancer health benefits [2]	Total lung cancer health benefits [2]	Total combined cancer health benefits [2]	Potential nonquantifiable health benefits
3	697.8–792.1	58.2–156.4	155.6–334.5	213.8–490.9	Skin Cancer; Kidney Cancer; Cancer of the Nasal Passages; Liver Cancer; Prostate Cancer; Cardiovascular Effects; Pulmonary Effects; Immunological Effects; Neurological Effects; Endocrine Effects.
5	414.8–471.7	52.0–113.3	139.1–242.3	191.1–355.6	
10	180.4–205.6	38.0–63.0	101.6–134.7	139.6–197.7	
20	66.8–76.5	20.1–21.5	46.1–53.8	66.2–75.3	

[1] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs and State costs for administration of water programs. The lower number shows costs annualized at a consumption rate of interest of 3%, EPA's preferred approach. The higher number shows costs annualized at 7%, which represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.
[2] The lower- and upper-bound bladder, lung, and combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble; these estimates include both mortality and morbidity.

b. National net benefits and benefit-cost ratios. Table III.E–8 describes the quantifiable net benefits and the benefit-cost ratios under various regulatory levels for both CWSs and NTNCWSs at 3% and 7% discount rates. The net benefits and benefit-cost ratios do not include any of the potential nonquantifiable health benefits that are listed in the previous table. As shown in Table III.E–8, under both the lower- and upper-bound estimates of avoided lung and bladder cancer cases, the net benefits decrease as the arsenic rule MCL options become increasingly more stringent. Similarly, the benefit-cost ratios decrease with each more stringent MCL option. Costs outweigh the quantified benefits for the lower-bound benefits estimates under all four MCL options. Benefit-cost ratios are equal to or greater than 1.0 for the upper-bound benefits estimates (at both 3% and 7% discount rates) for arsenic levels of 10 µg/L and 20 µg/L.

TABLE III.E—8. SUMMARY OF NATIONAL ANNUAL NET BENEFITS AND BENEFIT-COST RATIOS, COMBINED BLADDER AND LUNG CANCER CASES

[1999, $ millions] [1 2 3]

		Arsenic level (µg/L)			
		3	5	10	20
3% Discount Rate					
Lower Bound	Net Benefits	(484.0)	(223.7)	(40.8)	(0.6)
	B/C Ratio	0.3	0.5	0.8	1.0
Upper Bound	Net Benefits	(206.8)	(59.2)	17.3	8.5
	B/C Ratio	0.7	0.9	1.1	1.1
7% Discount Rate					
Lower Bound	Net Benefits	(578.3)	(280.6)	(66.0)	(10.3)
	B/C Ratio	0.3	0.4	0.7	0.9
Upper Bound	Net Benefits	(301.1)	(116.1)	(7.9)	(1.2)

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TABLE III.E—8. SUMMARY OF NATIONAL ANNUAL NET BENEFITS AND BENEFIT-COST RATIOS, COMBINED BLADDER AND LUNG CANCER CASES—Continued

[1999, $ millions][1 2 3]

	Arsenic level (µg/L)			
	3	5	10	20
B/C Ratio	0.6	0.8	1.0	1.0

[1] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs and State costs for administration of water programs. The lower number shows costs annualized at a consumption rate of interest of 3%, EPA's preferred approach. The higher number shows costs annualized at 7%, which represents the standard discount rate preferred by OMB for benefit-cost analyses of government programs and regulations.
[2] The lower- and upper-bound bladder, lung, and combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble; unquantified benefits are not included.
[3] Numbers in parentheses indicate negative numbers.

c. Incremental costs and benefits. Incremental costs and benefits are those that are incurred or realized in reducing arsenic exposures from one level to the next more stringent level (*e.g.*, from 20 µg/L to 10 µg/L). Estimates of incremental costs are useful in developing estimates of the cost-effectiveness of successively more stringent requirements.

Table III.E–9 shows the incremental total national risk reduction, arsenic mitigation costs, and monetized health benefits for the various arsenic levels valued using discount rates of three and seven percent.

TABLE III.E–9—ESTIMATES OF THE ANNUAL INCREMENTAL RISK REDUCTION, COSTS, AND BENEFITS OF REDUCING ARSENIC IN DRINKING WATER

[$ millions, 1999]

Benefit-cost element	Arsenic level (µg/L)			
	20	10	5	3
Incremental Risk Reduction: Fatal Cancers Avoided per Year[1]	10.2–11.3	11.1–18.5	7.8–23.9	3.5–20.4
Incremental Risk Reduction: Non-Fatal Cancers Avoided per Year[1]	8.5–8.8	7.6–17.1	5.9–20.6	2.6–17.7
Annual Incremental Monetized Benefits[2]	$66.2–$75.3	$73.4–$122.4	$51.5–$157.9	$22.7–$135.4
Annual Incremental Costs (3%)[3]	$66.8	$113.6	$234.4	$283.0
Annual Incremental Costs (7%)[3]	$76.5	$129.1	$266.0	$320.5

[1] Total fatal and non-fatal cancer cases avoided are discussed in section III.D.2 of this preamble.
[2] The lower- and upper-bound combined cancer benefits estimates correspond to the lower- and upper-bound risk estimates and cancer cases avoided as shown in section III.D.2 of this preamble.
[3] Costs include treatment, monitoring, O&M, and administrative costs to CWSs and NTNCWSs and State costs for administration of water programs.

d. Cost-per-case avoided. Cost-per-case avoided is a commonly used measure of the economic efficiency with which regulatory options are meeting the intended regulatory objectives. Table III.E–10 shows the results of an analysis in which the average national cost of achieving each unit of reduction in cases of bladder and lung cancer avoided, was calculated. The average annual cost per case avoided was computed at each MCL option for both 3% and 7% discount rates.

As shown in Table III.E–10, the cost per bladder and lung cancer case avoided ranges from $4.8 million down to $3.2 million at the 10 µg/L MCL, assuming a 3% discount rate. At a 7% discount rate, the cost per bladder and lung cancer case avoided ranges from $5.5 million down to $3.7 million at the 10 µg/L MCL. As expected, the cost per bladder and lung cancer case avoided decreases with increasing arsenic levels. This is due to lower compliance costs at higher levels for the standard.

TABLE III.E–10.—ANNUAL COST PER CANCER CASE AVOIDED FOR THE FINAL ARSENIC RULE—COMBINED BLADDER AND LUNG CANCER CASES

$ millions, 1999]

Arsenic level (µg/L)	Lower-bound estimate[1]	Upper-bound estimate[1]
3 % Discount Rate		
3	12.2	5.0
5	8.1	4.1
10	4.8	3.2
20	3.5	3.4
7 % Discount Rate		
3	13.8	5.7
5	9.2	4.7
10	5.5	3.7

TABLE III.E–10.—ANNUAL COST PER CANCER CASE AVOIDED FOR THE FINAL ARSENIC RULE—COMBINED BLADDER AND LUNG CANCER CASES—Continued

$ millions, 1999]

Arsenic level (µg/L)	Lower-bound estimate[1]	Upper-bound estimate[1]
20	4.0	3.9

[1] The lower- and upper-bound cost per cancer case avoided corresponds to the range of combined cancer benefits estimates as shown in Table III.E–3.

4. Affordability

As noted previously, section 1412(b)(4)(E)(ii) of SDWA, as amended, requires EPA, when promulgating a national primary drinking water regulation which establishes a maximum contaminant level (MCL), to list technology (considering source water quality) that achieves compliance with the MCL and is affordable for systems in three specific population size categories: 25–500, 501–3300, and 3301–10,000. If, for any given size category/source water quality combination, an affordable compliance technology cannot be identified, section 1412(b)(15)(A) requires the Agency to list a variance technology. Variance technologies may not achieve full compliance with the MCL but they must achieve the maximum contaminant reduction that is affordable considering the size of the system and the quality of the source water. In order for the technology to be listed, EPA must determine that this level of contaminant reduction is protective of public health.

A determination of national level affordability is concerned with identifying, for each of the given size categories, some central tendency or typical circumstance relating to their financial abilities. The metric EPA selected for this purpose is the median household income (MHI) for communities of the specified sizes. The household is thus the focus of the national-level affordability analysis. EPA considers treatment technology costs affordable to the typical household if they represent a percentage of MHI that appears reasonable when compared to other household expenditures. This approach is based on the assumption that the affordability to the median household served by the CWS can serve as an adequate proxy for the affordability of technologies to the system itself. The national-level affordability criteria have two major components: current annual water bills (baseline) and the affordability threshold (total % of MHI directed to drinking water). Current annual water bills were derived directly from the 1995 Community Water System Survey. Based on 1995 conditions, 0.75–0.78% of MHI is being directed to water bills for systems serving fewer than 10,000 persons.

The fundamental, core question in establishing national-level affordability criteria is: what is the threshold beyond which drinking water would no longer be affordable for the typical household in each system size category? Based upon careful analysis EPA believes this threshold to be 2.5% of MHI. In establishing this threshold, the Agency considered baseline household expenditures (as documented in the 1995 Consumer Expenditure Survey, Bureau of Labor Statistics) for piped water relative to expenditure benchmarks for other household goods, including those perceived as substitutes for piped water treated to higher standards, such as bottled water and point-of-use and point-of-entry devices. Based on these considerations, EPA concluded that current household water expenditures are low enough, relative to other expenditures, to support the cost of additional risk reductions. The detailed rationale for the selection of 2.5% MHI as the affordability threshold is provided in the guidance document entitled "Variance Technology Findings for Contaminants Regulated Before 1996." The difference between the affordability threshold and current water bills is the available expenditure margin. This represents the dollar amount by which the water bill of the typical (median) household could increase before exceeding the affordability threshold of 2.5% of MHI.

By definition, the MHI is the income value exactly in the middle of the income distribution. The median is a measure of central tendency; its purpose is to help characterize the nature of a distribution of values. In the case of income, which tends not to be evenly distributed, the median is a much better indicator of central tendency than the mean, or arithmetic average, that could be significantly skewed by a few large values. The Agency recognizes that there will be half the households in each size category with incomes above the median, and half the households with incomes below the median. The objective of a national-level affordability analysis is to look across all the households in a given size category of systems and determine what is affordable to the typical, or "middle of the road" household.

The Agency recognizes that baseline costs change over time as water systems comply with new regulations and otherwise update and improve their systems. To take account of this upward movement in the baseline, the Agency plans to adjust the baseline it employs in its calculation in two ways. First, actual changes in the baseline will be measured approximately every 5 years by the Community Water System Survey. These changes will reflect not only the increased costs resulting from EPA drinking water rules, but also any changes resulting from other factors that could affect capital or operating and maintenance costs. Second, to the extent practical and appropriate during the period between Community Water System Surveys, the baseline will be adjusted to reflect the cost of rules promulgated during that period.

MHI also changes from year to year, generally increasing in constant dollar terms. For example, since 1995 MHI has increased (in 1999$) by 9.6%. Thus, to determine the available expenditure margin (the difference between the affordability threshold and the baseline) for each successive rule, adjustments would need to be made in both the baseline and the MHI.

Given the narrow and specific purpose for which the national-level affordability criteria are used, the Agency is not adjusting either the baseline or the MHI for its analysis for the final arsenic rule. As noted previously, MHI has increased by 9.6%. The rules, which have been promulgated since the baseline was developed, are the Interim Enhanced Surface Water Treatment Rule, the Stage 1 Disinfectants and Disinfection ByProducts Rule, the revised Radionuclides Rule, the Consumer Confidence Report Rule and the revised Public Notification Rule. The Interim Enhanced Surface Water Treatment Rule applies only to systems serving greater than 10,000 persons, so it has essentially no impact on the baseline costs for smaller systems. The Stage 1 Disinfectants and Disinfection ByProducts Rule does apply to small systems, and it has an impact on only 12% of the nearly 68,200 ground water systems serving < 10,000 persons; and on 70% of the nearly 5200 surface water systems serving < 10,000 persons. The revised Radionuclides Rule has limited impact since it, for the most part, reaffirmed long-standing MCLs. The Consumer Confidence Rule and revised Public Notification Rule result in no capital expenditures and only very modest administrative costs.

The Agency believes that, for purposes of assessing national-level affordability of the arsenic rule, the unadjusted baseline and unadjusted MHI are appropriate. Making adjustments to these two factors would not materially alter the outcome of the analysis.

The distinction between national-level affordability criteria and affordability assessments for individual systems cannot be over-emphasized. The national-level affordability criteria serve only to guide EPA on the listing of an affordable compliance technology versus a variance technology for a given system size/source water combination for a given contaminant. In the case of arsenic, EPA has determined that nationally affordable technologies exist for all system size categories and has therefore not identified a variance technology for any system size/source water combination. This means that EPA believes that the typical household in each system size category can afford the costs associated with the listed compliance technologies. EPA

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recognizes that individual water systems may serve a preponderance of households with incomes well below the median or may face unusually high treatment costs due to some unusual local circumstance.

SDWA provides a number of tools that States can use to address affordability concerns for these individual water systems. Two of these tools are financial assistance under the Drinking Water State Revolving Fund (DWSRF) and extended compliance time-frames under an exemption. SDWA allows States to provide special assistance to water systems that the State determines to be disadvantaged, using State-developed affordability criteria. This special assistance may include forgiveness of principal, a negative interest rate, an interest rate lower than that charged to non-disadvantaged systems, and extended repayment periods of up to 30 years. To date, about half of the States have implemented disadvantaged community programs as part of their DWSRF. Almost one quarter of all loans made under the DWSRF have been made to systems classified as disadvantaged by the States.

In addition to special financial assistance through the DWSRF, as discussed previously, systems facing affordability concerns may also be eligible for extended time to achieve compliance under the terms of a State-issued exemption or may receive assistance under the Rural Utilities Service (RUS) program of the United States Department of Agriculture (see section I.L). Together with the approximately $1 billion per year being made available through the DWSRF, this results in a total of about $1.78 billion per year of Federal financial assistance available for drinking water.

Decisions that a drinking water system makes about how to allocate its costs to users and how to design rates can also have a significant effect on affordability for low-income households. A traditional declining block rate structure would be regressive and might result in the households with the least income subsidizing excessive water use by more affluent households. Numerous alternative rate designs are possible that are more progressive. Of particular interest in addressing affordability concerns is lifeline rates. Lifeline rates are a rate structure applicable to qualified residential customers that includes a specified block of water use priced below the standard charge for the customer class. Such rates are primarily designed to aid the poor in obtaining some minimum level of service at an affordable price.

The basic organizational or institutional structure of the drinking water system is another very important factor that influences the affordability of water service. The key issue here is the extent to which a given organizational or institutional structure is capable of achieving economic and operational efficiency. An especially important element of this efficiency relates to the degree to which a system seeks to work together with other systems. Systems that effectively work together, perhaps by combining management, will realize lower overall costs compared to the same systems working independently.

F. What MCL Is EPA Promulgating and What Is the Rationale for This Level?

1. Final MCL and Overview of Principal Considerations

EPA is today promulgating a final arsenic MCL of 10 µg/L. EPA's selection of this MCL is based on the SDWA statutory requirements for establishing an MCL and reflects the Agency's detailed evaluation and careful consideration of thousands of pages of comments. As part of this process, we have evaluated new data and analysis on occurrence, unit treatment costs, small system impacts, treatment technology availability, waste disposal options, and uncertainties regarding exposure and health effects data. Based on this new information, the Agency has revisited technical analyses, calculations, and judgments underlying the proposed MCL of 5 µg/L. As discussed in section III.E. in this preamble, the Agency has conducted a thorough revaluation of costs and has carefully considered substantial new analysis on this subject submitted by commenters. In addition, EPA has completed a detailed reassessment of the risks of arsenic in drinking water, and has made significant adjustments to provide a more quantitative evaluation of major sources of uncertainty discussed at proposal and emphasized by commenters from a number of different perspectives.

Today's rule, with a final MCL of 10 µg/L, reflects the application of several provisions under SDWA, the first of which generally requires that EPA set the MCL for each contaminant as close as feasible to the MCLG, based on available technology and taking costs to large systems into account. The 1996 SDWA amendments also require that the Administrator determine whether or not the quantifiable and nonquantifiable benefits of an MCL justify the quantifiable and nonquantifiable costs. This determination is to be based on the Health Risk Reduction and Cost Analysis (HRRCA) required under section 1412(b)(3)(C). The HRRCA must include consideration of seven analyses:

(1) The quantifiable and nonquantifiable benefits from treatment to the new MCL;

(2) The quantifiable and non quantifiable benefits resulting from reductions of co-occurring contaminants;

(3) The quantifiable and nonquantifiable costs resulting directly from the MCL;

(4) The incremental costs and benefits at the new MCL and alternatives considered;

(5) The health risks posed by the contaminant, including risks to vulnerable populations;

(6) Any increased risk resulting from compliance, including risks associated with co-occurring contaminants; and

(7) Any other relevant factor, including the uncertainties in the analyses and the degree and nature of risk.

Finally, the 1996 SDWA amendments provide new discretionary authority for the Administrator to set an MCL less stringent than the feasible level if the benefits of an MCL set at the feasible level would not justify the costs (section 1412(b)(6)) based on the HRRCA analysis. Today's rule establishing an MCL of 10 µg/L for arsenic is the second time EPA has invoked this new authority. (The first such time was in the final rule for uranium, which was published on December 7, 2000; EPA, 2000p.)

In addition to the feasible MCL of 3 µg/L, the Agency evaluated MCL options of 5 µg/L, 10 µg/L, and 20 µg/L and the various comments offered concerning these levels in response to the proposed rule. EPA has determined that a final MCL of 10 µg/L more appropriately meets the relevant statutory criteria referred to above, particularly after considering the following: Available information relating to the various health effects associated with arsenic; new analysis regarding the projected risk to the population of adverse health effects that would remain after implementation; the revised costs and benefits of the various options; the incremental costs and benefits; and the uncertainties in the benefit-cost and risk analyses. A summary of the results of the Agency's reanalysis of these various factors follows.

2. Consideration of Health Risks

The fifth and seventh HRRCA analyses focus on the health risks to be addressed by a new MCL. Estimates of risk levels to the population remaining after the regulation is in place provide a perspective on the level of public health protection and associated benefits. SDWA clearly places a particular focus on public health protection afforded by MCLs. For instance, where EPA decides to use its discretionary authority after a determination that the benefits of an MCL would not justify the costs, section 1412(b)(6) requires EPA to set the MCL at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." (EPA does not believe the sixth HRRCA analysis, consideration of increased risk likely to result from compliance is a significant factor in connection with selection of a final MCL; rather, we believe that many of the appropriate technologies for reducing arsenic will reduce many other co-occurring inorganic contaminants as well thereby decreasing, rather than increasing risk.)

The Agency based its evaluation of the risk posed by arsenic at the MCL options of 3 µg/L, 5 µg/L, 10 µg/L and 20 µg/L on a number of considerations, including the bladder cancer risk analysis developed by the National Research Council (NRC) of the National Academy of Sciences (NRC, 1999); the NRC's qualitative assessment of other possible adverse health effects; the lung cancer risk analysis developed by Morales et al. (2000); and findings of other relevant national and international studies. This information included, but was not limited to, findings from epidemiological studies in South America cited in the NRC report (NRC, 1999) and a study of a population exposed to high levels of arsenic in Millard County, Utah conducted by Lewis, *et al.* (1999).

Among the factors EPA considered in choosing the final MCL was Congress' intent that EPA "reduce * * * [scientific] uncertainty" in promulgating the arsenic regulation reflected in section 1412(b)(12) arsenic research plan provisions and the legislative history on the arsenic provision (S. Rep. 104–169, 104th Cong., 1st Sess. at 39–40). The uncertainties in the analyses of costs, benefits and risks are also a factor required to be considered in the HRRCA. All assessments of risk are characterized by an amount of uncertainty. Some of this uncertainty can be reduced by collecting more data or data of a different sort. For other types of uncertainty, improved data or assessment methods can allow one to define the degree to which an estimate is likely to be above or below the "true" risk. For the arsenic risk assessment, there are several definable sources of uncertainty that were taken into account. These include, but are not limited to, the following:

- Uncertainty about the exact exposure of individuals in the study population to arsenic in drinking water, water used in cooking, and food;
- Uncertainties associated with applying data from a population in rural Taiwan to the heterogenous population of the U.S. (including differences in health status and diet between the Taiwanese and the U.S. population); and
- Uncertainties concerning precisely how a chemical causes cancer in humans (the mode of action) that affects assessments of the extent and severity of health effects at low doses.

Section III.D. of the preamble to today's final rule provides a detailed explanation of how these uncertainties associated with the risk analysis were taken into account in developing a revised estimate of the risk of arsenic in drinking water. Based on comments and available information, the Agency has focused, in particular, on the first uncertainty bullet, and made two adjustments to its risk analysis to reduce uncertainty and more accurately apply data from the Taiwan study to the U.S. population. EPA has revised its quantified estimate of the risks of arsenic in drinking water to adjust for exposure to arsenic in both cooking water and food in the Taiwanese study and has also developed a risk range for the combined effects of bladder and lung cancer to reflect the scope of uncertainty underlying these estimates. Thus, one of the previously listed uncertainties has specifically been taken into account quantitatively, while others continue to be considered in a qualitative sense.

In EPA's judgment, use of a risk range more clearly supports a qualitative consideration and recognition of the uncertainties that are inherent in any risk analysis that substantially relies upon epidemiological information. EPA believes that the health risk analysis presented in section III.D. of today's rule comprises a plausible range of likely risk associated with various concentrations of arsenic in drinking water. As just suggested, we do not believe it is appropriate to select a central or "best estimate" of the risk, due to the uncertainties associated with the underlying health effects studies and the various plausible assumptions used in considering these uncertainties for our risk analysis. This revised analysis of risks was used in recalculating the benefits attributable to reducing arsenic in drinking water from its present levels. EPA also recognizes that the latter two bulleted sources of uncertainty may operate to reduce the risk estimates if it were possible to account for them quantitatively.

3. Comparison of Benefits and Costs

Under HRRCA analyses one and two, the Agency must consider both quantifiable and nonquantifiable health risk reduction benefits. Benefits considered in our analysis include those about which quantitative information is known and can be monetized as well as those which are more qualitative in nature (such as some of the non-cancer health effects potentially associated with arsenic) and which cannot currently be monetized. Important assumptions inherent in EPA's revised analysis of the benefits estimates include the value of a statistical life and willingness to pay to avoid illness. These assumptions and various adjustment factors considered for our benefits analysis are explained in detail in section III.E. of this preamble.

EPA considered the relationship of the monetized benefits to the monetized costs for each the regulatory levels it considered. While strict equality of monetized benefits and costs is not a requirement under section 1412(b)(6)(A), this relationship is an important consideration in the regulatory development process. The monetized costs and monetized benefits of this final rule, and the methodologies used to calculate them, are discussed in detail in section III. E. of this preamble and in the arsenic Economic Analysis.

EPA believes, however, that reliance on only an arithmetic analysis of whether monetized benefits outweigh monetized costs is inconsistent with the statute's instruction to consider both quantifiable and nonquantifiable costs and benefits. The Agency therefore examined and considered qualitative and non-monetized benefits in establishing the final MCL, as well as other factors discussed previously. These benefits are associated with avoiding certain adverse health impacts known to be caused by arsenic at higher concentrations, which may also be associated with low level concentrations, and include skin and prostate cancer as well as cardiovascular, pulmonary, neurological and other non-cancer effects. (These health effects are discussed in Section III.D. of this preamble.)

Other potential benefits not monetized for today's final rule include customer peace of mind from knowing drinking water has been treated for arsenic and reduced treatment costs for contaminants that may be co-treated with arsenic. (For example, increased use of coagulation and micro filtration

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by surface water systems will offer benefits with respect to removal of microbial contaminants and disinfection byproducts.)

HRRCA analyses three and four require EPA to consider the costs of compliance with the rule and the incremental costs and benefits. EPA has also revised the cost of compliance estimates associated with the various possible regulatory levels considered for today's final rulemaking. The central estimate of costs has risen modestly since the proposed rule based on our further analysis of the information and data provided by commenters. However, in response to comments, we have also performed a sensitivity analysis that addresses a number of variables in our analysis and which indicates that the costs of compliance could exceed our central estimate by as much as 22%.

In comparing monetized costs and benefits, we conducted several types of analyses, including:

- Comparison of total national costs and benefits (Table III.E–7);
- Analysis of incremental costs and benefits (comparing one regulatory option to another) (Table III.E–9);
- Estimates of net benefits (Table III.E–8); and
- Examination of benefit-cost ratios (Table III.E–8).

Detailed descriptions of our analyses appear in section III.E. of this preamble and in the Economic Analysis supporting today's rule. Our consideration of these analyses in support of the rationale for the final MCL is discussed below.

4. Rationale for the Final MCL

The rationale for the final MCL promulgated with today's rule is based on the HRRCA analyses outlined previously and the statutory criteria for setting an alternative (higher than feasible) MCL under section 1412(b)(6). These analyses include:

- A revised risk analysis of arsenic in drinking water;
- A revised analysis of total costs;
- A revised analysis of total benefits;
- A comparison of costs and benefits using various metrics at various MCL options (including incremental costs and benefits); and
- Other pertinent factors (including uncertainties and the degree and nature of risk).

In the proposed rule, EPA indicated a preference for a standard at 5 μg/L, but solicited comment on MCL options of 3 μg/L; 10 μg/L, and 20 μg/L, depending upon how uncertainties were addressed in the risk analysis as well in the calculation of costs and benefits. However, EPA also noted that, between the time of proposal and promulgation of the final rule, it would work to resolve as much of this uncertainty as possible. As described earlier, the principal revised analyses conducted since the rule was proposed and considered in our selection of the final MCL include: A revised analysis of the uncertainties of the health effects that has generated a revised risk range for the various MCL options considered; a revised range of benefits associated with our current estimates of the risks; and a revised analysis of costs, including uncertainty and sensitivity analyses. These revised analyses allow an updated comparison of the costs and benefits for the various regulatory options considered.

a. General considerations. As explained in section III.E. of today's preamble, both our benefits and cost estimates involve ranges, rather than point estimates, due to a variety of factors. Thus, our consideration of costs and benefits involved an examination and comparison of these ranges. As can be seen from Table III.E–7, both total costs and benefits increase as one examines progressively lower (*i.e.*, more stringent) regulatory options compared to higher options. However, the benefits and costs do not increase proportionately across the range of regulatory options as shown by a comparison of net benefits (defined as costs minus benefits). Progressively more stringent regulatory options become considerably more expensive, from a cost standpoint, than the corresponding increases in benefits, as reflected in decreasing net benefits. (see Table III.E–8.)

b. Relationship of MCL to the feasible level (3 μg/L). The MCL must be set as close as feasible to the MCLG, unless EPA invokes its discretionary authority under section 1412(b)(6) of SDWA to set an alternative MCL, which must then be set at a level that maximizes health risk reduction benefits at a cost that is justified by the benefits. As explained earlier in this preamble, the MCLG is zero and the feasible level is 3 μg/L. The Agency believes that there are several important considerations in examining the feasible level. In comparing the benefits and the costs at this level (see Table III.E–7), we note that it has the highest projected total national costs (relative to the other MCL options considered). In addition, while the benefits are highest at this level relative to the other MCL options, both the net benefits and the benefit/cost disparity at the feasible level are the least favorable of the regulatory options considered. For these reasons, we believe benefits of the feasible level do not justify the costs. Almost all commenters agreed with this conclusion in the proposal.

c. Reanalysis of proposed MCL and comparison to final MCL. Based on substantial public comment, EPA has reexamined the proposed MCL of 5 μg/L. In comparing this level to 10 μg/L, we note that both the net benefits and the benefit-cost relationships are less favorable for 5 μg/L as compared to 10 μg/L. Total national costs at 5 μg/L are also approximately twice the costs of an MCL of 10 μg/L. At 10 μg/L, EPA notes that the lung and bladder cancer risks to the exposed population after the rule's implementation are within the Agency's target risk range for drinking water contaminants of 1×10^{-6} to 1×10^{-4} or below. EPA recognizes that there is uncertainty in this quantification of cancer risk (as well as other health endpoints) and this risk estimate includes a number of assumptions, as discussed previously. EPA did not directly rely on the risk range in selecting the final MCL, since it is not part of the section 1412(b)(6) criteria; however, it is an important consideration, because it has a direct bearing on our estimates of the benefits of the rule.

d. Consideration of higher MCL options. EPA does not believe an MCL less stringent 10 μg/L is warranted from the standpoint of benefit-cost comparison. While total national costs associated with 20 μg/L are the lowest of the regulatory options considered, benefits are also the lowest of these options. Both regulatory options of 10 μg/L and 20 μg/L have relatively favorable benefit-cost relationships relative to lower regulatory options but are not significantly different from one another based on this comparison metric. However, the incremental, upper-bound benefits at 10 μg/L are more than twice those of 20 μg/L; and 10 μg/L is clearly the more protective level. Thus, we do not believe that an MCL of 20 μg/L would "maximize health risk reduction benefits" as required for an MCL established pursuant to section 1412(b)(6).

e. Conclusion. Strict parity of monetized costs and monetized benefits is not required to find that the benefits of a particular MCL option are justified under the statutory provisions of section 1412(b)(6) of SDWA. However, EPA believes that, based on comparisons of cost and benefits (using the various benefit-cost comparison tools discussed), the monetized benefits of a regulatory level of 10 μg/L best justify the costs. In addition, as discussed in section III.D. and elsewhere in today's preamble, our further qualitative consideration of the various sources of uncertainty in our understanding of arsenic since the proposal (e.g., such as that surrounding the mode of action), has led us to conclude that our estimate of risk (for the risks we have quantified) is most likely an upper bound of risks and that the higher MCL of 10 μg/L is appropriate. Finally, as discussed in section III.E. of this preamble EPA believes that there are a number of not yet quantified adverse health effects and potentially substantial non-monetized benefits at 10 μg/L that increase the overall benefits at this level.

In summary, based on our reanalysis of costs, benefits, and health risk reduction, and factoring in the uncertainties in these analyses and the degree and nature of risk, EPA believes the final MCL of 10 μg/L represents the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits and that the other regulatory options considered in the proposed rule do not satisfy the statutory requirements of section 1412(b)(6) of SDWA. We are therefore exercising our discretionary authority under the statute to establish an MCL at a level higher than the feasible level and setting that level at 10 μg/L.

IV. Rule Implementation

A. What Are the Requirements for Primacy?

States must revise their programs to adopt any part of today's rule that is more stringent than the approved State program. Primacy revisions must be completed in accordance with 40 CFR 142.12, and 142.16. States must submit their revised primacy application to the Administrator for approval. A State's request for final approval must be submitted to the Administrator no later than 2 years after promulgation of a new standard unless the State requests and is granted an additional 2-year extension.

For revisions of State programs, § 142.12 requires States to submit, among other things, "[a]ny additional materials that are listed in § 142.16 of this part for a specific EPA regulation, as appropriate." Today's rule does not require States to submit information in § 142.16(e) for primacy revisions associated with the revised arsenic MCL. The final rule notes that § 142.16(e) primacy revision information will only be required for new contaminants, not revisions of existing regulated contaminants.

B. What Are the Special Primacy Requirements?

Today's rule adds special primacy requirements in § 142.16(j) and § 142.16(k) to the State special primacy requirement section. Section 142.16(j) clarifies that for an existing regulated contaminant such as arsenic, States may indicate in the primacy application that they will use the existing monitoring plans and waiver criteria approved for primacy under the National Primary Drinking Water Standards (NPDWRs) for organic and inorganic contaminants (the Phase II/V rules). Alternatively, the State may inform the Agency in its application of any changes to the monitoring plans and waiver procedures.

Section 142.16(k) requires States to establish initial monitoring requirements for new systems and new sources. Many States already have developed monitoring programs for new systems and for systems that are using new sources of water. To meet the requirements of § 142.16(k), States that have existing requirements may simply explain to EPA in their primacy revision package their monitoring schedule and how the State can ensure that all new systems and new sources will comply with the existing MCLs and monitoring requirements. Some States may wish to explain that monitoring for new systems is established on a case-by-case basis. States should explain the factors that are considered as case-by-case determinations are made.

When a State develops or modifies an initial monitoring program for new systems and new sources, it should ensure that the program reflects the contaminant(s) of concern for that State, known contaminant use, historical data, and vulnerability. Because of varying contaminant uses and sources, some contaminants occur at higher levels in some regions of the country than in other regions. Additionally, the concentrations of some contaminants are known to show clear seasonal peaks, while others remain constant throughout the year. For example, some States may be concerned with atrazine and require multiple samples during a specified vulnerable period (*e.g.*, May 1–July 31), while another State may only require one sample for the entire year. Alternatively, another State may be concerned about trichloroethylene and require four quarterly samples.

C. What Are the State Recordkeeping Requirements?

The standard record keeping requirements for States under SDWA apply to the arsenic rule (§ 142.14). Today's rule does not modify or require additional recordkeeping requirements. States with primacy must keep all records of current monitoring requirements and the most recent monitoring frequency decision pertaining to each contaminant, including the monitoring results and other data supporting the decision, and the State's findings based on the supporting data and any additional bases for such decision. These records must be kept in perpetuity or until a more recent monitoring frequency decision has been issued.

D. What are the State Reporting Requirements?

Currently, States with primary enforcement responsibility must report to EPA information under § 142.15 regarding violations, variances and exemptions, and enforcement actions and general operations of State public water supply programs. Today's rule does not modify or require additional reporting requirements. The State reporting requirements that will apply to the arsenic standard are the same as all other regulated inorganic contaminants.

E. When Does a State Have To Apply for Primacy?

To maintain primacy for the Public Water Supply Supervision (PWSS) program and to be eligible for interim primacy enforcement authority for future regulations, States must adopt today's final rule. A State must submit a request for approval of program revisions that adopt the revised MCL and implement regulations within two years of promulgation, unless EPA approves an extension per § 142.12(b). Interim primacy enforcement authority allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application. To obtain interim primacy, a State must have primacy with respect to each existing NPDWR. Under interim primacy enforcement authority, States are effectively considered to have primacy during the period that EPA is reviewing their primacy revision application.

F. What Are Tribes Required To Do Under This Regulation?

Currently, the Navajo Nation is the only Tribe with primacy for all the National Primary Drinking Water Regulations, and it will be subject to the same requirements as a State. There are no other Federally recognized Indian tribes with primacy to enforce any of the drinking water regulations. EPA's Regions have responsibility for implementing the rules for all Tribes except the Navajo Nation under section 1451(a)(1) of SDWA. To obtain primacy authority for the revised arsenic MCL, Tribes must submit a primacy

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application to regulate inorganic contaminants (*i.e.*, the Phase II/V rule).

V. Responses to Major Comments Received

A. General Comments

1. Sufficiency of Information and Adequacy of Procedural Requirements To Support a Final Rule

A number of commenters challenged EPA's basis for promulgating a final rule, arguing that (1) there was insufficient technical information provided with the proposed rule, (2) various expert technical evaluations were not adequately considered, or (3) procedural requirements (*e.g.*, Unfunded Mandates Reform Act (UMRA), Small Business Regulatory and Enforcement Flexibility Act (SBREFA)) have not been fully satisfied. EPA respectfully disagrees, and we believe that the record of our actions is sufficient to support a final rulemaking. Other portions of the preamble to today's rule explain the technical evaluations performed in support of the proposed rule and the revised analyses conducted, based on comments and information submitted in response to the proposal. EPA recognizes that various questions about different aspects of this rulemaking have been the subject of an array of analyses and reports by various investigators. This area of investigation has also been dynamic, and there will undoubtedly be additional analyses after promulgation of the final rule that the Agency will need to consider in light of the requirement to periodically review (and revise as appropriate) all final drinking water regulations as provided by section 1412(b)(9) of SDWA. However, we believe that we have fully and appropriately considered all available and relevant information for the final rulemaking and do not need to repropose as several commenters suggest. We also believe that we have fully satisfied the procedural requirements of the pertinent statutory and Executive Order requirements. Section VI. of the preamble to today's final rule discusses these procedural requirements in more detail.

2. Suggestions for Development of an Interim Standard

Several commenters advocated an interim standard in view of the uncertainties associated with the health effects data, the costs of compliance with the final rule, and concerns over the interpretation of the "anti-backsliding" provision of SDWA related to review and revision of existing standards (section 1412(b)(9)). While EPA appreciates these concerns, we do not believe that they provide a sufficient basis for concluding that an interim standard be set. We agree with the recommendation of the National Academy of Sciences that there is sufficient information available now to develop a new lower drinking water standard for arsenic. We further believe that available information is sufficient to support a final, rather than an interim, standard. Finally, there is simply no authority in SDWA to establish an interim standard that does not comply with sections 1412(b)(4) and 1412(b)(6). However, we are committed to reviewing and revising, if appropriate, the final standard every six years (or sooner, if pertinent new information becomes available). In so doing, we must ensure that the revised standard provides for "equal or greater protection to the health of persons" as compared to the standard it replaces.

3. Public Involvement and Opportunity for Comment

Some commenters questioned whether the extent of public involvement in the development of today's rule was sufficient. Some commenters also suggested that the Agency use a negotiated rulemaking process for the final rule pursuant to the Federal Advisory Committee Act (FACA). EPA believes that public involvement throughout the development of this rule, has been extensive and far-reaching. As discussed in section I.N. earlier in this preamble, during the period 1996–2000, EPA conducted a number of Agency workgroup meetings on arsenic and advertised six stakeholder meetings (held in five locations) in the **Federal Register**. Five States also provided written comments on implementation issues during the workgroup process. Representatives of eight Federal agencies, 19 State offices, 16 associations representing the breadth of the public water system community, 13 corporations, 14 consulting engineering companies, two environmental organizations, three members of the press, 37 public utilities and cities, four universities, and one Indian tribe attended the stakeholder meetings on arsenic. EPA presented an overview of the arsenic rulemaking to over 900 Tribal representatives in 1998 and provided more detailed information in 1999 to 25 Tribal council members and water utility operators from 12 Indian tribes. In addition, EPA provided updates on our rulemaking activities at national and regional meetings of various groups and trade associations. We also participated in the American Water Works Association's (AWWA) technical workgroup meetings. As part of the Small Business Regulatory and Enforcement Flexibility Act (SBREFA) process, EPA also received valuable input from discussions with small entity representatives during SBREFA consultations for the arsenic rule. EPA obtained recommendations from the National Drinking Water Advisory Council (NDWAC) on the rule as a whole as well as on our approach benefits analysis and small systems affordability. We also posted discussion papers produced for our stakeholder interactions on the EPA Office of Ground Water and Drinking Water (OGWDW) Internet site and sent them directly to participants at stakeholder meetings and others who expressed interest. EPA also received over 1,100 comments on the June 22, 2000 proposed rule. EPA took these comments into consideration in developing today's final rule.

EPA agrees that the FACA-negotiated rulemaking process has been an effective one in the past for other complex rulemakings. However, EPA does not believe that a negotiated rulemaking at this point is consistent with the deadlines set by Congress for this rulemaking. We would point out, however, that the Agency has taken a number of active steps to ensure broad-based stakeholder involvement, as described previously, and has solicited expert points of view outside the Agency. Some of these actions included a charge to the National Academy of Sciences (NAS) to fully explore the most current health effects issues. A charge was also given to EPA's Science Advisory Board (SAB) to review key aspects of the proposed rule and EPA's underlying rationale. EPA believes that this combination of actions ensured that full and complete stakeholder involvement occurred, and that further negotiations would be unnecessary.

4. Relation of MCL to the Feasible Level

Several commenters questioned the feasible level of 3 μg/L contained in the proposed rule. Commenters believed that EPA has not accurately assessed the capabilities of laboratories to achieve the practical quantitation level (PQL) or of treatment technologies to reliably and consistently treat down to the feasible level. EPA disagrees and still believes that 3 μg/L is feasible from the standpoints of both analytical methods and treatment technologies. EPA discusses these issues in more detail in section III.B. of the preamble to today's final rule. Many of the comments on the proposed rule were concerned by the close proximity of the proposed

standard (5 μg/L) to the proposed feasible level (3 μg/L). However, comments regarding whether or not the proposed standard of 5 μg/L is feasible are not particularly germane to the setting of the final standard, which is well above any level identified by most commenters as being feasible.

5. Relationship of MCL to Other Regulatory Programs

Many commenters expressed concerns about the possible impact of a new revised drinking water standard for arsenic on other regulatory standards for arsenic. In particular, several commenters recommended that EPA consider the prospective costs of future Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) site clean-up actions, RCRA hazardous waste management costs, or national permit discharge elimination system (NPDES) permits to the extent that a new arsenic in drinking water standard leads to more stringent regulatory actions under those respective statutes. EPA disagrees and notes that SDWA specifically excludes from consideration under the HRRCA such prospective, ancillary costs in developing a drinking water standard (see section 1412(b)(3)(C) of SDWA).

6. Relation of MCL to WHO Standard

Several commenters on the proposed rule expressed a concern that the drinking water standard in the U.S. should be no more stringent than the standard developed for the World Health Organization (WHO). This comment dealt primarily with the proposed level of 5 μg/L and does not apply to the final MCL of 10 μg/L, which is identical to the WHO standard. However, while the thrust of the comment is now moot, EPA notes that the basis for the final MCL and the WHO standard are different. EPA's standard is based on consideration of all of the risk management factors required to be evaluated under SDWA (*e.g.*, risk, costs, benefits, treatment technology and analytical method capabilities, small systems affordability, etc.) while the WHO standard is based solely on health effects, without regard to any implementation considerations. Further, the health basis for the WHO standard is primarily an assessment of arsenic-induced skin cancer, whereas there are a number of health endpoints of concern in EPA's analysis including lung and bladder cancer. In summary, the two levels (the WHO standard and EPA's final MCL) happen to be the same but a possible future change in the WHO standard would not necessarily require a revision to EPA's MCL, for the reasons just discussed.

7. Regulation of Non-Transient Non-Community Water Systems (NTNCWSs)

Several commenters objected to the approach outlined in the proposed rule for addressing NTNCWSs (monitoring and reporting only) and pointed out the need for consistency in coverage of NTNCWSs in EPA's rules. These commenters noted that the rules originally promulgated in 1976 (arsenic and radionuclides) have not required coverage of NTNCWSs, whereas more recently promulgated rules have. In addition, EPA's proposed radon rule suggested not covering NTNCWSs and the recently promulgated radionuclides rule did not require coverage of NTNCWSs, but instead deferred this issue for future resolution. EPA agrees that the outcomes of its recent decisions with respect to coverage of NTNCWSs have been different. However, we considered the merits of each rulemaking on a case-by-case basis using a consistent set of criteria, namely the cost/benefit analysis required under section 1412(b)(4).

For the proposed arsenic rule, EPA carefully examined the risks posed by NTNCWSs and concluded preliminarily that the risks were such that, without coverage, consumers of water from NTNCWSs were projected to be within the target risk range. EPA acknowledges, however, that there is uncertainty associated with its information about exposure patterns for consumers of water from NTNCWSs and the demographics of these facilities. Thus, our understanding of the health risks (and associated possible benefits of removal) to consumers of water from NTNCWSs is uncertain. In the case of arsenic, EPA believes the additional uncertainty in the overall risk analysis argues against any finding at this point that these systems are substantially different in terms of exposure than community water systems. EPA also believes the decision to cover these facilities in today's rule is supported by consideration of the risks to certain subpopulations within the general population, such as children who consume water at day care facilities or schools that are served by NTNCWSs.

Concerns were also expressed about whether commenters were provided with sufficient information about the costs of full coverage. These commenters noted that EPA could not, without violating the notice and comment provisions of the Administrative Procedure Act, move to full coverage of these facilities in the final rule. EPA disagrees with this comment. The proposal clearly indicated that full coverage of NTNCWSs was an option on which comment was being requested and the supporting documents provided complete information about the costs of full coverage. (EPA, 2000h, see Table 6–9).

8. Extension of Effective Date for Large Systems

Commenters were generally supportive of EPA's proposed national determination (pursuant to section 1412(b)(10) of SDWA) that water systems covered by the rule, serving less than 10,000 persons, and needing to make capital improvements to comply with the new standard would need more than 3 years from the time of rule promulgation to accomplish this. Thus, the proposed rule suggested allowing a two-year extension for compliance with the new standard, beyond the three years provided after the promulgation date. However, several commenters suggested that this finding and the additional two years for compliance should be applicable to all systems, including those serving more than 10,000 persons, since extensive planning, design, and new equipment will also generally be needed by larger systems in a similar situation to comply with the new standard. EPA was persuaded by these comments, and has, as part of the implementation requirements for today's final rule, elected to apply this two-year extension to all facilities covered by today's rule.

B. Health Effects of Arsenic

1. Epidemiology Data

Many commenters were critical of the Taiwan epidemiologic study as a basis for EPA decision making, quantitative dose-response assessment, extrapolation of the dose-response from the observed range of exposure, and application of the same risk estimate to the U.S. population. No commenters challenged the EPA conclusion that this study and the other epidemiologic studies together show that arsenic is carcinogenic to humans. Some supported the risk analysis in the proposed rule and the notice of data availability (NODA) because it is relatively risk averse; others had criticisms.

The following issues were raised about the use of the Taiwan risk assessment to represent U.S. risk: Arsenic exposure from food and via cooking with contaminated water in Taiwan is higher than is typical for the U.S. population; exposure groupings were made at the village level and were assigned the median of the

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concentration of arsenic measured in the wells serving that village; not all wells serving all villages were measured and well concentrations varied seasonally; the Taiwan population was a rural population that was not well nourished, having deficits of selenium, possibly methionine or choline (methyl donors), zinc and other essential nutrients; and the Taiwan population may have unknown differences in genetic polymorphisms from the U.S. population. Similar concerns were raised about the South American studies.

Commenters also cited studies in the U.S. (Lewis *et al.*, 1999, Utah population) and Europe (Buchet *et al.*, 1999; Kurttio *et al.*, 1999) as support for the position that the risks from the Taiwan study overestimated the risks in the U.S.

Many commenters were convinced that the Lewis *et al.* (1999) study of a U.S. population is the best study to use in estimating U.S. risk. Since the Utah study did not observe cancer outcomes that one would expect if risks were as large as the Taiwan or South American studies suggest, these commenters believe that risks estimates from studies of populations outside of the U.S. overestimate U.S. risks.

Scientists generally agree that high doses of arsenic are associated with various cancer and noncancer health effects in humans. Epidemiology studies in humans demonstrate that arsenic induces skin and internal (*e.g.*, bladder and lung) cancers and non-cancer effects such as skin keratoses and vascular abnormalities when ingested in drinking water at high doses.

The epidemiologic investigations that have been most thorough in investigating the exposure and effects on humans of ingesting ground water contaminated with arsenic are those of populations in Taiwan (Chen *et al.*, 1985; 1988; 1992; Wu *et al.*, 1989), Argentina (Hopenhayn-Rich *et al.*, 1996; 1998), Chile (Smith *et al.*, 1998), and the U.S. (Lewis *et al.*, 1999). All of these and other, smaller studies have been considered in the Agency's deliberations on this rule.

The studies from Taiwan, Chile, Argentina and the U.S. employed the proper endpoints, selected correct study groups and grouped the people into discrete exposure groups. They also used acceptable methods and accounted for some known confounders. These studies, due to their relative sizes, varied in their statistical power to detect differences. The Utah study (Lewis *et al.*, 1999) contained 4,000 people while the Taiwan study had approximately 40,000 people and the two South American studies each had over 200,000 people. All of these epidemiology studies were ecological and retrospective studies. The Taiwan and South American studies had no individual exposure data. The Utah study associated persons with wells that had measured concentrations though exposure was calculated based on both level of arsenic and length of exposure. The Utah study followed exposed individuals to discern causes of later disease through carefully kept church records.

The Agency chose to make its quantitative estimates of risk based on the Taiwan study. This choice was endorsed by the EPA Science Advisory Board (SAB, 2000q; NRC, 1999). The database from Taiwan has the following advantages: Mortality data were drawn from a cancer registry; arsenic well water concentrations were measured for each of the 42 villages; there was a large, relatively stable study population that had life-time exposures to arsenic; there are limited measured data for the food intake of arsenic in this population; age- and dose-dependent responses with respect to arsenic in the drinking water were demonstrated; the collection of pathology data was unusually thorough; and the populations were quite homogeneous in terms of lifestyle. Studies in Argentina and Chile also showed lung and bladder risk of similar magnitude at comparable levels of exposure. EPA recognizes that there are problems with the Taiwan study that introduce uncertainties to the risk analysis such as: the ecological study design; the use of median exposure data at the village level; the low income and relatively poor diet of the Taiwanese study population (high levels of carbohydrates, low levels of protein, selenium and other essential nutrients); and high exposure to arsenic via food and cooking water.

As urged by many commenters, the Agency has considered and made adjustments in its dose-response assessment to reflect the quantitative effect of the high Taiwanese exposure to arsenic via food and cooking water. The Agency made an adjustment to the lower bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. In addition, an adjustment was made to the lower bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. We also considered several additional factors qualitatively in our final decision. These included the effect of the median well exposure data from the Taiwan study and the effects of nutritional factors such as selenium and methyl donors. However, we did not feel that there were sufficient data to account for these factors quantitatively.

The U.S. population cannot be considered to be made up entirely of well-nourished, genetically uniform persons. People of the Asian and Pacific Islander group make up about 4% (approximately 11 million) of the more than 270 million people in the U.S. (U.S. Census Bureau, 2000). In addition, there is a significant portion of the U.S. population living in poverty with poor nutrition. Thus, the Agency continues to believe that the Taiwan study is appropriate as a basis for risk assessment. The fact that the whole of the Taiwanese population was nutritionally vulnerable is a factor that the Agency has considered qualitatively as an uncertainty in risk assessment that may on average lead to overestimation of risk when applied to the U.S.

The Utah study (Lewis *et al.*, 1999) did not find any excess bladder or lung cancer risk after exposure to arsenic at concentrations of 14 to 166 μg/L. An important feature of the study is that it estimated excess risk by comparing cancer rates among the study population in Millard County, Utah to background rates in all of Utah. But the cancer rates observed among the study population, even those who consumed the highest levels of arsenic, were significantly lower than in all of Utah. This is evidence that there are important differences between the study and comparison populations besides their consumption of arsenic. One such difference is that Millard County is mostly rural, while Utah as a whole contains some large urban populations. Another difference is that the subjects of the Utah study were all members of the Church of Jesus Christ of Latter Day Saints, who for religious reasons have relatively low rates of tobacco and alcohol use. For these reasons, the Agency believes that the comparison of the study population to all of Utah is not appropriate for estimating excess risks. An alternative method of analysis is to compare cancer rates only among people within the study population who had high and low exposures. The Agency performed such an analysis on the Utah data, using the statistical technique of Cox proportional hazard regression (U.S. EPA, 2000x; Cox and Oakes, 1984). The results showed no detectable increased risk of lung or bladder cancers due to arsenic, even among subjects exposed to more than 100 μg/L on average. On the other hand, the excess risk could also not be distinguished statistically from the levels predicted by model 1 of Morales *et al.* (2000). These results show that the Utah study is not powerful enough to estimate excess risks with enough precision to be useful for the Agency's quantitative arsenic risk analysis. Furthermore, the SAB noted that "(a)lthough the data provided in published results of the Lewis, *et al.*, 1999 study imply that there was no excess bladder or lung cancer in this population, the data are not in a form that allows dose-response to be assessed dependably" (EPA, 2000q). Other studies in the U.S. (Morton *et al.*, 1976; Valentine *et al.*, 1992; Wong *et al.*, 1992) and Europe (Buchet *et al.*, 1999; Kurttio *et al.*, 1999) were also considered in EPA's evaluation of the risk from arsenic. However, these studies were not sufficient to develop a dose-response relationship.

2. Dose-Response Relationship

Numerous comments were received about the quantitative estimation of potential cancer risks to U.S. populations from drinking water exposure to arsenic. Concerns were raised about the extrapolation of the dose (exposure)—response relationship observed in a study of cancer incidence in an arseniasis-endemic area of Taiwan with high levels of arsenic in water (Chen *et al.*, 1988; Wu *et al.*, 1989; Chen *et al.*, 1992) to estimate potential response in the U.S. to arsenic in water at lower levels.

Some commenters asked whether it is appropriate to assume a linear dose response for arsenic given that arsenic does not appear to be directly reactive with DNA. Other commenters urged strict adherence to the linear approach, and recommended choosing an MCL that is below the 1/10,000 level of estimated risk based on that approach.

Some commenters also noted that independent scientific panels (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) who have considered the Taiwan study have raised the caution that using the Taiwan study to estimate U.S. risk at lower levels may result in an overly conservative estimation of U.S. risk. The independent panels have each said that below the observed range of the high level of contamination in Taiwan the shape of the dose-response relationship is likely to be sublinear. Thus, an assumption that the effects seen per dose increment remain the same from high to low levels of dose may overstate the U.S. risk. Some commenters have urged that the Agency model the dose-response relationship as a sublinear one, rather than as a linear one as in the proposal and NODA for the rule. These commenters consider adherence to the linear model as a failure of the Agency to use the best available, peer-reviewed science as required by SDWA.

After consideration of the arguments made by the commenters, the Agency continues to believe that the best approach, given the uncertainties associated with the available data, is to use the linear approach to set the MCLG for arsenic. In the proposal and the NODA, EPA discussed the fact that the available data on arsenic's carcinogenic mode of action point to several potential modes of action, but which one is operative is unknown. For this reason, the data do not support use of an alternative to linearity. The Agency recognizes that the dose-response relationship may be sublinear. The Agency has considered both a linear extrapolation and a nonlinear approach in the selection of an MCL in this final rule. (see section III.D.1.g. and the comment response document for a thorough discussion of the Agency's position on the dose-response assessment for arsenic.)

3. Suggestions That EPA Await Further Health Effects Research

Several commenters expressed the opinion that EPA should delay setting a standard for arsenic until more research studies have been completed. These commenters focused on research areas such as health effects (especially at low doses), the mode of action, and the dose-response curve. Other commenters questioned EPA's support of new research and tracking of ongoing research.

Since developing the Arsenic Research Plan as required by the 1996 SDWA amendments, EPA and stakeholders have established a substantial research program. Significant research has been completed, and further research is underway. EPA is tracking the progress of ongoing research and will make research results available to the public. EPA is committed to issuing the arsenic regulation based on best available science and believes that the research currently available is sufficient to do so.

EPA believes that the research underway may provide important new data for future rulemakings on arsenic. However, EPA does not believe that a determination on the arsenic MCL must be delayed until this research is complete. Indeed, the U.S. Court of Appeals for the District of Columbia Circuit found that EPA:

> cannot reject the "best available" evidence simply because of the possibility of contradiction in the future by evidence unavailable at the time of action—a possibility that will always be present" and that "[a]ll scientific conclusions are subject to some doubt; future hypothetical findings always have the potential to resolve the doubt. What is significant is Congress's requirement that the action be taken on the basis of the best available evidence at the time of rulemaking. The word "available" would be senseless if construed to mean "expected to be available at some future date" (*Chlorine Chemistry Council* v. *EPA*, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000)).

In the future, as part of the 6-year review process, the Agency will evaluate new data to determine if the MCLG and/or MCL promulgated in today's regulation should be revised.

Research pertaining to arsenic in the drinking water is a priority for the EPA. In addition, EPA supports and encourages other organizations to sponsor new epidemiology and toxicology studies on arsenic. The nature of scientific research is that as each study attempts to address or resolve a particular issue, it also raises more questions for investigation. EPA recognizes that even when the ongoing set of studies are complete, more are likely to follow. Uncertainty is inherent in science; at no point will "all" research be finished and "all" questions be answered.

4. Sensitive Subpopulations

Some commenters encouraged EPA to set the arsenic standard as low as possible to protect vulnerable populations. These commenters felt that EPA should consider human development and reproduction and variously defined vulnerable populations as persons with immune, cardiovascular, and nervous system disorders, children, low-income people, Native Americans, diabetics, and geriatric populations.

The 1996 SDWA amendments include specific provisions in section 1412(b)(3)(C)(i)(V) that require EPA to assess the effects of a contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. The NRC subcommittee (NRC, 1999) noted that there is a marked variation in susceptibility to arsenic-induced toxic effects which may be influenced by factors such as genetic polymorphisms (especially in metabolism), life stage at which exposures occur, sex, nutritional status, and concurrent exposures to other agents or environmental factors. EPA shares the view of the NRC report

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which concluded that there is insufficient scientific information to permit separate cancer risk estimates for potential subpopulations such as pregnant women, lactating women, and children and that factors that influence sensitivity to or expression of arsenic-associated cancer and noncancer effects need to be better characterized. The EPA agrees with NRC that there is not enough information to make risk conclusions regarding any specific subpopulations. However, EPA believes it is appropriate to consider effects on infants due to their greater consumption of water per body weight and is considering whether to issue a health advisory that will address this issue.

A study of a population in Chile exposed to about 800 µg/L in its drinking water for a period of years showed significant association with this exposure and fetal and infant mortality that declined to background when the water was treated to remove arsenic. This study was cited by a commenter as indicating more general sensitivity of fetuses and infants. The dose was one that had a range of significant arsenic toxicity effects on the adult population. It is logical that fetuses of mothers so exposed would be affected and infants would have received several times the adult exposure per kg body weight and, consequently, more toxicity. This study does not indicate disproportionate effects on fetuses or infants at low doses. Once the water was treated the effects declined to background (Hopenhayn-Rich *et al.*, 2000).

5. EPA's risk analysis

Several commenters felt that EPA did not follow the NRC recommendations that "the final calculated risk should be supported by a range of analyses over a fairly broad feasible range of assumptions", misinterpreted the NRC report, or relied solely on the NRC report and thus did not do an appropriate risk assessment for arsenic. Others viewed the NRC report as lacking peer review or as being politically motivated.

The SAB (EPA, 2000q, pgs. 2–3) discussed EPA's use of the NRC report. In the cover letter to the Administrator they stated:

* * * The NRC also noted a number of factors that likely differ between the Taiwanese study population and the U.S. population and which might influence the validity of arsenic cancer risk estimates in the United States. Even though the Agency did its own risk characterization (*i.e.*, they combined the NRC risk factors with U.S. exposure information and arsenic occurrence distributions to obtain a range of risks for use in their benefits analysis), they chose not to quantitatively take any of these factors into account at this time.

The Panel agrees with conclusions reached by the NRC in its 1999 report on arsenic, especially their conclusion that "there is sufficient evidence from human epidemiological studies * * * that chronic ingestion of inorganic arsenic arsenic [sic] causes bladder and lung, as well as skin cancer." The NRC also stated that currently the Taiwanese data are the best available for quantifying risk * * *. We note, however, that this Panel does not believe that resolution of all these factors can nor must be accomplished before EPA promulgates a final arsenic rule in response to the current regulatory deadlines. However, resolution of the critical factors * * *. in time for the next evaluation cycle for the arsenic regulation should be considered as a goal.

In closing the cover letter to the Administrator, the SAB stated:

Specifically, the majority of the Panel members felt that there is adequate basis for the Agency to consider use of its discretionary authority under the Safe Drinking Water Act of 1996 to consider MCLs other than the proposed 5 µg/L.

* * * The ultimate risk number derived from the Taiwanese study has proven very sensitive to the decision about the appropriateness of the comparison population. This of course, has important implications for the use of the data to estimate risk in the U.S. Also a study in Utah suggests that some U.S. populations may be less susceptible to the development of cancer, than those in Taiwan * * *. Also, a recently published study suggests that the incremental increases in lung and bladder cancers observed in the Taiwan study are of roughly the same magnitude, rather than the NRC's inference of a potentially two- to five-fold greater rate of lung cancer relative to bladder cancer.

As noted by the NRC, the mechanisms associated with arsenic-induced cancer most likely have a sublinear character, which implies that linear models, such as those used by the Agency, overestimate risk * * *. Nonetheless, the Panel agrees with the NRC that available data do not yet meet EPA's new criteria for departing from linear extrapolation of cancer risk.

The NRC Subcommittee on Arsenic in Drinking Water explored a number of model approaches using the Taiwan epidemiology data for bladder cancer. Although there are indications that the dose-response relationship for arsenic may be nonlinear at low doses, a convincing biological argument for selecting a nonlinear model is not yet available. Thus, according to EPA's draft 1996 guidelines and consistent with the 1986 guidelines, EPA determined that a point of departure approach was most appropriate to estimate low-dose risks. EPA agreed with NRC's choice of the Poisson model. In the NODA, based on the Morales et al. study (2000), EPA conducted a re-analysis of the bladder and lung cancer data using a Poisson model with no comparison population to estimate points of departure for each health endpoint. In addition to the re-analysis of bladder and lung cancer risk, EPA did a sensitivity analysis of the effect of exposure to arsenic through water used in preparing food in Taiwan. In response to comments received on the proposed rule and the NODA, EPA has also analyzed the effect of exposure to arsenic through food and considered the effect of village level exposure data. In summary, EPA's final risk calculation is supported by analyses of the effect of various assumptions and uncertainties on the risk estimate and reflects the best available science.

EPA believes that it has done a thorough risk analysis on arsenic. Arsenic health risks have remained a high priority at EPA for over 20 years, and EPA scientists have closely followed all scientific developments. EPA established four independent scientific panels to evaluate arsenic health risks (EPA, 2000q; NRC, 1999; EPA, 1997e; EPA, 1988) and provided a sense of the views of the broader scientific community. EPA participated in conducting one of the major cancer mortality studies available on arsenic (Lewis *et al.*, 1999). In the proposed rule and NODA, EPA used the 1999 NRC report's analysis of the Taiwan data as well as other published scientific papers to characterize the potential health hazards of ingested arsenic. The NRC report represents a thorough examination of the best available, peer reviewed science through the late 1990s. Other studies that were important in EPA's analysis were the Utah study (Lewis *et al.*, 1999) and the Morales *et al.* (2000) study. In selecting the proposed MCL, EPA considered the uncertainties of the quantitative dose-response assessment, particularly the possible nonlinearity of the dose-response. EPA also considered the unquantifiable risks from arsenic such as noncancer effects. In response to commenters, EPA expanded its analysis of the Utah study (U.S. EPA, 2000x) and delved further into the uncertainties in the Taiwan data. The Agency made an adjustment to the lower-bound risk estimates to take into consideration the effect of exposure to arsenic through water used in preparing food in Taiwan. In addition, an adjustment was made to the lower-bound risk estimates to take into consideration the relatively high arsenic concentration in the food consumed in Taiwan as compared to the U.S. EPA also investigated the effect of the ecological exposure data on its risk estimates. When villages with only one arsenic measurement were removed from the data set (on the theory that the exposure data was too uncertain), or when village means instead of medians were used for the exposure estimates, there was no statistically significant change in the estimated point of departure, using Model 1 of Morales *et al.* (2000). In summary, EPA believes that it has completed a thorough risk analysis on arsenic that used the best available, peer reviewed science.

The NRC subjected their draft report to a very rigorous external peer review using its own procedures that are well established and generally acknowledged as being independent and objective. The SAB also reviewed the NRC report and EPA's risk analysis, which was, in part, based on the NRC report. In addition, the public was provided an opportunity to comment on the EPA risk analysis as a part of the arsenic proposal and NODA.

EPA disagrees that the NRC report was politically motivated. The NRC Subcommittee on Arsenic in Drinking Water was composed of 16 highly respected scientific experts. EPA believes that this panel produced an impartial analysis of the data available on the toxicity of arsenic.

6. Setting the MCLG and the MCL

Some commenters were confused about the difference between MCLGs and MCLs, how EPA sets MCLGs and MCLs based on legal, scientific, and policy principles, and the relationship between the MCLG and costs and benefits. Other commenters were concerned about a perceived "anti-backsliding" provision for MCLGs and MCLs in SDWA.

In accordance with SDWA, standards set for contaminants consist of two components, a maximum contaminant level goal (MCLG) and a national primary drinking water regulation (NPDWR) (section 1412(b)(1)(A)), which specifies either "a maximum contaminant level (MCL) for such contaminant which is generally set as close to the maximum contaminant level goal as is feasible" (section 1412(b)(4)(B)) or a treatment technique if "it is not economically or technologically feasible to ascertain the level of the contaminant" (section 1412(b)(7)(A)).

SDWA defines an MCLG as "the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety" (section 1412(b)(4)(A)). MCLGs for all carcinogens are set at zero unless adequate scientific data support a higher MCLG. In accordance with the SDWA, the MCLG is based on the best available peer reviewed science. An MCLG is a goal, not a regulatory limit that the Agency expects to be attained by water systems.

The MCLG must be proposed simultaneously with a national primary drinking water regulation (section 1412(a)(3)), which specifies a maximum contaminant level (MCL) as close to the MCLG as technically feasible. The MCL is the enforceable standard. SDWA allows EPA to make an exception to setting the MCL as close to the MCLG as is feasible where the "Administrator determines * * * that the benefits of a maximum contaminant level * * * would not justify the costs of complying with the level." In this case, EPA may propose and promulgate an MCL "that maximizes health risk reduction benefits at a cost that is justified by the benefits" (section 1412(b)(6)). This exception was used to set the MCL for arsenic. EPA found that at the feasible level of 3 µg/L, the benefits of compliance did not justify the costs. The Agency determined that an MCL of 10 µg/L maximizes the health risk reduction benefits at a cost that is justified by the benefits (see preamble discussion of the risk management decision that was made for arsenic in section III.F.)

Some commenters argued that EPA sets the MCL within a risk-range of 10^{-4} to 10^{-6} without proper regard to the statutory requirements discussed above. This is not the case. As noted in the proposal, EPA has historically considered this risk range as protective of public health, and accordingly has sought to ensure that drinking water standards are within this risk range. However, the risk-range represents a policy goal for EPA, and is not a statutory factor in setting an MCL. In the case of arsenic, EPA did the benefit-cost analysis required by the statute. Having found that the benefits of an MCL at the feasible level were not justified by the costs, EPA set the MCL at 10 µg/L. This MCL maximizes health risk reduction benefits at a cost that is justified by the benefits.

EPA is required to review and revise as appropriate, each national primary drinking water regulation, at least every 6 years. Revisions to current regulations "shall maintain, or provide for greater protection of the health of persons" (section 1412(b)(9)). When new scientific data become available, the Agency may reevaluate the MCLG and MCL.

C. Occurrence

The principal concerns raised by the commenters and our responses are as follows:

1. Occurrence data

Several commenters expressed concern that EPA estimated occurrence using data from only 25 States and that the national estimate was thus not as robust as it should have been. Many of these commenters suggested that EPA should request data from all States/more systems before issuing the final rule.

It is true that we based our occurrence estimate on data from only 25 States. However, we believe that we have compiled the most comprehensive and accurate occurrence estimate possible with currently available data, and that this estimate adequately supports our various analyses and final decisions.

For our occurrence analysis, we relied on data submitted voluntarily by State drinking water agencies. In doing so, we collected the largest available database on arsenic in drinking water, consisting of almost 77,000 observations from more than 26,600 public water systems in 25 States. We received but did not use data from six States (Florida, Idaho, Iowa, Louisiana, Pennsylvania, and South Dakota), because the data either could not be linked to PWSs; did not indicate if results were censored; were all zero; did not provide analytical or reporting limits; or were rounded to the nearest 10 µg/L.

In response to our request in the proposed rule for additional occurrence data, we received additional data from several States. However, in each case, the submitted data either corresponded closely to observations already in our data set (California, New Mexico, Utah), or were of the wrong kind or insufficient quantity to use in our estimation (Iowa, Maryland, Nebraska, Oklahoma, Vermont, West Virginia).

Of the States from whom we did not receive usable data, we believe that many do not have databases of the kind and quality that we would need for our occurrence analysis. We therefore could not have obtained such information from other States without requiring, in some instances, new monitoring to be undertaken and new data to be compiled.

In forming our occurrence estimate, we did not ignore States for which we have no suitable data. We accounted for these States by assigning regional occurrence distributions to them. Our resulting national estimates compare relatively closely with those developed by the utility industry and by the U.S. Geological Survey (EPA, 2000r).

Some commenters indicated EPA should not use data from the U.S. Geological Survey's National Ambient Water Quality Assessment (NAWQA) or EPA's NIRS, SDWIS, or Rural Water

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Survey (RWS) to estimate occurrence. In forming our occurrence estimates, we used arsenic concentrations drawn only from our 25-State arsenic compliance monitoring database. We did not use observations from NAWQA, SDWIS, RWS, NAOS, NIRS, NOMS, Community Water System Survey (CWSS) or any other surveys or studies. As the preamble of the proposed rule (65 FR 38888 at 38903) states, we used National Organic Monitoring Survey (NOMS), RWS, and the 1978 CWSS in previous arsenic occurrence analyses, but did not use them for the present analysis because of their age and relatively high detection limits. The only information we used from SDWIS was the type and size of particular systems, and the numbers of systems and population served in different categories of systems. We used NAWQA, NAOS and NIRS only for comparison to our finished results.

2. Occurrence Methodology

Some commenters stated their belief that EPA had underestimated national occurrence because they believe that EPA did not have enough data with which to develop the estimate. Commenters also believed that, since the national occurrence is underestimated, noncompliance/co-occurrence are also underestimated.

We do not agree that we have underestimated arsenic occurrence. We have the largest existing database of arsenic in drinking water, with almost 77,000 observations from more than 26,600 public water systems in 25 States. We did not ignore States for which we have no data, but accounted for them by assigning regional occurrence distributions to them. Our data and methodology have been approved by an independent expert peer review panel. Our occurrence estimates are close to those of the NAOS and USGS.

Some commenters believe EPA's occurrence methodology is inconsistent with the way compliance is determined and that EPA should use a running annual average for estimating noncompliance.

We acknowledged in the proposed rule (65 FR 38888 at 38907) that our method of estimating occurrence is different from the method used for determining compliance with the MCL. Our method usually gives higher estimates, because we substitute non-zero values for non-detects, while under the regulatory definition of compliance, non-detects are assumed to equal zero. We believe our method is the best one despite the difference, for two reasons. First, our goal is to characterize arsenic occurrence as accurately as possible. Given a sound characterization of system-mean occurrence and of intra-system and intra-source variability, the numbers of systems and points of entry expected to fail the regulatory definition of compliance at some MCL option can be determined. The reverse calculation, on the other hand, is generally not possible. Second, as analytical methods improve and detection limits decrease, the difference between the two methods will decrease.

To the extent that our estimates disagree with those used for determining compliance, our estimates will be higher and thus will cause us to slightly overestimate the costs associated with any MCL option. Our estimates of benefits, on the other hand, should not be biased one way or the other by our occurrence estimate, since health risks are mainly determined by mean exposure over time, which we accurately characterize. The same would not be true if we used the regulatory definition of non-detects, which underestimates mean occurrence.

Commenters also pointed out that occurrence estimates in different parts of the rule and support documents are inconsistent. Although the analysis is internally consistent, apparent inconsistencies in the numbers arise from three sources: System versus site considerations, year of the SDWIS inventory, and use of best point or regressed estimates. With respect to the first point, because most large ground water systems have multiple entry points, some systems which have average concentrations below the MCL will still have impacted entry points. As a consequence, the number of impacted systems is much larger than the number of systems with mean concentrations above the MCL. In the proposal, this difference amounted to several hundred systems.

In connection with the second point, year of the SDWIS inventory, it is not unusual for there to be a change from year to year in the inventory of hundreds of water systems. This results from restructuring and consolidations, among other factors. In the final rule and supporting documents, we have tried to address this issue by consistently using a single set of baseline estimates, taken from EPA's Drinking Water Baseline Handbook (EPA, 2000b). Regardless, this factor is only responsible for a one or two percent variation in the impact estimate, and is not of sufficient significance to impact the decision making process.

The third issue relates to the representation of the mean system arsenic occurrence. In many tables, mean arsenic concentrations are presented which reflect our best point estimates. Nevertheless, the best estimate of national cost impacts derives from use of a best fit equation which incorporates all of the data. We have used these regressed fits in the development of the costs and benefits. The two sets of estimates are described in section III.C.4.

3. Co-Occurrence

Some commenters believe EPA has underestimated the co-occurrence of arsenic with radon. We agree that, based on the NWIS data, most systems with arsenic greater than 10 µg/L will also have radon greater than 300 pCi/L. However, only about 8% of all systems exceed both standards. Moreover, about 85% of such systems (again based on NWIS) have radon in the range of 300 to 1000 pCi/L, where incidental removal of radon will be most effective. We expect, for example, that systems with 300 to 1000 pCi/L of radon will be more likely to treat for arsenic by coagulation and microfiltration, which removes most radon incidentally by aeration. Therefore, we believe that the impact of co-occurrence of radon and arsenic will be small.

Some commenters believed that EPA did not evaluate the effect of different sulfate levels in its decision tree. We did evaluate several ranges of concentrations of sulfate and arsenic against each other (see 65 FR 38888 at 38938). The sulfate concentration ranges included 0 to 25, 25 to 120, 120 to 250, 250 to 500, and >500 mg/L. The arsenic concentration ranges included 0 to 2, 2 to 5, 5 to 10, 10 to 20, and >20 µg/L. For these ranges, there was no apparent change in co-occurrence of sulfate and arsenic as the concentrations increased. However, the Agency took the co-occurrence of arsenic and sulfate and the impact on anion exchange technology into consideration in the decision tree at sulfate levels of <20, 20 to 90, 90 to 120, and >120 mg/L. The revised decision tree for today's final rule only applies anion exchange when sulfate levels are less than 50 mg/L.

Some commenters expressed their belief that NWIS is inadequate to estimate national co-occurrence of arsenic and radon and that NWIS data should be verified as representative of PWS water use by requesting data from States. It is true that NWIS includes samples from non-drinking water supplies. NWIS is, however, the largest and best data base available for studying co-occurrence with over 40,000 ambient water samples. To the extent that non-drinking water samples affect our estimates, they should cause us to overestimate occurrence and therefore also co-occurrence. We realize that NWIS may not reflect conditions in any given State or water system; we use it only for deriving national estimates.

D. Analytical Methods

1. Analytical Interferences

Commenters expressed concern about the potential for matrix interferences in the analysis of arsenic at low levels. A potential for chloride interference when using ICP–MS with samples containing high levels of chloride was specifically noted by commenters. A commenter also stated that some investigators had reported arsenic results in drinking water samples that differed depending on the valence state of the arsenic in the sample (*i.e.*, As (III) or (V)) when using methods that used GHAA technology. The Agency agrees that interferences may be encountered when determining arsenic using the methods proposed in the June 2000 rule (including the GHAA technique). However, the Agency disagrees that the interferences are unexpected or impede compliance with the arsenic MCL of 0.01 mg/L. Four different measurement technologies are approved for the analysis of arsenic: AA furnace, AA-Platform, GHAA and ICP–MS with respective MDLs of 0.001 mg/L, 0.0005 mg/L, 0.001 mg/L, and 0.0014 mg/L. These technologies have been used for compliance determinations of arsenic for many years. The methods written around each of these technologies identify potential interferences and contain corrective procedures. In particular, the ICP–MS method warns of potential interferences from chloride and provides instructions to eliminate this problem.

2. Demonstration of PQL (Includes Acceptance Limits)

Several commenters agreed with the ±30% acceptance limit and the 0.003 mg/L PQL derived and proposed for arsenic. Other commenters expressed concerns that the PQL was not correctly derived or that the acceptance limits were too broad.

A commenter stated that the Agency should set the PQL at 5 to 10 times the method detection limits of 0.001mg/L which would result in a PQL range of 0.005 to 0.010 mg/L. As previously explained in section III.B.1 of this preamble, EPA only uses the MDL multiplier approach to derive a PQL when there is insufficient interlaboratory data to statistically derive a PQL. For arsenic, the Agency had ample WS data to derive a PQL using the interlaboratory approach.

Several commenters were concerned that the "PQL study is not realistic and does not account for matrix interference in real drinking water samples." In addition, some commenters stated that the "PQL should be set at a level that is achievable by laboratories on a routine basis." EPA disagrees that the PQL for arsenic is unrealistic, or that it has been set at a level that is unachievable on a routine basis. As explained in section III.B.1 of this preamble, EPA used the interlaboratory data from six recent WS studies to derive the arsenic PQL. The WS studies utilize reagent grade water (*i.e.*, blank water free of interferences) for the PE-samples that are analyzed in the WS study. Use of reagent water to prepare a test sample conforms with an accepted and longstanding practice in which a method developer validates an analytical method in blank water before looking for possible inaccuracies from matrix effects when the method is applied to a sample matrix (*e.g.*, a compliance drinking water sample). Reagent water is used as an initial benchmark for method development and testing, because it is interference-free and can be readily produced in any competent laboratory. A lab subsequently identifies and corrects for matrix effects by comparing its performance on reagent water to the results on the matrix (contaminated drinking water) or spiked matrix (clean drinking water spiked with arsenic) sample.

All of the methods approved for SDWA and Clean Water Act (CWA) compliance monitoring require that laboratories demonstrate acceptable performance in reagent grade water before drinking water samples are tested. A study conducted by Eaton (Eaton, 1994) found that the type of matrix and the analytical method used had no significant effect on the derivation of their PQL. This study included drinking waters with high total dissolved solids and total organic carbon, and arsenic concentrations that ranged from 0.001 to 0.010 mg/L. Thus, EPA disagrees with the comment that the PQL would be significantly different if derived in various drinking waters instead of in reagent water.

The Agency also believes that the derived PQL of 0.003 mg/L is realistic and is achievable on a routine basis. The derivation of the PQL for arsenic is consistent with the longstanding process used to determine PQLs for other metal contaminants regulated under SDWA. In deriving the PQL for arsenic, the Agency took into consideration the issue of laboratory capability, laboratory capacity, and the ability of laboratories to achieve a quantitation level on a routine basis. The PQL for arsenic was derived from data collected in WS studies in which PE-samples were prepared with reagent water spiked with low concentrations, <0.006 mg/L, of arsenic. These studies were conducted from 1992 to 1995. The number of EPA Regional and State laboratories that participated in each study ranged from 26 to 45 laboratories. Using acceptance limits of ±30% a linear regression analysis of this data yielded a PQL of 0.00258 mg/L. The Agency rounded up to derive the proposed PQL of 0.003 mg/L (3 µg/L) with a ±30% acceptance limit. Over 75% of the EPA Regional and State laboratories were able to report arsenic concentrations within ±30% of 3 µg/L. In addition, 62% of non-EPA laboratories that participated in these same WS studies were equally successful. The number of non-EPA laboratories in these WS studies ranged from 360 to 619 laboratories, which means that the number of laboratories that successfully analyzed the low concentration arsenic PE-samples ranged from 223 to 384. This data indicate that neither laboratory capacity nor capability will be a problem at a PQL of 3 µg/L ±30%. EPA, therefore, believes that competent laboratories are available, and with the use of the quality control instructions in the compliance methods will routinely achieve this level of performance.

Several commenters felt the acceptance limit of ±30% is too wide. The ±30% acceptance limit was based on a recommendation from the SAB. The SAB recommendation was to choose an acceptance limit similar to that set for other regulated metals (EPA, 1995). These limits range from ±15% for barium, beryllium, and chromium to ±30% for mercury and thallium (§ 141.23(k)(3)). EPA chose the upper (*i.e.*, wider) limit on this range to ensure that a sufficient number of laboratories could be certified for arsenic determinations (the number of laboratories that can achieve the accuracy acceptance limit increases as the limit is widened). Several commenters agreed with the proposed ±30% acceptance limit, because they shared EPA concerns about insufficient laboratory capacity if this limit was narrowed.

3. Acidification of samples

A commenter stated that the Agency needed to clarify that a sample can be collected in the field without acidification, and that acidification of the sample can be done later at the laboratory. The commenter believes that delaying acidification does not affect the compliance determination and that a

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laboratory is a better place in which to handle acids. The Agency agrees with this comment and had previously clarified in a final rule (64 FR 67450; December 1, 1999; see page 67452, item 11 and page 67456, item 3; EPA, 1999p), that acidification of samples may be conducted in the field or laboratory with acidification at the laboratory being the better and safer choice. In the 1999 rule, EPA noted that this change would be affected by amending footnote one to the table at § 141.23(k)(2) to read as follows:

> For cyanide determinations samples must be adjusted with sodium hydroxide to pH > 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4EC or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

Although the June 2000 proposal inadvertently omitted this footnote, today's final rule contains the correct footnote.

Another commenter believed that because the proposed sample preservation requirement for arsenic was new and supposedly untested, data collected under the previous requirements might not be comparable to data resulting from the new sample preservation requirement. These are not new analytical requirements. The commenter may have been misled by the statement in the preamble to the June 2000 arsenic proposal that EPA proposed to add a "new" requirement to the preservation and holding time table at § 141.23(k)(2). It is only new in the sense that EPA has codified the requirements in today's rule. Arsenic compliance data collected in the past and the arsenic data discussed in the June 2000 proposal were collected using these preservation and holding time conditions.

E. Monitoring and Reporting Requirements

1. Compliance Determinations

Most of the comments regarding compliance determinations requested the Agency to provide further clarification on this issue. Many commenters specifically asked EPA to specify whether samples collected quarterly as a result of an MCL violation are defined as compliance samples or confirmation samples. In today's final rule, the Agency has provided further clarification in the regulatory language to eliminate any misinterpretation.

The Agency defines quarterly samples as compliance samples that must be used to determine compliance. Confirmation samples are any samples that the State requires that go beyond the minimum Federally required samples defined in the following paragraph.

Systems will determine compliance based on the compliance samples obtained at each sampling point. If any sampling point is in violation of an MCL, the system has a MCL violation. For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point. Systems monitoring annually or less frequently whose sample result exceeds the MCL for inorganic contaminants in § 141.23(c), or whose sample result exceeds the trigger level for organic contaminants listed in §§ 141.24(f) or 141.24(h) must revert to quarterly sampling in the next quarter. The system will not be considered in violation of the MCL until it has completed one year of quarterly compliance sampling. If any sample result will cause the running annual average to exceed the MCL at any sample point (*i.e.*, the analytical result is greater than four times the MCL), the system is out of compliance with the MCL immediately. Systems may not monitor more frequently than specified by the State to determine compliance unless it has applied to and obtained approval from the State. If a system does not collect all required samples when compliance is based on a running annual average of quarterly samples, compliance will be based on the running annual average of the samples collected. If a sample result is less than the detection limit, zero will be used to calculate the annual average. States have the discretion to delete results of obvious sampling or analytic errors.

States still have the flexibility to require confirmation samples for positive or negative results. States may require more than one confirmation sample to determine the average exposure over a 3-month period. Confirmation samples must be averaged with the original analytical result to calculate an average over the 3-month period. The 3-month average must be used as one of the quarterly concentrations for determining the running annual average. The running annual average must be used for compliance determinations.

Some commenters requested rule language that clearly specifies how to determine compliance and others requested approval of scientific methodologies that more accurately reflect the average annual contaminant exposure. Today's rule requires that monitoring be conducted at all entry points to the distribution system. However, the State has discretion to require monitoring and determine compliance based on a case-by-case analysis of individual drinking water systems.

The Agency cannot in this rule address all of the possible outcomes that may occur at a particular water system; therefore, EPA encourages drinking water systems to inform State regulators of their individual circumstances. Some systems have implemented elaborate plans including targeted, increased monitoring that is much more representative of the average annual mean contaminant concentration to which individuals are being exposed. (Some States determine compliance based on a time or flow weighted average.) In many cases, the State can demonstrate that compliance is being calculated based on scientific methods that are more representative of the true contaminant concentration that individuals are being exposed to over a year, but it substantially increases the sampling and analytical costs.

Some States require that systems collect samples from wells that only operate for 1 month out of the year regardless of whether they are operating during scheduled sampling times. The State may determine compliance based on several factors including, but not limited to, the quantity of water supplied by a source, the duration of service of the source, and contaminant concentration.

2. Monitoring of POU Devices

Several commenters indicated that there will be many implementation problems with POU devices. EPA agrees that some issues such as scheduling and access for routine maintenance of POU devices, liability, and monitoring may be difficult but believes they can be alleviated with sufficient planning. The Agency will be providing POU operation and maintenance guidance for small systems after publication of the final rule. In general, EPA believes that POU systems can be easily installed, maintained, and monitored for removal efficacy.

EPA believes that it is feasible for public water systems to own, control, and maintain POE/POU devices for arsenic MCL compliance either directly or through a contract with a qualified party. This approach, however, requires more recordkeeping to monitor individual devices than does centralized treatment. Both POU AA and RO can be obtained with mechanical warnings to ensure that customers are notified of operational problems. In the case of activated alumina, such warnings include shut-off valves that are triggered prior to the adsorptive capacity of the media being exhausted, based on the volume of water treated. Reverse osmosis POU devices come with total dissolved solids detectors that activate warning lights when membrane integrity is compromised.

Systems having high arsenic concentrations in the finished water that choose to achieve compliance using POU treatment would shift from monitoring at a central location to monitoring at the POU devices. As is the case with any system that installs treatment to lower contaminant concentrations to levels below the MCL, the monitoring frequency is part of the compliance agreement between the Primacy Agency and the system. The compliance agreement must require monitoring that is as protective as monitoring for systems using centralized treatment and may not be less frequent than the routine monitoring required in today's rule (i.e., annual samples for surface water systems and one sample every three years for ground water systems). The Primacy Agency will be responsible for negotiating the monitoring schedule with the system for POU devices and may amend the compliance agreement with the system to increase or reduce the monitoring frequency to an alternate schedule depending upon maintenance, public responses, the implementation of the service agreement, and the initial monitoring results. For purposes of forecasting national compliance costs, EPA assumed that all POU devices would be monitored for arsenic with one sample taken the first year following installation, samples taken annually in subsequent years, and replacement of the filter cartridge at each POU site every 6 months.

3. Monitoring and Reporting for NTNCWSs

Most commenters disagreed with EPA's approach of requiring NTNCWSs to monitor and provide public notification. Instead, the majority of commenters indicated that EPA should either require full coverage or not regulate NTNCWSs. In today's rule making, EPA is requiring NTNCWSs to comply with the arsenic regulation, including the monitoring and reporting requirements associated with arsenic in § 141.23, the MCL listed in § 141.62, and the public notification requirements (NTNCWSs are subject to the same requirements as those of CWSs). EPA acknowledges that there is uncertainty associated with its information about exposure patterns for consumers of water from NTNCWSs and the demographics of these facilities. Thus, our understanding of the health risks to consumers of water from NTNCWSs is uncertain. In the case of arsenic, however, EPA believes the additional uncertainty in the overall risk analysis supports the decision to treat these facilities the same as CWSs. EPA also believes the decision to cover these facilities is underscored by consideration of the risks to children who consume water at day care facilities or schools that are served by NTNCWSs.

4. CCR Health Language and Reporting Date

Comments received on EPA's proposed consumer confidence reporting (CCR) requirements were equally split. Some commenters supported EPA's proposal to include health effects language in CCRs if a system detects arsenic above the revised MCL prior to the effective date. Others disagreed with the proposal because they believed providing this information prior to the effective date would be confusing to consumers and would not allow sufficient time to inform consumers about the risks associated with arsenic. These dissenting commenters generally felt that it would be more useful for systems to provide notice to consumers that the MCL has been revised and systems will be required to comply by the effective date of the revision.

The Agency believes that it is important to provide customers with the most current understanding of the risk presented by arsenic as soon as possible after establishing the new standard. In today's rule, community water systems that detect arsenic between the revised and existing MCL must include health effects language in their consumer confidence reports prior to the effective date of the revised MCL. The Agency does not believe that inclusion of this information will be unnecessarily confusing to consumers because, under the CCR rule systems have the flexibility to place this information in context. EPA expects that affected systems will include not only the health effects language but also an explanation that the current MCL has been revised and the system is not in violation because the new standard has not yet taken effect.

EPA is finalizing an MCL somewhat higher than the technologically feasible MCL. Since some commenters expressed concern about the risk that a higher-than-feasible MCL might present to certain consumers, EPA is requiring systems that detect arsenic at concentrations greater than 5 µg/L and up to and including 10 µg/L to provide additional information to their customers. EPA believes that consumers should be aware of the uncertainties surrounding the risks presented by very low levels of arsenic. While EPA addressed many of the sources of uncertainty in its risk analysis of arsenic in support of the final rule, several sources of uncertainty remain and will be considered in the future in the context of the periodic review and revision, if appropriate, of drinking water regulations as required by section 1412(b)(9) of SDWA.

5. Implementation Guidance

EPA appreciates the fact that the final rule will place a new implementation burden on many water systems, particularly small systems. This is particularly true of small ground water systems that heretofore have not been obliged to install, operate, and maintain a treatment facility. EPA also understands that new or more sophisticated treatment technologies will have obvious implications in terms of operator capacity. EPA has addressed this issue in several ways, and does not believe that it is an impediment to promulgating this new MCL. In brief, some of the ways these implementation concerns have been addressed are as follows. EPA has identified a number of affordable small system treatment technologies that are based on consideration of the capabilities of small system operators. Systems will have the latitude to choose the type of treatment technology that is most cost effective and appropriate (from an operation and maintenance standpoint) for their particular situation. EPA also plans to publish implementation guidance for small systems within 60 days of publication of the final rule that will provide helpful information to aid small systems in both selecting and operating small treatment technologies. EPA has exercised its statutory authority under section 1412(b)(10) of SDWA to provide an additional 2 years for small systems to comply with this rule (for a total of 5 years). Individual small systems may apply for exemptions with extensions that can provide for a total of an additional 9 years to comply with the requirements of this rule. Finally, EPA notes that the final rule provides more "buffer" between the feasible level (3 µg/L) and the MCL of 10 µg/L as compared to the proposed level of 5 µg/L. Thus, treatment facilities that experience operation difficulties would

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have more latitude in terms of the timing and type of corrective measures that would need to be taken than would be the case with a more stringent final MCL. For all of the above reasons, EPA does not believe that there are any insurmountable implementation problems associated with the final MCL for arsenic.

6. Rounding Analytical Results

Today's rule requires that data be reported to the nearest 0.001 mg/L (3 significant figures). Some commenters felt that the rounding approach described in the proposed rule would significantly impact State programs. The proposed rule solicited comment on an approach requiring all values greater than or equal to 6 to be rounded up and all values less than or equal to 4 to be rounded down (*i.e.* a value of 0.0056 mg/L would be rounded to 0.006 mg/L). Results ending in 5 would round the third significant digit to the closest "even" number. Therefore, a result of 0.0155 mg/L would be rounded to 0.016 mg/L, and 0.0145 mg/L would be rounded to 0.014 mg/L. Some commenters supported EPA's rounding approach. Other commenters indicated that implementing this revision would affect State data management operations and would require staff training.

The Agency recognizes that implementing a revision to the existing rounding guidance may impact State database and computer programs. In today's final rule, the Agency is encouraging States to continue using the rounding scheme that EPA recommended in the "Water Supply Guidance #72", dated April 6, 1981. EPA stated in this guidance that:

> All MCLs contained in the National Interim Primary Drinking Water Regulations are expressed in the number of significant digits permitted by the precision and accuracy of the specified analytical procedures. Data reported to the State or EPA should be in a form containing the same number of significant digits as the MCL. In calculating data for compliance purposes, it is necessary to round-off by dropping the digits that are not significant. The last significant digit should be increased by one unit if the digit dropped is 5, 6, 7, 8, or 9. If the digit is 0, 1, 2, 3, or 4 do not alter the preceding number.

For example, analytical results for arsenic of 0.0105 mg/L would round off to 0.011 mg/L while a result of 0.0104 mg/L would round off to 0.010 mg/L.

F. Treatment Technologies

1. Demonstration of Technology Performance

Many comments on the proposed arsenic rule (EPA, 2000i) expressed the concern that the treatment options that EPA designated as BAT for compliance with the arsenic MCL have not been adequately demonstrated in full-scale operation for arsenic removal. Commenters noted that there are relatively few arsenic treatment facilities in the U.S., and these facilities are generally small and were designed for an arsenic MCL of 50 µg/L. Although many of the treatment options designated as BAT are widely used for other water treatment objectives, commenters stated that the limited application of these technologies to arsenic removal, especially in large plants, creates uncertainty as to their efficacy and feasibility for this purpose. Commenters alleged that this situation makes it difficult for water systems to determine appropriate compliance technology choices and raises questions regarding the validity of EPA's estimates of costs for compliance with the arsenic MCL.

EPA notes that SDWA section 1412(b)(4)(E) states: [E]ach national primary drinking water regulation which establishes a maximum contaminant level shall list the technology, treatment technique, and other means which the Administrator finds to be feasible for purposes of meeting such maximum contaminant level.

SDWA defines feasible in section 1412(b)(4)(D) as follows:

> For the purposes of this subsection, the term "feasible" means feasible with the use of the best technology, treatment techniques, and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration).

Thus, SDWA requires EPA to list feasible compliance treatment options based on demonstration of efficacy under field conditions and taking cost into consideration.

For compliance with the arsenic MCL, EPA judged technologies to be a best available technology when the following criteria were satisfactorily met:

- The capability of a high removal efficiency;
- A history of full scale operation;
- General geographic applicability;
- Reasonable cost;
- Reasonable service life;
- Compatible with other water treatment processes; and
- The ability to bring all of the water in a system into compliance.

After reviewing a number of technologies, EPA identified the following as BAT for arsenic removal: ion exchange, activated alumina, reverse osmosis, modified coagulation/filtration, modified lime softening, electrodialysis reversal, and oxidation/filtration. EPA believes that all of these treatment options meet the SDWA criteria of demonstrated efficacy under field conditions and, further, meet the additional criteria listed above which EPA has historically used to identify BAT. Studies which support this assessment are described in "Technologies and Costs for Removal of Arsenic from Drinking Water" (EPA, 2000t). Consequently, identification of these technologies as BAT is appropriate.

EPA recognizes that application of the arsenic BAT treatment options to full-scale plants where they are optimized specifically for arsenic removal is limited. This is especially true in regard to large plants. Nevertheless, as stated previously, it is appropriate for EPA to identify these technologies as BAT because they have been demonstrated to be effective for arsenic removal under field conditions. Moreover, all of the technologies listed as BAT have an established history of successful application at full scale in water treatment plants for related treatment objectives, specifically including the removal of inorganic contaminants (EPA, 2000t). Ion exchange is applied in both municipal and POE/POU treatment for softening (i.e., removal of calcium and magnesium), as well as for removal of nitrate, arsenic, chromium, radium, uranium, and selenium. Activated alumina is used in water treatment plants to remove contaminants such as fluoride, arsenic, selenium, silica, and natural organic matter. Reverse osmosis has traditionally been employed to desalinate brackish water and sea water. Electrodialysis reversal systems are often used in treating brackish water to make it suitable for drinking, and have also been applied for wastewater recovery. Oxidation followed by filtration is utilized extensively in public water systems for removal of iron and manganese. Lime softening is widely applied for reducing calcium, magnesium, and other metals in large water treatment systems. Most surface water systems use coagulation/filtration processes for particulate removal, and a growing number of systems have modified these processes to increase removal of dissolved constituents, primarily TOC and certain metals.

EPA believes that the successful application of the arsenic BAT treatment options for the removal of contaminants other than arsenic is relevant to their ability to remove arsenic in full-scale plants. The physical and chemical mechanisms operative in these technologies for the removal of hardness, sodium, fluoride, TOC and other dissolved species are analogous to the mechanisms by which these technologies remove arsenic. In addition, none of these technologies have characteristics that would make them ineffective or infeasible at large scale or under long-term operation. The specific conditions under which optimized performance is achieved may differ somewhat between removal of arsenic and removal of other contaminants, just as they may differ from plant to plant based on water matrix and other treatment processes in use. However, because it has been shown that these technologies can remove arsenic under field conditions, and because these technologies have an established history of use for the removal of inorganic contaminants in full-scale systems, EPA believes it is appropriate and technically justified to conclude that they can be successfully used for arsenic removal in full-scale plants.

2. Barriers to Technology Application

EPA received many comments on the proposed arsenic rule (EPA, 2000i) that described challenges that systems would face in applying the technologies identified by EPA for compliance with the arsenic MCL. Among such challenges asserted by comments were the following: the cost and availability of adequately trained, certified operators, especially in small systems; hazards associated with the shipping, handling, and storage of chemicals, especially in regard to wells located in residential areas; and the infeasibility of water loss from treatment processes in arid regions. Note that comments dealing with residuals handling and disposal are addressed subsequently in section V.F.4 of this preamble.

In regard to water treatment plant operators, EPA believes that operator competency is critical for the protection of public health and the maintenance of safe, optimal, and reliable performance of water treatment and distribution facilities. Pursuant to SDWA section 1419(a), EPA has developed guidelines for the certification and recertification of the operators of community and nontransient noncommunity public water systems. These guidelines require that all operating personnel who make process control/system integrity decisions about water quality or quantity that affect public health must be properly certified by the State. EPA recognizes and has considered that the treatment technologies, which systems will install to comply with the arsenic MCL, may add complexity to existing treatment works or may be applied to previously untreated ground water. These situations will necessitate additional operator training to ensure that treatment processes are properly operated, and systems will incur additional costs associated with operator labor.

EPA believes there will be sufficient numbers of adequately trained and certified operators available to public water systems. Operator training programs are available throughout the U.S. through home study courses, classroom settings, and in-plant training. Current and new water treatment operators can obtain the training necessary to operate any of the treatment technologies considered for compliance with the arsenic MCL. EPA is developing a grants program pursuant to SDWA section 1419(d) to reimburse training and certification costs for operators employed by community water systems and nontransient, noncommunity water systems serving 3,300 or fewer people. This funding will reduce the compliance burden on these small systems, thereby increasing the likelihood that the systems will be able to reliably operate and maintain new treatment. Today's rule offers five years between promulgation and the time systems must be in compliance. An exemption can provide three additional years to achieve compliance, and this exemption may be renewed for up to six years for small systems. The Agency believes this amount of time will offer ample opportunity for States' operator training and certification programs to prepare operators.

EPA's Operator Certification Guidelines require that a certified operator be responsible, in charge, and available to all community and nontransient, noncommunity water systems. However, this does not mean a certified operator must be on site at every treatment facility 24 hours a day, 7 days a week. The treatment technologies do not necessarily require constant supervision of operators. Depending upon State requirements, regional certified operators could travel from facility to facility on a regular basis to oversee the efforts of the non-certified operators provided the certified operator was also available to the system on an on-call basis. Systems must consider their operational constraints in selecting treatment technologies and in establishing appropriate operational controls.

EPA has accounted for additional labor costs associated with the operation of treatment technologies for compliance with the arsenic MCL. The Agency's analyses of additional costs are described in "Technologies and Costs for Removal of Arsenic from Drinking Water" (EPA, 2000t). The labor rates used to develop operation and maintenance costs are conservative estimates based on loaded rates for certified operators in large and small systems.

Concerns expressed by commenters on the storage, handling, and application of chemicals used in arsenic treatment centered on hazards to the public health and safety if an accidental release occurred. These comments hinged on the fact that ground water systems may have wells located in residential and high population-density areas. Several commenters asserted that the risks from chemical application in these areas may outweigh the hazards associated with potentially elevated arsenic concentrations. Among the chemicals of concern are chlorine for pre-oxidation, and acids and bases for pH adjustment.

While EPA understands the nature of this concern, EPA does not believe that chemical usage for compliance with the arsenic MCL poses a significant risk. Systems using chemicals should employ established safety and emergency response procedures, along with effective operator training and certification. Measures that can be taken to alleviate potential problems with chemical handling and storage include: review chemical documentation to check quantity and quality; visually inspect chemicals and conduct appropriate verification tests; label and secure unloading points; verify adequate receiving tank capacity; inspect chemical containers for any damage or evidence of leaks; specify delivery at scheduled times; specify equipment necessary for safe handling and transfer of chemicals; and supervise unloading with trained personnel (Casale and LeChevallier, 2000).

Many community water systems currently disinfect with chlorine. This includes many small systems and ground water systems with wells in residential areas. Small systems and ground water systems typically apply chlorine as hypochlorite that carries relatively little risk. Liquified chlorine gas is generally cheaper and is used by many large systems. The use of chlorine gas involves certain risks associated with accidental leakage. However, these risks are well understood and are managed through high standards of equipment specification, operation and management procedures, and training of personnel (Porter *et al.*, 2000).

Systems using activated alumina may lower the pH of the feedwater in order to increase process efficiency, and subsequently raise the pH to stabilize the water. EPA believes that most large systems have a sufficient level of

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technical expertise to modify pH without difficulty. However, EPA recognizes that very small systems may lack the operator capacity to successfully rely on pH modification as a component of a treatment process. In estimating costs for compliance with the arsenic MCL, EPA assumed that most very small systems using activated alumina would not adjust the raw water pH. These plants would run under less-than-optimal conditions but would still meet the arsenic MCL. Furthermore, for small systems and for other systems that may lack the technical expertise to adjust pH, other treatment options are available. Because of the number and flexibility of treatment options available to systems, along with the training and certification of operators, EPA believes that hazards to the public as a result of arsenic treatment will be minimal.

In regard to concerns with water scarcity, EPA notes that of the technologies listed in the proposed rule as BAT, only reverse osmosis (RO) and electrodialysis reversal (EDR) produce reject water in a quantity likely to make them undesirable in arid regions. While EDR and RO were listed as BAT in the proposed rule, they were not used in the final national cost estimate because other options are more cost effective and do not reject a large volume of water like these two technologies. Thus, we did not assume that any systems would chose EDR and assumed that RO would only be used by a small fraction of small systems and only in POU devices. POU devices treat only a small fraction of the household water, so that any water loss is minimized. Consequently, EPA does not believe that commenters' concerns about water scarcity alter EPA's projections of systems' ability to comply with the arsenic MCL. Moreover, in today's rule EPA has established the MCL for arsenic at 10 ppb. At this level, it would be possible for many systems to use RO or EDR in a split-stream mode, treating a portion of the water, and blending treated and untreated water to achieve compliance. This option would enable systems to significantly reduce the amount of reject water produced were they to select these technologies.

In cases where the available water resources are limited, systems may select technologies like activated alumina, anion exchange, and coagulation assisted microfiltration where water loss is limited to a few percent or less. As discussed in "Technologies and Costs for Removal of Arsenic from Drinking Water" (EPA, 2000t), the principal water losses associated with anion exchange and activated alumina result from the rinsing of the beds after regeneration and, in some limited cases, backwashing for removal of solids. In normal operating conditions, EPA expects this waste water to amount to a small percentage of the total water produced.

3. Small System Technology Application

A number of commenters raised concerns over the small system compliance technologies described in the proposal. Many of these comments questioned the ability of small systems to apply these technologies. EPA has carefully considered these comments and responses to the significant issues are provided below (see section I.G. for a discussion of the affordable small system compliance technologies under today's final rule).

The most significant issues raised by comments addressed the application of Point-of-Use/Point-of-Entry (POU/POE) treatment in small systems. Comments cited requirements for preoxidation for activated alumina (AA) units as reasons why the POU/POE devices would not be desirable. EPA notes that many small systems have disinfection treatment systems in place that could act as preoxidation for POE/POU units. Comments also raised concerns regarding the brine or concentrate stream generated by reverse osmosis (RO) POU/POE units. Commenters questioned whether the systems would waste precious water in arid areas. EPA believes systems in arid areas are more likely to select activated alumina (AA) or another centralized treatment technology. Commenters also raised concern over the disposal of the concentrate from these units into sewer or septic systems. In response, EPA believes it would be highly unlikely for the concentrate stream to pose problems because only about 1% of the household water is treated, thereby minimally influencing the quality of the sewage discharged from the household. Finally, commenters questioned the ability of small systems to maintain POE/POU devices which are installed in private homes. EPA believes it is feasible for public water systems to own, control, and maintain POE/POU devices for arsenic MCL compliance either directly or through a contract with a qualified party. While EPA recognizes that access to homes for maintenance may be an issue for some systems, we believe that such access would be permitted in others, especially if significant cost savings could be achieved.

4. Waste Generation and Disposal

Many comments stated that EPA did not adequately consider problems with waste generation and disposal when evaluating which technologies would be most appropriately used for achieving compliance. Commenters expressed particular concern with anion exchange, activated alumina, and reverse osmosis because wastes generated from these processes, depending upon their operating and site specific conditions, could be hazardous or difficult to dispose of. Comments indicated that many utilities would have difficulty in achieving compliance with the proposed rule while also maintaining compliance with other environmental laws and regulations (e.g., RCRA and CWA). Commenters questioned EPA's analysis for the proposed rule that indicated that no RCRA hazardous wastes would need to be disposed in the decision tree.

Arsenic treatment technologies produce three different types of wastes: Brines, sludges and spent media. Depending upon arsenic concentration and the characteristics of the waste, each of these wastes can pose disposal challenges and has the potential for being classified as hazardous.

Arsenic wastes are defined as hazardous if their toxicity characteristic (TC) exceeds 5 mg/l of arsenic. The Toxicity Characteristic Leaching Procedure (TCLP) is a method by which waste is evaluated to determine if it exceeds the TC. If waste is < 0.5% dry-weight solids, then the liquid is defined as the TCLP extract and concentrations in it are compared against the TC level to determine if it is hazardous. If the waste is ≥ 0.5 % dry-weight solids, then a TCLP that conservatively simulates leaching from a landfill is used to determine if the TC level would be exceeded. EPA considered TC and TCLP results from residuals produced by the treatment technologies under consideration and selected only those technologies that would not produce a hazardous waste.

Upon the review of public comments and further analysis, EPA agrees with comments that some of the treatment train technologies in the decision tree of the proposed rule could have created hazardous wastes under certain operational circumstances. Thus, EPA has narrowed its selection of available technologies in the decision tree for the final rule as indicated in Table V.F–4.1. EPA believes that the treatment options included in Table V.F–4.1 can address all treatment challenges without creating hazardous wastes, while being able to achieve compliance with the final rule. EPA has revised its national costs upward to reflect the changes in the decision tree. These costs are described in more detail in this preamble and in support documents for this rule (EPA, 2000o and EPA, 2000t).

More specific rationale for the changes in the treatment train technologies considered in the decision tree are discussed in the following paragraphs and in the "Technology and Cost Document" (EPA, 2000t).

a. Anion exchange. When anion exchange resins are cleaned, they create a regeneration brine. Influent sulfate and arsenic concentrations, regeneration level, and rinse volume influence the resultant brine concentration levels of arsenic. EPA conducted modeling to determine the feasible operating conditions and source water arsenic and sulfate concentrations under which anion exchange could effectively remove arsenic without creating an arsenic brine that exceeded an arsenic concentration of 5 mg/L. Based on this analysis (EPA, 2000t), EPA determined brine arsenic concentrations could exceed 5 mg/L when: (a) Arsenic influent levels exceed 15 µg/L and sulfate concentrations exceed 25 mg/L, and (b) when arsenic influent levels exceed 25 µg/L and sulfate concentrations ranged between 25 and 90 mg/L. Based on this analysis, EPA eliminated landfills and evaporation ponds from the final decision tree for the conditions indicated in Table V.F–4.1.

As part of its proposed and final decision tree evaluation, EPA assumed that brine streams with < 0.5% solids could potentially be disposed of through domestic sewage or mixtures of domestic sewage to POTWs regardless of the TC, since this is excluded from regulation under RCRA. Piping the brine directly to the POTW without passing through the sewer system does not meet the exclusion, nor does trucking the brine to the POTW. Even though brine disposal via sewage to POTWs is not restricted by RCRA, EPA recognizes that brine disposal can be restricted by the POTW's pretreatment programs. POTWs may establish Technically Based Local Limits (TBLLs) for arsenic to control: arsenic concentrations in POTW biosolids, arsenic concentration in the POTW discharge, or total dissolved solids (TDS) in the POTW discharge.

Many comments indicated that significant increases in total dissolved solids would make brine disposal to a POTW unacceptable, especially in the Southwest where water resources are scarce. Even under the lowest regeneration level of 5.1 lb/ft^3 assumed in EPA's analysis, TDS increases would likely be prohibited by POTWs when influent sulfate concentrations exceed 90 mg/L, and limited to POTWs where brine volume is very small compared to total volume for sulfate concentrations between 25 and 90 mg/L. Therefore, as described in section I.F., EPA modified the compliance decision tree to assume systems with sulfate concentrations greater than 50 mg/L would not select anion exchange as a treatment technology. In its final decision tree, EPA assumed that drinking water plants with sulfate concentrations of less than 20 mg/l and with a regeneration frequency of 1500 bed volumes, or with sulfate concentrations between 20 and 50 mg/l and a regeneration frequency of 700 bed volumes, might use anion exchange with waste disposal via sewage to POTWs and be able to comply with local TBLLs. In the final decision tree less than 10% of the systems are assumed to use anion exchange versus over 50% of the systems being assumed to use this technology under the proposal.

b. Activated alumina. The proposed rule considered activated alumina with regeneration and listed discharge to a sanitary sewer as the disposal mechanism for the brines. Many comments on the proposed rule noted that TBLLs for arsenic or total dissolved solids might restrict discharge of brine streams to the sanitary sewer. Under today's final rule (see section I.F.), regeneration of activated alumina media is not recommended for a number of reasons, including the difficulty of disposing of the brines. In the final decision tree, EPA assumes disposal of spent AA media (either from central treatment or POU) to landfills as the waste disposal method for AA. EPA believes that spent AA media will be nonhazardous because the TCLP test is conducted using weak acid at a pH of 5 which is near the optimal pH for adsorption of arsenic onto AA (Kempic, 2000). Wang et al. (2000) evaluated AA spent media from two small systems having treating influent arsenic concentrations of > 50 µg/l and found TCLP with arsenic concentrations of 0.07 mg/L or less, well below the TCLP limit of 5 mg/L. Some public comments indicated concern that the TCLP test conditions at the pH of 5 may not reflect conditions at landfills which may have higher pHs. In response, EPA notes that the TCLP is the defining test specified in 40 CFR 261.24 for determining whether a waste is TC hazardous, and it applies regardless of the actual management of the waste unless some exemption applies.

In the final decision tree, EPA has revised the treatment train assumptions for AA to be operated in series (i.e., two treatment units in sequence rather than as singular units as was considered under the proposal) under various pH conditions (see Table V.F–4.2). Operation in series will allow longer-run times and more cost-efficient disposal of spent media. The range of pH conditions is assumed in consideration of public comments that some utilities will prefer to operate without pH adjustment, thereby minimizing oversight and the "footprint" of land needed for the treatment facilities (since no additional chemical feed or storage facilities are needed). While pH adjustment to low levels will optimize AA removal of arsenic, this may not be an option for certain facilities depending upon land availability. Therefore, EPA considers a wide range of pH conditions of AA in the series mode.

c. Reverse osmosis. Except for POU treatment, EPA did not use reverse osmosis in the decision tree of either the proposed or final rule (EPA, 2000h); EPA, 2000o). The concentrate stream from POU devices can be disposed of through discharge into domestic wastewater and thereby be exempt from RCRA regulation. It would also be highly unlikely for the concentrate stream to pose problems with TBLLs because only about 1% of the household water is treated, thereby minimally influencing the quality of the sewage reaching the POTW. Therefore, the decision tree to the final rule includes POU reverse osmosis.

TABLE V.F–4.1.—TREATMENT TRAINS IN FINAL VERSUS PROPOSED ARSENIC RULE DECISION TREE

Treatment train: treatment & residuals management combination	National cost estimate assumes will be selected by systems in		Reason for change
	Proposed rule	Final rule	
Regionalization	NO	NO	N/A
Alternate Source	NO	NO	N/A
Modify Lime Softening	YES	YES	N/A

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TABLE V.F–4.1.—TREATMENT TRAINS IN FINAL VERSUS PROPOSED ARSENIC RULE DECISION TREE—Continued

Treatment train: treatment & residuals management combination	National cost estimate assumes will be selected by systems in		Reason For Change
	Proposed rule	Final rule	
Modify Coagulation/Filtration	YES	YES	N/A
Anion Exchange (25 mg/L sulfate) & POTW discharge.	YES	YES	Treatment name revised—Anion Exchange (<20 mg/L sulfate).
Anion Exchange (150 mg/L sulfate) & POTW discharge.	NO	NO	N/A
Anion Exchange (25 mg/L sulfate) & Evaporation Pond, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Anion Exchange (150 mg/L sulfate) & Evaporation Pond, Landfill.	NO	NO	N/A
Activated Alumina (16500 Bed Volumes) & Landfill	YES	REVISED	Revised approach uses multiple columns in series operation.
Activated Alumina (3000 Bed Volumes) & Landfill	NO	NO	N/A
Reverse Osmosis & direct discharge	NO	NO	N/A
Reverse Osmosis & POTW discharge	NO	NO	N/A
Reverse Osmosis & Chemical Precipitation, Landfill.	NO	NO	N/A
Coagulation Microfiltration & Mech. Dewatering, Landfill.	YES	YES	N/A
Coagulation Microfiltration & Non-Mech. Dewatering, Landfill.	YES	YES	N/A
Oxidation Filtration & POTW discharge	YES	YES	N/A
Anion Exchange (25 mg/L sulfate) & Chem Precipitation, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Anion Exchange (150 mg/L sulfate) & Chem Precipitation, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Activated Alumina (16500 BV) & POTW	NO	NO	N/A
Activated Alumina (3000 BV) & POTW	NO	NO	N/A
Anion Exchange (90 mg/L sulfate) & POTW	YES	REVISED	Lower sulfate concentration selected to minimize total dissolved solids increase. Commenter issue—EPA evaluation.
Anion Exchange (90 mg/L sulfate) & Evaporation Pond, Landfill.	YES	NO	Brine stream may be hazardous waste. Commenter issue—EPA evaluation.
Point-of-Entry Activated Alumina	YES	NO	Run length only exceeds six months when finished water pH <7.5
Point-of-Use Reverse Osmosis	YES	YES	N/A
Point-of-Use Activated Alumina	YES	YES	N/A

TABLE V.F–4.2.—NEW OR REVISED TREATMENT TRAINS

Treatment Train	Revision
Activated Alumina (pH7-pH8) & Landfill.	Series Operation.
Activated Alumina (pH8–8.3) & Landfill.	Series Operation.
Activated Alumina (pH adjusted to pH6—23,100 Bed Volumes) & Landfill.	Series Operation.
Activated Alumina (pH adjusted to pH6—15,400 Bed Volumes) & Landfill.	Series Operation.
Anion Exchange (20–50 mg/L sulfate) & POTW.	Use 700 Bed Volumes as Run Length.

5. Emerging Technologies

A number of comments state that several of the emerging technologies discussed in the proposal (*e.g.*, granular ferric hydroxide, see section I.F) are likely to be the most cost effective treatment option for systems, particularly small systems. These comments state that systems may not select these emerging technologies because they have not been listed as BAT. In response, EPA must clarify that systems are not required to use BAT to achieve compliance with the MCL. A system may use any technology that is accepted by the State primacy agency provided the technology achieves compliance with the MCL. However, if a system is unable to meet the MCL with its chosen technology, the system will not be eligible for a variance unless the installed technology is listed as BAT. Other comments indicated that there will not be sufficient time for further testing of these emerging technologies prior to the effective date of the MCL. EPA notes that because of the capital improvements required for compliance with the MCL, the effective date of today's rule is 5 years from the date of promulgation for all system sizes. This should provide systems with adequate time for testing of the emerging technologies. Moreover, States may, as described in section I.H, provide small systems with up to an additional nine years to comply through exemptions.

G. Costs

1. Disparity of Costs

Many public comments stated that EPA substantially underestimated costs for implementing the proposed rule. Comments pertained to national cost or regional cost estimates and system level cost estimates. Commenters stated that EPA's national cost estimates were low because: (a) The decision tree led to an over selection of technologies with low associated costs, and (b) the system

level costs associated with the selected technologies were low. Elaboration of public comment concerns and EPA's response in each of these categories follows. Also, since many public comments referred to the report "Cost Implications of a Lower Arsenic MCL" (Frey *et al.*, 2000) as a basis for their comments, EPA analyzed the report in detail. As noted below, the Agency disagrees with the approach Frey *et al.* (2000) used to produce the cost estimates in this report.

a. What is EPA's response to major comments on the decision tree for the proposed rule? Commenters indicated that EPA's decision tree did not adequately recognize constraints in technology selection including feasibility of waste disposal, concerns with compliance with other EPA regulations (*e.g.*, RCRA and CWA), land availability, complexity of operation and availability of skill level (particularly for small systems), and excess use of water in water scarce areas. Particular concern was raised by the extent to which EPA predicted that anion exchange would be used given concerns with sulfate and total dissolved solids, chromatographic peaking (possible rapid breakthrough of arsenic at above influent concentration levels due to competition from other ions), and handling of regeneration process streams and disposal of wastes (some of which may be hazardous). Commenters also suggested that EPA over predicted the use of greensand filtration since it only removes a limited amount of arsenic at low iron concentrations. Comments suggested that EPA should consider much greater use of activated alumina in the spent media replacement mode with disposal to landfills because of facility of operation and low costs. Comments also suggested use of reverse osmosis and nano-filtration in areas unlikely to have a water scarcity problem. Although central treatment with reverse osmosis was listed as one of the possible compliance technologies under the proposed rule, it was not used in the EPA's decision tree.

In preparing the cost estimate for the proposed rule, EPA predicted compliance outcomes by considering: (1) Technologies already in place, (2) feasibility of application of the technology, and (3) least cost of technology. Given all available information at the time of proposal, EPA developed its decision tree. EPA received many informative comments pertaining to the feasibility of various treatment technologies considered. EPA agrees with public comments that some of the waste disposal options considered with anion exchange under the proposed rule could create hazardous wastes (see V.F.4. of this preamble). To address this concern EPA has eliminated the following treatment trains from its final decision tree: Anion exchange with chemical precipitation and disposal of waste to landfills, and anion exchange with discharge to evaporation ponds and disposal of waste to landfills.

EPA agrees with public comments that activated alumina is likely to be used by many more systems than EPA predicted in the proposal. In response to comments, EPA revised the treatment train assumptions for AA to be operated in series under various pH conditions. Operation in series will allow longer run times and more cost-efficient disposal of spent media. The range of pH conditions is assumed in consideration of public comments that some utilities will prefer to operate without pH adjustment, thereby minimizing oversight and the "footprint" needed for the treatment facilities. While pH adjustment to pH 6.0 will optimize AA removal of arsenic, this may not be an option for certain facilities depending upon available land and expertise. Thus, EPA recognizes higher operational costs for AA for a substantial number of systems operating at less than optimal pH.

Research (Subramanian *et al.*, 1997) indicates that oxidation filtration (greensand filtration) achieved about 80% removal of arsenic when the iron to arsenic ratio was 20:1 but less than 50% removal when the iron to arsenic ratio was 7:1. In developing national cost estimates, EPA assumed that systems would opt for this type of technology only if more than 300 µg/L of iron was present in the source water and no more than 50% arsenic removal was needed to achieve the MCL. EPA believes that its applicability assumptions for greensand filtration are conservative and therefore continues to support its usage in the decision tree for the final rule. Greensand filtration is a relatively inexpensive technology that may be appropriate for those systems that do not require much arsenic removal and have high iron in their source water. However, in the decision tree for the final rule, EPA lowered the expected use of greensand filtration to systems serving less than 3,300 (versus in systems serving less than 10,000 under the proposed rule) and reduced its usage by about ⅓ (EPA, 2000h; EPA, 2000h). This drop is mainly attributed to the change in the MCL and fewer systems having arsenic at levels between 5 µg/L and 10 µg/L than between 10 and 20 µg/L. The ranges 5–10 µg/L and 10–20 µg/L reflect the arsenic concentration ranges that systems would have to fall within to be able to consider greensand, if only 50% removal efficiency is assumed.

EPA continues to believe that reverse osmosis, while a very effective technology for removing arsenic, is not likely to be used as a centralized treatment option (even in areas of ample water supply) because of higher costs relative to other treatment options. EPA did not consider nanofiltration a likely compliance technology because of high costs relative to other technologies and decreased removal efficiency when operated to constrain production of waste streams.

b. What is EPA's response to comments on system level costs? Under the proposed rule EPA only included activated alumina (AA) costs for small systems. A number of comments indicated that EPA should revise its decision tree to include AA and associated costs for all system sizes because AA is more economical than anion exchange. After considering the information provided by these comments, EPA expanded estimates of the use of AA in the decision tree for the final rule. EPA also revised its decision tree and developed costs for four different types of AA treatment for all system sizes—two for unadjusted pH and two where the pH has been adjusted to the optimal pH of 6. (The effects of these changes in the decision tree analysis are described in section V.G.1). The main change between the design used for the proposed rule versus the final rule is that smaller columns containing the activated alumina are operated in series rather than as a single column. This will provide greater utilization of the media before disposal and is more consistent with the designs used by commenters in evaluating disposable activated alumina. EPA's new AA costs specify different unit cost equations and flow boundary conditions for small versus large systems. Also, EPA has included new operating and maintenance (O&M) costs for waste disposal of spent AA media. The effect of all these changes is, in general, to decrease capital costs but to increase O&M costs and to increase overall AA system level costs within a particular size category. Despite these increases in costs for AA, AA is by far the most used technology among ground water systems in the final decision tree. The "Arsenic Technologies and Costs" (T&C) document (EPA, 2000t) for the final rule describes in detail the basis for the unit costs used for each of the new types of AA treatment.

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Several comments indicated that EPA's cost estimates were calculated for flow rates outside of their boundary conditions and thus the accuracy of many of the unit costs are in error. EPA analyzed the data provided by these comments and revised the cost equations used to estimate unit costs for the final rule. We modified cost equations and flow boundary conditions for AA, modified coagulation filtration, modified lime softening, anion exchange, coagulation microfiltration, and POU treatment. Most of the unit costs increased relative to those used for the proposed rule. The T&C document (EPA, 2000t) describes the basis for the unit costs used for the final rule.

A number of comments stated that EPA's cost estimates should include pre-oxidation costs with AA in ground waters since many systems may not already be disinfecting. EPA must clarify that the cost estimates included prechlorination costs for any system that did not have existing disinfection treatment. For ground water systems, 13% to 54% (depending upon system size) of systems predicted to use AA were assumed to add pre-oxidation.

Several comments indicated that EPA's cost estimates for the proposal did not include corrosion control costs. However, the corrosion control costs were included as a component of the unit costs for the following technologies: modified lime softening, modified coagulation filtration, coagulation assisted microfiltration, and activated alumina options operating at the optimal pH. EPA believes that through appropriate use of corrosion control, systems will be able to comply with the lead and copper rule and meet the arsenic MCL.

c. What is EPA's response to comments that state the report "Cost Implications of a Lower Arsenic MCL" (Frey et al., 2000), be used as a basis for reflecting more realistic national costs than EPA's estimates? A number of comments noted that the report "Cost Implications of a Lower Arsenic MCL" (Frey *et al.*, 2000), "the Cost Implications Report," or "the report," provides best-case national estimated annualized costs of $1,460 million at the 5 μg/L arsenic MCL option and $605 million at the 10 μg/L MCL option. Many comments stated that EPA's national cost estimates were unrealistically low based upon the Cost Implications Report.

EPA appreciates the substantial level of information available from the Cost Implication Report in regard to evaluation of technological feasibility for arsenic removal. This report was one of several sources that influenced EPA to predict much less use of anion exchange and much greater use of activated alumina in the decision tree for the final rule. However, EPA believes that some parts of the report's analysis contributed to overestimating national cost estimates. These issues include differences in flow rate assumptions, unit costs, and national estimates for arsenic occurrence, summarized below. A more detailed analysis is available in EPA's Response to Comment Document for the final rule.

Flow rate assumptions. Flow rate assumptions are used with engineering cost models to estimate system level treatment costs for various technologies considered appropriate for achieving compliance. If flow rates are overestimated, system level treatment and national costs will be overestimated. EPA uses design flow rates to estimate capital costs and average flow rates to estimate operational and maintenance costs.

The Cost Implications Report (Frey *et al.*, 2000) uses significantly higher flow rates than EPA (EPA, 2000h; EPA, 2000o) for conducting national cost impact analysis for alternative arsenic MCLs. For most population categories of systems ranging between 3301 and 1 million people, AWWARF used flow rates that were 2–4 times higher than EPA's assumptions. Based on EPA's analysis of the Cost Implication Report it appears that the report used more system size categories than EPA and transferred flow rates for larger-system size categories into smaller-system size categories. EPA believes that differences in the flow rate assumptions would produce an estimate of at least $400 million per year higher than an estimate using EPA's flow rates for the proposed arsenic MCL option of 5 μg/L.

Since the release of the Cost Implications Report, the authors revised their analysis to include different flow rates (Frey *et al.*, October 2000), "the Updated Cost Implications Report." The updated report based its new flow rates on the equations provided in the Proposed Arsenic in Drinking Water Rule Regulatory Impact Analysis (EPA, 2000h). The flow rates for ground water systems were based on the population/flow equations for publicly owned ground water systems and the authors selected the midpoint in each population category (e.g., using a flow of systems serving 550,000 persons to estimate costs for systems serving between 100,000 and 1 million people). In the Updated Cost Implications Report the authors state that:

[T]he cost response to the difference in flow rates is mixed due to the large flow increases in the two largest population categories (100,0000 to 1 million and > 1 million) versus the decreases in the other flow categories (5,000 to 100,000).

EPA believes that the revised analysis with the new flow rates in the Updated Cost Implications Report still overestimates costs. First, the revised design and average flows are only larger for ground water systems with populations greater than 1 million people. Second, estimating flow rates for systems within a category using the population midpoint assumptions in the revised analysis continues to cause cost overestimates because many more systems in each population size category occur in the lower part of the range than the upper part of the range. For example, EPA's data indicate that, in the flow category of ground water systems serving 100,000 to 1 million people, one-half of the systems have populations under 173,000 people (EPA, December 1997 Freeze of Safe Drinking Water Information System) and that the mean population among systems is 248,000 people (EPA, 2000a). In its cost estimates, EPA considers the distribution of flow rates within each size category for estimating system level cost contributions to the national impact (EPA, 2000h; EPA, 2000o). Third, Table 4.6 of the Cost Implication Report (Frey *et al.*, 2000) provides a distribution of ground water systems nationally by system size and arsenic concentration, and indicates there are no ground water systems serving more than 1,000,000 projected to have arsenic concentrations that exceed 5 μg/L. Since no ground water systems serving more than 1,000,000 people need to treat for MCL options of 5 μg/L or higher, the national costs given in the revised report due to the revised flow rate assumptions in all categories should be lower for MCL options at or above 5 μg/L.

On a related issue, EPA believes that the operation and maintenance cost equations for anion exchange, activated alumina, coagulation/microfiltration, and nanofiltration in the Cost Implication Report (Frey *et al.*, 2000) were based on design flow rather than average flow. Using the operational and maintenance cost equations based on design flow rather than average flow significantly increases cost estimates, particularly for smaller systems (EPA's analysis indicates that for systems with a design flow of 1 M.D., the total annualized costs would increase by about 25% and for systems with a design flow of 10 M.D., the total annualized costs would increase by about 5%).

Unit Cost assumptions: The Cost Implication Report (Frey *et al.*, 2000) develops unit cost equations for a technology type based on a wide range of operating conditions, some of which may not be very cost effective (*e.g.*, anion exchange with sulfate concentrations ranging from 25 to 150 mg/l). Because of their recognized lack of cost effectiveness for particular situations, the technologies have limited application in the national compliance forecast, even in situations with sulfate concentrations less than 25 mg/L. This costing approach tends to overestimate costs for systems with favorable site specific conditions. On the other hand, EPA developed cost equations for technology types within an operating range for which the technology can most cost effectively operate (*e.g.*, anion exchange with sulfate concentrations of less than 25 mg/L) and used these equations for the limited number of systems that would meet the constraints. Utilities would not likely choose technologies unless they were favorable to use and thus only those conditions at which the technology is used should be costed, in our view.

EPA believes that the Cost Implication Report case study costs for activated alumina were significantly overestimated due to the vessel costs. The vendor quote used for vessel costs is for a complete activated alumina system, including the costs for vessels, media, pipes and valves, chemical feed and storage, start-up, shipping and contingencies. The vendor quote presents budget prices for three design flows and different size vessels are used for each design flow. The vessel sizes are listed with the budget price, along with many additional costs, which may have been a source of confusion. Since activated alumina is the most used technology in the compliance forecast in the Cost Implications Report, double counting full system costs for activated alumina will significantly affect national cost estimates, particularly for smaller systems.

Arsenic occurrence assumptions. The occurrence distributions based on the Frey and Edwards (1997) National Arsenic Occurrence Survey (NAOS) change throughout Chapter 4 of the Cost Implication Report. The national compliance costs are based on the occurrence distribution with the highest number of systems above the MCL options, but no basis is given for this selection. EPA believes that the arsenic occurrence distribution used in the report for the compliance forecast analysis significantly overestimates the distribution of arsenic occurrence above 20 μg/L and this significantly biases costs upward.

2. Affordability

Many commenters expressed concern that their system, or many households served by their system, would be unable to afford to comply with the proposed arsenic standard and that the DWSRF would be incapable of providing significant assistance. Concerns relating to costs and burden contributed to the Agency's decision to promulgate a standard of 10 μg/L rather than the proposed standard of 5 μg/L. The Agency's decision to promulgate a standard of 10 μg/L significantly reduces the impacts on small systems. At the proposed standard of 5 μg/L, about 6,500 community water systems would have needed to install treatment. At the promulgated standard of 10 μg/L, about 2,800 small community water systems (and 1100 NTNCWS) will need to install treatment. Total capital costs for the promulgated standard are 57% lower (for both community water systems and NTNCWS) than they would have been for the proposed standard. Although the number of systems needing to treat at the promulgated standard is well under one half of the number that would have needed to treat at the proposed standard, the household level impact for those systems needing to treat is about the same.

The Agency believes that affordability of drinking water at the household level is a function of two key variables: price of the water and the ability of the household to pay. Each of these two key variables is, in turn, a function of a number of other variables. A comprehensive and meaningful analysis of affordability for an individual system must include a complete assessment of all of the variables that influence both price and ability to pay. These variables are highly site specific. That is why the framework for addressing affordability concerns in SDWA consists of two distinct parts: (1) A national level affordability analysis focused on assessing what would be affordable (from a national perspective) for typical systems in a size class, and (2) State-level analysis, using State-developed criteria, to assess affordability for any specific system.

The price of drinking water (the actual charge imposed on the household for its water service) reflects the complex interplay of many variables. These variables include the water system's full cost of doing business, subsidies or other forms of financial assistance that offset some of the system's costs, and the allocation of costs by the water system to its users and the rate design employed by the water system. The system's cost of providing service is influenced by many different factors, *e.g.*, the quality of the source water available to the system, the type of treatment employed and the skill of its operation, and the basic organizational or institutional structure of the water system. Systems that effectively work together, perhaps by combining management, will realize lower overall costs compared to the same systems working independently. Section I.L discusses Federal financial assistance which is available to help systems comply with arsenic and other drinking water standards. Section III.E.4 further discusses issues considered by EPA in assessing the affordability of the arsenic rule.

One commenter submitted a study which concludes that establishing a new arsenic MCL at a level of 5 μg/L (or lower) will raise serious concerns about the affordability of water service for a majority of affected ground water systems. The Agency reviewed the study and notes a number of significant deficiencies in its assumptions and general methodology. The Agency disagrees with the commenter's selection of $50 per household per year as affordable on the basis of expenditures on lottery tickets and with the commenter's selection of $100 per household/year as posing "serious affordability concerns" on the basis of it representing some percentage of expenditures on health care or telephone service. The Agency notes that the Consumer Expenditure Survey, compiled by the Bureau of Labor Statistics, offers a broad overview of expenditure patterns across households of various incomes. The Consumer Expenditure Survey's data do not necessarily support the contention that an increase in water bills would force a low-income household to trade off health care or some other "essential" expenditure to pay the water bill. Clearly, however, individual household circumstances vary greatly and certain individual households may face difficult choices. Another important consideration is that assessing expenditure trade offs by low-income households must fully account for all the assistance such households can receive, including subsidized housing, medical care through Medicaid, food stamps, and so on. Simply looking at a low-income household on the basis of its cash income can overlook important assistance available. The commenter also assumes that if a regulation increases the cost of water by 0.5% of median household income in a community, it might raise an affordability concern. The commentor

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justifies this value by asserting that such an increase would be more than a 50% increase in the water bill for a typical household. The Agency finds this argument unconvincing. For a household with the median income, the water bill would represent about 0.9% of income. It is widely acknowledged that water has been historically underpriced. Thus, saying that no more than a 50% increase would be affordable is to accept the historic underpricing as appropriate. The commenter also assumes the cost estimates that EPA believes are significantly overestimated are correct. Thus, the commenter's conclusion that establishing a low arsenic standard will raise serious concerns about the affordability of water service for a majority of affected ground water systems is unsupported. The subsequent conclusion that existing variance and grant programs would not be adequate to alleviate affordability concerns is likewise unsupported. (See section I.H. of today's preamble for a discussion of variances and exemptions and section I.L. for a discussion of financial assistance available for complying with this rule.)

A number of commenters indicated that they did not agree with EPA's approach for assessing national level affordability. Affordability is a complex concept. Numerous different approaches have been developed for assessing affordability of drinking water and/or wastewater service. Many of these approaches are summarized in the Agency's publication "Information for States on Developing Affordability Criteria for Drinking Water" (EPA, 1998a). It is essential that the specific purpose for which any affordability criterion is developed be clearly understood. EPA's national affordability criteria are developed and applied for a very narrow and specific purpose.

Section 1412(b)(4)(E)(ii) of SDWA , as amended, requires EPA to list technology (considering source water quality) that achieves compliance with the MCL and is affordable for systems in three specific population size categories: 25–500, 501–3300, and 3301–10,000 when promulgating a national primary drinking water regulation which establishes an MCL. If, for any given size category/source water quality combination, an affordable compliance technology cannot be identified, section 1412(b)(15)(A) requires the Agency to list a variance technology. Variance technologies may not achieve full compliance with the MCL but they must achieve the maximum contaminant reduction that is affordable considering the size of the system and the quality of the source water. In order for the technology to be listed, EPA must determine that this level of contaminant reduction is protective of public health.

Thus, EPA developed national affordability criteria for the narrow and specific purpose of determining whether or not an affordable compliance technology exists, from a national perspective, for the specified size categories of systems, considering the quality of source waters available to them. The key point at issue here is what EPA should consider "affordable" from a national perspective. EPA does not define national level affordability in terms of what would be affordable to the least affluent water systems. Likewise, EPA does not define national level affordability in terms of what would be affordable to the most affluent water systems. Rather, a determination of national level affordability is concerned with identifying, for each of the given size categories, some central tendency or typical circumstance relating to their financial wherewithal.

The metric EPA selected for this purpose is the median household income for communities of the specified sizes. Some commenters expressed concern that EPA was using the national median household income (across all sizes of systems) in making judgments on national-level affordability. The Agency wishes to clarify that this was not the case. We used median household income for communities of the specified size categories, as documented in EPA's August 6, 1998 **Federal Register** notice (EPA, 1998h). The household is thus the focus of the national-level affordability analysis. EPA considers treatment technology costs affordable to the typical household if they represent a percentage of MHI that appears reasonable when compared to other household expenditures. This approach is based on the assumption that the affordability to the median household served by the CWS can serve as an adequate proxy for the affordability of technologies to the system itself. The national-level affordability criteria have two major components: current annual water bills (baseline) and the affordability threshold (total % of MHI directed to drinking water). Current annual water bills were derived directly from the 1995 Community Water System Survey. Based on 1995 conditions, 0.75–0.78% of MHI is being directed to water bills for systems serving fewer than 10,000 persons.

The fundamental, core question in establishing national-level affordability criteria is: what is the threshold beyond which drinking water would no longer be affordable for the typical household in each system size category? Based upon careful analysis, EPA believes this threshold to be 2.5% of MHI. In establishing this threshold, the Agency considered baseline household expenditures (as documented in the 1995 Consumer Expenditure Survey, Bureau of Labor Statistics) for piped water relative to expenditure benchmarks for other household goods, including those perceived as substitutes for higher quality piped water such as bottled water and POU/POE devices. Based on these considerations, EPA concluded that current household water expenditures are low enough, relative to other expenditures, to support the cost of additional risk reductions. The detailed rationale for the selection of 2.5% MHI as the affordability threshold is provided in the guidance document entitled "Variance Technology Findings for Contaminants Regulated Before 1996" (EPA, 1998l). The difference between the affordability threshold and current water bills is the available expenditure margin. This represents the dollar amount by which the water bill of the typical (median) household could increase before exceeding the affordability threshold of 2.5% of MHI.

The Agency recognizes that baseline costs change over time as water systems comply with new regulations and otherwise update and improve their systems. MHI also changes from year to year, generally increasing in constant dollar terms. For example, since 1995 MHI has increased (in 1999$) by 9.6%. Thus, to determine the available expenditure margin (the difference between the affordability threshold and the baseline) for each successive rule, adjustments would need to be made in both the baseline and the MHI. The Agency believes that, for purposes of assessing national-level affordability of the arsenic rule, the unadjusted baseline and unadjusted MHI are appropriate. Making adjustments to these two factors would not materially alter the outcome of the analysis, since both the baseline and the MHI would increase, and not by dramatically differing percentages. Thus the difference between the two would not significantly change.

By definition, the MHI is the income value exactly in the middle of the income distribution. The median is a measure of central tendency; its purpose is to help characterize the nature of a distribution of values. The Agency recognizes that there will be half the households in each size category with incomes above the median, and half the households with incomes below the median. The objective of a national-level affordability analysis is not to determine what is affordable to the poorest household in the U.S. Nor is it to determine what the richest household in the U.S. could afford. Rather, it is to look across all the households in a given size category of systems and determine what is affordable to the typical, or "middle of the road" household.

The distinction between national-level affordability criteria and affordability assessments for individual systems cannot be over-emphasized. The national-level affordability criteria serve only to guide EPA on the listing of an affordable compliance technology versus a variance technology for a given system size/source water combination for a given contaminant. In the case of arsenic, EPA determined that nationally affordable technologies exist for all system size categories and has therefore not identified a variance technology for any system size/source water combination. This means that EPA believes that the typical household in each system size category can afford the costs associated with the listed compliance technologies. EPA recognizes that individual water systems may serve a preponderance of households with incomes well below the median, or may face unusually high treatment costs due to some unusual local circumstance. As discussed more fully in sections I.H, I.L, and III.F.4, there are a number of tools available to address affordability concerns for these individual water systems. The major tools are financial assistance (low-interest loans and grants); extended compliance time-frames under a State-issued exemption; life-line and other types of rate structures that systems may use; and, restructuring of system management and operations through partnerships among systems.

3. Combined Cost of New Regulations

A number of commenters expressed concern about the cumulative cost to water systems of new drinking water regulations. The Agency recognizes this concern and acknowledges that there is a small percentage of systems faced with co-occurrence and for whom there will be multiple treatment requirements. However, for such systems, the Agency notes that installation of treatment for one contaminant (such as arsenic, in this case) may often reduce the amount of treatment needed to remove many types of subsequently regulated contaminants, since the initial treatment will likely remove at least some of the subsequently regulated contaminant; particularly, certain types of inorganic contaminants.

The most common cumulative impact will be that associated with initial monitoring. Most systems will need to conduct at least some limited initial monitoring for most regulated contaminants. However, for the vast majority of systems that will not detect the contaminant at levels of concern, subsequent monitoring will be limited and infrequent, with monitoring variances available for up to once every nine years.

4. Projected Effects of the New Standard on Other Regulatory Programs

Several commenters felt that EPA has underestimated the costs of the proposed rule by failing to fully consider the possible costs of a new, lower drinking water standard on other regulatory programs, particularly hazardous waste. EPA disagrees and does not believe that certain ancillary costs identified by commenters should be considered in the cost of compliance analysis nor should they be a factor considered in establishing the MCL. For instance, the prospective costs of future CERCLA site clean-up actions are not among the factors that SDWA requires EPA to consider in establishing an MCL. Moreover, there are a host of site-specific factors taken in account in any CERCLA site clean-up situation beyond the clean-up standard itself (which may be an MCL under the CERCLA requirement to consider "applicable or relevant and appropriate requirements" (ARARs)). In the case of RCRA, EPA notes that the arsenic in drinking water final rulemaking does not necessarily trigger a revision of the Toxicity Characteristic standard under RCRA. Thus, there are not necessarily any new costs to entities affected by RCRA requirements as a result of this rulemaking. In any case, SDWA section 1412(b)(3)(C)(i)(III) specifically excludes consideration of such costs from other regulatory programs in the development of drinking water standards.

H. Benefits of Arsenic Reduction

Significant comments on the benefits analysis for the proposed arsenic rule addressed the topics of the timing of health benefits accrual (latency); the use of the Value of Statistical Life (VSL) as a measure of health benefits; the use of alternative methodologies for benefits estimation; the Agency's consideration of non-quantifiable benefits in its regulatory decision-making process; the Agency's analysis of incremental costs and benefits of the proposed arsenic rule; and, the Agency's assumption that health risk reduction benefits will begin to accrue at the same time costs begin to accrue.

1. Timing of Benefits Accrual (Latency)

Some commenters argued that EPA should have discounted its health benefits for the arsenic rule over a cancer latency period. As noted in the proposed rule, EPA committed to taking this issue before the Science Advisory Board (SAB) for its advice and recommendations.

EPA brought this issue before the SAB in a meeting held on February 25, 2000 in Washington, DC (65 FR 5638, February 4, 2000; EPA, 2000a). The SAB submitted a final report on their findings and recommendations to us on July 27, 2000 (EPA, 2000j). This final report was made available on the EPA website at *www.epa.gov/sab/eeacf013.pdf*.

The SAB Panel noted that benefit-cost analysis, as described in the Agency's Guidelines [for economic analysis], is not the only analytical tool nor is efficiency the only appropriate criterion for social decision making, but notes that it is important to carry out such analyses in an unbiased manner with as much precision as possible. In its report, the SAB recommended that the Agency continue to use a wage-risk based VSL as its primary estimate; any appropriate adjustments that are made for timing and income growth should be part of the Agency's main analysis while any other proposed adjustments should be accounted for in sensitivity analyses to show how results would change if the VSL were adjusted for some of the major differences in the characteristics of the risk and of the affected populations.

Specifically, the SAB report recommended that: (1) Health benefits brought about by current policy initiatives (i.e., after a latency period) should be discounted to present value using the same rate that is used to discount other future benefits and costs in the primary analysis; (2) adjustments to the VSL for a "cancer premium" should be made as part of a sensitivity analysis; (3) adjustments to the VSL for voluntariness and controllability should be made as part of a sensitivity analysis; (4) altruism should be addressed in a sensitivity analysis and separately from estimation of the value of a statistical cancer fatality and the circumstances under which altruism can be included in a benefit-cost analysis are restrictive; (5) estimates of VSLs accruing in future years should be adjusted in the primary analysis to reflect anticipated income growth, using a range of income elasticities; (6) adjustments to the VSL for risk aversion should be made in a sensitivity analysis; (7) it is theoretically appropriate to calculate WTP for individuals whose ages correspond to

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those of the affected population, but that more research should be conducted in this area; and (8) no adjustment should be made to the VSL to reflect health status of persons whose cancer risks are reduced.

Consistent with the recommendations of the SAB, EPA developed a sensitivity analysis of the latency structure and associated benefits for arsenic, a summary of which is shown in Section III.E of the final preamble. This analysis consists of health-risk reduction benefits which reflect adjustments for discounting, incorporation of a range of latency period assumptions, adjustments for growth in income, and incorporation of other factors such as a voluntariness and controllability. Although the SAB recommended accounting for latency in a primary benefits analysis, the Agency believes that, in the absence of any sound scientific evidence of latency periods for arsenic related cancers, discounted benefits estimates for arsenic are more appropriately accounted for in a sensitivity analysis. Sensitivity analyses are generally reserved for examining the effects of accounting for highly uncertain factors, such as latency periods, on health risk reduction benefits estimates.

2. Use of the Value of Statistical Life (VSL)

Some commenters felt that the Value of Statistical Life (VSL) used by EPA in its analysis of benefits for the arsenic rule was incorrect. EPA disagrees with these commenters for several reasons. First, the VSL used by the Agency in its benefits analysis is based on the most current data available. The VSL, as recommended by Agency guidance and EPA's SAB, is derived from a statistical distribution of the values found in 26 wage-risk studies, which were chosen as the best such studies available from a larger body of studies. This examination of studies was undertaken by EPA's Office on Air and Radiation in the course of its Clean Air Act retrospective analysis. EPA believes the VSL estimate ($6.1 million, 1999 dollars) to be the best estimate at this time and is recommending that this value be used by the various program offices within the Agency. This estimate may, however, be updated in the future as additional information becomes available to assist the Agency in refining its VSL estimate. The VSL estimate is consistent with current Agency economic analysis guidance, which was reviewed by EPA's SAB.

Also, the use of the VSL for benefits valuation is consistent with recommendations from EPA's SAB, which discussed this issue in their meeting on February 25, 2000 in Washington, DC. The SAB's report on their findings and recommendations from the February meeting stated that:

> despite limitations of the VSL estimates, these seem to offer the best available basis at present for considering the value of fatal cancer risk reduction. We therefore recommend that the Agency continue to use a wage-risk-based VSL as its primary estimate, including appropriate sensitivity analyses to reflect the uncertainty of these estimates (EPA, 2000j).

In addition, some commenters disagreed with EPA's valuation of a human life. EPA disagrees with these commenters because the VSL does not represent the value of an actual human life. Rather, the VSL represents the value of people's willingness to pay for small changes in the risk of a fatality.

3. Use of Alternative Methodologies for Benefits Estimation

Several commenters suggested that the Agency use a Quality Adjusted Life Years (QALYs) or a Life Years approach in its valuation of health benefits for the arsenic rule. EPA disagrees with these commenters because the current economic literature does not support these methodologies and EPA believes these approaches are not sufficient for use in economic analyses.

The use of alternative methodologies, such as Quality Adjusted Life Years (QALYs) and a Life-Years approach, has been extensively discussed both within EPA and also before the Environmental Economics Advisory Committee (EEAC) of EPA's SAB. The QALY method allows information on life expectancy and quality of life to be combined into a single number for benefits valuation purposes. QALYs involve rating each year of life on a scale from zero to one, where one represents perfect health and zero represents the worst possible health state. Because patients themselves, or sometimes citizens of the community, are responsible for "rating" each year, these quality-of-life tradeoffs are highly subjective and may not be very meaningful. Regarding the use of QALYs, the SAB committee stated that "there are no published studies that show that persons with physical limitations or chronic illnesses are willing to pay less to increase their longevity than persons without these limitations. People with physical limitations appear to adjust to their conditions, and their WTP to reduce fatal risks is therefore not affected. The EEAC suggests that no adjustments be made to the VSL to reflect the health status of persons whose cancer risks are reduced, unless additional research documents such effects" (EPA, 2000j).

A Life-Years approach involves use of a Value of Statistical Life Year (VSLY) measure. The VSLY measure values life-years that would be lost if an individual were to die prematurely. The relationship between the value of risk reductions and expected life years remaining is complex; current research does not provide a definitive way of developing estimates of VSLY that are sensitive to such factors as current age, latency of effect, life years remaining, and social valuation of risk reduction. While age adjustments may be desirable from a theoretical standpoint, in the absence of such information, the mainstream economics literature does not support developing VSLY estimates.

The SAB's Environmental Economics Advisory Committee (EEAC), in its report, confirmed this finding. The use of VSLY for valuing life-years lost was found by the EEAC to not have a sufficient theoretical and empirical basis for making any adjustments at this time. While the EEAC agreed that the theoretically appropriate method is to calculate WTP for individuals whose ages correspond to those of the affected population, the Committee recommended that more research be conducted on this topic before the Agency makes any adjustments for age in its estimates of health risk reduction benefits.

Therefore, because of the limitations enumerated above, EPA disagrees with the use of the VSLY as a measure of benefits. This position has also been incorporated in the Agency's Guidelines for Preparing Economic Analyses (EPA, 2000n). The Agency's economic analysis guidelines were reviewed and approved by the Regulatory Policy Council and are considered when the Agency makes economic policy determinations.

At this time, current Agency policy is to use VSL estimates for the monetization of health risk reduction benefits. As noted already, this policy is also consistent with recommendations from the EPA's SAB, which discussed this issue in a meeting held on February 25, 2000 in Washington, DC.

4. Comments on EPA's Consideration of Nonquantifiable Benefits

Some commenters felt that EPA did not fully consider nonquantifiable benefits in their decision-making process. EPA respectfully disagrees with these commenters. SDWA requires that the Agency take into consideration any potential quantifiable and nonquantifiable benefits associated with regulating arsenic in drinking water. To this end, the Agency displayed quantifiable costs and benefits and nonquantifiable benefits in the same table in the proposal (see Table XI–1 of the proposed rule), so that quantifiable and nonquantifiable benefits were given equal consideration in the determination of a regulatory level. In selecting a proposed MCL of 5 μg/L, the Agency based its risk management decision on both the quantifiable bladder and lung cancer benefits and also on the significant amount of nonquantifiable benefits associated with regulating arsenic in drinking water. In addition, EPA has provided analysis and considered the nonquantified benefits in the same manner for the final rule.

By definition, nonquantifiable benefits cannot be measured and were not measured in the benefit-cost analysis for the arsenic rule. EPA attempted to consider these potential benefits in both the proposed and final rule since the Agency believes they might occur. Such nonquantifiable benefits may include skin cancer, kidney cancer, cancer of the nasal passages, liver cancer, prostate cancer, cardiovascular effects, pulmonary effects, immunological effects, neurological effects, endocrine effects, and customer peace-of-mind benefits from knowing their drinking water has been treated for arsenic.

As stated in section 1412(b)(4)(C) of the SDWA, "* * * the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C)." Paragraph (3)(C) contains the description of the seven Health Risk Reduction and Cost Analysis elements that the Agency must consider. These seven elements include quantifiable and nonquantifiable heath risk reduction benefits, quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, quantifiable and nonquantifiable costs, incremental costs and benefits, effects of the contaminant on the general population as well as on any sensitive sub-populations, possible increased health risks, and uncertainties in the analysis of any of these elements.

5. Comments on EPA's Assumption of Benefits Accrual Prior to Rule Implementation

As noted by some commenters, EPA does not make a benefits adjustment for the period prior to rule compliance. EPA does not make this adjustment for two reasons. First, EPA assumes that costs accrue during the same period and does not adjust these costs to account for a phasing in of the rule. Therefore, the analysis treats benefits and costs in exactly the same manner. Second, the Agency anticipates that many systems will begin installing treatment prior to the compliance date. This will ensure they are in compliance on the date that the rule takes effect. As treatment is installed to meet the compliance date, benefits will begin to accrue to those served by these systems.

I. Risk Management Decision

1. Role of Uncertainty in Decision Making

Several commenters questioned the proposed MCL on the basis of the uncertainties associated with aspects of the technical analyses supporting this rulemaking. Most of these comments dealt with the Agency's analysis of the health effects of arsenic. Section V.B. of today's preamble responds to these comments in more detail, and thus, only a relatively brief response to these comments, as they affect the risk management decision, is offered here. The uncertainties pointed out by commenters, together with the considerable costs of compliance with a new, lower standard, led several commenters to suggest that the Agency promulgate a significantly higher MCL than was proposed.

In response, EPA believes that several considerations are important. First, we note that humans are more sensitive to arsenic than laboratory animals. Thus, assessments of the health effects of arsenic necessarily rely, in part, on studies in which human populations have been exposed to relatively high levels (where demonstrable effects can be clearly seen and distinguished) and in which extrapolations to safe levels can be performed, and very low probabilities of adverse effects are projected. Uncertainties are inherent in any such analysis and would attach to similar kinds of contaminants (for which humans are more sensitive than animals and where no animal model exists). Second, EPA has more fully considered the various uncertainties to which many commenters refer and has striven to account for them either qualitatively and quantitatively. Third, the Agency requested and has carefully considered the advice of the National Research Council of the National Academy of Sciences and the Drinking Water Committee of the Science Advisory Board on these issues as a part of our deliberations leading to a final MCL. In summary, we believe that our analysis of the health risks of arsenic in drinking water is fully supportive of the final MCL and is based upon the best available science. While we acknowledge that uncertainties in our understanding of the health effects of arsenic remain, we believe there is sufficient information to support today's promulgated standard.

2. Agency's Interpretation of Benefits Justify Costs Provision

Many commenters offered a variety of points of view on EPA's cost-benefit analysis and on its interpretation of the provision of SDWA allowing the Administrator to set a level higher than the feasible level if the benefits of a standard do not justify the costs (section 1412(b)(6) of SDWA). EPA appreciates the many comments on its cost-benefit analysis, but respectfully disagrees with those comments that suggest its analysis is fundamentally flawed and does not support the proposed or final rule. Assessment of cost and benefits in cases where not all information can be precisely known, as is the case here, is a challenging exercise. Sections V.G. and V.H. of this preamble to the final rule provide a more detailed response to the various cost and benefit estimation comments received. In summary, we believe these costs and benefits have been correctly calculated, within the limits of available data and information, and that they adequately support both the proposed and final rule. Consistent with our statutory requirements, we have carefully considered costs and benefits analysis in proposing and promulgating a final rule that includes an MCL higher than the feasible level. Based on our further analysis of a variety of factors, including the costs and benefits, and after consideration of the various comments, we have decided to establish the final MCL at a higher level than proposed. As discussed in detail in section III.F. of this preamble, the Agency believes that, at an MCL of 10 μg/L, the benefits justify the costs. In our deliberations, we examined total national costs and benefits, incremental costs and benefits across various optional regulatory levels, and household costs for various system size categories. However, it is important to recognize that the Agency is also required to comply with the statutory requirement to "maximize health risk reduction." Thus, while evaluation of costs and benefits is a key consideration in the exercise of the discretionary authorities under section 1412(b)(6) of the SDWA, the decision criteria used in developing a final MCL also has an important risk reduction component.

Some commenters also stated their belief that the benefits must exceed the costs in order for a particular standard to be "justified" in accordance with

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section 1412(b)(6) of SDWA. EPA disagrees and believes, for several reasons, that the benefits of the final standard do justify the costs. First, in connection with this rulemaking, EPA notes that there are a number of non-monetizable benefits that limit the value of a strict numeric comparison of costs and benefits. Second, EPA has calculated a range of monetizable benefits and believes that a portion of the range of benefits do, in fact, "overlap" the costs. Finally, EPA notes that Congressional report language clarifies the intent of section 1412(b)(6) and indicates that benefits do not need to strictly equal or exceed costs in order for a particular regulatory standard associated with those costs to be justified. (see S. Rep. 104–169, 104th Cong., 1st Sess. at 33.)

3. Alternative Regulatory Approaches

A number of commenters suggested that EPA tailor the arsenic drinking water standard in light of local or regional considerations. Market-based and seasonal standards were suggested in this regard. EPA understands these comments and the desire of these commenters to exercise flexibility in local or Regional decision-making in order to reflect information about local arsenic occurrence patterns, local public health priorities, available resources, or other pertinent factors. EPA notes that SDWA does provide for local and Regional flexibility in the implementation of new standard in a variety of ways. State decisions on use of State Revolving Loan Funds and Public Water System Supervision grant funds should be based upon local needs, local priorities, and available local funds. In addition, States may provide variances to qualifying systems under section 1415(a) of SDWA. States may also grant exemptions to qualifying water systems to provide additional time to comply with a new standard (with an opportunity for extensions) to help address the kinds of situations that many commenters are concerned about. However, SDWA does not provide a basis for establishing regional, local, or further-tailored drinking water standards as these commenters suggest. Rather, SDWA is designed to ensure uniform levels of public health protection across the country (except as specifically provided for in variances from the standard). In addition, certain Executive Orders such as Executive Order Number 12898 (Environmental Justice) reinforce this SDWA requirement and are specifically designed to ensure that disadvantaged communities are not protected at levels that are less than those afforded nationally. Thus, EPA disagrees with the suggestion that the level of the final standard be altered to address local or regional considerations, or otherwise tailored, except as specifically provided for by SDWA.

4. Standard for Total Arsenic vs. Species-Specific Standards

Several commenters expressed concern that an arsenic in drinking water standard based on total arsenic may unfairly penalize many drinking water systems, since these commenters felt that only inorganic forms of arsenic are considered to be toxic. Thus, the argument goes: the portion of a compliance sample that is comprised of organic arsenic would unfairly "count against" the utility when determining whether or not the concentration of arsenic in the sample exceeds the MCL. EPA believes, based on our understanding of occurrence patterns of arsenic, that source waters overwhelmingly contain inorganic arsenic. However, EPA also believes that there is a recent body of scientific evidence that indicates organic arsenic may also be toxic. Thus, it is important to know the total amount of arsenic present—both inorganic and organic.

Allowing for only the relative concentration of inorganic arsenic to be measured in compliance samples would impose an additional expense and would only account for a portion of the potentially toxic arsenic present. EPA does not believe such an approach is appropriate for the reasons discussed and instead believes the final MCL should be expressed as total arsenic.

J. Health Risk Reduction and Cost Analysis (HRRCA)

1. Notice and Comment Requirement

Several commenters stated that EPA was required to publish the HRRCA for public comment prior to proposing the arsenic regulation. EPA respectfully disagrees with these commenters. SDWA section 1412(b)(3)(C) states that "when proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, and seek comment on, and use for purposes of paragraphs (4), (5), and (6) an analysis of * * *" the quantifiable and nonquantifiable health risk reduction benefits, the quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, the quantifiable and nonquantifiable costs, the incremental costs and benefits, the effects of the contaminant on the general population as well as on any sensitive subpopulations, any possible increased health risks, and uncertainties in the analysis of any of the above factors.

The above section of the statute provides for the publication of the HRRCA for any contaminant, except radon in drinking water, concurrently with the proposed regulation. Had Congress intended for the arsenic HRRCA to be published in advance of the proposal, the statute would have specifically provided for that, as it did in the case of radon. Section 1412(b)(13)(C) refers to the specific requirements for radon in drinking water. In this section of the statute, Congress required the Agency to publish the HRRCA for radon in drinking water six months in advance of the proposal.

In the proposed arsenic rule, the Agency provided an analysis of the costs, benefits, and other HRRCA requirements, which was shown in Section XIII of the preamble to the proposed rule. The public was provided a 90-day comment period in which to submit comments on all aspects of the proposed rule, including costs, benefits, and HRRCA requirements.

2. Conformance With SDWA Requirements

Some commenters felt that EPA did not meet the statutory requirements for conducting a HRRCA in section 1412(b)(3)(C)(i) and did not analyze the incremental costs and benefits associated with each alternative maximum contaminant level considered in conformance with SDWA requirements. EPA has met these requirements by conducting a HRRCA and an incremental analysis which are described in section XIII.D. of the preamble for the proposed rule. The HRRCA requirements, incremental costs, and incremental benefits are also discussed in the Economic Analysis of the proposed rule.

Some commenters also noted that EPA's incremental cost-benefit analysis lacked significant detail. The Agency addressed these concerns by adding more text to the incremental analysis section in the preamble for the final rule.

Several other commenters stated that the proper interpretation of SDWA is to use only an incremental analysis to determine if the benefits justify the costs. EPA respectfully disagrees with this interpretation because section 1412(b)(4)(C) of SDWA states "* * * the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C)." Paragraph (3)(C) contains the description of the seven Health Risk Reduction and Cost Analysis elements that the Agency must consider. These seven elements include quantifiable and nonquantifiable health risk reduction benefits, quantifiable and nonquantifiable health risk reduction benefits from reducing co-occurring contaminants, quantifiable and nonquantifiable costs, incremental costs and benefits, effects of the contaminant on the general population as well as on any sensitive subpopulations, possible increased health risks, and uncertainties in the analysis of any of these elements. The Agency must consider all seven elements, not just incremental benefits and costs, when making a determination as to whether the benefits of the proposed rule justify the costs.

VI. Administrative and Other Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735, October 4, 1993) the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or;
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it will have annual costs of more than $100 million. As such, this action was reviewed by OMB. Changes made in response to OMB suggestions or recommendations are documented in the public record. EPA prepared an Economic Analysis (EA) pursuant to Executive Order 12866 and a revised version of the EA is in the docket for this rule (EPA, 2000o).

B. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

The RFA provides default definitions for each type of small entity. It also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the **Federal Register** and taking comment (5 U.S.C. 601(3)–(5).) In addition to the above, to establish an alternative small business definition, agencies must consult with the Small Business Administration's (SBA) Chief Counsel for Advocacy.

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 persons. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested comment, consulted with the SBA, and finalized the alternative definition in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition would be applied to this regulation as well.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the regulated small entities in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report (EPA 1999e). A summary of the Panel's recommendations is presented at (65 FR 38963, June 22, 2000). All Panel's recommendations directly applicable to this rulemaking are included in this final rule.

As required by section 604 of the RFA, EPA also prepared a final regulatory flexibility analysis (FRFA) for today's final rule. The FRFA in combination with today's preamble, addresses the issues raised by public comments on the IRFA, which was part of the proposal of this rule. The FRFA is available for review in the docket, (EPA 2000w) and is summarized below.

The RFA requires EPA to address the following when completing an FRFA:

(1) A succinct statement of the need for, and objectives of, the rule;

(2) A summary of the significant issues raised by the public comments on the IRFA, a summary of the assessment of those issues, and a statement of any changes made to the proposed rule as a result of those comments;

(3) A description of the reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the rule and the type of professional skills needed to prepare the report or record;

(4) A description of the types and number of small entities to which the rule will apply, or an explanation why no estimate is available; and

(5) a description of the steps taken to minimize the significant impact on small entities consistent with the stated objectives of the applicable statutes, including a statement of the factual, policy, and legal reasons why EPA selected the alternative the final rule and why the other significant alternatives to the rule that were considered which affect the impact on small entities were rejected.

The following is a summary of the FRFA. The first requirement is discussed in section II. and III.D.1 of this preamble. The second, third, fourth and fifth requirements are summarized as follows.

a. *Comments on the IRFA.* Commenters on the IRFA raised a number of issues, largely concerned with the potential cost of the rule. In the proposed arsenic rule and the RIA supporting the proposal (EPA 2000h), EPA estimated the costs for small systems for the four arsenic MCL regulatory options and requested comment on the IRFA. Some commenters felt that EPA had underestimated the costs for small systems to comply with the arsenic proposal. In response to the comments, the Agency re-evaluated the economic effects on small entities after publication of the proposal (as discussed in greater detail in Section III.). EPA updated its assessment for the FRFA based on comments and the final regulatory decisions, *i.e.*, the final MCL level, full coverage of NTNCWS, and updated costs of compliance, including waste disposal costs.

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b. Reporting, Recordkeeping and Other Requirements for Small Systems. The arsenic rule continues to require small systems to maintain records and to report arsenic concentration levels at the point-of-entry to the water system's distribution system. NTNCWSs are added to the systems that must meet the MCL for arsenic by this rulemaking. Small systems are also required to provide arsenic information in the Consumer Confidence Report or other public notification if the system exceeds specific arsenic finished water concentrations including the MCL. Arsenic monitoring and reporting will be required annually for surface water (and mixed surface and ground water systems) or once every three years for ground water systems, unless the small system obtains a monitoring waiver from the State, demonstrating compliance with the proposed MCL. Other existing information and reporting requirements, such as Consumer Confidence Reports and public notification requirements, will be revised to include the lower arsenic MCL and a reporting requirement when one half of the MCL is exceeded (see section V.E.). As is the case for other contaminants, required information on system arsenic levels must be provided by affected systems and is not considered to be confidential. The professional skills necessary for preparing the reports are the same skill level required by small systems for current reporting and monitoring requirements for other drinking water standards.

The classes of small entities that are subject to the proposed arsenic rule include public water systems serving less than 10,000 people.

c. Number of Small Entities Affected. The number of small entities subject to today's rule is shown in Table VI.B–1 below.

TABLE VI.B–1.—PROFILE OF THE UNIVERSE OF SMALL WATER SYSTEMS REGULATED UNDER THE ARSENIC RULE

Water system type	System size category				
	<100	101–500	501–1,000	1,001–3,300	3,301–10,000
Publicly-Owned:					
CWS	1,729	5,795	3,785	6,179	3,649
NCWS	1,783	3,171	1,182	361	29
Privately-Owned:					
CWS	13,640	11,266	2,124	1,955	654
NCWS	8,178	4,162	902	411	56
Total Systems:					
CWS	15,369	17,061	5,909	8,134	4,303
NCWS	9,961	7,333	2,084	772	85
Total	25,330	24,394	7,993	8,906	4,388

Source: Safe Drinking Water Information System (SDWIS), December 1998 freeze.

EPA's FRFA estimates that the economic impact of the final rule will not be significant for the vast majority of small systems. Of the 71,011 small entities potentially affected by the Arsenic Rule, 94% are expected to incur average annualized costs of less than $40. This average reflects total costs for systems that will not need to modify or install treatment to meet the MCL and mostly reflects monitoring costs. This equates to approximately 0.001% of average annual revenue. The remaining 6%, 3,907 systems, estimated to need additional or modified treatment to meet the MCL are expected to incur average annualized costs of approximately $20,816, or 0.70% of average annual revenue. Although EPA has worked with small communities to minimize the burden of compliance with this rule, the Agency anticipates that several hundred systems may nevertheless experience costs in excess of 3% of annual revenues. As noted below, financial assistance and exemptions (providing additional time) are available for small systems for compliance.

d. Minimizing small system impact and the final MCL. As discussed in more detail in section I.L. of this preamble, EPA notes that $1.7 billion is available each year through the SRF and RUS program to support necessary capital improvements to ensure compliance. SDWA also provides small systems additional time to comply through a provision for exemptions. Systems serving fewer than 3,300 persons can apply for an exemption from the State (SDWA section 1416(b)(3)) that can provide up to an additional nine years to comply (for a total of 14 years from the effective date of the rule). EPA discusses in section III.F. of this preamble the decisions to select the final MCL. EPA is preparing a small entity compliance guide to help small entities comply with this rule as required by Section 212 of SBREFA. This guide will be available for small systems within a few months of the promulgation date of this rule. Small systems may obtain a copy of the guide from EPA's web site, www.epa.gov/safewater.

C. Unfunded Mandates Reform Act (UMRA) of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Tribal, and local governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a benefit-cost analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, Tribal, and local governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule, for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must

have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule contains a Federal mandate that may result in expenditures of $100 million or more for State, Tribal, and local governments, in the aggregate, or the private sector in any one year. A detailed description of this analysis is presented in EPA's Economic Analysis of the arsenic rule (EPA, 2000o) which is included in the Office of Water docket for this rule. Accordingly, EPA has prepared under section 202 of the UMRA a written statement which is summarized below.

a. Authorizing legislation. Today's rule is issued pursuant to section 1412(b)(13) of the 1996 amendments to SDWA that requires EPA to propose and promulgate a national primary drinking water regulation for arsenic, establishes a statutory deadline of January 1, 2000, to propose this rule, and establishes a statutory deadline of January 1, 2001, (and subsequently amended to June 22, 2001) to promulgate this rule.

b. Cost-benefit analysis. Section III. of this preamble, describing the Economic Analysis (EA) (EPA, 2000o), health risk analysis and the cost and benefit analysis for arsenic, contains a detailed analysis in support of the arsenic rule. Today's final rule is expected to have a total annualized cost of approximately $181 million (Exhibit 6–9, EPA, 2000o). This total annualized cost includes the total annual administrative costs of State, Tribal, and local governments, in aggregate, less than 1% of the cost, and total annual treatment, monitoring, reporting, and record keeping impacts on public water systems, in aggregate, of approximately $1.3 million. EPA estimates the total annual costs of administrative activities for compliance with the MCL to be approximately $2.7 million.

The EA includes both qualitative and monetized benefits for improvements in health and safety. EPA estimates the final arsenic rule will have total annual monetized benefits for bladder and lung cancer of approximately $140 to 198 million for the MCL of 10 μg/L. The monetized health benefits of reducing arsenic exposures in drinking water are attributable to the reduced incidence of fatal and non-fatal bladder and lung cancers. At an arsenic level of 10 μg/L, an estimated 21 to 30 fatal bladder and lung cancers and 12 to 26 non-fatal bladder and lung cancers per year are prevented.

In addition to quantifiable benefits, EPA has identified several potential non-quantifiable benefits associated with reducing arsenic exposures in drinking water. These potential benefits include health effects that are difficult to quantify because of the uncertainty surrounding their estimation. Non-quantifiable benefits may also include any peace-of-mind benefits specific to reduction of arsenic risks that may not be adequately captured in the Value of Statistical Life (VSL) estimate.

c. Financial Assistance. Section III of this preamble describes the various Federal programs available to provide financial assistance to State, Tribal, and local governments to administer and comply with this and other drinking water rules. The Federal government provides funding to States that have a primary enforcement responsibility for their drinking water programs through the Public Water Systems Supervision (PWSS) Grant program. Additional funding is available from other programs administered either by EPA or other Federal agencies. These include the Drinking Water State Revolving Fund (DWSRF) and Housing and Urban Development's Community Development Block Grant Program. Also, the Rural Utilities Service (RUS) of the United States Department of Agriculture (USDA) operates a Water and Waste Disposal Loan and Grant Program. This program provides low-interest loans and grants to public entities and not-for-profit corporations serving populations of 10,000 or fewer persons.

d. Estimates of future compliance costs and disproportionate budgetary effects. To meet the requirement in section 202 of the UMRA, EPA analyzed future compliance costs and possible disproportionate budgetary effects of an arsenic MCL of 10 μg/L to the extent reasonably feasible. The Agency believes that the cost estimates, indicated previously and discussed in more detail in section III of today's rule, accurately characterize future compliance costs of the rule.

With regard to the disproportionate impacts, EPA considered available data sources in analyzing the disproportionate impacts upon geographic or social segments of the nation or industry. While the percentage of systems impacted varies from region to region, no area has impacts substantial enough to create a disproportionate burden. For the proposal, EPA did identify (Table V–2, p. 38908) that there are a larger percentage of systems in the Western and New England regions, whose drinking water quality currently would exceed the MCL for arsenic. For such regions, total compliance, therefore, may be incrementally costlier than for systems in regions where a smaller percentage currently exceed the arsenic MCL. However, even this difference is not considered by EPA to represent a disproportionate impact.

To estimate the potential disproportionate impacts on social segments of this rule, this analysis also developed three other measures:

(1) Reviewing the impacts on small versus large CWSs;

(2) Reviewing the costs to public versus private CWSs; and

(3) reviewing the household costs for the rule.

Table 6–11 of the EA (EPA, 2000o) shows that the total treatment costs for small CWSs (serving fewer than 10,000 persons) is less than the total treatment for large CWSs; therefore, there is no disproportionate impact on small systems versus large systems. Table 8–29 of the EA shows that there is not a disproportionate impact when comparing costs for public CWSs to costs for private CWSs of the same size. Public systems have slightly higher costs than public CWSs. Table 8–30 of the EA show household costs by system size. Cost per household increases as system size decreases. Cost per household is higher for households served by smaller systems than larger systems. These values are expected for two reasons. First, smaller systems serve far fewer households than larger systems and, consequently, each household must bear a greater percentage share of the system's costs. Second, smaller systems tend to have higher influent arsenic concentrations that, on a per-capita or per-household basis, require more expensive treatment methods to achieve the target arsenic level.

Moreover, even if there were a disproportionate impact associated with the final MCL, EPA does not have any authority to tailor the regulation to provide regional or ownership relief. Finally, as previously noted, EPA adopted a 10 μg/L arsenic MCL rather than the proposed (5 μ/L) or feasible level (3 μg/L) of arsenic MCL in part because of the benefit cost issues raised by commenters. This should serve to mitigate the costs of the rule to some degree. EPA also provided delayed compliance deadlines for all systems

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which should also reduce the economic effect on systems with higher ground water arsenic levels.

EPA will prepare a small entity compliance guide, a monitoring/analytical manual, and a small systems technology manual that will assist the public and private sector.

e. Macroeconomic effects. As required under UMRA § 202, EPA is required to estimate the potential macro-economic effects of the regulation. These types of effects include those on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness. Macro-economic effects tend to be measurable in nationwide econometric models only if the economic impact of the regulation reaches 0.25% to 0.5% of Gross Domestic Product (GDP). In 1998, real GDP was $7,552 billion so a rule would have to cost at least $18 billion annually to have a measurable effect. A regulation with a smaller aggregate effect is unlikely to have any measurable impact unless it is highly focused on a particular geographic region or economic sector. The macro-economic effects on the national economy from the arsenic rule should be negligible based on the fact that, assuming 100% compliance, the total annual costs are approximately $181 million, and the costs are not expected to be highly focused on a particular geographic region or industry sector.

f. Summary of EPA's consultation with State, Tribal, and local governments. In developing the proposed rule, EPA consulted with small governments pursuant to its plan established under section 203 of the UMRA to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. Consistent with the intergovernmental consultation provisions of section 204 of UMRA, EPA held, prior to proposal, consultations with the governmental entities affected by this rule. EPA held four public meetings for stakeholders prior to proposal and an additional meeting after proposal. The Agency convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns, including small local governments. EPA consulted with small entity representatives prior to convening the Panel to get their input on the arsenic rule. Two of the small entities represented small governments. A detailed description of the SBREFA process can be found in the docket of this rulemaking (EPA, 1999e). EPA also made presentations at Tribal meetings in Nevada, Alaska, and California. In addition, EPA made presentations at meetings of the American Water Works Association (AWWA), the Association of State Drinking Water Administrators (ASDWA), the Association of California Water Agencies (ACWA), and the Association of Metropolitan Water Agencies (AMWA). Participants in EPA's stakeholder meetings also included representatives from the National Rural Water Association, AMWA, ASDWA, AWWA, ACWA, Rural Community Assistance Program, State departments of environmental protection, State health departments, State drinking water programs, and a Tribe.

g. Nature of State, Tribal, and local government concerns and how EPA addressed these concerns. In general, comments on the proposed UMRA discussion continued to cite costs and funding for compliance as concerns. EPA has further revised the costs for this final rule based on comments and continues to believe that there are affordable technologies (see section III.E.). Cost was one of the issues EPA considered in deciding to exercise its discretionary authority under section 1412(b)(6) of SDWA to propose that the MCL be set a level higher than the feasible level in the proposed rule of 5 µg/L and to set the final level of 10 µg/L. Commenters asked that funding be increased to the Drinking Water State Revolving Fund (DWSRF) or somehow fully fund compliance with the proposed requirements. While the DWSRF program is proving to be a significant source of funding, it cannot be viewed as the only source of funding. There are strategies other than Federal funding (such as system bundling) for meeting the arsenic rule. Federal, State and local governments, private business and utilities will need to work in partnership to help address the significant infrastructure needs for complying with today's rule.

h. Regulatory alternatives considered. As required under section 205 of the UMRA, EPA considered several regulatory alternatives in developing an MCL for arsenic in drinking water. In preparation for this consideration, the Regulatory Impact Analysis (EPA, 2000h) and Health Risk Reduction and Cost Analysis (HRRCA) for the proposed arsenic rule (EPA, 2000i, see section XIII.) evaluated arsenic levels of 3 µg/L, 5 µg/L, 10 µg/L, and 20 µg/L. (see section III. of the proposed rule for more discussion of the regulatory alternatives considered.)

i. Selection of the regulatory alternative. As explained in section III.F. of today's preamble, the Agency selected an MCL of 10 µg/L which is the most cost-effective alternative since it maximizes benefits.

D. Paperwork Reduction Act (PRA)

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*, and has assigned OMB control number 2040–0231.

Under this rule, respondents to the monitoring, reporting, and recordkeeping requirements include the owners and operators of community water systems and State officials that must report data to the Agency. Monitoring for arsenic is required at each entry point to the distribution system. States will have discretion in grandfathering existing data for determining initial monitoring baselines for the currently regulated contaminants.

EPA has estimated the burden associated with the specific information collection, record keeping and reporting requirements of the proposed rule in the accompanying Information Collection Request (ICR). The ICR for today's final rule compares the current requirements to the revised requirements for information collection, reporting and record-keeping. The States and the PWSs must perform start-up activities in preparing to comply with the arsenic rule. Start-up activities include reading the final rule to become familiar with the requirements and training staff to perform the required activities.

For PWSs, the number of hours required to perform each activity may vary by system size. This rule applies to community water systems and non-transient non-community water systems. There are approximately 74,607 PWSs and 56 States and territories considered in this ICR. During the first three years after promulgation of this rule, the average burden hours per respondent per year is estimated to be 8 hours for PWSs and 915 hours for States. During this period, the total burden hour per year for the approximately 74,663 respondents covered by this rule is estimated to be 667,179 hours to prepare to comply with this final arsenic rule. The average number of responses per year by PWSs is 49,738. The average number of responses for the States is expected to be 75 per year during the first three-year period. The average burden hours per response for PWSs is 4. The average burden hours per response for States is 229. Total annual labor costs during this first 3-year period are expected to be about $9.9 million per year for PWSs. The information collected is not confidential.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to collect information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. EPA is amending the table in Chapter 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

E. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (Pub. L. No. 104–113, section12(d), 15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide to Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's rule does not establish any technical standards; thus, NTTAA does not apply to this rule. However, it should be noted that systems complying with this rule need to use previously approved technical standards already included in § 141.23. As discussed in the proposed rule for arsenic (65 FR 38888) and in today's final rule (section I.F.1.), one consensus method (SM 3120B) and one EPA method (EPA 200.7), are withdrawn by this rule because the method detection limits for these methods are inadequate to reliably determine the presence of arsenic at the MCL of 10 µg/L. After the removal of these methods, the four remaining analytical methods currently approved for compliance monitoring of arsenic in drinking water are published by consensus organizations. The four methods published by these consensus organizations include SM 3113B, SM 3114B, ASTM 2972–93B and ASTM 2972–93C. These methods are described in the "Annual Book of ASTM Standards" (American Society for Testing and Materials, 1994 and 1996) and in "Standards for the Examination of Water and Wastewater" (APHA, 1992 and 1995).

F. Executive Order 12898: Environmental Justice

Executive Order 12898 establishes a Federal policy for incorporating environmental justice into Federal agencies' missions by directing agencies to identify and address disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. The Agency has considered environmental justice related issues concerning the potential impacts of this action and consulted with minority and low-income stakeholders.

On March 12, 1998, the Agency held a stakeholder meeting to address various components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, Tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call between 11 cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's drinking water programs. The major objectives for the March 12, 1998 meeting were:

- Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts;
- Identify key issues of concern to stakeholders, and;
- Receive suggestions from stakeholders concerning ways to increase representation of communities in EPA regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," (62 FR 19885 April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to the Executive Order because the Agency does not have reason to believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

H. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, imposes substantial direct compliance costs, and is not required by statute (unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation). EPA also may not issue a regulation that has federalism implications and preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

If EPA complies by consulting, Executive Order 13132 requires EPA to provide to the Office of Management

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and Budget (OMB), in a separately identified section of the preamble to the rule, a federalism summary impact statement (FSIS). The FSIS must include a description of the extent of EPA's prior consultation with State and local officials, a summary of the nature of their concerns and the agency's position supporting the need to issue the regulation, and a statement of the extent to which the concerns of State and local officials have been met. Also, when EPA transmits a draft final rule with federalism implications to OMB for review pursuant to Executive Order 12866, EPA must include a certification from the agency's Federalism Official stating that EPA has met the requirements of Executive Order 13132 in a meaningful and timely manner.

EPA has concluded that this rule will have federalism implications. This rule will impose substantial direct compliance costs on State and local governments, and the Federal government will not provide the funds necessary to pay those costs. Accordingly, EPA provides the following FSIS as required by section 6(b) of Executive Order 13132.

EPA consulted with State and local officials early in the process of developing the proposed regulation to permit them to have meaningful and timely input into its development. Summaries of the meetings have been included in the docket for this proposed rulemaking. EPA consulted extensively with State, Tribal, and local governments. For example, EPA held four public stakeholder meetings in Washington, D.C. (two meetings); San Antonio, Texas; and Monterey, California. An additional public stakeholder meeting was held after the proposal was published in Reno, Nevada. A summary of this meeting is included in the docket of this rulemaking. Invitations to stakeholder meetings were extended to the National Association of Counties, The National Governors' Association, the National Association of Towns and Townships, the National League of Cities, and the National Conference of State Legislators. In addition, several elected officials were part of the Small Business Advocacy Review Panel convened by EPA (as required by section 609(b) of the Regulatory Flexibility Act). EPA officials presented a summary of the rule to the National Governor's Association in a meeting on May 24, 2000. In addition, EPA scheduled a one-day stakeholders' meeting for the trade associations that represent elected officials on May 30, 2000 to discuss and solicit comment on this and other upcoming contaminant rules.

Several issues were raised by stakeholders (including elected officials) regarding the arsenic rule provisions, most of which were related to reducing burden and maintaining flexibility. The Office of Water was able to reduce burden and increase flexibility for the proposal in a number of areas in response to these comments (see section XIV.G. of the proposed rule).

Commenters on the proposed rule continued to request a reduction of burden and increased flexibility as well as to question the need for the rule. Section V. of this preamble and the Comment Response Document (EPA, 2000u) discuss the comments and EPA's response in detail. The Agency exercised its discretionary authority under section 1412(b)(6) of SDWA to propose that the MCL be set at a level higher than the feasible level in the proposed rule and, in the final rule, to move from the proposed level of 5 μg/L to 10 μg/L.

I. Executive Orders 13084 and 13175: Consultation and Coordination With Indian Tribal Governments

On November 6, 2000, the President issued Executive Order 13175 (65 FR 67249) entitled, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 took effect on January 6, 2001, and revokes Executive Order 13084 (Tribal Consultation) as of that date. EPA developed this final rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13984.

Under Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments," 63 FR 27655 (May 19, 1998), EPA may not issue a regulation that: is not required by statute, significantly or uniquely affects the communities of Indian Tribal governments, and imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian Tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

EPA has concluded that this rule may significantly or uniquely affect communities of Indian tribal governments. It may also impose substantial direct compliance costs on such communities, and the Federal government will not provide the funds necessary to pay the direct costs incurred by the Tribal governments in complying with this rule. In developing the rule, EPA consulted with Tribal governments to permit them to have meaningful and timely input into its development.

In order to inform and involve Tribal governments prior to proposing the arsenic rule, EPA staff attended the 16th Annual Consumer Conference of the National Indian Health Board on October 6–8, 1998, convened a Tribal consultation meeting on February 24–25, 1999, and conducted a series of workshops at the Annual Conference of the National Tribal Environmental Council on May 18–20, 1999. Tribal representatives were generally supportive of an arsenic standard that ensures a high level of water quality, but raised concerns over funding for regulations. With regard to the proposed arsenic rule, many Tribal representatives saw the health benefits as highly desirable, but felt that unless additional funds were made available, implementing the regulation would be difficult for many Tribes. Comments submitted on the proposed arsenic rule repeated the concern that Tribes might not be able to afford to meet the arsenic requirements.

The Agency believes that the requirements of this final rulemaking are affordable nationally, including Tribal PWSs. As discussed in section I.G. of this preamble, EPA has developed and applied a national affordability criterion to the projected costs of compliance of this rule for small systems (those serving less than 10,000 persons). Using this approach, EPA has identified affordable compliance technologies that small systems (including Tribal PWSs) may use to comply with today's final rule.

J. Plain Language

Executive Order 12866 and the President's memorandum of June 1, 1998 require each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. Of the several techniques typically utilized for writing readably, using a question and answer format, and using the word, "you" for whoever must comply, do the most to improve the look and sound of a regulation. The preamble for today's final rule uses the first principle and was developed using a plain language question and answer format. Today's final rule language does not use these principles since the rule only modifies or adds to existing regulatory language that is in the previous regulatory language format. EPA received comments on the use of plain language. Commenters suggested that the Agency had not clearly explained certain terms for example, "dose-response" and "parts per billion." The comments were centered around technical and scientific issues and terms that are often difficult to discuss in a plain language format. EPA considered these comments in writing the section of this final rule to which those comment apply. EPA made every effort to write this preamble to the final rule in as clear, concise, and unambiguous manner as possible.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective March 23, 2001.

L. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with section 1412 (d) and (e) of SDWA, the Agency discussed or submitted possible arsenic rule requirements to the Science Advisory Board (SAB), National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board (SAB) on the arsenic rule.

On March 13th and 14th, 2000 in Washington DC, the Agency met with the Science Advisory Board during meetings open to the public where several of the Agency's Drinking Water Rules were discussed. A copy of the SAB's comments may be found in the docket. SAB provided substantive comments on the proposed arsenic rule which are discussed in sections V.B. and V.F. of this preamble.

In addition, the National Drinking Water Advisory Council was consulted on this rulemaking on several occasions throughout the rule's development (*e.g.*, November 1999 in Baltimore, Maryland; April 2000 in San Francisco, CA; November 2000 in Arlington, VA). The summary of the deliberations and recommendations of the Council may be found in the docket for this rule.

The Agency coordinated with the Department of Health and Human Services in several ways. Representatives of the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), and the Food and Drug Administration (FDA) were invited to the Agency's stakeholder meetings on the arsenic rulemaking and on the mailing list for updates. We provided FDA staff with summaries of the meetings, meeting materials, and a briefing paper. In addition, the Agency maintained contact with CDC representatives on the status of CDC-funded research on skin adsorption that could have a bearing on the Agency's deliberations. EPA commented on and monitored the progress of the updated "Toxicological Profile for Arsenic" issued by ATSDR. Finally, we provided ongoing progress reports on the Agency's arsenic in drinking water rulemaking activities to representatives of FDA relative to the timing of bottled water regulations that need to follow the promulgation of the Agency's final rule.

M. Likely Effect of Compliance With the Arsenic Rule on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of SDWA as amended requires that, in promulgating a NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. The following summarizes the analysis performed to fulfill this statutory obligation. (EPA, 2000v)

Overall water system capacity is defined in guidance (EPA, 1998g) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial. Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity refers to the physical infrastructure of the water system, including the adequacy of source water and the adequacy of treatment, storage, and distribution infrastructure. It also refers to the ability of system personnel to adequately operate and maintain the system and to otherwise implement requisite technical knowledge. Managerial capacity is the ability of a water system to conduct its affairs in a manner enabling the system to achieve and maintain compliance with SDWA requirements. Managerial capacity refers to the system's institutional and administrative capabilities. Financial capacity is a water system's ability to acquire and manage sufficient financial resources to allow the system to achieve and maintain compliance with SDWA requirements.

The arsenic rule establishes five requirements that may impact the TMF capacity of PWSs:

(1) Compliance with MCL revised to 10 μg/L from 50 μg/L (40 CFR 141.62);

(2) Revised arsenic monitoring schedule [(modified to join the standard monitoring framework (SMF) used for other inorganic contaminants (IOCs)] (§ 141.23(c))—includes requirement for public notification of MCL exceedance, but not Consumer Confidence Report (CCR) requirements (§ 141.154);

(3) New source monitoring (§ 141.24);

(4) Removal of EPA Method 200.7 and SM 3120 from list of approved analytical methods to demonstrate compliance (§ 141.23); and

(5) Inclusion of arsenic health effects language in CCRs (§ 141.154).

The arsenic rule applies to all CWSs (54,370 systems) and NTNCWSs (20,255 systems)—74,625 systems in all (EPA, 2000b). However, many systems will not be affected by the new arsenic requirements. Table VI.M–1 provides a complete listing of the requirements and a description of the type and number of systems affected by each requirement.

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TABLE VI.M–1.—REQUIREMENTS OF THE ARSENIC RULE AND NUMBER OF SYSTEMS AFFECTED

Requirement	Affected systems [1]			
	Description	Number		
		CWSs	NTNCWSs	Total
Compliance with revised MCL (10 µg/L)	Systems with As ≥ 10 µg/L	3,024	1,080	4,104
Revised monitoring schedule	CWSs with As between 3 µg/L (PQL) and 50 µg/L and all NTNCWSs.	10,590	20,255	30,845
New source monitoring	Systems that develop a new source to meet the revised MCL.	~0	~ 0	<100
Removal of specified analytical methods	All CWSs that currently use banned methods.	<100	N/A	<100
Inclusion of health effects language in CCR	CWSs with As ≥5–25 µg/L	~4,000	N/A	~4,000

[1] Estimates derive from actual system impacts projected in cost benefit analysis. Will differ from system-level figures discussed earlier in preamble. Reflect all systems having impacts, including those partially impacted.

Those systems whose current source(s) will not meet the revised MCL must either develop a new source, install new treatment processes, or enhance their existing treatment processes. (The impact of developing a new source are included in the analysis of the new source requirement.) The installation, operation, and maintenance of new treatment technologies will require a substantial enhancement of these systems' technical capacity. Specifically, source water adequacy will be reduced (marginal sources may no longer be viable), the system will be required to greatly enhance its infrastructure (particularly its treatment processes) to meet the technical challenge posed by the revised MCL, and system operators will require correspondingly greater technical expertise to successfully operate new and more advanced treatment processes.

The impacts to the managerial capacity of systems affected by the revised arsenic MCL are not anticipated to be as great as the technical and financial challenges. Nonetheless, many system managers will need to review the implications of the revised MCL and may need to hire a more highly certified operator or provide additional training for the existing operator.

In addition, systems will need to rely upon and improve their interactions with the service community and technical/financial assistance providers. System management will need to explain the following issues: (1) The reason why the arsenic standard was revised, (2) the safety of the water that the system provides, and (3) the reason for new or higher fees. These activities are in addition to the inclusion of the health effects language in the CCR and therefore will impact the managerial capacity of a system.

The impacts of the arsenic rule requirements to the technical capacity of systems are closely tied to financial impacts. Systems that must install additional treatment processes or upgrade their current treatment processes may face significant costs. These costs may be especially difficult for many of the affected systems to absorb since many of them are relatively small (i.e., serving less than 3,300 customers), and therefore typically have a smaller revenue base and fewer households over which they may distribute the additional costs. The rule specifically allows the use of centrally managed POU-treatment devices to achieve compliance with the revised arsenic MCL. However, the installation, operation, maintenance, and management of these devices still represents a substantial expense for small systems.

To obtain funding from either public or private sources, systems will need to demonstrate sound financial accounting and budgeting practices, and the ability to repay their debts. As a result, many of the smallest systems that do not currently charge explicitly for water service (e.g., mobile home parks, camp grounds, etc.) may need to begin to bill their customers. Those systems that already charge for water service will likely need to increase their rates (sometimes requiring approval of the local public utilities commission (PUC)), and improve their recordkeeping procedures.

EPA anticipates that the revised monitoring and reporting framework will have a relatively limited impact on system capacity even though some CWSs will no longer be eligible for reduced monitoring and others will no longer be able to composite. NTNCWSs will be required to monitor for arsenic for the first time. To comply with this requirement system management will need to ensure that staff understand the new requirements, that monitoring records are properly maintained, and that the appropriate reports are provided to the State primacy agency and EPA. In addition, systems will face a slight increase in monitoring costs that may require systems to adjust their budgeting practices and fee structures. Nonetheless, since most systems are already familiar with the SMF for IOCs, the impact to capacity is minimal.

There will be a substantial impact on capacity for those systems that must develop a new source to meet the revised MCL. In addition to the monitoring requirements specified in the arsenic proposal, these systems will expend substantial effort and money to ensure that their new source(s) will consistently provide reliable production of high quality water.

Removing two currently approved analytical methods should not have a large impact on system capacity. Since similarly priced alternative methods are available, it was estimated that there would be little to no impact to the managerial and financial capacity of systems that currently rely on this method (or whose laboratory relies on this method). A system may need to ensure that the systems' laboratory uses an approved method and may need to ensure that the operator is aware of the change in approved analytical methods.

The requirement for affected systems (those with arsenic levels above half the revised MCL) to immediately begin incorporating health affects language into their CCRs will principally impact the managerial capacity of systems. Specifically, systems will need to: (1) incorporate information about arsenic into their CCRs; (2) explain to the service community the reason why they are including such information; (3) explain the health implications of current arsenic levels; and potentially, (4) explain how the system anticipates meeting the revised MCL. Moreover, affected systems will also need to prepare to respond to customer queries regarding the new arsenic information and the system's compliance status.

The arsenic rule will have a substantial impact on the capacity of the 4,100 CWSs and NTNCWSs that must reduce arsenic levels or develop new sources to meet the revised MCL. However, while the impact to these systems is significant, only five percent of all systems regulated under the Arsenic Rule (4,104 of 74,625) will be affected by this requirement. The new monitoring and reporting requirements, removal of approved analytical methods, and inclusion of health effects language in the CCR are expected to impact the capacity of approximately an additional 26,000 systems to a small degree. About 31,000 systems (i.e., 40% of regulated systems) are expected to experience minimal impact on their capacity as a result of the arsenic rule.

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 141

Environmental protection, Chemicals, Indian lands, Incorporation by reference, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indian lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: January 16, 2001.

Carol M. Browner,

Administrator.

For reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR parts 9, 141 and 142 as follows:

PART 9—OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326–1330, 1324, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Amend the table in § 9.1 by removing the entry for 141.23–141.24 and adding new entries for 141.23(a)–(b), 141.23 (c), and 141.23(d)–141.24 to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
National Primary Drinking Water Regulations	
* * * * *	
141.23A(a)–(b)	2040–0090
141.23(c)	2040–0231
141.23(d)–141.24	2040–0090
* * * * *	

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Subpart A—[Amended]

§ 141.2 [Amended]

2. In 40 CFR 141.2 revise the definition heading for "*Point-of-entry treatment device*" to read "*Point-of-entry treatment device (POE)*", and revise the definition heading for "*Point-of-use treatment device*" to read "*Point-of-use treatment device (POU)*".

3. Amend § 141.6 by revising paragraphs (a) and (c), and adding paragraphs (j) and (k) to read as follows:

§ 141.6 Effective dates.

(a) Except as provided in paragraphs (b) through (k) of this section, and in § 141.80(a)(2), the regulations set forth in this part shall take effect on June 24, 1977.

* * * * *

(c) The regulations set forth in §§ 141.11(d); 141.21(a), (c) and (i); 141.22(a) and (e); 141.23(a)(3) and (a)(4); 141.23(f); 141.24(e) and (f); 141.25(e); 141.27(a); 141.28(a) and (b); 141.31(a), (d) and (e); 141.32(b)(3); and 141.32(d) shall take effect immediately upon promulgation.

* * * * *

(j) The arsenic maximum contaminant levels (MCL) listed in § 141.62 is effective for the purpose of compliance on January 23, 2006.

Requirements relating to arsenic set forth in §§ 141.23(i)(4), 141.23(k)(3) introductory text, 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) revisions in Appendix A of subpart O for the consumer confidence rule, and Appendices A and B of subpart Q for the public notification rule are effective for the purpose of compliance on January 23, 2006. However, the consumer confidence rule reporting requirements relating to arsenic listed in § 141.154(b) and (f) are effective for the purpose of compliance on March 23, 2001.

(k) Regulations set forth in §§ 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) are effective for the purpose of compliance on January 22, 2004.

Subpart B—[Amended]

4. Amend § 141.11 by revising the second sentence of paragraph (a) and revising paragraph (b) to read as follows:

§ 141.11 Maximum contaminant levels for inorganic chemicals.

(a) * * * The analyses and determination of compliance with the 0.05 milligrams per liter maximum contaminant level for arsenic use the requirements of § 141.23.

(b) The maximum contaminant level for arsenic is 0.05 milligrams per liter for community water systems until January 23, 2006.

* * * * *

Subpart C—[Amended]

5. Amend § 141.23 by:

a. Adding a new entry for "Arsenic" in alphabetical order to the table in paragraph (a)(4)(i) and adding endnotes 6, 7 and 8,

b. Revising paragraphs (a)(5) and (c) introductory text,

c. Adding paragraph (c)(9),

d. Revising paragraphs (f)(1), (i)(1), and (i)(2),

e.–h. Adding paragraph (i)(4),

i. Revising the entries for arsenic in the table in paragraph (k)(1),

j. Revising paragraph (k)(2) introductory text,

k. Adding a new entry for "Arsenic" in alphabetical order to the table to paragraph (k)(2) and revising footnote 1,

l. Revising the last sentence in paragraph (k)(3) introductory text, and

m. Adding a new entry for "Arsenic" in alphabetical order to the table in paragraph (k)(3)(ii).

The revisions and additions read as follows:

§ 141.23 Inorganic chemical sampling and analytical requirements.

(a) * * *

(4) * * *

(i) * * *

DETECTION LIMITS FOR INFORGANIC CONTAMINANTS

Contaminant	MCL (mg/l)	Methodology	Detection Limit (mg/l)
*	*	* * * * *	*
Arsenic	[6]0.01	Atomic Absorption; Furnace	0.001
		Atomic Absorption; Platform—Stabilized Temperature	[7]0.0005
		Atomic Absorption; Gaseous Hydride	0.001
		ICP-Mass Spectrometry	[8]0.0014
*	*	* * * * *	*

* * * * *

[6] The value for arsenic is effective January 23, 2006. Unit then, the MCL is 0.05 mg/L.

[7] The MDL reported for EPA method 200.9 (Atomic Absorption; Platform—Stabilized Temperature) was determined using a 2x concentration step during sample digestion. The MDL determined for samples analyzed using direct analyses (i.e., no sample digestion) will be higher. Using multiple depositions, EPA 200.9 is capable of obtaining MDL of 0.0001 mg/L.

[8] Using selective ion monitoring, EPA Method 200.8 (ICP–MS) is capable of obtaining a MDL of 0.0001 mg/L.

* * * * *

(5) The frequency of monitoring for asbestos shall be in accordance with paragraph (b) of this section: the frequency of monitoring for antimony, arsenic, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium shall be in accordance with paragraph (c) of this section; the frequency of monitoring for nitrate shall be in accordance with paragraph (d) of this section; and the

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frequency of monitoring for nitrite shall be in accordance with paragraph (e) of this section.

* * * * *

(c) The frequency of monitoring conducted to determine compliance with the maximum contaminant levels in § 141.62 for antimony, arsenic, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium and thallium shall be as follows:

* * * * *

(9) All new systems or systems that use a new source of water that begin operation after January 22, 2004 must demonstrate compliance with the MCL within a period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

* * * * *

(f) * * *

(1) Where the results of sampling for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium indicate an exceedance of the maximum contaminant level, the State may require that one additional sample be collected as soon as possible after the initial sample was taken (but not to exceed two weeks) at the same sampling point.

* * * * *

(i) * * *

(1) For systems which are conducting monitoring at a frequency greater than annual, compliance with the maximum contaminant levels for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium is determined by a running annual average at any sampling point. If the average at any sampling point is greater than the MCL, then the system is out of compliance. If any one sample would cause the annual average to be exceeded, then the system is out of compliance immediately. Any sample below the method detection limit shall be calculated at zero for the purpose of determining the annual average. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

(2) For systems which are monitoring annually, or less frequently, the system is out of compliance with the maximum contaminant levels for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium or thallium if the level of a contaminant is greater than the MCL. If confirmation samples are required by the State, the determination of compliance will be based on the annual average of the initial MCL exceedance and any State-required confirmation samples. If a system fails to collect the required number of samples, compliance (average concentration) will be based on the total number of samples collected.

* * * * *

(4) Arsenic sampling results will be reported to the nearest 0.001 mg/L.

* * * * *

(k) * * *

(l) * * *

Contaminant and methodology [13]	EPA	ASTM [3]	SM [4]	Other
Arsenic [14]:				
Inductively Coupled Plasma [15]	[2] 200.7		[15] 3120B	
ICP-Mass Spectrometry	[2] 200.8			
Atomic Absorption; Platform	[2] 200.9			
Atomic Absorption; Furnace		D–2972–93C	3113B	
Hydride Atomic Absorption		D–2972–93B	3114B	

[2] "Methods for the Determination of Metals in Environmental Samples-Supplement I", EPA–600/R–94–111, May 1994. Available at NTIS, PB 95–125472.

[3] Annual Book of ASTM Standards, 1994 and 1996, Vols. 11.01 and 11.02, American Society for Testing and Materials. The previous versions of D1688–95A, D1688–95C (copper), D3559–95D (lead), D1293–95 (pH), D1125–91A (conductivity) and D859–94 (silica) are also approved. These previous versions D1688–90A, C; D3559–90D, D1293–84, D1125–91A and D859–88, respectively are located in the Annual Book of ASTM Standards, 1994, Vols. 11.01. Copies may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19426.

[4] 18th and 19th editions of Standard Methods for the Examination of Water and Wastewater, 1992 and 1995, respectively, American Public Health Association; either edition may be used. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street NW., Washington, DC 20005.

[13] Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2X preconcentration step during sample digestion, MDLs determined when samples are analyzed by direct analysis (*i.e.*, no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559–90D unless multiple in-furnace depositions are made.

[14] If ultrasonic nebulization is used in the determination of arsenic by Methods 200.7, 200.8, or SM 3120 B, the arsenic must be in the pentavalent state to provide uniform signal response. For methods 200.7 and 3120 B, both samples and standards must be diluted in the same mixed acid matrix concentration of nitric and hydrochloric acid with the addition of 100 µL of 30% hydrogen peroxide per 100ml of solution. For direct analysis of arsenic with method 200.8 using ultrasonic nebulization, samples and standards must contain one mg/L of sodium hypochlorite.

[15] After January 23, 2006 analytical methods using the ICP–AES technology, may not be used because the detection limits for these methods are 0.008 mg/L or higher. This restriction means that the two ICP–AES methods (EPA Method 200.7 and SM 3120 B) approved for use for the MCL of 0.05 mg/L may not be used for compliance determinations for the revised MCL of 0.01 mg/L. However, prior to 2005 systems may have compliance samples analyzed with these less sensitive methods.

* * * * *

(2) Sample collection for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite, selenium, and thallium under this section shall be conducted using the sample preservation, container, and maximum holding time procedures specified in the table below:

Contaminant	Preservative [1]	Container [2]	Time [3]
Arsenic	Conc HNO_3 to pH <2.	P or G	6 months

[1] For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time of collection. When chilling is indicated the sample must be shipped and stored at 4°C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2] P = plastic, hard or soft; G = glass, hard or soft.

[3] In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

* * * * *

(3) * * * To receive certification to conduct analyses for antimony, arsenic, asbestos, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, nitrate, nitrite and selenium and thallium, the laboratory must:

* * * * *

(ii) * * *

Contaminant	Acceptance limit
Arsenic	±30 at ≥0.003 mg/L

* * * * *

6. Amend § 141.24 by:

a. Adding a new sentence to the end of paragraph (f)(15) introductory text,

b. Revising paragraphs (f)(15)(i) and (f)(15)(ii) and adding new paragraphs (f)(15)(iii) through (f)(15)(v),

c. Adding paragraph (f)(22),

d. Adding a new sentence to the end of paragraph (h)(11) introductory text,

e. Revising paragraphs (h)(11)(i) and (h)(11)(ii) and adding new paragraphs (h)(11)(iii) through (h)(11)(v), and

f. Adding paragraph (h)(20).

The revisions and additions read as follows:

§ 141.24 Organic chemicals other than total trihalomethanes, sampling and analytical methods.

(f) * * *

(15) * * * If one sampling point is in violation of an MCL, the system is in violation of the MCL.

(i) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point.

(ii) Systems monitoring annually or less frequently whose sample result exceeds the MCL must begin quarterly sampling. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling.

(iii) If any sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately.

(iv) If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected.

(v) If a sample result is less than the detection limit, zero will be used to calculate the annual average.

* * * * *

(22) All new systems or systems that use a new source of water that begin operation after January 22, 2004 must demonstrate compliance with the MCL within a period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

* * * * *

(h) * * *

(11) * * * If one sampling point is in violation of an MCL, the system is in violation of the MCL.

(i) For systems monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point.

(ii) Systems monitoring annually or less frequently whose sample result exceeds the regulatory detection level as defined by paragraph (h)(18) of this section must begin quarterly sampling. The system will not be considered in violation of the MCL until it has completed one year of quarterly sampling.

(iii) If any sample result will cause the running annual average to exceed the MCL at any sampling point, the system is out of compliance with the MCL immediately.

(iv) If a system fails to collect the required number of samples, compliance will be based on the total number of samples collected.

(v) If a sample result is less than the detection limit, zero will be used to calculate the annual average.

* * * * *

(20) All new systems or systems that use a new source of water that begin operation after January 22, 2004 must demonstrate compliance with the MCL within a period of time specified by the State. The system must also comply with the initial sampling frequencies specified by the State to ensure a system can demonstrate compliance with the MCL. Routine and increased monitoring frequencies shall be conducted in accordance with the requirements in this section.

Subpart F—[Amended]

7. Amend the table in § 141.51(b) by adding a new entry for "Arsenic" in alphabetical order and adding a new endnote to read as follows:

§ 141.51 Maximum contaminant level goals for inorganic contaminants.

* * * * *

(b) * * *

Contaminant	MCLG (mg/L)
Arsenic	zero [1]

[1] This value for arsenic is effective January 23, 2006. Until then, there is no MCLG.

Subpart G—[Amended]

8. Amend § 141.60 by adding paragraph (b)(4) to read as follows:

§ 141.60 Effective dates.

* * * * *

(b) * * *

(4) The effective date for § 141.62(b)(16) is January 23, 2006.

9. Amend § 141.62 by:

a. Revising the first sentence of paragraph (b) introductory text,

b. Adding a new entry "(16)" for arsenic to the table in paragraph (b),

c. Adding a new entry for "Arsenic" in alphabetical order, adding new endnotes 4 and 5, adding a new item 12 and revising items 2 and 6 to list of "Key to BATs in Table" and revising the heading to the table in paragraph (c),

d. Adding paragraph (d).

The revisions and additions read as follows:

§ 141.62 Maximum Contaminant Levels for inorganic contaminants.

* * * * *

(b) The maximum contaminant levels for inorganic contaminants specified in

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paragraphs (b) (2)–(6), (b)(10), and (b)(11)–(16) of this section apply to community water systems and non-transient, non-community water systems. * * *

* * * * *

Contaminant	MCL (mg/L)
* * * * *	
(16) Arsenic	0.01

(c) * * *

BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(B)

Chemical Name	BAT(s)
* * *	* *
Arsenic[4]	1, 2, 5, 6, 7, 9, 12[5]
* * *	* *

[4] BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.
[5] To obtain high removals, iron to arsenic ratio must be at least 20:1.

Key to BATs in Table

1 = Activated Alumina
2 = Coagulation/Filtration (not BAT for systems < 500 service connections)
* * * * *
5 = Ion Exchange
6 = Lime Softening (not BAT for systems < 500 service connections)
7 = Reverse Osmosis
* * * * *
9 = Electrodialysis
* * * * *
12 = Oxidation/Filtration
* * * * *

(d) The Administrator, pursuant to section 1412 of the Act, hereby identifies in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for arsenic:

SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTs)[1] FOR ARSENIC[2]

Small system compliance technology	Affordable for listed small system categories[3]
Activated Alumina (centralized)	All size categories.
Activated Alumina (Point-of-Use)[4]	All size categories.
Coagulation/Filtration[5]	501–3,300, 3,301–10,000.
Coagulation-assisted Microfiltration	501–3,300, 3,301–10,000.
Electrodialysis reversal[6]	501–3,300, 3,301–10,000.
Enhanced coagulation/filtration	All size categories
Enhanced lime softening (pH> 10.5)	All size categories.
Ion Exchange	All size categories.
Lime Softening[5]	501–3,300, 3,301–10,000.
Oxidation/Filtration[7]	All size categories.
Reverse Osmosis (centralized)[6]	501–3,300, 3,301–10,000.
Reverse Osmosis (Point-of-Use)[4]	All size categories.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.
[2] SSCTs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.
[3] The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.
[4] When POU or POE devices are used for compliance, programs to ensure proper long-term operation, maintenance, and monitoring must be provided by the water system to ensure adequate performance.
[5] Unlikely to be installed solely for arsenic removal. May require pH adjustment to optimal range if high removals are needed.
[6] Technologies reject a large volume of water—may not be appropriate for areas where water quantity may be an issue.
[7] To obtain high removals, iron to arsenic ratio must be at least 20:1.

Subpart O—[Amended]

10. Amend § 141.154 by revising paragraph (b) and adding paragraph (f) to read as follows:

§ 141.154 Required additional health information.

* * * * *

(b) Ending in the report due by July 1, 2001, a system which detects arsenic at levels above 0.025 mg/L, but below the 0.05 mg/L, and beginning in the report due by July 1, 2002, a system that detects arsenic above 0.005 mg/L and up to and including 0.01 mg/L:

(1) Must include in its report a short informational statement about arsenic, using language such as: While your drinking water meets EPA's standard for arsenic, it does contain low levels of arsenic. EPA's standard balances the current understanding of arsenic's possible health effects against the costs of removing arsenic from drinking water. EPA continues to research the health effects of low levels of arsenic, which is a mineral known to cause cancer in humans at high concentrations and is linked to other health effects such as skin damage and circulatory problems.

(2) May write its own educational statement, but only in consultation with the Primacy Agency.

* * * * *

(f) Beginning in the report due by July 1, 2002 and ending January 22, 2006, a community water system that detects arsenic above 0.01 mg/L and up to and including 0.05 mg/L must include the arsenic health effects language prescribed by Appendix A to Subpart O.

11. Amend Appendix A to Subpart O by revising the entry for arsenic under "Inorganic contaminants:" and adding an endnote to read as follows:

Appendix A to Subpart O—Regulated Contaminants

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major Sources in drinking water	Health effects language
*	*	*	*	*	*	*
Inorganic contaminants:						
*	*	*	*	*	*	*
Arsenic (ppb)	[1]0.01	1000	[1]10	[1]0	Erosion of natural deposits; Runoff from orchards; Runoff from glass and electronics production wastes.	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
*	*	*	*	*	*	*

* * * * *

1. These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

Subpart Q—[Amended]

12. Amend Appendix A to Subpart Q by:

a. Revising the entry for "2. Arsenic" under "B. Inorganic Chemicals (IOCs)",

b. Redesignating endnotes 8 through 17 as endnotes 10 through 19 in the table and at the end of the table, and

c. Adding endnotes 8 and 9.

The revisions and additions read as follows:

Appendix A to Subpart Q—NPDWR Violations and Other Situations Requiring Public Notice [1]

Contaminant	MCL/MRDL/TT violations[2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * *	*	*	*	*
B. Inorganic Chemicals (IOCs).				
* * * *	*	*	*	*
2. Arsenic	2	[8]141.62(b)	3	[9]141.23(a), (c)
* * * *	*	*	*	*

Appendix A—Endnotes

1. Violations and other situations not listed in this table (e.g., reporting violations and failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

2. MCL–Maximum contaminant level, MRDL–Maximum residual disinfectant level, TT–Treatment technique.

* * * * *

8. The arsenic MCL citations are effective January 23, 2006. Until then, the citations are § 141.11(b) and § 141.23(n).

9. The arsenic Tier 3 violation MCL citations are effective January 23, 2006. Until then, the citations are § 141.23(a), (l).

* * * * *

13. Amend Appendix B to Subpart Q by:

a. Revising entry "9. Arsenic" under "C. Inorganic chemicals (IOCs)",

b. Redesignating endnotes 11 through 21 as endnotes 12 through 22 in the table and at the end of the table, and

c. Adding endnote 11.

The revisions and additions read as follows:

Appendix B to Subpart Q—Standard Health Effects Language for Public Notification

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
* * *	*	*	*
9. Arsenic[11]	0	0.01	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.

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Contaminant	MCLG [1] mg/L	MCL [2] mg/L	Standard health effects language for public notification
* * * * * * *			

Appendix B—Endnotes

1. MCLG–Maximum contaminant level goal.
2. MCL–Maximum contaminant level.

* * * * *

11. These arsenic values are effective January 23, 2006. Until then, the MCL is 0.05 mg/L and there is no MCLG.

* * * * *

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

1. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

Subpart B—[Amended]

2. Amend § 142.16 by revising paragraph (e) introductory text, reserving paragraph (i), and adding paragraphs (j) and (k) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(e) An application for approval of a State program revision which adopts the requirements specified in §§ 141.11, 141.23, 141.24, 141.32, 141.40, 141.61 and 141.62 for a newly regulated contaminant must contain the following (in addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that State regulations be at least as stringent as the federal requirements):

* * * * *

(i) [reserved]

(j) An application for approval of a State program revision which adopts the requirements specified in §§ 141.11, 141.23, 141.24, 141.32, 141.40, 141.61 and 141.62 for an existing regulated contaminant must contain the following (in addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that State regulations be at least as stringent as the federal requirements):

(1) If a State chooses to issue waivers from the monitoring requirements in §§ 141.23, 141.24, and 141.40, the State shall describe the procedures and criteria which it will use to review waiver applications and issue wavier determinations. The State shall provide the same information required in paragraph (e)(1)(i) and (ii) of this section. States may update their existing waiver criteria or use the requirements submitted under the National Primary Drinking Water Regulations for the inorganic and organic contaminants (i.e., Phase II/V rule) in 16(e) of this section. States may simply note in their application any revisions to existing waiver criteria or note that the same procedures to issue waivers will be used.

(2) A monitoring plan by which the State will ensure all systems complete the required monitoring by the regulatory deadlines. States may update their existing monitoring plan or use the same monitoring plan submitted under the National Primary Drinking Water Regulations for the inorganic and organic contaminants (i.e. Phase II/V rule) in 16(e) of this section. States may simply note in their application any revisions to an existing monitoring plan or note that the same monitoring plan will be used. The State must demonstrate that the monitoring plan is enforceable under State law.

(k) States establish the initial monitoring requirements for new systems and new sources. States must explain their initial monitoring schedules and how these monitoring schedules ensure that public water systems and sources comply with MCL's and monitoring requirements. States must also specify the time frame in which new systems will demonstrate compliance with the MCLs.

3. Amend the table in § 142.62(b) by adding a new entry for "Arsenic" in alphabetical order, adding new endnotes 4 and 5, adding a new item 12 to list of "Keys to BATs in Table" and revising the heading to the table in paragraph (b) to read as follows:

§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

* * * * *

(b) * * *

BAT FOR INORGANIC COMPOUNDS LISTED IN § 141.62(B)

Chemical name	BAT(s)
* * * * *	
Arsenic [4]	[5] 1, 2, 5, 6, 7, 9, 12
* * * * *	

[4] BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.
[5] To obtain high removals, iron to arsenic ratio must be at least 20:1.

* * * * *

Key to BATs in Table

1 = Activated Alumina
2 = Coagulation/Filtration (not BAT for systems < 500 service connections)
* * * * *
5 = Ion Exchange
6 = Lime Softening (not BAT for systems < 500 service connections)
7 = Reverse Osmosis
* * * * *
9 = Electrodialysis
* * * * *
12 = Oxidation/Filtration
* * * * *

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Federal Register

Monday,
January 22, 2001

Part IX

Department of the Interior

Bureau of Indian Affairs

25 CFR Part 15, et al.
Trust Management Reform: Leasing/ Permitting, Grazing, Probate and Funds Held in Trust; Final Rule

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Parts 15, 114, 115, 162 and 166

RIN 1076–AE00

Trust Management Reform: Leasing/Permitting, Grazing, Probate and Funds Held in Trust

AGENCY: Bureau of Indian Affairs.

ACTION: Final Rule.

SUMMARY: The Department of the Interior, Bureau of Indian Affairs (BIA), revises its regulations in the areas of probate, funds held in trust for Indian tribes and individual Indians, leasing/permitting, and grazing. These revisions are meant to further fulfill the Secretary's fiduciary responsibility to federally-recognized tribes and individual Indians. Particularly, revisions to the probate regulations institute necessary procedures to expedite the probate process for Indian decedents' estates. Revisions to regulations dealing with funds held in trust standardize the process for collecting, distributing, and accounting for individual Indian monies and monies held in trust for tribal governments. Revisions to leasing/permitting regulations implement the Indian Agricultural Resource Management Act and address appropriate procedures for entering into leases and permits on Indian lands and, more importantly, aid in properly determining and accounting for the value of such leases to individual land owners and tribal entities. Revisions in the grazing permit regulations address similar concerns and further standardize the process and forms utilized in granting permits on Indian lands. In the interests of economy of administration, and because all the revisions clarify and standardize Departmental policy, they are illustrated in one rulemaking vehicle.

EFFECTIVE DATE: March 23, 2001.

FOR FURTHER INFORMATION CONTACT: Duncan L. Brown, Department of the Interior, Office of the Secretary, 1849 C Street, NW., MS 7412 MIB, Washington, DC 20240, telephone 202/208–4582.

SUPPLEMENTARY INFORMATION:

I. Background
II. Response to Comments
III. Part-by-Part Analysis
IV. Procedural Requirements
A. Review Under Executive Order 12866
B. Review Under Executive Order 12988
C. Review Under the Regulatory Flexibility Act
D. Review Under Small Businesses Regulatory Enforcement Fairness Act of 1996
E. Review Under the Paperwork Reduction act
F. Review Under Executive Order 13132—Federalism
G. Review Under the National Environmental Policy Act
H. Review Under the Unfunded Mandates Reform Act of 1995

I. Background

Pursuant to the Department's "Trust Management Improvement Project—High Level Implementation Plan," certain parts within 25 CFR were identified for immediate revision. These parts were identified through an internal review by the Bureau of Indian Affairs (BIA) in consultation with the Office of the Special Trustee for American Indians (OST), and from tribal responses to consultations held in the field over a period of years. Additionally, non-governmental Indian organizations were consulted on areas of BIA trust management needing clarification and more uniform application of policy and administration throughout Indian Country. This rulemaking was initiated as an appropriate response to the Administration's stated goal of improving the administration and management of individual Indian and tribal trust resources. The Final Rule was developed with attention to Secretarial Order 3215, "Principles for the Discharge of the Secretary's Trust Responsibility," of April 28, 2000, which was converted to and made permanent in the Departmental Manual on October 31, 2000. See 303 DM 2.

The proposed regulation was published in the **Federal Register** on July 14, 2000, (65 FR 43874) with a 90-day public comment period. During the comment period, the BIA held eight formal tribal consultation sessions to discuss the proposed regulations and receive oral comments on the record. Additionally, the BIA met informally with the interested organizations, such as the policies and procedures working group formed with the National Congress of American Indians (NCAI) and the Inter-Tribal Agricultural Council, and encouraged them to provide written comments.

Comments were forwarded to a clearinghouse for compilation, and responses by the BIA to substantive comments are noted below. The comments and compilation documents were carefully reviewed by the regulation drafting teams, made up of BIA employees from central, regional and agency offices, and trust program attorneys from the Solicitor's Office. As noted in the part-by-part analysis below, in direct response to comments the regulations have been clarified and reorganized. Additionally, some sections have been deleted, while new provisions have been added to provide for increased clarity and precision. The regulations generally have been revised to afford greater recognition of tribal sovereignty and self-determination, as well as greater recognition of the inherent rights of the Indian landowners. Time frames for BIA or Departmental action have been added, as have provisions identifying the entity within the Department responsible for taking official action. Further, we have strengthened the provisions for the BIA's enforcement of leases and permits on trust and restricted lands, including collection of trust income. Further, we have revised and standardized the provisions in each part that address the creation and maintenance of trust records.

As we explain below in the part-by-part analysis, the passage of the Indian Land Consolidation Act Amendments of 2000, Public Law 106–462 (ILCA Amendments), extensively alters the legal framework governing activities on fractionated trust and restricted lands. As a result, at this time the Department will not issue new final regulations affecting business and residential leases. Such regulations will be re-proposed after the full impact of the ILCA Amendments is fully ascertained and more consultation with tribes is held.

Lastly, as explained more fully below, in order to accommodate many of the comments pertaining to Individual Indian Money (IIM) accounts, including supervised accounts and the use of IIM accounts to secure loans, the BIA will not issue final regulations in part 115 that would directly address these subjects. These provisions will be re-proposed for further comment and consultations.

To facilitate comparison between the Proposed Rule and the Final Rule, we have provided the following tables. Sections deleted from the Proposed Rule are denoted with asterisks (**) in the final regulation columns, and new sections added to the final regulations are denoted by their section numbers and a plus (+) sign in the column for final regulations.

25 CFR Part 15.—Probate of Indian Estates Except for Members of the Five Civilized Tribes

Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
.1	.1	.104	.106	.202	.202	.303	.303	.310	.310		+.405
.2	.2	.105	.104	.203	.203	.304	.304	.311	.311	.405	.403
.3	.3	.106	.105	.204	.206	.305	.305	.312	.312	.501	.501
.4	.4	.107	.107	.205	**	.306	.306	.401	.401	.502	.502
.101	.101	.108	.108	.206	.205	.307	.307	.402	.402	.503	**
.102	.102	.109	.109	.301	.301	.308	.308	.403	.403		+.503
.103	.103	.201	.201	.302	.302	.309	.309	.404	.404		+.504

25 CFR Part 115.—Trust Funds for Tribes and Individual Indians

Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
.1	.001	.208	.812	.311	**	.337	.502	.363	**	.389	**	.506	.607
.2	.002	.209	**	.312	**	.338	.503	.364	.418	.390	**	.507	.608
.100	.700	.210	.806	.313	**	.339	.504	.365	.413	.400	.900	.508	.609
.101	.701	.211	.814	.314	.409	.340	.403	.366	.428		+.400	.509	.610
.102	.103	.212	.818	.315	.416	.341	**	.367	.429	.401	.901	.510	.611
.102	.702	.213	.819	.316	**	.342	**	.368	.430		+.401	.511	.612
.103	.805	.214	.820	.317	**	.343	**	.369	**	.402	.902	.512	.613
.104	**	.215	.808	.318	**	.344	.422	.370	.431	.340	+.402	.513	.614
.105	**	.216	.809	.319	**	.345	.423	.371	**	.403	.903	.514	.615
.106	.703	.216	.813	.320	**	.346	.424	.372	**	.404	.904		+.606
.107	.705	.217	.810	.321	**	.347	.425	.373	**		+.406		+.616
.108	.706	.218	.811	.322	**	.348	.102	.374	**	.314	+.407	.515	.617
.109	.707	.219	.815	.323	**	.349	**	.375	**		+.408	.516	.618
.110	.708	.220	.816	.324	**	.350	**	.376	**		+.412	.517	.619
.111	.710	.221	.817	.325	**	.351	**	.377	**		+.414	.518	.620
.112	.711	.300	**	.326	**	.352	**	.378	**		+.419	.600	.107
.113	.712	.301	**	.327	**	.353	**	.379	**	.358	+.421	.700	.1000
.114	.713	.302	**	.328	.102	.354	**	.380	**		+.500	.701	**
.200	.800	.303	**	.329	.410	.355	**	.381	**	+.501	.702	.1001	
.201	.801	.304	.404	.330	.411	.356	**	.382	**		+.600	+.704	
.202	.802	.305	.709	.331	**	.357	.421	.383	**	.500	.601	.801	.105
.203	.803	.306	.405	.332	.415	.358	.420	.384	**	.501	**	.802	.106
.204	.709	.307	**	.333	**	.359	.417	.385	.104	.502	.602	.803	.100
.205	**	.308	**	.334	**	.360	.427	.386	**	.503	.603		.804
.206	**	.309	**	.335	**	.361	**	.387	**	.504	.604		+.807
.207	**	.310	**	.336	**	.362	**	.388	**	.505	.605		

Part 162.—Leases and Permits

Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
.1	.100	.23	.244	.42	.226	.83	**	.126	.252	.173	**
.1	.103	.24	.230	.43	.227	.84	**	.126	.619	.174	**
.2	.101	.25	.230	.44	.223	.85	**	.127	.240	.175	**
.3	.103	.26	.219	.45	.234	.86	**	.127	.612	.176	**
	+.105	.26	.220	.46	.234	.87	**		+.254	.177	**
	+.106	.26	.221	.47	.235	.88	**	.128	.255	.178	**
	+.107	.26	.223	.48	.236	.89	**		+.256	.179	**
.3	.200	.26	.231	.49	.236	.90	**	.129	**	.180	.111
.4	.108	.26	.238	.50	.236	.91	**	.130	.620	.180	.112
	+.109	.27	.229	.51	.237	.100	.226	.140	.102		+.300
.5	.202	.28	**	.52	.237	.101	.226	.141	**		+.400
.6	.203		+.231		+.239	.102	.110	.142	**	.190	.500
.7	.205	.29	.232	.60	**	.110	.228	.143	**	.191	.501
.8	.204	.30	.233	.61	**	.110	.241	.144	**	.192	.502
.9	.202	.31	.233	.62	.206	.111	.228	.145	**	.193	**
.10	**	.32	.224	.63	**	.111	.241	.146	**	.194	.503
.11	.201	.33	**	.64	.207	.112	.228	.147	.102	.195	**
.12	.214	.34	.224	.65	**	.112	.241	.150	.211		.601
.12	.215	.34	.613	.66	.207	.113	.228	.151	.211		.602
.13	.213	.35	.224	.66	.212	.113	.241	.152	.222		.603
.14	.217	.35	.247	.67	.104	.114	.228	.160	**		.604
.15	.217	.36	.248	.68	.104	.114	.241	.161	**		.605
.16	.217	.36	.615	.70	.102	.120	**	.162	**		.606
.17	.110	.37	.225	.70	.207	.121	.250	.163	**		.607

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PART 162.—LEASES AND PERMITS—Continued

Proposed	Final	Pro-posed	Final	Pro-posed	Final	Pro-posed	Final	Pro-posed	Final	Pro-posed	Final
.18	.218	.37	.249	.71	.208	.121	.617	.164	**	.....	.608
.19	**	.37	.614	.71	.209	.122	.251	.165	**	.....	.609
.20	.221	.37	.616	.72	.207	.122	.618	.166	**	.....	.610
.21	.230	.38	.248	.73	.210	.123	.251	.167	**	.....	.611
.21	.242	.38	.615	.74	.207	.123	.618	.168	**	.....	+.621
	.22	.230	.39	.224	.75	.216	.124	.251	.169	**	+.622
	+.243	.40	.224	.80	**	.124	.253	.170	**	.....	+.623
	+.245	.....	.....	.81	**	.125	.252	.171	**	.....	.....
.22	.246	.41	.226	.82	**	.125	.619	.172	**	.....	.....

25 CFR PART 166.—GRAZING PERMITS ON INDIAN LANDS

Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final	Proposed	Final
.1	.1	.122	.221	.....	+.308	.412	.418	.606	.607	.811	.811
	+.2	.123	.222	.206	.309	.413	.411	.607	.608	.812	.812
.2	.3	.124	.223	.207	.310	.414	.412	.700	.700	.813	.813
.100	.200	.125	.224	.208	.316	.415	.419	.701	.701	.814	.814
.101	.201	.126	.225	.209	.317	.416	.420	.....	+.702	.815	.815
.102	.203	.127	.226	.210	.311	.417	.414	.702	.703	.816	.816
.103	.204	.128	.1	.211	.312	.....	+.415	.703	.704	.817	.817
	+.205	.129	**	212	.313	.418	.413	.704	.706	.818	.818
.104	.202	.130	**	.....	+.314	.419	**	.705	.606	.819	.819
.105	.206	.131	**	.....	+.315	.420	.419	.706	.705	.900	**
.106	.207	.132	**	.300	.100	.421	.416	.707	**	.1000	.1000
.107	.208	.133	**	.301	.101	.422	.417	.....	+.707	.1000	.1001
.108	.209	.134	**	.302	.102	.....	.421	.708	.708	.1100	.900
.109	.209	.135	.1	.303	.103	.423	.422	.709	**	.1101	.901
.110	.209	.136	.227	.304	.104	.424	.423	.....	+.709	.1102	.902
.111	.212	.137	.228	.400	.400	.425	.424	.800	.800	.1103	.903
.112	.213	.138	.229	.401	.401	.500	.500	.801	.801	.1104	.904
.113	.214	.....	+.230	.402	.402	.501	.501	.802	.802	.1105	.905
.114	.210	.....	+.231	.403	.403	.502	.502	.803	.803	.1106	.906
	+.211	.200	.300	.404	.404	.503	.503	.804	.804	.1107	.907
.115	.215	.201	.301	.405	.405	.504	.504	.805	**	.1108	.908
.116	.216	.202	.302	.406	.406	.600	.600	.....	+.805	.1109	.909
.117	.217	.203	.303	.407	.407	.601	.601	.806	.806	.1110	.910
.118	.218	.....	+.304	.408	.309	.602	.602	.807	.807	.....	.....
.119	.219	.204	.305	.409	.408	.603	.603	.808	.808	.....	.....
.120	.220	.....	+.306	.410	.409	.604	.604	.809	.809	.....	.....
.121	**	.205	.307	.411	.410	.605	.605	.810	.810	.....	.....

II. Response to Comments

The Department solicited comments from all interested parties through its publication of the Proposed Rule on July 14, 2000, and further solicited informal comments through eight regional consultation sessions: Aberdeen, SD (August 7–8, 2000); Anchorage, AK (August 10, 2000); Oklahoma City, OK (August 10, 2000); Bloomington, MN (August 17, 2000); Albuquerque, NM (August 21 and 22, 2000) [two separate consultation meetings]; Billings, MT (August 24, 2000); and Reno, NV (August 28–29, 2000). Transcripts were made of these sessions in order to ensure that both oral and written comments were considered. Following the consultation meetings, several BIA regional and agency offices established informal local working groups with tribes to encourage discussion of the proposed regulations and submission of written comments. Throughout the comment period we met on an informal basis to discuss the regulations with interested organizations, including the NCAI working group and the Inter-Tribal Agricultural Council.

The Department received a total of 317 written comments on all parts of the proposed rulemaking, representing 349 individual signatures. Written responses were received from respondents in 25 states, although many responses were received in a format that did not reveal their geographic origin. The Department received 159 written responses from tribal governments (representing 168 signatures and including four tribal government resolutions), and 31 responses from non-governmental Indian organizations (representing 34 signatures). Six respondents identified themselves as tribal members. Additionally, one response was received from a state governmental entity, and five from business entities. The remaining respondents included unaffiliated individuals (57 responses) and federal agencies (58 responses, representing 78 individual signatures). All substantive comments were reviewed by the Department and, depending upon their merit, the Department accepted, accepted with revision, or rejected for reason particular comments made on each part of the rule. Substantive comments are summarized below.

A. General Comments—Overall Rulemaking

Many tribes, tribal organizations and individuals expressed strong opinions that the Department should not finalize these regulations as planned. Primarily, respondents expressed concern that the process by which the regulations were developed did not include sufficient time to analyze the scope of the regulations and identify and resolve issues, nor did it incorporate sufficient consultation with tribes and affected individuals. The regulations were proposed only after full communication of the Department's intentions after requesting information and opinions from the tribes and individual Indians affected by the regulations.

The Department has committed to this schedule in response to the tremendous need to improve the execution of the Secretary's trust responsibility in accordance with the American Indian Trust Fund Management Reform Act, 25 U.S.C. § 4001 *et seq.* We have committed to this schedule through the Department's High Level Implementation Plan, developed in cooperation with and under the oversight of the OST, and in response to ongoing litigation.

Well before the proposed regulations were published in the **Federal Register**, the Department recognized the need to complete these revisions prior to the end of the current Administration in order to prevent delays caused by the upcoming presidential transition. Based on priorities identified by BIA trust program staff, we identified the regulatory reforms that could be accomplished within this time frame and developed a schedule that would ensure consultation with tribes and consideration of their opinions to the greatest extent possible. We invited the NCAI to convene a work group of tribal representatives and other interested persons to assist in developing the regulations. To assist the NCAI, the BIA provided funding and agreed to meet as many times as necessary to complete the job. Also, we conducted early consultations with tribal leaders, advising them of the specific trust regulations to be addressed first. These meetings provided an early opportunity for meaningful input into the rule making process.

In a significant departure from past practice, the BIA distributed the preliminary drafts of the proposed regulations to the NCAI and to tribes through BIA regional directors, with a request for comments and recommendations. Several subsequent meetings were held with the NCAI working group to discuss the evolving draft regulations prior to publishing the proposed regulations on July 14, 2000. These meetings included the Assistant Secretary—Indian Affairs, the Deputy Commissioner of Indian Affairs, staff of the Trust Policies and Procedures (TPP) project, trust program managers, and trust program attorneys from the Solicitor's Office. Notably, tribal representatives from each BIA region and BIA managers participated in a three-day meeting in Mesa, AZ, in April 2000, to discuss the draft regulations.

Following the publication of the proposed rules, as noted above TPP staff conducted eight regional consultation meetings with tribal leaders, individual Indians, and other interested parties. In sum, despite the accelerated schedule for developing and issuing these regulations, tribes and individual Indians have had an extraordinary opportunity to provide meaningful input on the proposed regulations through informal consultations on the early drafts, formal consultations, and the public comment period.

Many respondents asserted that Executive Order 13084 required a negotiated rule-making process in developing and implementing the proposed regulations. Contrary to these assertions, Executive Order 13084 does not require a negotiated rule-making process.

We disagree with the concern expressed by several respondents that the proposed rules would create new processes and requirements in all areas of trust management, resulting in negative impacts to both tribes and individual Indians. Rather, these regulations strengthen the Department's exercise of its trust responsibility by codifying current practices and will provide an important measure of consistency and uniformity in these practices on a nationwide basis.

Many commenters believe that the proposed regulations did not sufficiently address the issues of tribal sovereignty and principles of tribal self-determination. We agree that the proposed regulations did not go far enough to recognize tribal sovereignty and self-determination, and have now made significant revisions within the bounds of existing law. However, many of the antiquated trust statutes that govern the actions of the Department predate the tribal self-determination legislation. When amendatory legislation is enacted, we will revise the regulations accordingly.

The management of trust records is integral to the performance of the trust responsibility, and must be carried out by all entities and individuals who undertake such activities, including tribes performing federal trust functions. It is essential that everyone managing trust assets, both tribes and the Department, be subject to the same requirements for the creation, maintenance, and retention of records that evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the management of trust assets. Without a consistent nationwide system for creating and maintaining trust records, the United States will be unable to fulfill its trust responsibilities to tribes or individual Indians. Accordingly, the records language in the proposed regulations have been modified to be consistent across the board.

Of particular importance are the provisions in each part that specify who owns trust records: Records are the property of the United States if they are made or received by a tribe or tribal organization in the conduct of a federal trust function under this part pursuant to Public Law 93–638 as amended, including the operation of a trust program, and evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under the regulations. If records are not covered by the preceding definition, but are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior, they are the property of the tribe. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under these regulations, the tribe may be prevented from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

The language is consistent in each part of the final regulations, and builds on the provisions that were proposed under part 115. The Department will provide more detailed direction on the management of trust records in 2001.

Finally, we received comments requesting that the Department include in the regulations provisions for the establishment and maintenance of an accounts receivable system. The Department is building such a system in its Trust Asset and Accounting Management System. However, we believe the regulations are not an appropriate place to address an accounts receivable system; to define such a system by regulation would remove operational flexibility that is necessary to address the many complex factors involved in managing trust assets.

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III. Part-by-Part Analysis

A. 25 CFR Part 15—Probate of Indian Estates

The purpose of this regulation is to describe the authorities, policies and procedures the BIA uses to probate an Indian decedent's estate. This is a revision to the existing part and amends and replaces the part in its entirety.

The regulation implements administrative procedures by which the BIA will process and determine certain probate cases where a hearing is not required nor requested. These procedures, embodying a return to the BIA of the responsibility to determine particular probate cases, are the result of the recommendations of the Department's Indian Probate Reinvention Lab (IPRL). Formed in 1999, the IPRL examined the Department's Indian probate process from a multi-agency perspective, including the BIA, the Office of Hearings and Appeals (OHA), which handles Indian probate cases requiring hearings, and the OST. The IPRL recommended, among other things, that the BIA establish attorney decision-makers at regional offices to handle certain probate cases under criteria to be established by regulation. This recommendation was based on an analysis that included reviewing reports from previous studies of Indian probate matters, site visits and interviews of customers and employees. The final revisions of part 15 will implement in the BIA the procedural aspects of the IPRL's recommendations. At the appropriate time, the OHA will amend its regulations to accommodate the BIA's responsibility for these probate cases and to ensure that the same standards and criteria for determining heirs and paying claims are consistently applied between the BIA and OHA.

In addition to establishing the process by which the attorney decision makers in the BIA will decide certain probate cases, the regulations in part 15 also address the summary processing of Indian estates. Formerly handled only by agency superintendents, summary distribution of estates will also be decided by the attorney decision makers. See 65 FR 25449–25450 (May 2, 2000).

The various subparts of part 15 address the purpose and scope of the Indian probate procedures; the definition of terms; the mechanics of initiating the probate process, including the appropriate notifications of the selection of the deciding official; the preparation of the probate package itself, including the identification of necessary documents to facilitate a timely process; the disposition of claims against an estate; the ultimate distribution of the decedent's assets to the determined heirs or devisees; and the procedures for appeals should a dispute arise during any stage of the probate process. Cross references have been made to the OHA's hearings and appellate procedures and disposition of funds held in trust for decedents.

General Observations Regarding Changes From Proposed Rule

Overall, respondents commended the Department for its efforts to address a longstanding problem with the probate backlog primarily caused by a lack of staffing and resources over the years. Commenters focused on the need for devising specific time frames for each step of the probate process to ensure timely processing of the estates including the preparation and submission of the probate package, issuance of decisions, and the closing of estates. A primary concern for many commenters in adding a new BIA deciding official to expedite the probate process was that probable heirs or beneficiaries should be advised of the right to a hearing before an ALJ. These concerns were given great consideration and incorporated into the final regulations.

Finally, to be consistent with the regulations published under parts 115, 162 and 166, we have added two sections addressing the maintenance of records relating to probate cases.

Subpart A—Introduction

Summary of Subpart

This subpart addresses the purpose and scope of the Indian probate procedures, the definition of terms used in part 15, and process for probating estates. This subpart sets forth the limitation on the scope of the application of part 15 to the Five Civilized Tribes in Oklahoma and the Osage Nation. The overall process from notification of death to the appeal of decisions is described by reference to other subparts.

Comments

The Secretary's jurisdiction to decide probate cases is limited to trust or restricted assets except as otherwise provided by federal laws for the Five Civilized Tribes and the Osage Nation. The Final Rule clarifies that trust lands of the Five Civilized Tribes and Osage Nation may be included in part 15. Several respondents requested more clarification of terms used in the regulations. In response to these requests, the definitions "OTFM," "probate clerk," "trust land" and "restricted land" have been added to § 15.2.

The Final Rule does not significantly depart from the Proposed Rule with respect to the basic steps in the probate process and the preparation of the probate package. In response to several comments, the steps in the probate process prior to the submission to a deciding official have been standardized and streamlined by requiring that all agencies and tribes prepare the probate package in the same manner as recommended by the IPRL. The final regulations reflect the addition of the attorney decision maker as a BIA deciding official to expedite the probate of estates in certain circumstances.

Subpart B—Starting the Probate Process

Summary of Subpart

This subpart includes the procedures for starting the probate process by notifying the BIA of the death of an Indian with trust or restricted assets; the preparation of the probate package itself, including the identification, collection, and submission of the necessary documents to the BIA to facilitate the timely processing of a probate package; the circumstances in which the family of a decedent may apply for emergency assistance for funeral arrangements; the assignment of the responsibility to the BIA agency to process the package; and the procedures for the potential heirs' disclaimer of interest in the estate.

Comments

We received several comments on the types of documents that should be acceptable as evidentiary documents to support the family heirship data. Of significant importance to these respondents is the reliability of documentation relied on for proof of death. In the Final Rule at § 15.101, we have clarified the documents necessary to prove death by requiring that a certified copy of a death certificate must be provided to the BIA. Only in circumstances where a death certificate is non-existent will the BIA accept other documents. This section also allows for a tribe to verify a member's death. Where evidence other than a death certificate is submitted to verify a death, an affidavit of death must be submitted that is prepared by the tribe with whom the decedent associated or someone with direct personal knowledge about the decedent's death.

Many comments addressed the provision that allows immediate assistance for funeral services from the decedent's IIM account. To distinguish between emergency financial assistance to pay for funeral arrangements prior to the burial of the decedent and claims for funeral expenses against the decedent's estate, we added the word "emergency" to the question. Some commenters objected to obtaining receipts for traditional burial services such as payment of cooks and grave-diggers and the direct payment to the service providers. We weighed these objections against the Secretary's trust responsibility for proper accounting of the decedent's IIM account. Thus, we renumbered the section to § 15.106 and divided it into four subparts to clarify the cost estimates for funeral arrangements and to achieve a compromise position between tribal traditions and the Secretary's trust responsibility to preserve the decedent's IIM account for the probable heirs and beneficiaries. In order to preserve the trust estate for probable heirs or beneficiaries, the BIA continues its long-standing practice of limiting the amount of money that may be distributed for funeral expenses prior to completion of the probate. Therefore, the Final Rule does not change the limit on the amount of money that can be disbursed for funeral expenses prior to the probate.

One of the problems causing significant delays in the processing of probate files is the time-intensive gathering of evidence required as supporting documents for the probate package. In certain situations where the decedent's family resides in a remote area without transportation or telephonic communications, the collection of documents proceeds very slowly. Some respondents stated that the BIA should assume an affirmative role in assisting the family in collecting documents, rather than place the burden of obtaining all of the supporting documents entirely on the decedent's family. We accepted these comments, and have changed the wording in the Final Rule at § 15.104 from "must" to "should."

Section 15.104 lists the documents that must be included in a probate package. This section has been rearranged to provide for documents that must be obtained from a court of competent jurisdiction, which may be a tribal or state court. Name changes and orders requiring the payment of child support were added at the suggestion of the commenters. The Final Rule at § 15.104 also provides that the probate package will contain all information provided by an interested party whether the BIA has requested it or not.

We received several suggestions on the manner in which an agency or tribe is assigned the responsibility for preparing probate packages for non-enrolled decedents and decedents enrolled in more than one tribe. The proposed standard was the agency that has jurisdiction over the trust property of the decedent or the greater amount of trust property. Respondents suggested that we assign responsibility to the agency with the strongest contacts with the decedent and/or the agency where the IIM account is located. The existing BIA policy which assigns the probate to the agency with the strongest association with the decedent has been incorporated in the Final Rule at § 15.108. The most expedient manner for processing the probate package is to maintain contact with a family member of the decedent who has lived nearby the decedent and is familiar with the family relationships of the decedent. This standard was continued because a decedent may reside within the jurisdiction or have more contacts with an agency that does not necessarily have jurisdiction over the greatest amount of the decedent's trust property. The likelihood of an agency or tribe obtaining the most information about the decedent comes from an agency with the strongest associations with the decedent.

While § 15.202(g) allows the submission of a disclaimer of interest to be filed with the probate order, the Final Rule at § 15.109 provides that the probable heir or beneficiary may renounce their interest anytime up to the time a deciding official issues an order. The final regulation also incorporates the existing requirement in 43 CFR Part 4, Subpart D, that a disclaimer of any Indian interest requires a formal hearing before an ALJ.

Subpart C—Preparing the Probate Package

Summary of Subpart

This subpart addresses the requisite documents that must be contained in a complete probate package; the selection of the deciding official and notice of this decision to the interested parties; the contents of the notice; the identification of the processing times; the right of the interested parties to request a formal hearing with an ALJ; the circumstances under which the BIA will refer a probate package to an ALJ; and the procedures for the summary distribution of an estate containing only trust cash assets of less than $5,000.

Comments

We have revised this section to address similar comments on the selection of the BIA or OHA deciding official, and the notice of this selection. Incorporating many of the comments received, we provide in the Final Rule a more comprehensive notice scheme that identifies the probable intestate heirs; states whether a will has been submitted and provides a copy; and states whether any claims have been filed against the estate. In response to several comments, a new section at § 15.204 has been added to clarify that the probable heirs or beneficiaries may request a hearing before an ALJ at any time before a decision has been made by an attorney decision maker.

Many commenters were concerned over the clarity of the criteria used by the probate specialist to weigh in determining where to send the probate package. In response, we have added several new items in § 15.205(c) to clarify the circumstances under which the probate package should be sent to an ALJ and to provide consistency with other sections. These items include questions involving paternity, disclaimers of interest by an Indian heir or beneficiary, and any challenges to the jurisdiction of a court that has issued an order which has been used as a supporting document in the probate. A new subsection (d) has been added to clarify that approval of settlement agreements among heirs must be by the OHA. To address the concern that a probate specialist may not foresee all of the kinds of problems identified in § 15.205, the attorney decision maker must review the probate package and determine whether there are any issues of fact or law that would require a formal hearing. If so, then the attorney decision maker will immediately forward the case to the appropriate ALJ.

In response to several requests for more clarity, the process for summary distribution has been reorganized and placed at the end of this subpart. The summary process provides that the BIA deciding officials (the superintendent, field representative, regional director in cases of self-governance tribes, or attorney decision maker) may decide cases that contain only trust cash assets of less than $5,000. Relocating this section clarifies that the criteria for selecting the deciding official applies to the expedited intestate and testate summary distribution process. Section 15.206 provides for 30 days for the probable heirs and beneficiaries to request a formal hearing before an ALJ; 60 days after notice has been sent for the BIA deciding official to assemble the probable heirs or beneficiaries and conduct an informal hearing; and 30 days for the BIA deciding official to issue a decision after the informal hearing. Under § 15.206(c), the BIA

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deciding official must apply §§ 15.302–311 to determine the distribution of the Indian estate. As recommended, the incorporation of these sections in the summary distribution process ensures that the same standards will be applied on a national scale by every BIA deciding official. Lastly, many respondents stated that they were confused by the differing appeal procedures of the decision of the superintendent and the attorney decision maker, and that the same appellate process should be in place for all BIA deciding officials. The Final Rule incorporates in § 15.206(d) a single appellate process for all BIA deciding officials.

Subpart D—Probate Processing, Claims and Distributions

Summary of Subpart

This subpart states when the BIA must forward the probate package to an ALJ for a formal hearing or to an attorney decision maker for an informal hearing. The choice of law to be applied to the facts of the Indian estate is defined to standardize the deciding official's application of law. This subpart also includes the process for submitting claims against the estate; allowance and payment of claims; priority of claims; reduction of claims; use of future income to pay claims; the payment of interest; the contents of the BIA deciding official's written decision/order; and the handling of the estate while an appeal is pending.

Comments

Numerous respondents requested that we clarify time frames and deadlines that the public and BIA must follow. Accordingly, § 15.301 imposes deadlines on the attorney decision maker for the regular processing of probate packages. The comments strongly recommend that if the attorney decision maker keeps the probate package, the attorney decision maker should hold informal hearings or conferences with the interested parties to identify any potential problems, will contests, or contested claims, which may prompt a formal hearing with an ALJ. Additionally, several commenters expressed a concern that the attorney decision maker should hold an informal hearing because many traditional Indian people may not feel comfortable or wish to make a written objection or request a formal hearing. We have accepted these comments. The Final Rule at § 15.301 incorporates the informal hearing procedure for all probate proceedings in the same manner as the existing regulations at 43 CFR 4.271.

Additional deadlines for the attorney decision maker have been incorporated in § 15.301 and § 15.310 to conduct an informal hearing and issue a decision. As many comments recommended, we will allow up to 180 days for an attorney decision maker to issue a decision.

The comments provide considerable discussion of what law is to be applied to determine heirs, approve wills, and determine whether or how to pay claims. Some tribes suggested that the Uniform Probate Code, a code adopted in portion by many states, be used on a national basis. Other tribes suggested that tribal law and tribal courts administer the Secretary's trust responsibility for the probate of Indian estates. Questions were raised about how conflicting intestate processes and land fractionation would be reconciled under tribal and state laws. Some commenters objected to the application of the inheritance laws of all fifty states. Others suggested that the law to be applied should be the law of the state where the IIM account is located. Some commenters stressed that there are also federal statutes that direct inheritance procedures in certain circumstances (e.g., Indian Land Consolidation Act) or for specific tribes (e.g., Standing Rock Sioux Tribe), and that the application of state probate law has been preempted in these circumstances. In addition to the statutory inheritance laws, many noted that the Secretary has approved tribal inheritance codes for several tribes.

These comments were considered in great depth. The Final Rule in § 15.302 continues the existing practice by acknowledging that, unless provided otherwise by federal law or by tribal inheritance codes approved by the Secretary, the state law of the decedent's domicile will determine the distribution of the estate.

There were nearly equal numbers of comments for and against the payment of any claims against an Indian decedent's estate. In particular, many were concerned that credit may not be extended if claims were precluded from Indian estates. The respondents opposing the allowance of any claims against the estate stated that in intestate situations an Indian decedent has not authorized any claims to be paid and that the assets of the estate rightfully belong to the heirs. Some tribes commented that the BIA should defer to any tribal law that addresses the filing and collection of creditors' claims. To the extent such requirements are included in a tribal inheritance code approved by the Secretary, the tribal laws will apply. Several commenters felt that trust assets should be used to pay debts only when there are no non-trust assets available. The Final Rule in § 15.303 allows the payment of claims out of trust cash assets only after evidence of exhaustion or non-existence of non-trust assets have been provided by the claimant.

Many respondents were concerned about the standards to be applied by the deciding officials in paying claims, as well as the priority of claims to be paid. Many stated that tribal claims should be a priority claim because tribes are generally the major creditor on Indian reservations. Many were concerned that failure to pay tribal loans by the estate would dramatically reduce the availability of credit to Indians. Several comments also stated that claims reduced to judgment in a court of competent jurisdiction should also be a priority. The Final Rule at § 15.305 incorporates both of these claims as priorities.

Comments from tribes and tribal advocates stated that the inclusion of the United States' claims as priority claim confers an economic benefit on the trustee that is inconsistent with its fiduciary duty. We agree. The trustee is obligated to preserve the estate for the benefit of the heirs and beneficiaries, and permitting the federal trustee to reach into the Indian trust corpus and seize property for his own benefit raises a serious conflict of interest and is inconsistent with fundamental principles of trust law. After serious consideration of the United States' role as trustee in light of potentially conflicting statutory provisions for collection of debts owed to the United States, we have deleted claims of the United States as a priority claimant against trust estates in § 15.305.

In response to many concerns that there was no provision for prorating general claims, the Final Rule at § 15.306 adds separate authority for the BIA deciding official to reduce or disallow both priority and general claims.

The BIA proposed to allow estates to remain open up to five years to pay creditors of the estate. In comparison, the current regulations at 43 CFR 4.251(d) allow an estate to remain open up to seven years. The majority of the commenters, however, objected to holding estates open for the payment of any claims, regardless of priority or general claims. Commenters stated that the United States, as trustee, has placed the creditors of Indian individuals in a better position than creditors of other non-Indian citizens by holding the estates open to pay creditor claims. After serious consideration and the weighing of comments, the Final Rule deletes the proposed section that holds estates open to pay claims.

We received comments both in favor of and against the suspension of interest that may accumulate on a claim against the estate before it is paid. Comments favoring the payment of interest stated that non-payment would create another road block to an Indian's ability to obtain credit. Comments opposed to paying interest stated that the estate should be preserved for the heirs. The Final Rule at § 15.309 leaves in place the Proposed Rule declining to pay interest or penalties on any type of claim that may accrue after the decedent's death.

The Proposed Rule in § 15.310 addressed the responsibility of the administrator of the estate to file tax returns. Many commenters noted an administrator is not generally appointed for Indian estates. Many also noted that the Secretary, as trustee, is the functional equivalent of the administrator of the estate and therefore the heirs should consult applicable tax laws to determine if there is any tax liability related to the estate. In response to these comments, this section was deleted in its entirety.

Finally, many respondents stated that the official roles of the BIA and the OTFM should be specifically defined in executing probate cases decisions, including the distribution of income. In response, the Final Rule at § 15.312 provides that in executing probate decisions, the BIA changes land title records as appropriate and the OTFM processes payments from IIM accounts and the distributes income in accordance with the probate decision.

Subpart E—Appeals

Summary of Subpart

This subpart addresses the procedures for appeal of the decision of the BIA deciding official. The time for appeal, the status of the estate during appeal, and the standard of review of the decision are set forth in this subpart.

Comments

Many respondents stated that it was too confusing to have two separate appellate processes for the superintendents and attorney decision makers. Two separate procedures might result in the interested parties filing an appeal with the wrong entity, which would adversely affect the exercise of their right to appeal. The Final Rule incorporates this recommendation and establishes only one route of appeal for probate decisions issued by BIA deciding officials.

One commenter questioned the definition of "known evidence" in appeal proceedings. Further, the commenter was concerned that the right to appeal the decision of an attorney decision maker during the 60–day appeal period would not allow for the submission of new evidence, nor would it allow an appeal on the basis that known evidence was not included in the probate package. After careful consideration, the Final Rule at § 15.403(b)(1) and (2) includes clarified provisions for requesting after-deadline appeals based on new or unknown evidence.

Commenters suggested that the regulations specify that review of decisions of the attorney decision makers should be *de novo*. Due to the expedited procedure, informal hearing process, and absence of a full record to review, we accept this comment. The Final Rule at § 15.405 adds a new section for the *de novo* standard of review before the ALJ.

Subpart F—Information and Records

Summary of Subpart

This subpart includes general questions regarding *ex parte* communications with a BIA deciding official and the contact persons for inquiries about the status of a probate case, and new provisions addressing applicable records ownership and retention requirements.

Comments

We received several comments on the proposal that members of the public could not directly contact the attorney decision makers. The commenters generally recognized that there is clearly a need to avoid even the appearance of impropriety, but that trained adjudicative personnel understand and know the constraints of their offices. One commenter stated that no similar restriction is imposed upon agency superintendents who decide summary distributions. Other responses emphasized the need for the BIA to ensure that attorney decision makers are independent and impartial. After weighing these competing interests, we provide in the Final Rule at § 15.501 a single standard for all BIA deciding officials that precludes off-the-record communications with the attorney decision maker that might be construed as attempting to influence the substance of the final probate decision.

The comments suggested that references to the nationwide tracking system be deleted as the system was not in place and there is no date certain when the system would be in place. We agree. In the Final Rule we have deleted the references to the nationwide tracking system.

B. 25 CFR Part 114—Special Deposits

The purpose of this part was to set forth the conditions governing the deposit, investment, and distribution of principal and interest on trust funds held by the Department in special deposit accounts. In addition, this part provided procedures required for determination of ownership and distribution of funds which are on deposit in account 14X6703, "Indian Moneys Proceeds of Labor Escrow Account—Pending Determination of Ownership." This special deposit account (IMPL Escrow Account) has been obsolete since September 30, 1987, as any unobligated balances were then deposited into miscellaneous receipts of the U.S. Treasury. Since this part dealt largely with this IMPL Escrow Account, the text of this part has been deleted in its entirety. Those provisions concerning other "special deposit accounts" are now referenced and explained in the newly revised part 115. It was the decision of the Department to move those provisions to part 115 because that part deals specifically with tribal and individual Indian trust funds. Part 114, therefore, has been "reserved."

Comments

No comments were received on the deletion of part 114 and its subsequent reservation within 25 CFR.

C. 25 CFR 115—Trust Funds for Tribes and Individual Indians

The purpose of this regulation is to describe how the Secretary, primarily through the BIA and the Office of Trust Funds Management (OTFM) within the Office of the Special Trustee (OST), carries out the trust duties owed to tribes and individual Indians in managing and administering trust assets for the exclusive benefit of tribes and individual Indian beneficiaries. The regulation also implements provisions of the American Indian Trust Fund Management Reform Act of 1994, Pub. L. 103–412, 108 Stat. 4239, 25 U.S.C. 4001 (Trust Reform Act). The Final Rule removes and reserves the existing part 114 (special deposit account provisions are incorporated into part 115) and amends and replaces part 115 in its entirety.

As the section-by-section chart above illustrates, there have been changes to the Final Rule from the Proposed Rule of July 14, 2000. These changes are, however, reasonably limited by the decision by the BIA to remove those proposed provisions that relate to Individual Indian Money (IIM) accounts

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for adults and to continue in large part with the language in the current 25 CFR 115 that addresses adult IIM accounts. This action was taken in response to the many comments received from tribes and individual Indians who were concerned with the rule's proposed supervised and encumbered IIM account provisions. In order to incorporate many of the recommendations, we believe that the Administrative Procedures Act requires that we re-propose those sections of the regulation for further public comment. Therefore, most of those sections included in subpart D of the proposed rule have been removed from the Final Rule, and will be re-proposed at a later time. The IIM account sections proposed for minors and estate accounts have been retained in the Final Rule. These sections have been amended or clarified to reflect many of the comments received. We have responded to the comment that suggested the Final Rule identify the responsibilities of OTFM and the BIA in managing and accounting for Indian trust funds, by specifying, where possible, whether OTFM or the BIA has the responsibility for an action. For more specific delegations of Secretarial authority regarding trust responsibility, we encourage interested parties to look on our web page at www.doi.gov. With respect to the numerous comments requesting language concerning how we will collect trust revenue, we refer you to parts 162 and 166.

Subpart A—Purpose, Definitions and Public Information

Summary of Subpart

Subpart A addresses the purpose of the regulation in providing guidance for the administration and management of tribal and IIM trust accounts. Additionally, definitions and common terms used throughout the subpart are explained in some detail.

Comments

Comments were received that encouraged the BIA to look to private sector trust management systems as a model for the Department's trust management system. Respondents also requested that the BIA designate a position of ultimate responsibility for the administration of trust property. The Secretary has the ultimate responsibility for the administration of trust property and a system of trust management is already in place with oversight provided by the Special Trustee as designated in the Trust Fund Reform Act. Comments received regarding the addition of more terms or clarification of definitions were accepted with more detail where appropriate, e.g., trust resources and legal disability. There were numerous calls seeking clarification of the definition of an "adult in need of assistance" while others strongly objected to the requirement of a court order as the only method to allow supervision of an account. Those comments were accepted in part and the definition of "adult in need of assistance" was amended to allow a determination either (a) through a BIA administrative process that is based on a finding by a licensed medical professional or licensed mental health professional, or (b) by an order or judgment of a court of competent jurisdiction. The determination must include language that the individual is "incapable of managing or administering his or her property, including his or her financial affairs."

Subpart B—IIM Accounts

Summary of Subpart

As discussed above, the proposed rule had sections regarding adult IIM accounts that will require re-proposal of these provisions before we can issue a Final Rule. In the development of the provisions to be re-proposed, we will take into consideration comments received during the July 14–October 12, 2000 comment period. Subpart B of the Final Rule is largely the verbatim illustration of part 115 as it currently reads in 25 CFR. This subpart deals with specific provisions for particular tribes (Five Civilized Tribes and the Agua Caliente Band of Missions Indians); adults under legal disability; payment by other Federal agencies; restrictions; and appeals. However, provisions dealing with minors' accounts, estate accounts and the hearing process for restricting an IIM account (which were regulated in the current part 115) have been revised in accordance with the proposed rule and moved to the new subparts C, D, and E of part 115 of the Final Rule. In addition, provisions dealing with voluntary deposits and purchase orders (which were regulated in the current part 115) have been removed in accordance with the proposed rule and those sections are reserved for future use.

Comments

Comments on the Proposed Rule generally concerned the supervised account and encumbered account sections of the proposal. In particular, the respondents focused on the requirement of an order from a court of competent jurisdiction in order for the BIA to (1) supervise an IIM account or (2) encumber an IIM account to pay a debt to a third party. We plan to re-propose these sections. In the interim, to maintain some standard for dealing with adult IIM accounts (which is an ongoing BIA function), the BIA decided to retain the sections concerning adult IIM accounts in the current part 115 in this subpart B. The one change that was made in the Final Rule that affects the provisions retained from the current part 115 is the addition of a definition for an "adult in need of assistance" which has been revised from the proposed rule as discussed in the comment section of the Subpart A discussion above.

Subpart C—IIM Accounts: Minors

Summary of Subpart

This subpart deals in some detail with the procedures related to the management and supervision of a minor's account. A withdrawal from a minor's supervised account will be permitted only under a BIA approved distribution plan that provides for expenditures directly related to the minor's health, education, or welfare. A custodial parent, a legal guardian or a person who the BIA recognizes as having the control and custody of the minor, who withdraws funds from a minor's supervised account on behalf of the minor must account to the BIA with receipts for the use of those funds. The minor will not have access to information concerning his/her account. Procedurally, the provisions state that information about a minor's account will be provided to the custodial parent(s) or legal guardian(s) in a quarterly statement of performance; supervised accounts will be reviewed annually; and emancipated minors will have supervised accounts but will have access to account information and may receive funds on their own behalf.

Comments

One comment noted that the BIA should not require minors (or adults) with supervised accounts to have a "legal guardian." We respond by reminding the public that all minor's accounts will be automatically supervised and that legally, a minor should always have a "custodial parent" or a "legal guardian", unless emancipated by a court of competent jurisdiction. There were comments that information about an account should not be provided to foster parents. We accepted those comments with revision. The BIA will only provide account information to parents, legal guardians and emancipated minors. We rejected those comments received that stated

that minors, specifically those who have reached the age of ten or thirteen, should have access to their account information. By law, minors are not legally capable of handling and managing their financial affairs. However, account information will be provided to emancipated minors although we do not accept the comment to allow emancipated minors unrestricted access to their account. All minors, including emancipated minors, will have supervised accounts. The BIA must be kept informed of the current address information for a minor, particularly if the minor's address is different from that of their parent or legal guardian.

A concern was raised about the necessity of obtaining receipts for all purchases made from those funds disbursed from a minor's supervised account. In addition there were comments suggesting that we differentiate between parents and legal guardians when requiring receipts for expenditures from a minor's supervised account. In response, we note that under a minor's distribution plan a parent or legal guardian will be treated equally and that receipts will be required for all expenditures unless a specific provision in the plan permits a minimal disbursement for a minor's miscellaneous expenditures to be made without requiring receipts for purchases. However, we stress that it is important for the integrity of the minor's supervised account that all withdrawals be appropriately documented. Comments were received that encouraged involvement of a parent(s) or legal guardian(s) in the development of the minor's distribution plan. We note that under normal circumstances, the parent(s) or legal guardian(s) will be involved in the development of both the evaluation plan and the distribution plan, and should sign the distribution plan acknowledging that they have read/reviewed the plan. In addition, parents and guardians are responsible for meeting the obligations detailed in those signed plans. Respondents were concerned about the potential necessity to distribute emergency funds from a minor's supervised account where that amount was not included in the distribution plan. We note that distribution plans may be amended at any time for emergencies or a change in circumstances, depending upon the needs of the minor. We accept in part the comments received to place a limit on the amount of funds to be distributed from a minor's supervised account and on the purposes for which a distribution may be made. Funds will not be automatically disbursed from a minor's supervised account to create a flow through account to anyone including a parent or legal guardian. Rather, the BIA will consider all available resources to meet the minor's needs when evaluating a request for funds from a minor's supervised account and in the development of the distribution plan. As a matter of policy, we strongly discourage the use of a minor's trust funds to meet the basic needs of a minor. All distributions must be made pursuant to the terms of an approved distribution plan and receipts for expenditures must be provided to the BIA. Finally, there were numerous comments that the BIA needs to recognize that there are informal custody arrangements and foster care placements for minors with IIM accounts and that there may be a need for disbursements from a minor's supervised account to a caregiver (referenced in comments as a "minor's payee") to help meet the minor's needs. We recognize that minor account holders may be cared for in informal living arrangements or in foster care situations, and that the Secretary may, in certain circumstances, need to recognize the caregiver and authorize limited disbursements that are in the best interests of the minor from the minor's supervised account. Other concerns raised included access by the caregiver to account information for a minor's supervised account. Account information will not be provided to the caregiver due to legal limitations such as the Privacy Act.

Subpart D—IIM Accounts: Estate Accounts

Summary of Subpart

This subpart reflects the notion in the current part 115 of providing for certain obligations and other expenditures that are attendant to an Indian decedent's estate. This is a new subpart in this Final Rule; however, its provisions were included in the Proposed Rule. The provisions in this subpart mirror the provisions contained within the Final Rule for 25 CFR part 15. Particularly, this subpart identifies when an estate account is established; how long an estate account remains open; refers to heirs to a decedent's account; establishes protocols for withdrawing monies prior to final probate; and dispositions to those having life estate interest in income-producing trust or restricted property.

Comments

Comments on Indian decedents' estates were captured in our discussions of part 15, Probate of Indian Estates above.

Subpart E—IIM Accounts: Hearing Process for Restricting an IIM Account

Summary of Subpart

This subpart outlines the notice requirement and hearing process (so-called "Kennerly" process) associated with placing a restriction on an IIM account under current §§ 115.102 and 115.104. This subpart outlines the circumstances under which the BIA will place a restriction on an IIM account; information that must be included in a notice to restrict an account; time lines for requesting a hearing to challenge BIA's decision to restrict an IIM account; pendency of a restriction during an appeal; and remedies available when an administrative error has been caused by BIA or OTFM.

Comments

We received several comments on this subpart, including that the BIA should only require the "Kennerly" process, described in the final rule in this subpart, for restricting an IIM account if there is no valid non-BIA proceeding. We note in response that the notice requirement has been in place in the current regulation for the past 40 years and, further, we must provide due process to all account holders before we take action against their account. We believe that due process is served (and our trust responsibility properly exercised) through the use of the notice and hearing process. Accordingly, we did not accept this comment for revision in the Final Rule. Other comments recommended that we not place a restriction on an account until after the hearing process is completed; that we add five (5) additional days to the time periods proposed for placing the restriction on an account; and that we extend the time period in which to request a hearing from 40 days to 90 days. We did not accept these comments because due process is provided within the time periods proposed. The funds at issue when an account is restricted will be protected and will not be disbursed until after the hearing process and appeal period, if any, have ended. One comment stated that we should explain that social services staff should not have the responsibility for collecting debts from an IIM account. In response, we note that social service providers are only involved in the development of a distribution plan where the BIA's decision is to supervise an IIM account, not when the account is to be encumbered. Finally, there were comments involving BIA's recognition

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of child support awards. Concerns included honoring excessive awards; limiting amounts awarded by a court of competent jurisdiction; and other comments stating that there should be no discretion to reduce the amount of a child support award to be paid from an IIM account. Consistent with federal policy, we believe that parents are responsible for providing support for their children and that child support awards are to be determined by courts of competent jurisdiction. If there is a dispute regarding a child support award and we are provided with notice of an appeal of a child support award, upon request we will postpone the hearing.

Subpart F—Trust Fund Accounts: General Information

Summary of Subpart

This subpart discusses the sources of trust funds that may be deposited into the Secretary's trust funds management system. Particularly, this subpart explains which trust funds may be accepted for deposit into a tribal or an IIM account; the process for depositing money into an account; the requirement that the Secretary must conduct an annual audit on trust funds; and an explanation of how trust funds deposited in a trust account earn income.

Comments

Several respondents suggested that this subpart should clearly state what money would be accepted into IIM accounts while others requested that we accept specific types of non-trust monies. In response, we have described in § 115.702 what sources of trust funds may be accepted for deposit into a trust account. We note that the BIA must have specific authority to accept non-trust monies into a trust account. Therefore, we will not accept pension funds, retirement funds, conveyance fees and child support awards into trust as requested. Some respondents were concerned that an annual audit on trust accounts was not required and others wanted the inclusion of language specifying the accounting standards to be used in the audit.

The Trust Reform Act requires that an annual audit be conducted on trust funds. Prescribed auditing standards will be used in conducting those audits. In addition, a number of comments concerned the timeliness of deposits of trust funds received by the Secretary into a trust account. Deposits received by the Secretary on behalf of a tribe or an individual will be deposited into a trust account within twenty-four hours, or no later than the close of business on the next business day following the receipt of funds at a location with a designated federal depository. Another respondent stated that to require a compacting tribe to make deposits payable to the Secretary on behalf of tribes or individual Indians within a twenty-four hour time period would create problems because many tribes are isolated, live hours away from banks and "it is not always practical to do banking but once a week." We respond that where a tribe has compacted or contracted with the federal government to operate a federal program and the tribe, operating the federal program on behalf of the Secretary, receives trust funds payable to the Secretary on behalf of the owner of the trust asset pursuant to a contract that specifies that payments are to be made to the Secretary, the tribe must follow the same standards as the Secretary under § 115.708 for the deposit of the trust funds into a trust account. We also received an inquiry as to whether interest earned on trust funds are automatically reinvested. Interest earned on trust funds is automatically reinvested. Although we called for comments regarding income derived from tribal operations, we do not address this issue in the Final Rule. We have provided a list of all sources of trust funds that will be accepted by the Secretary for deposit within the trust fund management system in § 115.702. Further, a tribe or individual Indian will not be allowed to deposit trust funds received through direct pay into a trust account, except when provided by law under 25 U.S.C. 3109. However, we have amended the regulation to allow the Secretary to accept for deposit trust funds made payable to the owner of the trust asset (direct pay) when submitted by the payor (e.g., lessee, permittee) when the payor presents evidence (i.e., an envelope marked by the United States Post Office "undeliverable") that shows attempted delivery to the tribe or individual owner of the trust asset. We are unable to respond in the regulation to the request for a listing of OTFM offices, however, a current list of OTFM offices may be obtained from Department's web page at www.doi.gov. There were several comments requesting that we identify the tax status of, and certain agency exemptions for, trust funds. We are unable to incorporate these recommendations as this rule regulates the Department of the Interior and not other federal agencies that have a trust responsibility to tribes and individual Indians. Comments also indicated that there was general confusion about when we would accept funds from another federal agency on behalf of an individual Indian. By law, we are only able to take funds from another federal agency when the federal agency has appointed the BIA as the representative payee to receive benefits on behalf of an individual Indian because there is no legal guardian to be appointed as representative payee.

Subpart G—Tribal Accounts

Summary of Subpart

This subpart discusses the trust funds that are deposited into tribal accounts and their management by the BIA. Particularly, the subpart outlines when, and how, OTFM opens a tribal account; information regarding a statement of performance and when it is sent to a tribe; which trust funds may be deposited; tribal investments and how they are managed; procedures for withdrawing tribal trust funds; and what happens to unclaimed per capita funds.

Comments

Respondents suggested that income under a 25 U.S.C. 450f *et seq.* contract or compact should be able to be deposited into tribal trust accounts so that they may be invested and the interest earned reinvested daily. Any funds appropriated to administer a 25 U.S.C. 450f *et seq.* contract or compact are not trust funds, and cannot be deposited into tribal IIM accounts. If trust funds are to be deposited into a trust account, the contract for the sale or use of trust lands or resources (e.g., lease, permit) must specify that payments be made payable to the Secretary on behalf of the trust owner regardless of whether the Secretary manages the program or a tribe has compacted or contracted with the Secretary to operate the federal program. If a tribe that is compacting or contracting the federal program which administers/manages the tribe's contract involving trust assets receives trust funds derived from those trust assets made payable to the Secretary, then the contracting or compacting tribe must deposit those funds into a Treasury General Account. Any payments made payable to a tribe (direct pay) will not be accepted for deposit into a tribal trust account.

Another comment suggested that time lines should be prescribed for processing tribal account withdrawals. We have provided time lines in response to this comment. We are unable to accept the comments requesting that we give tribes authority over trust fund investments. By law, the Secretary is responsible for making all trust fund investment decisions. However, we do accept with revision those comments requesting consultation with tribes on an annual basis because some tribes may not wish to meet with OTFM on an annual basis. Upon request by the tribe, OTFM will consult with a tribe annually regarding investments of tribal trust funds. Many respondents were concerned about a tribe requesting the return of unclaimed per capita funds. Unclaimed per capita funds will not automatically be returned to a tribe after six years. By law, a tribe may request, but is not required to request, the return of unclaimed per capita funds after six years. A decision to make a request for return of per capita funds is an internal tribal decision. Funds not returned to a tribe will remain in an "unclaimed per capita account." We have decided to remove several of the provisions regarding tribal budgets and budget approvals in response to comments that these sections were confusing and seemed to add requirements that were not required by law. Tribes must continue to present budgets for the use of trust funds to the Secretary when required by law. Tribes are also encouraged to meet with OTFM to discuss cash flow needs so that OTFM may make informed investment decisions regarding tribal trust funds.

Subpart H—Special Deposit Accounts

Summary of Subpart

This subpart, which replaces part 114, limits the types of monies that may be deposited into special deposit accounts. Particularly, this subpart includes an explanation of who receives the interest earned on trust funds in a special deposit account; when trust funds in a special deposit account are distributed to the owner of the funds; whether administrative or land conveyance fees paid as federal reimbursements can be deposited into special deposit accounts; and what other types of monies may be deposited into special deposit accounts.

Comments

We received one comment on this section which requested that conveyance fees be allowed for deposit into special deposit accounts. In response, we restate that the Secretary only has authority to accept trust funds into a trust account. Conveyance fees are not trust funds.

Subpart I—Records

Comments

As previously noted, the provisions addressing the ownership and maintenance of trust records associated with the performance of this part, contained in subpart H of the Proposed Rule, have been modified in response to comments. These provisions are found in subpart I of the Final Rule.

D. 25 CFR Part 162—Leases and Permits on Indian Lands

The purpose of this regulation is to describe the authorities, policies and procedures the BIA uses to grant, approve and administer surface leases and permits on certain Indian land and Government land. It revises, amends and replaces the existing part 162 in its entirety, and implements the American Indian Agriculture Resource Management Act (AIARMA), 25 U.S.C. 3703, *et seq.* with regard to leases on Indian agricultural land. With respect to those regulations governing the administration of leases on specific reservation lands, the Final Rule will not effect any substantive changes, but renumbers those sections. The section pertaining to the Colorado River Reservation has been removed at the request of the tribe.

This regulation balances the responsibilities the Secretary has as trustee of Indian land with the need for tribes and individual Indian landowners to exercise maximum control over their Indian agricultural lands. These regulations will apply to all leases in effect on the date the regulations take effect.

General Observations Regarding Changes From Proposed Rule

The recent enactment of the ILCA Amendments affects the management of Indian lands held by multiple Indian landowners, including both tribes and individual Indians. The policies introduced by this legislation require extensive revisions to the Department's regulations affecting the leasing of individually owned allotted lands. Specifically, section 219 of the ILCA Amendments addresses all leases or other agreements affecting individually owned allotted lands or any other trust or restricted lands. Because section 219 of the new statute expressly provides that it does not amend or modify the AIARMA, the Department is now issuing final regulations in part 162 that address agricultural leasing under the authority of the AIARMA. The Department will extensively revise the regulations governing non-agricultural leases at a later date. Because the ILCA Amendments also affect tribes that own fractional shares of trust or restricted lands, the Department will not finalize new regulations affecting non-agricultural leasing on tribal lands until the full extent of the ILCA Amendments is determined and new regulations are re-proposed and additional tribal consultations are conducted.

Nevertheless, leasing must be able to continue even on lands that are subject to the new provisions of the ILCA Amendments. For these lands, most of the provisions of the superseded version of part 162 are republished in subpart F, modified such that provisions that conflict with the new definitions or agricultural leases (now covered in subpart B) have been deleted. Subpart F will be replaced with future rules, as described above. Additionally, in response to many comments calling for the BIA to strengthen its enforcement of leases, sections are included in subpart F that address the BIA's duties to collect delinquent lease payments and enforce lease violations on trust and restricted lands. These sections are modeled directly on the related sections in subpart B. Both the general provisions applicable to all leases and the new subpart F note that, if any of the provisions of these regulations conflict with the ILCA Amendments, the statute will govern.

A few respondents objected to the implementation of the AIARMA in the context of the part 162 regulations, requesting that separate regulations be issued. We reject this comment. Because agricultural leases are a specialized form of the BIA's overall leasing program and are administered under the authority of the AIARMA in combination with the Indian Long-Term Leasing Act, 25 U.S.C. 415, there is no need for stand-alone AIARMA regulations.

Agricultural leases are administered in a manner that is significantly different from other types of leases on trust and restricted Indian lands, such as business and residential leases. The Department has responded to the majority of comments addressing both the proposed leasing and grazing regulations by significantly restructuring and clarifying the leasing regulations in order to address agricultural leases independently. Separate subparts C and D, for residential and business leases, respectively, are identified and reserved for future rulemaking after the impact of the ILCA Amendments is assessed.

The process of separating provisions pertaining to agricultural leases from those that govern residential and business leases, and the consideration of public comments as described below, has resulted in extensive refinement, clarification and restructuring of the agricultural lease provisions. In its final form, the provisions pertaining to agricultural leases do not closely resemble the final grazing regulations at part 166 as much as they did in the

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proposed regulations. Every effort has been made to ensure that both the agricultural lease provisions of part 162 and the grazing regulations at part 166 are substantively the same, to the greatest extent possible and practicable, insofar as they implement the provisions of the AIARMA. Additionally, specific provisions addressing trespass under the AIARMA that were contained in subpart L of the Proposed Rule have been deleted in favor of cross-referencing to the AIARMA trespass provisions in part 166.

In response to the majority of comments, the final agricultural leasing provisions reflect significant deference to tribal and individual Indian landowners, such as deferral to tribal laws and requirements for consultation between the BIA and the Indian landowner on all facets of management and enforcement activities, including enforcing lease and permit violations and trespass. The final regulations also provide more flexibility to the Indian landowner to negotiate, with the assistance of the BIA, desirable and favorable provisions in their leases. The BIA will provide subsequent guidance, including model lease language, to assist Indian landowners in negotiating their own leases.

The final leasing regulations provide for more pervasive deference to tribal law and tribal self-determination, not only as required under the AIARMA for grazing and agricultural leasing (subpart B), but also in the provisions that will apply to general leasing activities (subpart A). Several tribes and the NCAI pressed for more complete deference to tribal leasing decisions than the Department believes can be accommodated under current law, notwithstanding the Indian Self-Determination and Education Assistance Act, 25 U.S.C. 450 *et seq.* For example, the NCAI requested that the Department adopt regulations that would provide for routine approvals of tribal short-term leases. However, existing statutory authorities require meaningful review by the Secretary in carrying out the trust responsibility. Moreover, a rule providing for such routine approvals of tribal short-term leases would fail to take into account those tribes that do not yet have sufficient policies and procedures in place to ensure that the trust assets are properly managed.

Nevertheless, the Department is committed to speeding up its review, approval, administration and enforcement of leases. Throughout these regulations, reasonable time frames for action by the BIA have been inserted to strengthen the management of leases. For the reasons stated in the preceding paragraph, under existing law we must reject those comments seeking automatic lease approvals if the time frames are not met.

A few commenters, particularly the NCAI, requested that the BIA identify with specificity the individual official responsible for taking action or making a decision in any given instance. We reject these comments, as we believe such matters are properly addressed in Bureau and Departmental delegations of authority, which may be changed as work load and other factors demand. To commit to such delegations in regulations would inflexibly bind the BIA and Department from addressing pressing workforce needs in an efficient and effective manner. The NCAI further requested that the BIA adopt a "trust officer" model for managing trust land, similar to that used in the private sector. We believe such a model already exists at the individual BIA agency and field office level; the agency superintendent and field representative effectively serve as the responsible "trust officer" responsible for the administration of trust land within their jurisdiction.

Consistent with the majority of comments, the final regulations continue to provide for direct payment to Indian landowners for leases on their trust lands, as long as direct payment is a specific term in the lease or permit. In order to ensure that the Secretary can properly enforce lease and permit payment terms, leases and permits authorizing direct payments must require that tenants maintain documentary proof of payment. Several respondents suggested that the Secretary should require that proof of payment be submitted to the agency with every direct payment. However, such a requirement would be inconsistent with historic practice and would result in an unsustainable drain on agency resources. Absent a system for tracking such notices, the requirement would not produce the desired goal of ensuring prompt enforcement of payment of trust income. Further, it would be far less effective than relying on the Indian landowner to advise the BIA immediately upon discovering that a payment has not been made and requesting enforcement assistance. Therefore, the final regulations provide that the Indian landowner notify the Secretary that a required payment has not been made. The Secretary then will take prompt and effective action based on that specific information. The Department continues to recognize the advantages to Indian landowners of direct payments. However, this advantage necessarily brings with it increased responsibility of Indian landowners to assist in the enforcement of non-payment of their leases and permits. With this regulatory change, Indian landowners who opt for and negotiate direct payments are clearly notified of their responsibilities to notify the BIA of late payments. Similarly, tenants are notified both by these regulations and in the lease itself that documentary proof of payment will be necessary to demonstrate that a payment was timely made in the correct amount due, should there be any question about a payment.

The Department is not taking on any obligation to manage or account for funds paid directly to Indian landowners that are not actually held in trust by the United States. This is consistent with section 102(a) of the American Indian Trust Management Reform Act of 1994, 25 U.S.C. 4011. Although we invited the public to comment on the question of accounting for direct payments, no specific recommendations were received beyond a general recommendation to collect proof of payment.

In both general lease and permit enforcement, as well as in trespass enforcement, the final leasing regulations reflect the suggestions of a large number of commenters to establish reasonable time frames in which the BIA will take appropriate enforcement action, and to reduce the amount of procedural steps necessary for effective enforcement. Significantly, the final rule includes new provisions identifying the BIA's responsibility for collecting delinquent rent payments.

Subpart A—General Provisions

Summary of Subpart

Subpart A addresses the purpose and scope of part 162 and describes the general authorities, objectives and policies the BIA uses to approve, grant, administer and enforce surface leases of Indian land. This subpart also defines key terms used throughout part 162 and identifies the land, interests in land, and types of leases covered by part 162. This subpart describes how tribal laws will apply to leases, and how records are maintained that document the leasing of trust and restricted lands.

Comments

Subpart A of this Final Rule now includes new provisions addressing the scope of part 162, policy statements, and other general provisions not found in the Proposed Rule. As noted above, many commenters suggested that the Final Rule include separate standards

for different types of leases, including agricultural, business and residential leases. In response, this Final Rule provides for separate subparts for agricultural leases (subpart B), residential leases (subpart C), and business leases (subpart D). Subparts C and D are reserved for publication at a later date. Accordingly, we will not address any of the provisions in subpart E or elsewhere in the Proposed Rule concerning residential or business leases, or the comments relating to those provisions.

Section 162.101 of the Final Rule contains definitions of key terms used throughout part 162. In response to many comments, we have clarified and streamlined most of the definitions in concert with those used in the final rules at parts 151 and 166. We have added definitions for day, emancipated minor, fee interest, immediate family, interest, minor, mortgage, remainder, surety, and tenant. Several confusing terms have been deleted or revised. For example, we have deleted specific definitions of appeal bond and surety in favor of a single definition of bond. In response to many comments, we generally have discontinued using the term lessee in favor of tenant.

Several respondents raised questions about the scope of the Proposed Rule. In response, § 162.102 clarifies that only land and land interests held in trust or restricted status are covered, and § 162.103 defines the types of agreements covered. Section 162.102(b) sets forth the general rule with respect to the leasing of life estates and remainder interests, with a cross-reference to 25 CFR Part 179. The information in subpart J of the Proposed Rule concerning fee interests or "non-trust" interests has been relocated to § 162.102(c) of this Final Rule. In addition, the provision in § 162.70 of the Proposed Rule which recognized that tribes could lease tribal land without BIA approval under federal charters has been moved to § 162.102(d) of this Final Rule. Finally, § 162.102(e) of this Final Rule notes that to the extent part 162 conflicts with the recently-enacted ILCA Amendments, the provisions of the ILCA Amendments will govern. In § 162.103, the Final Rule expands the cross-references in § 162.1(a) of the Proposed Rule, to distinguish the surface leases and permits covered by part 162 from other transactions involving trust or restricted land.

Many questioned whether the individual Indian landowners of undivided interests in fractionated tracts would need leases from their co-owners (i.e., "owner's use"), before taking possession. In response, § 162.104(b) clarifies that an Indian landowner of an undivided interest may not take possession without a lease unless the Indian co-owners give their permission. We have not accepted the requests to eliminate the owner's use provision in its entirety. This provision is necessary to ensure protection for, and to foster cooperation and negotiation among, all Indian co-owners.

Several commenters also expressed confusion as to how the trespass rules in subpart L of the Proposed Rule would apply to leases. As previously noted, some suggested that failure to pay rent be treated immediately as trespass. In response, the special provisions on trespass have been removed, but those provisions (as still incorporated in part 166) have been cross-referenced in §§ 162.106(b) and 162.256 of this Final Rule. We have rejected the comments requesting that we treat non payment as trespass, based on the availability of contract remedies prior to the cancellation of the lease. We have noted, however, that we will treat any possession of Indian land without a lease as a trespass, whether or not it occurs it occurs on Indian agricultural land.

Several respondents indicated that the Proposed Rule did not sufficiently define the BIA's responsibilities in the leasing of trust and restricted land; promote tribal self-determination through the negotiation of tribal leases and the administration of reservation lands under self-determination contracts or self-governance compacts; or support tribal sovereignty through the formal recognition of tribal laws and leasing policies. We have accepted these comments. Accordingly, §§ 162.107–162.108 define our objectives in granting or approving leases involving trust or restricted land and our responsibilities in the administration and enforcement of such leases, as noted above. The policies expressed in §§ 162.107–162.108 are intended to reflect our strong support for the rights of Indian landowners, tribal governing authority, and tribal administration of BIA programs. In § 162.109(b) we expressly recognize that tribal laws will broadly apply to all land under tribal jurisdiction, and generally allow tribal laws to supersede or modify the regulations in part 162 with respect to leases of tribal land.

In the Proposed Rule, we invited comments with respect to the distribution of rents derived from unitized leases comprised of multiple tracts with different Indian landowners. In response to the small number of comments received, we have combined §§ 162.17 and 162.102 of the Proposed Rule in § 162.105 of this Final Rule. We continue to provide that rents will be distributed based on the size of the Indian landowner's interest in proportion to the acreage in the entire lease tract, unless the lease provides otherwise. We also clarify that minimum Indian landowner consent requirements will apply to each tract separately rather than to the unitized lease tract as a whole.

Finally, to be consistent with the regulations published under parts 15, 115, and 166, we have added two sections addressing the maintenance of records relating to probate cases. These provisions, §§ 162.111 and 162.112, replace subpart M of the Proposed Rule.

Subpart B—Agricultural Leases

Summary of Subpart

Subpart B, consisting of six groupings of sections, governs agricultural leases on Indian lands. Under "General Provisions" are sections addressing the applicability of tribal laws and policies to agricultural leases. The sections under "How to Obtain a Lease" set forth procedural requirements including who can grant agricultural leases, how the BIA approves such leases, the documentation and recording requirements for such leases, and the effective dates of leases and BIA decisions. "Lease Requirements" includes sections that describe mandatory lease provisions, the amount of rent to be paid and the manner of payment (including late payments and penalties), improvements, bonds, and insurance. Under "Lease Administration" are provisions governing administrative fees and amendments, assignments, subleases and mortgages. "Lease Enforcement" includes sections identifying the BIA's responsibilities and time frames for collection of delinquent rent payments and other violations of agricultural leases, lease cancellation procedures, emergency action and inspections by the BIA.

Comments

General Provisions

A large number of commenters questioned provisions in the Proposed Rule that implemented the AIARMA. As we noted above and provide with respect to part 166, we have rejected the comments suggesting that special AIARMA regulations be promulgated independent of the BIA's leasing and grazing programs. As noted, the AIARMA-based trespass provisions in subpart L of the Proposed Rule have

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been removed, leaving appropriate cross-references to 25 CFR Part 166. Many of the respondents were also concerned about the applicability of tribal laws and leasing policies. As indicated above, we have replaced § 162.4 of the Proposed Rule with the more specific § 162.109 in this Final Rule, to clarify that tribal laws will broadly apply to all types of leases, but will supersede or modify our regulations only in limited circumstances.

We have moved the AIARMA-based provisions found in §§ 162.5–162.9 and § 162.11 of the Proposed Rule to this heading in subpart B of the Final Rule. Consistent with the AIARMA, section 162.200 provides that subpart B will apply not only to agricultural leases, but also to business leases that support the Indian agricultural community. Section 162.201 provides that lands be managed in accordance with any agricultural resource management plan that have been adopted. As required by AIARMA, § 162.201(c) broadly authorizes waivers of regulations that are inconsistent with any agricultural resource management plan.

The provisions in §§ 162.5 and 162.9 of the Proposed Rule, relating to the implementation and enforcement of tribal laws affecting agricultural land, have been combined in § 162.202 of this Final Rule. In response to comments, § 162.202(b)(3) includes provisions that clarify that BIA appearances in tribal forums may be limited by Departmental regulations at 43 CFR Part 2, and by provisions in the AIARMA to preserve the sovereign immunity of the United States and limit tribal court review of BIA actions. Section 162.202(c) broadly authorizes waivers of regulations that are inconsistent with tribal laws.

Section 162.6 of the Proposed Rule, addressing when our standard regulations can be superseded or modified by certain types of tribal leasing policies, has been slightly modified and redesignated as § 162.203. It should also be noted that the broad AIARMA provision authorizing our approval of an agricultural lease of tribal land at any rate determined by tribal governing body has been incorporated in this Final Rule through standard regulations, at § 162.222(b), as well as through tribal policies made applicable under § 162.203 of the Final Rule. Although a number of commenters requested guidance as to how a superseding leasing policy might be adopted by a tribe, the Final Rule leaves the matter to the discretion of each tribe. The notice provisions in § 162.8 of the Proposed Rule have been clarified and extended to Indian landowners in § 162.204. Although some commenters objected to any notice requirement being placed on tribes, we continue to require that tribes provide us with notice of any tribal law or leasing policy that supersedes or modifies any of the regulations in part 162, so that we may provide the notices required by AIARMA. Finally, § 162.205 clarifies the provisions in § 162.7 of the Proposed Rule, authorizing individual Indian landowners to exempt their land from a leasing policy which supersedes or modifies one of our standard regulations prohibiting tenant preferences, requiring a bond, or guaranteeing three months notice before we grant a lease. Consistent with the AIARMA, we continue to require that at least 50% of the Indian landowners request the exemption and add a new provision that the exemption be requested each time a lease is granted or approved. Although numerous commenters objected to the exemption provision, these exemption rights are expressly provided for in AIARMA and have thus been retained in this Final Rule.

How To Obtain a Lease

In response to many comments, we have clarified the circumstances under which leases can be obtained through negotiation or advertisement or granted or approved without an appraisal or other documented valuation. In doing so, we have reduced and consolidated the provisions in subpart C of the Proposed Rule into §§ 162.206 and 162.212, respectively, in this Final Rule. Further, we have consolidated the provisions subpart D of the Proposed Rule into §§ 162.207–162.210 of the Final Rule, with several corrective amendments. The provisions relating to fair annual rental determinations, proposed in §§ 162.150–162.151 of the Proposed Rule, have been consolidated in § 162.211 of the Final Rule, with a clarification that fair annual rental determinations are not needed in cases where a lease may be approved at less than a fair annual rental, unless the Indian landowners request such a determination. We have also clarified that the BIA will determine fair annual rental value for leases on Indian lands by appraisal, advertisement, competitive bidding, or any other appropriate method that complies with the USPAP. The BIA does not intend to specify in part 162 the particular method for appraising Indian land; rather, ensuring flexibility in choosing an appraisal method allows the Secretary to most effectively discharge his responsibility as trustee.

Many respondents questioned the proposed provisions that addressed the granting of leases on fractionated tracts, including "owner's use" leases. In response, the provisions in the Proposed Rule that indicated that land being used by an Indian owner of a fractional interests could be leased to another party have been modified. Section 162.209(b) provides that we will not exercise our authority under 25 U.S.C. § 380 to grant a lease on behalf of all of the Indian owners of a fractionated tract where the Indian co-owners have given one of the Indian landowners permission to possess the tract without a lease.

A number of commenters objected to the provisions in § 162.12 of the Proposed Rule that identified the factors to be used in applying the "best interest" standard of review for lease approvals. Some noted that the BIA incorrectly applied 25 U.S.C. § 415(a). Others requested that the BIA consider additional factors beyond those provided in the statute. In response, § 162.214(a)(3) provides that we must assure ourselves that adequate consideration has been given to the five factors identified in 25 U.S.C. § 415, consistent with the statutory language. A sixth, non-statutory factor was suggested by the NCAI and identified in the Proposed Rule. This factor would require that we consider any tribal assessment of potential impacts on tribal culture and sovereignty. We received contradictory objections to this provision as being at once too paternalistic and yet too deferential to tribes. Because the sixth factor pertains primarily to long-term, business and residential leases, we have deleted it from the Final Rule for agricultural leases.

Many commenters requested that we include a time frame in which we must make a decision whether to grant or approve a lease. In response, § 162.214(b) requires action within 30 days, so long as the lease is in a form which has been previously accepted or approved, and all of the requisite supporting documents have been received. Those supporting documents are generally described in § 162.213, including a cross-reference to the bond requirement not found in proposed § 162.13, the corresponding provision of the Proposed Rule.

Many questions were raised about the effective dates of our decisions to grant or approve leases. With respect to the effective date of an agricultural lease, and the relation between the effective date of our decision to grant or approve the lease and the commencement date of the lease, the provisions in §§ 162.12(c) and 162.28 of the Proposed Rule have been consolidated and clarified in § 162.215 of the Final Rule. This section confirms that our decision can be made retroactively effective.

In response to numerous comments, we have significantly revised the applicability of the appeals process for decisions to grant or approve leases. Contrary to § 162.75 and subpart I of the Proposed Rule, § 162.216 makes a grant or approval decision effective immediately, notwithstanding any appeal that may be filed under 25 CFR Part 2.

Finally, we received many inquiries as to why we proposed only to record leases greater than one year in duration. We agree with those concerns and will record all leases. The Proposed Rule omitted mention of recording permits; the final rule provides that all permits will be recorded, as well. The provisions in §§ 162.14–162.16 of the Proposed Rule have been consolidated and clarified in § 162.217, expressly exempting permits from the recording requirement.

Lease Requirements

We received many comments requesting that the BIA be less prescriptive in mandatory lease requirements and allow for greater flexibility in negotiating leases that are favorable to the Indian landowner. We have balanced these concerns against the need for mandatory provisions that provide sufficient protection of Indian landowners. Accordingly, under the heading "Lease Requirements" are minimal mandatory provisions for agricultural leases, as well as provisions addressing matters that we strongly encourage be negotiated.

The mandatory provisions listed in § 162.26 of the Proposed Rule have been clarified and streamlined in §§ 162.219 and 162.220 of this Final Rule. Many respondents criticized the provisions relating to the description of the leased premises, as found in §§ 162.20 and 162.26(i) of the Proposed Rule, as being too restrictive for business purposes. We agree with these comments. In consolidating these sections in § 162.221 of the Final Rule, we state a clear preference for public or private surveys, but will accept any legal description that adequately identifies the property.

As previously noted in the general discussion of the changes to part 162, we have responded to the numerous comments received regarding direct rent payments. We are retaining the authority for direct payments and requiring tenants to retain documentation evidencing proof of payment. The provisions in §§ 162.41–162.42 and §§ 162.100–162.101 have been consolidated in § 162.226 of this Final Rule.

Section § 162.225 addresses late payments, combining §§ 162.34 and 162.36–162.37 from the Proposed Rule. In response to the majority of comments, this section provides that interest will begin to accrue immediately after a payment is missed, and that negotiated late payment penalties also may be imposed. Section 162.227 allows payments made directly to the Indian landowners to be made by any method specified in the lease. This section also allows payment by personal or business checks, in accordance with virtually every comment received on this issue. To minimize the risk to Indian landowners where such checks are dishonored, we have added a provision in § 162.248(d) stating that a lease is violated by the dishonoring of a check, and future payments must be made by one of the alternative methods identified in § 162.227.

Several commenters requested that the BIA allow greater flexibility in requirements for adjusting rental payments over the course of a lease. In response, § 162.223 provides for a minimum of one adjustment during the term of an agricultural lease, but Indian landowners may negotiate additional adjustments. We received few comments addressing the adjustment method and have clarified that the parties may negotiate the method of adjustment, with assistance from the BIA.

A number of comments also addressed the maximum lease term for agricultural leases. We have clarified this information in § 162.229, consistent with the AIARMA, to state that the maximum term for an agricultural lease is ten years, unless otherwise provided by law, and unless substantial investment in improvement of the land justifies extending the term up to 25 years.

Most commenters who addressed lease amendments, assignments, subleases, and leasehold mortgages requested that the BIA approve every such transaction. We agree that, with respect to agricultural leases, such approval continues to be necessary to protect Indian landowners. Section 162.230 has been amended accordingly, combining provisions in found in the Proposed Rule at §§ 162.21–162.25 and 162.87–162.90.

Many respondents requested additional clarity in the treatment of improvements to agricultural lands, both during and after the term of a lease. We have responded to these comments in §§ 162.232 and 162.233, by providing for negotiation of ownership of improvements in the lease, with suggestions for favorable terms, and provisions for BIA enforcement.

Finally, in response to many comments seeking strengthened remedies protecting Indian landowners in the event of lease violations, § 162.240 of the Final Rule amplifies the rights of Indian landowners to negotiate remedies that may be applied in addition to those taken by the BIA, including the possibility that the Indian landowner may cancel the lease. We also encourage Indian landowners to address the matter of tribal court jurisdiction for the resolution of lease disputes involving such negotiated remedies. However, this section provides that the BIA may not be bound by such decisions, but we generally will defer to tribal court proceedings as appropriate.

Lease Administration

Some commenters found the organization of the Proposed Rule confusing because it failed to distinguish clearly between the review and processing of a lease, and subsequent lease amendments, assignments, subleases, and leasehold mortgages. In response, we have created this grouping of sections entitled "Lease Administration," which combines the provisions relating to the review and processing of amendments, assignments, subleases, and leasehold mortgages, as contained in subpart B of the Proposed Rule, with the provisions relating to administrative fees, proposed in subpart G.

With respect to administrative fees specifically, several commenters felt that the provisions in subpart G of the Proposed Rule were unclear as to the authority of tribes to charge and collect such fees, whether or not the tribe is administering the leasing program under a self-determination contract or self-governance compact. In response, § 162.241 establishes a standard 3% fee, subject to modification by a tribe or a discretionary waiver by us, and clarifies who pays the fee, why it is paid, and when it is subject to tribal modification. This provision has a consistent counterpart in part 166. As indicated above, the provisions in § 162.114 of the Proposed Rule, relating to the payment of other types of fees and charges, have been relocated to § 162.228 of this Final Rule.

Many respondents noted that subpart E of the Proposed Rule, which was intended to apply only to business leases, contained general provisions applicable to other types of leases. We believe the reorganized structure of part 162 will address these concerns. As

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noted above in the general discussion of these Final Rules, numerous commenters suggested that the Final Regulations include time frames binding the BIA, with automatic approval of leases should BIA time frames be missed. With respect to agricultural leases, we added time frames to improve BIA review and approval procedures, but have rejected the comments suggesting automatic approval if the BIA fails to meet the specified time frames.

We have retained the basic structure and content of the Proposed Rule's standard of review provisions for assignments, subleases and mortgages, respectively. Additionally, in response to several comments, we have added a standard of review provision for lease amendments at § 162.242. We also eliminated the provision in the Proposed Rule that would have required that a tenant remain liable even after an assignment is approved, leaving such matters to negotiation between the parties. In § 162.45, we have added a provision stating that amendments, assignments, subleases, and leasehold mortgages are immediately effective upon approval, notwithstanding any appeal which may be filed under 25 CFR Part 2.

The recording requirement for leasehold mortgages, as found in § 162.22 of the Proposed Rule, has been extended to all subsequently approved lease documents by § 162.246 of this Final Rule.

Lease Enforcement

Many respondents criticized the enforcement provisions in subpart H of the Proposed Rule, recommending that we employ stricter definitions of our enforcement responsibilities, including time frames for BIA action. In particular, commenters urged us to develop very specific enforcement provisions governing enforcement of a tenant's failure to pay rent. We have accepted these comments, and have combined some of the collection provisions in subpart B of the Proposed Rule with the enforcement provisions in subpart H of the Proposed Rule. In response to several commenters, § 162.248 contains new provisions specifying the actions the BIA will take to enforce a tenant's failure to pay rent. These actions include a written notice of violation, immediate action to recover undisputed overdue rent prior to lease cancellation, and the acceptance of partial payments. Additionally, in § 162.249 we have added a new provision addressing the BIA's authority to assess against delinquent tenants special fees to cover the cost of collection. The inspection provision in § 162.121 of the Proposed Rule has been strengthened in § 162.250 of the Final Rule, providing that appropriate investigation will be initiated within five days of the date on which the BIA receives notice that a specific violation has occurred.

Many respondents requested that we strengthen the provisions by which we cancel leases for violations. Specifically, commenters requested that we speed up the cancellation process to better protect Indian landowners against financial losses during the pendency of any appeal of a cancellation decision. We have accepted these comments in the Final Rule. First, the provisions relating to notices of violations, found in §§ 162.122–162.124 of the Proposed Rule, have been consolidated and clarified in § 162.251 of the Final Rule, by eliminating the right of a tenant to appeal a notice of violation other than by responding to the notice itself. The provisions in §§ 162.123(c) and 162.125–162.127 of the Proposed Rule outlining the actions a tenant could take to cure a violation have been combined in § 162.252 of the Final Rule, with the election of remedies to be based in part on consultation with the Indian landowners. Second, special streamlined appeal provisions will be applied to lease cancellations. For example, in § 162.253, bonding requirements for decisions to cancel leases will differ from those in 25 CFR Part 2. Additionally, § 162.254 provides that cancellation decisions will be stayed only for thirty days pending the filing of an appeal. Third, the provisions relating to emergency actions from §§ 162.128–162.129 of the Proposed Rule have been consolidated and strengthened in § 162.255 of the Final Rule. Finally, § 162.256 provides that holdover tenants will be treated as trespassers.

Subpart C (Residential Leases) Is Reserved

Subpart D (Business Leases) Is Reserved

Subpart E—Special Requirements for Certain Reservations

Summary of Subpart

Subpart E identifies special provisions applicable only to leases made under special acts of Congress that apply only to certain Indian reservations. These provisions were in subpart N of the proposed regulations. Except for the removal, at the request of the tribe, of the section pertaining to the Colorado River Reservation, there have been no changes from the superseded or proposed regulations.

Subpart F—Non-Agricultural Leases

Summary of Subpart

As noted above, because of the enactment of the ILCA Amendments and the separation of agricultural leases into a distinct subpart, the BIA will promulgate new regulations for business and residential leases in the future. Until then, such leases must continue under existing authority. Therefore, new subpart F contains the general leasing authorities from the superseded regulations at 25 CFR 162.2–162.10, and §§ 162.12–162.13. In response to the many comments requesting stronger provisions for collection of lease rent and enforcement of lease provisions, subpart F contains new collection and enforcement provisions for non-agricultural leases, modeled on those in subpart B. Subpart F will be withdrawn when the new business and residential lease subparts are issued.

E. 25 CFR Part 166—Grazing Permits on Indian Lands

The purpose of this part is to describe the authorities, policies and procedures the Secretary uses to grant, approve and administer grazing permits on agricultural lands that are restricted against alienation or are held by the United States in trust for federally recognized Indian tribes and individual Indians, as well as certain lands owned by the federal government. It revises and entirely replaces the existing part 166, and implements the AIARMA with regard to grazing permits on Indian agricultural land and education in agriculture management. We have taken care to ensure consistency of related provisions in both parts 166 and 162 that implement the AIARMA.

Part 166 balances the Secretary's responsibilities as trustee of Indian land and resources with the need for Indian tribes and individual Indian landowners to exercise control over their agricultural trust lands and business affairs. Part 166 is organized to include ten subparts for the convenience of the reader. The expanded sections clarify existing policies and procedures governing the administration of grazing permits on Indian agricultural lands and is intended to bring consistency to the administration of grazing permits by the BIA. Part 166 does not address leasing of any type, nor does it address permitting for purposes other than grazing. Leasing of Indian lands is covered in part 162 of 25 CFR.

General Observations Regarding Changes From Proposed Rule

The Final Rule follows the format used in the Proposed Rule. Specific changes and responses to significant comments are outlined below.

Subpart A—Purpose, Scope, and Definitions

Summary of Subpart

Subpart A addresses the purpose and scope of part 166 and describes the authorities, policies, and procedures the Secretary uses to approve, grant, and administer grazing permits of Indian agricultural land. This subpart also defines key terms used throughout part 166. These terms are consistent with those found in the AIARMA.

Comments

As we noted in our general discussion of the final regulation and our discussion of part 162, several commenters recommended that the BIA develop a stand-alone rule to implement the AIARMA exclusively. This recommendation was not accepted. Part 166 fully implements the AIARMA as it pertains to grazing permits on Indian land.

One tribe recommended that the Final Rule not impact tribal grazing lands currently governed by other parts of Title 25 of the Code of Federal Regulations. This recommendation was accepted. Section 166.1(c) was added to clarify that tribal grazing programs authorized under separate statutory authority are not subject to part 166.

Several respondents requested clarification of definitions including "conservation practices," "fair annual rental," "majority interest," "on-and-off grazing permit," "owner's use," and "parcel." These comment were accepted and the revisions have been incorporated into the definitions found in subpart A. Also in response to several comments, all the definitions were reviewed and revised to maintain consistency with the AIARMA and part 162.

Subpart B—Tribal Policies and Laws Pertaining to Permits

Summary of Subpart

Under subpart B, tribal laws and ordinances, including laws regulating the environment, cultural or historic preservation, land use, and other activities under tribal jurisdiction, apply to grazing permits on Indian agricultural lands unless such tribal laws and ordinances are prohibited by federal law. Tribes are responsible for enforcing tribal laws and ordinances pertaining to Indian agricultural lands with the assistance of the Secretary.

Consistent with the AIARMA, this subpart makes clear that when authorized by an appropriate tribal resolution, the Secretary will comply with certain general tribal policies pertaining to permitting on Indian agricultural lands. Also consistent with the AIARMA, subpart B provides that individual Indian landowners who have at least a 50% interest in a fractionated tract of Indian land can exempt their Indian land from the Secretary's implementation of these certain general tribal policies by submitting a written request to the BIA.

Comments

Similar to part 162, many comments questioned provisions of part 166 that allow individual Indian land owners to exempt their lands from certain general tribal policies pertaining to permitting on Indian agricultural lands. Comments also recommended that tribes should not be authorized to define "highly fractionated undivided heirship lands." These comments were not accepted. Section 3715(b) of the AIARMA authorizes tribes to establish certain general tribal policies pertaining to permitting on Indian agricultural lands through an appropriate tribal resolution which also includes the authorization of tribes to define "highly fractionated undivided heirship lands" for notification purposes. Section 3715(c)(3) of the AIARMA authorizes individual Indian landowners who have at least a 50% interest in a fractionated tract of Indian land to exempt their Indian land from the Secretary's implementation of these certain general tribal policies pertaining to permitting on Indian agricultural lands by submitting a written request to the BIA. Part 166 fully complies with these provisions of the AIARMA.

Many comments recommended that tribes not be required to notify the BIA when new tribal laws or policies are enacted. These comments were not accepted. Section 3712(b) of the AIARMA requires the Secretary to provide notice of tribal laws or policies to persons or entities undertaking activities on Indian agricultural lands. It is reasonable to require tribes to notify the BIA of new applicable tribal laws or policies so that the Secretary may comply with the AIARMA. This notice requirement does not invalidate tribal laws or policies if tribes do not provide the BIA with notice of such new laws or policies. Finally, in response to comments, a provision was added in § 166.104 that states the BIA will notify affected Indian landowners, in addition to permittees, of new applicable tribal laws or policies.

Subpart C—Permit Requirements

Summary of Subpart

This subpart describes general requirements for obtaining a grazing permit, obtaining a grazing permit (leasehold) mortgage, modifying and assigning a grazing permit, and subpermitting of an existing grazing permit. This subpart also recognizes the authority of tribes to determine the duration of permits on tribal lands. Pursuant to the AIARMA, 25 USC 3715(a), subpart C provides that grazing permits would be generally granted for a period of ten years unless a longer term of up to 25 years is appropriate.

Subpart C recognizes that the Secretary has authority to grant or approve only permits of trust interests in Indian lands. Subpart C also makes clear that to ensure the preservation and proper use of trust lands, the Secretary requires permittees to conduct grazing operations in accordance with tribal goals and priorities for multiple use, sustained yield, agricultural resource management planning, and sound conservation practices. This subpart further requires permittees to fulfill all financial obligations to the Indian landowners and to conduct only those activities authorized by the grazing permit. Failure by a permittee to meet these expectations may result in an imposition of fines or penalties under subpart H, "Permit Violations," or subpart I, "Trespass," in order to protect the interests of the Indian landowners.

Comments

Several comments recommended a clarification of whether the BIA must approve tribal permits. The recommendation was accepted. Clarifications were made in § 166.1 of subpart A which describe specific circumstances for which Secretarial approval is not required for tribal permits.

Many respondents recommended that the regulations provide protection to Indian landowners so that their land may not be subpermitted at higher rates without a commensurate benefit to the Indian landowners. These recommendations were accepted. Section 166.229 provides protection to the Indian landowner by requiring BIA approval and the written consent of all parties to the permit (including Indian landowners) prior to an amendment, modification, assignment, transfer, or subpermit.

The proposal to eliminate the "on-and-off" grazing permit system that allowed for the administration of range units that involve both trust and non-trust lands was the subject of many

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concerns. These respondents raised concerns about prudent range management practices where grazing trust land is permitted adjacent to non-trust land where grazing also occurs. These comments were accepted. A new provision, § 166.308, was added to allow the modification of the number of animals on permitted Indian land in order to accommodate adjacent non-trust lands so long as the conservation plan and the permit for the permitted Indian land accounts for this practice. However, the Secretary has no management authority over non-trust lands and will not approve grazing on non-trust lands.

The non-trust interest provisions previously located in subpart C of the Proposed Rule was eliminated. A discussion of the Secretary's responsibility regarding non-trust interest is now found in § 166.1.

A small number of comments recommended that leasehold mortgages not be allowed on grazing permits. Because such mortgages can be an important mechanism for economic development, these comments were not accepted. Section 166.223 preserves the option of mortgages on the permitted interest for those wishing to do so. Such mortgages apply only to the permit interest, not the interest in Indian land, and are a valid source of secured lending. The BIA recognizes that leasehold mortgages should be available where the parties to the permit agree. Mortgaging a permit interest is not required, and the parties to the permit remain free to negotiate a provision to allow or disallow such mortgages.

Several comments recommended that part 166 contain a 30-day time frame for notifying permittees of the removal of tribal land from a range unit. These comments were not accepted. Permittees require a reasonable time to make other arrangements for their livestock when tribal lands are removed from a range unit. Thus, § 166.228 continues the current 180-day notice requirement.

Several comments recommended that tribes be responsible for conducting their own appraisals and valuations. While the comments have merit, the Secretary has a trust responsibility to ensure that appropriate valuation is obtained for each permit. Tribes may conduct their own valuations in addition to valuations required by part 166.

Several comments recommended that the BIA should not limit valuation methods to appraisals. These comments were accepted. Section 166.401 was re-written to clarify that additional valuation methods may be employed as appropriate if consistent with the Uniform Standards of Professional Appraisal Practices (USPAP).

Many comments recommended that emancipated minors be recognized as adults and be authorized to grant permits on their own behalf. These comments were accepted. Section 166.202 was re-written to enable emancipated minors to grant grazing permits on their own behalf.

A number of respondents recommended that part 166 clarify the Indian landowner's responsibility in negotiating and advertising permits. These comments were accepted. Sections 166.220 and 166.221 were clarified to reflect that Indian landowners may negotiate permits and advertise for bids. The BIA will continue to assist Indian landowners with negotiations and advertisement or negotiate or advertise on behalf of Indian landowners when requested.

Subpart D—Land and Operations Management

Summary of Subpart

Subpart D, "Land Operations and Management," describes how the BIA will establish range units and grazing capacity in consultation with Indian landowners.

All grazing permits issued under subpart D must be consistent with an agricultural resource management plan prepared in accordance with § 3711(b) of the AIARMA by a tribe or by the BIA in close consultation with a tribe. To ensure that a permittee's intended objectives regarding animal husbandry and other grazing issues represent sound practice, § 166.312 requires that a conservation management plan be developed with the permittee for each permit. The conservation management plan must be consistent with the tribe's approved agricultural resource management plan.

Comments

Several comments recommended that the Final Rule include an "on-and-off" grazing permit that allows the number of animals and/or season of use to be modified on the permitted land if adjacent trust or non-trust rangelands are used. These comments were accepted. Section 166.308 of this subpart describes how the number of animals and/or adjacent trust or non-trust rangelands may be included in an "on-and-off" grazing permit.

Several comments recommended that the final rule accommodate tribes that wish to decide livestock ownership requirements on tribal land, including those pertaining to non-Indian cattle owners and Indian cattle enterprises. These recommendations were accepted. A new provision, § 166.309, was added to support the tribe's authority to determine tribal livestock ownership requirements on tribal lands.

Several respondents recommended that conservation plans not be developed by permittees, and that tribes should be included when preparing and evaluating conservation plans. Many also recommended that part 166 provide greater specificity on how tribes should develop their agriculture resource management plans. Section 166.312 provides that conservation plans will be developed with the permittee for each permit and must be approved by the BIA prior to issuance of the permit. The conservation plan must also be consistent with the tribe's agriculture resource management plans in accordance with the AIARMA. As written, § 166.312 does not mandate options by which tribes may fund or contract plan development in order to maintain flexibility.

Several commenters recommended that part 166 identify who would be liable for completing or maintaining a conservation practice through a USDA cost share program or other similar program if the permittee no longer holds the permit. These comments were accepted. A new provision, § 166.315, was added that requires the parties to the permit to negotiate and identify which party will be responsible for completing and/or maintaining a conservation practice should the permit expire or be canceled.

Subpart E—Grazing Rental Rates, Payments, and Late Payment Collections

Summary of Subpart

Subpart E, "Grazing Rental Rates, Payments, and Late Payment Collections" preserves the ability of tribes to establish grazing rental rates on tribal lands. The BIA continues to set the grazing rental rates for individually owned Indian land. This subpart clarifies the procedures by which tribes may set grazing rental rates higher or lower than the BIA's established fair annual rental rate.

As trustee, the Secretary must determine the fair annual rental value of Indian trust lands in order to assist Indian landowners in negotiating permits with potential permittees and to determine if a permit is in the best interest of the Indian landowner. Subpart E clarifies that the BIA will determine fair annual rental value for grazing permits on Indian agricultural lands by appraisal, advertisement, competitive bidding, or any other appropriate method that complies with the USPAP. The BIA does not intend to specify in part 166 the particular method for appraising agricultural land; rather, ensuring flexibility in choosing an appraisal method allows the Secretary to most effectively discharge his responsibility as trustee.

Subpart E continues the practice of direct payments to Indian landowners, and requires adequate proof of payment.

In § 166.424, the BIA will prorate grazing rental payments made to each Indian landowner according to the forage production that each parcel of Indian land contributes to the permit, annual rental rate of each parcel, and the Indian landowner's interest in each parcel.

Comments

Many comments recommended that the BIA clarify and expand payment methods to allow greater flexibility for landowners such as by allowing rental payments by electronic funds transfer, personal, and business checks. These comments were accepted. In addition, § 166.419(c) allows for partial rental payments only under special circumstances with the written consent of the parties to the permit and the BIA approval when necessary to obtain the maximum payment possible for the Indian landowner.

Many comments were received about the BIA's obligation to collect late rental payments owed to Indian landowners. These comments were accepted. Part 166 includes new provisions that describe the BIA's responsibility in collecting late rental payments. For example, § 166.419 describes the collection actions the BIA will take (including canceling the permit, assessing payment penalties, interest, and administrative fees, and referring unpaid debts to the United States Department of Treasury for collection) against a permittee to collect on a late payment. The NCAI recommended that the BIA adopt a collection process from another federal agency that would initiate trespass action immediately for non-payment of rental payments. This recommendation was not accepted because permits must be canceled before a permittee can be determined to be in trespass.

Subpart F—Administrative and Tribal Fees

Summary of Subpart

Subpart F, "Administrative and Tribal Fees," provides a schedule of administrative fees based on the dollar value of the permit. This subpart provides a minimum and maximum administrative fee amount. The BIA continues to be able to waive such administrative fees. This subpart also acknowledges that tribes may establish and collect their own administrative fees in addition to administrative fees assessed by the BIA.

Comments

Several comments recommended that the BIA use a flat administrative fee rate to charge permittees for the administration of permits. These comments were accepted. The BIA will charge a flat three percent administrative fee based on the annual grazing rental to cover costs associated with the performance of administrative duties. The existing minimum and maximum administrative fees described in the proposed regulation were retained in § 166.501(b).

Subpart G—Bonding and Insurance Requirements

Summary of Subpart

Subpart G, "Bonding and Insurance Requirements," clarifies current BIA practices by requiring that a bond be provided for each permit issued to ensure performance and compliance with permit terms. Upon request of an Indian landowner, the BIA may waive the bond requirement. For grazing permits on tribal lands, this subpart recognizes tribal authority to negotiate the form of the bond.

Comments

Many comments recommended that part 166 include bonding requirements that address overgrazing on Indian lands. These comments were accepted. Section 166.601(a)(4) as described in the proposed regulation was retained and allows a bond to be applied to the costs of restoration and reclamation of Indian land damaged by a permittee. Also, § 166.602(b) states that Indian landowners may negotiate a permit term that specifies the use of any bond forms described in § 166.602(a).

Several comments recommended that the BIA pay interest on cash bonds. These comments were not accepted. Cash bonds are not trust funds and are not administered as trust funds, and therefore are ineligible for interest payments without additional statutory authority.

Subpart H—Permit Violations

Summary of Subpart

Subpart H, "Permit Violations," provides for Secretarial action should the BIA learn that a violation of the terms of a grazing permit may have occurred.

Comments

Several comments recommended that grazing unit inspections by the BIA for permit compliance be required more often than one time per year. These comments were not accepted. Due to the varying circumstances of each range unit, flexibility in grazing unit inspections must be maintained. While the BIA intends to increase its ability to monitor range units for permit compliance, the BIA must continue to rely on information provided by Indian landowners. Thus, § 166.703(a) was added to clarify that Indian landowners may contact the BIA to request that appropriate enforcement action be taken by the BIA should an Indian landowner believe that a violation has occurred.

Several comments recommended that the final rule support the tribe's authority to adopt its own appeal process for range unit violations. These comments were accepted. Section 166.702 was modified so that the parties to a grazing permit may negotiate a provision in the permit that would defer to tribal remedies for permit violations.

Subpart I—Trespass

Summary of Subpart

Subpart I, "Trespass," defines trespass under a grazing permit to include any unauthorized occupancy, use of or action on Indian agricultural or government lands assigned to the control of a tribe. This subpart describes the process for trespass notification, enforcement, actions, penalties, damages, and costs.

Comments

Many comments recommended that part 166 should include a trespass inspection schedule. These comments were not accepted. As with grazing unit inspections under subpart H, flexibility in inspections must be maintained to take into account varying range unit circumstances and the need to rely on Indian landowners. Part 166 provides that the BIA will continue to act on specific information about trespass on Indian agricultural lands. Section 166.801 clarifies our obligation to investigate and respond to allegations of trespass.

Several comments recommended that penalties received from a grazing trespass be paid directly to the permittee. These comments were partially accepted. Section 3713(c) of the AIARMA authorizes the payment of proceeds from trespass for the loss of forage or other damage. However, the

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AIARMA is unclear as to whether permittees are to receive all or some of such proceeds. The BIA recognizes that the loss of forage or other damage is often sustained by the permittee. In order to provide for trespass payments to permittees (as an affected party under section 166.818) for the loss of forage or damage due to trespass, the parties to the permit may include a trespass reimbursement provision in the permit that allows for such reimbursement.

One comment recommended the final rule should not suggest that tribes are required to adopt the trespass provisions of part 166 in order to secure tribal trespass jurisdiction. This comment was accepted. Section 166.802(b) was added to specifically recognize the authority of tribes to take any trespass action tribal law may allow.

Subpart J—Agriculture Education, Education Assistance, Recruitment, and Training

Summary of Subpart

Subpart J, Agriculture Education, Education Assistance, Recruitment, and Training, outlines the provisions for implementing subchapter II of the AIARMA, Education in Agriculture Management.

Comments

Many comments recommended that students receive one year of funding for one year worked in the agricultural education program in accordance with the AIARMA. This comment was accepted. Section 166.901(f)(3) was changed to support the requirement that students enter into an obligated service agreement to serve as a professional resource manager or agriculture-related professional with an approved organization for one year in exchange for each year in the program.

Subpart K—Records

As noted previously, new provisions have been added addressing the ownership and maintenance of trust records associated with the performance of this part. These provisions replace those in subpart K of the Proposed Rule.

IV. Procedural Requirements

A. Review Under Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), OMB must determine whether the regulatory action is "significant" and therefore subject to the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Accordingly, OMB has determined that this rule is not a significant regulatory action and is largely administrative and technical in nature. The rule describes how the federal government will administer its trust responsibility in managing the trust fund accounts. Thus, the impact of the rule is confined to the federal government and the Indian trust beneficiaries and does not impose a compliance burden on the economy generally. The Department did submit the entire Proposed Rule for review by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) as a significant policy matter impacting all federally-recognized Indian tribes and individual Indians. This decision was made because of the magnitude of the monies involved in Indian trust matters and the notion that any revisions to existing regulations that impact trust account management could have significant impacts on tribal governments, communities and individual Indians. In particular, the Department conducted an economic analysis of the revisions to part 115 and found that there were significant benefits in management, security and reporting of trust accounts and only small increases on tribal governments or individual Indians. The increased benefits are better identification of funds, ability to gain performance reports on tribal or individual accounts, clarifications in what funds could be deposited into such accounts, better distribution procedures, and clarifications on when and how such accounts could be restricted or otherwise encumbered. The revisions to part 115 were found to have potential for administrative savings.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section (b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. The Department of the Interior has determined that, to the extent permitted by law, the proposed regulation meets the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

This rule was reviewed under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities. This rule streamlines the Department's policies, procedures, provisions and clauses that apply to certain Indian trust resources. Indian tribes are not small entities under the Regulatory Flexibility Act. Any impacts on identified small entities affected by this rulemaking are minimal as they would concern a small number of farmers, ranchers, and individuals doing business on Indian lands. Accordingly, the Department of the Interior has determined that this regulation will not have a significant economic impact on a substantial number of small entities, and, therefore, no regulatory flexibility analysis has been prepared.

D. Review Under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more. The revised parts represent programs that are ongoing within the BIA and no new monies are being introduced into the stream of commerce. This rule will not result in a major increase in costs or prices. The effect of this rulemaking will be to streamline ongoing policies, procedures and management operations of the BIA in their handling of tribal and individual Indian trust resources. No increases in costs for administration will, therefore, be realized and no prices would be impacted through these administrative and technical clarifications of existing field practice. This rulemaking will not result in any significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets. The impact of the rulemaking will be realized by tribal governments and individual Indians having a protected trust resource. These administrative and technical clarifications of Departmental policy and procedure will not otherwise have a significant impact on any other small businesses or enterprises.

E. Review Under the Paperwork Reduction Act

This rulemaking requires an information collection from 10 or more parties and a submission under the Paperwork Reduction Act of 1995, Public Law 104–13, is required. Accordingly, the Department prepared an OMB form 83–I for review and approval by OMB. Having reviewed the submissions of the Department with respect to the burden hours of each part of this rulemaking, along with any comments that were submitted by the reviewing public, OMB has approved the information collection requirements contained in this rulemaking and has assigned OMB control number 1076–0154.

F. Review Under Executive Order 13132—Federalism

This rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. While this rule will impact tribal governments, there is no Federalism impact on the trust relationship or balance of power between the United States government and the various tribal governments affected by this rulemaking. Therefore, in accordance with Executive Order 13132, it is determined that this rule has no sufficient federalism implications to warrant the preparation of a Federalism Assessment.

G. Review Under the National Environmental Policy Act of 1969

This rule does not constitute a major federal action significantly affecting the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is necessary for this rule.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under section 202 of the Act, the Department generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "federal mandates" that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. The Department, however, determined that the rulemaking would uniquely affect tribal governments and, accordingly, followed Departmental and Administration protocols in consulting with tribal governments on this rulemaking. See discussion on consultations found in the Background section of this preamble. These consultations were in keeping with the President's Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments."

List of Subjects

25 CFR Part 15

Estates, Indians—law.

25 CFR Part 114

Accounting, Indians—business and finance.

25 CFR Part 115

Administrative practice and procedure, Indians—business and finance.

25 CFR Part 162

Indians—lands.

25 CFR Part 166

Grazing lands, Indians—lands, Livestock.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, amends 25 CFR as follows:

PART 15—PROBATE OF INDIAN ESTATES, EXCEPT FOR MEMBERS OF THE FIVE CIVILIZED TRIBES

1. Part 15 is revised to read as follows:

Subpart A—Introduction

Sec.
15.1 What is the purpose of this part?
15.2 What terms do I need to know?
15.3 Will the Secretary probate all the property in Indian estates?
15.4 How does the probate process work?

Subpart B—Starting the Probate Process

15.101 How do I begin the BIA probate process?
15.102 May I notify the BIA of a death if I am not related to the decedent?
15.103 When should the BIA be notified of a death?
15.104 What other documents does the BIA need to process a probate package?
15.105 Will the BIA wait to begin the probate process until it is notified of the decedent's death?
15.106 Can I get emergency assistance for funeral services from the decedent's IIM account?
15.107 Who prepares an Indian probate package?
15.108 What agency prepares the probate package if the decedent was not an enrolled member of a tribe or is a member of more than one tribe?
15.109 Can a probable heir or beneficiary give up his/her interest in trust or restricted lands or trust funds?

Subpart C—Preparing the Probate Package

15.201 What will the BIA do with the documents that I provide?
15.202 What must the complete probate package contain?
15.203 What happens after the BIA prepares the probate package?
15.204 After the probate package has been sent to a BIA deciding official, may I still request a formal hearing with an ALJ?
15.205 When will the BIA refer a probate to the OHA?
15.206 Is there a summary process for distributing an estate with only trust cash assets?

Subpart D—Probate Processing, Claims and Distributions

15.301 What does the attorney decision maker do with the probate package?
15.302 What law is used by the deciding official to determine the distribution of the trust estate?
15.303 If the decedent owed me money, how do I file a claim against the estate?

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15.304 How does the BIA deciding official determine if a claim will be allowed and paid?
15.305 What claims will be paid first?
15.306 Can the BIA deciding official reduce the amount of claims?
15.307 What if there is not enough money in the decedent's IIM account to pay all claims?
15.308 Will the BIA use future income to pay claims?
15.309 Will the BIA deciding official authorize payment of interest or penalties accruing after the date of death?
15.310 When will the BIA deciding official issue a decision on the probate?
15.311 What is in the written decision/order of the BIA deciding official?
15.312 What happens after the decision is made?

Subpart E—Appeals

15.401 May I appeal the decision of the BIA deciding official?
15.402 How do I file an appeal of the decision/order?
15.403 How long do I have to file an appeal?
15.404 What will happen to the estate if an appeal is filed?
15.405 How does the ALJ review a decision issued by a BIA deciding official?

Subpart F—Information and Records

15.501 If I have a question about a probate that has been assigned to a BIA deciding official, may I contact the deciding official directly?
15.502 How can I find out the status of a probate?
15.503 Who owns the records associated with this part?
15.504 How must records associated with this part be preserved?

Authority: Secs. 1, 2, 36 Stat. 855, as amended, 856, as amended, sec. 1, 38 Stat. 588, 42 Stat. 1185, as amended, secs. 1, 2, 56 Stat. 1021, 1022, 25 U.S.C. 372, 373, 374, 373a, 373b; Federal Records Act, as amended, 44 U.S.C. § 3101, *et seq.* (1950).

Cross reference: For special rules applying to proceedings in Indian Probate (Determination of Heirs and Approval of Wills, Except for Members of the Five Civilized Tribes and Osage Indians), including hearings and appeals within the jurisdiction of the Office of Hearings and Appeals, see Title 43, Code of Federal Regulations, Part 4, Subpart D; Funds of deceased Indians other than the Five Civilized Tribes, see Title 25 Code of Federal Regulations, Part 115.

Subpart A—Introduction

§ 15.1 What is the purpose of this part?

This part contains the procedures that the Secretary follows to initiate the probate of the trust estate of a deceased individual Indian who owned trust or restricted property. This part tells you how to file the necessary documents to probate the trust estate. This part also describes how probates will be processed by the BIA, and how probates may be sent to the OHA for disposition.

§ 15.2 What terms do I need to know?

ALJ means an administrative law judge or other employee of the Department of the Interior's Office of Hearings and Appeals (OHA) upon whom authority has been conferred by the Secretary to conduct hearings in accordance with 43 CFR Part 4 Subpart D.

BIA means the Bureau of Indian Affairs within the Department of the Interior.

IIM account means Individual Indian Money Account.

LTRO means the Land Titles and Records Office within the BIA.

OHA means the Hearings Division, Office of Hearings and Appeals, Department of the Interior.

OTFM means the Office of Trust Funds Management, within the Office of the Special Trustee for American Indians, Department of the Interior, or its authorized representative.

Agency means the agency office or any other designated office in the BIA having jurisdiction over trust or restricted property and money. This term also means any office of a tribe which has contracted or compacted the BIA probate function under 25 U.S.C. § 450f or 25 U.S.C. § 458cc.

Attorney decision maker means an attorney with the BIA, who reviews a probate package, determines heirs, approves wills and beneficiaries of the will, determines creditors claims, and issues a written decision.

Beneficiary means any individual who receives trust or restricted property or money in a decedent's will.

Day means a calendar day, unless otherwise stated.

Decedent means a person who is deceased.

Deciding official means the official with the delegated authority to make a decision on a probate matter, and may include a BIA regional director, agency superintendent, field representative, or attorney decision maker (BIA deciding official); or an OHA ALJ or other OHA designated official (OHA deciding official).

Decision/order means a written document issued by the deciding official determining heirs, approving wills and beneficiaries of the will, approving creditors claims, and ordering distribution of property and money.

Domicile means the legal residence of the person.

Estate means the trust cash assets, restricted or trust lands owned by the decedent at the time of his death.

Form OHA–7 means a form issued by the OHA which lists data for heirship and family history, and provides information on any wills, trust and restricted property, adoptions, names and addresses of all interested parties.

Heir means any individual who receives trust or restricted property or money from a decedent in an intestate proceeding.

IIM account means funds held in an individual Indian monies account by the OTFM or a tribe performing this function under a contract or compact.

Interested parties means any probable or actual heir, any beneficiary under a will, any party asserting a claim against a deceased Indian's estate, and any tribe having a statutory option to purchase the trust or restricted property interest of a decedent.

Intestate means the decedent died without a will.

Minor means an individual that has not reached age of majority as defined by the applicable tribal or state law.

Probate means the legal process by which applicable tribal law, state law, or federal law that affects the distribution of the decedent's estate is applied to: (1) determine the heirs; (2) approve wills and beneficiaries; and (3) transfer any funds held in trust by the Secretary for a decedent to the heirs, beneficiaries, or other persons or entities entitled by law.

Probate clerk means a BIA or tribal employee who is responsible for processing a probate package.

Probate specialist means the BIA or tribal employee who is trained in Indian probate matters.

Restricted land means land the title to which is held by an individual Indian or a tribe and which can only be alienated or encumbered by the owner with the approval of the Secretary because of limitations contained in the conveyance instrument pursuant to federal law.

Secretary means the Secretary of the Interior or an authorized representative.

Superintendent or Field Representative means an authorized representative of the Secretary of the Interior who is the officer in charge of a BIA agency or field office.

Testate means the decedent executed a will before his death.

Trust cash assets means the funds held in an IIM account.

Trust land means the land, or an interest therein, for which the United States holds fee title in trust for the benefit of an individual Indian.

Vendor or Creditor means any individual or company who submits a claim for payment from a decedent's estate.

We/Us means either an official of the BIA or a tribe performing probate functions under a BIA contract or compact.

Will means a written testamentary document, including any properly executed written changes, called codicils, which was signed by the decedent and was attested by two disinterested adult witnesses, that states who will receive the decedent's trust or restricted property.

You/I means an interested party, as defined herein, with an interest in the decedent's estate unless a specific section says otherwise.

§ 15.3 Will the Secretary probate all the property in Indian estates?

(a) No. We will probate only the trust or restricted property in the estate of an Indian decedent.

(b) We will not probate:

(1) Real or personal property in an estate of an Indian decedent that is not trust or restricted property;

(2) Restricted property derived from allotments in the estates of members of the Five Civilized Tribes (Cherokee, Choctaw, Chickasaw, Creek and Seminole) in Oklahoma; and

(3) Restricted interests derived from allotments made to Osage Indians in Oklahoma (Osage Nation) and Osage headright interests.

(c) We will probate the estate of a deceased member of the Five Civilized Tribes or Osage Nation who owns an interest in land derived from an individual Indian other than the Five Civilized Tribes or Osage Nation.

§ 15.4 How does the probate process work?

The basic steps of the probate process are:

(a) We find out about a person's death (see subpart B for details);

(b) We prepare a probate package which includes documents that you send us (see subpart C for details);

(c) We refer the completed probate package to a deciding official in the BIA or the OHA (see subpart D for details);

(d) The deciding official decides how to distribute the property and/or funds deposited in an IIM account (see subparts D and E for details).

Subpart B—Starting the Probate Process

§ 15.101 How do I begin the BIA probate process?

As soon as possible you should contact the nearest BIA agency or regional office where the decedent was enrolled to inform us of the decedent's death. You must provide a certified copy of the death certificate, if one exists. If a death certificate does not exist, you may provide one or more of the following:

(a) A copy of the obituary notice from a local newspaper; or

(b) Any other document that we accept that verifies the death, such as a church record or a court record; and

(c) An affidavit of death prepared by the tribe with whom the decedent was associated or someone who knows about the decedent's death that supports the information in paragraph (a) or (b) of this section.

§ 15.102 May I notify the BIA of a death if I am not related to the decedent?

Yes. You do not need to be related to the decedent in order to notify us of the death. You can be a friend, neighbor, or any other interested party.

§ 15.103 When should the BIA be notified of a death?

There is no deadline for notifying us of a death. However, you should notify us of a death as soon as possible after the person dies.

§ 15.104 What other documents does the BIA need to process a probate package?

(a) You should provide us with the following documents and information before we can begin to process the probate package.

(1) Social Security number of the decedent;

(2) The birth certificate or other record of birth of the decedent;

(3) All death records including those listed in § 15.101;

(4) A list of known creditors against the estate and their addresses;

(5) Current names and addresses of potential heirs and beneficiaries;

(6) Any statements renouncing an interest in the estate;

(7) Documents from a court of competent jurisdiction, including but not limited to:

(i) All marriage licenses of the decedent;

(ii) All divorce decrees of the decedent;

(iii) Adoption and guardianship records relevant to the decedent;

(iv) Any sworn statements regarding the decedent's family, including any statements of paternity or maternity;

(v) Any name changes; and

(vi) Order requiring payment of child support;

(8) All original or certified copies of wills and codicils, and any revocations; and

(9) Any additional documents you provide or that we request.

(b) You must inform us if any of the documents or information identified in this part are not available.

§ 15.105 Will the BIA wait to begin the probate process until it is notified of the decedent's death?

No. We may find out about the death of a person without being notified by an interested party. If we do, and if the decedent meets the criteria in § 15.3, we will initiate the process to collect the necessary documentation. You should not assume that we will find out about a death. To assure timely distribution of the estate, you should notify us as provided in § 15.101.

§ 15.106 Can I get emergency assistance for funeral services from the decedent's IIM account?

(a) If you are responsible for making the funeral arrangements on behalf of the family of a decedent who had an IIM account and you have an immediate need to pay for funeral arrangements prior to burial, you may make a request to the BIA for up to $1,000 from the decedent's IIM account if the decedent's IIM account has more than $2,500 in the account at the date of death.

(b) You must apply for this assistance and submit to the BIA an original itemized estimate of the cost of the service to be rendered and the identification of the service provider.

(c) We may approve reasonable costs up to $1,000 that are necessary for the burial services, taking into consideration the total amount in the account, the number of probable heirs or beneficiaries of whom we are aware, the amount of any claims against the account of which we are aware, and any other relevant factor.

(d) We will make payments directly to the providers of the services.

§ 15.107 Who prepares an Indian probate package?

The probate specialist or probate clerk at the agency or tribe where the decedent is an enrolled member will prepare the probate package in consultation with the probable heirs or beneficiaries who can be located.

§ 15.108 What agency prepares the probate package if the decedent was not an enrolled member of a tribe or is a member of more than one tribe?

(a) If the decedent was not an enrolled member of a tribe, but owns interests in trust or restricted property, the agency that has jurisdiction over the tribe with the strongest association with the decedent will prepare the probate package, unless otherwise provided by federal law.

(b) If the decedent was is a member of more than one tribe, the agency that has jurisdiction over the tribe with the strongest association with the decedent

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will prepare the probate package, unless otherwise provided by federal law.

§ 15.109 Can a probable heir or beneficiary give up his/her interest in trust or restricted lands or trust funds?

Unless otherwise provided by federal law or a tribal inheritance code approved by the Secretary, you must file a statement renouncing your interest with the BIA or the OHA before the deciding official issues an order.

(a) If you are a non-Indian and 21 years or older, you may give up all or part of your interest by submitting a notarized statement in which you renounce your interest in the estate.

(b) If you are an Indian and 21 years or older and you wish to give up all or part of your interest in the estate, we must refer your request to the OHA in accordance with 43 CFR 4.208.

Subpart C—Preparing the Probate Package

§ 15.201 What will the BIA do with the documents that I provide?

Once we receive the documents that you provide us under § 15.105, the probate specialist or probate clerk will:

(a) Use the documents to prepare a probate package; and

(b) Consult with you and any other sources to obtain any additional information needed for a complete package.

§ 15.202 What must the complete probate package contain?

The complete probate package must contain all of the following:

(a) A certified copy of the death certificate, if one exists, or some other reliable evidence of death as required by § 15.101;

(b) A completed Form OHA–7, "Data for Heirship Findings and Family History," certified by the BIA;

(c) A certified inventory of trust or restricted real property;

(d) A statement describing all income generating activity;

(e) A copy of the decedent's IIM account ledger showing:

(1) The balance of the account at the date of death; and

(2) The balance of the account at the date of probate package submission;

(f) All original or certified copies of wills, codicils and any revocations of wills or codicils;

(g) Any statements renouncing interest that have been submitted to the agency;

(h) Claims of creditors against the estate;

(i) All documentation of payment of claims paid prior to probate proceeding;

(j) All other documents required in § 15.105;

(k) Tribal options to purchase interests of a decedent;

(l) Affidavit of the probate clerk or probate specialist that all efforts to locate the probable heirs and beneficiaries have been exhausted; and

(m) Any other documentation that may be required at the time of probate proceedings.

§ 15.203 What happens after the BIA prepares the probate package?

Within 30 days after all the documents required by § 15.105 and § 15.202 are received, a probate specialist will review the probate package and determine who will be the appropriate deciding official.

(a) If the decedent's estate contains only trust cash assets of a value less than $5,000 not including any interest that may have accrued after the death of the decedent, the probate package may be processed in accordance with § 15.206 and may be referred to a BIA deciding official subject to the provisions in § 15.205.

(b) All other probate cases will be referred to a BIA attorney decision maker or an OHA deciding official subject to the provisions in § 15.205.

(c) We will notify all interested parties of:

(1) The right of the probable heirs or beneficiaries to request a formal hearing before an ALJ;

(2) The identification of the probable legal heirs; or

(3) The submission of an original or certified copy of a will or revocation and listed beneficiaries;

(4) Any known claims against the estate; and (5) The address of the designated office where the probate package has been sent.

(d) If the deciding official is at the BIA and you have not requested a formal hearing before an ALJ, the probate specialist will send the probate package to the BIA deciding official within 30 days after the date the probate specialists mailed the notice to you.

(e) If the deciding official is at the OHA, then we will send the probate package to the OHA deciding official and notify the probable heirs that they may ask the OHA for an in-person hearing at a site convenient to most of the parties, a video conference or teleconference hearing (if available), or a decision based on documents in the probate package.

(f) On the same day that the probate specialist has determined who will be the designated deciding official, we will notify you of this determination by certified mail, return receipt requested.

§ 15.204 After the probate package has been sent to a BIA deciding official, may I still request a formal hearing with an ALJ?

Yes, you may request a formal hearing before an ALJ at any time up until the date the BIA deciding official renders a decision.

§ 15.205 When will the BIA refer a probate to the OHA?

We will refer a probate to the OHA under § 15.203(d) if the probate specialist determines that a referral is appropriate. In determining whether to refer a probate to the OHA, the probate specialist will consider all of the criteria listed below:

(a) *Problems with the will.* The probate specialist will refer the probate package to the OHA if it appears that the will:

(1) Is likely to be contested;

(2) Is complex or ambiguous; or

(3) Is of questionable validity.

(b) *Contested claims.* The probate specialist will refer the probate package to the OHA if you:

(1) Contest a creditor claim; or

(2) Contest a claim made by a family member.

(c) *Other problems.* The probate specialist will be refer the probate package to the OHA if it appears there are:

(1) Questions about family relationships;

(2) Conflict in prior probate orders;

(3) Problems with the evidence;

(4) Questions about adoption of an heir;

(5) Questions involving paternity;

(6) Presumptions of death;

(7) Rights of minor heirs that might be jeopardized;

(8) Disclaimers of interests by Indian probable heirs or beneficiaries;

(9) Determinations of escheat under 43 CFR § 4.205;

(10) Challenges to the jurisdiction of any court that issued an order that has been used as a supporting document; or

(11) Questions concerning the decedent's domicile.

(d) *Approval of settlement agreements.* The probate specialist will refer the case to the OHA if there is a settlement agreement between heirs or beneficiaries as to the disposition of the estate.

§ 15.206 Is there a summary process for distributing an estate with only trust cash assets?

Yes. Unless otherwise provided by federal law or a tribal inheritance code approved by the Secretary, a decedent's estate that contains only trust cash assets of a value less than $5,000 not including any interest that may have accrued after the death of the decedent, may be summarily processed by a BIA deciding official.

(a) Within 30 days after notice under § 15.203 has been sent, the probable heirs may request a formal hearing before an ALJ to determine the proper distribution of the trust cash assets. Upon notice of a request for a formal hearing, the probate specialist will forward the probate package to the appropriate ALJ within five days.

(b) Within 60 days after notice under § 15.203 has been sent and if the probable heirs have not requested a formal hearing with an ALJ, the BIA deciding official to whom the probate has been referred will assemble the probable heirs and hold an informal hearing to determine the distribution of the trust cash assets.

(c) Within 30 days after the informal hearing, the BIA deciding official will prepare an order in accordance with § 15.302 through § 15.311.

(d) Any interested party may appeal a summary distribution decision in accordance with subpart E of this part.

Subpart D—Probate Processing, Claims and Distributions

§ 15.301 What does an attorney decision maker do with the probate package?

(a) Upon receipt of the probate package, the attorney decision maker reviews the probate package and determines whether there are issues of fact or law of the case that indicate that the probate package should be referred to the OHA. If any issues of fact or law that require a hearing are apparent from the review of the case, the attorney decision maker will refer the probate package to the appropriate ALJ within five days.

(b) Within 30 days after notice under § 15.203 has been sent, the probable heirs may request a formal hearing before an ALJ to determine the distribution of the estate. Within five days of the receipt of notice of a request for a formal hearing, the attorney decision maker will forward the probate package to the appropriate ALJ.

(c) Within 120 days after the notice under § 15.203 has been sent and if the probable heirs have not requested a formal hearing with an ALJ, the attorney decision maker will assemble the probable heirs and hold an informal hearing to determine the distribution of the estate.

(d) Within 60 days after the informal hearing, the attorney decision maker will issue an written order in accordance with § 15.310.

§ 15.302 What law is used by the deciding official to determine the distribution of the trust estate?

Unless otherwise provided by federal law or a tribal inheritance code approved by the Secretary, the law of the state where the decedent was domiciled will determine the distribution of the estate.

§ 15.303 If the decedent owed me money, how do I file a claim against the estate?

(a) If you wish to make a claim against the estate of a decedent, you must submit to us an original and two copies of an itemized statement of the debt showing the amount of the original debt and the remaining balance on the date of the decedent's death.

(b) The itemized statement must state whether you have filed a claim against the decedent's non-trust assets.

(c) We must receive your claim within 60 days from the date the BIA receives the verification of the decedent's death in § 15.101 to be included as part of the probate package.

§ 15.304 How does the BIA deciding official determine if a claim will be allowed and paid?

(a) The BIA deciding official may direct the payment of some or all of the debts of the decedent after reviewing the probate package in accordance with the standards provided at 43 CFR 4.250 (c) through (g), and no claim prohibited by 43 CFR 4.250 will be paid.

(b) No claim will be paid from trust or restricted assets where the BIA deciding official is aware that the decedent's non-trust estate may be available to pay the claim.

§ 15.305 What claims will be paid first?

(a) The first claims to be paid, referred to as priority claims, are paid in order of priority. The priority claims are:

(1) Funeral expenses (including the cemetery marker);

(2) Medical expenses for the last illness;

(3) Nursing home or other care facility expenses;

(4) A claim of an Indian tribe;

(5) A claim reduced to judgment by a court of competent jurisdiction.

(b) After payment of the priority claims, the BIA deciding official may authorize all remaining claims, referred to as general claims.

§ 15.306 Can the BIA deciding official reduce the amount of claims?

The BIA deciding official has the discretion to decide that part or all of an otherwise valid claim is unreasonable, reduce the claim to a reasonable amount, or disallow the claim in its entirety.

(a) If a claim is reduced, the BIA deciding official will order payment only of the reduced amount.

(b) The BIA deciding official may reduce or disallow both priority claims and general claims.

§ 15.307 What if there is not enough money in the decedent's IIM account to pay all claims?

(a) If there is not enough money in the IIM account to pay all claims, the BIA deciding official will order payment of the priority claims first in the order identified in § 15.305.

(b) If there is not enough in the IIM account to pay the priority claims, the BIA deciding official may order payment of the priority claims on a pro rata (reduced) basis.

(c) If less than $1,000 remains in the IIM account after payment of priority claims is ordered, the general claims may be ordered paid on a pro rata basis or disallowed in their entirety.

§ 15.308 Will the BIA use future income to pay claims?

No. The unpaid balance of any claims will not be enforceable against the estate after the estate is closed.

§ 15.309 Will the BIA deciding official authorize payment of interest or penalties accruing after the date of death?

No. Interest or penalties charged against either priority or general claims after date of death will not be paid.

§ 15.310 When will the BIA deciding official issue a decision on the probate?

Within 60 days after an informal hearing has been held, the BIA deciding official will issue a written decision/order in accordance with § 15.311. Upon receipt of the decision/order, the BIA deciding official will send all interested parties a copy of the decision/order.

§ 15.311 What is in the written decision/order of the BIA deciding official?

The BIA deciding official issues a written decision/order that:

(1) In intestate cases: Lists the names, relationship to the decedent, and shares of the heirs; provides citations to the law of descent and distribution; or the fact that the decedent died leaving no legal heirs;

(2) In testate cases: approves or disapproves a will; interprets provisions of the approved will; provides the names and relationship of the beneficiaries to the decedent; describes the property each beneficiary is to receive;

(3) Allows or disallows claims against the estate; orders the amount of payment for all approved claims;

(4) States whether the heirs or beneficiaries are Indian or non-Indian;

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(5) Determines any rights of dower, curtesy or homestead which may constitute a burden upon the interest of the heirs;

(6) Attaches a certified copy of the inventory of trust or restricted lands, if any; and

(7) Advises all interested parties of their appeal rights in accordance with subpart E of this part.

§ 15.312 What happens after the decision is made?

We will not pay claims, transfer title to land, or distribute trust cash assets for 75 days after the decision/order is mailed to the interested parties. After 75 days and if no appeal has been filed, the following actions will take place:

(a) The LTRO will change its land title records for the trust and restricted property in accordance with the decision/order; and

(b) The OTFM will pay claims and distribute the IIM account in accordance with the decision/order.

Subpart E—Appeals

§ 15.401 May I appeal the decision of the BIA deciding official?

You have a right to appeal the decision made by the BIA deciding official if you are an interested party and are affected by the probate decision.

§ 15.402 How do I file an appeal of the decision/order?

(a) To file an appeal of the decision/order, you may send or deliver a signed, written statement to the BIA deciding official where the probate package was sent that contains:

(1) The name of the decedent;

(2) A description of your relationship to the decedent;

(3) An explanation of why you are appealing; and

(4) Any errors you believe the BIA deciding official made.

(b) Within ten days from the receipt of the appeal, the BIA deciding official will notify all other interested parties of the appeal and forward the case to the appropriate ALJ.

§ 15.403 How long do I have to file an appeal?

(a) You must send or deliver your written appeal within 60 days of the date that appears on the decision mailed to you. If you mail your appeal, it must be postmarked within 60 days of the date of the decision.

(b) If the 60-day appeal period is missed, you still have a right to file a written statement with the BIA deciding official asking to have the decision changed for one or more of the following reasons:

(1) You did not receive notice of the probate;

(2) You have obtained new evidence or information after the decision was made; or

(3) You have evidence that was known at the time of the probate proceeding but was not included in the probate package.

(c) After we have received your request, we will forward it to the appropriate ALJ within ten days for action in accordance with 43 CFR Part 4, Subpart D.

§ 15.404 What will happen to the estate if an appeal is filed?

The BIA deciding official will refer your appeal to the appropriate ALJ in the same manner provided under 43 CFR § 4.210. Until the appeal has been resolved, the BIA will not distribute any of the decedent's property or modify the land title records and the OTFM will not pay claims or distribute any funds in the decedent's IIM account.

§ 15.405 How does the ALJ review a decision issued by a BIA deciding official?

The ALJ will conduct a *de novo* review; that is, conduct a formal hearing on the merits of the case.

Subpart F—Information and Records

§ 15.501 If I have a question about a probate that has been assigned to a BIA deciding official, may I contact the deciding official directly?

In order to avoid off-the-record communications with the BIA deciding official about your specific case that might be interpreted as an attempt to influence final decision on the probate case, you should direct your questions to the BIA deciding official's clerk or the probate specialist or probate clerk who prepared your probate package.

§ 15.502 How can I find out the status of a probate?

You may request information about the status of an Indian probate from any BIA agency or regional office.

§ 15.503 Who owns the records associated with this part?

(a) Records are the property of the United States if they:

(1) Are made or received by a tribe or tribal organization in the conduct of a federal trust function under this part, including the operation of a trust program pursuant to Public Law 93–638 as amended; and

(2) Evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under this part.

(b) Records not covered by paragraph (a) of this section that are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior under this part are the property of the tribe.

§ 15.504 How must records associated with this part be preserved?

(a) Any organization, including tribes and tribal organizations, that have records identified in § 15.503(a) must preserve the records in accordance with approved Departmental records retention procedures under the Federal Records Act, 44 U.S.C. Chapters 29, 31 and 33. These records and related records management practices and safeguards required under the Federal Records Act are subject to inspection by the Secretary and the Archivist of the United States.

(b) A tribe or tribal organization should preserve the records identified in § 15.503(b) for the period of time authorized by the Archivist of the United States for similar Department of the Interior records in accordance with 44 U.S.C. Chapter 33. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under this part, the tribe or tribal organization may be prevented from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

PART 114—SPECIAL DEPOSITS—[REMOVED AND RESERVED]

2. Under authority of 25 U.S.C. 2, 25 U.S.C. 9; Pub. L. 97–100; and Pub. L. 97–257, part 114 is removed and reserved.

PART 115—TRUST FUNDS FOR TRIBES AND INDIVIDUAL INDIANS

3. Part 115 is revised to read as follows:

Subpart A—Purpose, Definitions, and Public Information

Sec.

115.001 What is the purpose of this part?
115.002 What definitions do I need to know?

Subpart B—IIM Accounts

115.100 Osage Agency.
115.101 Individual accounts.
115.102 Adults under legal disability.
115.103 Payments by other Federal agencies.
115.104 Restrictions.
115.105 Funds of deceased Indians of the Five Civilized Tribes.
115.106 Assets of members of the Agua Caliente Band of Mission Indians.

115.107 Appeals.

Subpart C—IIM Accounts: Minors

115.400 Will a minor's IIM account always be supervised?
115.401 What is a minor's supervised account?
115.402 Will a minor have access to information about his or her account?
115.403 Who will receive information regarding a minor's supervised account?
115.404 What information will be provided in a minor's statement of performance?
115.405 How frequently will a minor's statement of performance be mailed?
115.406 Who provides an address of record for a minor's supervised account?
115.407 How is an address of record for a minor's supervised account changed?
115.408 May a minor's supervised account have more than one address on file with the BIA?
115.409 How is an address for a minor's residence changed?
115.410 What types of identification will the BIA or OTFM accept as "verifiable photo identification"?
115.411 What if the individual making a request regarding a minor's supervised account does not have any verifiable photo identification?
115.412 Will child support payments be accepted for deposit into a minor's supervised account?
115.413 Who may receive funds from a minor's supervised account?
115.414 What is an authorized disbursement request?
115.415 How will an authorized disbursement from a minor's supervised account be sent?
115.416 Will the United States post office forward mail regarding a minor's supervised account to a forwarding address left with the United States post office?
115.417 What portion of funds in a minor's supervised account may be withdrawn under a distribution plan?
115.418 What types of trust funds may a minor have?
115.419 Who develops a minor's distribution plan?
115.420 When developing a minor's distribution plan, what information must be considered and included in the evaluation?
115.421 What information will be included in the copy of the minor's distribution plan that will be provided to OTFM?
115.422 As a custodial parent, the legal guardian, the person who BIA has recognized as having control and custody of the minor, or an emancipated minor, what are your responsibilities if you receive trust funds from a minor's supervised account?
115.423 If you are a custodial parent, a legal guardian, or an emancipated minor, may BIA authorize the disbursement of funds from a minor's supervised account without your knowledge?
115.424 Who receives a copy of the BIA-approved distribution plan and any amendments to the plan?
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115.426 What is the BIA's responsibility regarding the management of a minor's supervised account?
115.427 What is the BIA's annual review process for a minor's supervised account?
115.428 Will you automatically receive all of your trust funds when you reach the age of 18?
115.429 What do you need to do when you reach 18 years of age to access your trust funds?
115.430 Will your account lose its supervised status when you reach the age of 18?
115.431 If you are an emancipated minor may you withdraw trust funds from your account?

Subpart D—IIM Accounts: Estate Accounts

115.500 When is an estate account established?
115.501 How long will an estate account remain open?
115.502 Who inherits the money in an IIM account when an account holder dies?
115.503 May money in an IIM account be withdrawn after the death of an account holder but prior to the end of the probate proceedings?
115.504 If you have a life estate interest in income-producing trust assets, how will you receive the income?

Subpart E—IIM Accounts: Hearing Process for Restricting an IIM Account

115.600 If BIA decides to restrict your IIM account under § 115.102 or § 115.104, what procedures must the BIA follow?
115.601 Under what circumstances may the BIA restrict your IIM account through supervision or an encumbrance?
115.602 How will the BIA notify you or your guardian, as applicable, of its decision to restrict your IIM account?
115.603 What happens if BIA's notice of its decision to place a restriction on your IIM account that is sent by United States certified mail is returned to the BIA as undeliverable for any reason?
115.604 When will BIA authorize OTFM to place a restriction on your IIM account?
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115.612 May you be represented by an attorney during your hearing?
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115.614 Why is the BIA hearing recorded?
115.615 How long after the hearing will BIA make its final decision?
115.616 What information will be included in BIA's final decision?
115.617 What happens when the BIA decides to supervise or encumber your IIM account after your hearing?
115.618 What happens if at the conclusion of the notice and hearing process we decide to encumber your IIM account because of an administrative error which resulted in funds that you do not own being deposited in your account or distributed to you or to a third party on your behalf?
115.619 If the BIA decides that the restriction on your IIM account will be continued after your hearing, do you have the right to appeal that decision?
115.620 If you decide to appeal the BIA's final decision pursuant to § 115.107, will the BIA restrict your IIM account during the appeal?

Subpart F—Trust Fund Accounts: General Information

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115.703 May we accept for deposit into a trust account money not specified in § 115.702?
115.704 May we accept for deposit into a trust account retirement checks/payments or pension fund checks/payments even though those funds are not specified in § 115.702?
115.705 May we accept for deposit into a trust account money awarded or assessed by a court of competent jurisdiction?
115.706 When funds are awarded or assessed by a court of competent jurisdiction in a cause of action involving trust assets, what documentation is required to deposit the trust funds into a trust account?
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115.801 How often will a tribe receive information about its trust account(s)?
115.802 May a tribe make a request to OTFM to receive information about its trust account more frequently?
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115.901 When will the trust funds in a special deposit account be credited or paid out to the owner of the funds?
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115.903 May cash bonds (e.g., performance bonds, appeal bonds, etc.) be deposited into a special deposit account?
115.904 Where earnest money is paid prior to Secretarial approval of a conveyance or contract instrument involving trust assets, may the BIA deposit that earnest money into a special deposit account?

Subpart I—Records

115.1000 Who owns the records associated with this part?
115.1001 How must records associated with this part be preserved?

Authority: R.S. 441, as amended, R.S. 463, R.S. 465; 5 U.S.C. 301; 25 U.S.C. 2; 25 U.S.C. 9; 43 U.S.C. 1457; 25 U.S.C. 4001; 25 U.S.C. 161(a); 25 U.S.C. 162a; 25 U.S.C. 164; Pub. L. 87–283; Pub. L. 97–100; Pub. L. 97–257; Pub. L. 103–412; Pub. L. 97–458; 44 U.S.C. 3101 *et seq.*

Subpart A—Purpose, Definitions, and Public Information

§ 115.001 What is the purpose of this part?

This part sets forth guidelines for the Secretary of the Interior, including any tribe or tribal organization if that entity is administering specific programs, functions, services or activities, previously administered by the Secretary of the Interior, but now authorized under a Self-Determination Act contract (pursuant to 25 U.S.C. § 450f) or a Self-Governance compact (pursuant to 25 U.S.C. § 558cc), to carry out the trust duties owed to tribes and individual Indians to manage and administer trust assets for the exclusive benefit of tribal and individual Indian beneficiaries pursuant to federal law, including the American Indian Trust Fund Management Reform Act of 1994, Public Law 103–412, 108 Stat. 4239, 25 U.S.C. § 4001 (Trust Reform Act).

§ 115.002 What definitions do I need to know?

As used in this part:

Account holder means a tribe or a person who owns the funds in a tribal or Individual Indian Money (IIM) account that is maintained by the Secretary.

Account means a record of trust funds that is maintained by the Secretary for the benefit of a tribe or a person.

Administratively restricted account means an IIM account that is placed on temporary hold by OTFM where an account holder's current address of record is unknown or where more documentation is needed to make a distribution from an account.

Adult means an individual who has reached 18 years of age, except when the individual's tribe has determined the age for adulthood to be older than 18 for access to tribal trust fund per capita proceeds.

Adult in need of assistance means an individual who has been determined to be "incapable of managing or administering his or her property, including his or her financial affairs" either (a) through a BIA administrative process that is based on a finding by a licensed medical professional or licensed mental health professional, or (b) by an order or judgment of a court of competent jurisdiction.

BIA means the Bureau of Indian Affairs, Department of the Interior, or its authorized representative.

Bond means security for the performance of certain obligations or a guaranty of such performance as furnished by a third-party surety. As used in this part, bonds may include cash bonds, performance bonds, and surety bonds.

Court of competent jurisdiction means a federal or tribal court with jurisdiction; however, if there is no tribal court with jurisdiction, then a state court with jurisdiction.

Day means a calendar day unless otherwise specified.

Department means the Department of the Interior or its authorized representative.

Deposits mean receiving funds, ordinarily through a Federal Reserve Bank, for credit to a trust fund account.

Emancipated minor means a person under 18 years of age who is married or who is determined by a court of competent jurisdiction to be legally able to care for himself or herself.

Encumber or encumbrance means to attach trust assets held by the Secretary with a claim, lien, or charge that has been approved by the Secretary.

Encumbered account means a trust fund account where some portion of the proceeds are obligated to another party.

Estate account means an account for a deceased IIM account holder.

FOIA means the Freedom of Information Act, 5 U.S.C. § 552.

Guardian means a person who is legally responsible for the care and management of an individual and his or her estate. This definition includes, but is not limited to, conservator or guardian of the property. However, this definition does not apply to property subject to § 115.106 of this part.

Individual Indian Money (IIM) accounts means an interest bearing account for trust funds held by the Secretary that belong to a person who has an interest in trust assets. These accounts are under the control and management of the Secretary. There are three types of IIM accounts: unrestricted, restricted, and estate accounts.

Legal disability means the lack of legal capability to perform an act which includes the ability to manage or administer his or her financial affairs as determined by a court of competent jurisdiction or another federal agency where the federal agency has determined that the adult requires a representative payee and there is no legal guardian to receive federal benefits on his or her behalf.

MSW means a Master of Social Work degree from an accredited college or university.

Minor means an individual who is not an adult as defined in this part.

Non-compos mentis means a person who has been determined by a court of competent jurisdiction to be of unsound mind or incapable of managing his or her own affairs.

OST means the Office of the Special Trustee for American Indians, Department of the Interior, or its authorized representative.

OTFM means the Office of Trust Funds Management, within the Office of the Special Trustee for American Indians, Department of the Interior, or its authorized representative.

Privacy Act means the Federal Privacy Act, 5 U.S.C. § 552a.

Restricted fee land(s) means land the title to which is held by an individual Indian or a tribe and which can only be alienated or encumbered by the owner with the approval of the Secretary because of limitations contained in the conveyance instrument pursuant to federal law.

Secretary means the Secretary of the Interior or an authorized representative; it also means a tribe or tribal organization if that entity is administering specific programs, functions, services or activities, previously administered by the Secretary of the Interior, but now authorized under a Self-Determination Act contract (pursuant to 25 U.S.C. § 450f) or a Self-Governance compact (pursuant to 25 U.S.C. § 558cc).

Special deposit account means a temporary account for the deposit of trust funds that cannot immediately be credited to the rightful account holders.

Supervised account means a restricted IIM account, from which all disbursements must be approved by the BIA, that is maintained for minors, emancipated minors, adults who are in need of assistance, adults who under legal disability, or adults who are non-compos mentis.

Tribal account or tribal trust account generally means a trust fund account for a federally recognized tribe that is maintained and held in trust by the Secretary.

Tribe means any Indian tribe, nation, band, pueblo, rancheria, colony, or community, including any Alaska Native Village or regional or village corporation as defined or established under the Alaska Native Claims Settlement Act which is federally recognized by the United States government for special programs and services provided by the Secretary to Indians because of their status as Indians. Tribe also means two or more tribes joined for any purpose, the joint assets of which include funds held in trust by the Secretary.

Trust account means a tribal account, an IIM account, or a special deposit account for trust funds maintained by the Secretary.

Trust assets mean trust lands, natural resources, trust funds, or other assets held by the federal government in trust for Indian tribes and individual Indians.

Trust funds means money derived from the sale or use of trust lands, restricted fee lands, or trust resources and any other money that the Secretary must accept into trust.

Trust land(s) means any tract or interest therein, that the United States holds in trust status for the benefit of a tribe or an individual Indian.

Trust Reform Act means the American Indian Trust Fund Management Reform Act of 1994, Pub. L. 103–412, 108 Stat. 4239, 25 U.S.C. § 4001.

Trust resources means any element or matter directly derived from Indian trust property.

Unrestricted account means an IIM account in which an Indian account holder may determine the timing and amount of disbursements from the account.

Voluntary hold means a request by an individual Indian with an unrestricted IIM account to keep his or her trust funds in a trust account instead of having the trust funds automatically disbursed.

We or *Us* or *Our* means the Secretary as defined in this part.

You or *Your* means an IIM account holder.

Subpart B—IIM Accounts

§ 115.100 Osage Agency.

The provisions of this part do not apply to funds the deposit or expenditure of which is subject to the provisions of part 117 of this subchapter.

§ 115.101 Individual accounts.

Except as otherwise provided in this part, adults shall have the right to withdraw funds from their accounts. Upon their application, or an application made in their behalf by the Secretary or his authorized representative, their funds shall be disbursed to them. All such disbursements will be made at such convenient times and places as the Secretary or his authorized representatives may designate.

§ 115.102 Adults under legal disability.

The funds of an adult who is non compos mentis or under other legal disability may be disbursed for his benefit for such purposes deemed to be for his best interest and welfare, or the funds may be disbursed to a legal guardian or curator under such conditions as the Secretary or his authorized representative may prescribe.

§ 115.103 Payments by other Federal agencies.

Moneys received from the Veterans Administration or other Government agency pursuant to the Act of February 25, 1933 (47 Stat. 907; 25 U.S.C. 14), may be accepted and administered for the benefit of adult Indians under legal disability or minors for whom no legal guardian or fiduciary has been appointed.

§ 115.104 Restrictions.

Funds of individuals may be applied by the Secretary or his authorized representative against delinquent claims of indebtedness to the United States or any of its agencies or to the tribe of which the individual is a member, unless such payments are prohibited by acts of Congress, and against money judgments rendered by courts of Indian offenses or under any tribal law and order code. Funds derived from the sale of capital assets which by agreement approved prior to such sale by the Secretary or his authorized representative are to be expended for specific purposes, and funds obligated under contractual arrangements approved in advance by the Secretary or his authorized representative or subject to deductions specifically authorized or directed by acts of Congress, shall be disbursed only in accordance with the agreements (including any subsequently approved modifications thereof) or acts of Congress. The funds of an adult whom the Secretary or his authorized representative finds to be in need of assistance in managing his affairs, even though such adult is not non compos mentis or under other legal disability, may be disbursed to the adult, within his best interest, under approved plans. Such finding and the basis for such finding shall be recorded and filed with the records of the account. For rules

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governing the payment of judgments from individual Indian money accounts, see § 11.208 of this chapter.

§ 115.105 Funds of deceased Indians of the Five Civilized Tribes.

Funds of a deceased Indian of the Five Civilized Tribes may be disbursed to pay ad valorem and personal property taxes, Federal and State estate and income taxes, obligations approved by the Secretary or his authorized representative prior to death of decedent, expenses of last sickness and burial and claims found to be just and reasonable which are not barred by the statute of limitations, costs of determining heirs to restricted property by the State courts, and claims allowed pursuant to part 16 of this chapter.

§ 115.106 Assets of members of the Agua Caliente Band of Mission Indians.

(a) The provisions of this section apply to money or other property, except real property, held by the United States in trust for such Indians, which may be used, advanced, expended, exchanged, deposited, disposed of, invested, and reinvested by the Director, Palm Springs Office, in accordance with the Act of October 17, 1968 (Pub. L. 90–597). The management or disposition of real property is covered in other parts of this chapter.

(b) Investments made by the Director, Palm Springs Office, under the Act of October 17, 1968, supra, shall be of such a nature as will afford reasonable protection of the assets of the individual Indian involved. The Director is authorized to enter into contracts for the management of the assets (except real property) of individual Indians. The consent of the individual Indian concerned must be obtained prior to the taking of actions affecting his assets, unless the Director determines, under the provisions of section (e) of the Act, that consent is not required.

(c) The Director may, consistent with normal business practices, establish appropriate fees for reports he requires from guardians, conservators, or other fiduciaries appointed under State law for members of the Band.

§ 115.107 Appeals.

Appeals from an action taken by an official of the Bureau of Indian Affairs may be taken pursuant to 25 CFR part 2, subject to the terms of subpart E.

Subpart C—IIM Accounts: Minors

§ 115.400 Will a minor's IIM account always be supervised?

Yes, all IIM accounts established by BIA for minors will be a supervised by the BIA.

§ 115.401 What is a minor's supervised account?

A minor's supervised account is a restricted IIM account from which all disbursements must be made pursuant to a distribution plan approved by the BIA that is established for:

(a) A minor, or

(b) An emancipated minor.

§ 115.402 Will a minor have access to information about his or her account?

A minor will not have access to information about his or her IIM account without approval of the custodial parent(s) or legal guardian. However, an emancipated minor will have access to information about his or her IIM account.

§ 115.403 Who will receive information regarding a minor's supervised account?

(a) The parent(s) with legal custody of the minor or the minor's legal guardian will receive a minor's statement of performance at the address of record for the minor's supervised account.

(b) An emancipated minor will receive his or her statement of performance at the address of record for the minor's supervised account.

§ 115.404 What information will be provided in a minor's statement of performance?

A minor's statement of performance will identify the source, type, and status of the funds deposited and held in the account; the beginning balance; the gains and losses; receipts and disbursements, if any; and the ending balance of the quarterly statement period for the minor's supervised account.

§ 115.405 How frequently will a minor's statement of performance be mailed?

We will mail a minor's statement of performance to the address of record quarterly, within and no later than 20 business days after the close of the quarterly statement period.

§ 115.406 Who provides an address of record for a minor's supervised account?

(a) The custodial parent or the legal guardian must provide an address to the BIA and this address will be the address of record for the minor's supervised account. Where applicable, a parent or legal guardian must provide a copy of the custodial order or guardianship order from a court of competent jurisdiction when providing the address of record for the minor's supervised IIM account.

(b) The emancipated minor must provide his or her address of record to the BIA.

(c) Upon receipt of the change of address of record from the parent or legal guardian, the BIA must provide the change of the address of record to the OTFM.

§ 115.407 How is an address of record for a minor's supervised account changed?

(a) To change an address of record for a minor's supervised IIM account, a custodial parent(s), legal guardian, or emancipated minor must provide BIA with the following information:

(1) The minor's or emancipated minor's name;

(2) The name of the custodial parent(s) or legal guardian, if applicable;

(3) A custody order from a court of competent jurisdiction or a copy of a guardianship, if applicable;

(4) The new address of the custodial parent(s), legal guardian, or emancipated minor; and

(5) The signature, mark or thumb print of a custodial parent, legal guardian, or emancipated minor that has been notarized by a notary public and/or witnessed by a DOI employee who has been shown verifiable photo identification. See § 115.410

(b) When requesting a change of an address of record, the following information will further assist us to identify the minor's account:

(1) The minor's or emancipated minor's IIM account number;

(2) The minor's or emancipated minor's date of birth;

(3) The minor's or emancipated minor's tribal enrollment number; and

(4) The minor's or emancipated minor's social security number.

§ 115.408 May a minor's supervised account have more than one address on file with the BIA?

Yes, a minor's supervised account may have more than one address on file with the BIA. We request that the parent, legal guardian, or the person who has been recognized by the BIA as having control and custody of the minor, notify us of the following addresses for the minor:

(a) The minor's residence;

(b) The address of record where the statement of performance will be mailed;

(c) The address where disbursement checks will be mailed or financial institution information for direct deposits of trust funds as authorized under an approved distribution plan.

§ 115.409 How is an address for a minor's residence changed?

(a) To change an address for a minor's residence, the custodial parent, legal guardian, or the person who has been recognized by the BIA as having control and custody of the minor must provide BIA with the following information:

(1) The minor's name;

(2) The name of the custodial parent(s) or legal guardian;

(3) A copy of a custodial order from a court of competent jurisdiction or a guardianship order, where applicable;

(4) The new address of the minor's residence; and

(5) The signature, mark or thumb print of the individual who is providing the updated address for the minor's residence that has been notarized by a notary public and/or witnessed by a DOI employee who has been shown verifiable photo identification. See § 115.410

(b) When requesting a change of an address for a minor's residence, the following information will further assist us to identify the minor's account:

(1) The minor's IIM account number;

(2) The minor's date of birth;

(3) The minor's tribal enrollment number (if known); and

(4) The minor's social security number (where known).

§ 115.410 What types of identification will the BIA or OTFM accept as "verifiable photo identification"?

BIA or OTFM will accept the following forms of identification as "verifiable photo identification":

(a) A valid driver's license;

(b) A government-issued photo identification card, such as a passport, security badge, etc.; or

(c) A tribal photo identification card.

§ 115.411 What if the individual making a request regarding a minor's supervised account does not have any verifiable photo identification?

If the individual making a request regarding a minor's supervised account does not have any verifiable photo identification, the individual may make a request in person at the BIA and we will talk with the individual and review information in the minor's file to see if we can attest to the individual's identity. If we cannot establish the identity of the individual, we will not accept the request.

§ 115.412 Will child support payments be accepted for deposit into a minor's supervised account?

The Secretary will not accept child support payments for deposit into a minor's supervised account.

§ 115.413 Who may receive funds from a minor's supervised account?

A custodial parent, a legal guardian, a person who has been recognized by the BIA as having control and custody of the minor, or an emancipated minor may be eligible to withdraw funds from a minor's supervised account if there is an authorized disbursement request that is based upon the terms of a BIA-approved distribution plan.

§ 115.414 What is an authorized disbursement request?

An authorized disbursement request is the form or letter that must be approved by the BIA that specifies the funds to be disbursed from an IIM account. The authorized disbursement request may not be issued to disburse funds from a minor's supervised account unless an approved distribution plan exists, the amount to be disbursed is in conformity with the distribution plan and the disbursement will be made to an individual or third party specified in the plan.

§ 115.415 How will an authorized disbursement from a minor's supervised account be sent?

OTFM will make an authorized disbursement based on the approved distribution plan from a minor's supervised account by:

(a) Making a direct deposit to a specified account at a financial institution (a direct deposit into the specified account will eliminate lost, stolen or damaged checks and will also eliminate delays associated with mailing the check);

(b) Mailing a check to the address of record or to a specified disbursement address; or

(c) Mailing a check to a specified third party's address.

§ 115.416 Will the United States post office forward mail regarding a minor's supervised account to a forwarding address left with the United States post office?

(a) Federal law does not allow the United States post office to forward checks that are issued by the federal government. Therefore, a check from a minor's supervised account will not be forwarded to an address left with the United States post office. The new address of record must be provided directly to BIA.

(b) Where a forwarding address has been provided to the United States post office, the United States post office will forward a statement of performance and general correspondence regarding a minor's supervised account that is mailed to the minor's address of record for a limited time period. However, it is the responsibility of a custodial parent, legal guardian, or emancipated minor to give BIA the new address of record for the minor's supervised account.

§ 115.417 What portion of funds in a minor's supervised account may be withdrawn under a distribution plan?

Trust money in a minor's supervised account will not be distributed without a review of other resources that may be available to meet the needs of the minor. Any trust funds of a minor that are distributed must be used for the direct benefit of the minor and in accordance with any additional limitations (*e.g.*, statutory, court order, tribal resolution, etc.) placed on the use of specific trust funds. Allowable uses may include health, education, or welfare when based upon a justified unmet need. The BIA will require receipts for expenditures of funds disbursed from a minor's account to a custodial parent, legal guardian, person who has been recognized by the BIA as having control and custody of the minor, or an emancipated minor.

§ 115.418 What types of trust funds may a minor have?

A minor may have one or more of the following types of trust funds:

(a) Judgment per capita funds: Withdrawals may only be made upon BIA approval of an application made under Public Law 97–458. See 25 CFR 1.2.

(b) Tribal per capita funds: Withdrawals may only be made under a BIA approved distribution plan and in accordance with the terms of the tribe's per capita resolution/document.

(c) Other trust funds: Withdrawals may only be made under a minor's BIA-approved distribution plan that is based on a justified unmet need for the minor's health, education, or welfare.

(d) Funds from other federal agencies (e.g., SSA, SSI, VA) received for the benefit of the minor: Withdrawals must be made only under a BIA-approved distribution plan that must be consistent with the disbursing agency's (e.g., SSA, SSI, VA) allowable uses for the funds.

§ 115.419 Who develops a minor's distribution plan?

A social service provider will develop a minor's distribution plan for approval by the BIA after evaluating the needs of the minor in consultation with a custodial parent, a legal guardian, the person who has been recognized by the BIA as having control and custody of the minor, or emancipated minor. A minor's distribution plan may only provide for those expenditures outlined in part § 115.417.

§ 115.420 When developing a minor's distribution plan, what information must be considered and included in the evaluation?

When developing a minor's distribution plan, the following information must be considered and included in the evaluation:

(a) Documentation which establishes who has physical custody of the minor

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(e.g., home visits, school records, medical records, etc.);

(b) A copy of any custodial orders or guardianship orders from a court of competent jurisdiction;

(c) The name(s) of the person and his or her relationship to the minor, if any, who make a request for a disbursement from the minor's account;

(d) An evaluation of other resources, including parental income, that may be available to meet the unmet needs of the minor;

(e) A list of the amounts, purposes, and dates for which disbursements will be made;

(f) The name(s) of the person to whom disbursements may be made, including, as applicable:

(1) A custodial parent;

(2) A legal guardian;

(3) The person who has been recognized by the BIA as having control and custody of the minor;

(4) An emancipated minor; and/or

(5) Any third parties to whom the BIA will make direct payment for goods or services provided to the minor and supported by an invoice or bill of sale;

(g) The date(s) (at least every six months) when the custodial parent, the legal guardian, the person who has been recognized by the BIA as having control and custody of the minor, or the emancipated minor must provide receipts to the BIA to show that expenditures were made in accordance with the approved distribution plan;

(h) Additional requirements and justification for those requirements, as necessary to ensure that any distribution(s) will benefit the minor;

(i) The dates the disbursement plan was developed, approved, and reviewed, and the date for the next scheduled review;

(j) The date(s) the distribution plan was amended and an explanation for any amendment(s) to the distribution plan, when an amendment is necessary;

(k) The signature of the BIA official approving the plan with the certification that the plan is in the best interest of the account holder; and

(l) The signature(s) of the custodial parent, legal guardian, with date(s) signed, certifying that he or she has been consulted and has agreed to the terms of the evaluation and the distribution plan.

§ 115.421 What information will be included in the copy of the minor's distribution plan that will be provided to OTFM?

A minor's distribution plan must contain the following:

(a) A copy of any custodial order or guardianship order from a court of competent jurisdiction;

(b) A list of the amounts, purposes, and dates for which disbursements will be made;

(c) The name(s) of the person(s) to whom disbursements may be made, including, as applicable:

(1) A custodial parent;

(2) A legal guardian;

(3) The person who has been recognized by the BIA as having control and custody of the minor and the address of that person;

(4) An emancipated minor; and/or

(5) Any third parties and the address(es) of the third parties to whom the direct payment will be made for goods or services provided to the minor and supported by an invoice or bill of sale, where applicable;

(d) The date that the disbursement plan was approved and the expiration date of the distribution plan; and

(e) The date and signature of the BIA official approving the plan with a certification that the plan is in the best interest of the account holder.

§ 115.422 As a custodial parent, the legal guardian, the person who BIA has recognized as having control and custody of the minor, or an emancipated minor, what are your responsibilities if you receive trust funds from a minor's supervised account?

If you are a custodial parent, the legal guardian, the person who BIA has recognized as having control and custody of the minor, or an emancipated minor who receives funds from a minor's supervised account, you must:

(a) Consult with the social service provider on the development of an evaluation;

(b) Sign an acknowledgment that you have reviewed the evaluation;

(c) Follow the terms of a distribution plan approved by the BIA;

(d) Follow any applicable court order;

(e) Provide receipts to the social services provider in accordance with terms of the evaluation for all expenses paid out of the minor's IIM funds;

(f) Review the statements of performance for the supervised account for discrepancies, if applicable;

(g) File tax returns on behalf of the account holder, if applicable; and

(h) Notify the social service provider of any change in circumstances that impairs your performance of your obligations under this part or inform the social service provider of any information regarding misuse of a minor's trust funds.

§ 115.423 If you are a custodial parent, a legal guardian, or an emancipated minor, may BIA authorize the disbursement of funds from a minor's supervised account without your knowledge?

At the Secretary's discretion, the BIA may authorize the disbursement of funds from a minor's supervised account for the benefit of the minor.

§ 115.424 Who receives a copy of the BIA-approved distribution plan and any amendments to the plan?

The BIA-approved distribution plan will be provided to:

(a) The custodial parent; or

(b) A legal guardian; or

(c) At the Secretary's discretion, in unusual circumstances, to a family member who has been recognized as having control and custody of the minor; or

(d) An emancipated minor; and

(e) OTFM.

§ 115.425 What will we do if we find that a distribution plan has not been followed or an individual has acted improperly in regard to his or her duties involving a minor's trust funds?

If we find that a distribution plan has not been followed or that a custodial parent, a legal guardian, or the person who has been recognized by the BIA as having control and custody of the minor has failed to satisfactorily account for expenses or has not used the minor's funds for the primary benefit of the minor, we will:

(a) Notify the individual; and

(b) Take action to protect the interests of the minor, which may include:

(1) Referring the matter for civil or criminal legal action;

(2) Demanding repayment from the individual who has improperly expended trust funds or failed to account for the use of trust funds;

(3) Liquidating a bond posted by the legal guardian, where applicable, to recover improperly expended trust funds up to the amount of the bond; or

(4) Immediately modifying the distribution plan for up to sixty days, including suspending the authority of the individual to receive further disbursements.

§ 115.426 What is the BIA's responsibility regarding the management of a minor's supervised account?

The BIA's responsibility in regard to the management of a minor's supervised account is to:

(a) Review and approve the evaluation and the distribution plan;

(b) Authorize OTFM to disburse IIM funds in accordance with an approved distribution plan; and

(c) Conduct annual reviews of case records for minors' supervised accounts

to ensure that the social service providers have managed the accounts in accordance with the approved evaluation and distribution plan.

§ 115.427 What is the BIA's annual review process for a minor's supervised account?

A BIA social worker with an MSW will conduct an annual review of minors' supervised accounts by:

(a) Verifying that all receipts for disbursements made under a distribution plan were collected in accordance with the terms specified in the evaluation;

(b) Reviewing the receipts for disbursements made from a minor's supervised account to ensure that all expenditures were made in accordance with the distribution plan;

(c) Reviewing all case worker reports and notes;

(d) Reviewing account records to insure that withdrawals and payments were made in accordance with the distribution plan;

(e) Verifying current addresses, including the address of record, the address of the minor's residence, and the disbursement address; and

(f) Deciding whether the distribution plan needs to be modified.

§ 115.428 Will you automatically receive all of your trust funds when you reach the age of 18?

No, we will not automatically send your trust funds to you when you reach the age of 18.

§ 115.429 What do you need to do when you reach 18 years of age to access your trust funds?

You must contact OTFM to request withdrawal of any or all of your trust funds that may be available to you. OTFM may require certain information from you to verify your identity, etc. prior to the release of your trust funds. All signatures must be notarized by a notary public or witnessed by a DOI employee. In addition, if you choose to have a check mailed to you, you must provide us with your address of record. If you choose to have your trust funds electronically transferred to you, you must provide your financial institution account information to OTFM.

§ 115.430 Will your account lose its supervised status when you reach the age of 18?

Your account will no longer be supervised when you reach the age of 18 unless statutory language or a tribal resolution specifies an age other than 18 years of age for access to specific trust funds. However, if a court of competent jurisdiction has found you to be non-compos mentis, under legal disability, or the BIA has determined you to be an adult in need of assistance, your account will remain supervised and you will be notified in accordance with subpart E.

§ 115.431 If you are an emancipated minor may you withdraw trust funds from your account?

If you are an emancipated minor, you may have access to some or all of your trust funds as follows:

(a) For judgment per capita funds: you may not make withdrawals from your account until you have reached the age specified in the judgment. Exceptions are only granted upon the approval of an application made under Public Law 97–458. See 25 CFR 1.2.

(b) Tribal per capita funds: access to these funds will be determined by tribal resolution.

(c) Other trust funds: You may be able to have supervised access to some or all of your funds, but the BIA must approve all requests for withdrawals from your account. You must work with the BIA to develop a distribution plan to access the funds in your account. In no instance will the BIA allow an emancipated minor to make unsupervised withdrawals.

(d) For funds from other federal agencies (*e.g.*, SSA, SSI, VA), you may be able to receive funds directly, but you must contact and make arrangements with the other federal agency. Direct receipt of funds from another federal agency will not change the supervised status of an emancipated minor's trust account.

Subpart D—IIM Accounts: Estate Accounts

§ 115.500 When is an estate account established?

An estate account is established when we receive notice of an account holder's death.

§ 115.501 How long will an estate account remain open?

An estate account will remain open until the funds have been distributed in accordance with the distribution and/or probate order.

§ 115.502 Who inherits the money in an IIM account when an account holder dies?

At the end of all probate procedures, funds remaining in a decedent's estate account will be distributed from the decedent's estate account and paid directly to or deposited into an IIM account of the decedent's heirs, beneficiaries, or other persons or entities entitled by law to receive the funds, where applicable. See 25 CFR part 15.

§ 115.503 May money in an IIM account be withdrawn after the death of an account holder but prior to the end of the probate proceedings?

(a) If you are responsible for making the funeral arrangements of a decedent who had an IIM account and you have an immediate need for emergency assistance to pay for funeral arrangements prior to burial, you may make a request to the BIA for up to $1,000 from the decedent's IIM account if the decedent's IIM account has more than $2,500 in the account at the date of death.

(b) You must apply for this assistance and submit to the BIA an original itemized estimate of the cost of the service to be rendered and the identification of the service provider.

(c) We may approve reasonable costs up to $1,000 that are necessary for the burial services.

(d) We will make payments directly to the providers of the service(s).

§ 115.504 If you have a life estate interest in income-producing trust assets, how will you receive the income?

If you have a life estate interest in income-producing trust assets, which is earning income, OTFM will open an IIM-life estate account for you and funds will be distributed after BIA has certified ownership of the trust funds.

Subpart E—IIM Accounts: Hearing Process for Restricting an IIM Account

§ 115.600 If BIA decides to restrict your IIM account under § 115.102 or § 115.104, what procedures must the BIA follow?

If under § 115.102 or § 115.104, the BIA has decided to limit your access to your IIM account (*i.e.*, decided to supervise the IIM account), or if the BIA has decided to pay creditors with funds from your IIM account, including creditors with judgments from Courts of Indian Offenses for which preliminary procedures are prescribed in 25 CFR 11.208, the BIA must notify you or your guardian, as applicable, to provide you or your guardian, as applicable, with an opportunity to challenge the BIA's decision to restrict your IIM account as specified in subpart E.

§ 115.601 Under what circumstances may the BIA restrict your IIM account through supervision or an encumbrance?

(a) The BIA may restrict your IIM account through supervision if the BIA:

(1) Receives an order from a court of competent jurisdiction that you are non-compos mentis; or

(2) Receives an order or judgment from a court of competent jurisdiction that you are an adult in need of assistance because you are "incapable of

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managing or administering property, including your financial affairs;" or

(3) Determines through an administrative process that you are an adult in need of assistance based on a finding by a licensed medical or mental health professional that you are "incapable of managing or administering property, including your financial affairs;" or

(4) Receives information from another federal agency that you are under a legal disability and that the agency has appointed a representative payee to receive federal benefits on your behalf.

(b) The BIA may restrict your IIM account through an encumbrance if the BIA:

(1) Receives an order from a court of competent jurisdiction awarding child support from your IIM account; or

(2) Receives from a third party:

(i) A copy of the original contract between you and the third party in which you used your IIM funds as security/collateral for the transaction;

(ii) A copy of the document showing that the BIA approved in advance the use of your IIM funds as security/collateral for the contract;

(iii) Proof of your default on the contract according to the terms of the contract; and

(iv) A copy of the original assignment of IIM income as security/collateral for the contract that is signed and dated by you and is notarized;

(3) Receives a money judgment from a Court of Indian Offenses pursuant to 25 CFR 11.208 or under any tribal law and order code;

(4) Is provided documentation showing that BIA or OTFM caused an administrative error which resulted in a deposit into your IIM account, or a disbursement to you, or to a third party on your behalf; or

(5) Is provided with proof of debts owed to the United States pursuant to § 115.104 of this part.

§ 115.602 How will the BIA notify you or your guardian, as applicable, of its decision to restrict your IIM account?

The BIA will notify you or your guardian, as applicable, of its decision to restrict your IIM account by:

(a) United States certified mail to your address of record;

(b) Personal delivery to you or your guardian, as applicable, or to your address of record;

(c) Publication for four consecutive weeks in your tribal newspaper if your whereabouts are unknown and in the local newspaper serving your last known address of record; or

(d) United States certified mail to you in care of the warden, if you are incarcerated. The BIA may send a copy of the notification to your attorney, if known.

§ 115.603 What happens if BIA's notice of its decision to place a restriction on your IIM account that is sent by United States certified mail is returned to the BIA as undeliverable for any reason?

If BIA's notice of its decision to place a restriction on your IIM account that is sent by United States certified mail is returned to the BIA as undeliverable for any reason, the BIA will remove the restriction on your account, which was placed five days after the notice was mailed, and will publish a notice in accordance with § 115.602(c) and § 115.605(b).

§ 115.604 When will BIA authorize OTFM to place a restriction on your IIM account?

BIA will authorize OTFM to place a restriction on your IIM account after providing OTFM with supporting documentation (i.e., receipts, notice of publication, etc.) of the following:

(a) Five (5) days after the date BIA mails you or your guardian, as applicable, notice of its decision to restrict your account by United States certified mail to your address of record;

(b) One (1) day after BIA has made personal delivery to you or your guardian, as applicable, or to your address of record of its notice of the BIA's decision to restrict your account; or

(c) Five (5) days after the fourth publication of the public notice of BIA's decision to restrict your account.

§ 115.605 What information will the BIA include in its notice of the decision to restrict your IIM account?

(a) When the BIA provides notice of its decision to restrict your IIM account by certified mail or personal delivery to you or your guardian, as applicable, the notice must contain:

(1) The name on the IIM account;

(2) The reason for the restriction;

(3) The amount to be encumbered, if applicable;

(4) A statement that your IIM account will be restricted 5 days after the date the notice was sent United States certified mail to your address of record;

(5) An explanation that you have 40 days from the date the notice was sent United States certified mail to request a hearing to challenge BIA's decision to restrict your IIM account;

(6) An explanation of how to request a hearing;

(7) A statement that the BIA will conduct the hearing and that you are assured a fair hearing;

(8) A copy of the fair hearing guidelines;

(9) A statement that you may contact the BIA to authorize immediate payment from your IIM account to pay the claim, if applicable;

(10) The address and phone number of the BIA office that made the decision to restrict your IIM account and provided the notice; and

(11) Other information as may be determined appropriate by the BIA.

(b) When the BIA provides public notice of its decision to restrict your account, the only information the public notice will include is:

(1) The name on the account;

(2) The date of first publication of the public notice;

(3) A statement that the BIA has decided to place a restriction on your IIM account;

(4) A statement that the public notice will be published once a week for four consecutive weeks;

(5) A statement that the BIA will place a restriction on your account five (5) days after the date of the fourth publication of the public notice;

(6) A statement that your opportunity to request a hearing to challenge BIA's decision to restrict your account will expire 30 days after the date of the fourth publication of the public notice; and

(7) An address and telephone number of the BIA office publishing the notice to request further information and instructions on how to request a hearing.

§ 115.606 What happens if you do not request a hearing to challenge BIA's decision to restrict your IIM account during the allotted time period?

If you or your guardian, as applicable, do not request a hearing to challenge BIA's decision to restrict your IIM account during the allotted time period, BIA's decision to restrict your IIM account will become final. BIA will follow the procedures outlined in § 115.616 through § 115.618, and § 115.620, as applicable.

§ 115.607 How do you request a hearing to challenge the BIA's decision to restrict your IIM account?

You or your guardian, as applicable, must request a hearing to challenge the BIA's decision to restrict your IIM account from the BIA office that made the decision and notified you of the restriction. Your request must:

(a) Be in writing;

(b) Specifically request a hearing to challenge the restriction; and

(c) Be hand delivered to the BIA office or postmarked within:

(i) 40 days of the date that BIA's notice was sent United States certified mail or personally delivered to the address of record, or

(ii) 30 days of the date of the final publication of the public notice.

§ 115.608 If you request a hearing to challenge BIA's decision to restrict your IIM account, when will BIA conduct the hearing?

BIA will conduct a hearing within ten (10) working days from its receipt of a written request from you or your guardian, as applicable, for a hearing to challenge the decision to restrict your IIM account.

§ 115.609 Will you be allowed to present testimony and/or evidence at the hearing?

Yes, you or your guardian, as applicable, will be provided the opportunity to present testimony and/or evidence as to the reasons the BIA should not restrict your IIM account, including information showing how an encumbrance may create an undue financial hardship, if applicable. You may not challenge a court order or judgment in this proceeding. However, if you have appealed an order or judgment from a court of competent jurisdiction, you or your guardian, as applicable, may present evidence of your appeal and the BIA hearing will be postponed until there is a final order from the court. The restriction on your IIM account will remain in place until after the hearing is concluded.

§ 115.610 Will you be allowed to present witnesses during a hearing?

Yes, you or your guardian, as applicable, may present witnesses during a hearing. You are responsible for any and all expenses which may be associated with presenting witnesses.

§ 115.611 Will you be allowed to question opposing witnesses during a hearing?

Yes, you or your guardian, as applicable, may question all opposing witnesses testifying during your hearing. You may also present witnesses to challenge opposing witness testimony.

§ 115.612 May you be represented by an attorney during your hearing?

Yes, you may have an attorney or other person represent you during your hearing. However, you are responsible for any and all expenses associated with having an attorney or other person represent you.

§ 115.613 Will the BIA record the hearing?

Yes, the BIA will record the hearing.

§ 115.614 Why is the BIA hearing recorded?

The BIA hearing will be recorded so that it will be available for review if the hearing process is appealed under § 115.107. The BIA hearing record must be preserved as a trust record.

§ 115.615 How long after the hearing will BIA make its final decision?

BIA will make its final decision within 10 business days of the end of the hearing.

§ 115.616 What information will be included in BIA's final decision?

BIA's final written decision to the parties involved in the proceeding will include:

(a) BIA's decision to remove or retain the restriction on the IIM account;

(b) A detailed justification for the supervision or encumbrance of the IIM account, where applicable;

(c) The amount(s) to be paid, the name and address of a third party to whom payment will be made, and the time period for repayment established under 617(a) of this part, where applicable;

(d) Any provision to allow for distributions to the account holder because of an undue financial hardship created by the encumbrance, if applicable; and

(e) Any other information the hearing officer deems necessary.

§ 115.617 What happens when the BIA decides to supervise or encumber your IIM account after your hearing?

BIA will provide OTFM with a copy of the distribution plan, after the BIA decides to:

(a) Supervise your IIM account. BIA social services staff will consult with you and/or your guardian to develop a distribution plan. Upon BIA approval, the distribution plan will be valid for one year.

(b) Encumber your IIM account. BIA will review your account balance and your future IIM income to develop a distribution plan that establishes the amount(s) to be paid and the dates payment(s) will be made to the specified party. Payments may need to be made over the course of one or more years if the amount owed to the specified party is greater than your current IIM account balance.

§ 115.618 What happens if at the conclusion of the notice and hearing process we decide to encumber your IIM account because of an administrative error which resulted in funds that you do not own being deposited in your account or distributed to you or to a third party on your behalf?

If we decide at the conclusion of the notice and hearing process to encumber your account because of an administrative error which resulted in funds that you do not own being deposited into your IIM account or distributed to you or to a third party on your behalf, we will consult with you or your guardian, as applicable, to determine how the funds will be repaid.

§ 115.619 If the BIA decides that the restriction on your IIM account will be continued after your hearing, do you have the right to appeal that decision?

Yes, if the BIA decides after your hearing to continue the restriction on your IIM account, you or your guardian, as applicable, have the right to appeal the decision under the procedures proscribed in § 115.107.

§ 115.620 If you decide to appeal the BIA's final decision pursuant to § 115.107, will the BIA restrict your IIM account during the appeal?

Yes, if under § 115.107 you or your guardian, as applicable, decide to appeal the BIA's final decision to:

(a) Supervise your IIM account, your IIM account will remain restricted during the appeal period.

(b) Encumber your IIM account, your IIM account will remain restricted up to the amount at issue during the appeal period. If your account balance is greater than the amount encumbered, those funds will be available to you upon request to and by approval of the Secretary.

Subpart F—Trust Fund Accounts: General Information

§ 115.700 Why is money held in trust for tribes and individual Indians?

Congress has passed a number of laws that require the Secretary to establish and administer trust fund accounts for Indian tribes and certain individual Indians who have an interest(s) in trust lands, trust resources, or trust assets.

§ 115.701 What types of accounts are maintained for Indian trust funds?

Indian trust funds are deposited in tribal accounts, Individual Indian Money (IIM) accounts, and special deposit accounts. The illustration below provides information on each of these trust accounts.

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Types of Trust Fund Accounts			Descriptions
Individual Indian Money (IIM) Accounts	Unrestricted IIM accounts		There are no restrictions on these accounts. Funds may be left on deposit, or paid to the account holder based upon instructions by the account holder.
	Restricted IIM accounts:	Administratively Restricted	A temporary hold is placed on an account by OTFM where an address of record for an account holder is unknown or where more documentation is needed to make a distribution from an account.
		Supervised	A restriction is placed on the account by the BIA and funds from these accounts may only be withdrawn under a BIA approved distribution plan. The following account holders will have supervised accounts: • minors, • emancipated minors, • adults who are non-compos mentis, • adults in need of assistance; and/or • adults under legal disability as defined in this part.
		Encumbered	A restriction is placed on the account by the BIA until money owed from an the account is paid to a specified party. The account holder may withdraw any money available in the account that is above the amount owed to specified parties.
	IIM Estate accounts		An account for a deceased IIM account holder.
Tribal Accounts			Generally, an account for a federally recognized tribe.
Special Deposit Accounts			An account for the temporary deposit of trust funds that cannot be distributed immediately to its rightful owners.

SOURCES	TRUST ACCOUNTS				
	Tribal	Individual Indian Money (IIM)			
		Unrestricted IIM Accounts	Restricted IIM Accounts		
			Administratively restricted	Supervised	Encumbered
Payments from the United States as a Result of —					
Federal laws requiring funds to be deposited in trust accounts.	✓	✓	✓	✓	✓
Settlement of a claim related to trust assets that requires the funds to be deposited in trust accounts	✓	✓	✓	✓	✓
A final order from a United States court for a cause of action directly related to trust assets requiring funds to be deposited in trust accounts	✓	✓	✓	✓	✓
Unobligated or unspent forestry funds specifically appropriated for the benefit of such Indian tribe	✓				
Designation of the BIA as the representative payee (by another federal agency) to receive certain Federal assistance payments, such as VA benefits, Social Security, or Supplemental Security Income, on behalf of an individual Indian because there is no legal guardian for that individual			✓	✓	
Payments resulting from —					
Money directly derived from the title conveyance (e.g. sale, probate, condemnation) or use of trust lands or restricted fee lands or trust resources, including any late payment penalties, when paid directly to the Secretary on behalf of the account holder	✓	✓	✓	✓	✓
Penalties for trespass on trust lands or restricted fee lands	✓	✓	✓	✓	✓

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Default or breach of the terms of a contract for the sale or use of trust lands, restricted fee lands, or trust resources arising from cash performance or surety bonds, or other source(s)	✓	✓	✓	✓	✓
A final order from a court of competent jurisdiction for a cause of action directly related to trust assets requiring funds to be deposited in trust accounts	✓	✓	✓	✓	✓
Deposits from an Indian Tribe —					
Redeposit of tribal trust funds previously withdrawn under an investment plan submitted and approved pursuant to the American Indian Trust Fund Management Reform Act of 1994, Pub. L. 103-412, 108 Stat. 4239, 25 U.S.C. § 4001 (Trust Reform Act)	✓				
Where a tribe under 25 U.S.C. 450f et seq. has contracted or compacted with the federal government to operate a federal program and the tribe, operating the federal program on behalf of the Secretary, receives trust funds for the sale or use of trust assets pursuant to a contract that specifies that payments are to be made to the Secretary on behalf of a tribe or an individual	✓	✓	✓	✓	✓
Legislative settlement funds or judgment funds withdrawn, but not spent, for a specific project. Documentation showing source of funds is required.	✓				
Deposits from other sources –					
Interest earned on trust fund deposits	✓	✓	✓	✓	✓
Disbursements of tribal trust funds held by OTFM to tribal members as per capita payments	✓			✓	
As permitted by law (25 U.S.C. § 3109) to be deposited into an Indian forest land assistance account	✓				

Funds derived directly from trust lands, restricted fee lands, or trust resources that are presented to the Secretary, on behalf of the tribe or individual Indian owner(s) of the trust asset, by the payor after being mailed to the owner(s) as required by contract (i.e., direct pay) and returned by mail to the payor as undeliverable	✓	✓	✓		✓

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§ 115.703 May we accept for deposit into a trust account money not specified in § 115.702?

No, we will not accept funds from sources that are not identified in the table in § 115.702 for deposit into a trust account.

§ 115.704 May we accept for deposit into a trust account retirement checks/payments or pension fund checks/payments even though those funds are not specified in § 115.702?

No, we will not accept retirement checks/payments or pension fund checks/payments or any funds from sources that are not identified in the table in § 115.702 for deposit into a trust account.

§ 115.705 May we accept for deposit into a trust account money awarded or assessed by a court of competent jurisdiction?

We will accept money awarded or assessed by a court of competent jurisdiction for a cause of action directly related to trust assets to be deposited into a trust account. Other funds awarded by a court of competent jurisdiction may not be deposited into a trust account.

§ 115.706 When funds are awarded or assessed by a court of competent jurisdiction in a cause of action involving trust assets, what documentation is required to deposit the trust funds into a trust account?

When funds are awarded or assessed by a court of competent jurisdiction in a cause of action involving trust assets, we must receive the funds awarded as stipulated in the court order and a copy of the court's order.

§ 115.707 Will the Secretary accept administrative fees for deposit into a trust account?

No. The Secretary will not accept administrative fees for deposit into a trust account because administrative fees are not trust funds. However, administrative fees may be deposited into a non-interest bearing, non-trust account with the BIA.

§ 115.708 How quickly will trust funds received by the Secretary on behalf of tribes or individual Indians be deposited into a trust account?

Trust funds received by the Secretary on behalf of a tribe or individual Indians will be deposited into a trust account within twenty-four hours, or no later than the close of business on the next business day following the receipt of funds at a location with a designated federal depository.

§ 115.709 Will an annual audit be conducted on trust funds?

Yes, in accordance with the Trust Reform Act an annual audit will be conducted on trust funds. Each tribe and IIM account holder will be notified when the Secretary has conducted an annual audit on a fiscal year basis of all the trust funds held by the United States for the benefit of tribes and individual Indians. This notice will be provided in the first quarterly statement of performance following the publication of the audit.

Investments and Interests

§ 115.710 Does money in a trust account earn interest?

Yes, all money deposited in a trust account is invested and earns interest or yield returns, or both.

§ 115.711 How is money in a trust account invested?

OTFM manages trust fund investments and its investment decisions are governed by federal statute. See 25 U.S.C. §§ 161(a) and 162a.

§ 115.712 What is the interest rate earned on money in a trust account?

The rate of interest on a trust account changes based on how the money is invested and how those investments perform.

§ 115.713 When does money in a trust account start earning interest?

Funds must remain on deposit at least one business day before interest is earned. Interest earnings of less than one cent are not credited to any account.

Subpart G—Tribal Accounts

§ 115.800 When does OTFM open a tribal account?

A tribal account is opened when OTFM receives income from the sources described in § 115.702.

§ 115.801 How often will a tribe receive information about its trust account(s)?

The OTFM is required to provide each tribe with a statement of performance quarterly, within or no later than 20 business days after the close of every quarterly statement period.

§ 115.802 May a tribe make a request to OTFM to receive information about its trust account more frequently?

Yes, a tribe may contact OTFM at any time to:

(a) Request information about account transactions and balances;

(b) Make arrangements to access account information electronically; or

(c) Receive a monthly statement.

§ 115.803 What information will be provided in a statement of performance?

The statement of performance will identify the source, type, and status of the trust funds deposited and held in a trust account; the beginning balance; the gains and losses; receipts and disbursements; and the ending account balance of the quarterly statement period.

§ 115.804 Will we account to a tribe for those trust funds the tribe receives through direct pay?

No, under the Trust Reform Act we are only responsible for accounting for those trust funds received into, and maintained by, the Department's trust funds management system.

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§ 115.805 If a tribe is paid directly under a contract for the sale or use of trust assets, will we accept those trust funds for deposit into a tribal trust account?

If a contract for the sale or use of trust assets specifies that payments are to be made directly to a tribe, we will not accept these trust funds into a tribal trust account. Where a tribe under 25 U.S.C. 450f *et seq.* has contracted or compacted with the federal government to operate a federal program and the tribe, operating the federal program on behalf of the Secretary, receives trust funds for the sale or use of trust assets pursuant to a contract that specifies that payments are to be made to the Secretary on behalf of a tribe or an individual [the owner of the trust assets], the tribe must follow § 115.708 for the deposit of the trust funds into the trust account.

§ 115.806 How will the BIA assist in the administration of tribal judgment fund accounts?

(a) If the tribe requests assistance or if Congress directs the Secretary to provide assistance, BIA will provide technical assistance on developing a judgment use and distribution plan to a tribe.

(b) BIA will review all tribal requests for distribution of tribal judgment funds to ensure that each request complies with any requirements associated with the use of that money found in statutory language, congressional directives, court orders, court-approved settlements, settlement agreements, use and distribution plans, or bond or loan payments.

Investing and Managing Tribal Trust Funds

§ 115.807 Will OTFM consult with tribes about investments of tribal trust funds?

Upon the request of a tribe, OTFM will consult with the tribe annually to develop investment strategies to accommodate the cash flow needs of the tribe.

§ 115.808 Could trust fund investments made by OTFM lose money?

The value of trust fund investments made by OTFM will vary depending on the type of investment and, including but not limited to, the following:

(a) Current interest rates;

(b) Whether the security/investment is held to its maturity; and

(c) Original purchase price.

However, as long as the purchase price of the security/investment is made at or below face value and the security/investment is held until maturity or payoff, the security/investment will not lose principal invested funds.

§ 115.809 May a tribe recommend to OTFM how to invest the tribe's trust funds?

Tribes may recommend certain investments to OTFM, but the recommendations must be in accordance with the statutory requirements set forth in 25 U.S.C. §§ 161a and 162a. The OTFM will make the final investment decision based on prudent investment practices.

§ 115.810 May a tribe directly invest and manage its trust funds?

A tribe may apply to withdraw its trust funds from OTFM for investment and management by the tribe. The tribe's request to withdraw funds must be in accordance with the requirements of the Trust Reform Act and 25 CFR part 1200, subpart B, unless otherwise specified by statutory language or the controlling document which governs the use of the trust funds.

§ 115.811 Under what conditions may a tribe redeposit funds with OTFM that were previously withdrawn under the Trust Reform Act?

Tribal trust funds withdrawn under the Trust Reform Act may be returned to OTFM under the following conditions:

(a) A tribe must make a written request to OTFM to redeposit all or part of the withdrawn trust funds;

(b) No tribal trust funds may be redeposited to a tribal trust account during the first six months after being withdrawn, except with the approval of the Secretary;

(c) Tribal trust funds may only be returned to OTFM a maximum of twice a year, except with the approval of the Secretary; and

(d) A tribe must return withdrawn trust funds in accordance with the requirements of the Trust Reform Act in 25 CFR, part 1200, subpart C.

§ 115.812 Is a tribe responsible for its expenditures of trust funds that are not made in compliance with statutory language or other federal law?

If a tribe's use of trust funds is limited by statutory language or other federal law(s) and a tribe uses those trust funds in direct violation of those laws, absent an approved modification which allows for the expenditures, we will require the tribe to reimburse its trust fund account.

§ 115.813 Is there a limit to the amount of trust funds OTFM will disburse from a tribal trust account?

OTFM will only disburse the available balance of the trust funds in a tribal trust account in accordance with a use and distribution plan, if applicable, and will not overdraw a tribal trust account. If a tribe's trust funds are invested in securities that have not matured, OTFM will only sell the asset to make cash available to the tribe if:

(a) There are no restrictions against the sale, and

(b) A tribe provides OTFM with a tribal resolution stating that:

(1) The security must be sold;

(2) The tribe acknowledges that they may incur a penalty when the security is sold; and

(3) The tribe acknowledges that the security may lose value if it is sold prior to maturity.

§ 115.814 If a tribe withdraws money from its trust account for a particular purpose or project, may the tribe redeposit any money that was not used for its intended purpose?

A tribe may redeposit funds not used for a particular purpose or project if:

(a) The funds were withdrawn in accordance with:

(1) The terms of Trust Reform Act;

(2) The terms of the legislative settlement; or

(3) The terms of a judgment use and distribution plan; and

(b) The tribe can provide documentation showing the source of the funds to be redeposited.

Withdrawing Tribal Trust Funds

§ 115.815 How does a tribe request trust funds from a tribal trust account?

To request trust funds from a tribal trust account, a tribe may:

(a) Make a written request to the BIA or the OTFM that is signed by the proper authorizing official(s), list the amount of trust funds to be withdrawn, provide any additional documentation or information required by law to withdraw certain trust funds, and must include a tribal resolution approving the withdrawal of the specified amount of trust funds; or

(b) Contact the OTFM to withdraw funds in accordance with the Trust Reform Act and 25 CFR part 1200.

§ 115.816 May a tribe's request for a withdrawal of trust funds from its trust account be delayed or denied?

(a) Action on a tribe's request for a withdrawal of trust funds may be delayed or denied if:

(1) The tribe did not submit all the necessary documentation;

(2) The tribe's request is not signed by the proper authorizing official(s);

(3) OTFM does not have documentation from the tribe certifying its recognized, authorizing officials;

(4) The tribe's request is in conflict with statutory language or the controlling document governing the use of the trust funds; or

(5) The BIA or OTFM requires clarification regarding the tribe's request.

(b) If action on a tribe's request to withdraw trust funds will be delayed or denied, the BIA or the OTFM will:

(1) Notify the tribe within ten (10) working days of the date of a request made under § 115.815(a);

(2) Notify the tribe under the time frames established in 25 CFR part 1200 for requests made under the Trust Reform Act; and

(3) Provide technical assistance to the tribe to address any problems.

§ 115.817 How does OTFM disburse money to a tribe?

Upon receipt of all necessary documentation, OTFM will process the request for disbursement and send the tribe the requested amount of trust funds within one business day. Whenever possible, trust funds will be disbursed electronically to an account in a financial institution designated by the tribe. If there are circumstances that preclude electronic payments, OTFM will mail a check.

Unclaimed Per Capita Funds

§ 115.818 What happens if an Indian adult does not cash his or her per capita check?

(a) If an Indian adult does not cash his or her per capita check within twelve (12) months of the date the check was issued, the check will be canceled and the trust funds will be deposited into a "returned per capita account" where the funds will be maintained until we receive a request for disbursement by the Indian adult or for disposition by a tribe pursuant to § 115.820.

(b) If an Indian adult's per capita check is returned to us as undeliverable, the trust funds will be immediately deposited into a "returned per capita account" where the funds will be maintained until we receive a request for disbursement by the individual or for disposition by a tribe pursuant to § 115.820.

§ 115.819 What steps will be taken to locate an individual whose per capita check is returned as undeliverable or not cashed within twelve (12) months of issuance?

The OTFM will notify a tribe of the names of the individuals whose per capita checks were returned as undeliverable or not cashed within twelve (12) months of issuance and will take reasonable action, including utilizing electronic search tools, to locate the individual entitled to receive the per capita funds.

§ 115.820 May OTFM transfer money in a returned per capita account to a tribal account?

Funds in a returned per capita account will not automatically be returned to a tribe. However, a tribe may apply under 25 U.S.C. 164 and Public Law 87–283, 75 Stat. 584 (1961), to have the unclaimed per capita funds transferred to its account for the tribe's use after six years have passed from the date of distribution.

Subpart H—Special Deposit Accounts

§ 115.900 Who receives the interest earned on trust funds in a special deposit account?

Generally, any interest earned on trust funds in a special deposit account will follow the principal (i.e., the tribe or individual who owns the trust funds in the special deposit account will receive the interest earned).

§ 115.901 When will the trust funds in a special deposit account be credited or paid out to the owner of the funds?

OTFM will disburse the trust funds from a special deposit account and deposit the trust funds in the owner's trust account following the BIA certification of the ownership of the funds and OTFM's receipt of such certification.

§ 115.902 May administrative or land conveyance fees paid as federal reimbursements be deposited in a special deposit account?

No, administrative or land conveyance fees paid as federal reimbursements may not be deposited with OTFM, which includes special deposit accounts. These fees must be deposited in the Federal Financial System.

§ 115.903 May cash bonds (e.g., performance bonds, appeal bonds, etc.) be deposited into a special deposit account?

No, cash bonds may not be deposited with OTFM, which includes the special deposit accounts at OTFM. Cash bonds held by the Secretary are to be deposited in non-interest bearing accounts until the term of the bonds expire.

§ 115.904 Where earnest money is paid prior to Secretarial approval of a conveyance or contract instrument involving trust assets, may the BIA deposit that earnest money into a special deposit account?

No, any money received prior to Secretarial approval of conveyance or contract instrument involving trust assets must be deposited into a non-interest bearing, non-trust account. After the Secretary approves the conveyance or contract instrument involving trust assets, the money designated by the conveyance or contract instrument will be deposited into a trust fund account.

Subpart I—Records

§ 115.1000 Who owns the records associated with this part?

(a) Records are the property of the United States if they:

(1) Are made or received by a tribe or tribal organization in the conduct of a federal trust function under this part, including the operation of a trust program pursuant to 25 U.S.C. 450f *et seq.*; and

(2) Evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under this part.

(b) Records not covered by paragraph (a) of this section that are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior under this part are the property of the tribe.

§ 115.1001 How must records associated with this part be preserved?

(a) Any organization, including tribes and tribal organizations, that have records identified in § 115.1000(a) must preserve the records in accordance with approved Departmental records retention procedures under the Federal Records Act, 44 U.S.C. Chapters 29, 31 and 33. These records and related records management practices and safeguards required under the Federal Records Act are subject to inspection by the Secretary and the Archivist of the United States.

(b) A tribe or tribal organization should preserve the records identified in § 115.1000(b) for the period of time authorized by the Archivist of the United States for similar Department of the Interior records in accordance with 44 U.S.C. Chapter 33. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under this part, the tribe or tribal organization may be prevented from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

PART 162—LEASES AND PERMITS

4. Part 162 is revised to read as follows:

Subpart A—General Provisions

Sec.

162.100 What are the purposes of this part?
162.101 What key terms do I need to know?

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162.102 What land, or interests in land, are subject to these regulations?
162.103 What types of land use agreements are covered by these regulations?
162.104 When is a lease needed to authorize possession of Indian Land?
162.105 Can tracts with different Indian landowners be unitized for leasing purposes?
162.106 What will BIA do if possession is taken without an approved lease or other proper authorization?
162.107 What are BIA's objectives in granting or approving leases?
162.108 What are BIA's responsibilities in administering and enforcing leases?
162.109 What laws, other than these regulations, will apply to leases granted or approved under this part?
162.110 Can these regulations be administered by tribes, on the Secretary's or on BIA's behalf?
162.111 Who owns the records associated with this part?
162.112 How must records associated with this part be preserved?
162.113 May decisions under this part be appealed?

Subpart B—Agricultural Leases

General Provisions

162.200 What types of leases are covered by this subpart?
162.201 Must agricultural land be managed in accordance with a tribe's agricultural resource management plan?
162.202 How will tribal laws be enforced on agricultural land?
162.203 When can the regulations in this subpart be superseded or modified by tribal laws and leasing policies?
162.204 Must notice of applicable tribal laws and leasing policies be provided?
162.205 Can individual Indian landowners exempt their agricultural land from certain tribal leasing policies?

How To Obtain a Lease

162.206 Can the terms of an agricultural lease be negotiated with the Indian landowners?
162.207 When can the Indian landowners grant an agricultural lease?
162.208 Who can represent the Indian landowners in negotiating or granting an agricultural lease?
162.209 When can BIA grant an agricultural lease on behalf of an Indian landowner?
162.210 When can BIA grant a permit covering agricultural land?
162.211 What type of valuation or evaluation methods will be applied in estimating the fair annual rental of Indian land?
162.212 When will the BIA advertise Indian land for agricultural leases?
162.213 What supporting documents must be provided prior to BIA's grant or approval of an agricultural lease?
162.214 How and when will BIA decide whether to approve an agricultural lease?
162.215 When will an agricultural lease be effective?
162.216 When will a BIA decision to approve an agricultural lease be effective?
162.217 Must an agricultural lease or permit be recorded?

Lease Requirements

162.218 Is there a standard agricultural lease form?
162.219 Are there any provisions that must be included in an agricultural lease?
162.220 Are there any formal requirements that must be satisfied in the execution of an agricultural lease?
162.221 How should the land be described in an agricultural lease?
162.222 How much rent must be paid under an agricultural lease?
162.223 Must the rent be adjusted under an agricultural lease?
162.224 When are rent payments due under an agricultural lease?
162.225 Will untimely rent payments made under an agricultural lease be subject to interest charges or late payment penalties?
162.226 To whom can rent payments be made under an agricultural lease?
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162.228 What other types of payments are required under an agricultural lease?
162.229 How long can the term of an agricultural lease run?
162.230 Can an agricultural lease be amended, assigned, sublet, or mortgaged?
162.231 How can the land be used under an agricultural lease?
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162.233 Who will own the improvements made under an agricultural lease?
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162.235 What form of bond can be accepted under an agricultural lease?
162.236 How will a cash bond be administered?
162.237 What insurance is required under an agricultural lease?
162.238 What indemnities are required under an agricultural lease?
162.239 How will payment rights and obligations relating to agricultural land be allocated between the Indian landowners and the tenant?
162.240 Can an agricultural lease provide for negotiated remedies in the event of a violation?

Lease Administration

162.241 Will administrative fees be charged for actions relating to agricultural leases?
162.242 How will BIA decide whether to approve an amendment to an agricultural lease?
162.243 How will BIA decide whether to approve an assignment or sublease under an agricultural lease?
162.244 How will BIA decide whether to approve a leasehold mortgage under an agricultural lease?
162.245 When will a BIA decision to approve an amendment, assignment, sublease, or mortgage under an agricultural lease be effective?
162.246 Must an amendment, assignment, sublease, or mortgage approved under an agricultural lease be recorded?

Lease Enforcement

162.247 Will BIA notify a tenant when a rent payment is due under an agricultural lease?
162.248 What will BIA do if rent payments are not made in the time and manner required by an agricultural lease?
162.249 Will any special fees be assessed on delinquent rent payments due under an agricultural lease?
162.250 How will BIA determine whether the activities of a tenant under an agricultural lease are in compliance with the terms of the lease?
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162.252 What will BIA do if a violation of an agricultural lease is not cured within the requisite time period?
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162.255 Can BIA take emergency action if the leased premises are threatened with immediate and significant harm?
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Subpart C—Residential Leases

[Reserved]

Subpart D—Business Leases

[Reserved]

Subpart E—Special Requirements for Certain Reservations 162.500 Crow Reservation.

162.500 Crow Reservation.
162.501 Fort Belknap Reservation.
162.502 Cabazon, Augustine, and Torres-Martinez Reservations, California.
162.503 San Xavier and Salt River Pima-Maricopa Reservations.

Subpart F—Non-Agricultural Leases

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162.602 Grants of leases by owners or their representatives.
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162.610 Subleases and assignments.
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162.612 Can a lease provide for negotiated remedies in the event of a violation?
162.613 Will BIA notify a tenant when a rent payment is due under a lease?
162.614 Will untimely rent payments made under a lease be subject to interest charges or late payment penalties?
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162.617 How will BIA determine whether the activities of a tenant under a lease are in compliance with the terms of the lease?
162.618 What will BIA do in the event of a violation under a lease?
162.619 What will BIA do if a violation of a lease is not cured within the requisite time period?
162.620 Will BIA's regulations concerning appeal bonds apply to cancellation decisions involving leases?
162.621 When will a cancellation of a lease be effective?
162.622 Can BIA take emergency action if the leased premises are threatened with immediate and significant harm?
162.623 What will BIA do if a tenant holds over after the expiration or cancellation of a lease?

Authority: 5 U.S.C. 301, R.S. 463 and 465; 25 U.S.C. 2 and 9. Interpret or apply sec. 3, 26 Stat. 795, sec. 1, 28 Stat. 305, secs. 1, 2, 31 Stat. 229, 246, secs. 7, 12, 34 Stat. 545, 34 Stat. 1015, 1034, 35 Stat. 70, 95, 97, sec. 4, 36 Stat. 856, sec. 1, 39 Stat. 128, 41 Stat. 415, as amended, 751, 1232, sec. 17, 43 Stat. 636, 641, 44 Stat. 658, as amended, 894, 1365, as amended, 47 Stat. 1417, sec. 17, 48 Stat. 984, 988, 49 Stat. 115, 1135, sec. 55, 49 Stat. 781, sec. 3, 49 Stat. 1967, 54 Stat. 745, 1057, 60 Stat. 308, secs. 1, 2, 60 Stat. 962, sec. 5, 64 Stat. 46, secs. 1, 2, 4, 5, 6, 64 Stat. 470, 69 Stat. 539, 540, 72 Stat. 968, 107 Stat. 2011, 108 Stat. 4572, March 20, 1996, 110 Stat. 4016; 25 U.S.C. 380, 393, 393a, 394, 395, 397, 402, 402a, 403, 403a, 403b, 403c, 409a, 413, 415, 415a, 415b, 415c, 415d, 477, 635, 3701, 3702, 3703, 3712, 3713, 3714, 3715, 3731, 3733; 44 U.S.C. 3101 *et seq.*

Subpart A—General Provisions

§ 162.100 What are the purposes of this part?

(a) The purposes of this part are to:

(1) Identify the conditions and authorities under which certain interests in Indian land and Government land may be leased;

(2) Describe the manner in which various types of leases may be obtained;

(3) Identify terms and conditions that may be required in various types of leases;

(4) Describe the policies and procedures that will be applied in the administration and enforcement of various types of leases; and

(5) Identify special requirements that apply to leases made under special acts of Congress that apply only to certain Indian reservations.

(b) This part includes six subparts, including separate, self-contained subparts relating to Agricultural Leases (Subpart B), Residential Leases (Subpart C, reserved), Business Leases (Subpart D, reserved), and Non-Agricultural Leases (Subpart F), respectively. Subpart E identifies special provisions applicable only to leases made under special acts of Congress that apply only to certain Indian reservations. Leases covered by subpart E are also subject to the general provisions in subparts A through F, respectively, except to the extent those general provisions are inconsistent with any of the special provisions in subpart E or any special act of Congress under which those leases are made.

(c) These regulations apply to all leases in effect when the regulations are promulgated; however, unless otherwise agreed by the parties, these regulations will not affect the validity or terms of any existing lease.

§ 162.101 What key terms do I need to know?

For purposes of this part:

Adult means an individual who is 18 years of age or older.

Agricultural land means Indian land or Government land suited or used for the production of crops, livestock or other agricultural products, or Indian land suited or used for a business that supports the surrounding agricultural community.

Agricultural lease means a lease of agricultural land for farming and/or grazing purposes.

AIARMA means the American Indian Agricultural Resources Management Act of December 3, 1993 (107 Stat. 2011, 25 U.S.C. 3701 *et seq.*), as amended on November 2, 1994 (108 Stat. 4572).

Assignment means an agreement between a tenant and an assignee, whereby the assignee acquires all of the tenant's rights, and assumes all of the tenant's obligations, under a lease.

BIA means the Bureau of Indian Affairs within the Department of the Interior and any tribe acting on behalf of BIA under § 162.109 of this part.

Bond means security for the performance of certain lease obligations, as furnished by the tenant, or a guaranty of such performance as furnished by a third-party surety.

Day means a calendar day.

Emancipated minor means a person under 18 years of age who is married or who is determined by a court of competent jurisdiction to be legally able to care for himself or herself.

Fair annual rental means the amount of rental income that a leased tract of Indian land would most probably command in an open and competitive market.

Fee interest means an interest in land that is owned in unrestricted fee status, and is thus freely alienable by the fee owner.

Fractionated tract means a tract of Indian land owned in common by Indian landowners and/or fee owners holding undivided interests therein.

Government land means any tract, or interest therein, in which the surface estate is owned by the United States and administered by BIA, not including tribal land that has been reserved for administrative purposes.

Immediate family means a spouse, brother, sister, lineal ancestor, lineal descendant, or member of the household of an individual Indian landowner.

Indian land means any tract in which any interest in the surface estate is owned by a tribe or individual Indian in trust or restricted status.

Indian landowner means a tribe or individual Indian who owns an interest in Indian land in trust or restricted status.

Individually-owned land means any tract, or interest therein, in which the surface estate is owned by an individual Indian in trust or restricted status.

Interest, when used with respect to Indian land, means an ownership right to the surface estate of Indian land that is unlimited or uncertain in duration, including a life estate.

Lease means a written agreement between Indian landowners and a tenant or lessee, whereby the tenant or lessee is granted a right to possession of Indian land, for a specified purpose and duration. Unless otherwise provided, the use of this term will also include permits, as appropriate.

Lessee means tenant, as defined in this section.

Life estate means an interest in Indian land that is limited, in duration, to the life of the life tenant holding the interest, or the life of some other person.

Majority interest means more than 50% of the trust or restricted interests in a tract of Indian land.

Minor means an individual who is less than 18 years of age.

Mortgage means a mortgage, deed of trust or other instrument that pledges a tenant's leasehold interest as security for a debt or other obligation owed by the tenant to a lender or other mortgagee.

NEPA means the National Environmental Policy Act (42 U.S.C. § 4321, *et seq.*)

Non compos mentis means a person who has been legally determined by a court of competent jurisdiction to be of unsound mind or incapable of managing his or her own affairs.

Permit means a written agreement between Indian landowners and the applicant for the permit, also referred to as a permittee, whereby the permittee is granted a revocable privilege to use Indian land or Government land, for a specified purpose.

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Remainder means an interest in Indian land that is created at the same time as a life estate, for the use and enjoyment of its owner after the life estate terminates.

Restricted land or restricted status means land the title to which is held by an individual Indian or a tribe and which can only be alienated or encumbered by the owner with the approval of the Secretary because of limitations contained in the conveyance instrument pursuant to federal law.

Secretary means the Secretary of the Interior or an authorized representative.

Sublease means a written agreement by which the tenant grants to an individual or entity a right to possession no greater than that held by the tenant under the lease.

Surety means one who guarantees the performance of another.

Tenant means a person or entity who has acquired a legal right of possession to Indian land by a lease or permit under this part.

Trespass means an unauthorized possession, occupancy or use of Indian land.

Tribal land means the surface estate of land or any interest therein held by the United States in trust for a tribe, band, community, group or pueblo of Indians, and land that is held by a tribe, band, community, group or pueblo of Indians, subject to federal restrictions against alienation or encumbrance, and includes such land reserved for BIA administrative purposes when it is not immediately needed for such purposes. The term also includes lands held by the United States in trust for an Indian corporation chartered under section 17 of the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. § 476).

Tribal laws means the body of law that governs land and activities under the jurisdiction of a tribe, including ordinances and other enactments by the tribe, tribal court rulings, and tribal common law.

Trust land means any tract, or interest therein, that the United States holds in trust status for the benefit of a tribe or individual Indian.

Undivided interest means a fractional share in the surface estate of Indian land, where the surface estate is owned in common with other Indian landowners or fee owners.

Us/We/Our means the Secretary or BIA and any tribe acting on behalf of the Secretary or BIA under § 162.110 of this part.

USPAP means the Uniform Standards of Professional Appraisal Practice, as promulgated by the Appraisal Standards Board of the Appraisal Foundation to establish requirements and procedures for professional real property appraisal practice.

§ 162.102 What land, or interests in land, are subject to these regulations?

(a) These regulations apply to Indian land and Government land, including any tract in which an interest is owned by an individual Indian or tribe in trust or restricted status.

(b) Where a life estate and remainder interest are both owned in trust or restricted status, the life estate and remainder interest must both be leased under these regulations, unless the lease is for less than one year in duration. Unless otherwise provided by the document creating the life estate or by agreement, rent payable under the lease must be paid to the life tenant under part 179 of this chapter.

(c) In approving a lease under these regulations, we will not lease any fee interest in Indian land, nor will we collect rent on behalf of any fee owners. The leasing of the trust and restricted interests of the Indian landowners will not be conditioned on a lease having been obtained from the owners of any fee interests. Where all of the trust or restricted interests in a tract are subject to a life estate held in fee status, we will approve a lease of the remainder interests only if such action is necessary to preserve the value of the land or protect the interests of the Indian landowners.

(d) These regulations do not apply to tribal land that is leased under a corporate charter issued by us pursuant to 25 U.S.C. § 477, or under a special act of Congress authorizing leases without our approval under certain conditions, except to the extent that the authorizing statutes require us to enforce such leases on behalf of the Indian landowners.

(e) To the extent any regulations in this part conflict with the Indian Land Consolidation Act Amendments of 2000, Public Law 106–462, the provisions of that Act will govern.

§ 162.103 What types of land use agreements are covered by these regulations?

(a) These regulations cover leases that authorize the possession of Indian land. These regulations do not apply to:

(1) Mineral leases, prospecting permits, or mineral development agreements, as covered by parts 211, 212 and 225 of this chapter and similar parts specific parts specific to particular tribes;

(2) Grazing permits, as covered by part 166 of this chapter and similar parts specific parts specific to particular tribes;

(3) Timber contracts, as covered by part 163 of this chapter;

(4) Management contracts, joint venture agreements, or other encumbrances of tribal land, as covered by 25 U.S.C. § 81, as amended;

(5) Leases of water rights associated with Indian land, except to the extent the use of such water rights is incorporated in a lease of the land itself; and

(6) Easements or rights-of-way, as covered by part 169 of this chapter.

(b) Where appropriate, the regulations in this part that specifically refer to leases will apply to permits that authorize the temporary, non-possessory use of Indian land or Government land, not including:

(1) Land assignments and similar instruments authorizing temporary uses by tribal members, in accordance with tribal laws or custom; and

(2) Trader's licenses issued under part 140 of this chapter.

§ 162.104 When is a lease needed to authorize possession of Indian Land?

(a) An Indian landowner who owns 100% of the trust or restricted interests in a tract may take possession without a lease or any other prior authorization from us.

(b) An Indian landowner of a fractional interest in a tract must obtain a lease of the other trust and restricted interests in the tract, under these regulations, unless the Indian co-owners have given the landowner's permission to take or continue in possession without a lease.

(c) A parent or guardian of a minor child who owns 100% of the trust interests in the land may take possession without a lease. We may require that the parent or guardian provide evidence of a direct benefit to the minor child. When the child reaches the age of majority, a lease must be obtained under these regulations to authorize continued possession.

(d) Any other person or legal entity, including an independent legal entity owned and operated by a tribe, must obtain a lease under these regulations before taking possession.

§ 162.105 Can tracts with different Indian landowners be unitized for leasing purposes?

(a) A lease negotiated by Indian landowners may cover more than one tract of Indian land, but the minimum consent requirements for leases granted by Indian landowners under subparts B through D of this part will apply to each tract separately. We may combine multiple tracts into a unit for leases negotiated or advertised by us, if we determine that unitization is in the Indian landowners' best interests and consistent with the efficient administration of the land.

(b) Unless otherwise provided in the lease, the rent or other consideration derived from a unitized lease will be distributed based on the size of each landowner's interest in proportion to the acreage within the entire unit.

§ 162.106 What will BIA do if possession is taken without an approved lease or other proper authorization?

(a) If a lease is required, and possession is taken without a lease by a party other than an Indian landowner of the tract, we will treat the unauthorized use as a trespass. Unless we have reason to believe that the party in possession is engaged in negotiations with the Indian landowners to obtain a lease, we will take action to recover possession on behalf of the Indian landowners, and pursue any additional remedies available under applicable law.

(b) Where a trespass involves Indian agricultural land, we will also assess civil penalties and costs under part 166, subpart I, of this chapter.

§ 162.107 What are BIA's objectives in granting or approving leases?

(a) We will assist Indian landowners in leasing their land, either through negotiations or advertisement. In reviewing a negotiated lease for approval, we will defer to the landowners' determination that the lease is in their best interest, to the maximum extent possible. In granting a lease on the landowners' behalf, we will obtain a fair annual rental and attempt to ensure (through proper notice) that the use of the land is consistent with the landowners' wishes. We will also recognize the rights of Indian landowners to use their own land, so long as their Indian co-owners are in agreement and the value of the land is preserved.

(b) We will recognize the governing authority of the tribe having jurisdiction over the land to be leased, preparing and advertising leases in accordance with applicable tribal laws and policies. We will promote tribal control and self-determination over tribal land and other land under the tribe's jurisdiction, through contracts and self-governance compacts entered into under the Indian Self-Determination and Education Assistance Act, as amended, 25 U.S.C. § 450f *et seq.*

§ 162.108 What are BIA's responsibilities in administering and enforcing leases?

(a) We will ensure that tenants meet their payment obligations to Indian landowners, through the collection of rent on behalf of the landowners and the prompt initiation of appropriate collection and enforcement actions. We will also assist landowners in the enforcement of payment obligations that run directly to them, and in the exercise of any negotiated remedies that apply in addition to specific remedies made available to us under these or other regulations.

(b) We will ensure that tenants comply with the operating requirements in their leases, through appropriate inspections and enforcement actions as needed to protect the interests of the Indian landowners and respond to concerns expressed by them. We will take immediate action to recover possession from trespassers operating without a lease, and take other emergency action as needed to preserve the value of the land.

§ 162.109 What laws, other than these regulations, will apply to leases granted or approved under this part?

(a) Leases granted or approved under this part will be subject to federal laws of general applicability and any specific federal statutory requirements that are not incorporated in these regulations.

(b) Tribal laws generally apply to land under the jurisdiction of the tribe enacting such laws, except to the extent that those tribal laws are inconsistent with these regulations or other applicable federal law. These regulations may be superseded or modified by tribal laws, however, so long as:

(1) The tribal laws are consistent with the enacting tribe's governing documents;

(2) The tribe has notified us of the superseding or modifying effect of the tribal laws;

(3) The superseding or modifying of the regulation would not violate a federal statute or judicial decision, or conflict with our general trust responsibility under federal law; and

(4) The superseding or modifying of the regulation applies only to tribal land.

(c) State law may apply to lease disputes or define the remedies available to the Indian landowners in the event of a lease violation by the tenant, if the lease so provides and the Indian landowners have expressly agreed to the application of state law.

§ 162.110 Can these regulations be administered by tribes, on the Secretary's or on BIA's behalf?

Except insofar as these regulations provide for the granting, approval, or enforcement of leases and permits, the provisions in these regulations that authorize or require us to take certain actions will extend to any tribe or tribal organization that is administering specific programs or providing specific services under a contract or self-governance compact entered into under the Indian Self-Determination and Education Assistance Act (25 U.S.C. § 450f *et seq.*).

§ 162.111 Who owns the records associated with this part?

(a) Records are the property of the United States if they:

(1) Are made or received by a tribe or tribal organization in the conduct of a federal trust function under 25 U.S.C. § 450f *et seq.*, including the operation of a trust program; and

(2) Evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under this part.

(b) Records not covered by paragraph (a) of this section that are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior under this part are the property of the tribe.

§ 162.112 How must records associated with this part be preserved?

(a) Any organization, including tribes and tribal organizations, that have records identified in § 162.111(a) must preserve the records in accordance with approved Departmental records retention procedures under the Federal Records Act, 44 U.S.C. Chapters 29, 31 and 33. These records and related records management practices and safeguards required under the Federal Records Act are subject to inspection by the Secretary and the Archivist of the United States.

(b) A tribe or tribal organization should preserve the records identified in § 162.111(b) for the period of time authorized by the Archivist of the United States for similar Department of the Interior records in accordance with 44 U.S.C. Chapter 33. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under this part, it may prevent the tribe or tribal organization from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

§ 162.113 May decisions under this part be appealed?

Yes. Except where otherwise provided in this part, appeals from decisions by the BIA under this part may be taken pursuant to 25 CFR part 2.

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Subpart B—Agricultural Leases

General Provisions

§ 162.200 What types of leases are covered by this subpart?

The regulations in this subpart apply to agricultural leases, as defined in this part. The regulations in this subpart may also apply to business leases on agricultural land, where appropriate.

§ 162.201 Must agricultural land be managed in accordance with a tribe's agricultural resource management plan?

(a) Agricultural land under the jurisdiction of a tribe must be managed in accordance with the goals and objectives in any agricultural resource management plan developed by the tribe, or by us in close consultation with the tribe, under AIARMA.

(b) A ten-year agricultural resource management and monitoring plan must be developed through public meetings and completed within three years of the initiation of the planning activity. Such a plan must be developed through public meetings, and be based on the public meeting records and existing survey documents, reports, and other research from federal agencies, tribal community colleges, and land grant universities. When completed, the plan must:

(1) Determine available agricultural resources;

(2) Identify specific tribal agricultural resource goals and objectives;

(3) Establish management objectives for the resources;

(4) Define critical values of the Indian tribe and its members and identify holistic management objectives; and

(5) Identify actions to be taken to reach established objectives.

(c) Where the regulations in this subpart are inconsistent with a tribe's agricultural resource management plan, we may waive the regulations under part 1 of this title, so long as the waiver does not violate a federal statute or judicial decision or conflict with our general trust responsibility under federal law.

§ 162.202 How will tribal laws be enforced on agricultural land?

(a) Unless prohibited by federal law, we will recognize and comply with tribal laws regulating activities on agricultural land, including tribal laws relating to land use, environmental protection, and historic or cultural preservation.

(b) While the tribe is primarily responsible for enforcing tribal laws pertaining to agricultural land, we will:

(1) Assist in the enforcement of tribal laws;

(2) Provide notice of tribal laws to persons or entities undertaking activities on agricultural land, under § 162.204(c) of this subpart; and

(3) Require appropriate federal officials to appear in tribal forums when requested by the tribe, so long as such an appearance would not:

(i) Be inconsistent with the restrictions on employee testimony set forth at 43 CFR Part 2, Subpart E;

(ii) Constitute a waiver of the sovereign immunity of the United States; or

(iii) Authorize or result in a review of our actions by a tribal court.

(c) Where the regulations in this subpart are inconsistent with a tribal law, but such regulations cannot be superseded or modified by the tribal law under § 162.109 of this part, we may waive the regulations under part 1 of this chapter, so long as the waiver does not violate a federal statute or judicial decision or conflict with our general trust responsibility under federal law.

§ 162.203 When can the regulations in this subpart be superseded or modified by tribal laws and leasing policies?

(a) The regulations in this subpart may be superseded or modified by tribal laws, under the circumstances described in § 162.109(b) of this part.

(b) When specifically authorized by an appropriate tribal resolution establishing a general policy for the leasing of tribal and individually-owned agricultural land, we will:

(1) Waive the general prohibition against tenant preferences in leases advertised for bid under § 162.212 of this subpart, by allowing prospective Indian tenants to match the highest responsible bid (unless the tribal leasing policy specifies some other manner in which the preference must be afforded);

(2) Waive the requirement that a tenant post a bond under § 162.234 of this subpart;

(3) Modify the requirement that a tenant post a bond in a form described in § 162.235 of this subpart;

(4) Approve leases of tribal land at rates established by the tribe, as provided in § 162.222(b) of this subpart.

(c) When specifically authorized by an appropriate tribal resolution establishing a general policy for the leasing of "highly fractionated undivided heirship lands" (as defined in the tribal leasing policy), we may waive or modify the three-month notice requirement in § 162.209(b) of this subpart, so long as:

(1) The tribal law or leasing policy adopts an alternative plan for providing notice to Indian landowners, before an agricultural lease is granted by us on their behalf; and

(2) A waiver or modification of the three-month notice requirement is needed to prevent waste, reduce idle land acreage, and ensure lease income to the Indian landowners.

(d) Tribal leasing policies of the type described in paragraphs (b) through (c) of this section will not apply to individually-owned land that has been made exempt from such laws or policies under § 162.205 of this subpart.

§ 162.204 Must notice of applicable tribal laws and leasing policies be provided?

(a) A tribe must provide us with an official copy of any tribal law or leasing policy that supersedes or modifies these regulations under §§ 162.109 or 162.203 of this part. If the tribe has not already done so, we will provide notice of such a tribal law or leasing policy to affected Indian landowners and persons or entities undertaking activities on agricultural land. Such notice will be provided in the manner described in paragraphs (b) through (c) of this section.

(b) We will provide notice to Indian landowners, as to the superseding or modifying effect of any tribal leasing policy and their right to exempt their land from such a policy. Such notice will be provided by:

(1) Written notice included in a notice of our intent to lease the land, issued under § 162.209(b) of this subpart; or

(2) Public notice posted at the tribal community building or the United States Post Office, or published in the local newspaper that serves the area in which the Indian owners' land is located, at the time the tribal leasing policy is adopted.

(c) We will provide notice to persons or entities undertaking activities on agricultural land, as to the general applicability of tribal laws and the superseding or modifying effect of particular tribal laws and leasing policies. Such notice will be provided by:

(1) Written notice included in advertisements for lease, issued under § 162.212 of this subpart; or

(2) Public notice posted at the tribal community building or the United States Post Office, or published in a local newspaper of general circulation, at the time the tribal law is enacted or the leasing policy adopted.

§ 162.205 Can individual Indian landowners exempt their agricultural land from certain tribal leasing policies?

(a) Individual Indian landowners may exempt their agricultural land from the application of a tribal leasing policy of a type described in § 162.203(b) through (c) of this subpart, if the Indian owners of at least 50% of the trust or restricted interests in the land submit a written objection to us before a lease is granted or approved.

(b) Upon our receipt of a written objection from the Indian landowners that satisfies the requirements of paragraph (a) of this section, we will notify the tribe that the owners' land has been exempted from a specific tribal leasing policy. If the exempted land is part of a unitized lease tract, such land will be removed from the unit and leased separately, if appropriate.

(c) The procedures described in paragraphs (a) and (b) of this section will also apply to withdrawing an approved exemption.

How to Obtain a Lease

§ 162.206 Can the terms of an agricultural lease be negotiated with the Indian landowners?

An agricultural lease may be obtained through negotiation. We will assist prospective tenants in contacting the Indian landowners or their representatives for the purpose of negotiating a lease, and we will assist the landowners in those negotiations upon request.

§ 162.207 When can the Indian landowners grant an agricultural lease?

(a) Tribes grant leases of tribally-owned agricultural land, including any tribally-owned undivided interest(s) in a fractionated tract, subject to our approval. Where tribal land is subject to a land assignment made to a tribal member or some other individual under tribal law or custom, the individual and the tribe must both grant the lease, subject to our approval.

(b) Adult Indian owners, or emancipated minors, may grant agricultural leases of their land, including undivided interests in fractionated tracts, subject to our approval.

(c) An agricultural lease of a fractionated tract may be granted by the owners of a majority interest in the tract, subject to our approval. Although prior notice to non-consenting individual Indian landowners is generally not needed prior to our approval of such a lease, a right of first refusal must be offered to any non-consenting Indian landowner who is using the entire lease tract at the time the lease is entered into by the owners of a majority interest. Where the owners of a majority interest grant such a lease on behalf of all of the Indian owners of a fractionated tract, the non-consenting Indian landowners must receive a fair annual rental.

(d) As part of the negotiation of a lease, Indian landowners may advertise their land to identify potential tenants with whom to negotiate.

§ 162.208 Who can represent the Indian landowners in negotiating or granting an agricultural lease?

The following individuals or entities may represent an individual Indian landowner:

(a) An adult with custody acting on behalf of his or her minor children;

(b) A guardian, conservator, or other fiduciary appointed by a court of competent jurisdiction to act on behalf of an individual Indian landowner;

(c) An adult or legal entity who has been given a written power of attorney that:

(1) Meets all of the formal requirements of any applicable tribal or state law;

(2) Identifies the attorney-in-fact and the land to be leased; and

(3) Describes the scope of the power granted and any limits thereon.

§ 162.209 When can BIA grant an agricultural lease on behalf of an Indian landowner?

(a) We may grant an agricultural lease on behalf of:

(1) Individuals who are found to be non compos mentis by a court of competent jurisdiction;

(2) Orphaned minors;

(3) The undetermined heirs and devisees of deceased Indian owners;

(4) Individuals who have given us a written power of attorney to lease their land; and

(5) Individuals whose whereabouts are unknown to us, after reasonable attempts are made to locate such individuals; and

(6) The individual Indian landowners of fractionated Indian land, when necessary to protect the interests of the individual Indian landowners.

(b) We may grant an agricultural lease on behalf of all of the individual Indian owners of a fractionated tract, where:

(1) We have provided the Indian landowners with written notice of our intent to grant a lease on their behalf, but the Indian landowners are unable to agree upon a lease during a three-month negotiation period immediately following such notice, or any other notice period established by a tribe under § 162.203(c) of this subpart; and

(2) The land is not being used by an Indian landowner under § 162.104(b) of this part.

§ 162.210 When can BIA grant a permit covering agricultural land?

(a) We may grant a permit covering agricultural land in the same manner as we would grant an agricultural lease under § 162.209 of this part. We may also grant a permit on behalf of individual Indian landowners, without prior notice, if it is impractical to provide notice to the owners and no substantial injury to the land will occur.

(b) We may grant a permit covering agricultural land, but not an agricultural lease, on government land.

(c) We will not grant a permit on tribal agricultural land, but a tribe may grant a permit, subject to our approval, in the same manner as it would grant a lease under § 162.207(a) of this subpart.

§ 162.211 What type of valuation or evaluation methods will be applied in estimating the fair annual rental of Indian land?

(a) To support the Indian landowners in their negotiations, and to assist in our consideration of whether an agricultural lease is in the Indian landowners' best interest, we must determine the fair annual rental of the land prior to our grant or approval of the lease, unless the land may be leased at less than a fair annual rental under § 162.222(b) through (c) of this subpart.

(b) A fair annual rental may be determined by competitive bidding, appraisal, or any other appropriate valuation method. Where an appraisal or other valuation is needed to determine the fair annual rental, the appraisal or valuation must be prepared in accordance with USPAP.

§ 162.212 When will the BIA advertise Indian land for agricultural leases?

(a) We will generally advertise Indian land for agricultural leasing:

(1) At the request of the Indian landowners; or

(2) Before we grant a lease under § 162.209(b) of this subpart.

(b) Advertisements will provide prospective tenants with notice of any superseding tribal laws and leasing policies that have been made applicable to the land under §§ 162.109 and 162.203 of this part, along with certain standard terms and conditions to be included in the lease. Advertisements will prohibit tenant preferences, and bidders at lease sales will not be afforded any preference, unless a preference in favor of individual Indians is required by a superseding tribal law or leasing policy.

(c) Advertisements will require sealed bids, and they may also provide for further competitive bidding among the prospective tenants at the conclusion of the bid opening. Competitive bidding should be supported, at a minimum, by a market study or rent survey that is consistent with USPAP.

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§ 162.213 What supporting documents must be provided prior to BIA's grant or approval of an agricultural lease?

(a) If the tenant is a corporation, partnership or other legal entity, it must provide organizational and financial documents, as needed to show that the lease will be enforceable against the tenant and the tenant will be able to perform all of its lease obligations.

(b) Where a bond is required under § 162.234 of this subpart, the bond must be furnished before we grant or approve the lease.

(c) The tenant must provide environmental and archaeological reports, surveys, and site assessments, as needed to document compliance with NEPA and other applicable federal and tribal land use requirements.

§ 162.214 How and when will BIA decide whether to approve an agricultural lease?

(a) Before we approve a lease, we must determine in writing that the lease is in the best interest of the Indian landowners. In making that determination, we will:

(1) Review the lease and supporting documents;

(2) Identify potential environmental impacts and ensure compliance with all applicable environmental laws, land use laws, and ordinances (including preparation of the appropriate review documents under NEPA);

(3) Assure ourselves that adequate consideration has been given, as appropriate, to:

(i) The relationship between the use of the leased premises and the use of neighboring lands;

(ii) The height, quality, and safety of any structures or other facilities to be constructed on the leased premises;

(iii) The availability of police and fire protection, utilities, and other essential community services;

(iv) The availability of judicial forums for all criminal and civil matters arising on the leased premises; and

(v) The effect on the environment of the proposed land use.

(4) Require any lease modifications or mitigation measures that are needed to satisfy any requirements of this subpart, or any other federal or tribal land use requirements.

(b) Where an agricultural lease is in a form that has previously been accepted or approved by us, and all of the documents needed to support the findings required by paragraph (a) of this section have been received, we will decide whether to approve the lease within 30 days of the date of our receipt of the lease and supporting documents. If we decide to approve or disapprove a lease, we will notify the parties immediately and advise them of their right to appeal the decision under part 2 of this chapter. Copies of agricultural leases that have been approved will be provided to the tenant, and made available to the Indian landowners upon request.

§ 162.215 When will an agricultural lease be effective?

Unless otherwise provided in the lease, an agricultural lease will be effective on the date on which the lease is approved by us. An agricultural lease may be made effective on some past or future date, by agreement, but such a lease may not be approved more than one year prior to the date on which the lease term is to commence.

§ 162.216 When will a BIA decision to approve an agricultural lease be effective?

Our decision to approve an agricultural lease will be effective immediately, notwithstanding any appeal that may be filed under part 2 of this chapter.

§ 162.217 Must an agricultural lease or permit be recorded?

(a) An agricultural lease or permit must be recorded in our Land Titles and Records Office with jurisdiction over the land. We will record the lease or permit immediately following our approval under this subpart.

(b) Agricultural leases of tribal land that do not require our approval, under § 162.102 of this part, must be recorded by the tribe in our Land Titles and Records Office with jurisdiction over the land.

Lease Requirements

§ 162.218 Is there a standard agricultural lease form?

Based on the need for flexibility in advertising, negotiating and drafting of appropriate lease terms and conditions, there is no standard agricultural lease form that must be used. We will assist the Indian landowners in drafting lease provisions that conform to the requirements of this part.

§ 162.219 Are there any provisions that must be included in an agricultural lease?

In addition to the other requirements of this part, all agricultural leases must provide that:

(a) The obligations of the tenant and its sureties to the Indian landowners will also be enforceable by the United States, so long as the land remains in trust or restricted status;

(b) Nothing contained in this lease shall operate to delay or prevent a termination of federal trust responsibilities with respect to the land by the issuance of a fee patent or otherwise during the term of the lease; however, such termination shall not serve to abrogate the lease. The owners of the land and the lessee and his surety or sureties shall be notified of any such change in the status of the land;

(c) There must not be any unlawful conduct, creation of a nuisance, illegal activity, or negligent use or waste of the leased premises; and

(d) The tenant must comply with all applicable laws, ordinances, rules, regulations, and other legal requirements, including tribal laws and leasing policies.

§ 162.220 Are there any formal requirements that must be satisfied in the execution of an agricultural lease?

(a) An agricultural lease must identify the Indian landowners and their respective interests in the leased premises, and the lease must be granted by or on behalf of each of the Indian landowners. One who executes a lease in a representative capacity under § 162.208 of this subpart must identify the owner being represented and the authority under which such action is being taken.

(b) An agricultural lease must be executed by individuals having the necessary capacity and authority to bind the tenant under applicable law.

(c) An agricultural lease must include a citation of the provisions in this subpart that authorize our approval, along with a citation of the formal documents by which such authority has been delegated to the official taking such action.

§ 162.221 How should the land be described in an agricultural lease?

An agricultural lease should describe the leased premises by reference to a public or private survey, if possible. If the land cannot be so described, the lease must include a legal description or other description that is sufficient to identify the leased premises, subject to our approval. Where there are undivided interests owned in fee status, the aggregate portion of trust and restricted interests should be identified in the description of the leased premises.

§ 162.222 How much rent must be paid under an agricultural lease?

(a) An agricultural lease must provide for the payment of a fair annual rental at the beginning of the lease term, unless a lesser amount is permitted under paragraphs (b) through (d) of this section. The tenant's rent payments may be:

(1) In fixed amounts; or

(2) Based on a share of the agricultural products generated by the lease, or a percentage of the income to be derived from the sale of such agricultural products.

(b) We will approve an agricultural lease of tribal land at a nominal rent, or at less than a fair annual rental, if such a rent is negotiated or established by the tribe.

(c) We will approve an agricultural lease of individually-owned land at a nominal rent or at less than a fair annual rental, if:

(1) The tenant is a member of the Indian landowner's immediate family, or a co-owner in the lease tract; or

(2) The tenant is a cooperative or other legal entity in which the Indian landowners directly participate in the revenues or profits generated by the lease.

(d) We will grant or approve a lease at less than a fair annual rental, as previously determined by an appraisal or some other appropriate valuation method, if the land is subsequently advertised and the tenant is the highest responsible bidder.

§ 162.223 Must the rent be adjusted under an agricultural lease?

(a) Except as provided in paragraph (c) of this section, an agricultural lease must provide for one or more rental adjustments if the lease term runs more than five years, unless the lease provides for the payment of:

(1) Less than a fair annual rental, as permitted under § 162.222(b) through (c) of this part; or

(2) A rental based primarily on a share of the agricultural products generated by the lease, or a percentage of the income derived from the sale of agricultural products.

(b) If rental adjustments are required, the lease must specify:

(1) How adjustments are made;

(2) Who makes the adjustments;

(3) When the adjustments are effective; and

(4) How disputes about the adjustments are resolved.

(c) An agricultural lease of tribal land may run for a term of more than five years, without providing for a rental adjustment, if the tribe establishes such a policy under § 162.203(b)(4) and negotiates such a lease.

§ 162.224 When are rent payments due under an agricultural lease?

An agricultural lease must specify the dates on which all rent payments are due. Unless otherwise provided in the lease, rent payments may not be made or accepted more than one year in advance of the due date. Rent payments are due at the time specified in the lease, regardless of whether the tenant receives an advance billing or other notice that a payment is due.

§ 162.225 Will untimely rent payments made under an agricultural lease be subject to interest charges or late payment penalties?

An agricultural lease must specify the rate at which interest will accrue on any rent payment not made by the due date or any other date specified in the lease. A lease may also identify additional late payment penalties that will apply if a rent payment is not made by a specified date. Unless otherwise provided in the lease, such interest charges and late payment penalties will apply in the absence of any specific notice to the tenant from us or the Indian landowners, and the failure to pay such amounts will be treated as a lease violation under § 162.251 of this subpart.

§ 162.226 To whom can rent payments be made under an agricultural lease?

(a) An agricultural lease must specify whether rent payments will be made directly to the Indian landowners or to us on behalf of the Indian landowners. If the lease provides for payment to be made directly to the Indian landowners, the lease must also require that the tenant retain specific documentation evidencing proof of payment, such as canceled checks, cash receipt vouchers, or copies of money orders or cashier's checks, consistent with the provisions of §§ 162.112 and 162.113 of this part.

(b) Rent payments made directly to the Indian landowners must be made to the parties specified in the lease, unless the tenant receives notice of a change of ownership. Unless otherwise provided in the lease, rent payments may not be made payable directly to anyone other than the Indian landowners.

(c) A lease that provides for rent payments to be made directly to the Indian landowners must also provide for such payments to be suspended and the rent thereafter paid to us, rather than directly to the Indian landowners, if:

(1) An Indian landowner dies;

(2) An Indian landowner requests that payment be made to us;

(3) An Indian landowner is found by us to be in need of assistance in managing his/her financial affairs; or

(4) We determine, in our discretion and after consultation with the Indian landowner(s), that direct payment should be discontinued.

§ 162.227 What form of rent payment can be accepted under an agricultural lease?

(a) When rent payments are made directly to the Indian landowners, the form of payment must be acceptable to the Indian landowners.

(b) Payments made to us may be delivered in person or by mail. We will not accept cash, foreign currency, or third-party checks. We will accept:

(1) Personal or business checks drawn on the account of the tenant;

(2) Money orders;

(3) Cashier's checks;

(4) Certified checks; or

(5) Electronic funds transfer payments.

§ 162.228 What other types of payments are required under an agricultural lease?

(a) The tenant may be required to pay additional fees, taxes, and/or assessments associated with the use of the land, as determined by the tribe having jurisdiction over the land. The tenant must pay these amounts to the appropriate tribal official.

(b) Except as otherwise provided in part 171 of this chapter, if the leased premises are within an Indian irrigation project or drainage district, the tenant must pay all operation and maintenance charges that accrue during the lease term. The tenant must pay these amounts to the appropriate official in charge of the irrigation project or drainage district. Failure to make such payments will constitute a violation of the lease under § 162.251.

§ 162.229 How long can the term of an agricultural lease run?

(a) An agricultural lease must provide for a definite lease term, specifying the commencement date. The commencement date of the lease may not be more than one year after the date on which the lease is approved.

(b) The lease term must be reasonable, given the purpose of the lease and the level of investment required. Unless otherwise provided by statute, the maximum term may not exceed ten years, unless a substantial investment in the improvement of the land is required. If such a substantial investment is required, the maximum term may be up to 25 years.

(c) Where all of the trust or restricted interests in a tract are owned by a deceased Indian whose heirs and devisees have not yet been determined, the maximum term may not exceed two years.

(d) An agricultural lease may not provide the tenant with an option to renew, and such a lease may not be renewed or extended by holdover.

§ 162.230 Can an agricultural lease be amended, assigned, sublet, or mortgaged?

(a) An agricultural lease may authorize amendments, assignments, subleases, or mortgages of the leasehold interest, but only with the written consent of the parties to the lease in the

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same manner the original lease was approved, and our approval. An attempt by the tenant to mortgage the leasehold interest or authorize possession by another party, without the necessary consent and approval, will be treated as a lease violation under § 162.251 of this subpart.

(b) An agricultural lease may authorize us, one or more of the Indian landowners, or a designated representative of the Indian landowners, to consent to an amendment, assignment, sublease, mortgage, or other type of agreement, on the landowners' behalf. A designated landowner or representative may not negotiate or consent to an amendment, assignment, or sublease that would:

(1) Reduce the rentals payable to the other Indian landowners; or

(2) Terminate or modify the term of the lease.

(c) Where the Indian landowners have not designated a representative for the purpose of consenting to an amendment, assignment, sublease, mortgage, or other type of agreement, such consent may be granted by or on behalf of the landowners in the same manner as a new lease, under §§ 162.207 through 162.209 of this subpart.

§ 162.231 How can the land be used under an agricultural lease?

(a) An agricultural lease must describe the authorized uses of the leased premises. Any use of the leased premises for an unauthorized purpose, or a failure by the tenant to maintain continuous operations throughout the lease term, will be treated as a lease violation under § 162.251 of this subpart.

(b) An agricultural lease must require that farming and grazing operations be conducted in accordance with recognized principles of sustained yield management, integrated resource management planning, sound conservation practices, and other community goals as expressed in applicable tribal laws, leasing policies, or agricultural resource management plans. Appropriate stipulations or conservation plans must be developed and incorporated in all agricultural leases.

§ 162.232 Can improvements be made under an agricultural lease?

An agricultural lease must generally describe the type and location of any improvements to be constructed by the lessee. Unless otherwise provided in the lease, any specific plans for the construction of those improvements will not require the consent of the Indian owners or our approval.

§ 162.233 Who will own the improvements made under an agricultural lease?

(a) An agricultural lease may specify who will own any improvements constructed by the tenant, during the lease term. The lease must indicate whether any improvements constructed by the tenant will remain on the leased premises upon the expiration or termination of the lease, providing for the improvements to either:

(1) Remain on the leased premises, in a condition satisfactory to the Indian landowners and us; or

(2) Be removed within a time period specified in the lease, at the tenant's expense, with the leased premises to be restored as close as possible to their condition prior to construction of such improvements.

(b) If the lease allows the tenant to remove the improvements, it must also provide the Indian landowners with an option to waive the removal requirement and take possession of the improvements if they are not removed within the specified time period. If the Indian landowners choose not to exercise this option, we will take appropriate enforcement action to ensure removal at the tenant's expense.

§ 162.234 Must a tenant provide a bond under an agricultural lease?

Unless otherwise provided by a tribe under § 162.203 of this subpart, or waived by us at the request of the owners of a majority interest in an agricultural lease tract, the tenant must provide a bond to secure:

(a) The payment of one year's rental;

(b) The construction of any required improvements;

(c) The performance of any additional lease obligations, including the payment of operation and maintenance charges under § 162.228(b) of this subpart; and

(d) The restoration and reclamation of the leased premises, to their condition at the commencement of the lease term or some other specified condition.

§ 162.235 What form of bond can be accepted under an agricultural lease?

(a) Except as provided in paragraph (b) of this section, a bond must be deposited with us and made payable only to us, and such a bond may not be modified or withdrawn without our approval. We will only accept a bond in one of the following forms:

(1) Cash;

(2) Negotiable Treasury securities that:

(i) Have a market value at least equal to the bond amount; and

(ii) Are accompanied by a statement granting full authority to us to sell such securities in case of a violation of the terms of the lease.

(3) Certificates of deposit that indicate on their face that our approval is required prior to redemption by any party;

(4) Irrevocable letters of credit issued by federally-insured financial institutions authorized to do business in the United States. A letter of credit must:

(i) Contain a clause that grants us the authority to demand immediate payment if the tenant violates the lease or fails to replace the letter of credit at least 30 days prior to its expiration date;

(ii) Be payable to us;

(iii) Be irrevocable during its term and have an initial expiration date of not less than one year following the date of issuance; and

(iv) Be automatically renewable for a period of not less than one year, unless the issuing financial institution provides us with written notice that it will not be renewed, at least 90 calendar days before the letter of credit's expiration date.

(5) A surety bond issued by a company approved by the U.S. Department of the Treasury; or

(6) Any other form of highly liquid, non-volatile security that is easily convertible to cash and for which our approval is required prior to redemption by any party.

(b) A tribe may accept and hold any form of bond described in paragraph (a) of this section, to secure performance under an agricultural lease of tribal land.

§ 162.236 How will a cash bond be administered?

(a) If a cash bond is submitted, we will retain the funds in an account established in the name of the tenant.

(b) We will not pay interest on a cash performance bond.

(c) If the bond is not forfeited under § 162.252(a) of this subpart, we will refund the bond to the tenant upon the expiration or termination of the lease.

§ 162.237 What insurance is required under an agricultural lease?

When necessary to protect the interests of the Indian landowners, an agricultural lease must require that a tenant provide insurance. Such insurance may include property, crop, liability and/or casualty insurance. If insurance is required, it must identify both the Indian landowners and the United States as insured parties, and be sufficient to protect all insurable improvements on the leased premises.

§ 162.238 What indemnities are required under an agricultural lease?

(a) An agricultural lease must require that the tenant indemnify and hold the United States and the Indian landowners harmless from any loss, liability, or damages resulting from the tenant's use or occupation of the leased premises, unless:

(1) The tenant would be prohibited by law from making such an agreement; or

(2) The interests of the Indian landowners are adequately protected by insurance.

(b) Unless the tenant would be prohibited by law from making such an agreement, an agricultural lease must specifically require that the tenant indemnify the United States and the Indian landowners against all liabilities or costs relating to the use, handling, treatment, removal, storage, transportation, or disposal of hazardous materials, or the release or discharge of any hazardous materials from the leased premises that occurs during the lease term, regardless of fault.

§ 162.239 How will payment rights and obligations relating to agricultural land be allocated between the Indian landowners and the tenant?

(a) Unless otherwise provided in an agricultural lease, the Indian landowners will be entitled to receive any settlement funds or other payments arising from certain actions that diminish the value of the land or the improvements thereon. Such payments may include (but are not limited to) :

(1) Insurance proceeds;

(2) Trespass damages; and

(3) Condemnation awards.

(b) An agricultural lease may provide for the tenant to assume certain cost-share or other payment obligations that have attached to the land through past farming and grazing operations, so long as those obligations are specified in the lease and considered in any determination of fair annual rental made under this subpart.

§ 162.240 Can an agricultural lease provide for negotiated remedies in the event of a violation?

(a) A lease of tribal agricultural land may provide the tribe with certain negotiated remedies in the event of a lease violation, including the power to terminate the lease. An agricultural lease of individually-owned land may provide the individual Indian landowners with similar remedies, so long as the lease also specifies the manner in which those remedies may be exercised by or on behalf of the landowners.

(b) The negotiated remedies described in paragraph (a) of this section will apply in addition to the cancellation remedy available to us under § 162.252(c) of this subpart. If the lease specifically authorizes us to exercise any negotiated remedies on behalf of the Indian landowners, the exercise of such remedies may substitute for cancellation.

(c) An agricultural lease may provide for lease disputes to be resolved in tribal court or any other court of competent jurisdiction, or through arbitration or some other alternative dispute resolution method. We may not be bound by decisions made in such forums, but we will defer to ongoing proceedings, as appropriate, in deciding whether to exercise any of the remedies available to us under § 162.252 of this subpart.

Lease Administration

§ 162.241 Will administrative fees be charged for actions relating to agricultural leases?

(a) We will charge an administrative fee each time we approve an agricultural lease, amendment, assignment, sublease, mortgage, or related document. These fees will be paid by the tenant, assignee, or subtenant, to cover our costs in preparing or processing the documents and administering the lease.

(b) Except as provided in paragraph (c) of this section, we will charge administrative fees based on the rent payable under the lease. The fee will be 3% of the annual rent payable, including any percentage-based rent that can be reasonably estimated.

(c) The minimum administrative fee is $10.00 and the maximum administrative fee is $500.00, and any administrative fees that have been paid will be non-refundable. However, we may waive all or part of these administrative fees, in our discretion.

(d) If all or part of the expenses of the work are paid from tribal funds, the tribe may establish an additional or alternate schedule of fees.

§ 162.242 How will BIA decide whether to approve an amendment to an agricultural lease?

We will approve an agricultural lease amendment if:

(a) The required consents have been obtained from the parties to the lease under § 162.230 and any sureties; and

(b) We find the amendment to be in the best interest of the Indian landowners, under the standards set forth in § 162.213 of this subpart.

§ 162.243 How will BIA decide whether to approve an assignment or sublease under an agricultural lease?

(a) We will approve an assignment or sublease under an agricultural lease if:

(1) The required consents have been obtained from the parties to the lease under § 162.230 and the tenant's sureties;

(2) The tenant is not in violation of the lease;

(3) The assignee agrees to be bound by, or the subtenant agrees to be subordinated to, the terms of the lease; and

(4) We find no compelling reason to withhold our approval in order to protect the best interests of the Indian owners.

(b) In making the finding required by paragraph (a)(4) of this section, we will consider whether:

(1) The Indian landowners should receive any income derived by the tenant from the assignment or sublease, under the terms of the lease;

(2) The proposed use by the assignee or subtenant will require an amendment of the lease;

(3) The value of any part of the leased premises not covered by the assignment or sublease would be adversely affected; and

(4) The assignee or subtenant has bonded its performance and provided supporting documents that demonstrate that the lease or sublease will be enforceable against the assignee or subtenant, and that the assignee or subtenant will be able to perform its obligations under the lease or sublease.

§ 162.244 How will BIA decide whether to approve a leasehold mortgage under an agricultural lease?

(a) We will approve a leasehold mortgage under an agricultural lease if:

(1) The required consents have been obtained from the parties to the lease under § 162.230 and the tenant's sureties;

(2) The mortgage covers only the tenant's interest in the leased premises, and no unrelated collateral;

(3) The loan being secured by the mortgage will be used only in connection with the development or use of the leased premises, and the mortgage does not secure any unrelated debts owed by the tenant to the mortgagee; and

(4) We find no compelling reason to withhold our approval in order to protect the best interests of the Indian landowners.

(b) In making the finding required by paragraph (a)(4) of this section, we will consider whether:

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(1) The tenant's ability to comply with the lease would be adversely affected by any new loan obligations;

(2) Any lease provisions would be modified by the mortgage;

(3) The remedies available to us or to the Indian landowners would be limited (beyond any additional notice and cure rights to be afforded to the mortgagee), in the event of a lease violation; and

(4) Any rights of the Indian landowners would be subordinated or adversely affected in the event of a loan default by the tenant.

§ 162.245 When will a BIA decision to approve an amendment, assignment, sublease, or mortgage under an agricultural lease be effective?

Our decision to approve an amendment, assignment, sublease, or mortgage under an agricultural lease will be effective immediately, notwithstanding any appeal that may be filed under part 2 of this chapter. Copies of approved documents will be provided to the party requesting approval, and made available to the Indian landowners upon request.

§ 162.246 Must an amendment, assignment, sublease, or mortgage approved under an agricultural lease be recorded?

An amendment, assignment, sublease, or mortgage approved under an agricultural lease must be recorded in our Land Titles and Records Office that has jurisdiction over the leased premises. We will record the document immediately following our approval under this subpart.

Lease Enforcement

§ 162.247 Will BIA notify a tenant when a rent payment is due under an agricultural lease?

We may issue bills or invoices to a tenant in advance of the dates on which rent payments are due under an agricultural lease, but the tenant's obligation to make such payments in a timely manner will not be excused if such bills or invoices are not delivered or received.

§ 162.248 What will BIA do if rent payments are not made in the time and manner required by an agricultural lease?

(a) A tenant's failure to pay rent in the time and manner required by an agricultural lease will be a violation of the lease, and a notice of violation will be issued under § 162.251 of this subpart. If the lease requires that rent payments be made to us, we will send the tenant and its sureties a notice of violation within five business days of the date on which the rent payment was due. If the lease provides for payment directly to the Indian landowners, we will send the tenant and its sureties a notice of violation within five business days of the date on which we receive actual notice of non-payment from the landowners.

(b) If a tenant fails to provide adequate proof of payment or cure the violation within the requisite time period described in § 162.251(b) of this subpart, and the amount due is not in dispute, we may immediately take action to recover the amount of the unpaid rent and any associated interest charges or late payment penalties. We may also cancel the lease under § 162.252 of this subpart, or invoke any other remedies available under the lease or applicable law, including collection on any available bond or referral of the debt to the Department of the Treasury for collection. An action to recover any unpaid amounts will not be conditioned on the prior cancellation of the lease or any further notice to the tenant, nor will such an action be precluded by a prior cancellation.

(c) Partial payments may be accepted by the Indian landowners or us, but acceptance will not operate as a waiver with respect to any amounts remaining unpaid or any other existing lease violations. Unless otherwise provided in the lease, overpayments may be credited as an advance against future rent payments, or refunded.

(d) If a personal or business check is dishonored, and a rent payment is therefore not made by the due date, the failure to make the payment in a timely manner will be a violation of the lease, and a notice of violation will be issued under § 162.251 of this subpart. Any payment made to cure such a violation, and any future payments by the same tenant, must be made by one of the alternative payment methods listed in § 162.227(b) of this subpart.

§ 162.249 Will any special fees be assessed on delinquent rent payments due under an agricultural lease?

The following special fees will be assessed if rent is not paid in the time and manner required, in addition to any interest or late payment penalties that must be paid to the Indian landowners under an agricultural lease. The following special fees will be assessed to cover administrative costs incurred by the United States in the collection of the debt:

The tenant will pay * * *	For * * *
(a) $50.00	Administrative fee for dishonored checks.
(b) $15.00	Administrative fee for BIA processing of each notice or demand letter.
(c) 18% of balance due.	Administrative fee charged by Treasury following referral for collection of delinquent debt.

§ 162.250 How will BIA determine whether the activities of a tenant under an agricultural lease are in compliance with the terms of the lease?

(a) Unless an agricultural lease provides otherwise, we may enter the leased premises at any reasonable time, without prior notice, to protect the interests of the Indian landowners and ensure that the tenant is in compliance with the operating requirements of the lease.

(b) If an Indian landowner notifies us that a specific lease violation has occurred, we will initiate an appropriate investigation within five business days of that notification.

§ 162.251 What will BIA do in the event of a violation under an agricultural lease?

(a) If we determine that an agricultural lease has been violated, we will send the tenant and its sureties a notice of violation within five business days of that determination. The notice of violation must be provided by certified mail, return receipt requested.

(b) Within ten business days of the receipt of a notice of violation, the tenant must:

(1) Cure the violation and notify us in writing that the violation has been cured;

(2) Dispute our determination that a violation has occurred and/or explain why we should not cancel the lease; or

(3) Request additional time to cure the violation.

§ 162.252 What will BIA do if a violation of an agricultural lease is not cured within the requisite time period?

(a) If the tenant does not cure a violation of an agricultural lease within the requisite time period, we will consult with the Indian landowners, as appropriate, and determine whether:

(1) The lease should be canceled by us under paragraph (c) of this section and §§ 162.253 through 162.254 of this subpart;

(2) We should invoke any other remedies available to us under the lease, including collecting on any available bond;

(3) The Indian landowners wish to invoke any remedies available to them under the lease; or

(4) The tenant should be granted additional time in which to cure the violation.

(b) If we decide to grant a tenant additional time in which to cure a violation, the tenant must proceed diligently to complete the necessary corrective actions within a reasonable or specified time period from the date on which the extension is granted.

(c) If we decide to cancel the lease, we will send the tenant and its sureties a cancellation letter within five business days of that decision. The cancellation letter must be sent to the tenant by certified mail, return receipt requested. We will also provide actual or constructive notice of a cancellation decision to the Indian landowners, as appropriate. The cancellation letter will:

(1) Explain the grounds for cancellation;

(2) Notify the tenant of the amount of any unpaid rent, interest charges, or late payment penalties due under the lease;

(3) Notify the tenant of its right to appeal under part 2 of this chapter, as modified by § 162.253 of this subpart, including the amount of any appeal bond that must be posted with an appeal of the cancellation decision; and

(4) Order the tenant to vacate the property within 30 days of the date of receipt of the cancellation letter, if an appeal is not filed by that time.

§ 162.253 Will BIA's regulations concerning appeal bonds apply to cancellation decisions involving agricultural leases?

(a) The appeal bond provisions in § 2.5 of part 2 of this chapter will not apply to appeals from lease cancellation decisions made under § 162.252 of this subpart. Instead, when we decide to cancel an agricultural lease, we may require that the tenant post an appeal bond with an appeal of the cancellation decision. The requirement to post an appeal bond will apply in addition to all of the other requirements in part 2 of this chapter.

(b) An appeal bond should be set in an amount necessary to protect the Indian landowners against financial losses that will likely result from the delay caused by an appeal. Appeal bond requirements will not be separately appealable, but may be contested during the appeal of the lease cancellation decision.

§ 162.254 When will a cancellation of an agricultural lease be effective?

A cancellation decision involving an agricultural lease will not be effective until 30 days after the tenant receives a cancellation letter from us. The cancellation decision will remain ineffective if the tenant files an appeal under § 162.253 of this subpart and part 2 of this chapter, unless the decision is made immediately effective under part 2. While a cancellation decision is ineffective, the tenant must continue to pay rent and comply with the other terms of the lease. If an appeal is not filed in accordance with § 162.253 of this subpart and part 2 of this chapter, the cancellation decision will be effective on the 31st day after the tenant receives the cancellation letter from us.

§ 162.255 Can BIA take emergency action if the leased premises are threatened with immediate and significant harm?

If a tenant or any other party causes or threatens to cause immediate and significant harm to the leased premises during the term of an agricultural lease, we will take appropriate emergency action. Emergency action may include trespass proceedings under part 166, subpart I, of this chapter, or judicial action seeking immediate cessation of the activity resulting in or threatening the harm. Reasonable efforts will be made to notify the Indian landowners, either before or after the emergency action is taken.

§ 162.256 What will BIA do if a tenant holds over after the expiration or cancellation of an agricultural lease?

If a tenant remains in possession after the expiration or cancellation of an agricultural lease, we will treat the unauthorized use as a trespass. Unless we have reason to believe that the tenant is engaged in negotiations with the Indian landowners to obtain a new lease, we will take action to recover possession on behalf of the Indian landowners, and pursue any additional remedies available under applicable law, including the assessment of civil penalties and costs under part 166, subpart I, of this chapter.

Subpart C—Residential Leases

[Reserved]

Subpart D—Business Leases

[Reserved]

Subpart E—Special Requirements for Certain Reservations

§ 162.500 Crow Reservation.

(a) Notwithstanding the regulations in other sections of this part 162, Crow Indians classified as competent under the Act of June 4, 1920 (41 Stat. 751), as amended, may lease their trust lands and the trust lands of their minor children for farming or grazing purposes without the approval of the Secretary pursuant to the Act of May 26, 1926 (44 Stat. 658), as amended by the Act of March 15, 1948 (62 Stat. 80). However, at their election Crow Indians classified as competent may authorize the Secretary to lease, or assist in the leasing of such lands, and an appropriate notice of such action shall be made a matter of record. When this prerogative is exercised, the general regulations contained in this part 162 shall be applicable. Approval of the Secretary is required on leases signed by Crow Indians not classified as competent or made on inherited or devised trust lands owned by more than five competent devisees or heirs.

(b) The Act of May 26, 1926 (44 Stat. 658), as amended by the Act of March 15, 1948 (62 Stat. 80), provides that no lease for farming or grazing purposes shall be made for a period longer than five years, except irrigable lands under the Big Horn Canal; which may be leased for periods of ten years. No such lease shall provide the lessee a preference right to future leases which, if exercised, would thereby extend the total period of encumbrance beyond the five or ten years authorized by law.

(c) All leases entered into by Crow Indians classified as competent, under the above-cited special statutes, must be recorded at the Crow Agency. Such recording shall constitute notice to all persons. Under these special statutes, Crow Indians classified as competent are free to lease their property within certain limitations. The five-year (ten-year in the case of lands under the Big Horn Canal) limitation is intended to afford a protection to the Indians. The essence of this protection is the right to deal with the property free, clear, and unencumbered at intervals at least as frequent as those provided by law. If lessees are able to obtain new leases long before the termination of existing leases, they are in a position to set their own terms. In these circumstances lessees could perpetuate their leaseholds and the protection of the statutory limitations as to terms would be destroyed. Therefore, in implementation of the foregoing interpretation, any lease which, on its face, is in violation of statutory limitations or requirements, and any grazing lease executed more than 12 months, and any farming lease executed more than 18 months, prior to the commencement of the term thereof or any lease which purports to cancel an existing lease with the same lessee as of a future date and take effect upon such cancellation will not be recorded. Under a Crow tribal program, approved by the Department of the Interior, competent Crow Indians may, under certain circumstances, enter into agreements

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which require that, for a specified term, their leases be approved. Information concerning whether a competent Crow Indian has executed such an instrument is available at the office of the Superintendent of the Crow Agency, Bureau of Indian Affairs, Crow Agency, Montana. Any lease entered into with a competent Crow Indian during the time such instrument is in effect and which is not in accordance with such instrument will be returned without recordation.

(d) Where any of the following conditions are found to exist, leases will be recorded but the lessee and lessor will be notified upon discovery of the condition:

(1) The lease in single or counterpart form has not been executed by all owners of the land described in the lease;

(2) There is, of record, a lease on the land for all or a part of the same term;

(3) The lease does not contain stipulations requiring sound land utilization plans and conservation practices; or

(4) There are other deficiencies such as, but not limited to, erroneous land descriptions, and alterations which are not clearly endorsed by the lessor.

(e) Any adult Crow Indian classified as competent shall have the full responsibility for obtaining compliance with the terms of any lease made by him pursuant to this section. This shall not preclude action by the Secretary to assure conservation and protection of these trust lands.

(f) Leases made by competent Crow Indians shall be subject to the right to issue permits and leases to prospect for, develop, and mine oil, gas, and other minerals, and to grant rights-of-way and easements, in accordance with applicable law and regulations. In the issuance or granting of such permits, leases, rights-of-way or easements due consideration will be given to the interests of lessees and to the adjustment of any damages to such interests. In the event of a dispute as to the amount of such damage, the matter will be referred to the Secretary whose determination will be final as to the amount of said damage.

§ 162.501 Fort Belknap Reservation.

Not to exceed 20,000 acres of allotted and tribal lands (non-irrigable as well as irrigable) on the Fort Belknap Reservation in Montana may be leased for the culture of sugar beets and other crops in rotation for terms not exceeding ten years.

§ 162.502 Cabazon, Augustine, and Torres-Martinez Reservations, California.

(a) Upon a determination by the Secretary that the owner or owners are not making beneficial use thereof, restricted lands on the Cabazon, Augustine, and Torres-Martinez Indian Reservations which are or may be irrigated from distribution facilities administered by the Coachella Valley County Water District in Riverside County, California, may be leased by the Secretary in accordance with the regulations in this part for the benefit of the owner or owners.

(b) All leases granted or approved on restricted lands of the Cabazon, Augustine, and Torres-Martinez Indian Reservations shall be filed for record in the office of the county recorder of the county in which the land is located, the cost thereof to be paid by the lessee. A copy of each such lease shall be filed by the lessee with the Coachella Valley County Water District or such other irrigation or water district within which the leased lands are located. All such leases shall include a provision that the lessee, in addition to the rentals provided for in the lease, shall pay all irrigation charges properly assessed against the land which became payable during the term of the lease. Act of August 25, 1950 (64 Stat. 470); Act of August 28, 1958 (72 Stat. 968).

§ 162.503 San Xavier and Salt River Pima-Maricopa Reservations.

(a) *Purpose and scope.* The Act of November 2, 1966 (80 Stat. 1112), provides statutory authority for long-term leasing on the San Xavier and Salt River Pima-Maricopa Reservations, Arizona, in addition to that contained in the Act of August 9, 1955 (69 Stat. 539), as amended (25 U.S.C. 415). When leases are made under the 1955 Act on the San Xavier or Salt River Pima-Maricopa Reservations, the regulations in part 162 apply. The purpose of this section is to provide regulations for implementation of the 1966 Act. The 1966 Act does not apply to leases made for purposes that are subject to the laws governing mining leases on Indian lands.

(b) *Duration of leases.* Leases made under the 1966 Act for public, religious, educational, recreational, residential, or business purposes may be made for terms of not to exceed 99 years. The terms of a grazing lease shall not exceed ten years; the term of a farming lease that does not require the making of a substantial investment in the improvement of the land shall not exceed ten years; and the term of a farming lease that requires the making of a substantial investment in the improvement of the land shall not exceed 40 years. No lease shall contain an option to renew which extends the total term beyond the maximum term permitted by this section.

(c) *Required covenant and enforcement thereof.* Every lease under the 1966 Act shall contain a covenant on the part of the lessee that he will not commit or permit on the leased land any act that causes waste or a nuisance or which creates a hazard to health of persons or to property wherever such persons or property may be.

(d) *Notification regarding leasing proposals.* If the Secretary determines that a proposed lease to be made under the 1966 Act for public, religious, educational, recreational, residential, or business purposes will substantially affect the governmental interests of a municipality contiguous to the San Xavier Reservation or the Salt River Pima-Maricopa Reservation, as the case may be, he shall notify the appropriate authority of such municipality of the pendency of the proposed lease. The Secretary may, in his discretion, furnish such municipality with an outline of the major provisions of the lease which affect its governmental interests and shall consider any comments on the terms of the lease affecting the municipality or on the absence of such terms from the lease that the authorities may offer. The notice to the authorities of the municipality shall set forth a reasonable period, not to exceed 30 days, within which any such comments shall be submitted.

(e) *Applicability of other regulations.* The regulations in part 162 of this title shall apply to leases made under the 1966 Act except where such regulations are inconsistent with this section.

(f) *Mission San Xavier del Bac.* Nothing in the 1966 Act authorizes development that would detract from the scenic, historic, and religious values of the Mission San Xavier del Bac owned by the Franciscan Order of Friars Minor and located on the San Xavier Reservation.

Subpart F—Non-Agricultural Leases

§ 162.600 What types of leases are covered by this subpart?

The regulations in this subpart apply to any leases other than agricultural leases, as defined in this part. To the extent that any of the regulations in this subpart conflict with the provisions of the Indian Land Consolidation Act Amendments of 2000, Pub. Law. 106–462, the provisions of that Act will govern.

§ 162.601 Grants of leases by Secretary.

(a) The Secretary may grant leases on individually owned land on behalf of:

(1) Persons who are non compos mentis;

(2) Orphaned minors;

(3) The undetermined heirs of a decedent's estate;

(4) The heirs or devisees to individually owned land who have not been able to agree upon a lease during the three-month period immediately following the date on which a lease may be entered into; provided, that the land is not in use by any of the heirs or devisees; and

(5) Indians who have given the Secretary written authority to execute leases on their behalf.

(b) The Secretary may grant leases on the individually owned land of an adult Indian whose whereabouts is unknown, on such terms as are necessary to protect and preserve such property.

(c) The Secretary may grant permits on Government land.

§ 162.602 Grants of leases by owners or their representatives.

The following may grant leases:

(a) Adults, other than those non compos mentis,

(b) Adults, other than those non compos mentis, on behalf of their minor children, and on behalf of minor children to whom they stand in loco parentis when such children do not have a legal representative,

(c) The guardian, conservator or other fiduciary, appointed by a state court or by a tribal court operating under an approved constitution or law and order code, of a minor or persons who are non compos mentis or are otherwise under legal disability,

(d) Tribes or tribal corporations acting through their appropriate officials.

§ 162.603 Use of land of minors.

The natural or legal guardian, or other person standing in loco parentis of minor children who have the care and custody of such children may use the individually owned land of such children during the period of minority without charge for the use of the land if such use will enable such person to engage in a business or other enterprise which will be beneficial to such minor children.

§ 162.604 Special requirements and provisions.

(a) All leases made pursuant to the regulations in this part shall be in the form approved by the Secretary and subject to his written approval.

(b) Except as otherwise provided in this part no lease shall be approved or granted at less than the present fair annual rental.

(1) An adult Indian owner of trust or restricted land may lease his land for religious, educational, recreational or other public purposes to religious organizations or to agencies of the federal, state or local government at a nominal rental. Such adult Indian may lease land to members of his immediate family with or without rental consideration.

(2) In the discretion of the Secretary, tribal land may be leased at a nominal rental for religious, educational, recreational, or other public purposes to religious organizations or to agencies of federal, state, or local governments; for purposes of subsidization for the benefit of the tribe; and for homesite purposes to tribal members provided the land is not commercial or industrial in character.

(3) Leases may be granted or approved by the Secretary at less than the fair annual rental when in his judgment such action would be in the best interest of the landowners.

(c) Unless otherwise provided by the Secretary a satisfactory surety bond will be required in an amount that will reasonably assure performance of the contractual obligations under the lease. Such bond may be for the purpose of guaranteeing:

(1) Not less than one year's rental unless the lease contract provides that the annual rental shall be paid in advance.

(2) The estimated construction cost of any improvement to be placed on the land by the lessee.

(3) An amount estimated to be adequate to insure compliance with any additional contractual obligations.

(d) The lessee may be required to provide insurance in an amount adequate to protect any improvements on the leased premises; the lessee may also be required to furnish appropriate liability insurance, and such other insurance as may be necessary to protect the lessor's interest.

(e) No lease shall provide the lessee a preference right to future leases nor shall any lease contain provisions for renewal, except as otherwise provided in this part. No lease shall be entered into more than 12 months prior to the commencement of the term of the lease. Except with the approval of the Secretary no lease shall provide for payment of rent in advance of the beginning of the annual use period for which such rent is paid. The lease contract shall contain provisions as to the dates rents shall become due and payable.

(f) Leases granted or approved under this part shall contain provisions as to whether payment of rentals is to be made direct to the owner of the land or his representative or to the official of the Bureau of Indian Affairs having jurisdiction over the leased premises.

(g) All leases issued under this part shall contain the following provisions:

(1) While the leased premises are in trust or restricted status, all of the lessee's obligations under this lease, and the obligations of his sureties, are to the United States as well as to the owner of the land.

(2) Nothing contained in this lease shall operate to delay or prevent a termination of federal trust responsibilities with respect to the land by the issuance of a fee patent or otherwise during the term of the lease; however, such termination shall not serve to abrogate the lease. The owners of the land and the lessee and his surety or sureties shall be notified of any such change in the status of the land.

(3) The lessee agrees that he will not use or cause to be used any part of the leased premises for any unlawful conduct or purpose.

(h) Leases granted or approved under this part on individually owned lands which provide for payment of rental direct to the owner or his representative shall contain the following provisions:

(1) In the event of the death of the owner during the term of this lease and while the leased premises are in trust or restricted status, all rentals remaining due or payable to the decedent or his representative under the provisions of the lease shall be paid to the official of the Bureau of Indian Affairs having jurisdiction over the leased premises.

(2) While the leased premises are in trust or restricted status, the Secretary may in his discretion suspend the direct rental payment provisions of this lease in which event the rentals shall be paid to the official of the Bureau of Indian Affairs having jurisdiction over the leased premises.

§ 162.605 Negotiation of leases.

(a) Leases of individually owned land or tribal land may be negotiated by those owners or their representatives who may execute leases pursuant to § 162.602 of this subpart.

(b) Where the owners of a majority interest, or their representatives, who may grant leases under § 162.602 of this subpart, have negotiated a lease satisfactory to the Secretary he may join in the execution of the lease and thereby commit the interests of those persons in whose behalf he is authorized to grant leases under § 162.601(a)(1), (2), (3), and (5) of this subpart.

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(c) Where the Secretary may grant leases under § 162.601 of this subpart he may negotiate leases when in his judgment the fair annual rental can thus be obtained.

§ 162.606 Advertisement.

Except as otherwise provided in this part, prior to granting a lease or permit as authorized under § 162.601 of this subpart the Secretary shall advertise the land for lease. Advertisements will call for sealed bids and will not offer preference rights.

§ 162.607 Duration of leases.

Leases granted or approved under this part shall be limited to the minimum duration, commensurate with the purpose of the lease, that will allow the highest economic return to the owner consistent with prudent management and conservation practices, and except as otherwise provided in this part shall not exceed the number of years provided for in this section. Except for those leases authorized by § 162.604(b)(1) and (2) of this subpart, unless the consideration for the lease is based primarily on percentages of income produced by the land, the lease shall provide for periodic review, at not less than five-year intervals, of the equities involved. Such review shall give consideration to the economic conditions at the time, exclusive of improvement or development required by the contract or the contribution value of such improvements. Any adjustments of rental resulting from such review may be made by the Secretary where he has the authority to grant leases, otherwise the adjustment must be made with the written concurrence of the owners and the approval of the Secretary.

(a) Leases for public, religious, educational, recreational, residential, or business purposes shall not exceed 25 years but may include provisions authorizing a renewal or an extension for one additional term of not to exceed 25 years, except such leases of land on the Hollywood (formerly Dania) Reservation, Fla.; the Navajo Reservation, Ariz., N. Mex., and Utah; the Palm Springs Reservation, Calif.; the Southern Ute Reservation, Colo.; the Fort Mohave Reservation, Calif., Ariz., and Nev.; the Pyramid Lake Reservation, Nev.; the Gila River Reservation, Ariz.; the San Carlos Apache Reservation, Ariz.; the Spokane Reservation, Wash.; the Hualapai Reservation, Ariz.; the Swinomish Reservation, Wash.; the Pueblos of Cochiti, Pojoaque, Tesuque, and Zuni, N. Mex.; and land on the Colorado River Reservation, Ariz., and Calif.; which leases may be made for terms of not to exceed 99 years.

(b) Leases granted by the Secretary pursuant to § 162.601(a)(3) of this subpart shall be for a term of not to exceed two years except as otherwise provided in § 162.605(b) of this subpart.

§ 162.608 Ownership of improvements.

Improvements placed on the leased land shall become the property of the lessor unless specifically excepted therefrom under the terms of the lease. The lease shall specify the maximum time allowed for removal of any improvements so excepted.

§ 162.609 Unitization for leasing.

Where it appears advantageous to the owners and advantageous to the operation of the land a single lease contract may include more than one parcel of land in separate ownerships, tribal or individual, provided the statutory authorities and other applicable requirements of this part are observed.

§ 162.610 Subleases and assignments.

(a) Except as provided in paragraphs (b), (c), and (d) of this section, a sublease, assignment, amendment or encumbrance of any lease or permit issued under this part may be made only with the approval of the Secretary and the written consent of all parties to such lease or permit, including the surety or sureties.

(b) With the consent of the Secretary, the lease may contain a provision authorizing the lessee to sublease the premises, in whole or in part, without further approval. Subleases so made shall not serve to relieve the sublessor from any liability nor diminish any supervisory authority of the Secretary provided for under the approved lease.

(c) With the consent of the Secretary, the lease may contain provisions authorizing the lessee to encumber his leasehold interest in the premises for the purpose of borrowing capital for the development and improvement of the leased premises. The encumbrance instrument, must be approved by the Secretary. If a sale or foreclosure under the approved encumbrance occurs and the encumbrancer is the purchaser, he may assign the leasehold without the approval of the Secretary or the consent of the other parties to the lease, provided, however, that the assignee accepts and agrees in writing to be bound by all the terms and conditions of the lease. If the purchaser is a party other than the encumbrancer, approval by the Secretary of any assignment will be required, and such purchaser will be bound by the terms of the lease and will assume in writing all the obligations thereunder.

(d) With the consent of the Secretary, leases of tribal land to individual members of the tribe or to tribal housing authorities may contain provisions permitting the assignment of the lease without further consent or approval where a lending institution or an agency of the United States makes, insures or guarantees a loan to an individual member of the tribe or to a tribal housing authority for the purpose of providing funds for the construction of housing for Indians on the leased premises; provided, the leasehold has been pledged as security for the loan and the lender has obtained the leasehold by foreclosure or otherwise. Such leases may with the consent of the Secretary also contain provisions permitting the lessee to assign the lease without further consent or approval.

§ 162.611 Payment of fees and drainage and irrigation charges.

(a) Any lease covering lands within an irrigation project or drainage district shall require the lessee to pay annually on or before the due date, during the term of the lease and in the amounts determined, all charges assessed against such lands. Such charges shall be in addition to the rental payments prescribed in the lease. All payments of such charges and penalties shall be made to the official designated in the lease to receive such payments.

(b) We will charge an administrative fee each time we approve an agricultural lease, amendment, assignment, sublease, mortgage, or related document. These fees will be paid by the tenant, assignee, or subtenant, to cover our costs in preparing or processing the documents and administering the lease.

(c) Except as provided in paragraph (d) of this section, we will charge administrative fees based on the rent payable under the lease. The fee will be 3% of the annual rent payable, including any percentage or cropshare rent that can be reasonably estimated.

(d) The minimum administrative fee is $10.00 and the maximum administrative fee is $500.00, and any administrative fees that have been paid will be non-refundable. However, we may waive all or part of these administrative fees, in our discretion.

(e) If all or part of the expenses of the work are paid from tribal funds, the tribe may establish an additional or alternate schedule of fees.

§ 162.612 Can a lease provide for negotiated remedies in the event of a violation?

(a) A lease of tribal land may provide the tribe with certain negotiated remedies in the event of a lease violation, including the power to terminate the lease. A lease of individually-owned land may provide the individual Indian landowners with similar remedies, so long as the lease also specifies the manner in which those remedies may be exercised by or on behalf of the landowners.

(b) The negotiated remedies described in paragraph (a) of this section will apply in addition to the cancellation remedy available to us under § 162.619(c) of this subpart. If the lease specifically authorizes us to exercise any negotiated remedies on behalf of the Indian landowners, the exercise of such remedies may substitute for cancellation.

(c) A lease may provide for lease disputes to be resolved in tribal court or any other court of competent jurisdiction, or through arbitration or some other alternative dispute resolution method. We may not be bound by decisions made in such forums, but we will defer to ongoing proceedings, as appropriate, in deciding whether to exercise any of the remedies available to us under § 162.619 of this subpart.

§ 162.613 Will BIA notify a tenant when a rent payment is due under a lease?

We may issue bills or invoices to a tenant in advance of the dates on which rent payments are due under a lease, but the tenant's obligation to make such payments in a timely manner will not be excused if such bills or invoices are not delivered or received.

§ 162.614 Will untimely rent payments made under a lease be subject to interest charges or late payment penalties?

A lease must specify the rate at which interest will accrue on any rent payment not made by the due date or any other date specified in the lease. A lease may also identify additional late payment penalties that will apply if a rent payment is not made by a specified date. Unless otherwise provided in the lease, such interest charges and late payment penalties will apply in the absence of any specific notice to the tenant from us or the Indian landowners, and the failure to pay such amounts will be treated as a lease violation under § 162.618 of this subpart.

§ 162.615 What will BIA do if rent payments are not made in the time and manner required by a lease?

(a) A tenant's failure to pay rent in the time and manner required by a lease will be a violation of the lease, and a notice of violation will be issued under § 162.618 of this subpart. If the lease requires that rent payments be made to us, we will send the tenant and its sureties a notice of violation within five business days of the date on which the rent payment was due. If the lease provides for payment directly to the Indian landowners, we will send the tenant and its sureties a notice of violation within five business days of the date on which we receive actual notice of non-payment from the landowners.

(b) If a tenant fails to provide adequate proof of payment or cure the violation within the requisite time period described in § 162.618(b) of this subpart, and the amount due is not in dispute, we may immediately take action to recover the amount of the unpaid rent and any associated interest charges or late payment penalties. We may also cancel the lease under § 162.619 of this subpart, or invoke any other remedies available under the lease or applicable law, including collection on any available bond or referral of the debt to the Department of the Treasury for collection. An action to recover any unpaid amounts will not be conditioned on the prior cancellation of the lease or any further notice to the tenant, nor will such an action be precluded by a prior cancellation.

(c) Partial payments and underpayments may be accepted by the Indian landowners or us, but acceptance will not operate as a waiver with respect to any amounts remaining unpaid or any other existing lease violations. Unless otherwise provided in the lease, overpayments may be credited as an advance against future rent payments, or refunded.

(d) If a personal or business check is dishonored, and a rent payment is therefore not made by the due date, the failure to make the payment in a timely manner will be a violation of the lease, and a notice of violation will be issued under § 162.618 of this subpart. Any payment made to cure such a violation, and any future payments by the same tenant, must be made by an alternative payment method approved by us.

§ 162.616 Will any special fees be assessed on delinquent rent payments due under a lease?

The following special fees will be assessed if rent is not paid in the time and manner required, in addition to any interest or late payment penalties that must be paid to the Indian landowners under a lease. The following special fees will be assessed to cover administrative costs incurred by the United States in the collection of the debt:

The tenant will pay . . .	For . . .
(a) $50.00	Administrative fee for dishonored checks.
(b) $15.00	Administrative fee for BIA processing of each notice or demand letter.
(c) 18% of balance due.	Administrative fee charged by Treasury following referral for collection of delinquent debt.

§ 162.617 How will BIA determine whether the activities of a tenant under a lease are in compliance with the terms of the lease?

(a) Unless a lease provides otherwise, we may enter the leased premises at any reasonable time, without prior notice, to protect the interests of the Indian landowners and ensure that the tenant is in compliance with the operating requirements of the lease.

(b) If an Indian landowner notifies us that a specific lease violation has occurred, we will initiate an appropriate investigation within five business days of that notification.

§ 162.618 What will BIA do in the event of a violation under a lease?

(a) If we determine that a lease has been violated, we will send the tenant and its sureties a notice of violation within five business days of that determination. The notice of violation must be provided by certified mail, return receipt requested.

(b) Within ten business days of the receipt of a notice of violation, the tenant must:

(1) Cure the violation and notify us in writing that the violation has been cured;

(2) Dispute our determination that a violation has occurred and/or explain why we should not cancel the lease; or

(3) Request additional time to cure the violation.

§ 162.619 What will BIA do if a violation of a lease is not cured within the requisite time period?

(a) If the tenant does not cure a violation of a lease within the requisite time period, we will consult with the Indian landowners, as appropriate, and determine whether:

(1) The lease should be canceled by us under paragraph (c) of this section and §§ 162.620 through 162.621 of this subpart;

(2) We should invoke any other remedies available to us under the lease, including collecting on any available bond;

(3) The Indian landowners wish to invoke any remedies available to them under the lease; or

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(4) The tenant should be granted additional time in which to cure the violation.

(b) If we decide to grant a tenant additional time in which to cure a violation, the tenant must proceed diligently to complete the necessary corrective actions within a reasonable or specified time period from the date on which the extension is granted.

(c) If we decide to cancel the lease, we will send the tenant and its sureties a cancellation letter within five business days of that decision. The cancellation letter must be sent to the tenant by certified mail, return receipt requested. We will also provide actual or constructive notice of a cancellation decision to the Indian landowners, as appropriate. The cancellation letter will:

(1) Explain the grounds for cancellation;

(2) Notify the tenant of the amount of any unpaid rent, interest charges, or late payment penalties due under the lease;

(3) Notify the tenant of its right to appeal under part 2 of this chapter, as modified by § 162.620 of this subpart, including the amount of any appeal bond that must be posted with an appeal of the cancellation decision; and

(4) Order the tenant to vacate the property within 30 days of the date of receipt of the cancellation letter, if an appeal is not filed by that time.

§ 162.620 Will BIA's regulations concerning appeal bonds apply to cancellation decisions involving leases?

(a) The appeal bond provisions in § 2.5 of part 2 of this chapter will not apply to appeals from lease cancellation decisions made under § 162.619 of this subpart. Instead, when we decide to cancel an agricultural lease, we may require that the tenant post an appeal bond with an appeal of the cancellation decision. The requirement to post an appeal bond will apply in addition to all of the other requirements in part 2 of this chapter.

(b) An appeal bond should be set in an amount necessary to protect the Indian landowners against financial losses that will likely result from the delay caused by an appeal. Appeal bond requirements will not be separately appealable, but may be contested during the appeal of the lease cancellation decision.

§ 162.621 When will a cancellation of a lease be effective?

A cancellation decision involving an agricultural lease will not be effective until 30 days after the tenant receives a cancellation letter from us. The cancellation decision will remain ineffective if the tenant files an appeal under § 162.620 of this subpart and part 2 of this chapter, unless the decision is made immediately effective under part 2. While a cancellation decision is ineffective, the tenant must continue to pay rent and comply with the other terms of the lease. If an appeal is not filed in accordance with § 162.620 of this subpart and part 2 of this chapter, the cancellation decision will be effective on the 31st day after the tenant receives the cancellation letter from us.

§ 162.622 Can BIA take emergency action if the leased premises are threatened with immediate and significant harm?

If a tenant or any other party causes or threatens to cause immediate and significant harm to the leased premises during the term of a lease, we will take appropriate emergency action. Emergency action may include judicial action seeking immediate cessation of the activity resulting in or threatening the harm. Reasonable efforts will be made to notify the Indian landowners, either before or after the emergency action is taken.

§ 162.623 What will BIA do if a tenant holds over after the expiration or cancellation of a lease?

If a tenant remains in possession after the expiration or cancellation of a lease, we will treat the unauthorized use as a trespass. Unless we have reason to believe that the tenant is engaged in negotiations with the Indian landowners to obtain a new lease, we will take action to recover possession on behalf of the Indian landowners, and pursue any additional remedies available under applicable law.

PART 166—GRAZING PERMITS

5. Part 166 is revised to read as follows:

Subpart A—Purpose, Scope, and Definitions

Sec.

166.1 What is the purpose and scope of this part?
166.2 Can the BIA waive the application of these regulations?
166.3 May decisions under this part be appealed?
166.4 What terms do I need to know?

Subpart B—Tribal Policies and Laws Pertaining to Permits

166.100 What special tribal policies will we apply to permitting on Indian agricultural lands?
166.101 May individual Indian landowners exempt their land from certain tribal policies for permitting on Indian agricultural lands?
166.102 Do tribal laws apply to permits?
166.103 How will tribal laws be enforced on Indian agricultural land?
166.104 What notifications are required that tribal laws apply to permits on Indian agricultural lands?

Subpart C—Permit Requirements

General Requirements

166.200 When is a permit needed to authorize possession of Indian land for grazing purposes?
166.201 Must parents or guardians of Indian minors who own Indian land obtain a permit before using land for grazing purposes?
166.202 May an emancipated minor grant a permit?
166.203 When can the Indian landowners grant a permit?
166.204 Who may represent an individual Indian landowner in granting a permit?
166.205 When can the BIA grant a permit on behalf of Indian landowners?
166.206 What requirements apply to a permit on a fractionated tract?
166.207 What provisions will be contained in a permit?
166.208 How long is a permit term?
166.209 Must a permit be recorded?
166.210 When is a decision by the BIA regarding a permit effective?
166.211 When are permits effective?
166.212 When may a permittee take possession of permitted Indian land?
166.213 Must I comply with any standards of conduct if I am granted a permit?
166.214 Will the BIA notify the permittee of any change in land title status?

Obtaining a Permit

166.215 How can I find Indian land available for grazing?
166.216 Who is responsible for permitting Indian land?
166.217 In what manner may a permit on Indian land be granted?
166.218 How do I acquire a permit through tribal allocation?
166.219 How do I acquire a permit through negotiation?
166.220 What are the basic steps for acquiring a permit through negotiation?
166.221 How do I acquire an advertised permit through competitive bidding?
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Authority: 5 U.S.C. 301; R.S. 463, 25 U.S.C. 2; R.S. 465, 25 U.S.C. 9; Sec. 6, 96 Stat. 986, 25 U.S.C. 466. Interpret or apply R.S. 2078, 25 U.S.C. 68; R.S. 2117, 25 U.S.C. 179; Sec. 3, 26 Stat. 795, 25 U.S.C. 397; Sec. 1, 28 Stat. 305, 25 U.S.C. 402; Sec. 4, 36 Stat. 856, 25 U.S.C. 403; Sec. 1, 39 Stat. 128, 25 U.S.C. 394; Sec. 1, 41 Stat. 1232, 25 U.S.C. 393; Sec. 16, 17, 48 Stat. 987, 988, 25 U.S.C. 476, 477; Sec. 1, 2, 4, 5, 6, 69 Stat. 539, 540, 25 U.S.C. 415, 415a, 415b, 415c, 415d, 25 U.S.C. 3701, 3702, 3703, 3711, 3712, 3713, 3714, 3731, 3732, 3733, 3734, 3741, 3742, 3743, 3744, 3745, 107 Stat. 2011; 44 U.S.C. § 3101, *et seq.*)

Subpart A—Purpose, Scope, and Definitions

§ 166.1 What is the purpose and scope of this part?

(a) The purpose of this part is to describe the authorities, policies, and procedures the BIA uses to approve, grant, and administer a permit for grazing on tribal land, individually-owned Indian land, or government land.

(b) If the BIA's approval is not required for a permit, these regulations will not apply.

(c) These regulations do not apply to any tribal land which is permitted under a corporate charter issued by us pursuant to 25 U.S.C. § 477, or under a special act of Congress authorizing permits without our approval under certain conditions, except to the extent that the authorizing statutes require us to enforce such permits on behalf of the Indian landowners.

(d) To the extent that any provisions of this part conflict with Section 213 of the Indian Land Consolidation Act Amendments of 2000, the provisions of that act will govern.

(e) In approving a permit on behalf of the Indian landowners, the BIA will not permit for fee interest owners nor will we collect rent on behalf of fee interest owners. Our permitting of the trust and restricted interests of the Indian landowners will not be conditioned on a permit having been obtained from any fee interest owners. However, where all of the trust or restricted interests in a tract are subject to a life estate held in fee status, we will approve a permit of the remainder interests of the Indian landowners only if such action is necessary to preserve the value of the land or protect the interests of the Indian landowners. Where a life estate and remainder interest are both owned in trust or restricted status, the life estate and remainder interest must both be permitted under these regulations, unless the permit is for less than one year in duration. Unless otherwise provided by the document creating the life estate or by agreement, rent payable under the permit must be paid to the holder of the life estate under part 179 of this title.

§ 166.2 Can the BIA waive the application of these regulations?

Yes. In any case in which these regulations conflict with the objectives of the agricultural resource management plan provided for in § 166.311 of this part, or with a tribal law, the BIA may waive the application of such regulations unless the waiver would constitute a violation of a federal statute or judicial decision or would conflict with the BIA's general trust responsibility under federal law.

§ 166.3 May decisions under this part be appealed?

Yes. Except where otherwise provided in this part, appeals from decisions by the BIA under this part may be taken pursuant to 25 CFR part 2.

§ 166.4 What terms do I need to know?

Adult means an individual Indian who is 18 years of age or older.

Agency means the agency or field office or any other designated office in the Bureau of Indian Affairs (BIA) having jurisdiction over trust or restricted property or money.

Agricultural product means:

(1) Crops grown under cultivated conditions whether used for personal consumption, subsistence, or sold for commercial benefit;

(2) Domestic livestock, including cattle, sheep, goats, horses, buffalo, swine, reindeer, fowl, or other animals specifically raised and used for food or fiber or as a beast of burden;

(3) Forage, hay, fodder, food grains, crop residues and other items grown or harvested for the feeding and care of livestock, sold for commercial profit, or used for other purposes; and

(4) Other marketable or traditionally used materials authorized for removal from Indian agricultural lands.

Agricultural resource management plan means a ten-year plan developed through the public review process specifying the tribal management goals and objectives developed for tribal agricultural and grazing resources. Plans developed and approved under AIARMA will govern the management and administration of Indian agricultural resources and Indian agricultural lands by the BIA and Indian tribal governments.

AIARMA means American Indian Agricultural Resources Management Act of December 3, 1993 (107 Stat. 2011, 25 U.S.C. 3701 *et seq.*), and amended on November 2, 1994 (108 Stat. 4572).

Allocation means the apportionment of grazing privileges without competition to tribal members or tribal entities, including the tribal designation of permittees and the number and kind of livestock to be grazed.

Animal Unit Month (AUM) means the amount of forage required to sustain one cow or one cow with one calf for one month.

Approving/approval means the action taken by the BIA to approve a permit.

Assign/assignment means an agreement between a permittee and an assignee, whereby the assignee acquires all of the permittee's rights, and assumes all of the permittee's obligations under a permit.

Assignee means the person to whom the permit rights for use of Indian land are assigned.

BIA means the Bureau of Indian Affairs within the Department of the Interior and any tribe acting on behalf of the BIA under this part.

Bond means security for the performance of certain permit obligations, as furnished by the permitee, or a guaranty of such performance as furnished by a third-party surety.

Conservation plan means a statement of management objectives for grazing, including contract stipulations defining required uses, operations, and improvements.

Conservation practice means a management action to protect, conserve, utilize, and maintain the sustained yield productivity of Indian agricultural land.

Day means a calendar day.

Encumbrance means mortgage, deed of trust or other instrument which secures a debt owed by a permittee to a lender or other holder of a leasehold mortgage on the permit interest.

Emancipated minor means a person under 18 years of age who is married or who is determined by a court of competent jurisdiction to be legally able to care for himself or herself.

Fair annual rental means the amount of rental income that a permitted parcel of Indian land would most probably command in an open and competitive market.

Farmland means Indian land, excluding Indian forest land, that is used for production of food, feed, fiber, forage, and seed, oil crops, or other agricultural products, and may be either dry land, irrigated land, or irrigated pasture.

Fee interest means an interest in land that is owned in unrestricted fee status, and is thus freely alienable by the fee owner.

Fractionated tract means a tract of Indian land owned in common by Indian landowners and/or fee owners holding undivided interests therein.

Government land means any tract, or interest therein, in which the surface estate is owned by the United States and administered by the BIA, not including tribal land which has been reserved for administrative purposes.

Grant/granting means the process of the BIA or the Indian landowner agreeing or consenting to a permit.

Grazing capacity means the maximum sustainable number of livestock that may be grazed on a defined area and within a defined period, usually expressed in an Animal Unit Month (AUM).

Grazing rental payment means the total of the grazing rental rate multiplied by the number of AUMs or acres in the permit.

Grazing rental rate means the amount you must pay for an AUM or acre based on the fair annual rental.

I/You means the person to whom these regulations directly apply.

Immediate family means the spouse, brothers, sisters, lineal ancestors, lineal descendants, or members of the household of an individual Indian landowner.

Indian agricultural land means Indian land, including farmland and rangeland, excluding Indian forest land, that is used for production of agricultural products, and Indian lands occupied by industries that support the agricultural community, regardless of whether a formal inspection and land classification has been conducted.

Indian land means any tract in which any interest in the surface estate is owned by a tribe or individual Indian in trust or restricted status.

Indian landowner means a tribe or individual Indian who owns an interest in Indian land in trust or restricted status.

Individually-owned Indian land means any tract, or interest therein, in which the surface estate is owned by an individual Indian in trust or restricted status.

Interest means, when used with respect to Indian land, an ownership right to the surface estate of Indian land that is unlimited or uncertain in duration, including a life estate.

Life estate means an interest in Indian land which is limited in duration to the life of the permittor holding the interest, or the life of some other person.

Majority interest means the ownership interest(s) that are greater than 50 percent of the trust or restricted ownership interest(s) in a tract of Indian land.

Minor means an individual who is less than 18 years of age.

Mortgage means a mortgage, deed of trust or other instrument which pledges a permittee's permit (leasehold) interest as security for a debt or other obligation owed by the permittee to a lender or other mortgagee.

Non compos mentis means a person who has been legally determined by a court of competent jurisdiction to be of unsound mind or incapable of transacting or conducting business and managing one's own affairs.

On-and-off grazing permit means a written agreement with a permittee for additional grazing capacity for other rangeland not covered by the permit.

Permit means a written agreement between Indian landowners and a permittee, whereby the permittee is granted a revocable privilege to use Indian land or Government land, for a specified purpose.

Permittee means an a person or entity who has acquired a legal right of possession to Indian land by a permit for grazing purposes under this part.

Range unit means rangelands consolidated to form a unit of land for the management and administration of grazing under a permit. A range unit may consist of a combination of tribal, individually-owned Indian, and/or government land.

Rangeland means Indian land, excluding Indian forest land, on which native vegetation is predominantly grasses, grass-like plants, half-shrubs or shrubs suitable for grazing or browsing use, and includes lands re-vegetated naturally or artificially to provide a forage cover that is managed as native vegetation.

Restricted land or restricted status means land the title to which is held by an individual Indian or a tribe and which can only be alienated or encumbered by the owner with the approval of the Secretary because of limitations contained in the conveyance instrument pursuant to federal law.

Subpermit means a written agreement, whereby the permittee grants to an individual or entity a right to possession (i.e., pasturing authorization), no greater than that held by the permittee under the permit.

Surety means one who guarantees the performance of another.

Sustained yield means the yield of agricultural products that a unit of land can produce continuously at a given level of use.

Trespass means any unauthorized occupancy, use of, or action on Indian lands.

Tribal land means the surface estate of land or any interest therein held by the United States in trust for a tribe, band, community, group or pueblo of Indians, and land that is held by a tribe, band, community, group or pueblo of Indians, subject to federal restrictions against alienation or encumbrance, and includes such land reserved for BIA administrative purposes when it is not immediately needed for such purposes. The term also includes lands held by the United States in trust for an Indian corporation chartered under section 17 of the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. 476).

Tribal law means the body of non-federal law that governs lands and

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activities under the jurisdiction of a tribe, including ordinances or other enactments by the tribe, tribal court rulings, and tribal common law.

Trust land means any tract, or interest therein, that the United States holds in trust status for the benefit of a tribe or individual Indian.

Undivided interest means a fractional share in the surface estate of Indian land, where the surface estate is owned in common with other Indian landowners or fee owners.

Us/We/Our means the BIA and any tribe acting on behalf of the BIA under 166.1 of this part.

Uniform Standards of Professional Appraisal Practices (USPAP) means the standards promulgated by the Appraisal Standards Board of the Appraisal Foundation to establish requirements and procedures for professional real property appraisal practice.

Written notice means a written letter mailed by way of United States mail, certified return receipt requested, postage prepaid, or hand-delivered letter.

Subpart B—Tribal Policies and Laws Pertaining to Permits

§ 166.100 What special tribal policies will we apply to permitting on Indian agricultural lands?

(a) When specifically authorized by an appropriate tribal resolution establishing a general policy for permitting of Indian agricultural lands, the BIA will:

(1) Waive the general prohibition against Indian operator preferences in permits advertised for bid under § 166.221 of this part, by allowing prospective Indian operators to match the highest responsible bid (unless the tribal law or leasing policy specifies some other manner in which the preference must be afforded);

(2) Waive or modify the requirement that a permittee post a surety or performance bond;

(3) Provide for posting of other collateral or security in lieu of surety or other bonds; and

(4) Approve permits of tribally-owned agricultural lands at rates determined by the tribal governing body.

(b) When specifically authorized by an appropriate tribal resolution establishing a general policy for permitting of Indian agricultural lands, and subject to paragraph (c) of this section, the BIA may:

(1) Waive or modify any general notice requirement of federal law; and

(2) Grant or approve a permit on "highly fractionated undivided heirship lands" as defined by tribal law.

(c) The BIA may take the action specified in paragraph (b) of this section only if:

(1) The tribe defines by resolution what constitutes "highly fractionated undivided heirship lands";

(2) The tribe adopts an alternative plan for notifying individual Indian landowners; and

(3) The BIA's action is necessary to prevent waste, reduce idle land acreage and ensure income.

§ 166.101 May individual Indian landowners exempt their land from certain tribal policies for permitting on Indian agricultural lands?

(a) The individual Indian landowners of Indian land may exempt their land from our application of a tribal policy referred to under § 166.100 of this part if:

(1) The Indian landowners have at least a 50% interest in such fractionated tract; and

(2) The Indian landowners submit a written objection to the BIA of all or any part of such tribal policies to the permitting of such parcel of land.

(b) Upon verification of the written objection we will notify the tribe of the Indian landowners' exemption from the specific tribal policy.

(c) The procedures described in paragraphs (a) and (b) of this section will also apply to withdrawing an approved exemption.

§ 166.102 Do tribal laws apply to permits?

Tribal laws will apply to permits of Indian land under the jurisdiction of the tribe enacting such laws, unless those tribal laws are inconsistent with applicable federal law.

§ 166.103 How will tribal laws be enforced on Indian agricultural land?

(a) Unless prohibited by federal law, we will recognize and comply with tribal laws regulating activities on Indian agricultural land, including tribal laws relating to land use, environmental protection, and historic or cultural preservation.

(b) While the tribe is primarily responsible for enforcing tribal laws pertaining to Indian agricultural land, we will:

(1) Assist in the enforcement of tribal laws;

(2) Provide notice of tribal laws to persons or entities undertaking activities on Indian agricultural land, under § 166.104(b) of this part; and

(3) Require appropriate federal officials to appear in tribal forums when requested by the tribe, so long as such an appearance would not:

(i) Be inconsistent with the restrictions on employee testimony set forth at 43 CFR Part 2, Subpart E;

(ii) Constitute a waiver of the sovereign immunity of the United States; or

(iii) Authorize or result in a review of our actions by a tribal court.

(c) Where the regulations in this subpart are inconsistent with a tribal law, but such regulations cannot be superseded or modified by the tribal law under § 166.2 of this part, we may waive the regulations under part 1 of this title, so long as the waiver does not violate a federal statute or judicial decision or conflict with our general trust responsibility under federal law.

§ 166.104 What notifications are required that tribal laws apply to permits on Indian agricultural lands?

(a) Tribes must notify us of the content and effective dates of new tribal laws.

(b) We will then notify affected Indian landowners and any persons or entities undertaking activities on Indian agricultural lands of the superseding or modifying effect of the tribal law. We will:

(1) Provide individual written notice; or

(2) Post public notice. This notice will be posted at the tribal community building, U.S. Post Office, and/or published in the local newspaper nearest to the Indian lands where activities are occurring.

Subpart C—Permit Requirements

General Requirements

§ 166.200 When is a permit needed to authorize possession of Indian land for grazing purposes?

(a) Unless otherwise provided for in this part, any person or legal entity, including an independent legal entity owned and operated by a tribe, must obtain a permit under these regulations before taking possession of Indian land for grazing purposes.

(b) An Indian landowner who owns 100% of the trust or restricted interests in a tract may take possession of that Indian land without a permit or any other prior authorization from us.

(c) If an Indian landowner does not own 100 percent (%) of his or her Indian land and wants to use the Indian land for grazing purposes, a permit must be granted by the majority interest of the fractionated tract.

§ 166.201 Must parents or guardians of Indian minors who own Indian land obtain a permit before using land for grazing purposes?

Parents or guardians need not obtain a permit for Indian lands owned by their minor Indian children if:

(a) Those minor children own 100 percent (%) of the land; and

(b) The minor children directly benefit from the use of the land. We may require the user to provide evidence of the direct benefits to the minor children. When one of the minor children becomes an adult, the permit will have to be obtained from the majority interest.

§ 166.202 May an emancipated minor grant a permit?

Yes. An emancipated minor may grant a permit.

§ 166.203 When can the Indian landowners grant a permit?

(a) Tribes grant permits of tribal land, including any tribally-owned undivided interest(s) in a fractionated tract. A permit granted by the tribe must be approved by us, unless the permit is authorized by a charter approved by us under 25 U.S.C. § 477, or unless our approval is not required under other applicable federal law. In order to permit tribal land in which the beneficial interest has been assigned to another party, the assignee and the tribe must both grant the permit, subject to our approval.

(b) Individual Indian landowners may grant a permit of their land, including their undivided interest in a fractionated tract, subject to our approval. Except as otherwise provided in this part, these Indian landowners may include the owner of a life estate holding 100 percent (%) interest in their land.

(c) The owners of a majority interest in the Indian ownership of a fractionated tract may grant a permit, subject to our approval, without giving prior notice to the minority Indian landowners as long as the minority interest owners receive fair annual rental.

§ 166.204 Who may represent an individual Indian landowner in granting a permit?

The following individuals or entities may represent an individual Indian landowner in granting a permit:

(a) An adult with custody acting on behalf of their minor children;

(b) A guardian, conservator, or other fiduciary appointed by a court of competent jurisdiction to act on behalf of an individual Indian landowner;

(c) An adult or legal entity who has been given a written power of attorney that:

(1) Meets all of the formal requirements of any applicable tribal or state law;

(2) Identifies the attorney-in-fact and the land to be permitted; and

(3) Describes the scope of the power granted and any limits thereon.

§ 166.205 When can the BIA grant a permit on behalf of Indian landowners?

(a) We may grant a permit on behalf of:

(1) An individual who is adjudicated to be non compos mentis by a court of competent jurisdiction;

(2) An orphaned minor;

(3) An Indian landowner who has granted us written authority to permit his or her land;

(4) The undetermined heirs and devisees of a deceased Indian landowner;

(5) An Indian landowner whose whereabouts are unknown to us after a reasonable attempt is made to locate the Indian landowner;

(6) Indian landowners, where:

(i) We have provided written notice of our intent to grant a permit on their behalf, but the Indian landowners are unable to agree upon a permit during a three-month negotiation period immediately following such notice, or any other notice period established by a tribe under § 166.100(c)(2) of this part; and

(ii) The land is not being used by an individual Indian landowner under § 166.200 of this part.

(7) The individual Indian owners of fractionated Indian land, when necessary to protect the interests of the individual Indian landowners.

§ 166.206 What requirements apply to a permit on a fractionated tract?

We may grant a permit on behalf of all Indian landowners of a fractionated tract as long as the owners receive fair annual rental. Before granting such a permit, we may offer a preference right to any Indian landowner who:

(a) Is in possession of the entire tract;

(b) Submits a written offer to permit the land, subject to any required or negotiated terms and conditions, prior to our granting a permit to another party; and

(c) Provides any supporting documents needed to demonstrate the ability to perform all of the obligations under the proposed permit.

§ 166.207 What provisions will be contained in a permit?

A permit, at a minimum, must include:

(a) Authorized user(s);

(b) Conservation plan requirements;

(c) Prohibition against creating a nuisance, any illegal activity, and negligent use or waste or resources;

(d) Numbers and types of livestock allowed;

(e) Season(s) of use;

(f) Grazing rental payment, payment schedule, and late payment interest and penalties;

(g) Administrative fees;

(h) Tribal fees, if applicable;

(i) Payment method;

(j) Range unit number or name;

(k) Animal identification requirements;

(l) A description (preferably a legal description) of the permitted area;

(m) Term of permit (including beginning and ending dates of the term allowed, as well as any option to renew, extend or terminate);

(n) Conditions for making improvements, if any;

(o) A right of entry by the BIA for purposes of inspection or enforcement purposes;

(p) A provision concerning the applicability of tribal jurisdiction;

(q) A provision stating how trespass proceeds are to be distributed; and

(r) A provision for the permittee to indemnify the United States and the Indian landowners against all liabilities or costs relating to the use, handling, treatment, removal, storage, transportation, or disposal of hazardous materials or the release or discharge of any hazardous material from the permitted premises that occur during the permit term, regardless of fault.

§ 166.208 How long is a permit term?

(a) The duration must be reasonable given the purpose of the permit and the level of investment required by the permittee to place the property into productive use.

(b) On behalf of the undetermined heirs of an individual Indian decedent owning 100 percent (%) interest in the land, we will grant or approve permits for a maximum term of two years.

(c) Permits granted for agricultural purposes will not usually exceed ten years. A term longer than ten years, but not to exceed 25 years unless authorized by other federal law, may be authorized when a longer term is determined by us to be in the best interest of the Indian landowners and when such permit requires substantial investment in the development of the lands by the permittee.

(d) A tribe may determine the duration of permits composed entirely of its tribal land or in combination with government land, subject to the same

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limitations provided in paragraph (d) of this section.

(e) A permit will specify the beginning and ending dates of the term allowed, as well as any option to renew, extend, or terminate.

(f) Permits granted by us for protection of the Indian land will be for no more than two years.

§ 166.209 Must a permit be recorded?

A permit must be recorded in our Land Titles and Records Office which has jurisdiction over the land. We will record the permit immediately following our approval under this subpart.

§ 166.210 When is a decision by the BIA regarding a permit effective?

Our decision to approve a permit will be effective immediately, notwithstanding any appeal which may be filed under Part 2 of this title. Copies of the approved permit will be provided to the permitee and made available to the Indian landowners upon request.

§ 166.211 When are permits effective?

Unless otherwise provided in the permit, a permit will be effective on the date on which the permit is approved by us. A permit may be made effective on some past or future date, by agreement, but such a permit may not be granted or approved more than one year prior to the date on which the permit term is to commence.

§ 166.212 When may a permittee take possession of permitted Indian land?

The permittee may take possession of permitted Indian land on the date specified in the permit as the beginning date of the term, but not before we approve the permit.

§ 166.213 Must I comply with any standards of conduct if I am granted a permit?

Yes. Permittees are expected to:

(a) Conduct grazing operations in accordance with the principles of sustained yield management, agricultural resource management planning, sound conservation practices, and other community goals as expressed in tribal laws, agricultural resource management plans, and similar sources.

(b) Comply with all applicable laws, ordinances, rules, regulations, and other legal requirements. You must also pay all applicable penalties that may be assessed for non-compliance.

(c) Fulfill all financial obligations of your permit owed to the Indian landowners and the United States.

(d) Conduct only those activities authorized by the permit.

§ 166.214 Will the BIA notify the permittee of any change in land title status?

Yes. We will notify the permittee if a fee patent is issued or if restrictions are removed. After we notify the permittee our obligation under § 166.228 of this part ceases.

Obtaining A Permit

§ 166.215 How can I find Indian land available for grazing?

You may contact a local BIA office or tribal office to determine what Indian land may be available for grazing permits.

§ 166.216 Who is responsible for permitting Indian land?

The Indian landowner is primarily responsible for granting permits on their Indian land, with the assistance and approval of the BIA, except where otherwise provided by law. You may contact the local BIA or tribal office for assistance in obtaining a permit for grazing purposes on Indian land.

§ 166.217 In what manner may a permit on Indian land be granted?

(a) A tribe may grant a permit on tribal land through tribal allocation, negotiation, or advertisement in accordance with § 166.203 of this part. We must approve all permits of tribal land in order for the permit to be valid, except where otherwise provided by law.

(b) Individual Indian landowners may grant a permit on their Indian land through negotiation or advertisement in accordance with § 166.203 of this part. We must approve all permits of Individual Indian land in order for the permit to be valid.

(c) We will grant permits through negotiation or advertisement for range units containing, in whole or part, individually-owned Indian land and range units that consist of, or in combination with individually-owned Indian land, tribal or government land, under § 166.205 of this part. We will consult with tribes prior to granting permits for range units that include tribal land.

§ 166.218 How do I acquire a permit through tribal allocation?

(a) A tribe may allocate grazing privileges on range units containing trust or restricted land which is entirely tribally-owned or which contains only tribal and government land under the control of the tribe.

(b) A tribe may allocate grazing privileges to its members and to tribally-authorized entities without competitive bidding on tribal and tribally-controlled government land.

(c) We will implement the tribe's allocation procedure by authorizing the grazing privileges on individually-owned Indian land and government land, subject to the rental rate provisions in § 166.400(b) and (c) of this part.

(d) A tribe may prescribe the eligibility requirements for allocations 60 days before granting a new permit or before an existing permit expires.

(e) 120 days before the expiration of existing permits, we will notify the tribe of the 60-day period during which the tribe may prescribe eligibility requirements.

(f) We will prescribe the eligibility requirements after the expiration of the 60-day period in the event satisfactory action is not taken by the tribe.

(g) Grazing rental rates for grazing privileges allocated from an existing permit, in whole or in part, must equal or exceed the rates paid by the preceding permittee(s). Tribal members will pay grazing rental rates established by the tribe on tribal lands.

§ 166.219 How do I acquire a permit through negotiation?

(a) Permits may be negotiated and granted by the Indian landowners with the permittee of their choice. The BIA may negotiate and grant permits on behalf of Indian landowners pursuant to § 166.205 of this part.

(b) Upon the conclusion of negotiations with the Indian landowners or their representatives, and the satisfaction of any applicable conditions, you may submit an executed permit and any required supporting documents to us for appropriate action. Where a permit is in a form that has previously been accepted or approved by us, and all of the documents needed to support the findings required by this part have been received, we will decide whether to approve the permit within 30 days of the date of our receipt of the permit and supporting documents. If we decide to approve or disapprove a permit, we will notify the parties immediately and advise them of their right to appeal the decision under part 2 of this title.

(c) In negotiating a permit, the Indian landowners may choose to include their land in the permit in exchange for their receipt of a share of the revenues or profits generated by the permit. Under such an arrangement, the permit may be granted to a joint venture or other legal entity owned, in part, by the Indian landowners.

(d) Receipt of permit payments based upon income received from the land will not, of itself, make the Indian landowner a partner, joint venturer, or associate of the permittees.

(e) We will assist prospective permittees in contacting the Indian landowners or their representatives, for the purpose of negotiating a permit.

§ 166.220 What are the basic steps for acquiring a permit through negotiation?

The basic steps for acquiring a permit by negotiation are as follows:

(a) The BIA or the Indian landowner will:

(1) Receive a request to permit from an Indian landowner or the potential permittee;

(2) Prepare the permit documents; and

(3) Grant the permit.

(b) A potential permittee will complete the requirements for securing a permit, (e.g., bond, insurance, payment of administrative fee, etc.);

(c) We will:

(1) Review the permit for proper documentation and compliance with all applicable laws and regulations;

(2) Approve the permit after our review;

(3) Send the approved permit to the permittee and, upon request, to the Indian landowner; and

(4) Record and maintain the approved permit.

§ 166.221 How do I acquire an advertised permit through competitive bidding?

(a) As part of the negotiation of a permit, Indian landowners may advertise their Indian land to identify potential permittees with whom to negotiate.

(b) When the BIA grants and approves a permit on behalf of an individual Indian landowner using an advertisement for bids, we will:

(1) Prepare and distribute an advertisement of lands available for permit that identifies the terms and conditions of the permit sale, including, for agricultural permits, any preference rights;

(2) Solicit sealed bids and conduct the public permit sale;

(3) Determine and accept the highest or best responsible bidder(s), which may require further competitive bidding after the bid opening; and

(4) Prepare permits for successful bidders.

(c) After completion of the steps in paragraph (b) of this section, the successful bidder must complete and submit the permit and satisfy all applicable requirements, (e.g., bond, insurance, payment of administrative fee, etc.).

(d) After review of the permit documentation for proper completion and compliance with all applicable laws and regulations, within 30 days we will:

(1) Grant and approve the permit on behalf of Indian landowners where we are authorized to do so by law;

(2) Distribute the approved permit to the permittee(s) and, upon request, to the Indian landowner(s); and

(3) Record and maintain the approved permit.

§ 166.222 Are there standard permit forms?

Yes. Standard permit forms, including bid forms, permit forms, and permit modification forms are available at our agency offices.

Permit (Leasehold) Mortgage

§ 166.223 Can I use a permit as collateral for a loan?

We may approve a permit containing a provision that authorizes the permittee to encumber the permit interest, known as a leasehold mortgage, for the development and improvement of the permitted Indian land. We must approve the leasehold mortgage that encumbers the permit interest before it can be effective. We will record the approved leasehold mortgage instrument.

§ 166.224 What factors does the BIA consider when reviewing a leasehold mortgage?

(a) We will approve the leasehold mortgage if:

(1) All consents required in the permit have been obtained from the Indian landowners and any surety or guarantor;

(2) The mortgage covers only the permit interest, and no unrelated collateral belonging to the permittee;

(3) The financing being obtained will be used only in connection with the development or use of the permitted premises, and the mortgage does not secure any unrelated obligations owed by the permittee to the mortgagee; and

(4) We find no compelling reason to withhold our approval, in order to protect the best interests of the Indian landowner.

(b) In making the finding required by paragraph (a)(4) of this section, we will consider whether:

(1) The ability to perform the permit obligations would be adversely affected by the cumulative mortgage obligations;

(2) Any negotiated permit provisions as to the allocation or control of insurance or condemnation proceeds would be modified;

(3) The remedies available to us or the Indian landowners would be limited (beyond the additional notice and cure rights to be afforded to the mortgagee), if the permittee defaults on the permit;

(4) Any rights of the Indian landowners would be subordinated or adversely affected in the event of a foreclosure, assignment in lieu of foreclosure, or issuance of a "new permit" to the mortgagee.

(c) We will notify the Indian landowners of our approval of the leasehold mortgage.

§ 166.225 May a permittee voluntarily assign a leasehold interest under an approved encumbrance?

With our approval, under an approved encumbrance, a permittee voluntarily may assign the leasehold interest to someone other than the holder of a leasehold mortgage if the assignee agrees in writing to be bound by the terms of the permit. A permit may provide the Indian landowners with a right of first refusal on the conveyance of the leasehold interest.

§ 166.226 May the holder of a leasehold mortgage assign the leasehold interest after a sale or foreclosure of an approved encumbrance?

Yes. The holder of a leasehold mortgage may assign a leasehold interest obtained by a sale or foreclosure of an approved encumbrance without our approval if the assignee agrees in writing to be bound by the terms of the permit. A permit may provide the Indian landowners with a right of first refusal on the conveyance of the permit interest (leasehold).

Modifying a Permit

§ 166.227 How can Indian land be removed from an existing permit?

(a)We will remove Indian land from the permit if:

(1)The trust status of the Indian land terminates;

(2) The Indian landowners request removal of their interest, with the written approval of the majority interest of the fractionated tract to be removed, and we determine that the removal is beneficial to such interests;

(3) A tribe allocates grazing privileges for Indian land covered by your permit under § 166.218 of this part;

(4) The permittee requests removal of the Indian land, the owners of the majority interest of the Indian land provides written approval of the removal of the Indian land, and we determine that the removal is warranted; or

(5) We determine that removal of the Indian land is appropriate, with the written approval of the owners of the majority interest of the Indian land.

(b) We will revise the grazing capacity to reflect the removal of Indian land and show it on the permit.

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§ 166.228 How will the BIA provide notice if Indian land is removed from an existing permit?

If the reason for removal is:

(a) Termination of trust status. We will notify the parties to the permit in writing within 30 days. The removal will be effective on the next anniversary date of the permit.

(b) A request from Indian landowners or the permittee, or our determination. We will notify the parties to the permit in writing within 30 days of such request. The removal will be effective immediately if all sureties, Indian landowners, and permittee agree. Otherwise, the removal will be effective upon the next anniversary date of the permit. If our written notice is within 180 days of the anniversary date of the permit, the removal of Indian land will be effective 180 days after the written notice.

(c) Tribal allocation under § 166.218 of this part. We will notify the parties to the permit in writing within 180 days of such action. The removal of tribal land will be effective on the next anniversary date of the permit. If our written notice is within 180 days of the anniversary date of the permit, the removal of Indian land will be effective 180 days after the written notice.

§ 166.229 Other than to remove land, how can a permit be amended, assigned, subpermitted, or mortgaged?

(a) We must approve an amendment, assignment, subpermit, or mortgage with the written consent of the parties to the permit in the same manner that the permit was approved, and the consent of the sureties.

(b) Indian landowners may designate in writing one or more of their co-owners or representatives to negotiate and/or agree to amendments on their behalf.

(1) The designated landowner or representative may:

(i) Negotiate or agree to amendments; and

(ii) Consent to or approve other items as necessary.

(2) The designated landowner or representative may not:

(i) Negotiate or agree to amendments that reduce the grazing rental payments payable to the other Indian landowners; or

(ii) Terminate the permit or modify the term of the permit.

(c) We may approve a permit for tribal land to individual members of a tribe which contains a provision permitting the assignment of the permit by the permittee or the lender without our approval when a lending institution or an agency of the United States:

(1) Accepts the interest in the permit (leasehold) as security for the loan; and

(2) Obtains the interest in the permit (leasehold) through foreclosure or otherwise.

(d) We will revise the grazing capacity and modify the permit.

§ 166.230 When will a BIA decision to approve an amendment, assignment, subpermit, or mortgage under a permit be effective?

Our decision to approve an amendment, assignment, subpermit, or mortgage under a permit will be effective immediately, notwithstanding any appeal which may be filed under Part 2 of this title. Copies of approved documents will be provided to the party requesting approval, and made available to the Indian landowners upon request.

§ 166.231 Must an amendment, assignment, subpermit, or mortgage approved under a permit be recorded?

An amendment, assignment, subpermit, or mortgage approved under a permit must be recorded in our Land Titles and Records Office which has jurisdiction over the Indian land. We will record the document immediately following our approval.

Subpart D—Land and Operations Management

§ 166.300 How is Indian agricultural land managed?

Tribes, individual Indian landowners, and the BIA will manage Indian agricultural land either directly or through contracts, compacts, cooperative agreements, or grants under the Indian Self-Determination and Education Assistance Act (Public Law 93–638, as amended).

§ 166.301 How is Indian land for grazing purposes described?

Indian land for grazing purposes should be described by legal description (e.g., aliquot parts, metes and bounds) or other acceptable description. Where there are undivided interests owned in fee status, the aggregate portion of trust and restricted interests should be identified in the description of the permitted land.

§ 166.302 How is a range unit created?

We create a range unit after we consult with the Indian landowners of rangeland, by designating units of compatible size, availability, and location.

§ 166.303 Can more than one parcel of Indian land be combined into one permit?

Yes. A permit may include more than one parcel of Indian land. Permits may include tribal land, individually-owned Indian land, or government land, or any combination thereof.

§ 166.304 Can there be more than one permit for each range unit?

Yes. There can be more than one permit for each range unit.

§ 166.305 When is grazing capacity determined?

Before we grant, modify, or approve a permit, in consultation with the Indian landowners, we will establish the total grazing capacity for each range unit based on the summation of each parcel's productivity. We will also establish the season(s) of use on Indian lands.

§ 166.306 Can the BIA adjust the grazing capacity?

Yes. In consultation with the Indian landowners or in the BIA's discretion based on good cause, we may adjust the grazing capacity using the best evaluation method(s) relevant to the ecological region.

§ 166.307 Will the grazing capacity be increased if I graze adjacent trust or non-trust rangelands not covered by the permit?

No. You will not receive an increase in grazing capacity in the permit if you graze trust or non-trust rangeland in common with the permitted land. Grazing capacity will be established only for Indian land covered by your permit.

§ 166.308 Can the number of animals and/or season of use be modified on the permitted land if I graze adjacent trust or non-trust rangelands under an on-and-off grazing permit?

Yes. The number of animals and/or season of use may be modified on permitted Indian land with an on-and-off grazing permit only when a conservation plan includes the use of adjacent trust or non-trust rangelands not covered by the permit and when that land is used in common with permitted land.

§ 166.309 Who determines livestock class and livestock ownership requirements on permitted Indian land?

(a) Tribes determine the class of livestock and livestock ownership requirements for livestock that may be grazed on range units composed entirely of tribal land or which include government land, subject to the grazing capacity prescribed by us under § 166.305 of this part.

(b) For permits on range units containing, in whole or part, individually-owned Indian land, we will adopt the tribal determination in paragraph (a) of this section.

§ 166.310 What must a permittee do to protect livestock from exposure to disease?

In accordance with applicable law, permittees must:

(a) Vaccinate livestock;

(b) Treat all livestock exposed to or infected with contagious or infectious diseases; and

(c) Restrict the movement of exposed or infected livestock.

Management Plans and Environmental Compliance

§ 166.311 Is an Indian agricultural resource management plan required?

(a) Indian agricultural land under the jurisdiction of a tribe must be managed in accordance with the goals and objectives in any agricultural resource management plan developed by the tribe, or by us in close consultation with the tribe, under the AIARMA.

(b) The ten-year agricultural resource management and monitoring plan must be developed through public meetings and completed within three years of the initiation of the planning activity. Such a plan must be developed through public meetings, and be based on the public meeting records and existing survey documents, reports, and other research from federal agencies, tribal community colleges, and land grant universities. When completed, the plan must:

(1) Determine available agricultural resources;

(2) Identify specific tribal agricultural resource goals and objectives;

(3) Establish management objectives for the resources;

(4) Define critical values of the tribe and its members and provide identified holistic management objectives; and

(5) Identify actions to be taken to reach established objectives.

(c) Where the regulations in this subpart are inconsistent with a tribe's agricultural resource management plan, we may waive the regulations under part 1 of this title, so long as the waiver does not violate a federal statute or judicial decision or conflict with our general trust responsibility under federal law.

§ 166.312 Is a conservation plan required?

A conservation plan must be developed for each permit with the permittee and approved by us prior to the issuance of the permit. The conservation plan must be consistent with the tribe's agricultural resource management plan and must address the permittee's management objectives regarding animal husbandry and resource conservation. The conservation plan must cover the entire permit period and reviewed by us on an annual basis.

§ 166.313 Is environmental compliance required?

Actions taken by the BIA under the regulations in this part must comply with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), applicable regulations of the Council on Environmental Quality (40 CFR part 1500), and applicable tribal laws and regulations.

Conservation Practices and Improvements

§ 166.314 Can a permittee apply a conservation practice on permitted Indian land?

Yes. A permittee can apply a conservation practice on permitted Indian land as long as the permittee has approval from the BIA and majority interest and the conservation practice is consistent with the conservation plan.

§ 166.315 Who is responsible for the completion and maintenance of a conservation practice if the permit expires or is canceled before the completion of the conservation practice?

Prior to undertaking a conservation practice, the BIA, landowner, and permittee will negotiate who will complete and maintain a conservation practice if the permit expires or is canceled before the conservation practice is completed. That conservation practice agreement will be reflected in the conservation plan and permit.

§ 166.316 Can a permittee construct improvements on permitted Indian land?

Improvements may be constructed on permitted Indian land if the permit contains a provision allowing improvements.

§ 166.317 What happens to improvements constructed on Indian lands when the permit has been terminated?

(a) If improvements are to be constructed on Indian land, the permit must contain a provision that improvements will either:

(1) Remain on the land upon termination of the permit, in a condition that is in compliance with applicable codes, to become the property of the Indian landowner; or

(2) Be removed and the land restored within a time period specified in the permit. The land must be restored as close as possible to the original condition prior to construction of such improvements. At the request of the permittee we may, at our discretion, grant an extension of time for the removal of improvements and restoration of the land for circumstances beyond the control of the permittee.

(b) If the permittee fails to remove improvements within the time allowed in the permit, the permittee may forfeit the right to remove the improvements and the improvements may become the property of the Indian landowner or at the request of the Indian landowner, we will apply the bond for the removal of the improvement and restoration of the land.

Subpart E—Grazing Rental Rates, Payments, and Late Payment Collections

Rental Rate Determination and Adjustment

§ 166.400 Who establishes grazing rental rates?

(a) For tribal lands, a tribe may establish a grazing rental rate that is less or more than the grazing rental rate established by us. We will assist a tribe to establish a grazing rental rate by providing the tribe with available information concerning the value of grazing on tribal lands.

(b) We will establish the grazing rental rate by determining the fair annual rental for:

(1) Individually-owned Indian lands; and

(2) Tribes that have not established a rate under paragraph (a) of this section.

(c) Indian landowners may give us written authority to grant grazing privileges on their individually-owned Indian land at a grazing rental rate that is:

(1) Above the grazing rental rate set by us; or

(2) Below the grazing rental rate set by us, subject to our approval, when the permittee is a member of the Indian landowner's immediate family as defined in this part.

§ 166.401 How does the BIA establish grazing rental rates?

An appraisal can be used to determine the rental value of real property. The development and reporting of the valuation will be completed in accordance with the Uniform Standards of Professional Appraisal Practices (USPAP). If an appraisal is not desired, competitive bids, negotiations, advertisements, or any other method can be used in conjunction with a market study, rent survey, or feasibility analysis developed in accordance with the USPAP.

§ 166.402 Why must the BIA determine the fair annual rental of Indian land?

The BIA must determine the fair annual rental of Indian land to:

(a) Assist the Indian landowner in negotiating a permit with potential permittees; and

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(b) Enable us to determine whether a permit is in the best interests of the Indian landowner.

§ 166.403 Will the BIA ever grant or approve a permit at less than fair annual rental?

(a) We will grant a permit for grazing on individually-owned Indian land at less than fair annual rental if, after competitive bidding of the permit, we determine that such action would be in the best interests of the individual Indian landowners.

(b) We may approve a permit for grazing on individually-owned Indian land at less than fair annual rental if:

(1) The permit is for the Indian landowner's immediate family or co-owner; or

(2) We determine it is in the best interest of the Indian landowners.

(c) We may approve a permit for grazing on tribal land at less than fair annual rental if the tribe sets the rate.

§ 166.404 Whose grazing rental rate will be applicable for a permit on tribal land?

The following grazing rental rate schedule will apply for tribal land:

If you are * * *	And if * * *	Then you will pay * * *
(a) Grazing livestock on tribal land	The tribe established the grazing rental rate	The rate set by the tribe.
(b) Grazing livestock on tribal land	No tribal grazing rental rate has been established.	The rate set by the BIA.
(c) The successful bidder for use of any of these specific parcels of Indian land.		Your rental rate bid, but not less than the minimum bid rate advertised.

§ 166.405 Whose grazing rental rate will be applicable for a permit on individually-owned Indian land?

The following grazing rental rate schedule will apply for individually-owned Indian land:

If you are * * *	Then you will pay * * *
(a) Grazing livestock on individually-owned Indian land.	The rate set by the BIA or by the individual Indian landowner and approved by us.
(b) The successful bidder for use of any of these specific parcels of Indian land.	Your rental rate bid, but not less than the minimum bid rate advertised, unless the permit is granted at less than fair annual rental under § 166.403.
(c) The recipient of an allocation from a bid unit	The bid rate or the appraised rate, whichever is higher.

§ 166.406 Whose grazing rental rate will be applicable for a permit on government land?

The following grazing rental rate schedule will apply for government land:

If you are * * *	And if * * *	Then you will pay * * *
(a) Grazing livestock on government land	The tribe has control over the land or the tribe has authority to set the rate.	The rate set by the tribe.
(b) Grazing livestock on government land	Government controls all use of the land	The rate set by the BIA.

§ 166.407 If a range unit consists of tribal and individually-owned Indian lands, what is the grazing rental rate?

The grazing rental rate for tribal land will be the rate set by the tribe. The grazing rental rate for individually-owned Indian land will be the grazing rental rate set by us.

§ 166.408 Is the grazing rental rate established by the BIA adjusted periodically?

Yes. To ensure that Indian landowners are receiving the fair annual return, we may adjust the grazing rental rate established by the BIA, based upon an appropriate valuation method, taking into account the value of improvements made under the permit, unless the permit provides otherwise, following the Uniform Standards of Professional Appraisal Practice.

(a) We will:

(1) Review the grazing rental rate prior to each anniversary date or when specified by the permit.

(2) Provide you with written notice of any adjustment of the grazing rental rate 60 days prior to each anniversary date.

(3) Allow the adjusted grazing rental rate to be less than the fair annual rental if we determine that such a rate is in the best interest of the Indian landowner.

(b) If adjusted, the grazing rental rate will become effective on the next anniversary date of the permit.

(c) These adjustments will be retroactive, if they are not made at the time specified in the permit.

(d) For permits granted by tribes, we will consult with the granting tribe to determine whether an adjustment of the grazing rental payment should be made. The permit must be modified to document the granting tribe's waiver of the adjustment. A tribe may grant a permit without providing for a rental adjustment, if the tribe establishes such a policy under § 166.100(a)(4) of this part and negotiates such a permit.

Rental Payments

§ 166.409 How is my grazing rental payment determined?

The grazing rental payment is the total of the grazing rental rate multiplied by the number of AUMs or acres covered by the permit.

§ 166.410 When are grazing rental payments due?

The initial grazing rental payment is due and payable as specified in the permit or 15 days after the BIA approves the permit, whichever is later. Subsequent payments are due as specified in the permit.

§ 166.411 Will a permittee be notified when a grazing rental payment is due?

Each permit states the schedule of rental payments agreed to by the parties. We will issue an invoice to the permittee 30 to 60 days prior to the rental payment due date.

§ 166.412 What if the permittee does not receive an invoice that a grazing rental payment is due?

If we fail to send an invoice or if we send an invoice and the permittee does not receive it, the permittee is still responsible for making timely payment of all amounts due under the permit.

§ 166.413 To whom are grazing rental payments made?

(a) A permit must specify whether grazing rental payments will be made directly to the Indian landowners or to us on behalf of the Indian landowners. If the permit provides for payment to be made directly to the Indian landowners, the permit must also require that the permittee retain specific documentation evidencing proof of payment, such as canceled checks, cash receipt vouchers, or copies of money orders or cashier's checks, consistent with the provisions of §§ 166.1000 and 166.1001 of this part.

(b) Grazing rental payments made directly to the Indian landowners must be made to the parties specified in the permit, unless the permittee receives a notice of a change of ownership. Unless otherwise provided in the permit, grazing rental payments may not be made payable directly to anyone other than the Indian landowners.

(c) A permit which provides for grazing rental payments to be made directly to the Indian landowners must also provide for such payments to be suspended and rent thereafter paid to us, rather than directly than to the Indian landowners, if:

(1) An Indian landowner dies;

(2) An Indian landowner requests that payment be made to us;

(3) An Indian landowner is found by us to be in need of assistance in managing his/her financial affairs; or

(4) We determine, in our discretion and after consultation with the Indian landowner(s), that direct payment should be discontinued.

§ 166.414 What forms of grazing rental payments are acceptable?

(a) When grazing rental payments are made directly to the Indian landowners, the form of payment must be acceptable to the Indian landowners.

(b) Payments made to us may be delivered in person or by mail. We will not accept cash, foreign currency, or third-party checks. We will accept:

(1) Personal or business checks drawn on the account of the permittee;

(2) Money orders;

(3) Cashier's checks;

(4) Certified checks; or

(5) Electronic funds transfer payments.

§ 166.415 What will the BIA do if the permittee fails to make a direct payment to an Indian landowner?

Within five business days of the Indian landowner's notification to us that a payment has not been received, we will contact the permittee either in writing or by telephone requesting that the permittee provide documentation (e.g., canceled check, cash receipt voucher, copy of a money order or cashier's check) showing that payment has been made to the Indian landowner. If the permittee fails to provide such documentation, we will follow the procedures identified in § 166.419 of this part to collect the money on behalf of the Indian landowner or to cancel the permit.

§ 166.416 May a permittee make a grazing rental payment in advance of the due date?

Rent may be paid no more than 30 days in advance, unless otherwise specified in the permit.

§ 166.417 May an individual Indian landowner modify the terms of the permit on a fractionated tract for advance grazing rental payment?

No. An individual Indian landowner of a fractionated tract may not modify a permit to allow a grazing rental payment in advance of the due date specified in the initial approved permit.

§ 166.418 When is a grazing rental payment late?

A grazing rental payment is late if it is not received on or before the due date.

Late Rental Payment Collections

§ 166.419 What will the BIA do if grazing rental payments are not made in the time and manner required by the permit?

(a) A permittee's failure to pay grazing rental payments in the time and manner required by a permit will be a violation of the permit, and a notice of violation will be issued under § 166.703 of this part. If the permit requires that grazing rental payments be made to us, we will send the permittee and its sureties a notice of violation within five business days of the date on which the grazing rental payment was due. If the permit provides for payment directly to the Indian landowner(s), we will send the permittee and its sureties a notice of violation within five business days of the date on which we receive actual notice of non-payment from the Indian landowner(s).

(b) If a permittee fails to provide adequate proof of payment or cure the violation within the requisite time period described in § 166.704 of this part, and the amount due is not in dispute, we may immediately take action to recover the amount of the unpaid rent and any associated interest charges or late payment penalties. We may also cancel the permit under § 166.705 of this part, or invoke any other remedies available under the permit or applicable law, including collection on any available bond or referral of the debt to the Department of the Treasury for collection. An action to recover any unpaid amounts will not be conditioned on the prior cancellation of the permit or any further notice to the permittee, nor will such an action be precluded by a prior cancellation.

(c) Partial payments may be accepted, under special circumstances, by the Indian landowners or us, but acceptance will not operate as a waiver with respect to any amounts remaining unpaid or any other existing permit violations. Unless otherwise provided in the permit, overpayments may be credited as an advance against future grazing rental payments.

(d) If a personal or business check is dishonored, and a grazing rental payment is therefore not made by the due date, the failure to make the payment in a timely manner will be a violation of the permit, and a written notice of violation will be issued under § 166.703 of this part. Any payment made to cure such a default, and any future payments by the same permittee, must be made by one of the alternative payment methods listed in § 166.414(b) of this part.

§ 166.420 Will any special fees be assessed on delinquent grazing rental payments due under a permit?

The following special fees will be assessed if a grazing rental payment is not paid in the time and manner required, in addition to any interest or late payment penalties which must be paid to the Indian landowners under a permit. The following special fees will be assessed to cover administrative costs incurred by the United States in the collection of the debt:

The permittee will pay * * *	For * * *
(a) $50.00	Administrative fee for checks returned by the bank for insufficient funds.
(b) $15.00	Administrative fee for the BIA processing of each demand letter.
(c) 18% of balance due.	Administrative fee charged by the Department of Treasury for collection.

§ 166.421 If a permit is canceled for non-payment, does that extinguish the permittee's debt?

No. The permittee remains liable for any delinquent payment. No future permits will be issued until all outstanding debts related to Indian agricultural lands are paid.

Compensation to Indian Landowners

§ 166.422 What does the BIA do with grazing rental payments received from permittees?

Unless arrangements for direct payment to the Indian landowners has been provided, the rent will be deposited to the appropriate account

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maintained by the Office of Trust Funds Management in accordance with part 115 of this title.

§ 166.423 How do Indian landowners receive grazing rental payments that the BIA has received from permittees?

Funds will be paid to the Indian landowners by the Office of Trust Funds Management in accordance with 25 CFR part 115.

§ 166.424 How will the BIA determine the grazing rental payment amount to be distributed to each Indian landowner?

Unless otherwise specified in the permit, the grazing rental payment will be distributed to each Indian landowner according to the forage production that each parcel of Indian land contributes to the permit, annual rental rate of each parcel, and the Indian landowner's interest in each parcel.

Subpart F—Administrative and Tribal Fees

§ 166.500 Are there administrative fees for a permit?

Yes. We will charge an administrative fee before approving any permit, subpermit, assignment, encumbrance, modification, or other related document.

§ 166.501 How are annual administrative fees determined?

(a) Except as provided in subsection (b), we will charge a three percent (%) administrative fee based on the annual grazing rent.

(b) The minimum administrative fee is $10.00 and the maximum administrative fee is $500.00.

(c) If a tribe performs all or part of the administrative duties for this part, the tribe may establish, collect, and use reasonable fees to cover its costs associated with the performance of administrative duties.

§ 166.502 Are administrative fees refundable?

No. We will not refund administrative fees.

§ 166.503 May the BIA waive administrative fees?

Yes. We may waive the administrative fee for a justifiable reason.

§ 166.504 Are there any other administrative or tribal fees, taxes, or assessments that must be paid?

Yes. The permittee may be required to pay additional fees, taxes, and/or assessments associated with the use of the land as determined by us or by the tribe. Failure to make such payments will constitute a permit violation under subpart H of this part.

Subpart G—Bonding and Insurance Requirements

§ 166.600 Must a permittee provide a bond for a permit?

Yes. A permittee, assignee or subpermittee must provide a bond for each permit interest acquired. Upon request by an Indian landowner, we may waive the bond requirement.

§ 166.601 How is the amount of the bond determined?

(a) The amount of the bond for each permit is based on the:

(1) Value of one year's grazing rental payment;

(2) Value of any improvements to be constructed;

(3) Cost of performance of any additional obligations; and

(4) Cost of performance of restoration and reclamation.

(b) Tribal policy made applicable by § 166.100 of this part may establish or waive specific bond requirements for permits.

§ 166.602 What form of bonds will the BIA accept?

(a) We will only accept bonds in the following forms:

(1) Cash;

(2) Negotiable Treasury securities that:

(i) Have a market value equal to the bond amount; and

(ii) Are accompanied by a statement granting full authority to the BIA to sell such securities in case of a violation of the terms of the permit.

(3) Certificates of deposit that indicate on their face that Secretarial approval is required prior to redemption by any party;

(4) Irrevocable letters of credit (LOC) issued by federally-insured financial institutions authorized to do business in the United States. LOC's must:

(i) Contain a clause that grants the BIA authority to demand immediate payment if the permittee defaults or fails to replace the LOC within 30 calendar days prior to its expiration date;

(ii) Be payable to the "Department of the Interior, BIA";

(iii) Be irrevocable during its term and have an initial expiration date of not less than one year following the date we receive it; and

(iv) Be automatically renewable for a period of not less than one year, unless the issuing financial institution provides the BIA with written notice at least 90 calendar days before the letter of credit's expiration date that it will not be renewed;

(5) Surety bond; or

(6) Any other form of highly liquid, non-volatile security subsequently approved by us that is easily convertible to cash by us and for which our approval is required prior to redemption by any party.

(b) Indian landowners may negotiate a permit term that specifies the use of any of the bond forms described in paragraph (a) of this section.

(c) A tribe may accept and hold any form of bond described in paragraph (a) of this section, to secure performance under a permit of tribal land.

§ 166.603 If cash is submitted as a bond, how is it administered?

If cash is submitted as a bond, we will establish an account in the name of the permittee and retain it.

§ 166.604 Is interest paid on a cash performance bond?

No. Interest will not be paid on a cash performance bond.

§ 166.605 Are cash performance bonds refunded?

If the cash performance bond has not been forfeited for cause, the amount deposited will be refunded to the depositor at the end of the permit period.

§ 166.606 What happens to a bond if a violation occurs?

We may apply the bond to remedy the violation, in which case we will require the permittee to submit a replacement bond of an appropriate amount.

§ 166.607 Is insurance required for a permit?

When we determine it to be in the best interest of the Indian landowners, we will require a permittee to provide insurance. If insurance is required, it must:

(a) Be provided in an amount sufficient to:

(1) Protect any improvements on the permit premises;

(2) Cover losses such as personal injury or death; and

(3) Protect the interest of the Indian landowner.

(b) Identify the tribe, individual Indian landowners, and United States as insured parties.

§ 166.608 What types of insurance may be required?

We may require liability or casualty insurance (such as for fire, hazard, or flood), depending upon the activity conducted under the permit.

Subpart H—Permit Violations

§ 166.700 What permit violations are addressed by this subpart?

This subpart addresses violations of permit provisions other than trespass. Trespass is addressed under subpart I of this part.

§ 166.701 How will the BIA determine whether the activities of a permittee under a permit are in compliance with the terms of the permit?

Unless the permit provides otherwise, we may enter the range unit at any reasonable time, without prior notice, to protect the interests of the Indian landowners and ensure that the permittee is in compliance with the operating requirements of the permit.

§ 166.702 Can a permit provide for negotiated remedies in the event of a permit violation?

(a) A permit of tribal land may provide the tribe with certain negotiated remedies in the event of a permit violation, including the power to terminate the permit. A permit of individually-owned Indian land may provide the individual Indian landowners with similar remedies, so long as the permit also specifies the manner in which those remedies may be exercised by or on behalf of the Indian landowners. Any notice of violation must be provided by written notice.

(b) The negotiated remedies described in paragraph (a) of this section will apply in addition to the cancellation remedy available to us under § 166.705(c) of this subpart. If the permit specifically authorizes us to exercise any negotiated remedies on behalf of the Indian landowners, the exercise of such remedies may substitute for cancellation.

(c) A permit may provide for permit disputes to be resolved in tribal court or any other court of competent jurisdiction, or through arbitration or some other alternative dispute resolution method. We may not be bound by decisions made in such forums, but we will defer to any ongoing proceedings, as appropriate, in deciding whether to exercise any of the remedies available to us under § 166.705 of this subpart.

§ 166.703 What happens if a permit violation occurs?

(a) If an Indian landowner notifies us that a specific permit violation has occurred, we will initiate an appropriate investigation within five business days of that notification.

(b) If we determine that a permit violation has occurred based on facts known to us, we will provide written notice to the permittee and the sureties of the violation within five business days.

§ 166.704 What will a written notice of a permit violation contain?

The written notice of a permit violation will provide the permittee with ten days from the receipt of the written notice to:

(a) Cure the permit violation and notify us that the violation is cured.

(b) Explain why we should not cancel the permit; or

(c) Request in writing additional time to complete corrective actions. If additional time is granted, we may require that certain corrective actions be taken immediately.

§ 166.705 What will the BIA do if a permit violation is not cured within the required time period?

(a) If the permittee does not cure a violation within the required time period, we will consult with the Indian landowners, as appropriate, and determine whether:

(1) The permit should be canceled by us under paragraph (c) of this section and §§ 166.706 through 166.707 of this subpart;

(2) We should invoke any other remedies available to us under the permit, including collecting on any available bond;

(3) The Indian landowners wish to invoke any remedies available to them under the permit; or

(4) The permittee should be granted additional time in which to cure the violation.

(b) If we decide to grant a permittee additional time in which to cure a violation, the permittee must proceed diligently to complete the necessary corrective actions within a reasonable or specified time period from the date on which the extension is granted.

(c) If we decide to cancel the permit, we will send the permittee and its sureties a written notice of cancellation within five business days of that decision. We will also provide actual or constructive notice of a cancellation decision to the Indian landowners, as appropriate. The written notice of cancellation will:

(1) Explain the grounds for cancellation;

(2) Notify the permittee of the amount of any unpaid rent, interest charges, or late payment penalties due under the permit;

(3) Notify the permittee of its right to appeal under Part 2 of this chapter, as modified by § 166.706 of this subpart, including the amount of any appeal bond that must be posted with an appeal of the cancellation decision; and

(4) Order the permittee to vacate the property within 30 days of the date of receipt of the written notice of cancellation, if an appeal is not filed by that time.

§ 166.706 Will the BIA's regulations concerning appeal bonds apply to cancellation decisions involving permits?

(a) The appeal bond provisions in § 2.5 of part 2 of this chapter will not apply to appeals from permit cancellation decisions made under § 166.705 of this subpart. Instead, when we decide to cancel a permit, we may require the permittee to post an appeal bond with an appeal of the cancellation decision. The requirement to post an appeal bond will apply in addition to all of the other requirements in part 2 of this chapter.

(b) An appeal bond should be set in an amount necessary to protect the Indian landowners against financial losses that will likely result from the delay caused by an appeal. Appeal bond requirements will not be separately appealable, but may be contested during the appeal of the permit cancellation decision.

§ 166.707 When will a cancellation of a permit be effective?

A cancellation decision involving a permit will not be effective for 30 days after the permittee receives a written notice of cancellation from us. The cancellation decision will remain ineffective if the permittee files an appeal under § 166.706 of this subpart and part 2 of this chapter, unless the decision is made immediately effective under part 2. While a cancellation decision is ineffective, the permittee must continue to pay rent and comply with the other terms of the permit. If an appeal is not filed in accordance with § 166.706 of this subpart and part 2 of this chapter, the cancellation decision will be effective on the 31st day after the permittee receives the written notice of cancellation from us.

§ 166.708 Can the BIA take emergency action if the rangeland is threatened with immediate, significant, and irreparable harm?

Yes. If a permittee or any other party causes or threatens to cause immediate, significant and irreparable harm to the Indian land during the term of a permit, we will take appropriate emergency action. Emergency action may include trespass proceedings under subpart I of this part, or judicial action seeking immediate cessation of the activity resulting in or threatening the harm. Reasonable efforts will be made to notify the Indian landowners, either

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before or after the emergency action is taken.

§ 166.709 What will the BIA do if a permittee holds over after the expiration or cancellation of a permit?

If a permittee remains in possession of Indian land after the expiration or cancellation of a permit, we will treat the unauthorized use as a trespass. Unless we have reason to believe that the permittee is engaged in negotiations with the Indian landowners to obtain a new permit, we will take action to recover possession of the Indian land on behalf of the Indian landowners, and pursue any additional remedies available under applicable law, including the assessment of civil penalties and costs under subpart I of this part.

Subpart I—Trespass

§ 166.800 What is trespass?

Under this part, trespass is any unauthorized occupancy, use of, or action on Indian agricultural lands. These provisions also apply to Indian agricultural land managed under an agricultural lease or permit under part 162 of this title.

§ 166.801 What is the BIA's trespass policy?

We will:

(a) Investigate accidental, willful, and/or incidental trespass on Indian agricultural land;

(b) Respond to alleged trespass in a prompt, efficient manner;

(c) Assess trespass penalties for the value of products used or removed, cost of damage to the Indian agricultural land, and enforcement costs incurred as a consequence of the trespass.

(d) Ensure that damage to Indian agricultural lands resulting from trespass is rehabilitated and stabilized at the expense of the trespasser.

§ 166.802 Who can enforce this subpart?

(a) The BIA enforces the provisions of this subpart. If the tribe adopts the provisions of this subpart, the tribe will have concurrent jurisdiction to enforce this subpart. Additionally, if the tribe so requests, we will defer to tribal prosecution of trespass on Indian agricultural lands.

(b) Nothing in this subpart shall be construed to diminish the sovereign authority of Indian tribes with respect to trespass.

Notification

§ 166.803 How are trespassers notified of a trespass determination?

(a) Unless otherwise provided under tribal law, when we have reason to believe that a trespass on Indian agricultural land has occurred, within five business days, we or the authorized tribal representative will provide written notice to the alleged trespasser, the possessor of trespass property, any known lien holder, and beneficial Indian landowner, as appropriate. The written notice will include the following:

(1) The basis for the trespass determination;

(2) A legal description of where the trespass occurred;

(3) A verification of ownership of unauthorized property (*e.g.*, brands in the State Brand Book for cases of livestock trespass, if applicable);

(4) Corrective actions that must be taken;

(5) Time frames for taking the corrective actions;

(6) Potential consequences and penalties for failure to take corrective action; and

(7) A statement that unauthorized livestock or other property may not be removed or disposed of unless authorized by us.

(b) If we determine that the alleged trespasser or possessor of trespass property is unknown or refuses delivery of the written notice, a public trespass notice will be posted at the tribal community building, U.S. Post Office, and published in the local newspaper nearest to the Indian agricultural lands where the trespass is occurring.

(c) Trespass notices under this subpart are not subject to appeal under 25 CFR part 2.

§ 166.804 What can I do if I receive a trespass notice?

If you receive a trespass notice, you will within the time frame specified in the notice:

(a) Comply with the ordered corrective actions; or

(b) Contact us in writing to explain why the trespass notice is in error. You may contact us by telephone but any explanation of trespass you wish to provide must be in writing. If we determine that we issued the trespass notice in error, we will withdraw the notice.

§ 166.805 How long will a written trespass notice remain in effect?

A written trespass notice will remain in effect for the same conduct identified in that written notice for a period of one year from the date of receipt of the written notice by the trespasser.

Actions

§ 166.806 What actions does the BIA take against trespassers?

If the trespasser fails to take the corrective action specified by us, we may take one or more of the following actions, as appropriate:

(a) Seize, impound, sell or dispose of unauthorized livestock or other property involved in the trespass. We may keep such property we seize for use as evidence.

(b) Assess penalties, damages, and costs, under § 166.812 of this subpart.

§ 166.807 When will we impound unauthorized livestock or other property?

We will impound unauthorized livestock or other property under the following conditions:

(a) Where there is imminent danger of severe injury to growing or harvestable crop or destruction of the range forage.

(b) When the known owner or the owner's representative of the unauthorized livestock or other property refuses to accept delivery of a written notice of trespass and the unauthorized livestock or other property are not removed within the period prescribed in the written notice.

(c) Any time after five days of providing notice of impoundment if you failed to correct the trespass.

§ 166.808 How are trespassers notified if their unauthorized livestock or other property are to be impounded?

(a) If the trespass is not corrected in the time specified in the initial trespass notice, we will send written notice of our intent to impound unauthorized livestock or other property to the unauthorized livestock or property owner or representative, and any known lien holder of the unauthorized livestock or other property.

(b) If we determine that the owner of the unauthorized livestock or other property or the owner's representative is unknown or refuses delivery of the written notice, we will post a public notice of intent to impound at the tribal community building, U.S. Post Office, and published in the local newspaper nearest to the Indian agricultural lands where the trespass is occurring.

(c) After we have given notice as described above, we will impound unauthorized livestock or other property without any further notice.

§ 166.809 What happens after my unauthorized livestock or other property are impounded?

Following the impoundment of unauthorized livestock or other property, we will provide notice that we will sell the impounded property as follows:

(a) We will provide written notice of the sale to the owner, the owner's representative, and any known lien holder. The written notice must include the procedure by which the impounded property may be redeemed prior to the sale.

(b) We will provide public notice of sale of impounded property by posting at the tribal community building, U.S. Post Office, and publishing in the local newspaper nearest to the Indian agricultural lands where the trespass is occurring. The public notice will include a description of the impounded property, and the date, time, and place of the public sale. The sale date must be at least five days after the publication and posting of notice.

§ 166.810 How do I redeem my impounded livestock or other property?

You may redeem impounded livestock or other property by submitting proof of ownership and paying all penalties, damages, and costs under § 166.812 of this subpart and completing all corrective actions identified by us under § 166.804 of this subpart.

§ 166.811 How will the sale of impounded livestock or other property be conducted?

(a) Unless the owner or known lien holder of the impounded livestock or other property redeems the property prior to the time set by the sale, by submitting proof of ownership and settling all obligations under § 166.804 and § 166.812 of this subpart, the property will be sold by public sale to the highest bidder.

(b) If a satisfactory bid is not received, the livestock or property may be re-offered for sale, returned to the owner, condemned and destroyed, or otherwise disposed of.

(c) We will give the purchaser a bill of sale or other written receipt evidencing the sale.

Penalties, Damages, and Costs

§ 166.812 What are the penalties, damages, and costs payable by trespassers on Indian agricultural land?

Trespassers on Indian agricultural land must pay the following penalties and costs:

(a) Collection of the value of the products illegally used or removed plus a penalty of double their values;

(b) Costs associated with any damage to Indian agricultural land and/or property;

(c) The costs associated with enforcement of the regulations, including field examination and survey, damage appraisal, investigation assistance and reports, witness expenses, demand letters, court costs, and attorney fees;

(d) Expenses incurred in gathering, impounding, caring for, and disposal of livestock in cases which necessitate impoundment under § 166.807 of this subpart; and

(e) All other penalties authorized by law.

§ 166.813 How will the BIA determine the value of forage or crops consumed or destroyed?

We will determine the value of forage or crops consumed or destroyed based upon the average rate received per month for comparable property or grazing privileges, or the estimated commercial value or replacement costs of such products or property.

§ 166.814 How will the BIA determine the value of the products or property illegally used or removed?

We will determine the value of the products or property illegally used or removed based upon a valuation of similar products or property.

§ 166.815 How will the BIA determine the amount of damages to Indian agricultural land?

We will determine the damages by considering the costs of rehabilitation and revegetation, loss of future revenue, loss of profits, loss of productivity, loss of market value, damage to other resources, and other factors.

§ 166.816 How will the BIA determine the costs associated with enforcement of the trespass?

Costs of enforcement may include detection and all actions taken by us through prosecution and collection of damages. This includes field examination and survey, damage appraisal, investigation assistance and report preparation, witness expenses, demand letters, court costs, attorney fees, and other costs.

§ 166.817 What happens if I do not pay the assessed penalties, damages and costs?

Unless otherwise provided by applicable tribal law:

(a) We will refuse to issue you a permit for use, development, or occupancy of Indian agricultural lands; and

(b) We will forward your case for appropriate legal action.

§ 166.818 How are the proceeds from trespass distributed?

Unless otherwise provided by tribal law:

(a) We will treat any amounts recovered under § 166.812 of this subpart as proceeds from the sale of agricultural property from the Indian agricultural land upon which the trespass occurred.

(b) Proceeds recovered under § 166.812 of this subpart may be distributed to:

(1) Repair damages of the Indian agricultural land and property;

(2) Reimburse the affected parties, including the permittee for loss due to the trespass, as negotiated and provided in the permit; and

(3) Reimburse for costs associated with the enforcement of this subpart.

(c) If any money is left over after the distribution of the proceeds described in paragraph (b) of this section, we will return it to the trespasser or, where we cannot identify the owner of the impounded property within 180 days, we will deposit the net proceeds of the sale into the accounts of the landowners where the trespass occurred.

§ 166.819 What happens if the BIA does not collect enough money to satisfy the penalty?

We will send written notice to the trespasser demanding immediate settlement and advising the trespasser that unless settlement is received within five business days from the date of receipt, we will forward the case for appropriate legal action. We may send a copy of the notice to the Indian landowner, permittee, and any known lien holders.

Subpart J—Agriculture Education, Education Assistance, Recruitment, and Training

§ 166.900 How are the Indian agriculture education programs operated?

(a) The purpose of the Indian agriculture education programs is to recruit and develop promising Indian and Alaska Natives who are enrolled in secondary schools, tribal or Alaska Native community colleges, and other post-secondary schools for employment as professional resource managers and other agriculture-related professionals by approved organizations.

(b) We will operate the student educational employment program as part of our Indian agriculture education programs in accordance with the provisions of 5 CFR 213.3202(a) and (b).

(c) We will establish an education committee to coordinate and carry out the agriculture education assistance programs and to select participants for all agriculture education assistance programs. The committee will include at least one Indian professional educator in the field of natural resources or agriculture, a personnel specialist, a representative of the Intertribal Agriculture Council, and a natural resources or agriculture professional

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from the BIA and a representative from American Indian Higher Education Consortium. The committee's duties will include the writing of a manual for the Indian and Alaska Native Agriculture Education and Assistance Programs.

(d) We will monitor and evaluate the agriculture education assistance programs to ensure that there are adequate Indian and Alaska Native natural resources and agriculture-related professionals to manage Indian natural resources and agriculture programs by or for tribes and Alaska Native Corporations. We will identify the number of participants in the intern, student educational employment program, scholarship, and outreach programs; the number of participants who completed the requirements to become a natural resources or agriculture-related professional; and the number of participants completing advanced degree requirements.

§ 166.901 How will the BIA select an agriculture intern?

(a) The purpose of the agriculture intern program is to ensure the future participation of trained, professional Indians and Alaska Natives in the management of Indian and Alaska Native agricultural land. In keeping with this purpose, we will work with tribes and Alaska Natives:

(1) To obtain the maximum degree of participation from Indians and Alaska Natives in the agriculture intern program;

(2) To encourage agriculture interns to complete an undergraduate degree program in natural resources or agriculture-related field; and

(3) To create an opportunity for the advancement of natural resources and agriculture-related technicians to professional resource management positions with the BIA, other federal agencies providing an agriculture service to their respective tribe, a tribe, or tribal agriculture enterprise.

(b) Subject to restrictions imposed by agency budgets, we will establish and maintain in the BIA at least 20 positions for the agriculture intern program. All Indians and Alaska Natives who satisfy the qualification criteria may compete for positions.

(c) Applicants for intern positions must meet the following criteria:

(1) Be eligible for Indian preference as defined in 25 CFR part 5;

(2) Possess a high school diploma or its recognized equivalent;

(3) Be able to successfully complete the intern program within a three-year period; and

(4) Possess a letter of acceptance to an accredited post-secondary school or demonstrate that one will be sent within 90 days.

(d) We will advertise vacancies for agriculture intern positions semi-annually, no later than the first day of April and October, to accommodate entry into school.

(e) In selecting agriculture interns, we will seek to identify candidates who:

(1) Have the greatest potential for success in the program;

(2) Will take the shortest time period to complete the intern program; and

(3) Provide the letter of acceptance required by paragraph (c)(4) of this section.

(f) Agriculture interns must:

(1) Maintain full-time status in an agriculture-related curriculum at an accredited post-secondary school;

(2) Maintain good academic standing;

(3) Enter into an obligated service agreement to serve as a professional resource manager or agriculture-related professional with an approved organization for one year in exchange for each year in the program; and

(4) Report for service with the approved organization during any break in attendance at school of more than three weeks.

(g) The education committee will evaluate annually the performance of the agriculture intern program participants against requirements to ensure that they are satisfactorily progressing toward completion of program requirements.

(h) We will pay all costs for tuition, books, fees, and living expenses incurred by an agriculture intern while attending an accredited post-secondary school.

§ 166.902 How can I become an agriculture educational employment student?

(a) To be considered for selection, applicants for the student educational employment program must:

(1) Meet the eligibility requirements in 5 CFR part 308; and

(2) Be accepted into or enrolled in a course of study at an accredited post-secondary institution which grants degrees in natural resources or agriculture-related curricula.

(b) Student educational employment steering committees established at the field level will select program participants based on eligibility requirements without regard to applicants' financial needs.

(c) A recipient of assistance under the student educational employment program will be required to enter into an obligated service agreement to serve as a natural resources or agriculture-related professional with an approved organization for one year in exchange for each year in the program.

(d) We will pay all costs of tuition, books, fees, and transportation to and from the job site to school, for an Indian or Alaska Native student who is selected for the cooperative education program.

§ 166.903 How can I get an agriculture scholarship?

(a) We may grant agriculture scholarships to Indians and Alaska Natives enrolled as full-time students in accredited post-secondary and graduate programs of study in natural resources and agriculture-related curricula.

(b) The education committee established in § 166.900(c) of this subpart will select program participants based on eligibility requirements stipulated in paragraphs (e) through (g) of this section without regard to applicants' financial needs or past scholastic achievements.

(c) Recipients of scholarships must reapply annually to continue to receive funding beyond the initial award period. Students who have received scholarships in past years, are in good academic standing, and have been recommended for continuation by their academic institution will be given priority over new applicants for scholarship assistance.

(d) The amount of scholarship funds an individual is awarded each year will be contingent upon the availability of funds appropriated each fiscal year and is subject to yearly change.

(e) Preparatory scholarships may be available for a maximum of three academic years of general, undergraduate course work leading to a degree in natural resources or agriculture-related curricula and may be awarded to individuals who:

(1) Possess a high school diploma or its recognized equivalent; and

(2) Are enrolled and in good academic standing at an acceptable post-secondary school.

(f) Undergraduate scholarships are available for a maximum of three academic years and may be awarded to individuals who:

(1) Have completed a minimum of 55 semester hours toward a bachelor's degree in a natural resources or agriculture-related curriculum; and

(2) Have been accepted into a natural resource or agriculture-related degree-granting program at an accredited college or university.

(g) Graduate scholarships are available for a maximum of five academic years for individuals selected into the graduate program of an accredited college or university that grants advanced degrees in natural resources or agriculture-related fields.

(h) A recipient of assistance under the scholarship program must enter into an obligated service agreement to serve as a natural resources or agriculture-related professional with the BIA, other federal agency providing assistance to their respective tribe, a tribe, tribal agriculture enterprise, or an ANCSA Corporation for one year for each year in the program.

(i) We will pay all scholarships approved by the education committee established in § 166.900 of this subpart for which funding is available.

§ 166.904 What is agriculture education outreach?

(a) We will establish and maintain an agriculture education outreach program for Indian and Alaska Native youth that will:

(1) Encourage students to acquire academic skills needed to succeed in post-secondary mathematics and science courses;

(2) Promote agriculture career awareness;

(3) Involve students in projects and activities oriented to agriculture related professions early so students realize the need to complete required pre-college courses; and

(4) Integrate Indian and Alaska Native agriculture program activities into the education of Indian and Alaska Native students.

(b) We will develop and carry out the program in consultation with appropriate community education organizations, tribes, ANCSA Corporations, Alaska Native organizations, and other federal agencies providing agriculture services to Indians.

(c) The education committee established under § 166.900(c) of this subpart will coordinate and implement the program nationally.

§ 166.905 Who can get assistance for postgraduate studies?

(a) The purpose of the postgraduate studies program is to enhance the professional and technical knowledge of Indian and Alaska Native natural resource and agriculture-related professionals working for an approved organization so that the best possible service is provided to Indian and Alaska Natives.

(b) We may pay the cost of tuition, fees, books, and salary of Alaska Natives and Indians who are employed by an approved organization and who wish to pursue advanced levels of education in natural resource or agriculture-related fields.

(c) The goal of the advanced study program is to encourage participants to obtain additional academic credentials such as a degree or diploma in a natural resources or agriculture-related field. Requirements of the postgraduate study program are:

(1) The duration of course work cannot be less than one semester or more than three years; and

(2) Students in the postgraduate studies program must meet performance standards as required by the graduate school offering the study program.

(d) Program applicants must submit application packages to the education committee. At a minimum, such packages must contain a resume and an endorsement signed by the applicant's supervisor clearly stating the need for and benefits of the desired training.

(e) The education committee must use the following criteria to select participants:

(1) Need for the expertise sought at both the local and national levels;

(2) Expected benefits, both locally and nationally; and

(3) Years of experience and the service record of the employee.

(f) Program participants will enter into an obligated service agreement to serve as a natural resources or agriculture-related professional with an approved organization for one year for each year in the program. We may reduce the obligated service requirement if the employee receives supplemental funding such as research grants, scholarships, or graduate stipends and, as a result, reduces the need for financial assistance under this part. If the obligated service agreement is breached, we will collect the amount owed us in accordance with § 166.910 of this subpart.

§ 166.906 What can happen if we recruit you after graduation?

(a) The purpose of the post graduation recruitment program is to recruit Indian and Alaska Native natural resource and trained agriculture technicians into the agriculture programs of approved organizations.

(b) We may assume outstanding student loans from established lending institutions of Indian and Alaska Native natural resources and agriculture technicians who have successfully completed a post-secondary natural resources or agriculture-related curriculum at an accredited institution.

(c) Indian and Alaska Natives receiving benefits under this program will enter into an obligated service agreement in accordance with § 166.901 of this subpart. Obligated service required under this program will be one year for every $5,000 of student loan debt repaid.

(d) If the obligated service agreement is breached, we will collect student loan(s) in accordance with § 166.910 of this subpart.

§ 166.907 Who can be an intern?

(a) Natural resources or agriculture personnel working for an approved organization may apply for an internship within agriculture-related programs of agencies of the Department of the Interior or other federal agencies providing an agriculture service to their respective reservations.

(b) Natural resources or agriculture-related personnel from other Department of the Interior agencies may apply through proper channels for "internships" within the BIA's agriculture programs. With the consent of a tribe or Alaska Native organization, the BIA can arrange for an Intergovernmental Personnel Act assignment in tribal or Alaska Native agriculture programs.

(c) Natural resources and agriculture personnel from agencies not within the Department of the Interior may apply, through proper agency channels and pursuant to an interagency agreement, for an "internship" within the BIA and, with the consent of a tribe or Alaska Native organization, we can facilitate an Intergovernmental Personnel Act assignment in a tribe, tribal agriculture enterprise, or Alaska Native Corporation.

(d) Natural resources or agriculture personnel from a tribe, tribal agriculture enterprise, or Alaska Native Corporation may apply, through proper channels and pursuant to a cooperative agreement, for an internship within another tribe, tribal forest enterprise, or ANCSA Corporation agriculture program.

(e) The employing agency of participating federal employees will provide for the continuation of salary and benefits.

(f) The host agency for participating tribal, tribal agriculture enterprise, or Alaska Native Corporation agriculture employees will provide for salaries and benefits.

(g) A bonus pay incentive, up to 25 percent (%) of the intern's base salary, may be provided to intergovernmental interns at the conclusion of the internship period. Bonus pay incentives will be at the discretion of and funded by the host organization and must be conditioned upon the host agency's documentation of the intern's superior performance, in accordance with the agency's performance standards, during the internship period.

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§ 166.908 Who can participate in continuing education and training?

(a) The purpose of continuing education and training is to establish a program to provide for the ongoing education and training of natural resources and agriculture personnel employed by approved organizations. This program will emphasize continuing education and training in three areas:

(1) Orientation training including tribal-federal relations and responsibilities;

(2) Technical agriculture education; and

(3) Developmental training in agriculture-based enterprises and marketing.

(b) We will maintain an orientation program to increase awareness and understanding of Indian culture and its effect on natural resources management and agriculture practices and on federal laws that effect natural resources management and agriculture operations and administration in the Indian agriculture program.

(c) We will maintain a continuing technical natural resources and agriculture education program to assist natural resources managers and agriculture-related professionals to perform natural resources and agriculture management on Indian land.

(d) We will maintain an agriculture land-based enterprise and marketing training program to assist with the development and use of Indian and Alaska Native agriculture resources.

§ 166.909 What are my obligations to the BIA after I participate in an agriculture education program?

(a) Individuals completing agriculture education programs with an obligated service requirement may be offered full time permanent employment with an approved organization to fulfill their obligated service within 90 days of the date all program education requirements have been completed. If employment is not offered within the 90-day period, the student will be relieved of obligated service requirements. Not less than 30 days before the start of employment, the employer must notify the participant of the work assignment, its location and the date work must begin. If the employer is other than the BIA, the employer must also notify us.

(b) Employment time that can be credited toward obligated service requirement will begin the day after all program education requirements have been completed, with the exception of the agriculture intern program which includes the special provisions outlined in § 166.901(f)(4) of this subpart. The minimum service obligation period will be one year of full time employment.

(c) The employer has the right to designate the location of employment for fulfilling the service obligation.

(d) A participant in any of the agriculture education programs with an obligated service requirement may, within 30 days of completing all program education requirements, request a deferment of obligated service to pursue postgraduate or post-doctoral studies. In such cases, we will issue a decision within 30 days of receipt of the request for deferral. We may grant such a request; however, deferments granted in no way waive or otherwise affect obligated service requirements.

(e) A participant in any of the agriculture education programs with an obligated service requirement may, within 30 days of completing all program education requirements, request a waiver of obligated service based on personal or family hardship. We may grant a full or partial waiver or deny the request for wavier. In such cases, we will issue a decision within 30 days of receiving the request for waiver.

§ 166.910 What happens if I do not fulfill my obligation to the BIA?

(a) Any individual who accepts financial support under agriculture education programs with an obligated service requirement, and who does not accept employment or unreasonably terminates employment must repay us in accordance with the following table:

If you are...	Then the costs that you must repay are...	And then the costs that you do not need to repay are...
(1) Agriculture intern	Living allowance, tuition, books, and fees received while occupying position plus interest.	Salary paid during school breaks or when recipient was employed by an approved organization.
(2) Cooperative education	Tuition, books, and fees plus interest.	
(3) Scholarship	Costs of scholarship plus interest.	
(4)Post graduation recruitment.	All student loans assumed by us under the program plus interest.	
(5) Postgraduate studies	Living allowance, tuition, books, and fees received while in the program plus interest.	Salary paid during school breaks or when recipient was employed by an approved organization.

(b) For agriculture education programs with an obligated service requirement, we will adjust the amount required for repayment by crediting toward the final amount of debt any obligated service performed before breach of contract.

Subpart K—Records

§ 166.1000 Who owns the records associated with this part?

(a) Records are the property of the United States if they:

(1) Are made or received by a tribe or tribal organization in the conduct of a federal trust function under 25 U.S.C. § 450f *et seq.*, including the operation of a trust program; and

(2) Evidence the organization, functions, policies, decisions, procedures, operations, or other activities undertaken in the performance of a federal trust function under this part.

(b) Records not covered by paragraph (a) of this section that are made or received by a tribe or tribal organization in the conduct of business with the Department of the Interior under this part are the property of the tribe.

§ 166.1001 How must a records associated with this part be preserved?

(a) Any organization, including tribes and tribal organizations, that have records identified in § 166.1000(a) of this part must preserve the records in accordance with approved Departmental records retention procedures under the Federal Records Act, 44 U.S.C. Chapters 29, 31 and 33. These records and related records management practices and safeguards required under the Federal Records Act are subject to inspection by the Secretary and the Archivist of the United States.

(b) A tribe or tribal organization should preserve the records identified in § 166.1000(b) of this part for the period of time authorized by the Archivist of the United States for similar Department of the Interior records in accordance with 44 U.S.C. Chapter 33. If a tribe or tribal organization does not preserve records associated with its conduct of business with the Department of the Interior under this part, it may prevent the tribe or tribal organization from being able to adequately document essential transactions or furnish information necessary to protect its legal and financial rights or those of persons directly affected by its activities.

Dated: December 21, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

[FR Doc. 01–1419 Filed 1–19–01; 8:45 am]

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Federal Register

Monday,
January 22, 2001

Part X

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 441 and 483
Medicaid Program; Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21; Final Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 441 and 483

[HCFA–2065–IFC]

RIN 0938–AJ96

Medicaid Program; Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period establishes a definition of a "psychiatric residential treatment facility" that is not a hospital and that may furnish covered Medicaid inpatient psychiatric services for individuals under age 21. This rule also sets forth a Condition of Participation (CoP) that psychiatric residential treatment facilities that are not hospitals must meet to provide, or to continue to provide, the Medicaid inpatient psychiatric services benefit to individuals under age 21. Specifically, this rule establishes standards for the use of restraint or seclusion that psychiatric residential treatment facilities must have in place to protect the health and safety of residents. This CoP acknowledges a resident's right to be free from restraint or seclusion except in emergency safety situations. We are requiring psychiatric residential treatment facilities to notify a resident (and, in the case of a minor, his or her parent(s) or legal guardian(s)) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that occurs while the resident is in the program. We believe these added requirements will protect residents against the inappropriate use of restraint or seclusion.

DATES: *Effective date:* These regulations are effective on March 23, 2001.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 23, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2065–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or C5–15–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to those addresses may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2065–IFC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690–7890).

For comments that relate to information collection requirements, mail a copy of comments to: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Julie Brown, HCFA–2065–IFC.

FOR FURTHER INFORMATION CONTACT: Mary Kay Mullen, (410)786–5480.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902(a)(9)(A) of the Social Security Act (the Act) requires the State health agency or other State medical agency to establish and maintain health standards for private and public institutions in which recipients of medical assistance, under the State plan, may receive care or services. Section 1905(h) of the Act defines the term "inpatient psychiatric hospital services for individuals under age 21" as inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital or in another inpatient setting that the Secretary has specified in regulations. In this interim final rule, we are defining psychiatric residential treatment facilities as an inpatient setting in conformity with the definition of an institution as set forth in section 1905(h).

The Medicaid program makes Federal funding available for State expenditures under an approved State Medicaid plan for inpatient psychiatric services for eligible individuals under 21 years of age in hospital and nonhospital settings. Nonhospital settings, which we are defining as psychiatric residential treatment facilities (facilities), are rapidly replacing hospitals in treating children and adolescents with psychiatric disorders. These facilities are generally a less restrictive alternative to a hospital for treating children and adolescents whose illnesses are less acute but who still require a residential environment.

On November 17, 1994, we published in the **Federal Register** (56 FR 59624) proposed regulations to establish standards for nonhospital psychiatric residential treatment facilities, to be contained in a new subpart F of 42 CFR part 483. Among the proposed standards was a prohibition on physical restraints and psychoactive drugs for purposes of discipline or convenience, when not required to treat the resident's psychiatric symptoms, or when not specified in the plan of treatment. Also included was a prohibition on the use of involuntary seclusion. Moreover, limitations were proposed on the use of drugs in doses that would interfere with the resident's daily living activities, or the use of drugs to control inappropriate behavior. These drugs would not be used unless they were an integral part of a plan of care directed specifically toward reducing and eventually eliminating that behavior, or when the harmful effects of the behavior clearly outweighed the potential harmful effects of the drugs.

We, as well as the Congress, have grown increasingly concerned about the danger posed to residents in psychiatric residential treatment facilities as a result of improper restraint and seclusion practices. Improper restraint and seclusion practices can lead to serious injury and even death of residents as well as staff. In March 1999, during the first session of the 106th Congress, members of the Senate and House of Representatives introduced three separate bills (S. 736, S. 750 and H.R. 1313) intended to protect individuals from the improper use of restraint or seclusion in Medicare and Medicaid-funded facilities. These bills were incorporated into the enactment of the Children's Health Act of 2000, which was signed by the President on October 17, 2000.

Advocates for persons with mental illness as well as the media have raised the public's awareness of restraint and seclusion practices that can lead to serious injury and death. The *Hartford Courant* (*Courant*), a Connecticut newspaper, published a series of articles in October 1998 citing the results of a

50-state survey that confirmed 142 deaths, that occurred during the previous decade, while or shortly after a patient was restrained or secluded. The first of a series of articles entitled "A Nationwide Pattern of Death," was published October 11, 1998. The survey focused on mental health and mental retardation facilities and group homes nationwide. According to a statistical estimate commissioned by the *Courant* that was conducted by the Harvard Center for Risk Analysis, between 50 and 150 deaths related to the use of restraint or seclusion occur every year across the country. The article further stated that of the 142 restraint-related deaths confirmed by the *Courant's* investigation, ages could be confirmed in 114 cases, and that more than 26 percent of those were children—nearly twice the proportion they represent in mental health institutions.

In 1999, at the request of the Congress, the General Accounting Office (GAO) conducted a study that focused on individuals receiving services in mental health and mental retardation facilities and group homes nationwide that receive public funding, primarily from the Medicare and Medicaid programs. Some objectives of the study were to determine the dangers of restraint and seclusion, the extent to which restraint and seclusion are used in inpatient and residential treatment facilities for individuals with mental illness or mental retardation, and the number of related injuries and deaths from their use. To gain at least a partial indication of the scope of the problem, the GAO obtained data on the number of deaths related to restraint or seclusion investigated by the Protection and Advocacy agencies in all 50 states and the District of Columbia in fiscal year 1998. On the basis of the partial information available from the 51 agencies, the GAO identified 24 deaths associated with restraint or seclusion during fiscal year 1998.

In September of 1999, the GAO issued a report titled "Improper Restraint or Seclusion Use Places People at Risk" (GAO/HEHS–99–176), which concluded that the improper use of restraint and seclusion can be dangerous to both people receiving treatment and to staff. The report stated that the full extent of related injuries and deaths from improper restraint or seclusion is unknown because there is no comprehensive reporting system to track injuries and deaths, or to track the rates of restraint or seclusion use by facility. In addition, according to the report, most facilities are not even required to report these data to oversight agencies. The report stated that because reporting is so fragmentary, there may be many more deaths related to the use of restraint or seclusion than are being reported.

The *Courant* series and the GAO report underscore our concern for the safety and welfare of children and adolescents when restraints or seclusion are employed in residential treatment facilities. We have therefore developed standards that describe the conditions under which restraint or seclusion can be used; that set an upper limit on the permissible length of time for each instance of restraint or seclusion use; that require education and training of staff, including the safe use of restraint and the safe use of seclusion; that require staff to directly monitor residents who are restrained or secluded for the entire duration of the procedure; and that prohibit the simultaneous use of restraints and seclusion.

On July 2, 1999, we published in the **Federal Register** an interim final rule that addressed, in part, the use of restraint and seclusion in hospitals, including psychiatric hospitals, entitled "Medicare and Medicaid Programs; Hospital Conditions of Participation; Patients' Rights" (64 FR 36070). We conducted substantial academic research on the issue of restraint and seclusion, which was discussed in the referenced hospital interim final rule. Although the research primarily involved elderly patients, its findings, we believe, are also relevant to individuals under age 21. As we said there: "Research indicates that the potential for injury or harm with the use of restraint is a reality. In a 1989 article published in the *Journal of the American Geriatrics Society*, Evans and Strumpf pointed to an association between the use of physical restraint and death during hospitalization (Evens, LK and Strumpf, NE: Tying down the elderly: A review of the literature on physical restraint. J Am Geriatr Soc (1989) 37:65–74; also see Robbins, LJ, Boyko E, Lane, J, et al.: Binding the elderly: A prospective study of the use of mechanical restraint in an acute care hospital. J Am Geriatr Soc (1987) 35:290; Frengley, JD and Mion, LC: Incidence of physical restraints on acute general medical wards. J Am Geriatr Soc (1986) 34:565; Strumpf, NE and Evans, LK: Physical restraint of the hospitalized elderly: Perceptions of patients and nurses. Nursing Research (1998) 37:132.) The FDA estimates that at least 100 deaths from the improper use of restraints may occur annually. Mion et al. further noted that 'Some evidence exists that the use of physical restraints is not a benign practice and is associated with adverse effects, such as longer length of hospitalization, higher mortality rates, higher rates of complications, and negative patient reactions. Physical restraints have a detrimental effect on the psychosocial well-being of the patient' (see Mion et al.: A further exploration of the use of physical restraints in hospitalized patients. J Am Geriatr Soc (1989) 37:955; Schafer, A: Restraints and the elderly: When safety and autonomy conflict. Can Med Assoc J (1985) 132:1257–1260.)"

"Research findings on the impact of restraints use have lead to research on and development of alternative methods for handling the behaviors and symptoms that historically prompted the application of restraint. However, various studies provide evidence that restraint is still being used when alternate solutions are available (see Donat, DC: Impact of a mandatory behavior consultation on seclusion/restraint utilization in psychiatric hospitals. J Behav Ther Exp Psychiatry (1998 March) 29:1, 13–9; Dunbar, J: Making restraint-free care work. Provider (1997 May) 75–76, 79; and Moss RJ: Ethics of mechanical restraints. Hasting Center Report (1991 Jan–Feb) 21 (1):22–25.)"

In the preamble of the July 1999 hospital interim final rule, we asked for comments on whether we should apply the hospital behavioral health standards on the use of restraint and seclusion to psychiatric residential treatment facilities that provide inpatient psychiatric services to individuals under age 21, or whether more stringent standards were warranted. Consumer advocacy groups that commented on extending the restraint and seclusion requirements to other types of providers and settings generally agreed that more stringent regulations should be applied with respect to the treatment of children. Their opinion was that the restraint of children and adolescents in these settings presents special hazards and concerns. Those comments will be addressed more specifically in the hospital final rule. Additionally, the 1999 GAO report described a study sponsored by the Center for Mental Health Services which indicated that there are higher restraint rates for children, including one State in which children in State-run facilities were restrained four times more frequently than adults. This report also noted that children are smaller and weaker than adults, so staff who are used to overpower adults may apply too much preasure or force when restraining children. For all of these reasons, HCFA has included standards in this rule that provide greater protection than those in

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existence or required by the Children's Health Act of 2000.

Generally, the requirements set forth in this rule governing the use of restraint and seclusion are consistent with both the November 1994 proposed rule and the July 1999 hospital interim final rule. Moreover, this rule also meets the specific requirements of section 3207 of the Children's Health Act of 2000 (Pub. L. 106–310) which requires that health care facilities receiving support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from any restraints or involuntary seclusion imposed for purposes of discipline or convenience. Specifically, section 591(c) of the Children's Health Act permits the Secretary to issue regulations that afford residents greater protections regarding restraint and seclusion than the standards published in the new law. Consistent with this section, this rule provides greater protections than those required in section 3207.

Psychiatric residential treatment facilities are fast replacing hospitals in providing long-term mental health services to children and adolescents, a highly vulnerable population. The dangers associated with the inappropriate use of restraint and seclusion, especially with this population were well documented in the GAO Report and the *Courant* series. According to the GAO Report, children are subjected to restraint and seclusion at higher rates than adults and are at greater risk of injury. Based on the mounting evidence of harm that can result from the use of restraint and seclusion, we are being more prescriptive in the way our restraint and seclusion standards are applied in psychiatric residential treatment facilities.

II. Provisions of the Interim Final Rule Effect of This Rule on the Survey and Certification Requirements

This interim final rule implements only one of the conditions of participation (CoPs) set forth in our November 1994 proposed rule. We are not implementing the remainder of the CoPs in that proposed rule at this time because many of the comments we received on that proposed rule are still under evaluation. We plan to address the remainder of the CoPs in our November 1994 proposed rule in a separate rule in the future. As discussed below, we are moving forward with this CoP because evidence indicates a pressing need for the promulgation and enforcement of restraint and seclusion rules for psychiatric residential treatment facilities.

Requiring psychiatric residential treatment facilities to meet these CoPs will require us to develop additional survey protocols and implementing guidelines to enforce these new requirements. We will solicit public comment on these survey protocols. Until such protocols are issued, we are requiring each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 under a State plan to attest, in writing, that the facility is in compliance with the standards set forth in this rule governing the use of restraint and seclusion. This attestation must be signed by the facility director. In addition, we are requiring the facility to provide the State Medicaid agency with its attestation of compliance. Since the facility will need time to implement these restraint and seclusion standards before it can come into compliance, we are allowing the facility 120 days from the effective date of this interim final rule to provide the State Medicaid agency with its attestation of compliance.

We will work with the States to develop a process for sampling psychiatric residential treatment facilities to validate their attestations of compliance with the restraint and seclusion standards.

This interim final rule establishes a definition of a psychiatric residential treatment facility as a facility other than a hospital that provides inpatient psychiatric services and sets forth a CoP entitled "Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21." This CoP is in addition to the existing regulatory requirements for these facilities in 42 CFR 441.151 through 441.182, which specify requirements applicable if a State plan provides for inpatient psychiatric services to individuals under age 21.

Section 441.151 General Requirements

This regulation amends § 441.151 by redesignating existing paragraphs, by adding explicit reference to residential treatment facilities, and by adding a new paragraph (b) to establish a CoP in part 483, subpart G, that facilities must meet in order to provide these services.

Section 483.352 Definitions

We have included in this section, definitions of terms as they apply to the standards in this rule governing the use of restraint and seclusion in psychiatric residential treatment facilities.

The definitions we have employed for "mechanical restraint" and "personal restraint" in this rule are modeled on the hospital definition of "restraint" codified in § 482.13(f)(1). In this rule, we distinguish between "personal" and "mechanical" restraint to clarify that mechanical restraint means any device attached or adjacent to a person's body, while personal restraint means the application of physical force on a person's body without the use of any device.

Section 483.354 General Requirements for Psychiatric Residential Treatment Facilities

This section clarifies that in addition to the requirements specified in this rule, psychiatric residential treatment facilities must meet the requirements in §§ 441.151 through 441.182 of this chapter.

Section 483.356 Protection of Residents

The purpose of this CoP is to protect residents in psychiatric residential treatment facilities from the inappropriate use of restraint or seclusion by addressing the right of each resident to be free from restraint or seclusion, in any form, imposed as a means of coercion, discipline, convenience, or retaliation.

An example of the inappropriate use of seclusion or restraint for purposes of coercion would be the use of seclusion or restraint with a resident whose behavior would not require its use, and who is not endangering others, but where seclusion or restraint is being used until the resident takes prescribed medications or attends a required group therapy session. We are seeking public comment on the use of the term coercion.

The CoP provides for the use of restraint or seclusion only in emergency safety situations to ensure the safety of the resident or others, and only until the emergency safety situation ends. An order for restraint or seclusion cannot be issued as a standing order. We also are prohibiting the simultaneous use of restraint and seclusion in psychiatric residential treatment facilities. Combining a mechanical restraint intervention with isolation (seclusion) is extremely restrictive and dangerous.

In § 483.356(c) we are requiring each facility to inform both the resident and, in the case of a minor, his or her parent(s) or legal guardian(s) of its policy regarding the use of restraint or seclusion. To comply with Executive Order 13166 (Improving Access to

Services for Persons with Limited English Proficiency) which was issued on August 11, 2000, each facility is required to communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and that, when necessary, interpreters or translators are provided. We believe that the resident (and, in the case of a minor, the parent(s) or legal guardian(s)) must be informed of the facility's restraint and seclusion policy at the time of admission to foster the selection of a provider best suited to meet the physical and mental health needs of the resident. We are also requiring the facility to provide a copy of the facility's policy to the resident, and if a minor, a copy to both the resident and the resident's parent(s) or legal guardian(s). The facility's policy must provide the information needed for contacting the State Protection and Advocacy Organization.

Section 483.358 Orders for the Use of Restraint or Seclusion

Under this new standard, restraint or seclusion may be imposed only in emergency safety situations.

This standard provides that only a board-certified psychiatrist, or a licensed physician with specialized training and experience in diagnosing and treating mental disorders, may order restraint or seclusion in emergency safety situations. This person must be the resident's treatment team physician, if available. When he or she is not available, the physician covering for the treatment team physician may order restraint or seclusion. The covering physician must meet these same requirements for training and experience.

We are limiting the authority to order the use of restraint and seclusion in psychiatric residential treatment facilities to a board-certified psychiatrist or a licensed physician with specialized training and experience in diagnosing and treating mental disorders. Our requirement that only a board-certified psychiatrist or a licensed physician may order restraint or seclusion is consistent with existing physician admission and certification of need for services requirements applicable if a State provides inpatient psychiatric services to individuals under age 21 in psychiatric facilities. Regulatory requirements at 42 CFR part 441, subpart D and part 456, subpart D require that inpatient psychiatric services for individuals under age 21 be provided under the direction of a physician, and that a physician must certify, in writing, that inpatient psychiatric services are necessary in the setting in which they will be provided.

Any order for restraint or seclusion must be the least restrictive intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff and must be limited to no longer than the duration of the emergency safety situation. If the physician is not present in the facility to order the use of restraint or seclusion, we are requiring in § 483.358(d) that a registered nurse obtain the physician's verbal order at the time the emergency safety intervention is initiated by staff. The physician's verbal order must be followed with the physician's signature verifying the verbal order. The ordering physician must be available to staff at least by phone for the duration of the restraint or seclusion to ensure the resident's safety.

The time limits for restraint or seclusion orders in this rule are consistent with the July 1999 hospital interim final rule: no more than 4 hours for residents ages 18 to 21, 2 hours for residents ages 9 to 17, and 1 hour for residents under age 9. We are soliciting comments on these time limits.

In § 483.358, we are also requiring that within 1 hour of the initiation of an emergency safety intervention, a face-to-face assessment of the physical and psychological well-being of the resident be conducted. We believe this assessment is necessary to ensure the safety of the resident during and immediately after he or she is restrained or secluded. We believe that requiring that this assessment be performed by a physician would be unrealistic because unlike hospitals, a psychiatric residential treatment facility may not have a physician present 24 hours a day. Therefore, when a physician is not present, we are allowing a clinically qualified registered nurse trained in the use of emergency safety interventions to perform the face-to-face assessment. Both the face-to-face assessment and the restraint or seclusion order must be documented in the resident's record by staff involved in the emergency safety intervention before the end of their shifts. The ordering physician must sign the order as soon as possible.

Section 483.360 Consultation With Treatment Team Physician

If the physician who orders the use of restraint or seclusion is not part of the resident's treatment team, the facility must consult with the resident's treatment team physician as soon as possible. We believe it is important that the team physician be made aware of any circumstances that have disrupted the physical or psychological well-being of the resident as soon as possible so that the team physician can evaluate the situation(s) that required the resident to be restrained or secluded and make appropriate modifications to the resident's plan of treatment. We are requiring documentation in the resident's record that the treatment team physician was contacted.

Section 483.362 Monitoring of the Resident in and Immediately After Restraint

We are requiring that clinical staff trained in the use of emergency safety interventions be physically present, continually assessing and monitoring the resident in restraint. If the emergency safety situation continues beyond the time limits of the order, a registered nurse must immediately contact the ordering physician in order to receive further instructions. A physician or registered nurse must evaluate the resident immediately after the restraint is removed. We believe these requirements will futher ensure resident safety.

Section 483.364 Monitoring of the Resident in and Immediately After Seclusion

We are requiring a resident in seclusion to be continually monitored and assessed by clinical staff, trained in the use of emergency safety interventions and that the staff monitoring the resident must be physically present in or immediately outside the seclusion room to ensure the safety of the resident. Video monitoring of the resident in seclusion will not meet this requirement because such monitoring cannot determine if a resident is experiencing a medical emergency such as cardiac arrest or asphyxiation.

This standard also specifies the characteristics of a room used for seclusion, including the requirements that the interior of the seclusion room be fully visible to staff and be free of any potentially hazardous conditions. We also are requiring that a physician or registered nurse evaluate the resident immediately after the resident is removed from seclusion. As stated in the discussion of § 483.262, we believe these requirements will ensure resident safety.

Section 483.366 Notification of Parent(s) or Legal Guardian(s)

We are requiring the facility to notify the parent(s) or legal guardian(s) whenever a resident who is a minor (as defined in this subpart) is restrained or

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secluded. Notification must be made as soon as possible after the initiation of each emergency safety intervention and must be documented in the resident's record.

Section 483.368 Application of Time Out

We have defined "time out" in § 483.352 "Definitions" to clarify that it is not a form of seclusion, because the resident in time out is not physically prevented from leaving the time out area. The regulation also clarifies that time out can take place away from other residents (exclusionary) or in the area of activity or in the presence of other residents (inclusionary). This section further requires staff to monitor the resident while he or she is in time out. We considered establishing time limits for time out, but because age, maturity level, health status, and other factors must be considered, we believe that the duration of time out should be based on professional judgement. We welcome comments on this issue.

Section 483.370 Postintervention Debriefings

In order to ensure the safety of resident's and others, we believe it is critical that the facility begin to quickly assess the circumstances that warranted the use of restraint or seclusion and to identify alternatives to reduce or eliminate their use. Therefore, we are requiring that within 24 hours after a resident has been restrained or secluded, staff involved in the emergency safety intervention and the resident, participate in a face-to-face discussion. This discussion can also include other staff and the resident's parent(s) or legal guardian(s) when it is deemed appropriate by the facility. As stated earlier, the facility must ensure that such discussions are conducted in a language that is understood by the resident and the resident's parent(s) or legal guardian(s). The discussion will provide both the resident and staff involved an opportunity to discuss the circumstances that resulted in the use of restraint or seclusion and strategies that all parties could employ to prevent the need for restraint or seclusion. However, we recognize that there may be clinical reasons why it may not be appropriate for a particular staff person involved in the emergency safety intervention to be part of the debriefing. If the presence of a particular staff person jeopardizes the well-being of the resident, it may not be advisable to include that staff person in a debriefing session. Therefore, this rule provides an exception to the requirement for those situations when the presence of a particular staff person jeopardizes the well-being of the resident.

We also are requiring a separate debriefing of staff involved in the emergency safety intervention, and a review by appropriate supervisory and administrative staff of the situation that required the use of restraint or seclusion. However, we are not requiring that this debriefing be face-to-face.

We believe staff debriefings may identify areas requiring modification of administrative policy and procedures pertaining to the use of restraint or seclusion, and may serve to reduce use of restraint or seclusion. We believe the debriefing is critical to ensuring the safety of the resident and others and should take place within 24 hours after the use of restraint or seclusion. We are specifically requesting comments regarding the 24 hour requirement for debriefings involving staff and a resident, as well as debriefings between staff involved in an intervention and appropriate administrative and supervisory staff.

Section 483.372 Medical Treatment for Injuries Resulting from an Emergency Safety Intervention

This standard requires qualified medical personnel to immediately provide medical treatment to a resident who is injured during restraint or seclusion and to document these injuries in the resident's record. Injuries sustained by staff during the restraint or seclusion of a resident must also be documented in the resident's record. We believe this information will be important in assisting the facility in identifying measures to improve the safety of its staff through modifications of existing policies and procedures in the safe use of restraint and seclusion, and modificaion of training programs. We are also requiring staff involved in an emergency safety intervention that results in injury to the resident or staff to meet with supervisory staff to evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

In our November 1994 proposed rule, we proposed a separate condition of participation in § 483.220 entitled "Health Services," which would require each facility to have written transfer agreement(s) in effect with one or more Medicaid-approved hospitals that reasonably ensures a resident will be transferred in a timely manner from the facility to the hospital when transfer is medically necessary for medical care or acute psychiatric care. In addition, we proposed to require that medical and other information needed for care of the resident be exchanged between the institutions, and that medical care be available to each resident 24 hours a day as may be necessary.

We received one comment on the transfer agreement requirement stating that it would be difficult to meet this requirement because most facilities are not affiliated with a hospital and that admission criteria and placement authority rests with each county and insurance provider. We considered the commenter's rationale but believe these agreements are necessary because the use of restraint or seclusion may place a resident at risk for an acute medical crisis. Therefore, we are incorporating in this CoP the requirement that each facility have written transfer agreement(s) or affiliations in place.

Section 483.374 Facility Reporting

According to the GAO report, reporting requirements play a central role in reducing restraint use and improving the safety of individuals in treatment settings. The report further states that in addition to tracking restraint rates, reporting of deaths or other significant events to an independent agency can contribute to improved safety for individuals in treatment settings. The GAO report specifically recommended that we mandate that any hospital or residential facility that treats persons with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds, report promptly to the State licensing body and the appropriate State Protection and Advocacy (P&A) system, all patient deaths and serious injuries among persons with mental illness or mental retardation, and to indicate whether restraint or seclusion was used during or immediately prior to the death or injury.

This interim final rule requires each facility to report a resident's death, any serious injury to a resident as defined in this subpart, and a resident's suicide attempt to the State Medicaid agency and, unless prohibited by State-law, the State-designated P&A system. These serious occurrences involving a resident must be reported to the State Medicaid agency and the State-designated P&A system no later than the close of business the next business day following the occurrence. We are also requiring each facility to document all serious occurrences in the resident's record. In the case of a minor, we are requiring the facility to notify (within 24 hours of the occurrence) the resident's parent(s) or legal guardian(s) in order to provide the parent(s) or legal guardian(s) the opportunity to participate in decisions that may have to

be made regarding the resident. We are requiring staff to document in the resident's record that these contacts were made. It should be noted that the facility reporting requirements in this rule exceed the minimum requirements for facility reporting in section 3207 of the Children's Health Act of 2000.

Regulations titled "Substance Abuse and Mental Health Services Administration; Requirements Applicable to Protection and Advocacy of Individuals with Mental Illness' published by the Department of Health and Human Services on October 15, 1997 (62 FR 53548) grant the P&A system the authority to protect and advocate for the rights of individuals with mental illness and to investigate reports of abuse and neglect in residential facilities that care for and treat individuals with mental illness. The P&As may have access to public and private facilities, residents, and clients, and to facilities' records of individuals with mental illness for the specific purpose of conducting independent investigations of incidents of abuse and neglect.

Under seperate guidance or rulemaking (as appropriate), we will direct the State Medicaid agency to report serious occurrences involving a resident of a psychiatric residential treatment facility to the State survey agency. Section 1902(a)(33)(B) of the Act requires States to survey institutional providers, to certify that they meet our regulations for participation in the Medicaid program under the State plan.

Section 483.376 Education and Training

We are requiring the facility to provide ongoing education and training for staff including training in the safe and appropriate use of restraint and seclusion, as well as alternative nonintrusive behavior modification techniques. We also are requiring that staff be certified in the use of cardiopulmonary resuscitation. This training must be performed by individuals qualified by education, training, and experience. Staff must be able to successfully demonstrate, in practice, all techniques learned related to emergency safety interventions. Staff personnel records must document that this training was successfully completed. Staff must demonstrate their competencies on a semiannual basis. Each facility must make all training programs and materials available for review by HCFA, the State Medicaid agency, and the State survey agency. It should be noted that the education and training requirements in this rule exceed the minimum requirements for education and training in section 3207 of the Children's Health Act of 2000.

We believe this training is essential because restraint and seclusion can be dangerous to both the individual being restrained or secluded and to staff applying restraint or seclusion. Restraining individuals can involve physical struggle, pressure on the chest, or other interruptions in breathing. Having staff trained in alternative techniques to avoid restraint use is important, but staff should also be trained in the proper application and removal of restraints and in how to monitor individuals in restraint or seclusion. The GAO report stated that the Joint Commission on Accreditation of Health Care Facilities (JCAHO) had reviewed 20 restraint-related deaths and found that in 40 percent, the cause of death was asphyxiation, while strangulation, cardiac arrest, or fire had caused the remainder. The report recommended that we require any inpatient or residential facility that treats persons with mental illness to ensure that staff regularly receives training and refresher courses in alternate methods to handle agitated or potentially violent patients and document their receipt of training as a requirement for receiving Medicare and Medicaid funds.

III. Response to Comments on November 1994 Proposed Standards Governing Restraints and Seclusion

In response to our November 1994 proposed rule, we received the following comments, which specifically addressed our proposed standards for restraints. Most of the commenters suggested that our standards address seclusion as well as restraints. We agree with the commenters and have included in this interim final rule standards addressing the use of both seclusion and restraint.

One commenter stated that we should prohibit the use of any type of restraint, including seclusion and time-out rooms. Six commenters stated we should prohibit restraints because they are not therapeutic and if they are allowed for one purpose, they cannot be monitored for other uses.

While we recognize that serious consequences can result from the inappropriate use of restraint or seclusion as discussed previously, we believe that restraint or seclusion used only in an emergency safety situation to ensure the safety of the resident or others is permissible when staff have been properly trained in the safe use of such interventions. Therefore, we have rejected these comments because we believe that the type of intervention used to ensure the safety of a resident or others during an emergency safety situation should be the decision of the professionals involved in the situation.

Three commenters contended that restraints/seclusion should not be included in the plan of care and should be used only when an individual is a danger to himself or others, or is a serious disruption to the therapeutic environment. They also stated that restraints should be used only as long as physical danger continues. We generally agree with these comments, and as discussed previously, have limited the use of restraint or seclusion to emergency safety situations to ensure the safety of the resident or others in the facility. We are permitting the use of restraint or seclusion only until the emergency safety situation has ceased and the safety of the resident or safety of others can be ensured, even if the restraint or seclusion order has not expired. We are specifically prohibiting the use of standing orders for restraint or seclusion in these facilities.

Two commenters suggested deleting "involuntary" before seclusion in the proposed "freedom from abuse standard" and suggested we include seclusion under our "restraint" standard. We are not including a standard entitled "freedom from abuse" in this rule. Rather, we have separately defined restraint, seclusion, and time out in this rule. We believe our definitions of seclusion and time out sufficiently address the difference between "voluntary" and "involuntary seclusion" and therefore address the commenter's concerns.

Seven commenters stated that we should allow seclusion because it is less intrusive and restrictive than restraints, but that we should specify procedures governing its use, including authorization by the attending physician within a brief period before it is imposed, observation at frequent intervals and access to meals and toilet. These commenters stated that parents should be notified within 24 hours and that the treatment team should meet as soon as possible but within 24 hours to discuss any potential modification of the treatment plan based on the conditions that led to seclusion, and that a discussion with the individual should take place following seclusion. As noted previously, we have included standards governing the use of seclusion as well as restraints in this rule including the requirement that a physician must order restraint or seclusion. We are allowing a registered nurse to obtain the physician's verbal order at the time that restraint or

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seclusion is initiated, but are requiring that the physician's verbal order be followed up with the physician's signature verifying the order. We are requiring that staff be physically present continually assessing and monitoring a resident in restraint or seclusion. We are also requiring that if a resident is a minor as defined in this subpart, the parent or guardian must be notified of the use of restraint or seclusion as soon as possible after the initiation of an emergency safety intervention. While we are not requiring that the treatment team meet within 24 hours of a resident being restrained or secluded, we are requiring that if the physician ordering the use of restraint or seclusion is not the resident's treatment team physician, then the ordering physician or a registered nurse must consult with the resident's treatment team physician as soon as possible. Some of these commenters recommended that seclusion be supervised by a psychiatrist or licensed psychologist. We agree with the need for supervision of a resident in restraint as well as seclusion but do not agree that supervision should be performed by a psychiatrist or licensed psychologist because the services of a psychiatrist or licensed psychologist may not always be available in these facilities. However, to ensure resident safety, we are requiring that clinical staff continually monitor and assess a resident in restraint or seclusion.

One commenter stated that only the least intrusive passive restraints for the protection of the individual or others be used and that we not allow seclusion or time out rooms or chemical restraints, mechanical restraints or adverse conditioning. We are not adopting the recommendation that we restrict a facility's use of restraints to the least intrusive passive restraints. While we recognize the commenter's concern, we believe that the type of intervention used to protect a resident should be the decision of the professionals involved with the situation. Our standards governing orders for restraint and seclusion require a physician to order the least restrictive intervention that is most likely to be effective in the emergency safety situation. Furthermore, we have included standards requiring that staff receive education and training in identifying behavior and events that may trigger an emergency safety situation, as well as education and training in the use of nonphysical intervention skills such as de-escalation, active listening and mediation conflict resolution. With regard to the comment that time out not be allowed, we have defined "time out" to clarify that it is not a form of seclusion, because the resident in time out cannot be physically prevented from leaving the time-out area.

Four commenters stated we should entirely prohibit the use of restraints on youngsters and that only time out and other means should be used in times of crisis. As stated above, we believe that the type of intervention used to ensure the safety of a resident or others in an emergency safety situation should be the decision of the professionals involved in that specific situation. These commenters also contended that restraints are too often justified on the basis of self-protection when they are really used for staff convenience, and that if restraints are allowed in certain circumstances, it is not possible to monitor for improper use. We recognize the commenter's concern and, therefore, our restraint and seclusion policy states that a resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation. We believe that the standards governing restraint and seclusion, including allowing only a board-certified psychiatrist or a licensed physician to order restraint or seclusion, imposing time limits on the use of restraint and seclusion that are consistent with JCAHO standards, requiring continual monitoring and assessment of residents in restraint or seclusion, and requiring that a resident's record be documented each time restraint or seclusion is used, will serve to ensure the safety of residents and diminish the inappropriate use of restraint and seclusion.

One commenter stated that a resident's parents should be notified within 24 hours whenever seclusion is used and that the treatment team should meet as soon as possible to discuss any needed modification to the plan. The commenter suggested that plan modifications should be based on analysis of the conditions leading to seclusion and discussion with the individual following seclusion. We partially agree with these comments and are requiring a facility to notify the parent(s) or legal guardian(s) of a minor resident who is restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention. In addition, we are requiring that postintervention debriefings be conducted within 24 hours after the use of restraint or seclusion. The first debriefing will provide the resident and staff involved in the use of a restraint or seclusion the opportunity to discuss the circumstances that resulted in its use, as well as opportunity for the resident and staff to develop strategies that can be employed to prevent the future use of restraint or seclusion. A second debriefing between appropriate supervisory and administrative staff and staff directly involved in the restraint or seclusion of a resident must be provided to allow for a review and discussion of the situation that required the use of restraint or seclusion, including a discussion of alternative techniques that staff might have employed and procedures staff could implement to prevent future restraint or seclusion. We are requiring that changes identified through these debriefings be documented in the resident's treatment plan.

One commenter suggested we delete the provision that a facility may not administer any psychoactive drugs for purposes of discipline or convenience from our standard on restraints. The commenter stated that facilities do not "use" drugs, and stated that drugs are prescribed by a physician as clinically appropriate in his or her opinion. The commenter asserted that this provision interferes with the practice of medicine. We agree and have not included this language in our standards governing restraints in this interim final rule. However, we are prohibiting the use of any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation.

One commenter stated that we need program standards for the prescription and administration of medication, especially psychoactive medication. We have rejected the suggestion that we set standards governing the use of medications because we believe to do so would amount to our practicing medicine. We have generally declined to set standards that would limit or preclude the professional discretion of physicians. However, we are prohibiting the use of any form of restraint when used for coercion, discipline, or convenience because these uses are medically unnecessary. Another commenter argued that the standard governing drugs is much too loose and suggested six conditions relating to drug therapy that we should include as part of our standard. As stated above, we do not believe that we have authority to set standards of practice regarding the use of medications. Two commenters suggested we establish a separate condition of participation for pharmacy services because medication is a primary component of active treatment, and risk of medication error is substantial. We have rejected this suggestion at this time because we are currently publishing only standards

governing the use of restraint and seclusion in this interim final rule.

IV. Response to Comments on This Interim Final Rule

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this document, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

In accordance with the requirements of the Administrative Procedures Act (APA), we ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the final rule is made effective. The notice of proposed rulemaking required by the APA includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subject matter and issues involved. Consistent with that practice, the November 1994 proposed rule proposed limitations on the use of restraint and seclusion by psychiatric residential treatment facilities that provide inpatient psychiatric services to individuals under age 21 that we have clarified and further developed in this interim final rule. In addition, we provided the public with notice of our heightened concern on this issue in our request for comment in the July 1999 interim final rule on hospital restraint and seclusion standards.

We have made some important additions to the 1994 proposed rule based both on comments received in response to the proposed rule and on the information sources referenced in this preamble. To the extent that there are provisions of this interim final rule that are not a logical outgrowth of the 1994 proposed rule, we are waiving the APA rulemaking procedure. The APA rulemaking procedure can be waived if the agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that the danger and risks to children and adolescents from inappropriate restraint and seclusion practices are substantiated by continued reports of deaths and serious injuries that are occurring in residential settings. To protect the health and safety of residents, we believe we are justified in applying more prescriptive standards in this interim final rule governing the use of restraint and seclusion in psychiatric residential treatment facilities than those proposed in the November 1994 proposed rule or those promulgated in the July 1999 hospital interim final rule.

Significant public attention has been focused on restraint and seclusion practices in psychiatric residential treatment facilities providing services to children and adolescents. In response to concerns about the inappropriate use of restraint and seclusion in these facilities, the Congress passed and the President signed in October 2000, legislation to regulate the use of restraint and seclusion in facilities that receive Medicare and Medicaid funding. That legislation, the Childrens Health Act of 2000, provides additional explicit statutory authority for many of the provisions of this rule.

As we noted, the *Courant* articles of October 1998 reported that 142 individuals had died in restraint-related incidents in the preceding decade. It was reported that many of these deaths were the result of improper use of mechanical restraints and that some could have been prevented by routine monitoring of the individual. One-third of the deaths reported by the *Courant* were due to asphyxia, and one-quarter were due to cardiac-related causes. As noted earlier, a GAO report published in September 1999, identified 24 deaths associated with restraint or seclusion in fiscal year 1998. The GAO indicated that the source of the data on the number of deaths reported was restraint or seclusion-related deaths that were investigated by the Protection and Advocacy agencies in all 50 states and the District of Columbia in fiscal year 1998. The GAO study concluded that the full extent of related injuries and deaths from improper restraint or seclusion practices is unknown because there is no comprehensive reporting system to track injuries and deaths, or a system that tracks the rates of restraint or seclusion use by a facility. The report stated that because reporting is so fragmentary, many more deaths related to restraint or seclusion may have occurred. And finally, even as we prepare to publish this rule, the media continue to investigate and report abusive practices, including deaths and injuries to children that are the result of inappropriate use of restraint and seclusion in psychiatric residential treatment facilities.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis because delaying the effective date of the rule would be contrary to public interest. We are providing a 60-day period for public comment.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain information collection requirements.

Section 441.151 General Requirements

Paragraph (a)(4) of this section requires that inpatient psychiatric services for individuals under age 21 must be certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with § 441.152.

The certification requirement of this section is not new. The paperwork burden is contained in the referenced § 441.152, which specifies the certification requirements, has been approved under OMB #0938–0754.

Section 483.356 Protection of Residents

Paragraph (c) of this section, "Notification of facility policy," requires facility staff to inform each incoming resident (and, in the case of a minor, the resident's parent(s) or legal guardian(s)) at admission, of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the facility. Staff must obtain an acknowledgment, in writing, from the resident, or in the case of a minor, the

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resident's parent(s) or legal guardian(s), that he or she has been informed of the facility's policy. Staff must file the written acknowledgment in the resident's record.

In order to estimate the burden of this requirement on facilities, we used data from National Center for Health Statistics, *Health, United States* published in 1999 (page 278) which indicated that there were 459 psychiatric residential treatment facilities in 1994, the latest year for which data are available. We estimate an annual growth rate in the number of these facilities to be 2 percent. Using this growth rate, we determined that there would be approximately 475 to 500 psychiatric residential treatment facilities nationally as of FFY 2001. These data showed that there are approximately 70 residents per facility at any one time. This equates to a total nationwide bed capacity approximating 35,000 beds. Through an informal survey of providers, we estimate an average resident length of stay to be 9 months and based on a 9-month stay, each facility would admit an estimated average of 95 residents per year, or an estimated total of up to 47,500 residents nationally. We believe it will take each facility 8 hours to develop a policy statement regarding the use of restraints and seclusion, and an average of 30 minutes to present the information to each incoming resident and the parent(s) or guardian(s), and to obtain and file the acknowledgment.

Thus, there will be a one-time burden of 4,000 hours nationwide to develop the statement and an annual burden of 48 hours per psychiatric residential treatment facility and 23,750 hours nationally to disclose the policy.

Section 483.358 Orders for the Use of Restraint or Seclusion

In accordance with paragraph (d) of this section, a physician's verbal order must be obtained by a registered nurse at the time the emergency safety intervention is initiated by staff if a written order cannot be easily obtained, and the verbal order must be followed with the physician's signature verifying the verbal order.

While the information collection requirement in this paragraph is subject to the PRA, we believe the burden associated with it is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

In accordance with paragraph (h) of this section, each order for restraint or seclusion must be documented in the resident's record. Documentation must include—

(1) The ordering physician's name;

(2) The date and time the order was obtained;

(3) The emergency safety intervention ordered, including the length of time for which the physician authorized its use;

(4) The time the emergency safety intervention actually began and ended;

(5) The time and results of any 1 hour assessments required in paragraph (f) of this section.

(6) The emergency safety situation that required the resident to be restrained or put in seclusion; and

(7) The name, title, and credentials of staff involved in the emergency safety intervention.

There are an estimated average of 47 situations per month per psychiatric residential treatment facility where restraint or seclusion is used, or approximately 282,000 situations nationally, per year. We estimate that it will take approximately 30 minutes per situation, or 282 hours annually per psychiatric residential treatment facility, for a national total of 141,000 hours annually to comply with the documentation requirements.

In accordance with paragraph (i) of this section, the facility must maintain an aggregate record of all emergency safety situations, the interventions used, and their outcomes.

Based on 15 minutes per situation, we estimate that it will take 141 hours per psychiatric residential treatment facility, and a national total of 70,500 hours annually to comply with this documentation requirement.

In accordance with paragraph (j) of this section, the physician ordering the restraint or seclusion must sign the order in the resident's record as soon as possible, but no later than 24 hours after the order is issued.

While these information collection requirements are subject to the PRA, we believe the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

§ 483.360 Consultation With Treatment Team Physician

Paragraph (a) of this section requires that, if the physician ordering the use of restraint or seclusion is not part of the resident's treatment team, the facility must consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion. Paragraph (f) of this section requires the facility to document in the resident's record the date and time the team physician was consulted.

We estimate that it will take approximately 30 minutes per situation, 282 hours annually per psychiatric residential treatment facility, or 141,000 hours nationally to comply with the documentation and disclosure requirements of this section, based on an assumption that approximately half of the situations will require that the facility staff separately notify the treatment team physician.

Section 483.366 Notification of Parent(s) or Legal Guardian(s)

If the resident is a minor as defined in § 483.352, paragraph (a) of this section requires the facility to notify the parent(s) or legal guardian(s) of a resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

Paragraph (b) of this section requires the facility to document in the resident's record that the parent(s) or legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

We estimate that it will take 30 minutes to notify a parent or guardian and 15 minutes to document that notification. The total annual burden will be 423 hours per psychiatric residential treatment facility and 211,500 hours nationally, based on the assumption that virtually all of the residents will be minors as defined in § 483.352.

Section 483.370 Postintervention Debriefings

Paragraph (c) of this section requires that staff document in the resident's record that the debriefing sessions required by this section took place.

This documentation will take approximately 30 minutes per situation, or an annual burden of 282 hours per psychiatric residential treatment facility and 141,000 hours nationally.

Section 483.372 Medical Treatment for Injuries Occurring as a Result of an Emergency Safety Situation

Paragraph (b) of this section requires the psychiatric residential treatment facility to have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

(1) A resident will be transferred from the facility to the hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

(3) Services are available to each resident 24 hours a day, 7 days a week.

Paragraph (c) of this section requires that staff document in the resident's record all injuries that occur as a result of an emergency safety situation, including injuries to staff resulting from that intervention.

While these information collection requirements are subject to the PRA, we believe the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 483.374 Facility Reporting

Paragraph (a) of this section requires each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 to attest, in writing, that the facility is in compliance with our standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

We estimate that it will take 8 hours per facility to be able to attest to compliance with the standards. This is a one-time burden. The national burden will be 500 multiplied by 8, or 4,000 hours.

Paragraph (b) of this section requires that the facility report serious occurrences involving a resident to both the State Medicaid Agency and, unless prohibited by State law, the State-designated Protection and Advocacy System. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility. In the case of a minor, the facility must also notify the parent(s) or legal guardian(s) of the resident involved in a serious occurrence.

Staff must document in the resident's record that the contacts above were made.

The burden for notifying parent(s) or legal guardian(s) is addressed under § 483.366.

We estimate that it will take an additional 15 minutes to document that these contacts were made, for an average annual burden of 141 hours per psychiatric residential treatment facility, with an annual national total of 70,500 burden hours.

Section 483.376 Education and Training

Paragraph (f) requires facilities to provide for assessments of staff education and training needs by requiring staff to demonstrate their competencies related to the use of emergency safety interventions on a semiannual basis. This section also provides for staff to demonstrate, on an annual basis, their competency in the use of cardiopulmonary resuscitation.

Paragraph (g) of this section requires the facility to document in the staff personnel records that the training required by § 483.376 was successfully completed.

While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Comments

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Attn: Julie Brown, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, HCFA Desk Officer.

VII. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this interim final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, all psychiatric residential treatment facilities are considered to be small entities. Individuals and States are not included in the definition of a small entity. Consistent with the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. This regulation does not have an impact on small rural hospitals. However, to the extent the rule may have significant effects on psychiatric residential treatment facilities and their residents, or be viewed as controversial, we believe it is desirable to inform the public of our projections of the likely effects of the proposals.

The Unfunded Mandates Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in a mandated expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more. This rule has no mandated consequential effect on State, local, or on tribal governments, or the private sector. We have described the anticipated effects of this regulation below.

We have reviewed this interim final rule with comment under the threshold criteria of Executive Order 13132, Federalism. We have determined that this interim final rule with comment does not significantly affect the rights, roles, and responsibilities of States.

This rule is the product of serious concern about improper use of restraints and seclusion in psychiatric residential treatment facilities. This led us to set forth this interim final rule with comment to ensure the protection of residents of these facilities from improper restraint and seclusion

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practices that could contribute to death or serious injury.

B. Anticipated Effects

1. Effect on Psychiatric Residential Treatment Facilities

We believe that many psychiatric residential treatment facilities are already in compliance with this rule because of State laws governing the use of restraint and seclusion, as well as their own quality assurance and improvement systems. Additionally, psychiatric residential treatment facilities must meet current Federal requirements for accreditation in order to provide inpatient psychiatric services to individuals under age 21. We are aware that the national accrediting organizations are currently in the process of revising their standards governing the use of restraint and seclusion. Therefore, the impact of this rule will not be determinable to the extent that the accrediting organizations' revised restraint and seclusion standards are or are not compatible with the requirements of this rule.

There are several provisions that will have an impact on psychiatric residential treatment facilities. The facilities will have to notify a parent(s) or a legal guardian(s) when restraint or seclusion is used, and ensure that staff are provided with initial and ongoing education and training in the proper and safe use of seclusion and the proper and safe use of restraint, and in techniques and alternative methods for handling resident behavior, symptoms, and situations that traditionally have been treated by the use of restraints or seclusion.

There will be facility costs associated with developing a policy on the use of restraint and seclusion in emergency safety situations and ensuring that this policy statement is available to residents and family members as well as facility staff.

We anticipate that some facilities will need additional registered nurses to be present during all shifts, including weekends, because we are requiring that, when a physician is not present to order the use of restraint or seclusion, a registered nurse must be present to obtain the physician's verbal order, and to contact the ordering physician should an emergency safety situation continue beyond the time limit of the physician's order. In addition, when a physician is not available, we are requiring a registered nurse to perform the 1 hour assessment of an individual who is restrained or secluded, and to evaluate the resident's well-being after he or she is removed from restraint or seclusion.

While psychiatric residential treatment facilities generally offer a less restrictive alternative to hospital treatment of psychiatric conditions, they are recognized as an inpatient setting for the purposes of providing mental health services under the Medicaid Inpatient Psychiatric Services Under Age 21 benefit. Unlike hospitals, which have a full cadre of medical professional staff present on a 24-hour basis, psychiatric residential treatment facilities may not be required to provide 24-hour coverage by licensed medical professional staff. In our informal research, we found that some facilities employ medical professional staff on a less than 24-hour basis. One facility contracts with a physician to provide 24-hour "on-call" coverage which does not equate to continual onsite coverage by medical staff. Since these facilities are providing medically necessary services in an inpatient setting, we believe that medical professional staff should be present on a 24-hour basis.

An emergency safety situation involving a resident of a facility can occur at any time, requiring staff to use restraints or seclusion as an emergency intervention to ensure the resident's safety or the safety of others. These emergencies often occur in the evening or on weekends when staffing levels may be lower than during the day. When such a situation occurs in a hospital, trained medical professional staff are onsite 24 hours a day to assist in the proper and safe application and monitoring of restraints. However, while psychiatric residential treatment facilities provide essentially the same inpatient care to vulnerable children and adolescents, trained medical professional staff are not required to be present 24 hours a day. This disparity creates increased risk for serious injury or even death when staff are faced with an emergency safety situation requiring the use of restraint or seclusion. Therefore, we believe that it is not only reasonable but critical to resident safety that we require these facilities to provide 24-hour onsite coverage by a registered nurse. It would be irresponsible not to extend the same level of protections to children and adolescents in these facilities that are provided in a hospital.

In addition, this rule requires psychiatric residential treatment facilities to report both to the State Medicaid agency and the State-designated P&A system, any serious occurrence, including a resident's death, a serious injury to a resident, or a resident's suicide attempt. In the case of a minor, the facility must also notify the parent(s) or legal guardian(s) of the resident involved in a serious occurrence. We believe that this new reporting requirement will have only a minimal cost impact on facilities.

The *Hartford Courant*, a Connecticut newspaper, heightened public awareness of this issue with a series of articles in October 1998 citing the results of a study that identified 142 deaths from the use of seclusion and restraint in behavioral health treatment facilities over the past 10 years. However, this number includes deaths from the use of seclusion and restraint in more than just the psychiatric residential treatment facility setting. We believe the nationwide reporting of deaths and serious injuries in psychiatric residential treatment facilities will contribute to the reduction of deaths or serious injuries that result from the inappropriate use of restraint and seclusion.

We believe that there will be costs associated with developing and implementing training programs for facility staff. However, we are not prescribing how facilities will meet the training requirements. Therefore, psychiatric residential treatment facilities will be afforded the flexibility to provide the training directly through "in-house" training or to obtain a contractor to provide the training either at the facility or off-site.

2. Effect on Beneficiaries

The implementation of this regulation will serve to protect residents and staff of psychiatric residential treatment facilities. We anticipate that the benefits will include a significant reduction in the inappropriate use of restraint and seclusion which will result in a reduction in the number of deaths and serious injuries to residents and facility staff.

3. Effect on Medicaid Program

We expect the implementation of this regulation will generate some costs to the Medicaid program. There will be additional facility costs as described in the table below.

C. Summary of Estimated Costs

The following are the assumptions and the methodology we used to derive the estimated costs for implementing this rule. We are soliciting public comments regarding any available information that may affect the cost estimates associated with the implementation of this rule.

ANNUAL COST
[$ Millions]

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Psych. Residential Treatment Facility Costs:					
Medicaid—Federal Share	16	31	31	33	34
Medicaid—State Share	12	24	24	25	26
Other Payers	1	3	3	3	3
Total	29	58	58	61	63
State Medicaid Administrative Costs:					
Federal Share	1	1	1	1	1
State Share	1	1	1	1	1
Total	2	2	2	2	2
Fed. Admin. Costs for Survey and Certification					
Total	(1)	(1)	(1)	(1)	(1)

[1]Less than $0.5 million.

Psychiatric Residential Treatment Facility Costs

Psychiatric residential treatment facility costs are comprised of three categories: (1) additional registered nursing staff, (2) staff training, and (3) facility reporting.

Data from *Health, United States, 1999* (National Center for Health Statistics, p. 278) indicate that there were 459 psychiatric residential treatment facilities in 1994, the latest year for which data are available. Resident care staff in these facilities totaled about 44,000 in that same year. Using a 2 percent growth rate trend developed from the *Health US 1999* data above, we projected the number of facilities and the number of resident care staff for Federal fiscal years (FFY) 2001 through 2005.

1. *New staff costs.* The *Health US 1999* data on staffing for psychiatric residential treatment facilities shows an average of 3.2 full-time-equivalent (FTE) registered nurses per facility. The requirement for 24 hour per day registered nurse coverage would require a minimum of 4.2 FTEs (168 hours per week divided by 40 hours per week per FTE). Each facility would, at a minimum, have to provide for an average of one additional FTE registered nurse. For these estimates we have assumed an increase of 1.5 FTE registered nurses per facility, which translates into a requirement for approximately 790 additional registered nurses to provide the necessary coverage in all psychiatric residential treatment facilities in FFY 2001. We trended the registered nurse staffing requirement forward through 2005 based on our estimation that resident population growth would approximate 2 percent per year. The numbers of registered nurses needed to provide coverage in years subsequent to FFY 2001 will vary with changes in the numbers of residents. We assumed the total annual compensation (salary and fringe benefits) for each registered nurse to be $56,000 in FFY 2001, totalling $44.2 million nationally. The total costs are estimated to increase by 3 percent per year thereafter. Data taken from the *Nursing Department Compensation Report 1999–2000* (Hospital and Healthcare Compensation Service, Oakland New Jersey, page 18) indicate that the annual national average base salary for inpatient hospital psychiatric nursing positions (equivalent in skills and payment level to the nurses working in psychiatric residential treatment facilities) would approximate $19.99 per hour or $41,580 annually for 1999, the latest year for which data are available. The Report indicates that the average increase in psychiatric nursing salaries approximates 3 percent per year. Using a 3 percent growth rate we projected the annual salary for psychiatric nurses for Federal fiscal years 2001 through 2005. We added a factor of 27.0 percent to psychiatric nurses salary for fringe benefit costs. The term fringe benefits includes paid leave, supplemental pay, insurance, retirement, savings and other benefits. The 27.0 percent was shown for nurse fringe benefit costs in the publication: *Employer Costs for Employee Compensation, 1986–1998*, Table 2, Employer Costs Per Hour Worked for Employee Compensation and Costs as a Percent of Total Compensation: Civilian Workers, by Occupational and Industry Group, March 1998" (U.S. Department of Labor, Bureau of Labor Statistics, page 10). The rate of fringe benefits to salary ranged from 27.0 to 27.7 percent over the period from March 1994 through March 1998, with the majority at 27.0 percent, as shown in Tables 2, 18, 34, 50, and 66 of the same publication. The year 1998 is the latest period for which such data are available. As a result, we used 27.0 percent as a constant in our cost projection for Federal fiscal years 2001 through 2005 as any variation in rate would represent a very limited change in projected fringe benefit costs.

2. *Training costs.* Existing Federal Medicaid regulations at 42 CFR 441.151 require that a psychiatric facility that provides inpatient psychiatric services to individuals under age 21 be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization, with comparable standards that is recognized by the State. Most of these facilities are currently accredited by JCAHO. In August 2000, JCAHO published its Comprehensive Accreditation Manual for Hospitals, which includes revised behavioral health care standards governing the use of restraint and seclusion. These revised restraint and seclusion standards apply to all behavioral health care settings, including residential treatment centers. Specifically, JCAHO strengthened existing standards governing training requirements for direct care staff in the safe use of restraint and seclusion and the requirement for education and assessment of staff competence in minimizing the use of restraint and seclusion. These new standards will take effect January 1, 2001.

We have made the following assumptions with regard to staff training: (1) That the revised JCAHO

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training requirements for facility accreditation will not fully meet the training requirements under this interim final rule, and therefore have included estimated costs for staff training which we obtained through research on consultants who provide this specific service; (2) that, at a minimum, staff training to meet the requirements of this rule would cost approximately $250 per staff person for initial training, and approximately $100 annually for ongoing staff training, and (3) that only 10 percent of staff would fully meet the training requirements under this rule.

We estimated that by FFY 2001 the facility staff would have grown to approximately 50, 000 from the 44,000 staffing estimate for 1994 (see page 69). We assume that approximately 90 percent of the facility staff, or about 45,000 employees would require training in the use of restraint and seclusion,. We estimate that approximately 75 percent of the staff to be trained, or 33,750, would require initial training at an estimated $250 per person, totaling approximately $8.4 million. The remaining 11,250 staff would require ongoing training at about $100 per employee, amounting to an estimated $1.1 million.

In addition to direct training costs, we also assumed that facilities would incur related consulting costs averaging 10 hours per month per facility at a cost of $40 per hour. Inflation for all training and related costs was assumed to be 5 percent per year.

3. *Reporting costs.* In the absence of any current verifiable data on serious occurrences involving residents in psychiatric residential treatment facilities, we have assumed the costs of the required reporting of these events to be approximately $250 per facility, per year. We are soliciting comments regarding any available information on actual reporting costs.

Total estimated facility costs of compliance, as shown in the above table, are estimated to be $58 million in the first full year of implementation (FFY 2002). This figure represents about 1.6 percent of the total projected expenditures of $3.3 billion for psychiatric residential treatment facilities in that year, as derived from the *Health US 1999* data.

State Medicaid Administration Costs

States will have additional responsibilities and costs for survey and certification requirements associated with the requirements of this regulation. Beginning in Federal fiscal year 2001, we project there will be 500 residential treatment facilities, or an average of 10 facilities per state. For each state, we estimated an annual survey agency cost equivalent to 5 days to conduct 2 onsite reviews (20 percent sample) to validate facility attestation to our new restraint and seclusion standards. We also estimated that documentary reviews of facility attestations, including any necessary follow up with facilities in conjunction with the attestation would require the survey agency to incur costs equivalent to 5 days. We also estimated costs associated with restraint and seclusion complaints which would require investigation by the survey agency. We estimated 2 complaints annually requiring onsite follow up by the survey agency, including enforcement activities and appeals-related activities. We estimated each complaint would require 2 days for onsite visits, 2 days for follow up and 1 day for appeals-related activities for a total of 10 days for 2 complaints. We assumed the need for an additional one-tenth of an FTE per state to support this additional workload.

Current expenditures indicate an average cost (salary and benefits) of $50,000 for state survey agency professional personnel; one-tenth of one FTE would cost $5,000 per year. Because these are Medicaid-only facilities, the survey and certification costs will be paid under the Medicaid program. Based on the current 75/25 Federal-state match, the average expenditures for each state would be $3,750 in Federal Medicaid funds, and $1,250 in state-matching funds.

Other Assumptions

Available evidence indicates that residents of psychiatric residential treatment facilities are overwhelmingly Medicaid-eligible. Therefore, we have assumed that 95 percent of the costs incurred by these facilities to implement these new regulations would be defrayed by the Medicaid program and 5 percent by other payers. We are assuming that States will continue to fully fund the costs of this benefit.

D. Alternatives Considered

We originally considered developing one set of requirements regulating the use of restraint and seclusion for all provider types in the Medicare and Medicaid programs. However, based on public comments received in response to the interim final regulation addressing a similar CoP for hospitals, and recent concerns about restraint and seclusion use for behavior management situations, we concluded that one set of requirements did not afford all patients (or residents) with adequate protections. Moreover, with the enactment of the Children's Health Act of 2000, the Secretary no longer has the discretion to leave this benefit unregulated.

E. Conclusion

The CoP for psychiatric residential treatment facilities sets forth a series of requirements to ensure each resident's physical and emotional health and safety. These requirements address each resident's right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation. The CoP is a new requirement for facilities that provide inpatient psychiatric residential treatment services to Medicaid eligible individuals under age 21. In accordance with the Regulatory Flexibility Act, we have examined the burden this rule may impose on small entities and certify that this rule will not have a significant impact on a substantial number of intities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professionals, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

A. Part 441 is amended as set forth below:

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 441.151 is revised to read as follows:

§ 441.151 General requirements.

(a) Inpatient psychiatric services for individuals under age 21 must be:

(1) Provided under the direction of a physician;

(2) Provided by—

(i) A psychiatric hospital or an inpatient psychiatric program in a hospital, accredited by the Joint Commission on Accreditation of Healthcare Organizations; or

(ii) A psychiatric facility that is not a hospital and is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

(3) Provided before the individual reaches age 21, or, if the individual was receiving the services immediately before he or she reached age 21, before the earlier of the following—

(i) The date the individual no longer requires the services; or

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with § 441.152.

(b) Inpatient psychiatric services furnished in a psychiatric residential treatment facility as defined in § 483.352 of this chapter, must satisfy all requirements in subpart G of part 483 of this chapter governing the use of restraint and seclusion.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

B. Part 483 is amended as set forth below:

1. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. A new subpart G, consisting of §§ 483.350 through 483.376, is added to part 483 to read as follows:

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

Sec.

483.350 Basis and scope.
483.352 Definitions.
483.354 General requirements for psychiatric residential treatment facilities.
483.356 Protection of residents.
483.358 Orders for the use of restraint or seclusion.
483.360 Consultation with treatment team physician.
483.362 Monitoring of the resident in and immediately after restraint.
483.364 Monitoring of the resident in and immediately after seclusion.
483.366 Notification of parent(s) or legal guardian(s).
483.368 Application of time out.
483.370 Postintervention debriefings.
483.372 Medical treatment for injuries resulting from an emergency safety intervention.
483.374 Facility reporting.
483.376 Education and training.

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

§ 483.350 Basis and scope.

(a) *Statutory basis.* Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106–310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

(b) *Scope.* This subpart imposes requirements regarding the use of restraint or seclusion in psychiatric residential treatment facilities, that are not hospitals, providing inpatient psychiatric services to individuals under age 21.

§ 483.352 Definitions.

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

(1) Is administered to manage a resident's behavior in a way that reduces the safety risk to the resident or others;

(2) Has the temporary effect of restricting the resident's freedom of movement; and

(3) Is not a standard treatment for the resident's medical or psychiatric condition.

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation.

Emergency safety situation means unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs and that calls for an emergency safety intervention as defined in this section.

Mechanical restraint means any device attached or adjacent to the resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

Minor means a minor as defined under State law and, for the purpose of this subpart, includes a resident who has been declared legally incompetent by the applicable State court.

Personal restraint means the application of physical force without the use of any device, for the purpose of restricting the free movement of a resident's body.

Psychiatric Residential Treatment Facility means a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter, to individuals under age 21, in an inpatient setting.

Restraint means a "personal restraint," "mechanical restraint," or "drug used as a restraint" as defined in this section.

Seclusion means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

Serious injury means any significant impairment of the physical condition of the resident as determined by qualified medical personnel. This includes, but is not limited to, burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else.

Staff means those individuals with responsibility for managing a resident's health or participating in an emergency safety intervention and who are employed by the facility on a full-time, part-time, or contract basis.

Time out means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

§ 483.354 General requirements for psychiatric residential treatment facilities.

A psychiatric residential treatment facility must meet the requirements in § 441.151 through § 441.182 of this chapter.

§ 483.356 Protection of residents.

(a) *Restraint and seclusion policy for the protection of residents.* (1) Each resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

(2) An order for restraint or seclusion must not be written as a standing order or on an as-needed basis.

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(3) Restraint or seclusion must not result in harm or injury to the resident and must be used only—

(i) To ensure the safety of the resident or others during an emergency safety situation; and

(ii) Until the emergency safety situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired.

(4) Restraint and seclusion must not be used simultaneously.

(b) *Emergency safety intervention.* An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of the behavior, and the resident's chronological and developmental age; size; gender; physical, medical, and psychiatric condition; and personal history (including any history of physical or sexual abuse).

(c) *Notification of facility policy.* At admission, the facility must—

(1) Inform both the incoming resident and, in the case of a minor, the resident's parent(s) or legal guardian(s) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the program;

(2) Communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and when necessary, the facility must provide interpreters or translators;

(3) Obtain an acknowledgment, in writing, from the resident, or in the case of a minor, from the parent(s) or legal guardian(s) that he or she has been informed of the facility's policy on the use of restraint or seclusion during an emergency safety situation. Staff must file this acknowledgment in the resident's record; and

(4) Provide a copy of the facility policy to the resident and in the case of a minor, to the resident's parent(s) or legal guardian(s).

(d) *Contact information.* The facility's policy must provide contact information, including the phone number and mailing address, for the appropriate State Protection and Advocacy organization.

§ 483.358 Orders for the use of restraint or seclusion.

(a) Only a board-certified psychiatrist, or a physician licensed to practice medicine with specialized training and experience in the diagnosis and treatment of mental diseases, may order the use of restraint or seclusion.

(b) If the resident's treatment team physician is available, only he or she can order restraint or seclusion. If the resident's treatment team physician is unavailable, the physician covering for the treatment team physician can order restraint or seclusion. The covering physician must meet the same requirements for training and experience described in paragraph (a) of this section.

(c) The physician must order the least restrictive emergency safety intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff.

(d) If the physician is not available to order the use of restraint or seclusion, the physician's verbal order must be obtained by a registered nurse at the time the emergency safety intervention is initiated by staff and the physicians verbal order must be followed with the physician's signature verifying the verbal order. The ordering physician must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

(e) Each order for restraint or seclusion must:

(1) Be limited to no longer than the duration of the emergency safety situation; and

(2) Under no circumstances exceed 4 hours for residents ages 18 to 21; 2 hours for residents ages 9 to 17; or 1 hour for residents under age 9.

(f) Within 1 hour of the initiation of the emergency safety intervention, a physician or clinically qualified registered nurse trained in the use of emergency safety interventions must conduct a face-to-face assessment of the physical and psychological well being of the resident, including but not limited to—

(1) The resident's physical and psychological status;

(2) The resident's behavior;

(3) The appropriateness of the intervention measures; and

(4) Any complications resulting from the intervention.

(g) Each order for restraint or seclusion must include—

(1) The ordering physician's name;

(2) The date and time the order was obtained; and

(3) The emergency safety intervention ordered, including the length of time for which the physician authorized its use.

(h) Staff must document the intervention in the resident's record. That documentation must be completed by the end of the shift in which the intervention occurs. If the intervention does not end during the shift in which it began, documentation must be completed during the shift in which it ends. Documentation must include all of the following:

(1) Each order for restraint or seclusion as required in paragraph (g) of this section.

(2) The time the emergency safety intervention actually began and ended.

(3) The time and results of the 1-hour assessment required in paragraph (f) of this section.

(4) The emergency safety situation that required the resident to be restrained or put in seclusion.

(5) The name of staff involved in the emergency safety intervention.

(i) The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

(j) The physician ordering the restraint or seclusion must sign the order in the resident's record as soon as possible.

§ 483.360 Consultation with treatment team physician.

If the physician ordering the use of restraint or seclusion is not the resident's treatment team physician, the ordering physician or registered nurse must—

(a) Consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion; and

(b) Document in the resident's record the date and time the team physician was consulted.

§ 483.362 Monitoring of the resident in and immediately after restraint.

(a) Clinical staff trained in the use of emergency safety interventions must be physically present, continually assessing and monitoring the physical and psychological well-being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.

(b) If the emergency safety situation continues beyond the time limit of the physician's order for the use of restraint, a registered nurse must immediately contact the ordering physician in order to receive further instructions.

(c) A physician, or a registered nurse trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the restraint is removed.

§ 483.364 Monitoring of the resident in and immediately after seclusion.

(a) Clinical staff, trained in the use of emergency safety interventions, must be physically present in or immediately outside the seclusion room, continually assessing, monitoring, and evaluating the physical and psychological well-being of the resident in seclusion. Video monitoring does not meet this requirement.

(b) A room used for seclusion must—

(1) Allow staff full view of the resident in all areas of the room; and

(2) Be free of potentially hazardous conditions such as unprotected light fixtures and electrical outlets.

(c) If the emergency safety situation continues beyond the time limit of the physician's order for the use of seclusion, a registered nurse must immediately contact the ordering physician in order to receive further instructions.

(d) A physician, or a registered nurse trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

§ 483.366 Notification of parent(s) or legal guardian(s).

If the resident is a minor as defined in this subpart:

(a) The facility must notify the parent(s) or legal guardian(s) of the resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

(b) The facility must document in the resident's record that the parent(s) or legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

§ 483.368 Application of time out.

(a) A resident in time out must never be physically prevented from leaving the time out area.

(b) Time out may take place away from the area of activity or from other residents, such as in the resident's room (exclusionary), or in the area of activity or other residents (inclusionary).

(c) Staff must monitor the resident while he or she is in time out.

§ 483.370 Postintervention debriefings.

(a) Within 24 hours after the use of restraint or seclusion, staff involved in an emergency safety intervention and the resident must have a face-to-face discussion. This discussion must include all staff involved in the intervention except when the presence of a particular staff person may jeopardize the well-being of the resident. Other staff and the resident's parent(s) or legal guardian(s) may participate in the disussion when it is deemed appropriate by the facility. The facility must conduct such discussion in a language that is understood by the resident's parent(s) or legal guardian(s). The discussion must provide both the resident and staff the opportunity to discuss the circumstances resulting in the use of restraint or seclusion and strategies to be used by the staff, the resident, or others that could prevent the future use of restraint or seclusion.

(b) Within 24 hours after the use of restraint or seclusion, all staff involved in the emergency safety intervention, and appropriate supervisory and administrative staff, must conduct a debriefing session that includes, at a minimum, a review and discussion of—

(1) The emergency safety situation that required the intervention, including a discussion of the precipitating factors that led up to the intervention;

(2) Alternative techniques that might have prevented the use of the restraint or seclusion;

(3) The procedures, if any, that staff are to implement to prevent any recurrence of the use of restraint or seclusion; and

(4) The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.

(c) Staff must document in the resident's record that both debriefing sessions took place and must include in that documentation the names of staff who were present for the debriefing, names of staff that were excused from the debriefing, and any changes to the resident's treatment plan that result from the debriefings.

§ 483.372 Medical treatment for injuries resulting from an emergency safety intervention.

(a) Staff must immediately obtain medical treatment from qualified medical personnel for a resident injured as a result of an emergency safety intervention.

(b) The psychiatric residential treatment facility must have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

(1) A resident will be transferred from the facility to a hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

(3) Services are available to each resident 24 hours a day, 7 days a week.

(c) Staff must document in the resident's record, all injuries that occur as a result of an emergency safety intervention, including injuries to staff resulting from that intervention.

(d) Staff involved in an emergency safety intervention that results in an injury to a resident or staff must meet with supervisory staff and evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

§ 483.374 Facility reporting.

(a) *Attestation of facility compliance.* Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest, in writing, that the facility is in compliance with HCFA's standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

(1) A facility with a current provider agreement with the Medicaid agency must provide its attestation to the State Medicaid agency by July 21, 2001.

(2) A facility enrolling as a Medicaid provider must meet this requirement at the time it executes a provider agreement with the Medicaid agency.

(b) *Reporting of serious occurrences.* The facility must report each serious occurrence to both the State Medicaid agency and, unless prohibited by State law, the State-designated Protection and Advocacy system. Serious occurrences that must be reported include a resident's death, a serious injury to a resident as defined in § 483.352 of this part, and a resident's suicide attempt.

(1) Staff must report any serious occurrence involving a resident to both the State Medicaid agency and the State-designated Protection and Advocacy system by no later than close of business the next business day after a serious occurrence. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

(2) In the case of a minor, the facility must notify the resident's parent(s) or legal guardian(s) as soon as possible, and in no case later than 24 hours after the serious occurrence.

(3) Staff must document in the resident's record that the serious occurrence was reported to both the State Medicaid agency and the State-designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident's record, as

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well as in the incident and accident report logs kept by the facility.

§ 483.376 Education and training.

(a) The facility must require staff to have ongoing education, training, and demonstrated knowledge of—

(1) Techniques to identify staff and resident behaviors, events, and environmental factors that may trigger emergency safety situations;

(2) The use of nonphysical intervention skills, such as de-escalation, mediation conflict resolution, active listening, and verbal and observational methods, to prevent emergency safety situations; and

(3) The safe use of restraint and the safe use of seclusion, including the ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

(b) Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

(c) Individuals who are qualified by education, training, and experience must provide staff training.

(d) Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

(e) Staff must be trained and demonstrate competency before participating in an emergency safety intervention.

(f) Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

(g) The facility must document in the staff personnel records that the training and demonstration of competency were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

(h) All training programs and materials used by the facility must be available for review by HCFA, the State Medicaid agency, and the State survey agency.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 28, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 01–1649 Filed 1–19–01; 8:45 am]

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

Federal Register

Monday,
January 22, 2001

Part XI

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Part 2, et al.
Federal Acquisition Regulation; Electronic and Information Technology Accessibility; Proposed Rule

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 7, 10, 11, 12, and 39

[FAR Case 1999–607]

RIN 9000–AI69

Federal Acquisition Regulation; Electronic and Information Technology Accessibility

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) are proposing to amend the Federal Acquisition Regulation (FAR) to implement Subsection 408(b) of Title IV of the Workforce Investment Act of 1998, (Pub. L. 105–220). Subsection 408(b) requires the FAR to be revised to incorporate standards developed by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board").

DATES: Interested parties should submit comments in writing on or before March 23, 2001 to be considered in the formulation of a final rule.

ADDRESSES: Submit written comments to: General Services Administration, FAR Secretariat (MVR), 1800 F Street, NW, Room 4035, ATTN: Laurie Duarte, Washington, DC 20405.

Submit electronic comments via the Internet to: farcase.1999-607@gsa.gov

Please submit comments only and cite FAR case 1999–607 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: The FAR Secretariat, Room 4035, GS Building, Washington, DC, 20405, at (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Ms. Linda Nelson, Procurement Analyst, at (202) 501–1900. Please cite FAR case 1999–607.

SUPPLEMENTARY INFORMATION:

A. Background

On August 7, 1998, the President signed into law the Workforce Investment Act of 1998, Public Law 105–220. Title IV of the Act is the Rehabilitation Act Amendments of 1998. Subsection 408(b) amended section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Subsection 508(a)(1) requires that when Federal departments or agencies develop, procure, maintain, or use Electronic and Information Technology (EIT), they shall ensure that the EIT allows Federal employees with disabilities to have access to and use of information and data that is comparable to the access to and use of information and data by other Federal employees. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal department or agency, have access to and use of information and data that is comparable to that provided to the public without disabilities. Comparable access is not required if it would impose an undue burden.

Subsection 508(a)(2)(A) required the Access Board to publish standards setting forth a definition of EIT and the technical and functional performance criteria necessary for accessibility for such technology by February 7, 2000. Subsection 508(a)(3) requires the Federal Acquisition Regulatory Council to revise the Federal Acquisition (FAR) to incorporate the Access Board's standards up to six months after the Access Board regulations are published. The Access Board published the final standards in the **Federal Register** at 65 FR 80500, December 21, 2000.

This proposed rule implements the Access Board's regulations by—

1. Including the definition of the term "electronic and information technology", a term added by the statute.

2. Incorporating the EIT Standards in acquisition planning, market research and when describing agency needs.

3. Adding a new Subpart 39.X to implement the Access Board's rule. Acquisitions of EIT will be required to meet the EIT accessibility standards unless an exception applies (*i.e.*, micro-purchase, national security system, acquired by a contractor incidental to a contract, located in spaces frequented only by service personnel for maintenance, repair or occasional monitoring of equipment; or would impose an undue burden (significant difficulty or expense)). The exemption for micro-purchases is made in recognition of the fact that almost all micro-purchases are made using the Governmentwide commercial purchase card. Government personnel, who are not warranted contracting officers, use the purchase card to purchase commercial-off-the-shelf items. Use of the purchase card makes it generally impractical to comply with the EIT accessibility standards unless all commercial-off-the-shelf products incorporate the standards. Manufacturers are continuing to develop products that comply with the EIT accessibility standards. It is expected that almost all products will comply with the standards within the next two years. Therefore, we have established a sunset date of January 1, 2003, for the micro-purchase exemption. Prior to that date, the Government will revisit the state of technology and the pace at which manufacturers have conformed to the required standards.

B. Executive Order 12866

The Access Board determined that their proposed rule that provides the accessibility standard is an economically significant regulatory action under E.O. 12866 with a cost over $100,000,000, and is a major rule under 5 U.S.C. 804. An Economic Assessment was accomplished and can be reviewed at http://www.access-board.gov/sec508/508index.htm. The Councils have determined that the assessment conducted by the Access Board provides an adequate Economic Assessment of both the Access Board rule and this change to the FAR. Accordingly, the Access Board's regulatory assessment meets the requirement of performing a regulatory assessment for this change to the FAR and no further assessment is necessary.

This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is a major rule under 5 U.S.C. 804.

B. Regulatory Flexibility Act

The changes may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because small businesses who choose to market their products to the Federal Government must ensure that their electronic and information technology supplies or services meet the substantive requirements of the Access Board's standards. Since this may result in increased costs of producing and selling their products, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and the analysis is summarized as follows:

The objective of this rule is to revise the FAR to improve the accessibility of electronic and information technology used by the Federal Government. The standards developed by the Access Board will affect Federal employees with disabilities as well as members of the public with disabilities who seek to use Federal electronic and information technologies to access information. This increased access reduces barriers to employment in the Federal Government for individuals with disabilities. Failure of an agency to purchase electronic and information technology that complies with the standards promulgated under the Act may result in any individual with a disability filing a complaint seeking to enforce compliance with the standards.

This rule will apply to all contractors that manufacture, sell, or lease electronic and information technology supplies or services. For many contractors, this may simply involve a review of the supply or service with the standards to confirm compliance. For other contractors, these standards could require redesign of a supply or service. Based on fiscal year 1999 information from the Federal Procurement Data System, we estimate that there are approximately 11,000 contractors to which the rule will apply. Approximately 59 percent, or 6,500, of these contractors are small businesses.

Since the statute imposes private enforcement, where individuals with disabilities can file civil rights lawsuits, the Government has little flexibility for alternatives in writing this regulation. To meet the requirements of the law, we cannot exempt small businesses from any part of the rule.

The FAR Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the FAR Secretariat. The Councils will consider comments from small entities concerning the affected FAR parts 2, 7, 10, 11, 12, and 39 in accordance with 5 U.S.C. 610. Comments must be submitted separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 1999–607), in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 2, 7, 10, 11, 12, and 39

Government procurement.

Dated: January 16, 2001.

Al Matera,

Acting Director, Federal Acquisition Policy Division.

Therefore, DoD, GSA, and NASA propose that 48 CFR parts 2, 7, 10, 11, 12, and 39 be amended as set forth below:

1. The authority citation for 48 CFR parts 2, 7, 10, 11, 12, and 39 continues to read as follows:

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 2—DEFINITION OF WORDS AND TERMS

2. In section 2.101, add in alphabetical order, the definition "Electronic and information technology (EIT)" to read as follows:

2.101 Definitions.

* * * * *

Electronic and information technology (EIT) has the same meaning as "information technology" except EIT also includes any equipment or interconnected system or subsystem of equipment that is used in the creation, conversion, or duplication of data or information. The term EIT, includes, but is not limited to, telecommunication products (such as telephones), information kiosks and transaction machines, worldwide web sites, multimedia, and office equipment (such as copiers and fax machines).

* * * * *

PART 7—ACQUISITION PLANNING

3. In section 7.103, redesignate paragraphs (o) through (r) as (p) through (s); and add a new paragraph (o) to read as follows:

7.103 Agency-head responsibilities.

* * * * *

(o) Ensuring that acquisition planners specify needs and develop plans, drawings, work statements, specifications, or other product descriptions that address Electronic and Information Technology Accessibility Standards (see 36 CFR part 1194) in proposed acquisitions (see 11.002(e)) and that these standards are included in requirements planning, as appropriate (see subpart 39.X).

* * * * *

PART 10—MARKET RESEARCH

4. In section 10.001, add paragraph (a)(3)(vii) to read as follows:

10.001 Policy.

(a) * * *

(3) * * *

(vii) Assess the availability of electronic and information technology that meets all or part of the applicable accessibility standards issued by the Architectural and Transportation Barriers Compliance Board at 36 CFR part 1194 (see subpart 39.X).

* * * * *

PART 11—DESCRIBING AGENCY NEEDS

5. In section 11.002, add paragraph (f) to read as follows:

11.002 Policy.

* * * * *

(f) In accordance with Section 508 of the Rehabilitation Act of 1973, (29 U.S.C. 794d), requiring activities must prepare requirements documents for electronic and information technology that comply with the applicable accessibility standards issued by the Architectural and Transportation Barriers Compliance Board at 36 CFR part 1194 (see subpart 39.X).

PART 12—ACQUISITION OF COMMERICIAL ITEMS

6. Amend section 12.202 by adding a sentence to the end of paragraph (c) to read as follows:

12.202 Market research and description of agency need.

* * * * *

(c) * * * This includes requirements documents for electronic and information technology that comply with the applicable accessibility standards issued by the Architectural and Transportation Barriers Compliance Board at 36 CFR part 1194 (see subpart 39.X).

PART 39—ACQUISITION OF INFORMATION TECHNOLOGY

7. Revise section 39.000 to read as follows:

39.000 Scope of part.

This part prescribes acquisition policies and procedures for use in acquiring—

(a) Information technology, including financial management systems, consistent with other parts of this regulation, OMB Circular No. A–127, Financial Management Systems, and OMB Circular No. A–130, Management of Federal Information Resources; and

(b) Electronic and information technology.

8. Add subpart 39.X, consisting of sections 39.X01 through 39.X04, to read as follows:

Subpart 39.X—Electronic and Information Technology

Sec.

39.X01 Scope of subpart.
39.X02 Definition.
39.X03 Applicability.
39.X04 Exceptions.

Authority: 40 U.S.C. 486(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

39.X01 Scope of subpart.

This subpart implements Section 508 of the Rehabilitation Act of 1973, (29 U.S.C. 794d) and the Architectural and Transportation Barriers Compliance Board Electronic and Information

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Technology (EIT) accessibility standards (36 CFR part 1194). When acquiring EIT, agencies must ensure that—

(a) Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

(b) Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

39.X02 Definition.

Undue burden, as used in this subpart, means a significant difficulty or expense.

39.X03 Applicability.

Unless an exception at 39.X04 applies, acquisitions of EIT must meet the applicable accessibility standards at 36 CFR part 1194. When acquiring commercial items, an agency must comply with those accessibility standards that are available in the commercial marketplace in time to meet the agency's delivery requirements.

39.X04 Exceptions.

The requirements in 39.X03 do not apply to EIT that—

(a) Is purchased in accordance with subpart 13.2 (micro-purchases) prior to January 1, 2003. However, contracting officers and other individuals designated in accordance with 1.603–3 are encouraged to comply with the applicable accessibility standards to the maximum extent practicable;

(b) Is for a national security system;

(c) Is acquired by a contractor incidental to a contract;

(d) Is located in spaces frequented only by service personnel for maintenance, repair or occasional monitoring of equipment; or

(e) Would impose an undue burden on the agency.

(1) *Basis.* In determining whether compliance with all or part of the applicable accessibility standards in 36 CFR part 1194 would be an undue burden, an agency must consider—

(i) The difficulty or expense of compliance; and

(ii) Agency resources available to its program or component for which the supply or service is being acquired.

(2) *Undue burden documentation.* (i) The requiring official must document an undue burden decision and provide the documentation to the contracting officer for inclusion in the contract file.

(ii) When acquiring commercial items, an undue burden determination is not required to address standards that are not yet available in the commercial marketplace in time to meet the agency delivery requirements. The requiring official must document the nonavailability and provide the documentation to the contracting officer for inclusion in the contract file.

[FR Doc. 01–1657 Filed 1–19–01; 8:45 am]
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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION 1985

Federal Register

Monday,
January 22, 2001

Part XII

Department of Energy

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430
Energy Conservation Program for Consumer Products: Central Air Conditioners and Heat Pumps Energy Conservation Standards; Final Rule

Finding of No Significant Impact Energy Conservation Program for Consumer Products; Notice

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DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

10 CFR Part 430

[Docket Number EE–RM–98–440]

RIN 1904–AA77

Energy Conservation Program for Consumer Products: Central Air Conditioners and Heat Pumps Energy Conservation Standards

AGENCY: Office of Energy Efficiency and Renewable Energy, Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE or Department) has determined that revised energy conservation standards for central air conditioners and heat pumps will result in significant conservation of energy, are technologically feasible, and are economically justified. On this basis, the Department is today amending the existing energy conservation standards for central air conditioners and heat pumps.

EFFECTIVE DATE: The effective date of this rule is February 21, 2001.

ADDRESSES: A copy of the Technical Support Document (TSD) may be read at the DOE Freedom of Information Reading Room, U.S. Department of Energy, Forrestal Building, Room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–3142, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays. Copies of the TSD may be obtained from: the Codes and Standards Internet site at: http://www.eren.doe.gov/buildings/codes_standards/applbrf/central_air_conditioner.html or from the U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Mail Station EE–41, 1000 Independence Avenue, SW., Washington, DC 20585–0121. (202) 586–9127.

FOR FURTHER INFORMATION CONTACT: Dr. Michael E. McCabe, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–41, 1000 Independence Avenue, SW., Washington, DC 20585–0121, (202) 586–0854, e-mail: michael.e.mccabe@ee.doe.gov, or Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, GC–72, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507, e-mail: eugene.margolis@hq.doe.gov.

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I. Introduction

A. Consumer Overview

1. Background

The Department of Energy (DOE or the Department) is directed by the Energy Policy and Conservation Act to consider establishing minimum efficiency standards for various consumer products, including central air conditioners and heat pumps. Today's final rule adopts standards that are consistent with these requirements of the law. The Department is amending the almost ten year old minimum efficiency standards for new central air conditioners and heat pumps. These amended standards take into account a decade of technological advancements and will save consumers and the nation money, significant amounts of energy, and have substantial environmental and economic benefits.

When today's adopted standards go into effect, they will essentially raise the energy efficiency standards to 13 SEER for new central air conditioners and to 13 SEER/7.7 HSPF for new central air conditioning heat pumps (heat pumps). SEER, Seasonal Energy Efficiency Ratio, is the Department's measure of energy efficiency for the seasonal cooling performance of central air conditioners and heat pumps. HSPF, Heating Seasonal Performance Factor, is the Department's measure of energy efficiency for the seasonal heating performance of heat pumps. The standards will apply to products manufactured for sale in the United States, as of January 23, 2006. The standard for split-system air conditioners, the most common type of residential air conditioning equipment, represents a 30 percent improvement in energy efficiency. For split-system heat pumps, the new standard would represent a 30 percent improvement in cooling efficiency and a 13 percent improvement in heating efficiency. The standard will also increase the cooling efficiency of single-package air conditioners and single-package heat pumps by 34 percent and the heating efficiency of single-package heat pumps by 17 percent. Finally, the Department is not yet adopting new standards for some products to ensure that more efficient versions remain available for niche applications. The Department has determined that the new standards are the highest efficiency levels that are technically feasible and economically justified as required by law. Therefore, the Department is amending the energy conservation standards for residential central air conditioners and heat pumps.

2. Central Air Conditioner and Heat Pump Features

The amended efficiency levels can be met by central air conditioner and heat pump designs that are already available in the market. We fully expect variations of these models to exist under the new standards, offering all the features and utility that are found in currently available products.

3. Consumer Benefits

Table I.1 summarizes the "characteristics" of today's typical central air conditioners and heat pumps. Table I.2 presents the implications for the average consumer of the standards becoming effective in 2006.

TABLE I.1.—CHARACTERISTICS OF TODAY'S TYPICAL CENTRAL AIR CONDITIONERS AND HEAT PUMPS [1]

	Split system air conditioner	Split system heat pump	Single package air conditioner	Single package heat pump
Average Installed Price	$2,236	$3,668	$2,607	$3,599
Annual Utility Bill [2]	$189	$453	$189	$453
Life Expectancy (years)	18.4	18.4	18.4	18.4
Energy Consumption per year (kWh)	2,305	6,549	2,305	6,549

[1] "Typical" equipment have cooling and heating efficiencies of 10 SEER and 6.8 HSPF, respectively.
[2] Utility bill pertains to the energy cost of operating the air conditioner or heat pump.

TABLE I.2.—IMPLICATIONS OF NEW STANDARDS FOR THE AVERAGE CONSUMER

	Split system air conditioner	Split system heat pump	Single package air conditioner	Single package heat pump
Year Standard Comes into Effect	2006	2006	2006	2006
New Average Installed Price	$2,571	$4,000	$3,032	$4,034
Estimated Price Increase	$335	$332	$425	$435
Annual Utility Bill Savings	$42	$70	$42	$70
Average Net Saving over Equipment Life	$113	$372	$29	$353
Energy Savings per Year (kWh)	532	1081	532	1081

The most typical air conditioner (*i.e.*, split system air conditioners which comprise approximately 65 percent of today's central air conditioning and heat pump market) has an installed price of $2,236 and an annual utility cost of $189. In order to meet the 2006 standard, the Department estimates that the installed price of a typical air conditioner will be $2,571, an increase of $335. This price increase will be offset by an annual energy savings of about $42 on the utility bills. The most typical heat pump (*i.e.*, split system heat pump) currently has an installed price of $3,668 and an annual utility cost of $453. In order to meet the 2006 standard, the Department estimates that the installed price of a typical heat pump will be $4,000, an increase of $332. This price increase will be offset by an annual energy savings of about $70 on the utility bills.

The Department recognizes that most consumers pay energy prices that are higher or lower than the "typical" consumer and operate their equipment more or less often. Consequently, the Department has investigated the effects of the different energy prices across the nation and different air-conditioning usage patterns. The Department estimates that 61 percent of all consumers purchasing a new typical air conditioner will either save money or will be negligibly impacted as a result of the 2006 standard. In the case of a new typical heat pump, 94 percent of all consumers either save money or will be negligibly impacted.

The Department also investigated how these standards might affect low income consumers. On average, the Department estimates that it is likely that low income air conditioner and heat pump consumers will also save money as a result of the standard.

4. National Benefits

The standards will provide benefits to the nation. DOE estimates the standards will save approximately 4.2 quads of energy over 25 years (2006 through 2030). This is equivalent to all the energy consumed by nearly 26 million American households in a single year. We also estimate this standard will have a net benefit to the nation's consumers of $1 billion over the same period. In 2020, the standards will avoid the construction of five 400 megawatt coal-fired plants and thirty-four 400 megawatt gas-fired plants. These energy savings will result in cumulative greenhouse gas emission reductions of approximately 33 million metric tons (Mt) of carbon, or an amount equal to that produced by approximately 3 million cars every year. Additionally, air pollution will be reduced by the elimination of approximately 94 thousand metric tons of nitrous oxides (NO_x) from 2006 through 2020.

B. Authority

Part B of Title III of the Energy Policy and Conservation Act (EPCA), Pub. L. 94–163, as amended by the National

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Energy Conservation Policy Act, Pub. L. 95–619, by the National Appliance Energy Conservation Act, Pub. L. 100–12, by the National Appliance Energy Conservation Amendments of 1988, Pub. L. 100–357, and by the Energy Policy Act of 1992, Pub. L. 102–486 [1] created the Energy Conservation Program for Consumer Products other than Automobiles. The consumer products subject to this program (often referred to hereafter as "covered products") include central air conditioners and heat pumps.

Under the Act, the program consists essentially of three parts: testing, labeling, and Federal energy conservation standards.

The National Appliance Energy Conservation Act of 1987 (NAECA) prescribed initial Federal energy conservation standards for central air conditioners and heat pumps. EPCA Section 325(d), 42 U.S.C. 6295(d). The Act specifies that the Department is to review the standards January 1, 1994. EPCA Section 325(d)(3)(A), 42 U.S.C. 6295(d)(3)(A).

Any new or amended standard must be designed so as to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. EPCA Section 325(o)(2)(A), 42 U.S.C. 6295(o)(2)(A).

Section 325(o)(2)(B)(i) provides that before DOE determines whether a standard is economically justified, it must first solicit comments on a proposed standard. After reviewing comments on the proposal, and before it adopts a standard, DOE must then determine whether the benefits of the standard exceed its burdens, based, to the greatest extent practicable, on a weighing of the following seven factors:

"(i) The economic impact of the standard on the manufacturers and on the consumers of the products subject to such standard;

(ii) The savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products which are likely to result from the imposition of the standard;

(iii) The total projected amount of energy savings likely to result directly from the imposition of the standard;

(iv) Any lessening of the utility or the performance of the covered products likely to result from the imposition of the standard;

(v) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the imposition of the standard;

(vi) The need for national energy conservation; and

(vii) Other factors the Secretary considers relevant."

In addition, section 325(o)(2)(B)(iii) establishes a rebuttable presumption of economic justification in instances where the Secretary determines that "the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy * * * savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure * * *." The rebuttable presumption test is an alternative path to establishing economic justification.

C. Background

The existing standards for residential central air conditioners and heat pumps have been in effect since 1992. As described above, the descriptor for air conditioner and heat pump cooling efficiency is SEER and the descriptor for heat pump heating efficiency is HSPF. The current central air conditioner and heat pump efficiency standards are as follows:

—Split system air conditioners and heat pumps—10 SEER/6.8 HSPF
—Single package air conditioners and heat pumps—9.7 SEER/6.6 HSPF

On September 8, 1993, DOE published an Advance Notice of Proposed Rulemaking (ANOPR) announcing the Department's intention to revise the existing central air conditioner and heat pump efficiency standard. 58 FR 47326. During a workshop on June 30, 1998, we presented for comment an analytical framework for the central air conditioner and heat pump standards rulemaking. The analytical framework described the different analyses to be conducted, the method for conducting them, the use of new spreadsheets, and the relationship of the various analyses. On November 24, 1999, DOE published a Supplemental ANOPR. 64 FR 66306. On October 5, 2000, DOE published a Notice of Proposed Rulemaking (NOPR or proposed rule). 65 FR 59590. The energy efficiency standards proposed for residential central air conditioning heat pumps (heat pumps) were as follows:

—Split system and single-package air conditioners—12 SEER
—Split system and single package heat pumps—13 SEER/7.7 HSPF
—Through-the-Wall air conditioners and heat pumps—11 SEER/7.1 HSPF.

In addition to the increase proposed in SEER and HSPF, the Department requested comments on a proposal to adopt a standard for steady-state cooling efficiency, EER.[2] The proposal on EER was designed to ensure more efficient operation at high outdoor temperature, during periods when electricity use by air conditioners is at its peak.

The proposed rule provided additional background information on the current standards, the history of previous rulemakings and the procedures, interpretations and policies which guide the Department in developing new efficiency standards, which are set forth as the Process Improvement Rule. 61 FR 36974. A public hearing was held in Washington, DC on November 16, 2000, to hear oral views, data and arguments on the proposed rule.

II. General Discussion

A. Technological Feasibility

1. General

There are central air conditioners and heat pumps in the market at all of the efficiency levels prescribed in today's final rule. The Department, therefore, believes all of the efficiency levels adopted by today's final rule are technologically feasible.

2. Maximum Technologically Feasible Levels

Pursuant to section 325(p)(2) of the Act, and as discussed in the proposed rule, the Department determined that 18 SEER is the maximum technologically feasible (Max Tech) level for cooling efficiency for all product classes and capacities covered by this rulemaking. 65 FR 59593. The Max Tech level for heating efficiency, is 9.4 HSPF which is the highest HSPF rating currently available in residential heat pumps.

B. Energy Savings

1. Determination of Savings

The Department forecasted energy savings through the use of a national energy savings (NES) spreadsheet as discussed in the proposed rule. 65 FR 59590, 59593 (October 5, 2000). The spreadsheets and assumptions upon which the results of today's final rule is based are unchanged.

2. Significance of Savings

As discussed in the proposed rule, section 325(o)(3)(B) of the Act prohibits the Department from adopting a standard for a product if that standard would not result in "significant" energy savings. The energy savings for the standard levels we are adopting today are non-trivial—indeed they are substantial—and therefore we consider them "significant" within the meaning of section 325 of the Act.

C. Rebuttable Presumption

The National Appliance Energy Conservation Act established new criteria for determining whether a standard level is economically justified. Section 325(o)(2)(B)(iii) of the Act states:

"If the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy * * * savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure, there shall be a rebuttable presumption that such standard level is economically justified. A determination by the Secretary that such criterion is not met shall not be taken into consideration in the Secretary's determination of whether a standard is economically justified."

If, according to the test procedure, the increase in initial price of an appliance due to a conservation standard would repay itself to the consumer in energy savings in less than three years, then we presume that such standard is economically justified. This presumption of economic justification can be rebutted upon a proper showing.

The standard levels we are adopting today do not satisfy the criteria set forth above. Therefore, we cannot presume them to be economically justified and have performed additional analysis to support the Secretary's determination that they are indeed economically justified.

D. Economic Justification

As noted earlier, Section 325(o)(2)(B)(i) of the Act provides seven factors to be evaluated in determining whether a conservation standard is economically justified.

1. Economic Impact on Manufacturers and Consumers

We considered the economic impact on manufacturers and consumers as discussed in the proposed rule. 65 FR 59590, 59593 (October 5, 2000).

2. Life-cycle-costs

We considered life-cycle-costs as discussed in the proposed rule. 65 FR 59590, 59594 (October 5, 2000). The installed price and operation and maintenance costs were calculated for a range of consumers around the nation to estimate the range in life cycle cost benefits that consumers would expect to achieve due to new standards.

3. Energy Savings

While significant conservation of energy is a separate statutory requirement for establishing an energy conservation standard, the Act requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from revised standards.

4. Lessening of Utility or Performance of Products

This factor cannot be quantified. In establishing classes of products, the Department has attempted to eliminate any degradation of utility or performance in the products covered by today's final rule. Attributes that affect utility include the product's ability to cool and dehumidify. In some applications, noise levels may also be an aspect of utility. Product size or configuration can also be considered utility if a change in size would cause the consumer to install the product in a location or in a manner inconsistent with the consumer's preferences.

5. Impact of Lessening of Competition

It is important to note that this factor has two parts; on the one hand, it assumes that there could be some lessening of competition as a result of standards; and on the other hand, it directs the Attorney General to gauge the impact, if any, of that effect.

In order to assist the Attorney General in making such a determination, the Department provided the Attorney General with copies of the proposed rule and the Technical Support Document for review. The Attorney General's response is discussed in section V.D.5 below, and is reprinted at the end of the rule.

6. Need of the Nation To Conserve Energy

The Secretary recognizes that energy conservation benefits the Nation in several important ways. Enhanced energy efficiency improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts of energy production.

7. Other Factors

This provision allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to be relevant. EPCA Section 325(o)(2)(B)(i)(VI), 42 U.S.C. 6295(o)(2)(B)(i)(VI).

Under this factor, we considered the potential improvement to the reliability of the electrical system. Recent summertime electric power outages in various regions of our country resulted in disruption of many peoples' lives and businesses. The schedule contained in the Act called for the Department to revise the standards for central air conditioners and heat pumps by 1994, to be effective in 1999. For reasons explained in the proposed rule and ANOPR, promulgation of many standards including those for central air conditioners and heat pumps was delayed.

While central air conditioning accounts for about 10 percent of residential electricity consumption, it can account for several times this amount during peak hours on hot summer days, when electricity reliability is most strained. A 30 percent improvement in air conditioner efficiency would reduce the nation's total annual electricity use by approximately 2 percent after it was fully phased in. However, the same efficiency improvement would provide a greater percentage reduction in peak loads, reducing the prospect of brownouts and price spikes. These peak load reductions are critical given that the conditions leading to grid instability can occur well before peak demand even equals supply.

The Final Report [3] by the team of experts convened by the Secretary to investigate the electric power problem included the recommendation to increase the energy efficiency of central air conditioners as one means for enhancing reliability. This recommendation led the Secretary to put this rulemaking on the fast track and to advance the publication of today's final rule for central air conditioners and heat pumps. Thus, the Department has considered effects of the rule on electric power system reliability.

III. Methodology

As discussed in the proposed rule, the Department developed new analytical tools for this and other recent rulemakings. The first tool was a

[1] Part B of Title III of the Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act, the National Appliance Energy Conservation Act, the National Appliance Energy Conservation Amendments of 1988, and the Energy Policy Act of 1992, is referred to in this notice as EPCA, or the "Act." Part B of Title III is codified at 42 U.S.C. 6291 *et seq.* Part B of Title III of the Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act only, is referred to in this notice as the National Energy Conservation Policy Act.

[2] EER, Energy Efficiency Ratio, is a steady-state measure of energy efficiency which measures efficiency at a prescribed outdoor temperature (95 °F), and is one of the test conditions in the Department's test procedure used to develop the SEER.

[3] "Report of the U.S. Department of Energy's Power Outage Study Team: Findings and Recommendations to Enhance Reliability from the Summer of 1999", March 2000.

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spreadsheet that calculates life-cycle-cost (LCC) and payback period. The second calculates national energy savings and national net present value (NPV). The Department also completely revised the methodology used in assessing manufacturer impacts including the adoption of the Government Regulatory Impact Model (GRIM). Additionally, DOE developed a new approach using the National Energy Modeling System (NEMS) to estimate impacts of air conditioner energy efficiency standards on electric utilities and the environment.

In order to estimate production costs for this rulemaking, we used an efficiency level approach, with cost data provided by the Air Conditioning and Refrigeration Institute (ARI) and through our own reverse engineering methods. The ARI cost data presented the minimum, mean, and maximum cost estimates for the sample of ARI members who participated. The data covered each product class at each efficiency level through 15 SEER, and was expressed relative to the base cost for each manufacturer. The reverse engineering methodology, conceived as a way to validate the ARI data, analyzed seventy-one samples, mostly selected by manufacturers, using design data provided by manufacturers. We physically examined three of these models. In refining our results, we reviewed our detailed cost estimates for split air conditioners with a major manufacturer.

The benefits of reverse engineering include the transparency of the methods, data, and assumptions used to produce the estimates, and the insights gained into the design options used to achieve the different efficiency levels. The ARI data provides none of these benefits, but does draw on the considerable expertise of the manufacturers involved in producing the underlying estimates describing all of the products on the market. One benefit of the reverse engineering analysis is that results are expressed in absolute costs instead of relative costs. Absolute costs are needed to represent production costs at the minimum efficiency level and are helpful in representing the production costs at higher efficiency levels.

Regarding the analytical methodology, the Department continues to use the spreadsheets and approaches explained in the proposed rule. 65 FR at 59594–59597. We have applied them to develop the analysis further in this final rule. We added new analysis based on the manufacturing cost estimates that we had derived through reverse engineering techniques. Also, because its results were similar to those derived using our 18.4-year equipment life assumption, we are no longer considering the 14-year equipment lifetime scenarios in the economic analysis. Finally, the emissions reductions analysis now also estimates the discounted value of cumulative emission reductions.

IV. Discussion of Comments

Since we opened the docket for this rulemaking, we have received over 800 comments from a diverse set of interested parties, including manufacturers and their representatives, states, energy conservation advocates, heating and air-conditioning contractors, consumers, electric utilities and others. The comments addressed the burdens and benefits associated with more stringent standards, aspects of our analysis, the merits of the different trial standard levels and standard options we considered, and the DOE rulemaking process. Many comments raised issues that we substantially addressed in the proposed rule and Supplementary ANOPR. Comments received during the most recent comment period are addressed below, and some previous comments are revisited.

A. Burdens and Benefits

This section discusses comments we received on the burdens and benefits associated with more stringent minimum efficiency standards, organized into the seven factors that the Secretary considers as a basis for deciding whether a standard level is economically justified.

1. Economic Impacts

a. *Economic Impacts on Manufacturers.* According to our manufacturer impact analysis, more stringent efficiency standards burden most manufacturers by causing them to make new investments in capacity, research and development, and testing. We also expect most manufacturers to experience lower profitability and sales volumes for several years after the adopted standards become effective. Some manufacturers in our analysis benefit under more stringent standards.

ARI characterizes the financial burdens on the industry overall as severe. They also assert that the hydrochloroflourocarbons (HCFC) phaseout results in cumulative burdens. (ARI, No. 100 at pp. 6 and 13). Some manufacturers noted that EER and thermal expansion valve (TXV) requirements would add to the burden. (York, No. 90, at pp. 4–5). The Natural Resources Defense Council (NRDC) questions whether we considered that reverse engineering-based prices reduce impacts through price elasticity effects, but noted that industry impacts did not seem to change across trial standard levels, and the Oregon Office of Energy (OOE) believes that we have overstated manufacturer impacts since they are already making investments in new technologies to help them improve product efficiency. (NRDC, No. 88 at p. 15; and OOE, No. 84 at p.5).

The reduction in industry net present value does increase with increasing standard levels, particularly since we consider it more likely that the Roll-up [4] scenario will occur under higher standard levels. Individual manufacturers themselves discussed their situations with us at length, and we have incorporated the information they presented to us into our manufacturer impact analysis. In adopting this rule, we have assumed that the Roll-up scenario is the most likely outcome resulting from a new 13 SEER standard for all product classes. We did consider the change in sales volumes driven by changes in the underlying cost assumptions.

Many comments described what they consider disproportionate impacts on manufacturers of niche products. Those comments are discussed in Section IV.4 below.

The Department has considered the manufacturer burdens as described in the manufacturer impact analysis of the TSD in adopting the new standard. These include cumulative burdens. It also considers the extent to which the differences among efficiency scenarios change the implications of more stringent standards.

b. *Economic Impacts on Consumers.* Many comments mention the economic burdens that more stringent efficiency standards can place on consumers who are sensitive to increases in first cost. Many noted that our decision should consider burdens on consumers caused by long median payback periods. Some comments emphasized that disproportionate impacts on low income consumers due to an expected increase in installed price would reduce the number of consumers who would be able to afford new air conditioners. Some comments suggested that this effect could increase health problems and deaths. The Mercatus Center stated that the Department believed consumers pass up energy efficient equipment because they are misinformed about

[4] The Roll-up scenario assumes that the proportion of equipment with efficiency ratings above the new standard level will not increase compared to their proportion today.

operating costs, therefore the Department should construct a program to correct this deficiency. (ARI, No. 100 at pp. 2 and 5; American Public Power Association (APPA), No. 113 at p. 2; Manufactured Home Institute (MHI), No. 99 at p. 1; Lennox, No. 91 at p. 3; Consumer Federation of America (CFA), No. 110 at p. 1; Nebraska Public Power District (NPPD), No. 109 at p. 2; National Association of Home Builders (NAHB), No. 94 at p. 1; Nordyne, No. 101 at p. 2; Trane, No. 93 at p. 4; York, No. 90 at pp. 4–5; and Mercatus Center, No. 115 at pp. 18–19).

CFA considers lower energy bills a benefit and would support regional standards and public assistance programs to mitigate long payback periods and disproportionate impacts on consumers. (CFA, No. 110 at p. 2).

Many comments express the belief that, for various reasons, we either underestimated or overestimated economic impacts on consumers. Those comments are addressed in Section IV.B. below.

We recognize that increases in first cost and long payback periods are generally considered burdens on consumers. Based on the reverse engineering derived manufacturing cost estimates, however, our analysis shows that, at the adopted standard levels, the payback period is shorter than the life of the equipment. This means that over the life of the product, any increase in price will be paid back to the average consumer. Thus, the new efficiency standards should provide the average consumer with a long term economic benefit. Also, we have examined impacts on low income consumers, and found them to benefit overall. Consumers concerned about potential health effects should note that assistance programs are already available to assist them with their air conditioning purchases, and that room air conditioners will continue to be available when cooling in individual rooms could mitigate their health concerns.

2. Life-Cycle Costs

ARI, The Trane Company (Trane), American Electric Power (AEP), Mercatus Center, Southern Company, Dominion Virginia Power (Dominion), and Edison Electric Institute (EEI) asserted that the percent of consumers realizing life-cycle-cost savings at the standard levels issued in the proposed rule were too low and did not warrant an increase in the minimum efficiency standard. (ARI, No. 100 at p. 2; Trane, No. 93 at p. 4; AEP, No. 83 at p. 1; Mercatus Center, No. 115; Southern Company, No. 96 at p. 2; Dominion, No. 103 at p. 3 and Transcript No. 73 at pp. 50–51; and EEI, Transcript No. 73 at pp. 176–178). Carrier Corp. asserted that there were too many consumers incurring life-cycle-cost increases at 12 SEER. (Carrier, No. 92 at p. 5). In contrast, the American Council for an Energy-Efficient Economy (ACEEE), the Alliance to Save Energy (ASE), the Pacific Gas and Electric Company (PG&E), and NRDC argued that the percent of consumers realizing life-cycle-cost savings from a particular standard level is not the appropriate measure for establishing an updated efficiency standard. Because air-conditioning use is highly dependent on climatic conditions and because these are national standards, it is to be expected that some consumers in the Northern part of the U.S. will realize net costs from an increased standard but will be offset by consumers in the Southern part of the U.S. who will realize life-cycle cost savings from more efficient air-conditioning equipment. Due to this disparity, they argue it is better to base the standard on national average life-cycle-cost results. (ACEEE, No. 104 at p. 13; ASE, No. 81 at p.9; PG&E, No. 104 at p. 5; and NRDC, No. 88 at pp. 19–21).

EPCA requires the Department to consider life-cycle-cost as one of the seven factors in determining economic justification. In determining economic justification, the Secretary must determine whether the benefits of a standard exceed the burdens. Life-cycle-cost is just one of the factors to be considered and there is no mathematical formula for weighing the benefits and burdens of the various factors. There are also no mathematical thresholds for life-cycle-cost as implied by EEI and ACEEE. (EEI, Transcript No. 73 at p. 177; and ACEEE, Transcript No. 73 at p. 182). The Department notes that under the standards in today's rule, consumers on average will have lower life-cycle costs. Furthermore, it appears that EPCA, in requiring DOE to set national standards that maximize energy savings for appliances where there will obviously be regional differences in usage and energy costs, contemplated that the level of life cycle cost savings would vary among consumers.

We have quantified the distribution of life cycle costs among consumers and have considered it, along with other information, in the weighing of the benefits and burdens of each standard level we assessed.

3. Energy Savings

ARI states that the Department overestimated the energy savings realized from efficiency standards by basing the savings on source energy consumption at the power plant, rather than site energy consumption at the household or commercial building. (ARI, No. 100 at p. 11). While neither stating that the energy savings estimated by the Department were too great or too low, ASE claims that 70 billion kWh would be saved from a 13 SEER standard coupled with a minimum EER requirement of 11.6 and mandatory use of TXVs. (ASE, No. 81 at p. 12). ACEEE also claims that significant national energy savings will be realized from a 13 SEER standard, an 11.6 minimum EER requirement, mandatory use of TXVs, and an HSPF standard of 7.9.

NAECA prescribes that consumer energy savings be evaluated based on site rather than source energy consumption. However, the Department believes national energy savings evaluated at the source reflects a more accurate representation of the energy consumption being avoided from a standard. Evaluating energy at the source takes into account the efficiency of the generation source as well as the transmission and distribution of the electricity. The Department accounts for site energy consumption in its analysis of consumer life-cycle-cost impacts. With regard to the magnitude of the energy being saved from a standard, the Department is confident in its National Energy Savings (NES) spreadsheet model to forecast the source energy savings realized from all standard levels, including a 13 SEER standard. Discussions with regard to minimum EER standards and TXV requirements are presented later in this Chapter.

4. Lessening of Utility or Performance of Products

Comments regarding lessening of utility related mainly to the impacts that more stringent standards may have on the availability of niche products and some products that are not typically considered "niche". Most comments stated that those products face size constraints that they will find difficult, if not impossible, to conform to under more stringent standards. That result could lead to the removal of the products from the market, or to equipment prices that are higher than the market would be able to sustain. (Friedrich, No. 116 at p. 1; Unico, No. 117 at pp. 1–2; Carrier, No. 92 at p. 8; Lennox, No. 91 at p. 7; Trane, No. 93 at p. 18; Mitsubishi, No. 87 at p. 1; Armstrong, No. 86 at pp. 1–3; and Fujitsu, No. 85 at p. 1).

We recognize that contractors and consumers do take product size into account when making a purchase, and that size constraints can make it more

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difficult for manufacturers to offer equipment meeting performance needs. This is true for niche products, which we discuss elsewhere, as well as for conventional products. The same was the case when the 10 SEER minimum standards were agreed upon and established in 1987. Manufacturers can attempt to prevent size constraints from degrading performance or utility by offering smaller 13 SEER equipment than they typically offer today. The technical options for achieving that objective include existing and emerging technologies. Therefore, we do not consider it likely that products will be unavailable that meet the new 13 SEER standard, and have substantially the same capacities, performance and range of sizes as today's products.

If the size of 13 SEER equipment does not generally decrease under new standards, some consumers may be required to incur additional installation expense to accommodate the larger equipment. We discuss this in more depth in Section IV.B.2.e. The Department did consider that possibility when adopting today's standards.

Along a separate line, Southern Company is concerned that higher efficiency equipment will reduce dehumidification, which is an important attribute in moderate, humid, climates. (Southern Company, No. 96 at pp. 4–5). The equipment's ability to dehumidify is a function of its design and not necessarily its efficiency. As we stated in the proposed rule, evidence indicates that sensible heat ratios in high efficiency equipment are similar to those at the baseline. We trust that under a more stringent standard, manufacturers will seek to serve the needs of the market with products that dehumidify properly.

5. Impact of Lessening of Competition

The Department of Justice (DOJ) and others commented that the more stringent standards contained in the proposed rule could lessen competition. (DOJ, No. 112; Trane, No. 93 at p. 12; and EEI, No. 80 at p. 8). Aspects of our manufacturer impact analysis support that conclusion. We discuss the DOJ concerns in more depth in Section V.D.5. The letter from the Department of Justice is attached in the Appendix of this rulemaking. We recognize that the standard levels we are adopting could accelerate the consolidation trend among major manufacturers. However, as discussed in the manufacturer impact analysis, we do not expect that any manufacturer or group of manufacturers will be able to use the standards as an opportunity to consolidate their market power. (*See* TSD, Chapter 8). Therefore, we believe that competition will remain vigorous under the adopted standard, and any lessening of competition that does occur will not result in price increases or loss of choice and utility for consumers.

Other comments note that a large fraction of today's models would not be able to meet more stringent standards. (AEP, No. 83 at p. 1; Dominion, No. 68 at p. 2; ARI, No. 100 at p. 11; and EEI, No. 80 at p. 8). In the manufacturer impact analysis, we considered that manufacturers will have to design new products to meet any increased standard level. Furthermore, products are technologically feasible through 18 SEER. So, while many of today's models may not be available under more stringent standards, we fully expect variations of those models to be available, offering all the features and utility of currently available products.

6. Need of the Nation To Conserve Energy

Of the approximately 800 comments we have received, the vast majority were from individuals and organizations who made similar claims regarding the benefits that would be associated with a 13 SEER standard and an EER standard for air conditioners and heat pumps. These benefits included savings for consumers, avoided emissions and electrical capacity, and the reduced occurrence of brownouts and blackouts. Although our analysis is not able to substantiate many of these claims, all of these issues relate to the need of our nation to conserve energy. We recognize that a broad cross-section of citizens and organizations are concerned about these issues and in the potential for more stringent standards to address them.

We discuss more specific comments related to economic benefits and electric system capacity in other sections of this chapter. In this section, we discuss the comments we received regarding environmental benefits.

ASE claims that a 13 SEER standard coupled with an 11.6 EER minimum standard and a mandatory TXV requirement would yield environmental benefits in the form of the following air-borne emission reductions: 15 million metric tons of carbon, 40,000 tons of nitrous oxides, and 200,000 tons of sulfur dioxide in 2020. Northeast Energy Efficiency Partnership (NEEP) also states that significant carbon dioxide emission reductions could be achieved with a 13 SEER standard relative to a 12 SEER standard. (ASE, No. 81 at p. 12; and NEEP, No. 118 at p. 2). The Northwest Power Planning Council (NWPPC) states that the Department used the average heat rate of avoided plants rather than the heat rate of operating plants displaced by the efficiency standards when determining emission reductions. As a result, NWPPC claims that the emissions mitigated by the standards were underestimated (NWPPC, No. 76 at p. 6).

National energy savings realized from central air conditioner and heat pump efficiency standards are directly translated into reduced air-borne emissions at electric power plants. The magnitude of the emission reductions are determined through the use of NEMS–BRS [5], a version of NEMS used for appliance standards analyses. NEMS–BRS is based on the AEO2000 version with minor modifications. NEMS offers a sophisticated picture of the effect of standards since its scope allows it to measure the interactions between the various energy supply and demand sectors and the economy as a whole. Thus, although the Department agrees with ASE that emissions will be avoided from new air conditioner and heat pump efficiency standards, the Department believes that the magnitude of those emission reductions are best estimated with NEMS–BRS. In the case of SO_2, the Clean Air Act Amendments of 1990 set an emissions cap on all power generation. The attainment of this target, however, is flexible among generators and is enforced by applying market forces, through the use of emissions allowances and tradable permits. As a result, accurate simulation of SO_2 trading tends to imply that physical emissions effects will be zero because emissions will always be at, or near, the ceiling. This fact has caused considerable confusion in the past. We do not believe there is a potential benefit in reductions in SO_2 emissions from electricity savings as long as emissions of SO_2 are at or near the emission ceilings. With regard to the issue of heat rates, contrary to NWPPC's assertion, the Department did use the heat rates of displaced power plants in determining the emission reductions resulting from efficiency standards.

7. Other Factors

With regard to other factors, the issue of electric system reliability attracted numerous comments. EEI, AEP, and

[5] EIA approves use of the name NEMS to describe only an AEO version of the model without any modification to code or data. Because our analysis entails some minor code modifications and the model is run under various policy scenarios that deviate from AEO assumptions, the name NEMS–BRS refers to the model as used here. For more information on NEMS, please refer to the National Energy Modelling System: An Overview 1998. DOE/EIA–0581 (98), February, 1998. BRS is DOE's Office of Building Research and Standards.

Dominion Virginia Power stated many changes are occurring in the electric utility industry at the same time electric load is continuing to grow. As a result, the overall effect of any end-use efficiency measure, such as an air conditioner and heat pump standard, is likely small. (EEI, Transcript, No. 73 at p. 224; AEP, No. 83 at p. 4; and Dominion, No. 103 at p. 4). Southern Company argued that once a standard is established, new load growth forecasts incorporating its effects will likely be made and investment decisions will be accordingly adjusted. In other words, since the effects of this rule do not become noticeable until five or more years after its 2006 effective date, utilities will have ample time to plan and construct capacity in response to expectations of load growth, reserve margin, and, where competition has become normal practice, to prices. (Southern Company, Transcript No. 73 at p. 241). Synapse Energy Economics (Synapse), along with ACEEE, NWPPC, NRDC, ASE, and PG&E noted that there is a real issue in meeting increased demand, due in large part to increased air conditioner usage. Synapse also notes that conventional assumptions about the ability of the power system to meet growing load are increasingly coming into question as the barriers to system expansion are not inadequate price incentives or unwillingness to invest, but rather siting (of generation, transmission, and distribution capability), environmental, and other constraints. (Synapse, Transcript No. 73 at p. 243; ACEEE, No. 104 at pp. 13–15; NWPPC, Transcript No. 73 at p. 253; NRDC, No. 88 at pp. 4 and 6; ASE, No. 81 at pp. 7 and, 10; and PG&E, Transcript No. 73 at p. 251).

In a March 2000 final report, the DOE Power Outage Study Team described several power outages that occurred in the summer of 1999. During early July, a heat storm affected much of the East from New England down past the Mid-Atlantic causing many problems. From July 3 through 8, service was interrupted to a total of 110,000 Long Island Power Authority (LIPA) customers for varying periods. During that period, two new system peak loads were set and LIPA activated its Commercial Peak Reduction Program, appealed to its other large customers to voluntarily curtail their use of electricity and reduced system-wide voltage by five percent. Many organizations and government offices responded by closing early or cutting back on their electricity use. On July 6, the eastern half of the Pennsylvania, New Jersey, Maryland Interconnection grid experienced sudden and steep voltage declines as an all-time-high peak load was recorded. The integrity of the system was maintained by reducing voltage, curtailing contractually interruptible customers and appealing for voluntary load reductions. On that same day, Delmarva Power and Light had a capacity shortfall that resulted in rotating outages from 10:30 a.m. until 7:30 p.m. affecting 138,000 customers. In the Chicago area on July 30, Commonwealth Edison set all-time-peak demand during a period of intense heat and humidity. Resulting system failures caused more than 100,000 customers temporary losses of power for up to several hours. The summer of 2000 has seen similar types of problems in the state of California.

Outages such as these can cost millions of dollars per hour depending on which and how many customers are affected. Although we recognize that system adequacy may only play a small part in ensuring system reliability, the Department is convinced, especially due to recent expansion shortfalls in the Western part of the U.S., that system reliability is an important issue which can be addressed, to some degree, by increased air conditioner and heat pump standards. The impacts of standards could be potentially beneficial in lowering overall system stress and postponing necessary investment. This is especially important since annual investment in transmission has roughly halved since the levels of the 1970's [6]. The potential benefit of air conditioner and heat pump efficiency improvements is a factor in establishing the standards being issued today. In addition, the Department is continuing to establish national equipment standards in the form of the current efficiency descriptors (i.e., SEER and HSPF), as discussed below, it will examine ways to provide additional credit in the test procedure for EER rather than using such additional measures as minimum EER standards and mandatory TXV requirements.

B. Analysis and Assumptions

1. Engineering Analysis

a. Reliance on ARI and Reverse Engineering Cost Estimates. The Department considered primarily two sets of data for relating the manufacturing costs of current baseline (minimum SEER) equipment to the manufacturing costs of higher efficiency equipment which would become baseline equipment under new standards: one source provided by the industry through ARI and the other source determined from the Department's reverse engineering analysis. In the proposed rule, our analyses and conclusions relied heavily on the ARI manufacturing cost estimates, and less on the reverse engineering cost estimates.

However, several comments questioned the validity of the ARI results and recommended we rely more heavily, if not exclusively, on the reverse engineering estimates. They cited various reasons, including retail price information that matched the ARI Mean, the greater transparency of the reverse engineering process and results, and the natural tendencies of manufacturers to overestimate the costs of complying with more stringent standards. The same comments even suggest that the reverse engineering cost estimates may themselves be overestimates. (OOE, No. 84 at p. 3; NRDC, No. 88 at pp. 3–15; ASE, No. 81 at p. 11; and NEEP, No. 188 at p. 3).

Other comments supported the use of the ARI data, citing the experience of the manufacturers and apparent flaws in the assumptions and methodology used in the reverse engineering analysis, which was designed as a validation tool. These perceived flaws included the small number of tear-downs performed. However, ARI and some of its members recognize that the reverse engineering results fall within their range and seem to validate their data to some extent. (ARI, Transcript No. 14 at p. 42, No. 48 at p. 2 and No. 100 at p. 9; Carrier, No. 92; Trane, No. 93; and Lennox, No. 91 at p. 4).

While we recognize the expertise of ARI's members related to projecting the cost of producing central air conditioning equipment, we have several concerns with the ARI data. First, ARI has not satisfactorily explained why their cost data at 12 SEER and higher levels display such a large range between the minimum and maximum values. We are convinced that, in order to remain competitive, manufacturers will have to adopt relatively similar paths to increase the efficiency of their baseline products to meet the new minimum standards. This will tend to result in actual costs that are closer to the ARI Minimum values than to the ARI Mean values.

We are also concerned with how closely the data on recent Wisconsin retail prices, submitted by ACEEE, agrees with the ARI Mean cost estimates. Once we adopt a higher minimum efficiency level, we believe that the retail prices of baseline equipment that must meet that level

[6] "Hirst, E., "Expanding U.S. Transmission Capacity." Paper prepared for Edison Electric Institute, Washington D.C., July 2000: p. 8–9.

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will decline below the price of equipment currently at that level. York International Corporation (York) and ARI confirmed, for example, that their markups generally increase on higher efficiency equipment, and Star Supply Company seemed to imply that distributor markups increase with increasing efficiency. (Star Supply Co., No. 95 at p. 2; York, Transcript No. 73 at p. 117; and ARI, No. 100 at p. 3). Those markups are reflected in the current retail prices of those products. Due to competitive pressures at the baseline level, today's markups would not be sustainable for baseline equipment that meets, but does not exceed, a new standard. In addition, as noted by John Compton of Home Excellence, Inc. (HEI), a heating and air-conditioning contractor, the new, more efficient, baseline equipment would likely possess fewer of the premium features found in today's high efficiency equipment. (HEI, Transcript No. 73 at p. 123). For those reasons, current retail price data would overestimate the relative cost of high efficiency products under new standards. The agreement between ARI's mean cost data and the Wisconsin retail price data suggests that the ARI cost data correspond to today's costs of producing high efficiency equipment rather than to the lower production costs we would expect under new standards.

The reverse engineering analysis, on the other hand, is transparent and the results fall within the ARI range and nearer to the ARI Minimum where we expect competitive pressure to drive manufacturing costs. Seventy-one samples were analyzed using bills-of-materials provided manufacturers, supplemented with three physical teardowns, and detailed estimates for split air conditioners were reviewed with a major manufacturer. Our reverse engineering methodology, though originally conceived as a validation exercise, is itself a valid method of estimating equipment production costs, and is well suited for use in this rulemaking as an indicator of the most likely production costs under new standards.

Based on a consideration of the above, we conclude that the reverse engineering cost estimates are more representative of what actual production costs will be under new standards and that the ARI Mean cost data very likely overestimate those costs. For that reason, we are weighing the reverse engineering cost estimates heavily in our decision-making. We continue to provide the results based on the ARI Mean data cost to illustrate an upper bound, which we believe will be quite an unlikely outcome.

b. *Consideration of Emerging Technologies.* ACEEE and others commented we should have included the savings that could result from the use of emerging technologies rather than presenting them separately. The Oregon Energy Office and Thermalex, Inc. also expressed more optimism regarding the applicability and probability of adoption for microchannel heat exchangers than we had expressed in the TSD. (ACEEE, Transcript No. 73 at p. 88; ASE, No. 81 at pp. 8, 9 and 12; OOE, No. 84 at p. 5; and Thermalex, No. 89 at pp. 1–2).

Trane and York dispute some of the claims regarding the potential of emerging technologies. (Trane, No. 93 at p. 7; and York, No. 90 at p.4).

According to our engineering analysis described in Section 4.5 of the TSD, on a system basis, emerging technologies cannot make a significant cost impact below 14 SEER. That explains why they are not in widespread use today. At 14 SEER and above, some emerging technologies could compete quite favorably with the technologies that currently dominate in some applications. We did not analyze standard levels at 14 SEER, instead we examined 13 SEER and 18 SEER, the Max Tech level. ACEEE contends that, had we evaluated life-cycle-costs using reverse engineering analysis combined with emerging technology impacts, a standard level as high as 14 SEER may have been justified after all, and should have been considered. (ACEEE, Transcript No. 73 at p. 171, and No. 101 at p. 7).

From our ANOPR analysis based on ARI mean costs, we concluded that standard levels between 13 SEER and 18 SEER did not warrant further consideration. York had stated that ARI's cost data already included the benefits of emerging technologies although we could not verify the methods they used to incorporate them. (York, Transcript No. 14 at p. 116; and ARI, Transcript No. 14 at p. 115). Economic impact results based on reverse engineering were more favorable, but still were far from compelling. For example, the impact on national net present value was negative $8.4 billion for 14 SEER split air conditioners. We believe that incorporating the modest reduction in cost due to the most likely impact of emerging technologies (about 10 percent for split air conditioners) would not have resulted in a 14 SEER level being economically justified.

Overall, we considered the potential of emerging technologies to penetrate the market in 13 SEER products under a 13 SEER standard to be higher than under lower standard levels. Partially for that reason, we believe that the burdens that could accrue from increases in the size of baseline equipment under a 13 SEER standard can be somewhat mitigated by the use of emerging technologies.

2. Life Cycle Cost (LCC) Analysis

a. *Probability-based analysis.* Trane questioned the use of a Monte Carlo probability-based analysis because they claim that several of the distributions used to characterize the inputs to the analysis are erroneous. (Trane, No. 93 at pp. 4–5).

As part of the process to improve the energy efficiency standards analysis, the Department uses a probability-based analysis to determine a distribution of life-cycle cost impacts for consumers utilizing central air conditioners and heat pumps. Most of the inputs to the analysis are characterized with distributions. While some of the input distributions are based on limited data, no other data have been offered to recharacterize the distributions. Therefore, the Department sees no compelling reason to alter its assumptions regarding the input distributions.

b. *Energy Use.* Trane claimed that the 1997 Residential Energy Consumption Survey (RECS) sample is too small and may not accurately represent the population of central air conditioner and heat pump consumers. In addition, they claimed that the Department is not accurately representing the saturation of air-conditioned households. Trane stated that the saturation reported by the Department (37.6 percent) is inconsistent with the saturation reported by RECS (47 percent). (Trane, No. 93 at pp. 4–5).

As part of the process to improve the energy efficiency standards analysis, the Department is committed to use sensitivity analysis tools to evaluate the potential distribution of impacts among different subgroups of consumers. The Department believes that RECS provides a nationally representative household data set which is suited for conducting the type of sensitivity analyses suggested by the Process Rule. Limiting the RECS households to those equipped with either central air conditioners or heat pumps, the LCC analysis performs a household-by-household analysis that predicts the percentage of households that will incur net life-cycle cost savings or costs from an increased efficiency standard. With regard to apparent discrepancies between air-conditioned household saturations, the 37.6 percent saturation value cited by Trane represents only those households with central air conditioners. When including homes with central air-conditioning heat pumps, the household saturation used by the Department in its LCC analysis matches the 47 percent saturation level reported by RECS.

c. *Electricity Prices.* Wholesale electricity cost data for the period of 1998 through October, 2000, presented by experts on behalf of the Appliance Standards Awareness Project (ASAP), demonstrated dramatic variations in seasonal wholesale electricity costs for regions of the country (i.e., California, New England, New York, and the Pennsylvania-New Jersey-Maryland region) that have recently deregulated their electric utility industry. In particular, wholesale costs during summer months and especially certain summer day hours were significantly greater than annual average wholesale costs. Wholesale electricity cost data for the period spanning 1998 through 1999 for six regulated North American Electric Reliability Council (NERC) regions were also presented showing that summer costs were also significantly greater than average annual costs. (Synapse, Transcript, No. 73 at pp.127–137 and No. 108 at p. 5). Asserting that DOE's marginal prices based on 1996 and 1997 data are regulated and do not reflect the marginal cost of electricity under a deregulated market, ASAP, ACEEE, NWPPC, and Synapse argued that based on recent wholesale electricity cost data, marginal costs will significantly exceed average costs during periods when air conditioners are operating.[7] Future marginal electricity prices are also likely to increase as electricity markets through out the U.S. are deregulated. (ASAP, No. 108 at p. 1; ACEEE, Transcript No. 73 at pp. 154–158; NWPPC, No. 76 at pp. 3–4; and Synapse, Transcript No. 73 at pp. 152–153).

Dominion Virginia Power (Dominion), The Southern Company (Southern), and EEI all disagree with the assertion that higher marginal costs will result from higher wholesale electricity costs. Dominion stated that recent deregulation pilot programs in Virginia revealed that residential consumers are not being offered rates that reflect the costs of generation (e.g., time of use rates). Southern warned that it is premature to draw conclusions from wholesale electricity costs this early into the deregulation process. Extremely high wholesale prices now may not be an indicator as what will happen to retail prices in the future. Southern also warned that the specific problems facing California with regard to wholesale electricity costs are not representative of the current situation in the Southeast where peak prices were considerably lower in the summer of 2000 on pooled prices than they were the previous summer because of greater supply availability. EEI argued that flat rate retail pricing will likely continue into the future even under a deregulated market. Electricity suppliers will hedge against any probable summer price spikes by offering high enough flat rates so that financial losses incurred during times of high summer wholesale costs will be more than offset by the profits earned during times when wholesale costs are low (*e.g.*, off peak summer hours or the winter season). (EEI, Transcript No. 73 at pp. 148–150; Dominion, Transcript No. 73 at pp. 158–160; and Southern Company, No. 96 at pp. 6–7).

As was stated in the proposed rule, the method for establishing marginal electricity prices only allows for defining marginal prices for those years in which data are available. In the case of residential pricing, the data for establishing marginal prices (the 1997 RECS[8]) was taken from the years 1996 and 1997. For commercial buildings, utility tariffs used to establish marginal prices were collected in the year 1997. On average, residential marginal prices for households with central air conditioners are 3 percent lower than average rates while for households with heat pumps marginal prices are 7 percent lower. Space-cooling marginal prices in commercial buildings are on average 2 percent greater than average commercial rates. Our method for determining marginal prices provides a snapshot of recent retail rates and may or may not accurately reflect what marginal prices will be like in the future. Although wholesale electricity costs for four deregulated electricity markets demonstrate higher wholesale electricity costs during times when air conditioners are likely to be used, we cannot speculate as to how wholesale electricity prices will be translated into retail prices to residential consumers. Thus, rather than speculating as to how electricity deregulation may impact marginal electricity prices, we are retaining our existing method for establishing marginal prices.

With the above said, the Department investigated the sensitivity of consumer life-cycle costs (aggregated to a national level in the form of a net present value (NPV)) to increases in the marginal electricity price. As will be reported in Chapter V, Analytical Results, the NPV of a 13 SEER standard based on Reverse Engineering manufacturing costs is a savings to the nation of $1 billion. An increase in the marginal electricity price of 3 cents/kWh yields a further increase in the operating cost savings so that the NPV equals $5 billion. Although the Department will continue to rely on its existing method for establishing marginal electricity prices, we recognize that future changes in the electric utility industry due to deregulation could significantly change future electricity prices and, as a result, improve the economic benefits of the standards being issued today.

d. *Product Life.* ARI, Carrier Corp., and The Trane Company all asserted that the 18.4-year average equipment lifetime assumed by the Department is not representative of actual central air conditioner and heat pump life. Both Carrier and Trane believed the lifetime is 15 years while ARI stated that the lifetime is even lower at 13 years. (ARI, No. 100 at p. 4; Carrier, No. 92 at p. 5; and Trane, No. 93 at p. 8).

The basis of the 18.4-year equipment lifetime was a survey conducted on more than 2,100 heat pumps in a seven state region of the U.S.[9]. The survey determined not only the lifetime of a complete heat pump system, but the life of the original compressor as well. Although the system lifetime is on average over 18 years, the survey also showed that the original compressor lifetime was, on average, 14 years. Thus, the survey indicated that essentially all heat pump owners replaced their original compressor once in the lifetime of system. Since the heat pump survey clearly indicates that the original compressor is replaced once in a system's life, DOE's analysis was based on the inclusion of a repair cost for the compressor. Conducting the analysis in this manner retains the average system lifetime of 18.4 years but explicitly addresses the replacement cost of the compressor, which is the most expensive component of a system. As indicated by the survey data, the compressor was assumed to be replaced in the 14th year of the system's life. Although a shorter equipment lifetime is possible, the Department has not been provided with more substantive data to support discontinuing its use of the above mentioned survey data. The Department believes that the survey

[7] Marginal prices exclude fixed charges, average prices include fixed charges.

[8] Residential Energy Consumption Survey.

[9] "Bucher, M.E., Grastataro, C.M., and Coleman, W.R., "Heat Pump Life and Compressor Longevity in 'Diverse Climates.'" ASHRAE Transacitons, 1990, 96(1): p. 1567–1571.

data provides an accurate representation of central air conditioner and heat pump life. In addition, an average lifetime of 14 years was run as a scenario for the analyses conducted for the proposed rulemaking showing that the resulting consumer economics were very close to the results generated with the 18.4-year average life coupled with compressor replacement costs.

e. *Installation Cost.* International Comfort Products (ICP) and HEI stated that the consumer's installation costs, *e.g.* labor and materials costs, exclusive of equipment cost, for installing a central air conditioner or heat pump will increase with product efficiency. (ICP, Transcript No. 73 at pp. 126–127; and HEI, Transcript No. 73 at pp. 92–93). ICP specifically voiced concerns over the installation cost differences between baseline (10 SEER) and 14 SEER equipment stating that the more efficient equipment, due its increased physical size, would incur higher labor expenses as a result of needing extra personnel to install the equipment. Other comments claimed that installation costs would be impacted by larger and more efficient units for those installations with size constraints such as equipment closets in manufactured homes and certain replacement installations in single-family homes. (MHI, No. 99 at p. 4; York, No. 90 at p. 5; and Lennox, No. 91 at p. 7).

Throughout the analysis we have assumed that installation costs would remain constant as efficiency increased. We remain unconvinced based on the comments we have received that our assumption is necessarily incorrect. Even if installation costs do generally rise as the size and weight of equipment increases, manufacturers will have the incentive under new standards to reduce the size of 13 SEER equipment using various approaches at their disposal. These include existing design options that we have mentioned, such as adopting variable speed and modulating capacity technologies, converting to microchannel heat exchangers, increasing the size of the unconstrained outdoor unit or indoor unit only, or changing the footprint or elevation of the unit. These possible solutions are applicable to manufactured homes as well as site-built homes.

For those reasons, we are retaining our assumption that installation costs remain constant as efficiency levels rise.

f. *Markups.* ARI, York, Carrier and Trane commented that we had apparently assumed that markups decreased as efficiency levels increased, and provided evidence to the contrary. (ARI, No. 100 at p. 3; York, No. 90 at p. 4; Carrier, No. 92 at p. 5; and Trane, No. 93 at p. 12).

In fact, we did assume for the Manufacturer Impact Analysis that markups increase with increasing efficiency under a given standard level. This agrees with the comments. However, for the consumer economic analyses, as the minimum standard level increases, we assumed that some of the markups on the baseline product do decrease. Comments did not address that issue, and we believe our assumption is correct. Appendix D of the TSD provides more information on this issue.

3. Shipments/National Energy Savings

a. Adjustments to NAECA Shipment Scenario. ACEEE and the NEEP assert that the NAECA efficiency scenario we developed is not at all representative of the effect of the NAECA standard as we claim. (ACEEE; Transcript No. 73 at p. 213 and No. 118 at p. 4). They point out that the distribution of equipment higher than 10 SEER in 1993 was 18 percent, and that our NAECA scenarios apply much smaller fractions of shipments than 18 percent.

As we mentioned in the TSD for the proposed rule (section 8.3.5), the NAECA scenario represents the effect that NAECA had on equipment efficiency in the market. A further explanation is warranted. While sales of equipment rated higher than 10 SEER was indeed 18 percent in 1993, it was 10 percent in 1992, 7 percent in 1991, 5 percent in 1990 and 3 percent in 1989. A trend of improving efficiency had already been in place since the late 1970's. NAECA, which became effective in 1992, clearly did not cause all the high efficiency shipments that existed in 1993. However, NAECA did seem to stimulate more high efficiency shipments than could have been explained by the ongoing trend. It is that enhancement to the status quo that our NAECA scenario attempts to reproduce. Thus, under our NAECA scenario, shipments above the 13 SEER level increase from 1 percent under the base case to 7 percent with a 13 SEER standard. Expecting them to increase from 1 percent to 18 percent as ACEEE and NEEP seem to assert is not at all representative of the NAECA experience and is more in line with the Shift scenario that we developed.

b. *Fuel Switching.* Several comments noted the potential for fuel- or equipment-switching from heat pumps to either gas-fired or electric resistance heating equipment due to the disparity in the standards proposed for central air conditioners (12 SEER) and heat pumps (13 SEER). The comments stated that the incremental purchase price of a 13 SEER heat pump relative to a 12 SEER air conditioner with either a gas-fired or electric resistance heating system is great enough to drive heat pump consumers to an alternative space-conditioning system. (ARI, No. 100 at p. 10; Southern Company, No. 96 at p. 3; AEP, No. 83 at p. 2; Carrier, No. 92 at p. 4; EEI, No. 80 at p. 8; York, No. 90 at p. 7; and Lennox, No. 91 at pp. 4–6).

Acknowledging the potential for fuel- or equipment-switching, both ASE and ACEEE recommended setting both air conditioner and heat pump standards to 13 SEER. (ASE, Transcript No. 73 at p. 197; and ACEEE, Transcript No. 73 at pp. 202–203).

From the perspective of saving the maximum amount of energy that is economically justifiable, the biggest "fuel" switching concern is from heat pumps to a combination of central air conditioners and electric resistance heating. This may occur in households that have only electric service and where the incremental purchase price of heat pumps is too great. Such a price increase might occur if the standard on heat pumps is significantly higher than the standard for central air conditioners.

Based on data from the 1997 RECS, a little over 14 percent of households have either baseboard or forced air electric resistance heating with room or central air conditioning compared to almost 10 percent of households which have heat pumps. Because there are already such a large percentage of households that utilize a combination of central or room air-conditioning with resistance heat to meet their space-conditioning needs, this supports the possibility that some purchasers would choose to switch to resistance heat from heat pumps.

Compared to heat pumps meeting the standards issued in the proposed rule (*i.e.*, 13 SEER and 7.7 HSPF), electric resistance heating uses over 225 percent of the energy for the same amount of heating. Therefore, if a standard of 13 SEER and 7.7 HSPF is issued for heat pumps while a 12 SEER standard is set for central air conditioners, a mere 4 percent of heat pump households would need to switch to central air conditioners and electric resistance heating to negate the energy savings achieved from increasing the heat pump standard from 12 SEER/7.4 HSPF to 13 SEER/7.7 HSPF.

If heat pump and air conditioner standards were set at different levels, the price differential between the two would increase on the order of $200. Under those conditions, we consider it likely that at least 4 percent of prospective heat pump owners would switch to lower-priced resistance heat. Therefore, we have weighed this concern in adopting today's standard levels, which require air conditioners and heat pumps to meet the same minimum efficiency standard so as to reduce the likelihood of switching to resistance heating.

A larger price differential between heat pumps and air conditioners will also tend to encourage switching to gas or oil fired furnaces. It is not our objective to encourage or discourage that type of fuel switching. Therefore, we also considered this potential effect in our decision to establish air conditioner and heat pump efficiency standards at the same SEER level.

c. *Drop in Shipments in New Construction Market.* ACEEE argued that DOE's forecasts for more efficient air-conditioning equipment estimated too large of a drop in shipments to the new construction market. They state that because the new construction market already has an 80 percent saturation rate it is unlikely that this market will forego the installation of more efficient air-conditioning equipment due to its associated increased purchase price. (ACEEE, Transcript No. 73 at pp. 219–221). This is effectively an argument that the price elasticity of air conditioners and heat pumps in the new construction market should be much lower than we have assumed.

Historical saturation data, however, seems to confirm that the price elasticity in the new construction market is closer to what was derived for the Shipments Analysis, which is already much lower than the elasticity we assumed in the replacement market, for example. As the price of air conditioners and heat pumps has dropped over time relative to household income, the saturation of air-conditioning and heat pump equipment has increased in the new housing market to its current value of 80 percent. Because of the high saturation in the new construction market, the purchase price elasticity for the new housing market is small relative to the replacement market. But although the price elasticity is small, a decrease in shipments to the new construction market will still be likely when equipment prices increase (as we expect to occur under a new efficiency standard). As a result, for the case of a 13 SEER standard for split system air conditioners for example, shipments to the new construction market drop by approximately 3 percent based on reverse engineering manufacturing cost data. For comparison purposes, shipments to the early replacement market drop much more significantly (approximately 15 percent) as this market is far less saturated and the resulting purchase price elasticity is much more elastic. For those reasons, we retained our assumed price elasticity in the analysis.

4. Manufacturer Impact Analysis

A few comments addressed the manufacturer impact analysis. Trane disputes our assumed manufacturer markups. ARI commented that a survey of their members revealed that our markup assumptions are grossly underestimated, but the TSD (Table 8.7) reveals that, in fact, their survey data agrees with the markups we used in the GRIM analysis to estimate manufacturer impacts. (Trane, No. 93 at pp. 12 and 22; and ARI, No. 100 at p. 3).

Trane also pointed out several oversights and simplifications relating to our characterization of manufacturers and our apparent failure to present cash flow results and other important indicators of financial strength. (Trane, No. 93 at pp. 6, 11–13 and 23). We believe that Chapter 8 of the TSD addresses most of Trane's concerns. No evidence cited in the comments suggest that our assumptions contain errors that would warrant significant change in our conclusions regarding manufacturing impacts.

5. Utility Impacts

a. *Peak Demand Impacts.* ACEEE asserts that the peak power impacts presented in the proposed rule underestimate the true peak generation impacts due to central air conditioner and heat pump standards. ACEEE's assertion is based on what they consider as more accurate and significantly greater peak impacts as estimated by the Appliance Standards Awareness Project (ASAP).[10] (ACEEE, No. 104 at pp. 5–6). APPA warned that excessively high SEER standards could increase peak demand. (APPA, No. 113 at p. 1).

For purposes of comparing the estimated peak impacts from the Department's analysis based on the use of NEMS–BRS and those from ASAP, it is helpful to consider the concept of a conservation load factor (CLF). The CLF was first introduced by researchers at Lawrence Berkeley National Laboratory to allow for the straightforward calculation of the peak demand avoided from a given amount of energy savings.[11] The CLF is defined as:

$$CLF = \frac{\text{Annual Site Energy Savings (kWh)}}{\text{Peak Load Savings (kW)} \cdot 8760 \text{ hours}}$$

Thus, a conservation technology that saves a constant amount of power on a continuous basis has a CLF of 1.0. Because air conditioning use occurs most often during times of peak demand, the CLF is significantly lower. The lower the CLF, the greater the amount of peak load savings achieved for a given amount of annual energy savings.

For a 13 SEER central air conditioner and heat pump standard, NEMS–BRS forecasts peak demand savings which result in a nationally representative CLF of 0.22. In contrast, for the same 13 SEER standard, ASAP forecasts energy and peak demand savings which result in CLFs ranging from 0.08 to 0.14. Based on the above discrepancy in the CLF, ACEEE asserts that the peak demand savings forecasted by NEMS–BRS are too low. The Department disagrees with ACEEE's position for two reasons: (1) ASAP's peak savings estimates rely on suspect air conditioner demand data, and (2) metered end-use data from air-conditioned households in California and Florida indicate that the NEMS–BRS-based CLF value of 0.22 is reasonable.

With regard to ASAP's peak demand estimates, regional calculations are based on peak demand data from a single 1988 study by the Narragansett Electric Co. (an electric utility in the Northeast).[12] Although ASAP increased

[10] Staying cool: How Energy-Efficient Air Conditioners Can Prevent Blackouts, Cut Pollution and Save Money, Appliance Standards Awareness Project, July 2000, Authors: J. Thone, T. Kubo, and S. Nadel.

[11] Conservation Screening Curves to Compare Efficiency Investments to Power Plants: Applications to Commercial Sector Conservation Programs, Lawrence Berkeley National Laboratory, Berkeley, CA, August 1990, published in the Proceedings of the 1990 ACEEE Summer Study on Energy Efficiency in Buildings, Authors: J. Koomey, A. Rosenfeld, and A. Gadgil.

[12] Personal communication with Steve Nadel, ACEEE, October, 2000.

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the Northeast peak demand data by 25 percent for the two Southern divisions and decreased it by 25 percent for the Pacific division, no basis for these adjustments are provided. Because of ASAP's reliance on peak demand data from only one region of the country, we do not place much confidence in the peak generation savings provided by ASAP.

As opposed to the ASAP results, metered end-use data from Southern California and Florida indicate that climate has a much larger affect on the CLF than reported by ASAP. In Southern California, a metered end-use study conducted on 132 air-conditioned households in Southern California Edison's service area revealed that the CLF for this region is likely 0.08.[13] In Homestead, Florida, a metered end-use study conducted on ten air-conditioned homes indicated that the CLF is likely 0.42.[14] Although strong conclusions cannot be drawn from only two studies, the metered end-use results do provide the Department with some confidence that the NEMS–BRS CLF estimate of 0.22 is reasonable since it falls between the CLF range provided by the two metered end-use studies. Therefore, we have reason to believe that our assumption is more valid than ASAP's.

Obviously more research needs to be conducted in the area of peak demand impacts due to increased air conditioner efficiency. But until such extensive research is conducted, the Department sees no reason to discontinue its use of NEMS-BRS to estimate peak demand savings.

6. Projection of Trends

Several comments suggested or asserted that we should project historical trends that they believe exist. These include price reductions or productivity improvements in manufacturing. (ACEEE, Transcript No. 73 at pp. 64 and 88–90; and NRDC, Transcript No. 73 at pp. 105 and 115), post-standard product efficiencies (ACEEE, Transcript No. 73 at p. 210), and electricity prices. (ASAP, No. 108 at p. 1; ACEEE, Transcript No. 73 at pp. 154–158; NWPPC, No. 76 at pp. 3–4; and Synapse, Transcript No. 73 at pp. 152–153).

Other comments responded to some of these suggestions. With regard to the issue of price reductions or productivity improvements, some contend that reductions are due to declining commodity metals prices rather than any increases in production efficiency. (Lennox, No. 91 at pp. 4–5). On the issue of efficiency trends, EEI claims that rather than post-standard efficiency increases, the Department neglected to account for pre-standard efficiency increases. (EEI, Transcript No. 73 at pp. 206–208). Counter to claims that electricity prices will increase in the future due to the deregulation of the electric utility industry, others state that the future path of deregulation is so uncertain that it is unknown as to whether prices will decline or increase. (EEI, Transcript No. 73 at pp. 148–150; Dominion, Transcript No. 73 at pp. 158–160; and Southern Company, No. 96 at pp. 6–7).

In these instances where we have conflicting opinions about what is responsible for creating a trend, we have no basis for changing our initial assumption. Usually, we rely on the most recent set of data we have available to us to make projections into the future. In the case of efficiency trends, we rely on existing trends that seem to indicate that efficiency will remain static after a new standard becomes effective. In the case of electricity prices, we rely on the projections provided in the Annual Energy Outlook, which is publicly and readily available, and which we assume is unbiased with respect to parties interested in the outcome of this rulemaking. Since this is the case for all the supposed trends listed above, we have not changed any of our projections.

C. Other Comments

1. HCFC Phaseout

Comments noted that as efficiency increases, refrigerant charge may increase also. This could cause the United States to reach its cap on HCFC–22 use earlier, resulting in higher prices for HCFC–22 than we have considered. (Carrier, No. 92 at p. 4). We would point out that occurrence would likely accelerate the transition to HCFC-free refrigerants. There are also other options available for manufacturers to improve equipment efficiency without increasing equipment size or charge. Both of these factors will have the effect of suppressing increases in refrigerant prices over the long term.

2. Ozone Reduction Catalyst Requirement

ARI and its members remind us to consider the potential impact on the industry of Texas' proposed requirement to mandate the application of ozone reduction technology in its most severe non-attainment areas. (ARI, No. 100 at p. 13; and Carrier, No. 92 at p. 4).

We understand that Texas has since withdrawn its proposal. However, the TSD does include a preliminary estimate of the burden of this requirement on the industry and, to the extent that other states may pursue the same course of action, included that in our consideration of cumulative burden. We consider that widespread requirements for this technology will not be likely, due to its apparently high cost, questionable efficacy, and possible reduction in energy efficiency.

D. Additional Standard Requirements

1. EER Standard

In the proposed rule, we discussed including a requirement for a new standard based on a system's energy efficiency ratio (EER) in addition to its seasonal energy efficiency ratio (SEER). That new standard was to be established at the median of available EER ratings at a particular SEER level. Our objective was to ensure that any increase in the SEER standard also resulted in an increase in equipment efficiency under the warmer conditions best measured by EER. That resulting drop in peak power demand would then help avoid the need for new power plants and, in the view of many stakeholders, improve power system reliability. We asked whether an EER standard would impose a significant burden on manufacturers, would significantly affect the cost of equipment considered in our analysis, would negatively impact the sale of modulating equipment, or would significantly improve power system reliability.

Several comments, including those of environmental advocacy groups and some utilities, supported adding an EER standard and urged us to adopt the median EER standards we proposed. They cited potential benefits that would accrue from avoidance of new power plant capacity and a reduction in the occurrence of blackouts. NRDC believes that the Act requires us to adopt an EER-based standard. Underlying these comments is a belief that SEER standards alone cannot guarantee those benefits. Carrier supports an EER-based standard only in lieu of a SEER-based standard because it would harmonize with International Standards Organization testing requirements. (ACEEE, Transcript No. 73 at p. 62; NWPPC, Transcript No. 73 at p. 161; ASE, No. 81 at p. 1; NPPD, No. 109 at p. 1; OOE, No. 84 at p. 2; NRDC, No. 88 at p. 3; Omaha Public Power District (OPPD), No. 111 at p. 2; and Carrier, No. 92 at p. 8).

Other comments took an opposing position on the grounds that including an EER standard would impede the application of modulating components; that we are not permitted to adopt a standard other than SEER and have not sufficiently analyzed the validity of an EER-based standard; that an EER standard would eliminate products from the market; that an EER standard will not improve electric system reliability, particularly nationwide; and that there are burdens associated with testing and certifying EER. (National Comfort Products (NCP), No. 77 at p. 3; EEI, Transcript No. 73 at p. 327 and No. 80 at pp. 3 and 9; Dominion, Transcript No. 73 at p. 264 and No. 68 at p. 2; Trane, No. 93 at p. 14; York, No. 90 at pp. 1–4; ARI, Transcript No. 73 at p. 320 and No. 100 at p. 16; Goodman, Transcript No. 73 at p. 302; and Southern, Transcript No. 73 at p. 243).

It is true that under the efficiency level approach, we assume that all equipment at the same SEER level costs the same to produce regardless of the combination of design options chosen to achieve that SEER level. These options include those that raise EER, including compressor and heat exchanger upgrades, as well as those that do not raise EER, such as thermostatic expansion valves. For any given SEER and HSPF levels, the efficiency level approach cannot differentiate equipment cost based on different EER choices.

Underlying the efficiency level approach, however, is the assumption that manufacturers make cost-optimal choices based on their own unique situations. Therefore, a manufacturer who was required to raise the EER of its equipment from the 10th percentile to the 50th percentile (median) would indeed incur added costs since its design choices would no longer be cost-optimal for its own circumstances. Since efficiency levels are expressed in terms of SEER and HSPF only, we would have to depart from the efficiency level approach in order to quantify those costs.

We are still convinced that the stringent physical relationship between EER and SEER in equipment rated through 12 SEER, which is comprised exclusively of non-modulating equipment, would remain intact under new standards and for the foreseeable future. Under the adopted 13 SEER standard, we have less certainty since there are counteracting incentives. On the one hand, to reduce warranty claims, manufacturers have a strong incentive to simplify the design of baseline equipment. This suggests they will favor heat exchanger or compressor improvements that improve EER.

On the other hand, manufacturers will have a strong incentive to reduce the size of 13 SEER baseline equipment. Although microchannel heat exchangers could reduce size and improve EER, manufacturers could also choose to introduce variable speed or capacity modulation technologies that can induce them to lower EER at a given SEER level. As the cost of power electronics and control technologies come down, this possibility becomes more likely.

However, even if variable speed or modulating technologies eventually predominate, and thereby reduce EERs in typical equipment, they would still reduce peak demand compared to today's 10 SEER baseline equipment. Furthermore, because variable speed and modulating equipment mitigate the cyclic losses that are due to widespread over sizing, the aggregated peak demand of a group of modulating air conditioners with lower EERs will likely be lower than that of a similar group of non-modulating air conditioners with higher EERs at the same SEER level. Also, utilities have the opportunity with modulating equipment to offer customers the option to allow the utility to "lock" the equipment into low-capacity operation in return for a lower electricity price.

Finally, although the Department is interested in reducing peak demand, the primary purpose of appliance efficiency standards is to save energy. An EER standard could be counterproductive by discouraging variable speed and modulation, which can save substantial amounts of energy over the cooling season while providing consumers with additional benefits not found in single speed and non-modulating equipment.

Although the Department believes that EPCA permits adoption of an EER standard, for the foregoing reasons, we do not believe that the Act requires or suggests that we establish such a standard under the circumstances here. Given the adopted standard levels, a national EER standard is both unnecessary and undesirable. Most benefits accruing from an EER standard will likely accrue from the SEER standards alone, without the associated burdens on manufacturers and the disincentives to apply energy-saving modulating technologies. Therefore, we have not adopted an EER standard in this rule.

2. TXV Requirement

In the proposed rule, we discussed the issues associated with mandating thermostatic expansion valves, or TXVs. We did not propose such a requirement, but we recognized that such a requirement may be capable of saving a great deal of energy. We discussed our options for encouraging their use.

Many comments continue to express strong support for a TXV requirement. Many cite a report submitted by Proctor Engineering (Proctor) that describes the results of a field study covering 4,000 units in California. The study concluded that 62 percent of equipment is mischarged by more than 5 percent, and that TXVs, which perform better than fixed orifices in undercharged conditions, could save 11 percent of the energy used by that equipment. (Proctor No. 105; OOE, No. 84 at p. 2; NRDC, No. 88; California Energy Commission (CEC), No. 98 at p. 1; ACEEE, No. 101 at p. 8; PG&E No. 104 at p. 1; and ASAP, Transcript No. 73 at p. 4).

Other comments expressed some resistance to a TXV requirement, particularly regarding our authority to establish one. Some also express concerns about problems associated with TXVs. (NCP, No. 77 at p. 4; Trane, No. 93 at p. 19; York, No. 90 at pp. 4–5; Lennox, No. 91 at p. 3; EEI No. 80 at p. 3; and Carrier, No. 92 at p. 10).

In response to our concern that mandating TXVs would stifle the development of other, perhaps preferable, technologies, Proctor and ACEEE suggested performance tests that could be applied in lieu of a TXV requirement. They would reward equipment that possessed a TXV or performed as well while undercharged or when airflow is restricted. This approach is at least partially endorsed by others. (NRDC No. 88 at p. 17; CEC No. 199 at p. 1; and OOE, No. 84 at p. 8). Some of the commenters preferred that we initially specify TXVs but then phase out that requirement in favor of a performance-based approach.

As we alluded to in the proposed rule, a performance-based approach is also our preference and is certainly in the spirit of EPCA. As such, the SEER test procedure, not a TXV requirement, appears to be the most appropriate vehicle for assuring that an equipment's efficiency rating is based on its performance characteristics. In fact, TXVs already receive credit in the test procedure because of their superior cyclic performance. We are not eager to circumvent the test procedure, particularly when the key data either are not available or have not been thoroughly reviewed by all interested

[13] Residential Appliance End-Use Survey; Collection of Residential Appliance Time-of-Use Energy Load Profiles; 1991 Results, prepared by Quantum Consulting Inc., Berkeley, CA for Southern California Edison Co., San Dimas, CA, November, 1992.

[14] Monitored Energy Use Patterns in Low-Income Housing (FSEC-PF–300), Florida Solar Energy Center, Cocoa, FL, 1996, Authors: D. S. Parker, M. D. Mazzara, and J. R. Sherwin.

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parties. That said, we favor a SEER test procedure that fairly evaluates equipment performance under conditions that represent those encountered in the field. We would prefer to encourage correct charging or proper airflow, but we recognize that practical barriers exist, and we will take steps to evaluate whether the SEER test procedure can and should be amended to better reflect equipment performance under improper charge or airflow.

In sum, we are not adopting a TXV requirement in this rulemaking. Any alterations in the SEER test procedure to further encourage the use of TXVs will be undertaken in a separate process. In addition to pursuing modifications to the test procedure, we encourage parties interested in encouraging the broader application of TXVs to pursue other avenues. These include voluntary programs like Energy Star, tax incentives, and other state and local initiatives, which can all be tied to the presence of a device like a TXV. States also have the opportunity to apply to us for an exemption from preemption that would allow them to implement their own requirements based on their own unique circumstances.

3. HSPF Levels

Some comments urged us to reconsider our proposed HSPF levels, particularly to reflect differences among the HSPF-SEER relationships across capacity ratings. Trane commented that HSPF-SEER factors for heat pumps are lower with 410A refrigerant than with HCFC–22, and that the current proposal for HSPF is too high for 410A by as much as 3 to 5 percent. (ARI, No. 100 at p. 11; Carrier, No. 92 at p. 7; and Trane, No. 93 at p. 8). Others urged us to adopt HSPF levels at the median for each SEER level we considered. (OOE, No. 84 at p. 11; and ACEEE, No. 104 at p. 12).

As we explained in the proposed rule, we established the HSPF levels corresponding to SEER levels in an attempt to maintain the existing offset between the minimum HSPF and the minimum SEER. Heating energy is a large fraction of total heat pump energy consumption, so we prefer not to relax that relationship without sound evidence regarding the burdens that would be mitigated. We are reluctant to adopt a more stringent level since we are aware that heat pump design is difficult and costly, and that improvements in HSPF typically are associated with a reduction in SEER. Too stringent a standard would impose considerable design and testing burdens on manufacturers, could result in the permanent loss of heat pump market share to electric resistance heat, and could encourage fuel switching.

For those reasons, we are retaining our proposed minimum HSPF levels in the standards adopted today.

V. Analytical Results and Conclusions

A. Trial Standard Levels

We examined five standard levels. Table V.1 presents the trial standards levels analyzed for today's final rule and the corresponding efficiency level for each class of product. Trial standard level 5 is the max tech level for each class of product.

TABLE V.1.—TRIAL STANDARDS LEVELS FOR CENTRAL AIR CONDITIONERS AND HEAT PUMPS (SEER)

Trial standard level	Split air conditioners	Packaged air conditioners	Split heat pumps	Packaged heat pumps
1	11	11	11	11
2	12	12	12	12
3	12	12	13	13
4	13	13	13	13
5	18	18	18	18

For each trial standard level examined, several different scenarios were analyzed consisting of variations on: (1) Electricity price and housing projections; (2) equipment efficiency distributions; (3) manufacturer cost estimates; and (4) societal discount rate. Electricity price and housing projections were based on three different AEO 2000 forecasts: (1) Reference Case, (2) High Growth Case, and (3) Low Growth Case. We analyzed three efficiency scenarios, each of which assumed a different efficiency distribution after new standards would take effect: (1) NAECA scenario, (2) Roll-up scenario, and (3) Shift scenario. Under the standard levels we are adopting, we believe that the Roll-up scenario most closely represents the most likely impact of the new standards, as explained in Chapter 8 of the TSD. We analyzed two manufacturer cost scenarios: (1) Based on reverse engineering data, and (2) based on ARI-provided mean cost data. For the reasons expressed in Parts III and IV of this document, we believe that the reverse engineering data most closely represents the costs as they will actually be under the new standards. We assumed a societal discount rate of 7 percent for calculating net present value (NPV). However, a 3 percent value was investigated as an alternative scenario in accordance with the Office of Management and Budget's (OMB) Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements.

Our decision on today's final rule was arrived at by placing more emphasis on some scenarios rather than others. Our estimates of electricity price and housing projections relied primarily on the AEO2000 reference case. We considered primarily the NAECA and Roll-up efficiency scenarios with an increasing expectation of the Roll-up scenario occurring for more stringent trial standard levels. Finally, we expect manufacturer costs to lie closer to the reverse engineering estimates (which lie between the ARI minimum and ARI mean values).

The results presented in this chapter include only those that are needed to supplement or replace the results we presented in the proposed rule, which still form a basis for our decision with the exception that we are no longer considering the 14-year life scenarios. We believe that the 18.4-year life with a compressor replacement in the 14th year addresses the concerns of those who believe that actual equipment life is closer to 14 years and achieves substantially the same analytical results. Therefore, all analyses below assume an 18.4-year average equipment lifetime with a compressor replacement in the 14th year.

B. Significance of Energy Savings

To estimate the energy savings through 2030 due to revised standards, we compared the energy consumption of central air conditioners and heat pumps under the base case to energy consumption of central air conditioners and heat pumps under the revised standard.

Table V.2 shows the range of cumulative energy savings based on the AEO 2000 Reference, High Growth, and Low Growth cases for each trial standard level. The parameters shown are the two manufacturing costs and the three equipment shipment efficiency scenarios.

TABLE V.2.—RANGE OF NATIONAL ENERGY SAVINGS WITH AEO PRICE FORECAST

Trial standard level	Range of national energy savings for units sold from 2006 to 2030 (quads)					
	Reverse engineering costs			ARI mean costs		
	NAECA	Roll-up	Shift	NAECA	Roll-up	Shift
1	1.7 to 1.8	1.5 to 1.6	1.9 to 2.0	1.7 to 1.8	1.5 to 1.6	1.9 to 20
2	2.9 to 3.2	2.8 to 3.0	3.4 to 3.6	2.9 to 3.2	2.8 to 3.0	3.4 to 3.6
3	3.4 to 3.7	3.3 to 3.5	3.8 to 4.1	3.4 to 3.6	3.3 to 3.5	3.8 to 4.1
4	4.3 to 4.6	4.1 to 4.4	4.7 to 5.0	4.2 to 4.5	4.1 to 4.4	4.6 to 4.9
5	8.4 to 9.0	8.4 to 9.0	8.4 to 9.0	8.1 to 8.7	8.1 to 8.7	8.1 to 8.7

C. Payback Period

As discussed above, the Act requires the Department to examine payback periods to determine if the three-year rebuttable presumption of economic justification applies. As prescribed by the Act, the rebuttable payback period is "calculated under the applicable test procedure * * *".

The annual space-cooling and space-heating energy consumption calculated based on the hours of use in the test procedure are on the order of 50 percent greater than the weighted-average energy consumption data used in the life-cycle-cost (LCC) analysis. The LCC data are based on the 1997 RECS for residential buildings and hourly simulations for commercial buildings. Since the test procedure assumes higher annual operating hours than the RECS data implied, the use of test procedure energy consumption results in rebuttable payback periods which are shorter than median payback periods calculated from the LCC analysis.

In Table V.3, we list the rebuttable payback periods versus SEER efficiency level for the four product classes, using the 1997 RECS energy consumption data. This information shows that both classes of heat pumps are presumed to be economically justified up to a 12 SEER efficiency level, using the reverse engineering cost estimates.

TABLE V.3.—SUMMARY OF REBUTTABLE PAYBACK PERIOD (YEARS)

Product class/efficiency level	Reverse engineering costs	ARI mean costs
Split System Central Air Conditioner:		
11	3.5	4.7
12	4.5	5.8
13	5.2	7.6
18	7.3	11.3
Split System Heat Pump:		
11	1.3	2.5
12	1.8	3.3
13	3.2	4.5
18	5.8	6.8
Single Package Air Conditioner:		
11	3.5	7.3
12	3.3	6.2
13	6.8	9.8
18	8.6	13.3
Single Package Heat Pump:		
11	2.1	3.7
12	1.8	4.0
13	4.3	6.5
18	5.4	7.2

D. Economic Justification

1. Economic Impact on Manufacturers and Consumers

Estimated economic impacts of standards on manufacturers are based on the methodology described in the proposed rule; however, in today's final rule the manufacturer impact analysis has been expanded to include impacts based on reverse engineering cost estimates as well as ARI manufacturing cost data. The economic impacts on manufacturers are presented in terms of industry net present value (INPV) as well as change in INPV. INPV is calculated by summing the stream of annual discounted cash flows beginning from the base year of the analysis (2000) and continuing explicitly for ten years after the implementation of the standard and adding the discounted value of the industry at the end of the ten-year period (see TSD Section 8.4.4 and Appendix G). The discount rate is based on the industry's weighted average cost of capital. This method of calculating INPV provides one measure of the fair value of the industry in today's dollars. The impact of new standards on INPV is then the difference between the INPV in the base case (no new standards) and the INPV is the standards case (with new standards).

Data are presented for the base case and for trial standard levels 1 through 4, in Tables V.4 through V.9. As can be observed, manufacturer impacts are relatively insensitive between the

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manufacturing cost estimates, but sensitive to the shipment scenarios. The proposed rule provides additional information on the methodology, assumptions and results.

TABLE V.4.—CHANGES IN INDUSTRY NET PRESENT VALUE—REVERSE ENGINEERING RELATIVE COST, NAECA EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,539		
1	1,509	(30)	−2
2	1,380	(159)	−10
3	1,368	(171)	−11
4	1,370	(169)	−11

TABLE V.5.—CHANGES IN INDUSTRY NET PRESENT VALUE—REVERSE ENGINEERING RELATIVE COST, ROLL-UP EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,539		
1	1,379	(160)	−10
2	1,226	(313)	−20
3	1,220	(319)	−21
4	1,236	(303)	−20

TABLE V.6.—CHANGES IN INDUSTRY NET PRESENT VALUE—REVERSE ENGINEERING RELATIVE COST, SHIFT EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,539		
1	1,658	119	8
2	1,772	233	15
3	1,776	237	15
4	1,824	285	19

TABLE V.7.—CHANGES IN INDUSTRY NET PRESENT VALUE—ARI MEAN MANUFACTURING COST, NAECA EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,603		
1	1,566	(37)	−2
2	1,417	(186)	−12
3	1,406	(197)	−12
4	1,420	(183)	−11

TABLE V.8.—CHANGES IN INDUSTRY NET PRESENT VALUE—ARI MEAN MANUFACTURING COST, ROLL-UP EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,603		
1	1,422	(181)	−11
2	1,241	(362)	−23
3	1,236	(367)	−23
4	1,268	(335)	−21

TABLE V.9.—CHANGES IN INDUSTRY NET PRESENT VALUE—ARI MEAN MANUFACTURING COST, SHIFT EFFICIENCY MIX

Standard level	Industry net present value ($ million)	Change in INPV from base case	
		$ million	Percent
Base	1,603		
1	1,740	137	9
2	1,825	222	14
3	1,854	251	16
4	1,914	311	19

Table V.10 provides the change in INPV relative to the base case (with no change in standards) for trial standard levels 1 through 4. Data are presented for two industry segments (lower cost manufacturers and higher cost manufacturers), and for the three shipment efficiency scenarios.

TABLE V.10.—CHANGE IN INDUSTRY NET PRESENT VALUE (PERCENT) RELATIVE TO BASE—COMPARISON BETWEEN LOWER (L) AND HIGHER (H) COST MANUFACTURERS

Standard level	Reverse engineering relative cost (in percent)						ARI mean manufacturing cost (in percent)					
	NAECA		Roll-up		Shift		NAECA		Roll-up		Shift	
	L	H	L	H	L	H	L	H	L	H	L	H
1	5	−4	3	−15	8	8	5	−5	3	−16	7	9
2	7	−16	5	−28	13	16	7	−17	5	−31	12	14
3	8	−17	6	−29	14	16	9	−19	6	−32	14	16
4	12	−18	10	−29	19	18	15	−19	13	−31	21	19

For the group most negatively impacted, *i.e.*, the higher cost group, Table V.11 presents the Return on Invested Capital (ROIC) in year 2011 associated with the base case, and with each new standard level for the NAECA and Roll-up shipment efficiency scenarios.

TABLE V.11.—RETURN ON INVESTED CAPITAL (ROIC) IN 2011 FOR HIGHER COST MANUFACTURERS

Standard level	Reverse engineering (in percent)		ARI manufacturing costs (in percent)	
	NAECA	Roll-up	NAECA	Roll-up
Base	13.0	13.0	13.3	13.3
1	12.2	10.7	12.3	10.7
2	10.2	8.5	0.2	8.4
3	10.0	8.4	10.0	8.3
4	9.7	8.4	9.6	8.3

Consumers will also be affected by increased efficiency standards in that they will experience higher purchase prices and lower operating costs. These impacts are best captured by changes in life cycle costs which are discussed below.

2. Life-Cycle-Cost (LCC)

We analyzed the net effect by calculating the LCC. Inputs required for calculating LCC include total installed costs (*i.e.*, equipment price plus installation costs), annual energy savings, average and marginal electricity prices, electricity price trends, repair costs, maintenance costs, equipment lifetime, and discount rates.

The output of the LCC model is the mean LCC savings for each product class as well as a probability distribution or likelihood of LCC reduction or increase. The LCC analysis for today's final rule employs a concept described in the proposed rule with regard to the percentage of consumers (both residential and commercial) that are impacted to a substantial degree by an increase in the minimum efficiency standard.

Table V.12 summarizes the LCCs for baseline split systems and single package central air conditioners and heat pumps and also shows a 2 percent threshold which helped us identify those consumers who are impacted to a more substantial degree.

TABLE V.12.—BASELINE LIFE-CYCLE-COSTS

Product Class	Baseline LCC	2% of Baseline LCC
Split Air Conditioners	$5,170	$103
Split Heat Pumps	9,679	194
Single Package Air Conditioners	5,629	113
Single Package Heat Pumps	9,626	193

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Tables V.13 and V.14 depict the LCC results for split system and single package central air conditioners and heat pumps. The tables show the average LCC values for the baseline and each trial standard level. Since manufacturer cost data were not available for the 18 SEER efficiency levels, 15 SEER cost data were used for all 18 SEER calculations resulting in 18 SEER LCC results which underestimate their true cost level. The data in Tables V.13 and V.14 also present the difference in LCC at each efficiency level relative to the baseline. The differences represent either an LCC savings or an LCC cost increase. In addition, the tables show the subset of consumers (both residential and commercial) at each efficiency level who are impacted in one of three ways: consumers who achieve net LCC savings in excess of 2 percent of the baseline LCC, consumers whose change in LCC is within ±2 percent of the baseline LCC, and consumers who achieve a net LCC increase exceeding 2 percent of the baseline LCC.

TABLE V.13.—SUMMARY OF LCC RESULTS BASED ON REVERSE ENGINEERING MANUFACTURING COSTS

Product Class/Efficiency Level	Average LCC	Average LCC Savings (Costs)	Percent of consumers with		
			Net Savings (>2 %)	Net Savings or Costs (±2%)	Net Costs (>2 %)
Split System Central Air Conditioner:					
10	$5,170				
11	5,095	$75	28	70	2%
12	5,057	113	35	40	25%
13	5,057	113	34	27	39%
18	5,307	(137)	25	7	68%
Split System Heat Pump:					
10	9,679				
11	9,470	209	40	60	0%
12	9,314	365	58	42	0%
13	9,307	372	52	42	6%
18	9,720	(41)	28	15	57%
Single Package Air Conditioner:					
10	5,629				
11	5,551	78	27	72	1%
12	5,466	163	40	51	9%
13	5,600	29	28	20	52%
18	5,905	(276)	21	6	73%
Single Package Heat Pump:					
10	9,626				
11	9,419	207	39	61	0
12	9,205	421	66	34	0
13	9,273	353	50	38	12
18	9,460	166	37	15	48

TABLE V.14.—SUMMARY OF LCC RESULTS BASED ON ARI MEAN MANUFACTURING COSTS

Product class/efficiency level	Average LCC	Average LCC savings (costs)	Percent of consumers with		
			Net savings (> 2%)	Net savings or (costs) (± 2%)	Net costs (> 2%)
Split System Central Air Conditioner:					
10	$5,170				
11	5,126	$44	23	68	9
12	5,125	45	27	34	39
13	5,199	(29)	25	17	58
18	5,725	(555)	15	4	81
Split System Heat Pump:					
10	9,679				
11	9,529	150	30	70	0
12	9,437	242	42	55	3
13	9,464	215	39	39	22
18	9,955	(276)	23	11	66
Single Package Air Conditioner:					
10	5,629				
11	5,649	(20)	16	47	37
12	5,600	29	26	30	44
13	5,804	(175)	18	11	71
18	6,370	(741)	12	4	84
Single Package Heat Pump:					
10	9,626				
11	9,492	134	28	72	0
12	9,372	254	44	49	7
13	9,514	112	33	31	36

TABLE V.14.—SUMMARY OF LCC RESULTS BASED ON ARI MEAN MANUFACTURING COSTS—Continued

Product class/efficiency level	Average LCC	Average LCC savings (costs)	Percent of consumers with		
			Net savings (> 2%)	Net savings or (costs) (± 2%)	Net costs (> 2%)
18	9,922	(296)	24	10	66

Consumer subgroup impacts have been estimated by determining the LCC impacts of the trial standard levels on those consumers who are below the poverty line (*e.g.*, for a family of four, this constitutes a household income of less than $16,036). To perform this calculation, we used the subset of RECS 97 data for households that are considered low-income.[15] Table V.15 and V.16 summarize the impacts on low-income consumers who utilize central air conditioners and heat pumps.

TABLE V.15.—SUMMARY OF LCC RESULTS ON LOW-INCOME CONSUMERS BASED ON REVERSE ENGINEERING MANUFACTURING COSTS

Product class/efficiency level	Average LCC	Average LCC savings (costs)	Percent of consumers with		
			Net savings (> 2%)	Net Savings or (costs) (± 2%)	Net costs (> 2%)
Split System Central Air Conditioner:					
10	$4,906				
11	4,855	$51	21	74	5
12	4,841	65	28	38	34
13	4,863	43	26	24	50
18	5,176	(270)	17	6	77
Split System Heat Pump:					
10	8,965				
11	8,836	129	26	74	0
12	8,742	223	44	56	0
13	8,780	185	39	49	12
18	9,389	(424)	15	10	75
Single Package Air Conditioner:					
10	5,327				
11	5,272	55	21	77	2
12	5,202	125	34	52	14
13	5,364	(37)	21	18	61
18	5,704	(377)	15	5	80
Single Package Heat Pump:					
10	9,149				
11	9,057	118	24	76	0
12	8,973	265	53	47	0
13	9,145	148	36	44	20
18	9,619	(284)	20	14	66

TABLE V.16.—SUMMARY OF LCC RESULTS ON LOW-INCOME CONSUMERS BASED ON ARI MEAN MANUFACTURING COSTS

Product class/efficiency level	Average LCC	Average LCC savings (costs)	Percent of consumers with		
			Net savings (> 2%)	Savings/costs (± 2%)	Net costs (> 2%)
Split System Central Air Conditioner:					
10	$4,906				
11	4,887	$19	17	66	17
12	4,903	3	20	29	51
13	5,007	(101)	17	14	69
18	5,598	(692)	10	2	88
Split System Heat Pump:					
10	8,965				
11	8,890	75	16	84	0
12	8,862	103	27	64	9
13	8,948	17	25	40	35
18	9,610	(645)	11	8	81
Single Package Air Conditioner:					
10	5,327				

[15] Approximately 7 percent of the RECS 97 households with central air conditioners and 9 percent of the households with heat pumps met this criteria.

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TABLE V.16.—SUMMARY OF LCC RESULTS ON LOW-INCOME CONSUMERS BASED ON ARI MEAN MANUFACTURING COSTS—Continued

Product class/efficiency level	Average LCC	Average LCC savings (costs)	Percent of consumers with		
			Net savings (> 2%)	Savings/costs (± 2%)	Net costs (> 2%)
11	5,283	44	11	42	47
12	5,313	14	20	27	53
13	5,568	(241)	12	9	79
18	6,158	(831)	10	2	88
Single Package Heat Pump:					
10	9,149				
11	9,057	92	21	78	1
12	8,973	176	35	53	12
13	9,145	4	25	27	48
18	9,619	(470)	18	8	74

In comparing the LCC results on the subgroup of consumers who are low-income (Tables V.15 and V.16) versus all central air conditioner and heat pump consumers (Tables V.13 and V.14), it appears that low-income consumers have lower savings at the different trial standard levels than the general population of central air conditioner and heat pump consumers. Table V.17 directly compares the LCC impacts of the final rule on both the low-income subgroup and all consumers.

TABLE V.17.—COMPARISON OF LCC IMPACTS OF THE FINAL RULE ON ALL CONSUMERS VS. LOW-INCOME CONSUMERS

Product class	SEER	Reverse engineering costs				ARI mean costs			
		Average LCC savings (costs)		Percent of consumers with net costs (>2% of baseline LCC)		Average LCC savings (costs)		Percent of consumers with net costs (>2% of baseline LCC)	
		All consumers	Low-income	All consumers	Low-income	All consumers	Low-income	All consumers	Low-income
Split System A/C	13	$113	$43	39	50	($29)	($101)	58	69
Split System HP	13	372	185	6	12	215	17	22	35
Single Package A/C	13	29	(37)	52	61	(175)	(241)	71	79
Single Package HP	13	353	148	12	20	112	4	36	48

3. Net Present Value and Net National Employment

The net present value analysis is a measure of the cumulative benefit or cost to the Nation that would result from more stringent standards. As with the determination of national energy savings, four different scenarios were analyzed for each trial standard level consisting of variations on: (1) Electricity price and housing projections; (2) shipment efficiency distributions; (3) manufacturer cost estimates; and (4) societal discount rate. Electricity price and housing projections were based on three different AEO 2000 forecasts: (1) Reference Case, (2) High Growth Case, and (3) Low Growth Case. Three efficiency scenarios were analyzed which forecast the shipment efficiency distribution after new standards: (1) NAECA scenario, (2) Roll-up scenario, and (3) Shift scenario. For these results the equipment lifetime was assumed to be 18.4 years, coupled with the inclusion of compressor replacement costs and an assumed societal discount rate of 7 percent. The range of NPVs are reported in Table V.18.

TABLE V.18: RANGE OF NET PRESENT VALUE WITH ELECTRICITY PRICE AND HOUSING PROJECTIONS

Trial standard level	Net present value for unites sold from 2006 to 2030 (billion 98$)					
	Reverse engineering costs			ARI mean costs		
	NAECA	Rool-up	Shift	NAECA	Roll-up	Shift
1	1 to 2	2	1 to 2	0	1	0 to −1
2	2	2 to 3	0 to −1	−1	0 to 1	−3 to −4
3	1 to 2	2 to 3	−1 to −2	−1 to −2	0 to −1	−5
4	0 to 1	1 to 2	−3 to −4	−5 to −6	−4	−10
5	−10 to −11	−10 to −11	−10 to −11	−22	−22	−22

In order to show the sensitivity of the NPVs in Table V.18 to the various input assumptions, Tables V.19 through V.22 report the range of NPV results for a range of assumptions and scenarios relative to the base case national equipment and operating costs for all central air-conditioning and heat pump equipment. By the "base case" we mean the case of no new efficiency standards. The results in Table V.19 and V.20 are the AEO 2000 Reference Case forecast of

electricity prices and housing. The total costs are presented for the base case and each trial standard level. The discount rate is 7 percent. In addition, the NPV (the difference in total costs between the base case and trial standard level), as well as the NPV as a percentage of the "Base Case Total Costs," are calculated for each trial standard level.

TABLE V.19.—NET PRESENT VALUES RESULTS RELATIVE TO BASE CASE TOTAL EQUIPMENT AND OPERATING COSTS BASED ON REVERSE ENGINEERING MANUFACTURING COSTS

TSL	Base case total costs billion 98$	Efficiency scenario							
		NAECA			Roll-up			Shift	
		Total costs billion 98$	NPV		Total costs billion 98$	NPV		Total costs billion 98$	NPV	
			Billion 98$	As percent of base case total		Billion 98$	As percent of base case total		Billion 98$	As percent of base case total
1	379	378	2	0.4	377	2	0.5	378	1	0.4
2	379	377	2	0.5	377	3	0.7	380	(1)	0.2
3	379	378	1	0.4	377	2	0.6	381	(2)	0.5
4	379	379	0	0.0	376	1	0.3	383	(4)	0.9
5	379	390	(10)	−2.7	390	(10)	−2.7	390	(10)	−2.7

TABLE V.20.—NET PRESENT VALUES RELATIVE TO BASE CASE TOTAL EQUIPMENT AND OPERATING COSTS BASED ON ARI MEAN MANUFACTURING COSTS

TSL	Base case total costs billion 98$	Efficiency scenario							
		NAECA			Roll-up			Shift	
		Total costs billion 98$	NPV		Total costs billion 98$	NPV		Total costs billion 98$	NPV	
			Billion 98$	As percent of base case total		Billion 98$	As percent of base case total		billion 98$	as percent of base case total
1	381	381	0	0.0	381	1	0.2	385	0	−0.1
2	381	382	(1)	−0.3	381	0	0.0	388	(3)	−0.9
3	381	383	(2)	−0.5	382	(1)	−0.2	390	(5)	−1.4
4	381	387	(5)	−1.4	386	(4)	−1.1	395	(10)	−2.5
5	381	403	(22)	−5.8	403	(22)	−5.8	407	(22)	−5.8

Table V.21 shows how a 3 percent discount rate[16] impacts the net present value. Only the Roll-up efficiency scenario and the AEO Reference Case electricity price and housing projection were considered in analyzing the impacts from a 3 percent discount rate.

TABLE V.21: NET PRESENT VALUES RESULTS BASED ON 3-PERCENT DISCOUNT RATE

TSL	Reverse engineering costs				ARI mean costs			
	Base case total costs billion 98$	Trial standard level			Base case total costs billion 98$	Trial standard level		
		Total cost billion 98$	Net present value 98$	As percent of base case total costs		Total cost billion 98$	Net present value billion 98$	As percent of base cast total costs
1	708	701	7	0.9	712	707	4	0.6
2	708	697	11	1.6	712	705	6	0.9
3	708	697	11	1.6	712	706	6	0.8
4	708	697	11	1.5	712	711	0	0.0
5	708	716	(8)	−1.2	712	746	(35)	−4.9

The proposed rule also estimated the national employment impacts due to each of the five trial standard levels. As discussed in the proposed rule, the energy efficiency standards for central air conditioners and heat pumps are expected to reduce electricity bills for residential and commercial consumers and the resulting net savings are expected to be redirected to other forms of economic activity. These shifts in

[16] A societal discount rate of 3 percent value was investigated as a scenario in accordance with the Office of Management and Budget's (OMB) Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements.

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spending and economic activity are expected to affect the demand for labor.

As we did for the proposed rule, the Department estimated the impacts of the new standards on national labor demand using an input/output model of the U.S. economy. The model characterizes the interconnections among 35 economic sectors using data from the Bureau of Labor Statistics. For some years after the new standards go into effect, new consumer expenditure on air conditioners and heat pumps each year outpaces their annual energy savings. This activity redirects expenditures into the manufacturing sector, which is less labor intensive than other sectors of the economy,[17] producing a loss of jobs in those sectors that is larger than the gain of jobs in manufacturing. Also, a loss of jobs results in the utility sector due to its loss of revenues. As annual consumer energy savings begin to exceed annual new expenditures on air conditioners, eventually the new standards will produce a net gain in national employment.

The increases or decreases in the net demand for labor in the economy estimated by the input/output model due to air conditioner and heat pumps standards are likely to be very small relative to total national employment. For the following reasons any modest changes in employment are in doubt:

- Unemployment is now at the lowest rate in 30 years. If unemployment remains very low during the period when the standards are put into effect, it is unlikely that the standards alone could result in any change in national employment levels;
- Neither the BLS data nor the input-output model used by DOE include the quality or wage level of the jobs. The losses or gains from any potential employment change may be offset if job quality and pay also change; and
- The net benefits or losses from potential employment changes are a result of the estimated net present value of benefits or losses likely to result from air conditioner and heat pump standards. It may not be appropriate to separately identify and consider any employment impacts beyond the calculation of net present value.

Taking into consideration these legitimate concerns regarding the interpretation and use of the employment impacts analysis, the Department concludes only that the proposed central air conditioner and heat pump standards are likely to result in no appreciable job losses to the nation.

[17] Bureau of Economic Analysis, Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II)

4. Impact on Utility or Performance of Products

As detailed in Section V of the proposed rule, in establishing classes of products we believe the adopted standards will not result in any degradation of utility or performance in the covered products.

5. Impact of Any Lessening of Competition

The Act directs the Department to consider any lessening of competition that is likely to result from standards. It further directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and transmit such determination to the Secretary, not later than 60 days after the publication of a proposed rule, together with an analysis of the nature and extent of such impact. EPCA Section 325(o)(2)(B)(i)(V) and (B)(ii), 42 U.S.C. 6295(o)(2)(B)(i)(V) and (B)(ii).

In order to assist the Attorney General in making such a determination, the Department provided the Department of Justice (DOJ) with copies of the proposed rule and the TSD for review. At DOE's request, the DOJ reviewed the manufacturer impact analysis interview questionnaire to ensure that it would provide insight concerning any lessening of competition due to any proposed trial standard levels.

As previously discussed in section II.D.4 above, the Department of Justice concluded that the residential central air conditioner and heat pump standards contained in the proposed rule could have an adverse impact on competition. The proposed standards would have changed the current central air conditioner and heat pump efficiency standards of 10 SEER/6.8 HSPF for split system air conditioners and heat pumps and 9.7 SEER/6.6 HSPF for single package air conditioners and heat pumps to 12 SEER for air conditioners and 13 SEER/7.7 HSPF for heat pumps. Through-the-wall equipment was the only exception. We proposed an 11 SEER standard for that class.

DOJ identified three possible competitive problems presented by the proposed standards. First, DOJ stated that the proposed 13 SEER heat pump standard would have a disproportionate impact on smaller manufacturers. They stated that currently less than 20 percent of the total current product lines meet the proposed standards, but for some small manufacturers, 100 percent of their product lines fail to satisfy the proposed standard.

Second, DOJ stated that the proposed standard for heat pumps, and in some instances for air conditioners, would have an adverse impact on some manufacturers of products (including those products referred to in the proposed rule as "niche products") used to retrofit existing housing and used in manufactured housing. These manufacturers could not, according to DOJ, make units that comply with the rule and fit into the available space.

Third, DOJ expressed concern that the proposed heat pump standard of 13 SEER could make heat pumps less competitive with alternative heating and cooling systems. Because the standard would result in increases in the size and cost of heat pumps, it is possible that purchasers would shift away from heat pumps to other systems that include electric resistance heat, reducing the competition that presently exists between heat pumps and those other systems.[18]

The Department of Justice urged the Department of Energy to take into account these possible impacts on competition in determining its final energy efficiency standard for air conditioners and heat pumps. DOJ wrote that the Department of Energy should consider setting a lower SEER standard for heat pumps, such as the standard included in Trial Standard Level 2, and a lower SEER standard for air conditioners for retrofit markets where there are space constraints (such as markets served by niche products) and for manufactured housing.

As we noted in the Supplementary ANOPR and proposed rule, nearly all small manufacturers produce only niche products. DOJ's first concern relates to disproportionate impacts on small manufacturers, which are substantially the same group as the niche product manufacturers. Furthermore, niche products almost exclusively serve applications with severe space constraints. Today's final rule prescribes standards only for those products that are not severely space-constrained, and therefore substantially eliminates their first concern regarding the impact of more stringent standards on small manufacturers.

[18] DOJ also wrote about our request for comments on a proposal to adopt a standard for steady-state cooling efficiency (EER). The regulation language in the proposed rule did not include a provision regarding an EER standard, and DOJ limited its views to the standards set forth in the proposed regulation language, indicating that if the Department proposes rule language in the future incorporating an EER standard, DOJ would address the competitive impact of that standard.

DOJ's second concern about products intended for space constrained markets are more difficult to address since the standards apply to products at the point of manufacture and not the point of installation. We have removed one element of this concern by not specifying new standards for niche products, primarily due to our concern over their continued viability in replacement applications. However, we recognize that larger conventional equipment also poses problems in replacement applications and that these problems may be more complex in manufactured homes. Nevertheless, air conditioner and heat pump manufacturers do have options for increasing the efficiency of equipment without increasing the size of both the indoor and outdoor units, and we expect products utilizing those options to be available to consumers during the time when the standards we are adopting today are in effect.

As to DOJ's third concern regarding possible shifting in the market from heat pumps to resistance heaters, we have adopted the same minimum SEER requirement for heat pumps as we have for air conditioners. That action substantially reduces the incentive for consumers to switch, thereby addressing that concern.

In summary, the standards we are adopting should effectively eliminate most of DOJ's concerns regarding the lessening of competition, even under TSL 4. To the extent that we have not fully eliminated all their concerns, however, we have considered the remaining possibility for lessening of competition as we weighed the burdens of today's adopted standards.

6. Need of the Nation To Save Energy

The Secretary recognizes the need of the Nation to save energy. Enhanced energy efficiency improves the nation's energy security, and reduces the environmental impacts of energy production. Improved efficiency of central air conditioners and heat pumps is also likely to improve the reliability of the nation's electric system. The energy savings from central air conditioner and heat pump standards result in reduced emissions of carbon and NO_X. Cumulative emissions savings over the 15-year period modeled are shown in Table V.22. The results presented in Table V.22 are based only on the AEO 2000 Reference Case for electricity price and housing projections and the NAECA efficiency scenario.

TABLE V.22.—CUMULATIVE EMISSIONS REDUCTIONS BASED ON AEO 2000 REFERENCE CASE AND NAECA EFFICIENCY SCENARIO (2006–2020)

Trial standard level	Reverse engineering costs		ARI mean costs	
	Carbon (Mt)	NO_X (kt)	Carbon (Mt)	NO_X (kt)
1	13.2	36.7	13.4	37.2
2	23.8	72.7	23.7	67.9
3	27.7	84.4	27.4	78.6
4	32.6	85.8	33.6	102.5
5	63.0	184.2	63.7	193.7

The impact of varying electricity price and housing projections (i.e., different AEO cases) as well as different efficiency scenarios were considered for the Trial Standard Level 4. Table V.23 shows how carbon and NO_X emissions are impacted by the different projections and scenarios.

TABLE V.23.—CUMULATIVE EMISSIONS REDUCTIONS FOR FINAL STANDARD (2006–2020) AND THE IMPACT OF DIFFERENT ELECTRICITY PRICE/HOUSING PROJECTIONS AND EFFICIENCY SCENARIOS

Electricity price and housing projection	Efficiency scenario	Reverse engineering costs		ARI mean costs	
		Carbon (Mt)	NO_X (kt)	Carbon (Mt)	NO_X (kt)
AEO reference case	NAECA	32.6	85.8	33.6	102.5
AEO reference case	Roll-up	32.7	93.8	31.3	87.5
AEO reference case	Shift	36.0	107.1	34.9	97.9
AEO low growth case	NAECA	28.5	97.2	27.5	95.8
AEO high growth case	NAECA	42.2	92.4	42.8	103.1

The annual carbon emission reductions range up to 6.8 Mt in 2020 and the NO_X emissions reductions up to 27.0 kt in 2015.[19] [20] Total carbon and NO_X emissions for each trial standard level are reported in the Environmental Assessment, in the TSD.

The Department makes no effort to monetize the benefits of the actual emission reductions, but there may be time related differences in the perceived value of the emissions depending on when they occur, as with monetized benefits that accumulate over time. Emission reductions that occur sooner are often more desirable than equivalent reductions that occur later. Like monetary benefits, the health, recreational and ecosystem benefits that result from emission reductions are often perceived to have a greater value if they occur sooner, rather than later. To the extent that the different trial standard levels have slightly different shipment distributions over time, some trial standard levels might have a slightly higher proportion of earlier emission reductions than another trial standard level. To show the possible effect of the different timing patterns of the emissions, the Department is also presenting discounted emissions. These calculations were done using the same seven percent discount rate as was used for discounting monetized benefits. We show discounted cumulative emission savings from 2006 through 2030 in Table V.24.

[19] Million metric tons (Mt).

[20] Thousand metric tons (kt).

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TABLE V.24.—CUMULATIVE DISCOUNTED EMISSIONS REDUCTIONS BASED ON AEO 2000 REFERENCE CASE AND NAECA EFFICIENCY SCENARIO (2006–2020)

Trial standard level	Reverse engineering costs		ARI mean costs	
	Carbon (Mt)	NO_X (kt)	Carbon (Mt)	NO_X (kt)
1	4.7	15.7	4.8	15.7
2	8.5	30.3	8.5	29.2
3	9.8	35.2	9.8	33.8
4	11.6	36.7	12.0	43.3
5	22.3	77.1	22.7	81.1

7. Other Factors

This provision allows the Secretary of Energy, in determining whether a standard is economically justified, to consider any other factors that the Secretary deems to be relevant. EPCA Section 325(o)(2)(B)(i)(VI), 42 U.S.C. 6295(o)(2)(B)(i)(VI). The Secretary has decided to consider the impact on peak power requirements and electric utility system reliability.

Peak power impacts on electric utilities from increases in the central air conditioner and heat pump standard are calculated using the NEMS–BRS model. NEMS–BRS is used to estimate peak power impacts by calculating the reduction in planned generation capacity due to an increase in the minimum efficiency standard. Table V.25 shows the estimated reductions in installed generation capacity, in gigawatts (GW), in the year 2020, due to each of the trial standard levels. Of the installed generating capacity avoided, 13 percent would have been provided by coal power plants. The remaining percentage (87 percent) would have been supplied by either gas-fired, oil-fired, or dual-fired power plants. The results presented in Table V.25 are based only on the AEO 2000 Reference Case for electricity price and housing projections and the NAECA efficiency scenario.

TABLE V.25.—INSTALLED GENERATION CAPACITY REDUCTIONS IN THE YEAR 2020 BASED ON AEO 2000 REFERENCE CASE AND NAECA EFFICIENCY SCENARIO

Trial standard level	Reverse engineering costs	ARI mean costs
	Installed generating capacity reduction (GW)	Installed generating capacity reduction (GW)
1	6.5	6.4
2	10.6	10.6
3	12.4	12.3
4	15.5	15.4
5	28.8	28.6

The impact of varying electricity price and housing projections (i.e., different AEO cases) as well as different efficiency scenarios were considered only for the final standard (trial standard level 4). Table V.26 shows how installed generation capacity is impacted by the different projections and scenarios.

TABLE V.26.—INSTALLED GENERATION CAPACITY REDUCTIONS IN THE YEAR 2020 FOR FINAL STANDARD AND THE IMPACT OF DIFFERENT ELECTRICITY PRICE/HOUSING PROJECTIONS AND EFFICIENCY SCENARIOS

Electricity price and housing projection	Efficiency scenario	Reverse engineering costs	ARI mean costs
		Installed generating capacity reduction (GW)	Installed generating capacity reduction (GW)
AEO reference case	NAECA	15.5	15.4
AEO reference case	Roll-up	15.5	15.0
AEO reference case	Shift	16.6	16.4
AEO low growth case	NAECA	14.5	13.9
AEO high growth case	NAECA	16.0	15.6

E. Conclusion

Section 325(o)(2)(A) of the Act, 42 U.S.C. 6295(o)(2)(A), specifies that any new or amended energy conservation standard for any type (or class) of covered product shall be designed to achieve the maximum improvement in energy efficiency which the Secretary determines is technologically feasible and economically justified. In determining whether a standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens. EPCA Section 325(o)(2)(B)(i), 42 U.S.C. 6295(o)(2)(B)(i). The amended standard must "result in significant conservation of energy." EPCA Section 325(o)(3)(B), 42 U.S.C. 6295(o)(3)(B).

We consider the impacts of standards beginning with the max tech level, i.e., Trial Standard Level 5. We then consider less efficient levels until we reach the level which is technologically feasible and economically justified.

To aid the reader as we discuss the benefits or burdens of the trial levels, we have included a summary of the analysis results in Table V.27.[21] Table V.27 presents a summary of quantitative analysis results for each Trial Standard Level based on the assumptions we consider most plausible. These include manufacturing cost estimates from the reverse engineering, an 18.4-year equipment lifetime with one compressor replacement at 14 years, and electricity prices based on the AEO2000 Reference Case.

TABLE V.27.—SUMMARY OF QUANTITATIVE RESULTS [1]

	Trial std 1	Trial std 2	Trial std 3	Trial std 4	Trial std 5
Primary energy saved (quads)[2]	1.5	2.9	3.4	4.2	8.6
Generation capacity offset (GW)[3]	6.5	10.6	12.4	15.5	28.8
NPV ($billion):.					
7% Discount rate, roll-up	2	3	2	1	(10)
7% Discount rate, NAECA	2	2	1	0	(10)
3% Discount rate, roll-up	7	11	11	11	(8)
Cumulative emissions reductions through 2020:					
Carbon equivalent (Mt)[3]	13.2	23.8	27.7	32.7	63.0
NO_X (kt)[3]	36.7	72.7	84.4	93.8	184.2
Cumulative change in INPV ($ million)[4]:					
Roll-up	(160)	(313)	(319)	(303)	
NAECA	(30)	(159)	(171)	(169)	
Life cycle cost savings ($)[5]:					
Split AC	75	113	113	113	(137)
Packaged AC	78	163	163	29	(276)
Split HP	209	365	372	372	(41)
Packaged HP	207	421	353	353	166
Payback (years)[6]:					
Split AC	7.8	9.8	9.8	11.3	19.6
Packaged AC	7.7	7.5	7.5	14.5	25.1
Split HP	2.7	3.9	6.4	6.4	14.0
Packaged heat pump	4.6	4.0	8.4	8.4	12.8

[1] Parentheses indicate negative (–) values.
[2] Energy savings based on Roll-up efficiency scenario.
[3] Values based on NAECA efficiency scenario with the exception of TSL 4 which is based on the Roll-up scenario.
[4] Not calculated at Trial Standard Level 5.
[5] Negative values indicate LCC increases.
[6] Payback periods are median values.

In addition to the quantitative results, we also consider other burdens and benefits that affect economic justification. The potential to improve the reliability of the electricity system is the major benefit we have not quantified explicitly. In areas where the occurrence of blackouts (and brownouts) can be reduced through expansion of system capacity, the economic value of avoided blackouts associated with reductions in peak load cannot exceed the value of the avoided capacity expansion. That value is already captured in our analysis as savings in consumer utility bills. However, in areas that do not expect to be able to maintain adequate capacity reserves, the value of avoided blackouts associated with reductions in peak demand can far exceed the normal costs of capacity expansion.[22]

We also recognize that the adopted standards could result in additional burdens. These include a possible increase in health problems caused by consumers forgoing air conditioner purchases, a possible reduction in the ability of the product to dehumidify, a possible lessening of competition, and possible difficulty in installing the new baseline products into replacement applications. However, we generally believe that these burdens are capable of being mitigated at any standard level, except possibly Trial Standard Level 5. Section IV discusses our response to comments regarding benefits and burdens and explains our viewpoints on those issues.

First we considered Trial Standard Level 5, the maximum technologically achievable efficiency level for each of four classes, representing uniform 18 SEER requirements. The manufacturing cost we assume for Trial Standard Level 5 is equal to 15 SEER equipment, although we would expect that assumption to understate the cost and price of the product. Trial Standard Level 5 will likely save 8.6 quads of energy which the Department considers significant. These savings will result in the avoidance of approximately 29 GW of installed generation capacity. For comparison, the generating capacity is equivalent to roughly 75 large, 400 megawatt, power plants,[23] approximately 3.7 percent of current installed generating capacity nationwide

[21] All cumulative effects that are not monetary are not discounted. Monetary effects are discounted to 1998 dollars.

[22] For instance, if capacity-related blackouts cost a region $1 billion, society would be willing to pay up to $1 billion to prevent them. If those blackouts can be prevented through either a capacity expansion or a reduction in peak demand, and the new capacity would cost $100 million, the value of the reduction in peak demand can be no more than $100 million. If the region is short on capacity and cannot add new capacity quickly, however, the same reduction in peak demand then can equal the value of the avoided blackout ($1 billion) since there is no feasible alternative.

[23] DOE estimates 9 coal-fired power plants and 66 gas-fired power plants can be avoided. See TSD, Chapter 11 and Appendix H.

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and more than 13 percent of the anticipated growth in capacity needed by 2020. The emissions reductions are 63.0 Mt of carbon equivalent and 184.2 kt of NO_X.

At Trial Standard Level 5, the average consumer would experience an increase in LCC. Purchasers of split central air-conditioners, the predominant class of central air conditioner with 65 percent of the sales of central air conditioners and heat pumps, would lose on average $137 over the life of the appliance. Purchasers of split heat pumps, the predominant class of heat pump, would lose on average $41. Again, these results do not include the additional price the consumer would pay over the price of a 15 SEER product, which would increase the life cycle cost considerably. Furthermore, for the nation as a whole, Trial Standard Level 5 would result in a net cost of $10 billion in NPV. We did not calculate manufacturer impacts at this trial standard level, determining based on preliminary evaluation that they would be severe and unacceptable.

The Secretary concludes that at Trial Standard Level 5, the benefits of energy savings, generating capacity reductions and emission reductions would be outweighed by the burdens of negative economic impacts to the nation, to the vast majority of consumers and to the manufacturers. Consequently, the Secretary has concluded that Trial Standard Level 5, the Max Tech Level, is not economically justified.

Next, we considered Trial Standard Level 4. This level specifies 13 SEER equipment for all product classes. In considering Trial Standard Level 4 the Roll-up efficiency scenario and reverse engineering cost data are the assumptions we consider to be the most probable as discussed in Part V.A, Trial Standard Levels. Primary energy savings would likely be 4.2 quads which the Department considers significant. The estimated reduction in installed generating capacity is approximately 15 GW, and reduced emissions would range up to 32.7 Mt of carbon equivalent and up to 93.8 kt of NO_X.

The average air conditioner owner would save $113 over the life of a split air conditioner and $29 over the life of a packaged air conditioner. These equate to median payback periods of 11.3 years and 14.5 years, respectively. Low income consumers of split air conditioners and split heat pumps also incur LCC savings ($43 for split air conditioner owners and $185 savings for split heat pump owners). In addition, the average heat pump owner would benefit, saving $372 over the life of a split heat pump and $353 over the life of a packaged heat pump. These equate to median payback periods between 6.4 and 8.4 years, respectively. Trial Standard Level 4 will lower peak electricity demand compared to the base case. That will allow utility service areas to either avoid new capacity or, to the extent that peak loads contribute to reliability problems, improve system reliability. The increase in national net present value is expected to be $1 billion. The decrease in the net present value of the air conditioning and heat pump manufacturing industry is expected to be $300 million.

After carefully considering the analysis, comments, and benefits versus burdens, the Department is amending the energy conservation standards for central air conditioners and central air conditioning heat pumps at Trial Standard Level 4. The Department concludes this standard saves a significant amount of energy and is technologically feasible and economically justified. In determining economic justification, the Department finds that the benefits of energy savings, the projected amount of avoided power plant capacity or improvement in system reliability that accompanies expected reduction in peak demand, consumer life cycle cost savings, national net present value increase and emission reductions resulting from the standards outweigh the burdens. The burdens include the loss of manufacturer net present value, increases in consumer life cycle cost for some users of products covered by today's final rule, any possible increase in health problems caused by consumers forgoing air conditioner purchases, any possible reduction in the ability of the product to dehumidify, any possible lessening of competition, and any possible difficulty in installing the new baseline products into replacement applications.

In the proposed rule, we proposed to adopt Trial Standard Level 3. The Department's decision to instead adopt the more stringent standards represented by Trial Standard Level 4 was influenced by comments we received during the intervening comment period. First, comments we received regarding the prices and markups applied to today's equipment persuaded us that the reverse engineering cost data are much more likely than the ARI Mean cost data to represent the actual costs of producing equipment under more stringent standards. Placing more weight on the costs represented by the reverse engineering data substantially improved the economic benefits to air conditioner owners, demonstrating that the benefits of Trial Standard Level 4 outweigh the burdens. Second, many comments expressed concern that adopting heat pump standards that were more stringent than air conditioner standards would encourage more consumers to purchase electric resistance furnaces and air conditioners instead of heat pumps. In response to those comments, we verified that the energy savings from the more efficient heat pumps would be eliminated if only a small fraction of heat pump owners (4 percent) switched to resistance heating. That possibility provided added justification for adopting the same minimum standards for heat pumps as for air conditioners.

Given our decision to adopt a 13 SEER standard for both central air conditioners and central air conditioning heat pumps, we believe further evaluation is needed before we can issue final standards for air conditioners or heat pumps that currently are intended to serve applications with severe space constraints, exemplified by what we have referred to as "niche" products. Based on our preliminary assessment of "highest viable efficiency levels" we identified for these products in the TSD (Table 4.23), the comments stating that these products would have difficulty in meeting the standards proposed in the proposed rule, and the concerns expressed by the Department of Justice, we have serious concerns about whether 13 SEER is an appropriate standard for most such products. On the other hand, we are uncertain whether it would be prudent for us to apply the standards contained in the proposed rule to niche products in light of the 13 SEER standard we are adopting today for other products. Doing so may create a strong tendency for niche products, with lower minimum efficiency standards than conventional products, to be applied in conventional applications.

Therefore, today's final rule provides efficiency standards for all residential central air conditioners and heat pumps, except the niche products. We are referring to these products more generally as "space-constrained products", since they are specifically intended for severely space-constrained applications. We define them as having the following characteristics:

(1) Rated cooling capacities no greater than 30,000 BTU/hr

(2) An outdoor or indoor unit having at least two overall exterior dimensions or an overall displacement that:

(a) are (is) substantially smaller than those of other units that are (i) currently usually installed in site-built single family homes, and (ii) of a similar cooling, and, if a heat pump, heating, capacity, and

(b) if increased, would certainly result in a considerable increase in the cost of installation or would certainly result in a significant loss in the utility of the product to the consumer.

(3) Of a product type that was available for purchase in the United States as of December 1, 2000.

Based on the information we have gathered thus far in this rulemaking, we believe space-constrained products would include equipment described as:

- through-the-wall packaged and split
- ductless split
- single package and non-weatherized

Small duct, high velocity equipment is covered by today's standards. As discussed in the proposed rule (65 FR at 59609–10), DOE addressed the concerns for that equipment by modifying the test procedure to allow those products to be tested as coil-only equipment. Also, the standards in today's rule will clearly apply to the types of central air conditioners and heat pumps normally installed in site-built single family homes.

The Department will re-open the comment period in this rulemaking to address standards for space-constrained products, and plans to publish a final rule in the **Federal Register** no later than eighteen (18) months from the date of publication of today's rule. The rule covering space-constrained products will establish new product classes, to the extent necessary, and minimum efficiency standards for these products. It will also contain an assessment of technical feasibility and economic justification in accordance with the requirements of the Act. The Department intends to make the rule for space-constrained products effective on January 23, 2006.

Before reopening the comment period, we will initially identify those product types we believe should be treated as space-constrained products, and will begin to assess the impact of a rulemaking for these products on small businesses. To aid in this process, we will seek shortly the following information from each manufacturer of those products that we believe may meet the definition of space-constrained products:

(1) the number of employees employed by the company as of December 31, 2000 (to assist us in determining whether we should consider the company to be a small business entity);

(2) a list of proposed space-constrained products, providing for each type of product:

(a) a description of its intended applications

(b) a description based on physical characteristics, manufacturing characteristics, capacity, and performance attributes that would distinguish it from other types of products, and which would be enforceable at the point of manufacture

(c) a list of models produced of that product type by the manufacturer, containing for each model: Physical dimensions, rated capacities, and range of efficiency ratings available;

(3) a statement of whether the number of units produced by the manufacturer was less than or greater than 100,000 units in the year 2000; and

(4) an estimate of the percentage of units produced by the manufacturer that the manufacturer estimates are installed as replacements for similar units.

The Department encourages companies that believe they manufacture space-constrained products to immediately submit this information, without awaiting a request from DOE, to Ms. Geraldine Paige at the address indicated at the beginning of this notice.

We will make the information we obtain publicly available (excluding confidential information) through a **Federal Register** notice. A comment period will follow during which time the public will have an opportunity to review the published information and respond to the Department. Following the close of the comment period, we will issue in the **Federal Register** our determination of which of the published products we believe are space-constrained products and which we believe are not. We expect these steps to proceed simultaneously with the other activities to set standards for such products.

VI. Procedural Issues and Regulatory Review

A. Review Under the National Environmental Policy Act

The Department prepared an Environmental Assessment (EA) (DOE/EA–1352) available from: U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Mail Station EE–41, 1000 Independence Avenue, SW, Washington, DC 20585–0121, (202) 586–0854. We found the environmental effects associated with various standard efficiency levels for central air conditioners and heat pumps to be not significant, and therefore we are publishing, elsewhere in this issue of the **Federal Register**, a Finding of No Significant Impact (FONSI) pursuant to the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the regulations of the Council of Environmental Quality (40 CFR Parts 1500–1508), and the Department's regulations for compliance with NEPA (10 CFR Part 1021).

B. Review Under Executive Order 12866, "Regulatory Planning and Review"

Today's regulatory action has been determined to be an "economically significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review." 58 FR 51735 (October 4, 1993). Accordingly, today's action was subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

The draft submitted to OIRA and other documents submitted to OIRA for review have been made a part of the rulemaking record and are available for public review in the Department's Freedom of Information Reading Room, 1000 Independence Avenue, SW, Washington, DC 20585, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, telephone (202) 586–3142.

The proposed rule contained a summary of the Regulatory Analysis which focused on the major alternatives considered in arriving at the approach to improving the energy efficiency of consumer products. The reader is referred to the complete draft "Regulatory Impact Analysis," which is contained in the TSD, available as indicated at the beginning of this notice. It consists of: (1) A statement of the problem addressed by this regulation, and the mandate for government action; (2) a description and analysis of the feasible policy alternatives to this regulation; (3) a quantitative comparison of the impacts of the alternatives; and (4) the national economic impacts of the proposed standard.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires an assessment of the impact of regulations on small businesses. To be categorized as a "small" air conditioning and warm air heating equipment manufacturer, a firm must employ no more than 750 employees.

The Department prepared a manufacturing impact analysis which was made public and available to all residential central air conditioner and heat pump manufacturers. Other impacts on small businesses were previously discussed in the proposed rule. 65 FR 59590, 59629–30 (October 5, 2000). The Department reaffirms its certification in the proposed rule.

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Today's rule will not have a significant impact on a substantial number of small entities, and preparation of a regulatory flexibility analysis is unnecessary.

Most small businesses engaged in the manufacture of central air conditioners and heat pumps produce products that we have called "niche" products. To address the concerns of the Department of Justice and many commenters regarding the impacts of more stringent standards on small manufacturers, we are continuing our evaluation of standards for those products and have not issued new standards for them as part of this rule.

D. Review Under the Paperwork Reduction Act

No new information or record keeping requirements are imposed by this rulemaking. Accordingly, no Office of Management and Budget clearance is required under the Paperwork Reduction Act. 44 U.S.C. 3501 et seq.

E. Review Under Executive Order 12988, "Civil Justice Reform"

With respect to the review of existing regulations and the promulgation of new regulations, Section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE reviewed today's final rule under the standards of section 3 of the Executive Order and determined that, to the extent permitted by law, the final regulations meet the relevant standards.

F. "Takings" Assessment Review

DOE has determined pursuant to Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 52 FR 8859 (March 18, 1988), that this regulation would not result in any takings that might require compensation under the Fifth Amendment to the United States Constitution.

G. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. Agencies also must have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. DOE published its intergovernmental consultation policy on March 14, 2000. 65 FR 13735. DOE has examined today's final rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. State regulations that may have existed on the products that are the subject of today's final rule were preempted by the Federal standards established in NAECA. States can petition the Department for exemption from such preemption to the extent, and based on criteria, set forth in EPCA.

H. Review Under the Unfunded Mandates Reform Act

With respect to a proposed regulatory action that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector of $100 million or more (adjusted annually for inflation), section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires a Federal agency to publish estimates of the resulting costs, benefits and other effects on the national economy. 2 U.S.C. 1532(a), (b). UMRA also requires each Federal agency to develop an effective process to permit timely input by state, local, and tribal governments on a proposed significant intergovernmental mandate. The Department's consultation process is described in a notice published in the **Federal Register** on March 18, 1997 (62 FR 12820). Today's final rule may impose expenditures of $100 million or more on the private sector. It does not contain a Federal intergovernmental mandate.

Section 202 of UMRA authorizes an agency to respond to the content requirements of UMRA in any other statement or analysis that accompanies the proposed rule. 2 U.S.C. 1532(c). The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The Supplementary Information section of the Notice of Final Rulemaking and "Regulatory Impact Analysis" section of the TSD for this Final Rule responds to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the rule unless DOE publishes an explanation for doing otherwise or the selection of such an alternative is inconsistent with law. As required by section 325(o) of the Energy Policy and Conservation Act (42 U.S.C. 6295(o)), today's final rule establishes energy conservation standards for central air conditioners and heat pumps that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in the "Regulatory Impact Analysis" section of the TSD for today's final rule.

I. Review Under the Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. No. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule or policy that may affect family well-being. Today's final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under the Plain Language Directives

Section 1(b)(12) of Executive Order 12866 requires that each agency draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty. Similarly, the Presidential memorandum of June 1, 1998 (63 FR 31883) directs the heads of executive departments and agencies to use plain language in all proposed and final rulemaking documents published in the **Federal Register**.

Today's rule uses the following general techniques to abide by Section 1(b)(12) of Executive Order 12866 and the Presidential memorandum of June 1, 1998:

- Organization of the material to serve the needs of the readers (stakeholders);
- Use of common, everyday words in short sentences; and
- Shorter sentences and sections.

K. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of today's final rule prior to the effective date set forth at the outset of this notice. DOE also will submit the supporting analyses to the Comptroller General (GAO) and make them available to each House of Congress. The report will state that it has been determined that the rule is a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Energy conservation, Household appliances.

Issued in Washington, DC, on January 16, 2001.

Dan W. Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, Part 430 of Chapter II of Title 10, Code of Federal Regulations is amended, as set forth below.

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

1. The authority citation for Part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

2. Section 430.2 is amended by adding a definition for "space-constrained products" in alphabetical order to read as follows:

§ 430.2 Definitions.

* * * * *

Space constrained product means a central air conditioner or heat pump:

(1) That has rated cooling capacities no greater than 30,000 BTU/hr;

(2) That has an outdoor or indoor unit having at least two overall exterior dimensions or an overall displacement that:

(i) Are (is) substantially smaller than those of other units that are (i) currently usually installed in site-built single family homes, and (ii) of a similar cooling, and, if a heat pump, heating, capacity, and

(ii) If increased, would certainly result in a considerable increase in the usual cost of installation or would certainly result in a significant loss in the utility of the product to the consumer; and

(3) Of a product type that was available for purchase in the United States as of December 1, 2000.

* * * * *

3. Section 430.32 of Subpart C is amended by revising paragraph (c) to read as follows:

§ 430.32 Energy and water conservation standards and effective dates.

* * * * *

(c) *Central air conditioners and central air conditioning heat pumps.* (1) Split system central air conditioners and central air conditioning heat pumps manufactured after January 1, 1992, and before January 23, 2006, and single package central air conditioners and central air conditioning heat pumps manufactured after January 1, 1993, and before January 23, 2006, shall have Seasonal Energy Efficiency Ratio and Heating Seasonal Performance Factor no less than:

Product class	Seasonal energy efficiency ratio	Heating seasonal performance factor
(i) Split systems	10.0	6.8
(ii) Single package systems	9.7	6.6

(2) Central air conditioners and central air conditioning heat pumps manufactured on or after January 23, 2006, shall have Seasonal Energy Efficiency Ratio and Heating Seasonal Performance Factor no less than:

Product class	Seasonal energy efficiency ratio (SEER)	Heating seasonal performance factor (HSPF)
(i) Split system air conditioners	13	
(ii) Split system heat pumps	13	7.7
(iii) Single package air conditioners	13	
(iv) Single package heat pumps	13	7.7
(v) Space constrained products	[reserved]	[reserved]

* * * * *

Appendix

[The following letter from the Department of Justice will not appear in the Code of Federal Regulations.]

DEPARTMENT OF JUSTICE,

Antitrust Division, Main Justice Building, 950 Pennsylvania Avenue NW., Washington, DC 20530–0001, (202) 514–2401/(202) 616–2645 (f), antitrust@justice.usdoj.gov (internet), http://www.usdoj.gov (World Wide Web).

December 4, 2000.

Mary Anne Sullivan, General Counsel, Department of Energy, Washington, DC 20585.

Dear General Counsel Sullivan:

I am responding to your October 16, 2000 letter seeking the views of the Attorney General about the potential impact on competition of two proposed energy efficiency standards: one for clothes washers and the other for residential central air conditioners and heat pumps. Your request was submitted pursuant to Section 325(o)(2)(B)(i) of the Energy Policy and Conservation Act, 42 U.S.C. § 6291, 6295 ("EPCA"), which requires the Attorney General to make a determination of the impact of any lessening of competition that is likely to result from the imposition of proposed energy efficiency standards. The Attorney General's responsibility for responding to requests from other departments about the effect of a program on competition has been delegated to the Assistant Attorney General for the Antitrust Division in 28 CFR § 0.40(g).

We have reviewed the proposed standards and the supplementary information published in the Federal Register notices and submitted to the Attorney General, which include information provided to the Department of Energy by manufacturers. We have additionally conducted interviews with members of the industries.

We have concluded that the proposed clothes washer standard would not adversely affect competition. In reaching this conclusion, we note that the proposed standard is based on a joint recommendation submitted to the Department of Energy by manufacturers and energy conservation advocates. That recommendation states that virtually all manufacturers of clothes washers who sell in the United States participated in arriving at the recommendation through their trade association, that the recommendation

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was developed in consultation with small manufacturers, and that the manufacturers believe the new standard would not likely reduce competition. We note further that, as the industry recommended, the proposed standard will be phased in over six years, which will allow companies that do not already have products that meet the proposed standard sufficient time to redesign their product lines.

With respect to the proposed residential central air conditioner and heat pump standard, we have concluded that there could be an adverse impact on competition. The proposed standard, Trial Standard Level 3, is expressed in terms of two industry measurements: SEER (Seasonal Energy Efficiency Ratio) and HSPF (Heating Seasonal Performance Factor).[1] These standards would change from the current central air conditioner and heat pump efficiency standards of 10 SEER/6.8 HSPF for split system air conditioners and heat pumps and 9.7 SEER/6.6 HPSF for single package air conditioners and heat pumps to 12 SEER for air conditioners and 13 SEER/7.7 HPSF for heat pumps.

We have identified three possible competitive problems presented by the proposed standards. First, the proposed 13 SEER heat pump standard would have a disproportionate impact on smaller manufacturers. Currently less than 20% of the total current product lines meet the proposed standards, but for some small manufacturers, 100% of their product lines fail to satisfy the proposed standard.

Second, the proposed standard for heat pumps, and in some instances for air conditioners, would have an adverse impact on some manufacturers of these products (including those products referred to in the Federal Register notice as "niche products") used to retrofit existing housing and used in manufactured housing. These manufacturers could not make units that comply with the rule and fit into the available space.

Third, the proposed heat pump standard of 13 SEER could make heat pumps less competitive with alternative heating and cooling systems. Because the standard will result in increases in the size and cost of heat pumps, it is possible that purchasers will shift away from heat pumps to other systems that include electric resistance heat, reducing the competition that presently exists between heat pumps and those other systems.

The Department of Justice urges the Department of Energy to take into account these possible impacts on competition in determining its final energy efficiency standard for air conditioners and heat pumps. The Department of Energy should consider setting a lower SEER standard for heat pumps, such as the standard included in Trial Standard Level 2, and a lower SEER standard for air conditioners for retrofit markets where there are space constraints (such as markets served by niche products) and for manufactured housing.

Sincerely,

A. Douglas Melamed,

Acting Assistant Attorney General.

[FR Doc. 01–1790 Filed 1–18–01; 11:30 am]

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[1] The **Federal Register** notice also requested comments on a proposal to adopt a standard for steady-state cooling efficiency (EER) and discussed several options the Department of Energy is considering. The proposed rule set forth in the notice does not, however, include a provision regarding an EER standard, and the views of the Department of Justice expressed in this letter are limited to the impact of any lessening of competition * * * that is likely to result from the imposition of the [proposed] standard," as required by EPCA. If the Department of Energy proposes a rule in the future incorporating an EER standard, the Department will then evaluate that proposed rule and express its views about the competitive impact of that standard.

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Finding of No Significant Impact Energy Conservation Program for Consumer Products

AGENCY: Department of Energy.

ACTION: Finding of No Significant Impact (FONSI) for Energy Conservation Standard for Residential Central Air Conditioners and Heat Pumps.

SUMMARY: The Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act and the National Appliance Energy Conservation Act, and the National Appliance Energy Conservation Amendments, prescribes energy conservation standards for certain major household appliances, and requires the Department of Energy (DOE) to administer an energy conservation program for these products. Based on an Environmental Assessment (EA), DOE/EA–1352, DOE has determined that the adoption of energy efficiency Trial Standard Level (TSL) 4 for residential central air conditioners and heat pumps, as adopted by the Final Rule entitled the "Energy Conservation Program for Consumer Products: Residential Central Air Conditioners and Heat Pumps Energy Conservation Standards," would not be a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA). Therefore, an environmental impact statement (EIS) is not required, and the Department is issuing this finding of no significant impact (FONSI).

ADDRESSES: Public Availability: Copies of the EA are available from: U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Forrestal Building, Mail Station EE–41, 1000 Independence Avenue, S.W., Washington, D.C., 20585–0121, (202) 586–9127.

FOR FURTHER PROGRAM INFORMATION CONTACT: Dr. Michael E. McCabe, Office of Energy Efficiency and Renewable Energy (EE–41), U.S. Department of Energy, 1000 Independence Avenue, S.W., Washington, D.C. 20585–0121, (202) 586–9127.

For Further Information Regarding the DOE NEPA Process, Contact: Carol Borgstrom, Director, Office of NEPA Policy and Assistance (EH–42), 1000 Independence Avenue, S.W., Washington, D.C. 20585–0119, (202) 586–4600.

SUPPLEMENTARY INFORMATION:

Description of the Proposed Action: The proposed action is the establishment of a revised energy conservation standard (TSL 4) for residential central air conditioners and heat pumps.

Environmental Impacts: The EA evaluates the environmental impacts of a range of new energy conservation standards for residential central air conditioners and heat pumps. The results are presented for each potential trial standard level. Each potential trial standard level is an alternative action, and the environmental impacts of each alternative are compared to what would be expected to happen if no new standard were adopted, i.e., the "no action" alternative.

The main environmental impact is decreased emissions from fossil-fueled electricity generation. All of the minimum efficiency levels considered for this appliance product category would result in decreased electricity use and, therefore, a reduction in power plant emissions. The proposed efficiency standard would generally decrease air pollution by decreasing future energy demand. The environmental analysis considers two pollutants, nitrogen oxides (NO_X) and sulfur dioxide (SO_2), and one emission, carbon. The Department, in the Notice of Proposed Rulemaking, proposed TSL 3. However, in the Final Rule, DOE is adopting TSL 4, an alternative that was also analyzed in the EA. The results of the analysis show an estimated cumulative reduction of 27.7 to 32.7 million tons of carbon equivalent emissions, and 84.4 to 93.8 thousand tons NO_X for TSLs 3 and 4, respectively, through the year 2020. This would be a national reduction of 0.19% and 0.23% of carbon equivalent emissions, and 0.08% and 0.09% of NO_X. Because emissions of SO_2 from power plants are capped by clean air legislation, physical emissions of this pollutant from electricity generation will be only minimally affected by residential central air conditioners and heat pumps standards. The maximum SO_2 allowed by law will most likely still be produced, but because SO_2 emissions are traded, and if SO_2 emissions are lowered due to less power generation, then the cost of SO_2 emission credits may decrease slightly. Therefore, the EA did not consider changes in power sector SO_2 emissions because they will be negligible.

Determination: Based upon the EA, DOE has determined that the adoption of the proposed energy-efficiency standard for residential central air conditioners and heat pumps would not constitute a major Federal action significantly affecting the quality of the human environment, within the meaning of NEPA. Therefore, an EIS is not required, and the Department is issuing this FONSI.

Issued in Washington, D.C., the 4th day, of January 2001.

Dan W. Reicher,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 01–1791 Filed 1–18–01; 11:30 am]

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Federal Register

Monday,
January 22, 2001

Part XIII

The President

Proclamation 7391—Religious Freedom Day, 2001

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Presidential Documents

Title 3—

The President

Proclamation 7391 of January 15, 2001

Religious Freedom Day, 2001

By the President of the United States of America

A Proclamation

Each year we commemorate the anniversary of the religious freedom statute adopted by the Virginia legislature in 1786. This statute, which reflects the wisdom and foresight of its author, Thomas Jefferson, and its cosponsor, James Madison, became the model for the First Amendment to our Constitution, and it has had enormous and far-reaching consequences for the life of our Nation.

Just a few weeks ago, we saw how much that freedom means to all of us, as we celebrated Christmas, Hanukkah, and the Eid Al-Fitr within the same week. These holidays belonging to the Christian, Jewish, and Muslim faiths were observed freely and in peace by millions of people across our country—an occurrence unimaginable in some regions of the world, where people suffer persecution and even death for worshipping according to their conscience. Because of religious freedom, Americans have been spared much of the violence, bitterness, and conflict that have scarred so many other societies, and our Nation has benefited immeasurably from the many contributions of generations of men and women who emigrated to America because their right to worship was protected by the Constitution and the courts and respected by their fellow citizens.

But religious freedom is not a right we enjoy solely by virtue of being Americans; it is a fundamental human right that should be honored in every Nation around the globe. That is why I have sought to make it an integral part of U.S. foreign policy and to raise international awareness that many countries continue to engage in or tolerate egregious violations of their citizens' right to worship. I am proud that we have expanded reporting on religious freedom in every country, and that through our Ambassador at Large for International Religious Freedom, we have strived to promote religious freedom where it is threatened or denied and to intervene on behalf of those who are suffering because of their religious beliefs and practices.

More than 2 centuries ago, our founders sought to protect the religious freedom that inherently belongs to every human being. Now the responsibility falls to our generation, not only to preserve that right, but also to work together for the day when all people can worship freely and in peace.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim January 16, 2001, as Religious Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies, activities, and programs, and I urge all Americans to reaffirm their devotion to the fundamental principles of religious freedom and tolerance.

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IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

[FR Doc. 01–1908
Filed 1–18–01; 9:12 am]
Billing code 3195–01–P



Federal Register

Monday,
January 22, 2001

Part XIV

Environmental Protection Agency

40 CFR Part 745
Lead; Notification Requirements for Lead-based Paint Abatement Activities and Training; Proposed Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[OPPTS–62165; FRL–6764–7]

RIN 2070–AD31

Lead; Notification Requirements for Lead-based Paint Abatement Activities and Training

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Under the authority of Section 407 of the Toxic Substances Control Act (TSCA), as amended by the Residential Lead-Based Paint Hazard Reduction Act of 1992, also known as "Title X (ten)," EPA proposes to establish notification procedures for certified lead abatement professionals conducting lead-based paint activities, and accredited training programs providing lead-based paint activities courses. Specifically, this proposal seeks to establish the procedures that would be used to provide the notification to the Agency that is currently required prior to the commencement of lead-based paint abatement activities. This proposal also seeks to establish provisions which would require accredited training programs to notify the Agency under the following conditions: (1) Prior to providing lead-based paint activities training courses, and (2) following completion of lead-based paint activities training courses. These notification requirements are necessary to provide EPA compliance monitoring and enforcement personnel with information necessary to track compliance activities and to prioritize inspections. Today's proposal, will help to prevent lead poisoning in children under the age of six by supporting the Agency's implementation of the mandate in Title X to ensure that lead abatement professionals involved in inspecting, assessing or removing lead-based paint, dust or soil are trained and certified to conduct these activities.

DATES: Comments, identified by docket control number OPPTS–62165, must be received by EPA on or before February 21, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. under **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–62165 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Mike Wilson, National Program Chemicals Division (7404), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 260–4664; e-mail address: wilson.mike@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you operate a training program required to be accredited under 40 CFR 745.225, or if you are a lead abatement professional (individual or firm) who must be certified to conduct lead-based paint abatement activities in accordance with 40 CFR 745.226. Specifically, the proposed procedure for notification of the commencement of lead-based paint abatement activities applies to both the certified supervisor and certified firm employing that supervisor conducting lead-based paint abatement activities. The proposed procedure for notification of lead-based paint activities training courses applies to the training manager of an accredited training program.

This proposed rule applies only in States and Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324. For further information regarding the authorization status of States and Indian tribes contact the National Lead Information Center (NLIC) at 1–800–424–LEAD. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Code	Examples of Potentially Affected Entities
Lead abatement professionals	562910	Firms and supervisors engaged in lead-based paint activities.
Training programs	611519	Training programs providing training services in lead-based paint activities.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action applies to certain entities. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in 40 CFR part 745. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the Internet Home Page for the EPA Lead Program at http://www.epa.gov/lead/. You can also access an electronic copy of this document by going directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/, and look up this document using the date of publication. To access information about lead-based paint and the Lead Program, go directly to EPA's Lead Home Page at http://www.epa.gov/lead.

2. *In person*. The Agency has established an official record for this action under docket control number OPPTS–62165. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Non-confidential Information Center, North East Mall Rm. B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Center is (202) 260–7099.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS–62165 in the subject line on the first page of your response.

1. *By mail*. Submit your comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier*. Deliver your comments to: OPPT Document Control Office (DCO) in East Tower Rm. G–099, Waterside Mall, 401 M St., SW., Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260–7093.

3. *Electronically*. You may submit your comments electronically by e-mail to: oppt.ncic@epa.gov, or mail your computer disk to the address identified above. Do not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments will also be accepted on standard disks in WordPerfect 6.1/8 or ASCII file format. All comments in electronic form must be identified by docket control number OPPTS–62165. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI Information That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person identified under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

We invite you to provide your views on the various options we propose, new approaches we may not have considered, the potential impacts of the various options (including possible unintended consequences), and any data or information that you would like the Agency to consider during the development of the final action. You may find the following suggestions helpful for preparing your comments:

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide copies of any technical information and/or data you used that support your views.
- If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
- Provide specific examples to illustrate your concerns.
- Offer alternative ways to improve the proposed rule or collection activity.
- Make sure to submit your comments by the deadline in this notice.
- To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. Background

A. How Does this Action Fit into EPA's Overall Lead Program?

The Residential Lead-Based Paint Hazard Reduction Act of 1992 (Title X) amended TSCA by adding a new Title IV. Several sections of Title X directed EPA to promulgate regulations aimed at fulfilling the purposes of Title X. These included TSCA section 402, Lead-Based Paint Activities Training and Certification, which directs EPA to promulgate regulations to govern the training and certification of individuals engaged in lead-based paint activities, the accreditation of training programs, and the establishment of standards for conducting lead-based paint activities. Section 404 of TSCA requires that EPA establish procedures for States seeking to establish their own programs for lead-based paint activities. On August 29, 1996, EPA promulgated a final rule under sections 402 and 404 of TSCA titled "Lead; Requirements for Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities" (61 FR 45778). This rule is codified at 40 CFR part 745, subparts L and Q.

One of the standards EPA developed for performing lead-based paint activities, codified at 40 CFR 745.227(e)(4), requires notification to EPA prior to the commencement of lead-based paint abatement activities in a residential dwelling, or child-occupied facility, or as a result of a Federal, State, Tribal, or local order. However, the current 40 CFR 745.227(e)(4) does not detail specific notification procedures. Today's proposal includes such procedures.

Today's proposal also includes requirements for accredited training programs (accredited under 40 CFR 745.225) to notify the Agency of lead-based paint activities course schedules prior to being taught and provide information after the completion of a training course. Currently, accredited training programs are asked to voluntarily notify the Agency prior to offering a lead-based paint activities course. This proposal seeks to codify this practice.

These proposed notification requirements for lead-based paint abatement activities and training courses will assist significantly in the implementation of lead-based paint activities regulations codified at 40 CFR part 745 subpart L. The notification provisions will help to assure compliance by facilitating observation of abatement activities and training by EPA compliance monitoring and enforcement personnel.

B. What is the Agency's Authority for Taking this Action?

EPA is issuing this proposed rule under the authority of section 407 of the Toxic Substance Control Act (TSCA), 15 U.S.C. 2687. Section 407 states that regulations of the Administrator under Subchapter IV of TSCA shall include such recordkeeping and reporting requirements as may be necessary to insure effective implementation. EPA regulations under Subchapter IV of TSCA include lead-based paint activities regulations, which this proposal seeks to amend, codified at 40 CFR part 745 subpart L.

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III. Proposal

A. What are the Requirements for Notification of Lead-based Paint Abatement Activities?

Today's proposed rule includes the procedures that will be used to satisfy the requirements for the notification of commencement of lead-based paint abatement activities in § 745.227(e). This provision includes instructions which would require firms certified under 40 CFR 745.226 to provide notification to the Agency prior to conducting lead-based paint abatement activities. The original notice, signed by a certified supervisor, would be required to be received by the Agency at least 10 business days prior to the start of lead-based paint abatement activities. An abbreviated notification period is provided for lead-based paint abatement activities conducted in response to an elevated blood lead (EBL) determination and/or a Federal, State, Tribal, or local emergency abatement order, where the firm is unable to comply with the standard notification period due to the necessity for an expeditious response to such event. If lead-based paint abatement activities are expected to begin on a date other than that specified in the original notice or if the other reported information changes, an updated notice would be required. This proposal would prohibit lead-based paint abatement activities from starting on any date other than the one contained in the applicable notification. This notification provision would provide EPA compliance monitoring and enforcement personnel with information necessary to track compliance activity and to prioritize compliance inspections. The notice would include the following:

1. Notification type (Original, Updated, Cancellation).
2. Date when lead-based paint abatement activities will commence.
3. Date when lead-based paint abatement activities will end (approximation using best professional judgement).
4. Firm's name, EPA certification number, address, and phone number.
5. Type of building on/in which abatement work will be performed.
6. Property name (if applicable).
7. Property address for abatement work, including nearest cross streets.
8. Copy of Federal/State/Tribal/Local emergency abatement order, if applicable.
9. Name, EPA certification number, and signature of the Certified Supervisor.
10. Approximate square footage/acreage to be abated.
11. Brief description of abatement activities to be performed.

Notification would be accomplished using any of the following methods: written notice, or E-mail. All notices submitted by E-mail must be followed with written notice within 24 hours of submission. Written notification would be accomplished using either the sample form titled "Notification of Lead-Based Paint Abatement Activities" or a similar form. All written notices would be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery. When using the U.S. Postal Service for delivery, an additional three business days should be factored in to ensure Agency receipt of the notice by the required date. The notice would have to be signed by a certified supervisor. Notification instructions and sample forms would be obtained from the National Lead Information Center (NLIC) at 1–800–424–LEAD, or the Internet at http://www.epa.gov/lead.

B. What are the Requirements for Notification of Lead-based Paint Activities Training?

Today's proposed rule includes requirements for the notification of lead-based paint activities training in 40 CFR 745.225(c). This provision would require training programs certified under 40 CFR 745.225 to provide notification to the Agency prior to conducting lead-based paint activities courses. The original notice would be required to be received by the Agency at least 10 business days prior to the start of a lead-based paint activities course. An updated notice would be required if the starting date for a lead-based paint activities course is changed to a date other than that specified in the original notice or if the other reported information changes. This proposed rule would also prohibit lead-based paint activities courses from starting on any date other than the date which is contained in the applicable notification. This notification provision would provide EPA compliance monitoring and enforcement personnel with information necessary to track training program compliance and to prioritize compliance inspections. The notice would include the following:

1. Notification type (Original, Updated, Cancellation).
2. Training program name, EPA accreditation number, address, and phone number.
3. Course discipline, type (initial/refresher), and the language in which instruction will be given.
4. Date(s) and time(s) of training.
5. Training location(s) phone number, and street address (including nearest cross streets).
6. Principal instructors name.
7. Training manager's name and signature.

Training programs would also be required to provide notice to the Agency following completion of a lead-based paint activities course. This notice would be provided to the Agency within 10 business days of course completion. This notification provision would provide information necessary for the following: (1) the evaluation of certification applications, and (2) to properly evaluate the training and certification credentials of individuals conducting lead-based paint abatement activities. This notice would include the following:

1. Training program name, EPA accreditation number, address, and phone number.
2. Course discipline and type (initial/refresher).
3. Date(s) of training.
4. The following student information:
a. Name.
b. Address.
c. Social security number.
d. Course completion certificate number.
e. Student test scores.
5. Training manager's name and signature.

Notification of lead-based paint activities course schedules and notice following completion of lead-based paint activities courses would be accomplished using any of the following methods: written notice, or by E-mail. All notices submitted by E-mail would be followed up with a written notice. Written notification of lead-based paint activities course schedules would be accomplished using either the sample form titled "Lead-based Paint Activities Training Course Schedule" or similar form. Written notification following lead-based paint activities courses would be accomplished using either the sample form titled "Lead-based Paint Activities Training Course Follow-up" or similar form. All written notices would be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery. When using the U.S. Postal Service for delivery, an additional 3 business days should be factored in to ensure Agency receipt of the notice by the required date. The notice would have to be signed by the Training Manager. Notification instructions and sample forms would be obtained from the National Lead Information Center (NLIC) at 1–8001–4241–LEAD, or on the Internet at http://www.epa.gov/lead/.

C. What Were the Principal Issues Considered During the Development of this Proposal?

1. *How is notification accomplished?* While considering notification methods, the Agency reviewed the notification provisions of several existing State lead-based paint abatement programs, as well as a similar Agency program for asbestos abatement, the National Emission Standards for Hazardous Air Pollutants (NESHAP) program. It was determined that each of these programs require notification in writing, delivered by hand, postal service, or commercial delivery service.

The NESHAP program received comments regarding the use of faxed notification. In the 1990 final rule (55 FR 48406), the NESHAP program responded that EPA did not consider fax notification to be sufficiently reliable, at the time, to allow their use but might consider the use of facsimile machines in the future when their reliability improved.

For purposes of this proposal, the Agency would like to make use of existing technology to simplify the lead-based paint abatement and training notification process. The use of fax machines today is commonplace and reliability concerns are greatly diminished. Also, E-mail is a reliable and effective communication tool. Therefore, in addition to the more traditional notification methods (mail, commercial delivery service, or hand delivery) the Agency is proposing to allow fax and E-mail notification. In allowing E-mail notifications, the Agency is proposing that E-mail notification would require follow-up written notification for the record. However, the original E-mail notice would satisfy the applicable notification time requirements.

The Agency is also particularly interested in receiving comments on other electronic reporting mechanisms, including web-based on-line reporting. Under the Government Paperwork Elimination Act (GPEA) of 1998, Public Law No. 105–277, all Federal agencies are required to have an electronic means of reporting to government as an alternative to reporting on paper by October 2003, and such submissions and transactions must be given the same legal effect as a paper submission. It requires Federal agencies to provide individuals or entities the option to submit information, transact business with the Agency, and maintain records electronically, when practicable. In addition, the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000, Public Law No. 106–229, is intended to eliminate legal barriers to the use of electronic technology in business-to-business and consumer transactions. It's basic purpose is to promote the use of electronic signatures, electronic contract formation, and electronic record-keeping in private commerce by establishing legal equivalence between: (1) Contracts written on paper and contracts in electronic form; (2) pen-and-ink signatures and electronic signatures; and (3) other legally-required written documents and the same information in electronic form.

In compliance with these mandates, EPA is developing a centralized Agency-wide electronic report receiving system, called the "Central Data Exchange" (CDX). Once CDX is in place for a particular reporting or submission requirement, regulated entities that wish to submit electronic documents directly to EPA would be able to do so using CDX. In addition, until CDX is available, and parallel to CDX, the Office of Pollution Prevention and Toxics (OPPT) is also developing a user-friendly electronic reporting process for the information that is submitted to EPA under sections 4, 5, 8, and 12(b) of TSCA. OPPT expects to implement these electronic reporting options in the first quarter of 2001. In providing comments on additional electronic options to consider for the notification covered in this proposed rule, EPA asks commenters to also provide estimates for the reporting burden associated with electronic reporting, differences between the burden of reporting electronically versus in paper, availability of technology necessary for electronic reporting, and comments or preferences between on-line web-based notifications and e-mail electronic options.

The Agency also considered telephone notification and found it inappropriate because it would increase administrative burden, and would be less reliable due to inherent problems associated with transcribing verbal information. Therefore, the Agency does not intend to allow telephone notification.

2. *Time periods for notification.* In determining when EPA would require receipt of abatement and training notifications, the Agency considered input from the following:

(1) A similar regulatory program NESHAP.

(2) Existing state notification requirements.

(3) EPA's Office of Enforcement and Compliance Assistance (OECA).

The Agency operates a similar regulatory program, the NESHAP, which requires Agency notification for asbestos stripping and removal. The NESHAP program requires original notification to be postmarked 10 business days prior to the commencement of asbestos stripping and removal projects. NESHAP notification is required in writing, to be delivered by hand, U.S. Postal Service, or commercial delivery service. The 10 business day period is necessary to review the notice, assign appropriate personnel, arrange for travel, and dispatch Agency representatives. Travel is often required due to the large geographical areas for which the 10 EPA regional offices are responsible.

The Agency also reviewed several existing State programs including California, Texas, Oklahoma, and New Jersey. These States require 5 days, 7 days, 10 days, and 14 business days respectively for original notification of lead-based paint abatement activities. Each of these State programs require notification in writing. Although it is difficult to directly compare specific notification provisions due primarily to differences in staffing and jurisdictional areas at the State level, it is important to note that the EPA proposed 10 business day notification period is readily comparable to the notification periods of these States.

OECA manages the enforcement and compliance assurance activities for the NESHAP program. While the two programs are similar in nature, the lead-based paint activities program has a more complex regulatory structure with more disciplines and requirements than NESHAP. Therefore, OECA recommends that notification be received by the Agency at least 10 business days prior to the start of lead-based paint abatement activities and training courses, to assure that adequate time is allotted for compliance monitoring staff and managers to thoroughly review, select, and prepare for potential inspections of work sites and training programs. OECA staff emphasize the many activities which must be conducted in preparation for a site inspection including: (1) Notification processing; (2) inspection determination; (3) travel authorization; (4) pre-inspection notification; (5) preliminary compliance review; and (6) travel.

In conclusion, the Agency believes that receipt of notification 10 business days prior to conducting lead-based paint abatement activities or training courses is necessary to facilitate the inspection of abatement and training locations. The proposal also would also include provisions for updating the original notification. The Agency determined that a 10 business day

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notification would also apply to a change in course location, or if the course is to be presented earlier than described in the original notification. Other changes, including cancellation of a session, need only be received by the Agency at least 2 business days before the session is scheduled to begin. Such notification periods are appropriate to allow proper allocation of EPA compliance monitoring and enforcement resources, and to prevent the arrival of Agency personnel at the wrong location or time.

3. *Abbreviated notification time period.* The Agency understands that situations arise which require prompt action and that in these situations a firm may find it difficult, if not impossible, to satisfy the standard 10 business day notification period for lead-based paint abatement activities. In defining when these instances might occur, the Agency identified those abatement activities which are required in response to a determination that a child has an elevated blood lead level (EBL) or as a result of a Federal, State, Tribal, or local emergency abatement order as those which would require such prompt action. Notification time periods in such instances would be abbreviated and require documentation showing evidence of an EBL determination or a copy of the order to be included as part of the written notification.

IV. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this proposed rule is not a "significant regulatory action" subject to review by OMB under E.O. 12866, because this action does not meet any of the criteria for a "significant regulatory action" under section 3(f) of E.O. 12866.

The estimated costs for the first year of implementation are estimated to be approximately $440,000, decreasing to an average annual estimated cost of approximately $395,000 in subsequent years. For additional information about these estimated costs, please refer to the document entitled "Information Collection Request (ICR) Supporting Statement for a Proposed Addendum to EPA ICR No. 1715 entitled TSCA section 402/404 Training and Certification, Accreditation, and Standards for Lead-Based Paint Activities" (herein the ICR Addendum (EPA ICR No. 1715.03)). This document, identified as EPA ICR No. 1715.03, is an addendum to the existing ICR. A copy is available in the public version of the official record described in Unit I.B.2., and may also be obtained as described in Unit IV.C.

B. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Agency hereby certifies that this action, if promulgated as proposed, will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is as follows. The Agency already assessed the potential small entity impacts of the notification requirement that was contained in the 1998 final rule as part of the economic analysis that was prepared for that rulemaking, a copy of which is available in the public version of the official record for this proposed rule as described in Unit I.B.2. In addition, the Agency has estimated the impacts of the other requirements contained in this proposed rule, which are presented in the ICR Addendum (EPA ICR No. 1715.03).

In considering the potential small entity impacts of this proposed rule, the Agency believes that its previous determination regarding the Lead Abatement Training and Certification Final Rule is not affected by the notification procedures contained in this proposed rule. Based on the estimated total costs of this proposed rule as presented in the ICR Addendum (EPA ICR No. 1715.03), EPA has determined that this rulemaking is not likely to result in a significant impact on a substantial number of small entities. In general, EPA strives to minimize potential adverse impacts on small entities when developing regulations to achieve the environmental and human health protection goals of the statute and the Agency.

For the purpose of analyzing the potential impacts of this proposed rule on small entities, EPA used the definition for small entities that is found in section 601 of the RFA. Under section 601, "small entity" is defined as: (1) A small business that meets Small Business Administration (SBA) size standards codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The SBA size standards for the small businesses potentially affected by this proposed rule is 500 employees or less for lead abatement firms whose primary activity is classified as environmental remediation (NAICS code 562910), and revenues of $5 million or less for firms that are accredited to provide lead-based paint training (NAICS code 611519). Since SBA recently amended its small business size standards, which previously classified small business sizes according to the Standard Industrial Classification (SIC) system, to classify small business sizes according to the NAICS system, the analysis for the Lead Abatement Training and Certification Final Rule uses the SBA size standards that were in place in 1996, when that analysis and rule were completed. Although it is possible that certain businesses could gain or lose "small" status as a result of SBA's conversion to NAICS, EPA does not believe that any such changes would affect its conclusion to certify under the RFA, because the incremental costs per entity are not significant, regardless of the entity's size. By definition, individuals, States and Indian tribes are not considered small entities under the RFA.

This rule only applies in those States that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies if that State chooses to seek certification to perform lead abatement activities or accreditation to provide lead training. As such, small governmental jurisdictions are only impacted if there isn't a State authorized program and then only if the small governmental entity chooses to seek certification to perform lead abatement activities or accreditation to provide lead training on their own.

Small abatement firms and training providers are only impacted if there isn't an authorized State program in their State, and then only if they seek certification to perform lead abatement activities or accreditation to provide lead training. EPA estimates that, in EPA administered states, there could be approximately 1,167 abatement firms with 15.36 notifications per firm each year, and approximately 51 training providers with an estimated 17.93 notifications in the first year and an estimated 4 notifications in subsequent years.

The estimated average cost per notification for abatement firms is approximately $5, with an estimated total cost per entity of approximately $75. The estimated average cost per notification for training providers is approximately $32, with an estimated total cost per entity of approximately $298 in the first year and approximately $67 in subsequent years. EPA believes that the impact of these costs would be proportional for both small and large firms, and that the impacts may be slightly lower for small governmental jurisdictions that fund abatement work due to lower wage rates and overhead expenses. Overall, EPA believes that these costs would not result in a significant impact on affected small entities.

Small non-profit organizations are only impacted if they seek certification to perform lead abatement activities or accreditation to provide lead training on their own. Although EPA believes that non-profit organizations may seek certification, EPA does not have sufficient information about these organizations or their intentions regarding certification or accreditation. Nevertheless, given the low costs for notification and the relatively small number of non-profit organizations EPA believes are likely to seek certification or accreditation, EPA does not believe that this affects the Agency's determination that this rule is not expected to have a significant impact on a substantial number of small entities.

Any comments regarding the impacts that this action may impose on small entities, should be submitted to the Agency in the manner specified under Unit I.C. In addition, information relating to this determination will be provided to the Chief Counsel for Advocacy of the Small Business Administration upon request, and is included in the public version of the official record for this rulemaking.

C. Paperwork Reduction Act

The information collection requirements contained in this proposed rule have been submitted to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., and in accordance with the procedures at 5 CFR 1320.11. An Information Collection Request (ICR) document has been prepared by EPA (the ICR Addendum (EPA ICR No. 1715.03)), a copy of which has been placed in the public version of the official record described in Unit I.B.2., and which may also be accessed electronically on EPA's homepage at http://www.epa.gov/icr.

The information requirements contained in this proposal are not effective until promulgation and OMB approval, which is represented by a currently valid OMB control number. An agency may not conduct or sponsor and a person is not required to respond to a collection of information subject to OMB approval under the PRA unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations, after initial publication in the **Federal Register**, are maintained in a list at 40 CFR part 9.

The proposed rules contain four requirements that would impose paperwork burdens: reading and interpreting the proposed rules, the notification of lead-based paint abatement activities, the notification of lead-based paint activities training courses, and notification following completing of lead-based paint activities training courses. Paperwork burdens are estimated to be 21,254 total hours for the first year of implementation, and 19,048 hours annually in subsequent years.

Under the PRA, "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Comments, submitted as instructed under Unit I.C., are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. The final rule will respond to any OMB or public comments received on the information collection requirements contained in this proposal.

D. Unfunded Mandates Reform Act (UMRA)

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law No. 104–4), EPA has determined that this regulatory action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. This proposed rule applies only in States and Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those States and Indian Tribes who choose to seek certification to perform lead abatement activities or accreditation to provide lead training. As such, the rule will not impose an enforceable duty on any State, local or Tribal governments. Since, this proposed rule is estimated to cost approximately $439,573 in the first year of implementation, and $395,157 annually in subsequent years, it is not expected to result in expenditures by the private sector of $100 million or more in any given year. As a result, the UMRA requirements in sections 202, 204, and 205 do not apply to this proposed rule.

This proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Therefore, no action is needed under section 203 of the UMRA.

E. Executive Orders 13084 and 13175

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19,1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments, because this proposed rule applies only in Indian Tribes that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those Indian Tribes who choose to seek certification to perform lead abatement activities or accreditation to provide lead training. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

On November 6, 2000, the President issued Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249). Executive Order 13175 took effect on January 6, 2001, and revokes Executive Order 13084 as of that date.

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EPA developed this proposed rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed tribal considerations under Executive Order 13084. EPA believes that the differences between the Executive Order do not affect the Agency's activities for this proposed rule. EPA will, however, analyze and fully comply with the requirements of Executive Order 13175 before promulgating the final rule.

F. Executive Order 13132

Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have federalism implications, because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This proposed rule applies only in States that do not have authorized programs pursuant to 40 CFR 745.324, and then only applies to those States who choose to seek certification to perform lead abatement activities or accreditation to provide lead training.

Although section 6 of Executive Order 13132 does not apply to this rule, EPA consulted with the States at meetings of the Forum on State and Tribal Toxics Action and the annual EPA meeting with State Lead Program representatives.

G. Executive Order 12898

Pursuant to Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. The Agency's analysis has determined that this proposed action has no disproportionate impact on minority or low income populations.

H. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), applies to any rule that (1) is economically significant as defined under OMB's guidance related to section 3(f)(1) of Executive Order 12866, and (2) addresses an environmental health or safety risk that EPA has reason to believe has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children; and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not an "economically significant regulatory action" as defined by Executive Order 12866 (see Unit IV.A.). Although this proposed rule is associated with EPA's overall lead-based-paint management program which is designed to reduce health risks to children, this rule itself simply establishes an Agency notification procedure and does not directly address environmental health or safety risk. This proposed rule does, however, help to further the Agency's efforts to prevent lead poisoning in children under the age of six by supporting the Agency's implementation of the mandate in Title X, which requires that lead abatement professionals involved in inspecting, assessing or removing lead-based paint, dust or soil be trained and certified to conduct these activities.

I. National Technology Transfer and Advancement Act

This regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. The Agency invites comment on the potential use of voluntary consensus standards in this rulemaking, and, specifically, invites the public to identify potentially applicable consensus standard(s) and to explain why such standard(s) should be used here.

J. Executive Order 12630

EPA has complied with Executive Order 12630, entitled *Governmental Actions and Interference with Constitutionally Protected Property Rights* (53 FR 8859, March 15, 1988), by examining the takings implications of this rule in accordance with the Attorney General's "Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the Executive Order.

K. Executive Order 12988

In issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988, entitled *Civil Justice Reform* (61 FR 4729, February 7, 1996).

List of Subjects in 40 CFR Part 745

Environmental protection, Fees, Hazardous substances, Lead poisoning, Reporting and recordkeeping requirements.

Dated: January 16, 2001.

Carol M. Browner,

Administrator.

Therefore, it is proposed that 40 CFR part 745 be amended as follows:

PART 745—[AMENDED]

1. The authority citation for part 745 would continue to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2615, 2681–2692, and 42 U.S.C. 4852d.

2. In § 745.223 by adding in alphabetical order definitions for "Business day"; "Lead abatement professional"; "Lead-based paint activities courses"; and "Training provider" to read as follows:

§ 745.223 Definitions.

* * * * *

Business day means Monday through Friday with the exception of Federal holidays.

* * * * *

Lead abatement professional means an individual certified to conduct lead-based paint activities under § 745.226 as a worker, supervisor, project designer, inspector, or risk assessor.

* * * * *

Lead-based paint activities courses means training courses (worker, supervisor, inspector, risk assessor, project designer) provided by accredited training programs.

* * * * *

Training provider means any business entity accredited under § 745.225 that offers lead-based paint activities courses.

* * * * *

3. In § 745.225 by adding paragraphs (c)(13) and (c)(14) to read as follows:

§ 745.225 Accreditation of training programs: target housing and child-occupied facilities.

* * * * *

(c) * * *

(13) The training manager shall provide notification of lead-based paint activities courses offered.

(i) The training manager shall provide the agency with notice of all lead-based paint activities courses offered. The original notice must be received by the agency at least 10 business days prior to offering any lead-based paint activities course.

(ii) The training manager shall provide the agency updated notice when lead-based paint activities courses will begin on a date other than the one specified in the original notification, as follows:

(A) For lead-based paint activities courses beginning prior to the original start date an updated notice must be received by the agency at least 10 business days before the revised start date.

(B) For lead-based paint activities courses beginning after the original start date an updated notice must be received by the agency at least 2 business days before the original start date.

(iii) The training manager shall update the agency of any change in location of lead-based paint activities courses at least 10 business days prior to the scheduled course start date.

(iv) The training manager shall also update the agency regarding any course cancellations, or any other change to the original notice. Updated notices must be received by the agency at least 2 business days prior to the scheduled course start date.

(v) Each notice, including updates, shall include the following:

(A) Notification type (original, update, cancellation).

(B) Training program name, EPA accreditation number, address, and phone number.

(C) Course discipline, type (initial/refresher), and the language in which instruction will be given.

(D) Date(s) and time(s) of training.

(E) Training location(s) phone number, and street address.

(F) Principal instructors name.

(G) Training manager's name and signature.

(vi) Notification shall be accomplished using any of the following methods: written notice, or by E-mail. All notices submitted by E-mail must be followed with written notice within 24 hours of submission. Written notification of lead-based paint activities course schedules can be accomplished by using either the sample form titled "Lead-based Paint Activities Training Course Schedule" or a similar form developed by the training program containing the required information. All written notices shall be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (Persons submitting notification by U.S. Postal Service are reminded that they should allow three additional business days for delivery in order to ensure that the agency receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD, or on the Internet at http://www.epa.gov/lead.

(vii) Lead-based paint activities courses shall not begin on a date, or at a location other than that specified in the original notice unless an updated notice identifying a new date or location is submitted, in which case the course must begin on the date and location specified in the updated notice.

(viii) No training program shall provide lead-based paint activities courses without first notifying the agency of such activities in accordance with the requirements of this paragraph.

(14) The training manager shall provide notification following completion of lead-based paint activities courses.

(i) The training manager shall provide the agency notice after the completion of any lead-based paint activities course which shall be received by the agency no later than 10 business days following course completion.

(ii) The notice shall include the following:

(A) Training program name, EPA accreditation number, address, and phone number.

(B) Course discipline and type (initial/refresher).

(C) Date(s) of training.

(D) The following information for each student who took the course:

(*1*) Name.

(*2*) Address.

(*3*) Social security number.

(*4*) Course completion certificate number.

(*5*) Student test score.

(E) Training manager's name and signature.

(iii) Notification shall be accomplished using any of the following methods: written notice, or by E-mail. All notices submitted by E-mail must be followed with written notice within 24 hours of submission. Written notification following lead-based paint activities training courses can be accomplished by using either the sample form titled "Lead-based Paint Activities Training Course Follow-up" or a similar form developed by the training program containing the required information. All written notices shall be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (Persons submitting notification by U.S. Postal Service are reminded that they should allow three additional business days for delivery in order to ensure that the agency receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD, or on the Internet at http://www.epa.gov/lead.

* * * * *

4. In § 745.227 by revising paragraph (e)(4) to read as follows:

§ 745.227 Work practice standards for conducting lead-based paint activities: target housing and child-occupied facilities.

* * * * *

(e) * * *

(4) A certified firm shall notify EPA of lead-based paint abatement activities as follows:

(i) Except as provided in paragraph (e)(4)(ii) of this section, the agency must be notified prior to conducting lead-based paint abatement activities. The original notice must be received by the agency at least 10 business days before lead-based paint abatement activities begin.

(ii) Notice for abatement activities required in response to an elevated blood lead level (EBL) determination, or Federal, State, tribal, or local emergency abatement order must be received by the agency as early as possible before, but not later than the day lead-based paint abatement activities begin. Documentation showing evidence of an EBL determination or a copy of the Federal/State/tribal/local emergency abatement order must be included in the

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written notification to take advantage of this abbreviated notification period.

(iii) Updated notice of a new start date must be provided to the agency for lead-based paint abatement activities that will begin on a date other than the date specified in the original notification notice, as follows:

(A) For lead-based paint abatement activities beginning prior to the original start date an updated notice must be received by the agency at least 10 business days before the revised start date.

(B) For lead-based paint abatement activities beginning after the original start date an updated notice must be received by the agency at least 2 business days before the original start date.

(iv) The certified firm shall update the agency of any change in location of lead-based paint abatement activities at least 10 business days prior to the project start date.

(v) The certified firm shall also update the agency regarding the cancellation of any lead-based paint abatement activities, or other significant changes including, but not limited to, when the square footage or acreage to be abated changes by at least 20 percent. This updated notice must be received by the agency at least 2 business days prior to the project start date.

(vi) The following shall be included in each notice:

(A) Notification type (original, updated, cancellation).

(B) Date when lead-based paint abatement activities will commence.

(C) Date when lead-based paint abatement activities will end (approximation using best professional judgement).

(D) Firm's name, EPA certification number, address, phone number.

(E) Type of building (e.g. single family dwelling, multi-family dwelling, child-occupied facilities) on/in which abatement work will be performed.

(F) Property name (if applicable).

(G) Property address including apartment or unit number (if applicable) for abatement work.

(H) Documentation showing evidence of an EBL determination or a copy of the Federal/State/tribal/local emergency abatement order, if applicable.

(I) Name, EPA certification number, and signature of the certified supervisor.

(J) Approximate square footage/acreage to be abated.

(K) Brief description of abatement activities to be performed.

(vii) Notification shall be accomplished using any of the following methods: written notice, or by E-mail. All notices submitted by E-mail must be followed by written notice within 24 hours of submission. Written notification can be accomplished using either the sample form titled "Notification of Lead-based Paint Abatement Activities" or similar form. All written notices shall be delivered by U.S. Postal Service, fax, commercial delivery service, or hand delivery (Persons submitting notification by U.S. Postal Service are reminded that they should allow 3 additional business days for delivery in order to ensure that the agency receives the notification by the required date). Instructions and sample forms can be obtained from the NLIC at 1–800–424–LEAD, or on the Internet at http://www.epa.gov/lead.

(viii) Lead-based paint abatement activities shall not begin on a date, or at a location other than that specified in either an original, or updated notice, in the event of changes to the original notice.

(ix) No firm or individual shall engage in lead-based paint abatement activities, as defined in § 745.223, prior to notifying the agency of such activities according to requirements of this paragraph.

* * * * *

[FR Doc 01–1797 Filed 1–17–01; 4:34 p.m.]

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Federal Register

Monday,
January 22, 2001

Part XV

Small Business Administration

13 CFR Part 108
New Markets Venture Capital Program; Interim Final Rule
New Markets Venture Capital Program; Notice of Funds Availability Inviting Applications; Notice

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 108

New Markets Venture Capital Program

AGENCY: U.S. Small Business Administration.

ACTION: Interim final rule.

SUMMARY: The U.S. Small Business Administration ("SBA") is adding a new Part 108 to implement the New Markets Venture Capital Program Act of 2000 ("the Act"). The Act authorizes SBA to issue regulations necessary to implement the program. The regulations set forth the requirements for:

Newly-formed venture capital companies to qualify to become New Markets Venture Capital ("NMVC") companies to make developmental venture capital investments in smaller enterprises located in low-income geographic areas and provide operational assistance to such enterprises receiving such investments; and

Existing Specialized Small Business Investment Companies ("SSBICs") to qualify for grants to provide operational assistance to smaller enterprises located in low-income geographic areas and which such SSBICs have financed or expect to finance.

SBA will begin accepting applications for this program immediately. See Notice of Funds Availability published in today's **Federal Register**.

EFFECTIVE DATE: This regulation becomes effective on February 21, 2001.

DATES: Submit comments on or before March 23, 2001.

ADDRESSES: Written comments should be sent to Austin Belton, Investment Division, Office of New Markets Venture Capital, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Austin Belton, Director, Office of New Markets Venture Capital, 202–205–6510.

SUPPLEMENTARY INFORMATION:

I. Background

The New Markets Venture Capital Program Act of 2000 ("the Act") was created by the Consolidated Appropriations Act of 2001, Pub. L. No. 106–554, enacted December 21, 2000. Congress recognized that despite the nation's overall economic prosperity, many underserved areas in America have not experienced such prosperity and millions of Americans living in these areas do not have access to jobs or entrepreneurial opportunities. It enacted the New Markets Venture Capital ("NMVC") Program to help create an economic infrastructure in such underserved areas by encouraging business growth through program-supported investment. This type of investing is known in the community development venture capital industry as "double bottomline" investing, because the investments have both an anticipated financial and social return. Social returns include creating sustainable jobs at businesses receiving investments from NMVC companies, and encouraging such businesses to provide much-needed new products and services within underserved areas.

Congress noted that between 1997 and 1998, the median income for the nation's households rose 3.5 percent in real terms, yet 12.7 percent of Americans (34.5 million people) still live below the poverty line. Many of these Americans live in inner city and rural areas, where job opportunities are scarce and there is little to attract small business investors. In rural and urban communities, poverty remains a persistent problem. Job growth is well below the national average, with unemployment at or above 14%. Unemployment is 7.5% in the African American urban community, and is 6.4% in the Hispanic urban population; both are nearly double the national average. Despite these statistics, Congress found that it is not enough to create jobs in these pockets of poverty, rather these communities need a new economic infrastructure to enable them to develop their full potential and participate fully in the economic mainstream. The NMVC program will encourage the growth of such an infrastructure by supporting new equity capital investments by NMVC companies and SSBICs and by providing operational assistance to smaller enterprises located in low-income geographic areas whose growth will foster the creation of wealth and job opportunities in such areas.

SBA will enter into participation agreements with NMVC companies to fulfill these statutory purposes. The Act authorizes SBA to guarantee debentures of NMVC companies. Such debentures leverage the private capital that NMVC companies must raise and enable them to make the equity investments in low-income geographic areas contemplated by the Act. The Act also authorizes SBA to provide grants to NMVC companies to provide operational assistance to smaller enterprises in which they invest. In addition, the Act enhances the ability of existing SSBICs to invest in smaller enterprises in low-income areas by giving them grants to provide operational assistance to such enterprises in connection with such investments.

SBA intends to enter into participation agreements with NMVC companies that have a solid business plan for making investments in the low-income geographic areas targeted by the Act, and that have the most likelihood of expanding economic opportunities in such areas.

II. Section by Section Analysis

The following is a section by section analysis of SBA's regulations to add a new part 108 to title 13 of the Code of Federal Regulations to implement the Act.

A. *General Information About the Regulations.*

1. *Low-Income Geographic Areas.* The benefits of the NMVC program are targeted toward low-income geographic areas. SBA's definition of "Low-Income Geographic Areas" in section 108.50 mimics the definition of the same term in section 351(3) of the Small Business Investment Act of 1958, as amended by the Act (the "SBIAct"). SBA wishes to educate the public about the areas identified by Congress that will receive the benefits of the NMVC program. This will allow the public to better understand the impact of the NMVC program. Accordingly, SBA provides the following information concerning how you, a member of the public, may determine which geographic areas fall within the statutory definitions.

The Act sets forth six bases for determining low-income geographic areas.

(1) *Any census tract or equivalent county division as defined by the Bureau of the Census of the United States Department of Commerce in which the poverty rate is 20 percent or more.* The Bureau of the Census is the Federal agency responsible for gathering data regarding population and poverty levels. To determine whether a particular census tract or equivalent county division meets this criteria, you can visit the Bureau of the Census web site at http://www.census.gov/geo/www/ezstate/poverty.html. Data on this web site is based on data from the Bureau of the Census CPH–3 series of publications from the "1990 Census of Population and Housing: Population and Housing Characteristics for Census Tracts and Block Numbering Areas." The "1990 Population" and "Land Area (Square Miles)" columns are from Table 1 of the CPH–3 reports. The columns "Persons for Whom Poverty Status Determined" and "Percent Below Poverty Level" are from CPH–3 Table 19. You can view this same information by visiting any local Federal Depository Library. For the location of the nearest Federal Depository Library, call toll-free 1–888–293–6498 or contact the Bureau of the Census, Washington, D.C. 20233. These resources list the poverty rate for each census tract and equivalent county division within each state. You will need to look for only those tracts or divisions in which the poverty rate is 20 percent or more to determine the areas that fall within a low-income geographic area for purposes of the NMVC program.

(2) *Any census tract or equivalent county division as defined by the Bureau of the Census that is located in a metropolitan area and in which 50 percent or more of the households in that tract or division have an income below 60 percent of the area median gross income.* This criteria corresponds to the definition of "qualified census tract" as set forth in the Low Income Housing Tax Credit (LIHTC) program under § 42 of the Internal Revenue Code. The Department of Housing and Urban Development (HUD) implements the LIHTC program. The Secretary of HUD designates the qualified census tracts by Notice published periodically in the **Federal Register**. These notices are titled "Statutorily Mandated Designation of Qualified Census Tracts and Difficult Development Areas for Section 42 of the Internal Revenue Code of 1986." The notice identifies qualified areas by census tract or division number. You may find a list and map of all tract and division numbers by visiting the Bureau of the Census web site at: http://www.census.gov.

You can find HUD's most recent Notice regarding the LIHTC program at 60 FR 21246 (May 1, 1995), or by visiting HUD's web site at: http://www.huduser.org/datasets/qct/dda2000.html. You can view this same information by visiting any local Federal Depository Library. For the location of the nearest Federal Depository Library, call toll-free 1–888–293–6498 or contact the Bureau of the Census, Washington, DC 20233.

(3) *Any census tract or equivalent county division as defined by the Bureau of the Census that is not located in a metropolitan area and in which the median household income for such tract or division does not exceed 80 percent of the statewide median household income.* The Bureau of the Census is the Federal agency responsible for gathering data regarding households and income. You will need to put together several pieces of information in order to determine whether a particular tract or division meets this criteria.

First, you must identify a tract or division number. You may find a list and map of all tract and division numbers by visiting the Bureau of the Census web site at: http://www.census.gov.

Second, you must determine whether the tract or division is located within a metropolitan area. You may find a list of all metropolitan areas in Bureau of the Census publication "State and Metropolitan Area Databook 1997–98," Table B–1. This publication is available on the Bureau of the Census web site at: http://www.census.gov/prod/3/98pubs/smadb-97.pdf. (You need Adobe Acrobat Reader in order to view this publication.) If your census tract or division is not included in this Table, then it is not located within a metropolitan area.

Third, you must determine the median household income for your tract or division. The necessary income statistics for this determination are available in Bureau of the Census "Summary Tape File (STF) 3A," Table P80A. You can access this information at the Bureau of the Census web site at: http://venus.census.gov/cdrom/lookup.

Fourth, you must determine whether the median household income for your tract or division exceeds 80 percent of the statewide median household income. You may find median household income statistics, by state, in Bureau of the Census publication "Historical Income Tables—Households," Table H–8. You may view this Table at the Bureau of the Census web site at: http://www.census.gov/hhes/income/histinc/h08.html. All of this Bureau of the Census statistical information is available from any local Federal Depository Library. For the location of the nearest Federal Depository Library, call toll-free 1–888–293–6498 or contact the Bureau of the Census, Washington, DC 20233.

(4) *Any area located within a HUBZone.* You may find out if an area is located within a HUBZone by visiting SBA's web site at: http://eweb1.sba.gov/hubzone/internet/general/findout.cfm, or visiting or contacting your nearest SBA office.

(5) *Any area located within an Urban Empowerment Zone ("EZ") or Urban Enterprise Community ("EC").* You may find out whether an area is located within an Urban EZ or EC by visiting HUD's web site at: http://www.hud.gov/cpd/ezec/, or contacting HUD.

(6) *Any area located within an Rural EZ or Rural EC.* You may find out whether an area is located within a Rural EZ or EC by visiting the United States Department of Agriculture's web site at: http://www.ers.usda.gov/epubs/other/typolog, or contacting the Department of Agriculture.

2. *Regulations modeled after SBIC regulations.*

As you read through the section by section analysis of particular regulations, you will see that we modeled many of these regulations on similar regulations governing SBA's Small Business Investment Company ("SBIC") program, found in part 107 of this title. In addressing the challenge of implementing the NMVC program, SBA is able to draw upon the experience that it has gained over the last 43 years in administering the SBIC program.

The SBIC program was created by the Small Business Investment Act of 1958 in response to a Federal Reserve study finding that small businesses in general were unable to obtain the long-term debt and equity funds that they needed for success. The basic objective of the program is to attract and supplement private capital, managed by private investment managers, to meet that need. SBA licenses such companies as SBICs, regulates their activities to ensure that they are financially sound and serve the program's public policy objectives, and supplements their private capital by guaranteeing debentures or other securities that they issue.

The SBIC program has been extraordinarily successful in recent years and today represents a major factor in small business financing. It is estimated that 34 percent of all companies receiving institutional venture capital in 1999 obtained it from an SBIC. In fiscal year 2000, SBICs invested a record $5.5 billion in more than 3,000 small growth companies. This was accomplished with a budget appropriation of just $24.3 million.

A key strength of the SBIC program lies in the fact that all investment decisions are made by private individuals with their own money at first risk. However, this also represents a limitation in that such investment activities are profit driven and few of the small businesses being served are located in urban or rural areas. Urban and rural investments typically are smaller and more costly to make, and they require significantly more assistance over the investment period than most SBIC investments. At the same time, they generally offer a more limited profit potential to the investor. The NMVC program addresses these factors by adding to the SBIC structure an operational assistance grant subsidy and by recruiting managers and investors that have an economic development objective in addition to their financial one.

Because of these many similarities between SBICs and NMVC companies and between these two venture capital

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programs, SBA will incorporate into the NMVC program many of the SBIC regulations that SBA believes are fundamental to the safety and soundness of the SBIC program.

3. *Section-by-section analysis.*

Sections 108.10 through 108.50 briefly describe the NMVC program, state the legal basis for the program, definitions, and provide guidance on how to read part 108. Most of the definitions come directly from part 107 of this title, which governs the SBIC program. Most of the newly defined terms come directly from the Act, and SBA has not supplemented or modified them. SBA also sets forth several new definitions, including terms "Low-Income Enterprise" and "Low-Income Investment" as a shorter way to describe equity capital investments in a smaller enterprise that, at the time of the initial financing, has its principal office located in a low-income geographic area.

Sections 108.100 through 108.160 describe the qualifications for the NMVC program. NMVC companies must be newly-formed, for-profit entities. SBA requires that NMVC companies be organized under state law and be either corporations, limited liability companies, or limited partnerships. They must have qualified management, have economic development as their primary mission, and identify particular low-income geographic areas in which they propose to focus their investment activities. SBA models these regulations on the SBIC program, including the requirements that NMVC companies must have management and ownership diversity and that SBA will require pre-approval of all management expenses of a NMVC company (see §§ 107.100 through 107.160 of this title).

Sections 108.200 through 108.240 address capitalization of an NMVC company, including minimum capital requirements, permitted sources of capital, and limitations on non-cash contributions to capital. These regulations also are modeled on similar regulations in the SBIC program (see §§ 107.200 through 107.250 of this title).

Sections 108.300 through 108.330 sets forth policies and procedures for application for designation as a NMVC company. SBA will allow submission of applications for participation in the NMVC program only during a specific application period, to be set forth in a Notice of Funds Availability subsequently published in the **Federal Register**, as opposed to a rolling admissions process. SBA will use this method of selecting applicants for three reasons. One reason is that SBA believes this method will enable SBA to achieve the statutory directive of ensuring, to the extent possible and given the applications received, nationwide availability of developmental venture capital. SBA will compare applications both for quality and other criteria described in the regulations, and for the geographic areas they intend to cover so as to choose the best applications for each geographic area and avoid duplication within specific geographic areas. Another reason is that SBA has received one-year appropriated funds for operational assistance grants, and the statute requires SBA to distribute available appropriated funds evenly among NMVC companies and SSBICs that apply for such grants. (See discussion of §§ 108.2000 through 108.2040 for more information about how SBA will administer the operational assistance grant program.) Submission of all applications for these grant funds at the same time will allow SBA to evenly distribute these funds among all eligible recipients. Third, SBA believes this procedure will allow SBA to orderly administer appropriated funds it may receive in subsequent fiscal years, by allowing SBA to open up the NMVC program to new rounds of applicants.

SBA will require applicants for participation in the NMVC program to submit an application, similar to the application for the SBIC program but which also includes the requirement for a comprehensive business plan. Many of the topics SBA will require applicants to include in their business plans are outlined in section 354(b) of the Act regarding application for the NMVC program. In addition, SBA will use the following additional topics: market analysis of the specific low-income areas towards which the applicant proposes to target its investments and other activities, operational capacity and investment strategies, plans for raising capital and matching funds for operational assistance grants, and projected amount of investment in low-income areas as opposed to outside those areas. Based in part on the experience of other Federal agencies with similar economic development programs, SBA believes these additional topics will allow SBA to ensure that applicants understand the objectives of the NMVC program and have a good plan for accomplishing those objectives and for creating and maintaining a viable investment fund.

SBA also will assess a fee for application for participation in the NMVC program to ensure that applicants are professional venture capital firms committed to participate in the program.

Sections 108.340 through 108.395 describe SBA's evaluation criteria and selection process for participation in the NMVC program. SBA will consider ten criteria in its evaluation and selection of applicants for participation in the NVMC program. Most of the specified criteria are set forth in the Act. SBA will use the following additional selection criteria not specifically described in the Act: The quality of the applicant's business plan in terms of meeting the objectives of the program; the strength and likelihood for success of the applicant's operations and investment strategies; the need for developmental venture capital investments in the geographic areas in which the applicant proposes to concentrate its activities and the extent of the applicant's understanding of the markets in such geographic areas. Based in part on the experience of other Federal agencies with similar economic development programs, SBA believes these additional evaluation criteria are effective indicators of whether the objectives of the NMVC program will be met.

The Act provides for SBA to conditionally approve companies for participation in the NMVC program, based on SBA's evaluation of their applications. Conditionally approved companies must raise the required amounts of capital and of matching funds for the operational assistance grant award from SBA within a time period specified by SBA. As provided in the Act, SBA will finally approve as NMVC companies all conditionally approved NMVC companies that raise the required amount of capital within the time period specified by SBA and sign a participation agreement with SBA. The regulations also set forth procedures under which SBA may grant to conditionally approved companies, as provided in the Act, an exception to the requirement to raise all of their required matching funds for their operational assistance grants before SBA designates them as finally approved NMVC companies.

Sections 108.400 through 108.470 describe SBA's requirements for changes in ownership, control, or structure of a NMVC company. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.400 through 107.475 of this title).

Sections 108.500 through 108.585 describe SBA's requirements for managing the operations of a NMVC company. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.500 through 107.590 of this title).

Sections 108.600 through 108.680 describe SBA's record keeping, record retention, and reporting requirements for NMVC companies. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.600 through 107.680 of this title). SBA also will require each NMVC company to provide reports concerning the community development impact of each investment it makes, as well as reports on its administration and use of grant funds as required by Circular A–110 of the Office of Management and Budget, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations." SBA anticipates that to the extent not inconsistent with SBA's regulations for the NMVC program, NMVC companies' administration and use of grant funds will be subject to OMB Circular A–110 and to Part 31 of the Federal Acquisition Regulations, 48 CFR 31.000 et seq., "Contract Cost Principles and Procedures." OMB Circular A–110 is optional for use in connection with grants to commercial organizations. SBA will apply it to NMVC companies in order to take advantage of existing and well-known grant administrative procedures and policies to facilitate SBA's orderly administration of grants to NMVC companies. (See the discussion of §§ 108.2000 through 108.2040 concerning applicability of these same procedures and policies to grants to SSBICs.)

Sections 108.690 through 108.692 describe SBA's requirements for SBA's examinations of NMVC companies. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.690 through 107.692 of this title).

Sections 108.700 through 108.885 describe SBA's requirements for determining the eligibility of financings of small businesses by NMVC companies, and regarding types of allowable financings. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.700 through 107.885 of this title).

Section 108.710 sets forth the requirement that at the close of each year, 80 percent of the concerns that NMVC companies have financed must be smaller enterprises that, as of the time of the initial financing, had their principal office in a low-income geographic area and in which the NMVC companies have made equity capital investments as defined in the regulations (see § 108.50). This regulation implements the requirement outlined in the definition of "participation agreement" in section 351(6)(B) of the SBIAct. SBA interprets this statutory section as requiring 80 percent of the smaller enterprises in which a NMVC company invests, as opposed to 80 percent of the dollars invested by the NMVC company. SBA believes that this interpretation of the 80 percent requirement gives the NMVC company maximum flexibility to make other investments that will ensure the overall economic viability of its fund.

Sections 108.1100 through 108.1720 describe SBA's requirements and procedures for NMVC companies to obtain leverage from SBA and the procedures governing how SBA will fund leverage. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.1100 through 107.1720 of this title).

Sections 108.1810 through 108.1840 describe defaults by NMVC companies on the terms and conditions governing their participation in the NMVC program, and SBA's remedies upon such defaults. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.1810 through 107.1840 of this title).

Section 108.1900 concerns termination by a NMVC company of its participation in the NMVC program. This regulation is modeled after a similar regulation for the SBIC program (see § 107.1900 of this title).

Sections 108.1910 through 108.1930 address miscellaneous issues, including application for an exemption from regulatory requirements and the effect of regulation changes on transactions previously consummated. These regulations are modeled after similar regulations for the SBIC program (see §§ 107.1910 through 107.1930 of this title).

Section 108.1940 sets forth procedures under which SBA may designate additional census tracts or equivalent county divisions as low-income geographic areas. This regulation implements the authority given to SBA's Administrator in section 351(3)(A)(iii) of the SBIAct. SBA has designed these procedures to allow for maximum opportunity by interested members of the public to ask SBA to designate specific census tracts or equivalent county divisions as additional low-income geographic areas.

Sections 108.2000 through 108.2040 sets forth requirements and procedures for operational assistance grants to both NMVC companies and to SSBICs. SBA will award such grants only after receiving and evaluating applications in response to a Notice of Funds Availability published in the **Federal Register**. SBA will award grants to SSBICs and to NMVC companies in such a way as to promote developmental venture capital investments nationwide and in both urban and rural areas.

SBA also will require SSBICs to provide reports on its administration and use of grant funds as required by Circular A–110 of the Office of Management and Budget, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and other Non-Profit Organizations." SBA anticipates that to the extent not inconsistent with these regulations, SSBICs' administration and use of grant funds will be subject to OMB Circular A–110 and to part 31 of the Federal Acquisition Regulations, 48 CFR 31.000 *et seq.*, "Contract Cost Principles and Procedures." OMB Circular A–110 is optional for use in connection with grants to commercial organizations. SBA will apply it to SSBICs in order to take advantage of existing and well-known grant administrative procedures and policies to facilitate SBA's orderly administration of grants to SSBICs.

III. Justification for Publishing Interim Final Status Rule

In general, SBA publishes a rule for public comment before issuing a final rule, in accordance with the Administrative Procedure Act, 5 U.S.C. 553 and 13 CFR 101.108. The Administrative Procedure Act, however, does provide an exception from that general rule where the agency finds good cause to omit public participation. 5 U.S.C. 553(b)(3)(B). The good cause requirement is satisfied when prior public participation can be shown to be impractical or contrary to the public interest.

To accomplish its statutory mandate, SBA must expeditiously designate and enter into participation agreements with NMVC companies. In December 2000, to address the equity needs of low-income communities, Congress passed and President Clinton signed into law legislation creating the NMVC program. Current funding for these grants lapses if not obligated prior to October 1, 2001. Therefore, SBA must act immediately to make NMVC company designations before that date.

SBA finds that good cause exists to publish this rule as an interim final rule without first soliciting public comment, because advance solicitation of comment is impractical and contrary to the public interest for the following reason. It would be contrary to the public interest to delay the effectiveness of the rule based on the practical necessity of preparing an application for designation as an NMVC company and raising the capital and matching

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resources within the timeframe allowed by the appropriation statute for operational assistance grants.

NMVC companies will be newly formed, for-profit investment funds with private management. Their objective will be to promote economic development and the creation of wealth and job opportunities in low-income geographic areas and among individuals living in such areas. NMVC companies will pursue this objective by making equity investments in smaller enterprises, primarily located in low-income geographic areas.

Individuals interested in forming NMVC companies must apply for this designation by submitting to SBA a formal application that provides information about (1) their business plan and management team; (2) the need for developmental venture capital investments in the geographic areas in which they intend to invest; (3) the extent to which they will concentrate their activities on serving these areas and the anticipated impact of their activities on economic opportunities in these areas; (4) their plan for providing operational assistance to their portfolio companies; and (5) their ability to raise the required minimum investment capital and operational assistance funding.

The SBA will select applicants for initial "conditional" approval after giving consideration to this information, and the need to locate NMVC companies nationally, and in urban and rural areas.

Further, the conditionally approved NMVC companies must raise a minimum of $5,000,000 in regulatory capital and binding commitments in cash or in kind equal to thirty percent of their regulatory capital for operational assistance to their portfolio companies. SBA will then award matching grants to the NMVC companies for operational assistance. SBA will provide this matching funding in fiscal year 2001 out of current funding appropriated for that purpose.

Therefore, the entities that may develop an application for designation need to know the requirements of the program in time to develop their strategic plans and begin raising required matching funds. Given the short time frame for SBA to collect, evaluate, and select NMVC companies, delay in prescribing the criteria for designating NMVC companies would cause undue burden on these efforts and make it extremely difficult for applicants to develop their strategic plans and raise required matching funds in a timely fashion. Therefore, SBA believes it is impractical and contrary to the public interest to further delay the benefits of the NMVC program.

Although this rule is being published as an interim final rule pursuant to 5 U.S.C. 553(b)(3)(B), comments are hereby solicited from interested members of the public. These comments must be submitted on or before March 23, 2001. SBA may then consider these comments in making any necessary revisions to these regulations.

IV. Regulatory Compliance Section—Compliance With Executive Orders 12866, 12988 and 13132, and the Paperwork Reduction Act (44 U.S.C. Ch. 35)

Compliance With Executive Order 12866

The Office of Management and Budget (OMB) has reviewed this rule as a "significant" regulatory action under Executive Order 12866. A regulatory assessment is set forth below.

Low-income communities in the United States face multiple and varied barriers to sustainable growth. But a common obstacle for virtually all such communities is that they are unable to attract sufficient equity capital and technical assistance for starting and expanding businesses. Federal Reserve Board Chair Alan Greenspan has observed that equity capital is crucial to the existence of an innovative and productive business community, especially in lower-income communities. Yet the existing private venture-capital industry is heavily concentrated in affluent, high technology regions located in only a handful of states.

In order to promote economic development and address the unmet equity needs of smaller businesses located in low-income areas, Congress passed and President Clinton signed into law the legislation creating the NMVC program. SBA will use these regulations to implement and administer the NMVC program. NMVC companies will be newly formed, for-profit investment companies with private management. Their objective will be to create an economic infrastructure in underserved areas. The NMVC companies will accomplish this by making equity investments in smaller enterprises, primarily located in low-income geographic areas. SBA anticipates that this type of investing will generate both financial and social returns. The social returns can include creating sustainable jobs at businesses receiving investments from NMVC companies, and encouraging such businesses to provide much-needed new products and services within underserved areas.

SBA estimates that the NMVC program will cost approximately $1 million annually to administer. The cost to the government includes the costs of staff (including benefits) and all other overhead expenses. The Agency will select participants for the NMVC program and regulate NMVC operations to ensure that public policy objectives are being met. Toward that end, SBA will require NMVC companies to provide regular performance reports and take part in annual financial examinations.

SBA estimates that it will cost an NMVC company approximately $6,000 to apply for designation as an NMVC company, not including a $5,000 application fee. This includes the cost of one staff person at a level comparable to a Federal employee at a GS–13 grade level spending 160 hours to complete the application. After receiving designation as an NMVC company, the annual cost to the NMVC company will be based on compliance with the reporting requirements of the program. The Agency anticipates that compliance with the reporting requirements of the program will cost approximately $1,500. This includes the cost of one staff person at a level comparable to a Federal employee at a GS–13 grade level spending approximately 40 hours preparing the required performance and financial reports. The costs to NMVC companies and SSBICs that choose to participate in the grant aspect of the program include approximately $1,500 to prepare the initial grant application (approximately 40 hours of work), and approximately $600 annually thereafter to prepare the required quarterly status reports (approximately 16 hours of work). Again, these costs are estimated based upon one staff person at a level comparable to a Federal employee at a GS–13 grade level. There is also a fee payable by the NMVC company each time SBA examines the company. This rulemaking action includes a base fee for the examination of $3,500.

SBA believes that there are no alternatives to the planned regulatory action that could more adequately address the equity needs of the nation's low-income areas. In developing the regulations, application package and reporting materials SBA purposefully followed proven industry practices. Based upon the foregoing, SBA believes that it is implementing the congressionally-mandated NMVC program in the most cost effective and efficient manner.

Compliance With Executive Order 12988

SBA certifies that this rule is drafted, to the extent practicable, in accordance with the standards set forth in section 3 of Executive Order 12988.

Compliance With Executive Order 13132

For purposes of Executive Order 13132, SBA has determined that this rule has no federalism implications because the legislation authorizing it addresses private, for-profit concerns (NMVC companies) working directly with entrepreneurs.

Compliance With Paperwork Reduction Act, 44 U.S.C. Ch. 35

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, the collection of information ("collection") for this program includes the NMVC program application package and reporting and recordkeeping requirements. SBA previously requested from the Office of Management and Budget ("OMB") an emergency clearance of this collection. OMB reviewed and approved the collection and assigned OMB control number 3245–0332.

Simultaneously with the publication of this rule in the **Federal Register**, SBA will make available to the public the collection on SBA's web site at http://www.sba.gov/inv or you may request a copy by calling Terri Dennin at (202) 205–6234.

The following is a list of sections of this regulation that describe generally the collection requirements for the NMVC program and reasons why SBA believes it needs to collect such information.

I. New Markets Venture Capital Companies

A. Applying for Designation as a NMVC Company

As referenced in § 108.310 (Contents of application) and § 108.320 (Contents of a comprehensive business plan), SBA will request information such as basic identifying data and core data, management and organization information, descriptions of past and present performance in developmental venture capital investments in smaller enterprises and in low-income geographic areas, technical qualifications of the applicant, descriptions of activities proposed using debentures issued by NMVC companies, and reporting capabilities.

SBA needs this information to evaluate applicants and to ensure that selections are made in furtherance of the NMVC program's objectives. SBA understands that the respondents to these requests will be limited to those organizations meeting the requirements set forth in § 108.100 (Business form); § 108.110 (Qualified management); § 108.120 (Economic development primary mission); and § 108.140 (Management and ownership diversity requirement). Based upon the Agency's knowledge of the industry, SBA estimates that approximately 15–20 applicants will apply to participate in the NMVC program. Respondents will need to submit the information referenced in §§ 108.310 and 108.320 only at the time of application to participate in the NMVC program. SBA estimates that it will take respondents 216 hours to complete an application and to fulfill the reporting and record keeping requirements referenced below.

B. New Markets Venture Capital Company Reporting and Recordkeeping Requirements

As referenced in §§ 108.600 to 108.680, SBA will request financial information including, but not limited to, financial statements, economic impact and community development information, and portfolio financing reports and valuations.

SBA needs this information to evaluate the performance and success of NMVC companies in fulfilling the objectives of their participation agreements and their actual venture capital investments in smaller enterprises located in low-income geographic areas.

C. Applying for Operational Assistance Grants

As referenced in § 108.2000 (Operational Assistance grants to NMVC Companies and SSBICs), SBA will request such basic information on NMVC companies which apply for operational assistance grants as how the applicant plans to use the grant funds to provide operational assistance to smaller enterprises in which it will make its investments, including the types of assistance it proposes to provide as well as the entities it intends to use to provide such services; a description of its plans to obtain binding commitments for contributions and the source of those commitments as well as the extent of expressions of interest to commit such funds (including the possible purchase of an annuity) to match SBA's funds. The request for operational assistance grant funds will be part of the applicant's application for designation as a NMVC company.

SBA needs this information to ensure that selections are made in furtherance of the operational assistance grant program's objectives. SBA understands that the respondents to this request will be limited to NMVC companies. Based upon SBA's knowledge of the industry, SBA estimates that approximately 15–20 applicants will apply for operational assistance grants under the NMVC program. Grant recipients will have to comply with the reporting and record keeping requirements as set forth in OMB Circular A–110. SBA estimates that it will take respondents 16 hours annually to comply with the reporting and record keeping requirements related to such grants.

II. Specialized Small Business Investment Companies ("SSBICs")

A. Applying for Operational Assistance Grants

As referenced in § 108.2000 (Operational Assistance grants to NMVC Companies and Specialized Small Business Investment Companies), SBA will request such basic information on SSBICs which apply for operational assistance grants as how the applicant plans to use the grant funds to provide operational assistance to smaller enterprises in which it will make its investments, including the types of assistance it proposes to provide as well as the entities it intends to use to provide such services; a description of its plans to obtain binding commitments for contributions and the source of those commitments as well as the extent of expressions of interest to commit such funds (including the possible purchase of an annuity) to match SBA's funds.

SBA needs this information to ensure that selections are made in furtherance of the operational assistance grant program's objectives. SBA understands that the respondents to this request will be limited to SSBICs. Based upon SBA's knowledge of the industry, SBA estimates that approximately 5 SSBICs will apply for operational assistance grants under this program. Respondents will need to submit Standard Form 424 to participate in the operational assistance grant program. SBA estimates that it will take respondents 56 hours to apply for an operational assistance grant and to fulfill the reporting and record keeping requirements related to such grants as set out in OMB Circular A–110.

III. Request for Comments

With regard to each collection of information discussed above and contained in the collection itself, SBA is

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seeking your comment on the following issues:

(a) Whether the information SBA will request on the application is necessary for SBA's proper implementation and measurement of the performance of the NMVC program;

(b) The accuracy of the burden estimate (time estimated to complete each collection of information request);

(c) Ways to minimize the burden estimates, and

(d) Ways to enhance the quality of the information being collected.

Please send comments on or before March 23, 2001 on the data collection requirements to Austin Belton, Investment Division, Office of New Markets Venture Capital, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416.

List of Subjects in 13 CFR Part 108

Community development, Government securities, Grant programs—business, Securities, Small businesses.

For the reasons stated in the preamble, the Small Business Administration is adding 13 CFR part 108 as follows:

PART 108—NEW MARKETS VENTURE CAPITAL ("NMVC") PROGRAM

Sec.

Subpart A—Introduction to Part 108

108.10 Description of the New Markets Venture Capital Program.
108.20 Legal basis and applicability of this part 108.
108.30 Amendments to Act and regulations.
108.40 How to read this part 108.

Subpart B—Definition of Terms Used in Part 108

108.50 Definition of terms.

Subpart C—Qualifications for the NMVC Program

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108.100 Business form.
108.110 Qualified management.
108.120 Economic development primary mission.
108.130 Identified Low Income Geographic Areas.
108.140 SBA approval of initial Management Expenses.
108.150 Management and ownership diversity requirement.
108.160 Special rules for NMVC Companies formed as limited partnerships.

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108.200 Adequate capital for NMVC Companies.
108.210 Minimum capital requirements for NMVC Companies.
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108.240 Limitations on including non-cash capital contributions in Private Capital.

Subpart D—Application and Approval Process for NMVC Company Designation

108.300 When and how to apply for designation as a NMVC Company.
108.310 Contents of application.
108.320 Contents of comprehensive business plan.
108.330 Application fee.

Subpart E—Evaluation and Selection of NMVC Companies.

108.340 Evaluation and selection—general.
108.350 Eligibility and completeness.
108.360 Evaluation criteria.
108.370 Conditional approval.
108.380 Final approval as a NMVC Company.

Subpart F—Changes in Ownership, Structure, or Control

Changes in Control or Ownership of NMVC Company

108.400 Changes in ownership of 10 percent or more of NMVC Company but no change of Control.
108.410 Changes in Control of NMVC Company (through change in ownership or otherwise).
108.420 Prohibition on exercise of ownership or Control rights in NMVC Company before SBA approval.
108.430 Notification to SBA of transactions that may change ownership or Control.
108.440 Standards governing prior SBA approval for a proposed transfer of Control.
108.450 Notification to SBA of pledge of NMVC Company's shares.

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108.460 Restrictions on Common Control or ownership of two (or more) NMVC Companies.

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108.470 SBA approval of merger, consolidation, or reorganization of NMVC Company.

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108.502 Representations to the public.
108.503 NMVC Company's adoption of an approved valuation policy.
108.504 Equipment and office requirements.
108.506 Safeguarding the NMVC Company's assets/Internal controls.
108.507 Violations based on false filings and nonperformance of agreements with SBA.
108.509 Employment of SBA officials.

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108.510 SBA approval of NMVC Company's Investment Adviser/Manager.
108.520 Management Expenses of a NMVC Company.

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108.530 Restrictions on investments of idle funds by NMVC Companies.

Borrowing by NMVC Companies From Non-SBA Sources

108.550 Prior approval of secured third-party debt of NMVC companies.

Voluntary Decrease in Regulatory Capital

108.585 Voluntary decrease in NMVC Company's Regulatory Capital.

Subpart H—Recordkeeping, Reporting, and Examination Requirements for NMVC Companies

Recordkeeping Requirements for NMVC Companies

108.600 General requirement for NMVC Company to maintain and preserve records.
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Reporting Requirements for NMVC Companies

108.630 Requirement for NMVC companies to file financial statements and supplementary information with SBA (SBA Form 468).
108.640 Requirement to file portfolio financing reports (SBA Form 1031).
108.650 Requirement to report portfolio valuations to SBA.
108.660 Other items required to be filed by NMVC Company with SBA.
108.680 Reporting changes in NMVC Company not subject to prior SBA approval.

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108.690 Examinations.
108.691 Responsibilities of NMVC Company during examination.
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108.720 Small Businesses that may be ineligible for financing.
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Subpart J—SBA Financial Assistance for NMVC Companies (Leverage)

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108.1100 Type of Leverage and application procedures.
108.1120 General eligibility requirement for Leverage.
108.1130 Leverage fees payable by NMVC Company.
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108.1150 Maximum amount of Leverage for a NMVC Company.

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108.1200 SBA's Leverage commitment to a NMVC Company—application procedure, amount, and term.
108.1220 Requirement for NMVC Company to file financial statements at the time of request for a draw.
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108.1700 Transfer by SBA of its interest in a NMVC Company's Leverage security.
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108.1810 Events of default and SBA's remedies for NMVC Company's noncompliance with terms of Debentures.

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108.1830 NMVC Company's Capital Impairment definition and general requirements.
108.1840 Computation of NMVC Company's Capital Impairment Percentage.

Subpart L—Ending Operations as a NMVC Company

108.1900 Termination of participation as a NMVC Company.

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108.1910 Non-waiver of SBA's rights or terms of Leverage security.
108.1920 NMVC Company's application for exemption from a regulation in this part 108.
108.1930 Effect of changes in this part 108 on transactions previously consummated.
108.1940 Procedures for designation of additional Low-Income Geographic Areas

Subpart N—Requirements and Procedures for Operational Assistance Grants to NMVC Companies and SSBICs

108.2000 Operational Assistance grants to NMVC Companies and SSBICs.
108.2010 Restrictions on use of Operational Assistance grant funds.
108.2020 Amount of Operational Assistance grant.
108.2030 Matching requirements.
108.2040 Reporting and recordkeeping requirements.

Authority: 15 U.S.C. 634(b)(6) and Pub. L. 106–544.

Subpart A—Introduction to Part 108

§ 108.10 Description of the New Markets Venture Capital Program.

The New Markets Venture Capital ("NMVC") Program is a developmental venture capital program for the purpose of promoting economic development and the creation of wealth and job opportunities in low-income geographic areas and among individuals living in such areas. SBA selects and then enters into participation agreements with selected newly formed venture capital companies, and provides leverage in the form of debenture guarantees to such companies to allow them to make equity capital investments in smaller enterprises located in low-income geographic areas. SBA also awards grants to such companies and to Specialized Small Business Investment Companies so that they can provide operational assistance to such smaller enterprises in connection with such investments.

§ 108.20 Legal basis and applicability of this part 108.

The regulations in this part implement Part B of Title III of the Small Business Investment Act of 1958, as amended. All NMVC Companies must comply with all applicable SBA regulations, accounting guidelines and valuation guidelines for NMVC Companies, available from SBA.

§ 108.30 Amendments to Act and regulations.

A NMVC Company is subject to all existing and future provisions of the Act and parts 108 and 112 of title 13 of the Code of Federal Regulations.

§ 108.40 How to read this part 108.

(a) *Center headings.* All references in this part to SBA forms, and instructions for their preparation, are to the current issue of such forms. Center headings are descriptive and are used for convenience only. They have no regulatory effect.

(b) *Capitalizing defined terms.* Terms defined in § 108.50 have initial capitalization in this part 108.

(c) *"You."* The pronoun "you" as used in this part 108 means a NMVC Company unless otherwise noted.

Subpart B—Definition of Terms Used in Part 108

§ 108.50 Definition of terms.

Act means the Small Business Investment Act of 1958, as amended.

Affiliate or *Affiliates* has the meaning set forth in § 121.103 of this chapter.

Applicant means any entity submitting an application to SBA for designation as a NMVC Company under this part.

Articles mean articles of incorporation or charter for a Corporate NMVC Company, the partnership agreement or certificate for a Partnership NMVC Company, and the operating agreement or other organizational documents for a LLC NMVC Company.

Assistance or *Assisted* means Financing of or management services rendered to a Small Business by or through a NMVC Company pursuant to the Act and these regulations.

Associate of a NMVC Company means any of the following:

(1) (i) An officer, director, employee or agent of a Corporate NMVC Company;

(ii) A Control Person, employee or agent of a Partnership NMVC Company;

(iii) A managing member of a LLC NMVC Company;

(iv) An Investment Adviser/Manager of any NMVC Company, including any Person who contracts with a Control Person of a Partnership NMVC Company to be the Investment Adviser/Manager of such NMVC Company; or

(v) Any Person regularly serving a NMVC Company on retainer in the capacity of attorney at law.

(2) Any Person who owns or controls, or who has entered into an agreement to own or control, directly or indirectly, at least 10 percent of any class of stock of a Corporate NMVC Company or 10

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percent of the membership interests of an LLC NMVC Company, or a limited partner's interest of at least 10 percent of the partnership capital of a Partnership NMVC Company. However, neither a limited partner in a Partnership NMVC Company nor a non-managing member in an LLC NMVC Company is considered an Associate if such Person is an entity Institutional Investor whose investment in the Partnership, including commitments, represents no more than 33 percent of the capital of the NMVC Company and no more than five percent of such Person's net worth.

(3) Any officer, director, partner (other than a limited partner), manager, agent, or employee of any Associate described in paragraph (1) or (2) of this definition.

(4) Any Person that directly or indirectly Controls, or is Controlled by, or is under Common Control with, a NMVC Company.

(5) Any Person that directly or indirectly Controls, or is Controlled by, or is under Common Control with, any Person described in paragraphs (1) and (2) of this definition.

(6) Any Close Relative of any Person described in paragraphs (1), (2), (4), and (5) of this definition.

(7) Any Secondary Relative of any Person described in paragraphs (1), (2), (4), and (5) of this definition.

(8) Any concern in which—

(i) Any person described in paragraphs (1) through (6) of this definition is an officer; general partner, or managing member; or

(ii) Any such Person(s) singly or collectively Control or own, directly or indirectly, an equity interest of at least 10 percent (excluding interests that such Person(s) own indirectly through ownership interests in the NMVC Company).

(9) Any concern in which any Person(s) described in paragraph (7) of this definition singly or collectively own (including beneficial ownership) a majority equity interest, or otherwise have Control. As used in this paragraph (9), "collectively" means together with any Person(s) described in paragraphs (1) though (7) of this definition.

(10) For the purposes of this definition, if any Associate relationship described in paragraphs (1) through (7) of this definition exists at any time within six months before or after the date that a NMVC Company provides Financing, then that Associate relationship is considered to exist on the date of the Financing.

(11) If any NMVC Company has any ownership interest in another NMVC Company, the two NMVC companies are Associates of each other.

Capital Impairment has the meaning set forth in § 108.1830(b).

Central Registration Agent or *CRA* means one or more agents appointed by SBA for the purpose of issuing TCs and performing the functions enumerated in § 108.1620 and performing similar functions for Debentures funded outside the pooling process.

Close Relative of an individual means:

(1) A current or former spouse;

(2) A father, mother, guardian, brother, sister, son, daughter; or

(3) A father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, or daughter-in-law.

Commitment means a written agreement between a NMVC Company and an eligible Small Business that obligates the NMVC Company to provide Financing (except a guarantee) to that Small Business in a fixed or determinable sum, by a fixed or determinable future date. In this context the term "agreement" means that there has been agreement on the principal economic terms of the Financing. The agreement may include reasonable conditions precedent to the NMVC Company's obligation to fund the commitment, but these conditions must be outside the NMVC Company's control.

Common Control means a condition where two or more Persons, either through ownership, management, contract, or otherwise, are under the Control of one group or Person. Two or more NMVC companies are presumed to be under Common Control if they are Affiliates of each other by reason of common ownership or common officers, directors, or general partners; or if they are managed or their investments are significantly directed either by a common independent investment advisor or managerial contractor, or by two or more such advisors or contractors that are Affiliates of each other. This presumption may be rebutted by evidence satisfactory to SBA.

Community Development Finance means debt and equity-type investments in low-income communities.

Conditionally Approved NMVC Company means a company that—

(1) Has applied for participation as a NMVC Company, and

(2) SBA has conditionally approved to participate in the NMVC program for a specified period of time not to exceed two years, subject to the company fulfilling the requirements to be a NMVC Company within that specified period of time.

Control means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a NMVC Company or other concern, whether through the ownership of voting securities, by contract, or otherwise.

Control Person means any Person that controls a NMVC Company, either directly or through an intervening entity. A Control Person includes:

(1) A general partner of a Partnership NMVC Company;

(2) Any Person serving as the general partner, officer, director, or manager (in the case of a limited liability company) of any entity that controls a NMVC Company, either directly or through an intervening entity;

(3) Any Person that—

(i) Controls or owns, directly or through an intervening entity, at least 10 percent of a Partnership NMVC Company or any entity described in paragraphs (1) or (2) of this definition; and

(ii) Participates in the investment decisions of the general partner of such Partnership NMVC Company;

(4) Any Person that controls or owns, directly or through an intervening entity, at least 50 percent of a Partnership NMVC Company or any entity described in paragraphs (1) or (2) of this definition.

Corporate NMVC Company. See definition of NMVC Company in this section.

Debentures means debt obligations issued by NMVC companies pursuant to section 355 of the Act and held or guaranteed by SBA.

Debt Securities are instruments evidencing a loan with an option or any other right to acquire Equity Securities in a Small Business or its Affiliates, or a loan which by its terms is convertible into an equity position. Consideration must be paid for all options that you acquire.

Developmental Venture Capital means capital in the form of Equity Capital Investments in Smaller Enterprises made with a primary objective of fostering economic development in Low-Income Geographic Areas.

Distribution means any transfer of cash or non-cash assets to SBA, its agent or Trustee, or to partners in a Partnership NMVC Company, or to shareholders in a Corporate NMVC Company, or to members in an LLC NMVC Company. Capitalization of Retained Earnings Available for Distribution constitutes a Distribution to the NMVC Company's non-SBA partners, shareholders, or members.

Equity Capital Investments means investments in the form of common or preferred stock, limited partnership interests, options, warrants, or similar equity instruments, including subordinated debt with equity features if such debt provides only for interest payments contingent upon and limited to the extent of earnings. Equity Capital Investments must not require amortization. Equity Capital Investments may be guaranteed by one or more third parties; however, neither Equity Capital Investments nor such guarantee may be collateralized or otherwise secured. Investments classified as Debt Securities (see §§ 108.800(b) and 108.815) are not precluded from qualifying as Equity Capital Investments. Equity Capital Investments may provide for royalty payments only if the royalty payments are based on the earnings of the concern.

Equity Securities means stock of any class in a corporation, stock options, warrants, limited partnership interests in a limited partnership, membership interests in a limited liability company, or joint venture interests.

Financing or *Financed* means outstanding financial assistance provided to a Small Business by a NMVC Company, whether through:

(1) Loans;

(2) Debt Securities;

(3) Equity Securities;

(4) Guarantees; or

(5) Purchases of securities of a Small Business or from an underwriter (see § 108.825).

Guaranty Agreement means the contract entered into by SBA which is a guarantee backed by the full faith and credit of the United States Government as to timely payment of principal and interest on Debentures and SBA's rights in connection with such guarantee.

Includible Non-Cash Gains means those non-cash gains (as reported on SBA Form 468) that are realized in the form of Publicly Traded and Marketable securities or investment grade debt instruments. For purposes of this definition, investment grade debt instruments means those instruments that are rated "BBB" or "Baa", or better, by Standard & Poor's Corporation or Moody's Investors Service, respectively. Non-rated debt may be considered to be investment grade if a NMVC Company obtains a written opinion from an investment banking firm acceptable to SBA stating that the non-rated debt instrument is equivalent in risk to the issuer's investment grade debt.

Institutional Investor means:

(1) *Entities*. Any of the following entities if the entity has a net worth (exclusive of unfunded commitments from investors) of at least $1 million, or such higher amount as is specified in this paragraph (1). (See also § 108.230(c)(4) for limitations on the amount of an Institutional Investor's commitment that may be included in Private Capital.)

(i) A State or National bank, trust company, savings bank, or savings and loan association.

(ii) An insurance company.

(iii) A 1940 Act Investment Company or Business Development Company (each as defined in the Investment Company Act of 1940, as amended (15 U.S.C. 8a–1 *et seq.*).

(iv) A holding company of any entity described in paragraph (l)(i), (ii) or (iii) of this definition.

(v) An employee benefit or pension plan established for the benefit of employees of the Federal government, any State or political subdivision of a State, or any agency or instrumentality of such government unit.

(vi) An employee benefit or pension plan (as defined in the Employee Retirement Income Security Act of 1974, as amended (Pub. L. 93–406, 88 Stat. 829), excluding plans established under section 401(k) of the Internal Revenue Code of 1986 (26 U.S.C. 401(k)), as amended).

(vii) A trust, foundation or endowment exempt from Federal income taxation under the Internal Revenue Code of 1986, as amended.

(viii) A corporation, partnership or other entity with a net worth (exclusive of unfunded commitments from investors) of more than $10 million.

(ix) A State, a political subdivision of a State, or an agency or instrumentality of a State or its political subdivision.

(x) An entity whose primary purpose is to manage and invest non-Federal funds on behalf of at least three Institutional Investors described in paragraphs (l)(i) through (l)(ix) of this definition, each of whom must have at least a 10 percent ownership interest in the entity.

(xi) Any other entity that SBA determines to be an Institutional Investor.

(2) *Individuals*. (i) Any of the following individuals if he/she is also a permanent resident of the United States:

(A) An individual who is an Accredited Investor (as defined in the Securities Act of 1933, as amended (15 U.S.C. 77a–77aa)) and whose commitment to the NMVC Company is backed by a letter of credit from a State or National bank acceptable to SBA.

(B) An individual whose personal net worth is at least $2 million and at least ten times the amount of his or her commitment to the NMVC Company. The individual's personal net worth must not include the value of any equity in his or her most valuable residence.

(C) An individual whose personal net worth, not including the value of any equity in his or her most valuable residence, is at least $10 million.

(ii) Any individual who is not a permanent resident of the United States but who otherwise satisfies paragraph (2)(i) of this definition provided such individual has irrevocably appointed an agent within the United States for the service of process.

Investment Adviser/Manager means any Person who furnishes advice or assistance with respect to operations of a NMVC Company under a written contract executed in accordance with the provisions of § 108.510.

Lending Institution means a concern that is operating under regulations of a state or Federal licensing, supervising, or examining body, or whose shares are publicly traded and listed on a recognized stock exchange or NASDAQ and which has assets in excess of $500 million; and which, in either case, holds itself out to the public as engaged in the making of commercial and industrial loans and whose lending operations are not for the purpose of financing its own or an Associate's sales or business operations.

Leverage means financial assistance provided to a NMVC Company by SBA through the guaranty of a NMVC Company's Debentures, and any other SBA financial assistance evidenced by a security of the NMVC Company.

Leverageable Capital means Regulatory Capital, excluding unfunded commitments.

LLC NMVC Company. See definition of NMVC Company in this section.

Loan means a transaction evidenced by a debt instrument with no provision for you to acquire Equity Securities.

Loans and Investments means Portfolio securities, assets acquired in liquidation of Portfolio securities, operating concerns acquired, and notes and other securities received, as set forth in the Statement of Financial Position of SBA Form 468.

Low-Income Enterprise means a Smaller Enterprise that, as of the time of the initial Financing, has its Principal Office located in a Low-Income Geographic Area.

Low-Income Geographic Area ("LI Area") means—

(1) any population census tract (or in the case of an area that is not tracted for population census tracts, the equivalent county division, as defined by the Bureau of the Census of the United

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States Department of Commerce for purposes of defining poverty areas), if—

(i) The poverty rate for that census tract is not less than 20 percent;

(ii) In the case of a tract—

(A) That is located within a metropolitan area, 50 percent or more of the households in that census tract have an income equal to less than 60 percent of the area median gross income; or

(B) That is not located within a metropolitan area, the median household income for such tract does not exceed 80 percent of the statewide median household income; or

(C) As determined by the Administrator in accordance with § 108.1940 of this part, a substantial population of Low-Income Individuals reside, an inadequate access to investment capital exists, or other indications of economic distress exist in that census tract; or

(2) Any area located within—

(i) A Historically Underutilized Business Zone ("HUBZone") as defined in section 3(p) of the Small Business Act and 13 CFR 126.103;

(ii) An Urban Empowerment Zone or Urban Enterprise Community (as designated by the Secretary of the United States Department of Housing and Urban Development); or

(iii) A Rural Empowerment Zone or Rural Enterprise Community (as designated by the Secretary of the United States Department of Agriculture).

Low-Income Individual means an individual whose income (adjusted for family size) does not exceed—

(1) For metropolitan areas, 80 percent of the area median income; and

(b) For nonmetropolitan areas, the greater of—

(i) 80 percent of the area median income, or

(ii) 80 percent of the statewide nonmetropolitan area median income.

Low-Income Investment means an Equity Capital Investment in a Low-Income Enterprise.

Management Expenses has the meaning set forth in § 108.520.

NAICS Manual means the latest issue of the North American Industrial Classification System Manual, prepared by the Office of Management and Budget, and available from the U.S. Government Printing Office, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

New Markets Tax Credit program means the tax credit created by the Consolidated Appropriations Act of 2001, Pub L. No. 106–554, enacted December 21, 2000, to be implemented by the Internal Revenue Service, United States Department of Treasury.

New Markets Venture Capital Company or *NMVC Company* means a corporation (Corporate NMVC Company), a limited partnership organized as required by § 108.160 (Partnership NMVC Company), or a limited liability company (LLC NMVC Company) that—

(a) has been granted final approval by SBA under § 108.390 of this part, and

(b) has entered into a Participation Agreement with SBA. For certain purposes, the Entity General Partner of a Partnership NMVC Company is treated as if it were a NMVC Company (see § 108.160(a).

1940 Act Company means a NMVC Company which is registered under the Investment Company Act of 1940.

1980 Act Company means a NMVC Company which is registered under the Small Business Investment Incentive Act of 1980.

Operational Assistance means management, marketing, and other technical assistance that assists a Small Business with its business development.

Original Issue Price means the price paid by the purchaser for securities at the time of issuance.

Participation Agreement means an agreement between SBA and a company to which SBA has granted final approval under section 108.390 of this part, that—

(a) details the company's operating plan and investment criteria; and

(b) requires the company to make investments in Smaller Enterprises at least 80 percent of which Smaller Enterprises are located in LI Areas.

Partnership NMVC Company. See definition of NMVC Company in this section.

Person means a natural person or legal entity.

Pool means an aggregation of SBA guaranteed Debentures approved by SBA.

Portfolio means the securities representing a NMVC Company's total outstanding Financing of Smaller Enterprises. It does not include idle funds or assets acquired in liquidation of Portfolio securities.

Portfolio Concern means a Small Business Assisted by a NMVC Company.

Principal Office means the location where the greatest number of the concern's employees at any one location perform their work. However, for those concerns whose "primary industry" (see 13 CFR 121.107) is service or construction (see 13 CFR 121.201), the determination of principal office excludes the concern's employees who perform the majority of their work at job-site locations to fulfill specific contract obligations.

Private Capital has the meaning set forth in § 108.230.

Publicly Traded and Marketable means securities that are salable without restriction or that are salable within 12 months pursuant to Rule 144 (17 CFR 230.144) of the Securities Act of 1933, as amended, by the holder thereof, and are of a class which is traded on a regulated stock exchange, or is listed in the Automated Quotation System of the National Association of Securities Dealers (NASDAQ), or has, at a minimum, at least two market makers as defined in the relevant sections of the Securities Exchange Act of 1934, as amended (15 U.S.C. 77b *et seq.*), and in all cases the quantity of which can be sold over a reasonable period of time without having an adverse impact upon the price of the stock.

Regulatory Capital means:

(1) *General.* Regulatory Capital means Private Capital, excluding non-cash assets contributed to a NMVC Company, a Conditionally Approved NMVC Company, or an Applicant, and non-cash assets purchased by a Conditionally Approved NMVC Company or an Applicant, unless such assets have been converted to cash or have been approved by SBA for inclusion in Regulatory Capital. For purposes of this definition, sales of contributed non-cash assets with recourse or borrowing against such assets shall not constitute a conversion to cash.

(2) *Exclusion of questionable commitments.* An investor's commitment to a NMVC Company, Conditionally Approved NMVC Company, or Applicant is excluded from Regulatory Capital if SBA determines that the collectability of the commitment is questionable.

(3) *Exclusion of amounts designated for Operational Assistance match.* Regulatory Capital excludes any portion of Private Capital that is designated as matching resources in accordance with § 108.2030(b)(3).

Relevant Venture Capital Finance means Equity Capital Investments with the intention of creating wealth and job opportunities in low-income communities.

Retained Earnings Available for Distribution means Undistributed Net Realized Earnings less any Unrealized Depreciation on Loans and Investments (as reported on SBA Form 468), and represents the amount that a NMVC Company may distribute to investors (including SBA) as a profit Distribution, or transfer to Private Capital.

SBA means the Small Business Administration, 409 Third Street, SW., Washington, DC 20416.

Secondary Relative of an individual means:

(1) A grandparent, grandchild, or any other ancestor or lineal descendent who is not a Close Relative;

(2) An uncle, aunt, nephew, niece, or first cousin; or

(3) A spouse of any person described in paragraph (1) or (2) of this definition.

Small Business means a small business concern as defined in section 103(5) of the Act (including its Affiliates), and which meets the criteria applicable to the Small Business Investment Company program as set forth in part 121 of this chapter.

Smaller Enterprise means any Small Business that:

(1) Together with its Affiliates has a net worth of not more than $6.0 million and average net income after Federal income taxes (excluding any carry-over losses) for the preceding two years no greater than $2.0 million, or

(2) Both together with its Affiliates, and by itself, meets the size standard of § 121.201 of this title at the time of Financing for the industry in which it is then primarily engaged.

Specialized Small Business Investment Companies (*SSBICs*) means any small business investment company that—

(1) invests solely in small business concerns that contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages; and

(2) was licensed under section 301(d) of the Small Business Investment Act, as in effect before September 30, 1996.

Trust means the legal entity created for the purpose of holding guaranteed Debentures and the guaranty agreement related thereto, receiving, holding and making any related payments, and accounting for such payments.

Trust Certificate Rate means a fixed rate determined by the Secretary of the Treasury at the time Debentures are pooled, taking into consideration the current average market yield on outstanding marketable obligations of the United States with maturities comparable to the maturities of the Trust Certificates being guaranteed by SBA, adjusted to the nearest one-eighth of one percent.

Trust Certificates (TCs) means certificates issued by SBA, its agent or Trustee and representing ownership of all or a fractional part of a Trust or Pool of Debentures.

Trustee means the trustee or trustees of a Trust.

Undistributed Net Realized Earnings means Undistributed Realized Earnings less Non-cash Gains/Income, each as reported on SBA Form 468.

Unrealized Appreciation means the amount by which a NMVC Company's valuation of each of its Loans and Investments, as determined by its Board of Directors or General Partner(s) in accordance with NMVC Company's valuation policies, exceeds the cost basis thereof.

Unrealized Depreciation means the amount by which a NMVC Company's valuation of each of its Loans and Investments, as determined by its Board of Directors or General Partner(s) in accordance with NMVC Company's valuation policies, is below the cost basis thereof.

Unrealized Gain (Loss) on Securities Held means the sum of the Unrealized Appreciation and Unrealized Depreciation on all of a NMVC Company's Loans and Investments, less estimated future income tax expense or estimated realizable future income tax benefit, as appropriate.

Subpart C—Qualifications for the NMVC Program

Organizing a NMVC Company

§ 108.100 Business form.

A NMVC Company must be a newly formed for-profit entity or, subject to § 108.150, a newly formed for-profit subsidiary of an existing entity. It must be organized under State law solely for the purpose of performing the functions and conducting the activities contemplated under the Act. It may be organized as a corporation ("Corporate NMVC Company"), a limited partnership ("Partnership NMVC Company"), or a limited liability company ("LLC NMVC Company").

§ 108.110 Qualified management.

An Applicant must show, to the satisfaction of SBA, that its current or proposed management is qualified and has the knowledge, experience, and capability in Community Development Finance or Relevant Venture Capital Finance, necessary for investing in the types of businesses contemplated by the Act, these regulations and its business plan. In determining whether an Applicant's current or proposed management team has sufficient qualifications, SBA will consider information provided by the Applicant and third parties concerning the background, capability, education, training and reputation of its general partners, managers, officers, key personnel, and investment committee and governing board members. The Applicant must designate at least one individual as the official responsible for contact with SBA.

§ 108.120 Economic development primary mission.

The primary mission of a NMVC Company must be economic development of one or more LI Areas.

§ 108.130 Identified Low-Income Geographic Areas.

A NMVC Company must identify the specific LI Areas in which it intends to make Developmental Venture Capital investments and provide Operational Assistance under the NMVC program.

§ 108.140 SBA approval of initial Management Expenses.

A NMVC Company must have its Management Expenses approved by SBA at the time of designation as a NMVC Company. (See § 108.520 for the definition of Management Expenses.)

§ 108.150 Management and ownership diversity requirement.

(a) *Diversity requirement.* You must have diversity between management and ownership in order to be a NMVC Company. To establish diversity, you must meet the requirements in paragraphs (b) and (c) of this section unless SBA approves otherwise.

(b) *Percentage ownership requirement.* No Person or group of Persons who are Affiliates of one another may own or control, directly or indirectly, more than 70 percent of your Regulatory Capital or your Leverageable Capital.

(c) *Non-affiliation requirement.* At least 30 percent of your Regulatory Capital and Leverageable Capital must be owned and controlled by Persons unaffiliated with your management and unaffiliated with each other, and whose investments are significant in dollar and percentage terms as determined by SBA. Such Persons must not be your Associates (except for their status as your shareholders, limited partners or members) and must not Control, be Controlled by, or be under Common Control with any of your Associates. A single "acceptable" Institutional Investor may be substituted for two or three of the three investors who are otherwise required. The following Institutional Investors are "acceptable" for this purpose:

(1) Entities whose overall activities are regulated and periodically examined by state, Federal or other governmental authorities satisfactory to SBA;

(2) Entities listed on the New York Stock Exchange;

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(3) Entities that are publicly traded and that meet both the minimum numerical listing standards and the corporate governance listing standards of the New York Stock Exchange;

(4) Public or private employee pension funds;

(5) Trusts, foundations, or endowments, but only if exempt from Federal income taxation; and

(6) Other Institutional Investors satisfactory to SBA.

(d) *Voting requirement.* The investors required for you to satisfy diversity may not delegate their voting rights to any Person who is your Associate, or who Controls, is Controlled by, or is under Common Control with any of your Associates, without prior SBA approval.

(e) *Requirement to maintain diversity.* You must maintain management-ownership diversity while you are a NMVC Company. If, at any time, you no longer have the required management-ownership diversity, you must:

(1) Notify SBA within 10 days; and

(2) Re-establish diversity within six months.

§ 108.160 Special rules for NMVC Companies formed as limited partnerships.

(a) *Entity General Partner.* (1) A general partner which is a corporation, limited liability company or partnership (an "Entity General Partner") shall be organized under state law solely for the purpose of serving as the general partner of one or more NMVC companies.

(2) SBA must approve any person who will serve as an officer, director, manager, or general partner of the Entity General Partner. This provision must be stated in an Entity General Partner's Certificate of Incorporation, operating agreement, limited partnership agreement or other similar governing instrument.

(3) An Entity General Partner is subject to the same examination and reporting requirements as a NMVC Company under sections 361 and 362 of the Act. The restrictions and obligations imposed upon a NMVC Company by §§ 108.1810, 108.30, 108.410 through 108.450, 108.470, 108.500, 108.510, 108.585, 108.600, 108.680, 108.690 through 108.692, and 108.1910 apply also to an Entity General Partner of a NMVC Company.

(4) The general partner(s) of your Entity General Partner(s) will be considered your general partner.

(5) If your Entity General Partner is a limited partnership, its limited partners may be considered your Control Person(s) if they meet the definition for Control Person in § 108.50.

(b) *Other requirements for Partnership NMVC Companies.* If you are a Partnership NMVC Company:

(1) You must have a minimum duration of 10 years or two years following the maturity of your last-maturing Leverage security, whichever is longer. After 10 years, if all Leverage has been repaid or redeemed and all amounts due SBA, its agent, or Trustee have been paid, the Partnership NMVC Company may be terminated by a vote of your partners;

(2) None of your general partner(s) may be removed or replaced by your limited partners without prior written approval of SBA;

(3) Any transferee of, or successor in interest to, your general partner shall have only the rights and liabilities of a limited partner pending SBA's written approval of such transfer or succession; and

(4) You must incorporate all the provisions in this paragraph (b) in your limited partnership agreement.

(c) *Obligations of a Control Person.* All Control Persons are bound by the disciplinary provisions of sections 365 and 366 of the Act and by the conflict-of-interest rules under § 108.730. The term NMVC Company, as used in §§ 108.30, 108.460, and 108.680, includes all of the NMVC Company's Control Persons. The conditions specified in § 108.1810 and § 108.1910 apply to all general partners.

(d) *Liability of general partner for partnership debts to SBA.* Subject to section 365 of the Act, your general partner is not liable solely by reason of its status as a general partner for repayment of any Leverage or debts you owe to SBA unless SBA, in the exercise of reasonable investment prudence, and with regard to your financial soundness, determines otherwise prior to the purchase or guaranty of your Leverage.

(e) *Special Leverage requirement.* Before your first issuance of Leverage, you must furnish SBA with evidence that you qualify as a partnership for tax purposes, either by a ruling from the Internal Revenue Service or by an opinion of counsel.

Capitalizing a NMVC Company

§ 108.200 Adequate capital for NMVC Companies.

You must meet the requirements of these §§ 108.200–108.240 in order to qualify for designation as a NMVC Company and to receive Leverage.

§ 108.210 Minimum capital requirements for NMVC Companies.

You must have Regulatory Capital of at least $5,000,000 and Leverageable capital of at least $500,000 to become a NMVC Company.

§ 108.230 Private Capital for NMVC Companies.

(a) *General.* Private Capital means the contributed capital of a NMVC Company, plus unfunded binding commitments by Institutional Investors (including commitments evidenced by a promissory note) to contribute capital to a NMVC Company.

(b) *Contributed capital.* For purposes of this section, contributed capital means the paid-in capital and paid-in surplus of a Corporate NMVC Company, the members' contributed capital of a LLC NMVC Company, or the partners' contributed capital of a Partnership NMVC Company, in each case subject to the limitations in paragraph (c) of this section.

(c) *Exclusions from Private Capital.* Private Capital does not include:

(1) Funds borrowed by a NMVC Company from any source.

(2) Funds obtained through the issuance of Leverage.

(3) Funds obtained directly from any Federal agency or department.

(4) Any portion of a commitment from an Institutional Investor with a net worth of less than $10 million that exceeds 10 percent of such Institutional Investor's net worth.

(d) *Non-cash capital contributions.* Capital contributions in a form other than cash are subject to the limitations in § 108.240.

(e) *Contributions with borrowed funds.* You may not accept any capital contribution made with funds borrowed by a Person seeking to own an equity interest (whether direct or indirect, beneficial or of record) of at least 10 percent of your Private Capital. This exclusion does not apply if:

(1) Such Person's net worth is at least twice the amount borrowed; or

(2) SBA gives its prior written approval of the capital contribution.

§ 108.240 Limitations on including non-cash capital contributions in Private Capital.

Non-cash capital contributions to a NMVC Company or Applicant are included in Private Capital only if they fall into one of the following categories:

(a) Direct obligations of, or obligations guaranteed as to principal and interest by, the United States.

(b) Services rendered or to be rendered to you, priced at no more than their fair market value and approved by SBA.

(c) Tangible assets used in your operations, priced at no more than their fair market value.

(d) Other non-cash assets approved by SBA.

Subpart D—Application and Approval Process for NMVC Company Designation

§ 108.300 When and how to apply for designation as a NMVC Company.

(a) *Notice of Funds Availability ("NOFA").* SBA will publish a NOFA in the **Federal Register**, advising potential applicants of the availability of funds for the NMVC program. An entity may then submit an application for designation as a NMVC Company. When submitting its application, an Applicant must comply with both these regulations and any requirements specified in the NOFA, including submission deadlines. The NOFA may specify limitations, special rules, procedures, and restrictions for a particular funding round.

(b) *Application form.* An Applicant must apply for designation as a NMVC Company using the application packet provided by SBA. Upon receipt of an application, SBA may request clarifying or technical information on the materials submitted as part of the application.

§ 108.310 Contents of application.

Each Applicant must submit a complete application, including the following:

(a) *Amounts.* The Applicant must indicate the amounts of—

(1) Regulatory Capital it proposes to raise;

(2) Binding commitments for contributions in cash or in-kind it proposes to raise, and/or an annuity it proposes to purchase, in accordance with the requirements of § 108.2030, as its matching resources for its Operational Assistance grant award (the aggregate of which must be not less than 30 percent of the Regulatory Capital it proposes to raise under paragraph (a)(1) of this section).

(b) *Comprehensive business plan.* The Applicant must submit a comprehensive business plan covering at least a five-year period, addressing the specific items described in § 108.320, and which demonstrates that the Applicant has the capacity to operate successfully as a NMVC Company.

(c) *New Markets Tax Credit program.* Applicant must address if and to what extent it intends to conform its activities to the New Markets Tax Credit laws. If Applicant plans to seek a New Markets Tax Credit, Applicant also must state the amount of tax credit allocation it intends to seek.

§ 108.320 Contents of comprehensive business plan.

(a) *Executive summary.* The executive summary must include a description of—

(1) The Applicant;

(2) Its strategy for how it proposes to make successful Developmental Venture Capital investments in identified LI Areas;

(3) The markets in the LI Areas it proposes to serve; and

(4) How it intends to work with community organizations in and be accountable to the residents of identified LI Areas in order to facilitate its Developmental Venture Capital investments.

(b) *Capacity, skills, and experience of the management team.* An Applicant must provide information generally as to the background, capability, education, reputation and training of its general partners, managers, officers, key personnel, investment committee and governing board members. The Applicant also must provide information specifically on these individuals' qualifications and reputation in the areas of Community Development Finance and/or Relevant Venture Capital Finance, including the impact of these individuals' activities in these areas.

(c) *Market analysis.* An Applicant must provide an analysis of the LI Areas in which it intends to focus its Developmental Venture Capital investments and Operational Assistance to Smaller Enterprises, demonstrating that the Applicant understands the market and the unmet capital needs in such areas and how its activities will meet these unmet capital needs through Developmental Venture Capital investments and will have a positive economic impact on those areas. The analysis must include a description of the extent of the economic distress in the identified LI Areas. An Applicant also must analyze the extent of the demand in such areas for Developmental Venture Capital investments and any factors or trends that may affect the Applicant's ability to make effective Developmental Venture Capital investments.

(d) *Operational capacity and investment strategies.* An Applicant must submit information concerning its policies and procedures for underwriting and approving its Developmental Venture Capital investments, monitoring its portfolio, and maintaining internal controls and operations.

(e) *Regulatory Capital.* An Applicant must include a detailed description of how it plans to raise its Regulatory Capital. An Applicant must discuss its potential sources of Regulatory Capital, the estimated timing on raising such funds, and the extent of the expressions of interest to commit such funds to the Applicant.

(f) *Plan for providing Operational Assistance.* An Applicant must describe how it plans to use its grant funds to provide Operational Assistance to Smaller Enterprises in which it will make Developmental Venture Capital investments. Its plan must address the types of Operational Assistance it proposes to provide, and whether and to what extent it intends to provide the Operational Assistance through the use of licensed professionals, either from its own staff or from outside entities.

(g) *Matching resources for Operational Assistance grant.* An Applicant must include a detailed description of how it plans to obtain binding commitments for contributions in cash or in-kind, and/or to purchase an annuity, to match the funds requested from SBA for the Applicant's Operational Assistance grant. If it proposes to obtain commitments for cash or in-kind contributions, it also must estimate the ratio of cash to in-kind contributions (in no event may in-kind contributions exceed 50 percent of the total contributions). Applicant must discuss its potential sources of matching resources, the estimated timing on raising such funds, and the extent of the expressions of interest to commit such funds to the Applicant. Potential sources of matching resources must satisfy the requirements in § 108.2030(b)(1).

(h) *Projected Amount of Investment in LI Areas.* An Applicant must describe the amount of its total Regulatory Capital and Leverage that it proposes to invest in Smaller Enterprises located in LI Areas, as compared to the amount that it proposes to invest in Small Businesses located outside of LI Areas.

(i) *Projected impact.* An Applicant must describe the criteria and economic measurements to be used to evaluate whether and to what extent it has met the objectives of the NMVC program. It must include:

(1) A description of the extent to which it will concentrate its Developmental Venture Capital investments and Operational Assistance activities in identified LI Areas;

(2) An estimate of the social, economic, and community development benefits to be created within identified LI Areas over the next five years or more as a result of its activities;

(3) A description of the criteria to be used to measure the benefits created as a result of its activities;

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(4) A discussion about the amount of such benefits created that it will consider to constitute successfully meeting the objectives of the NMVC program.

(j) *Affiliates and business relationships.* Applicant must submit information regarding the management and financial strength of any parent or holding entity, affiliated firm or entity, or any other firm or entity essential to the success of the Applicant's business plan.

§ 108.330 Application fee.

An Applicant must pay to SBA an application processing fee of $5,000, of which $2,000 is payable at the time of application submission and the remaining $3,000 of which is payable if and when SBA designates the Applicant as a NMVC Company.

Subpart E—Evaluation and Selection of NMVC Companies.

§ 108.340 Evaluation and selection—general.

SBA will evaluate and select an Applicant to participate in the NMVC program solely at SBA's discretion, based on SBA's review of the Applicant's application materials, interviews or site visits with the Applicant, and background investigations conducted by SBA and other Federal agencies. SBA's evaluation and selection process is intended to—.

(a) Ensure that Applicants are evaluated on a competitive basis and in a fair and consistent manner;

(b) Take into consideration the unique proposals presented by Applicants;

(c) Ensure that each Applicant that SBA designates as a NMVC Company can fulfill successfully the goals of its comprehensive business plan; and

(d) Ensure that SBA selects Applicants in such a way as to promote Developmental Venture Capital investments nationwide and in both urban and rural areas.

§ 108.350 Eligibility and completeness.

SBA will not consider any application that is not complete or that is submitted by an Applicant that does not meet the eligibility criteria described in subpart C of this part. SBA, at its sole discretion, may request from an Applicant additional information concerning eligibility criteria or easily completed portions of the application in order to allow SBA to consider that Applicant's application.

§ 108.360 Evaluation criteria.

SBA will evaluate and select an Applicant for participation in the NMVC program by considering the following criteria—

(a) The quality of the Applicant's comprehensive business plan in terms of meeting the objectives of the NMVC program;

(b) The likelihood that the Applicant will fulfill the goals described in its comprehensive business plan;

(c) The capability of the Applicant's management team;

(d) The strength and likelihood for success of the Applicant's operations and investment strategies;

(e) The need for Developmental Venture Capital investments in the LI Areas in which the Applicant intends to invest;

(f) The extent to which the Applicant will concentrate its activities on serving the LI Areas in which it intends to invest, including the ratio of resources that it proposes to invest in such areas as compared to other areas;

(g) The Applicant's demonstrated understanding of the markets in the LI Areas in which it intends to focus its activities;

(h) The likelihood that and the time frame within which the Applicant will be able to—

(1) Raise the Regulatory Capital it proposes to raise for its investments, and

(2) Obtain the binding commitments for contributions in cash or in-kind and/or an annuity it proposes to obtain as its matching resources for its Operational Assistance grant award;

(i) The strength of the Applicant's proposal to provide Operational Assistance to Smaller Enterprises in which it plans to invest;

(j) The extent to which the activities proposed by the Applicant will promote economic development and the creation of wealth and job opportunities in the LI Areas in which it intends to invest and among individuals living in LI Areas; and

(k) The strength of the Applicant's application compared to applications submitted by other Applicants intending to invest in the same or proximate LI Areas.

§ 108.370 Conditional approval.

From among the Applicants submitting eligible and complete applications, SBA will select a number of Applicants and will conditionally approve such selected Applicants to participate in the NMVC program. SBA will give each such Conditionally Approved NMVC Company a specific period of time, not to exceed two years, to satisfy the requirements to become a NMVC Company.

§ 108.380 Final approval as a NMVC Company.

(a) *General rule.* With respect to each Conditionally Approved NMVC Company, SBA will either:

(1) Grant final approval to participate in the NMVC program and designate such company as a NMVC Company, if such Conditionally Approved NMVC Company:

(i) Within the specific period of time SBA gave to it when SBA conditionally approved it for participation in the NMVC program, has raised:

(A) At least $5,000,000 of Regulatory Capital; and

(B) At least $1,500,000 of matching resources for its Operational Assistance grant award or 30 percent of the Regulatory Capital it raised, whichever is greater; and

(ii) Enters into a Participation Agreement with SBA; or

(2) Revoke SBA's conditional approval of the company, at which time it is no longer a Conditionally Approved NMVC Company and must not participate in the NMVC program or represent itself as a Conditionally Approved NMVC Company.

(b) *Exception to requirement to raise matching resources.*

(1) *General.* At its discretion and based upon a showing of good cause, SBA may consider a Conditionally Approved NMVC Company to have satisfied the requirement in paragraph (a)(1)(i)(B) of this section to raise matching resources in the amount of at least 30 percent of its Regulatory Capital if the Conditionally Approved NMVC Company—

(i) Already has raised at least 20 percent of the total amount of required matching resources; and

(ii) Has a viable plan that reasonably projects its capacity to raise the remainder of the required amount of matching resources.

(2) *Request for exception.* Before the expiration of the time period given to it by SBA to meet the requirements to become a NMVC Company, a Conditionally Approved NMVC Company may submit to SBA a request that SBA grant the exception described in paragraph (b)(1) of this section. Such Conditionally Approved NMVC must present to SBA evidence of good cause for such request, as well as evidence supporting the elements of the exception described in such paragraph.

(3) *No applicability to Regulatory Capital.* The exception described in this section applies only to matching resources for the Operational Assistance grant award. Under no circumstances will SBA designate a Conditionally Approved NMVC Company as a NMVC Company if such Conditionally Approved NMVC Company does not raise the required minimum amount of Regulatory Capital within the time period SBA gave it to do so.

Subpart F—Changes in Ownership, Structure, or Control

Changes in Control or Ownership of NMVC Company

§ 108.400 Changes in ownership of 10 percent or more of NMVC Company but no change of Control.

You must obtain SBA's prior written approval for any proposed transfer or issuance of ownership interests that results in the ownership (beneficial or of record) by any Person, or group of Persons acting in concert, of at least 10 percent of any class of your stock, partnership capital or membership interests.

§ 108.410 Changes in Control of NMVC Company (through change in ownership or otherwise).

You must obtain SBA's prior written approval for any proposed transaction or event that results in Control by any Person(s) not previously approved by SBA.

§ 108.420 Prohibition on exercise of ownership or Control rights in NMVC Company before SBA approval.

Without prior written SBA approval, no change of ownership or Control may take effect and no officer, director, employee or other Person acting on your behalf shall:

(a) Register on your books any transfer of ownership interest to the proposed new owner(s);

(b) Permit the proposed new owner(s) to exercise voting rights with respect to such ownership interest (including directly or indirectly procuring or voting any proxy, consent or authorization as to such voting rights at any meeting of shareholders, partners or members);

(c) Permit the proposed new owner(s) to participate in any manner in the conduct of your affairs (including exercising control over your books, records, funds or other assets; participating directly or indirectly in any disposition thereof; or serving as an officer, director, partner, manager, employee or agent); or

(d) Allow ownership or Control to pass to another Person.

§ 108.430 Notification to SBA of transactions that may change ownership or Control.

You must promptly notify SBA as soon as you have knowledge of transactions or events that may result in a transfer of Control or ownership of at least 10 percent of your capital. If there is any doubt as to whether a particular transaction or event will result in such a change, report the facts to SBA.

§ 108.440 Standards governing prior SBA approval for a proposed transfer of Control.

SBA approval is contingent upon full disclosure of the real parties in interest, the source of funds for the new owners' interest, and other data requested by SBA. As a condition of approving a proposed transfer of control, SBA may:

(a) Require an increase in your Regulatory Capital;

(b) Require the new owners or the transferee's Control Person(s) to assume, in writing, personal liability for your Leverage, effective only in the event of their direct or indirect participation in any transfer of Control not approved by SBA; or

(c) Require compliance with any other conditions set by SBA, including compliance with the requirements for minimum capital and management-ownership diversity as in effect at such time for new NMVC Companies.

§ 108.450 Notification to SBA of pledge of NMVC Company's shares.

(a) You must notify SBA in writing, within 30 calendar days, of the terms of any transaction in which:

(1) Any Person, or group of Persons acting in concert, pledges shares of your stock (or equivalent ownership interests) as collateral for indebtedness; and

(2) The shares pledged are at least 10 percent of your Regulatory Capital.

(b) If the transaction creates a change of ownership or Control, you must comply with § 108.400 or § 108.410, as appropriate.

Restrictions on Common Control or Ownership of Two or More NMVC Companies

§ 108.460 Restrictions on Common Control or ownership of two (or more) NMVC Companies.

Without SBA's prior written approval, you must not have an officer, director, manager, Control Person, or owner (with a direct or indirect ownership interest of at least 10 percent) who is also:

(a) An officer, director, manager, Control Person, or owner (with a direct or indirect ownership interest of at least 10 percent) of another NMVC Company; or

(b) An officer or director of any Person that directly or indirectly controls, or is controlled by, or is under Common Control with, another NMVC Company.

Change in Structure of NMVC Company

§ 108.470 SBA approval of merger, consolidation, or reorganization of NMVC Company.

You may not merge, consolidate, change form of organization (corporation or partnership) or reorganize without SBA's prior written approval. Any such merger or consolidation will be subject to § 108.440.

Subpart G—Managing the Operations of a NMVC Company

General Requirements

§ 108.500 Lawful operations under the Act.

You must engage only in the activities contemplated by the Act and in no other activities.

§ 108.502 Representations to the public.

You may not represent or imply to anyone that the SBA, the U.S. Government or any of its agencies or officers has approved any ownership interests you have issued or obligations you have incurred. Be certain to include a statement to this effect in any solicitation to investors. Example: You may not represent or imply that "SBA stands behind the NMVC Company" or that "Your capital is safe because SBA's experts review proposed investments to make sure they are safe for the NMVC Company."

§ 108.503 NMVC Company's adoption of an approved valuation policy.

(a) *Valuation guidelines.* You must prepare, document and report the valuations of your Loans and Investments in accordance with the Valuation Guidelines for SBICs issued by SBA. These guidelines may be obtained from SBA's Investment Division.

(b) *SBA approval of valuation policy.* You must have a written valuation policy approved by SBA for use in determining the value of your Loans and Investments. You must either:

(1) Adopt without change the model valuation policy set forth in section III of the Valuation Guidelines for SBICs; or

(2) Obtain SBA's prior written approval of an alternative valuation policy.

(c) *Responsibility for valuations.* Your board of directors, managing members, or general partner(s) will be solely responsible for adopting your valuation policy and for using it to prepare valuations of your Loans and Investments for submission to SBA. If SBA reasonably believes that your valuations, individually or in the

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aggregate, are materially misstated, it reserves the right to require you to engage, at your expense, an independent third party acceptable to SBA to substantiate the valuations.

(d) *Frequency of valuations.*

(1) You must value your Loans and Investments at the end of the second quarter of your fiscal year, and at the end of your fiscal year.

(2) On a case-by-case basis, SBA may require you to perform valuations more frequently.

(3) You must report material adverse changes in valuations at least quarterly, within thirty days following the close of the quarter.

(e) *Review of valuations by independent public accountant.*

(1) For valuations performed as of the end of your fiscal year, your independent public accountant must review your valuation procedures and the implementation of such procedures, including adequacy of documentation.

(2) The independent public accountant's report on your audited annual financial statements (SBA Form 468) must include a statement that your valuations were prepared in accordance with your approved valuation policy.

§ 108.504 Equipment and office requirements.

(a) *Computer capability.* You must have a personal computer with a modem, and be able to use this equipment to prepare reports (using SBA provided software) and transmit them to SBA. In addition, you must have access to the Internet and the capability to send and receive electronic mail via the Internet.

(b) *Facsimile capability.* You must be able to receive facsimile messages 24 hours per day at your primary office.

(c) *Accessible office.* You must maintain an office that is convenient to the public and is open for business during normal working hours.

§ 108.506 Safeguarding the NMVC Company's assets/internal controls.

You must adopt a plan to safeguard your assets and monitor the reliability of your financial data, personnel, Portfolio, funds and equipment. You must provide your bank and custodian with a certified copy of your resolution or other formal document describing your control procedures.

§ 108.507 Violations based on false filings and nonperformance of agreements with SBA.

The following shall constitute a violation of this part:

(a) *Nonperformance.* Nonperformance of any of the requirements of any Debenture or of any written agreement with SBA.

(b) *False statement.* In any document submitted to SBA:

(1) Any false statement knowingly made; or

(2) Any misrepresentation of a material fact; or

(3) Any failure to state a material fact. A material fact is any fact that is necessary to make a statement not misleading in light of the circumstances under which the statement was made.

§ 108.509 Employment of SBA officials.

Without SBA's prior written approval, for a period of two years after the date of your most recent issuance of Leverage (or the receipt of any SBA Assistance as defined in part 105 of this chapter), you are not permitted to employ, offer employment to, or retain for professional services, any person who:

(a) Served as an officer, attorney, agent, or employee of SBA on or within one year before such date; and

(b) As such, occupied a position or engaged in activities which, in SBA's determination, involved discretion with respect to the granting of SBA Assistance.

Management and Compensation

§ 108.510 SBA approval of NMVC Company's Investment Adviser/Manager.

You may employ an Investment Adviser/Manager who will be subject to the supervision of your board of directors, managing members, or general partner. If you have Leverage or plan to seek Leverage, you must obtain SBA's prior written approval of the management contract. SBA's approval of an Investment Adviser/Manager for one NMVC Company does not indicate approval of that manager for any other NMVC Company.

(a) *Management contract.* The contract must:

(1) Specify the services the Investment Adviser/Manager will render to you and to the Small Businesses in your Portfolio, and

(2) Indicate the basis for computing Management Expenses.

(b) *Material change to approved management contract.* If there is a material change, both you and SBA must approve such change in advance. If you are uncertain if the change is material, submit the proposed revision to SBA.

§ 108.520 Management Expenses of a NMVC Company.

SBA must approve any increases in your Management Expenses.

(a) *Definition of Management Expenses.* Management Expenses include:

(1) Salaries;

(2) Office expenses;

(3) Travel;

(4) Business development;

(5) Office and equipment rental;

(6) Bookkeeping; and

(7) Expenses related to developing, investigating and monitoring investments.

(b) Management Expenses do not include services provided by specialized outside consultants, outside lawyers and independent public accountants, if they perform services not generally performed by a venture capital company.

Cash Management by a NMVC Company

§ 108.530 Restrictions on investments of idle funds by NMVC Companies.

(a) *Permitted investments of idle funds.* Funds not invested in Small Businesses must be maintained in:

(1) Direct obligations of, or obligations guaranteed as to principal and interest by, the United States, which mature within 15 months from the date of the investment, or

(2) Repurchase agreements with federally insured institutions, with a maturity of seven days or less. The securities underlying the repurchase agreements must be direct obligations of, or obligations guaranteed as to principal and interest by, the United States. The securities must be maintained in a custodial account at a federally insured institution; or

(3) Certificates of deposit with a maturity of one year or less, issued by a federally insured institution; or

(4) A deposit account in a federally insured institution, subject to a withdrawal restriction of one year or less; or

(5) A checking account in a federally insured institution; or

(6) A reasonable petty cash fund.

(b) *Deposit of funds in excess of the insured amount.*

(1) You are permitted to deposit funds in a federally insured institution in excess of the institution's insured amount, but only if the institution is "well capitalized" in accordance with the definition set forth in regulations of the Federal Deposit Insurance Corporation, as amended (12 CFR 325.103).

(2) Exception: You may make a temporary deposit (not to exceed 30 days) in excess of the insured amount, in a transfer account established to facilitate the receipt and disbursement of funds or to hold funds necessary to honor Commitments issued.

(c) *Deposit of funds in Associate institution.* A deposit in, or a repurchase agreement with, a federally insured institution that is your Associate is not considered a Financing of such Associate under § 108.730, provided the terms of such deposit or repurchase agreement are no less favorable than those available to the general public.

Borrowing by NMVC Companies From Non–SBA Sources

§ 108.550 Prior approval of secured third-party debt of NMVC companies.

(a) *Definition.* In this § 108.550, "secured third-party debt" means any non-SBA debt secured by any of your assets, including secured guarantees and other contingent obligations that you voluntarily assume and secured lines of credit.

(b) *General rule.* You must get SBA's written approval before you incur any secured third-party debt or refinance any debt with secured third-party debt, including any renewal of a secured line of credit, increase in the maximum amount available under a secured line of credit, or expansion of the scope of a security interest or lien. For purposes of this paragraph (b), "expansion of the scope of a security interest or lien" does not include the substitution of one asset or group of assets for another, provided the asset values (as reported on your most recent annual Form 468) are comparable.

(c) *Conditions for SBA approval.* As a condition of granting its approval under this § 108.550, SBA may impose such restrictions or limitations as it deems appropriate, taking into account your historical performance, current financial position, proposed terms of the secured debt and amount of aggregate debt you will have outstanding (including Leverage). SBA will not favorably consider any requests for approval which include a blanket lien on all your assets, or a security interest in your investor commitments in excess of 125 percent of the proposed borrowing.

(d) *Thirty-day approval.* Unless SBA notifies you otherwise within 30 days after it receives your request, you may consider your request automatically approved if:

(1) You are in regulatory compliance;

(2) The security interest in your assets is limited to either those assets being acquired with the borrowed funds or an asset coverage ratio of no more than 2:1;

(3) Your request is for approval of a secured line of credit that would not cause your total outstanding borrowings (not including Leverage) to exceed 50 percent of your Leverageable Capital.

Voluntary Decrease in Regulatory Capital

§ 108.585 Voluntary decrease in NMVC Company's Regulatory Capital.

You must obtain SBA's prior written approval to reduce your Regulatory Capital by more than two percent in any fiscal year. At all times, you must retain sufficient Regulatory Capital to meet the minimum capital requirements in the Act and § 108.210, and sufficient Leverageable Capital to avoid having excess Leverage in violation of section 355(d) of the Act.

Subpart H—Recordkeeping, Reporting, and Examination Requirements for NMVC Companies

Recordkeeping Requirements for NMVC Companies

§ 108.600 General requirement for NMVC Company to maintain and preserve records.

(a) *Maintaining your accounting records.* You must establish and maintain your accounting records using SBA's standard chart of accounts for SBICs, unless SBA approves otherwise.

(b) *Location of records.* You must keep the following records at your principal place of business or, in the case of paragraph (b)(3) of this section, at the branch office that is primarily responsible for the transaction.

(1) All your accounting and other financial records;

(2) All minutes of meetings of directors, stockholders, executive committees, partners, or other officials; and

(3) All documents and supporting materials related to your business transactions, except for any items held by a custodian under a written agreement between you and a Portfolio Concern or non-SBA lender, or any securities held in a safe deposit box, or by a licensed securities broker in an amount not exceeding the broker's per-account insurance coverage.

(c) *Preservation of records.* You must retain all the records that are the basis for your financial reports. Such records must be preserved for the periods specified in this paragraph (c), and must remain accessible for the first two years of the preservation period.

(1) You must preserve for at least 15 years or, in the case of a Partnership NMVC Company or LLC NMVC Company, at least two years beyond the date of liquidation:

(i) All your accounting ledgers and journals, and any other records of assets, asset valuations, liabilities, equity, income, and expenses.

(ii) Your Articles, bylaws, minute books, and NMVC Company application.

(iii) All documents evidencing ownership of the NMVC Company including ownership ledgers, and ownership transfer registers.

(2) You must preserve for at least six years all supporting documentation (such as vouchers, bank statements, or canceled checks) for the records listed in paragraph (b)(l) of this section.

(3) After final disposition of any item in your Portfolio, you must preserve for at least six years:

(i) Financing applications and Financing instruments.

(ii) All loan, participation, and escrow agreements.

(iii) Size status declarations (SBA Form 480).

(iv) Any capital stock certificates and warrants of the Portfolio Concern that you did not surrender or exercise.

(v) All other documents and supporting material relating to the Portfolio Concern, including correspondence.

(4) You may substitute a microfilm or computer-scanned or generated copy for the original of any record covered by this paragraph (c).

(d) *Additional requirement.* You must comply with the recordkeeping and record retention requirements set forth in Circular A–110 of the Office of Management and Budget.

§ 108.610 Required certifications for Loans and Investments.

For each of your Loans and Investments, you must have the documents listed in this section. You must keep these documents in your files and make them available to SBA upon request.

(a) SBA Form 480, the Size Status Declaration, executed both by you and by the concern you are financing. By executing this document, both parties certify that the concern is a Small Business. For securities purchased from an underwriter in a public offering, you may substitute a prospectus showing that the concern is a Small Business.

(b) SBA Form 652, a certification by the concern you are financing that it will not illegally discriminate (see part 112 of this chapter).

(c) A certification by the concern you are financing of the intended use of the proceeds. For securities purchased from an underwriter in a public offering, you may substitute a prospectus indicating the intended use of proceeds.

(d) For each Low-Income Investment, a certification by the concern you are financing as to the basis for its qualification as a Low-Income Enterprise.

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§ 108.620 Requirements to obtain information from Portfolio Concerns.

All the information required by this section is subject to the requirements of § 108.600 and must be in English.

(a) *Information for initial Financing decision.* Before extending any Financing, you must require the applicant to submit such financial statements, plans of operation (including intended use of financing proceeds), cash flow analyses, projections, and such community economic development information about the company, as are necessary to support your investment decision. The information submitted must be consistent with the size and type of the business and the amount of the proposed Financing.

(b) *Updated financial and community economic development information.*

(1) The terms of each Financing must require the Portfolio Concern to provide, at least annually, sufficient financial and community economic development information to enable you to perform the following required procedures:

(i) Evaluate the financial condition of the Portfolio Concern for the purpose of valuing your investment;

(ii) Determine the continued eligibility of the Portfolio Concern;

(iii) Verify the use of Financing proceeds; and

(iv) Evaluate the community economic development impact of the Financing.

(2) The president, chief executive officer, treasurer, chief financial officer, general partner, or proprietor of the Portfolio Concern must certify the information submitted to you.

(3) For financial and valuation purposes, you may accept a complete copy of the Federal income tax return filed by the Portfolio Concern (or its proprietor) in lieu of financial statements, but only if appropriate for the size and type of the business involved.

(4) The requirements in this paragraph (b) do not apply when you acquire securities from an underwriter in a public offering (see § 108.825). In that case, you must keep copies of all reports furnished by the Portfolio Concern to the holders of its securities.

(c) *Information required for examination purposes.* You must obtain any information requested by SBA's examiners for the purpose of verifying the certifications made by a Portfolio Concern under § 108.610. In this regard, your Financing documents must contain provisions requiring the Portfolio Concern to give you and/or SBA's examiners access to its books and records for such purpose.

Reporting Requirements For NMVC Companies

§ 108.630 Requirement for NMVC companies to file financial statements and supplementary information with SBA (SBA Form 468).

(a) *Annual filing of Form 468.* For each fiscal year, you must submit to SBA financial statements and supplementary information prepared on SBA Form 468. You must file Form 468 on or before the last day of the third month following the end of your fiscal year, except for the information required under paragraphs (e) and (f) of this section, which must be filed on or before the last day of the fifth month following the end of your fiscal year.

(1) *Audit of Form 468.* An independent public accountant acceptable to SBA must audit the annual Form 468.

(2) *Insurance requirement for public accountant.* Unless SBA approves otherwise, your independent public accountant must carry at least $1,000,000 of Errors and Omissions insurance, or be self-insured and have a net worth of at least $1,000,000.

(b) *Interim filings of Form 468.* When requested by SBA, you must file interim reports on Form 468. SBA may require you to file the entire form or only certain statements and schedules. You must file such reports on or before the last day of the month following the end of the reporting period. When you submit a request for a draw under an SBA Leverage commitment, you must also comply with any applicable filing requirements set forth in § 108.1220.

(c) *Standards for preparation of Form 468.* You must prepare SBA Form 468 in accordance with SBA's Accounting Standards and Financial Reporting Requirements for Small Business Investment Companies.

(d) *Where to file Form 468.* Submit all filings of Form 468 to the Office of New Markets Venture Capital in the Investment Division of SBA.

(e) *Reporting of social, economic, or community development impact information on Form 468.* Your annual filing of SBA Form 468 must include an assessment of the social, economic, or community development impact of each Financing. This assessment must specify the fulltime equivalent jobs created, the impact of the Financing on the revenues and profits of the business and on taxes paid by the business and its employees, and a listing of the number and percentage of employees who reside in LI Areas.

(f) *Reporting of community development information.* For each Financing of a Low-Income Enterprise, your Form 468 must include an assessment of such Financing with respect to:

(1) The social, economic or community development benefits achieved as a result of the Financing;

(2) How and to what extent such benefits fulfilled the goals of your comprehensive business plan and Participation Agreement;

(3) Whether you consider the Financing or the results of the Financing to have fulfilled the objectives of the NMVC program; and

(4) Whether, and if so, how you achieved accountability to the residents of the LI Area in connection with that Financing.

§ 108.640 Requirement to file portfolio financing reports (SBA Form 1031).

For each Financing you make (excluding guarantees), you must submit a Portfolio Financing Report on SBA Form 1031 within 30 days of the closing date.

§ 108.650 Requirement to report portfolio valuations to SBA.

You must determine the value of your Loans and Investments in accordance with § 108.503. You must report such valuations to SBA within 90 days of the end of the fiscal year in the case of annual valuations, and within 30 days following the close of other reporting periods. You must report material adverse changes in valuations at least quarterly, within thirty days following the close of the quarter.

§ 108.660 Other items required to be filed by NMVC Company with SBA.

(a) *Reports to owners.* You must give SBA a copy of any report you furnish to your investors, including any prospectus, letter, or other publication concerning your financial operations or those of any Portfolio Concern.

(b) *Documents filed with SEC.* You must give SBA a copy of any report, application or document you file with the Securities and Exchange Commission.

(c) *Litigation reports.* When you become a party to litigation or other proceedings, you must give SBA a report within 30 days that describes the proceedings and identifies the other parties involved and your relationship to them.

(1) The proceedings covered by this paragraph (c) include any action by you, or by your security holder(s) in a personal or derivative capacity, against an officer, director, Investment Adviser or other Associate of yours for alleged breach of official duty.

(2) SBA may require you to submit copies of the pleadings and other documents SBA may specify.

(3) Where proceedings have been terminated by settlement or final judgment, you must promptly advise SBA of the terms.

(4) This paragraph (c) does not apply to collection actions or proceedings to enforce your ordinary creditors' rights.

(d) *Notification of criminal charges.* If any officer, director, or general partner of the NMVC Company, or any other person who was required by SBA to complete a personal history statement, is charged with or convicted of any criminal offense other than a misdemeanor involving a minor motor vehicle violation, you must report the incident to SBA within 5 calendar days. Such report must fully describe the facts that pertain to the incident.

(e) *Reports concerning Operational Assistance grant funds.* You must comply with all reporting requirements set forth in Circular A–110 of the Office of Management and Budget and any grant award document executed between you and SBA.

(f) *Other reports.* You must file any other reports SBA may require in writing.

§ 108.680 Reporting changes in NMVC Company not subject to prior SBA approval.

(a) *Changes to be reported for post-approval.* This section applies to any changes in your Articles, ownership, capitalization, management, operating area, or investment policies that do not require SBA's prior approval. You must report such changes to SBA within 30 days for post approval.

(b) *Approval by SBA.* You may consider any change submitted under this section § 108.680 to be approved unless SBA notifies you to the contrary within 90 days after receiving it. SBA's approval is contingent upon your full disclosure of all relevant facts and is subject to any conditions SBA may prescribe.

Examinations of NMVC Companies by SBA for Regulatory Compliance

§ 108.690 Examinations.

All NMVC companies must submit to annual examinations by or at the direction of SBA for the purpose of evaluating regulatory compliance.

§ 108.691 Responsibilities of NMVC Company during examination.

You must make all books, records and other pertinent documents and materials available for the examination, including any information required by the examiner under § 108.620(c). In addition, the agreement between you and the independent public accountant performing your audit must provide that any information in the accountant's working papers be made available to SBA upon request.

§ 108.692 Examination fees.

(a) *General.* SBA will assess fees for examinations in accordance with this § 108.692. Unless SBA determines otherwise on a case by case basis, SBA will not assess fees for special examinations to obtain specific information.

(b) *Base fee.* A base fee of $3,500 will be assessed, subject to adjustment in accordance with paragraph (c) of this section.

(c) *Adjustments to base fee.* The base fee will be decreased based on the following criteria:

(1) If you have no outstanding regulatory violations at the time of the commencement of the examination and SBA did not identify any violations as a result of the most recent prior examination, you will receive a 15% discount on your base fee; and

(2) If you were fully responsive to the letter of notification of examination (that is, you provided all requested documents and information within the time period stipulated in the notification letter in a complete and accurate manner, and you prepared and had available all information requested by the examiner for on-site review), you will receive a 10% discount on your base fee.

(d) *Delay fee.* If, in the judgment of SBA, the time required to complete your examination is delayed due to your lack of cooperation or the condition of your records, SBA may assess an additional fee of up to $500 per day.

Subpart I—Financing of Small Businesses by NMVC Companies

Determining the Eligibility of a Small Business for NMVC Financing

§ 108.700 Compliance with size standards in part 121 of this chapter as a condition of Assistance.

You are permitted to provide financial assistance and management services only to a Small Business. To determine whether an applicant meets the size standards for a Small Business, you may use either the financial size standards in § 121.301(c)(1) of this chapter or the industry standard covering the industry in which the applicant is primarily engaged, as set forth in § 121.301(c)(2) of this chapter.

§ 108.710 Requirement to finance Low-Income Enterprises.

(a) *Low-Income Enterprise Financings.* At the close of each of your fiscal years, at least 80 percent of your Portfolio Concerns must be Low-Income Enterprises in which you have an Equity Capital Investment.

(b) *Non-compliance with this section.* If you have not reached the percentage required in paragraph (a) of this section at the end of any fiscal year, then you must be in compliance by the end of the following fiscal year. However, you will not be eligible for additional Leverage until such time as you reach the required percentage (see § 108.1120).

§ 108.720 Small Businesses that may be ineligible for financing.

(a) *Relenders or reinvestors.* You are not permitted to finance any business that is a relender or reinvestor. Relenders or reinvestors are businesses whose primary business activity involves, directly or indirectly, providing funds to others, purchasing debt obligations, factoring, or long-term leasing of equipment with no provision for maintenance or repair.

(b) *Passive Businesses.* You are not permitted to finance a passive business.

(1) *Definition.* A business is passive if:

(i) It is not engaged in a regular and continuous business operation (for purposes of this paragraph (b), the mere receipt of payments such as dividends, rents, lease payments, or royalties is not considered a regular and continuous business operation); or

(ii) Its employees are not carrying on the majority of day to day operations, and the company does not provide effective control and supervision, on a day to day basis, over persons employed under contract; or

(iii) It passes through substantially all of the proceeds of the Financing to another entity.

(2) *Exception for pass-through of proceeds to subsidiary.* You may finance a passive business if it is a Small Business and it passes substantially all the proceeds through to one or more subsidiary companies, each of which is an eligible Small Business that is not passive. For the purpose of this paragraph (b) (2), "subsidiary company" means a company in which at least 50 percent of the outstanding voting securities are owned by the Financed passive business.

(3) *Exception for certain Partnership NMVC companies.* With the prior written approval of SBA, if you are a Partnership NMVC Company, you may form one or more wholly owned corporations in accordance with this paragraph (b) (3). The sole purpose of

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such corporation(s) must be to provide Financing to one or more eligible, unincorporated Small Businesses. You may form such corporation(s) only if a direct Financing to such Small Businesses would cause any of your investors to incur unrelated business taxable income under section 511 of the Internal Revenue Code of 1986, as amended (26 U.S.C. 511). Your investment of funds in such corporation(s) will not constitute a violation of § 108.730(a).

(c) *Real Estate Businesses.*

(1) You are not permitted to finance:

(i) Any business classified under sector 233 (Building, Developing, and Contracting) of the NAICS Manual, or

(ii) Any business listed under sector 531 (Real Estate) unless at least 80 percent of the revenue is derived from non-Affiliate sources.

(2) You are not permitted to finance a business, regardless of NAICS classification, if the Financing is to be used to acquire or refinance real property, unless the Small Business:

(i) Is acquiring an existing property and will use at least 51 percent of the usable square footage for an eligible business purpose; or

(ii) Is building or renovating a building and will use at least 67 percent of the usable square footage for an eligible business purpose; or

(iii) Occupies the subject property and uses at least 67 percent of the usable square footage for an eligible business purpose.

(d) *Project Financing.* You are not permitted to finance a business if:

(1) The assets of the business are to be reduced or consumed, generally without replacement, as the life of the business progresses, and the nature of the business requires that a stream of cash payments be made to the business's financing sources, on a basis associated with the continuing sale of assets. Examples include real estate development projects and oil and gas wells; or

(2) The primary purpose of the Financing is to fund production of a single item or defined limited number of items, generally over a defined production period, and such production will constitute the majority of the activities of the Small Business. Examples include motion pictures and electric generating plants.

(e) *Farm land purchases.* You are not permitted to finance the acquisition of farmland. Farmland means land, which is or is intended to be used for agricultural or forestry purposes, such as the production of food, fiber, or wood, or is so taxed or zoned.

(f) *Public interest.* You are not permitted to finance any business if the proceeds are to be used for purposes contrary to the public interest, including but not limited to activities which are in violation of law, or inconsistent with free competitive enterprise.

(g) *Foreign investment.*—(1) *General rule.* You are not permitted to finance a business if:

(i) The funds will be used substantially for a foreign operation; or

(ii) At the time of the Financing or within one year thereafter, more than 49 percent of the employees or tangible assets of the Small Business are located outside the United States (unless you can show, to SBA's satisfaction, that the Financing was used for a specific domestic purpose).

(2) *Exception.* This paragraph (g) does not prohibit a Financing used to acquire foreign materials and equipment or foreign property rights for use or sale in the United States.

(h) *Financing NMVC companies.* You are not permitted to provide funds, directly or indirectly, that the Small Business will use:

(1) To purchase stock in or provide capital to a NMVC Company; or

(2) To repay an indebtedness incurred for the purpose of investing in a NMVC Company.

§ 108.730 Financings which constitute conflicts of interest.

(a) *General rule.* You must not self-deal to the prejudice of a Small Business, the NMVC Company, its shareholders or partners, or SBA. Unless you obtain a prior written exemption from SBA for special instances in which a Financing may further the purposes of the Act despite presenting a conflict of interest, you must not directly or indirectly:

(1) Provide Financing to any of your Associates, except for a Small Business that satisfies all of the following conditions:

(i) Your Associate relationship with the Small Business is described by paragraph (8) or (9) of the definition of Associate in § 108.50,

(ii) No Person triggering the Associate relationship identified in paragraph (a)(1)(i) of this section is a Close Relative or Secondary Relative of any Person described in paragraphs (1), (2), (4), or (5) of the definition of Associate in § 108.50, and

(iii) No single Associate of yours has either a voting interest or an economic interest in the Small Business exceeding 20 percent, and no two or more of your Associates have either a voting interest or an economic interest exceeding 33 percent. Economic interests shall be computed on a fully diluted basis, and both voting and economic interests shall exclude any interest owned through the NMVC Company.

(2) Provide Financing to an Associate of another NMVC Company if one of your Associates has received or will receive any direct or indirect Financing or a Commitment from that NMVC Company or a third NMVC Company (including Financing or Commitments received under any understanding, agreement, or cross dealing, reciprocal or circular arrangement).

(3) Borrow money from:

(i) A Small Business Financed by you;

(ii) An officer, director, or owner of at least a 10 percent equity interest in such business; or

(iii) A Close Relative of any such officer, director, or equity owner.

(4) Provide Financing to a Small Business to discharge an obligation to your Associate or free other funds to pay such obligation. This paragraph (a)(4) does not apply if the obligation is to an Associate Lending Institution and is a line of credit or other obligation incurred in the normal course of business.

(b) *Rules applicable to Associates.* Without SBA's prior written approval, your Associates must not, directly or indirectly:

(1) Borrow money from any Person described in paragraph (a)(3) of this section.

(2) Receive from a Small Business any compensation in connection with Assistance you provide (except as permitted under § 108.825(c)), or anything of value for procuring, attempting to procure, or influencing your action with respect to such Assistance.

(c) *Applicability of other laws.* You are also bound by any restrictions in Federal or State laws governing conflicts of interest and fiduciary obligations.

(d) *Financings with Associates—(1) Financings with Associates requiring prior approval.* Without SBA's prior written approval, you may not Finance any business in which your Associate has either a voting equity interest or total equity interests (including potential interests) of at least five percent, except as otherwise permitted under paragraph (a)(1) of this section.

(2) *Other Financings with Associates.* If you and an Associate provide Financing to the same Small Business, either at the same time or at different times, you must be able to demonstrate to SBA's satisfaction that the terms and conditions are (or were) fair and equitable to you, taking into account any differences in the timing of each party's financing transactions.

(3) *Exceptions to paragraphs (d)(1) and (d)(2) of this section.* A Financing that falls into one of the following categories is exempt from the prior approval requirement in paragraph (d)(1) of this section or is presumed to be fair and equitable to you for the purposes of paragraph (d)(2) of this section, as appropriate:

(i) Your Associate is a Lending Institution that is providing financing under a credit facility in order to meet the operational needs of the Small Business, and the terms of such financing are usual and customary.

(ii) Your Associate invests in the Small Business on the same terms and conditions and at the same time as you.

(iii) Both you and your Associate are NMVC companies.

(e) *Use of Associates to manage Portfolio Concerns.* To protect your investment, you may designate an Associate to serve as an officer, director, or other participant in the management of a Small Business. You must identify any such Associate in your records available for SBA's review under § 108.600. Without SBA's prior written approval, the Associate must not:

(1) Have any other direct or indirect financial interest in the Portfolio Concern that exceeds, or has the potential to exceed, the percentages of the Portfolio Concern's equity set forth in paragraph (a)(1) of this section.

(2) Receive any income or anything of value from the Portfolio Concern unless it is for your benefit, with the exception of director's fees, expenses, and distributions based upon the Associate's ownership interest in the Concern.

(f) *1940 and 1980 Act Companies: SEC exemptions.* If you are a 1940 or 1980 Act Company and you receive an exemption from the Securities and Exchange Commission for a transaction described in this § 108.730, you need not obtain SBA's approval of the transaction. However, you must promptly notify SBA of the transaction.

(g) *Restriction on options obtained by NMVC Company's management and employees.* Your employees, officers, directors, managing members or general partners, or the general partners of the management company that is providing services to you or to your general partner, may obtain options in a Financed Small Business only if:

(1) They participate in the Financing on a *pari passu* basis with you; or

(2) SBA gives its prior written approval; or

(3) The options received are compensation for service as a member of the board of directors of the Small Business, and such compensation does not exceed that paid to other outside directors. In the absence of such directors, fees must be reasonable when compared with amounts paid to outside directors of similar companies.

§ 108.740 Portfolio diversification ("overline" limitation).

(a) Without SBA's prior written approval, you may provide Financing or a Commitment to a Small Business only if the resulting amount of your aggregate outstanding Financings and Commitments to such Small Business and its Affiliates does not exceed 20 percent of the sum of:

(1) Your Regulatory Capital as of the date of the Financing or Commitment; plus

(2) Any permitted Distribution(s) you made during the five years preceding the date of the Financing or Commitment which reduced your Regulatory Capital.

(b) For the purposes of paragraph (a) of this section, you must measure each outstanding Financing at its current cost plus any amount of the Financing that was previously written off.

§ 108.760 How a change in size or activity of a Portfolio Concern affects the NMVC Company and the Portfolio Concern.

(a) *Effect on NMVC Company of a change in size of a Portfolio Concern.* If a Portfolio Concern no longer qualifies as a Small Business you may keep your investment in the concern and:

(1) Subject to the overline limitations of § 108.740, you may provide additional Financing to the concern up to the time it makes a public offering of its securities.

(2) Even after the concern makes a public offering, you may exercise any stock options, warrants, or other rights to purchase Equity Securities which you acquired before the public offering, or fund Commitments you made before the public offering.

(b) *Effect of a change in business activity occurring within one year of NMVC Company's initial Financing.*

(1) *Retention of Investment.* Unless you receive SBA's written approval, you may not keep your investment in a Portfolio Concern, small or otherwise, which becomes ineligible by reason of a change in its business activity within one year of your initial investment.

(2) *Request for SBA's approval to retain investment.* If you request that SBA approve the retention of your investment, your request must include sufficient evidence to demonstrate that the change in business activity was caused by an unforeseen change in circumstances and was not contemplated at the time the Financing was made.

(3) *Additional Financing.* If SBA approves your request to retain an investment under paragraph (b)(2) of this section, you may provide additional Financing to the Portfolio Concern to the extent necessary to protect against the loss of the amount of your original investment, subject to the overline limitations of § 108.740.

(c) *Effect of a change in business activity occurring more than one year after the initial Financing.* If a Portfolio Concern becomes ineligible because of a change in business activity more than one year after your initial Financing you may:

(1) Retain your investment: and

(2) Provide additional Financing to the Portfolio Concern to the extent necessary to protect against the loss of the amount of your original investment, subject to the overline limitations of § 108.740.

Structuring NMVC Company's Financing of Eligible Small Businesses

§ 108.800 Financings in the form of equity interests.

You may not, inadvertently or otherwise:

(a) Become a general partner in any unincorporated business; or

(b) Become jointly or severally liable for any obligations of an unincorporated business.

§ 108.820 Financings in the form of guarantees.

(a) *General rule.* At the request of a Small Business or where necessary to protect your existing investment, you may guarantee the monetary obligation of a Small Business to any non-Associate creditor.

(b) *Exception.* You may not issue a guaranty if:

(1) You would become subject to State regulation as an insurance, guaranty or surety business; or

(2) The amount of the guaranty plus any direct Financings to the Small Business exceed the overline limitations of § 108.740, except that a pledge of the Equity Securities of the issuer or a subordination of your lien or creditor position does not count toward your overline.

(c) *Pledge of NMVC Company's assets as guaranty.* For purposes of this section, a guaranty with recourse only to specific asset(s) you have pledged is equal to the fair market value of such asset(s) or the amount of the debt guaranteed, whichever is less.

§ 108.825 Purchasing securities from an underwriter or other third party.

(a) *Securities purchased through or from an underwriter.* You may purchase

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the securities of a Small Business through or from an underwriter if:

(1) You purchase such securities within 90 days of the date the public offering is first made;

(2) Your purchase price is no more than the original public offering price; and

(3) The amount paid by you for the securities (less ordinary and reasonable underwriting charges and commissions) has been, or will be, paid to the Small Business, and the underwriter certifies in writing that this requirement has been met.

(b) *Recordkeeping requirements.* You must keep records available for SBA's inspection which show the relevant details of the transaction, including, but not limited to, date, price, commissions, and the underwriter's certifications required under paragraph (c) of this section.

(c) *Underwriter's requirements.* The underwriter must certify whether it is your Associate. You may pay reasonable and customary commissions and expenses to an Associate underwriter for the portion of an offering that you purchase.

(d) *Securities purchased from another NMVC Company or from SBA.* You may purchase from, or exchange with, another NMVC Company, Portfolio securities (or any interest therein). Such purchase or exchange may only be made on a non-recourse basis. You may not have more than one-third of your total assets (valued at cost) invested in such securities. If you have previously sold Portfolio securities (or any interest therein) on a recourse basis, you shall include the amount for which you may be contingently liable in your overline computation.

(e) *Purchases of securities from other non-issuers.* You may purchase securities of a Small Business from a non-issuer not previously described in this § 108.825 if such acquisition is a reasonably necessary part of the overall sound Financing of the Small Business.

Limitations on Disposition of Assets

§ 108.885 Disposition of assets to NMVC Company's Associates.

Except with SBA's prior written approval, you are not permitted to dispose of assets (including assets acquired in liquidation) to any Associate. As a prerequisite to such approval, you must demonstrate that the proposed terms of disposal are at least as favorable to you as the terms obtainable elsewhere.

Subpart J—SBA Financial Assistance for NMVC Companies (Leverage)

General Information About Obtaining Leverage

§ 108.1100 Type of Leverage and application procedures.

(a) *Type of Leverage available.* You may apply for Leverage from SBA in the form of a guarantee of your Debentures.

(b) *Applying for Leverage.* The Leverage application process has two parts. You must first apply for SBA's conditional commitment to reserve a specific amount of Leverage for your future use. You may then apply to draw down Leverage against the commitment. See §§ 108.1200 through 108.1240.

(c) *Where to send your application.* Send all Leverage applications to SBA, Investment Division Office of New Markets Venture Capital, 409 Third Street, S.W., Washington, DC 20416.

§ 108.1120 General eligibility requirement for Leverage.

To be eligible for Leverage, you must be in compliance with the Act, the regulations in this part, and your Participation Agreement.

§ 108.1130 Leverage fees payable by NMVC Company.

There is no fee for the issuance of Debentures by a NMVC Company.

§ 108.1140 NMVC Company's acceptance of SBA remedies under § 108.1810.

If you issue Leverage, you automatically agree to the terms and conditions in § 108.1810 as it exists at the time of issuance. The effect of these terms and conditions is the same as if they were fully incorporated in the terms of your Leverage.

Maximum Amount of Leverage for Which a NMVC Company is Eligible

§ 108.1150 Maximum amount of Leverage for a NMVC Company.

The face amount of a NMVC Company's outstanding Debentures may not exceed 150 percent of its Leverageable Capital.

Conditional Commitments by SBA to Reserve Leverage for a NMVC Company

§ 108.1200 SBA's Leverage commitment to a NMVC Company—application procedure, amount, and term.

(a) *General.* Under the provisions in §§ 108.1200 through 108.1240, you may apply for SBA's conditional commitment to reserve a specific amount and type of Leverage for your future use. You may then apply to draw down Leverage against the commitment.

(b) *Applying for a Leverage commitment.* SBA will notify you when it is accepting requests for Leverage commitments. Upon receipt of your request, SBA will send you a complete application package.

(c) *Limitations on the amount of a Leverage commitment.* The amount of a Leverage commitment must be a multiple of $5,000. SBA, in its discretion, may determine a minimum dollar amount for Leverage commitments. Any such minimum amounts will be published in Notices in the **Federal Register** from time to time.

(d) *Term of Leverage commitment.* SBA's Leverage commitment will automatically lapse on the expiration date stated in the commitment letter issued to you by SBA.

§ 108.1220 Requirement for NMVC Company to file financial statements at the time of request for a draw.

(a) If you submit a request for a draw against SBA's Leverage commitment more than 90 days since your submission of an annual Form 468 or a Form 468 (Short Form), you must:

(1) Give SBA a financial statement on Form 468 (Short Form), and

(2) File a statement of no material adverse change in your financial condition since your last filing of Form 468.

(b) You will not be eligible for a draw if you are not in compliance with this § 108.1220.

§ 108.1230 Draw-downs by NMVC Company under SBA's Leverage commitment.

(a) *NMVC Company's authorization of SBA to guarantee securities.* By submitting a request for a draw against SBA's Leverage commitment, you authorize SBA, or any agent or trustee SBA designates, to guarantee your Debenture and to sell it with SBA's guarantee.

(b) *Limitations on amount of draw.* The amount of a draw must be a multiple of $5,000. SBA, in its discretion, may determine a minimum dollar amount for draws against SBA's Leverage commitments. Any such minimum amounts will be published in Notices in the **Federal Register** from time to time.

(c) *Effect of regulatory violations on NMVC Company's eligibility for draws.*

(1) *General rule.* You are eligible to make a draw against SBA's Leverage commitment only if you are in compliance with all applicable provisions of the Act and SBA regulations (i.e., no unresolved statutory or regulatory violations) and your Participation Agreement.

(2) *Exception to general rule.* If you are not in compliance, you may still be eligible for draws if:

(i) SBA determines that your outstanding violations are of non-substantive provisions of the Act or regulations or your Participation Agreement and that you have not repeatedly violated any non-substantive provisions; or

(ii) You have agreed with SBA on a course of action to resolve your violations and such agreement does not prevent you from issuing Leverage.

(d) *Procedures for funding draws.* You may request a draw at any time during the term of the commitment. With each request, submit the following documentation:

(1) A statement certifying that there has been no material adverse change in your financial condition since your last filing of SBA Form 468 (see also § 108.1220 for SBA Form 468 filing requirements).

(2) If your request is submitted more than 30 days following the end of your fiscal year, but before you have submitted your annual filing of SBA Form 468 (Long Form) in accordance with § 108.630(a), a preliminary unaudited annual financial statement on SBA Form 468 (Short Form).

(3) A statement certifying that to the best of your knowledge and belief, you are in compliance with all provisions of the Act and SBA regulations (i.e., no unresolved regulatory or statutory violations) and your Participation Agreement, or a statement listing any specific violations you are aware of. Either statement must be executed by one of the following:

(i) An officer of the NMVC Company;

(ii) An officer of a corporate general partner of the NMVC Company; or

(iii) An individual who is authorized to act as or for a general partner of the NMVC Company.

(4) A statement that the proceeds are needed to fund one or more particular Small Businesses or to provide liquidity for your operations. If required by SBA, the statement must include the name and address of each Small Business, and the amount and anticipated closing date of each proposed Financing.

(e) *Reporting requirements after drawing funds.*

(1) Within 30 calendar days after the actual closing date of each Financing funded with the proceeds of your draw, you must file an SBA Form 1031 confirming the closing of the transaction.

(2) If SBA required you to provide information concerning a specific planned Financing under paragraph (d)(3) of this section, and such Financing has not closed within 60 calendar days after the anticipated closing date, you must give SBA a written explanation of the failure to close.

(3) If you do not comply with this paragraph (e), you will not be eligible for additional draws. SBA may also determine that you are not in compliance with the terms of your Leverage under §§ 108.1810.

§ 108.1240 Funding of NMVC Company's draw request through sale to third-party.

(a) *NMVC Company's authorization of SBA to arrange sale of securities to third-party.* By submitting a request for a draw of Debenture Leverage, you authorize SBA, or any agent or trustee SBA designates, to enter into any agreements (and to bind you to such agreements) necessary to accomplish:

(1) The sale of your Debenture to a third-party at a rate approved by SBA; and

(2) The purchase of your security from the third-party and the pooling of your security with other securities with the same maturity date.

(b) *Sale of Debentures to a third-party.* If SBA arranges for the sale of your Debenture to a third-party, the sale price may be an amount discounted from the face amount of the Debenture.

Funding Leverage by Use of SBA Guaranteed Trust Certificates ("TCs")

§ 108.1600 SBA authority to issue and guarantee Trust Certificates.

(a) *Authorization.* Section 356 of the Act authorizes SBA to issue TCs and to guarantee the timely payment of the principal and interest thereon. Any guarantee by SBA of such TC is limited to the principal and interest due on the Debentures in any Trust or Pool backing such TC. The full faith and credit of the United States is pledged to the payment of all amounts due under the guarantee of any TC.

(b) *SBA authority to arrange public or private fundings of Leverage.* SBA in its discretion may arrange for public or private financing under its guarantee authority. Such financing arranged by SBA may be accomplished by the sale of individual Debentures, aggregations of Debentures, or Pools or Trusts of Debentures.

(c) *Pass-through provisions.* TCs shall provide for a pass-through to their holders of all amounts of principal and interest paid on the Debentures in the Pool or Trust against which they are issued.

(d) *Formation of a Pool or Trust holding Leverage Securities.* SBA shall approve the formation of each Pool or Trust. SBA may, in its discretion, establish the size of the Pools and their composition, the interest rate on the TCs issued against Trusts or Pools, fees, discounts, premiums and other charges made in connection with the Pools, Trusts, and TCs, and any other characteristics of a Pool or Trust it deems appropriate.

§ 108.1610 Effect of prepayment or early redemption of Leverage on a Trust Certificate.

(a) The rights, if any, of a NMVC Company to prepay any Debenture is established by the terms of such security, and no such right is created or denied by the regulations in this part.

(b) SBA's rights to purchase or prepay any Debenture without premium are established by the terms of the Guaranty Agreement relating to the Debenture.

(c) Any prepayment of a Debenture pursuant to the terms of the Guaranty Agreement relating to such security shall reduce the SBA guarantee of timely payment of principal and interest on a TC in proportion to the amount of principal that such prepaid Debenture represents in the Trust or Pool backing such TC.

(d) SBA shall be discharged from its guarantee obligation to the holder or holders of any TC, or any successor or transferee of such holder, to the extent of any such prepayment, whether or not such successor or transferee shall have notice of any such prepayment.

(e) Interest on prepaid Debentures shall accrue only through the date of prepayment.

(f) In the event that all Debentures constituting a Trust or Pool are prepaid, the TCs backed by such Trust or Pool shall be redeemed by payment of the unpaid principal and interest on the TCs; provided, however, that in the case of the prepayment of a Debenture pursuant to the provisions of the Guaranty Agreement relating to the Debenture, the CRA shall pass through pro rata to the holders of the TCs any such prepayments including any prepayment penalty paid by the obligor NMVC Company pursuant to the terms of the Debenture.

§ 108.1620 Functions of agents, including Central Registration Agent, Selling Agent and Fiscal Agent.

(a) *Agents.* SBA may appoint or cause to be appointed agent(s) to perform functions necessary to market and service Debentures or TCs pursuant to this part.

(1) *Selling Agent.* As a condition of guaranteeing a Debenture, SBA may cause each NMVC Company to appoint a Selling Agent to perform functions that include, but are not limited to:

(i) Selecting qualified entities to become pool or Trust assemblers ("Poolers").

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(ii) Receiving guaranteed Debentures as well as negotiating the terms and conditions of sales or periodic offerings of Debentures and/ or TCs on behalf of NMVC companies.

(iii) Directing and coordinating periodic sales of Debentures and/or TCs.

(iv) Arranging for the production of Offering Circulars, certificates, and such other documents as may be required from time to time.

(2) *Fiscal Agent.* SBA shall appoint a Fiscal Agent to:

(i) Establish performance criteria for Poolers.

(ii) Monitor and evaluate the financial markets to determine those factors that will minimize or reduce the cost of funding Debentures.

(iii) Monitor the performance of the Selling Agent, Poolers, CRA, and the Trustee.

(iv) Perform such other functions as SBA, from time to time, may prescribe.

(3) *Central Registration Agent.* Pursuant to a contract entered into with SBA, the CRA, as SBA's agent, will do the following with respect to the Pools or Trust Certificates for the Debentures:

(i) Form an SBA-approved Pool or Trust

(ii) Issue the TCs in the form prescribed by SBA;

(iii) Transfer the TCs upon the sale of original issue TCs in any secondary market transaction;

(iv) Receive payments from NMVC companies;

(v) Make periodic payments as scheduled or required by the terms of the TCs, and pay all amounts required to be paid upon prepayment of Debentures;

(vi) Hold, safeguard, and release all Debentures constituting Trusts or Pools upon instructions from SBA;

(vii) Remain custodian of such other documentation as SBA shall direct by written instructions;

(viii) Provide for the registration of all pooled Debentures, all Pools and Trusts, and all TCs;

(ix) Perform such other functions as SBA may deem necessary to implement the provisions of this section.

(b) *Functions.* Either SBA or an agent appointed by SBA may perform the function of locating purchasers, and negotiating and closing the sale of Debentures and TCs. Nothing in the regulations in this part shall be interpreted to prevent the CRA from acting as SBA's agent for this purpose.

§ 108.1630 SBA regulation of Brokers and Dealers and disclosure to purchasers of Leverage or Trust Certificates.

(a) *Brokers and Dealers.* Each broker, dealer, and Pool or Trust assembler approved by SBA pursuant to these regulations shall either be regulated by a Federal financial regulatory agency, or be a member of the National Association of Securities Dealers (NASD), and shall be in good standing in respect to compliance with the financial, ethical, and reporting requirements of such body. They also shall be in good standing with SBA as determined by the SBA Associate Administrator for Investment (see paragraph (c) of this section) and shall provide a fidelity bond or insurance in such amount as SBA may require.

(b) *Suspension and/or termination of Broker or Dealer.* SBA shall exclude from the sale and all other dealings in Debentures or TCs any broker or dealer:

(1) If such broker's or dealer's authority to engage in the securities business has been revoked or suspended by a supervisory agency. When such authority has been suspended, SBA will suspend such broker or dealer for the duration of such suspension by the supervisory agency.

(2) If such broker or dealer has been indicted or otherwise formally charged with a misdemeanor or felony bearing on its fitness, such broker or dealer may be suspended while the charge is pending. Upon conviction, participation may be terminated.

(3) If such broker or dealer has suffered an adverse final civil judgment holding that such broker or dealer has committed a breach of trust or violation of law or regulation protecting the integrity of business transactions or relationships, participation in the market for Debentures or TCs may be terminated.

(c) *Termination/suspension proceedings.* A broker's or dealer's participation in the market for Debentures or TCs will be conducted in accordance with part 134 of this chapter. SBA may, for any of the reasons stated in paragraphs (b) (1) through (b)(3) of this section, suspend the privilege of any broker or dealer to participate in this market. SBA shall give written notice at least ten (10) business days prior to the effective date of such suspension. Such notice shall inform the broker or dealer of the opportunity for a hearing pursuant to part 134 of this chapter.

§ 108.1640 SBA access to records of the CRA, Brokers, Dealers and Pool or Trust assemblers.

The CRA and any broker, dealer and Pool or Trust assembler operating under the regulations in this part shall make all books, records and related materials associated with Debentures and TCs available to SBA for review and copying purposes. Such access shall be at such party's primary place of business during normal business hours.

Miscellaneous

§ 108.1700 Transfer by SBA of its interest in a NMVC Company's Leverage security.

Upon such conditions and for such consideration as it deems reasonable, SBA may sell, assign, transfer, or otherwise dispose of any Debenture held by or on behalf of SBA. Upon notice by SBA, a NMVC Company will make all payments of principal and interest as shall be directed by SBA. A NMVC Company will be liable for all damage or loss which SBA may sustain by reason of such disposal, up to the amount of the NMVC Company's liability under such security, plus court costs and reasonable attorney's fees incurred by SBA.

§ 108.1710 SBA authority to collect or compromise its claims.

SBA may, upon such conditions and for such consideration as it deems reasonable, collect or compromise all claims relating to obligations held or guaranteed by SBA, and all legal or equitable rights accruing to SBA.

§ 108.1720 Characteristics of SBA's guarantee.

If SBA agrees to guarantee a NMVC Company's Debentures, such guarantee will be unconditional, irrespective of the validity, regularity or enforceability of the Debentures or any other circumstances that might constitute a legal or equitable discharge or defense of a guarantor. Pursuant to its guarantee, SBA will make timely payments of principal and interest on the Debentures.

Subpart K—NMVC Company's Noncompliance With Terms of Leverage

§ 108.1810 Events of default and SBA's remedies for NMVC Company's noncompliance with terms of Debentures.

(a) *Applicability of this section.* By issuing Debentures, you automatically agree to the terms, conditions and remedies in this section, as in effect at the time of issuance and as if fully set forth in the Debentures.

(b) *Automatic events of default.* The occurrence of one or more of the events in this paragraph (b) causes the remedies in paragraph (c) of this section to take effect immediately.

(1) *Insolvency.* You become equitably or legally insolvent.

(2) *Voluntary assignment.* You make a voluntary assignment for the benefit of creditors without SBA's prior written approval.

(3) *Bankruptcy.* You file a petition to begin any bankruptcy or reorganization proceeding, receivership, dissolution or other similar creditors' rights proceeding, or such action is initiated against you and is not dismissed within 60 days.

(c) *SBA remedies for automatic events of default.* Upon the occurrence of one or more of the events in paragraph (b) of this section:

(1) Without notice, presentation or demand, the entire indebtedness evidenced by your Debentures, including accrued interest, and any other amounts owed SBA with respect to your Debentures, is immediately due and payable; and

(2) You automatically consent to the appointment of SBA or its designee as your receiver under section 363(c) of the Act.

(d) *Events of default with notice.* For any occurrence (as determined by SBA) of one or more of the events in this paragraph (d), SBA may avail itself of one or more of the remedies in paragraph (e) of this section.

(1) *Fraud.* You commit a fraudulent act that causes detriment to SBA's position as a creditor or guarantor.

(2) *Fraudulent transfers.* You make any transfer or incur any obligation that is fraudulent under the terms of 11 U.S.C. 548.

(3) *Willful conflicts of interest.* You willfully violate § 108.730.

(4) *Willful non-compliance.* You willfully violate one or more of the substantive provisions of the Act or any substantive regulation promulgated under the Act or any substantive provision of your Participation Agreement.

(5) *Repeated Events of Default.* At any time after being notified by SBA of the occurrence of an event of default under paragraph (f) of this section, you engage in similar behavior that results in another occurrence of the same event of default.

(6) *Transfer of Control.* You willfully violate § 108.410, and as a result of such violation you undergo a transfer of Control.

(7) *Non-cooperation under § 108.1810(h).* You fail to take appropriate steps, satisfactory to SBA, to accomplish any action SBA may have required under paragraph (h) of this section.

(8) *Non-notification of Events of Default.* You fail to notify SBA as soon as you know or reasonably should have known that any event of default exists under this section.

(9) *Non-notification of defaults to others.* You fail to notify SBA in writing within ten days from the date of a declaration of an event of default or nonperformance under any note, debenture or indebtedness of yours, issued to or held by anyone other than SBA.

(e) *SBA remedies for events of default with notice.* Upon written notice to you of the occurrence (as determined by SBA) of one or more of the events in paragraph (d) of this section:

(1) SBA may declare the entire indebtedness evidenced by your Debentures, including accrued interest and/or any other amounts owed SBA with respect to your Debentures, immediately due and payable: and

(2) SBA may avail itself of any remedy available under the Act, specifically including institution of proceedings for the appointment of SBA or its designee as your receiver under section 363 (c) of the Act.

(f) *Events of default with opportunity to cure.* For any occurrence (as determined by SBA) of one or more of the events in this paragraph (f), SBA may avail itself of one or more of the remedies in paragraph (g) of this section.

(1) *Excessive Management Expenses.* Without the prior written consent of SBA, you incur Management Expenses in excess of those permitted under §§ 108.510 and 108.520.

(2) *Improper Distributions.* You make any Distribution to your shareholders or partners, except with the prior written consent of SBA, other than:

(i) Distributions permitted under § 108.585; and

(ii) Payments from Retained Earnings Available for Distribution based on either the shareholders' pro-rata interests or the provisions for profit distributions in your partnership agreement, as appropriate.

(3) *Failure to make payment.* Unless otherwise approved by SBA, you fail to make timely payment of any amount due under any security or obligation of yours that is issued to, held or guaranteed by SBA.

(4) *Failure to maintain Regulatory Capital.* You fail to maintain the minimum Regulatory Capital required under these regulations or, without the prior written consent of SBA, you reduce your Regulatory Capital except as permitted by § 108.585.

(5) *Capital Impairment.* You have a condition of Capital Impairment as determined under § 108.1830.

(6) *Cross-default.* An obligation of yours that is greater than $100,000 becomes due or payable (with or without notice) before its stated maturity date, for any reason including your failure to pay any amount when due. This provision does not apply if you pay the amount due within any applicable grace period or contest the payment of the obligation in good faith by appropriate proceedings.

(7) *Nonperformance.* You violate or fail to perform one or more of the terms and conditions of any security or obligation of yours that is issued to, held or guaranteed by SBA, or of any agreement (including your Participation Agreement) with or conditions imposed by SBA in its administration of the Act and the regulations promulgated under the Act.

(8) *Noncompliance.* Except as otherwise provided in paragraph (d)(5) of this section, SBA determines that you have violated one or more of the substantive provisions of the Act or any substantive regulation promulgated under the Act.

(9) *Failure to maintain diversity.* You fail to maintain diversity between management and ownership as required by § 108.150.

(g) *SBA remedies for events of default with opportunity to cure.*

(1) Upon written notice to you of the occurrence (as determined by SBA) of one or more of the events of default in paragraph (f) of this section, and subject to the conditions in paragraph (g)(2) of this section:

(i) SBA may declare the entire indebtedness evidenced by your Debentures, including accrued interest, and/or any other amounts owed SBA with respect to your Debentures, immediately due and payable; and

(ii) SBA may avail itself of any remedy available under the Act, specifically including institution of proceedings for the appointment of SBA or its designee as your receiver under section 363(c) of the Act.

(2) SBA may invoke the remedies in paragraph (g)(1) of this section only if:

(i) It has given you at least 15 days to cure the default(s); and

(ii) You fail to cure the default(s) to SBA's satisfaction within the allotted time.

(h) *Repeated non-substantive violations.* If you repeatedly fail to comply with one or more of the non-substantive provisions of the Act or any non-substantive regulation promulgated under the Act, SBA, after written notification to you and until you cure such condition to SBA's satisfaction, may deny you additional Leverage and/ or require you to take such actions as SBA may determine to be appropriate under the circumstances.

(i) *Consent to removal of officers, directors, or general partners and/or appointment of receiver.* The Articles of each NMVC Company must include the following provisions as a condition to

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the purchase or guarantee by SBA of Leverage. Upon the occurrence of any of the events specified in paragraphs (d)(1) through (d)(6) or (f)(1) through (f)(3) of this section as determined by SBA, SBA shall have the right, and you consent to SBA's exercise of such right:

(1) With respect to a Corporate NMVC Company, upon written notice, to require you to replace, with individuals approved by SBA, one or more of your officers and/or such number of directors of your board of directors as is sufficient to constitute a majority of such board; or

(2) With respect to a Partnership NMVC Company or an LLC NMVC Company, upon written notice, to require you to remove the person(s) responsible for such occurrence and/or to remove the general partner or manager of the NMVC Company, which general partner or manager shall then be replaced in accordance with NMVC Company's Articles by a new general partner or manager approved by SBA; and/or

(3) With respect to a Corporate or Partnership or LLC NMVC Company, to obtain the appointment of SBA or its designee as your receiver under section 363(c) of the Act for the purpose of continuing your operations. The appointment of a receiver to liquidate a NMVC Company is not within such consent, but is governed instead by the relevant provisions of the Act.

Computation of NMVC Company's Capital Impairment

§ 108.1830 NMVC Company's Capital Impairment definition and general requirements.

(a) *Significance of Capital Impairment condition.* If you have a condition of Capital Impairment, you are not in compliance with the terms of your Leverage. As a result, SBA has the right to impose the applicable remedies for noncompliance in § 108.1810(g).

(b) *Definition of Capital Impairment condition.* You have a condition of Capital Impairment if your Capital Impairment Percentage, as computed in § 108.1840, exceeds 70 percent.

(c) *Quarterly computation requirement and procedure.* You must determine whether you have a condition of Capital Impairment as of the end of each fiscal quarter. You must notify SBA promptly if you are capitally impaired.

(d) *SBA's right to determine NMVC Company's Capital Impairment condition.* SBA may make its own determination of your Capital Impairment condition at any time.

§ 108.1840 Computation of NMVC Company's Capital Impairment Percentage.

(a) *General.* This section contains the procedures you must use to determine your Capital Impairment Percentage. You must compare your Capital Impairment Percentage to the maximum permitted under § 108.1830(b) to determine whether you have a condition of Capital Impairment.

(b) *Preliminary impairment test.* If you satisfy the preliminary impairment test, your Capital Impairment Percentage is zero and you do not have to perform any more procedures in this § 108.1840. Otherwise, you must continue with paragraph (c) of this section. You satisfy the test if the following amounts are both zero or greater:

(1) The sum of Undistributed Net Realized Earnings, as reported on SBA Form 468, and Includible Non-Cash Gains.

(2) Unrealized Gain (Loss) on Securities Held.

(c) *How to compute your Capital Impairment Percentage.*

(1) If you have an Unrealized Gain on Securities Held, compute your Adjusted Unrealized Gain using paragraph (d) of this section. If you have an Unrealized Loss on Securities Held, continue with paragraph (c)(2) of this section.

(2) Add together your Undistributed Net Realized Earnings, your Includible Non-cash Gains, and either your Unrealized Loss on Securities Held or your Adjusted Unrealized Gain.

(3) If the sum in paragraph (c)(2) of this section is zero or greater, your Capital Impairment Percentage is zero.

(4) If the sum in paragraph (c)(2) of this section is less than zero, drop the negative sign, divide by your Regulatory Capital (excluding Treasury Stock), and multiply by 100. The result is your Capital Impairment Percentage.

(d) *How to compute your Adjusted Unrealized Gain.*

(1) Subtract Unrealized Depreciation from Unrealized Appreciation. This is your "Net Appreciation".

(2) Determine your Unrealized Appreciation on Publicly Traded and Marketable securities. This is your "Class I Appreciation".

(3) Determine your Unrealized Appreciation on securities that are not Publicly Traded and Marketable and meet the following criteria, which must be substantiated to the satisfaction of SBA (this is your "Class 2 Appreciation"):

(i) The Small Business that issued the security received a significant subsequent equity financing by an investor whose objectives were not primarily strategic and at a price that conclusively supports the Unrealized Appreciation;

(ii) Such financing represents a substantial investment in the form of an arm's length transaction by a sophisticated new investor in the issuer's securities; and

(iii) Such financing occurred within 24 months of the date of the Capital Impairment computation, or the Small Business' pre-tax cash flow from operations for its most recent fiscal year was at least 10 percent of the Small Business' average contributed capital for such fiscal year.

(4) Perform the appropriate computation from the table in § 107.1840(d)(4).

(5) Reduce the gain computed in paragraph (d) (4) of this section by your estimate of related future income tax expense. Subject to any adjustment required by paragraph (d)(6) of this section, the result is your Adjusted Unrealized Gain for use in paragraph (c)(2) of this section.

(6) If any securities that are the source of either Class 1 or Class 2 Appreciation are pledged or encumbered in any way, you must reduce the Adjusted Unrealized Gain computed in paragraph (d)(5) of this section by the amount of the related borrowing or other obligation, up to the amount of the Unrealized Appreciation on the securities.

Subpart L—Ending Operations as a NMVC Company

§ 108.1900 Termination of participation as a NMVC Company.

You may not terminate your participation as a NMVC Company without SBA's prior written approval. Your request for approval must be accompanied by an offer of immediate repayment of all of your outstanding Leverage (including any prepayment penalties thereon), or by a plan satisfactory to SBA for the orderly liquidation of the NMVC Company.

Subpart M—Miscellaneous

§ 108.1910 Non-waiver of SBA's rights or terms of Leverage security.

SBA's failure to exercise or delay in exercising any right or remedy under the Act or the regulations in this part does not constitute a waiver of such right or remedy. SBA's failure to require you to perform any term or provision of your Leverage does not affect SBA's right to enforce such term or provision. Similarly, SBA's waiver of, or failure to enforce, any term or provision of your Leverage or of any event or condition set forth in § 108.1810 does not constitute a waiver of any succeeding breach of such term or provision or condition.

§ 108.1920 NMVC Company's application for exemption from a regulation in this part 108.

(a) *General.* You may file an application in writing with SBA to have a proposed action exempted from any procedural or substantive requirement, restriction, or prohibition to which it is subject under this part, unless the provision is mandated by the Act. SBA may grant an exemption for such applicant, conditionally or unconditionally, provided the exemption would not be contrary to the purposes of the Act.

(b) *Contents of application.* Your application must be accompanied by supporting evidence that demonstrates to SBA's satisfaction that:

(1) The proposed action is fair and equitable; and

(2) The exemption requested is reasonably calculated to advance the best interests of the NMVC program in a manner consistent with the policy objectives of the Act and the regulations in this part.

§ 108.1930 Effect of changes in this part 108 on transactions previously consummated.

The legality of a transaction covered by the regulations in this part is governed by the regulations in this part in effect at the time the transaction was consummated, regardless of later changes. Nothing in this part bars SBA enforcement action with respect to any transaction consummated in violation of provisions applicable at the time, but no longer in effect.

§ 108.1940 Procedures for designation of additional Low-Income Geographic Areas.

(a) *General.* On its own initiative or upon written request by a Person which addresses the relevant factor(s) set forth in paragraph (b) of this section, SBA may consider whether to designate additional census tracts (or equivalent county divisions) as LI Areas.

(b) *Criteria.* SBA will consider one or more of the following factors in determining whether to designate a particular census tract (or equivalent county division) as an additional LI Area:

(1) A substantial number of Low-Income Individuals reside in that census tract (or equivalent county division).

(2) As adequately supported by studies or other analyses or reliable data, that census tract (or equivalent county division) has a pattern of unmet needs for investment capital.

(3) As adequately supported by studies or other analyses or reliable data, that census tract (or equivalent county division) has indications of economic distress.

(c) *Procedure for designation.* (1) If SBA decides to consider the designation of an additional LI Area, SBA will publish in the **Federal Register** a notice that it is considering such designation. SBA will advise the public that it will consider any comments supporting or opposing the designation, submitted within a specified time period.

(2) In making a final decision on whether to designate a particular census tract (or equivalent county division) as an additional LI Area, SBA will consider evidence submitted by any requester, SBA's own research, any public comments submitted, and any other information deemed relevant by SBA.

(3) If SBA designates a particular census tract (or equivalent county division) as an additional LI Area, SBA will publish a notice in the **Federal Register** and, if appropriate, will amend this part 108 to include the additional LI Area.

Subpart O—Requirements and Procedures for Operational Assistance Grants to NMVC Companies and SSBICs

§ 108.2000 Operational Assistance Grants to NMVC Companies and SSBICs.

(a) *NMVC Companies.* Regulations governing Operational Assistance grants to NMVC Companies may be found in subparts D and E of this part 108.

(b) *SSBICs.*—(1) *Notice of Funds Availability ("NOFA").* SBA will publish a NOFA in the **Federal Register**, advising SSBICs of the availability of funds for Operational Assistance grants to SSBICs. This NOFA will be the same as the NOFA described in § 108.300(a), or will be published simultaneously with that NOFA. An SSBIC may submit an application for an Operational Assistance grant only during the time period specified for such purpose in the NOFA.

(2) *Eligibility.* An SSBIC is eligible to apply for an Operational Assistance grant if:

(i) It intends to increase its Regulatory Capital, as in effect on December 21, 2000, and to make Low-Income Investments in the amount of such increase;

(ii) It intends to raise binding commitments for contributions in cash or in-kind, and/or to purchase an annuity, in an amount not less than 30 percent of the intended increase in its Regulatory Capital described in paragraph (b)(2)(i) of this section; and

(iii) It has a plan describing how it intends to use the requested grant funds to provide Operational Assistance to Smaller Enterprises in which it has made or expects to make Developmental Venture Capital Investments.

(3) *How to Apply.* An SSBIC must apply for an Operational Assistance grant using the application packet provided by SBA. Upon receipt of an application, SBA may request clarifying or technical information on the materials submitted as part of the application.

(4) *Contents of Application.* Each application must contain the information specified in the application packet provided by SBA, including the following information:

(i) *Amounts.* An SSBIC must specify the amount of Operational Assistance grant funds it seeks from SBA and the amount of Regulatory Capital it intends to raise after December 21, 2000.

(ii) *Plan.* An SSBIC must submit a plan addressing the following issues:

(A) The SSBIC must describe how it plans to use its grant funds to provide Operational Assistance to Smaller Enterprises in which it will make Developmental Venture Capital investments. Its plan must address the types of Operational Assistance it proposes to provide, and whether and to what extent it intends to provide the Operational Assistance through the use of licensed professionals, either from its own staff or from outside entities.

(B) The SSBIC must include a detailed description of how it plans to obtain binding commitments for contributions in cash or in-kind, and/or to purchase an annuity, to match the funds requested from SBA for the SSBIC's Operational Assistance grant. If it proposes to obtain commitments for cash or in-kind contributions, it also must estimate the ratio of cash to in-kind contributions (in no event may in-kind contributions exceed 50 percent of the total contributions). The SSBIC must discuss its potential sources of matching resources, the estimated timing on raising such match, and the extent of the expressions of interest to commit such match to the SSBIC.

(C) The SSBIC must describe the amount of Low-Income Investments it intends to make.

(5) *Evaluation and selection.* SBA's evaluation and selection process is intended to ensure that SSBIC requests are evaluated on a competitive basis and in a fair and consistent manner. SBA will evaluate and select SSBICs for an Operational Assistance grant award solely at SBA's discretion, by considering the following criteria:

(A) The strength of the SSBIC's application, including the strength of its proposal to provide Operational

Assistance to Smaller Enterprises in which it intends to invest;

(B) The SSBIC's regulatory compliance status; and

(C) The likelihood that and the time frame within which the SSBIC will be able to raise and obtain the matching resources described in paragraph (b)(4)(B) of this section.

(6) *Grant award.* An SSBIC selected for an Operational Assistance grant award will receive a grant award only if it increases its Regulatory Capital and raises the matching resources required in § 108.2030 by a date established by SBA.

§ 108.2010 Restrictions on use of Operational Assistance grant funds.

(a) *Restrictions applicable only to SSBICs.* An SSBIC that receives an Operational Assistance grant must use both grant funds awarded by SBA and its matching resources only to provide Operational Assistance in connection with a Low-Income Investment made by the SSBIC with Regulatory Capital raised after December 21, 2000.

(b) *Restrictions applicable to NMVC Companies and SSBICs.* A NMVC Company or a SSBIC that receives an Operational Assistance grant must not use either grant funds awarded by SBA or its matching resources for "general and administrative expense," as defined in the Federal Acquisition Regulations, "Contract Cost Principles and Procedures," 48 CFR 31.001.

§ 108.2020 Amount of Operational Assistance grant.

(a) *Amount of grant to NMVC Company.* NMVC Companies are eligible for an Operational Assistance grant award equal to the amount of matching resources raised by the NMVC Company in accordance with §§ 108.380(a)(10)(i)(B) and 108.2030.

(b) *Amount of grant to SSBIC.* SSBICs are eligible for an Operational Assistance grant award equal to the amount of matching resources raised by the SSBIC in accordance with §§ 108.2000 and 108.2030.

(c) *Pro rata reductions.* In the event that the total amount of funds available to SBA for purposes of making Operational Assistance grant awards to NMVC Companies and SSBICs is not sufficient to award grants in the amounts described in subsections (a) and (b), SBA will make pro rata reductions in the amounts otherwise awarded to each such NMVC Company and SSBIC.

§ 108.2030 Matching requirements.

(a) *General.* All Operational Assistance grant funds SBA awards to an NMVC Company or a SSBIC must be matched on a dollar for dollar basis with funds or other resources raised by the NMVC Company or SSBIC.

(b) *Allowable sources.* (1) Any source other than SBA is an allowable source of matching resources for an Operational Assistance grant award.

(2) Neither a NMVC Company nor a SSBIC may use funds or other resources that it has used to satisfy a legal requirement for obtaining funds under any other Federal program, to satisfy the matching resources requirements described in this part 108.

(3) A portion of Private Capital may be designated as matching resources if the designated funds are used to purchase an annuity pursuant to paragraph (c)(2)(iv) of this section or are otherwise segregated in a manner acceptable to SBA.

(c) *Type and form of matching resources.* (1) Matching resources may come from cash contributions or in-kind contributions. In-kind contributions cannot exceed 50 percent of the total amount of match raised by the NMVC Company or SSBIC.

(2) Matching resources may be in the form of:

(i) Cash,

(ii) In-kind contributions,

(iii) Binding commitments for cash or in-kind contributions that may be payable over a multiyear period acceptable to SBA (but not to exceed 10 years), and/or

(iv) An annuity, purchased with funds other than Regulatory Capital, from an insurance company acceptable to SBA and that may be payable over a multiyear period acceptable to SBA (but not to exceed 10 years).

(d) *Amount of matching resources.*

(1) *NMVC Companies.* The amount of matching resources required of an NMVC Company is set forth in § 108.380(a)(1)(i)(B).

(2) *SSBICs.* The amount of matching resources required of an SSBIC is 30 percent of the increase in its Regulatory Capital since December 21, 2000, with which it has made or will make Low-Income Investments.

§ 108.2040 Reporting and recordkeeping requirements.

(a) *NMVC Companies.* Policies governing reporting, record retention, and recordkeeping requirements applicable to NMVC Companies may be found in subpart H of this part 108.

(b) *SSBICs.* An SSBIC receiving an Operational Assistance grant award must comply with all reporting, record retention and recordkeeping requirements set forth in Circular A–110 of the Office of Management and Budget and any grant award document executed between SBA and the SSBIC, as well as the reporting requirements in § 108.630(f) and the filing requirement in § 108.640.

Dated: January 12, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1710 Filed 1–19–01; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

New Markets Venture Capital Program; Notice of Funds Availability (NOFA) Inviting Applications for the New Markets Venture Capital Program

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Funds Availability (NOFA) inviting applications.

SUMMARY: The New Markets Venture Capital Program Act of 2000 ("the Act") authorizes the U.S. Small Business Administration ("SBA") to select participants for the New Markets Venture Capital ("NMVC") Program and to provide financial assistance, including grant awards, under that program. The Administrator of the SBA invites applications for designation as a New Markets Venture Capital company and for grant awards available both to participants in the NMVC Program and to Specialized Small Business Investment Companies ("SSBICs"). The interim final rule (13 CFR part 108) published in today's **Federal Register** provides guidance on the contents of the necessary application materials, evaluation criteria and other program requirements. Applicants for designation as a NMVC company can find more detailed application content requirements in the NMVC company application packet, which is available on SBA's website at http://www.sba.gov/inv. SSBICs applying for a grant award can request a grant application packet from SBA at the phone number set forth below.

Subject to funding availability, SBA expects to designate 15 to 20 NMVC companies and to award up to $30 million in appropriated funds under this NOFA. SBA reserves the right to select and fund some, all, or none of the applicants for designation as a NMVC company, and the right to fund some, all, or none of the SSBIC applications for grant awards submitted in response to this NOFA.

DATES: Applications may be submitted to SBA immediately. The deadline for receipt of an application is 6:00 p.m. EST on April 19, 2001. Applications received in SBA's offices after that date and time will be rejected and returned to the sender.

ADDRESSES: Applications must be sent to Austin Belton, Director, Office of New Markets Venture Capital, Investment Division, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416. Applications sent electronically or by facsimile will not be accepted.

FOR APPLICATIONS AND FURTHER INFORMATION CONTACT: If you have any questions about the requirements for this program or application procedures, or wish to request an application package, contact Austin Belton, Director, Office of New Markets Venture Capital, 202–205–6510. Applications and other information regarding SBA and its programs may be downloaded from SBA's web site at http://www.sba.gov/inv.

Program Authority: Consolidated Appropriations Act of 2001, Pub. L. No. 106–554, and 13 CFR part 108.

Dated: January 12, 2001.

Aida Alvarez,

Administrator.

[FR Doc. 01–1711 Filed 1–19–01; 8:45 am]

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Federal Register

Monday,
January 22, 2001

Part XVI

Department of Education

34 CFR Part 361
State Vocational Rehabilitation Services Program; Final Rule

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DEPARTMENT OF EDUCATION

34 CFR Part 361

RIN 1820–AB52

State Vocational Rehabilitation Services Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the State Vocational Rehabilitation Services Program (VR program) by revising the scope of employment outcomes under the VR program. These regulations redefine the term "employment outcome" (as it applies to the VR program) to mean outcomes in which an individual with a disability works in an integrated setting. This action is necessary to reflect the purpose of Title I of the Rehabilitation Act of 1973, as amended (Act), which is to enable individuals with disabilities who participate in the VR program to achieve an employment outcome in an integrated setting.

DATES: These regulations are effective October 1, 2001, but may be implemented by States prior to that date, as discussed in the appendix.

FOR FURTHER INFORMATION CONTACT: Beverlee Stafford, U.S. Department of Education, 400 Maryland Avenue, SW., room 3014, Mary E. Switzer Building, Washington, DC 20202–2531. Telephone (202) 205–8831. If you use a telecommunications device for the deaf (TDD), you may call (202) 205–5538.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to Katie Mincey, Director, Alternate Formats Center, U.S. Department of Education, 400 Maryland Avenue, SW., room 1000, Mary E. Switzer Building, Washington, DC 20202–2531. Telephone (202) 260–9895. If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The VR program provides necessary vocational rehabilitation (VR) services to enable eligible individuals with disabilities, particularly those with significant disabilities, to enter or continue to work in the integrated labor market along with the general population. Through the VR program, State agencies work with individuals with disabilities to assist those individuals in achieving employment, ideally a competitive job in an integrated setting. Integrated employment settings refer to those settings that are typically found in the community in which individuals with disabilities have the same opportunity to interact with others as is given to any other person (see 34 CFR 361.5(b)(33)(ii) for a detailed definition). Accordingly, these regulations revise the scope of employment outcomes under the VR program in order to assist program participants to attain jobs in an integrated setting.

On June 26, 2000, we published a notice of proposed rulemaking (NPRM) for this part, 34 CFR part 361, in the **Federal Register** (65 FR 39492) in which we proposed the major changes that are to take effect in these final regulations. It is important that we clarify that on January 17, 2000, we published final regulations for this part in the **Federal Register** to implement changes to the Rehabilitation Act of 1973 made by the Rehabilitation Act Amendments of 1998 contained in Title IV of the Workforce Investment Act of 1998 (WIA), as amended (1998 Amendments). The final regulations being promulgated in this present publication are pursuant to the June 26, 2000 NPRM and establish additional changes to 34 CFR part 361 that were not included in the final regulations implementing the 1998 Amendments published in the **Federal Register** on January 17, 2000.

We decided to publish these final regulations (revising the term "employment outcome" as it applies to the VR program) separately from the final regulations implementing the 1998 Amendments since these regulations do not take effect until fiscal year (FY) 2002 (or sooner at the discretion of each State). In contrast, the final regulations implementing the 1998 Amendments will be effective for all States 30 days after the date of publication. Moreover, we are publishing these regulations, with their delayed effective date, at this time in order to give State units, individuals with disabilities, and other service providers sufficient time to prepare for the changes that will result from these regulatory changes.

The proposed regulatory changes that we discussed in the preamble to the NPRM preceding these final regulations (65 FR 39492–39494) have been maintained in these final regulations. These changes include the following:

- Amending the regulatory definition of "employment outcome" under the VR program to refer to outcomes that occur in integrated settings.
- Amending the regulatory referral requirements to require the State unit to refer to local extended employment providers any individual with a disability who makes an informed choice to pursue extended employment (also referred to as "non-integrated employment" or "sheltered employment") as his or her long-term employment goal.
- Making conforming changes to the regulatory requirements concerning records of service and annual reviews of non-competitive outcomes.

As we discussed in detail in the preamble to the NPRM, the statutory authority for redefining the term "employment outcome," for purposes of the VR program, is based on section 7(11) of the Act. That statutory provision defines "employment outcome" under the VR program as full-time or, if appropriate, part-time competitive employment in the integrated labor market, supported employment, or any other vocational outcome, as defined by the Secretary (including the vocational outcome of self-employment, telecommuting, or business ownership), that is consistent with the Act. Accordingly, the Act entrusts the Secretary to determine the scope of employment outcomes, other than competitive employment (*i.e.*, integrated work at or above minimum wage—see 34 CFR 361.5(b)(11)) and supported employment (*i.e.*, integrated work with ongoing support services—see 34 CFR 361.5(b)(53)), that individuals with disabilities may pursue under the VR program. Pursuant to this authority, the Secretary has determined that defining "employment outcome" under the VR program as employment that occurs in integrated settings is necessary to ensure that persons with significant disabilities are supported in pursuing competitive and supported employment. We believe this change is consistent with the Act's emphasis on the integration into society of persons with disabilities and on the ability of individuals with disabilities, including those with the most significant disabilities, to achieve employment in integrated settings if necessary services and supports are provided.

We also noted in the NPRM, and discuss at length in the Analysis of Comments and Changes in the appendix to these regulations, that the regulatory changes we are establishing do not affect the ability of State VR agencies from serving individuals in extended employment settings for purposes of preparing those individuals for employment in integrated settings. The key change is that extended employment, for purposes of participating in the VR program, represents an interim step in the rehabilitation process rather than an end point of that process.

At the same time, we note that some persons with disabilities may prefer to work in extended employment facilities long-term. In recognition of that fact, and because we fully value the choice of work made by each person with a disability (regardless of whether that work occurs in an integrated setting), we have sought to ensure through these regulations that those wanting to work in extended employment can access the services they need directly from local extended employment facilities.

In addition, we note that many jobs obtained by individuals with disabilities under certain types of set-aside contracts authorized by the Javits-Wagner-O'Day Act (JWOD), 41 USC 46–48, satisfy the definition of "employment outcome" under the VR program. More specifically, those service-related and other jobs performed under JWOD contracts or other programs that satisfy the definition of "integrated setting" in 34 CFR 361.5(b)(33)(ii) would constitute an "employment outcome" (for purposes of the VR program) under these regulations. The determination as to whether any job, including those obtained under JWOD contracts, meets the regulatory definition of "integrated setting," and therefore qualifies as an "employment outcome" (for purposes of the VR program), must be made by State units on a case-by-case basis.

These final regulations include limited changes from the NPRM. In particular, while retaining the proposed October 1, 2001, effective date, we have clarified that States may implement the changes sooner at their discretion. The purpose of this sliding effective date is to reflect the fact that some States already have implemented policies in which all VR program participants pursue employment in an integrated setting. In addition, we have amended the proposed regulations to—

- Amend the regulatory definition of "extended employment" to eliminate redundant language. This definition also reflects the fact that some individuals may enter extended employment for training and other job-readiness purposes through the VR program, while others may enter it for long-term employment through other resources. Therefore, we have deleted from the definition any implication that training serves as the sole purpose of extended employment. Participants in the VR program who receive VR training services on a transitional basis in an extended employment setting may receive other VR services as well, such as diagnostics and assessment services, in an extended employment setting;
- Require that, before referring to local extended employment providers an individual with a disability who chooses to pursue extended employment, the State unit must provide the individual with information concerning the VR program, integrated employment options, the circumstances in which an individual can receive VR services in an extended employment setting, and the individual's ability to return to the VR agency at any point that he or she decides to pursue employment in an integrated setting, and, as appropriate, refer the individual to the Social Security Administration in order to obtain information concerning the ability of individuals with disabilities to work while receiving benefits from the Social Security Administration;
- Require that applicants under the VR program who are unable to work in an integrated setting be referred to local extended employment providers;
- Require that individuals who were initially found eligible for VR services, but are later determined unable to work in an integrated setting, be referred to local extended employment providers; and
- Include technical amendments to other sections of the current regulations (specifically, §§ 361.45 and 361.46 concerning the individualized plan for employment and § 361.56 concerning closure of the record of services) that were not included in the NPRM but are necessary to conform to the revised definition of the term "employment outcome" under the VR program.

We explain more fully each of these changes in the Analysis of Comments and Changes in Appendix B at the end of these final regulations.

We also include a set of general questions and answers in Appendix A to these regulations, which will be codified in the Code of Federal Regulations. These questions and answers provide a short explanation of the changes made by these final regulations pursuant to comments received by the public.

Finally, we wish to emphasize that nothing in these final regulations is intended to alter the fact that extended employment is a legitimate and valued employment option for people with disabilities (*e.g.*, those who make an informed choice to work in an extended employment setting). Nor do these regulations have any effect on the requirements of other Federal programs that financially support extended employment facilities, including definitions of terms such as "employment," "job," or "work" used in those programs or corresponding Federal statutes. The chief purpose of these regulations is to ensure, as we believe Title I of the Act intends, that participants in the VR program, particularly those with significant disabilities, are afforded a full opportunity to integrate within their communities and participate in jobs that are available to the general population.

Analysis of Comments and Changes

In response to our invitation in the NPRM, more than 3,000 parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM is published in Appendix B at the end of these final regulations.

We group major issues according to subject. We discuss other substantive issues under the sections of the regulations to which they pertain. Generally, we do not address technical and other minor changes, as well as suggested changes that the law does not authorize the Secretary to make.

National Education Goals

The eight National Education Goals focus the Nation's education reform efforts and provide a framework for improving teaching and learning.

These regulations address the National Education Goal that every adult American, including individuals with disabilities, will possess the knowledge and skills necessary to compete in a global economy and exercise the rights and responsibilities of citizenship.

Executive Order 12866

We have reviewed these final regulations in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with these final regulations are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of these final regulations, we have determined that the benefits of the final regulations justify the costs.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

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Summary of Potential Costs and Benefits

We discussed the potential costs and benefits of these final regulations in the preamble to the NPRM (65 FR 39492–39496), including throughout the section-by-section analysis. Our analysis of potential costs and benefits generally remains the same as in the NPRM, although we include additional discussion of potential costs and benefits in Appendix B to these final regulations titled Analysis of Comments and Changes.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 does not require you to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. We display the valid OMB control number assigned to the collection of information in these final regulations at the end of the affected sections of the regulations.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Federalism

Executive Order 13132 requires us to ensure meaningful and timely input by State and local elected officials in the development of regulatory policies that have federalism implications. "Federalism implications" means substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

These regulations implement various statutory changes to the State Vocational Rehabilitation Services Program. We do not believe that these regulations have federalism implications as defined in Executive Order 13132 or that they preempt State law. Accordingly, the Secretary has determined that these regulations do not contain policies that have federalism implications.

Assessment of Educational Impact

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Based on the response to the NPRM and on our review, we have determined that these final regulations do not require transmission of information that any other agency or authority of the United States gathers or makes available.

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(Catalog of Federal Domestic Assistance Number: 84.126 State Vocational Rehabilitation Services Program)

List of Subjects in 34 CFR Part 361

Reporting and recordkeeping requirements, State-administered grant program—education, Vocational rehabilitation.

Dated: December 18, 2000.

Richard W. Riley,

Secretary of Education.

For the reasons discussed in the preamble and the appendix to these regulations, the Secretary amends part 361 of title 34 of the Code of Federal Regulations as follows:

PART 361—STATE VOCATIONAL REHABILITATION SERVICES PROGRAM

1. The authority citation for part 361 continues to read as follows:

Authority: 29 U.S.C. 709(c), unless otherwise noted.

2. Section 361.5 is amended by revising paragraphs (b)(16) and (b)(19) to read as follows:

§ 361.5 Applicable definitions.

* * * * *

(b) * * *

(16) *Employment outcome* means, with respect to an individual, entering or retaining full-time or, if appropriate, part-time competitive employment, as defined in § 361.5(b)(11), in the integrated labor market, supported employment, or any other type of employment in an integrated setting, including self-employment, telecommuting, or business ownership, that is consistent with an individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

* * * * *

(19) *Extended employment* means work in a non-integrated or sheltered setting for a public or private nonprofit agency or organization that provides compensation in accordance with the Fair Labor Standards Act.

* * * * *

3. Section 361.37 is amended by—

A. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d) respectively;

B. Adding a new paragraph (b); and

C. Revising the authority citation following the section to read as follows:

§ 361.37 Information and referral programs.

* * * * *

(b) The State unit must refer to local extended employment providers an individual with a disability who makes an informed choice to pursue extended employment as the individual's employment goal. Before making the referral required by this paragraph, the State unit must—

(1) Consistent with § 361.42(a)(4)(i) of this part, explain to the individual that the purpose of the vocational rehabilitation program is to assist individuals to achieve an employment outcome as defined in § 361.5(b)(16) (i.e., employment in an integrated setting);

(2) Consistent with § 361.52 of this part, provide the individual with information concerning the availability of employment options, and of vocational rehabilitation services, in integrated settings;

(3) Inform the individual that services under the vocational rehabilitation program can be provided to eligible individuals in an extended employment setting if necessary for purposes of training or otherwise preparing for employment in an integrated setting;

(4) Inform the individual that, if he or she initially chooses not to pursue employment in an integrated setting, he or she can seek services from the designated State unit at a later date if, at that time, he or she chooses to pursue employment in an integrated setting; and

(5) Refer the individual, as appropriate, to the Social Security Administration in order to obtain information concerning the ability of individuals with disabilities to work while receiving benefits from the Social Security Administration.

* * * * *

(**Authority:** Sections 7(11), 12(c), 101(a)(5)(D), 101(a)(10)(C)(ii), and 101(a)(20) of the Act; 29 U.S.C. 709(c), 721(a)(5)(D), 721(a)(10)(C)(ii), and 721(a)(20))

4. Section 361.43 is amended by revising paragraph (d) and revising the authority citation following the section to read as follows:

§ 361.43 Procedures for ineligibility determination.

* * * * *

(d) Refer the individual—

(1) To other programs that are part of the One-Stop service delivery system under the Workforce Investment Act that can address the individual's training or employment-related needs; or

(2) To local extended employment providers if the ineligibility determination is based on a finding that the individual is incapable of achieving an employment outcome as defined in § 361.5(b)(16).

* * * * *

(**Authority:** Sections 12(c), 102(a)(5), and 102(c) of the Act; 29 U.S.C. 709(c), 722(a)(5), and 722(c))

5. Section 361.45 is amended by revising paragraph (b)(2) to read as follows:

§ 361.45 Development of the individualized plan for employment.

* * * * *

(b) * * *

(2) The IPE must be designed to achieve a specific employment outcome, as defined in § 361.5(b)(16), that is selected by the individual consistent with the individual's unique strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

* * * * *

6. Section 361.46 is amended by revising paragraph (a)(1) to read as follows:

§ 361.46 Content of the individualized plan for employment.

(a) * * *

(1) A description of the specific employment outcome, as defined in § 361.5(b)(16), that is chosen by the eligible individual and is consistent with the individual's unique strengths, resources, priorities, concerns, abilities, capabilities, career interests, and informed choice.

* * * * *

7. Section 361.47 is amended by revising paragraphs (a)(8) and (a)(10) to read as follows:

§ 361.47 Record of services.

(a) * * *

(8) In the event that an individual's IPE provides for vocational rehabilitation services in a non-integrated setting, a justification to support the need for the non-integrated setting.

* * * * *

(10) In the event an individual achieves an employment outcome in which the individual is compensated in accordance with section 14(c) of the Fair Labor Standards Act or the designated State unit closes the record of services of an individual in extended employment on the basis that the individual is unable to achieve an employment outcome consistent with § 361.5(b)(16) or that an eligible individual through informed choice chooses to remain in extended employment, documentation of the results of the annual reviews required under § 361.55, of the individual's input into those reviews, and of the individual's or, if appropriate, the individual's representative's acknowledgment that those reviews were conducted.

* * * * *

8. Section 361.55 is revised to read as follows:

§ 361.55 Annual review of individuals in extended employment and other employment under special certificate provisions of the Fair Labor Standards Act.

(a) The State plan must assure that the designated State unit conducts an annual review and reevaluation in accordance with the requirements in paragraph (b) of this section for an individual with a disability served under this part—

(1) Who has achieved an employment outcome in which the individual is compensated in accordance with section 14(c) of the Fair Labor Standards Act; or

(2) Whose record of services is closed while the individual is in extended employment on the basis that the individual is unable to achieve an employment outcome consistent with § 361.5(b)(16) or that the individual made an informed choice to remain in extended employment.

(b) For each individual with a disability who meets the criteria in paragraph (a) of this section, the designated State unit must—

(1) Annually review and reevaluate the status of each individual for 2 years after the individual's record of services is closed (and thereafter if requested by the individual or, if appropriate, the individual's representative) to determine the interests, priorities, and needs of the individual with respect to competitive employment or training for competitive employment;

(2) Enable the individual or, if appropriate, the individual's representative to provide input into the review and reevaluation and must document that input in the record of services, consistent with § 361.47(a)(10), with the individual's or, as appropriate, the individual's representative's signed acknowledgment that the review and reevaluation have been conducted; and

(3) Make maximum efforts, including identifying and providing vocational rehabilitation services, reasonable accommodations, and other necessary support services, to assist the individual in engaging in competitive employment as defined in § 361.5(b)(11).

(Approved by the Office of Management and Budget under control number 1820–0500.)

(**Authority:** Sections 12(c) and 101(a)(14) of the Act; 29 U.S.C. 709(c) and 721(a)(14))

9. Section 361.56 is amended by revising paragraph (a) to read as follows:

§ 361.56 Requirements for closing the record of services of an individual who has achieved an employment outcome.

* * * * *

(a) *Employment outcome achieved.* The individual has achieved the employment outcome that is described in the individual's IPE in accordance with § 361.46(a)(1) and is consistent with the individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice.

* * * * *

10. Sections 361.10, 361.12, 361.13, 361.14, 361.15, 361.16, 361.17, 361.18, 361.19, 361.20, 361.21, 361.22, 361.23, 361.24, 361.25, 361.26, 361.27, 361.28, 361.29, 361.30, 361.31, 361.32, 361.34, 361.35, 361.36, 361.37, 361.38, 361.40, 361.41, 361.46, 361.47, 361.48, 361.49, 361.50, 361.51, 361.52, 361.53, 361.54, 361.57, 361.60 and 361.62 are amended by adding after the section and before the authority citation "(Approved by the Office of Management and Budget under control number 1820–0500)".

11. Appendix A is added to part 361 to read as follows:

Appendix A to Part 31—Questions and Answers

The following questions and answers provide a summary of some of the most

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common and critical questions that we received regarding this part 361 and the applicable responses. As is evident from the responses, we maintain that redefining the term "employment outcome" for purposes of the VR program to mean outcomes that occur in integrated settings will promote the provision of opportunities for all VR-eligible individuals to pursue the types of jobs that generally are available to the public.

Is Extended Employment Still a Legitimate Employment Option?

Yes. Employment in a sheltered setting is a legitimate and valuable employment option for individuals with disabilities. Implementation of these regulations will not change that fact. Individuals still may choose to pursue long-term extended employment outside of the VR program, and these regulations ensure that those individuals' needs are met by requiring the VR agency to make the necessary referral to local extended employment providers.

Do the Regulations Restrict Individual Choice?

No. We interpret the concept of individual choice in the Act as a choice among the employment outcomes under the VR program specified in the statute or by the Secretary in regulations.

Extended employment (i.e., sheltered or non-integrated employment) remains both an initial step toward achieving integrated employment under the VR program and a long-term employment option through sources of support other than the VR program. In recognizing that some individuals with disabilities may wish to work in an extended employment setting, these regulations require the VR agency to ensure that these individuals are afforded the opportunity to do so by referring them to local extended employment providers. Those providers currently support the vast majority of sheltered workers through non-VR program resources. Moreover, persons wishing to prepare for integrated employment by initially working in an extended employment setting also may do so. In these cases, the VR agency cannot discontinue VR services until the individual transitions to integrated work in the community.

Can State Agencies Refuse To Serve Those With the Most Significant Disabilities?

No. Both the Act and regulations guard against that result. Persons with disabilities may not be excluded from the VR program based on an assumption or belief that the individual is incapable of working in an integrated setting. Rather, State units are required to establish clear and convincing evidence that an individual is incapable of achieving an employment outcome, for purposes of the VR program, and must conduct a trial work assessment of the individual's abilities before it can refuse services to any individual who it initially believes is incapable of working in an intergrated job setting.

Are Homemaker and Unpaid Family Worker Considered Employment Outcomes for Purposes of the VR Program?

Yes. The chief purpose of the regulations is to ensure that individuals with disabilities participating in the VR program are able to pursue the same type of employment opportunities that are available to the general public. Extended employment jobs, unlike homemakers and unpaid family workers, are primarily reserved for those with disabilities.

Will the Regulations Serve To Close Down Sheltered Workshops?

No. Sheltered workshops are primarily supported by other State, local, and private resources and rely very little on VR program funds. Persons who prefer to work in extended employment on a long-term basis are assured access to local extended employment programs through the referral requirements in the regulations. Also, those participants in the VR program who can best prepare for integrated employment by working in an extended employment setting as part of a training and assessment program are able to follow that path as well. Thus, extended employment programs and sheltered workshops continue to serve essentially the same role that they currently serve.

Appendix B

Analysis of Comments and Changes

Note: The following appendix will not appear in the Code of Federal Regulations.

§ 361.5(b)(15) Applicable Definitions; Employment Outcome

General

Comments: More than 3,000 comments were received in response to the NPRM published in the **Federal Register** on June 26, 2000 (65 FR 39492).

Many commenters voiced strong support for the proposed definition of "employment outcome" that would revise the scope of that term under the VR program to include only those outcomes in which an individual with a disability works in an integrated setting. Several commenters predicted that the proposed revision would result in more opportunities for individuals with disabilities to work in integrated settings (also referred to throughout this appendix as "integrated employment") and in the elimination of barriers to competitive jobs for individuals with significant disabilities. Other commenters noted that, consistent with the purpose of the Act, the proposed regulations supported the transition of adults with significant disabilities from extended employment settings (also referred to as sheltered or non-integrated settings) to integrated employment. Finally, several commenters, while supporting the proposed regulations, asked for additional clarification on several issues. Those issues, and any corresponding changes to the proposed regulations, are addressed in this appendix.

Many commenters strongly opposed the proposed regulations and asked that the NPRM be rescinded or that any final rulemaking be delayed for further study of the potential impact of the proposed regulations. A number of commenters believed that the proposed revision to the definition of "employment outcome," for purposes of the VR program, was inconsistent with the spirit and intent of the Act, particularly the Act's emphasis on giving individuals with disabilities the opportunity to make informed choices in selecting an employment outcome under the VR program. Other commenters declared that the proposed regulations would restrict the number and variety of job options available to individuals with significant disabilities, lead to individuals being denied access to VR services, and weaken the priority the Act places on serving individuals with the most significant disabilities.

We also received many comments from individuals with disabilities, as well as their friends, family members, and advocates, who expressed the fear that the proposed regulations would lead to the elimination of extended (also referred to as sheltered) employment programs in which individuals with disabilities often participate.

Discussion: Due to the extensive detail of the previous comments on the proposed definition of "employment outcome," and the significance of the issues raised in each, we address these comments, and other related comments, under applicable topical headings that follow.

Informed Choice

Comments: As previously indicated, several commenters asserted that the proposed regulations would limit choices for individuals who prefer to work in extended employment settings and, therefore, would be contrary to the Act's emphasis on informed choice of the individual.

Discussion: While we fully agree that the Act places a premium on individuals with disabilities being able to exercise informed choice throughout the rehabilitation process, we do not agree that these regulations are inconsistent with that emphasis. We interpret the statute as allowing individuals to exercise their choice among employment outcomes under the VR program that are specified in the Act or by the Secretary in regulations.

Moreover, despite the changes made by these regulations, we want to make it clear that extended employment remains both an initial step toward achieving integrated employment under the VR program and a long-term employment option through sources of support other than the VR program. These regulations continue to allow State VR agencies to provide individuals with VR services by enabling persons to work in extended employment settings in order to prepare for employment in an integrated setting. We recognize that extended employment settings offer some individuals with significant disabilities valuable training and work experience for that purpose. The key change made by these regulations is that extended employment serves as an interim step in the rehabilitation process rather than an end point to the VR process.

If an individual makes an informed choice (as will be explained in more detail later in this appendix), that he or she wants to pursue long-term employment in a non-integrated setting (*e.g.*, extended or sheltered employment), he or she may still do so. These final regulations require the designated State unit to refer that individual to local extended employment providers who can meet the individual's needs.

Extended employment providers support the vast majority of sheltered workers through other State, local, and private resources. Currently, the VR program provides very few financial resources to extended employment providers. Given this fact, these regulations will not have the effect, as feared by some, of ending the existence of extended employment opportunities.

In addition, we have amended the referral requirements in § 361.37 of the regulations to ensure that individuals receive sufficient information concerning the scope of the VR program and integrated employment opportunities. This information will enable individuals to make a fully informed choice regarding whether to pursue integrated employment through the VR program or extended employment through other sources.

The changes made by these regulations ensure that the VR program promotes opportunities for individuals with disabilities, particularly those with significant disabilities, to pursue integrated employment options. Moreover, the regulations require each State unit to preserve individual choice in the manner in which the Act intends.

Changes: None.

Employment Options

Comments: Several commenters who supported the proposed regulations suggested that removing sheltered employment from the scope of "employment outcomes" under the VR program will enable counselors to assist individuals with disabilities to obtain jobs in integrated settings and with potentially better pay.

Other commenters who opposed the proposed regulations suggested that the proposed requirements would restrict the number and variety of job options for individuals with the most significant disabilities, many of whom do not have the skills or abilities to work in integrated employment settings.

Discussion: We believe, as do many of the commenters who wrote in favor of these regulations, that these regulatory changes will lead to more individuals with significant disabilities entering integrated employment. Moreover, we believe that these regulations will serve to expand job options in general for individuals with significant disabilities while, at the same time, ensuring that individuals still can access extended employment through appropriate resources.

Specifically, these regulations require VR agencies to ensure (to the extent they have not done so already) that individuals with significant disabilities are assisted in pursuing work in the integrated labor market. Prior to these final regulations, participants in the VR program sometimes have been directed toward sheltered work at the outset of entering the rehabilitation process without first having the opportunity to pursue employment in an integrated setting as they may have preferred.

We recognize that a small number of individuals with the most significant disabilities may not have, or be able to obtain, the skills and abilities to work in integrated employment settings. In those cases in which that decision is reached, it is the responsibility of the State VR agency to refer the individual to extended employment providers.

Finally, we again note that extended employment remains an interim step in the rehabilitation process leading to employment in an integrated setting. As such, extended employment represents a means of receiving support services and valuable work experience rather than a final employment outcome under the VR program.

Changes: In recognizing that some individuals with the most significant disabilities may not have, or be able to obtain, the skills and abilities to work in integrated employment settings, we have added to the final regulations, in § 361.43(d)(2), the requirement that State agencies also refer to extended employment providers any individual who the agency determines is incapable of achieving an employment outcome (*i.e.*, integrated employment) under the VR program.

Homemakers and Unpaid Family Workers

Comments: Several commenters stated that the Rehabilitation Services Administration should not eliminate from the VR program paid jobs in extended employment while continuing to accept homemakers and unpaid family workers as unpaid employment outcomes. Other commenters felt that the proposed definition of "employment outcome," for purposes of the VR program, effectively eliminated homemakers and unpaid family workers from the scope of employment outcomes under the VR program.

Discussion: The definition of "employment outcome," for purposes of the VR program, in these final regulations modifies the prior regulatory definition by requiring that "employment outcomes" under the VR program occur in integrated settings. The final regulations do not address wage issues, meaning that non-wage earning (and other sub-minimum wage) employment outcomes, as long as they occur in integrated settings, satisfy the VR program definition of "employment outcome" in § 361.5(b)(16). While we strongly believe that individuals with disabilities receiving VR services should pursue employment outcomes with competitive wages, the final regulations do not mandate that result.

The chief purpose of the regulations is to ensure that individuals with disabilities participating in the VR program are able to pursue the same type of outcomes that are available to the general public. Because homemaker and unpaid family worker outcomes are available in the community, homemakers and unpaid family workers are considered to occur in integrated settings, as defined in § 361.5(b)(33), and thus meet the revised definition of "employment outcome" under the VR program, as defined in § 361.5(b)(16).

Changes: None.

Access to VR Services for Persons With Significant Disabilities

Comments: Some commenters predicted that the proposed regulations would result in fewer individuals with significant disabilities receiving services under the VR program. These commenters expressed concern that VR counselors will be reluctant to serve individuals with significant or the most significant disabilities if they believe those individuals are less likely to achieve employment outcomes in integrated settings. The commenters believed that counselors will focus their efforts only on those who are clearly capable of integrated work.

Discussion: We recognize the commenters' concerns, yet believe that those concerns are addressed through the eligibility criteria and procedures that VR agencies must follow. Those criteria and corresponding procedures are unchanged by these regulations. We emphasize that it is critical for VR agencies to ensure that persons with significant disabilities are not excluded from the VR program based on an assumption, belief, or preliminary impression that the individual is incapable of working in an integrated setting.

The Act establishes a clear priority for serving persons with the most significant disabilities (through the order of selection requirements) and requires that the eligibility process specified in the Act be followed in determining whether an individual is to receive VR services. A discussion of that process and its application to persons with significant disabilities follows.

In accordance with section 102(a) of the Act and § 361.42 of the regulations, an individual is eligible to receive VR services if he or she is "an individual with a disability" (*i.e.*, the individual has an impairment that results in an impediment to employment and can benefit in terms of an employment outcome from VR services). The individual also must require VR services in order to prepare for, secure, retain, or regain employment.

In light of these criteria, a counselor's decision not to serve (but rather refer to an extended employment provider) an individual with a disability on the basis that the individual cannot achieve integrated employment would mean, in effect, that the counselor has concluded that the individual cannot benefit in terms of an *employment outcome* under the VR program (*i.e.*, integrated work) from VR services. The Act and regulations, however, state that any individual seeking VR services is "presumed [able] to benefit in terms of an employment outcome from VR services." Moreover, for the State agency to overcome that statutory presumption, it must demonstrate with *clear and convincing evidence* that the individual is incapable of benefiting in terms of an employment outcome under the VR program due to the severity of the applicant's disability. Finally, in order to establish the requisite "clear and convincing evidence," the agency first must explore the individual's abilities, capabilities, and capacity to perform in work situations by affording the individual trial work experiences (see section 102(a) of the Act and § 361.42 of the regulations).

Thus, in the absence of clear and convincing evidence following a trial work

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assessment of the individual's abilities (or, as appropriate, an extended evaluation under § 361.42(f) of the regulations), VR agencies must consider each individual, including those with the most significant disabilities, capable of achieving integrated employment. In other words, the Act establishes the general expectation that individuals with the most significant disabilities, if given necessary services and supports, are able to work in integrated settings. These regulations ensure that every opportunity is afforded so that this expectation is realized.

In addition, because extended employment remains an interim step in the rehabilitation process, VR agencies may not refuse to serve an individual who wishes to receive services in an extended employment setting for purposes of preparing for employment in an integrated setting.

We recognize that the regulations impose heightened accountability and greater effort on the part of VR agencies. For those reasons, we intend to monitor closely State implementation of the final regulations during our annual review and periodic on-site monitoring of State VR agencies in order to ensure that persons with significant disabilities receive VR services in pursuit of integrated employment. We also want to ensure that individuals who receive initial services in an extended employment setting also receive the VR services they need to transition to integrated employment in the community.

Changes: None.

Effectiveness of Extended Employment

Comments: A number of commenters, citing relevant research over the past three decades, stated that many individuals in extended employment have not been able to transition to the competitive labor market. These commenters observed that entities that operate sheltered workshops often retain their most productive workers, thus resulting in few of these individuals transitioning to integrated employment. Consequently, the commenters urged that the proposed regulations be revised to disallow extended employment as an interim step in the rehabilitation process.

Other commenters who supported the proposed regulations asserted that nearly 90 percent of individuals with developmental disabilities and more than 65 percent of individuals who are blind earn less than the minimum wage working in extended employment.

Several commenters who opposed the revised regulatory definition of "employment outcome," for purposes of the VR program, stated that "place-and-train methodologies" used by VR programs have left numerous people with disabilities adrift in the labor market with part-time, low-wage jobs, no peer group, and limited social outlets. These commenters further contend that extended employment programs function as a safety net for individuals with significant disabilities, providing additional opportunities for training and employment in a safe, protective work environment. Other commenters stated that the proposed regulations "devalued" individuals in extended employment programs and the work they perform.

Discussion: We agree that extended employment programs have traditionally served as a safety net for individuals with significant disabilities who cannot perform integrated work in the community or who choose to work only among their disabled peers. We also recognize that extended employment programs offer opportunities in which individuals with significant disabilities can obtain useful training and work experience. For these reasons, we wish to emphasize that we in no way devalue the dignity or the worth of extended employment programs or the individuals who work in those settings. Rather, we have amended the existing regulations in order to focus the VR program on the statutory purpose (*i.e.*, the purpose reflected in Title I of the Rehabilitation Act) of giving persons with disabilities, including those with significant or the most significant disabilities, the opportunity to work in the community and to achieve economic self-sufficiency.

While extended employment settings serve a useful purpose in society and benefit some VR participants, we again note that extended employment providers receive very little financial support from the VR program. As we noted in the NPRM, a relatively small number of VR program participants have achieved employment outcomes in sheltered settings in recent years—approximately 3.5 percent of VR program outcomes nationwide in 1998, according to the most current data available. Thus, it is evident that many State units already have not been treating extended employment as a final employment outcome under the VR program. Those agencies have come to realize, as is reflected through the Act's legislative history, that historically participants in the VR program too often were placed in sheltered settings as a final outcome rather than as a temporary placement from which they could transition to a job in the community. While this philosophy has evolved in many State VR agencies, and is followed nationally through these regulations, extended employment remains a safety net, and an appropriate work environment, and continues to be supported by those resources on which it has primarily relied.

We also believe that these regulatory changes will spur VR agencies to closely follow program participants in extended employment settings and assist in their transition to integrated work. Prior to these regulations, VR agencies were permitted to terminate VR services to an individual in extended employment. We expect these final regulations will cause VR agencies to increase their efforts with regard to individuals whom they serve in non-integrated settings until the individual transitions to integrated employment.

Changes: None.

Availability of Opportunities for Integrated Employment

Comments: As noted earlier, many individuals who supported the proposed regulations believed that the change would hasten the movement toward integrated employment and the elimination of barriers to integrated jobs for individuals with significant disabilities.

In contrast, a number of commenters who opposed the proposed regulations reasoned that extended employment should continue to be included as an "employment outcome" under the VR program because integrated employment opportunities are rarely available in rural areas or Indian reservations. These commenters stated that extended employment is often the sole work opportunity for people with significant disabilities who reside in these underserved areas.

Discussion: Extended employment, whether accessed through resources other than the VR program or used as an interim step toward integrated employment under the VR program, remains a viable opportunity for individuals in rural areas or elsewhere. As indicated previously, extended employment facilities offer some persons with disabilities important services. Accordingly, we expect that many individuals with disabilities will continue to pursue extended employment and, therefore, have ensured through these regulations that opportunities in extended employment can be accessed. At the same time, however, we do not believe that the prevalence of extended employment options in certain areas should mean that VR program participants not be given the opportunity to pursue integrated employment as is intended by the Act.

We recognize that defining "employment outcome" under the VR program as a job in an integrated setting will require some VR agencies to work to broaden integrated job options for program participants. Nevertheless, we fully believe, like many of the commenters, that the obligations on VR agencies resulting from the regulations are consistent with the VR program's statutory emphasis on integration. Thus, to the extent integrated employment opportunities are limited in rural, reservation, or other areas, it is incumbent on the local VR unit to work with employers to expand integrated job opportunities for individuals with significant disabilities.

Changes: None.

Continuation of Extended Employment Programs

Comments: We received many comments from individuals with disabilities, and their family members and friends, who expressed the fear that the changes to the prior regulations would lead to the elimination of extended employment programs and the closing of sheltered workshops where individuals with disabilities currently work.

Discussion: As indicated throughout this analysis of comments, the regulations do *not* eliminate extended employment programs or serve to close sheltered workshops. We again note the valuable contributions these facilities make to society and the high regard in which they are held by some of the commenters to the proposed regulations. Still, extended employment programs generally are funded by other State, local, and private resources and rely very little on VR program funds as evidenced by (1) the small percentage of VR program participants who have exited the program while in a sheltered setting, and (2) the fact that several

VR agencies already follow a policy of working with individuals in pursuit of integrated employment. Moreover, the regulations ensure that persons who choose to work in extended employment on a long-term basis are able to access local extended employment programs through the required referral process under § 361.37 of the regulations.

At the same time, individuals who choose to prepare for integrated employment under the VR program by temporarily working in an extended employment setting are able to follow that path as well. The State VR agencies will continue to provide necessary services to enable these individuals to gain valuable work experience in extended employment facilities and transition to integrated employment at a later time. If an individual chooses to remain in extended employment or if it is determined that the individual is unable to achieve employment in an integrated setting (although § 361.55 of the regulations requires the agency later to review whether the individual's choice or readiness for integrated employment has changed), the VR agency must refer that individual to the local extended employment provider to ensure that the individual's needs continue to be met. In this way, extended employment programs and sheltered workshops continue to serve the same valued role in the society as they currently serve.

Changes: None.

§ 361.37 Establishment and Maintenance of Information and Referral Programs

Comments: A few commenters viewed as unduly burdensome the proposed requirements concerning the State unit's obligation to refer to local extended employment providers any individual who chooses extended employment as their employment goal.

Some commenters stated that State, local, and private resources that support extended employment programs are insufficient to absorb the additional referrals that would result from the proposed regulations. In contrast, other commenters supported the proposed regulations, including the referral requirements, stating that extended employment programs operated by community rehabilitation programs will continue since those organizations do not rely on VR program funds to support their extended employment operations.

Discussion: As discussed previously, the proposed regulations in this section required State VR agencies to refer individuals with disabilities to local extended employment providers if the individual chooses to work in an extended employment setting on a long-term basis rather than pursue employment in an integrated setting under the VR program.

We do not believe that the limited burden associated with the referral requirements in this section are inappropriate or unjustified. While we recognize that the requirements in § 361.37 imposed additional responsibilities on VR agencies, those requirements are designed to ensure that each individual with a disability can receive services through applicable resources. As for those applicants under the VR program who choose to pursue extended employment long-term, the VR agency should ensure that those individuals are made aware of the scope of available extended employment service providers and should make referrals that are consistent with each individual's informed choice.

Section 361.37 of the final regulations requires State VR agencies to provide sufficient information to all applicants to ensure that they are making an informed choice in either applying for VR services or choosing to pursue extended employment on a long-term basis. In particular, these regulations require State agencies to inform individuals of the purpose of the VR program, the availability of VR services and employment options in an integrated setting, the availability of services in an extended employment setting as a means of assisting the individual to transition into integrated employment, the right to return to the VR program for assistance if the individual chooses later to seek employment in an integrated setting, and, when appropriate, the availability of information from the Social Security Administration concerning the ability of individuals with disabilities to work while receiving benefits from the Social Security Administration.

Many of these information requirements are consistent with the informational requirements in § 361.42. In addition, it is important that individuals with disabilities who are receiving, or have been found eligible for, Social Security benefits be informed of recent reforms that are designed to reduce a key work disincentive by enabling individuals with disabilities to work and continue receiving Social Security benefits. We believe that the need for this critical information, and its potential effect on an individual's interest in pursuing integrated work in the community, justifies requiring VR agencies to ensure that an individual with a disability can access it when appropriate. The purpose behind this requirement, as with each of the informational requirements in § 361.37(b), is to ensure that individuals make truly informed choices among the wide scope of employment options—both integrated and non-integrated—available to persons with disabilities. We do note, however, that if the individual proceeds to complete the VR agency's application, pursuant to § 361.42(a)(4), after receiving the information specified in this section of the regulations, there can be no question that the individual intends to pursue integrated employment under the VR program.

Moreover, an individual with a disability who requires VR services to achieve an employment outcome cannot be refused services unless the State unit establishes clear and convincing evidence, following a trial work assessment, that the severity of the individual's disability prevents that individual from working in an integrated setting.

Finally, in the limited instances in which the State unit establishes the requisite clear and convincing evidence that the individual is incapable of achieving integrated employment, the amended regulations also require that those persons be referred to local extended employment programs in the community that can better address their employment needs (that added referral requirement is located in § 361.43 of the final regulations).

Changes: We have amended the proposed regulations to ensure that VR agencies provide individuals with sufficient information to make a fully informed choice between pursuing integrated employment under the VR program or extended employment through other sources. Section 361.37 of these final regulations requires the State unit, prior to referring an individual with a disability who chooses to pursue extended employment to local extended employment providers, to inform the individual of the purpose of the VR program, the availability of integrated employment options, the fact that VR services can be provided to eligible individuals in an extended employment setting for purposes of training or otherwise preparing for integrated employment, and the ability of the individual to seek VR services at a later date if at that time the individual chooses to pursue employment in an integrated setting, and, as appropriate, to refer the individual to the Social Security Administration in order to obtain information concerning the ability of individuals with disabilities to work while receiving benefits from the Social Security Administration.

§ 361.43 Procedures for Ineligibility Determination

Comments: None.

Discussion: Although amendments to this section of the current regulations were not proposed in the NPRM, we have determined, based on the comments we received, that a change to this section is warranted. We believe that it is important to ensure that persons found too severely disabled to work in an integrated setting are referred to local extended employment facilities so that these individuals can still take advantage of the work opportunities that the facilities offer.

The proposed regulations, in particular § 361.37, would have applied a referral requirement only to those who initially choose to pursue extended employment as their long-term employment goal. However, we also believe that persons who seek to participate in the VR program but are found, based on clear and convincing evidence following a trial work assessment, incapable of achieving integrated employment should be given the same valuable opportunity to work in an extended employment setting with support from appropriate sources. As we indicated in the discussion under § 361.37, we also believe it is important for the VR agency to ensure that these individuals are made aware of the different extended employment service providers available in the area so that individuals can be referred to providers consistent with their informed choice.

Changes: We have amended the proposed regulations to require in § 361.43 that individuals who are found unable to work in an integrated setting be referred to local extended employment providers.

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§ 361.45 Development of the Individualized Plan for Employment and § 361.46 Content of the Individualized Plan for Employment

Comments: None.

Discussion: Both § 361.45 (concerning the development of the individualized plan for employment (IPE)) and § 361.46 (concerning IPE content) require technical changes to conform to the revised definition of the term "employment outcome" under the VR program and have been amended accordingly.

Changes: We have revised §§ 361.45 and 361.46 to conform to the revised definition of "employment outcome" under the VR program.

§ 361.55 Annual Review of Individuals in Extended Employment and Other Employment Under Special Certificate Provisions of the Fair Labor Standards Act

Comments: A few commenters who opposed the proposed regulations stated that the annual review requirements in the NPRM would not be effective in identifying individuals who may be ready to transition from extended employment to integrated employment in the community, including supported employment. The commenters asserted that under existing regulations State VR agencies have not conducted annual reviews of persons in extended employment; have been reluctant to reopen service records of those in extended employment and investigate alternative work settings; and have not taken into consideration advances in rehabilitation technology and the availability of community supports that may facilitate transition to integrated employment.

On the other hand, at least one State unit stated that annual reviews of individuals in extended employment have been effective and that it is unlikely that persons would remain in extended employment if they sought and were capable of competitive employment.

Finally, one commenter asked that we clarify this section of the proposed regulations, in particular the circumstances under which individuals are to receive annual reviews.

Discussion: We understand that there is uncertainty in the disability field concerning the extent to which reviews of VR program participants in extended employment have resulted in individuals transitioning to jobs in integrated settings. VR agencies must be vigorous in determining which individuals can, and wish to, transition to integrated employment (particularly competitive employment); in providing necessary supports to facilitate that transition; and in ensuring that annual reviews are more than cursory exercises (see e.g., Senate Report No. 105–166, p. 13, for more information on that point).

The statutory requirements concerning annual reviews of those in extended employment are key factors underlying these regulations. Those requirements, specifically section 101(a)(14) of the Act, establish an expectation that extended employment is not intended to serve as a final outcome under the VR program, but rather as an interim step through which eligible individuals can prepare for competitive employment. Given the importance of the reviews in enabling individuals with significant disabilities to transition to work in an integrated setting when desired by the individual, those reviews should be thorough evaluations of readiness for integrated work so that the State unit can effectively determine the interests, priorities, and needs of the individual with respect to employment in integrated settings.

To enhance the effectiveness of the annual reviews, § 361.55 of the regulations requires that the review and reevaluation of an individual's readiness for competitive employment provide for input from the individual or the individual's representative. We believe this requirement, which is based on corresponding requirements in the Act, will help ensure that State units make maximum efforts to assist individuals in transitioning from extended employment to integrated employment consistent with their desires.

While we do not believe it is necessary to revise § 361.55(a), we wish to clarify the instances in which reviews under this section of the regulations must be conducted. Specifically, annual reviews (for two years, and thereafter at the individual's request) are required if a VR program participant has—(1) achieved an employment outcome in which the individual is compensated in accordance with section 14(c) of the Fair Labor Standards Act (i.e., the individual is working in an integrated setting, but is compensated at less than the minimum wage); (2) had his or her record of services closed while in extended employment on the basis that the individual is unable to achieve an employment outcome; or (3) had his or her record of services closed while in extended employment because the individual has made an informed choice to remain in extended employment.

If an individual with a disability, in conjunction with the State unit, chooses to receive VR services initially in an extended employment setting in order to prepare for competitive employment, it is incumbent on the State unit to monitor closely the individual's progress. However, it is important to note that the annual review requirements of this section do not apply in that situation since the individual's program of VR services is ongoing and the individual's record of services remains open.

Changes: None.

§ 361.56 Requirements for Closing the Record of Services of an Individual Who Has Achieved an Employment Outcome

Comments: None.

Discussion: Section 361.56, which specifies the criteria for closing the record of services for an individual who has achieved an employment outcome under the VR program, like §§ 361.45 and 361.46 discussed previously, has been slightly revised in these final regulations to reflect the revised definition of the term "employment outcome" under the VR program.

Changes: We have amended § 361.56 to conform to the revised definition of "employment outcome" in § 361.5(b)(16).

Effective Date

Comments: A number of commenters suggested that the final regulations should provide VR agencies with the flexibility to implement the new regulations before the effective date proposed in the NPRM (October 1, 2001).

Discussion: As explained in the NPRM, we proposed requiring States to implement the regulatory changes in FY 2002 to minimize any potentially adverse impact on VR agencies or eligible individuals. At the same time, however, we are aware that some agencies already have established policies under which all VR program participants pursue integrated employment. We believe those policies are entirely consistent with the Act and the purpose of these regulations. Therefore, we are requiring that States implement these regulatory changes on or before October 1, 2001. After that date, an "employment outcome" under the VR program means employment in an integrated setting.

Changes: We have amended the regulations to allow VR agencies to implement the requirements in these regulations prior to FY 2002 at their discretion. The final regulations require that the requirements be implemented no later than October 1, 2001.

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National Park Service

36 CFR Part 7

Special Regulations, Areas of the National Park System; Final Rule

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DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

RIN 1024–AC82

Special Regulations, Areas of the National Park System

AGENCY: National Park Service, DOI.

ACTION: Final Rule.

SUMMARY: The National Park Service (NPS) is phasing out snowmobile use in Yellowstone National Park (Yellowstone), the John D. Rockefeller, Jr., Memorial Parkway (the Parkway), and, with some exceptions, in Grand Teton National Park (Grand Teton), and snowplane use in Grand Teton. This implements portions of an approved Winter Use Management Plan for the parks, to come into compliance with the legal requirements that apply to snowmobile use in national parks.

DATES: This rule becomes effective February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Kym Hall, Regulations Program Manager, National Park Service, 1849 C Street, NW., Room 7413, Washington, DC 20240. Telephone: (202) 208–4206. Fax: (202) 208–6756. Email: Kym_Hall@nps.gov.

SUPPLEMENTARY INFORMATION: The NPS (we) published the proposed rule on December 18, 2000. Background information on the rule is in that **Federal Register** notice (65 FR 79024).

Changes to Proposed Rule

We have made one set of substantive changes to the rule as originally proposed. A section of Public Law 106–554 (enacted after our proposal) provides that, prior to July 31, 2001, no new rules may be promulgated to reduce during the winter seasons of 2000–2001 or 2001–2002 snowmobile use in any units of the national park system below current use patterns. The rule does not include any such restrictions for the winter of 2000–2001. For the winter of 2001–2002, the proposed rule included daily limits on snowmobile use of all three parks at historic levels, to prevent increases in use; restrictions on nighttime snowmobile operation; and repeal of the current designation of seven routes in Yellowstone for snowmobile use. To avoid any questions about consistency with the recent statute, we have deleted these elements from the final rule. The statute explicitly allows emergency restrictions on snowmobile use during the winters of 2000–2001 and 2001–2002, and if warranted we will take action to protect park resources and values, or public or employee health or safety.

The remainder of this final rule is substantively identical to what was proposed.

Analysis of Public Comments

We provided 30 days for public comment on our proposal, through January 17, 2001. By midnight of that day, we had received 5,273 comments in the form of letters, postcards and e-mails. We analyzed comments as we received them, and analyzed every comment we received. Nearly all raised the same issues as earlier comments on the draft environmental impact statement (DEIS) and final environmental impact statement (FEIS) on the winter use plan for the parks. A few did raise new issues. Of the comments, 817 supported continued snowmobile use in the parks, 61 opposed both snowmobile and snowcoach use, and 4,395 supported the rule. Following is a summary of the comments we received on the proposed rule and our responses to them.

Issue 1—Most comments supported ending snowmobile use in the parks to protect air and water quality, restore natural quiet, reduce wildlife disturbances, and restore the tranquillity and serenity of the winter experience of the parks.

NPS Response—These comments support our action.

Issue 2—Some people said that snowmobiles do not affect the parks, that this rule unfairly discriminates against one particular use of the parks, or that we have no basis for ending a use that we have long allowed under the same legal requirements we now cite as reasons for ending it.

NPS Response—The **Federal Register** notice on the proposed rule summarizes the legal requirements that apply to snowmobile use in parks ("the applicable legal requirements"). In these parks, we have allowed snowmobile use to continue and expand, despite those requirements. (By contrast, in Glacier National Park, we halted snowmobile use soon after Executive Order 11644 was issued.) Having now studied the impacts of snowmobile use in these parks, we acknowledge that we have not complied with the applicable legal requirements. This rule will bring us into compliance.

Issue 3—Some comments said we should not take away visitors' personal freedom to ride snowmobiles where and when they want to, leaving as their only option travel in snowcoaches driven by somebody else.

NPS Response—We understand that many people enjoy the freedom snowmobiles provide. However, we must comply with the applicable legal requirements. Snowmobilers will continue to be able to ride snowmobiles where and when they want to on other lands, including nearby national forest lands that are open to snowmobile use. In other parks, when necessary to protect their resources and values, we have prohibited travel by individual motor vehicles, providing mass transit instead. This has been widely acceptable to visitors to those parks. We believe this change will be acceptable to visitors to these parks, too.

Issue 4—Many comments opposed eliminating most snowmobile use in the parks because of the adverse economic impacts they expect on businesses and gateway communities.

NPS Response—We believe this rule is the best way to comply with the applicable legal requirements while reducing possible adverse economic impacts. See the "Regulatory Flexibility Act" section, below.

Issue 5—Numerous comments urged us to require the use of cleaner and quieter snowmobiles rather than prohibiting the use of all snowmobiles.

NPS Response—Some newer snowmobiles have promise for reducing some impacts, but not enough for the use of large numbers of those machines to be consistent with the applicable legal requirements. Cleaner, quieter snowmobiles would do little, if anything, to reduce the most serious impacts on wildlife, which are caused more by inappropriate use of snowmobiles than by the machines themselves. Quieter snowmobiles are still noisy, and are audible at a greater distance than 4-track conversion snowcoaches. Since snowcoaches carry many passengers and snowmobiles only one or two, snowcoaches can accommodate the same level of overall winter visitation with far fewer noise impacts on the natural soundscape and other visitors than even quieter snowmobiles. Also, the ultimate extent to which some new snowmobiles may produce less air pollution over their useful life is unclear in the absence of emission standards, testing, and certification. Under the Clean Air Act, the EPA has the authority to establish emission standards for snowmobiles, and it is at least two or three years away from setting any such standards, which then would not take effect for additional years. The need for us to comply with the applicable legal requirements does not allow for such a delay.

Issue 6—Some comments said that we are mandated by law to conserve park resources and values, and so we should not allow as much, or any, snowmobile and snowcoach use as this rule allows.

NPS Response—Our statutory mandate includes providing for enjoyment of the parks. When, as here, we can allow motorized winter access while also complying with legal requirements and our management objectives, we believe it appropriate to do so.

Issue 7—Some comments claimed this rule is inappropriately burdening small businesses, or even unlawfully doing so in violation of the Regulatory Flexibility Act.

NPS Response—See the "Regulatory Flexibility Act" section, below. That law requires us to consider how to fulfill our objectives with fewer impacts on small entities. After considering a range of alternatives, we believe this rule is the alternative that complies with the applicable legal requirements and our management objectives with the fewest impacts on small businesses.

Issue 8—Some comments said we are relying too much on snowcoaches, expressing concerns about their reliability, the comfort of passengers, their availability for purchase in sufficient numbers and at prices affordable for businesses, and their lack of speed.

NPS Response—Snowcoaches have been used successfully in national parks for over 45 years. We believe their mechanical reliability is satisfactory. They are fast enough for Yellowstone destinations to be within reach for a trip of reasonable duration. They are comfortable enough—for most passengers, more comfortable than snowmobiles. Businesses currently operate 45 snowcoaches in the parks, indicating their viability as a business option. Additional businesses have already expressed interest in new economic opportunities resulting from this rule, from producing them for sale to operating them in the parks.

Issue 9—Some people urged us to end snowmobile use in the parks more quickly, to comply with the applicable legal requirements sooner than in four years.

NPS Response—Under our Management Policies 2000, if there is an impairment of park resources and values from ongoing activities, as here, we must eliminate it as soon as reasonably possible. If the impairment is not from permanent impacts, as here, in determining how soon that is, we may make due allowance for avoiding unacceptable social, economic, or environmental effects of the action eliminating the impairment. We believe that eliminating this impairment sooner than in four years would cause unacceptable effects on the communities and small businesses supporting and relying on snowmobile use in the parks. We believe the same principles should govern the timing of our coming into compliance with the other applicable legal requirements. Also, as indicated above, Congress has limited our authority to reduce snowmobile use in the 2000–2001 and 2001–2002 winter seasons. We will take other steps in the interim, such as increasing ranger efforts to keep inappropriate snowmobile use from disturbing wildlife, to mitigate the impacts of snowmobile use to the extent reasonably possible.

Issue 10—Some commenters stated that the public comment period on this rule was too short, particularly in light of the complexities of the issue.

NPS Response—This rule is based on an alternative in the DEIS and FEIS, on which we had three formal comment periods, and received and considered more than 59,000 comments. Given that and the relative lack of new issues raised by this rule, we believe 30 days for comment on the rule is adequate.

Issue 11—Some commenters said that this rule will drastically reduce winter use of the parks, contrary to the laws creating these parks and the national park system.

NPS Response—We believe this rule will allow the greatest number of people to visit the parks in ways that are consistent with the applicable legal requirements.

Issue 12—Some comments said that the NPS needs to consider the cost to the taxpayer of this program, along with the cost of new or upgraded facilities necessary to support it, and/or to develop a snowcoach implementation plan on such issues.

NPS Response—NPS disagrees that significant infrastructure is required to implement the rule. Snowcoaches currently operate effectively with existing facilities. We will develop the necessary plans and facilities in a timely manner to implement the changes that will result from this rule. If the development of any of those plans or facilities require their own environmental assessments or other studies, we will conduct those assessments or studies before making final decisions.

Issue 13—Some comments said we should have used more information supplied by the state and local governments that were cooperating agencies in the preparation of the EIS.

—The role of cooperating agencies in the development of an EIS is to participate in the internal review process, and provide information and opinion to the lead agency. It is the responsibility of the lead agency to decide which information to use in the EIS. When we chose to use other information than that provided by the cooperating agencies, we still included the information they provided in the FEIS.

Issue 14—Some commenters complained that, while we base this decision on the provision of the NPS Organic Act that we must leave parks unimpaired, we are not giving equal weight to the portion of the same provision that directs us to provide opportunities for enjoyment of the parks.

NPS Response—The NPS Organic Act, 16 U.S.C. 1 *et seq.*, does establish a mandate that we provide for enjoyment of the parks, but that is subject to the Act's overall limitation that we may not allow for the impairment of park resources and values. The overriding nature of the prohibition on impairment is clear from the language of the Act. The courts have also consistently interpreted the Act this way.

Issue 15—Some comments suggested letting snowmobiles in the parks only during certain designated periods of the winter, so that snowmobilers during those periods and other users during other periods could each enjoy the experiences they prefer.

NPS Response—Separating snowmobile and non-snowmobile visitors would only address the impact that snowmobile use has on other users, not the other adverse effects of snowmobile use, which we are also required to address under the applicable legal requirements.

Issue 16—Some commenters stated that the impacts of snowmobile use on wildlife identified in the FEIS are minor enough that they do not support one of the stated reasons for this rule, which is the elimination of adverse impacts to wildlife from snowmobile use in these parks.

NPS Response—Our general regulation on snowmobile use, 36 CFR 2.18, prohibits any snowmobile use that disturbs wildlife. The FEIS and studies referred to in it document ways in which snowmobile use in the parks disturbs wildlife. Based on the same information, we have also determined that the snowmobile use occurring in Yellowstone impairs its resources and values, including wildlife. The impacts include, in particular, the effects on bison in Yellowstone's roadways of snowmobiles, especially from those operated inappropriately by inexperienced operators. Bison are frequently herded back and forth on the

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roadways, requiring unnatural energy expenditures during the time of year of greatest stress to them, from high snow, extreme cold, and food shortages.

Issue 17—Some commenters said this rule will lead to increased snowmobile use on nearby national forest lands, which we must analyze before taking this action.

NPS Response—The FEIS includes a detailed discussion of potential impacts on adjacent national forest lands.

Issue 18—Some comments proposed limiting snowmobile numbers, and/or requiring snowmobilers to travel in guided groups, instead of ending snowmobile use.

NPS Response—Achieving compliance with the applicable legal requirements while still allowing snowmobile use would require very strict limits on the numbers of both snowmobiles and snowcoaches. (We have not done a detailed analysis of the actual limits that would be necessary.) As a result, that would sharply limit overall winter use of the parks, reducing the opportunities for public enjoyment of the parks and causing even greater adverse impacts on affected gateway communities and businesses. We chose instead to allow use of the parks by snowcoaches, which, because they have far fewer and less extensive adverse impacts than snowmobiles, can be accommodated, we now believe, without numerical limits.

Issue 19—Some commenters claimed that the air quality analyses on which this rule is based are not adequate.

NPS Response—We believe the data reported in the FEIS and in other NPS studies, particularly Air Quality Concerns Related to Snowmobile Usage in National Parks (NPS 2000), are adequate to support the conclusions on which this rule is based.

Issue 20—Some commenters stated that this rule will restrict winter access to the parks by disabled persons, in violation of federal law.

NPS Response—Disabled people will be able to ride in snowcoaches, with appropriate means of access provided, so their access will not be denied.

Issue 21—Some commenters claimed that NPS is regulating only winter vehicles and their impacts, and ignoring similar impacts and impairment from vehicles in the park in the summer.

NPS Response—Our planning effort focused on winter use activities in these parks, as required by the court order settling a lawsuit. Also, the applicable executive orders apply to snowmobile and snowcoach use, not other uses of the parks, and our general regulation on snowmobile use applies only to that use. However, when appropriate, we compared winter conditions and activities to those of other seasons, on such points as how snowmobiles and snowplanes are audible for greater distances than other motor vehicles, how the natural soundscapes in the park in winter are quieter than in other seasons, and how snowmobiles produce more carbon monoxide and hydrocarbon emissions in Yellowstone than all other motor vehicles.

Issue 22—NPS can mitigate impacts on wildlife by providing more rangers as in the summer, thus making the snowmobile ban unnecessary.

NPS Response—We will increase ranger patrols to reduce the impacts of snowmobile use on wildlife and the safety of visitors. We do not believe, however, especially within the constraints of our budgets and personnel limits, that increased ranger patrols can achieve compliance with the applicable legal requirements and our management objectives for the parks.

Issue 23—Some commenters suggested that, since most snowmobiles in the parks use Yellowstone's West Entrance, we should limit snowmobiles only there, not elsewhere.

NPS Response—Adverse impacts of snowmobile use on wildlife, air quality, and the enjoyment of other visitors occur throughout Yellowstone. Limiting snowmobiles only at the West Entrance would not address all impacts throughout the park, and might merely shift that use and its impacts to other entrances.

Issue 24—The visitor use (snowmobile) numbers provided in the draft rule are incorrect and should be recalculated.

NPS Response—We have deleted the proposed use limits for the winter of 2001–2002. We believe the use limits for the winter of 2002–2003 are correctly calculated, on the grounds stated in the notice on the proposed rule.

Issue 25—Some commenters said that the restriction Congress adopted in December on new NPS rules restricting snowmobile prevents us from adopting this rule.

NPS Response—As explained above, we removed from the proposed rule all of its elements that arguably could be considered to be inconsistent with the statutory provision.

Issue 26—Some commenters recommended that we end the grooming of roads in Yellowstone (whether for snowmobiles or snowcoaches), because groomed roads promote the migration of bison out of the park in the winter, onto lands where they may be killed out of concern over the possible transmission of brucellosis to livestock.

NPS Response—As documented in the FEIS, bison use groomed roads within the park, but there is no conclusive evidence on the extent to which groomed roads lead to migration of bison out of the park. The NPS and other involved federal agencies have recently adopted a new bison management plan that should reduce the killing of bison that have left the park. The plan does not rely on ending the winter grooming of Yellowstone roads.

Issue 27—Some commenters stated that we should allow a longer phase-in period before eliminating snowmobile use, to reduce the adverse economic impacts of that action.

NPS Response—As stated in the response to issue 10, our interpretation of the NPS Organic Act in our Management Policies 2000 requires us to eliminate an impairment as soon as reasonably possible. Because we believe it is possible to eliminate the impairment in Grand Teton by the winter of 2002–2003 and in Yellowstone and the Parkway by the winter of 2003–2004 without causing unacceptable social, economic, or environmental effects, we do not have the authority to delay any longer than that in eliminating the impairment. We believe it is reasonable and appropriate for the same principles to apply with respect to the timeline required to come into compliance with the applicable requirements of executive orders and NPS regulations.

Issue 28—Some commenters noted that the FEIS appears to identify the same impacts on wildlife from snowcoaches and from snowmobiles, undercutting our reasoning for ending snowmobile use and replacing it with expanded snowcoach use.

NPS Response—Snowcoaches have far less of an impact on wildlife than snowmobiles. First, snowcoaches, being operated by trained drivers under NPS-issued permits, are much less likely to be operated in a manner that harasses wildlife (especially bison on the roadways in Yellowstone) than are snowmobiles, which are often operated by people inexperienced with the parks in winter. Second, snowcoaches are quieter than snowmobiles, reducing the noise impacts on wildlife. Also, a single snowcoach carries many passengers, and a snowmobile only one or two, so the use of snowcoaches means 'fewer vehicles will be operating in and disturbing wildlife in the parks.

Issue 29—Some commenters stated that we failed to consider and respond to several issues raised in comments on the DEIS, as we are required to do.

NPS Response—While we did consider and respond to all of the approximately 46,500 comments on the DEIS, we combined some comments and responses into general categories, as is legally permissible.

Issue 30—Some commenters claimed that we may not allow grooming of road surfaces in winter or the operation of snowcoaches, since we have no regulations that specifically provide for those operations.

NPS Response—We do not need to have regulations specifically authorizing all management activities we undertake or public uses we allow in parks. Both road grooming and snowcoach operations are allowable under general NPS authorities.

Issue 31—Some comments suggested that we install a monorail public transit system that could provide access to the interior of Yellowstone year-round, instead of providing any other winter motorized access to the park.

NPS Response—We did not analyze a monorail option, because we believe it would be too expensive, even if technologically feasible. It also would take years to complete, longer than we can wait to comply with the applicable legal requirements.

Issue 32—Some commenters suggested that we should prohibit the use of snowmobiles and/or snowcoaches in the parks for our own administrative uses.

NPS Response—It would not be feasible to completely eliminate the administrative use of snowmobiles and/or snowcoaches in the parks. To begin with, NPS employees and their families live in the interior of Yellowstone, in areas not open to any other motor vehicles in the winter. However, we are ending recreational use of snowmobiles by NPS employees and their families, acquiring more snowcoaches to use instead of snowmobiles for administrative purposes, and otherwise reducing the impacts of our use of snowmobiles and snowcoaches.

Issue 33—Some people said the FEIS was not detailed enough, either in general or on one or more particular issues.

NPS Response—We believe the FEIS includes adequate detail. The Environmental Protection Agency (EPA), which reviewed the adequacy of the FEIS, also found it to be satisfactory. It does summarize and incorporate by reference much data available elsewhere, as is allowable.

Issue 34—Some comments pointed out that adoption of the rule is essential for the NPS to have the authority to phase in compliance with the applicable legal requirements, that without a rule such as this we would need to take immediate action to come into compliance.

NPS Response—We believe this is correct.

Issue 35—The Continental Divide Snowmobile Trail and the Grassy Lake Road should remain open to provide access to adjacent public lands.

NPS Response—We believe that ending snowmobile use of these trails is necessary to comply with the applicable legal requirements and fulfill our management objectives for the park. We are allowing continued snowmobile use on short routes to adjacent lands open to snowmobile use, or to provide access to private property, when that can be done without violating the applicable legal requirements. Neither is the case for these two routes.

Issue 36—Requiring that all visitors be accompanied by a guide is overstepping NPS authority and is unwarranted. Further it will have no beneficial impact on employment in the surrounding communities as stated in the proposed rule.

NPS Response—We believe this is an important requirement to mitigate the impacts of snowmobile use on wildlife and the safety of other visitors during the last year before the use is ended.

Issue 37—NPS should not allow roads to continue to be groomed because it alters the parks' wildlife population movement and dynamics, particularly in relation to bison.

The FEIS is deficient because NPS failed to evaluate and analyze the considerable scientific evidence documenting the adverse impact of road grooming on park wildlife, particularly bison, and the inconsistency of road grooming with NPS' natural regulation mandate.

NPS Response—As documented in the FEIS, bison use groomed roads within the park, but there is no conclusive evidence that groomed roads lead to migration of bison out of the park. The impacts of road grooming on all wildlife species of concern are addressed for each alternative in the FEIS. Available literature on this topic was reviewed and cited as necessary in the FEIS.

Issue 38—The FEIS is deficient because NPS failed to properly consider and respond to several issues raised in comments submitted on the DEIS.

NPS Response—We considered and responded to all comments on the DEIS. Similar comments were grouped and responded to in like fashion.

Issue 39—The NPS failed to consider the impacts of road grooming on threatened and endangered species in violation of the Endangered Species Act.

NPS Response—We did consider and document these impacts in the FEIS and in a biological assessment concurred in by the U.S. Fish and Wildlife Service.

Issue 40—Some comments said we are required to ban snowmobile use, based on our finding of impairment, whether or not a final rule is published.

NPS Response—We are required under the Organic Act to eliminate the impairment. We believe that the rulemaking process is the most appropriate process for doing so in this instance.

Issue 41—Some comments from employees of Yellowstone National Park raised concerns about the health effects on them of exposure to air pollutants from snowmobiles and concerns about excessive numbers of violations by snowmobile operators of such laws as speed limits, creating public safety hazards.

NPS Response—We are very concerned about the adverse health effects from air emissions on our employees, particularly those working at Yellowstone's West Entrance station. If we need to take additional steps to protect the health of NPS employees, we will do so. Over time, the rule will reduce both health and law enforcement problems.

Compliance With Other Laws

Regulatory Planning and Review

This document is a significant rule and has been reviewed by the Office of Management and Budget under Executive Order 12866.

1. This rule will not have an effect of $100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. These conclusions are based on the analysis contained in the FEIS and a report we commissioned on the economic impact of this regulation, "Proposed Restrictions on Snowmobile Riding in Yellowstone and Grand Teton National Parks and the John D. Rockefeller Memorial Parkway" (LawGibb Group, Arcadis JSA, and Research Triangle Institute, January 2001). According to these analyses, the total effect on the economy is likely to be between $4.8 million and $19 million annually.

2. This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. Implementing actions under this rule will not interfere with plans by other agencies or local

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government plans, policies, or controls since this is an agency specific change.

3. This rule does not alter the budgetary effects or entitlements, grants; user fees, or loan programs or the rights or obligations of their recipients. It only affects the use of over-snow machines within specific national parks. No grants or other forms of monetary supplement are involved.

4. This rule may raise novel legal or policy issues. The issue has generated local as well as national interest on the subject in the greater Yellowstone area. We received over 63,000 public comments on the scope of the DEIS, the FEIS, and the rule.

Regulatory Flexibility Act

Based on our economic analysis and supporting documents, we certified in our notice on the proposed rule that the rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Nonetheless, we have now contracted for a separate and more detailed analysis of the economic impacts of the rule, especially on small entities, "Proposed Restrictions on Snowmobile Riding in Yellowstone and Grand Teton National Parks and the John D. Rockefeller Memorial Parkway" (LawGibb Group, Arcadis JSA, and Research Triangle Institute, January 2001). It estimates that the total adverse economic effect on businesses (mostly small businesses) will likely range from $4.8 million to $10 million annually. Based on the FEIS and this report, we have determined and again certify that there will not be a significant economic effect on a substantial number of small entities from this rule. We summarize our analysis as follows:

Statement of need and objectives of the rule—to come into compliance with the applicable legal requirements and to fulfill park management objectives, as stated in the notice on the proposed rule and in this notice.

Issues raised in public comments—See the FEIS, Volume III (parts 1, 2, and 3) and our responses in this document.

Small entities affected—Most affected will be 70 snowmobile rental businesses and 11 snowcoach tour companies, which could lose between $4.1 million to $4.4 million annually. Most are in West Yellowstone, Montana, with others in other gateway communities. Hotels, restaurants, gas stations, and retail establishments, again mostly in West Yellowstone but also in other gateway communities, will be less affected, and could lose between $700,000 to $5.6 million annually. One local government, the city of West Yellowstone, will be an affected small entity, and could lose between $80,000 to $125,000 from reduced resort tax receipts. From a national perspective, these impacts do not constitute a significant impact to a substantial number of small entities.

Reporting and recordkeeping requirements for small businesses—There are none.

Alternatives considered to reduce impacts—We have considered various alternatives, and have made various decisions, to mitigate the impacts of this rule on small entities. We believe this rule complies with the applicable legal requirements with the fewest adverse impacts on small entities, for several reasons.

First, we rejected the approach, included in the preferred alternative in the DEIS, of plowing the road between Yellowstone's West Entrance and Old Faithful in the winter, keeping it open to wheeled vehicles, and closing it to snowmobiles and snowcoaches. This approach was opposed by approximately 99% of the people who commented on this part of the DEIS, in large part because of the adverse economic impact it would have on West Yellowstone and businesses there dependent on oversnow recreation in Yellowstone.

Second, while it might be possible to comply with the applicable legal requirements while allowing some continued use of both snowmobiles and snowcoaches in the parks, the numbers of both snowmobiles and snowcoaches would have to be very strictly limited, to comply with the strict standards of the applicable requirements. As a result, this approach would end up drastically reducing the number of winter visitors to the parks, with a much greater adverse economic impact than under this rule. We did not choose this approach.

Third, we also could have chosen to comply with the applicable legal requirements by allowing only snowcoaches, not also snowmobiles, in the parks, but limiting the number of snowcoaches allowed to lessen their impact. This, too, would lead to a reduction in winter visitation to the parks more than this rule might.

Fourth, other approaches that we have considered that would continue to allow significant numbers of snowmobiles to use the parks would fail to comply with the applicable legal requirements. These include relying on air pollution emission standards established by EPA; establishing our own stricter noise emission limits; and restricting snowmobile use to more limited areas of the parks or to more limited times. We are not free to continue to violate those requirements just to avoid the possible impacts of complying with them.

Steps taken to minimize economic impacts—We have made several decisions on how to implement this action to mitigate any adverse economic impacts, especially those on small entities. To begin with, the elimination of snowmobiles will be phased over four winter seasons, allowing significant time for affected businesses to adjust to providing snowcoach service instead. Next, snowcoach access to the parks will require a concession permit from us. Permits will be awarded to numerous small businesses in the surrounding communities. We have already authorized existing snowmobile operators to add snowcoach service, and authorized existing snowcoach operators to add more coaches. Finally, we will join with the tourism offices of the affected states and counties, as well as destination marketing organizations, to market winter visitation to the parks under the new rules. We have committed $100,000 in fiscal year 2001 for this purpose.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

A. Does not have an annual effect on the economy of $100 million or more. From the FEIS, estimated economic loss and employment impacts of implementing actions under this rule are: In the five-county, greater Yellowstone area, an estimated loss of $14.4 to $19.2 million; in the three state area surrounding the parks, a possible loss of $7.7 million to a possible increase of $7.0 million. Increased winter visitation from new visitors to the parks who have not visited them because of the impacts of snowmobiles could substantially offset the estimated loss and employment reductions from a reduction in visitation by current winter visitors.

B. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The potential loss of revenue from snowmobile users will likely be offset by visitors using snowcoaches to visit the park. Additionally, the summer visitation to the region would continue to exist and would not likely cause local businesses to need to raise prices to maintain their revenues.

C. Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This rulemaking has no effect on methods of manufacturing or production and specifically affects the Wyoming region, not national or U.S. based enterprises.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local or tribal governments or the private sector. It addresses public use of national park lands, and imposes no requirements on other agencies or governments.

Takings (Executive Order 12630)

In accordance with Executive Order 12630, the rule does not have significant takings implications. Private property within or adjacent to the parks will still be afforded the same access during winter as before this rule. No other property is affected.

Federalism (Executive Order 13132)

In accordance with Executive Order 13132, the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. It addresses public use of national park lands, and imposes no requirements on other agencies or governments.

Civil Justice Reform (Executive Order 12988)

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This regulation does not require an information collection from 10 or more parties and a submission under the Paperwork Reduction Act is not required. An OMB form 83–I is not required.

National Environmental Policy Act

This rule is a major Federal action significantly affecting the quality of the human environment. A Final Environmental Impact Statement has been completed and a Record of Decision issued which this rule implements in part.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government to Government Relations with Native American Tribal Governments" (59 FR 22951) our departmental manual, 512 DM 2, and in compliance with Executive Order 13175, Consultation and Coordination With Indian Tribal Governments, issued on November 6, 2000 (65 FR 67249), we have evaluated potential effects on federally recognized Indian tribes and have determined that there are no potential effects. Numerous tribes in the area were consulted in the development of the EIS. Their major concern was to reduce the adverse effects on wildlife by snowmobiles. This rule does that.

Drafting Information

The principal contributors to this rule have been Stephen C. Saunders, Deputy Assistant Secretary of the Interior for Fish and Wildlife and Parks; T. Destry Jarvis, Senior Advisor to the Assistant Secretary for Fish and Wildlife and Parks; Karen S. Kovacs, Senior Advisor to the Assistant Secretary for Fish and Wildlife and Parks; Molly Ross, Assistant Solicitor, Branch of National Parks, Office of the Solicitor; Kym A. Hall, NPS Regulations Program Manager; Sarah Creachbaum and Bob Rossman Outdoor Recreation Planners, Grand Teton; and John Sacklin, Supervisory Park Resource Planner, Yellowstone.

List of Subjects in 36 CFR Part 7

District of Columbia, National parks, Reporting and recordkeeping requirements.

We amend 36 CFR part 7 as set forth below:

PART 7—SPECIAL REGULATIONS; AREAS OF THE NATIONAL PARK SYSTEM

1. The authority for part 7 continues to read as follows:

Authority: 16 U.S.C. 1, 3, 9a, 460(q), 462(k); Sec. 7.96 also issued under D.C. Code 8–137 (1981) and D.C. Code 40–721 (1981).

2. In § 7.13, remove the heading of paragraph (l), revise paragraphs (l)(1) and (l)(2) introductory text, add a heading to paragraph (l)(2), and add paragraphs (l)(3) through (l)(14) to read as follows:

§ 7.13 Yellowstone National Park.

* * * * *

(l)(1) *May I operate a snowmobile in Yellowstone National Park?* You may operate a snowmobile in Yellowstone National Park in compliance with the public use limits and operating conditions established in this section. Effective with the end of the winter use season of 2003–2004, snowmobile use in Yellowstone National Park is prohibited, except for essential administrative use and in emergency situations as determined by the Superintendent.

(2) *What routes are designated for snowmobile use in the park through the winter season of 2001–2002?* Effective until the end of the winter use season of 2001–2002, snowmobile use shall be limited to the unplowed roadway, which is defined as that portion of the roadway located between the road shoulders designated by snow poles or poles, ropes, and signs erected by the superintendent to regulate snowmobile activity, of the following routes for snowmobile use:

* * * * *

(3) *What is a winter use season?* A winter use season is that portion of the winter months that begins each year in approximately late November, through the following year ending in approximately the middle of March. Specific dates are dependent on weather conditions and the availability of NPS facilities and resources and may be adjusted at the discretion of the Superintendent. Appropriate notice will be given to the public of determined start and ending dates each season.

(4) *When snowmobile use is authorized, where may I operate my snowmobile?* You may operate your snowmobile upon designated routes established within the park. On designated routes, snowmobile use is limited to the unplowed roadway, which is distinguished as that portion of the roadway located between the road shoulders and is designated by snow poles or other poles, ropes, fencing, or signs erected to regulate snowmobile activity. The unplowed roadway may also be distinguished by the interior boundaries of the berm created by the packing and grooming of the unplowed roadway. Snowmobiles may also be operated in pullouts or parking areas that are groomed or marked similarly to roadways.

(5) *What routes are designated for snowmobile use in the park during the winter season of 2002–2003?* During the winter use season of 2002–2003, the following routes are designated for snowmobile use:

(i) The Grand Loop Road from its junction with Terrace Springs Drive to Norris Junction.

(ii) Norris Junction to Canyon Junction.

(iii) The Grand Loop Road from Norris Junction to Madison Junction.

(iv) The West Entrance Road from the park boundary at West Yellowstone to Madison Junction.

(v) The Grand Loop Road from Madison Junction to West Thumb.

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(vi) The South Entrance Road from the South Entrance to West Thumb.
(vii) The Grand Loop Road from West Thumb to its junction with the East Entrance Road.
(viii) The East Entrance Road from the East Entrance to its junction with the Grand Loop Road.
(ix) The Grand Loop Road from its junction with the East Entrance Road to Canyon Junction.
(x) The South Canyon Rim Drive.
(xi) Any groomed or marked pullouts or parking areas along each of these routes.
(xii) In the developed areas of Madison Junction, Old Faithful, Grant Village, Lake, Fishing Bridge, Canyon, Indian Creek, and Norris, snowmobile routes to scenic points of interest, lodging, and other facilities will be designated by appropriate snow poles and signs and will be limited to the unplowed roadways in those areas.
(xiii) The Superintendent may open or close these routes after taking into consideration the location of wintering wildlife, appropriate snow cover, and other factors that may relate to public safety.
(xiv) Maps detailing the designated routes will be available from Park Headquarters.

(6) *What criteria may the Superintendent use to determine the routes within the developed areas referred to in paragraph (l)(5)(xii) of this section?* The Superintendent shall use the criteria in Executive Order 11644 (3 CFR, 1971–1975 Comp., p. 666) and may use other criteria to determine use routes within the developed areas of Madison Junction, Old Faithful, Grant Village, Lake, Fishing Bridge, Canyon, Indian Creek and Norris including the most direct route of access, weather and snow conditions, and those routes necessary to eliminate congestion and improve the circulation of the visitor use patterns in the interest of public safety.

(7) *What limits are established for the numbers of snowmobiles permitted to use the park each day?* For the winter use season 2002–2003, the numbers of snowmobiles allowed to use the park each day are listed in the following table:

Park entrance gate or area	Maximum daily number of snowmobiles allowed per gate
(i) North Entrance	60
(ii) West Entrance	278
(iii) East Entrance	65
(iv) South Entrance	90

(8) *May I operate a snowcoach in Yellowstone National Park?* Snowcoaches may be operated in Yellowstone National Park under a Concessions Contract or Permit authorized by the Superintendent. Snowcoach operation is subject to the conditions of the permit and all other conditions identified in this section.

(9) *What is a snowcoach?* A snowcoach is a self-propelled mass transit vehicle intended for travel on snow, having a curb weight of over 1000 pounds (450 kilograms), driven by a track or tracks and steered by skis or tracks, having a capacity of at least 8 passengers.

(10) *What routes are designated for snowcoach use?* Snowcoaches may operate on the same routes designated for snowmobile use in paragraph (l)(5) of this section and the following designated routes:
(i) Firehole Canyon Drive.
(ii) Fountain Flat Road.
(iii) Virginia Cascades Drive.
(iv) North Canyon Rim Drive.
(v) Riverside Drive.
(vi) Lake Butte Overlook Drive.
(vii) The portion of the Grand Loop Road from Canyon Junction to Washburn Hot Springs Overlook.

(11) *What other conditions are placed on snowmobile and snowcoach operations?* Snowmobiles and snowcoaches may be operated in the park under the following conditions:
(i) Snowcoaches, and during the winter use season of 2002–2003 snowmobiles, may not be operated in the park between the hours of 9:00 p.m. and 8:00 a.m. except by authorization.
(ii) Idling a snowmobile or snowcoach is limited to 10 minutes at any one time.
(iii) Snowmobiles or snowcoaches that stop on designated routes must pull over to the far right next to the snow berm. Stopping the vehicle in a hazardous location, or where the view of the vehicle might be obscured, such as on a curve, is prohibited. Pullouts must be utilized when available and accessible.
(iv) Snowmobiles and snowcoaches must be properly registered and display a valid state registration sticker.
(v) Snowmobile operators must possess a valid state motor vehicle operator's license or learner's permit. The license or permit must be carried on the operator's person at all times.
(vi) Persons operating a snowmobile while possessing a learner's permit must be accompanied and supervised within line of sight, but no further than 100 yards, by a responsible person 21 years of age or older possessing a valid state motor vehicle operator's license.
(vii) Allowing or permitting an unlicensed driver to operate a snowmobile is prohibited.
(viii) During the winter season of 2002–2003, snowmobiles must be accompanied by an NPS permitted guide and may not travel in groups of more than 11 snowmobiles.

(12) *May I operate a snowplane in the park?* The operation of snowplanes in Yellowstone National Park is prohibited.

(13) *What is a snowplane?* A snowplane is a self-propelled vehicle intended for over-the-snow travel and driven by a pusher-propeller.

(14) *Are there any other forms of over-snow transportation allowed in the park?* No other forms of motorized over-snow transportation are permitted for use in the park unless specifically approved by the Superintendent and are consistent with the requirements of the applicable Executive Orders and the park's management plans.

* * * * *

3. In § 7.21, remove the heading of paragraph (a), revise paragraphs (a)(1), (a)(2) introductory text, and (a)(3), add a heading to paragraph (a)(2), and add paragraphs (a)(4) through (a)(12) to read as follows:

§ 7.21 John D. Rockefeller, Jr., Memorial Parkway.

(a)(1) *May I operate a snowmobile in the Parkway?* You may operate a snowmobile in the Parkway in compliance within the public use limits and operating conditions established in this section until the end of the winter use season of 2002–2003 at which time snowmobile use in the Parkway is prohibited except for essential administrative use and in emergency situations as determined by the Superintendent.

(2) *What routes are designated for snowmobile use in the Parkway prior to the winter use season of 2002–2003?* Effective until the end of the winter use season of 2001–2002, the following are the designated routes to be open to snowmobile use:

* * * * *

(3) *What is a winter use season?* A winter use season is that portion of the winter months that begins each year in approximately late November through the following year ending in approximately the middle of March. Dates are dependent on weather conditions and the availability of NPS facilities and resources and may be adjusted at the discretion of the Superintendent. Appropriate notice will be given to the public of determined start and ending dates each season.

(4) *What routes are designated for snowmobile use in the Parkway in the winter use season of 2002–2003?* During the winter use season of 2002–2003, the following routes are designated for snowmobile use:
(i) The Continental Divide Snowmobile Trail (CDST) along U.S. Highway 89/287 from the southern boundary of the Parkway to Flagg Ranch.
(ii) Along U.S. Highway 89/287 from Flagg Ranch to the northern boundary of the Parkway.
(iii) Grassy Lake Road from Flagg Ranch to the western boundary of the Parkway.
(iv) The Superintendent may open or close these routes after taking into consideration the location of wintering wildlife, appropriate snow cover, and other factors that may relate to public safety.
(v) Maps detailing the designated routes will be available from Park Headquarters.

(5) *What limits are established for the numbers of snowmobiles permitted to use the Parkway each day?* For the winter use season 2002–2003, the numbers of snowmobiles allowed to use the Parkway each day are listed in the following table:

Park entrance gate or area	Maximum number of snowmobiles allowed per gate
(i) Continental Divide Snowmobile Trail (along U.S. 89/287) from the southern boundary of the JDR Parkway to Flagg Ranch	25
(ii) (Along U.S. 89/287) Flagg Ranch to northern boundary of Parkway	90
(iii) Grassy Lake Road	25

(6) *May I operate a snowcoach in the Parkway?* Snowcoaches may be operated in the Parkway under a Concessions Contract or Permit authorized by the Superintendent. Snowcoach operation is subject to the conditions of the permit and all other conditions identified in this section.

(7) *What is a snowcoach?* A snowcoach is a self-propelled mass transit vehicle intended for travel on snow, having a curb weight of over 1000 pounds (450 kilograms), driven by a track or tracks and steered by skis or tracks, having a capacity of at least 8 passengers.

(8) *What routes are designated for snowcoach use?* Snowcoaches may operate on the routes designated for snowmobile use in paragraphs (a)(4)(i) through (iii) of this section.

(9) *What other conditions are placed on snowmobile and snowcoach operations?* Snowmobiles and snowcoaches may be operated under the following conditions:
(i) Snowmobiles or snowcoaches that stop on designated routes must pull over to the far right next to the snow berm. Stopping the vehicle in a hazardous location, or where the view of the vehicle might be obscured, such as on a curve, is prohibited. Pullouts must be utilized when available and accessible.
(ii) Snowmobiles and snowcoaches must be properly registered and display a valid state registration sticker.
(iii) Snowmobile operators must possess a valid state motor vehicle operator's license or learner's permit. The license or permit must be carried on the operator's person at all times.
(iv) Persons operating a snowmobile while possessing a learner's permit must be accompanied and supervised within line of sight, but no further than 100 yards, by a responsible person 21 years of age or older possessing a valid state motor vehicle operator's license.
(v) Allowing or permitting an unlicensed driver to operate a snowmobile is prohibited.
(vi) Snowcoaches, and during the winter use season of 2002–2003 snowmobiles, may not be operated in the park between the hours of 9 p.m. and 8 a.m. except by authorization.

(10) *May I operate a snowplane in the Parkway?* The operation of snowplanes in the Parkway is prohibited.

(11) *What is a snowplane?* A snowplane is a self-propelled vehicle intended for over-the-snow travel and driven by a pusher-propeller.

(12) *Are there any other forms of over-snow transportation allowed in the Parkway?* No other forms of motorized over-snow transportation are permitted for use in the Parkway unless specifically approved by the Superintendent and are consistent with the requirements of the applicable Executive Orders and the park's management plans.

* * * * *

4. Paragraph (g) of § 7.22 is revised to read as follows:

§ 7.22 Grand Teton National Park.

* * * * *

(g)(1) *May I operate a snowmobile in Grand Teton National Park?* Until the end of the winter use season of 2001–2002, you may operate a snowmobile on the routes and areas designated in paragraphs (g)(2) through (g)(4) of this section in compliance with operating standards established by the Superintendent. During the winter use season of 2002–2003, you may operate a snowmobile on the route designated in paragraph (g)(6) of this section in compliance with the public use limits and operating standards established by the Superintendent. Effective the winter use season of 2003–2004, snowmobile use will be restricted to the routes and purposes in paragraphs (g)(10), (11), (12), and (13) of this section. All other snowmobile use is prohibited, except for essential administrative use and in emergency situations as determined by the Superintendent.

(2) Effective until the end of the winter use season 2001–2002, the following are the designated routes to be open to snowmobile use: The Spread Creek Road; the unplowed portion of the Pacific Creek Road; the unplowed portion of the Ditch Creek Road; the Lost Creek Ranch Road, those portions of the unplowed roads connecting with the Shadow (Antelope) Mountain Forest Service Road at Cunningham Cabin, Lost Creek Road and Antelope Flats Road; the unplowed portions of the Moose-Wilson Road; and the unplowed portion of the Teton Park Road north of Cottonwood Creek to a line of markers south of Timbered Island, around the east side of Timbered Island north to the line of markers at South Jenny Lake Junction, and then north to Signal Mountain Lodge, except during the period previous to opening of Potholes-Baseline Flats areas when the Teton Park Road will be open through to Signal Mountain, the Jenny Lake Loop Road, the Spalding Bay Road, the String Lake Picnic Area Road, the Signal Mountain Summit Road, the Signal Mountain Launch Ramp Road, and the Lizard Creek Campground Road.

(3) Effective until the end of the winter use season 2001–2002, the following are the designated areas open to snowmobile use: The Potholes-Baseline Flats area east of the Teton Park Road north of the Cottonwood Creek, north of the Bar BC access road, east of Timbered Island, west of the River Road or as marked at the top of the Snake River Bench, northwest of Timbered Island as marked to the Teton Park Road and bounded on the north by the RKO Road.

(4) Effective until the end of the winter use season 2001–2002, the following water surface is designated for snowmobile and snowplane use: The frozen surface of Jackson Lake.

(5) *What is a winter use season?* A winter use season is that portion of the winter months that begins each year in approximately late November, through

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the following year ending in approximately the middle of March. Specific dates are dependent on weather conditions and the availability of park facilities and resources and may be adjusted at the discretion of the Superintendent. Appropriate notice will be given to the public of determined start and ending dates each season.

(6) *What routes and limits are designated for snowmobile use in the park during the winter use season of 2002–2003?* For the winter use season of 2002–2003, the Continental Divide Snowmobile Trail along U.S. 26/287 from Moran to the eastern park boundary and along U.S. 89/287 from Moran to the north park boundary is designated for snowmobile use. The Superintendent may open or close this route after taking into consideration the location of wintering wildlife, appropriate snow cover, and other factors that may relate to public safety. A maximum of 25 snowmobiles is allowed to use this route each day.

(7) *What other conditions are placed on snowmobile operations?* Snowmobiles may be operated in the park under the following conditions:

(i) Snowmobiles that stop on designated routes must pull over to the far right next to the snow berm. Stopping the vehicle in a hazardous location, or where the view of the vehicle might be obscured, such as on a curve, is prohibited. Pullouts must be utilized when available and accessible.

(ii) Snowmobiles must be properly registered and display a valid state registration sticker.

(iii) Snowmobile operators must possess a valid state motor vehicle operator's license or learner's permit. The license or permit must be carried on the operator's person at all times. Snowmobile operators are not required to possess a valid drivers license while operating on the public access routes designated in paragraph (g)(10) of this section and the private property access routes designated in paragraph (g)(12) of this section.

(iv) Persons operating a snowmobile while possessing a learner's permit must be accompanied and supervised within line of sight, but no farther than 100 yards, by a responsible person 21 years of age or older possessing a valid state motor vehicles operator's license.

(v) Allowing or permitting an unlicensed driver to operate a snowmobile is prohibited.

(vi) Snowcoaches, and during the winter use season of 2002–2003 snowmobiles, may not be operated in the park between the hours of 9 p.m. and 8 a.m.

(8) *May I operate a snowplane in the park?* If you had a permit to operate a snowplane on Jackson Lake during the winter use season 2000–2001, you may obtain a permit to operate a snowplane on Jackson Lake during the winter use season of 2001–2002. Effective at the end of the winter use season 2001–2002, snowplane use in Grand Teton National Park is prohibited.

(9) *What is a snowplane?* A snowplane is a self-propelled vehicle intended for over-the-snow travel and driven by a pusher-propeller.

(10) *May I continue to access public lands via snowmobile through the park?* Reasonable and direct access via snowmobile to adjacent public lands will continue to be permitted on designated routes through the park. The following routes are designated for access via snowmobile to public lands:

(i) From the parking area at Shadow Mountain directly along the unplowed portion of the road to the east park boundary.

(ii) Along the unplowed portion of the Ditch Creek Road directly to the east park boundary.

(iii) From the Cunningham Cabin pullout on U.S. 26/89 near Triangle X to the east park boundary.

(11) *For what purpose may I use the routes designated in paragraph (g)(10) of this section?* You may use those routes designated in paragraph (g)(10) of this section to gain direct access to public lands adjacent to the park boundary.

(12) *May I continue to access private property within or adjacent to the park via snowmobile?* Reasonable and direct access via snowmobile to private property will continue to be permitted via designated routes in the park. The following routes are designated for access to private property within or adjacent to the park:

(i) The unplowed portion of Antelope Flats Road off U.S. 26/89 to private lands in the Craighead Subdivision.

(ii) The unplowed portion of the Teton Park Road to that piece of land commonly referred to as the "Clark Property".

(iii) From the Moose-Wilson Road to the land commonly referred to as the "Barker Property" until the Department of the Interior takes full possession of that land.

(iv) From the Moose-Wilson Road to the land commonly referred to as the "Wittimer Property" until the Department of the Interior takes full possession of that land.

(v) From the Moose-Wilson Road to those two pieces of land commonly referred to as the "Halpin Properties".

(vi) From either end of the plowed sections of the Moose-Wilson Road to that piece of land commonly referred to as the "JY Ranch".

(vii) From Highway 26/89/187 to those lands commonly referred to as the "Meadows", the "Circle EW Ranch", the "Moulton Property, the "Levinson Property" and the "West Property".

(viii) From Cunningham Cabin pullout on U.S. 26/89 near Triangle X the piece of land commonly referred to as the "Lost Creek Ranch".

(ix) Maps detailing designated routes will be available from Park Headquarters.

(13) *For what purpose may I use the routes designated in paragraph (g)(12) of this section?* Those routes designated in paragraph (g)(12) of this section are to access private property within or directly adjacent to the park boundary. Use of these roads via snowmobile is authorized only for the landowners and their representatives or guests. Recreational use of these roads by anyone is prohibited.

(14) *Are there any other forms of over-snow transportation allowed in the park?* No other forms of motorized over-snow transportation are permitted for use in the park unless specifically approved by the Superintendent and are consistent with the requirements of the applicable Executive Orders and the park's management plans.

Dated: January 18, 2001.

Stephen C. Saunders,

Acting Assistant Secretary, Fish and Wildlife and Parks.

[FR Doc. 01–1944 Filed 1–19–01; 8:45 am]

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Federal Register

Monday,
January 22, 2001

Part XVIII

The President

Executive Order 13191—Implementation of the African Growth and Opportunity Act and the United States-Caribbean Basin Trade Partnership Act

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Federal Register
Vol. 66, No. 14
Monday, January 22, 2001

Presidential Documents

Title 3—

The President

Executive Order 13191 of Janaury 17, 2001

Implementation of the African Growth and Opportunity Act and the United States-Caribbean Basin Trade Partnership Act

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the African Growth and Opportunity Act (Title I of Public Law 106–200) (AGOA), the United States-Caribbean Basin Trade Partnership Act (Title II of Public Law 106–200) (CBTPA), the Caribbean Basin Economic Recovery Act (19 U.S.C. 2701 *et seq.*), and section 301 of title 3, United States Code, and in order to expand international trade and enhance our economic partnership with sub-Saharan Africa and the Caribbean Basin, promote investment and economic development and reduce poverty in those regions, and create new economic opportunities for American workers and businesses, it is hereby ordered as follows:

Part I—Implementation of the AGOA

Section 1. *Apparel Articles Assembled from Fabrics or Yarn Not Available in Commercial Quantities.* The Committee for the Implementation of Textile Agreements (the "Committee") is authorized to exercise the authority vested in the President under section 112(b)(5)(B)(i) of the AGOA (19 U.S.C. 3721(b)(5)(B)(i)) to determine whether yarns or fabrics cannot be supplied by the domestic industry in commercial quantities in a timely manner. The Committee shall establish procedures to ensure appropriate public participation in any such determination. The Committee and the United States Trade Representative (USTR) are jointly authorized to exercise the authority vested in the President under sections 112(b)(5)(B)(ii), (iii), and (v) of the AGOA (19 U.S.C. 3721(b)(5)(B)(ii), (iii), and (v)) to obtain advice from the appropriate advisory committee, to submit a report to the appropriate Congressional committees, and to consult with those Congressional committees. The USTR is authorized to exercise the authority vested in the President under section 112(b)(5)(B)(ii) of the AGOA to obtain advice from the U.S. International Trade Commission (USITC).

Sec. 2. *Handloomed, Handmade, and Folklore Articles.* The Committee, after consultation with the Commissioner, United States Customs Service (Commissioner), is authorized to exercise the authority vested in the President under section 112(b)(6) of the AGOA (19 U.S.C. 3721(b)(6)) to consult with beneficiary sub-Saharan African countries and to determine which, if any, particular textile and apparel goods shall be treated as being handloomed, handmade, or folklore articles. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 3. *Certain Interlinings.* The Committee is authorized to exercise the authority vested in the President under section 112(d)(1)(B)(iii) of the AGOA (19 U.S.C. 3721(d)(1)(B)(iii)) to determine whether U.S. manufacturers are producing interlinings in the United States in commercial quantities. The Committee shall establish procedures to ensure appropriate public participation in any such determination. The determination or determinations of the Committee under this section shall be set forth in a notice or notices that the Committee shall cause to be published in the **Federal Register**. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 4. *Penalties for Transshipments.* The Committee, after consultation with the Commissioner, is authorized to exercise the authority vested in the President under section 113(b)(3) of the AGOA (19 U.S.C. 3722(b)(3)) to

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determine, based on sufficient evidence, whether an exporter has engaged in transshipment and to deny for a period of 5 years all benefits under section 112 of the AGOA (19 U.S.C. 3721) to any such exporter, any successor of such exporter, and any other entity owned or operated by the principal of such exporter. The determination or determinations of the Committee under this section shall be set forth in a notice or notices that the Committee shall cause to be published in the **Federal Register**. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 5. *Effective Visa Systems.* Pursuant to sections 112(a) and 113(a)(1) of the AGOA (19 U.S.C. 3721(a) and 3722(a)(1)), the USTR is authorized to direct the Commissioner to take such actions as may be necessary to ensure that textile and apparel articles described in section 112(b) of the AGOA (19 U.S.C. 3721(b)) that are entered, or withdrawn from warehouse, for consumption are accompanied by an appropriate export visa, if the preferential treatment described in section 112(a) of the AGOA is claimed with respect to such articles.

Part II—Implementation of the CBTPA

Sec. 6. *Apparel Articles Assembled from Fabrics or Yarn Not Available in Commercial Quantities.* The Committee is authorized to exercise the authority vested in the President under section 213(b)(2)(A)(v)(II)(aa) of the CBERA (19 U.S.C. 2703(b)(2)(A)(v)(II)(aa)), as added by section 211(a) of the CBTPA, to determine whether yarns or fabrics cannot be supplied by the domestic industry in commercial quantities in a timely manner. The Committee shall establish procedures to ensure appropriate public participation in any such determination. The Committee and the USTR are jointly authorized to exercise the authority vested in the President under sections 213(b)(2)(A)(v)(II)(bb), (cc), and (ee) of the CBERA (19 U.S.C. 2703(b)(2)(A)(v)(II)(bb), (cc), and (ee)), as added by section 211(a) of the CBTPA, to obtain advice from the appropriate advisory committee, to submit a report to the appropriate Congressional committees, and to consult with those Congressional committees. The USTR is authorized to exercise the authority vested in the President under section 213(b)(2)(A)(v)(II)(bb) of the CBERA to obtain advice from the USITC.

Sec. 7. *Certain Interlinings.* The Committee is authorized to exercise the authority vested in the President under section 213(b)(2)(A)(vii)(II)(cc) of the CBERA (19 U.S.C. 2703(b)(2)(A)(vii)(II)(cc)), as added by section 211(a) of the CBTPA, to determine whether U.S. manufacturers are producing interlinings in the United States in commercial quantities. The Committee shall establish procedures to ensure appropriate public participation in any such determination. The determination or determinations of the Committee under this section shall be set forth in a notice or notices that the Committee shall cause to be published in the **Federal Register**. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 8. *Handloomed, Handmade, and Folklore Articles.* The Committee, after consultation with the Commissioner, is authorized to exercise the authority vested in the President under section 213(b)(2)(C) of the CBERA (19 U.S.C. 2703(b)(2)(C)), as added by section 211(a) of the CBTPA, to consult with representatives of CBTPA beneficiary countries for the purpose of identifying particular textile and apparel goods that are mutually agreed upon as being handloomed, hand made, or folklore goods within the meaning of that section. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 9. *Penalties for Transshipments.* The Committee, after consultation with the Commissioner, is authorized to exercise the authority vested in the President under section 213(b)(2)(D) of the CBERA (19 U.S.C. 2703(b)(2)(D)), as added by section 211(a) of the CBTPA, to determine, based on sufficient evidence, whether an exporter has engaged in transshipment and, if transshipment has occurred, to deny all benefits under the CBTPA to any such exporter, and any successor of such exporter, for a period of 2 years; to request that any CBTPA beneficiary country through whose territory transshipment has occurred take all necessary and appropriate actions to prevent such transshipment; and to impose the penalty provided in section 213(b)(2)(D)(ii) of the CBERA on a CBTPA beneficiary country if the Committee determines that such country is not taking such actions. The determination or determinations of the Committee under this section shall be set forth in a notice or notices that the Committee shall cause to be published in the **Federal Register**. The Commissioner shall take such actions to carry out any such determination as directed by the Committee.

Sec. 10. *Bilateral Emergency Tariff Actions.* The Committee is authorized to exercise the authority vested in the President under section 213(b)(2)(E) of the CBERA (19 U.S.C. 2703(b)(2)(E)), as added by section 211(a) of the CBTPA, to take bilateral emergency tariff actions, if the Committee determines that the conditions provided in section 213(b)(2)(E) of the CBERA are satisfied. The Committee shall establish procedures to ensure appropriate public participation in any such determination. The determination or determinations of the Committee under this section shall be set forth in a notice or notices that the Committee shall cause to be published in the **Federal Register**. The Commissioner shall take such actions to carry out any such bilateral emergency tariff action as directed by the Committee.

Part III—General Provisions

Sec. 11. *Judicial Review.* This order does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

William J. Clinton

THE WHITE HOUSE,
January 17, 2001.

[FR Doc. 01–2014
Filed 1–19–01; 8:45 am]
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Federal Register

Monday,
January 22, 2001

Part XIX

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 679

Fisheries of the Exclusive Economic Zone Off Alaska; Steller Sea Lion Protection Measures for the Groundfish Fisheries Off Alaska; Final 2001 Harvest Specifications and Associated Management Measures for the Groundfish Fisheries Off Alaska and Emergency Interim Rule to Revise Certain Provisions of the American Fisheries Act; Interim Final Rules

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 010112013–1013–01; I.D. 011101B]

RIN 0648–AO82

Fisheries of the Exclusive Economic Zone Off Alaska; Steller Sea Lion Protection Measures for the Groundfish Fisheries Off Alaska; Final 2001 Harvest Specifications and Associated Management Measures for the Groundfish Fisheries Off Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Emergency interim rule; request for comments.

SUMMARY: NMFS issues an emergency interim rule to implement Steller sea lion protection measures to avoid the likelihood that the groundfish fisheries off Alaska will jeopardize the continued existence of the western population of Steller sea lions or adversely modify its critical habitat. These management measures will disperse fishing effort over time and area and provide protection from fisheries competition for prey in waters adjacent to rookeries and important haulouts. This action also announces final 2001 harvest specifications and associated management measures for the groundfish fisheries of the Bering Sea and Aleutian Islands management area (BSAI) and the Gulf of Alaska (GOA). The intended effect of this emergency interim rule is to protect the endangered western population of Steller sea lions, as required under the Endangered Species Act (ESA), and to conserve and manage the groundfish resources in the BSAI and the GOA in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Effective January 18, 2001 through July 17, 2001, except for:

50 CFR 679.22(a)(11)(v), (a)(12)(v), and (b)(3)(iv) will be effective on 1200 hours (Noon) A.l.t., June 10, 2001, through July 17, 2001, and

Sections 679.4(l); 679.5(a)(4)(iv); 679.5(f)(3); 679.5(i)(1)(iii); 679.5(o); 679.20(a)(5)(i)(D); 679.20(d)(1)(iv); 679.21(d)(8); 679.21(e)(3)(v); 679.50(c)(5); 679.50(d)(5) and subpart F will be effective January 18, 2001, through December 31, 2001.

Comments must be received by February 21, 2001.

ADDRESSES: Comments may be sent to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK, 99802, Attn: Lori Gravel, or delivered to room 401 of the Federal Building, 709 West 9th Street, Juneau, AK. Comments will not be accepted if submitted via e-mail or Internet. Copies of the November 30, 2000, Biological Opinion and Incidental Take Statement on Authorization of the BSAI groundfish fisheries based on the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands and Authorization of the GOA groundfish fisheries based on the Fishery Management Plan for Groundfish of the Gulf of Alaska (Comprehensive BiOp), including the Reasonable and Prudent Alternative (RPA), may be obtained from the same address. The Comprehensive BiOp is also available on the NMFS Alaska Region home page at http://www.fakr.noaa.gov.

Copies of the Final 2001 Stock Assessment and Fishery Evaluation (SAFE) reports, dated November 2000, are available from the North Pacific Fishery Management Council, West 4th Avenue, Suite 306, Anchorage, AK, 99510 or from their home page at http://www.fakr.noaa.gov/npfmc.

FOR FURTHER INFORMATION CONTACT: Sue Salveson, Sustainable Fisheries Division, Alaska Region, 907–586–7228 or email at sue.salveson@noaa.gov.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fisheries in the exclusive economic zone off Alaska under the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area and the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMPs). The North Pacific Fishery Management Council (Council) prepared the FMPs under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801, *et seq*. Regulations governing U.S. fisheries and implementing the FMPs appear at 50 CFR parts 600 and 679. NMFS also has management responsibility for certain threatened and endangered species, including Steller sea lions, under the Endangered Species Act of 1973 (ESA), 16 U.S.C. 1531, *et seq.*, and the authority to promulgate regulations to enforce provisions of the ESA to protect such species.

Introduction

The preamble to this emergency rule contains two parts. Part I explains the background surrounding actions taken to protect the endangered western population of Steller sea lions, including information on the development and specific provisions of the RPA developed in the Comprehensive BiOp. Part II describes the harvest specifications for the 2001 groundfish fisheries of the BSAI and GOA. These specifications are consistent with the 2001 Steller sea lion protection measures.

Part I. Steller Sea Lion Protection Measures

Background

In 1990, NMFS designated the Steller sea lion as a threatened species under the ESA. The designation followed severe declines throughout much of the GOA and Aleutian Islands region. In 1993, NMFS defined critical habitat for the species to include (among other areas), the marine areas within 20 nautical miles (nm) of major rookeries and haulouts of the species west of 144° W longitude. In 1997, NMFS recognized two separate populations, and reclassified the western population (west of 144° W longitude) as endangered.

NMFS first began collecting information on the abundance of Steller sea lions during the 1950s and 1960s. However, the first counts based on reliable data were not available until the late 1970s; these counts reported approximately 109,800 animals. During the 1980s, a precipitous decline of Steller sea lions was observed. By 1996, the population had declined by 80 percent from the late 1970s. Counts of adult and juvenile Steller sea lions have continued to decline over the last few years, but at a lower rate.

NMFS believes that multiple factors have contributed to the decline, but considerable evidence indicates that lack of available prey is a significant factor. Foraging studies confirm that Steller sea lions depend on pollock, Pacific cod, and Atka mackerel as major prey sources, and that they may be particularly sensitive to reduced availability of prey during the winter. The significance of pollock, Pacific cod, and Atka mackerel in the diet of sea lions may have increased since the 1970s due to shifts in the Bering Sea ecosystem related to atmospheric and oceanographic changes.

In accordance with the requirements of the ESA, the NMFS Office of Protected Resources issued a biological opinion on the pollock fisheries of the BSAI and GOA and the Atka mackerel fishery of the Aleutian Islands subarea, dated December 3, 1998, and revised December 16, 1998 (1998–1 BiOp). The 1998–1 BiOp concluded that the BSAI and GOA pollock trawl fisheries, as

projected for 1999 through 2002, were likely to jeopardize the endangered western population of Steller sea lions and adversely modify critical habitat designated for this population. The term "jeopardize" means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species" (50 CFR 402.02). The phrase "adversely modify its critical habitat" means "a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical" (50 CFR 402.02). The 1998–1 BiOp also concluded that the Atka mackerel fishery, as modified by recent regulatory changes (64 FR 3446, January 22, 1999), was not likely to jeopardize the endangered western population of Steller sea lions or adversely modify its critical habitat.

The 1998–1 BiOp did not prescribe a single RPA for the BSAI and GOA pollock fisheries, but rather established a framework to avoid the likelihood of jeopardizing the continued existence of the western population of Steller sea lions or adversely modifying their critical habitat. The framework consisted of three principles: (1) Temporal dispersion of fishing effort, (2) spatial dispersion of fishing effort, and (3) protection from fisheries competition for Steller sea lion prey in waters adjacent to rookeries and important haulouts. For each of these principles, the 1998–1 BiOp provided guidance on the development of management measures to meet the objectives and, ultimately, to avoid jeopardy and adverse modification. The 1998–1 BiOp stated that certain conservation measures could be phased in over a 2-year period.

In December 1998, NMFS staff briefed the Council on the 1998–1 BiOp. The Council then prepared recommendations for alternative management measures based on the RPA guidelines to avoid jeopardy and adverse modification. The Council's recommendation did not contain Bering Sea subarea (BS) pollock harvest specifications for the second half of 1999. However, the Council planned to recommend these measures prior to mid-1999. The Council also recommended closing all but nine of the haulout zones specified by the 1998–1 BiOp in the BSAI and GOA. NMFS determined these recommendations to be acceptable as part of a 2-year phase-in strategy, in which equivalent or better protections would be extended for those areas for 2000 and beyond.

On December 16, 1998, NMFS adopted the measures recommended by the Council (with modifications) into the 1998–1 BiOp as part of the reasonable and prudent alternatives for the Alaska pollock fisheries. NMFS published an emergency interim rule implementing these measures in the **Federal Register** on January 22, 1999 (64 FR 3437), as amended on February 17, 1999 (64 FR 7814), and on February 25, 1999 (64 FR 9375), which was effective through July 19, 1999. The preamble to the emergency rule provides a detailed description of the purpose and need for the implementation of emergency measures in 1999.

The Council met again in February, April, and June 1999 to consider recommendations for extending the emergency rule for the second half of 1999, and, at its June meeting, voted to extend the emergency rule. Using the Council's recommendation, NMFS extended the emergency rule through December 31, 1999 (64 FR 39087, July 21, 1999; technical amendment 64 FR 43297, August 10, 1999), with revisions that included BS pollock harvest specifications for the second half of 1999.

In June 1999, the Council also deliberated on various management measures to implement permanently the reasonable and prudent alternatives as described in the 1998–1 BiOp for 2000 and beyond. After significant debate and public comment, the Council voted to recommend a series of conservation measures to protect Steller sea lions.

Greenpeace, the American Oceans Campaign, and the Sierra Club challenged the 1998–1 BiOp in the U.S. District Court for the Western District of Washington (*Greenpeace* v. *NMFS*, Civ. No. C98–0492Z (W.D. Wash.)). In an Order issued on July 9, 1999 (and amended on July 13, 1999), the Court upheld the no-jeopardy conclusion for the Atka mackerel fishery and the jeopardy conclusion for the pollock fisheries. However, the Court also found that "the Reasonable and Prudent Alternatives * * * were arbitrary and capricious * * * because they were not justified under the prevailing legal standards and because the record does not support a finding that they were reasonably likely to avoid jeopardy." On August 6, 1999, the Court remanded the 1998–1 BiOp back to NMFS for further analysis and explanation.

To comply with the Court's Order, NMFS conducted additional analyses and completed the Revised Final Reasonable and Prudent Alternatives (RFRPAs) on October 15, 1999. The RFRPAs describe management measures that will avoid the likelihood that the pollock fisheries authorized by regulations will jeopardize the continued existence of the endangered western population of Steller sea lions or adversely modify their critical habitat.

NMFS evaluated the measures recommended by the Council in June 1999 as part of the RFRPA analyses, and determined that these measures (with modification to season dates, haulout protections, and spatial dispersion in the Bering Sea) achieved the principles identified in the 1998–1 BiOp and the RFRPAs, and these were subsequently incorporated into the October 15, 1999, RFRPAs mentioned above. NMFS implemented the modified measures (then the RFRPAs) by emergency interim rule for the 2000 groundfish fisheries (65 FR 3892, January 25, 2000, and 65 FR 36795, June 12, 2000). Greenpeace, the American Oceans Campaign, the Sierra Club, and fishing industry representatives have challenged the adequacy of the RFRPAs in the U.S. District Court for the Western District of Washington. That judicial challenge is still pending.

In December 1998, NMFS also issued an additional biological opinion evaluating the effects of the 1999 Federal groundfish fisheries in the BSAI and the GOA on endangered and threatened species and their critical habitat (1998–2 BiOp). Greenpeace, the American Oceans Campaign, and the Sierra Club also challenged the legal adequacy of the 1998–2 BiOp, resulting in a Court Order finding it too narrow in scope. (*Greenpeace* v. *NMFS*, 80 F. Supp. 2d 1137 (W.D. Wash. 2000)). On July 19, 2000, the Court issued an injunction prohibiting fishing for groundfish with trawl gear in the exclusive economic zone within Steller sea lion critical habitat west of 144° W. longitude until NMFS issued a comprehensive biological opinion adequately analyzing the full scope of the FMPs. (*Greenpeace* v. *NMFS*, 106 F. Supp. 2d 1066 (W.D. Wash. 2000)). The critical habitat areas closed by the Court's injunction were defined in regulations codified at 50 CFR 226.202, and in Tables 1 and 2 of 50 CFR part 226. Pursuant to the ESA, NMFS issued an interim final rule prohibiting fishing for groundfish with trawl gear in Steller sea lion critical habitat specified in the Court's injunction (65 FR 49766, August 15, 2000).

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In response to the Court's Order that found the 1998–2 BiOp inadequate, NMFS issued the Comprehensive BiOp on November 30, 2000. The Comprehensive BiOp evaluates all authorized federal groundfish fisheries and the overall management framework established by the GOA and BSAI FMPs. After analyzing the cumulative, direct, and indirect effects of the groundfish fisheries authorized by the GOA and BSAI FMPs on listed species, NMFS concluded in the Comprehensive BiOp that the Alaska groundfish fisheries, as currently prosecuted, jeopardize the continued existence of the western population of Steller sea lions and adversely modify its critical habitat. This conclusion was reached based on information that pollock, Pacific cod, and Atka mackerel are the main prey species for which Steller sea lions compete with the fisheries; that this competition causes reduced availability of prey, an effect of particular concern within Steller sea lion critical habitat, that reduced availability of prey leads to nutritional stress; and that nutritional stress, especially of juveniles and to a lesser extent adult females, is the leading hypothesis to explain the continued decline of the western population of Steller sea lions. The Comprehensive BiOp included an RPA that would allow a modified fishery to occur in a manner that would avoid jeopardy to the continued existence of Steller sea lions and adverse modification to their critical habitat.

On December 21, 2000, the President signed Public Law 106–554. This law contains a one-year timetable for implementing the RPA as well as provisions affecting its implementation. In the following discussion, references will be made to these provisions whenever they affect implementation of the RPA.

Section 209 of Public Law 106–554, paragraph (c)(3) also requires that "(t)he 2001 Bering Sea/Aleutian Islands and Gulf of Alaska groundfish fisheries shall be managed in accordance with the fishery management plan and federal regulations in effect for such fisheries prior to July 15, 2000 * * * and said regulations are hereby restored to full force and effect." NMFS has determined that this statutory provision extends through 2001 the interim emergency regulations promulgated in 2000 to implement the American Fisheries Act, Public Law 105–277 (AFA). In addition, NMFS has determined that this statutory provision does not invalidate fishery management plan amendments or regulatory amendments approved or implemented after July 15, 2000, that do not directly affect measures governing the interaction of fisheries with endangered Steller sea lions, and that such amendments remain in full force and effect. These measures include: Amendment 58 (Chinook salmon bycatch controls published at 65 FR 60587, October 12, 2000) and Amendment 64 (fixed gear allocations of Pacific cod published at 65 FR 51553, August 24, 2000) to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Area; Amendment 59 to the Fishery Management Plan for Groundfish of the Gulf of Alaska that established the Sitka Sound Marine reserve (65 FR 67305, November 9, 2000); and three separate regulatory amendments that require vessel monitoring systems onboard vessels that are used to participate in the BSAI Atka mackerel fishery (65 FR 61264, October 17, 2000), an extension of the Pacific halibut donation program beyond 2000 (65 FR 78119, December 14, 2000), adjustments to observer coverage requirements established for the Community Development Quota (CDQ) Program (65 FR 69483, November 17, 2000), and an extension of regulations governing observer coverage for the Alaska groundfish fisheries beyond 2000 (65 FR 80381, December 21, 2000).

Specific Elements of the 2001 Management Measures

The measures proposed to be implemented in this emergency rule, as well as for the remainder of 2001, are discussed below. Initially, NMFS did not contemplate a one-year phase-in for the RPA. However, after consideration of Public Law 106–554 (signed into law on December 21, 2001), NMFS reassessed 2001 protection measures relative to the concept of a phase-in. This assessment was conducted under the objective of maintaining strict adherence to ESA standards for no jeopardy to endangered listed species or adverse modification to their critical habitat during the one-year phase-in period. NMFS determined, as previously explained, that the short time period until full implementation of the protection measures is achieved (January 1, 2002), along with immediate implementation of many of the protection measures by this emergency rule, will ensure that the fisheries are not likely to jeopardize the continued existence of any listed species or destroy or adversely modify the critical habitat of any listed species during the period of the phase-in.

Specifically, Steller sea lion protection measures that are being put into place in this emergency rule as of January 20, 2001, affecting fishing for all of 2001 that are in addition to status quo fishing under the current FMP, include measures that were in place as RFRPAs under the previous biological opinion for all areas: (1) No transit zones within 3 nm of 37 rookery sites, (2) closure within 10 or 20 nm of 37 rookeries to all trawling year-round, and (3) closure to pollock fishing within 10 or 20 nm of 75 haulouts, seasonally or year-round based on use by sea lions. In the Bering Sea pollock fishery measures include: (1) Four seasons with harvest limits within sea lion critical habitat foraging areas; and (2) two seasons (40:60 percent allocation) outside critical habitat, continuation of Bering Sea fishery cooperatives established under the American Fisheries Act, and the Gulf of Alaska pollock fishery distributed over 4 seasons (30:15:30:25 percent allocation). In the Atka mackerel fishery, measures include: (1) A VMS requirement, (2) continuation of two equal seasons, (3)restrictions on harvests in critical habitat and new, reduced 2001 critical habitat harvest limits for Atka mackerel in the Aleutian Islands.

Measures from the RPA in the comprehensive 2000 biological opinion that have never been implemented before, but will be effective January 20, 2001, reflecting the fact that the pollock roe fisheries and the GOA Pacific cod fishery (all gears) and the BSAI trawl Pacific cod fishery typically conclude by mid-March include: (1) Prohibiting groundfish fishing by federally permitted vessels within 3 nm of more than 75 important haulout sites identified under established criteria, (2) establishing two fishing seasons for Pacific cod, January 1–June 10 (60 percent of the allocation) and June 11–December 31 (40 percent), (3) reduction of the allowable catch for Gulf of Alaska pollock from the Council's recommended 2001 level by 10 percent (reduction is less than the 20 percent reduction calculated under the Global Control Rule developed under the biological opinion because it is limited by the new appropriations law (P.L. 106–554)), and (4) a cap of the 2001 Bering Sea pollock harvest in the Steller sea lion conservation area to no more than the amount authorized in the final 2000 harvest specifications, effectively capping the Bering Sea pollock harvest in critical habitat at the 2000 level until the biological opinion is fully implemented in 2002. Additionally, by June 10, 2001, the emergency rule would implement the closed areas contained in the biological opinion for the pollock, Pacific cod, and Atka mackerel fisheries. The Council would have the opportunity to suggest modifications to these closures for the remainder of 2001 provided they meet the requirements of the biological opinion (*e.g.*, close at least 50 percent of critical habitat to the three fisheries and maximize protection of Steller sea lion pups and juveniles). The full RPA would be implemented by January of 2002, including additional seasonal restrictions and harvest limits, unless alternative strategies are developed that meet the objectives of the RPA in removing jeopardy and adverse modification.

After reviewing this phase-in as an alternative strategy for implementation of Steller sea lion protection measures, NMFS has determined that it is a reasonable alternative way to implement the RPA while maintaining the goal of removing the threat of jeopardy and adverse modification from this fishery, provided that the phase-in is complete by January of 2002. This conclusion was reached because, if we assume that the average annual 4 percent rate of decline for Steller sea lions over the past decade is due to fishing, as discussed in the biological opinion (2000), immediate implementation of the RPA is expected to reverse that rate of decline to a level around minus 0.7 percent by the end of 2001, although this rate would likely not be detectable for four years. Using the phase-in approach, NMFS expects the measures being implemented in January and June of 2001 to reduce the average annual rate of decline in 2001 to between approximately minus 2.0 and minus 2.5 percent. The one-year time frame for achieving the effect of full RPA implementation (minus 0.7 percent rate) would have an undetectable effect on the recovery and sustainability of the Steller sea lion population. This represents the most reasonable method of complying with all applicable law, including P.L. 106-554 (which did not exist at time of development of the original RPA)and the ESA.

The 2001 protection measures that are implemented in January and June address the competition between the groundfish fishery and non-human predators in the marine ecosystem in several ways. First, these measures as described will modify the existing harvest control rule to ensure that during 2001 enough prey resources exist overall and that prey densities are sufficient to supply all competitors on a large scale. Second, the protection measures will distribute the catch of important prey species over space and time to reduce the effects of localized depletion. Localized depletion is the reduction of prey resources below a threshold necessary to effectively supply predators in a specific area during a specific time period. Finally, the RPA will prohibit fishing in areas immediately surrounding rookery and haulout sites and curtail fishing for important prey species in significant portions of designated critical habitat to relieve competition in areas considered important to Steller sea lion survival and recovery.

Modify the Existing Harvest Control Rule

The RPA includes a modification of the existing harvest control rule for pollock, Pacific cod, and Atka mackerel. NMFS currently uses a harvest control rule when determining the maximum allowable biological catch (ABC). Under the existing control rule, ABC for a majority of stocks, including pollock, Pacific cod, and Atka mackerel, is based on a fishing mortality rate that would reduce the spawning biomass per recruit to 40 percent of its unfished level, if the biomass of the target stock is projected to be at or above a biomass necessary to achieve maximum sustainable yield. However, if the biomass of the target stock is projected to be below a biomass necessary to achieve maximum sustainable yield, then the fishing mortality rate is reduced in a linear fashion until the biomass is 5 percent of a biomass necessary to achieve maximum sustainable yield. At this point, when the spawning biomass per recruit of the target stock is reduced to 2 percent of its unfished level, the fishing mortality rate is 0, and all fishing for that target stock is stopped.

The modification of the existing control rule contained in the RPA (also known as the Global Control Rule) will require a more aggressive linear reduction in fishing mortality rate when the biomass of a pollock, Pacific cod, or Atka mackerel stock is projected to be below a biomass necessary to achieve maximum sustainable yield. This means that the fishing mortality rate will be reduced more rapidly when the biomass of the target stock is projected to be below a biomass necessary to achieve maximum sustainable yield. This adjustment to the fishing mortality rate also means that all fishing for a target species would stop when the spawning biomass per recruit of the target stock is reduced to 20 percent of its unfished level, rather than when the spawning biomass per recruit of the target stock is reduced to 2 percent of its unfished level as in the existing control rule. The Global Control Rule is designed to ensure adequate levels of each prey species is maintained for Steller sea lions by more rapidly reducing the fishing mortality rate when the biomass of the target stock is projected to be below a biomass necessary to achieve maximum sustainable yield and by stopping fishing for those prey species when their population size is 10 times larger than under the existing control rule.

The application of the Global Control Rule in 2001 is modified by Public Law 106–554, which provides at section 209(c)(5) that "[t]he harvest reduction requirement ('Global Control Rule') shall take effect immediately in any 2001 groundfish fishery in which it applies, but shall not cause a reduction in the total allowable catch of any fishery of more than 10 percent." Based on this provision, the reduction in the amount of GOA pollock that can be harvested in 2001 will be limited to 10 percent of the total allowable catch for that species. This reduction is less than the 20 percent reduction calculated under the Global Control Rule developed under the biological opinion because it as limited by the subsequent requirements of implementation of Public Law 106–554. The Global Control Rule will be fully implemented in 2002.

Distribution of the Catch of Prey Species Over Time and Area

The 2001 Steller sea lion protection measures include fishing seasons [1] for pollock, Pacific cod, Atka mackerel, and BS pollock critical habitat harvest limits. Seasons for pollock and Atka mackerel for 2001 remain the same as under Steller sea lion protection measures implemented in 2000. This is consistent with the RPA. For Pacific cod, the RPA also required two seasons outside critical habitat and four seasons inside critical habitat. The 2001 protection measures will implement two new seasons for Pacific cod that did not exist in 2000, phasing in full implementation of the four seasons by 2002. These new seasons for Pacific cod, like the seasons for pollock and Atka mackerel, will distribute the affected fisheries over time. Critical habitat harvest limits for pollock and Atka mackerel will be implemented by this emergency rule consistent with the requirements of the RPA. Critical habitat harvest limits for Pacific cod will be implemented by January 1, 2002, when it will become more practicable for NMFS to monitor smaller vessels that are used to fish for Pacific cod. For example, more effective monitoring and enforcement of harvest limits would include use of tools like vessel monitoring systems and electronic

[1] Times for all openings and closures of seasons are specified in 50 CFR 679.23.

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logbooks. Critical habitat limits will distribute the affected fisheries over area.

1. BSAI Pollock Seasons and Critical Habitat Limits

Fishing for pollock in the BSAI during the first half of 2001 will be conducted in the same manner as in 2000. This emergency rule will continue to prohibit directed fishing for pollock in the Aleutian Islands subarea (AI). Fishing seasons also are continued for the four sectors of the Bering Sea pollock fishery that are defined in the AFA. These fishing seasons are summarized in Table 1.

This emergency rule extends the repeal of the "fair start" provisions that required vessels fishing for pollock in the Bering Sea to cease fishing for groundfish during the week preceding each pollock season or face a mandatory stand-down period during the first week of the pollock season. The Council determined that these fair start requirements were no longer necessary given the changes to the pollock fishery that occurred under the AFA.

The biological opinion notes that in order to maximize protection of Steller sea lion pups and juveniles, at least 50 percent of critical habitat should be closed to pollock, Pacific cod, and Atka mackerel fishing and that closed areas must provide for the statistical design of a monitoring program that will evaluate the effectiveness of protection measures. This emergency rule also will extend the use of the Steller sea lion conservation area (SCA) established by the emergency rule published January 25, 2000 (65 FR 3892). However, these are only adequate as part of an overall phase-in approach that will implement the full closure scenario (or an equally effective alternative approach) contemplated by the RPA in the 2000 biological opinion by 2002. The SCA includes the portion of Bering Sea critical habitat known as the Bogoslof foraging area and the portion of the Catcher Vessel Operational Area (CVOA) that extends eastward from the Bogoslof foraging area. This eastern block of the CVOA overlaps with the pollock trawl exclusion zone for Sea Lion Rocks (Amak Island). Inclusion of this eastern block in the SCA is necessary to provide sufficient protection from concentrated fishing and resulting localized depletions of sea lion prey in (1) the narrow corridor between the Bogoslof foraging area and the Sea Lion Rocks (Amak Island) trawl exclusion zone and (2) the adjacent portions of critical habitat.

The SCA consists of the area of the Bering Sea between 170°00′ W longitude and 163°00′ W longitude, south of straight lines connecting the following points in the order listed:

55°00′ N lat 170°00′ W long.;
55°00′ N lat 168°00′ W long.;
55°30′ N lat 168°00′ W long.;
55°30′ N lat 166°00′ W long.;
56°00′ N lat 166°00′ W long.;
56°00′ N lat 163°00′ W long.

This emergency rule specifies the amount of the annual total allowable catch (TAC), that can be taken from the SCA in each season listed in Table 1. The TAC is equal to the sum of each sector's directed fishing allowance (DFA) plus the incidental catch allowance (ICA). This amount is capped at the harvest amounts authorized for 2000 until the full RPA is implemented in 2002. Effectively, the SCA allocations using the 2000 TACs is 149,208 mt higher than under the full RPA. Although the 2000 harvest levels were based on specified percentages of the 2000 pollock TAC, the 2001 SCA harvest limits are established as the actual 2000 harvest limit in metric tons. The pollock SCA harvest limit specified for each industry sector is further apportioned to the fishing seasons identified in Table 1 according to the percentages set out in the emergency rule published in the **Federal Register** on January 25, 2000 (65 FR 3892). As a result, each sector's 2001 seasonal harvest limit in the SCA is unchanged from the tonnage level specified for 2000, except to the extent that NMFS adjusts the ICA (See Part II and § 679.22(a)(11)(iv)(E)(1) for specific amounts in metric tons). Further, the increase in the Bering Sea pollock TAC in 2001 from 2000, which occurred because more pollock is available for harvest in 2001, will be harvested outside the SCA. This action is taken to further ensure adequate prey resources inside critical habitat.

TABLE 1.—BERING SEA SUBAREA POLLOCK FISHING SEASONS FOR ALL SECTORS

Bering Sea subarea—	Season			
	A	B	C	D
Outside the SCA[1]	January 20–June 10 (combined A/B season)		June 10–November 1 (combined C/D season)	
Inside the SCA	Jan. 20–April 1	April 1–June 10	June 10–Aug. 20	Aug. 20–Nov. 11

[1] For the area outside the SCA, there will be two seasorial pairs, A/B and C/D, that are allocated the annual Bering Sea subarea directed fishing allowance by sector.

NMFS will monitor catch by each industry sector and close the SCA to directed fishing for pollock by sector when NMFS determines that the specified SCA limit has been reached. In accordance with the Council's intent to address small vessel safety concerns, inshore catcher vessels less than or equal to 99 ft (30.2 m) LOA will continue to be exempt from SCA closures during the fall and winter months unless the cap for the inshore sector has been reached. Under the authority of the AFA, NMFS will separate the inshore fishery into cooperative and non-cooperative sector allocations. For each sector, NMFS will announce the closure of the SCA to catcher vessels over 99 ft (30.2 m) LOA before the inshore sector SCA limit is reached. NMFS will implement the closure in a manner intended to leave remaining quota within the SCA that is sufficient to support directed fishing for pollock by vessels less than or equal to 99 ft (30.2 m) LOA for the duration of the inshore sector opening. This measure will be implemented only during the A, B, and D seasons because of Council's intent to address vessel safety concerns during these time periods of severe weather.

Over harvest and under harvest of SCA amounts may be "rolled over" from the A season SCA limit to the B season SCA limit so that no single season exceeds 15 percent of the annual TAC, and that the combined A/B limit inside the SCA of 20 percent is not exceeded.

2. BSAI Atka Mackerel Seasons and Critical Habitat Limits

As required by P.L. 106–554, fishing for Atka mackerel in the BSAI during the first half of the 2001 will be conducted as specified in current regulations. As such, critical habitat limits in the western and central Aleutian Islands districts will be reduced as required under existing regulations at 50 CFR 679.22(a)(8)(iii)(B). The A season for Atka mackerel will begin January 1, 2001, and end April 15, 2001. The B season will begin September 1, 2001, and end November 1, 2001. Fifty percent of the annual TACs for the western, central, and eastern Aleutian Islands districts is available during each season. Critical habitat harvest limits on the amount of 2001 TAC apportioned to the respective areas during each season are: Western area, 48 percent; central area, 46 percent; and eastern area, 0 percent.

This emergency rule makes two general changes to the regulations governing the Atka mackerel fishery not specific to implementing the biological opinion, but that require change. First, correction is made to regulations at § 679.20(c)(2)(ii) that establish annual interim harvest amounts to indicate that in any given year the first proposed seasonal allowance of Atka mackerel TACs would be available at the beginning of the fishing year as interim TAC amounts until superseded by final harvest specifications. Second, a regulatory reference to 50 CFR part 226 at § 679.22(a)(8)(iii)(A) is removed. Instead, the regulations now refer to a new Table 21 in 50 CFR part 679 that contains a complete list of corrected rookery and haulout sites that are used to identify different fishery restrictions surrounding these areas and implemented under 50 CFR part 679.

3. BSAI and GOA Pacific Cod Seasons

This emergency rule separates the BSAI and GOA Pacific cod TACs into two separate seasonal allowances, a change from prior years in which there were no seasonal splits. The new A season begins on January 1, 2001, and ends June 10, 2001. Sixty percent of the annual TAC of BSAI and GOA Pacific cod, after subtraction of any reserves and incidental catch, will be available for harvest during the A season and will be apportioned among the various sectors as provided in §§ 679.20(a)(6)(iii) and 679.20(a)(7). The new B season begins at noon A.l.t. on June 10, 2001, and ends on December 31, 2001. Forty percent of the annual TAC of BSAI Pacific cod, after subtraction of any reserves and incidental catch, will be available for harvest during the B season and will be apportioned among the various sectors as provided in §§ 679.20(a)(6)(iii) and 679.20(a)(7). Apportioning Pacific cod between two seasons will affect the ability of fishermen to fully utilize the TAC for Pacific cod. Pacific cod tends to aggregate during the early part of the calendar year and is easier to locate and catch. In previous years, a large portion of the Pacific cod TAC was taken during the early part of the calendar year. Also, as Pacific cod becomes disaggregated, the increased fishing time and effort to catch the same amount of fish means commensurate increases in bycatch, which also can affect the success of fully utilizing the TAC. Finally, these effects will be further exacerbated in future years because the 60/40 percentage split between the A and B seasons will be in place for 2001 only. In subsequent years, the percentage split will be changed to 40 percent in the A season and 60 percent in the B season. This change is consistent with the conclusions in the Comprehensive BiOp, which indicated that a greater proportion of essential prey should be made available to Steller sea lions during the winter season. Any over harvest or under harvest of Pacific cod harvest from the A season may be subtracted from or added to the subsequent B season.

4. GOA Pollock Seasons

In accordance with P.L. 106–544, fishing for pollock in the GOA during the first half of the 2001 will be conducted in the same manner as in 2000. Fishing seasons and pollock TAC apportionments in the Western and Central (W/C) Regulatory Areas of the GOA are summarized in Table 2.

TABLE 2.—POLLOCK FISHING SEASONS AND TAC APPORTIONMENTS FOR THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA

Season	TAC apportionment (in percent)	Season dates
A	30	January 20–March 1.
B	15	March 15–May 31.
C	30	August 20–September 15.
D	25	October 1–November 1.

The TAC for pollock during the A/B season in the combined W/C Regulatory Areas will continue to be apportioned among Statistical Areas 610, Shelikof Strait, and areas 620 and 630 outside of Shelikof Strait in proportion to the distribution of the pollock biomass as determined by the most recent NMFS surveys. Consistent with current regulations, pollock fishing seasons are not established for the Eastern Regulatory Area.

In the GOA, overall pollock fishery harvest rates have varied from about 5 percent of the total biomass to about 10 percent since 1990. From 1994 to 1999, the estimated harvest rate in Shelikof Strait has been on the order of 1 percent to 3 percent of the total biomass, well below the overall harvest rate for the GOA. This discrepancy suggests that the biomass of pollock in Shelikof Strait is under-utilized relative to the biomass of pollock outside the Strait. Therefore, pollock biomass outside the Strait must be over-utilized relative to the overall harvest rate. This relative over-utilization of pollock outside Shelikof Strait could have had a detrimental effect on the availability of pollock to Steller sea lions in those outer regions. To ameliorate this effect, Shelikof Strait received a separate apportionment in 2000. This separate apportionment will continue with this emergency rule.

The Shelikof Strait conservation area is defined as the area bounded by straight lines and shoreline connecting the following coordinates in the following order:

58°51′ N lat 153°15′ W long.;
58°51′ N lat 152°00′ W long.; and, the intersection of 152°00′ W long with Afognak Island; aligned counterclockwise around the shoreline of Afognak, Kodiak, and Raspberry Islands to
57°00′ N lat 154°00′ W long.;
56°30′ N lat 154°00′ W long.;
56°30′ N lat 155°00′ W long.;
56°00′ N lat 155°00′ W long.;
56°00′ N lat 157°00′ W long.; and the intersection of 157°00′ W long. with the Alaska Peninsula.

As in 2000, the Shelikof Strait conservation area TAC apportionment is determined for the A and B seasons based on the most recent winter

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hydroacoustic survey data. Specific harvest amounts can be found under Part II of this action. The GOA TAC for areas 610, 620, and 630 outside of the Shelikof Strait conservation area, will be determined based on the biomass available outside of Shelikof Strait. NMFS will prohibit directed fishing for pollock within Shelikof Strait when the seasonal apportionment of the pollock TAC for the Shelikof Strait conservation area has been reached.

The 300,000 lb (136 mt) trip limit for catcher vessels harvesting pollock in the directed pollock fisheries of the GOA supports the temporal distribution objectives of the RPA and is maintained by this rule. A catcher vessel fishing for groundfish in the GOA will be prohibited from retaining on board more than 300,000 lb (136 mt) of pollock harvested in the GOA. This trip limit will not exempt vessels from existing regulations that require 100 percent retention of pollock when directed fishing for pollock is open. A vessel would have to stop fishing for pollock during a fishing trip before the 300,000 lb (136 mt) trip limit is reached to avoid a violation of either the 300,000 lb (136 mt) trip limit or the 100 percent retention requirement for pollock.

In addition, to prevent the large scale use of tender vessels to avoid the trip limit restriction, this rule also will continue to prohibit vessels from operating as tenders in the GOA east of 157°00′ W longitude. Vessels operating as tenders in the GOA west of 157°00′ W longitude will be prohibited from retaining on board more than 600,000 lb (272 mt) (the equivalent of two fishing trips) of unprocessed pollock that was harvested in the GOA. Tendering west of 157°00′ W longitude is allowed because smaller vessels delivering to Sand Point and King Cove are more dependent on tenders than the larger vessels that operate east of 157°00′ W longitude and deliver primarily to Kodiak.

Closed Areas

The RPA recognized the existing 3 nautical mile (nm) no-entry zones around rookeries listed in 50 CFR 223.202. Those regulations are still in effect. Those sites that are subject to the no-entry zones under 50 CFR 223.202 are also listed in Table 21 to 50 CFR part 679 for fishing closures. However, persons should refer to 50 CFR 223.202 for the appropriate locations of the no-entry zones. In some cases those locations may be different than locations for the same sites that are also listed in Table 21 to 50 CFR part 679. NMFS apologizes for any confusion that these differences may cause and plans to rectify any differences in the near future. However, until that occurs, persons are advised to consult with 50 CFR 223.202 for the proper location of no-entry zones and Table 21 to 50 CFR part 679 for proper location of sites for fishery closures.

This emergency rule closes designated haulout areas to directed fishing for groundfish consistent with the conclusion in the Comprehensive BiOp that protecting areas immediately surrounding rookery and haulout sites is particularly critical to Steller sea lion survival and recovery. These closures prohibit all federally-permitted groundfish vessels from fishing within 3 nm of haulouts designated as protection zones for the pollock fishery in 2000. These haulout sites are listed in Table 21 to 50 CFR part 679 and were identified as important to the foraging needs of Steller sea lions in the 1998–1 BiOp and in the RFRPAs for the pollock fishery.

These closed areas, as well as others discussed below, are designed to provide sufficient protection to Steller sea lions, consistent with the hierarchy of concerns established in the Comprehensive BiOp, as well as previous biological opinions. The hierarchy of concerns indicates that concerns about the effects of the groundfish fisheries on Steller sea lions are greatest around rookeries and haulouts. Protecting rookeries and haulouts is important so that the most vulnerable Steller sea lions, lactating females, young-of-the-year, and juveniles, are provided access to essential prey resources.

Under this emergency rule, a another type of closure of areas deemed important to Steller sea lions will become effective on June 10. These closures were identified in the Comprehensive BiOp under the RPA and will prohibit directed fishing for pollock, Pacific cod, and Atka mackerel in 66 percent of Steller sea lion critical habitat. These closed areas include portions of Steller sea lion forage area, as well as a subset of the rookeries and haulouts listed in Table 21 to 50 CFR part 679.

Pollock Trawl Exclusion Zones

Under Public Law 106–554, regulations that governed the 2000 pollock fishery off Alaska are extended into 2001 except as modified through this rule. Thus, the Aleutian Islands closure to directed pollock fishing is extended into 2001. The Aleutian Islands closure originally was implemented in 1999 and is designed to protect the waters surrounding rookeries and major haulouts of Steller sea lions in and around the Aleutian Islands.

The prohibition on directed fishing for pollock within either 10 or 20 nm of rookeries and important haulouts in the Bering Sea and the Gulf of Alaska also is extended consistent with Public Law 106–554. The location, size, and period of each exclusion zone are set out in Table 21 of this emergency rule. Note that the location of some of these sites and extent of closed areas around these sites are different from the sites defined as critical habitat in 50 CFR 226.202. Table 21 to 50 CFR part 679 does not define critical habitat. Table 21 to 50 CFR part 679 defines protection zones for Steller sea lions as required by the RPA and site locations are based on new information gained from recent surveys of the Steller sea lion sites. Similar to the site locations in 50 CFR 223.202, NMFS intends to update site locations in 50 CFR part 226 by proposed and final rulemaking in the near future based on this new information. This update will ensure consistency between site locations listed in Table 21 to 50 CFR part 679 and in 50 CFR part 226. However, the public is advised that the site locations in the Table 21 to 50 CFR part 679 are the ones to be used for purposes of compliance with this rule.

NMFS developed these exclusion zones on the basis of 10 Steller sea lion counts conducted since 1979, during the reproductive season (summer) and non-reproductive season (winter). NMFS used the following criteria to identify sites that require exclusion zones and to determine the period of the closure and the radius of the zone:

1. *Rookeries.* If the site is a rookery, a 10 or 20-nm year-round pollock trawl exclusion zone.

2. *Summer haulouts.* If the site is a summer haulout, with greater than 200 sea lions in a summer survey since 1979, and fewer than 75 sea lions in winter surveys since 1979, a 10 or 20-nm exclusion zone from June 1 through November 1.

3. *Winter haulouts.* If the site is a winter haulout, with less than 200 sea lions in summer surveys since 1979, and greater than 75 sea lions in a winter survey since 1979, a 10 or 20-nm exclusion zone from November 1 through June 1.

4. *Year-round haulouts.* If the site is a year-round haulout with greater than 200 sea lions in a summer survey since 1979, and greater than 75 sea lions in a winter survey since 1979, a 10 or 20 nm year-round exclusion zone.

In the Bering Sea, the Walrus Island rookery meets the requirements under the guidelines in the RPA for closure to 20 nm. However, because this site falls entirely within the Pribilof Island Area Habitat Conservation Zone (see § 679.22(a)(6)), which is closed to trawling year-round, a 20-nm closure of this area to directed fishing for pollock would be redundant and is not necessary.

In the GOA, two of the haulout sites that qualify for closure to 10 nm under criteria in the 1998–1 BiOp, Point Elrington and The Needles, lie entirely within Alaska State waters. The State of Alaska has developed protection measures for these haulouts similar to Federal protection measures that provide for spatial and temporal distribution of pollock harvests. Therefore, these sites are not established as exclusion zones under this emergency rule.

This rule closes another GOA site, Sea Lion Rocks, for a radius of 10 nm to all vessels longer than 60 ft (18.3 m) length overall (LOA). Sea Lion rocks will not be closed to vessels less than or equal to 60 ft (18.3 m) LOA between 3 nm and 10 nm due to the relatively lower levels of harvests by such vessels and safety concerns for small boats in the region. Historically, from 1994 through 1998, vessels longer than 60 ft (18.3 m) LOA have accounted for 72 percent of total harvests in this area.

Catcher Vessel Exclusive Fishing Seasons

In 2000, the Council recommended that catcher vessels be prohibited from participating in directed fishing for pollock in both the BS and GOA in concurrent seasons, except for catcher vessels less than 125 ft (38.1 m) LOA that fish in the GOA east of 157°00′ W longitude. For example, if a catcher vessel chose to participate in the combined BS A/B season, it would not be eligible to participate in the W/C GOA until the start of the GOA C season. Similarly, if a catcher vessel chose to participate in the GOA A season, it would not be eligible to participate in the BS until the start of the next BS season, which would be the C/D season.

Part II. Specifications

The FMP and its implementing regulations require NMFS, after consultation with the Council, to specify annually the total allowable catch (TAC) for each target species and for the "other species" category, the sum of which must be within the optimum yield range of 1.4 million to 2.0 million metric tons (mt) for the BSAI and within the optimum yield range of 116,000 mt to 800,000 mt for the GOA (§ 679.20(a)(1)).

NMFS is implementing the 2001 TAC specifications for the BSAI and GOA through this emergency rule. The normal procedure of publishing proposed, interim, and final TAC specifications was not followed in 2001 because of the impracticability of publishing proposed specifications prior to the issuance of the Comprehensive BiOp. NMFS anticipated that changes required by the Comprehensive BiOp to protect endangered Steller sea lions would have a significant enough impact on proposed harvest specifications for the BSAI and GOA to require republication of the proposed specifications. To avoid the uncertainty and disruption to the fisheries that would have been caused by republishing proposed specifications, including a potential delay to the season because the Comprehensive BiOp was not due out until November 30, 2000, NMFS decided to use its authority to issue the final 2001 specifications by emergency rule. NMFS anticipates that the normal procedure will be used to implement harvest specifications in the future.

This emergency interim rule includes the following provisions for the BSAI and GOA: (1) Specifications of overfishing levels (OFL), acceptable biological catch (ABC), and total allowable catch (TAC) amounts for each groundfish species category; (2) apportionments of reserves; (3) allocations of the sablefish TAC to vessels using hook-and-line and trawl gear; (4) apportionments of pollock TAC among regulatory areas, seasons, and allocations among different industry sectors including Bering Sea fishery cooperatives; (5) apportionments of Pacific cod TAC among regulatory areas, seasons, and allocations among different industry sectors; (6) apportionment of Atka mackerel in the BSAI among seasons, gear, and regulatory areas; (7) PSC limits; (8) fishery and seasonal apportionments of the Pacific halibut PSC limits; (9) fishery apportionments of other PSC limits in the BSAI; (10) Pacific halibut assumed discard mortality rates; (11) groundfish harvest and PSC limitations for AFA vessels; and (12) closures to directed fishing for specified groundfish targets. A discussion of each of these measures follows.

Acceptable Biological Catch (ABC) and TAC Specifications

The final ABC levels are based on the best available scientific information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods used to calculate stock biomass. The FMPs specify the formulas, or tiers, to be used in computing ABCs and overfishing levels. The formulas applicable to a particular stock or stock complex are determined by the level of reliable information available to fishery scientists. This information is categorized into a successive series of six tiers.

In December 2000, the Scientific and Statistical Committee (SSC), Advisory Panel (AP), and Council reviewed current biological information about the condition of groundfish stocks in the BSAI and GOA. This information was compiled by the Council's Plan Teams and is presented in the final 2001 SAFE reports for the BSAI and GOA groundfish fisheries, dated November 2000 (See **ADDRESSES**). The SAFE reports contain a review of the latest scientific analyses and estimates of each species' biomass and other biological parameters, as well as summaries of the available information on the BSAI and GOA ecosystem and the economic condition of groundfish fisheries off Alaska. From these data and analyses, the Plan Teams estimate an ABC for each species or species category.

The Council considered the ecological, socioeconomic, and ecosystem information in the SAFE reports, recommendations from its SSC and AP, as well as public testimony when recommending ABCs and TACs at its December 2000 meeting. The Council also reviewed their recommended ABC and TAC recommendations at an emergency meeting during January 2001, relative to the emergency rule provisions for SSL protection measures.

The final specifications are set forth in Tables 3 through 30 of this action. For 2001, the sum of TACs is 2 million mt in the BSAI and 285,994 mt in the GOA.

Bering Sea and Aleutian Islands Management Area

In December 2000, the SSC, AP, and Council reviewed the BSAI Plan Team's recommendations for OFL and ABC levels. Except for Bogoslof pollock, Atka mackerel and the "other species" category, the SSC, AP, and Council endorsed the Plan Team's ABC recommendations. Based on the best available information, the SSC recommended lower ABCs for Bogoslof pollock and the "other species" category and slightly higher ABCs for Atka mackerel than the Plan Team recommended. For Bogoslof pollock, the SSC recommended a lower ABC than the Plan Team by reducing the fishing mortality based on the ratio of the current biomass to a target biomass of about 2 million mt. For "other species,"

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the Plan Team recommended an ABC based on mean catch since 1977. The SSC disagreed with this approach and recommended using a Tier 5 approach under the FMP. For Atka mackerel, the SSC adopted a slightly higher ABC than the Plan Team by increasing the fishing mortality rate. For all species, the AP endorsed the ABCs recommended by the SSC, and the Council adopted the AP's recommendations.

The Council's TAC recommendations were based on the ABCs as adjusted for other biological and socioeconomic considerations, including maintaining the total TAC within the required OY range of 1.4 million to 2.0 million mt. The Council adopted the AP's TAC recommendations with the exception of the "other red rockfish."

Through 2000, the "other red rockfish" complex was comprised of northern, sharpchin, rougheye, and shortraker rockfish in the Bering Sea subarea. In the Aleutian Islands subarea, this complex was split out into two groups comprised of northern/sharpchin and rougheye/shortraker rockfish. For 2001, the Council recommended species-specific BSAI OFLs and ABCs for each species in the "other red rockfish" complex to reduce the potential for one species to be fished disproportionately to its abundance and resulting overfishing concerns.

For the non-CDQ fisheries, the Council recommended separate TACs for the Bering Sea and Aleutian Islands subareas for each of the four species in the other red rockfish complex. To further reduce the potential for differential harvesting, the Council recommended that these species be placed on bycatch only status in 2001. The Council also recommended that sharpchin rockfish, which were previously included in the "other red rockfish" complex, be moved into the other rockfish complex.

NMFS agrees with these recommendations, but will not be able to implement all of them in 2001 due to unanticipated monitoring constraints in the fixed gear fisheries. These species are reported by observers using group species codes, which, under current observer procedures, cannot be separated into specific species and incorporated into routine observer reports prior to the 2001 fishing year. Thus NMFS is modifying the Council's recommendation and is establishing BSAI wide OFL and ABC amounts for sharpchin/northern and rougheye/shortraker rockfish. The Bering Sea subarea now will be managed as the Aleutian Islands subarea has in the past, with two groups: Sharpchin/northern rockfish and shortraker/rougheye rockfish. Splitting the Bering Sea subarea "other red rockfish" complex into two groups addresses overfishing concern by decreasing the TAC amounts. To remain consistent with previous years' management, until species specific reporting is feasible, sharpchin rockfish will remain in a group with northern rockfish instead of being placed in the other rockfish group. The final ABCs as recommended by the Council and modified and approved by NMFS are listed in Table 3.

The Council recommended that the Bering Sea "other red rockfish" species category not be separated into individual species groups for the CDQ fisheries. The CDQ reserves for rockfish are 7.5 percent of the TAC. If CDQ reserves were specified for the new rockfish TAC categories, they would be 1.4 mt for Bering Sea sharpchin/northern and 8.7 mt for Bering Sea shortraker/rougheye. If these CDQ reserves were further divided among the six CDQ groups, the sharpchin/northern rockfish CDQ amounts available to each group would be between 100 kg and 325 kg. The Council recommended not splitting out the CDQ reserves to the individual species group because these small quotas could prevent the CDQ groups from harvesting much of their other groundfish CDQs. Therefore, consistent with Council intent to avoid premature closure of the CDQ fisheries, NMFS will continue to specify the CDQ reserve for the Bering Sea "other red rockfish" complex. The CDQ reserve for this complex will be calculated as the sum of an amount equal to 7.5 percent of the TAC for Bering Sea shortraker/rougheye plus 7.5 percent of the TAC for sharpchin/northern, for a total of 10 mt to the CDQ reserve for the "other red rockfish" complex. The Aleutian Islands rockfish TAC categories will remain the same in 2001 as in 2000 for both the CDQ and non-CDQ fisheries.

None of the Council's recommended TACs for 2001 exceeds the final ABC for any species category. NMFS finds that the Council's recommended TACs are consistent with the biological condition of groundfish stocks as described in the 2001 SAFE document and approves them with the exception of the "other red rockfish" complex. NMFS has modified the Council's TAC recommendations for this complex as described above to accommodate monitoring and reporting constraints.

Table 3 lists the 2001 OFL, ABC, TAC, ITAC, and Community Development Quota (CDQ) reserve amounts, overfishing levels, and initial apportionments of groundfish in the BSAI. The apportionment of TAC amounts among fisheries and seasons is discussed below.

TABLE 3.—2001 ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND OVERFISHING LEVELS OF GROUNDFISH IN THE BERING SEA AND ALEUTIAN ISLANDS AREA (BSAI) [1]

[All amounts are in metric tons]

Species	Area	Overfishing level	ABC	TAC	ITAC [2]	CDQ reserve [3]
Pollock [4]	Bering Sea (BS)	3,536,000	1,842,000	1,400,000	1,209,600	140,000
	Aleutian Islands (AI)	31,700	23,800	2,000	1,800	200
	Bogoslof District	60,200	8,470	1,000	900	100
Pacific cod	BSAI	248,000	188,000	188,000	159,800	14,100
Sablefish [5]	BS	1,910	1,560	1,560	663	215
	AI	3,070	2,500	2,500	531	422
Atka mackerel	Total	138,000	69,300	69,300	58,905	5,198
	Western AI	.....	27,900	27,900	23,715	2,093
	Central AI	.....	33,600	33,600	28,560	2,520
	Eastern AI/BS	.....	7,800	7,800	6,630	585
Yellowfin sole	BSAI	209,000	176,000	113,000	96,050	8,475
Rock sole	BSAI	271,000	228,000	75,000	63,750	5,625
Greenland turbot	Total	31,000	8,400	8,400	7,140	630
	BS	.....	5,628	5,628	4,784	422

TABLE 3.—2001 ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), CDQ RESERVE ALLOCATION, AND OVERFISHING LEVELS OF GROUNDFISH IN THE BERING SEA AND ALEUTIAN ISLANDS AREA (BSAI) [1]—Continued

[All amounts are in metric tons]

Species	Area	Overfishing level	ABC	TAC	ITAC [2]	CDQ reserve [3]
	AI	.....	2,772	2,772	2,356	208
Arrowtooth flounder	BSAI	141,500	117,000	22,011	18,709	1,651
Flathead sole	BSAI	102,000	84,000	40,000	34,000	3,000
Other flatfish [6]	BSAI	147,000	122,000	28,000	23,800	2,100
Pacific ocean perch	BS	2,040	1,730	1,730	1,471	130
	AI Total	11,800	10,200	10,200	8,670	765
	Western AI	.....	4,740	4,740	4,029	356
	Central AI	.....	2,560	2,560	2,176	192
	Eastern AI	.....	2,900	2,900	2,465	218
Sharpchin/Northern [7]	BSAI	9,020	6,764	6,764	5,749	.....
	BS	.....	.....	19	16	(7)
	AI	.....	.....	6,745	5,733	506
Shortraker/Rougheye [7]	BSAI	1,369	1,028	1,028	874	
	BS	.....	.....	116	99	(7)
	AI	.....	.....	912	775	68
Other rockfish [8]	BS	482	361	361	307	27
	AI	901	676	676	575	51
Squid	BSAI	2,620	1,970	1,970	1,675	148
Other species [9]	BSAI	69,000	33,600	26,500	22,525	1,988
Total		4,836,812	2,927,359	2,000,000	1,717,494	185,400

[1] Amounts are in metric tons. These amounts apply to the entire Bering Sea (BS) and Aleutian Islands (AI) management area unless otherwise specified. With the exception of pollock, and for the purpose of these specifications, the Bering Sea subarea includes the Bogoslof District.

[2] Except for pollock and the portion of the sablefish TAC allocated to hook-and-line or pot gear, 15 percent of each TAC is put into a reserve. The ITAC for each species is the remainder of the TAC after the subtraction of the reserve.

[3] Except for pollock and the hook-and-line or pot gear allocation of sablefish, one half of the amount of the TACs placed in reserve, or 7.5 percent of the TACs, is designated as a CDQ reserve for use by CDQ participants (see § 679.31).

[4] The AFA requires that 10 percent of the annual pollock TAC be allocated as a directed fishing allowance for the CDQ sector. NMFS then subtracts 4 percent of the remainder as an incidental catch allowance of pollock, which is not apportioned by season or area. The remainder is further allocated by sector as follows: inshore, 50 percent; catcher/processor, 40 percent; and motherships, 10 percent. NMFS, under regulations at § 679.24(b)(4), prohibits nonpelagic trawl gear to engage in directed fishing for non-CDQ pollock in the BSAI.

[5] The ITAC for sablefish reflected in Table 3 is for trawl gear only. Regulations at § 679.20(b)(1) do not provide for the establishment of an ITAC for the hook-and-line or pot gear allocation for sablefish. Twenty percent of the sablefish TAC allocated to hook-and-line gear or pot gear and 7.5 percent of the sablefish TAC allocated to trawl gear is reserved for use by CDQ participants (see § 679.31(c)).

[6] "Other flatfish" includes all flatfish species, except for Pacific halibut (a prohibited species), flathead sole, Greenland turbot, rock sole, yellowfin sole, and arrowtooth flounder.

[7] The CDQ reserves for shortraker, rougheye, sharpchin, and northern rockfish will continue to be managed as the "other red rockfish" complex for the BS. For 2001 the CDQ reserve is 10 mt.

[8] "Other rockfish" includes all Sebastes and Sebastolobus species except for Pacific ocean perch, sharpchin, northern, shortraker, and rougheye rockfish.

[9] "Other species" includes sculpins, sharks, skates and octopus. Forage fish, as defined at § 679.2, are not included in the "other species" category.

Reserves and the Pollock Incidental Catch Allowance (ICA)

Regulations at § 679.20(b)(1)(i) require that 15 percent of the TAC for each target species or species group, except for the hook-and-line and pot gear allocation of sablefish, be placed in a non-specified reserve. The AFA supersedes this provision for pollock by requiring that the 2001 TAC for this species be fully allocated among the CDQ program, the ICA, inshore, catcher/processor, and mothership directed fishery allowances.

Regulations at § 679.20(b)(1)(iii) require that one-half of each TAC amount placed in the non-specified reserve be allocated to the groundfish CDQ reserve and that 20 percent of the hook-and-line and pot gear allocation of sablefish be allocated to the fixed gear sablefish CDQ reserve. Section 206(a) of the AFA requires that 10 percent of the pollock TAC be allocated to the pollock CDQ reserve. With the exception of the hook-and-line and pot gear sablefish CDQ reserve, the regulations do not further apportion the CDQ reserves by gear. Regulations at § 679.21(e)(1)(i) also require that 7.5 percent of each PSC limit, with the exception of herring, be withheld as a prohibited species quota (PSQ) reserve for the CDQ fisheries. Regulations governing the management of the CDQ and PSQ reserves are set forth at §§ 679.30 and 679.31.

Under section 206(b) of the AFA, NMFS allocates a pollock ICA of 4 percent of the pollock TAC after subtraction of the 10 percent CDQ reserve. This is a reduction from the 5 percent ICA specified for 2000. The 2001 allowance is based on an examination of the incidental catch of pollock in non-pollock target fisheries from 1997 through 2000. During this 4-year period, the incidental catch of pollock ranged from a low of 3 percent in 1998 to a high of about 6 percent in 1997, with a 4-year average of 4 percent. In 2000, the actual incidental catch was only 4 percent of the TAC instead of the 5 percent ICA withheld at the beginning of the year. As a result, 9,000 mt of pollock were reallocated to the directed fishing allowance for non-CDQ fisheries in the fall (65 FR 62646, October 19, 2000). Based on this experience, NMFS believes that a 2001 ICA of 4 percent is sufficient, even if incidental catch of pollock in the Pacific cod fishery increases under SSL protection measures (see Pacific cod seasons below).

The regulations do not designate the remainder of the non-specified reserve

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by species or species group, and any amount of the reserve may be reapportioned to a target species or to the "other species" category during the year, providing that such reapportionments do not result in overfishing. The Regional Administrator has determined that the ITACs specified for the species listed in Table 4 need to be supplemented from the non-specified reserve because U.S. fishing vessels have demonstrated the capacity to harvest the full TAC allocations. Therefore, in accordance with § 679.20(b)(3), NMFS is apportioning the amounts shown in Table 4 from the non-specified reserve to increase the ITAC to an amount that is equal to TAC minus the CDQ reserve.

TABLE 4.—APPORTIONMENT OF RESERVES TO ITAC CATEGORIES

[All amounts are in metric tons]

Species—area or subarea	Reserve amount	Final ITAC
Atka mackerel—Western Aleutian District	2,093	25,808
Atka mackerel—Central Aleutian District	2,520	31,080
Atka mackerel—Eastern Aleutian District and Bering Sea subarea	585	7,215
Pacific ocean perch—Western Aleutian District	356	4,385
Pacific ocean perch—Central Aleutian District	192	2,368
Pacific ocean perch—Eastern Aleutian District	218	2,683
Pacific cod—BSAI	14,100	173,900
Sharpchin/Northern rockfish-Aleutian Islands subarea	506	6,239
Shortraker/Rougheye rockfish—Aleutian Islands subarea	68	843
Greenland turbot—Bering Sea subarea	422	5,206
Greenland turbot—Aleutian Islands subarea	208	2,564
Total	21,268	262,291

Pollock Allocations Under the AFA

Section 206(a) of the AFA requires the allocation of 10 percent of the BSAI pollock TAC as a directed fishing allowance to the CDQ program. The remainder of the BSAI pollock TAC, after the subtraction of an allowance for the incidental catch of pollock by vessels, including CDQ vessels, harvesting other groundfish species, must be allocated as follows: 50 percent to catcher vessels harvesting pollock for processing by the inshore component, 40 percent to catcher/processors and catcher vessels harvesting pollock for processing by catcher/processors in the offshore component, and 10 percent to catcher vessels harvesting pollock for processing by motherships in the offshore component. These amounts are listed in Table 5.

The AFA also contains several specific requirements concerning pollock and pollock allocations. First, paragraph 210(c) of the AFA requires that not less than 8.5 percent of the pollock allocated to vessels for processing by offshore catcher/processors be available for harvest by offshore catcher vessels listed in section 208(b) harvesting pollock for processing by offshore catcher/processors listed in paragraph 208(e). Second, paragraph 208(e)(21) of the AFA specifies that catcher/processors eligible to fish for pollock under such paragraph are prohibited from harvesting in the aggregate a total of more than one-half of a percent (0.5 percent) of the pollock allocated to vessels for processing by offshore catcher/processors. Third, paragraph 210(e)(1) of the AFA specifies that no particular individual, corporation, or other entity may harvest, through a fishery cooperative or otherwise, a total of more than 17.5 percent of the pollock available to be harvested in the directed pollock fishery. Other provisions of the AFA, including inshore pollock cooperative allocations and AFA catcher vessel harvest limitations are discussed later in this section. Table 5 lists the 2001 allocations of pollock TAC as described by the AFA.

SCA Harvest Limits

As described in Part I, this emergency rule establishes pollock harvest limits in the SCA at a level that do not exceed the harvest in metric tons authorized for the 2000 fishery. These amounts, by sector, are listed in Table 5.

TABLE 5.—ALLOCATIONS OF THE POLLOCK TAC AND DIRECTED FISHING ALLOWANCE TO THE INSHORE, CATCHER/PROCESSOR, MOTHERSHIP, AND CDQ COMPONENTS [1]

[All amounts are in metric tons]

Area and Sector	2001 DFA	A/B Season [1]			C/D Season [1 2]		
		A/B DFA	A SCA limit [3]	B SCA Limit [3]	C/D DFA	C SCA Limit [3]	D SCA Limit [3]
Bering Sea subarea	1,400,000	560,000	166,751	55,497	840,000	48,210	80,142
CDQ	140,000	56,000	28,247	9,339	84,000	9,567	15,718
ICA [4]	50,400						
AFA Inshore	604,800	241,920	81,802	27,267	362,880	39,440	65,734
AFA C/Ps [5]	483,840	193,536	38,564	12,854	290,304	0	0
Catch by C/Ps	442,714	177,085			265,628		
Catch by CVs [5]	41,126	16,451			24,676		
Restricted C/P cap [6]	2,419	968			1,452		
AFA Motherships	120,960	48,384	14,607	4,869	72,576	0	0
Excessive shares cap [7]	211,680						
Aleutian Islands ICA [8]	2,000						

TABLE 5.—ALLOCATIONS OF THE POLLOCK TAC AND DIRECTED FISHING ALLOWANCE TO THE INSHORE, CATCHER/PROCESSOR, MOTHERSHIP, AND CDQ COMPONENTS [1]—Continued

[All amounts are in metric tons]

Area and Sector	2001 DFA	A/B Season [1]			C/D Season [1 2]		
		A/B DFA	A SCA limit [3]	B SCA Limit [3]	C/D DFA	C SCA Limit [3]	D SCA Limit [3]
Bogoslof District ICA [8]	1,000						

[1] After subtraction for the CDQ reserve and the incidental catch allowance, the pollock TAC is allocated as follows: inshore component—50 percent, catcher/processor component—40 percent, and mothership component—10 percent. Under paragraph 206(a) of the AFA, the CDQ reserve for pollock is 10 percent. NMFS, under regulations at § 679.24(b)(4), prohibits nonpelagic trawl gear to engage in directed fishing for non-CDQ pollock in the BSAI. The A/B season, January 20—June 10, is allocated 40 percent and the C/D season, June 10—October 31 is allocated 60 percent.

[2] This emergency interim rule expires on July 17, 2001, before the B season will conclude. Therefore, the B season is not fully authorized unless the emergency interim rule is extended.

[3] The SCA limits are established as the amount, in metric tons, authorized for the 2000 pollock fishery (65 FR 3896, January 25, 2000).

[4] The pollock incidental catch allowance for the BS subarea is 4 percent of the TAC after subtraction of the CDQ reserve.

[5] Subsection 210(c) of the AFA requires that not less than 8.5 percent of the directed fishing allowance allocated to listed catcher/processors (C/Ps) shall be available for harvest only by eligible catcher vessels (CVs) delivering to listed catcher/processors.

[6] The AFA requires that vessels described in section 208(e)(21) be prohibited from exceeding a harvest amount of one-half of one percent of the directed fishing allowance allocated to vessels for processing by AFA catcher/processors.

[7] Paragraph 210(e)(1) of the AFA specifies that "No particular individual, corporation, or other entity may harvest, through a fishery cooperative or otherwise, a total of more than 17.5 percent of the pollock available to be harvested in the directed pollock fishery."

[8] Consistent with the RPAs, the Aleutian Islands subarea and the Bogoslof District are closed to directed fishing for pollock. The amounts specified are for incidental catch amounts only, and are not apportioned by season or sector.

Allocation of the Atka Mackerel TAC

Due to concerns about the potential impact of the Atka mackerel fishery on Steller sea lions and their critical habitat, NMFS issued regulations that implement temporal and spatial dispersion of fishing effort in the Atka mackerel fisheries. Regulations at § 679.20(a)(8)(ii) apportion the Atka mackerel ITAC into two equal seasonal allowances. After subtraction of the jig gear allocation, the first allowance is made available for directed fishing from January 1 to April 15 (A season), and the second seasonal allowance is made available from September 1 to November 1 (B season) (Table 6). According to § 679.22(a)(8), fishing with trawl gear in areas defined as Steller sea lion critical habitat (See Table 21 to 50 CFR part 679) within the Western and Central Aleutian Districts, is prohibited during each Atka mackerel season after specified percentages of the TAC are harvested within designated critical habitat areas. In 2001, the specified percentage of each seasonal allowance within critical habitat is 48 percent in the Western Aleutian District and 46 percent in the Central Aleutian District (§ 679.22(a)(8)(iii)(B)). A Steller sea lion critical habitat closure to fishing with trawl gear within an area will remain in effect until NMFS closes Atka mackerel to directed fishing within the same area. The regulations do not establish critical habitat closures based on Atka mackerel catch percentages inside critical habitat areas for the Eastern Aleutian District and Bering Sea subarea.

Under § 679.20(a)(8)(i), up to 2 percent of the Eastern Aleutian District and the Bering Sea subarea Atka mackerel ITAC may be allocated to the jig gear fleet. The Council determines the amount of this allocation annually, based on several criteria including the anticipated harvest capacity of the jig gear fleet. In December 2000, the Council recommended that 1 percent of the Atka mackerel TAC in the Eastern Aleutian District and Bering Sea subarea be allocated to the jig gear fleet based on historic harvest capacity of the fleet. NMFS finds that this is consistent with the status of the stock and with the regulatory framework stated above. Based on an ITAC of 7,215 mt, the jig gear allocation is 72 mt.

TABLE 6.—SEASONAL AND SPATIAL APPORTIONMENTS, GEAR SHARES, AND CDQ RESERVE OF THE BSAI ATKA MACKEREL TAC

[All amounts are in metric tons]

Subarea & component	TAC	CDQ reserve	TACI [1]	Seasonal apportionment [2]			
				A season [3]		B Season [4]	
				Total	CH Limit [5]	Total	CH limit [5]
Western Aleutian District	27,900	2,093	25,808	12,904	6,194	12,904	6,194
Central Aleutian District	33,600	2,520	31,080	15,540	7,148	15,540	7,148
Eastern AI/BS subarea [6]	7,800	585	7,215				
Jig (1%) [7]			72				
Other gear (99%)			7,143	3,572		3,572	
Total	69,300	5,198	64,103	32,016		32,016	

[1] The reserves have been released for Atka mackerel see (Table 4).

[2] The seasonal apportionment of Atka mackerel is 50 percent in the A season and 50 percent in the B season.

[3] The A season is January 1 through noon April 15.

[4] The B season is September 1 through noon November 1.

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[5] Critical habitat (CH) allowance refers to the amount of each seasonal allowance that is available for fishing inside critical habitat (50 CFR part 679 Table 21). In 2001, the percentage of each seasonal allowance available for fishing inside critical habitat is 48 percent in the Western AI and 46 percent in the Central AI. When these critical habitat allowances are reached, critical habitat areas will be closed to trawling until NMFS closes Atka mackerel to directed fishing within the same district.

[6] Eastern Aleutian District and Bering Sea subarea.

[7] Regulations at § 679.20 (a)(8) require that up to 2 percent of the Eastern AI/BS area ITAC be allocated to the jig gear fleet. The amount of this allocation is 1 percent and was determined by the Council based on anticipated harvest capacity of the jig gear fleet. The jig gear allocation is not apportioned by season.

Allocation of the Pacific Cod TAC

Under § 679.20(a)(7), 2 percent of the Pacific cod ITAC is allocated to vessels using jig gear, 51 percent to vessels using hook-and-line or pot gear, and 47 percent to vessels using trawl gear. Under § 679.20(a)(7)(i)(B), the portion of the Pacific cod TAC allocated to trawl gear is further allocated 50 percent to catcher vessels and 50 percent to catcher/processors. Under regulations at § 679.20(a)(7)(i)(C)(*1*), a portion of the Pacific cod allocated to hook-and-line or pot gear is set aside as an ICA of Pacific cod in directed fisheries for groundfish other than Pacific cod by vessels using these gear types. Based on anticipated bycatch in these fisheries, the Council proposed an ICA of 500 mt. The remainder of Pacific cod is further allocated to vessels using hook-and-line or pot gear as the following directed fishing allowances: 80 percent to hook-and-line catcher/processor vessels, 0.3 percent to hook-and-line catcher vessels, 18.3 percent to pot gear vessels, and 1.4 percent to catcher vessels under 60 feet LOA using hook-and-line or pot gear.

Due to concerns about the potential impact of the Pacific cod fishery on Steller sea lions and their critical habitat, NMFS is implementing under this emergency rule temporal dispersion of fishing effort in the Pacific cod fisheries by apportioning the Pacific cod ITAC into two seasonal allowances. The first allowance, 60 percent of the ITAC, is made available for directed fishing from January 1 to June 10, and the second seasonal allowance, 40 percent of the ITAC, is made available from June 10 to December 31. Table 7 lists the 2001 allocations and seasonal apportionments of the Pacific cod ITAC.

TABLE 7.—2001 GEAR SHARES AND SEASONAL APPORTIONMENTS OF THE BSAI PACIFIC COD TAC

Gear sector	Percent	Share [1] (mt)	Seasonal apportionment [2]	
			Date	Amount (mt)
Jig	2	3,478	Jan 1–Jun 10	2,087
			Jun 10–Dec 31	1,391
Total hook-and-line and pot gear allocation of Pacific cod TAC	51	88,689		
Hook-and-line Catcher Processors	80	70,551	Jan 1–Jun 10	42,331
			Jun 10–Dec 31	28,220
Hook-and-Line Catcher Vessels	0.3	265	Jan 1–Jun 10	159
			Jun 10–Dec 31	106
Pot Gear Vessels	18.3	16,139	Jan 1–Jun 10	9,683
			Jun 10–Dec 31	6,455
Catcher Vessels < 60 feet LOA using Hook-and-line or Pot gear	1.4	1,235	Jan 1–Jun 10	741
			Jun 10–Dec 31	494
Hook-and-line and pot gear sub-total	100	88,189		
Hook-and-line and pot gear Incidental Catch Allowance		500		500
Trawl gear	47	81,733		
Catcher Vessel	50	40,867	Jan 1–Jun 10	24,520
			Jun 10–Dec 31	16,347
Catcher Processor	50	40,867	Jan 1–Jun 10	24,520
			Jun 10–Dec 31	16,347
Total		173,900		

[1] The reserve have been released for Pacific cod see (Table 4).

[2] The first season is allocated 60 percent of the TAC and the second season is allocated 40 percent of the TAC. Any unused portion of the first seasonal Pacific cod allowance will be reapportioned to the second seasonal allowance.

Allocation of the Shortraker and Rougheye Rockfish TAC

Under § 679.20(a)(9), the ITAC of shortraker rockfish and rougheye rockfish specified for the Aleutian Islands subarea is allocated 30 percent to vessels using non-trawl gear and 70 percent to vessels using trawl gear. Based on a 2001 ITAC of 843 mt, the trawl allocation is 590 mt and the non-trawl allocation is 253 mt.

Sablefish Gear Allocation

Regulations at § 679.20(a)(4) (iii) and (iv) require that sablefish TACs for the BS and AI subareas be allocated between trawl and hook-and-line or pot gear. Gear allocations of TACs for the Bering Sea subarea are 50 percent for trawl gear and 50 percent for hook-and-line or pot gear and for the Aleutian Islands subarea are 25 percent for trawl gear and 75 percent for hook-and-line or pot gear. Regulations at § 679.20(b)(1)(iii)(B) require that 20 percent of the hook-and-line and pot gear allocation of sablefish be reserved as sablefish CDQ. Additionally, regulations at § 679.20(b)(1)(iii)(A) require that 7.5 percent of the trawl gear allocation of sablefish (one half of the reserve) be reserved as groundfish CDQ. Gear allocations of the sablefish TAC and CDQ reserve amounts are specified in Table 8.

TABLE 8.—GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TAC

[All amounts are in metric tons]

Subarea & gear	Percent of TAC	Share of TAC	ITAC [1]	CDQ reserve
Bering Sea:				
Trawl [2]	50	780	663	59
Hook-&-line/pot gear [3]	50	780	N/A	156
Total	100	1,560	663	215
Aleutian Islands:				
Trawl [2]	25	625	531	47
Hook-&-line/pot gear [3]	75	1,875	N/A	375
Total	100	2,500	531	422

[1] Except for the sablefish hook-and-line and pot gear allocation, 15 percent of TAC is apportioned to reserve. The ITAC is the remainder of the TAC after the subtraction of these reserves.

[2] For the portion of the sablefish TAC allocated to vessels using trawl gear, one half of the reserve (7.5 percent of the specified TAC) is reserved for the multi-species CDQ program.

[3] For the portion of the sablefish TAC allocated to vessels using hook-and-line or pot gear, 20 percent of the allocated TAC is reserved for use by CDQ participants. Regulations in § 679.20(b)(1) do not provide for the establishment of an ITAC for sablefish allocated to hook-and-line or pot gear.

Allocation of Prohibited Species Catch (PSC) Limits for Halibut, Crab, Salmon, and Herring

PSC limits for halibut are set in regulations at § 679.21(e). For the BSAI trawl fisheries, the limit is 3,675 mt mortality of Pacific halibut. For non-trawl fisheries, the limit is 900 mt mortality. PSC limits for crab and herring are specified annually based on abundance and spawning biomass. On June 15, 2000, the Pacific halibut and crab PSC limits and associated bycatch allowances for the BSAI trawl fisheries were reduced under regulations implementing Amendment 57 to the FMP for the Groundfish Fishery of the BSAI. Amendment 57 (65 FR 31105, May 16, 2000) prohibits the use of nonpelagic trawl gear in the BSAI directed fishery for pollock. The anticipated reductions in the halibut and crab bycatch resulted in corresponding reductions in the PSC limits for these species. New Chinook Salmon PSC limits were established for the BSAI pollock fishery under Amendment 58 and its implementing regulations at § 679.21(e)(1)(vii). These PSC limits are reduced annually over the next 4 year period. In 2001, the chinook salmon PSC limit for the pollock fishery is 41,000 fish.

The criteria for determining the PSC limits for red king crab in Zone 1 are set forth at § 679.21(e)(1)(ii). For 2001, the PSC limit of red king crab in Zone 1 for trawl vessels is 97,000 animals. The number of mature female red king crab is estimated in 2001 to be above the threshold of 8.4 million animals, and the effective spawning biomass is estimated to be 39.9 million lb (18,099 mt) which is greater than 14.5 million lb (6,577 mt) but less than 55 million lb (24,948 mt). Based on the criteria set out at § 679.21(e)(1)(ii)(B), the limit is 97,000 animals.

The criteria for determining the PSC limits for *C. bairdi* crabs are set forth in § 679.21(e)(1)(iii). The 2001 *C. bairdi* PSC limit for trawl gear is 730,000 animals in Zone 1 and 2,070,000 animals in Zone 2. These limits are based on survey data from 2000. In Zone 1, *C. bairdi* abundance was estimated to be greater than 150 million and less than 270 million animals. In Zone 2, *C. bairdi* abundance was estimated to be greater than 175 million animals and less than 290 million animals.

Under § 679.21(e)(1)(iv), the PSC limit for *C. opilio* is based on total abundance as indicated by the NMFS annual bottom trawl survey. The *C. opilio* PSC limit is set at 0.1133 percent of the Bering Sea abundance index. Based on the 2000 survey estimate of 3.2 billion animals, the calculated limit would be 3,625,600 animals. Because this limit is less than 4.5 million, under § 679.21(e)(1)(iv)(B), the 2001 *C. opilio* PSC limit is 4,350,000 animals.

Under § 679.21(e)(1)(vi), the PSC limit of Pacific herring caught while conducting any trawl operation for groundfish in the BSAI is 1 percent of the annual eastern Bering Sea herring biomass. NMFS' best estimate of 2001 herring biomass is 152,574 mt. This amount was derived using 2000 survey data and an age-structured biomass projection model developed by the Alaska Department of Fish and Game (ADF&G). Therefore, the herring PSC limit for 2001 is 1,526 mt.

Under § 679.21(e)(1)(i), 7.5 percent of each PSC limit specified for crab and halibut is reserved as a PSQ reserve for use by the groundfish CDQ program. Regulations at § 679.21(e)(3) require the apportionment of each trawl PSC limit into PSC bycatch allowances for seven specified fishery categories. Regulations at § 679.21(e)(4)(ii) authorize the apportionment of the non-trawl halibut PSC limit among five fishery categories. The fishery bycatch allowances for the trawl and non-trawl fisheries are listed in Table 9. These amounts are unchanged from those recommended by the Council at its December 2000 meeting.

Regulations at § 679.21(e)(3)(ii)(B) establish criteria under which NMFS must specify an annual red king crab bycatch limit for the Red King Crab Savings Subarea (RKCSS). The regulations limit the RKCSS to 35 percent of the trawl bycatch allowance specified for the rock sole/flathead sole/"other flatfish" fishery category and must be based on the need to optimize the groundfish harvest relative to red king crab bycatch. The Council recommended and NMFS approves a red king crab bycatch limit equal to 35 percent of the trawl bycatch allowance specified for the flatfish fishery within the RKCSS in order maximum harvest of groundfish relative to red king crab bycatch.

Regulations at § 679.21(e)(4)(ii) authorize exemption of specified non-trawl fisheries from the halibut PSC limit. As in past years, NMFS, after consultation with the Council, is exempting pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from halibut bycatch restrictions because these fisheries use selective gear types that take few halibut compared to other gear types such as nonpelagic trawl. In 2000, total

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groundfish catch for the pot gear fishery in the BSAI was approximately 19,872 mt with an associated halibut bycatch mortality of about 4 mt. The 2000 groundfish jig gear fishery harvested about 72 mt of groundfish. Most vessels in the jig gear fleet are less than 60 ft (18.3 m) LOA and are exempt from observer coverage requirements. As a result, observer data are not available on halibut bycatch in the jig gear fishery. However, NMFS assumes a negligible amount of halibut bycatch mortality because of the selective nature of this gear type and the likelihood that halibut caught with jig gear have a high survival rate when released.

As in past years, the Council recommended that the sablefish IFQ fishery be exempt from halibut bycatch restrictions because of the sablefish and halibut IFQ program (subpart D of 50 CFR part 679). The sablefish IFQ program requires legal-sized halibut to be retained by vessels using hook-and-line gear if a halibut IFQ permit holder is aboard and is holding unused halibut IFQ. This action results in less halibut discard in the sablefish fishery. In 1995, about 36 mt of halibut discard mortality was estimated for the sablefish IFQ fishery. A similar estimate for 1996 through 2000 has not been calculated, but NMFS has no information indicating that it would be significantly different. NMFS approves the Council's recommendation to exempt the hook-and-line sablefish from halibut bycatch restrictions.

Regulations at § 679.21(e)(5) authorize NMFS, after consultation with the Council, to establish seasonal apportionments of PSC amounts in order to maximize the ability of the fleet to harvest the available groundfish TAC and to minimize bycatch. The factors to be considered are: (1) Seasonal distribution of prohibited species, (2) seasonal distribution of target groundfish species, (3) PSC bycatch needs on a seasonal basis relevant to prohibited species biomass, (4) expected variations in bycatch rates throughout the year, (5) expected start of fishing effort, and (6) economic effects of seasonal PSC apportionments on industry sectors. In December 2000, the Council's AP recommended seasonal PSC apportionments in order to maximize harvest among gear types, fisheries, and seasons while minimizing bycatch of PSC based upon the criteria above. NMFS approves the PSC apportionments specified in Table 9, below. However, NMFS recognizes that the Council did not have the opportunity in December 2000, to evaluate the effects of SSL protection measures implemented by this emergency rule on PSC bycatch needs throughout the year with respect to factors listed above. After consulting with the Council at its emergency January 2001 meeting, NMFS will consider amending PSC seasonal apportionments and amounts.

TABLE 9.—PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL AND NON-TRAWL FISHERIES [1]

[All amounts are in metric tons]

	Prohibited species and zone					
	Halibut mortality (mt) BSAI	Herring (mt) BSAI	Red King Crab (animals) Zone 1	C. opilio (animals) COBLZ [2]	C. bairdi (animals) Zone 1	C. bairdi (animals) Zone 2
TRAWL FISHERIES						
Yellowfin sole	911	139	11,664	2,876,981	253,894	1,246,502
January 20–March 31	286					
April 1–May 20	196					
May 21–July 3	49					
July 1–December 31	380					
Rocksole/oth.flat/flat sole [3]	854	20	64,782	469,130	272,126	415,501
January 20–March 31	498					
April 1–July 31	179					
July 1–December 31	177					
RKC savings subarea [3]			22,674			
Turbot/sablefish/arrowtooth [4]		9		40,238		
Rockfish (July 1–December 31) [5]	69	7		40,237		7,658
Pacific cod	1,334	20	11,664	524,736	136,400	225,941
Pollock/Atka/other [6]	232	146	1,615	72,428	12,830	19,148
Midwater trawl pollock		1,184				
Total Trawl PSC	3,400	1,526	89,725	4,023,750	675,250	1,914,750
NON-TRAWL FISHERIES						
Pacific cod—Total	755					
Jan. 1–June 10 [7]	300					
June 11–July 31	0					
August 1–Dec. 31	455					
Other non-trawl–Total	78					
May 1–December 31	78					
Groundfish pot & jig	Exempt					
Sablefish hook-&-line	Exempt					
Total Non-Trawl	833					
PSQ Reserve [8]	342		7,275	326,250	54,750	155,250
Grand Total	4,575	1,526	97,000	4,350,000	730,000	2,070,000

[1] Refer to § 679.2 for definitions of areas.
[2] *C. opilio* Bycatch Limitation Zone. Boundaries are defined at 50 CFR part 679, fig. 13.

[3] The Council at its December 2000 meeting limited red king crab for trawl fisheries within the RKCSS to 35 percent of the total allocation to the rock sole, flathead sole, and other flatfish fishery category (§ 679.21(e)(3)(ii)(B)).
[4] Greenland turbot, arrowtooth flounder, and sablefish fishery category.
[5] The Council at its December 2000 meeting apportioned the rockfish PSC amounts from July 1–December 31, to prevent fishing for rockfish before July 1, 2001.
[6] Pollock other than pelagic trawl pollock, Atka mackerel, and "other species" fishery category.
[7] Any unused halibut PSC from the first trimester may be rolled over into the third trimester.
[8] With the exception of herring, 7.5 percent of each PSC limit is allocated to the multi-species CDQ program as PSQ reserve. The PSQ reserve is not allocated by fishery, gear or season.

To monitor halibut bycatch mortality allowances and apportionments, the Administrator, Alaska Region, NMFS (Regional Administrator), will use observed halibut bycatch rates, assumed mortality rates, and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. The Regional Administrator monitors a fishery's halibut bycatch mortality allowances using assumed mortality rates that are based on the best information available, including information contained in the annual SAFE reports.

The Council recommended, and NMFS concurs, that the assumed halibut mortality rates developed by staff of the International Pacific Halibut Commission (IPHC) for the 2001 BSAI groundfish fisheries be adopted for purposes of monitoring halibut bycatch allowances established for 2001. Results from analysis of halibut release condition data for 1999 showed continued stability in halibut discard mortality rates (DMRs) for many fisheries. Plots of annual DMRs against the 10-year mean indicated little change since 1990 for some fisheries, particularly the major trawl fisheries. DMRs were more variable for the smaller fisheries which typically take minor amounts of halibut bycatch. A new procedure for determining Preseason Assumed DMRs was proposed by the IPHC and adopted by the Council, which included use of the long-term mean DMR for a 3-year period before revisions are proposed except for BSAI longline Pacific cod, for which the Council recommended setting annual DMRs. The IPHC will also continue to conduct annual analyses of observer data and recommend changes to the Preseason Assumed DMR where a fishery DMR shows large variation from the mean. The justification for these mortality rates is discussed in the final SAFE report dated November 2000.

TABLE 10.—ASSUMED PACIFIC HALIBUT MORTALITY RATES FOR THE BSAI FISHERIES

Fishery	Preseason assumed mortality (percent)
Hood-and-line gear fisheries:	
Rockfish	25
Pacific cod	12
Greenland turbot	16
Sablefish	22
Other Species	12
Trawl gear fisheries:	
Midwater pollock	84
Non-pelagic pollock	76
Yellowfin sole	81
Rock sole	76
Flathead sole	67
Other flatfish	71
Rockfish	69
Pacific cod	67
Atka mackerel	75
Greenland turbot	70
Sablefish	50
Other species	67
Pot gear fisheries:	
Pacific cod	8
Other species	8
CDQ Trawl fisheries:	
Atka mackerel	82
Midwater pollock	90
Non-pelagic pollock	88
Rockfish	88
Yellowfin sole	83
CDQ Hood-and-line fisheries:	
Pacific cod	10

Directed Fishing Closures

In accordance with § 679.20(d)(1)(i), if the Regional Administrator determines that any allocation or apportionment of a target species or "other species" category has been or will be reached, the Regional Administrator may establish a directed fishing allowance for that species or species group. If the Regional Administrator establishes a directed fishing allowance, and that allowance is or will be reached before the end of the fishing year, NMFS will prohibit directed fishing for that species or species group in the specified subarea or district (§ 697.20(d)(1)(iii)). Similarly, under § 679.21(e), if the Regional Administrator determines that a fishery category's bycatch allowance of halibut, red king crab, or *C. bairdi* Tanner crab for a specified area has been reached, the Regional Administrator will prohibit directed fishing for each species in that category in the specified area.

The Regional Administrator has determined that the following remaining allocation amounts will be necessary as incidental catch to support other anticipated groundfish fisheries for the 2001 fishing year:

	(mt)
Bogoslof District:	
Pollock	1,000
Aleutian Islands subarea:	
Pollock	2,000
Sharpchin/northern rockfish	6,239
Shortraker/rougheye rockfish	843
"Other rockfish"	575
Bering Sea subarea:	
Pacific ocean perch	1,471
"Other rockfish"	307
Sharpchin/northern rockfish	16
Shortraker/rougheye rockfish	99

Consequently, in accordance with § 679.20(d)(1)(i), the Regional Administrator establishes the directed fishing allowances for the above species or species groups as zero.

Therefore, in accordance with § 679.20(d)(1)(iii), NMFS immediately is prohibiting directed fishing for these species in the specified areas and these closures will remain in effect through 2400 hrs, Alaska local time (A.l.t.), December 31, 2001, effective January 18, 2001.

In addition, the BSAI, Zone 1, annual red king crab allowance specified for the trawl rockfish fishery (§ 679.21(e)(3)(iv)(D)) is 0 mt and the BSAI first seasonal halibut bycatch allowance specified for the trawl rockfish fishery is 0 mt. The BSAI annual halibut bycatch allowance specified for the trawl Greenland turbot/arrowtooth flounder/sablefish fishery categories, (§ 679.21(e)(3)(iv)(C)) is 0 mt. Therefore, in accordance with § 679.21(e)(7)(ii) and (v), NMFS is prohibiting directed fishing for rockfish by vessels using trawl gear in Zone 1 of the BSAI and directed fishing for Greenland turbot/arrowtooth flounder/sablefish by vessels using trawl gear in the BSAI for the entire 2001 fishing year. NMFS is also prohibiting directed fishing for rockfish outside Zone 1 in the BSAI until 1200 hrs, A.l.t. July 1, 2001.

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While these closures are in effect, the maximum retainable bycatch amounts at § 679.20(e) and (f) apply at any time during a fishing trip. These closures to directed fishing are in addition to closures and prohibitions found in regulations at 50 CFR part 679. Refer to § 679.2 for definitions of areas. In the BSAI, "Other rockfish" includes *Sebastes* and *Sebastolobus* species except for Pacific ocean perch, shortraker, rougheye, sharpchin, and northern rockfish.

BS Subarea Inshore Pollock Allocations

Under § 679.20(a)(5)(i)(C), NMFS must subdivide the inshore allocation into allocations for cooperatives and vessels not fishing in a cooperative (i.e., the open access sector). In addition, under § 679.22(a)(11)(iv), NMFS must establish harvest limits inside the Steller sea lion conservation area (SCA) and provide a set-aside so that catcher vessels less than or equal to 99 ft (30.2 m) LOA have the opportunity to operate entirely within the SCA during the A, B and D seasons. Accordingly, Table 11 lists the apportionment of the BS subarea inshore pollock allocation into allocations for vessels fishing in a cooperative and for vessels not participating in a cooperative and establishes a cooperative-sector SCA set-aside for AFA catcher vessels less than or equal to 99 ft (30.2 m) LOA. The SCA set-aside for sector catcher vessels less than or equal to 99 ft (30.2 m) LOA that are not participating in a cooperative will be established inseason based on actual participation levels and is not included in Table 11. These allocations may be revised based on any corrections to AFA vessels' catch history.

TABLE 11.—BERING SEA SUBAREA POLLOCK ALLOCATIONS TO THE COOPERATIVE AND OPEN ACCESS SECTORS OF THE INSHORE POLLOCK FISHERY

[Amounts are expressed in metric tons]

	A/B season TAC	A season inside SCA [1]	B season inside SCA	C/D season TAC	C season inside SCA [1]	D season inside SCA
Cooperative sector:						
Vessels > 99 ft	n/a	70,890	23,630	n/a	n/a	56,966
Vessels ≤ 99 ft	n/a	10,593	3,531	n/a	n/a	8,512
Total	240,976	81,483	27,161	361,465	39,286	65,478
Open access sector	944	[2] 319	[2] 106	1,415	154	[2] 256
Total inshore	241,920	81,802	27,267	362,880	39,440	65,734

[1] Steller sea lion conservation area established at § 679.22(a)(11)(iv).

[2] SCA limitations for vessels less than or equal to 99 ft LOA that are not participating in a cooperative will be established on an inseason basis in accordance with § 679.22(a)(11)(iv)(D)(2) which specifies that "the Regional Administrator will prohibit directed fishing for pollock by vessels catching pollock for processing by the inshore component greater than 99 ft (30.2 m) LOA before reaching the inshore SCA harvest limit during the A, B and D seasons to accommodate fishing by vessels less than or equal to 99 ft (30.2 m) inside the SCA for the duration of the inshore seasonal opening."

Under § 679.4, NMFS set out procedures for AFA inshore catcher vessel pollock cooperatives to apply for and receive cooperative fishing permits and inshore pollock allocations. NMFS received applications from seven inshore catcher vessel cooperatives.

Table 12 lists the pollock allocations to the seven inshore catcher vessel pollock cooperatives that have been approved and permitted by NMFS for the 2001 fishing year. Allocations for cooperatives and vessels not participating in cooperatives are not made for the AI subarea because the AI subarea has been closed to directed fishing for pollock. These allocations may be revised based on any corrections to AFA vessels' catch history.

TABLE 12.—BERING SEA SUBAREA INSHORE COOPERATIVE ALLOCATIONS

Cooperative name and member vessels	Sum of member vessel's official catch histories [1]	Percentage of inshore sector allocation (percent)	Annual co-op allocation
Akutan Catcher Vessel Association:			
ALDEBARAN, ARCTURUS, BLUE FOX, CAPE KIWANDA, COLUMBIA, DOMINATOR, DONA MARTITA, EXODUS, GLADIATOR, GOLDEN DAWN, GOLDEN PISCES, HAZEL LORRAINE, INTREPID EXPLORER, LESLIE LEE, LISA MELINDA, MAJESTY, MARCY J, MARGARET LYN, NORDIC EXPLORER, NORTHERN PATRIOT, NORTHWEST EXPLORER, PACIFIC RAM, PACIFIC VIKING, PEGASUS, PEGGIE JO, PERSEVERANCE, PREDATOR, RAVEN, ROYAL AMERICAN, SEEKER, SOVEREIGNTY, TRAVELER, VIKING EXPLORER	265,244	29.889	180,769
Arctic Enterprise Association:			
ARCTIC EXPLORER, BRISTOL EXPLORER, OCEAN EXPLORER, PACIFIC EXPLORER	50,008	5.635	34,080
Northern Victor Fleet Cooperative:			
ANITA J, NORDIC FURY, PACIFIC FURY, GOLDRUSH, EXCALIBUR II, HALF MOON BAY, SUNSET BAY, COMMODORE, STORM PETREL, POSEIDON, ROYAL ATLANTIC, MISS BERDIE	72,024	8.116	49,086
Peter Pan Fleet Cooperative:			
AMBER DAWN, AMERICAN BEAUTY, ELIZABETH F, OCEAN HOPE 1, OCEANIC, OCEAN LEADER, TOPAZ, WALTER N	15,309	1.725	10,433

TABLE 12.—BERING SEA SUBAREA INSHORE COOPERATIVE ALLOCATIONS—Continued

Cooperative name and member vessels	Sum of member vessel's official catch histories [1]	Percentage of inshore sector allocation (percent)	Annual co-op allocation
Unalaska Cooperative:			
ALASKA ROSE, BERING ROSE, DESTINATION, GREAT PACIFIC, MESSIAH, MORNING STAR, MS AMY, PROGRESS, SEA WOLF, VANGUARD, WESTERN DAWN	106,714	12.025	72,727
UniSea Fleet Cooperative:			
ALSEA, AMERICAN EAGLE, ARGOSY, AURIGA, AURORA, DEFENDER, GUN-MAR, NORDIC STAR, PACIFIC MONARCH, SEADAWN, STARFISH, STARLITE, STARWARD	210,922	23.768	143,749
Westward Fleet Cooperative:			
A.J., ALASKAN COMMAND, ALYESKA, ARCTIC WIND, CAITLIN ANN, CHELSEA K, HICKORY WIND, FIERCE ALLEGIANCE, OCEAN HOPE 3, PACIFIC CHALLENGER, PACIFIC KNIGHT, PACIFIC PRINCE, VIKING, WESTWARD I	163,750	18.452	111,598
Open access AFA vessels	3,463	0.390	2,359
Total inshore allocation	887,435	100	604,800

[1] Under 679.62(e)(1) the individual catch history for each vessel is equal to the vessel's best 2 of 3 years inshore pollock landings from 1995 through 1997 and includes landings to catcher/processors for vessels that made 500 or more mt of landings to catcher/processors from 1995 through 1997.

2001 Unrestricted AFA Catcher/Processor Sideboards

Regulations at § 679.63(a) establish a formula for setting AFA catcher/processor sideboard limits for non-pollock groundfish and PSC in the BSAI. The basis for these sideboard amounts was recommended by the Council and is described in detail in the Emergency Interim Rule to Implement Major Provisions of the AFA (64 FR 4520, January 28, 2000). The 2001 catcher/processor sideboards are set out in Table 13 below.

All non-pollock groundfish that is harvested by unrestricted AFA catcher/processors, whether as targeted catch or bycatch, will be deducted from the harvest limits in Table 13. However, non-pollock groundfish that is delivered to listed catcher/processors by catcher vessels will not be deducted from the 2001 harvest limits for the listed catcher/processors.

TABLE 13.—2001 UNRESTRICTED BSAI AFA CATCHER/PROCESSOR GROUNDFISH SIDEBOARDS

[Amounts are expressed in metric tons]

Target species	Area	1995–1997 Total catch	1995–1997 Available TAC	1995–1997 Ratio	2001 ITAC available to trawl C/Ps	2001 C/P sideboard amount
Pacific cod trawl	BSAI	13,547	51,450	0.263	40,867	10,748
Sablefish trawl	BS	8	1,736	0.005	663	3
	AI	1	1,135	0.001	531	1
Atka mackerel	Western AI					
	A season [1]	n/a	n/a	0.200	12,904	2,581
	CH limit [2]					1,239
	B season	n/a	n/a	0.200	12,904	2,581
	CH limit					1,239
	Central AI					
	A season [1]	n/a	n/a	0.115	15,540	1,787
	CH limit					882
	B season	n/a	n/a	0.115	15,540	1,787
	CH limit					882
Yellowfin sole	BSAI	123,003	527,000	0.233	96,050	22,380
Rock sole	BSAI	14,753	202,107	0.073	63,750	4,654
Greenland turbot	BS	168	16,911	0.010	5,206	52
	AI	31	6,839	0.005	2,564	13
Arrowtooth flounder	BSAI	788	36,873	0.021	18,709	393
Flathead sole	BSAI	3,030	87,975	0.034	34,000	1,156
Other flatfish	BSAI	12,145	92,428	0.131	23,800	3,118
Pacific ocean perch	BS	58	5,760	0.010	1,471	15
	Western AI	356	12,440	0.029	4,385	127
	Central AI	95	6,195	0.015	2,368	36
	Eastern AI	112	6,265	0.018	2,683	48
Sharpchin/northern	BS			0.078	16	
	AI	1,034	13,254	0.078	6,239	487
Shortraker/rougheye	BS			0.024	99	
	AI	68	2,827	0.024	843	20
Other rockfish	BS	39	1,026	0.038	307	12
	AI	95	1,924	0.049	575	28
Squid	BSAI	7	3,670	0.002	1,675	3

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TABLE 13.—2001 UNRESTRICTED BSAI AFA CATCHER/PROCESSOR GROUNDFISH SIDEBOARDS—Continued

[Amounts are expressed in metric tons]

Target species	Area	1995–1997			2001 ITAC available to trawl C/Ps	2001 C/P sideboard amount
		Total catch	Available TAC	Ratio		
Other species	BSAI	3,551	65,925	0.054	22,525	1,216

[1] The seasonal apportionment of Atka mackerel in the open access fishery is 50 percent in the A season and 50 percent in the B season. Unrestricted AFA catcher/processors are limited to harvesting no more than 20 and 11.5 percent of the available TAC in the Western and Central AI subareas respectively. Unrestricted AFA catcher/processors are prohibited from harvesting Atka mackerel in the Eastern Aleutian Islands District and Bering Sea subarea (paragraph 211(b)(2)(C)).

[2] Critical habitat (CH) allowance refers to the amount of each seasonal allowance that is available for fishing inside critical habitat (50 CFR part 679 Table 21). In 2001, the percentage of TAC available for fishing inside critical habitat area is 48 percent in the Western AI and 46 percent in the Central A1. When these critical habitat allowances are reached, critical habitat areas will be closed to trawling until NMFS closes Atka mackerel to directed fishing within the same district.

Regulations at § 679.63(a)(2) establish a formula for PSC sideboards for unrestricted AFA catcher/processors. These amounts are equivalent to the percentage of prohibited species bycatch limits harvested in the non-pollock groundfish fisheries by the AFA catcher/processors listed in subsection 208(e) and section 209 of the AFA from 1995 through 1997. Prohibited species amounts harvested by these catcher/processors in BSAI non-pollock groundfish fisheries from 1995 through 1997 are shown in Table 14. These data were used to calculate the relative amount of prohibited species catch limits harvested by pollock catcher/processors, which were then used to determine the prohibited species harvest limits for unrestricted AFA catcher/processors in the 2001 non-pollock groundfish fisheries.

PSC that is caught by unrestricted AFA catcher/processors participating in any non-pollock groundfish fishery listed in Table 13 shall accrue against the 2001 PSC limits for the listed catcher/processors. Regulations at § 679.21(e)(3)(v) provide authority to close directed fishing for non-pollock groundfish for unrestricted AFA catcher/processors once a 2001 PSC limitation listed in Table 14 is reached.

Crab or halibut PSC that is caught by unrestricted AFA catcher/processors while fishing for pollock will accrue against the bycatch allowances annually specified for either the midwater pollock or the pollock/Atka mackerel/other species fishery categories under § 679.21(e).

TABLE 14.—2001 UNRESTRICTED BSAI AFA CATCHER/PROCESSOR PROHIBITED SPECIES SIDEBOARD AMOUNTS

PSC species	1995–1997			2001 PSC available to trawl vessels	2001 C/P limit
	PSC catch	Total PSC	Ratio		
Halibut mortality	955	11,325	0.084	3,400	286 mt.
Red king crab	3,098	473,750	0.007	89,725	628 crab.
C. opilio	2,323,731	15,139,178	0.153	4,023,750	615,634 crab.
C. bairdi:					
Zone 1	385,978	2,750,000	0.140	675,250	94,535 crab.
Zone 2	406,860	8,100,000	0.050	1,914,750	95,738 crab.

2001 AFA Catcher Vessel Sideboards

Regulations at § 679.63(b) establish a formula for setting AFA catcher vessel groundfish and PSC sideboard amounts for the BSAI. The basis for these sideboard amounts was recommended by the Council and is described in detail in the Emergency Interim Rule to Implement Major Provisions of the AFA (64 FR 4520, January 28, 2000). The 2001 AFA catcher vessel sideboards amounts are shown in Tables 15 and 16.

All harvests of groundfish sideboard species made by non-exempt AFA catcher vessels, whether as targeted catch or bycatch, will be deducted from the sideboard limits listed in Table 15.

TABLE 15.—2001 BSAI AFA CATCHER VESSEL (CV) SIDEBOARDS

[Amounts are expressed in metric tons]

Species	Fishery by area/season/processor/gear	Ratio of 1995–1997 AFA CV catch to 1995–1997 TAC	2001 initial TAC	2001 catcher vessel sideboard
Pacific cod	BSAI:			
	jig gear:			
	Jan 1–Jun 10	0.0000	2,087	0
	Jun 10–Dec 31	0.0000	1,391	0
	hook-and-line CV:			
	Jan 1–Jun 10	0.0006	159	0
	Jun 10–Dec 31	0.0006	106	0
	Pot gear:			
	Jan 1–Jun 10	0.0006	9,683	6
	Jun 10–Dec 31	0.0006	6,455	4

TABLE 15.—2001 BSAI AFA CATCHER VESSEL (CV) SIDEBOARDS—Continued

[Amounts are expressed in metric tons]

Species	Fishery by area/season/processor/gear	Ratio of 1995–1997 AFA CV catch to 1995–1997 TAC	2001 initial TAC	2001 catcher vessel sideboard
	CV < 60 feet LOA using hook-and-line or pot gear:			
	Jan 1–Jun 10	0.0006	741	0
	Jun 10–Dec 31	0.0006	494	0
	trawl gear:			
	catcher vessel:			
	Jan 1–Jun 10	0.7703	24,520	18,888
	Jun 10–Dec 31	0.7703	16,347	12,592
	catcher/processor:			
	Jan 1–Jun 10	0.0000	24,520	0
	Jun 10–Dec 31	0.0000	16,347	0
Sablefish	BS trawl gear	0.0006	663	0
	AI trawl gear	0.0608	531	32
Atka mackerel	Eastern AI/BS:			
	jig gear	0.0031	72	0
	other gear:			
	Jan 1–Apr 15	0.0031	3,572	11
	Sept 1–Nov 1	0.0031	3,572	11
	Central AI:			
	Jan–Apr 15	0.0001	15,540	2
	inside CH	0.0001	7,148	1
	Sept 1–Nov 1	0.0001	15,540	2
	inside CH	0.0001	7,148	1
	Western AI:			
	Jan–Apr 15	0.0000	12,904	0
	inside CH	0.0000	6,194	0
	Sept 1–Nov 1	0.0000	12,904	0
	inside CH	0.0000	6,194	0
Yellowfin sole	BSAI	0.0712	96,050	6,839
Rock sole	BSAI	0.0255	63,750	1,626
Greenland Turbot	BS	0.0405	5,206	211
	AI	0.0021	2,564	5
Arrowtooth flounder	BSAI	0.0583	18,709	1,091
Other flatfish	BSAI	0.0558	23,800	1,328
POP	BS	0.1018	1,471	150
	Eastern AI	0.0048	2,683	13
	Central AI	0.0011	2,368	3
	Western AI	0.0000	4,385	0
Sharpchin/Northern	BS	0.0280	16	0
	AI	0.0015	6,239	9
Shortraker/Rougheye	BS	0.0280	99	3
	AI	0.0011	843	1
Other rockfish	BS	0.0379	307	12
	AI	0.0031	575	2
Squid	BSAI	0.3885	1,675	651
Other species	BSAI	0.0283	22,525	637
Flathead Sole	BS trawl gear	0.0490	34,000	1,666

Regulations at § 679.63(b) establish a formula for PSC sideboards for AFA catcher vessels. The AFA catcher vessel PSC bycatch limit for halibut in the BSAI, and each crab species in the BSAI for which a trawl bycatch limit has been established as a percentage of the PSC limit equal to the ratio of aggregate retained groundfish catch by AFA catcher vessels in each PSC target category from 1995 through 1997 relative to the retained catch of all vessels in that fishery from 1995 through 1997. These amounts are listed in Table 16.

Halibut and crab PSC that is caught by AFA catcher vessels participating in any non-pollock groundfish fishery listed in Table 15 will accrue against the 2001 PSC limits for the AFA catcher vessels. Regulations at § 679.21(d)(8) and (e)(3)(v) provide authority to close directed fishing for non-pollock groundfish for AFA catcher vessels once a 2001 PSC limitation listed in Table 16 for the BSAI is reached. PSC that is caught by AFA catcher vessels while fishing for pollock in the BSAI will accrue against either the midwater pollock or the pollock/Atka mackerel/other species fishery categories.

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TABLE 16.—2001 AFA CATCHER VESSEL (CV) PROHIBITED SPECIES CATCH (PSC) SIDEBOARD AMOUNTS [1] FOR THE BSAI

PSC species	Target fishery category [2] and season	Ratio of 1995–1997 AFA CV retained catch to total retained catch	2001 PSC Limit	2001 AFA catcher vessel PSC sideboard
Halibut	Pacific cod trawl	0.6183	1,334	825
	Pacific cod hook-and-line or pot	0.0022	755	2
	Yellowfin sole:			
	Jan. 20–Mar. 31	0.1144	286	33
	Apr. 1–May 20	0.1144	196	22
	May 21–July 3	0.1144	49	6
	July 1–Dec. 31	0.1144	380	43
	Rock sole/Flathead sole/Oth. flat:			
	Jan. 20–Mar. 31	0.2841	498	141
	Apr. 1–July 3	0.2841	179	51
	July 1–Dec. 31	0.2841	177	50
	Turbot/Arrowtooth/Sablefish	0.2327	0	0
	Rockfish	0.0245	69	2
	Pollock/Atka mackerel/Other sp	0.0227	232	5
Red King Crab Zone 1	Pacific cod	0.6183	11,664	7,212
	Yellowfin sole	0.1144	11,664	1,334
	Rock sole/Flathead sole/Oth. flat	0.2841	64,782	18,405
	Pollock/Atka mackerel/Other sp	0.0227	1,615	37
C. opilio COBLZ [3 4]	Pacific cod	0.6183	524,736	324,444
	Yellowfin sole	0.1144	2,876,981	329,127
	Rock sole/Flathead sole/Oth. flat	0.2841	469,130	133,280
	Pollock/Atka mackerel/Other sp	0.0227	72,428	1,644
	Rockfish [5]	0.0245	40,237	986
	Turbot/Arrowtooth/Sablefish	0.2327	40,238	9,363
C. bairdi Zone 1	Pacific cod	0.6183	136,400	84,336
	Yellowfin sole	0.1144	253,894	29,045
	Rock sole/Flathead sole/Oth. flat	0.2841	272,126	77,311
	Pollock/Atka mackerel/Other sp	0.0227	12,830	291
C. bairdi Zone 2	Pacific cod	0.6183	225,941	139,699
	Yellowfin sole	0.1144	1,246,502	142,600
	Rock sole/Flathead sole/Oth. flat	0.2841	415,501	118,044
	Pollock/Atka mackerel/Other sp	0.0227	19,148	435
	Rockfish	0.0245	7,658	188

[1] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.
[2] Target fishery categories are defined in regulation at § 679.21(e)(3)(iv).
[3] *C. opilio* Bycatch Limitation Zone. Boundaries are defined at Figure 13 of 50 CFR part 679.
[4] The Council at its December 2000 meeting limited red king crab for trawl fisheries within the RKCSS to 35 percent of the total allocation to the rock sole, flathead sole, and other flatfish fishery category (§ 679.21(e)(3)(ii)(B)).
[5] The Council at its December 2000 meeting apportioned the rockfish PSC amounts from July 1—December 31 to prevent fishing for rockfish before July 1, 2001.

2001 Sideboard Directed Fishing Closures

Catcher/Processor Sideboard Closures

The Regional Administrator has determined that many of the AFA catcher/processor sideboard amounts listed in Table 13 are necessary as incidental catch to support other anticipated groundfish fisheries for the 2001 fishing year. In accordance with § 679.20(d)(1)(iv), the Regional Administrator establishes these following amounts as directed fishing allowances. The Regional Administrator finds that many of these directed fishing allowances will be reached before the end of the year. Therefore, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing by unrestricted AFA catcher/processors for the species in the specified areas set out in Table 17.

TABLE 17.—AFA UNRESTRICTED CATCHER/PROCESSOR SIDEBOARD DIRECTED FISHING CLOSURES.[1] THESE CLOSURES TAKE EFFECT 1200 HRS A.L.T., JANUARY 20, 2001 AND REMAIN IN EFFECT THROUGH 2400 HRS, A.L.T., DECEMBER 31, 2001

Species	Area	Gear types
Sablefish trawl	BSAI	all
Greenland turbot	BSAI	all
Arrowtooth flounder	BSAI	all
Pacific ocean perch	BSAI	all
Sharpchin/Northern rockfish	BSAI	all
Shortraker/Rougheye rockfish	BSAI	all
Other rockfish	BSAI	all
Squid	BSAI	all

TABLE 17.—AFA UNRESTRICTED CATCHER/PROCESSOR SIDEBOARD DIRECTED FISHING CLOSURES.[1] THESE CLOSURES TAKE EFFECT 1200 HRS A.L.T., JANUARY 20, 2001 AND REMAIN IN EFFECT THROUGH 2400 HRS, A.L.T., DECEMBER 31, 2001—Continued

Species	Area	Gear types
Other species	BSAI	all

[1] Maximum retainable percentages may be found in Table 11 to 50 CFR part 679.

AFA Catcher Vessel Sideboard Closures

The Regional Administrator has determined that many of the AFA catcher vessel sideboard amounts listed in Table 15 are necessary as incidental catch to support other anticipated groundfish fisheries for the 2001 fishing year. In accordance with § 679.20(d)(1)(iv), the Regional Administrator establishes these amounts as directed fishing allowances. The Regional Administrator finds that many of these directed fishing allowances will be reached before the end of the year. Therefore, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing by non-exempt AFA catcher vessels for the species in the specified areas set out in Table 18.

TABLE 18.—AFA CATCHER VESSEL SIDEBOARD DIRECTED FISHING CLOSURES[1]

[These Closures take effect 12 noon A.L.T., January 20, 2001. These closures will remain in effect through 2400 hrs, A.L.T., December 31, 2001]

Species	Area	Gear
Pacific cod	BSAI	Hook-and-line, pot, jig.
Sablefish	BSAI	Trawl.
Atka mackerel	BSAI	All.
Greenland Turbot	BSAI	All.
Arrowtooth flounder	BSAI	All.
Pacific ocean perch	BSAI	All.
Sharpchin/northern rockfish	BSAI	All.
Shortraker/rougheye rockfish	BSAI	All.
Other rockfish	BSAI	All.
Squid	BSAI	All.
Other species	BSAI	All.

[1] Maximum retainable percentages may be found in Table 11 to 50 CFR part 679.

Gulf of Alaska

The SSC adopted the OFL recommendations from the Plan Team, which were provided in the November 2000 GOA SAFE report (See **ADDRESSES**), for all groundfish species categories. The SSC also adopted the ABC and area apportionment recommendations from the Plan Team, which were provided in the GOA SAFE report, for all of the groundfish species categories.

The Council adopted the SSC's ABC and AP's TAC recommendations for all species, except other rockfish in the Eastern GOA. The Council requested that NMFS set the TAC for other rockfish in the Eastern GOA at levels which would be sufficient to allow for bycatch to be retained throughout the fishing year but that would be insufficient to allow for a directed fishery to occur. The SSC's, AP's and Council's recommendation for the method of apportioning the sablefish ABC among management areas includes commercial fishery as well as survey data as in 2000. NMFS stock assessment scientists believe that the use of unbiased commercial fishery data reflecting catch-per-unit effort provides a desirable input for stock distribution assessments. The use of commercial fishery data would need to be evaluated annually to assure that unbiased information is included in stock distribution models. The Council's recommendation for sablefish area apportionments also takes into account the prohibition on the use of trawl gear in the Southeast Outside (SEO) District of the Eastern GOA and makes available 5 percent of the combined Eastern GOA ABCs to trawl gear for use as incidental catch in other directed groundfish fisheries in the West Yakutat (WYK) District.

NMFS agrees with the Council's approach for the 2001 harvest specifications, except for pollock. The Comprehensive BiOp sets forth an RPA to previous management measures to avoid jeopardizing or adversely modifying the critical habitat of the western population of Steller sea lions. One element of the RPA is to adopt a more conservative harvest strategy for fish removal at the FMP level, also called the Global Control Rule (GCR) (See discussion in Part I of this preamble above). The GCR decreases the likelihood that the biomass of pollock, Pacific cod and Atka mackerel, principal prey species of Steller sea lions, will drop below 40 percent of the estimated unfished level of spawning biomass per recruit, the $B_{40\%}$ level. In the GOA in 2001, the GCR would apply to the combined Western, Central, and West Yakutat Regulatory Area (W/C/WYK) stock of pollock as the projected spawning biomass in 2001 for this stock is estimated to be 202,800 mt, below the $B_{40\%}$ value of 247,000 mt. Application of the GCR to this stock of pollock in the GOA would lower the Council's recommended ABC (and TAC) from 99,350 mt to 80,462 mt in 2001, a reduction of 18,888 mt or 19 percent. Public Law 106–544, phases-in the implementation of the GCR in 2001. Specifically, section 209(c)(5) states that when the GCR applies in 2001 it "shall not cause a reduction in the total allowable catch of any fishery of more than ten percent." NMFS therefore is adjusting the Council's recommended TAC of pollock in the combined W/C/WYK area downward by 10 percent (9,935 mt) from 99,350 mt to 89,415 mt. This action is discussed in more detail below.

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As in previous years, the Plan Team, SSC, and Council recommended that total removals of Pacific cod from the GOA not exceed ABC recommendations. Accordingly, the Council recommended that the TACs be adjusted downward from the ABCs by amounts equal to the 2001 guideline harvest levels (GHL) established for Pacific cod by the State of Alaska (State) for a State-managed fishery in State waters. The effect of the State's GHL on the Pacific cod TAC is discussed in greater detail below.

The Council's recommended ABCs, as adjusted by the 2001 GCR are listed in Table 19. These amounts reflect harvest amounts that are less than the specified overfishing amounts. The sum of 2001 ABCs for all assessed groundfish is 447,710 mt, which is lower than the 2000 ABC total of 448,010 mt.

2001 Harvest Specifications

Specifications of TAC and Reserves

The Council recommended TACs all equal to ABCs for deep-water flatfish, rex sole, sablefish, shortraker and rougheye rockfish, northern rockfish, Pacific Ocean perch, pelagic shelf rockfish, thornyhead rockfish, demersal shelf rockfish, and Atka mackerel. The Council-recommended TACs are less than the ABC for Pacific cod, flathead sole, shallow-water flatfish, arrowtooth flounder, and other rockfish. NMFS has adjusted the Council's recommended TAC for pollock in the combined W/C/WYK area downward from recommended ABC level by 9,935 mt as described above (Table 19).

The TAC for pollock in the combined W/C/WYK area of the GOA has decreased from 93,540 mt in 2000 to 89,415 mt in 2001. The 2001 TAC in the SEO District of the Eastern GOA is unchanged from 2000 at 6,460 mt. The apportionment of pollock TAC among the W/C/WYK areas of the GOA reflects the current biomass distribution.

Under this emergency interim rule, the annual pollock TAC in the Western and Central GOA is divided into four seasonal apportionments. The annual pollock TAC in the combined Western and Central GOA of 87,080 mt is the result of the combined W/C/WYK annual TAC of 89,415 mt less the WYK annual TAC of 2,335 mt. Thirty percent of the annual TAC in the Western and Central Regulatory Areas in the GOA is apportioned to the A season (January 20 through March 1) in the Western GOA, Shelikof Strait, and Statistical Areas 620 and 630 (outside of Shelikof Strait) in the Central GOA (§ 679.20(a)(5)(ii)); 15 percent to the B season (March 15 through May 31) in the Western GOA, Shelikof Strait, and Statistical Areas 620 and 630 (outside of Shelikof Strait) in the Central GOA; 30 percent to the C season (August 20 through September 15) in the Western GOA and Statistical Areas 620 and 630 in the Central GOA; and 25 percent to the D season (October 1 through November 1) in the Western GOA and Statistical Areas 620 and 630 in the Central GOA (§ 679.23(d)(2)(i) through (iv)). The derivation of the seasonal apportionment amounts in the Western and Central GOA areas is discussed below.

The 2001 Pacific cod TAC is affected by the State's developing fishery for Pacific cod in State waters in the Central and Western GOA, as well as Prince William Sound (PWS). The SSC, AP, and Council recommended that the sum of all State and Federal water Pacific cod removals should not exceed the ABC. Accordingly the Council recommended that Pacific cod TAC be reduced from ABC levels to account for State GHLS in each regulatory area of the GOA so that the TAC for (1) the Eastern GOA be lower than the ABC by 1,190 mt, (2) the Central GOA be lower than the ABC by 8,400 mt, and (3) the Western GOA be lower than the ABC by 6,100 mt. These amounts reflect the sum of State's 2001 GHLs in these areas which are 25 percent, 21.75 percent, and 25 percent of the Eastern, Central, and Western GOA ABCs respectively. These percentages are unchanged from 2000.

NMFS is also establishing seasonal apportionments of the annual Pacific cod TAC in the Western and Central Regulatory Areas at 60 percent of the annual TAC to an A season from January 1 through June 10 and at 40 percent of the annual TAC to a B season from June 10 to December 31. These seasonal apportionments of the annual Pacific cod TAC are discussed in greater detail below.

The Council requested that NMFS set TAC for other rockfish in the Eastern GOA at levels sufficient to allow bycatch to be retained throughout the year but that would be insufficient to allow directed fishing to occur in 2001. Based on catches from 1996 though 2000, NMFS has determined that a TAC of 150 mt in the West Yakutat District and 100 mt in the Southeast Outside District in the Eastern GOA will be sufficient to allow other rockfish to be retained as bycatch throughout the 2001 fishing year but not provide an amount sufficient to conduct a directed fishery.

The FMP specifies that the amount for the "other species" category is calculated as 5 percent of the combined TAC amounts for target species. The GOA-wide "other species" TAC is 13,619 mt, which is 5 percent of the sum of the combined TAC amounts (272,375 mt) for the assessed target species. The sum of the TACs for all GOA groundfish is 285,994 mt, which is within the OY range specified by the FMP. The sum of the TACs is lower than the 2000 TAC sum of 298,510 mt. NMFS has reviewed the Council's recommended TAC specifications and apportionments and, with the exception of pollock as noted in the combined W/C/WYK area, hereby approves these specifications under § 679.20(c)(3)(ii). The 2001 ABCs, TACs, and OFLs are shown in Table 19.

TABLE 19.—2001 ABCS, TACS, AND OVERFISHING LEVELS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT (W/C/WYK), WESTERN (W), CENTRAL (C), SHELIKOF STRAIT, EASTERN (E) REGULATORY AREAS, AND IN THE WEST YAKUTAT (WYK), SOUTHEAST OUTSIDE (SEO), AND GULF-WIDE (GW) DISTRICTS OF THE GULF OF ALASKA

[Values are in metric tons]

Species and area [1]	ABC	TAC	Overfishing
Pollock: [2]			
Shumagin (610)	35,240	31,724	
Chirikof (620)	14,260	12,841	
Kodiak (630)	26,650	23,996	
Shelikof	20,680	18,619	
WYK (640)	2,520	2,235	
Subtotal W/C/WYK	99,350	89,415	117,750

TABLE 19.—2001 ABCS, TACS, AND OVERFISHING LEVELS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT (W/C/WYK), WESTERN (W), CENTRAL (C), SHELIKOF STRAIT, EASTERN (E) REGULATORY AREAS, AND IN THE WEST YAKUTAT (WYK), SOUTHEAST OUTSIDE (SEO), AND GULF-WIDE (GW) DISTRICTS OF THE GULF OF ALASKA—Continued

[Values are in metric tons]

Species and area [1]	ABC	TAC	Overfishing
SEO (650)	6,460	6,460	8,610
Total	105,810	95,875	126,360
Pacific cod: [3]			
W	24,400	18,300	
C	38,650	30,250	
E	4,750	3,560	
Total	67,800	52,110	91,200
Flatfish [4] (deepwater):			
W	280	280	
C	2,710	2,710	
WYK	1,240	1,240	
SEO	1,070	1,070	
Total	5,300	5,300	6,980
Rex sole: [4]			
W	1,230	1,230	
C	5,660	5,660	
WYK	1,540	1,540	
SEO	1,010	1,010	
Total	9,440	9,440	12,300
Flathead sole:			
W	8,490	2,000	
C	15,720	5,000	
WYK	1,440	1,440	
SEO	620	620	
Total	26,270	9,060	34,210
Flatfish [5] (shallow-water):			
W	19,510	4,500	
C	16,400	12,950	
WYK	790	790	
SEO	1,160	1,160	
Total	37,860	19,400	45,330
Arrowtooth flounder:			
W	16,480	8,000	
C	99,590	25,000	
WYK	24,220	2,500	
SEO	7,860	2,500	
Total	148,150	38,000	173,550
Sablefish: [6]			
W	2,010	2,010	
C	5,410	5,410	
WYK	2,060	2,060	
SEO	3,360	3,360	
Subtotal: E	5,420	5,420	
Total	12,840	12,840	15,720
Pacific [7] ocean perch:			
W	1,280	1,280	1,520
C	9,610	9,610	11,350
WYK	870	870	
SEO	1,750	1,750	
Subtotal: E	13,510	13,510	3,090
Total			15,960
Short raker/rougheye: [8]			
W	210	210	
C	930	930	
E	590	590	
Total	1,730	1,730	2,510
Other rockfish: [9, 10]			
W	20	20	

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TABLE 19.—2001 ABCs, TACs, AND OVERFISHING LEVELS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT (W/C/WYK), WESTERN (W), CENTRAL (C), SHELIKOF STRAIT, EASTERN (E) REGULATORY AREAS, AND IN THE WEST YAKUTAT (WYK), SOUTHEAST OUTSIDE (SEO), AND GULF-WIDE (GW) DISTRICTS OF THE GULF OF ALASKA—Continued

[Values are in metric tons]

Species and area [1]	ABC	TAC	Overfishing
C	740	740	
WYK	250	150	
SEO	3,890	100	
Total	4,900	1,010	6,390
Northern Rockfish: [10, 12]			
W	600	600	
C	4,280	4,280	
E	N/A	N/A	
Total	4,880	4,880	5,780
Pelagic shelf rockfish: [13]			
W	550	550	
C	4,080	4,080	
WYK	580	580	
SEO	770	770	
Total	5,980	5,980	9,040
Thornyhead rockfish:			
W	420	420	
C	970	970	
E	920	920	
Total	2,310	2,310	2,770
Demersal shelf rockfish: [11]			
SEO	330	330	410
Atka mackerel: GW	600	600	6,200
Other species: [14] GW	15 N/A	13,619	N/A
Total [16]	447,710	285,994	554,710

[1] Regulatory areas and districts are defined at § 679.2.

[2] Pollock is apportioned in the Western/Central Regulatory areas to the Shelikof Strait conservation area (defined at § 679.22(b)(2)(iii)(B)) in the A and B seasons only (§ 679.22(b)(2)(iii)(A)) in accordance with § 679.22(b)(2)(iii)(C) and the remainder to the three statistical areas in the combined Western/Central Regulatory Area outside the Shelikof Strait based on the relative distribution of pollock biomass at 56 percent, 4 percent, and 40 percent in Regulatory areas 610, 620, and 630 respectively. During the C and D seasons pollock is apportioned based on the relative distribution of pollock biomass at 42 percent, 25 percent, and 33 percent in Regulatory Areas 610, 620, and 630 respectively. These seasonal apportionments are shown in Tables 21 and 22. In the West Yakutat and Southeast Outside Districts of the Eastern Regulatory Area, pollock is not divided into seasonal allowances.

[3] The annual Pacific cod TAC is apportioned 60 percent to an A season and 40 percent to a B season in the Western and Central Regulatory Areas of the GOA. Pacific cod is allocated 90 percent for processing by the inshore component and 10 percent for processing by the offshore component. Seasonal apportionments and component allocations of TAC are shown in Table 23.

[4] "Deep water flatfish" means Dover sole, Greenland turbot, and deepsea sole.

[5] "Shallow water flatfish" means flatfish not including "deep water flatfish," flathead sole, rex sole, or arrowtooth flounder.

[6] Sablefish is allocated to trawl and hook-and-line gears (Table 20).

[7] "Pacific ocean perch" means *Sebastes alutus*.

[8] "Shortraker/rougheye rockfish" means *Sebastes borealis* (shortraker) and *S. aleutianus* (rougheye).

[9] "Other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat District means slope rockfish and demersal shelf rockfish. The category "other rockfish" in the Southeast Outside District means Slope rockfish.

[10] "Slope rockfish" means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergrey), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), and *S. reedi* (yellowmouth). In the Eastern GOA only, "slope rockfish" also includes northern rockfish, *S. polyspinous*.

[11] "Demersal shelf rockfish" means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[12] "Northern rockfish" means *Sebastes polyspinis*.

[13] "Pelagic shelf rockfish" means *Sebastes ciliatus* (dusky), *S. entomelas* (widow), and *S. flavidus* (yellowtail).

[14] "Other species" means sculpins, sharks, skates, squid, and octopus. The TAC for "other species" equals 5 percent of the TACs of assessed target species.

[15] N/A means not applicable.

[16] The total ABC is the sum of the ABCs for assessed target species.

Apportionment of Reserves

Regulations implementing the FMP require 20 percent of each TAC for pollock, Pacific cod, flatfish, and the "other species" category be set aside in reserves for possible apportionment at a later date (§ 679.20(b)(2)). For the preceding 12 years, including 2000, NMFS reapportioned all of the reserves in the final harvest specifications except for Pacific cod. Between 1997 and 2000, NMFS retained the Pacific cod reserve to provide for a management buffer to account for excessive fishing effort and incomplete or late catch reporting. NMFS believes this is no longer necessary as estimates of catch and incidental catch needs in other directed fisheries have improved in recent years. For 2001, NMFS has reapportioned all of the reserve for pollock, Pacific cod, flatfish, and "other species". Specifications of TAC shown in Table 19 reflect apportionment of reserve amounts for these species and species groups.

Allocations of the Sablefish TACs to Vessels Using Hook-and-Line and Trawl Gear

Under § 679.20(a)(4)(i) and (ii), sablefish TACs for each of the regulatory areas and districts are allocated to hook-and-line and trawl gear. In the Western and Central Regulatory Areas, 80 percent of each TAC is allocated to hook-and-line gear and 20 percent of each TAC is allocated to trawl gear. In the Eastern Regulatory Area, 95 percent of the TAC is allocated to hook-and-line gear and 5 percent is allocated to trawl gear. The trawl gear allocation in the Eastern Regulatory Area may only be used to support incidental catch of sablefish in directed fisheries for other target species. In recognition of the trawl ban in the SEO District of the Eastern Regulatory Area, the Council recommended that 5 percent of the combined Eastern GOA sablefish be allocated to trawl gear in the WYK District and the remainder to vessels using hook-and-line gear. In the SEO District, 100 percent of the sablefish TAC is allocated to vessels using hook-and-line gear. This recommendation results in an allocation of 271 mt to trawl gear and 1,789 mt to hook-and-line gear in the WYK District and 3,360 mt to hook-and-line gear in the SEO District. Table 20 shows the allocations of the 2001 sablefish TACs between hook-and-line gear and trawl gear.

TABLE 20.—2001 SABLEFISH TAC SPECIFICATIONS IN THE GULF OF ALASKA AND ALLOCATIONS THEREOF TO HOOK-AND-LINE AND TRAWL GEAR

[Values are in metric tons]

Area/District	TAC	Hook-and-line apportionment	Trawl apportionment
Western	2,010	1,608	402
Central	5,410	4,328	1,082
West Yakutat	2,060	1,789	271
Southeast Outside	3,360	3,360	0
Total	12,840	11,085	1,755

Apportionments of Pollock TAC Among Seasons and Regulatory Areas, and Allocations for Processing by Inshore and Offshore Components

In the GOA, pollock is apportioned by season and area, and is further allocated for processing by inshore and offshore components. Under this emergency interim rule extending the 2000 RFRPAs, the annual pollock TAC specified for the Western and Central Regulatory Areas of the GOA is apportioned into four seasonal allowances of 30, 15, 30, and 25 percent, respectively (§ 679.20(a)(5)(ii)(C)). As established by § 679.23(d)(2), the A, B, C, and D season allowances are available from January 20 through March 1, from March 15 through May 31, from August 20 through September 15, and from October 1 through November 1 respectively.

To prevent localized depletions of pollock outside the Shelikof Strait conservation area (defined at § 679.22(b)(2)(iii)(B)), this emergency rule also extends seasonal apportionments of pollock TAC within Shelikof Strait during the A and B seasons. The derivation of these harvest limits are explained here and listed in Tables 19 and 22. The Shelikof area apportionments during the A and B seasons are derived from the most recent (2000) NMFS survey estimate of pollock biomass of 334,900 mt in the critical habitat of the Shelikof Strait divided by the most recent (2000) estimate of total GOA pollock biomass of 705,900 mt (equals 0.4746) multiplied by the A and B seasonal apportionments of the combined W/C pollock TAC (87,180 mt), i.e., 30 percent of the annual TACs (26,154 mt) in the A season and 15 percent of the annual TACs in the B season (13,077 mt) in the GOA (§ 679.22(b)(2)(iii)(C)).

The remainder of the A and B seasonal allowances of pollock TAC in the Western and Central Regulatory Areas are apportioned among statistical area 610, and statistical areas 620 and 630 outside the Shelikof Strait conservation area in proportion to the distribution of pollock biomass as determined by the four most recent NMFS summer surveys. Pollock TACs in the Western and Central Regulatory Areas in the C and D seasons are apportioned among statistical areas 610, 620, and 630 in proportion to the distribution of pollock biomass as determined by the four most recent NMFS summer surveys. Within any fishing year, underage or overage of a seasonal allowance may be added to or subtracted from subsequent seasonal allowances in a manner to be determined by the Regional Administrator, provided that a revised seasonal allowance does not exceed 30 percent of the annual TAC apportionment (§ 679.20(a)(5)(ii)(C)). The WYK and SEO District pollock TACs of 2,235 mt and 6,460 mt, respectively, are not allocated seasonally.

Regulations at § 679.20(a)(6)(ii) require that 100 percent of the pollock TAC in all regulatory areas and all seasonal allowances thereof be allocated to vessels catching pollock for processing by the inshore component after subtraction of amounts that are projected by the Regional Administrator to be caught by, or delivered to, the offshore component incidental to directed fishing for other groundfish species. The amount of pollock available for harvest by vessels harvesting pollock for processing by the offshore component is that amount actually taken as bycatch during directed fishing for groundfish species other than pollock, up to the maximum retainable bycatch amounts allowed under regulations at § 679.20(e) and (f). At this time, these bycatch amounts are unknown and will be determined during the fishing year.

The biomass distribution of pollock in the Western and Central GOA, area apportionments, and seasonal apportionments for the A and B seasons are summarized in Table 21 and for the C and D seasons in Table 22, except that amounts of pollock for processing by the inshore and offshore component are not shown.

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TABLE 21.—DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA (W/C GOA); BIOMASS DISTRIBUTION, AREA APPORTIONMENTS, AND SEASONAL ALLOWANCES OF ANNUAL TAC FOR THE A AND B SEASONS IN 2001

Statistical area	Biomass percent	2001 annual TAC	Seasonal Allowances of annual TAC	
			A (30%)	B (15%)
Shelikof	47.46	18,619	12,413	6,206
Shumagin (610)	29.47	31,724	7,707	3,854
Chirikof [1] (620)	2.14	12,841	560	280
Kodiak [1] (630)	20.93	23,996	5,474	2,737
Total	100.00	87,180	26,154	13,077

[1] A and B seasonal allowances in the Chirikof and Kodiak Districts are outside the Shelikof Strait defined at 679.22(b)(3)(iii)(B).

TABLE 22.—DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA (W/C GOA); BIOMASS DISTRIBUTION, AREA APPORTIONMENTS, AND SEASONAL ALLOWANCES OF ANNUAL TAC FOR THE C AND D SEASONS IN 2001

Statistical area	Biomass percent	2001 annual TAC	Seasonal Allowances of annual TAC [1]	
			C (30%)	D (25%)
Shelikof	.....	18,619	[2]	[2]
Shumagin (610)	42.05	31,724	10,998	9,165
Chirikof (620)	25.03	12,841	6,546	5,455
Kodiak (630)	32.92	23,996	8,610	7,175
Total	100.00	87,180	26,154	21,975

[1] These emergency interim regulations for pollock in the GOA which specify A and B season dates and harvest limitations, expires June 10, 2001, before the C and D seasons are scheduled to begin. Therefore, the C and D seasons are not authorized unless either this emergency rule is extended, or proposed and final rulemaking is completed.
[2] Not apportioned.

Seasonal Apportionments of Pacific Cod TAC and Allocations for Processing of Pacific Cod TAC Between Inshore and Offshore Components

As described in Part I above, Pacific cod fishing is divided into two seasons in the Western and Central Regulatory Areas. The A season begins on January 1, 2001 and ends on June 10, 2001, the B season begins on June 10, 2001 and ends on December 31, 2001. After subtraction of incidental catch, 60 percent and 40 percent will be available for harvest during the A and B seasons, respectively, and will be apportioned between the inshore and offshore processing components as provided in 50 CFR § 679.20(a)(6)(iii).

The time of all openings and closures of fishing seasons, other than the beginning and ending of the calender fishing year, is 1200 hours, A.l.t. For purposes of clarification NMFS points out that the dates for the A season and the B season Pacific cod fishery dates differ from those of the A, B, C, and D seasons for the pollock fisheries. NMFS finds that seasonal apportionments of Pacific cod TAC in the Eastern GOA are not necessary at this time as less than 60 percent of the annual TAC in the Eastern GOA is normally harvested during the A season. Any overage or underage of Pacific cod harvest from the A season shall be subtracted from or added to the subsequent B season.

Regulations at § 679.20(a)(6)(iii) require that the TAC apportionment of Pacific cod in all regulatory areas be allocated to vessels catching Pacific cod for processing by the inshore and offshore components. Ninety percent of the Pacific cod TAC in each regulatory area is allocated to vessels catching Pacific cod for processing by the inshore component. The remaining 10 percent of the TAC is allocated to vessels catching Pacific cod for processing by the offshore component. These seasonal apportionments and allocations of the Pacific cod TAC for 2001 are shown in Table 23.

TABLE 23.—2001 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TAC AMOUNTS IN THE GULF OF ALASKA; ALLOCATIONS FOR PROCESSING BY THE INSHORE AND OFFSHORE COMPONENTS

[Values are in mt]

Regulatory area	TAC	Component allocation	
		Inshore (90%)	Offshore (10%)
Western	18,300	16,470	1,830
A Season (60%)	10,980	9,882	1,098
B Season (40%)	7,320	6,588	732
Central	30,250	27,225	3,025

TABLE 23.—2001 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TAC AMOUNTS IN THE GULF OF ALASKA; ALLOCATIONS FOR PROCESSING BY THE INSHORE AND OFFSHORE COMPONENTS—Continued

[Values are in mt]

Regulatory area	TAC	Component allocation	
		Inshore (90%)	Offshore (10%)
A Season (60%)	18,150	16,335	1,815
B Season (40%)	12,250	10,890	1,210
Eastern	3,560	3,204	356
Total	52,110	46,899	5,211

Pacific Halibut PSC Mortality Limits

Under § 679.21(d), annual Pacific halibut PSC limits are established and apportioned to trawl and hook-and-line gear and may be established for pot gear.

As in 2000, the Council recommended that pot gear, jig gear, and the hook-and-line sablefish fishery be exempted from the non-trawl halibut limit for 2001. The Council recommended these exemptions because of the low halibut bycatch mortality experienced in the pot gear fisheries (7 mt in 2000) and because of the 1995 implementation of the sablefish and halibut Individual Fishing Quota program, which allows legal-sized halibut to be retained in the sablefish fishery. Halibut mortality for the jig gear fleet cannot be estimated because these vessels do not carry observers. However, halibut mortality is assumed to be very low given the small amount of groundfish harvested by this gear type (62 mt in 2000) and the assumed high survival rate of any halibut that are incidentally taken and discarded.

As in 2000, the Council recommended a hook-and-line halibut PSC mortality limit of 300 mt. Ten mt of this limit are apportioned to the demersal shelf rockfish fishery in the Southeast Outside District. The fishery is defined at § 679.21(d)(4)(iii)(A) and historically has been apportioned this amount in recognition of its small-scale harvests. Observer data are not available to verify actual bycatch amounts given most vessels are less than 60 ft. LOA and are exempt from observer coverage. The remainder of the PSC limit is seasonally apportioned among the non-sablefish hook-and-line fisheries as shown in Table 24.

The Council continued to recommend a trawl halibut PSC mortality limit of 2,000 mt for 2001. The PSC limit has remained unchanged since 1989. Regulations at § 679.21(d)(3)(iii) authorize separate apportionments of the trawl halibut PSC limit between trawl fisheries for deep-water and shallow-water species. Regulations at § 679.21(d)(5) authorize seasonal apportionments of halibut PSC limits. For 2001, the Council recommended delaying the release of the third seasonal apportionment of trawl halibut PSC limits to July 4 to facilitate inseason management of directed trawl fisheries, particularly rockfish. However, NMFS finds that for the year 2001 this delay is not necessary and that inseason management of directed trawl fisheries would be improved with the release of the third seasonal apportionment of trawl halibut PSC limits on July 1, 2001.

NMFS concurs in the Council's recommendations described above and listed in Table 24. The following types of information as presented in, and summarized from, the current SAFE report, or as otherwise available from NMFS, Alaska Department of Fish and Game, the International Pacific Halibut Commission (IPHC), or public testimony were considered:

(A) Estimated Halibut Bycatch in Prior Years

The best available information on estimated halibut bycatch is data collected by observers during 2000. The calculated halibut bycatch mortality by trawl, hook-and-line, and pot gear through December 31, 2000, is 1,888 mt, 276 mt, and 7 mt, respectively, for a total halibut mortality of 2,171 mt.

Halibut bycatch restrictions seasonally constrained trawl gear fisheries during the 2000 fishing year. Trawling for the deep-water fishery complex was closed for the second quarter on May 13 (65 FR 31288, May 17, 2000) and for the third quarter on August 23 (65 FR 51772, August 25, 2000). The shallow-water fishery complex was closed for the second quarter on May 28 (65 FR 34991, June 1, 2000) and for the third quarter on August 11 (65 FR 49946, August 16, 2000). The three seasonal apportionments of the hook-and-line halibut bycatch mortality limit resulted in closures of hook-and-line fisheries for groundfish other than sablefish and demersal shelf rockfish on March 9 (65 FR 13698, March 14, 2000), May 18 (65 FR 31104, May 16, 2000), and on September 1 (65 FR 54179, September 7, 2000).

(B) Expected Changes in Groundfish Stocks

In December 2000 the Council adopted higher ABCs for pollock, arrowtooth flounder, and Pacific Ocean perch than those established for 2000. The Council adopted lower ABCs for Pacific cod, sablefish, northern rockfish, demersal shelf rockfish, and thornyhead rockfish than those established for 2000. More information on these changes is included in the final SAFE report (November 2000) and in the Council and SSC December 2000 meeting minutes.

(C) Expected Changes in Groundfish Catch

The total of the 2001 TACs for the GOA is 285,994 mt, a decrease of 4 percent from the 2000 TAC total of 298,510 mt. Those fisheries for which the 2001 TACs are lower than in 2000 are pollock (decreased to 95,875 mt from 100,000 mt), Pacific cod (decreased to 52,110 mt from 58,715 mt), sablefish (decreased to 12,840 mt from 13,330 mt), northern rockfish (decreased to 4,880 mt from 5,120 mt), other rockfish (decreased to 1,010 mt from 4,900 mt), demersal shelf rockfish (decreased to 330 mt from 340 mt), thornyhead rockfish (decreased to 2,310 mt from 2,360 mt), and other species (decreased to 13,619 mt from 14,215 mt). Those species for which the 2001 TACs are higher than in 2000 are arrowtooth flounder (increased to 38,000 mt from 35,000 mt) and Pacific Ocean perch (increased to 13,510 mt from 13,020 mt).

(D) Current Estimates of Halibut Biomass and Stock Condition

The most recent halibut stock assessment was conducted by the IPHC in December 2000. The halibut resource is considered to be healthy, with total

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catch near record levels. The current exploitable halibut biomass for 2001 is estimated to be 249,007 mt, using an age-specific estimate for 2001. In the age-specific estimate, the assumption is that the selection of fish by the survey is based primarily on the age of the fish and reflects the availability of fish of different ages on the grounds. This is an increase from the estimate of 135,172 mt in 2000. The difference is in large part due to omitting a precautionary downward correction used in the 1999 assessment which was based on presumed increased fishing power of baits recently used in the surveys. The 2000 estimate for exploitable biomass in 2001 of 249,007 mt is now similar to the 1998 estimate for exploitable biomass in 1999 of 227,366 mt before the fishing power correction was made. The exploitable biomass of the Pacific halibut stock apparently peaked at 326,520 mt in 1988 (Sullivan, 1998). The long-term average reproductive biomass for the Pacific halibut resource was estimated at 118,000 mt (Parma, 1998). Long-term average yield was estimated at 26,980 mt, round weight (Parma, 1998). The species is fully utilized. Recent average catches (1994–96) were 33,580 mt for the U.S. and 6,410 mt for Canada, for a combined total of 39,990 mt for the entire Pacific halibut resource. This catch was 48 percent higher than long-term potential yield, which reflects the good condition of the Pacific halibut resource. In January 2000 the IPHC recommended commercial catch limits totaling 33,910 mt (round weight equivalents) for Alaska in 2000, down from 35,314 mt in 1999. Though November 24, 2000, commercial hook-and line harvests of halibut in Alaska total 33,056 mt (round weight equivalents).

The major change in the assessment results for 2000 came from the elimination of the downward correction in recent survey catch rates that was applied in 1999, to account for a suspected increase in the fishing power of the surveys due to a bait change in 1993. Experiments conducted in 2000 have shown that the precautionary adjustment is not required. The stock assessment shows only minor changes for the southern portion of the range (Areas 2A, 2B, and 2C). Improvements in the estimated biomass of the stock in Area 3A are accounted for largely by the change in the treatment of historical survey data. Weight at age for halibut in the central portion of the range increased slightly in 2000 over the very low values of recent years. However, recruitment of year classes born between 1989 and 1993 appears to be poor. The outlook for the stock biomass over the near future is for a decline from the record high levels of recent years until increased recruitment to the stock occurs.

IPHC staff preliminary 2001 commercial catch limit recommendations for 2001 in Alaska total 63.5 million lb (dressed weight) which is equivalent to 38,406 mt (round weight) an increase of 4,496 mt from 2000. Additional information on the Pacific halibut stock assessment may be found in the final SAFE report (November 2000) and in the IPHC's 2000 Pacific halibut stock assessment (December 2000).

(E) Other Factors

The allowable commercial catch of halibut will be adjusted to account for the overall halibut PSC mortality limit established for groundfish fisheries. The 2001 groundfish fisheries are expected to use the entire proposed halibut PSC limit of 2,300 mt. The allowable directed commercial catch is determined by accounting for the recreational and subsistence catch, waste, and bycatch mortality and then providing the remainder to the directed fishery. Groundfish fishing is not expected to adversely affect the halibut stocks.

Methods available for reducing halibut bycatch include: (1) Reducing halibut bycatch rates through the Vessel Incentive Program; (2) modifications to gear; (3) changes in groundfish fishing seasons; (4) individual transferable quota programs; and (5) time/area closures.

Reductions in groundfish TAC amounts provide no incentive for fishermen to reduce bycatch rates. Costs that would be imposed on fishermen as a result of reducing TAC amounts depend on the species and amounts of groundfish foregone.

Trawl vessels carrying observers for purposes of complying with observer coverage requirements (50 CFR 679.50) are subject to the Vessel Incentive Program. This program encourages trawl fishermen to avoid high halibut bycatch rates while conducting groundfish fisheries by specifying bycatch rate standards for various target fisheries.

Current regulations (§ 679.2 Authorized fishing gear (11)) specify requirements for biodegradable panels and tunnel openings for groundfish pots to reduce halibut bycatch. As a result, low bycatch and mortality rates of halibut in pot fisheries have justified exempting pot gear from PSC limits.

The regulations also define pelagic trawl gear in a manner intended to reduce bycatch of halibut by displacing fishing effort off the bottom of the sea floor when certain halibut bycatch levels are reached during the fishing year. The definition provides standards for physical conformation (§ 679.2, see Authorized fishing gear) and performance of the trawl gear in terms of crab bycatch (§ 679.7(a)(14)). Furthermore, all hook-and-line vessel operators are required to employ careful release measures when handling halibut bycatch (§ 679.7(a)(13)). These measures are intended to reduce handling mortality, to increase the amount of groundfish harvested under the available halibut mortality bycatch limits, and to possibly lower overall halibut bycatch mortality in groundfish fisheries.

The sablefish/halibut IFQ program (implemented in 1995) was intended, in part, to reduce the halibut discard mortality in the sablefish fishery.

Consistent with the goals and objectives of the FMP to reduce halibut bycatch while providing an opportunity to harvest the groundfish OY, NMFS approves the assignments of 2,000 mt and 300 mt of halibut PSC limits to trawl and hook-and-line gear, respectively. While these limits would reduce the harvest quota for commercial halibut fishermen, NMFS has determined that they would not result in unfair allocation to any particular user group. NMFS recognizes that some halibut bycatch will occur in the groundfish fishery, but the Vessel Incentive Program, required modifications to gear, and implementation of the halibut/sablefish IFQ program are intended to reduce adverse impacts on halibut fishermen while promoting the opportunity to achieve the OY from the groundfish fishery. NMFS and the Council will review the methods available for reducing halibut bycatch listed here to determine their effectiveness, and will initiate changes, as necessary, in response to this review or to public testimony and comment.

Fishery and Seasonal Apportionments of the Halibut PSC Limits

Under § 679.21(d)(5), NMFS seasonally apportions the halibut PSC limits based on recommendations from the Council. The FMP requires that the following information be considered by the Council in recommending seasonal apportionments of halibut PSC limits: (a) Seasonal distribution of halibut, (b) seasonal distribution of target groundfish species relative to halibut distribution, (c) expected halibut bycatch needs on a seasonal basis relative to changes in halibut biomass and expected catches of target groundfish species, (d) expected bycatch rates on a seasonal basis, (e) expected changes in directed groundfish fishing seasons, (f) expected actual start of fishing effort, and (g) economic effects of establishing seasonal halibut allocations on segments of the target groundfish industry.

In December 2000, the Council's AP recommended seasonal PSC apportionments in order to maximize harvest among gear types, fisheries, and seasons while minimizing bycatch of PSC based upon the criteria above. NMFS is approving the PSC apportionments specified in Tables 24 and 25, below. However, NMFS recognizes that the Council did not have the opportunity in December 2000 to evaluate the effects of SSL protection measures implemented by this emergency rule on PSC bycatch needs throughout the year with respect to factors listed above. After consulting with the Council at its emergency January 2001 meeting, NMFS will consider amending PSC seasonal apportionments and amounts. Regulations at § 679.21(d)(5)(iii) and (iv) specify that any overages or shortfalls in a seasonal apportionment of a PSC limit will be deducted from or added to the next respective seasonal apportionment within the 2001 season.

TABLE 24.—FINAL 2001 PACIFIC HALIBUT PSC LIMITS, ALLOWANCES, AND APPORTIONMENTS

[The Pacific halibut PSC limit for hook-and-line gear is allocated to the demersal shelf rockfish (DSR) fishery and fisheries other than DSR. The hook-and-line sablefish fishery is exempt from halibut PSC limits. (Values are im mt)]

Trawl gear		Hook-and-line gear			
		Other than DSR		DSR	
Dates	Amount	Dates	Amount	Dates	Amount
Jan 1–Apr 1	450 (23%)	Jan 1–May 17	175 (60%)	Jan 1–Dec 31	10 (100%)
Apr 1–Jun 10	400 (20%)	May 17–Aug 31	30 (10%)		
Jun 10–Jul 1	250 (12%)				
Jul 1–Oct 1	600 (30%)	Aug 31–Dec 31	85 (30%)		
Oct 1–Dec 31	300 (15%)				
Total	2,000 (100%)		290 (100%)		10 (100%)

Regulations at § 679.21(d)(3)(iii) authorize apportionments of the trawl halibut PSC limit to a deep-water species complex, comprised of sablefish, rockfish, deep-water flatfish, rex sole and arrowtooth flounder; and a shallow-water species complex, comprised of pollock, Pacific cod, shallow-water flatfish, flathead sole, Atka mackerel, and "other species." The apportionment for these two fishery complexes is presented in Table 25.

TABLE 25.—FINAL 2001 APPORTIONMENT OF PACIFIC HALIBUT PSC TRAWL LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES COMPLEX AND THE SHALLOW-WATER SPECIES COMPLEX

[Values are in metric tons]

Season	Shallow-water	Deep-water	Total
Jan. 20–Apr. 1	350	100	450
Apr. 1–Jun. 10	100	300	400
Jun. 10–Jul. 1	250	0	250
Jul. 1–Oct. 1	200	400	600
Subtotal:			
Jan. 20–Sep. 30	900	800	1,700
Oct. 1–Dec. 31			300
Total			2,000

No apportionment between shallow-water and deep-water fishery complexes during the 4th quarter.

Halibut Discard Mortality Rates

The Council recommended that the revised halibut discard mortality rates (DMRs) recommended by the IPHC be adopted for purposes of monitoring halibut bycatch mortality limits established for the 2001 groundfish fisheries. NMFS concurs in the Council's recommendation. The IPHC recommended use of a long-term average as preseason assumed DMRs for the 2001–2003 groundfish fisheries. The IPHC recommendation also includes a provision that revised DMRs would be proposed should analysis indicate that a fishery's annual DMR diverges substantially (up or down) from the long-term average. Most of the IPHC's assumed DMRs were based on an average of mortality rates determined from NMFS observer data collected between 1990 and 1999. Rates were lacking for some fisheries, so rates from the most recent years were used. For the "other species" fishery, where insufficient mortality data are available, the mortality rate of halibut caught in the Pacific cod fishery for that gear type was recommended as a default rate. The majority of the assumed mortality rates recommended for 2001 differ slightly from those used in 2000 in the GOA. The recommended rates for hook-and-line targeted fisheries range from 8 to 24 percent. The recommended rates for trawl targeted fisheries range from 58 to 72 percent. The recommended rate for all pot targeted fisheries is 14 percent. The 2001 assumed DMRs are listed in Table 26.

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TABLE 26.—2001 ASSUMED PACIFIC HALIBUT MORTALITY RATES FOR VESSELS FISHING IN THE GULF OF ALASKA

[Listed values are percent of halibut bycatch assumed to be dead]

Gear and target	Mortality rate
Hook-and-Line:	
Pacific cod	14
Rockfish	8
Other species	14
Sablefish	24
Trawl:	
Midwater pollock	72
Rockfish	69
Shallow-water flatfish	69
Pacific cod	61
Deep-water flatfish	60
Flathead sole	58
Rex sole	61
Bottom pollock	61
Arrowtooth Flounder	62
Atka mackerel	70
Sablefish	66
Other species	61
Pot:	
Pacific cod	14
Other species	14

Non-Exempt American Fisheries Act (AFA) Catcher Vessel Groundfish Harvest and PSC Limitations

As discussed in Part I, above, Pub. L. 106–554 extends interim AFA regulations through 2001. One of the provisions implemented by these AFA regulations was to place groundfish harvesting and processing limitations, also called sideboards, on AFA catcher/processors and catcher vessels in the GOA. These limitations are considered necessary for fishermen and processors who have received exclusive harvesting and processing privilege under the AFA to protect the interests of fishermen and processors who have not directly benefitted from the AFA. In the GOA catcher/processors are prohibited from fishing for any species of fish (§ 679.7(k)(1)(ii)) and from processing any groundfish harvested in Statistical Area 630 of the GOA (§ 679.7(k)(1)(iv)). The Council recommended that certain AFA catcher vessels in the GOA be exempt from groundfish harvest limitations. Exempted AFA catcher vessels in the GOA are those less than 125 ft (38.1 m) LOA whose annual BSAI pollock landings totaled less than 5100 mt and that made 40 or more GOA groundfish landings from 1995 through 1997 (§ 679.63(b)(1)(i)(B)).

For non-exempt AFA catcher vessels in the GOA harvest limitations are based upon their traditional harvest levels of TAC in groundfish fisheries covered by the GOA FMP. The amounts of the groundfish harvest limits in the GOA are based on the retained catch of non-exempt AFA catcher vessels of each sideboard species from 1995 through 1997 divided by the TAC for that species over the same period (§ 679.63(b)(1)(ii)(C)). These amounts are listed in Table 27. All harvests of sideboard species made by non-exempt AFA catcher vessels, whether as targeted catch or bycatch, will be deducted from the sideboard limits in Table 27.

TABLE 27.—FINAL 2001 GOA NON-EXEMPT AFA CATCHER VESSEL (CV) GROUNDFISH HARVEST LIMITATIONS (SIDEBOARDS)

[Values are in mt]

Species and apportionments and allocations by area/season/processor/Gear	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	2001 TAC	2001 non-exempt AFA catcher vessel sideboard
Pollock:			
A Season (W/C areas only) January 20–March 1:			
Shelikof Strait	0.1672	12,431	2,075
Shumagin (610)	0.6238	7,707	4,808
Chirikof (620)(outside Shelikof)	0.1262	560	71
Kodiak (630)(outside Shelikof)	0.1984	5,474	1,086
B Season (W/C areas only) March 15–May 31:			
Shelikof Strait	0.1672	6,206	1,038
Shumagin (610)	0.6238	3,854	2,404
Chirikof (620) (outside Shelikof)	0.1262	280	35
Kodiak (630) (outside Shelikof)	0.1984	2,737	543
C Season (W/C areas only) August 20–September 15:			
Shumagin (610)	0.6238	10,998	6,861
Chirikof (620)	0.1262	6,546	826
Kodiak (630)	0.1984	8,610	1,708
D Season (W/C areas only) October 1—November 1:			
Shumagin (610)	0.6238	9,165	5,717
Chirikof (620)	0.1262	5,465	688
Kodiak (630)	0.1984	7,175	1,424
Annual:			
WYK (640)	0.3642	2,235	814
SEO (650)	0.3542	6,460	2,353
Pacific cod:			
A Season (W/C areas only) January 1–June 10:			
W inshore	0.1310	9,882	1,295
offshore	0.1206	1,098	113
C inshore	0.0542	16,335	885
offshore	0.0721	1,815	131
B Season (W/C areas only) June 10–December 31:			
W inshore	0.1310	6,588	863
offshore	0.1206	732	75
C inshore	0.0542	10,980	596
offshore	0.0721	1,210	87

TABLE 27.—FINAL 2001 GOA NON-EXEMPT AFA CATCHER VESSEL (CV) GROUNDFISH HARVEST LIMITATIONS (SIDEBOARDS)—Continued

[Values are in mt]

Species and apportionments and allocations by area/season/processor/Gear	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	2001 TAC	2001 non-exempt AFA catcher vessel sideboard
Annual:			
E inshore	0.0000	3,206	0
offshore	0.0078	356	3
Flatfish deep-water:			
W	0.0000	280	0
C	0.0620	2,710	168
E	0.0021	2,310	5
Rex sole:			
W	0.0043	1,230	5
C	0.0117	5,660	66
E	0.0026	2,550	7
Flathead sole:			
W	0.0129	2,000	26
C	0.0097	5,000	49
E	0.0008	2,060	2
Flatfish shallow-water:			
W	0.0260	4,500	117
C	0.0420	12,950	544
E	0.0106	1,950	21
Arrowtooth flounder:			
W	0.0047	8,000	38
C	0.0206	25,000	515
E	0.0016	5,000	8
Sablefish:			
W trawl gear	0.0023	402	1
C trawl gear	0.0384	1,082	44
E trawl gear	0.0236	271	7
Pacific Ocean perch:			
W	0.0051	1,280	7
C	0.0692	9,610	655
E	0.0255	2,620	59
Shortraker/Rougheye:			
W	0.0000	210	0
C	0.0145	930	13
E	0.0105	590	6
Other rockfish:			
W	0.0000	20	0
C	0.0410	740	3
E	0.0000	250	0
Northern rockfish:			
W	0.0005	600	0
C	0.0307	4,280	131
Pelagic shelf rockfish:			
W	0.0004	550	0
C	0.0000	4,480	0
E	0.0066	1,350	9
Thornyhead rockfish:			
W	0.0118	420	5
C	0.0118	970	11
E	0.0118	920	11
Demersal shelf rockfish:			
SEO	0.0000	330	0
Atka mackerel:			
Gulfwide	0.0443	600	27
Other species:			
Gulfwide	0.0067	13,619	91

PSC bycatch limits for non-exempt AFA catcher vessels in the GOA are based upon the ratio of aggregate retained groundfish catch by non-exempt AFA catcher vessels in each PSC target category from 1995 through 1997 relative to the retained catch of all vessels in that fishery from 1995 through 1997 (§ 679.63(b)(1)(iii)). These amounts are shown in Table 28.

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TABLE 28.—FINAL 2001 NON-EXEMPT AFA CATCHER VESSEL PROHIBITED SPECIES CATCH (PSC) LIMITS FOR THE GOA

[Values are in mt]

PSC species	Taget fishery and Season	Ratio*	2001 PSC limit	2001 non-exempt AFA catcher vessel PSC limit
Halibut (mortality in mt)	Trawl 1st Seasonal Allowance—January 20–April 1.			
	Shallow water targets	0.340	350	119
	Deep water targets	0.070	100	7
	Trawl 2nd Seasonal Allowance—April 1–June 10.			
	Shallow water	0.340	100	34
	Deep water targets	0.070	300	21
	Trawl 3rd Seasonal Allowance—June 10–July 1.			
	Shallow water targets	0.340	250	85
	Deep water targets	0.070	0	0
	Trawl 4th Seasonal Allowance—July 1–October 1.			
	Shallow water targets	0.340	200	68
	Deep water targets.			
	Trawl 5th Seasonal Allowance—October 1–December 31.			
	All targets	0.205	300	62

*Of 1995–1997 Non-Exempt AFA CV Retained Catch to Total Retained Catch.

Closures

In accordance with § 679.20(d)(1)(i), if the Regional Administrator determines that the amount of a target species or "other species" category apportioned to a fishery or, with respect to pollock and Pacific cod, to an inshore or offshore component allocation, will be reached, the Regional Administrator may establish a directed fishing allowance for that species or species group. If the Regional Administrator establishes a directed fishing allowance, and that allowance is or will be reached before the end of the fishing year, NMFS will prohibit directed fishing for that species or species group in the specified GOA Regulatory Area or district (§ 679.20(d)(1)(iii)).

The Regional Administrator has determined that the following TAC amounts (Table 29) are necessary as incidental catch to support other anticipated groundfish fisheries for the 2001 fishing year.

TABLE 29.—INCIDENTAL CATCH NEEDED TO SUPPORT OTHER DIRECTED FISHERIES IN THE GOA IN 2001

[Amounts are in mt]

Target	Regulatory Area	Gear/Component	Amount
Atka Mackerel	Entire GOA	All	600
Thornyhead Rockfish	Entire GOA	All	2,310
Shortraker Rougheye Rockfish	Entire GOA	All	1,730
Other Rockfish	Entire GOA	All	1,010
Sablefish	Entire GOA	Trawl	1,755
Pollock	Entire GOA	All/offshore	0
Pollock	Statistical Area 620	All/inshore	
		A Season	560
		B Season	280

Consequently, in accordance with § 679.20(d)(1)(i), the Regional Administrator establishes the directed fishing allowances for the above species or species groups as zero and in accordance with § 679.20(d)(1)(iii) NMFS is prohibiting directed fishing for those species, areas, gear types, components, and seasons listed in Table 29.

Regulations at § 679.63(b)(iv) provide for management of AFA catcher vessel groundfish harvest limits and PSC bycatch limits using directed fishing closures and PSC closures according to procedures set out at § 679.20(d)(1)(iv) and § 679.21(d)(8). The Regional Administrator has determined that in addition to the closures listed above many of the non-exempt AFA catcher vessel sideboard amounts listed in Table 27 are necessary as incidental catch to support other anticipated groundfish fisheries for the 2001 fishing year.In accordance with § 679.20(d)(1)(iv) the Regional Administrator establishes these amounts as directed fishing allowances. The Regional Administrator finds that many of these directed fishing allowances will be reached before the end of the year. Therefore, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing by non-exempt AFA catcher vessels in the GOA for the species and specified areas set out in Table 30.

TABLE 30.—NON-EXEMPT AFA CATCHER VESSEL SIDEBOARD DIRECTED FISHING CLOSURES IN THE GOA

Species	Regulatory area/ district	Gear
Pacific cod	E GOA	All.
Deep-water flatfish.	W and E GOA	All.
Rex sole	W and E GOA	All.
Flathead sole	E GOA	All.
Shallow-water flatfish.	E GOA	All.
Arrowtooth flounder.	E GOA	All.
Pacific Ocean perch.	W GOA	All.

TABLE 30.—NON-EXEMPT AFA CATCHER VESSEL SIDEBOARD DIRECTED FISHING CLOSURES IN THE GOA—Continued

Species	Regulatory area/ district	Gear
Northern rockfish.	W GOA	All.
Pelagic shelf rockfish.	entire GOA	All.
Demersal shelf rockfish.	SEO District	All.
Other species	entire GOA	All.

Classification

The Administrator, Alaska Region, NMFS (Regional Administrator for Fisheries, NOAA (AA), has determined that this rule is necessary for the conservation and management of the groundfish fisheries of the BSAI and GOA. The Regional Administrator also determined that this proposed rule is consistent with the Magnuson-Stevens Act and other applicable laws.

This action has been determined to be significant for purposes of E.O. 12866. This rule contains no reporting, recordkeeping, or compliance requirements, and no relevant Federal rules exist which may duplicate, overlap, or conflict with this proposed rule.

Public Law 106–554, enacted December 21, 2000, required that the Secretary of Commerce amend the regulations governing the groundfish fisheries of the BSAI and GOA by January 20, 2001. The time available to meet this statutory deadline makes it impracticable to provide prior notice and an opportunity for public comment. Therefore, there is good cause to waive those requirements pursuant to 5 U.S.C. 553(b)(2). For the same reason there is good cause to waive the 30-day delay in effective date pursuant to 5 U.S.C. 553(b)(3). Because this rule is not subject to the requirement to provide notice or an opportunity for comment by 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Thus, no initial or final regulatory flexibility analysis has been prepared. However, because this rule is considered economically significant, the following economic discussion is provided.

The RPA will reduce the likelihood of western Steller sea lion extinction. Many persons value the existence of the Steller sea lions, either because they value the species for itself or they value the species contribution to ecosystem diversity. This "existence value" should be counted in a benefit-cost analysis. Similarly, the reduced likelihood of extinction has value for those who would use Steller stocks for subsistence hunting or ecotourism. No studies have been conducted to determine the size of these benefits from Steller sea lion preservation.

The RPA global control rule may lead to direct reductions in the harvest of pollock, Pacific cod, and Atka mackerel. The RPA also contains provisions that will increase operating costs for fishing operations and possibly reduce revenues through impacts on product quality. These increased costs and decreased revenues are also likely to lead to reduced harvests. Fishing and processing operations will thus find their net revenues reduced because of increased costs and reduced production and quality. Production decreases should lead to product price increases that may offset these losses in part. Production decreases will also be associated with welfare losses to U.S. consumers. Increases in management complexity will lead to increased costs for fishery management. Many of the areas where fishing will be restricted are heavily used by small vessels; serious safety issues will be raised if these vessels are forced to fish further offshore.

Due to extremely limited information on the costs of fishing and on the responsiveness of prices to changes in production, it has not been possible to do a complete benefit and cost analysis. A simulation model has been used to estimate the change in gross revenues the processing and fishing industries may face if the RPA is adopted. This model evaluates revenue changes due to production changes, but does not estimate price-related impacts. If fishermen are totally unable to compensate for reduced harvests in restricted times and places by fishing elsewhere, the simulation indicates that industry revenues would drop by about $401 million/year. It is much more likely that the industry will be able to compensate, at least to some extent by changing its fishing patterns. Under one set of assumptions about the industry's ability to compensate, revenues were found to drop by about $225 million/year. These changes are for gross revenues, not net revenues. A high degree of uncertainty surrounds these estimates; however, they may provide a sense of the magnitudes of the impacts associated with the RPA. Many factors discussed earlier are not accounted for by these revenue change estimates.

While the benefits of this RPA will be distributed widely through the U.S. population, the costs will be heavily concentrated on the fishing industry and on the communities dependent on it. Community impacts on Kodiak Island, the Alaska Peninsula and the Aleutians are expected to be severe. These communities are small, remote, generally without road access to other places, and, with few alternative employment opportunities, are heavily dependent on fishing.

The President has directed Federal agencies to use plain language in their communications with the public, including regulations. These regulations have been drafted to comply with that directive. We seek public comment on any ambiguity or unnecessary complexity arising from the language used in this rule.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Recordkeeping and reporting requirements.

Dated: January 16, 2001.

Penelope D. Dalton,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For reasons set out in the preamble, 50 CFR part 679 is amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 is revised to read as follows:

Authority: 16 U.S.C. 773 *et seq.*; 1801 *et seq.*; 3631 *et seq.*; Title II of Division C, Pub. L. 105–277; Sec. 3027, Pub. L. 106–31; 113 Stat. 57; 16 U.S.C. 1540(f); and Sec. 209, Pub. L. 106–554.

2. In § 679.2 the definitions for "Appointed agent for service of process", "Designated cooperative representative", and under paragraph (4) the definition of "Directed fishing" are added in alphabetical order to read as follows:

§ 679.2 Definitions.

* * * * *

Appointed agent for service of process (applicable through December 31, 2001) means an agent appointed by the members of an inshore catcher vessel cooperative to serve on behalf of the cooperative. The appointed agent for service of process may be the owner of a vessel listed as a member of the cooperative or a registered agent. If at any time the cooperative's appointed agent for service of process becomes unable to accept service, then the cooperative members are required to notify the Regional Administrator of a substitute appointed agent.

* * * * *

Designated cooperative representative (applicable through December 31, 2001) means an individual who is designated

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by the members of an inshore pollock cooperative to fulfill requirements on behalf of the cooperative including, but not limited to, the signing of cooperative fishing permit applications and completing and submitting inshore catcher vessel pollock cooperative catch reports.

* * * * *

Directed fishing means * * *

(4) (applicable through December 31, 2001) With respect to the harvest of groundfish by AFA catcher/processors and AFA catcher vessels, any fishing activity that results in the retention of an amount of a species or species group on board a vessel that is greater than the maximum retainable bycatch amount for that species or species group as calculated under § 679.20.

* * * * *

3. In § 679.4, paragraph (l) is added to read as follows:

§ 679.4 Permits.

* * * * *

(l) *AFA permits* (applicable through December 31, 2001)—(1) *General*—(i) *Applicability.* In addition to any other permit and licensing requirements set out in this part, any vessel used to engage in directed fishing for a non-CDQ allocation of pollock in the BSAI and any shoreside processor, stationary floating processor, or mothership that receives pollock harvested in a non-CDQ directed pollock fishery in the BSAI must have a valid AFA permit onboard the vessel or at the facility location at all times while non-CDQ pollock is being harvested or processed. An AFA permit does not exempt a vessel operator, vessel, or processor from any other applicable permit or licensing requirement required under this part or in other state or Federal regulations.

(ii) *Duration.* Except as provided in paragraph (l)(6)(iv) of this section, and unless suspended or revoked, AFA vessel and processor permits are valid until December 31, 2004.

(iii) *Application for permit.* NMFS will issue AFA vessel and processor permits to the current owner(s) of a qualifying vessel or processor if the owner(s) submits to the Regional Administrator a completed AFA permit application that is subsequently approved.

(iv) *Amended permits.* AFA vessel and processor permits may not be used on or transferred to any vessel or processor that is not listed on the permit. However, AFA permits may be amended to reflect any change in the ownership of the vessel or processor. An application to amend an AFA permit must include the following:

(A) The original AFA permit to be amended, and

(B) A completed AFA permit application signed by the new vessel or processor owner.

(2) *AFA catcher/processor permits*—(i) *Unrestricted.* NMFS will issue to an owner of a catcher/processor an unrestricted AFA catcher/processor permit if the catcher/processor is one of the following (as listed in AFA paragraphs 208(e)(1) through (20)):

AMERICAN DYNASTY (USCG documentation number 951307);
KATIE ANN (USCG documentation number 518441);
AMERICAN TRIUMPH (USCG documentation number 646737);
NORTHERN EAGLE (USCG documentation number 506694);
NORTHERN HAWK (USCG documentation number 643771);
NORTHERN JAEGER (USCG documentation number 521069);
OCEAN ROVER (USCG documentation number 552100);
ALASKA OCEAN (USCG documentation number 637856);
ENDURANCE (USCG documentation number 592206);
AMERICAN ENTERPRISE (USCG documentation number 594803);
ISLAND ENTERPRISE (USCG documentation number 610290);
KODIAK ENTERPRISE (USCG documentation number 579450);
SEATTLE ENTERPRISE (USCG documentation number 904767);
US ENTERPRISE (USCG documentation number 921112);
ARCTIC STORM (USCG documentation number 903511);
ARCTIC FJORD (USCG documentation number 940866);
NORTHERN GLACIER (USCG documentation number 663457);
PACIFIC GLACIER (USCG documentation number 933627);
HIGHLAND LIGHT (USCG documentation number 577044);
STARBOUND (USCG documentation number 944658).

(ii) *Restricted.* NMFS will issue to an owner of a catcher/processor a restricted AFA catcher/processor permit if the catcher/processor is not listed in § 679.4(l)(2)(i) and is determined by the Regional Administrator to have harvested more than 2,000 mt of pollock in the 1997 BSAI directed pollock fishery.

(3) *AFA catcher vessel permits.* NMFS will issue to an owner of a catcher vessel an AFA catcher vessel permit containing sector endorsements and sideboard restrictions upon receipt and approval of a completed application for an AFA catcher vessel permit.

(i) *Qualifying criteria*—(A) *Catcher vessels delivering to catcher/processors.* NMFS will endorse an AFA catcher vessel permit to authorize directed fishing for pollock for delivery to a catcher/processor if the catcher vessel:

(*1*) Is one of the following (as listed in paragraphs 208(b)(1) through (7) of the AFA):

AMERICAN CHALLENGER (USCG documentation number 633219);
FORUM STAR (USCG documentation number 925863);
MUIR MILACH (USCG documentation number 611524);
NEAHKAHNIE (USCG documentation number 599534);
OCEAN HARVESTER (USCG documentation number 549892);
SEA STORM (USCG documentation number 628959);
TRACY ANNE (USCG documentation number 904859); or

(*2*) Is not listed in § 679.4(l)(3)(i)(A)(*1*) and is determined by the Regional Administrator to have delivered at least 250 metric tons and at least 75 percent of the pollock it harvested in the directed BSAI pollock fishery in 1997 to catcher/processors for processing by the offshore component.

(B) *Catcher vessels delivering to AFA motherships.* NMFS will endorse an AFA catcher vessel permit to authorize directed fishing for pollock for delivery to an AFA mothership if the catcher vessel:

(*1*) Is one of the following (as listed in paragraphs 208(c)(1) through (19) and subsection 211(e) of the AFA):

ALEUTIAN CHALLENGER (USCG documentation number 603820);
ALYESKA (USCG documentation number 560237);
AMBER DAWN (USCG documentation number 529425);
AMERICAN BEAUTY (USCG documentation number 613847);
CALIFORNIA HORIZON (USCG documentation number 590758);
MAR-GUN (USCG documentation number 525608);
MARGARET LYN (USCG documentation number 615563);
MARK I (USCG documentation number 509552);
MISTY DAWN (USCG documentation number 926647);
NORDIC FURY (USCG documentation number 542651);
OCEAN LEADER (USCG documentation number 561518);
OCEANIC (USCG documentation number 602279);
PACIFIC ALLIANCE (USCG documentation number 612084);
PACIFIC CHALLENGER (USCG documentation number 518937);
PACIFIC FURY (USCG documentation number 561934);
PAPADO II (USCG documentation number 536161);

TRAVELER (USCG documentation number 929356);
VESTERAALEN (USCG documentation number 611642);
WESTERN DAWN (USCG documentation number 524423);
LISA MARIE (USCG documentation number 1038717); or

(*2*) Is not listed in § 679.4(l)(3)(i)(B)(*1*) and is determined by the Regional Administrator to have delivered at least 250 mt of pollock for processing by motherships in the offshore component of the BSAI directed pollock fishery in any one of the years 1996 or 1997, or between January 1, 1998, and September 1, 1998, and is not eligible for an endorsement to deliver pollock to catcher/processors under § 679.4(l)(3)(i)(A).

(C) *Catcher vessels delivering to AFA inshore processors.* NMFS will endorse an AFA catcher vessel permit to authorize directed fishing for pollock for delivery to an AFA inshore processor if the catcher vessel:

(*1*) Is the LISA MARIE (USCG documentation number 1038717); or

(*2*) is not eligible for an endorsement to deliver pollock to catcher/processors under § 679.4(l)(3)(i)(A), and:

(*i*) Is determined by the Regional Administrator to have delivered at least 250 mt of pollock harvested in the directed BSAI pollock fishery for processing by the inshore component in any one of the years 1996 or 1997, or between January 1, 1998, and September 1, 1998; or

(*ii*) Is less than 60 ft (18.3 m) LOA and is determined by the Regional Administrator to have delivered at least 40 mt of pollock harvested in the directed BSAI pollock fishery for processing by the inshore component in any one of the years 1996 or 1997, or between January 1, 1998 and September 1, 1998.

(ii) *Application for AFA catcher vessel permit.* A completed application for an AFA catcher vessel permit must contain:

(A) *Vessel information.* The vessel name, ADF&G registration number, USCG documentation number, vessel telephone number (if any), gross tons, shaft horsepower, and registered length (in feet);

(B) *Owner information.* Owner name(s), tax ID number(s), business mailing address(es), business telephone number(s), business fax number(s), business e-mail address(es), and managing company (if any);

(C) *Vessel AFA qualification information.* AFA catcher vessel permit endorsement(s) requested; and

(D) *Vessel crab activity information required for crab sideboard endorsements.* The owner of an AFA catcher vessel wishing to participate in any BSAI king or Tanner crab fishery must apply for a crab sideboard endorsement authorizing the catcher vessel to retain that crab species. An AFA catcher vessel permit may be endorsed for a crab species if the owner requests a crab sideboard endorsement, provides supporting documentation that the catcher vessel made the required legal landing(s) of a crab species, and the Regional Administrator verifies the legal landing(s) according to the following criteria:

(*1*) *Bristol Bay Red King Crab (BBRKC):* A legal landing of any BSAI king or Tanner crab species in 1996, 1997, or on or before February 7, 1998. A BBRKC sideboard endorsement also authorizes a vessel to retain Bairdi Tanner crab harvested during the duration of a BBRKC opening if the vessel is otherwise authorized to retain Bairdi Tanner crab while fishing for BBRKC under state and Federal regulations.

(*2*) *St. Matthew Island blue king crab:* A legal landing of St. Matthew Island blue king crab in that fishery in 1995, 1996, or 1997.

(*3*) *Pribilof Island red and blue king crab:* A legal landing of Pribilof Island blue or red king crab in that fishery in 1995, 1996, or 1997.

(*4*) *Aleutian Islands (Adak) brown king crab:* A legal landing of Aleutian Islands brown king crab during in each of the 1997/1998 and 1998/1999 fishing seasons.

(*5*) *Aleutian Islands (Adak) red king crab:* A legal landing of Aleutian Islands red king crab in each of the 1995/1996 and 1998/1999 fishing seasons.

(*6*) *Opilio Tanner crab:* A legal landing of *Chionoecetes(C.) opilio* Tanner crab in each of 4 or more years from 1988 to 1997.

(*7*) *Bairdi Tanner crab:* A legal landing of *C. bairdi* Tanner crab in 1995 or 1996.

(E) *Vessel exemptions from AFA catcher vessel groundfish sideboard directed fishing closures.* An AFA catcher vessel permit may contain exemptions from certain groundfish sideboard directed fishing closures. If a vessel owner is requesting an exemption from groundfish sideboard-directed closures, the application must provide supporting documentation that the catcher vessel qualifies for the exemption based on the criteria set out below. The Regional Administrator will review the vessel's catch history according to the following criteria:

(*1*) *BSAI Pacific cod.* For a catcher vessel to qualify for an exemption from AFA catcher vessel sideboards in the BSAI Pacific cod fishery, the catcher vessel must be less than 125 ft LOA, have harvested a combined total of less than 5,100 mt of BSAI pollock, and have made 30 or more legal landings of Pacific cod in the BSAI directed fishery for Pacific cod during the combined years 1995, 1996, and 1997.

(*2*) *GOA groundfish species.* For a catcher vessel to qualify for an exemption from AFA catcher vessel sideboards in the GOA groundfish fisheries, the catcher vessel must be less than 125 ft LOA, have harvested a combined total of less than 5,100 mt of BSAI pollock and made 40 or more legal landings of GOA groundfish during the combined years 1995, 1996, and 1997.

(F) *Certification of notary and applicant.* Owner signature(s), date of signature, printed name(s), and stamp and signature of a notary public.

(4) *AFA mothership permits.* NMFS will issue to an owner of a mothership an AFA mothership permit if the mothership is one of the following (as listed in paragraphs 208(d)(1) through (3) of the AFA):

EXCELLENCE (USCG documentation number 967502);
GOLDEN ALASKA (USCG documentation number 651041); and
OCEAN PHOENIX (USCG documentation number 296779).

(i) *Cooperative processing endorsement.* The owner of an AFA mothership who wishes to process pollock harvested by a fishery cooperative formed under § 679.60 must apply for and receive a cooperative processing endorsement on the vessel's AFA mothership permit.

(ii) *Application for AFA mothership permit.* A completed application for an AFA mothership permit must contain:

(A) *Type of permit requested.* Type of processor and whether requesting an AFA co-operative endorsement.

(B) *Mothership information.* The mothership name, ADF&G processor code, USCG documentation number, Federal fisheries permit number, gross tons, shaft horsepower, and registered length (in feet), and business telephone number, business FAX number, and business e-mail address used onboard the mothership.

(C) *Owner information.* Owner name(s), tax ID number(s), business mailing address(es), business telephone number(s), business fax number(s), business e-mail address(es), and managing company (if any);

(D) *AFA entity/AFA crab facility ownership information.* If the applicant is applying for a cooperative pollock processing endorsement, the AFA mothership application must identify all of the individuals, corporations or other

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entities that comprise the AFA entity that owns the inshore processor, and also must list the name, type of facility, ADF&G processor code, and nature and percentage of ownership or control of each of each AFA crab facility that is associated with such AFA entity; and

(E) *Certification of notary and applicant.* Owner signature(s), date of signature, printed name(s), and notary stamp and signature of a notary public.

(5) *AFA inshore processor permits.* NMFS will issue to an owner of a shoreside processor or stationary floating processor an AFA inshore processor permit upon receipt and approval of a completed application.

(i) *Qualifying criteria*—(A) *Unrestricted processors.* NMFS will issue an unrestricted AFA inshore processor permit to a shoreside processor or stationary floating processor if the Regional Administrator determines that the processor facility processed annually more than 2,000 mt round-weight of pollock harvested in the inshore component of the directed BSAI pollock fishery during each of 1996 and 1997.

(B) *Restricted processors.* NMFS will issue a restricted AFA inshore processor permit to a shoreside processor or stationary floating processor if the Regional Administrator determines that the facility processed pollock harvested in the inshore component of the directed BSAI pollock fishery during 1996 or 1997, but did not process annually more than 2,000 mt round-weight of BSAI pollock during each of 1996 and 1997.

(ii) *Cooperative processing endorsement.* The owner of an AFA inshore processor who wishes to process pollock harvested by a fishery cooperative formed under § 679.61 must apply for and receive a cooperative processing endorsement on the AFA inshore processor permit.

(iii) *Single geographic location requirement.* An AFA inshore processor permit authorizes the processing of pollock harvested in the BSAI directed pollock fishery in only a single geographic location during a fishing year. For the purpose of this paragraph, single geographic location means:

(A) *Shoreside processors.* The physical location at which the land-based shoreside processor first processed BSAI pollock harvested in the BSAI directed pollock fishery during a fishing year;

(B) *Stationary floating processors.* A location within Alaska state waters that is within 5 nm of the position in which the stationary floating processor first processed BSAI pollock harvested in the BSAI directed pollock fishery during a fishing year.

(iv) *Application for permit.* A completed application for an AFA inshore processor permit must contain:

(A) *Type of permit requested.* Type of processor, whether requesting an AFA cooperative endorsement, and amount of BSAI pollock processed in 1996 and 1997;

(B) *Stationary floating processor information.* The vessel name, ADF&G processor code, USCG documentation number, Federal processor permit number, gross tons, shaft horsepower, registered length (in feet), and business telephone number, business FAX number, and business E-mail address used onboard the vessel.

(C) *Shoreside processor information.* The processor name, Federal processor permit number, ADF&G processor code, business street address; business telephone and FAX numbers, and business e-mail address.

(D) *Owner information.* Owner name(s), tax ID number(s), business mailing address(es), business telephone number(s), business fax number(s), business e-mail address(es), and managing company (if any);

(E) *AFA entity/AFA crab facility ownership information.* If the applicant is applying for a cooperative pollock processing endorsement, the AFA inshore processor application must identify all of the individuals, corporations or other entities that comprise the AFA entity that owns the inshore processor, and also must list the name, type of facility, ADF&G processor code, and nature and percentage of ownership or control of each AFA crab facility that is associated with such AFA entity; and

(F) *Certification of notary and applicant.* Owner signature(s), date of signature, printed name(s), and notary stamp and signature of a notary public.

(6) *Inshore cooperative fishing permits*—(i) *General.* NMFS will issue to an inshore catcher vessel cooperative formed under section 1 of the Act of June 25, 1934 (15 U.S.C. 521) for the purpose of cooperatively managing directed fishing for pollock for processing by an AFA inshore processor an AFA inshore cooperative fishing permit upon receipt and approval of a completed application.

(ii) *Application for permit.* A completed application for an inshore cooperative fishing permit must contain the following information:

(A) *Cooperative contact information.* Name of cooperative; name of cooperative representative; and business mailing address, business telephone number, business fax number, and business e-mail address of the cooperative;

(B) *Designated cooperative processor.* The name and physical location of AFA Inshore Processor that is designated in the cooperative contract as the processor to whom the cooperative has agreed to deliver at least 90 percent of its BSAI pollock catch. If the processor is a stationary floating processor, the single geographic location (latitude and longitude) at which the processor will process BSAI pollock under the AFA; and Federal processor permit number of the AFA inshore processor;

(C) *Cooperative contract information.* A copy of the cooperative contract and a written certification that:

(*1*) The contract was signed by the owners of at least 80 percent of the qualified catcher vessels. For the purpose of this paragraph, a catcher vessel is a qualified catcher vessel if:

(*i*) it delivered more pollock harvested in the BSAI inshore directed pollock fishery to the AFA inshore processor designated under paragraph (l)(6)(ii)(B) of this section than to any other shoreside processor or stationary floating processor during the year prior to the year in which the cooperative fishing permit will be in effect; and

(*ii*) the owner(s) of the catcher vessel in question has submitted a completed application for an AFA catcher vessel permit to the Regional Administrator that was received on or before December 31, 1999 and which is not subsequently denied.

(*2*) The cooperative contract requires that the cooperative deliver at least 90 percent of its BSAI pollock catch to its designated AFA processor; and

(*3*) Each catcher vessel in the cooperative is a qualified catcher vessel and is otherwise eligible to fish for groundfish in the BSAI, has an AFA catcher vessel permit with an inshore endorsement, and has no permit sanctions or other type of sanctions against it that would prevent it from fishing for groundfish in the BSAI;

(D) *Business review letter.* A copy of a letter from a party to the contract requesting a business review letter on the fishery cooperative from the Department of Justice, and any response to such request;

(E) *Vessel information.* For each cooperative catcher vessel member: Vessel name, ADF&G registration number, USCG documentation number, AFA permit number; and

(F) *Certification of notary and applicant.* Signature and printed name of cooperative representative, date of signature, and notary stamp or seal of a notary public.

(iii) *Duration of cooperative fishing permits.* Inshore cooperative fishing permits are valid for 1 calendar year.

(iv) *Add or subtract vessels to a cooperative fishing permit.* The cooperative representative must submit a new application to add or subtract a catcher vessel to or from an inshore cooperative fishing permit to the Regional Administrator prior to the application deadline. Upon approval by the Regional Administrator, NMFS will issue an amended cooperative fishing permit.

(v) *Application deadline.* An inshore cooperative fishing permit application and any subsequent contract amendments that add or subtract vessels must be received by the Regional Administrator by December 1 prior to the year in which the inshore cooperative fishing permit will be in effect. Inshore cooperative fishing permit applications or amendments to inshore fishing cooperative permits received after December 1 will not be accepted by the Regional Administrator for the subsequent fishing year.

(*7*) *Replacement vessels.* (i) In the event of the actual total loss or constructive total loss of an AFA catcher vessel, AFA mothership, or AFA catcher/processor, the owner of such vessel may replace such vessel with a replacement vessel. The replacement vessel will be eligible in the same manner as the original vessel after submission and approval of an application for an AFA replacement vessel provided that:

(A) Such loss was caused by an act of God, an act of war, a collision, an act or omission of a party other than the owner or agent of the vessel, or any other event not caused by the willful misconduct of the owner or agent;

(B) The replacement vessel was built in the United States and if ever rebuilt, was rebuilt in the United States;

(C) The USCG certificate of documentation with fishery endorsement for the replacement vessel is issued within 36 months of the end of the last year in which the eligible vessel harvested or processed pollock in the directed pollock fishery;

(D) If the eligible vessel is greater than 165 ft (50.3 m) in registered length, or more than 750 gross registered tons, or has engines capable of producing more than 3,000 shaft horsepower, the replacement vessel is of the same or lesser registered length, gross registered tons, and shaft horsepower;

(E) If the eligible vessel is less than 165 ft (50.3 m) in registered length, of fewer than 750 gross registered tons, and has engines incapable of producing more than 3,000 shaft horsepower, the replacement vessel is less than each of such thresholds and does not exceed by more than 10 percent the registered length, gross registered tons or shaft horsepower of the eligible vessel; and

(F) If the replacement vessel is already an AFA catcher vessel, the inshore cooperative catch history of both vessels may be merged in the replacement vessel for the purpose of determining inshore cooperative allocations except that a catcher vessel with an endorsement to deliver pollock to AFA catcher/processors may not be simultaneously endorsed to deliver pollock to AFA motherships or AFA inshore processors.

(ii) *Application for permit.* A completed application for an AFA permit for replacement vessel must contain:

(A) *Identification of lost AFA eligible vessel.*

(*1*) Name, ADF&G vessel registration number, USCG documentation number, AFA permit number, gross tons, shaft horsepower, and registered length from USCG documentation of the vessel;

(*2*) Name(s), tax ID number(s), business mailing address(es), telephone number(s), FAX number(s), and e-mail address(es) of owner(s);

(*3*) Last year in which this vessel harvester or processed pollock in a BSAI directed pollock fishery; and

(*4*) Description of how the vessel was lost or destroyed. Attach a USCG Form 2692 or insurance papers to verify the claim.

(B) *Identification of replacement vessel.*

(*1*) Name, ADF&G vessel registration number, USCG documentation number, gross tons, shaft horsepower, registered length, net tons, and length overall (in feet) from USCG documentation, and Federal Fisheries Permit number of the vessel;

(*2*) Name(s), tax ID number(s), business mailing address(es), business telephone number(s), business FAX number(s), and business e-mail address(es) of the owner(s);

(*3*) YES or NO indication of whether the vessel was built in the United States; and

(*4*) YES or NO indication of whether the vessel has ever been rebuilt, and if so whether it was rebuilt in the United States.

(C) *Certification of applicant and notary.* Signature(s) and printed name(s) of owner(s) and date of signature; signature, notary stamp or seal of notary public, and date notary commission expires.

(8) *Application evaluations and appeals*—(i) *Initial evaluation.* The Regional Administrator will evaluate an application for an AFA fishing or processing permit submitted in accordance with this paragraph (l) and compare all claims in the application with the information in the official AFA record. Claims in the application that are consistent with information in the official AFA record will be accepted by the Regional Administrator. Inconsistent claims in the application, unless supported by evidence, will not be accepted. An applicant who submits inconsistent claims or fails to submit the information specified in the application for an AFA permit will be provided a 60-day evidentiary period to submit the specified information, submit evidence to verify the applicant's inconsistent claims, or submit a revised application with claims consistent with information in the official AFA record. An applicant who submits claims that are inconsistent with information in the official AFA record has the burden of proving that the submitted claims are correct.

(ii) *Additional information and evidence.* The Regional Administrator will evaluate additional information or evidence to support an applicant's inconsistent claims submitted within the 60-day evidentiary period. If the Regional Administrator determines that the additional information or evidence meets the applicant's burden of proving that the inconsistent claims in his or her application are correct, the official AFA record will be amended and the information will be used in determining whether the applicant is eligible for an AFA permit. However, if the Regional Administrator determines that the additional information or evidence does not meet the applicant's burden of proving that the inconsistent claims in his or her application is correct, the applicant will be notified by an initial administrative determination that the applicant did not meet the burden of proof to change information in the official AFA record.

(iii) *Sixty-day evidentiary period.* The Regional Administrator will specify by letter a 60-day evidentiary period during which an applicant may provide additional information or evidence to support the claims made in his or her application, or to submit a revised application with claims consistent with information in the official AFA record, if the Regional Administrator determines that the applicant did not meet the burden of proving that the information on the application is correct through evidence provided with the application. Also, an applicant who fails to submit required information will have 60 days to provide that information. An applicant will be

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limited to one 60-day evidentiary period. Additional information or evidence, or a revised application received after the 60-day evidentiary period specified in the letter has expired will not be considered for the purposes of the initial administrative determination.

(iv) *Initial administrative determinations (IAD).* The Regional Administrator will prepare and send an IAD to the applicant following the expiration of the 60-day evidentiary period if the Regional Administrator determines that the information or evidence provided by the applicant fails to support the applicant's claims and is insufficient to rebut the presumption that the official AFA record is correct, or if the additional information, evidence, or revised application is not provided within the time period specified in the letter that notifies the applicant of his or her 60-day evidentiary period. The IAD will indicate the deficiencies in the application, including any deficiencies with the information, the evidence submitted in support of the information, or the revised application. The IAD also will indicate which claims cannot be approved based on the available information or evidence. An applicant who receives an IAD may appeal under the appeals procedures set out at § 679.43. An applicant who avails himself or herself of the opportunity to appeal an IAD will receive an interim AFA permit that authorizes a person to participate in an AFA pollock fishery, and will have the specific endorsements and designations based on the claims in his or her application. An interim AFA permit will expire upon final agency action.

(v) *Effect of cooperative allocation appeals.* An AFA inshore cooperative may appeal the pollock quota share issued to the cooperative under § 679.61; however, final agency action on the appeal must occur prior to December 15 for the results of the appeal to take effect during the subsequent fishing year.

* * * * *

4. In § 679.5, paragraphs (a)(4)(iv), (f)(3), (f)(4), (i)(1)(iii), and (o) are added to read as follows:

§ 679.5 Recordkeeping and reporting.

(a) * * *

(4) * * *

(iv) *Shoreside processor electronic logbook report.* (Applicable through December 31, 2001.) The manager of a shoreside processor or stationary floating processor receiving groundfish from AFA catcher vessels must use NMFS-approved software to report catcher vessel deliveries to NMFS as required under this section, and maintain the shoreside processor electronic logbook report described at paragraph (f)(3) of this section, and printed reports required under this section to record the information described at paragraph (f)(4) of this section. The owner of a shoreside processor or stationary floating processor is responsible for compliance and must ensure that the operator, manager, or representative complies with the requirements of this paragraph described at paragraph (f)(3) of this section.

* * * * *

(f) * * *

(3) *Shoreside processor electronic logbook report*—(Applicable through December 31, 2001.) (i) *Requirement.* The manager of a shoreside processor or stationary floating processor that receives deliveries of groundfish from one or more AFA catcher vessels must record in and submit a shoreside processor electronic logbook report for each catcher vessel delivery and must print and retain reports required under this section for the duration of the fishing year.

(ii) *Applicability.* (A) Processors that use the shoreside processor electronic logbook to record all deliveries and that receive from NMFS an electronic return receipt for each delivery report are exempt from the requirement to maintain shoreside processor DCPLs as described at paragraph (f)(1) and (f)(2) of this section and are exempt from the requirement to submit quarterly DCPL logsheets to NMFS Enforcement as described at paragraph (a)(14)(iii)(A) of this section.

(B) Processors that submit the shoreside processor electronic logbook report and that receive from NMFS an electronic return receipt for each delivery report are exempt from the requirement to maintain and submit WPRs to the Regional Administrator as described at paragraph (i) of this section.

(C) Processors that submit the shoreside processor electronic logbook report, receive from NMFS a return receipt for each delivery report, and that are receiving deliveries of fish under a CDQ program are exempt from the requirement to submit CDQ delivery reports to the Regional Administrator as described at paragraph (n)(1) of this section.

(iii) *Time limit and submittal.* (A) The shoreside processor electronic logbook report must be submitted daily to NMFS as an electronic file. A dated return-receipt will be generated and sent by NMFS to the processor confirming receipt and acceptance of the report. Processors must retain the return receipt as proof of report submission. If a processor does not receive a return receipt from NMFS, the processor must contact NMFS within 24 hours for further instruction on submission of electronic logbook reports.

(B) Information entered daily and described at § 679.5(f)(3)(iv)(B) must be entered each day on the day they occur.

(C) Information for each delivery described at § 679.5(f)(3)(iv)(C) must be submitted to NMFS by noon of the following day for each delivery of groundfish.

(iv) *Information required.* The manager must enter the following information into the shoreside processor electronic logbook:

(A) *Information entered once (at software installation) or whenever it changes:*

(*1*) Shoreside processor name, ADF&G processor code, Federal processor permit number, and processor e-mail address;

(*2*) State port code;

(*3*) Name, telephone and FAX numbers of representative.

(B) *Information entered daily:*

(*1*) Indicate if no deliveries or no production;

(*2*) Number of observers on site;

(*3*) Whether harvested in BSAI or GOA;

(*4*) Product by species code, product code, and whether primary, ancillary, or reprocessed/rehandled;

(*5*) Product weight (in lb or mt).

(C) *Information entered for each delivery:*

(*1*) Date fishing began and delivery date;

(*2*) Vessel name (optional) and ADF&G number;

(*3*) Whether delivery is from a buying station;

(*4*) If received from a buying station:

(*i*) Type: vessel, vehicle, or other.

(*ii*) Name of buying station and date received by buying station.

(*iii*) If a vessel, ADF&G number.

(*iv*) If a vehicle, license plate number.

(*v*) If other, description;

(*5*) Whether a discard DFL was received from catcher vessel; if discard DFL not received, reason given;

(*6*) ADF&G fish ticket number or delivery;

(*7*) Management program name and identifying number (whether CDQ, research program, experimental fishery, IFQ, or AFA coop);

(*8*) Gear type of harvester;

(*9*) Landed species by species code, product code, and weight (in pounds or mt) for each species of each delivery;

(*10*) Discard or disposition species by species code, product code, and weight (in pounds or mt) of groundfish or PSC herring;

(*11*) Discard or disposition species by species code, product code, and count (in numbers of animals) of PSC halibut, salmon, or crab;

(*12*) If a CDQ delivery, discard or disposition species by species code, product code, weight (in pounds or mt) and count of PSQ halibut;

(*13*) ADF&G statistical area(s) where fishing occurred; and estimated percentage of total delivered weight corresponding to each area.

(*4*) *Shoreside processor electronic logbook printed reports.* (i) The manager must output at the processing plant daily reports of the shoreside processor electronic logbook in two formats generated by the required software onto paper consisting of a Shoreside Logbook Daily Production Report and a Delivery Worksheet. The processor must maintain copies of both of these printouts throughout the fishing year and must make them available to observers, NMFS personnel, and authorized officers upon request.

(ii) *Information required*—(A) *Delivery worksheet.* Name of processor; ADF&G fish ticket number; management program name (whether CDQ, research program, experimental fishery, IFQ, or cooperative) and identifying number; catcher vessel name (optional) and ADF&G vessel number; date fishing began; delivery date; gear type by harvester; landed species by species code and product code and weight (in lb) for each species of each delivery; ADF&G statistical area and percentage of total delivered weight in each area, Federal reporting area; discard or disposition by species code and product code; weight of each discard or disposition species (in lb), number of each discard or disposition species (in lb) (if groundfish or herring); number of each species discard or disposition species if PSC halibut, salmon or crab.

(B) *Shoreside logbook daily production.* Processor name; Federal processor number; ADF&G processor code; date; number of observers on site; indicate if no production and/or no deliveries; last sent date; last modified date; product by species code and product code whether primary, ancillary, or reprocessed/rehandled; and product weight in lb.

* * * * *

(i) *Weekly production report (WPR).*

* * *

(1) * * *

(iii) (applicable through December 31, 2001) If a shoreside processor or stationary floating processor and if using software approved by the Regional Administrator as described in § 679.5(f)(3), the shoreside processor or stationary floating processor is exempt from the requirements to submit a WPR.

* * * * *

(o) *Catcher vessel cooperative pollock catch report.* (Applicable through December 31, 2001.) (1) *Applicability.* The designated representative of each AFA inshore processor catcher vessel cooperative must submit to the Regional Administrator a catcher vessel cooperative pollock catch report detailing each delivery of pollock harvested under the allocation made to that cooperative. The owners of the member catcher vessels in the cooperative are jointly responsible for compliance and must ensure that the designated representative complies with the applicable recordkeeping and reporting requirements of this section.

(2) *Time limits and submittal.* (i) The cooperative pollock catch report must be submitted by one of the following methods:

(A) an electronic data file in a format approved by NMFS; or

(B) by fax.

(ii) The cooperative pollock catch report must be received by the Regional Administrator by 1200 hours, A.l.t. 1 week after the date of completion of delivery.

(3) *Information required.* The cooperative pollock catch report must contain the following information: Cooperative account number; catcher vessel ADF&G number; inshore processor Federal processor permit number; delivery date; amount of pollock (in lb) delivered plus weight of at-sea pollock discards; ADF&G fish ticket number.

* * * * *

5. In § 679.7, paragraphs (a)(11) and (b) are suspended until July 17, 2001, and paragraphs (a)(17) and (j) are added to read as follows:

§ 679.7 Prohibitions.

* * * * *

(a) * * *

(17) *Tender vessel*—(Applicable through July 17, 2001.) (i) Use a catcher vessel or catcher/processor as a tender vessel before offloading all groundfish or groundfish product harvested or processed by that vessel.

(ii) Use a catcher vessel or catcher/processor to harvest groundfish while operating as a tender vessel.

* * * * *

(j) *Prohibitions specific to the GOA*—(Applicable through July 17, 2001.) (1) *Southeast Outside trawl closure.* Use any gear other than non-trawl gear in GOA east of 140° W long.

(2) *Catcher vessel trip limit for pollock.* Retain on board a catcher vessel at any time, more than 300,000 pounds (136 mt) of unprocessed pollock.

(3) *Tender vessel restrictions for pollock.* (i) Operate as a tender vessel east of 157°00′ W long. for pollock harvested in the GOA.

(ii) Operate as a tender vessel west of 157°00′ W long. while retaining on board at any time more than 600,000 lb (272 mt) of unprocessed pollock.

* * * * *

6. In § 679.20, paragraphs (a)(5)(i)(A), (a)(5)(ii)(B), and (c)(2)(ii) are suspended until July 17, 2001 and paragraphs (a)(5)(i)(B), (a)(5)(ii)(C), (c)(2)(iii), (c)(7), and (d)(1)(iv) are added to read as follows:

§ 679.20 General limitations.

* * * * *

(a) * * *

(5) * * *

(i) * * *

(B) *BSAI seasonal allowances*—(Applicable through July 17, 2001.) (*1*) *Inshore, catcher/processor, mothership, and CDQ components.* The portion of the Bering Sea subarea pollock directed fishing allowance allocated to each component under Sections 206(a) and 206(b) of the American Fisheries Act will be divided into two seasonal allowances corresponding to the two fishing seasons set out at § 679.23(e)(5), as follows: A/B Season, 40 percent; C/D Season, 60 percent.

(*2*) *Inseason Adjustments.* Within any fishing year, the Regional Administrator may add or subtract the under harvest or over harvest of a seasonal allowance, by component, according to the harvest limitations below. The Steller Sea Lion Conservation Area (SCA) is defined at § 679.22(a)(11)(iv).

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Bering Sea subarea	Combined A/B season, maximum overall harvest of 40% of annual pollock TAC		Combined C/D season, maximum overall harvest of 60% of annual pollock TAC	
Inside SCA	Maximum harvest limit of 20% of annual pollock TAC for A+B combined, and 15% for A or B singly.		Maximum harvest limit of 4.5% of annual pollock TAC.	Maximum harvest limit of 7.5% of annual pollock TAC.
Season	A	B	C	D

* * * * *

(ii) * * *

(C) *GOA seasonal allowances.* (Applicable through July 17, 2001.) Each apportionment established under paragraph (a)(5)(ii)(A) of this section will be divided into four seasonal allowances corresponding to the four fishing seasons set out at § 679.23(d)(3) of this part as follows: A Season, 30 percent; B Season, 15 percent; C Season, 30 percent; D Season, 25 percent. Within any fishing year, under harvest or over harvest of a seasonal allowance may be added to or subtracted from subsequent seasonal allowances in a manner to be determined by the Regional Administrator, provided that a revised seasonal allowance does not exceed 30 percent of the annual TAC apportionment.

* * * * *

(c) * * *

(2) * * *

(iii) *BSAI.* (Applicable through July 17, 2001.) Except for pollock, Atka mackerel, and the hook and line and pot gear allocation of sablefish, one quarter of each proposed initial TAC and apportionment thereof, one quarter of each CDQ reserve established by paragraph (b)(1)(iii) of this section, and one quarter of the proposed PSQ reserve and prohibited species catch allowances established by § 679.21.

(A) The interim specifications for pollock and Atka mackerel will be equal to the first seasonal allowance for pollock and Atka mackerel that is published in the proposed specifications under paragraph (c)(1) of this section.

(B) The interim specifications for CDQ pollock will be equal to the first seasonal allowance that is published in the proposed specifications under paragraph (c)(1) of this section.

* * * * *

(7) *BSAI and Western and Central GOA Pacific cod season allocations.* The annual TAC Pacific cod in the BSAI and the Western and Central GOA will be divided, after the subtraction of any reserves and incidental catch, between the A Season and B Season as follows:

(i) A Season, January 1, 2001, to June 10, 2001, 60 percent;

(ii) B Season, June 10, 2001, to December 31, 2001, 40 percent;

(iii) Each season apportionment will be allocated among the various sectors as provided in §§ 679.20(a)(6)(iii) and 679.20(a)(7).

(iv) Any overage or underage of Pacific cod harvest from the A Season may be subtracted from or added to the subsequent B Season.

* * * * *

(d) * * *

(1) * * *

(iv) *AFA sideboard limitations.* (Applicable through December 31, 2001.) (A) If the Regional Administrator determines that any sideboard harvest limit for a group of AFA vessels established under § 679.63 has been or will be reached, the Regional Administrator may establish a directed fishing allowance for the species or species group applicable only to the identified group of AFA vessels.

(B) In establishing a directed fishing allowance under paragraph (d)(1)(iv)(A) of this section, the Regional Administrator shall consider the amount of the harvest limitation established for a group of AFA vessels under § 679.63 that will be taken as incidental catch by those vessels in directed fishing for other species.

* * * * *

7. In § 679.21 paragraphs (d)(8) and (e)(3)(v) are added to read as follows:

§ 679.21 Prohibited species bycatch management.

* * * * *

(d) * * *

(8) *AFA halibut bycatch limitations.* (Applicable through December 31, 2001). Halibut bycatch limits for AFA catcher vessels will be established according to the procedure and formula set out in § 679.63(b) and managed through directed fishing closures for AFA catcher vessels in the groundfish fisheries to which the halibut bycatch limit applies.

* * * * *

(e) * * *

(3) * * *

(v) *AFA prohibited species catch limitations.* (Applicable through December 31, 2001.) Halibut and crab PSC limits for AFA catcher/processors and AFA catcher vessels will be established according to the procedures and formulas set out in § 679.63 (a) and (b) and managed through directed fishing closures for AFA catcher/processors and AFA catcher vessels in the groundfish fisheries for which the PSC limit applies.

* * * * *

8. In § 679.22, paragraphs (a)(7), (a)(8), and (b)(2) are suspended until July 17, 2001 and paragraphs (a)(11), (a)(12), (a)(13), (b)(3), and (b)(5) are added to read as follows:

§ 679.22 Closures.

(a) * * *

(11) *Steller sea lion protection areas, Bering Sea subarea and Bogoslof District*—(Applicable through July 17, 2001.) (i) *Year-round trawl closures.* Until 1200 hours, A.l.t., June 10, 2001, trawling is prohibited within 10 nm of selected Steller sea lion rookeries in the Bering Sea subarea and Bogoslof District. These rookeries are listed in Table 21 to this part and are identifiable by a designation of "Bering Sea" in column 2, "R" or "H" in column 7, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (a)(11)(v) of this section for fishing prohibitions.

(ii) *Seasonal trawl closures.* During January 20 through 1200 hours, A.l.t., June 10, or a date earlier than June 10 if directed fishing for pollock is prohibited for all sectors under § 679.20, trawling is prohibited within 20 nm of selected Steller sea lion rookeries in the Bering Sea subarea and Bogoslof District. These rookeries are listed in Table 21 to this part and are identifiable by a designation of "Bering Sea" in column 2, "R" in column 7, and "Y" in column 14.

(iii) *Pollock closures.* Until 1200 hours, A.l.t., June 10, 2001, directed fishing for pollock, including pollock CDQ, is prohibited within 10 or 20 nm of selected Steller sea lion rookery and haulout sites in Bering Sea subarea and Bogoslof District. These sites are listed in Table 21 to this part and are identifiable by a designation of "Bering Sea" in column 2, "R" or "H" in column 7, and "Y" in column 14. The radius and time period of the closure for each site can be determined by referencing columns 10 and 11. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (a)(11)(v) of this section for fishing prohibitions.

(iv) *Steller sea lion conservation area (SCA)*—(A) *General.* Directed fishing for pollock by vessels catching pollock for processing by the inshore component, catcher/processors in the offshore component, motherships in the offshore component, or directed fishing for pollock CDQ, is prohibited within the SCA for the duration of a fishing season when the Regional Administrator announces, by notification in the **Federal Register**, that the criteria set out in paragraph (a)(11)(iv)(D) of this section have been met by that industry component.

(B) *Boundaries.* The SCA consists of the area of the Bering Sea subarea between 170°00′ W long. and 163°00′ W long., south of straight lines connecting the following points in the order listed:
55°00′ N lat. 170°00′ W long.;
55°00′ N lat. 168°00′ W long.;
55°30′ N lat. 168°00′ W long.;
55°30′ N lat. 166°00′ W long.;
56°00′ N lat. 166°00′ W long.; and,
56°00′ N lat. 163°00′ W long.

(C) *Seasons*—Subject to other provisions of this part, directed fishing for pollock within the SCA is authorized only during the following seasons:

(*1*) *A season.* From 1200 hours, A.l.t., January 20, through 1200 hours, A.l.t., April 1;

(*2*) *B season.* From 1200 hours, A.l.t., April 1, through 1200 hours, A.l.t., June 10;

(*3*) *C season.* From 1200 hours, A.l.t., June 10, through 1200 hours, A.l.t., August 20;

(*4*) *D season.* From 1200 hours, A.l.t., August 20, through 1200 hours, A.l.t., November 1.

(D) *Criteria for closure*—(*1*) *General.* The directed fishing closures identified in paragraph (a)(11)(iv)(A) of this section will take effect when the Regional Administrator determines that the harvest of a seasonal limit of pollock within the SCA reaches the amounts specified in the following table:

SEASONAL DFA APPORTIONMENT AND HARVEST LIMITS WITHIN THE SCA

[In metric tons]

Industry sector	A/B (40% of annual DFA)		C/D (60% of annual DFA)	
	A–SCA limit	B–SCA limit	C–SCA limit	D–SCA limit
Inshore	81,802	27,267	39,440	65,734
C/P	38,564	12,854	0	0
Mothership	14,607	4,869	0	0
CDQ	28,247	9,339	9,567	15,718

(*2*) *Inshore catcher vessels greater than 99 ft (30.2 m) LOA.* The Regional Administrator will prohibit directed fishing for pollock to vessels greater than 99 ft (30.2 m) LOA, catching pollock for processing by the inshore component before reaching the inshore SCA harvest limit during the A, B, and D seasons to accommodate fishing by vessels less than or equal to 99 ft (30.2 m) inside the SCA for the duration of the inshore seasonal opening. The Regional Administrator will estimate how much of the inshore seasonal allowance is likely to be harvested by catcher vessels less than or equal to 99 ft (30.2 m) LOA and reserve a sufficient amount of the inshore SCA allowance to accommodate fishing by such vessels after the closure of the SCA to inshore vessels greater than 99 ft (30.2 m) LOA. The Regional Administrator will prohibit directed fishing for all inshore catcher vessels within the SCA when the inshore limit specified in paragraph (a)(11)(iv)(E)(*1*) of this section has been met.

(v) *Steller sea lion management areas.* (A) The following sea lion management areas are established in the Bering Sea subarea and the Bogoslof district:

(*1*) *Area 7.* All waters within the SCA, as defined in 50 CFR § 679.22(a)(11)(iv)(B), east to the eastern boundary of the SCA, and west to a line connecting the point 55° 30′ N lat./166° W long. with the point 54° 51′ N lat./164° 33′ 33″ W long., including 20 nm seaward of selected sites. These sites are listed in Table 21 to this part and are identifiable by "Bering Sea" in column 2 and "7" in column 16.

(*2*) *Area 8.* All waters within the SCA, as defined in 50 CFR § 679.22(a)(11)(iv)(B), east to a line connecting the point 55° 30′ N lat./166° W long. with the point 54° 51′ N lat./164° 33′ 33″ W long., and west to the eastern boundary of area 518, as described in figure 1 of this part.

(*3*) *Area 9.* All waters within the SCA, as defined in 50 CFR § 679.22(a)(11)(iv)(B), east to the eastern boundary of area 518, as described in figure 1 of this part, west to the western boundary of area 518, as described in figure 1 of this part, and north to 55° N lat.

(B) Directed fishing for pollock and Pacific cod is prohibited in Steller sea lion management areas 8 and 9.

(C) Directed fishing for pollock and Pacific cod is prohibited within 3 nm of selected sites in Steller sea lion management area 7.

(12) *Steller sea lion protection areas, Aleutian Islands Subarea*—(Applicable through July 17, 2001.) (i) *10-nm closures.* Until 1200 hours, A.l.t., June 10, 2001, trawling is prohibited within 10 nm of selected Steller sea lion rookeries in the Aleutian Islands subarea. These rookeries are listed in Table 21 to this part and are identifiable by a designation of "Aleutian Islands" in column 2, "R" in column 7, "10 nm" in column 13, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (a)(12)(v) of this section for fishing prohibitions.

(ii) *20-nm closures.* Until 1200 hours, A.l.t., June 10, 2001, trawling is prohibited within 20 nm of selected Steller sea lion rookeries in the Aleutian Islands subarea. These rookeries are listed in Table 21 to this part and are identifiable by a designation of "Aleutian Islands" in column 2, "R" in column 7, "20 nm" in column 13, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (a)(12)(v) of this section for fishing prohibitions.

(iii) *Western and Central Aleutian Islands closures.* (A) *General.* Trawling is prohibited within 20 nm of selected rookery and haulout sites in the Aleutian Islands subarea when the Regional Administrator announces by notification in the **Federal Register** that the criteria for a trawl closure in a district set out in paragraph (a)(12)(iii)(B) of this section has been met. These sites are listed in Table 21 to this part and are identifiable by a designation of "Aleutian Islands" in column 2 and "Y" in column 14.

(B) *Criteria for closure.* The trawl closures identified in paragraph (a)(12)(iii)(A) of this section will take effect when the Regional Administrator

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determines that the harvest of a seasonal allowance of Atka mackerel specified under § 679.20(a)(8)(ii)(A) reaches the following percentages identified for each year and district:

Year	Western (543)	Central (542)
1999	65 percent	80 percent.
2000	57 percent	67 percent.
2001	48 percent	46 percent.
2002 and after.	40 percent	40 percent.

(C) *Duration of closure.* A Steller sea lion trawl closure within a district will remain in effect until NMFS closes Atka mackerel to directed fishing within the same district.

(D) *CDQ fishing.* A CDQ group is prohibited from exceeding the CDQ portion of the percentage of annual Atka mackerel in the Western and/or Central districts of the AI specified in paragraph (a)(12)(iii)(B) of this section for all sites identified in paragraph (a)(12)(iii)(A) of this section.

(iv) *Pollock closure.* Directed fishing for pollock is prohibited at all times within the Aleutian Islands subarea.

(v) *Steller sea lion management areas.* (A) The following sea lion management areas are established in the Aleutian Islands subarea:

(*1*) *Area 12.* All waters 20 nm seaward of selected sites in area 541, as described in figure 1 of this part, and all waters within the area between 52° N lat. and 53° N lat and between 173° 30′ W long. and 172° 30′ W long. These sites are listed in Table 21 to this part and are identifiable by "Aleutian Islands" in column 2 and "12" in column 16.

(*2*) *Area 13.* All waters 20 nm seaward of selected sites in area 542 and 543, as described in figure 1 of this part. These sites are listed in Table 21 to this part and are identifiable by "Aleutian Islands" in column 2 and "13" in column 16.

(B) Directed fishing for pollock, Pacific cod, and Atka mackerel is prohibited in Steller sea lion management area 13.

(C) Directed fishing for pollock, Pacific cod, and Atka mackerel by all federally permitted vessels is prohibited within 3 nm of selected sites in Steller sea lion management area 12.

(13) *No fishing zones.* (Applicable through July 17, 2001.) Until 1200 hours, A.l.t., June 10, 2001, directed fishing for groundfish by all federally permitted vessels is prohibited within 3 nm of selected Steller sea lion haulout sites in the BSAI. These sites are listed in Table 21 to this part and are identifiable by a designation "Bering Sea" or "Aleutian Islands" in column 2, "H" or "RPA" in column 7, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (a)(11)(v) of this section for fishing prohibitions in the Bering Sea subarea and the Bogoslof district and paragraph (a)(12)(v) of this section for fishing prohibitions in the Aleutian Islands subarea.

* * * * *

(b) * * *

(3) *Steller sea lion protection areas*—(Applicable through July 17, 2001.) (i) *Year-round trawl closures.* Until 1200 hours, A.l.t., June 10, 2001, trawling is prohibited within 10 nm of selected Steller sea lion rookeries in the GOA west of 144° W. longitude. These rookeries are listed in Table 21 to this part and are identifiable by a designation of "Gulf of Alaska" in column 2, "R" in column 7, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (b)(3)(iv) of this section for fishing prohibitions.

(ii) *Pollock closures.* Until 1200 hours, A.l.t., June 10, 2001, directed fishing for pollock is prohibited within 10 or 20 nm of selected Steller sea lion rookery and haulout sites in GOA west of 144° W. longitude. These sites are listed in Table 21 to this part and are identifiable by a designation of "Gulf of Alaska" in column 2, "R" or "H" in column 7, and "Y" in column 14. The radius and time period of the closure for each site can be determined by referencing columns 10 and 11. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (b)(3)(iv) of this section for fishing prohibitions.

(iii) *Shelikof Strait conservation area*—(A) *General.* Directed fishing for pollock is prohibited within the Shelikof Strait conservation area during the A and B seasons, defined at § 679.23(d)(3) of this part, when the Regional Administrator announces through notification in the **Federal Register** that the A or B season catch of pollock from within the Shelikof Strait conservation area reaches the amount determined by paragraph (b)(3)(iii)(C) of this section.

(B) *Boundaries.* The Shelikof Strait conservation area consists of the area bound by straight lines and shoreline connecting the following coordinates in the following order:

58°51′ N lat. 153°15′ W long.
58°51′ N lat. 152°00′ W long.

and the intersection of 152°00′ W long. with Afognak Island; aligned counterclockwise around the shoreline of Afognak, Kodiak, and Raspberry Islands to

57°00′ N lat. 154°00′ W long.
56°30′ N lat. 154°00′ W long.
56°30′ N lat. 155°00′ W long.
56°00′ N lat. 155°00′ W long.

and the intersection of 157°00′ W long. with the Alaska Peninsula.

(C) *Determination of TAC.* NMFS will publish the pollock TAC for the Shelikof Strait conservation area in the annual specifications pursuant to § 679.20(c). The TAC is determined by calculating a ratio equal to the most recent estimate of pollock biomass in Shelikof Strait divided by the most recent estimate of total pollock biomass in the GOA. NMFS will multiply this ratio by the overall pollock TAC for the GOA and then multiply that sum by the seasonal TAC apportionment to determine the Shelikof Strait apportionment.

(iv) *Steller sea lion management areas.* (A) The following sea lion management areas are established in the GOA:

(1) *Area 1.* All waters 20nm seaward of selected sites east to 144° W long., west to 148° 45′ W long., and excluding waters inside of areas 639 and 649, as described in Figure 3 to part. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "1" in column 16.

(*2*) *Area 2.* All waters 20nm seaward of selected sites east to 148°45′ W long., in Shelikof Strait west to 154° W long., including all waters of Shelikof Strait, and on the east side of Kodiak Island south to a line connecting the point 57°31′3″ N lat./152°17′48″ W long. with the point 57°24′36″ N lat./151°40′29″ W long. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "2" in column 16.

(*3*) *Area 3.* All waters 20 nm seaward of selected sites on the east side of Kodiak Island north to a line connecting the point 57°31′3″ N lat./152°17′48″ W long. with the point 57°24′36″ N lat./151°40′29″ W long., in Shelikof Strait east to 154° W long., including all waters of Shelikof Strait south to a line connecting the point 56° 38′ N lat./157°27′ W long. with the point 56°24′ N lat./154°41′ W long. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "3" in column 16.

(*4*) *Area 4.* All waters 20 nm seaward of selected sites north to a line connecting the point 56°38′ N lat./157°27′ W long. with the point 56°24′ N lat./154°41′ W long. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "4" in column 16.

(*5*) *Area 5.* All waters 20 nm seaward of selected sites west to 161°15′ W long. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "5" in column 16.

(*6*) *Area 6.* All waters 20 nm seaward of selected sites east to 161°15′ W long. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "6" in column 16.

(*7*) *Area 10.* All waters 20 nm seaward of selected sites in area 610, as described in Figure 3 to part. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "10" in column 16.

(*8*) *Area 11.* All waters 20 nm seaward of selected sites in area 610, as described in Figure 3 to part. These sites are listed in Table 21 to this part and are identifiable by "Gulf of Alaska" in column 2 and "11" in column 16.

(B) Directed fishing for pollock and Pacific cod is prohibited in Steller sea lion management areas 2, 4, 6, 10, and 11.

(C) Directed fishing for pollock and Pacific cod is prohibited by all federally permitted vessels is prohibited within 3 nm of selected sites in Steller sea lion management areas 1, 3, and 5.

* * * * *

(5) *No fishing zones.* (Applicable through July 17, 2001.) Until 1200 hours, A.l.t., June 10, 2001, directed fishing for groundfish by all federally permitted vessels is prohibited within 3 nm of selected Steller sea lion haulout sites in the GOA west of 144° W. longitude. These sites are listed in Table 21 to this part and are identifiable by a designation "Gulf of Alaska" in column 2, "H" or "RPA" in column 7, and "Y" in column 14. After 1200 hours, A.l.t., June 10, 2001, refer to paragraph (b)(3)(iv) of this section for fishing prohibitions.

* * * * *

9. In § 679.23, paragraphs (d)(2), (e)(2), and (e)(4)(iii) are suspended until July 17, 2001 and paragraphs (d)(3), (d)(4), (e)(4)(iv), (e)(4)(v), (e)(5), (e)(6), and (i) are added to read as follows:

§ 679.23 Seasons.

* * * * *

(d) * * *

(3) *Directed fishing for pollock.* (Applicable through July 17, 2001.) Subject to other provisions of this part, directed fishing for pollock in the Western and Central Regulatory Areas is authorized only during the following four seasons:

(i) *A season.* From 1200 hours, A.l.t., January 20, through 1200 hours, A.l.t., March 1;

(ii) *B season.* From 1200 hours, A.l.t., March 15, through 1200 hours, A.l.t., May 31;

(iii) *C season.* From 1200 hours, A.l.t., August 20, through 1200 hours, A.l.t., September 15.

(iv) *D season.* From 1200 hours, A.l.t., October 1, through 1200 hours, A.l.t., November 1.

(4) *Directed fishing for Pacific cod.* (Applicable through July 17, 2001.) (i) *Fixed gear.* Subject to other provisions of this part, directed fishing for Pacific cod with fixed gear in the Western and Central Regulatory Areas is authorized only during the following two seasons:

(A) *A season.* From 0001 hours, A.l.t., January 1, through 1200 hours, A.l.t., June 10; and

(B) *B season.* From 1200 hours, A.l.t., June 10, through 2400 hours, A.l.t., December 31.

(ii) *Trawl gear.* Subject to other provisions of this part, directed fishing for Pacific cod with trawl gear in the Western and Central Regulatory Areas is authorized only during the following two seasons:

(A) *A season.* From 1200 hours, A.l.t., January 20, through 1200 hours, A.l.t., June 10; and

(B) *B season.* From 1200 hours, A.l.t., June 10, through 2400 hours, A.l.t., December 31.

* * * * *

(e) * * *

(4) * * *

(iv) *Groundfish CDQ.* (Applicable through July 17, 2001.) Fishing for groundfish CDQ species, other than pollock CDQ, and fixed gear sablefish CDQ under subpart C of this part, is authorized from 0001 hours, A.l.t., January 1, through the end of each fishing year, except as provided under paragraph (c) of this section.

(v) *Pollock CDQ.* (Applicable through July 17, 2001.) Fishing for pollock CDQ is authorized under paragraph (e)(5)(i) of this section.

(5) *Directed fishing for pollock in the Bering Sea subarea*— (Applicable through July 17, 2001.) (i) *Inshore, offshore catcher/processor, and mothership components and pollock CDQ fisheries.* Subject to other provisions of this part, directed fishing for pollock by vessels catching pollock for processing by the inshore component, catcher/processors in the offshore component, and motherships in the offshore component in the Bering Sea subarea or directed fishing for pollock CDQ in the Bering Sea subarea is authorized only during the following two seasons:

(A) *A/B season.* From 1200 hours, A.l.t., January 20, through 1200 hours, A.l.t., June 10;

(B) *C/D season.* From 1200 hours, A.l.t., June 10, through 1200 hours, A.l.t., November 1;

(6) *Directed fishing for Pacific cod*—(Applicable through July 17, 2001.) (i) *Fixed gear.* Subject to other provisions of this part, directed fishing for Pacific cod with fixed gear in the BSAI is authorized only during the following two seasons:

(A) *A season.* From 0001 hours, A.l.t., January 1, through 1200 hours, A.l.t., June 10; and

(B) *B season.* From 1200 hours, A.l.t., June 10, through 2400 hours, A.l.t., December 31.

(ii) *Trawl gear.* Subject to other provisions of this part, directed fishing for Pacific cod with trawl gear in the BSAI is authorized only during the following two seasons:

(A) *A season.* From 1200 hours, A.l.t., January 20, through 1200 hours, A.l.t., June 10; and

(B) *B season.* From 1200 hours, A.l.t., June 10, through 2400 hours, A.l.t., November 1.

* * * * *

(i) *Catcher vessel exclusive fishing seasons for pollock.* (Applicable through July 17, 2001.) Catcher vessels are prohibited from participating in directed fishing for pollock under the following conditions. Vessels less than 125 ft (38.1 m) LOA are exempt from this restriction when fishing east of 157°00′ W. long. Bering Sea and GOA seasons are specified at § 679.23(d)(3) and § 679.23(e)(5).

If you own or operate a catcher vessel and engage in directed fishing for pollock in the. * * *	During the * * *	Then you are prohibited from subsequently engaging in directed fishing for pollock in the * * *
Bering Sea subarea	A/B season	GOA until the following C season.
	C/D season	GOA until the A season of the next year.
GOA	A season	BSAI until the following C/D season.
	B season	BSAI until the following C/D season.
	C season	BSAI until the A/B season of the following year.
	D season	BSAI until the A/B season of the following year.

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10. In § 679.50 paragraphs (c)(5) and (d)(5) are added to read as follows:

§ 679.50 Groundfish Observer Program applicable through December 31, 2001.

* * * * *

(c) * * *

(5) *AFA catcher/processors and motherships*—(Applicable through December 31, 2001.) (i) *Coverage requirement.*

(A) *Unrestricted AFA catcher/processors and AFA motherships.* The owner or operator of an unrestricted AFA catcher/processor or AFA mothership must provide at least two NMFS certified observers for each day that the vessel is used to harvest, process, or take deliveries of groundfish. More than two observers are required if the observer workload restriction at § 679.50(c)(5)(iii) would otherwise preclude sampling as required under § 679.62(a)(1).

(B) *Restricted AFA catcher/processors.* The owner or operator of a restricted AFA catcher/processor must provide at least two NMFS certified observers for each day that the vessel is used to engage in directed fishing for pollock in the BSAI, or takes deliveries of pollock harvested in the BSAI. When a restricted AFA catcher/processor is not engaged in directed fishing for BSAI pollock and is not receiving deliveries of pollock harvested in the BSAI, the observer coverage requirements at § 679.50(c)(1)(iv) apply.

(ii) *Certification level.* At least one of the observers required under paragraphs (c)(5)(i)(A) and (B) of section must be certified as a lead CDQ observer as specified in paragraph (h)(1)(i)(E)(*1*) of this section.

(iii) *Observer work load.* The time required for the observer to complete sampling, data recording, and data communication duties may not exceed 12 consecutive hours in each 24-hour period, and, the observer may not sample more than 9 hours in each 24-hour period.

* * * * *

(d) * * *

(5) *AFA inshore processors*—(Applicable through December 31, 2001.) (i) *Coverage level.* An AFA inshore processor is required to provide a NMFS certified observer for each 12 consecutive hour period of each calendar day during which the processor takes delivery of, or processes, groundfish harvested by a vessel engaged in a directed pollock fishery in the BSAI. A processor that takes delivery of or processes pollock for more than 12 consecutive hours in a calendar day is required to provide two NMFS-certified observers for each such day.

(ii) *Multiple processors.* An observer deployed to an AFA inshore processor may not be assigned to cover more than one processor during a calendar day in which the processor receives or processes pollock harvested in the BSAI directed pollock fishery.

* * * * *

11. In part 679, add subpart F to read as follows:

Subpart F—American Fisheries Act Management Measures (Applicable Through December 31, 2001)

Sec.

679.59 Authority and related regulations.
679.60 Catcher/processor and mothership pollock cooperatives.
679.61 Inshore pollock cooperatives.
679.62 Requirements for vessels and processors.
679.63 Harvest limitations in other fisheries.
679.64 AFA inshore processor and AFA mothership crab processing sideboard limits.

Subpart F—American Fisheries Act Management Measures (Applicable Through December 31, 2001)

§ 679.59 Authority and related regulations.

Regulations under this subpart were developed by the National Marine Fisheries Service and the North Pacific Fishery Management Council to implement the American Fisheries Act (AFA) [Div. C, Title II, Subtitle II, Pub. L. 105–277, 112 Stat. 2681 (1998)]. Additional regulations that implement specific provisions of the AFA are set out at § 679.2 *Definitions*, § 679.4 *Permits*, § 679.5 *Recordkeeping and reporting*, § 679.7 *Prohibitions*, § 679.20 *General limitations*, § 679.21 *Prohibited species bycatch management*, § 679.28 *Equipment and operational requirements for Catch Weight Measurement*, § 679.31 *CDQ reserves*, and § 679.50 *Groundfish Observer Program applicable through December 31, 2000.*

§ 679.60 Catcher/processor and mothership pollock cooperatives.

(a) *Applicability.* Any fishery cooperative formed under section 1 of the Act of June 25, 1934 (15 U.S.C. 521) for the purpose of cooperatively managing directed fishing for BSAI pollock for processing by catcher/processors or motherships must comply with the provisions of this section.

(b) *Filing of fishery cooperative contracts.* Any contract implementing a fishery cooperative for the purpose of cooperatively managing directed fishing for BSAI pollock for processing by catcher/processors or motherships, and any material modifications to any such contract must be filed not less than 30 days prior to the start of fishing under the contract with the Council and with the Regional Administrator, together with a copy of a letter from a party to the contract requesting a business review letter on the fishery cooperative from the Department of Justice and any response to such request. Any fishery cooperative intending to deliver pollock to an AFA mothership also must notify the owners of the AFA mothership not less than 30 days prior to the start of fishing under the contract.

(c) *Required elements.* Any cooperative contract filed under paragraph (b) of this section must contain the following information:

(1) A list of parties to the contract,

(2) A list of all vessels and processors that will harvest and process pollock harvested under the cooperative,

(3) The amount or percentage of pollock allocated to each party to the contract, and

(4) For a cooperative that includes catcher vessels delivering pollock to motherships or catcher/processors, penalties to prevent each non-exempt member catcher vessel from exceeding an individual vessel sideboard limit for each BSAI or GOA sideboard species or species group that is issued to the vessel by the cooperative in accordance with the following formula:

(i) The aggregate individual vessel sideboard limits issued to all member vessels in a cooperative must not exceed the aggregate contributions of each member vessel towards the overall groundfish sideboard amount as calculated by NMFS under § 679.63(b) and as announced to the cooperative by the Regional Administrator, or

(ii) In the case of two or more cooperatives that have entered into an inter-cooperative agreement, the aggregate individual vessel sideboard limits issued to all member vessels subject to the inter-cooperative agreement must not exceed the aggregate contributions of each member vessel towards the overall groundfish sideboard amount as calculated by NMFS under § 679.63(b) and as announced to NMFS by the Regional Administrator.

(d) *Annual report.* Any fishery cooperative governed by this section must submit annual preliminary and final written reports on fishing activity to the North Pacific Fishery Management Council, 605 West 4th Ave, Suite 306, Anchorage, AK 99501, for public distribution. The preliminary report covering activities through November 1 must be submitted by December 1 of each year and the final report must be submitted by January 31 of each year.

(1) *Required contents.* The preliminary and final written reports must contain, at a minimum:

(i) The cooperative's allocated catch of pollock and sideboard species, and any sub-allocations of pollock and sideboard species made by the cooperative to individual vessels on a vessel-by-vessel basis;

(ii) The cooperative's actual retained and discarded catch of pollock, sideboard species, and PSC on a area-by-area and vessel-by-vessel basis;

(iii) A description of the method used by the cooperative to monitor fisheries in which cooperative vessels participated; and

(iv) A description of any actions taken by the cooperative to penalize vessels that exceed their allowed catch and bycatch in pollock and all sideboard fisheries.

§ 679.61 Inshore pollock cooperatives.

(a) *Applicability.* Any fishery cooperative formed under section 1 of the Act of June 25, 1934 (15 U.S.C. 521) for the purpose of cooperatively managing directed fishing for pollock for processing by an AFA inshore processor must comply with the provisions of this section.

(b) *Filing of fishery cooperative contracts.* Any contract implementing a fishery cooperative for the purpose of cooperatively managing directed fishing for pollock for processing by an AFA inshore processor, any material modifications to any such contract, and a copy of a letter from a party to the contract requesting a business review letter on the fishery cooperative from the Department of Justice and any response to such request, must be filed with the Council and with the Regional Administrator no later than 30 days prior to the start of fishing under the contract.

(c) *Required elements.* Any cooperative contract filed under paragraph (b) of this section must contain the following:

(1) A list of parties to the contract,

(2) A list of all vessels and processors that will harvest and process pollock harvested under the cooperative,

(3) The amount or percentage of pollock allocated to each party to the contract, and

(4) Penalties to prevent each non-exempt member catcher vessel from exceeding an individual vessel sideboard limit for each BSAI or GOA groundfish sideboard species or species group that is issued to the vessel by the cooperative in accordance with the following formula:

(i) The aggregate individual vessel sideboard limits issued to all member vessels in a cooperative must not exceed the aggregate contributions of each member vessel towards the overall groundfish sideboard amount as calculated by NMFS under § 679.63(b) and as announced to the cooperative by the Regional Administrator, or

(ii) In the case of two more cooperatives that have entered into an inter-cooperative agreement, the aggregate individual vessel sideboard limits issued to all member vessels subject to the inter-cooperative agreement must not exceed the aggregate contributions of each member vessel towards the overall groundfish amount as calculated by NMFS under § 679.63(b) and as announced to NMFS by the Regional Administrator.

(d) *Responsible parties*—(1) *Designated representative.* Any cooperative formed under this section must appoint a designated representative to fulfill regulatory requirements on behalf of the cooperative including, but not limited to, the signing of cooperative fishing permit applications and completing and submitting inshore catcher vessel pollock cooperative catch reports. The owners of the member catcher vessels in the cooperative are jointly responsible for compliance and must ensure that the designated representative complies with all applicable regulations in this part.

(2) *Agent for service of process.* (i) Any cooperative formed under this section must appoint an agent who is authorized to receive and respond to any legal process issued in the United States with respect to all owners and operators of vessels listed on the cooperative fishing permit. The cooperative must provide the Regional Administrator with the name, address and telephone number of the appointed agent on the application for an inshore cooperative fishing permit. Service on or notice to the cooperative's appointed agent constitutes service on or notice to all members of the cooperative.

(ii) The owners and operators of all member vessels of an inshore pollock cooperative are responsible for ensuring that the agent is capable of accepting service on behalf of the cooperative for at least 5 years from the expiration day of the AFA permit. The owners and operators of all member vessels of a cooperative are also responsible for ensuring that a substitute agent is designated and the Agency is notified of the name, address and telephone number of the substitute representative in the event the previously designated representative is no longer capable of accepting service on behalf of the cooperative or the cooperative members within that 5-year period.

(e) *Cooperative pollock allocations.* An inshore pollock cooperative that applies for and receives an AFA inshore cooperative fishing permit under § 679.4(l)(6) will receive a sub-allocation of the annual inshore pollock allocation that is determined according to the following procedure:

(1) *Calculation of individual vessel catch histories.* The Regional Administrator will calculate an official AFA inshore cooperative catch history for every catcher vessel that made a landing of inshore pollock in the Bering Sea Subarea and/or Aleutian Islands Subarea during 1995, 1996, or 1997 according to the following steps:

(i) *Determination of annual landings.* For each year from 1995 through 1997 the Regional Administrator will determine each vessel's total inshore landings; from the Bering Sea Subarea and Aleutian Islands Subarea separately.

(ii) *Offshore compensation.* If a catcher vessel made a total of 500 or more mt of landings of Bering Sea Subarea pollock or Aleutian Islands Subarea pollock to catcher/processors or offshore motherships other than the EXCELLENCE (USCG documentation number 967502); GOLDEN ALASKA (USCG documentation number 651041); or OCEAN PHOENIX (USCG documentation number 296779) over the 3-year period from 1995 through 1997, then all offshore pollock landings made by that vessel from 1995 through 1997 will be added to the vessel's inshore catch history by year and subarea.

(iii) *Best two out of three years.* After steps (i) and (ii) are completed, the 2 years with the highest landings will be selected for each subarea and added together to generate the vessel's official AFA inshore cooperative catch history for each subarea. A vessel's best 2 years may be different for the Bering Sea subarea and the Aleutian Islands Subarea.

(2) *Calculation of cooperative quota share.* Each inshore pollock cooperative that applies for and receives an AFA inshore pollock cooperative fishing permit will receive an annual quota share percentage of pollock for each subarea of the BSAI that is equal to the sum of each member vessel's official AFA inshore cooperative catch history for that subarea divided by the sum of the official AFA inshore cooperative catch histories of all catcher vessels that made BSAI inshore pollock landings from that subarea in 1995, 1996, or 1997. The cooperative's quota share percentage will be listed on the

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cooperative's AFA pollock cooperative permit.

(3) *Conversion of quota share to annual TAC allocation.* Each inshore pollock cooperative that receives a quota share percentage for a fishing year will receive an annual allocation of Bering Sea and/or Aleutian Islands pollock that is equal to the cooperative's quota share percentage for that subarea multiplied by the annual inshore pollock allocation for that subarea. Each cooperative's annual pollock TAC allocation may be published in the interim, and final BSAI TAC specifications notices.

(f) *Cooperative fishing restrictions.* AFA inshore pollock cooperatives must comply with the following fishing restrictions.

(1) *Eligible vessels.* Only catcher vessels listed on the cooperative's AFA inshore cooperative fishing permit are permitted to harvest the cooperative's annual cooperative allocation.

(2) *Quota management.* All BSAI inshore pollock harvested by a member vessel while engaging in directed fishing for inshore pollock in the BSAI during the fishing year for which the annual cooperative allocation is in effect will accrue against the cooperative's annual pollock allocation regardless of whether the pollock was retained or discarded.

(3) *Reporting of cooperative catch.* Each inshore pollock cooperative must report to the Regional Administrator its BSAI pollock harvest on daily basis according to the recordkeeping and reporting requirements set out at § 679.5(o).

(g) *Annual report.* Any fishery cooperative governed by this section must submit annual preliminary and final written reports on fishing activity to the North Pacific Fishery Management Council, 605 West 4th Ave, Suite 306, Anchorage, AK 99501, for public distribution. The preliminary and final reports must contain the same elements and must be submitted according to the same deadlines as the preliminary and final reports required under § 679.60(d).

§ 679.62 Requirements for vessels and processors.

(a) *AFA catcher/processors and AFA motherships—(1) Unrestricted AFA catcher/processors and AFA motherships.*

(i) *Catch weighing.* All groundfish landed by unrestricted AFA catcher/processors or received by AFA motherships must be weighed on a NMFS-certified scale and made available for sampling by a NMFS certified observer. The owner and operator of an unrestricted AFA catcher/processor or an AFA mothership must ensure that the vessel is in compliance with the scale requirements described at § 679.28(b), that each groundfish haul is weighed separately, and that no sorting of catch takes place prior to weighing.

(ii) *Observer sampling station.* The owner and operator of an unrestricted AFA catcher/processor or AFA mothership must provide an observer sampling station as described at § 679.28(d) and must ensure that the vessel operator complies with the observer sampling station requirements described at § 679.28(d) at all times that the vessel harvests groundfish or receives deliveries of groundfish harvested in the BSAI or GOA.

(2) *Restricted AFA catcher/processors.* The owner or operator of a restricted AFA catcher/processor must comply with the catch weighing and observer sampling station requirements set out in paragraph (a)(1) of this section at all times the vessel is engaged in directed fishing for pollock in the BSAI.

(b) *AFA inshore processors—(1) Catch Weighing.* All groundfish landed by AFA catcher vessels engaged in directed fishing for pollock in the BSAI must be sorted and weighed on a scale approved by the State of Alaska under § 679.28(c) and be made available for sampling by a NMFS certified observer. The observer must be allowed to test any scale used to weigh groundfish in order to determine its accuracy.

(2) The plant manager or plant liaison must notify the observer of the offloading schedule for each delivery of BSAI pollock by an AFA catcher vessel at least 1 hour prior to offloading. An observer must monitor each delivery of BSAI pollock from an AFA catcher vessel and be on site the entire time the delivery is being weighed or sorted.

§ 679.63 Harvest limitations in other fisheries.

(a) *AFA catcher/processor sideboards.* The Regional Administrator will establish restrictions on the ability of unrestricted AFA catcher/processors to engage in directed fishing for BSAI groundfish species other than pollock. Such limits will be established and managed as follows:

(1) *Calculation of groundfish harvest limits.* For each groundfish species or species group in which a TAC is specified for an area or subarea of the BSAI, the Regional Administrator will establish annual AFA catcher/processor harvest limits as follows:

(i) *Pacific cod.* The Pacific cod harvest limit will be equal to the 1997 aggregate catch of Pacific cod by catcher/processors listed in paragraphs 208(e)(1) through (20) and 209 of the AFA in non-pollock target fisheries divided by the Pacific cod TAC available to catcher/processors in 1997 multiplied by the Pacific cod TAC available for harvest by catcher/processors in the year in which the harvest limit will be in effect.

(ii) *Aleutian Islands Pacific ocean perch.* The Aleutian Islands Pacific ocean perch harvest limit will be equal to the aggregate 1996 through 1997 catch of Aleutian Islands Pacific ocean perch by catcher/processors listed in paragraphs 208(e)(1) through (20) and 209 of the AFA in non-pollock target fisheries divided by the sum of the Aleutian Islands Pacific ocean perch TACs available to catcher/processors in 1996 and 1997 multiplied by the Aleutian Islands Pacific ocean perch TAC available for harvest by catcher/processors in the year in which the harvest limit will be in effect.

(iii) *Atka mackerel.* The Atka mackerel harvest limit for each area and season will be equal to:

(A) Bering Sea subarea and Eastern Aleutian Islands, zero;

(B) Central Aleutian Islands, 11.5 percent of the annual TAC specified for Atka mackerel; and

(C) Western Aleutian Islands, 20 percent of the annual TAC specified for Atka mackerel.

(iv) *Remaining groundfish species.* Except as provided for in paragraphs (a)(2)(1)(i) through (a)(2)(1)(iii) of this section, the harvest limit for each BSAI groundfish species or species group will be equal to the aggregate 1995 through 1997 catch of that species by catcher/processors listed in paragraphs 208(e)(1) through (20) and 209 of the AFA in non-pollock target fisheries divided by the sum of the TACs of that species or species group available to catcher/processors in 1995 through 1997 multiplied by the TAC of that species available for harvest by catcher/processors in the year in which the harvest limit will be in effect.

(2) *Calculation of halibut and crab PSC bycatch limits.* For each halibut or crab PSC limit specified for catcher/processors in the BSAI, the Regional Administrator will establish an annual unrestricted AFA catcher/processor PSC limit equal to the estimated aggregate 1995 through 1997 PSC bycatch of that species by catcher/processors listed in paragraphs 208(e)(1) through (20) and 209 of the AFA while engaged in directed fishing for species other than pollock divided by the aggregate PSC bycatch limit of that species for catcher/processors from 1995 through 1997 multiplied by the PSC limit of that species available to catcher/processors in the year in which the harvest limit will be in effect.

(3) *Management of AFA catcher/processor sideboard limits.* The Regional Administrator will manage groundfish harvest limits and PSC bycatch limits for AFA catcher/processors in accordance with the procedures set out in § 679.20(d)(1)(iv), and § 679.21(e)(3)(v).

(b) *AFA catcher vessel sideboards.* The Regional Administrator will establish restrictions on the ability of AFA catcher vessels to engage in directed fishing for other groundfish species in the GOA and BSAI. Such restrictions will be established and managed as follows:

(1) *Calculation of groundfish and PSC sideboards.* For each groundfish species or species group in which a TAC is specified for an area or subarea of the GOA and BSAI; and for each halibut and crab PSC limit, the Regional Administrator will establish annual AFA catcher vessel groundfish harvest limits and PSC bycatch limits as follows:

(i) *Affected vessels.* Catcher vessel harvest limits and PSC bycatch limits will apply to all AFA catcher vessels in all GOA and non-pollock BSAI groundfish fisheries except:

(A) *BSAI Pacific cod—(1)* AFA catcher vessels less than 125 ft (38.1 m) LOA that are determined by the Regional Administrator to have harvested a combined total of less than 5,100 mt of BSAI pollock, and to have made 30 or more legal landings of Pacific cod in the BSAI directed fishery for Pacific cod from 1995 through 1997 will be exempt from sideboard closures for BSAI Pacific cod.

(2) AFA catcher vessels with mothership endorsements will be exempt from BSAI Pacific cod catcher vessel sideboard directed fishing closures after March 1 of each fishing year.

(B) *GOA groundfish.* AFA catcher vessels less than 125 ft (38.1 m) LOA that are determined by the Regional Administrator to have harvested less than 5100 mt of BSAI pollock and to have made 40 or more landings of GOA groundfish from 1995 through 1997 will be exempt from GOA groundfish catcher vessel sideboard directed fishing closures.

(ii) *Calculation of BSAI and GOA groundfish harvest limits—(A) BSAI Groundfish other than BSAI Pacific cod.* The AFA catcher vessel groundfish harvest limit for each BSAI groundfish species or species group other than BSAI Pacific cod will be equal to the aggregate retained catch of that groundfish species or species group from 1995 through 1997 by AFA catcher vessels not exempted under § 679.63(b)(1)(i)(A)*(1)*; divided by the sum of the TACs available to catcher vessels for that species or species group from 1995 through 1997; multiplied by the TAC available to catcher vessels in the year or season in which the harvest limit will be in effect.

(B) *BSAI Pacific cod.* The AFA catcher vessel groundfish harvest limit for BSAI Pacific cod will be equal to the retained catch of BSAI Pacific cod in 1997 by AFA catcher vessels not exempted under § 679.63(b)(1)(i)(A)*(1)* divided by the BSAI Pacific cod TAC available to catcher vessels in 1997; multiplied by the BSAI Pacific cod TAC available to catcher vessels in the year or season in which the harvest limit will be in effect.

(C) *GOA groundfish.* The AFA catcher vessel groundfish harvest limit for each GOA groundfish species or species group will be equal to the aggregate retained catch of that groundfish species or species group from 1995 through 1997 by AFA catcher vessels not exempted under § 679.63(b)(1)(i)(B); divided by the sum of the TACs of that species or species group available to catcher vessels from 1995 through 1997; multiplied by the TAC available to catcher vessels in the year or season in which the harvest limit will be in effect.

(iii) *Calculation of BSAI and GOA PSC bycatch limits.* The AFA catcher vessel PSC bycatch limit for halibut in the BSAI and GOA, and each crab species in the BSAI for which a trawl bycatch limit has been established will be a portion of the PSC limit equal to the ratio of aggregate retained groundfish catch by AFA catcher vessels in each PSC target category from 1995 through 1997 relative to the retained catch of all vessels in that fishery from 1995 through 1997.

(iv) *Management of AFA catcher vessel sideboard limits.* The Regional Administrator will manage groundfish harvest limits and PSC bycatch limits for AFA catcher vessels using directed fishing closures and PSC closures according to the procedures set out at § 679.20(d)(1)(iv), § 679.21(d)(8), and § 679.21(e)(3)(v).

§ 679.64 AFA inshore processor and AFA mothership crab processing sideboard limits.

(a) *Applicability.* The crab processing limits in this section apply to any AFA inshore or mothership entity that receives pollock harvested in the BSAI directed pollock fishery by a fishery cooperative established under § 679.60 or § 679.61.

(b) *Calculation of crab processing sideboard limits.* Upon receipt of an application for a cooperative processing endorsement from the owners of an AFA mothership or AFA inshore processor, the Regional Administrator will calculate a crab processing cap percentage for the associated AFA inshore or mothership entity. The crab processing cap percentage for each BSAI king or Tanner crab species will be equal to the percentage of the total catch of each BSAI king or Tanner crab species that the AFA crab facilities associated with the AFA inshore or mothership entity processed in the aggregate, on average, in 1995, 1996, and 1997.

(c) *Notification of crab processing sideboard percentage limits.* An AFA inshore or mothership entity's crab processing cap percentage for each BSAI king or Tanner crab species will be listed on each AFA mothership or AFA inshore processor permit that contains a cooperative pollock processing endorsement.

(d) *Conversion of crab processing sideboard percentages and notification of crab processing sideboard poundage caps.* Prior to the start of each BSAI king or Tanner crab fishery, NMFS will convert each AFA inshore or mothership entity's crab processing sideboard percentage to a poundage cap by multiplying the crab processing sideboard percentage by the pre-season guideline harvest level established for that crab fishery by ADF&G. The Regional Administrator will notify each AFA inshore or mothership entity of its crab processing sideboard poundage cap through a letter to the owner of the AFA mothership or AFA inshore processor and by publishing the crab processing poundage caps on the NMFS-Alaska Region world wide web home page (http://www.fakr.noaa.gov).

(e) *Overages.* In the event that the actual harvest of a BSAI crab species exceeds the pre-season Guideline harvest level (GHL) announced for that species, an AFA inshore or mothership entity may exceed its crab processing cap without penalty up to an amount equal to the AFA inshore or mothership entity's crab processing percentage multiplied by the final official harvest amount of that crab species as determined by ADF&G and announced by NMFS on the NMFS-Alaska Region world wide web home page (http://www.fakr.noaa.gov).

12. In 50 CFR part 679, Tables 12, 13, and 20 to part 679 are suspended, and Table 21 to part 679 is added to read as follows:

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TABLE 21 TO 50 CFR PART 679 STELLER SEA LION PROTECTION AREAS IN THE BERING SEA, ALEUTIAN ISLANDS AND GULF OF ALASKA

Site name	Management region	Boundaries from		Boundaries to		ESA listed or RPA*	No transit zone 3 nm	Critical habitat nm
		Latitude (N)	Longitude (W)	Latitude (N)	Longitude (W)			
St. Lawrence I./S Punuk I.	Bering Sea	63 04.00 N	168 51.00 W			H		20
St. Lawrence I./SW Cape.	Bering Sea	63 18.00 N	171 26.00 W			H		20
Hall I	Bering Sea	60 37.00 N	173 00.00 W			H		20
St Paul I./Sea Lion Rock.	Bering Sea	57 06.00 N	170 17.50 W			H		20
St Paul I./NE Pt	Bering Sea	57 15.00 N	170 06.50 W			H		20
Walrus I. (Pribilofs)	Bering Sea	57 11.00 N	169 56.00 W			R	3	20
St. George I/Dalnoi Pt..	Bering Sea	56 36.00 N	169 46.00 W			H		20
St. George I./S Rookery.	Bering Sea	56 33.50 N	169 40.00 W			H		20
Cape Newenham	Bering Sea	58 39.00 N	162 10.50 W			H		20
Round (Walrus Islands).	Bering Sea	58 36.00 N	159 58.00 W			H		20
Attu I./Cape Wrangell	Aleutian Islands	52 54.60 N	172 27.90 E	52 55.40 N	172 27.20 E	R	3	20
Agattu I./Gillon Pt	Aleutian Islands	52 24.13 N	173 21.31 E			R	3	20
Attu I./Chirikof Pt	Aleutian Islands	52 49.75 N	173 26.00 E			H		20
Agattu I./Cape Sabak	Aleutian Islands	52 22.50 N	173 43.30 E	52 21.80 N	173 41.40 E	R	3	20
Alaid I	Aleutian Islands	52 46.50 N	173 51.50 E	52 45.00 N	173 56.50 E	H		20
Shemya I	Aleutian Islands	52 44.00 N	174 08.70 E			H		20
Buldir I	Aleutian Islands	52 20.25 N	175 54.03 E	52 20.38 N	175 53.85 E	R	3	20
Kiska I./Cape St. Stephen.	Aleutian Islands	51 52.50 N	177 12.70 E	51 53.50 N	177 12.00 E	R	3	20
Kiska I./Sobaka & Vega.	Aleutian Islands	51 49.50 N	177 19.00 E	51 48.50 N	177 20.50 E	H		20
Kiska I./Lief Cove	Aleutian Islands	51 57.16 N	177 20.41 E	51 57.24 N	177 20.53 E	R	3	20
Kiska I./Sirius Pt.	Aleutian Islands	52 08.50 N	177 36.50 E			H		20
Tanadak I. (Kiska)	Aleutian Islands	51 56.80 N	177 46.80 E			H		20
Segula I.	Aleutian Islands	51 59.90 N	178 05.80 E	52 03.06 N	178 08.80 E	H		20
Ayugadak Point	Aleutian Islands	51 45.36 N	178 24.30 E			R	3	20
Rat I./Krysi Pt	Aleutian Islands	51 49.98 N	178 12.35 E			RPA		
Little Sitkin I.	Aleutian Islands	51 59.30 N	178 29.80 E			H		20
Amchitka I./Column Rocks.	Aleutian Islands	51 32.32 N	178 49.28 E			R	3	20
Amchitka I./East Cape.	Aleutian Islands	51 22.26 N	179 27.93 E	51 22.00 N	179 27.00 E	R	3	20
Amchitka I./Cape Ivakin.	Aleutian Islands	51 24.46 N	179 24.21 E			RPA		
Semisopochnoi/Petrel Pt.	Aleutian Islands	52 01.40 N	179 36.90 E	52 01.50 N	179 39.00 E	R	3	20
Semisopochnoi I./Pochnoi Pt.	Aleutian Islands	51 57.30 N	179 46.00 E			R	3	20
Amatignak I./Nitrof Pt	Aleutian Islands	51 13.00 N	179 07.80 W			H		20
Unalga & Dinkum Rocks.	Aleutian Islands	51 33.67 N	179 04.25 W	51 35.09 N	179 03.66 W	H		20
Ulak I./Hasgox Pt	Aleutian Islands	51 18.90 N	178 58.90 W	51 18.70 N	178 59.60 W	R	3	20
Kavalga I	Aleutian Islands	51 34.50 N	178 51.73 W	51 34.50 N	178 49.50 W	H		20
Tag I	Aleutian Islands	51 33.50 N	178 34.50 W			R	3	20
Ugidak I	Aleutian Islands	51 34.95 N	178 30.45 W			H		20
Gramp Rock	Aleutian Islands	51 28.87 N	178 20.58 W			R	3	20
Tanaga I./Bumpy Pt	Aleutian Islands	51 55.00 N	177 58.50 W	51 55.00 N	177 57.10 W	H		20
Bobrof I.	Aleutian Islands	51 54.00 N	177 27.00 W			H		20
Kanaga I./Ship Rock	Aleutian Islands	51 46.70 N	177 20.72 W			H		20
Kanaga I./North Cape	Aleutian Islands	51 56.50 N	177 09.00 W			H		20
Adak I	Aleutian Islands	51 35.50 N	176 57.10 W	51 37.40 N	176 59.60 W	R	3	20
Little Tanaga Strait	Aleutian Islands	51 49.09 N	176 13.90 W			H		20
Great Sitkin I	Aleutian Islands	52 06.00 N	176 10.50 W	52 07.00 N	176 07.00 W	H		20
Anagakalk I	Aleutian Islands	51 50.86 N	175 53.00 W			H		20
Kasatochi I	Aleutian Islands	52 11.11 N	175 31.00 W			R	3	20
Atka I./N. Cape	Aleutian Islands	52 24.20 N	174 17.80 W			H		20
Amlia I./Sviech. Harbor.	Aleutian Islands	52 01.80 N	173 23.90 W			H		20
Segigik I	Aleutian Islands	52 00.50 N	173 09.30 W			H		20
Amlia I./East	Aleutian Islands	52 05.70 N	172 59.00 W	52 05.75 N	172 57.50 W	H		20
Tanadak I. (Amlia)	Aleutian Islands	52 04.20 N	172 57.60 W			H	20	

TABLE 21 TO 50 CFR PART 679 STELLER SEA LION PROTECTION AREAS IN THE BERING SEA, ALEUTIAN ISLANDS AND GULF OF ALASKA—Continued

Site name	Management region	Boundaries from		Boundaries to		ESA listed or RPA*	No transit zone 3 nm	Critical habitat nm
		Latitude (N)	Longitude (W)	Latitude (N)	Longitude (W)			
Agligadak I	Aleutian Islands	52 06.09 N	172 54.23 W			R	3	20
Seguam I./Saddleridge Pt.	Aleutian Islands	52 21.05 N	172 34.40 W	52 21.02 N	172 33.60 W	R	3	20
Seguam I./Finch Pt	Aleutian Islands	52 23.40 N	172 27.70 W	52 23.25 N	172 24.30 W	H		20
Seguam I./South Side	Aleutian Islands	52 21.60 N	172 19.30 W	52 15.55 N	172 31.22 W	H		20
Amukta I. & Rocks	Aleutian Islands	52 27.25 N	171 17.90 W			H		20
Chagulak I	Aleutian Islands	52 34.00 N	171 10.50 W			H		20
Yunaska I	Aleutian Islands	52 41.40 N	170 36.35 W			R	3	20
Uliaga	Bering Sea	53 04.00 N	169 47.00 W	53 05.00 N	169 46.00 W	H		
Chuginadak	Gulf of Alaska	52 46.70 N	169 41.90 W			H		20
Kagamil	Bering Sea	53 02.10 N	169 41.00 W			H		20
Samalga	Gulf of Alaska	52 46.00 N	169 15.00 W			RPA		
Adugak I	Bering Sea	52 54.70 N	169 10.50 W			R	3	20
Umnak I./Cape Asiik	Bering Sea	53 25.00 N	168 24.50 W			H		20
Ogchul I	Gulf of Alaska	52 59.71 N	168 24.24 W			R	3	20
Bogoslof I./Fire Island	Bering Sea	53 55.69 N	168 02.05 W			R	3	20
Polivnoi Rock	Gulf of Alaska	53 15.96 N	167 57.99 W			H		20
Emerald I	Gulf of Alaska	53 17.50 N	167 51.50 W			H		20
Unalaska/Cape Izigan	Gulf of Alaska	53 13.64 N	167 39.37 W			RPA		
Unalaska/Bishop Pt	Bering Sea	53 58.40 N	166 57.50 W			RPA		
Akutan I./Reef-lava	Bering Sea	54 08.10 N	166 06.19 W	54 09.10 N	166 05.50 W	H		20
Unalaska I./Cape Sedanka.	Gulf of Alaska	53 50.50 N	166 05.00 W			H		20
Old Man Rocks	Gulf of Alaska	53 52.20 N	166 04.90 W			H		20
Akutan I./Cape Morgan.	Gulf of Alaska	54 03.39 N	165 59.65 W	54 03.70 N	166 03.68 W	R	3	20
Akun I./Billings Head	Bering Sea	54 17.62 N	165 32.06 W	54 17.57 N	165 31.71 W	R	3	20
Rootok	Gulf of Alaska	54 03.90 N	165 31.90 W	54 02.90 N	165 29.50 W	RPA		
Tanginak I	Gulf of Alaska	54 12.00 N	165 19.40 W			H		20
Tigalda/Rocks NE	Gulf of Alaska	54 09.60 N	164 59.00 W	54 09.12 N	164 57.18 W	H		20
Unimak/Cape Sarichef.	Bering Sea	54 34.30 N	164 56.80 W			RPA		
Aiktak	Gulf of Alaska	54 10.99 N	164 51.15 W			RPA		
Ugamak I	Gulf of Alaska	54 13.50 N	164 47.50 W	54 12.80 N	164 47.50 W	R	3	20
Round (GOA)	Gulf of Alaska	54 12.05 N	164 46.60 W			RPA		
Sea Lion Rock (Amak).	Bering Sea	55 27.82 N	163 12.10 W			R	3	20
Amak I. and rocks	Bering Sea	55 24.20 N	163 09.60 W	55 26.15 N	163 08.50 W	H		20
Bird I	Gulf of Alaska	54 40.00 N	163 17.15 W			H		20
Caton I	Gulf of Alaska	54 22.70 N	162 21.30 W			H		20
South Rocks	Gulf of Alaska	54 18.14 N	162 41.25 W			H		20
Clubbing Rocks (S)	Gulf of Alaska	54 41.98 N	162 26.74 W			R	3	20
Clubbing Rocks (N)	Gulf of Alaska	54 42.75 N	162 26.72 W			R	3	20
Pinnacle Rock	Gulf of Alaska	54 46.06 N	161 45.85 W			R	3	20
Sushilnoi Rocks	Gulf of Alaska	54 49.30 N	161 42.73 W			RPA		
Olga Rocks	Gulf of Alaska	55 00.45 N	161 29.81 W	54 59.09 N	161 30.89 W	RPA		
Jude I	Gulf of Alaska	55 15.75 N	161 06.27 W			H		20
Sea Lion Rocks (Shumagins).	Gulf of Alaska	55 04.70 N	160 31.04 W			H		20
Nagai I./Mountain Pt	Gulf of Alaska	54 54.20 N	160 15.40 W	54 56.00 N	160 15.00 W	H		20
The Whaleback	Gulf of Alaska	55 16.82 N	160 05.04 W			H		20
Chernabura I	Gulf of Alaska	54 45.18 N	159 32.99 W	54 45.87 N	159 35.74 W	R	3	20
Castle Rock	Gulf of Alaska	55 16.47 N	159 29.77 W			H		20
Atkins I	Gulf of Alaska	55 03.20 N	159 17.40 W			R	3	20
Spitz I	Gulf of Alaska	55 46.60 N	158 53.90 W			H		20
Mitrofania	Gulf of Alaska	55 50.20 N	158 41.90 W			RPA		
Kak	Gulf of Alaska	56 17.30 N	157 50.10 W			RPA		
Lighthouse Rocks	Gulf of Alaska	55 46.79 N	157 24.89 W			H		20
Sutwik I	Gulf of Alaska	56 31.05 N	157 20.47 W	56 32.00 N	157 21.00 W	H		20
Chowiet I	Gulf of Alaska	56 00.54 N	156 41.42 W	56 00.30 N	156 41.60 W	R	3	20
Nagai Rocks	Gulf of Alaska	55 49.80 N	155 47.50 W			H		20
Chirikof I	Gulf of Alaska	55 46.50 N	155 39.50 W	55 46.44 N	155 43.46 W	R	3	20
Puale Bay	Gulf of Alaska	57 40.60 N	155 23.10 W			H		20
Kodiak/Cape Ikoliik	Gulf of Alaska	57 17.20 N	154 47.50 W			H		20
Takli I	Gulf of Alaska	58 01.75 N	154 31.25 W			H		20
Cape Kuliak	Gulf of Alaska	58 08.00 N	154 12.50 W			H		20
Cape Gull	Gulf of Alaska	58 11.50 N	154 09.60 W	58 12.50 N	154 10.50 W	H		20

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TABLE 21 TO 50 CFR PART 679 STELLER SEA LION PROTECTION AREAS IN THE BERING SEA, ALEUTIAN ISLANDS AND GULF OF ALASKA—Continued

Site name	Management region	Boundaries from		Boundaries to		ESA listed or RPA*	No transit zone 3 nm	Critical habitat nm
		Latitude (N)	Longitude (W)	Latitude (N)	Longitude (W)			
Kodiak/Cape Ugat	Gulf of Alaska	57 52.41 N	153 50.97 W			H		20
Sitkinak/Cape Sitkinak.	Gulf of Alaska	56 34.30 N	153 50.96 W			H		20
Shakun Rock	Gulf of Alaska	58 32.80 N	153 41.50 W			H		20
Twoheaded I	Gulf of Alaska	56 54.50 N	153 32.75 W	56 53.90 N	153 33.74 W	H		20
Cape Douglas (Shaw I.).	Gulf of Alaska	59 00.00 N	153 22.50 W			RPA		
Kodiak/Cape Barnabas.	Gulf of Alaska	57 10.20 N	152 53.05 W			H		20
Kodiak/Gull Point	Gulf of Alaska	57 21.45 N	152 36.30 W			H		20
Latax Rocks	Gulf of Alaska	58 40.10 N	152 31.30 W			H		20
Ushagat I./SW	Gulf of Alaska	58 54.75 N	152 22.20 W			H		20
Ugak I	Gulf of Alaska	57 23.60 N	152 17.50 W	57 21.90 N	152 17.40 W	H		20
Sea Otter I	Gulf of Alaska	58 31.15 N	152 13.30 W			H		20
Long I	Gulf of Alaska	57 46.82 N	152 12.90 W			H		20
Sud I	Gulf of Alaska	58 54.00 N	152 12.50 W			H		20
Kodiak/Cape Chiniak	Gulf of Alaska	57 37.90 N	152 08.25 W			H		20
Sugarloaf I	Gulf of Alaska	58 53.25 N	152 02.40 W			R	3	20
Sea Lion Rocks (Marmot).	Gulf of Alaska	58 20.53 N	151 48.83 W			H		20
Marmot I	Gulf of Alaska	58 13.65 N	151 47.75 W	58 09.90 N	151 52.06 W	R	3	20
Nagahut Rocks	Gulf of Alaska	59 06.00 N	151 46.30 W			H		20
Perl	Gulf of Alaska	59 05.75 N	151 39.75 W			RPA		
Gore Point	Gulf of Alaska	59 12.00 N	150 58.00 W			H		20
Outer (Pye) I	Gulf of Alaska	59 20.50 N	150 23.00 W	59 21.00 N	150 24.50 W	R	3	20
Steep Point	Gulf of Alaska	59 29.05 N	150 15.40 W			RPA		
Seal Rocks (Kenai)	Gulf of Alaska	59 31.20 N	149 37.50 W			H	see note	20
Chiswell Islands	Gulf of Alaska	59 36.00 N	149 34.00 W			H		20
Rugged Island	Gulf of Alaska	59 49.80 N	149 23.30 W	59 51.00 N	149 25.30 W	RPA		
Point Elrington	Gulf of Alaska	59 56.00 N	148 15.20 W			H		20
Perry I	Gulf of Alaska	60 44.00 N	147 54.60 W			H		20
The Needle	Gulf of Alaska	60 06.64 N	147 38.17 W			H		20
Point Eleanor	Gulf of Alaska	60 35.00 N	147 34.00 W			H		20
Wooded I. (Fish I.)	Gulf of Alaska	59 52.90 N	147 20.65 W			R	see note	20
Glacier Island	Gulf of Alaska	60 51.30 N	147 14.50 W			RPA		
Seal Rocks (Cordova).	Gulf of Alaska	60 09.78 N	146 50.30 W			R	see note	20
Cape Hinchinbrook	Gulf of Alaska	60 14.00 N	146 38.50 W			RPA		
Middleton I	Gulf of Alaska	59 28.30 N	146 18.80 W			H		20
Hook Point	Gulf of Alaska	60 20.00 N	146 15.60 W			H		20
Cape St. Elias	Gulf of Alaska	59 47.50 N	144 36.20 W			H		20
Cape Fairweather	Gulf of Alaska	58 47.50 N	137 56.30 W			H		
Graves Rock	Gulf of Alaska	58 14.30 N	136 45.40 W			H		

*RPA sites meet the criteria in the 1998 Biological Opinion for the protection of Steller sea lions but are not listed in 50 CFR part 226. These sites are not included in closures of critical habitat in the Aleutian Islands subarea upon attainment of critical habitat limits specified for the Aleutian Islands Atka mackerel fishery.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 010111009–1009–01; I.D. 122600A]

RIN 0648–AO72

Fisheries of the Exclusive Economic Zone Off Alaska; Emergency Interim Rule to Revise Certain Provisions of the American Fisheries Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Emergency interim rule; request for comments.

SUMMARY: NMFS issues emergency interim regulations to supersede certain provisions of the American Fisheries Act (AFA). The elements of this emergency interim rule include a revised definition of "qualified catcher vessel" for the purpose of determining eligibility for inshore cooperatives, a revised formula to allocate the Bering Sea and Aleutian Islands Management Area (BSAI) pollock total allowable catch (TAC) among inshore cooperatives, a revised formula for establishing crab processing sideboard limits, revised observer coverage requirements for catcher/processors and motherships participating in the AFA and Community Development Quota program (CDQ) pollock fisheries, and revised authority to publish and manage AFA catcher/processors and AFA catcher vessel groundfish harvesting sideboards. This action is necessary to implement requirements of the AFA for the 2001 fishing year. The intended effect of this action is to further the socioeconomic objectives of the AFA.

DATES: Effective January 18, 2001 through July 17, 2001. Comments on this emergency interim rule must be received by February 21, 2001.

ADDRESSES: Comments must be sent to Sue Salveson, Assistant Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel, or delivered to Federal Building, Fourth Floor, 709 West 9th Street, Juneau, AK, and marked Attn: Lori Gravel. Comments may also be sent via facsimile (fax) to (907) 586-7465. Comments will not be accepted if sent by e-mail. Copies of the Environmental Assessment/Regulatory Impact Review (EA/RIR) prepared for this action may be obtained from Alaska Region, NMFS.

FOR FURTHER INFORMATION CONTACT: Kent Lind, 907-586-7228 or kent.lind@noaa.gov

SUPPLEMENTARY INFORMATION: NMFS manages the U.S. groundfish fisheries in the exclusive economic zone (EEZ) of the BSAI and Gulf of Alaska (GOA) under the fishery management plans (FMPs) for groundfish in the respective areas. With Federal oversight, the State of Alaska manages the commercial king crab and Tanner crab fisheries in the BSAI and the commercial scallop fishery off Alaska under the FMPs for those fisheries. The North Pacific Fishery Management Council (Council) prepared, and NMFS approved, the FMPs under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.* Regulations implementing the FMPs appear at 50 CFR part 679. General regulations governing U.S. fisheries also appear at 50 CFR part 600.

American Fisheries Act—Background Information

The AFA (Div. C, Title II, Subtitle II, Pub. L. No. 105-277, 112 Stat. 2681 (1998)) enacted on October 21, 1998, made profound changes to the BSAI pollock fishery and, to a lesser extent, to the groundfish and crab fisheries within the EEZ off Alaska. The major provisions of the AFA were implemented on an interim basis by emergency rule published January 28, 2000 (65 FR 4520, extended 65 FR 39107, June 23, 2000). Detailed information on the AFA may be found in the January 2000 emergency interim rule and in the EA/RIR developed for that emergency interim rule. The Council has prepared FMP Amendments 61/61/13/8 to implement the major provisions of the AFA (Amendment 61 to the FMP for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area, Amendment 61 to the FMP for Groundfish of the Gulf of Alaska, Amendment 13 to the FMP for the King and Tanner Crab Fisheries in the Bering Sea/Aleutian Islands, and Amendment 8 to the FMP for the Scallop Fishery off Alaska). If the amendments are approved, implementing regulations are expected to be effective by mid-2001. This emergency interim rule gives immediate effect to certain revisions necessary for the start of the groundfish fisheries in 2001.

Development of Emergency Interim Rule

The measures contained in this emergency interim rule were developed over the course of several Council meetings held June through October 2000.

In June 2000, the Council examined the AFA definition of "qualified catcher vessel" in paragraph 210(b)(3) of the AFA and recommended that the definition be superseded by the revision contained in this emergency interim rule to allow a retired or inactive vessel to maintain membership in an inshore cooperative. In addition, the Council examined the AFA formula used to establish allocations for inshore cooperatives and the inshore "open access" fishery and recommended that the formula be superseded by a new formula set out in this emergency interim rule.

In September 2000, the Council examined proposed changes to crab processing sideboard limits and adopted a revision to the years used to calculate crab processing sideboard amounts by using 1995 through 1998 to determine crab processing history and counting the 1998 processing year twice (double weight).

In October 2000, the Council reviewed the implementation schedule for Amendments 61/61/13/8 and determined that its previous recommendations with respect to the definition of "qualified catcher vessel," the inshore cooperative allocation formula, and the crab processing sideboard limits should be implemented by emergency interim rule in order to be effective by the start of the 2001 pollock fishery. In addition, the Council recommended that the change in observer coverage for catcher/processors and motherships participating in the pollock CDQ fishery should be revised. These recommendations, along with the 2001 catcher/processor and catcher vessel harvesting sideboards publishing authority, comprise the elements of this action.

This emergency interim rule would be superseded by the final rule to implement FMP Amendments 61/61/13/8, if such a final rule is approved by NMFS. FMP Amendments 61/61/13/8 supersede some of the requirements found in the AFA. All the management measures implemented by this emergency interim rule are the same as a number of the management measures in FMP Amendments 61/61/13/8. The primary five elements of this emergency interim rule are summarized below.

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1. Definition of Qualified Catcher Vessel

In June 2000, the Council adopted a definition of "qualified catcher vessel" that would supersede the definition contained in the AFA. Paragraph 210(b)(3) of the AFA currently defines "qualified catcher vessel" as follows:

QUALIFIED CATCHER VESSEL. For the purposes of this subsection, a catcher vessel shall be considered a "qualified catcher vessel" if, during the year prior to the year in which the fishery cooperative will be in effect, it delivered more pollock to the shoreside processor to which it will deliver pollock under the fishery cooperative in paragraph (1) than to any other shoreside processor.

This definition effectively prevents the retirement of catcher vessels that are no longer needed to harvest a cooperative's annual allocation of pollock because each vessel is required to make a qualifying landing every year to remain in a cooperative in each subsequent year. The Council is recommending that this definition be replaced with a new definition of "qualified catcher vessel." Under this new definition, an inactive vessel would remain qualified to join the cooperative that is associated with the processor to which it delivered more pollock than any other inshore processor during the last year in which the vessel participated in the inshore sector of the BSAI- directed pollock fishery. The Council's recommended change would not affect vessels that were active in the BSAI pollock fishery during the year prior to the year in which the cooperative fishing permit will be in effect.

The Council derives its authority to supersede certain provisions of the AFA and to recommend an alternative definition of "qualified catcher vessel" from paragraph 213(c)(1) of the AFA. Paragraph 213(c)(1) provides that:

CHANGES TO FISHERY COOPERATIVE LIMITATIONS AND POLLOCK CDQ ALLOCATION. The North Pacific Council may recommend and the Secretary may approve conservation and management measures in accordance with the Magnuson-Stevens Act—

(1) that supersede the provisions of this title, except for sections 206 and 208, for conservation purposes or to mitigate adverse effects in fisheries or on owners of fewer than three vessels in the directed pollock fishery caused by this title or fishery cooperatives in the directed pollock fishery, provided such measures take into account all factors affecting the fisheries and are imposed fairly and equitably to the extent practicable among and within the sectors in the directed pollock fishery;

In making the recommendation to supersede the AFA definition of "qualified catcher vessel," the Council determined that this change meets the criteria set out in paragraph 213(c)(1) of the AFA because the action would mitigate adverse effects on owners of fewer than three catcher vessels in the directed pollock fishery. Such vessels are smaller, on average, than the processor-owned catcher vessel fleets, and most of the smallest AFA catcher vessels are independently owned. Many of these smaller independently owned vessels may be less safe to operate in the wintertime at great distances from shore under new Steller sea lion protection measures that have restricted fishing in most nearshore areas to protect Steller sea lion critical habitat (65 FR 3892, January 25, 2000, extended 65 FR 36795, June 12, 2000). Maintaining the existing requirement that all such vessels fish each year to remain qualified to join a cooperative each following year could force small catcher vessel owners to take unnecessary risks.

In addition, some catcher vessels that are eligible to fish for pollock under the AFA have since been lost or may no longer be safe to operate without major rebuilding. Under this change, the owners of such vessels could remain in cooperatives without the need to rebuild or deploy new vessels into the BSAI pollock fishery. In making this recommendation, the Council noted that a primary objective of the AFA is to reduce excess capacity in the BSAI pollock fishery and that changing the definition of "qualified catcher vessel" will further that objective.

Finally, the Council determined that special circumstances existed in the fishery that made immediate emergency action necessary. During the 2000 fishery, the owners of a number of smaller AFA catcher vessels had intended to fish for BSAI pollock during the C/D season in order to qualify for cooperatives. However, on August 7, 2000, the United States District Court for the Western District of Washington issued an Order enjoining all groundfish trawling within Steller sea lion critical habitat west of 144° W. long. until further order of the Court. The injunction became effective at 11 a.m. Alaska time on August 8, 2000. As a result of the injunction prohibiting trawling in critical habitat, the owners of many of the smaller AFA catcher vessels chose not to fish during the C/D season due to the distances from shore required to fish under the injunction. These vessel owners believed that the Council's action to supersede the AFA definition of qualified catcher vessel would allow them to maintain membership in their cooperatives without the need to participate in the 2000 C/D season under the injunction. The Council noted that emergency action would be required to allow such vessels to remain in cooperatives for the 2001 fishing year and determined that such emergency action was warranted, given the extraordinary and unforseen circumstances of the injunction.

2. Inshore Cooperative Allocations

Subparagraph 210(b)(1)(B) of the AFA sets out a specific formula for determining the allocation of pollock to each inshore cooperative as follows:

...the Secretary shall allow only such catcher vessels...to harvest the aggregate percentage of the directed fishing allowance under section 206(b)(1) in the year in which the fishery cooperative will be in effect that is equivalent to the aggregate total amount of pollock harvested by such catcher vessels...in the directed pollock fishery for processing by the inshore component during 1995, 1996, and 1997 relative to the aggregate total amount of pollock harvested in the directed pollock fishery for processing by the inshore component during such years and shall prevent such catcher vessels...from harvesting in aggregate in excess of such percentage of such directed fishing allowance.

In other words, under the AFA, each inshore cooperative's pollock allocation is a percentage of the inshore sector allocation that is equal to the aggregate inshore landings by all member vessels in the cooperative from 1995 through 1997 relative to the total inshore landings during that period.

However, paragraph 213(c)(3) of the AFA provides the Council with the authority to recommend an alternative allocation formula:

The North Pacific Council may recommend and the Secretary may approve conservation and management measures in accordance with the Magnuson-Stevens Act...that supersede the criteria required in paragraph (1) of section 210(b) to be used by the Secretary to set the percentage allowed to be harvested by catcher vessels pursuant to a fishery cooperative under such paragraph.

Using this authority, the Council is recommending three changes that would supersede the inshore cooperative allocation formula set out in the AFA. These changes are contained in this emergency interim rule and described below.

a. *Offshore compensation.* The first change would allow inshore catcher vessels to receive inshore catch history credit for landings made to catcher/processors if the vessel made cumulative landings to catcher/processors of more than 499 mt of BSAI pollock during the 1995 through 1997 qualifying period. The Council is recommending this change to assist the cooperatives in meeting the intent of paragraph 210(b)(4) of the AFA, which requires that:

Any contract implementing a fishery cooperative under paragraph (1) which has been entered into by the owner of a qualified catcher vessel eligible under section 208(a) that harvested pollock for processing by catcher/processors or motherships in the directed pollock fishery during 1995, 1996, and 1997 shall, to the extent practicable, provide fair and equitable terms and conditions for the owner of such qualified catcher vessel.

The Council believes that catcher vessels with sustained participation delivering to catcher/processors, but excluded from delivering to catcher/processors under subsection 208(b) of the AFA, should not be disadvantaged by the new management regime. The Council chose 499 mt as the threshold based on information presented in an analysis, which indicated that 499 mt provided a reasonable distinction between vessels with significant history of delivering to catcher/processors and vessels that had only incidental deliveries to catcher/processors during the 1995 through 1997 qualifying period. Only deliveries to catcher/processors would be considered for such "compensation" and not deliveries made to the three motherships listed in subsection 208(d) of the AFA because any vessel with more than 250 mt of pollock deliveries to one of the three AFA motherships during the qualifying period earned an endorsement to deliver pollock to AFA motherships under the AFA and "lost" no fishing privileges as a result of the AFA.

b. *Using the best 2 of 3 years from 1995-1997.* The second change would modify the allocation formula so that the share of the BSAI pollock TAC that each catcher vessel brings into a cooperative would be based on average annual pollock landings in its best 2 out of 3 years from 1995 through 1997. This change, along with the offshore compensation formula, was unanimously endorsed by industry representatives during public testimony. These changes are viewed as a more equitable method of allocating pollock catch because some vessels may have missed all or part of the inshore fishery in a given year due to such unavoidable circumstances as vessel breakdowns or lack of markets.

c. *Revised open access formula.* Finally, the third change to the allocation formula would reduce the denominator in the formula from "the aggregate total amount of pollock harvested in the directed pollock fishery for processing by the inshore component" to "the aggregate total amount of pollock harvested by AFA catcher vessels with inshore sector endorsements." The effect of this change is to eliminate from the formula all 1995 through 1997 catch history made by vessels that are not AFA catcher vessels with inshore sector endorsements. One consequence of the current formula is that all inshore catch history made by non-AFA vessels and by AFA catcher vessels without inshore endorsements defaults to the open access sector. The Council believes that this results in an inshore open access allocation that is unfairly inflated to the detriment of vessels in cooperatives. Inflating the open access quota in such a manner provides incentives for vessels to leave cooperatives, which could prevent rationalizing the BSAI pollock fishery, an objective of AFA. Under this recommended change, the cooperative and the open access sectors would be treated equally, and allocations to both sectors would be based only on the fishing histories of the vessels in each group. All three of these changes will be incorporated into proposed FMP Amendments 61/61/13/8 as Council recommendations that supersede the AFA and are included in this emergency interim rule for implementation in 2001.

3. Crab Processing Sideboards

Subparagraph 211(c)(2)(A) of the AFA establishes limits on crab processing by AFA inshore processors and AFA motherships that receive pollock harvested by a fishery cooperative:

Effective January 1, 2000, the owners of the motherships eligible under section 208(d) and the shoreside processors eligible under section 208(f) that receive pollock from the directed pollock fishery under a fishery cooperative are hereby prohibited from processing, in the aggregate for each calendar year, more than the percentage of the total catch of each species of crab in directed fisheries under the jurisdiction of the North Pacific Council than facilities operated by such owners processed of each such species in the aggregate, on average, in 1995, 1996, 1997. For the purposes of this subparagraph, the term "facilities" means any processing plant, catcher/processor, mothership, floating processor, or any other operation that processes fish. Any entity in which 10 percent or more of the interest is owned or controlled by another individual or entity shall be considered to be the same entity as the other individual or entity for the purposes of this subparagraph.

These crab processing limits were intended by Congress to prevent negative spillover effects of AFA on other fisheries, hence the term "sideboards." NMFS first implemented these limits by emergency interim rule published January 28, 2000 (65 FR 4520, extended at 65 FR 39107). However, in September 2000 the Council recommended that the years used to calculate crab processing sideboard amounts be revised by adding 1998 and by giving it a double weight. This action was based, in part, on concerns expressed by some crab fishermen and AFA processors that too many non-AFA processors have left the crab fisheries since 1997 and that the 1995 through 1997 years did not accurately reflect the composition of the crab processing industry at the time of passage of the AFA. Some crab fishermen testified to the Council that AFA crab processing limits were restricting markets for crab fishermen and having a negative effect on exvessel prices. By adding 1998 and by giving it a double weight relative to 1995 through 1997, the Council believes that the crab processing limits would more accurately reflect the status of the crab processing industry at the time of passage of the AFA and that such a change to supersede this provision of the AFA is warranted to mitigate adverse effects on markets for crab fishermen.

4. CDQ and AFA Observer Requirements

Under the emergency interim rules governing the AFA pollock fishery in 1999 and 2000, AFA catcher/processors and motherships were required to have one lead CDQ observer at all times, but the second observer requirement could be filled by any NMFS-certified observer. However, the CDQ program imposed a higher requirement of one lead CDQ observer and a second CDQ observer for catcher/processors and motherships participating in the CDQ pollock fishery. Under this emergency interim rule, the observer requirements for catcher/processors and motherships in the AFA and CDQ pollock fisheries would use the same standard requiring at least one lead CDQ observer aboard at all times, but allow the second observer position to be filled by any NMFS-certified observer.

Observer requirements in the AFA program and the directed pollock fishery in the CDQ program are reasonably consistent. The data quality needs for CDQ and AFA pollock catch accounting are virtually identical. Further, vessels will often fish for CDQ and AFA-allocated pollock during the same fishing trip, and similar observer requirements will simplify observer deployment logistics. Therefore, NMFS is amending the current observer requirements under the CDQ program for only those catcher/processors and motherships participating in the directed fishery for pollock CDQ to be consistent with the AFA observer requirements for those vessel classes.

5. Catcher/Processor and Catcher Vessel Groundfish Sideboards

Section 211(a), (b), and (c) of the AFA requires NMFS to establish sideboard

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limits for AFA catcher/processors and AFA catcher vessels. This requirement of the AFA was implemented through the emergency interim rule published January 28, 2000 (65 FR 4520, extended 65 FR 39107, June 23, 2000). Upon recommendation of the Council, this emergency interim rule takes a more streamlined approach for publishing and managing sideboard amounts. Under this action, NMFS will simply publish catcher/processor and catcher vessel groundfish sideboard amounts based on recommendations from the Council and manage these sideboards through directed fishing closures. This approach is distinct from the previous emergency rule, which specified each individual sideboard amount in regulation although the practical effect will be the same. The Council determined that emergency action is necessary to implement the AFA-mandated sideboard measures for the start of the 2001 fishing year. In the absence of sideboards, participants in other fisheries could be severely disadvantaged by an influx of unregulated fishing effort from AFA vessels.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this rule is necessary to respond to an emergency situation and that it is consistent with the Magnuson-Stevens Act, AFA, and other applicable laws.

Pursuant to the National Environmental Policy Act, an EA/RIR was developed for this action. The EA/RIR may be obtained from the Alaska Regional Office (see **ADDRESSES**).

This emergency interim rule has been determined to be not significant for the purposes of Executive Order 12866.

Because prior notice and opportunity for public comment are not required for this emergency interim rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

NMFS finds that there is good cause to waive the requirement to provide prior notice and an opportunity for public comment pursuant to authority set forth at 5 U.S.C. 553(b)(B) as such procedure would be impracticable and contrary to the public interest. This action is necessary to provide participants in the BSAI groundfish fishery the opportunity to reorganize inshore catcher vessel cooperatives for the 2001 fishing year in the manner recommended by the Council and requested by the industry. This action is also necessary to implement sideboard restrictions to protect participants in other Alaska fisheries from negative impacts as a result of fishery cooperatives formed under the AFA. The need to avoid delaying the start of the pollock season to implement these measures constitutes good cause to waive, pursuant to authority set forth at 5 U.S.C. 553(d)(3), the 30-day delay in effective date otherwise required by 5 U.S.C. 553(d).

On November 30, 2000, NMFS issued a new programmatic Biological Opinion under section 7 of the Endangered Species Act. This opinion is comprehensive in scope and considers the fisheries and the overall management framework established by the respective FMPs to determine whether that framework contains necessary measures to ensure the protection of listed species and critical habitat. The opinion determines whether the BSAI or GOA groundfish fisheries, as implemented under the respective FMPs, jeopardize the continued existence of listed species in the areas affected by the fisheries (i.e., the action areas) or adversely modify critical habitat of such species. NMFS determined that fishing activity under the FMPs is likely to jeopardize the continued existence of the western population of Steller sea lions and is likely to adversely modify their designated critical habitat. NMFS has developed a reasonable and prudent alternative (RPA) with multiple components for the groundfish fisheries in the BSAI and GOA. The components of the RPA address (1) the harvest strategy for fish removal at the global or FMP level and (2) the protection of Steller sea lions from groundfish fisheries at global and regional scales and in both temporal and spatial dimensions. Nothing in this action is expected to impact endangered or threatened marine mammals and fish or bird species in ways that were not considered in the current or previous consultations.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Recordkeeping and reporting requirements.

Dated: January 16, 2001

Penelope D. Dalton,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR part 679 is amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.*, 1801 *et seq.*, and 3631 *et seq.*

2. In § 679.2, the definition of "AFA qualified catcher vessel" is added in alphabetical order to read as follows:

§ 679.2 Definitions.

* * * * *

AFA qualified catcher vessel (applicable through July 17, 2001) is a vessel that delivered more pollock to the AFA inshore processor that is associated with the inshore catcher vessel cooperative that the vessel wishes to join than to any other inshore processor in the last year in which the vessel engaged in directed fishing for pollock in the BSAI for delivery to the inshore sector. Notwithstanding the definition of this term at paragraph 210(b)(3) of the AFA, and for purposes of determining eligibility to participate in an AFA inshore cooperatives under § 679.20(a)(5)(i)(D).

* * * * *

3. In § 679.20, paragraphs (a)(5)(i)(D), (a)(5)(i)(E), and (c)(3)(iv) are added, and (d)(1)(iv) is suspended and (d)(1)(v) is added to read as follows:

§ 679.20 General limitations.

* * * * *

(a) * * *

(5) * * *

(i) * * *

(D) *AFA sectoral allocations* (applicable through July 17, 2001). Allocations of BSAI pollock to the CDQ program and to the inshore, catcher/processor, and mothership sectors will be made in accordance with section 206 of the AFA except that:

(*1*) *Inshore cooperative membership.* Participation in inshore catcher vessel cooperatives formed under paragraph 210(b)(1) of the AFA is limited to "AFA-qualified catcher vessels" as defined in § 679.2.

(*2*) *Inshore cooperative allocation formula.* NMFS will allocate Bering Sea Subarea pollock to each inshore cooperative according to the formula set out in paragraph 210(b)(1) of the AFA with the following changes and according to the following steps:

(*i*) *Determination of official catch history.* NMFS will establish an official catch history for each AFA inshore catcher vessel that is equal to the sum of the 2 highest years of inshore sector pollock landings made by such vessel from 1995 to 1997.

(*ii*) *Offshore compensation.* If an inshore catcher vessel made more than 499 mt of BSAI pollock landings to catcher/processors in the aggregate during the period 1995 through 1997, all BSAI pollock landings made to catcher/processors by such vessel would be added to its official catch history prior to determination of the vessel's best 2 of 3 years.

(*iii*) *Cooperative allocation formula.* Each inshore catcher vessel cooperative approved by NMFS under paragraph 210(b)(1) of the AFA will receive an allocation of the interim and final Bering Sea subarea inshore pollock TAC that is equal to the sum of each member vessel's official catch histories divided by the sum of official catch histories of all AFA inshore catcher vessels, multiplied by the interim and final TAC allocations, respectively.

(E) AFA crab processing sideboards (applicable through July 17, 2001). NMFS will determine crab processing sideboard limits for each AFA entity in accordance with the formula set out in subparagraph 211(c)(2)(A) of the AFA, except that the years used to calculate crab processing sideboard amounts will also include 1998 processed amounts, and NMFS will give the 1998 amounts double-weight in the formula.

* * * * *

(c) * * *

(3) * * *

(iv) Sideboard publication (applicable through July 17, 2001). NMFS will publish AFA sideboard limits for AFA catcher vessels and AFA catcher/processors for each groundfish species and groundfish species group for which final specifications are published under paragraph (c)(3)(i) of this section. Sideboard amounts will be based on recommendations from the Council consistent with section 211 of the AFA.

* * * * *

(d) * * *

(1) * * *

(v) *AFA sideboard closures* (applicable through July 17, 2001). If the Regional Administrator determines that any sideboard harvest limit for a group of AFA vessels published under § 679.20 (c)(3)(iv) has been or will be reached, the Regional Administrator may establish a directed fishing allowance for the species or species group applicable only to the identified group of AFA vessels. In establishing a directed fishing allowance, the Regional Administrator shall consider the amount that will be taken as incidental catch by those vessels in directed fishing for other species.

* * * * *

4. In § 679.50, paragraphs (c)(4)(i), (c)(5), and (d)(5) are suspended, and paragraphs (c)(4)(vi), (c)(6), and (d)(6) are added to read as follows:

§ 679.50 Groundfish observer program applicable through December 31, 2002.

* * * * *

(c) * * *

(4) * * *

(vi) *Motherships or catcher/processors using trawl gear* (applicable through July 17, 2001). (A) A mothership or catcher/processor using trawl gear to participate in a directed fishery for pollock CDQ must have at least two NMFS-certified observers aboard the vessel, at least one of whom must be certified as a lead CDQ observer as described at paragraph (h)(1)(i)(E) of this section.

(B) A mothership or catcher/processor using trawl gear to participate in a directed fishery for other than pollock CDQ must have at least two CDQ observers as described at paragraphs (h)(1)(i)(D) and (E) of this section aboard the vessel, at least one of whom must be certified as a lead CDQ observer.

(6) AFA catcher/processors and motherships (*applicable through July 17, 2001*)—*(i) Coverage requirement.*

(A) (Applicable through July 17, 2001). Unrestricted AFA catcher/processors and AFA motherships. The owner or operator of an unrestricted AFA catcher/processor or AFA mothership must provide at least two NMFS certified observers for each day that the vessel is used to harvest, process, or take deliveries of groundfish. More than two observers are required if the observer workload restriction at § 679.50(c)(5)(iii) would otherwise preclude sampling as required under § 679.62(a)(1).

(B) (Applicable through July 17, 2001). Restricted AFA catcher/processors. The owner or operator of a restricted AFA catcher/processor must provide at least two NMFS certified observers for each day that the vessel is used to engage in directed fishing for pollock in the BSAI, or takes deliveries of pollock harvested in the BSAI. When a restricted AFA catcher/processor is not engaged in directed fishing for BSAI pollock and is not receiving deliveries of pollock harvested in the BSAI, the observer coverage requirements at § 679.50(c)(1)(iv) apply.

(ii) (Applicable through July 17, 2001). Certification level. At least one of the observers required under paragraphs (c)(5)(i)(A) and (B) of this section must be certified as a lead CDQ observer as specified in paragraph (h)(1)(i)(E)(1) of this section.

(iii) (Applicable through July 17, 2001). Observer work load. The time required for the observer to complete sampling, data recording, and data communication duties may not exceed 12 consecutive hours in each 24-hour period, and, the observer may not sample more than 9 hours in each 24-hour period.

(d) * * *

(6) *AFA inshore processors* (applicable through July 17, 2001).—(i) Coverage level. An AFA inshore processor is required to provide a NMFS certified observer for each 12 consecutive hour period of each calendar day during which the processor takes delivery of, or processes, groundfish harvested by a vessel engaged in a directed pollock fishery in the BSAI. A processor that takes delivery of or processes pollock for more than 12 consecutive hours in a calendar day is required to provide two NMFS-certified observers for each day.

(ii) (Applicable through July 17, 2001). Multiple processors. An observer deployed to an AFA inshore processor may not be assigned to cover more than one processor during a calendar day in which the processor receives or processes pollock harvested in the BSAI directed pollock fishery.

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Federal Register

Monday,
January 22, 2001

Part XX

The President

Proclamation 7392—Boundary Enlargement and Modifications of the Buck Island Reef National Monument

Proclamation 7393—Establishment of the Carrizo Plain National Monument

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Federal Register
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Presidential Documents

Title 3—

The President

Proclamation 7392 of January 17, 2001

Boundary Enlargement and Modifications of the Buck Island Reef National Monument

By the President of the United States of America

A Proclamation

Buck Island Reef National Monument was established on December 28, 1961 (Presidential Proclamation 3443), just north of St. Croix in the U.S. Virgin Islands, for the purpose of protecting Buck Island and its adjoining shoals, rocks, and undersea coral reef formations. Considered one of the finest marine gardens in the Caribbean Sea, the unique natural area and the rare marine life which are dependent upon it are subject to the constant threat of commercial exploitation and destruction. The monument's vulnerable floral and faunal communities live in a fragile, interdependent relationship and include habitats essential for sustaining the tropical marine ecosystem: coral reefs, sea grass beds, octocoral hardbottom, sand communities, algal plains, shelf edge, and oceanic habitats. The boundary enlargement effected by this proclamation brings into the monument additional objects of scientific and historic interest, and provides necessary further protection for the resources of the existing monument.

The expansion area includes additional coral reefs (patch, pur and groove, and deep and wall), unusual "haystacks" of elkhorn coral, barrier reefs, sea grass beds, and sand communities, as well as algal plains, shelf edge, and other supporting habitats not included within the initial boundary. Oceanic currents carry planktonic larvae of coral reef associated animals to the shallow nearshore coral reef and sea grass habitats, where they transform into their juvenile stage. As they mature over months or years, they move offshore and take up residence in the deeper coral reefs, octocoral hardbottom, and algal plains. Between the monument's nearshore habitats and its shelf edge spawning sites are habitats that play essential roles during specific developmental stages of many reef-associated species, including spawning migrations of many reef fish species and crustaceans. Several threatened and endangered species forage, breed, nest, rest, or calve in the waters included in the enlarged monument, including humpback whales, pilot whales, four species of dolphins, brown pelicans, least terns, and the hawksbill, leatherback, and green sea turtles. Countless species of reef fishes, invertebrates, plants, and over 12 species of sea birds utilize this area.

The ecologically important shelf edge is the spawning site for many reef species, such as most groupers and snappers, and the spiny lobster. Plummeting to abyssal depths, this habitat of vertical walls, honeycombed with holes and caves, is home to deepwater species and a refuge for other species.

The expansion area also contains significant cultural and historical objects. In March 1797, the slave ship Mary, captained by James Hunter of Liverpool, sank in this area, and its cargo of 240 slaves was saved and brought to Christiansted. In March 1803, the General Abercrombie, captained by James Booth of Liverpool, also wrecked in this area, and its cargo of 339 slaves was brought to Christiansted. Slave shipwrecks in U.S. waters are rare. The monument contains remnants of these wrecks. Other wrecks may also exist in the monument.

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Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as an addition to the Buck Island Reef National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as an addition to the Buck Island Reef National Monument, for the purpose of care, management, and protection of the objects of historic and scientific interest situated on lands within the said monument, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Buck Island Reef National Monument Boundary Enlargement" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 18,135 marine acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument.

For the purpose of protecting the objects identified above, the Secretary shall prohibit all boat anchoring, provided that the Secretary may permit exceptions for emergency or authorized administrative purposes, and may issue permits for anchoring in deep sand bottom areas, to the extent that it is consistent with the protection of the objects.

For the purposes of protecting the objects identified above, the Secretary shall prohibit all extractive uses. This prohibition supersedes the limited authorization for extractive uses included in Proclamation 3443 of December 28, 1961.

Lands and interests in lands within the monument not owned or controlled by the United States shall be reserved as a part of the monument upon acquisition of title or control thereto by the United States.

The Secretary of the Interior shall manage the monument through the National Park Service, pursuant to applicable legal authorities, to implement the purposes of this proclamation. The National Park Service will manage the monument in a manner consistent with international law.

The Secretary of the Interior shall prepare a management plan, including the management of vessels in the monument, within 2 years that will address any further specific actions necessary to protect the objects identified above.

The enlargement of this monument is subject to valid existing rights.

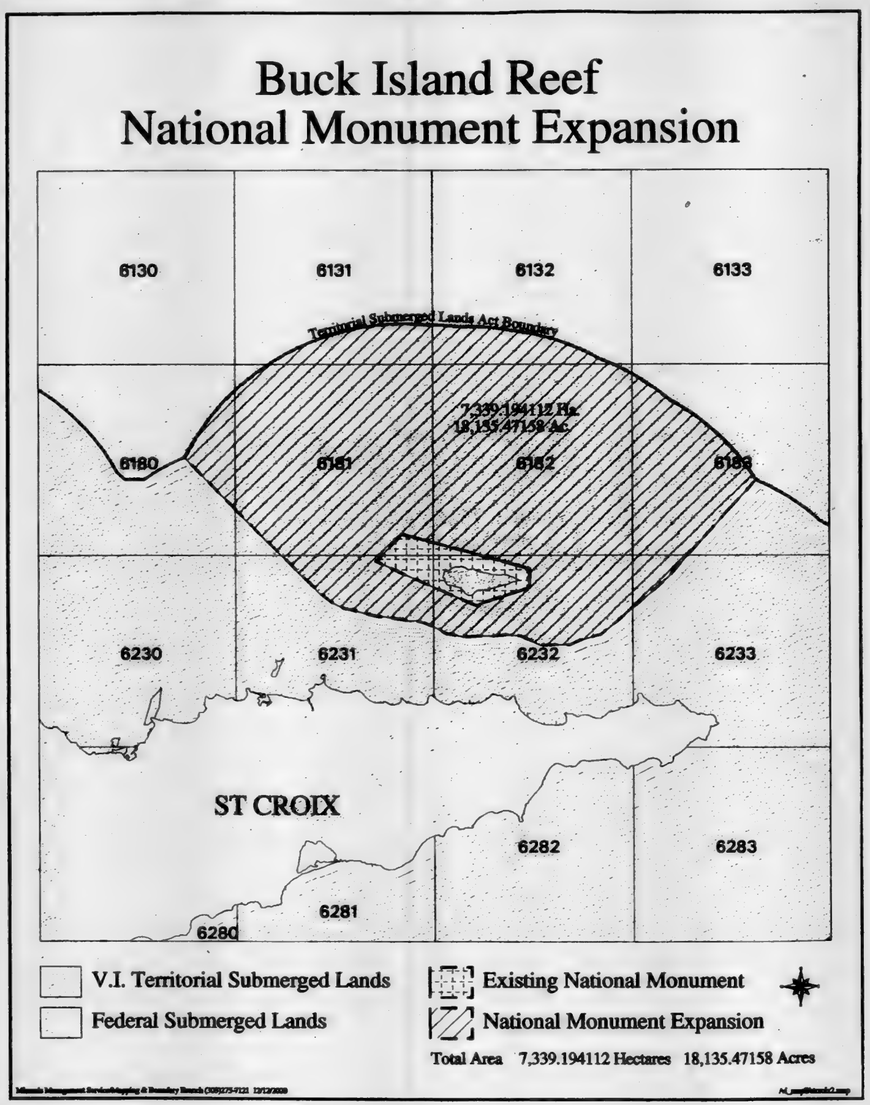
Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

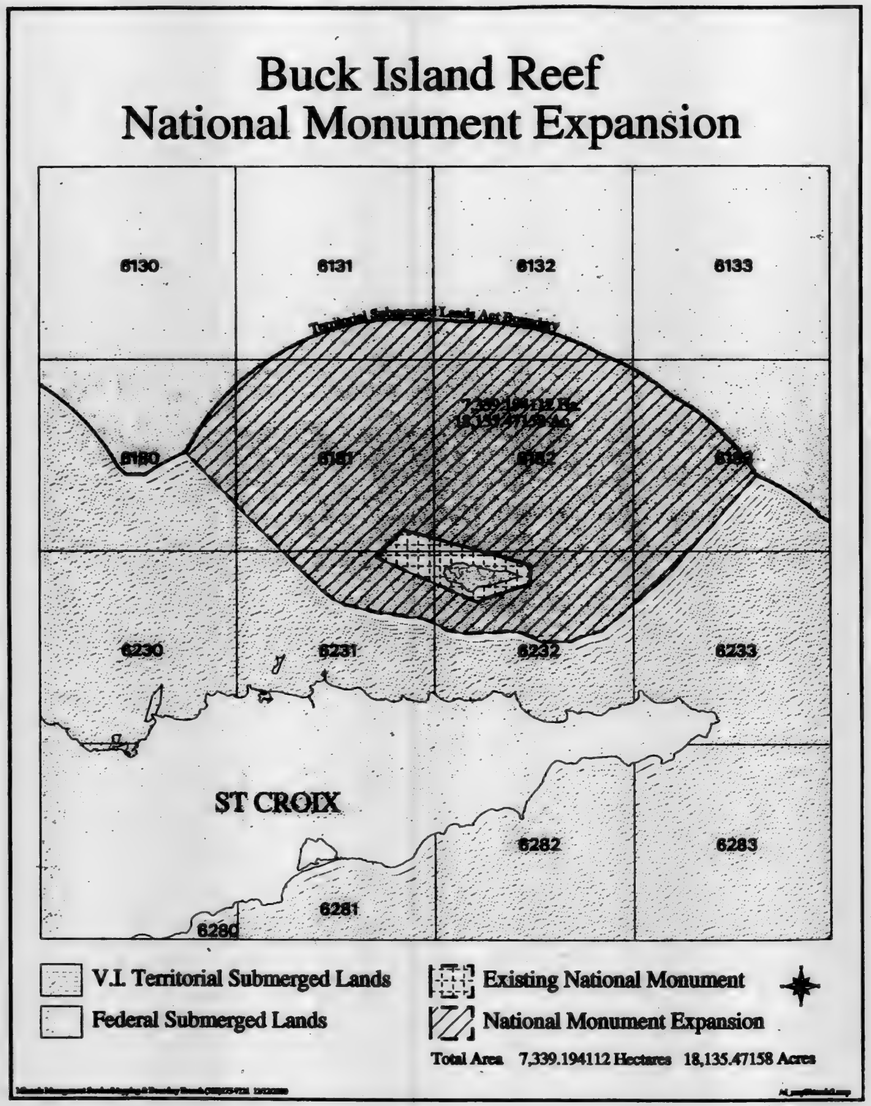
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Presidential Documents

Proclamation 7393 of January 17, 2001

Establishment of the Carrizo Plain National Monument

By the President of the United States of America

A Proclamation

Full of natural splendor and rich in human history, the majestic grasslands and stark ridges in the Carrizo Plain National Monument contain exceptional objects of scientific and historic interest. Since the mid-1800s, large portions of the grasslands that once spanned the entire four hundred mile expanse of California's nearby San Joaquin Valley and other valleys in the vicinity have been eliminated by extensive land conversion to agricultural, industrial, and urban land uses. The Carrizo Plain National Monument, which is dramatically bisected by the San Andreas Fault zone, is the largest undeveloped remnant of this ecosystem, providing crucial habitat for the long-term conservation of the many endemic plant and animal species that still inhabit the area.

The monument offers a refuge for endangered, threatened, and rare animal species such as the San Joaquin kit fox, the California condor, the blunt-nosed leopard lizard, the giant kangaroo rat, the San Joaquin antelope squirrel, the longhorn fairy shrimp, and the vernal pool fairy shrimp. It supports important populations of pronghorn antelope and tule elk. The area is also home to many rare and sensitive plant species, including the California jewelflower, the Hoover's woolly-star, the San-Joaquin woolly-threads, the pale-yellow layia, the forked fiddleneck, the Carrizo peppergrass, the Lost Hills saltbush, the Temblor buckwheat, the recurved larkspur, and the Munz's tidy-tips. Despite past human use, the size, isolation, and relatively undeveloped nature of the area make it ideal for long-term conservation of the dwindling flora and fauna characteristic of the San Joaquin Valley region.

The Carrizo Plain National Monument also encompasses Soda Lake, the largest remaining natural alkali wetland in southern California and the only closed basin within the coastal mountains. As its name suggests, Soda Lake concentrates salts as water is evaporated away, leaving white deposits of sulfates and carbonates. Despite this harsh environment, small plant and animal species are well adapted to the setting, which is also important to migratory birds. During the winter months the lake fills with water and teems with thousands of beautiful lesser sandhill cranes, long-billed curlews, and mountain plovers.

The Carrizo Plain National Monument owes its existence to the geologic processes that occur along the San Andreas Fault, where two of the Earth's five great tectonic plates slide past one another, parallel to the axis of the Plain. Shifting along the fault created the Plain by rumpling the rocks to the northeast into the Temblor Range and isolating the Plain from the rest of the San Joaquin Valley. The area is world-famous for its spectacular exposures of fault-generated landforms. Stream valleys emerge from the adjacent mountains, only to take dramatic right-angle turns where they intersect the fault. Ponds and sags form where the ground is extended and subsides between branches of the fault. Benches form where the fault offsets valley walls. Many dramatic landscape features are products of the interplay between very rapid fault movement and slower erosion. The dry climate of the area produces low erosion rates, thereby preserving the spectacular effects of fault slip, folding, and warping. On the Plain, these fault-related events

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happen intermittently, but with great force. In 1857, the strongest earthquake in California's recorded history ripped through the San Andreas Fault, wrenching the western side of the Carrizo Plain National Monument thirty-one feet northward.

The area is also distinguished for its significant fossil assemblages. The Caliente Formation, exposed on the southeast side of the Caliente Range, is host to abundant and diverse terrestrial fossil mammal remains of the Miocene Epoch (from 13 million to 25 million years ago). Fossils of five North American provincial mammalian ages (Arikareean, Hemingfordian, Barstovian, Clarendonian, Hemphillian) are represented in sedimentary rocks in that formation. These terrestrial fossil remains are interlaced with marine sedimentary rocks bearing fossils of mollusks, pectens, turitellas, and oysters.

In addition to its geologic and biological wealth, the area is rich in human history. Archaeologists theorize that humans have occupied the Carrizo Plain National Monument area since the Paleo-Indian Period (circa 11,000 to 9,000 B.C.). Bedrock mortar milling features, village middens, and elaborate pictographs are the primary manifestations of prehistoric occupation. Some of these, such as the Painted Rock and Sulphur Springs rock art sites, are recognized as world class. European expeditions through the area date back to the late 1700s, with settlement beginning in the 1850s. Livestock ranching, farming, and mining activities in the last century and a half are evidenced by numerous artifacts and historic ranch properties within the area.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Carrizo Plain National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Carrizo Plain National Monument, for the purpose of protecting the objects identified above, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Carrizo Plain National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 204,107 acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument. For the purpose of protecting the objects identified above, the Secretary shall prohibit all motorized and mechanized vehicle use off road, except for emergency or authorized administrative purposes.

Lands and interests in lands within the proposed monument not owned by the United States shall be reserved as a part of the monument upon acquisition of title thereto by the United States.

The Secretary of the Interior shall manage the monument through the Bureau of Land Management, pursuant to applicable legal authorities, to implement the purposes of this proclamation.

The Secretary of the Interior shall prepare a management plan that addresses the actions, including road closures or travel restrictions, necessary to protect the objects identified in this proclamation.

The establishment of this monument is subject to valid existing rights.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of California with respect to fish and wildlife management.

There is hereby reserved, as of the date of this proclamation and subject to valid existing rights, a quantity of water sufficient to fulfill the purposes for which this monument is established. Nothing in this reservation shall be construed as a relinquishment or reduction of any water use or rights reserved or appropriated by the United States on or before the date of this proclamation.

Laws, regulations, and policies followed by the Bureau of Land Management in issuing and administering grazing permits or leases on all lands under its jurisdiction shall continue to apply with regard to the lands in the monument.

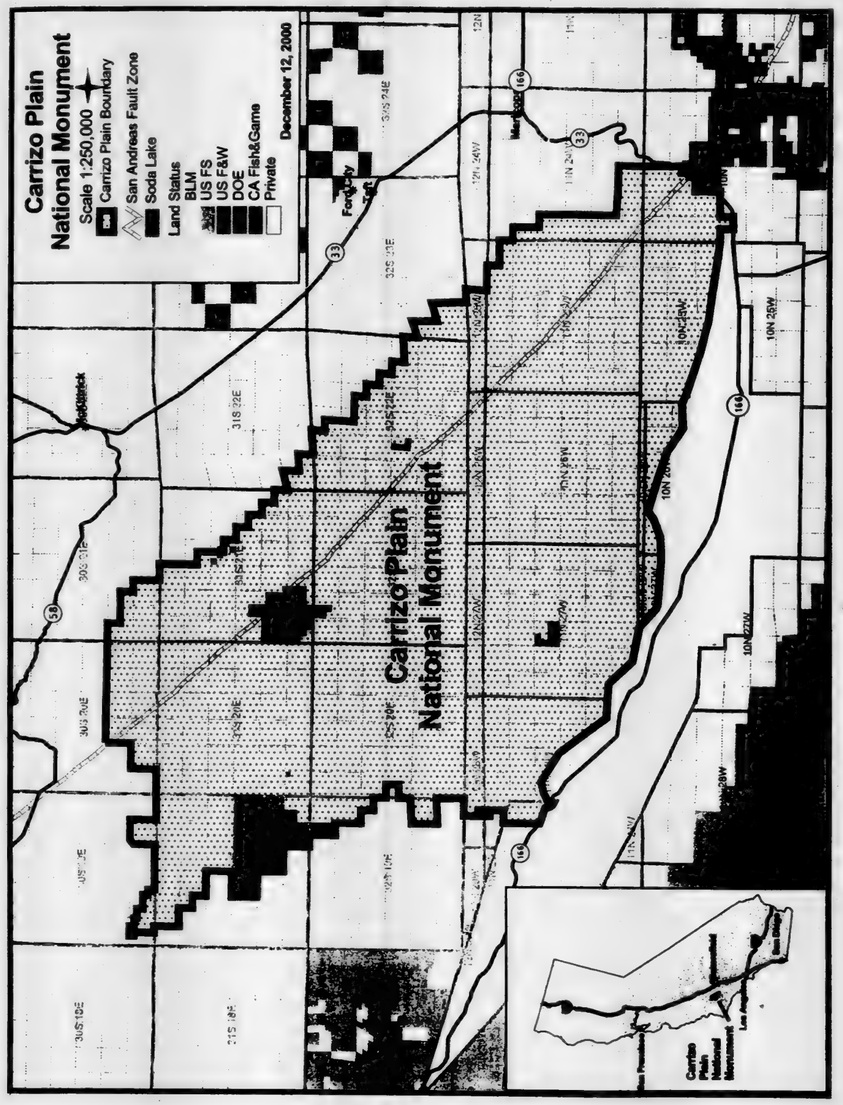
Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

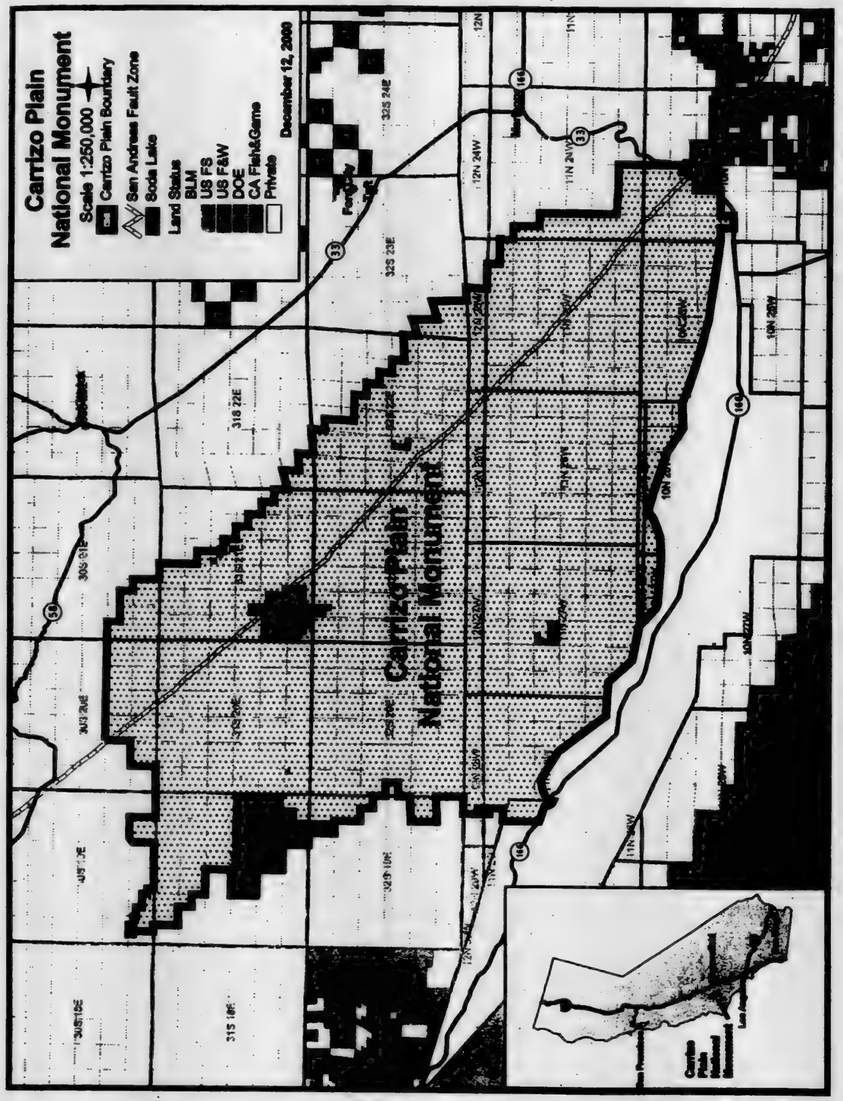
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Presidential Documents

Proclamation 7394 of January 17, 2001

Establishment of the Kasha-Katuwe Tent Rocks National Monument

By the President of the United States of America

A Proclamation

Located on the Pajarito Plateau in north central New Mexico, the Kasha-Katuwe Tent Rocks National Monument is a remarkable outdoor laboratory, offering an opportunity to observe, study, and experience the geologic processes that shape natural landscapes, as well as other cultural and biological objects of interest. The area is rich in pumice, ash, and tuff deposits, the light-colored, cone-shaped tent rock formations that are the products of explosive volcanic eruptions that occurred between 6 and 7 million years ago. Small canyons lead inward from cliff faces, and over time, wind and water have scooped openings of all shapes and sizes in the rocks and have contoured the ends of the ravines and canyons into smooth semicircles. In these canyons, erosion-resistant caprocks protect the softer tents below. While the formations are uniform in shape, they vary in height from a few feet to 90 feet, and the layering of volcanic material intersperses bands of grey with beige colored rock.

Amid the formations and in contrast to the muted colors of the rocks of the monument, vibrant green leaves and red bark of manzanita, a shrubby species from the Sierra Madre of Mexico, cling to the cracks and crevices of the cliff faces. Red-tailed hawks, kestrels, violet-green swallows, and Western bluebirds soar above the canyons and use the pinion and ponderosa covered terrain near the cliffs.

The complex landscape and spectacular geologic scenery of the Kasha-Katuwe Tent Rocks National Monument has been a focal point for visitors for centuries. Human settlement is believed to have begun in the monument as a series of campsites during the Archaic period, from approximately 5500 B.C. During the fifteenth century, several large ancestral pueblos were established in the area. Their descendants, the Pueblo de Cochiti, still inhabit the surrounding area. Although the Spanish explorer Don Juan de Oñate reached the Pajarito Plateau in 1598, it was not until the late eighteenth century that families began to claim land grants around Tent Rocks from the Spanish Crown. Remnants of human history are scattered throughout the monument.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Kasha-Katuwe Tent Rocks National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of

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June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Kasha-Katuwe Tent Rocks National Monument, for the purpose of protecting the objects identified above, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Kasha-Katuwe Tent Rocks National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 4,148 acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument.

For the purpose of protecting the objects identified above, the Secretary shall prohibit all motorized and mechanized vehicle use off road, except for emergency or authorized administrative purposes.

Lands and interests in lands within the proposed monument not owned by the United States shall be reserved as a part of the monument upon acquisition of title thereto by the United States.

The Secretary of the Interior shall manage the monument through the Bureau of Land Management, pursuant to applicable legal authorities and in close cooperation with the Pueblo de Cochiti, to implement the purposes of this proclamation.

The Secretary of the Interior shall prepare, within 3 years of this date, a management plan for this monument, and shall promulgate such regulations for its management as he deems appropriate. The management plan shall include appropriate transportation planning that addresses the actions, including road closures or travel restrictions, necessary to protect the objects identified in this proclamation and to further the purposes of the American Indian Religious Freedom Act of August 11, 1978 (42 U.S.C. 1996).

Only a very small amount of livestock grazing occurs inside the monument. The Secretary of the Interior shall retire the portion of the grazing allotments within the monument, pursuant to applicable law, unless the Secretary specifically finds that livestock grazing will advance the purposes of the proclamation.

The establishment of this monument is subject to valid existing rights.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of New Mexico with respect to fish and wildlife management.

This proclamation does not reserve water as a matter of Federal law. Nothing in this reservation shall be construed as a relinquishment or reduction of any water use or rights reserved or appropriated by the United States on or before the date of this proclamation. The Secretary shall work with appropriate State authorities to ensure that any water resources needed for monument purposes are available.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

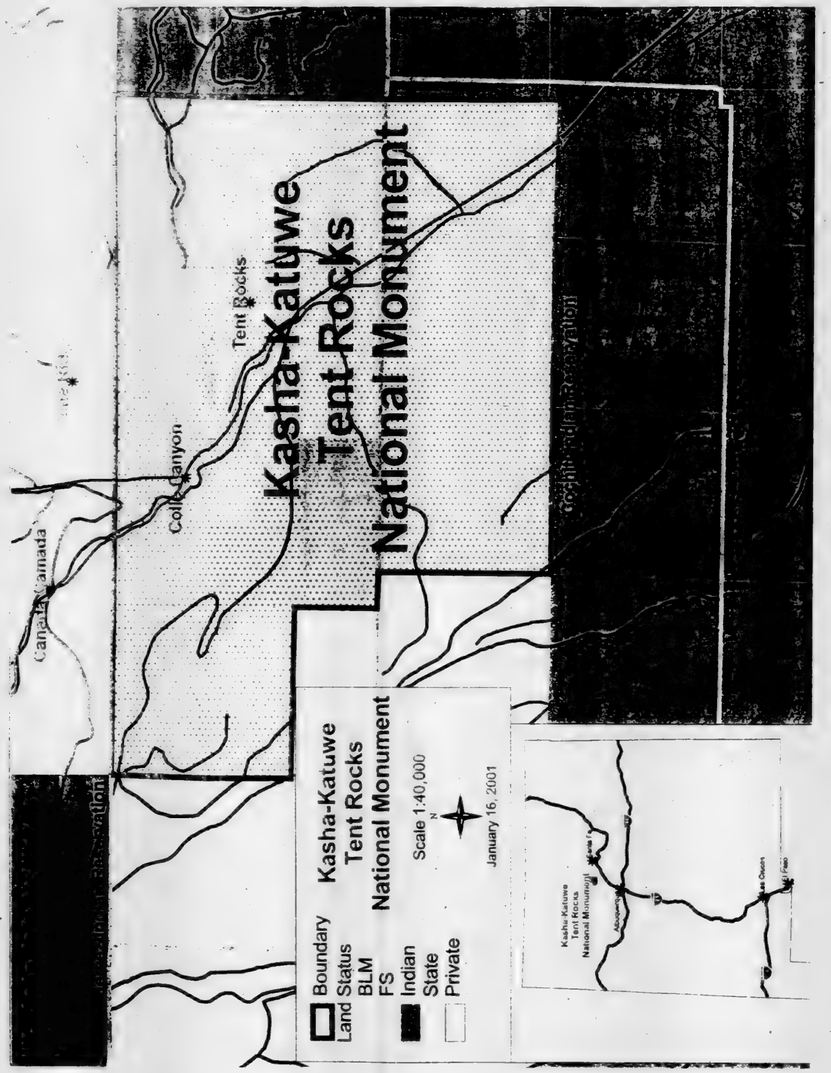
Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the

Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

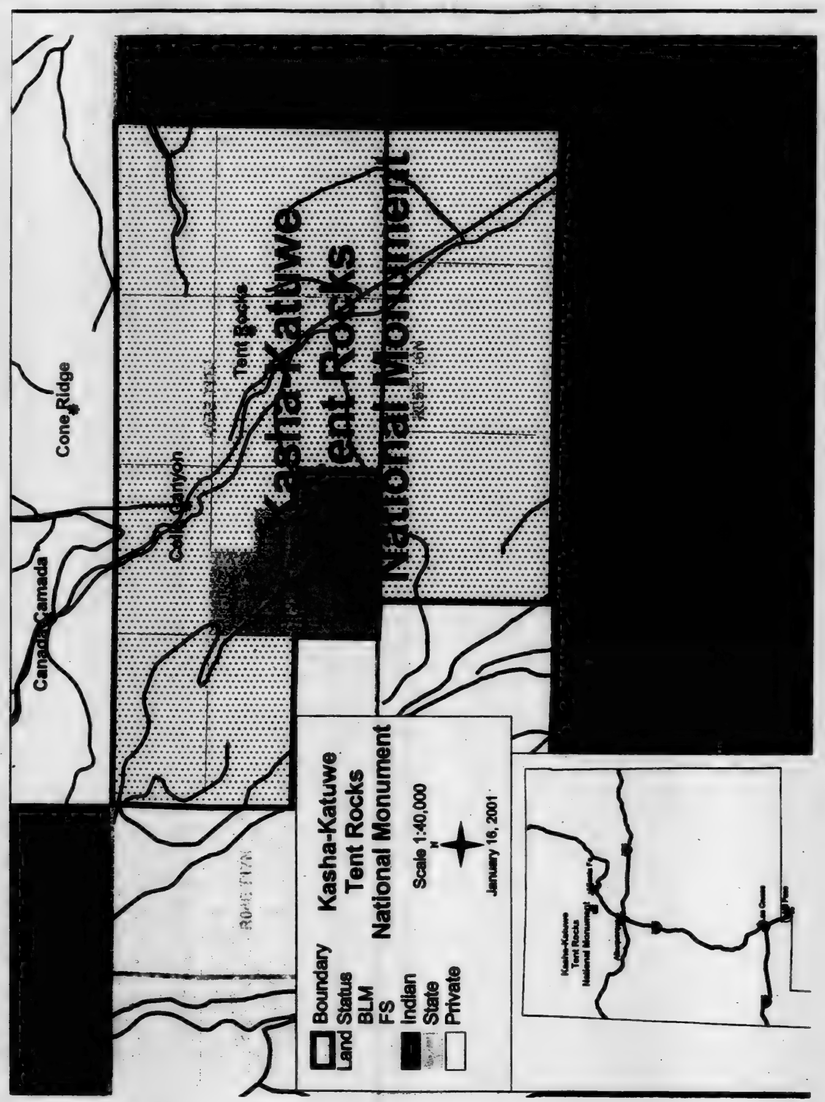
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Monday, January 22, 2001

Presidential Documents

Proclamation 7395 of January 17, 2001

Establishment of the Minidoka Internment National Monument

By the President of the United States of America

A Proclamation

The Minidoka Internment National Monument is a unique and irreplaceable historical resource which protects historic structures and objects that provide opportunities for public education and interpretation of an important chapter in American history—the internment of Japanese Americans during World War II.

On February 19, 1942, President Franklin D. Roosevelt signed Executive Order 9066, authorizing the Secretary of War and military commanders to designate military areas from which "any or all persons may be excluded" and to "provide for residents of any such area who are excluded therefrom, such transportation, food, shelter, and other accommodations as may be necessary."

Starting in early 1942, military authorities began designating military exclusion areas in the States of California, Washington, Oregon, and Arizona, and the territory of Alaska. Following the signing of Executive Order 9066, American citizens and resident aliens of Japanese ancestry living in the designated exclusion areas were ordered to evacuate their homes and businesses and report to temporary assembly centers located at fairgrounds, horse racetracks, and other make-shift facilities.

To provide more permanent accommodations for the evacuees, President Roosevelt established the War Relocation Authority (WRA) in March 1942. The WRA oversaw the construction of ten relocation centers on Federally owned lands in remote areas of six western States and Arkansas, including the Minidoka Relocation Center in Idaho. Alaskan Native residents of the Aleutian and Pribiloff Islands and members of other ethnic and religious groups were also relocated or interned during the course of the war.

Established in August 1942, the Minidoka Relocation Center, also known as the Hunt Site, was located on Federal lands in Jerome County, in south central Idaho. During its operation from August 1942 to October 1945, the population reached a peak of 9,397 Japanese Americans from Washington State, Oregon, and Alaska. The Center included over 33,000 acres of land with administrative and residential facilities located on approximately 950 acres. The Center had more than 600 buildings including administrative, religious, residential, educational, mess, medical, manufacturing, warehouse, security, and other structures.

Living conditions at Minidoka and the other centers were harsh. Internees were housed in crude barracks and cramped quarters, and they shared communal facilities. Internees engaged in irrigated agriculture, livestock production, and light manufacturing to produce food and garments for the camp. Approximately 1,000 internees from Minidoka served in the U.S. military. Fifty-four Japanese American servicemen from Minidoka were killed in action.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic

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landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of lands, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Minidoka Internment National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Minidoka Internment National Monument for the purpose of protecting the historic structures and objects of historic interest contained therein, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Minidoka Internment National Monument" attached to and forming a part of this proclamation. The Federal lands and interests in land reserved consist of approximately 72.75 acres, which is the smallest area compatible with the proper care and management of the structures and objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land or other Federal laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing.

The Secretary of the Interior, pursuant to legal authorities, shall manage the monument and shall transfer administration of the monument to the National Park Service to implement the purposes of this proclamation.

To carry out the purposes of this proclamation and to interpret the relocation and internment of Japanese Americans during World War II, the Secretary of the Interior, through the National Park Service, shall prepare a management plan for the monument within 3 years of this date.

This proclamation does not reserve water as a matter of Federal law nor relinquish any water rights held by the Federal Government existing on this date. The Secretary shall work with appropriate State authorities to ensure that any water resources needed for monument purposes are available.

The establishment of this monument is subject to valid existing rights, provided that nothing in this proclamation shall interfere with the operation and maintenance of the Northside Canal to the extent that any such activities, that are not valid existing rights, are consistent with the purposes of the proclamation.

Nothing in this proclamation shall be deemed to enlarge or diminish the rights of any Indian tribe.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however the national monument shall be the dominant reservation.

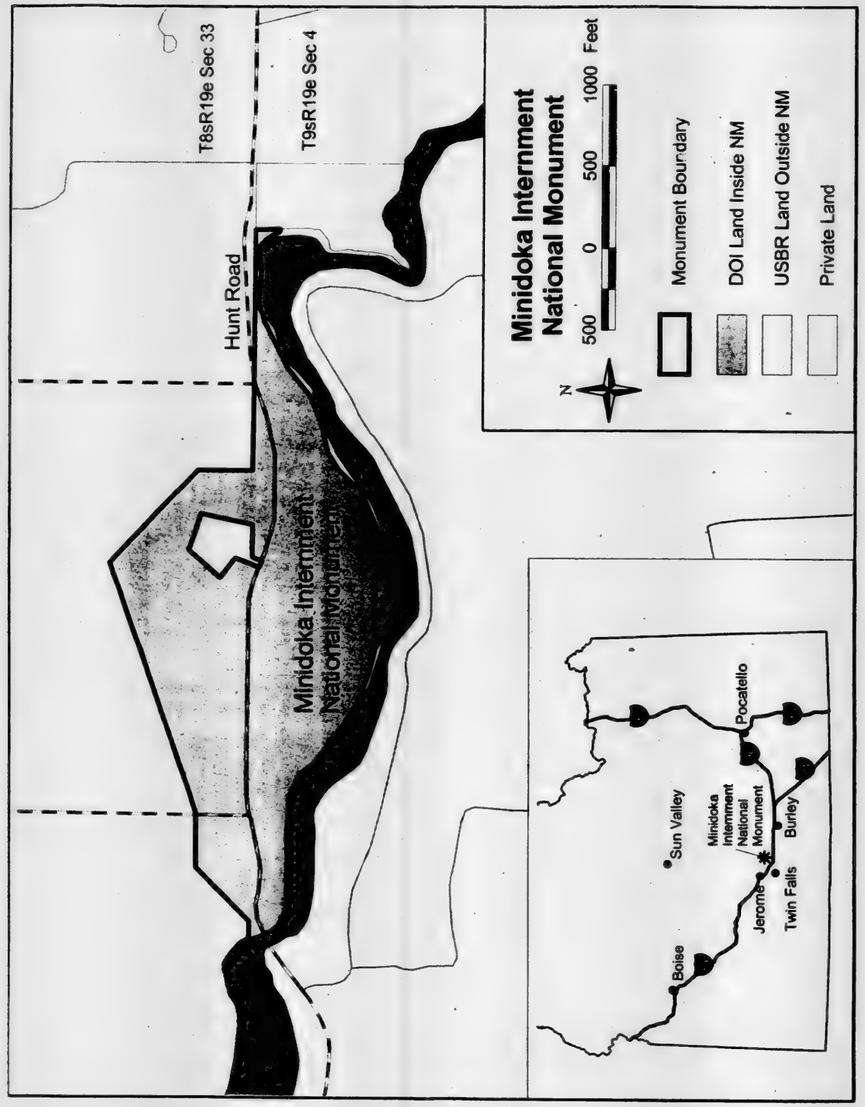
Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the

Independence of the United States of America the two hundred and twenty-fifth.

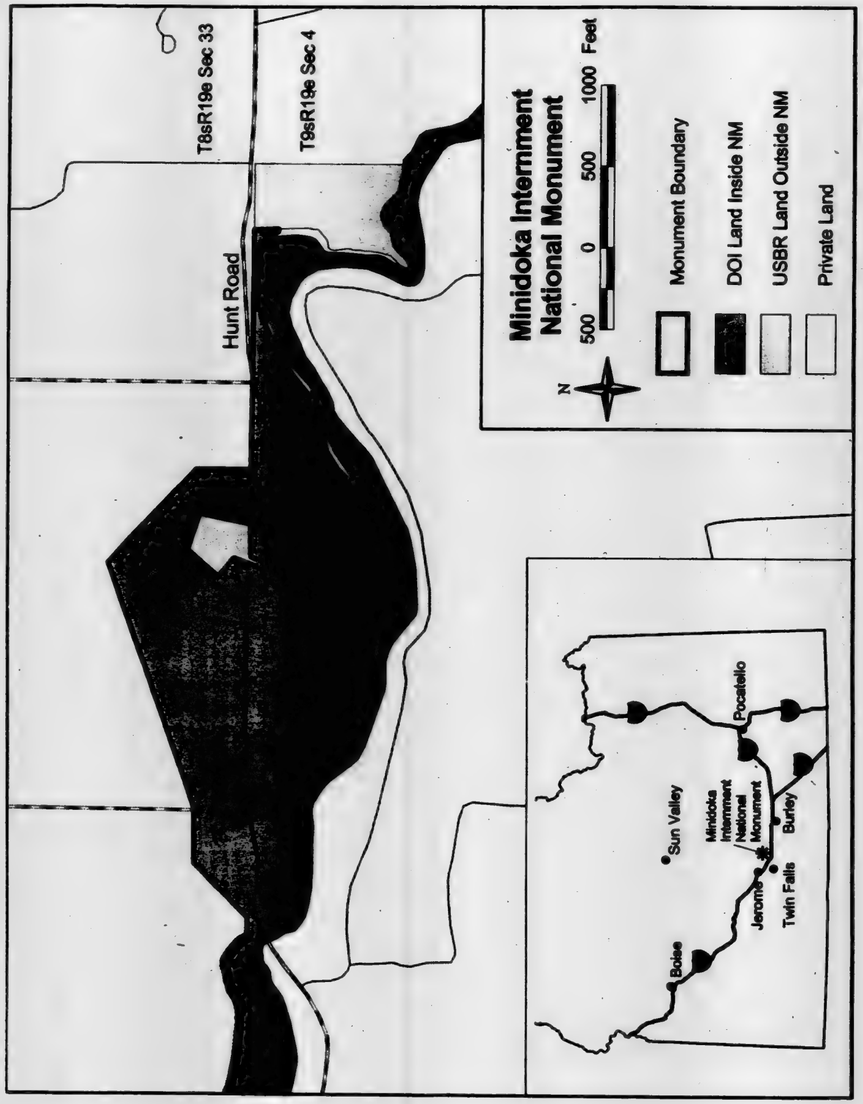
William J. Clinton

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Proclamation 7396 of January 17, 2001

Establishment of the Pompeys Pillar National Monument

By the President of the United States of America

A Proclamation

Pompeys Pillar National Monument is a massive sandstone outcrop that rises from an almost two-acre base on the banks of the Yellowstone River 150 feet toward Montana's Big Sky, east of Billings. The monument's premier location at a natural ford in the Yellowstone River, and its geologic distinction as the only major sandstone formation in the area, have made Pompeys Pillar a celebrated landmark and outstanding observation point for more than eleven thousand years of human occupation. Hundreds of markings, petroglyphs, and inscriptions left by visitors have transformed this geologic phenomenon into a living journal of the American West.

The monument's most notable visitor, Captain William Clark of the Lewis and Clark Expedition, arrived at Pompeys Pillar on July 25, 1806, on his return trip from the Pacific coast. Clark's journal recorded his stop at this "remarkable rock" with its "extensive view in every direction." He described an idyllic landscape of grassy plains, snow-capped mountains, and cliffs abutting the wandering river. Clark marked his presence by engraving his name and the date of his visit on the outcrop. This simple inscription is the only remaining physical evidence of Lewis and Clark's epic journey. In his journal, Clark named the rock Pompy's Tower, Pompy being Clark's nickname for Sacagawea's young son, Jean Baptiste Charbonneau, who was born at the expedition's winter camp at Fort Mandan on February 11, 1805. The name was changed to Pompeys Pillar by author Nicholas Biddle when his account of the Expedition was published in 1814.

Ethnographic and archaeological evidence indicates that the Pillar was a place of ritual and religious activity. Hundreds of petroglyphs on the face of the rock, noted by Clark in his journal, reflect the importance of the monument to early peoples. The Crow people, the dominant residents of the region when Clark passed through, call the pillar the "Mountain Lions Lodge" in their language, and it figures prominently in Crow oral history. Pompeys Pillar also includes the markings and signature of a host of characters from the pioneer past, including fur trappers, Yellowstone River steamboat men, frontier army troops, railroad workers, missionaries, and early settlers. In 1873, Lieutenant Colonel George Armstrong Custer and his men camped at its base, where they came under attack from Sioux snipers.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Pompeys Pillar National Monument:

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NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Pompeys Pillar National Monument, for the purpose of protecting the objects identified above, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Pompeys Pillar National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 51 acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing.

Lands and interests in lands within the proposed monument not owned by the United States shall be reserved as a part of the monument upon acquisition of title thereto by the United States.

The Secretary of the Interior shall manage the monument through the Bureau of Land Management, pursuant to applicable legal authorities, to implement the purposes of this proclamation.

The establishment of this monument is subject to any valid existing rights, including the mineral estate held by the United States in trust for the Crow Tribe.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of Montana with respect to fish and wildlife management.

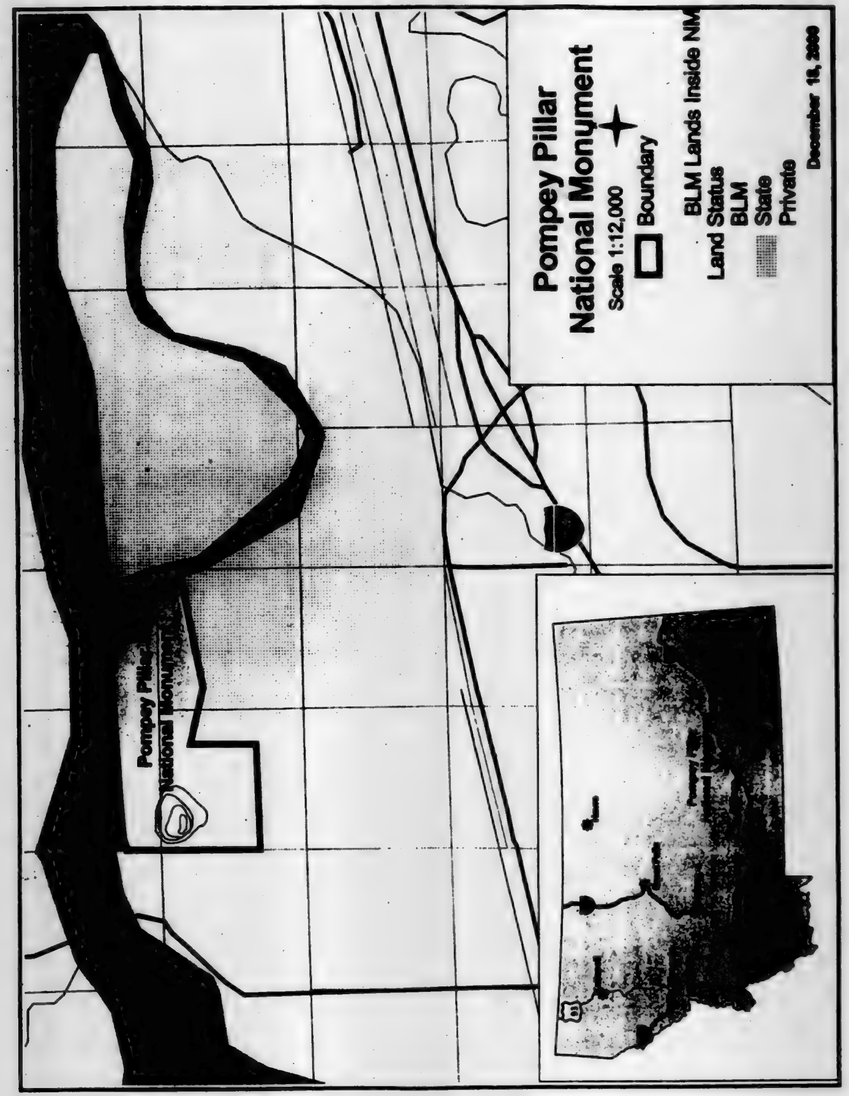
This proclamation does not reserve water as a matter of Federal law. Nothing in this reservation shall be construed as a relinquishment or reduction of any water use or rights reserved or appropriated by the United States on or before the date of this proclamation. The Secretary shall work with appropriate State authorities to ensure that any water resources needed for monument purposes are available.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however,the national monument shall be the dominant reservation. Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

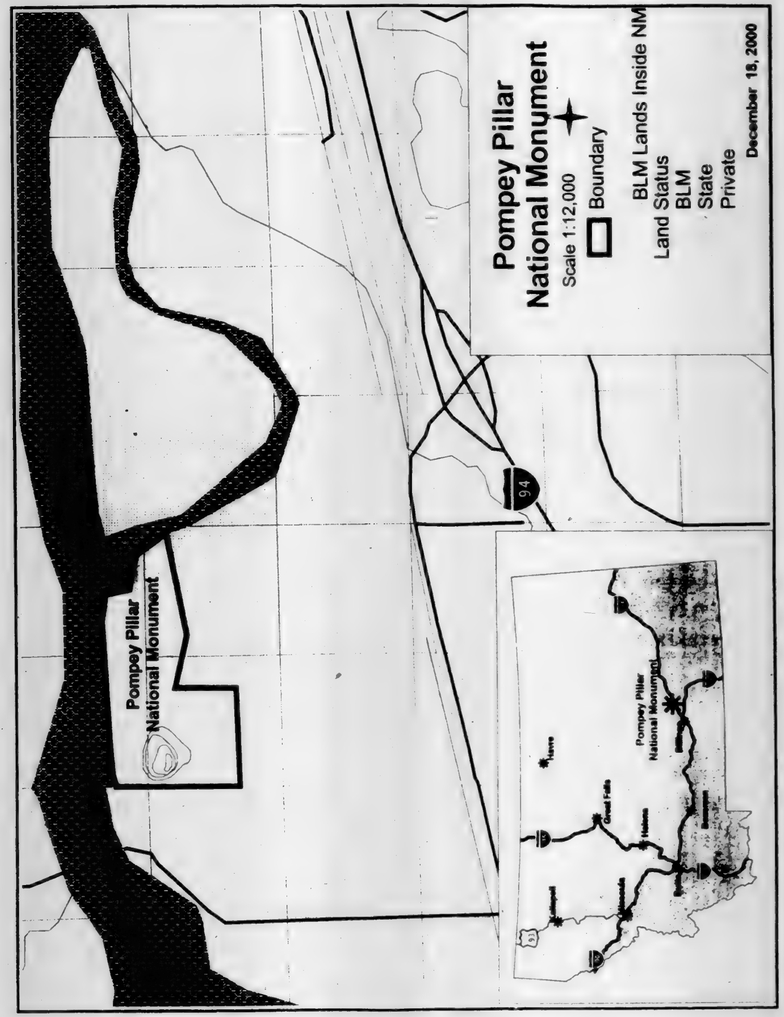
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Presidential Documents

Proclamation 7397 of January 17, 2001

Establishment of the Sonoran Desert National Monument

By the President of the United States of America

A Proclamation

The Sonoran Desert National Monument is a magnificent example of untrammeled Sonoran desert landscape. The area encompasses a functioning desert ecosystem with an extraordinary array of biological, scientific, and historic resources. The most biologically diverse of the North American deserts, the monument consists of distinct mountain ranges separated by wide valleys, and includes large saguaro cactus forest communities that provide excellent habitat for a wide range of wildlife species.

The monument's biological resources include a spectacular diversity of plant and animal species. The higher peaks include unique woodland assemblages, while the lower elevation lands offer one of the most structurally complex examples of palo verde/mixed cacti association in the Sonoran Desert. The dense stands of leguminous trees and cacti are dominated by saguaros, palo-verde trees, ironwood, prickly pear, and cholla. Important natural water holes, known as tinajas, exist throughout the monument. The endangered acuna pineapple cactus is also found in the monument.

The most striking aspect of the plant communities within the monument are the abundant saguaro cactus forests. The saguaro is a signature plant of the Sonoran Desert. Individual saguaro plants are indeed magnificent, but a forest of these plants, together with the wide variety of trees, shrubs, and herbaceous plants that make up the forest community, is an impressive site to behold. The saguaro cactus forests within the monument are a national treasure, rivaling those within the Saguaro National Park.

The rich diversity, density, and distribution of plants in the Sand Tank Mountains area of the monument is especially striking and can be attributed to the management regime in place since the area was withdrawn for military purposes in 1941. In particular, while some public access to the area is allowed, no livestock grazing has occurred for nearly 50 years. To extend the extraordinary diversity and overall ecological health of the Sand Tanks Mountains area, land adjacent and with biological resources similar to the area withdrawn for military purposes should be subject to a similar management regime to the fullest extent possible.

The monument contains an abundance of packrat middens, allowing for scientific analysis of plant species and climates in past eras. Scientific analysis of the midden shows that the area received far more precipitation 20,000 years ago, and slowly became more arid. Vegetation for the area changed from juniper- oak-pinion pine woodland to the vegetation found today in the Sonoran Desert, although a few plants from the more mesic period, including the Kofa Mountain barberry, Arizona rosewood, and junipers, remain on higher elevations of north-facing slopes.

The lower elevations and flatter areas of the monument contain the creosote-bursage plant community. This plant community thrives in the open expanses between the mountain ranges, and connects the other plant communities together. Rare patches of desert grassland can also be found throughout the monument, especially in the Sand Tank Mountains area. The washes

in the area support a much denser vegetation community than the surrounding desert, including mesquite, ironwood, paloverde, desert honeysuckle, chuperosa, and desert willow, as well as a variety of herbaceous plants. This vegetation offers the dense cover bird species need for successful nesting, foraging, and escape, and birds heavily use the washes during migration.

The diverse plant communities present in the monument support a wide variety of wildlife, including the endangered Sonoran pronghorn, a robust population of desert bighorn sheep, especially in the Maricopa Mountains area, and other mammalian species such as mule deer, javelina, mountain lion, gray fox, and bobcat. Bat species within the monument include the endangered lesser long-nosed bat, the California leaf-nosed bat, and the cave myotis. Over 200 species of birds are found in the monument, including 59 species known to nest in the Vekol Valley area. Numerous species of raptors and owls inhabit the monument, including the elf owl and the western screech owl. The monument also supports a diverse array of reptiles and amphibians, including the Sonoran desert tortoise and the red-backed whiptail. The Bureau of Land Management has designated approximately 25,000 acres of land in the Maricopa Mountains area as critical habitat for the desert tortoise. The Vekol Valley and Sand Tank Mountain areas contain especially diverse and robust populations of amphibians. During summer rainfall events, thousands of Sonoran green toads in the Vekol Valley can be heard moving around and calling out.

The monument also contains many significant archaeological and historic sites, including rock art sites, lithic quarries, and scattered artifacts. Vekol Wash is believed to have been an important prehistoric travel and trade corridor between the Hohokam and tribes located in what is now Mexico. Signs of large villages and permanent habitat sites occur throughout the area, and particularly along the bajadas of the Table Top Mountains. Occupants of these villages were the ancestors of today's O'odham, Quechan, Cocopah, Maricopa, and other tribes. The monument also contains a much used trail corridor 23 miles long in which are found remnants of several important historic trails, including the Juan Bautista de Anza National Historic Trail, the Mormon Battalion Trail, and the Butterfield Overland Stage Route.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS, it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Sonoran Desert National Monument.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Sonoran Desert National Monument, for the purpose of protecting the objects identified above, all lands and interest in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Sonoran Desert National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 486,149 acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

For the purpose of protecting the objects identified above, all motorized and mechanized vehicle use off road will be prohibited, except for emergency or authorized administrative purposes.

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Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of Arizona with respect to fish and wildlife management.

The establishment of this monument is subject to valid existing rights.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument. Lands and interests in lands within the monument not owned by the United States shall be reserved as a part of the monument upon acquisition of title thereto by the United States.

This proclamation does not reserve water as a matter of Federal law nor relinquish any water rights held by the Federal Government existing on this date. The Federal land management agencies shall work with appropriate State authorities to ensure that water resources needed for monument purposes are available.

The Secretary of the Interior shall manage the monument through the Bureau of Land Management, pursuant to applicable legal authorities, to implement the purposes of this proclamation. That portion identified as Area A on the map, however, shall be managed under the management arrangement established by section 3 of Public Law No. 99-606, 100 Stat. 3460-61, until November 6, 2001, at which time, pursuant to section 5(a) of Public Law No. 99-606, 100 Stat. 3462-63, the military withdrawal terminates. At that time, the Secretary of the Interior shall assume management responsibility for Area A through the Bureau of Land Management.

The Secretary of the Interior shall prepare a management plan that addresses the actions, including road closures or travel restrictions, necessary to protect the objects identified in this proclamation.

Laws, regulations, and policies followed by the Bureau of Land Management in issuing and administering grazing permits or leases on all lands under its jurisdiction shall continue to apply with regard to the lands in the monument; provided, however, that grazing permits on Federal lands within the monument south of Interstate Highway 8 shall not be renewed at the end of their current term; and provided further, that grazing on Federal lands north of Interstate 8 shall be allowed to continue only to the extent that the Bureau of Land Management determines that grazing is compatible with the paramount purpose of protecting the objects identified in this proclamation.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

Nothing in this proclamation shall preclude low level overflights of military aircraft, the designation of new units of special use airspace, or the use or establishment of military flight training routes over the lands included in this proclamation.

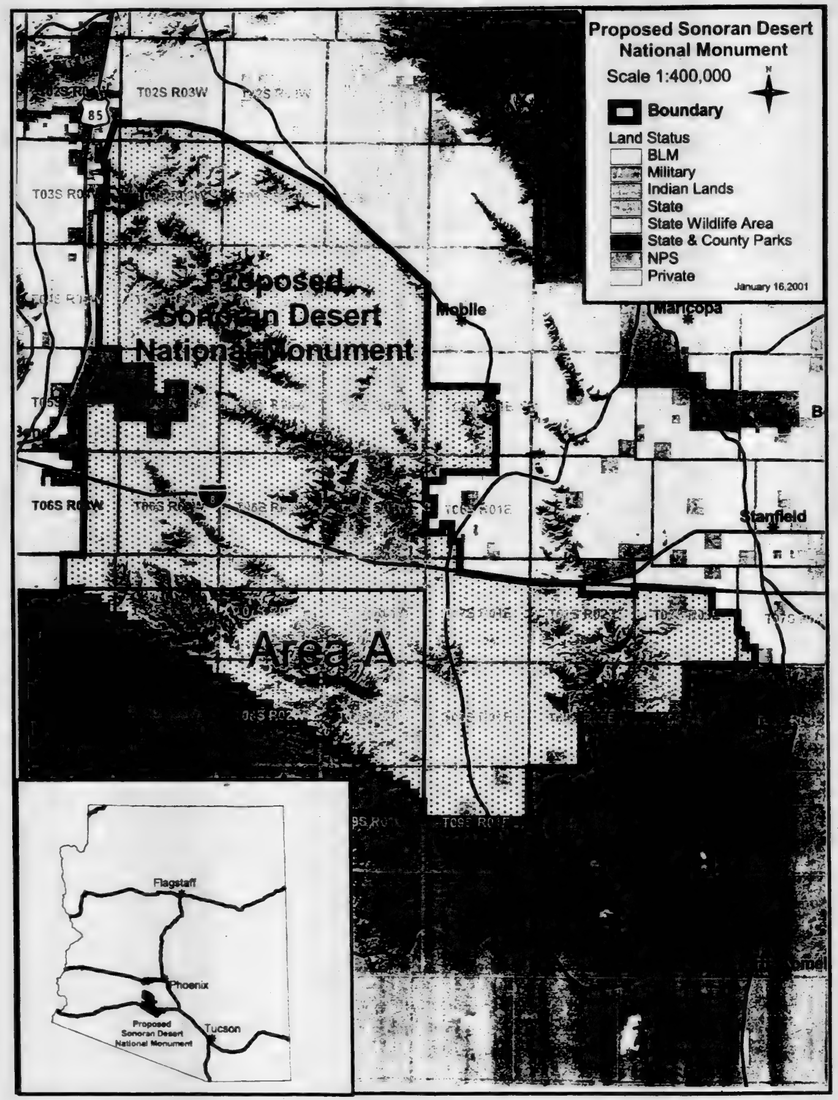
In order to protect the public during operations at the adjacent Barry M. Goldwater Range, and to continue management practices that have resulted in an exceptionally well preserved natural resource, the current procedures for public access to the portion of the monument depicted as Area A on the attached map shall remain in full force and effect, except to the extent that the United States Air Force agrees to different procedures which the Bureau of Land Management determines are compatible with the protection of the objects identified in this proclamation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

William J. Clinton

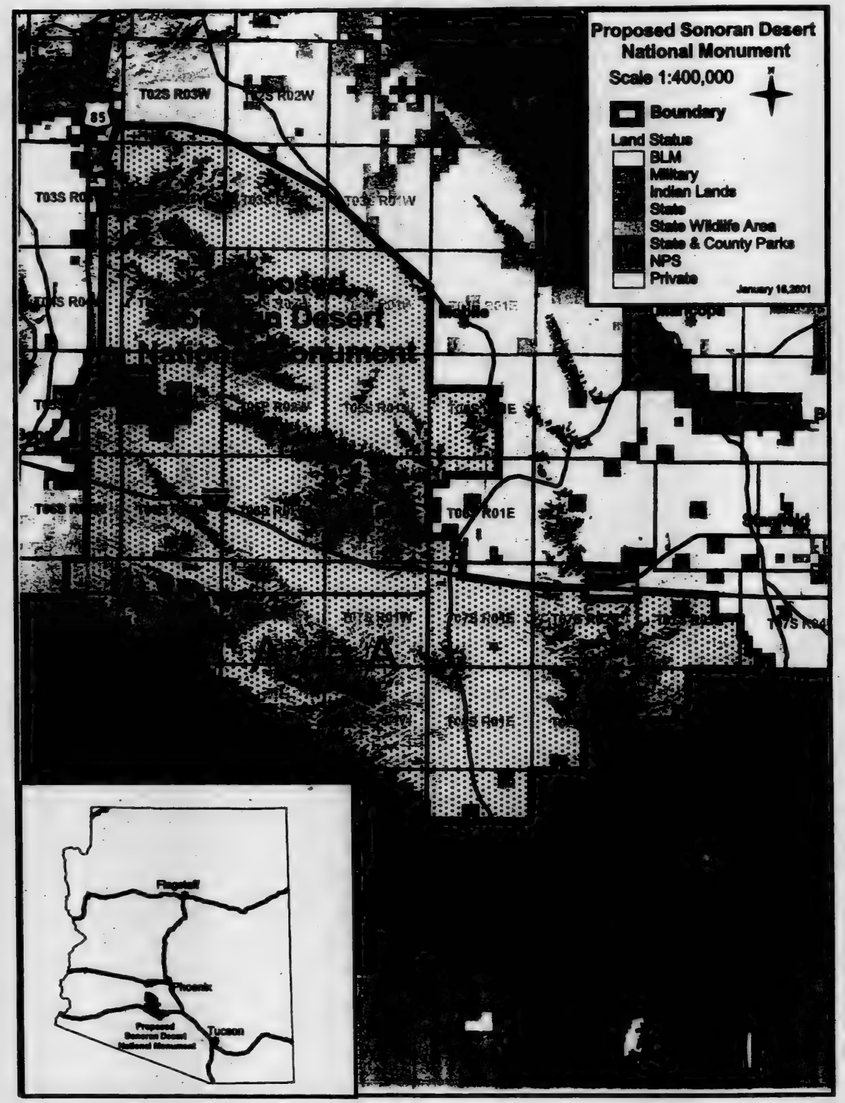
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Presidential Documents

Proclamation 7398 of January 17, 2001

Establishment of the Upper Missouri River Breaks National Monument

By the President of the United States of America

A Proclamation

The Upper Missouri River Breaks National Monument contains a spectacular array of biological, geological, and historical objects of interest. From Fort Benton upstream into the Charles M. Russell National Wildlife Refuge, the monument spans 149 miles of the Upper Missouri River, the adjacent Breaks country, and portions of Arrow Creek, Antelope Creek, and the Judith River. The area has remained largely unchanged in the nearly 200 years since Meriwether Lewis and William Clark traveled through it on their epic journey. In 1976, the Congress designated the Missouri River segment and corridor in this area a National Wild and Scenic River (Public Law 94–486, 90 Stat. 2327). The monument also encompasses segments of the Lewis and Clark National Historic Trail, the Nez Perce National Historic Trail, and the Cow Creek Island Area of Critical Environmental Concern.

Lewis and Clark first encountered the Breaks country of the monument on their westward leg. In his journal, Clark described the abundant wildlife of the area, including mule deer, elk, and antelope, and on April 29, 1805, the Lewis and Clark expedition recorded the first big horn sheep observation by non-Indians in North America. Lewis' description of the magnificent White Cliffs area on the western side of the monument is especially vivid, and not just for his sometimes colorful spellings:

"The hills and river Clifts which we passed today exhibit a most romantic appearance.... The bluffs of the river rise to hight of from 2 to 300 feet and in most places nearly perpendicular; they are formed of remarkable white sandstone which is sufficiently soft to give way readily to the impression of water...

"The water in the course of time ... has trickled down the soft sand clifts and woarn it into a thousand grotesque figures, which with the help of a little immagination and an oblique view, at a distance are made to represent eligant ranges of lofty freestone buildings, having their parapets well stocked with statuary; collumns of various sculptures both grooved and plain, are also seen supporting long galleries in front of these buildings; in other places on a much nearer approach and with the help of less immagination we see the remains or ruins of eligant buildings; some collumns standing and almost entire with their pedestals and capitals; others retaining their pedestals but deprived by time or accident of their capitals, some lying prostrate an broken othe[r]s in the form of vast pyramids of conic structure bearing a serees of other pyramids on their tops...

As we passed on it seemed as if those seens of visionary inchantment would never have and [an] end; for here it is too that nature presents to the view of the traveler vast ranges of walls of tolerable workmanship, so perfect indeed are those walls that I should have thought that nature had attempted here to rival the human art of masonry..."

The monument is covered with sedimentary rocks deposited in shallow seas that covered central and eastern Montana during the Cretaceous period.

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Glaciers, volcanic activity, and erosion have since folded, faulted, uplifted, and sculpted the landscape to the majestic form it takes today.

The area remains remote and nearly as undeveloped as it was in 1805. Many of the biological objects described in Lewis' and Clark's journals continue to make the monument their home. The monument boasts the most viable elk herd in Montana and one of the premier big horn sheep herds in the continental United States. It contains essential winter range for sage grouse as well as habitat for prairie dogs. Lewis sent Jefferson a prairie dog specimen which was, as Lewis noted at the time, "new to science." Abundant plant life along the River and across the Breaks country supports this wildlife. The lower reach of the Judith River, just above its confluence with the Missouri, contains one of the few remaining fully functioning cottonwood gallery forest ecosystems on the Northern Plains. Arrow Creek, originally called Slaughter River by Lewis and Clark, contains the largest concentration of antelope and mule deer in the monument as well as important spawning habitat for the endangered pallid sturgeon. An undammed tributary to the Missouri River, Arrow Creek is a critical seed source for cottonwood trees for the flood plain along the Missouri.

The cliff faces in the monument provide perching and nesting habitat for many raptors, including the sparrow hawk, ferruginous hawk, peregrine falcon, prairie falcon, and golden eagle. Several pairs of bald eagles nest along the River in the monument and many others visit during the late fall and early winter. Shoreline areas provide habitat for great blue heron, pelican, and a wide variety of waterfowl. The River and its tributaries in the monument host forty-eight fish species, including goldeye, drum, sauger, walleye, northern pike, channel catfish, and small mouth buffalo. The monument has one of the six remaining paddlefish populations in the United States. The River also supports the blue sucker, shovel nose sturgeon, sicklefin, sturgeon chub, and the endangered pallid sturgeon.

The Bullwacker area of the monument contains some of the wildest country on all the Great Plains, as well as important wildlife habitat. During the stress-inducing winter months, mule deer and elk move up to the area from the river, and antelope and sage grouse move down to the area from the benchlands. The heads of the coulees and breaks also contain archeological and historical sites, from teepee rings and remnants of historic trails to abandoned homesteads and lookout sites used by Meriwether Lewis.

Long before the time of Lewis and Clark, the area was inhabited by numerous native tribes, including the Blackfeet, Assiniboin, Gros Ventre (Atsina), Crow, Plains Cree, and Plains Ojibwa. The confluence of the Judith and Missouri Rivers was the setting for important peace councils in 1846 and 1855. In 1877, the Nez Perce crossed the Missouri and entered the Breaks country in their attempt to escape to Canada. The Cow Island Skirmish occurred in the Breaks and was the last encounter prior to the Nez Perce surrender to the U.S. Army at the Battle of Bear Paw just north of the monument. Pioneers and the Army followed Lewis and Clark in the 1830s establishing Fort Piegan, Fort McKenzie, and Fort Benton. Remnants of this rich history are scattered throughout the monument, and the River corridor retains many of the same qualities and much of the same appearance today as it did then.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Upper Missouri River Breaks National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Upper Missouri River Breaks National Monument, for the purpose of protecting the objects identified above, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Upper Missouri River Breaks National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 377,346 acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument. The establishment of this monument is subject to valid existing rights. The Secretary of the Interior shall manage development on existing oil and gas leases within the monument, subject to valid existing rights, so as not to create any new impacts that would interfere with the proper care and management of the objects protected by this proclamation.

The Secretary of the Interior shall prepare a transportation plan that addresses the actions, including road closures or travel restrictions, necessary to protect the objects identified in this proclamation.

For the purpose of protecting the objects identified above, the Secretary shall prohibit all motorized and mechanized vehicle use off road, except for emergency or authorized administrative purposes.

Lands and interests in lands within the proposed monument not owned by the United States shall be reserved as a part of the monument upon acquisition of title thereto by the United States.

The Secretary of the Interior shall manage the monument through the Bureau of Land Management, pursuant to applicable legal authorities, including the National Wild and Scenic Rivers Act, to implement the purposes of this proclamation.

Because waters of the Upper Missouri River through the monument area have already been reserved through the Congress's designation of the area as a component of the National Wild and Scenic River System in 1976, this proclamation makes no additional reservation of water; except in two small tributaries, the Judith River and Arrow Creek. These tributaries contain outstanding objects of biological interest that are dependent on water, such as a fully functioning cottonwood gallery forest ecosystem that is rare in the Northern Plains. Therefore, there is hereby reserved, as of the date of this proclamation and subject to valid existing rights, a quantity of water in the Judith River and Arrow Creek sufficient to fulfill the purposes for which this monument is established. Nothing in this reservation shall be construed as a relinquishment or reduction of any water use or rights reserved or appropriated by the United States on or before the date of this proclamation.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of Montana with respect to fish and wildlife management.

Nothing in this proclamation shall be deemed to enlarge or diminish the rights of any Indian tribe.

Laws, regulations, and policies followed by the Bureau of Land Management in issuing and administering grazing permits or leases on all lands under its jurisdiction shall continue to apply with regard to the lands in the monument.

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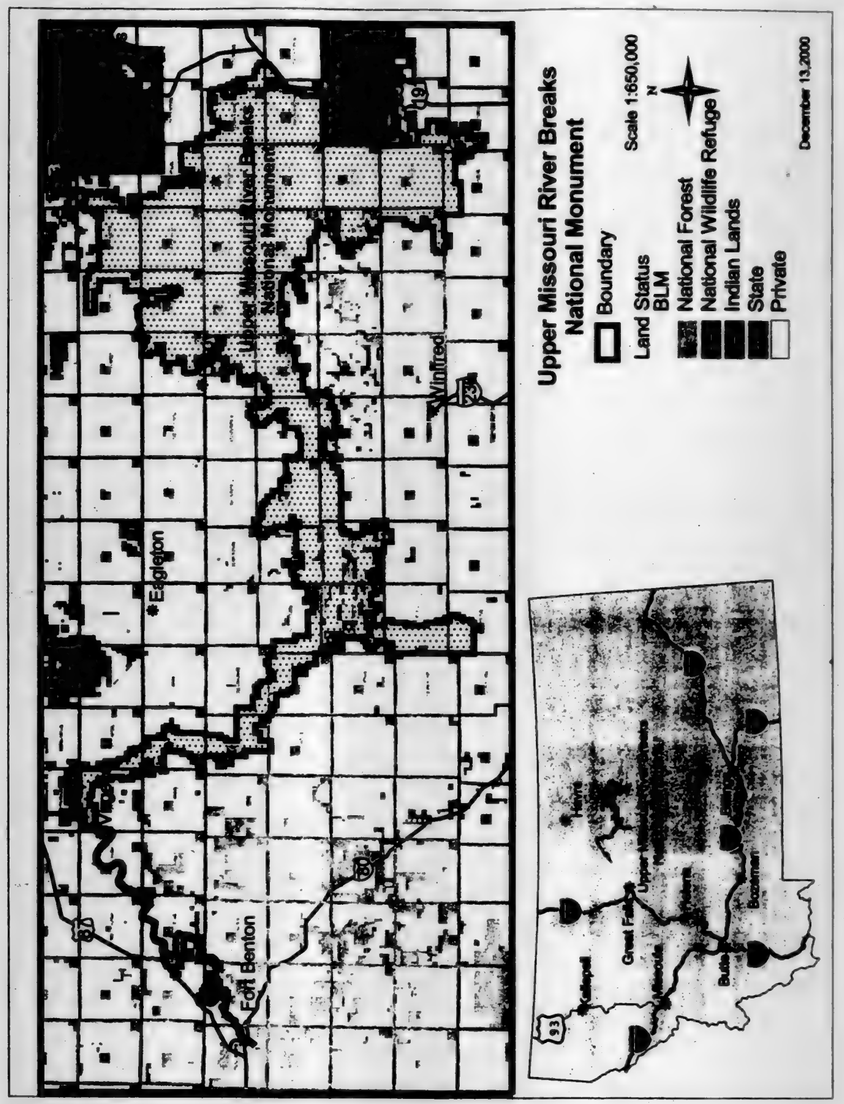
Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

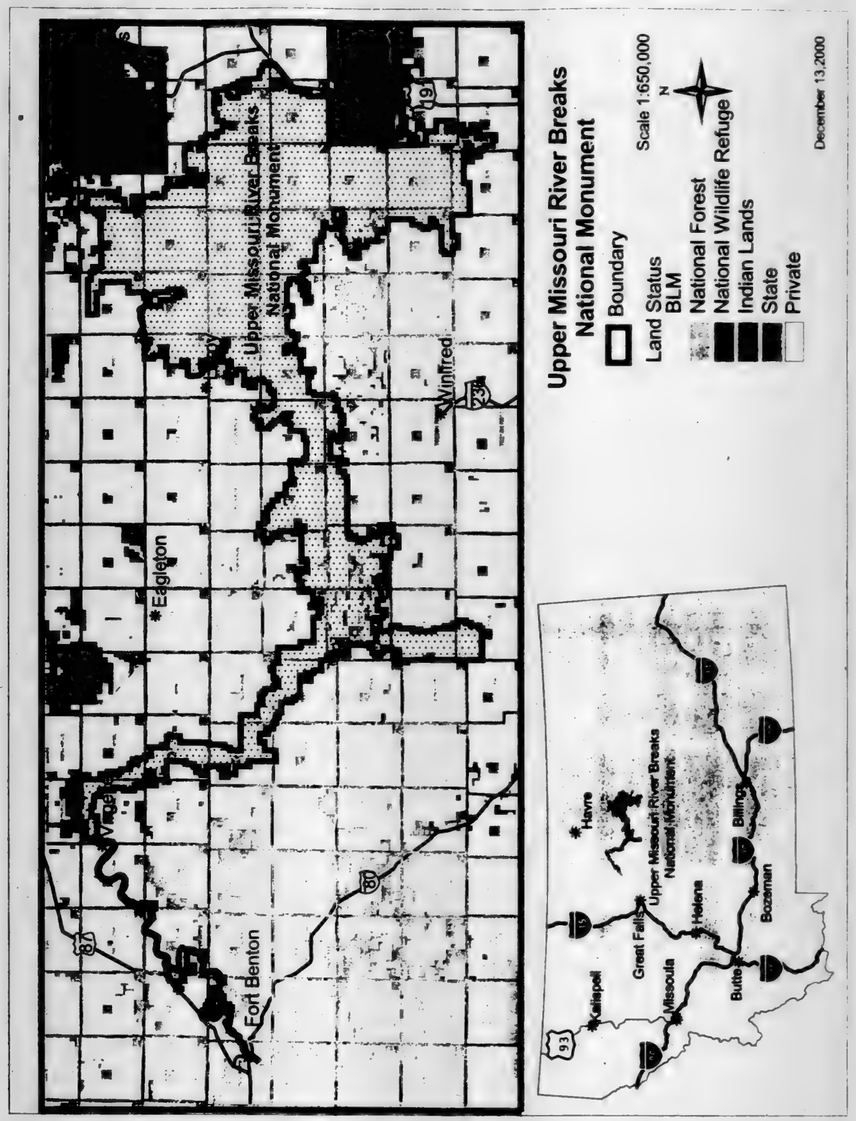
William J. Clinton

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Presidential Documents

Proclamation 7399 of January 17, 2001

Establishment of the Virgin Islands Coral Reef National Monument

By the President of the United States of America

A Proclamation

The Virgin Islands Coral Reef National Monument, in the submerged lands off the island of St. John in the U.S. Virgin Islands, contains all the elements of a Caribbean tropical marine ecosystem. This designation furthers the protection of the scientific objects included in the Virgin Islands National Park, created in 1956 and expanded in 1962. The biological communities of the monument live in a fragile, interdependent relationship and include habitats essential for sustaining and enhancing the tropical marine ecosystem: mangroves, sea grass beds, coral reefs, octocoral hardbottom, sand communities, shallow mud and fine sediment habitat, and algal plains. The fishery habitats, deeper coral reefs, octocoral hardbottom, and algal plains of the monument are all objects of scientific interest and essential to the long-term sustenance of the tropical marine ecosystem.

The monument is within the Virgin Islands, which lie at the heart of the insular Caribbean biome, and is representative of the Lesser Antillean biogeographic province. The island of St. John rises from a platform that extends several miles from shore before plunging to the abyssal depths of the Anegada trough to the south and the Puerto Rican trench to the north, the deepest part of the Atlantic Ocean. This platform contains a multitude of species that exist in a delicate balance, interlinked through complex relationships that have developed over tens of thousands of years.

As part of this important ecosystem, the monument contains biological objects including several threatened and endangered species, which forage, breed, nest, rest, or calve in the waters. Humpback whales, pilot whales, four species of dolphins, brown pelicans, roseate terns, least terns, and the hawksbill, leatherback, and green sea turtles all use portions of the monument. Countless species of reef fish, invertebrates, and plants utilize these submerged lands during their lives, and over 25 species of sea birds feed in the waters. Between the nearshore nursery habitats and the shelf edge spawning sites in the monument are habitats that play essential roles during specific developmental stages of reef-associated species, including spawning migrations of many reef fish species and crustaceans.

The submerged monument lands within Hurricane Hole include the most extensive and well-developed mangrove habitat on St. John. The Hurricane Hole area is an important nursery area for reef associated fish and invertebrates, instrumental in maintaining water quality by filtering and trapping sediment and debris in fresh water runoff from the fast land, and essential to the overall functioning and productivity of regional fisheries. Numerous coral reef-associated species, including the spiny lobster, queen conch, and Nassau grouper, transform from planktonic larvae to bottom-dwelling juveniles in the shallow nearshore habitats of Hurricane Hole. As they mature, they move offshore and take up residence in the deeper coral patch reefs, octocoral hardbottom, and algal plains of the submerged monument lands to the south and north of St. John.

The monument lands south of St. John are predominantly deep algal plains with scattered areas of raised hard bottom. The algal plains include communities of mostly red and calcareous algae with canopies as much as half a meter high. The raised hard bottom is sparsely colonized with corals, sponges, gorgonians, and other invertebrates, thus providing shelter for lobster, groupers, and snappers as well as spawning sites for some reef fish species. These algal plains and raised hard bottom areas link the shallow water reef, sea grass, and mangrove communities with the deep water shelf and shelf edge communities of fish and invertebrates.

Section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Government of the United States to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected.

WHEREAS it appears that it would be in the public interest to reserve such lands as a national monument to be known as the Virgin Islands Coral Reef National Monument:

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by the authority vested in me by section 2 of the Act of June 8, 1906 (34 Stat. 225, 16 U.S.C. 431), do proclaim that there are hereby set apart and reserved as the Virgin Islands Coral Reef National Monument, for the purpose of protecting the objects identified above, all lands and interests in lands owned or controlled by the United States within the boundaries of the area described on the map entitled "Virgin Islands Coral Reef National Monument" attached to and forming a part of this proclamation. The Federal land and interests in land reserved consist of approximately 12,708 marine acres, which is the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of this monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or leasing or other disposition under the public land laws, including but not limited to withdrawal from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument. For the purpose of protecting the objects identified above, the Secretary shall prohibit all boat anchoring, except for emergency or authorized administrative purposes.

For the purposes of protecting the objects identified above, the Secretary shall prohibit all extractive uses, except that the Secretary may issue permits for bait fishing at Hurricane Hole and for blue runner (hard nose) line fishing in the area south of St. John, to the extent that such fishing is consistent with the protection of the objects identified in this proclamation.

Lands and interests in lands within the monument not owned or controlled by the United States shall be reserved as a part of the monument upon acquisition of title or control thereto by the United States.

The Secretary of the Interior shall manage the monument through the National Park Service, pursuant to applicable legal authorities, to implement the purposes of this proclamation. The National Park Service will manage the monument in a manner consistent with international law.

The Secretary of the Interior shall prepare a management plan, including the management of vessels in the monument, within 3 years, which addresses any further specific actions necessary to protect the objects identified in this proclamation.

The establishment of this monument is subject to valid existing rights.

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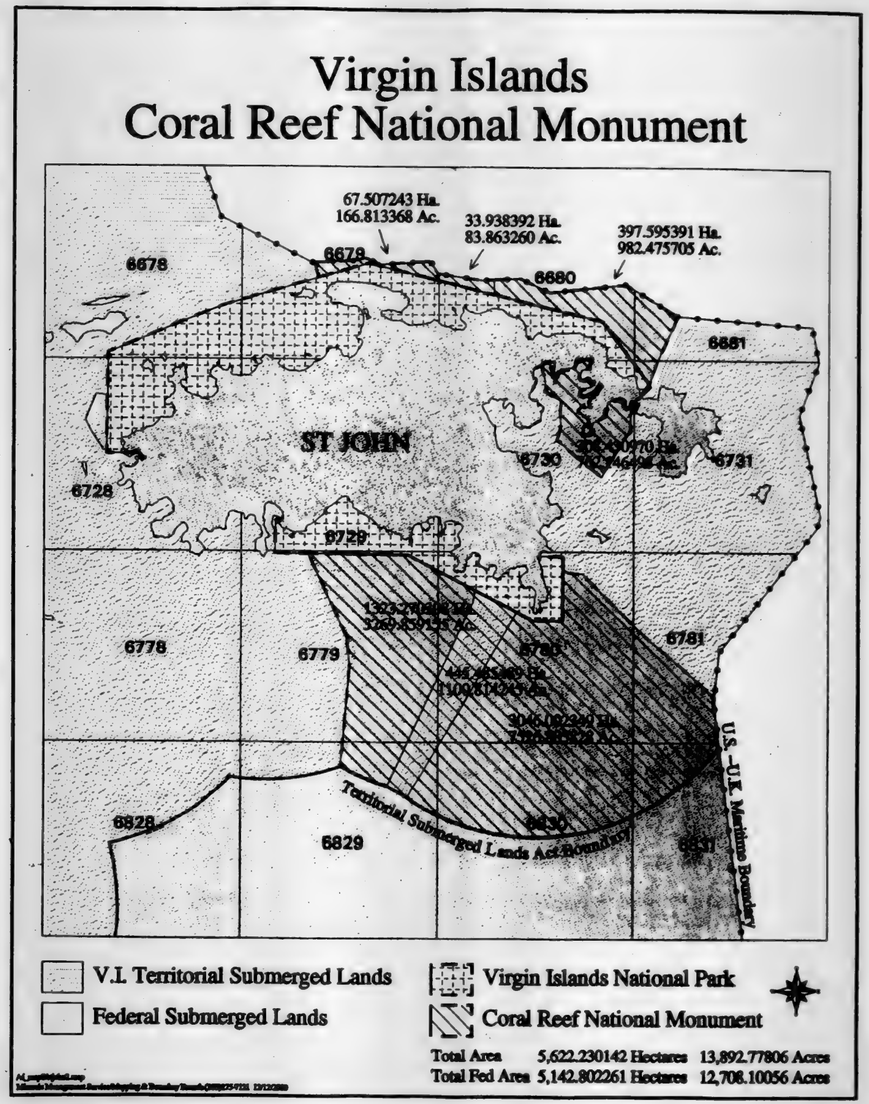
Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the national monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this seventeenth day of January, in the year of our Lord two thousand one, and of the Independence of the United States of America the two hundred and twenty-fifth.

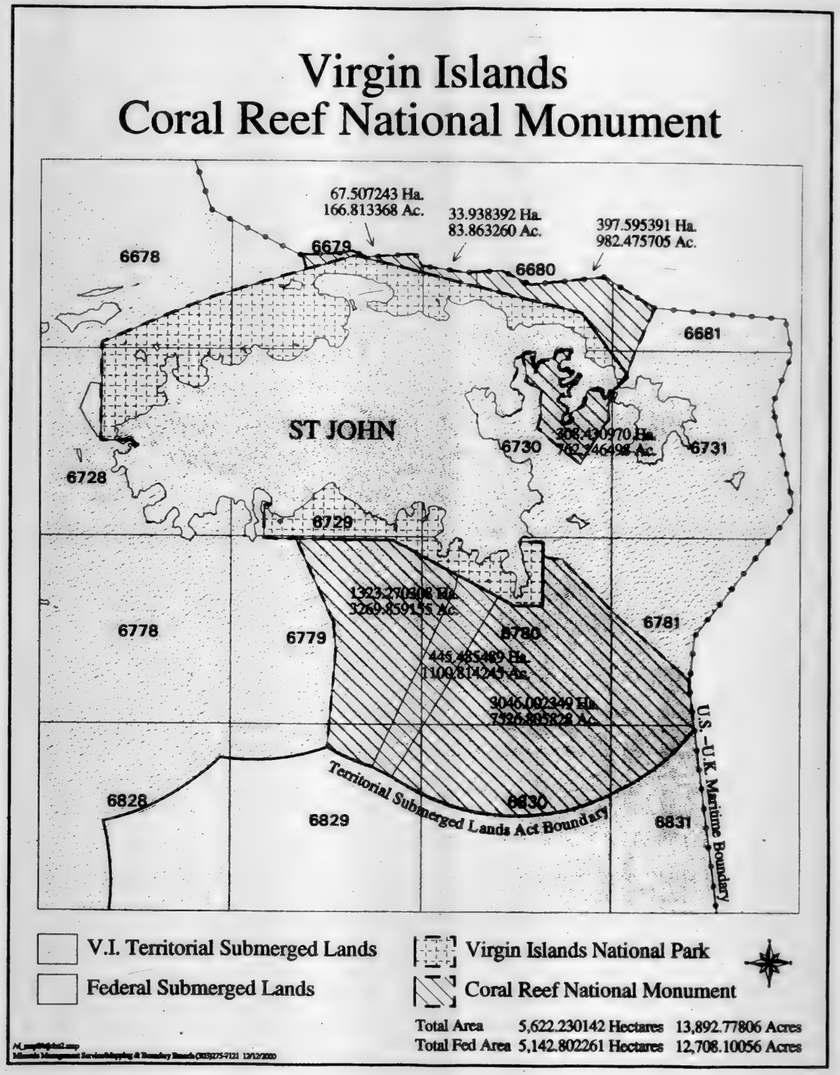
William J Clinton

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Federal Register

Monday,
January 22, 2001

Part XXI

The President

Notice of January 19, 2001—Continuation of Emergency Regarding Terrorists Who Threaten To Disrupt the Middle East Peace Process

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Federal Register
Vol. 66, No. 14
Monday, January 22, 2001

Presidential Documents

Title 3—

The President

Notice of January 19, 2001

Continuation of Emergency Regarding Terrorists Who Threaten To Disrupt the Middle East Peace Process

On January 23, 1995, by Executive Order 12947, I declared a national emergency to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by grave acts of violence committed by foreign terrorists that disrupt the Middle East peace process. The order, issued pursuant to the International Emergency Economic Powers Act, among other authorities, blocks the assets in the United States, or in the control of United States persons, of foreign terrorists who threaten to disrupt the Middle East peace process. I also prohibited transactions or dealings by United States persons in such property. On August 20, 1998, by Executive Order 13099, I identified four additional persons, including Usama bin Ladin, who threaten to disrupt the Middle East peace process. I have annually transmitted notices of the continuation of this national emergency to the Congress and the **Federal Register**. Last year's notice of continuation was published in the **Federal Register** on January 21, 2000. Because terrorist activities continue to threaten the Middle East peace process and vital interests of the United States in the Middle East, the national emergency declared on January 23, 1995, and the measures made effective on January 24, 1995, to deal with that emergency must continue in effect beyond January 23, 2001. Therefore, in accordance with section 202(d)2 of the National Emergencies Act (50 U.S.C. 1622(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency with respect to foreign terrorists who threaten to disrupt the Middle East peace process.

This notice shall be published in the **Federal Register** and transmitted to the Congress.

William J. Clinton

THE WHITE HOUSE,
January 19, 2001.

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